DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center WO66 G609
Silver Spring, MD 20993 0002

August 5, 2015

Boston Scientific Corporation
Carole Sykes
V.P. Clinical and Regulatory Affairs
453 Ravendale Drive, Suite H
Mountain View, CA 94043

Re: K150692
Trade/Device Name: AXIOS™ Stent with Electrocautery Enhanced Delivery System
Regulation Number: 21 CFR§ 876.5015
Regulation Name: Pancreatic drainage stent and delivery system
Regulatory Class: II
Product Code: PCU, KNS
Dated: April 29, 2015
Received: June 24, 2015

Dear Carole Sykes,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K150692

Device Name
AXIOS Stent with Electrocautery Enhanced Delivery System

Indications for Use *(Describe)*

The AXIOS Stent with Electrocautery Enhanced Delivery System is indicated for use to facilitate transgastric or transduodenal endoscopic drainage of symptomatic pancreatic pseudocysts ≥ 6cm in size, with ≥ 70% fluid content that are adherent to the gastric or bowel wall. Once placed, the AXIOS Stent functions as an access port allowing passage of standard and therapeutic endoscopes to facilitate debridement, irrigation and cystoscopy. The stent is intended for implantation up to 60 days and should be removed upon confirmation of pseudocyst resolution.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

Date Prepared:	March 17, 2015
Submitter:	Boston Scientific Corp.
Address:	453 Ravendale Drive, Suite H, Mountain View, CA 94043
Phone:	(650) 868-4331
Fax:	(650) 961-9901
Contact Person:	Carole Sykes VP Clinical and Regulatory Affairs
Trade Name/Proprietary Name:	AXIOS Stent with Electrocautery Enhanced Delivery System
Class:	II
Common Name:	Pancreatic drainage stent and delivery system and endoscopic electrosurgery device
Classification/Name:	Pancreatic drainage stent and accessories and endoscopic electrosurgery accessories
Regulation:	21 CRF 876.5015 / 21 CFR 876.4300
Product Code:	PCU / 78KNS
Predicate Devices (Legally marketed devices to which substantial equivalence is claimed):	Xlumena, Inc. AXIOS Stent and Delivery System K140561 and K123250 Wilson-Cook Medical, Inc. Wilson-Cook Cystotome K022595

I. Device Description:

The AXIOS Stent with Electrocautery Enhanced Delivery System is intended for the endoscopic placement of a flexible, MR conditional, fully-covered, self-expanding braided Nitinol stent for transgastric or transduodenal endoscopic drainage of symptomatic pancreatic pseudocysts. The AXIOS Stent with Electrocautery Enhanced Delivery System is comprised of two main components: (1) AXIOS Stent and (2) Electrocautery Enhanced Delivery System.

The subject premarket notification describes modifications to the cleared AXIOS Delivery System to add electrocautery to facilitate precise access to anatomic targets as well as the staged placement of the currently cleared AXIOS Stent. The AXIOS Stent with Electrocautery Enhanced Delivery System incorporates the same identical implantable stent that is preloaded within the current AXIOS Delivery System (K123250). Both the AXIOS Stent and Delivery System were originally cleared under 510(k) K123250 and most recently under 510(k) K140561.

As with the non-cautery AXIOS devices, the Electrocautery Enhanced AXIOS Delivery System is compatible with commercially-available 0.035-inch endoscopic guidewires and intended to be used in the gastrointestinal tract in conjunction with commercially-

available echoendoscopes. The Electrocautery Enhanced Delivery System has been modified to connect with an off-the- shelf electrosurgical unit or generator that is compliant to IEC 60601-1-2 and IEC 60601-2-2. The generator must be installed and put into service according to the EMC information provided in the generator manufacturer's guidance and declaration for electromagnetic compatibility.

Cables and patient return electrodes that are specified by generator manufacturer must be used for connection.

The AXIOS Stent with Electrocautery Enhanced Delivery System is provided sterile, disposable and intended for single use. The Electrocautery Enhanced AXIOS Delivery System is IEC compliant.

II. Indications for Use:

The AXIOS™ Stent with Electrocautery Enhanced Delivery System is indicated for use to facilitate transgastric or transduodenal endoscopic drainage of symptomatic pancreatic pseudocysts ≥ 6cm in size, with ≥ 70% fluid content that are adherent to the gastric or bowel wall. Once placed, the AXIOS stent functions as an access port allowing passage of standard and therapeutic endoscopes to facilitate debridement, irrigation and cystoscopy. The stent is intended for implantation up to 60 days and should be removed upon confirmation of pseudocyst resolution.

III. Summary of Technological Characteristics of the Proposed Device Compared to the Predicate Device:

The AXIOS Stent with Electrocautery Enhanced Delivery System is substantially equivalent to the legally marketed predicate devices identified in Table 1. The AXIOS Stent with Electrocautery Enhanced Delivery System is substantially equivalent in terms of intended use / indications for use, technological characteristics and principles of operation to the predicate AXIOS Stent and Delivery System which was cleared by FDA in 510(k)s K123250 and K140561, and the Wilson-Cook Medical Cystotome cleared by FDA in 510(k) K022595.

Table 1. Comparison of AXIOS Stent with Electrocautery Enhanced Delivery System with Predicate Devices

Feature			
	SUBJECT DEVICE AXIOS Stent with Electrocautery Enhanced Delivery System	**PRIMARY PREDICATE DEVICE Xlumena AXIOS Stent with (non-cautery) Delivery System**	**REFERENCE PREDICATE DEVICE Wilson-Cook Medical Wilson-Cook Cystotome**
510(k) Number	K150692	K140561 and K123250	K022595

Feature	SUBJECT DEVICE AXIOS Stent with Electrocautery Enhanced Delivery System	PRIMARY PREDICATE DEVICE Xlumena AXIOS Stent with (non-cautery) Delivery System	REFERENCE PREDICATE DEVICE Wilson-Cook Medical Wilson-Cook Cystotome
Indications for Use	To facilitate transgastric or transduodenal endoscopic drainage of symptomatic pancreatic pseudocysts ≥ 6cm in size, with ≥ 70% fluid content that are adherent to the gastric or bowel wall. Once placed, the AXIOS Stent functions as an access port allowing passage of standard and therapeutic endoscopes to facilitate debridement, irrigation and cystoscopy. The stent is intended for implantation up to 60 days and should be removed upon confirmation of pseudocyst resolution.	Same	For use as an electrosurgical accessory to cannulate the transgastric or transduodenal wall and into a pancreatic pseudocyst that is visibly bulging into the gastrointestinal tract.
Class	II	Same	Same
Classification/ Regulation Name	Pancreatic drainage stent and accessories and endoscopic electrosurgery accessories	Pancreatic drainage stent and accessories	Endoscopic electrosurgery accessories
Regulation Number	21CFR 876.5015 21CFR 876.4300	21CFR 876.5015	21CFR 876.4300
Product Code	PCU and 78KNS	PCU	78KNS
Outer Catheter Length	138 cm	Same	165 CM
Inner Catheter Sheath Diameter	9 Fr with preloaded Stent	Same	5 Fr with 0.038" needle knife
Guidewire Compatibility	0.035"	Same	Same
Endoscope Compatibility	Compatible with 3.7 mm diameter or larger working channel	Same	Same
Placement Site	Transgastric or transduodenal wall and into a pancreatic pseudocyst	Same	Same
Pseudocyst Size	≥ 6cm in size	Same	≥ 4cm in size

Feature	SUBJECT DEVICE AXIOS Stent with Electrocautery Enhanced Delivery System	PRIMARY PREDICATE DEVICE Xlumena AXIOS Stent with (non-cautery) Delivery System	REFERENCE PREDICATE DEVICE Wilson-Cook Medical Wilson-Cook Cystotome
Mode of Access or Operation	Electrosurgically punctures hole at the placement site. Fine wire electrocautery element (0.006" SS wire); electrosurgically active wire using pure cutting current to access pseudocyst. After access, deploy the AXIOS Stent using a two stage process. Distal stent flange first followed by the proximal flange.	Access path at placement site is created using conventional access tools. After access, deploy the AXIOS Stent using a two stage process. Distal stent flange first followed by the proximal flange.	Electrosurgically punctures hole at the placement site. Needle 0.038" knife tip; electrosurgically active knife using pure cutting current to access pseudocyst. Enlarge incision with a cauterizing diathermic ring and 10 Fr outer catheter. Utilizes a 0.035" wire for placement of a stent or drainage kit via compatible endoscope.
Stent Deployment Mechanism	Deployed via handle controls. Distal stent flange first followed by the proximal flange.	Same	N/A
Cutting Current	80-120 Watts	N/A	80-120 Watts
Sterilization Method	EO	EO	EO

IV. Summary of the Nonclinical Tests Performed:

Nonclinical testing performed includes: Bench Performance, Biocompatibility, Electromagnetic Compatibility / Electrical Safety, and Animal Testing. The nonclinical test results demonstrate that the modified device continues to meet product design specifications.

1. Bench Performance

Bench performance testing was conducted for the AXIOS Stent with Electrocautery Enhanced Delivery System to demonstrate that the modified delivery system continues to meet the requirements of the product design specification and perform in accordance with its intended use. There have been no design or material changes to the AXIOS Stent; it is identical to the AXIOS Stent cleared in K123250 and K140561. The bench performance testing was conducted for the modifications to the Electrocautery Enhanced Delivery System Catheter and Handle only and included the following testing:

- RF Compatibility / Safety
- Tensile Strength testing
- Unsheathing Force (Distal Flange)
- Effect of Retainer (Stent Retention Force)

- Design Validation Testing
- Transportation and Conditioning Testing
- Shelf Life and Package Testing
- Magnetic Resonance testing was confirmed via ASTM F2052-14, ASTM F2213-06, ASTM F2182-11a and ASTM F2119-13.

Where applicable, performance testing was conducted in accordance with the following standards:

- ISO 10555-1:2013 - *Sterile, single-use intravascular catheters Part 1. General requirements*
- ISO 594-1:1986 - *Conical Fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 1 : General Requirements*

Design Verification testing included assessment of device dimensions, stent deployment and tensile testing of the applicable joints. The AXIOS Stent with Electrocautery Enhanced Delivery System was tested for design validation attributes. AXIOS Systems were evaluated in an *ex vivo* simulated use model for performance to the product specification. Based on the results of the bench performance testing, the modified Electrocautery Enhanced Delivery Systems meets the product design specification and performance requirements for its proposed intended use.

The AXIOS Stent with Electrocautery Enhanced Delivery System was evaluated in an Ex-Vivo Tissue Model to measure the comparative thermal effects of the AXIOS Electrocautery Enhanced Delivery System (11F) vs. the 10F Cook Cystotome on porcine tissue. In all tissue samples, the Electrocautery Enhanced Delivery System caused statistically significant less thermal damage to the tissue as compared to the Cystotome.

2. <u>Biocompatibility</u>

To verify the biocompatibility of the AXIOS Stent with Electrocautery Enhanced Delivery System the Company conducted biocompatibility testing pursuant to ISO 10993-1:2009 and FDA's Draft Guidance Document *Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing (2013)"*. Biocompatibility testing was conducted in accordance with the GLP regulations (21 CFR, Part 58).

The Electrocautery Enhanced Delivery System (Hot AXIOS Delivery System) is an "external communicating device" in contact with tissue for limited duration ($\leq$24 hour) during pseudocyst access and stent implant procedures. Based on these characteristics, the following biocompatibility tests were performed: Cytotoxicity – ISO MEM Elution Method, L-929 Cells, Sensitization - ISO Guinea Pig Maximization Study, Irritation - ISO Intracutaneous Reactivity in Rabbits and Systemic (Acute) Toxicity - ISO Systemic Toxicity in Mice. There have been no changes to the AXIOS Stent design or materials; it is identical to the AXIOS Stent cleared in 510(k)s K123250 and K140561, therefore no new biocompatibility testing is warranted. Based on the test results, the Electrocautery Enhanced Delivery System is

biocompatible for the intended use.

3. Electromagnetic Compatibility and Electrical Safety

The AXIOS Stent with Electrocautery Enhanced Delivery System (Hot AXIOS Device) was evaluated by Intertek NA, for conformance to the IEC 60601 family of standards. All completed testing passed the acceptance criteria as outlined in IEC 60601-1, 60601-1-6, 60601-2-2, 60601- 2-18, and ISO 14971 and as specified in the Final Study Reports provided by Intertek NA, Inc.

4. Animal

The safety and effectiveness of the AXIOS Stent with Electrocautery Enhanced Delivery System (Hot AXIOS) during transmural endoscopic access and drainage of a simulated pancreatic pseudocyst and the biliary tract was evaluated. The study evaluated the safety and performance of the AXIOS Stent with Electrocautery Enhanced Delivery System when performing a simulated endoscopic drainage procedure in a porcine model using the 06x08mm and 20x10mm stent models.

Cautery access and stent deployment using the AXIOS Stent with Electrocautery Enhanced Delivery System were compared to standard techniques as represented by access with the commercially available Cystotome (Cook Medical, Limerick Ireland) and the placement of an 20x10mm Stent with Electrocautery Enhanced Delivery System (the Electrocautery Enhanced Delivery System was not energized). A direct comparison of tissue heat affects and healing were evaluated post cautery access and AXIOS Stent placement. Effectiveness of the Electrocautery Enhanced Delivery System to access the target anatomy and deliver the AXIOS stent (device performance) was also assessed.

The study animals were survived for one (1) month after stent implantation followed by stent removal. Study animals were survived another 7 days after stent removal for histopathological evaluation. Histological evaluation of the heat affects and healing of the implant site was performed.

Access using cautery was successfully achieved and stents were successfully deployed in all animals. None of the stents migrated from the original position and all stents remained patent during the implant period (1 month). The tissue surrounding the stent implant sites was healthy in all animals. The gross and histological evaluation of the tissues treated with either the control (AXIOS without cautery) or test device (AXIOS with Electrocautery Enhanced Delivery System) showed excellent healing between the two luminal structures (bile duct or jejunum and stomach). Thermal heat effects were not apparent grossly or histologically within the tissues evaluated in the AXIOS Electrocautery Enhanced Delivery System treated animals.

V. Summary of Clinical Tests Performed:

A prospective multi-center, single-arm clinical study was conducted to demonstrate the safety and effectiveness of the AXIOS Stent with Electrocautery Enhanced Delivery System for

endoscopic transenteric drainage of pancreatic pseudocysts. The AXIOS Stent with Electrocautery Enhanced Delivery System is intended for the endoscopic ultrasonography (EUS) guided creation of an internal drainage conduit between the pancreatic pseudocyst and the stomach or duodenum. The AXIOS Electrocautery Enhanced Delivery System is designed to facilitate the creation of the access tract using electrosurgery while minimizing device exchanges for pseudocyst access. The design and manufacturing of AXIOS Stent remains unchanged.

Safety was evaluated as freedom from major complications with regard to stent placement and removal. Stent migration and tissue response for the period up to seven days after stent removal were also evaluated. Pseudocyst resolution and AXIOS device performance were evaluated to characterize effectiveness.

The study group consisted of symptomatic subjects who provided consent and were treated with the AXIOS Stent with Electrocautery Enhanced Delivery System.

Effectiveness: AXIOS Stents were placed in subjects with no intra-operative complications. AXIOS stent patency was confirmed with drainage visualized for all stents placed. In subjects treated PP, 100% of AXIOS devices remained in position at 30 or 60 days, and 81.1% of stent lumens remained patent at 30 days and 100% at 60 days. The AXIOS stent was successfully implanted in all study subjects (100%). Successful removal of the AXIOS stent was achieved in all subjects (100%) in which endoscopic removal PP was attempted. Overall clinical success was achieved in 83.3% of subjects.

Safety: Study results demonstrated that there were no unanticipated events related to the use of the device. Ninety percent (90%) of subjects were free from major complications. Ninety-three percent (93.3%) of subjects experienced no serious adverse events related to the device or index procedure. Serious adverse events deemed related to the AXIOS device or the index procedure was the same type of events as those generally associated with endoscopic pancreatic pseudocyst drainage with commercially available stents and delivery systems.

Conclusion:

The AXIOS Stent design and construction is optimized for controlled placement, maintaining patency, preventing migration and easy removal. Once placed, the stent provides a large diameter conduit and the bi-flange design secures access to the pseudocyst. The stent is provided fully covered to minimize tissue ingrowth.

The Electrocautery Enhanced Delivery System was used for access in 100% of patients and performed as intended in all cases. There were no adverse events or unanticipated adverse device effects attributed to electrocautery use.

The study of the AXIOS Stent with Electrocautery Enhanced Delivery System demonstrated the system to be predictable and easy to use. There were no intraoperative adverse events during AXIOS Stent placement and two during removal (both were minor bleeding not requiring transfusion). There were no unanticipated complications or new risks related to the

implantation and removal of the AXIOS Stent. The AXIOS Stent with Electrocautery Enhanced Delivery System is deployed using electrocautery in conjunction with current strategies and techniques for clinical assessment and treatment. In conclusion, the AXIOS Stent with Electrocautery Enhanced Delivery System is safe and effective for the endoscopic transenteric drainage of pancreatic pseudocysts.

VI. Substantial Equivalence:

Based on the results of the Bench Performance, Biocompatibility, Electromagnetic Compatibility / Electrical Safety and Animal testing, as well as clinical evaluations, the AXIOS Stent with Electrocautery Enhanced Delivery System is substantially equivalent to the currently cleared AXIOS Stent and Delivery System which was cleared by FDA in 510(k)s K123250 and K140561, and the Wilson-Cook Medical Cystotome cleared by FDA in 510(k) K022595. In regard to intended use/indication for use, technological characteristics, and principles of operation the modifications do not affect the performance or function of the device. The minor differences in the design between the modified and cleared devices do not raise any new types of safety or effectiveness questions as confirmed by non-clinical and clinical testing. Therefore, the AXIOS Stent with Electrocautery Enhanced Delivery System is substantially equivalent to the previously cleared predicate devices.

VII. Conclusions:

Boston Scientific concludes that based on the results of the Bench Performance, Biocompatibility, Electromagnetic Compatibility / Electrical Safety, Animal and Clinical Testing, that the modified AXIOS Stent with Electrocautery Enhanced Delivery System is substantially equivalent to the predicate devices.

K150692 / A1

Boston Scientific

Endoscopy
100 Boston Scientific Way
Marlborough, MA 01752
Mail Stop: MB-16
508.683.4000 Tel
508.683.5090 Fax
www.bostonscientific.com

April 03, 2015

Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – W066-G609
Silver Spring, MD 20993-0002

(b)(4)Proprietary Information

[redacted]

Dear Sir/Madam:

(b)(4)Proprietary Information

[redacted]

The eCopy is an exact duplicate of the paper copy.

CONFIDENTIAL

1-CD
03

(b)(4)Proprietary Information-Draft

CONSULTING MEMO

Date: July 19, 2015

To: Mark Antonino, M.S.
CDRH/ODE/DRGUD/GEDB

From: Daniel Krainak, Ph.D.
Office of *In Vitro* Diagnostics and Radiological Health (OIR)
Division of Radiological Health (DRH)
Magnetic Resonance and Electronic Products Branch (MREP)

Subject: K150692/S001
AXIOS Stent with Electrocautery Enhanced Delivery System (10x10 Stent)
AXIOS Stent with Electrocautery Enhanced Delivery System (15x10 Stent)
Xlumena, Inc.

I. Summary

(b)(4)Proprietary Information

[redacted]

II. Background & Scope

(b)(4)Proprietary Information

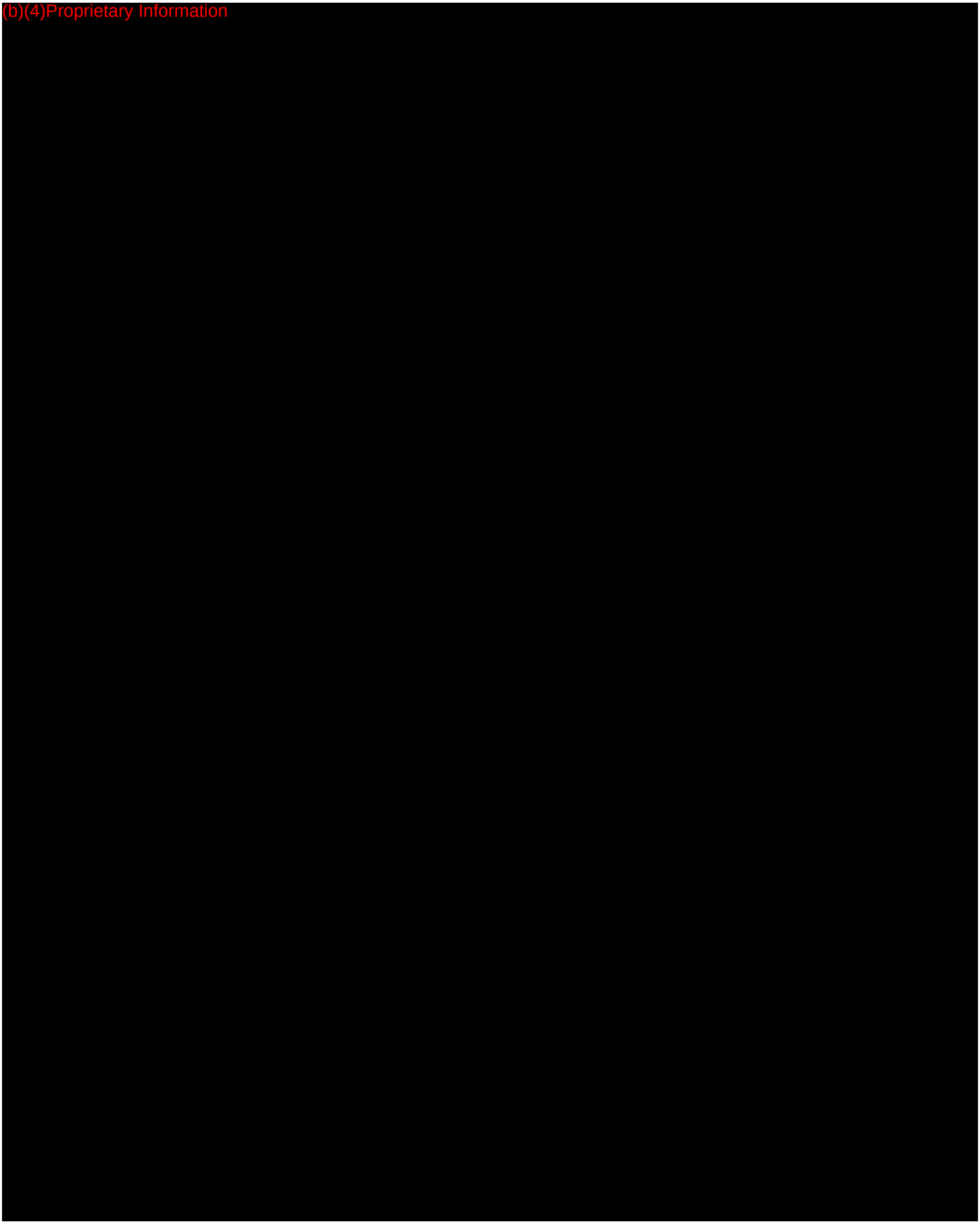
[redacted]

III. Deficiencies

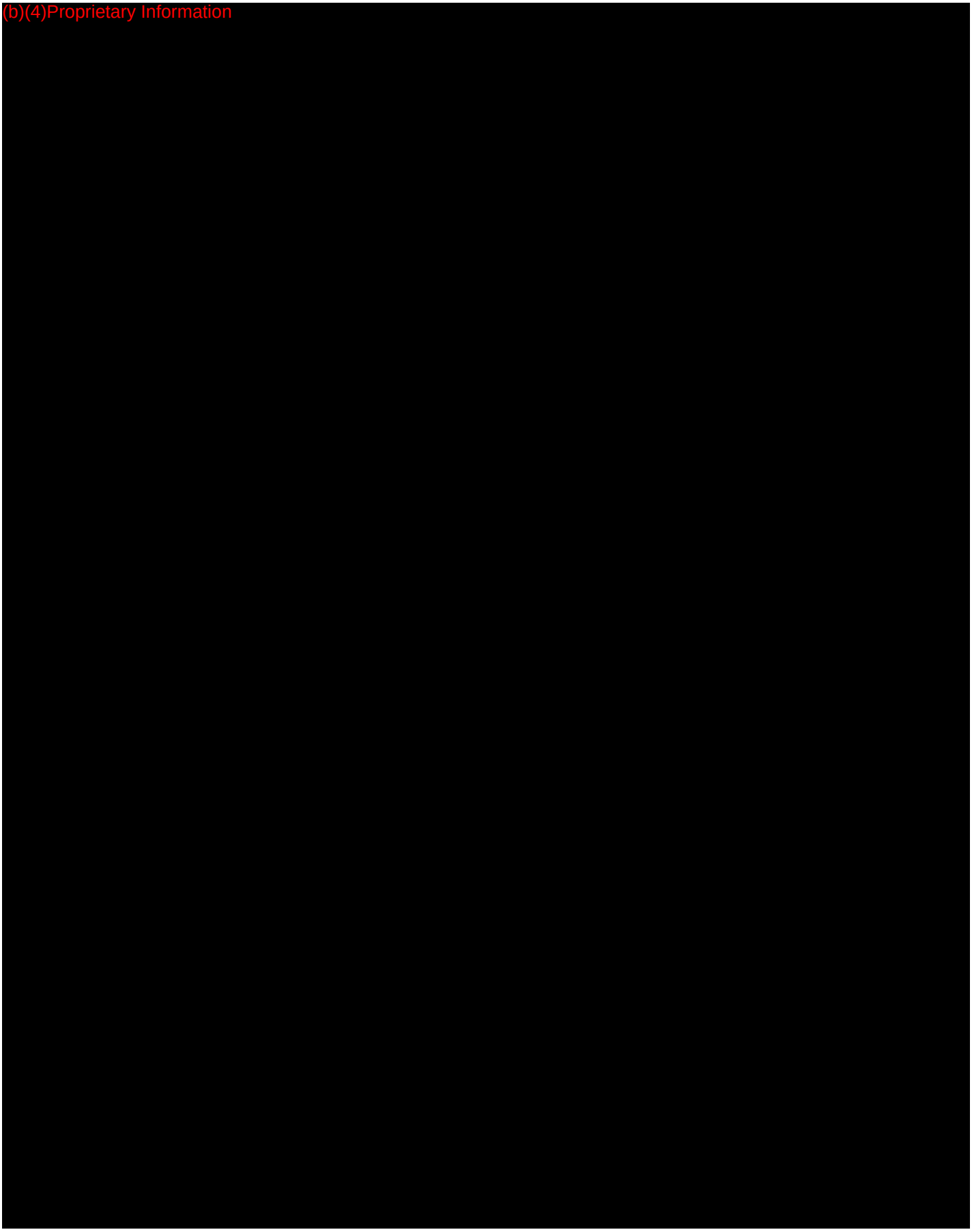
(b)(4)Proprietary Information

[redacted]

(b)(4)Proprietary Information



(b)(4)Proprietary Information



(b)(4)Proprietary Information

[redacted]

V. Signature

Daniel Krainak -S
2015.07.19 22:24:24 -04'00'

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug
Administration

Memorandum

Date: July 16, 2015

Subject: K150692/S001 – Biocompatibility Review

Device: AXIOS™ Stent with Electrocautery Enhanced Delivery System

To: Mark Antonino, Lead reviewer
CDRH/ODE/DRGUD/GEDB

From: Qin Zhang, Ph.D., DABT
CDRH/ODE/DRGUD/GEDB

Sponsor: Boston Scientific Corp.
Mountain View, CA 94043

PURPOSE OF SUBMISSION

(b)(4)Proprietary Information [redacted]

INDICATIONS FOR USE

(b)(4)Proprietary Information [redacted]

DEVICE DESCRIPTION

(b)(4)Proprietary Information [redacted]

(b)(4)Proprietary Information

[redacted]

1. **AXIOS Stent**

(b)(4)Proprietary Information

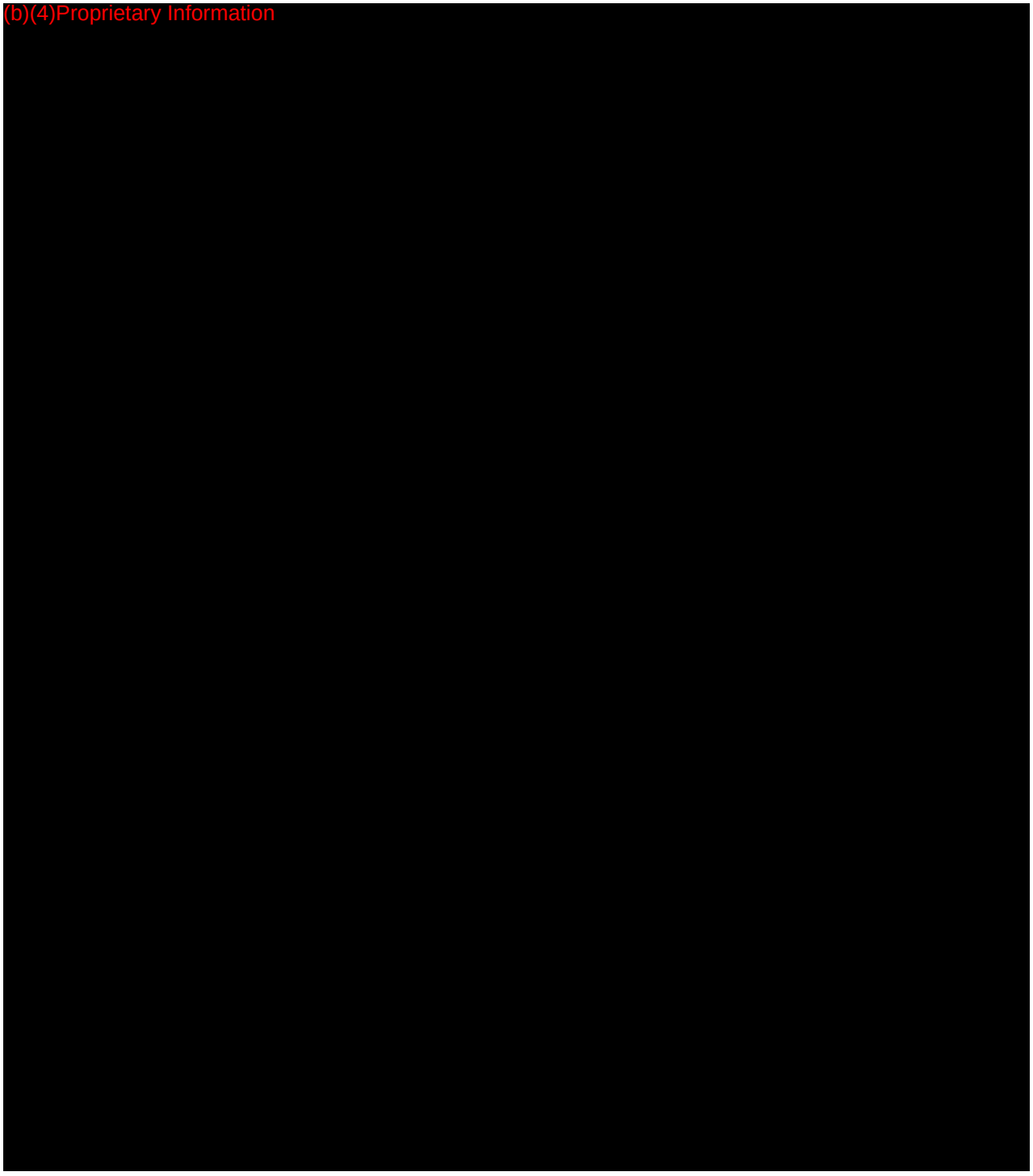
[redacted]

2. **Delivery System**

(b)(4)Proprietary Information

[redacted]

(b)(4)Proprietary Information



(b)(4)Proprietary Information

[redacted]

(b)(4)Proprietary Information

PREDICATE DEVICE

(b)(4)Proprietary Information

(b)(4)Proprietary Information

[redacted]

DOCUMENTS REVIEWED BY REVIEWER:

(b)(4)Proprietary Information

[redacted]

(b)(4)Proprietary Information

[redacted]

CONCLUSIONS/RECOMMENDATIONS: (b)(4)Proprietary Information

[redacted]

Qin Zhang -S
2015.07.16 13:26:41
-04'00'

Food and Drug Administration
CDRH/ODE/DRGUD/GEDB
WO66
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
240-402-9980

Premarket Notification [510(k)] Review

Date: August 3, 2015
To: FILE
From: Mark Antonino
Subject: Traditional 510(k)# K150692/S001

Applicant: Boston Scientific Corp.	**Device Trade Name:** AXIOS™ Stent with Electrocautery Enhanced Delivery System
Contact: Carole Sykes	**Contact Title:** VP Clinical And Regulatory Affairs
Correspondent Firm:	**Phone:** (650) 961-9900 **Email:** csykes@xlumena.com
FDA Received Date: June 24, 2015	**Due Date:** August 9, 2015
Reg #: 876.5015 **Reg Name:** Pancreatic Drainage Stent And Delivery System	**Class:** II **Product Code(s):** PCU
Reg #: 876.4300 Reg Name: Endoscopic electrosurgical unit and accessories	Class: II Product Code(s): KNS

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Owner
K140561	PCU	Axios Stent And Delivery System (with 10mm X 10mm Stent) Axios Stent And Delivery System (with 15mm X 10mm Stent)	Xlumena, Inc.
K123250		Axios Stent And Delivery System	Xlumena, Inc
K022595	KNS	Wilson-cook Cystotome	Wilson-Cook Medical, Inc.

Review Summary

(b)(4)Proprietary Information

[redacted]

Recommendation

I recommend that the AXIOS™ Stent with Electrocautery Enhanced Delivery System is/are Substantially Equivalent (SESE)

Review Team

Lead Reviewer	Mark Antonino (CDRH/ODE/DRGUD/GEDB)
Clinical	Marty Golding (CDRH/ODE/DRGUD/GEDB)
Electrical Safety, EMC, and Thermal Safety	Tuan Nguyen (CDRH\ODE\DRGUD\ULDB)
Biocompatibility	Qin Zhang (CDRH/ODE/DRGUD/GEDB)
MRI Safety Labeling	Daniel Krainak (CDRH/OIR/DRH/MREP)

I. Purpose and History

(b)(4)Proprietary Information

[redacted]

(b)(4)Proprietary Information

[redacted]

II. Device/System Description

Device Characteristics	Yes	No	Inadequate Or Marked
Is the intended use or fundamental technology new?	☐	☒	☐
Is the device life-supporting or life sustaining?	☐	☒	☐
Are there any direct or indirect patient contacting components?	☒	☐	☐
• Is the device or a component an implant?	☒	☐	☐
Does the device use software/firmware?	☐	☒	☐
Does the device or a component need sterilization (by manufacturer or user)?	☒	☐	☐
The device/system uses or is	a single use device(s) (SUD)		☐
Is the device a combination product?	N - Not a Part 3 Combination Product		☐
Is the device electrical (battery or wall powered)?	Yes, it is mains powered Only		☐

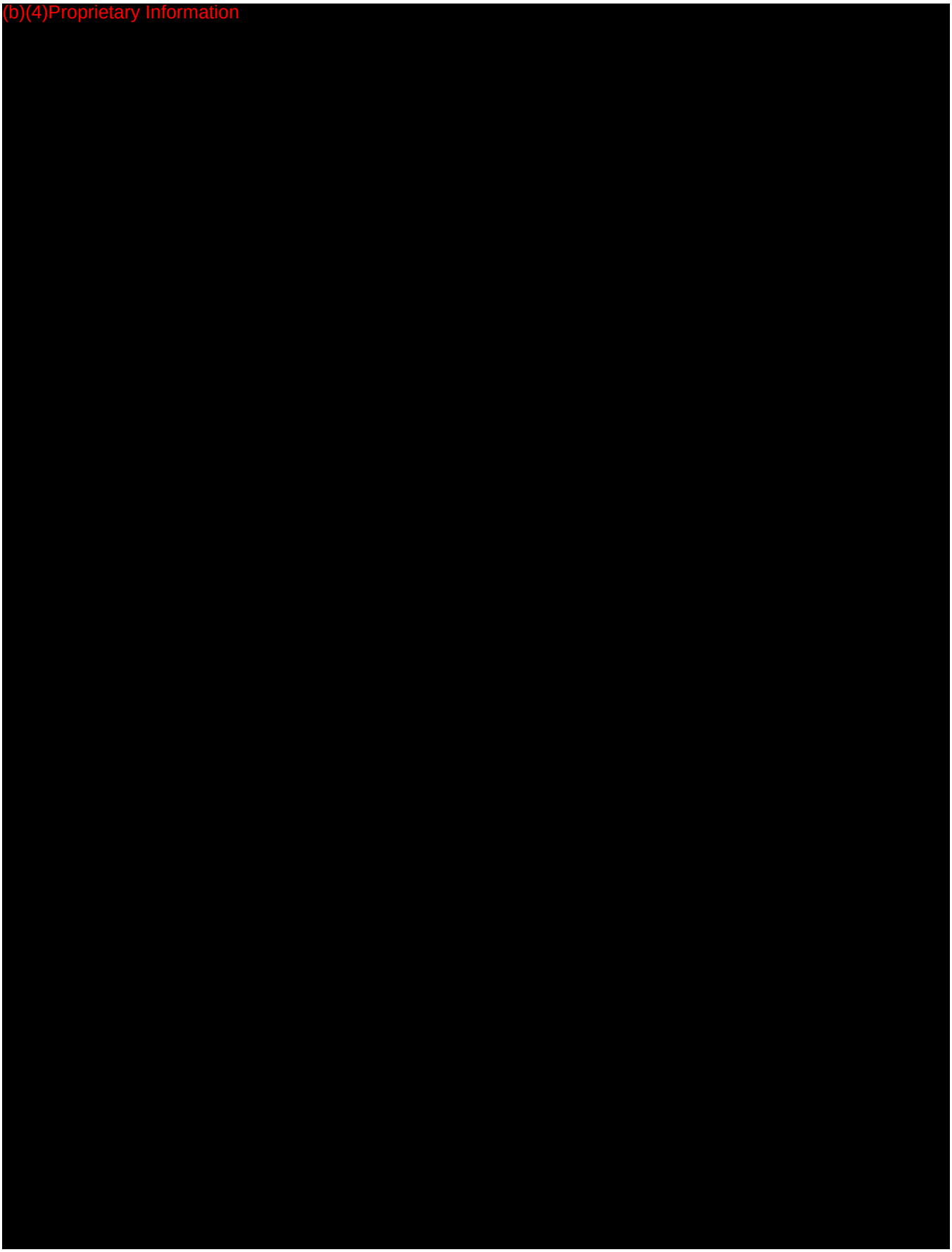
Device Characteristics	Yes	No	Inadequate Or Marked
Check the attributes that are applicable to this submission.			

	Nanotechnology	Reprocessed SUD	Companion Diagnostic
Yes	☐	☐	☐
No	☒	☒	☒
Unknown	☐	☐	☐

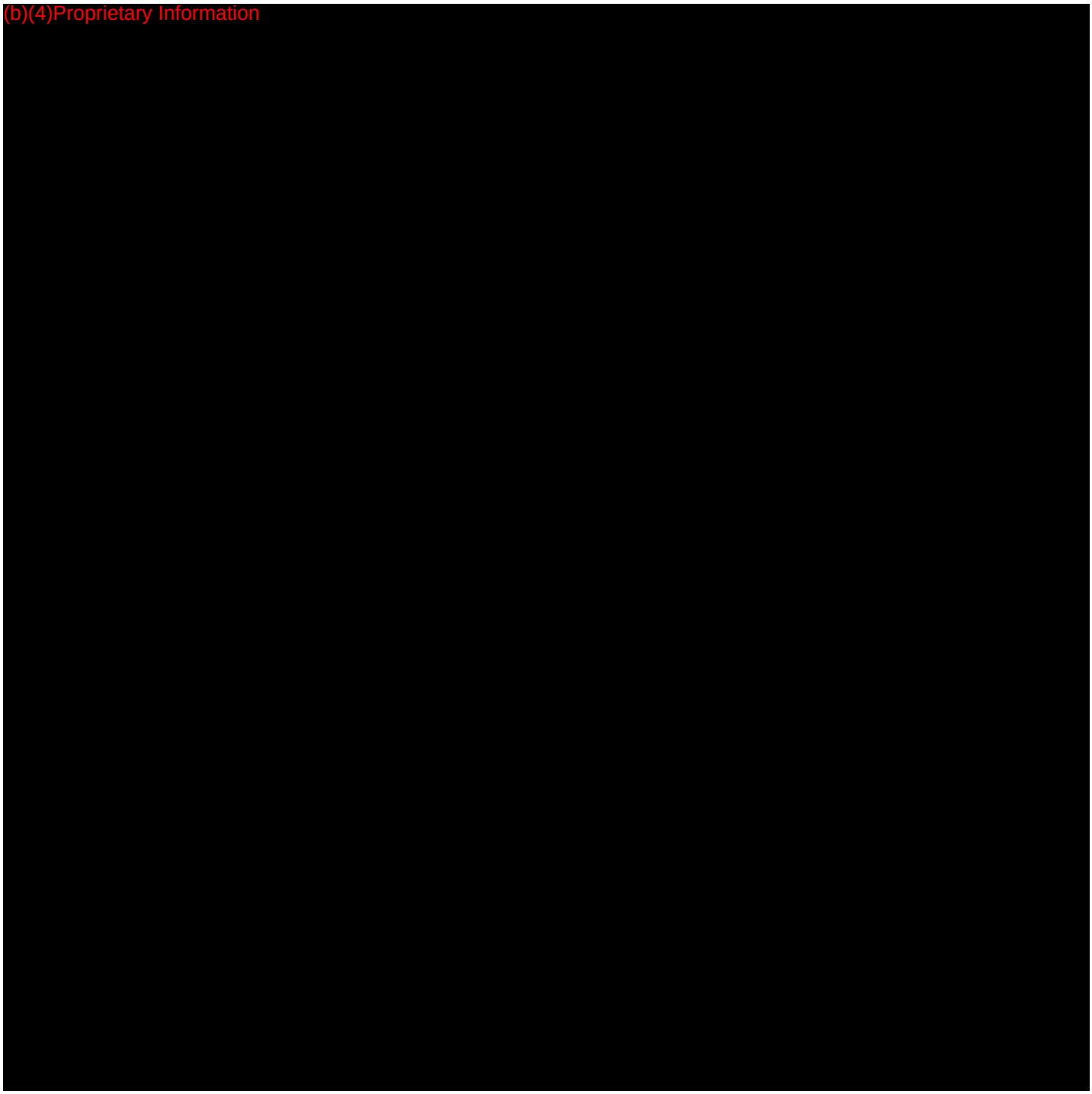
Device Description Table: Summary of important device characteristics

(b)(4)Proprietary Information

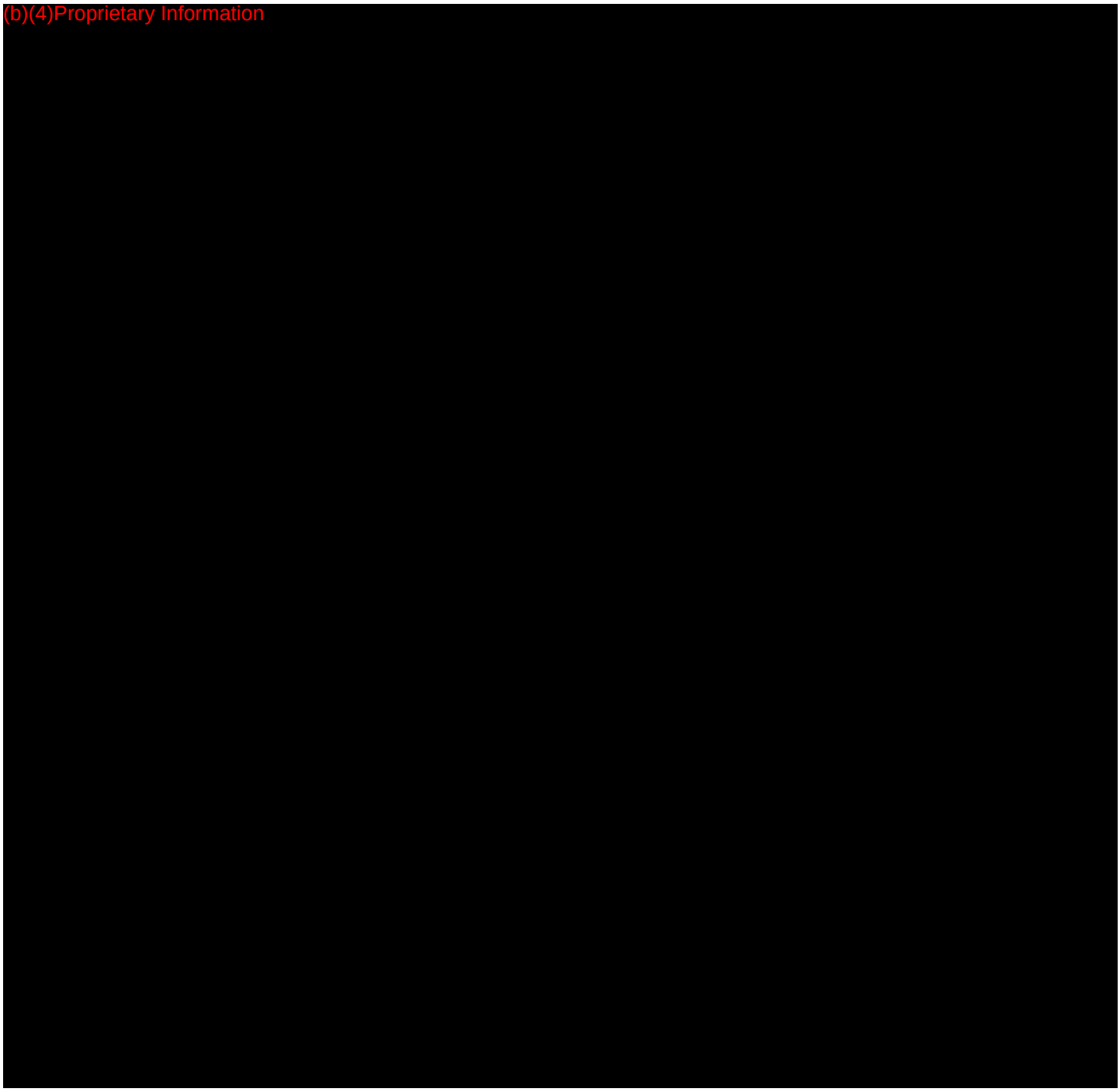
(b)(4)Proprietary Information



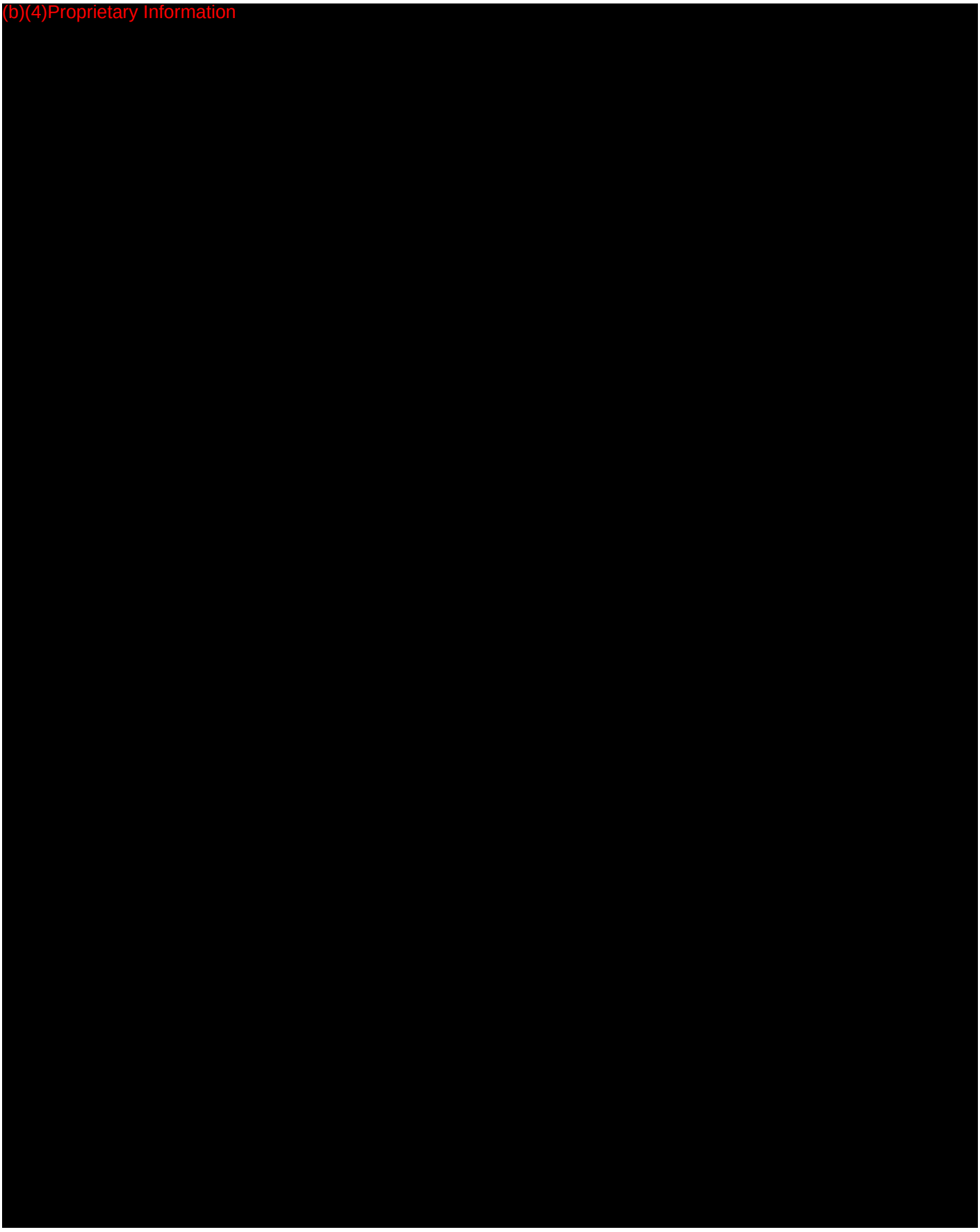
(b)(4)Proprietary Information



(b)(4)Proprietary Information



(b)(4)Proprietary Information



(b)(4)Proprietary Information

[redacted]

Reviewer Recommendation

The Device Description is acceptable.

III. Comparison of Indications for Use to Predicate Devices

Comparison of Indications for Use

Subject

510(k) #: K150692 Rx/OTC: Rx

Intended Population	Adults Only	Adults and Pediatrics	Transitional Adolescent A	Transitional Adolescent B	Adolescent	Child	Infant	Neonate/ Newborn
Yes	☒	☐	☐	☐	☐	☐	☐	☐
No	☐	☒	☒	☒	☒	☒	☒	☒
Unknown	☐	☐	☐	☐	☐	☐	☐	☐

(b)(4)Proprietary Information

[redacted]

Comparison of Indications for Use

(b)(4)Proprietary Information

[redacted]

Reviewer Recommendation

The Comparison of the Indications for Use is acceptable.

IV. Comparison of Technology to Predicate Devices

(b)(4)Proprietary Information

[redacted]

(b)(4)Proprietary Information

[redacted]

Reviewer Recommendation

The Comparison of the Technology to Predicate Devices is acceptable.

V. Labeling

Labeling Review Needed?	Yes ☒	No ☐
Usability Consult Needed?	Yes ☐	No ☒

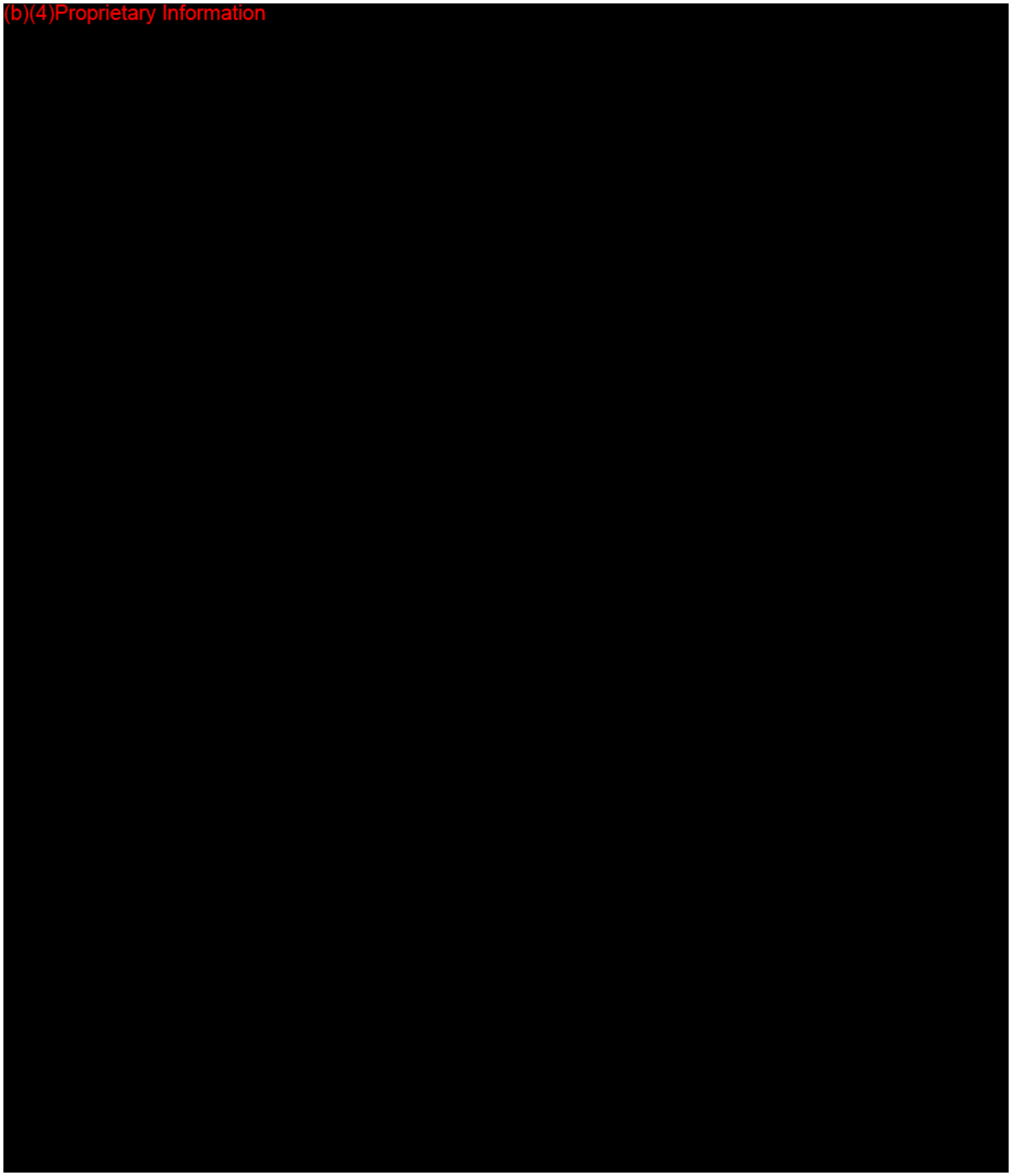
A General Labeling Requirements

General Labeling Requirements	Yes	No/N/A	Inadequate or Marked
Is the prescription statement (or "Rx only") included?	☒	☐	☐
The indications for use are consistent with the IFU page?	☒	☐	☐
Appropriate contraindications provided?	☒	☐	☐
Appropriate warnings provided?	☒	☐	☐
Instructions are in accordance with the guidance (if applicable)?	☐	☒	☐
Appropriate labeling inside device?	☐	☒	☐
Appropriate label/indicator outside device?	☒	☐	☐

General Labeling Requirements	Yes	No|N/A	Inadequate or Marked
Appropriate Manual labeling?	☒	☐	☐
What MRI safety information does the labeling contain?	MR Conditional		☐

Labeling Table: A summary of the adequacy of several labeling requirements.

(b)(4)Proprietary Information



(b)(4)Proprietary Information

[redacted]

Reviewer Recommendation

The Labeling is acceptable.

VI. Cleaning, Disinfection, Sterilization, Shelf-Life and Reuse

Sterility Review Needed?	Yes ☒	No ☐
Sterility Consult Needed?	Yes ☐	No ☒

Sterilization Information	Inadequate or Marked
(b)(4)Proprietary Information	

(b)(4)Proprietary Information

Table 16-2. AXIOS Stent with Electrocautery Enhanced Delivery System Packaging Components

Component	Materials	Dimensions
(b)(4)Proprietary Information		

T

Shelf Life

(b)(4)Proprietary Information

(b)(4)Proprietary Information

Reviewer Recommendation

Cleaning, Sterilization, Shelf-Life and Reuse descriptions are acceptable.

VII. Biocompatibility

Biocompatibility Review Needed?	Yes ☒	No ☐
Biocompatibility Consult Needed?	Yes ☐	No ☒

Qin Zhang, PhD (CDRH/ODE/DRGUD/GEDB) performed a biocompatibility consult for the subject device (see attached).

The sponsor identified the following list of components and materials:

Catheter Component Name	Material	Colorant / Additive	Patient Contact
(b)(4)Proprietary Information			

Catheter Component Name	Material	Colorant / Additive	Patient Contact
(b)(4)Proprietary Information			

(b)(4)Proprietary Information

Dr. Zhang provided the following overview of biocompatibility testing:

Summary of biocompatibility testing conducted on the Electrocautery Enhanced Delivery System

Sample ID & Test (Standard) [Test Lab, Study #]	Test System	Controls (Extraction ratio, vehicle, time and temperature)	Test Article Extraction Ratio, Extraction Vehicle, Extraction Time and Temperature, Test Dose	Test method	Results
(b)(4)Proprietary Information					

Sample ID & Test (Standard) [Test Lab, Study #]	Test System	Controls (Extraction ratio, vehicle, time and temperature)	Test Article Extraction Ratio, Extraction Vehicle, Extraction Time and Temperature, Test Dose	Test method	Results
(b)(4)Proprietary Information					

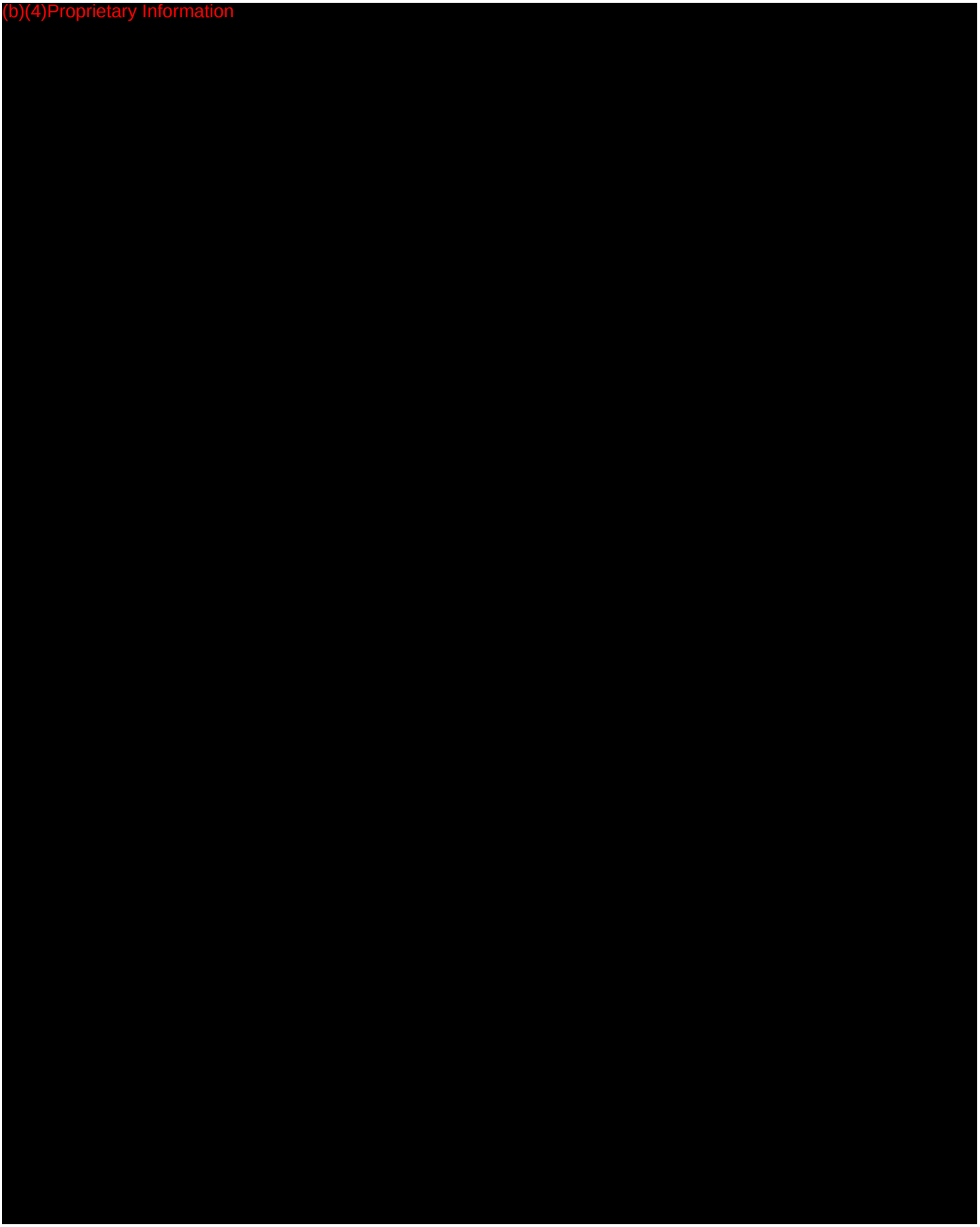
Sample ID & Test (Standard) [Test Lab, Study #]	Test System	Controls (Extraction ratio, vehicle, time and temperature)	Test Article Extraction Ratio, Extraction Vehicle, Extraction Time and Temperature, Test Dose	Test method	Results
(b)(4)Proprietary Information					

Sample ID & Test (Standard) [Test Lab, Study #]	Test System	Controls (Extraction ratio, vehicle, time and temperature)	Test Article Extraction Ratio, Extraction Vehicle, Extraction Time and Temperature, Test Dose	Test method	Results
(b)(4)Proprietary Information					

Dr. Zhang made the following recommendations:

(b)(4)Proprietary Information

(b)(4)Proprietary Information



Reviewer Recommendation

The Biocompatibility is acceptable.

VIII. Software/Firmware

N/A: the device does not contain Software/Firmware.

Reviewer Recommendation

The Software is acceptable.

IX. EMC & Electrical, Mechanical and Thermal Safety & Risk Analysis

EMC Review Needed?	Yes ☐	No ☒
EMC Consult Needed?	Yes ☐	No ☒

Tuan Nguyen, PhD (CDRH\ODE\DRGUD\ULDB) performed an EMC, electrical, mechanical, thermal safety and risk analysis for the subject device (see attached).

The following was reviewed:

Electromagnetic Compatibility Information (IEC 60601-1-2)		Inadequate or Marked
Describe the device(s)/accessory(ies)/component(s) that were tested to the right.	Stent, Generator, Neural Electrode, Foot Switch, Cable	☐
Was a recognized edition of standard [redacted] used for testing?	Yes	☐
Does the device receive radio frequency energy for the purpose of its operation?	Yes	☐
• Does the labeling include the frequency and frequency band the device receives?	Yes	☐
Does the device deliver radio frequency energy to a patient, or use wireless technology?	No	☐
Is the device intended to be used in domestic establishments?	No	☐
Does the device draw more than 16 A of mains current?	No	☐
Does the device use cables (excluding power supply cables)?	Yes	☐
Does the device use an applied part?	No	☐
Does the device contain only simple components like motors and switches and no other electronic circuitry?	No	☐
Is the device standalone lighting equipment only?	No	☐
Is the device information technology equipment?	No	☐
EMC Emissions Testing (from CISPR 11/EN 55011)		
Was emissions testing performed?	Yes	☐
Were emissions measurements at a Test Site or In Situ?	Test Site	☐
If the device is labeled for use only in a shielded location, what is the minimum shielding value in dB ?	12.2 dB	☐
[redacted]		☐

(b)(4)Proprietary Information

Electromagnetic Compatibility Information (IEC 60601-1-2)	Inadequate or Marked
Yes	
Do the electromagnetic radiation disturbance limits comply with the following, and are the measured emissions below these limits when the antenna is vertically and horizontally angled:	
(b)(4)Proprietary Information	☐

EMC Immunity Testing (from IEC 60601-1-2)	
(b)(4)Proprietary Information	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

Electromagnetic Compatibility Information (IEC 60601-1-2)	Inadequate or Marked
(b)(4)Proprietary Information [redacted]	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

(b)(4)Proprietary Information [redacted]

The following table summarizes the EMC review:

TABLE 1 – ELECTROMAGNETIC COMPATIBILITY TESTS

Test	Standard	Acceptance Criteria	Test Result
(b)(4)Proprietary Information [redacted]			

(b)(4)Proprietary Information

[redacted]

Reviewer Recommendation

The EMC, EMT and Risk Analysis are acceptable.

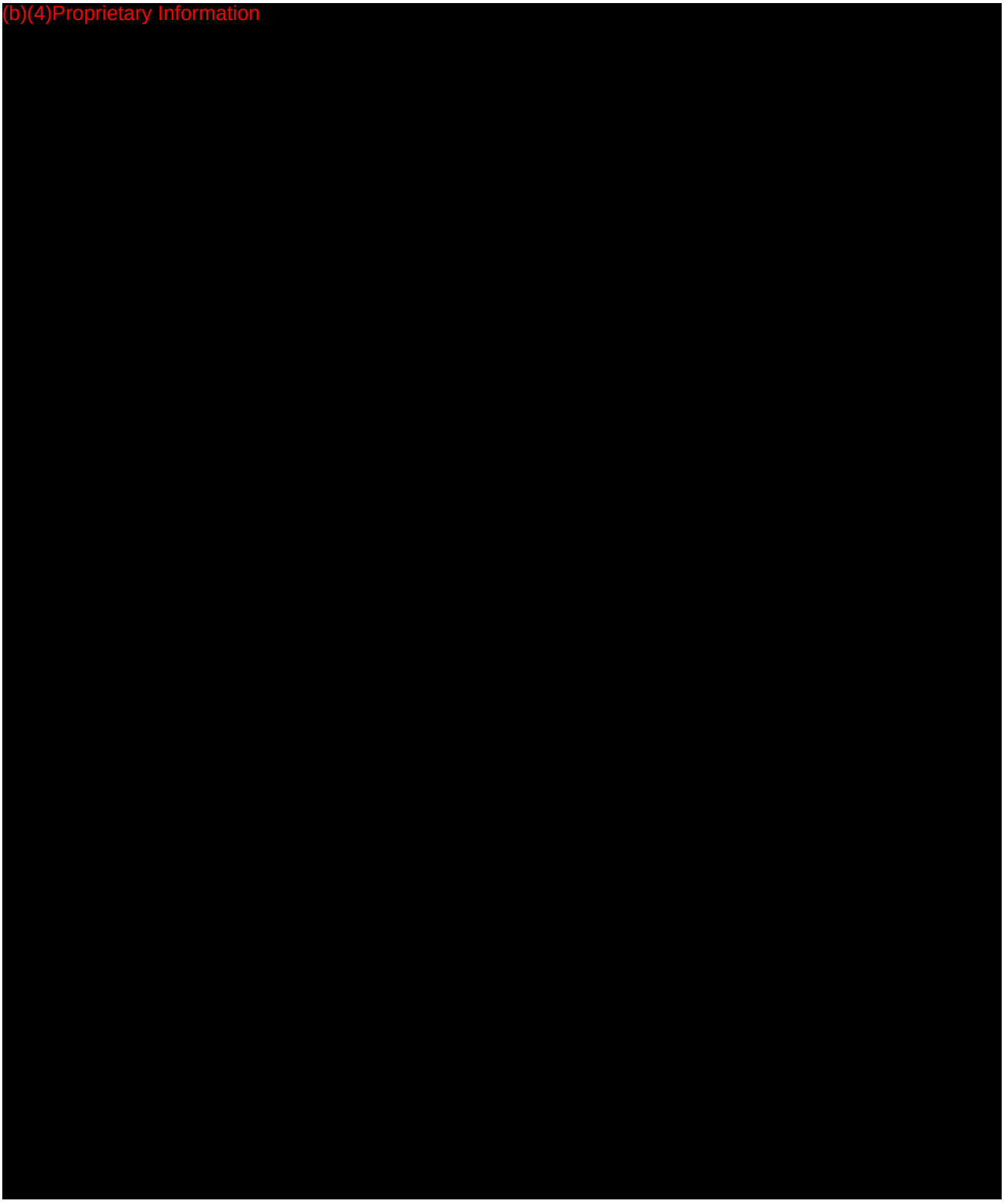
X. Performance Testing

A Bench Testing

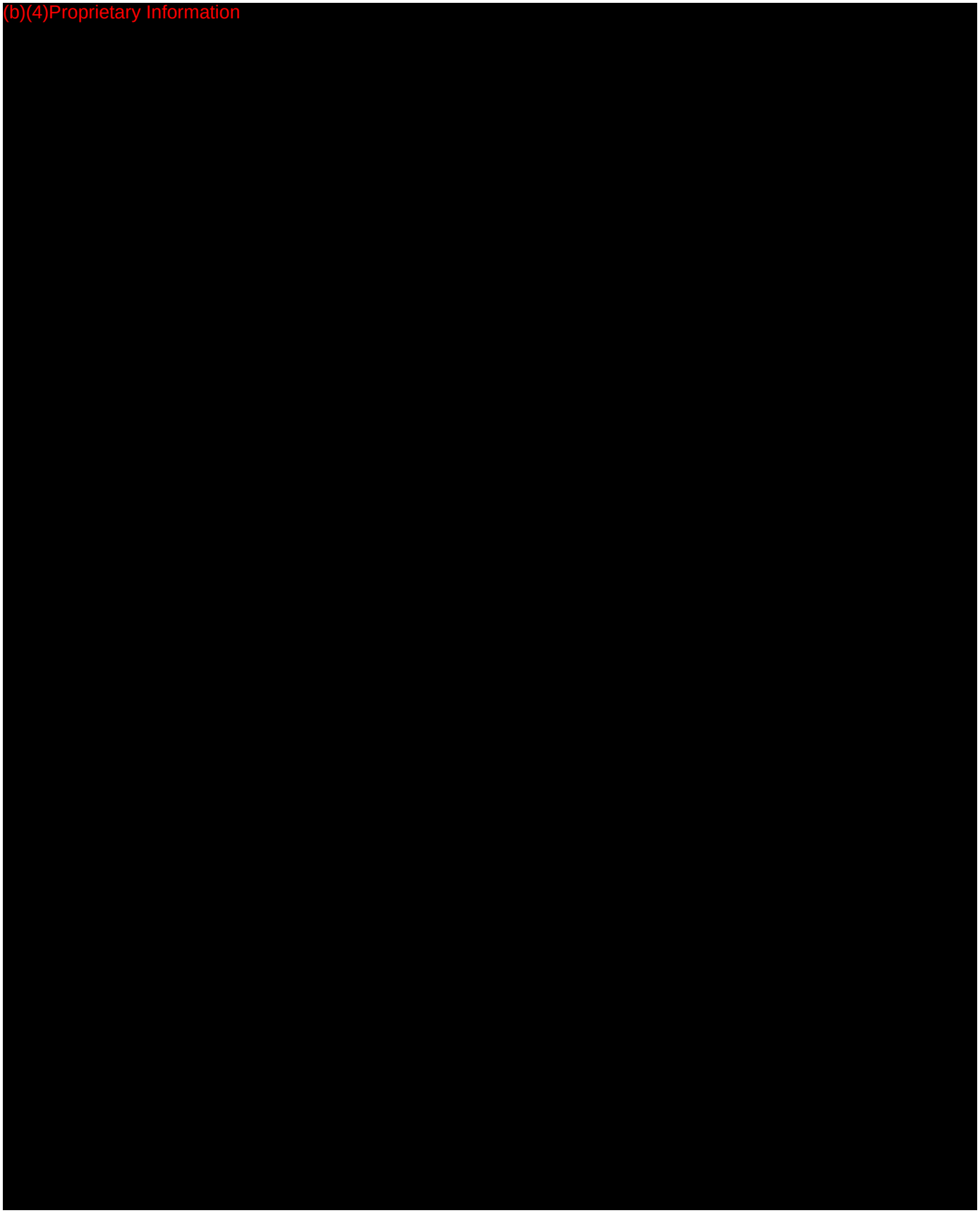
(b)(4)Proprietary Information

[redacted]

(b)(4)Proprietary Information



(b)(4)Proprietary Information



(b)(4)Proprietary Information

K150692 Appendix #	Specification Description	Acceptance Value	Specification Justification	Test Method
(b)(4)Proprietary Information				

K150692 Appendix #	Specification Description	Acceptance Value	Specification Justification	Test Method
(b)(4)Proprietary Information				

PS ID #	TM#	TM Name	Type	k-factor	Acceptance Criteria	Results	PASS/FAIL
(b)(4)Proprietary Information							

PS ID #	TM#	TM Name	Type	k-factor	Acceptance Criteria	Results	PASS/FAIL
(b)(4)Proprietary Information							

(b)(4)Proprietary Information

(b)(4)Proprietary Information

Acceptance Criteria:

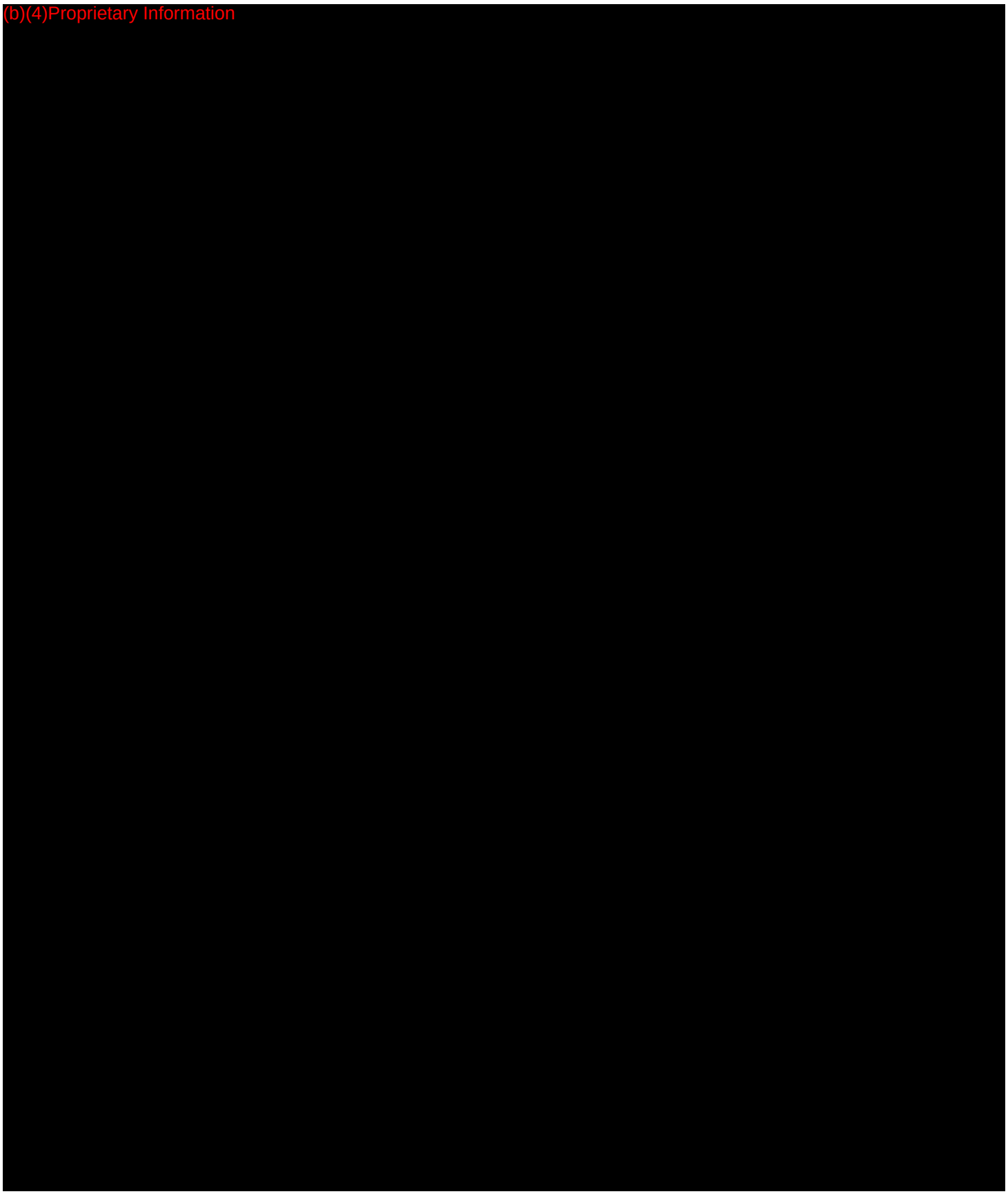
ID Number	Specification Description	Value	Specification Justification	Test Method

(b)(4)Proprietary Information

Track Force Testing Summary			
Unit	Average Track Force (g)	Stdev	(90/90) C/R

(b)(4)Proprietary Information

(b)(4)Proprietary Information



(b)(4)Proprietary Information

[redacted]

B Animal Testing

(b)(4)Proprietary Information

[redacted]

Step #	Step Description	ID	SPEC NAME	SPECIFICATION DESCRIPTION	RI	n	TP/TM	Action	Yes / No

(b)(4)Proprietary Information

Step #	Step Description	ID	SPEC NAME	SPECIFICATION DESCRIPTION	RI	n	TP/TM	Action	Yes / No

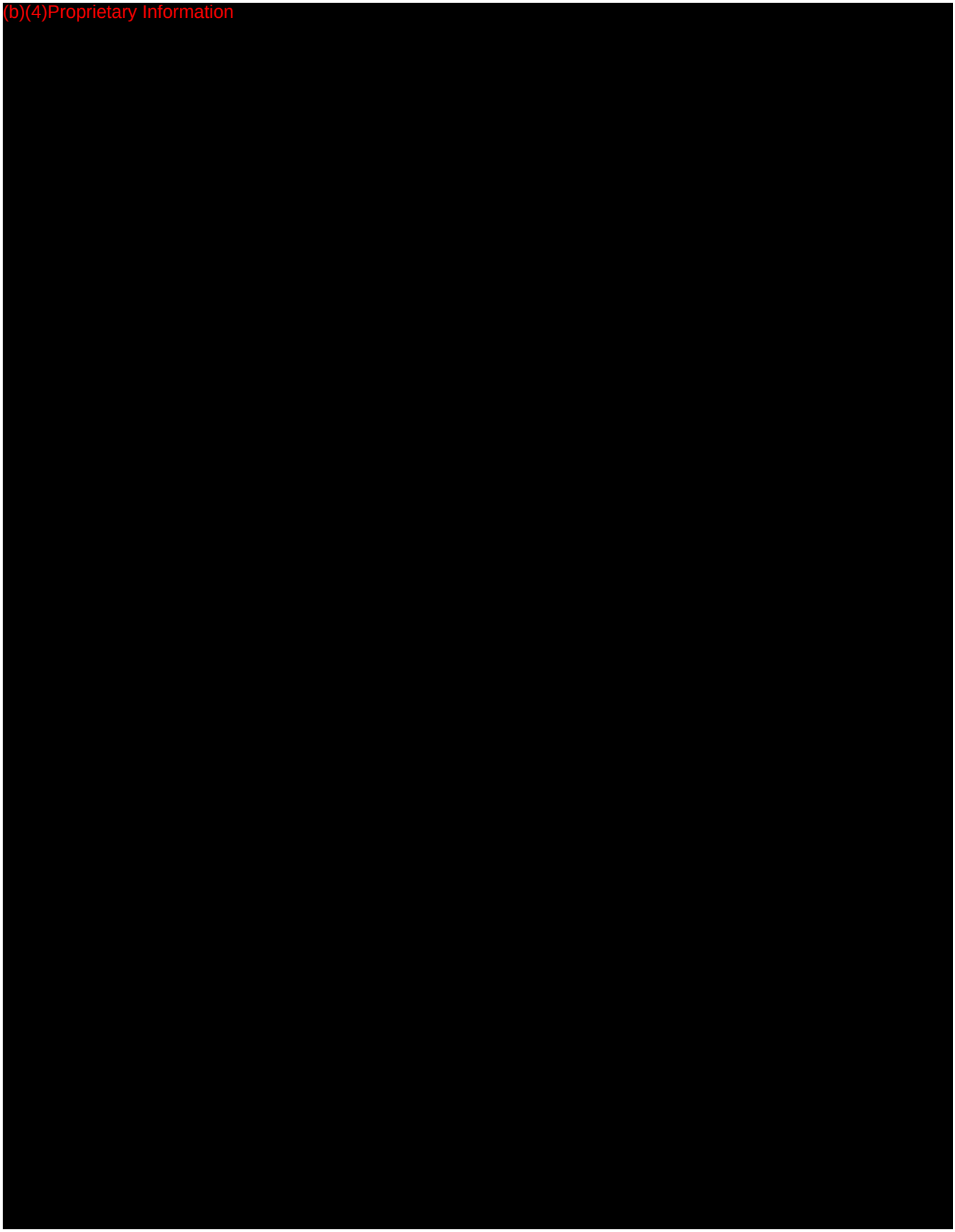
(b)(4)Proprietary Information

Step #	Step Description	ID	SPEC NAME	SPECIFICATION DESCRIPTION	RI	n	TP/TM	Action	Yes / No
(b)(4)Proprietary Information									

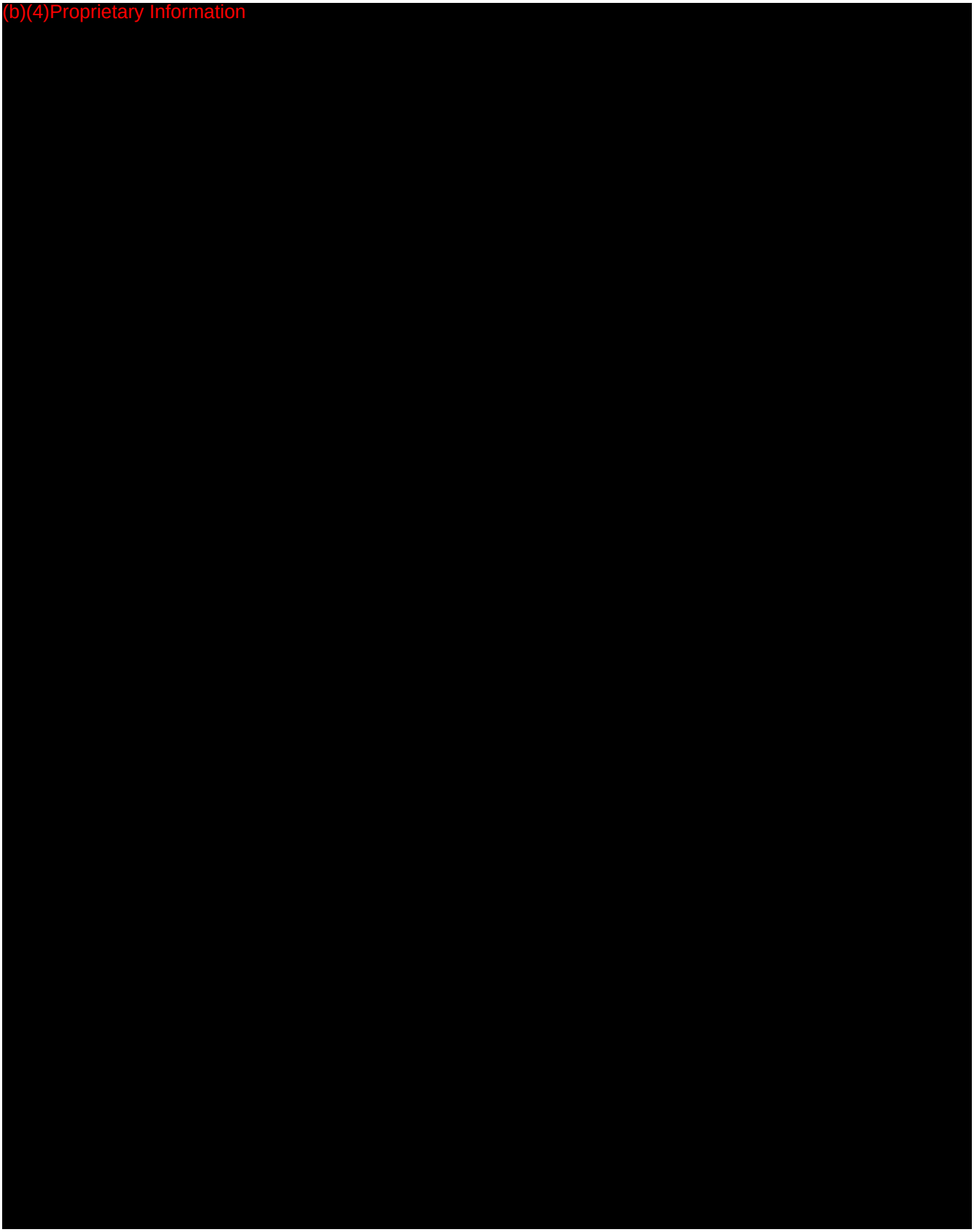
Step #	Step Description	ID	SPEC NAME	SPECIFICATION DESCRIPTION	RI	n	TP/TM	Action	Yes / No
(b)(4)Proprietary Information									

(b)(4)Proprietary Information

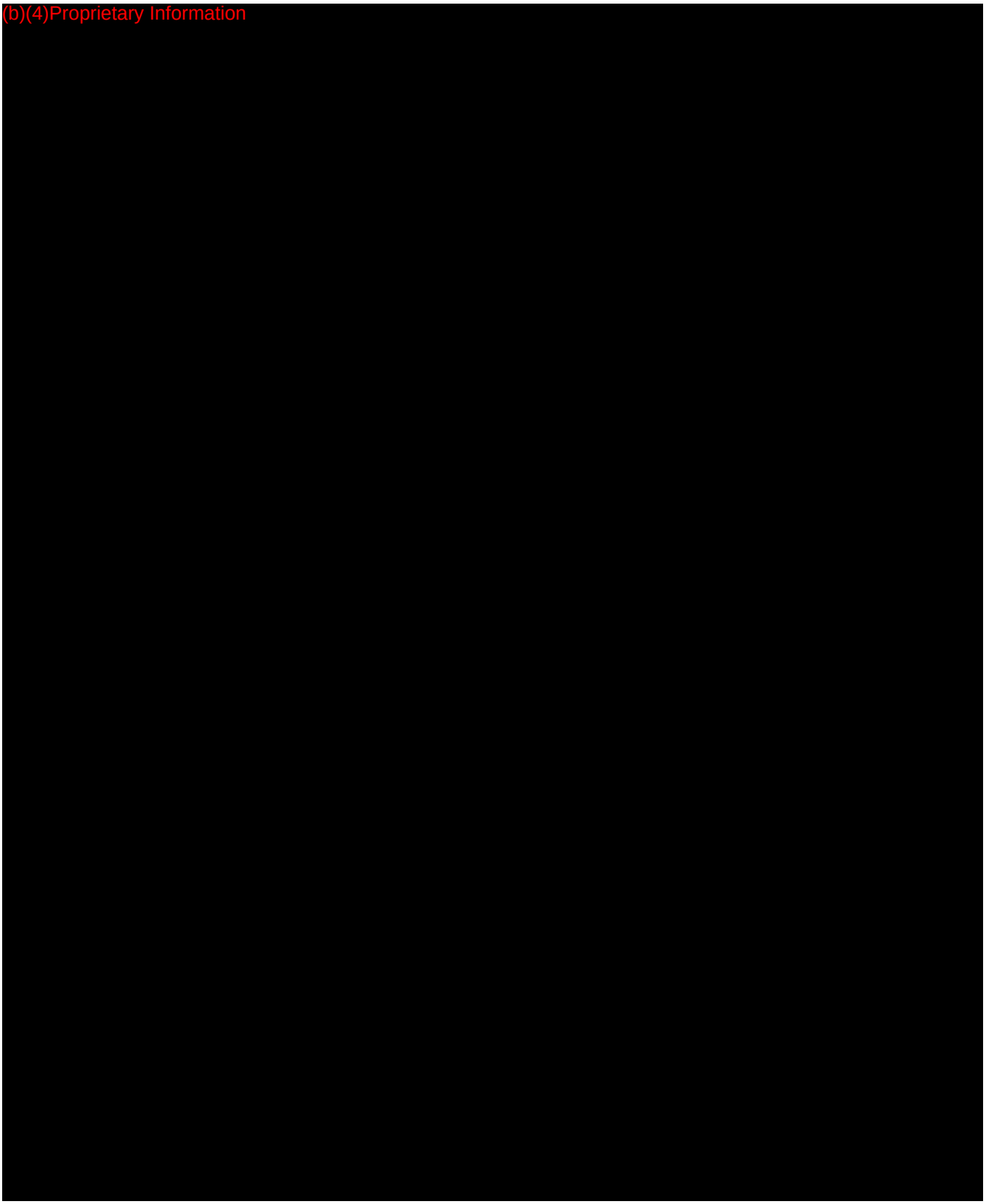
(b)(4)Proprietary Information



(b)(4)Proprietary Information



(b)(4)Proprietary Information



Characteristics	Study Population (N=30)
(b)(4)Proprietary Information	

Results:

Effectiveness Measure	Subset	30-day Visit	60-day Visit	Success Rate
(b)(4)Proprietary Information				

Adverse Events:

				Time Period		
Event #	Subject ID	SAE Cluster	DSMC Determination	Index Procedure - Before Stent Removal	At Stent Removal	7-days Post-stent Removal
(b)(4)Proprietary Information						

				Time Period		
Event #	Subject ID	SAE Cluster	DSMC Determination	Index Procedure - Before Stent Removal	At Stent Removal	7-days Post-stent Removal
(b)(4)Proprietary Information						

Subject ID	Major Complication	Day(s) Post Stent Placement	Seriousness	Severity	Device Related	Index Procedure Related	Resolution	Causality
(b)(4)Proprietary Information								

Device Malfunction	Time point	Subject ID	Reason	Corrective Action

(b)(4)Proprietary Information

[redacted]

Reviewer Recommendation

The Performance Testing [Verification & Validation] is acceptable.

XI. SE Flowchart Questions

Substantial Equivalence Determination	Yes	No
Is the predicate device legally marketed?	☒	☐
Do the devices have the same intended use?	☒	☐

(b)(4)Proprietary Information

[redacted]

(b)(4)Proprietary Information

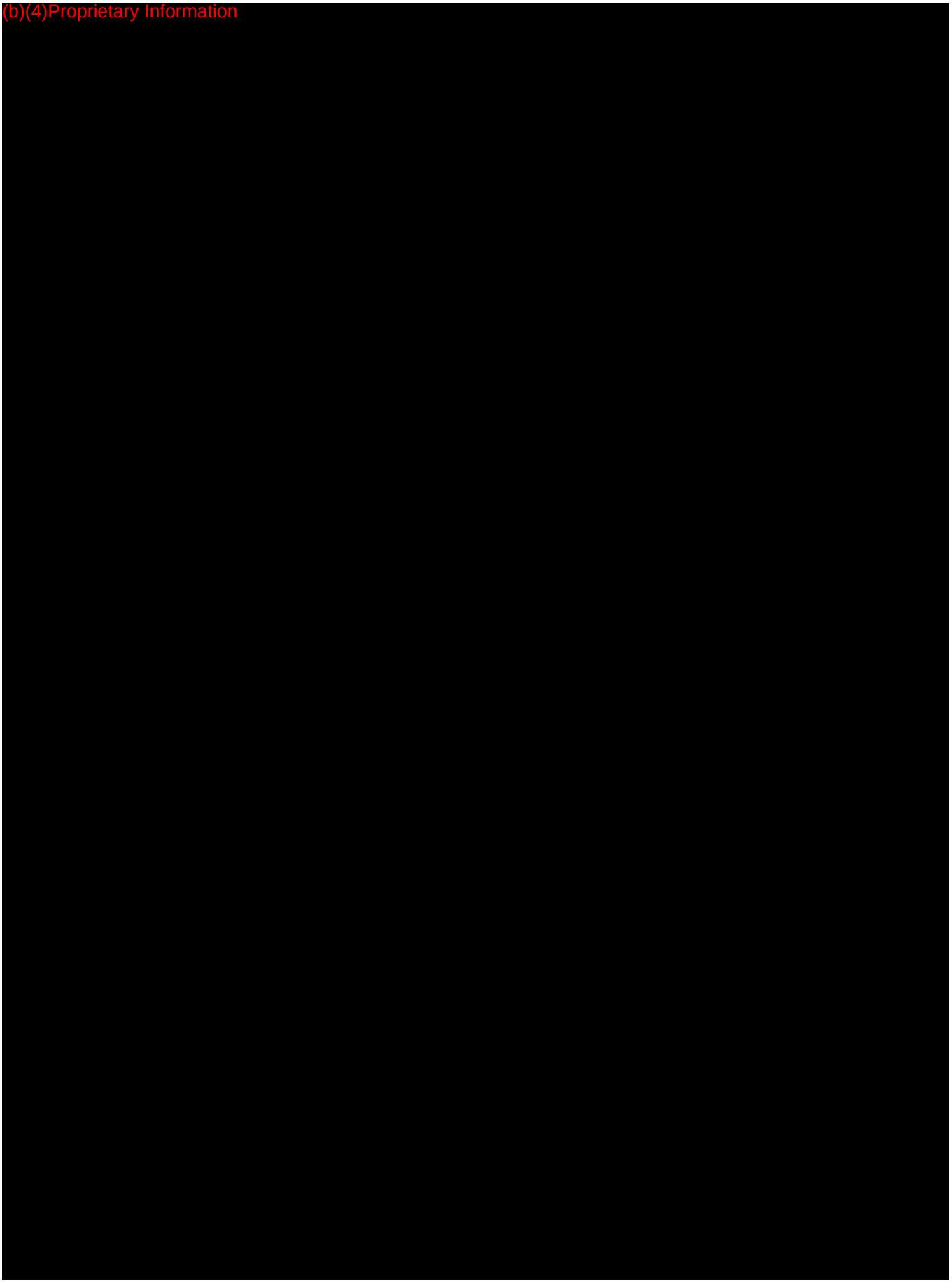
[redacted]

XII. Original Deficiencies

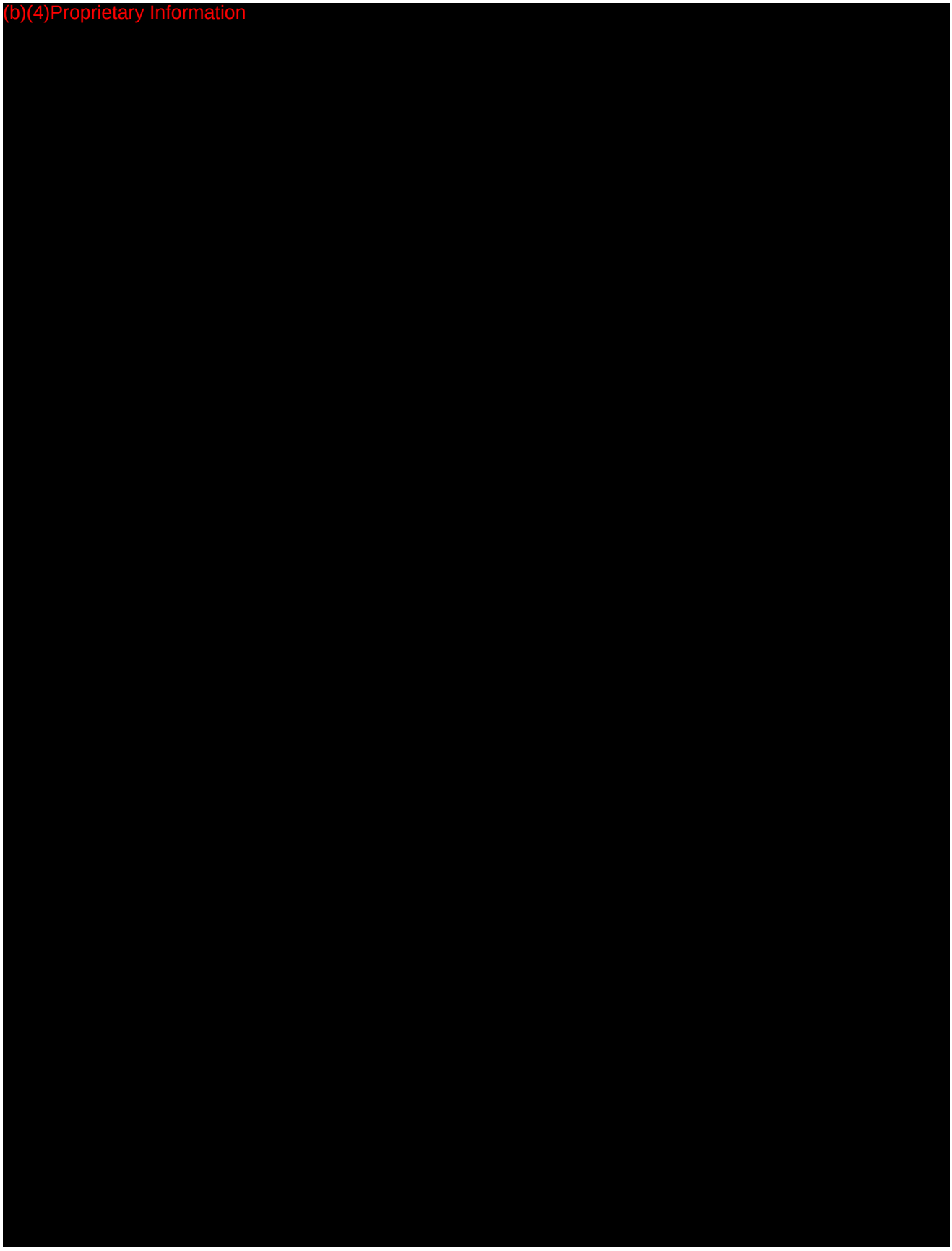
(b)(4)Proprietary Information

[redacted]

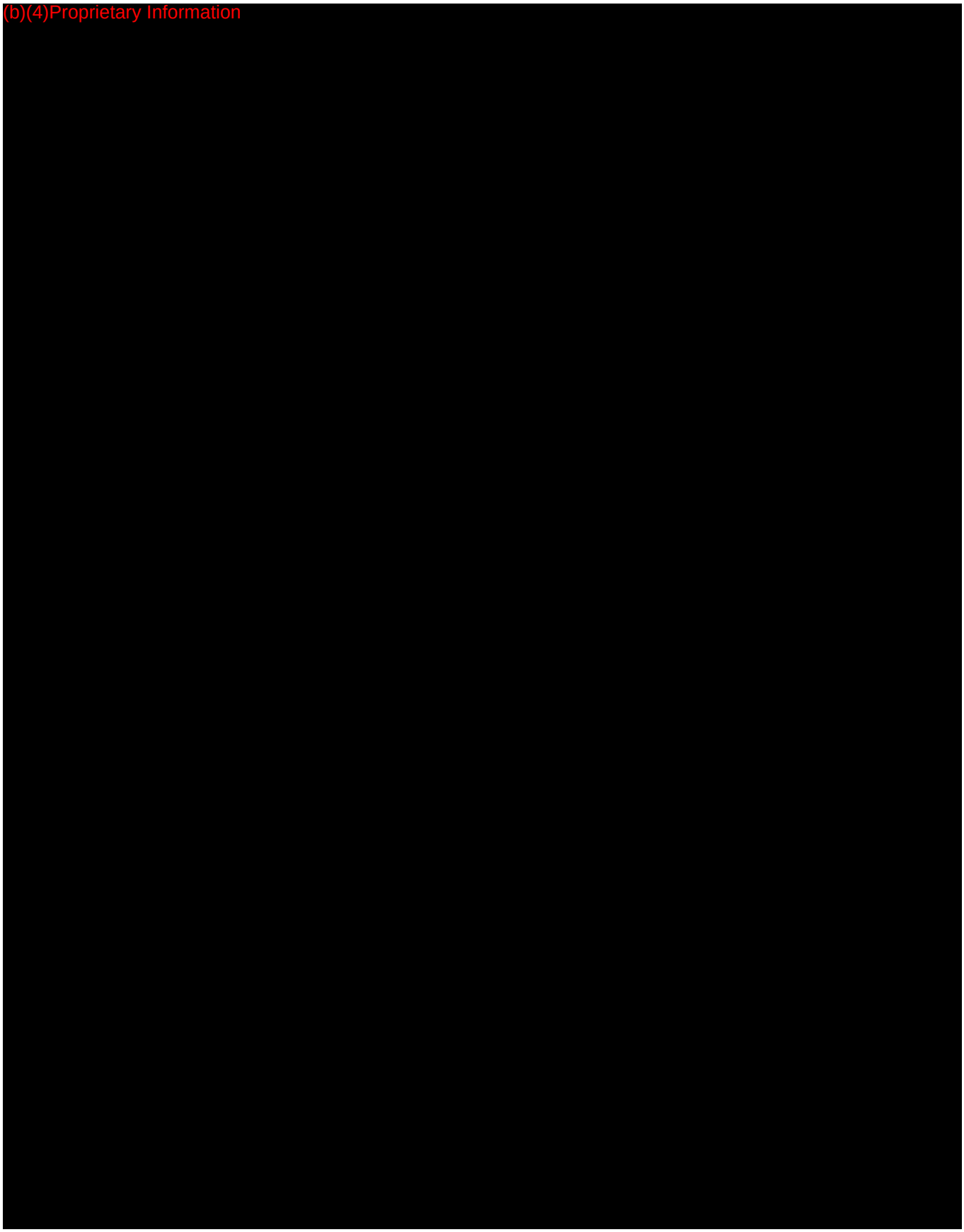
(b)(4)Proprietary Information



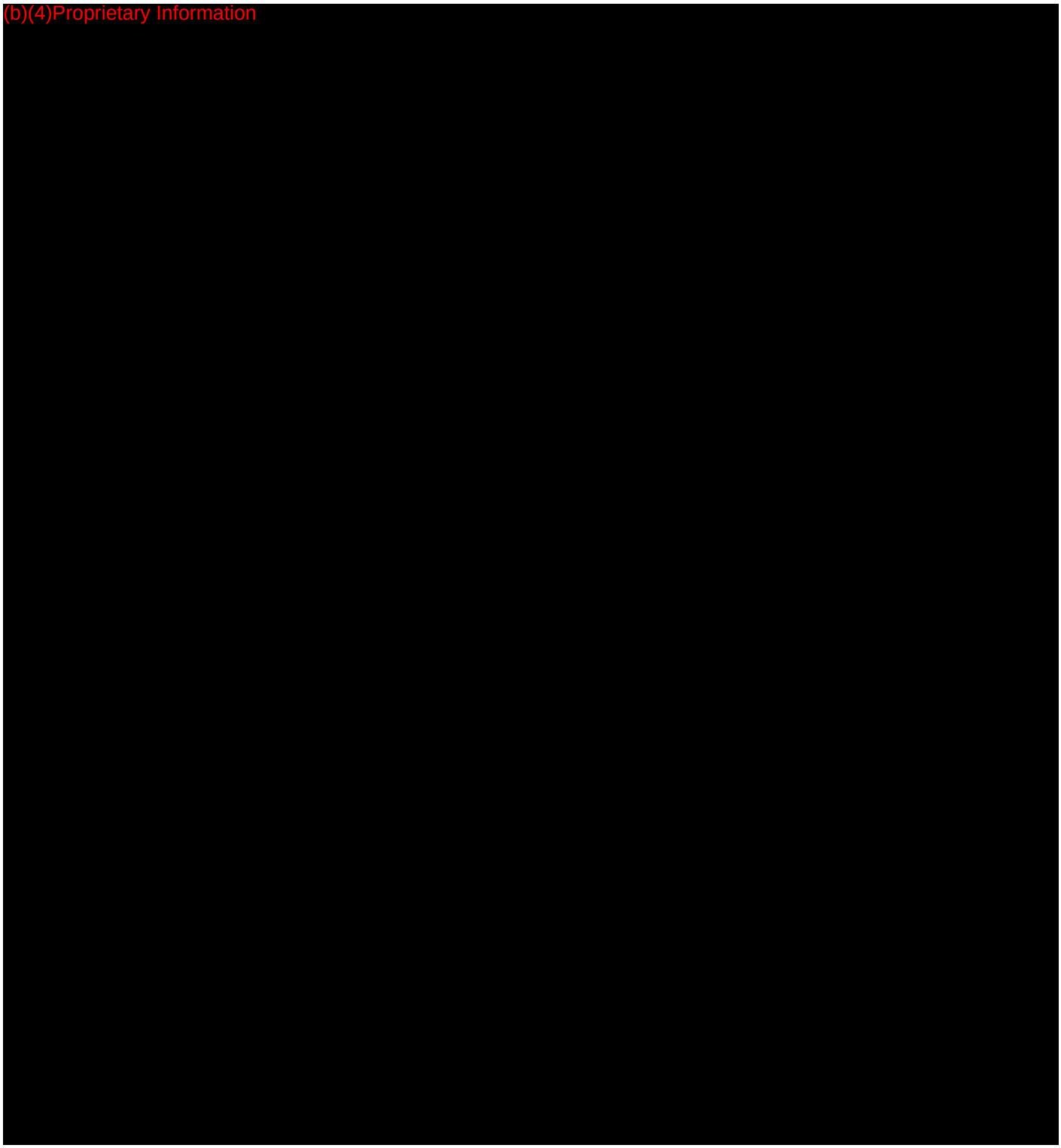
(b)(4)Proprietary Information



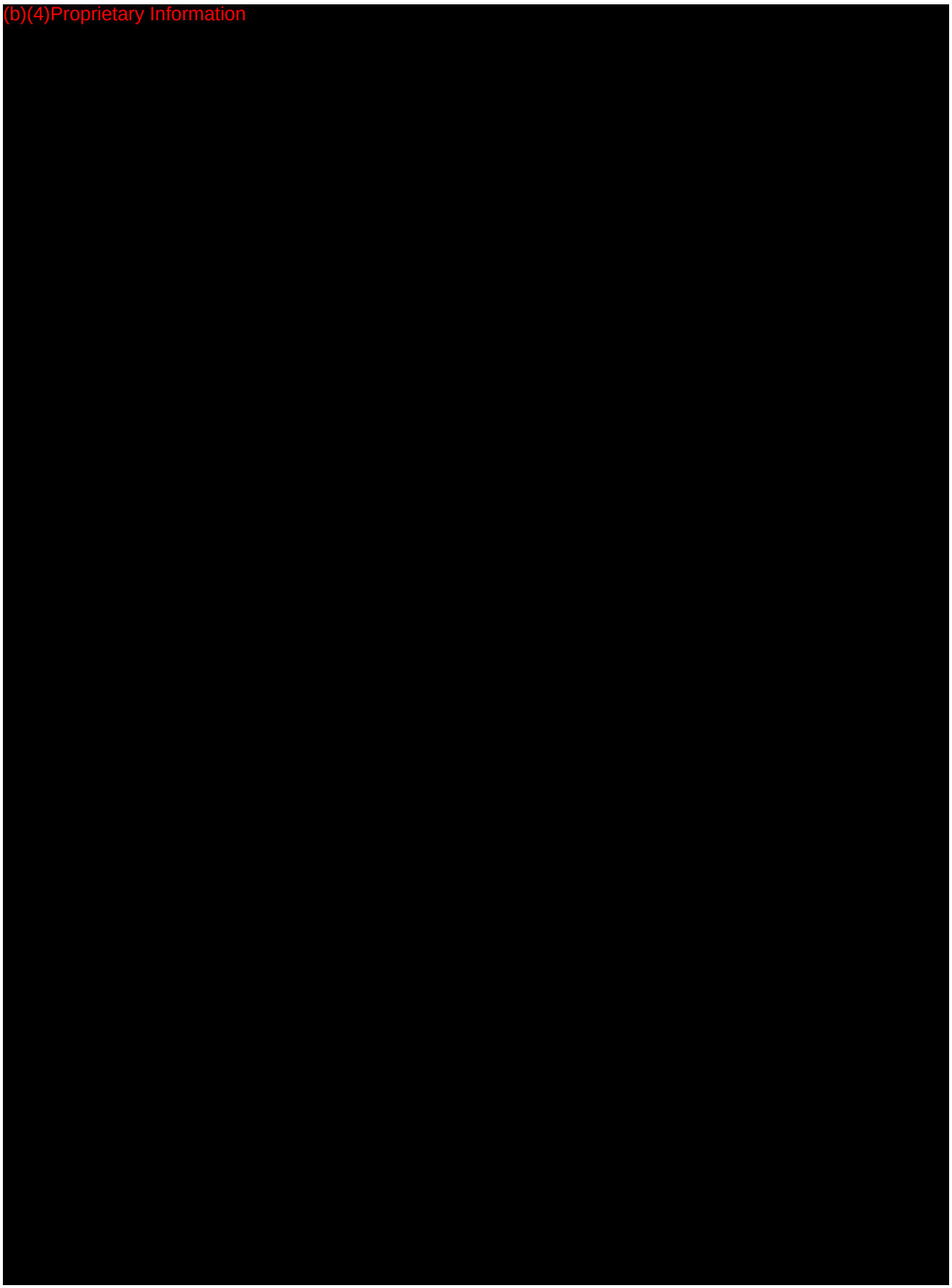
(b)(4)Proprietary Information



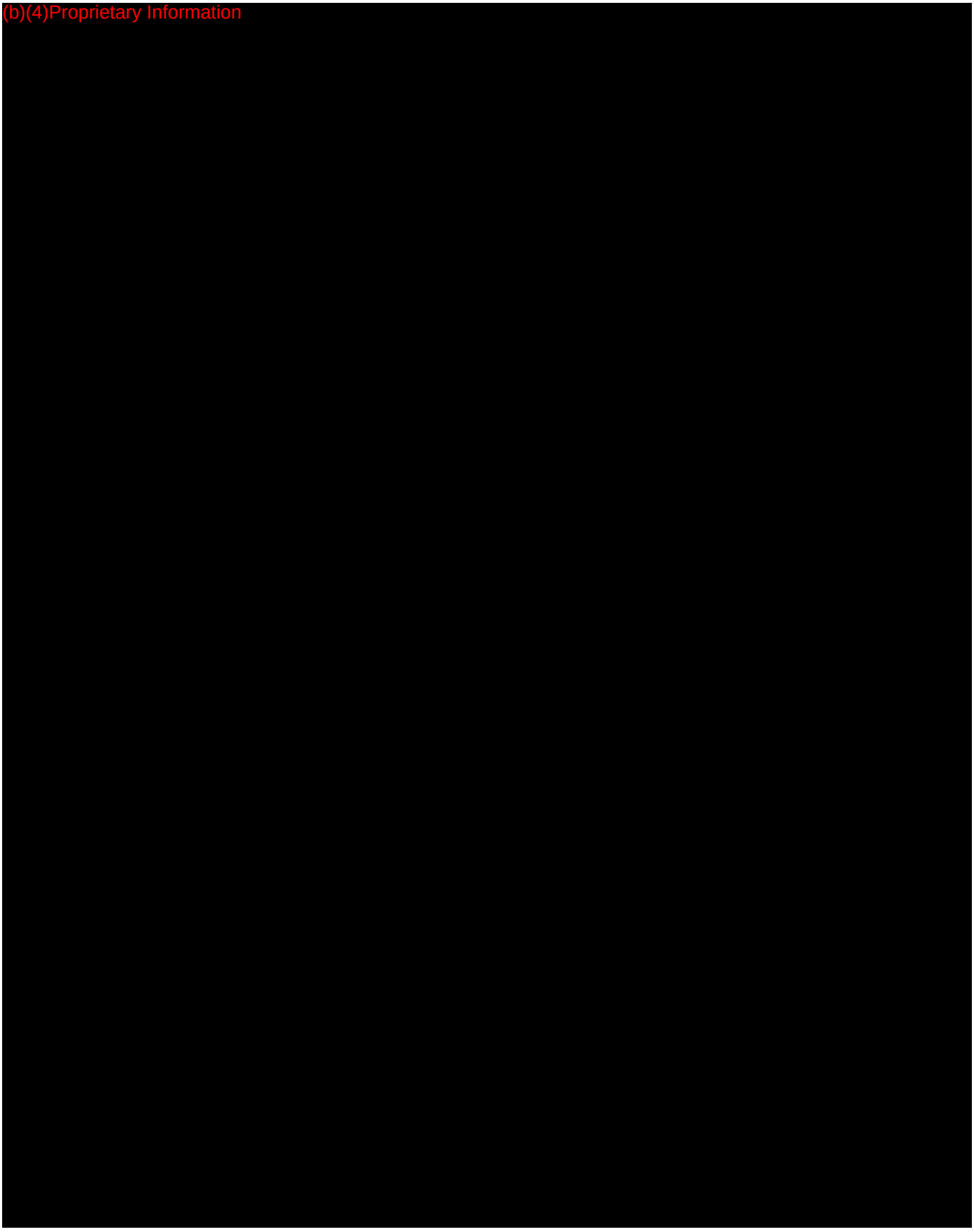
(b)(4)Proprietary Information



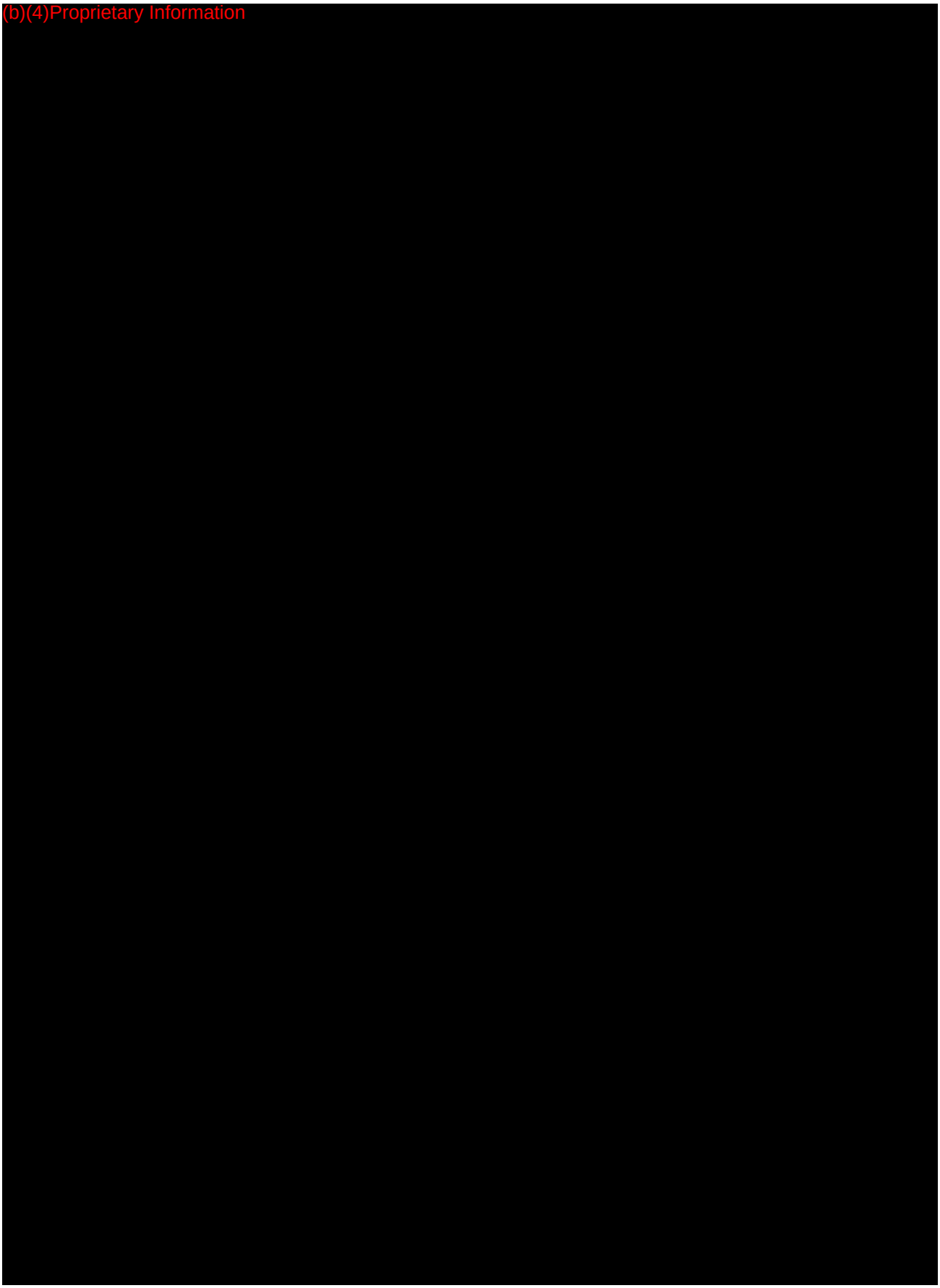
(b)(4)Proprietary Information



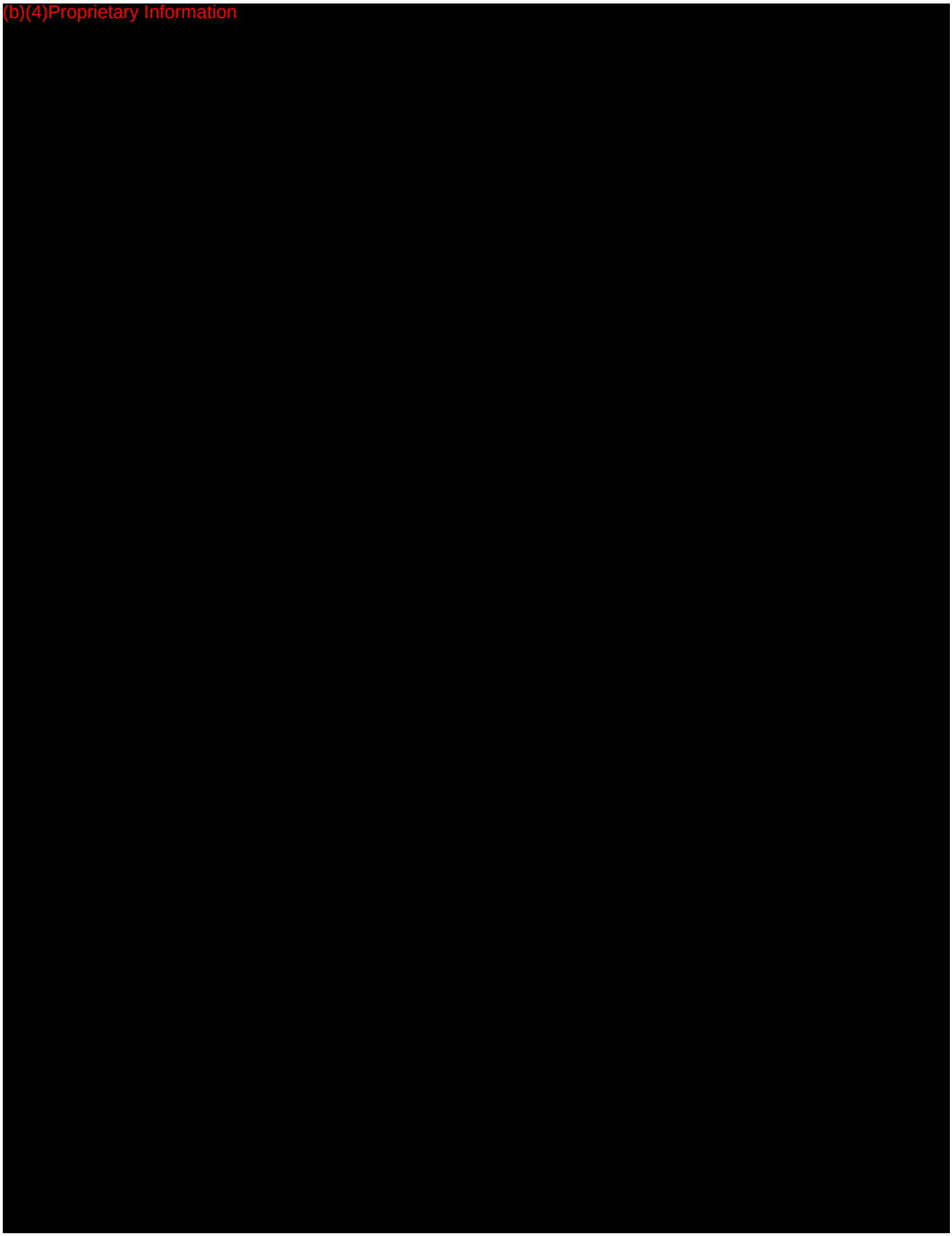
(b)(4)Proprietary Information



(b)(4)Proprietary Information



(b)(4)Proprietary Information



Digital Signature Concurrence Table	
Reviewer Sign-Off	Mark J. Antonino -S 2015.08.03 13:40:06 -04'00'

Contains Nonbinding Recommendations

Print Form

Acceptance Checklist for Traditional 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.

510(k) #: K150692 Date Received by DCC: March 18, 2015

Lead Reviewer: Mark J. Antonino, MS

Branch: GEDB Division: DRGUD Center/Office: CDRH/ODE

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete. It means the reviewer did not assess the element during RTA and the element will be assessed during the substantive review.

Preliminary Questions

Answers in the shaded blocks indicate consultations with Center advisor is needed	Yes	No
1) Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Office Jurisdiction Liaison to determine the appropriate action, and inform division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If the product does not appear to be a device or such a combination product, mark "No."	X	
Comments?		
2. Is the application with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the application is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Office Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If application should not be reviewed by your Center mark "No."	X	
Comments?		
3) If a Request for Designation was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission? b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission ? If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or appropriate CBER Jurisdiction Liaison to determine the appropriate action and inform your division management. Provide summary of Jurisdictional Officer's/Liaison's determination. If the answer to either question is no, mark "No." If there was no RFD, skip this question.		
Comments?		
4) Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."	X	
Comments?		

5) Is there a pending PMA for the same device with the same indications for use? If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.		X
Comments?		
6) If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM - BIMO) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm		X
Comments?		

If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.
If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.
If the answer to 4 is "No," the lead reviewer should consult division management and other Center resources to determine the appropriate action.
If the answer to 5 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.
If the answer to 6 is "Yes," then contact CDRH/OC/DBM-BIMO or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with the BIMO Staff, and indicate BIMO's recommendation/action.

Organizational Elements

Failure to include these items alone generally should not result in an RTA designation.

	Yes	No
1) Submission contains a Table of Contents	X	
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	X	
3) All pages of the submission are numbered.	X	
4) Type of 510(k) is identified (i.e., traditional, abbreviated, or special)	X	
Comments?		

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
A. Administrative				
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	X			
2) Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or 510(k) cover letter):	X			
a) Device trade name or proprietary name	X			
b) Device common name	X			
c) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	X			
3) Submission contains Indications for Use Statement with Rx and/or OTC designation (see also 21 CFR 801.109).	X			
4) Submission contains 510(k) Summary or 510(k) Statement	X			
a) Summary contains all elements per 21 CFR 807.92 *(See also* 510(k) Summary Checklist*)*	X			
b) Statement contains all elements per 21 CFR 807.93			X	
5) Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended* format.	X			
6) Submission contains Class III Summary and Certification. *See recommended* content			X	
7) Submission contains clinical data	X			
a) Submission includes completed Financial Certification (Form 3454) or Disclosure (Form 3455) information for each covered clinical study included in the submission.	X			
b) Submission includes completed Certification of Compliance with the requirements of ClinicalTrials.gov Data Bank (Form 3674) (42 U.S.C. 282(j)(5)(B)) for each applicable device clinical trial included in the submission.	X			
8) If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (Form 3654) or includes detailed information about how and the extent to which the standard has been followed.	X			
9) The submission identifies prior submissions for the same device for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device.	X			
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed. For additional information regarding the Pre-Submission process, please refer to the Draft Guidance "Medical Devices: The Pre-Submission Program and Meetings with FDA Staff." Once finalized, this guidance will represent the Agency's current thinking on this topic.			X	

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
B. Device Description				
10)				
a) If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement.			X	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
11) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:				
a) A description of the principle of operation and mechanism of action for achieving the intended effect.	X			
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	X			
c) A list and description of each device for which clearance is requested.	X			
12) Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions.	X			
13) If device is intended to be marketed with multiple components, accessories, and/or as part of a system				
a) Submission includes a list of all components and accessories to be marketed with the subject device.	X			
b) Submission includes a description (as detailed in item 11(a) and (b) and 12 above) of each component or accessory.	X			
c) A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance.	X			
C. Substantial Equivalence Discussion				
14) Submitter has identified a predicate device.	X			
a) Predicate's 510(k) number, trade name, and model number (if applicable) provided. For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding* documenting preamendment status *is available online.*	X			
b) The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.	X			
15) Submission includes a comparison of the following for the predicate(s) and subject device				
a) Indications for Use	X			

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
b) Technology, including features, materials, and principles of operation	X			
16) Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate), affect safety or effectiveness, or raise different questions of safety and effectiveness (see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f))	X			
D. Proposed Labeling (see also 21 CFR part 801)				
If *in vitro* diagnostic (IVD) device, criteria 17 & 19 may be omitted.				
17) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual) that include a description of the device, its intended use, and the directions for use.	X			
a) Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).	X			
b) Submission includes directions for use that - include statements of all conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) AND - includes directions for layperson (see 21 CFR 801.5) OR submission states that device qualifies for exemption per 21 CFR 801 Subpart D	X			
18) If indicated for prescription use, labeling includes the prescription use statement (see 21 CFR 801.109(b)(1)) or "Rx only" symbol [See also Alternative to Certain Prescription Device Labeling Requirements]	X			
19) General labeling provisions				
a) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).	X			
b) Labeling includes device common or usual name. (21 CFR 801.61)	X			
20)				
a) If there are requirements regarding labeling, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes labeling to establish that the submitter has followed the device-specific requirement.			X	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes labeling to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
c) If there is a special controls document applicable to the device, the submission includes labeling to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.			X	

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
21) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.			X	
E. Sterilization				
If IVD device and sterilization is not applicable, select "N/A" and criteria below will be omitted from checklist.				
Submission states that the device and/or accessories are: (one of the below must be checked)				
X provided sterile				
provided non-sterile but sterilized by the end user				
non-sterile when used				
Information regarding the sterility status of the device is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
22) Assessment of the need for sterilization information				
a) Identification of device, and/or accessories, and/or components that are provided sterile.	X			
b) Identification of device, and/or accessories, and/or components that are end user sterilized.			X	
c) Identification of device, and/or accessories, and/or components that are reusable and cleaning /disinfection instructions are provided.			X	
23) If the device, and/or accessory, and/or a component is provided sterile:				
a) Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.).	X			
b) A description of method to validate the sterilization parameters (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided for each proposed sterilization method. *Note, the sterilization validation report is not required.*	X			
c) For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits.	X			
d) Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.)	X			
e) Sterility Assurance Level (SAL) is stated.	X			
24) If the device, and/or accessory, and/or a component is end user sterilized:			X	
25)				
a) If there are requirements regarding sterility, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes sterility information to establish that the submitter has followed the device-specific requirement.			X	

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes sterility information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
c) If there is a special controls document applicable to the device, the submission includes sterility information to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.			X	
F. Shelf Life				
26) Proposed shelf life/expiration date stated	X			
27) For sterile device, submission includes summary of methods used to establish that device will remain sterile through the proposed shelf life or a rationale for why testing to establish shelf life is not applicable.	X			
28) Submission includes summary of methods used to establish that device performance is not adversely affected by aging or includes a rationale for why the storage conditions are not expected to affect device safety or effectiveness.	X			
G. Biocompatibility				
If IVD device, select "N/A" and the below criteria will be omitted from checklist.				
Submission states that there: (one of the below must be checked)				
X are direct or indirect (e.g., through fluid infusion) patient-contacting components.				
are no direct or indirect (e.g., through fluid infusion) patient-contacting components.				
Information regarding the patient contact status of the device is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
29) Submission includes list of patient-contacting device components and associated materials of construction, including identification of color additives, if present	X			
30) Submission identifies contact classification (e.g., surface-contacting, less then 24 hour duration, etc.)	X			
31) Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test, OR a statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).	X			
H. Software				

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
Submission states that the device: (one of the below must be checked)				
does contain software/firmware.				
☒ does not contain software/firmware.				
Information regarding whether the device contains software is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
I. EMC and Electrical Safety				
Submission states that the device: (one of the below must be checked)				
☒ does require EMC and Electrical Safety evaluation.				
does not require EMC and Electrical Safety evaluation.				
Information regarding whether the device requires EMC and Electrical Safety evaluation is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
34) Submission includes evaluation of electrical safety (e.g., per IEC 60601-1, or equivalent FDA-recognized standard, and if applicable, the device-specific standard), OR submission includes electrical safety evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	☒			
35) Submission includes evaluation of electromagnetic compatibility (e.g., per IEC 60601-1-2 or equivalent FDA-recognized standard and if applicable, the device-specific standard) OR submission includes electromagnetic compatibility evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	☒			
J. Performance Data - General If IVD device, select "N/A" and the below criteria will be omitted from checklist. Performance data criteria relating to IVD devices will be addressed in Section K.				
36) Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre-defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test supports a finding of substantial equivalence.		☒		☒
Comments?	You provide "Design Verification Testing Summaries" and Test protocols (e.g. Attachment 22). However, you do not indicate if acceptance criteria is based on an FDA recognized performance standard or a predicate device. Please address if the acceptance criteria (noted in each Design Verification Test) is based on an FDA recognized performance standard or a predicate device.			

Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
37)				
a) If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement.			X	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
c) If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.			X	
38) If literature is referenced in the submission, submission includes:			X	
39) For each completed nonclinical (i.e., animal) study conducted				
a) Submission includes a study protocol which includes all elements as outlined in 21 CFR 58.120.				
b) Submission includes final study report which includes all elements outlined in 21 CFR 58.185.				
c) Submission contains a statement that the study was conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58), or, if the study was not conducted in compliance with the GLP regulation, the submission explains why the noncompliance would not impact the validity of the study data provided to support a substantial equivalence determination.	X			

K. Performance Characteristics - In Vitro Diagnostic Devices Only

(Also see 21 CFR 809.10(b)(12))

Submission states that the device: (one of the below must be checked)

	is an in vitro diagnostic device.
X	is not an in vitro diagnostic device.

Decision: ○ Accept ○ Refuse to Accept

If Accept, notify applicant.

If Refuse to Accept, notify applicant in writing and include a copy of this checklist.

Digital Signature Concurrence Table

Reviewer Sign-Off	
Branch Chief Sign-Off (digital signature optional)*	
Division Sign-Off (digital signature optional)*	

* Branch and Division review of checklist and concurrence with decision required. Branch and Division digital signature optional.

CONSULTING MEMO

Date: April 13, 2015

To: Mark Antonino, M.S.
CDRH/ODE/DRGUD/GEDB

From: Daniel Krainak, Ph.D.
Office of *In Vitro* Diagnostics and Radiological Health (OIR)
Division of Radiological Health (DRH)
Magnetic Resonance and Electronic Products Branch (MREP)

Subject: K150692
AXIOS Stent with Electrocautery Enhanced Delivery System (10x10 Stent)
AXIOS Stent with Electrocautery Enhanced Delivery System (15x10 Stent)
Xlumena, Inc.

I. Summary

(b)(4)Proprietary Information

[redacted]

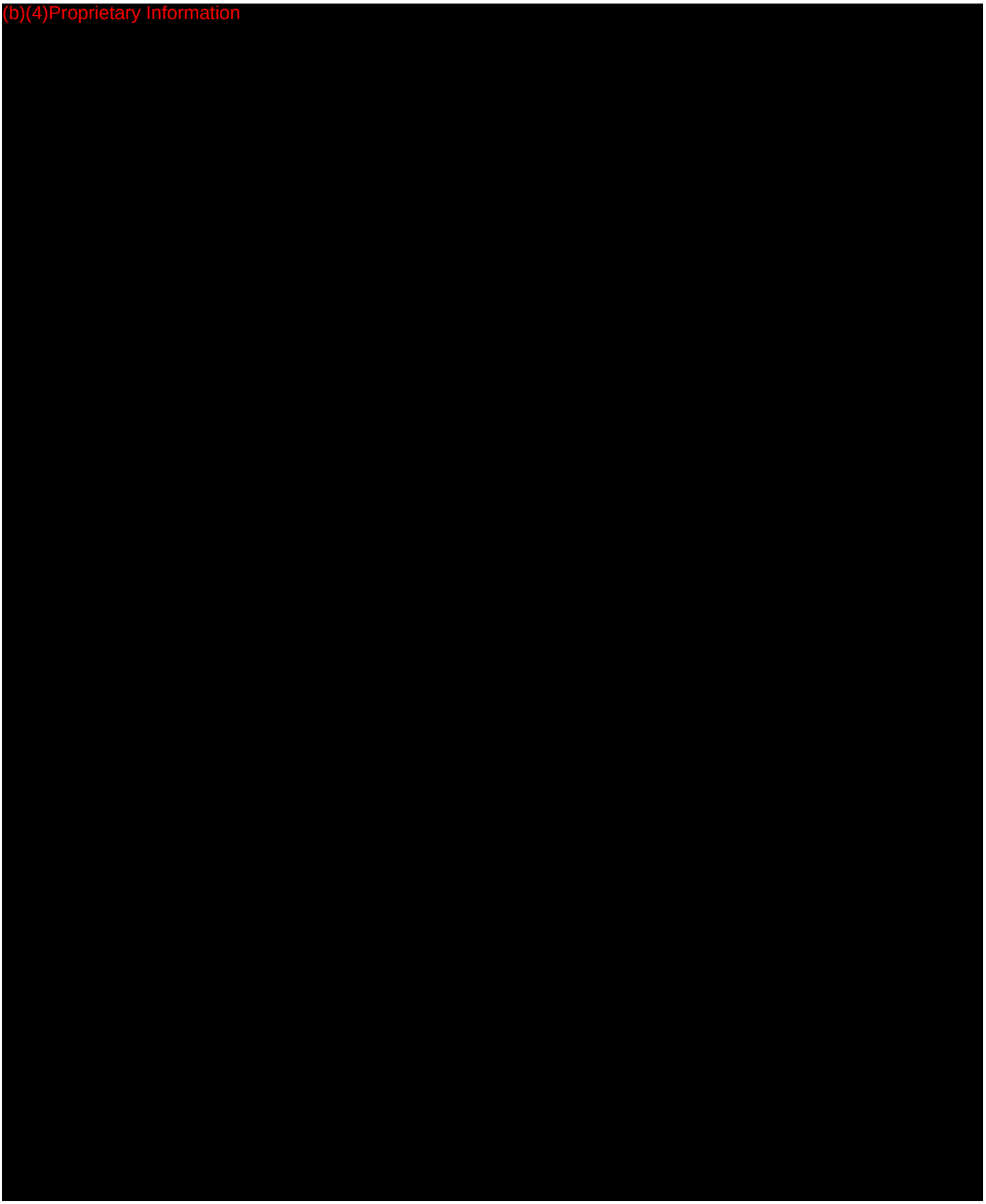
II. Background & Scope

(b)(4)Proprietary Information

[redacted]

III. Device Description

(b)(4)Proprietary Information



(b)(4)Proprietary Information

IV. MR Compatibility Testing

(b)(4)Proprietary Information

V. Proposed MR Conditional labeling

(b)(4)Proprietary Information

(b)(4)Proprietary Information

[redacted]

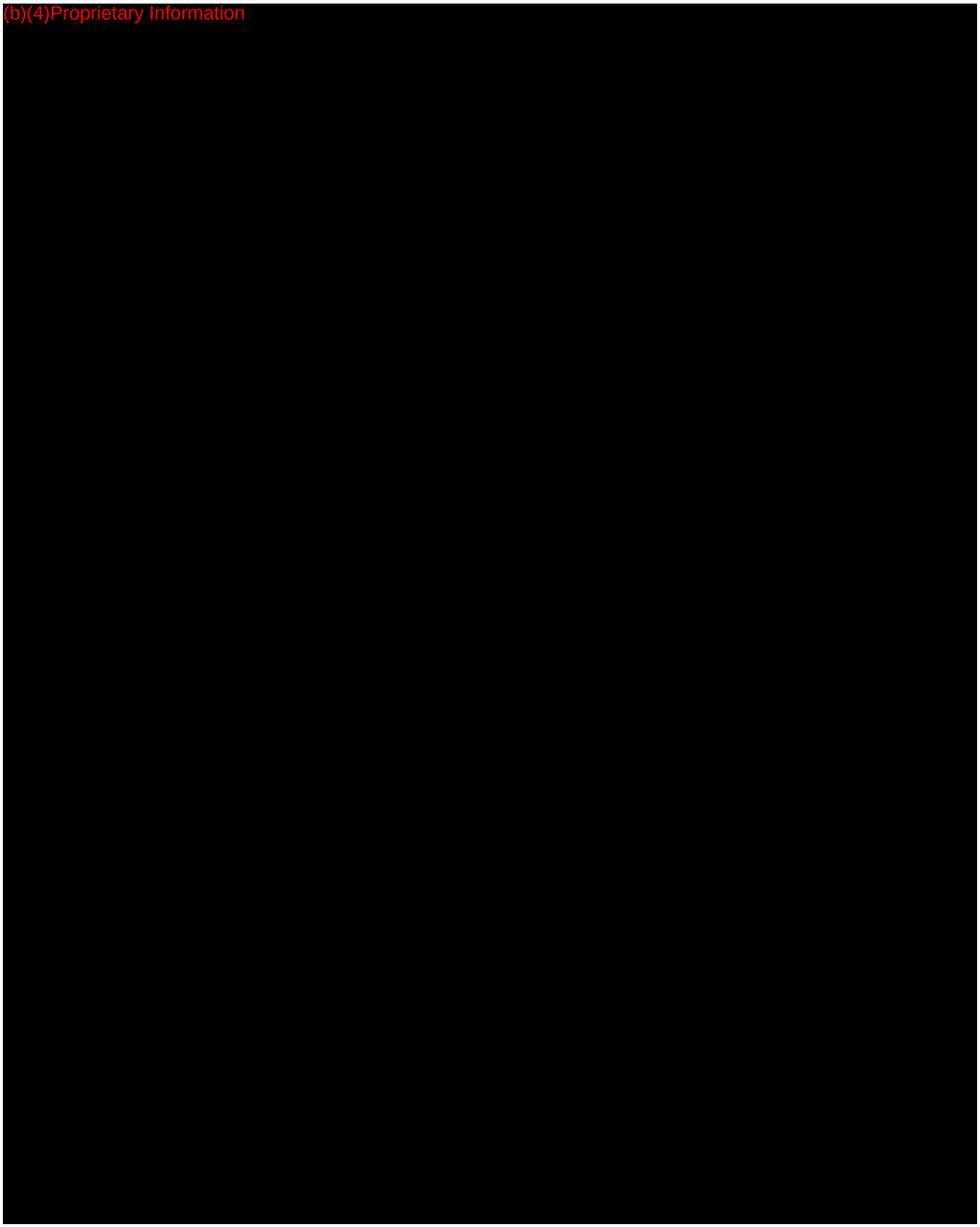
VI. References

(b)(4)Proprietary Information

[redacted]

VII. Deficiencies

(b)(4)Proprietary Information



(b)(4)Proprietary Information

[redacted]

VIII. Signature

Daniel Krainak -S
2015.04.14 13:46:30 -04'00'

Food and Drug Administration
CDRH/ODE/DRGUD/ULDB
WO66 RMG118
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
301-796-5174

Engineering Consult

Date: April 13, 2015
To: Mark Antonino
From: Tuan Nguyen
Subject: Traditional 510(k)# K150692

Applicant: Xlumena, Inc.	**Device Trade Name:** Axios Stent With Electrocautery Enhanced Delivery System (10x10 Stent), Axios Stent With Electrocautery Enhanced Delivery System (15x10 Stent)
Contact: Carole Sykes	**Contact Title:** VP Clinical and Regulatory Affairs
Correspondent Firm: Xlumena, Inc.	**Phone:** (650) 961-9900 **Email:** csykes@xlumena.com
FDA Received Date: March 18, 2015	**Due Date:** June 16, 2015
Reg #: 876.5010 **Reg Name:** Biliary Catheter and Accessories	**Class:** II **Product Code(s):** PCU
Reg #: 876.4300 Reg Name: Endoscopic electrosurgical unit and accessories	Class: II Product Code(s): KNS

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Owner
K140561	PCU	Axios Stent And Delivery System (with 10mm X 10mm Stent) Axios Stent And Delivery System (with 15mm X 10mm Stent)	Xlumena, Inc.
K123250 (NENI)	PCU	Axios Stent And Delivery System	Xlumena, Inc
K022595	KNS	Wilson-cook Cystotome	Wilson-cook Medical, Inc.

Review Summary

From the EMC, electrical, mechanical, thermal safety and risk analysis perspective, the AXIOS Stent with Electrocautery Enhanced Delivery System is found to be safe and substantially equivalent to the predicates AXIOS Stent and Delivery System (K140561) and Wilson-Cook Medical Cystotome (K022595).

Recommendation

I recommend that the Axios Stent With Electrocautery Enhanced Delivery System (10x10 Stent), Axios Stent With Electrocautery Enhanced Delivery System (15x10 Stent) is/are [Choose Decision]

I. Purpose and History

(b)(4)Proprietary Information

[redacted]

II. Device/System Description

Device Characteristics	Yes	No	Inadequate Or Marked
Is the intended use or fundamental technology new?	☐	☒	☐
Is the device life-supporting or life sustaining?	☐	☒	☐
Are there any direct or indirect patient contacting components?	☒	☐	☐
• Is the device or a component an implant?	☐	☒	☐
Does the device use software/firmware?	☐	☒	☐
Does the device or a component need sterilization (by manufacturer or user)?	☐	☒	☐
The device/system uses or is	a single use device(s) (SUD)		☐
Is the device a combination product?	N - Not a Part 3 Combination Product		☐
Is the device electrical (battery or wall powered)?	Yes, it is mains powered Only		☐

Check the attributes that are applicable to this submission.

	Nanotechnology	Reprocessed SUD	Companion Diagnostic
Yes	☐	☐	☐
No	☒	☒	☒
Unknown	☐	☐	☐

(b)(4)Proprietary Information

[redacted]

(b)(4)Proprietary Information

[redacted]

Comparison of Indications for Use

(b)(4)Proprietary Information

[redacted]

Comparison of Indications for Use
(b)(4)Proprietary Information

General Labeling Requirements	Yes	No/N/A	Inadequate or Marked
Is the prescription statement (or "Rx only") included?	☒	☐	☐
The indications for use are consistent with the IFU page?	☐	☐	☐
Appropriate contraindications provided?	☐	☐	☐
Appropriate warnings provided?	☐	☐	☐
Instructions are in accordance with the guidance (if applicable)?	☐	☐	☐
Appropriate labeling inside device?	☐	☐	☐
Appropriate label/indicator outside device?	☐	☐	☐
Appropriate Manual labeling?	☐	☐	☐
What MRI safety information does the labeling contain?		Not Needed	☐

Biocompatibility Review Needed?	Yes ☐	No ☒
Biocompatibility Consult Needed?	Yes ☐	No ☒

III. EMC & Electrical, Mechanical and Thermal Safety & Risk Analysis

EMC Review Needed?	Yes ☒	No ☐
EMC Consult Needed?	Yes ☒	No ☐

Electromagnetic Compatibility Information (IEC 60601-1-2)		Inadequate or Marked
Describe the device(s)/accessory(ies)/component(s) that were tested to the right.	Stent, Generator, Neural Electrode, Foot Switch, Cable	☐
Was a recognized edition of standard IEC 60601-1-2 used for testing?	Yes	☐
Does the device receive radio frequency energy for the purpose of its operation?	Yes	☐
• Does the labeling include the frequency and frequency band the device receives?	Yes	☐
Does the device deliver radio frequency energy to a patient, or use wireless technology?	No	☐
Is the device intended to be used in domestic establishments?	No	☐
Does the device draw more than 16 A of mains current?	No	☐
Does the device use cables (excluding power supply cables)?	Yes	☐
Does the device use an applied part?	No	☐
Does the device contain only simple components like motors and switches and no other electronic circuitry?	No	☐
Is the device standalone lighting equipment only?	No	☐
Is the device information technology equipment?	No	☐
EMC Emissions Testing (from CISPR 11/EN 55011)		
Was emissions testing performed?	Yes	☐
Were emissions measurements at a Test Site or In Situ?	Test Site	☐
If the device is labeled for use only in a shielded location, what is the minimum shielding value in dB ?	12.2 dB	☐
Do mains terminal disturbance voltage limits comply with the following, and are the measured emissions below these limits when the antenna is vertically and horizontally angled: When input power ≤ 12 kVA: For F = 0.15 - 0.50 MHz: Quasi-Peak = 79 dB, Avg = 66 dB For F = 0.50 - 5 MHz: Quasi-Peak = 73 dB, Avg = 60 dB For F = 5 - 30 MHz: Quasi-Peak = 73 dB, Avg = 60 dB When input power > 12 kVA: For F = 0.15 - 0.50 MHz: Quasi-Peak = 100 dB, Avg = 90 dB For F = 0.50 - 5 MHz: Quasi-Peak = 86 dB, Avg = 76 dB For F = 5 - 30 MHz: Quasi-Peak = 90-73 dB, Avg = 80-60 dB		☐

Electromagnetic Compatibility Information (IEC 60601-1-2)		Inadequate or Marked
	Yes	
Do the electromagnetic radiation disturbance limits comply with the following, and are the measured emissions below these limits when the antenna is vertically and horizontally angled: With 10 meter measuring distance: For F = 30 - 230 MHz: (≤ 20kVA) = 40 dB, (> 20 kVA) = 50 dB For F = 230 - 1000 MHz: (≤ 20kVA) = 47 dB, (> 20 kVA) = 50 dB With 3 meter measuring distance: For F = 30 - 230 MHz: (≤ 20kVA) = 50 dB, (> 20 kVA) = 60 dB For F = 230 - 1000 MHz: (≤ 20kVA) = 57 dB, (> 20 kVA) = 60 dB	Yes	☐
EMC Immunity Testing (from IEC 60601-1-2)		
Was immunity testing performed?	Yes	☐
Are the functions determined to be Essential Performance defined and acceptable?	Yes	☐
Is the Essential Performance defined in the labeling?	Yes	☐
Are the EMC Immunity pass/fail criteria adequate given the risk profile and the stated Essential Performance of the device?	Yes	☐
Electrostatic Discharge (ESD) (Sec. 6.2.2)		
Air Electrostatic Discharge (ESD) Test Levels were ±2, ±4, and ±8 kV?	Yes	☐
Contact Electrostatic Discharge (ESD) Test Levels were ±2, ±4, and ±6 kV?	Yes	☐
• Were any failures in the testing or degradations noted that might affect the safety or effectiveness of the device?	No	☐
Electrical fast transients and bursts (Sec. 6.2.4)		
Is the Electrical fast transients and bursts test level ±2 kV for AC and DC power lines?	Yes	☐
Is the Electrical fast transients and bursts test level ±1 kV, for signal and interconnecting cables greater than 3 meters (9.8 feet) long (excluding applied part cables)?	Yes	☐
• Were any failures in the testing or degradations noted that might affect the safety or effectiveness of the device?	No	☐
Surges (Sec. 6.2.5)		
Is the Power Surge test level ±0.5, ±1 and ±2 kV for AC lines to earth?	Yes	☐
Is the Power Surge test level ±0.5 and ±1 kV for AC lines to other lines?	Yes	☐
• Were any failures in the testing or degradations noted that might affect the safety or effectiveness of the device?	No	☐
Radiated RF electromagnetic fields (Sec. 6.2.3)		
What is the Radiated RF Electromagnetic Field (immunity) test level used?	< 3 V/m	☐
Is the device labeled for use only in a shielded location, and is the lower test level acceptably justified?	No	☐
• Were any failures in the testing or degradations noted that might affect the safety or effectiveness of the device?	No	☐
Conducted disturbances, induced by RF fields Sec. 6.2.6)		

Electromagnetic Compatibility Information (IEC 60601-1-2)		Inadequate or Marked
Is the "Conducted Disturbances, induced by RF fields" frequency test range from 150 KHz – 80 MHz?	Yes	☐
• Were any failures in the testing or degradations noted that might affect the safety or effectiveness of the device?	No	☐
What is the "Conducted Disturbances, induced by RF fields" voltage test level?	< 3 Vrms	☐
Is the device labeled for use only in a shielded location, and is the lower test level acceptably justified?	Yes	☐
• Were any failures in the testing or degradations noted that might affect the safety or effectiveness of the device?	No	☐
Voltage dips, short interruptions and voltage variations on power supply input lines (Sec. 6.2.7)		
Is the rated input power ≤ 1 kVA?	Yes	☐
Does degradation of performance occur when an input voltage drop of 95% for 0.5 periods, 60% for 5 periods, and 30% for 25 periods occurs?	Yes	☐
Does the device remain safe, experience no permanent failures, and is resettable when an input voltage drop of 95% for 5 seconds occurs?	Yes	☐
Magnetic fields (Sec. 6.2.8)		
Is the magnetic field immunity test level 3 A/m at a frequency of 60 Hz?	Yes	☐
• Were any failures in the testing or degradations noted that might affect the safety or effectiveness of the device?	No	☐
EMC Final Questions		
In your opinion, does the device remain adequately safe and effective for its intended use in response to all of the emissions measurements and immunity testing?	Yes	☐
If any device modifications were needed in order to pass any of the EMC testing, did the sponsor provide a description of these modifications and a statement that they will all be incorporated into the production units?	No Modifications Needed	☐
Does the sponsor include information addressing the exposure to common EMI emitters (testing or labeling mitigation)?	Yes	☐
Is there documentation demonstrating compliance with the standards' labeling requirements?	Yes	☐
Are there additional components that were tested for EMC differently?	No	☐

(b)(4)Proprietary Information

TABLE 1 – ELECTROMAGNETIC COMPATIBILITY TESTS

Test	Standard	Acceptance Criteria	Test Result
(b)(4)Proprietary Information			

Reviewer Recommendation

The EMC, EMT and Risk Analysis are acceptable.

IV. Performance Testing

A Bench Testing

(b)(4)Proprietary Information

Reviewer Recommendation

The Performance Testing is acceptable.

Substantial Equivalence Determination	Yes	No
Is the predicate device legally marketed?	☒	☐
Do the devices have the same intended use?	☒	☐
Please explain how the intended use of the subject device is similar to or different from the predicate device:		
Do the devices have the same technological characteristics?	☒	☐

(b)(4)Proprietary Information

[redacted]

Digital Signature Concurrence Table	
Reviewer Sign-Off	Tuan Nguyen -S 2015.04.13 07:59:33 -04'00'

Tuan Nguyen, Ph.D.
Biomedical Engineer
ODE/DRGUD/ULDB

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

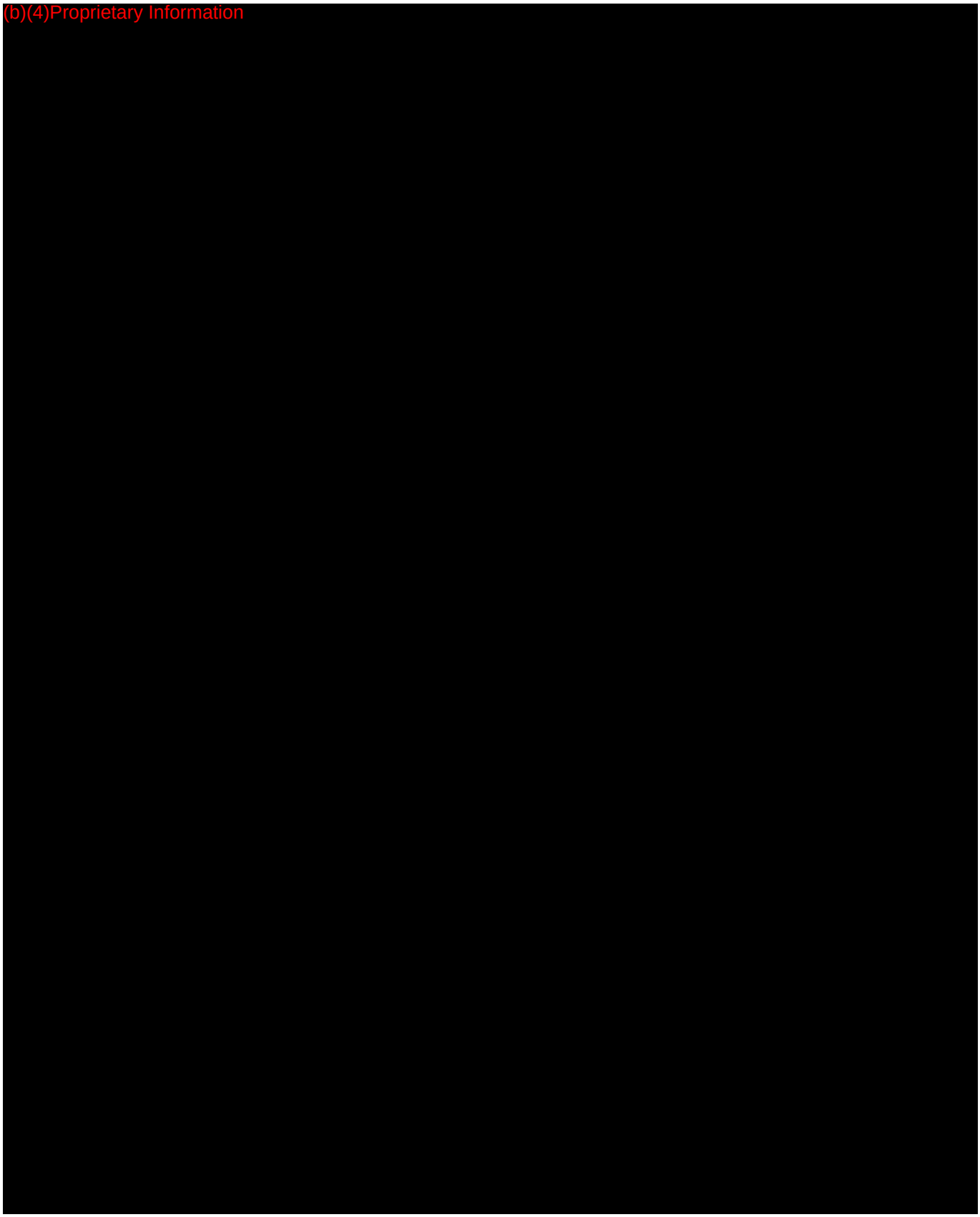
K150692
Xlumena, Inc.
Device Trade Name: The AXIOS™ Stent with Electrocautery Enhanced Delivery System
Contact Name: Carole Sykes

DEFICIENCY LIST

(b)(4)Proprietary Information

[redacted]

(b)(4)Proprietary Information



Memo

To: Mark Antonino, ~~P. D.~~
From: Martin Golding, M.D.
Date: April 3, 2015
Re: K150692, AXIOS Stent with Electrocautery Enhanced Delivery System
Xlumina

Background

(b)(4)Proprietary Information

[redacted]

Device

(b)(4)Proprietary Information

[redacted]

(b)(4)Proprietary Information

Animal study

(b)(4)Proprietary Information

(b)(4)Proprietary Information

Clinical protocol (Appendix U)

(b)(4)Proprietary Information

Instructions for use (indications for use)

(b)(4)Proprietary Information

(b)(4)Proprietary Information

Summary

(b)(4)Proprietary Information

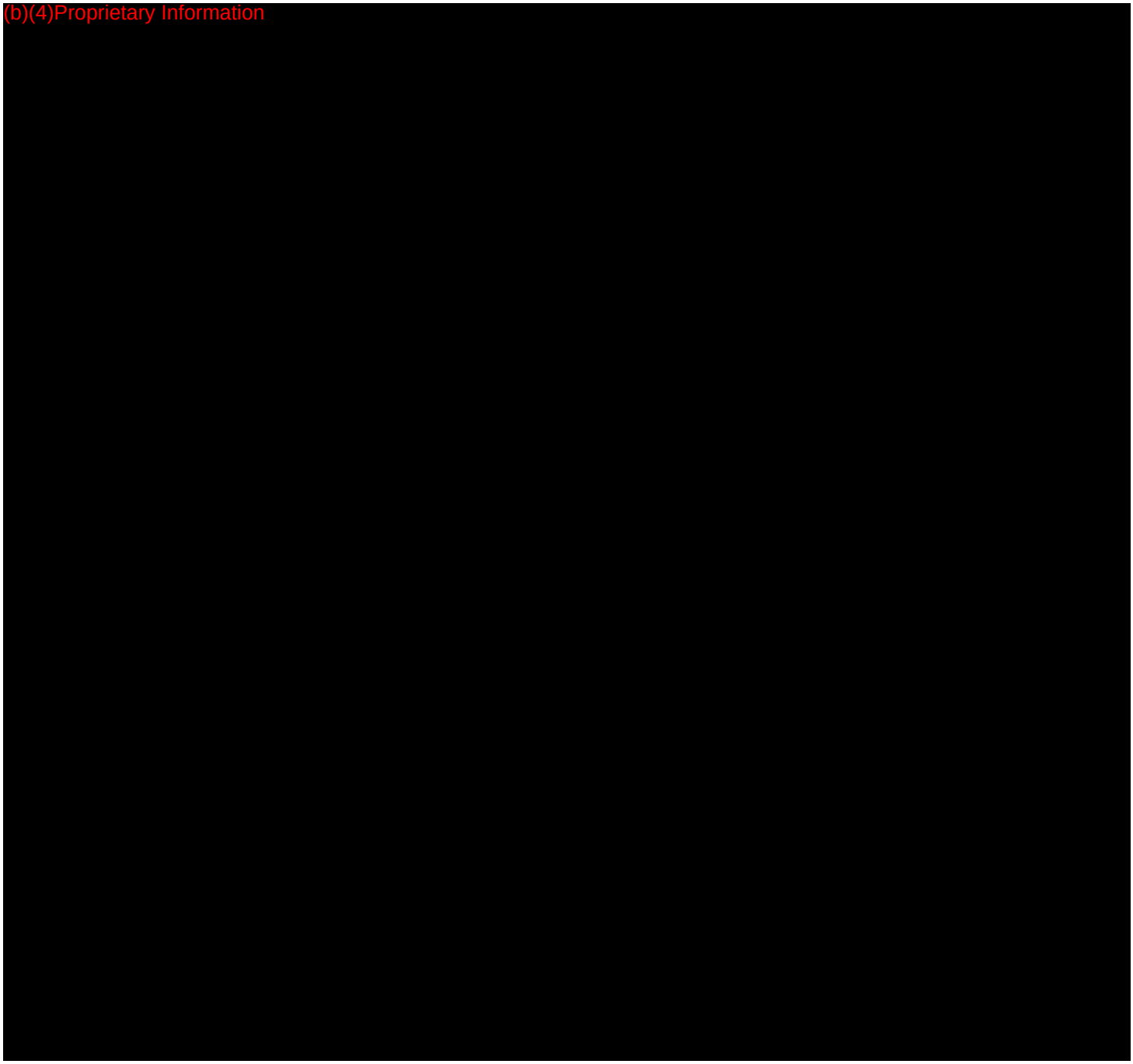
[redacted]

Martin I. Golding -S
2015.04.03
11:02:48 -04'00'

Martin Golding, M.D.

To: Mark Antonino, CDRH/FDA
From: Carole Sykes, Xlumena, Inc., a Boston Scientific Company
Re: Email question on 7/28/2015 concerning K150692

(b)(4)Proprietary Information



(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b) (6)

(b)(4)P i t

(b)(4)P i t

(b)(4)Proprietary Information-Testing

(b) (6)

(b)(4)Proprietary Information-Testing

(b) (6)

(b)(4)Proprietary Information-Testing

(b) (6)

(b)(4)Proprietary Information-Testing

(b) (6)

(b)(4)Proprietary Information-Testing

(b) (6)

(b)(4)Proprietary Information-Testing

(b) (6)

(b)(4)Proprietary Information-Testing

(b) (6)

(b)(4)Proprietary Information-Testing

(b) (6)

(b)(4)Proprietary Information-Testing

(b) (6)

(b)(4)Proprietary Information-Testing

(b) (6)

(b)(4)Proprietary Information-Testing

(b) (6)

(b)(4)Proprietary Information-Testing

(b) (6)

(b)(4)Proprietary Information-Testing

(b) (6)

(b)(4)Proprietary Information-Testing

(b) (6)

(b)(4)Proprietary Information-Testing

APPENDIX I: TESTING FLOWCHART

(b) (6)

(b)(4)Proprietary Information-Testing

(b) (6)

(b)(4)Proprietary Information-Testing

(b) (6)

(b)(4)Proprietary Information-Testing

(b) (6)

(b)(4)Proprietary Information-Testing

(b) (6)

(b)(4)Proprietary Information-Testing

(b) (6)

(b)(4)Proprietary Information-Testing

(b) (6)

(b)(4)Proprietary Information-Testing

(b) (6)

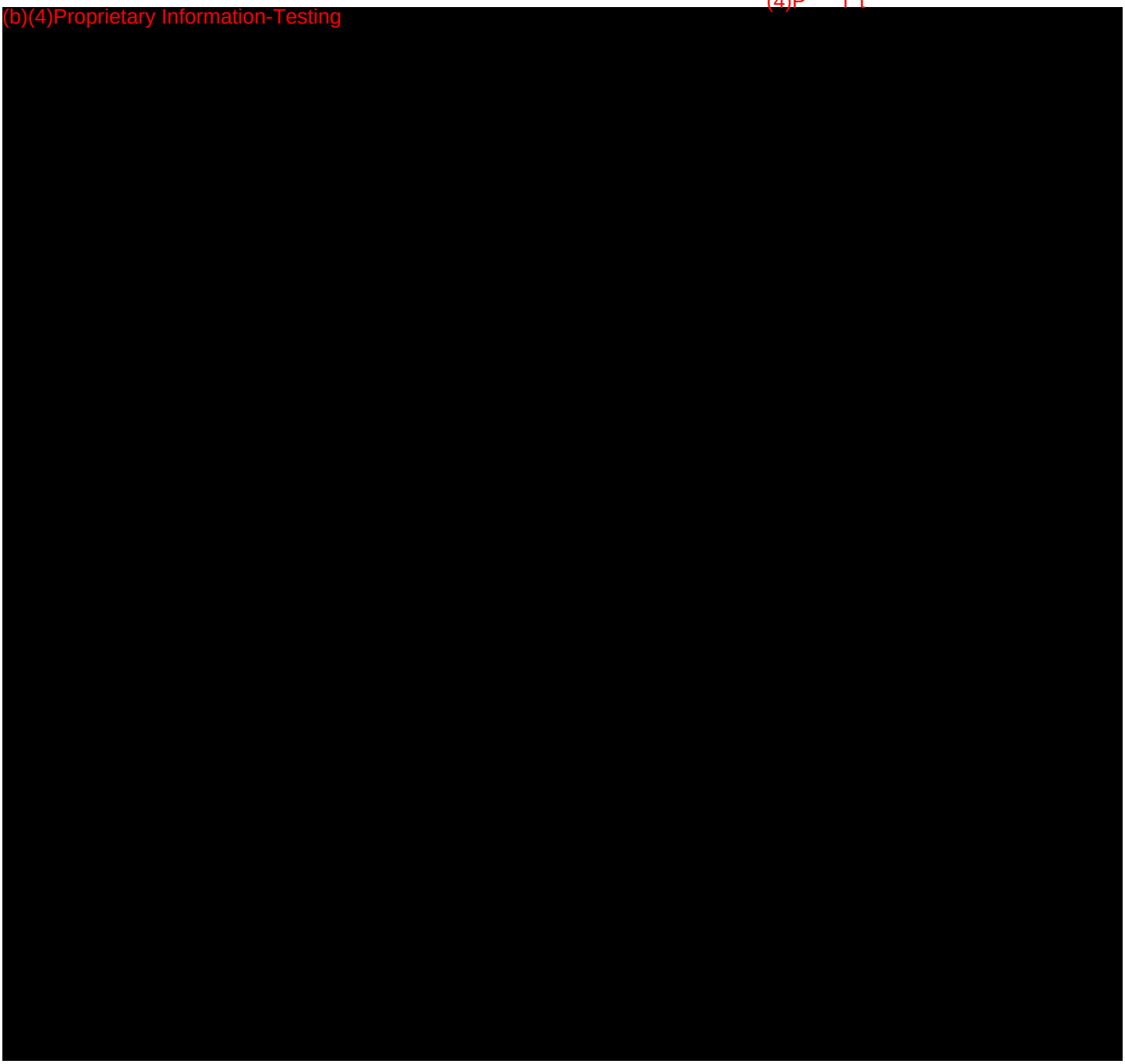
(b)(4)Proprietary Information-Testing

(b) (4)P i

(b) (6)

(b) (4)P i t

(b)(4)Proprietary Information-Testing



(b) (4)P i

(b) (6)

(b) (4)P i t

(b)(4)Proprietary Information-Testing

(b) (4)P i

(b) (6)

(b) (4)P i t

(b)(4)Proprietary Information-Testing

(b)(4)P i

(b) (6)

(b)(4)P i t

(b)(4)Proprietary Information-Testing

(b)(4)P i

(b) (6)

(b)(4)P i t

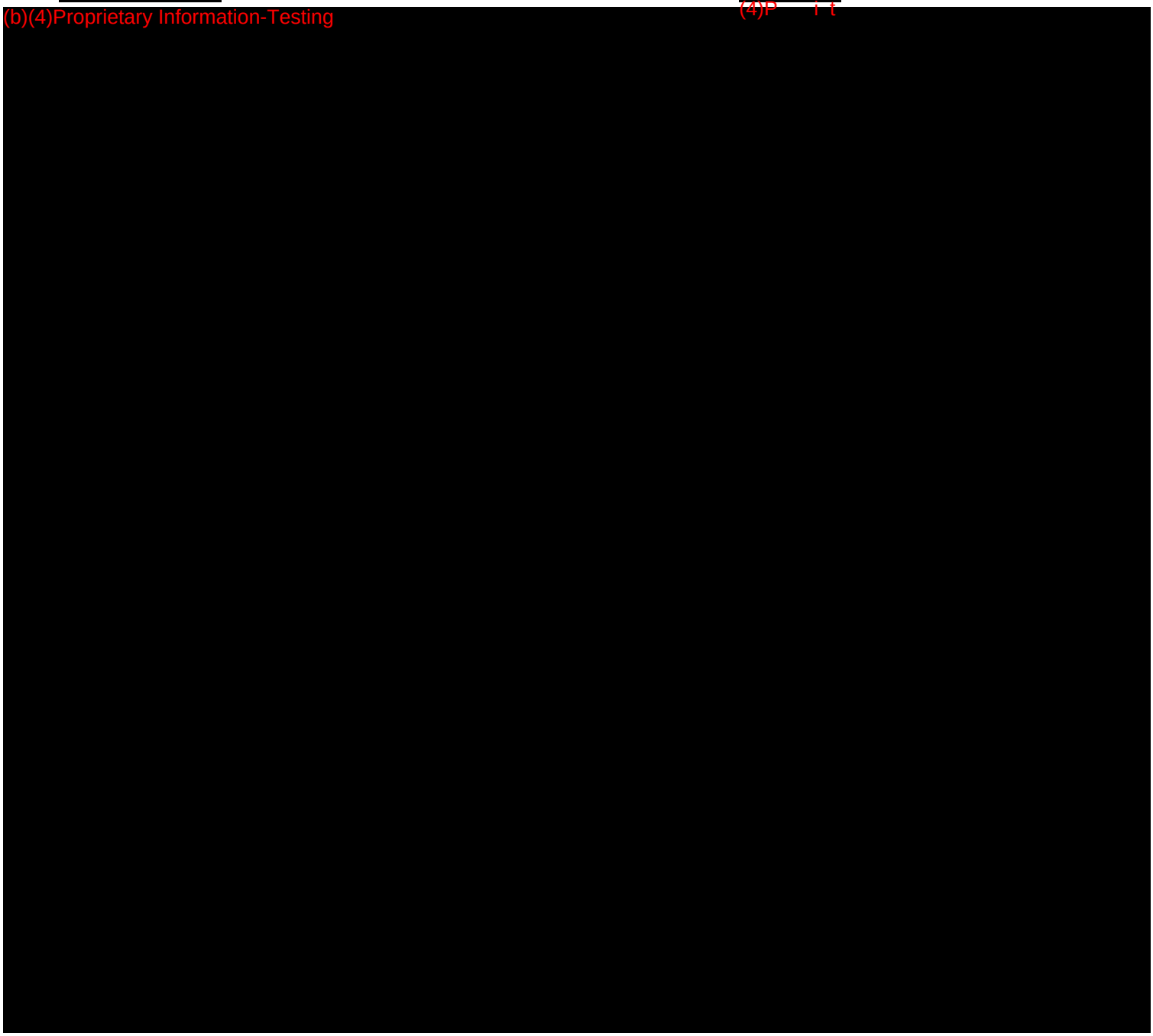
(b)(4)Proprietary Information-Testing

(b)(4)P i

(b) (6)

(b)(4)P i t

(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing

(b) (6)

Appendix I: AXIOS BD 12 Month Shelf Life Test Protocol.

(b) (4)Propriet

(b) (4)P i

(b) (6)

(b) (4)P i t

Appendix II: Test Methods and Completed Data Sheets for (b) (4)Propriet

(b) (6)

(b) (4)P i

(b) (4)Propriet ary Informatio

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information

K150692 Appendix #	Specification Description	Acceptance Value	Specification Justification	Test Method
(b)(4)Proprietary Information				

K150692 Appendix #	Specification Description	Acceptance Value	Specification Justification	Test Method
(b)(4)Proprietary Information				

K150692 Appendix #	Specification Description	Acceptance Value	Specification Justification	Test Method
(b)(4)Proprietary Information				

(b)(4)Proprietary Information

K150692 Appendix #	Specification Description	Value	Specification Justification	Test Method
(b)(4)Proprietary Information				

The BSC contact for Premarket Notification K150692 is:

Carole Sykes
VP, Regulatory and Clinical Affairs
Xlumena, Inc.
453 Ravendale Drive Suite H
Mountain View CA 94043
cell: 650-868-4331
fax:650.961.9901
csykes@xlumena.com

Sincerely

Robert T. Miragliuolo
VP, Regulatory Affairs - Endoscopy
Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752
(508) 683-4186
miraglir@bsci.com

K150692

March 17, 2015

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center -WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Traditional 510(k) Premarket Notification
AXIOS Stent with Electrocautery Enhanced Delivery System

Dear Sir or Madam:

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act ("FD&C Act"), 21 U.S.C. § 360(K) and 21 C.F.R. § 807.87 (1997), Xlumena, Inc. ("the Company") is submitting the enclosed Traditional Premarket ["510(k)"] Notification for the AXIOS Stent with Electrocautery Enhanced Delivery System. The AXIOS Stent with Electrocautery Enhanced Delivery System is designed for use with standard off-the-shelf endoscopic and electrosurgical devices to deliver a flexible, MR conditional, fully-covered, self-expanding braided Nitinol stent for transgastric or transduodenal endoscopic drainage of symptomatic pancreatic pseudocysts. The subject premarket notification describes modifications to add electrocautery to the cleared AXIOS Delivery System which is used to provide access and delivery of the currently cleared AXIOS Stent. There have been no modifications to the preloaded AXIOS Stent. Both the AXIOS Stent and Delivery System were originally cleared under K123250 and most recently under K140561.

Two copies of this 510(k) Submission have been provided: one paper copy and one electronic copy (eCopy) prepared in accordance with CDRH's electronic copy program. The eCopy is an exact duplicate of the paper copy.

510(k) Submitter: Xlumena, Inc.
453 Ravendale Drive, Suite H
Mountain View, CA 94043

Telephone: (650) 961-9900
Facsimile: (650) 961-9901

Contact: Carole Sykes, V.P. Clinical and Regulatory Affairs
csykes@Xlumena.com

1 - CD

Establishment Registration: 3008516478

Trade Name/Model Number(s): AXIOS™ Stent with Electrocautery Enhanced Delivery System

Catalog Number	Description	Stent Size			Delivery System Outer Diameter
		Lumen Diameter	Saddle Length	Flange Diameter	
HXS-10-10	AXIOS Electrocautery Enhanced Delivery System with 10x10 Stent	10 mm	10 mm	21 mm	10.8Fr
HXS-15-10	AXIOS Electrocautery Enhanced Delivery System with 15x10 Stent	15 mm	10 mm	24 mm	10.8Fr

Classification Name: Pancreatic drainage stent and delivery system

Device Class: Class II

Regulation: 21 CFR 876.5015 / 21 CFR 876.4300

Product Code: PCU / 78KNS

Review Panel: Reproductive, Gastro-Renal and Urological Devices

Predicate Device Information:

Manufacturer	Name of Predicate Device	510(k) #	Clearance Date
Xlumena, Inc.	AXIOS Stent and Delivery System	K140561 K123250	April 23, 2014 December 18, 2013
Wilson-Cook Medical, Inc.	Wilson-Cook Cystotome	K022595	October 17, 2002

Reason for Submission

This Traditional 510(k) submission is to request premarket clearance for the AXOIS Stent with Electrocautery Delivery System. The AXIOS Stent with Delivery System was cleared via 510(k)s K123250 and K140561. The scope of this 510(k) is for modifications to the Delivery System to add electrocautery in order to facilitate access of target anatomies followed by the staged and precise placement of the AXIOS Stent using a single device. (b)(4)Proprietary

(b)(4)Proprietary Information

Indications for Use
Identical to the cleared Xlumena AXIOS Stent and Delivery System:

The AXIOS™ Stent with Electrocautery Enhanced Delivery System is indicated for use to facilitate transgastric or transduodenal endoscopic drainage of symptomatic pancreatic pseudocysts ≥ 6cm in size, with ≥ 70% fluid content that are adherent to the gastric or bowel wall. Once placed, the AXIOS stent functions as an access port allowing passage of standard and therapeutic endoscopes to facilitate debridement, irrigation and cystoscopy. The stent is intended for implantation up to 60 days and should be removed upon confirmation of pseudocyst resolution.

Refer to **Table 1**. Design and Use of the Device.

Table 1. Design and Use of the Device

Question	Yes	No
1. Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
2. Is the device intended for over-the-counter use (21CFR 807 Subpart C)?		X
3. Does the device contain components derived from a tissue or other biological source?		X
4. Is the device provided sterile?	X	
5. Is the device intended for single use?	X	
6. Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?	N/A	N/A
7. Does the device contain a drug?		X
8. Does the device contain a biologic?		X
9. Does the device use software?		X
10. Does the submission include clinical information?	X	
11. Is the device implanted?	X*	

* The AXIOS Stent is implanted for up to 60 days

The AXIOS Stent with Electrocautery Enhanced Delivery System, with the modifications required for electrocautery, is substantially equivalent to the AXIOS Stent with Delivery System (non-cautery) [510(k) K123250 and K140561] and the Wilson-Cook Cystotome cleared in 510(k) K022595 based on the intended use / indications for use, as well as technological characteristics and principles of operation. Bench performance, biocompatibility, electrical safety, electromagnetic compatibility, animal and clinical evaluations (b)(4)Proprietary Information provided in the subject premarket notification demonstrate that the AXIOS Stent with Electrocautery Enhanced Delivery System is safe and effective for its intended use.

The Company considers its intent to market the AXIOS Stent with Electrocautery Enhanced Delivery System to be confidential commercial information. Xlumena, Inc. has not disclosed its intent to market the AXIOS Stent with Electrocautery Enhanced Delivery System to anyone except its employees, others with a financial interest in the Company, its advertising and law firms, clinical investigators and its consultants. The Company, therefore, requests that FDA not

disclose the existence of this application until such time as final action on the submission is taken.

In addition, some of the material in this application may be trade secret or confidential commercial or financial information within the meaning of 21 C.F.R. § 20.61 and, therefore, not disclosable under the Freedom of Information Act, even after the existence of the application becomes public. We ask that FDA consult with the Company as provided in 21 C.F.R. § 20.45 before making any part of this submission publicly available.

We trust that the information contained in the subject 510(k) Premarket Notification will be sufficient to enable FDA to find the AXIOS Stent with Electrocautery Enhanced Delivery System to be substantially equivalent to the predicate devices. Please direct any questions or requests for additional information to me at 650-868-4331 or by email at csykes@Xlumena.com.

Sincerely,

Carole Sykes
V.P. Clinical and Regulatory Affairs
Xlumena, Inc.

Traditional 510(k) Premarket Notification

AXIOS™ STENT WITH ELECTROCAUTERY ENHANCED DELIVERY SYSTEM

March 17, 2015

Sponsor and Manufacturer
Xlumena, Inc.
453 Ravendale Drive, Suite H
Mountain View, CA 94043
Telephone: 650-961-9900
Facsimile: 650-961-9901

CONFIDENTIAL

TABLE OF CONTENTS		
Section No.	**Section Description**	**Page**
VOLUME 1		
1	Medical Device User Fee Cover Sheet (Form FDA 3601)	5
2	CDRH Premarket Review Submission Cover Sheet (Form FDA 3514)	8
3	510(k) Cover Letter	18
4	510(k) Acceptance Checklist	23
5	Indications for Use Statement (Form FDA 3881)	24
6	510(k) Summary	26
7	Standards Data Report (Form FDA 3654)	27
8	Truthful and Accuracy Statement	28
9	Class III Summary and Certification	30
10	Financial Certification or Disclosure Statement and Certification of Compliance with ClinicalTrial.gov Data Bank (Form FDA-3674)	31
11	Declarations of Conformity and Summary Reports	32
12	Executive Summary	33
13	Device Description A. Summary of Main Features B. Detailed Device Description 1. AXIOS Stent 2. AXIOS Electrocautery Enhanced Delivery System 3. Ancillary Devices C. Proposed Modifications D. Principles of Operation E. Device Operation and Stent Deployment Steps	35
14	Substantial Equivalence Discussion A. Intended Use / Indications for Use B. Technological Characteristics and Principles of Operation C. Material Changes D. Conclusions	52
15	Proposed Labeling	58
16	Sterilization, Packaging and Shelf Life A. Sterilization B. Packaging C. Packaging Validation D. Shelf Life	60
17	Biocompatibility A. Components and Materials B. Biocompatibility Testing C. Conclusions	73
18	Software	78

Attachments

VOLUME 2	
1	Acceptance Checklist for Traditional 510(k)
2	510(k) Summary
3	Standards FDA Form 3654
4	Financial Certifications or Disclosure Statements Certification of Compliance with ClincialTrials.gov
5	Predicate Device Information – Xlumena AXIOS Stent with Delivery System
6	Predicate Device Information – Wilson-Cook Cystotome
7	AXIOS Stent with Electrocautery Enhanced Delivery System Instructions for Use (b)(4)Proprietary
8	AXIOS Stent with Electrocautery Enhanced Delivery System Instructions for Use (b)(4)Proprietary Information
9	AXIOS Stent with Electrocautery Enhanced Delivery System Instructions for Use (b)(4)Proprietary Information
10	AXIOS Stent with Electrocautery Enhanced Delivery System 10 x 10 Stent (b)(4)P Pouch Label
11	AXIOS Stent with Electrocautery Enhanced Delivery System 15 x 10 Stent (b)(4)P Pouch Label
12	AXIOS Stent with Electrocautery Enhanced Delivery System 10 x 10 Stent Supplemental Label
13	AXIOS Stent with Electrocautery Enhanced Delivery System 15 x 10 Stent Supplemental Label
14	AXIOS Stent with Electrocautery Enhanced Delivery System Box Label
15	AXIOS Stent Implant Card
16	(b) Hot AXIOS (b)(4)Proprietary Test Protocol
17	(b) Hot AXIOS (b)(4)Proprietary Test Report
18	(b) AXIOS / Hot AXIOS (b)(4)Proprietary Information Report
19	(b)(4)Proprietary Information Test Method
20	(b)(4)Proprietary Information Test Method
21	(b)(4)Proprietary Information Test Method
22	(b) Hot AXIOS (b)(4)Proprietary Information Test Method
23	(b)(4)Proprietary Information Test Method
VOLUME 3	
24	(b) AXIOS Delivery System Biocompatibility Protocol
25	(b) (4)Prop AXIOS Delivery System Biocompatibility Report

VOLUME 3 (CONTINUED)	
26	(b)(4) IEC 60601 Compatibility Test Report
27	(b)(4) Hot AXIOS RF Radiated Emissions Test Report
VOLUME 4	
28	(b)(4) Hot AXIOS (b)(4) Proprietary Information Design Verification Test Protocol
29	(b)(4) Hot AXIOS (b)(4) Proprietary Information Design Verification Test Report
30	(b)(4) Hot AXIOS RF Safety Test Method
31	(b)(4) Xlumena Ex-Vivo & Device Validation Models
32	(b)(4) AXIOS Tissue Study Protocol
33	(b)(4) Hot AXIOS Tissue Study Report
34	(b)(4) Hot AXIOS In-Vivo (b)(4) Proprietary Information Study Protocol
35	(b)(4) Hot AXIOS In-Vivo (b)(4) Proprietary Information Study Report
36	(b)(4) AXIOS Stent with Electrocautery Enhanced Delivery System Clinical Protocol
VOLUME 5	
37	(b)(4) AXIOS Stent with Electrocautery Enhanced Delivery System Clinical Report
38	(b)(4) AXIOS (b)(4) Proprietary Information Sterilization Re-Validation Report

SECTION 1: MEDICAL DEVICE USER FEE COVER SHEET

The Medical Device User Fee Cover Sheet (Form FDA 3601) is enclosed to allow the FDA to begin processing this submission based on evidence that the User Fee has been paid.

Form Approved: OMB No. 0910-0511 Expiration Date: April 30, 2016. See Instructions for OMB Statement.

VOL1 PAGE 78

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION **MEDICAL DEVICE USER FEE COVER SHEET**	PAYMENT IDENTIFICATION NUMBER: (b)(4) Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)	2. CONTACT NAME
XLUMENA 453 Ravendale Drive, Suite H Mountain View CA 94043 US	Carole Sykes 2.1 E-MAIL ADDRESS csykes@xlumena.com 2.2 TELEPHONE NUMBER (include Area code) 650-9619900 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 650-9619900
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****9669	

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm

Select an application type:

[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA

[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] 30-Day Notice

3.1 Select a center

[X] CDRH
[ ] CBER

3.2 Select one of the types below

[X] Original Application

Supplement Types:

[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)

[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE

EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates

[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only

[ ] The sole purpose of the application is to support conditions of use for a pediatric population

[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. ~~IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED~~ DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT

Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 8455 Colesville Road, COLE-14-14253 Silver Spring, MD 20993-0002
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b) (4) [redacted]

Form FDA 3601 (05/13)

"Close Window" Print Cover sheet

SECTION 2: CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

The CDRH Premarket Review Submission Cover Sheet (Form FDA 3514) is enclosed to provide basic administrative information regarding this Traditional 510(k) Submission.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
March 17, 2015	(b)	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Request for Feedback
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-Submission
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Informational Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Submision Issue Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Day 100 Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Agreement Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Determination Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Study Risk Determination
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
Xlumena, Inc.	3008516478		
Division Name *(if applicable)*	Phone Number *(including area code)*		
	(650) 961-9900		
Street Address	FAX Number *(including area code)*		
453 Ravendale Drive, Suite H	(650) 961-9901		
City	State / Province	ZIP/Postal Code	Country
Mountain View	CA	94043	USA
Contact Name			
Carole Sykes			
Contact Title	Contact E-mail Address		
VP Clinical and Regulatory Affairs	csykes@xlumena.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name *(if applicable)*	Phone Number *(including area code)*		
Street Address	FAX Number *(including area code)*		
City	State / Province	ZIP Code	Country
Contact Name			
Contact Title	Contact E-mail Address		

PSC Publishing Services (301) 443-6740 EF

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Response to FDA correspondence:

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☐ New Device
- ☐ Additional or Expanded Indications
- ☒ Change in Technology

- ☒ Other Reason *(specify)*:

Modifications to add electrocautery to the AXIOS Delivery Catheter System, cleared as part of the AXIOS Stent with Delivery System in K123250 and K140561.

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	PCU	2	78KNS	3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☒ 510 (k) summary attached
☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K123250 and K140561	1	AXIOS Stent and Delivery System	1	Xlumena, Inc.
2	K022595	2	Wilson-Cook Cystotome Endoscopic Electrosurgery Device	2	Wilson-Cook Medical, Inc.
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Pancreatic drainage stent and delivery system

	Trade or Proprietary or Model Name for This Device		Model Number
1	AXIOS Stent with Electrocautery Enhanced Delivery System (10x10 Stent)	1	HXS-10-10
2	AXIOS Stent with Electrocautery Enhanced Delivery System (15x10 Stent)	2	HXS-15-10
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1 123250	2 140561	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☒ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
PCU		☐ Class I ☒ Class II
Classification Panel		☐ Class III ☐ Unclassified
Reproductive, Gastro-Renal and Urological Devices		

Indications *(from labeling)*

The Xlumena AXIOS Stent with Electrocautery Enhanced Delivery System is indicated for use to facilitate transgastric or transduodenal endoscopic drainage of symptomatic pancreatic pseudocysts ≥ 6cm in size, with ≥ 70% fluid content that are adherent to the gastric or bowel wall. Once placed, the AXIOS Stent functions as an access port allowing passage of standard and therapeutic endoscopes to facilitate debridement, irrigation and cystoscopy. The stent is intended for implantation up to 60 days and should be removed upon confirmation of pseudocyst resolution.

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	FDA Document Number *(if known)*

SECTION H — MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☒ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler
Company / Institution Name: Xlumena, Inc.		Establishment Registration Number: 3008516478
Division Name *(if applicable)*		Phone Number *(including area code)*: (650) 961-9900
Street Address: 453 Ravendale Drive, Suite H		FAX Number *(including area code)*: (650) 961-9901
City: Mountain View	State / Province: CA	ZIP Code: 94043 — Country: USA
Contact Name: Carole Sykes	Contact Title: VP Clinical and Regulatory Affairs	Contact E-mail Address: csykes@xlumena.com

(b)(4)Proprietary Information

[redacted]

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number
Division Name *(if applicable)*		Phone Number *(including area code)*
Street Address		FAX Number *(including area code)*
City	State / Province	ZIP Code — Country
Contact Name	Contact Title	Contact E-mail Address

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H *(Continued)*

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)*		
Street Address		FAX Number *(including area code)*		
City		State / Province	ZIP Code	Country
Contact Name	Contact Title		Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)*		
Street Address		FAX Number *(including area code)*		
City		State / Province	ZIP Code	Country
Contact Name	Contact Title		Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)*		
Street Address		FAX Number *(including area code)*		
City		State / Province	ZIP Code	Country
Contact Name	Contact Title		Contact E-mail Address	

Add Continuation Page

SECTION I — UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	ISO 10993-1	ISO	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process	2009 Reviewed 2013 no update	10/15/2009

(b)(4)Proprietary Information

[redacted]

Please include any additional standards to be cited on a separate page.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.

The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

510(k) SUBMISSION: STANDARDS LIST

Item	Standards No.	Standards Organization	Standards Title	Version	Date	Recognition Number
1	ISO 10993-1:2009 Reviewed (2013) no update	ISO	Biological evaluation of medical devices - Part 1: Evaluation and testing within a Risk Management Process	2009	10/15/2009	2-156

(b)(4)Proprietary Information

[redacted]

510(k) SUBMISSION: STANDARDS LIST

Item	Standards No.	Standards Organization	Standards Title	Version	Date	Recognition Number
(b)(4)Proprietary Information						
31	ISO 10555-1: 2013	ISO	Sterile, Single-Use Intravascular Catheters – Part 1: General Requirements	2013	07/01/2013	6-301
32	ISO 594-1:1986	ISO	Conical fittings with a 6%(luer) taper for syringes, needles and certain other medical equipment – Part 1: General Requirements	1986	06/15/1986	6-11
33	ISO 13485:2012	ISO	Medical Devices – Quality Management Systems – Requirements for regulatory purposes	2012	08/30/2012	None
34	BS EN ISO 14971:2012 Corrected version 2007-10-01	ISO	Medical Devices-Application of risk management to medical devices	2012	07/31/2012	None
35	IEC 60601-1-11{Ed 2} 2015-01	IEC	Medical Electrical Equipment: General Requirements for Safety	2015	01/20/2015	None
36	IEC 60601-2-2: 2009	IEC	Medical Electrical Equipment: Particular Requirements for the Basic Safety and Essential Performance of High Frequency Surgical Equipment and High Frequency Surgical Accessories	2009	7/31/2009	6-336
(b)(4)Proprietary Information						
38	ASTM F2052-14	ASTM	Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment[1]	2014	05/15/2014	8-381

510(k) SUBMISSION: STANDARDS LIST

Item	Standards No.	Standards Organization	Standards Title	Version	Date	Recognition Number
(b)(4)Proprietary Information						
40	ASTM F2182-11a	ASTM	Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging[1]	2011	04/15/2011	8-227
41	ASTM F2213-06	ASTM	Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment[1]	2011	10/01/2011	8-128
42	IEC 60601-2-18	IEC	Medical electrical equipment – Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment	2009-08	8/12/2009	4-187
(b)(4)Proprietary Information						
46	BS EN 60601-1-2 (IEC60601-1-2:2007 modified)	BS EN	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests	2010	07/31/2010	19-1
47	BS EN 60601-1 (IEC60601-1:2005)	BS EN	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	2006+A11:2011	02/29/2012	None
48	BS EN 60601-1-6 (IEC60601-1-6:2010)	BS EN	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability	2010	05/31/2010	5-85

SECTION 3: 510(K) COVER LETTER

The 510(k) Cover Letter is attached and has been written to meet the suggested content and style described in Appendix A of the "Guidance for Industry and FDA Staff; Format for Traditional and Abbreviated 510(k)s," dated August 12, 2005.

March 17, 2015

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center -WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Traditional 510(k) Premarket Notification
AXIOS Stent with Electrocautery Enhanced Delivery System

Dear Sir or Madam:

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act ("FD&C Act"), 21 U.S.C. § 360(K) and 21 C.F.R. § 807.87 (1997), Xlumena, Inc. ("the Company") is submitting the enclosed Traditional Premarket ["510(k)"] Notification for the AXIOS Stent with Electrocautery Enhanced Delivery System. The AXIOS Stent with Electrocautery Enhanced Delivery System is designed for use with standard off-the-shelf endoscopic and electrosurgical devices to deliver a flexible, MR conditional, fully-covered, self-expanding braided Nitinol stent for transgastric or transduodenal endoscopic drainage of symptomatic pancreatic pseudocysts. The subject premarket notification describes modifications to add electrocautery to the cleared AXIOS Delivery System which is used to provide access and delivery of the currently cleared AXIOS Stent. There have been no modifications to the preloaded AXIOS Stent. Both the AXIOS Stent and Delivery System were originally cleared under K123250 and most recently under K140561.

Two copies of this 510(k) Submission have been provided: one paper copy and one electronic copy (eCopy) prepared in accordance with CDRH's electronic copy program. The eCopy is an exact duplicate of the paper copy.

510(k) Submitter: Xlumena, Inc.
453 Ravendale Drive, Suite H
Mountain View, CA 94043

Telephone: (650) 961-9900
Facsimile: (650) 961-9901

Contact: Carole Sykes, V.P. Clinical and Regulatory Affairs
csykes@Xlumena.com

Establishment Registration: 3008516478

Trade Name/Model Number(s): AXIOS™ Stent with Electrocautery Enhanced Delivery System

Catalog Number	Description	Stent Size			Delivery System Outer Diameter
		Lumen Diameter	Saddle Length	Flange Diameter	
HXS-10-10	AXIOS Electrocautery Enhanced Delivery System with 10x10 Stent	10 mm	10 mm	21 mm	10.8Fr
HXS-15-10	AXIOS Electrocautery Enhanced Delivery System with 15x10 Stent	15 mm	10 mm	24 mm	10.8Fr

Classification Name: Pancreatic drainage stent and delivery system

Device Class: Class II

Regulation: 21 CFR 876.5015 / 21 CFR 876.4300

Product Code: PCU / 78KNS

Review Panel: Reproductive, Gastro-Renal and Urological Devices

Predicate Device Information:

Manufacturer	Name of Predicate Device	510(k) #	Clearance Date
Xlumena, Inc.	AXIOS Stent and Delivery System	K140561 K123250	April 23, 2014 December 18, 2013
Wilson-Cook Medical, Inc.	Wilson-Cook Cystotome	K022595	October 17, 2002

Reason for Submission

This Traditional 510(k) submission is to request premarket clearance for the AXOIS Stent with Electrocautery Delivery System. The AXIOS Stent with Delivery System was cleared via 510(k)s K123250 and K140561. The scope of this 510(k) is for modifications to the Delivery System to add electrocautery in order to facilitate access of target anatomies followed by the staged and precise placement of the AXIOS Stent using a single device. (b)(4)Proprietary Information [redacted]

Indications for Use
Identical to the cleared Xlumena AXIOS Stent and Delivery System:

The AXIOS™ Stent with Electrocautery Enhanced Delivery System is indicated for use to facilitate transgastric or transduodenal endoscopic drainage of symptomatic pancreatic pseudocysts ≥ 6cm in size, with ≥ 70% fluid content that are adherent to the gastric or bowel wall. Once placed, the AXIOS stent functions as an access port allowing passage of standard and therapeutic endoscopes to facilitate debridement, irrigation and cystoscopy. The stent is intended for implantation up to 60 days and should be removed upon confirmation of pseudocyst resolution.

Refer to **Table 1**. Design and Use of the Device.

Table 1. Design and Use of the Device

Question	Yes	No
1. Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
2. Is the device intended for over-the-counter use (21CFR 807 Subpart C)?		X
3. Does the device contain components derived from a tissue or other biological source?		X
4. Is the device provided sterile?	X	
5. Is the device intended for single use?	X	
6. Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?	N/A	N/A
7. Does the device contain a drug?		X
8. Does the device contain a biologic?		X
9. Does the device use software?		X
10. Does the submission include clinical information?	X	
11. Is the device implanted?	X*	

* The AXIOS Stent is implanted for up to 60 days

The AXIOS Stent with Electrocautery Enhanced Delivery System, with the modifications required for electrocautery, is substantially equivalent to the AXIOS Stent with Delivery System (non-cautery) [510(k) K123250 and K140561] and the Wilson-Cook Cystotome cleared in 510(k) K022595 based on the intended use / indications for use, as well as technological characteristics and principles of operation. Bench performance, biocompatibility, electrical safety, electromagnetic compatibility, animal and clinical evaluations (b)(4)Proprietary Information provided in the subject premarket notification demonstrate that the AXIOS Stent with Electrocautery Enhanced Delivery System is safe and effective for its intended use.

The Company considers its intent to market the AXIOS Stent with Electrocautery Enhanced Delivery System to be confidential commercial information. Xlumena, Inc. has not disclosed its intent to market the AXIOS Stent with Electrocautery Enhanced Delivery System to anyone except its employees, others with a financial interest in the Company, its advertising and law firms, clinical investigators and its consultants. The Company, therefore, requests that FDA not

disclose the existence of this application until such time as final action on the submission is taken.

In addition, some of the material in this application may be trade secret or confidential commercial or financial information within the meaning of 21 C.F.R. § 20.61 and, therefore, not disclosable under the Freedom of Information Act, even after the existence of the application becomes public. We ask that FDA consult with the Company as provided in 21 C.F.R. § 20.45 before making any part of this submission publicly available.

We trust that the information contained in the subject 510(k) Premarket Notification will be sufficient to enable FDA to find the AXIOS Stent with Electrocautery Enhanced Delivery System to be substantially equivalent to the predicate devices. Please direct any questions or requests for additional information to me at 650-868-4331 or by email at csykes@Xlumena.com.

Sincerely,

Carole Sykes
V.P. Clinical and Regulatory Affairs
Xlumena, Inc.

SECTION 4: 510(K) ACCEPTANCE CHECKLIST

The 510(k) Acceptance (RTA) Checklist for Traditional 510(k)s is provided in **Attachment 1**.

SECTION 5: INDICATIONS FOR USE STATEMENT

The Indications for Use Statement (Form 3881) is provided on the following page.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
AXIOS Stent with Electrocautery Enhanced Delivery System

Indications for Use *(Describe)*

The AXIOS Stent with Electrocautery Enhanced Delivery System is indicated for use to facilitate transgastric or transduodenal endoscopic drainage of symptomatic pancreatic pseudocysts ≥ 6cm in size, with ≥ 70% fluid content that are adherent to the gastric or bowel wall. Once placed, the AXIOS Stent functions as an access port allowing passage of standard and therapeutic endoscopes to facilitate debridement, irrigation and cystoscopy. The stent is intended for implantation up to 60 days and should be removed upon confirmation of pseudocyst resolution.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

SECTION 6: 510(K) SUMMARY

In accordance with 21 CFR 807.92, a separate, stand-alone 510(k) summary is provided in **Attachment 2**. The summary has been prepared in accordance with the suggested content and style described in the "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]. Guidance for Industry and Food and Drug Administration Staff," dated July 28, 2014.

Note: Any statement regarding "substantial equivalence" made in this submission only relates to whether the product addressed in this submission may be lawfully marketed without premarket approval or reclassification, and is not intended to be interpreted as an admission or any other type of evidence in any *patent proceeding, including patent infringement, litigation or proceeding before any Patent Office. The present submission and statements therein therefore should not be construed as affecting or relating to the scope of any patent or patent application, or to whether the product addressed in this submission, or its use, may be considered indistinct, from a patentability perspective, from any of the other devices referenced in this filing.*

SECTION 7: STANDARDS DATA REPORT

FDA Form 3654 is provided for all referenced standards in this Traditional 510(k) Submission (**Attachment 3**).

SECTION 8: TRUTHFUL AND ACCURACY STATEMENT

A Truthful and Accurate Statement is provided as required by 21 CFR 807.87(k) on the following page.

Premarket Notification Truthful and Accurate Statement

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as Vice President of Clinical and Regulatory Affairs at Xlumena, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has knowingly been omitted.

Carole Sykes
V.P. Clinical and Regulatory Affairs
Xlumena, Inc.

3/17/15
Date

SECTION 9: CLASS III SUMMARY AND CERTIFICATION

The AXIOS Stent with Electrocautery Enhanced Delivery System is a Class II device, therefore the Class III Summary and Certification is not applicable.

SECTION 10: FINANCIAL CERTIFICATION OR DISCLOSURE STATEMENT AND CERFICATION OF COMPLIANCE WITH CLINICALTRIALS.GOV DATA BANK

Financial Certifications or Disclosure Statements as well as Certification of Compliance with ClincialTrials.gov (ClinicalTrials.gov Identifier: NCT02146352) are provided in **Attachment 4**.

SECTION 11: DECLARATIONS OF CONFORMITY AND SUMMARY REPORTS

This section is not applicable to the AXIOS Stent with Electrocautery Enhanced Delivery System as the subject pre-market notification is a Traditional 510(k) Submission.

SECTION 12: EXECUTIVE SUMMARY

Xlumena is submitting the enclosed Traditional Premarket ["510(k)"] Notification for the AXIOS Stent with Electrocautery Enhanced Delivery System. The AXIOS Stent with Electrocautery Enhanced Delivery System is designed for use with standard off-the-shelf endoscopic and electrosurgical devices to deliver a flexible, MR conditional, fully-covered, self-expanding braided Nitinol stent for transgastric or transduodenal endoscopic drainage of symptomatic pancreatic pseudocysts. The subject premarket notification describes modifications to add electrocautery to the cleared AXIOS Delivery System which is used to provide access and delivery of the cleared AXIOS Stent. There have been no modifications to the preloaded AXIOS Stent. Both the AXIOS Stent and Delivery System were originally cleared under K123250 and most recently under K140561.

Intended Use / Indications for Use:

There have been no changes to the intended use / indications for use. Identical to the cleared Xlumena AXIOS Stent and Delivery System:

The AXIOS Stent with Electrocautery Enhanced Delivery System is indicated for use to facilitate transgastric or transduodenal endoscopic drainage of symptomatic pancreatic pseudocysts ≥ 6cm in size, with ≥ 70% fluid content that are adherent to the gastric or bowel wall. Once placed, the AXIOS stent functions as an access port allowing passage of standard and therapeutic endoscopes to facilitate debridement, irrigation and cystoscopy. The stent is intended for implantation up to 60 days and should be removed upon confirmation of pseudocyst resolution.

Trade/Proprietary Name: AXIOS Stent with Electrocautery Enhanced Delivery System

Catalog Number	Description	Stent Size			Delivery System Outer Diameter
		Lumen Diameter	Saddle Length	Flange Diameter	
HXS-10-10	AXIOS Electrocautery Enhanced Delivery System with 10x10 Stent	10 mm	10 mm	21 mm	10.8Fr
HXS-15-10	AXIOS Electrocautery Enhanced Delivery System with 15x10 Stent	15 mm	10 mm	24 mm	10.8Fr

Classification Name: Pancreatic drainage stent and delivery system

Device Class: Class II

Regulation: 21 CRF 876.5015 / 21 CFR 876.4300

Product Code: PCU / 78KNS

Panel: Reproductive, Gastro-Renal and Urological Devices

Predicate Device Information:

Manufacturer	Name of Predicate Device	510(k) #	Clearance Date
Xlumena, Inc.	AXIOS Stent and Delivery System	K140561 K123250	April 23, 2014 December 18, 2013
Wilson-Cook Medical, Inc.	Wilson-Cook Cystotome	K022595	October 17, 2002

This Traditional 510(k) submission is to request premarket clearance for the AXOIS Stent with Electrocautery Delivery System. The AXIOS Stent with Delivery System was cleared via 510(k) K123250 and K140561. The scope of this 510(k) is for modifications to the Delivery System to add electrocautery in order to facilitate access of target anatomies followed by the staged and precise placement of the AXIOS Stent using a single device. (b)(4)Proprietary Information [redacted]

The AXIOS Stent with Electrocautery Enhanced Delivery System, with the subject modifications required for electrocautery, is substantially equivalent to the AXIOS Stent with Delivery System (non-cautery) [510(k) K123250 and K140561] and the Wilson-Cook Cystotome cleared in 510(k) K022595 based on the intended use / indications for use, as well as technological characteristics and principles of operation. Bench performance, biocompatibility, electrical safety, electromagnetic compatibility, animal and clinical evaluations (b)(4)Proprietary Information provided in the subject premarket notification demonstrate that the AXIOS Stent with Electrocautery Enhanced Delivery System is safe and effective for its intended use.

SECTION 13: DEVICE DESCRIPTION

The AXIOS Stent with Electrocautery Enhanced Delivery System is intended for the endoscopic placement of a flexible, MR conditional, fully-covered, self-expanding braided Nitinol stent for transgastric or transduodenal endoscopic drainage of symptomatic pancreatic pseudocysts. The subject premarket notification describes modifications to the cleared AXIOS Delivery System to add electrocautery to facilitate precise access to anatomic targets as well as the staged placement of the currently cleared AXIOS Stent. The AXIOS Stent with Electrocautery Enhanced Delivery System is designed for use with standard off-the-shelf endoscopic and electrosurgical devices. The AXIOS Stent with Electrocautery Enhanced Delivery System incorporates the identical implantable stent that is preloaded within the current AXIOS Delivery System (K123250). Both the AXIOS Stent and Delivery System were originally cleared under 510(k) K123250 and most recently under 510(k) K140561.

A. Summary of Main Features

(b)(4)Proprietary Information The main features of the AXIOS Stent with Electrocautery Enhanced Delivery System are presented in **Table 13-1**. There have been no changes to the AXIOS Stent; it is identical to the stent cleared in 510(k) K123250 and K140561.

Table 13-1. AXIOS Stent with Electrocautery Enhanced Delivery System - Main Features

Component / Design	Feature Description
Electrocautery Enhanced AXIOS Delivery System	
Catheter	• Provided sterile, for single use • Working Length: 138 cm • Outer Diameter 10.8 Fr • (b)(4)Proprietary Information • Electrocautery Tip for precise cutting ⇒ Monopolar 1500Vp-p Rated Accessory Voltage* ⇒ IEC 60601-1compliant*
Handle	• Staged delivery system for precise stent placement ⇒ (b)(4)Proprietary Information " ⇒(b)(4)Proprietary Information
Guidewire Compatibility**	0.035" insulated guidewires
Endoscope Compatibility**	• Compatible with 3.7 mm diameter or larger working channel • (b)(4)Proprietary Information

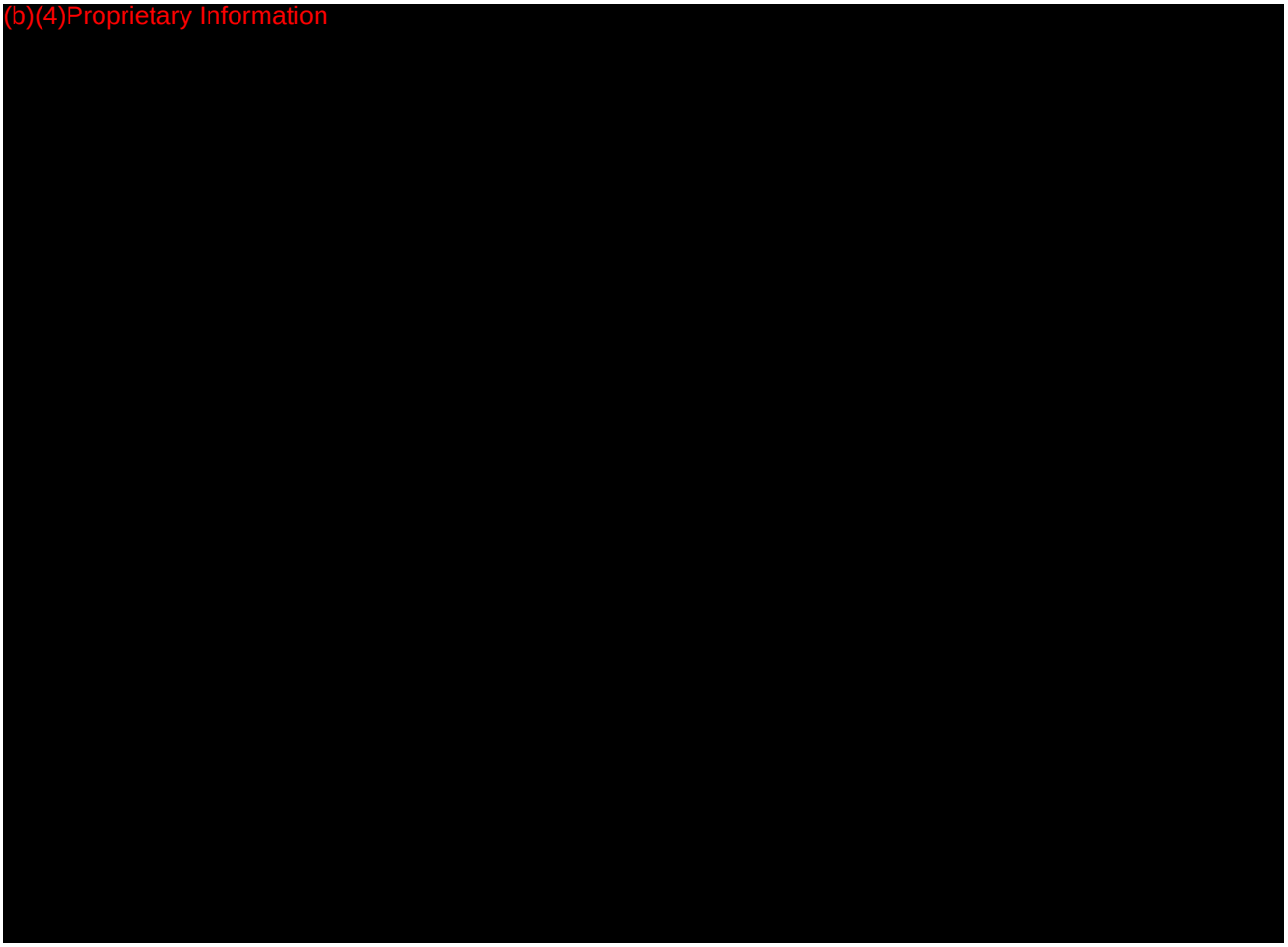
Component / Design	Feature Description
Electrosurgical Unit or Generator**	• Compliant to IEC 60601-1-2 and IEC 60601-2-2 • ERBE ESU Model ICC200, cleared by FDA in K933157 and ERBE ESU Model VIO 300D, cleared by FDA in K083452
AXIOS Stent	
Design	• Bi-flange or double anchor for Staged and Precise positioning • Flange/anchor designed to ⇒ hold tissue layers in apposition ⇒ prevent migration • MR conditional • Provided sterile, for single use
Sizes	• Large stent lumen diameter and short flow path/conduit to ⇒ Facilitate passive efficient drainage ⇒ Facilitate passage of endoscopic tools for assessment and treatment
Material	• Nitinol (Nickel-Titanium) ⇒ (b)(4)Proprietary Information ⇒ (b)(4)Proprietary Information ⇒ (b)(4)Proprietary Information
Covering	• Fully covered (b) ⇒ (b)(4)Proprietary Information minimize tissue ingrowth ⇒ (b)(4)Proprietary and minimizes tissue ingrowth allowing for (b) stent removal
Visualization	• The Stent is delivered constrained within a delivery system and deployed under visualization ⇒ EUS confirmation of first (distal) flange deployment ⇒ Direct endoscopic or EUS viewing of second (proximal) flange deployment ⇒ (b)(4)Proprietary Information

for Electrocautery

**** Off-the-shelf devices; separately provided**

The AXIOS Stent with Electrocautery Enhanced Delivery System is provided sterile, disposable and is intended for single use. **Figure 13-1** provides a photograph of the AXIOS Stent with Electrocautery Enhanced Delivery System with labeled main features.

Figure 13-1. AXIOS Stent with Electrocautery Enhanced Delivery System



B. Detailed Device Description

The AXIOS Stent with Electrocautery Enhanced Delivery System is comprised of two main components: (1) AXIOS Stent and (2) Electrocautery Enhanced Delivery System.

1. AXIOS Stent

There have been no changes made to the design or materials of the AXIOS Stent. The AXIOS Stent is identical to the stent cleared in K123520 (De Novo) and K140561 ((b)(4)Proprietary Information). The AXIOS Stent is a flexible, MR conditional, fully-covered self-expanding braided Nitinol stent, which is preloaded into the Delivery System. The AXIOS Stent is designed with two flanges on each end to prevent migration and to enable tissue plane apposition, and a "saddle" in between the flanges to span the tissue implant distance (**Figure 13-2**). The stent is fully covered (b)(4)Proprietary to (b)(4)Proprietary discourage tissue in-growth within the Nitinol and facilitate removal. The AXIOS Stent is placed under partial or full endoscopic ultrasound (EUS) guidance and is provided in two lumen diameters and lengths (**Table 13-2**).

(b)(4)Proprietary Information

(b)(4)Proprietary Information

Table 13-2. AXIOS Stent Sizes

Catalog Number	Description	Stent Size			Delivery System Outer Diameter
		Lumen Diameter	Saddle Length	Flange Diameter	
HXS-10-10	Electrocautery Enhanced AXIOS Delivery System with 10x10 Stent	10 mm	10 mm	21 mm	10.8Fr
HXS-15-10	Electrocautery Enhanced AXIOS Delivery System with 15x10 Stent	15 mm	10 mm	24 mm	10.8Fr

(b)(4)Proprietary Information

2. AXIOS Electrocautery Enhanced Delivery System

Similar to the cleared non-cautery AXIOS Delivery System, the modified AXIOS Electrocautery Enhanced Delivery System consists of a catheter and an integrated handle (b)(4)Proprietary Information As with the predicate non-cautery AXIOS Delivery System, the AXIOS Electrocautery Enhanced Delivery System is designed to be used in the gastrointestinal tract with commercially available echoendoscopes with a 3.7 mm diameter or larger working channel and is compatible with commercially available 0.035-inch insulated endoscopic guidewires.

The Electrocautery Enhanced Delivery System has been modified to connect with an off-the-shelf electrosurgical unit or generator that is compliant to IEC 60601-1-2 and IEC 60601-2-2. The generator must be installed and put into service according to the EMC information provided

in the generator manufacturer's guidance and declaration for electromagnetic compatibility. Cables and patient return electrodes that are specified by generator manufacturer must be used for connection.

(b)(4)Proprietary Information

[redacted]

a. Electrocautery Enhanced Catheter Body

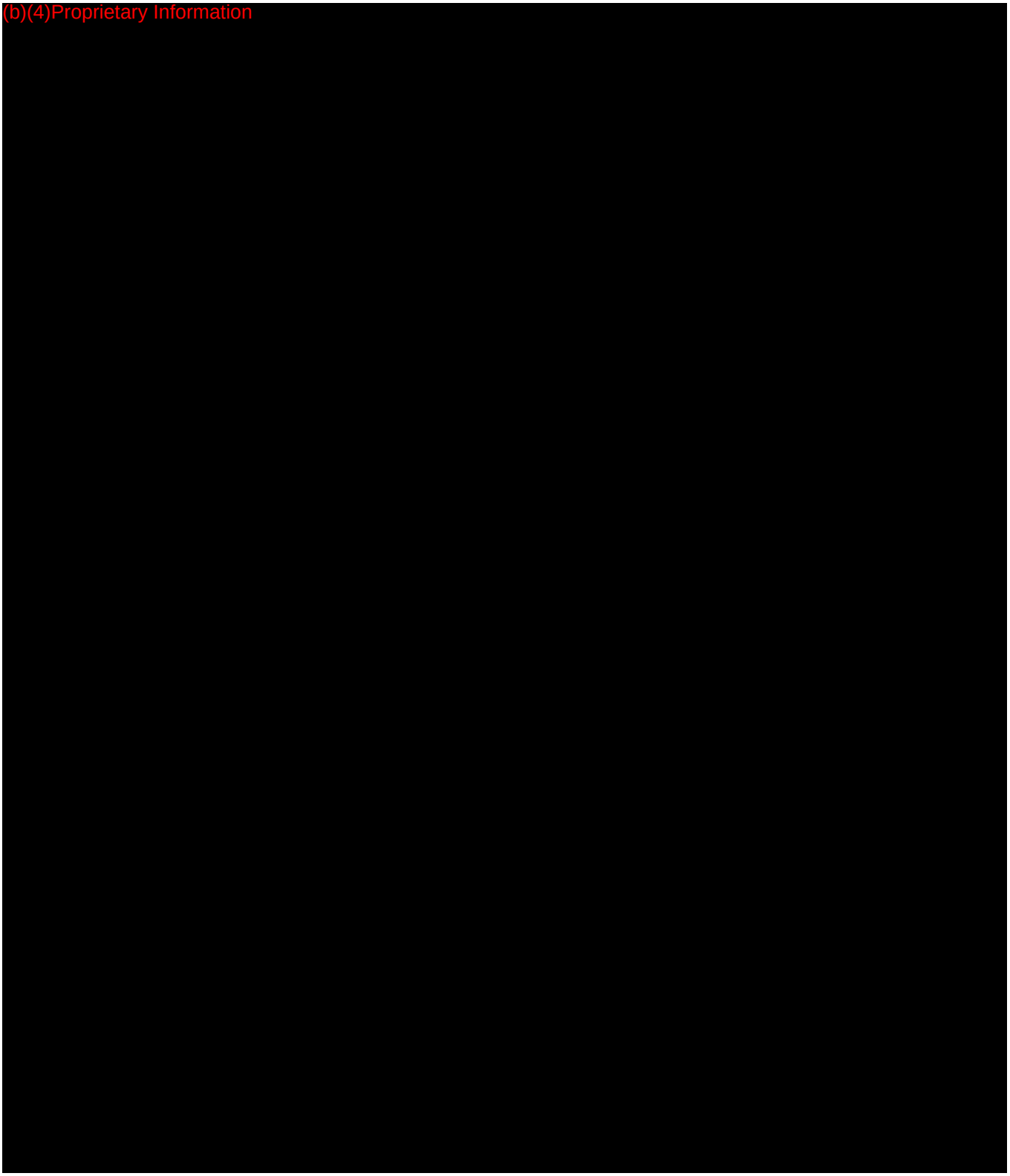
The Electrocautery Enhanced Delivery System Catheter has a 138 cm working length with an outer diameter of 10.8F; identical to the currently cleared delivery catheter. (b)(4)Proprietary Information

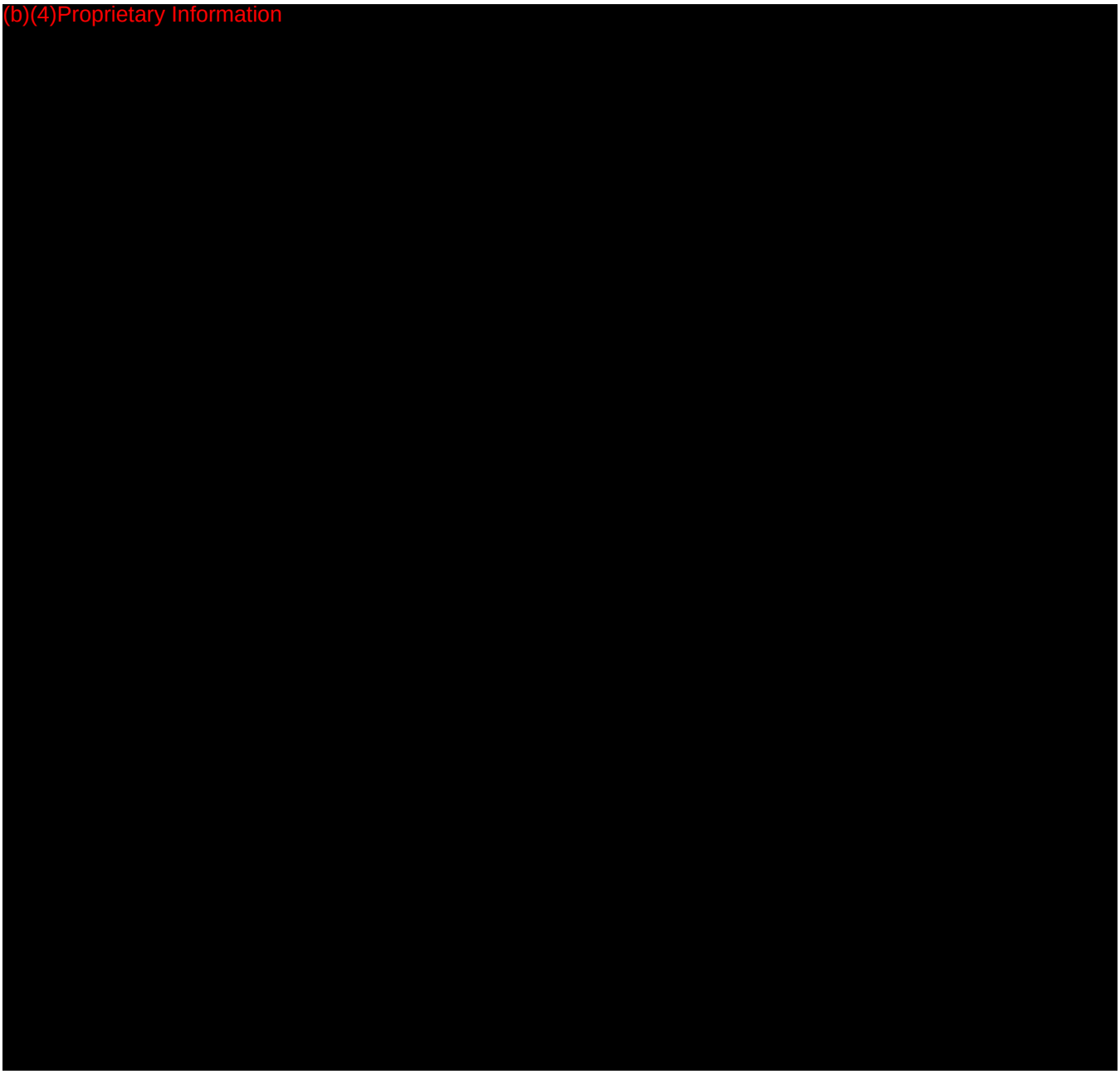
[redacted]

(b)(4)Proprietary Information

[redacted]

(b)(4)Proprietary Information





(b)(4)Proprietary Information

[redacted]

3. Ancillary Devices

Ancillary equipment required for the use of the AXIOS Stent with Electrocautery Enhanced Delivery System includes commercially available surgical supplies and devices, as follows:

- 0.035" Insulated Guidewire

(b)(4)Proprietary Information

[redacted]

- Electrosurgical Unit or Generator

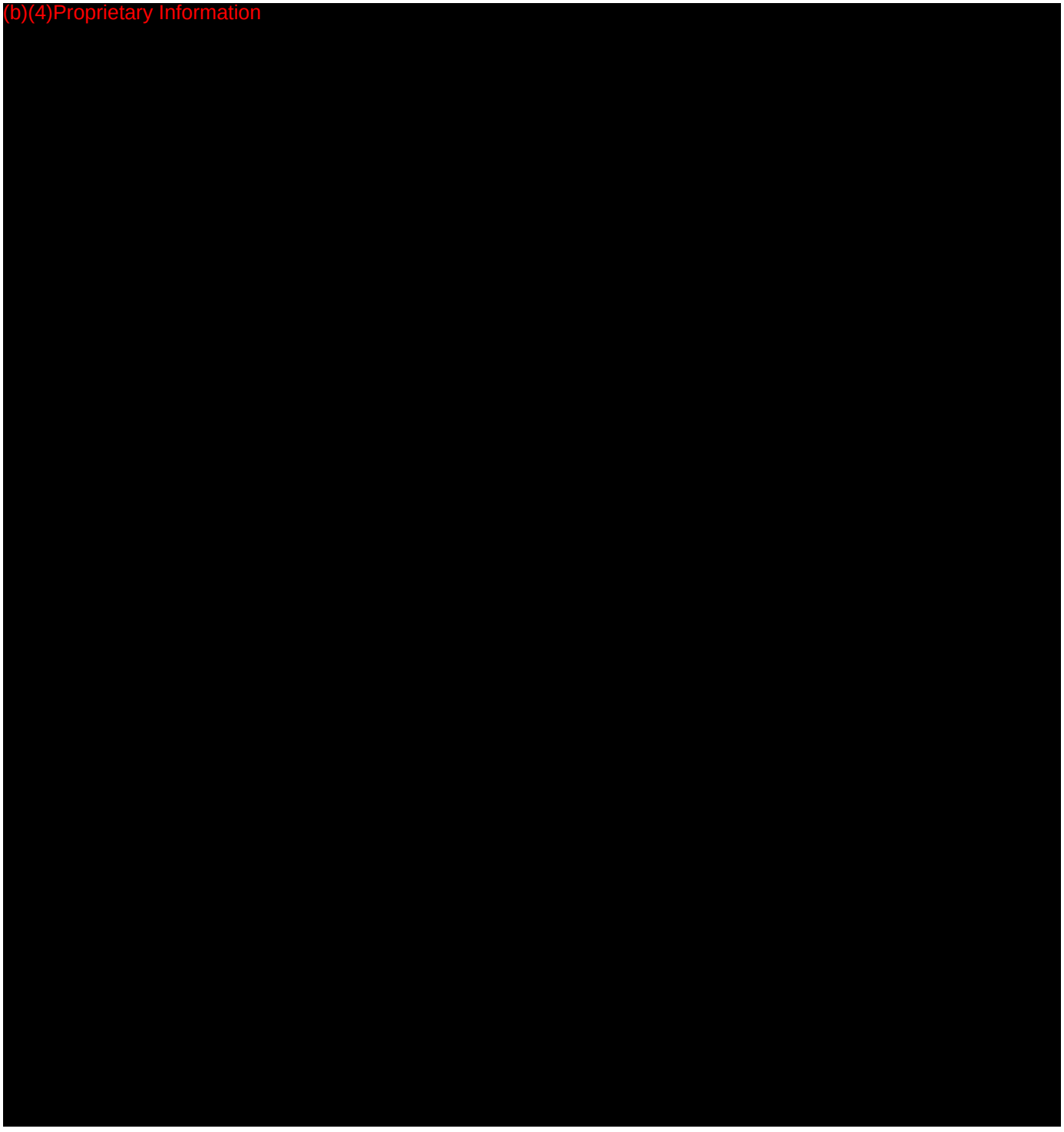
The AXIOS Stent with Electrocautery Enhanced Delivery System is designed to be used in conjunction with the ERBE Model ICC200 or later models such as the ERBE VIO 300D, a commercially available, EMC compliant Electrosurgical Unit (ESU). The ERBE ESU Model ICC200 was cleared by FDA in K933157 and ERBE ESU Model VIO 300D was cleared by FDA in K083452. (b)(4)Proprietary Information [redacted]. The Electrocautery Enhanced Delivery System has been tested in accordance with IEC standards: IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-2-2, IEC 60601-2-18, AAMI ES60601-1 and is rated to withstand 1500Vp-p (750Vp) of monopolar energy.

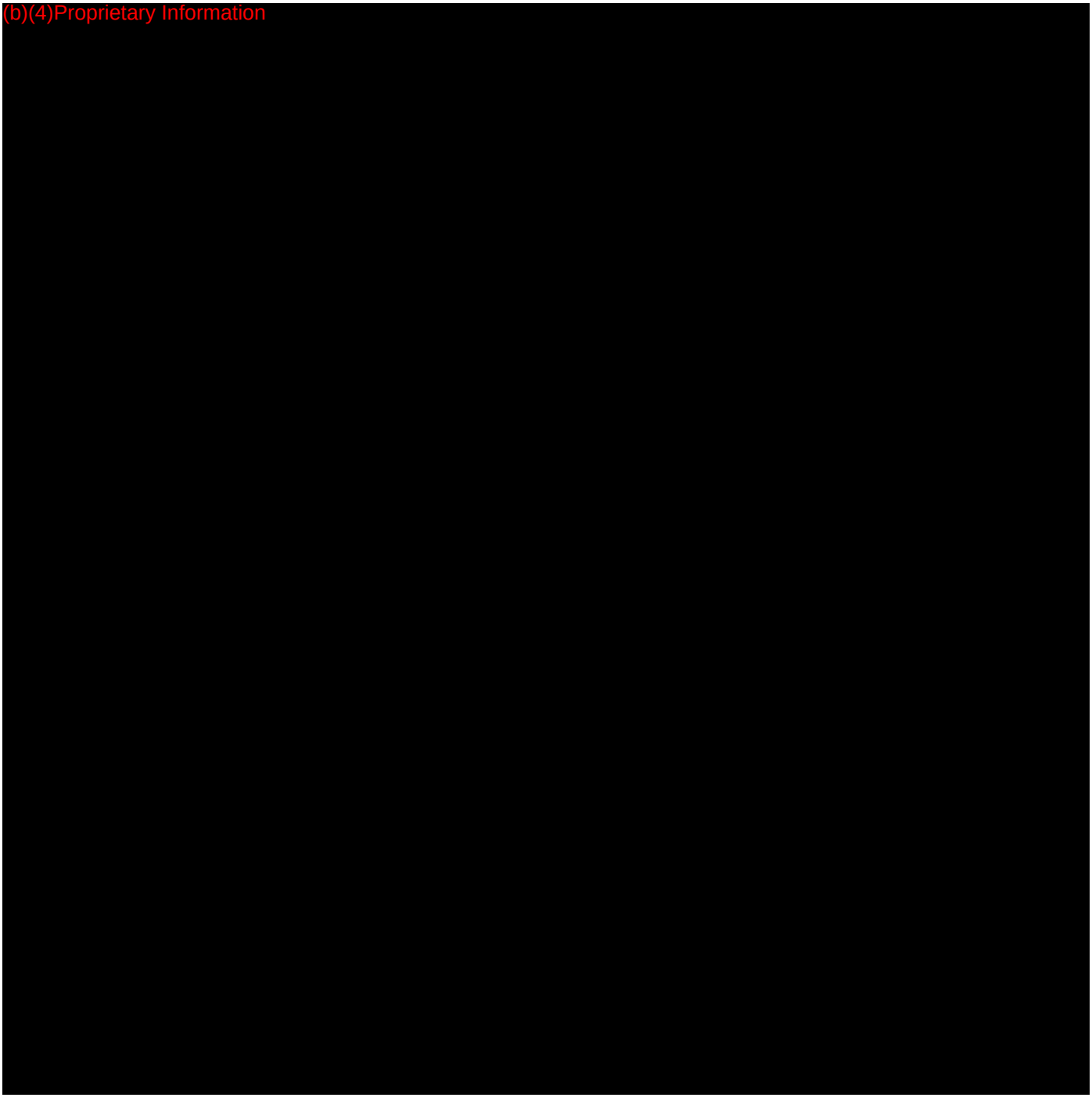
[1] Somogyi, L. M.D. et Al. (2007) Guidewires for use in GI Endoscopy, Technology Statues Evaluation Report. The American Society for Gastrointestional Endoscopy, Gastrointestinal Endoscopy, Volume 65 (4), 571-576.

Recommended ESU settings can be found in the instructions for use (IFU) (**Attachment 7**).

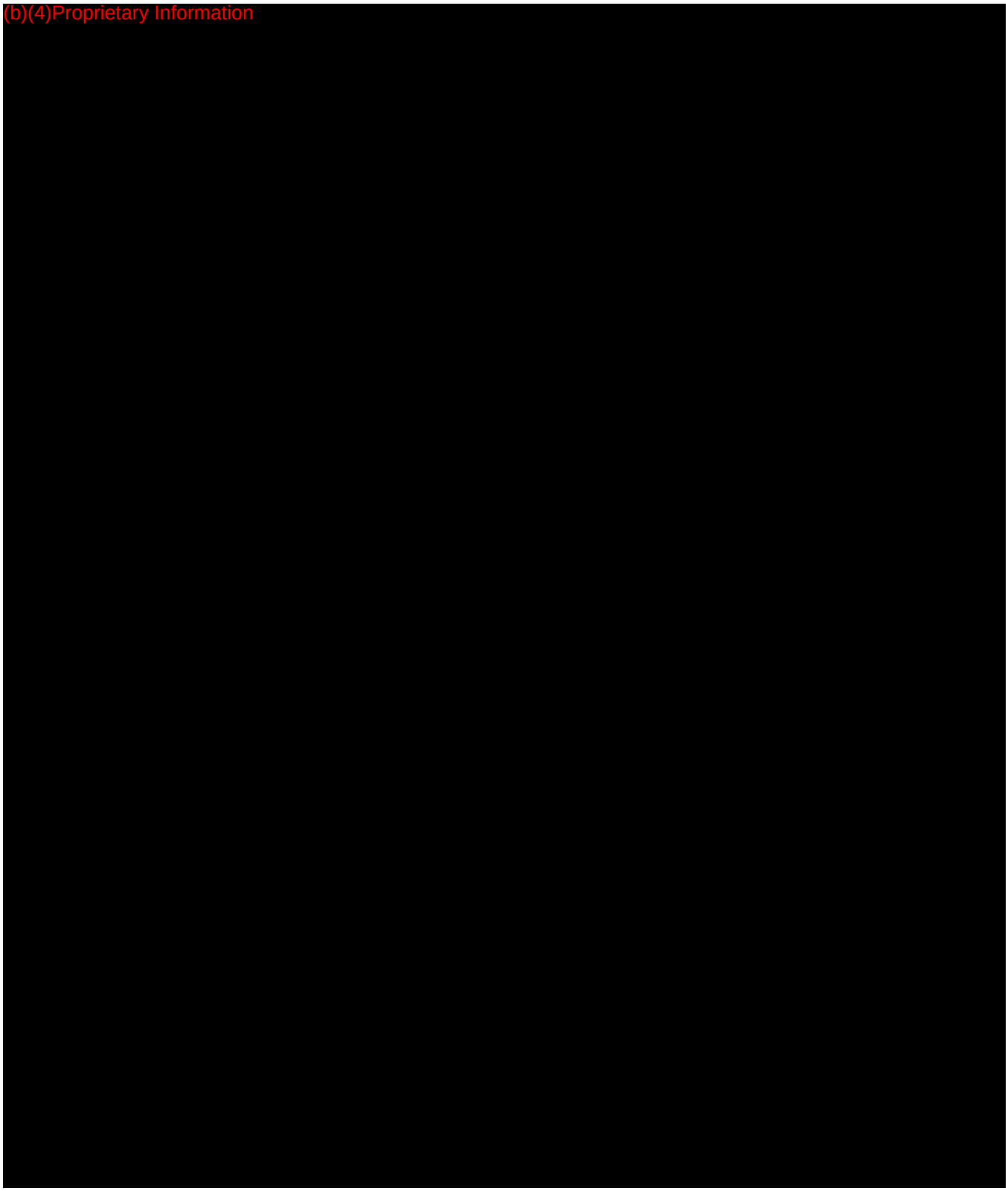
- Echoendoscope with a 3.7mm or greater working channel
- Other equipment may include a 19-gauge FNA needle, Bougie dilators and dilating balloons, if desired.

(b)(4)Proprietary Information

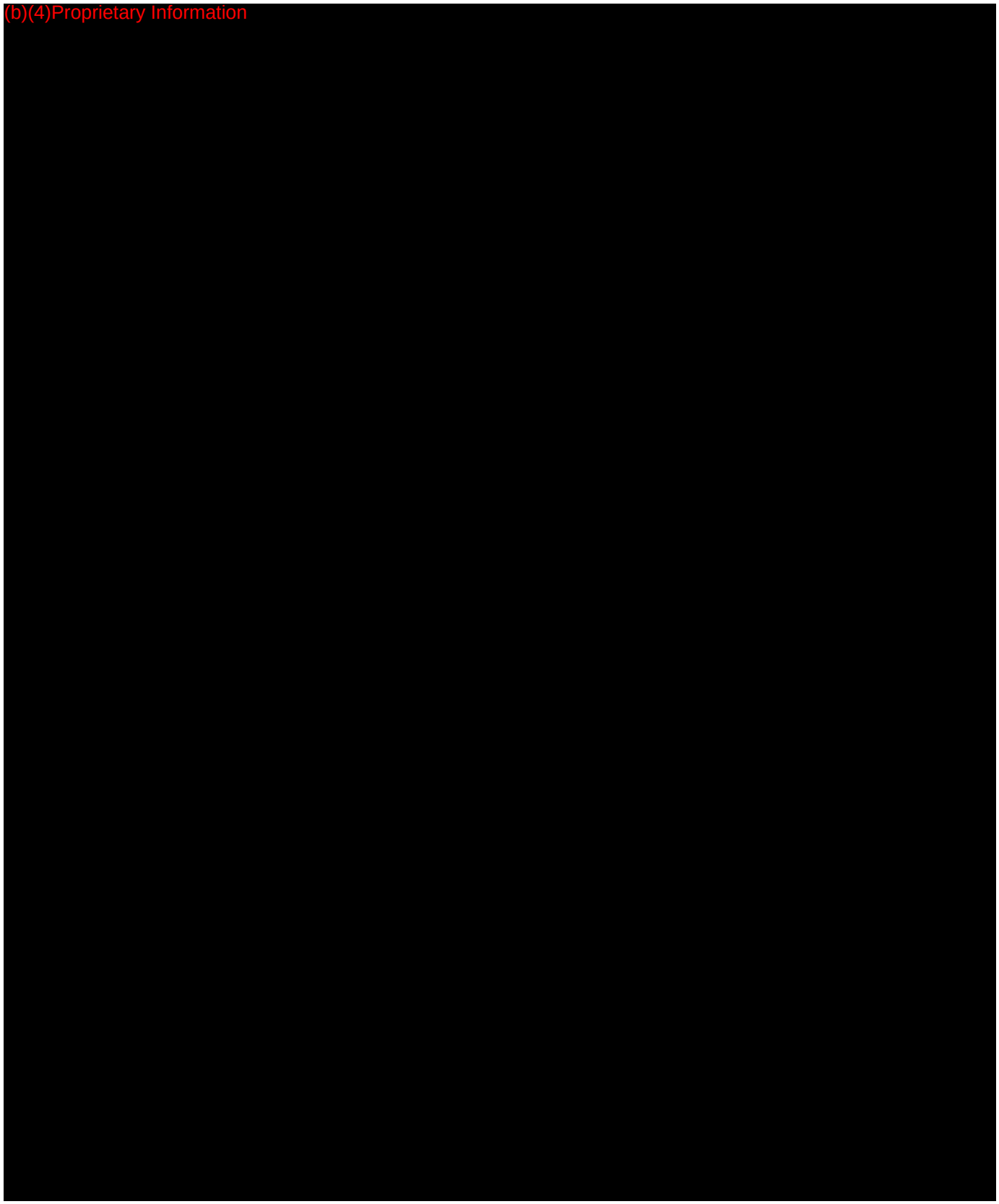




(b)(4)Proprietary Information



(b)(4)Proprietary Information



(b)(4)Proprietary Information

[redacted]

E. Device Operation and Stent Deployment Steps

The AXIOS Stent with Electrocautery Enhanced Delivery System is intended for the placement of a flexible, fully-covered, self-expanding braided Nitinol stent under partial or full endoscopic ultrasonography (EUS) guidance to facilitate the transgastric or transduodenal endoscopic drainage of symptomatic pancreatic pseudocysts.

A summary of the stent deployment procedure using the Electrocautery Enhanced Delivery System is provided as follows.

1. Prior to beginning the procedure, the package and product is inspected for damage or defects. Inspection of the distal end of the catheter is performed to ensure there is no gap between the distal catheter and the nose cone (**Figure 13-10**).

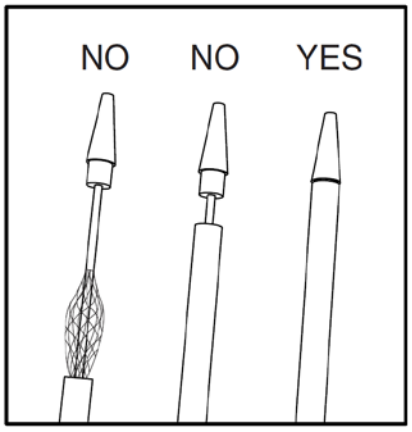


Figure 13-10: The two examples on the left ("NO") show separation of the nose cone from the catheter (Do Not Use). The "YES" drawing shows the correct position of the nose cone.

2. Prepare compatible electrosurgical generator according to the generator Operators Manual.
3. Connect Olympus / Cook type electrosurgical cable with a 3mm female monopolar plug into the AXIOS Stent with Electrocautery Enhanced Delivery System and the other to the generator.

[2] Odell, R. Pearls, pitfalls, and advancement in the delivery of electrosurgical energy during laparoscopy. Problems in General Surgery. 2002; vol. 19(2): 5-17.

[3] Munro, M.G. and Fu, Y.S. Loop electrosurgical excision with a laparoscopic electrode and carbon dioxide laser vaporization: comparison of thermal injury characteristics in the rat uterine horn. Am *J Obstet Gynecol.* 1995;172:1257–62.

4. Follow recommendations provided by the manufacturer of the generator for the proper placement and application of the patient return (neutral) electrode.
5. Power on the generator and set to Autocut (for ERBE Generators) with power between 80-120 Watts, 400-500Vp.
6. Identify site for AXIOS Stent placement.
7. (Optional) Insert 0.035" guidewire if using over-the-wire technique.
8. Lower the echoendoscope elevator.
9. Using your echoendoscope, select an access location that is free from intervening blood vessels, where the wall between the GI tract and pseudocyst is 10mm or less, and where the pseudocyst diameter is large enough to accommodate 3-4cm of AXIOS Electrocautery Enhanced Delivery Catheter insertion.
10. Wet the entire length of the AXIOS Electrocautery Enhanced Delivery Catheter with sterile water or normal saline and insert the catheter into the working channel of the echoendoscope.
11. Advance the AXIOS Electrocautery Enhanced Delivery Catheter until the handle Luer lock aligns and fits into the working channel fitting. If using the over-the wire technique, the AXIOS Electrocautery Enhanced Delivery Catheter should be placed over the guidewire before inserting it into the working channel.
12. Rotate the winged Luer lock clockwise to secure the delivery system handle to the echoendoscope as in **Figure 13-11**.

Figure 13-11: Align the handle with the echoendoscope and attach it by rotating the Luer lock fitting clockwise.

13. Connect the AXIOS Electrocautery Enhanced Delivery System to the 3mm monopolar electrosurgical active cable so that the 3.0mm plug fits securely. Ensure the generator is at the proper settings.
14. Using EUS imaging, re-confirm your position for stent delivery. Unlock the catheter lock (**Figure 13-12**) and advance the (black) catheter control hub (**Figure 13-13**) until the distal catheter position is visible.

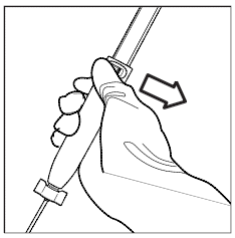


Figure 13-12: Push the catheter lock to the right to unlock the catheter and to the left to relock it.

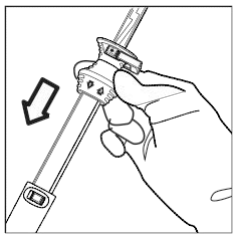


Figure 13-13: With the catheter unlocked, carefully advance the catheter control hub (in the direction indicated by the "1" arrow on the hub) so that the distal end of the catheter moves towards and into the target structure.

15. Advance the AXIOS Electrocautery Enhanced Delivery Catheter tip using the catheter control hub to tent the tissue for visualization on EUS. Energize the device and advance carefully

into the target structure. After entry into the target structure, power off the generator and unplug the delivery system.

16. Using EUS imaging, ensure that the tip of the AXIOS Electrocautery Enhanced Delivery Catheter is positioned at least 3-4 cm within the inner margin of the target structure. Lock the catheter lock to ensure that the delivery catheter does not move during deployment of the stent first (distal) flange.
17. Deploy the first (distal) flange of the stent. Press down on the yellow safety clip to remove it from the stent deployment hub.

Figure 13-14: Remove the yellow safety clip.

18. Under EUS imaging, deploy the stent first (distal) flange by unlocking the stent lock (**Figure 13-15)** and retracting the stent deployment hub to the halfway point indicated on the handle (**Figure 13-16**). A "click" will be heard as the stent deployment hub automatically locks into place (at the "2" arrow line). Verify with EUS imaging that the stent first (distal) flange is deployed inside the target structure (do not proceed to next step until verified).

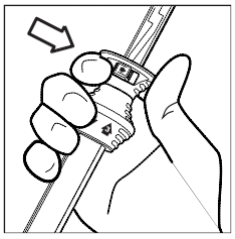


Figure 13-15: Push the stent lock to the right to unlock the stent deployment hub. The lock automatically relocks when the hub reaches the stent first (distal) flange deployment stop.

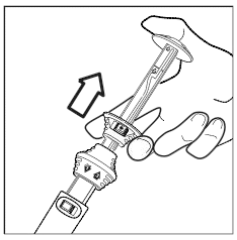
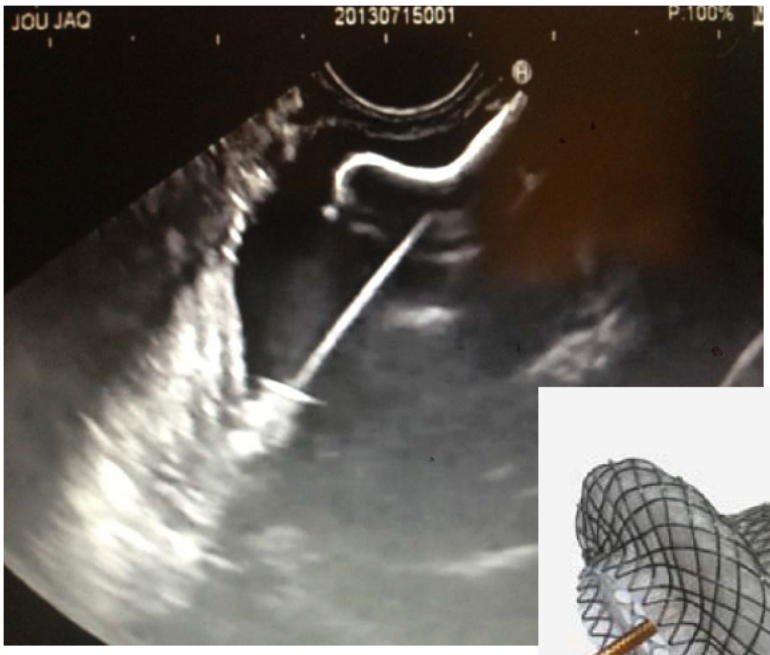


Figure 13-16: Holding the handle and stent deployment hub like a syringe, retract the hub to release the stent first (distal) flange. The hub will "click" and lock into place at the "2" arrow line.

The first (distal) flange is deployed and visible on ultrasound.



19. Deploy the stent second (proximal) flange using one of two approaches: under endoscopic view or under EUS guidance.

a. Endoscopic view:

i. Switching to endoscopic view, retract the echoendoscope until the catheter shaft is visible passing through the gastric or duodenal wall.

ii. Confirm at least 2-3mm of the black band is visible in the gastrointestinal tract (**Figure 13-17**). This indicates that the catheter is correctly positioned for deployment of the stent second (proximal) flange.

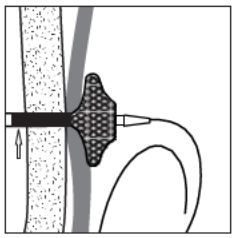


Figure 13-17: Under endoscopic view, confirm that at least 2-3 mm of the black band is visible in GI tract (see arrow).

iii. To deploy the stent second (proximal) flange, unlock the stent lock and retract the stent deployment hub to the top of the handle in the direction indicated by the "4" arrow (**Figure 13-18**).

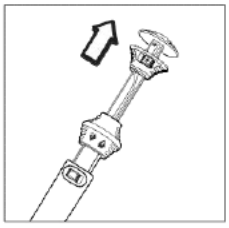


Figure 13-18: Deploy the stent second (proximal) flange by retracting the stent deployment hub in the direction indicated by the "4" arrow on the handle.

iv. Under direct endoscopic visualization, verify that the stent second (proximal) flange is deployed within the gastrointestinal tract.

b. EUS guidance:

i. With the first (distal) flange in EUS view, unlock the catheter lock and retract the catheter control hub so that the first (distal) flange approaches the inner wall of the target structure. Retract the first (distal) flange gently against the inner wall of the structure until it changes shape from a flat or disk-like shape (no load) to an oval shape (small load).

ii. Maintaining the first (distal) flange against the inner wall with an oval shape, re-lock the catheter lock.

iv. Unlock the stent lock and retract the stent deployment hub to the top of the handle in the direction indicated by the "4" arrow (**Figure 13-19**).

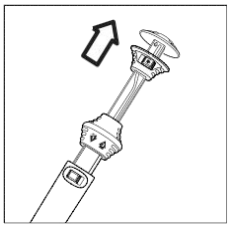


Figure 13-19: Under EUS view, deploy the stent second (proximal) flange by retracting the stent deployment hub.

v. The second (proximal) flange of the stent is now released but may remain in the working channel. If the second (proximal) flange remains in the working channel of the echoendoscope, ensure the first (distal) flange remains correctly in position, and advance the catheter control hub while retracting the scope in a 1-to-1 fashion until the second (proximal) flange releases from the scope and is visualized on endoscopy or EUS.

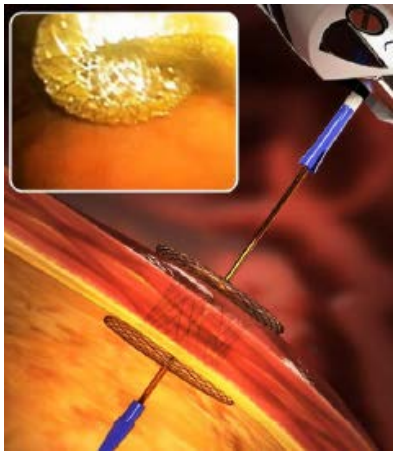


Figure 13-20: The first (distal) flange is deployed creating tissue apposition between the two organ layers. The second (proximal) flange is visible on endoscopic view in the small image window.

18. If desired, place a balloon catheter over the insulated guidewire and into the central lumen of the stent to dilate the stent up to the nominal diameter.

19. Stent Removal: under endoscopic visualization, place a standard endoscopic snare over the stent flange (e.g., Boston Scientific Profile Polypectomy Snare 27mm x 240 mm, Catalog # 6257). Tighten the snare until the stent lumen (saddle) collapses. Pull the snare away from the gastrointestinal wall until the stent is removed from the tract. Remove the endoscope to extract the stent. Stent removal may also be performed with endoscopic forceps. The stent is braided in such a way that it will not unravel if a wire is broken. The mechanism for stent removal is the combined action of stent collapse and pulling motion.

Complete instructions for use (IFUs) describing the intended use and directions for operating the AXIOS Stent with Electrocautery Enhanced Delivery System is provided in **Attachment 7**.

SECTION 14: SUBSTANTIAL EQUIVALENCE RATIONALE

The term "substantially equivalent" as used herein refers to a determination of substantial equivalence defined in Section 513 of the Federal Food, Drug and Cosmetic Act as amended by the Safe Medical Devices Act of 1990 and 1992.

The Xlumena AXIOS Stent with Electrocautery Enhanced Delivery System is substantially equivalent to the legally marketed predicate devices identified in **Table 14-1**. The AXIOS Stent with Electrocautery Enhanced Delivery System is substantially equivalent based on the intended use / indications for use, technological characteristics and principles of operation to the predicate AXIOS Stent and Delivery System which was cleared by FDA in 510(k)s K123250 and K140561, and the Wilson-Cook Medical Cystotome cleared by FDA in 510(k) K022595.

Table 14-1. AXIOS Stent with Electrocautery Enhanced Delivery System Predicate Devices

Manufacturer	Name of Predicate Device	510(k) #	Clearance Date
Xlumena, Inc.	AXIOS Stent and Delivery System	K140561 K123250	April 23, 2014 December 18, 2013
Wilson-Cook Medical, Inc.	Wilson-Cook Cystotome	K022595	October 17, 2002

Predicate device information for the AXIOS Stent with Electrocautery Enhanced Delivery System is provided in **Attachment 5** (Xlumena AXIOS Stent with Delivery System - non-cautery) and **Attachment 6** (Wilson-Cook Cystotome). A Substantial Equivalence Chart for the AXIOS Stent with Electrocautery Enhanced Delivery System is provided in **Table 14-2**, which describes the similarities and differences of the subject device to the legally marketed predicate devices to which equivalency is claimed.

Table 14-2. AXIOS Stent with Electrocautery Enhanced Delivery System Substantial Equivalence Chart

Characteristic	**SUBJECT DEVICE** **Xlumena AXIOS Stent with Electrocautery Enhanced Delivery System**	**PRIMARY PREDICATE DEVICE** **Xlumena AXIOS Stent with (non-cautery) Delivery System**	**REFERENCE PREDICATE DEVICE** **Wilson-Cook Medical** **Wilson-Cook Cystotome**
510(k) Number	TBD	K140561and K123250	K022595
Intended Use / Indications for Use	To facilitate transgastric or transduodenal endoscopic drainage of symptomatic pancreatic pseudocysts ≥ 6cm in size, with ≥ 70% fluid content that are adherent to the gastric or bowel wall. Once placed, the AXIOS Stent functions as an access port allowing passage of standard and therapeutic endoscopes to facilitate debridement, irrigation and cystoscopy. The stent is intended for implantation up to 60 days and should be removed upon confirmation of pseudocyst resolution.	Same	For use as an electrosurgical accessory to cannulate the transgastric or transduodenal wall and into a pancreatic pseudocyst that is visibly bulging into the gastrointestinal tract.
Class	II	Same	Same
Common Name	Pancreatic drainage stent and delivery system and endoscopic electrosurgery device	Pancreatic drainage stent and delivery system	Endoscopic electrosurgery device
Classification/ Regulation Name	Pancreatic drainage stent and accessories and endoscopic electrosurgery accessories	Pancreatic drainage stent and accessories	Endoscopic electrosurgery accessories
Regulation Number	21CFR 876.5015 21CFR 876.4300	21CFR 876.5015	21CFR 876.4300
Product Code	PCU and 78KNS	PCU	78KNS
Outer Catheter Length	138 cm	Same	165 cm
Outer Catheter Shaft Diameter	10.8 Fr	Same	10 Fr
Inner Catheter Sheath Diameter	9 Fr with preloaded Stent	Same	5 Fr with 0.038” needle knife
Guidewire Compatibility	0.035”	Same	Same
Endoscope Compatibility	Compatible with 3.7 mm diameter or larger working channel	Same	Same
Placement Site	Transgastric or transduodenal wall and into a pancreatic pseudocyst	Same	Same
Pseudocyst Size	≥ 6cm in size	Same	≥ 4cm in size

Characteristic	SUBJECT DEVICE Xlumena AXIOS Stent with Electrocautery Enhanced Delivery System	PRIMARY PREDICATE DEVICE Xlumena AXIOS Stent with (non-cautery) Delivery System	REFERENCE PREDICATE DEVICE Wilson-Cook Medical Wilson-Cook Cystotome
Mode of Access or Operation	Electrosurgically punctures hole at the placement site. Fine wire electrocautery element (0.006" SS wire); electrosurgically active wire using pure cutting current to access pseudocyst. After access, deploy the AXIOS Stent using a two stage process. Distal stent flange first followed by the proximal flange.	Access path at placement site is created using conventional access tools. After access, deploy the AXIOS Stent using a two stage process. Distal stent flange first followed by the proximal flange.	Electrosurgically punctures hole at the placement site. Needle 0.038" knife tip; electrosurgically active knife using pure cutting current to access pseudocyst. Enlarge incision with a cauterizing diathermic ring and 10 Fr outer catheter. Utilize a 0.035" wire for placement of a stent or drainage kit via compatible endoscope.
Stent Deployment Mechanism	Deployed via handle controls. Distal stent flange first followed by the proximal flange.	Same	N/A
Cutting Current	80-120 Watts	N/A	80-120 Watts
(b)(4)Proprietary Information	[redacted]	[redacted]	[redacted]
Sterilization	Ethylene Oxide (EO)	Ethylene Oxide (EO)	Ethylene Oxide (EO)

A. Intended Use / Indications for Use

The AXIOS Stent with Electrocautery Enhanced Delivery System is substantially equivalent in terms of intended use / indications for use to the predicate AXIOS Stent and Delivery System which was cleared by FDA in 510(k)s K123250 and K140561, and the Wilson-Cook Medical, Inc. Cystotome cleared by FDA in 510(k) K022595.

The intended use / indications for use of the AXIOS Stent with Electrocautery Enhanced Delivery System is identical to that of the predicate (non-cautery) AXIOS Stent and Delivery System in that both systems:

> Facilitate transgastric or transduodenal endoscopic drainage of symptomatic pancreatic pseudocysts ≥ 6cm in size, with ≥ 70% fluid content that are adherent to the gastric or bowel wall. Once placed, the AXIOS Stent functions as an access port allowing passage of standard and therapeutic endoscopes to facilitate debridement, irrigation and cystoscopy. The stent is intended for implantation up to 60 days and should be removed upon confirmation of pseudocyst resolution.

In addition, the intended use / indications for use of the modified AXIOS Stent with Electrocautery Enhanced Delivery System are essentially the same as the Wilson-Cook Cystotome (electrocautery access device) in that both systems are:

> For use as electrosurgery accessories to cannulate the transgastric or transduodenal wall, and into pancreatic pseudocysts which are visibly bulging into the gastrointestinal tract.

While the AXIOS Stent with Electrocautery Enhanced Delivery System is specifically indicated for drainage of symptomatic pancreatic pseudocysts ≥ 6cm in size and the Cystotome electrosurgical device is intended for symptomatic pancreatic pseudocysts ≥ 4 cm in size, this difference does not raise any new issues of safety or effectiveness as demonstrated by the results of the animal and clinical studies; **Section 21** and **Section 22**, respectively.

B. Technological Characteristics and Principles of Operation

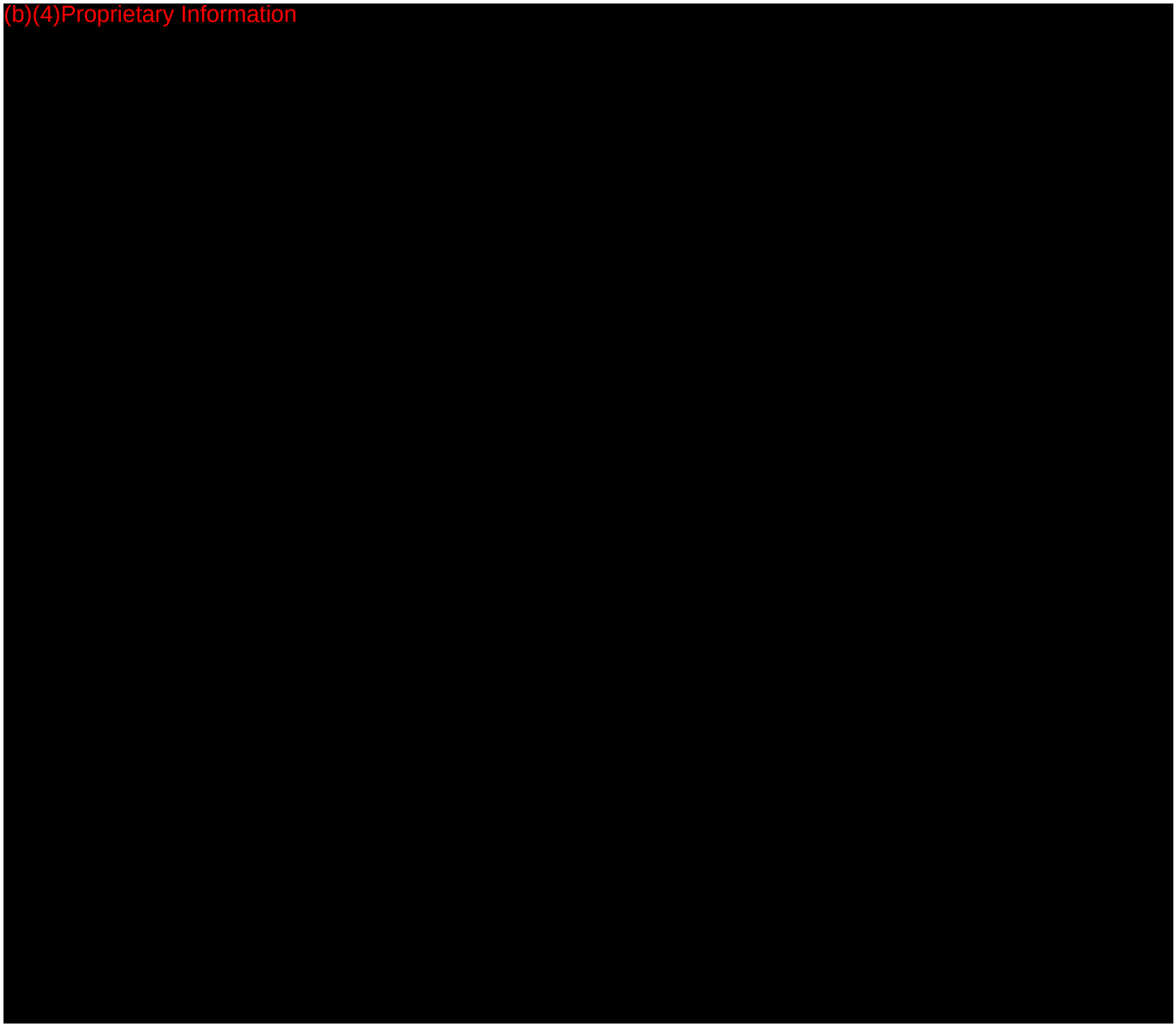
The AXIOS Stent with Electrocautery Enhanced Delivery System is substantially equivalent based on the technological characteristics and principles of operation to the Xlumena AXIOS Stent Delivery System (K123250 and K140561). The AXIOS Stent with Electrocautery Enhanced Delivery System is identical to the currently cleared non-cautery AXIOS Stent and Delivery System (K123250 and K140561) in that both devices enable the endoscopic placement of a flexible, MRI compatible fully-covered, self-expanding Nitinol stent for transenteric drainage of symptomatic pancreatic pseudocysts. The AXIOS Stent design has not changed and is identical to the stent cleared in K123250 and K140561.

The Electrocautery Enhanced Delivery System design is identical to the predicate non-cautery Delivery System in terms of outer and inner catheter shaft (sheath) diameters, guidewire

compatibility (0.035”), endoscope compatibility (≥3.7 mm working channel), stent placement (pre-loaded) on the inner catheter sheath, and stent deployment mechanism (via handle controls). The mechanism of positioning and delivery of the AXIOS Stent remains unchanged; it is identical to the current Delivery System (K123250). Both Delivery Systems facilitate access and deployment of the AXIOS Stent through the transgastric or transduodenal wall and into a ≥ 6 cm pancreatic pseudocyst.

The modified Delivery System, Electrocautery Enhanced Delivery Catheter, incorporates electrocautery pure cutting mode features which enable access across the transgastric or transduodenal wall and into the pancreatic pseudocyst. The Electrocautery Enhanced Delivery System has been modified to connect with an off-the-shelf electrosurgical unit or generator that is complaint to IEC 60601-1-2 and IEC 60601-2-2. A monopolar plug has been added to the catheter handle to connect to the electrosurgical unit.

(b)(4)Proprietary Information



Use of electrocautery in transmural endoscopic ultrasound procedures to enable access across the transgastric or transduodenal wall and into pancreatic pseudocysts is not a new method of access as seen by the predicate Wilson-Cook Cystotome device (K022595). The AXIOS Stent with Electrocautery Enhanced Delivery System is designed to use electrocautery to cannulate the transgastric or transduodenal wall into a pancreatic pseudocyst, similar to the Wilson-Cook Cystotome. Both devices use equivalent RF energy between 80-120 watts in pure cutting mode to enable access to the target anatomies. While the AXIOS Stent with Electrocautery Enhanced Delivery System is designed to access and drain pseudocysts ≥ 6cm, and the Wilson-Cook Cystotome is designed to access pseudocysts ≥ 4cm (and drain with other devices), this difference does not raise any new issues of safety or effectiveness as both systems access the same type of pseudocysts utilizing the same electrocautery cautery and transgastric endoscopic methods. The safety and performance of the AXIOS Electrocautery Enhanced Delivery System has been demonstrated in the bench performance, biocompatibility, electrical safety / electromagnetic compatibility, animal and clinical studies provided in **Section 20**, **Section 17**, **Section 19**, **Section 21** and **Section 22**, respectively.

C. Material Changes

The new materials used in the fabrication of the AXIOS Electrocautery Enhanced Delivery System are summarized in **Table 17-2** provided in **Section 17** (Biocompatibility). The minor material changes do not raises any new issues of biocompatibility as all materials have been tested in accordance with EN ISO 10993-1 and have been demonstrated to be biocompatible based on the results of testing provided in **Section 17**. Additionally, the new materials do not impact the performance of the delivery catheter as demonstrated by the results of the Bench Performance testing provided in **Section 20**. Note that the AXIOS Stent design and materials are unchanged; they are identical to the AXIOS Stent cleared in K123250 and K140561.

D. Conclusions

The modified AXIOS Stent with Enhanced Electrocautery Delivery System has the same intended use / indications for use as the currently cleared AXIOS Stent with Delivery System (K123250 and K140561). In addition, the intended use / indications for use of the AXIOS Stent with Electrocautery Enhanced Delivery System are substantially similar to the Wilson-Cook Cystotome Electrocautery Access device (K022595).

Any differences in the technological characteristics or principles of operation between the modified AXIOS Stent with Electrocautery Enhanced Delivery System and the cleared AXIOS Stent with Delivery System or Cystotome do not raise new questions of safety or effectiveness as confirmed by the bench performance, biocompatibility, electrical safety / electromagnetic compatibility, animal and clinical study test results provided in **Section 20**, **Section 17**, **Section 19**, **Section 21** and **Section 22**, respectively. Therefore, the AXIOS Stent with Electrocautery Enhanced Delivery System is substantially equivalent to the previously cleared predicate devices.

SECTION 15: PROPOSED LABELING

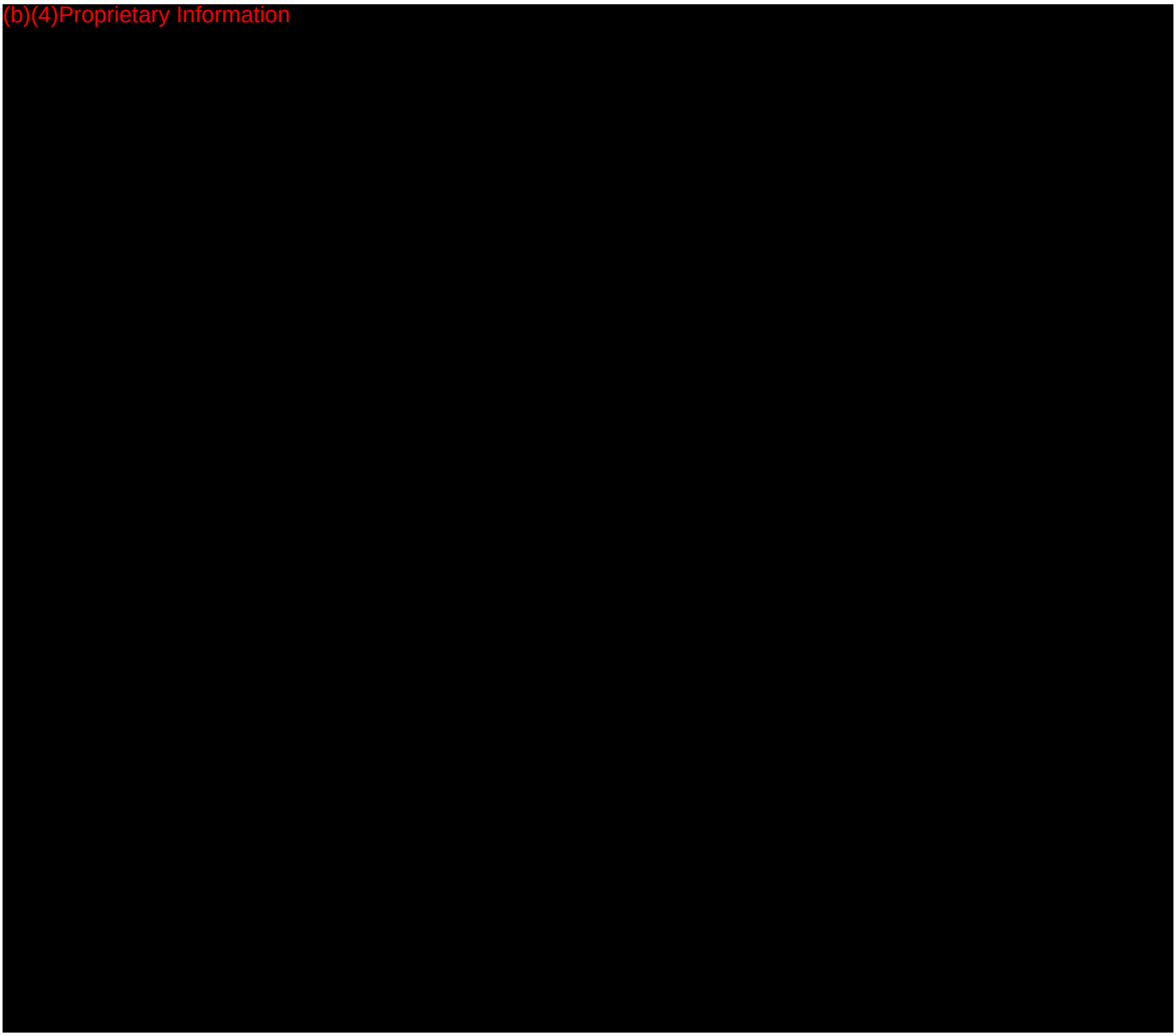
Draft product labels and the Instructions for Use for the AXIOS Stent with Electrocautery Delivery System are provided in the following Attachments listed in **Table 15-1**:

Table 15-1. AXIOS Stent with Electrocautery Delivery System Draft Labeling

Labeling	Label Description	Attachment
IFU 510(k)	AXIOS Stent with Electrocautery Enhanced Delivery System Instructions for Use (b)(4)Proprietary	**Attachment 7**
IFU IDE	AXIOS Stent with Electrocautery Enhanced Delivery System Instructions for Use (b) (4)P) Used in IDE Study	**Attachment 8**
IFU Redlines	AXIOS Stent with Electrocautery Enhanced Delivery System Instructions for Use (b)(4)Proprietary Redlines	**Attachment 9**
(b) (4)P Pouch	AXIOS Stent with Electrocautery Enhanced Delivery System 10 x 10 Stent (b) (4)P Pouch Label	**Attachment 10**
(b) (4)P Pouch	AXIOS Stent with Electrocautery Enhanced Delivery System 15 x 10 Stent (b) (4)P Pouch Label	**Attachment 11**
Supplemental Label	AXIOS Stent with Electrocautery Enhanced Delivery System 10 x 10 Stent Supplemental Label	**Attachment 12**
Supplemental Label	AXIOS Stent with Electrocautery Enhanced Delivery System 15 x 10 Stent Supplemental Label	**Attachment 13**
Product Box Label (for both stent sizes)	AXIOS Stent with Electrocautery Enhanced Delivery System Box Label	**Attachment 14**
Stent Implant Card	AXIOS Stent Implant Card	**Attachment 15**

The proposed Instructions for Use for the AXIOS Stent with Electrocautery Enhanced Delivery System is provided along with the Instructions for Use utilized in the IDE Clinical Study in **Attachment 7** and **8**, respectively. Redline changes from the version used in the clinical study are provided in **Attachment 9**. **Table 15-2** provides a summary of changes to the Instructions for Use.

(b)(4)Proprietary Information



SECTION 16: STERILIZATION, PACKAGING AND SHELF LIFE

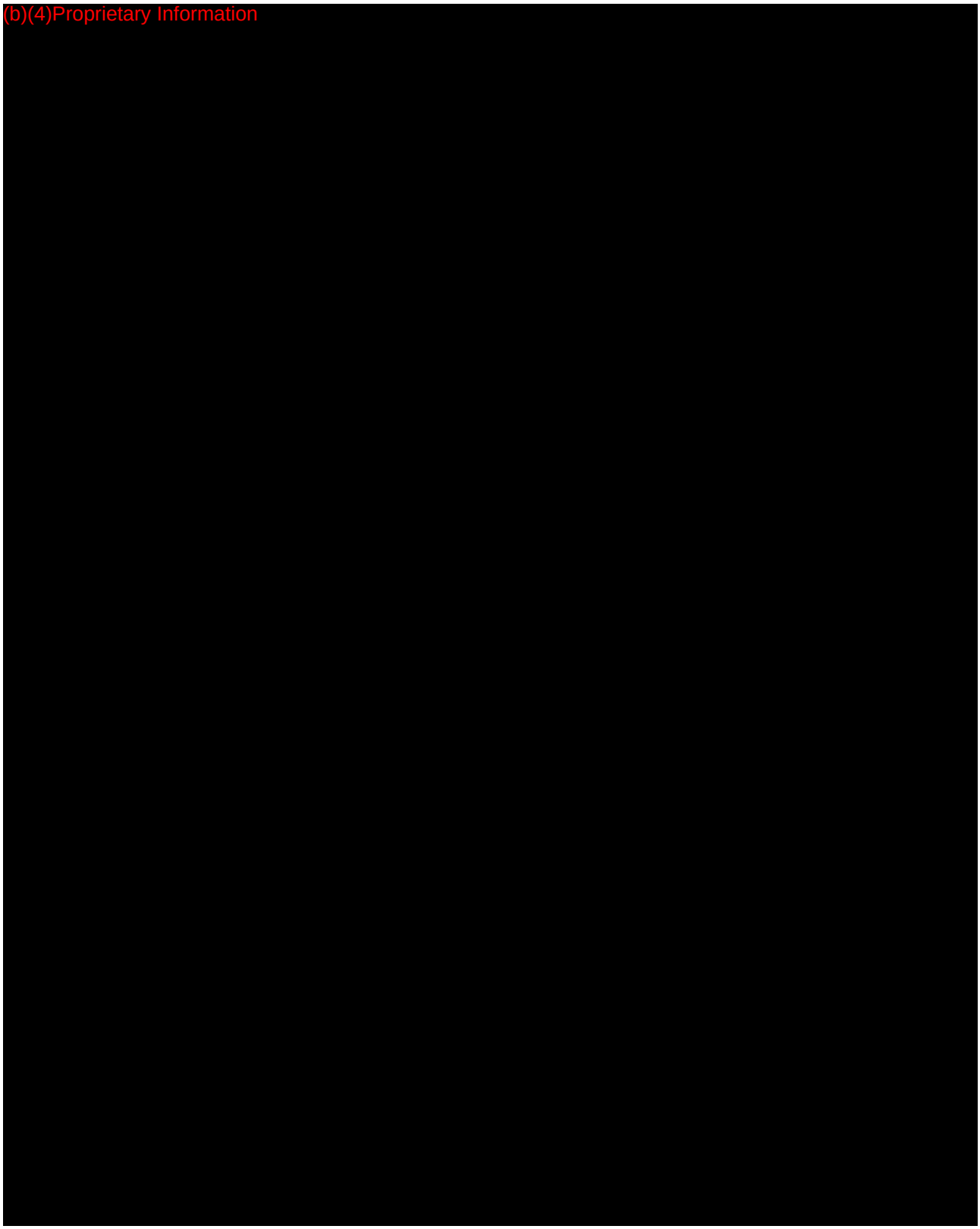
A. Sterilization

The AXIOS Stent with Electrocautery Enhanced Delivery System will be supplied sterile via ethylene oxide (EO) sterilization. The AXIOS Stent with Electrocautery Enhanced Delivery System is not intended for reuse / re-sterilization by the user. (b)(4)Proprietary Information [redacted] A complete copy of the Sterilization Validation Report is provided in **Attachment 38**.

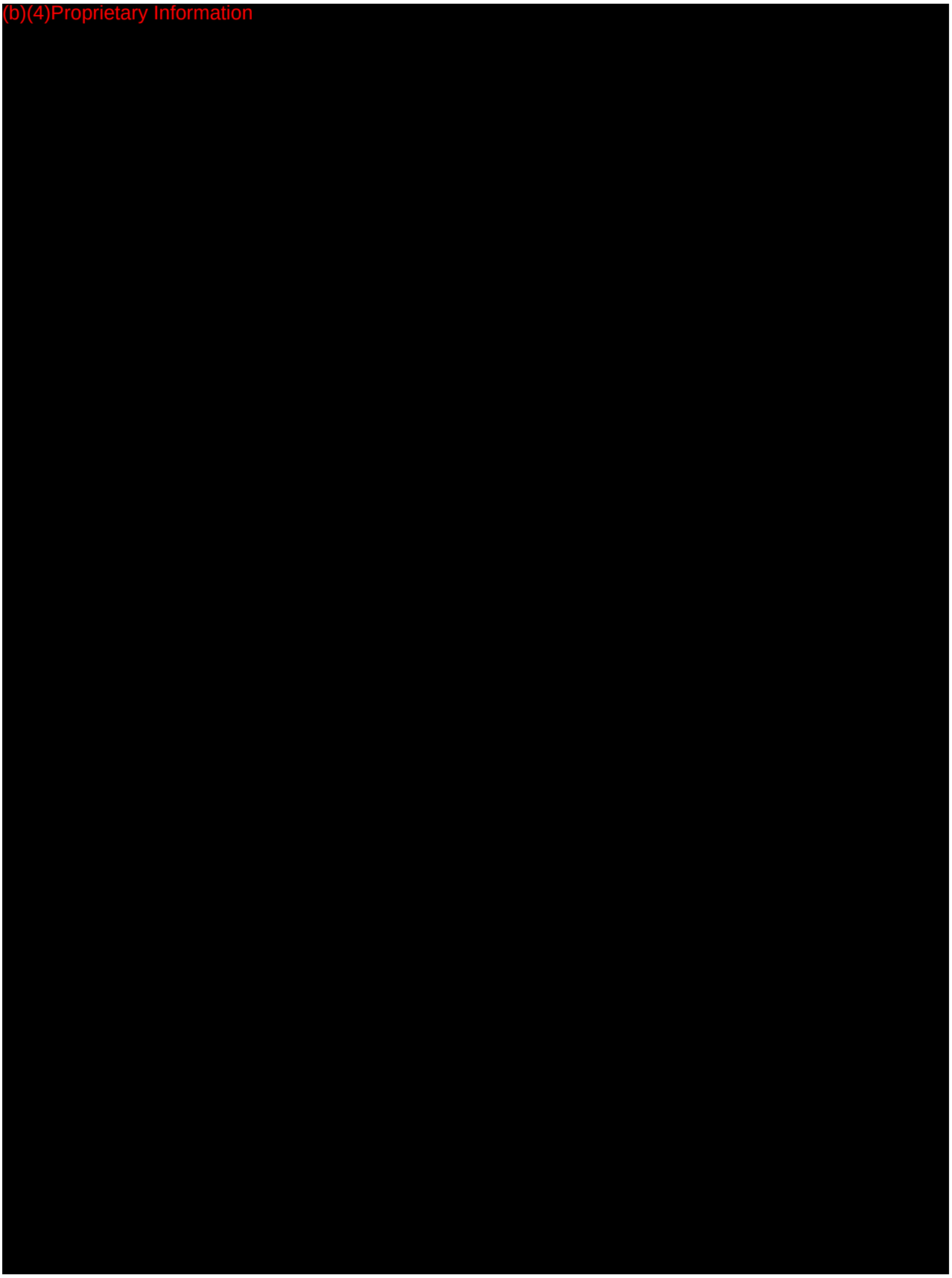
1. Sterilization Method

Each AXIOS Stent with Electrocautery Enhanced Delivery System lot is sterilized by ethylene oxide (EO) (b)(4)Proprietary Information [redacted]

(b)(4)Proprietary Information [redacted]



(b)(4)Proprietary Information

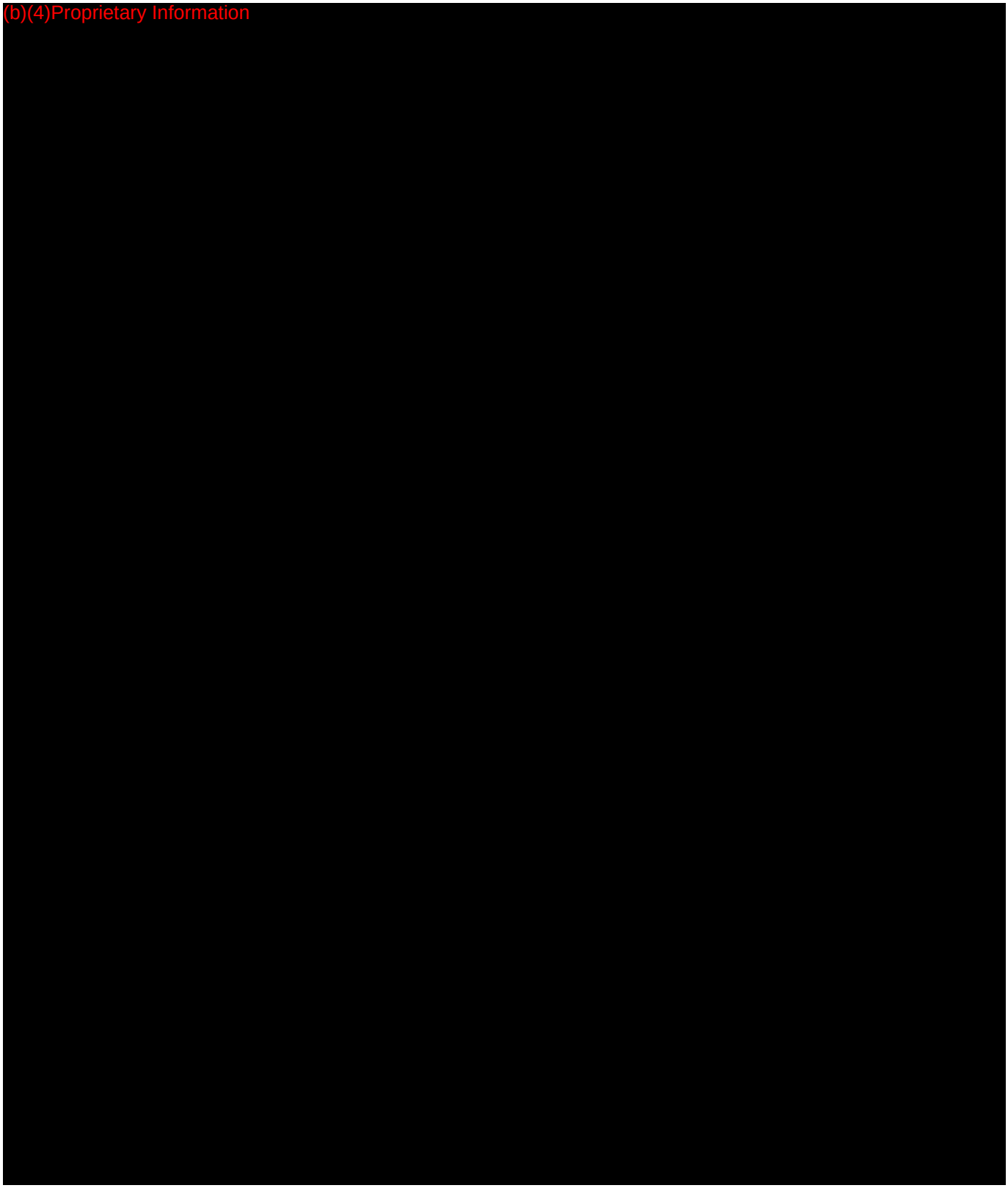


(b)(4)Proprietary Information

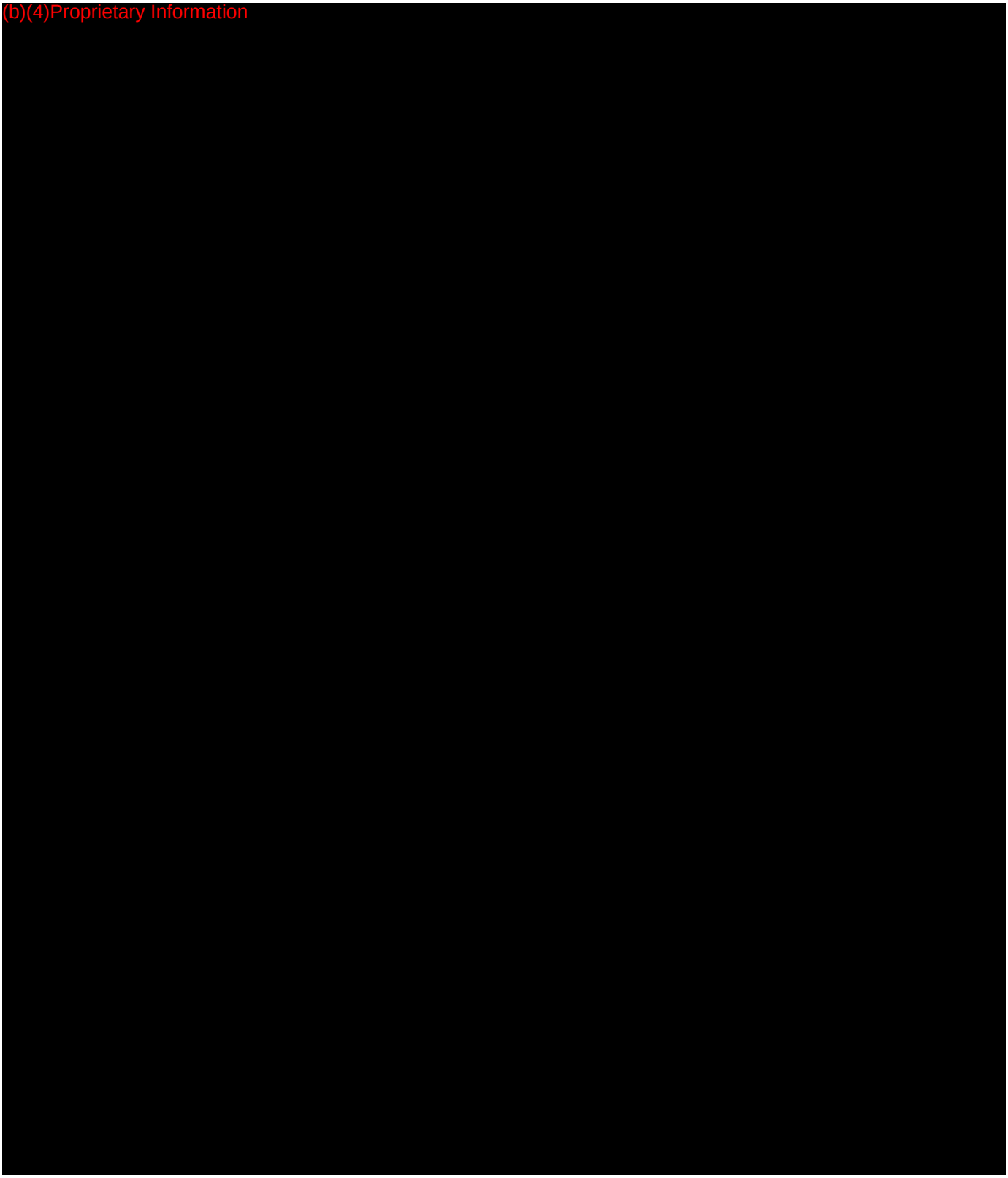
(b)(4)Proprietary Information A copy of the Instructions for Use is placed in each product box. (b)(4)Proprietary Information

(b)(4)Proprietary Information

(b)(4)Proprietary Information



(b)(4)Proprietary Information

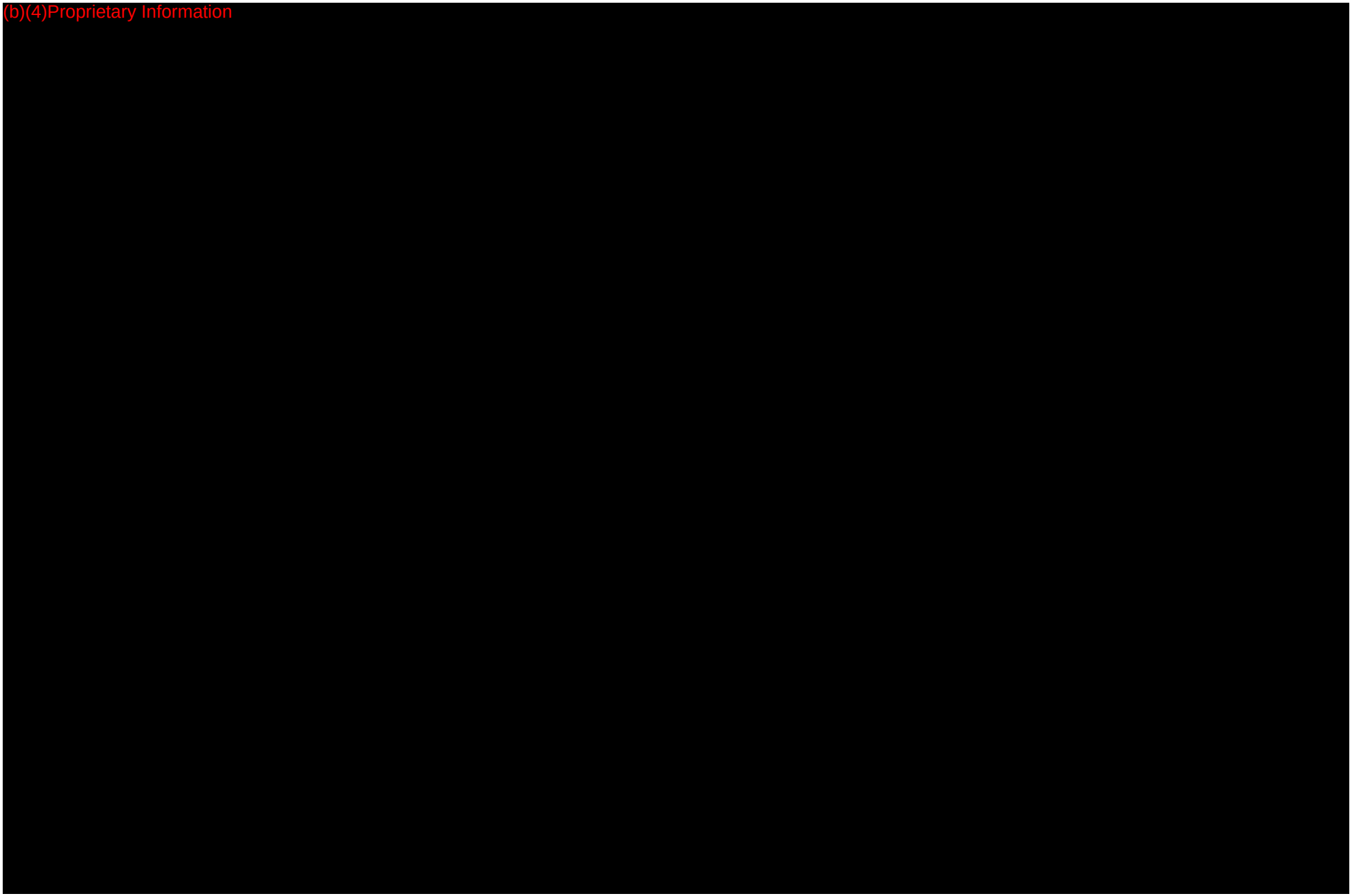


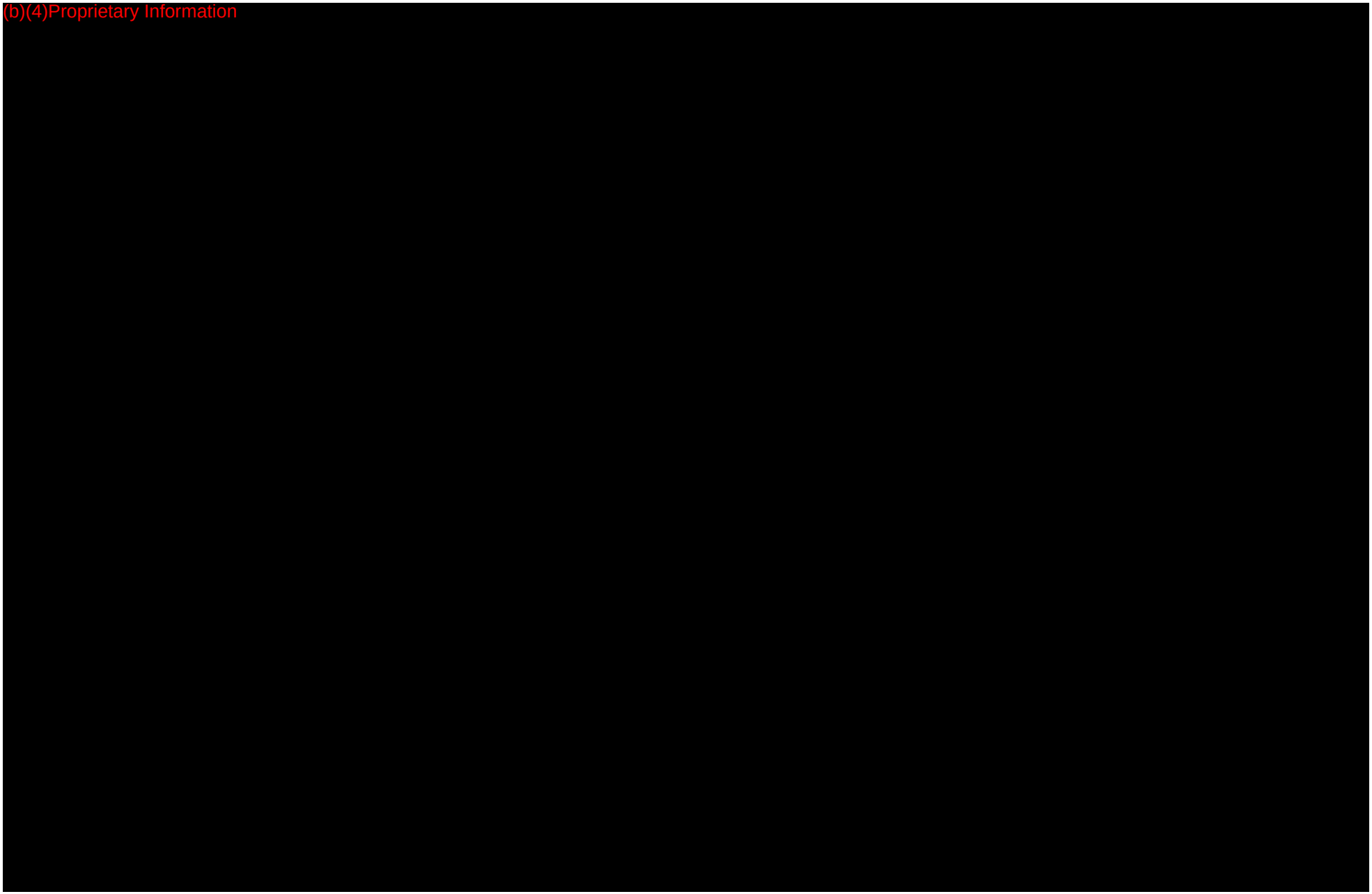
D. Shelf Life

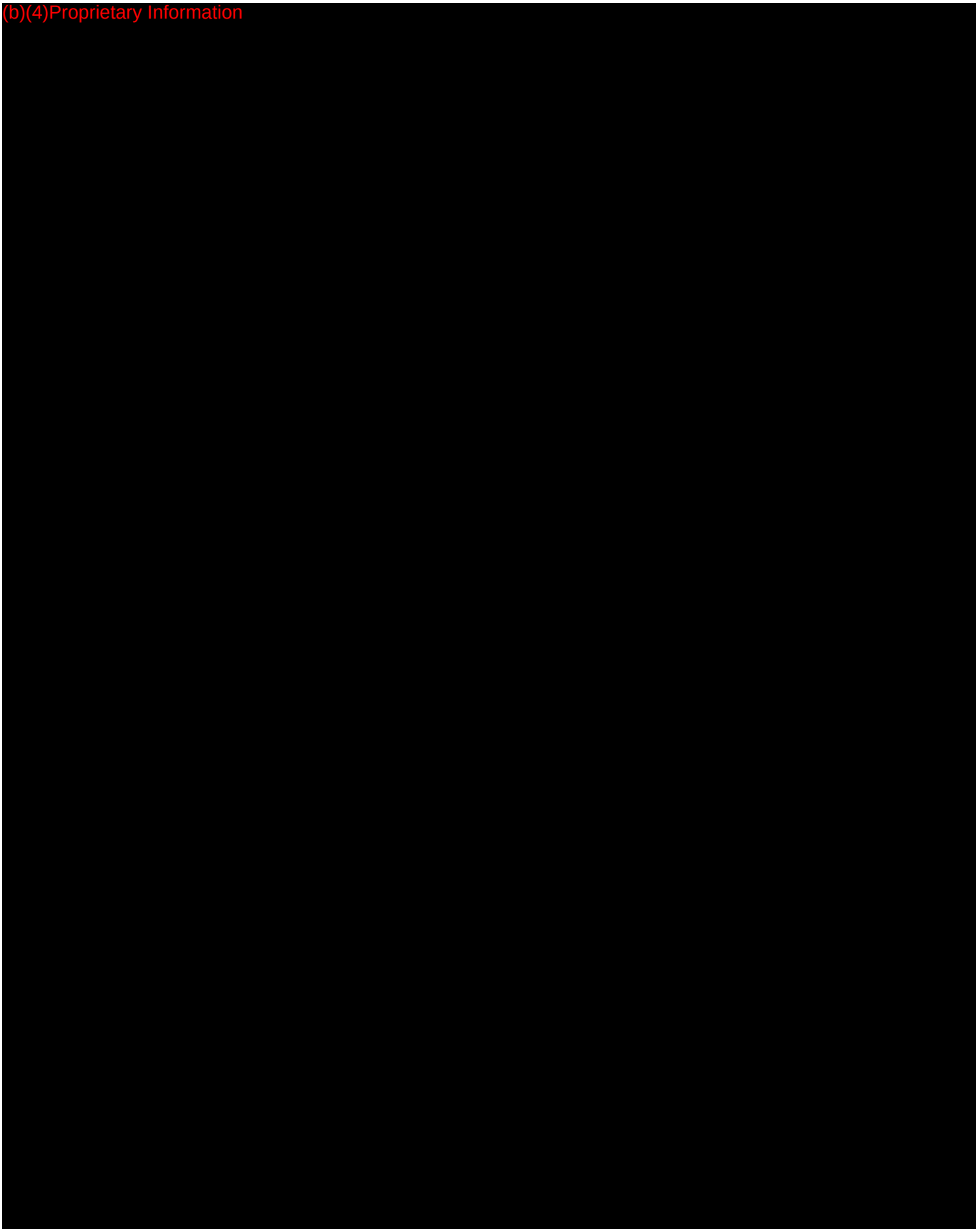
Xlumena intends to label the AXIOS Stent with Electrocautery Enhanced Delivery System with a twelve (12) month shelf life.

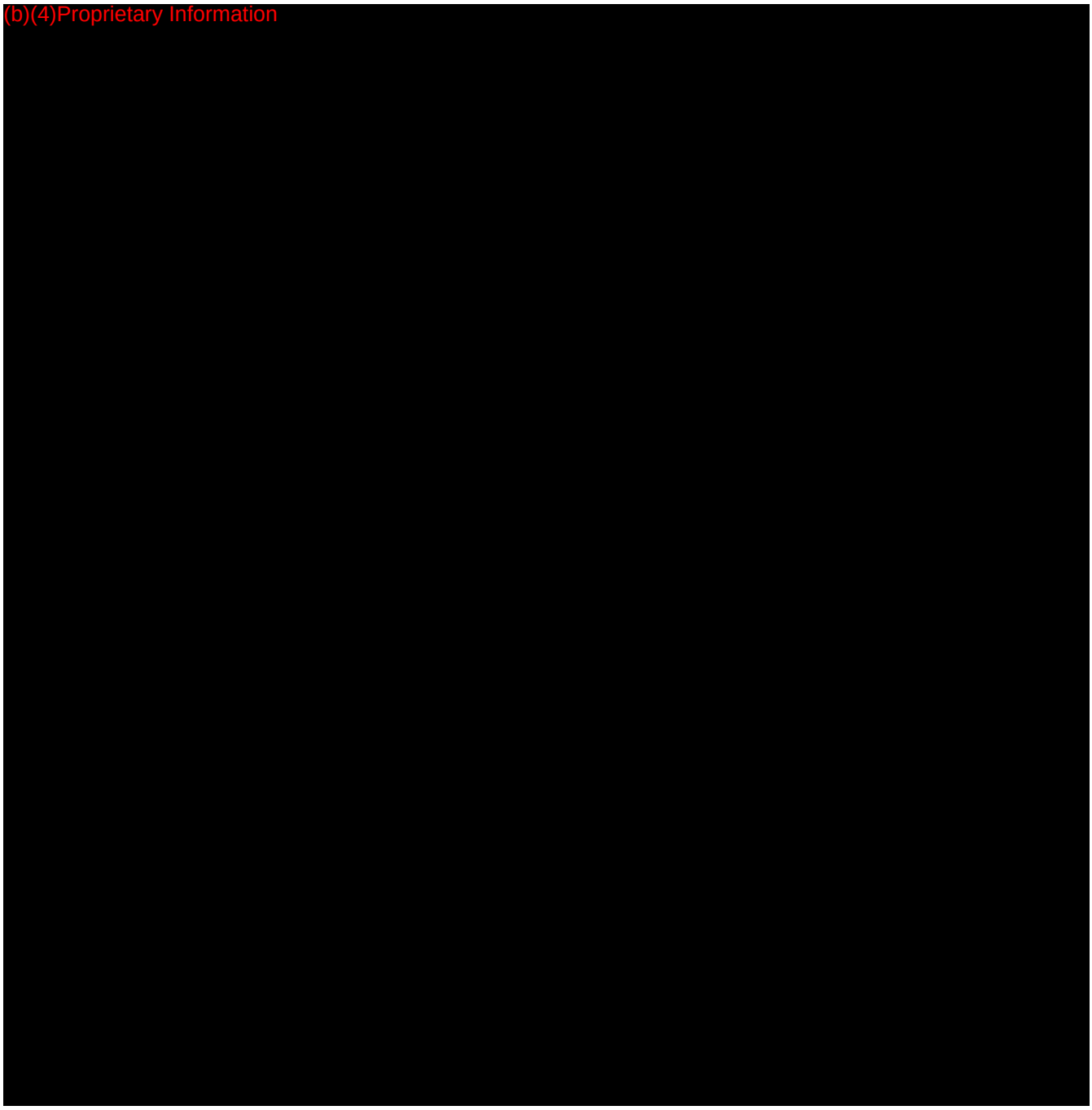
(b)(4)Proprietary Information

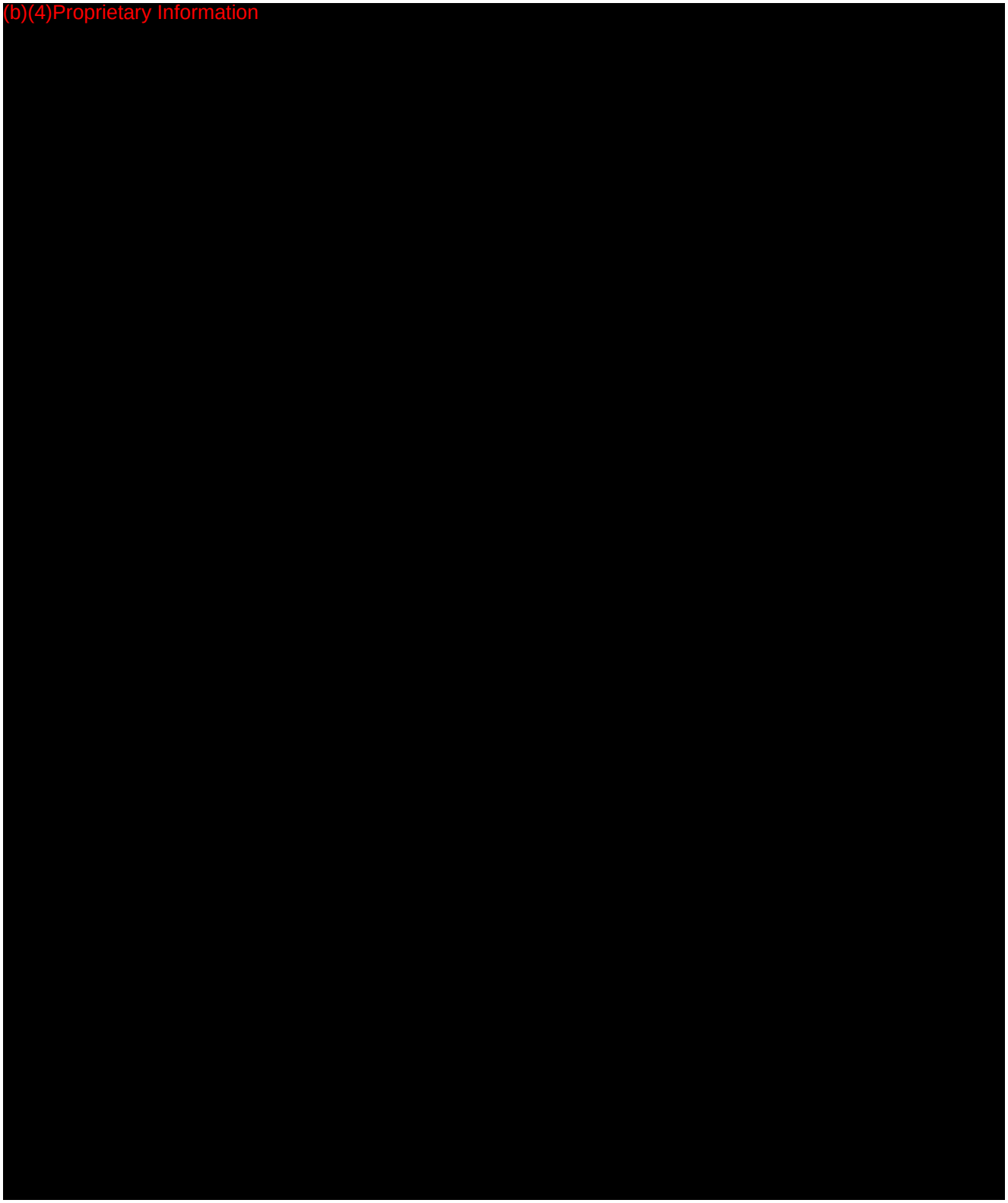
(b)(4)Proprietary Information











SECTION 17: BIOCOMPATIBILITY

A. Components and Materials

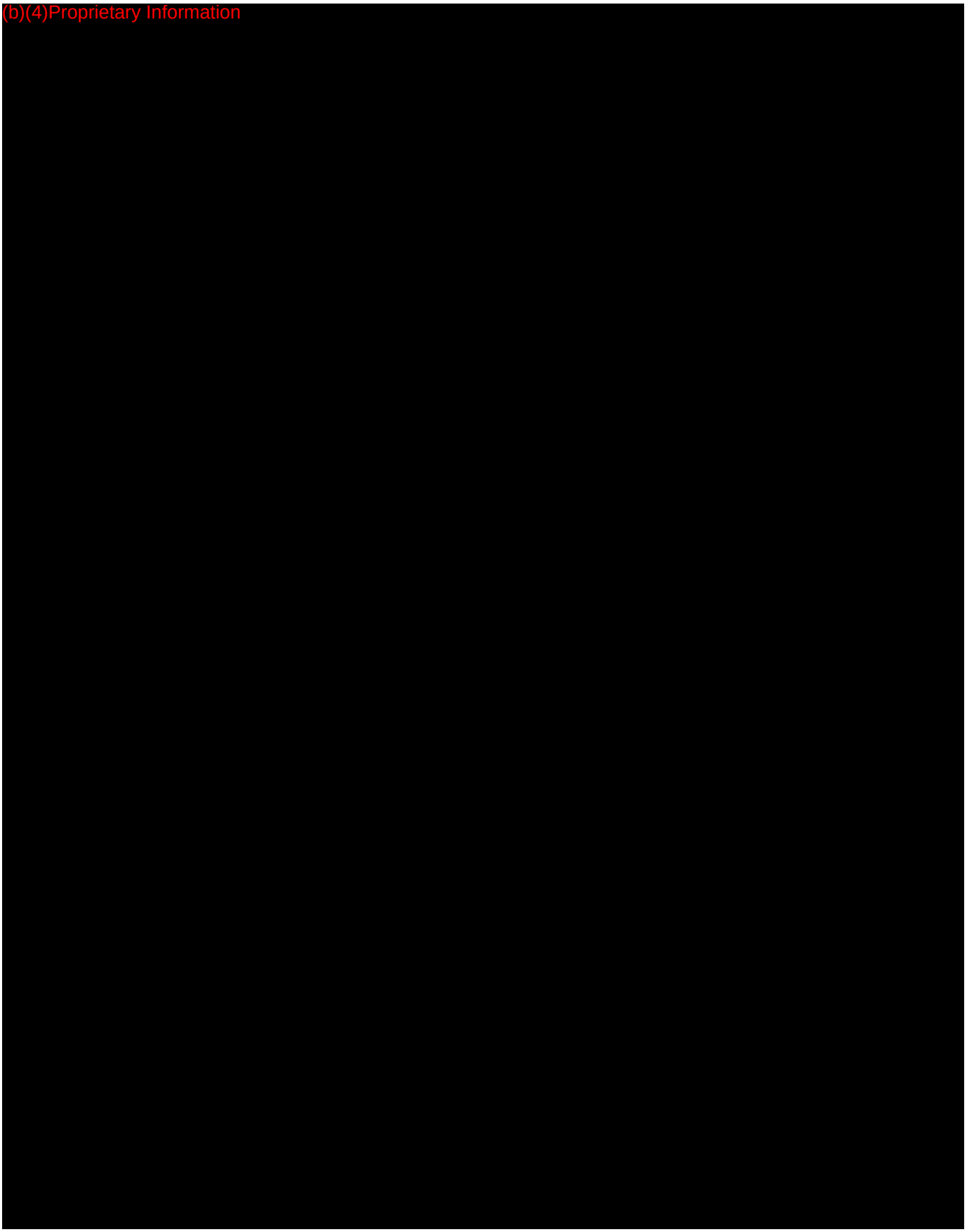
The materials used in the fabrication of the AXIOS Stent with Electrocautery Enhanced Delivery System, including the Stent and Delivery System (also referred to as the Hot AXIOS Delivery System) are used in other currently marketed interventional devices and have proven biocompatibility as required by ISO 10993-1:2009 and FDA's Draft Guidance Document *Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing (2013).*

(b)(4)Proprietary Information

The AXIOS Stent is identical to the AXIOS Stent cleared in K123250 and most recently under K140561; there are no changes to the design or the materials. (b)(4)Proprietary Information

(b)(4)Proprietary Information

(b)(4)Proprietary Information



(b)(4)Proprietary Information

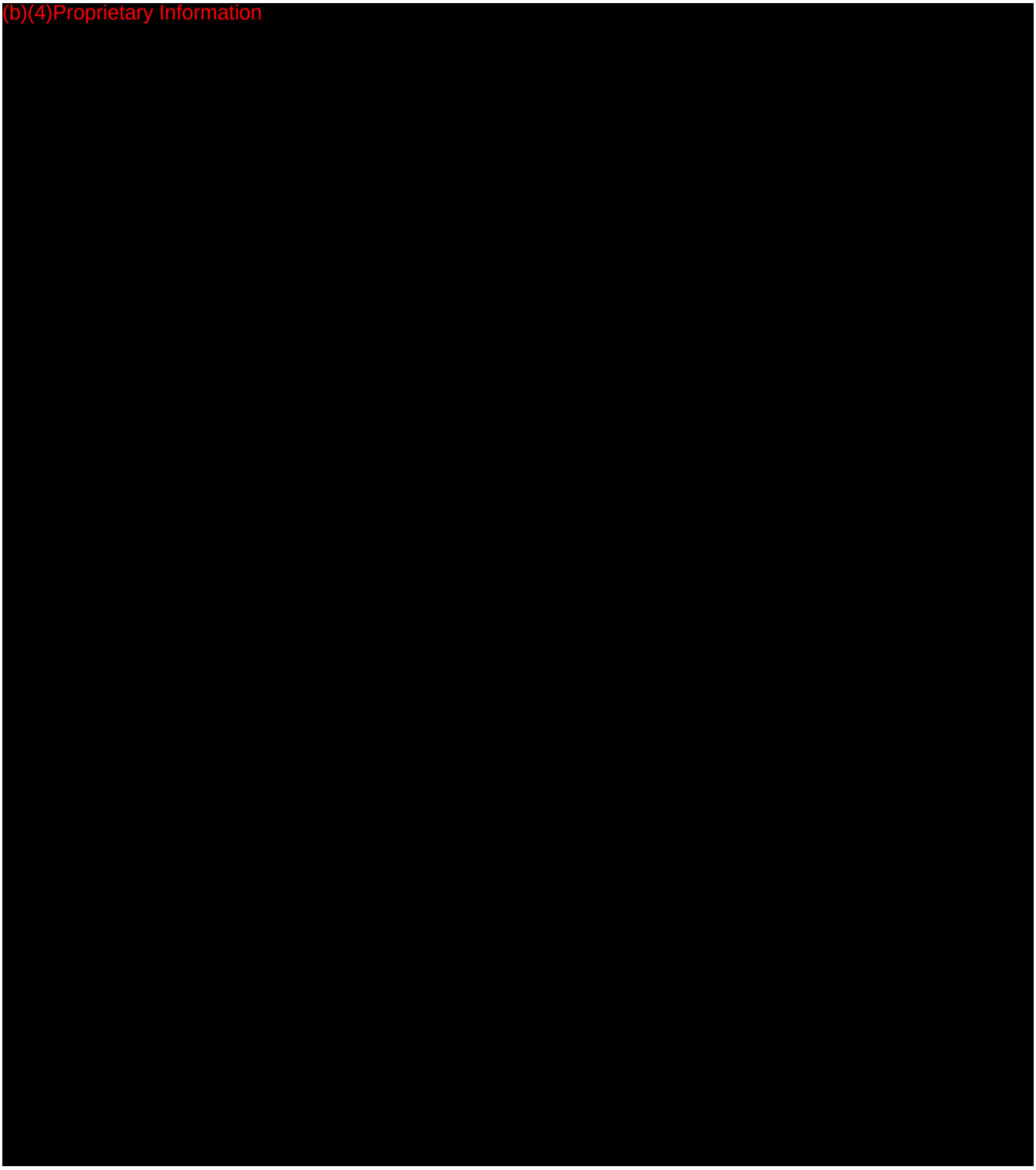
[redacted]

B. Biocompatibility Testing

To verify the biocompatibility of the AXIOS Stent with Electrocautery Enhanced Delivery System the Company conducted biocompatibility testing pursuant to ISO 10993-1:2009 and FDA's Draft Guidance Document *Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing (2013)"*, which specifically outlines the types of biocompatibility tests that are required based on the nature of the device and the extent and duration of its contact with blood or tissues. Biocompatibility testing was conducted in accordance with the GLP regulations (21 CFR, Part 58).

There have been no changes to the AXIOS Stent design or materials; it is identical to the AXIOS Stent cleared in 510(k)s K123250 and K140561, (b)(4)Proprietary Information

[redacted]



C. Conclusion

The Electrocautery Enhanced Delivery System with subject modifications passed all of the biocompatibility tests required per ISO 10993-1:2009. Based on the test results, the Electrocautery Enhanced Delivery System is biocompatible for their intended use. The biocompatibility test protocol and report are provided in **Attachments 24** and **25**, respectively.

SECTION 18: SOFTWARE

Not Applicable. The AXIOS Stent with Electrocautery Enhanced Delivery System does not contain software.

SECTION 19: ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY

A. Electromagnetic Compatibility and Electrical Safety

The AXIOS Stent with Electrocautery Enhanced Delivery System (Hot AXIOS Device) was evaluated by Intertek NA, for conformance to the IEC 60601family of standards as well as ISO 14971 Risk Management standard listed in **Table 19-1**.

(b)(4)Proprietary Information

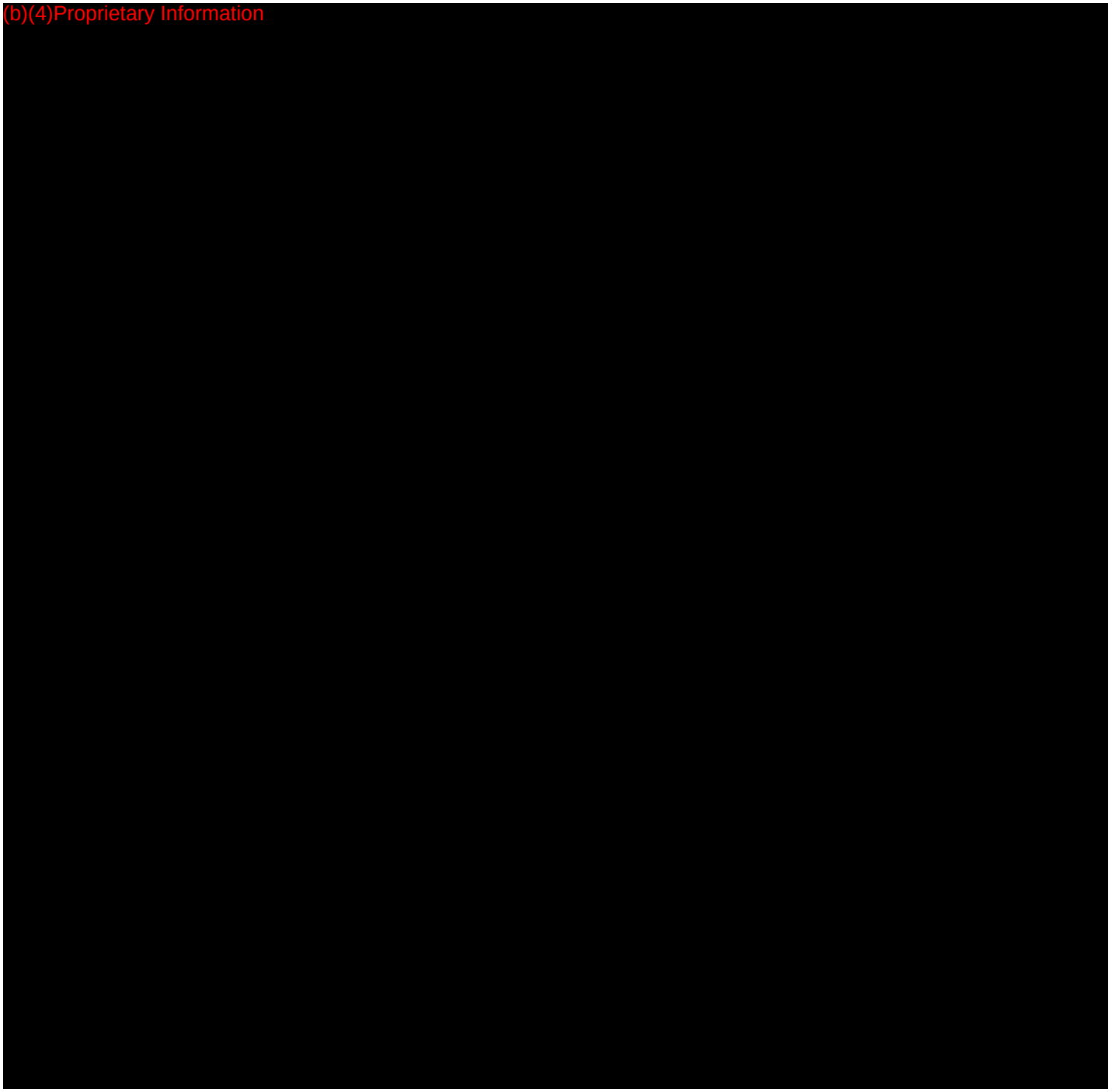
[redacted]

Table 19-1. Applicable IEC 60601 Safety and Electromagnetic Compatibility Standards

Standard	Title
IEC 60601-1	Issue 2005/12/15, Ed:3.0 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance; Corrigendum 1: 12/2006; Corrigendum 2: 12/2007
IEC 60601-1-2	Issue 2007/03/01, Ed:3.0 Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests
IEC 60601-1-6	Issue 2010/01/27, Ed: 3.0 Medical Electrical Equipment – Part 1-6: General requirements for safety – Collateral Standard: Usability.
IEC 60601-2-2	Issue 2009/02/23, Ed: 5.0 Medical Electrical Equipment – Part 2-2: Particular Requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories.
IEC 60601-2-18	Issue 2009/08/12 Ed:3.0 Medical Electrical Equipment – Part 2: Particular Requirements for the Safety of Endoscopic Equipment
AAMI ES60601-1	Issue 2006/03/09: 2005 Version Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance; Amd. C1: 2009, Amd.2:2010
ISO 14971	Issue 2007/10/01: 2007 Medical Devices – Application of risk management to medical devices, ISO 14971:2007

A summary of the test results for the applicable portions of the specified standards is provided below in **Table 19-2**. All completed testing passed the acceptance criteria as outlined in IEC 60601-1, 60601-1-6, 60601-2-2, 60601-2-18, and ISO 14971 and as specified in the Final Study Reports provided by Intertek NA, Inc. (**Attachment 26**).

(b)(4)Proprietary Information



In conclusion, the AXIOS Stent with Electrocautery Enhanced Delivery System performed in accordance with requirements of the electromagnetic compatibility and electrical safety standards.

B. RF Radiated Emissions

The AXIOS Stent with Electrocautery Enhanced Delivery System (Hot AXIOS Device) was tested by Intertek NA, for RF radiated emissions in accordance with the standards listed in **Table 19-3**.

Table 19-3. Applicable Standards for RF Radiated Emissions

Standard	Title
IEC 60601-1:2006+A11:2011	General requirements for basic safety and essential performance.
IEC 60601-1-2:2007	Medical electrical equipment – Part 1-2: General requirements for safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.
IEC 60601-2-2:2009+A11:2011	Medical electrical equipment –Part 2-2: Particular requirements for the safety of high frequency surgical equipment and high frequency surgical accessories.
IEC 60601-2-18 3rd Edition 2009-08	Particular requirements for the basic safety and essential performance of endoscopic equipment.

1. Test Summary

(b)(4)Proprietary Information

[redacted]

2. Discussion

(b)(4)Proprietary Information

[redacted]

(b)(4)Proprietary Information

3. Conclusion

(b)(4)Proprietary Information

Xlumena has concluded that the AXIOS Stent with Electrocautery Enhanced Delivery System does not alter the EMC compliance of the (b)(4)Proprietary electrosurgical generator to the subject standards. The RF Radiated Emissions report is provided in **Attachment 27**.

[4] Table 3. Electromagnetic radiation disturbance limits for Group 1 equipments (CISPR 11).

SECTION 20: PERFORMANCE TESTING - BENCH

A. Design Verification / Design Validation Studies

Bench performance testing was conducted for the AXIOS Stent with Electrocautery Enhanced Delivery System to demonstrate that the modified delivery system continues to meet the requirements of the product design specification and perform in accordance with its intended use. There have been no design or material changes to the AXIOS Stent; it is identical to the AXIOS Stent cleared in K123250 and K140561. (b)(4)Proprietary Information

Where applicable, performance testing was conducted in accordance with the following standards:

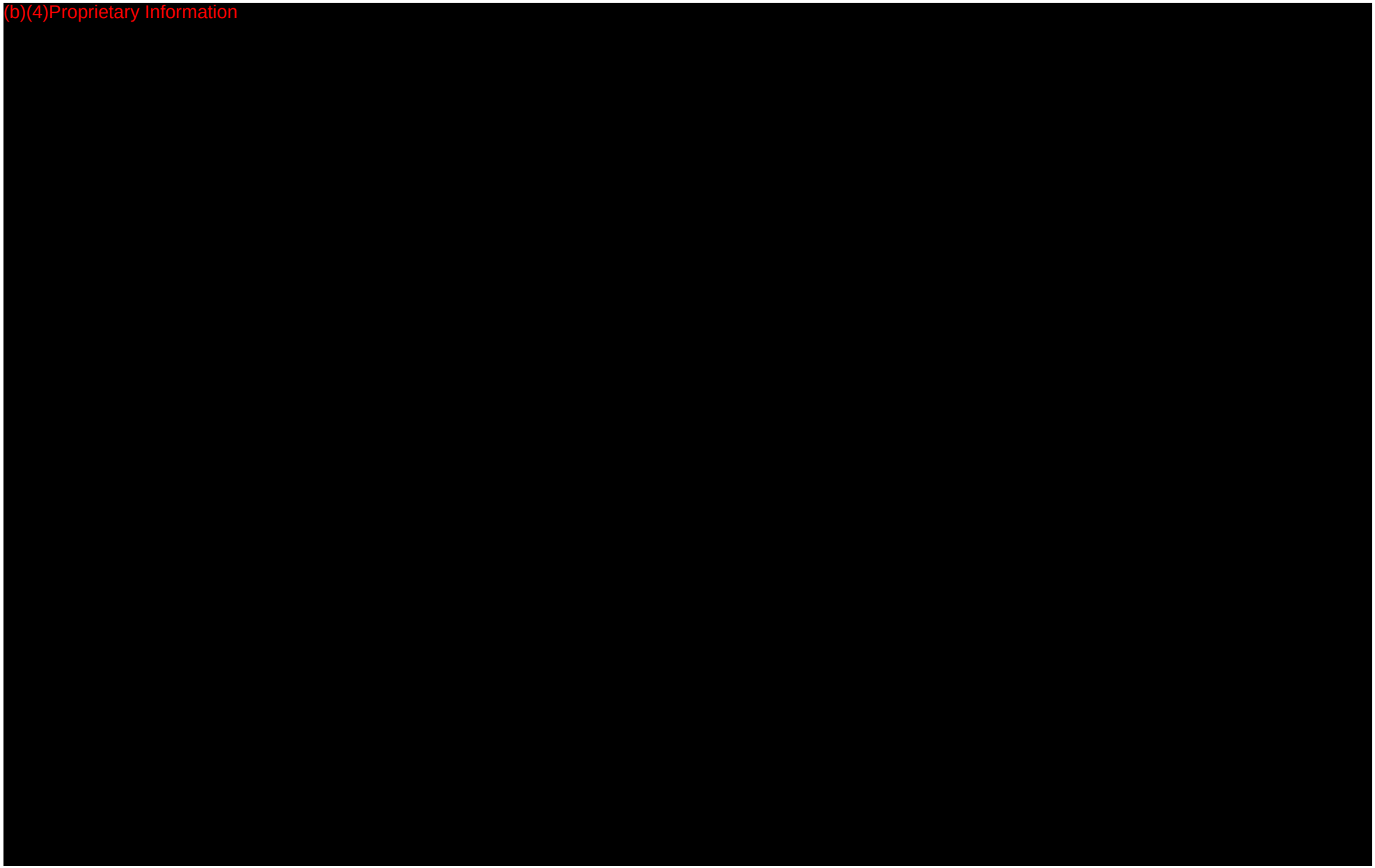
- ISO 10555-1:2013 - *Sterile, single-use intravascular catheters Part 1. General requirements*
- ISO 594-1:1986 - *Conical Fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 1 : General Requirements*

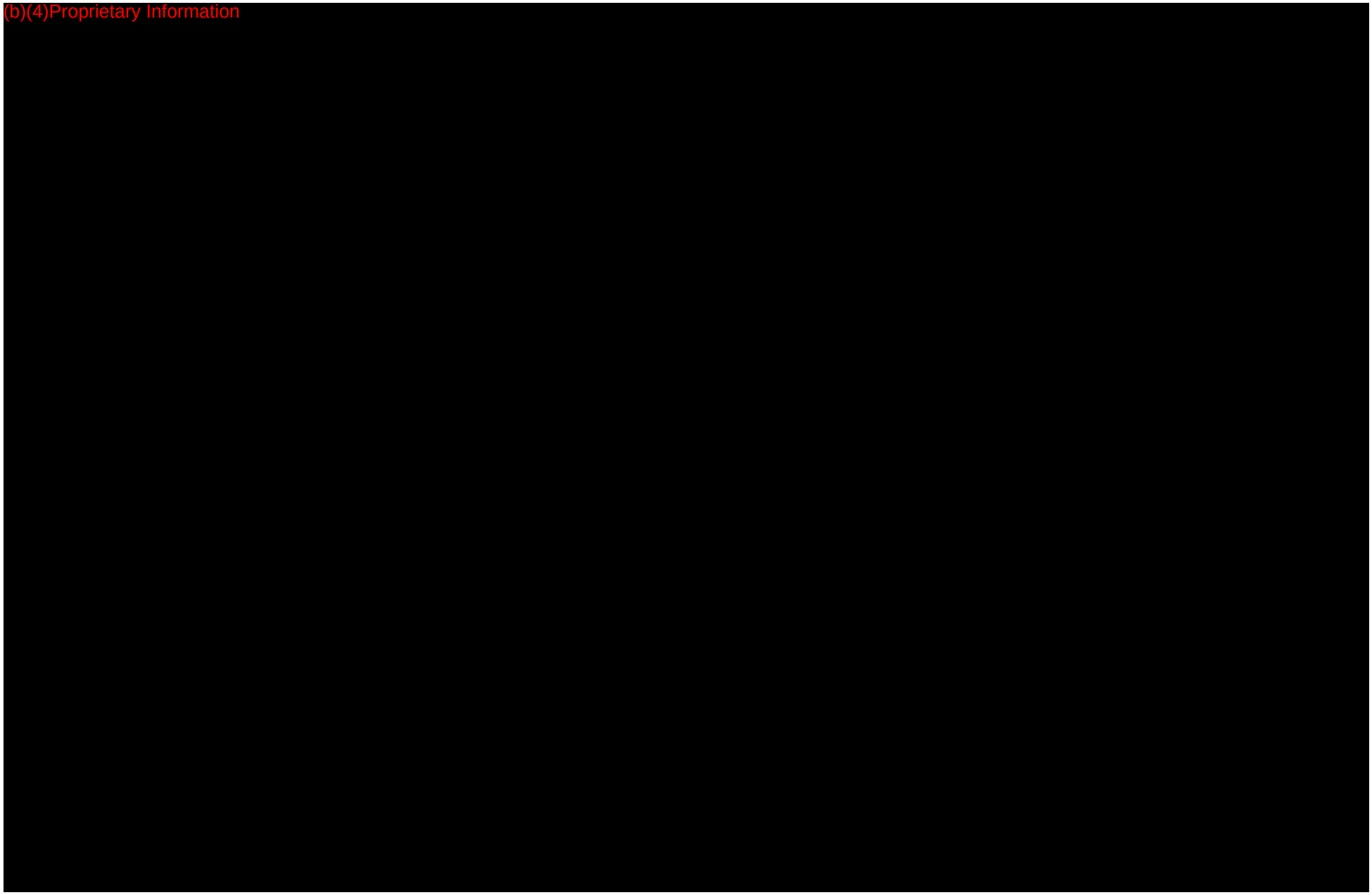
(b)(4)Proprietary Information

Table 20-1. Bench Performance Testing Documentation

Document		Document Number	Attachment
Hot AXIOS (b)(4)Proprietary	Design Verification Test Protocol	(b)(4)Proprietary Information	Attachment 28
Hot AXIOS (b)(4)Proprietary	Design Verification Test Report		Attachment 29
Hot AXIOS RF Safety Test Method			Attachment 30
AXIOS (b)(4)Proprietary Information	Test Method		Attachment 20
AXIOS Stent Deployment Test Method			Attachment 21
Hot AXIOS HOT AXIOS Delivery System (b)(4)P	Test Method		Attachment 22

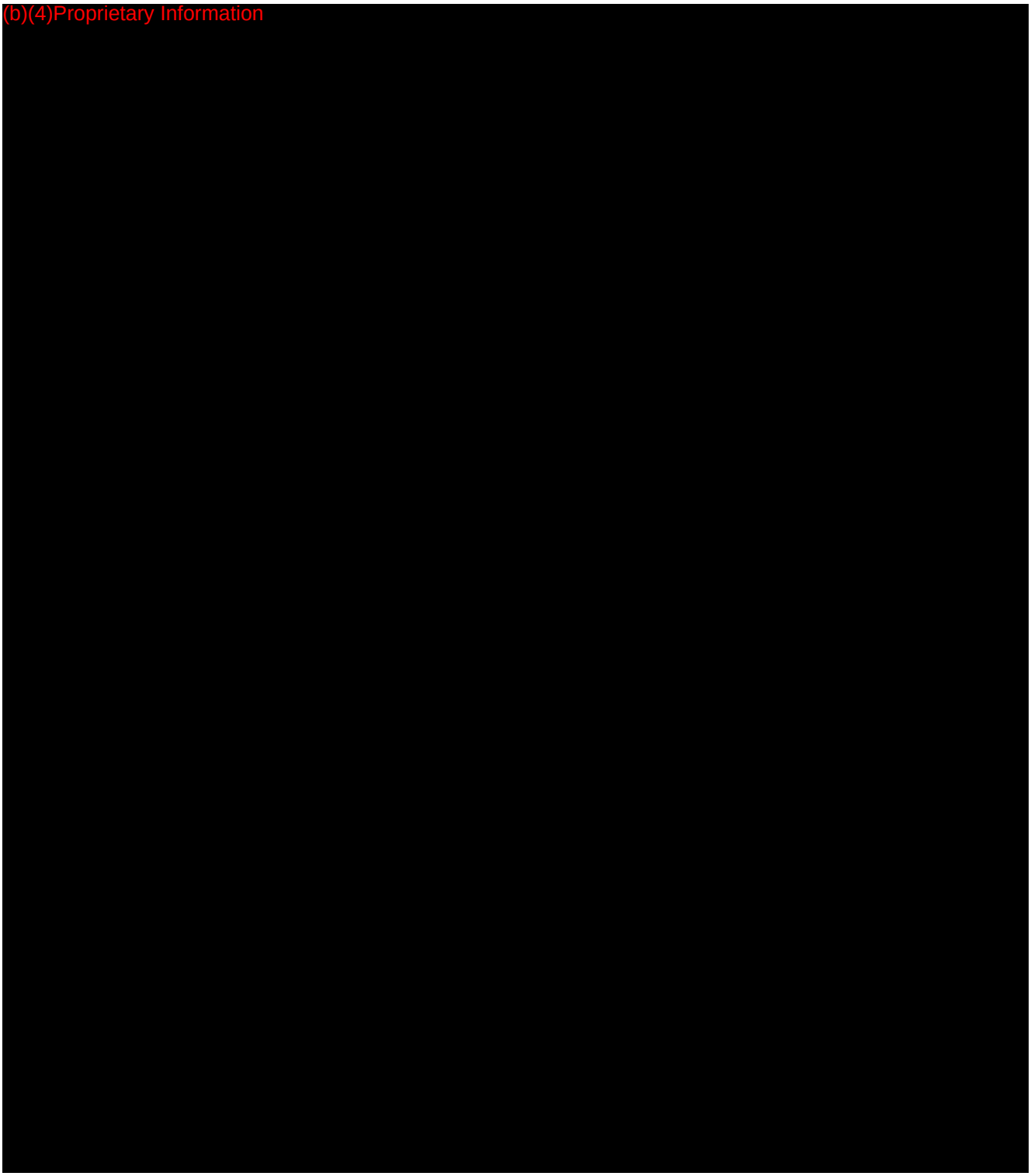
(b)(4)Proprietary Information



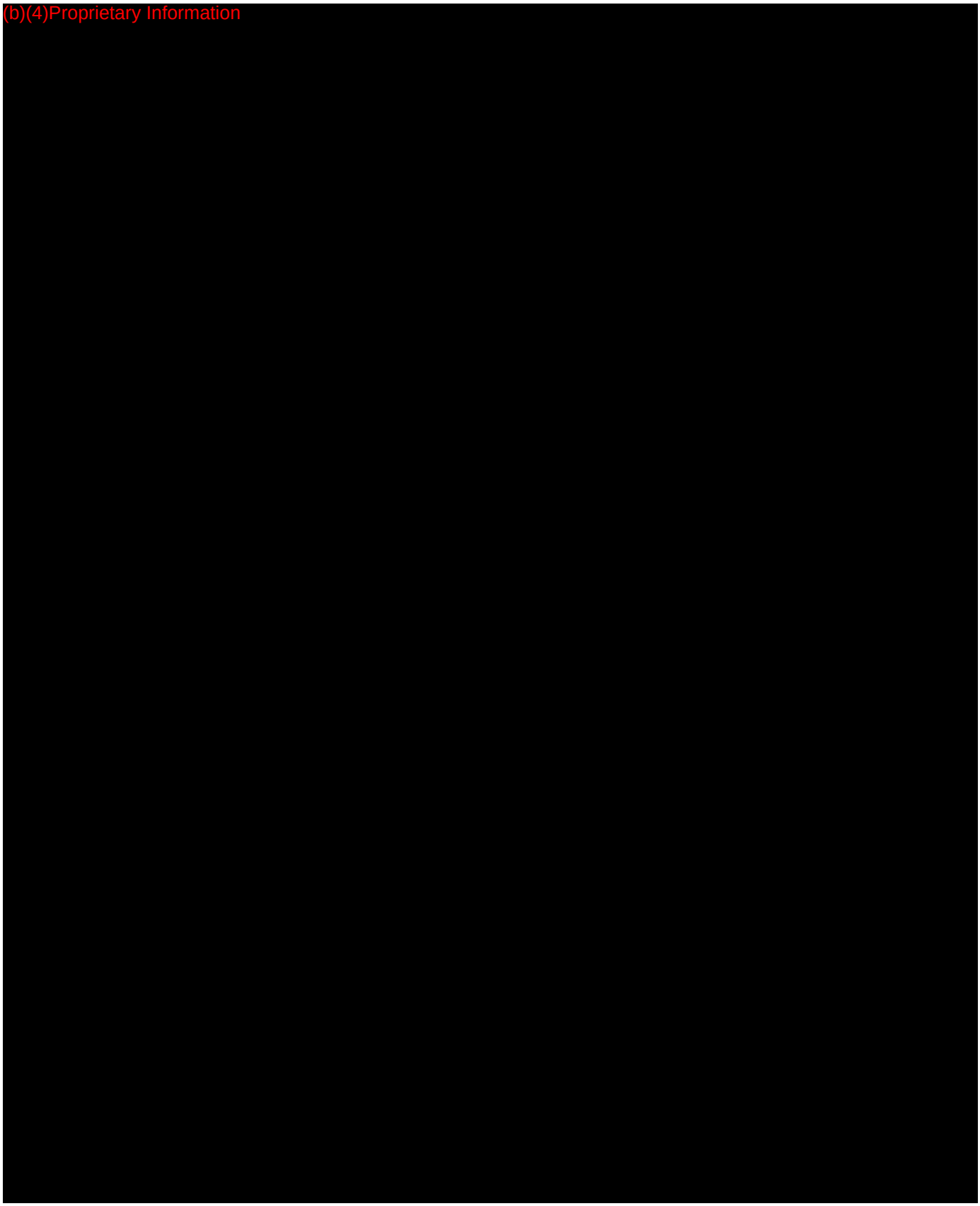


Design Verification Testing Summaries

(b)(4)Proprietary Information



(b)(4)Proprietary Information



(b)(4)Proprietary Information

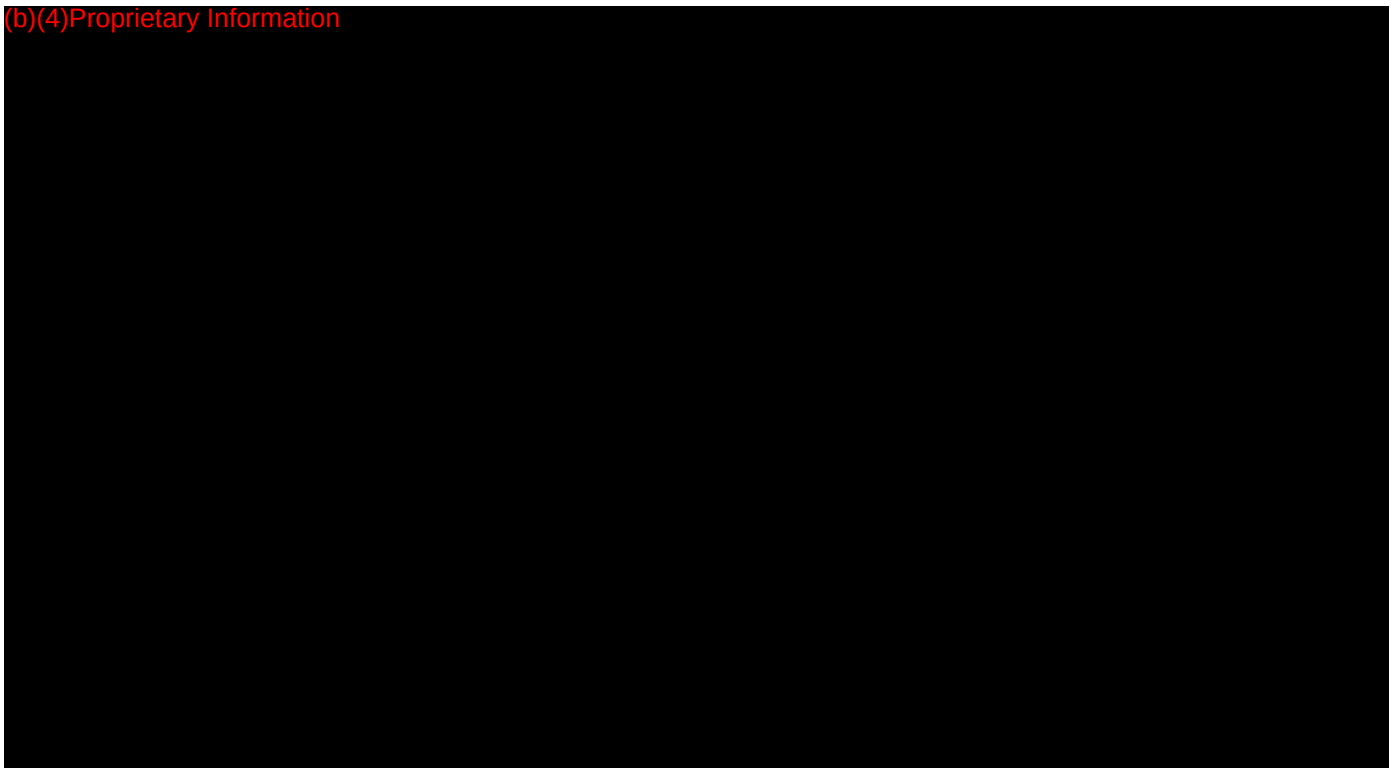
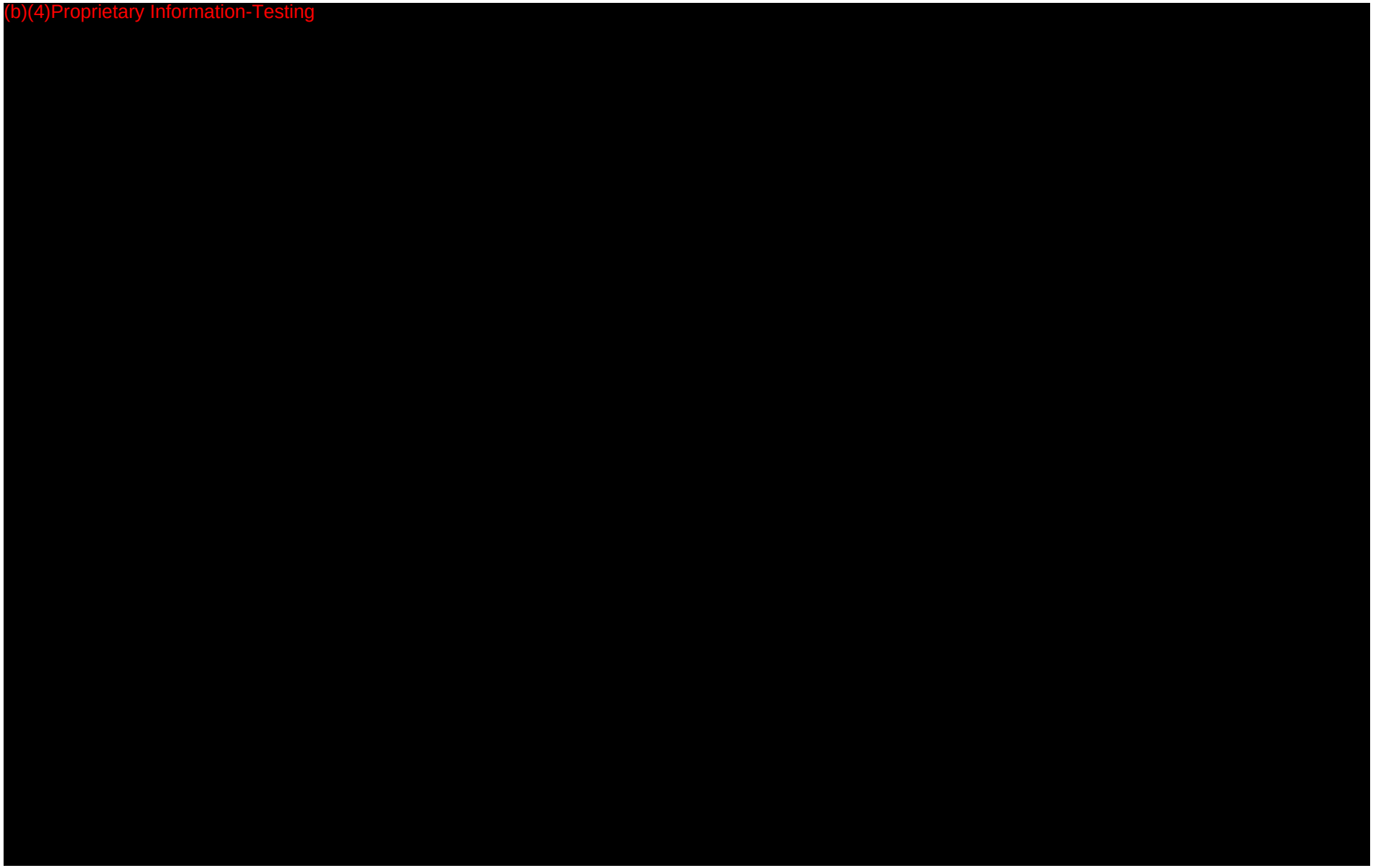
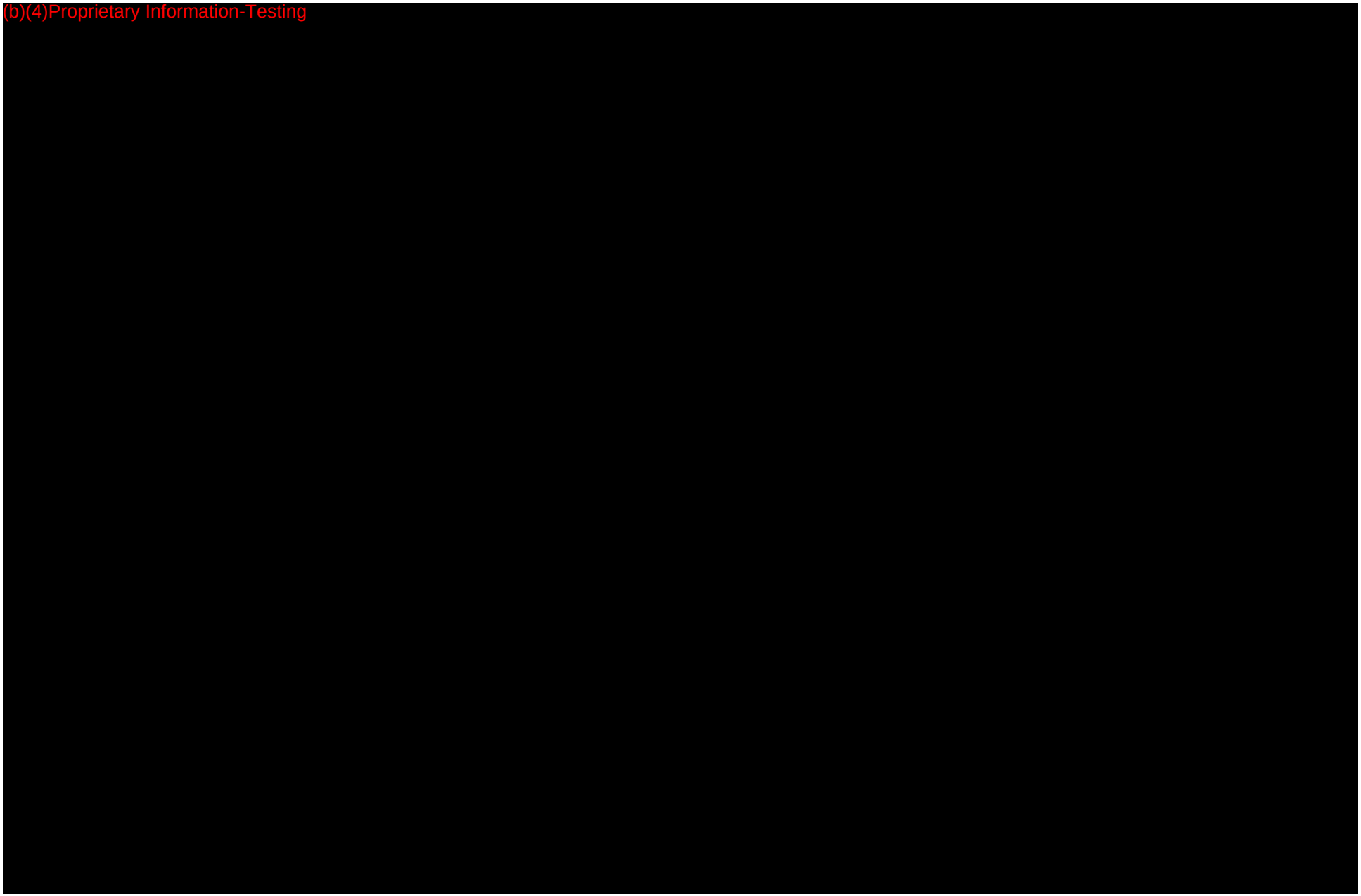
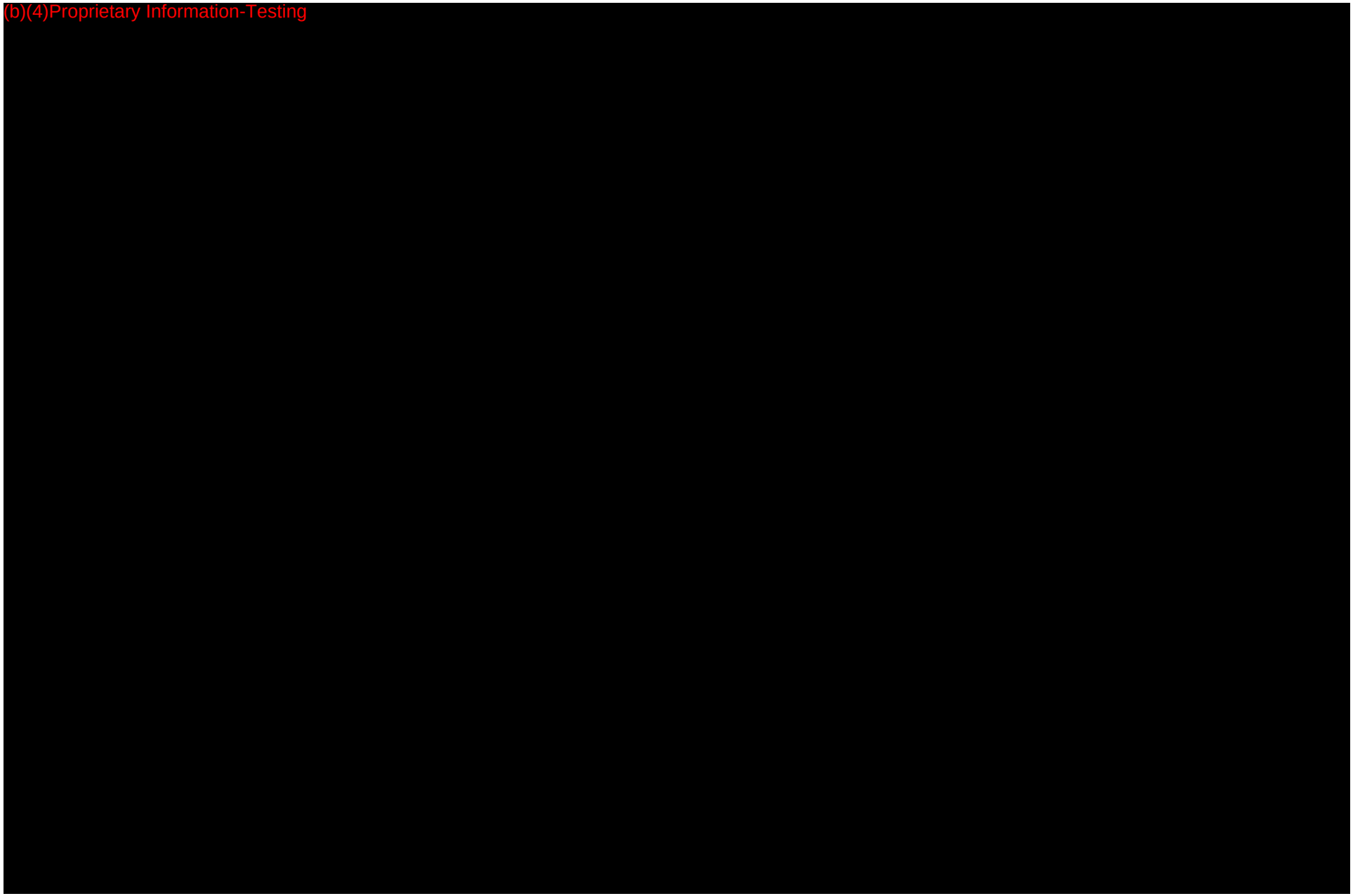


Table 20-4. Design Validation Test Results

(b)(4)Proprietary Information







(b)(4)Proprietary Information-Testing

[redacted]

Conclusion

Based on the results of the bench performance testing, the modified Electrocautery Enhanced Delivery Systems meets the product design specification and performance requirements for its proposed intended use.

B. AXIOS Ex-Vivo Tissue Study

1. Purpose / Objective

The purpose of this study was to measure the comparative thermal effects of the AXIOS Electrocautery Enhanced Delivery System (11F Hot AXIOS) vs. the 10F Cook Cystotome on porcine tissue. The test protocol and report (b)(4)Proprietary Information-Testing are provided in **Attachment 32** and **Attachment 33,** respectively.

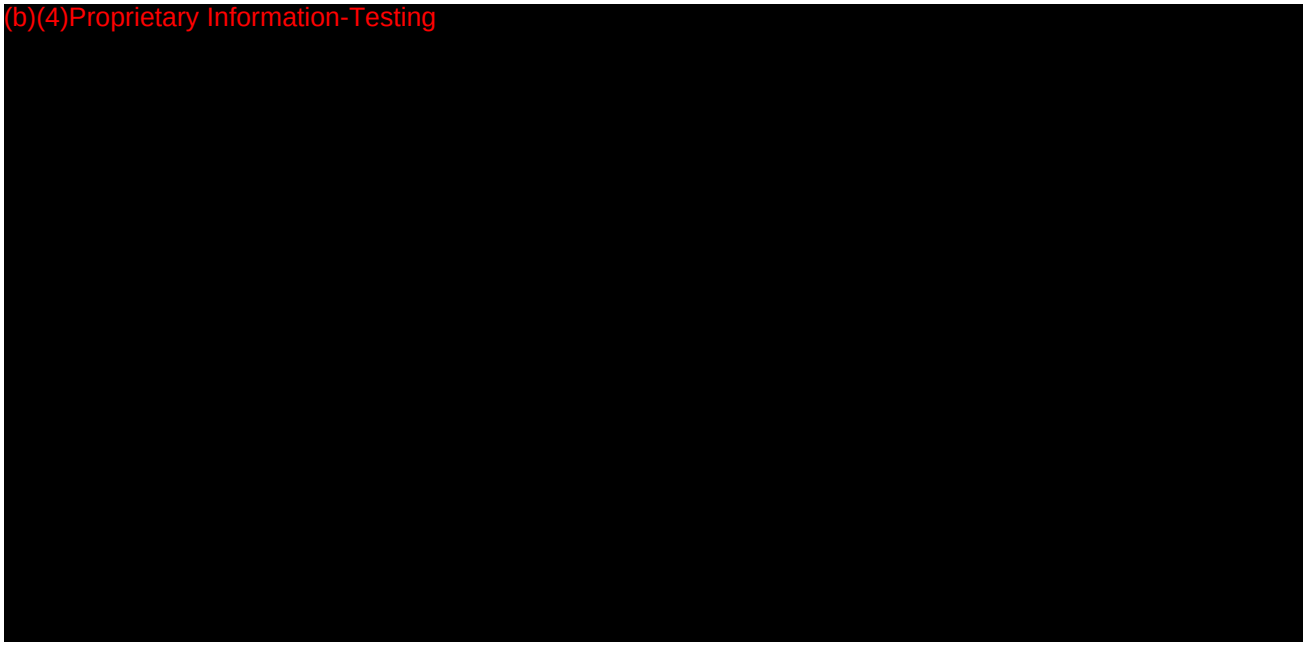
The AXIOS Electrocautery Enhanced Delivery System (Hot AXIOS Device) is designed to access anatomic targets using electrocautery followed by the staged and precise placement of the AXIOS stent. (b)(4)Proprietary Information-Testing [redacted] the AXIOS Electrocautery Enhanced Delivery System and the Cook Cystotome to assess the thermal effects of each device.

2. Study Design

(b)(4)Proprietary Information-Testing [redacted]

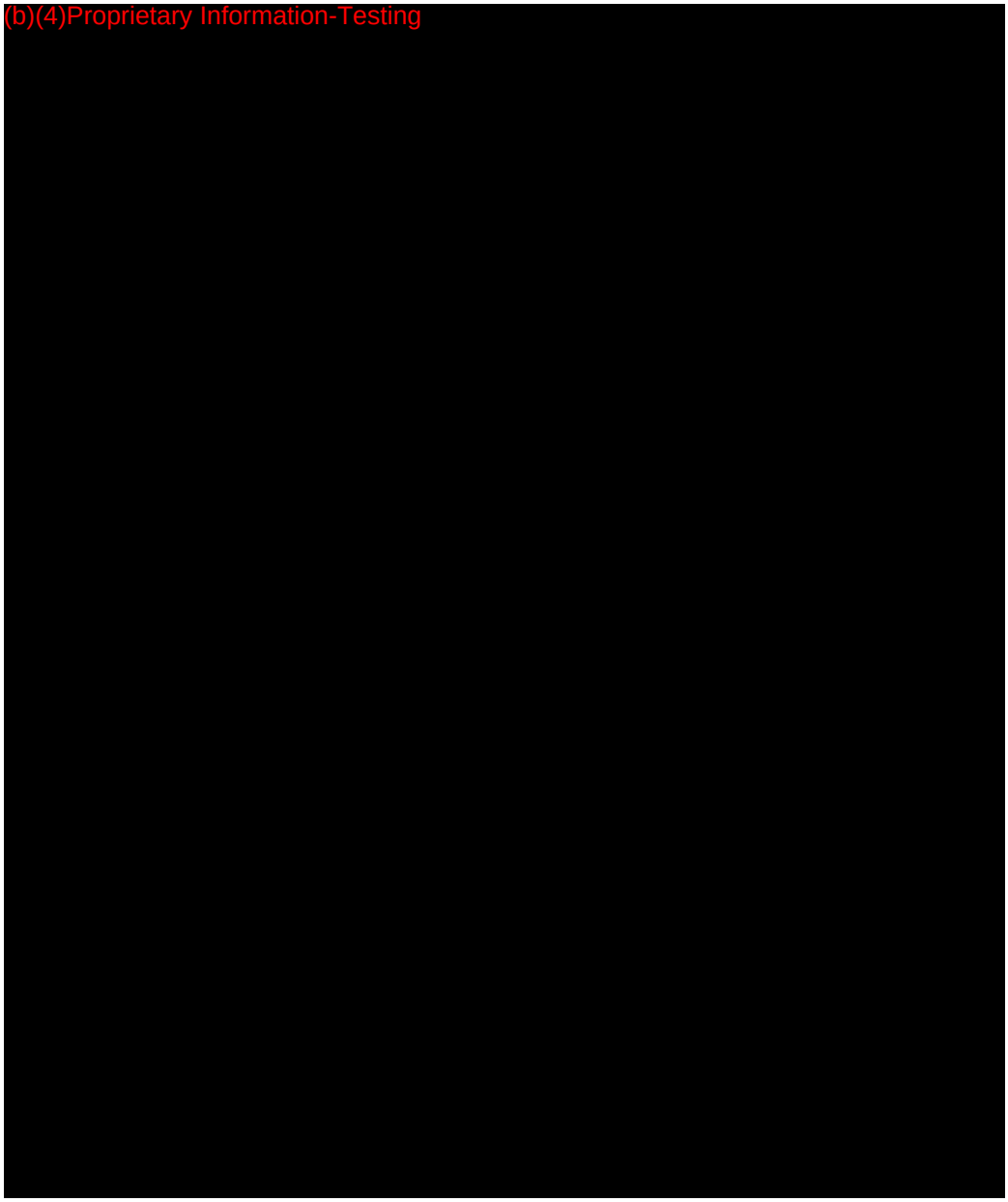
3. Acceptance Criteria

(b)(4)Proprietary Information-Testing



4. Results

The results of the testing are summarized below in **Table 20-5** and **Table 20-6**.



(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing, the Electrocautery Enhanced Delivery System caused statistically significant less thermal damage to the tissue as compared to the Cystotome. (b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing the Electrocautery Enhanced Delivery System caused statistically significant less thermal damage to the tissue as compared to the Cystotome. (b)(4)Proprietary Information

(b)(4)Proprietary Information-Testing

.

(b)(4)Proprietary Information-Testing

.

SECTION 21: PERFORMANCE TESTING - ANIMAL

Xlumena conducted an in vivo animal studies to evaluate the safety and performance of the AXIOS Stent with Electrocautery Enhanced Delivery System for endoscopic transenteric drainage of pancreatic pseudocysts. (b)(4)Proprietary Information-Testing [redacted]

In Vivo Animal Study Electrocautery Heat Effects and Healing Post Transluminal Drainage

A. Purpose / Objective

The purpose of the study was to evaluate the safety and effectiveness of the AXIOS Stent with Electrocautery Enhanced Delivery System (Hot AXIOS) during transmural endoscopic access and drainage of a simulated pancreatic pseudocyst and the biliary tract. This study evaluated the safety and performance of the AXIOS Stent with Electrocautery Enhanced Delivery System when performing a simulated endoscopic drainage procedure in a porcine model using the 06x08mm and 20x10mm stent models.

Cautery access and stent deployment using the AXIOS Stent with Electrocautery Enhanced Delivery System were compared to standard techniques as represented by access with the commercially available Cystotome (Cook Medical, Limerick Ireland) and the placement of an 20-10mm Stent with Electrocautery Enhanced Delivery System (i.e., Electrocautery Enhanced Delivery System was not energized). A direct comparison of tissue heat affects and healing were evaluated post cautery access and AXIOS Stent placement. Effectiveness of the Electrocautery Enhanced Delivery System to access the target anatomy and deliver the AXIOS stent (device performance) was also assessed.

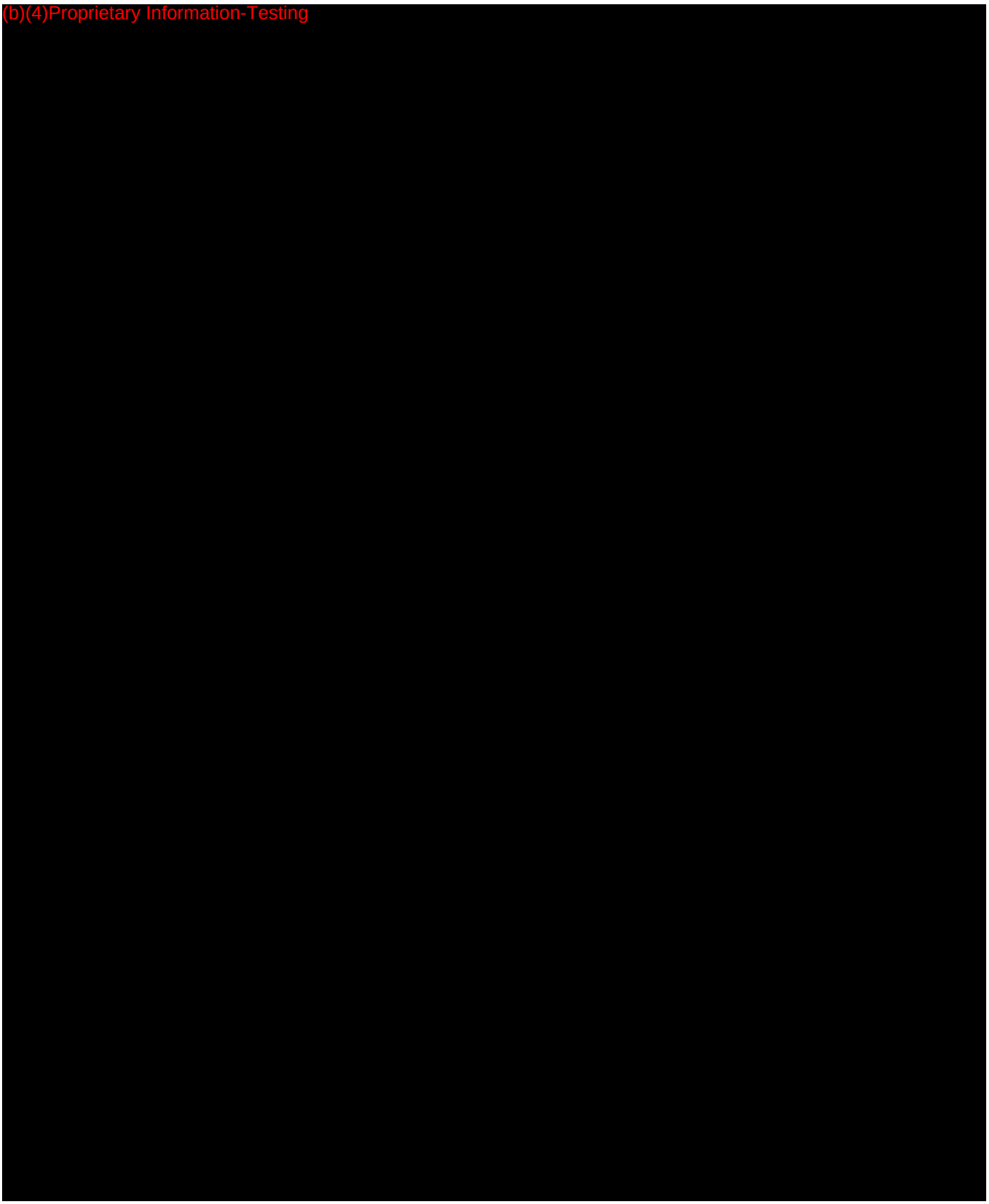
The study animals were survived for one (1) month after stent implantation followed by stent removal. Study animals were survived another 7 days after stent removal for histopathological evaluation. Histological evaluation of the heat affects and healing of the implant site was performed.

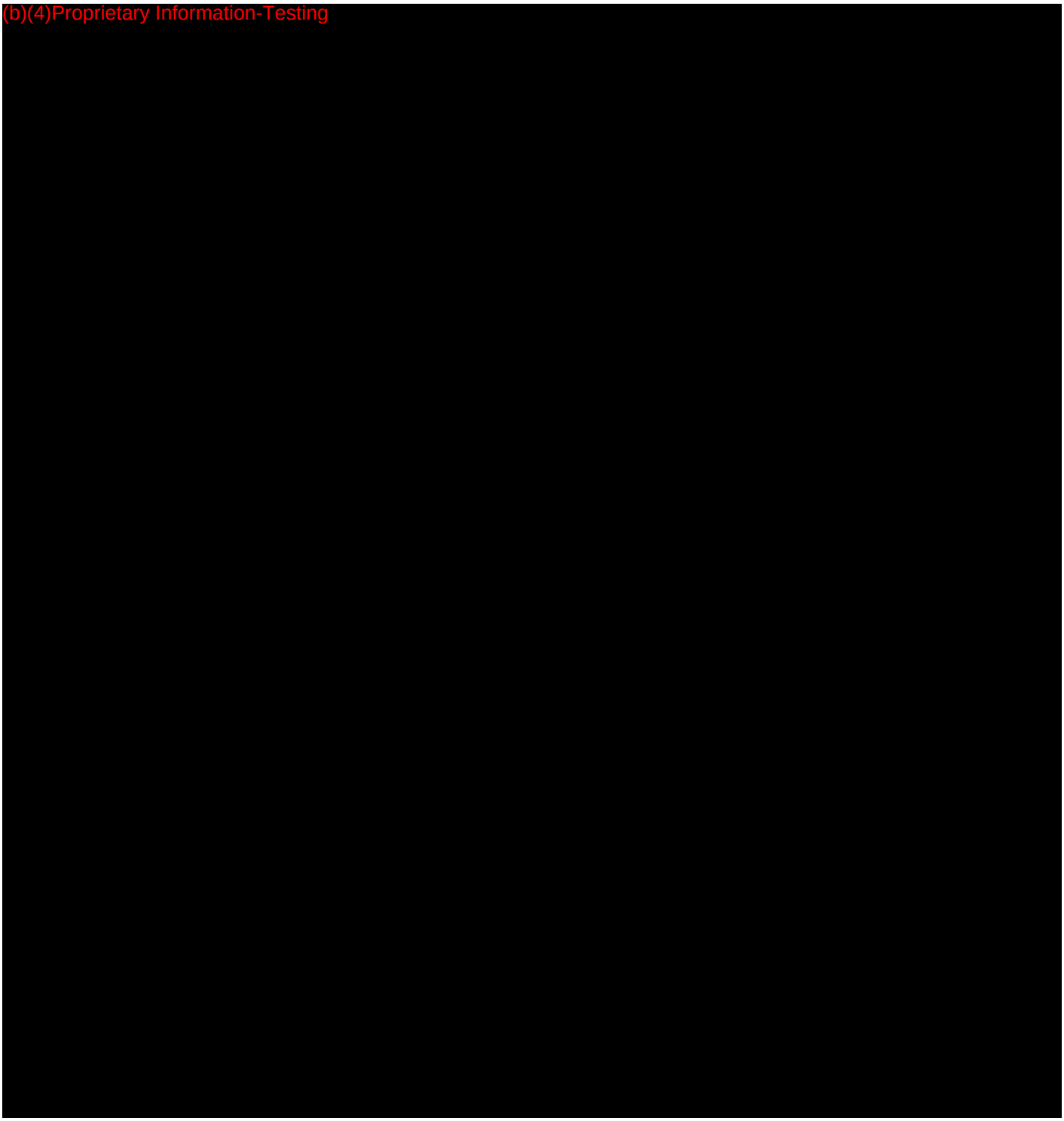
The study protocol and report (b)(4)Proprietary Information-Testing are provided in **Attachment 34** and **Attachment 35**, respectively.

B. Study Endpoints

(b)(4)Proprietary Information-Testing [redacted]

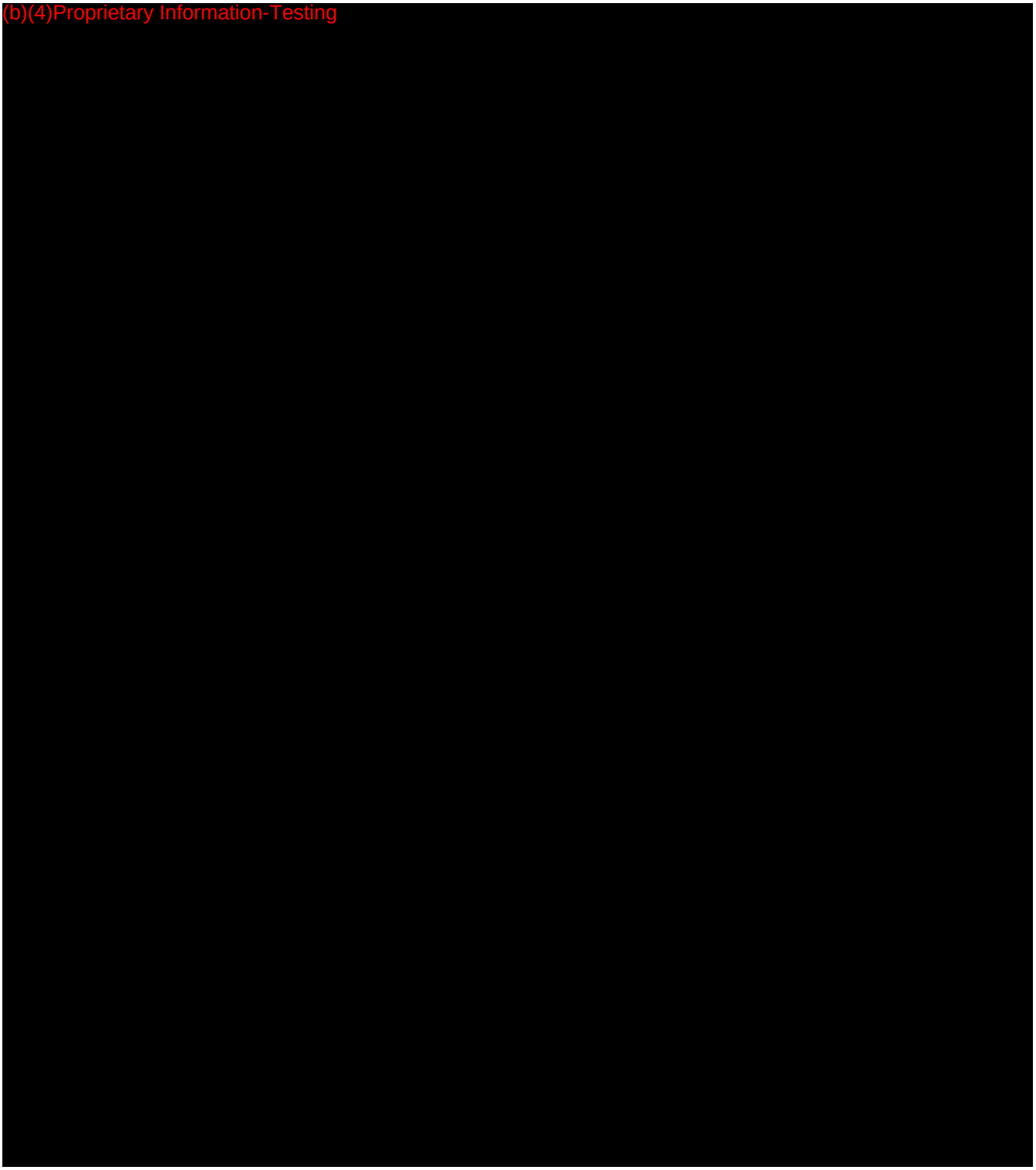
(b)(4)Proprietary Information-Testing

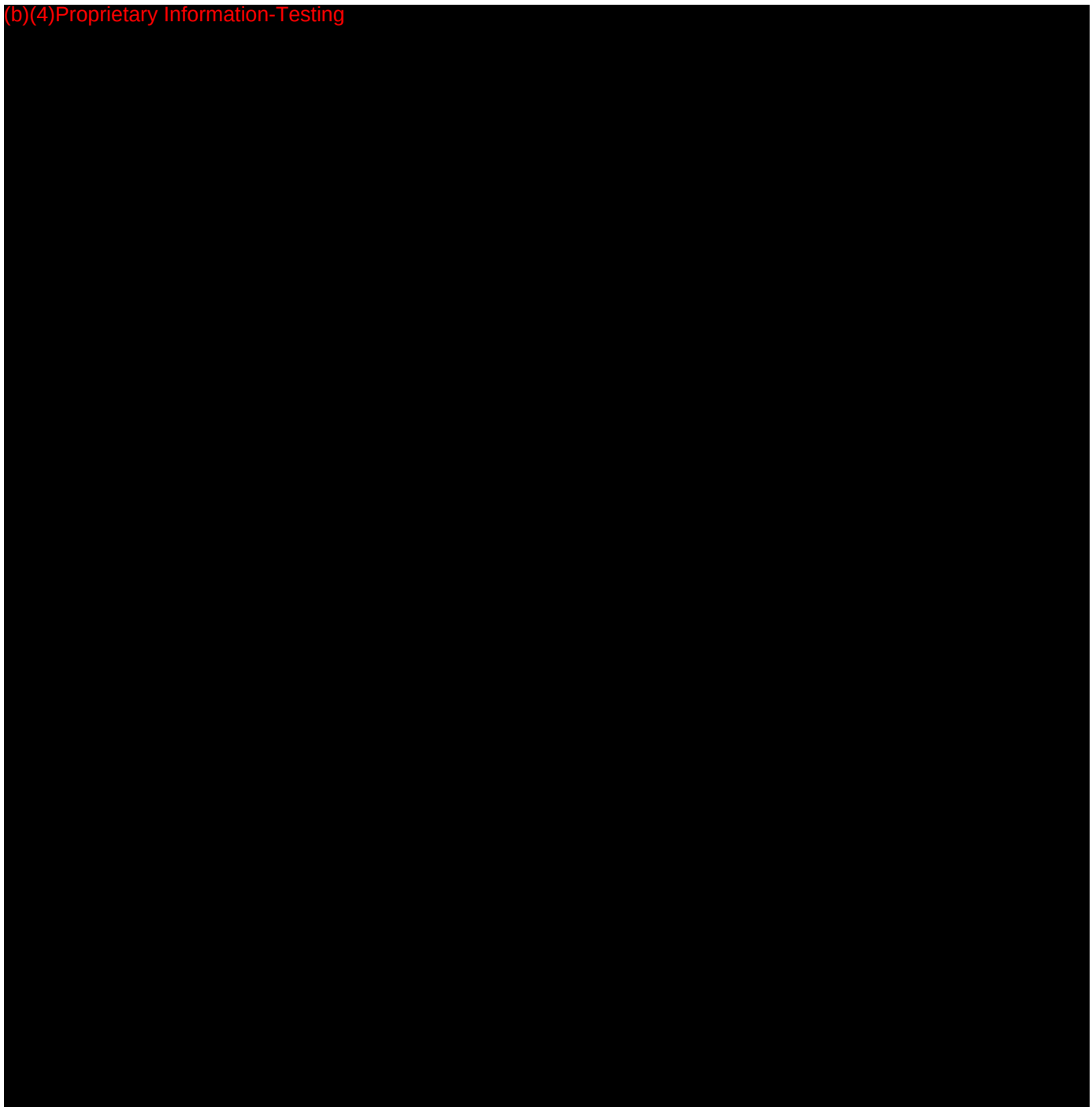




[7] Desai RK, Tagliabue JR, Wegryn SA, Einstein DM. CT evaluation of wall thickening in the the alimentary tract. Radiographics 1991;11:771-783.

[8] Soft Tissue Damage And Healing. http://www.iaaf.org/download/download?filename=abc15012-7233-41f3-9ff2-2480dd2ebdd1.pdf&urlslug=Chapter%209%3A%20Soft%20tissue%20damage%20and%20healing.



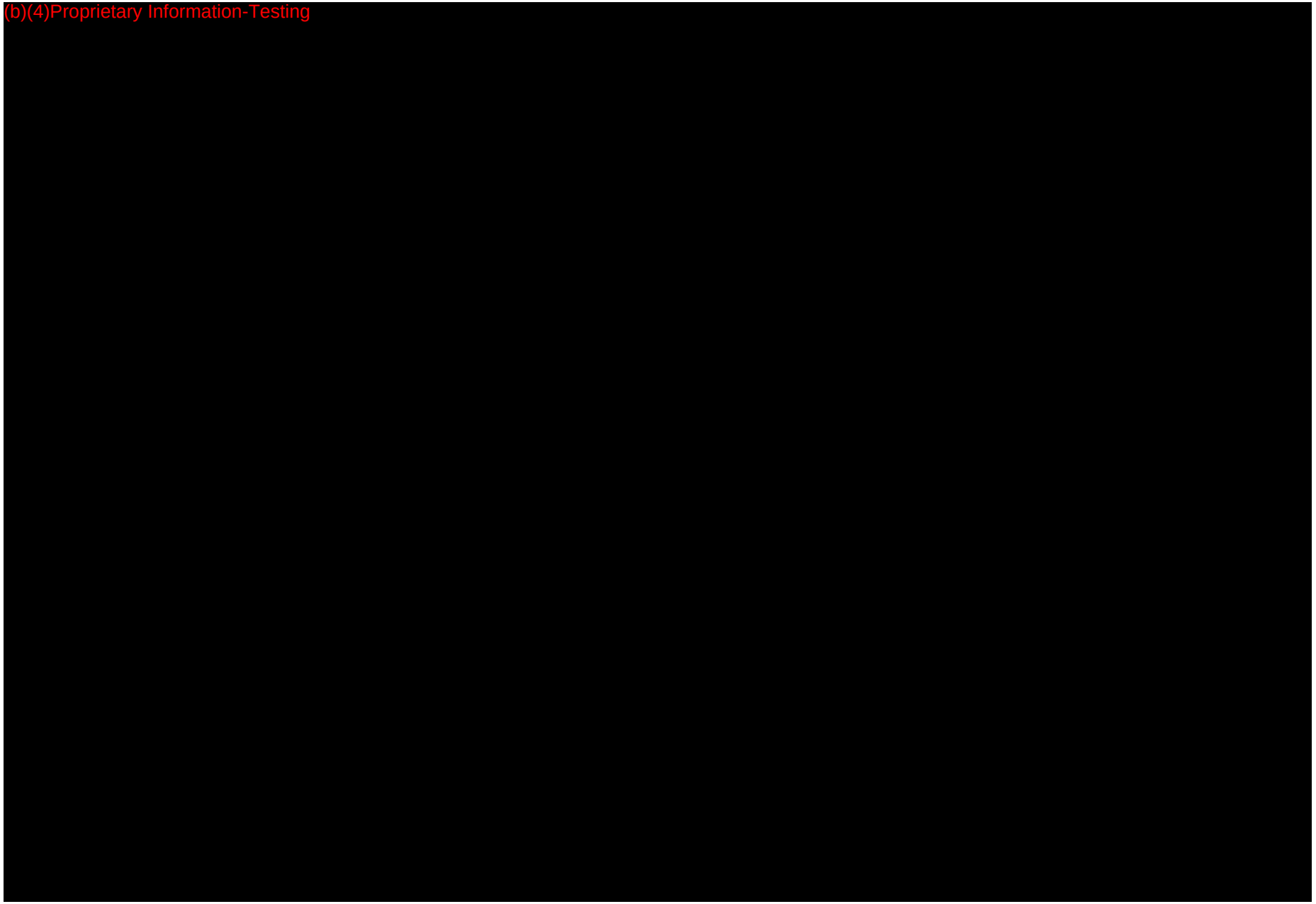


(b)(4)Proprietary Information-Testing

E. Results

(b)(4)Proprietary Information-Testing

The test results are summarized in **Table 21-2**.



(b)(4)Proprietary Information-Testing

1. Cautery Site Condition after 30 Days

(b)(4)Proprietary Information. All tissue appeared normal at 30 days post-cautery.

2. Stent Retention (Patency and Removal) after 30 Days

(b)(4)Proprietary Information All stents were patent and remained in place throughout the duration of the study. Tissue appeared normal throughout the study. (b)(4)Proprietary Information

3. Device Effectiveness

(b)(4)Proprietary Information

4. Device Safety

(b)(4)Proprietary Information

- (b)(4)Proprietary Information

[redacted]

(b)(4)Proprietary Information

[redacted]

G. Conclusions

In (b)(4)Prop animals, access using cautery was successfully achieved and stents were successfully deployed in all five animals. None of the stents migrated from the original position and all stents remained patent during the implant period (1 month). The tissue surrounding the stent implant sites was healthy in all animals.

(b)(4)Proprietary Information

[redacted]

This study demonstrated that the AXIOS Stent with Electrocautery Enhanced Delivery System performed as intended and did not raise any new issues of safety or performance.

SECTION 22: PERFORMANCE TESTING - CLINICAL

A. Summary of Clinical Investigation

Xlumena conducted a prospective multi-center, single-arm clinical study under IDE G130264 to demonstrate the safety and effectiveness of the AXIOS Stent with Electrocautery Enhanced Delivery System for endoscopic transenteric drainage of pancreatic pseudocysts. The AXIOS Stent with Electrocautery Enhanced Delivery System is intended for the endoscopic ultrasonography (EUS) guided creation of an internal drainage conduit between the pancreatic pseudocyst and the stomach or duodenum. The AXIOS Electrocautery Enhanced Delivery System is designed to facilitate the creation of the access tract using electrosurgery while minimizing device exchanges for pseudocyst access. The design and manufacturing of AXIOS Stent remains unchanged.

(b)(4)Proprietary Information

The Clinical Protocol and Report are provided in **Attachment 36** and **Attachment 37**, respectively.

B. Purpose / Objective

To demonstrate the safety and effectiveness of the AXIOS Stent with Electrocautery Enhanced Delivery System in the (b)(4)Proprietary Information for endoscopic drainage (b pancreatic pseudocysts (b)(4)Proprietary Information

C. Study Endpoints

Effectiveness Endpoints

(b)(4)Proprietary Information

(b)(4)Proprietary Information

Safety Endpoints

(b)(4)Proprietary Information

D. Study Design

The clinical evaluation of the AXIOS Stent with Electrocautery Enhanced Delivery System is a prospective, multi-center, (b)(4)Proprietary ngle-arm (b)(4)Proprietary) study (b)(4)Proprietary (b)(4)Proprietary Information No interim analysis was performed.

E. Patient Population and Selection Criteria

(b)(4)Proprietary Information

(b)(4)Proprietary Information

F. Study Procedures

(b)(4)Proprietary Information

(b)(4)Proprietary Information

G. Clinical Investigation Results

1. Study Investigators and Patient Enrollment

The AXIOS Stent with Electrocautery Enhanced Delivery System was evaluated in a prospective, multi-center, (b) , single-arm (b)(4)Proprietary study (b)(4)Proprietary Information

Table 22-2. Summary of Study Investigators and Patient Enrollment

Site #	Site	Investigator(s)	Enrolled Subjects (N)
(b)(4)Proprietary Information			

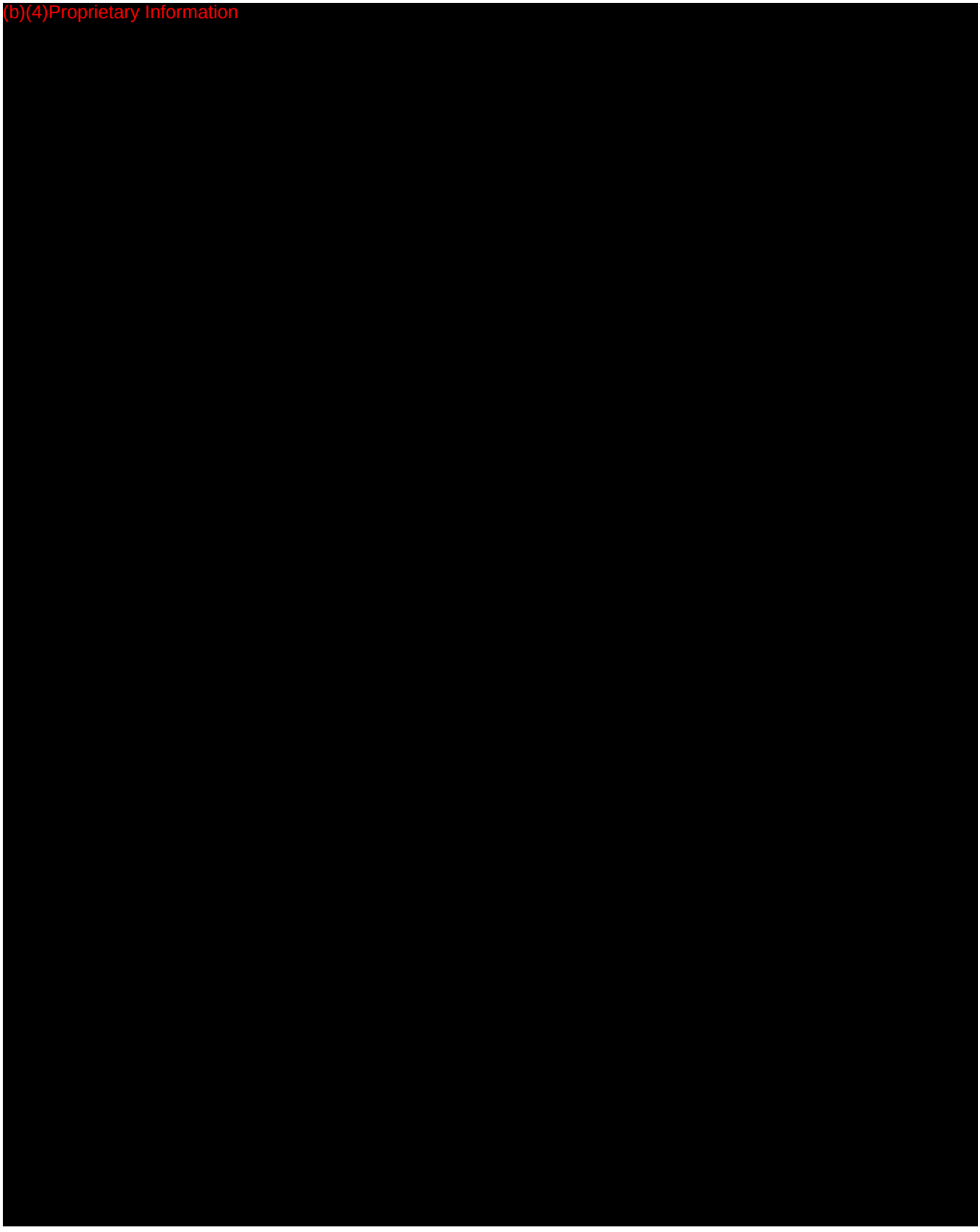
2. **Subject Accountability**

(b)(4)Proprietary Information

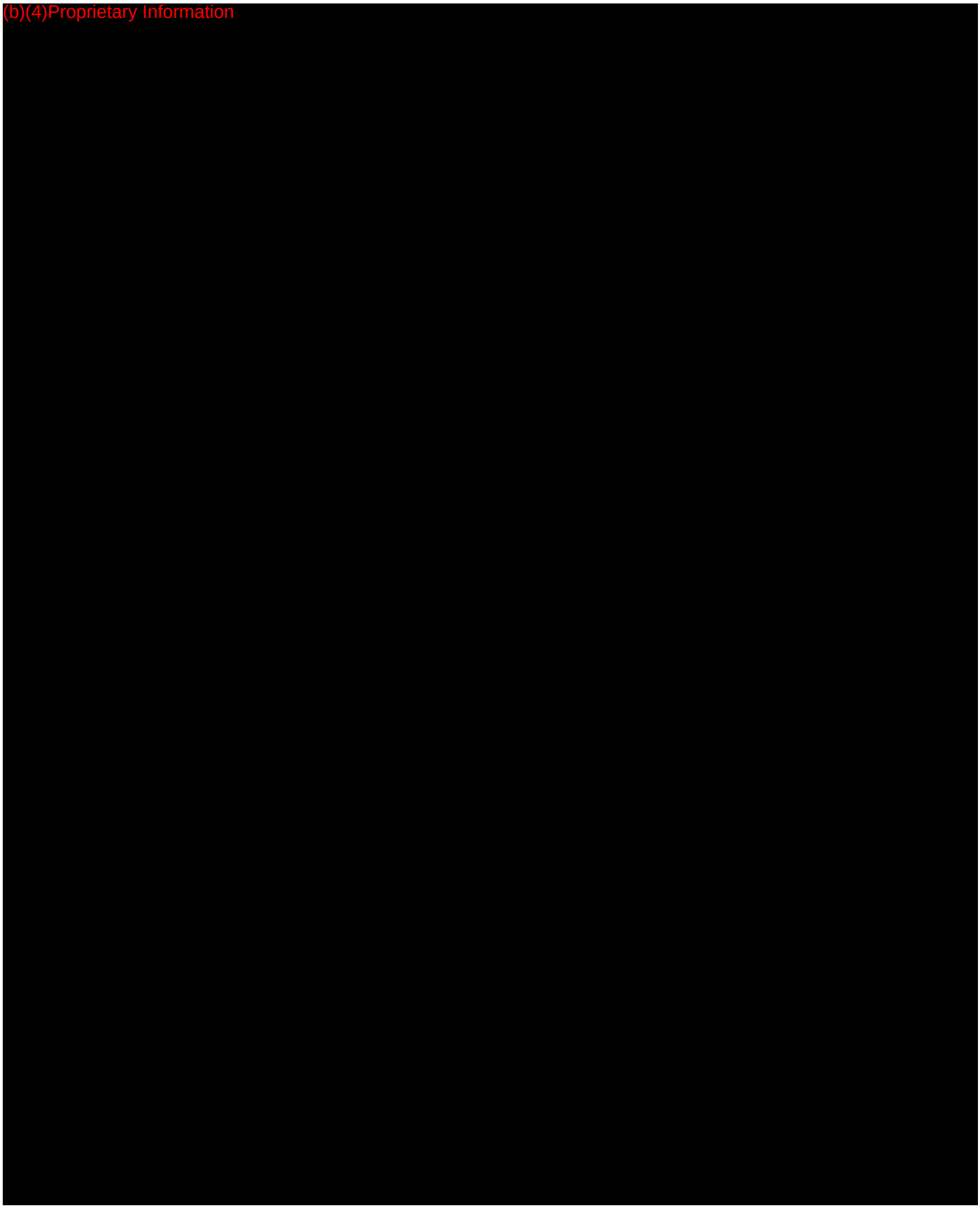
3. **Patient Demographics and Procedural Characteristics**

(b)(4)Proprietary Information

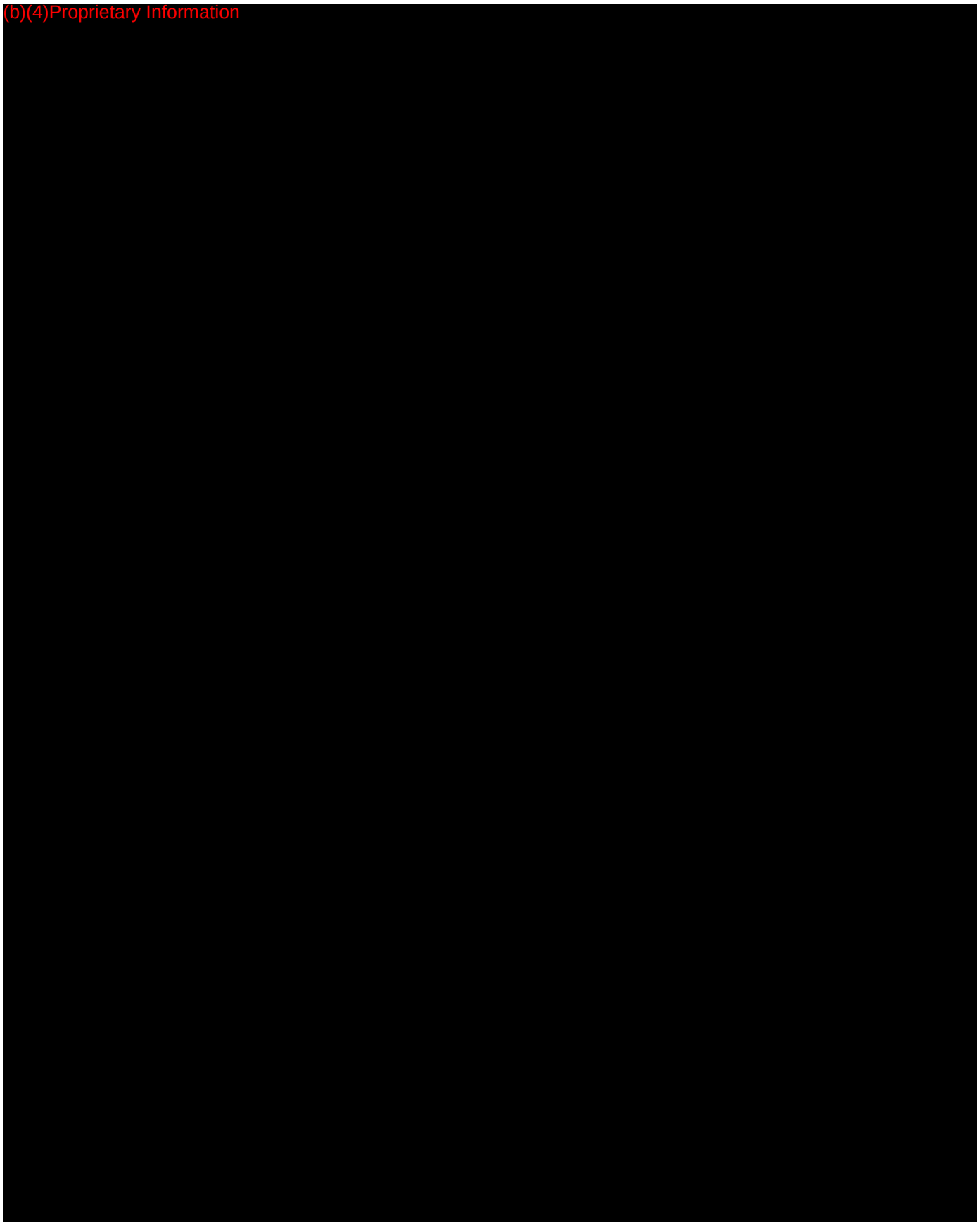
(b)(4)Proprietary Information



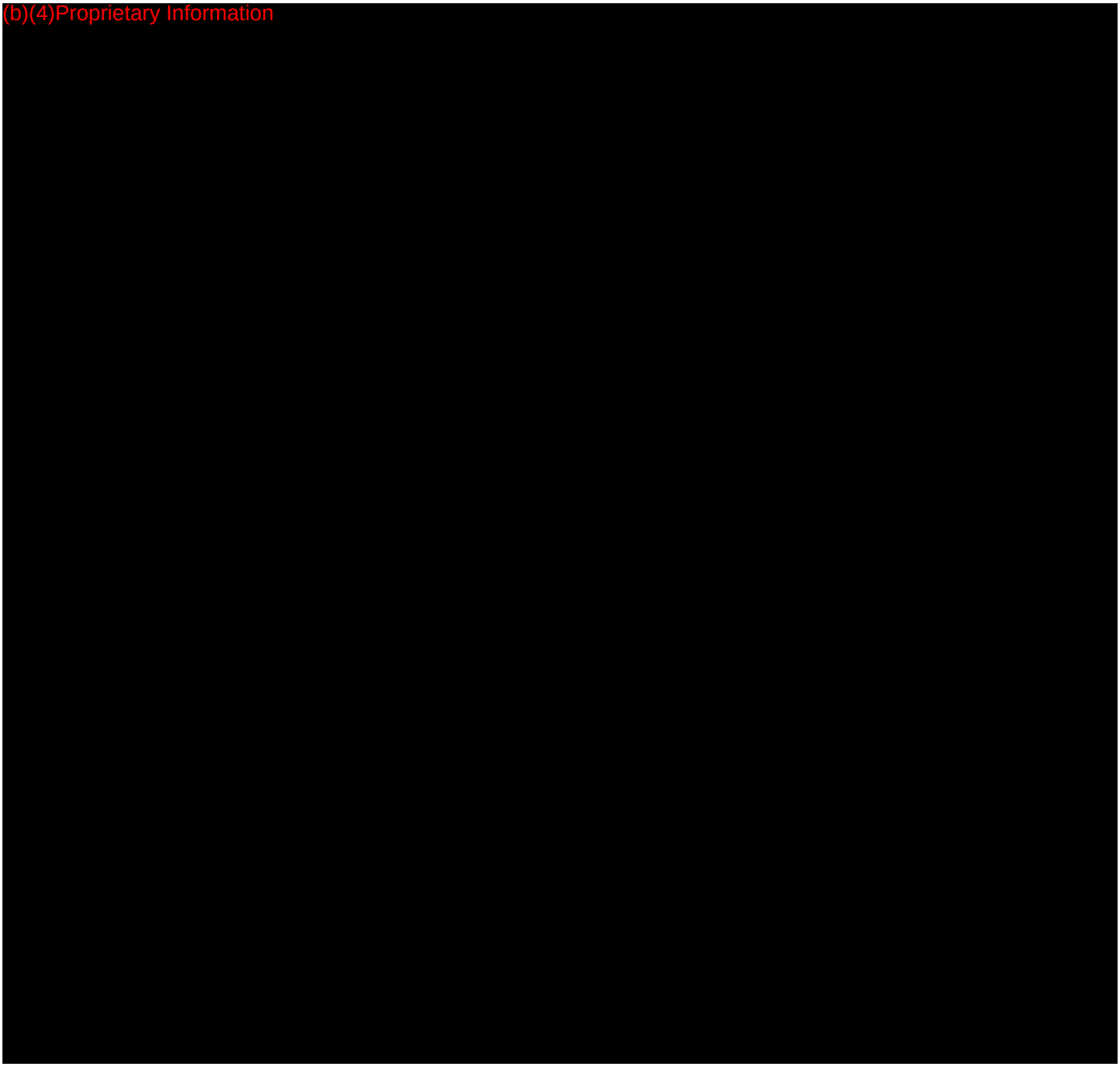
(b)(4)Proprietary Information



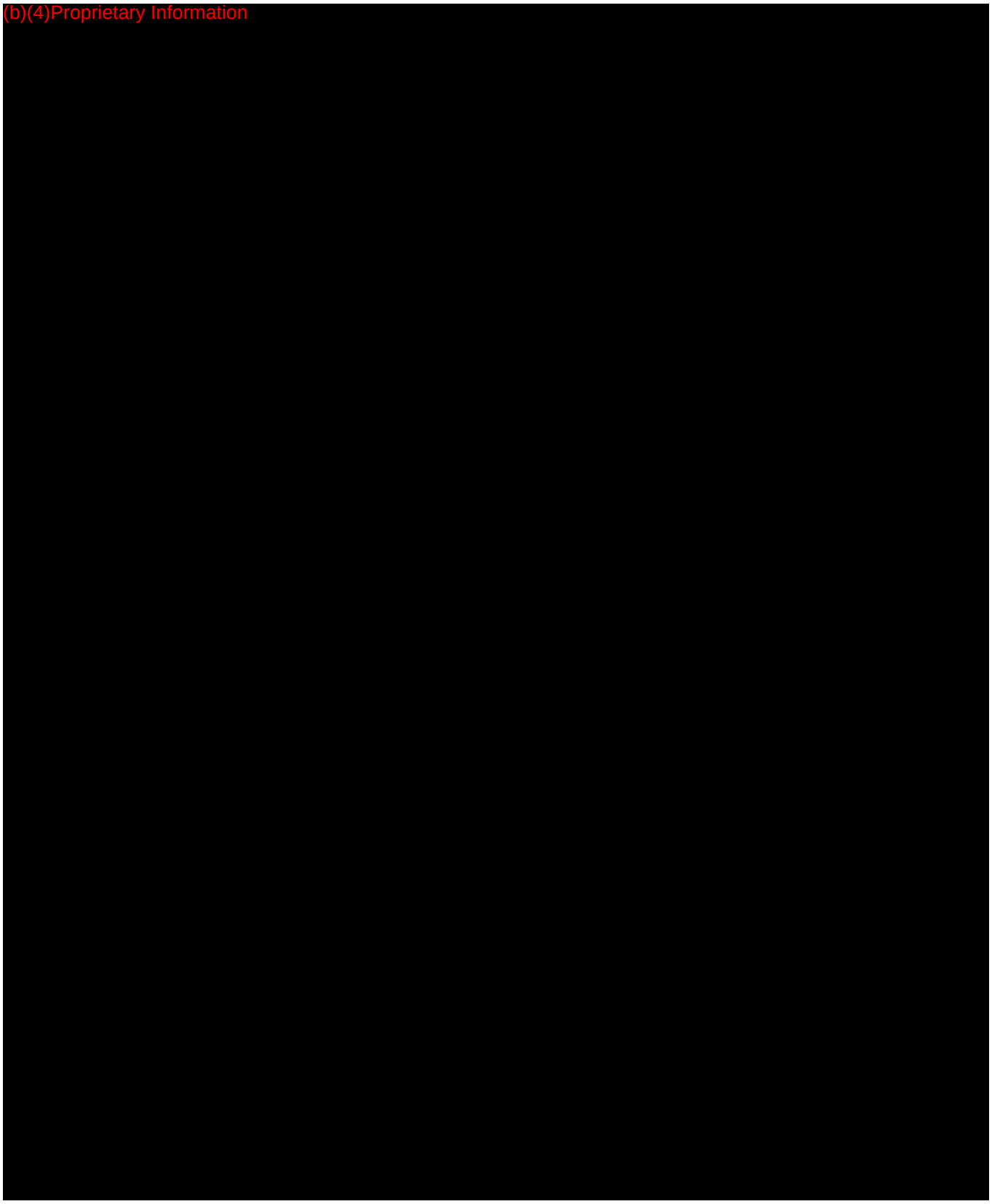
(b)(4)Proprietary Information



(b)(4)Proprietary Information



(b)(4)Proprietary Information



(b)(4)Proprietary Information

[redacted]

The data presented supports the ability to effectively drain pancreatic pseudocysts with the AXIOS stent. (b)(4)Proprietary Information [redacted]

In subjects treated PP, 100% of AXIOS devices remained in position at 30 or 60 days, and 81.1% of stent lumens remained patent at 30 days and 100% at 60 days. The AXIOS stent was successfully implanted in all study subjects (100%). Successful removal of the AXIOS stent was achieved in all subjects (100%) in which endoscopic removal PP was attempted. Overall, clinical success was achieved in 83.3% of subjects.

(b)(4)Proprietary Information

[redacted]

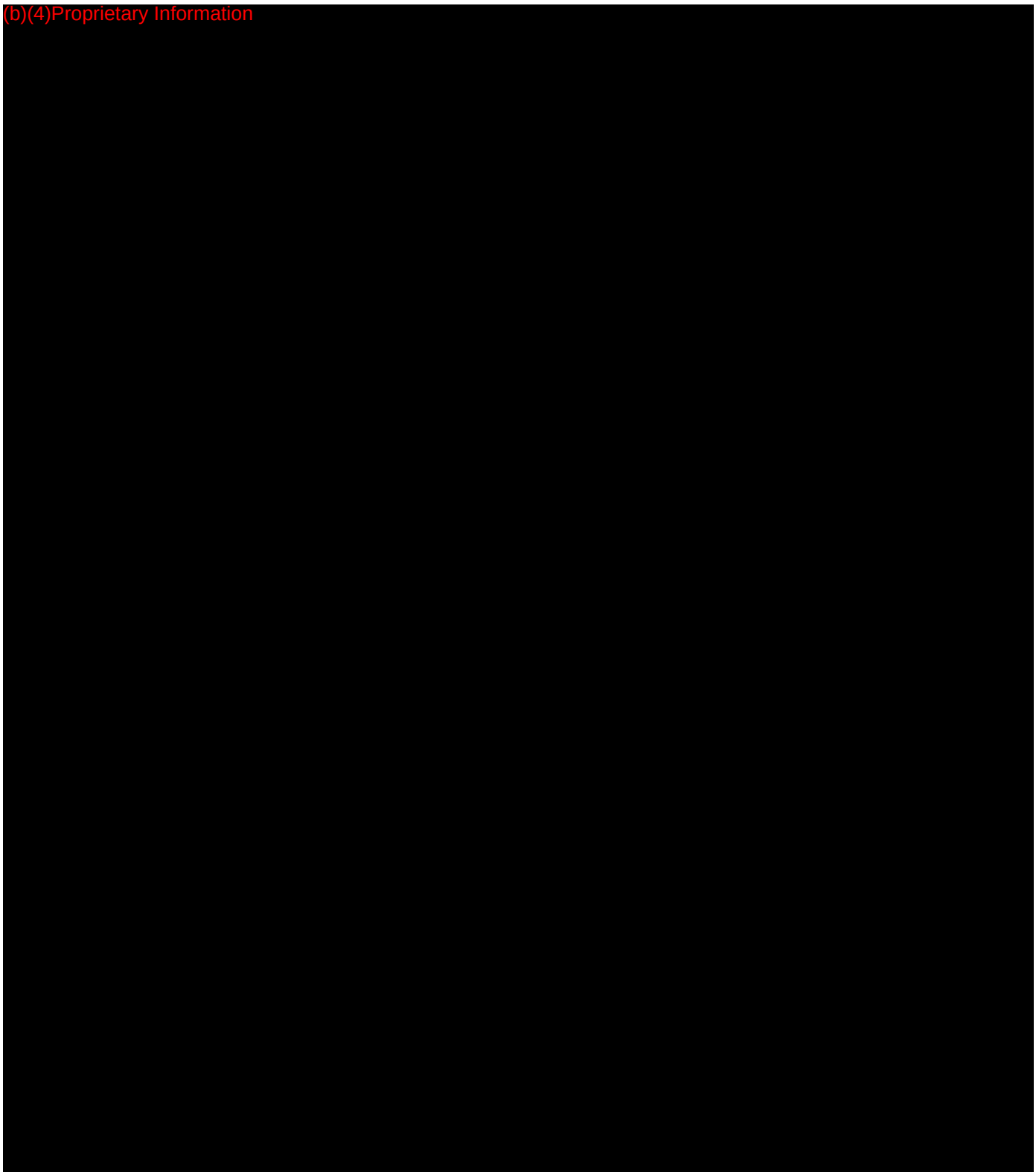
(b)(4)Proprietary Information

Study results demonstrated that there were no unanticipated events related to the use of the device. Ninety percent (90%) of subjects were free from major complications. Ninety-three percent (93.3%) of subjects experienced no serious adverse events related to the device or index procedure. Serious adverse events deemed related to the AXIOS device or the index procedure was the same type of events as those generally associated with endoscopic pancreatic pseudocyst drainage with commercially available stents and delivery systems. Additional details are provided in the Study Report **Attachment 37**.

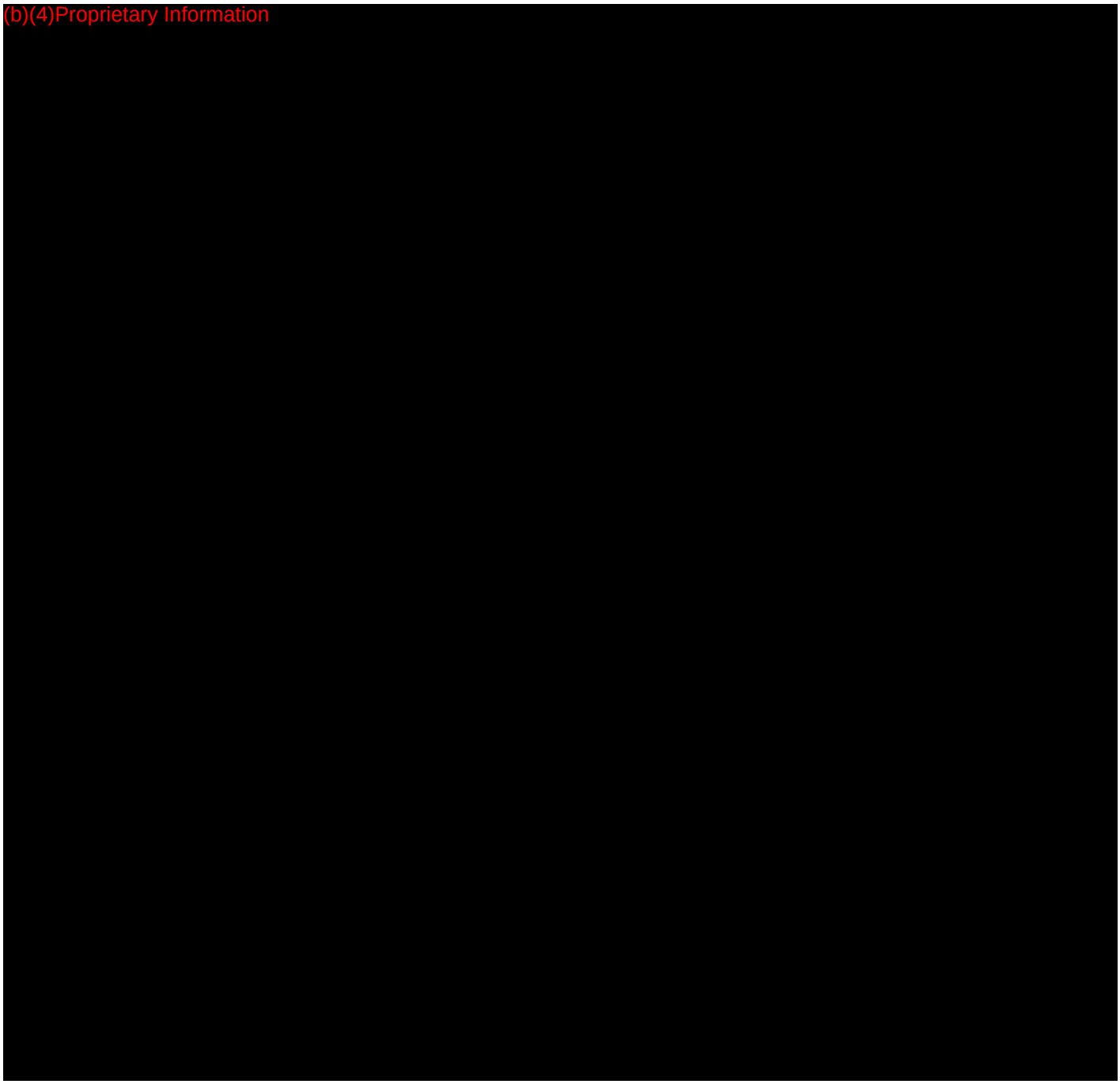
(b)(4)Proprietary Information

(b)(4)Proprietary Information

(b)(4)Proprietary Information



(b)(4)Proprietary Information



(b)(4)Proprietary Information

A review of adverse events confirmed there were no unanticipated events. (b)(4)Proprietary Information

(b)(4)Proprietary Information

(b)(4)Proprietary Information

Additionally, there were no adverse events related to the use of electrocautery for accessing the pseudocyst.

7. Performance Comparison

(b)(4)Proprietary Information

The AXIOS Electrocautery Enhanced Delivery System clinical success rate of 83.3% (b)(4)Proprietary Information

(b)(4)Proprietary Information

8. Device Malfunctions

(b)(4)Proprietary Information

(b)(4)Proprietary Information

[redacted]

9. Conclusions

The AXIOS Stent design and construction is optimized for controlled placement, maintaining patency, preventing migration and easy removal. Once placed, the stent provides a large diameter conduit and the bi-flange design secures access to the pseudocyst. The stent is provided fully covered to minimize tissue ingrowth.

The Electrocautery Enhanced Delivery System was used for access in 93.3% of patients and performed as intended in all cases. There were no adverse events or unanticipated adverse device effects attributed to electrocautery use.

The study of the AXIOS Stent with Electrocautery Enhanced Delivery System demonstrated the system to be predictable and easy to use. There were no intraoperative adverse events during AXIOS Stent placement with electrocautery. There were no unanticipated complications or new risks related to the implantation and removal of the AXIOS Stent. The AXIOS Stent with Electrocautery Enhanced Delivery System was deployed using electrocautery in conjunction with current strategies and techniques for clinical assessment and treatment.

(b)(4)Proprietary Information

[redacted]

(b)(4)Proprietary Information

Xlumena concludes that the AXIOS Stent(s) with Electrocautery Enhanced Delivery System is safe and effective for the endoscopic transenteric drainage of pancreatic pseudocysts.

ATTACHMENT 1

Acceptance Checklist for Traditional 510(k)s

(should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.

510(k) Number:_____ Date Received by DCC:_____

Lead Reviewer Name:_____Branch:_____ Division:_____Office:_____

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during RTA and that element will be assessed during substantive review.

Preliminary Questions		
Answers in the shaded blocks indicate consultation with Center advisor is needed.	**Yes**	**No**
1. Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Office Jurisdiction Liaison to determine the appropriate action, and inform division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If the product does not appear to be a device or such a combination product, mark "No."	X	
Comments:		
2. Is the application with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the application is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Office Jurisdiction Liaison to determine the appropriate action and inform your division management. Provide a summary of the Jurisdictional Officer's/Liaison's determination. If application should not be reviewed by your Center mark "No."	X	
Comments:		
3. If a Request for Designation (RFD) was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following:	N/A	
a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission? **b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission?** If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or appropriate CBER Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide summary of Jurisdictional Officer's/Liaison's determination.* If the answer to either question above is no, mark "No." If there was no RFD, skip this question.	N/A	
Comments:		
4. Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."	X	

Preliminary Questions Answers in the shaded blocks indicate consultation with Center advisor is needed.	Yes	No
Comments:		
5. Is there a pending PMA for the same device with the same indications for use? If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.		X
Comments:		
6. If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM - BIMO) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at http://www fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453 ht m.	N/A	

If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.
If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.
If the answer to 4 is "No", the lead reviewer should consult division management and other Center resources to determine the appropriate action.
If the answer to 5 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.
If the answer to 6 is "Yes," then contact CDRH/OC/DBM – BIMO or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with the BIMO Staff, and indicate BIMO's recommendation/action.

Organizational Elements *Failure to include these items alone generally should not result in an RTA designation*	Yes	No
a. Submission contains Table of Contents	X	
b. Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	X	
c. All pages of the submission are numbered *All pages should be numbered in such a manner that information can be referenced by page number. This may be done either by consecutively numbering the entire submission, or numbering the pages within a section (e.g., 12-1, 12-2…).*	X	
d. Type of 510(k) is identified– traditional, abbreviated, or special *If type of 510(k) is not designated, review as a traditional*	X	
Comments:		

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed			
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.			
• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.	**Yes**	**N/A**	**No**

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed					
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.				**Yes**	**N/A**	**No**
A.	**Administrative**					
	1.	All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)		X		☐
		Comments:				
	2.	Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or 510(k) cover letter):		X		☐
		a.	Device trade name or proprietary name	X		☐
		b.	Device common name	X		☐
		c.	Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	X		☐
		Comments:				
	3.	Submission contains Indications for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109) *Submitter should use format appropriate for the reviewing Center/Office (CDRH/ODE, CDRH/OIVD, CBER/OBRR, CBER/OCTGT). If not provided in correct format, request the correct format during substantive review.*		X		☐
		Comments:				
	4.	Submission contains 510(k) Summary or 510(k) Statement *Either a) or b) must be answered "Yes" to be considered complete. Identify any missing element(s) in Comments.*		Sec 6 Att. 2		☐
		a.	Summary contains all elements per 21 CFR 807.92 *See also 510(k) Summary Checklist*	Sec 6; Att. 2	☐	☐
		b.	Statement contains all elements per 21 CFR 807.93	☐	X	☐
		Comments:				
	5.	Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended format. Select "Yes" if statement is present and includes the text in the recommended format, and is signed by a responsible person of the firm (not consultant).*		Sec 8		☐
		Comments:				

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed					
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.				**Yes**	**N/A**	**No**
	6.	Submission contains Class III Summary and Certification *See recommended content. Form should be signed by a responsible person of the firm, not a consultant. Select "N/A" only if submission is not a Class III 510(k).*		☐	X	☐
		Comments:				
	7.	Submission contains clinical data *Select "N/A" if the submission does not contain clinical data. If "N/A" is selected, parts a and b below are omitted from the checklist.*		X	☐	
		a.	Submission includes completed Financial Certification (FDA Form 3454) or Disclosure (FDA Form 3455) information for each covered clinical study included in the submission. *Select "N/A" if the submitted clinical data is not a "covered clinical study" as defined in the Guidance for Industry- Financial Disclosures by Clinical Investigators*	X	☐	☐
		b.	Submission includes completed Certification of Compliance with requirements of ClinicalTrials.gov Data Bank (FDA Form 3674) (42 U.S.C. 282(j)(5)(B)) for each applicable device clinical trial included in the submission. *Select "N/A" if the submitted clinical data is not an "applicable device clinical trial" as defined in Title VIII of FDAAA, Sec. 801(j)*	X	☐	☐
		Comments:				
	8.	If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains complete Standards Data Report for 510(k)s (FDA Form 3654) *There should be a completed form for each referenced national or international standard.* *Select "N/A" only if submission does not reference any standards.*		Sec 7; Att. 3	☐	☐
		Comments:				
	9.	The submission identifies prior submissions for the same device for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre- Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device. *This information may be included in the Cover Letter (i.e., as a statement that there were no prior submissions for the device or a listing of the number(s) of the prior submissions). Alternatively, a list of submission numbers may be found in Section F (prior related submissions section) of the CDRH Coversheet form (Form 3514) to address this criterion. Please be advised that if this section of the form is left blank, it should not be considered a statement that there were no prior submissions.*		Sec 2 and 3	☐	☐

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.				**Yes**	**N/A**	**No**
		a.	If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed. *To address this criterion, the submission may include a separate section with the prior submission number(s), a copy of the FDA feedback (e.g., letter, meeting minutes), and a statement of how or where in the submission this prior feedback was addressed. Note that the adequacy of how the feedback was addressed should be assessed during the substantive review.* For additional information regarding the Pre-Submission process, please refer to the Draft Guidance "Medical Devices: The Pre-Submission Program and Meetings with FDA Staff." (http://www fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm310375 htm). Once finalized, this guidance will represent the Agency's current thinking on this topic. *Select "N/A" if the submitter states there were no prior submissions in criterion above.*	☐	X	☐
		Comments:				
B.	**Device Description**			Sec 13		
	10.	a.	If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement. *Select "N/A" if there are no applicable requirements in a device- specific regulation. Select "No" if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.*	☐	☐	☐
		b.	If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*	☐	☐	X
		Comments:				
	11.	Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:		Sec 13		
		a.	A description of the principle of operation and mechanism of action for achieving the intended effect.	Sec 13D		☐

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.				**Yes**	**N/A**	**No**
		b.	A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	Sec 13E		☐
		c.	A list and description of each device for which clearance is requested. *Select "N/A" if there is only one device or model. "Device" may refer to models, part numbers, or various sizes, etc.*	Sec 3 and Sec 13	☐	☐
		Comments:				
	12.	Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions. *In lieu of drawings, schematics, etc. of each device to be marketed, "representative" drawings, etc. may be provided, where "representative" is intended to mean that the drawings, etc. provided capture the differences in design, size, and other important characteristics of the various models, sizes, or versions of the device(s) to be marketed.* *Select "N/A" if the submitter provided a rationale for why the submission does not contain engineering drawings, schematics, etc. (e.g., device is a reagent and figures are not pertinent to describe the device).*		Sec 13B, C and E	☐	☐
		Comments:				
	13.	If device is intended to be marketed with multiple components, accessories, and/or as part of a system, *Select "N/A" if the device is not intended to be marketed with multiple components, accessories, and/or as part of a system.*		X	☐	
		a.	Submission includes a list of all components and accessories to be marketed with the subject device.	Sec B		☐
		b.	Submission includes a description (as detailed in item 11.a. and b. and 12 above) of each component or accessory. *Select "N/A" if the component(s)/accessory (ies) has been previously cleared, or is exempt, and the proposed indications for use are consistent with the cleared indications.*	☐	X	☐
		c.	A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance. *Select "N/A" if the submission states that the component(s)/ accessory (ies) does not have a prior 510(k) clearance or the component(s)/accessory(ies) is 510(k) exempt.*	Sec 13 B; as applicable	☐	☐
		Comments:				

Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.					**Yes**	**N/A**	**No**
C.	**Substantial Equivalence Discussion**				Sec 14		
	14.	Submitter has identified a predicate(s) device			Sec 14		☐
		a.	Predicate's 510(k) number, trade name, and model number (if applicable) provided. For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ComplianceActivities/ucm072746.htm).*		Sec 14		☐
		b.	The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.		Sec 14		☐
		Comments:					
	15.	Submission includes a comparison of the following for the predicate(s) and subject device					
		a.	Indications for use		Sec 14		☐
		b.	Technology, including features, materials, and principles of operation		Sec 14		☐
		Comments:					
	16.	Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate), affect safety or effectiveness, or raise different questions of safety and effectiveness (see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)) *If there is no difference between the subject and predicate(s) with respect to indications for use or technology, this should be explicitly stated, in which case "N/A" should be selected. Select "No" only if the submission does not include an analysis of differences as described above or a statement that there are no differences. Note that the adequacy of the analysis should be assessed during the substantive review; only the presence of such an analysis is required for acceptance. In addition, note that due to potential differences in manufacturing that may not be known to the submitter, the fact that no differences are identified does not necessarily mean that no performance testing is needed.*			Sec 14	☐	☐

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.				**Yes**	**N/A**	**No**
		Comments:				
D.	**Proposed Labeling (see also 21 CFR part 801)** *If in vitro diagnostic (IVD) device, criteria 17, 18, and 19 may be omitted. These criteria will be omitted from the checklist if "N/A" is selected. IVD labeling is addressed in section 21 below.*			Sec 15 Att. 7-15	☐	
	17.	Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual) that include a description of the device, its intended use, and the directions for use		Sec 15		☐
		a.	Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided)	Sec 15 and Sec 6		☐
		b.	Submission includes directions for use that -Includes statements of all conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) AND -Includes directions for layperson (see 21 CFR 801.5) OR submission states that device qualifies for exemption per 21 CFR 801 Subpart D	Sec 15		☐
		Comments:				
	18.	If indicated for prescription use, labeling includes the prescription use statement (see 21 CFR 801.109(b)(1)) or "Rx only" symbol [See also Alternative to Certain Prescription Device Labeling Requirements] *Select "N/A" if not indicated for prescription use.*		Sec 15	☐	☐
		Comments:				
	19.	General labeling provisions				
		a.	Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1)	Sec 15		☐
		b.	Labeling includes device common or usual name (21 CFR 801.61) *Select "N/A" if device is for prescription use only.*	Sec 15 Rx use only	☐	☐
		Comments:				

Elements of a Complete Submission (RTA Items) **(21 CFR 807 87 unless otherwise indicated)** Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.				**Yes**	**N/A**	**No**
	20.	a.	If there are requirements regarding labeling, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes labeling to establish that the submitter has followed the device-specific requirement. *Select "N/A" if there are no applicable requirements in a device- specific regulation. Select "No" if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.*	X	☐	☐
		b.	If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes labeling to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance have been addressed should be assessed during the substantive review.*	☐	☐	X
		c.	If there is a special controls document applicable to the device, the submission includes labeling to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how mitigation measures in a special controls document have been addressed should be assessed during the substantive review.*	X	☐	☐
		Comments:				
	21.		If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10. *Select "N/A" if not an in vitro diagnostic device.*	☐	X	☐
E.	**Sterilization** *If in vitro diagnostic (IVD) device and sterilization is not applicable, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.*			Sec 16A	☐	

Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

				Yes	N/A	No
• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.						
	Submission states that the device and/or accessories are: (*one of the below must be checked*) provided sterile X provided non-sterile but sterilized by the end user non-sterile when used __ This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "non-sterile when used" is selected, the sterility-related criteria below are omitted from the checklist. If information regarding the sterility status of the device is not provided, select "No."*					☐
	Comments:					
	22.	Assessment of the need for sterilization information				
		a.	Identification of device, and/or accessories, and/or components that are provided sterile.	Sec 16A	☐	☐
		b.	Identification of device, and/or accessories, and/or components that are end user sterilized	☐	X	☐
		c.	Identification of device, and/or accessories, and/or components that are reusable and cleaning/disinfection instructions are provided.	☐	X	☐
		Comments:				
	23.	If the device, and/or accessory, and/or a component is provided sterile: *Select "N/A" if no part of the device, accessories, or components is provided sterile, otherwise complete a-e below.*		Sec 16A	☐	
		a.	Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.)	Sec 16A		☐
		b.	A description of method to validate the sterilization parameters (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided for each proposed sterilization method. *Note, the sterilization validation report is not required.*	Sec 16A		☐
		c.	For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits. *Select "N/A" if not sterilized using chemical sterilants.*	Sec 16A	☐	☐
		d.	Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.)	Sec 16B and C		☐
		e.	Sterility Assurance Level (SAL) stated	Sec 16A		☐

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.				**Yes**	**N/A**	**No**
		Comments:				
	24.	If the device, and/or accessory, and/or a component is end user sterilized: *Select "N/A" if no part of the device, accessories, or components are end user sterilized, otherwise complete a-d below.*			X	
		a.	Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.)	☐		☐
		b.	A description of method to validate the sterilization parameters (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided for each proposed sterilization method. *Note, the sterilization validation is not required.*	☐		☐
		c.	Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.)	☐		☐
		d.	Submission includes sterilization instructions for end user	☐		☐
		Comments:				
	25.	a.	If there are requirements regarding sterility, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes sterility information to establish that the submitter has followed the device-specific requirement. *Select "N/A" if there are no applicable requirements in a device- specific regulation. Select "No" if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.*	X	☐	☐
		b.	If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes sterility information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance have been addressed should be assessed during the substantive review.*	☐	X	☐

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.				**Yes**	**N/A**	**No**
		c.	If there is a special controls document applicable to the device, the submission includes sterility information to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how mitigation measures in a special controls document have been addressed should be assessed during the substantive review.*	X	☐	☐
		Comments:				
F.	**Shelf Life**			Sec 16D		
	26.	Proposed shelf life/ expiration date stated *Select "N/A" if the device is not provided sterile and the submitter states that storage conditions could not affect device safety or effectiveness.*		Sec 16D	☐	☐
		Comments:				
	27.	For sterile device, submission includes summary of methods used to establish that device sterility will remain substantially equivalent to that of the predicate through the proposed shelf life, or a rationale for why testing to establish shelf life is not applicable. *Select "N/A" if the device is not provided sterile.*		Sec 16A-D	☐	☐
		Comments:				
	28.	Submission includes summary of methods used to establish that device performance is not adversely affected by aging and therefore device performance will remain substantially equivalent to that of the predicate, or includes a rationale for why the storage conditions are not expected to affect device safety or effectiveness.		Sec 16A-D Att 16-18		☐
		Comments:				
G.	**Biocompatibility** *If in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.*			Sec 17	☐	

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed					
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
	Submission states that there: (*one of the below must be checked*) Are **X** are not ___ direct or indirect (e.g., through fluid infusion) patient-contacting components. This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. If "are not" is selected, the biocompatibility-related criteria below are omitted from the checklist. If information regarding whether the device is patient-contacting is not provided, select "No."				
	Comments:				
	29.	Submission includes list of patient-contacting device components and associated materials of construction, including identification of color additives, if present	Sec 17A		☐
		Comments:			
	30.	Submission identifies contact classification (e.g., surface-contacting, less than 24 hour duration)	Sec 17A		☐
		Comments:			
	31.	Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test, OR a statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).	Sec 17B Att 24-25		☐
		Comments:			
H.	**Software**			N/A	
	Submission states that the device: (*one of the below must be checked*) Does ___ does not _X_ contain software/firmware. This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. If "does not" is selected, the software-related criterion is omitted from the checklist. If information regarding whether the device contains software is not provided, select "No."				
	Comments:				
	32.	Submission includes a statement of software level of concern and rationale for the software level of concern	☐	☐	☐

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed					
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
		Comments:			
	33.	All applicable software documentation provided based on level of concern identified by the submitter, as described in Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, or the submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through an alternative approach (i.e., the submitter has identified an alternate approach with a rationale).	☐	☐	☐
		Comments:			
I.	**EMC and Electrical Safety**		Sec 19	☐	☐
	Submission states that the device: (*one of the below must be checked*) Does X does not _ require EMC and Electrical Safety evaluation.				
	This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not" is selected, the EMC-related and Electrical Safety-related criteria below are omitted from the checklist. If information regarding whether the device requires EMC and Electrical Safety evaluation is not provided, select "No."*				
	Comments:				
	34.	Submission includes evaluation of electrical safety (e.g., per IEC 60601-1, or equivalent FDA-recognized standard, and if applicable, the device-specific standard), OR submission includes electrical safety evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	Sec 17 Att 26 - 27		☐
		Comments:			
	35.	Submission includes evaluation of electromagnetic compatibility (e.g., per IEC 60601-1-2 or equivalent FDA-recognized standard and if applicable, the device-specific standard) OR submission includes electromagnetic compatibility evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	Sec 17 Att 26 - 27		☐
		Comments:			

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.				**Yes**	**N/A**	**No**
J.	**Performance Data – General** *If in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected. Performance data criteria relating to IVD devices will be addressed in Section K.*			Sec 20	☐	
	Comments:					
	36.		Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre- defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test supports a finding of substantial equivalence. *Full test reports provided for all completed tests/evaluations (e.g., bench evaluations, comparative performance tests, etc.). Select "N/A" if the submission does not include performance data.*	Sec 20 Att 28 – 29 Att 19-23, 30-31 Att 32-33	☐	☐
		Comments:				
	37.	a.	If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement. *Select "N/A" if there are no applicable requirements in a device- specific regulation. Select "No" if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.*	X	☐	☐
		b.	If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance have been addressed should be assessed during the substantive review.*	☐	☐	X

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.				**Yes**	**N/A**	**No**
		c.	If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how mitigation measures in a special controls document have been addressed should be assessed during the substantive review.*	X	☐	☐
		Comments:				
	38.	If literature is referenced in the submission, submission includes: *Select "N/A" if the submission does not reference literature. Note that the applicability of the referenced article to support a substantial equivalence finding should be assessed during the substantive review; only the presence of a discussion is required to support acceptance.*			X	
		a.	Legible reprints or a summary of each article	☐		☐
		b.	Discussion of how each article is applicable to support the substantial equivalence of the subject device to the predicate.	☐		☐
		Comments:				
	39.	For each completed nonclinical (i.e., animal) study conducted, *Select "N/A" if no animal study was conducted. Note that this section does not address biocompatibility evaluations, which are assessed in Section G of the checklist,*		Sec 21		
		a.	Submission includes a study protocol which includes all elements as outlined in 21 CFR 58.120	Sec 21 Att. 34		☐
		b.	Submission includes final study report which includes all elements outlined in 21 CFR 58.185	Sec 21 Att. 35		☐
		c.	Submission contains a statement that the study was conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58), or, if the study was not conducted in compliance with the GLP regulation, the submission explains why the noncompliance would not impact the validity of the study data provided to support a substantial equivalence determination.	Sec 21 Att. 34 - 35		☐
		Comments:				
K.	**Performance Characteristics – In Vitro Diagnostic Devices Only (see also 21 CFR 809.10(b)(12))**				N/A	

Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

				Yes	N/A	No
• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.						
	Submission indicates that device: (*one of the below must be checked*) is is not X an in vitro diagnostic device (IVD). *If "is not" is selected, the performance data-related criteria below are omitted from the checklist.*					
	Comments:					
	40.	Submission includes the following studies, as appropriate for the device type, including associated protocol descriptions, study results and line data:			N/A	
		a.	Precision/reproducibility	☐	☐	☐
		b.	Accuracy (includes as appropriate linearity; calibrator or assay traceability; calibrator and/or assay stability protocol and acceptance criteria; assay cut-off; method comparison or comparison to clinical outcome; matrix comparison; and clinical reference range or cutoff.	☐	☐	☐
		c.	Sensitivity (detection limits, LoB, LoD, LoQ where relevant for the device type).	☐	☐	☐
		d.	Analytical specificity	☐	☐	☐
		Comments:				
	41.	a.	If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement. *Select "N/A" if there are no applicable requirements in a device- specific regulation. Select "No" if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.*	☐	N/A	☐
		b.	If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance have been addressed should be assessed during the substantive review.*	☐	N/A	☐

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.				**Yes**	**N/A**	**No**
		c.	If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how mitigation measures in a special controls document have been addressed should be assessed during the substantive review.*	☐	☐	☐
		Comments:				

Decision: Accept _____ Refuse to Accept _____

If Accept, notify applicant; if Refuse to Accept, notify applicant in writing and include a copy of this checklist.

Reviewer Signature: _____ Date: _____

Supervisory Signature: _____ Date: _____

ATTACHMENT 2

510(K) SUMMARY

Date Prepared:	March 17, 2015
Submitter:	Xlumena, Inc.
Address:	453 Ravendale Drive, Suite H, Mountain View, CA 94043
Phone:	(650) 868-4331
Fax:	(650) 961-9901
Contact Person:	Carole Sykes VP Clinical and Regulatory Affairs
Trade Name/Proprietary Name:	AXIOS Stent with Electrocautery Enhanced Delivery System
Class:	II
Common Name:	Pancreatic drainage stent and delivery system and endoscopic electrosurgery device
Classification/Name:	Pancreatic drainage stent and accessories and endoscopic electrosurgery accessories
Regulation:	21 CRF 876.5015 / 21 CFR 876.4300
Product Code:	PCU / 78KNS
Predicate Devices (Legally marketed devices to which substantial equivalence is claimed):	Xlumena, Inc. AXIOS Stent and Delivery System K140561 and K123250 Wilson-Cook Medical, Inc. Wilson-Cook Cystotome K022595

I. Device Description:

The AXIOS Stent with Electrocautery Enhanced Delivery System is intended for the endoscopic placement of a flexible, MR conditional, fully-covered, self-expanding braided Nitinol stent for transgastric or transduodenal endoscopic drainage of symptomatic pancreatic pseudocysts. The AXIOS Stent with Electrocautery Enhanced Delivery System is comprised of two main components: (1) AXIOS Stent and (2) Electrocautery Enhanced Delivery System.

The subject premarket notification describes modifications to the cleared AXIOS Delivery System to add electrocautery to facilitate precise access to anatomic targets as well as the staged placement of the currently cleared AXIOS Stent. The AXIOS Stent with Electrocautery Enhanced Delivery System incorporates the same identical implantable stent that is preloaded within the current AXIOS Delivery System (K123250). Both the AXIOS Stent and Delivery System were originally cleared under 510(k) K123250 and most recently under 510(k) K140561.

As with the non-cautery AXIOS devices, the Electrocautery Enhanced AXIOS Delivery System is compatible with commercially-available 0.035-inch endoscopic guidewires and intended to be used in the gastrointestinal tract in conjunction with commercially-available echoendoscopes. The Electrocautery Enhanced Delivery System has been modified to connect with an off-the-shelf electrosurgical unit or generator that is compliant to IEC 60601-1-2 and IEC 60601-2-2. The generator must be installed and put into service according to the EMC information provided in the generator manufacturer's guidance and declaration for electromagnetic compatibility.

Cables and patient return electrodes that are specified by generator manufacturer must be used for connection.

The AXIOS Stent with Electrocautery Enhanced Delivery System is provided sterile, disposable and intended for single use. The Electrocautery Enhanced AXIOS Delivery System is IEC compliant.

II. Indications for Use:

The AXIOS™ Stent with Electrocautery Enhanced Delivery System is indicated for use to facilitate transgastric or transduodenal endoscopic drainage of symptomatic pancreatic pseudocysts ≥ 6cm in size, with ≥ 70% fluid content that are adherent to the gastric or bowel wall. Once placed, the AXIOS stent functions as an access port allowing passage of standard and therapeutic endoscopes to facilitate debridement, irrigation and cystoscopy. The stent is intended for implantation up to 60 days and should be removed upon confirmation of pseudocyst resolution.

III. Summary of Technological Characteristics of the Proposed Device Compared to the Predicate Device:

The Xlumena AXIOS Stent with Electrocautery Enhanced Delivery System is substantially equivalent to the legally marketed predicate devices identified in Table 1. The AXIOS Stent with Electrocautery Enhanced Delivery System is substantially equivalent in terms of intended use / indications for use, technological characteristics and principles of operation to the predicate AXIOS Stent and Delivery System which was cleared by FDA in 510(k)s K123250 and K140561, and the Wilson-Cook Medical Cystotome cleared by FDA in 510(k) K022595.

Table 1. Comparison of AXIOS Stent with Electrocautery Enhanced Delivery System with Predicate Devices

Feature			
	SUBJECT DEVICE AXIOS Stent with Electrocautery Enhanced Delivery System	**PRIMARY PREDICATE DEVICE Xlumena AXIOS Stent with (non-cautery) Delivery System**	**REFERENCE PREDICATE DEVICE Wilson-Cook Medical Wilson-Cook Cystotome**
510(k) Number	TBD	K140561and K123250	K022595
Indications for Use	To facilitate transgastric or transduodenal endoscopic drainage of symptomatic pancreatic pseudocysts ≥ 6cm in size, with ≥ 70% fluid content that are adherent to the gastric or bowel wall. Once placed, the AXIOS Stent functions as an access port allowing passage of standard and	Same	For use as an electrosurgical accessory to cannulate the transgastric or transduodenal wall and into a pancreatic pseudocyst that is visibly bulging into the gastrointestinal tract.

Feature	SUBJECT DEVICE AXIOS Stent with Electrocautery Enhanced Delivery System	PRIMARY PREDICATE DEVICE Xlumena AXIOS Stent with (non-cautery) Delivery System	REFERENCE PREDICATE DEVICE Wilson-Cook Medical Wilson-Cook Cystotome
	therapeutic endoscopes to facilitate debridement, irrigation and cystoscopy. The stent is intended for implantation up to 60 days and should be removed upon confirmation of pseudocyst resolution.		
Class	II	Same	Same
Classification/ Regulation Name	Pancreatic drainage stent and accessories and endoscopic electrosurgery accessories	Pancreatic drainage stent and accessories	Endoscopic electrosurgery accessories
Regulation Number	21CFR 876.5015 21CFR 876.4300	21CFR 876.5015	21CFR 876.4300
Product Code	PCU and 78KNS	PCU	78KNS
Outer Catheter Length	138 cm	Same	165 CM
Inner Catheter Sheath Diameter	9 Fr with preloaded Stent	Same	5 Fr with 0.038" needle knife
Guidewire Compatibility	0.035"	Same	Same
Endoscope Compatibility	Compatible with 3.7 mm diameter or larger working channel	Same	Same
Placement Site	Transgastric or transduodenal wall and into a pancreatic pseudocyst	Same	Same
Pseudocyst Size	≥ 6cm in size	Same	≥ 4cm in size
Mode of Access or Operation	Electrosurgically punctures hole at the placement site. Fine wire electrocautery element (0.006" SS wire); electrosurgically active wire using pure cutting current to access pseudocyst. After access, deploy the AXIOS Stent using a two stage process. Distal stent flange first followed by the proximal flange.	Access path at placement site is created using conventional access tools. After access, deploy the AXIOS Stent using a two stage process. Distal stent flange first followed by the proximal flange.	Electrosurgically punctures hole at the placement site. Needle 0.038" knife tip; electrosurgically active knife using pure cutting current to access pseudocyst. Enlarge incision with a cauterizing diathermic ring and 10 Fr outer catheter. Utilizes a 0.035" wire for placement of a stent or drainage kit via compatible endoscope.
Stent Deployment Mechanism	Deployed via handle controls. Distal stent flange first followed by the proximal flange.	Same	N/A

Feature	SUBJECT DEVICE AXIOS Stent with Electrocautery Enhanced Delivery System	PRIMARY PREDICATE DEVICE Xlumena AXIOS Stent with (non-cautery) Delivery System	REFERENCE PREDICATE DEVICE Wilson-Cook Medical Wilson-Cook Cystotome
Cutting Current	80-120 Watts	N/A	80-120 Watts
Sterilization Method	EO	EO	EO

IV. Summary of the Nonclinical Tests Performed:

Nonclinical testing performed includes: Bench Performance, Biocompatibility, Electromagnetic Compatibility / Electrical Safety, and Animal Testing. The nonclinical test results demonstrate that the modified device continues to meet product design specifications.

1. Bench Performance

Bench performance testing was conducted for the AXIOS Stent with Electrocautery Enhanced Delivery System to demonstrate that the modified delivery system continues to meet the requirements of the product design specification and perform in accordance with its intended use. There have been no design or material changes to the AXIOS Stent; it is identical to the AXIOS Stent cleared in K123250 and K140561. The bench performance testing was conducted for the modifications to the Electrocautery Enhanced Delivery System Catheter and Handle only.

Where applicable, performance testing was conducted in accordance with the following standards:

- ISO 10555-1:2013 - *Sterile, single-use intravascular catheters Part 1. General requirements*
- ISO 594-1:1986 - *Conical Fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 1 : General Requirements*

Design Verification testing included assessment of device dimensions, stent deployment and tensile testing of the applicable joints. The AXIOS Stent with Electrocautery Enhanced Delivery System was tested for design validation attributes. AXIOS Systems were evaluated in an *ex vivo* simulated use model for performance to the product specification. Based on the results of the bench performance testing, the modified Electrocautery Enhanced Delivery Systems meets the product design specification and performance requirements for its proposed intended use.

The AXIOS Stent with Electrocautery Enhanced Delivery System was evaluated in an Ex-Vivo Tissue Model to measure the comparative thermal effects of the AXIOS Electrocautery Enhanced Delivery System (11F) vs. the 10F Cook Cystotome on porcine tissue. In all tissue samples, the Electrocautery Enhanced Delivery System caused statistically significant less thermal damage to the tissue as compared to the Cystotome.

2. Biocompatibility

To verify the biocompatibility of the AXIOS Stent with Electrocautery Enhanced Delivery System the Company conducted biocompatibility testing pursuant to ISO 10993-1:2009 and FDA's Draft Guidance Document *Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing (2013)"*. Biocompatibility testing was conducted in accordance with the GLP regulations (21 CFR, Part 58).

The Electrocautery Enhanced Delivery System (Hot AXIOS Delivery System) is an "external communicating device" in contact with tissue for limited duration (≤24 hour) during pseudocyst access and stent implant procedures. Based on these characteristics, the following biocompatibility tests were performed: Cytotoxicity – ISO MEM Elution Method, L-929 Cells, Sensitization - ISO Guinea Pig Maximization Study, Irritation - ISO Intracutaneous Reactivity in Rabbits and Systemic (Acute) Toxicity - ISO Systemic Toxicity in Mice. There have been no changes to the AXIOS Stent design or materials; it is identical to the AXIOS Stent cleared in 510(k)s K123250 and K140561, therefore no new biocompatibility testing is warranted. Based on the test results, the Electrocautery Enhanced Delivery System is biocompatible for the intended use.

3. Electromagnetic Compatibility and Electrical Safety

The AXIOS Stent with Electrocautery Enhanced Delivery System (Hot AXIOS Device) was evaluated by Intertek NA, for conformance to the IEC 60601 family of standards. All completed testing passed the acceptance criteria as outlined in IEC 60601-1, 60601-1-6, 60601-2-2, 60601-2-18, and ISO 14971 and as specified in the Final Study Reports provided by Intertek NA, Inc.

4. Animal

The safety and effectiveness of the AXIOS Stent with Electrocautery Enhanced Delivery System (Hot AXIOS) during transmural endoscopic access and drainage of a simulated pancreatic pseudocyst and the biliary tract was evaluated. The study evaluated the safety and performance of the AXIOS Stent with Electrocautery Enhanced Delivery System when performing a simulated endoscopic drainage procedure in a porcine model using the 06x08mm and 20x10mm stent models.

Cautery access and stent deployment using the AXIOS Stent with Electrocautery Enhanced Delivery System were compared to standard techniques as represented by access with the commercially available Cystotome (Cook Medical, Limerick Ireland) and the placement of an 20x10mm Stent with Electrocautery Enhanced Delivery System (the Electrocautery Enhanced Delivery System was not energized). A direct comparison of tissue heat affects and healing were evaluated post cautery access and AXIOS Stent placement. Effectiveness of the Electrocautery Enhanced Delivery System to access the target anatomy and deliver the AXIOS stent (device performance) was also assessed.

The study animals were survived for one (1) month after stent implantation followed by stent removal. Study animals were survived another 7 days after stent removal for histopathological evaluation. Histological evaluation of the heat affects and healing of the implant site was performed.

Access using cautery was successfully achieved and stents were successfully deployed in all animals. None of the stents migrated from the original position and all stents remained patent during the implant period (1 month). The tissue surrounding the stent implant sites was healthy in all animals. The gross and histological evaluation of the tissues treated with either the control (AXIOS without cautery) or test device (AXIOS with Electrocautery Enhanced Delivery System) showed excellent healing between the two luminal structures (bile duct or jejunum and stomach). Thermal heat effects were not apparent grossly or histologically within the tissues evaluated in the AXIOS Electrocautery Enhanced Delivery System treated animals.

V. Summary of Clinical Tests Performed:

Xlumena conducted a prospective multi-center, single-arm clinical study to demonstrate the safety and effectiveness of the AXIOS Stent with Electrocautery Enhanced Delivery System for endoscopic transenteric drainage of pancreatic pseudocysts. The AXIOS Stent with Electrocautery Enhanced Delivery System is intended for the endoscopic ultrasonography (EUS) guided creation of an internal drainage conduit between the pancreatic pseudocyst and the stomach or duodenum. The AXIOS Electrocautery Enhanced Delivery System is designed to facilitate the creation of the access tract using electrosurgery while minimizing device exchanges for pseudocyst access. The design and manufacturing of AXIOS Stent remains unchanged.

Safety was evaluated as freedom from major complications with regard to stent placement and removal. Stent migration and tissue response for the period up to seven days after stent removal were also evaluated. Pseudocyst resolution and AXIOS device performance were evaluated to characterize effectiveness.

The study group consisted of symptomatic subjects who provided consent and were treated with the AXIOS Stent with Electrocautery Enhanced Delivery System.

Effectiveness: AXIOS Stents were placed in subjects with no intra-operative complications. AXIOS stent patency was confirmed with drainage visualized for all stents placed. In subjects treated PP, 100% of AXIOS devices remained in position at 30 or 60 days, and 81.1% of stent lumens remained patent at 30 days and 100% at 60 days. The AXIOS stent was successfully implanted in all study subjects (100%). Successful removal of the AXIOS stent was achieved in all subjects (100%) in which endoscopic removal PP was attempted. Overall clinical success was achieved in 83.3% of subjects.

Safety: Study results demonstrated that there were no unanticipated events related to the use of the device. Ninety percent (90%) of subjects were free from major complications. Ninety-three percent (93.3%) of subjects experienced no serious adverse events related to the device or index procedure. Serious adverse events deemed related to the AXIOS device or the index procedure was the same type of events as those generally associated with endoscopic pancreatic pseudocyst drainage with commercially available stents and delivery systems.

Conclusion:

The AXIOS Stent design and construction is optimized for controlled placement, maintaining patency, preventing migration and easy removal. Once placed, the stent provides a large diameter conduit and the bi-flange design secures access to the pseudocyst. The stent is provided fully covered to minimize tissue ingrowth.

The Electrocautery Enhanced Delivery System was used for access in 100% of patients and performed as intended in all cases. There were no adverse events or unanticipated adverse device effects attributed to electrocautery use.

The study of the AXIOS Stent with Electrocautery Enhanced Delivery System demonstrated the system to be predictable and easy to use. There were no intraoperative adverse events during AXIOS Stent placement and two during removal (both were minor bleeding not requiring transfusion). There were no unanticipated complications or new risks related to the implantation and removal of the AXIOS Stent. The AXIOS Stent with Electrocautery Enhanced Delivery System is deployed using electrocautery in conjunction with current strategies and techniques for clinical assessment and treatment. In conclusion, the AXIOS Stent with Electrocautery Enhanced Delivery System is safe and effective for the endoscopic transenteric drainage of pancreatic pseudocysts.

VI. Substantial Equivalence:

Based on the results of the Bench Performance, Biocompatibility, Electromagnetic Compatibility / Electrical Safety and Animal testing, as well as clinical evaluations, the AXIOS Stent with Electrocautery Enhanced Delivery System is substantially equivalent to the currently cleared AXIOS Stent and Delivery System which was cleared by FDA in 510(k)s K123250 and K140561, and the Wilson-Cook Medical Cystotome cleared by FDA in 510(k) K022595. In regard to intended use/indication for use, technological characteristics, and principles of operation the modifications do not affect the performance or function of the device. The minor differences in the design between the modified and cleared devices do not raise any new types of safety or effectiveness questions as confirmed by non-clinical and clinical testing. Therefore, the AXIOS Stent with Electrocautery Enhanced Delivery System is substantially equivalent to the previously cleared predicate devices.

VII. Conclusions:

Xlumena concludes that based on the results of the Bench Performance, Biocompatibility, Electromagnetic Compatibility / Electrical Safety, Animal and Clinical Testing, that the modified AXIOS Stent with Electrocautery Enhanced Delivery System is substantially equivalent to the predicate devices.

ATTACHMENT 3

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

(b)(4)Proprietary Information

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-179	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: #G95-1 "Use of International Standard ISO-10993

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
(b)(4)Proprietary Information

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1,2,3,4	Scope, Normative References, Terms and Definitions, General Principles	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Categorization of Medial Devices	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
(b)(4)Proprietary Information

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6,7	Biological Evaluation Process, Interpretation of Biological Evaluation Data	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

(b)(4)Proprietary Information

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-175	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: #G95-1 "Use of International Standard ISO-10993

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
(b)(4)Proprietary Information

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1,2,3	Scope, Normative references, Definitions	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	(b)(4)Proprietary	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
(b)(4)Proprietary Information		☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

(b)(4)Proprietary Information

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-153	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☐
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: #G95-1 "Use of International Standard ISO-10993

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
(b)(4)Proprietary Information

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1,2,3	Scope, Normative References, Terms and Definitions	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4,5,6	Sample and control preparation, Cell lines, Culture medium	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7,8,9,10	(b)(4)Proprietary Information	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

(b)(4)Proprietary Information

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-120	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☐
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: #G95-1 "Use of International Standard ISO-10993

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

(b)(4)Proprietary Information

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1,2,3	Scope, Normative references, Terms and definitions	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	Common provisions for implantation test methods	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5,6	Test methods and general aspects, Test reports	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

(b)(4)Proprietary Information

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-408	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: #G95-1 "Use of International Standard ISO-10993

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

(b)(4)Proprietary Information

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1,2,3	Scope, Normative references, Terms and definitions	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	Requirements	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Product release	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

(b)(4)Proprietary Information

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-174	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☐
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: #G95-1 "Use of International Standard ISO-10993

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
(b)(4)Proprietary Information

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1,2,3,4	Scope, Normative references, Term and definitions, General principles	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5,6	(b)(4)Proprietary Information	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7,8	(b)(4)Proprietary Information	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

(b)(4)Proprietary Information

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-176	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: #G95-1 "Use of International Standard ISO-10993

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
(b)(4)Proprietary Information

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1,2,3,4	Scope, Normative references, Terms and definitions, General considerations	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	(b)(4)Proprietary	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	(b)(4)Proprietary Information	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

(b)(4)Proprietary Information

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3]	# N/A	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
(b)(4)Proprietary Information

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1,2,3	Scope, Definitions, Selection of sterilization facility	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	Written agreement between product manufacturer and contract sterilizer	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Validation program	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

(b)(4)Proprietary Information

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3]	# N/A	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
(b)(4)Proprietary Information

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1,2,3	Scope, Definitions, EO sterilization processing equipment	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	Determination of minimum product temperature prior to preconditioning	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Calculation of moisture content	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

(b)(4)Proprietary Information

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3]	# N/A	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

(b)(4)Proprietary Information

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1, 2, 3	Scope, Terms and Definitions, Process and equipment characterization	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4, 5	Process definition, Validation	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Maintaining process effectiveness	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

(b)(4)Proprietary Information

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3]	# N/A	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

(b)(4)Proprietary Information

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1, 2	Scope, Terms and Definitions	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
3	Product adoption	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	Process equivalence	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

(b)(4)Proprietary Information

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-331	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

(b)(4)Proprietary Information

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1,2,3	Scope, Normative references, Terms and definitions	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	Quality management system	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5,6	Sterilizing agent characterization, Process and equipment characterization	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

(b)(4)Proprietary Information

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3]	# N/A	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
(b)(4)Proprietary Information

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1, 2, 3, 4	Scope, Normative references, Terms & definitions, Quality Management Syste	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5, 6, 7	Sterilizing agent Characterization, Process & eqpt characterization, Product def	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
8, 9, 10, 11, 12	Process def, Validation, Routine monitoring & control, Product release, Mtng p	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

(b)(4)Proprietary Information

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-407	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

(b)(4)Proprietary Information

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1,2,3	Scope, Normative references, Terms and definitions	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	Quality management system elements	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Selection of product	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

(b)(4)Proprietary Information

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-327	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☒
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

(b)(4)Proprietary Information

[redacted]

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1,2,3	Scope, Normative references, Terms and definitions	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	Quality management system elements	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Selection of product	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

(b)(4)Proprietary Information

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-327	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
(b)(4)Proprietary Information

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1,2,3,4	Scope, Referenced Documents, Terminology, Significance and Use	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5,6,7,8	Test Specimen, Conditioning, Acceptance Criteria, Procedure	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
9-17,18,19,20	Hazard Elements and Test Schedules, Report, Precision and Bias, Keywords	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

(b)(4)Proprietary Information

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3]	# N/A	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☐	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☐
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☐
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☐
Is there an FDA guidance [6] that is associated with this standard?	☐	☐
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

(b)(4)Proprietary Information

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1, 2	Scope, Normative References	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
3	Terms and definitions	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	Requirements	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

(b)(4)Proprietary Information

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-355	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

(b)(4)Proprietary Information

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1,2,3,4	Scope, Normative references, Terms and definitions, General requirements	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Materials and preformed sterile barrier systems	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6,7	Design & development requirements for packaging, information to be provided	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

(b)(4)Proprietary Information

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3]	# N/A	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

(b)(4)Proprietary Information

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1, 2, 3, 4, 5	Scope, Referenced Documents, Terminology, Significance and Use, Apparatus	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6, 7, 8, 9	Safety Precautions, Test Specimens, Conditioning, Procedure	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
10, 11, 12	Report, Precision and Bias, Keywords	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

(b)(4)Proprietary Information

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3]	# N/A	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

(b)(4)Proprietary Information

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1, 2, 3, 4	Scope, Referenced Documents, Terminology, Significance and Use	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5, 6, 7	Atmospheric Conditions, Apparatus, Procedure	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
8, 9, 10	Report, Precision and Bias, Keywords	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

(b)(4)Proprietary Information

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3]	# N/A	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

(b)(4)Proprietary Information

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1, 2, 3, 4, 5	Scope, Referenced Documents, Terminology, Significance and Use, Apparatus	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6, 7, 8	Safety Precautions, Test Specimens, Calibration & Standardization	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
9, 10, 11, 12, 13	Conditioning, Procedure, Report, Precision and Bias, Keywords	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

(b)(4)Proprietary Information

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3]	# N/A	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

(b)(4)Proprietary Information

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1, 2, 3, 4	Scope, Referenced Documents, Terminology, Significance and Use	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5, 6, 7, 8	Apparatus, Sampling, Test Specimens, Procedure	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
9, 10, 11	Report, Precision and Bias, Keywords	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

(b)(4)Proprietary Information

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-283	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

(b)(4)Proprietary Information

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1,2,3,4	Scope, Reference Document	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5,6,7,8,9	Interferences, Apparatus, Sampling, Aging and Conditioning, Procedure	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
10,11	Precision and Bias, Report	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

(b)(4)Proprietary Information

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-283	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

(b)(4)Proprietary Information

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1,2,3,4	Scope, Referenced Documents, Terminology, Summary of Test Method	☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *	N/A	
DESCRIPTION	N/A	
JUSTIFICATION	N/A	

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5,6,7	Significance and Use, Apparatus, Procedure	☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *	N/A	
DESCRIPTION	N/A	
JUSTIFICATION	N/A	

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
8	Precision and Bias	☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *	N/A	
DESCRIPTION	N/A	
JUSTIFICATION	N/A	

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

(b)(4)Proprietary Information

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-229	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

(b)(4)Proprietary Information

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1,2,3,4	Scope, Referenced Documents, Terminology, Significance and Use	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5,6,7	Apparatus, Accelerated Aging Theory, Accelerated Aging Plan	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
8,9,10	Post-Aging Testing Guidance, Report, Keywords	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

(b)(4)Proprietary Information

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-359	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☐
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

(b)(4)Proprietary Information

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1,2,3	Scope, Referenced Documents, Terminology	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4,5,6	Summary of Test Method, Significance and Use, Apparatus	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7,8,9,10,11,12	Sampling, Conditioning, Procedure, Report, Precision and Bias, Keywords	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

(b)(4)Proprietary Information

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3]	# N/A	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
(b)(4)Proprietary Information

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1	Overview	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
2	Testing	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
3	Report	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

(b)(4)Proprietary Information

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3]	# N/A	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☐	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☐
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☐
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☐
Is there an FDA guidance [6] that is associated with this standard?	☐	☐
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
BS EN 980:2008: Graphical symbols for use in the labeling of medical devices

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1, 2	Scope, Normative references	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
3, 4	Terms and definitions, General requirements	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5, 6	Symbols already in use, New symbols	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

(b)(4)Proprietary Information

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3]	# N/A	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

(b)(4)Proprietary Information [redacted]

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1, 2, 3	Scope, Normative References, Terms and Conditions	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4, 5	Requirements, Requirements for Provision of Information	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Documentation	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

(b)(4)Proprietary Information

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#5-73	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

(b)(4)Proprietary Information

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1,2,3	Scope, Normative References, Terms and Conditions	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	General Requirements	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Symbols	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

(b)(4)Proprietary Information

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#6-301	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

(b)(4)Proprietary Information

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1,2,3	Scope, Normative references, Terms and Definitions	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	Requirements	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

(b)(4)Proprietary Information

DESCRIPTION
This section refers to force break.

JUSTIFICATION

(b)(4)Proprietary Information

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5,6	Designation of nominal size, Information to be supplied by the manufacturer	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

(b)(4)Proprietary Information

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 6-11	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

(b)(4)Proprietary Information

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
0, 1	Introduction, Scope and field of Application	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
2, 3	References, Dimensions	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4, 5	Requirements, Test Methods	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

(b)(4)Proprietary Information

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3]	# N/A	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

(b)(4)Proprietary Information

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
0, 1, 2, 3	Introduction, Scope, Normative references, Terms & definitions	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4, 5, 6	Quality Management Sys, Management Responsibility, Resource management	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7, 8	Product Realization, Measurement, analysis and Improvement	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

(b)(4)Proprietary Information

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#5-40	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Medical Device Use-Safety : Incorporating Human Factors Engineering into Risk Management

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
(b)(4)Proprietary Information

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1,2,3	Scope, Terms and Definitions, General requirements for risk management.	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4,5,6,7	Risk analysis, Risk eval, Risk control, Eval of overall residualrisk acceptability	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
8,9	Risk management report, Production and post-production Information	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

(b)(4)Proprietary Information

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3]	# N/A	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☐	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☐
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☐
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☐
Is there an FDA guidance [6] that is associated with this standard?	☐	☐
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
(b)(4)Proprietary Information

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1, 2, 3	Scope, object and related standards, Normative references, Terms & definitions	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4, 5	(b)(4)Proprietary Information	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	(b)(4)Proprietary Information	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

(b)(4)Proprietary Information

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 6-336	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
(b)(4)Proprietary Information

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
201.1, 201.2, 201.3	Scope, object and related standards, Normative references, Terms & definitions	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
201.4, 201.5	(b)(4)Proprietary Information	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
201.6, 201.7	(b)(4)Proprietary Information	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

(b)(4)Proprietary Information

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 5-87	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Draft Guidance - Applying Human Factors and Usability Engineering to Optimize Medical Device Design

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

(b)(4)Proprietary Information

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1, 2, 3	Scope, Normative references, Terms and definitions	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4, 5	Principles, USABILITY ENGINEERING PROCESS	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6, 7	ACCOMPANYING DOCUMENT, Training and materials for training	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

(b)(4)Proprietary Information

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#8-124	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☐
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
(b)(4)Proprietary Information

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1,2,3,4	Scope, Referenced Documents, Terminology, Summary of Test Method	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5,6,7,8	Significance and Use, Apparatus, Test Specimens, Procedure	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
9,10,11,12	Calculations, Report, Precision and Bias, Keywords	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

(b)(4)Proprietary Information

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#8-153	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☐
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

(b)(4)Proprietary Information

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1,2,3,4	Scope, Reference Documents, Terminology, Summary of Test Method	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5,6,7	Significance and Use, Apparatus, Test Specimen	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
8,9,10,11	Procedure, Report, Precision and Bias, Keywords	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

(b)(4)Proprietary Information

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#8-227	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
(b)(4)Proprietary Information

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1,2,3,4	Scope, Referenced Documents, Terminology, Summary and Test Method	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5,6,7	Significance and Use, Apparatus, Test Specimens	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
8	Procedure	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

(b)(4)Proprietary Information

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#8-128	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

(b)(4)Proprietary Information

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1,2,3,4	Scope, Referenced Documents, Terminology, Summary of Test Method	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5,6,7,8	Significance and Use, Apparatus, Test Specimens, Procedure	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
9,10,11,12	Calculation, Report, Precision and Bias, Keywords	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

(b)(4)Proprietary Information

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 4-187	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

(b)(4)Proprietary Information

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
201.1, 201.2	Scope, object and related standards, Normative references	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
201.3, 201.4	Terms and definitions, General requirements	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
201.5	General requirements for testing of ME EQUIPMENT	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

(b)(4)Proprietary Information

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 8-335	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

(b)(4)Proprietary Information

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1, 2, 3, 4	Scope, Referenced Documents, Terminology, Product Classification	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5, 6	Ordering Information, Materials and Manufacture	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7	Chemical Composition Requirements	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

(b)(4)Proprietary Information

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3]	# N/A	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

(b)(4)Proprietary Information

[redacted]

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1, 2, 3, 4, 5	Scope, Referenced Documents, Terminology, Significance and Use, Apparatus	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6, 7	Sampling Test Specimens and Test Units, Calibration and Standardization	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
8, 9, 10, 11, 12	Conditioning, Procedure, Report, Precision and Bias, Keywords	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

(b)(4)Proprietary Information

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3]	# N/A	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
(b)(4)Proprietary Information

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1, 2, 3, 4	Scope, Referenced Documents, Terminology, Significance and Use	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5, 6, 7, 8	Apparatus, Sampling, Test Specimen, Procedure	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
9, 10, 11	Report, Precision and Bias, Keywords	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

(b)(4)Proprietary Information

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 19-1	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
(b)(4)Proprietary Information

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1, 2, 3	Scope, object and related standards, Normative references, Terms & definitions	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4, 5	General requirements, Identification, marking and documents	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	(b)(4)Proprietary Information	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

(b)(4)Proprietary Information

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3]	# None	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
(b)(4)Proprietary Information

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1, 2, 3	Scope, object and related standards, Normative references, Terms & definitions	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4, 5	(b)(4)Proprietary Information	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6, 7	(b)(4)Proprietary Information	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

(b)(4)Proprietary Information

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 5-85	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
(b)(4)Proprietary Information

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1, 2, 3	Scope, object and related standards, Normative references, Terms & definitions	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	General requirements	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	(b)(4)Proprietary Information	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

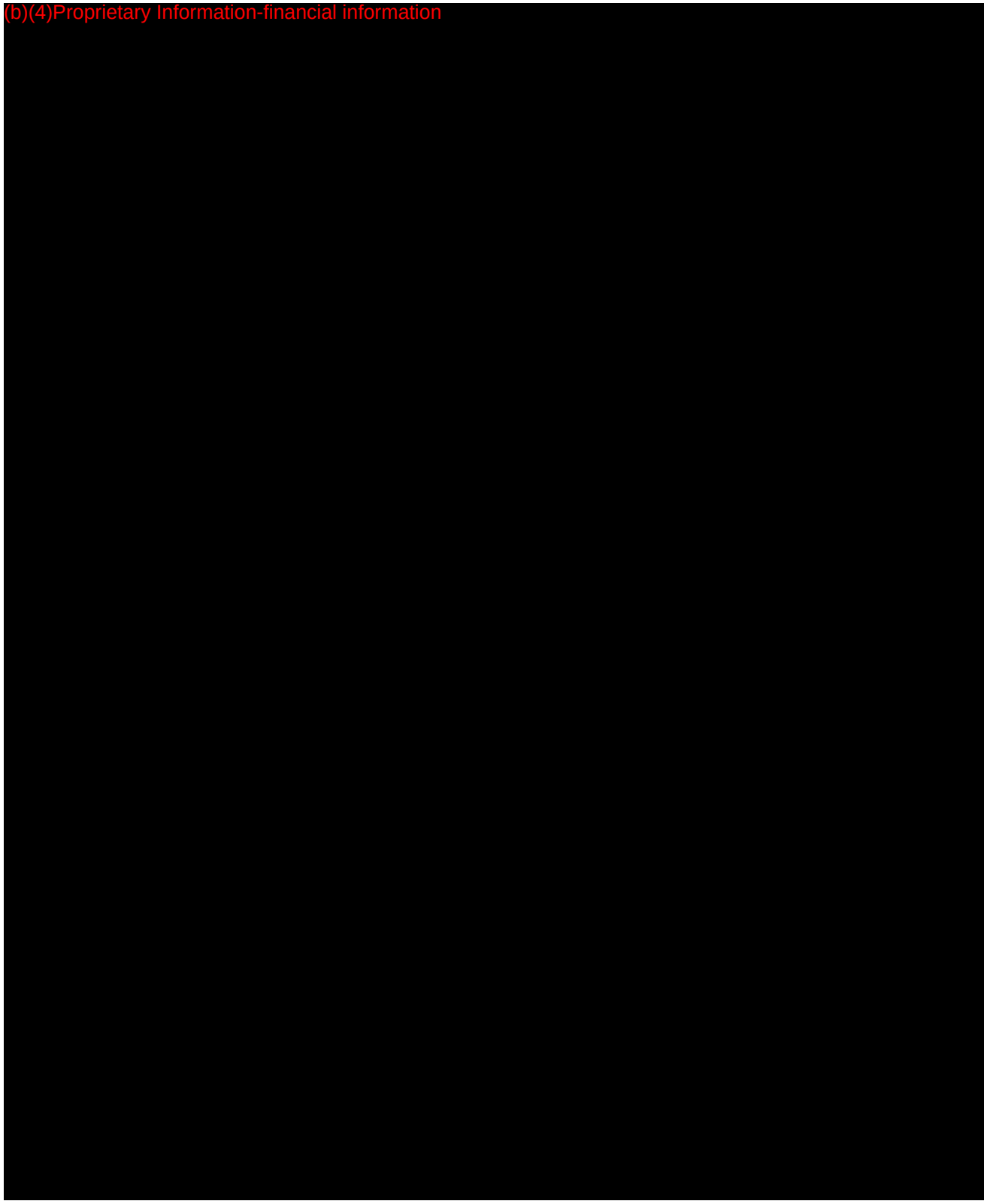
ATTACHMENT 4

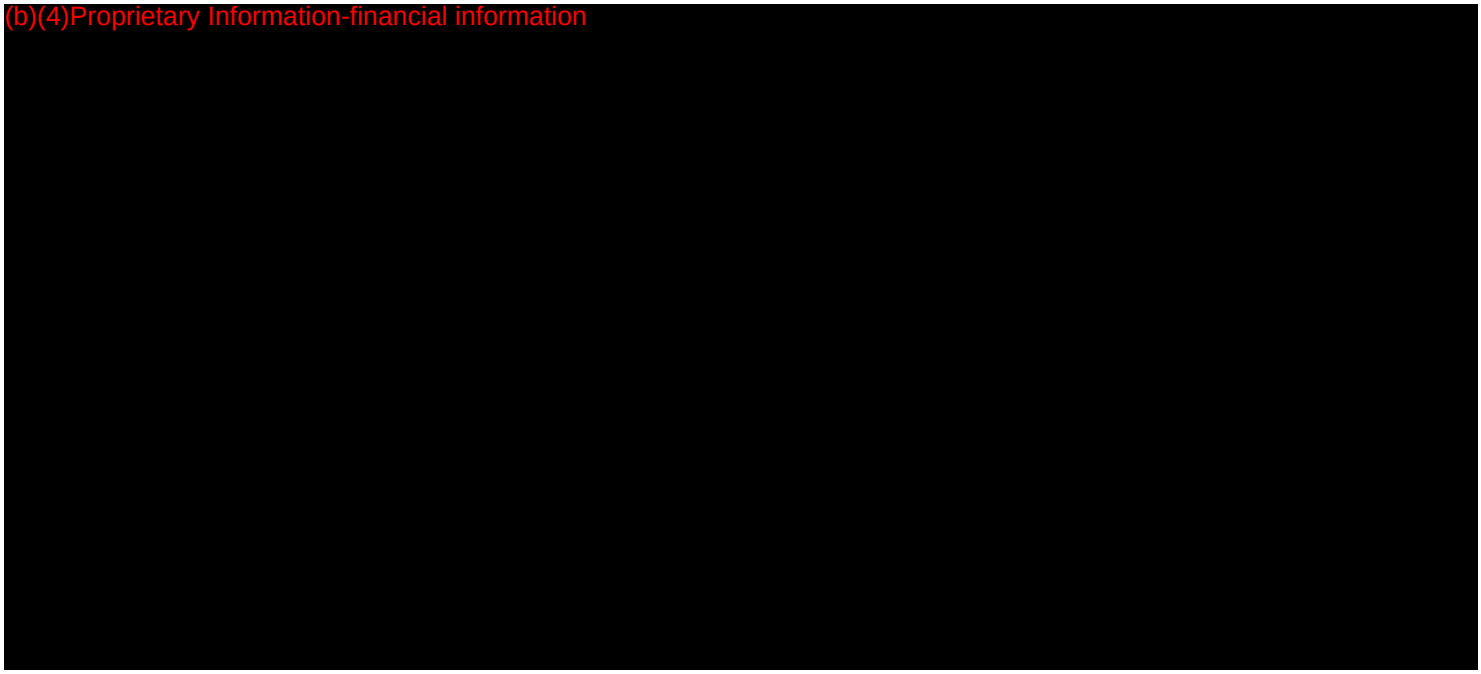
(b)(4)Proprietary Information-financial information

[redacted]

(b)(4)Proprietary Information-financial information

(b)(4)Proprietary Information-financial information





(b)(4)Proprietary Information

ATTACHMENT 5

Xlumena

AXIOS™

Stent and Delivery System

TABLE OF CONTENTS

AXIOS™
Stent and Delivery System

DEVICE DESCRIPTION

The AXIOS™ Stent and Delivery System is an endoscopic device designed to enable the therapeutic endosonographer to deliver a transenteric stent between the gastrointestinal tract and a pancreatic pseudocyst.

The AXIOS™ Stent is a flexible, MRI compatible, fully-covered self-expanding metal stent that is preloaded within the Delivery System.

The AXIOS™ Delivery System is compatible with therapeutic echoendoscopes having a working channel of 3.7 mm diameter or larger.

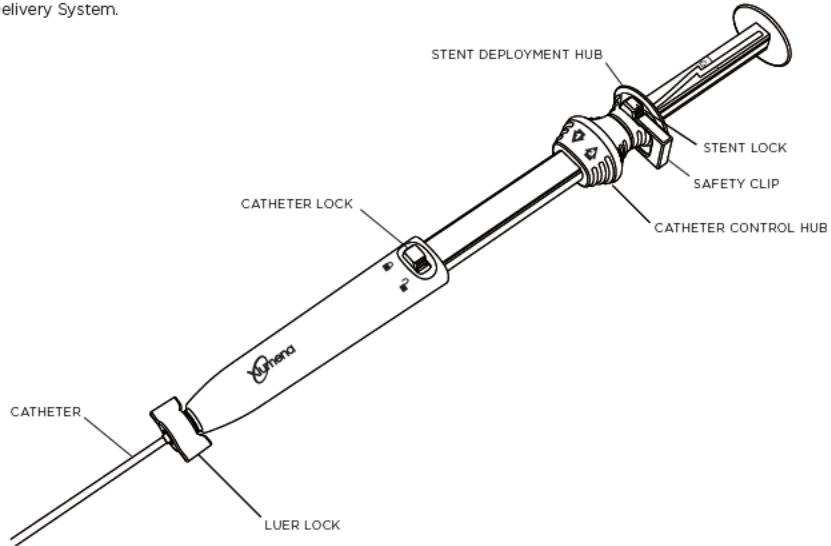


FIGURE 1. AXIOS™ Delivery System handle. The catheter control hub advances and retracts the catheter. The stent deployment hub releases the stent from the catheter.

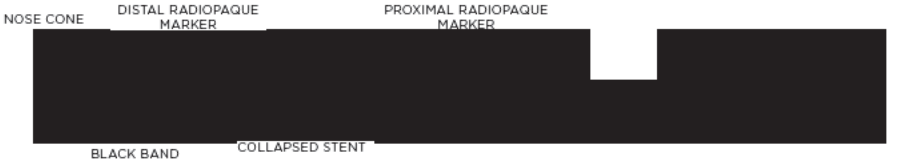


FIGURE 2. The collapsed stent is contained within the distal end of the catheter. A black band at the end of the catheter is used to position the stent proximal flange for deployment. Two radiopaque bands indicate the proximal and distal edges of the stent.

RECOMMENDED STENT SELECTION METHOD (see Stent Size Table)

- Select the 10mm diameter stent for draining anechoic fluid collections with EUS imaging (i.e., pseudocyst is predominantly fluid-filled).
- Select the 15mm diameter stent for more complex pseudocyst content (e.g., necrosis, pus, etc.), or if debridement, lavage, irrigation and cystoscopy will be needed.

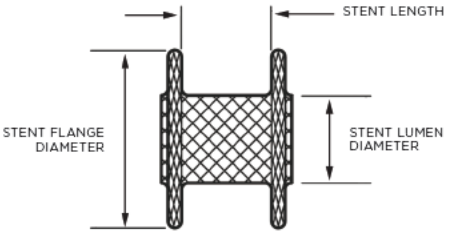


FIGURE 3. The stent is made of Nitinol wire and fully covered with silicone.

STENT SIZE

Catalog/Model Number	Description	Stent Size (nominal)			Delivery System Outer Diam.
		Flange Diameter	Lumen Diameter	Stent Length	
AXS(US)-10-10	AXIOS System with 10x10 Stent	21 mm	10 mm	10 mm	10.8 Fr
AXS(US)-15-10	AXIOS System with 15x10 Stent	24 mm	15 mm	10 mm	10.8 Fr

PACKAGE CONTENTS

One (1) AXIOS™ Stent and Delivery System

STORAGE

Store in a cool, dry place.

INDICATIONS FOR USE

The Xlumena AXIOS™ Stent and Delivery System is indicated for use to facilitate transgastric or transduodenal endoscopic drainage of symptomatic pancreatic pseudocysts ≥ 6cm in size, with ≥ 70% fluid content that are adherent to the gastric or bowel wall. Once placed, the AXIOS Stent functions as an access port allowing passage of standard and therapeutic endoscopes to facilitate debridement, irrigation and cystoscopy. The stent is intended for implantation up to 60 days and should be removed upon confirmation of pseudocyst resolution.

CONTRAINDICATIONS

- All cardiovascular applications.
- Cystic neoplasms.
- Pseudoaneurysms.
- Duplication cysts.
- Non-inflammatory fluid collections.
- Patients with abnormal coagulation.
- Patients with altered anatomy that precludes the physician's ability to deliver the stent.
- Patients with intervening gastric varices or vessels within a one centimeter radius of the device needle.
- Patients with any prior true anaphylactic reaction to contrast agents, nitinol (nickel titanium), silicone or any other materials contacting the patient.

WARNINGS AND PRECAUTIONS

- Placement of the AXIOS™ Stent should be performed by physicians familiar with endoscopic ultrasonography and received training for endoscopic stent placement techniques.
- Package contents are supplied sterile by ethylene oxide (EO). Do not use if sterile barrier is open or damaged. If the product or package is damaged, contact Xlumena, Inc.
- Do not use this device in any echoendoscope with a working channel smaller than 3.7 mm.
- The stent cannot be resheathed once deployment has been initiated.
- The AXIOS Stent implantation should not exceed 60 days.
- Long-term patency of this stent has not been established. Periodic evaluation of the stent is advised.
- For single patient use only. Do not reuse, reprocess, or resterilize. Reuse, reprocessing, or resterilization may lead to device failure, create a risk of contamination and/or cause the transmission of infectious disease(s). Reuse of the device may lead to injury, illness, or death.
- Do not remove the stent from its delivery system prior to use.
- This stent must only be placed using the delivery system provided.
- Do not use this device for any purpose other than its stated intended use.
- Care is required during dilation, debridement, irrigation, and cystoscopy procedures through the stent, to prevent air/fluid leak and/or stent dislodgement.
- Examine all components to be used during procedure. Do not use a device that has been cut, burned or damaged.

POTENTIAL COMPLICATIONS

Potential complications associated with the use of the AXIOS™ Stent and Delivery System may include those often associated with any endoscopic procedure. These complications include:

- Partial or failed stent expansion, stent collapse.
- Device failure, including failure to deliver the stent.
- Stent ingrowth/failure to remove stent.
- Stent migration/dislodgement.
- Adverse reaction to implant and/or delivery system (e.g., abdominal or back pain, nausea, infection, fever, chronic inflammation/foreign body reaction).
- Excessive bleeding (requiring intervention).
- Leakage of pseudocyst or bowel contents/peritonitis.
- Tissue damage or ulceration (during stent implantation and/or removal).
- Pneumoperitoneum.
- Perforation.
- Surgical intervention (endoscopy, transfustion or surgery).
- Death.

CLINICAL STUDY

Results from a multi-center clinical study demonstrate the safety and effectiveness of the AXIOS Stent and Delivery System. An overview of the study protocol is provided in the table below.

Overview of AXIOS Study Protocol

Study Objective:	To demonstrate the safety and effectiveness of the AXIOS Stent and Delivery System for endoscopic drainage of symptomatic pancreatic pseudocysts
Device Name:	AXIOS Stent and Delivery System
Study Design:	Prospective, multi-center, non-blinded, single-arm (nonrandomized)
Subjects Enrolled:	32 (18 male and 15 female)
Number of sites:	Seven (7) investigational sites
Safety Endpoint:	Freedom from major complications through the duration of AXIOS stent implantation and 1-week post-stent removal
Effectiveness Endpoint:	Acceptable rate of stent lumen patency; stent removability; technical and clinical success at 30 days and/or 60 days
Study Population:	Subjects between 18 and 75 years of age, suitable for transluminal drainage of symptomatic pancreatic pseudocysts that are greater than or equal to 6 cm in diameter and adherent to the bowel wall are candidates for study treatment
Assessments:	
Pre-Op	General/physical health and abdominal imaging were assessed to identify condition(s) that would affect the planned course of the treatment (e.g., co-morbidities, medications etc.)
IntraOp	Endoscopy with endosonography (EUS)
PostOp	At 30 days, 60 days and 1 week post stent removal: General/physical health, endoscopy and/or radiographic imaging; subsequent intervention. At 3 months and 6 months: Telephone follow-up regarding General/physical health; subsequent intervention
Adverse Events	Monitored throughout study

Patient Selection Criteria

Inclusion Criteria: Subjects must meet all criteria.

1. Age between 18 and 75 years old, male or female.
2. Eligible for endoscopic intervention.
3. Acceptable candidate for endoscopic transluminal pancreatic pseudocyst drainage.
4. Symptomatic pancreatic pseudocyst having the following characteristics:
   a. Greater than or equal to 6 cm in size (based upon the maximum cross-sectional area in the CT scan),
   b. Adherent to bowel wall, and
   c. ≥70% fluid content.
5. Subject understands the study requirements and the treatment procedures and provides written Informed Consent using a form that has been approved by the local Institutional Review Board or Ethics Committee before any study-specific tests or procedures are performed.
6. Subject is willing to comply with all specified follow-up evaluations, including willingness to undergo a pre/post CT imaging study.

Exclusion Criteria: Subjects meeting any of the following criteria were excluded from study.

1. The fluid collection to be drained is an immature pseudocyst.
2. The fluid collection to be drained is a cystic neoplasm.
3. The fluid collection to be drained is a pseudoaneurysm.
4. The fluid collection to be drained is a duplication cyst.
5. The fluid collection to be drained is a non-inflammatory fluid collection.
6. There is more than one pseudocyst requiring drainage.
7. Abnormal coagulation:
   a. INR > 1.5 and not correctable
   b. presence of a bleeding disorder
   c. platelets < 50,000/mm^3.
8. Altered anatomy that precludes the physician's ability to deliver the stent (decision on a case by case basis).
9. Intervening gastric varices or vessels within a one centimeter radius of the needle (visible using endoscopy or endoscopic ultrasound).
10. Any prior true anaphylactic reaction to contrast agents, nitinol (nickel titanium), silicone or any other materials contacting the patient.
11. Female of childbearing potential with a positive pregnancy test prior to the procedure or intends to become pregnant during the study.
12. Currently participating in another investigational drug of device study that has not completed the primary endpoint or that clinically interferes with the endpoints of this study.

Study Results

The Intent-to-Treat study group consisted of 33 subjects who provided consent and treated with the AXIOS Stent and Delivery System. The group included one subject who received two stents for two distinct pseudocysts. Three (3) patients not receiving stents, and an additional patient who had pigtail stents and a nasocystic tube placed alongside the AXIOS stent (through a second cystgastrostomy) were excluded from the Per-Protocol analysis. A modified Intent-to-Treat subset (n=30) included all subjects who received an AXIOS stent during the index procedure (i.e., underwent successful AXIOS stent placement).

Patients (55% male) were 53 years of age (average). Eighty-five percent (85%) of study subjects had a history of pancreatitis. Gallstone disease and alcohol abuse were present in 20% of subjects. Pancreatic pseudocysts with average diameter of 9.0 cm (stdev 3.3 cm) were treated.

Effectiveness: Thirty (30) stents were placed in 33 subjects with no intra-operative complications. AXIOS stent patency was confirmed with drainage visualized for all stents placed. The overall effectiveness demonstrated for AXIOS Stent and Delivery System is summarized in the table below.

AXIOS Overall Effectiveness.

Effectiveness Measure	Study Subset	Overall Effectiveness by Endpoint
Technical success, defined as Placement of the AXIOS stent, and	**Intent-to-Treat**	**90.9% (30/33)**
Removal of the AXIOS stent using a standard endoscopic tools.	**modified Intent-to-Treat**	**96.7% (29/30)**
Stent lumen patency	**Per-Protocol**	**93.1% (27/29)**
Debridements		31.0% (9/29)
Supplemental stenting (stent-in-stent)		10.3% (3/29)
Clinical success, defined as at least a 50% decrease in pseudocyst size, based on radiographic analysis,	**Per-Protocol**	**86.2% (25/29)**
Overall Effectiveness	**Per-Protocol**	**86.2% (25/29)**

Immediate post procedure endoscopic exams, as well as exams at stent removal noted no injury to surrounding tissue at the AXIOS stent site. Resolution of the treated pancreatic pseudocysts was achieved in a majority of the subjects. For some subjects, debridement, lavage, irrigation and cystoscopy was required and performed through the AXIOS Stent as an access port. AXIOS stent removal was readily performed using standard endoscopic tools (snares, forceps, etc.) with no injury to the treatment site.

Safety: The pivotal study results demonstrated that there were no unanticipated events related to the use of the device or the echoendoscopic approach in its deployment. Serious adverse events deemed related to the AXIOS device or the index procedure were the same type of events as those generally associated with endoscopic pancreatic pseudocyst drainage with commercially available stents and delivery systems (see table below).

Serious Adverse Events

Events*	% (n/N)
Access site-related bleeding requiring transfusion;	0
Access site-related infection requiring IV/IM antibiotics and extended hospitalization;	3.0% (1/33)
Surgery for access-site related perforation;	0
Stent migration/dislodgement into the pseudocyst or enteral lumen;	3.0% (1/33)
Tissue injury (ulceration to the submucosa at site of stent implant as observed to persist through 1-week post-stent removal);	0
Back pain due to drainage leak/peritonitis	3.0% (1/33)
Pseudoaneurysm requiring embolization	3.0% (1/33)
Fever and prolonged hospitalization	3.0% (1/33)
Abdominal Pain requiring endoscopy	3.0% (1/33)
Overall Rate	**15.2% (5/33)**

* rates based on Intent-to-Treat; Subjects may experience more than one event

Conclusion

The AXIOS stent design and construction is optimized for controlled placement, maintaining patency, preventing migration and easy removal. Once placed, the stent provides a large diameter conduit and the bi-flange design secures access to the pseudocyst. The stent is provided fully covered to minimize tissue ingrowth.

The study of the AXIOS Stent and Delivery System demonstrated the AXIOS devices to be predictable and easy to use. There were no intraoperative adverse events during AXIOS stent placement or removal. There were no unanticipated complications or new risks related to the implantation and removal of the AXIOS stent. The AXIOS Stent and Delivery System is deployed using current strategies and techniques for clinical assessment and treatment. In conclusion, the AXIOS devices were safe and effective for the endoscopic transenteric drainage of symptomatic pancreatic pseudocysts.

INSTRUCTIONS FOR USE

Device Inspection

- **Do not use if the sterile barrier (inner packaging) is open or damaged.**
- **Carefully remove the AXIOS™ Stent and Delivery System from its packaging.**
- Inspect the device for damage or defects.
- Check that the distal end of the catheter is not separated from the nose cone (Figure 4).
- Do not use if the distal end of the catheter is separated from the nose cone. Return the product to Xlumena, Inc.

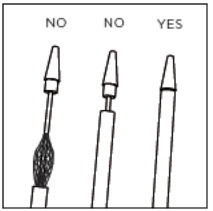


FIGURE 4. The two examples on the left ("NO") show separation of the nose cone from the catheter. The "YES" drawing illustrates the correct position of the nose cone as contiguous with the catheter.

Preparation

- Select a site for stent placement that is clear of intervening blood vessels. The stent should be placed at maximal wall adherence and at the largest diameter of the pseudocyst.
- The AXIOS™ Delivery System requires an access site of at least 10Fr. Access the pseudocyst with a 19G needle 10Fr cystotome or the NAVIX Access Device. Bougie, balloon diliation or cystotomes can be used to enlarge the tract to accommodate the AXIOS™ catheter.
- Ensure that a 0.035 inch guidewire has been placed through the echoendoscope working channel and into the target structure.
- Ensure that the echoendoscope elevator is in the lowered (open) position (Figure 5).

FIGURE 5. Ensure the elevator is in the lowered (open) position when inserting or advancing the delivery system. The up (closed) elevator position is incorrect and will inhibit catheter advancement.

Procedure

1. **Wet and insert the catheter into the echoendoscope and secure the Luer lock.** Wet the catheter with sterile water or normal saline. Access the pseudocyst via the Seldinger technique. Slowly insert the catheter into the working channel of the therapeutic echoendoscope over the 0.035 inch guidewire, being careful not to bend or kink the catheter. Advance the AXIOS™ Delivery System until the handle Luer lock aligns and fits into the working channel fitting. Rotate the winged Luer lock clockwise to secure the delivery system handle to the echoendoscope (Figure 6).

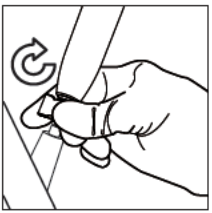


FIGURE 6. Align the handle with the echoendoscope and attach it by rotating the Luer lock fitting clockwise.

NOTE: After fitting the delivery system into the echoendoscope, the catheter tip will not be visible under endoscopic ultrasound (EUS) or endoscopic view. It will be visible only when the catheter is advanced as described in step 2.

2. **Position the guidewire and catheter to the target structure.** Using EUS imaging, visualize the guidewire through the target structure. Unlock the catheter lock (Figure 7) and advance the (black) catheter control hub (Figure 8) until the distal catheter position is visible.

3. **If necessary adjust echoendoscope elevator.** Under EUS imaging, adjust the echoendoscope elevator to the desired angle.

   NOTE: The AXIOS™ stent cannot be resheathed after the stent distal flange has been deployed.

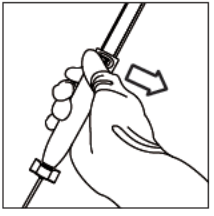


FIGURE 7. Push the catheter lock to the right to unlock the catheter and to the left to relock it.

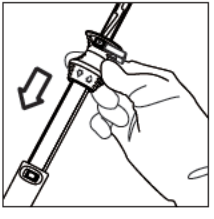


FIGURE 8. With the catheter unlocked, carefully advance the catheter control hub (in the direction indicated by the "1" arrow on the hub) so that the distal end of the catheter moves towards and into the target structure.

   CAUTION: Do not attempt to advance or retract the delivery system against resistance until the cause of resistance has been determined.

4. **Confirm distal catheter into target structure.** Using EUS imaging, ensure that the distal end of the catheter is positioned at the desired location. Advance carefully, especially if resistance is felt. Retract the catheter control hub slightly until the catheter is seen moving proximally on the EUS image. This removes compression from the catheter shaft and facilitates stent deployment. Make sure that the distal catheter is at least 3-4 cm beyond the inner margin of the target structure. **Lock the catheter lock to ensure that the delivery catheter does not move during deployment of the stent distal flange.**

5. **Deploy the stent distal flange.** Press down on the yellow safety clip to remove it from the stent deployment hub. Under EUS imaging, deploy the stent distal flange by unlocking the stent lock (Figure 9) and retracting the stent deployment hub to the halfway point indicated on the handle (Figure 10). A "click" will be heard as the stent deployment hub automatically locks into place (at the "2" arrow line).

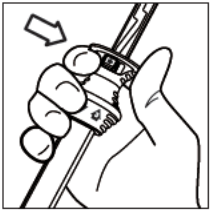


FIGURE 9. Push the stent lock to the right to unlock the stent deployment hub. The lock automatically relocks when the hub reaches the stent distal flange deployment stop.

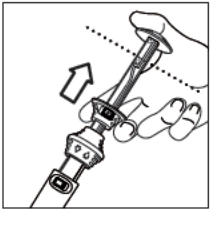


FIGURE 10. Holding the handle and hub like a syringe, retract the hub to release the stent distal flange. The hub will "click" and lock into place at the "2" arrow line.

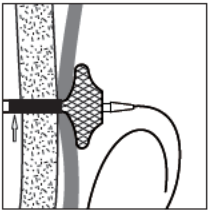


FIGURE 11. Under endoscopic view, confirm at least 2-3 mm of the black band is visible in GI tract (see arrow). This indicates that the stent distal flange is correctly positioned against the lumen wall.

CAUTION: Do not advance the catheter control hub once the stent distal flange has been deployed. The catheter control hub should remain locked to avoid unintended stent proximal flange deployment.

Very Important: Before moving on to the next step, verify with EUS imaging that the stent distal flange is deployed inside the target structure.

CAUTION: Excessive retraction may pull the stent out of the target structure or result in poor positioning of the stent distal flange.

6. **Switch to endoscopic view.** Pull the echoendoscope off the stomach or duodenal wall to obtain an endoscopic view of the stent catheter as it exits the wall. The black band may be visible at this point.

   CAUTION: Under endoscopic view, confirm that at least 2-3 mm of the black band is visible in the gastrointestinal tract (Figure 11). This indicates that the stent is correctly positioned for the deployment of the stent proximal flange.

7. **Position the stent proximal flange with the catheter control hub.** If necessary, unlock the catheter lock and retract the catheter control hub (Figure 12) until at least 2-3 mm of the black band is visible in the gastrointestinal tract under direct endoscopic view. Lock the catheter lock to ensure that the catheter does not move during deployment of the stent proximal flange.

CAUTION: Never advance the catheter control hub during stent deployment. This can result in the premature deployment of the stent proximal flange.

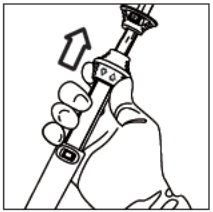


FIGURE 12. If necessary, carefully retract the catheter control hub (as indicated by the "3" arrow on the hub). Under endoscopic view, position the stent proximal flange for deployment by confirming that at least 2-3 mm of the black band is visible in the GI tract.

8. **Deploy the stent proximal flange.** Unlock the stent lock and retract the stent deployment hub to the top of the handle in the direction indicated by the "4" arrow (Figure 13). Under direct endoscopic visualization, verify that the stent proximal flange is deployed within the gastrointestinal tract.

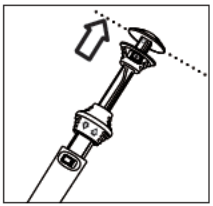


FIGURE 13. Under endoscopic view, deploy the stent proximal flange by retracting the stent deployment hub.

Delivery System Removal from Echoendoscope

Following deployment of the AXIOS™ Stent, rotate the Luer lock at the base of the handle counterclockwise. Remove the delivery catheter by pulling it upward and out of the working channel. If desired, maintain the guidewire position across the target structure as the catheter is removed.

Dispose of the delivery system in accordance with institutional guidelines for biohazardous medical waste.

Stent Dilation

CAUTION: Care is required during dilation of the stent, to prevent air/fluid leak and/or stent dislodgement.

If desired, place a balloon catheter over the guidewire and into the central lumen of the stent. Dilate the stent 10 mm for the AXS-10-10 and AXS-15-10. Post-dilation allows the AXIOS™ stent flanges to fully expand, which secure the stent in place and optimizes transenteric drainage.

Additional Procedures

CAUTION: Care is required during debridement, irrigation, and cystoscopy procedures through the stent, to prevent air leak and/or stent dislodgement.

The AXIOS™ stent bi-flange design and large diameter provides a secure conduit for additional diagnostic interventions. Once placed, the AXIOS™ stent functions as a port allowing passage of standard and therapeutic endoscopes to facilitate debridement, irrigations and cystoscopy.

AXIOS™ Stent Removal

Under endoscopic visualization, place a standard endoscopic snare over the stent proximal flange. Tighten the snare until the stent lumen collapses. Pull the snare away from the gastrointestinal wall until the stent is removed from the tract.

> **NOTE:** The snare must be large enough to fit over the proximal flange of the AXIOS™ Stent (which can be up to 24 mm in diameter). The echoendoscope will need to be removed in order to retrieve the stent.

Stent removal may also be performed with endoscopic forceps. The stent is braided in such a way that it will not unravel if the forceps happen to break a wire.

Once removed, the stent must be disposed of according to institutional guidelines for biohazardous medical waste.

TROUBLESHOOTING

Some echoendoscope and elevator positions result in excess friction between the catheter and the working channel. Friction can produce length-wise compression (shortening) of the catheter as it is advanced through the working channel and conversely, extension (lengthening) when the catheter is retracted. Friction impacts the performance of the AXIOS™ Delivery System; therefore the solutions below include both lowering (opening) the elevator and straightening the echoendoscope.

PROBLEM	POTENTIAL SOLUTION(S)
There is excessive resistance when trying to pass the catheter through the working channel.	• If the catheter is less than 2 cm from full insertion, lower (open) the echoendoscope elevator and straighten the distal end of the echoendoscope. • If the catheter is less than 10 cm from full insertion, straighten the echoendoscope. • If the catheter is more than 10 cm from full insertion, remove it from the echoendoscope. Pass another tool to see if the working channel is obstructed.
The catheter cannot be advanced from its post-insertion position.	• Make sure the catheter is unlocked. • Ensure the echoendoscope elevator is lowered (open). • Straighten the echoendoscope position. • Remove the catheter from the working channel and confirm that it is not kinked or damaged and that the nose cone is contiguous with the catheter. • Lubricate the distal end of the catheter and reinsert it into the working channel.
The catheter can be advanced but it does not enter the target structure.	• Ensure that the access site is at least 10Fr. The AXIOS™ catheter is 10.8Fr and will not easily enter an opening smaller than 10Fr. • Under EUS imaging, ensure that the guidewire is visible. Confirm that the nose cone and catheter are axially aligned with the guidewire at the target structure. • Adjust/realign the echoendoscope position.
Resistance makes it difficult to retract the stent deployment hub.	• Ensure the echoendoscope elevator is lowered (open). • Straighten the echoendoscope as much as possible. • Reduce friction within the catheter: 1. Remove the catheter from the echoendoscope. Insert a guidewire through the proximal end of the Delivery System until the guidewire extends out of the distal tip at least 15 cm (this prevents catheter damage). 2. Hold the catheter straight. Slowly retract the stent deployment hub until the distal end of the stent is visible. 3. Carefully push the nose cone proximally until it is seated against the distal end of the catheter (see Figure 4). 4. Remove the guidewire and reinsert the catheter into the echoendoscope working channel.

PROBLEM	POTENTIAL SOLUTION(S)
The stent distal flange is not deployed even though the stent deployment hub has clicked into position (at the "2" arrow line).	• Ensure the echoendoscope elevator is lowered (open). • Straighten the echoendoscope position. • Unlock the catheter lock, advance the catheter control hub, and confirm the stent distal flange deployment. Retract and advance the catheter control hub as necessary. Relock the catheter lock. • To limit deployment hub travel, grasp the handle at 5-10 mm above the "2" arrow line. Unlock the stent lock and carefully retract the stent deployment hub while closely monitoring the EUS image. Stop retracting the hub immediately when the stent distal flange has deployed. **DO NOT RETRACT MORE THAN 1 CM.** **CAUTION:** Retracting the deployment hub too far may result in the entire stent deploying inside the target structure.
The catheter cannot be seen (or is seen with difficulty) on the endoscopic view when attempting to deploy the stent proximal flange.	Under EUS imaging, retract the catheter control hub so that the stent distal flange is seen tugging against the inner target wall. Deploy the stent proximal flange in accordance with Instructions for Use.
The stent proximal flange does not deploy even though the stent deployment hub has been retracted to the top of the handle.	Unlock the catheter lock and slowly advance the catheter control hub to push the stent proximal flange out of the echoendoscope working channel.
There is excessive resistance and the catheter lock has not been released when trying to pass the catheter through the working channel. **After the catheter is advanced into endoscopic view, there is an observed separation between the tip (nose cone) and the outer sheath. The stent may or may not be partially visible.**	• Unlock the catheter lock and advance the catheter 2-3 cm beyond the echoendoscope elevator. Lock the catheter lock. • Lock the echoendoscope elevator in the up (closed) position to hold the outer catheter sheath. • Withdraw the catheter by unlocking the catheter lock and pulling the handle until either: – the sheath and tip are in contact and the tip is resheathed, or – the sheath or tip is near the echoendoscope elevator. • Ensure the echoendoscope elevator is lowered (open) and advance the catheter. • If the tip is resheathed, continue with the procedure as normal. • If resheathing procedure is unsuccessful, withdraw the device and return it to Xlumena, Inc.

WARRANTY

Xlumena, Inc. warrants that reasonable care has been used in the design and manufacture of this product. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to any other implied warranties of merchantability or fitness. Handling, storage, cleaning, and sterilization of this device as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond Xlumena's control can directly affect the device and the results obtained from its use. Xlumena's obligation under this warranty is limited to the repair or replacement of this device. Xlumena shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this device. Xlumena neither assumes, nor authorizes any other person to assume other or additional liability or responsibility in connection with this device. Xlumena assumes no liability for any device reuse, reprocessing or resterilization, and makes no warranties, expressed or implied, including but not limited to merchantability or fitness for the intended use, of said device.

MRI INFORMATION

MR Conditional

Non-clinical testing demonstrated that the AXIOS™ Stent is MR Conditional.

A patient with an implanted AXIOS™ Stent can be scanned safely under the following conditions:

- Static magnetic field of 3-Tesla or less
- Maximum spatial gradient magnetic field of 720-Gauss/cm or less

MRI-Related Heating

In non-clinical testing, the AXIOS™ Stent produced a maximum temperature change of +1.7°C during MRI performed for 15 minutes of scanning (i.e., per pulse sequence) in the 3-Tesla (3-Tesla/128-MHz, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MR system.

Therefore, the MRI-related heating experiments for the AXIOS™ Stent at 3-Tesla using a transmit/receive RF body coil at an MR system reported whole body averaged SAR of 2.9-W/kg (i.e., associated with a calorimetry measured whole body averaged value of 2.7-W/kg) indicated that the greatest amount of heating that occurred in association with these specific conditions was equal to or less than +1.7°C.

Artifact Information

MR image quality may be compromised if the area of interest is in the exact same area, or relatively close to, the position of the AXIOS™ Stent. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary. The maximum artifact size (i.e., as seen on the gradient echo pulse sequence) extends approximately 10 mm relative to the size and shape of the AXIOS™ Stent.

Artifacts at 3 Tesla

Pulse Sequence	T1-SE	T1-SE	GRE	GRE
Signal Void Size	423 mm²	504 mm²	808 mm²	712 mm²
Plane Orientation	Parallel	Perpendicular	Parallel	Perpendicular

The safety of the delivery system has not been evaluated in the MR environment, and therefore, the delivery system should not be used in the MR environment.

DEFINITION OF SYMBOLS

	CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician		Consult Instructions for Use
	Lot Number		Manufactured By
	Use By Date		MR Conditional
	Do Not Use If Package Is Damaged		Authorized Representative in the European Community
	Not made with natural rubber latex		
	Single Use Only/Do Not Re-use		
	Do Not Re-sterilize		
	Keep Dry		
	Catalogue/Model number		
	Sterilized Using Ethylene Oxide		

Please carry this card at all times and show it to any medical personnel that may be treating you

Xlumena

Patient Name:

Date of Implant:

Site of Implant:

Hospital Name:

Implanting Physician:

Implanting Physician:
Telephone

Patient Information Card
IMPLANTED DEVICE

AFFIX DEVICE LABEL HERE

Notify your physician prior to your MRI Scan.
Non-clinical testing demonstrated that the AXIOS™ stent is MR Conditional.
A patient with this device can be scanned safely immediately after placement under the following conditions:

- Static magnetic field of 3-Tesla or less
- Maximum spatial gradient magnetic field of 720-Gauss/cm or less
- Maximum whole body averaged specific absorption rate (SAR) of 2-W/Kg for 15 minutes of scanning

For questions regarding your AXIOS Stent or procedure, please contact your implanting physician or Xlumena at 1-888-XLUMENA.

PATENTS AND TRADEMARKS

XLUMENA and AXIOS are trademarks of
Xlumena, Inc.
Patents Pending: 8,425,539; 8,454,632; 8,357,193.

CUSTOMER SERVICE

EC REP

HealthLink Europe BV
De Tweeling 20-22
's-Hertogenbosch 5215 MC
The Netherlands
Phone: +31.13.547.9300
Fax: +31.13.547.9301

Xlumena, Inc.
453 Ravendale Drive, Suite H
Mountain View, CA 94043,
United States of America
Phone: +1.650.961.9900
Fax: +1.650.961.9901

EU Customer Service
E-mail: cs@healthlinkeurope.com
Phone: +31(0)73.303.0597
Fax: +31(0)20.799.8032

US Customer Service
E-mail: customerservice@xlumena.com
Phone: +1.888.XLUMENA (+1.650.961.9900)
Fax: +1.650.961.9901

CE
0459

LBS01118.C

AXIOS™

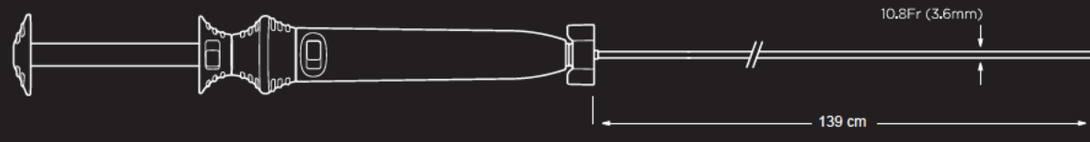
Stent and Delivery System

REF AXS(US)-10-10 10.8Fr (3.6mm)

Fully covered stent, MRI compatible

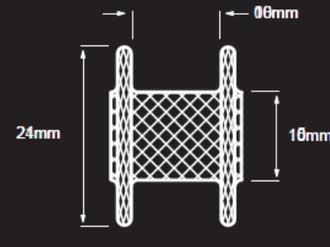
Recommended guidewire: 0.035 in (0.89mm)

(1) Disposable AXIOS Stent and Delivery System



10mm
Lumen diameter

10mm
Stent length



		MR	MR Conditional
Rx ONLY	CAUTION Federal (USA) law restricts this device to sale by or on the order of a physician		Consult Instructions for Use
LOT	Lot Number	REF	Catalogue / Model number
	Use By Date	STERILE EO	Sterilized Using Ethylene Oxide
	Do Not Use if Package is Damaged		Keep Dry
2	Single Use Only / Do Not Re-use	2 RESTERILIZE	Do Not Re-sterilize
LATEX	Not made with natural rubber latex		Manufactured By

lot #
Xlumena AXIOS Stent and Delivery System
REF AXS(US)-10-10

lot #
Xlumena AXIOS Stent and Delivery System
REF AXS(US)-10-10

lot #
Xlumena AXIOS Stent and Delivery System
REF AXS(US)-10-10

USA Customer Service +1.888.958.6362

MR | STERILE EO | Rx ONLY | EC REP HealthLink Europe BV, De Tweeling 20-22, 's-Hertogenbosch 5215 MC, The Netherlands, Tel: +31.13.547.9300 | 2 RESTERILIZE | LATEX | CE 0459 | LOT | lot # use by

Xlumena Inc. 453 Ravendale Drive, Suite H, Mountain View, CA 94043 xlumena.com

Patents Pending
8,425,539
8,454,632
8,357,193

LBS0112 A

AXIOS™
Stent and Delivery System
REF AXS(US)-10-10 10.8Fr (3.6mm)

10mm Lumen Diameter

10mm Stent Length

AXIOS™

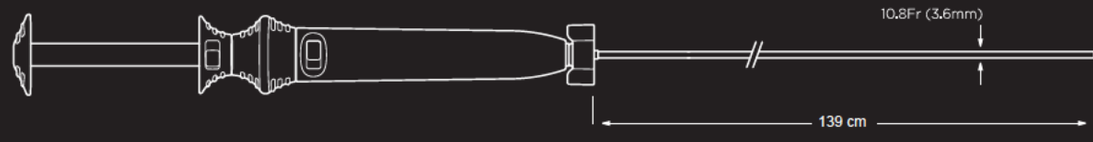
Stent and Delivery System

REF AXS(US)-10-[illegible] 10.8Fr (3.6mm)

Fully covered stent, MRI compatible

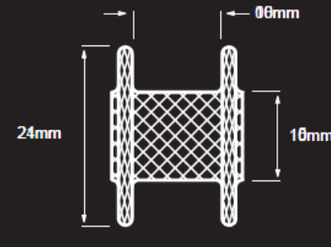
Recommended guidewire: 0.035 in (0.89mm)

(1) Disposable AXIOS Stent and Delivery System



16mm
Lumen diameter

06mm
Stent length



		MR	MR Conditional
Rx ONLY	CAUTION Federal (USA) law restricts this device to sale by or on the order of a physician		Consult Instructions for Use
LOT	Lot Number	REF	Catalogue / Model number
	Use By Date	STERILE EO	Sterilized Using Ethylene Oxide
	Do Not Use if Package is Damaged		Keep Dry
	Single Use Only / Do Not Re-use		Do Not Re-sterilize
LATEX	Not made with natural rubber latex		Manufactured By

lot #
Xlumena AXIOS Stent and Delivery System REF AXS(US)-10-06

lot #
Xlumena AXIOS Stent and Delivery System REF AXS(US)-10-06

lot #
Xlumena AXIOS Stent and Delivery System REF AXS(US)-10-06

USA Customer Service +1.888.958.6362

MR | STERILE EO | Rx ONLY | EC REP HealthLink Europe BV, De Tweeling 20-22, 's-Hertogenbosch 5215 MC, The Netherlands, Tel: +31.13.547.9300 | 0459 | LOT | lot # use by

Xlumena Inc. 453 Ravendale Drive, Suite H, Mountain View, CA 94043 xlumena.com

Patents Pending
8,425,539
8,454,632
8,357,193

LBS01[illegible]A

AXIOS™
Stent and Delivery System
REF AXS(US)-10-[illegible] 10.8Fr (3.6mm)

16mm Lumen Diameter

06mm Stent Length

ATTACHMENT 6

OCT 17 2002

K022595 - 12 -
Page 1 of 1

9. 510(K) SUMMARY

Submitted By:
Margaret J. Posner, Regulatory Affairs Specialist
Wilson-Cook Medical Inc.
4900 Bethania Station Road
Winston-Salem, NC 27105-4191
336-744-0157
July 29, 2002

Names of Device:

Trade Name:	Wilson-Cook Cystotome
Common/Usual Name:	Endoscopic electrosurgery device
Classification Name:	Endoscopic electrosurgery accessory 21 CFR 876.4300 (78KNS); Class II

Predicate Devices:
The Wilson-Cook Cystotome is comparable to predicate devices including the Wilson-Cook Needle Knife Papillotome (K972674); the Boston Scientific Autotome™ RX (K013153); and the Boston Scientific Microvasive Gold Probe (K970278).

Device Description:
The Wilson-Cook Cystotome consists of an inner wire with needle knife tip, a 5 Fr inner sheath, and a 10 Fr outer sheath equipped with a diathermic ring at its distal tip. The proximal end of the device will include a handle with connectors for active cords and a fitting to provide for injection of contrast fluid.

Intended Use:
The Wilson-Cook Cystotome is intended for use as an electrosurgical accessory to electrosurgically cannulate the transgastric or transduodenal wall and into a pancreatic pseudocyst, when it is visibly bulging into the gastrointestinal tract. It is supplied sterile and is intended for single use.

Substantial Equivalence:
The Wilson-Cook Cystotome is comparable to predicate devices with similar technological characteristics and intended use, specifically to perform electrosurgical procedures through an endoscope.

Discussion of Tests and Test Results:
The Wilson-Cook Cystotome underwent electrical testing, simulated use testing, and clinical testing. Test results provide reasonable assurance the device will perform in accordance with its intended use.

Conclusions Drawn from Tests:
Being similar to predicate devices with respect to intended use and technology, and having test results that indicate the device will perform in accordance with its intended use, the Wilson-Cook Cystotome meets the requirements for 510(k) substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 17 2002

Ms. Margaret J. Posner
Regulatory Affairs Specialist
Wilson-Cook Medical
GI Endoscopy
4900 Bethania Station Road
WINSTON-SALEM NC 27105

Re: K022595
Trade/Device Name: Wilson-Cook Cystotome
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: II
Product Code: 78 KNS
Dated: August 2, 2002
Received: August 5, 2002

Dear Ms. Posner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K022595

Device Name: Wilson-Cook Cystotome

Indications For Use:

The Wilson-Cook Cystotome is intended for use as an electrosurgical accessory to cannulate the transgastric or transduodenal wall and into a pancreatic pseudocyst that is visibly bulging into the gastrointestinal tract. This device is supplied sterile and is intended for single use only.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Segman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K022595

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)

IFU0005-7

COOK® MEDICAL

Cystotome
Цистотом
Cystotom
Cystotom
Cystotoom
Tsüstotoom
Cystotome
Cystotome
Κυστεοτόμος
Hólyagmetsző
Cistotomo
Cistotomijas ierīce
Cistotomija
Cystotomi-instrument
Cystotom
Cistótomo
Cistotom
Cystotóm
Cistótomo
Cystotom

English

INTENDED USE
This device is designed to electrosurgically puncture a hole in the transgastric or transduodenal wall and into a pancreatic pseudocyst, when it is visibly bulging into the gastrointestinal tract.

NOTES
Do not use this device for any purpose other than the stated intended use.

If the package is open or damaged when received, do not use.

Visually inspect with particular attention to kinks, bends and breaks. If an abnormality is detected that would prohibit proper working condition, do not use. Please notify Cook for return authorization.

Store in a dry location, away from temperature extremes.

CAUTION
U.S. Federal Law restricts this device to sale by or on the order of a physician.

CONTRAINDICATIONS
Contraindications include those specific to blood coagulation disease, interposing vessels between the pseudocyst wall and that of the stomach or the duodenum. If the pseudocyst is < 4cm in diameter do not proceed.

POTENTIAL COMPLICATIONS
Potential complications associated with GI endoscopy include, but are not limited to: sepsis, perforation, hemorrhage, aspiration, fever, infection, allergic reaction to medication, hypotension, respiratory depression or arrest, cardiac arrhythmia or arrest.

PRECAUTIONS
Refer to package label for minimum channel size required for this device.

Maximum rated input voltage for this device is 2.0 kVp-p.

Any electrosurgical accessory constitutes a potential electrical hazard to patient and operator. Possible adverse effects include, but are not limited to: fulguration, burns, nerve and/or muscle stimulation and cardiac arrhythmia.

Before using this device, follow recommendations provided by electrosurgical unit manufacturer to ensure patient safety through proper placement and utilisation of patient return electrode. Ensure a proper path from patient return electrode to electrosurgical unit is maintained throughout procedure.

Examine all components to be used during procedure. Do not use a device that has been cut, burned or damaged. Damaged device insulation may cause unsafe currents in either patient or operator.

Switch electrosurgical unit to "off" position when not in use.

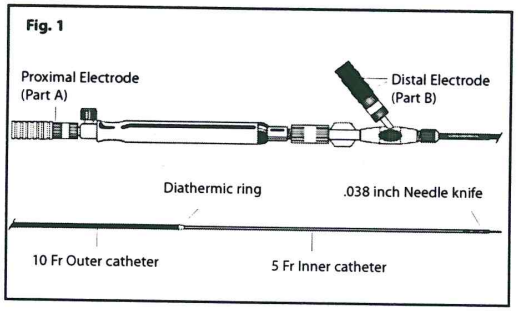
When applying current, ensure needle knife is completely out of endoscope. Contact of needle knife with endoscope may cause grounding, which can result in patient injury, operator injury, a broken needle knife and/or damage to endoscope.

INSTRUCTIONS FOR USE **Illustrations**

1. Upon removing from package, uncoil device. **Note:** Do not extend or retract the needle knife while the device is coiled as this may cause damage to the device. Extend and retract the needle when the device is straight.
2. Examine features of device. It consists of a 10 French outer catheter with a diathermic ring, a 5 French inner catheter with a removable .038 inch needle knife and electrodes located distal and proximal to the handle. Proximal electrode (Part A) is indicated for needle knife, the distal electrode (Part B) is indicated for the diathermic ring (see Fig. 1).
3. With the electrosurgical unit off, prepare equipment. Active cord fittings should fit snugly into both device handle and electrosurgical unit. **Note:** Set the unit to pure cutting current (80-120 watts).
4. With the needle knife fully retracted into sheath, introduce device into endoscope accessory channel. Advance device in short increments until it is endoscopically visualized exiting the scope.
5. Once tip is visualized exiting scope, position catheter and extend needle knife to desired length. Identify position of cyst bulging into stomach and/or duodenum. With electrosurgical unit off determine position of puncture site.
6. Following electrosurgical unit manufacturer's instructions, verify desired settings and activate electrosurgical unit.
7. Puncture pseudocyst with needle knife using the pure cutting current.
8. Once puncture is complete, turn electrosurgical unit off and disconnect active cord from device handle.

9. With needle in the cyst, inject contrast to fill pseudocyst under fluroscopic visualisation.
10. Remove needle knife by unlocking proximal electrode from handle. **Note:** Before each introduction of a wire guide into a device, wet wire guide in a sterile water or saline bath. A contrast filled catheter may make wire guide difficult to advance. Flush contrast from catheter with sterile water or saline before each introduction of wire guide. Advance wire guide into pancreatic pseudocyst to facilitate the introduction of a stent or drainage set.
11. Push 10 French outer catheter while slightly pulling back inner catheter.
12. When diathermic ring comes in contact with digestive wall, place active cord on distal electrode (Part B) and advanced into cyst, using pure cutting current (80-120 watts). **Caution: To avoid electric shock, ensure that ring does not come in contact with wire guide. When electrosurgical current is being applied, do not advance the diathermic ring beyond the proximal catheter marking.**
13. Turn off electrosurgical unit and disconnect active cord from side arm and from electrosurgical unit. Wipe active cord with damp cloth to remove all foreign matter. Store in a loose coil. **Note:** Wrapping active cord tightly may damage device.
14. Fluid from cyst can be collected for analysis. Device can be removed leaving wire guide in place to facilitate introduction of stents or Drainage set.
Upon completion of procedure, dispose of device per institutional guidelines for biohazardous medical waste.

Fig. 1



Proximal Electrode (Part A)	Distal Electrode (Part B)
Проксимален електрод (A)	Дистален електрод (B)
Proximální elektroda (část A)	Distální elektroda (část B)
Proksimal elektrode (del A)	Distal elektrode (del B)
Proximale elektrode (deel A)	Distale elektrode (deel B)
Proksimaalne elektrood (osa A)	Distaalne elektrood (osa B)
Électrode proximale (partie A)	Électrode distale (partie B)
Proximale Elektrode (Teil A)	Distale Elektrode (Teil B)
Εγγύς ηλεκτρόδιο (μέρος Α)	Περιφερικό ηλεκτρόδιο (μέρος Β)
Proximális elektróda („A" rész)	Disztális elektróda („B" rész)
Elettrodo prossimale (A)	Elettrodo distale (B)
Proksimālais elektrods (daļa A)	Distālais elektrods (daļa B)
Proksimalinis elektrodas (A dalis)	Distalinis elektrodas (B dalis)
Proksimal elektrode (del A)	Distal elektrode (del B)
Elektroda proksymalna (część A)	Elektroda dystalna (część B)
Eléctrodo proximal (componente A)	Eléctrodo distal (componente B)
Electrod proximal (Partea A)	Electrod distal (Partea B)
Proximálna elektróda (časť A)	Distálna elektróda (časť B)
Electrodo proximal (parte A)	Electrodo distal (parte B)
Proximal elektrod (del A)	Distal elektrod (del B)

Diathermic ring	.038 inch Needle knife
Диатермичен пръстен	0,038 инча (0,97 мм) иглен нож
Diatermický kroužek	Jehlový papilotom 0,038 palce (0,97 mm)
Diatermiring	0,038 tomme (0,97 mm) kanylekniv
Diathermische ring	0,038 inch (0,97 mm) naaldmespapillotoom
Diatermiline rõngas	0,038-tolline (0,97 mm) punkteerimisnuga
Anneau diathermique	Aiguille de coupe de 0,038 inch (0,97 mm)
Diathermie-Ring	Nadelmesser (0,038 Inch [0,97 mm])
Διαθερμικός δακτύλιος	Βελονοτόμος 0,038" (0,97 mm)
Diatermikus gyűrű	0,038 hüvelykes (0,97 mm) tűkés
Anello diatermico	Ago di taglio da 0,038 pollici (0,97 mm)
Diatermiskais gredzens	0,038 collas (0,97 mm) adatas asmens
Diaterminis žiedas	0,038 col. (0,97 mm) adatinis peilis
Diatermisk ring	0,038 tomme (0,97 mm) nålekniv
Pierścień diatermiczny	Nóż igłowy o średnicy 0,038 cala (0,97 mm)
Anel diatérmico	Agulha cortante de 0,038 polegadas (0,97 mm)
Inel diatermic	Partea activă a acului, de 0,038 inci (0,97 mm)
Diatermický krúžok	Nôž s ihlou veľkosti 0,038 palcov (0,97 mm)
Anillo diatérmico	Cuchilla de aguja de 0,038 pulgadas (0,97 mm)
Diatermiring	0,038 tums (0,97 mm) nålkniv

10 Fr Outer catheter	5 Fr Inner catheter
Външен катетър 10 Fr	Вътрешен катетър 5 Fr
Vnější katetr 10 French	Vnitřní katetr 5 French
10 French ydre kateter	5 French indre kateter
10 Fr buitenste katheter	5 Fr binnenste katheter
10 Fr väline kateeter	5 Fr sisemine kateeter
Cathéter externe 10 Fr.	Cathéter interne 5 Fr.
Außenkatheter (10 French)	Innenkatheter (5 French)
Εξωτερικός καθετήρας 10 Fr	Εσωτερικός καθετήρας 5 Fr
10 Fr méretű külső katéter	5 Fr méretű belső katéter
Catetere esterno da 10 Fr	Catetere interno da 5 Fr
10 Fr ārējais katetrs	5 Fr iekšējais katetrs
10 Fr išorinis kateteris	5 Fr vidinis kateteris
10 Fr ytre kateter	5 Fr indre kateter
Cewnik zewnętrzny 10 F	Cewnik wewnętrzny 5 F
Cateter externo de 10 Fr	Cateter interno de 5 Fr
Cateter extern de 10 Fr	Cateter intern de 5 Fr
Vonkajší katéter veľkosti 10 Fr.	Vnútorný katéter veľkosti 5 Fr.
Catéter exterior de 10 Fr	Catéter interior de 5 Fr
10 Fr. ytterkateter	5 Fr. innerkateter

This device is designed for single use only. Attempts to reprocess, resterilize, and/or reuse may lead to device failure and/or transmission of disease.

Това изделие е предназначено само за еднократна употреба. Опитите за повторна обработка, повторна стерилизация и/или повторна употреба могат да доведат до повреда на изделието и/или до предаване на заболяване.

Toto zařízení je určeno pouze k jednorázovému použití. Pokusy o opakované ošetření prostředku, jeho resterilizaci a/nebo opakované použití mohou vést k selhání prostředku a/nebo k přenosu onemocnění.

Dette udstyr er kun beregnet til engangsbrug. Forsøg på genbehandling, resterilisering og/eller genbrug kan resultere i svigt af udstyret og/eller overførelse af sygdom.

Dit hulpmiddel is uitsluitend bestemd voor eenmalig gebruik. Pogingen om het hulpmiddel voor hergebruik geschikt te maken, het opnieuw te steriliseren en/of het opnieuw te gebruiken kunnen leiden tot het falen van het hulpmiddel en/of ziekteoverdracht.

Seade on ette nähtud ainult ühekordseks kasutamiseks. Taastöötluse, resteriliseerimise ja/või taaskasutuse katsed võivad põhjustada seadme tõrkeid ja/või haiguse ülekannet.

Ce dispositif est destiné exclusivement à un usage unique. Toute tentative de retraiter, de restériliser et/ou de réutiliser ce dispositif peut provoquer une défaillance du dispositif et/ou causer une transmission de maladie.

Das Produkt ist nur zum einmaligen Gebrauch bestimmt. Wiederaufbereitungs-, Resterilisierungs- und/oder Wiederverwendungsversuche können zum Ausfall des Produkts und/oder zur Übertragung von Krankheiten führen.

Αυτή η συσκευή έχει σχεδιαστεί για μία χρήση μόνο. Προσπάθειες επανεπεξεργασίας, επαναποστείρωσης ή/και επαναχρησιμοποίησης ενδέχεται να οδηγήσουν σε αστοχία της συσκευής ή/και σε μετάδοση νόσου.

Az eszköz kizárólag egyszeri használatra szolgál. Az újrafelhasználásra való előkészítés, az újrasterilizálás és/vagy az újrafelhasználás az eszköz meghibásodásához és/vagy betegségátvitelhez vezethet.

Il presente dispositivo è esclusivamente monouso. Tentativi di riprocessare, risterilizzare e/o riutilizzare possono causare il guasto del dispositivo e/o la trasmissione della malattia.

Šī ierīce paredzēta tikai vienreizējai lietošanai. Ierīces atkārtotas apstrādes, sterilizācijas un/vai lietošanas mēģinājumi var radīt tās funkcijas zudumu un/vai slimību pārnešanu.

Šis įtaisas yra skirtas naudoti tik vieną kartą. Mėginant pakartotinai apdoroti, sterilizuoti ir (arba) naudoti, galima sugadinti įtaisą ir (arba) perduoti ligą.

Denne anordningen er kun beregnet for engangsbruk. Forsøk på bearbeiding for gjenbruk, resterilisering og/eller gjenbruk kan føre til funksjonssvikt og/eller overføring av sykdom.

Urządzenie to jest przeznaczone wyłącznie do jednorazowego użytku. Próby ponownego poddawania jakimkolwiek procesom, ponownej sterylizacji i/lub ponownego użycia mogą prowadzić do awarii urządzenia i/lub przeniesienia choroby.

Este dispositivo destina-se a uma única utilização. As tentativas de reprocessá-lo, reesterilizá-lo e/ou reutilizá-lo podem conduzir à falha do dispositivo e/ou à transmissão de doença.

Acest dispozitiv este exclusiv de unică folosință. Tentativele de reprocesare, resterilizare și/sau reutilizare pot duce la defectarea dispozitivului și/sau transmiterea de boli.

Toto zariadenie je navrhnuté len na jednorazové použitie. Pokusy o opakované spracovanie, opakovanú sterilizáciou a/alebo opakované použitie môžu viesť k zlyhaniu zariadenia a/alebo prenosu choroby.

Este dispositivo está concebido para un solo uso. Cualquier intento de reprocesar, reesterilizar o reutilizar el dispositivo puede hacer que éste falle u ocasionar la transmisión de enfermedades.

Denna produkt är avsedd endast för engångsbruk. Försök att bearbeta, omsterilisera och/eller återanvända produkten kan leda till att produkten inte fungerar och/eller orsaka sjukdomsöverföring.

This symbol on the label indicates that this device contains phthalates. Specific phthalates contained in the device are identified beside or below the symbol by the following acronyms:

- **BBP: Benzyl butyl phthalate**
- **DBP: Di-n-butyl phthalate**
- **DEHP: Di(2-ethylhexyl) phthalate**
- **DIDP: Diisodecyl phthalate**
- **DINP: Diisononyl phthalate**
- **DIPP: Diisopentyl phthalate**
- **DMEP: Di(methoxyethyl) phthalate**
- **DNOP: Di-n-Octyl phthalate**
- **DNPP: Di-n-pentyl phthalate**

Този символ върху етикета означава, че това устройство съдържа фталати. Конкретните фталати, съдържащи се в устройството, се идентифицират до или под символа от следните акроними:

- **BBP: Бензилбутилфталат**
- **DBP: Ди-n-бутилфталат**
- **DEHP: Ди(2-етилхексил)фталат**
- **DIDP: Диизодецилфталат**
- **DINP: Диизононилфталат**
- **DIPP: Диизопентилфталат**
- **DMEP: Ди(метоксиетил)фталат**
- **DNOP: Ди-n-октилфталат**
- **DNPP: Ди-n-пентилфталат**

Tento symbol na štítku znamená, že toto zařízení obsahuje ftaláty. Konkrétní ftaláty obsažené v tomto zařízení jsou identifikovány vedle symbolu nebo pod ním za použití následujících zkratek:

- **BBP: benzylbutylftalát**
- **DBP: di-n-butylftalát**

- **DEHP: di(2-ethylhexyl)ftalát**
- **DIDP: diisodecylftalát**
- **DINP: diisononylftalát**
- **DIPP: diisopentylftalát**
- **DMEP: di(methoxyethyl)ftalát**
- **DNOP: di-n-oktylftalát**
- **DNPP: di-n-pentylftalát**

Dette symbol på mærkaten indikerer, at produktet indeholder phthalater. Specifikke phthalater, som dette produkt indeholder, identificeres ved siden af eller under symbolet vha. følgende akronymer:

- **BBP: Benzylbutylphthalat**
- **DBP: Di-n-butylphthalat**
- **DEHP: Di(2-ethylhexyl)- phthalat**
- **DIDP: Diisodecylphthalat**
- **DINP: Diisononylphthalat**
- **DIPP: Diisopentylphthalat**
- **DMEP: Di(methoxyethyl)- phthalat**
- **DNOP: Di-n-octylphthalat**
- **DNPP: Di-n-pentylphthalat**

Dit symbool op het etiket wijst erop dat dit hulpmiddel ftalaten bevat. De specifieke ftalaten in het hulpmiddel staan naast of onder het symbool aangeduid met de volgende afkortingen:

- **BBP: benzylbutylftalaat**
- **DBP: di-n-butylftalaat**
- **DEHP: di(2-ethylhexyl)ftalaat**
- **DIDP: di-isodecylftalaat**
- **DINP: di-isononylftalaat**
- **DIPP: di-isopentylftalaat**
- **DMEP: di(methoxyethyl)ftalaat**
- **DNOP: di-n-octylftalaat**
- **DNPP: di-n-pentylftalaat**

See sümbol märgisel näitab, et antud seade sisaldab ftalaate. Sümboli kõrval või selle all on järgmiste akronüümidega tähistatud konkreetsed seadmes sisalduvad ftalaadid:

Efficiently treat bulging pancreatic pseudocysts.

Cystotome®

CYSTOENTEROSTOMY NEEDLE KNIFE

With an electrosurgical needle knife and a diathermic ring, the Cook Medical Cystotome is a combination device that allows efficient treatment for bulging pancreatic pseudocysts. The wire-guided Cystotome also maintains position throughout therapeutic treatment for easier and faster endoscopic cystoenterostomy.

COOK® MEDICAL

www.cookmedical.com

Cystotome®

CYSTOENTEROSTOMY NEEDLE KNIFE

Used to electrosurgically puncture a hole in the transgastric or transduodenal wall and into a pancreatic pseudocyst, when it is visibly bulging into the gastrointestinal tract.

Supplied sterile and is disposable – intended for single use only.

- Make initial incision with .038" needle knife in a 5 Fr catheter
- Immediately enlarge incision with follow-on cauterizing diathermic ring and 10 Fr outer catheter
- Accepts .035" wire guide to maintain position after first incision and facilitate placement of a stent or a drainage kit
- Combining a needle knife and diathermic ring eliminates need for instrument change, reducing procedure time
- Multiple integrated components – needle knife, diathermic ring, and wire-guide compatibility – are a platform for expeditious delivery of therapeutic treatment

Order Number	Reference Part Number	Outer Catheter French Size Fr	Outer Catheter Length cm	Inner Catheter French Size Fr	Inner Catheter Length cm	Diathermic Ring French Size Fr	Color Connection
G30550	CST-10	10	165	5	190	10	Purple

*Minimum accessory channel 3.7 mm. *Recommend Tracer Metro Direct wire guide, sold separately. Active cord available separately.*

Some products or part numbers may not be available in all markets. Contact your local Cook representative or Customer Service for details.

Customer Service

EMEA: EDI – www.cookmedical.com/edi.do
Distributors: +353 61239240, ssc.distributors@cookmedical.com
Austria: +43 179567121, oe.orders@cookmedical.com
Belgium: +32 27001633, be.orders@cookmedical.com
Denmark: +45 38487607, da.orders@cookmedical.com
Finland: +358 972519996, fi.orders@cookmedical.com
France: +33 171230269, fr.orders@cookmedical.com
Germany: +49 6950072804, de.orders@cookmedical.com
Hungary: +36 17779199, hu.orders@cookmedical.com
Ireland: +353 61239252, ie.orders@cookmedical.com
Italy: +39 0269682853, it.orders@cookmedical.com
Netherlands: +31 202013367, nl.orders@cookmedical.com
Norway: +47 23162968, no.orders@cookmedical.com
Spain: +34 912702691, es.orders@cookmedical.com
Sweden: +46 858769468, se.orders@cookmedical.com
Switzerland – French: +41 448009609, fr.orders@cookmedical.com
Switzerland – Italian: +41 448009609, it.orders@cookmedical.com
Switzerland – German: +41 448009609, de.orders@cookmedical.com
United Kingdom: +44 2073654183, uk.orders@cookmedical.com

www.cookmedical.com

Americas: EDI – www.cookmedical.com/edi.do
Phone: +1 812.339.2235, 800.457.4500, Fax: 800.554.8335
E-mail: orders@cookmedical.com

Australia:
Phone: +61 738411188, 1800777222, Fax: +61 738411288, 1800077283
E-mail: cau.custserv@cookmedical.com

COOK® MEDICAL

Clinical Clip

PANCREATIC PSEUDOCYST DRAINAGE

Study courtesy of:
Colin J McKay, Senior Lecturer in Surgery,
Pancreatic Unit,
Glasgow Royal Infirmary, UK

HISTORY

A 44 year old female presented with persistent upper abdominal pain, vomiting and weight loss. CT identified a 6cm cystic mass. ERCP showed no ductal communication. EUS-guided aspiration revealed high amylase content, normal CEA and acellular cytology. Endoscopic cystogastrostomy was performed.

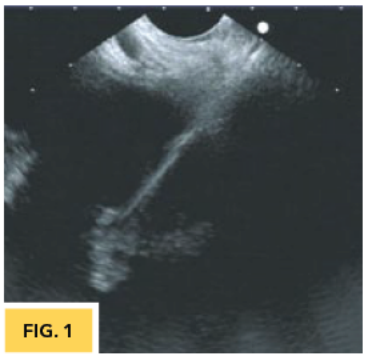


FIG. 1

PROCEDURE

Cyst drainage was achieved using the Wilson-Cook **Cystotome**™ device and a linear EUS scope with a 3.8mm working channel. The bulging cyst was identified on EUS and an appropriate, avascular puncture site selected with the aid of Doppler (See Figure 1). The cyst was entered with the 5Fr needle knife of the Cystotome using cutting diathermy and puncture confirmed on EUS.

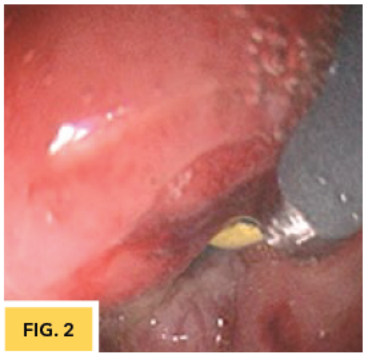


FIG. 2

The 5Fr needle knife was replaced with a super-stiff guide wire and the puncture site enlarged with the 10Fr outer sheath using blend diathermy (See Figure 2).

The Cystotome was exchanged over the wire for a 10mm balloon dilator. Following deflation of the balloon there is often a large quantity of fluid released into the stomach (See Figure 3).

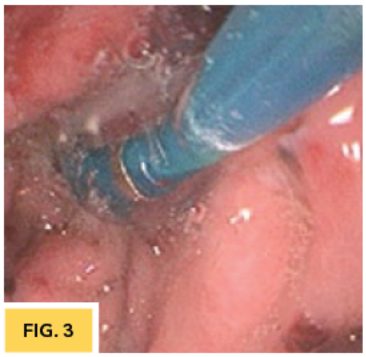


FIG. 3

Two 7Fr, 4cm pigtail stents were then placed into the cyst completing drainage (See Figure 4). For infected cysts, a nasobiliary catheter can beplaced in the cyst and lavage instituted.

OUTCOME

In this case, EUS-guided drainage with the Cystotome resulted in complete resolution of the cyst. This was confirmed on follow-up EUS 6 weeks later, at which time the stents were removed.

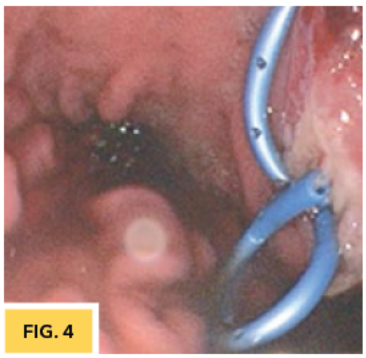


FIG. 4

COOK ENDOSCOPY
4900 Bethania Station Road, Winston-Salem, NC 27105 U.S.A.
Phone: 336 744-0157, Toll Free: (USA) 800 457-4500, Fax: 336 744-5231

www.cookmedical.com

L-18658/1107

ATTACHMENT 7

Hot AXIOS™

Stent and Electrocautery-Enhanced Delivery System

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

TABLE OF CONTENTS

Hot AXIOS™

Stent and Electrocautery-Enhanced Delivery System

DEVICE DESCRIPTION

The Hot AXIOS™ Stent and Electrocautery-Enhanced Delivery System is an endoscopic device designed to enable the ultrasound trained interventional endoscopist to deliver a transenteric stent between the gastrointestinal tract and a pancreatic pseudocyst.

The AXIOS™ Stent is a flexible, fully-covered self-expanding nitinol stent that is preloaded within the Electrocautery-Enhanced Delivery System.

The Hot AXIOS™ Delivery System is an electrocautery-enhanced delivery system that is compatible with therapeutic echoendoscopes having a working channel of 3.7 mm diameter or larger.

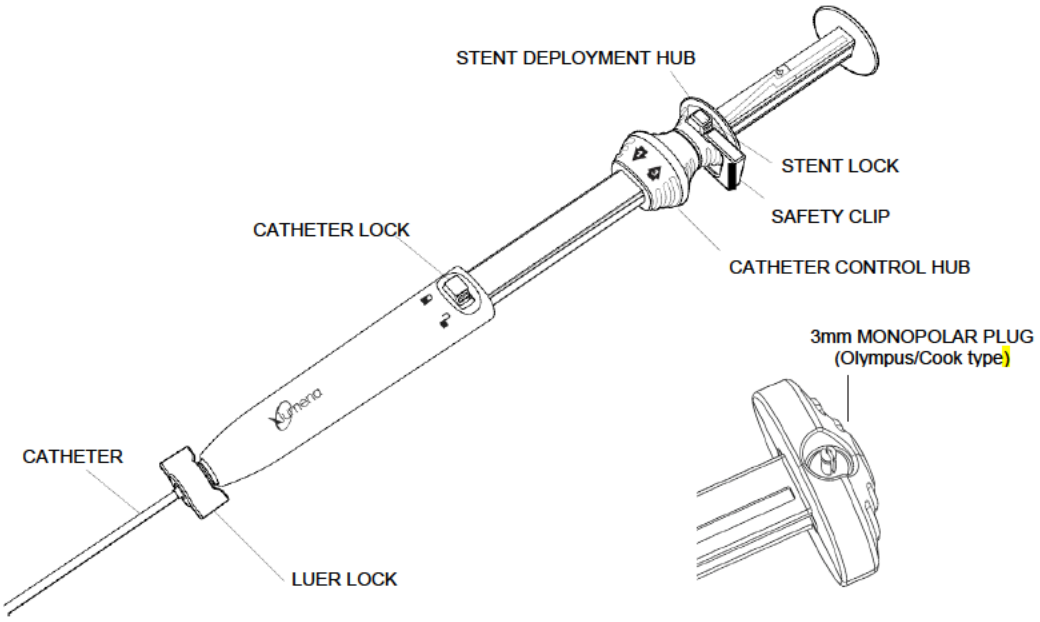


FIGURE 1. Hot AXIOS™ Electrocautery- Enhanced Delivery System handle. The catheter control hub advances and retracts the catheter. The stent deployment hub releases the stent from the catheter. Monopolar plug for connection to electrosurgical generator.

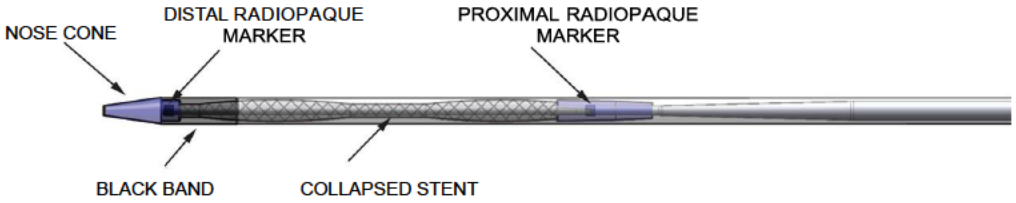


FIGURE 2. The collapsed stent is contained within the distal end of the catheter. A black band at the end of the catheter is used to position the stent second flange for deployment under direct visualization. Two radiopaque bands indicate the proximal and distal edges of the stent.

RECOMMENDED STENT SELECTION METHOD

Pseudocyst. Select the stent LUMEN diameter based on pseudocyst contents via endoscopic ultrasound (EUS) imaging. For example, select 15 mm in the presence of necrotic material and select 10 mm (or 15 mm) for 100% fluid contents.

The 10mm stent length can accommodate combined GI tract and pseudocyst wall thickness up to 10mm as assessed by EUS during the procedure..

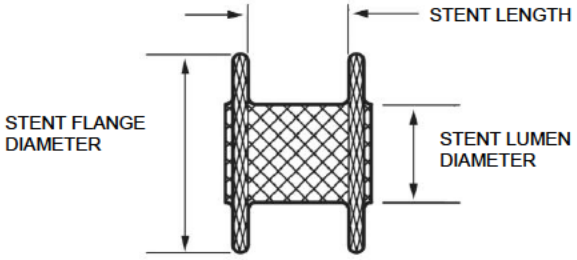


FIGURE 3. The stent is made of Nitinol wire and fully covered with silicone.

STENT SIZE

Catalog / Model Number	Description	Stent Size (nominal)			Delivery System Outer Diam.
		Flange Diameter	Lumen Diameter	Stent Length	
HXS(US)-10-10	Electrocautery-Enhanced AXIOS System with 10x10 Stent	21 mm	10 mm	10 mm	10.8 Fr
HXS(US)-15-10	Electrocautery-Enhanced AXIOS System with 15x10 Stent	24 mm	15 mm	10 mm	10.8 Fr

PACKAGE CONTENTS
One (1) Hot AXIOS™ Stent and Electrocautery-Enhanced Delivery System

TRANSPORTATION CONDITIONS

Temperature	-29 to 60°C
Humidity	10 to 90%RH
Air pressure	70-106kPa

STORAGE & OPERATING CONDITIONS

Temperature	10 to 30°C
Humidity	10 to 75%RH
Air pressure	70 to 106kPa
General Environment:	Endoscopy Lab or Operating Suite within Hospital Buildings

INDICATIONS FOR USE
The Xlumena Hot AXIOS™ Stent and Electrocautery-Enhanced Delivery System is indicated for use to facilitate transgastric or transduodenal endoscopic drainage of symptomatic pancreatic pseudocysts ≥ 6cm in size, with ≥ 70% fluid content that are adherent to the gastric or bowel wall. Once placed, the AXIOS™ Stent functions as an access port allowing passage of standard and therapeutic endoscopes to facilitate debridement, irrigation and cystoscopy. The stent is intended for implantation up to 60 days and should be removed upon confirmation of pseudocyst resolution.

CONTRAINDICATIONS
This device is contraindicated for use in any and all cardiovascular applications.

Additional contraindications include:

- Cystic neoplasms.
- Pseudoaneurysms.
- Duplication cysts.
- Non-inflammatory fluid collections.
- Patients with abnormal coagulation.
- Patients who require ongoing complete anticoagulation with heparin, lovenox or warfarin post AXIS Stent implant have an increased possibility of bleeding generally and at the implant site.
- Patients with altered anatomy that precludes the physician's ability to deliver the stent.
- Patients with intervening gastric varices or vessels within a one centimeter radius of the device insertion location.
- Patients that have allergies or are sensitive to any of the device materials.
- Patients with contraindications to use of electrical devices.

POTENTIAL COMPLICATIONS
Potential complications associated with the use of the Hot AXIOS™ Stent and Electrocautery- Enhanced Delivery System may include those often associated with any endoscopic procedure. These complications include:

1. Anesthesia complica ions.
2. Improper AXIOS™ Stent placement; incomplete deployment; stent migration into the pseudocyst or, GI tract; separation of coating material from stent;; stent fracture; coating material wear; coating material failure; puncture of coating material.
3. Tissue ingrowth or overgrowth leading to difficulty or a failure to remove stent.
4. Stent dislodgement.
5. Adverse reaction to implant materials and/or delivery system (e.g., abdominal or back pain, nausea, infection, fever, chronic inflammation or foreign body reaction).
6. Minor or excessive bleeding requiring intervention.
7. Leakage of pseudocyst or bowel contents causing inflammation or peritonitis.
8. Stent occlusion.
9. Local infection at the implant site.

10. Tissue damage during stent implantation and/or removal.
11. Ulceration or erosion of mucosal or organ wall linings.
12. Pneumoperitoneum.
13. Sepsis (bacterial, endotoxin or fungal).
14. Perforation.
15. Surgical intervention (endoscopy, transfusion or surgery).
16. Persistent connection to the pseudocyst after removal (fistula).
17. Unintended electrical shock, muscle stimula ion or burns.
18. Cardiac arrhythmia or arrest.
19. Death.

WARNINGS AND PRECAUTIONS

1. Placement of the AXIOS™ Stent should be performed by physicians familiar with endoscopic ultrasonography and who have received training for AXIOS™ Stent placement techniques.
2. Package contents are supplied sterile by ethylene oxide (EO). Do not use if sterile barrier is open or damaged.
3. For single-patient use only. Do not reuse, reprocess, or resterilize. Reuse, reprocessing, or resterilization may lead to device failure, create a risk of contamination and/or cause the transmission of infectious disease(s). Reuse of the device may lead to injury, illness, or death.
4. Before use, examine the outer surface of devices which are intended to be inserted into a patient or used during procedure. Do not use a device that has unintended rough surfaces, sharp edges or protrusions which may cause harm. Cut, burned or damaged device insulation may cause unsafe currents in either patient or operator.
5. Do not use this device in any echoendoscope with a working channel smaller than 3.7 mm.
6. Do not remove the stent from its delivery system prior to use.
7. This stent must only be placed using the delivery system provided.
8. No modification of this equipment is allowed.
9. Do not use this device for any purpose other than its stated intended use.
10. AXIOS™ Stent implantation should not exceed 60 days; performance beyond 60 days has not been established.
11. Long-term patency of the AXIOS™ Stent has not been established. Periodic evaluation of the stent is advised.
12. Do not use in patients who have electronic implants such as cardiac pacemakers without first consulting a qualified professional (e.g., cardiologist). A possible hazard exists because interference with the action of the electronic implant may occur, or the implant may be damaged.
13. INSPECT the Hot AXIOS™ Electrocautery-enhanced Delivery System, endoscope, and the connector cable for damage prior to use and, especially, the insulation of endoscopic instruments. This may be done visually under magnification or with a high voltage insulation testing device. Insulation failures may result in burns or other injuries to the patient or operator.
14. Interference of high frequency medical electrical equipment may adversely influence operation of other electronic equipment.
15. Before use, compatibility with electrosurgical generators, accessories and other endoscopic equipment should be checked according to any criteria for safe use. Using incompatible equipment or equipment not specified by this Instruction for Use can result in patient injury or equipment damage. (see Technical Specifications)
16. Select cables, patient return electrodes and other medical electrical equipment that are Type BF applied parts. Use of medical electrical equipment other than those specified may result in increased emissions or decreased immunity of the generator.
17. Use caution with endoscopic equipment, accessories, and other medical / non-medical electrical equipment to avoid risks caused by their use together.
18. Any electrosurgical accessory constitutes a potential electrical hazard to the patient and operator. Safe and effective electrosurgery is dependent not only on equipment design but, to a large extent, on factors under the control of the operator.
19. Avoid high frequency output settings where the maximum output voltage may exceed rated accessory voltage (Hot AXIOS™ Electrocautery-enhanced Delivery System rated accessory voltage is 750Vp or 1500Vp-p).
20. Patient risks may result from gas embolism caused by over-insufflation of air, inert gas prior to high frequency surgery, or laser assist gas.

21. Do not use in the presence of flammable anesthetics or oxidizing gases (such as nitrous oxide (N_2O) and oxygen) or in close proximity to volatile solvents (such as ether or alcohol), as explosion may occur.
22. Do not place instruments near or in contact with flammable materials (such as gauze or surgical drapes). Instruments that are activated or hot from use may cause a fire.
23. When energized endoscopes are used with energized endotherapy devices, patient leakage currents may be additive. When applying current, ensure the active tip of the AXIOS™ Electrocautery-enhanced Delivery System is completely outside the endoscope. Contact between the active element (located on the nose cone) and the echoendoscope may cause grounding, which can result in patient injury, operator injury, or damage to the endoscope.
24. Aspirate fluid from the area before activating he instrument. Conductive fluids (e.g., blood or saline) in direct contact with or in close proximity to an active electrode may carry electrical current or heat away from target issues, which may cause unintended burns to the patient.
25. Do not activate the instrument when not in contact wi h target tissue, as this may cause injuries due to capacitive coupling.
26. The surface of the active electrode may remain hot enough to cause burns after the RF current is turned off.
27. Ensure proper placement of return electrode on patient and connection to generator. Failure to do so could result in harm to pa ient including burns.
28. Temporary loss of EUS imaging may occur due to electromagne ic interference of the activated catheter tip. Normal EUS operation will resume immediately after deactivation of the catheter tip.
29. Use pure cut generator set ings with Hot AXIOS™ Electrocautery-enhanced Delivery System. Do not use blended or coagulation generator modes. Blended or coagulation modes may result in failure to access, prolonged time to access, tissue tenting or resistance.
30. Do not attempt to advance or retract the delivery system against resistance until the cause of resistance has been determined.
31. Care is required during dilation, debridement, irrigation, and cystoscopy procedures hrough the stent, to prevent air/fluid leak and/or stent dislodgement.
32. Ensure correct generator installation. The generator must be installed and put into service according to the EMC information provided in the generator manufacturer's guidance and declara ion for electromagnetic compatibility. Refer to the Technical Specifications Table to confirm that this device is compa ible with the equipment being used.
33. Connect the Hot AXIOS™ Stent and Electrocautery-enhanced Delivery System to the electrosurgical unit only when the unit is off. Failure to do so may result in an injury or electrical shock to the patient or operating room personnel.
34. Due to concerns about the carcinogenic and infectious potential of electrosurgical by-products (such as tissue smoke plume and aerosols), protective eyewear, filtration masks, and effective smoke evacuation equipment should be used during the procedure.
35. Prior to increasing the intensity, check the adherence of the return electrode and its connections. Apparent low output or failure of the device to func ion correctly at the normal operating set ings may indicate faulty application of he return electrode or poor contact in its connections.
36. If the electrosurgical device is operated in a mode without the CQM or a CQM compatible monitoring return electrode is not used, loss of safe contact between the return electrode and the patient will not result in an alarm.

TECHNICAL SPECIFICATIONS

Catalog Numbers:	HXS-10-10, HXS-15-10
Use:	Sterile, Single-Patient Use
Electrode Dimensions (nominal):	 Keyhole diameter: 0.042 inches (3.1 F) Total Cut Length: 0.115 inches (8.8 F)
Energy:	Monopolar
Part Type:	BF Applied Part
Maximum Rated Input:	1.5 kV peak-to-peak (750Vp)
Recommended Generator Settings:	Pure cut mode, 80-120 Watts (400-500Vp).
Compatible Electrosurgical Unit or Generator:	Select an electrosurgical unit or generator that is compliant to IEC 60601-1-2 and IEC 60601-2-2:

	ERBE VIO 300D **ERBE I** **ERBE VIO 300S** **ERBE V** Power off the generator when not in use.
Minimum Electrosurgical Generator Requirements:	➢ Power Output > 50 Watts ➢ Peak Voltage (Vp) > 300Vp ➢ Pure Cut Mode
Electromagnetic Compatibility:	Refer to the generator manual for the manufacturer's guidance and declaration to electromagnetic compatibility.
Connectors:	Monopolar endoscopic cable, Olympus/Cook-Type, 3mm female plug. Select cables specified by generator manufacturer.
Dispersive Pad:	Select pad or return electrode specified by generator manufacturer.
Guidewire Compatibility:	0.035 inches, insulated
Echoendoscope Compatibility:	Working channel of 3.7 mm diameter or larger.

INSTRUCTIONS FOR USE

Device Inspection

WARNING: Do not use if the sterile barrier (inner packaging) is open or damaged.

1. **Remove from packaging**. Carefully remove the HOT AXIOS™ Stent with Electrocautery-Enhanced Delivery System from its packaging.

2. **Inspect device**. Inspect the device for damage or defects.

   WARNING: Before use, examine the outer surface of devices which are intended to be inserted into a patient or used during procedure. Do not use a device that has unintended rough surfaces, sharp edges or protrusions which may cause harm. Cut, burned or damaged device insulation may cause unsafe currents in either patient or operator.

3. **Inspect tip.** Check that the distal end of the catheter is not separated from he nose cone (Figure 4). Do not use if the distal end of the catheter is separated from the nose cone. Return the product to Xlumena, Inc.

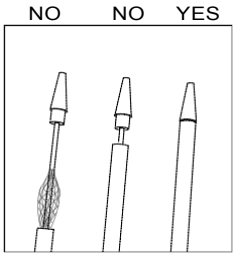


FIGURE 4. The two examples on the left (“NO”) show separa ion of the nose cone from the catheter. The “YES” drawing illustrates the correct position of the nose cone as contiguous with the catheter.

Preparation

4. **Select electrosurgical generator**. The Hot AXIOS™ Stent and Electrocautery-Enhanced Delivery System is an accessory device that is intended to be used in conjunction with an electrosurgical unit or generator that is compliant to IEC 60601-1-2 and IEC 60601-2-2. See Technical Specifications Table for generator requirements and compatibility.

5. **Connect 3mm monopolar cable to generator**. Select Olympus / Cook type electrosurgical cable with a 3mm female monopolar plug on the end hat will connect to the Hot AXIOS™ Stent and Electrocautery-Enhanced Delivery System. Connect the cable to the generator, ensuring it fits securely. Do not yet attach cable to AXIOS™ catheter to avoid unintended delivery of energy.

   CAUTION: Electrosurgical cables with 4mm plugs are not compa ible with the Hot AXIOS™ Stent and Electrocautery-Enhanced Delivery System.

6. **Apply return electrode to patient**. Follow recommendations provided by the manufacturer of the electrosurgical generator for the proper preparation, placement and u ilization of the patient return electrode. Ensure that a proper path from the patient return electrode to the electrosurgical unit is maintained throughout the procedure.

7. **Power on the generator and check settings.** Power on the generator and ensure the correct settings (see recommended settings in Technical Specification Table). ONLY pure cut set ings should be used (80-120 Watts, 400-500Vp). Using the ERBE

electrosurgical generators, the "Autocut" setting corresponds to the pure cut setting. Do not use ERBE "Endocut" setting.

CAUTION: DO NOT USE blended or coagulation electrosurgical generator modes with the Hot AXIOS™ Stent and Electrocautery-Enhanced Delivery System. Blended or coagulation modes may result in failure to access, prolonged time to access, tissue tenting or resistance.

8. **Identify site for AXIOS™ stent placement**. Using EUS, survey the stomach and duodenum for a good site for AXIOS™ stent placement. Select a site that is clear of intervening blood vessels, where the pseudocyst is close to the GI tract (within 10mm), and where the pseudocyst has a large enough diameter to accommodate insertion of the AXIOS™ catheter (catheter should pass 3-4cm into the pseudocyst).

9. **Insert guidewire (optional).** If using over-the-wire technique (see Procedure instruction 1), ensure that a 0.035 inch insulated guidewire has been placed through the echoendoscope working channel and into the target structure.

10. **Lower elevator.** Ensure that the echoendoscope elevator is in the lowered (open) position (Figure 5).

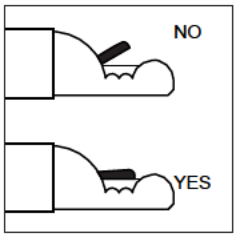


FIGURE5. Ensure the elevator is in the lowered (open) position. The up (closed) elevator position is incorrect and will inhibit catheter advancement.

Procedure

1. **Determine approach and position echoendoscopes**. There are two approaches you can use for Hot AXIOS™ stent placement into the target structure: over-the-wire (Seldinger technique) or freestyle. In the over-the-wire technique, access is obtained to the pseudocyst using standard methods (e.g., using an FNA needle) and a guidewire is placed into he pseudocyst. The Hot AXIOS™ delivery catheter is front loaded over the guidewire. In freestyle, the Hot AXIOS™ cautery-enhanced tip is aimed and passed directly through the GI and pseudocyst walls into the pseudocyst without a guidewire.

    a. Using your echoendoscope, select an access location that is free from intervening blood vessels, where the wall between the GI tract and pseudocyst is 10mm or less, and where the pseudocyst diameter is large enough to accommodate 3-4cm of AXIOS™ catheter insertion.

        i. If using over-the wire technique, pass your chosen access device into the collection such that .035" insulated guidewire can be placed into the collection, then remove access device. Continue to Procedure instruction 2.

        ii. If using freestyle technique, continue direc ly to Procedure instruction 2.

2. **Wet and insert the AXIOS™ catheter**. Wet the entire length of the Hot AXIOS™ catheter with sterile water or normal saline. Carefully insert the catheter into the working channel of the therapeutic echoendoscope and advance it until the handle Luer lock aligns and fits into the working channel fitting. If using the over-the wire technique, the AXIOS™ catheter should be placed over the guidewire before inserting it into the working channel. Be careful not to bend or kink the catheter during insertion. Rotate the winged Luer lock clockwise to secure the delivery system handle to the echoendoscope (Figure 6).

NOTE: After fitting the AXIOS™ delivery system into the echoendoscope, the catheter tip will not be visible under endoscopic ultrasound (EUS) or endoscopic view. It will be visible only when the catheter is advanced as described in Procedure instruction 4.

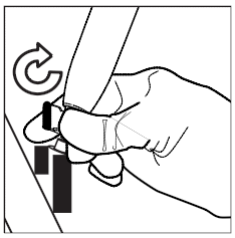


FIGURE 6. Align the handle with the echoendoscope and attach it by rotating the Luer lock fitting clockwise.

3. **Connect to generator.** Connect the AXIOS™ Electrocautery Enhanced Delivery System to the 3mm monopolar electrosurgical active cable so that the 3.0mm plug fits securely. Ensure the generator is at desired settings (Use pure cut mode, 80-120 Watts, 400-500Vp).

4. **Confirm position, unlock and visualize.** Using EUS imaging, re-confirm your position for stent delivery. Unlock the catheter lock (Figure 7) and advance the (black) catheter control hub (Figure 8) until the distal catheter position is visible.

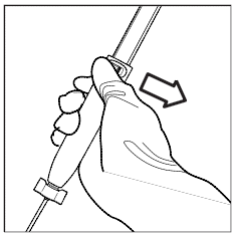


FIGURE 7. Push the catheter lock to the right to unlock the catheter and to the left to relock it.

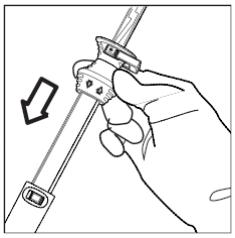


FIGURE 8. With the catheter unlocked, carefully advance the catheter control hub (in the direction indicated by the "1" arrow on the hub) so that the distal end of the catheter moves towards and into the target structure.

5. **If necessary adjust echoendoscope elevator.** Under EUS imaging, adjust the echoendoscope elevator to the desired angle. The angle of approach should be as perpendicular to the pseudocyst wall as possible.

6. **Energize and advance.** Advance the AXIOS™ catheter tip using the catheter control hub to tent the tissue for visualization on EUS. Power-On the electrosurgical generator using the foot pedal and advance carefully into the target structure. After entry into he target structure, Power-Off the generator and disconnect the monopolar electrosurgical cable. Typically, the electrosurgery energy is applied from 1-3 seconds to gain access into the target structure.

7. **WARNING:** Apply only enough energy to enter the target structure, prolonged energy delivery may cause unintended damage to tissues or perforation.

   CAUTION: Temporary EUS imaging artifact may occur due to electromagnetic interference of the activated catheter tip. Normal EUS operation will resume immediately after deactivation of the catheter tip.

8. **Confirm AXIOS™ catheter tip within target structure, lock catheter.** Using EUS imaging, ensure that the tip of the AXIOS™ catheter is posi ioned at least 3-4 cm within the inner margin of the target structure. Lock the catheter lock to ensure that the delivery catheter does not move during deployment of the stent first flange.

CAUTION: The stent cannot be resheathed after the stent first flange has been deployed.

9. **Deploy the stent first flange.** Press down on the yellow safety clip to remove it from the stent deployment hub. Under EUS imaging, deploy the stent first flange by unlocking the stent lock (Figure 9) and retracting the stent deployment hub to the halfway point indicated on the handle (Figure 10). A "click" will be heard as the stent deployment hub automatically locks into place (at the "2" arrow line). Verify with EUS imaging that the stent first flange is deployed inside the target structure (do not proceed to next step until verified).

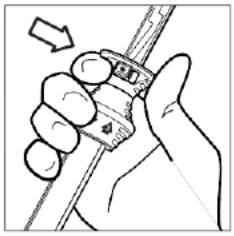


FIGURE 9. Push the stent lock to the right to unlock he stent deployment hub. The lock automatically relocks when the hub reaches the stent first flange deployment stop.

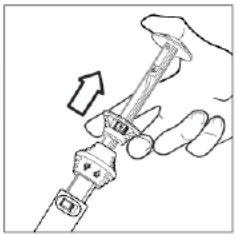


FIGURE 10. Holding the handle and stent deployment hub like a syringe, retract the hub to release the stent first flange. The hub will "click" and lock into place at the "2" arrow line.

10. **Deploy the stent second flange.** There are two approaches you can use for deploying the second flange: under endoscopic visualization or under EUS guidance.

    a. **Endoscopic visualization:**

        i. **Switch to endoscopic view.** Retract the echoendoscope until the catheter shaft is visible passing through the gastric or duodenal wall.

            WARNING: Excessive retraction may pull the stent out of the target structure or result in poor positioning of the stent first flange.

        ii. **Visualize the black band.** Confirm at least 2-3mm of the black band is visible in the gastrointestinal tract (Figure 11). This indicates that the catheter is correctly positioned for deployment of the stent second flange. If 2-3mm is not visible, follow step 9aiii. Otherwise, proceed to 9aiv.

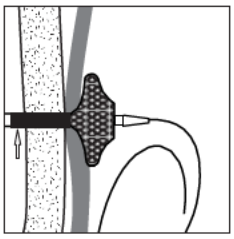


FIGURE 11. Under endoscopic view, confirm that at least 2-3 mm of the black band is visible in GI tract (see arrow). This indicates that the stent first flange is correctly positioned against the lumen wall.

            WARNING: Confirm at least 2-3mm of he black band is visible. If insufficient shaft length is visible, the second flange may be deployed into the collection or peritoneal space

        iii. **If 2-3mm of the black band is not visible,** unlock the catheter lock and retract the catheter control hub (Figure 12) un il 2-3mm is visible. Then re-lock the ca heter lock to ensure the catheter does not move during deployment of the stent second flange.

            WARNING: Failure to re-lock the catheter lock will result in the incorrect deployment of the second flange inside the collection.

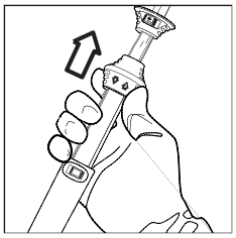


FIGURE 12. If necessary, carefully retract the catheter control hub (as indicated by the “3” arrow on the hub). Under endoscopic view, position the catheter for deployment of the second flange by confirming at least 2-3 mm of he black band is visible in the GI tract.

iv. Deploy the stent second flange. Unlock the stent lock and retract the stent deployment hub to the top of the handle in the direction indicated by the "4" arrow (Figure 13).

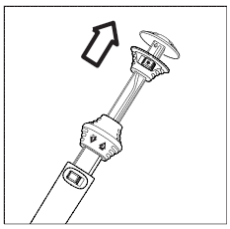


FIGURE 13. Under endoscopic view, deploy the stent second flange by retracting the stent deployment hub in the direction indicated by the “4” arrow on the handle.

v. Verify correct deployment. Under direct endoscopic visualiza ion, verify that the stent second flange is deployed within the gastrointestinal tract.

b. <u>EUS guidance</u>.

i. **Position the catheter for second flange delivery.** With the first flange in EUS view, unlock the catheter lock and retract the catheter control hub so that the first flange approaches the inner wall of the target structure. Retract the first flange gently against the inner wall of the structure until it changes shape from a flat or disk-like shape (no load) to an oval shape (small load).

WARNING: Do not retract the first flange forcefully against the inner wall. Excessive retraction may pull the stent out of the target structure or result in poor positioning of the stent first flange.

ii. **Re-lock catheter.** Maintaining the first flange against the inner wall with an oval shape, re-lock the catheter lock.

WARNING: Failure to re-lock the catheter lock will result in the incorrect deployment of second flange inside the collection.

iv. **Deploy the stent second flange.** Unlock the stent lock and retract the stent deployment hub to the top of the handle in the direction indicated by the “4” arrow (Figure 14). The second flange of the stent is now released but may remain in the working channel. If he second flange remains in the working channel of the echoendoscope, while ensuring that the first flange remains correctly in position, advance the catheter control hub while retracting the scope in a 1-to-1 fashion until the second flange releases from the scope and is visualized on endoscopy or EUS.

WARNING: If you do not advance the ca heter control hub and retract the scope in a 1-to-1 fashion, there is a risk that the stent may deploy into the collection or the first flange may be pulled into the GI tract.

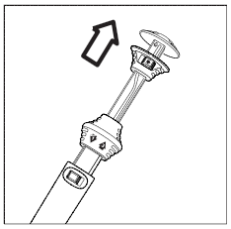


FIGURE 14. Under EUS view, deploy the stent second flange by retracting the stent deployment hub.

Delivery System Removal from Echoendoscope
Following deployment of the AXIOS Stent, rotate the Luer lock at the base of the handle counterclockwise. Remove the delivery catheter by pulling it upward and out of the working channel. If desired, maintain the insulated guidewire position across the target structure as the catheter is removed.

Dispose of the delivery system in accordance with institutional guidelines for biohazardous medical waste.

AXIOS™ Stent Dilation
If desired, place a balloon catheter over the insulated guidewire and into the central lumen of the stent. Dilate the stent up to the nominal diameter. Post-dilation allows the AXIOS stent flanges to fully expand, which secures the stent in place and optimizes transenteric drainage.

Additional Procedures
The AXIOS™ stent bi-flange design and large diameter provides a secure conduit for additional diagnostic and therapeutic interventions. Once placed, the AXIOS™ stent functions as a port allowing passage of standard and therapeutic endoscopes to facilitate debridement, irrigations and cystoscopy.

> **WARNING:** Care is required during dilation, debridement, irrigation, and cystoscopy procedures through the stent, to prevent air/fluid leak and/or stent dislodgement.

Stent Removal
Under endoscopic visualization, place a standard endoscopic snare over the stent flange. Tighten the snare until the stent lumen collapses. Pull the snare away from the gastrointestinal wall until the stent is removed from the tract. Remove the endoscope to extract the stent.

NOTE: The snare must be large enough to fit over the flange of the AXIOS stent (which can be up to 24 mm in diameter, see Stent Size table at beginning of document).

Stent removal may also be performed with endoscopic forceps. The stent is braided in such a way that it will not unravel if a wire is broken.

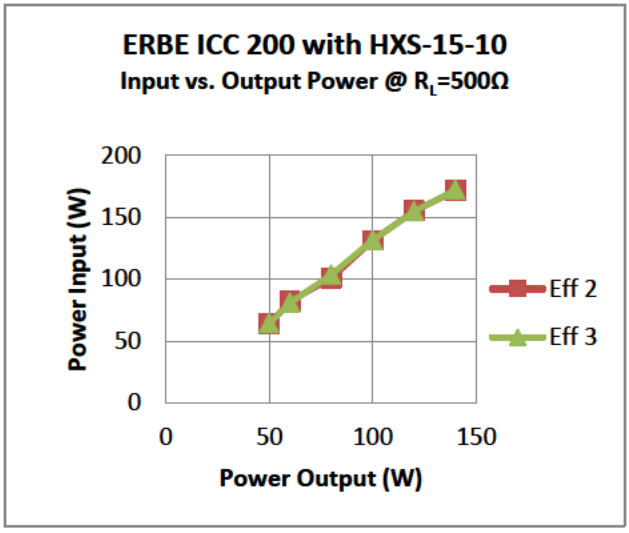
Once removed, the stent must be disposed of according to institutional guidelines for biohazardous medical waste.

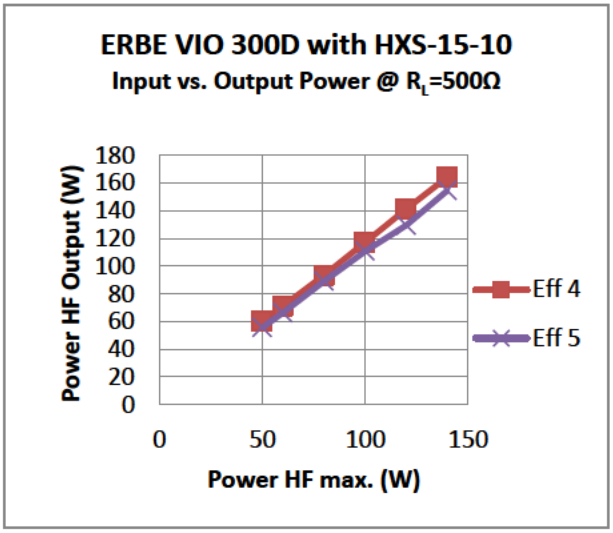
TROUBLESHOOTING
Some echoendoscope and elevator positions result in excess friction between the catheter and the working channel. Friction can produce length-wise compression (shortening) of the catheter as it is advanced through the working channel and conversely, extension (lengthening) when the catheter is retracted. Friction impacts the performance of the AXIOS Electrocautery Enhanced Delivery System; therefore the solutions below include both lowering (opening) the elevator and straightening the echoendoscope.

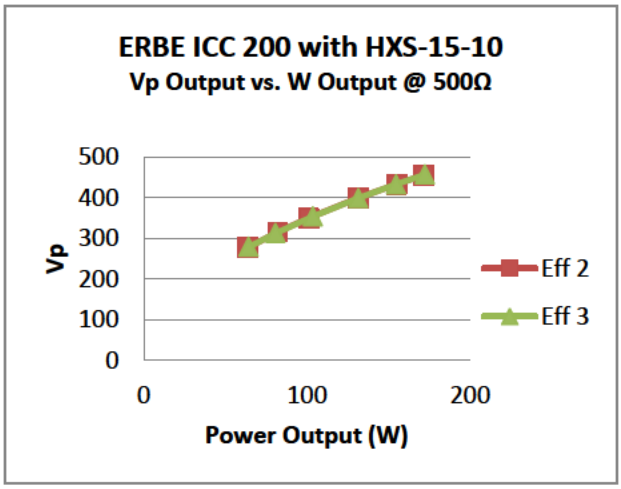
PROBLEM	POTENTIAL SOLUTION(S)
There is excessive resistance when trying to pass the catheter through the working channel.	• If the catheter is less than 2 cm from full inser ion, lower (open) he echoendoscope elevator and straighten the distal end of the echoendoscope. • If the catheter is less than 10 cm from full insertion, straighten the echoendoscope. • If the catheter is more than 10 cm from full insertion, remove it from the echoendoscope. Pass another tool to see if the working channel is obstructed.
The catheter cannot be advanced from its post-insertion position.	• Make sure the catheter is unlocked. • Ensure the echoendoscope elevator is lowered (open). • Straighten the echoendoscope position. • Remove the catheter from the working channel and confirm that it is not kinked or damaged and that the nose cone is contiguous with the catheter. • Wet the entire working length of the catheter and reinsert it into the working channel.
The catheter can be advanced but it does not enter the target structure.	• Under EUS imaging, ensure that the insulated guidewire is visible. Confirm that the nose cone and catheter are coaxially aligned with the insulated guidewire at the target structure. • Adjust/realign the echoendoscope position. • Ensure proper electrical connection between the electrosurgical generator and the Hot AXIOS™ Electrocautery Enhanced Delivery System. • Ensure that he patient is properly grounded in accordance with manufacturers recommendations for the return electrode. • Check generator to ensure appropriate settings.
Resistance makes it difficult to retract the stent deployment hub.	• Ensure the echoendoscope elevator is lowered (open). • Straighten the echoendoscope as much as possible. • Exchange the device for a new one.
The stent first flange is not deployed even though the stent deployment hub has clicked into position (at the "2" arrow line).	• Ensure the echoendoscope elevator is lowered (open). • Straighten the echoendoscope position. • Unlock the catheter lock, raise the elevator, advance the catheter control hub, and confirm the stent first flange deployment. Retract and advance the catheter control hub as necessary. Relock the catheter lock. • To limit deployment hub travel, grasp the handle at 5-10 mm above the "2" arrow line. Unlock the stent lock and carefully retract the stent deployment hub while closely monitoring the EUS image. Stop retracting the hub immediately when the stent first flange has deployed. DO NOT RETRACT MORE THAN 1 CM. **WARNING:** Retracting the deployment hub too far may result in the entire stent deploying inside the target structure.

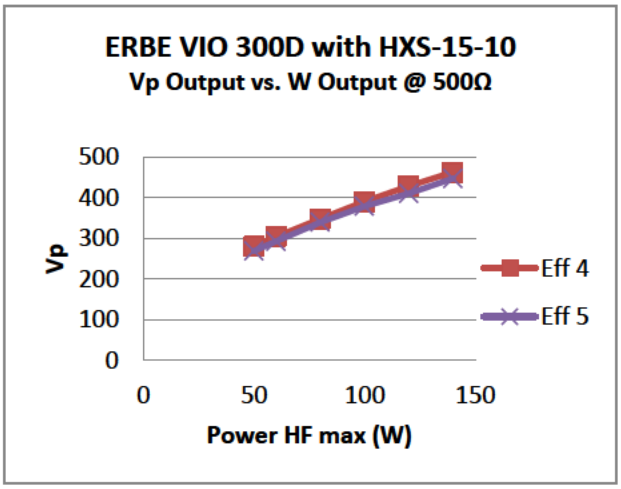
PROBLEM	POTENTIAL SOLUTION(S)
The catheter cannot be seen (or is seen with difficulty) on the endoscopic view when attempting to deploy the stent second flange.	Under EUS imaging, retract the catheter control hub so hat the stent first flange is seen tugging against the inner target wall. Deploy the stent second flange in accordance with Instructions for Use.
The stent second flange does not deploy even though the stent deployment hub has been retracted to the top of the handle.	Unlock the catheter lock and slowly advance the catheter control hub to push the stent second flange out of the echoendoscope working channel.
There is excessive resistance and the catheter lock has not been released when trying to pass the catheter through the working channel. **After the catheter is advanced into endoscopic view, there is an observed separation between the tip (nose cone) and the outer sheath. The stent may or may not be partially visible.**	• Unlock the catheter lock and advance the catheter 2-3 cm beyond the echoendoscope elevator. Lock the catheter lock. • Lock the echoendoscope elevator in the up (closed) position to hold the outer catheter sheath. • Withdraw the catheter by unlocking the catheter lock and pulling the handle until either: - the sheath and tip are in contact and the tip is resheathed, or - the sheath or tip is near the echoendoscope elevator. • Ensure the echoendoscope elevator is lowered (open) and advance he catheter. • If the catheter tip can be reset to Figure 4 “yes” position without dislodging the stent then, continue with the procedure as normal. • If resheathing procedure is unsuccessful, withdraw the device and return it to Xlumena, Inc.
After positioning the first flange, the catheter has moved retrograde into the echoendoscope working channel and the second flange is deployed in the working channel.	To complete the second flange deployment, keep the EUS image of the first flange in view and apply gentle traction to the echoendoscope. • Maintain the first flange image on EUS to guide the echoendoscope retraction. Do not retract such that the first flange changes shape beyond an ‘American football’ shape. • Wi h this mild traction in place, open catheter lock and slowly move the ca heter out of the echoendoscope to expel the second flange from the echoendoscope working channel.
The catheter is unable to be removed from the echoendoscope after the stent has been deployed.	• Method 1 – Position the echoendoscope tip in the full down and gently tug on the catheter to remove it from the scope. If this does not work proceed to method 2. • Method 2 – While maintaining slight tension on the catheter, move the elevator lever to the fully closed position, then open the elevator while tugging gently on the catheter. The movement of the elevator will allow the back shoulder of the ceramic nose cone to slip into the channel and be removed. • Method 3 - Move the stent deployment hub back to its original position by moving the gray stent deployment hub downward to the number 2 marker on the handle. Then, either break off the plastic leg just below the #2 line, or push the leg in while moving the deployment hub below the #2 line toward its original position. The tip of the catheter should be visible on the endo view, confirm that the nose cone and the catheter are flush. If not, pull the elevator lever downward and pull the catheter back. This maneuver should snug up the two components and allow he easy removal of he AXIOS™ handle.

OUTPUT POWER AND VOLTAGE









WARRANTY

Xlumena, Inc. warrants that reasonable care has been used in the design and manufacture of this product. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to any o her implied warranties of merchantability or fitness. Handling, storage, cleaning, and sterilization of this device as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond Xlumena's control can directly affect the device and the results obtained from its use. Xlumena's obligation under this warranty is limited to the repair or replacement of this device. Xlumena shall not be liable for any incidental or consequen ial loss, damage, or expense directly or indirectly arising from the use of this device. Xlumena neither assumes, nor authorizes any other person to assume o her or additional liability or responsibility in connection with this device. Xlumena assumes no liability for any device reuse, reprocessing or resterilization, and makes no warranties, expressed or implied, including but not limited to merchantability or fitness for the intended use, of said device.

MRI INFORMATION

MR Conditional

Non-clinical testing demonstrated that the AXIOS™ Stent is MR Conditional.

A patient with an implanted AXIOS™ Stent can be scanned safely under the following conditions:

- Static magnetic field of 3-Tesla or less
- Maximum spatial gradient magnetic field of 720-Gauss/cm or less

MRI-Related Heating
In non-clinical testing, the AXIOS™ Stent produced a maximum temperature change of +1.7°C during MRI performed for 15 minutes of scanning (i.e., per pulse sequence) in the 3-Tesla (3-Tesla/128-MHz, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MR system.

Therefore, the MRI-related heating experiments for the AXIOS™ Stent at 3-Tesla using a transmit/receive RF body coil at an MR system reported whole body averaged SAR of 2.9-W/kg (i.e., associated with a calorimetry measured whole body averaged value of 2.7-W/kg) indicated that the greatest amount of heating that occurred in association with these specific conditions was equal to or less than +1.7°C.

Artifact Information
MR image quality may be compromised if the area of interest is in the exact same area, or relatively close to, the position of the AXIOS™ Stent. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary. The maximum artifact size (i.e., as seen on the gradient echo pulse sequence) extends approximately 10 mm relative to the size and shape of the AXIOS™ Stent.

Artifacts at 3 Tesla

Pulse Sequence	T1-SE	T1-SE	GRE	GRE
Signal Void Size	423 mm^2	504 mm^2	808 mm^2	712 mm^2
Plane Orientation	Parallel	Perpendicular	Parallel	Perpendicula

The safety of the delivery system has not been evaluated in the MR environment, and therefore, the delivery system should not be used in the MR environment.

DEFINITIONS OF SYMBOLS

Rx ONLY	CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician		Type BF Applied Part
	Consult Instructions for Use	MR	MR Conditional
LOT	Lot Number	REF	Catalogue/Model number
	Use By Date		Keep Dry
	Do Not Use if Package is Damaged	%	Humidity Limitation
	Do Not Re-use		Pressure Limitation
LATEX	Not made with natural rubber latex.		Temperature Limitation
STERILE EO	Sterilized Using Ethylene Oxide		Manufactured By
STERILIZE	Do Not Re-sterilize	EC REP	Authorized Representative in the European Community

PATENTS AND TRADEMARKS
XLUMENA, AXIOS and Endolink are trademarks of Xlumena, Inc.
Patents Pending: 8,425,539; 8,454,632; 8,357,193.

CUSTOMER SERVICE

US CUSTOMER SERVICE
E-mail:
customerservice@xlumena.com
Phone: +1.888.XLUMENA
(+1.650.961.9900)
Fax: +1.650.961.9901

Xlumena, Inc.
453 Ravendale Drive, Suite H
Mountain View, CA 94043
United States of America
Phone: +1.650.961.9900
Fax: +1.650.961.9901

EU CUSTOMER SERVICE
E-mail:
cs@healthlinkeurope.com
Phone: +31(0)73.303.0597
Fax: +31(0)20.799.8032

EC REP **HealthLink Europe BV**
De Tweeling 20-22
's-Hertogenbosch 5215 MC
The Netherlands
Phone: +31.13.547.9300
Fax: +31.13.547.9301

CE **0459**

ATTACHMENT 8

(b)(4)Proprietary Information-Investigation Info

(b)(4)Proprietary Information-Investigation Info

(b)(4)Proprietary Information-Investigation Info

(b)(4)Proprietary Information-Investigation Info

(b)(4)Proprietary Information-Investigation Info

(b)(4)Proprietary Information-Investigation Info

(b)(4)Proprietary Information-Investigation Info

(b)(4)Proprietary Information-Investigation Info

(b)(4)Proprietary Information-Investigation Info

(b)(4)Proprietary Information-Investigation Info

(b)(4)Proprietary Information-Investigation Info

(b)(4)Proprietary Information-Investigation Info

(b)(4)Proprietary Information-Investigation Info

(b)(4)Proprietary Information-Investigation Info

(b)(4)Proprietary Information-Investigation Info

(b)(4)Proprietary Information-Investigation Info

(b)(4)Proprietary Information-Investigation Info

(b)(4)Proprietary Information-Investigation Info

(b)(4)Proprietary Information-Investigation Info

ATTACHMENT 9

(b)(4)Proprietary Information-Draft

(b)(4)Proprietary Information-Draft

(b)(4)Proprietary Information-Draft

(b)(4)Proprietary Information-Draft

(b)(4)Proprietary Information-Draft

(b)(4)Proprietary Information-Draft

(b)(4)Proprietary Information-Draft

(b)(4)Proprietary Information-Draft

(b)(4)Proprietary Information-Draft

(b)(4)Proprietary Information-Draft

(b)(4)Proprietary Information-Draft

(b)(4)Proprietary Information-Draft

(b)(4)Proprietary Information-Draft

(b)(4)Proprietary Information-Draft

(b)(4)Proprietary Information-Draft

(b)(4)Proprietary Information-Draft

(b)(4)Proprietary Information-Draft

(b)(4)Proprietary Information-Draft

(b)(4)Proprietary Information-Draft

(b)(4)Proprietary Information-Draft

(b)(4)Proprietary Information-Draft

(b)(4)Proprietary Information-Draft

(b)(4)Proprietary Information-Draft

(b)(4)Proprietary Information-Draft

(b)(4)Proprietary Information-Draft

(b)(4)Proprietary Information-Draft

(b)(4)Proprietary Information-Draft

(b)(4)Proprietary Information-Draft

(b)(4)Proprietary Information-Draft

(b)(4)Proprietary Information-Draft

ATTACHMENT 10

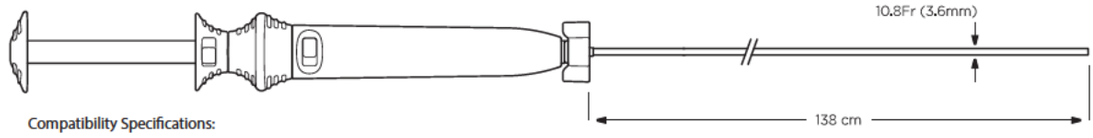
Hot AXIOS™

Stent and Electrocautery Enhanced Delivery System

REF HXS(US)-10-10

(1) Fully covered AXIOS Stent with disposable Electrocautery Enhanced Delivery System

CE 0459

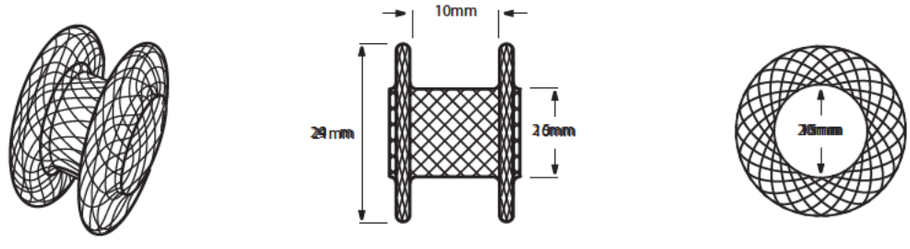


Compatibility Specifications:

- Minimum Scope Channel Size: Ø 3.7mm
- Maximum Guidewire Size: 0.035"
- Required Active Cable Size: 3mm MONOPOLAR PLUG (Olympus/Cook type)

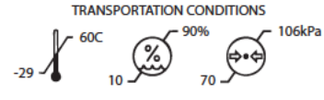
10mm Lumen Diameter X **10mm** Stent Length

Patents Pending
8,425,539
8,454,632
8,357,193

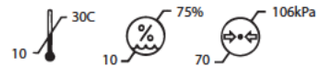


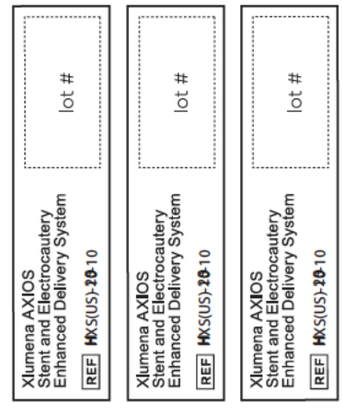
Rx ONLY	CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician		Type BF Applied Part
	Consult Instructions for Use	MR	MR Conditional
LOT	Lot Number	REF	Catalogue / Model number
	Use By Date		Keep Dry
	Do Not Use if Package is Damaged		Humidity Limitation
2	Single Use Only / Do Not Re-use		Pressure Limitation
LATEX	Not made with natural rubber latex		Temperature Limitation
STERILE EO	Sterilized Using Ethylene Oxide		Manufactured By
2 STERILIZE	Do Not Re-sterilize	EC REP	Authorized Representative

TRANSPORTATION CONDITIONS



STORAGE & OPERATING CONDITIONS





Xlumena, Inc.
USA Customer Service +1.888.958.6362
453 Ravendale Drive, Suite H, Mountain View, CA 94043

EC REP HealthLink Europe BV
De Tweeling 20-22
's-Hertogenbosch 5215 MC
The Netherlands
Tel: +31.13.547.9300

Hot AXIOS™

Stent and Electrocautery Enhanced Delivery System

REF HXS(US)-10-10

10mm Lumen Diameter

CE 0459 LOT lot # use by

LBS01183.B

ATTACHMENT 11

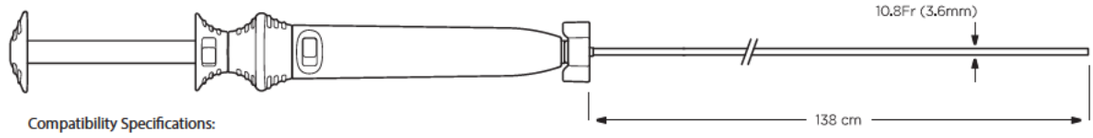
Hot AXIOS™

Stent and Electrocautery Enhanced Delivery System

REF HXS(US)-10-10

(1) Fully covered AXIOS Stent with disposable Electrocautery Enhanced Delivery System

CE 0459

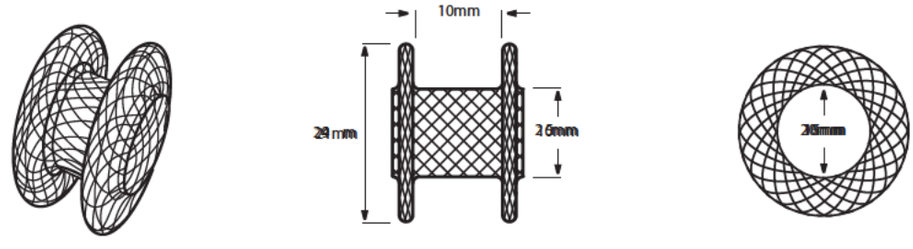


Compatibility Specifications:

- Minimum Scope Channel Size: Ø 3.7mm
- Maximum Guidewire Size: 0.035"
- Required Active Cable Size: 3mm MONOPOLAR PLUG (Olympus/Cook type)

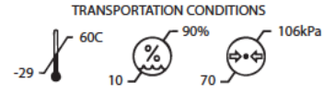
10mm Lumen Diameter X **10mm** Stent Length

Patents Pending
8,425,539
8,454,632
8,357,193

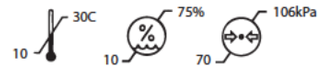


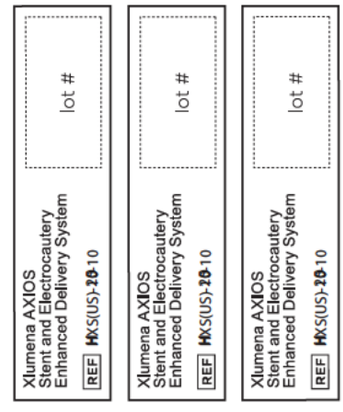
Rx ONLY	CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician		Type BF Applied Part
	Consult Instructions for Use	MR	MR Conditional
LOT	Lot Number	REF	Catalogue / Model number
	Use By Date		Keep Dry
	Do Not Use if Package is Damaged		Humidity Limitation
2	Single Use Only / Do Not Re-use		Pressure Limitation
LATEX	Not made with natural rubber latex		Temperature Limitation
STERILE EO	Sterilized Using Ethylene Oxide		Manufactured By
2 STERILIZE	Do Not Re-sterilize	EC REP	Authorized Representative

TRANSPORTATION CONDITIONS



STORAGE & OPERATING CONDITIONS





Xlumena, Inc.
USA Customer Service +1.888.958.6362
453 Ravendale Drive, Suite H, Mountain View, CA 94043

EC REP HealthLink Europe BV
De Tweeling 20-22
's-Hertogenbosch 5215 MC
The Netherlands
Tel: +31.13.547.9300

Hot AXIOS™

Stent and Electrocautery Enhanced Delivery System

REF HXS(US)-10-10

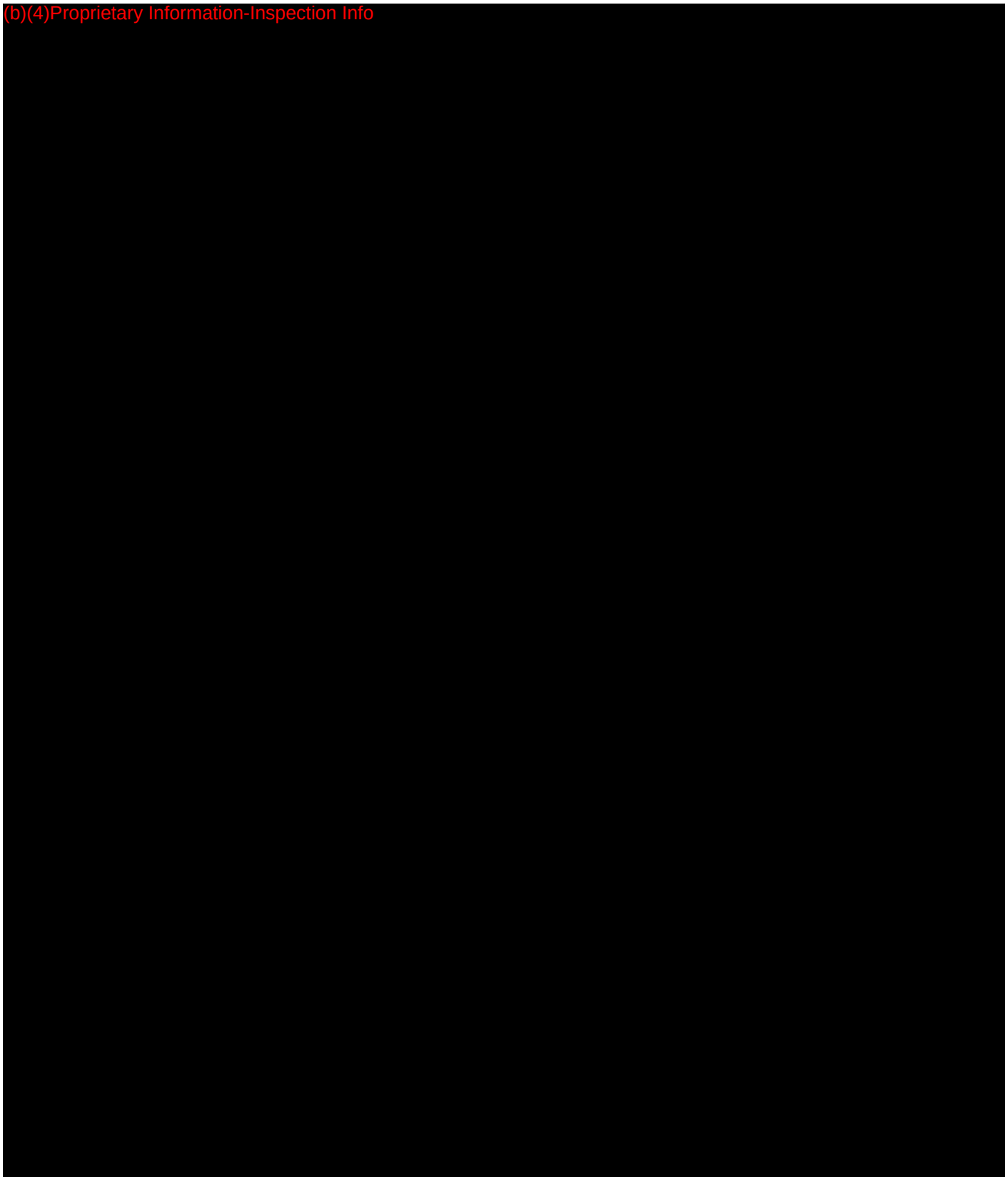
10mm Lumen Diameter

CE 0459 LOT lot # use by

LBS01183.B

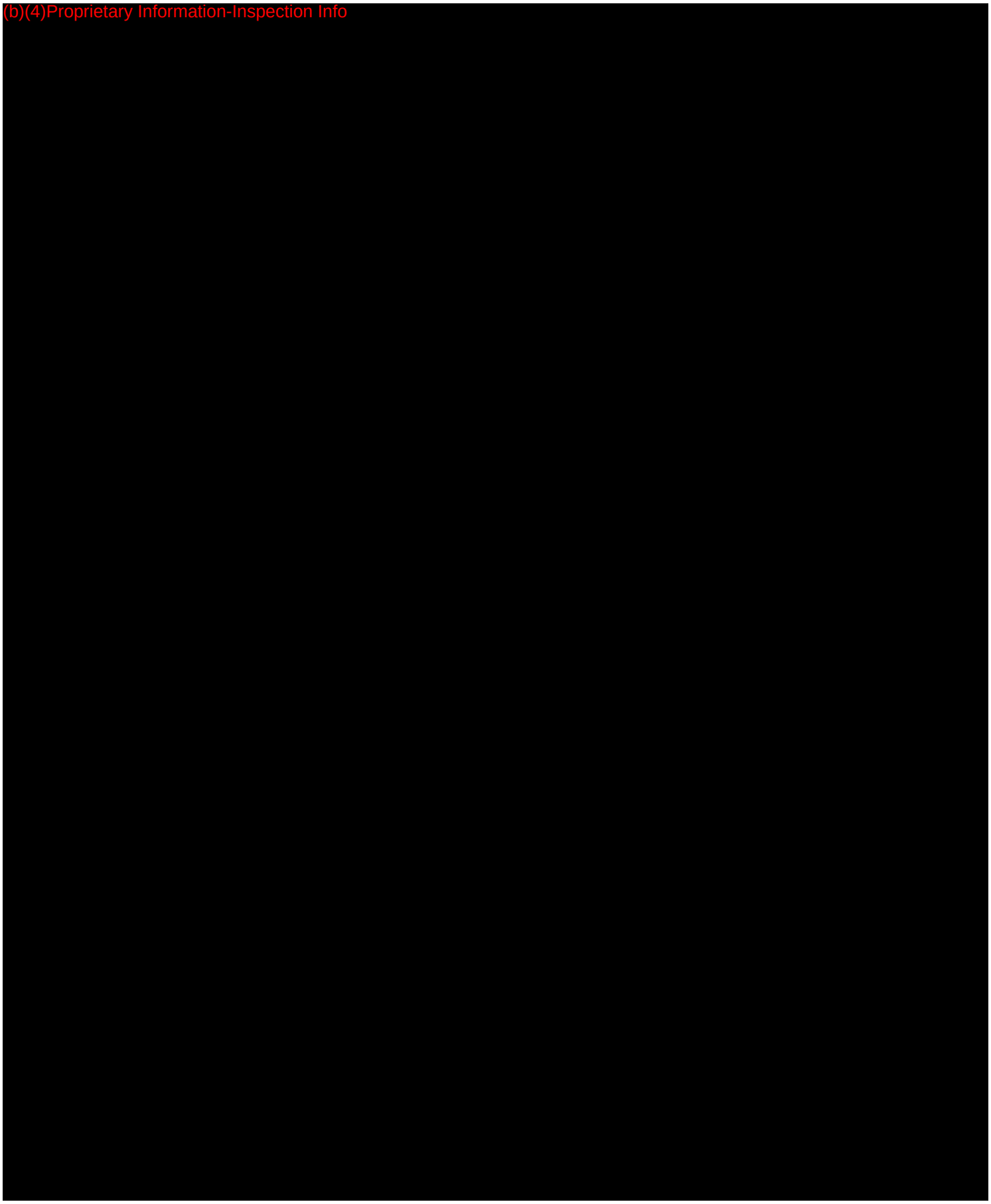
ATTACHMENT 12

(b)(4)Proprietary Information-Inspection Info



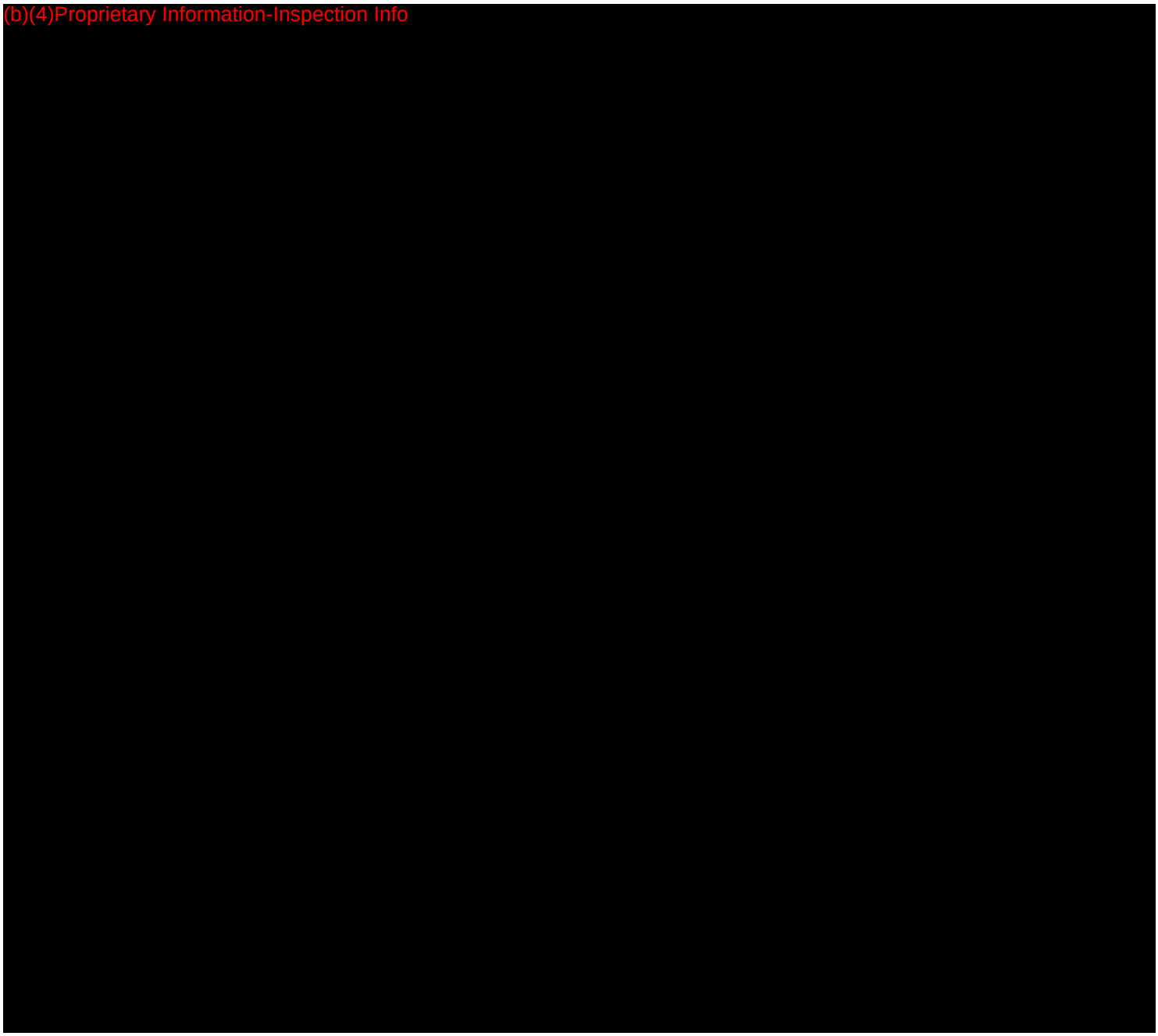
ATTACHMENT 13

(b)(4)Proprietary Information-Inspection Info

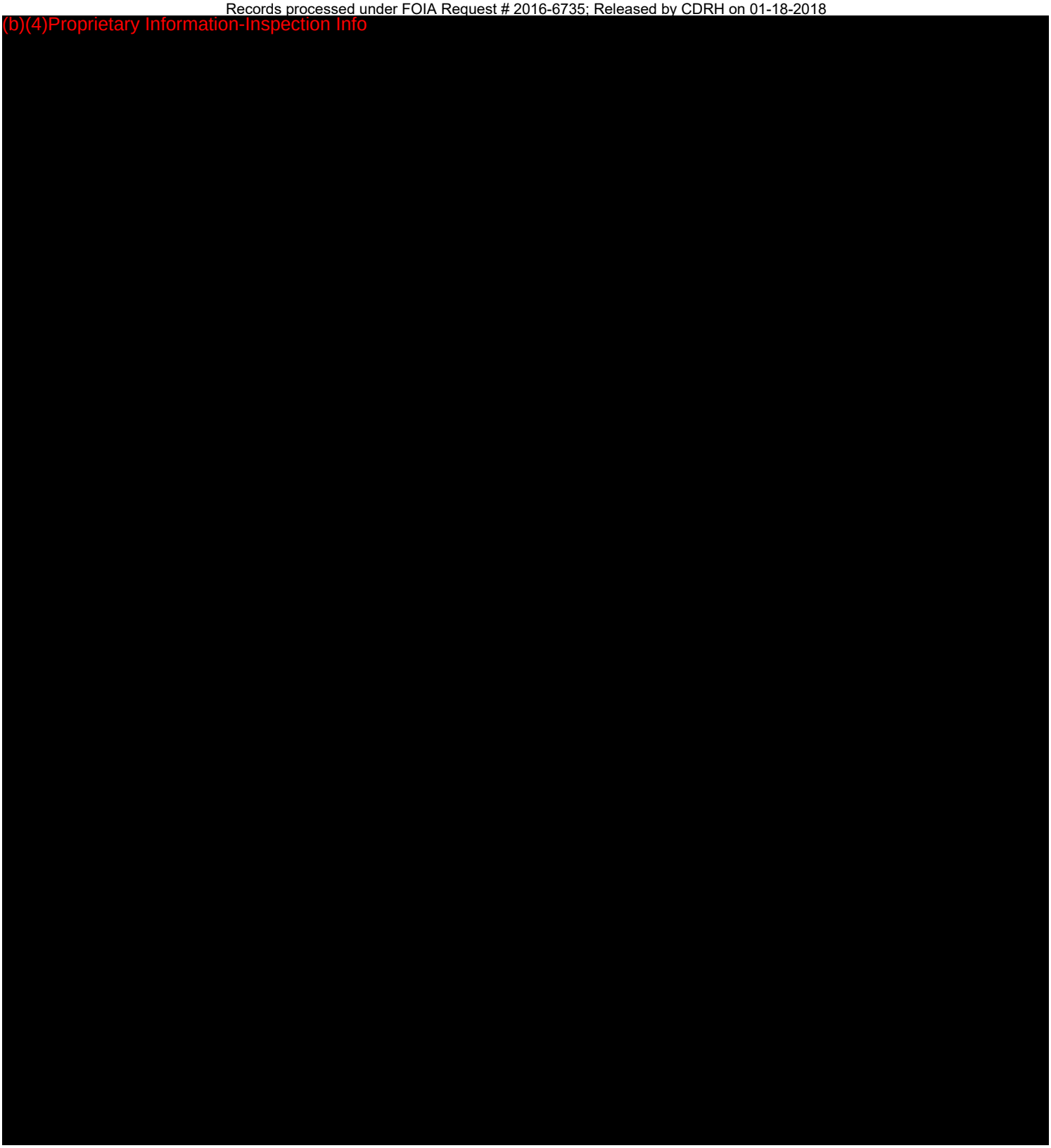


ATTACHMENT 14

(b)(4)Proprietary Information-Inspection Info



(b)(4)Proprietary Information-Inspection Info



(b)(4)Proprietary Information-Inspection Info

ATTACHMENT 15

Please carry this card at all times and show it to any medical personnel that may be treating you.

therapy | AXIOS

Patient Name	
Date of Implant	
Site of Implant	
Hospital Name	
Implanting Physician	
Implanting Physician Phone	

Xlumena

IMPLANTED DEVICE PATIENT INFORMATION CARD

AFFIX DEVICE LABEL HERE

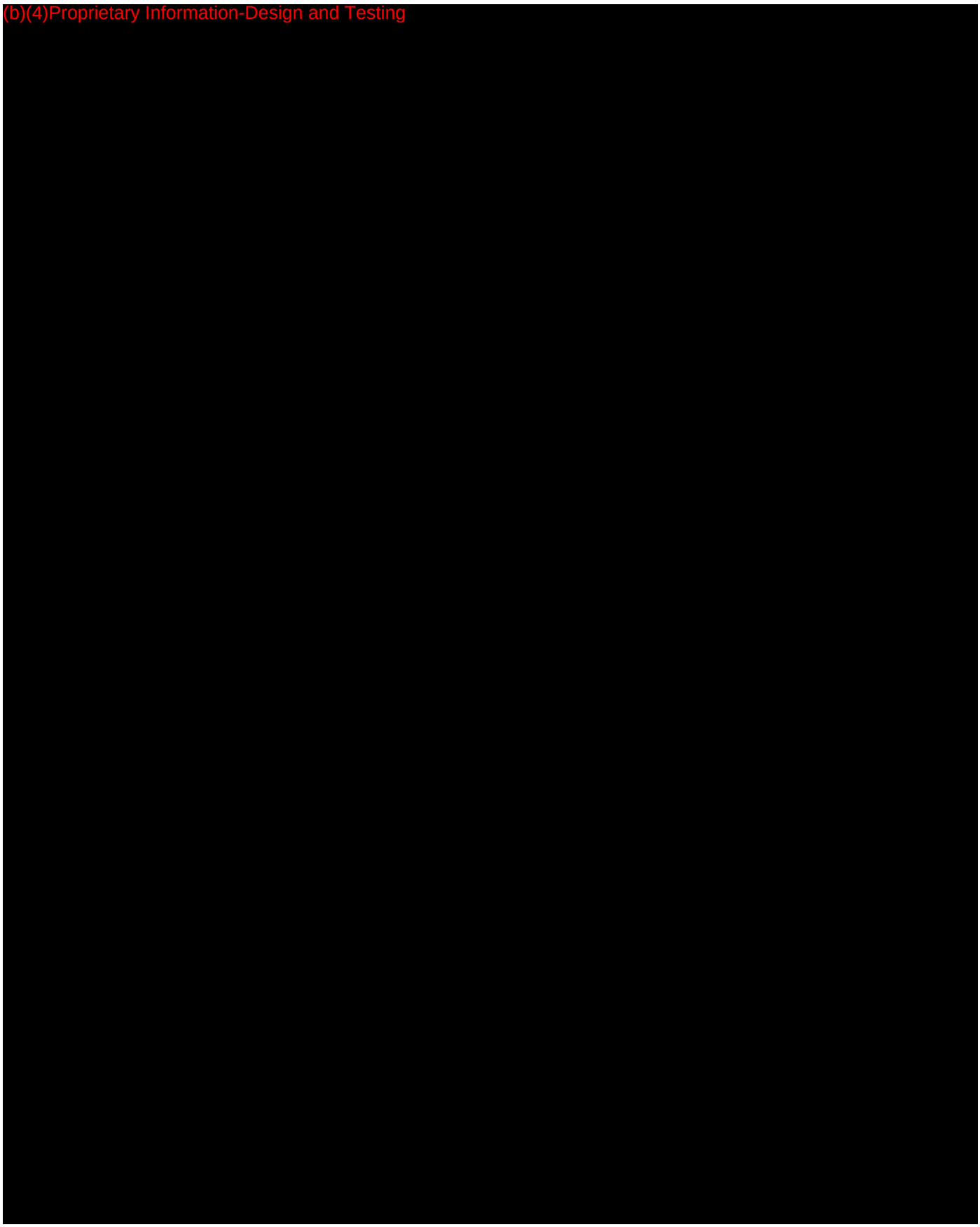
Notify your physician prior to your MRI Scan.
Non-clinical testing demonstrated that the AXIOS™ Stent is MR Conditional.
A patient with this device can be scanned safely immediately after placement under the following conditions:

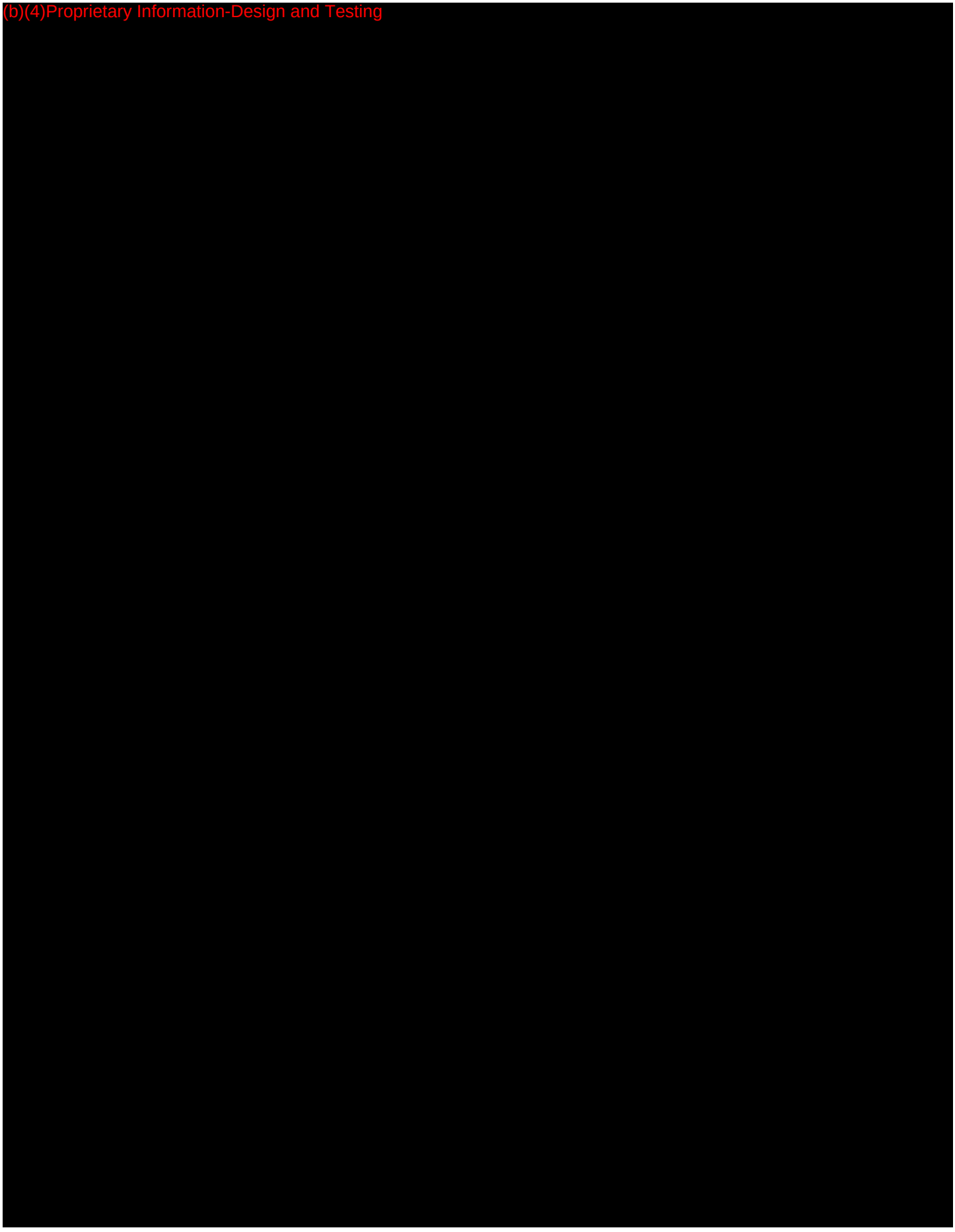
- Static magnetic field of 3-Tesla or less
- Maximum spatial gradient magnetic field of 720-Gauss/cm or less
- Maximum whole body averaged specific absorption rate (SAR) of 2-W/Kg for 15 minutes of scanning

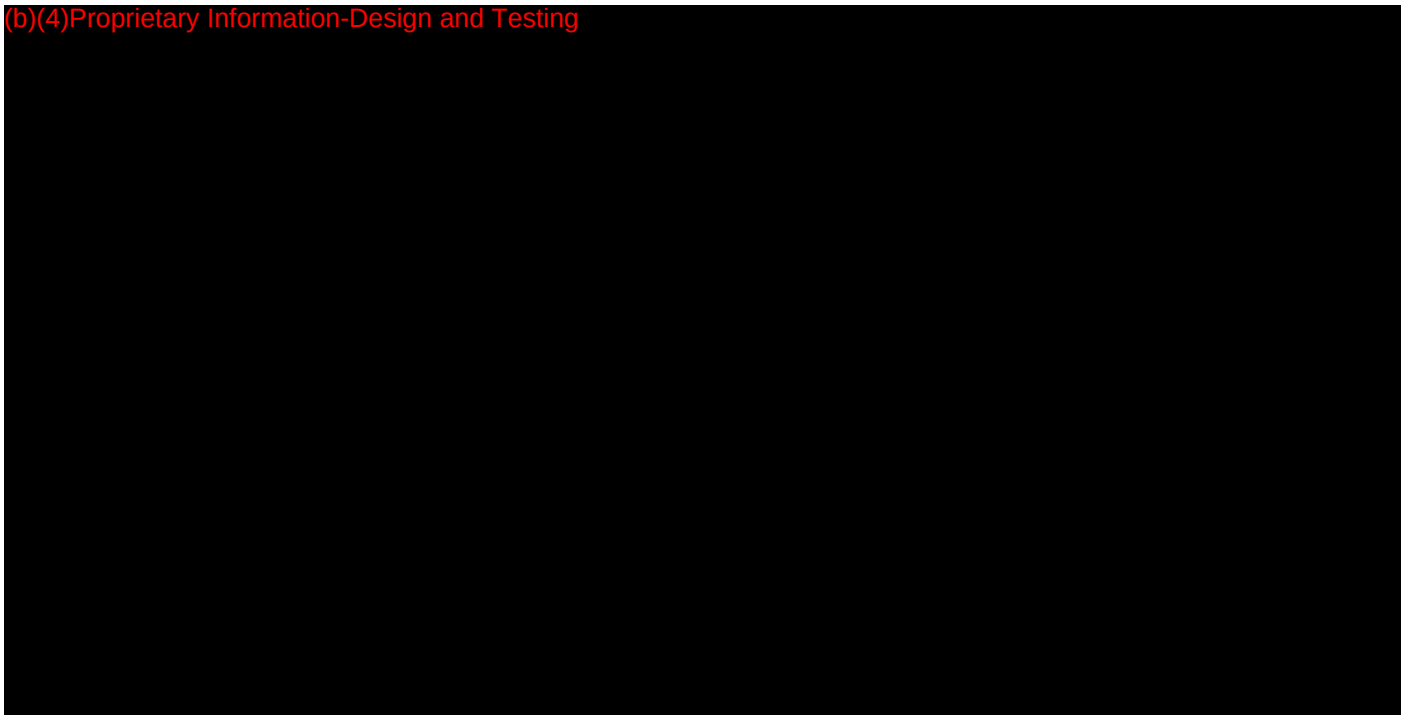
For questions regarding your AXIOS Stent or procedure, please contact your implanting physician or Xlumena at 1-888-XLUMENA.

PM00763.B

ATTACHMENT 16

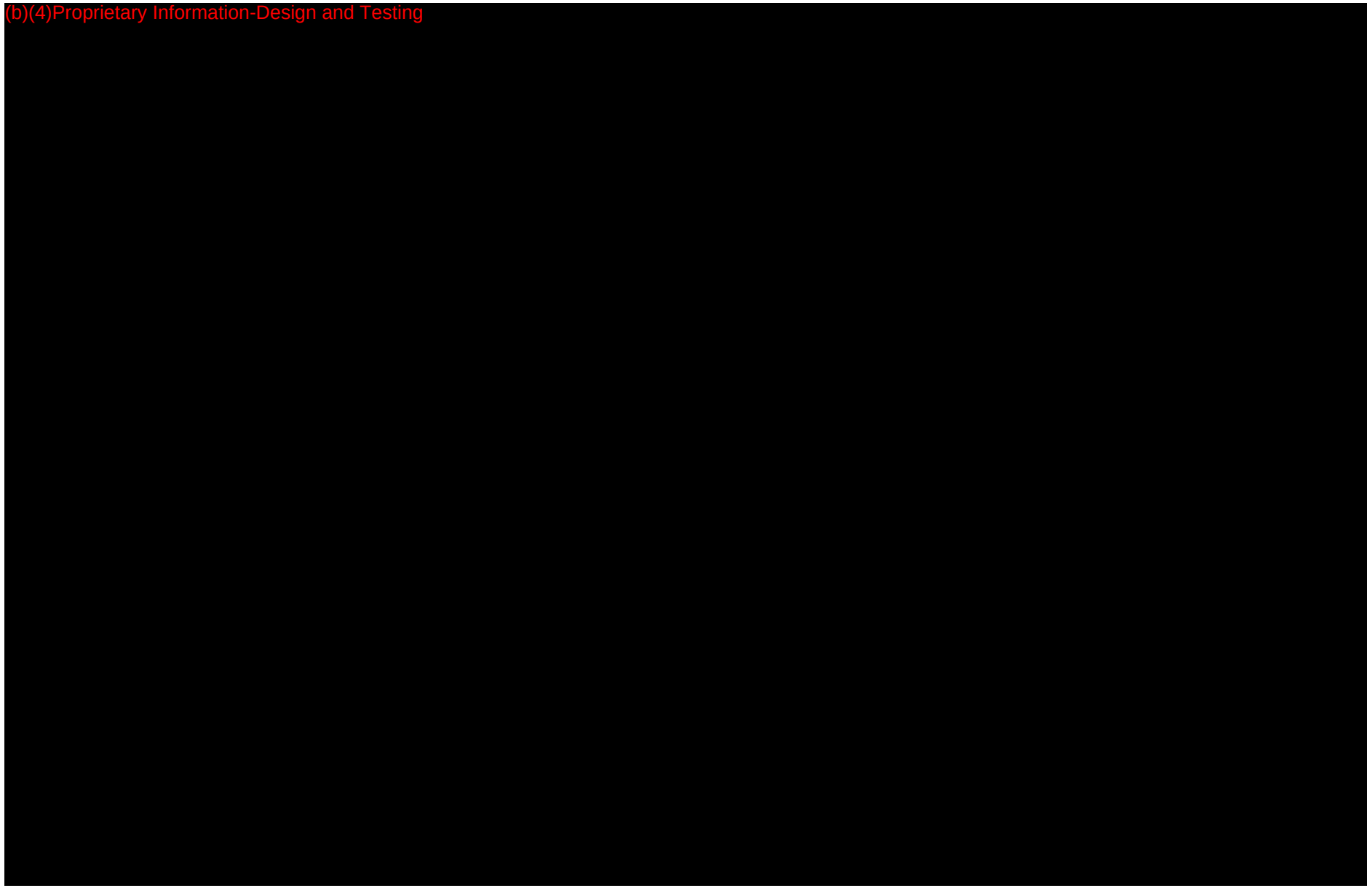


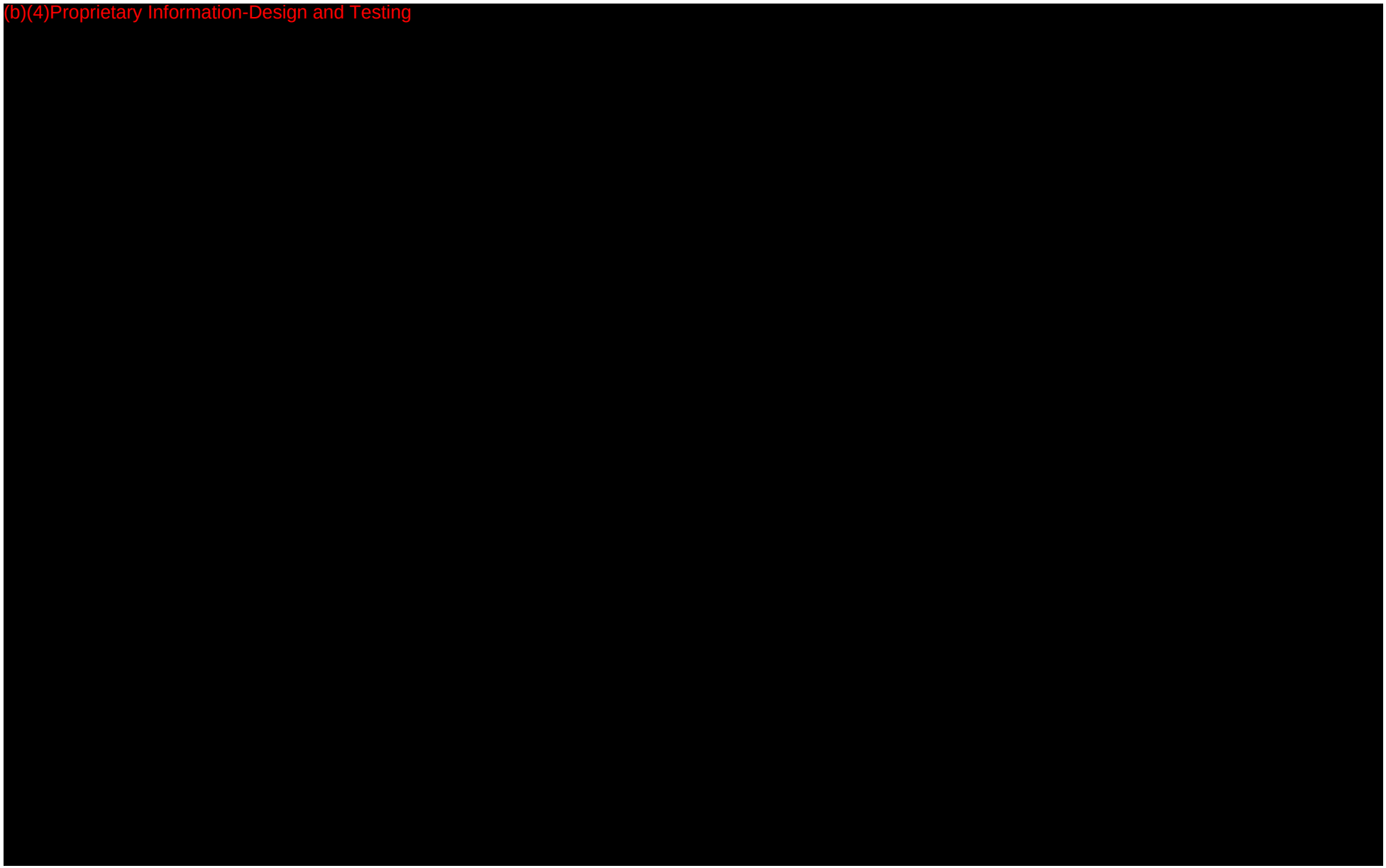


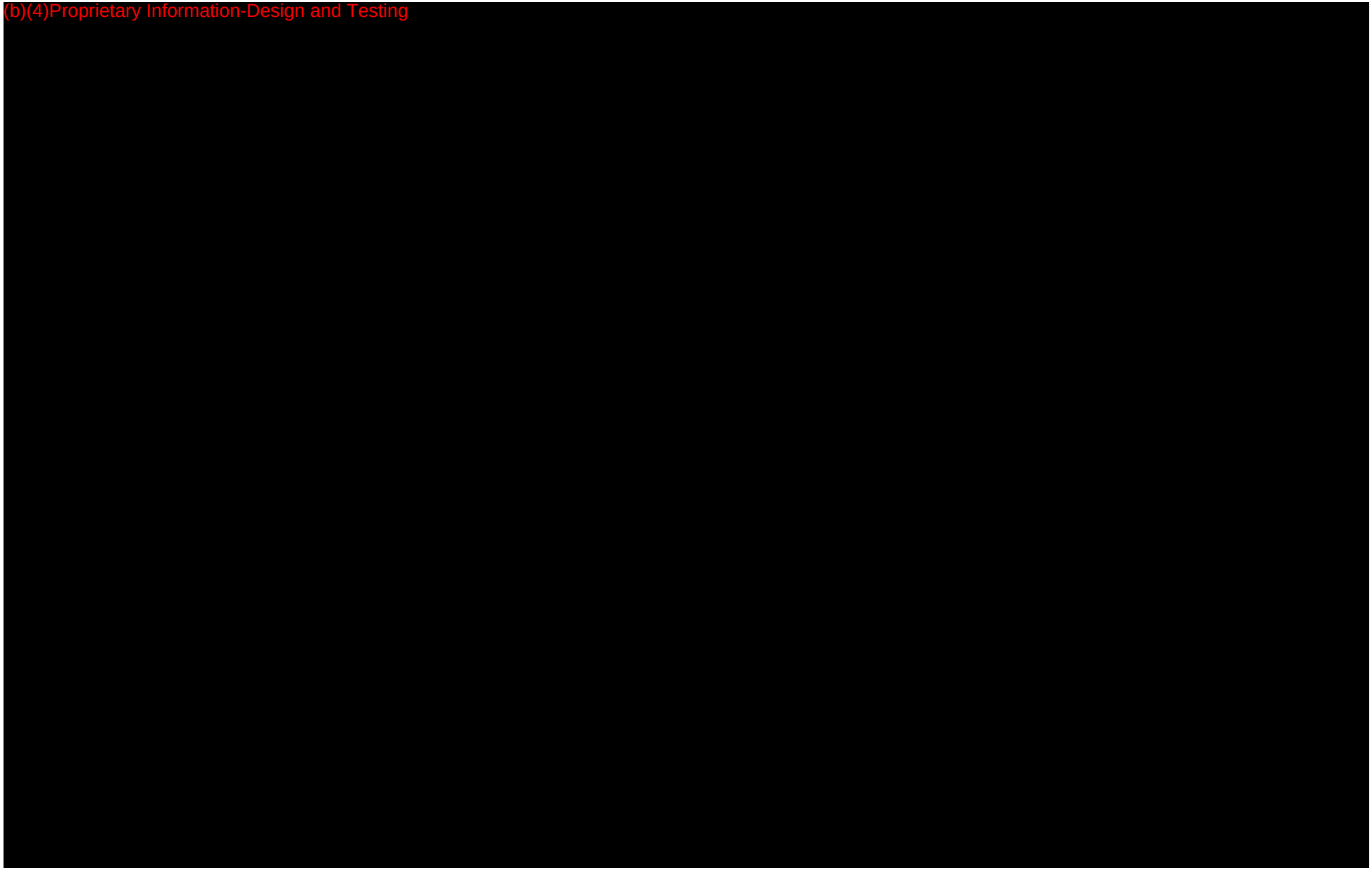


Design Verification Testing

(b)(4)Proprietary Information-Design and Testing



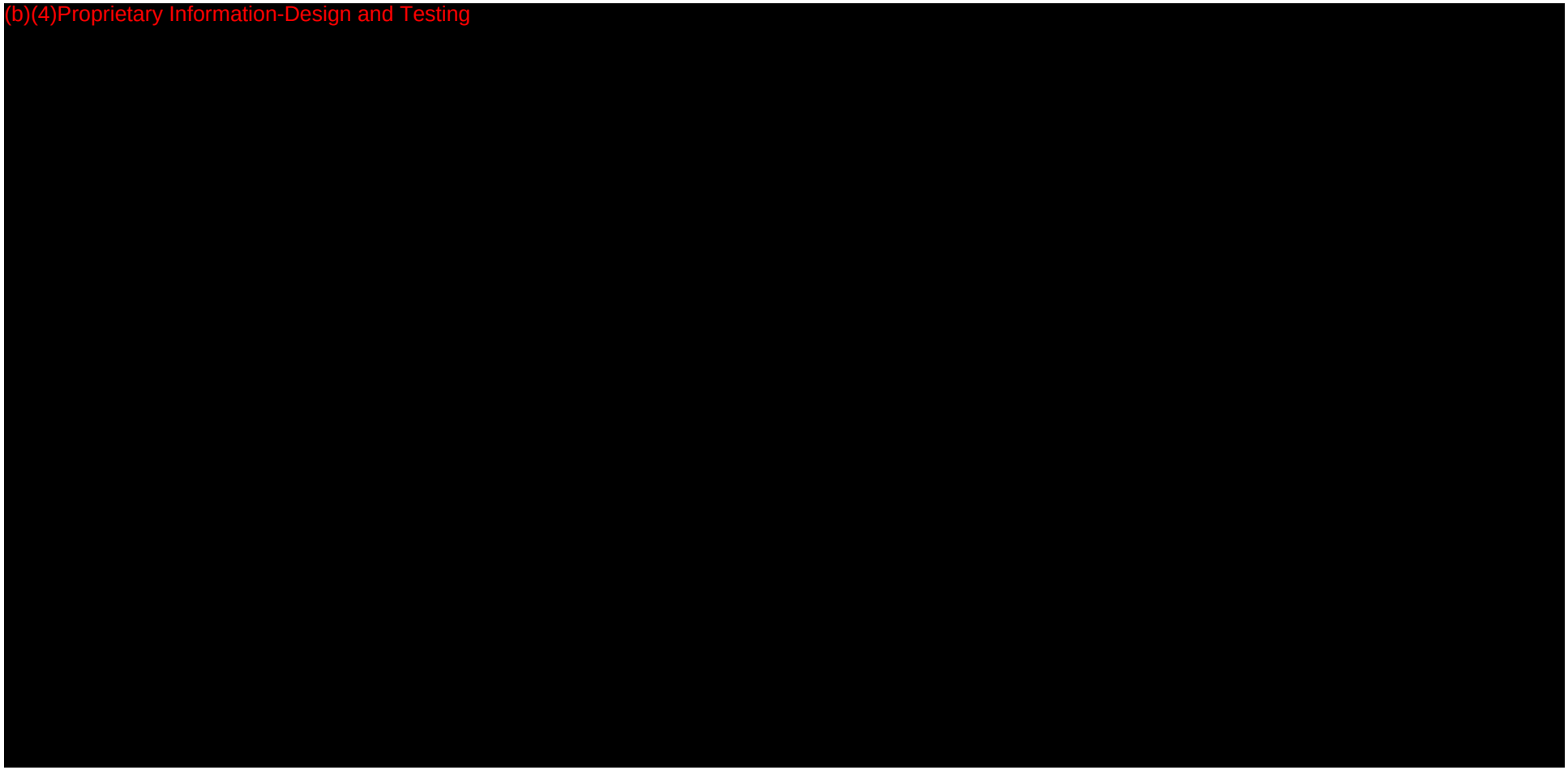




(b)(4)Proprietary Information-Design and Testing

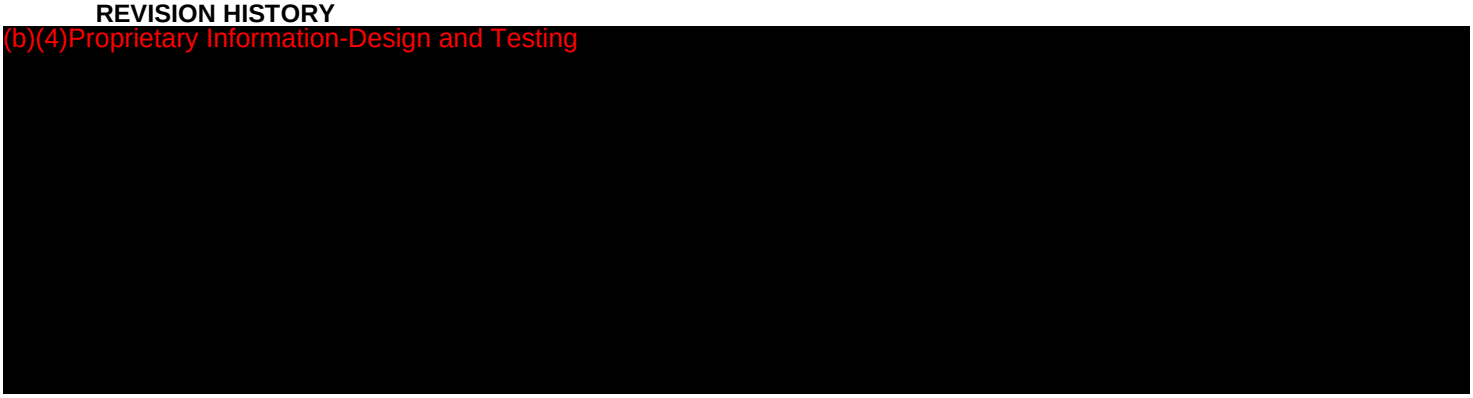
APPENDIX I: TESTING FLOWCHART

(b)(4)Proprietary Information-Design and Testing



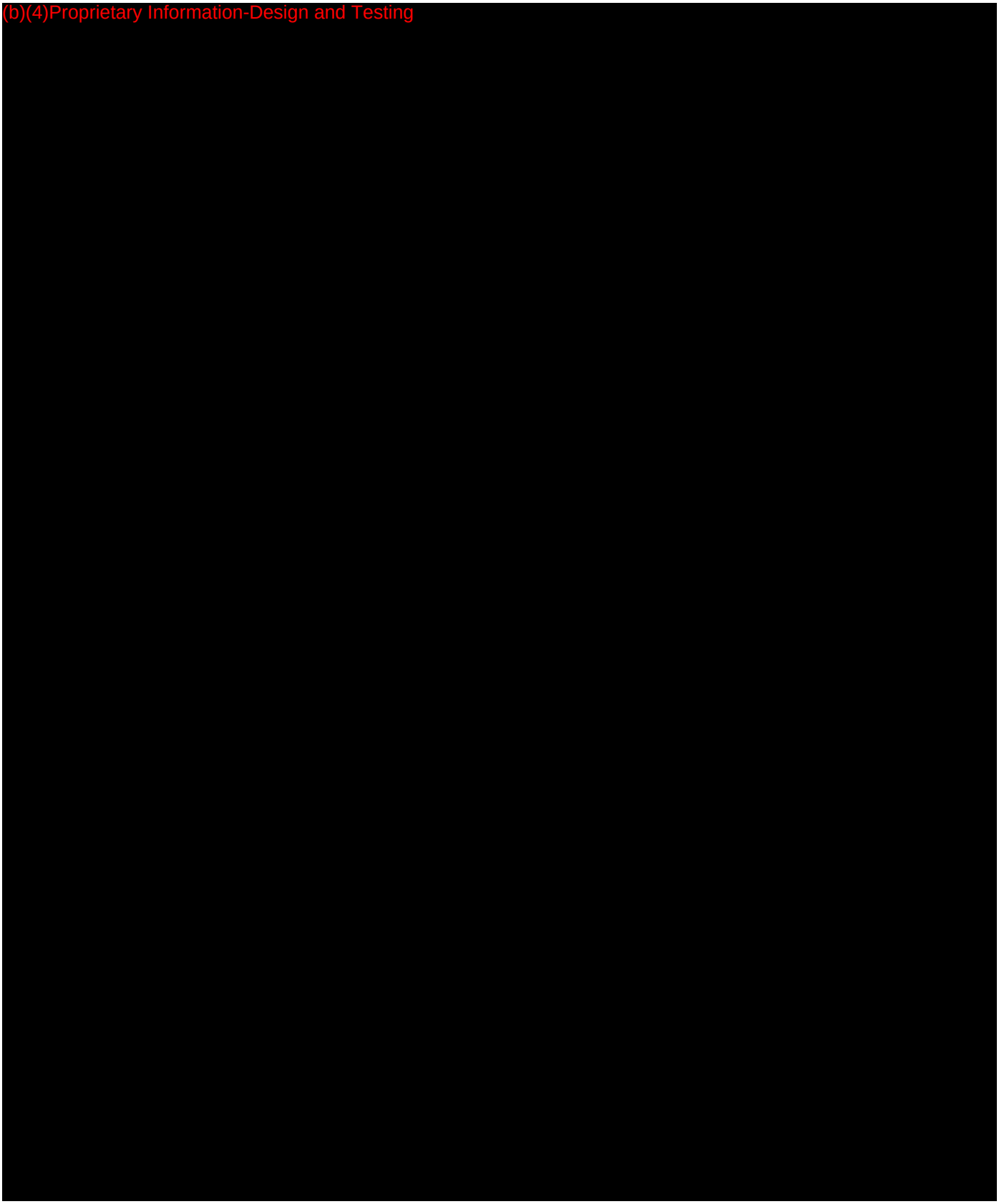
REVISION HISTORY

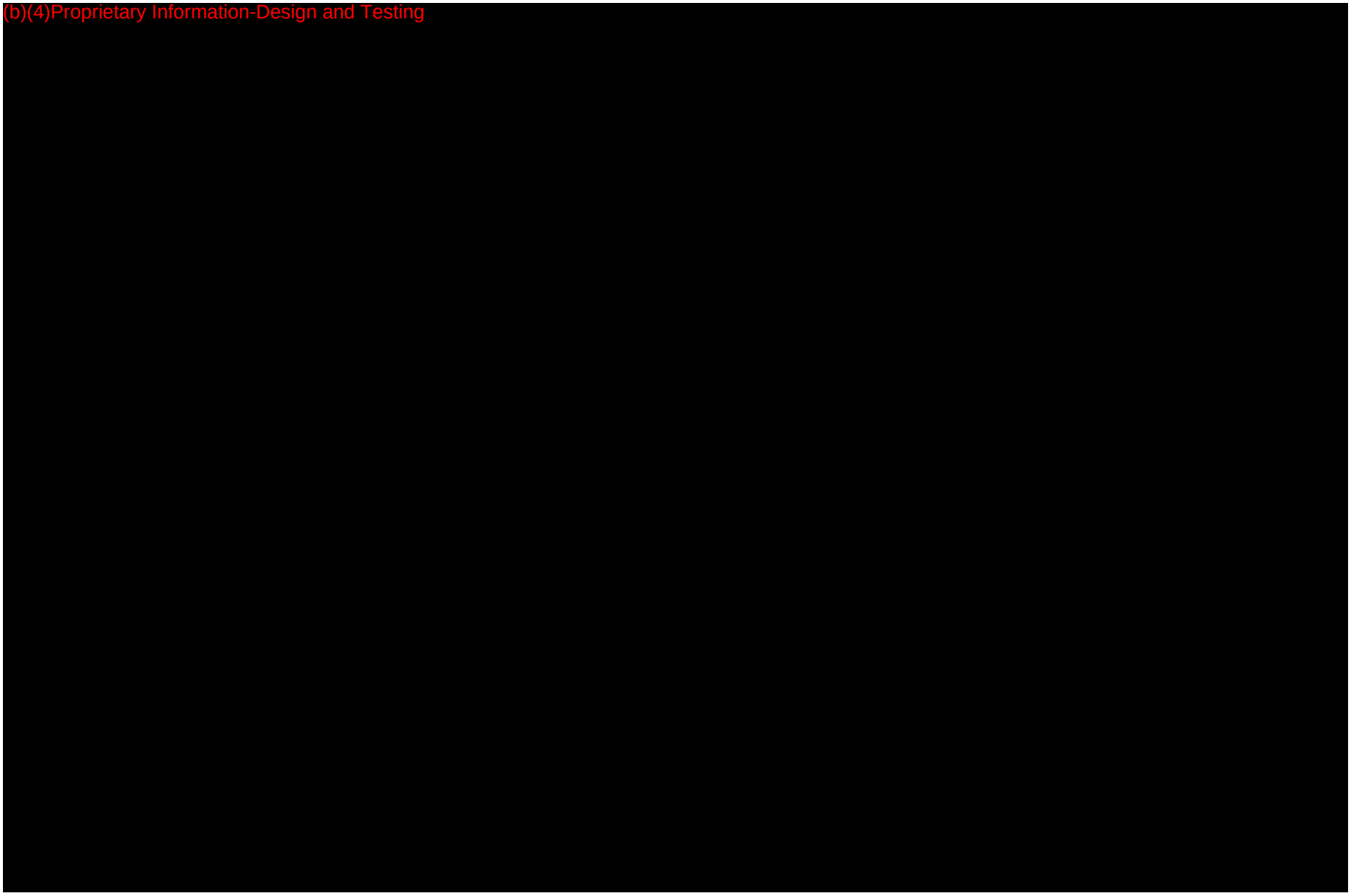
(b)(4)Proprietary Information-Design and Testing

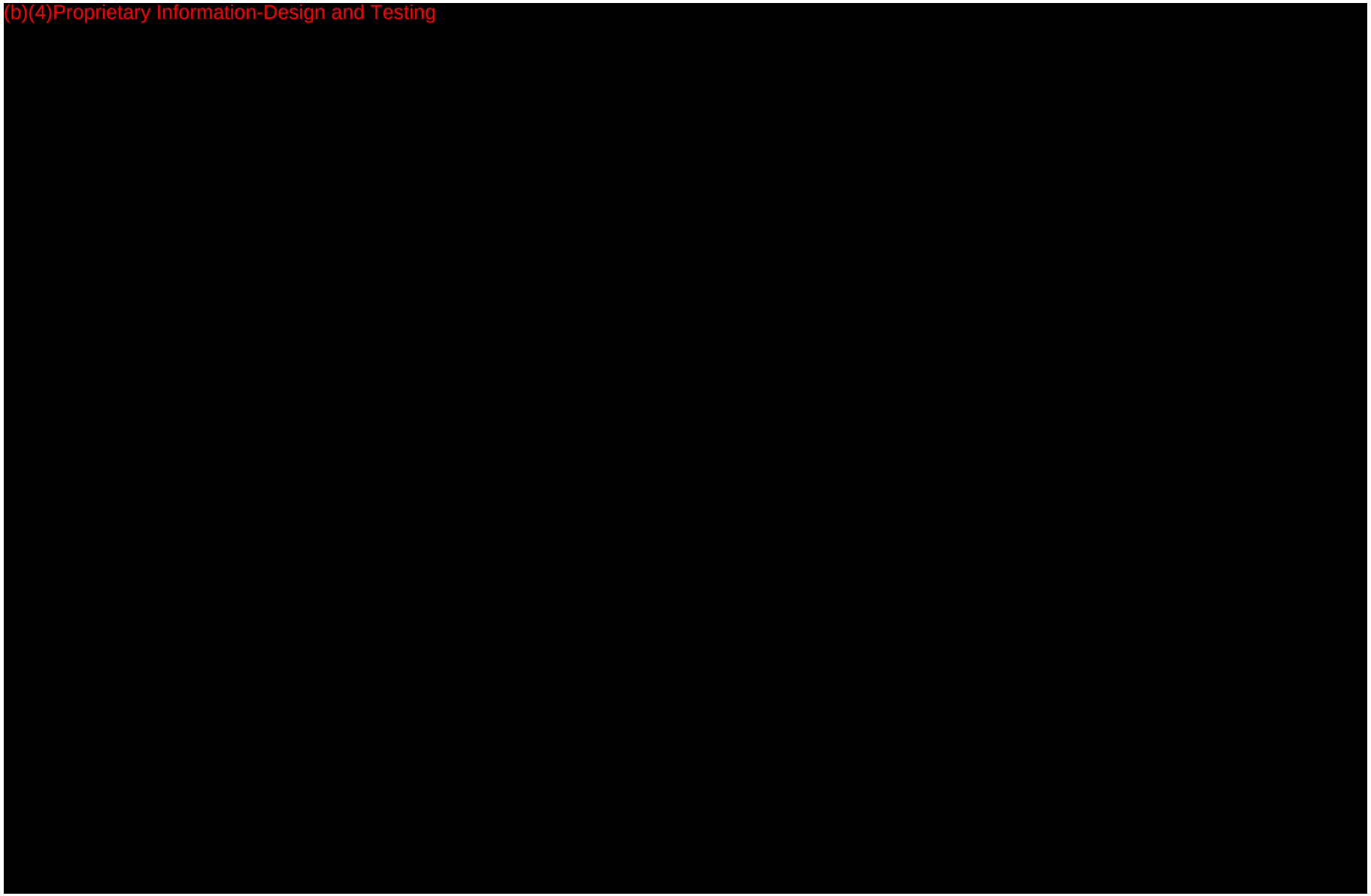


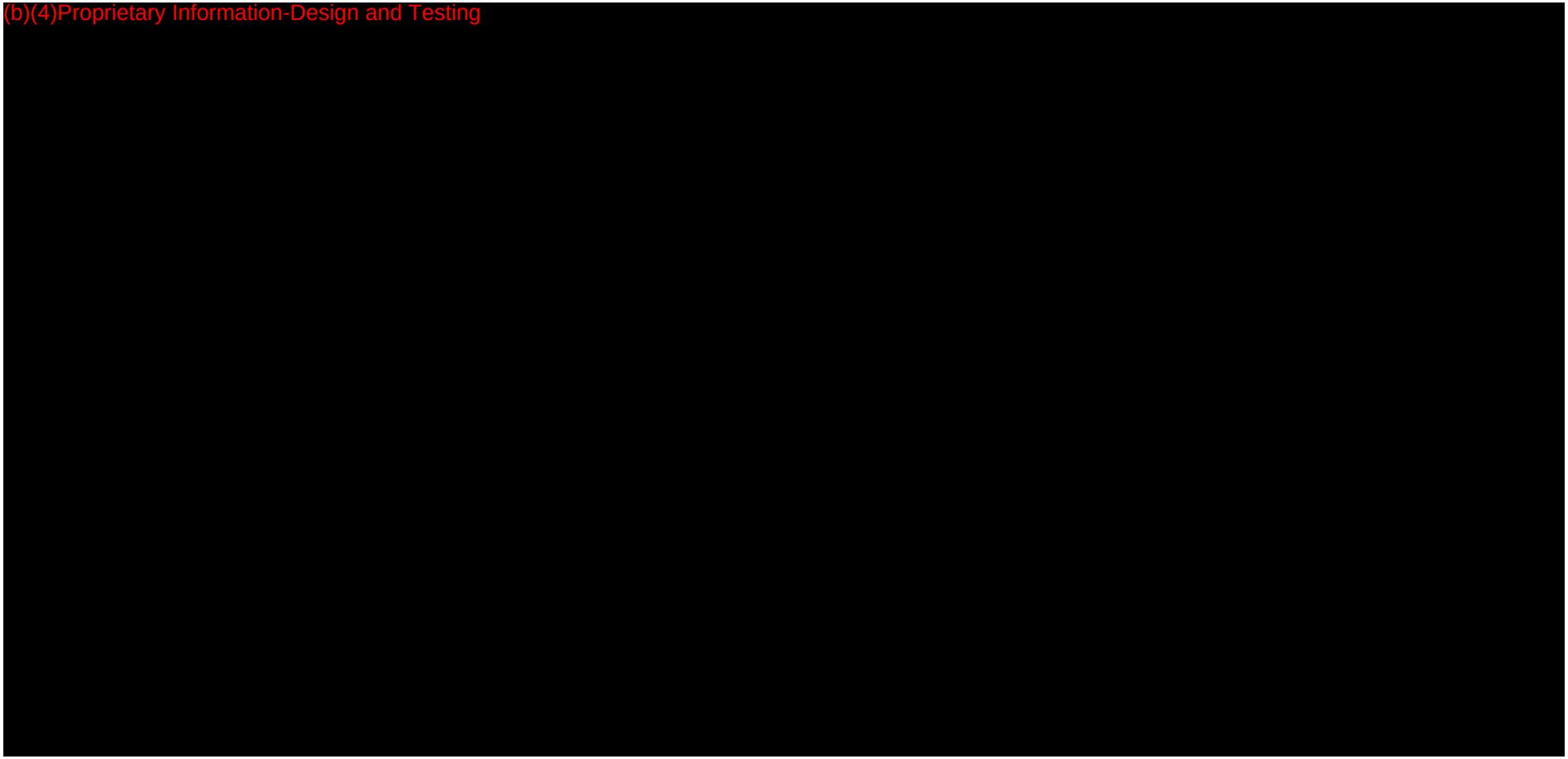
ATTACHMENT 17

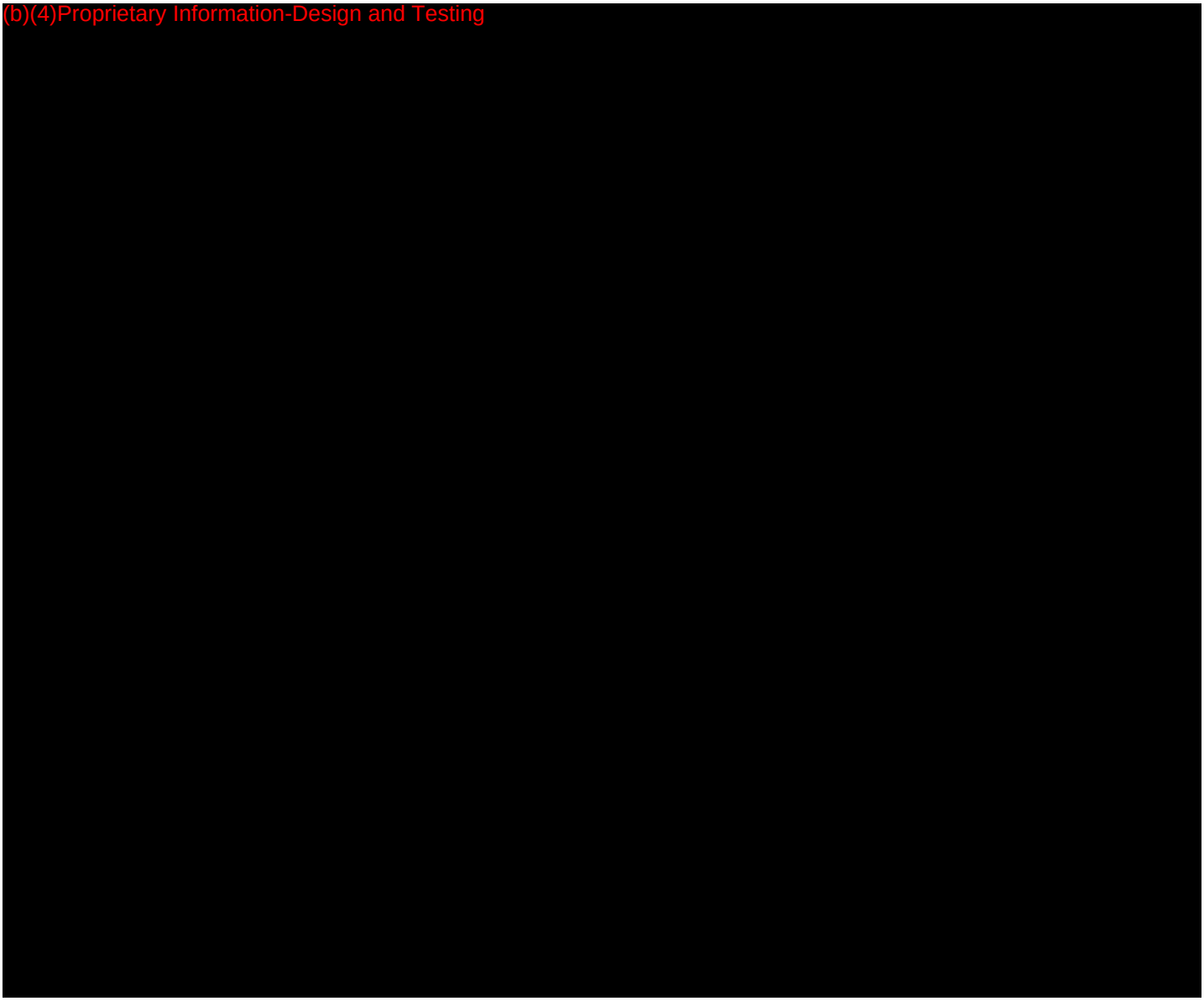
(b)(4)Proprietary Information-Design and Testing





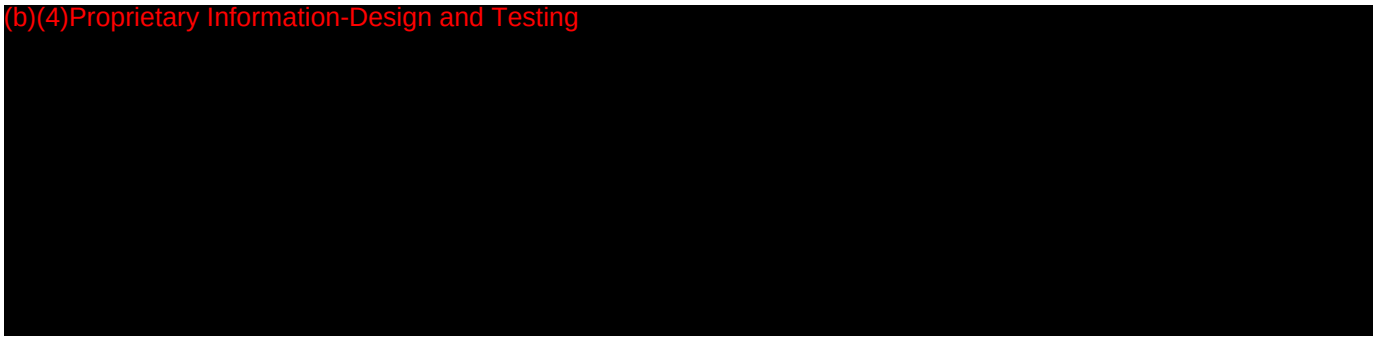




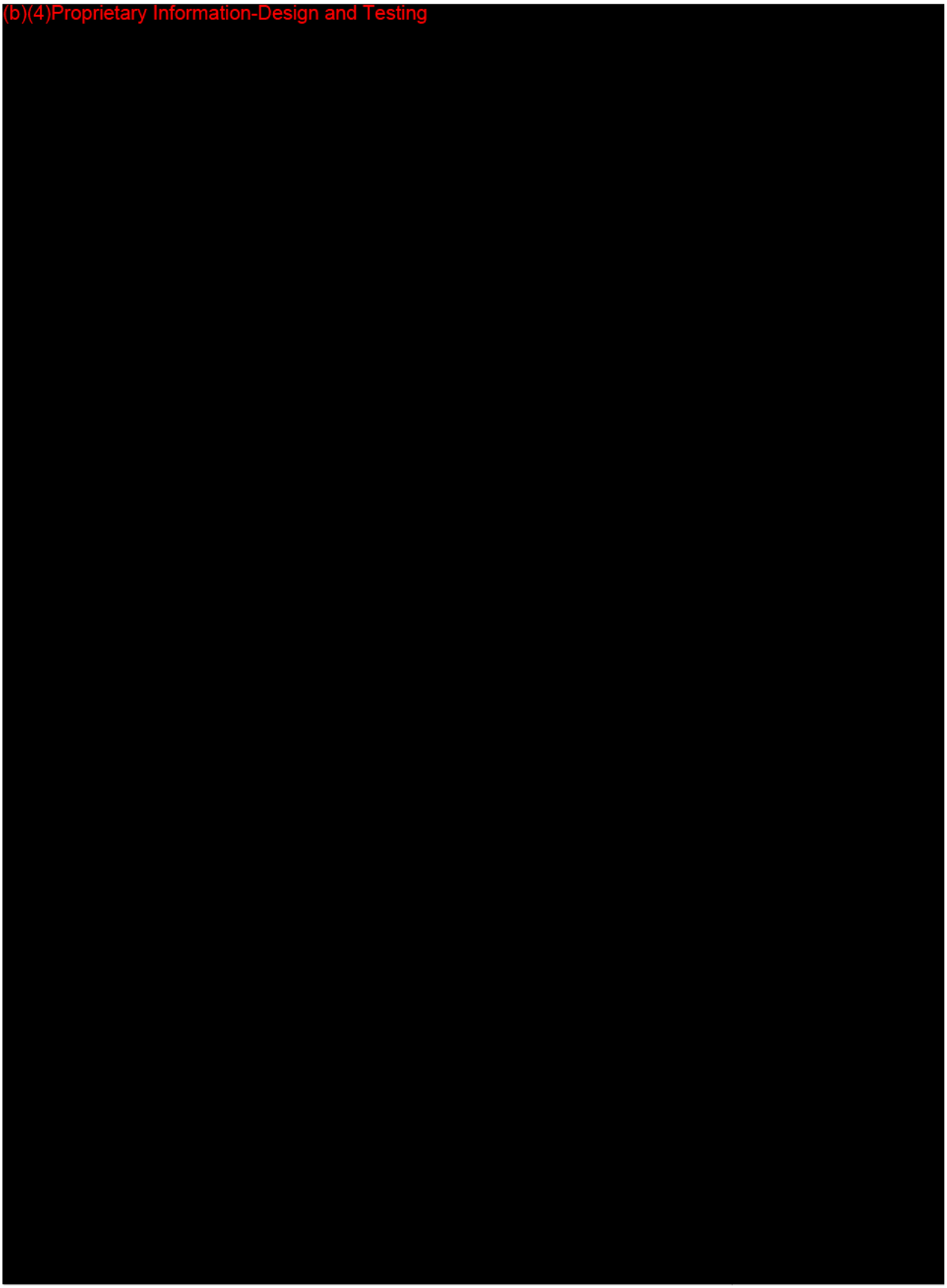


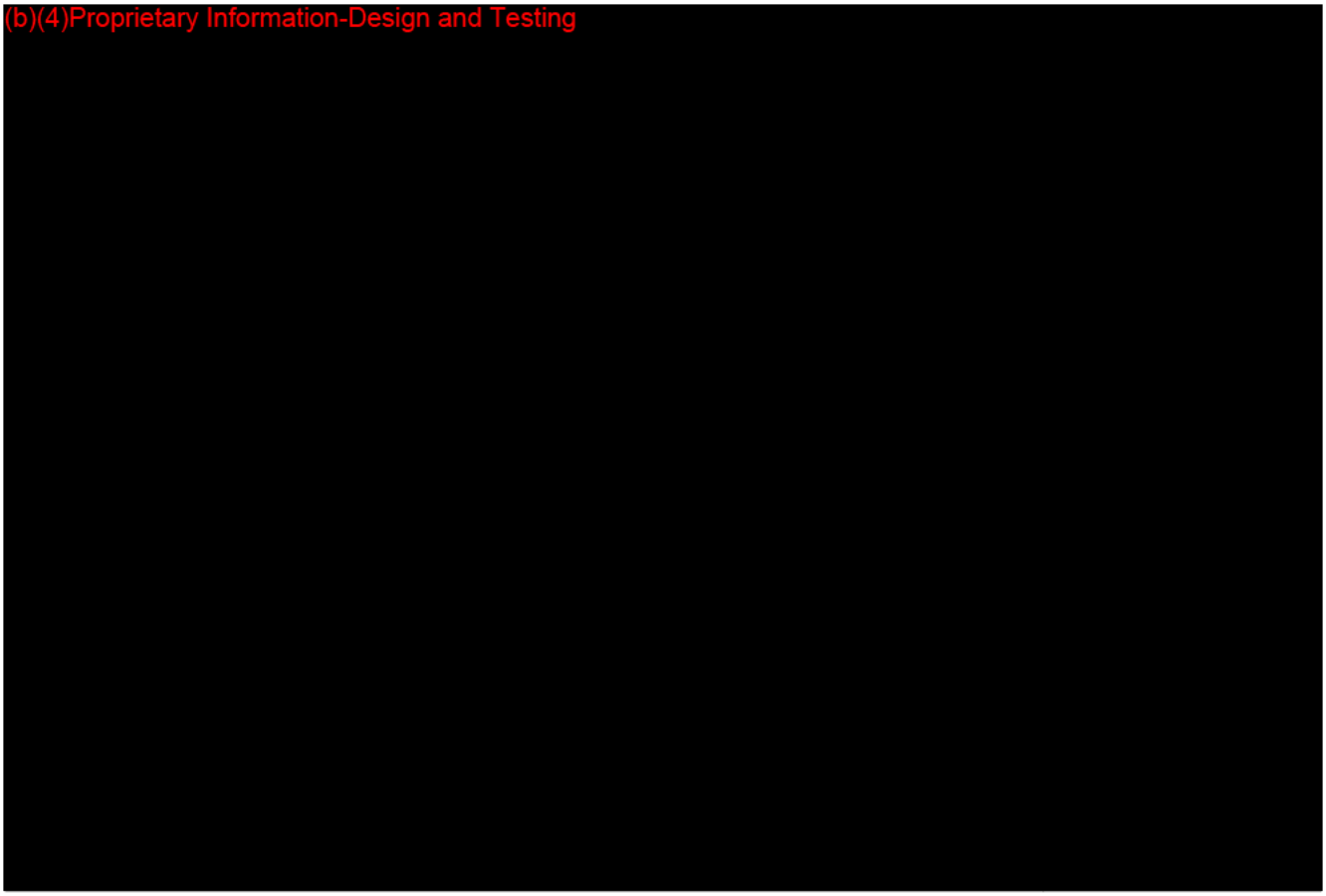
(b)(4)Proprietary Information-Design and Testing

(b)(4)Proprietary Information-Design and Testing

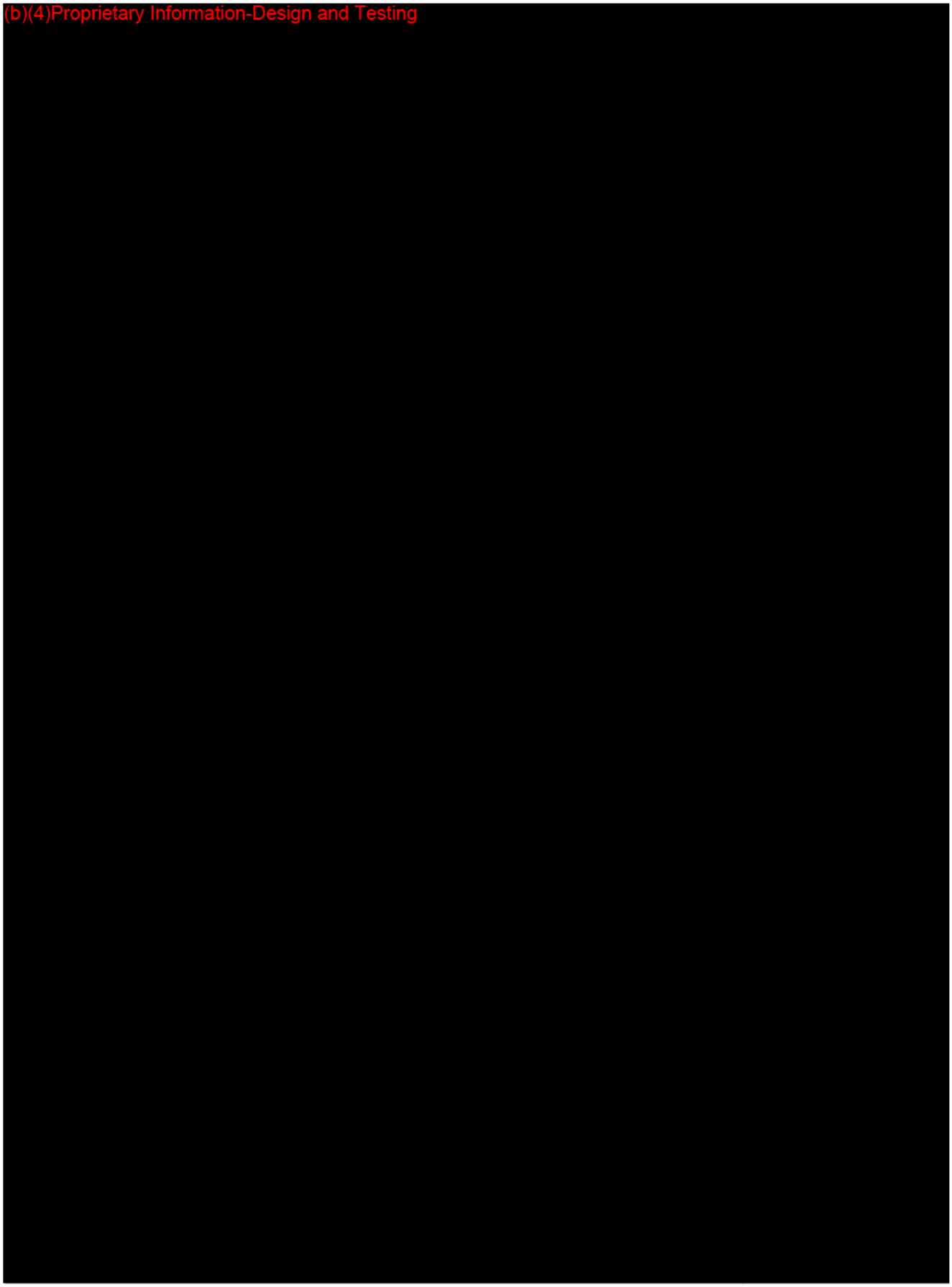


(b)(4)Proprietary Information-Design and Testing



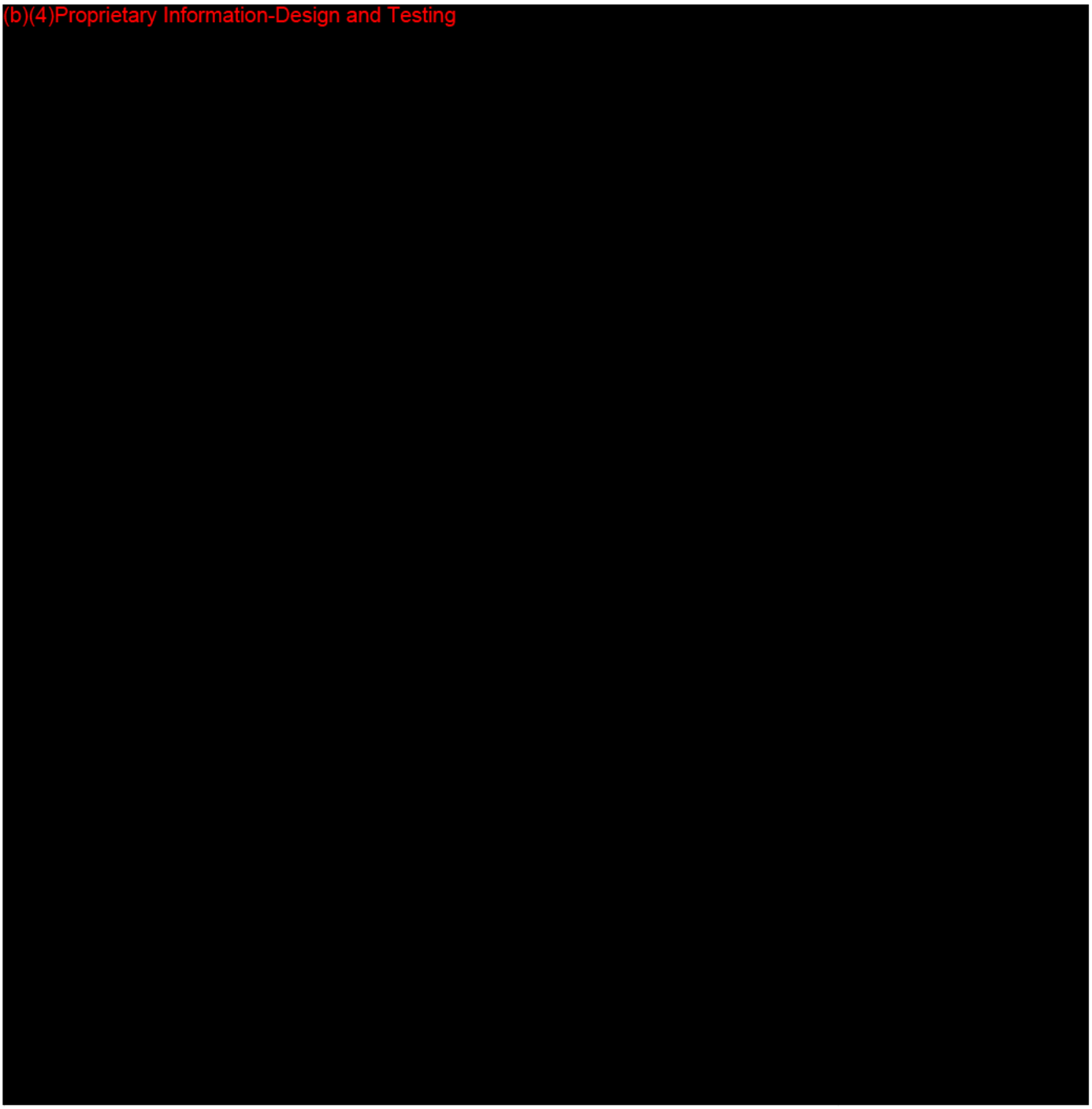


(b)(4)Proprietary Information-Design and Testing



(b)(4)Proprietary Information-Design and Testing

[redacted]



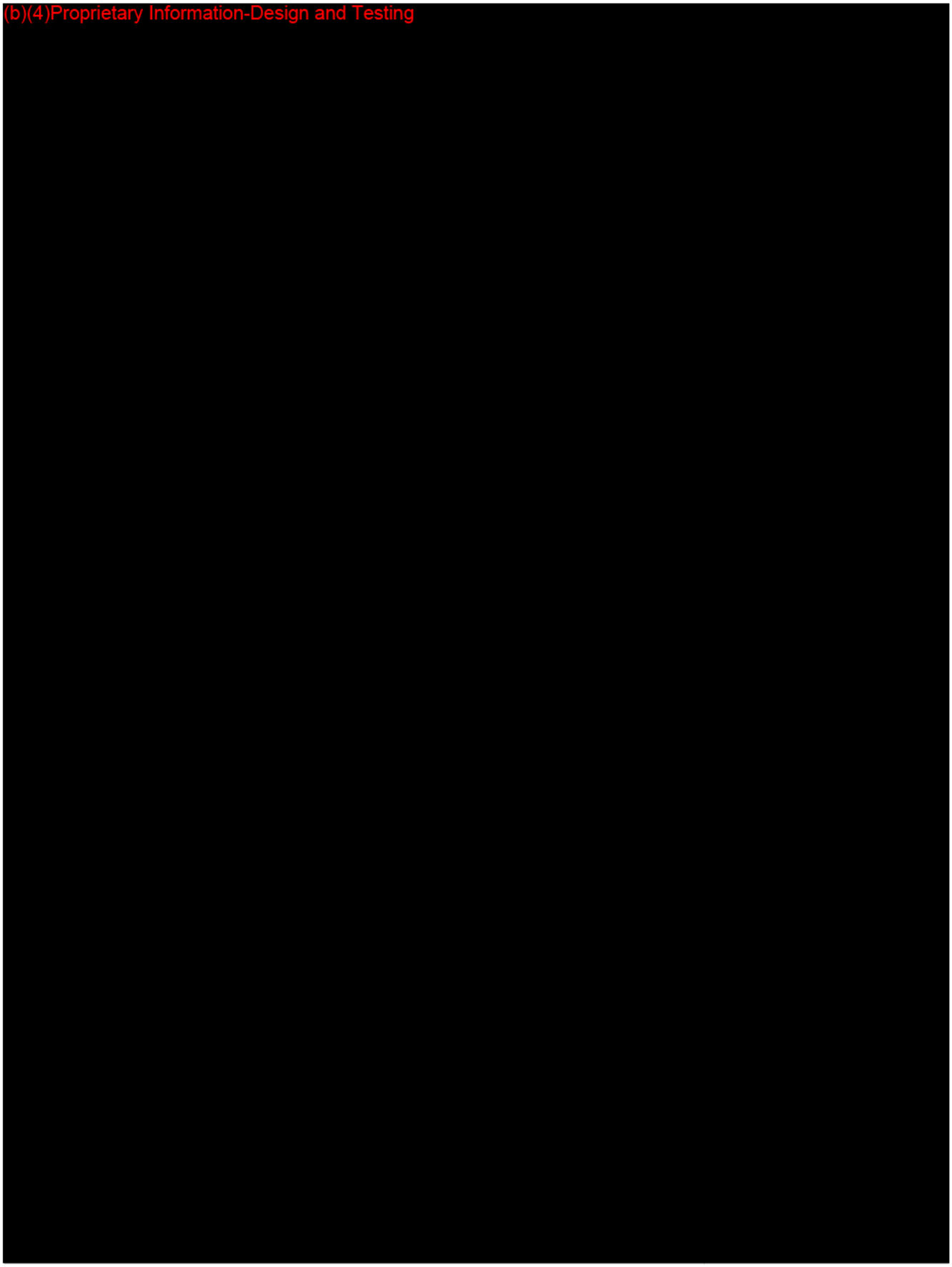
(b)(4)Proprietary Information-Design and Testing

[redacted]

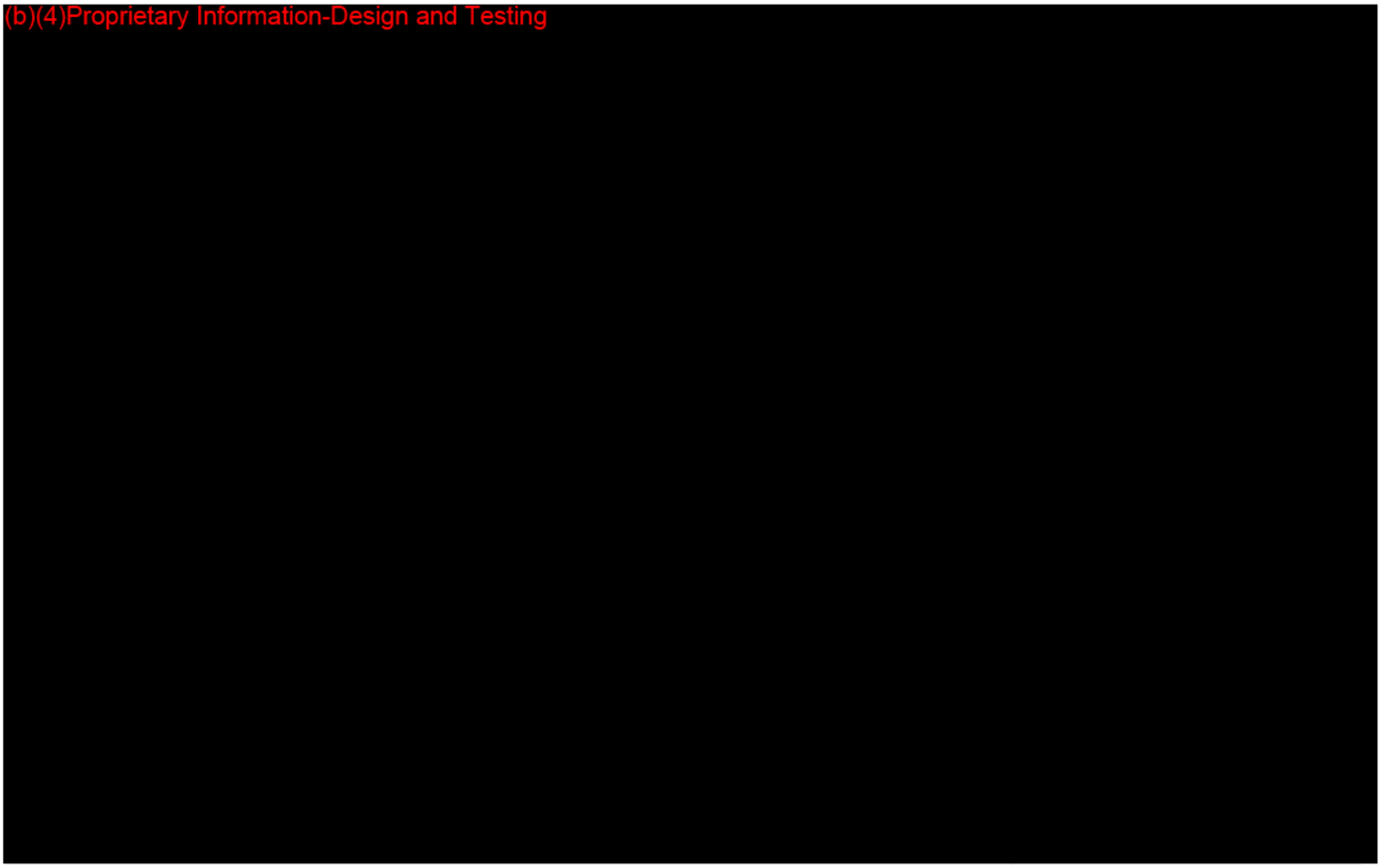
(b)(4)Proprietary Information-Design and Testing

[redacted]

(b)(4)Proprietary Information-Design and Testing



(b)(4)Proprietary Information-Design and Testing



(b)(4)Proprietary Information-Design and Testing

(b)(4)Proprietary Information-Design and Testing

[redacted]

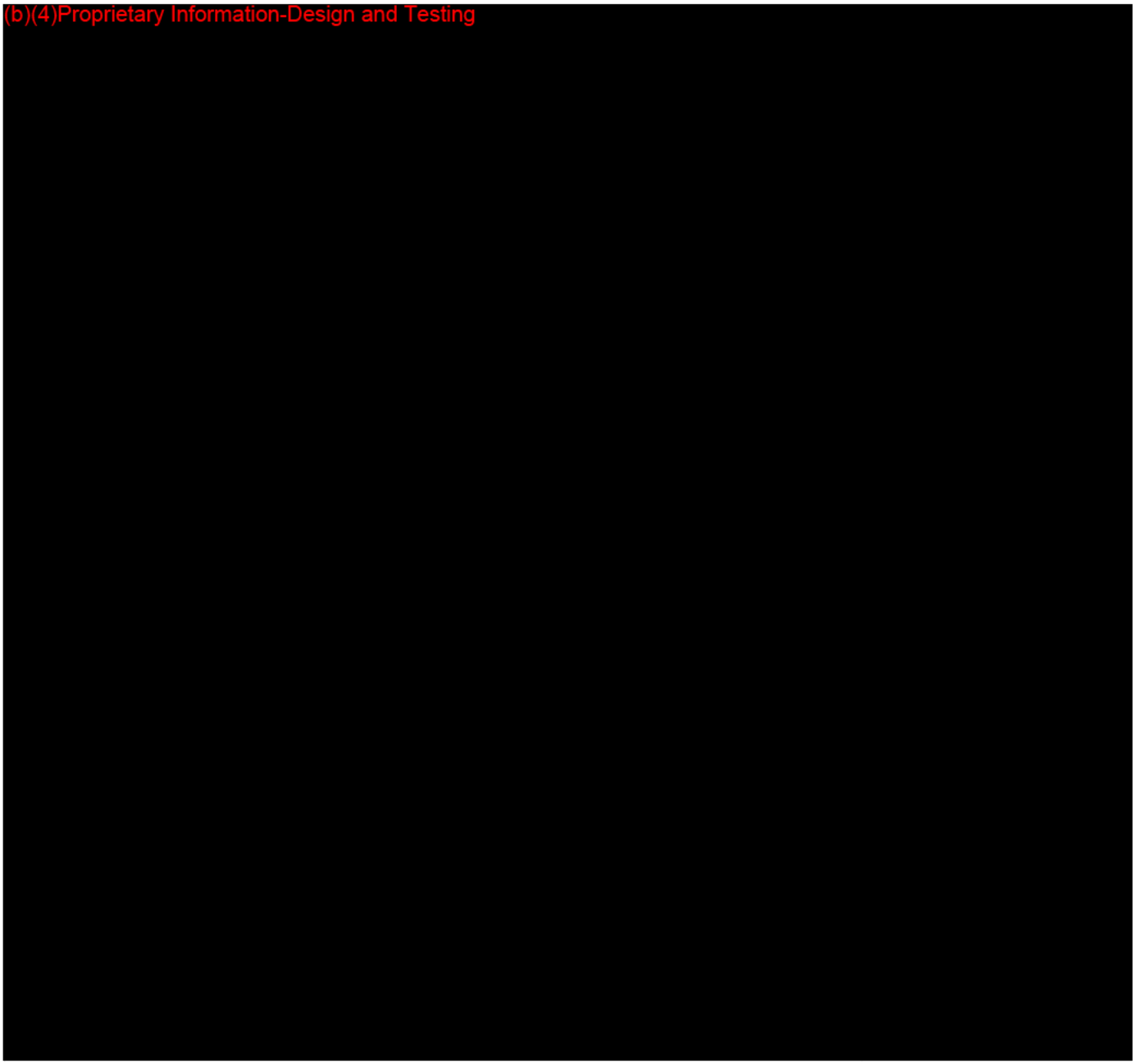
(b)(4)Proprietary Information-Design and Testing

[redacted]

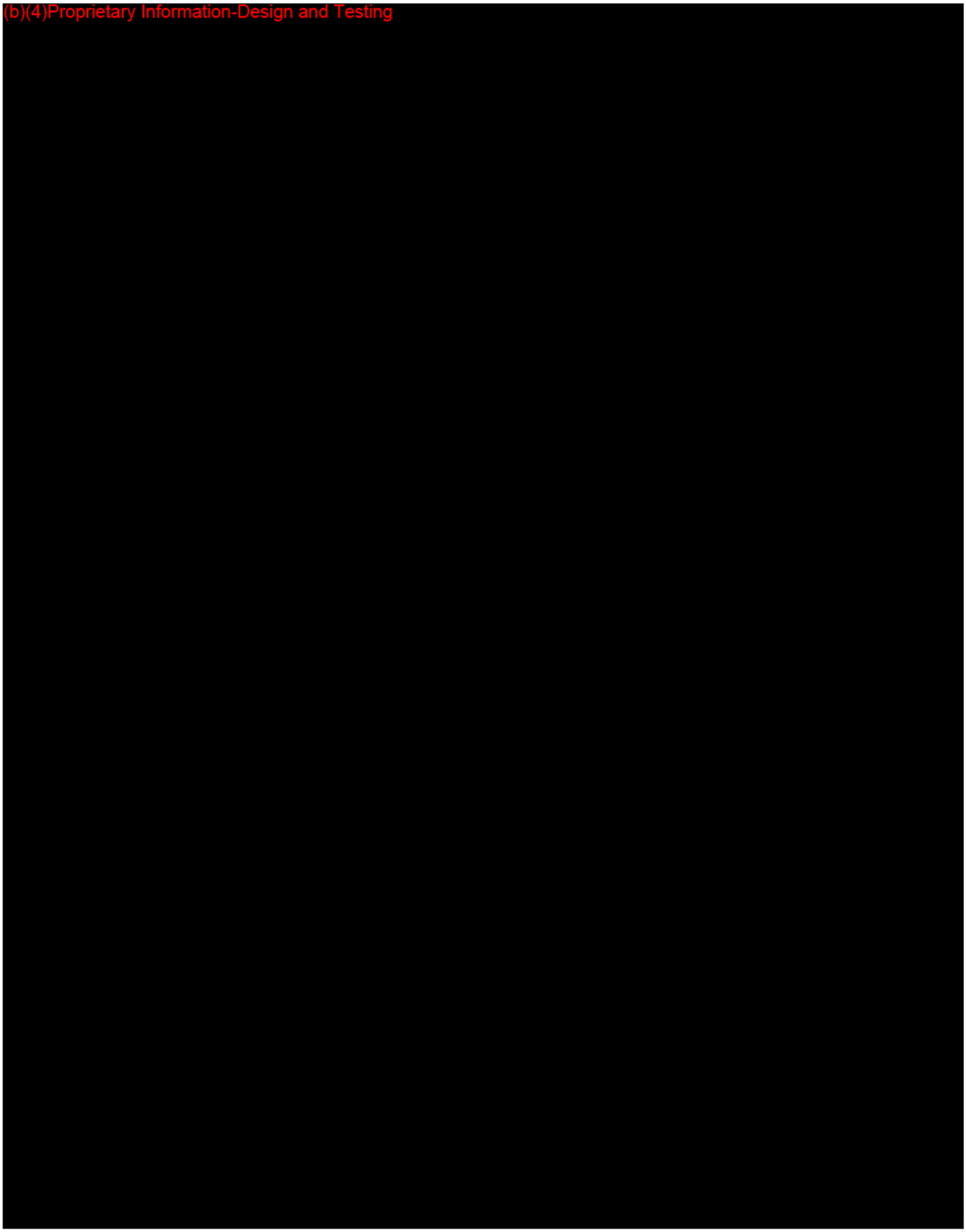
(b)(4)Proprietary Information-Design and Testing

[redacted]

(b)(4)Proprietary Information-Design and Testing



(b)(4)Proprietary Information-Design and Testing



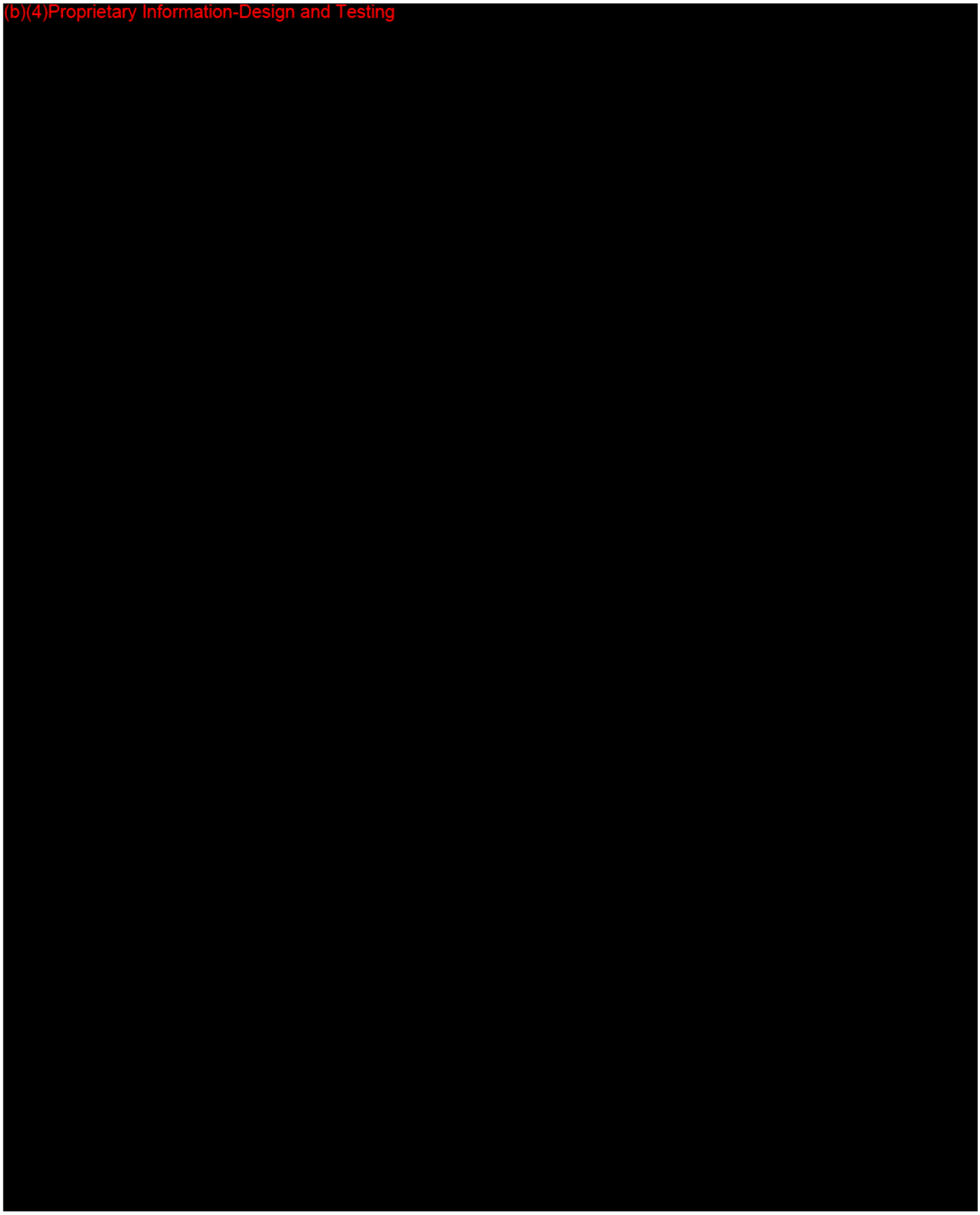
(b)(4)Proprietary Information-Design and Testing

[redacted]

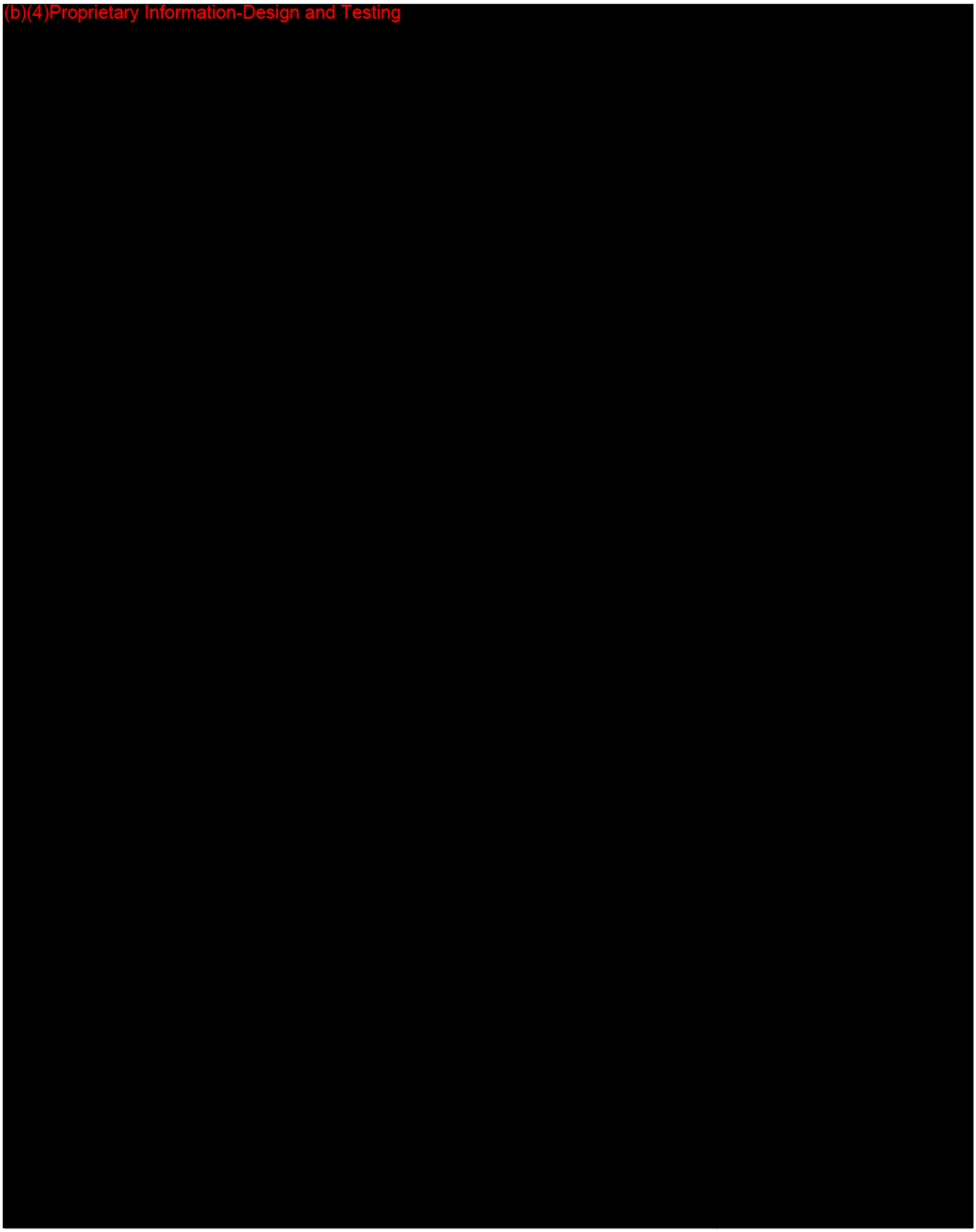
(b)(4)Proprietary Information-Design and Testing

[redacted]

(b)(4)Proprietary Information-Design and Testing



(b)(4)Proprietary Information-Design and Testing



(b)(4)Proprietary Information-Design and Testing

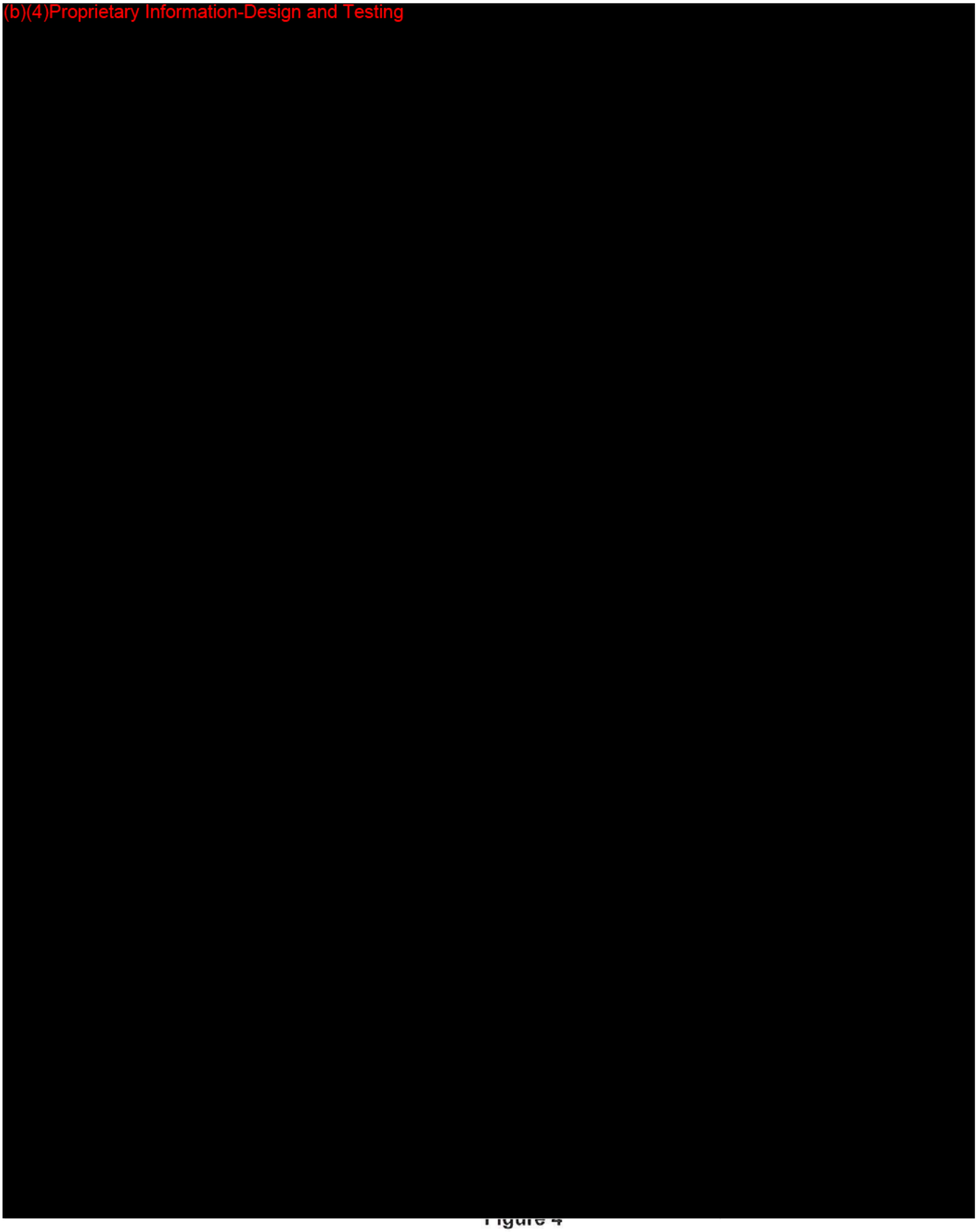
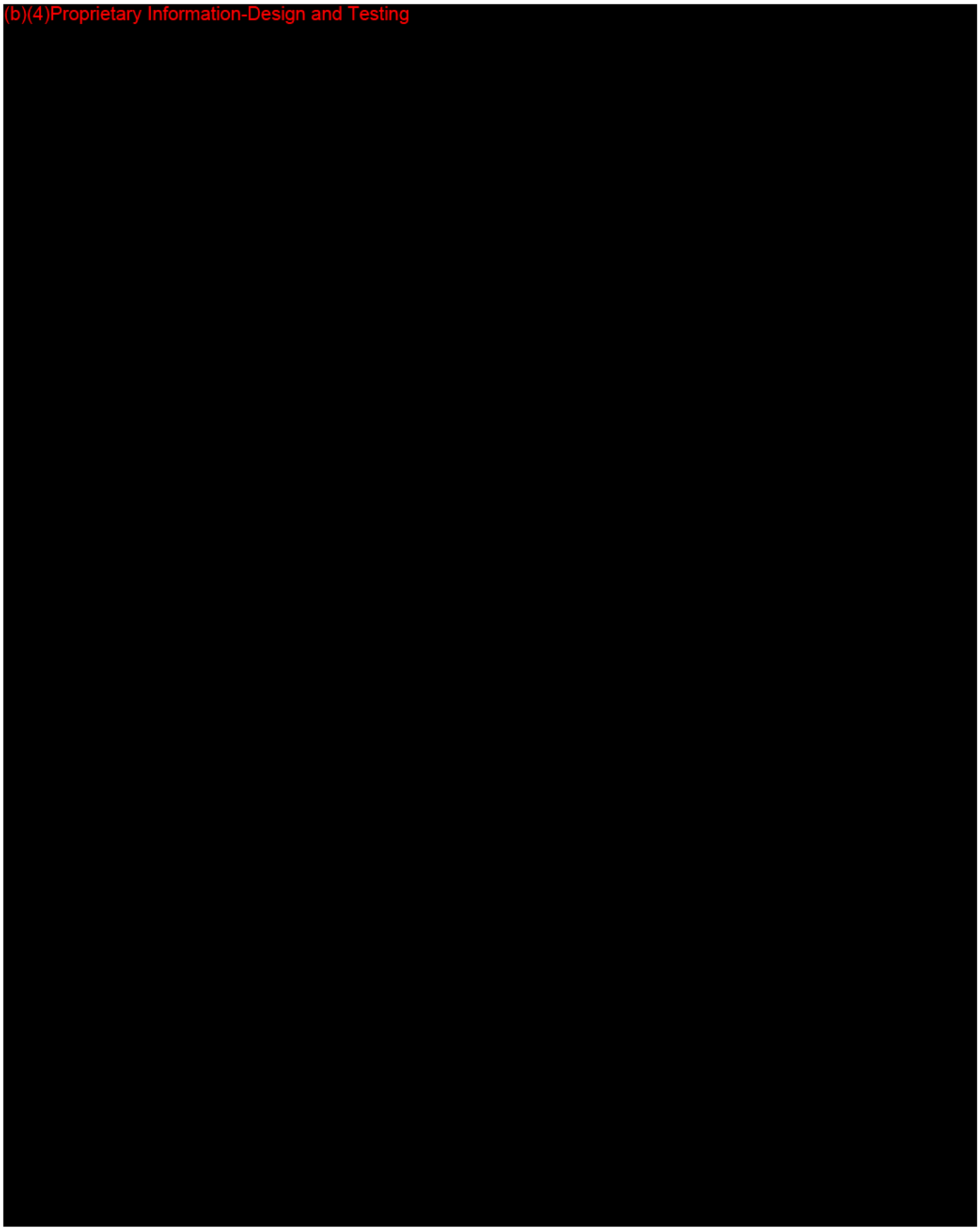
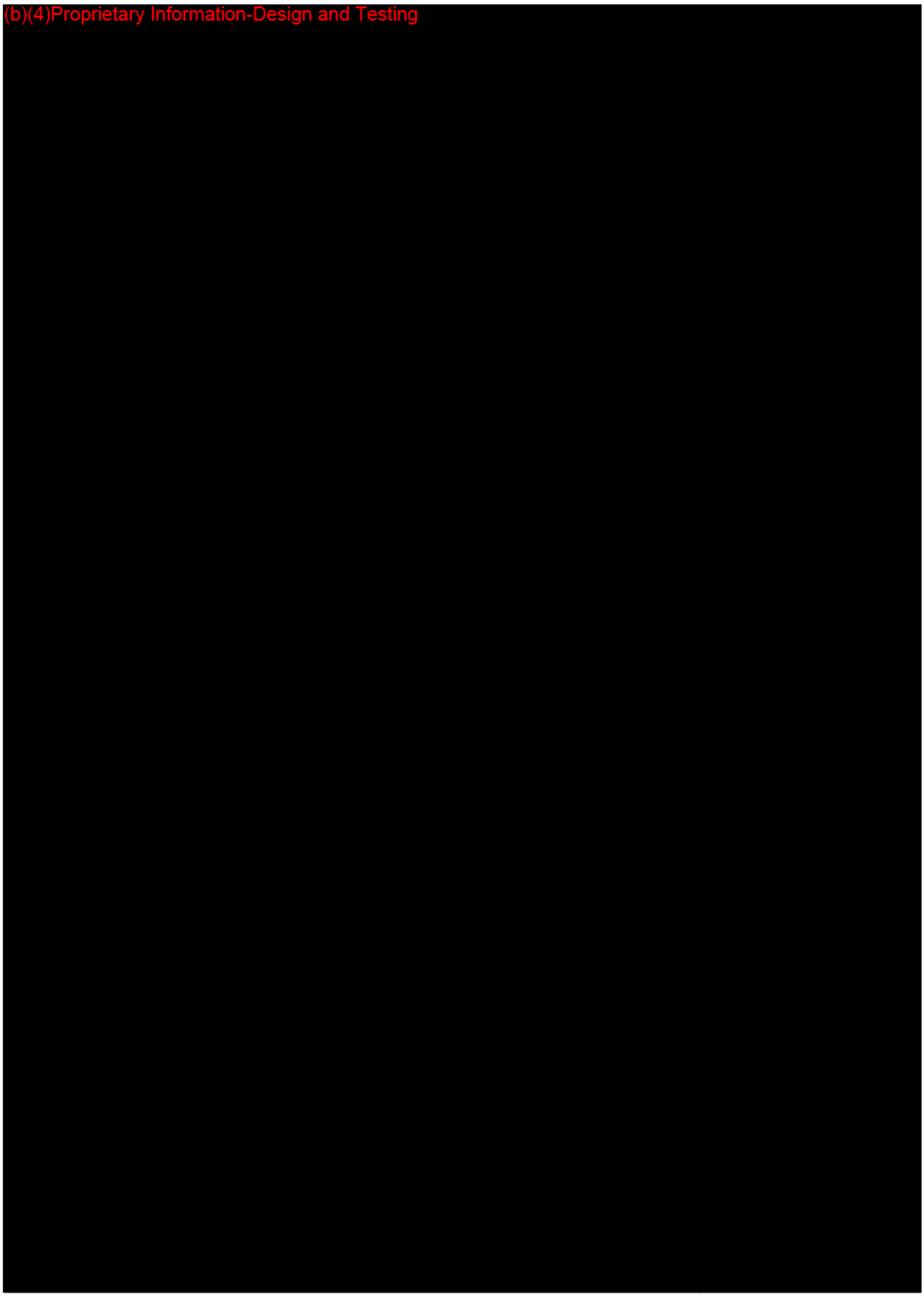


Figure 4

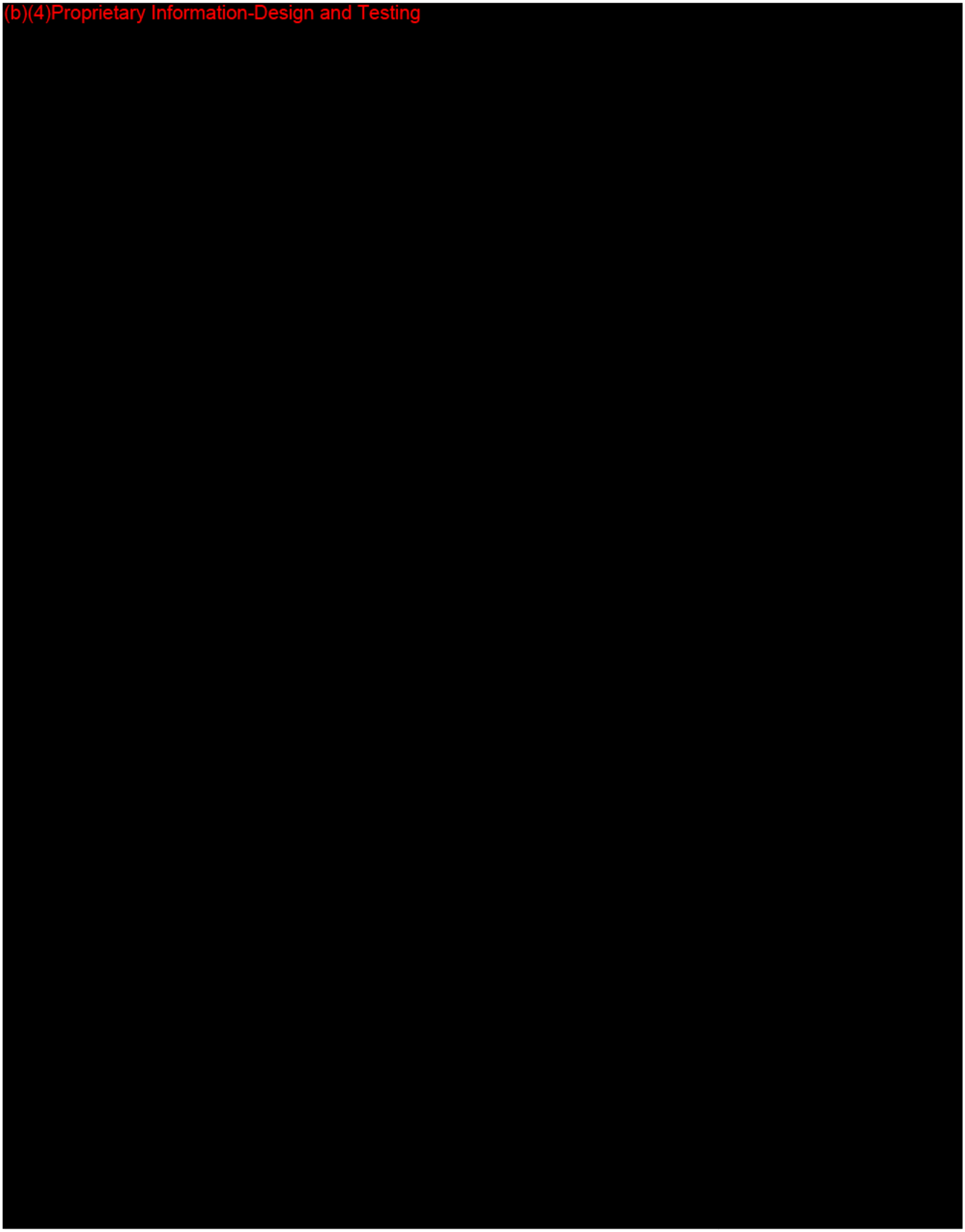
(b)(4)Proprietary Information-Design and Testing



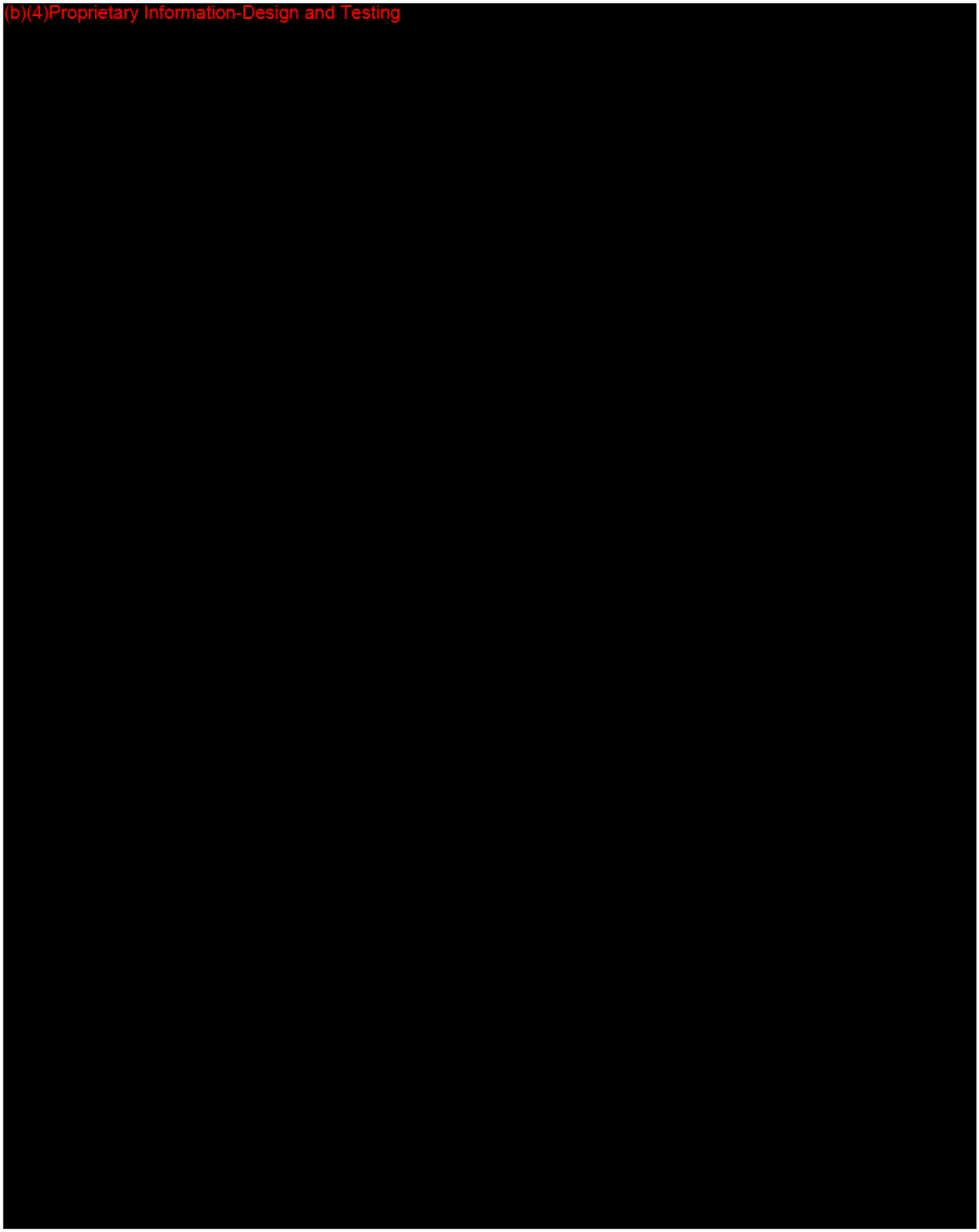
(b)(4)Proprietary Information-Design and Testing



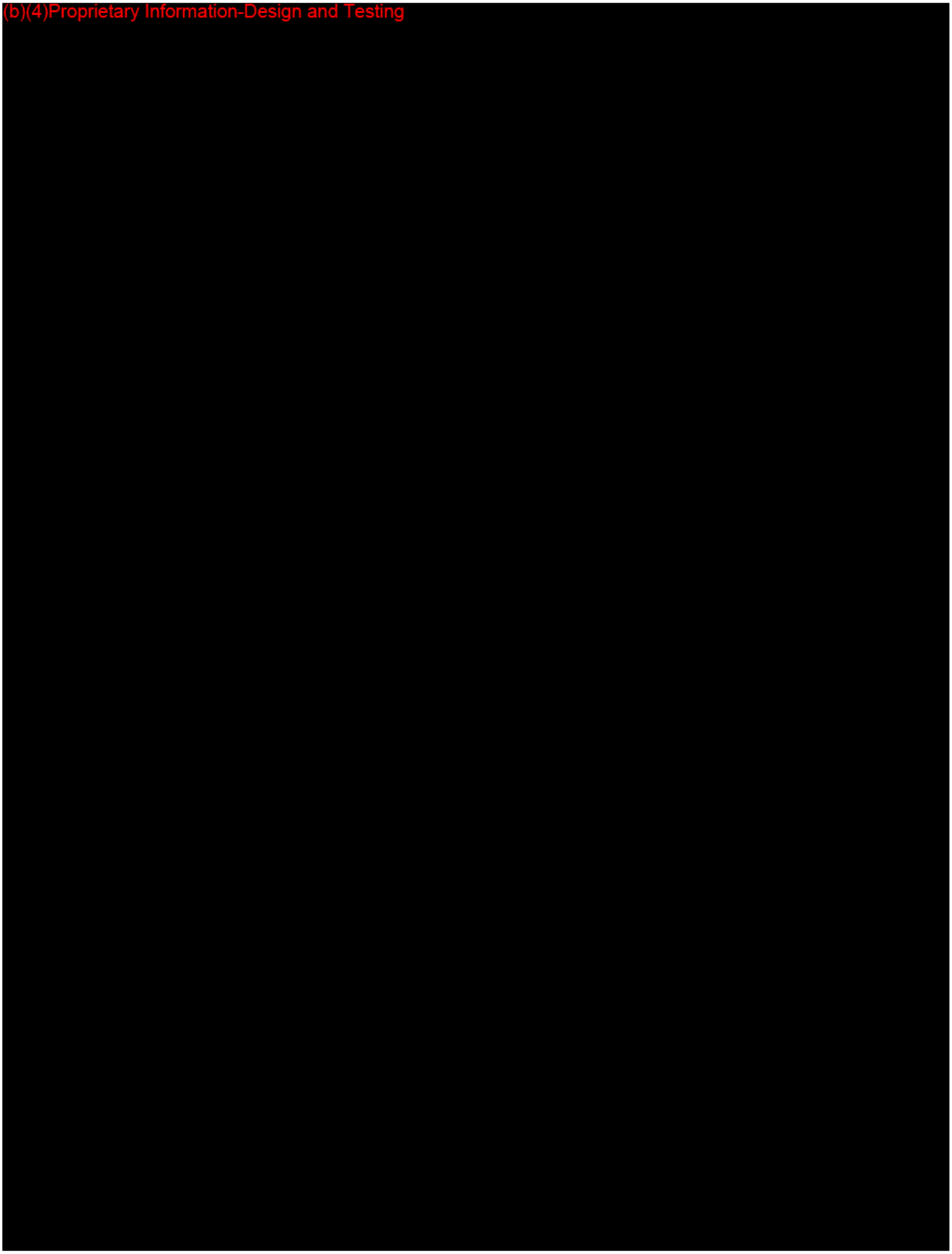
(b)(4)Proprietary Information-Design and Testing



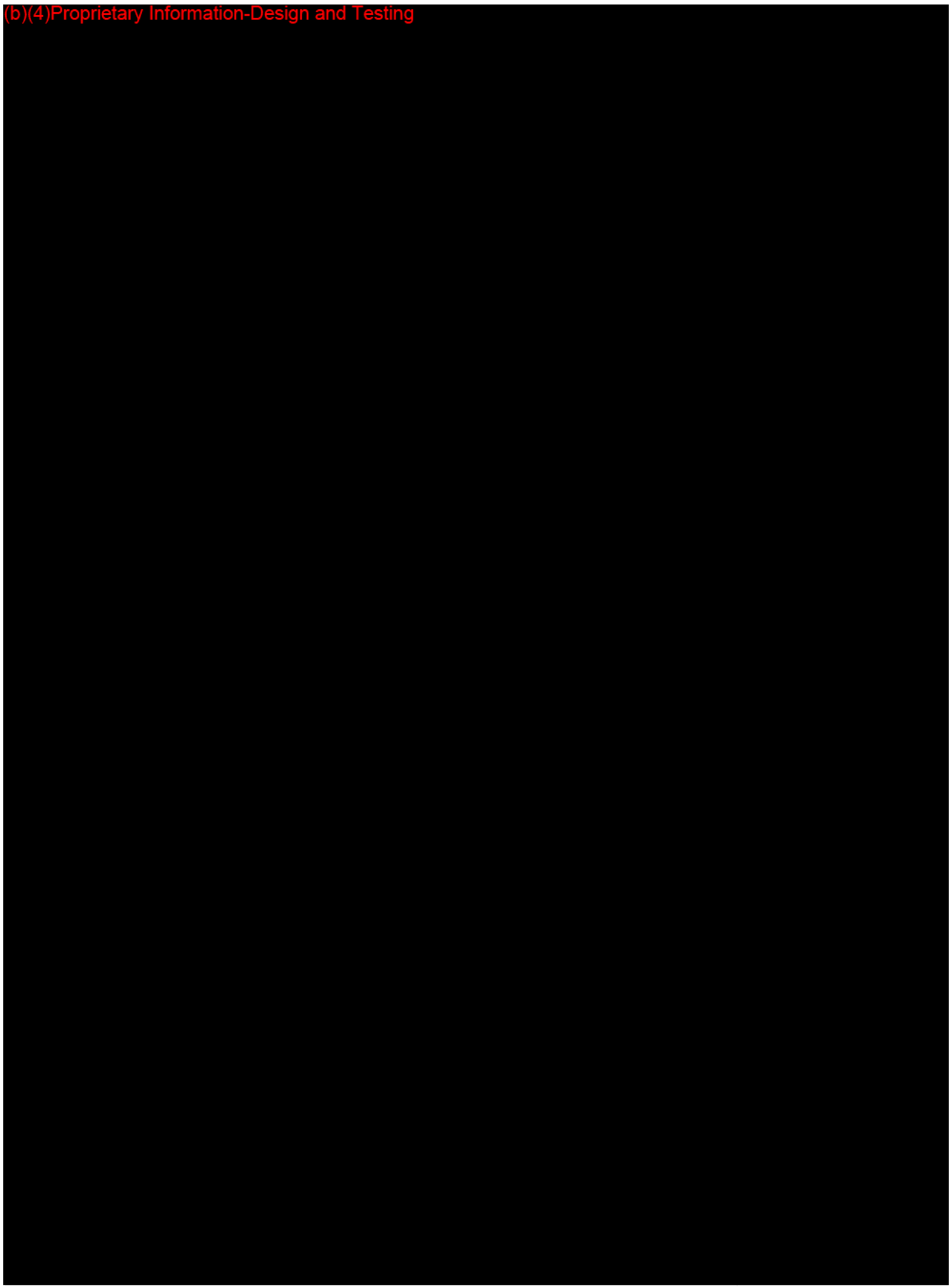
(b)(4)Proprietary Information-Design and Testing



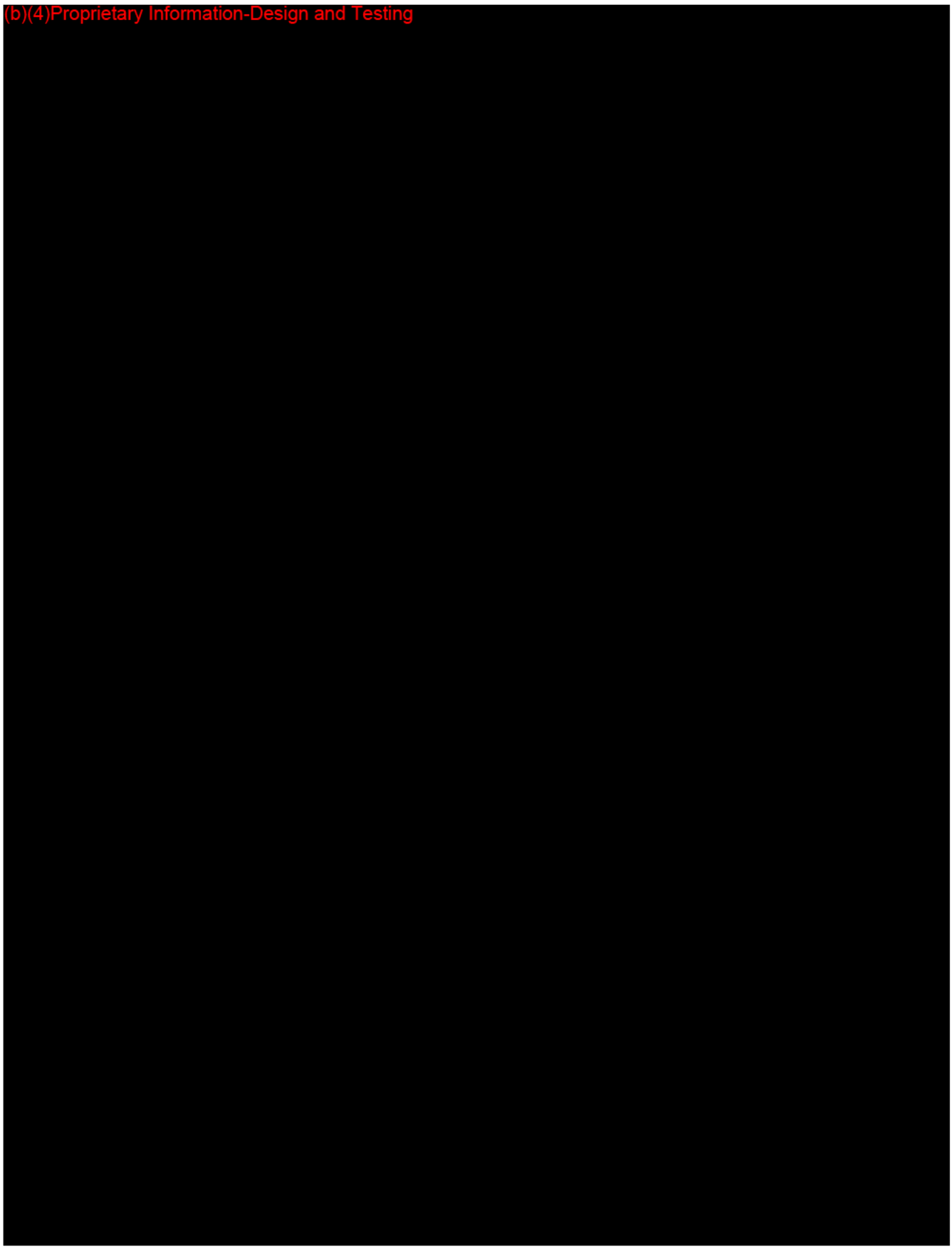
(b)(4)Proprietary Information-Design and Testing



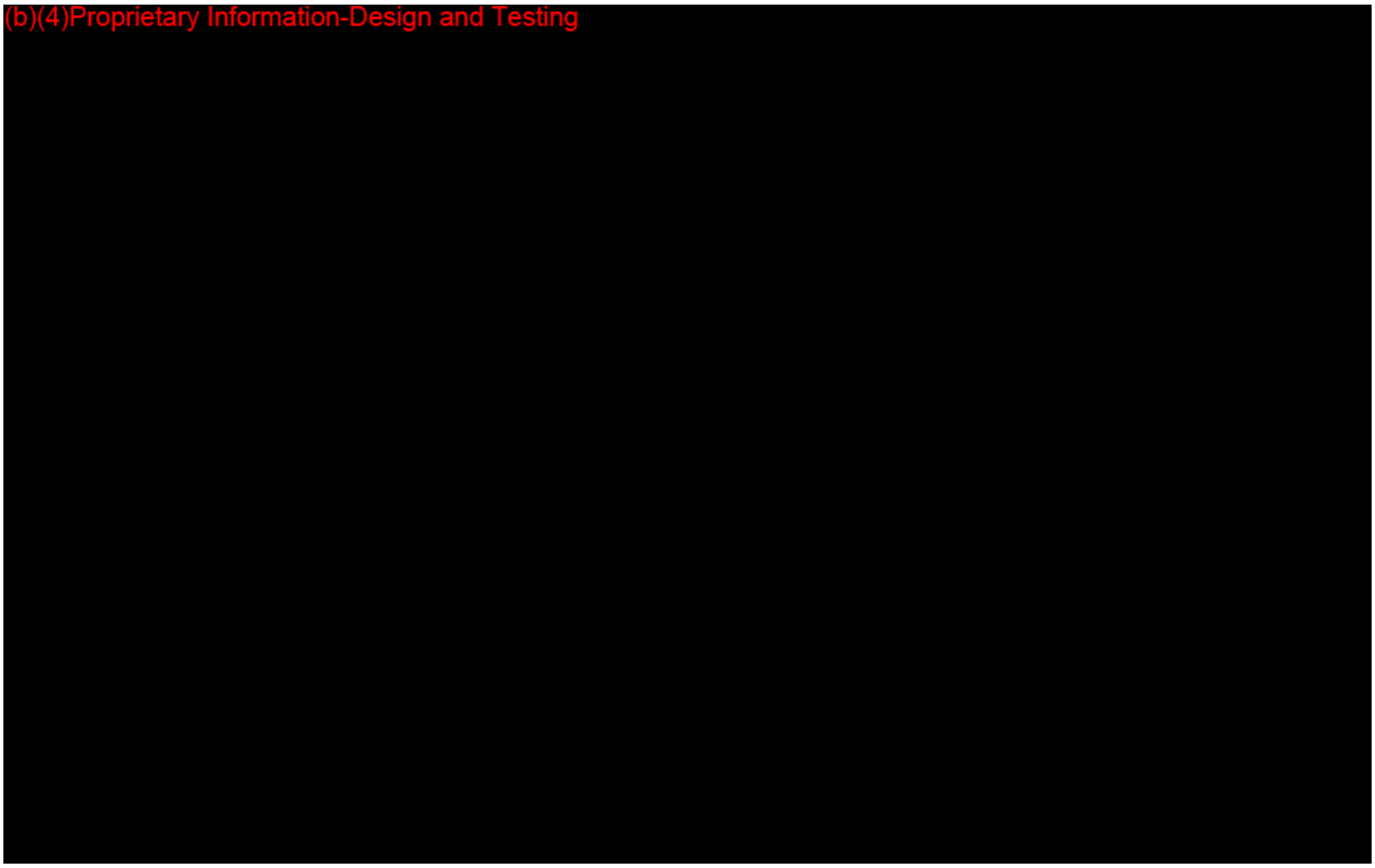
(b)(4)Proprietary Information-Design and Testing

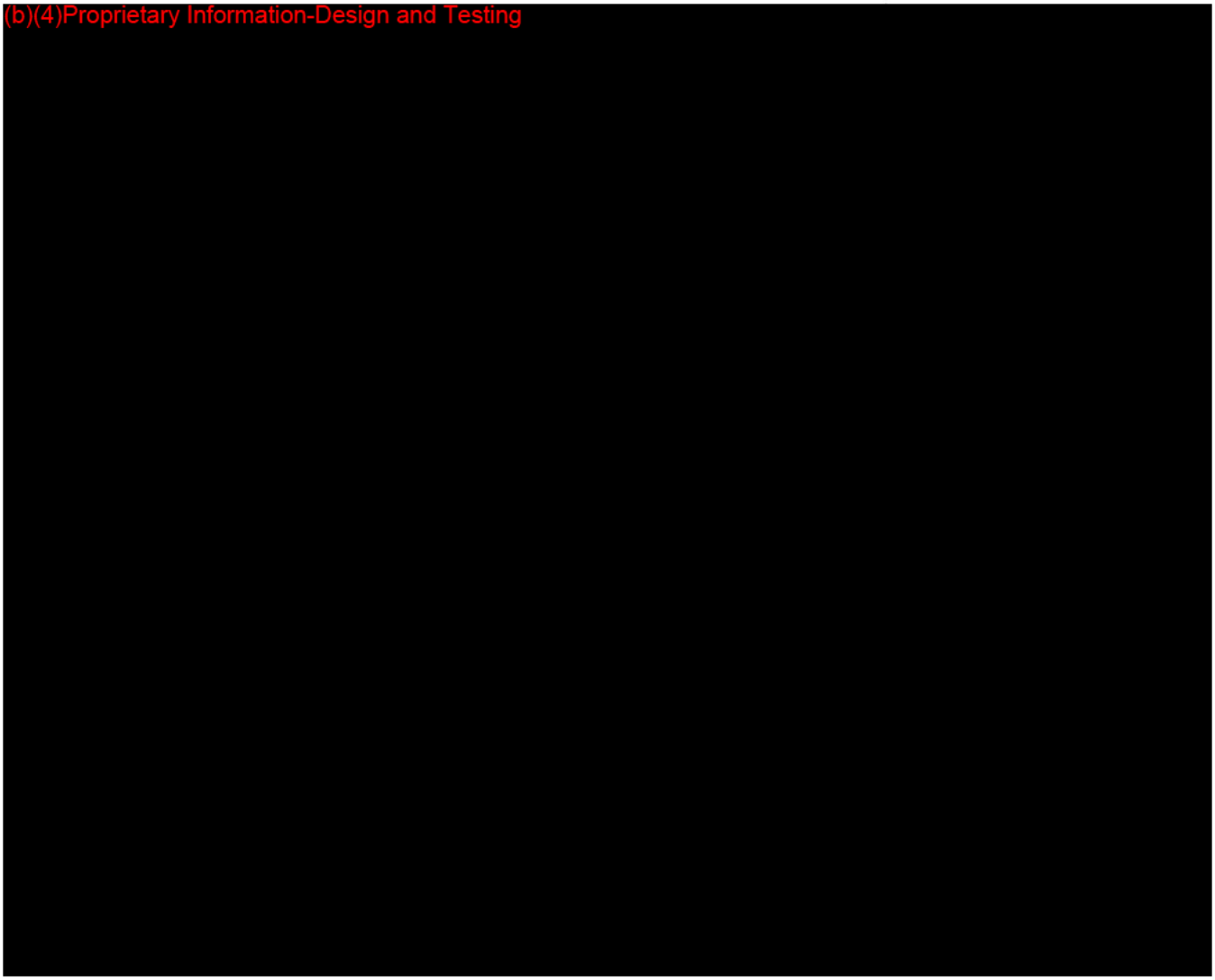


(b)(4)Proprietary Information-Design and Testing

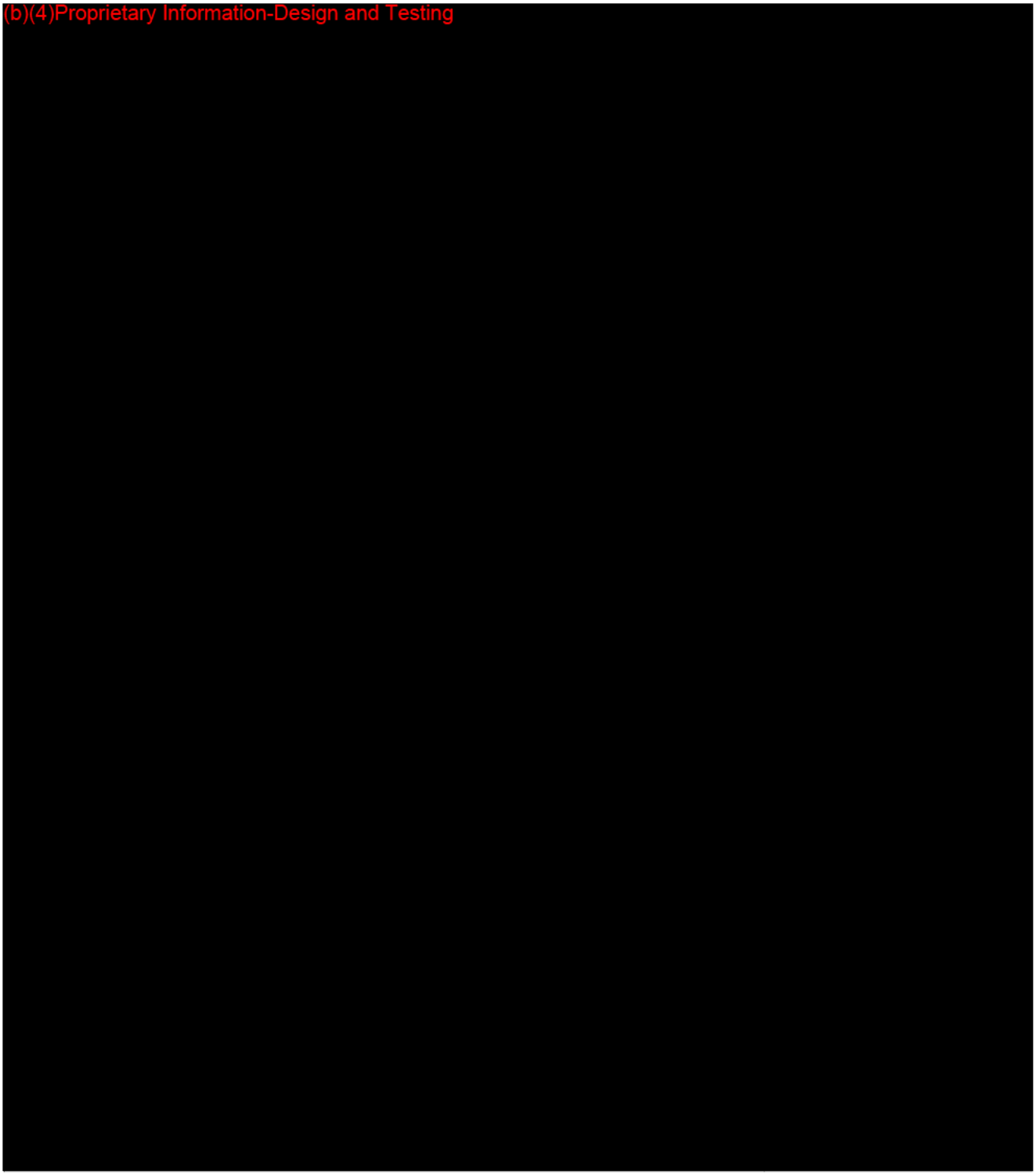


(b)(4)Proprietary Information-Design and Testing

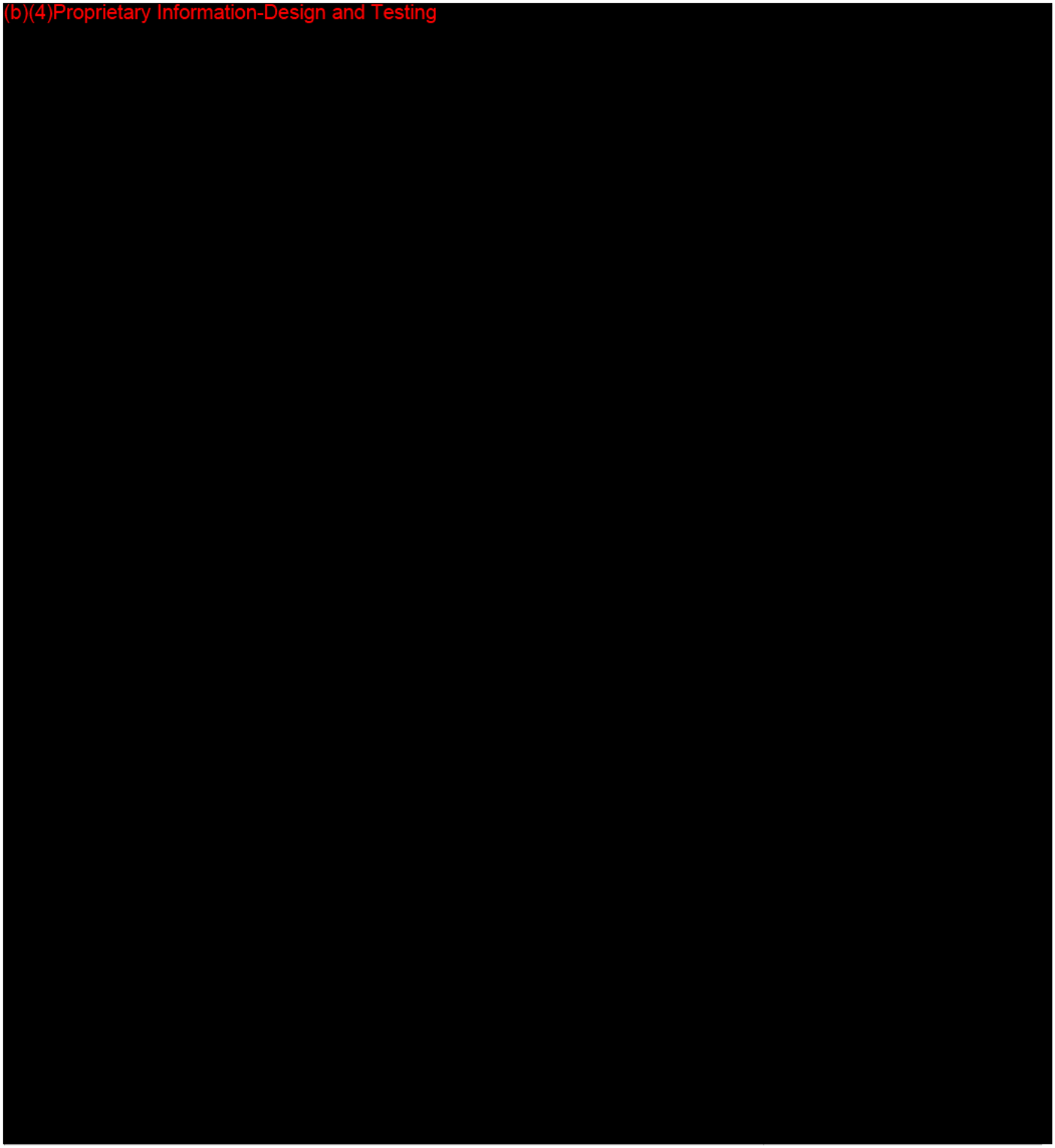




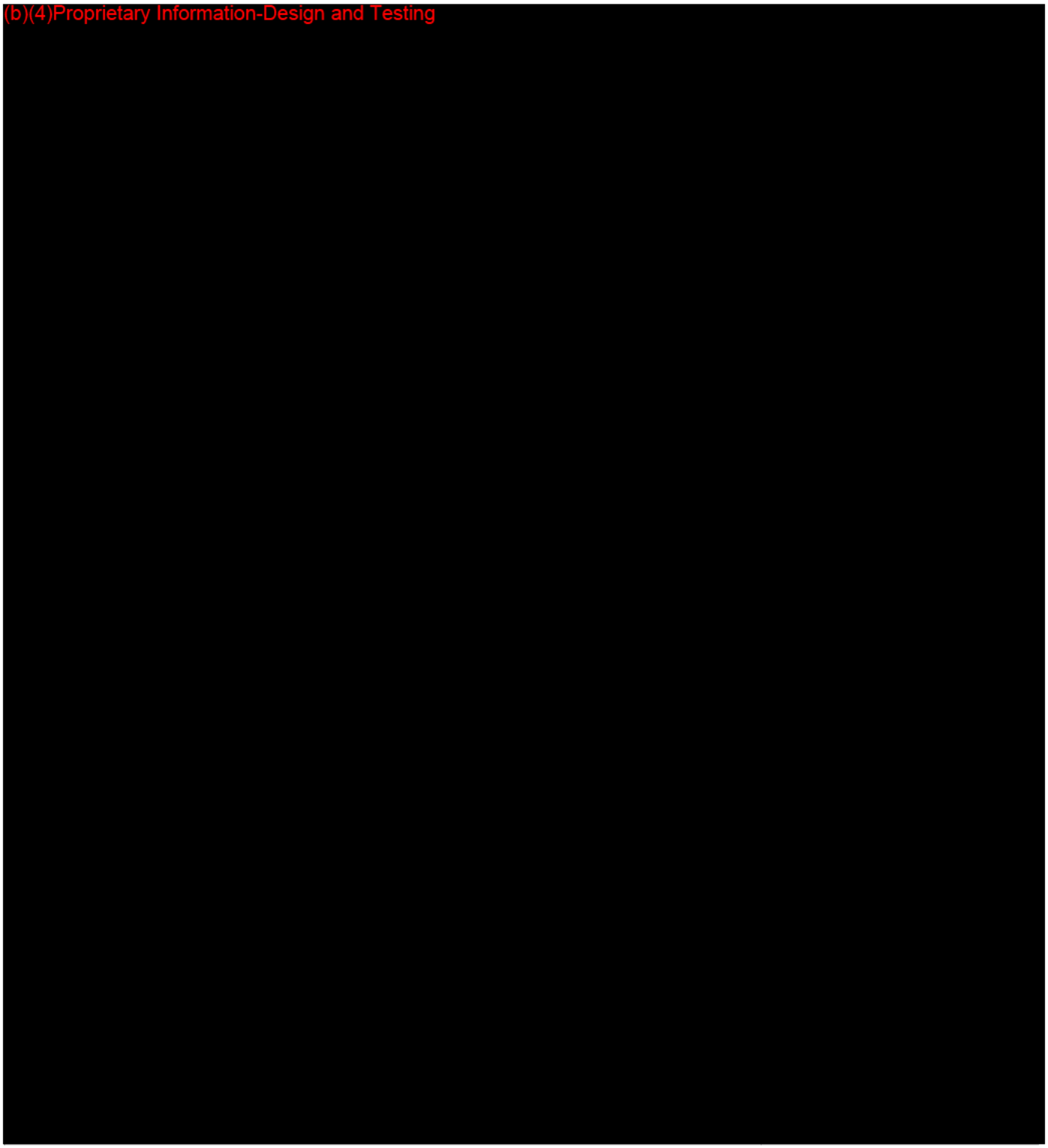
(b)(4)Proprietary Information-Design and Testing



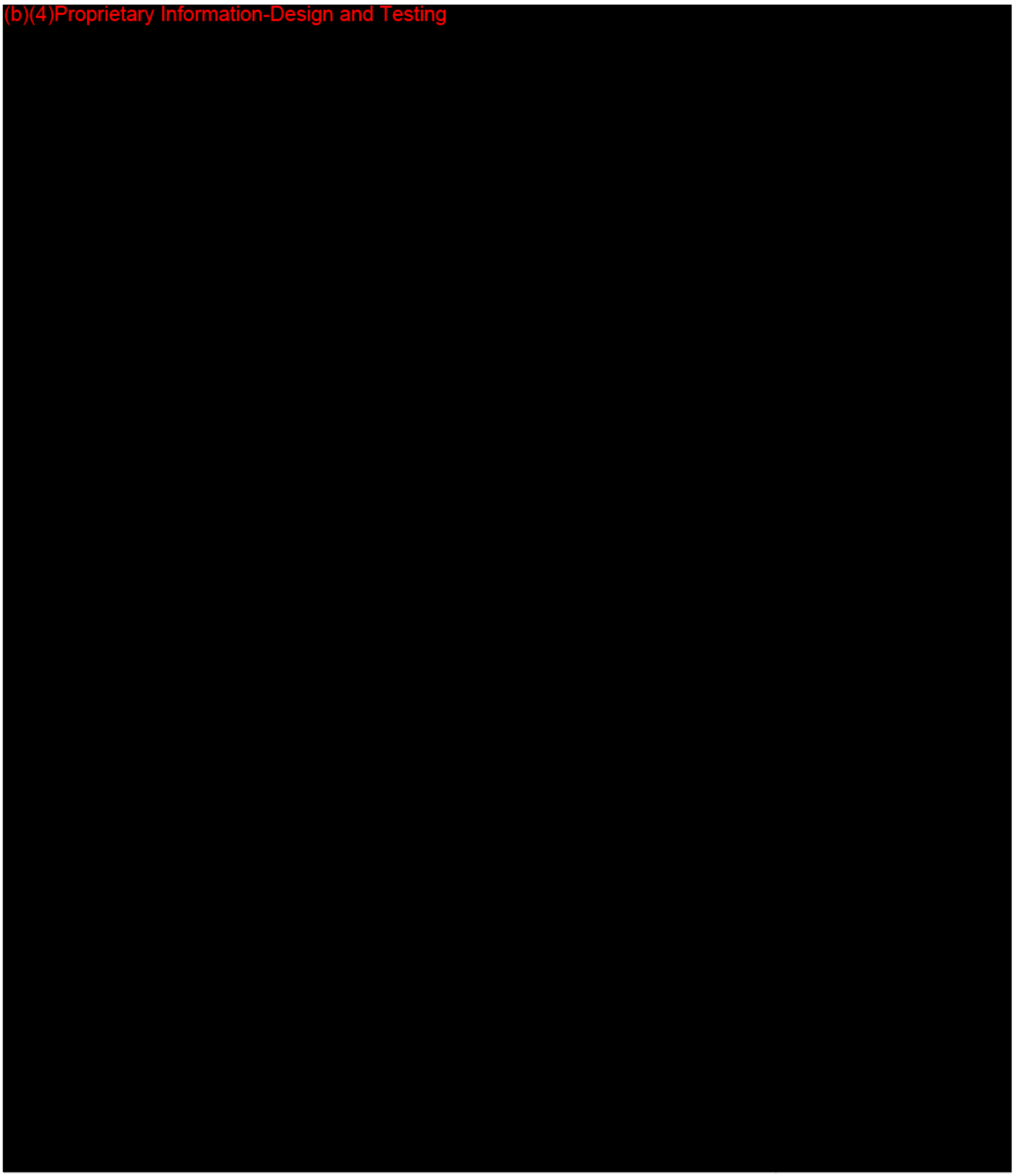
(b)(4)Proprietary Information-Design and Testing



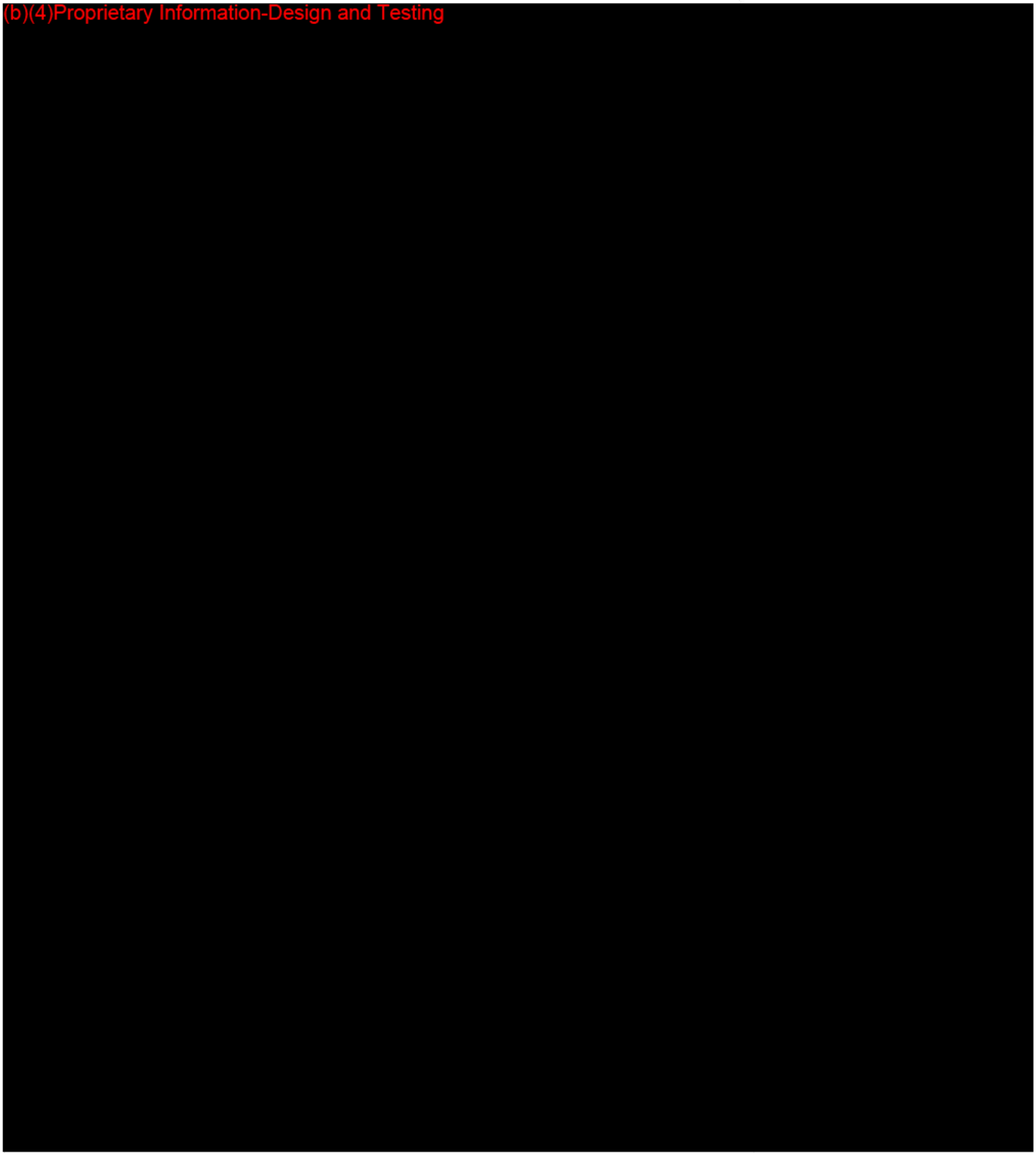
(b)(4)Proprietary Information-Design and Testing



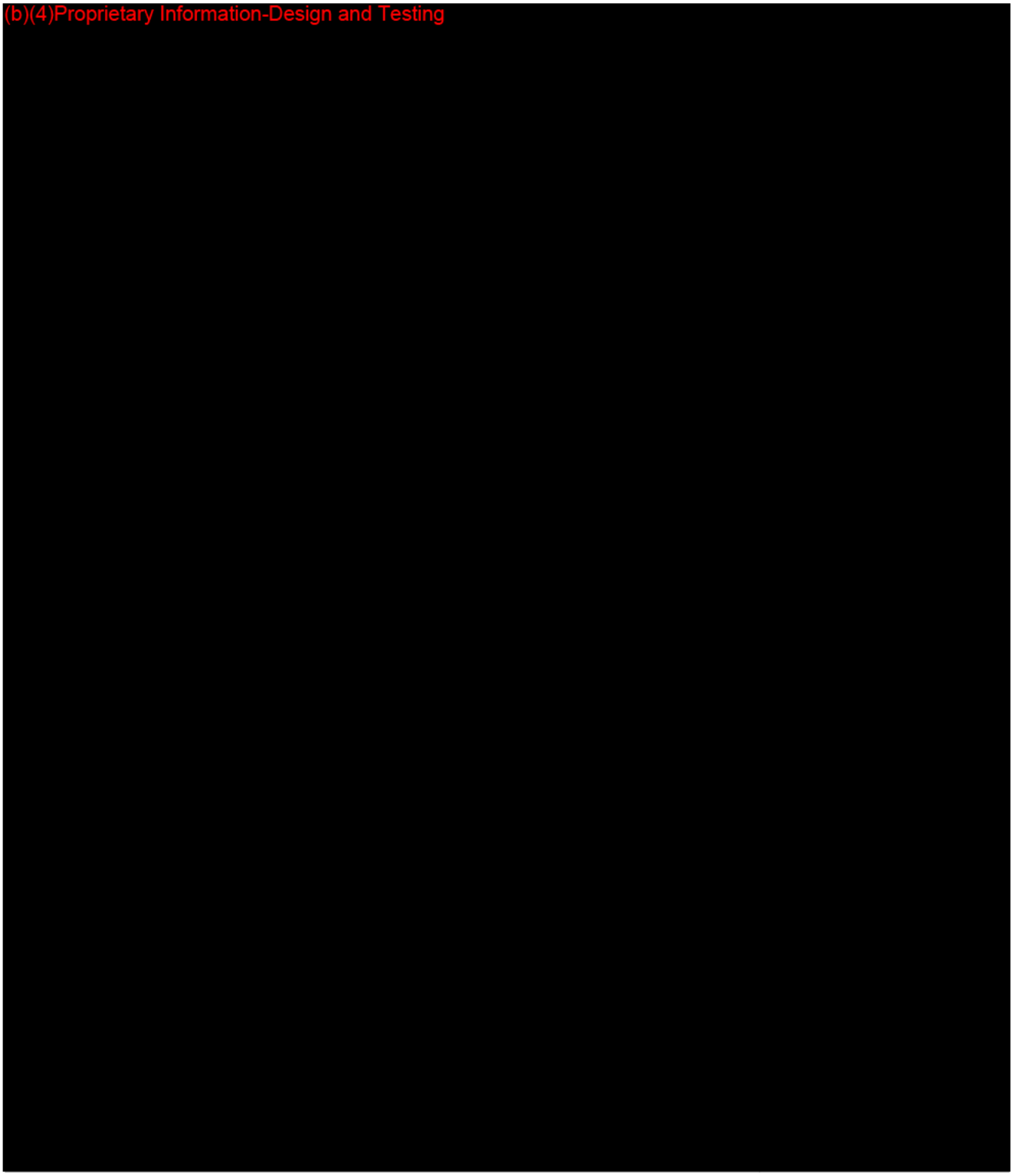
(b)(4)Proprietary Information-Design and Testing



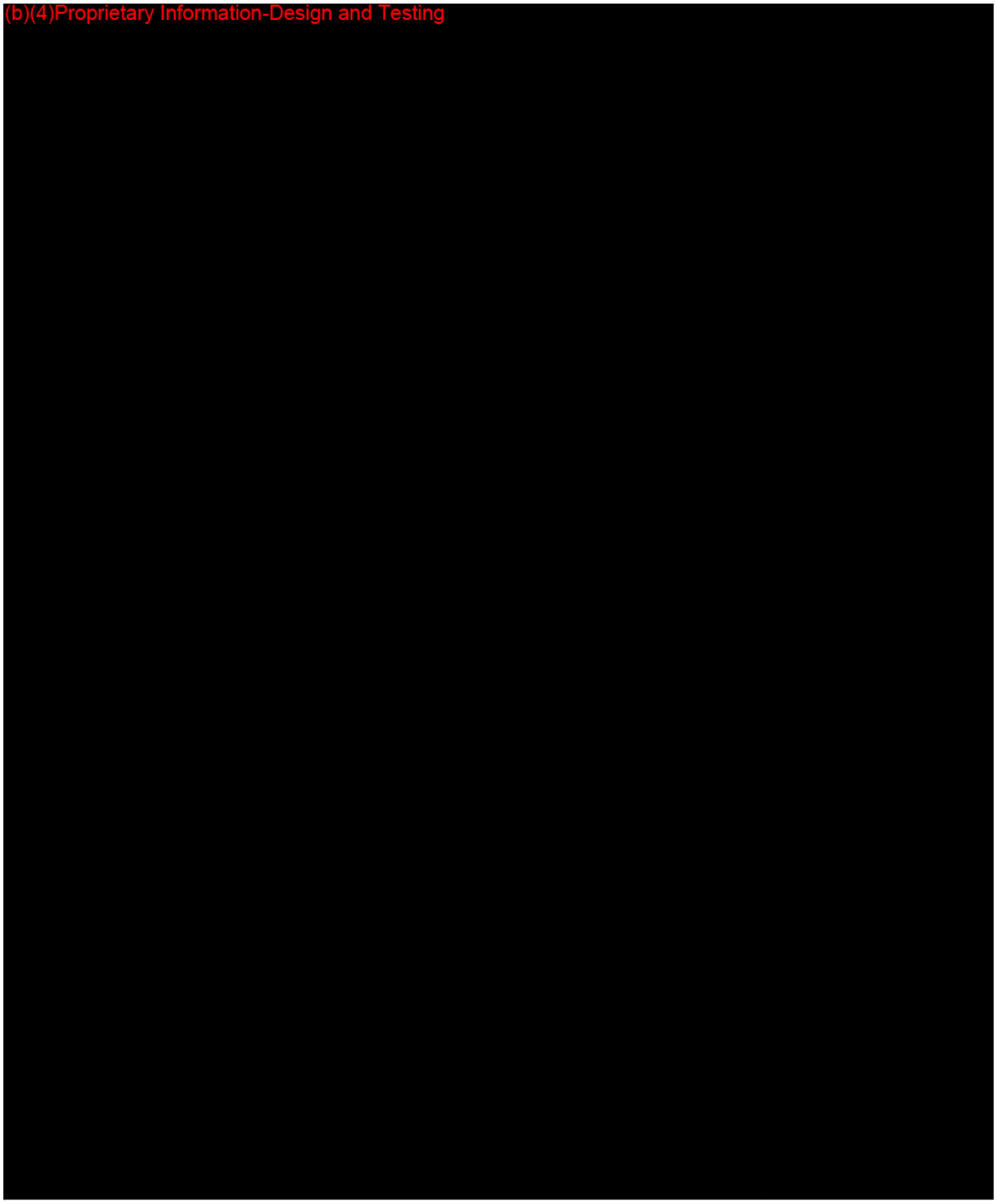
(b)(4)Proprietary Information-Design and Testing



(b)(4)Proprietary Information-Design and Testing



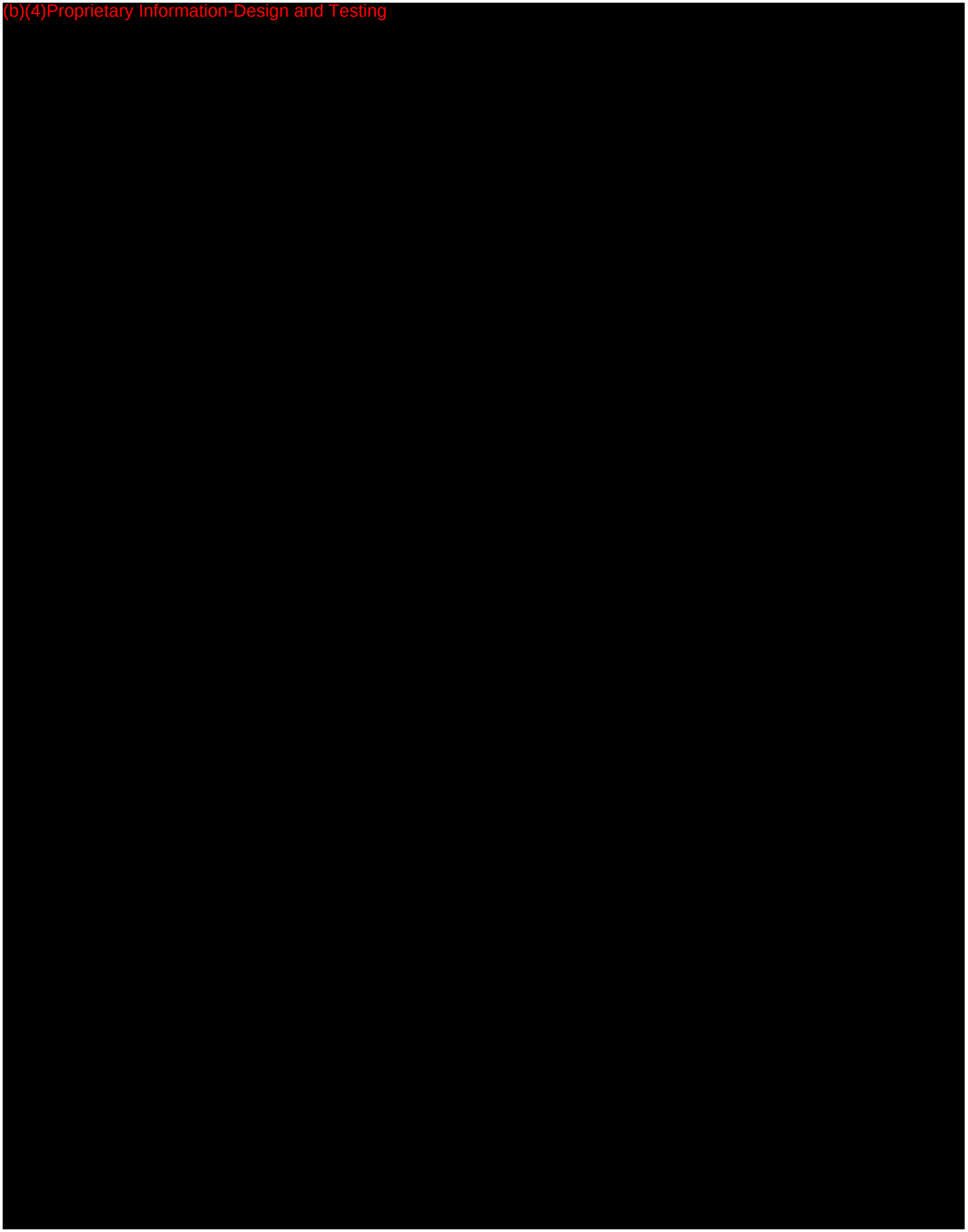
(b)(4)Proprietary Information-Design and Testing



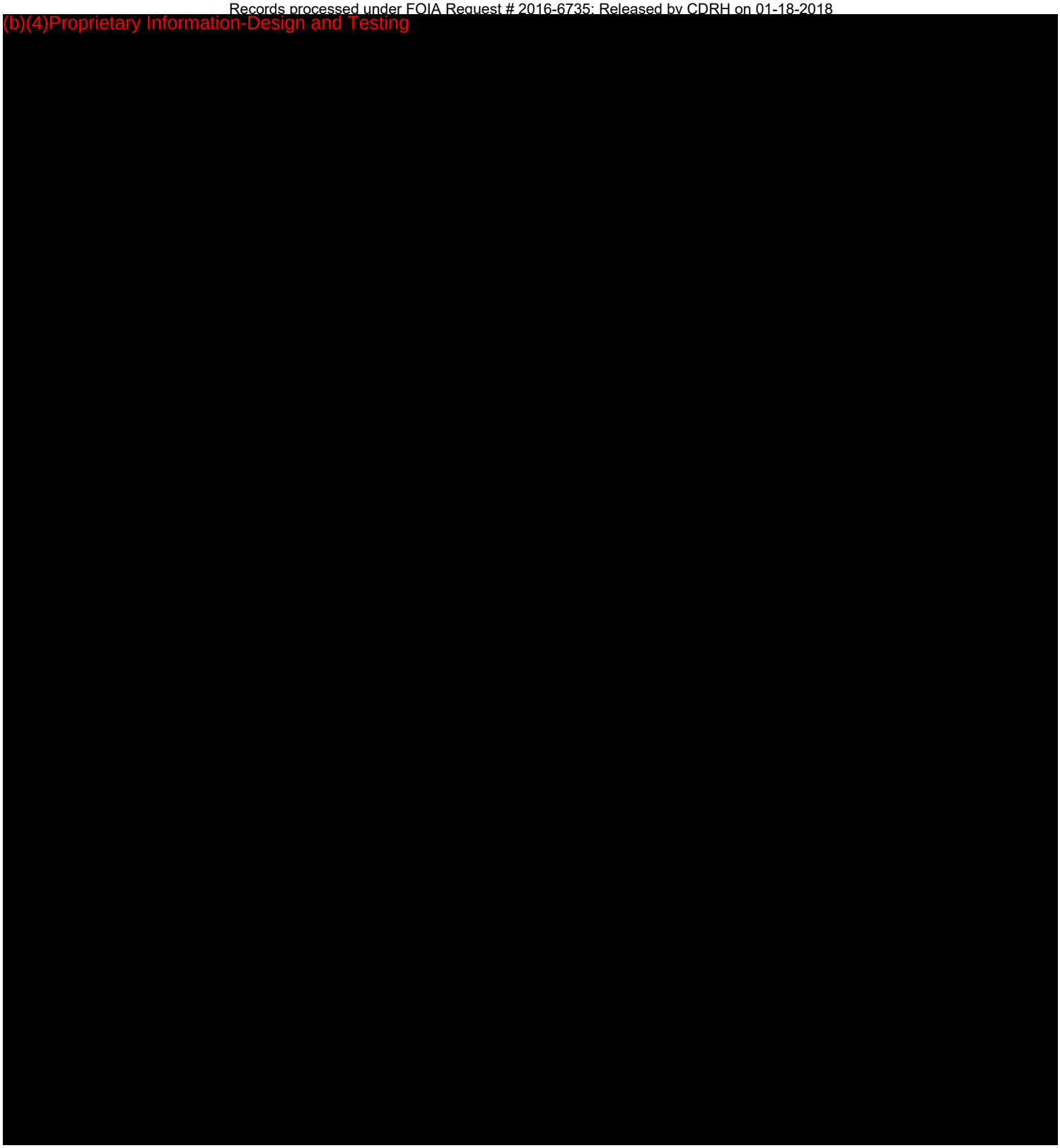
(b)(4)Proprietary Information-Design and Testing

ATTACHMENT 18

(b)(4)Proprietary Information-Design and Testing



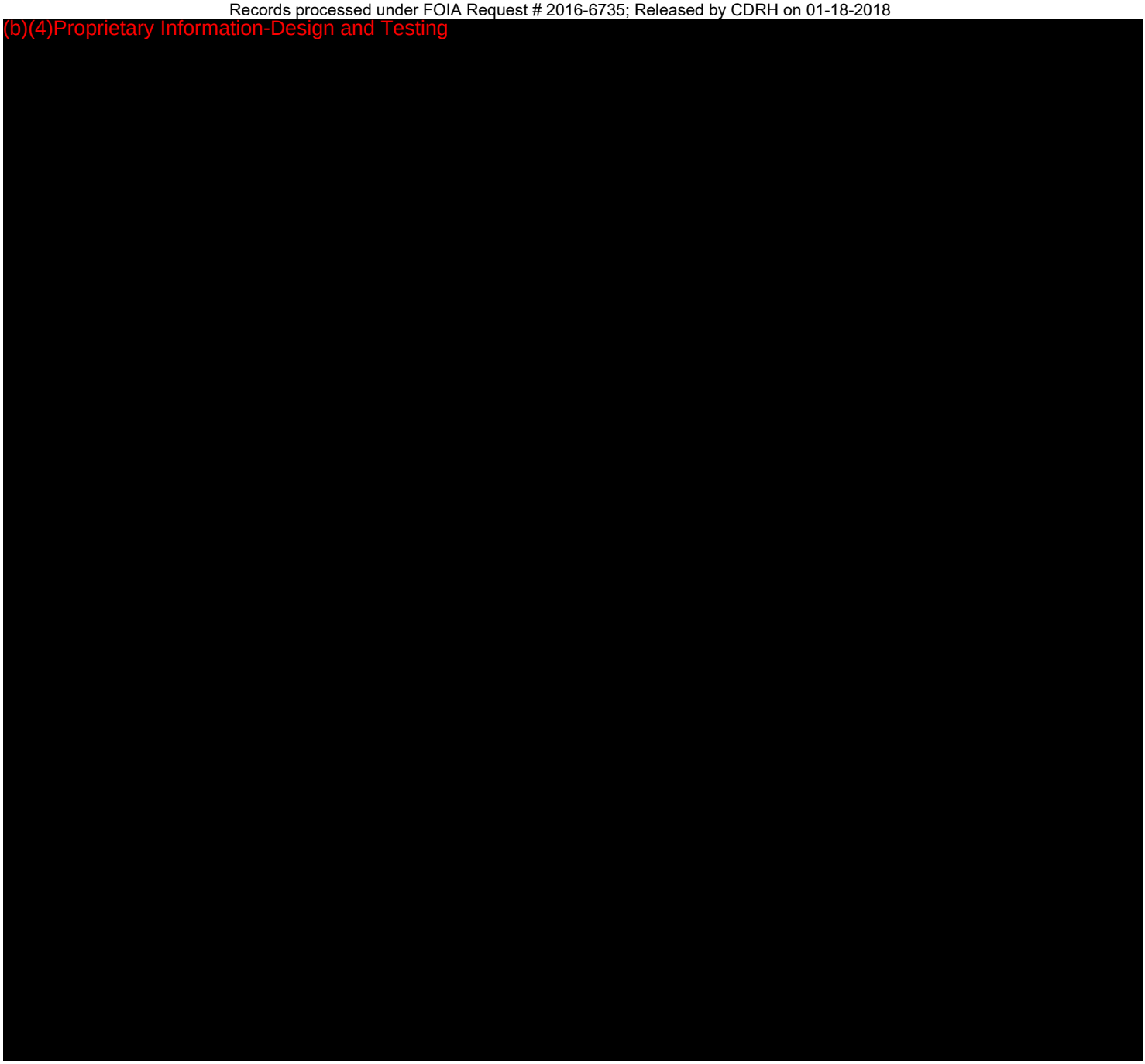
(b)(4)Proprietary Information-Design and Testing



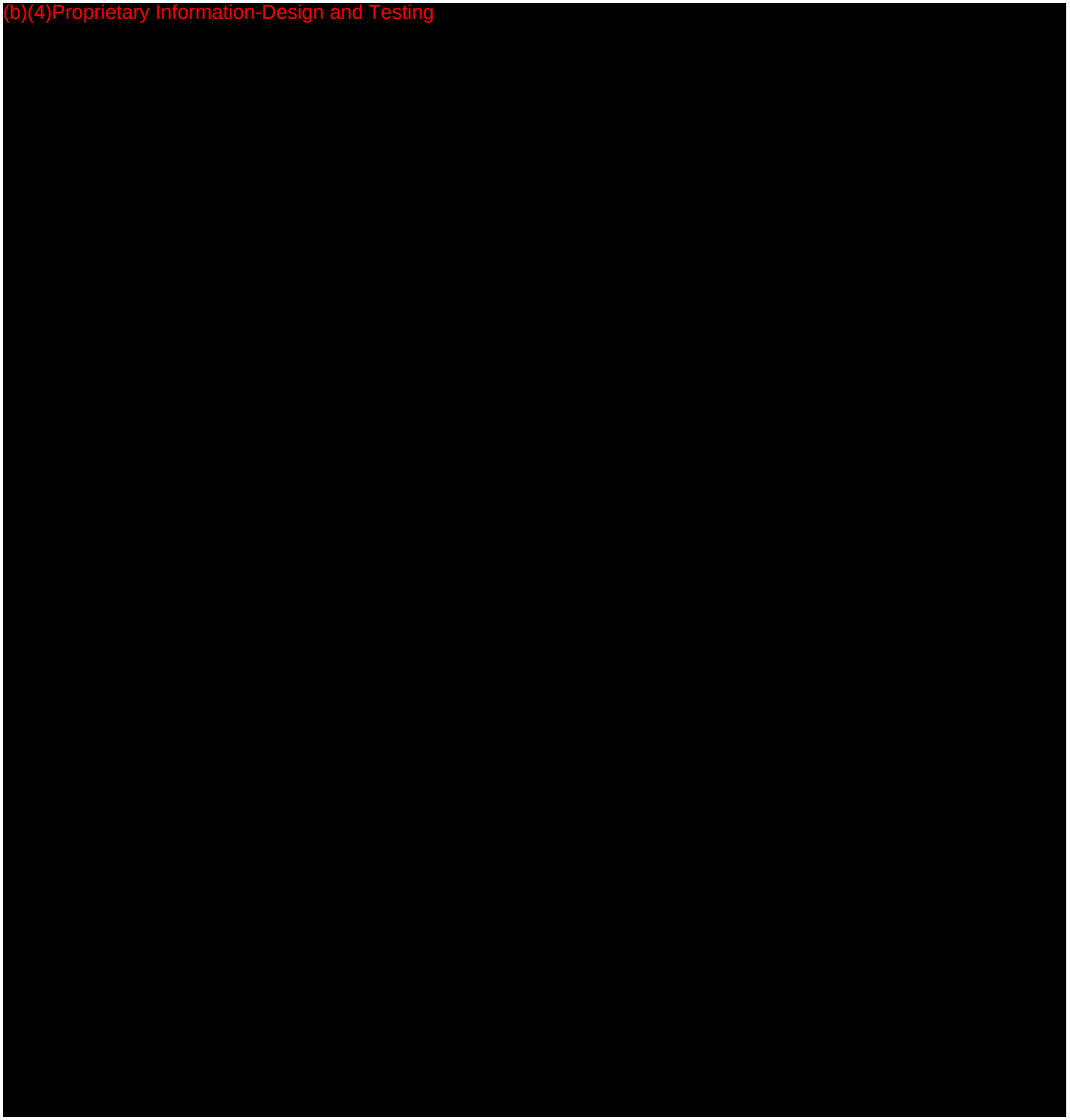
(b)(4)Proprietary Information-Design and Testing

[redacted]

(b)(4)Proprietary Information-Design and Testing



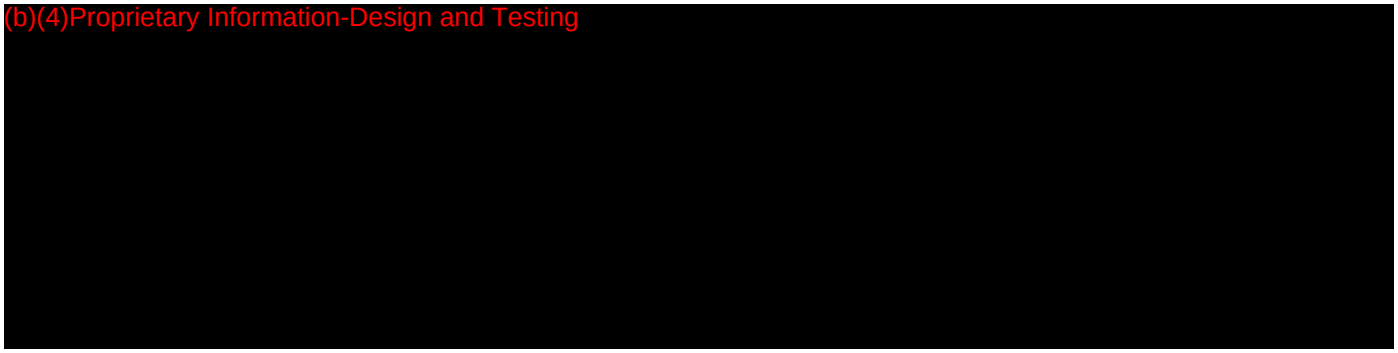
(b)(4)Proprietary Information-Design and Testing



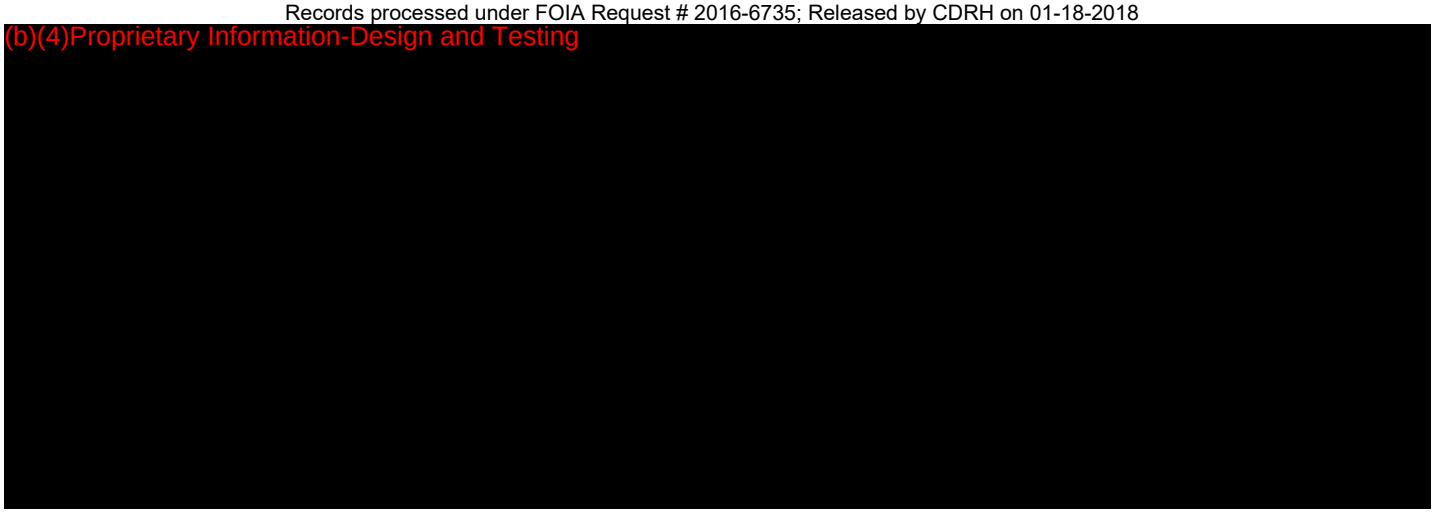
(b)(4)Proprietary Information-Design and Testing

[redacted]

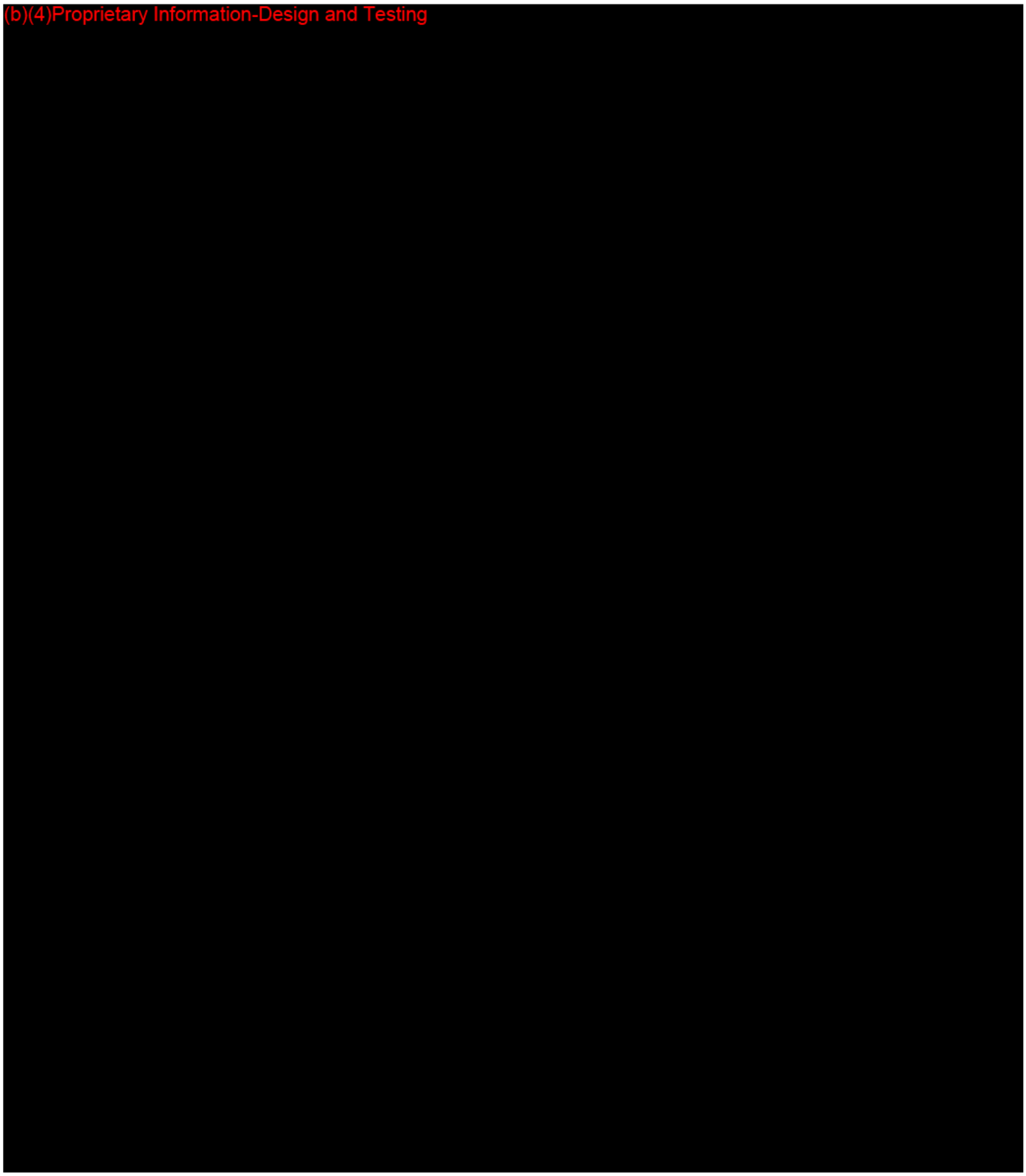
(b)(4)Proprietary Information-Design and Testing



(b)(4)Proprietary Information-Design and Testing



(b)(4)Proprietary Information-Design and Testing

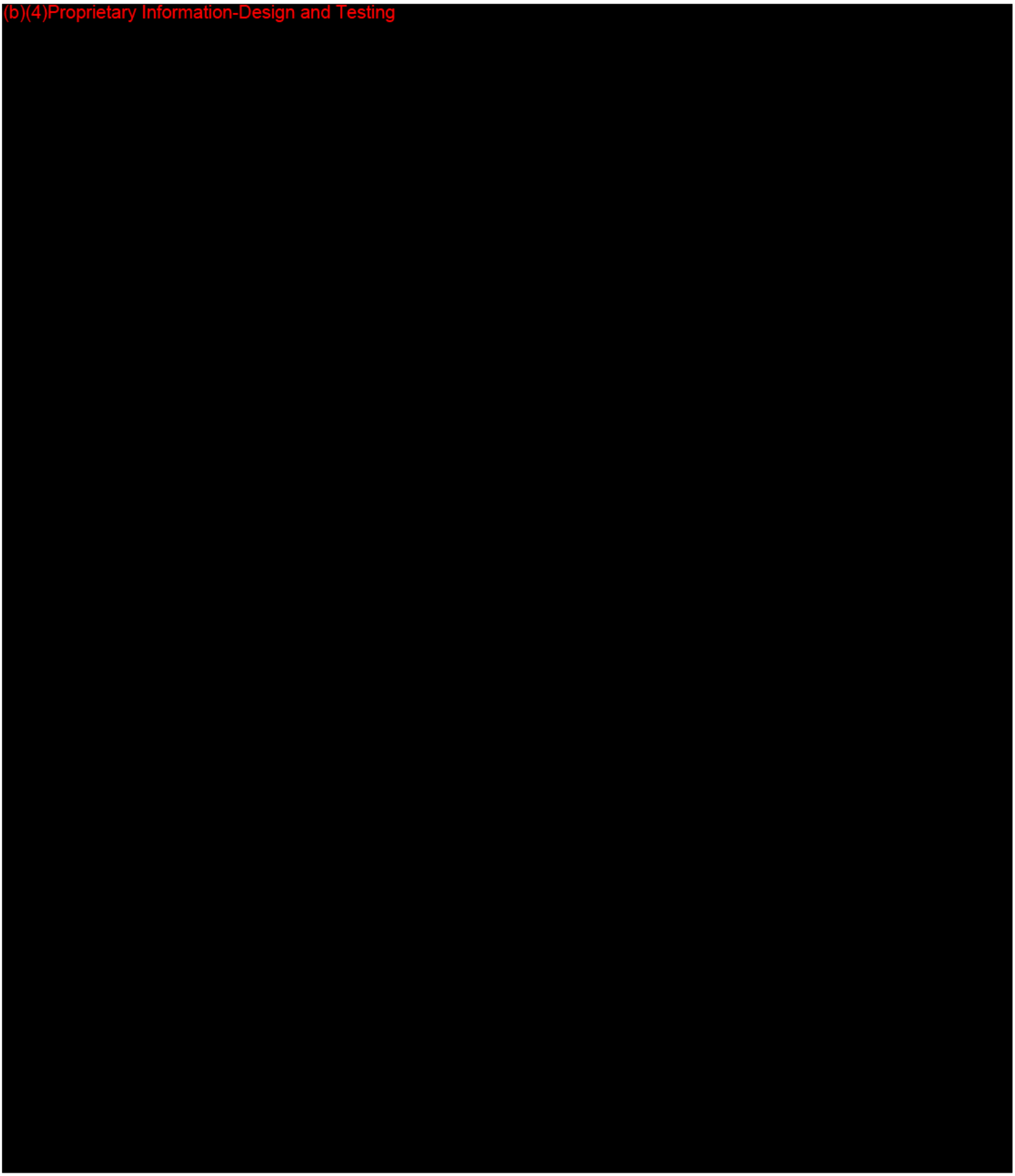


(b)(4)Proprietary Information-Design and Testing

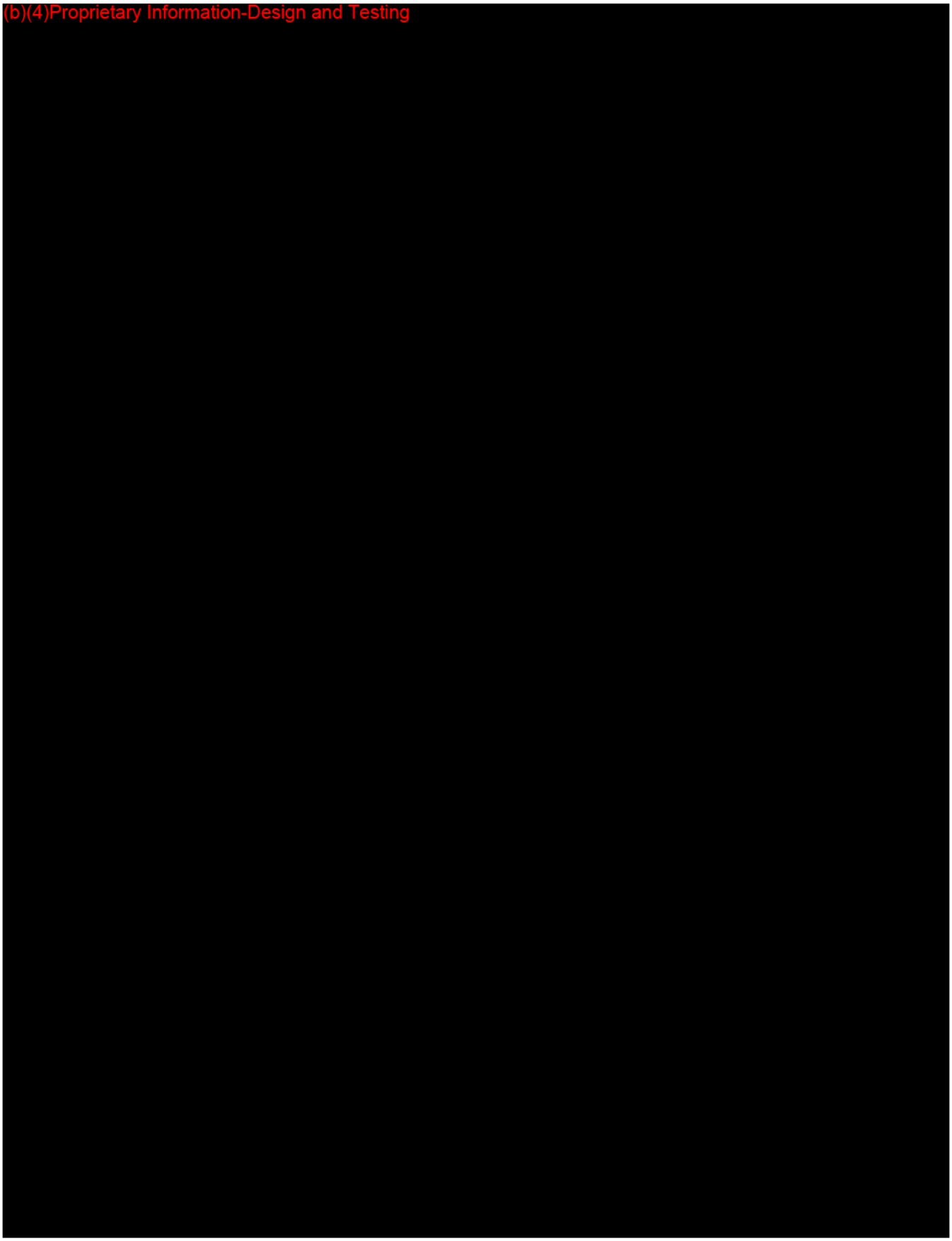
(b)(4)Proprietary Information-Design and Testing

[redacted]

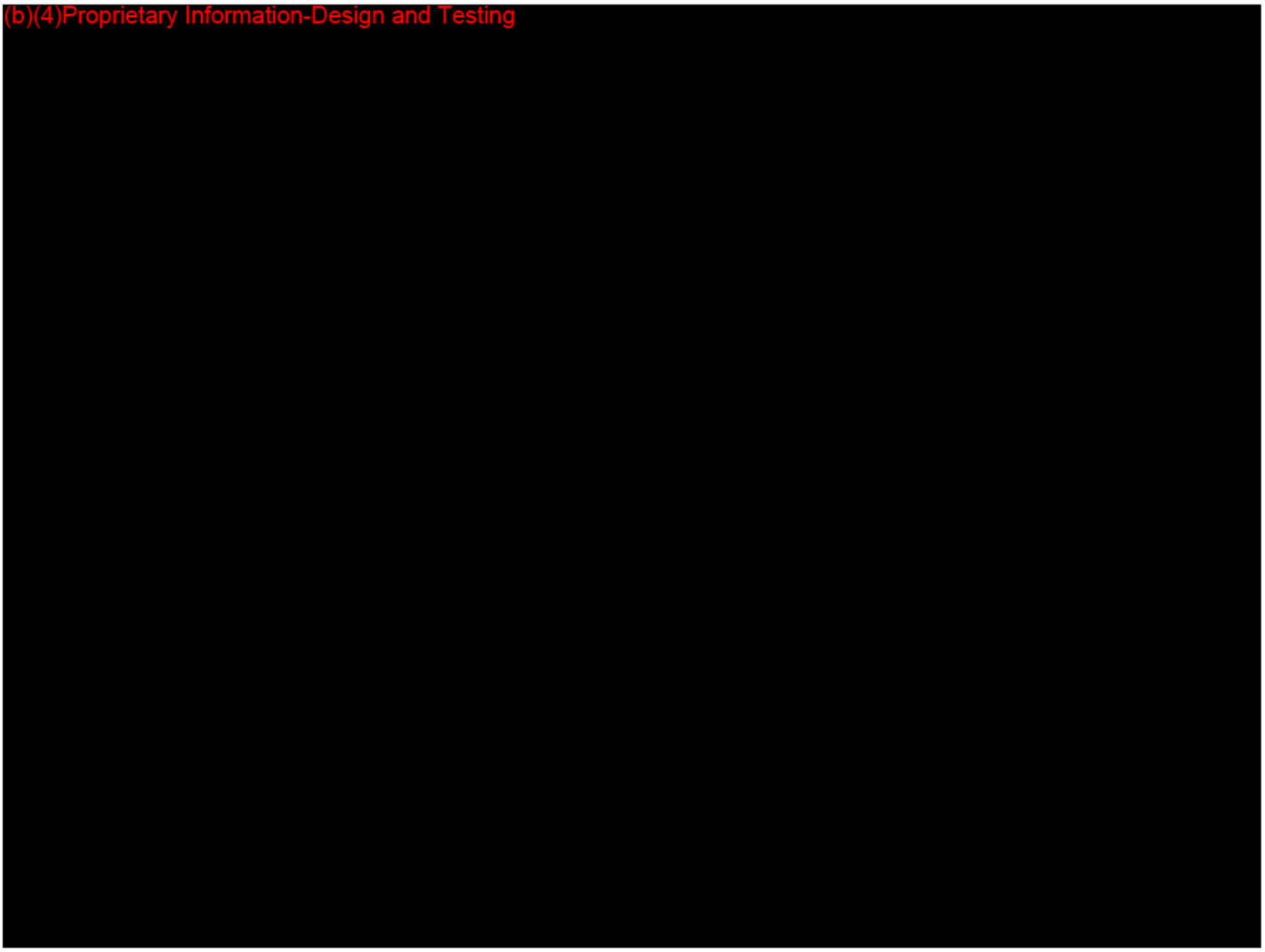
(b)(4)Proprietary Information-Design and Testing



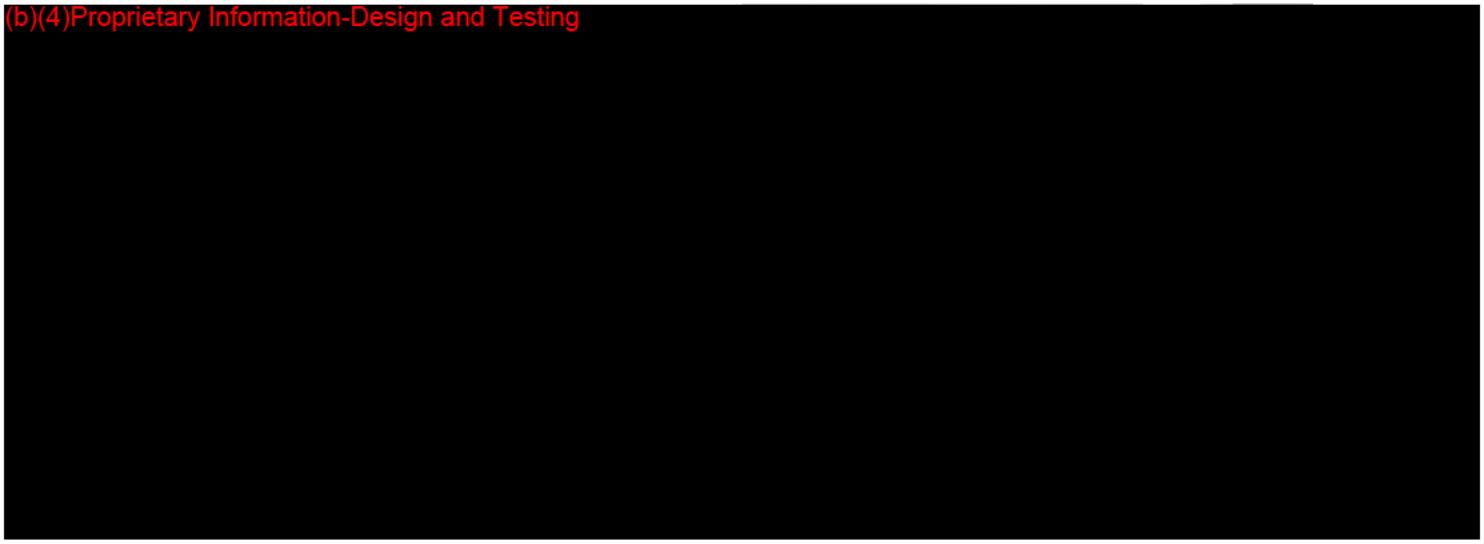
(b)(4)Proprietary Information-Design and Testing



(b)(4)Proprietary Information-Design and Testing

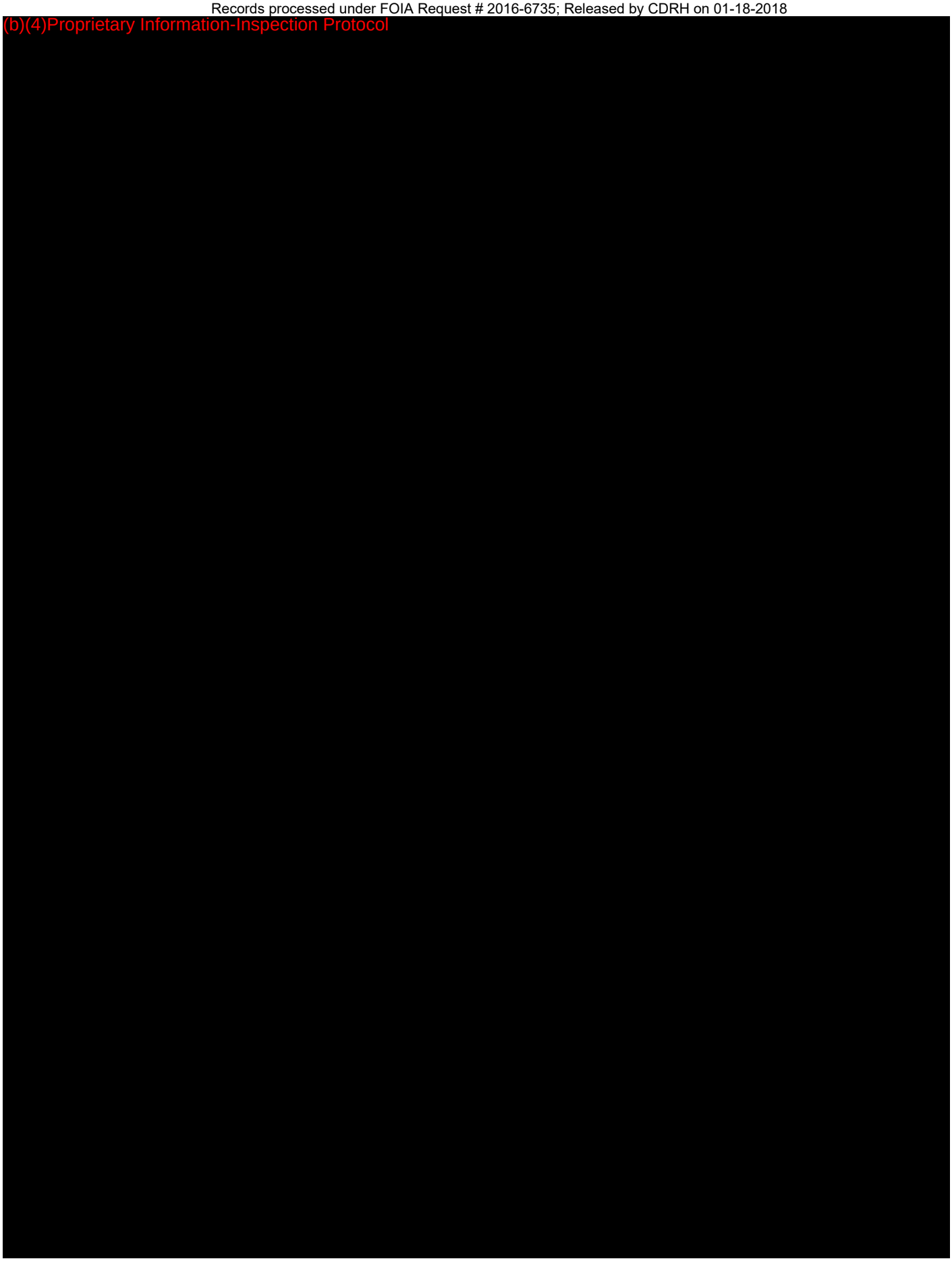


(b)(4)Proprietary Information-Design and Testing

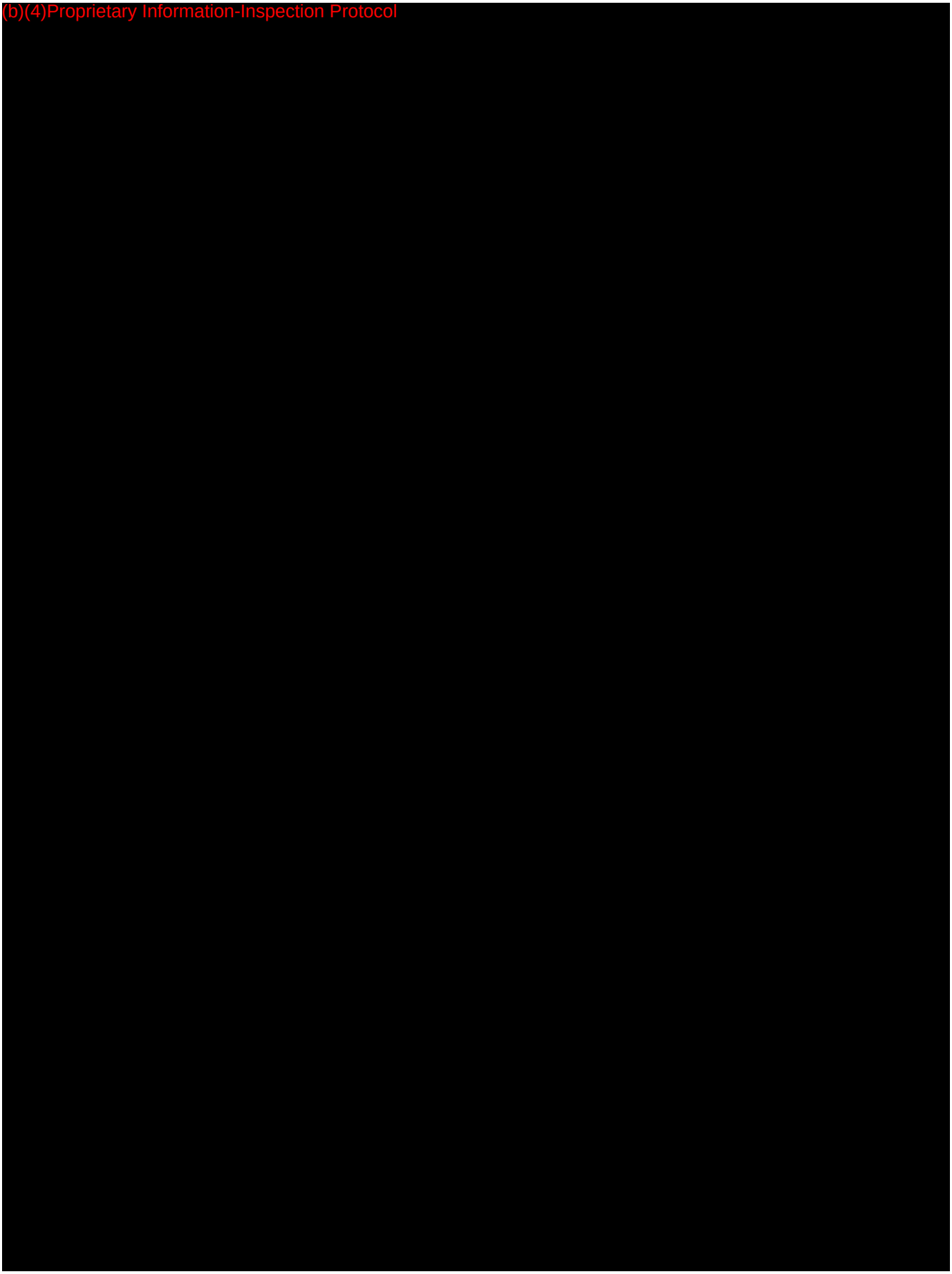


ATTACHMENT 19

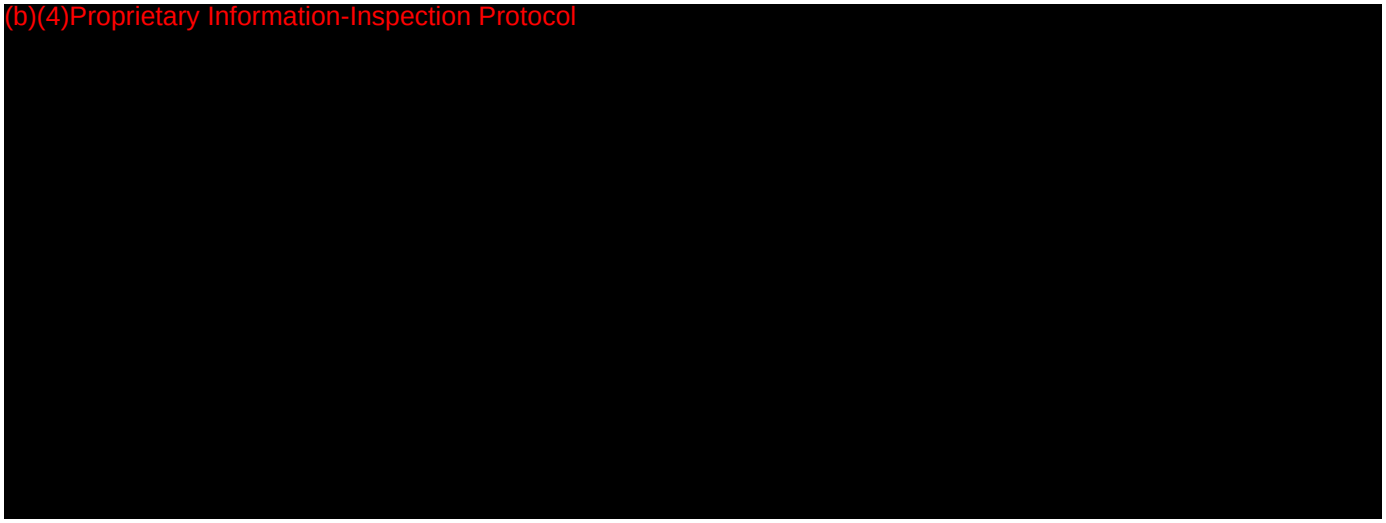
(b)(4)Proprietary Information-Inspection Protocol



(b)(4)Proprietary Information-Inspection Protocol

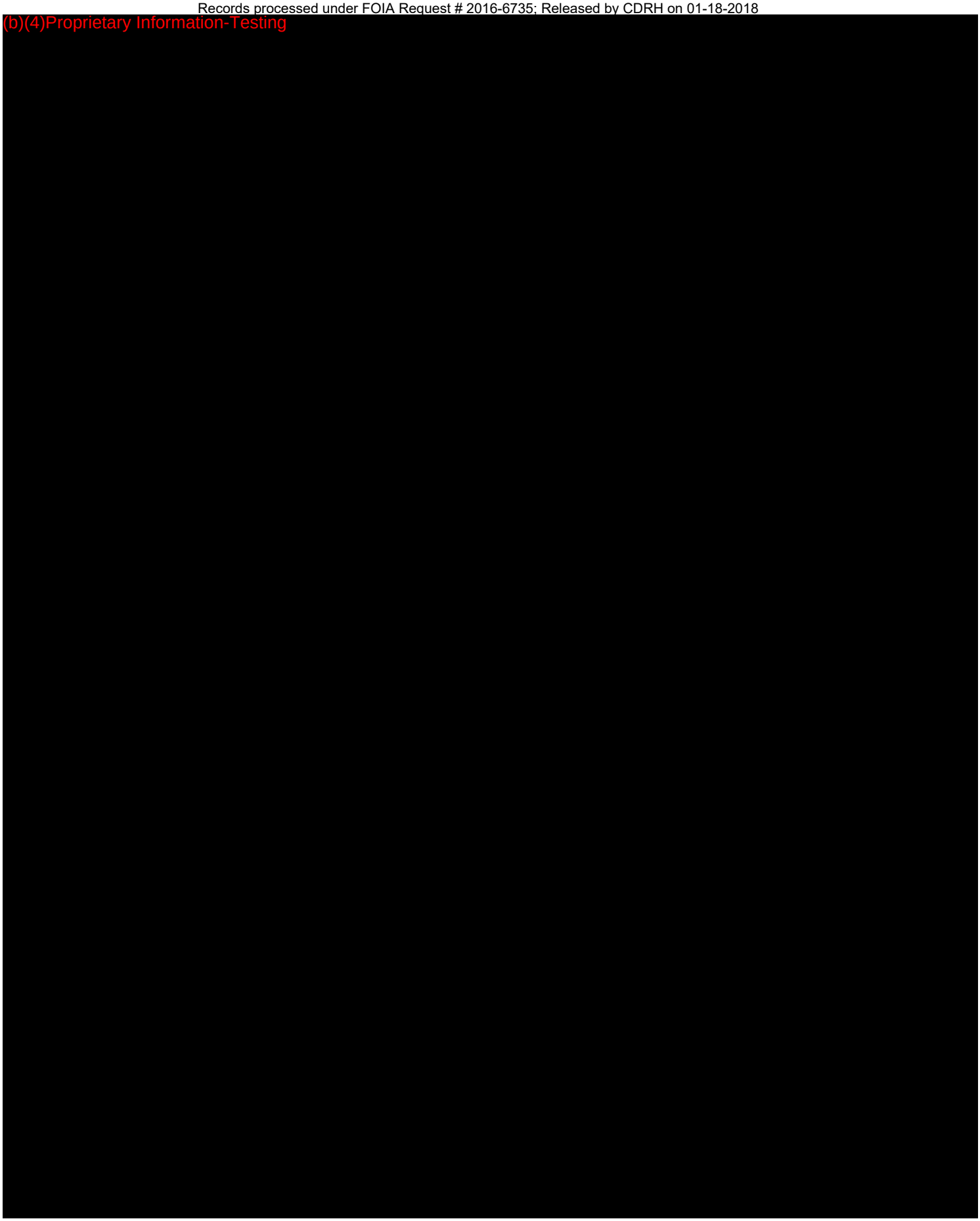


(b)(4)Proprietary Information-Inspection Protocol



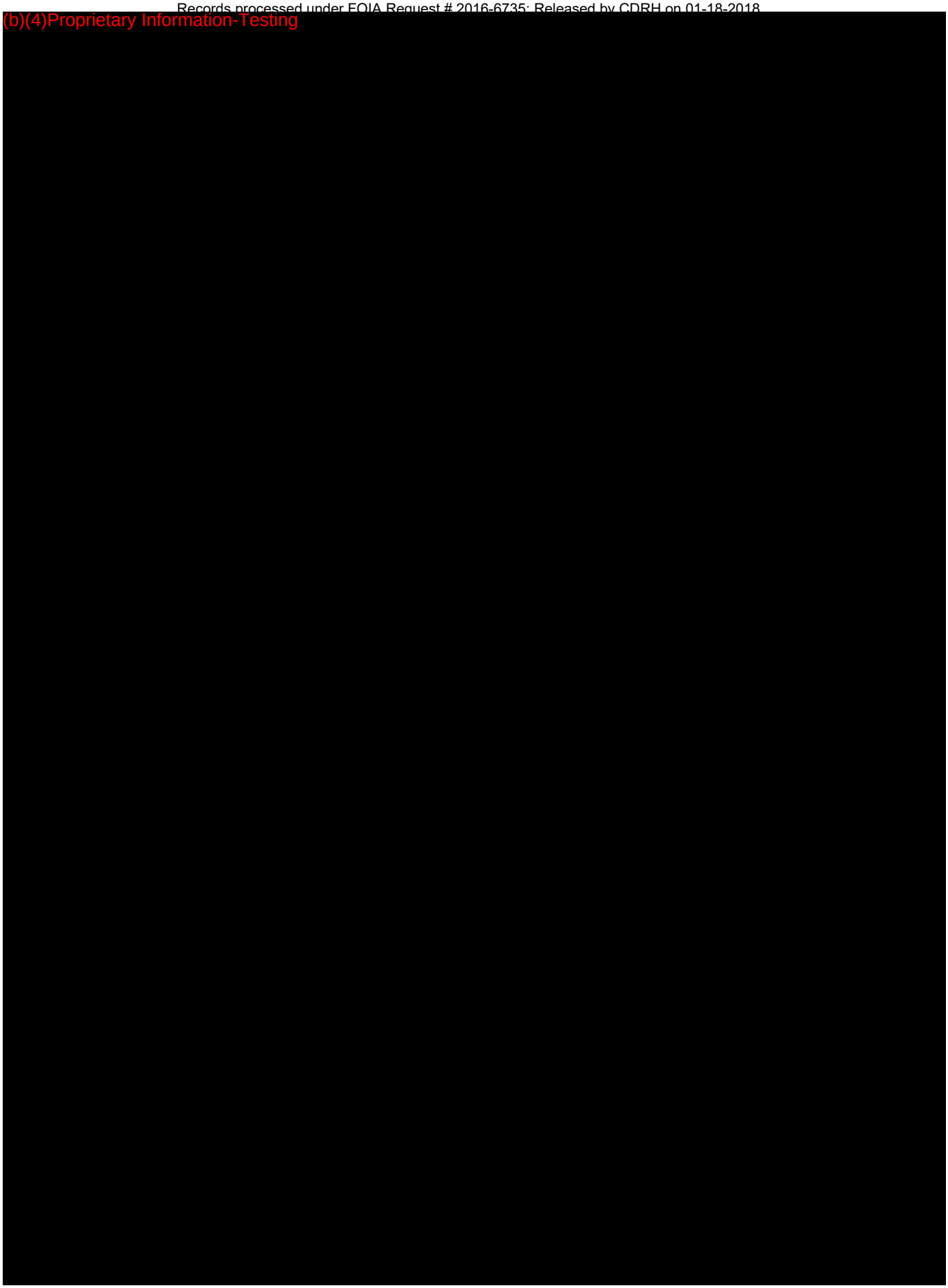
ATTACHMENT 20

(b)(4)Proprietary Information-Testing

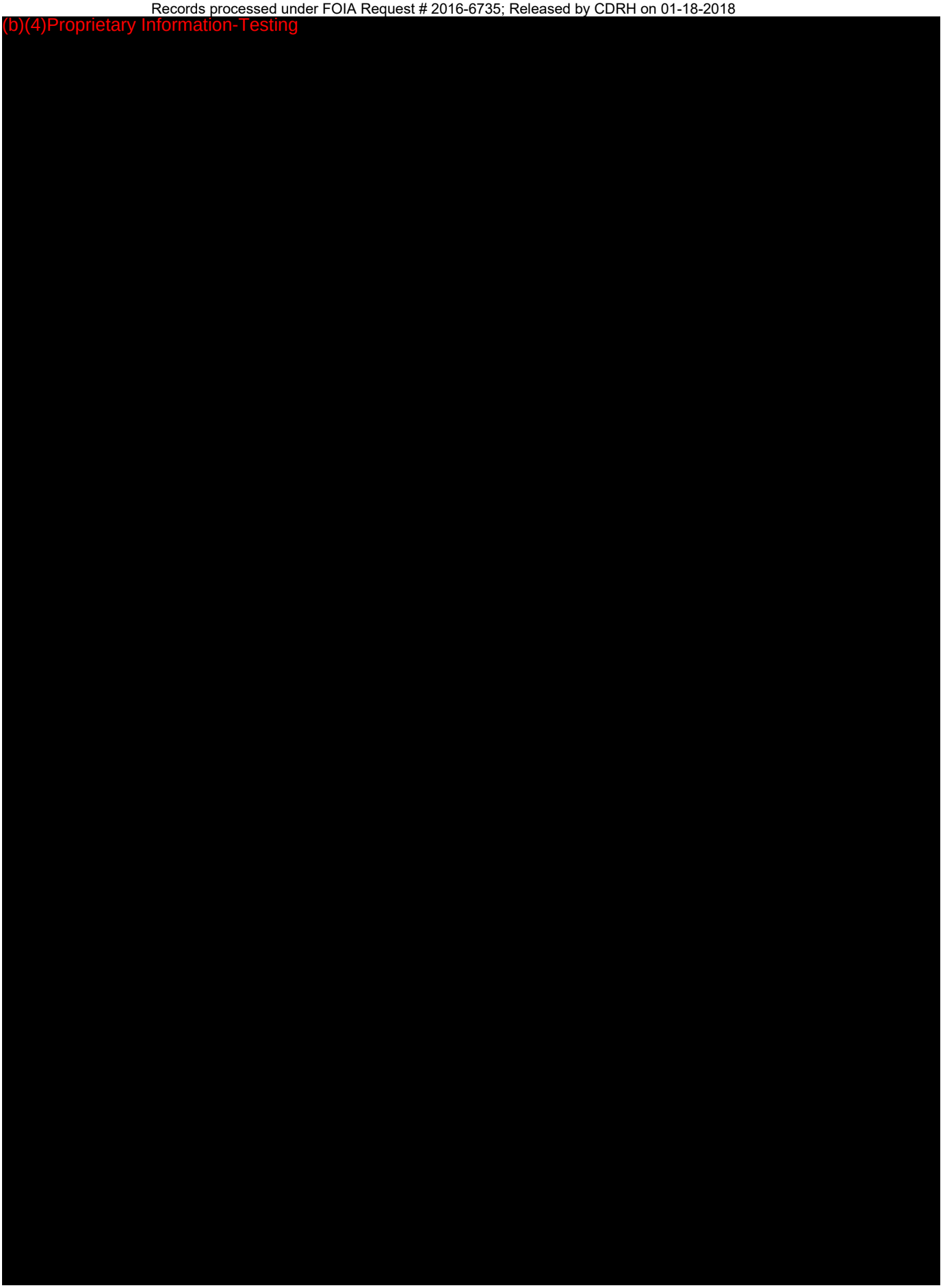


(b)(4)Proprietary Information-Testing

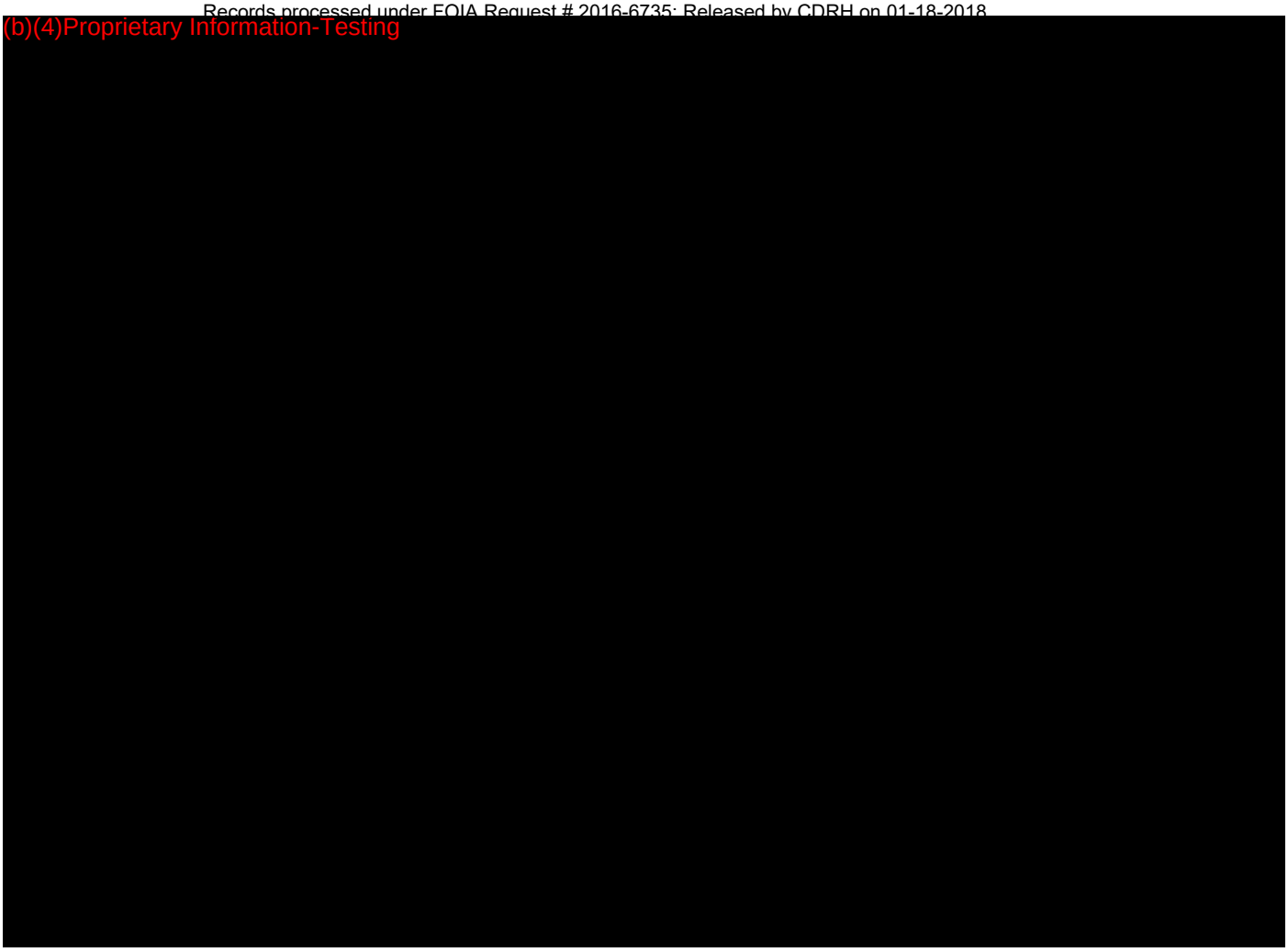
(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing

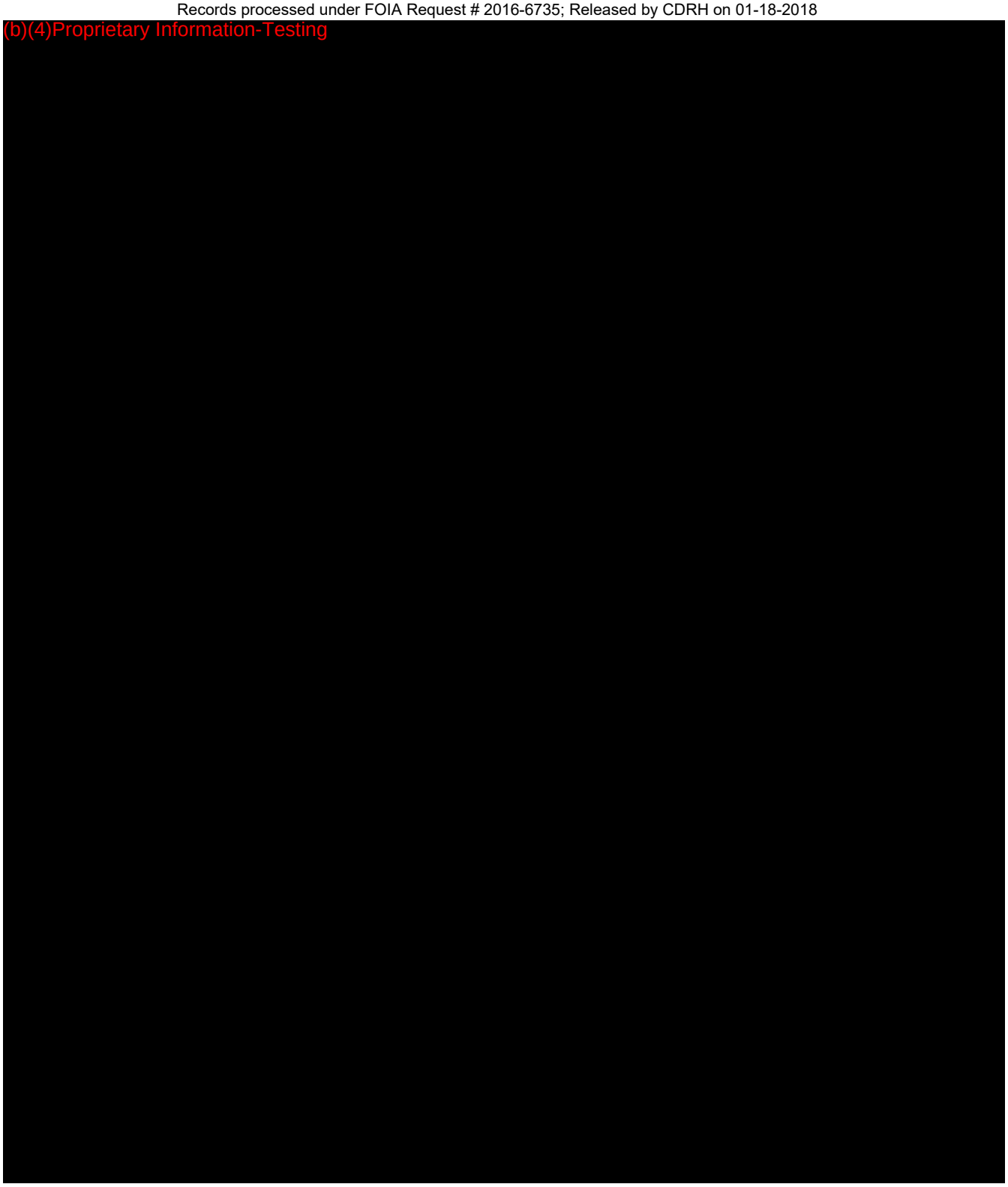


(b)(4)Proprietary Information-Testing

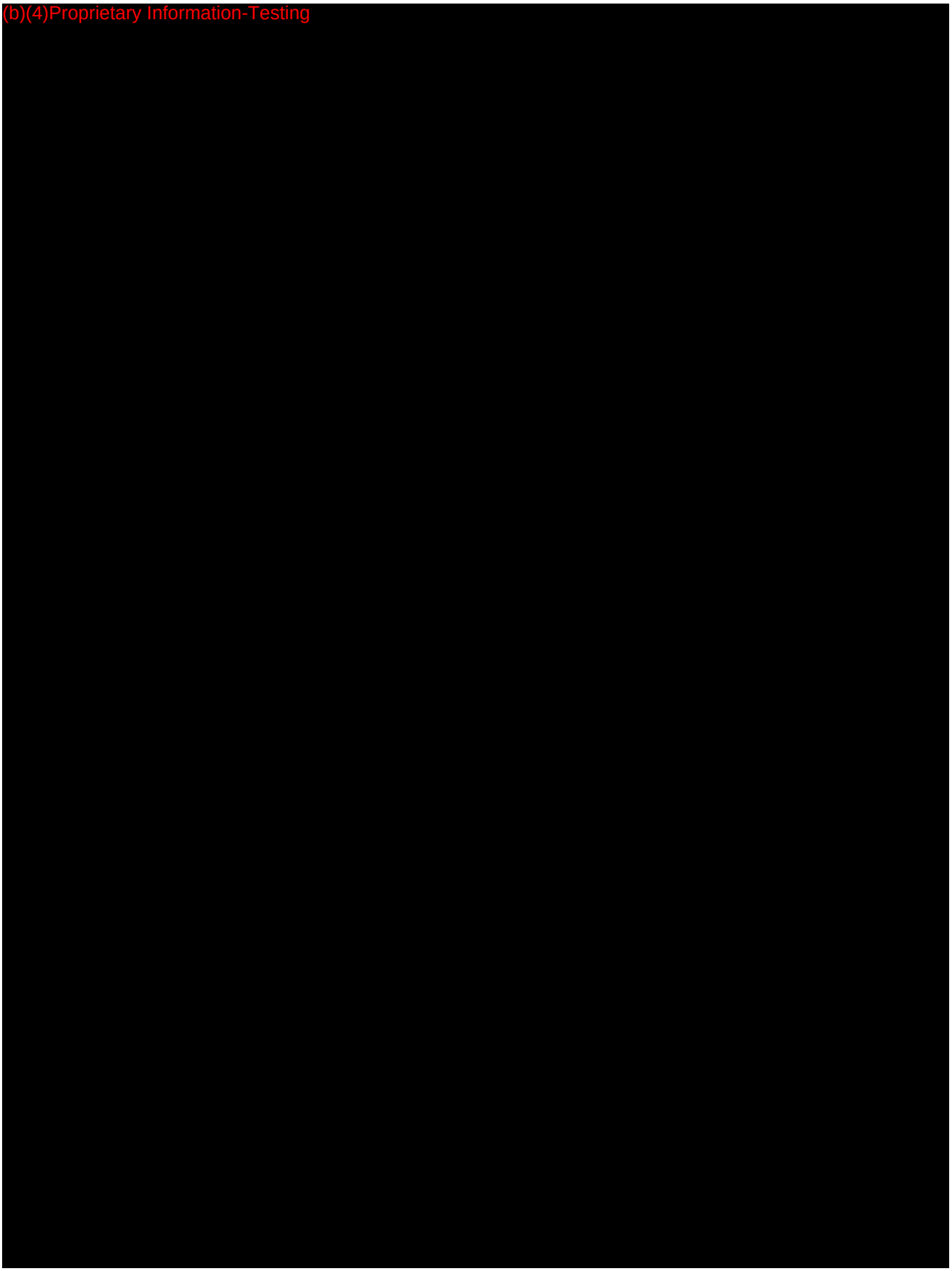


ATTACHMENT 21

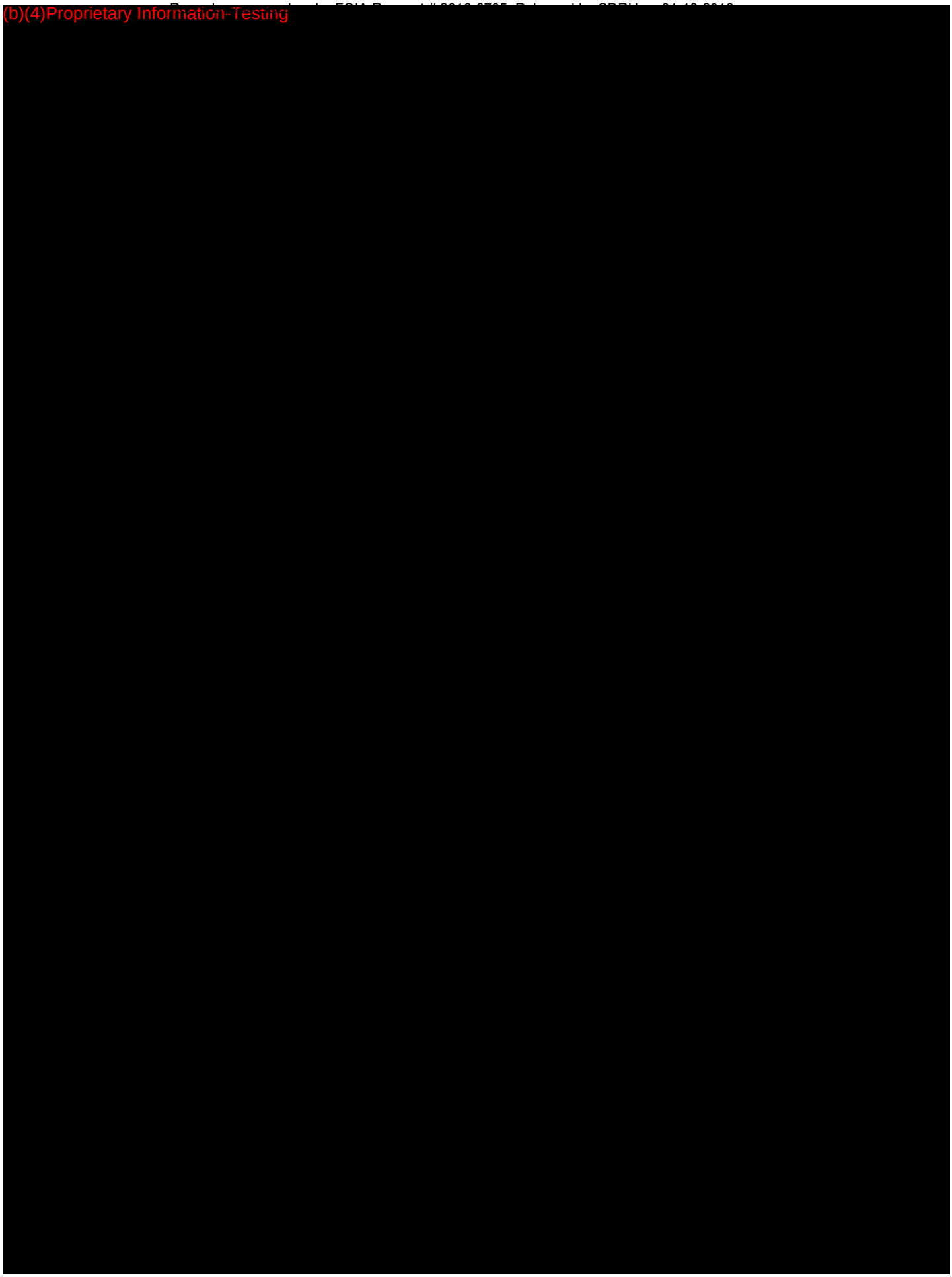
(b)(4)Proprietary Information-Testing



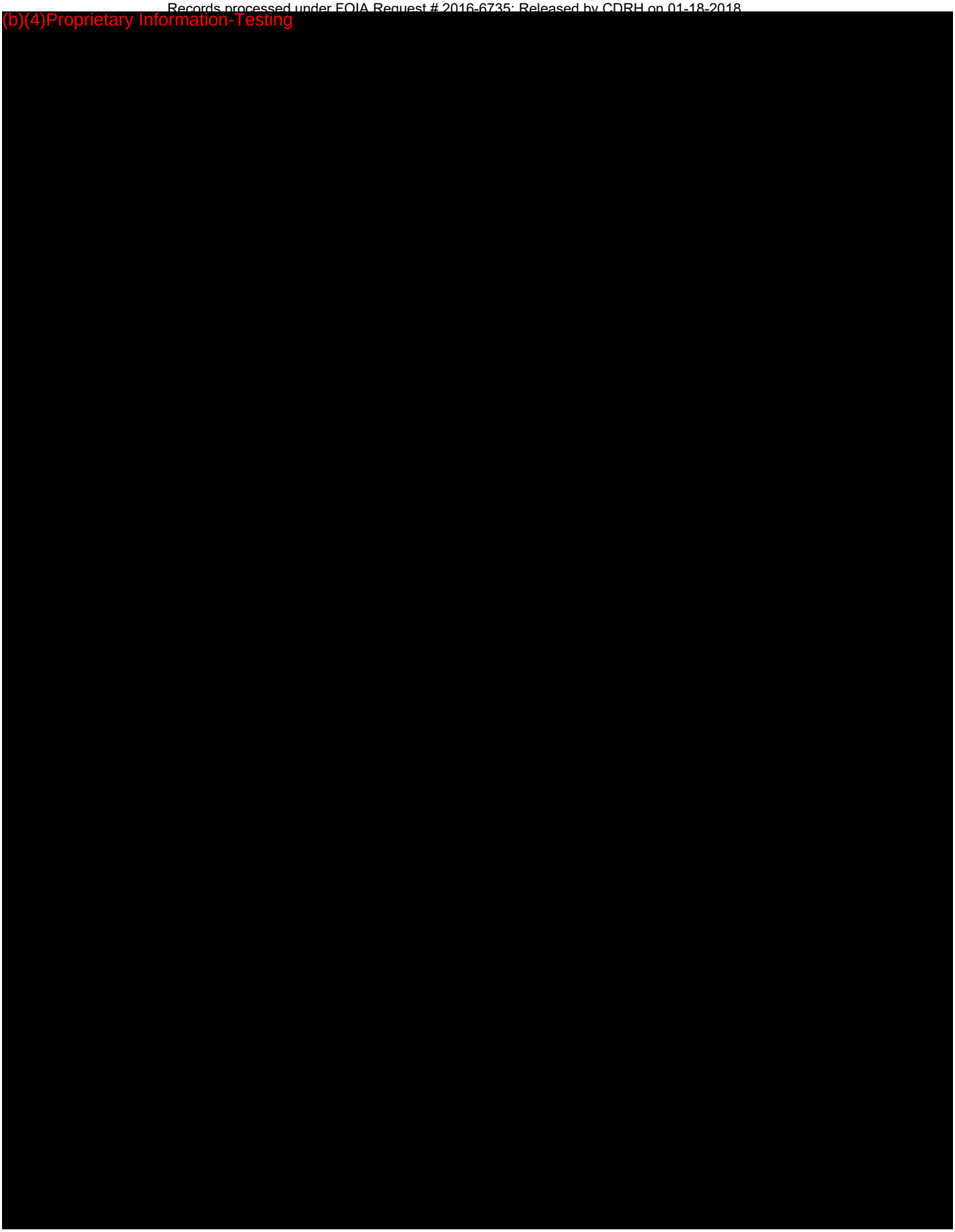
(b)(4)Proprietary Information-Testing



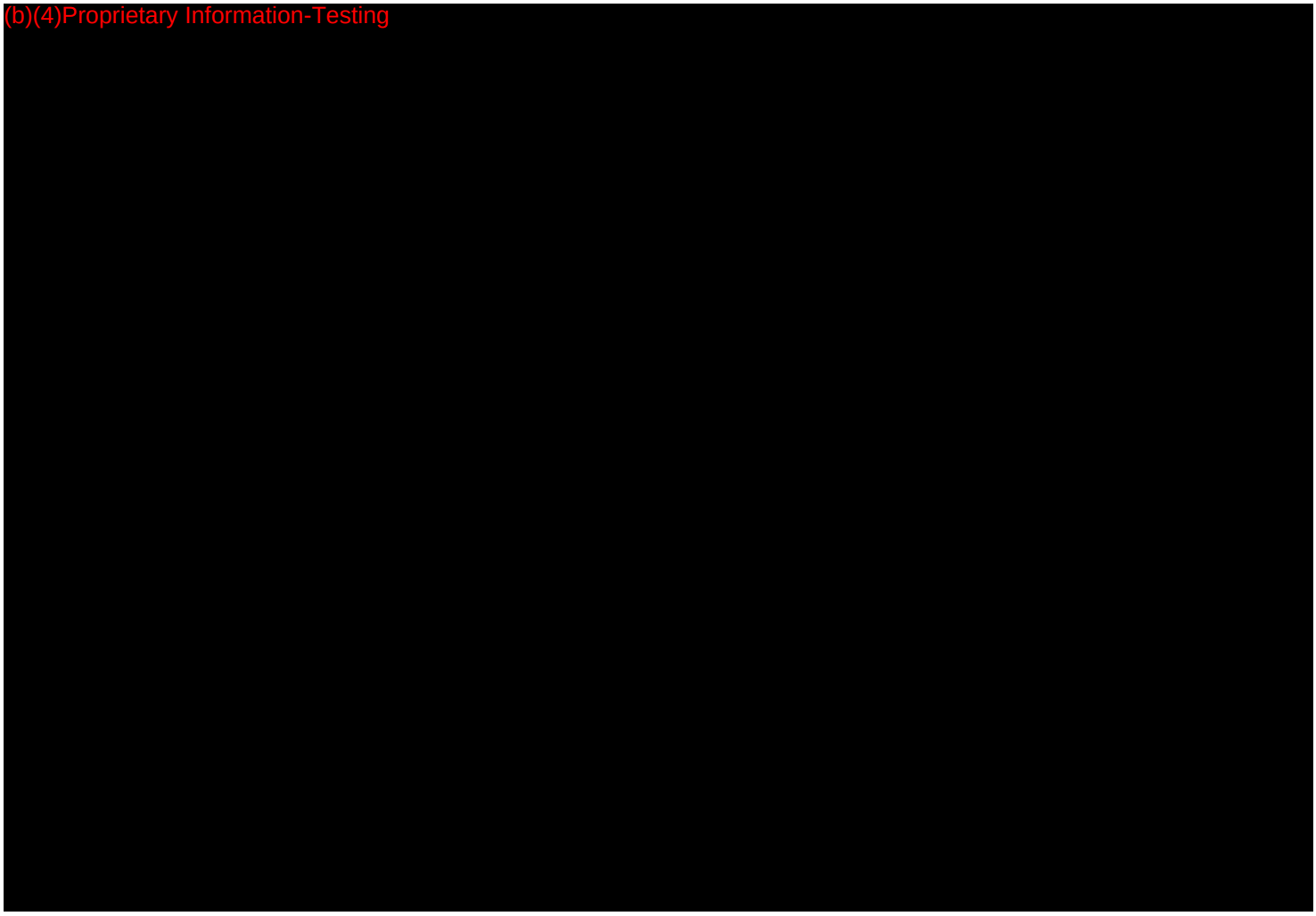
(b)(4)Proprietary Information - Testing



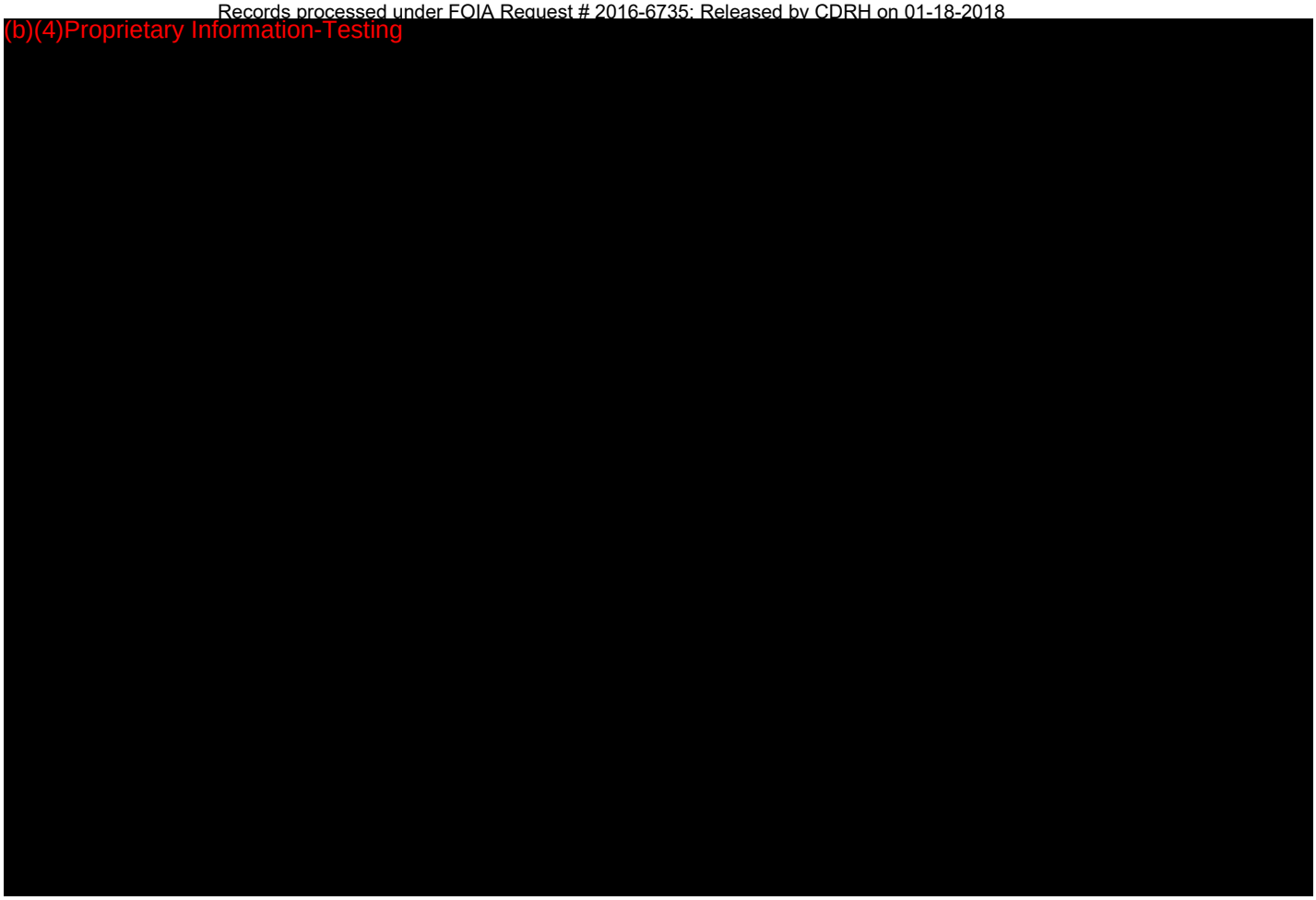
(b)(4)Proprietary Information-Testing



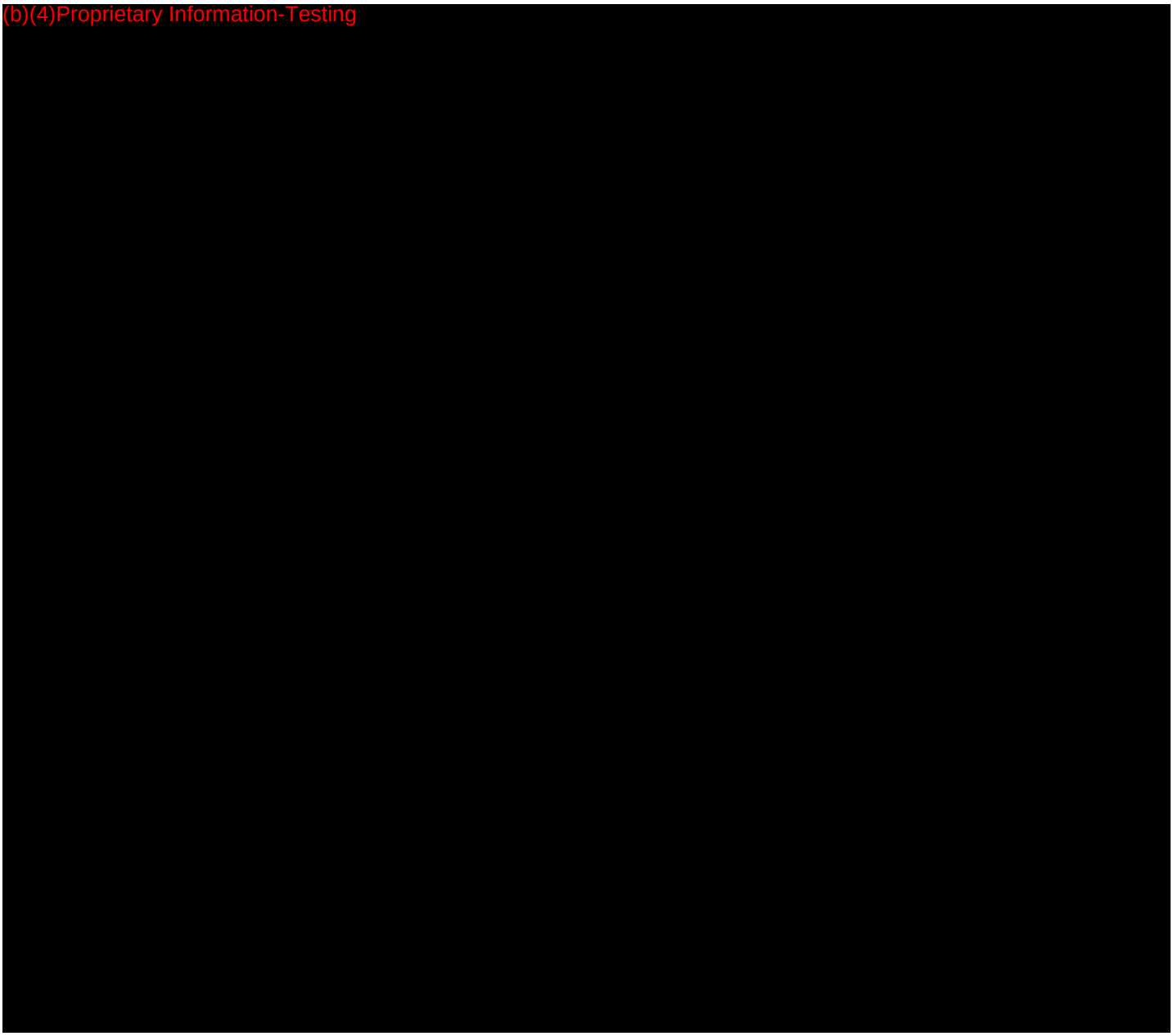
(b)(4)Proprietary Information-Testing



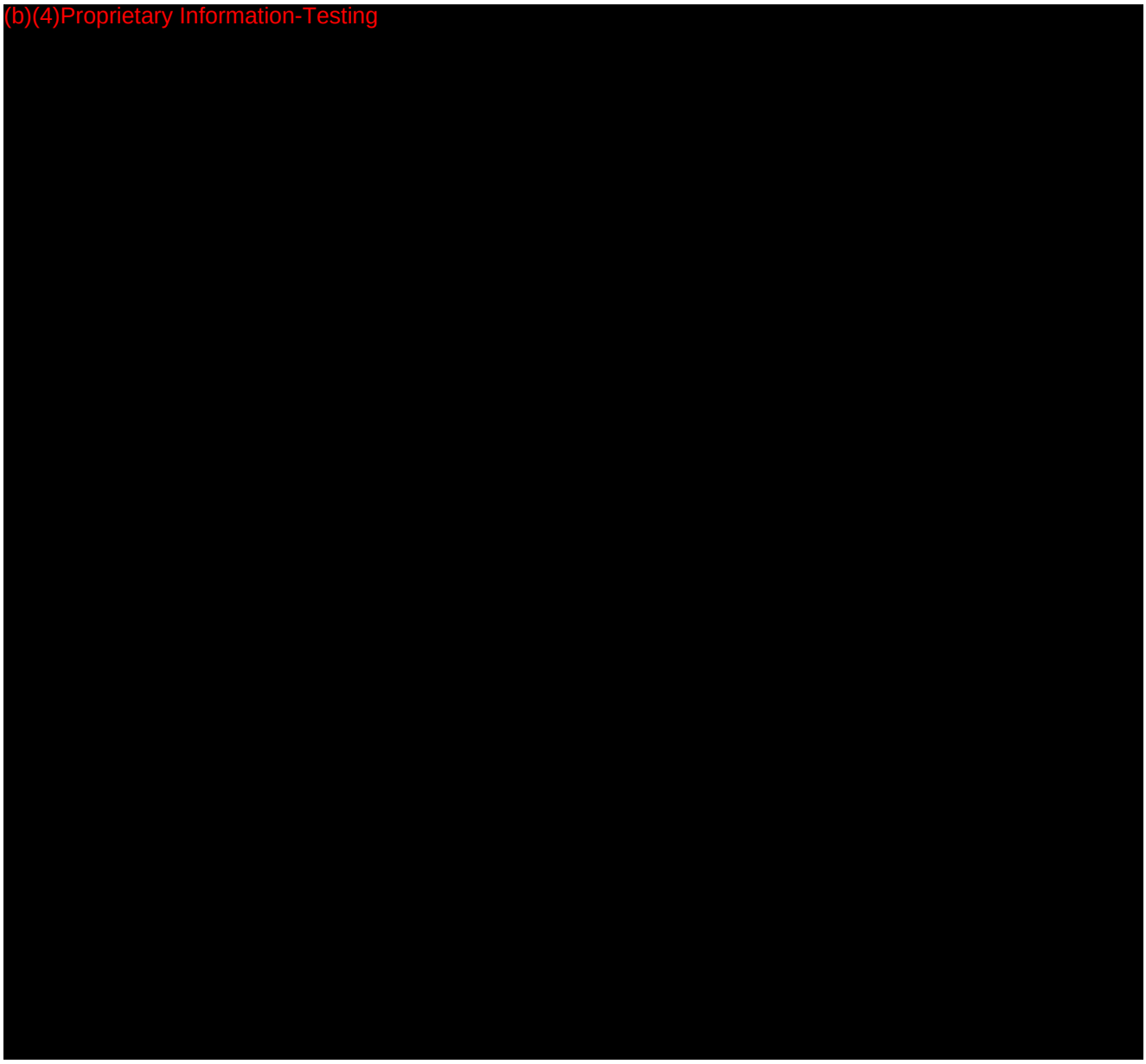
(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing



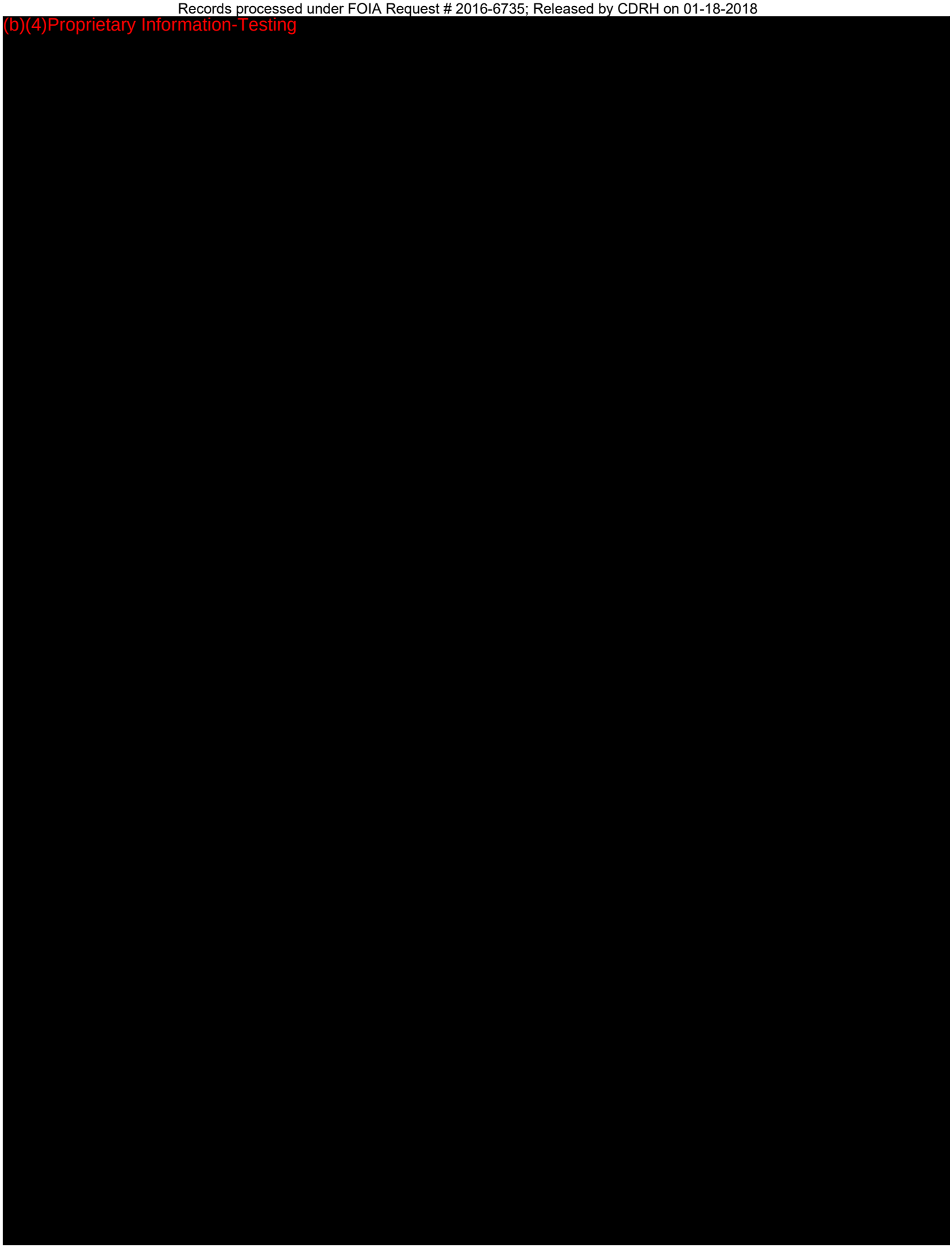
(b)(4)Proprietary Information-Testing



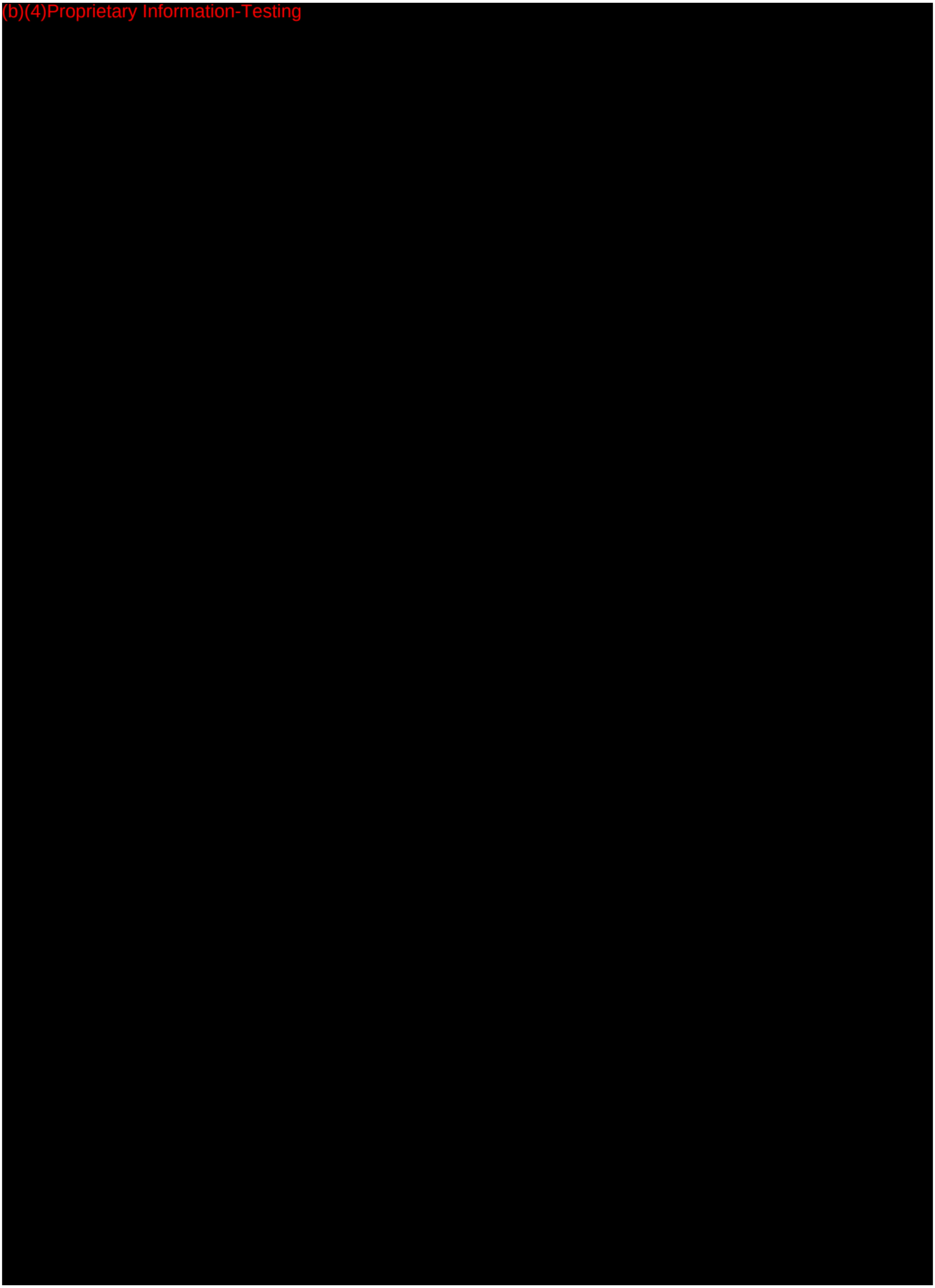
(b)(4)Proprietary Information-Testing

ATTACHMENT 22

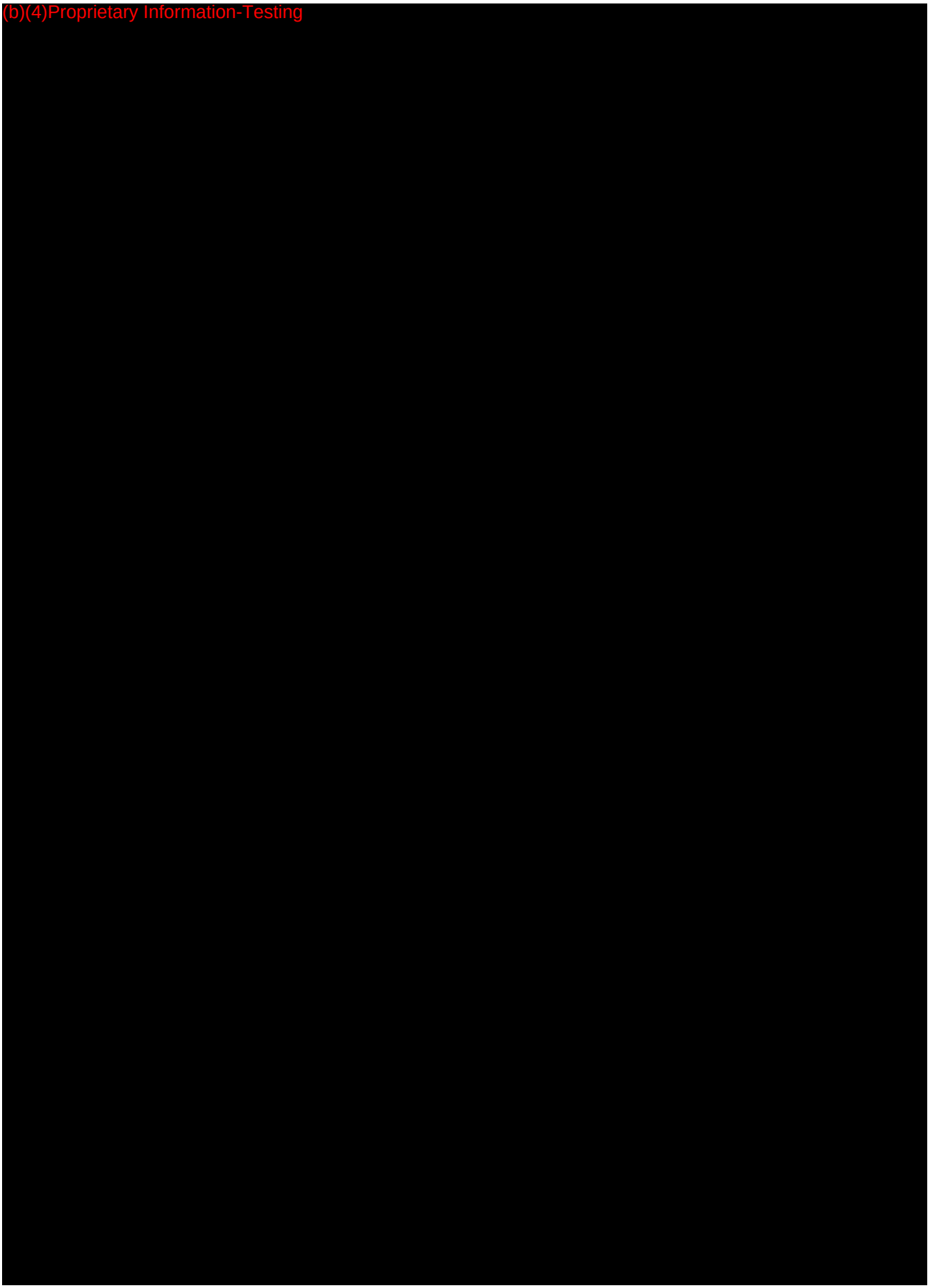
(b)(4)Proprietary Information-Testing



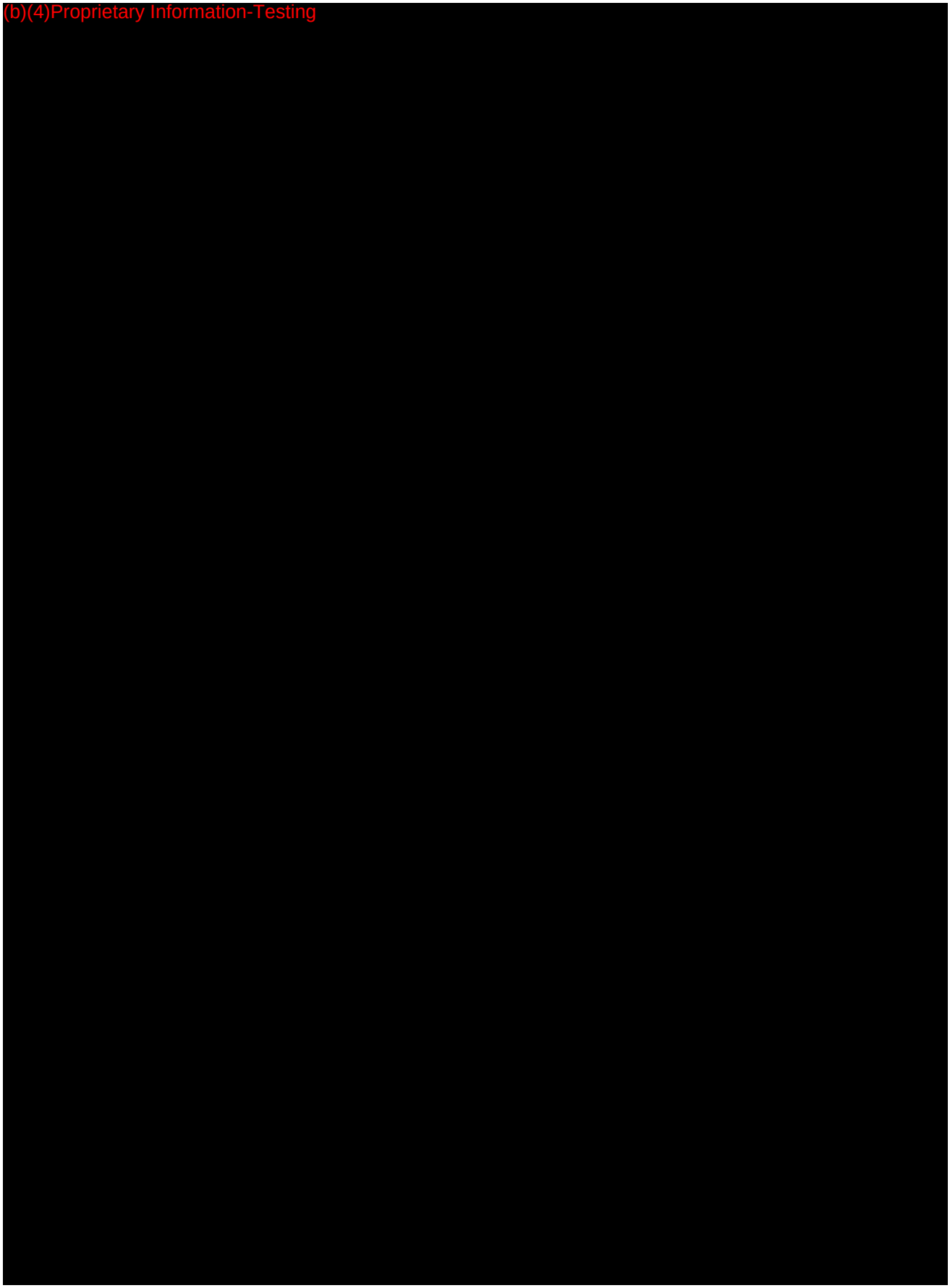
(b)(4)Proprietary Information-Testing



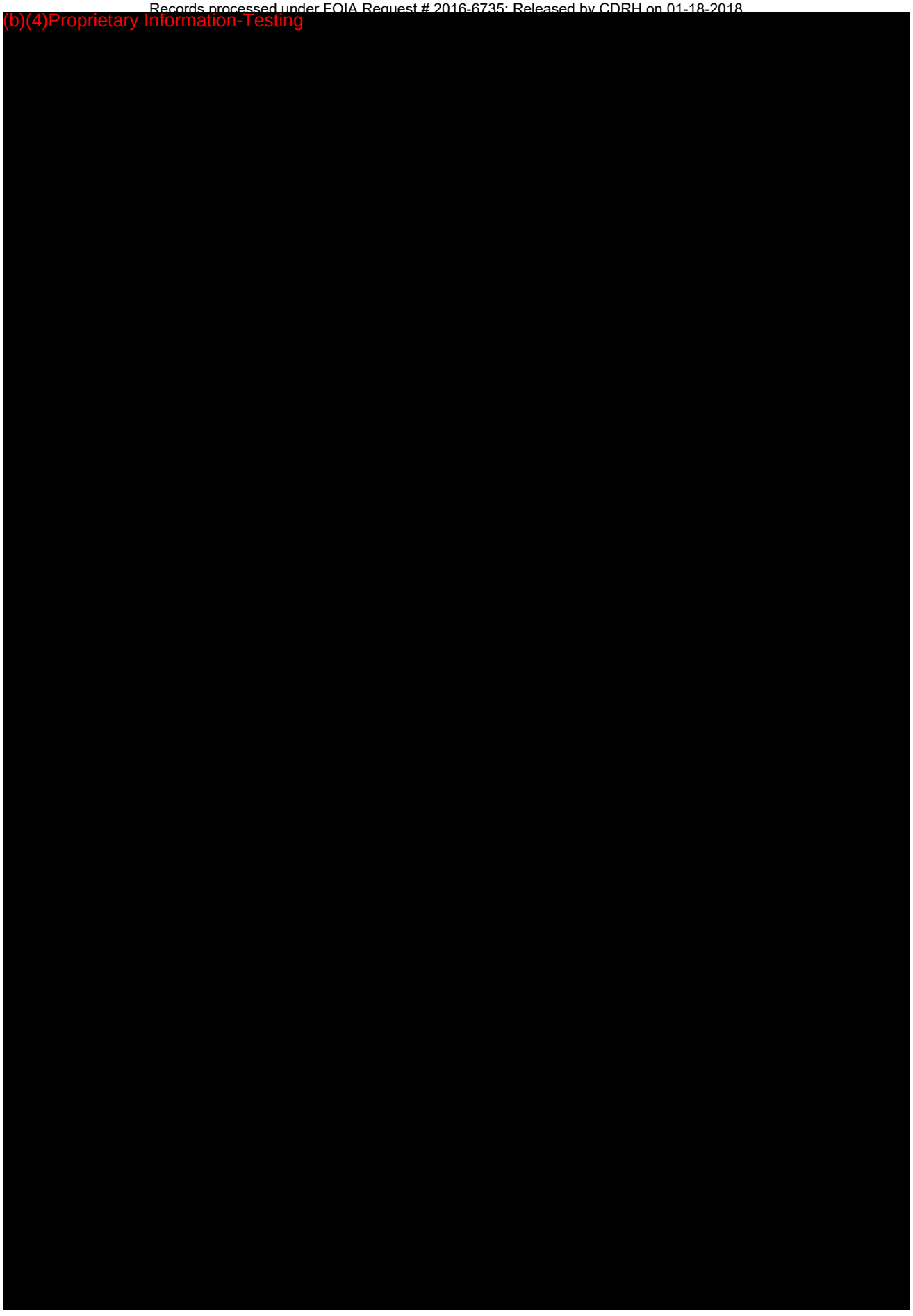
(b)(4)Proprietary Information-Testing



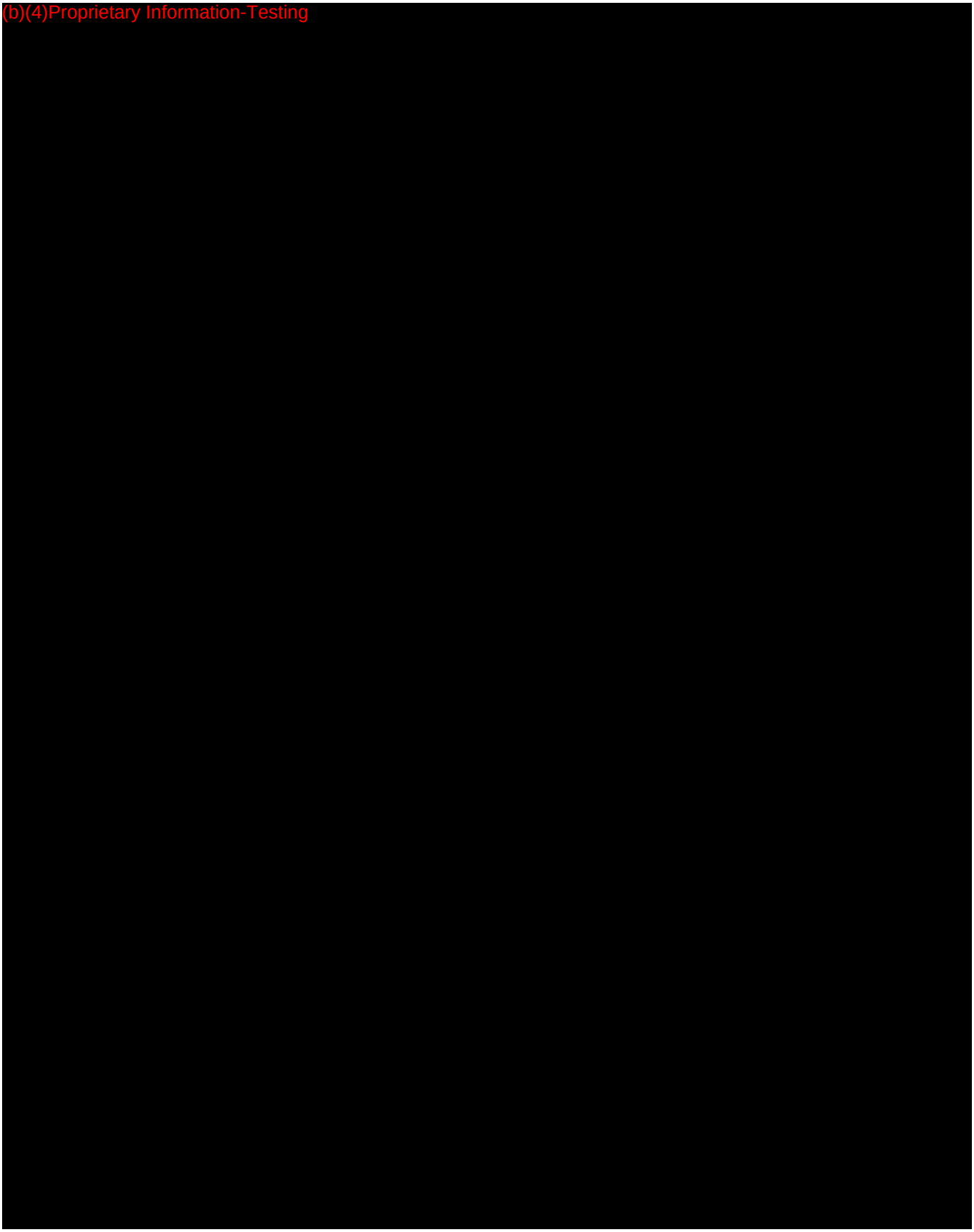
(b)(4)Proprietary Information-Testing



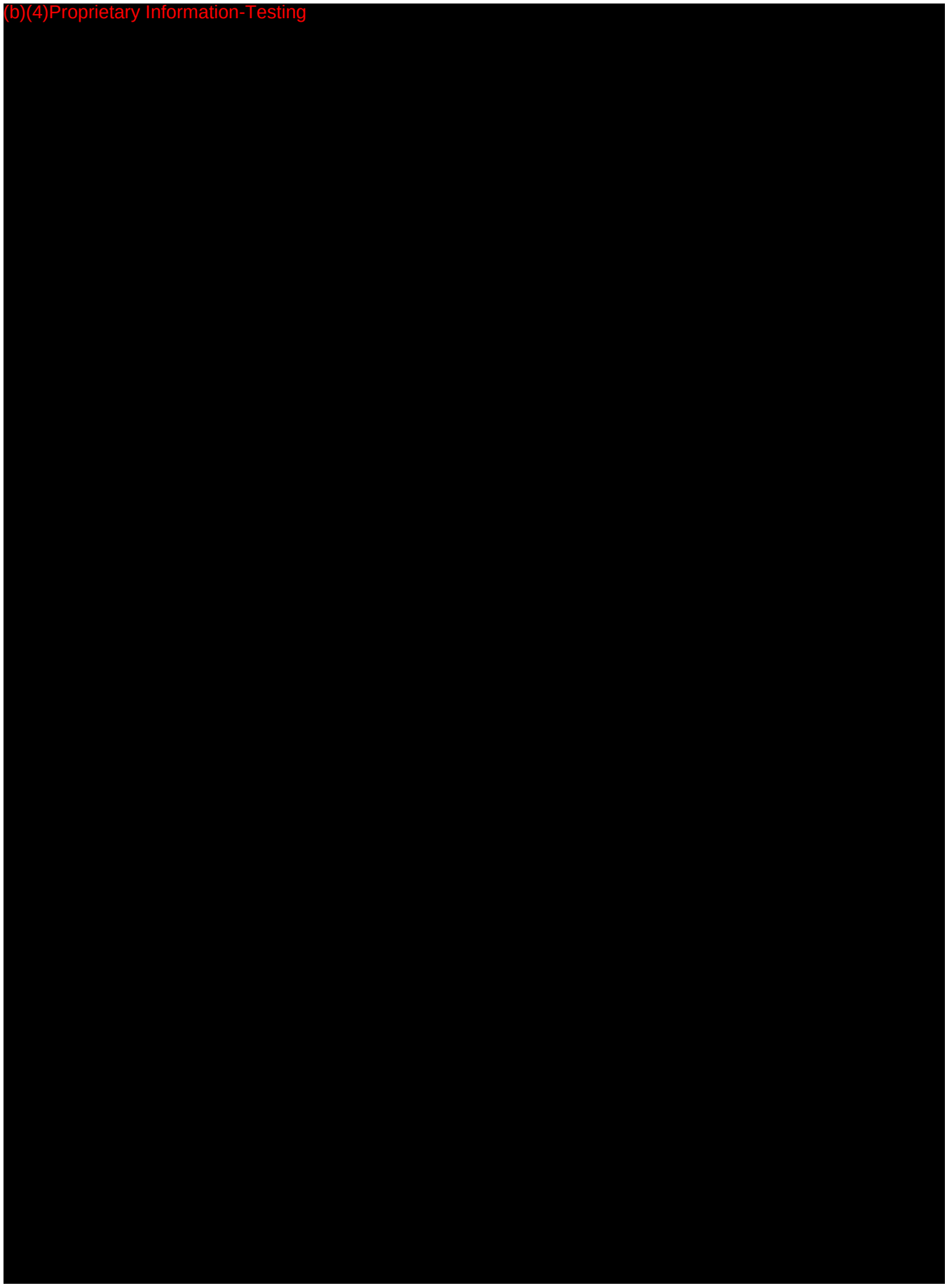
(b)(4)Proprietary Information-Testing



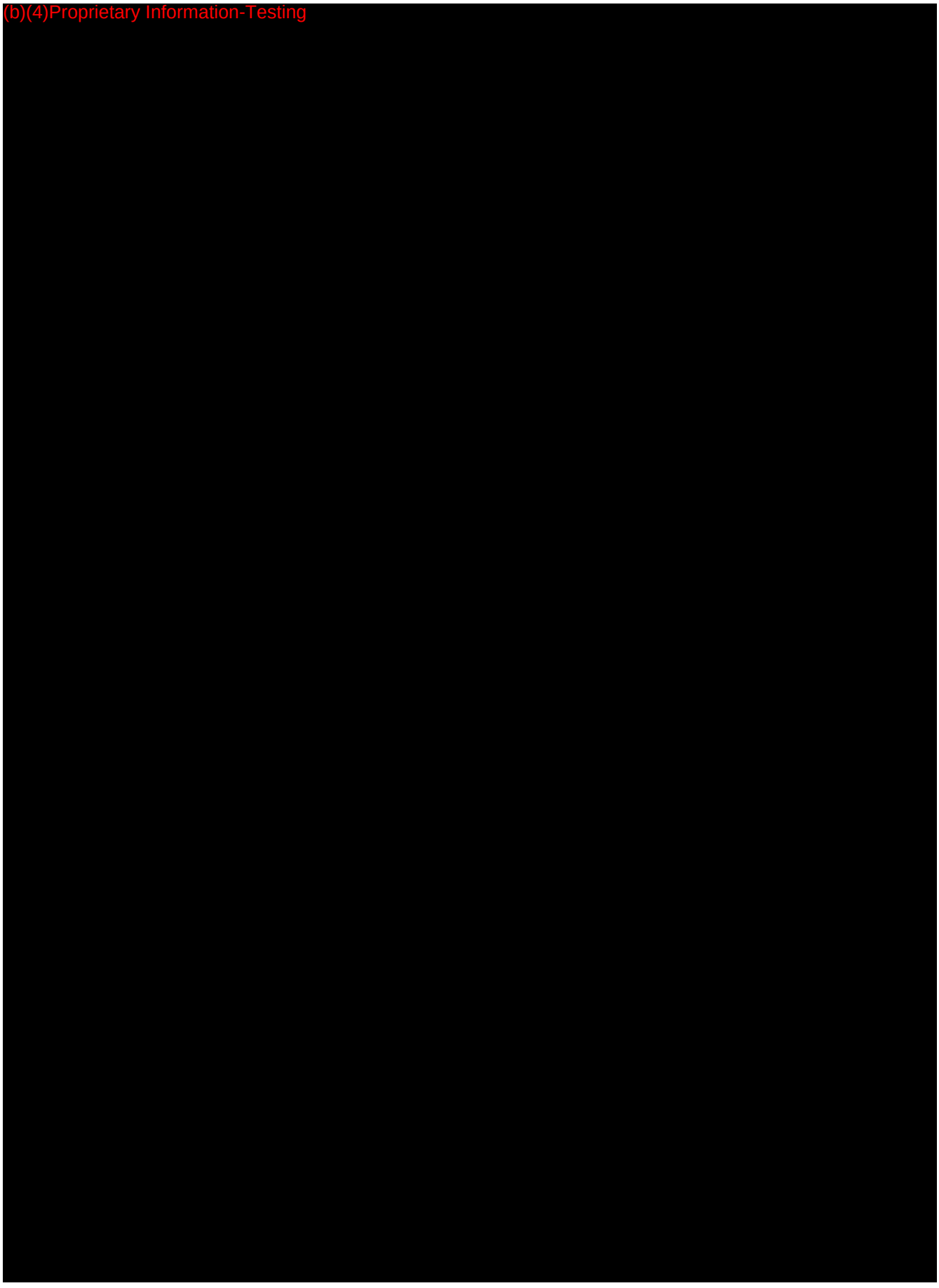
(b)(4)Proprietary Information-Testing



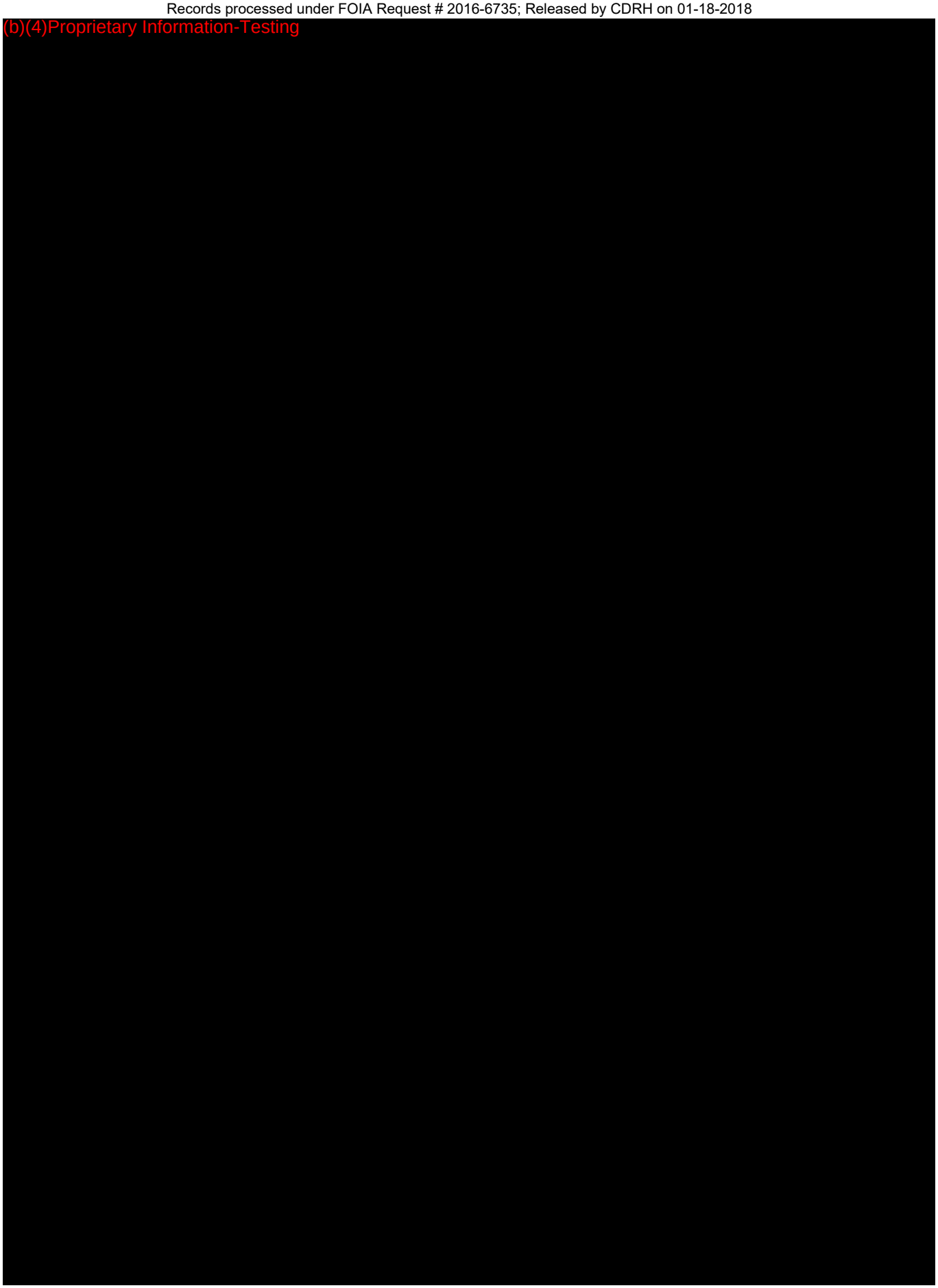
(b)(4)Proprietary Information-Testing



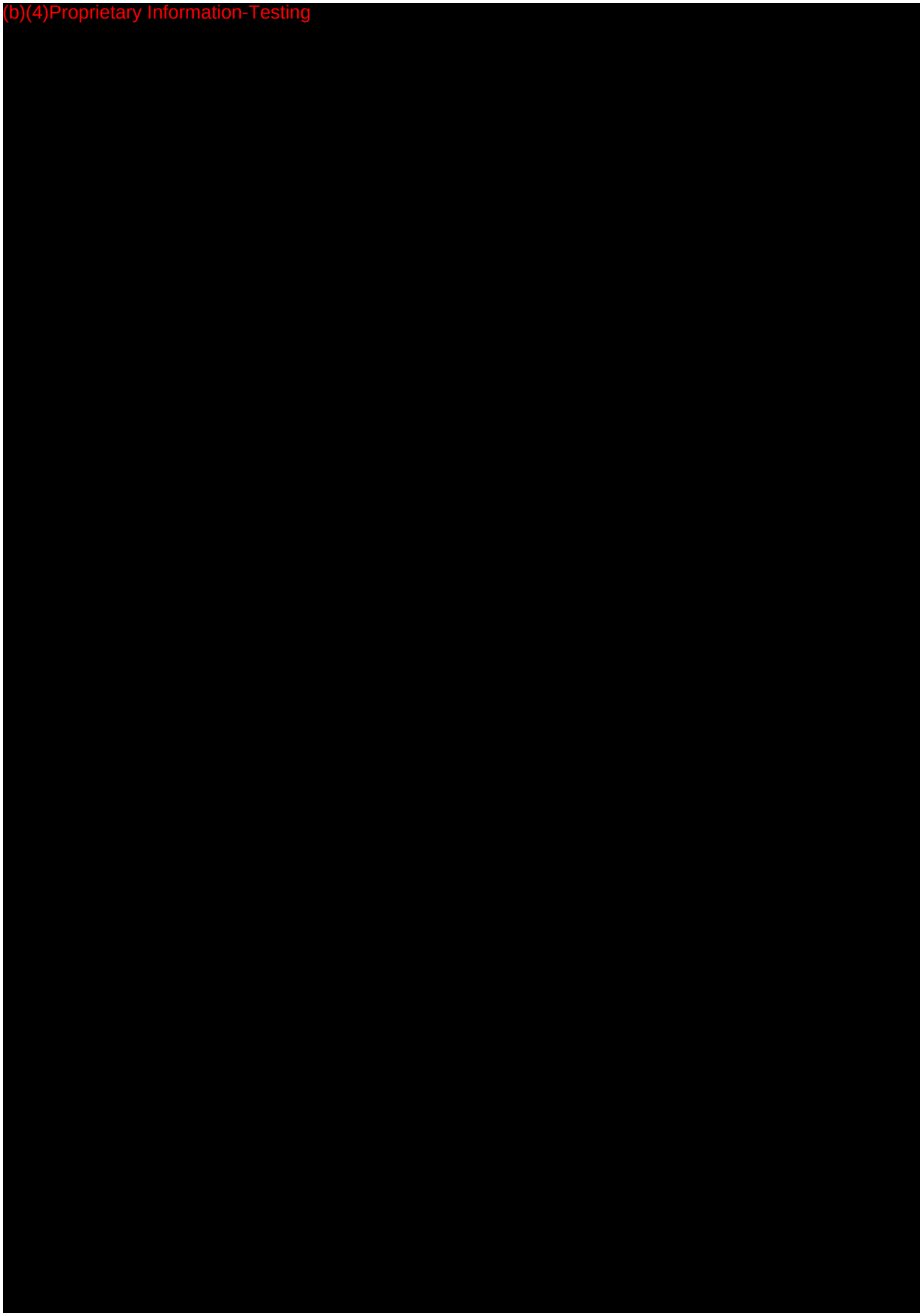
(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing



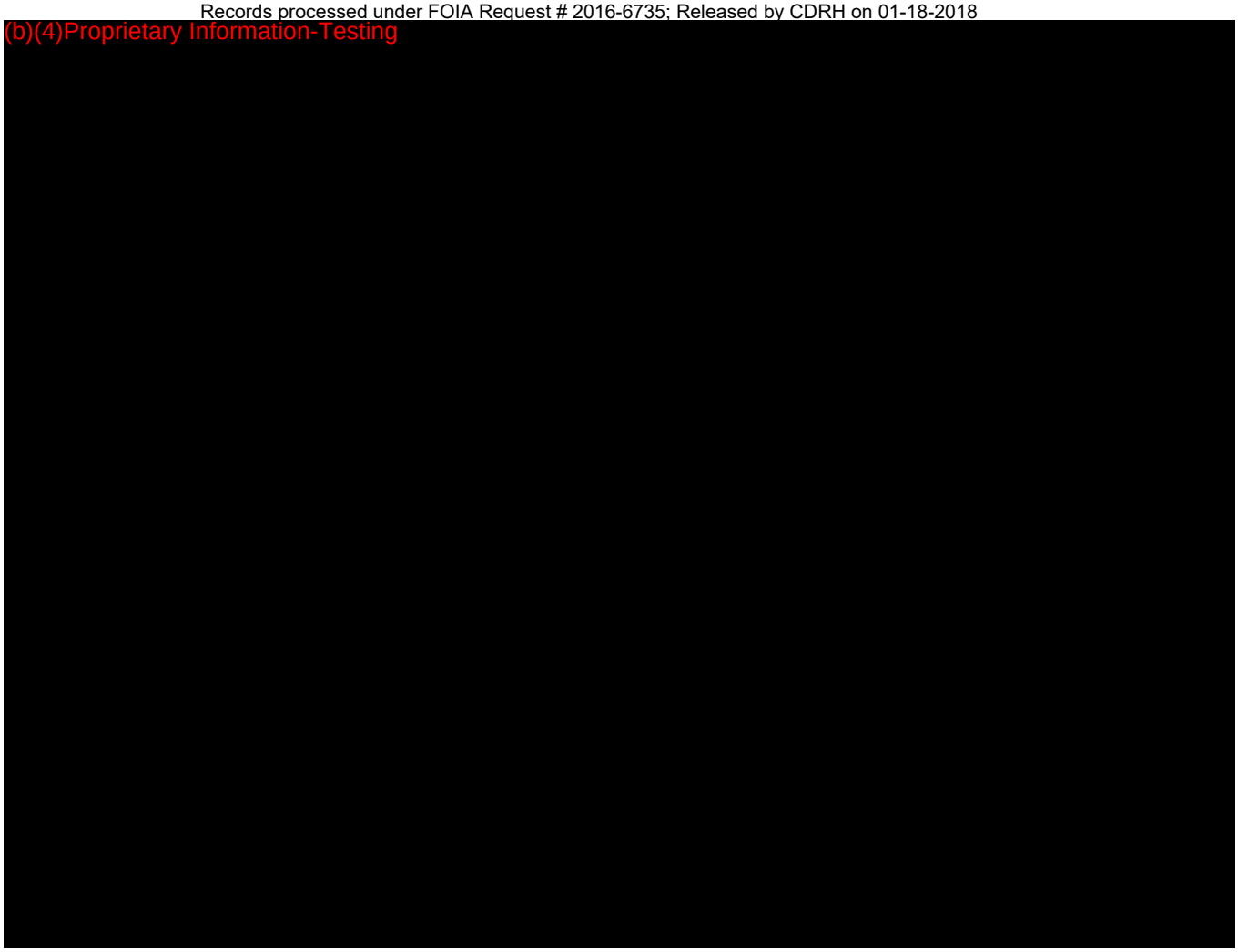
(b)(4)Proprietary Information-Testing



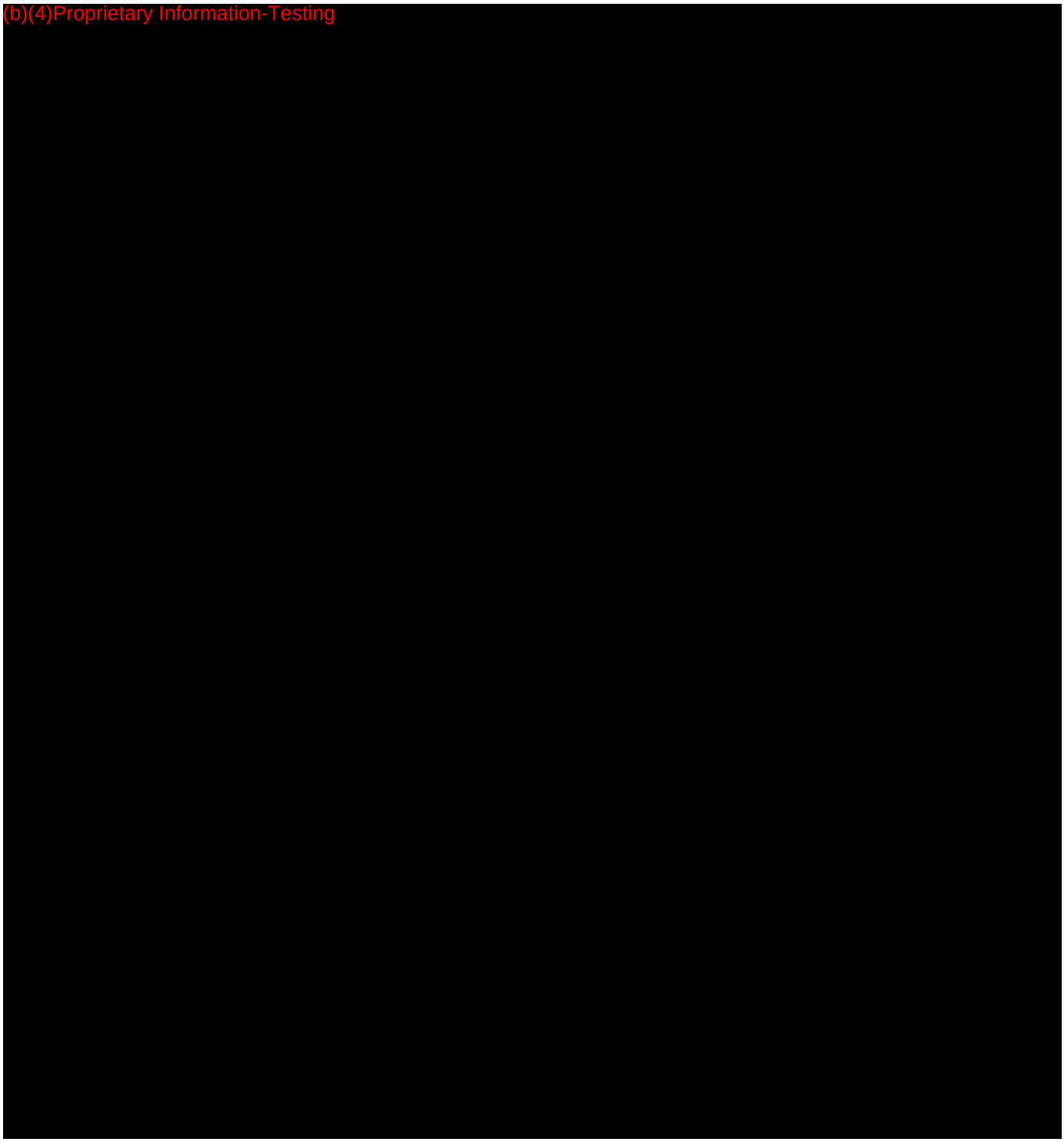
(b)(4)Proprietary Information-Testing

[redacted]

(b)(4)Proprietary Information-Testing

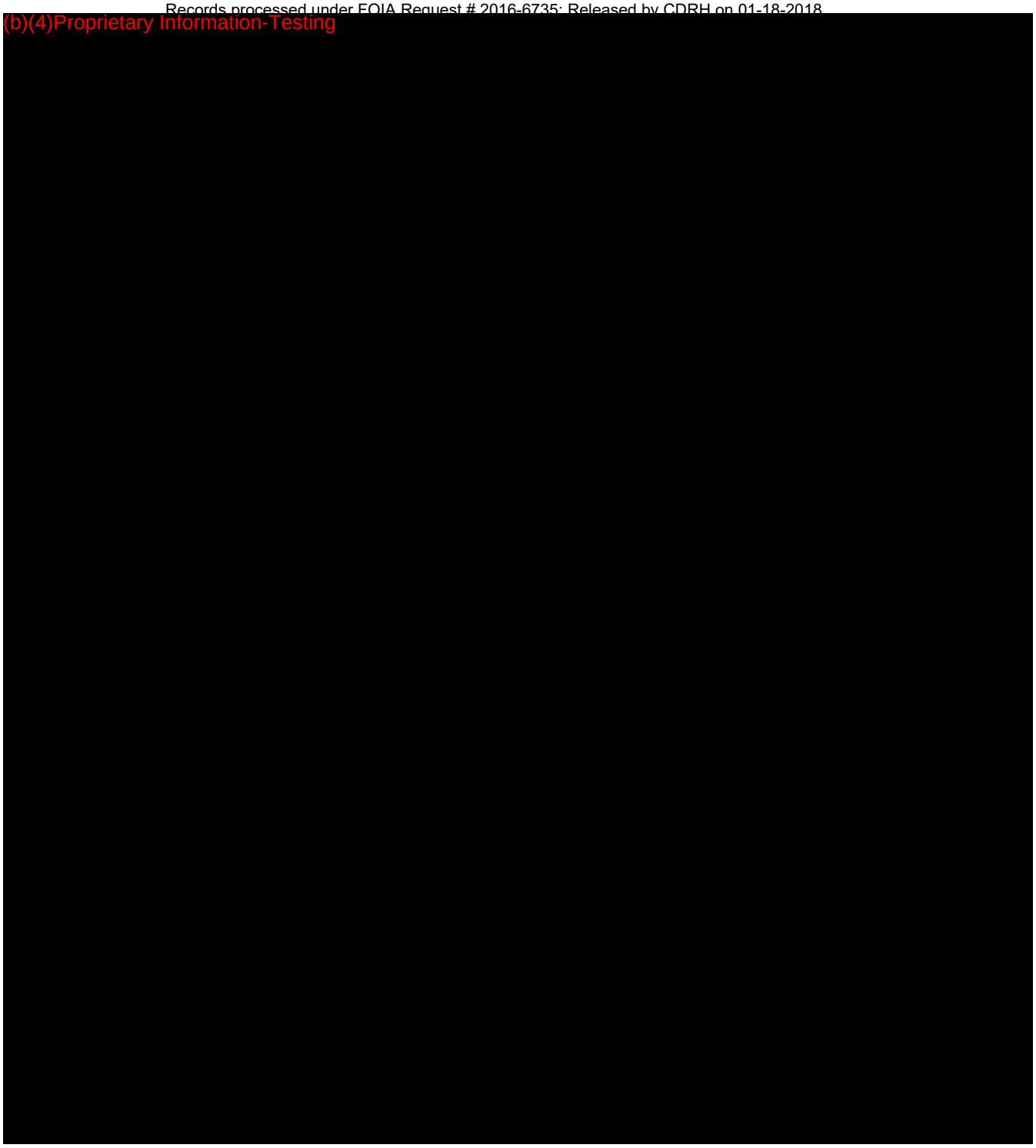


(b)(4)Proprietary Information-Testing

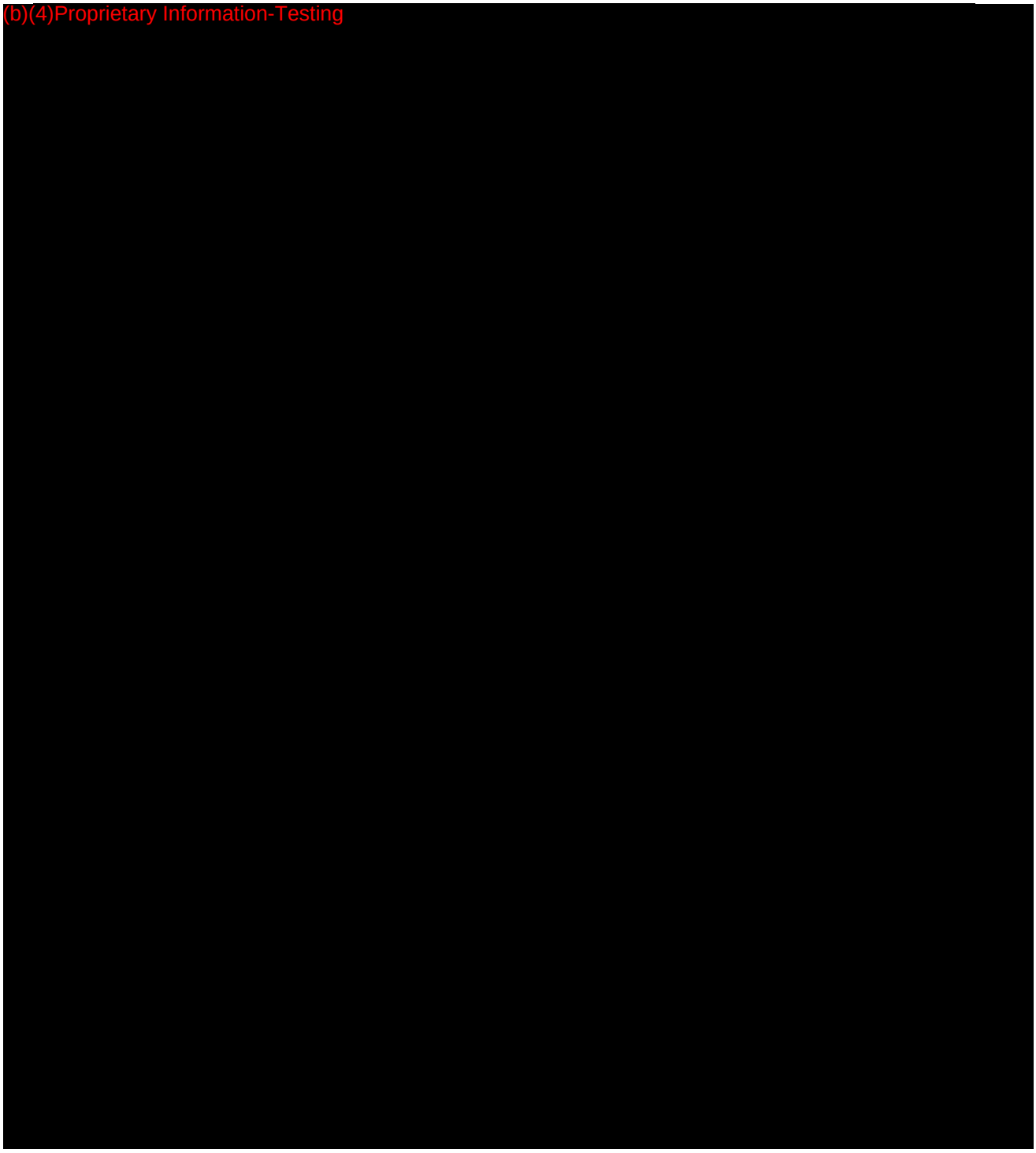


(b)(4)Proprietary Information-Testing

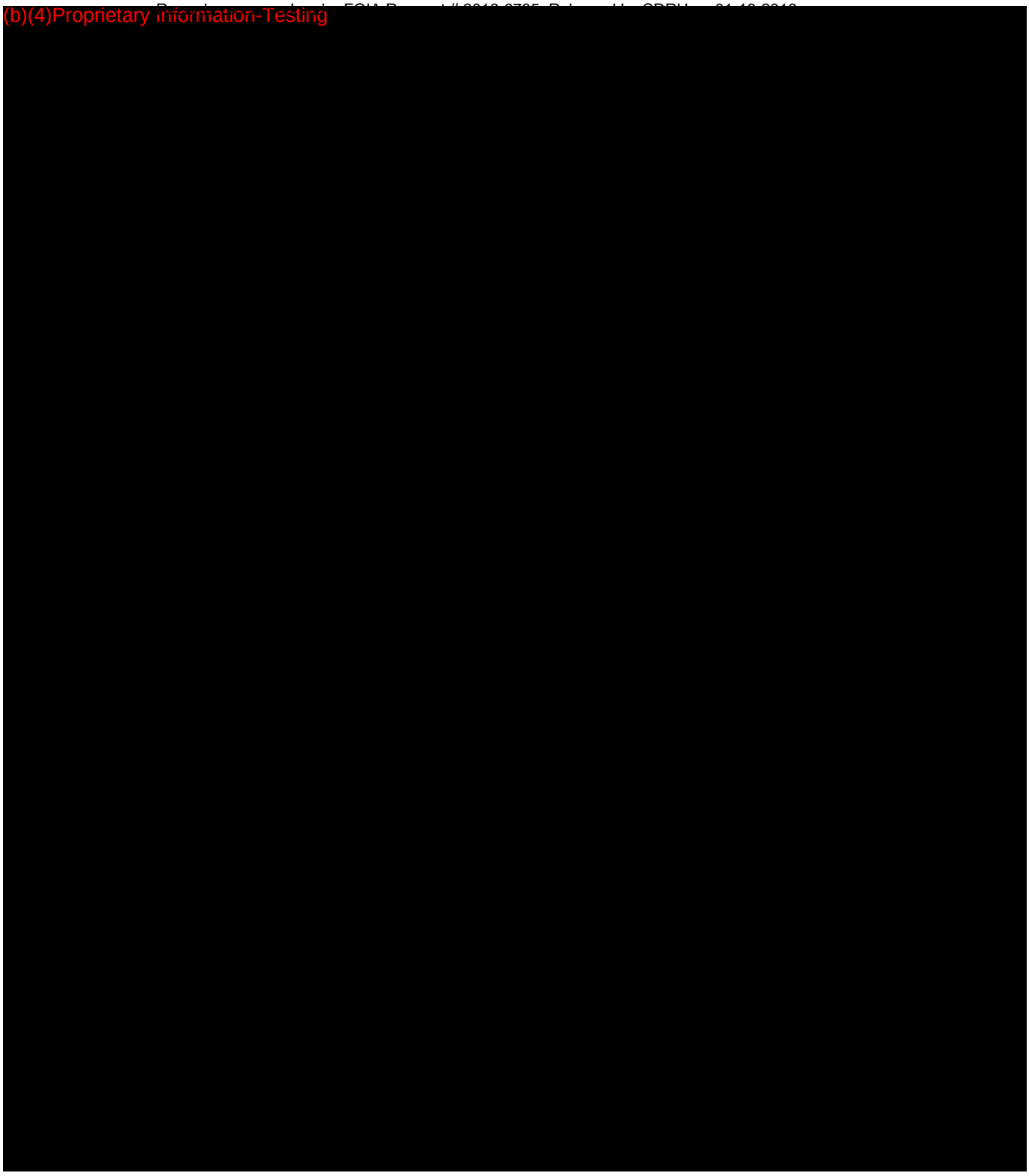
(b)(4)Proprietary Information-Testing



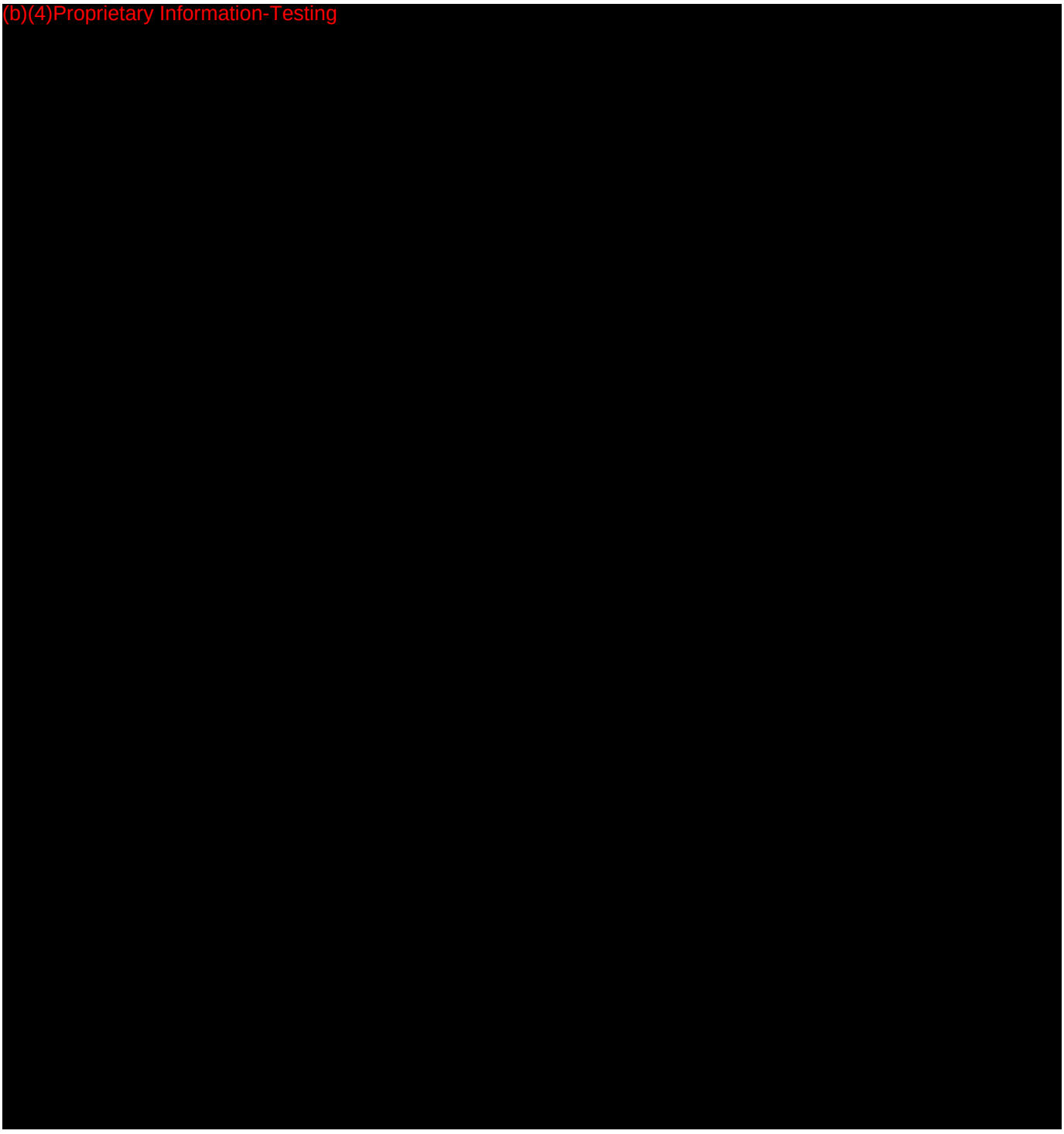
(b)(4)Proprietary Information-Testing



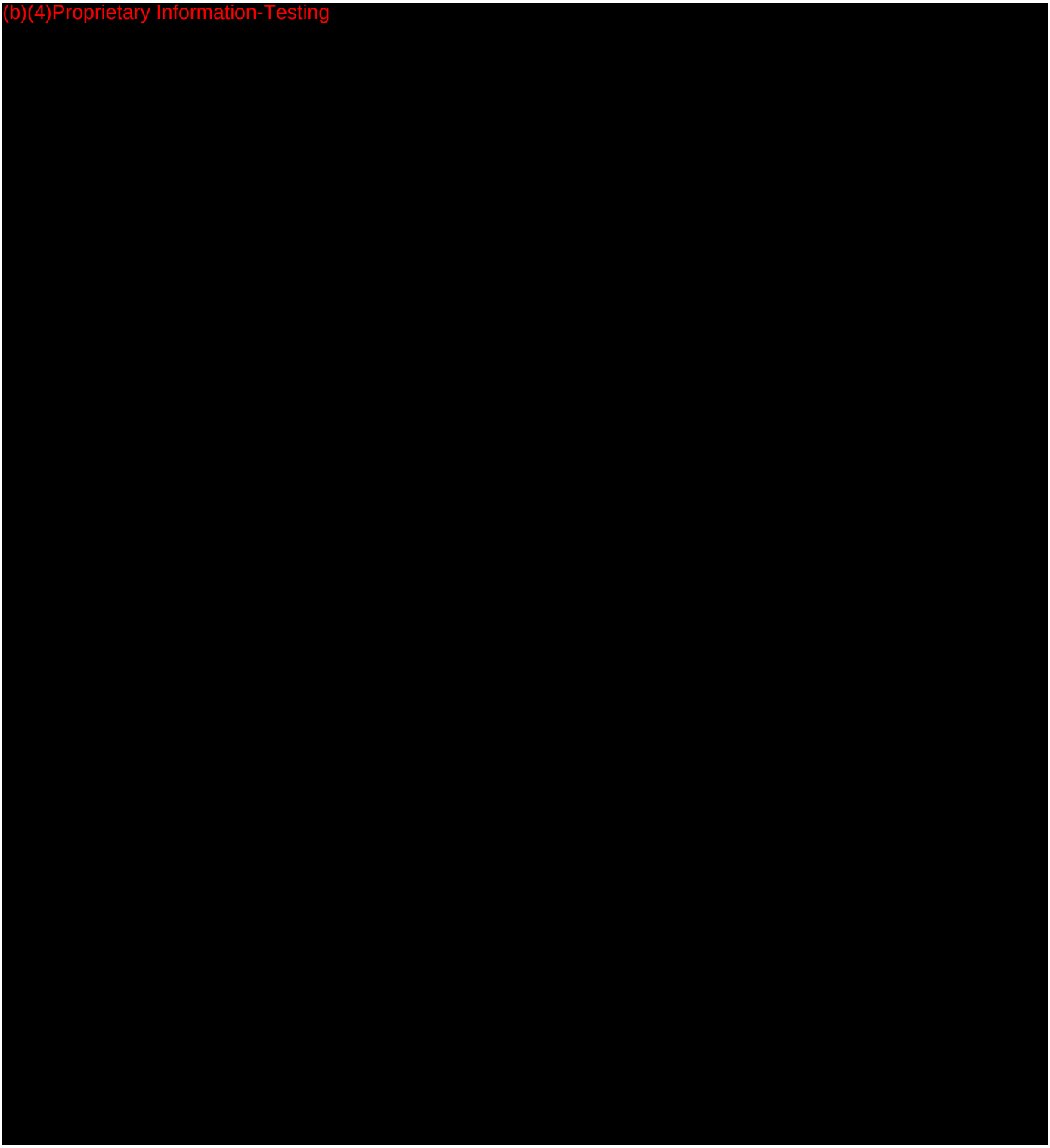
(b)(4)Proprietary information-Testing



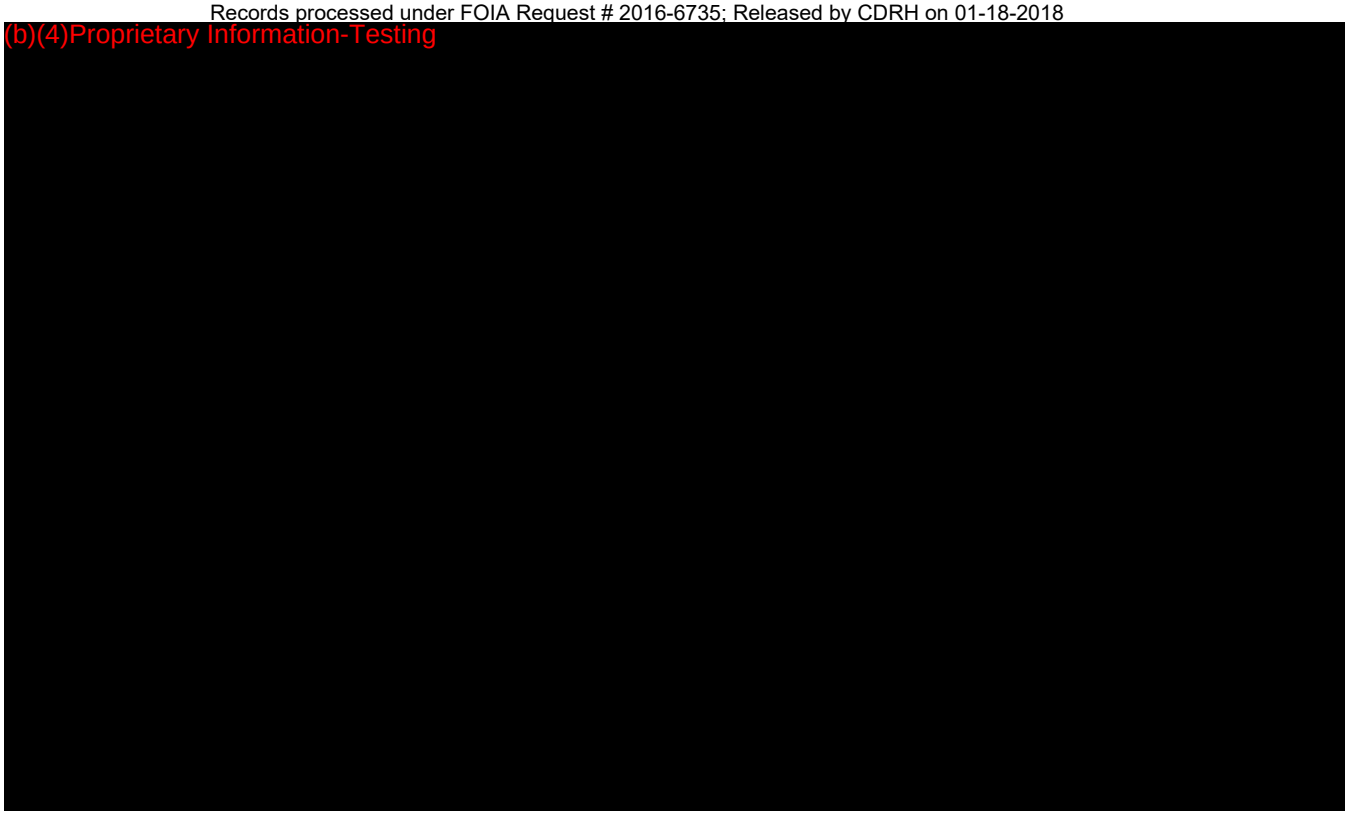
(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing

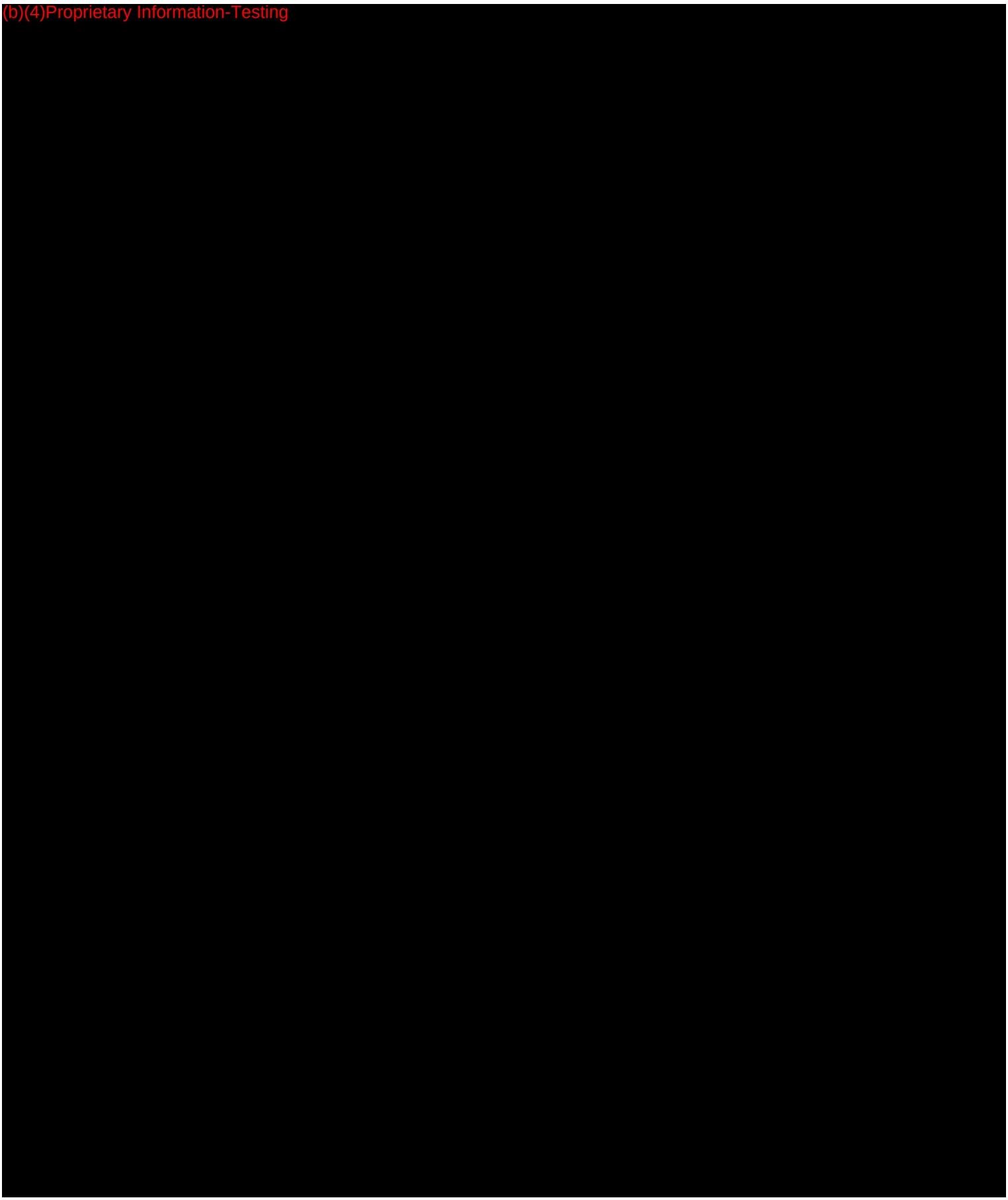


(b)(4)Proprietary Information-Testing

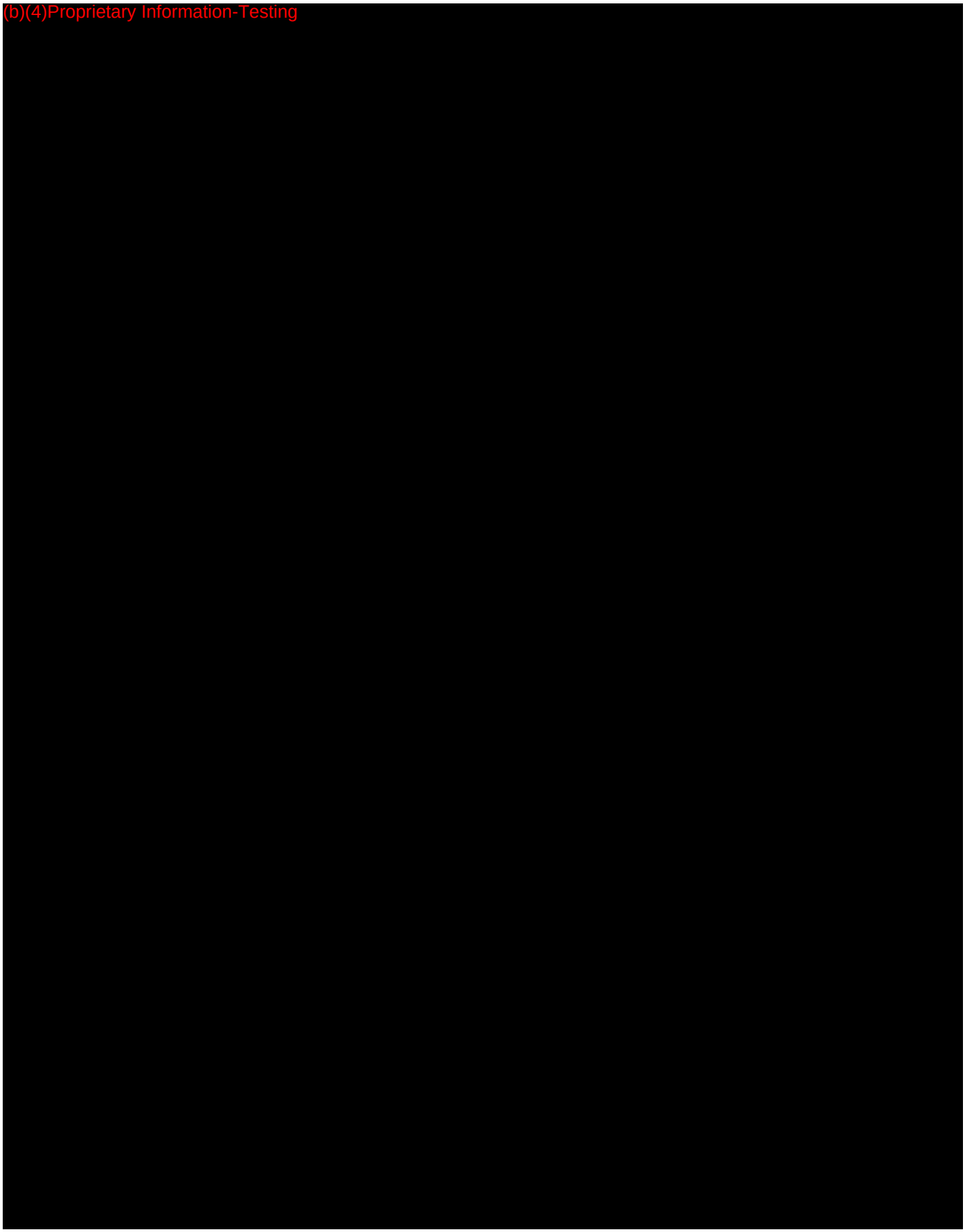


ATTACHMENT 23

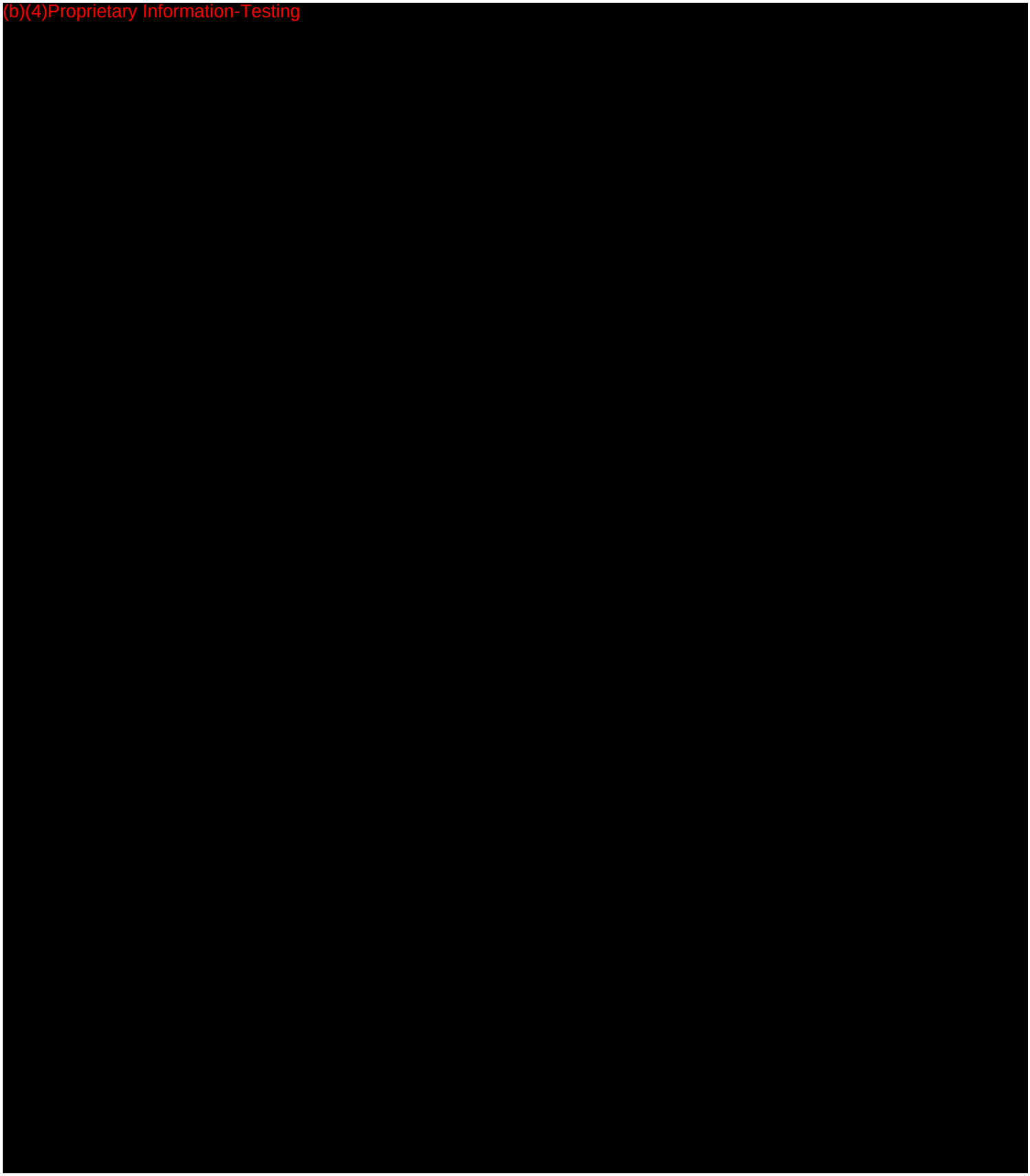
(b)(4)Proprietary Information-Testing



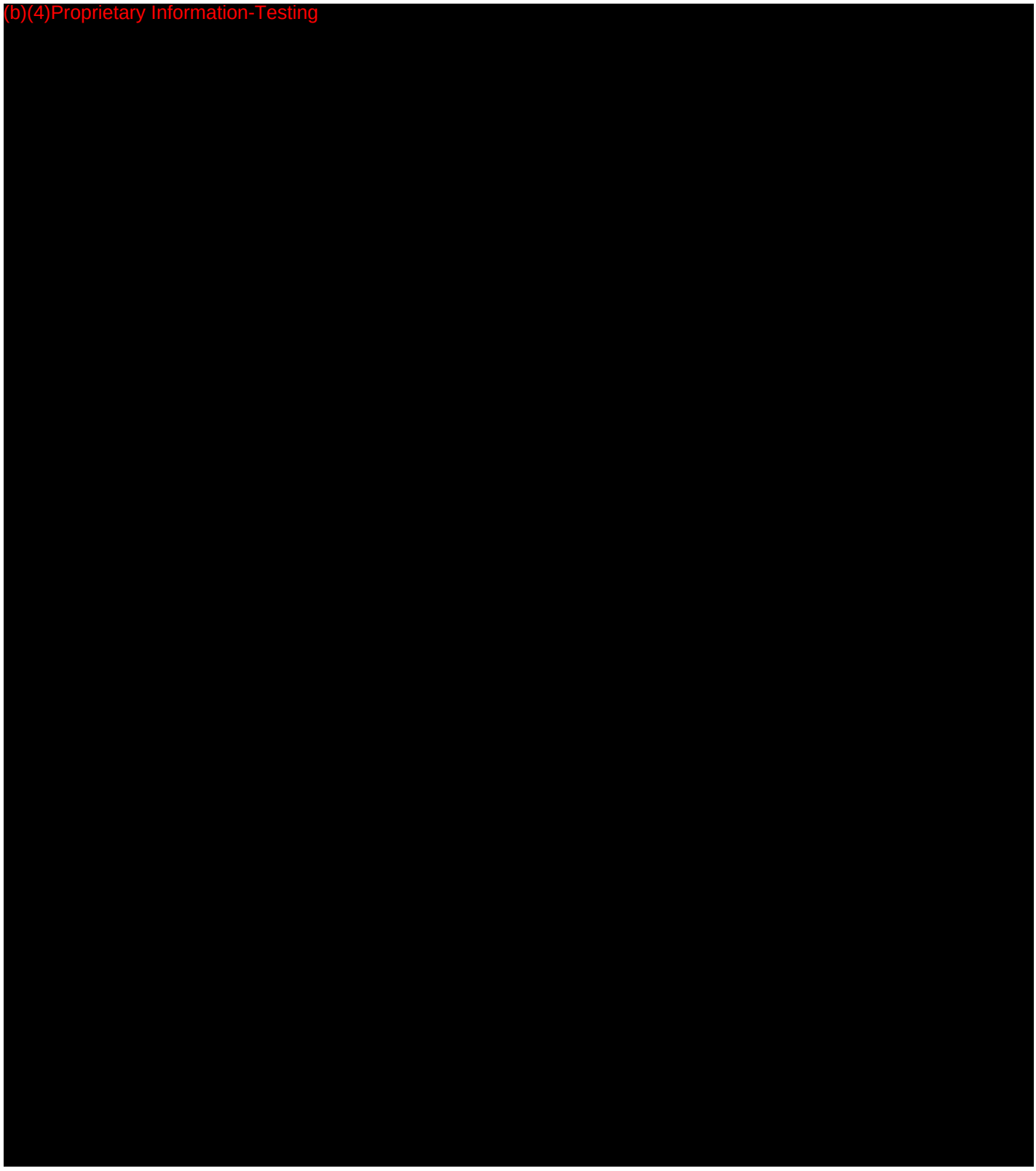
(b)(4)Proprietary Information-Testing



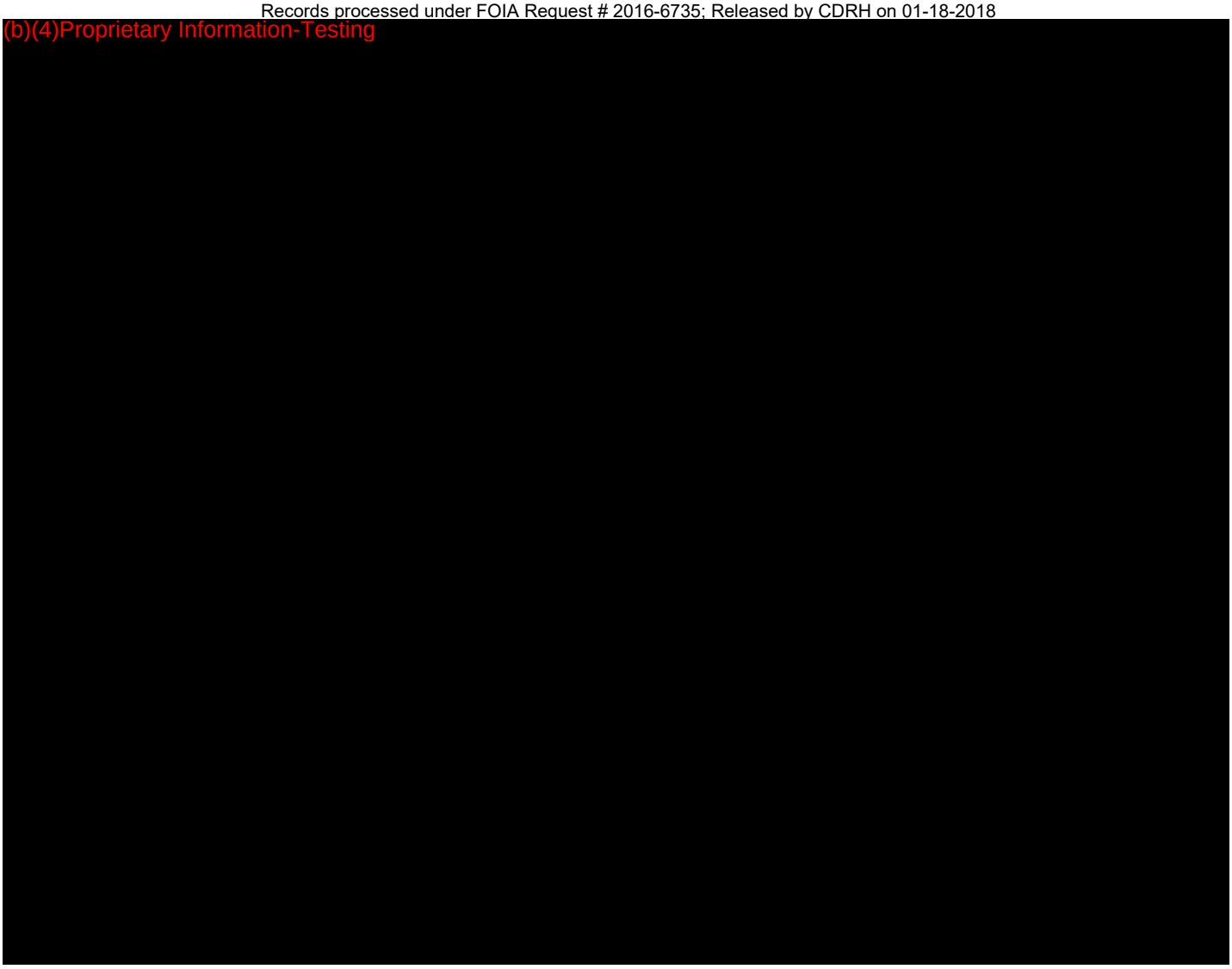
(b)(4)Proprietary Information-Testing



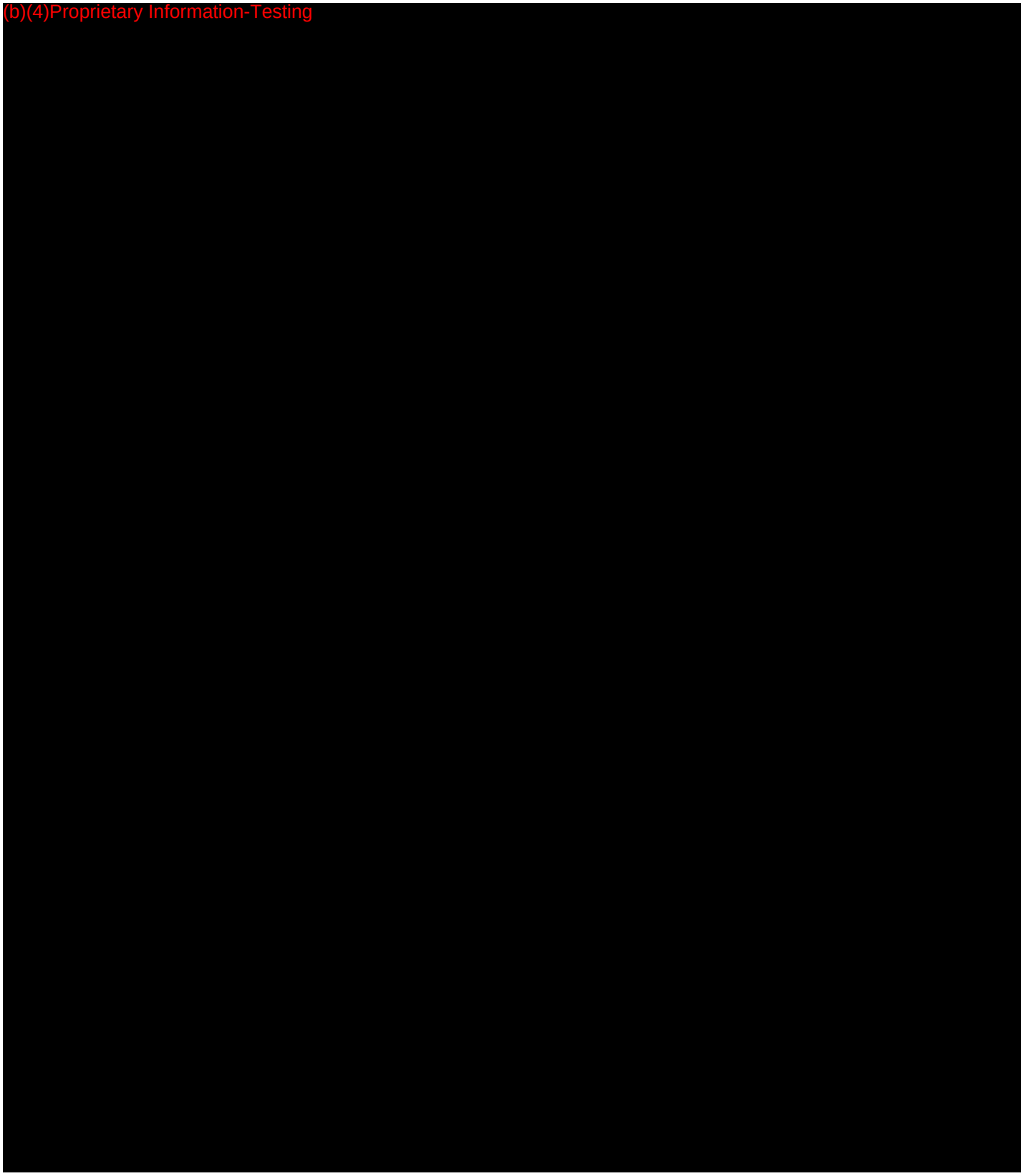
(b)(4)Proprietary Information-Testing



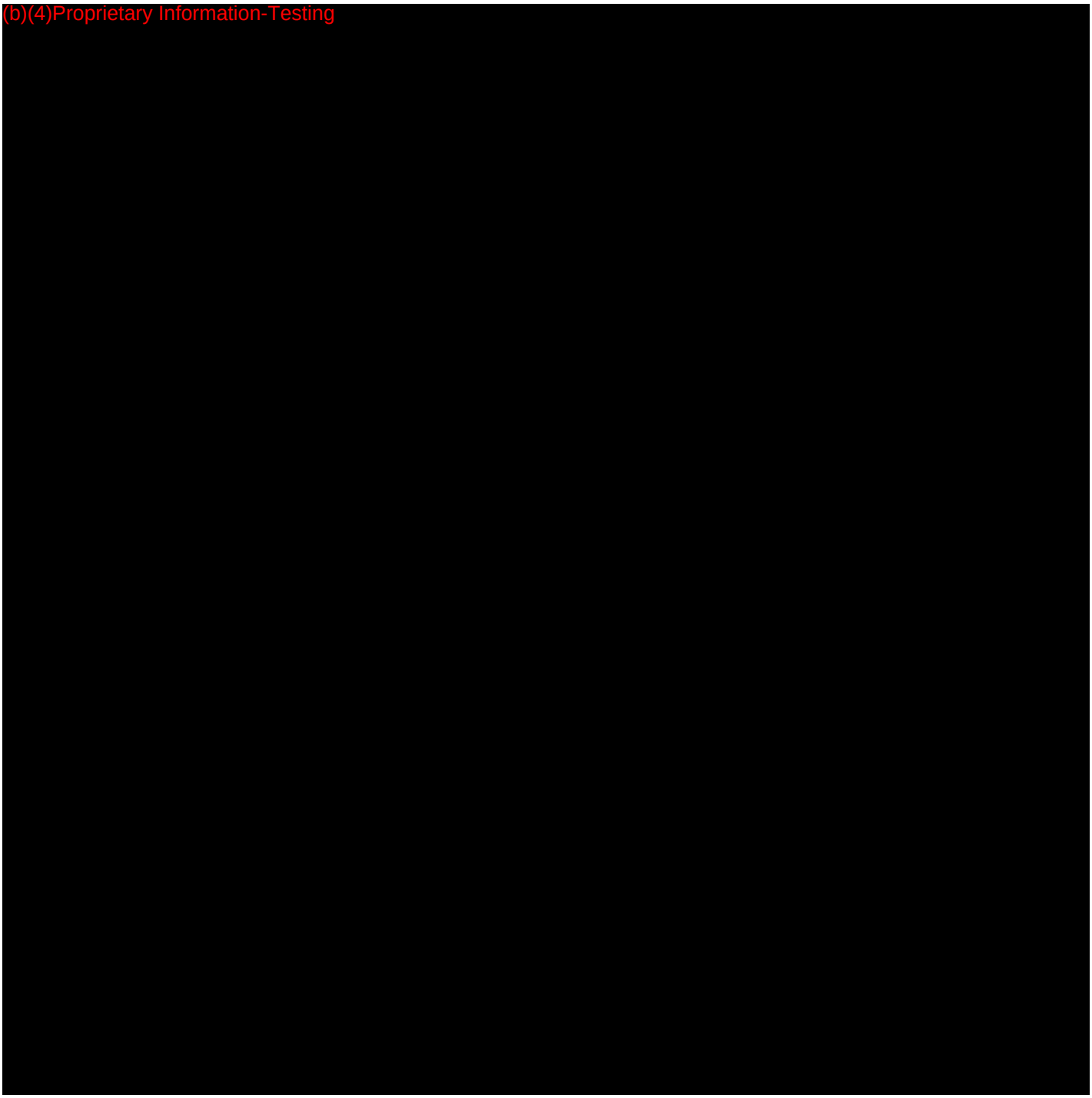
(b)(4)Proprietary Information-Testing



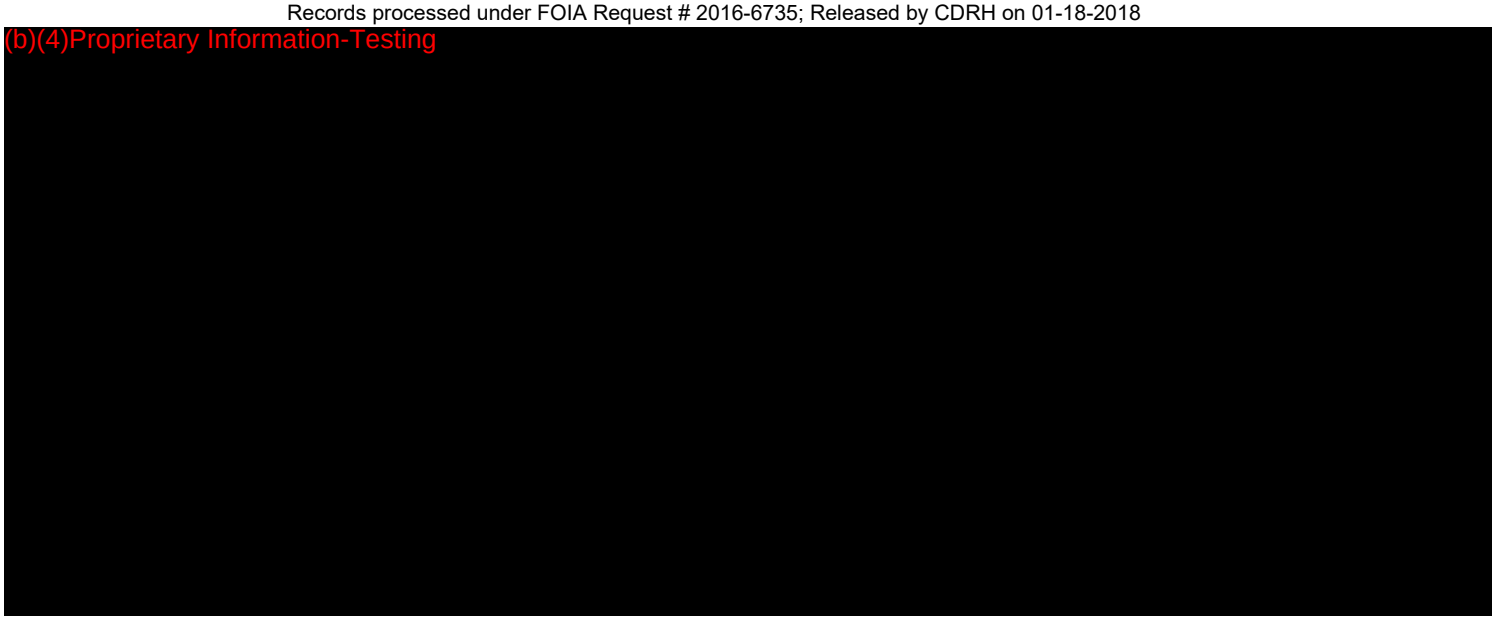
(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing

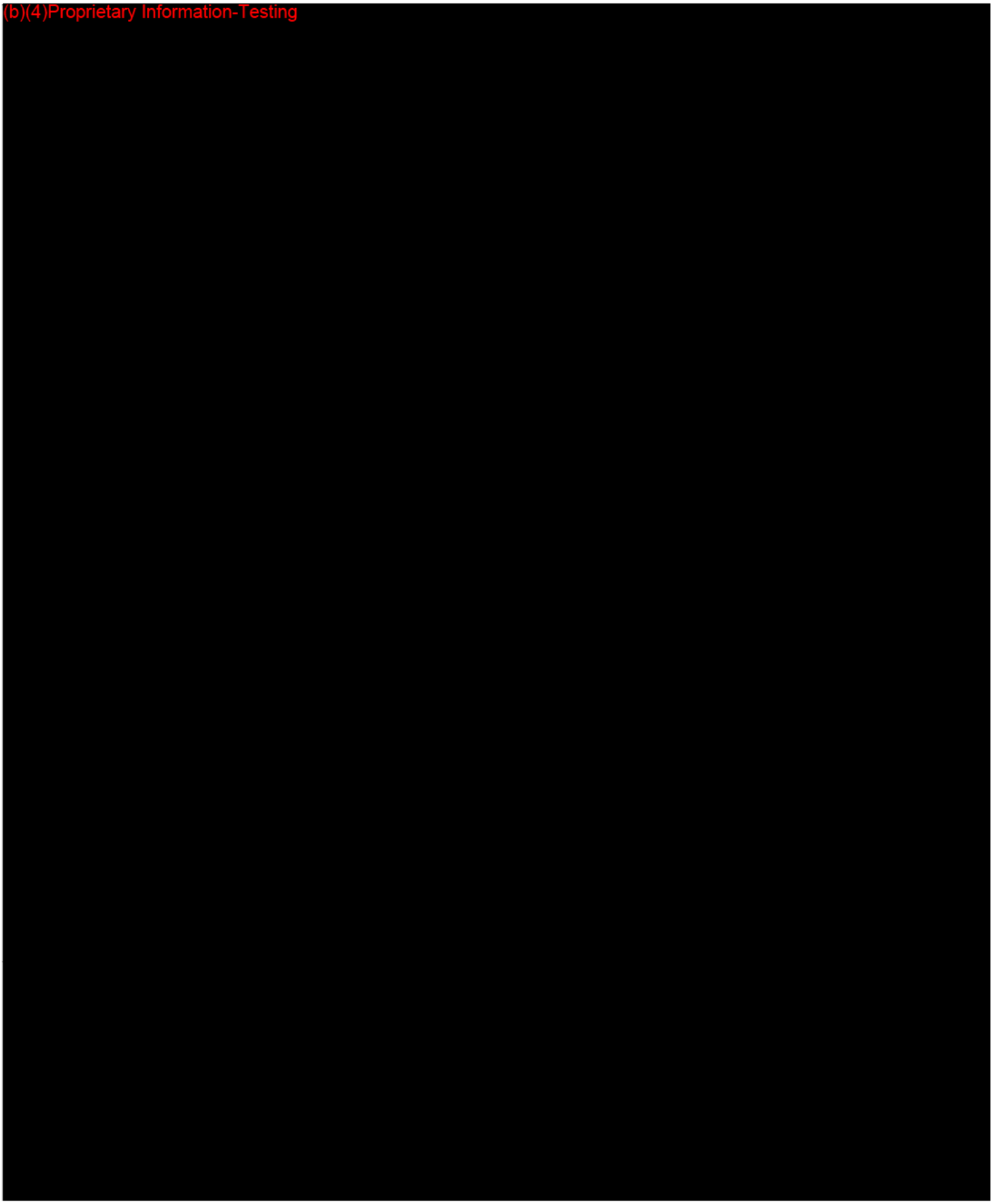


(b)(4)Proprietary Information-Testing

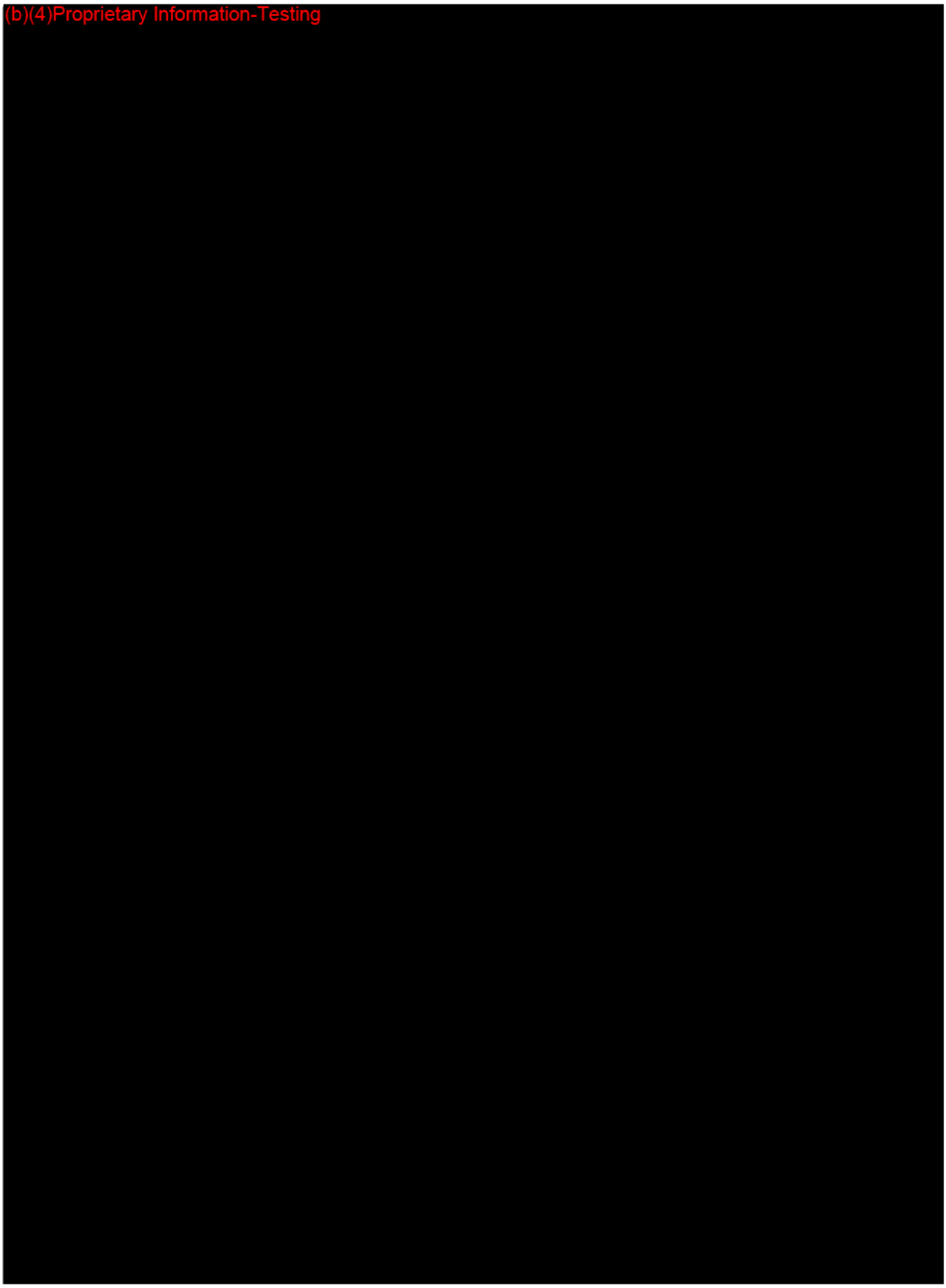


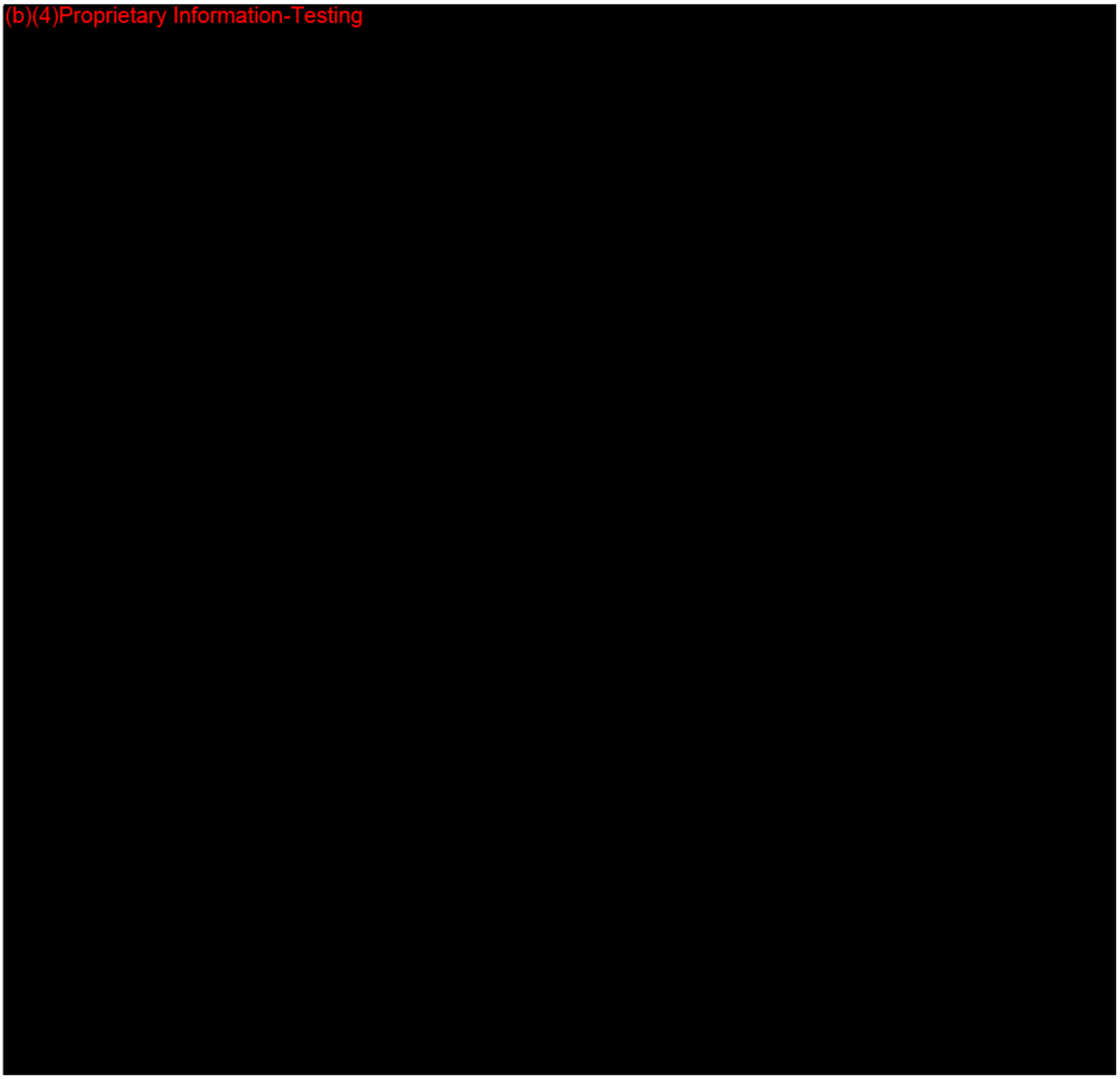
ATTACHMENT 24

(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing



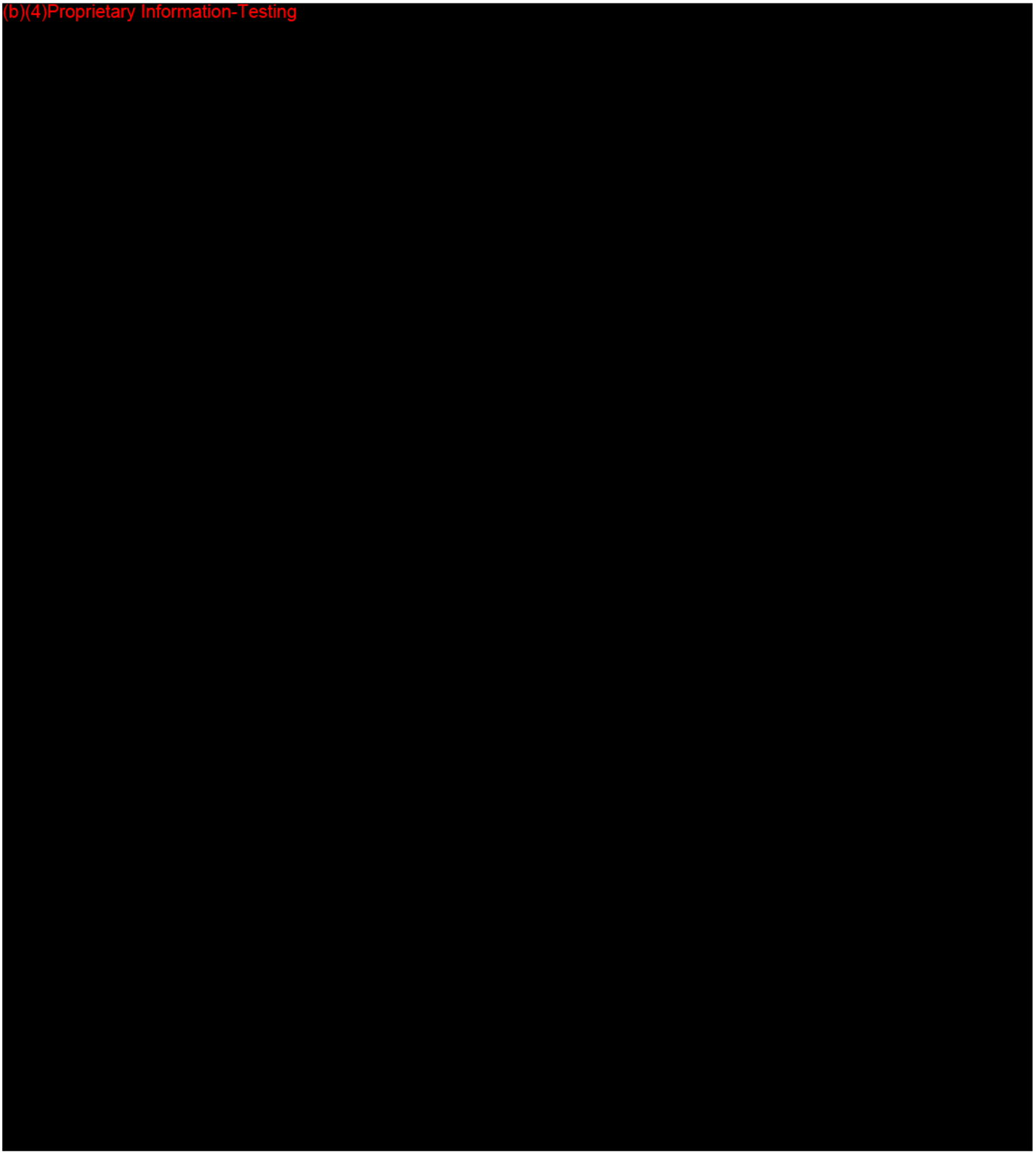


(b)(4)Proprietary Information-Testing

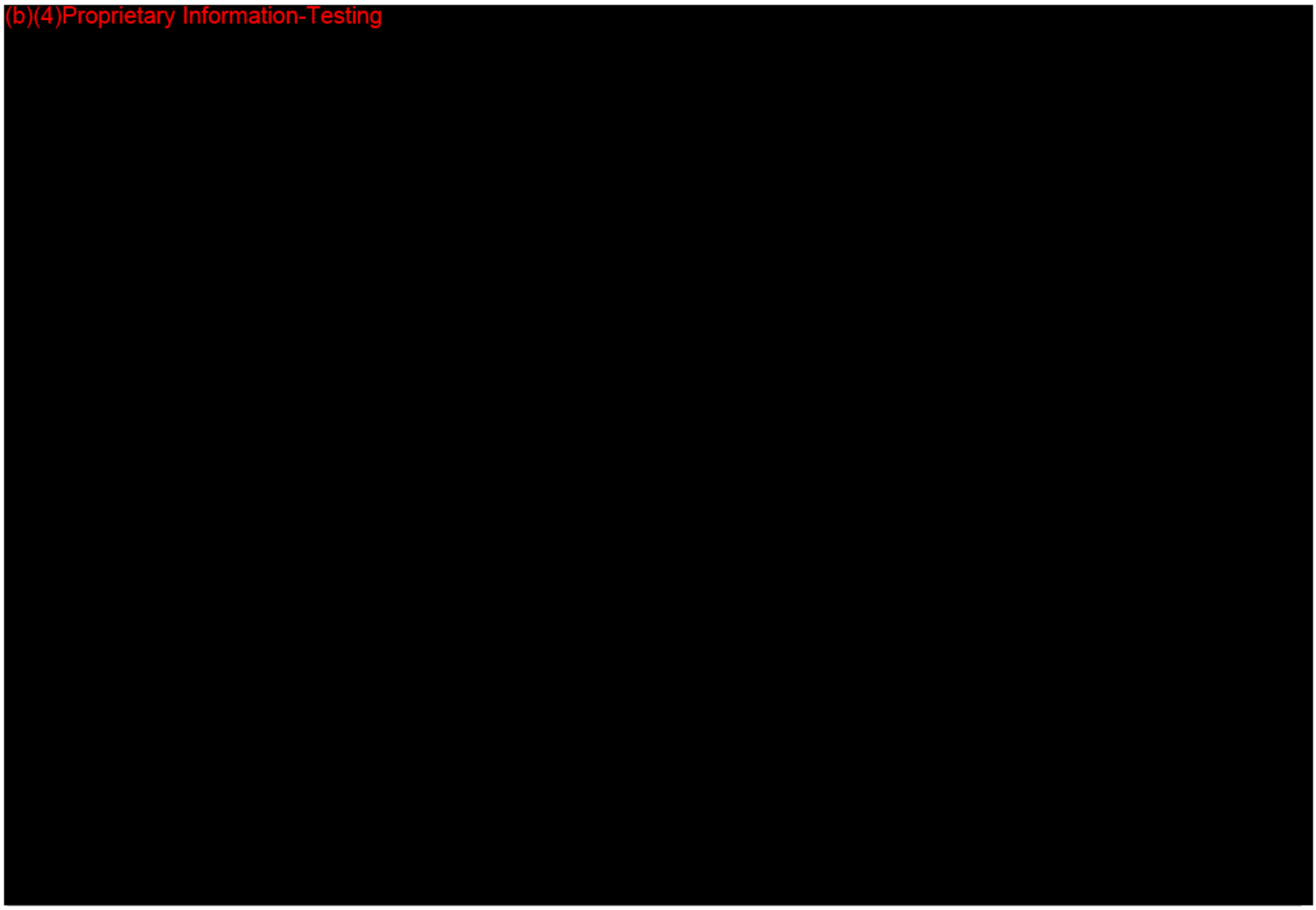
(b)(4)Proprietary Information-Testing

[redacted]

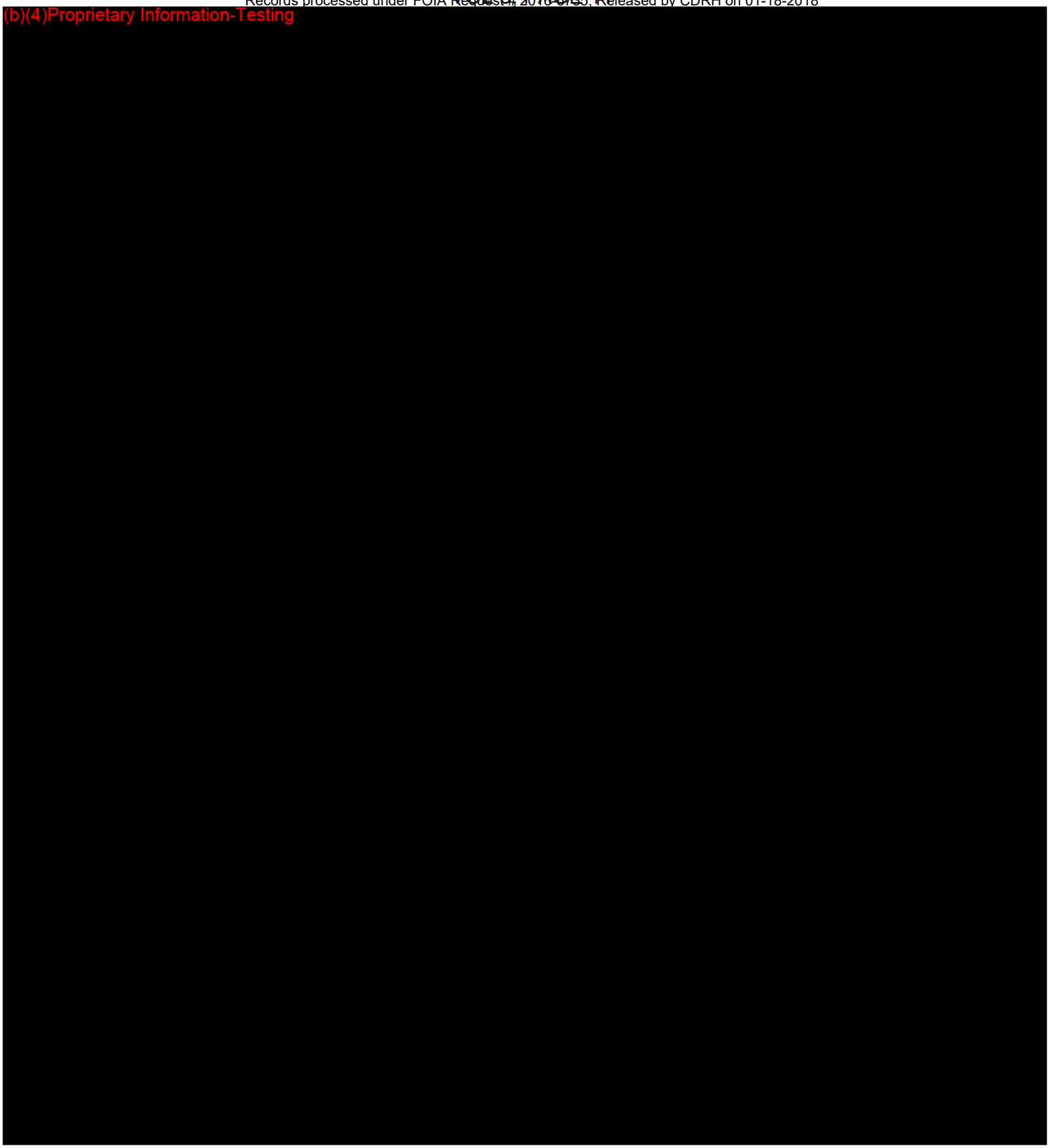
(b)(4)Proprietary Information-Testing



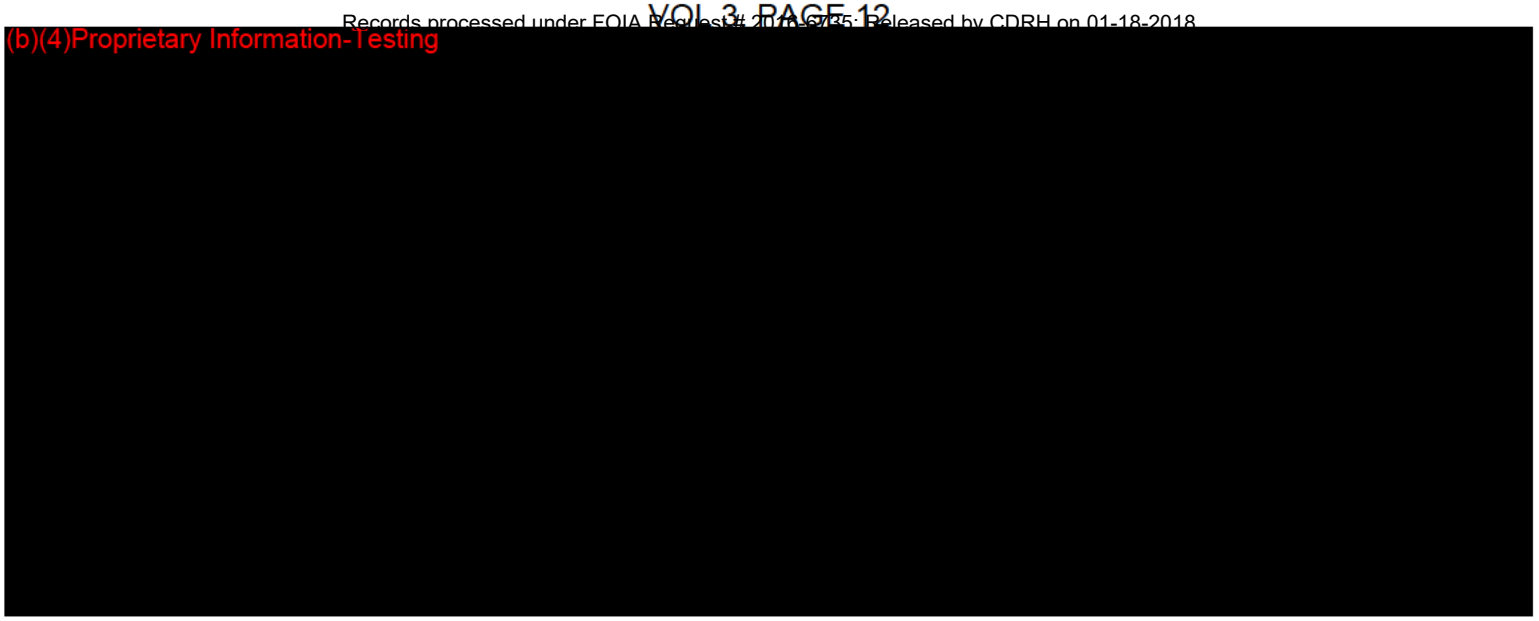
(b)(4)Proprietary Information-Testing

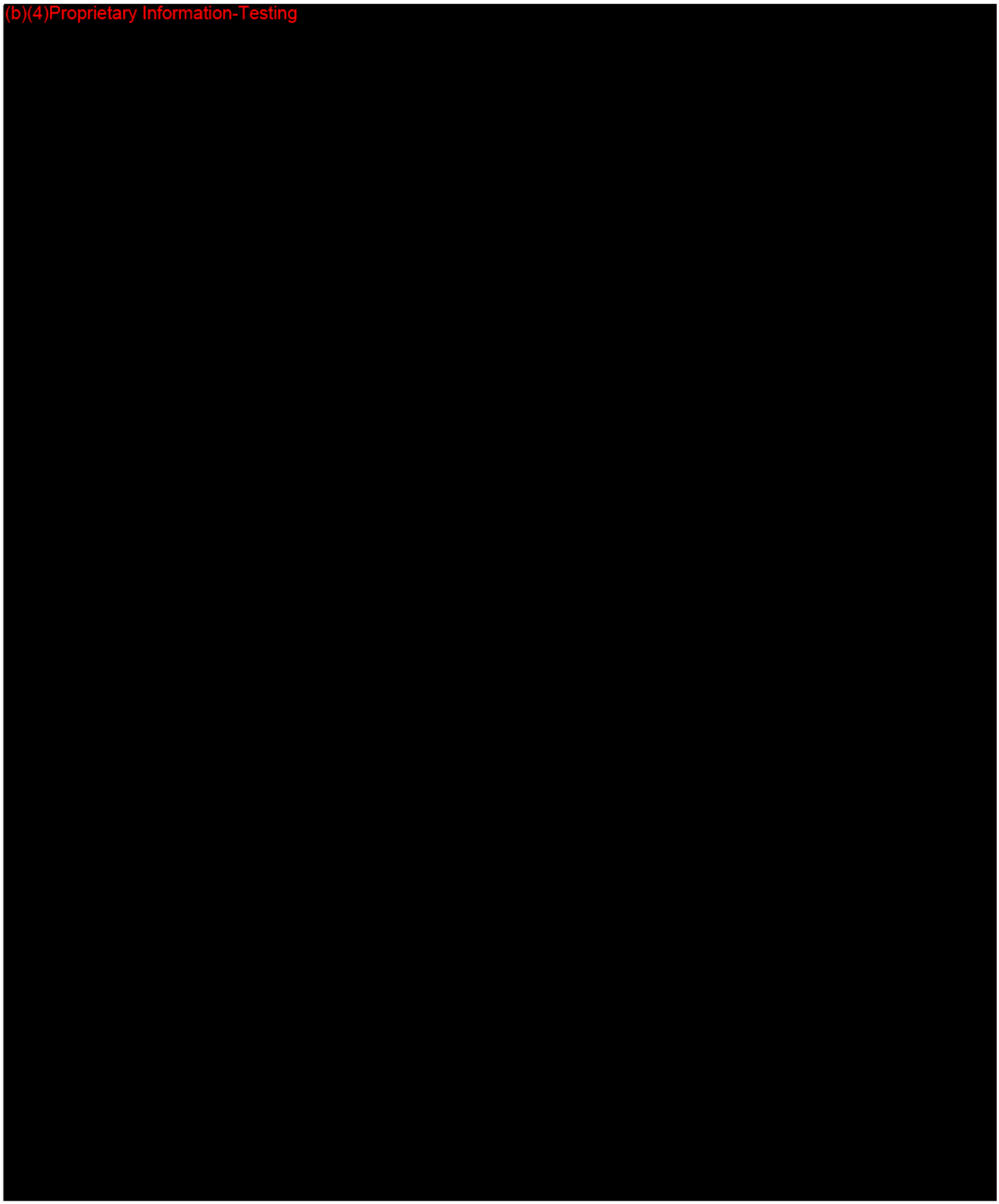


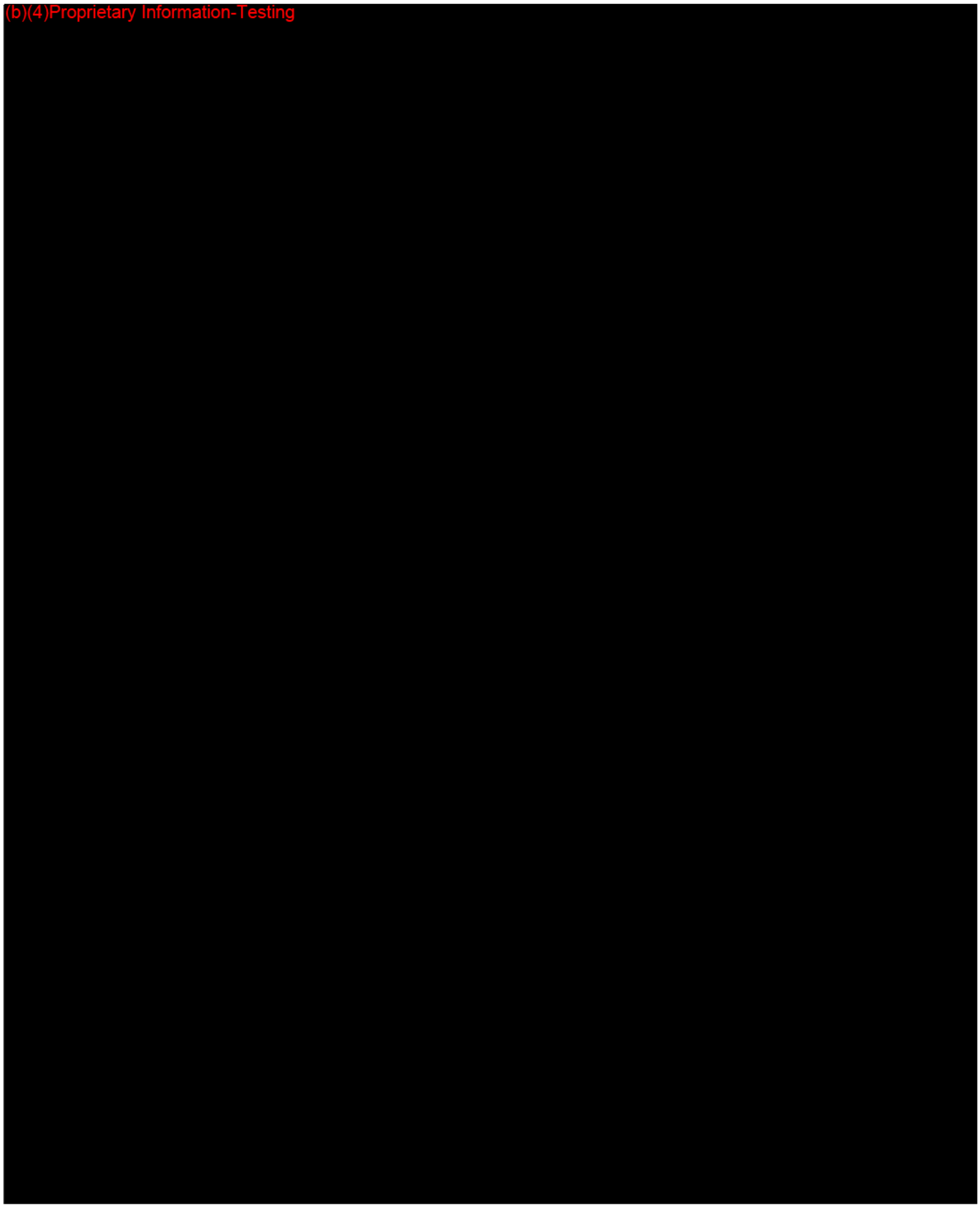
(b)(4)Proprietary Information-Testing

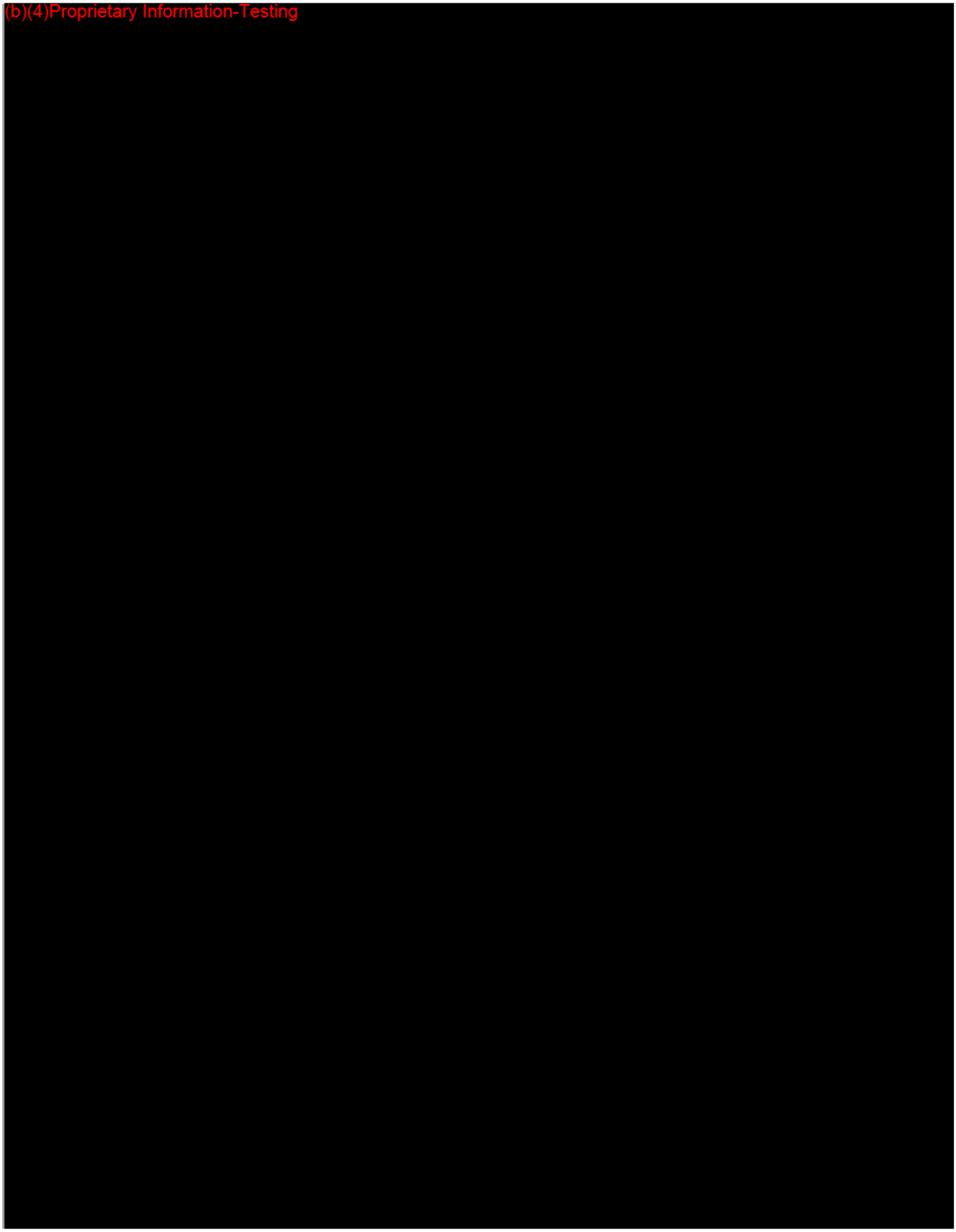


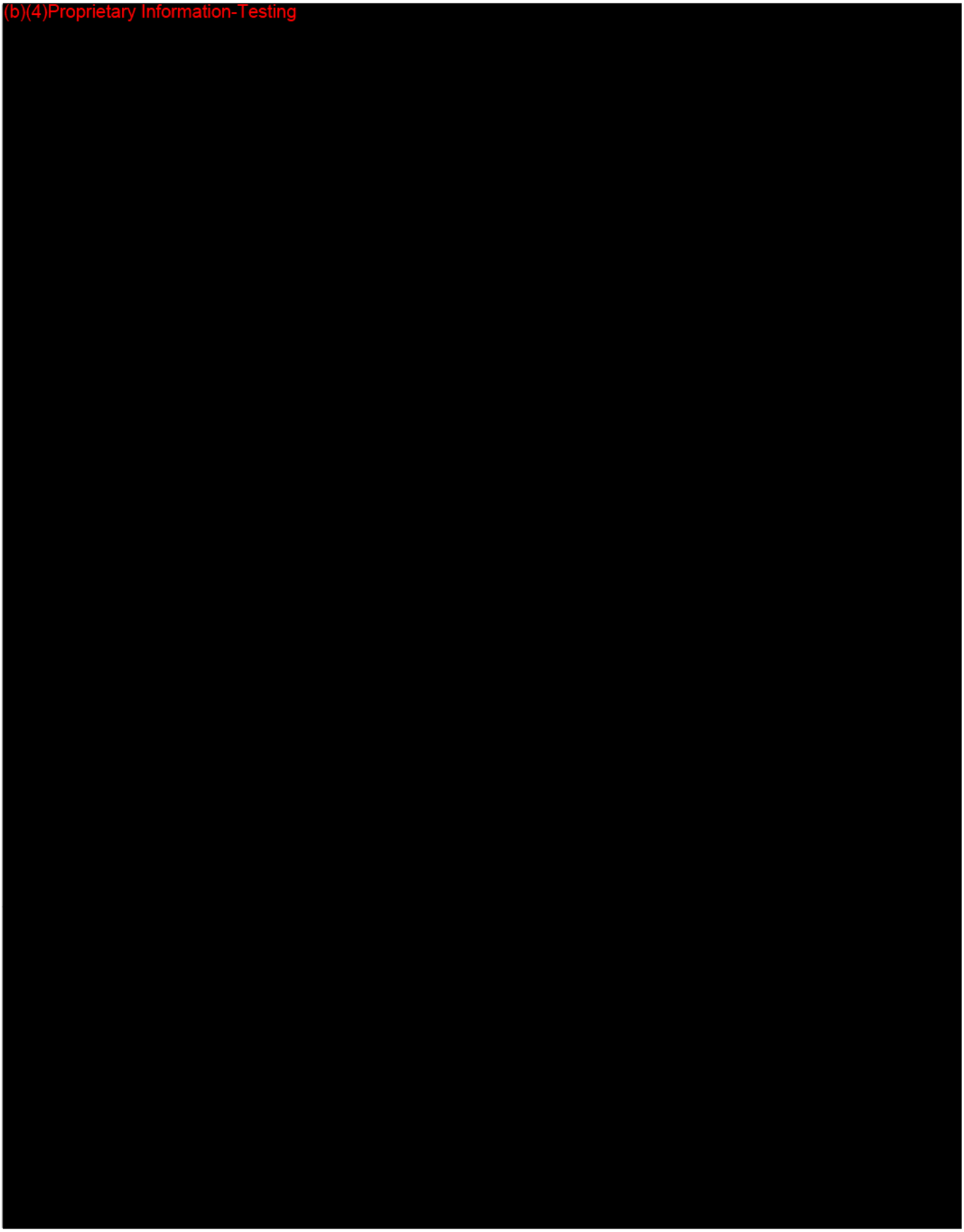
(b)(4)Proprietary Information-Testing



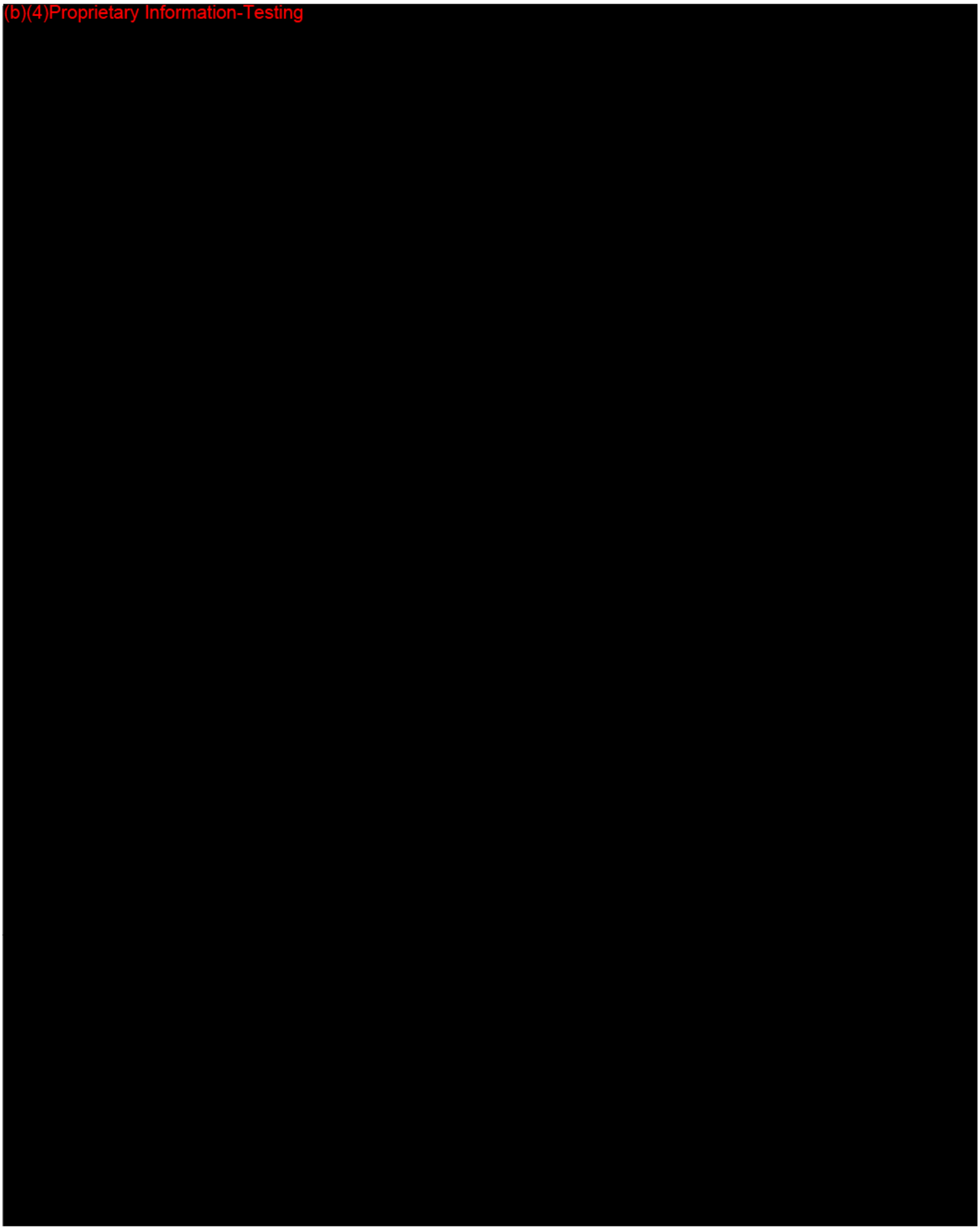


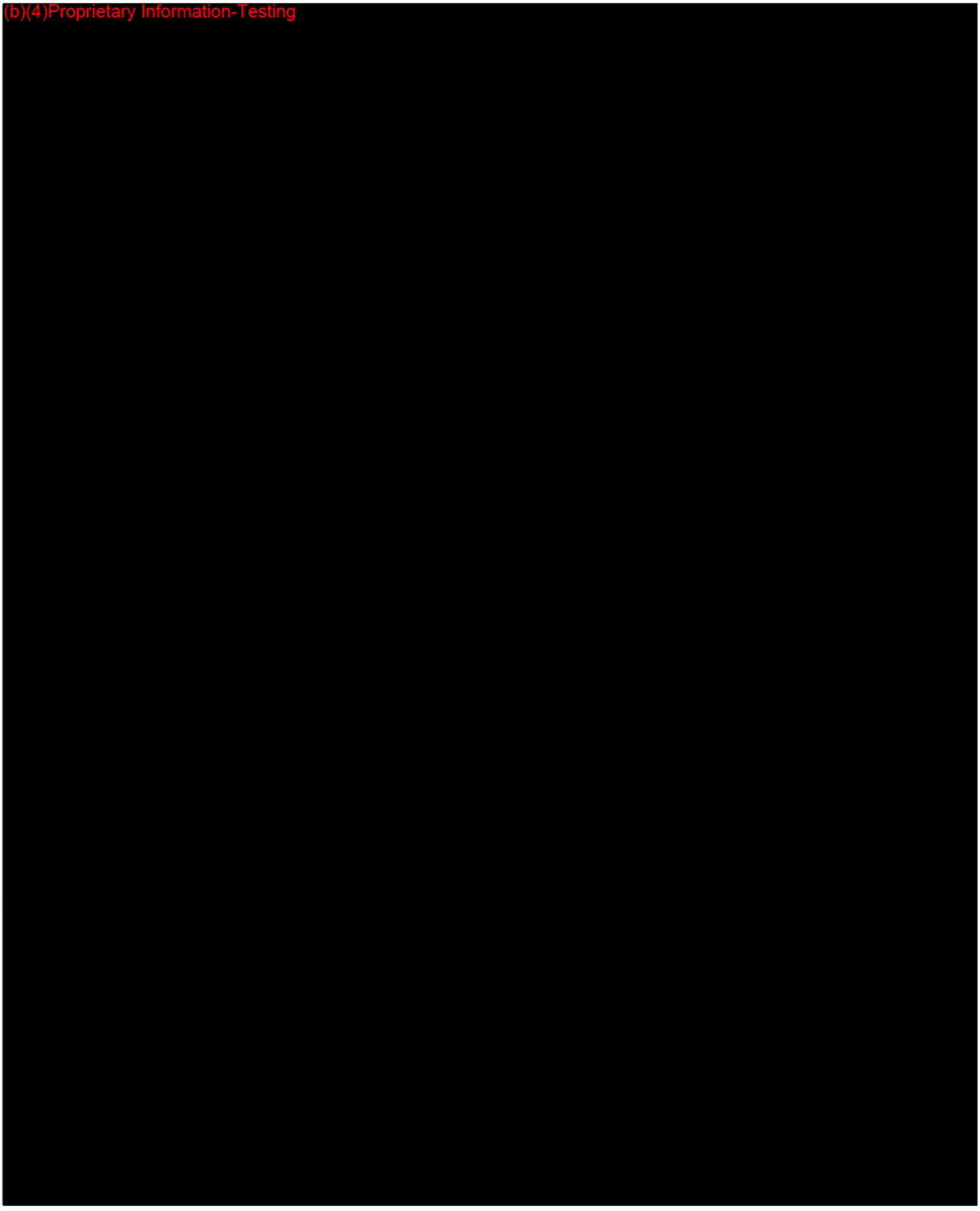




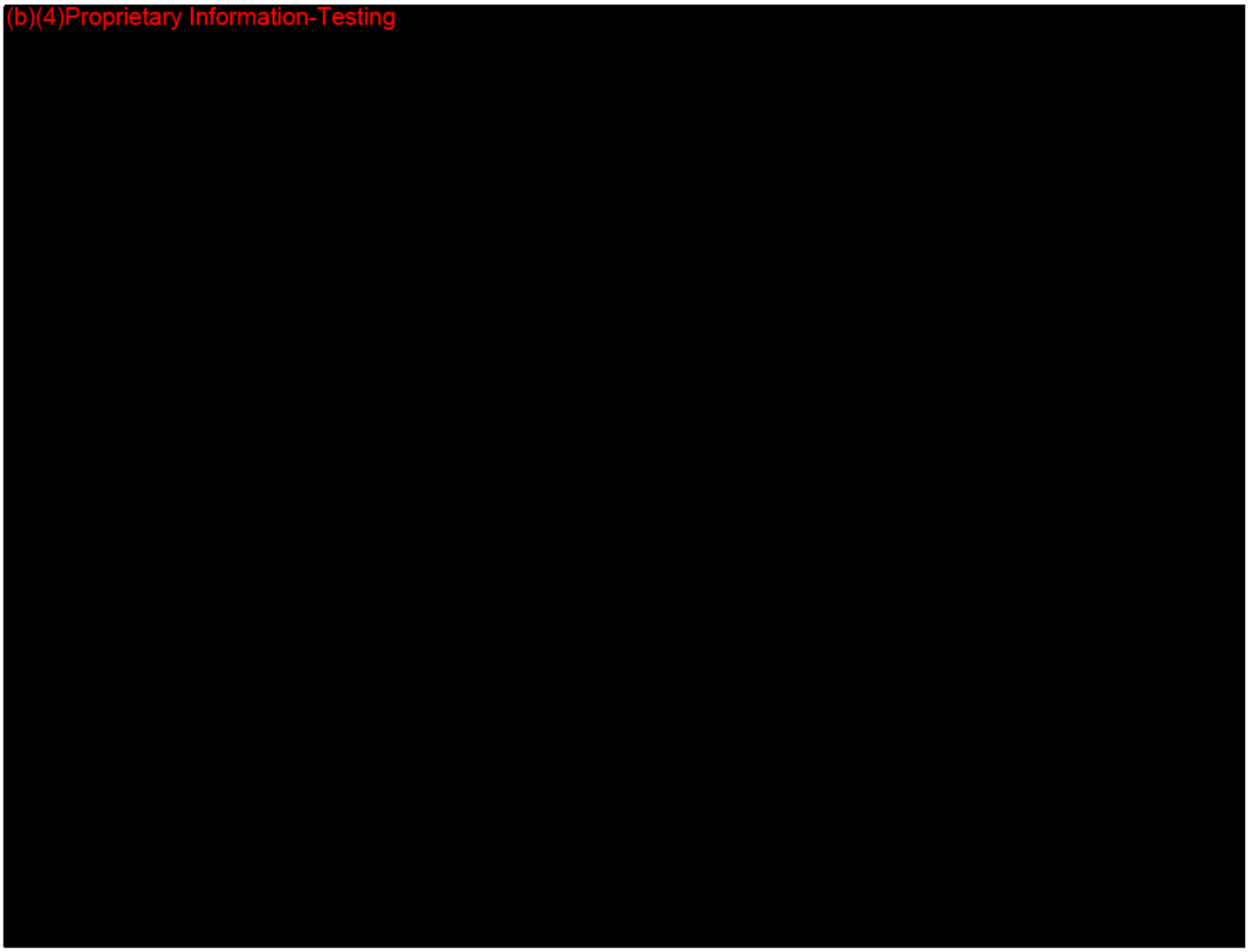


(b)(4)Proprietary Information-Testing

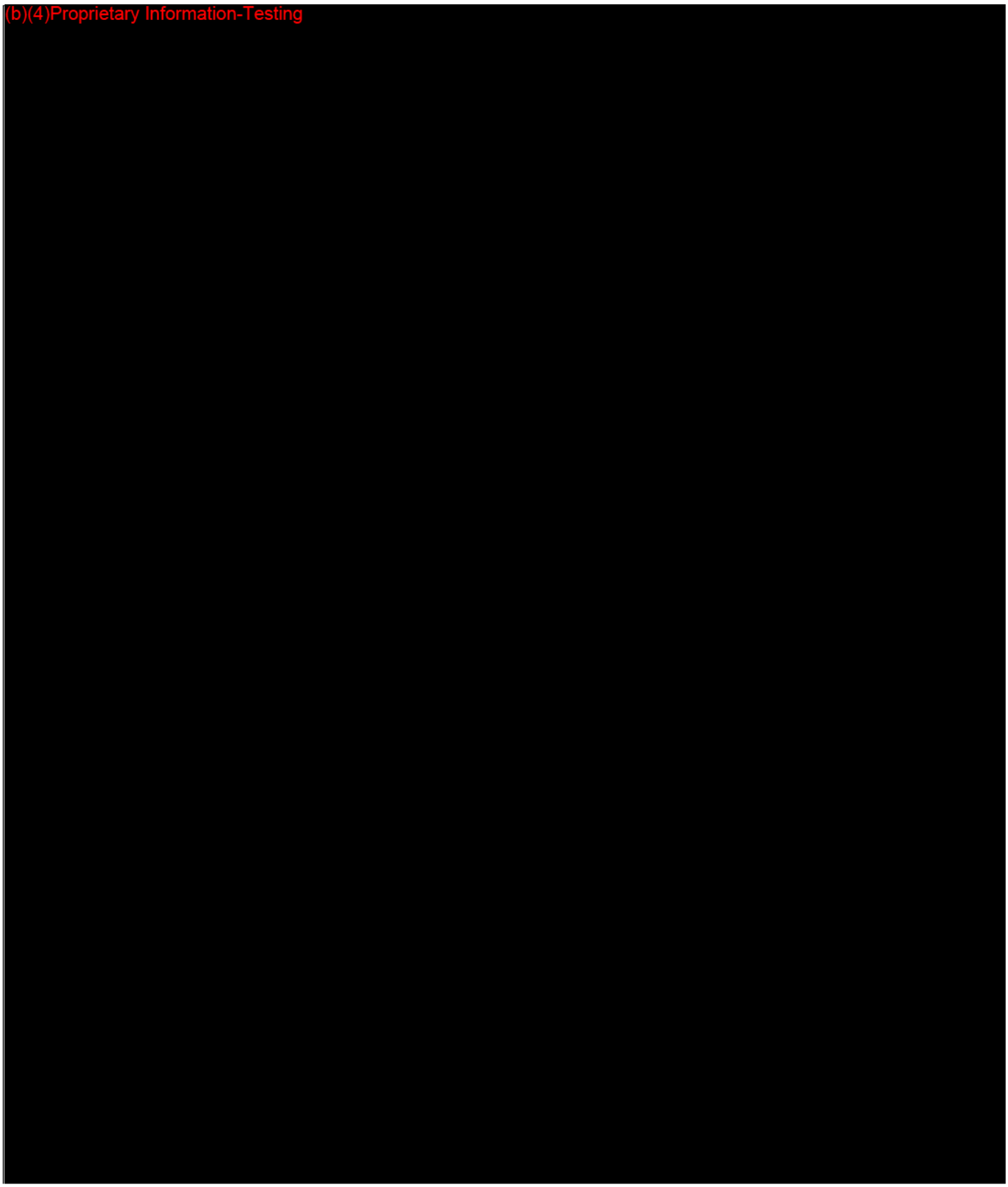




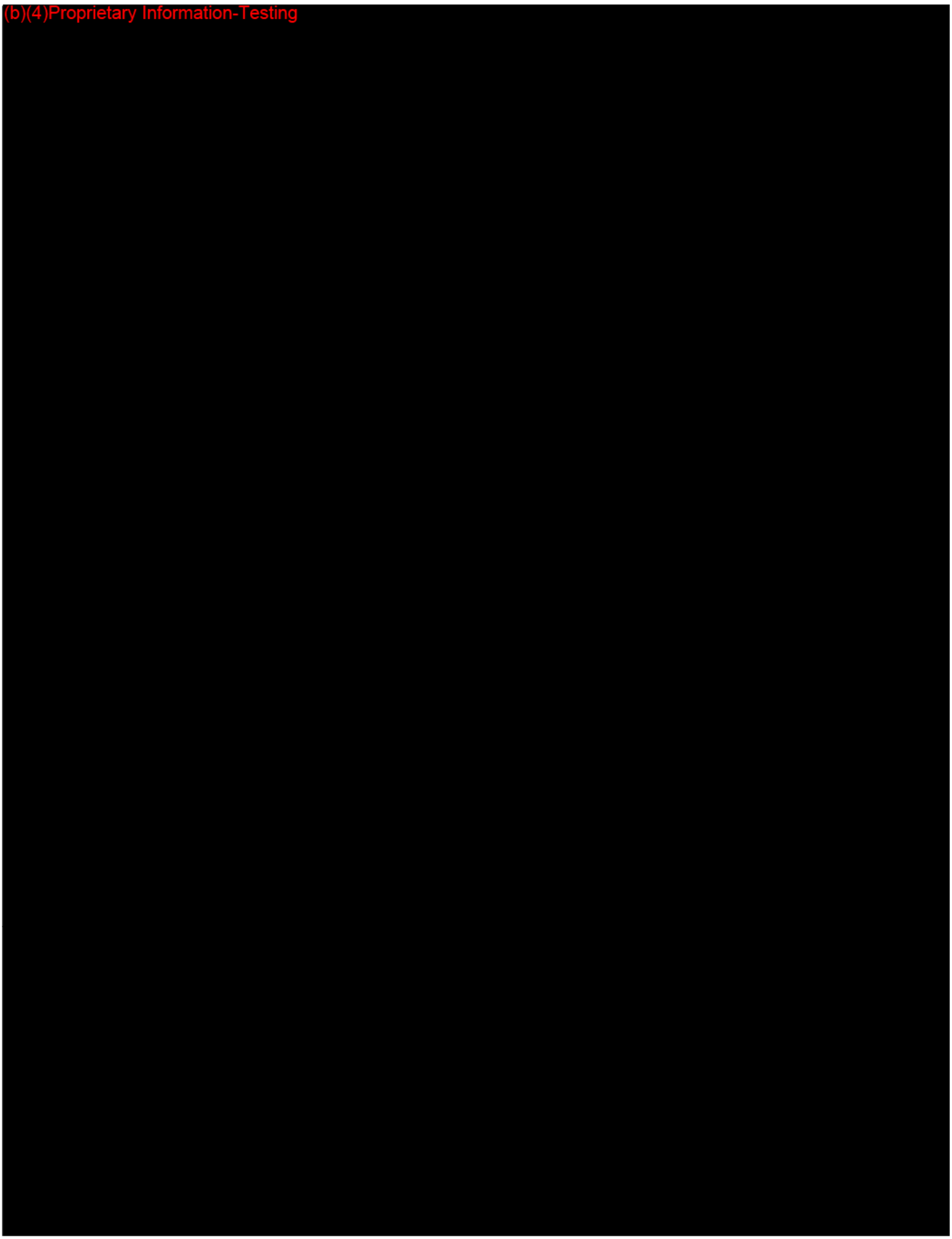
(b)(4)Proprietary Information-Testing

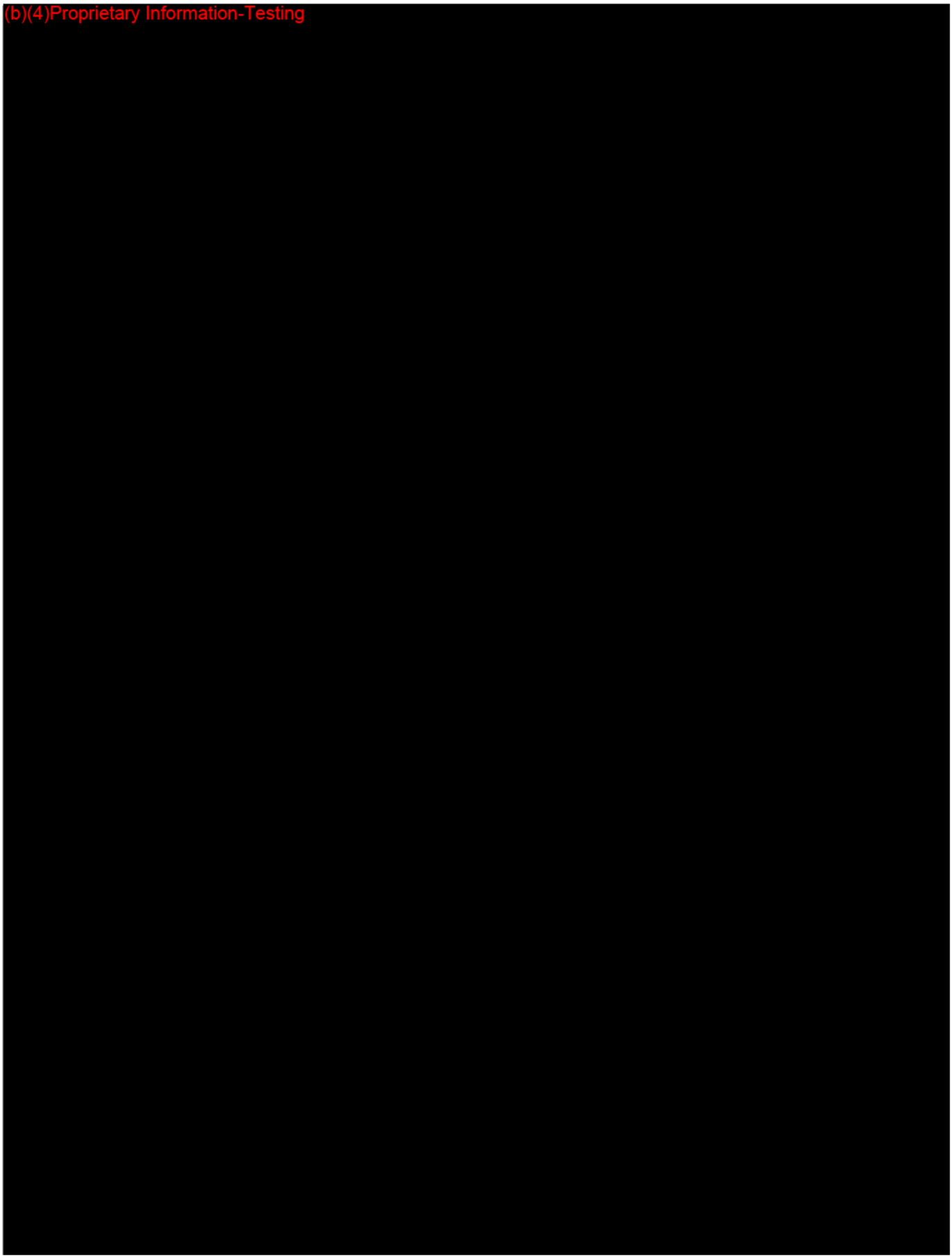


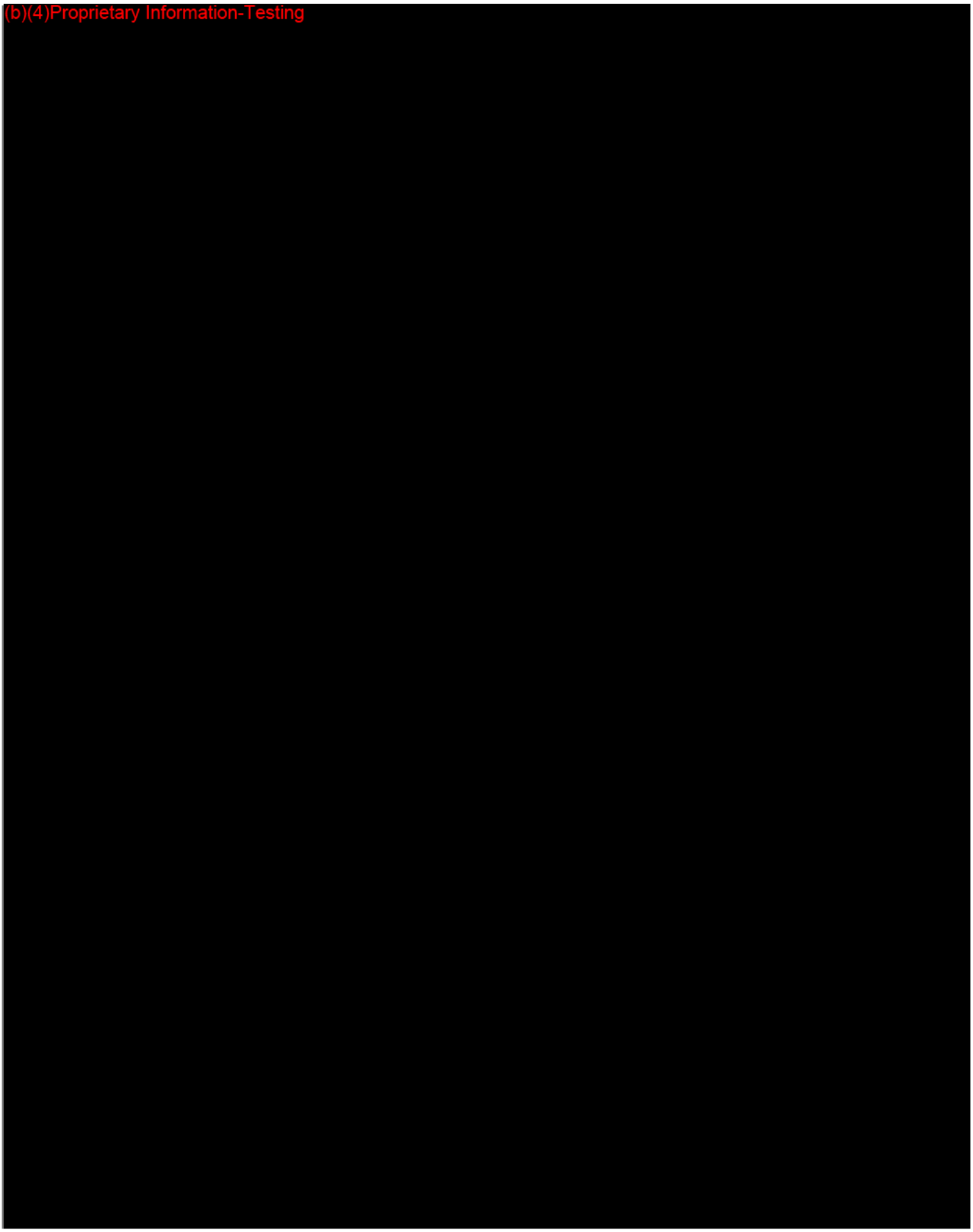
(b)(4)Proprietary Information-Testing

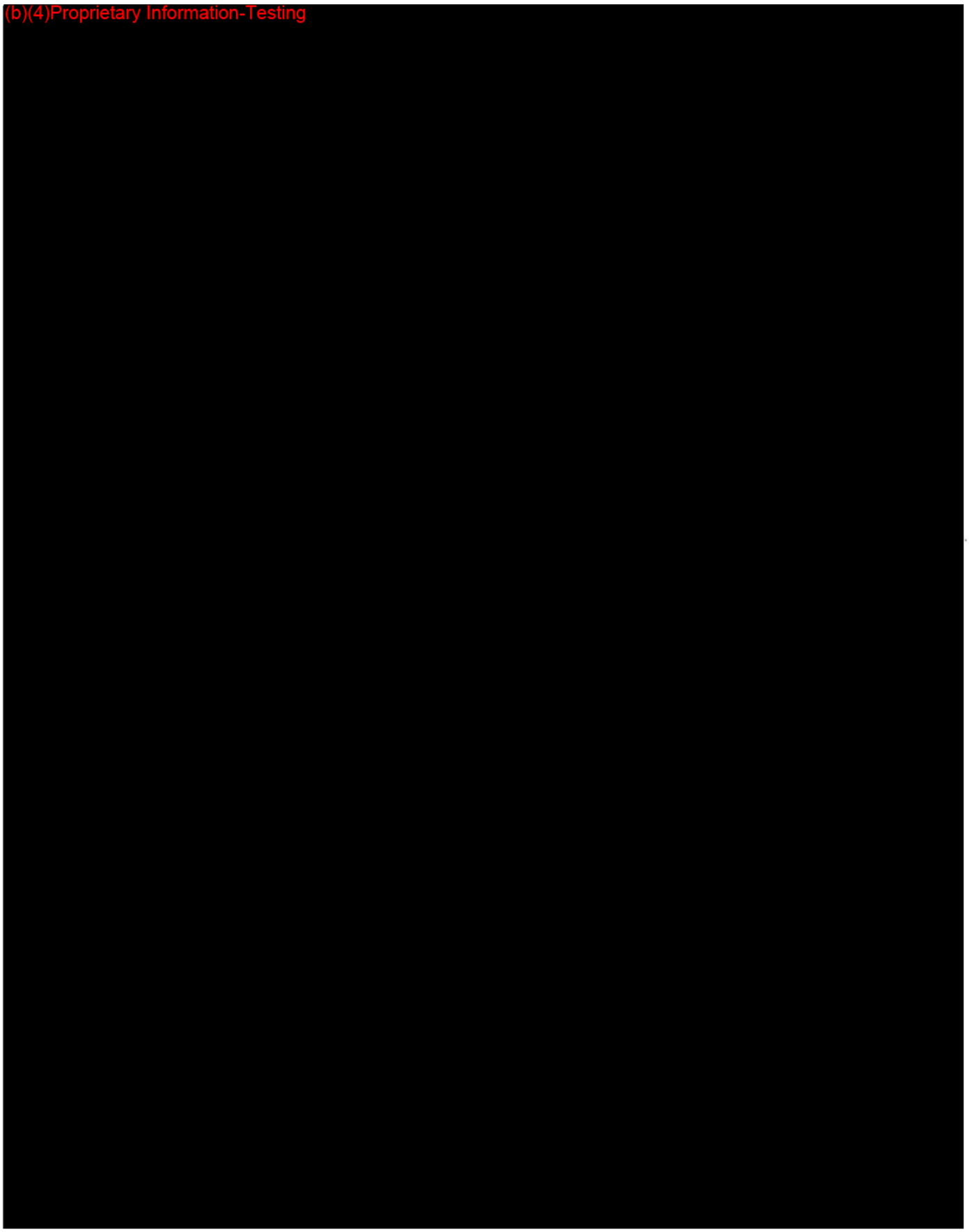


(b)(4)Proprietary Information-Testing

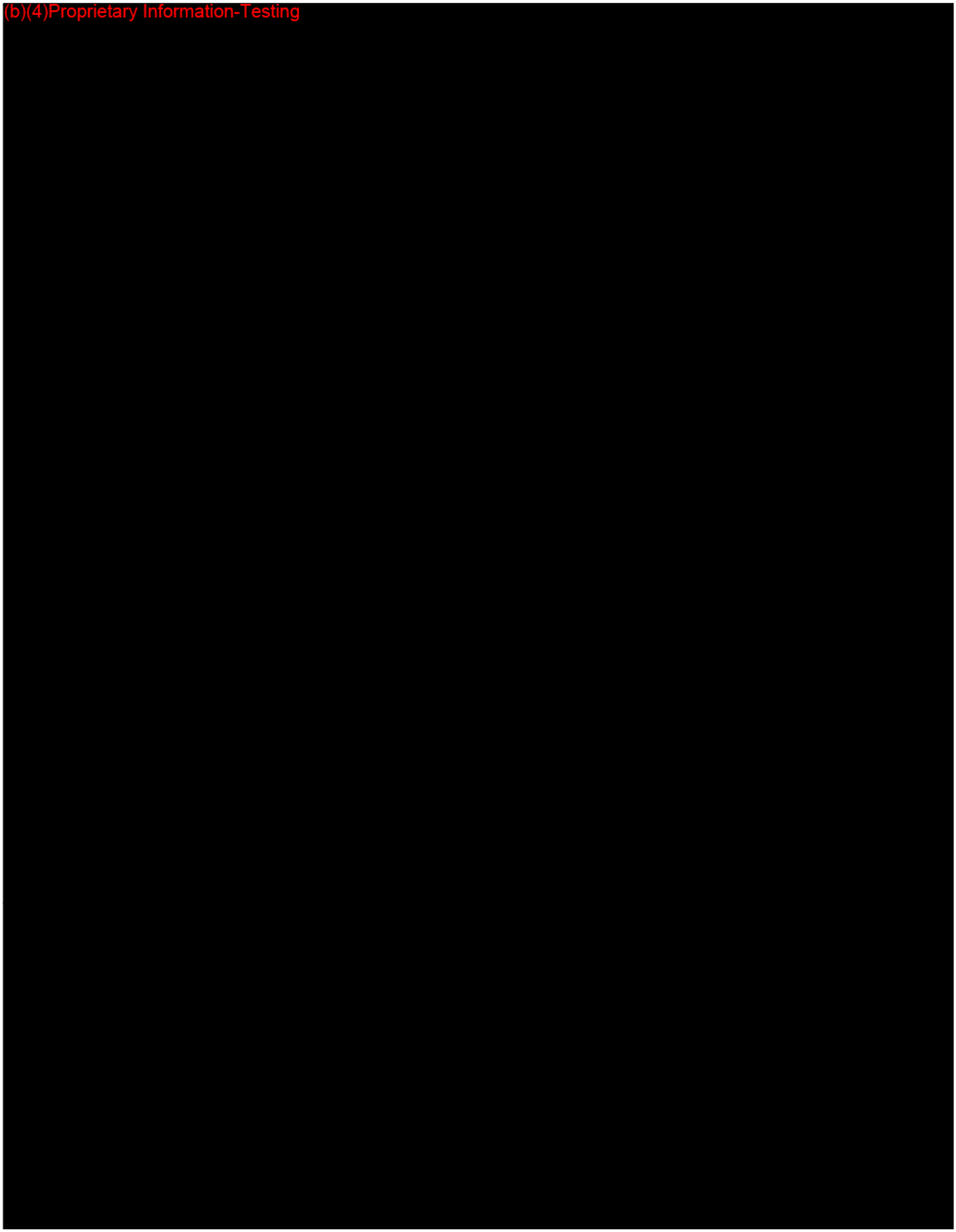


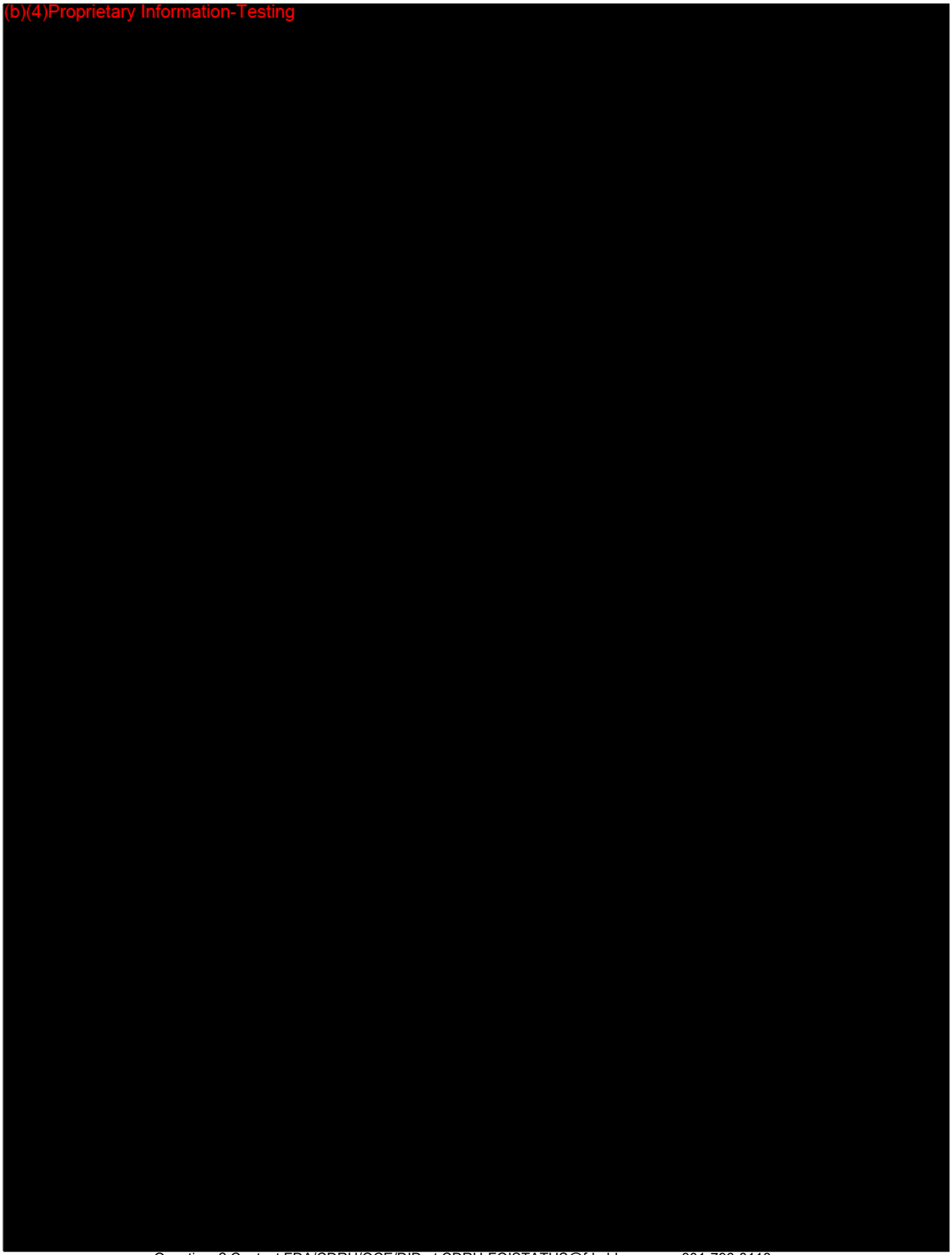


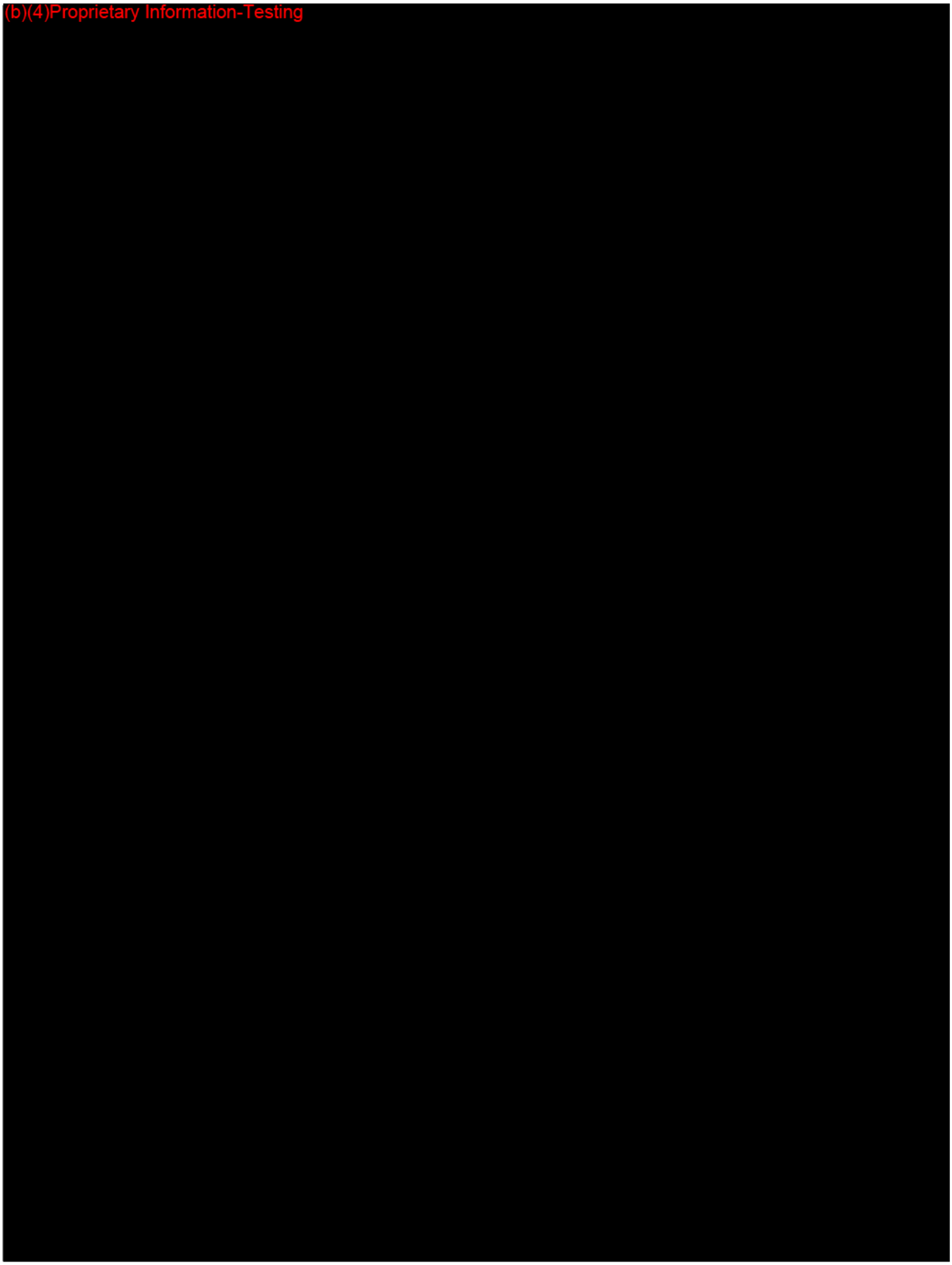




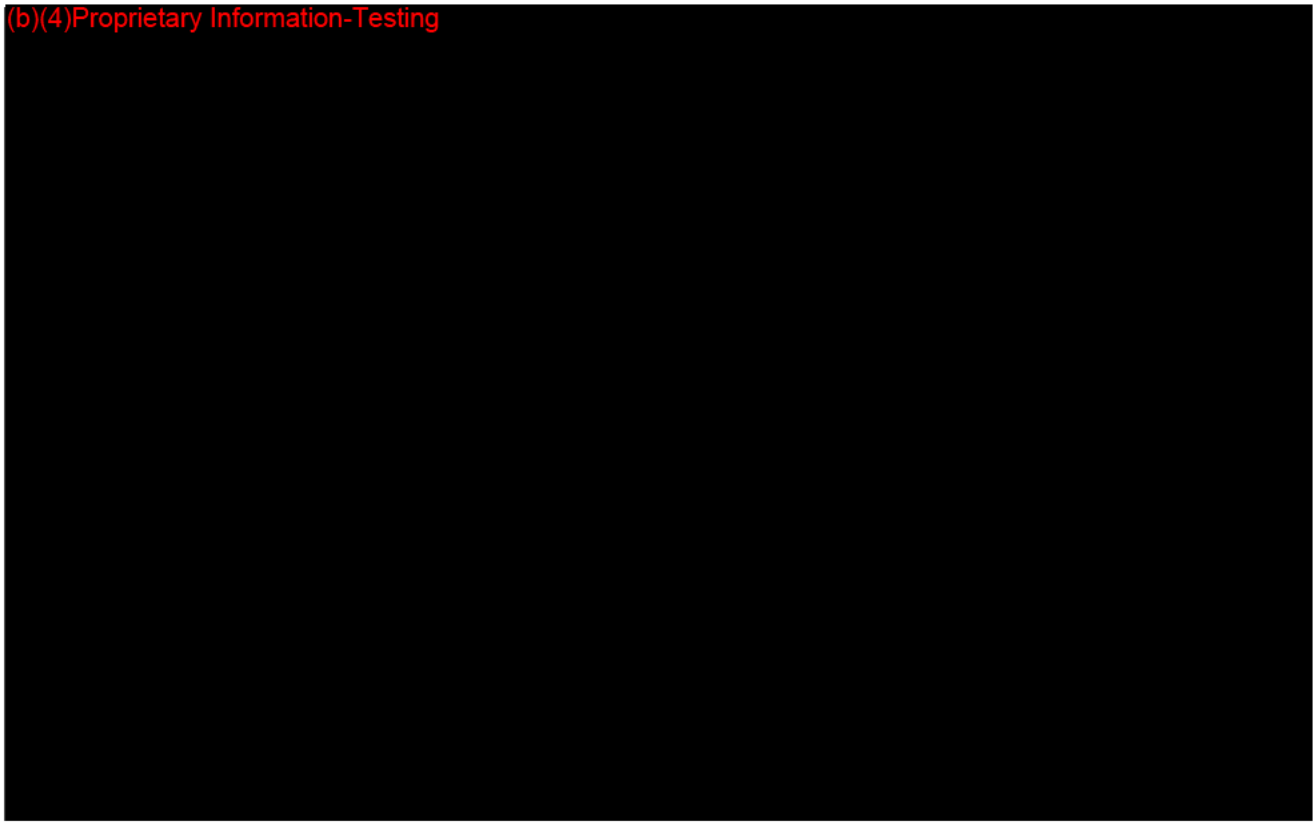
(b)(4)Proprietary Information-Testing



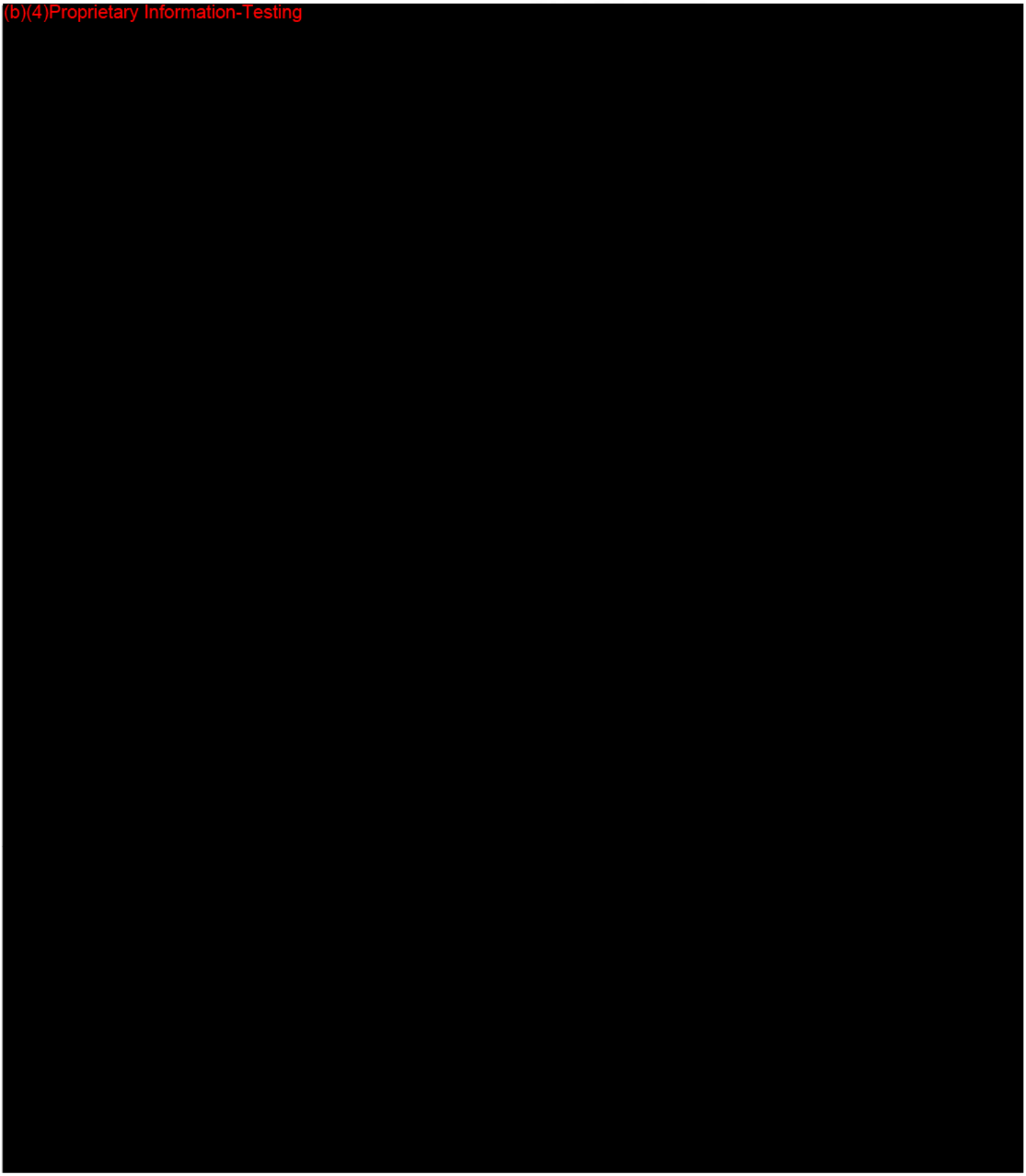




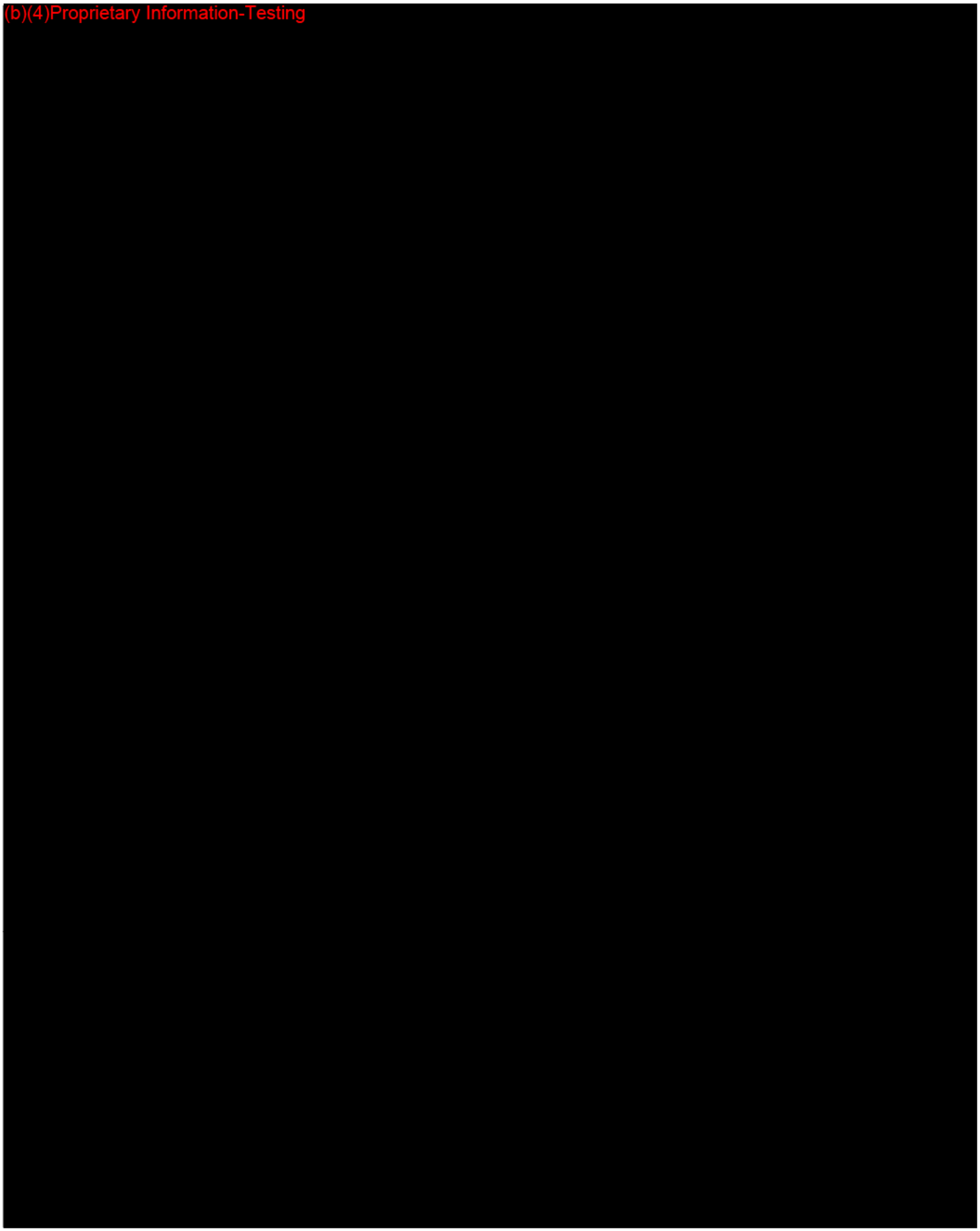
(b)(4)Proprietary Information-Testing



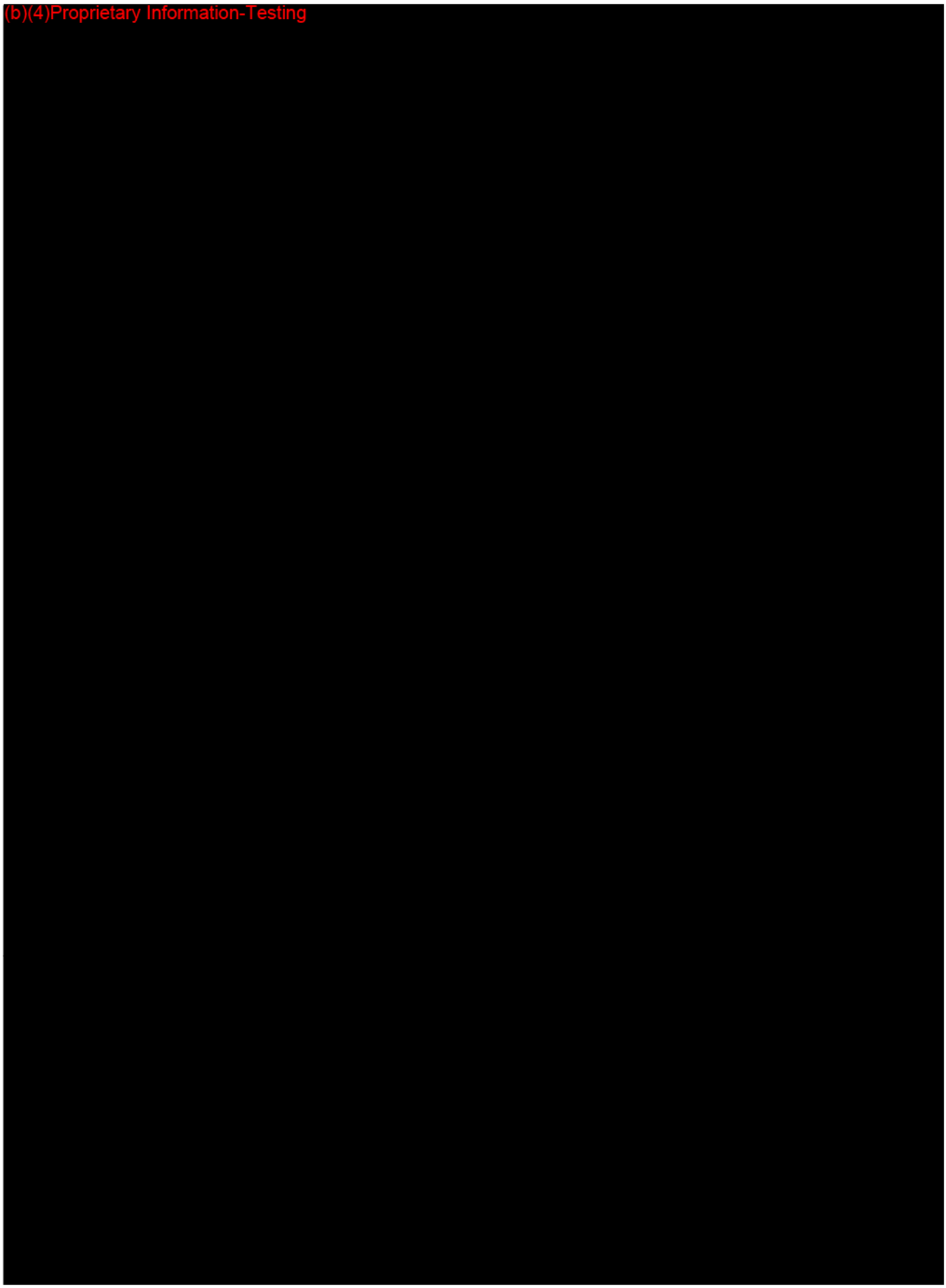
(b)(4)Proprietary Information-Testing

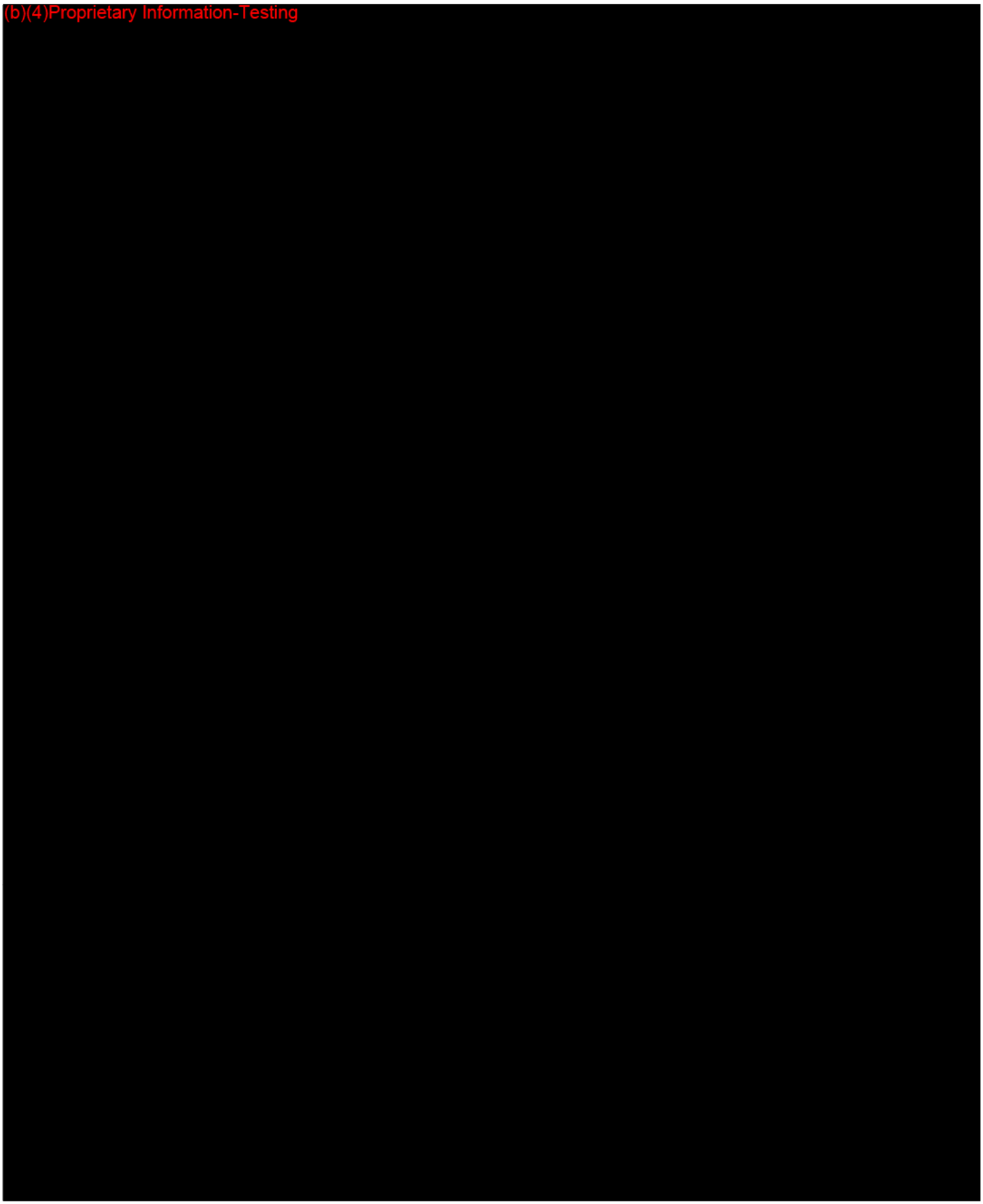


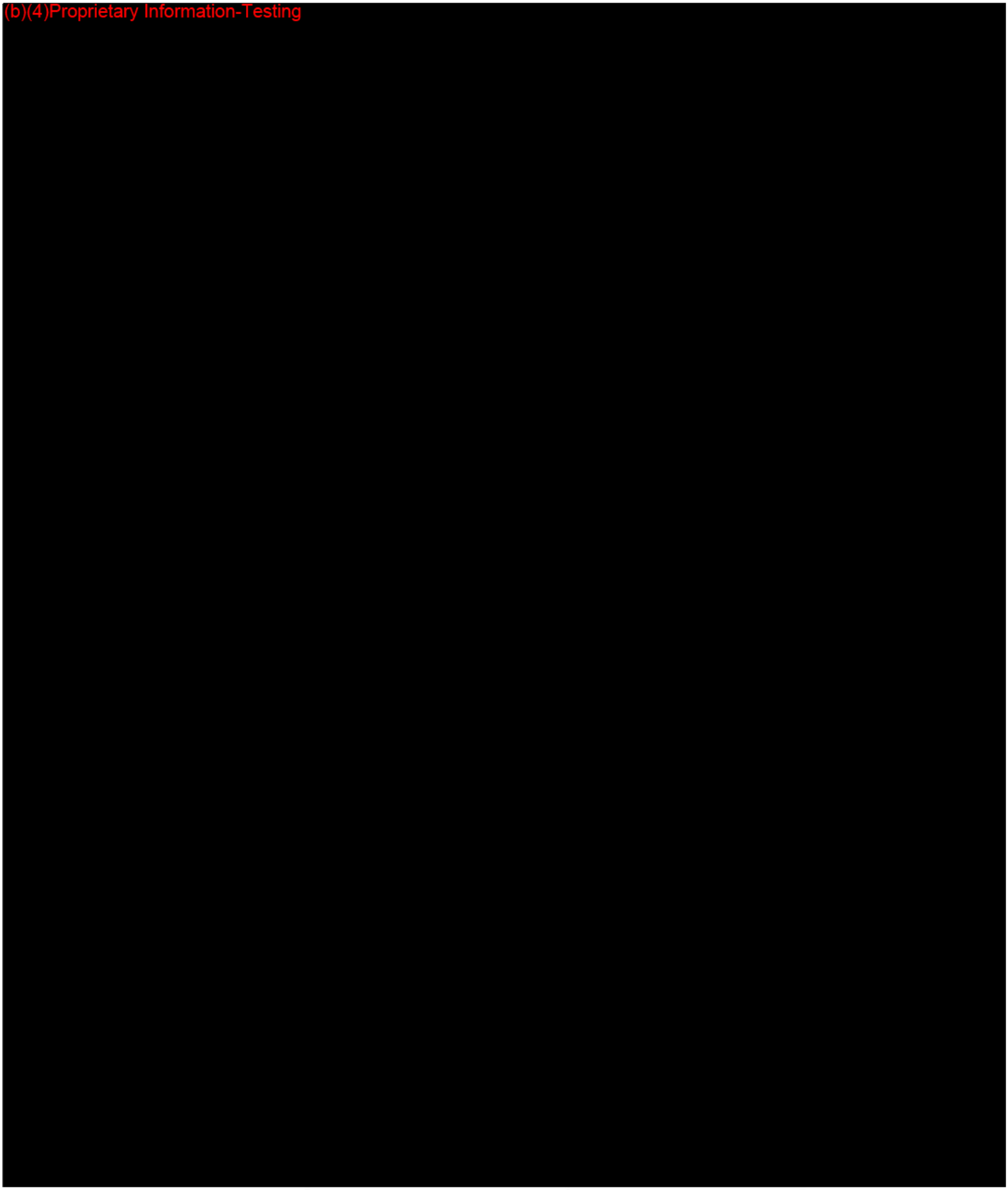
(b)(4)Proprietary Information-Testing

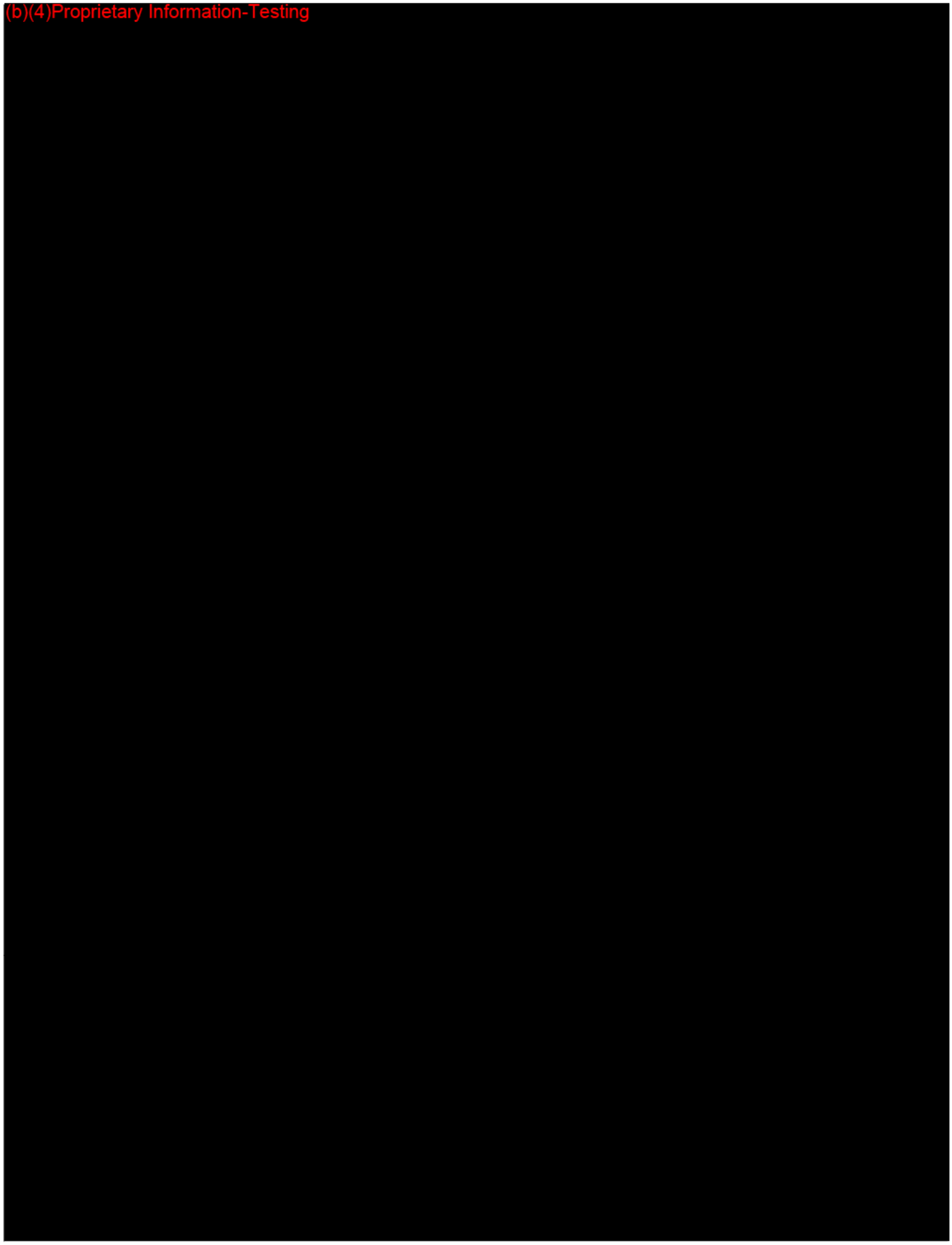


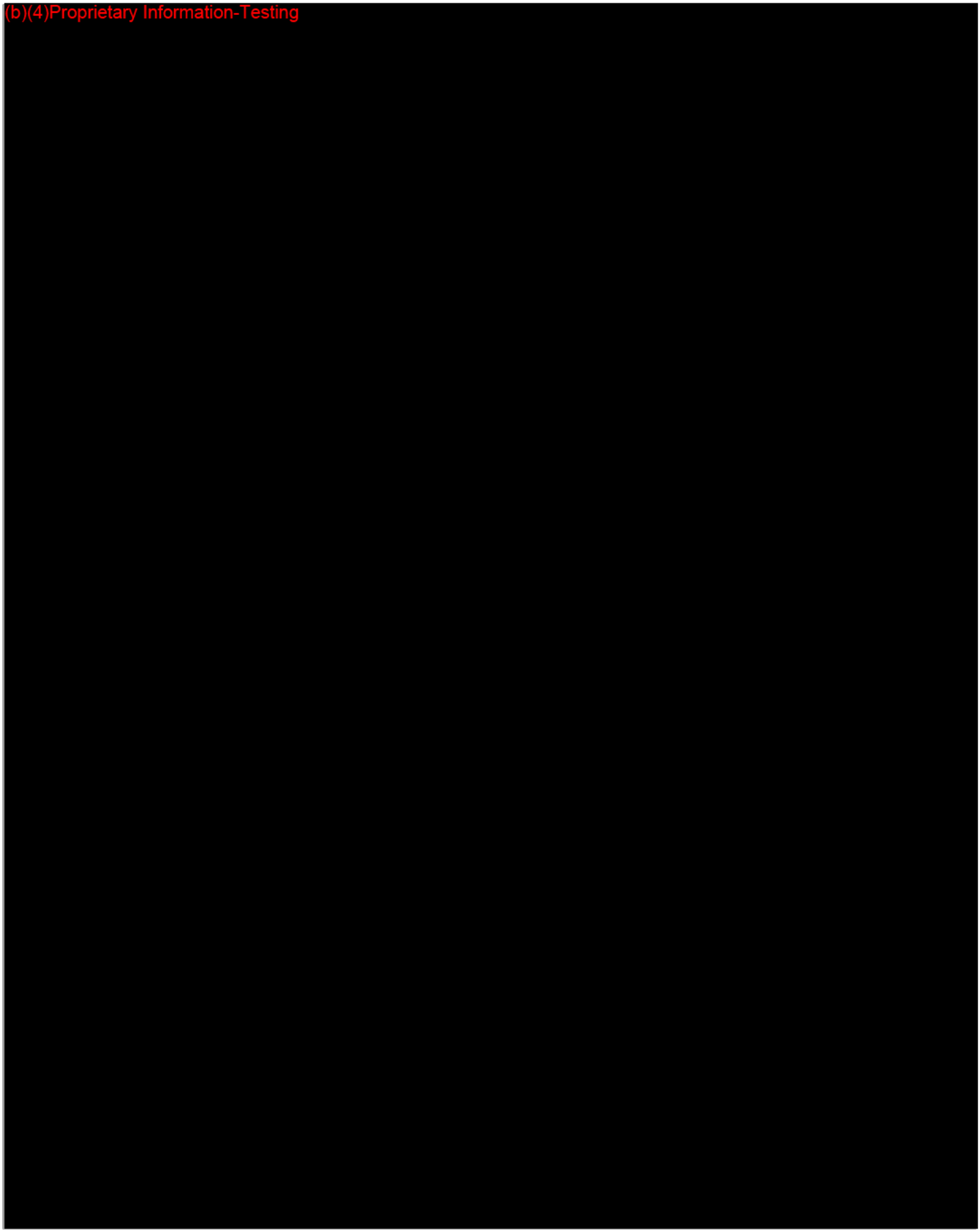
(b)(4)Proprietary Information-Testing



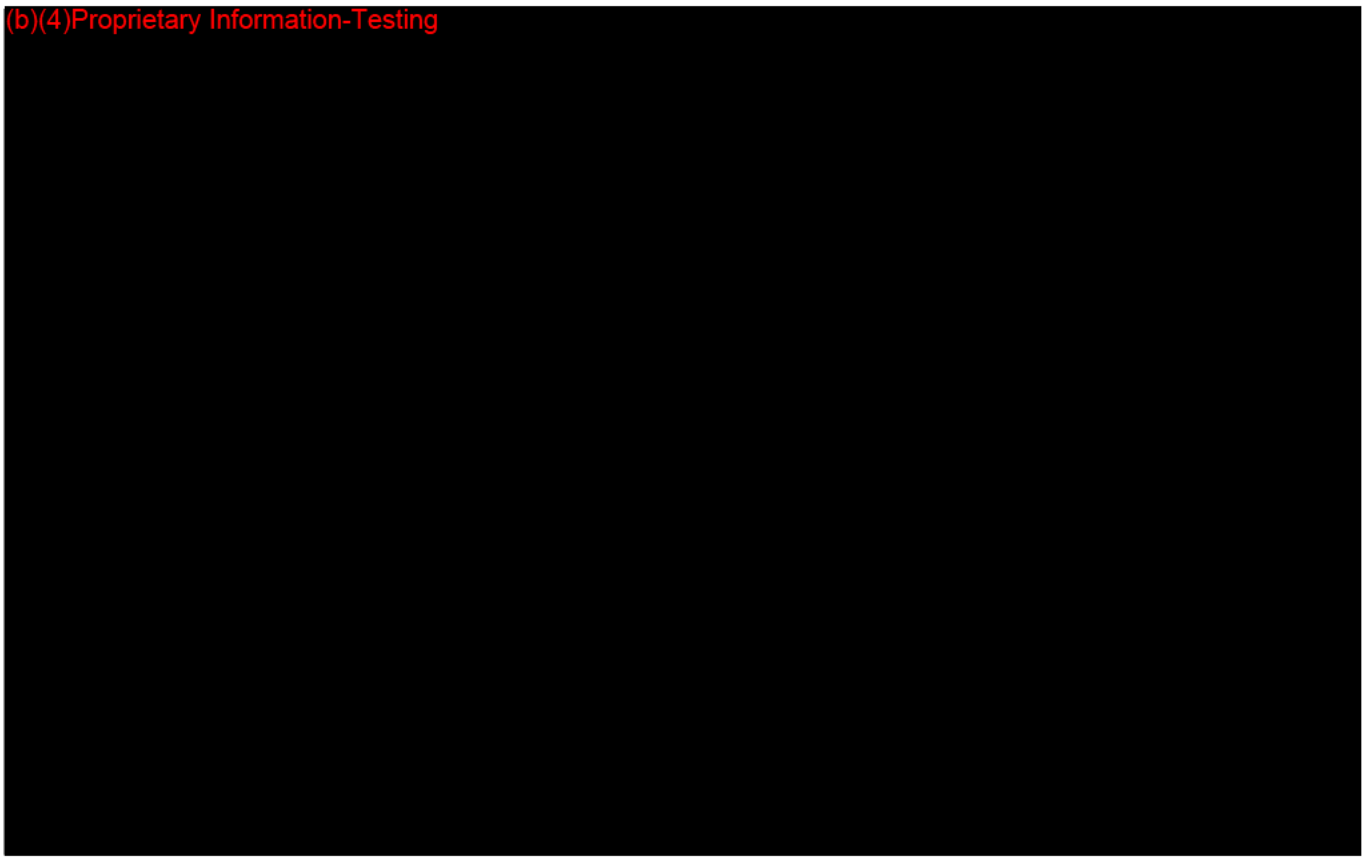


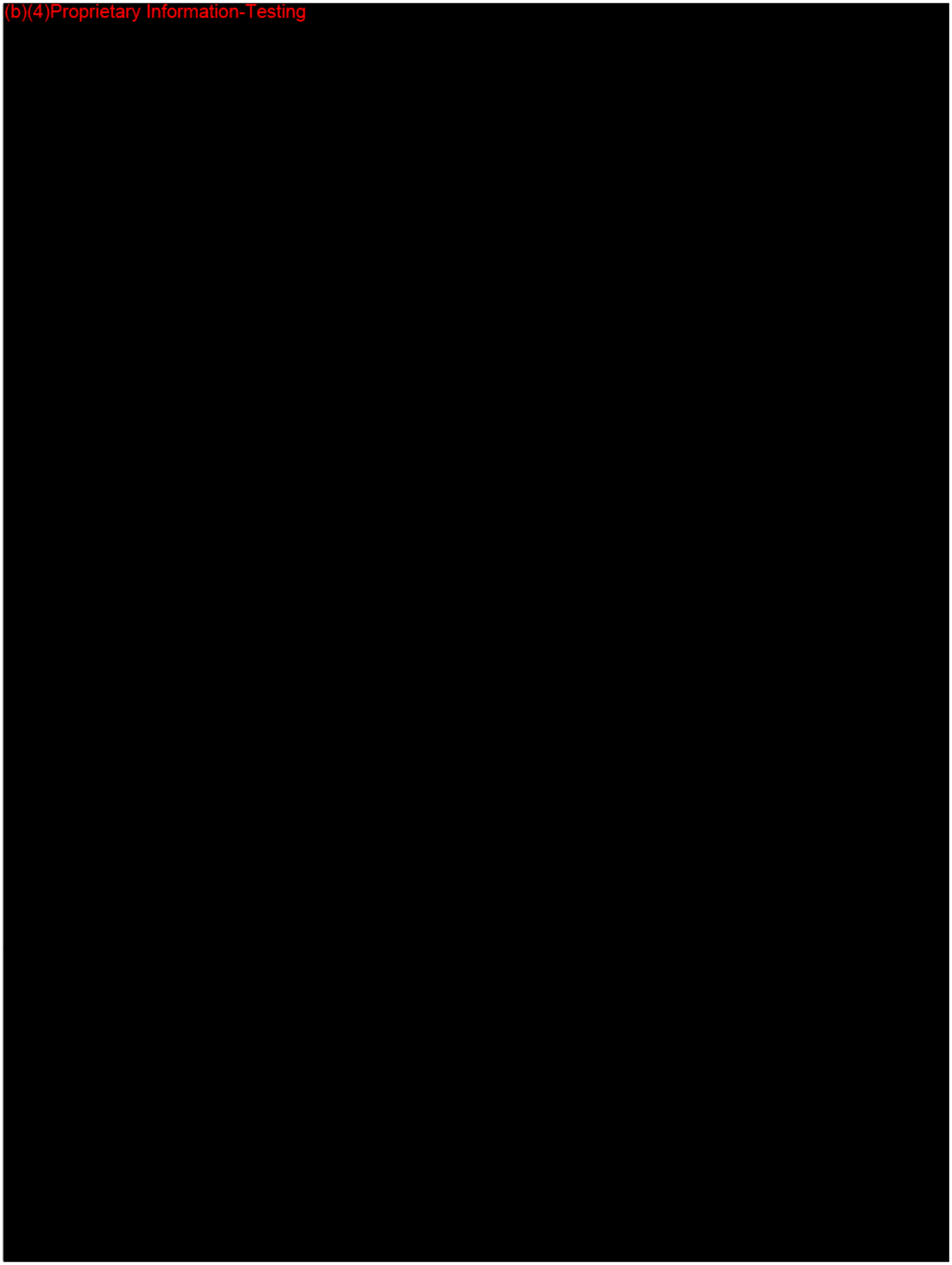




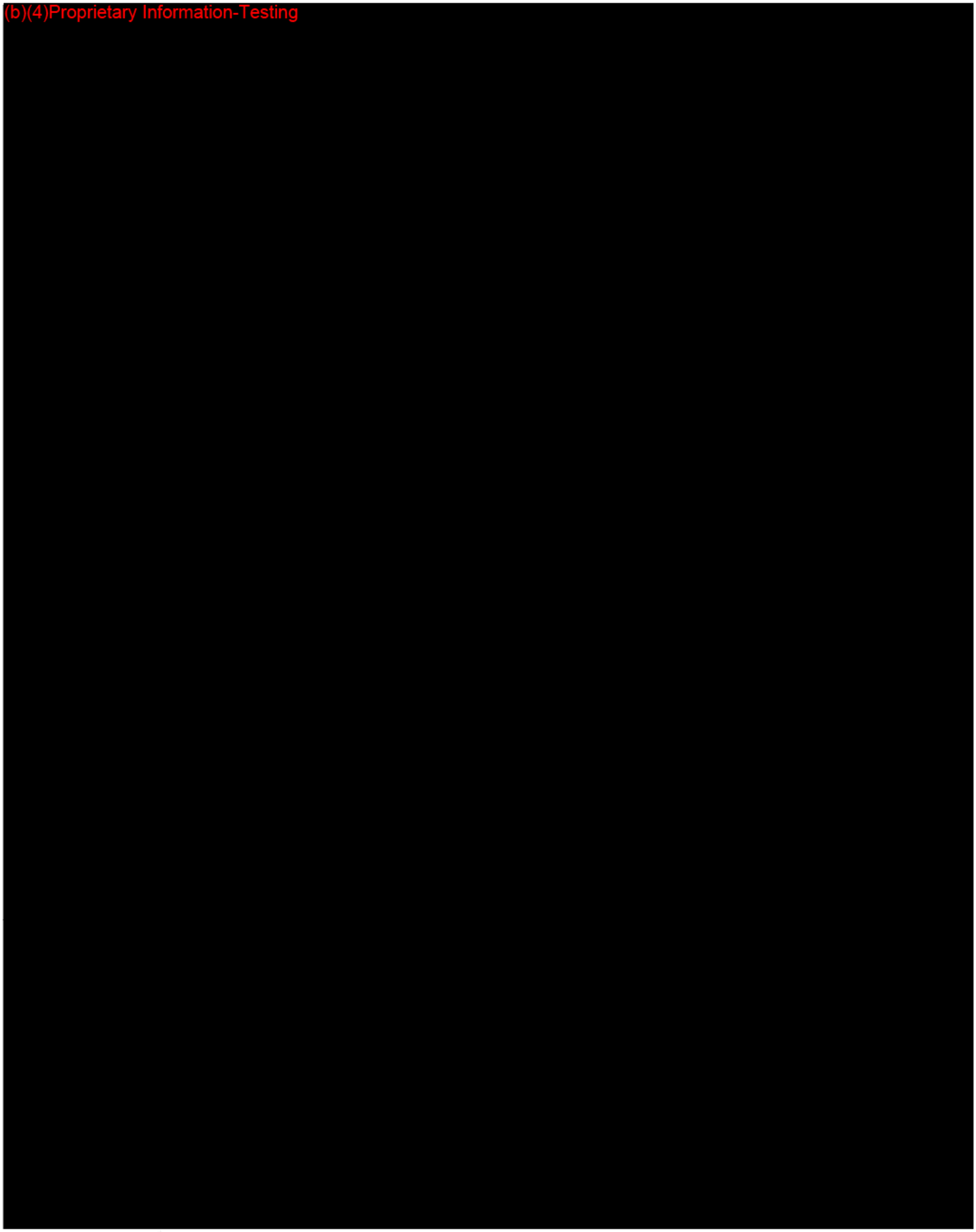


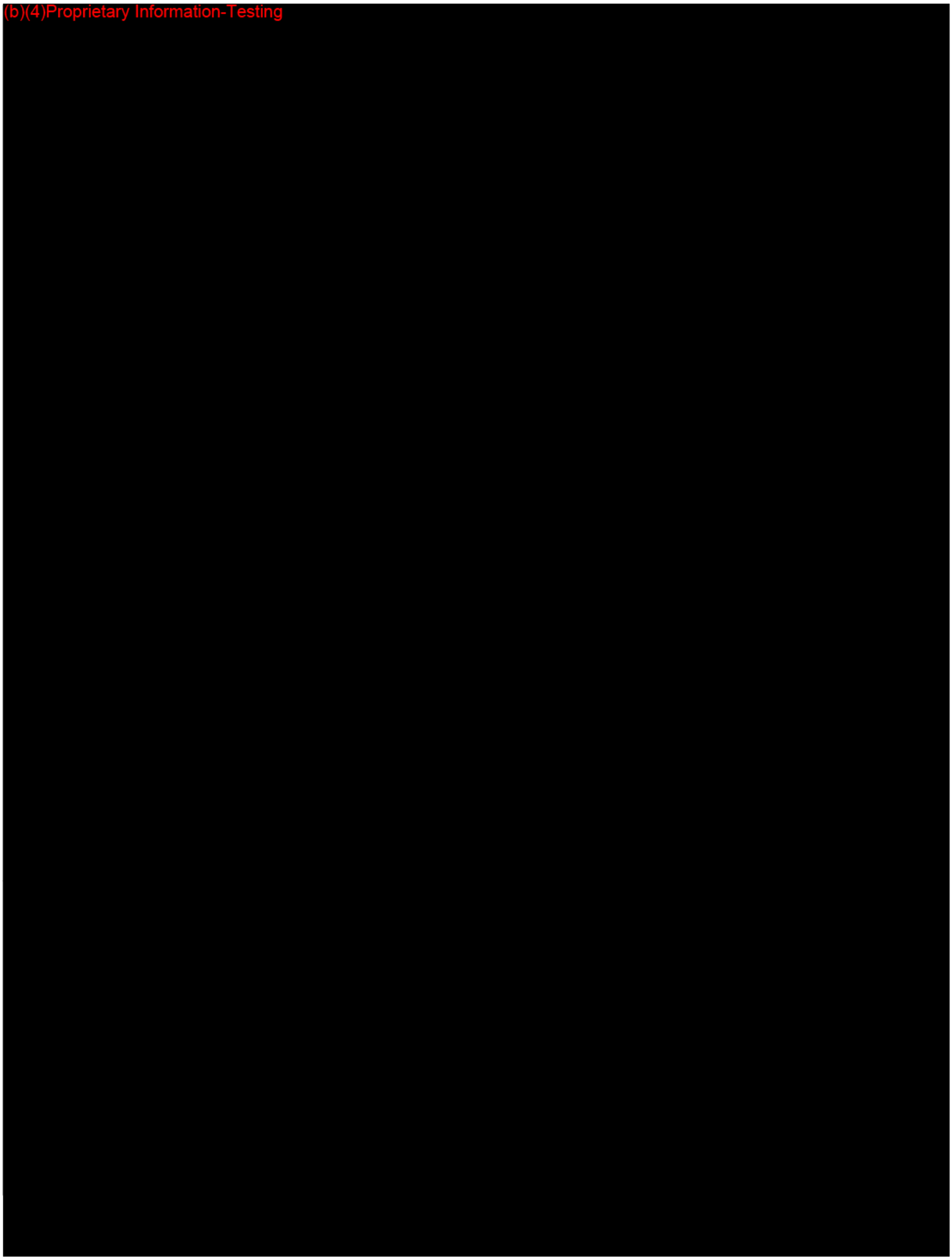
(b)(4)Proprietary Information-Testing

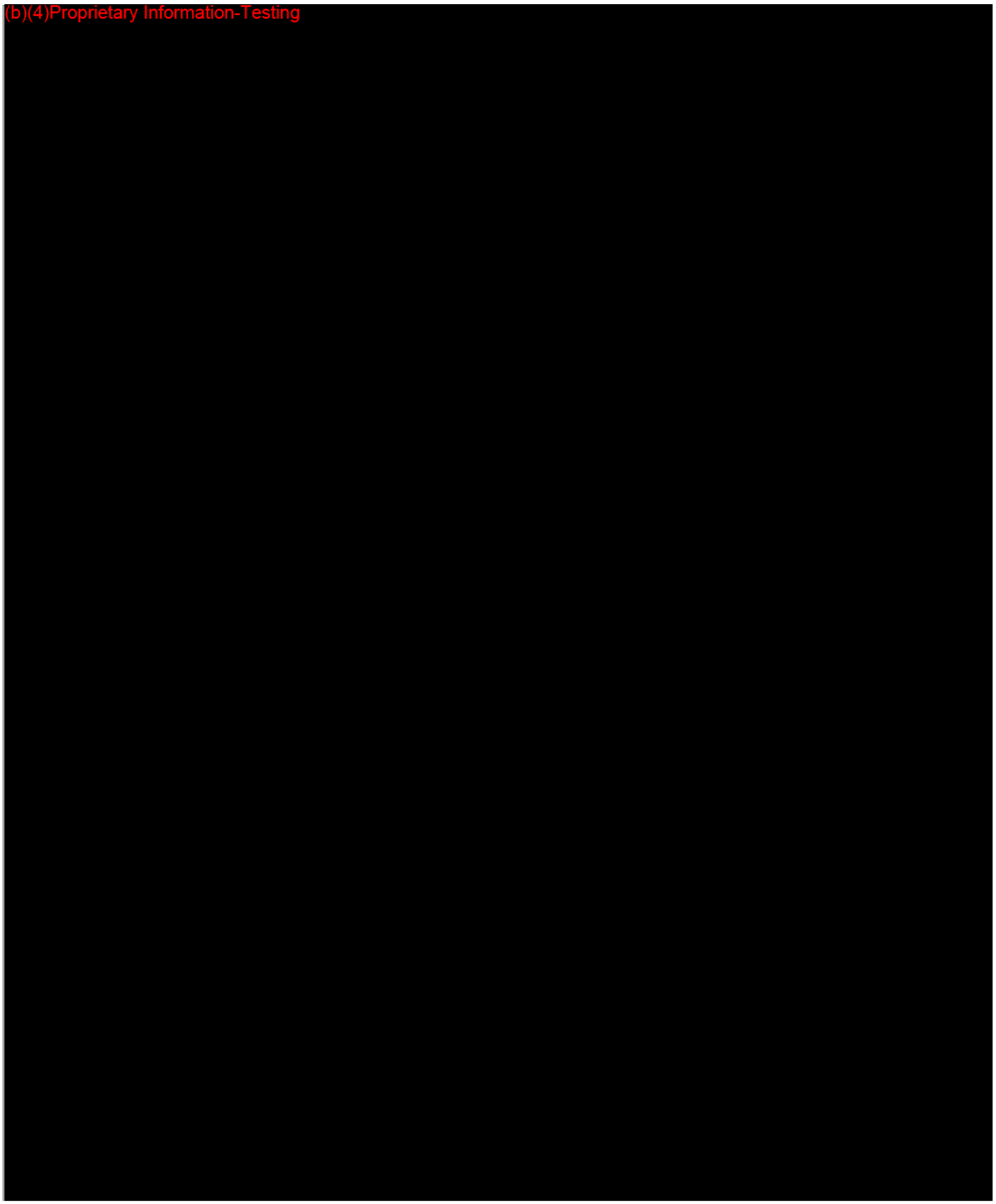


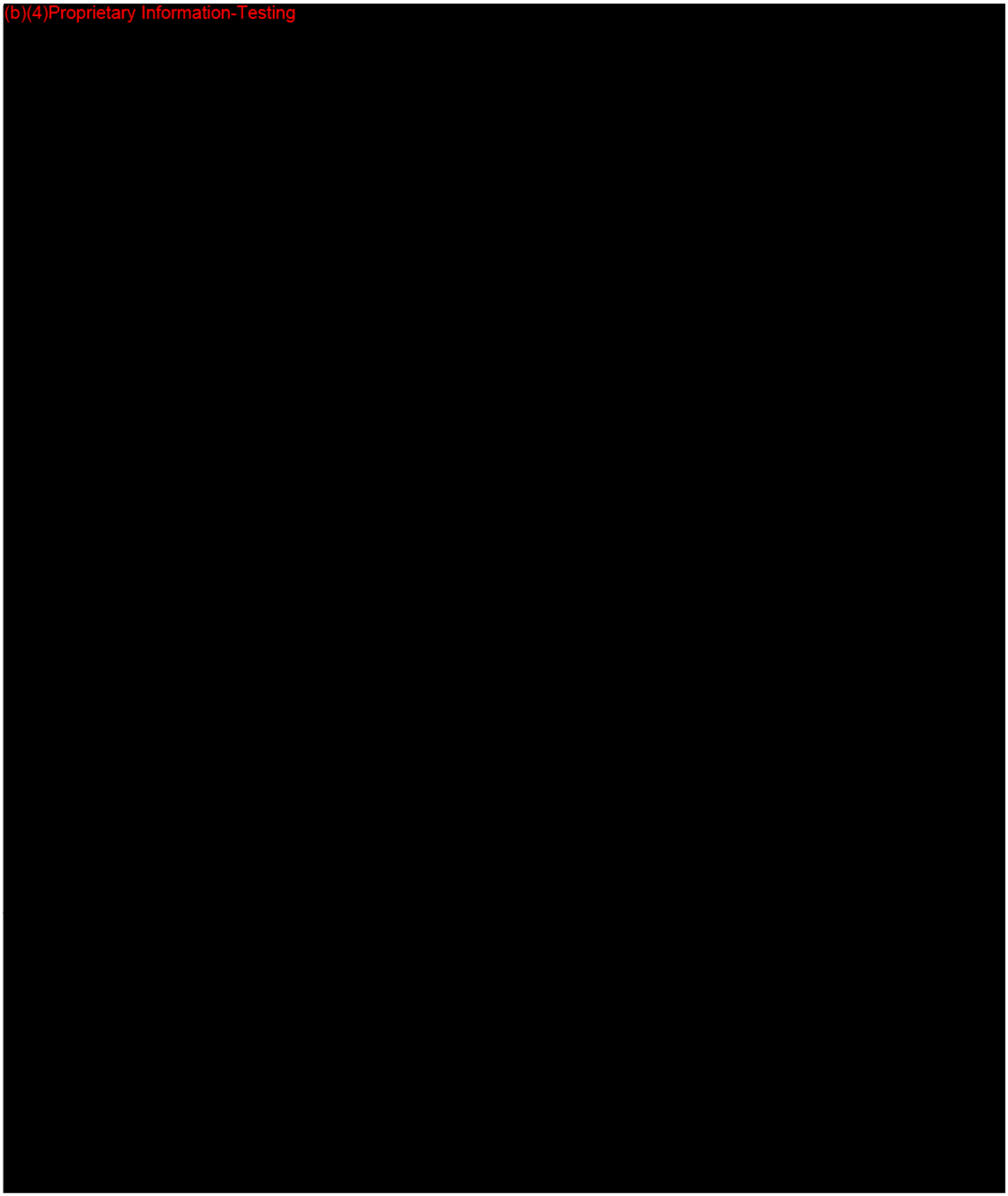


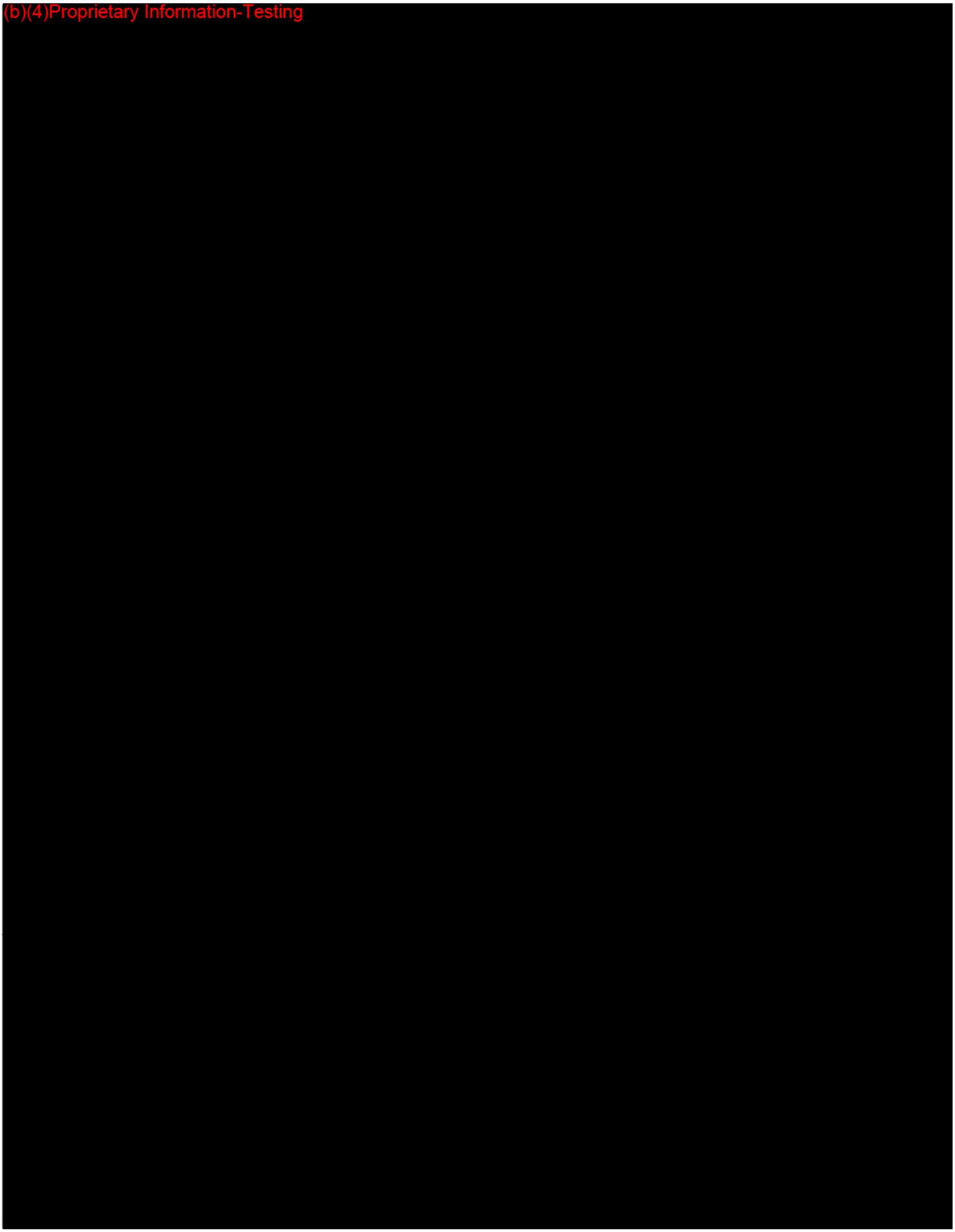
(b)(4)Proprietary Information-Testing



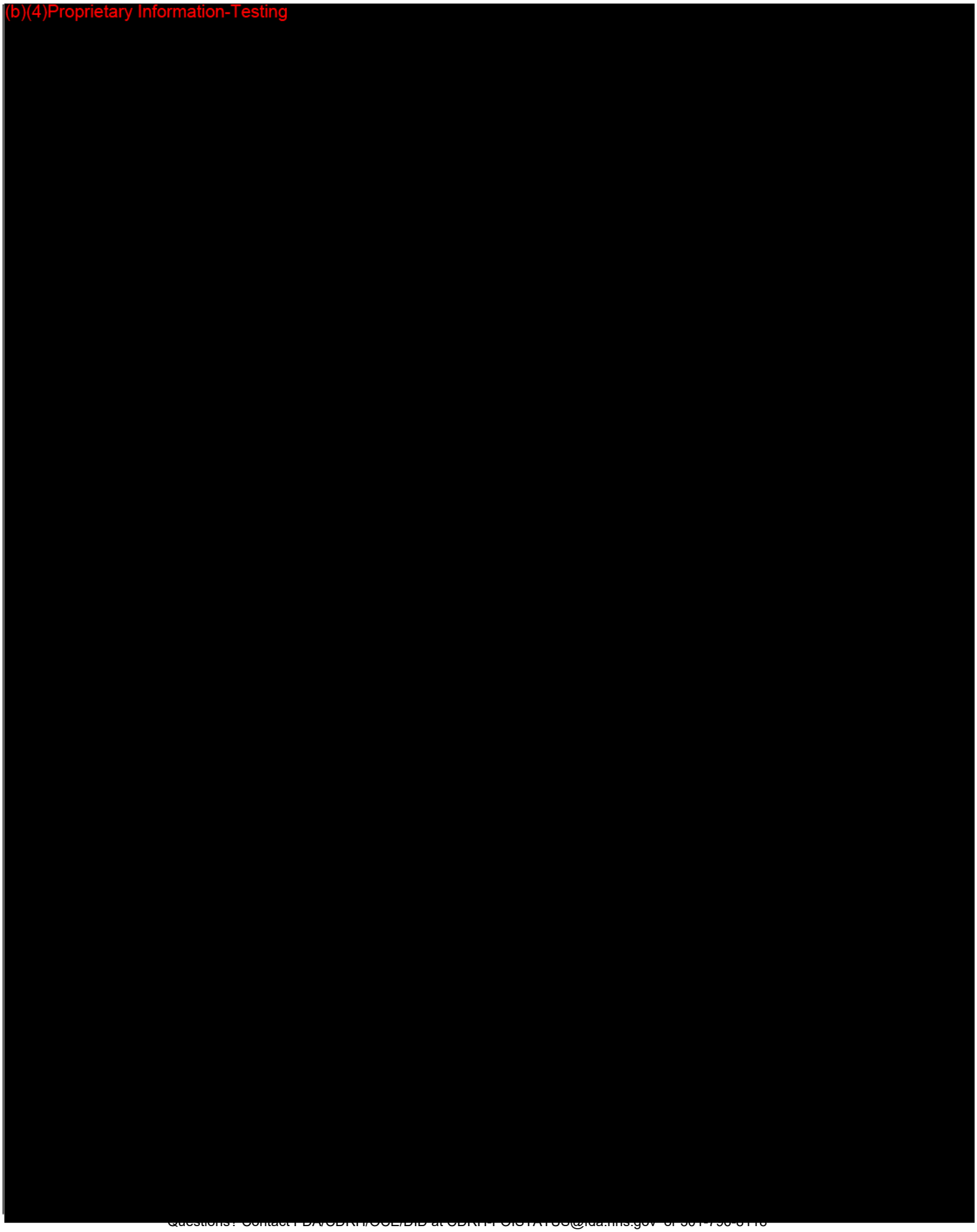




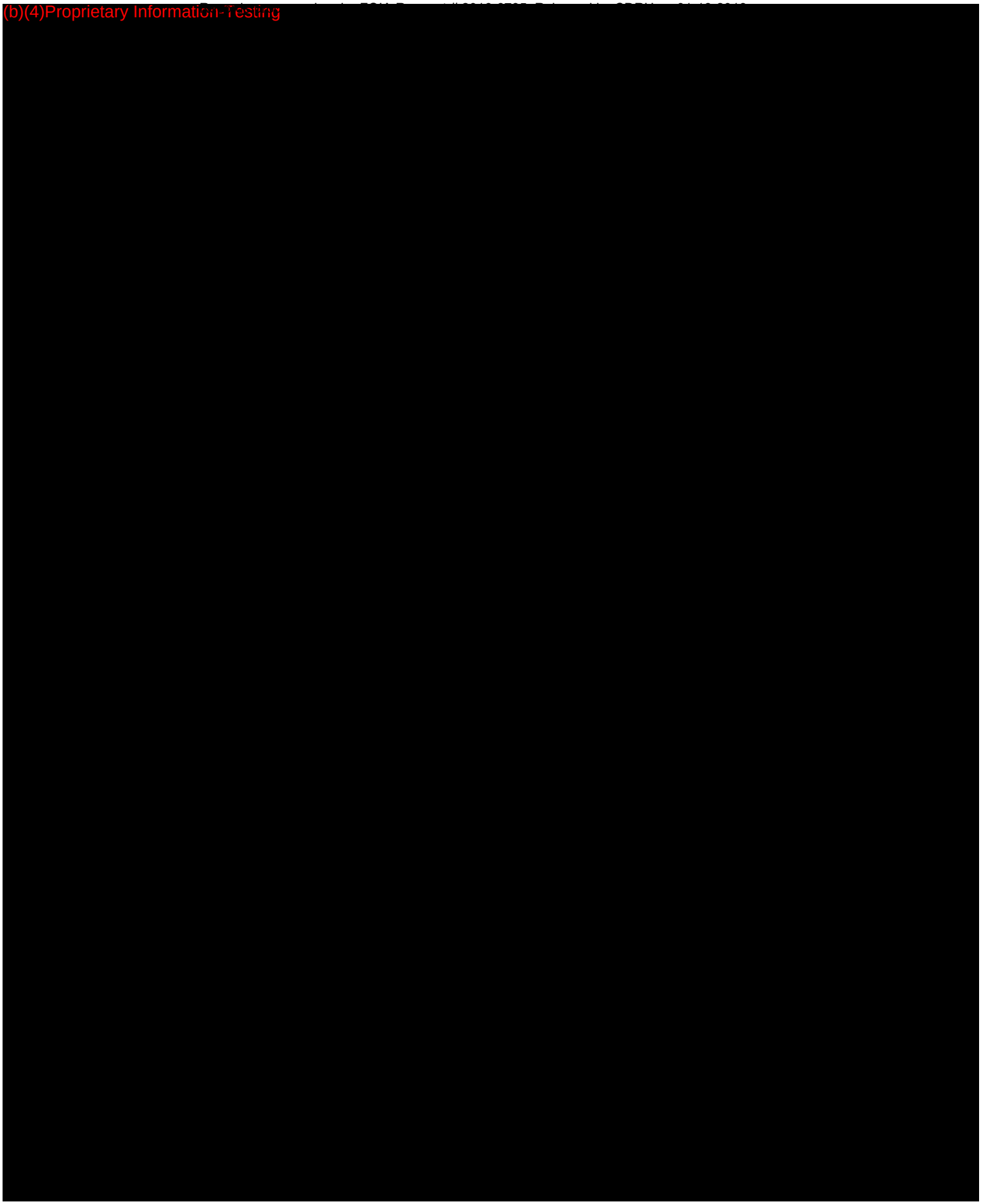




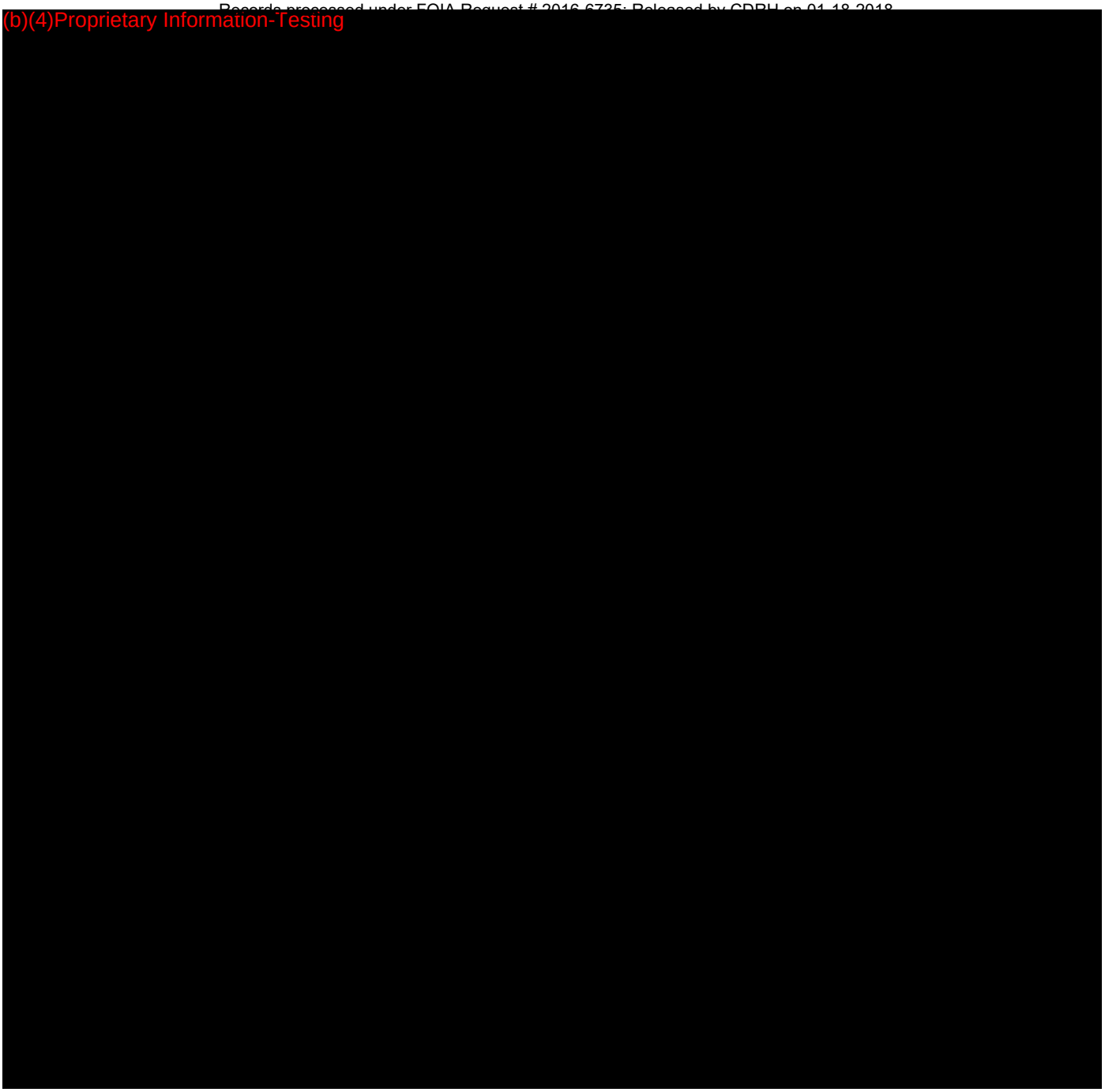
(b)(4)Proprietary Information-Testing



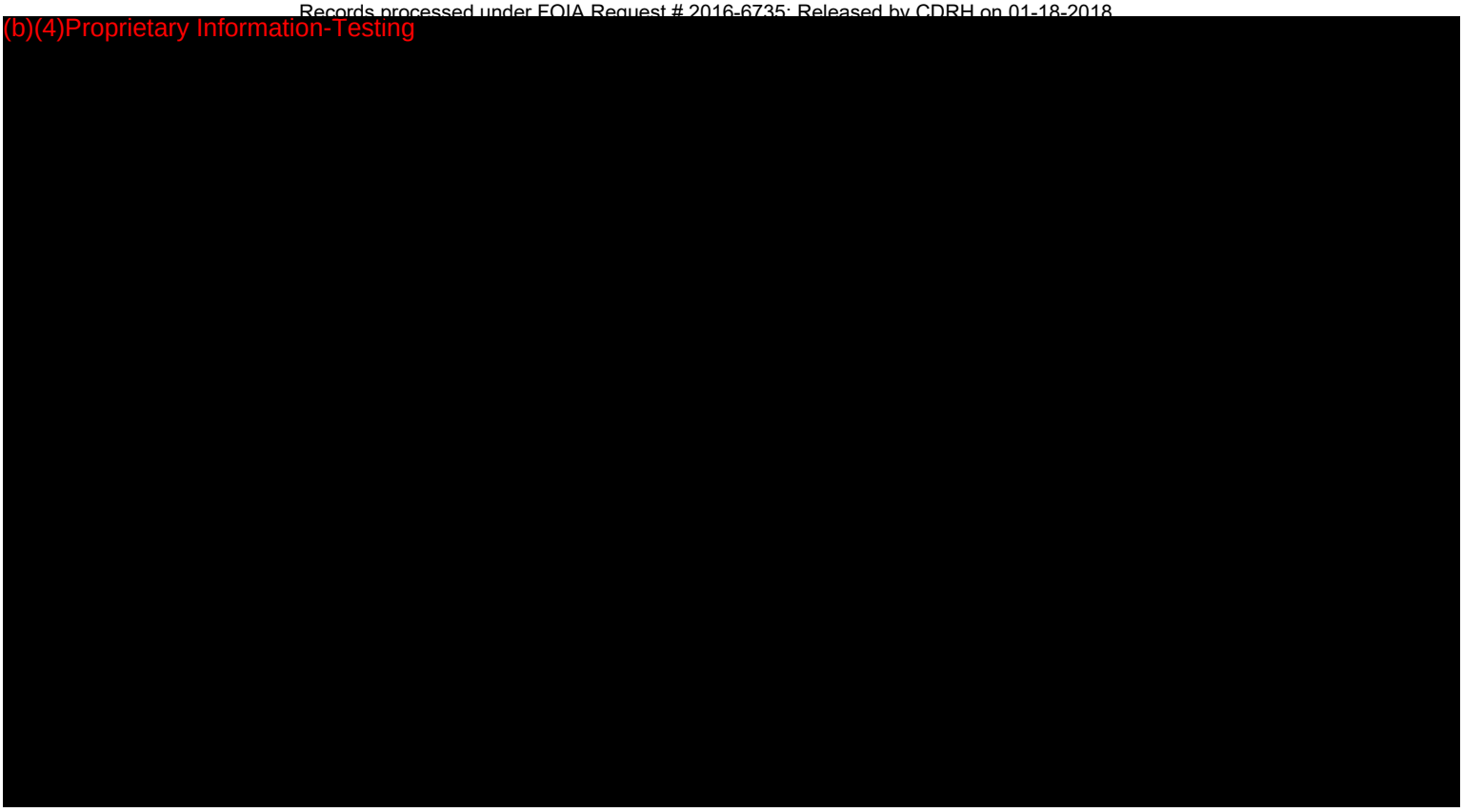
ATTACHMENT 25

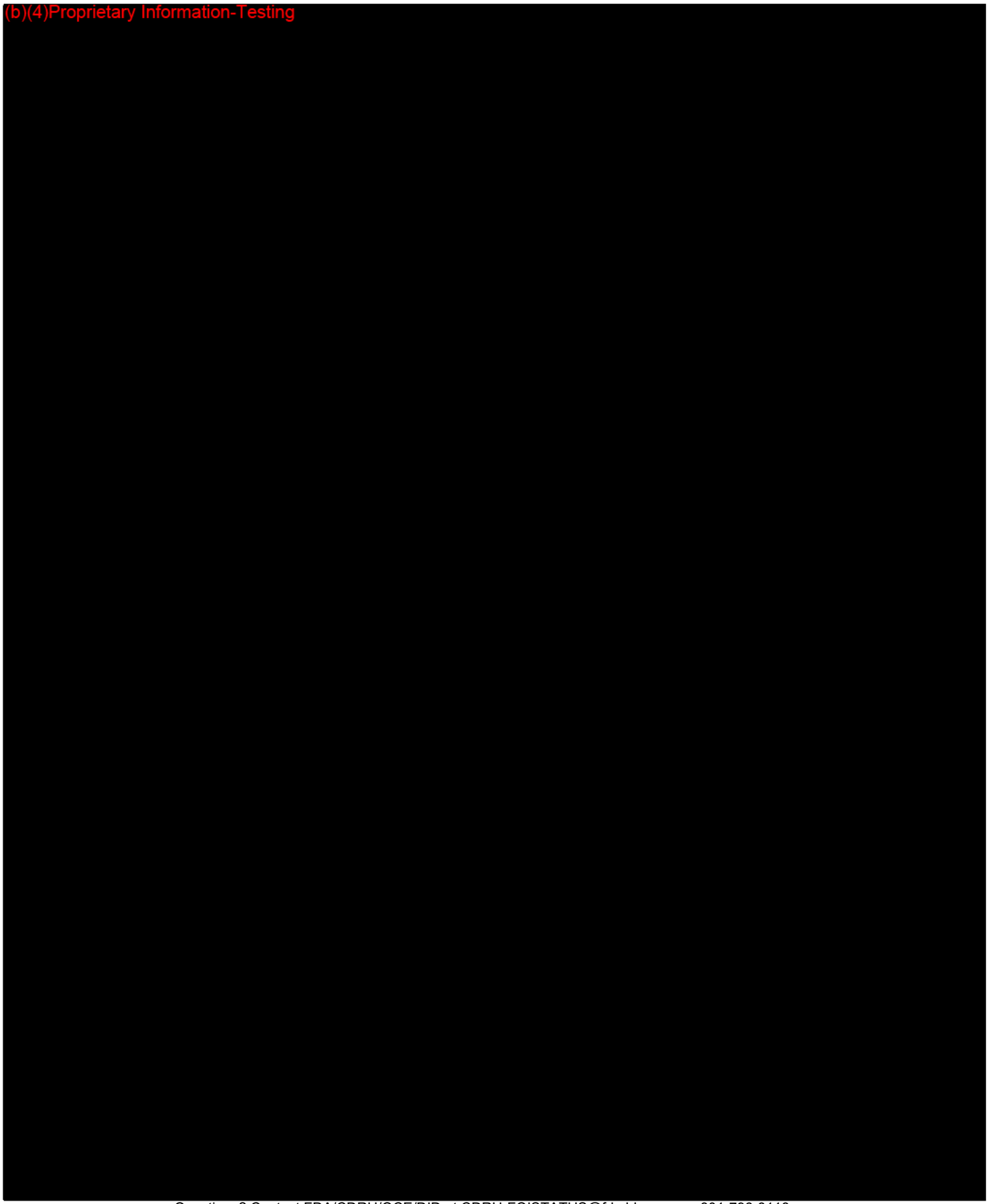


(b)(4)Proprietary Information-Testing



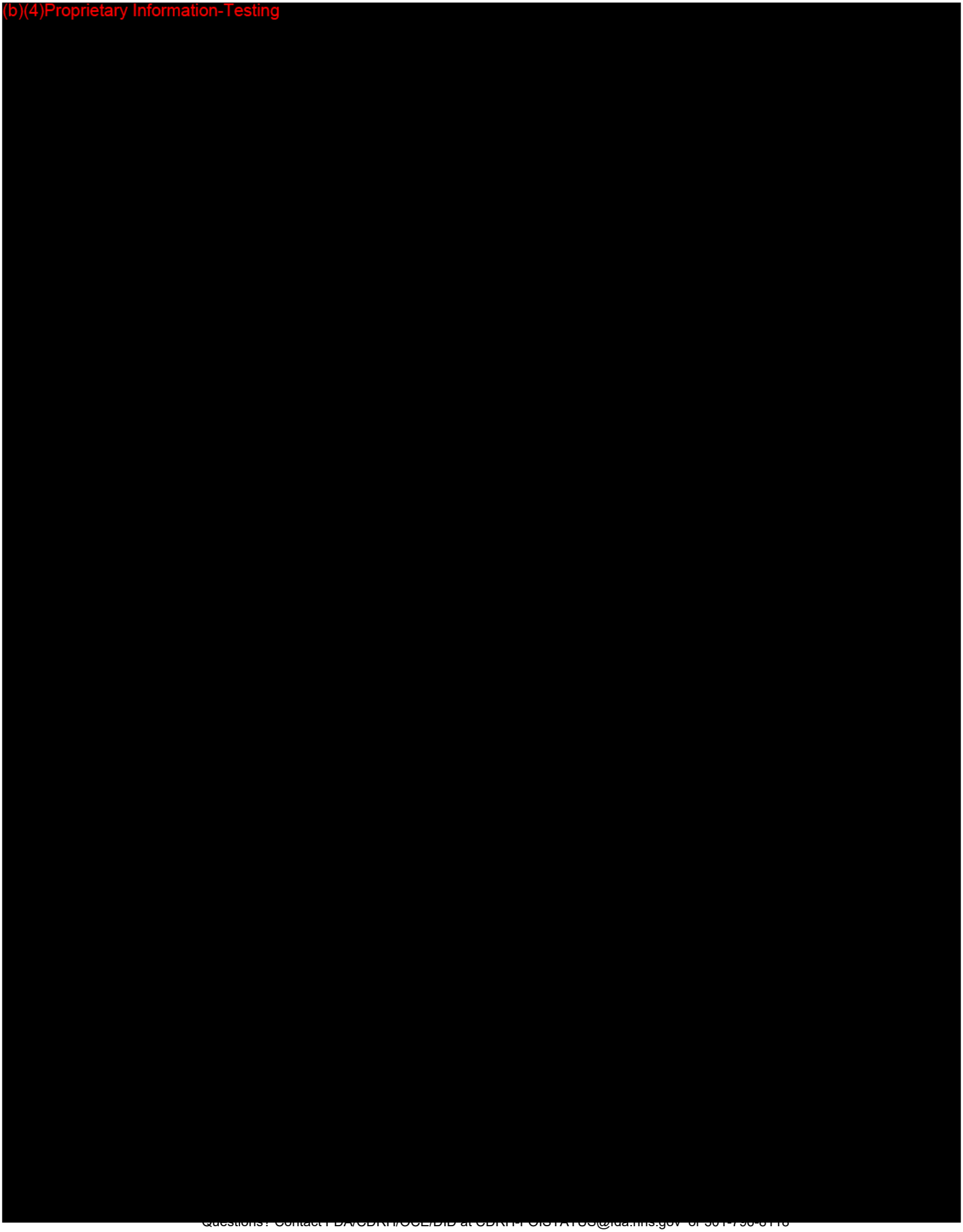
(b)(4)Proprietary Information-Testing

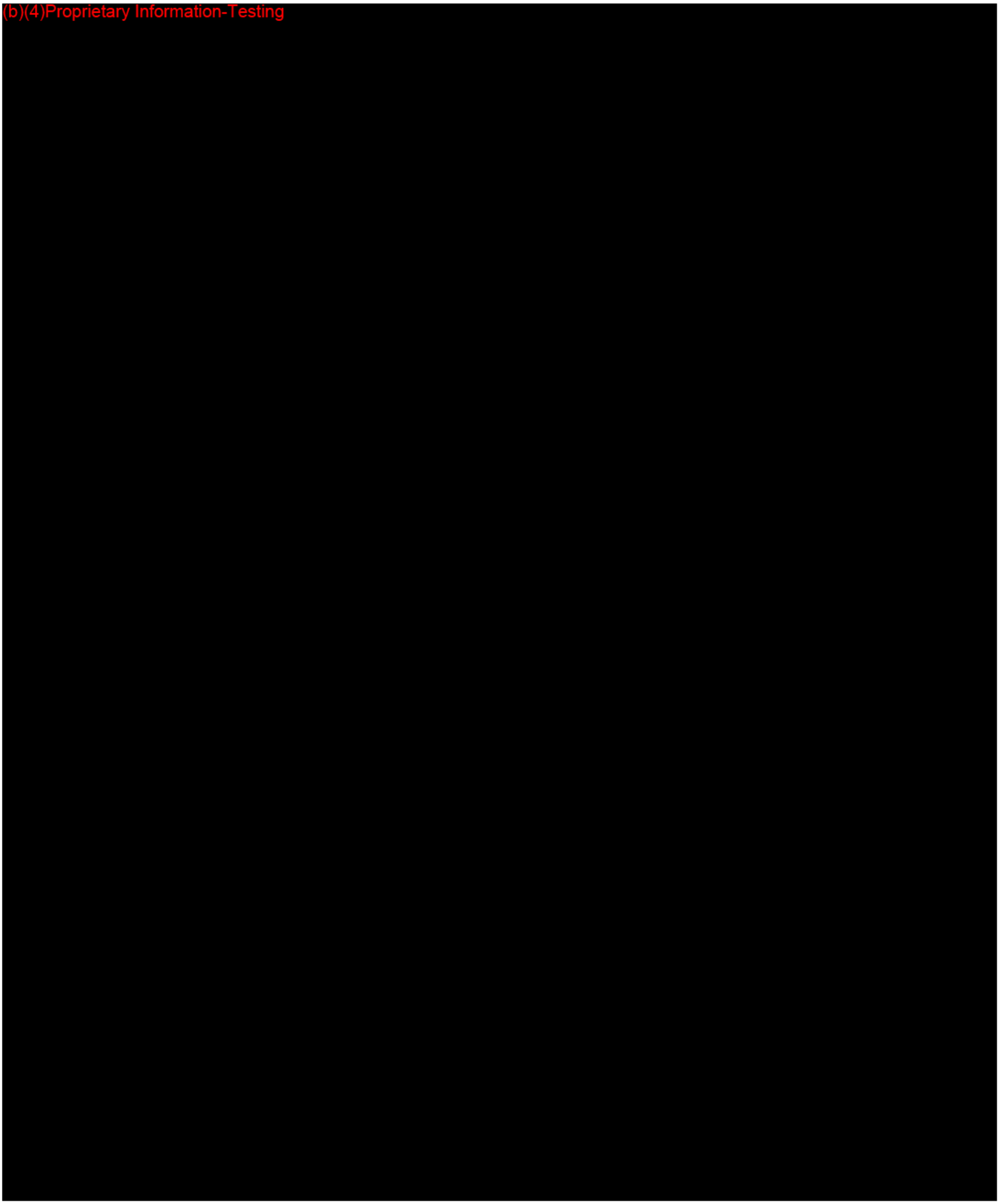


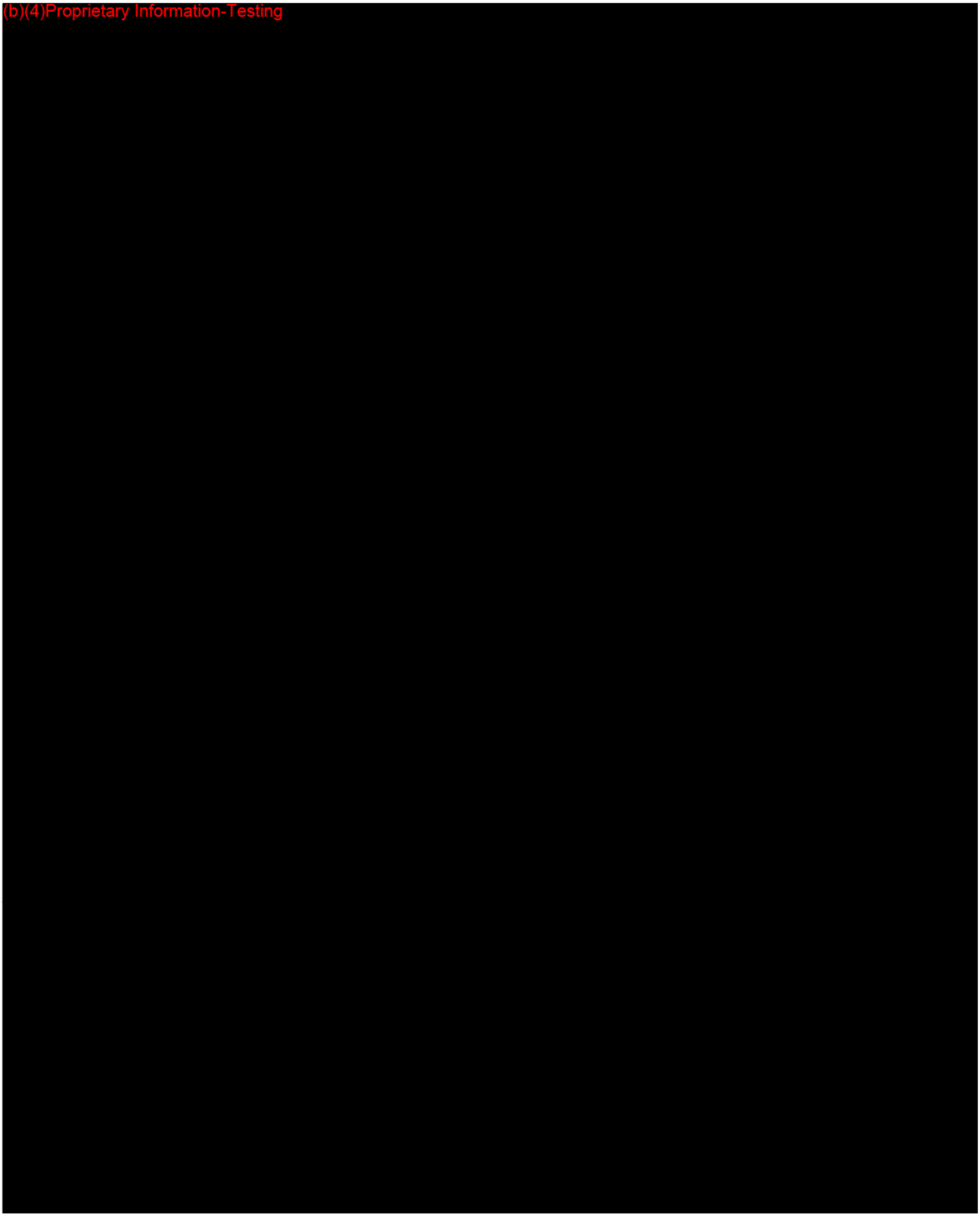


(b)(4)Proprietary Information-Testing

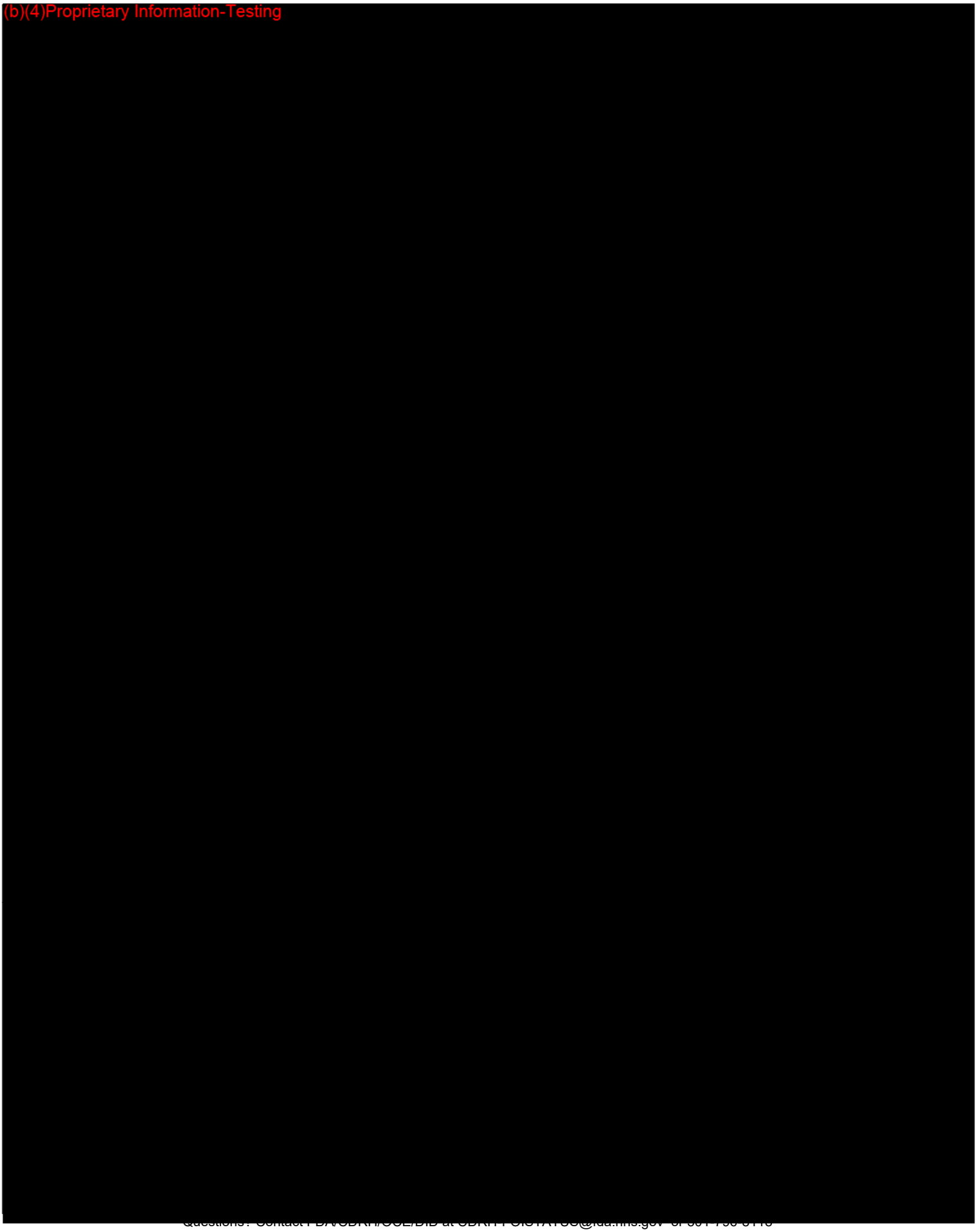
(b)(4)Proprietary Information-Testing



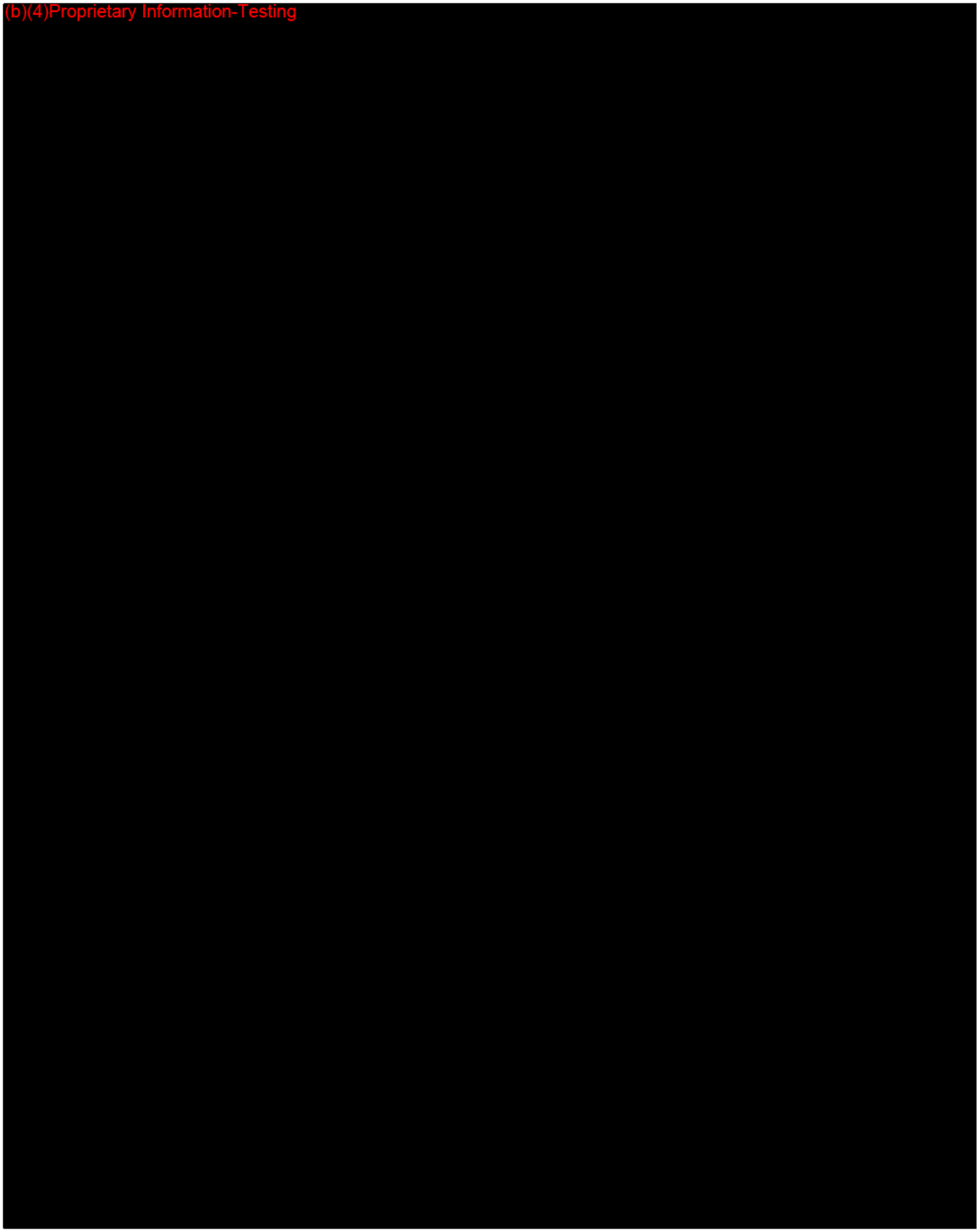


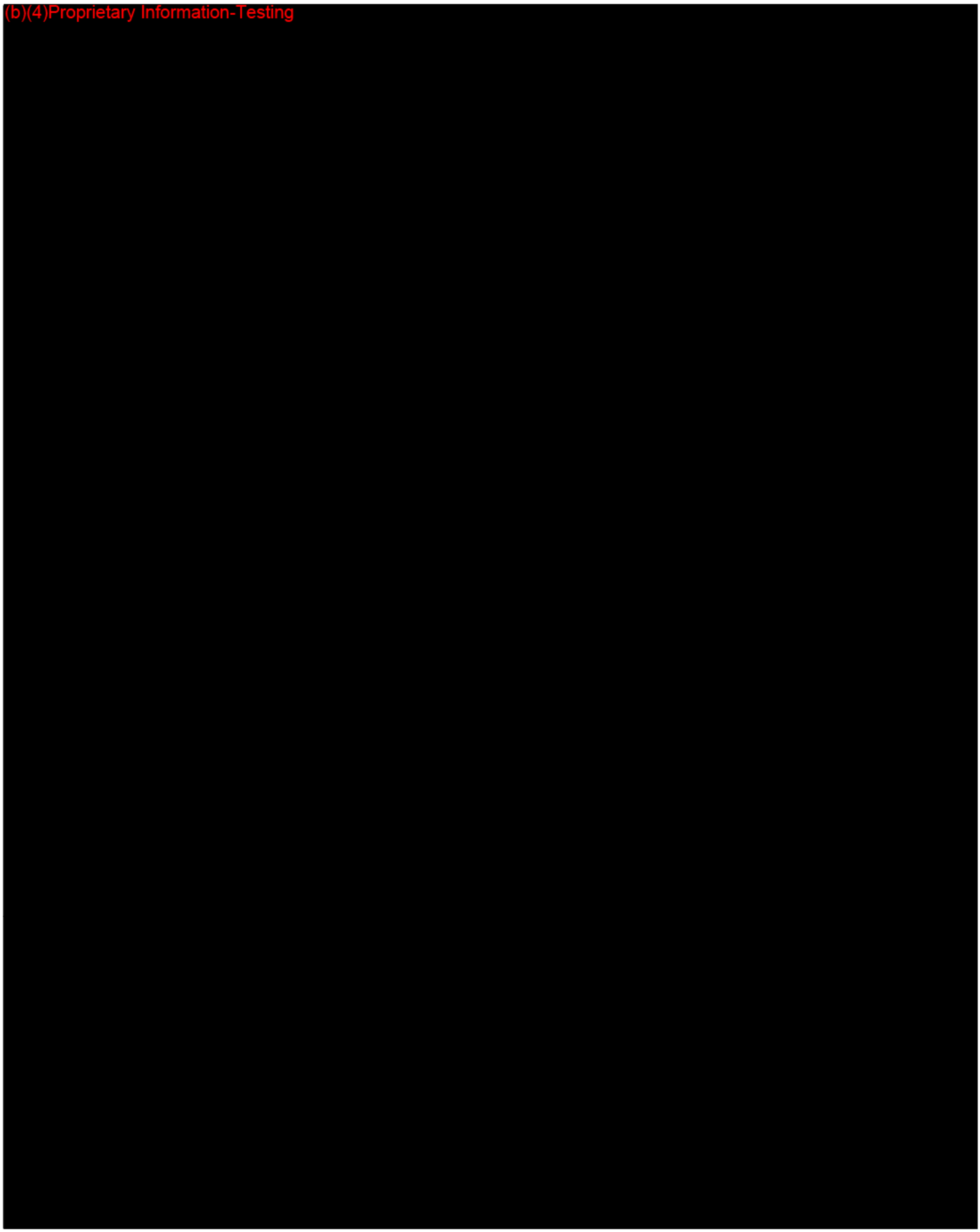


(b)(4)Proprietary Information-Testing

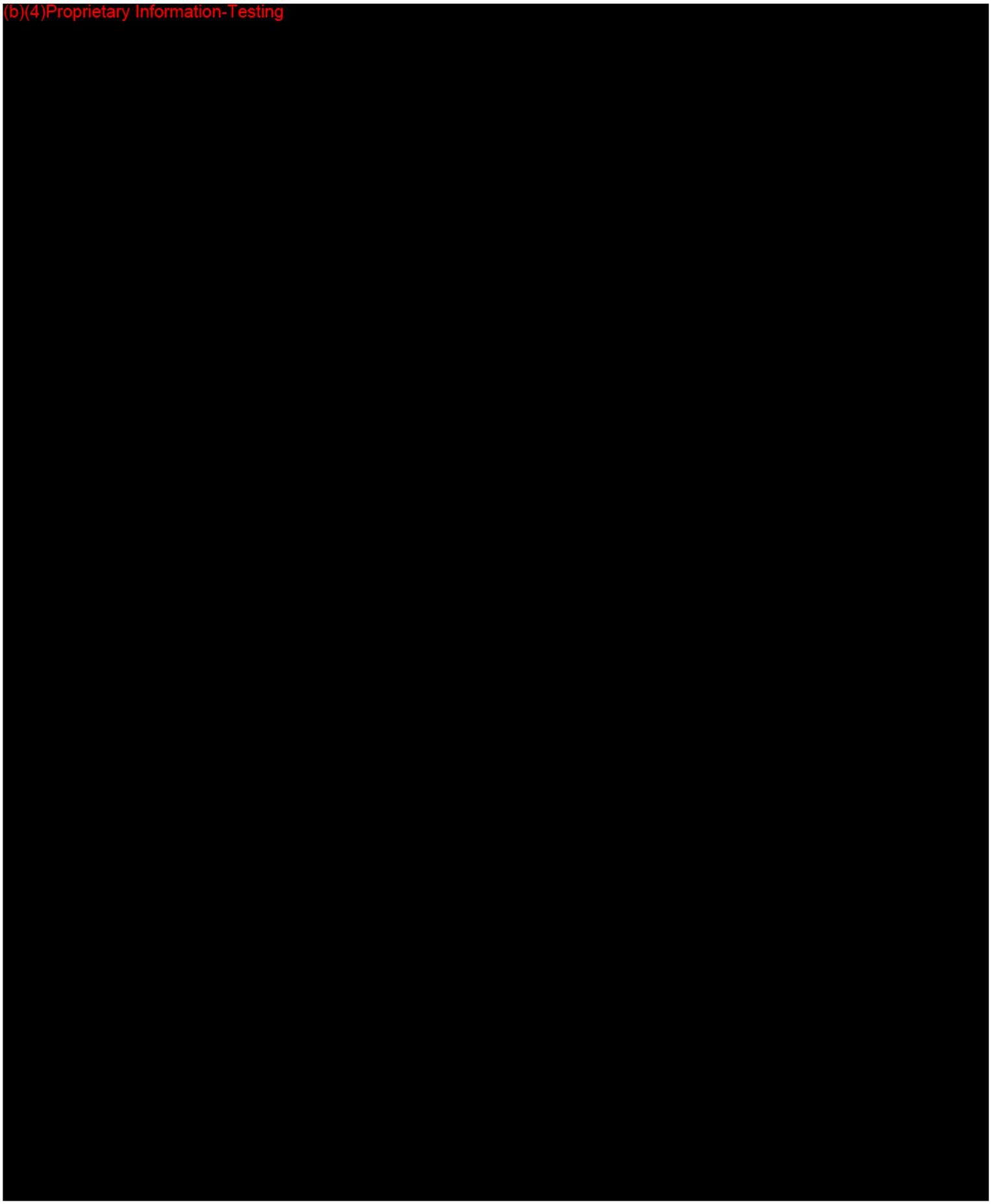


(b)(4)Proprietary Information-Testing

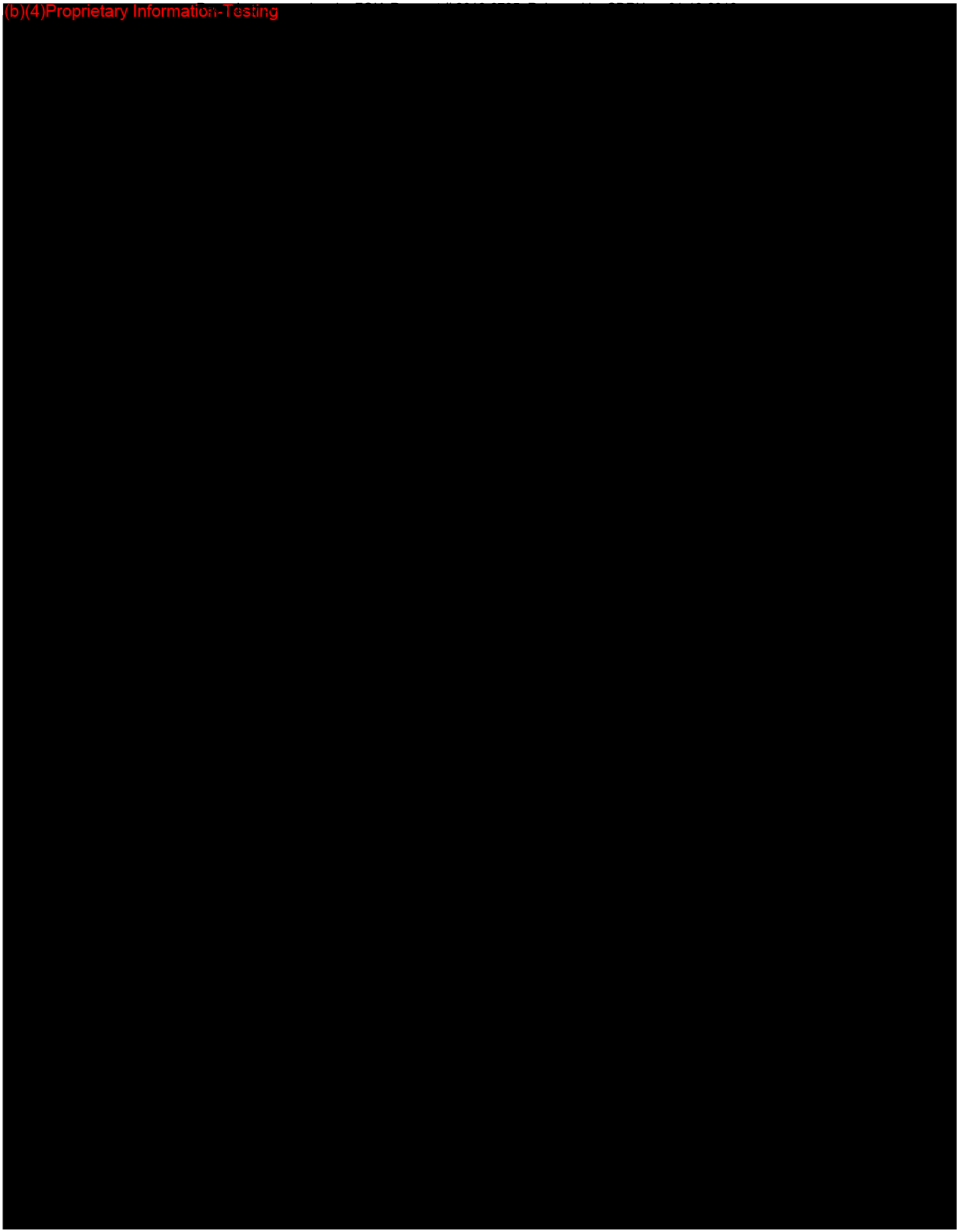




(b)(4)Proprietary Information-Testing

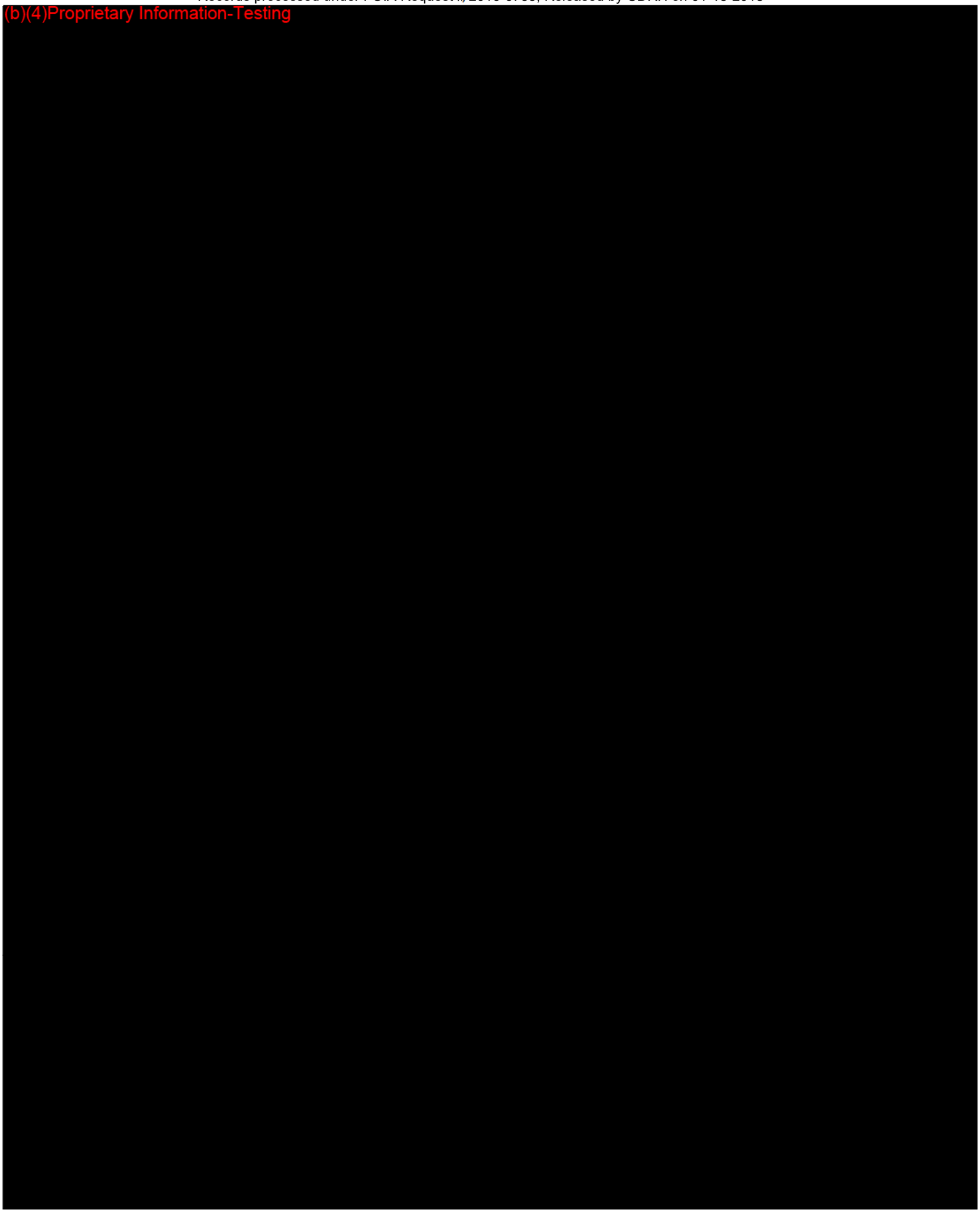


(b)(4)Proprietary Information-Testing

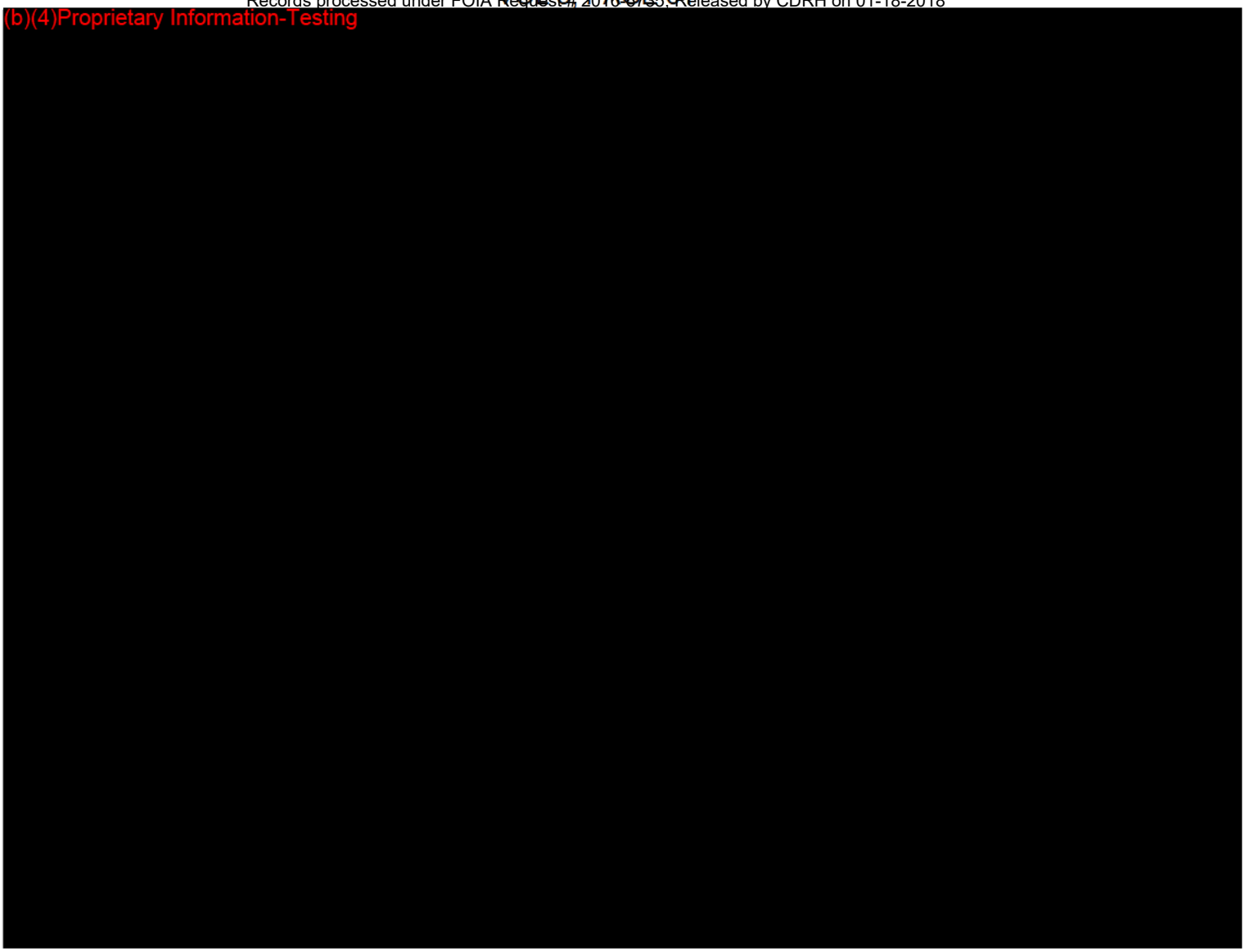


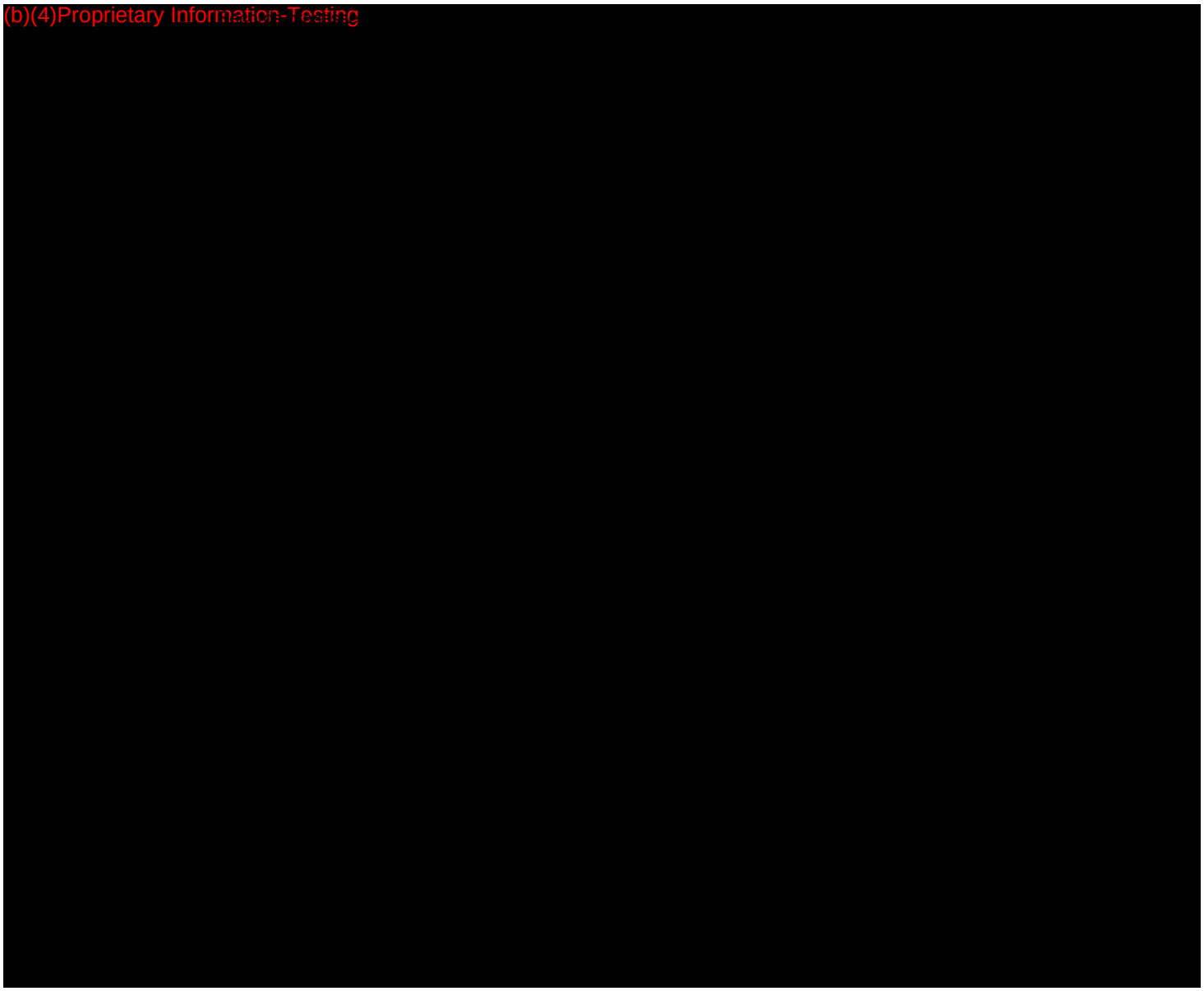
(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

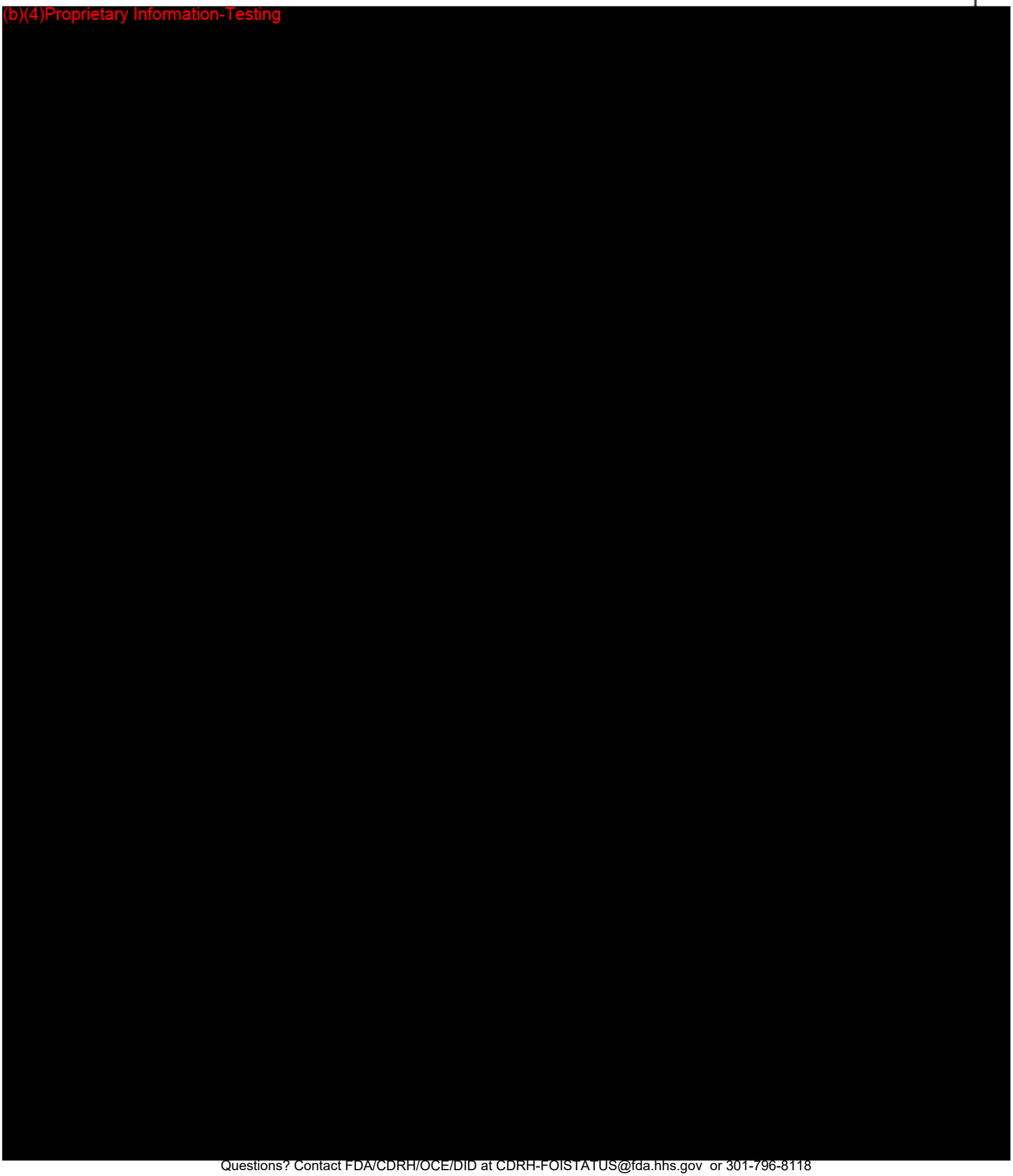


(b)(4)Proprietary Information-Testing

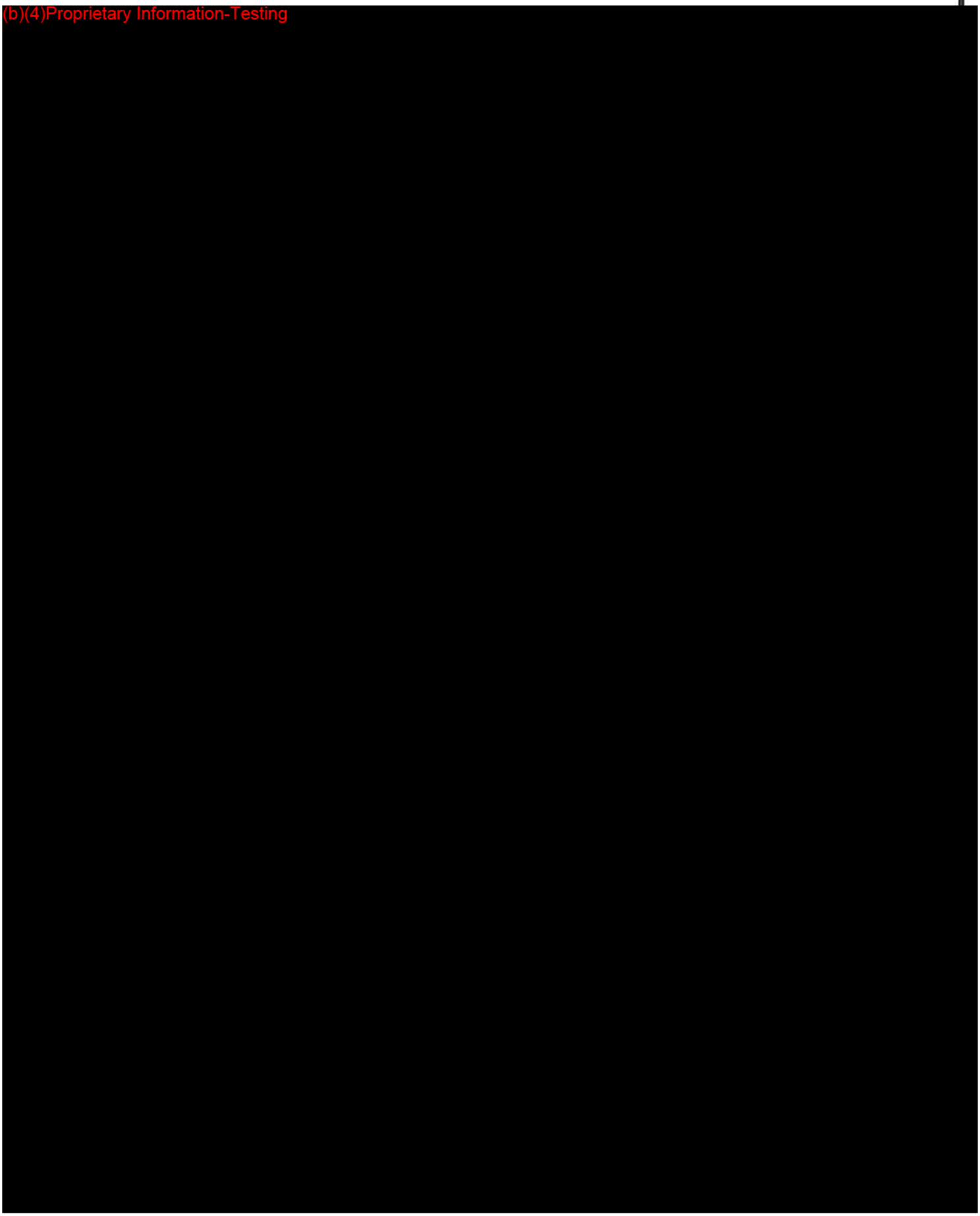



(b)(4)Proprietary Information-Testing

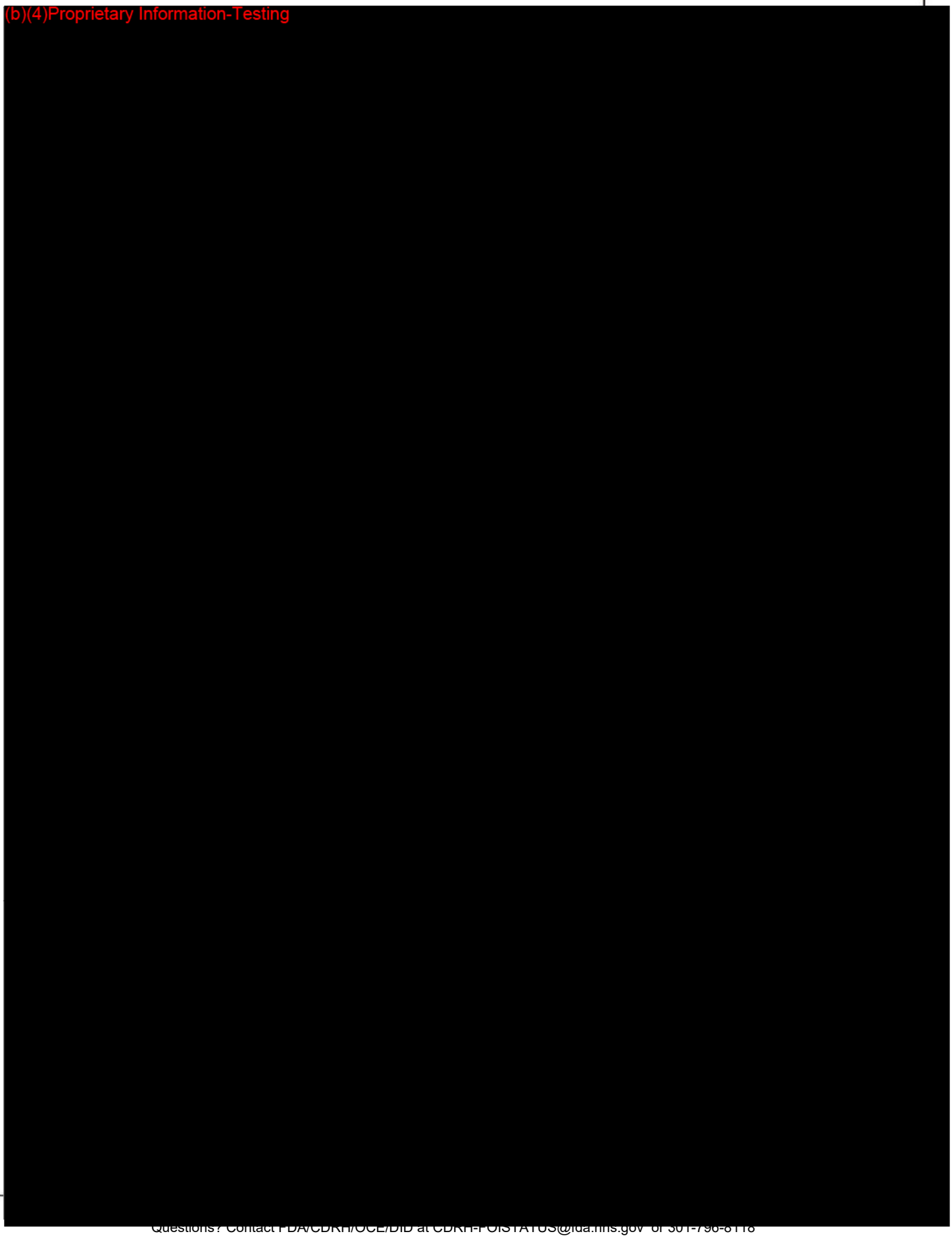
(b)(4)Proprietary Information-Testing



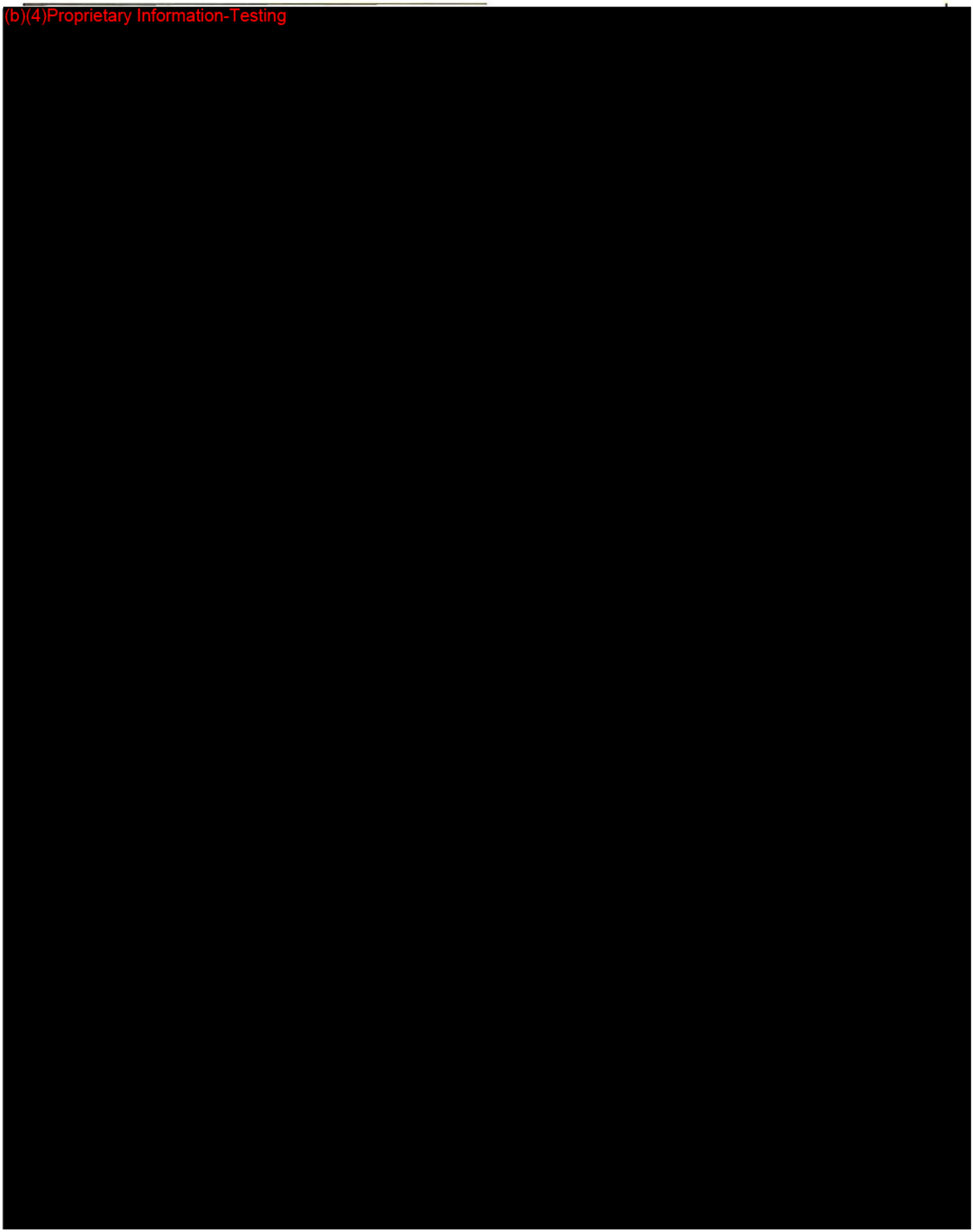
(b)(4)Proprietary Information-Testing



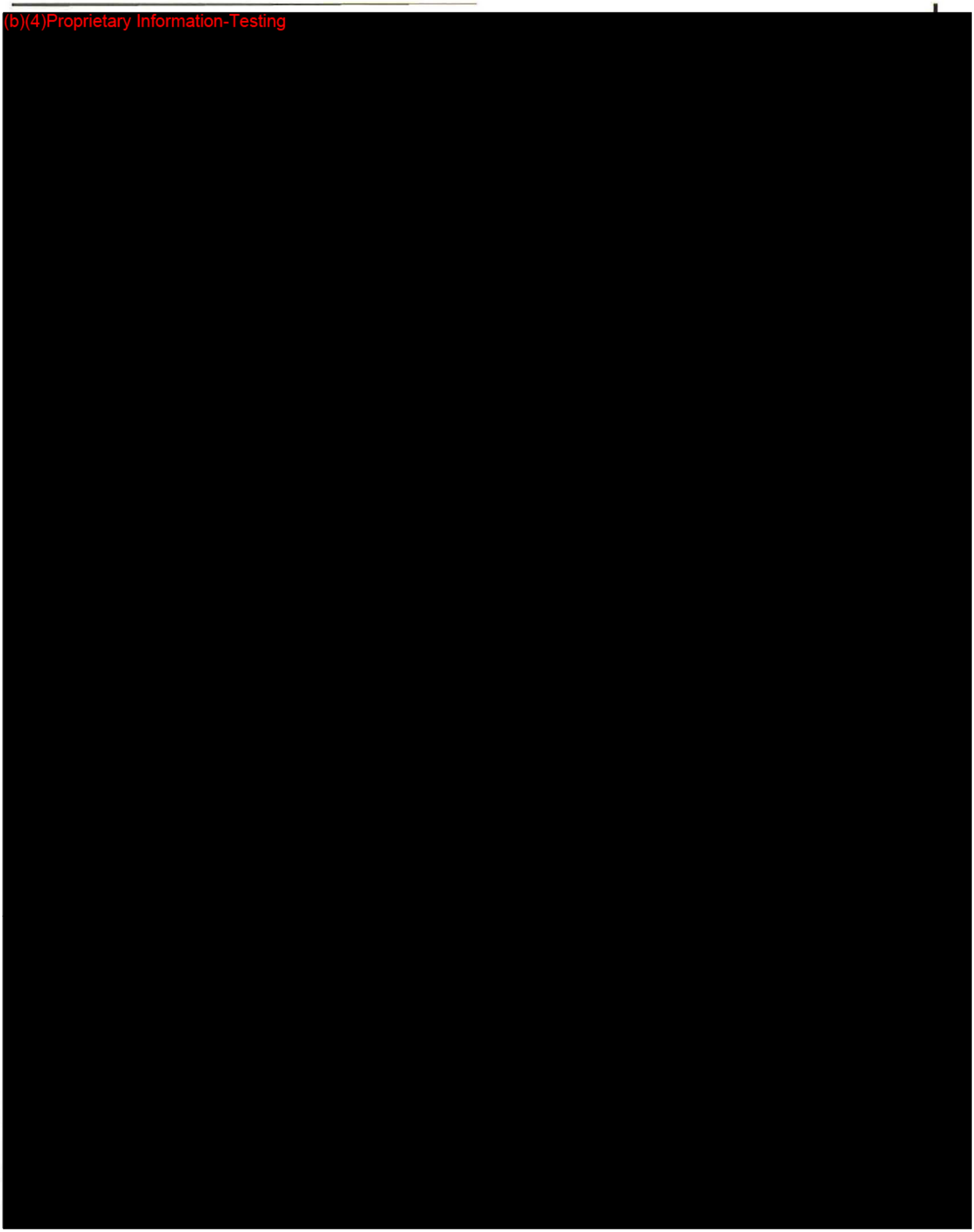
(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing

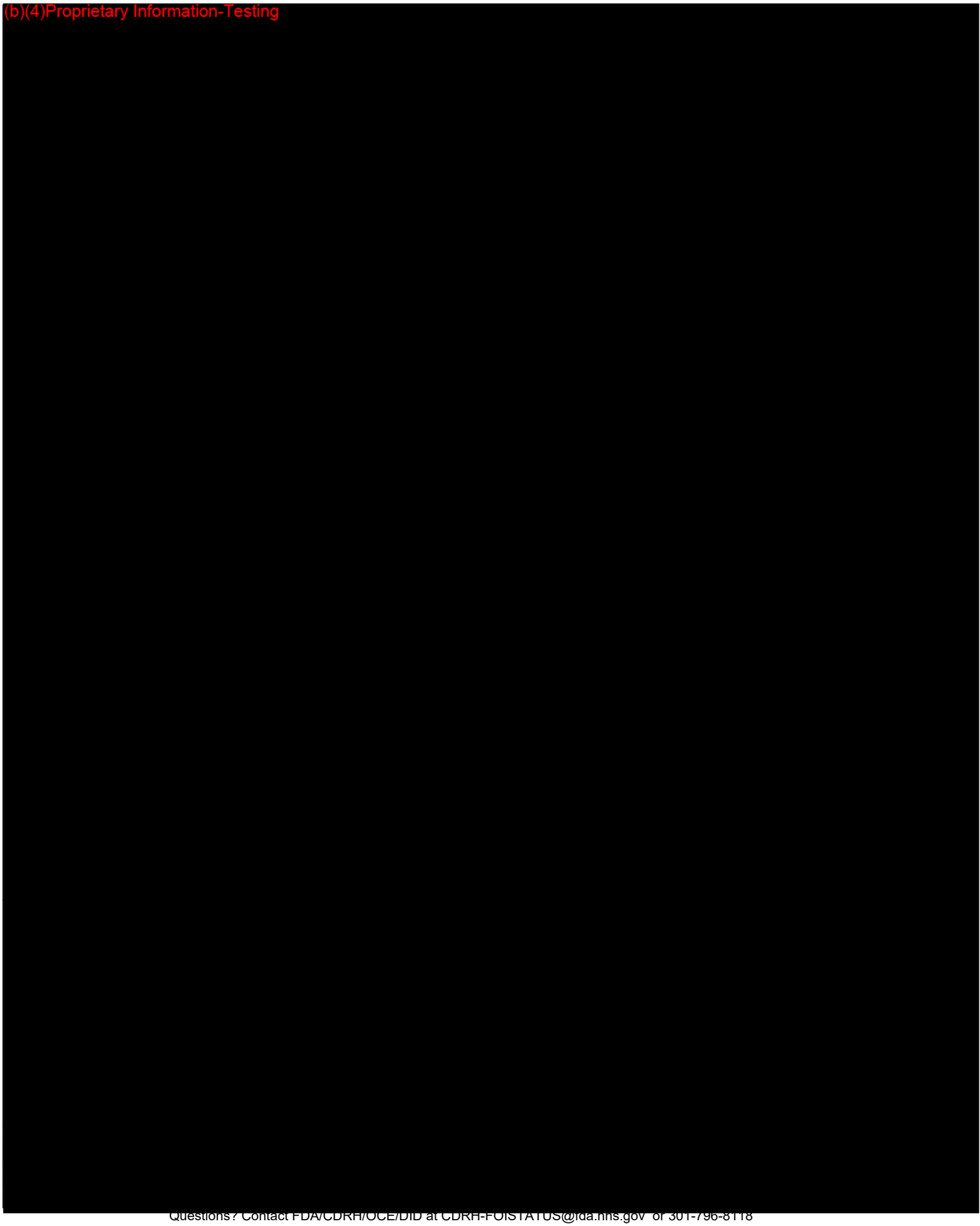


(b)(4)Proprietary Information-Testing

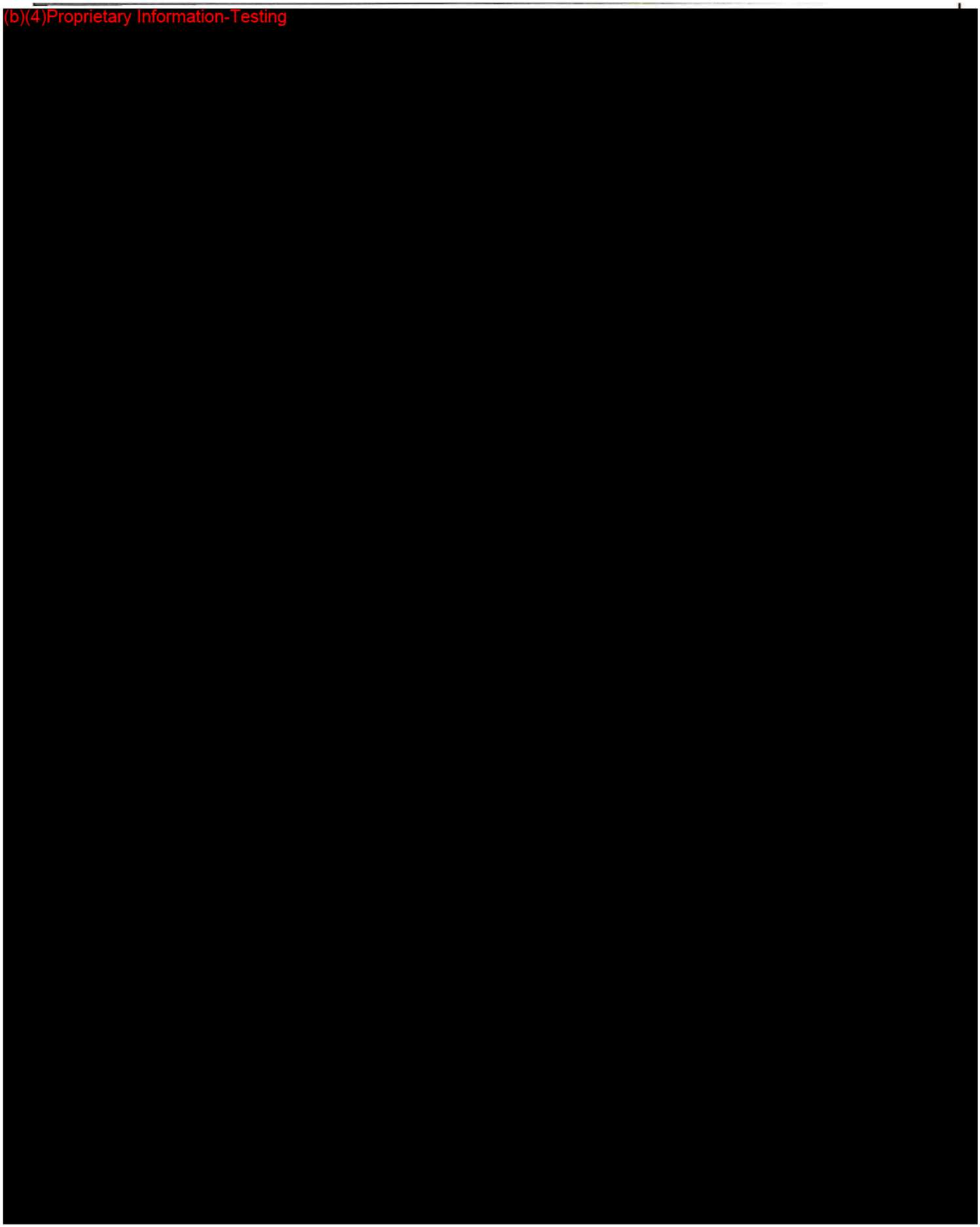


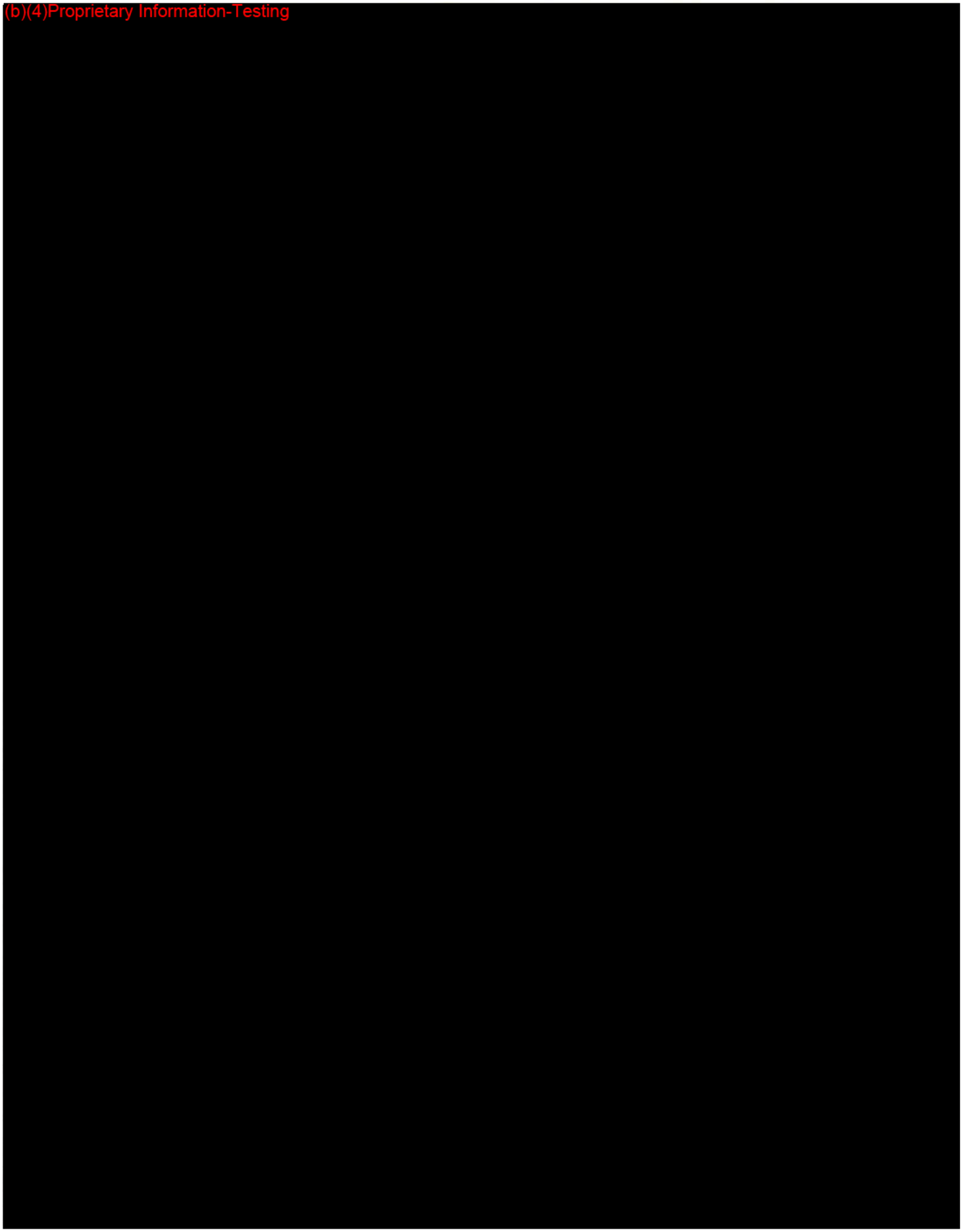
(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

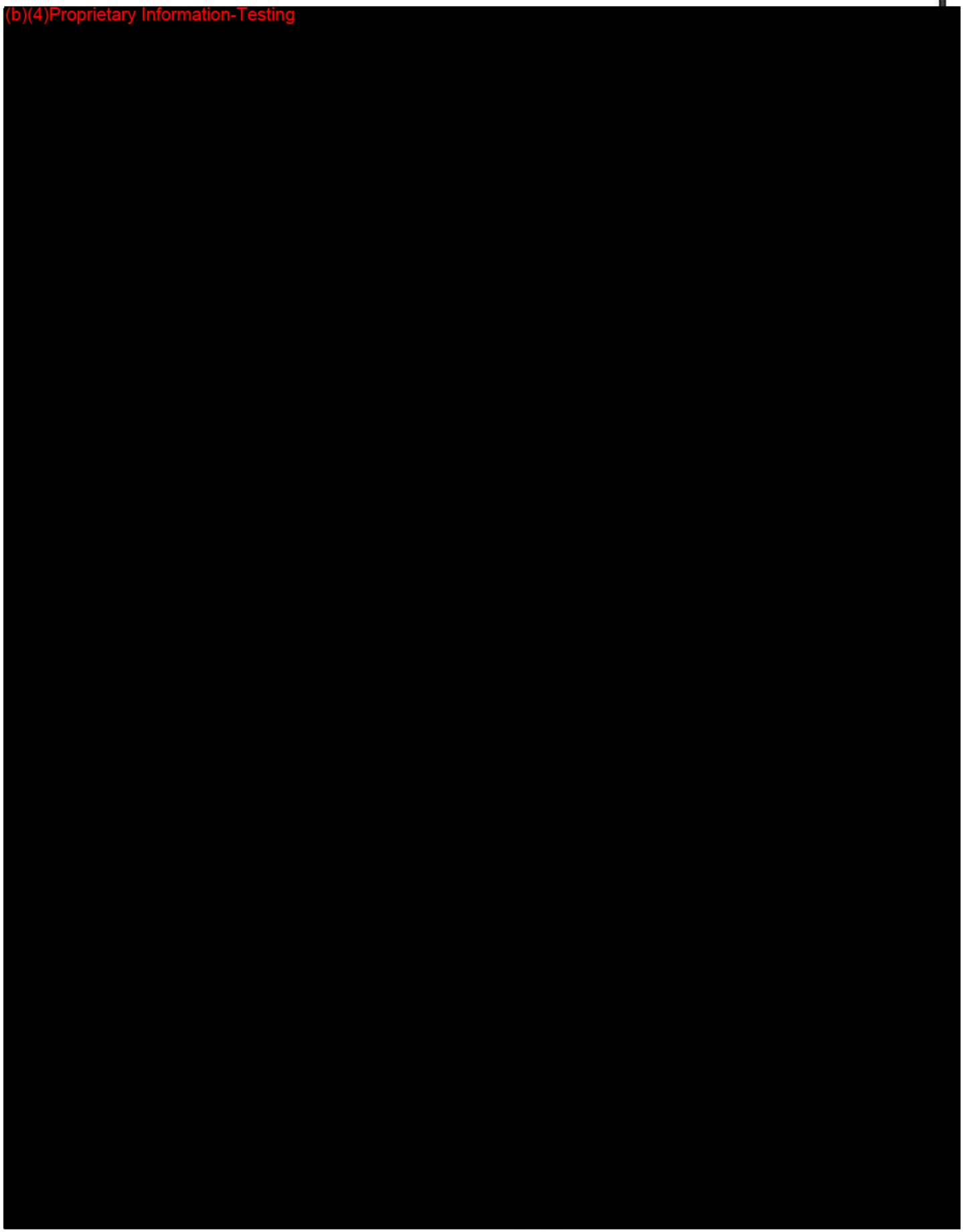


(b)(4)Proprietary Information-Testing





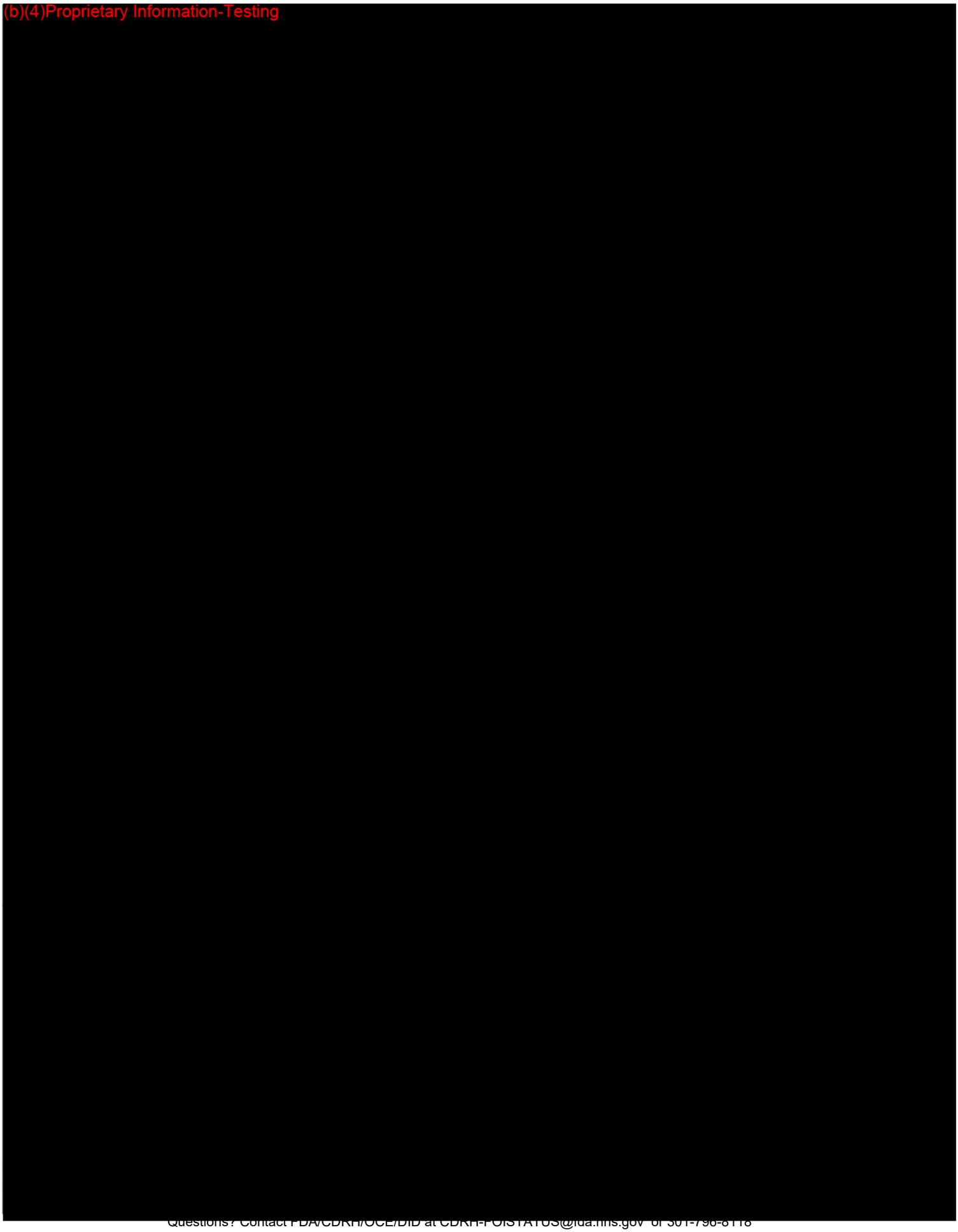
(b)(4)Proprietary Information-Testing



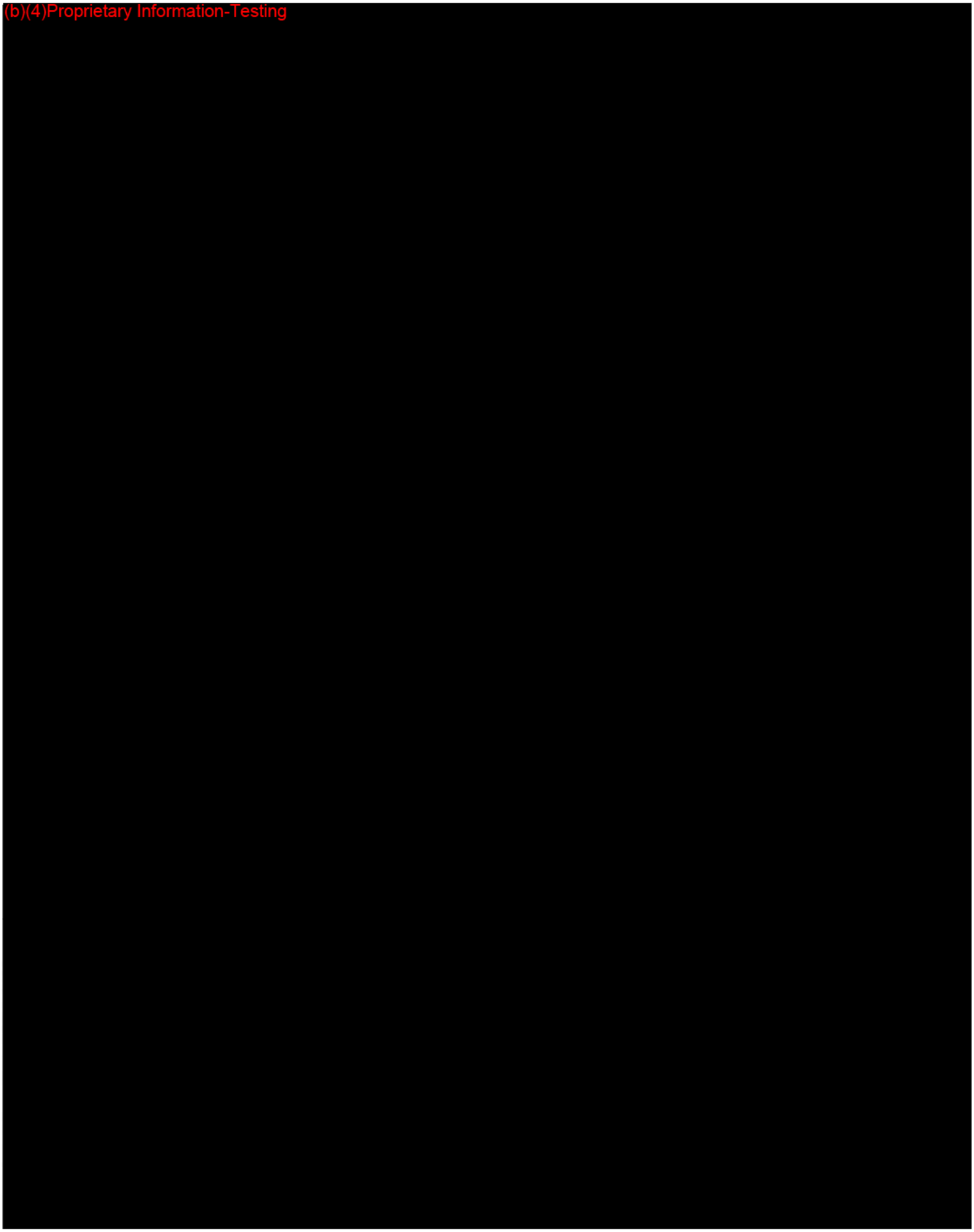
(b)(4)Proprietary Information-Testing

[redacted]

(b)(4)Proprietary Information-Testing

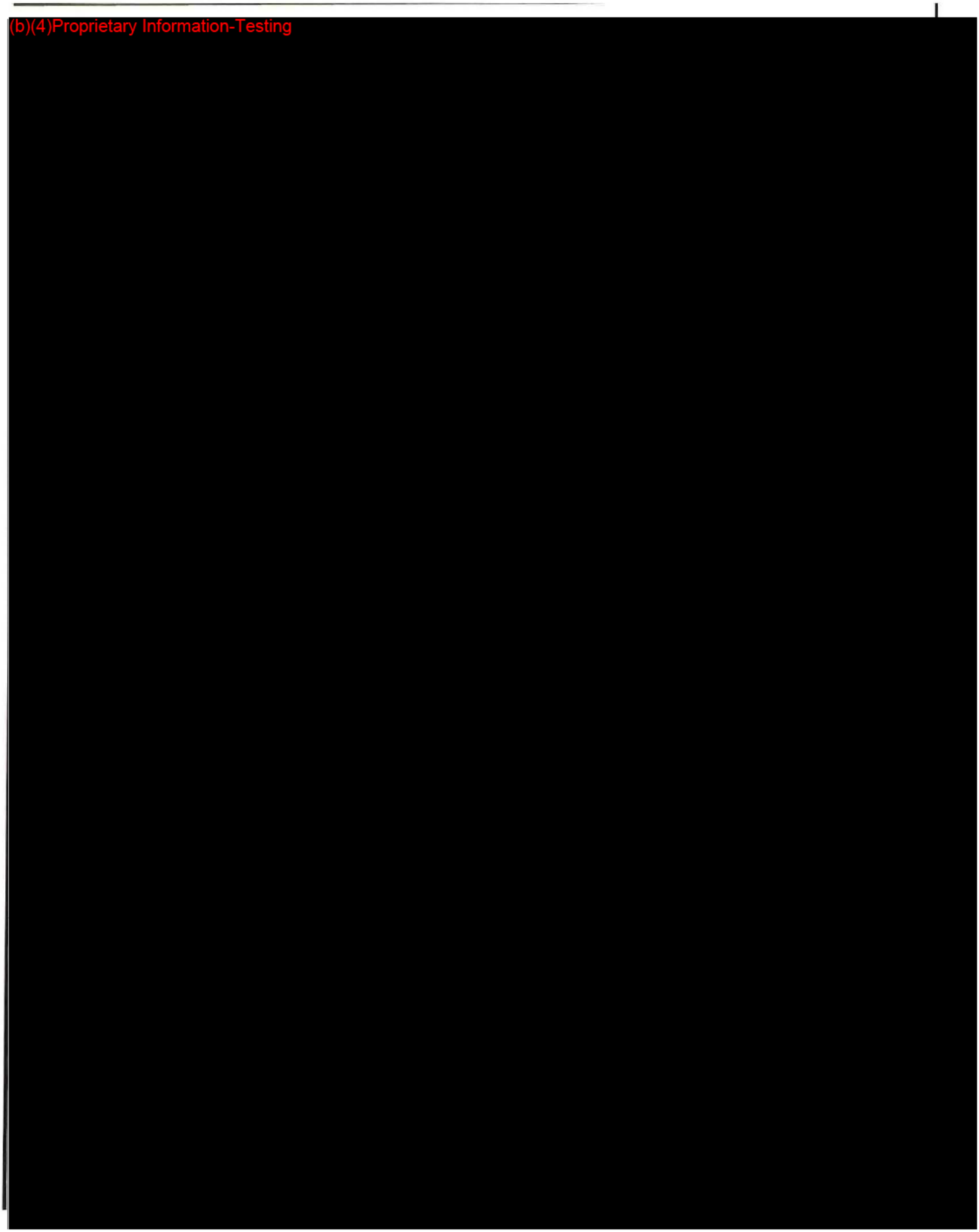


(b)(4)Proprietary Information-Testing



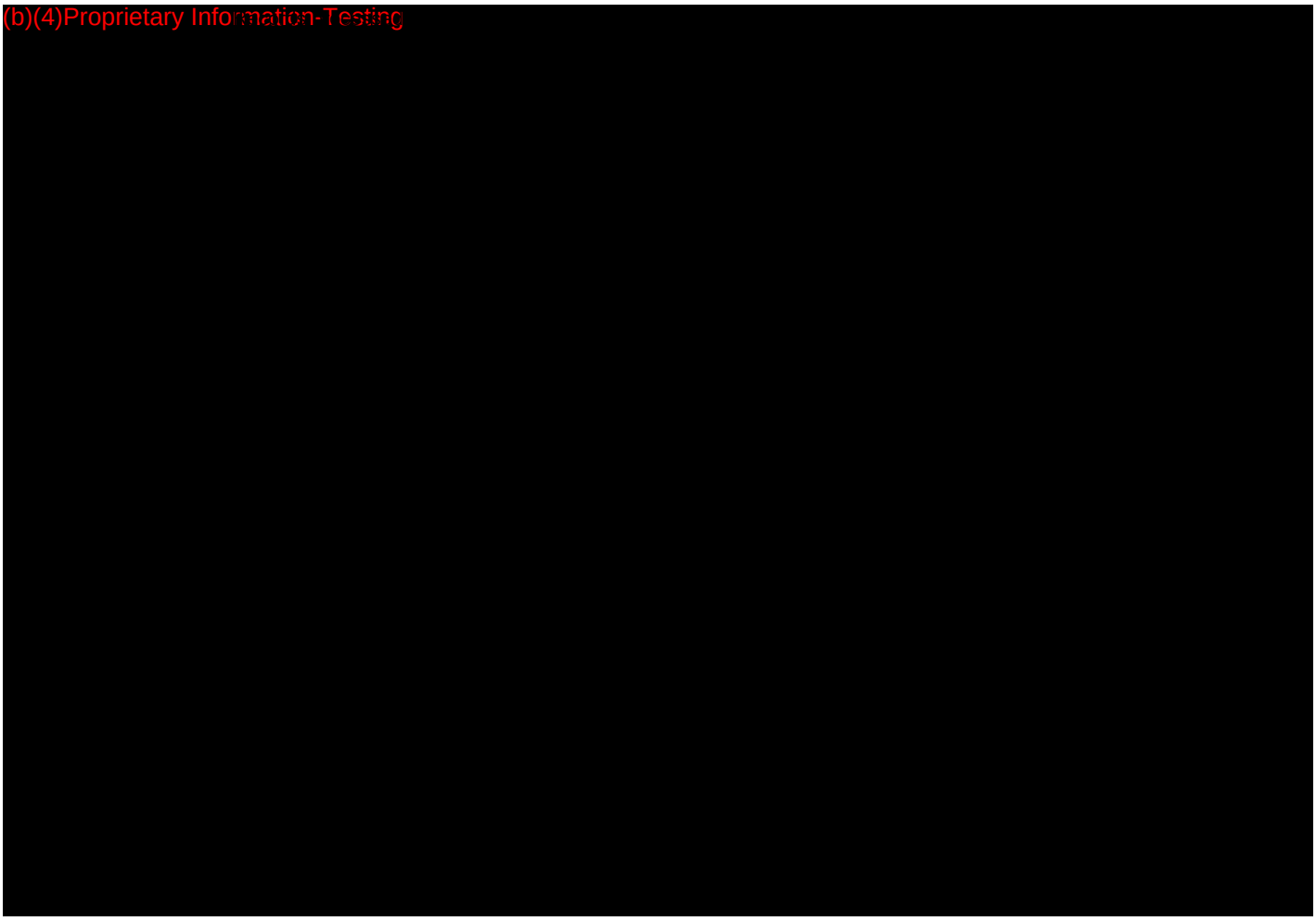
(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

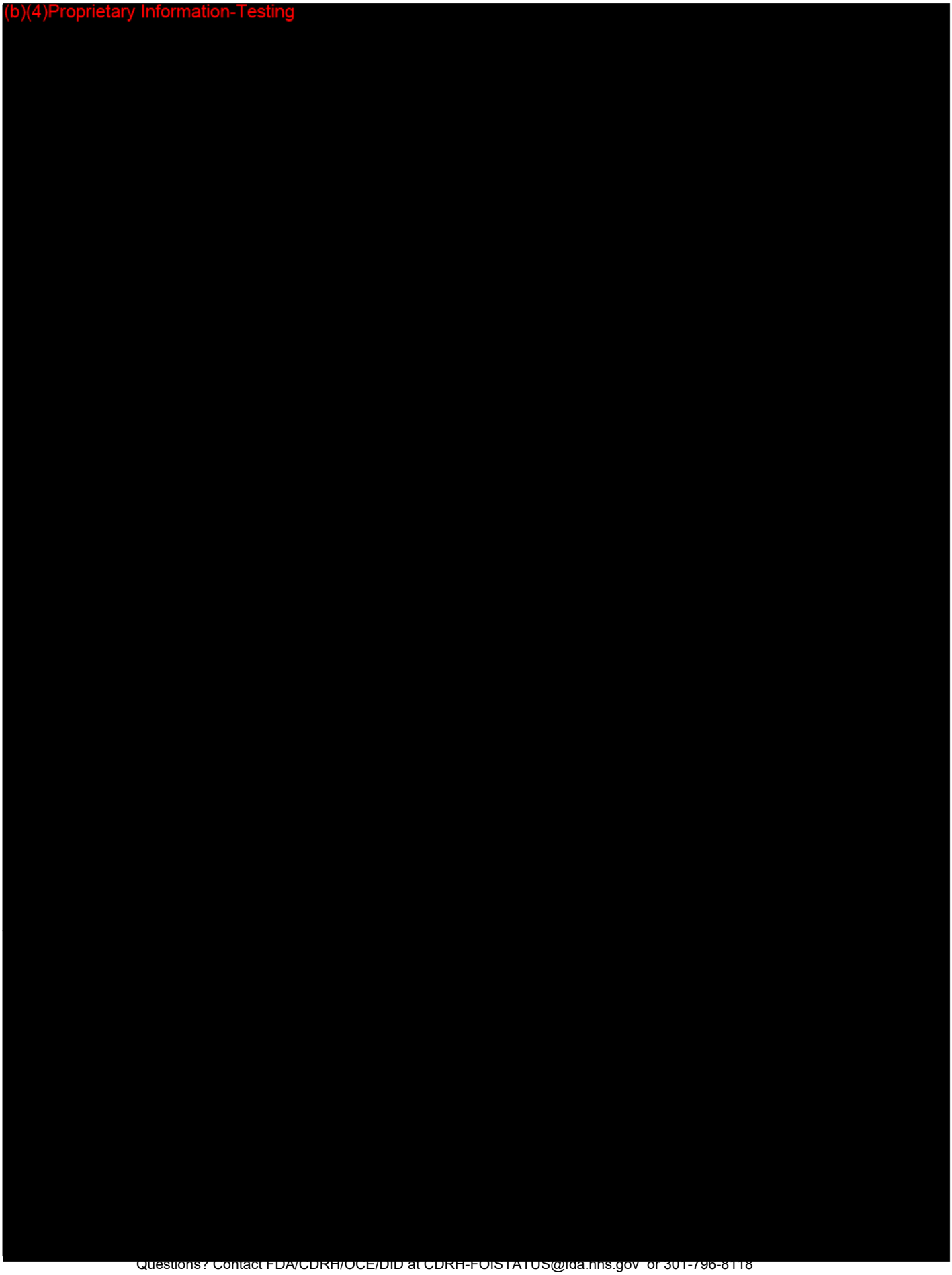


(b)(4)Proprietary Information-Testing

[redacted]

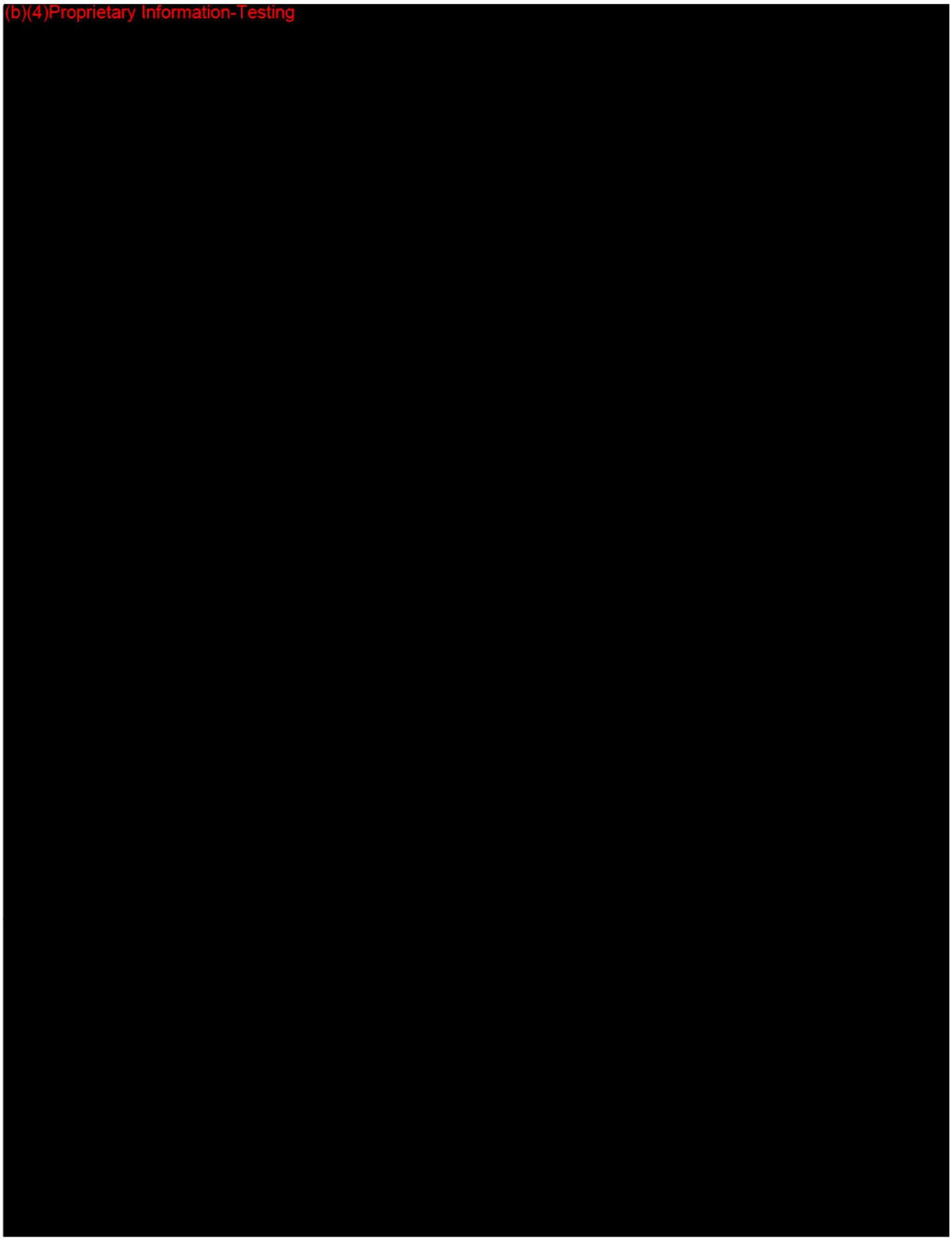

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

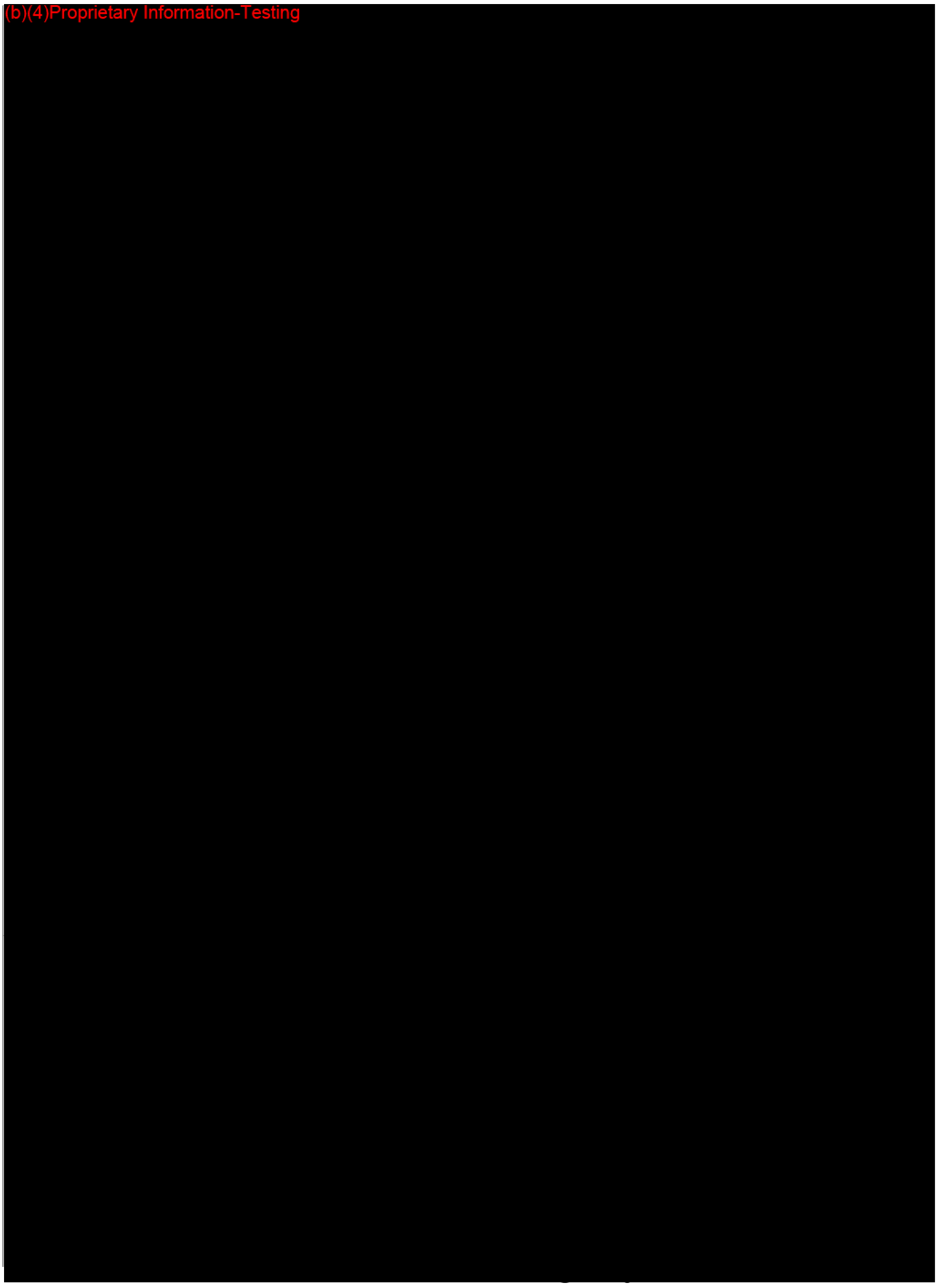


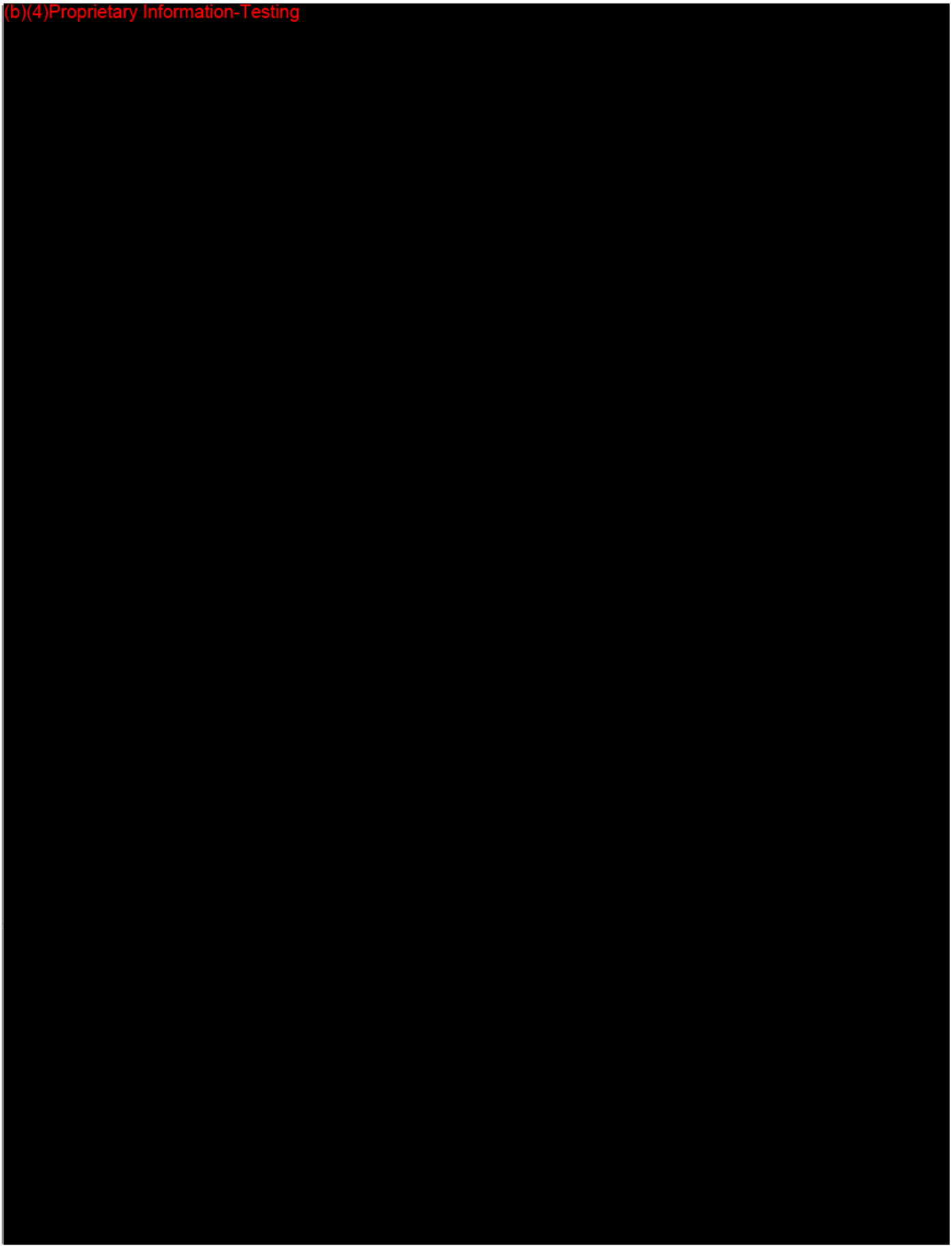
(b)(4)Proprietary Information-Testing

[redacted]

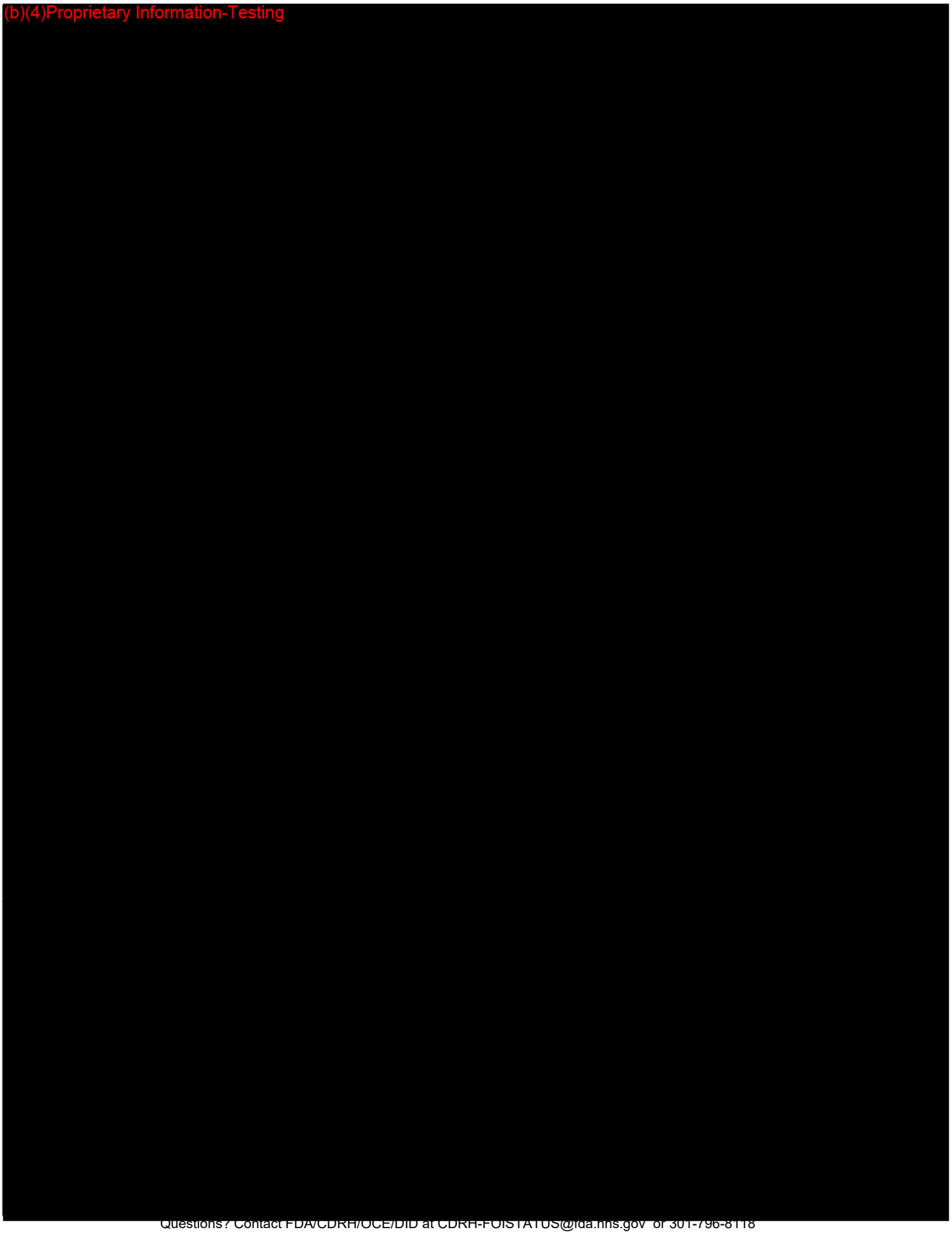


(b)(4)Proprietary Information-Testing

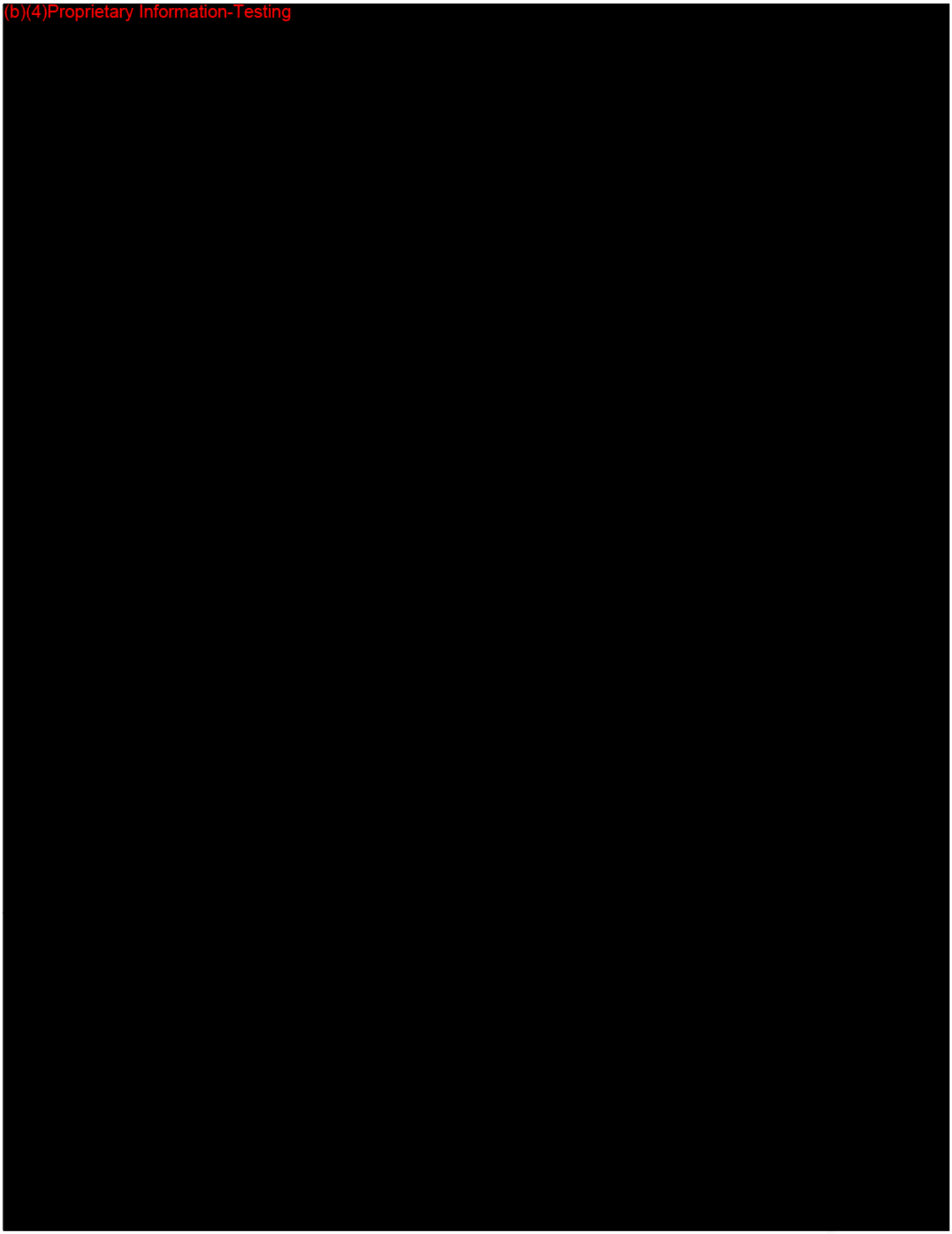


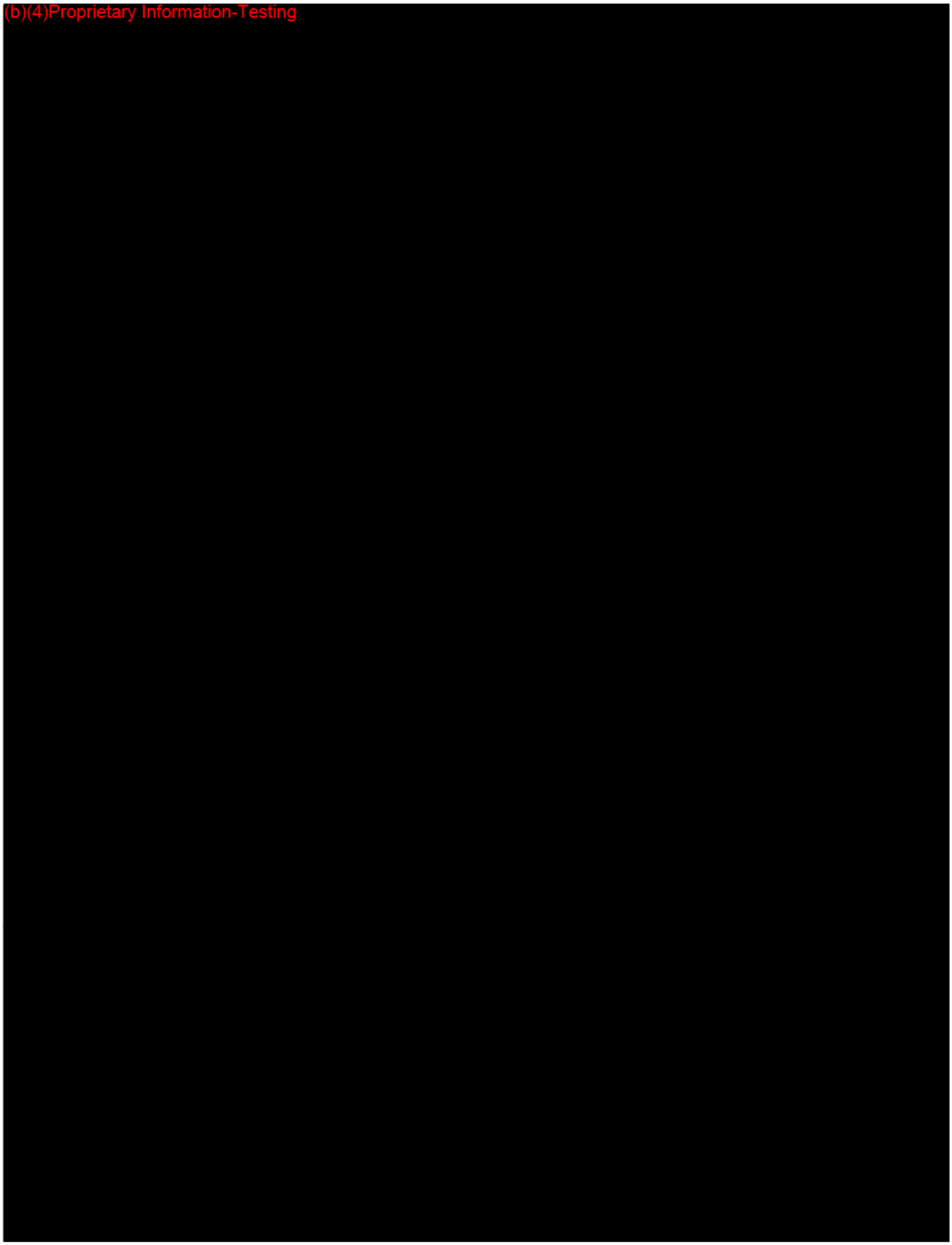


(b)(4)Proprietary Information-Testing

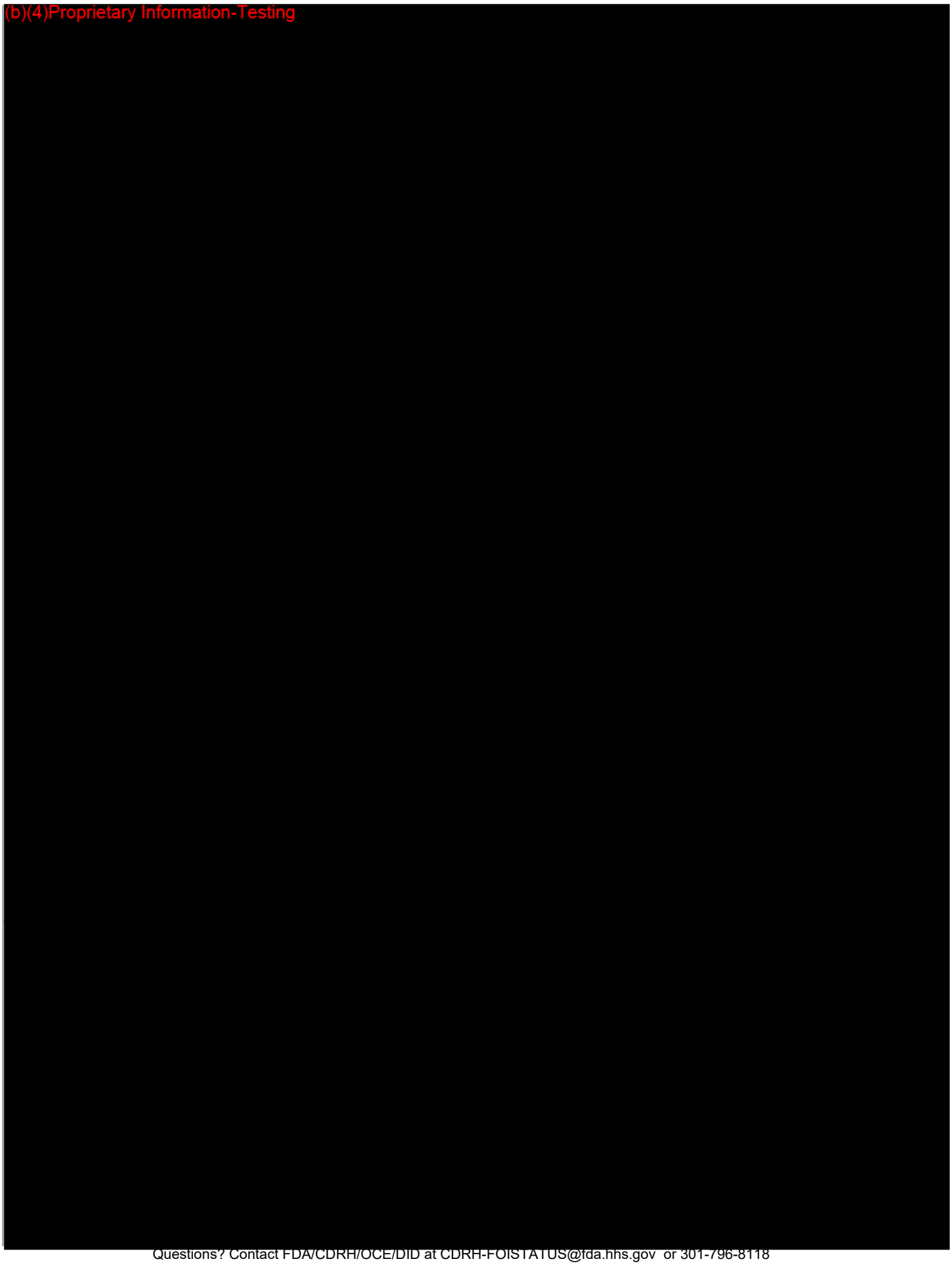


(b)(4)Proprietary Information-Testing

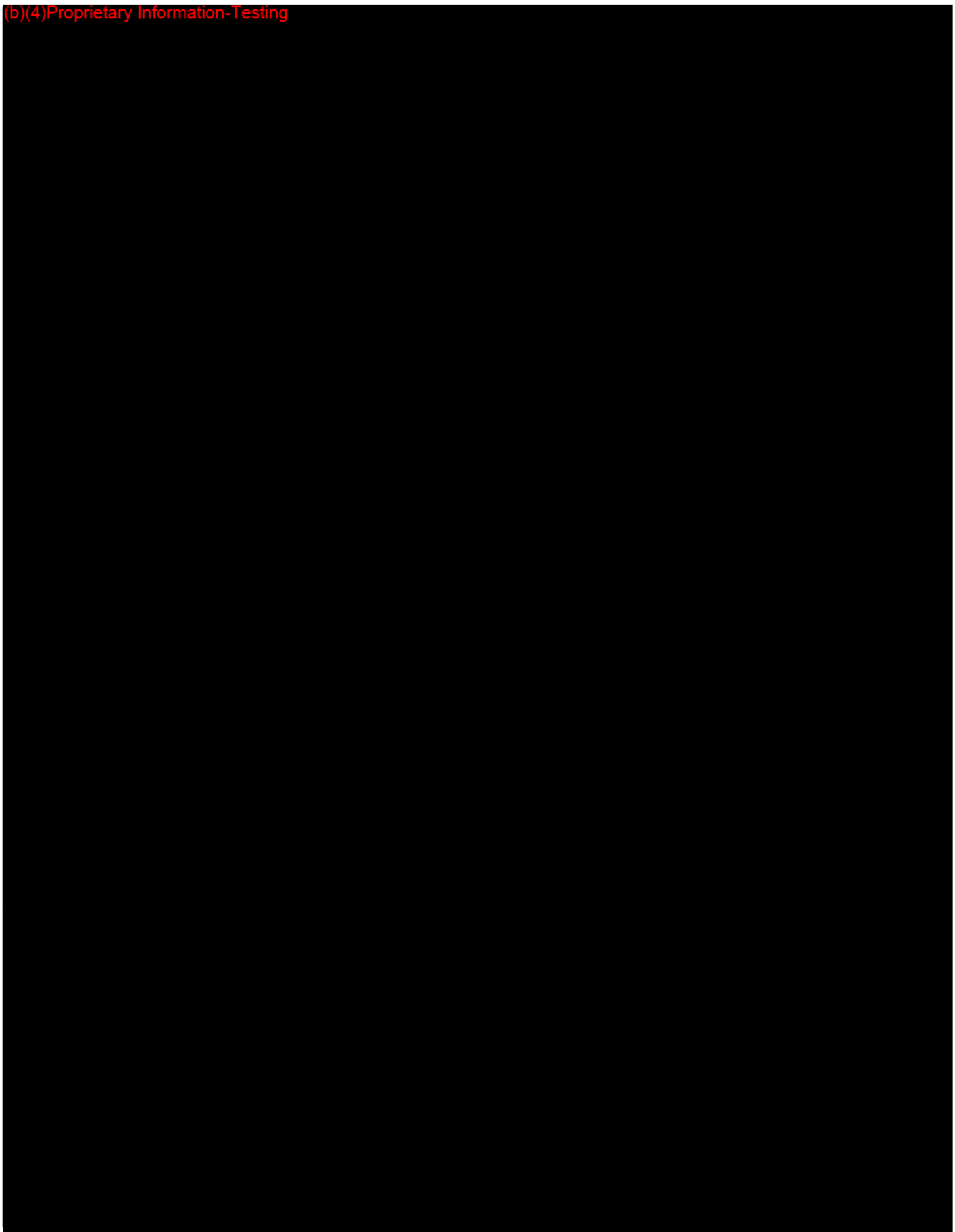




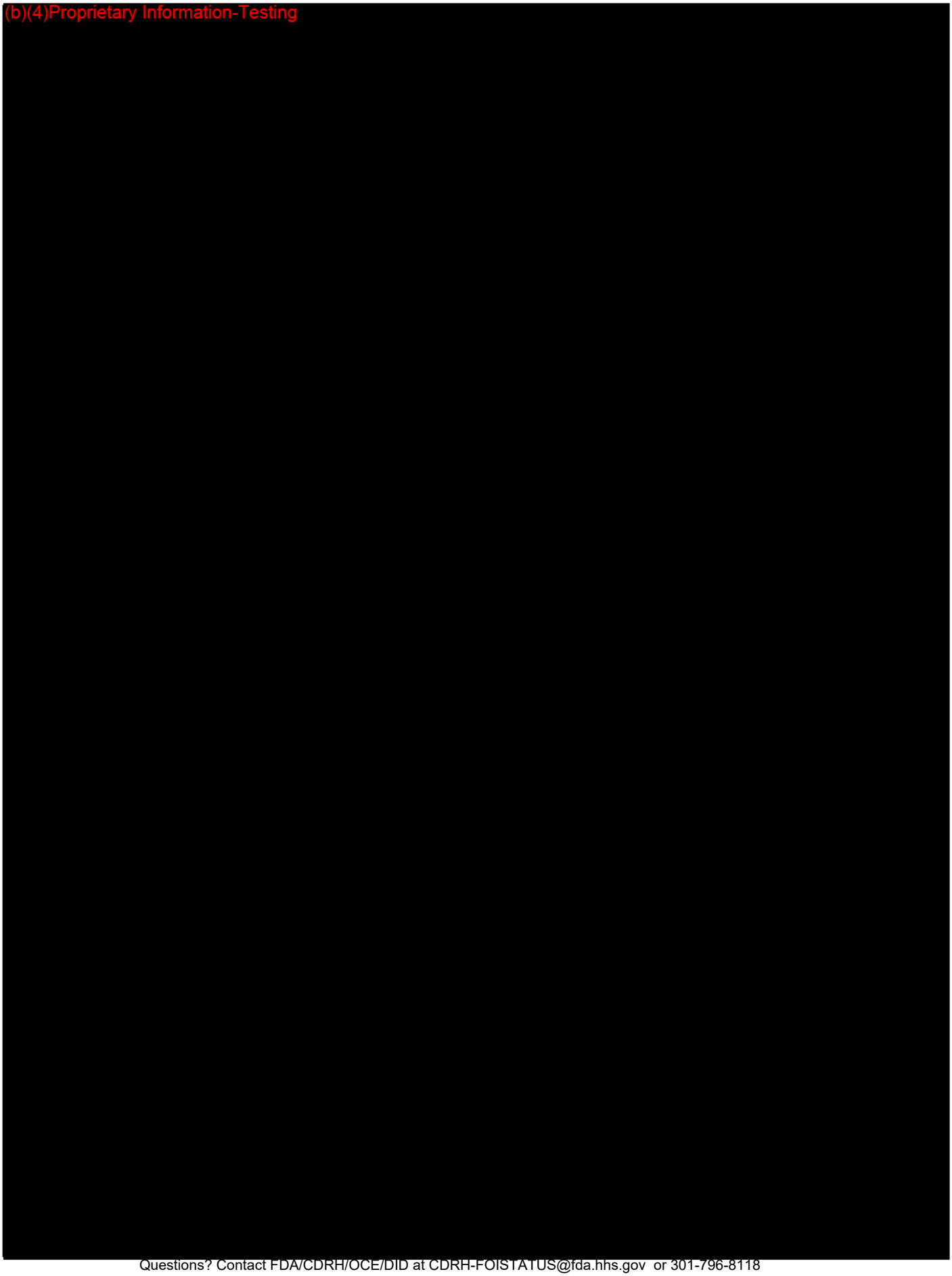
(b)(4)Proprietary Information-Testing



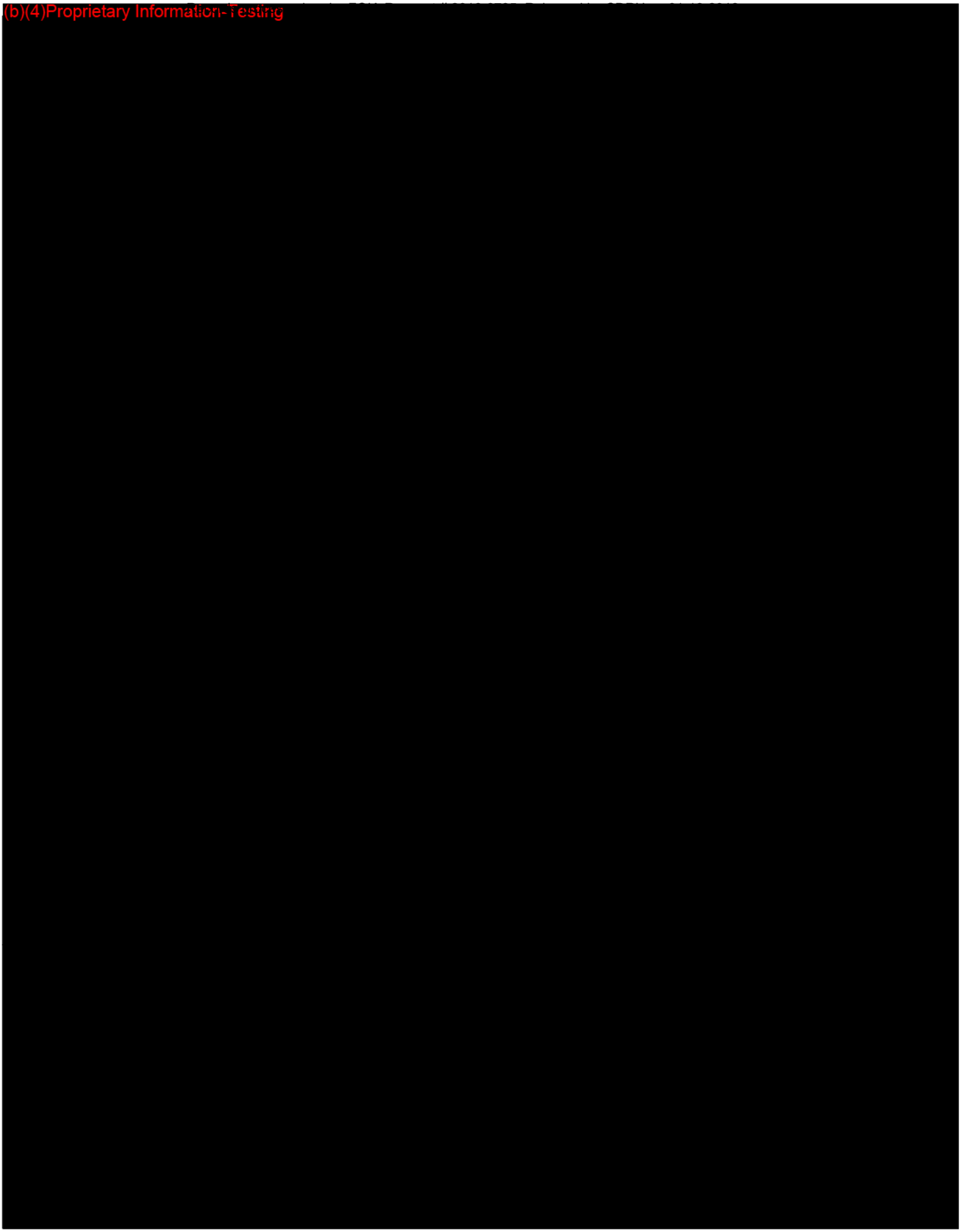
(b)(4)Proprietary Information-Testing

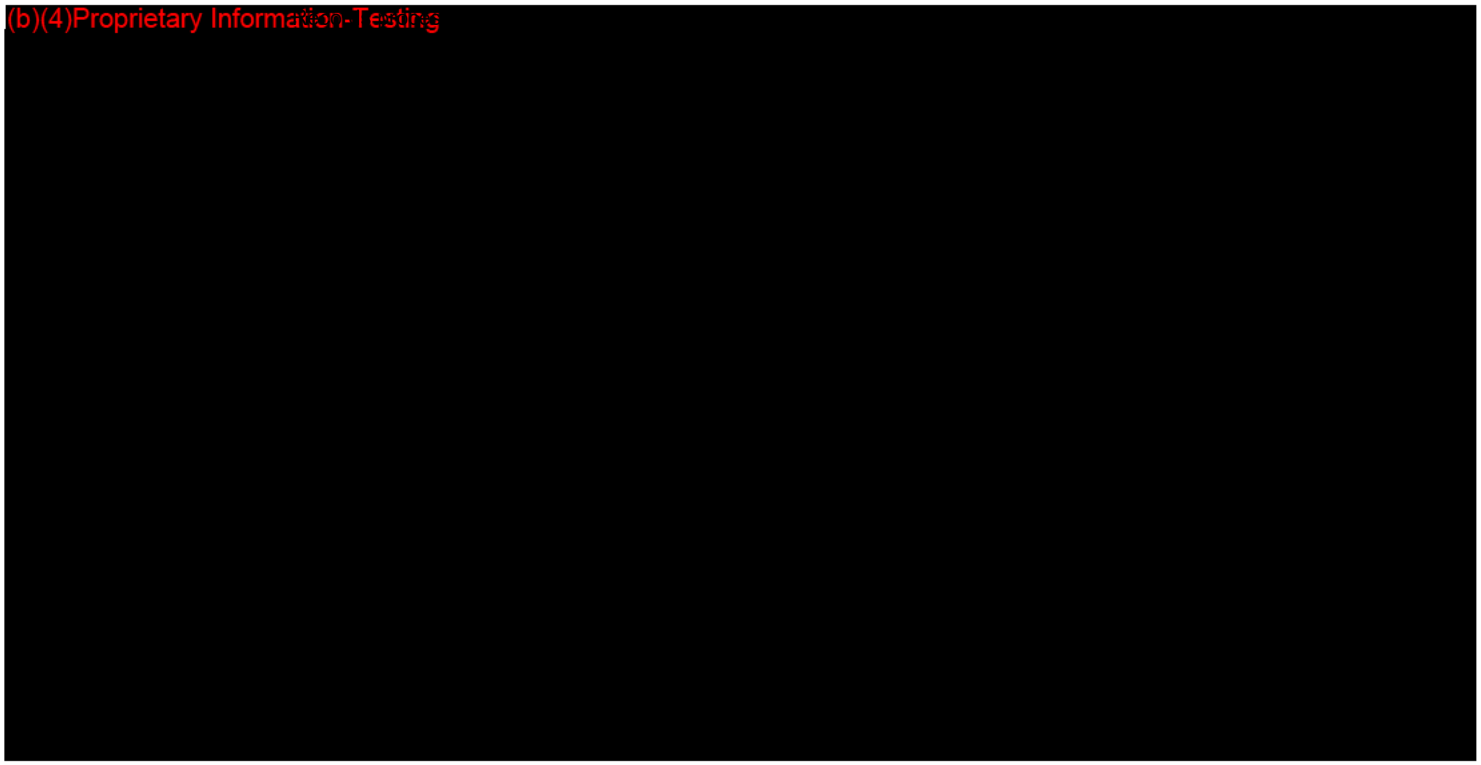


(b)(4)Proprietary Information-Testing



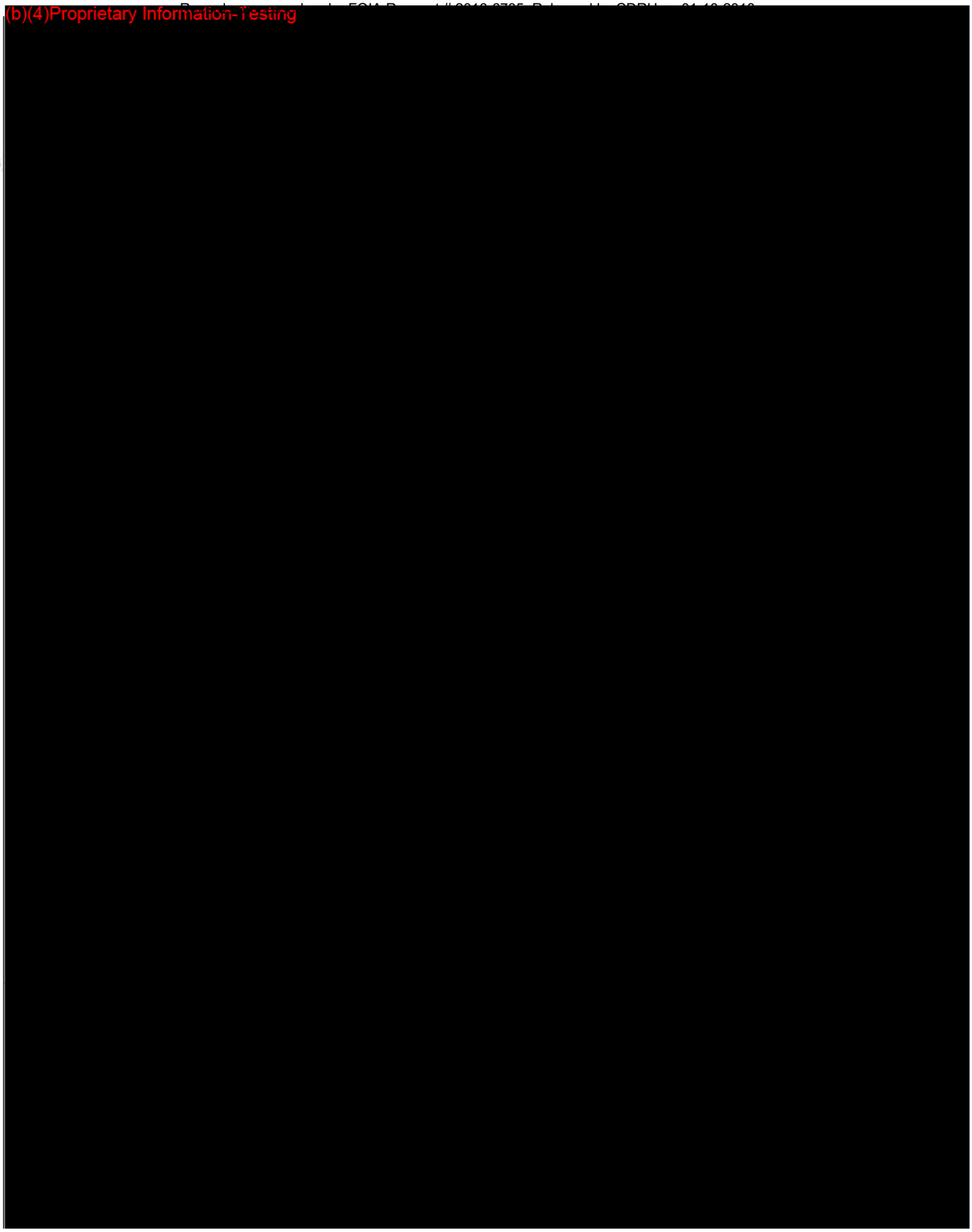
(b)(4)Proprietary Information-Testing



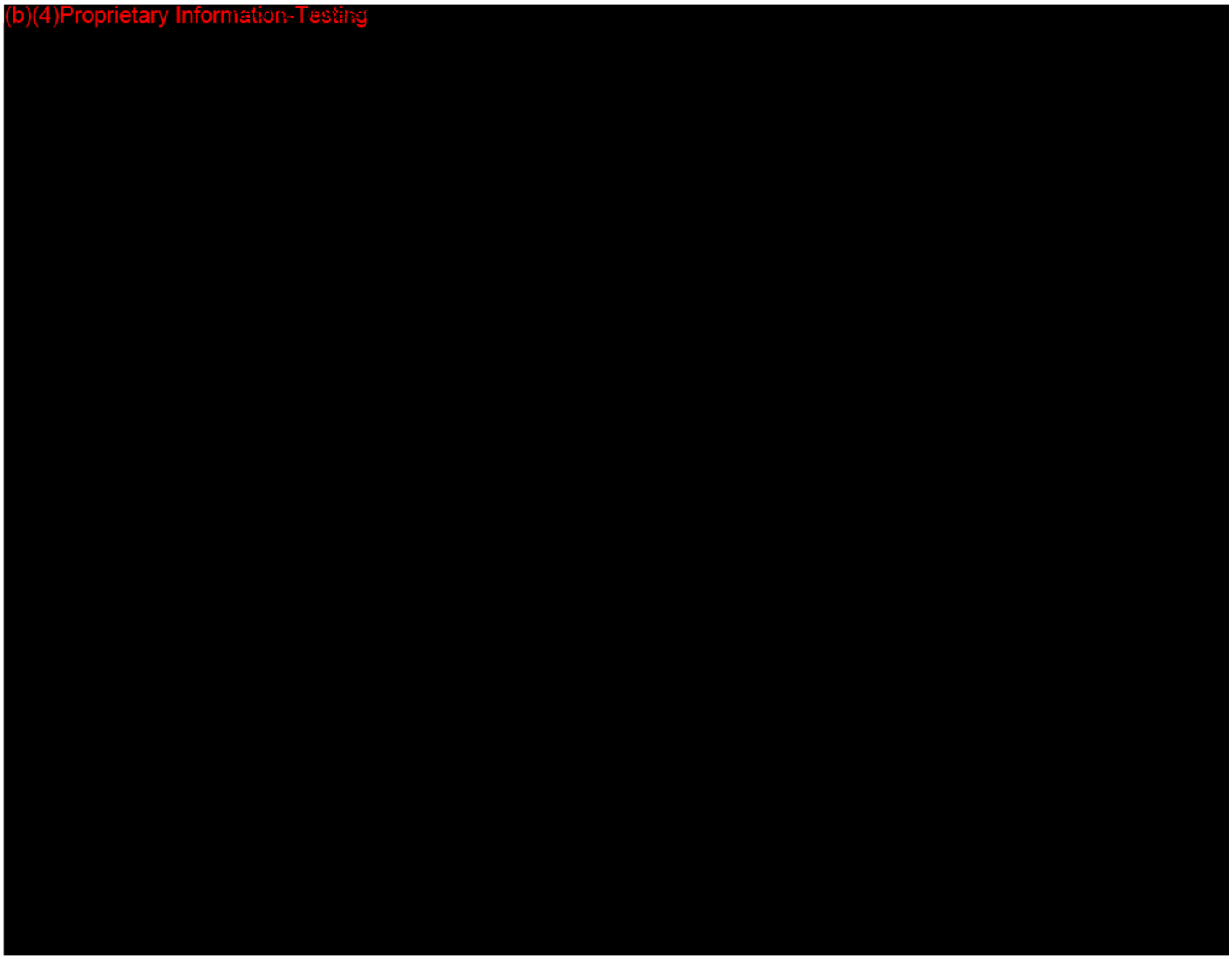


REV062413

(b)(4)Proprietary Information-Testing

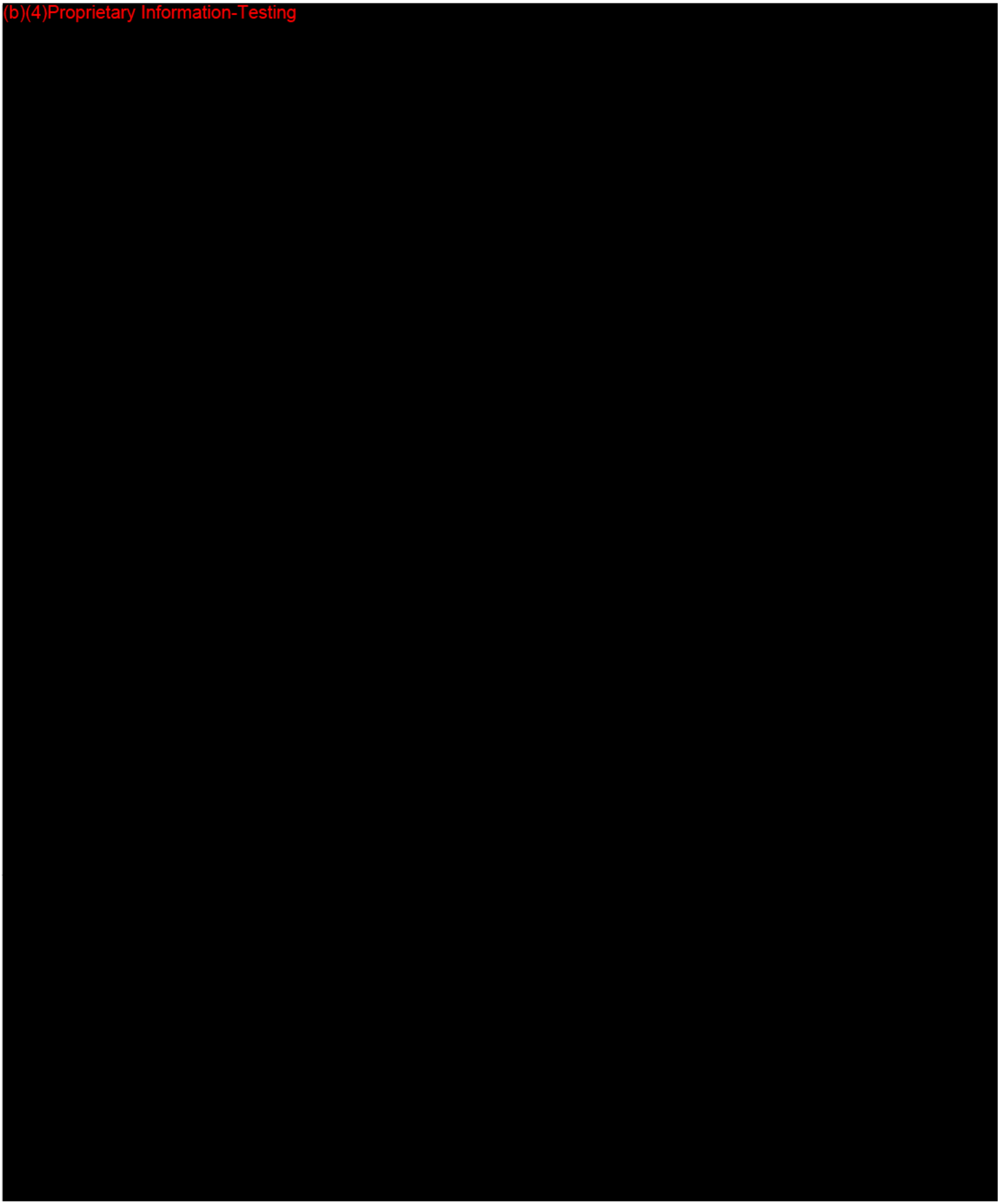


(b)(4)Proprietary Information-Testing

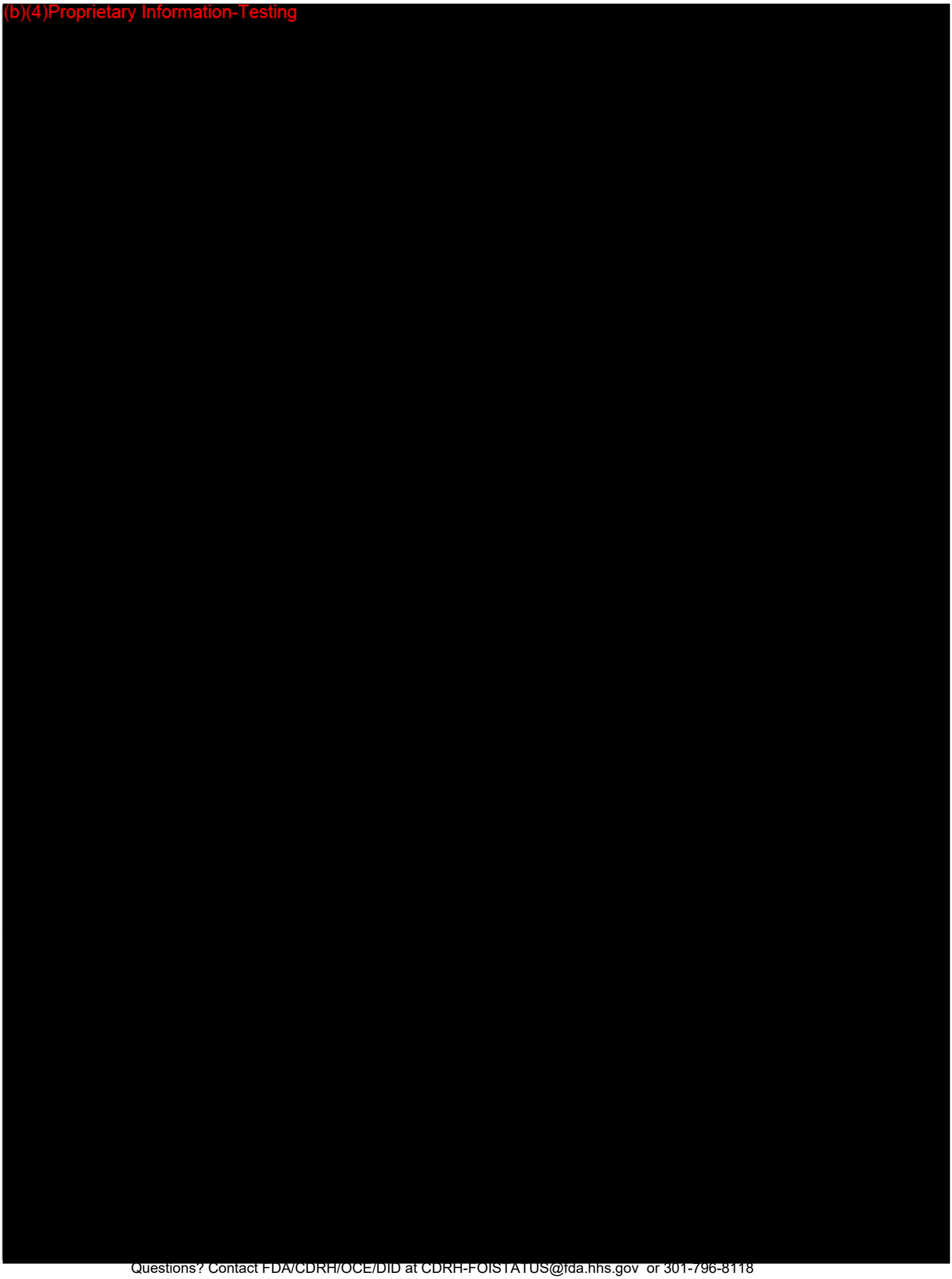


REV062413

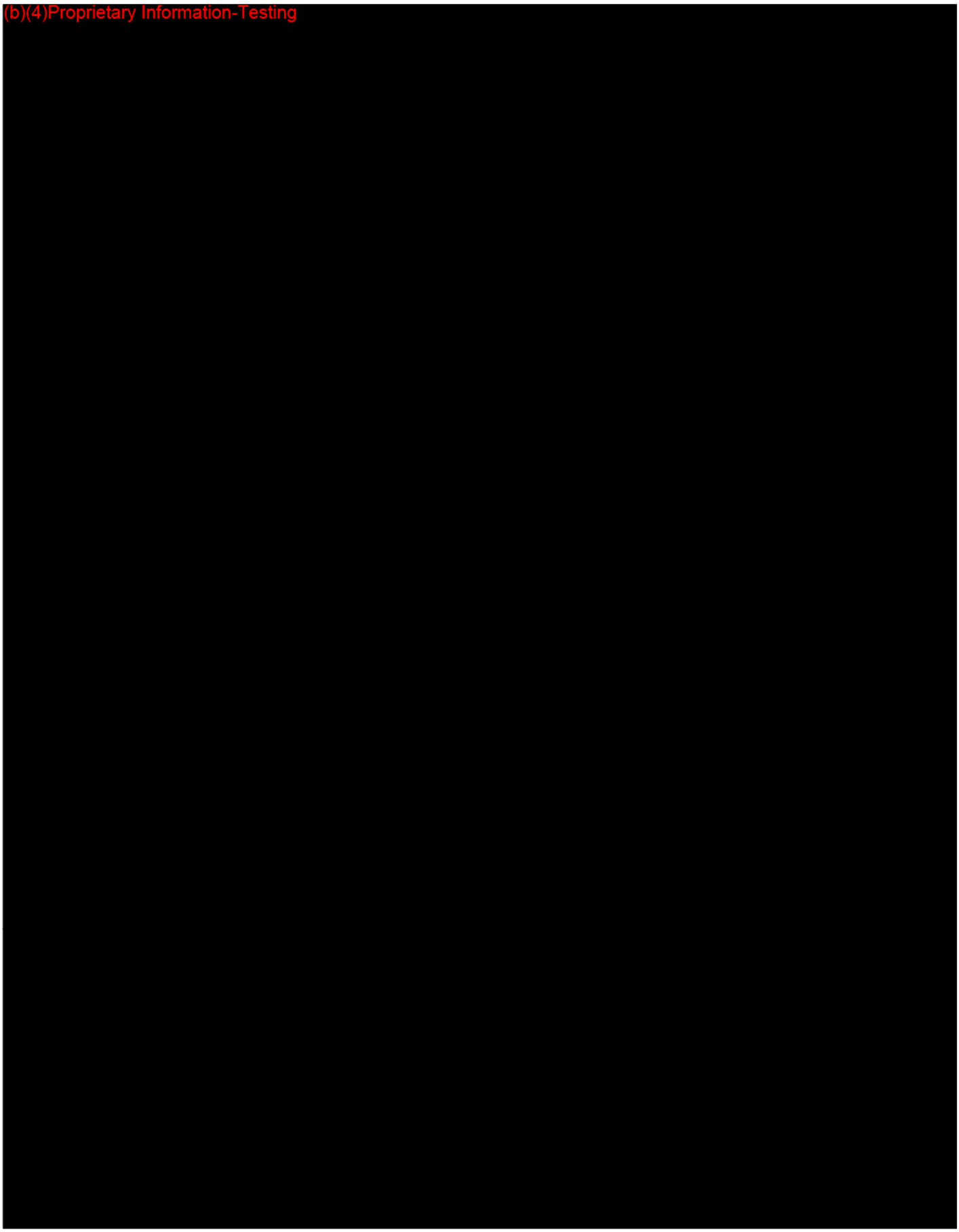
(b)(4)Proprietary Information-Testing

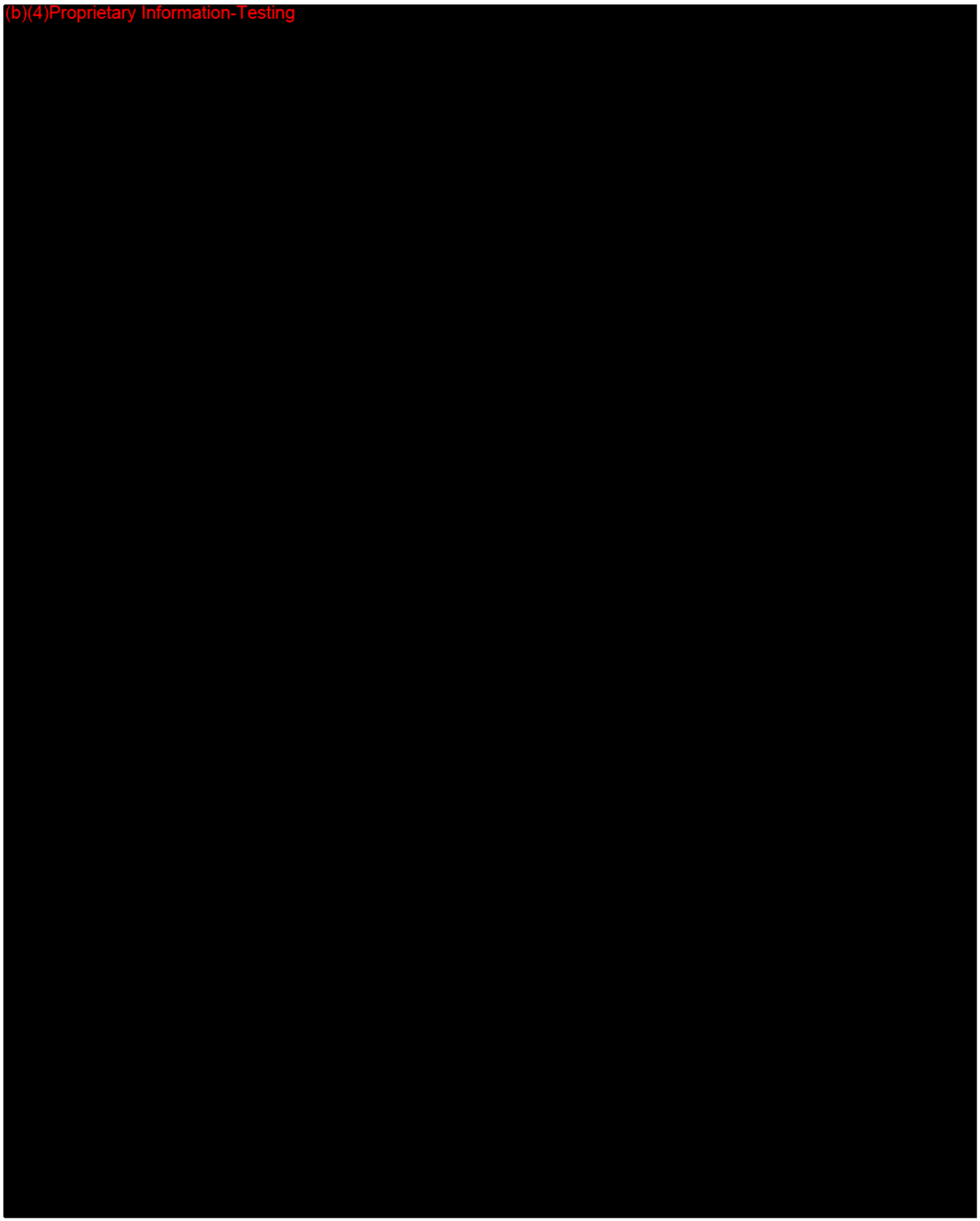


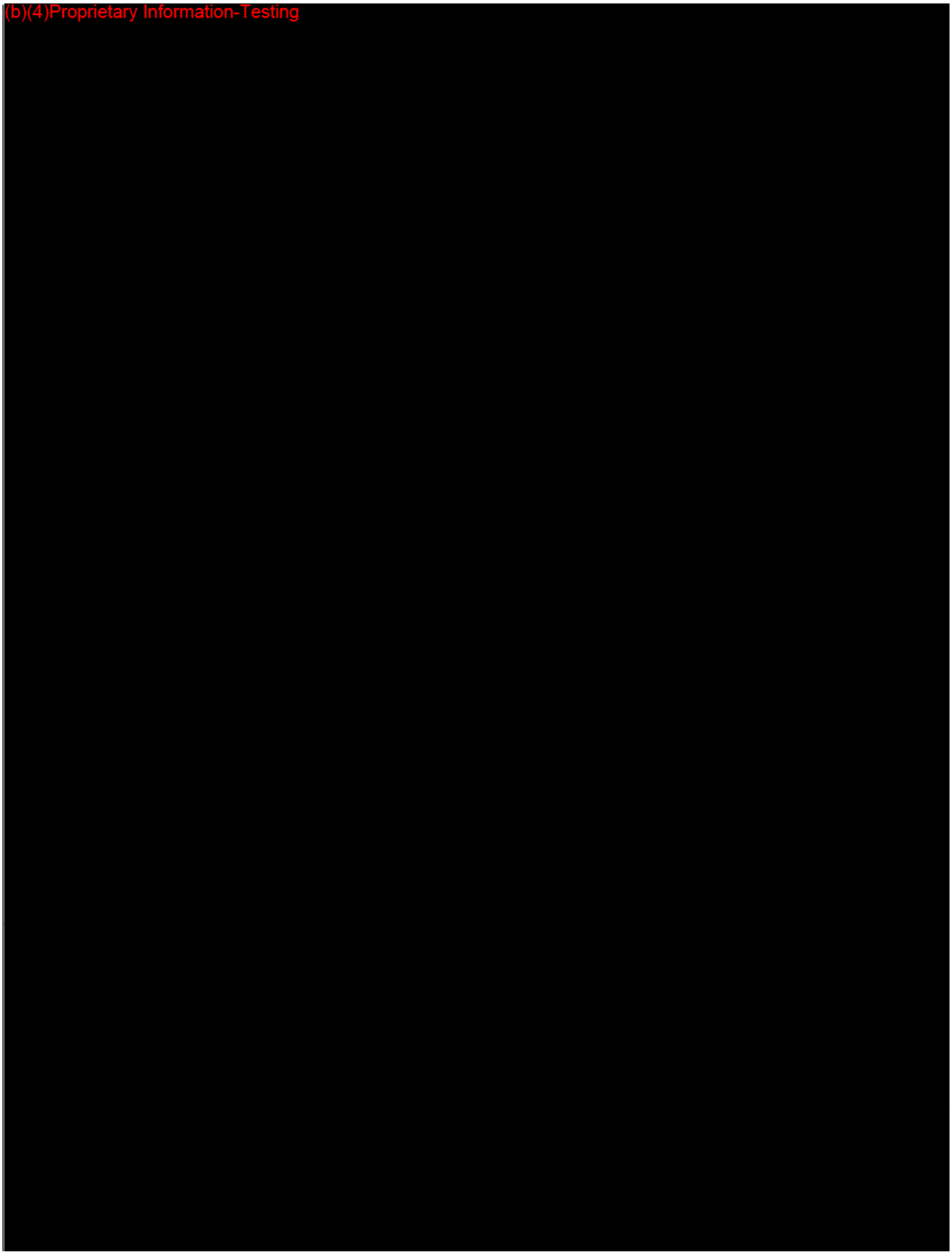
(b)(4)Proprietary Information-Testing

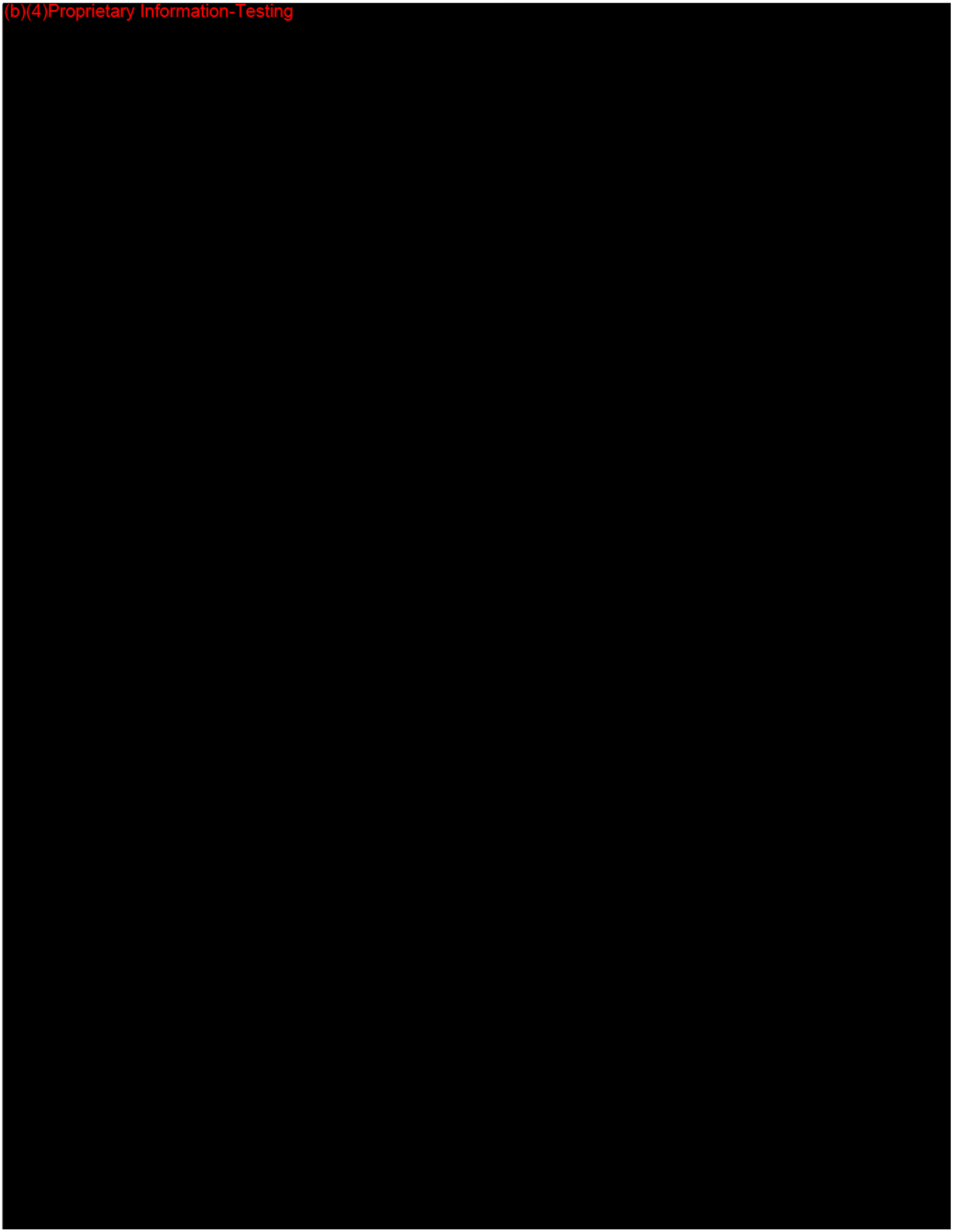


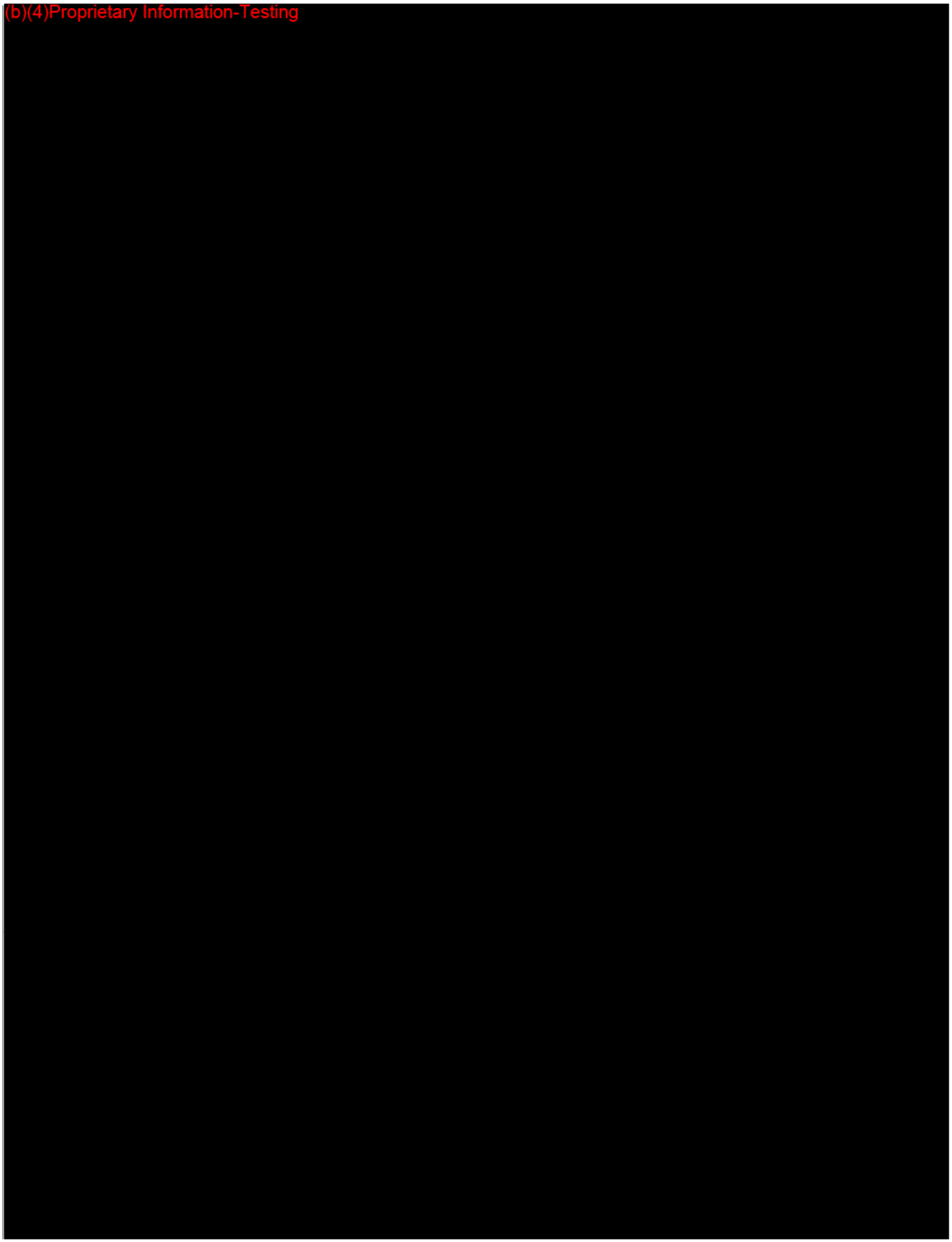
(b)(4)Proprietary Information-Testing



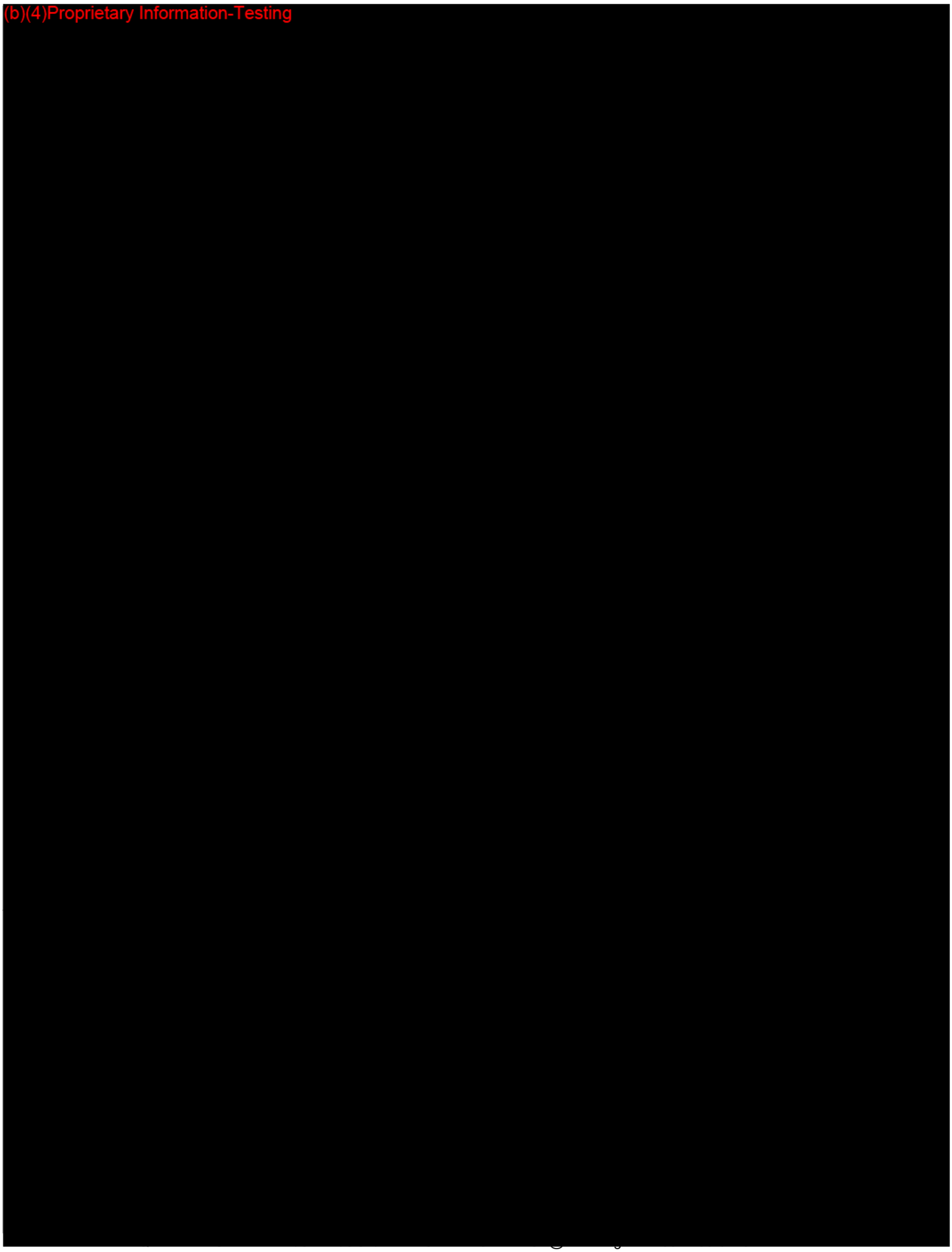


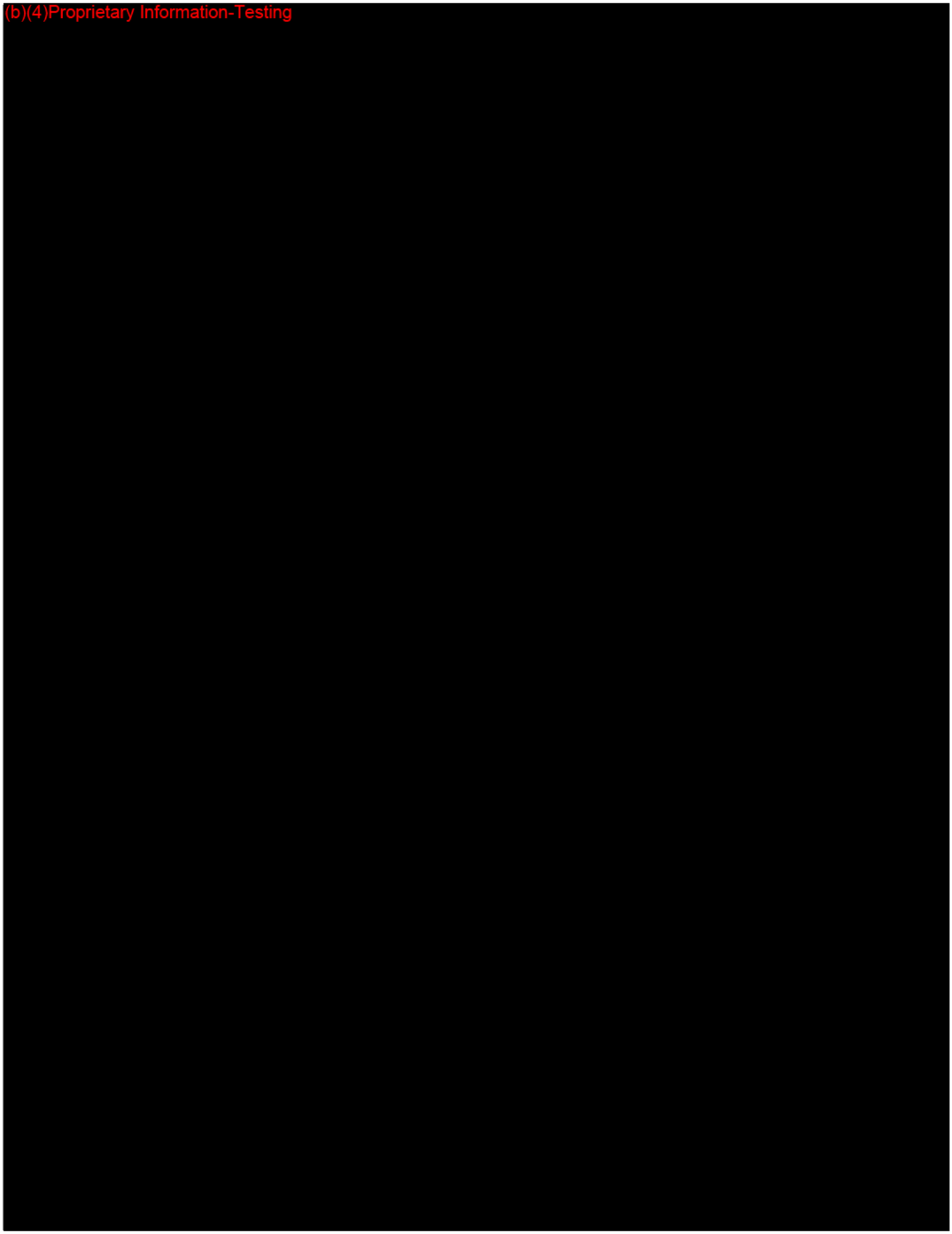




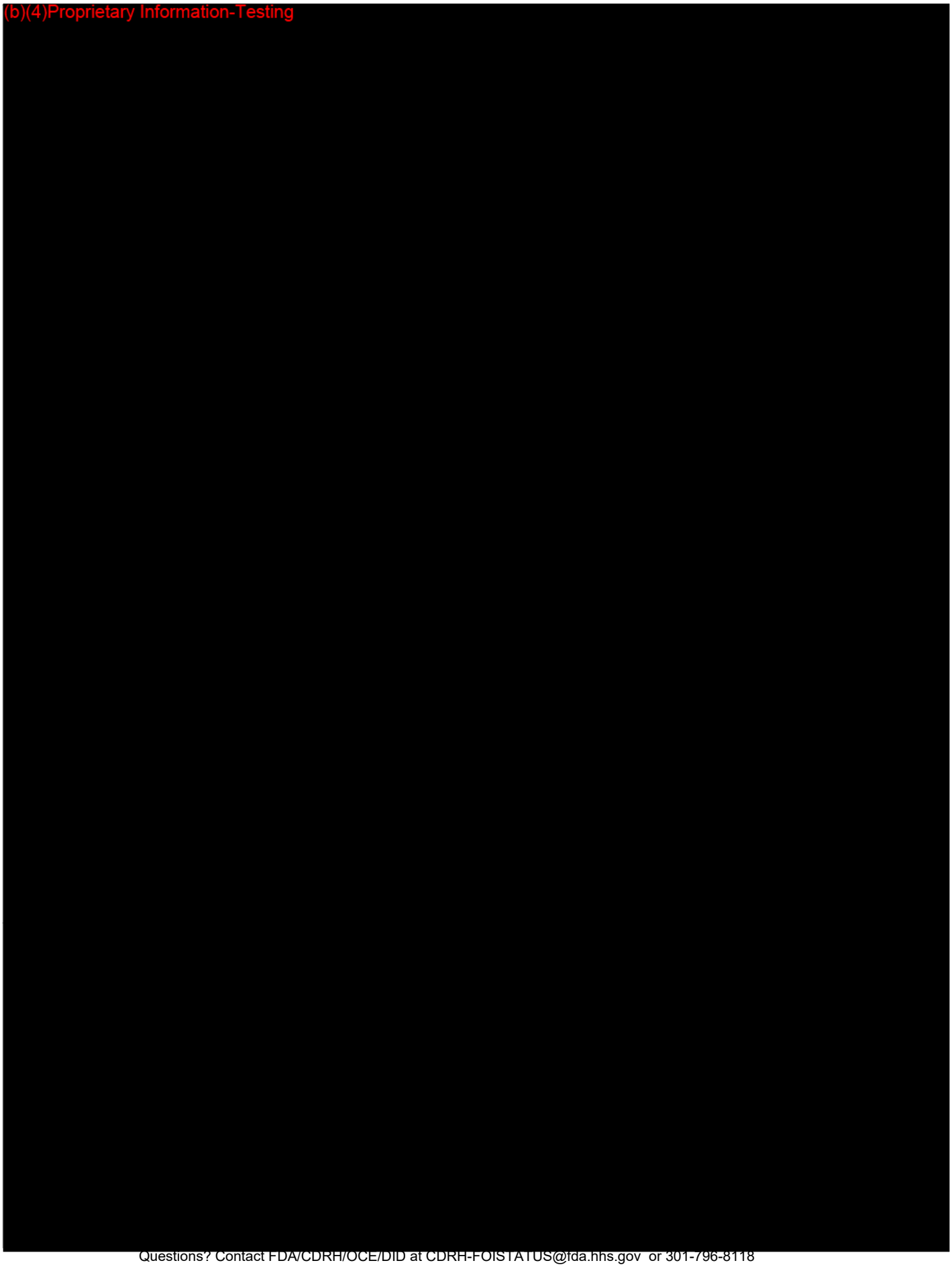


(b)(4)Proprietary Information-Testing

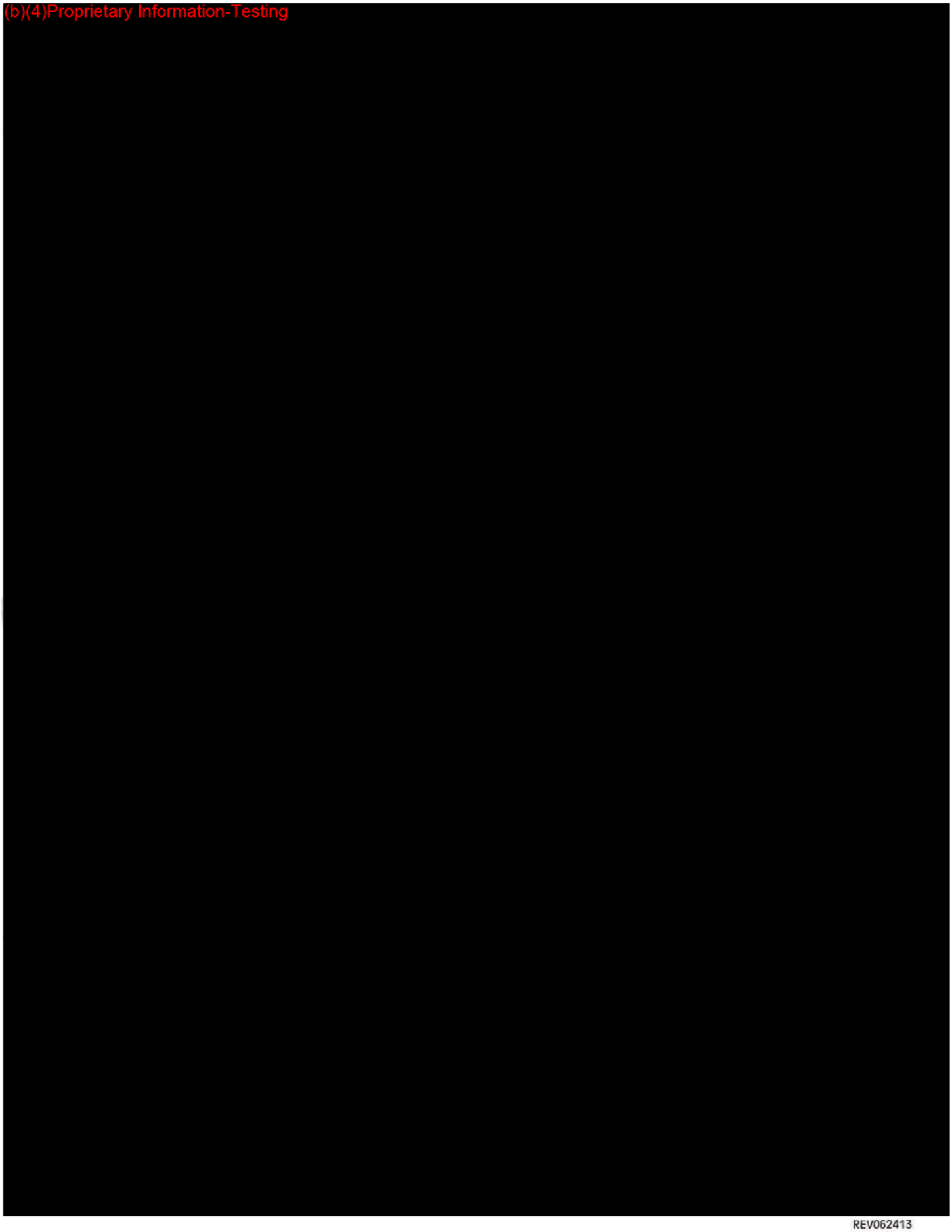




(b)(4)Proprietary Information-Testing

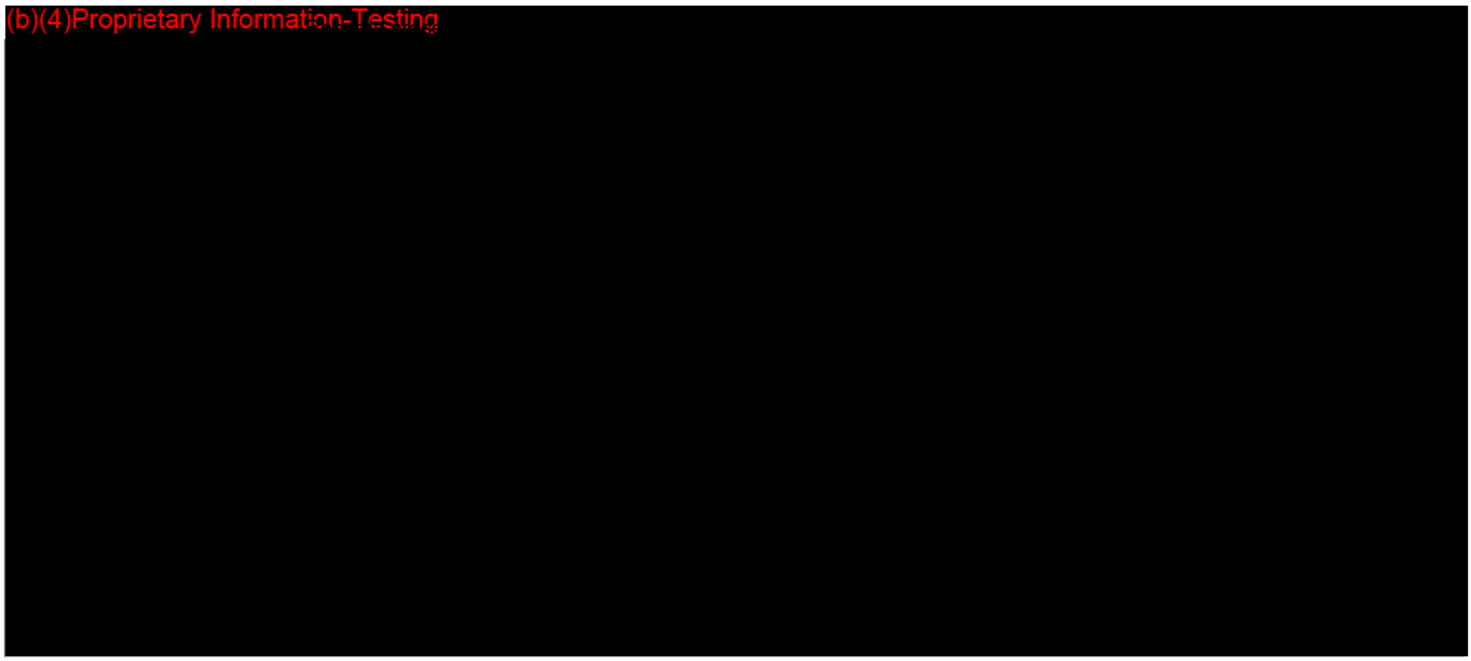


(b)(4)Proprietary Information-Testing



REV062413

(b)(4)Proprietary Information-Testing

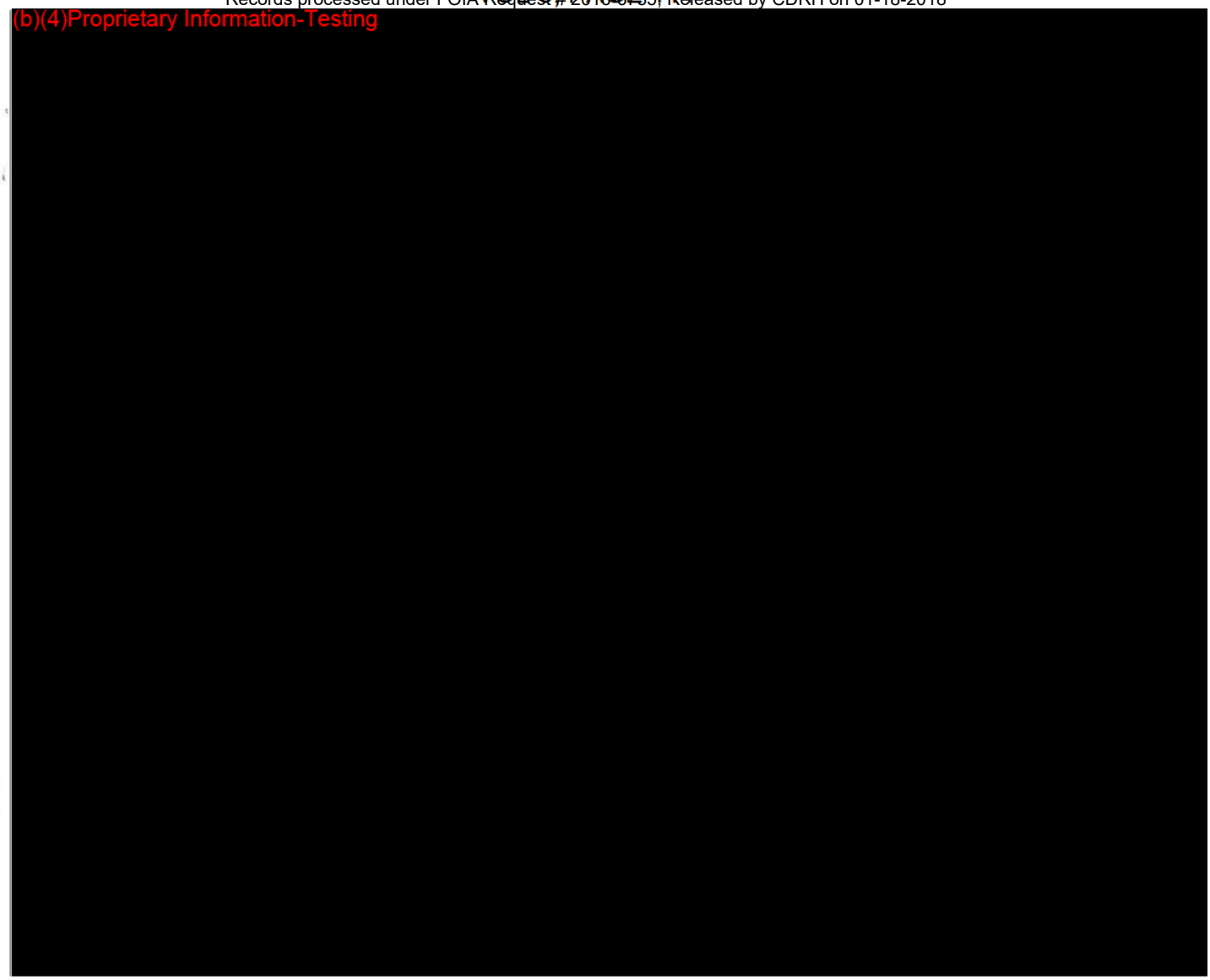


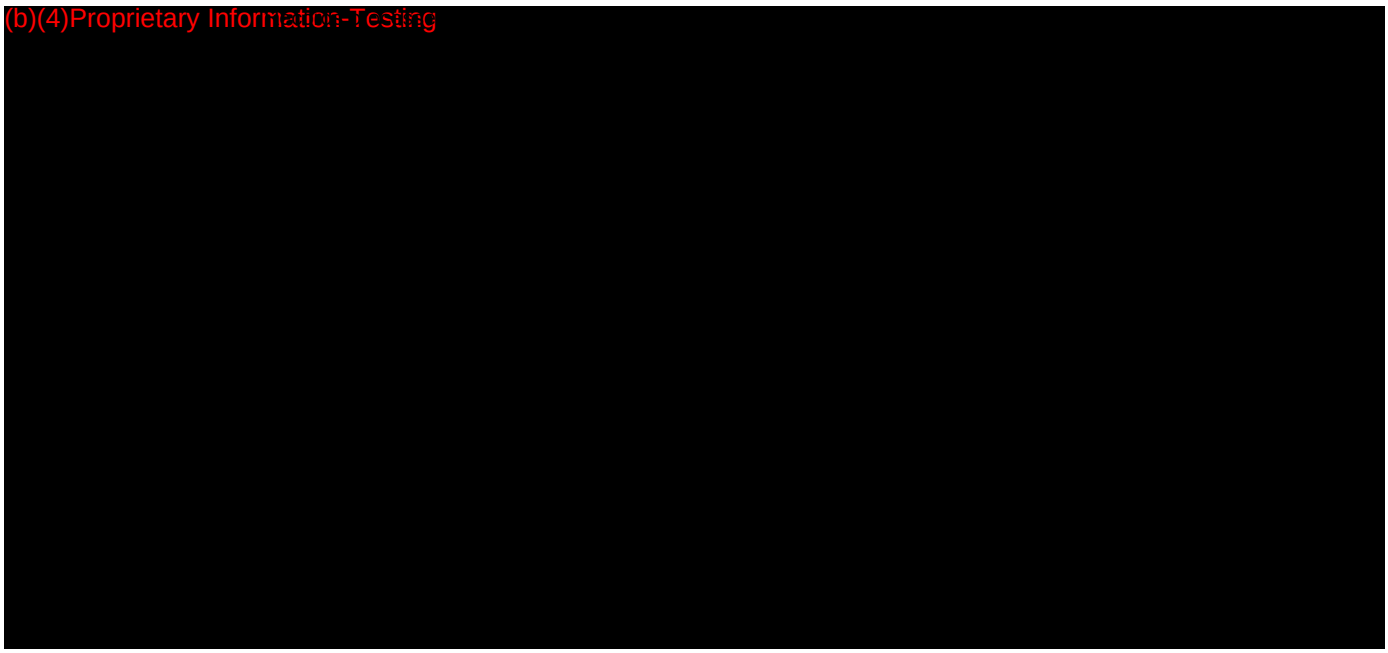
REV062413

(b)(4)Proprietary Information-Testing

[redacted]

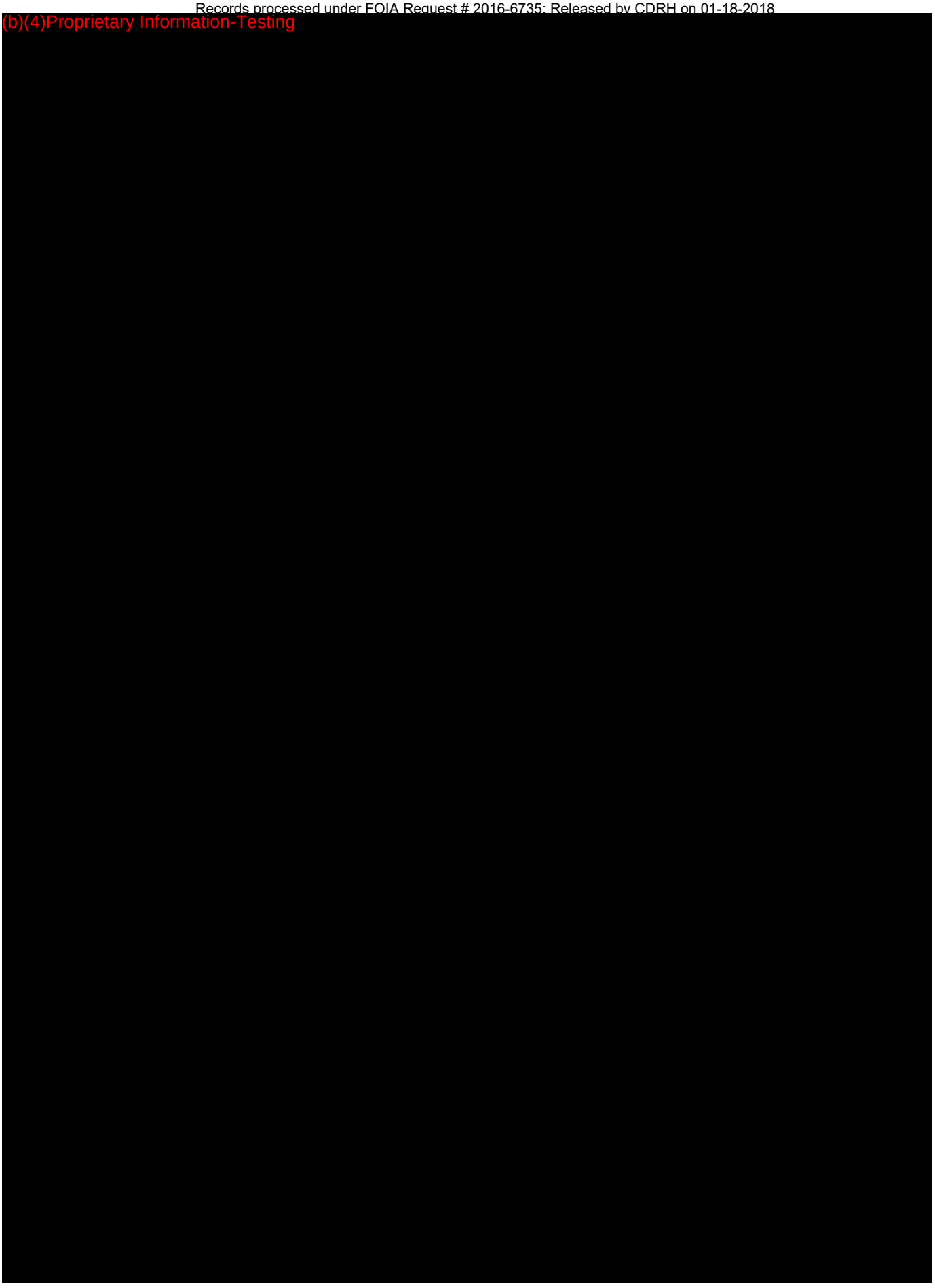
(b)(4)Proprietary Information-Testing



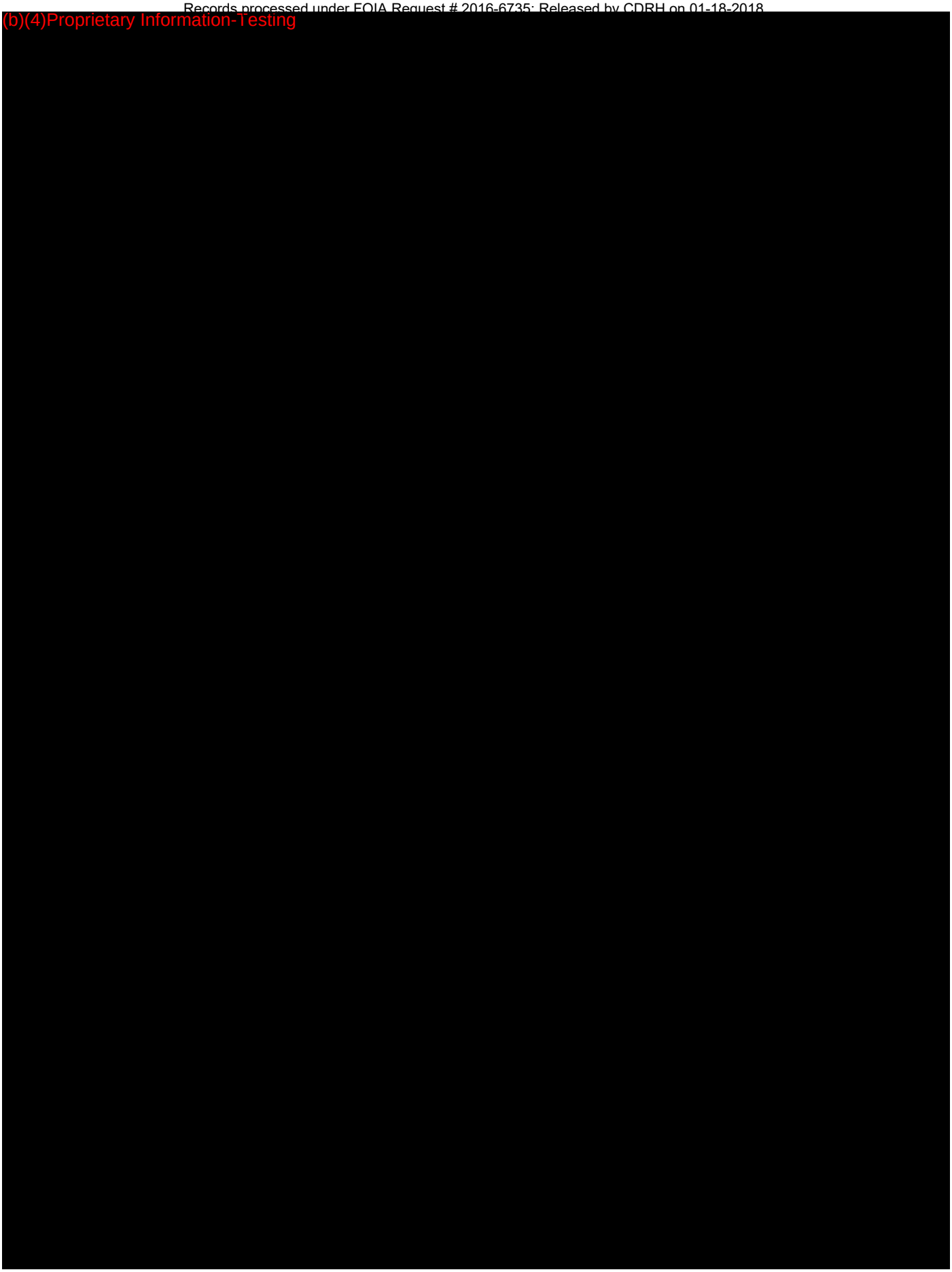

(b)(4)Proprietary Information-Testing

ATTACHMENT 26

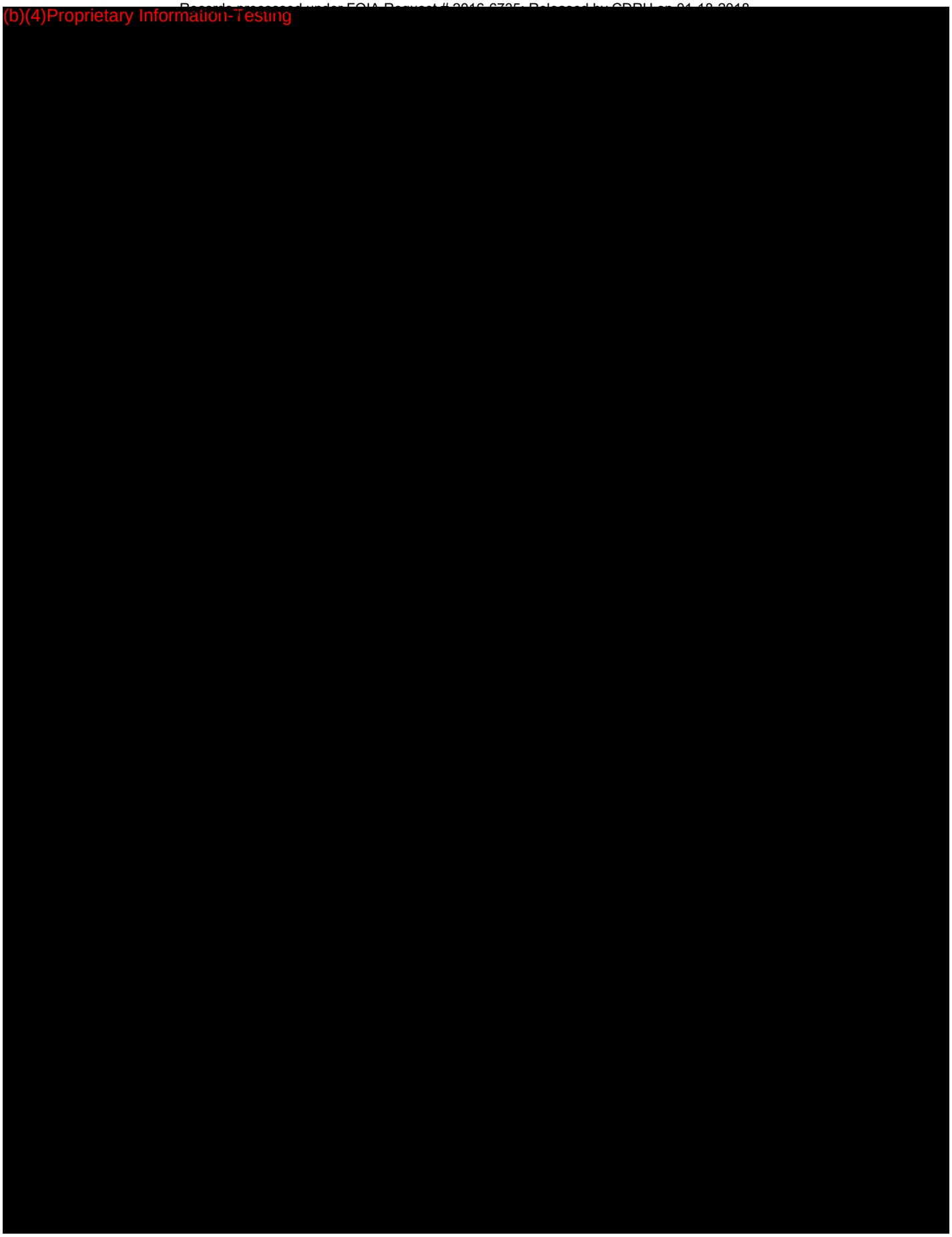
(b)(4)Proprietary Information-Testing



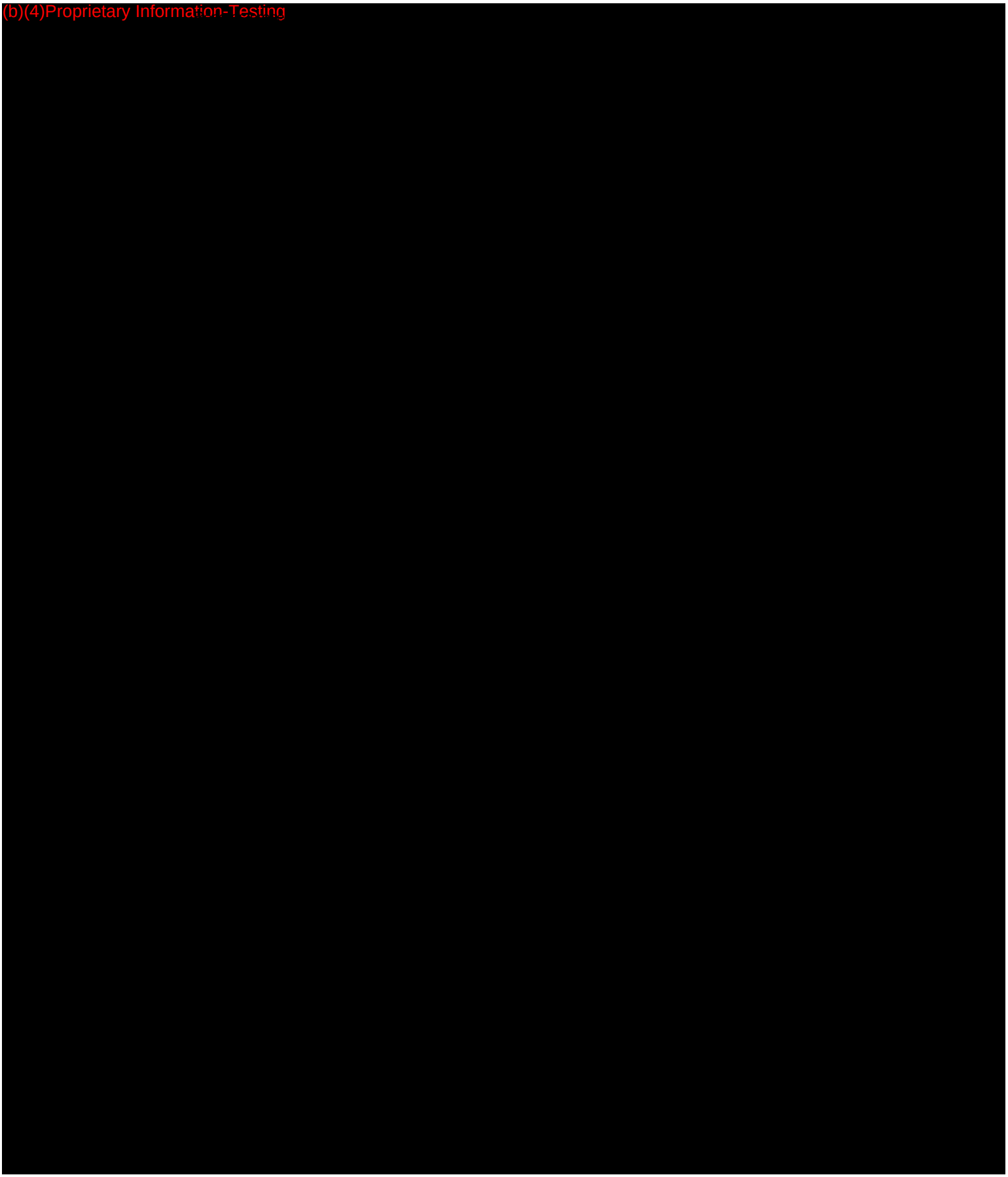
(b)(4)Proprietary Information-Testing



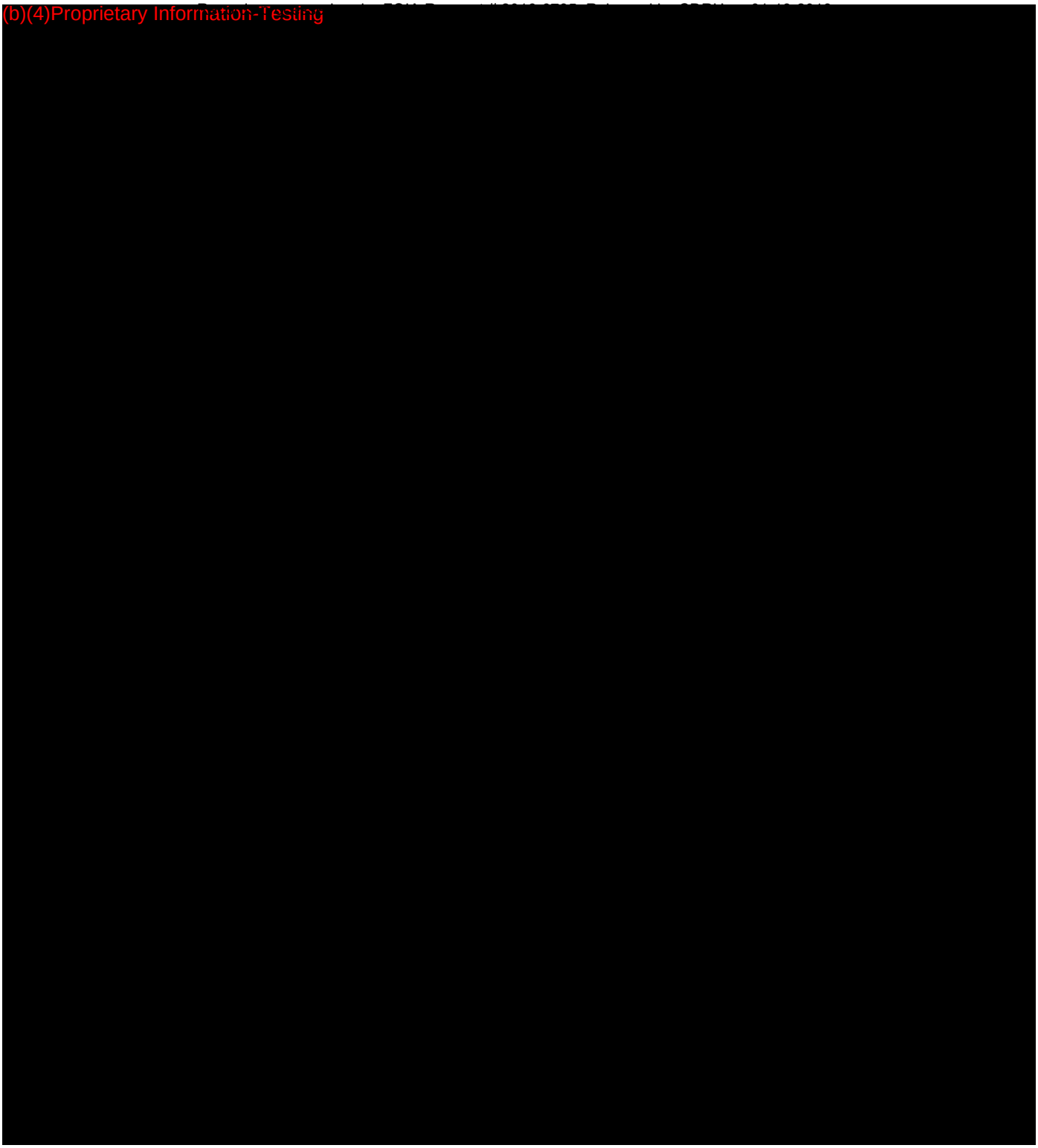
(b)(4)Proprietary Information-Testing



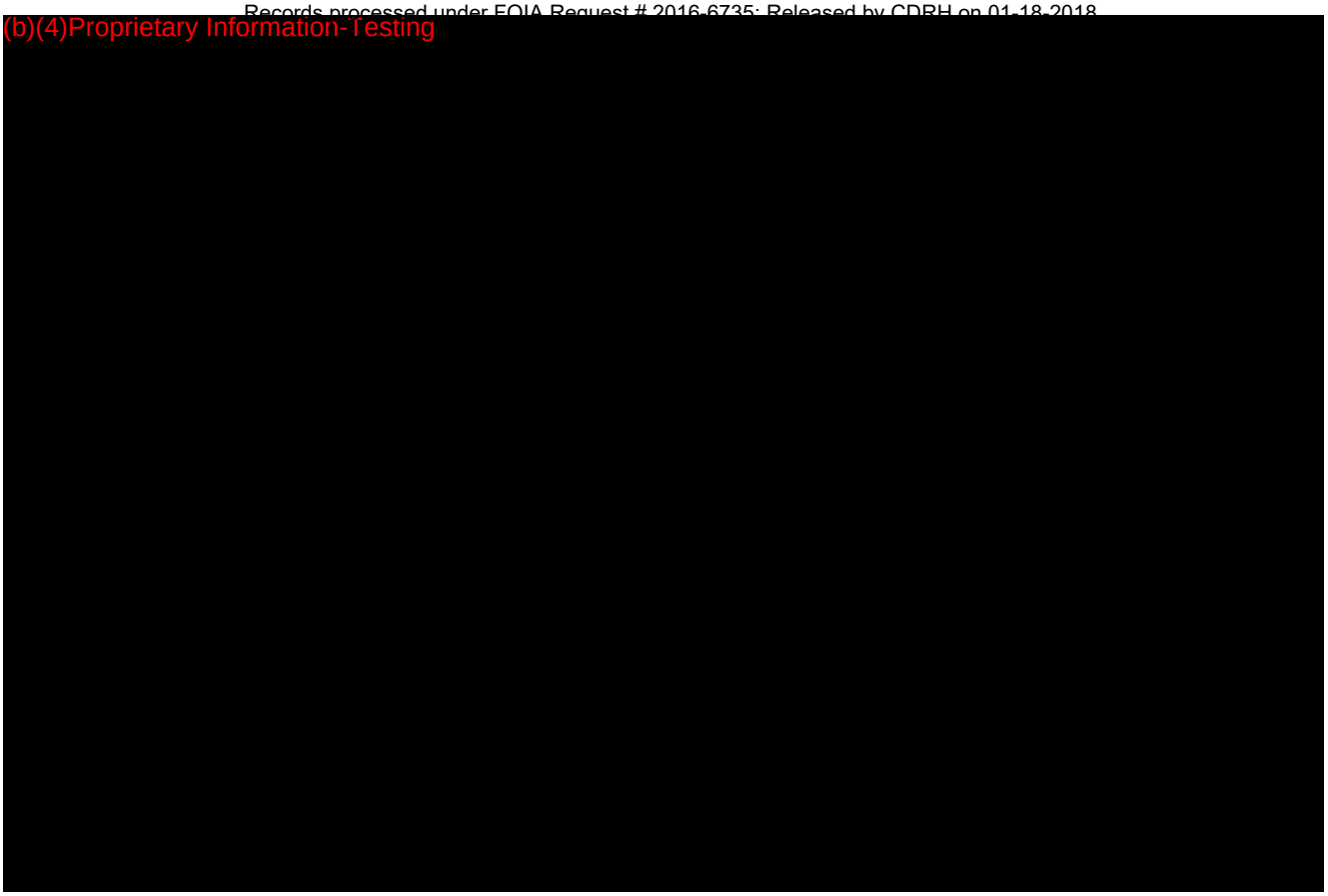
(b)(4)Proprietary Information-Testing



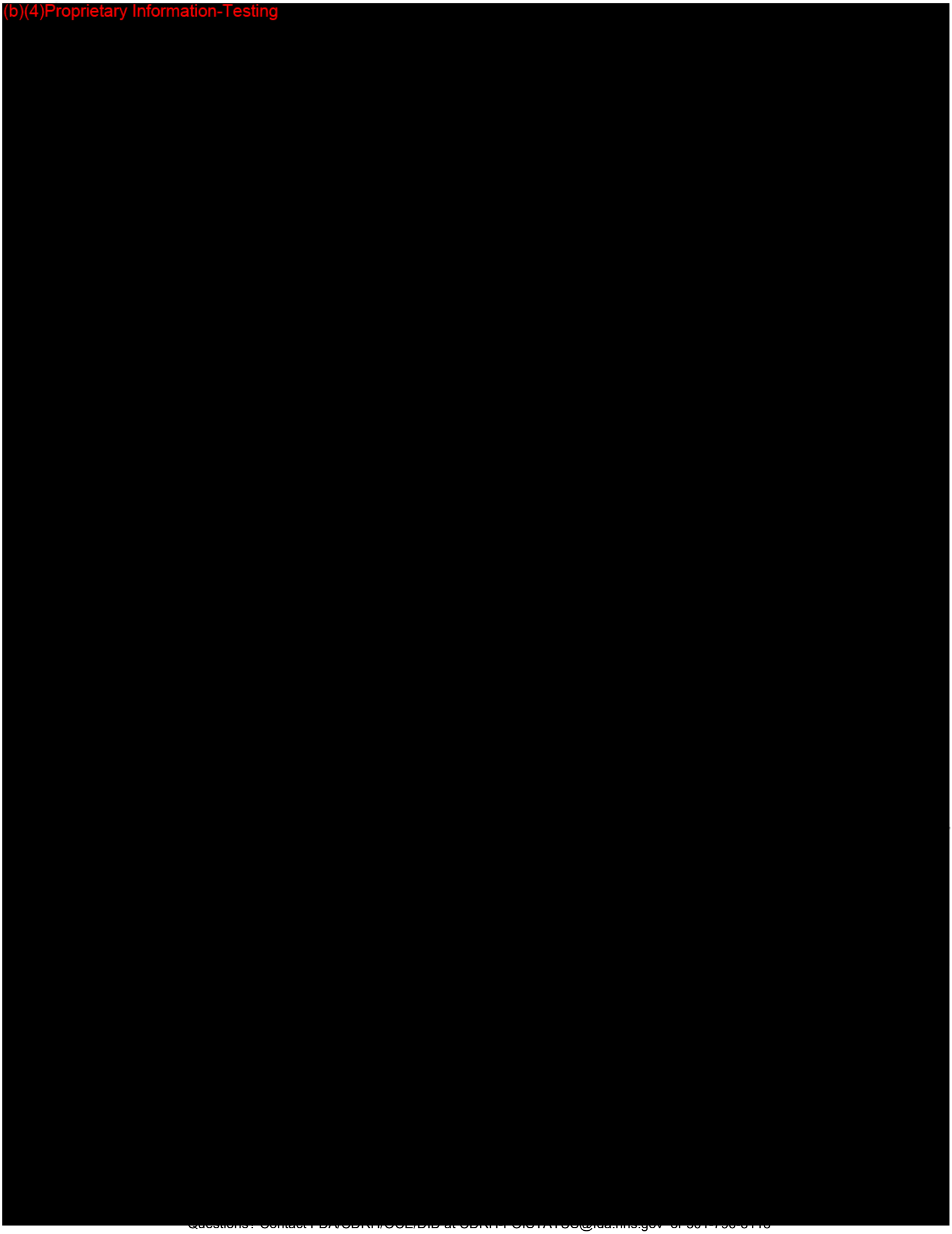
(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing



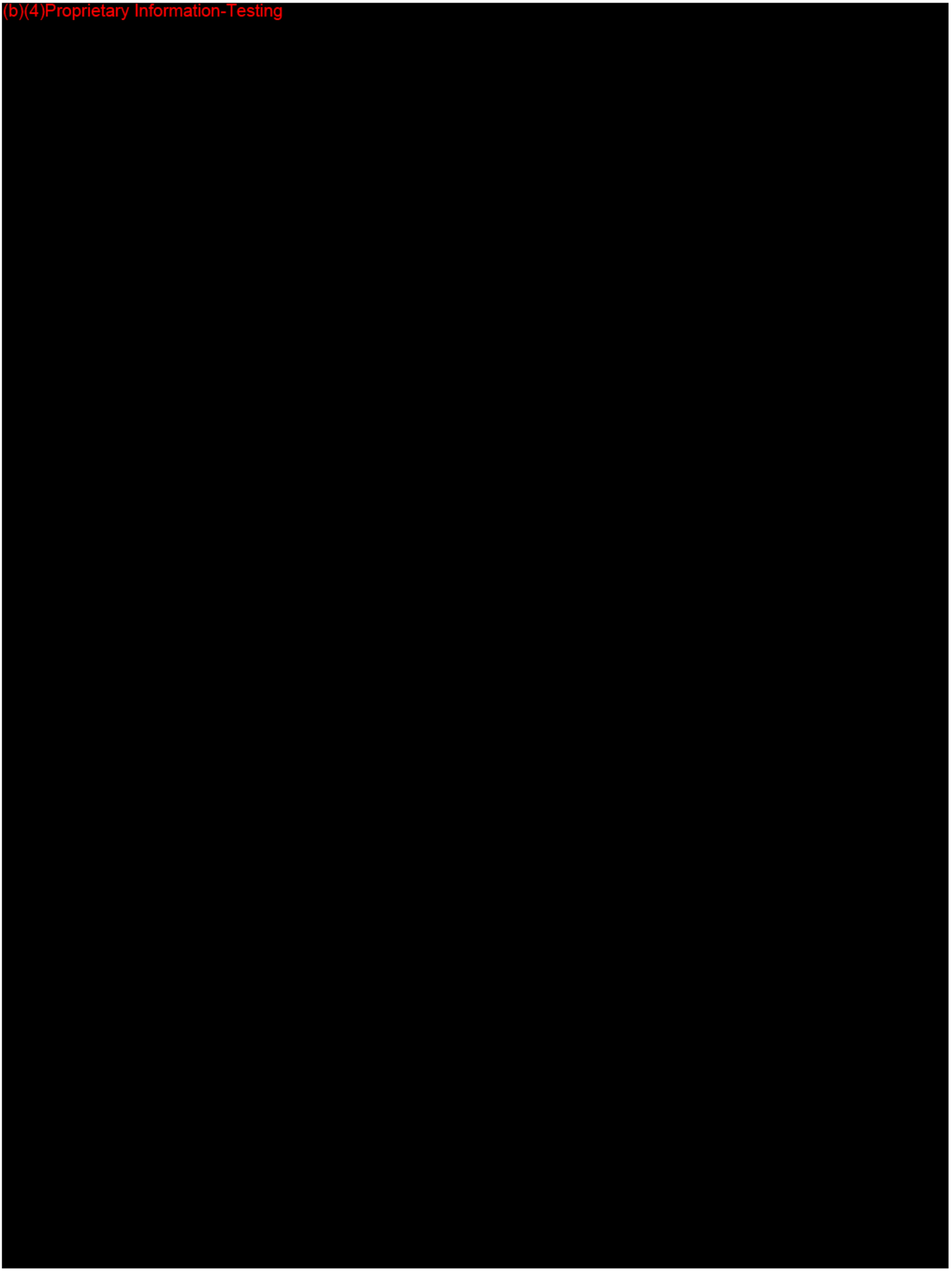
(b)(4)Proprietary Information-Testing



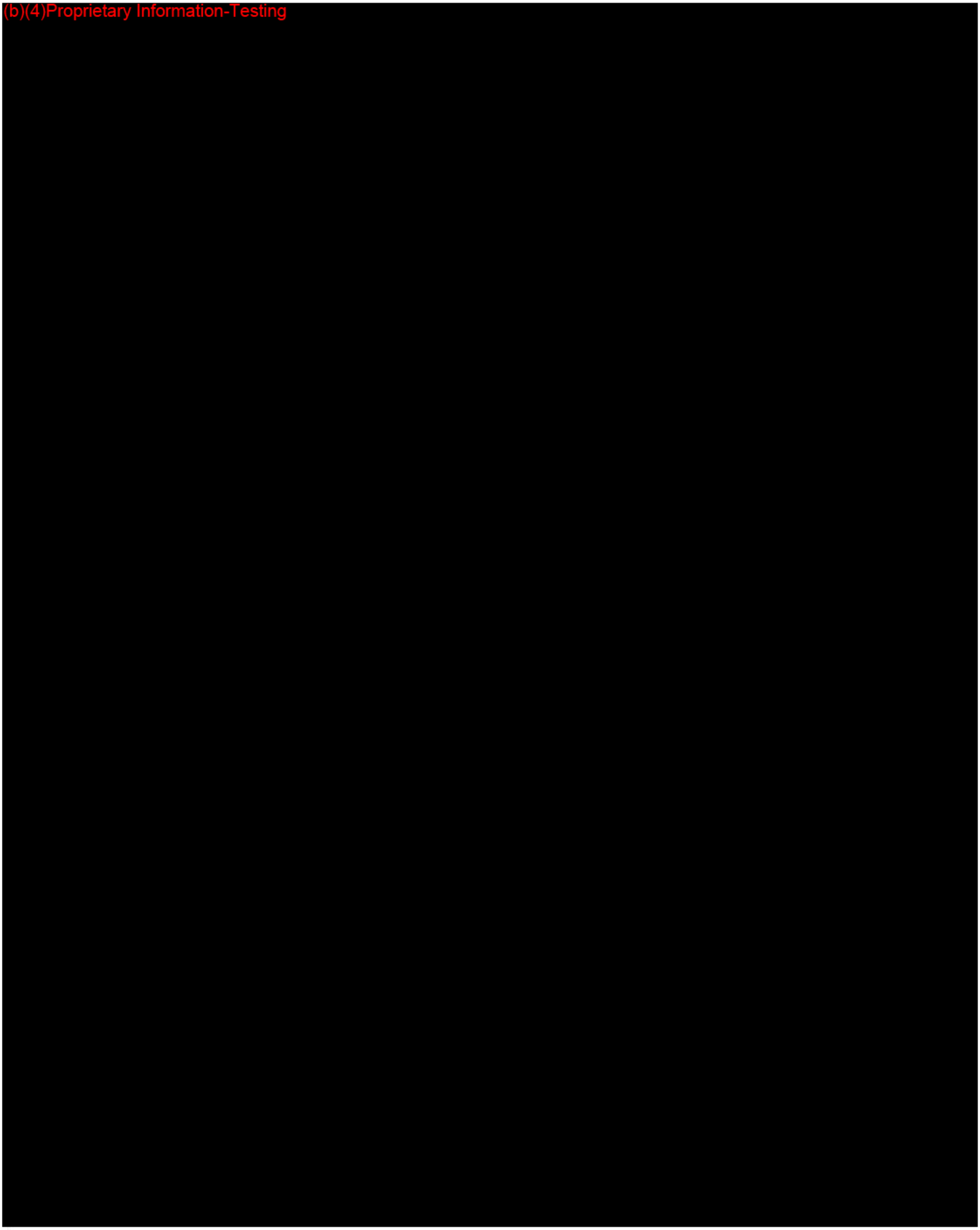
(b)(4)Proprietary Information-Testing

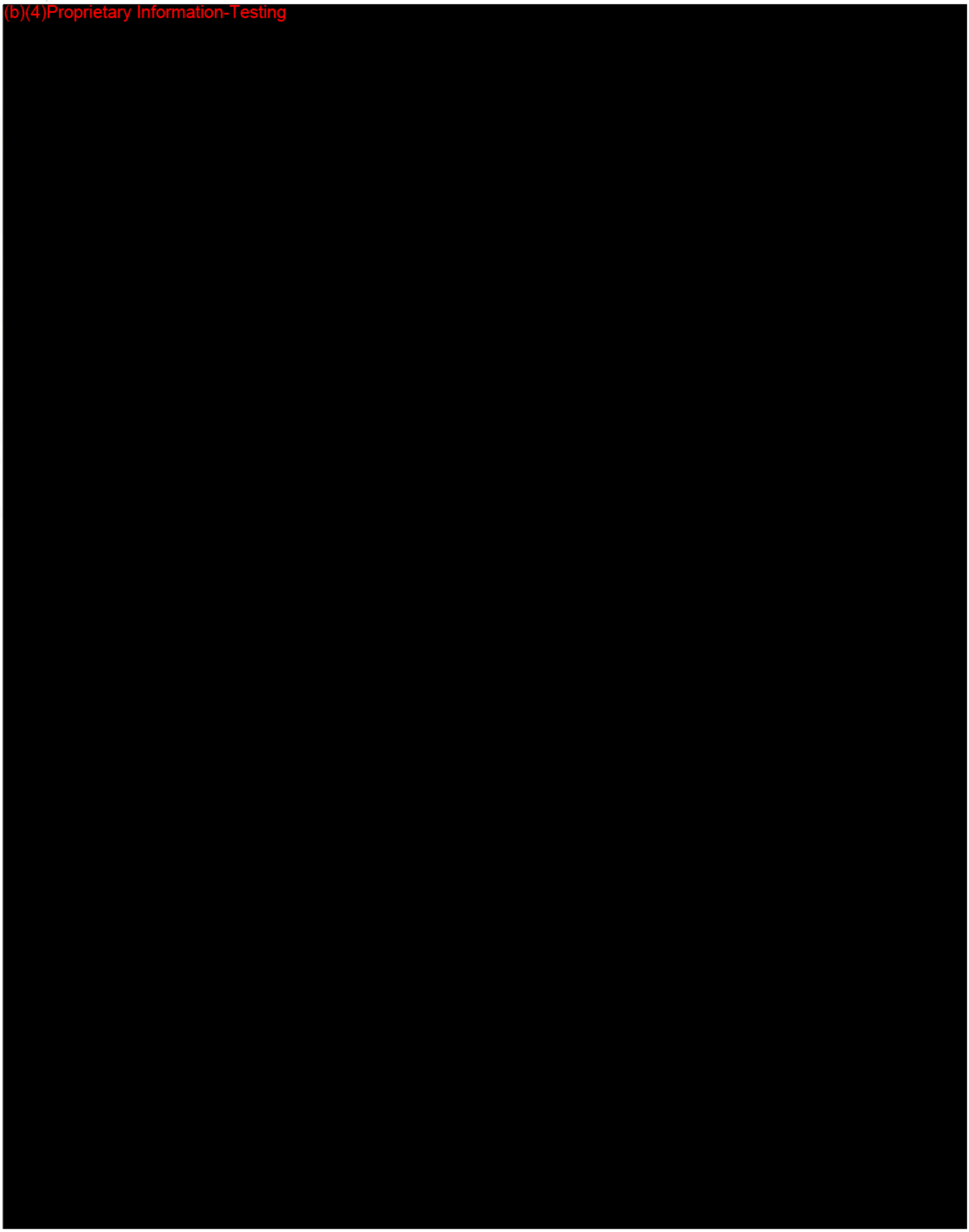
[redacted]

(b)(4)Proprietary Information-Testing

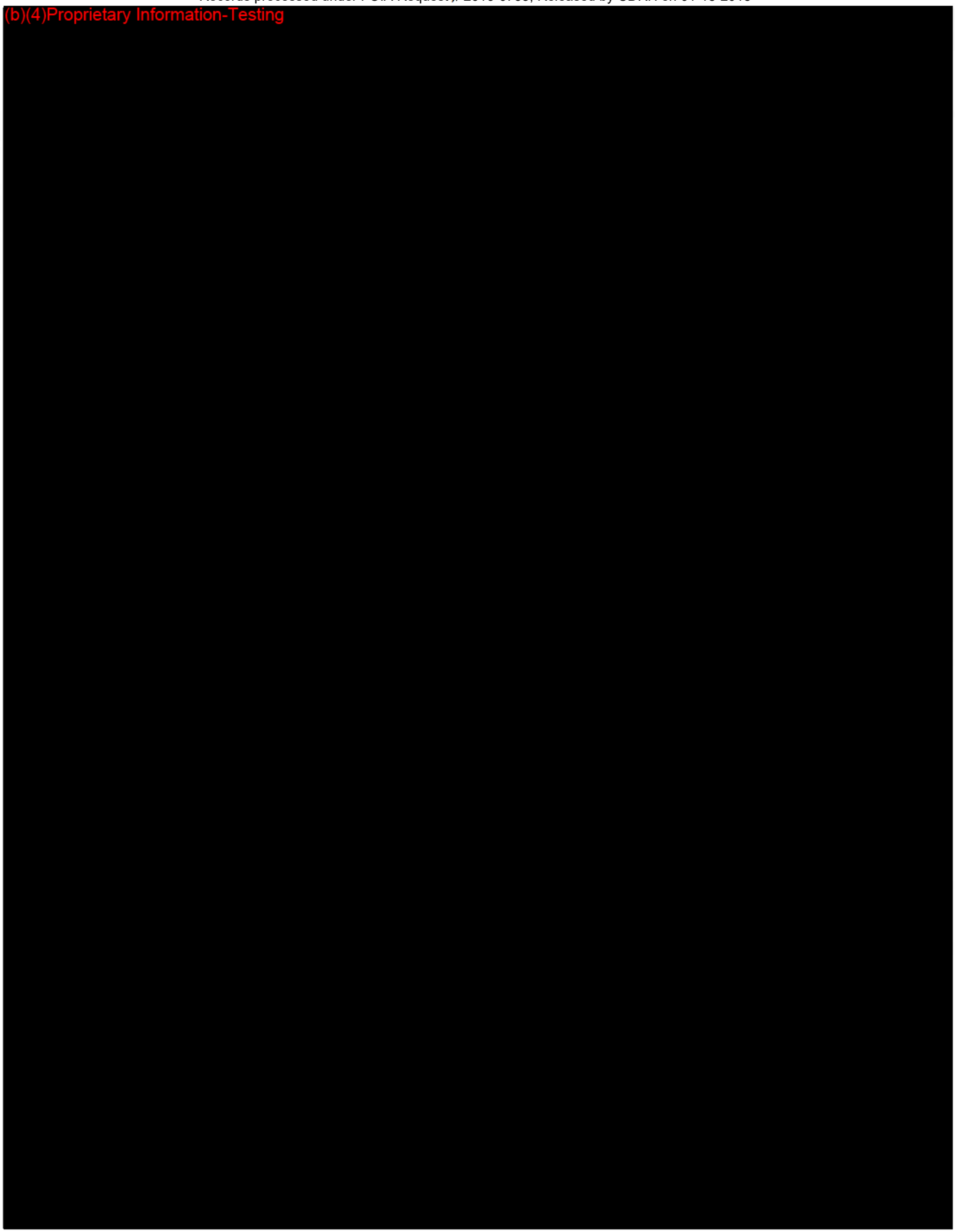


(b)(4)Proprietary Information-Testing

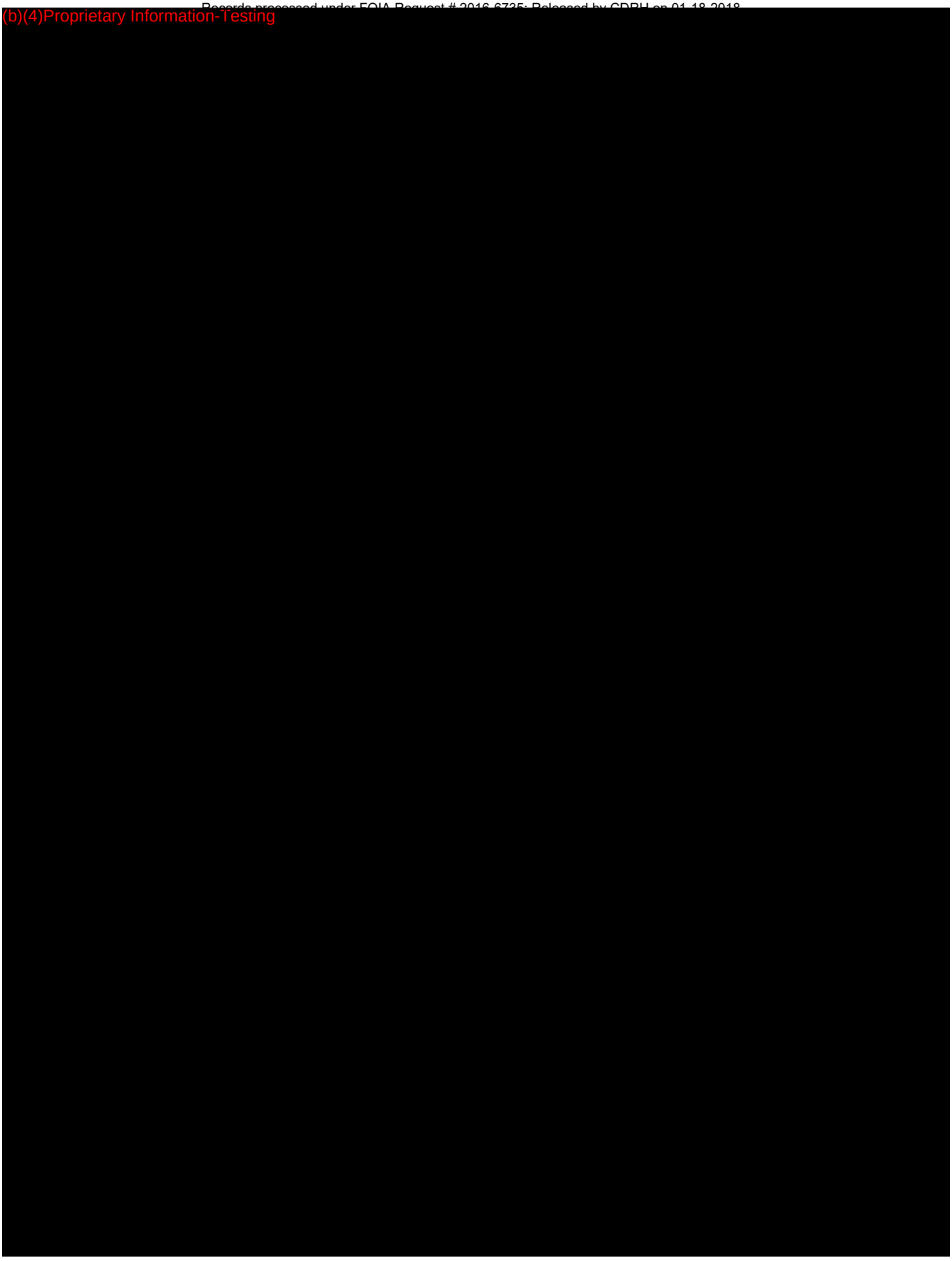




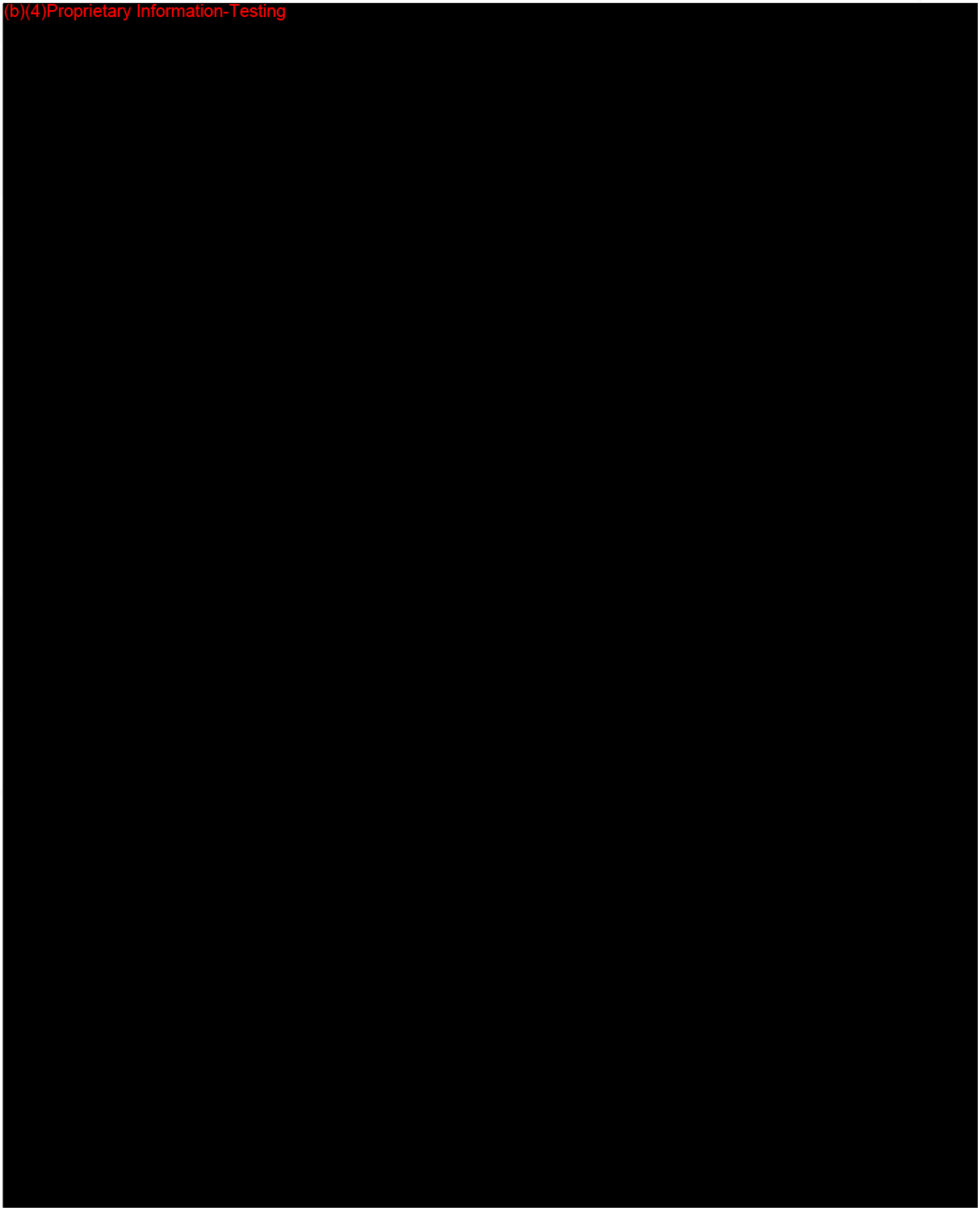
(b)(4)Proprietary Information-Testing

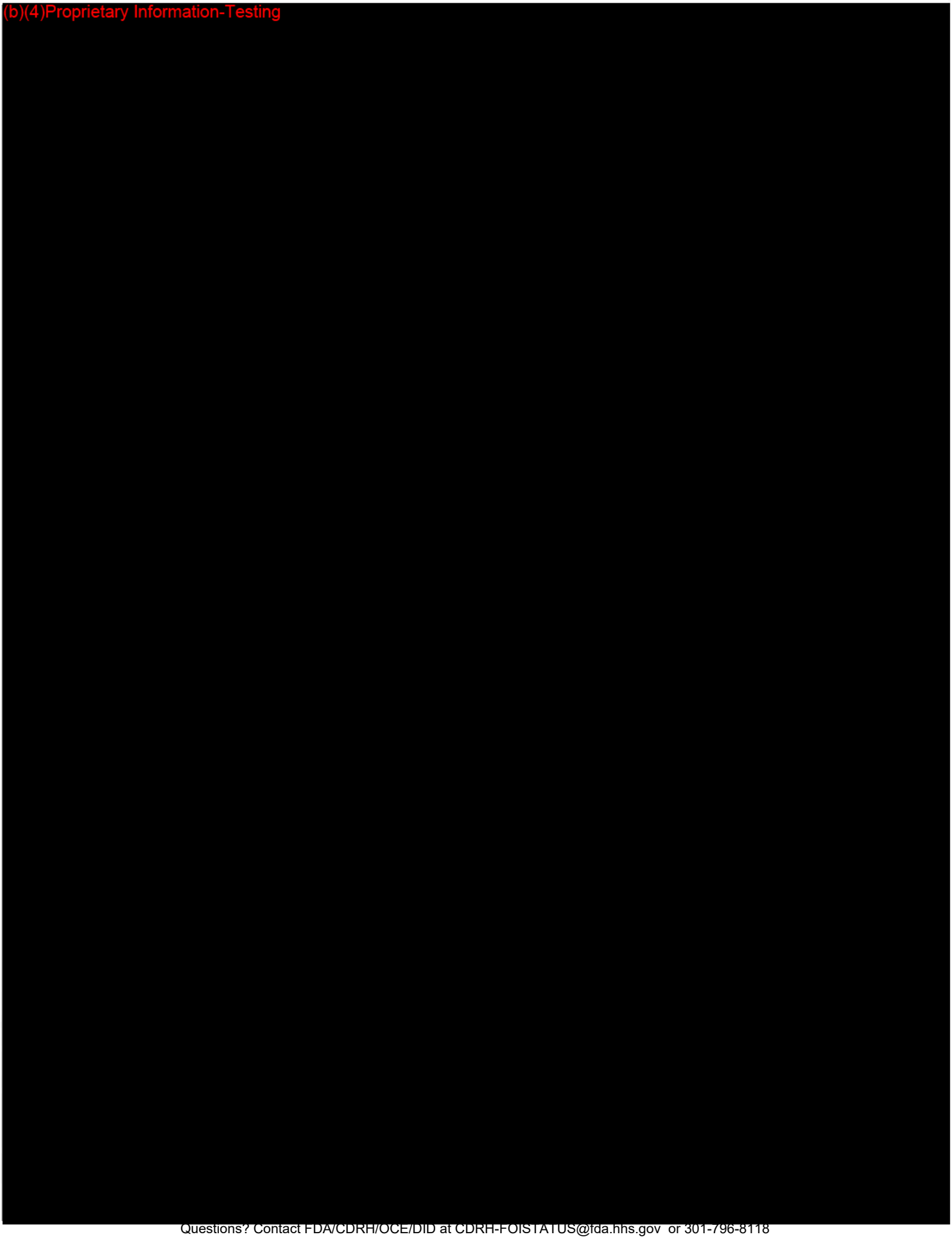


(b)(4)Proprietary Information-Testing

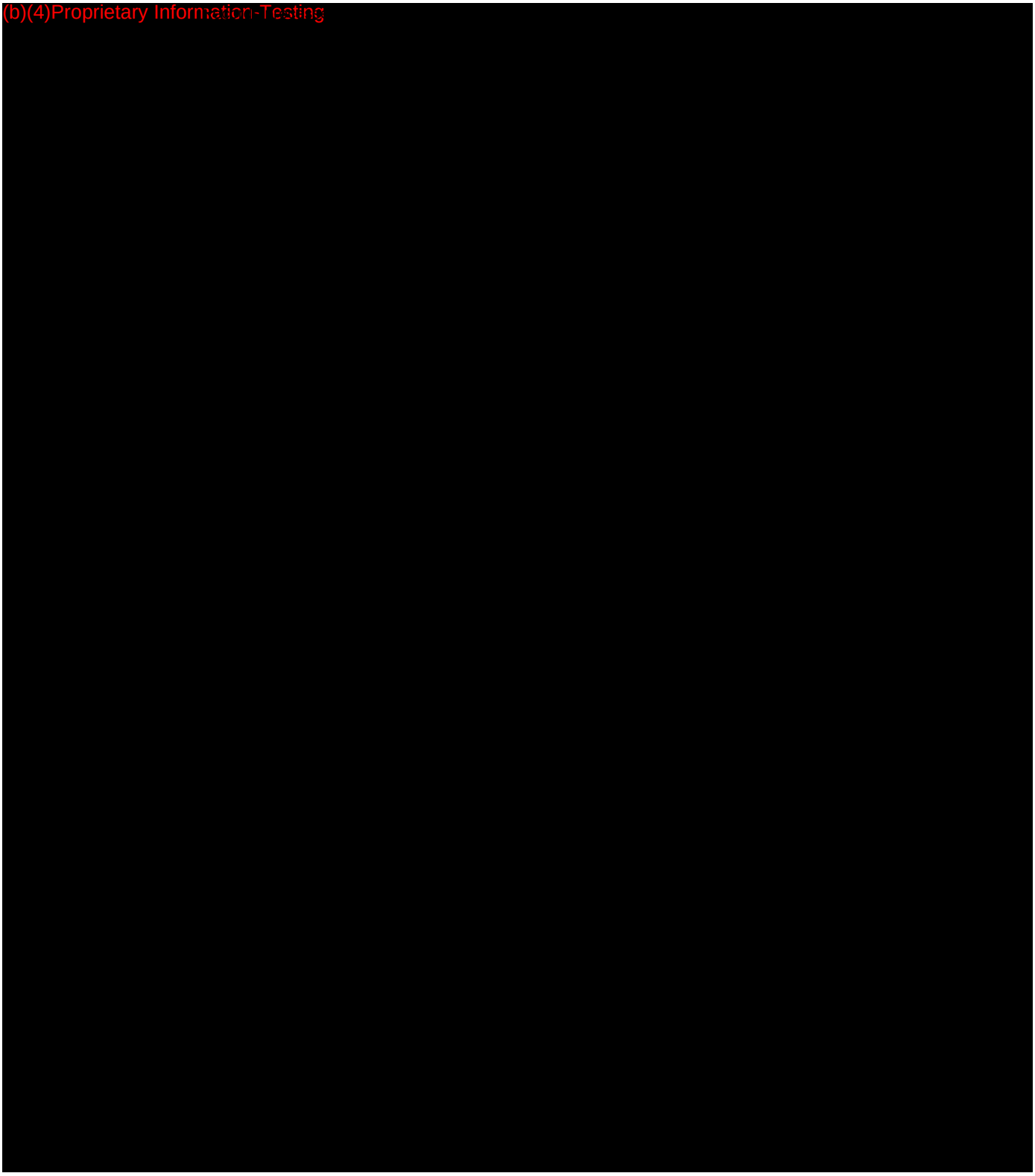


(b)(4)Proprietary Information-Testing

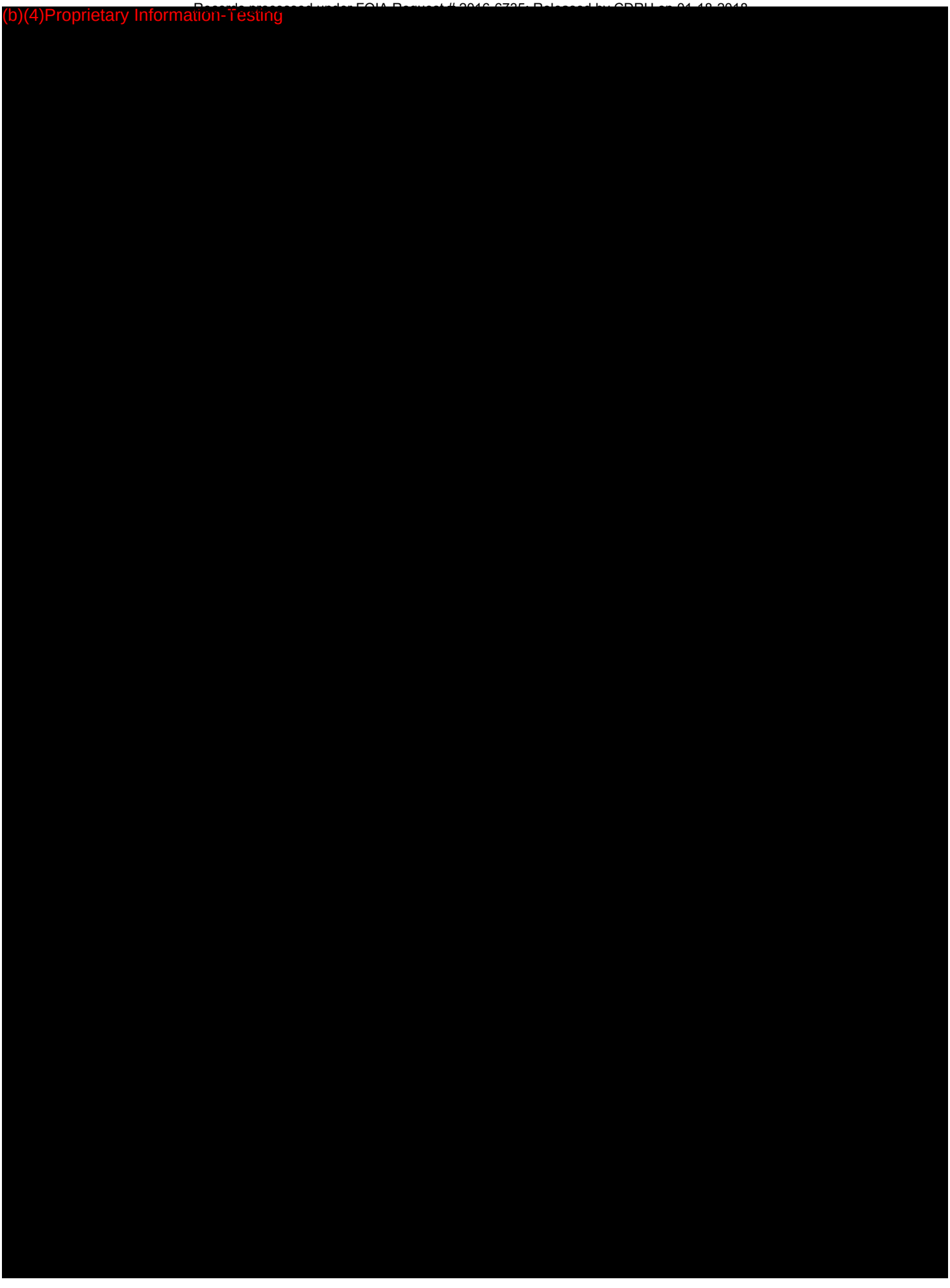




(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing

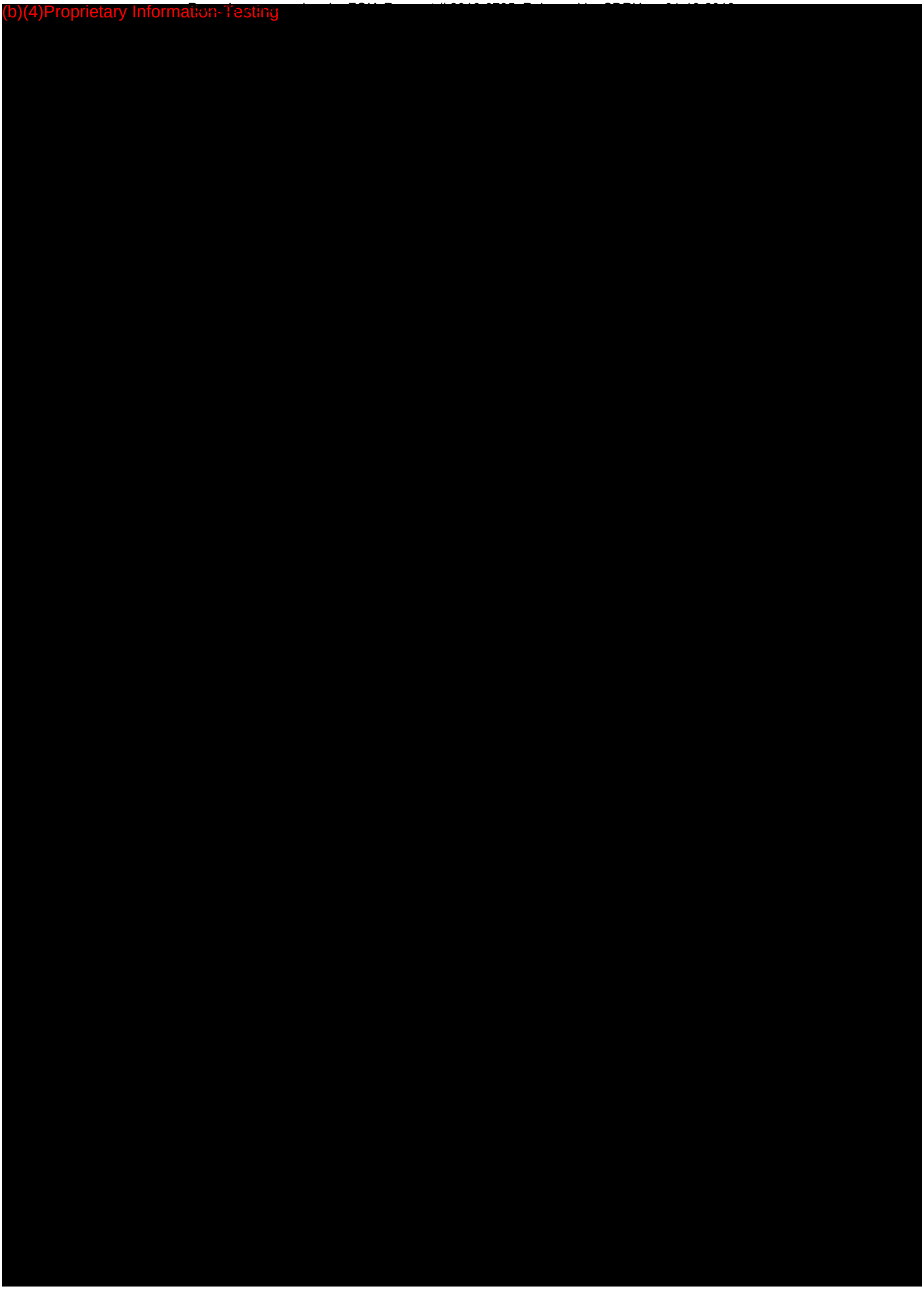
[redacted]

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

[redacted]

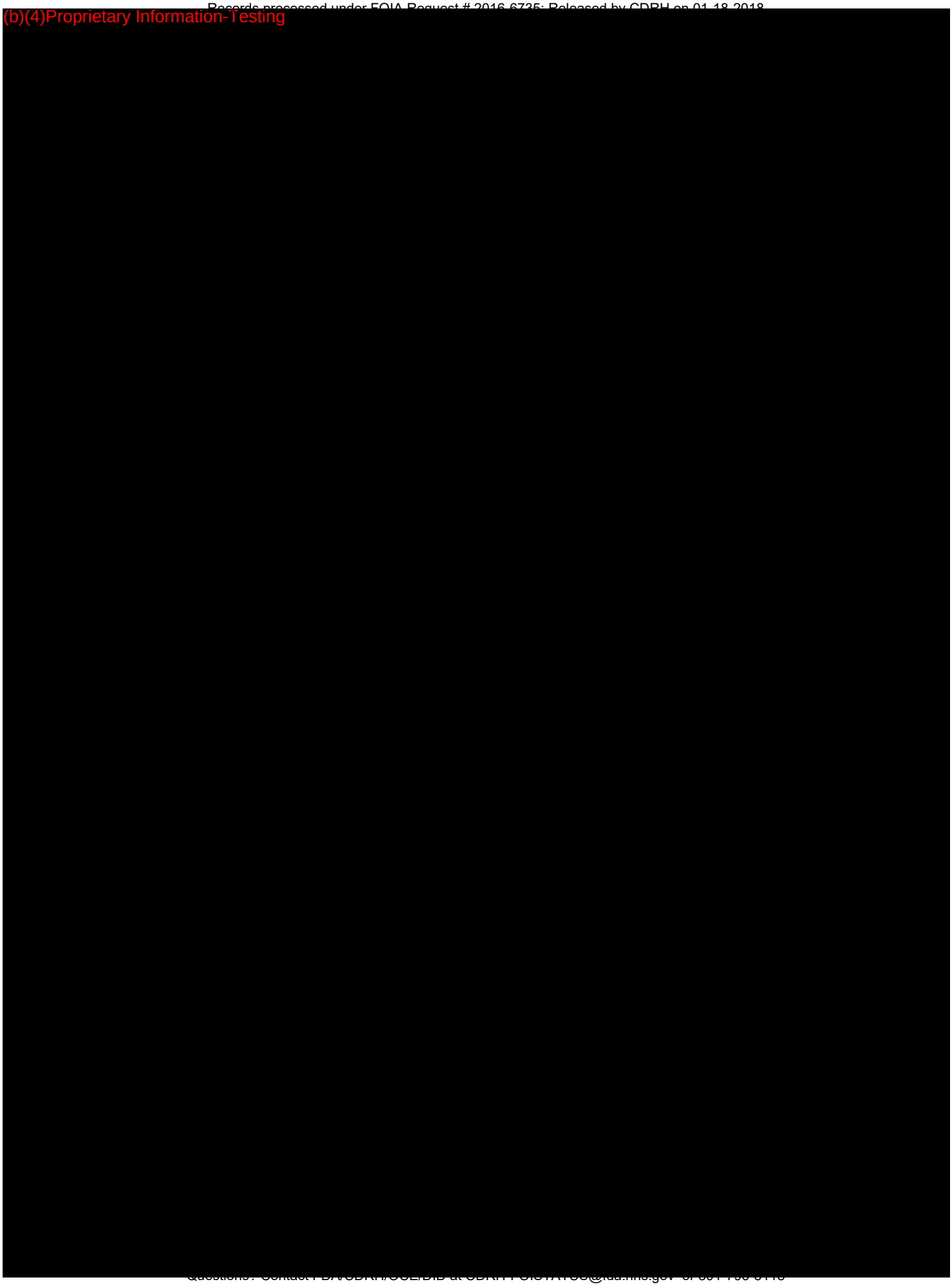
(b)(4)Proprietary Information-Testing



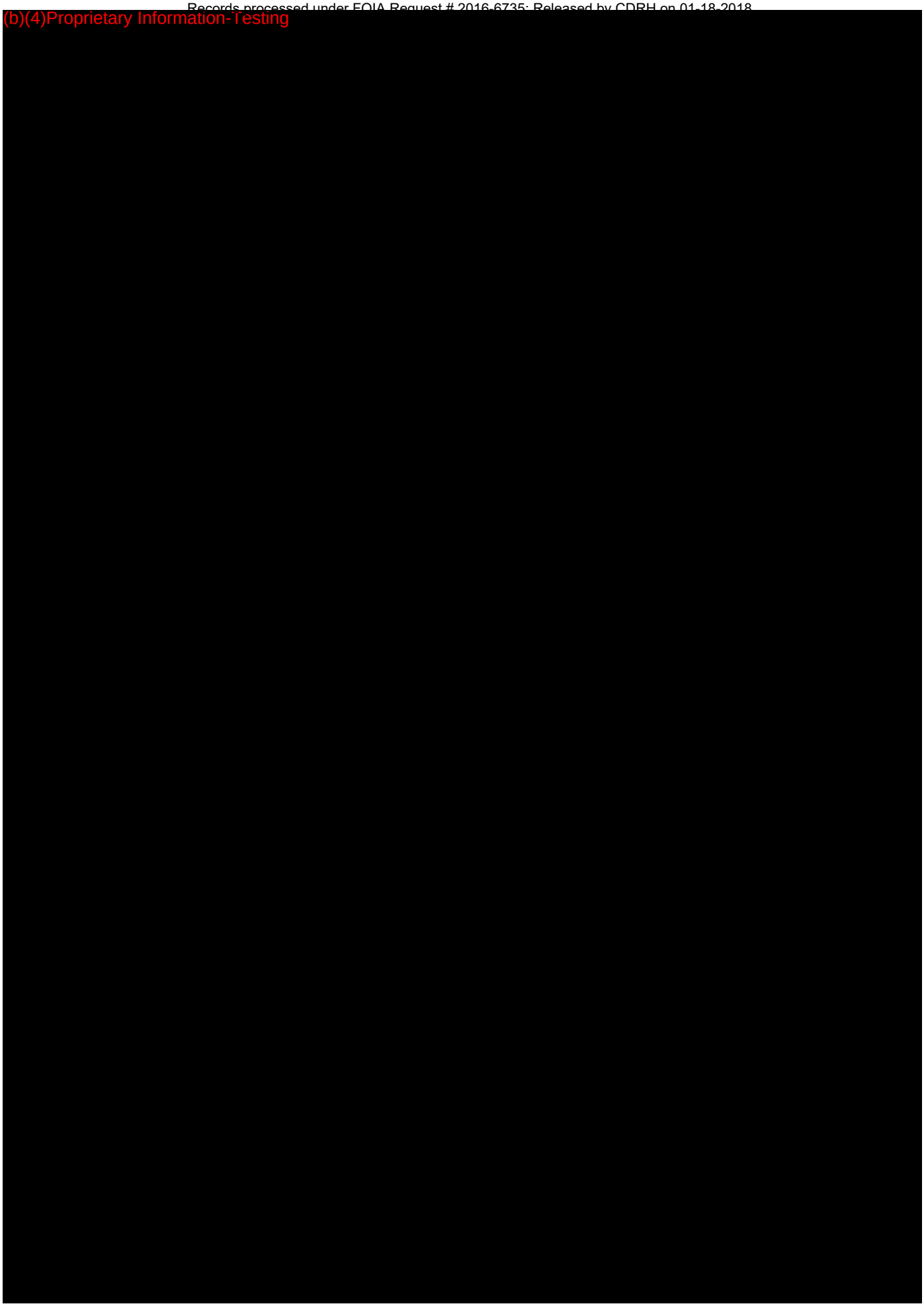
(b)(4)Proprietary Information-Testing

[redacted]

(b)(4)Proprietary Information-Testing



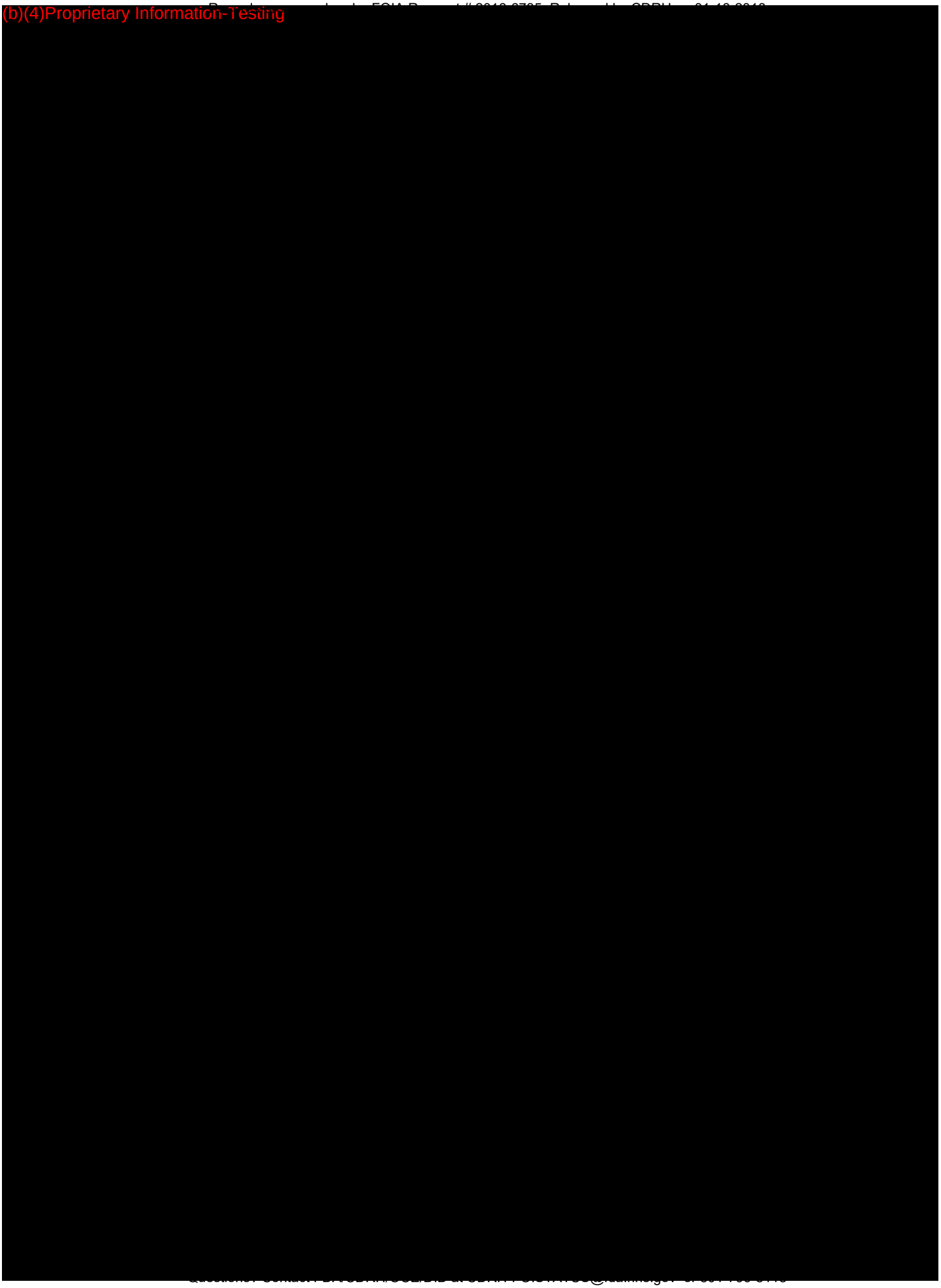
(b)(4)Proprietary Information-Testing



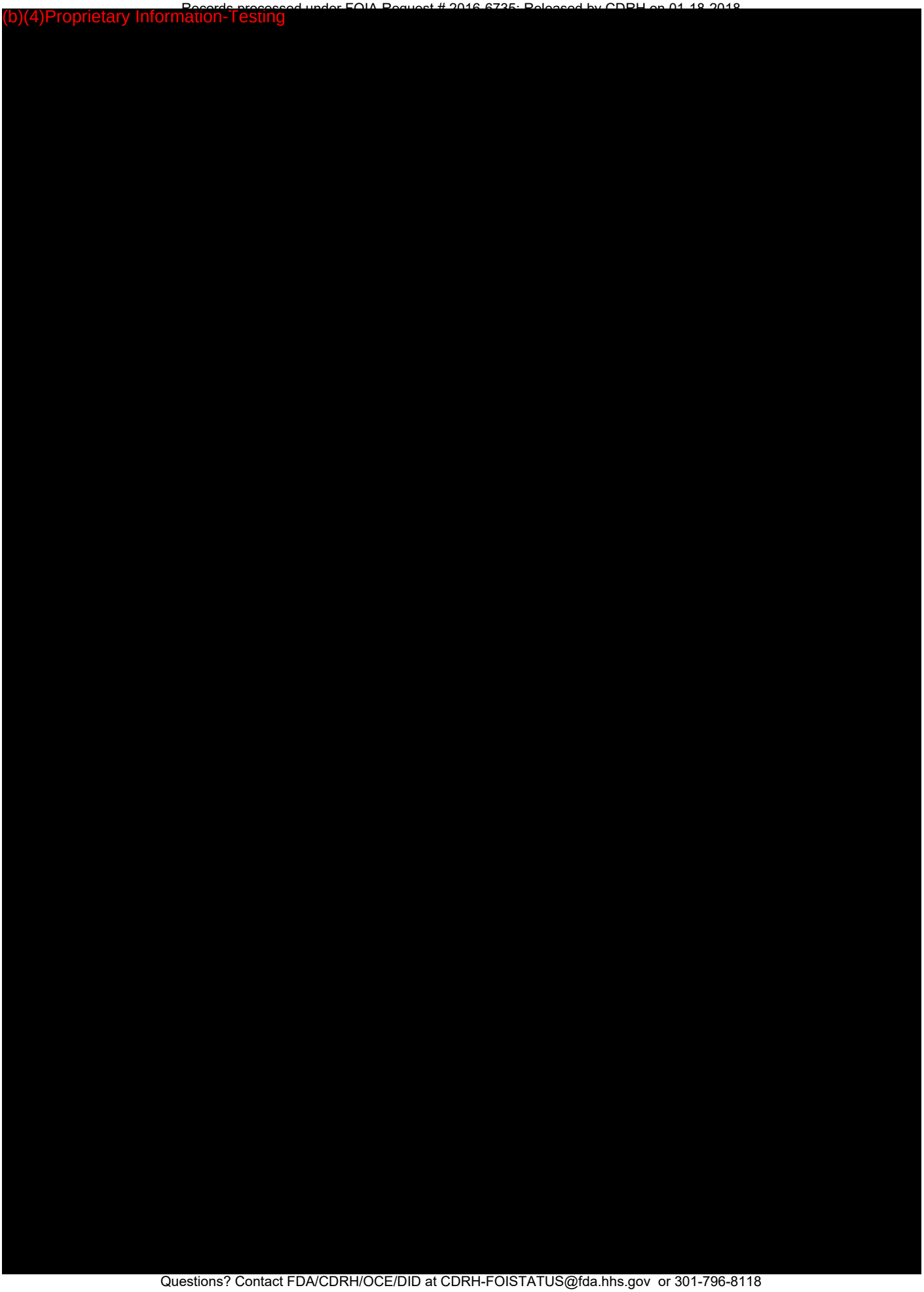
(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

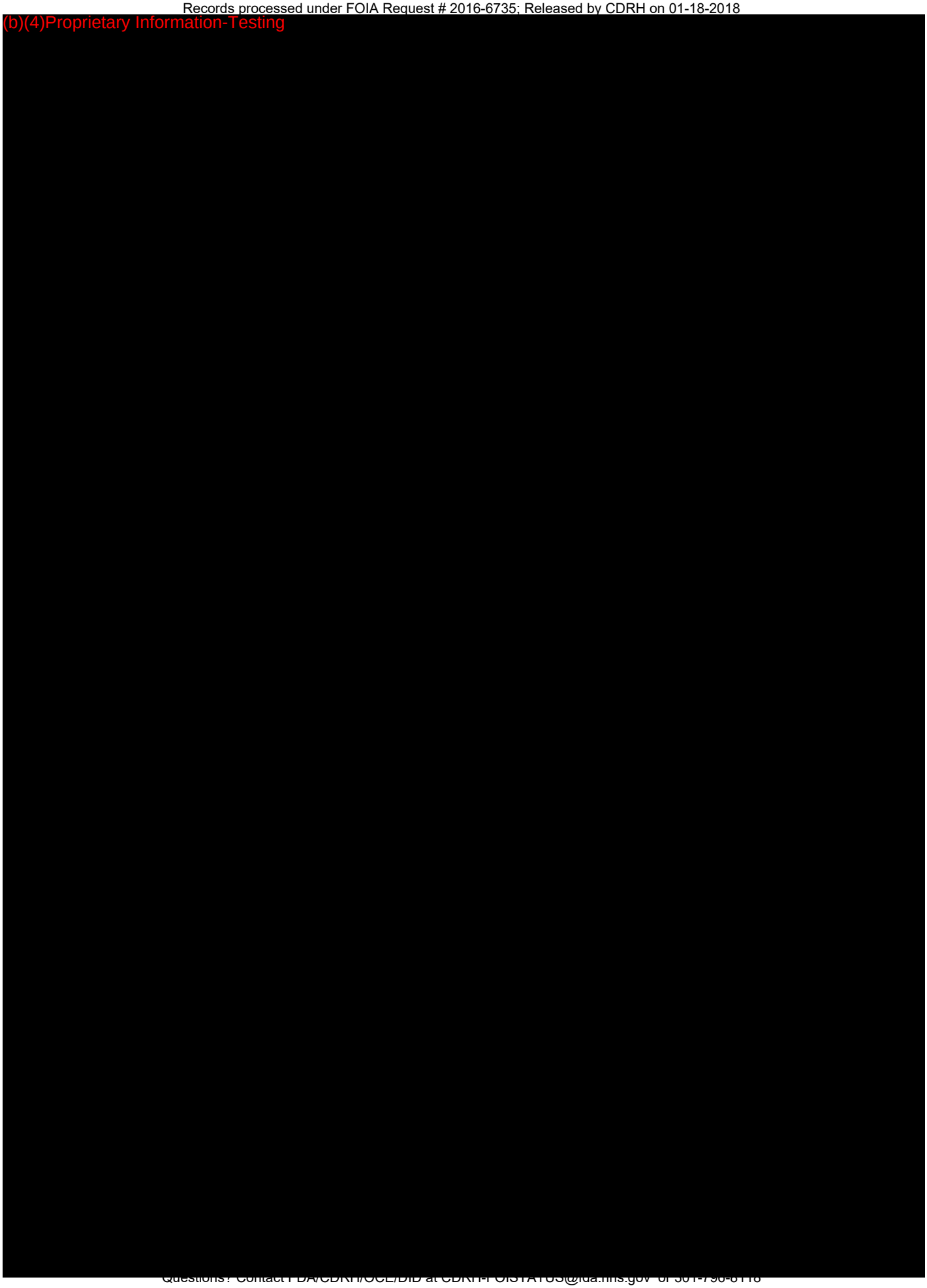
[redacted]



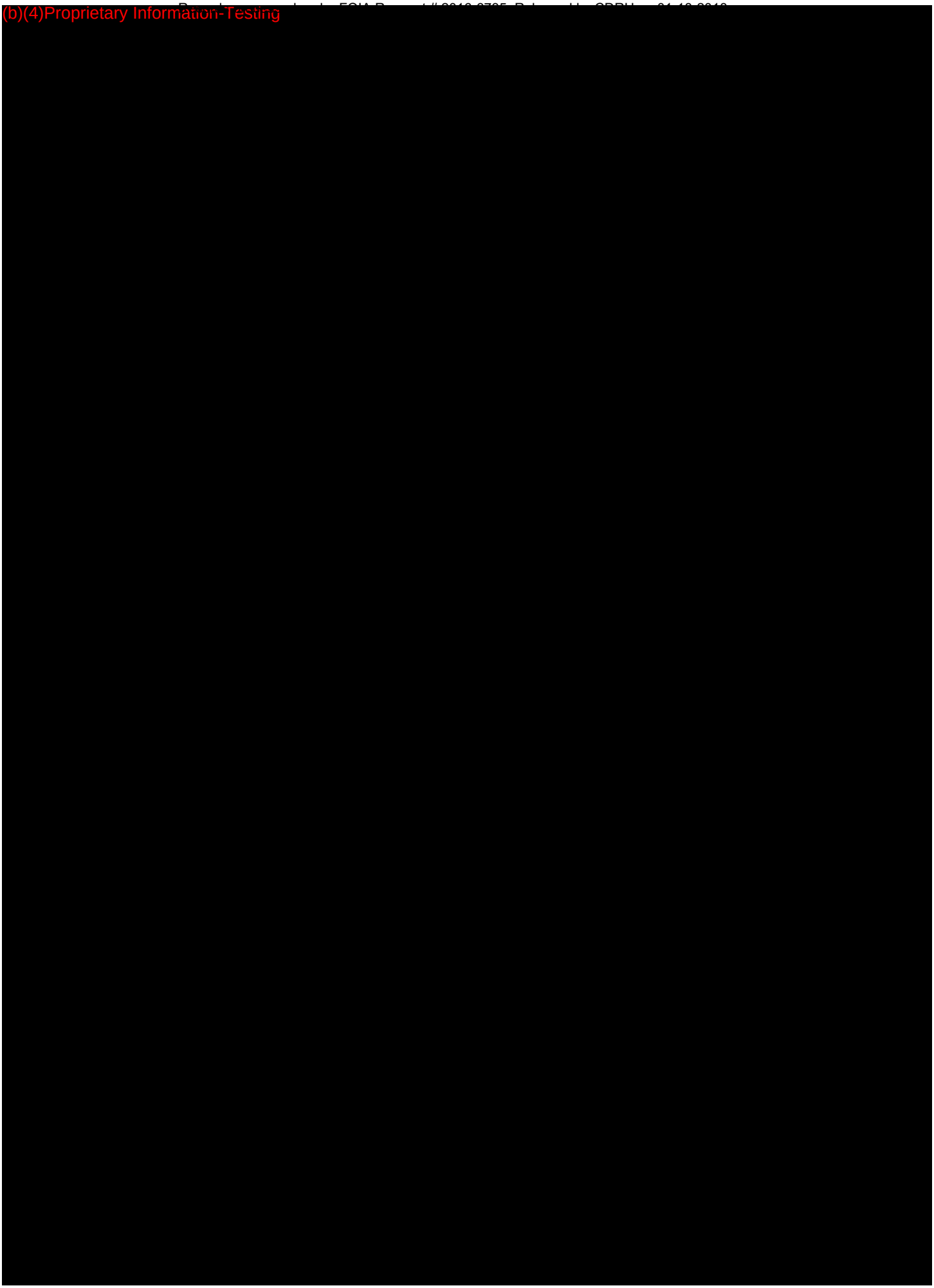
(b)(4)Proprietary Information-Testing



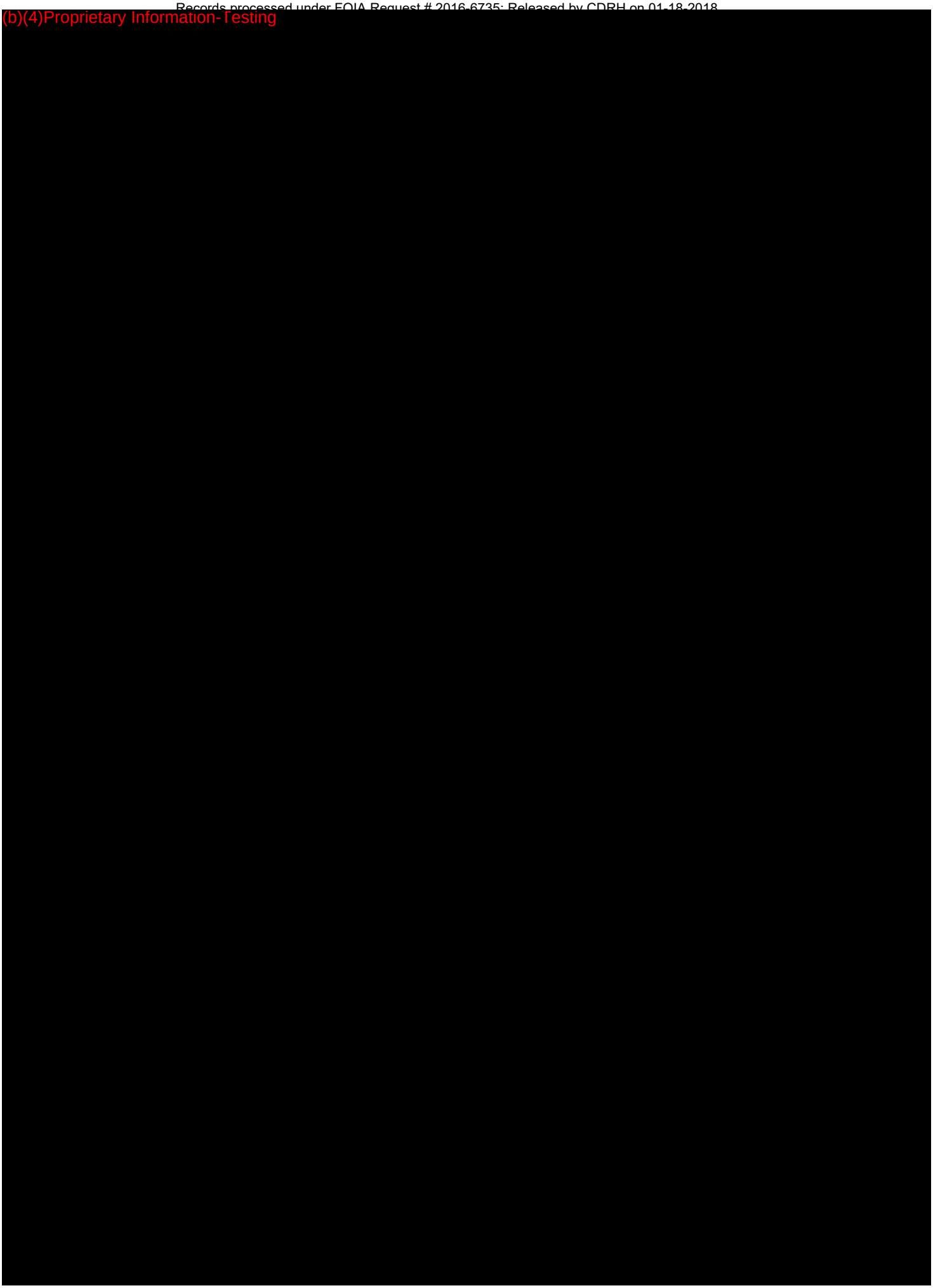
(b)(4)Proprietary Information-Testing



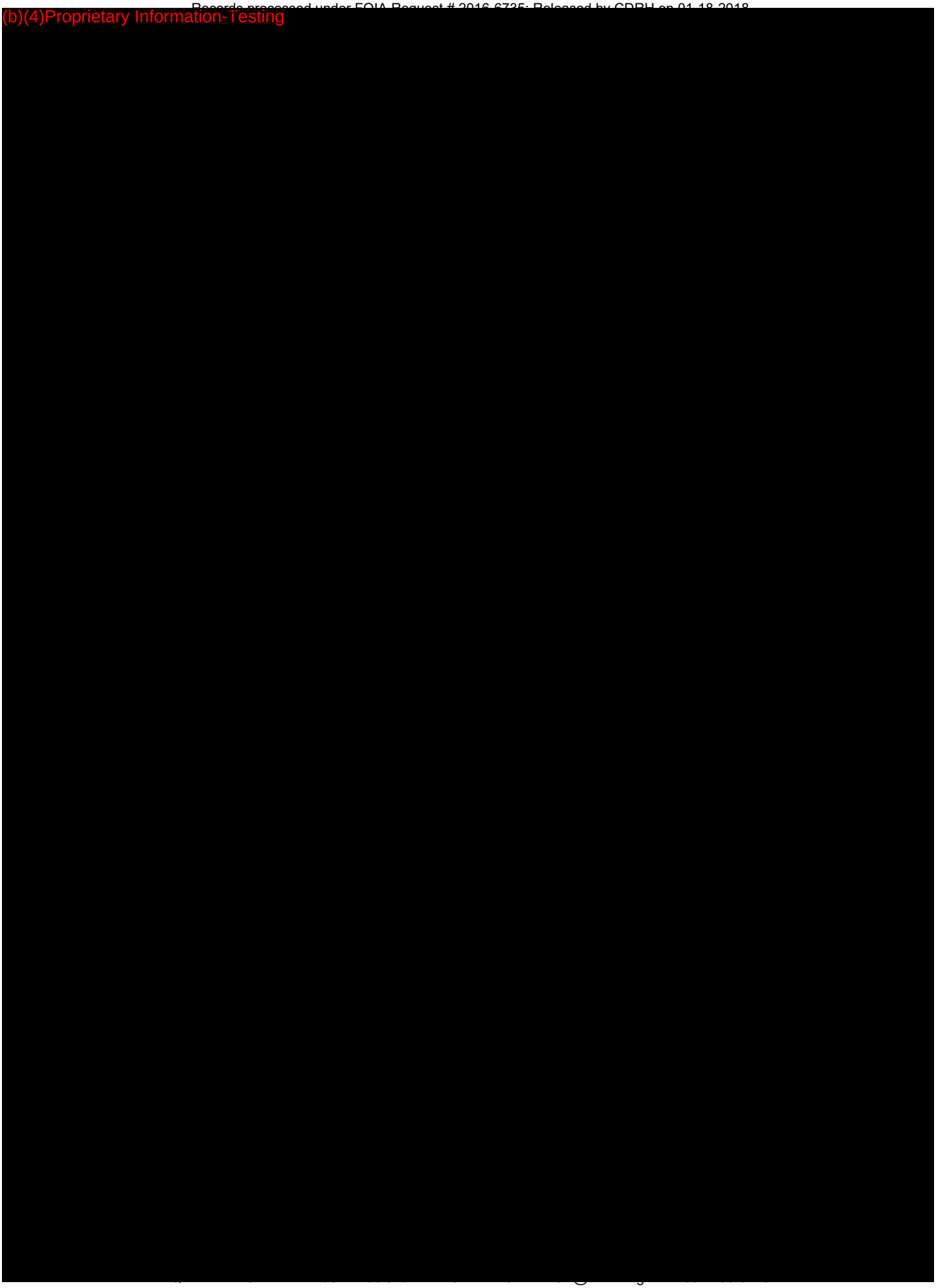
(b)(4)Proprietary Information-Testing



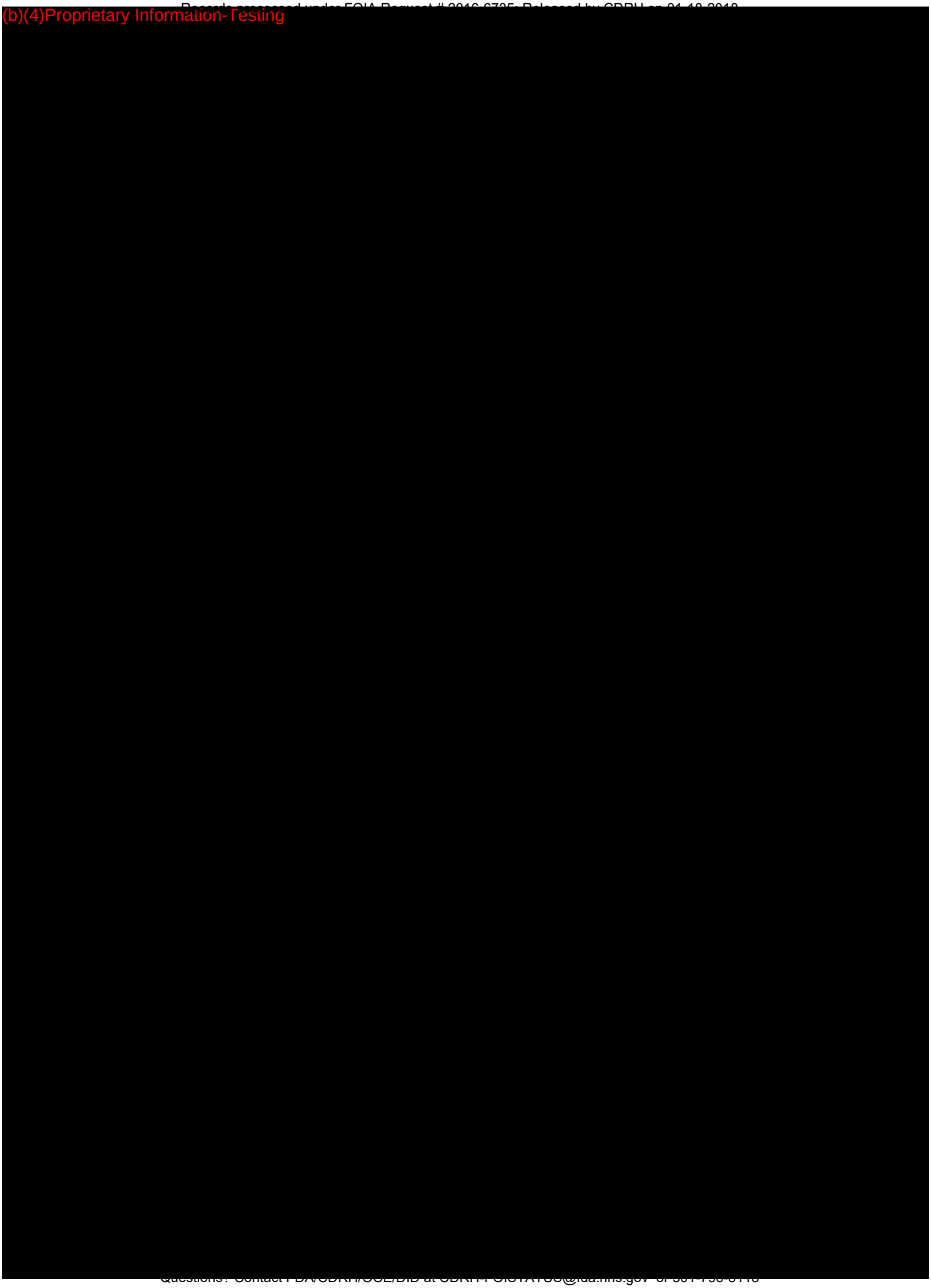
(b)(4)Proprietary Information- Testing



(b)(4)Proprietary Information-Testing



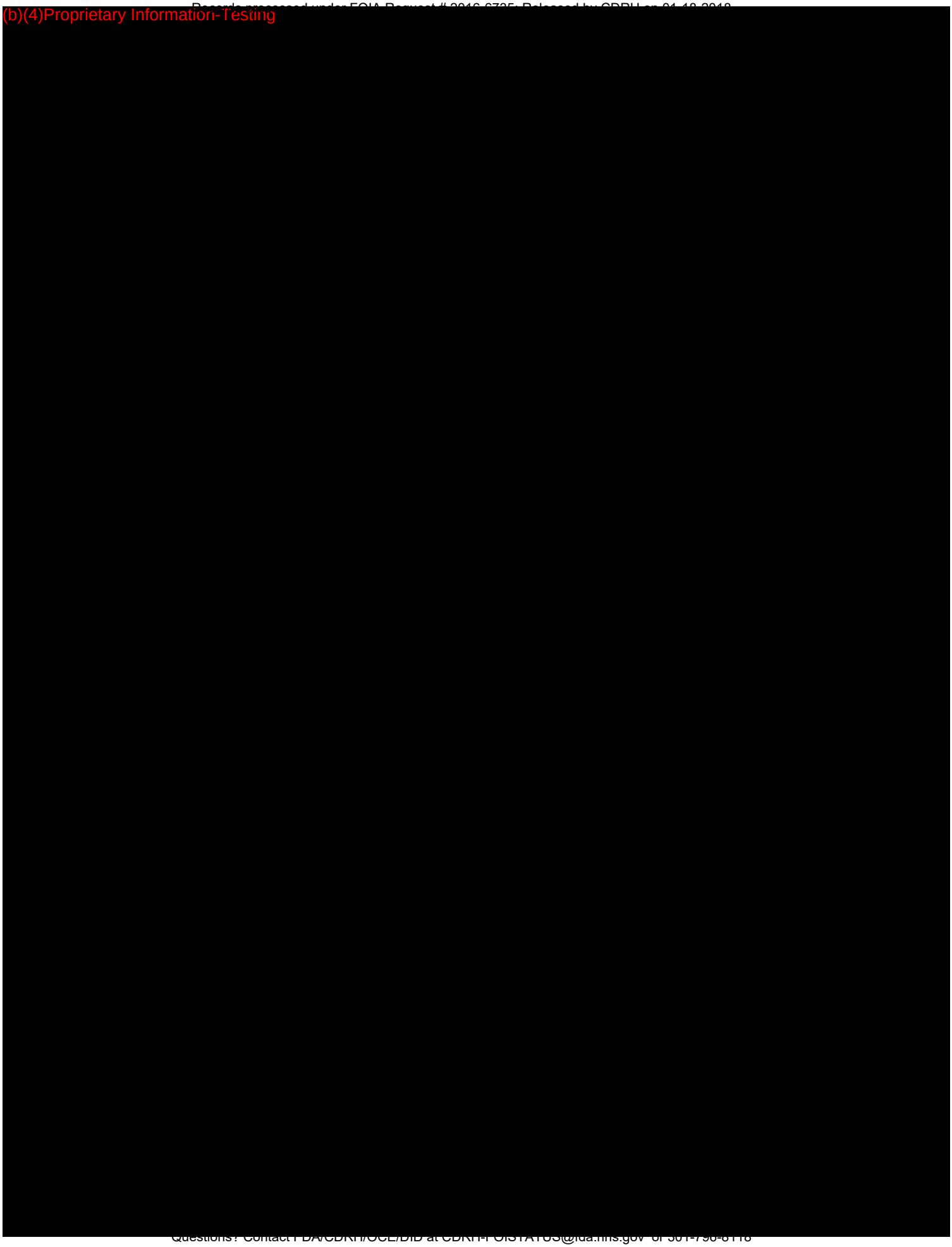
(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing

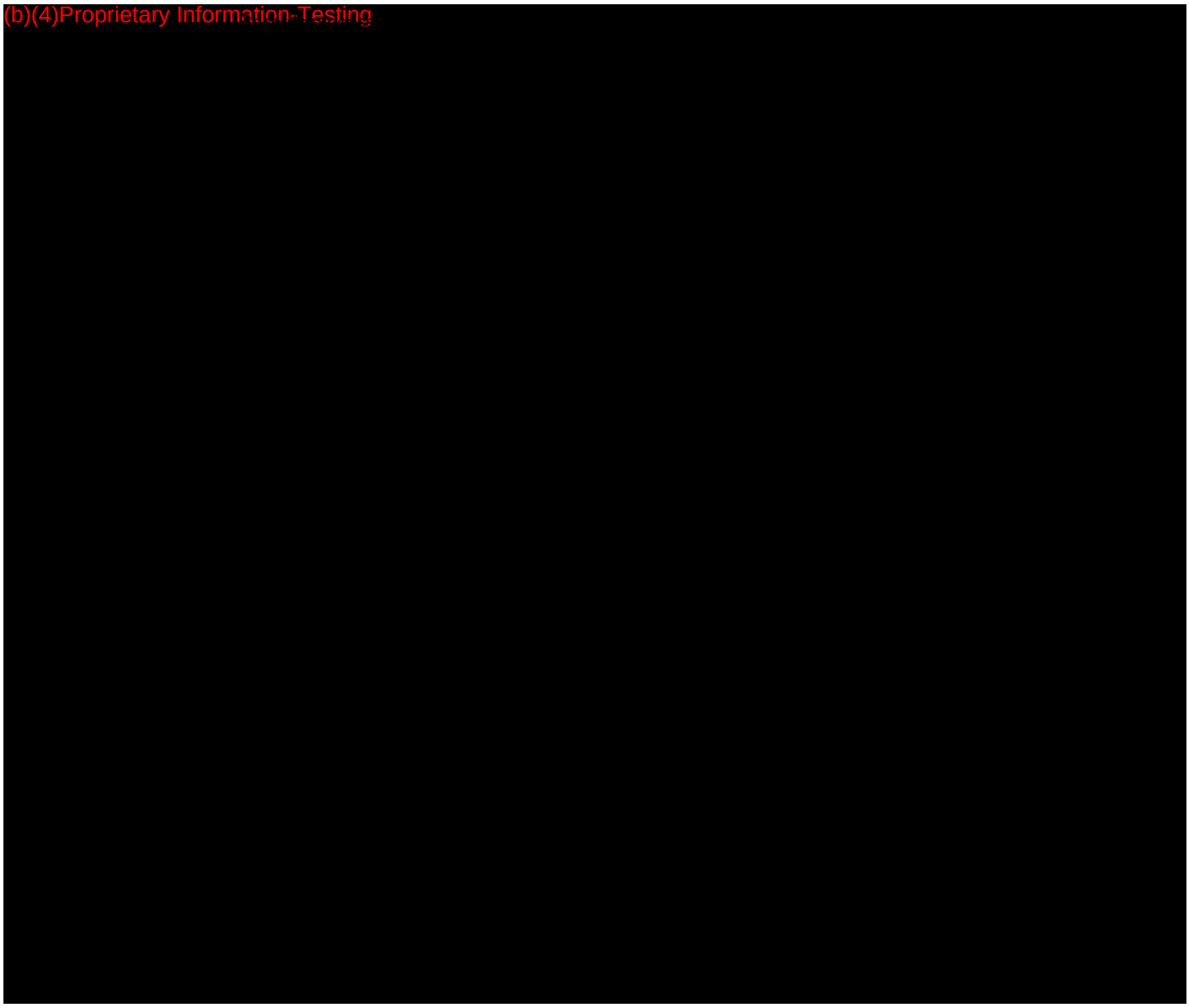
[redacted]

(b)(4)Proprietary Information-Testing



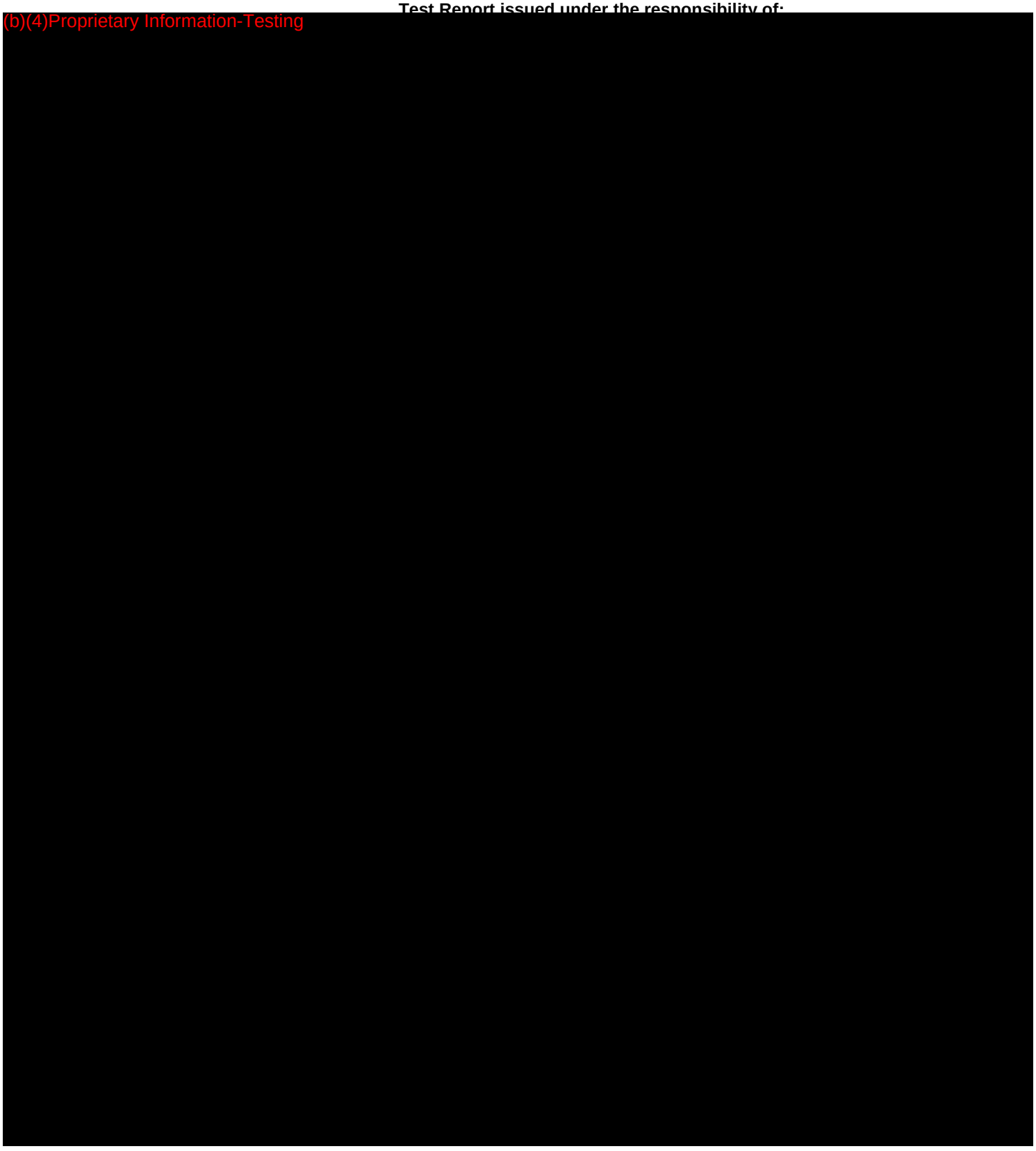
(b)(4)Proprietary Information-Testing

[redacted]

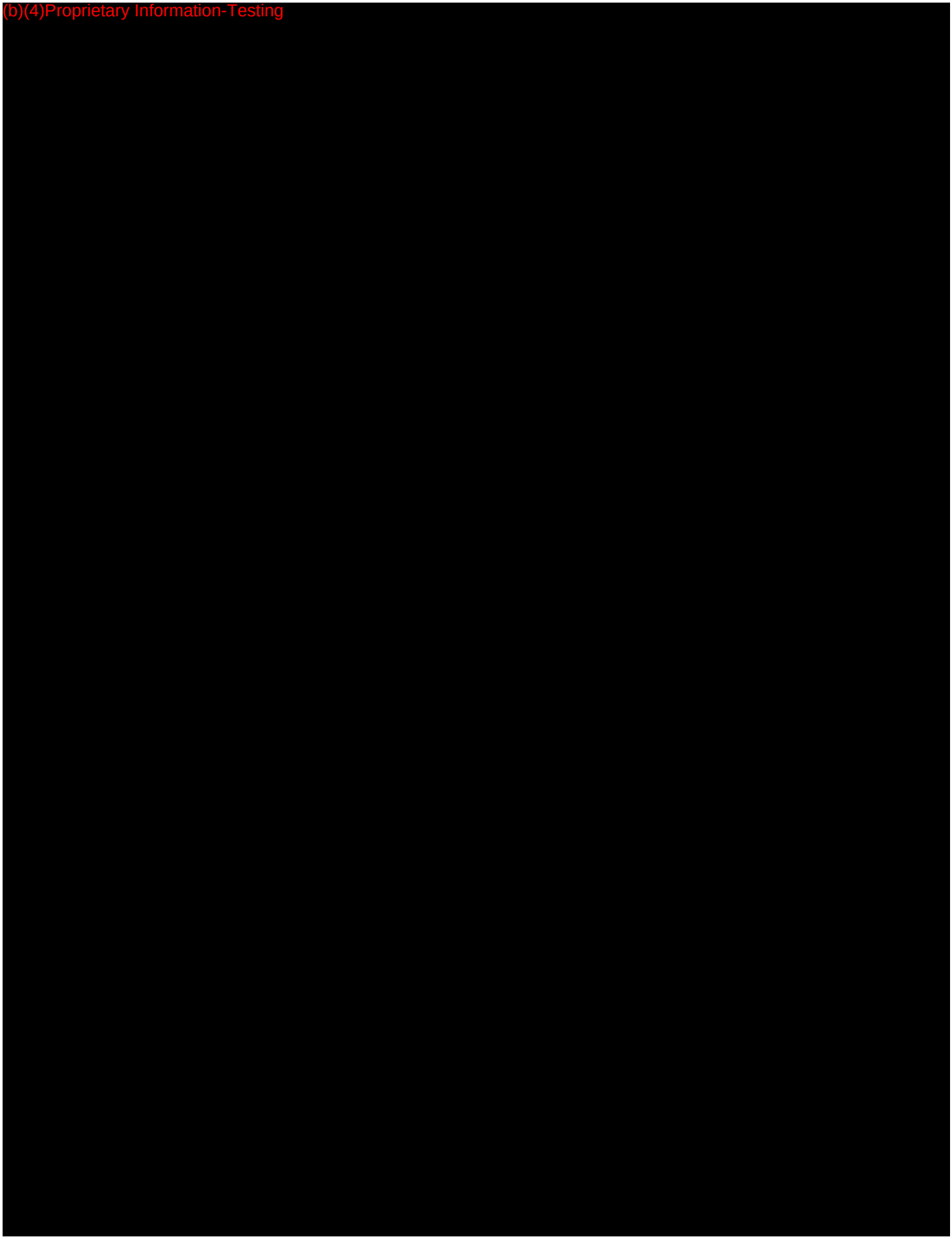


Test Report issued under the responsibility of:

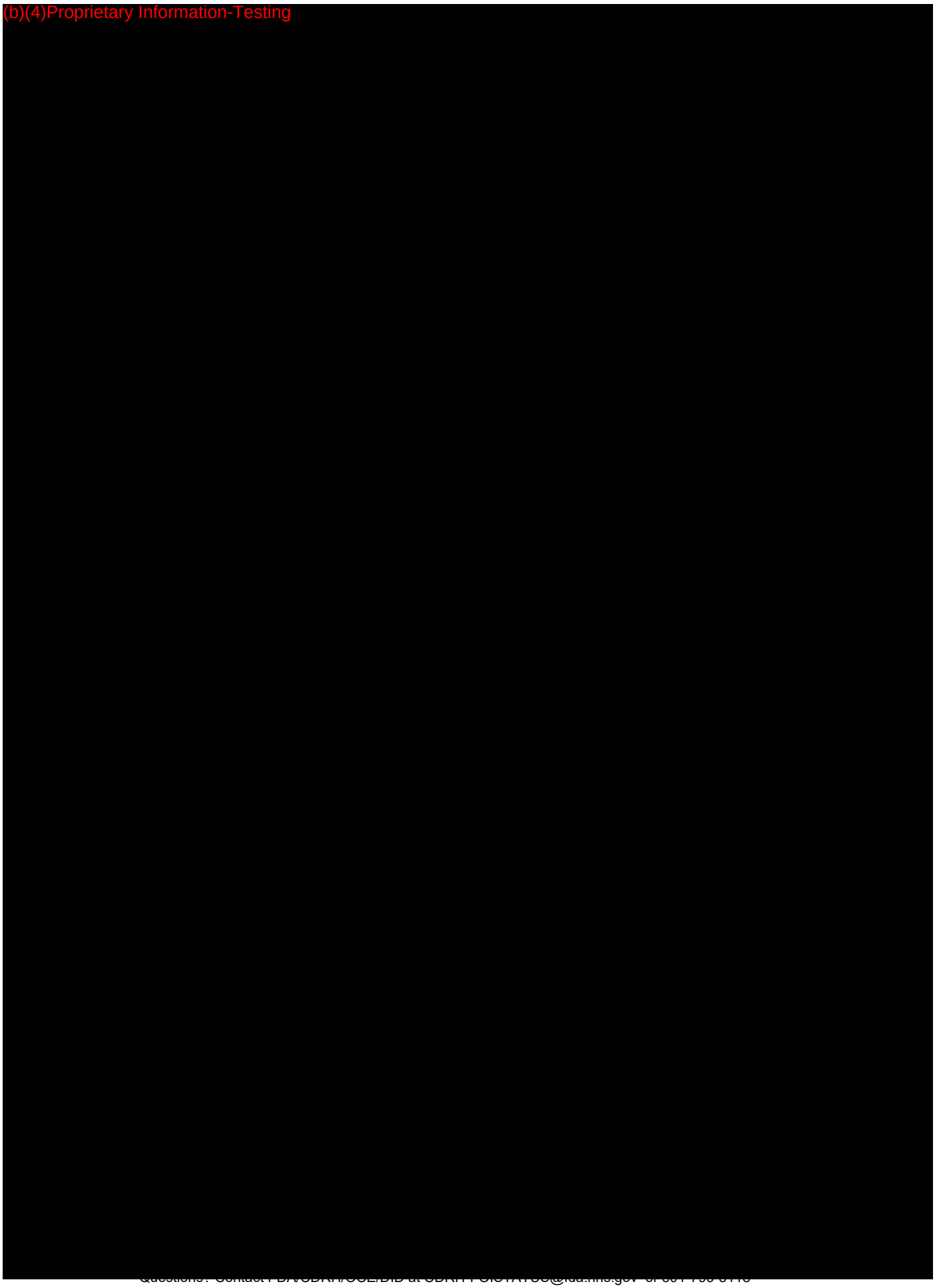
(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing



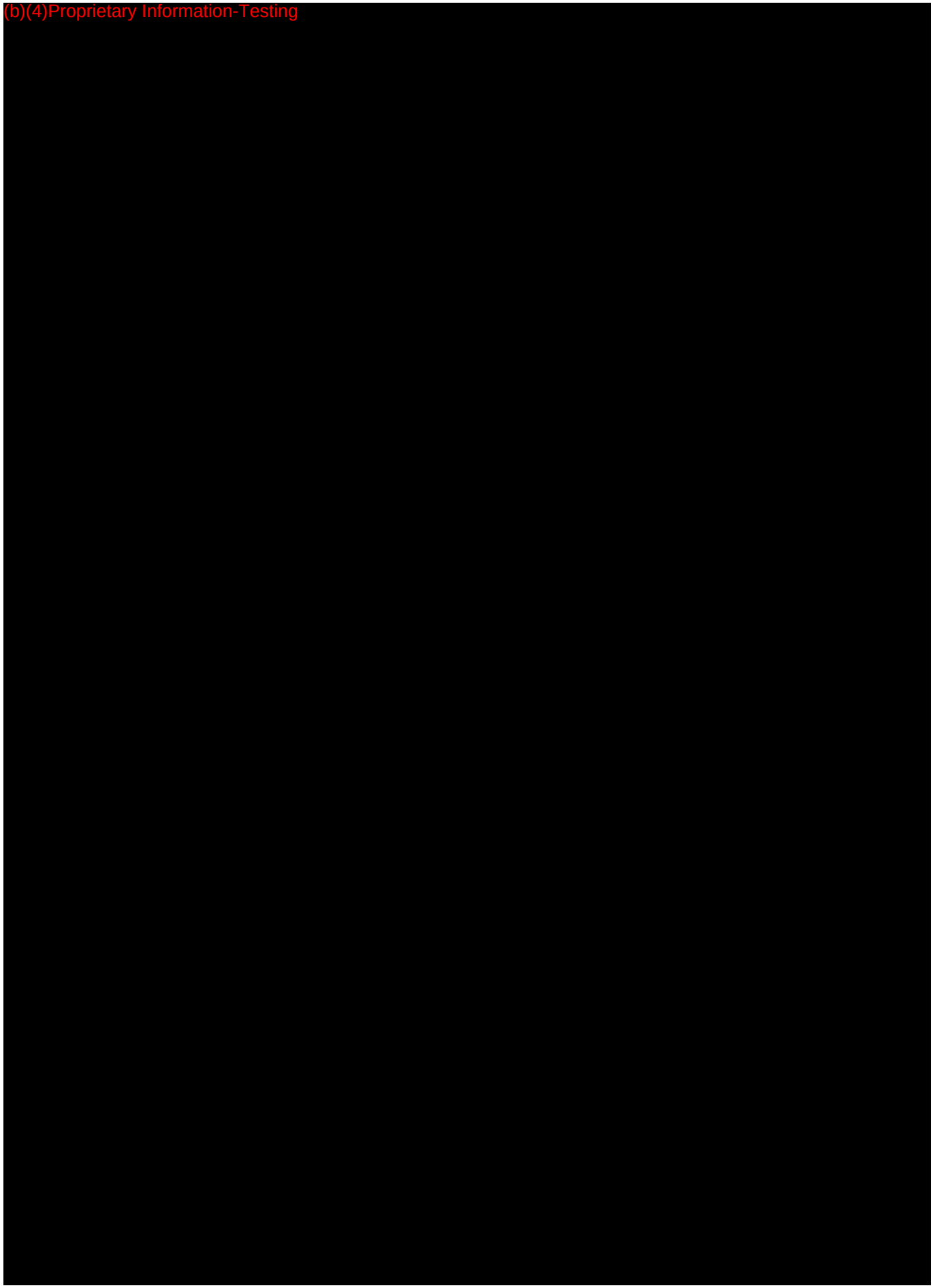
(b)(4)Proprietary Information-Testing

[redacted]

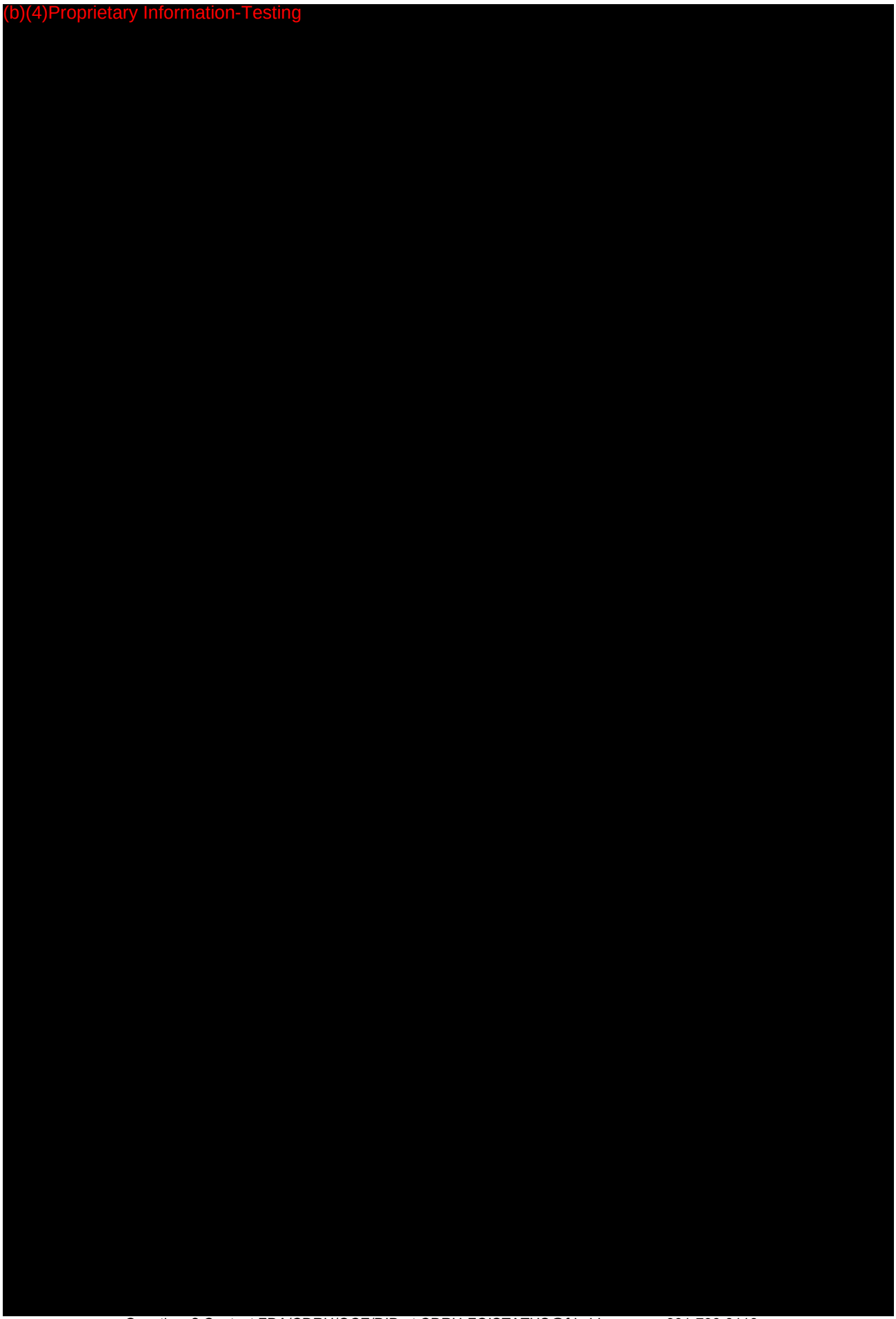
(b)(4)Proprietary Information-Testing

[redacted]

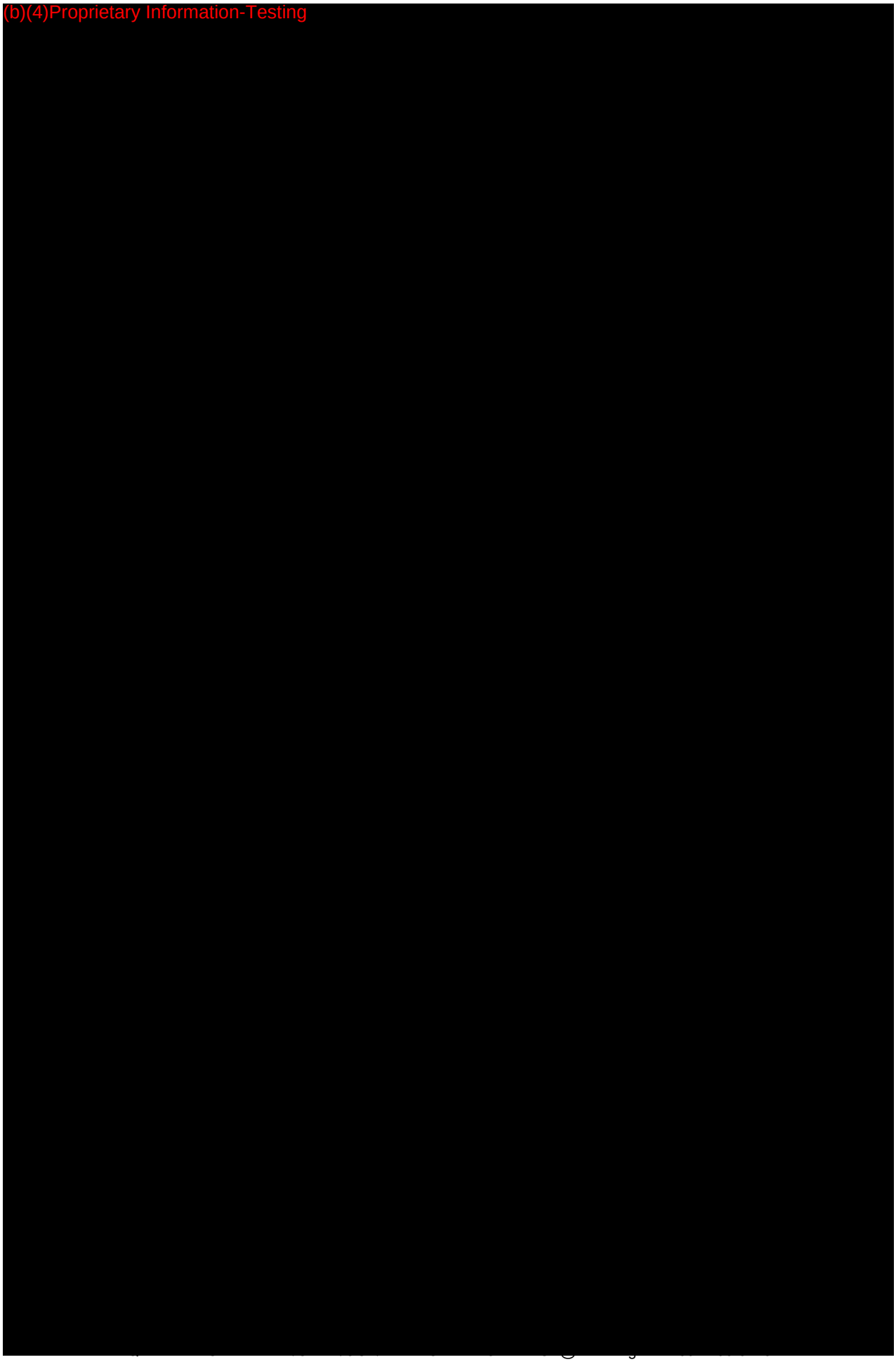
(b)(4)Proprietary Information-Testing



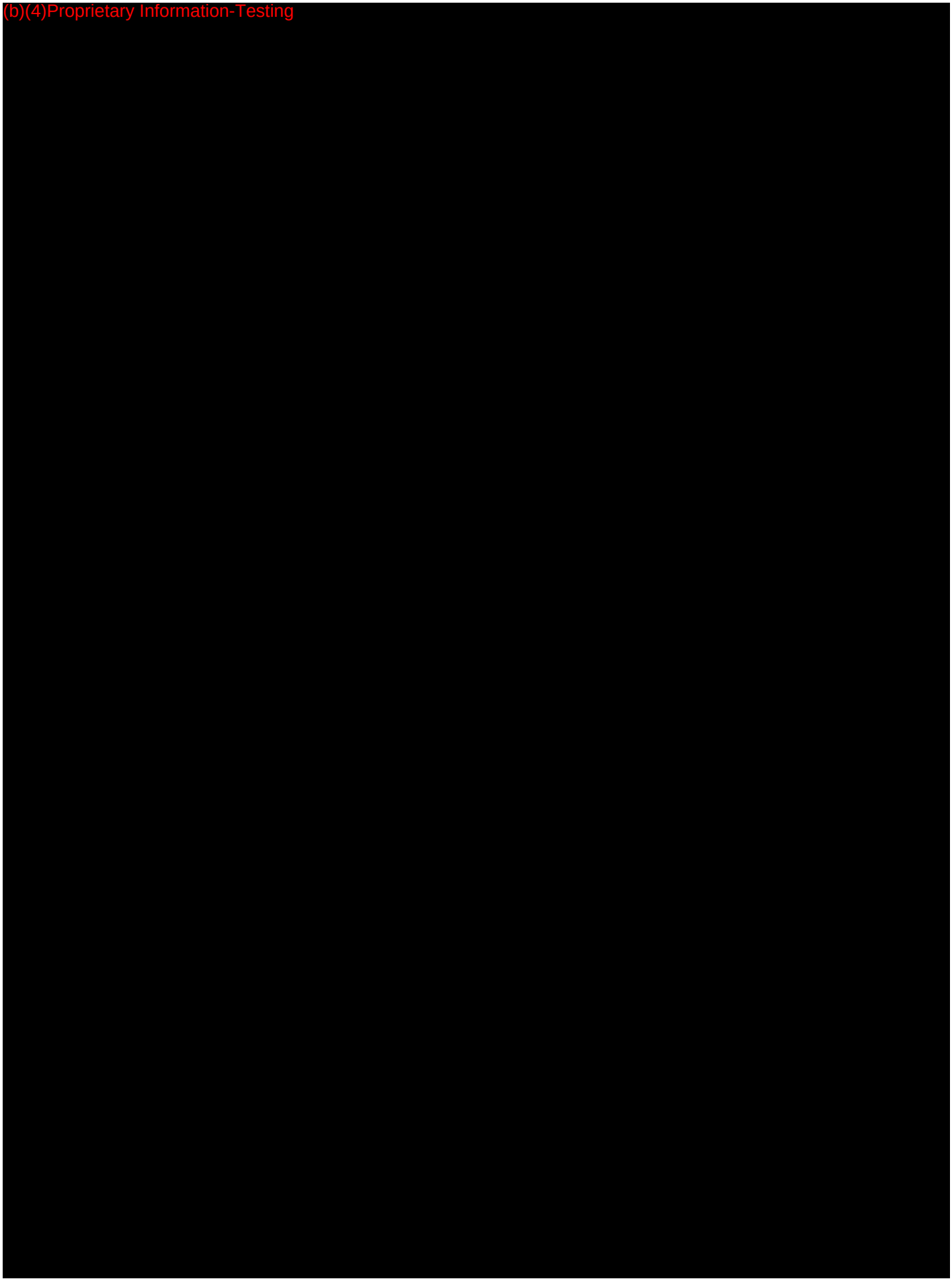
(b)(4)Proprietary Information-Testing



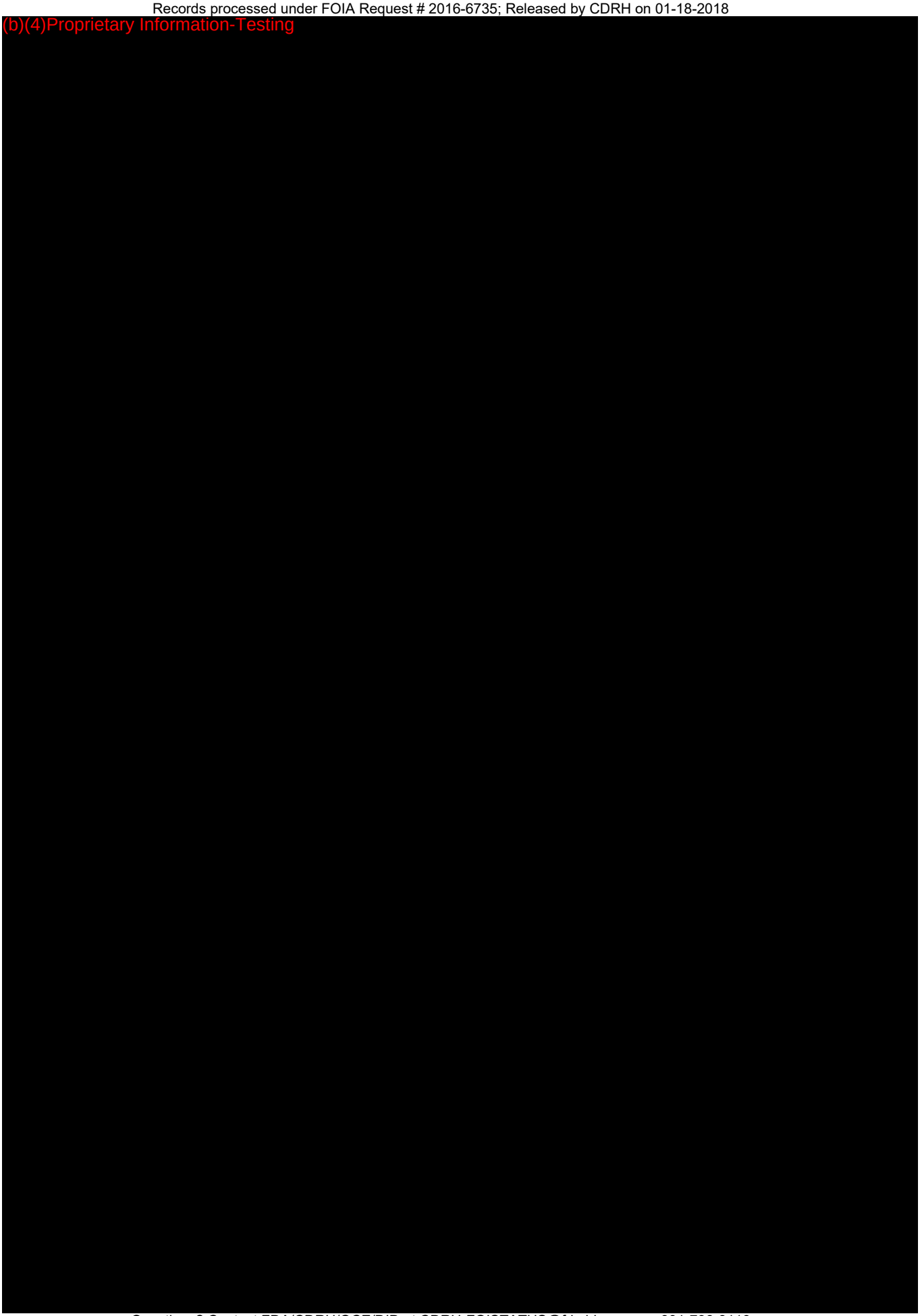
(b)(4)Proprietary Information-Testing



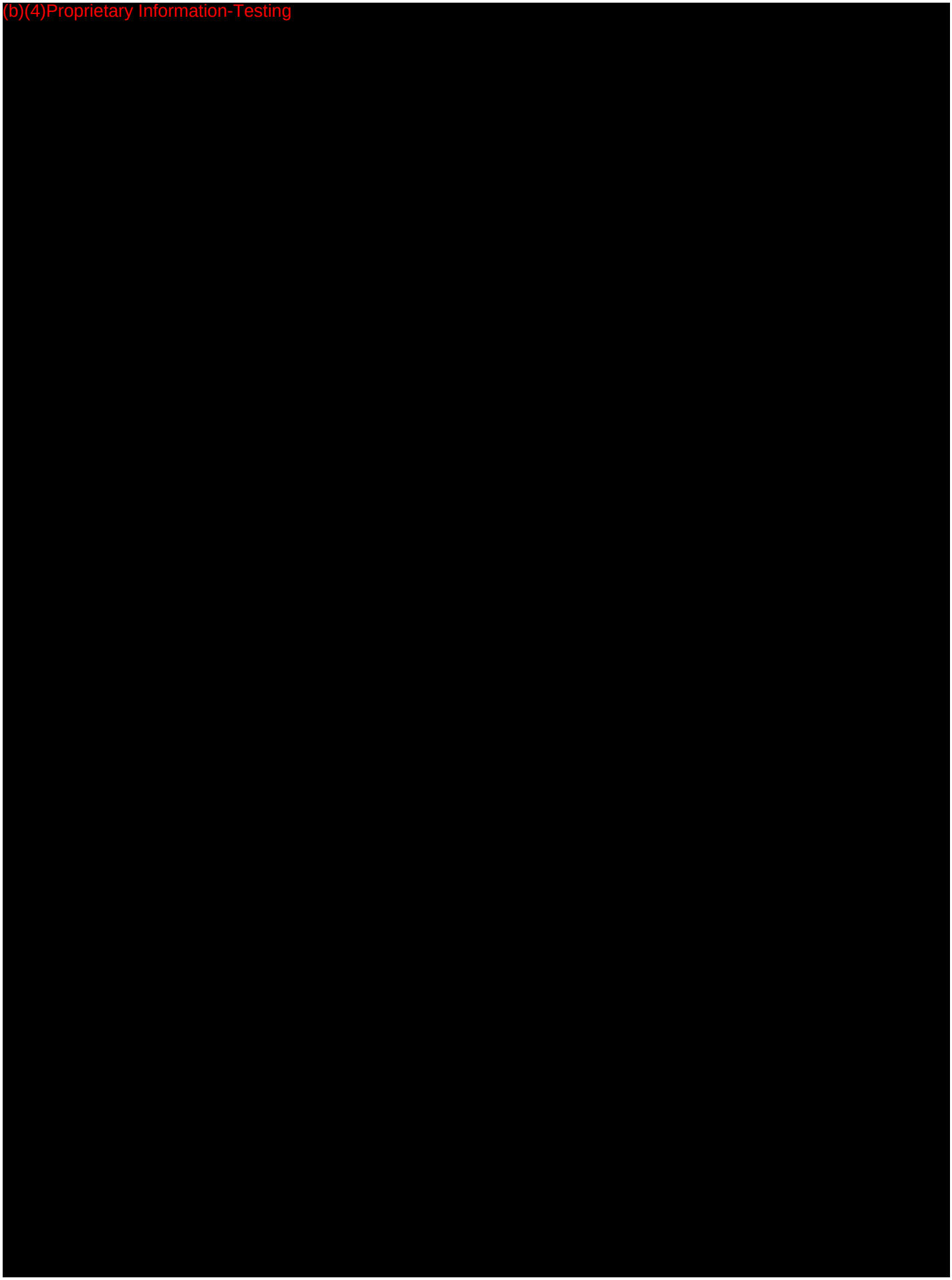
(b)(4)Proprietary Information-Testing



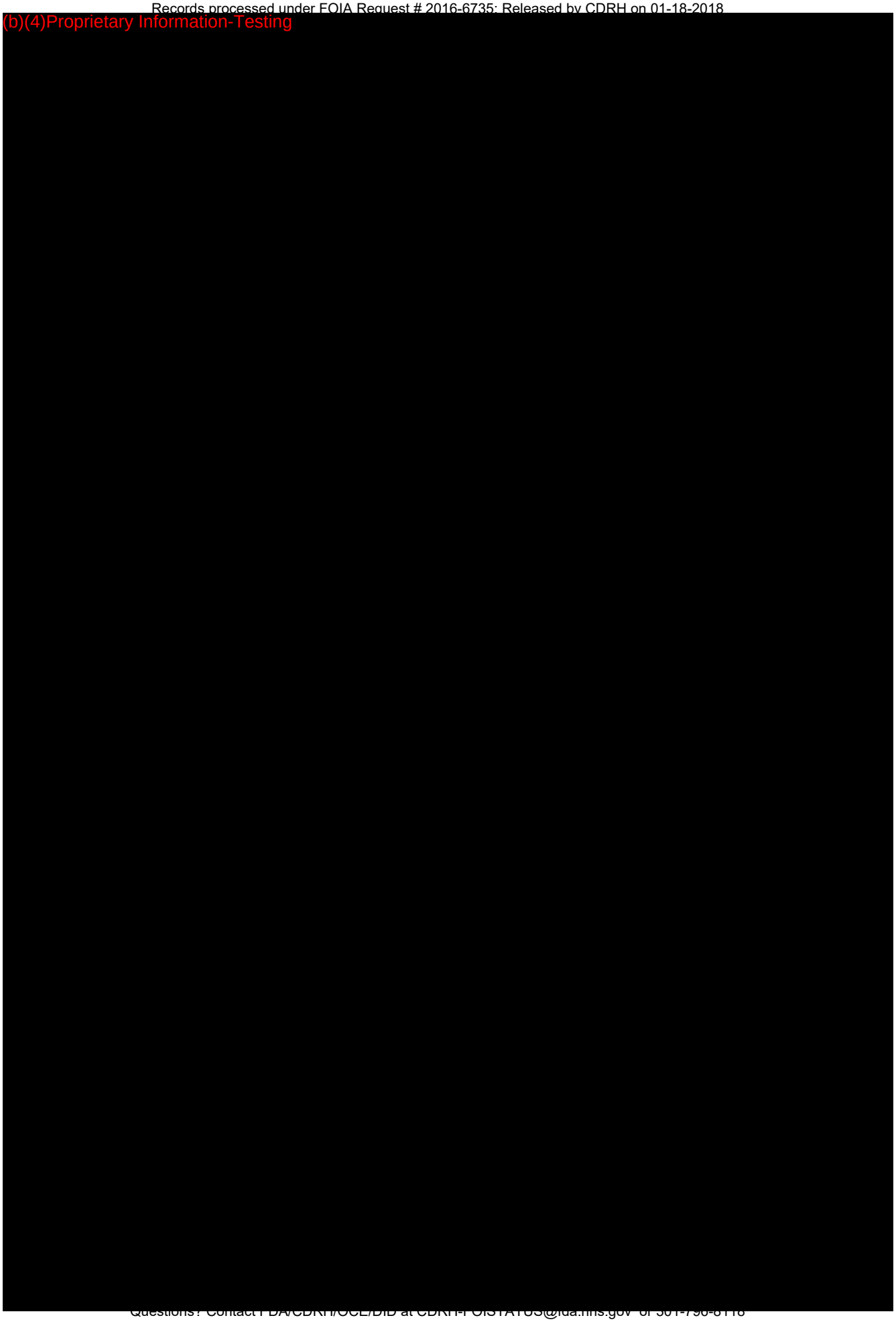
(b)(4)Proprietary Information-Testing



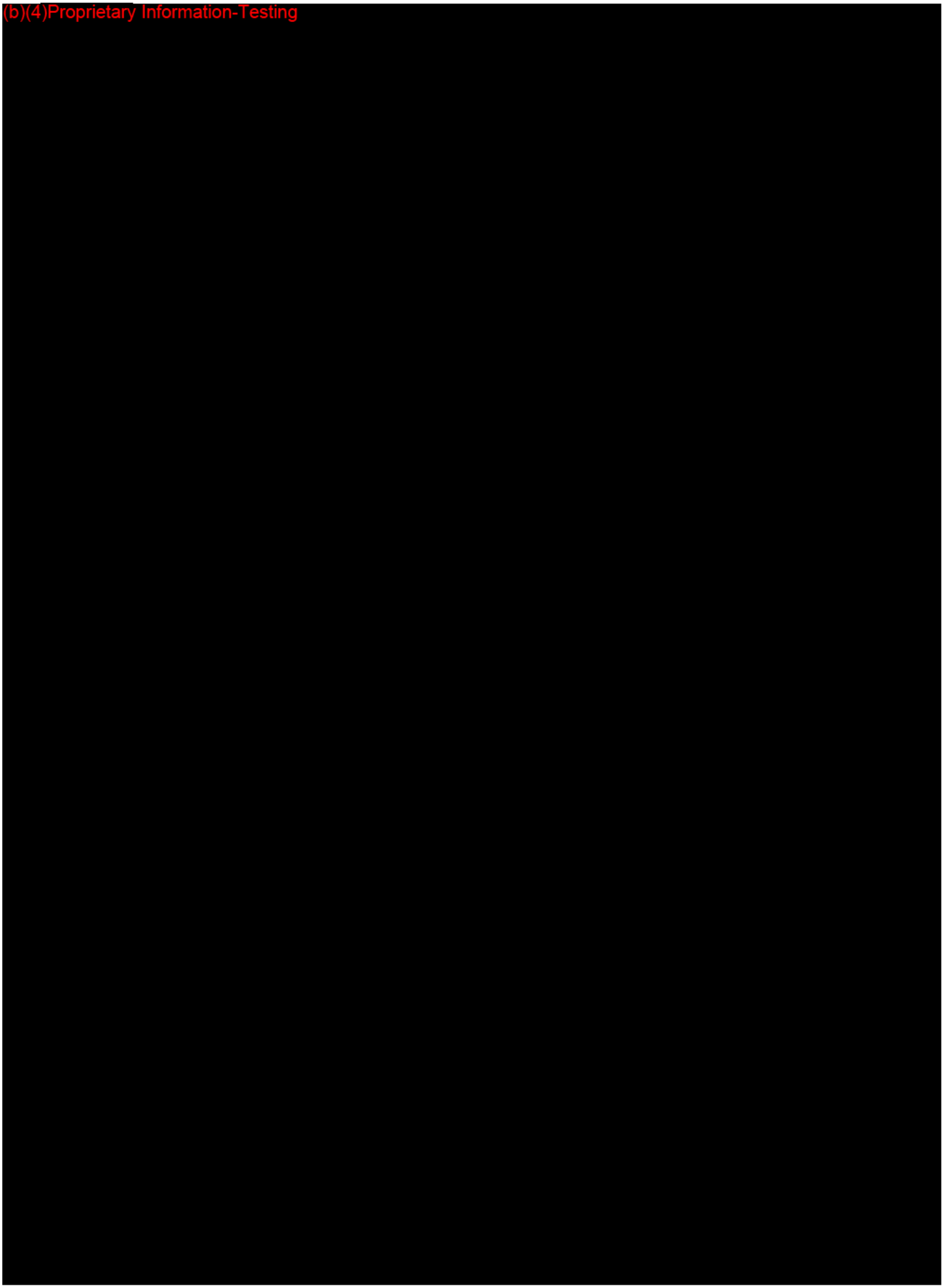
(b)(4)Proprietary Information-Testing



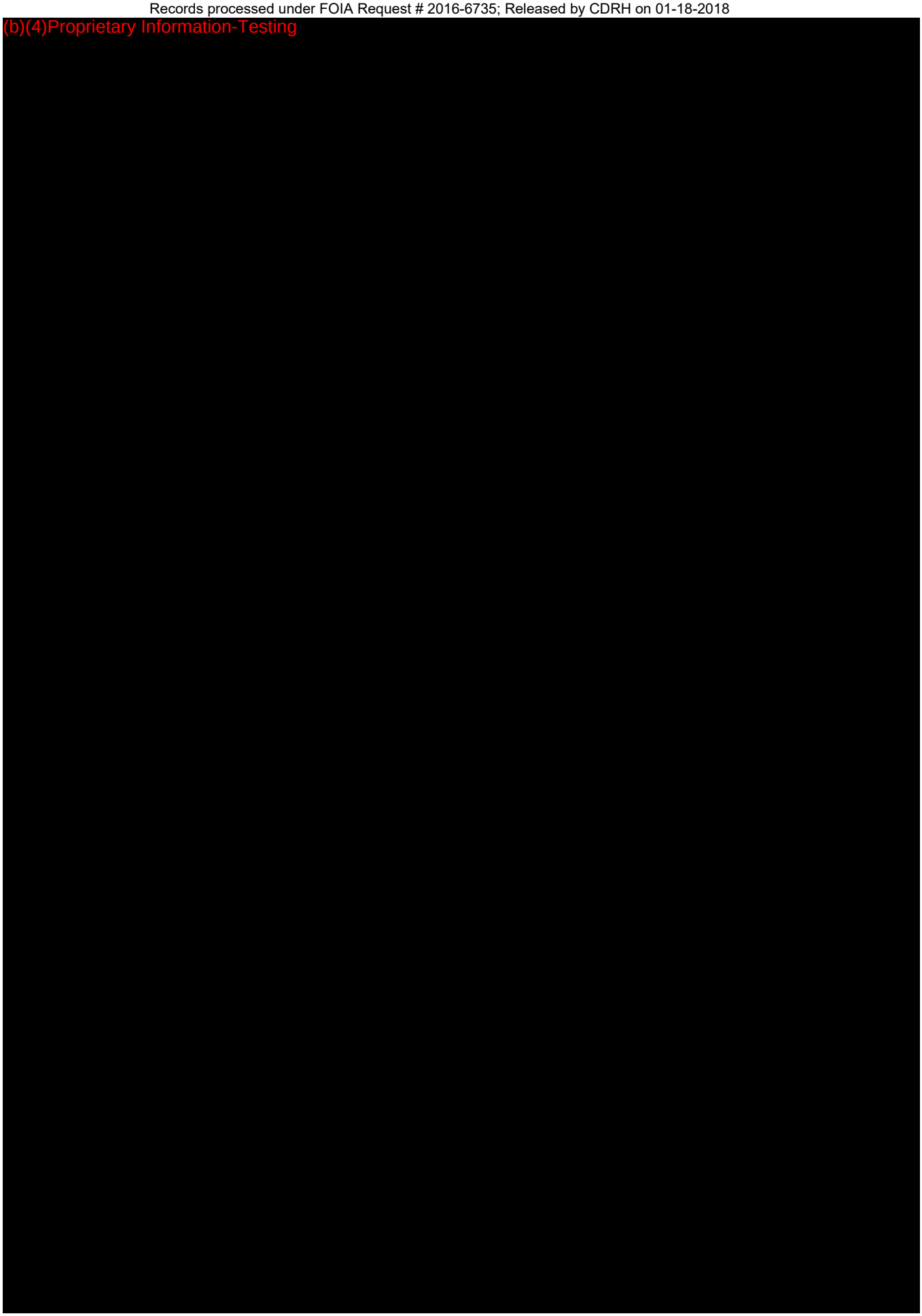
(b)(4)Proprietary Information-Testing



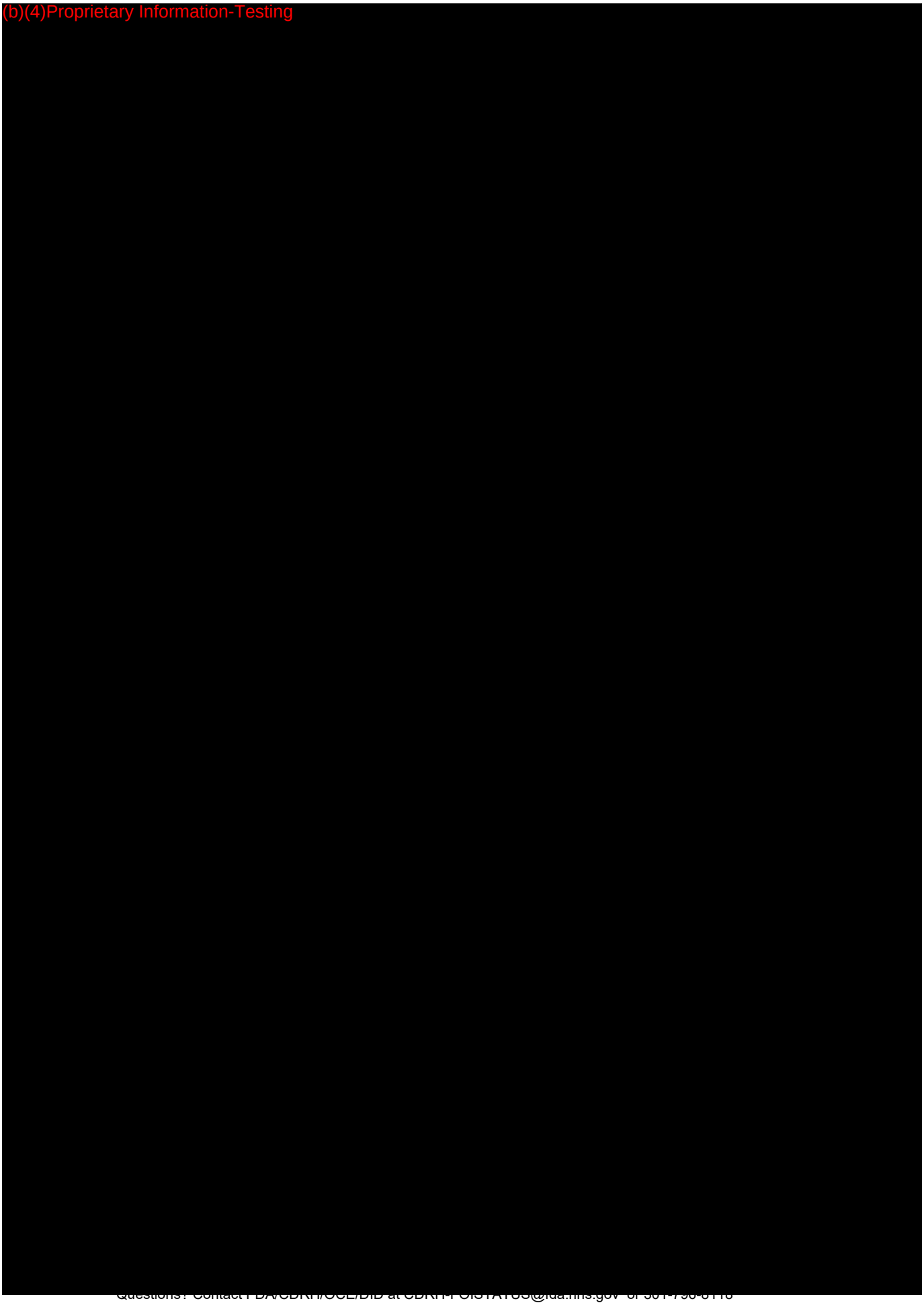
(b)(4)Proprietary Information-Testing



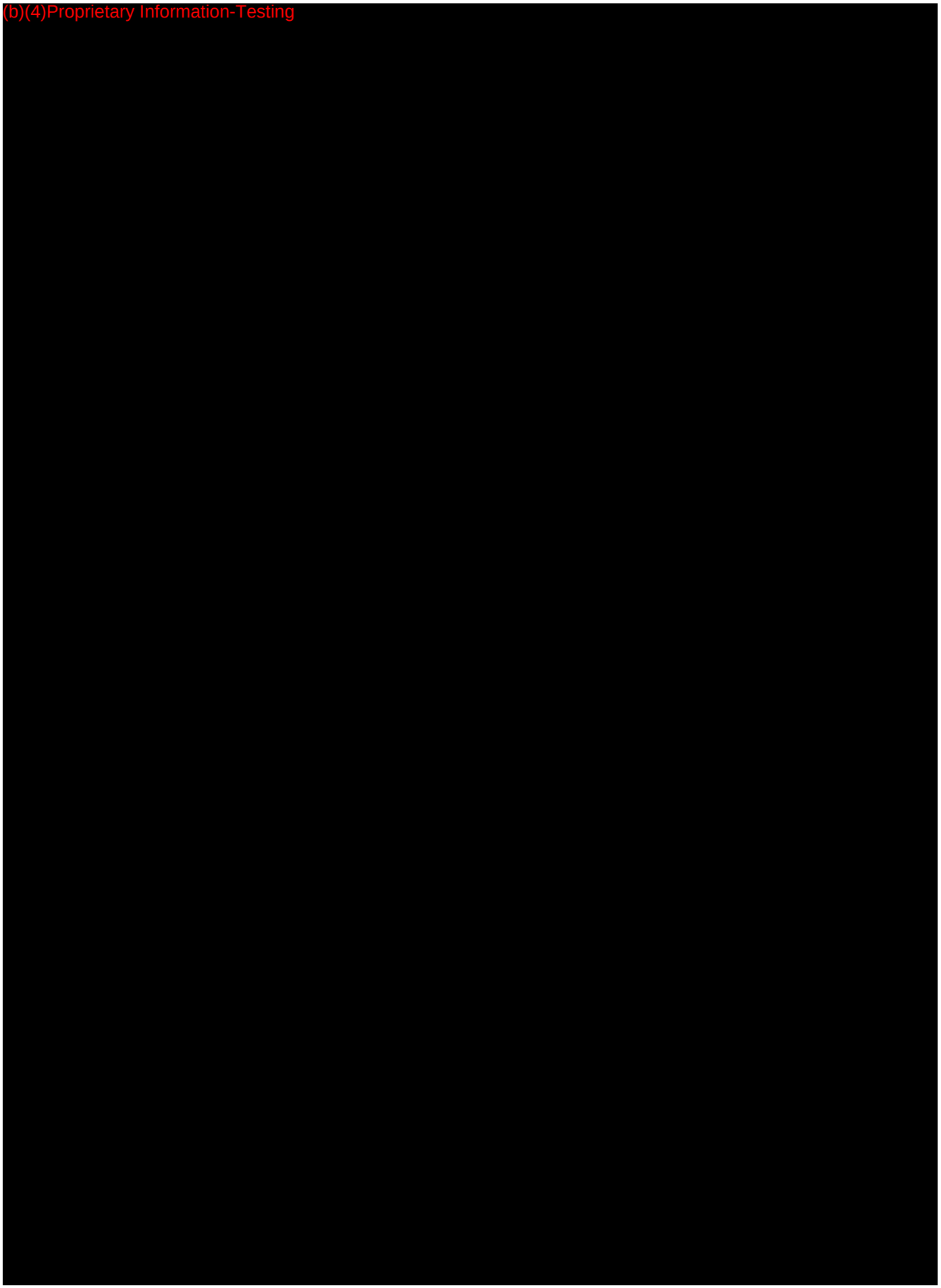
(b)(4)Proprietary Information-Testing



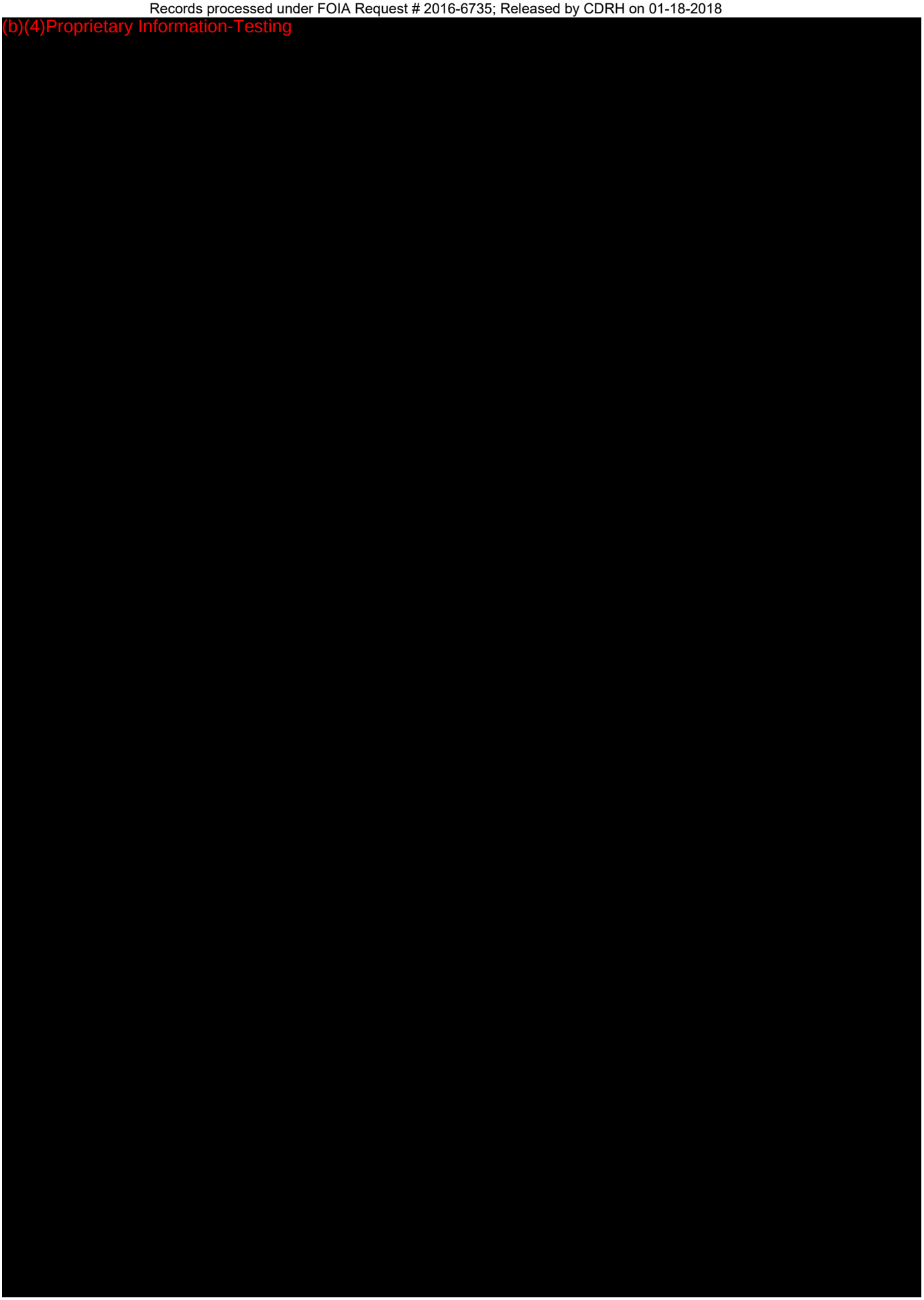
(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing



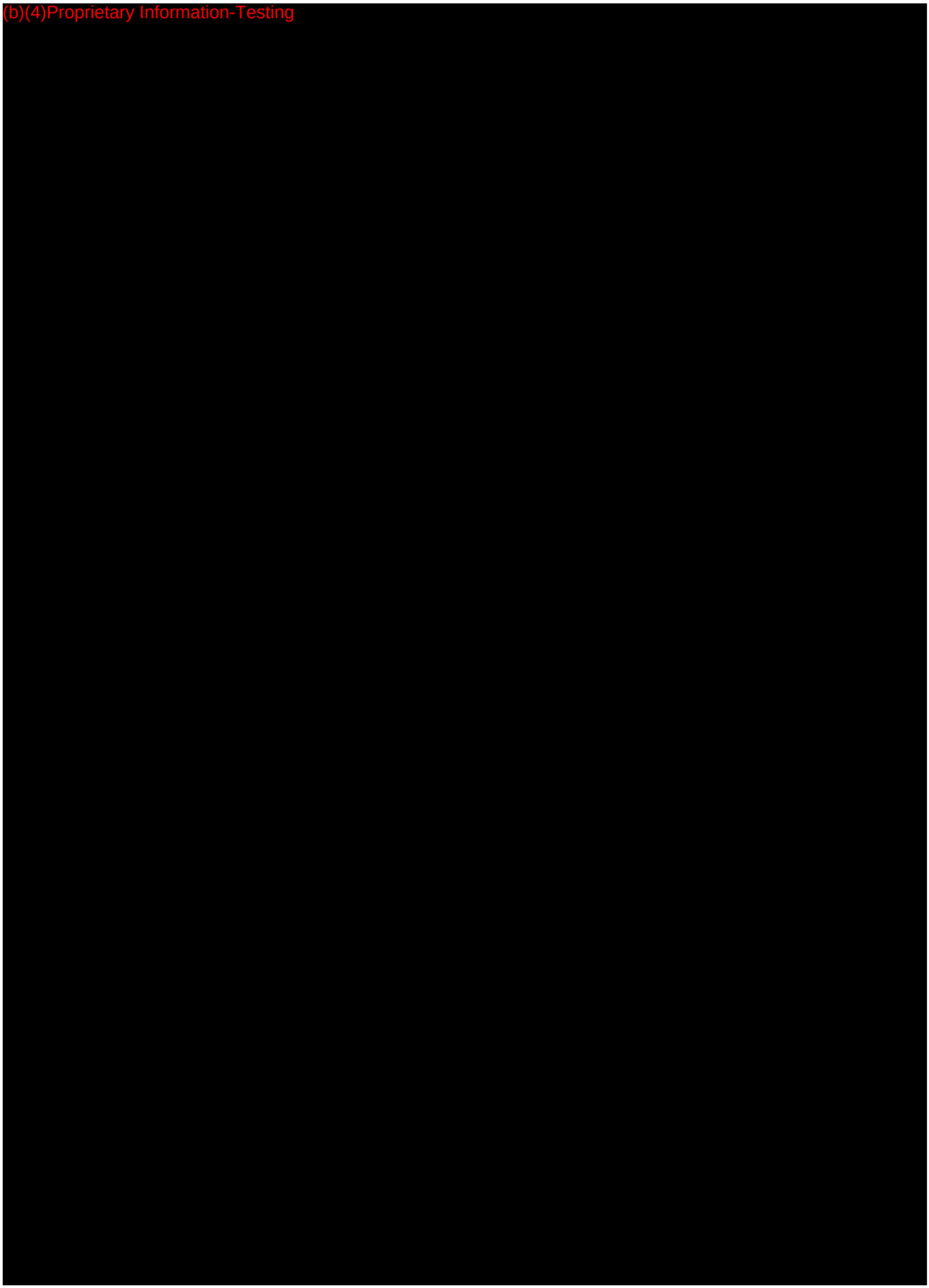
(b)(4)Proprietary Information-Testing



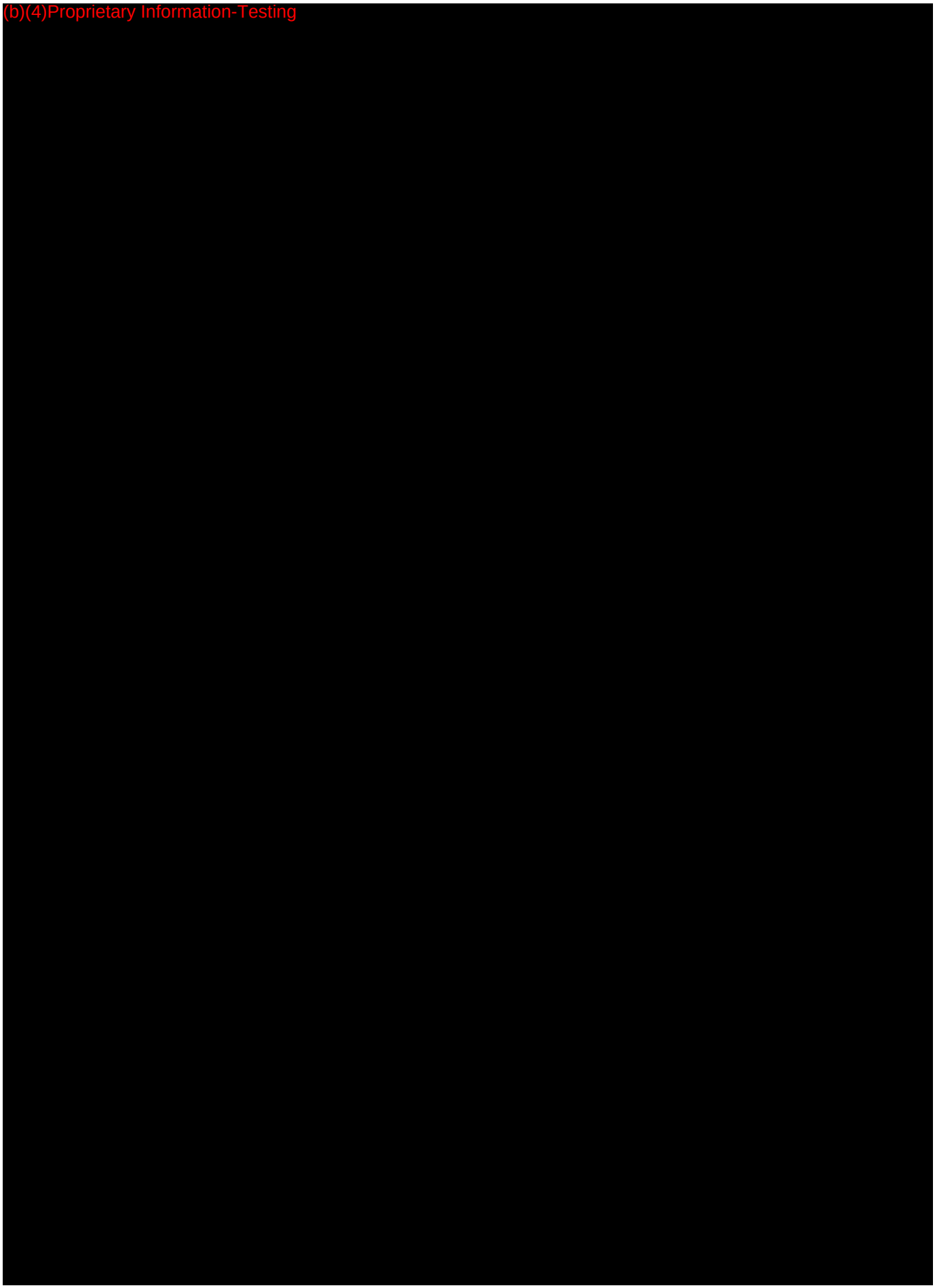
(b)(4)Proprietary Information-Testing

[redacted]

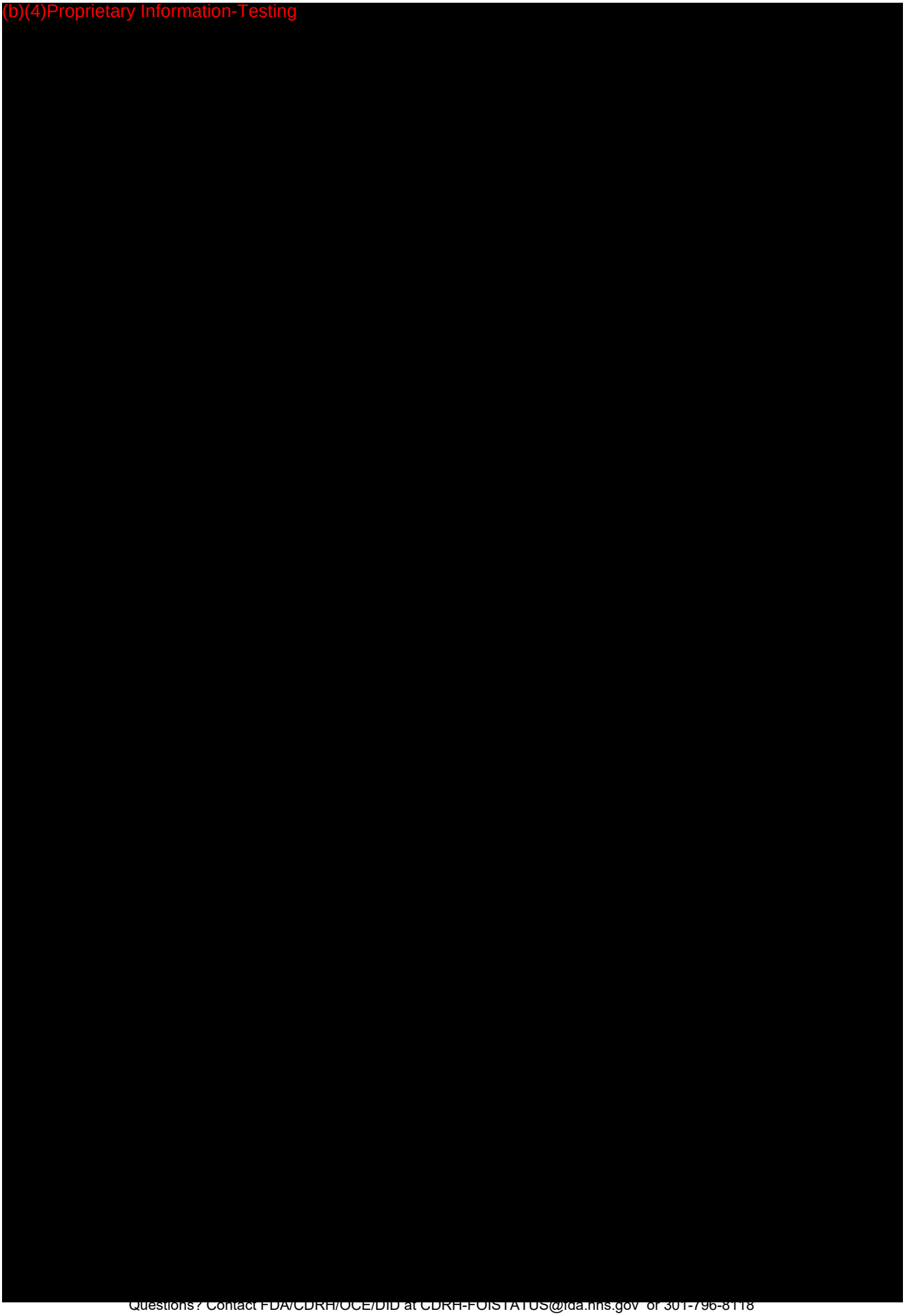
(b)(4)Proprietary Information-Testing



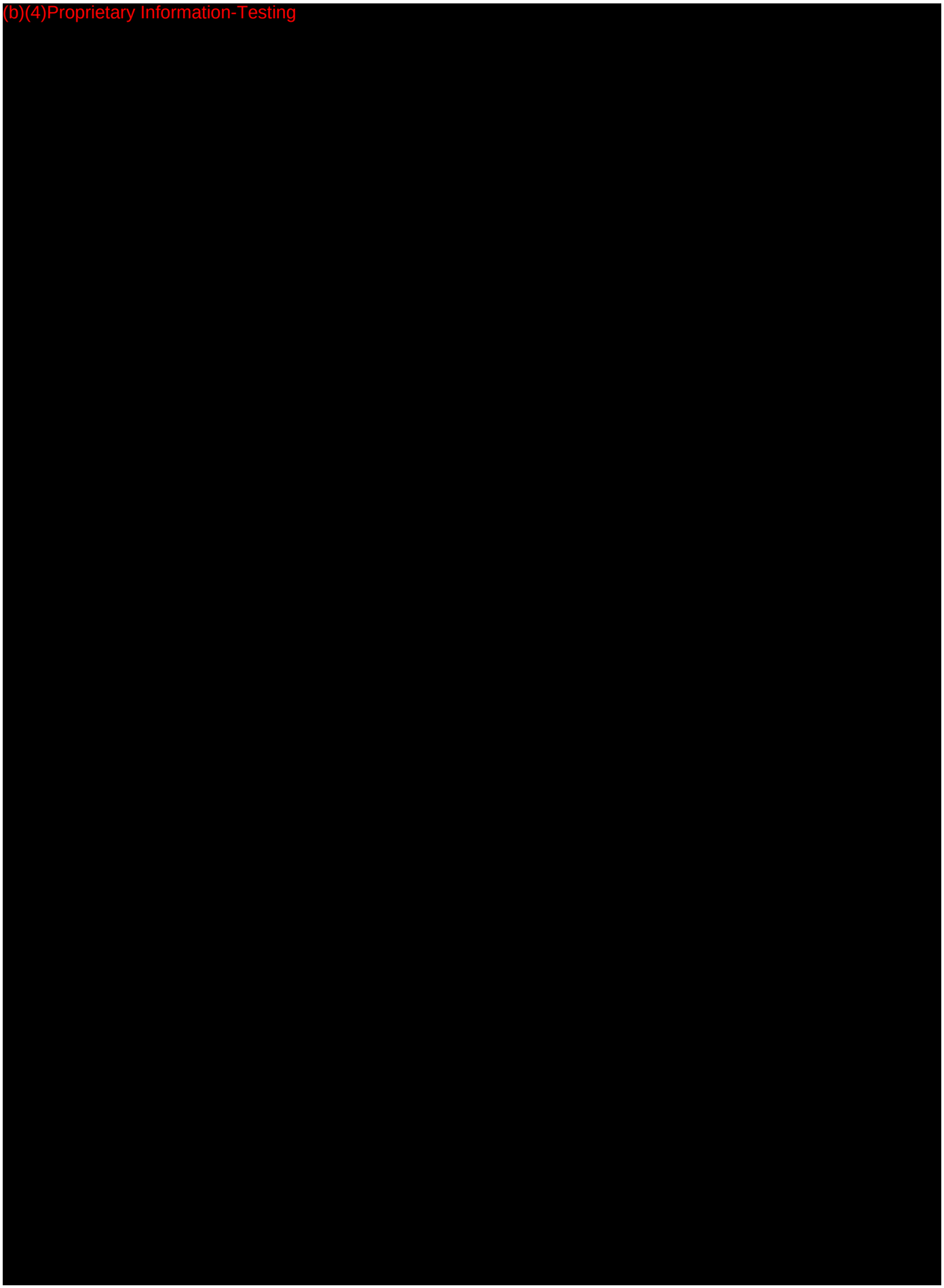
(b)(4)Proprietary Information-Testing



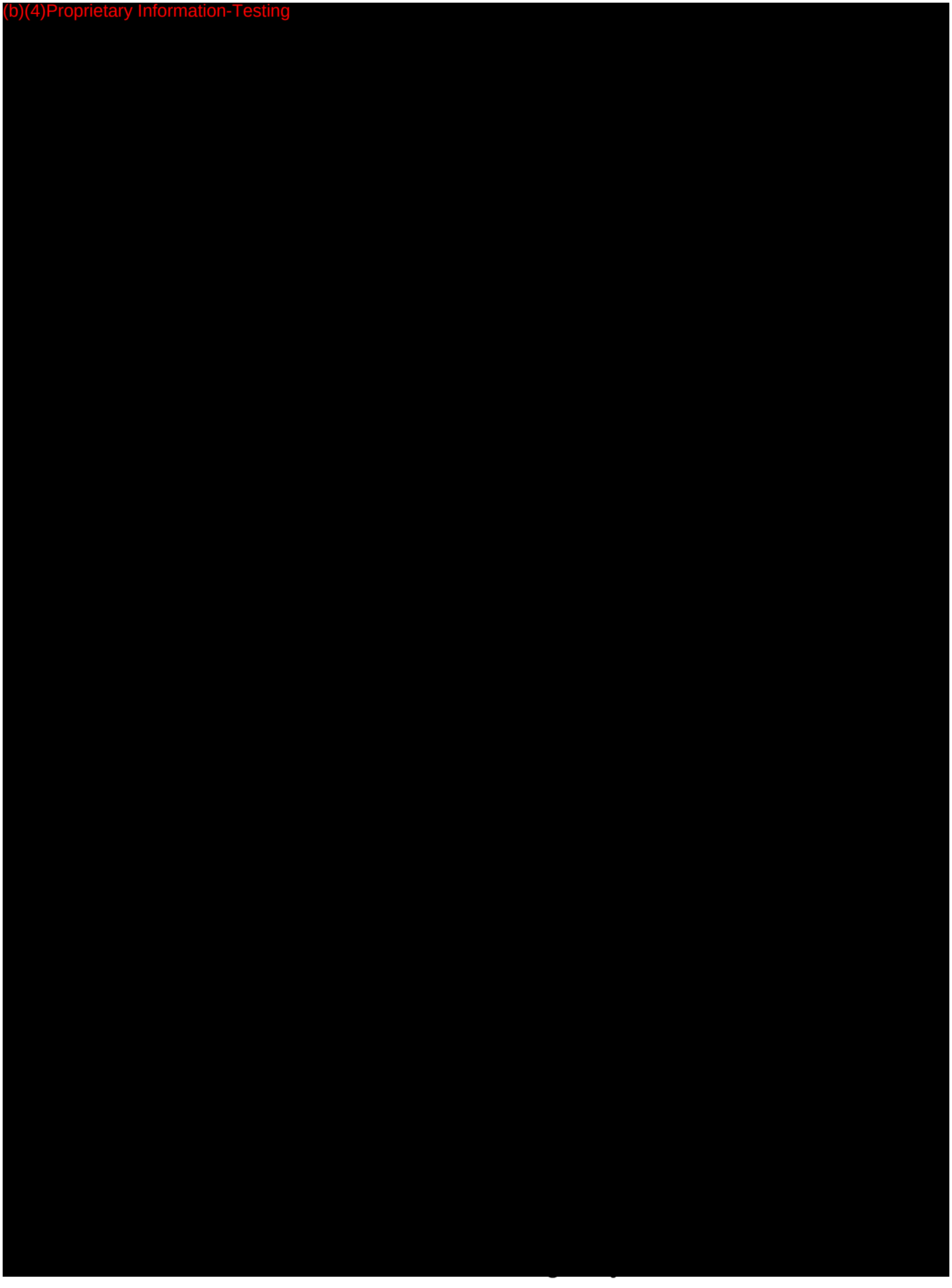
(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing

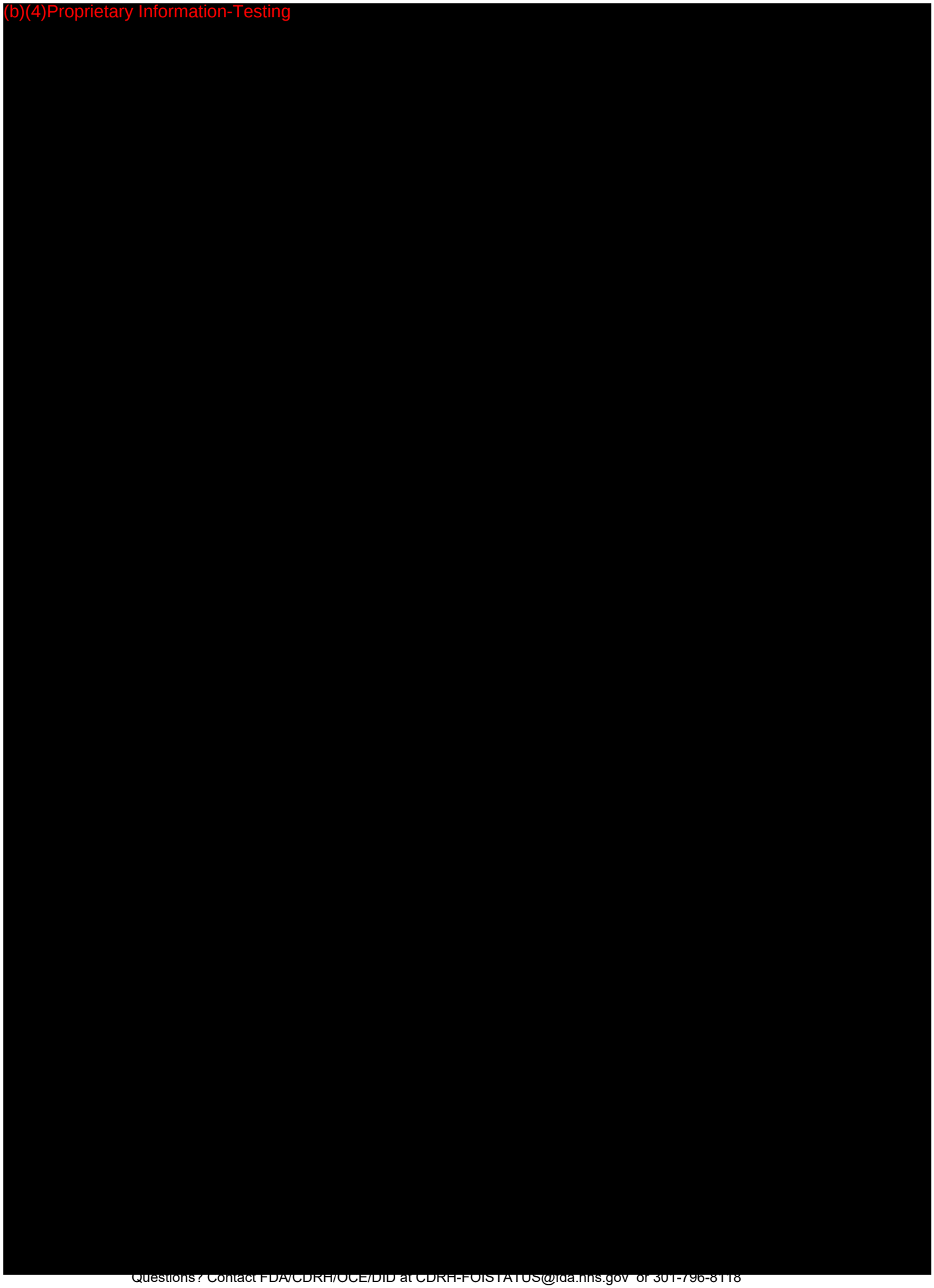


(b)(4)Proprietary Information-Testing

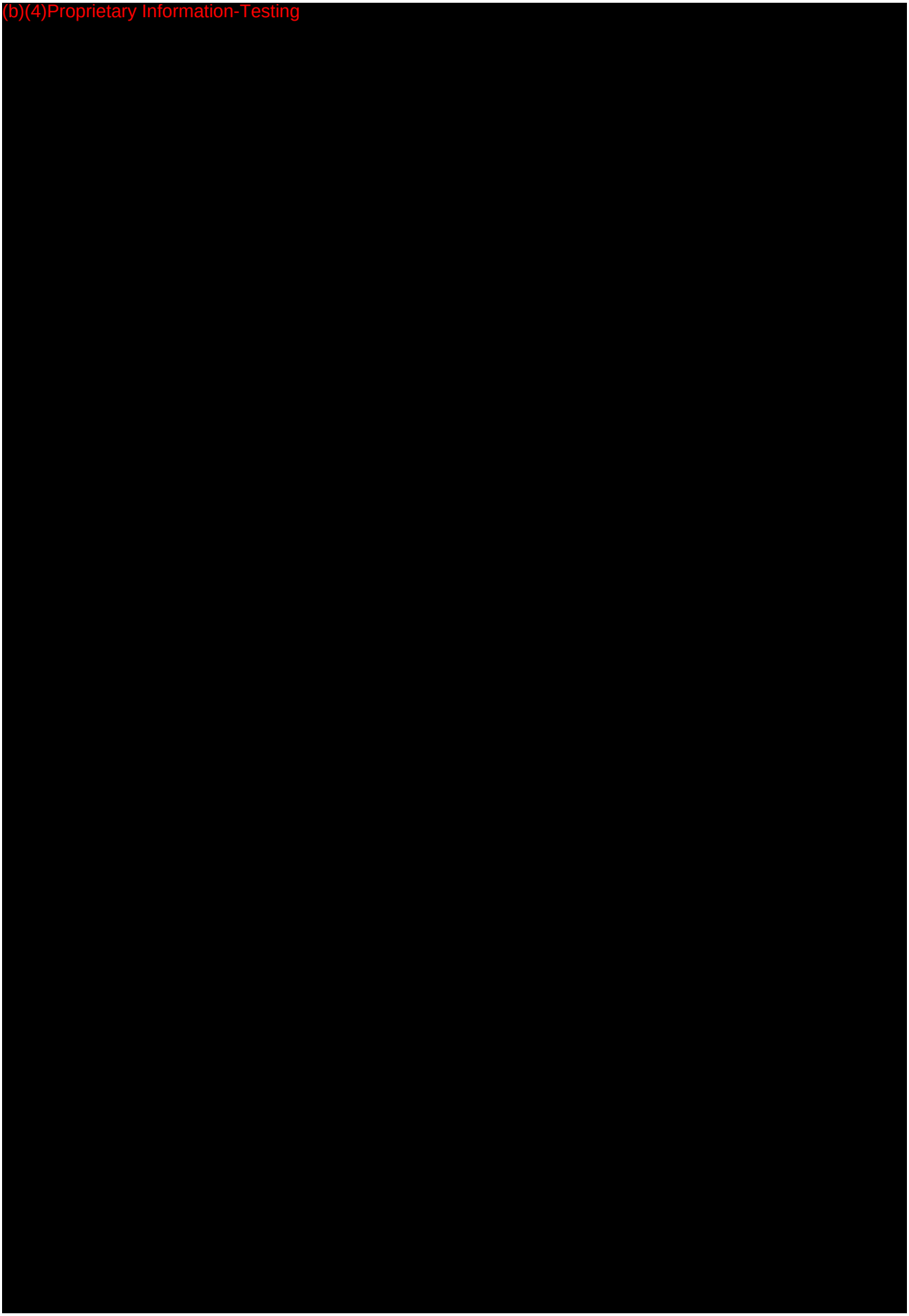


(b)(4)Proprietary Information-Testing

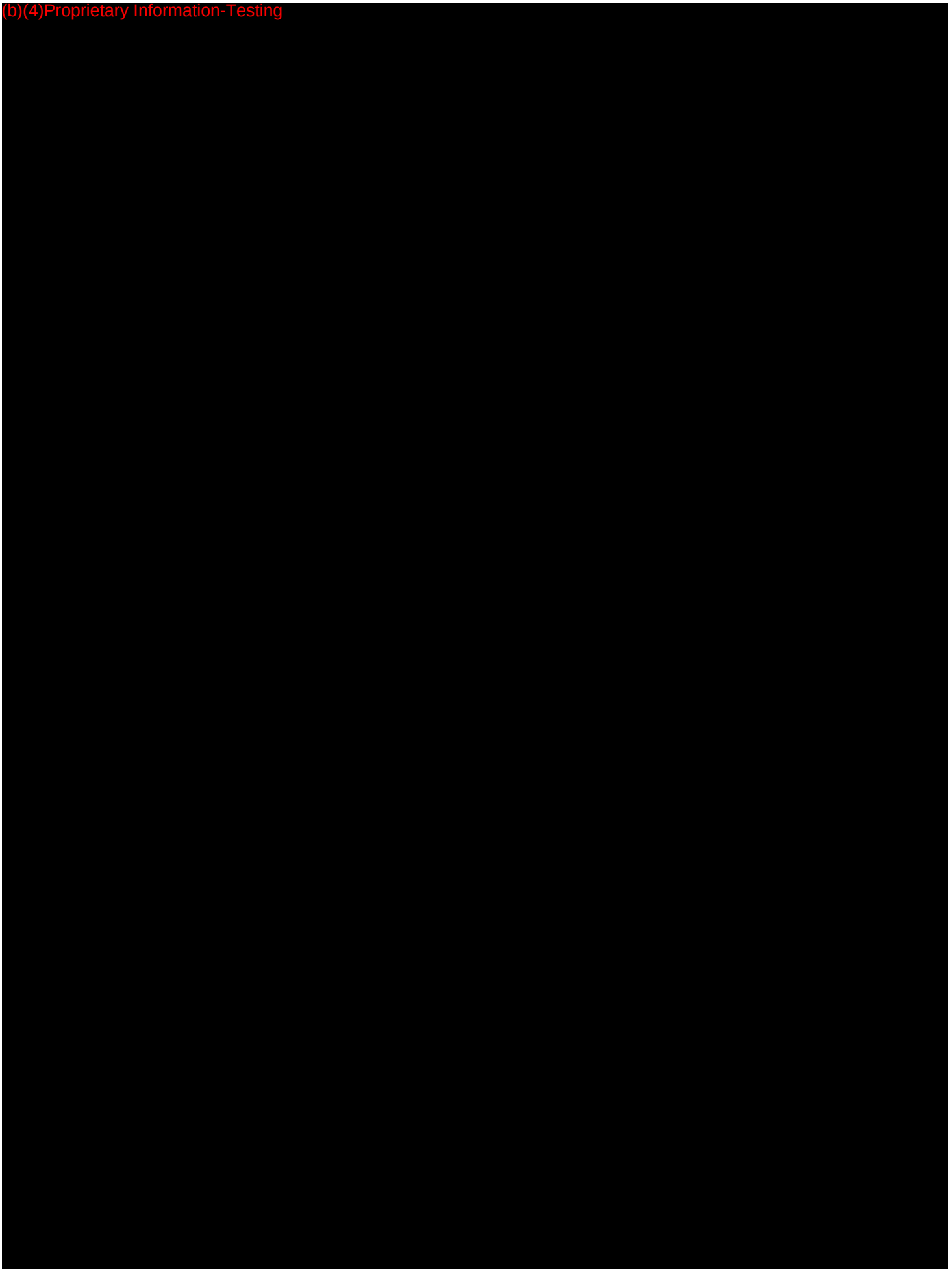
(b)(4)Proprietary Information-Testing

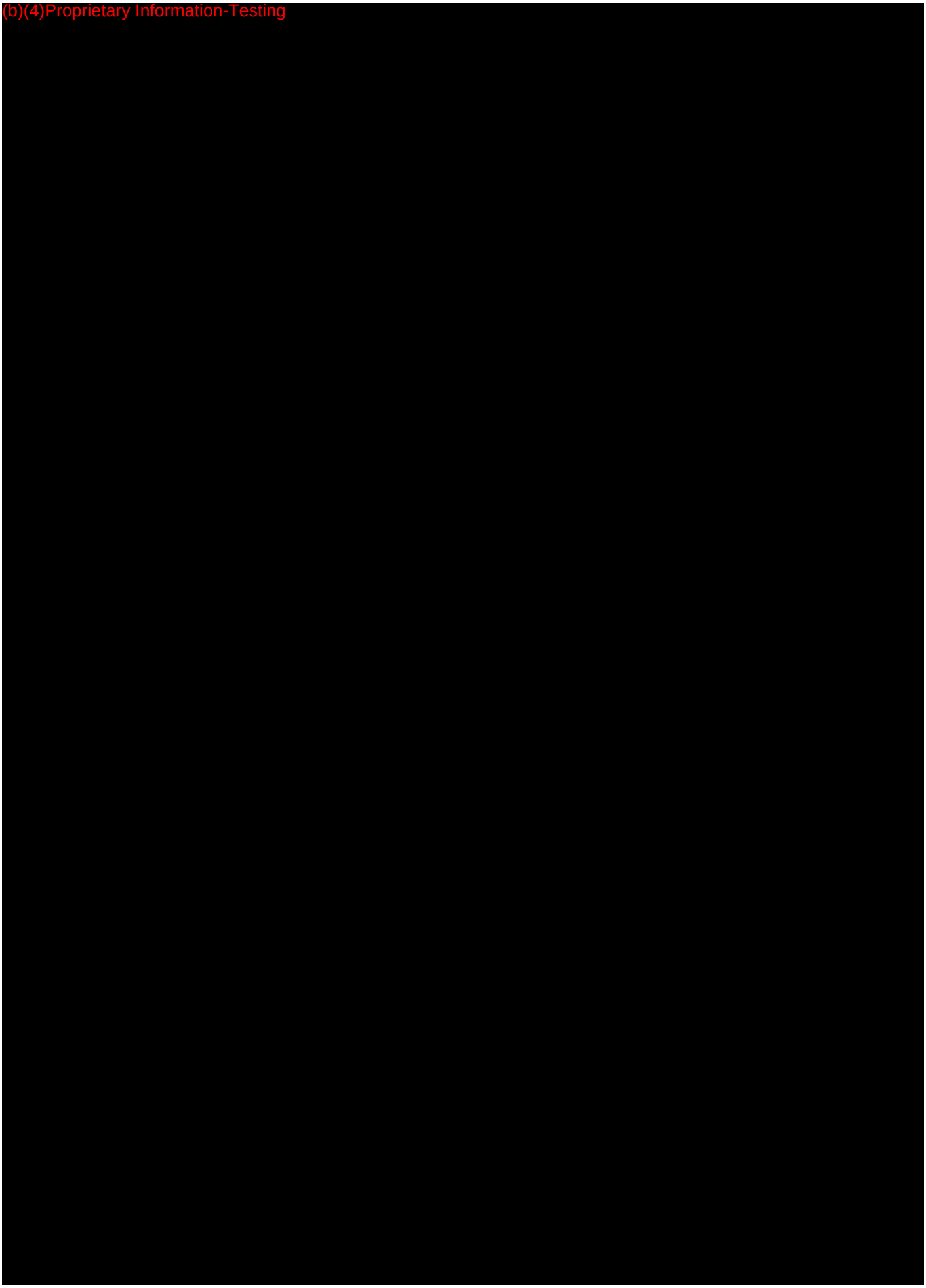


(b)(4)Proprietary Information-Testing

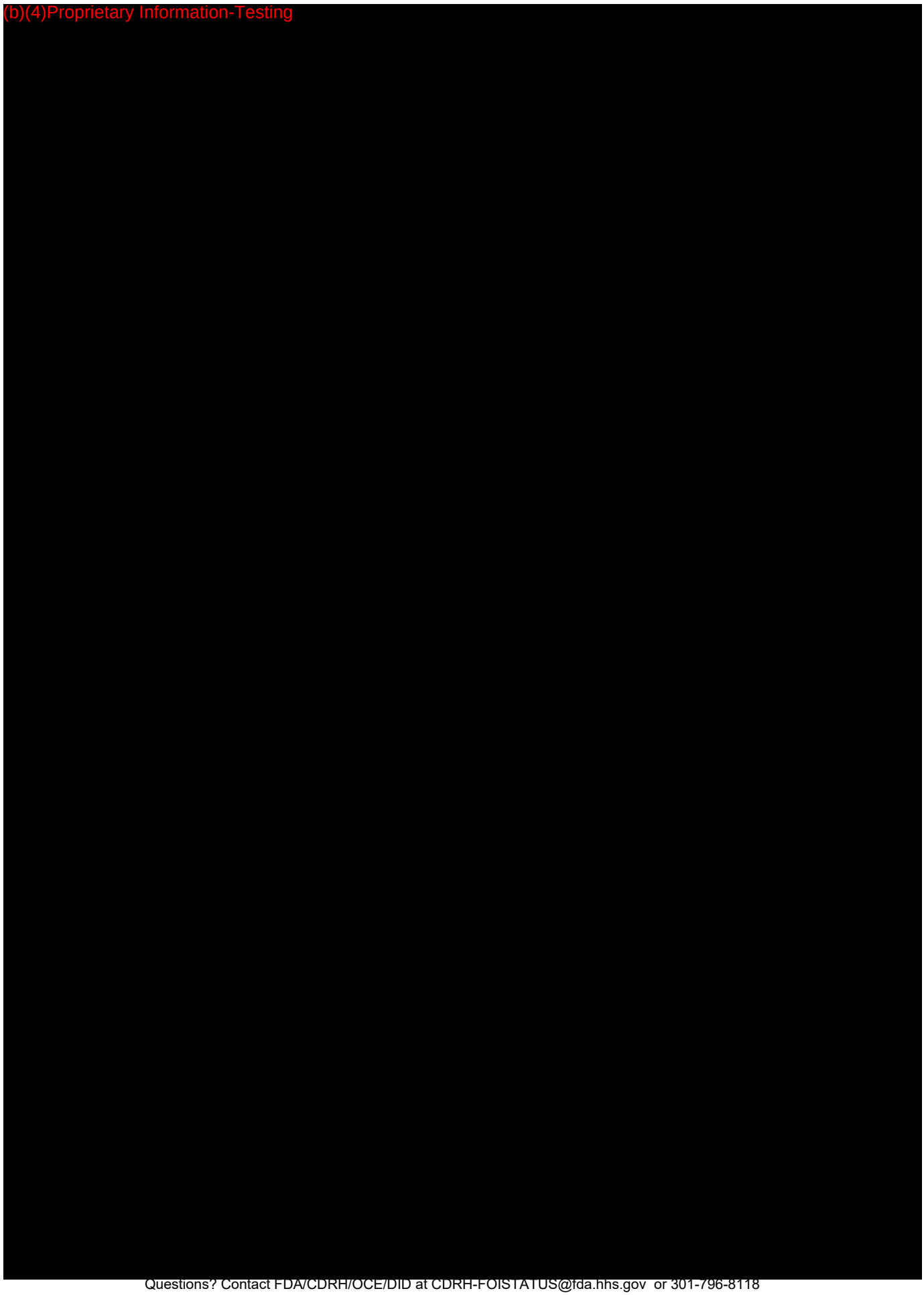


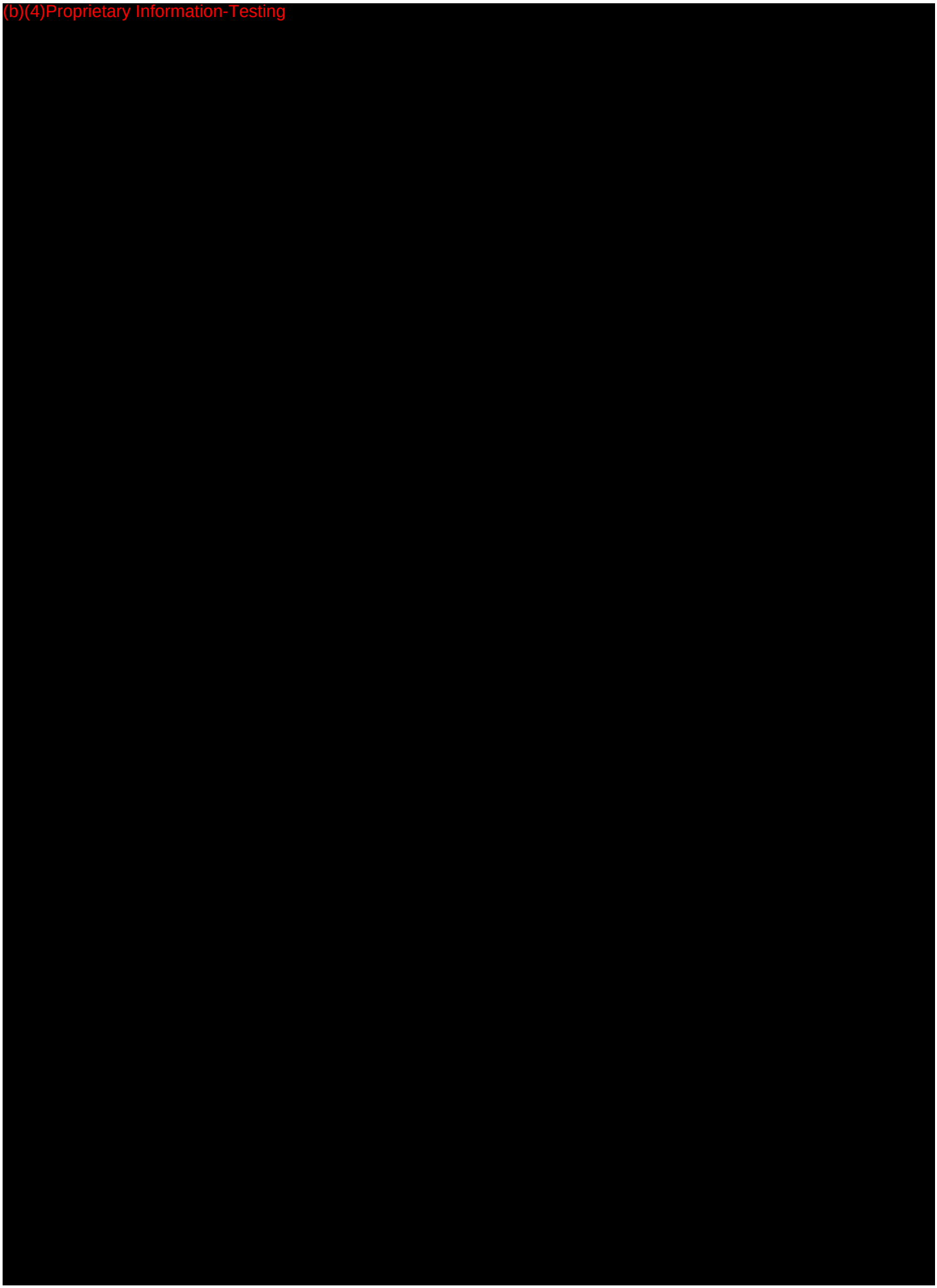
(b)(4)Proprietary Information-Testing



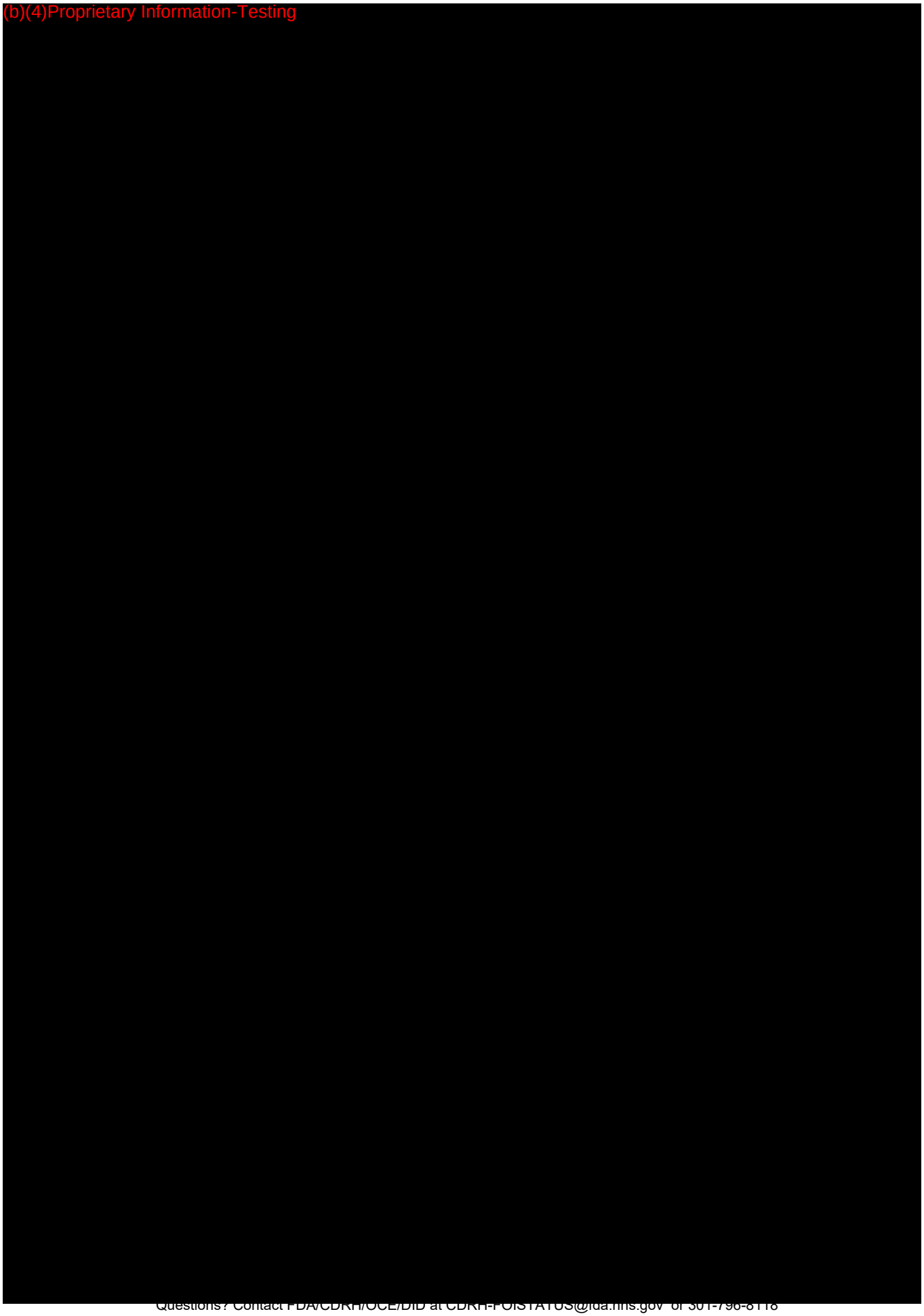


(b)(4)Proprietary Information-Testing

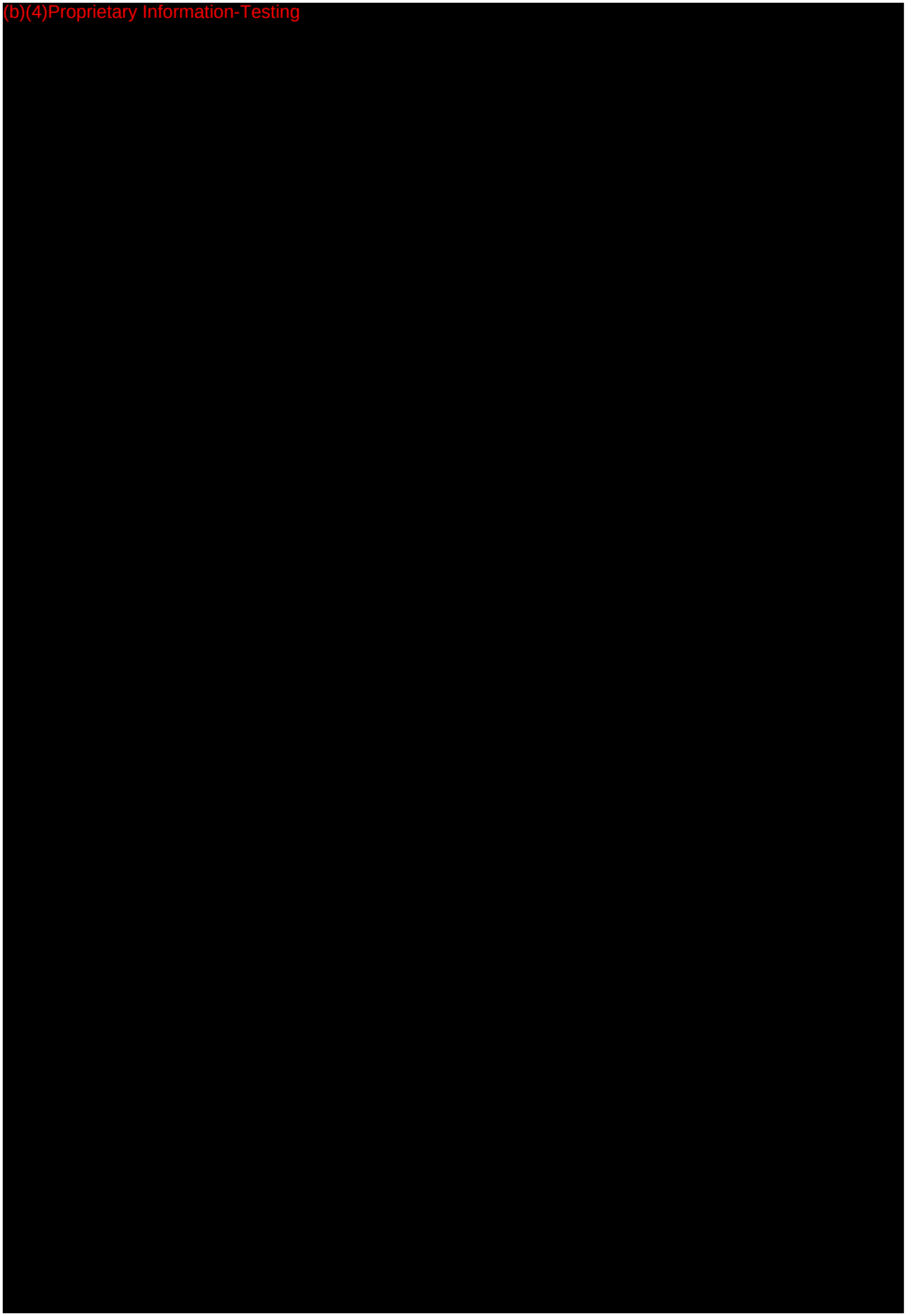




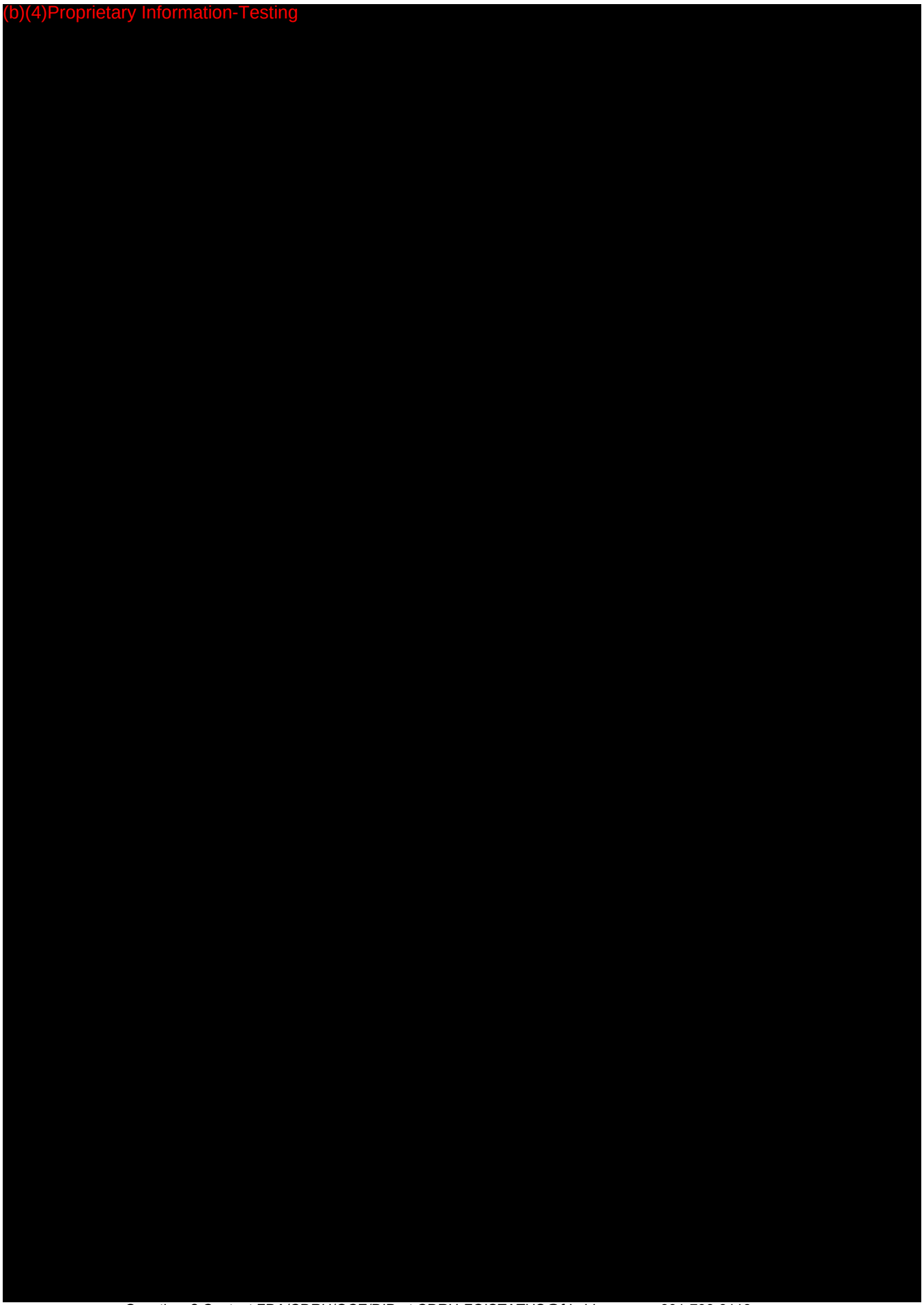
(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing

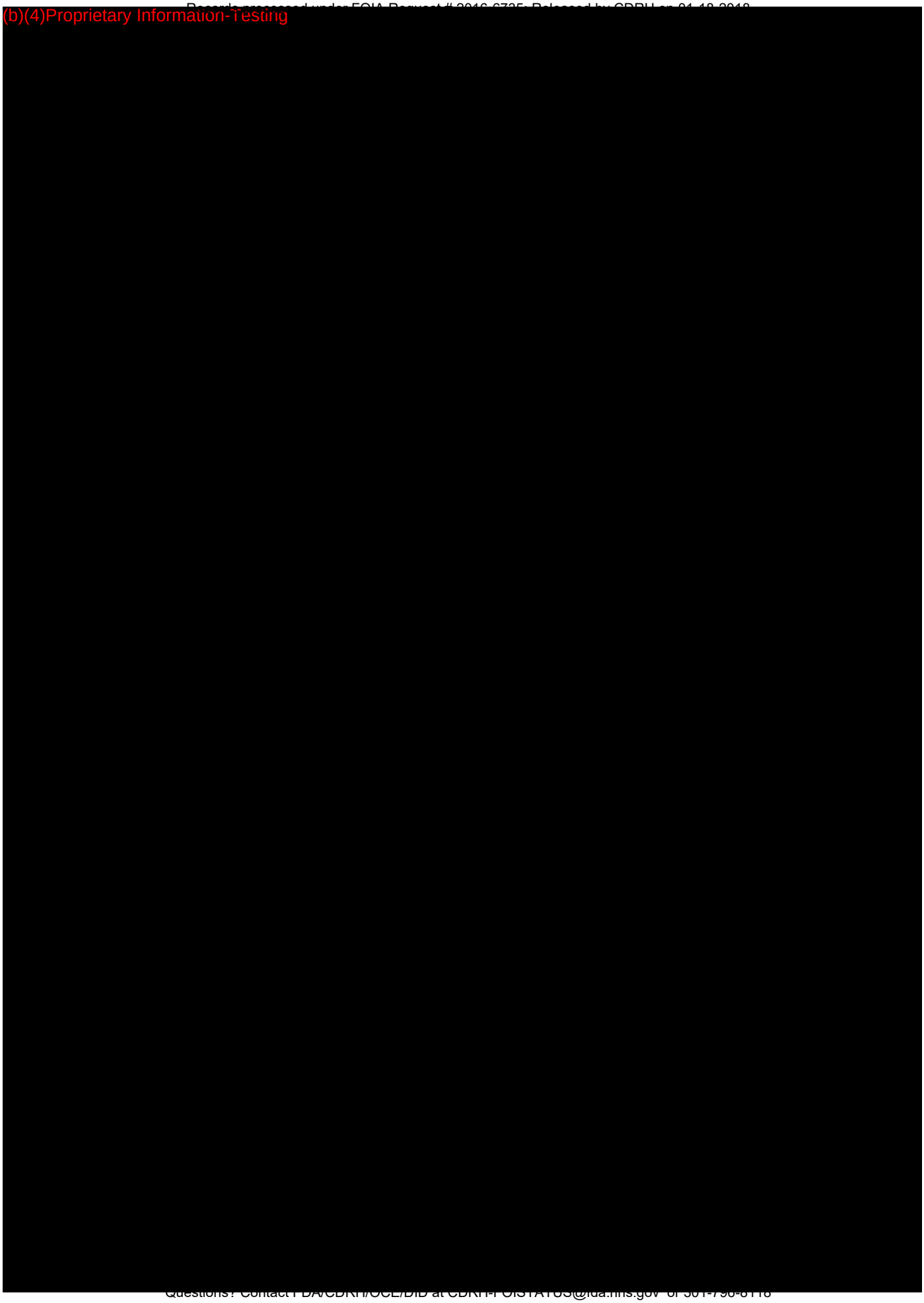


(b)(4)Proprietary Information-Testing

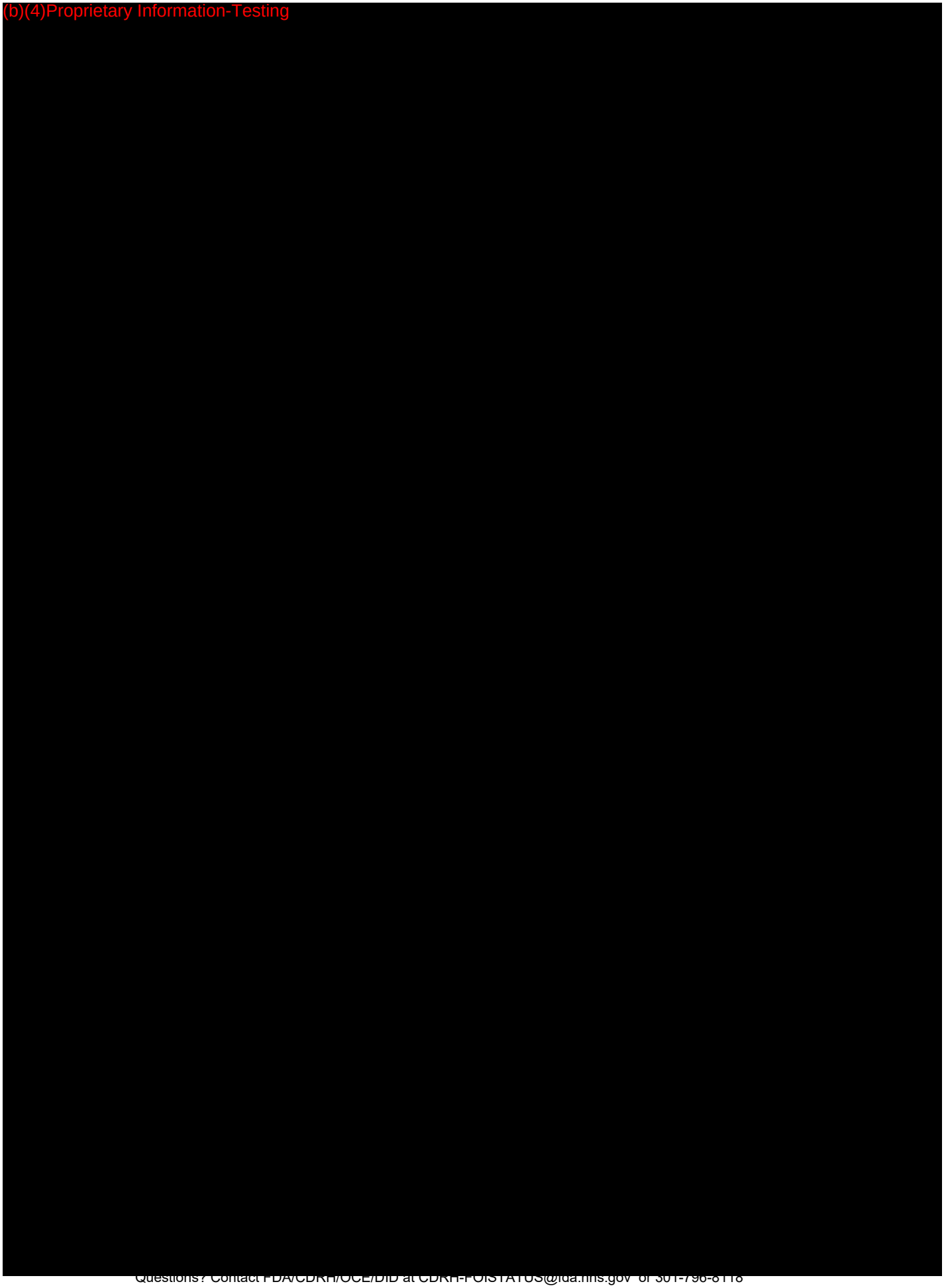


(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

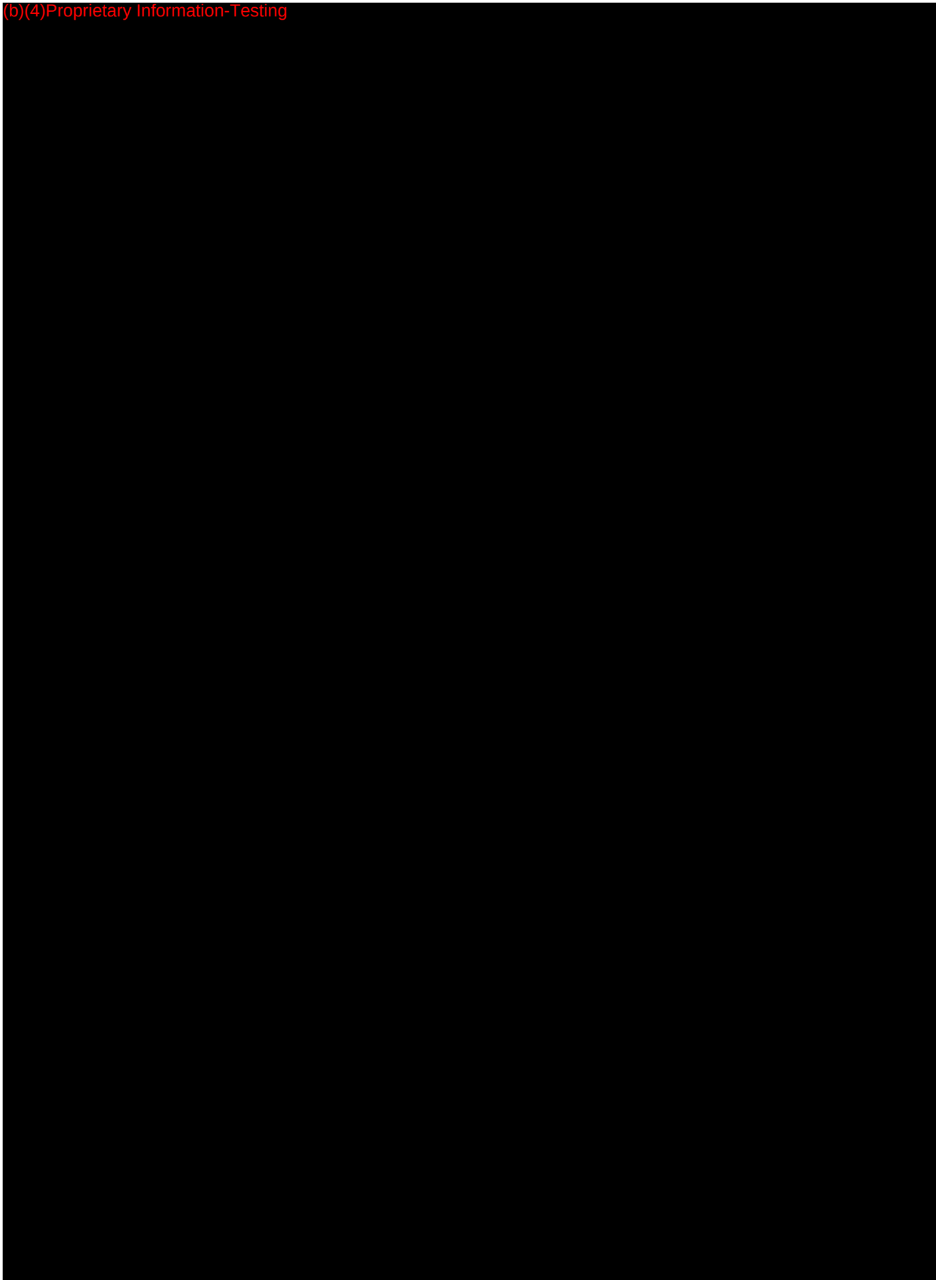


(b)(4)Proprietary Information-Testing

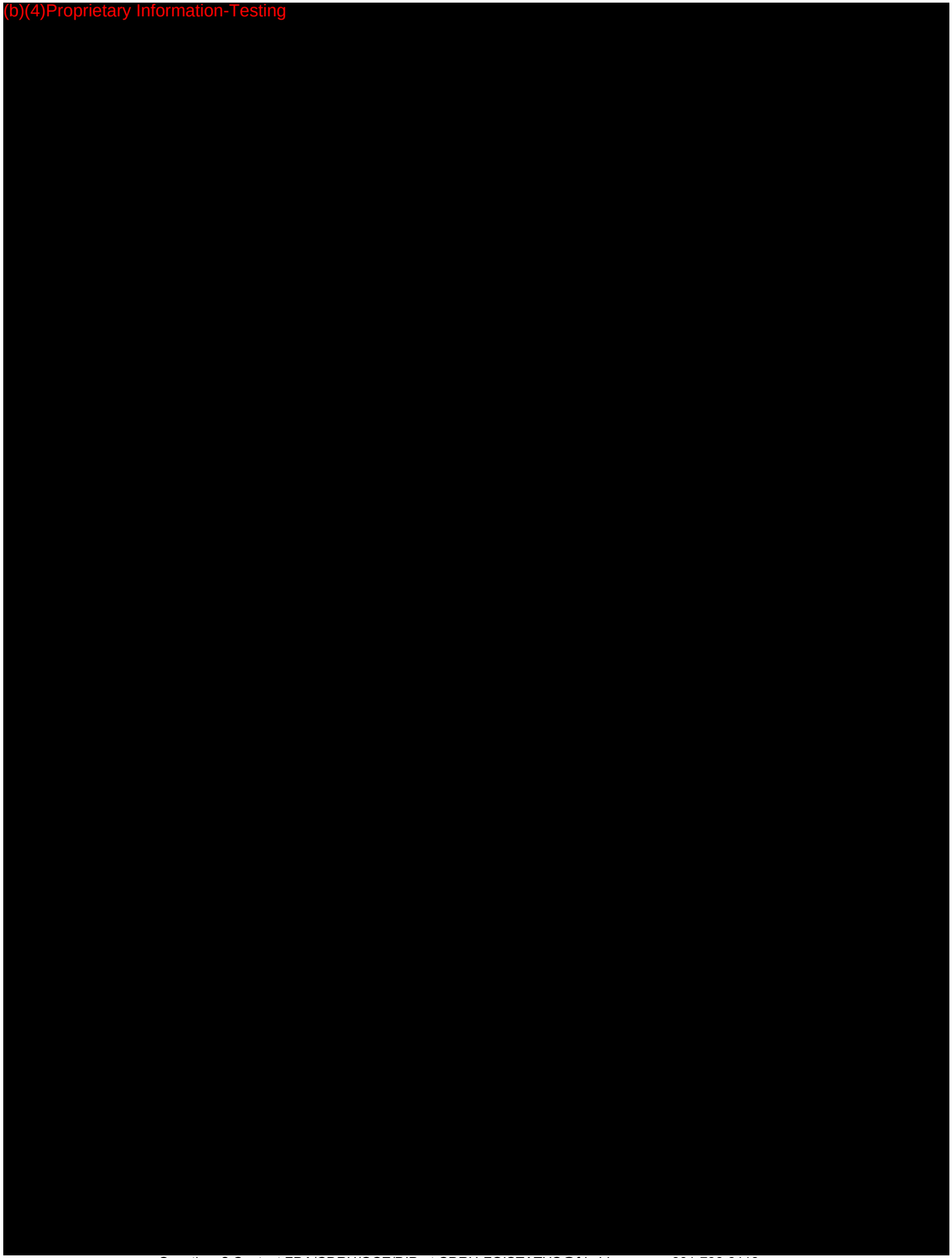


(b)(4)Proprietary Information-Testing

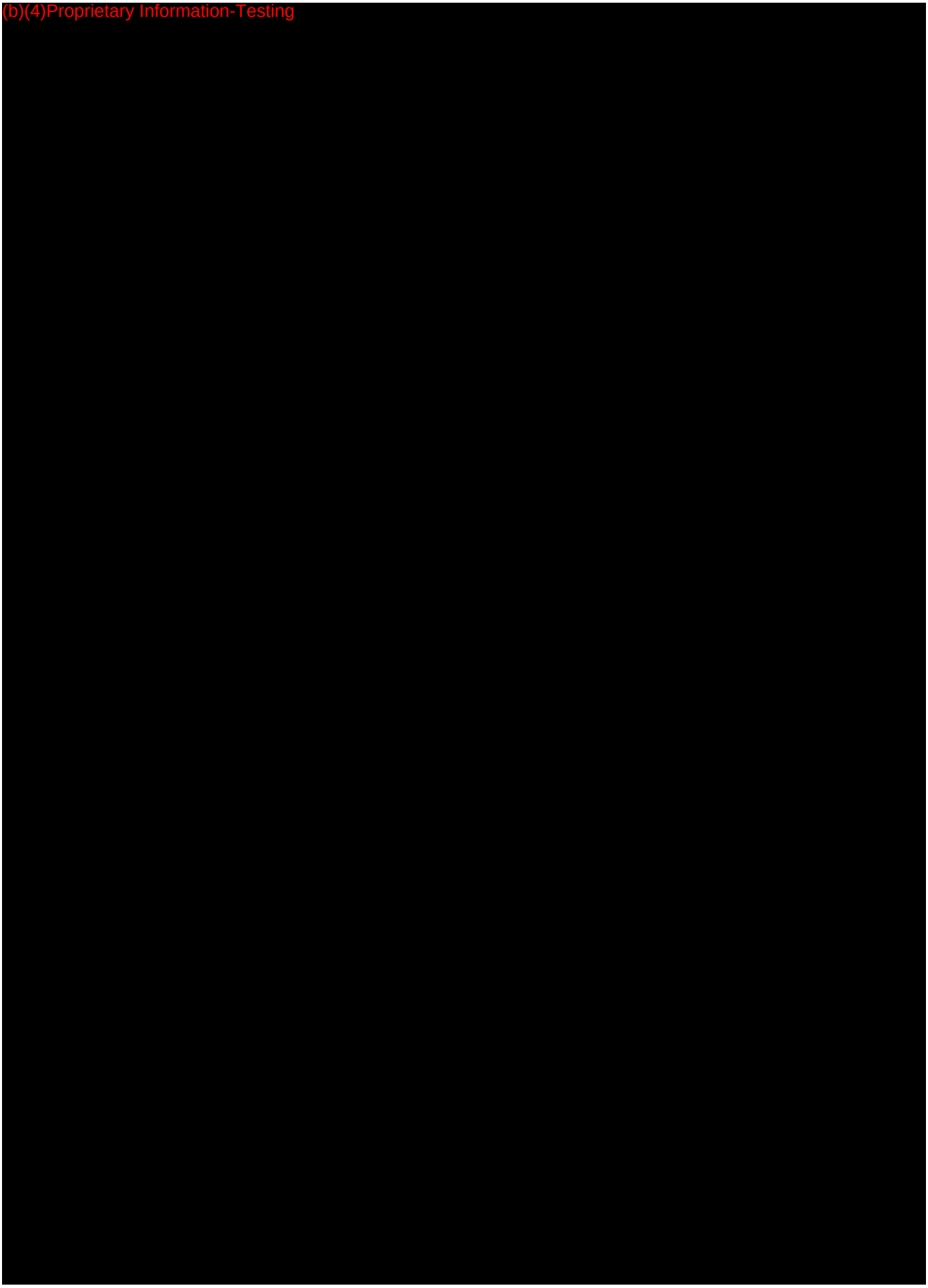
(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing



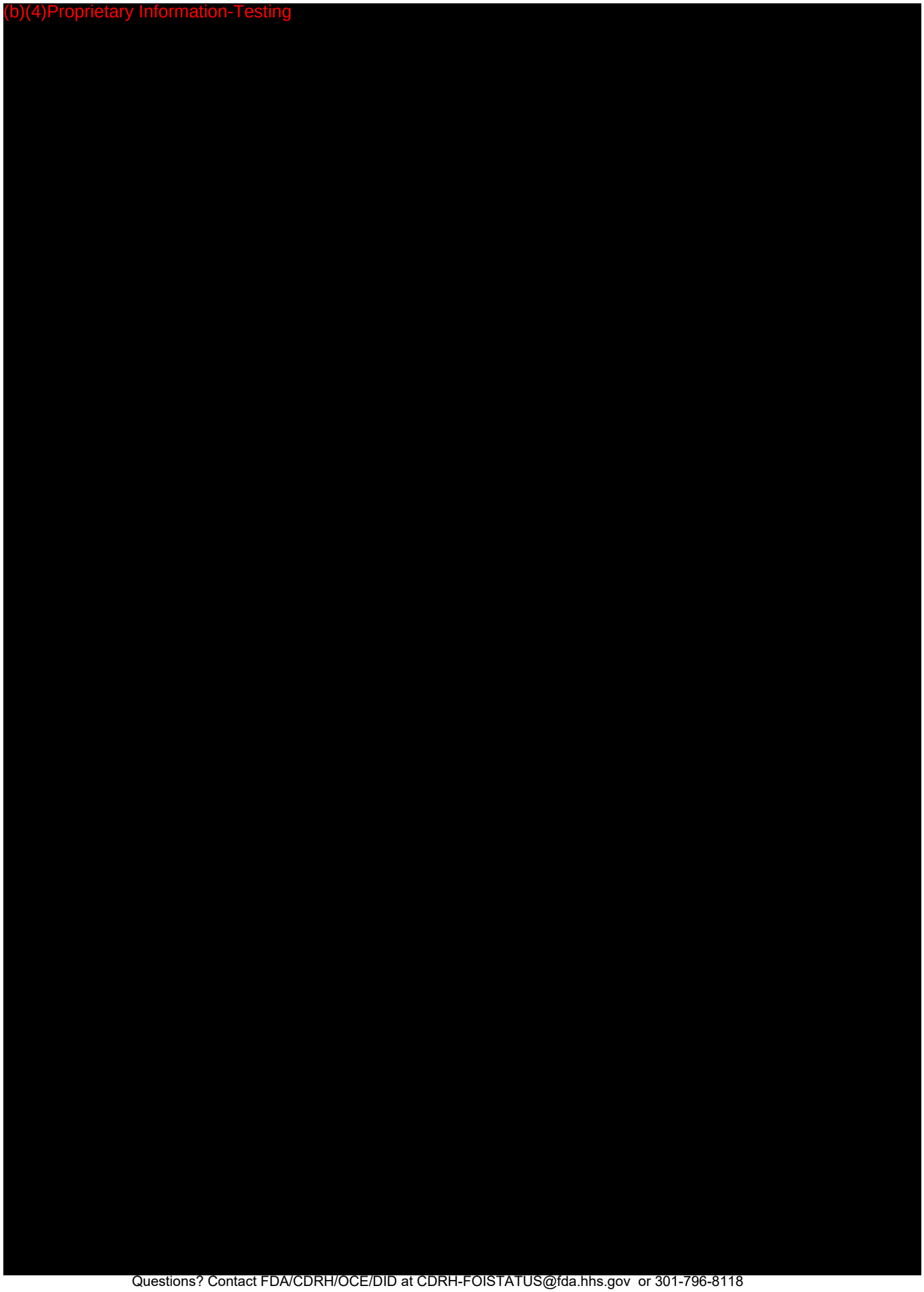
(b)(4)Proprietary Information-Testing



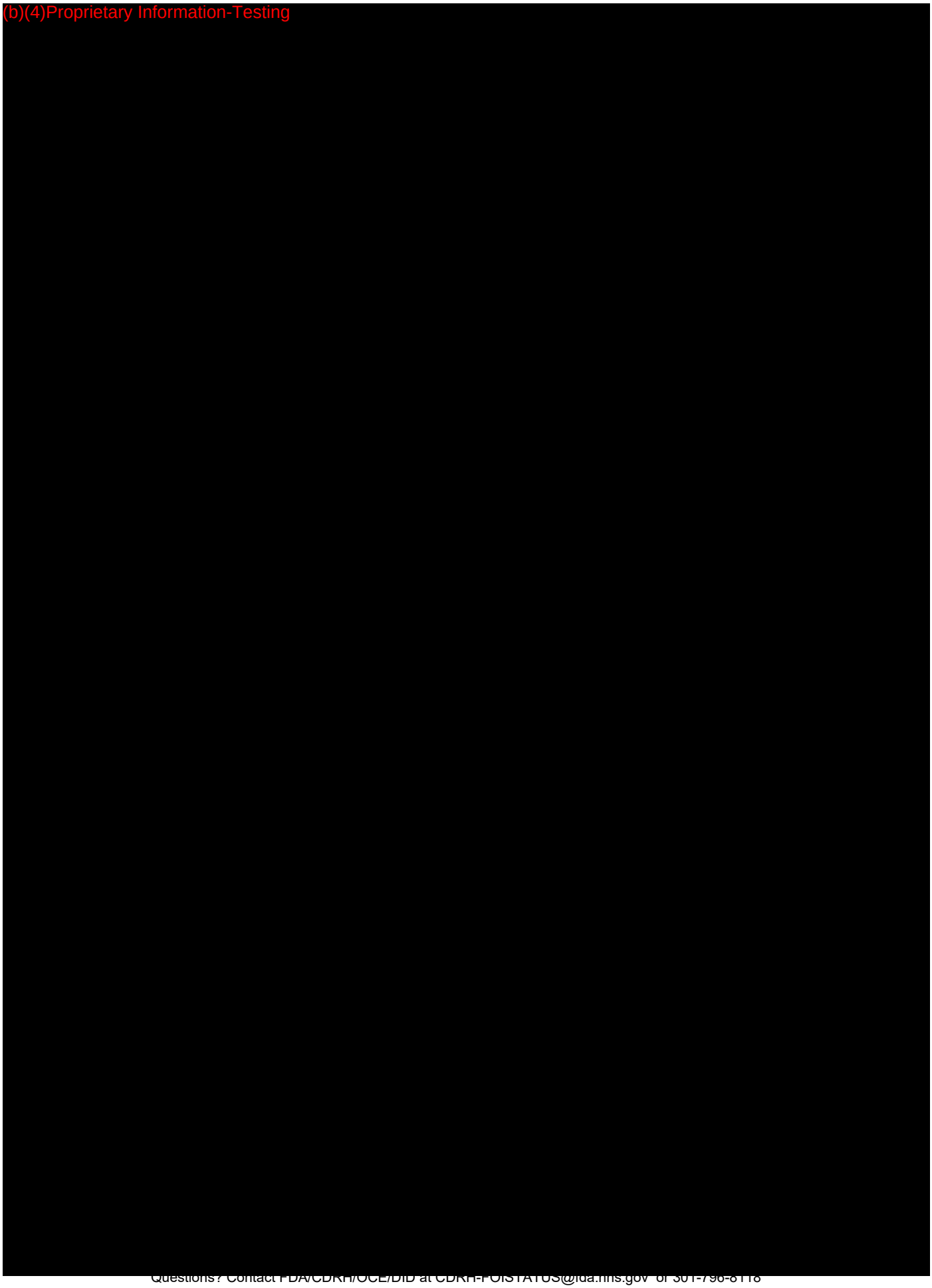
(b)(4)Proprietary Information-Testing

[redacted]

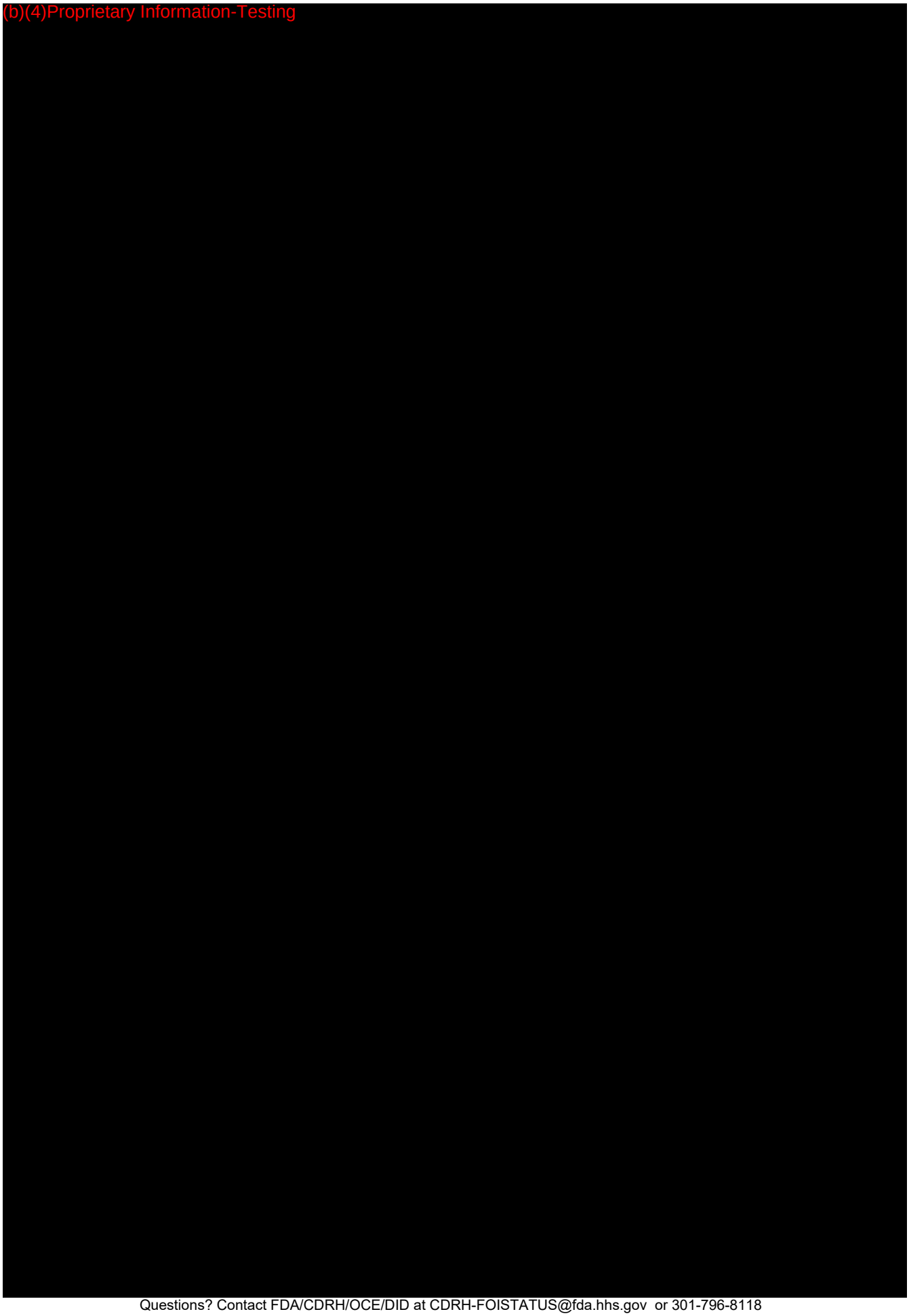
(b)(4)Proprietary Information-Testing



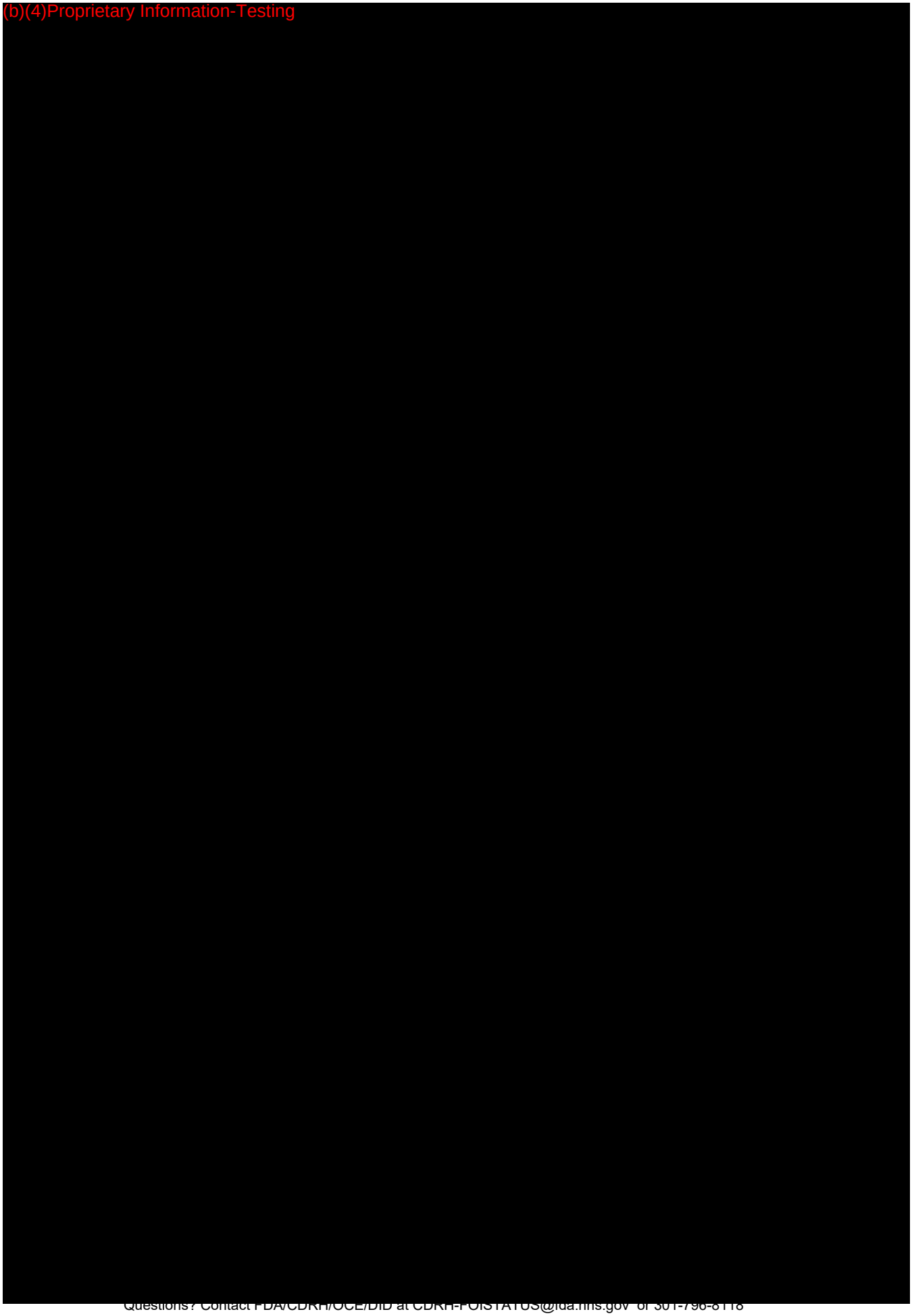
(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing



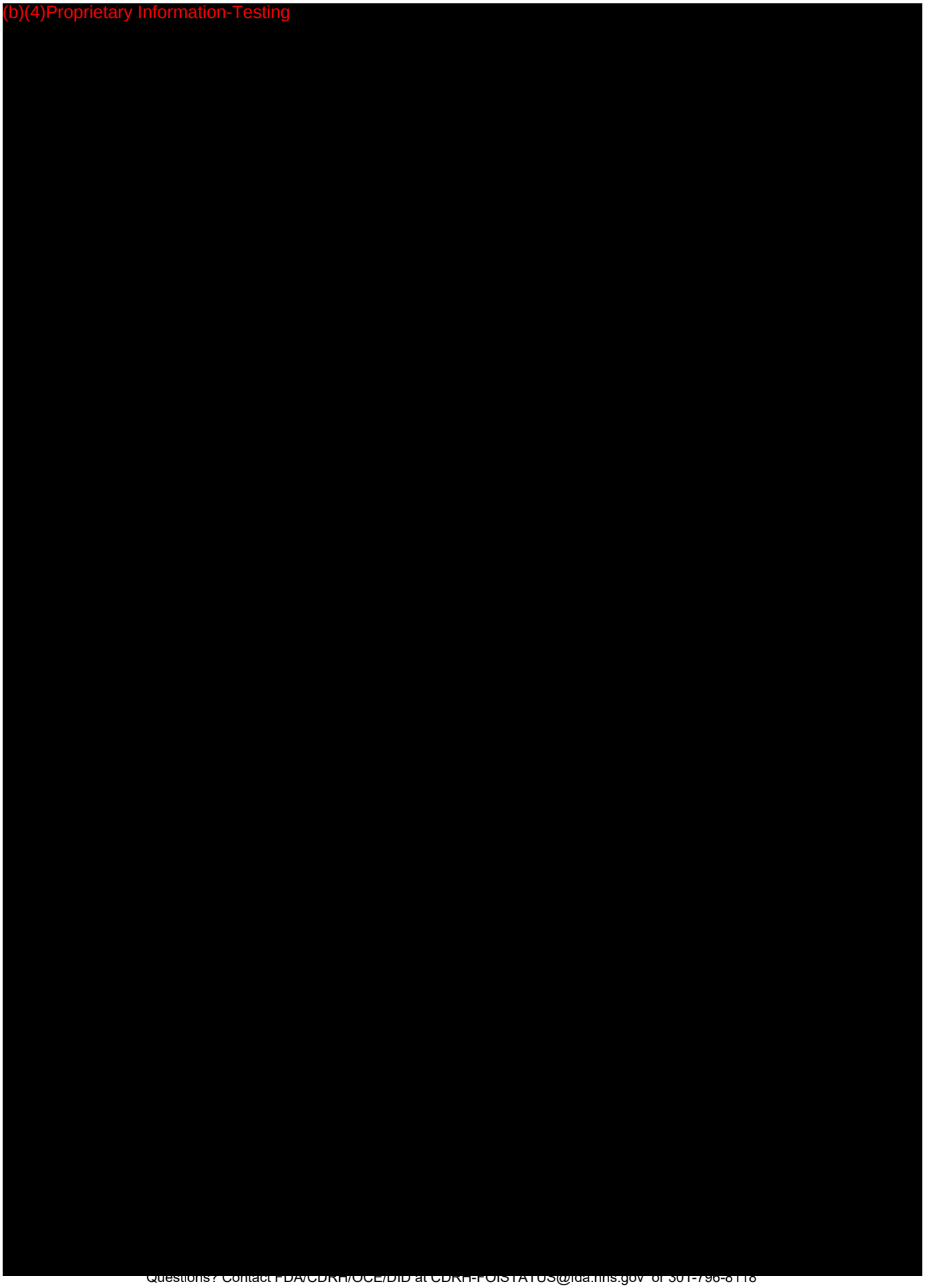
(b)(4)Proprietary Information-Testing



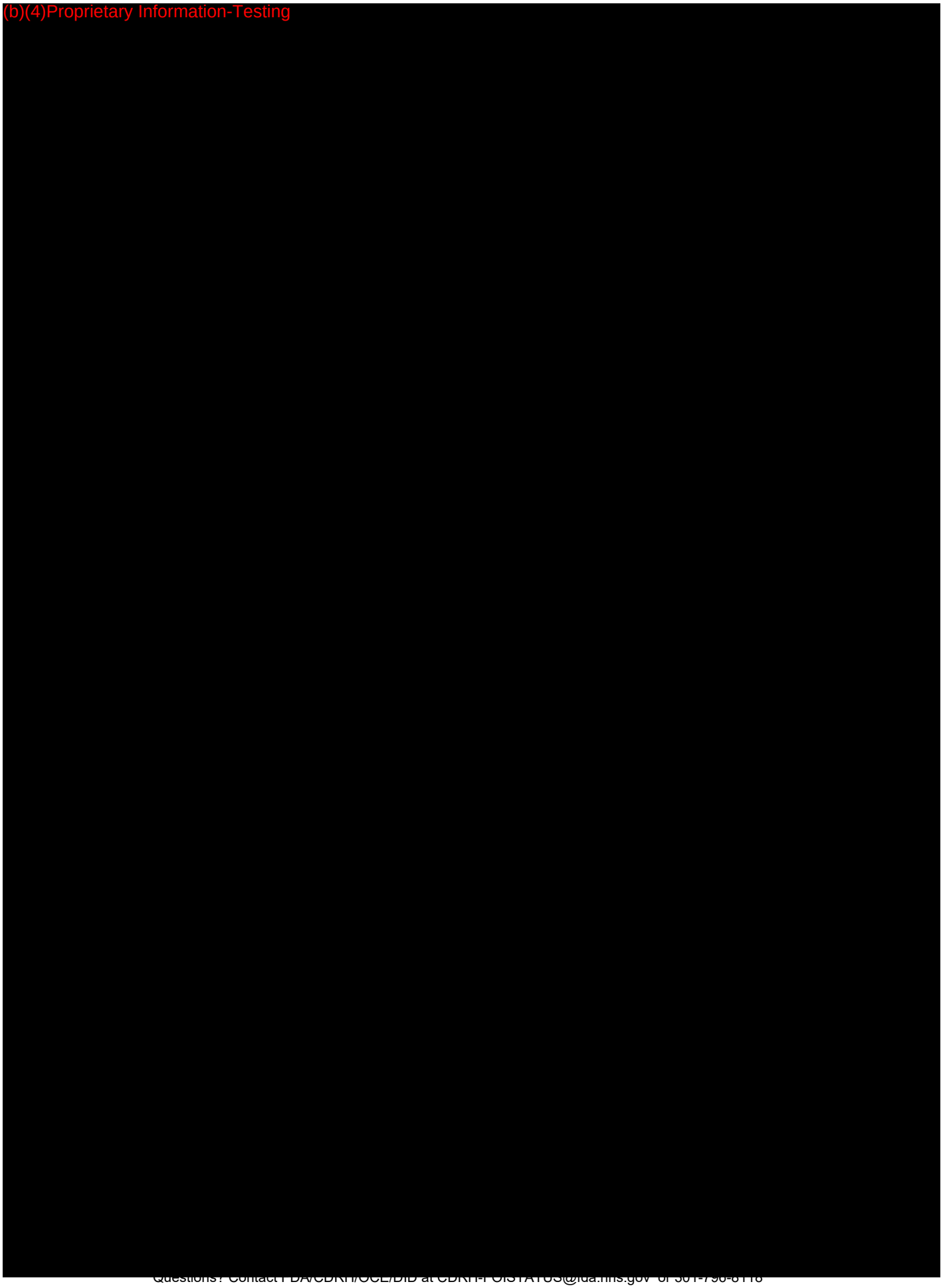
(b)(4)Proprietary Information-Testing

[redacted]

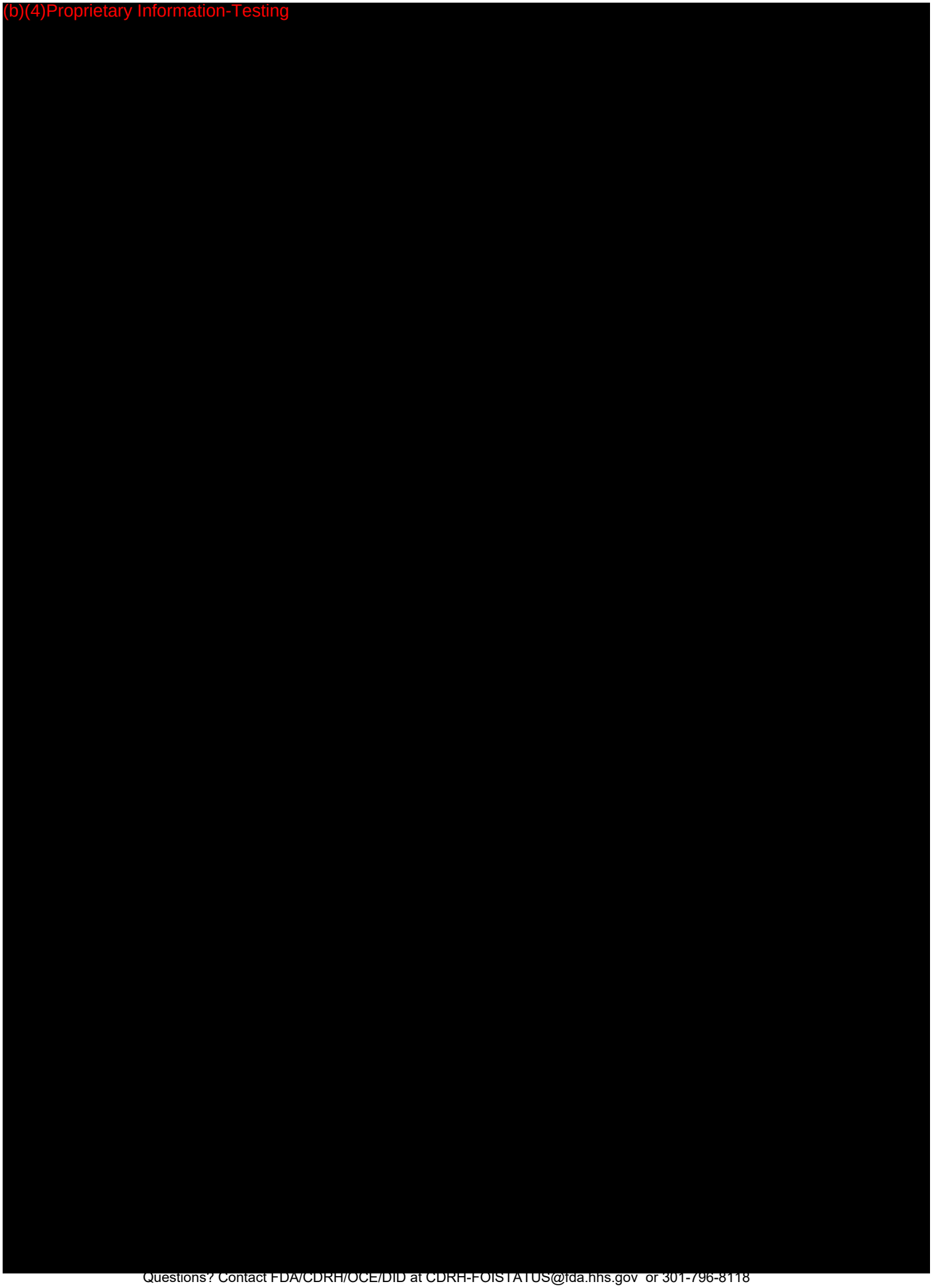
(b)(4)Proprietary Information-Testing



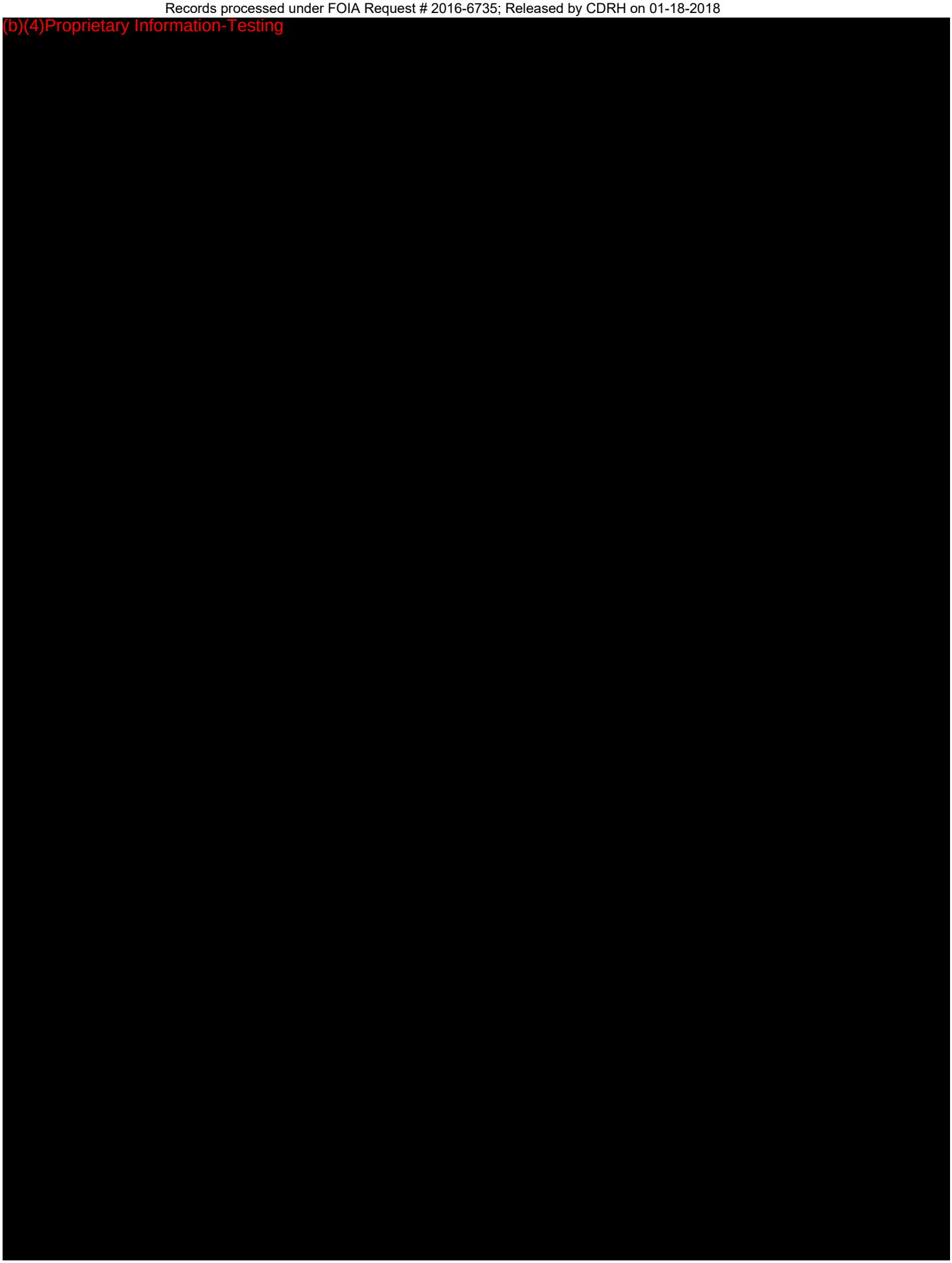
(b)(4)Proprietary Information-Testing



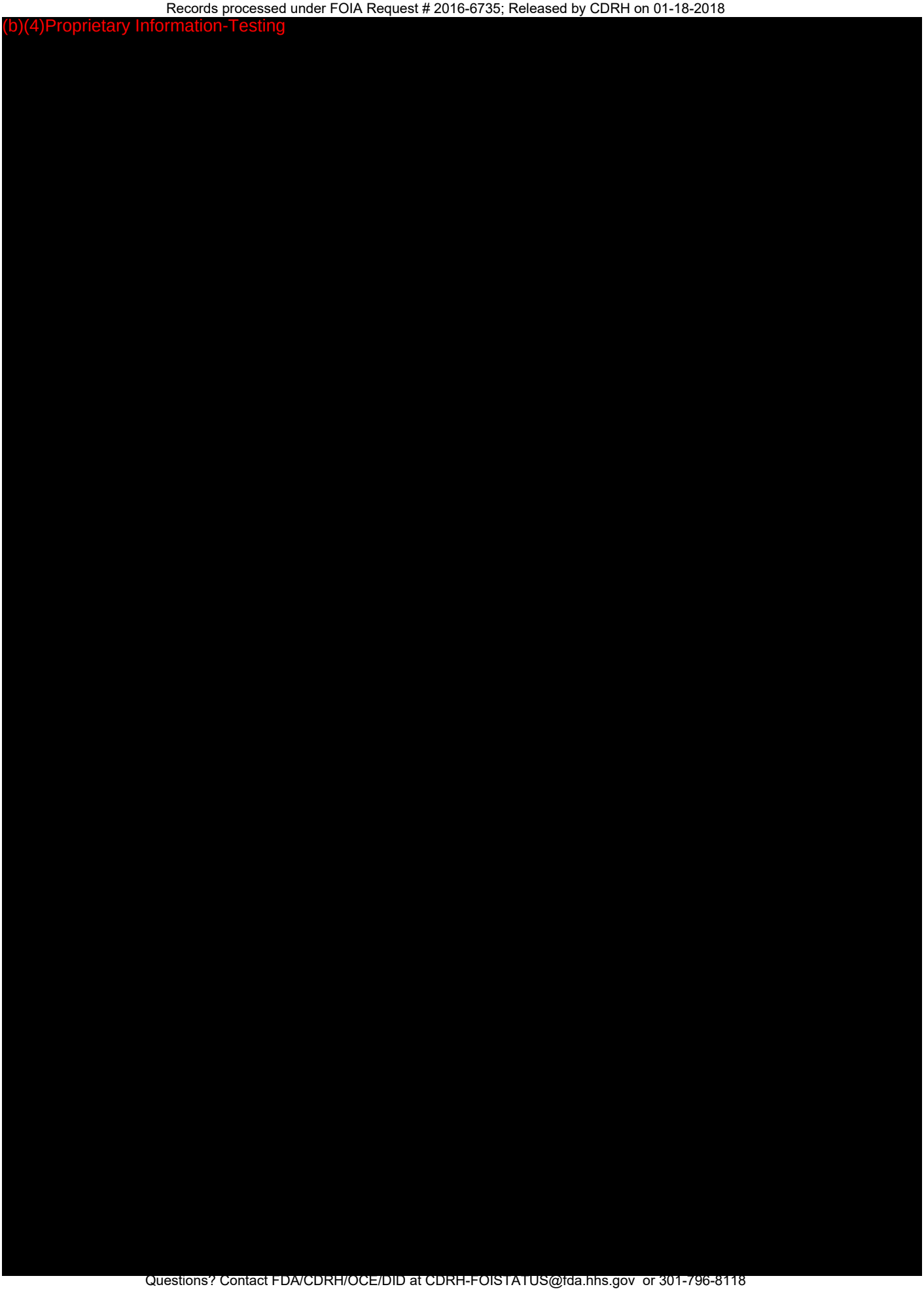
(b)(4)Proprietary Information-Testing



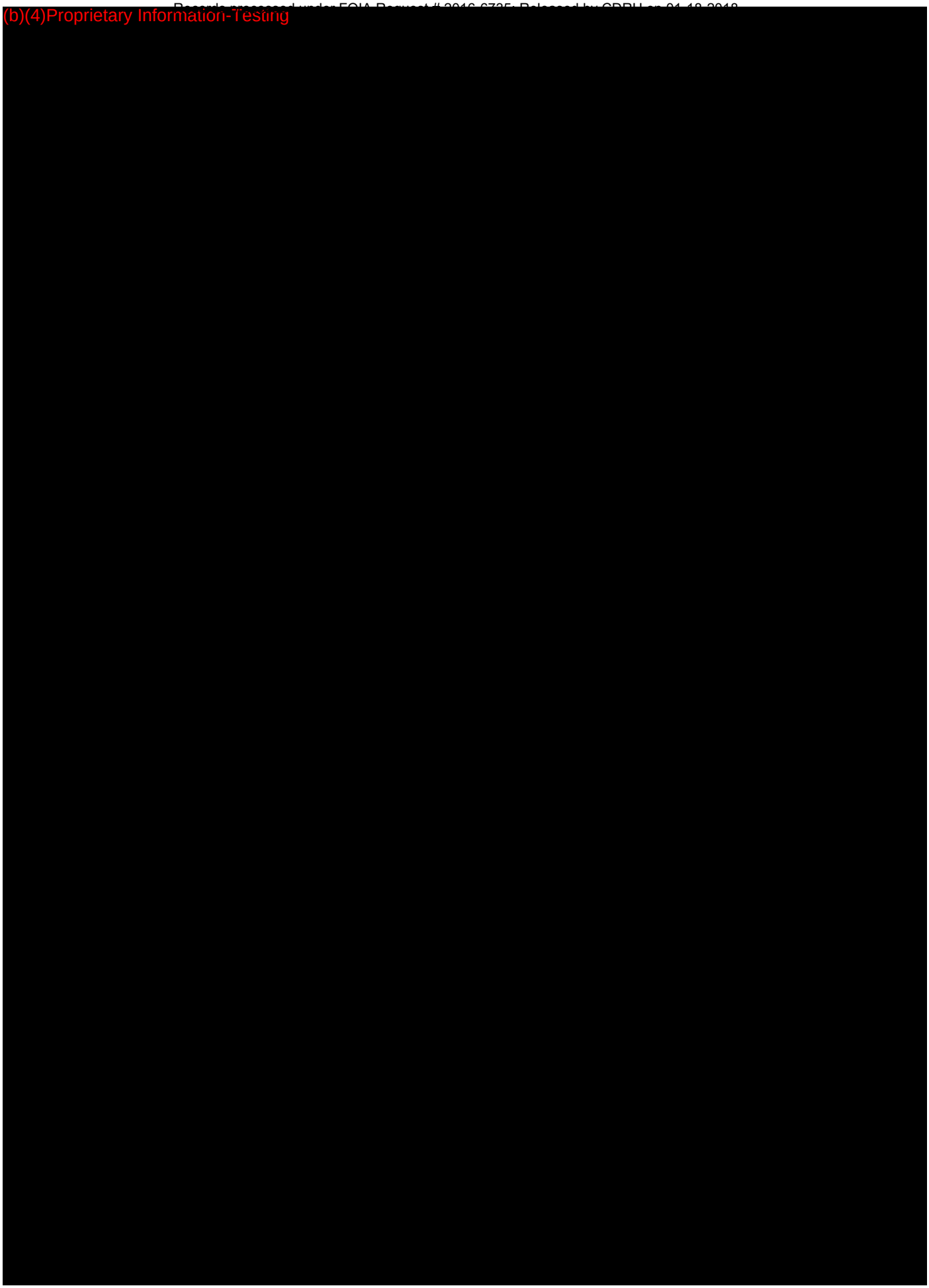
(b)(4)Proprietary Information-Testing



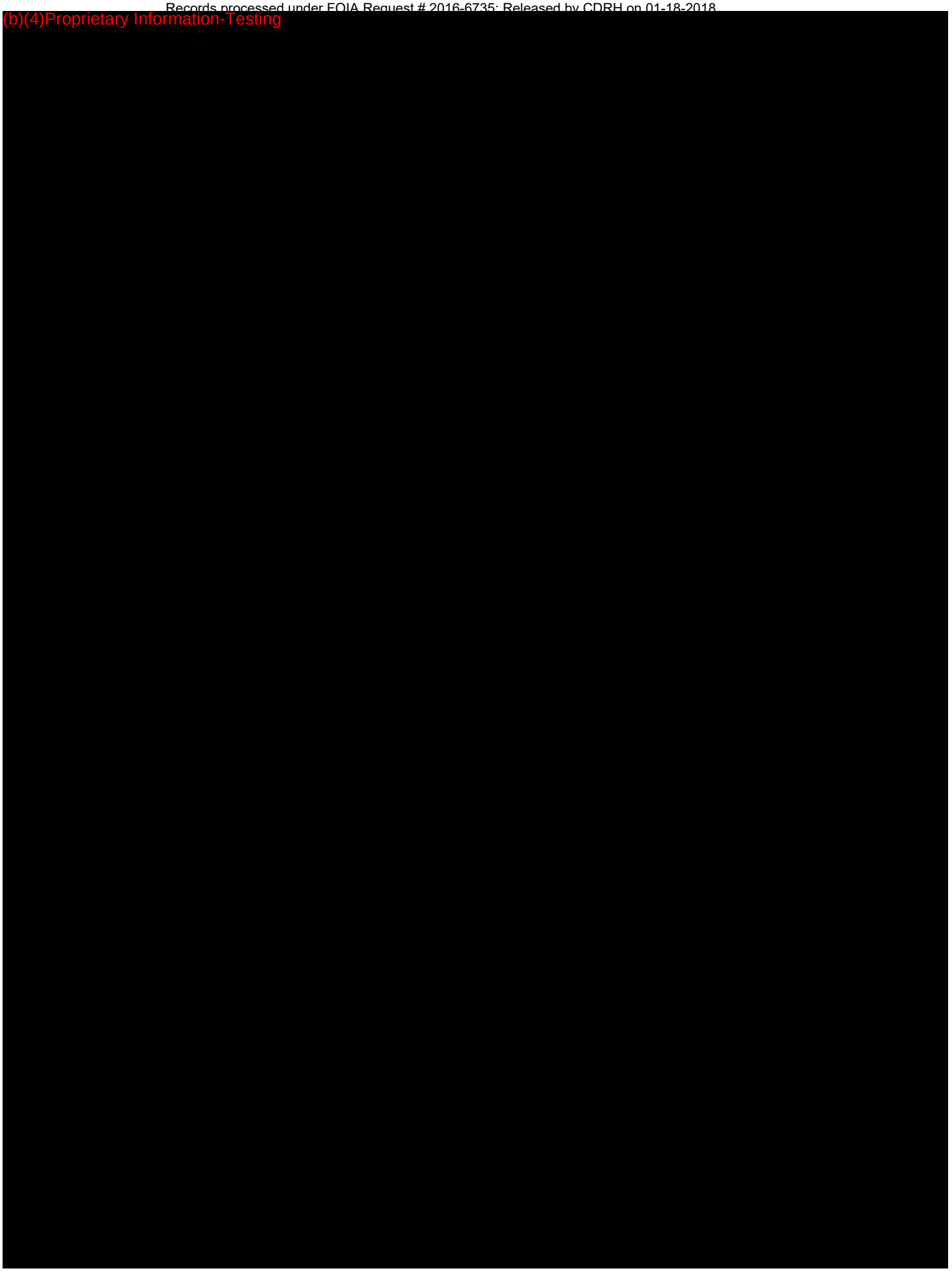
(b)(4)Proprietary Information-Testing



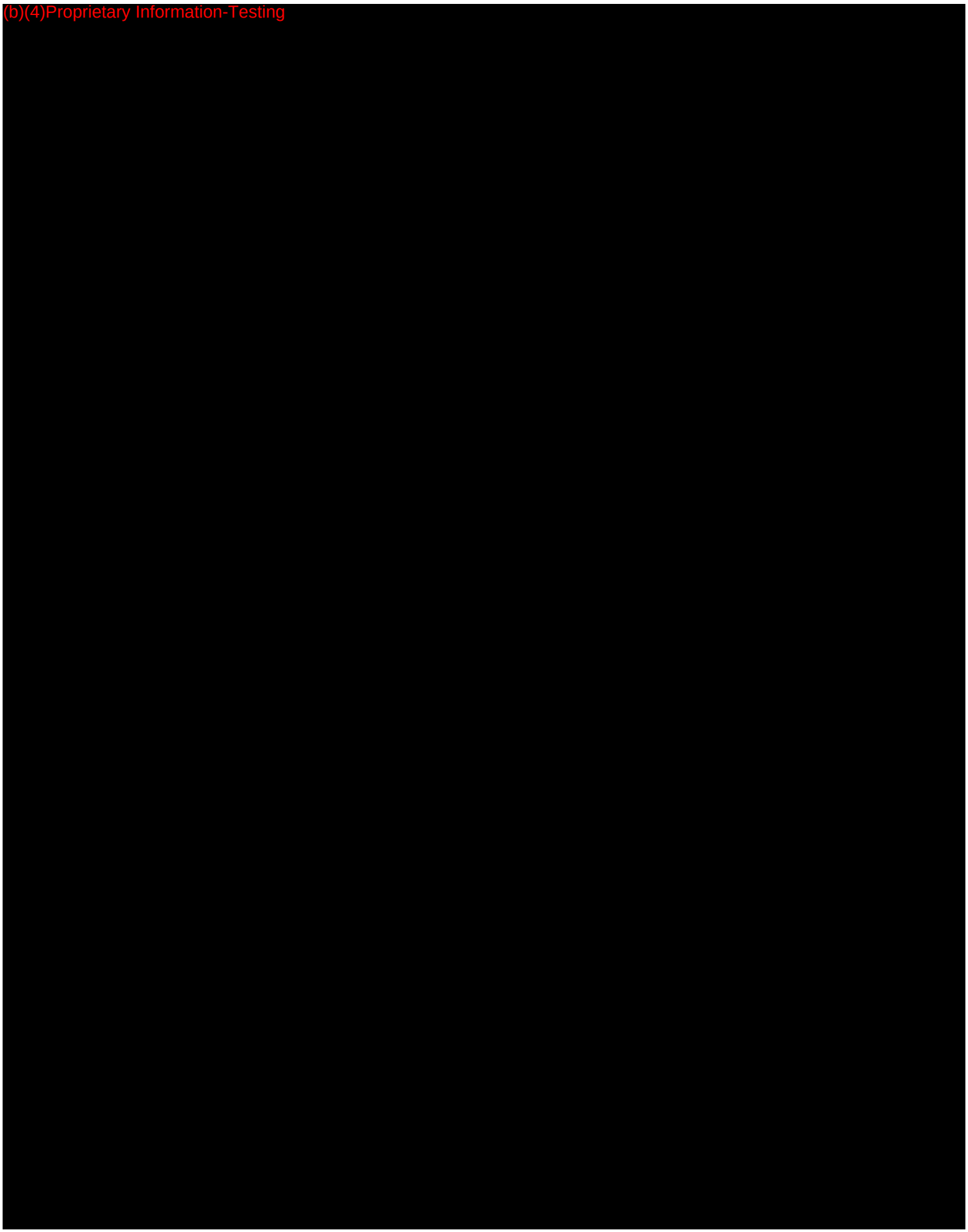
(b)(4)Proprietary Information-Testing



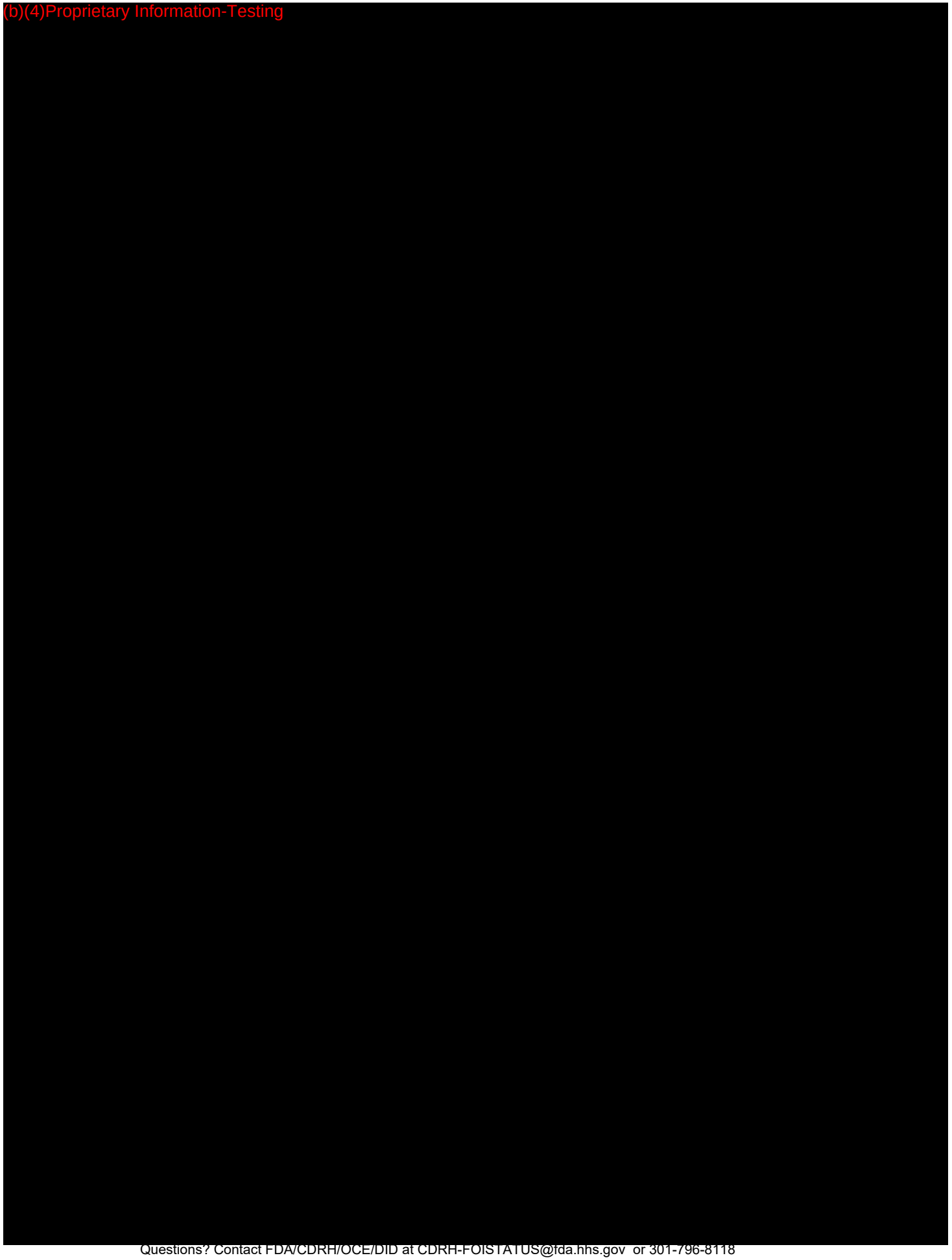
(b)(4)Proprietary Information-Testing



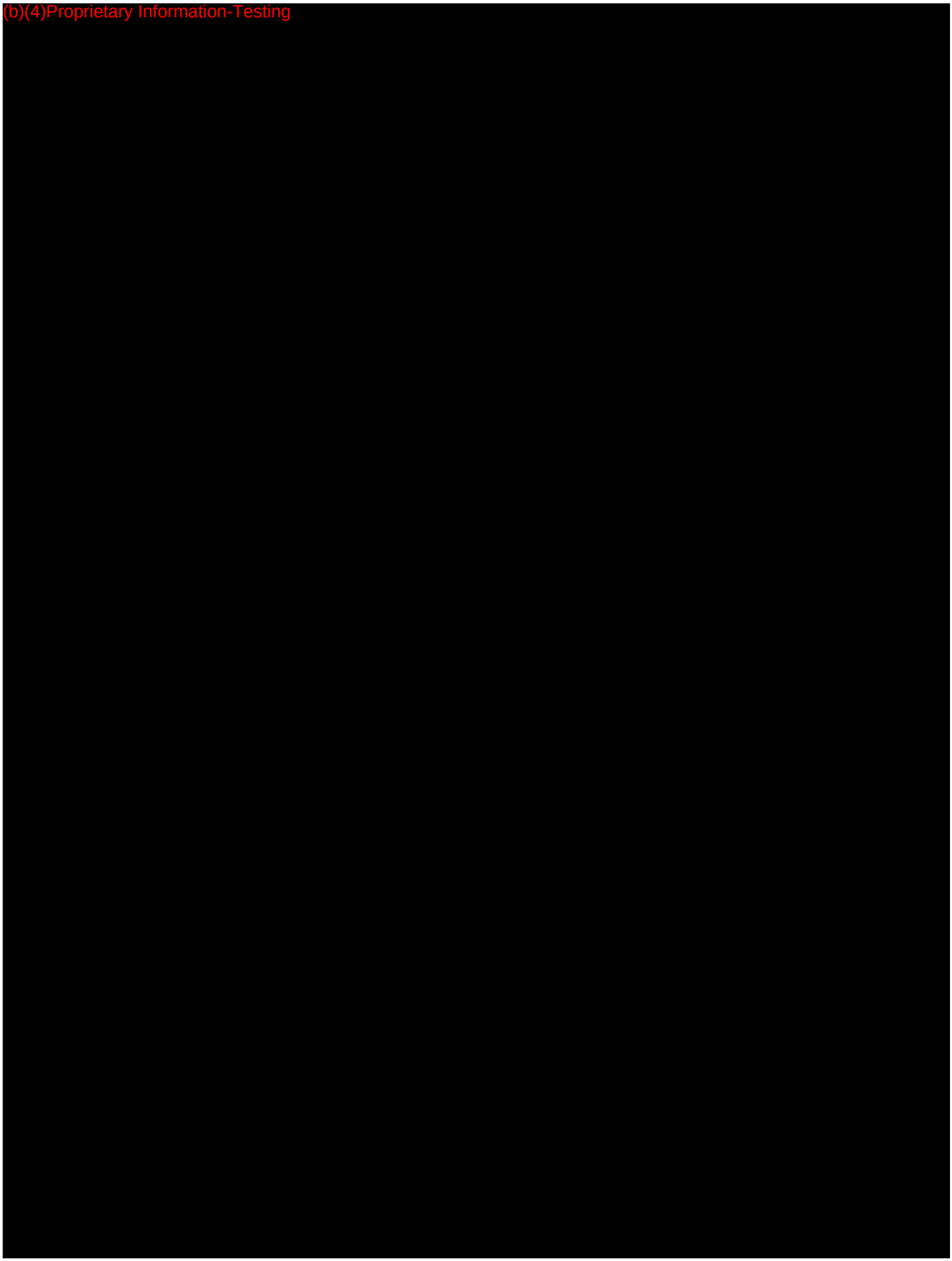
(b)(4)Proprietary Information-Testing



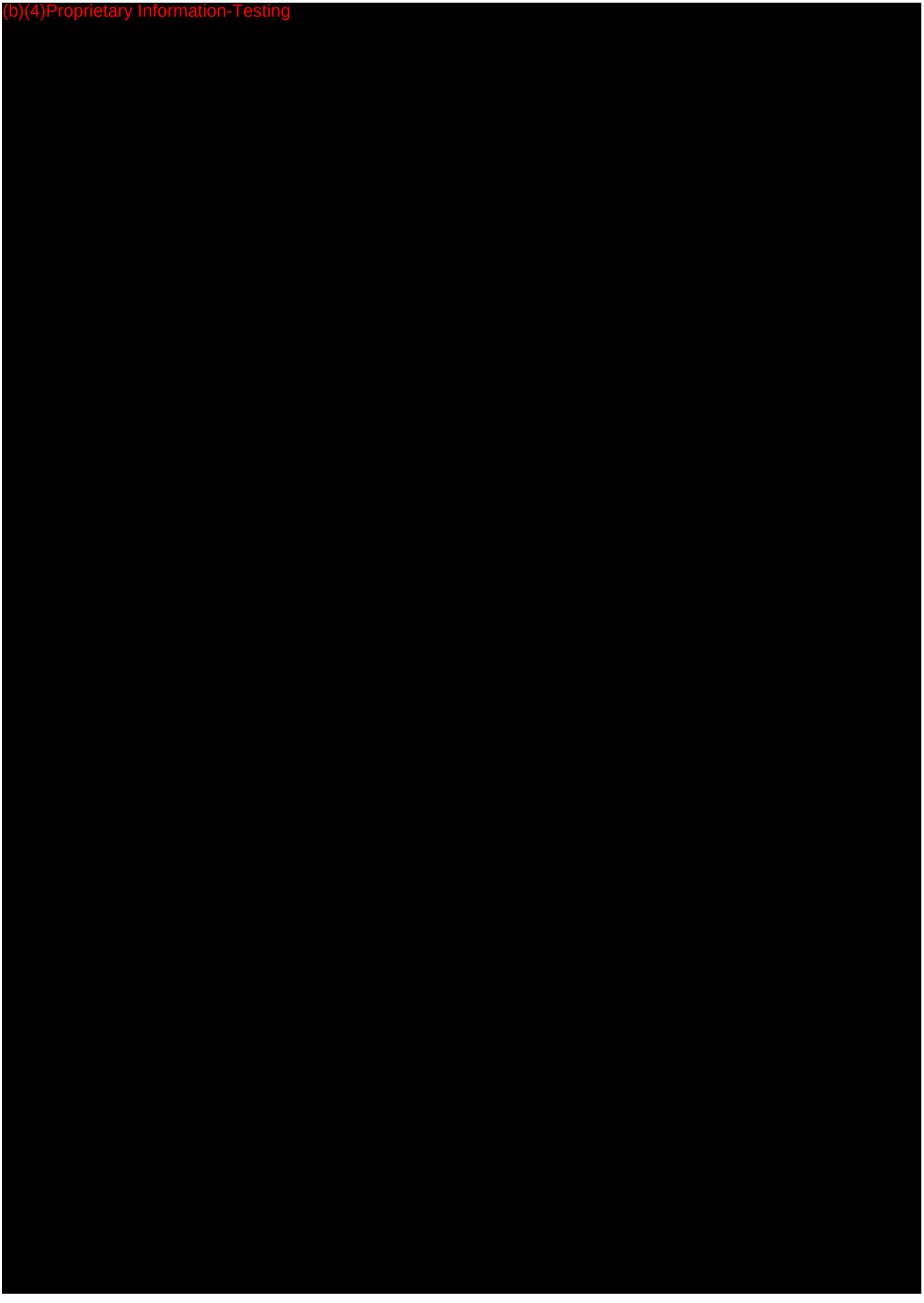
(b)(4)Proprietary Information-Testing



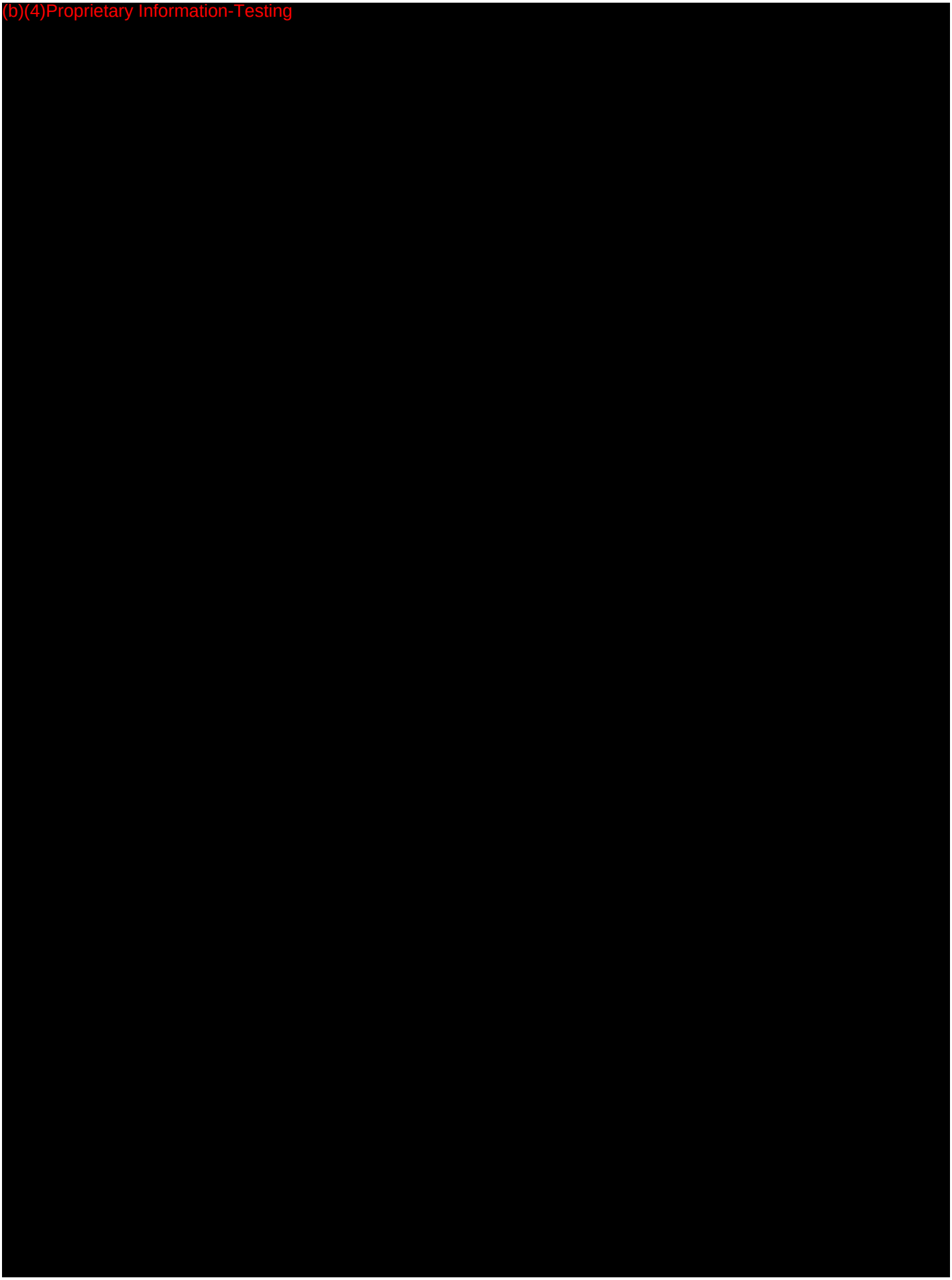
(b)(4)Proprietary Information-Testing



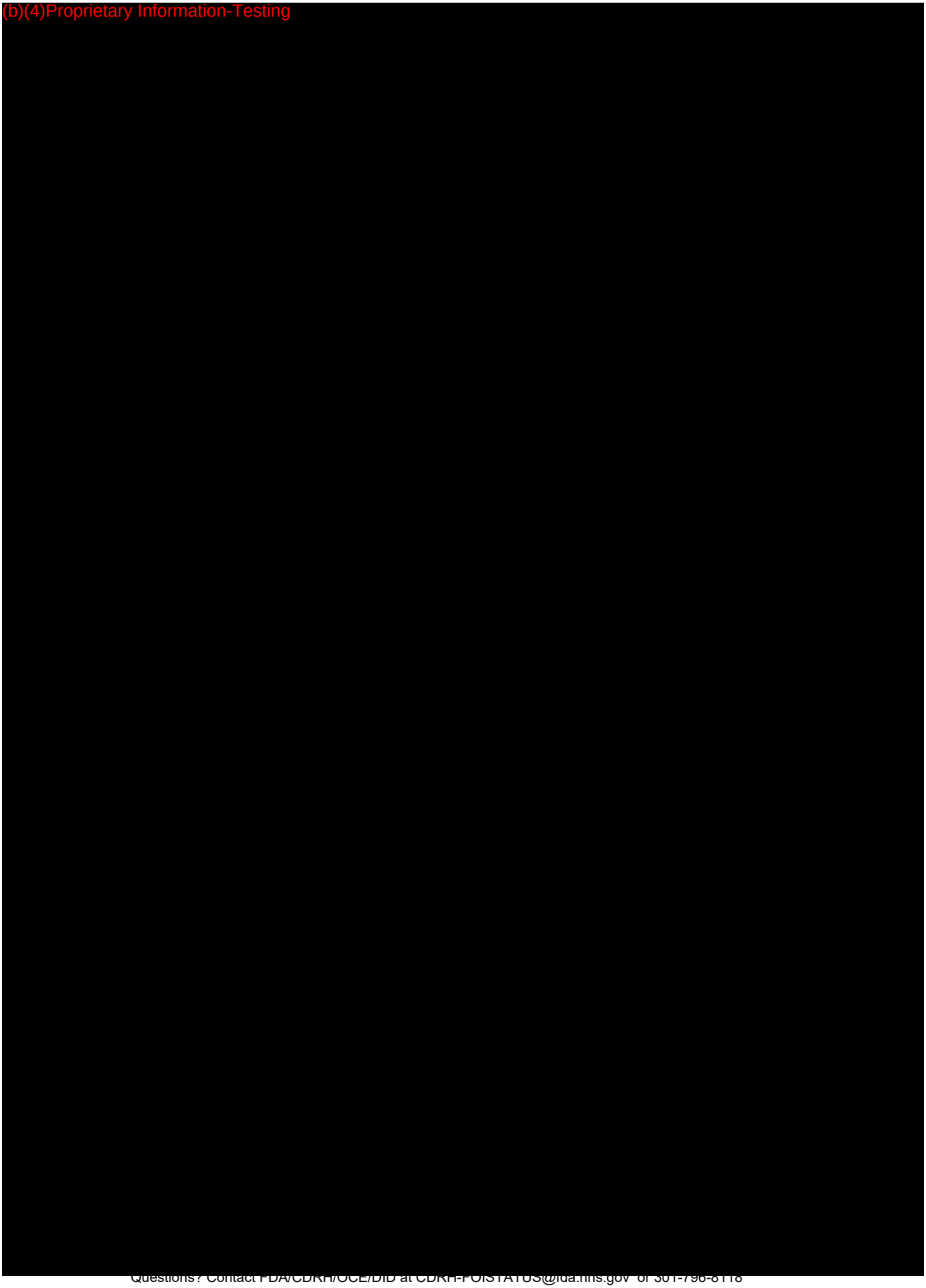
(b)(4)Proprietary Information-Testing



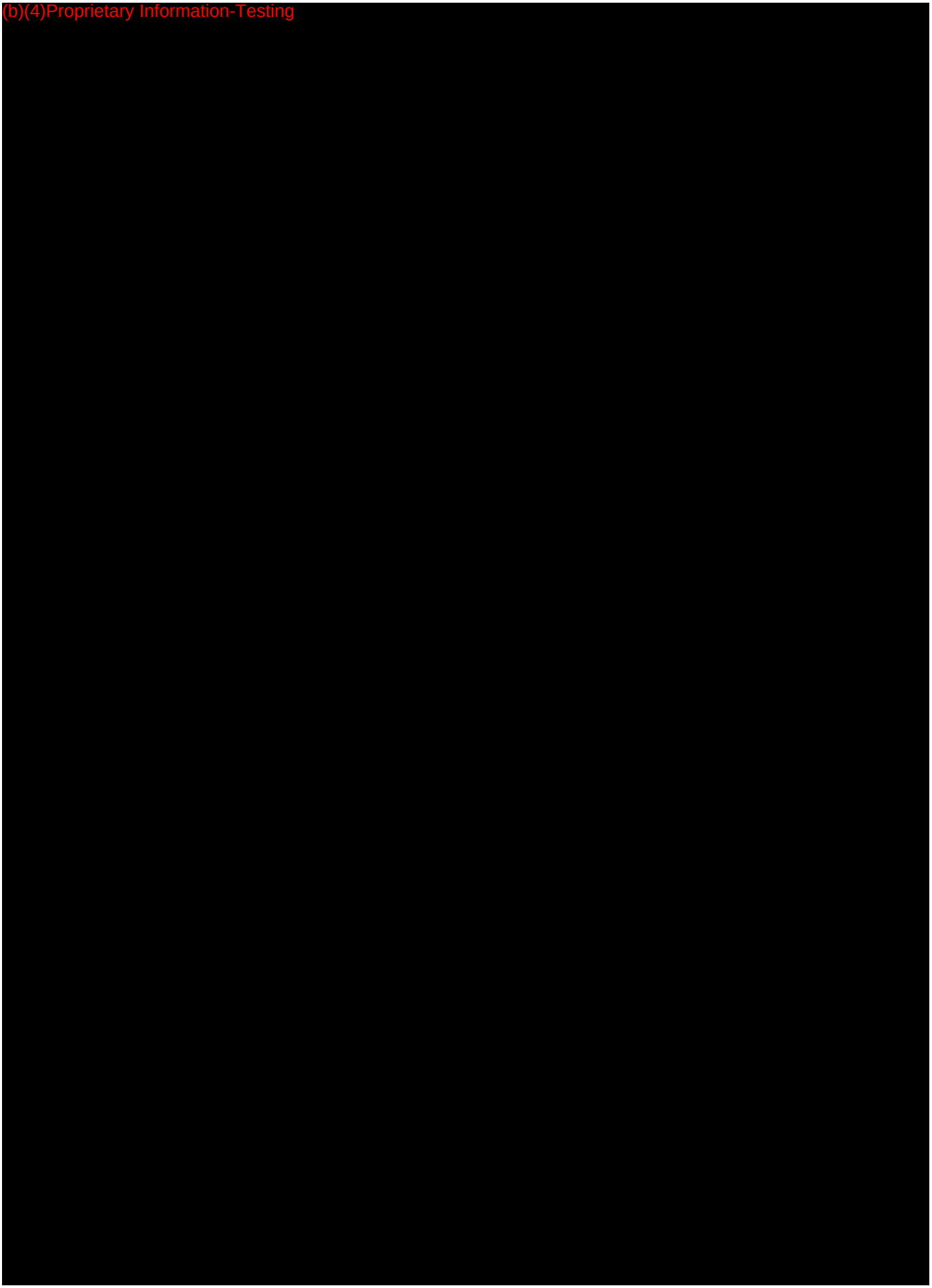
(b)(4)Proprietary Information-Testing



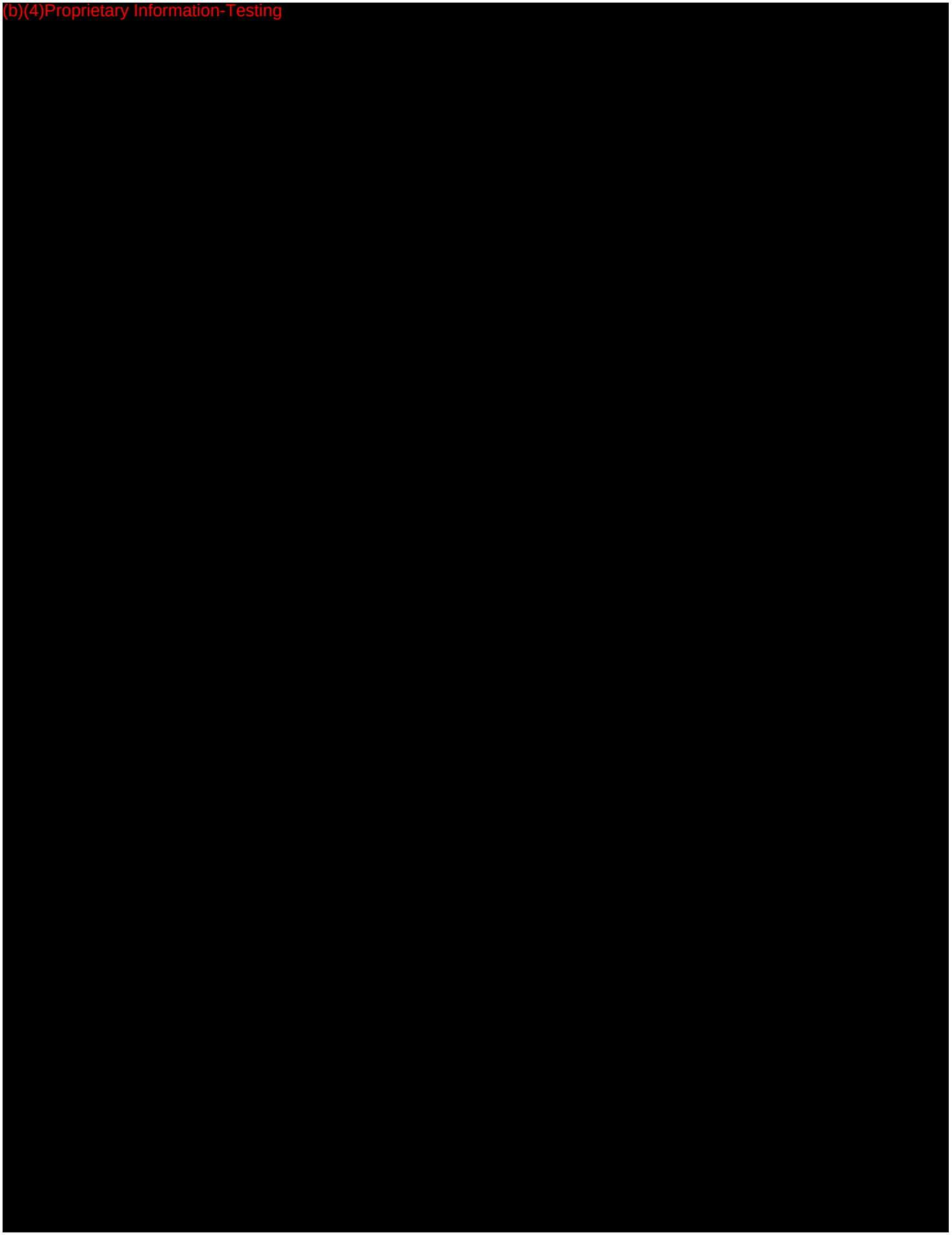
(b)(4)Proprietary Information-Testing



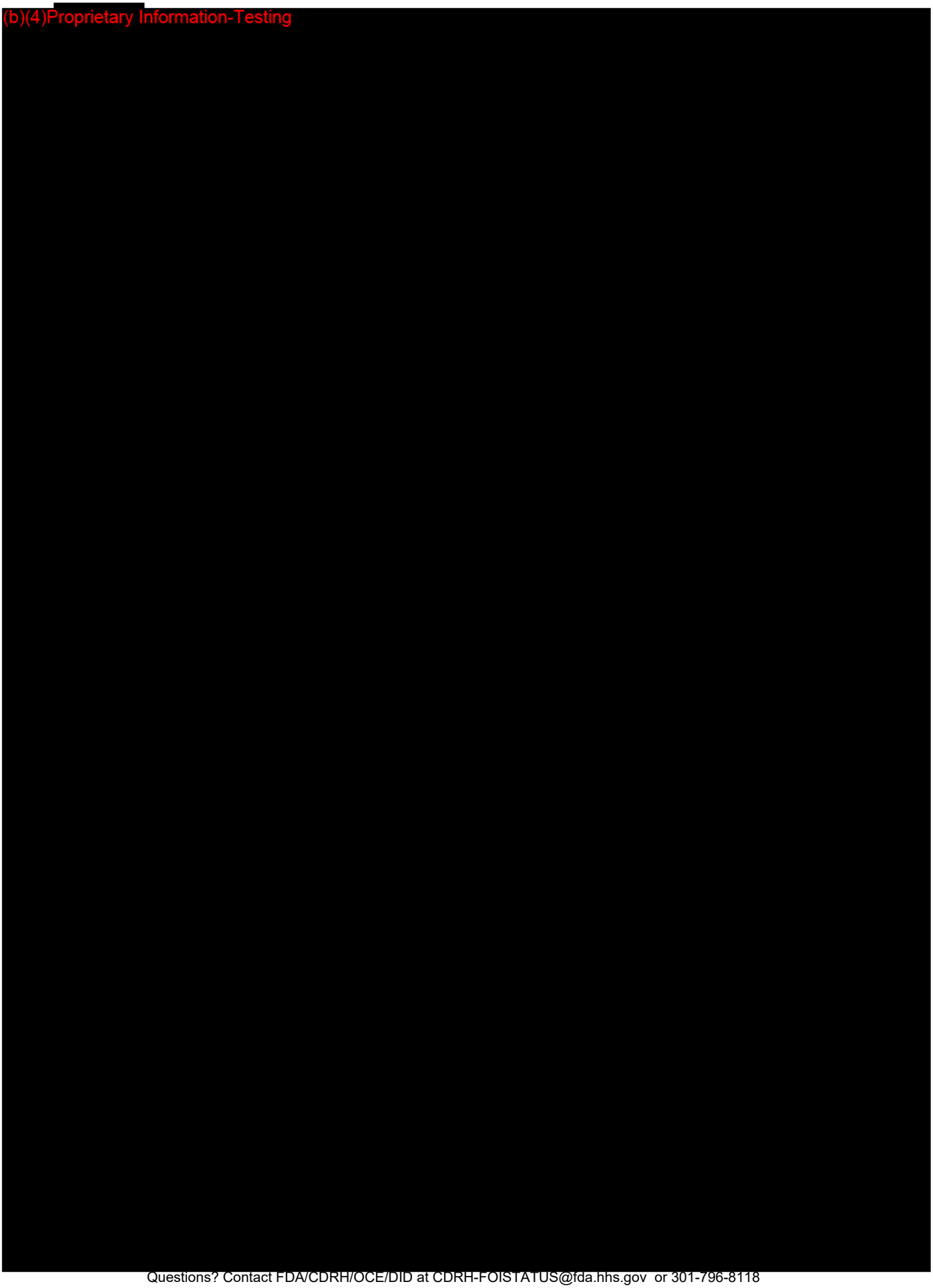
(b)(4)Proprietary Information-Testing

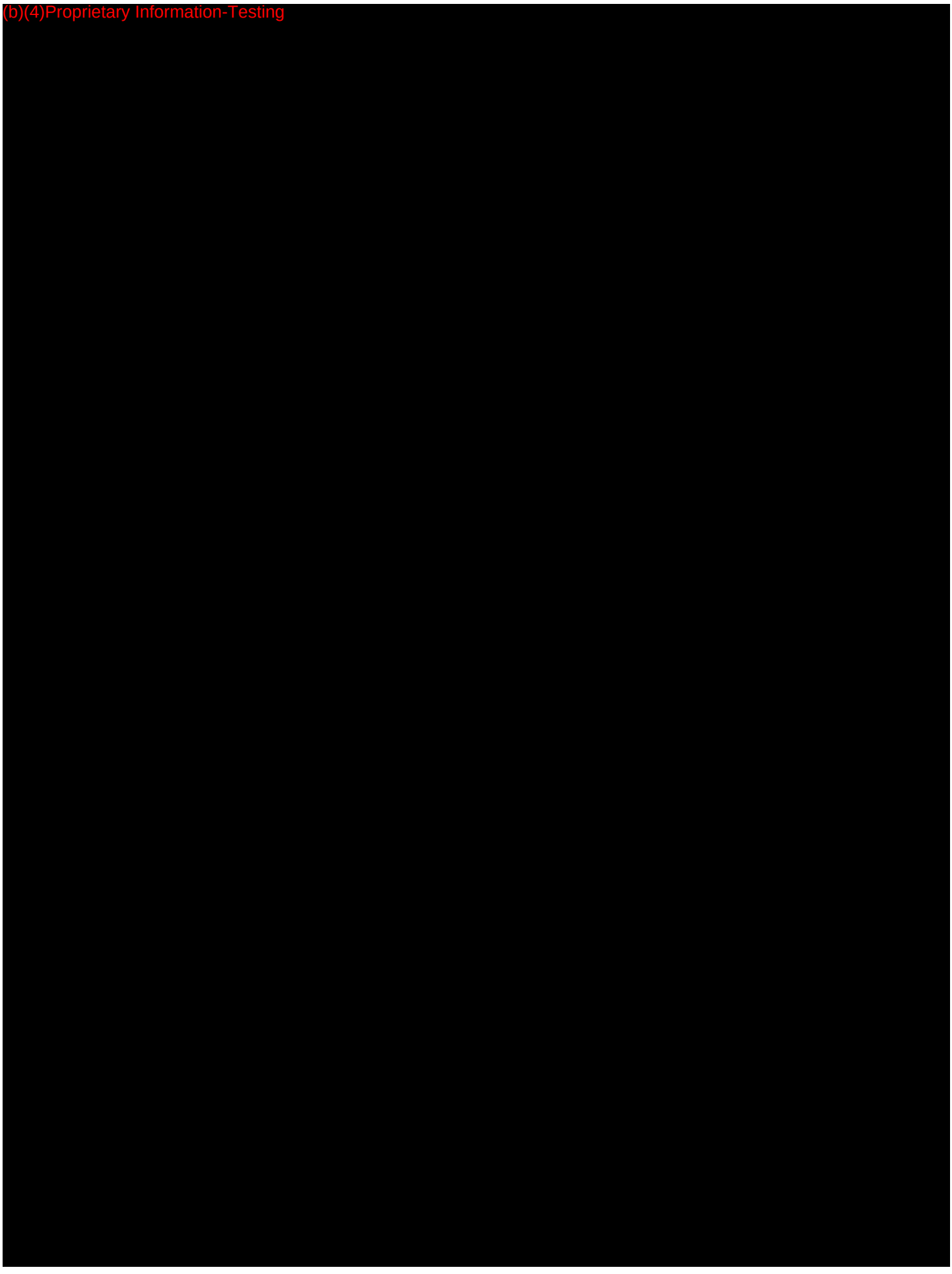


(b)(4)Proprietary Information-Testing

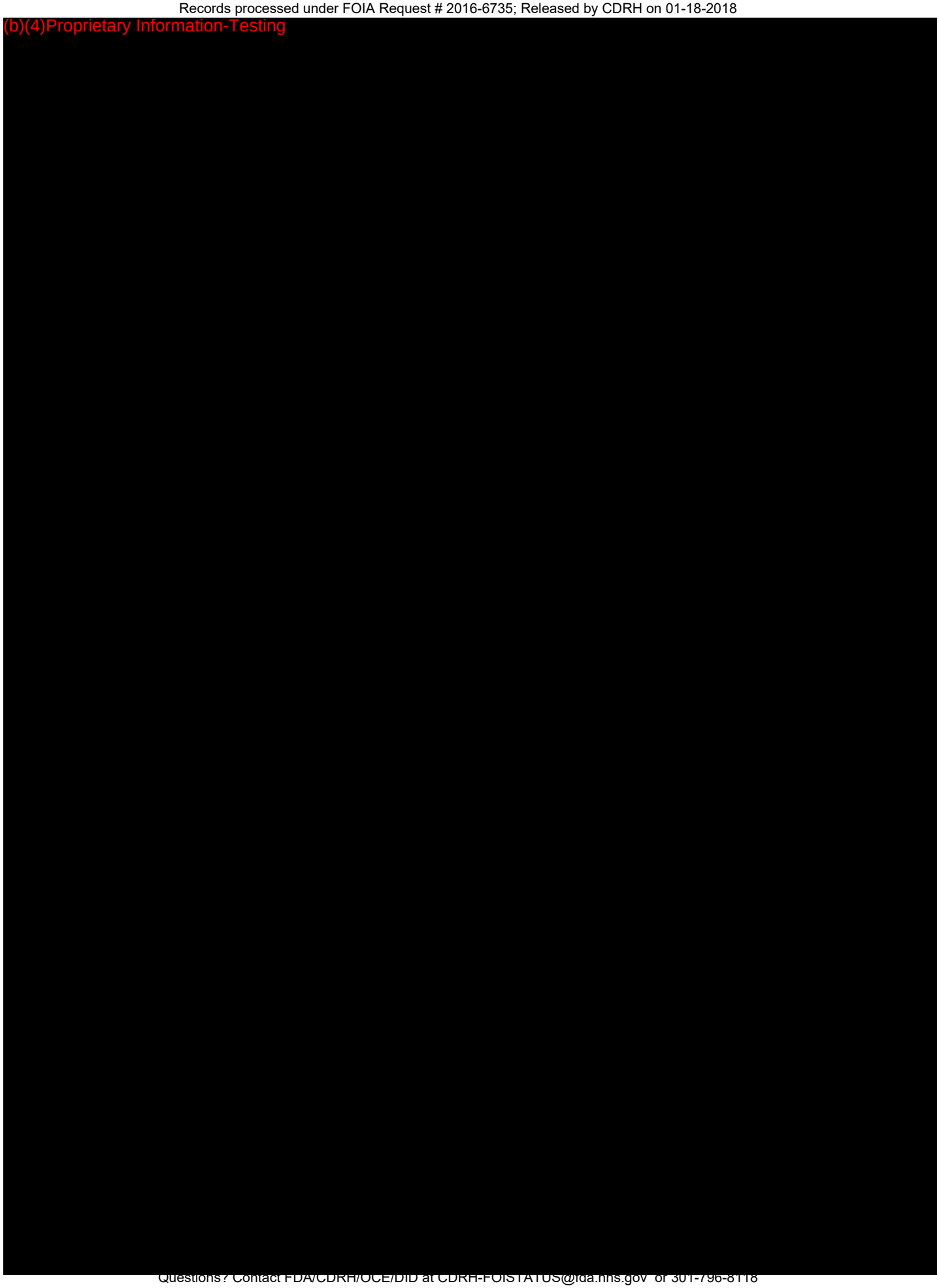


(b)(4)Proprietary Information-Testing





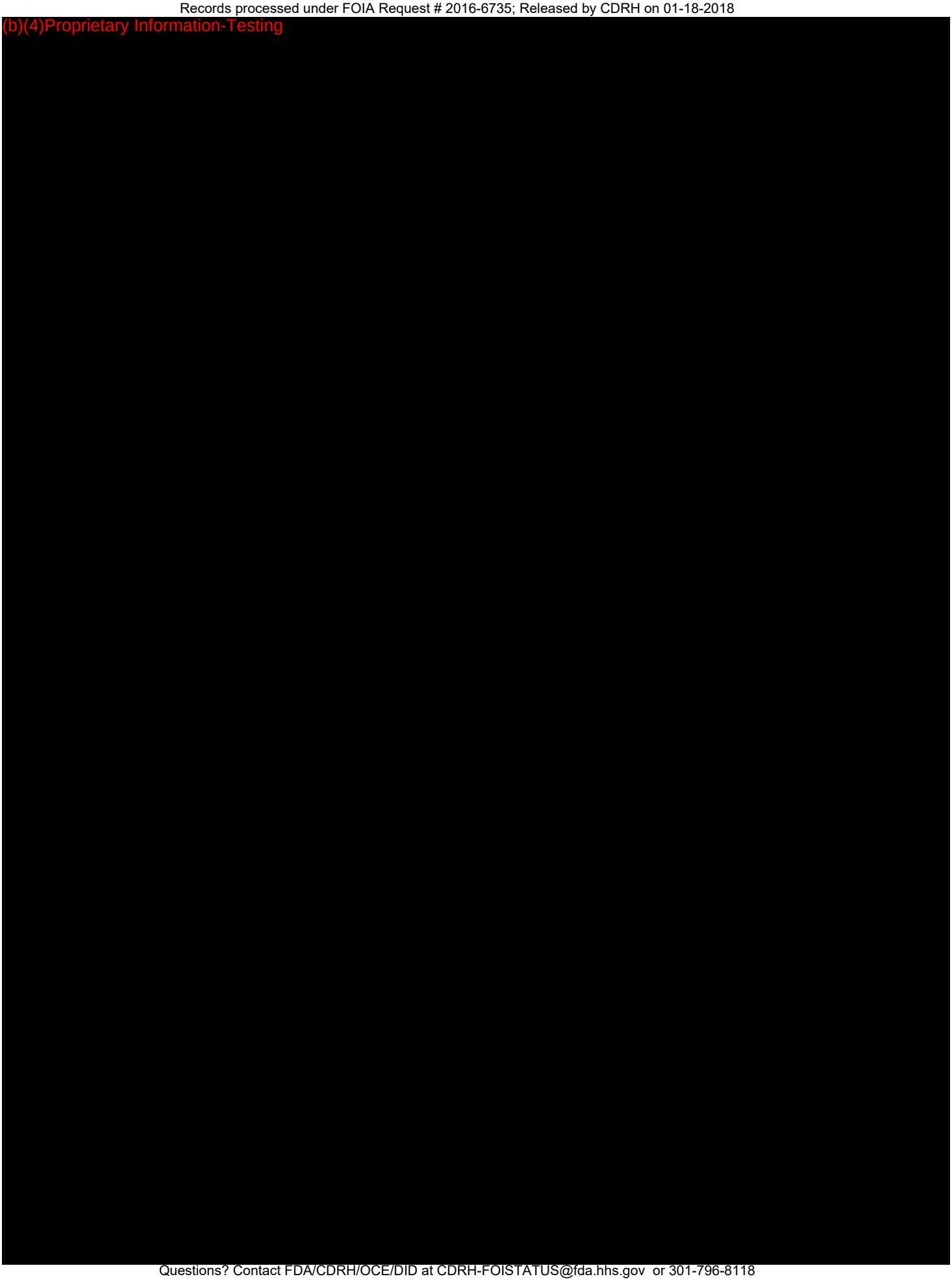
(b)(4)Proprietary Information-Testing



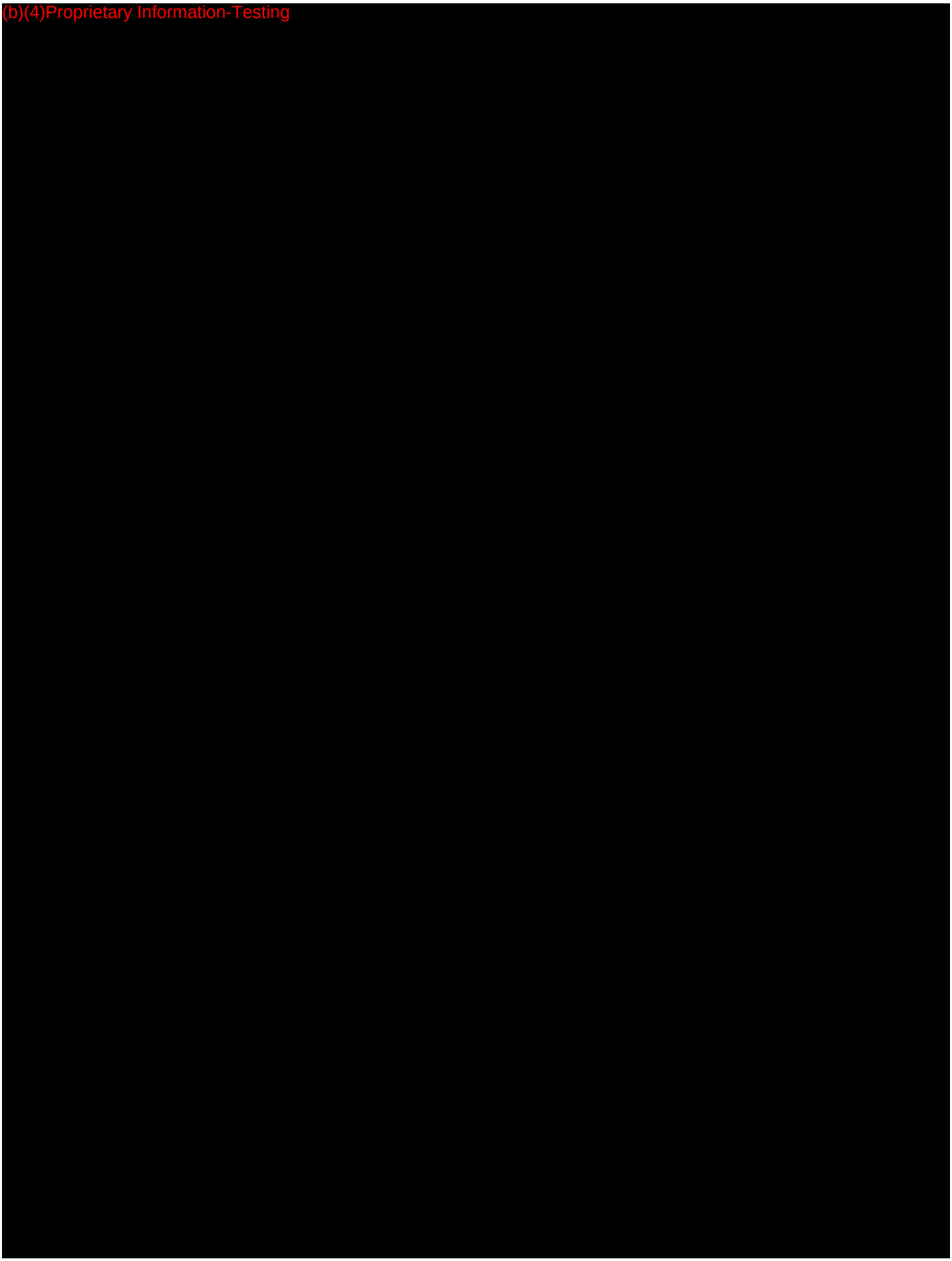
(b)(4)Proprietary Information-Testing

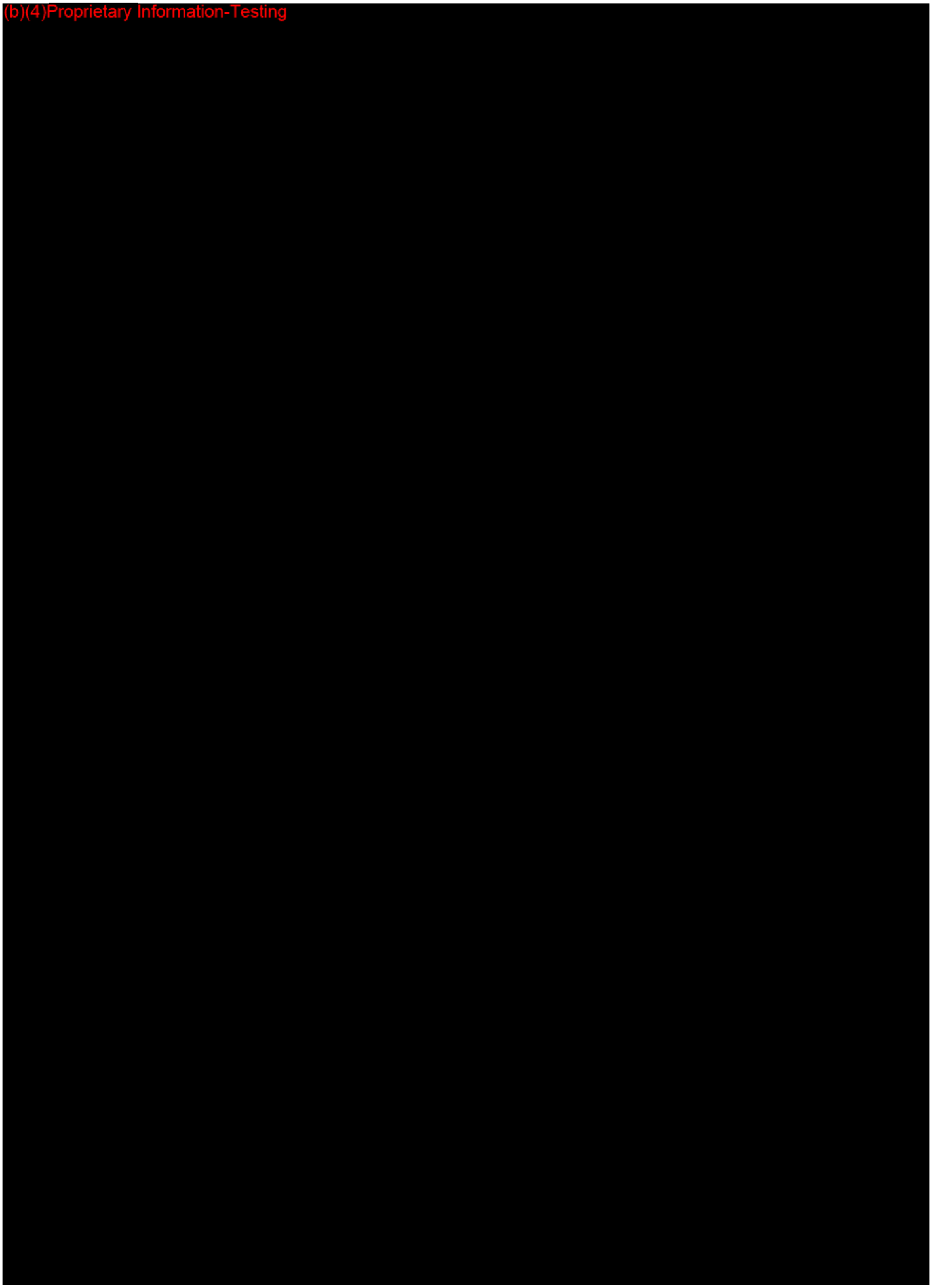
[redacted]

(b)(4)Proprietary Information-Testing

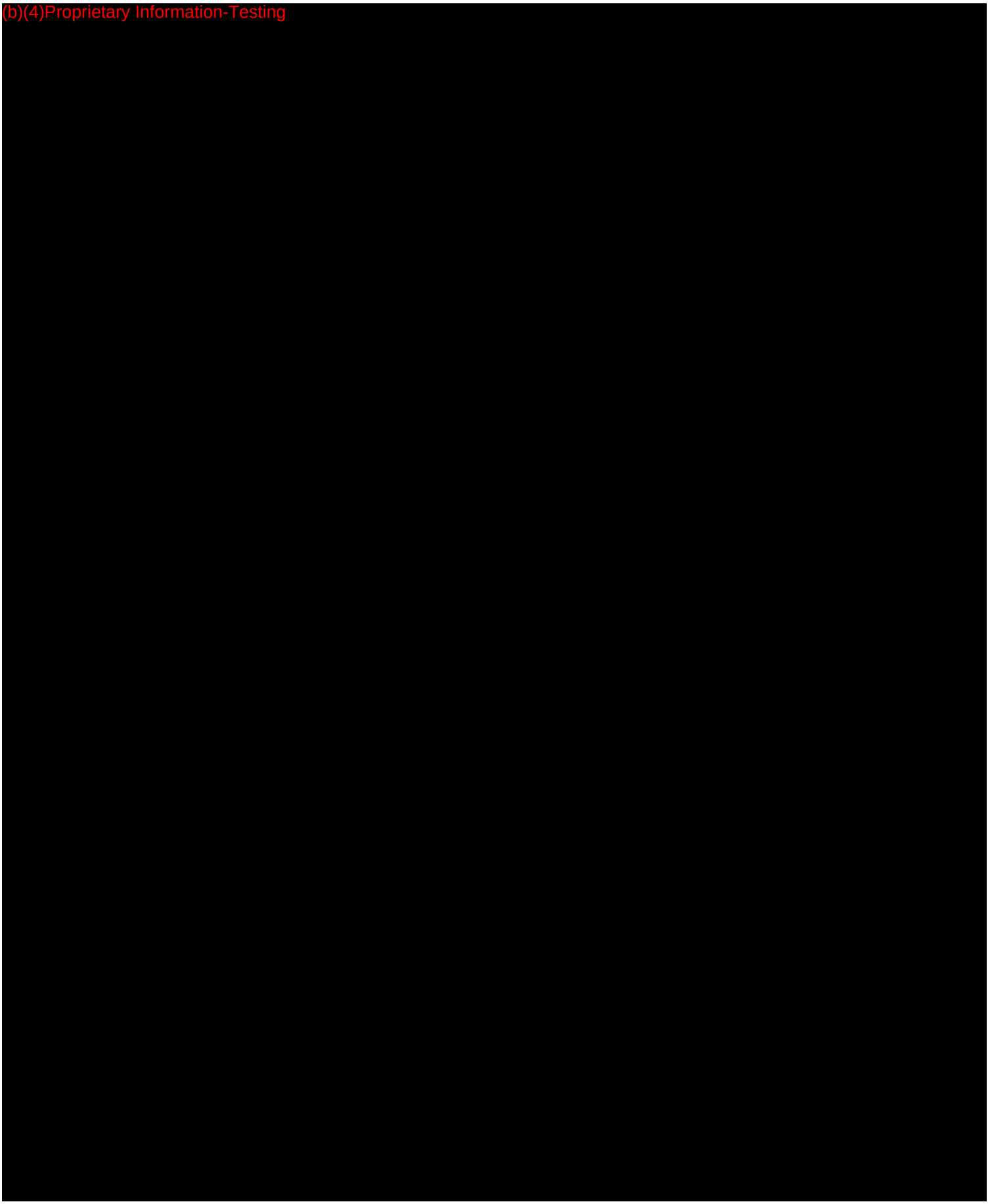


(b)(4)Proprietary Information-Testing

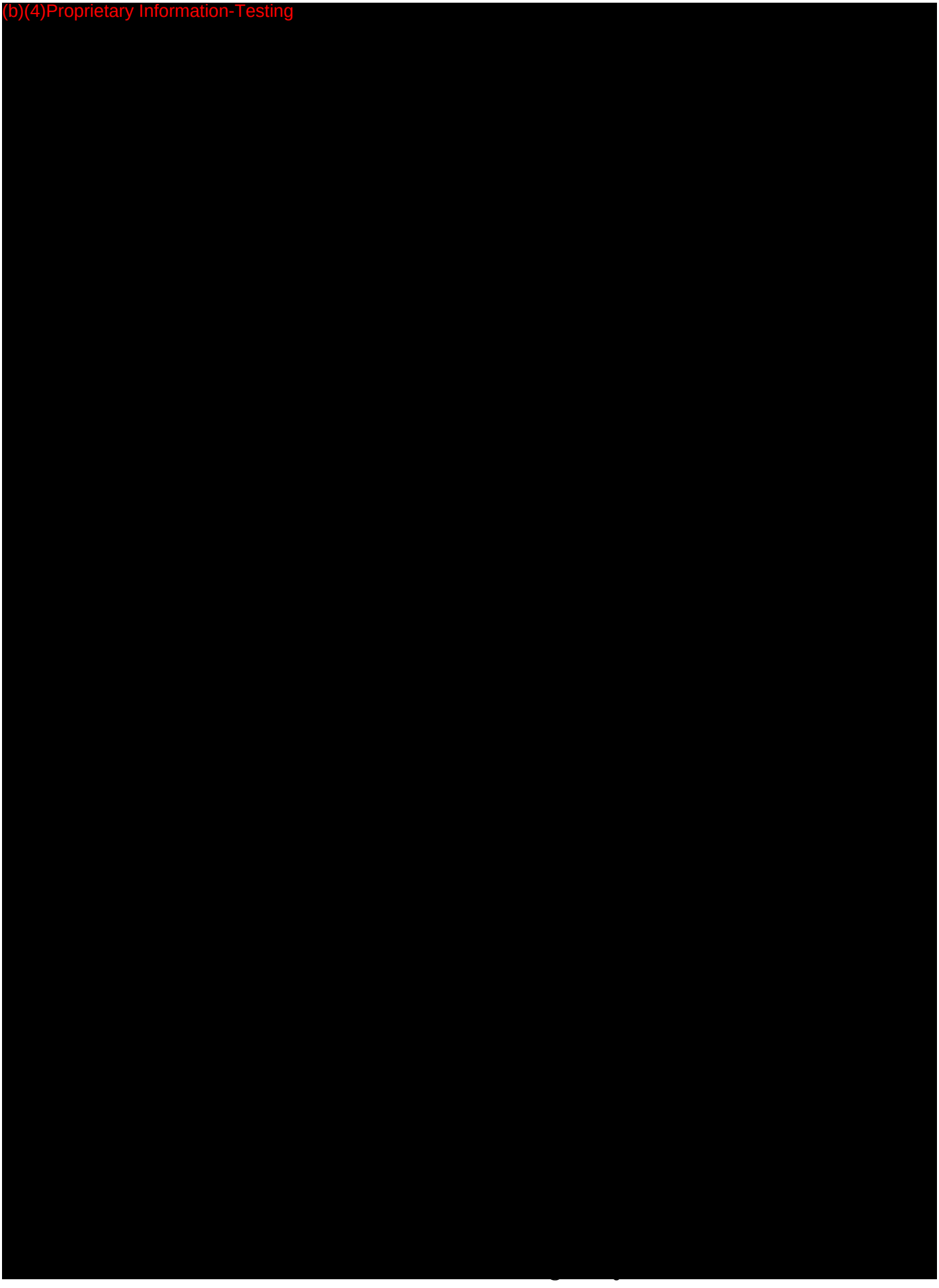




(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing



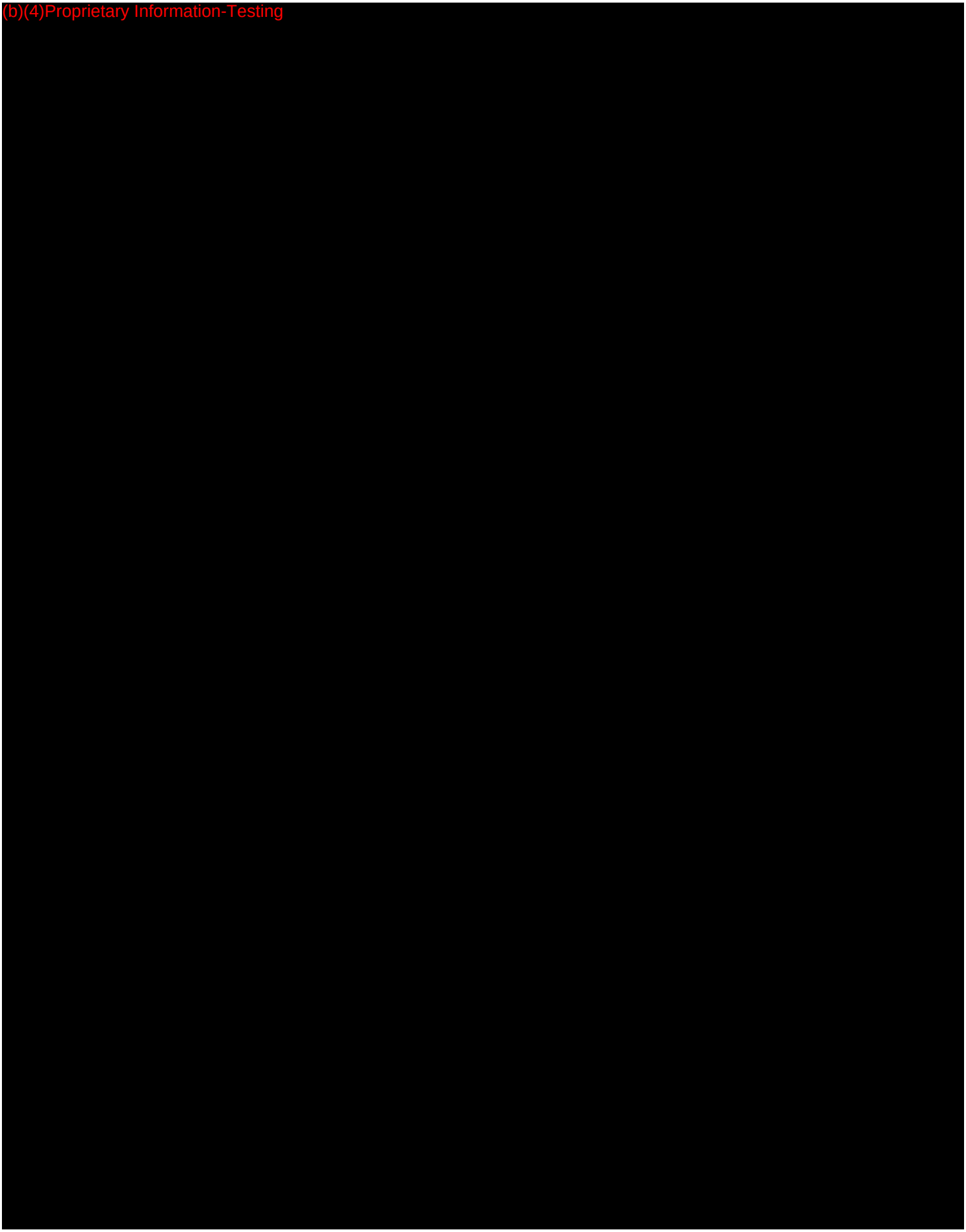
(b)(4)Proprietary Information-Testing

[redacted]

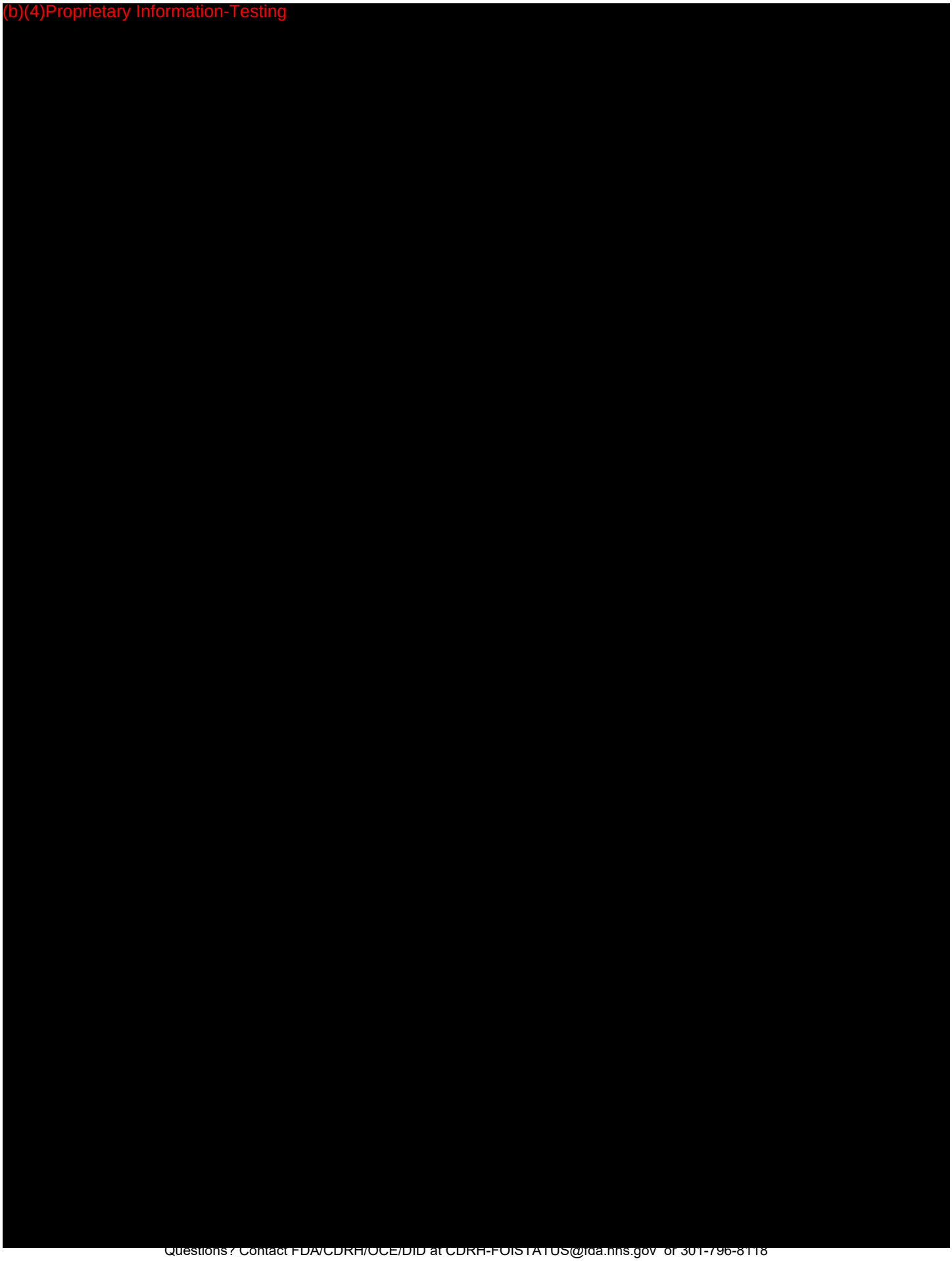
(b)(4)Proprietary Information-Testing

[redacted]

(b)(4)Proprietary Information-Testing



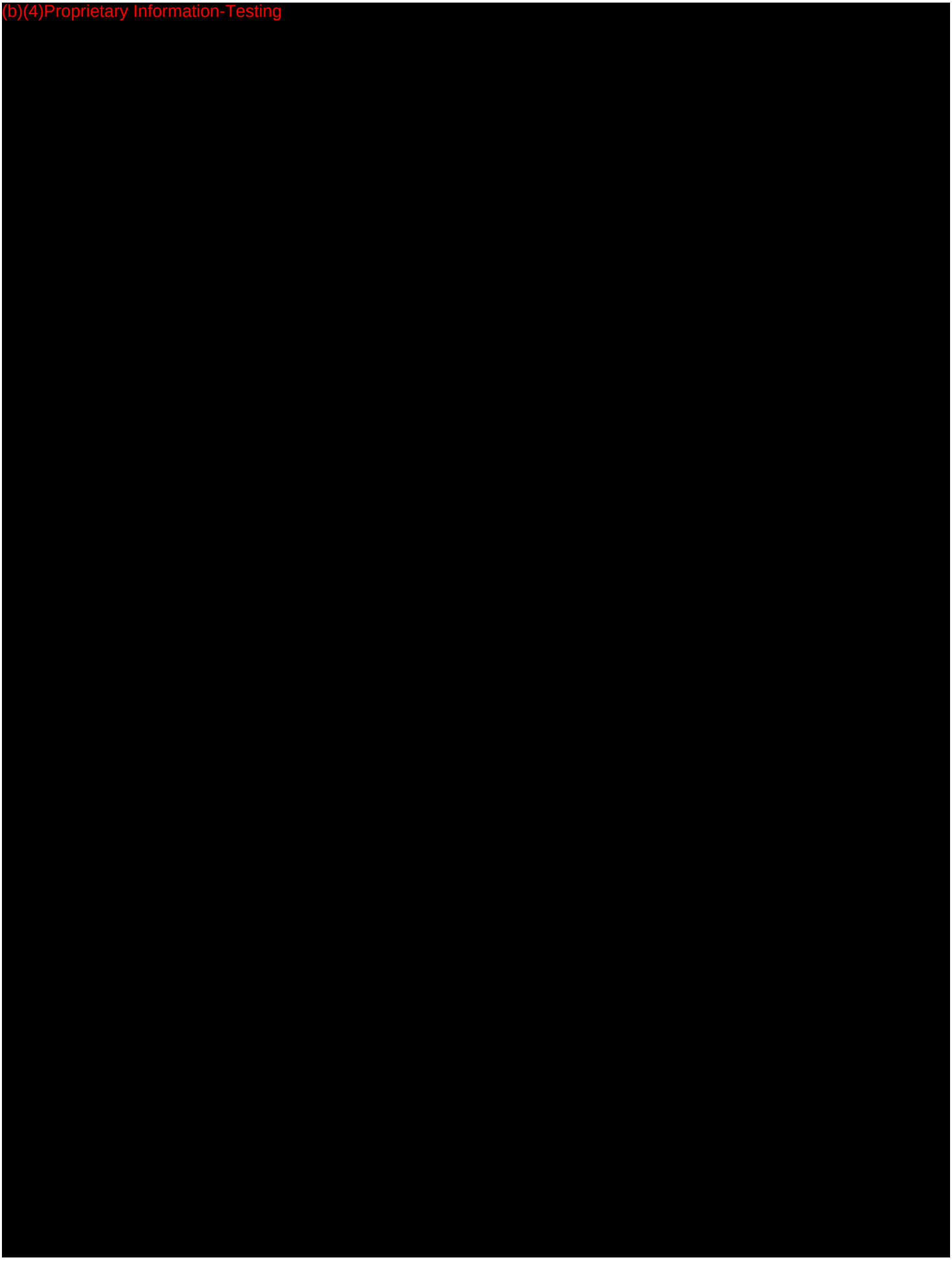
(b)(4)Proprietary Information-Testing



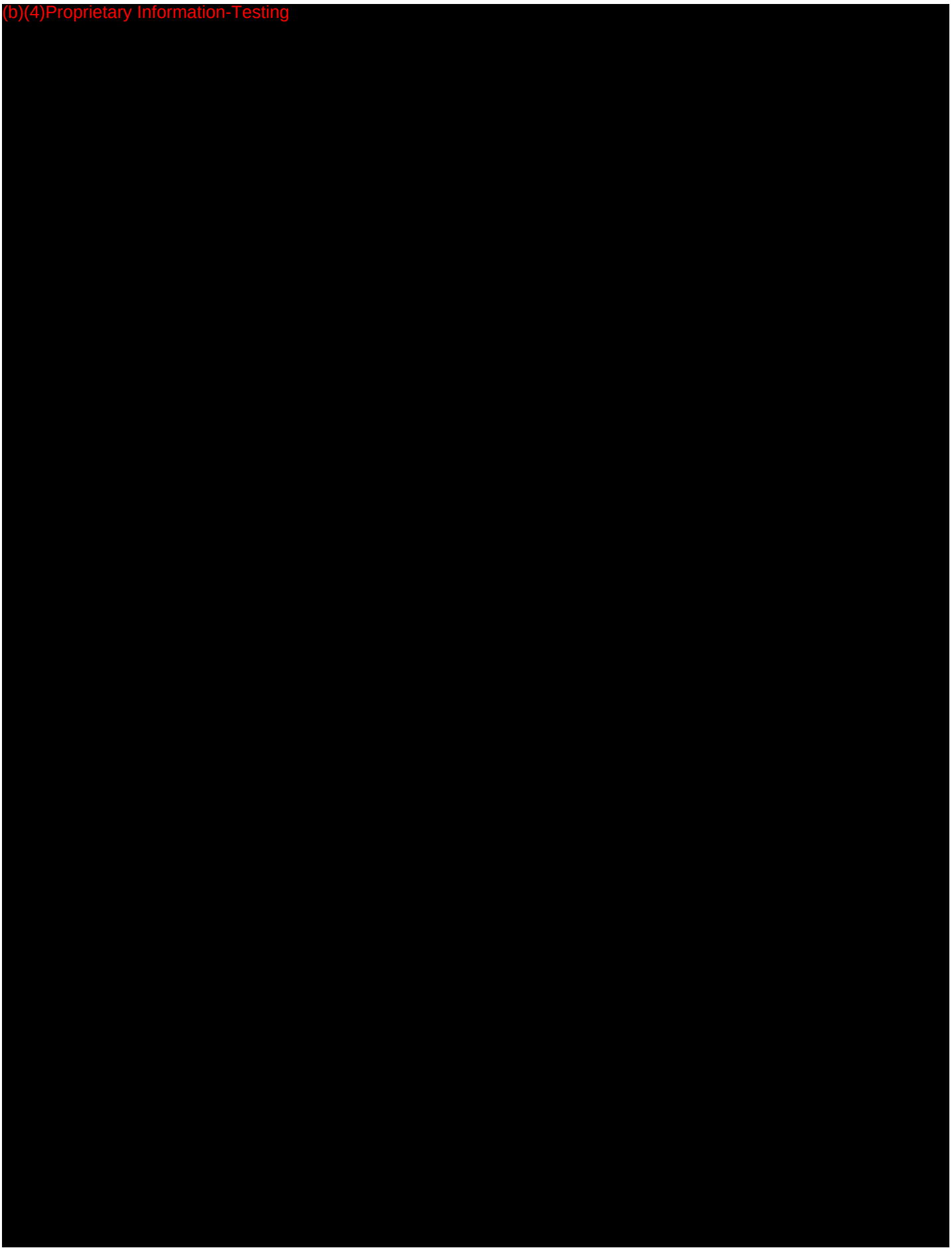
(b)(4)Proprietary Information-Testing

[redacted]

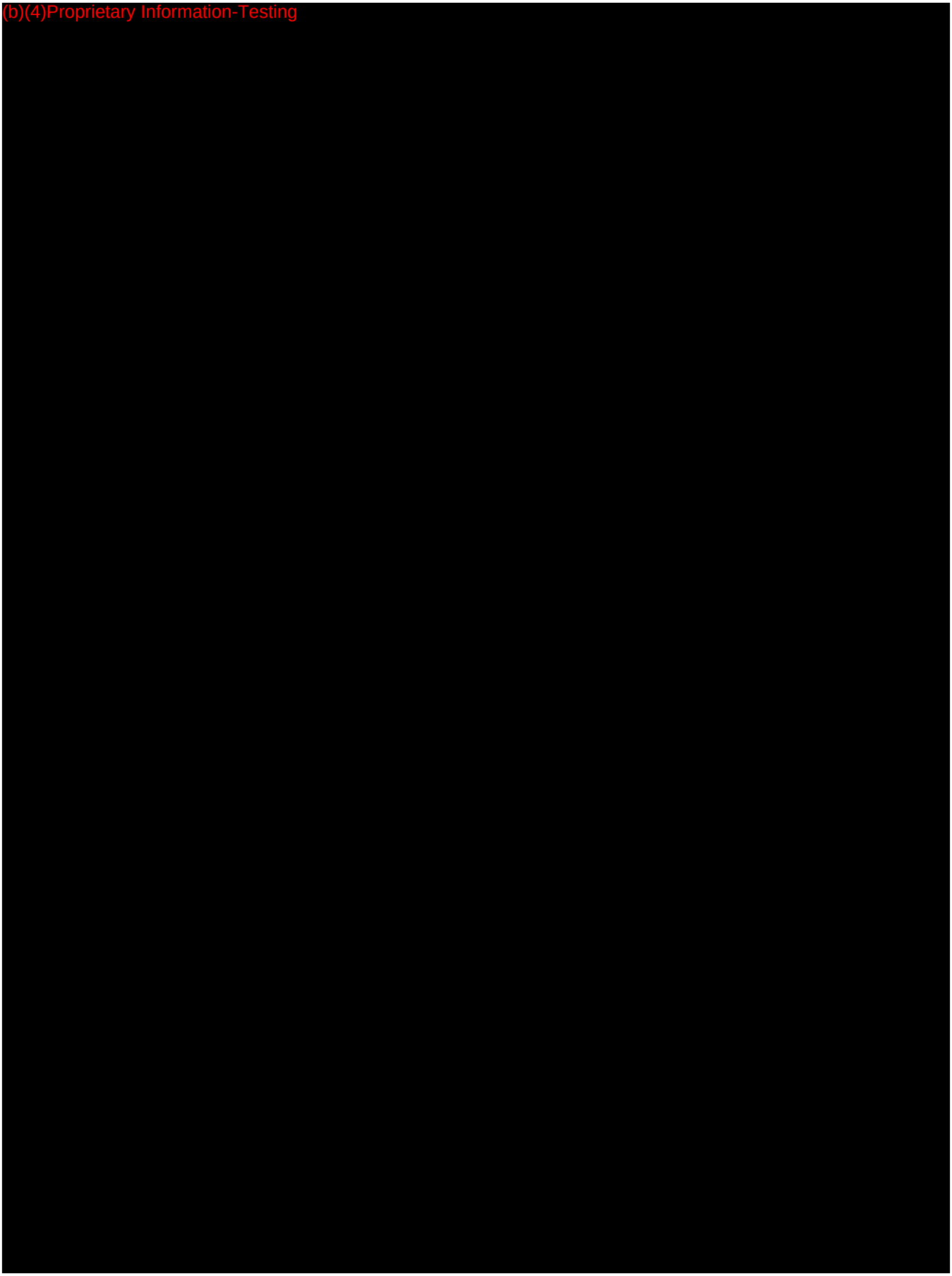
(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing



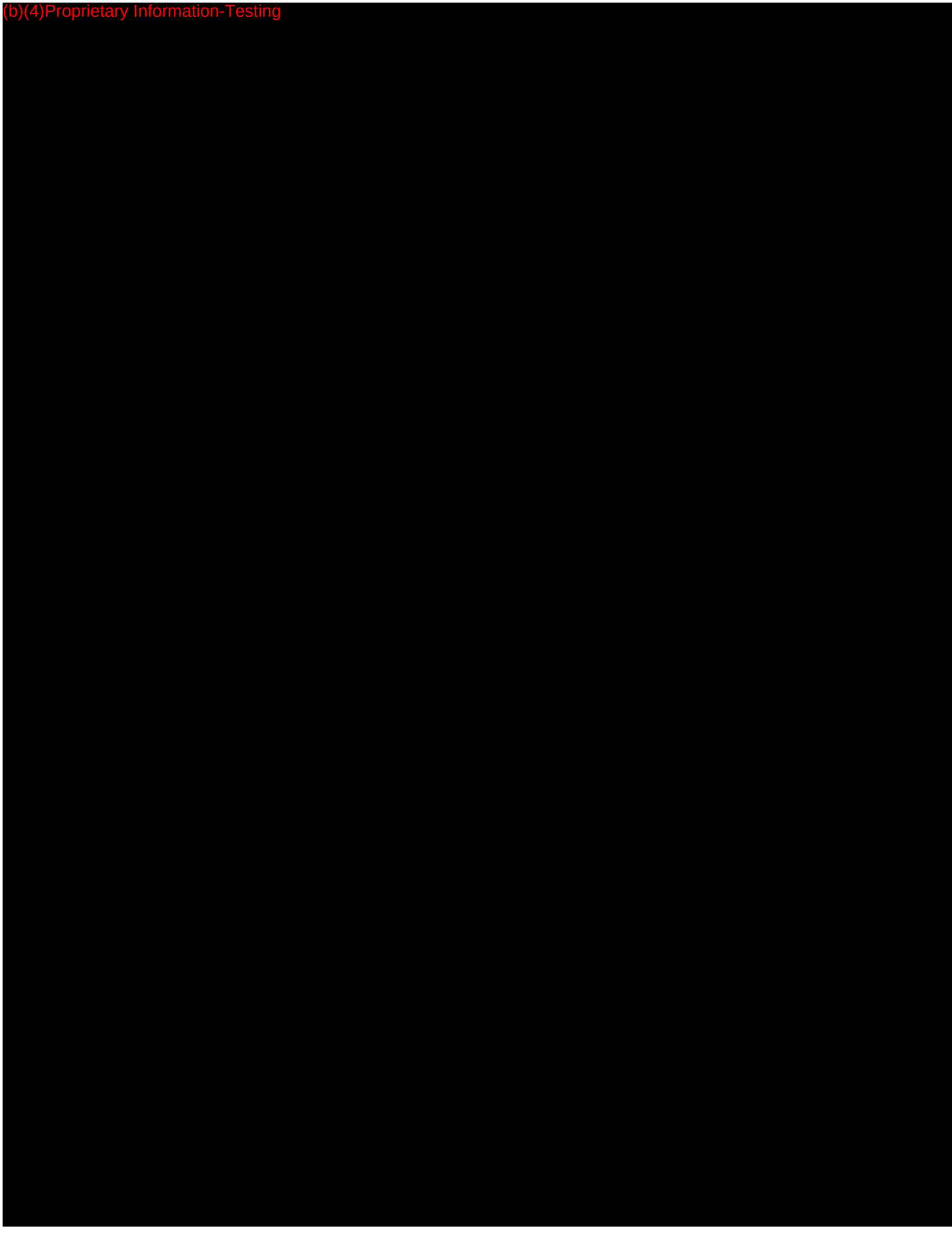
(b)(4)Proprietary Information-Testing



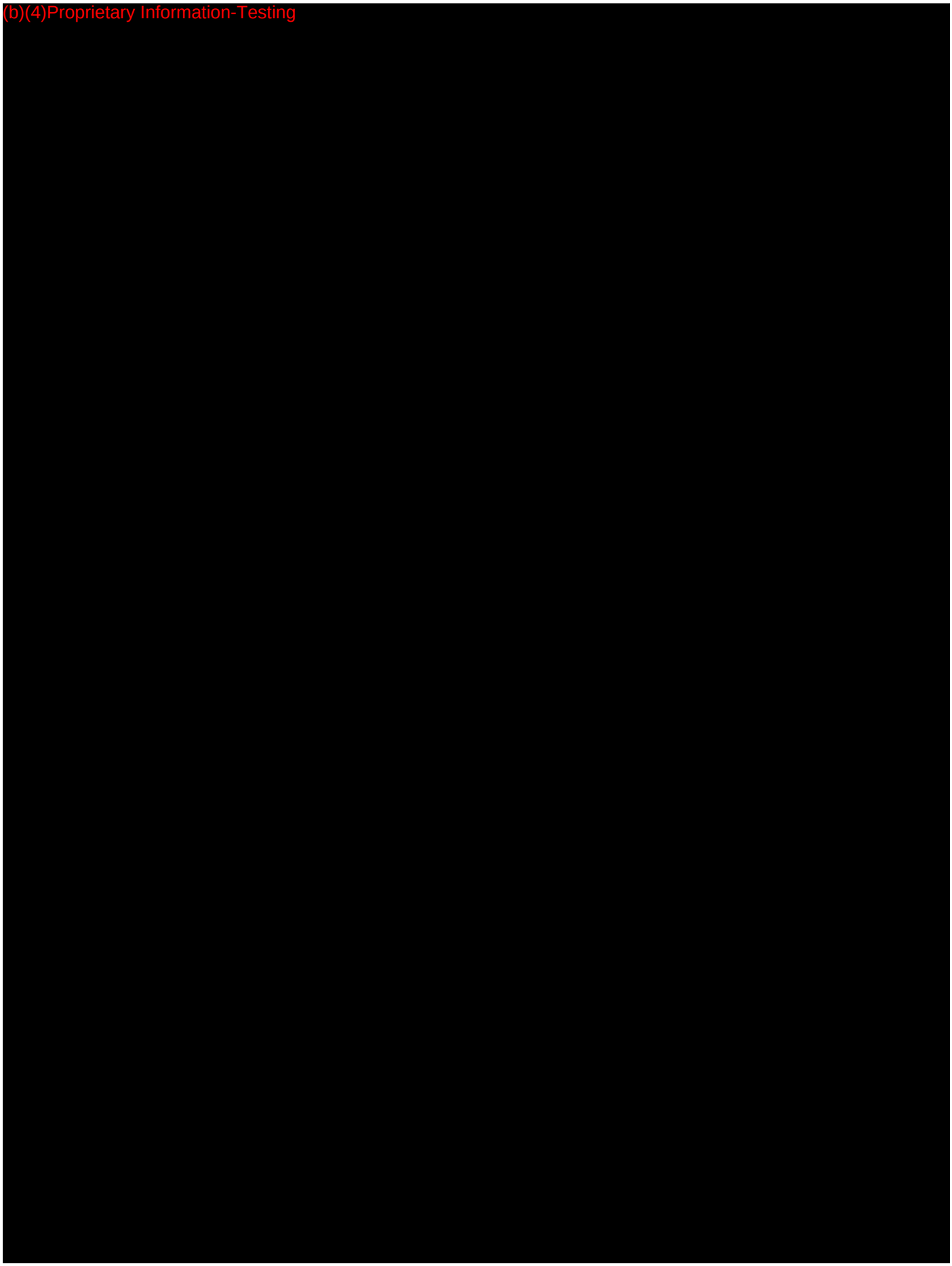
(b)(4)Proprietary Information-Testing

[redacted]

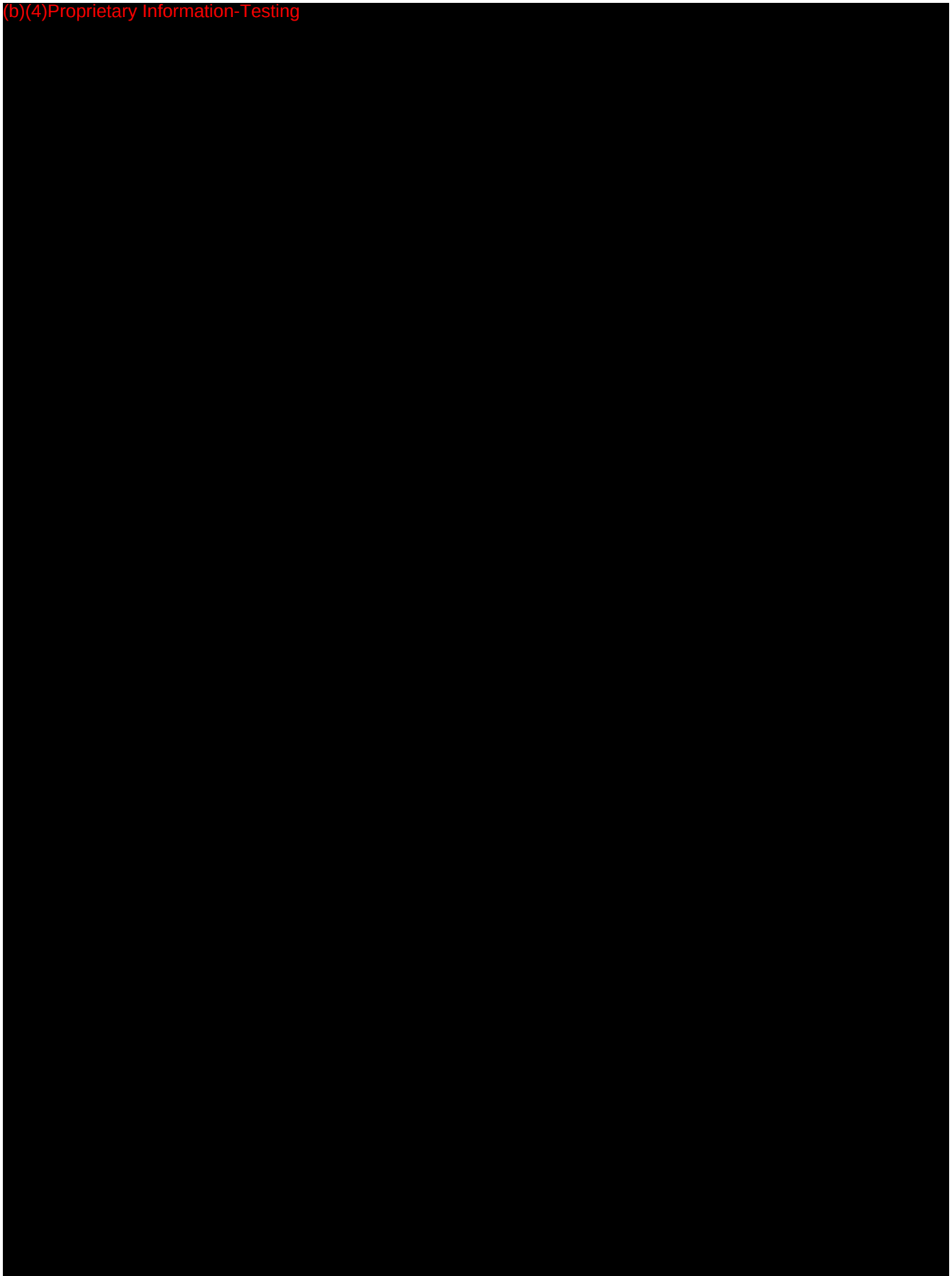
(b)(4)Proprietary Information-Testing



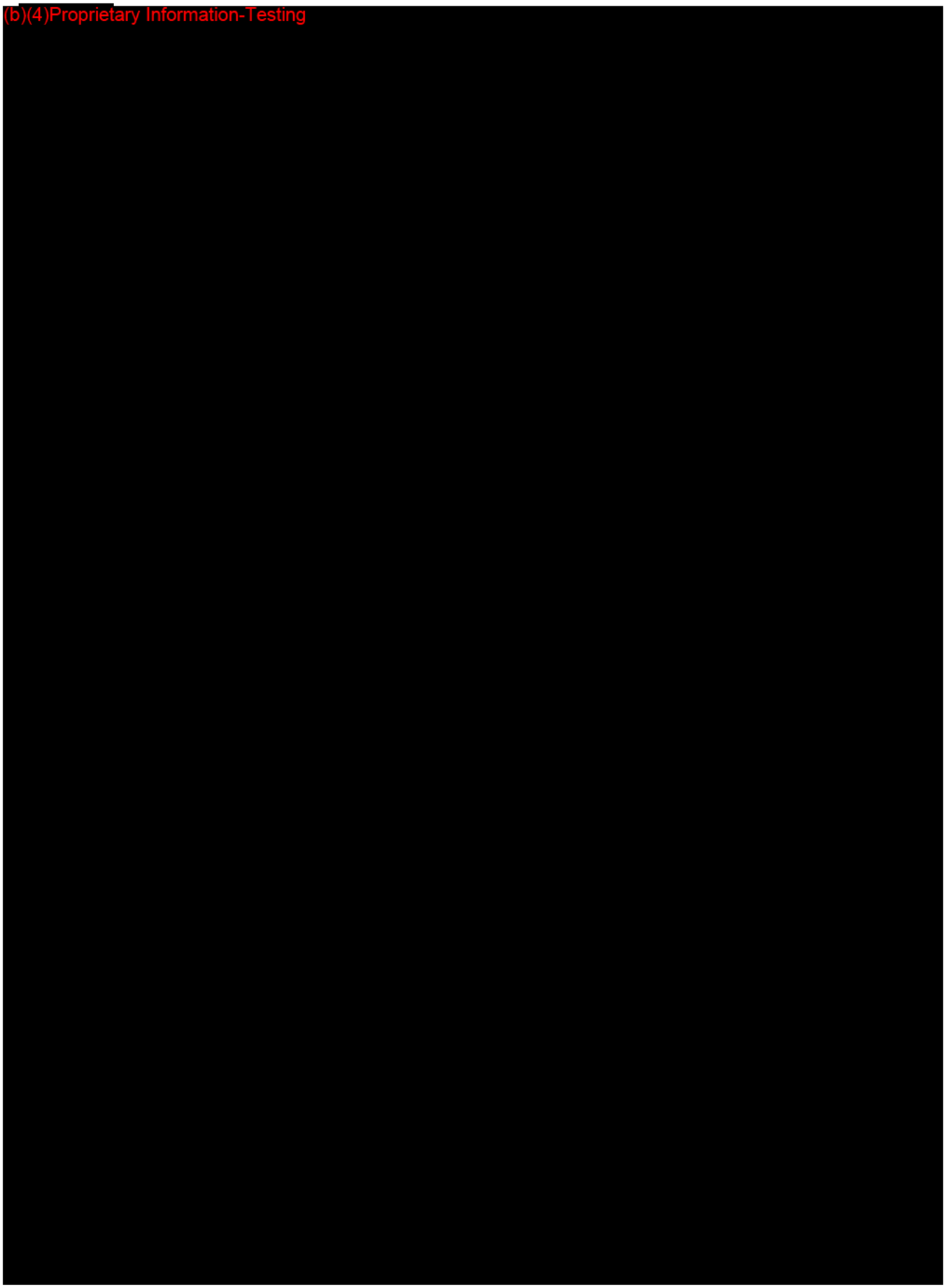
(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing

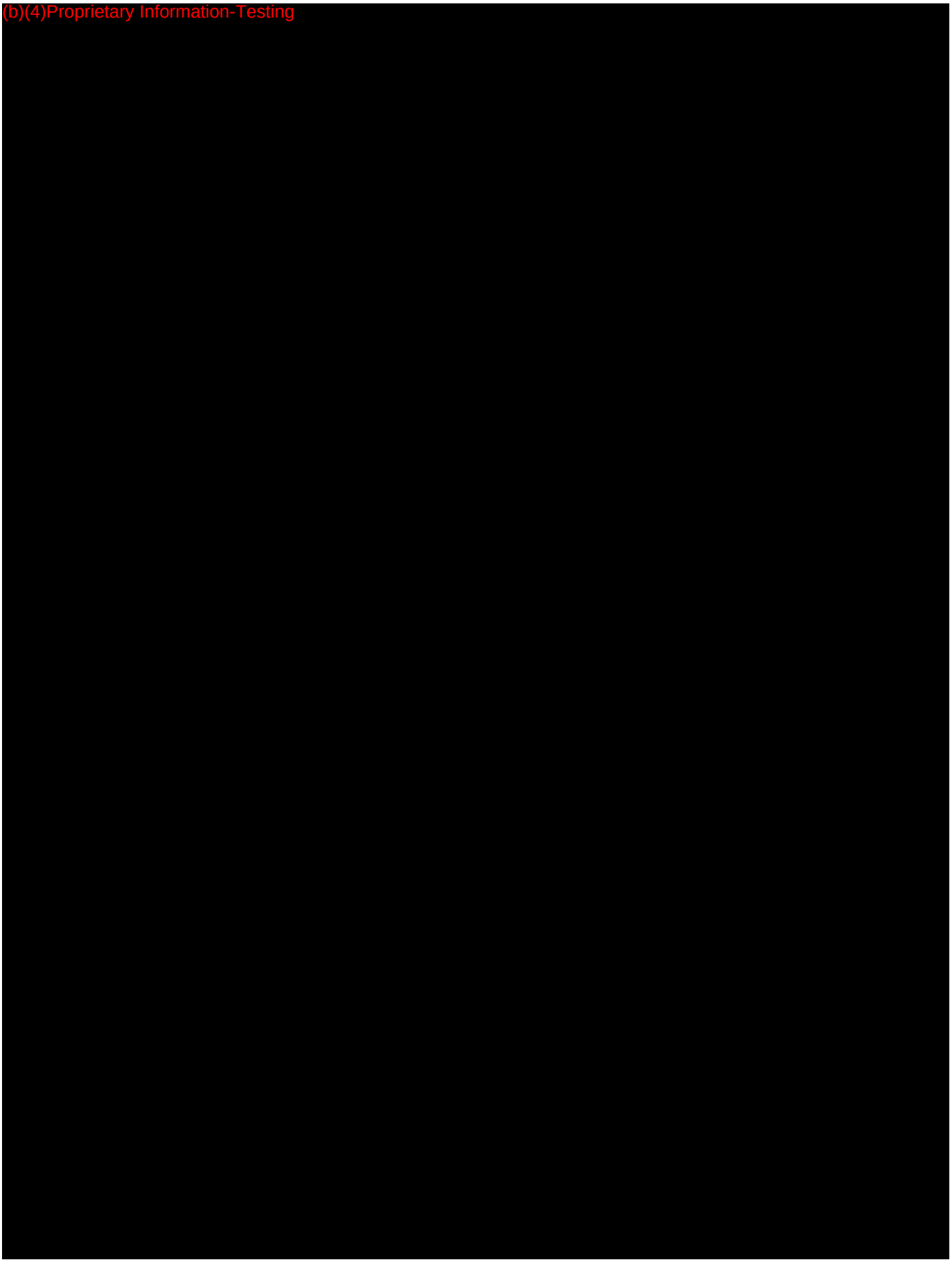


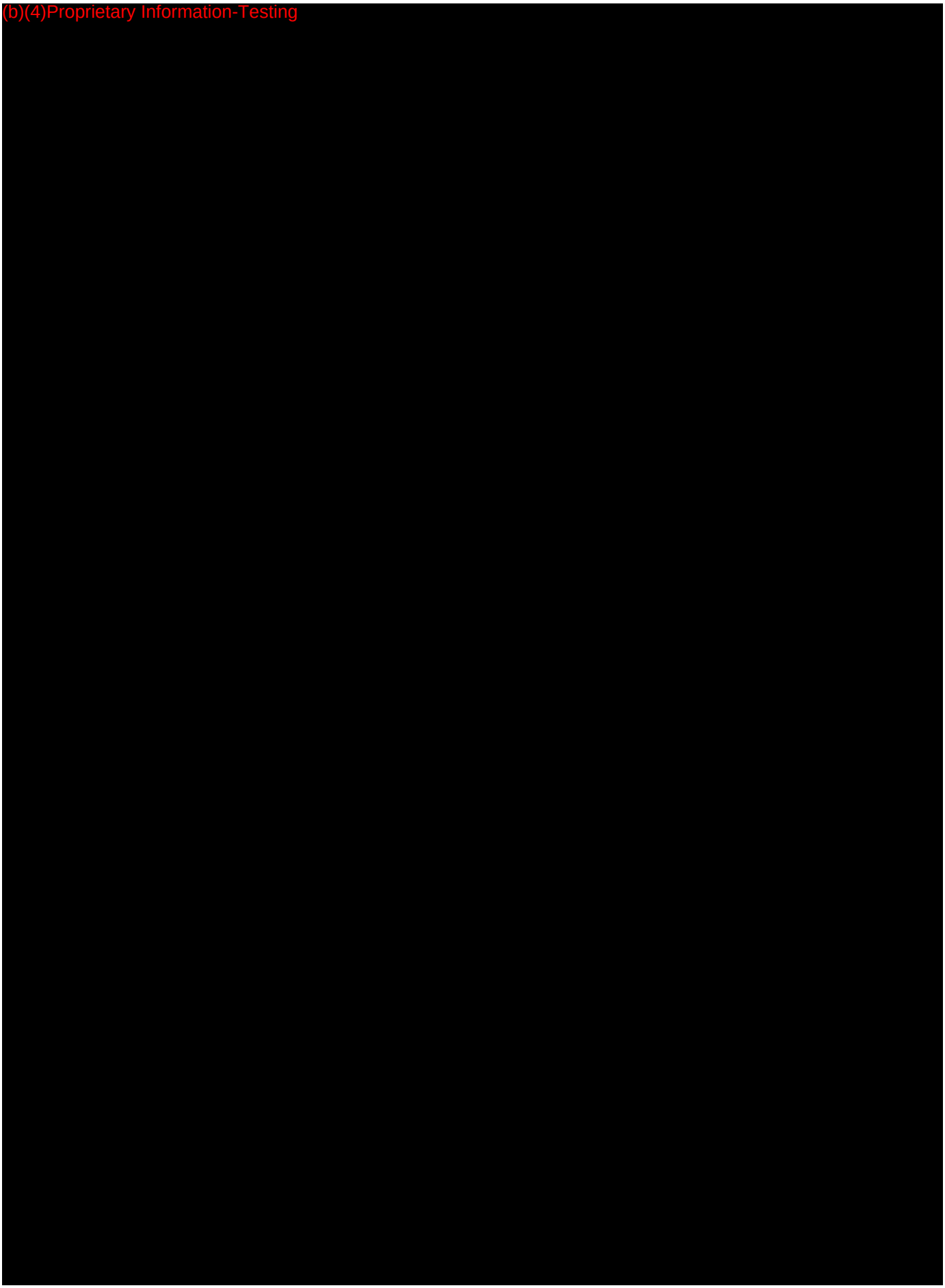
(b)(4)Proprietary Information-Testing



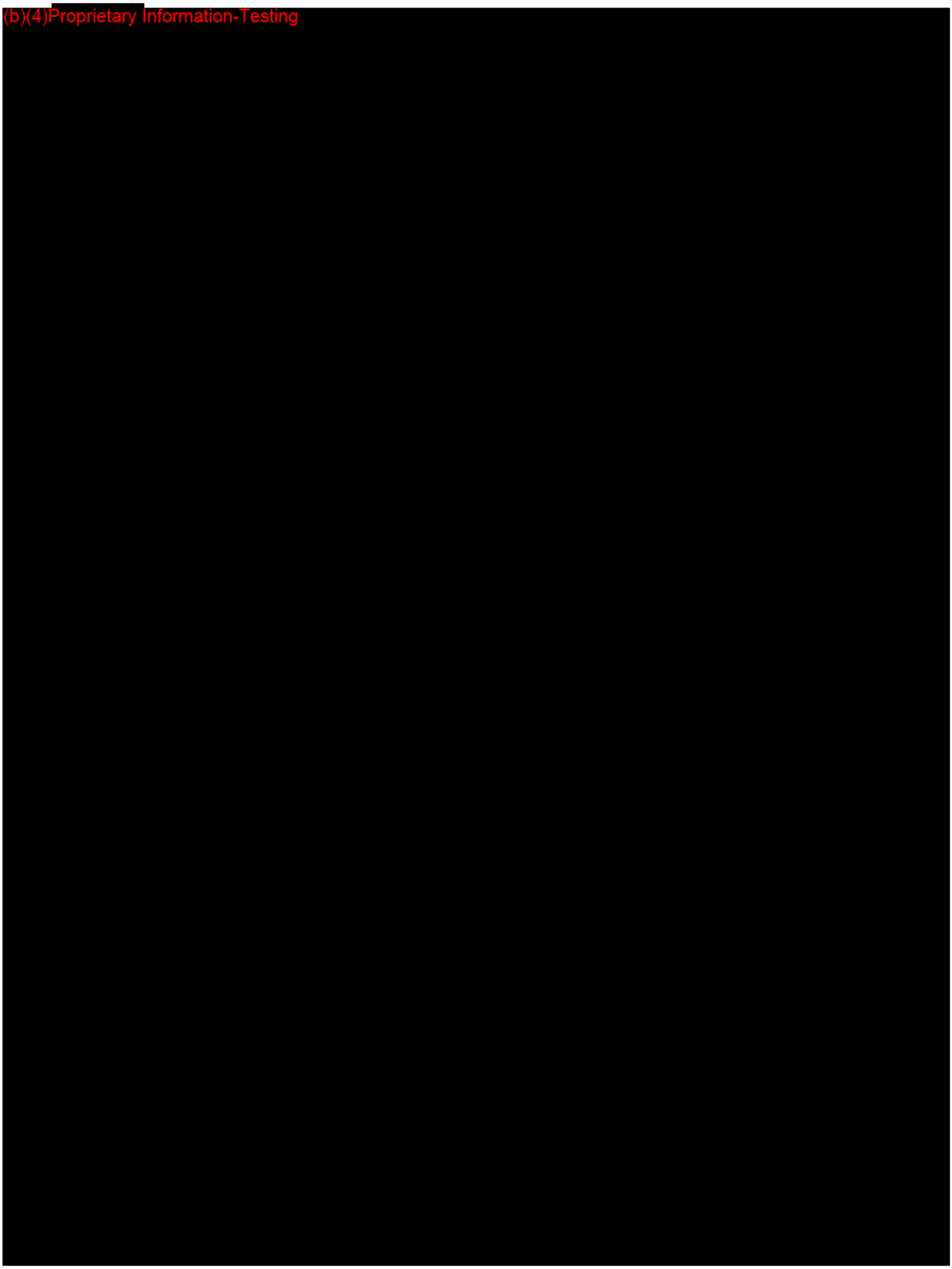
(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

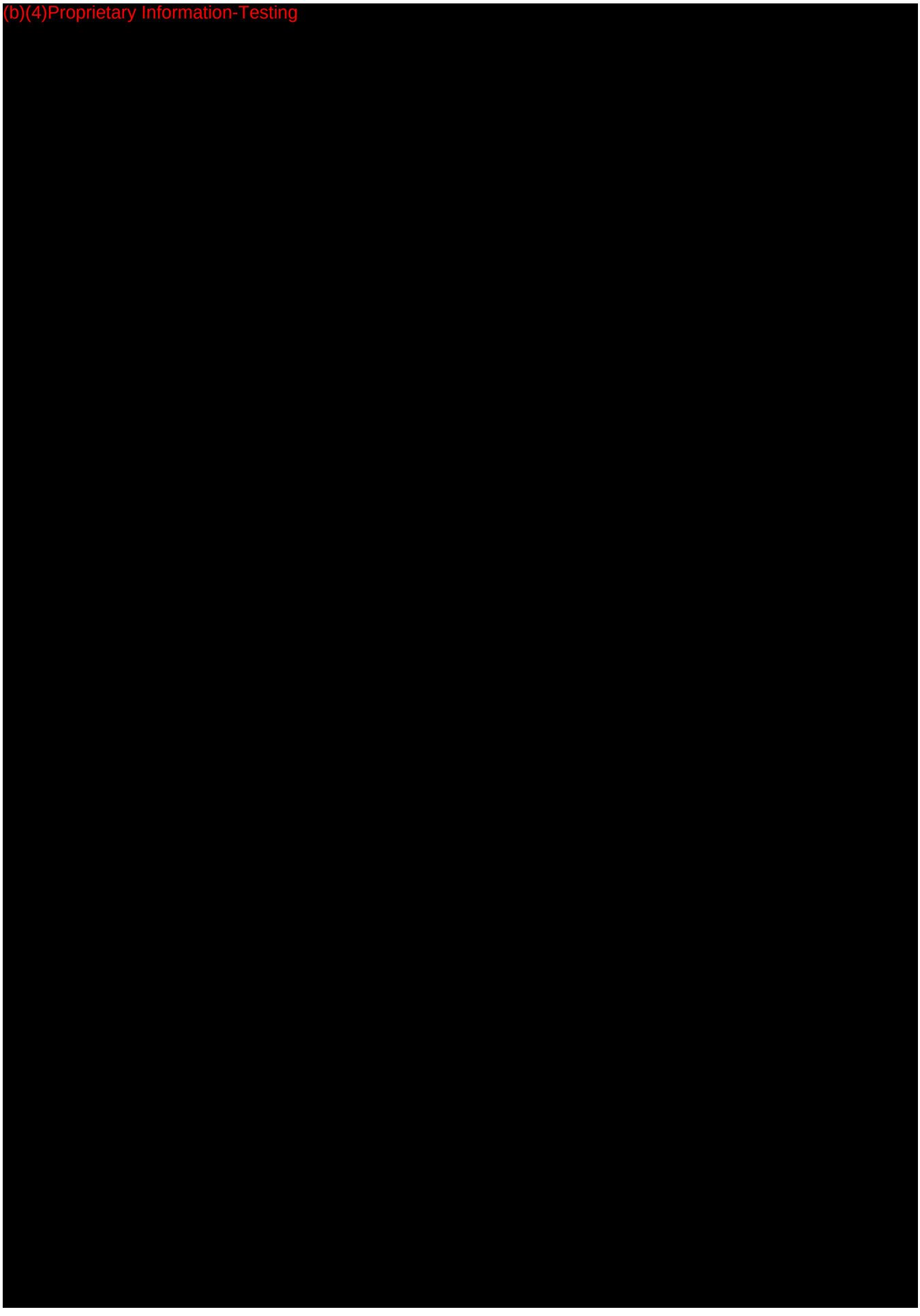




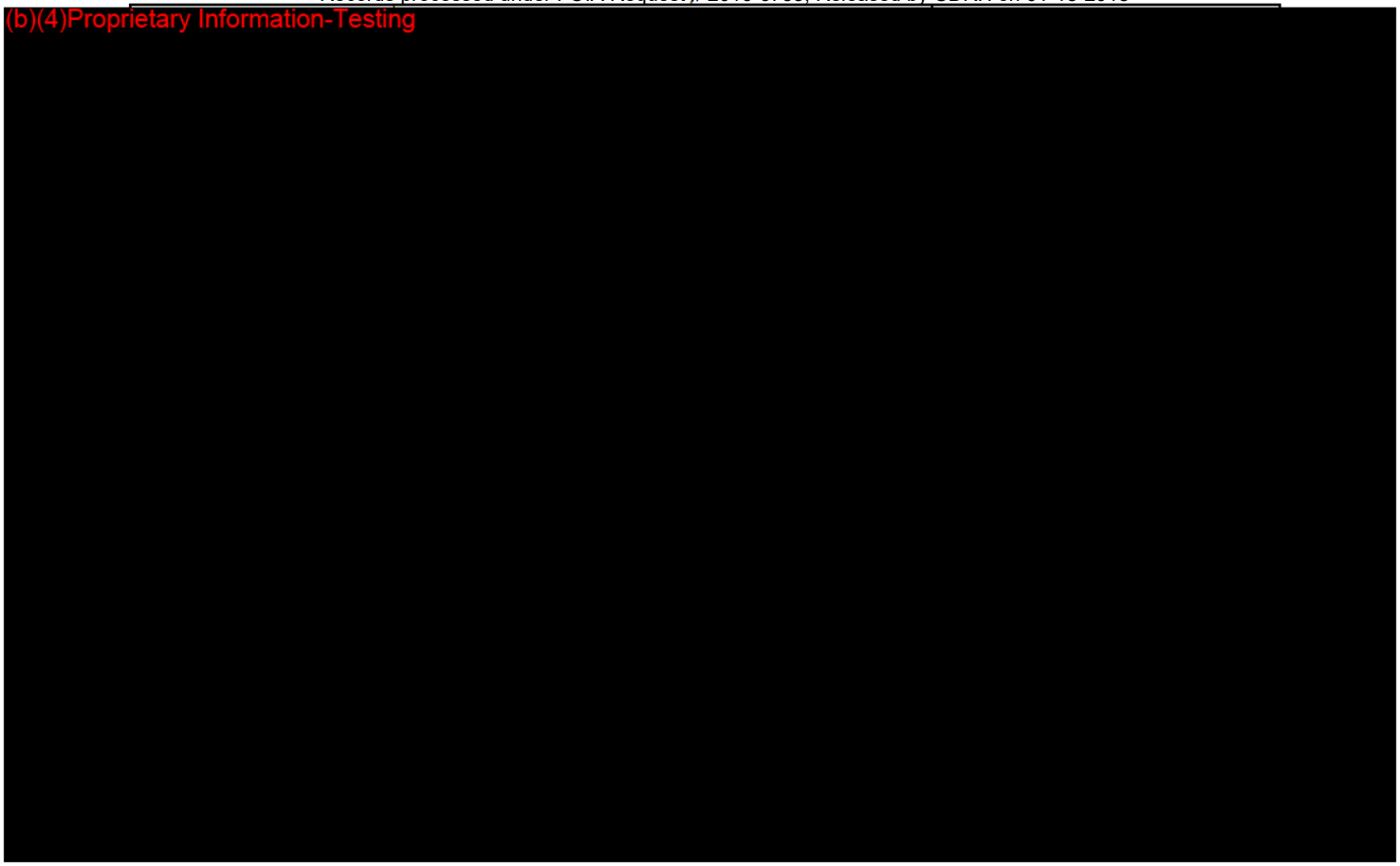
(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing

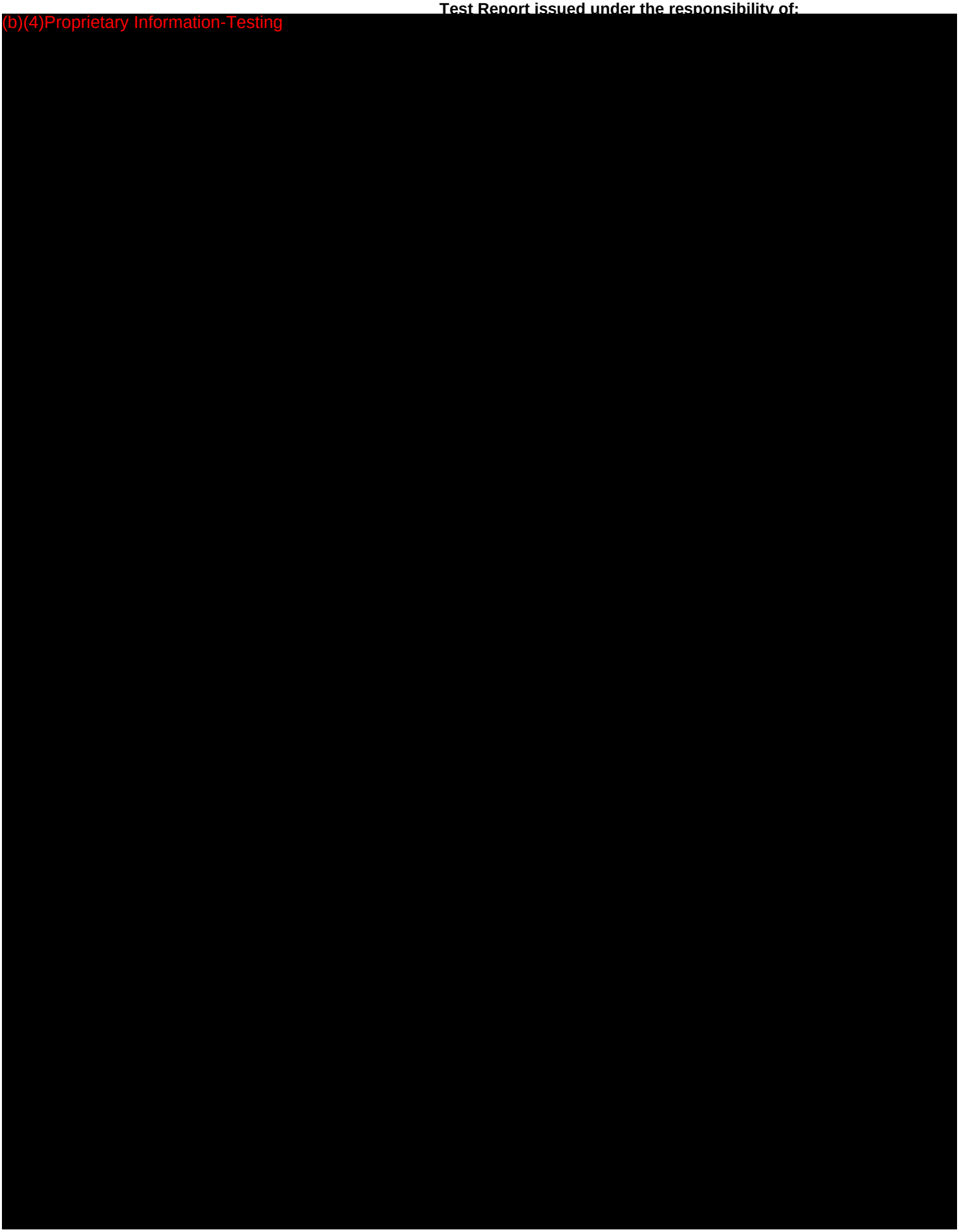


(b)(4)Proprietary Information-Testing

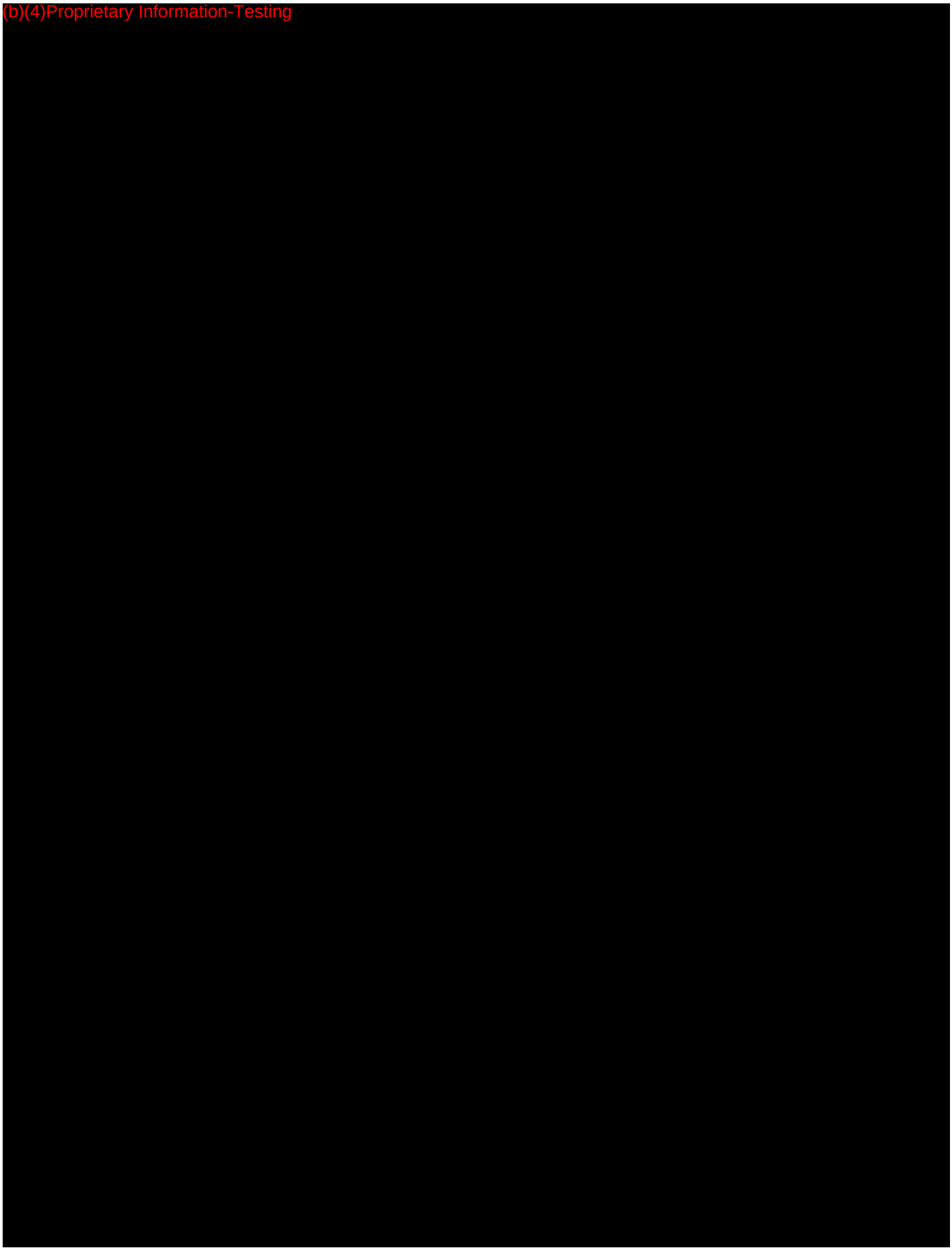


Test Report issued under the responsibility of:

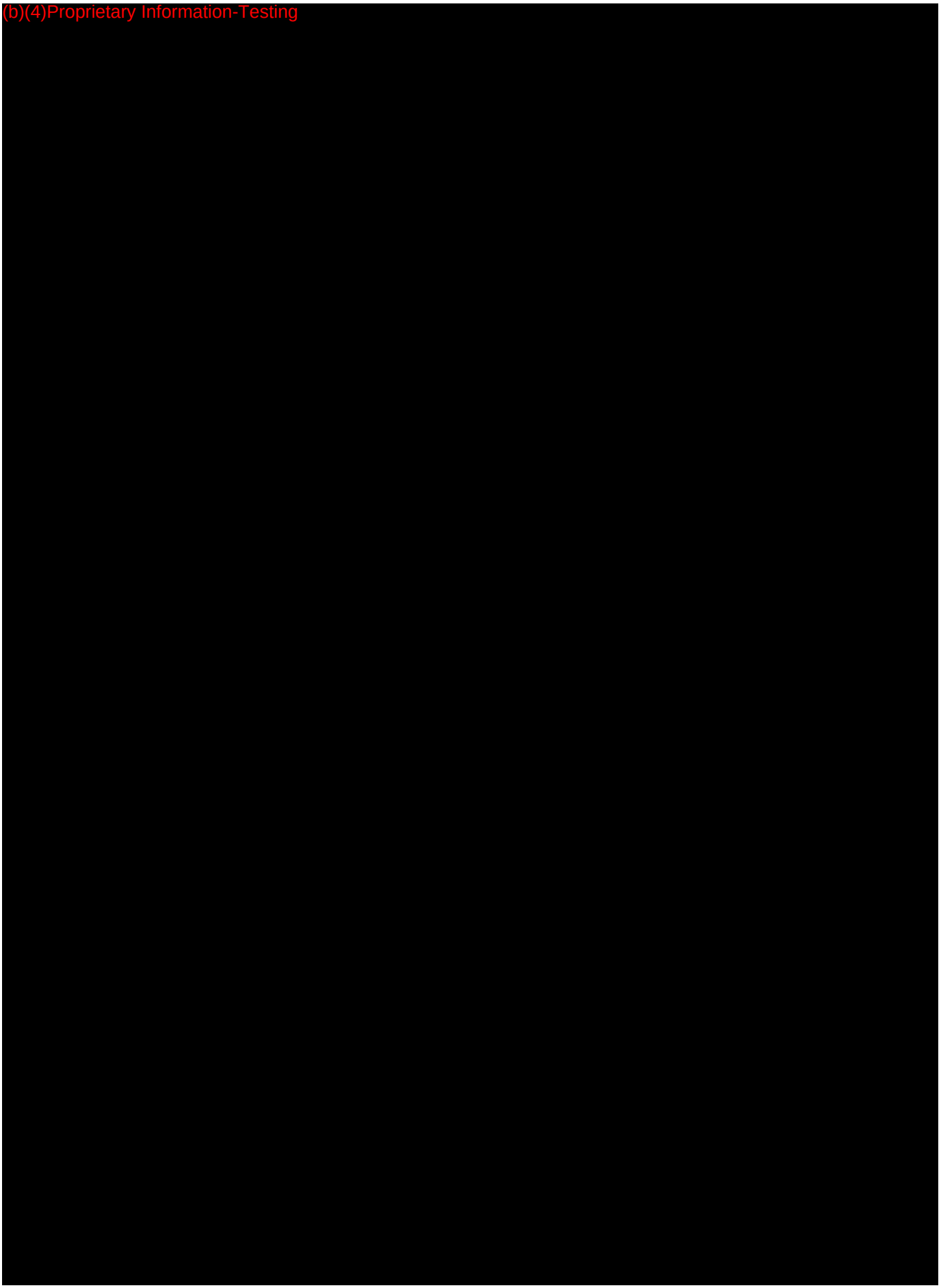
(b)(4)Proprietary Information-Testing



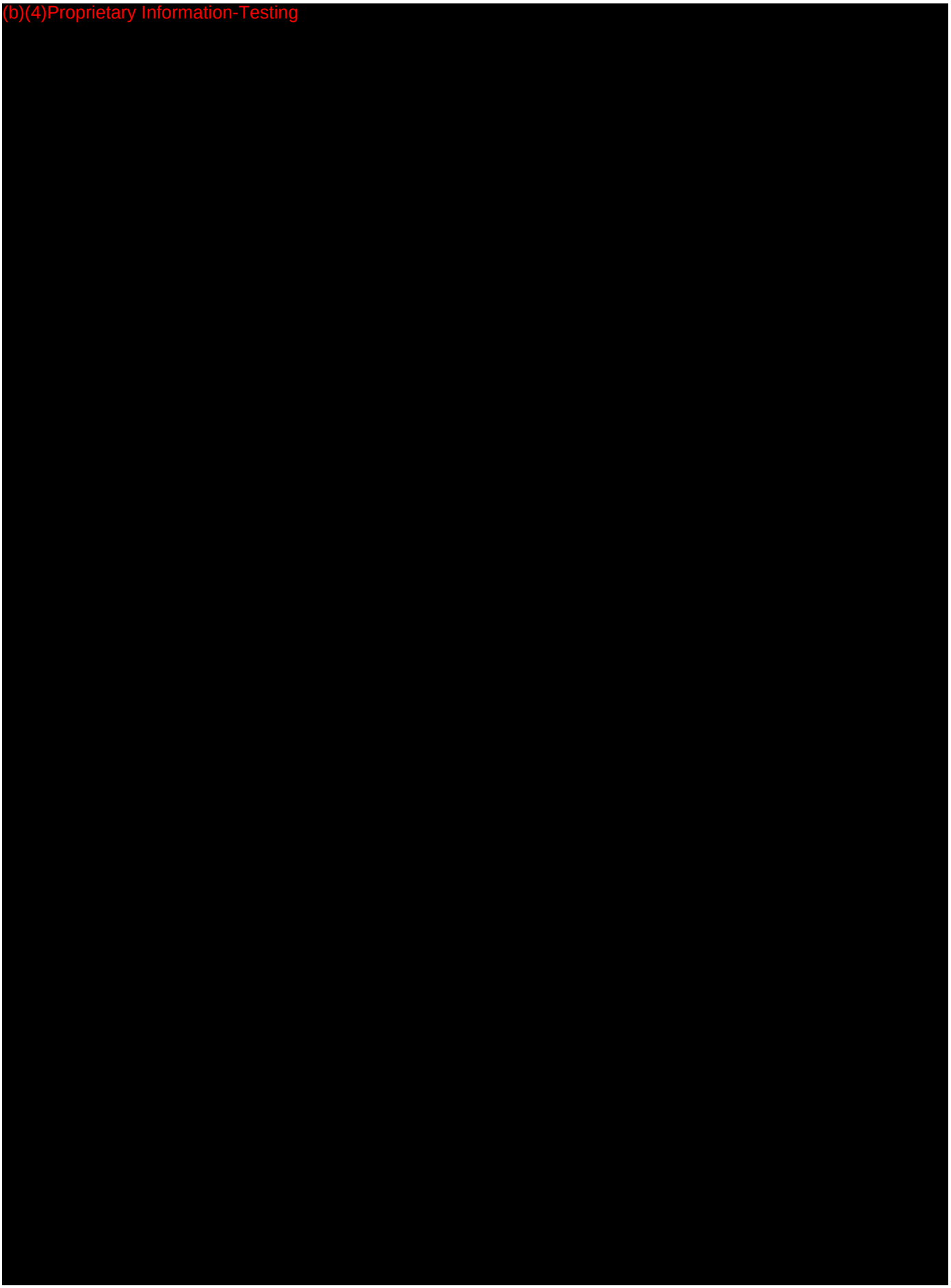
(b)(4)Proprietary Information-Testing

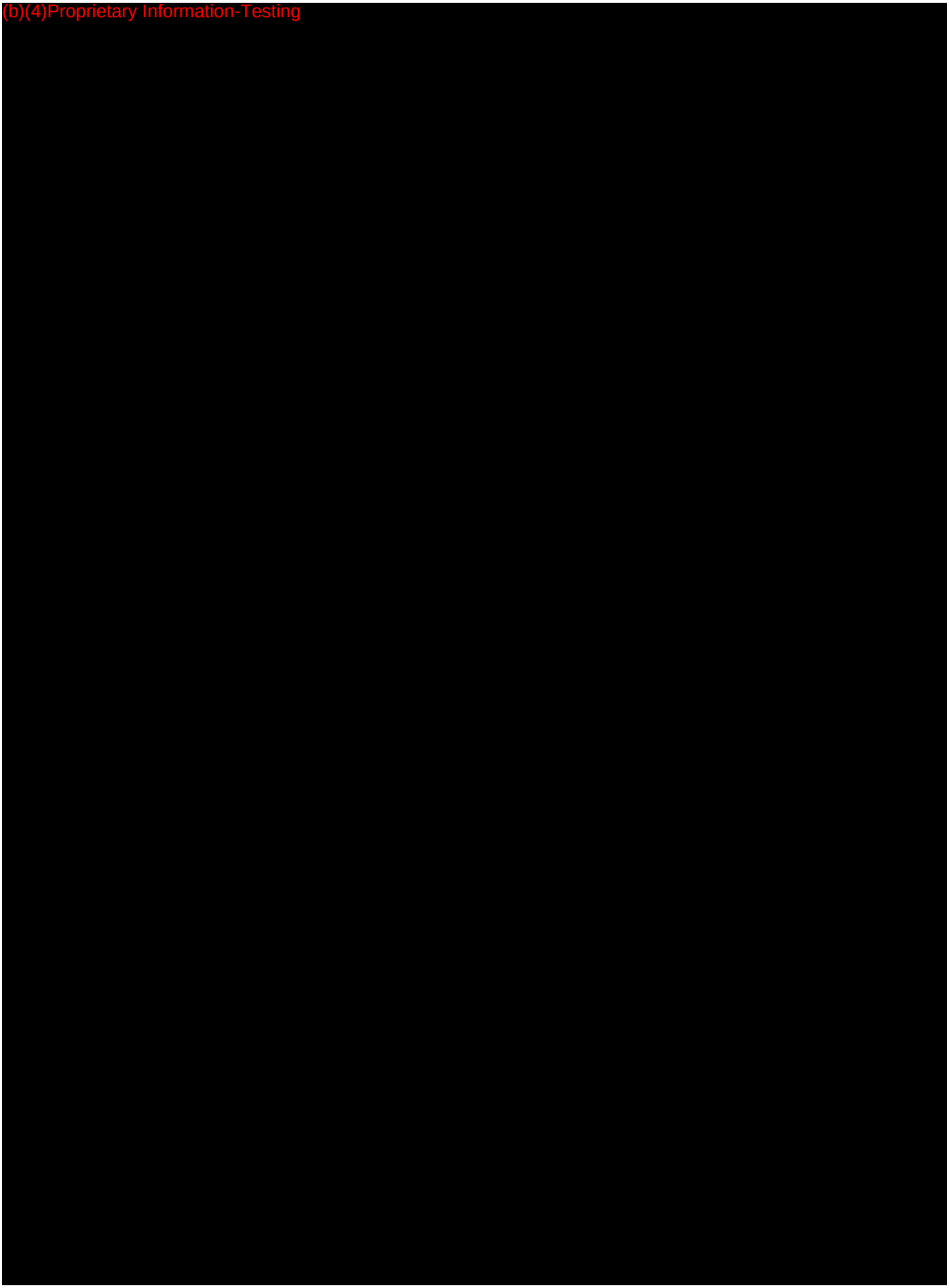


(b)(4)Proprietary Information-Testing

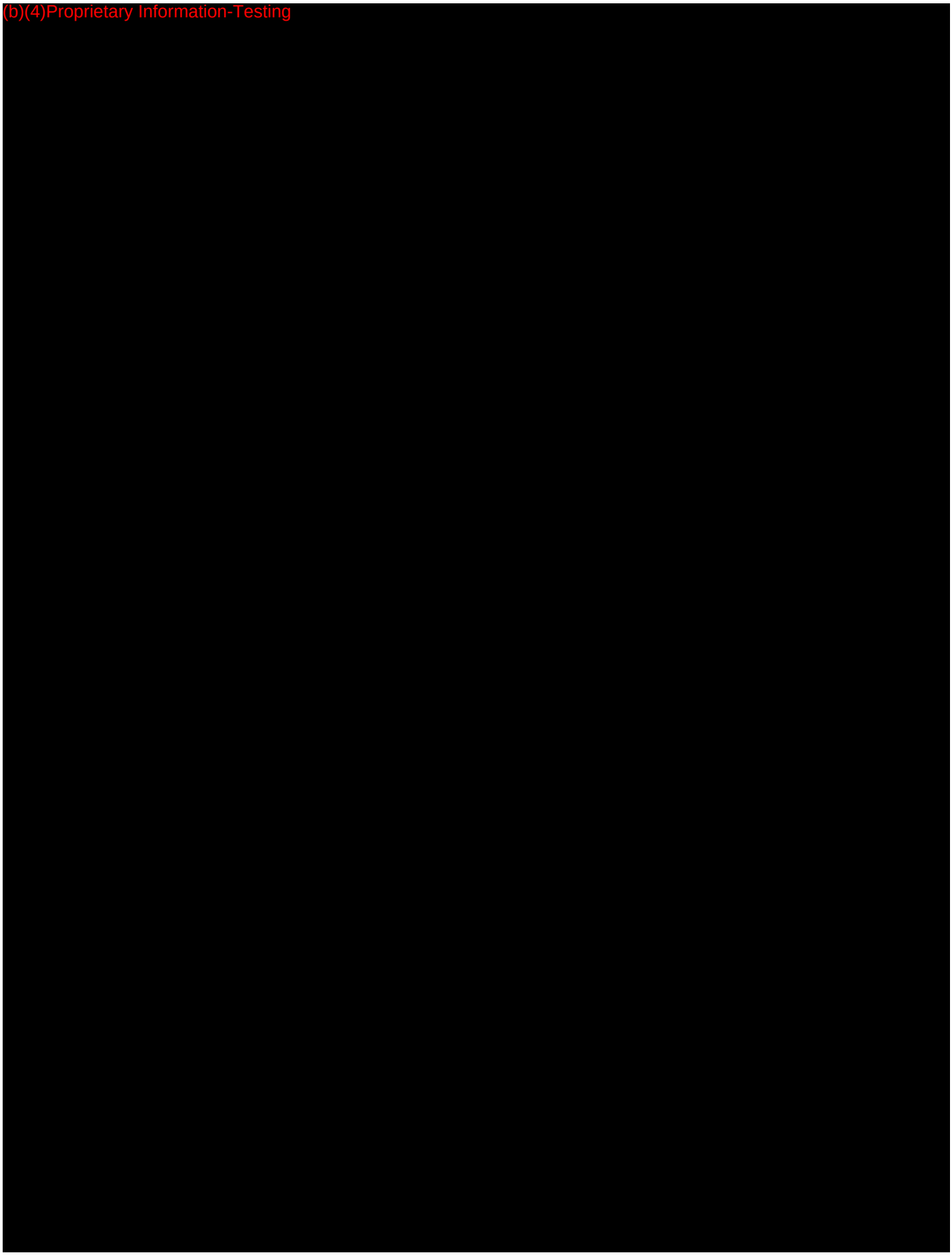


(b)(4)Proprietary Information-Testing

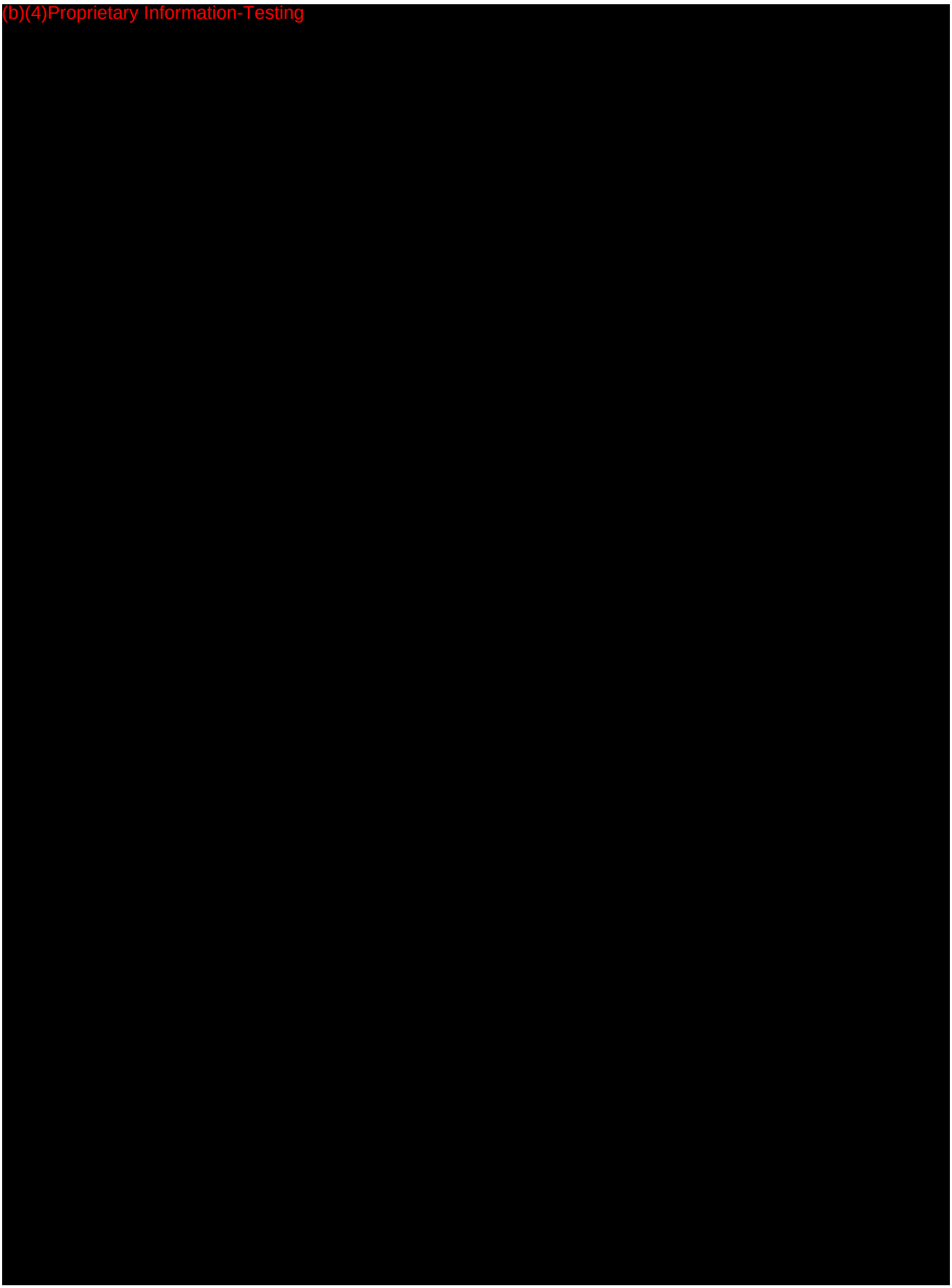




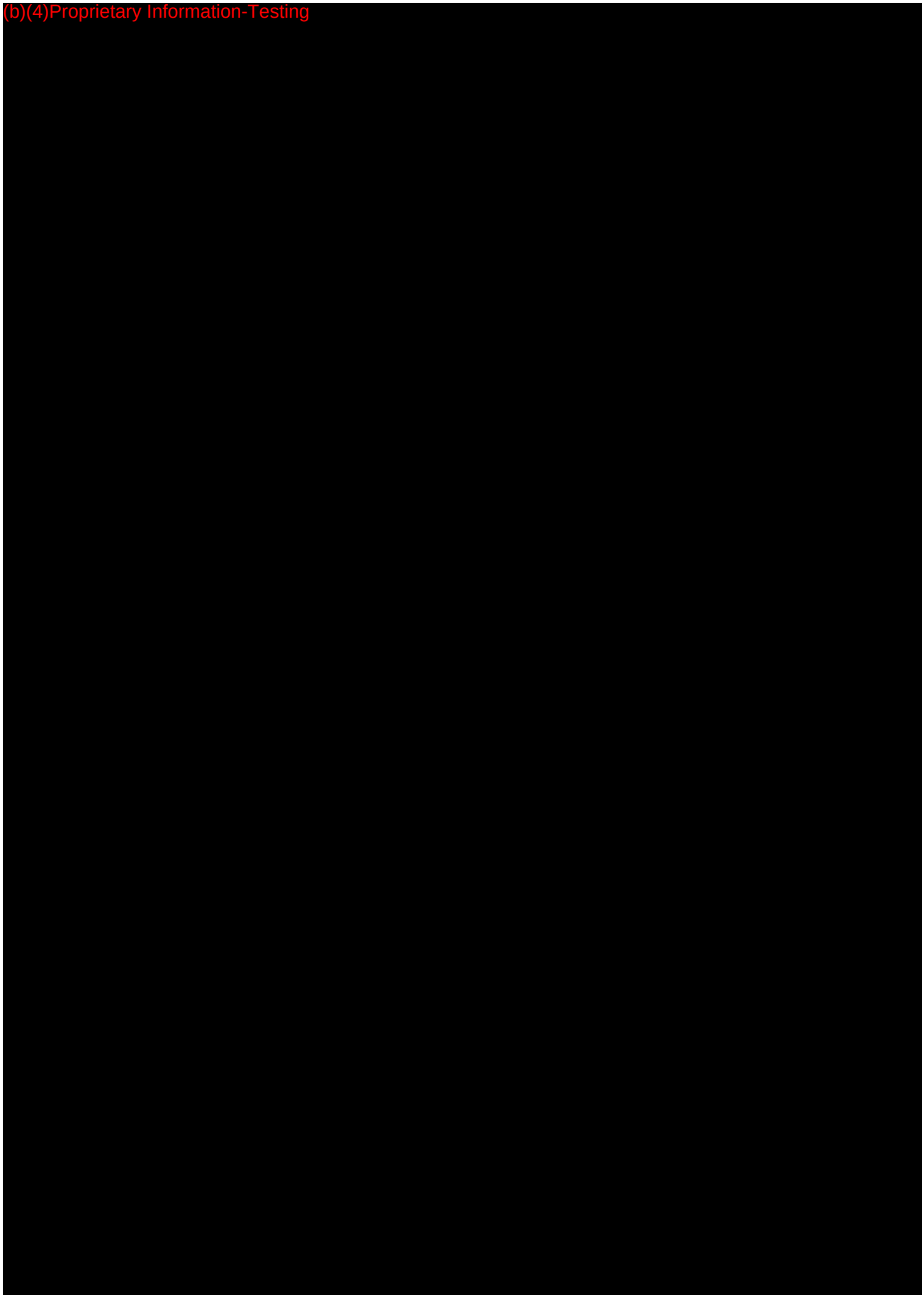
(b)(4)Proprietary Information-Testing



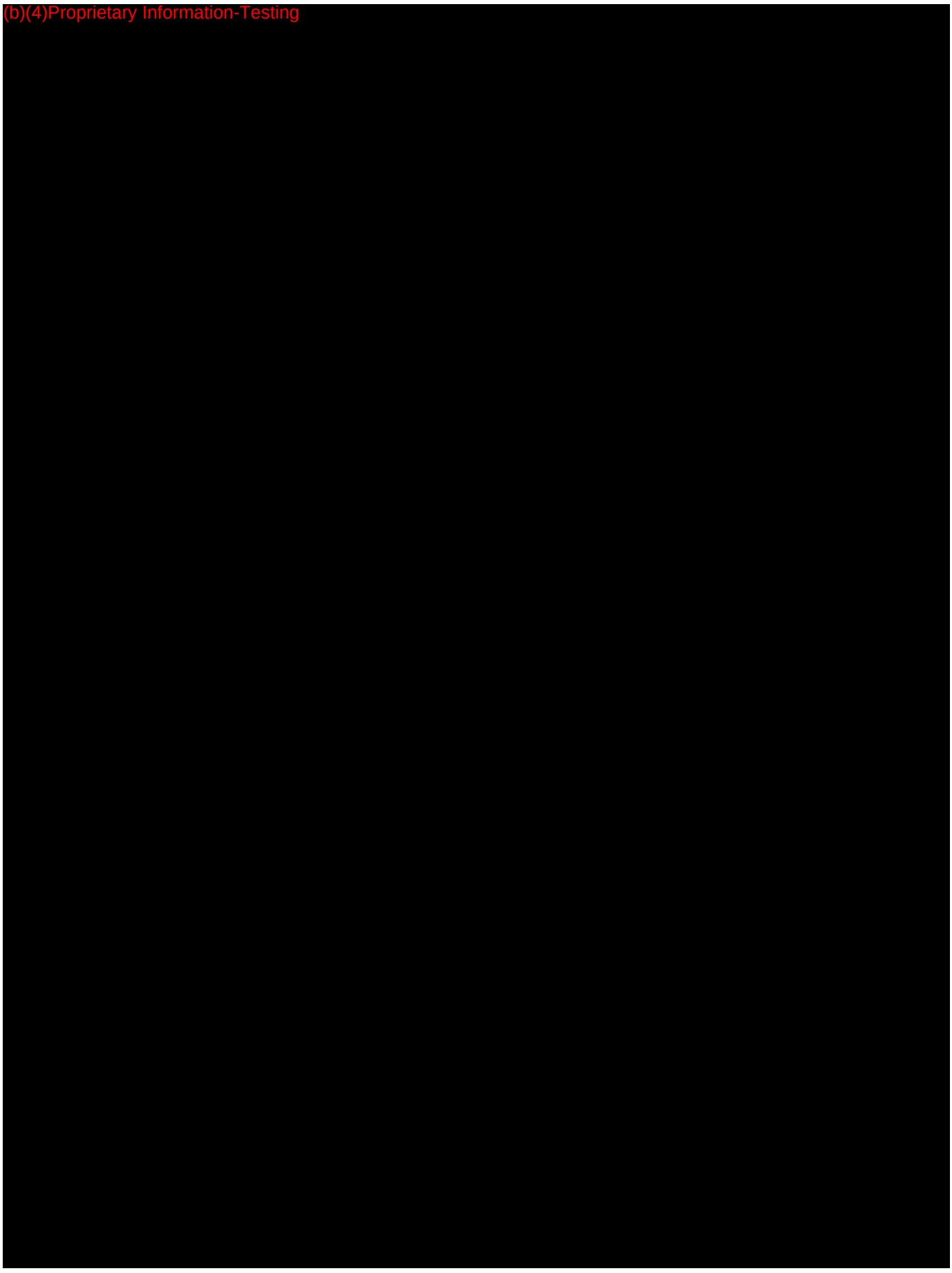
(b)(4)Proprietary Information-Testing



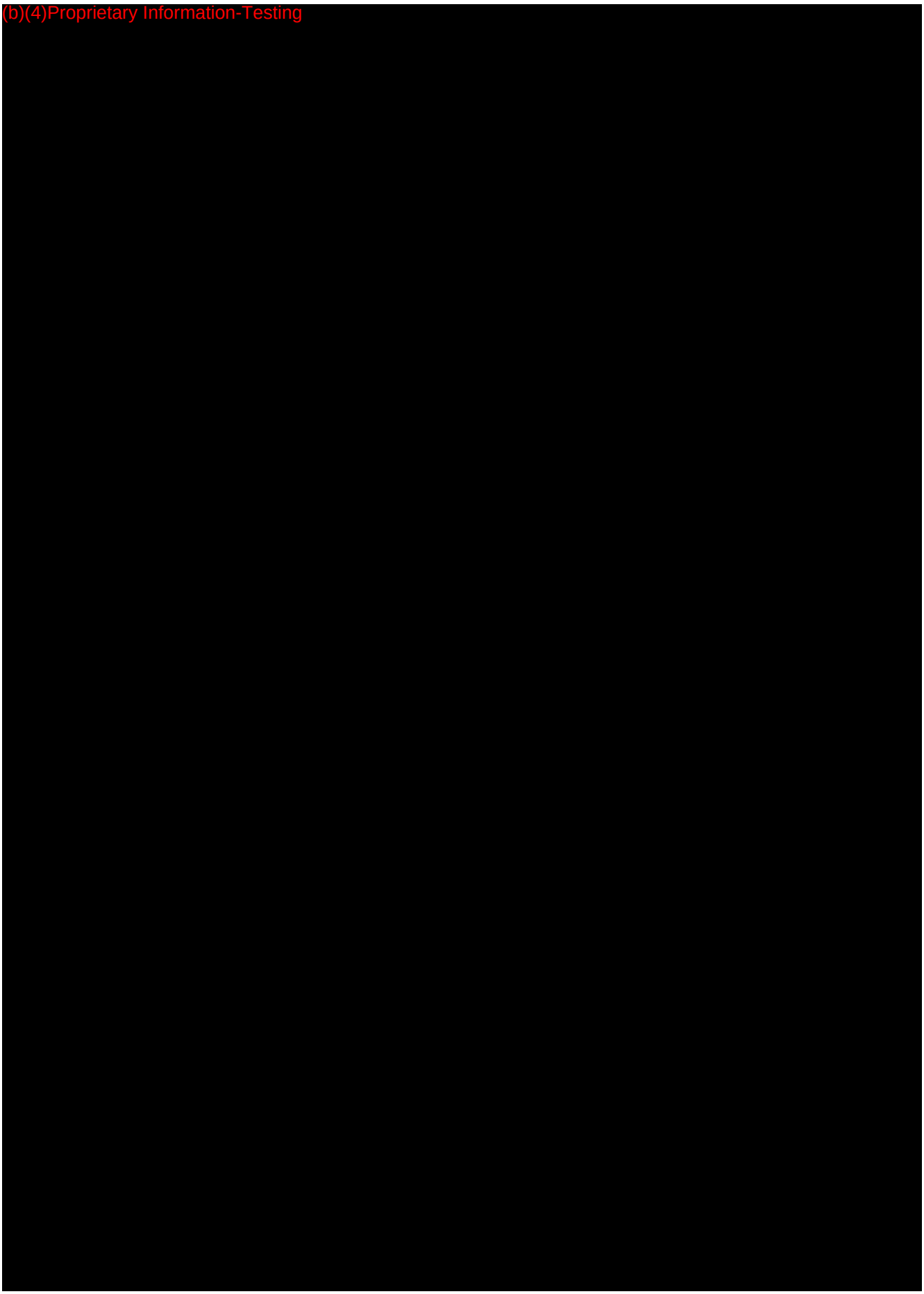
(b)(4)Proprietary Information-Testing



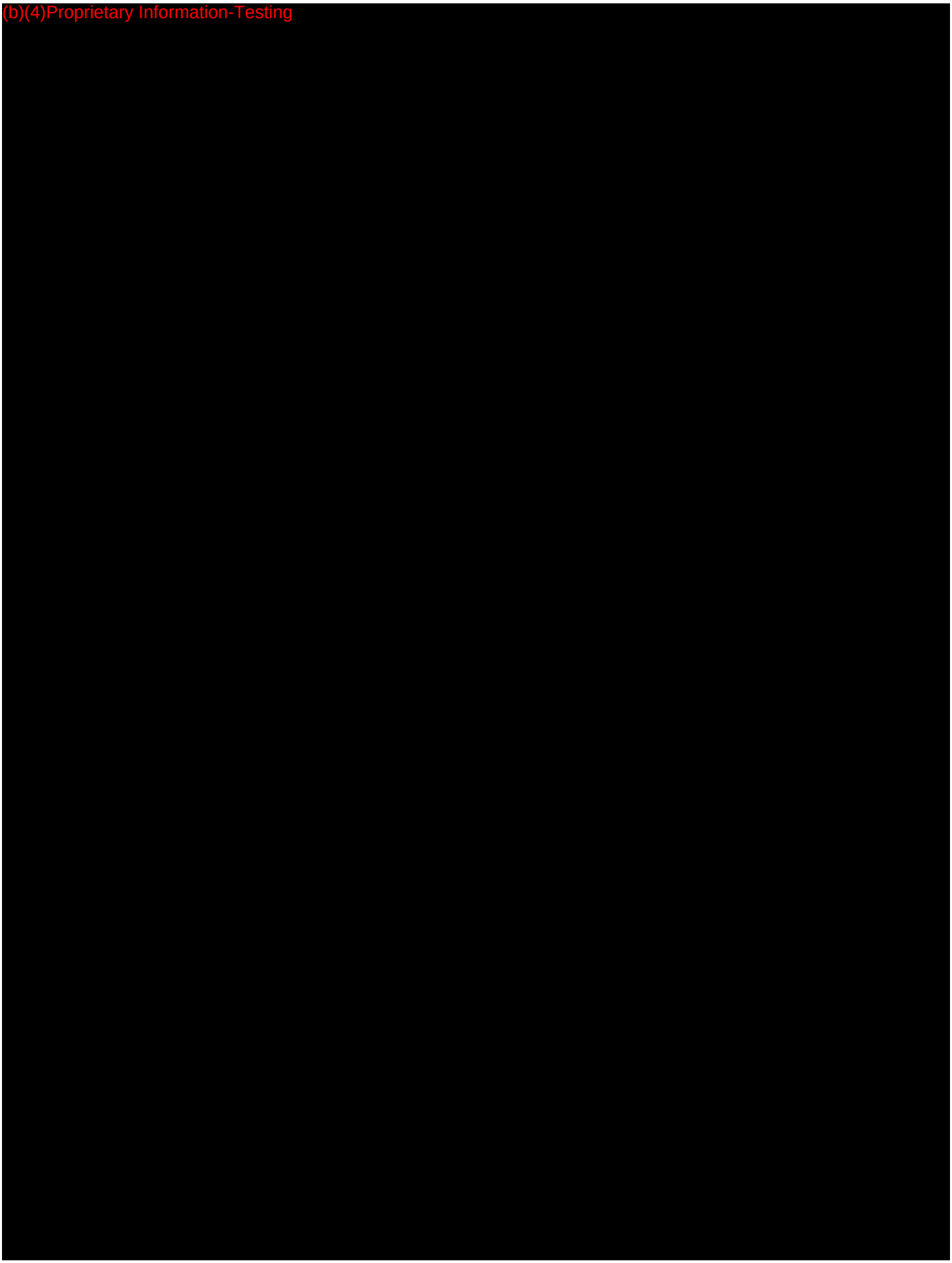
(b)(4)Proprietary Information-Testing



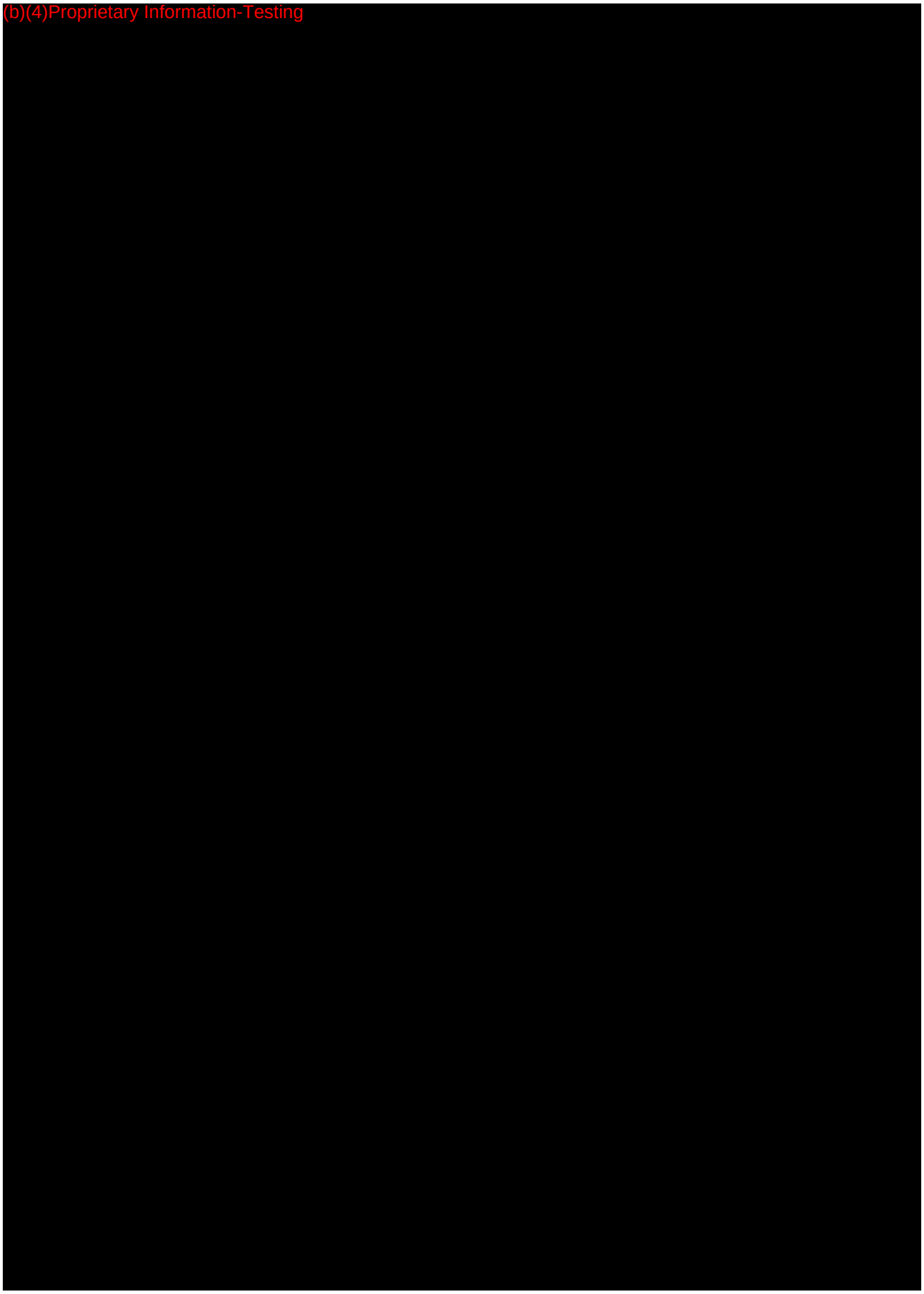
(b)(4)Proprietary Information-Testing



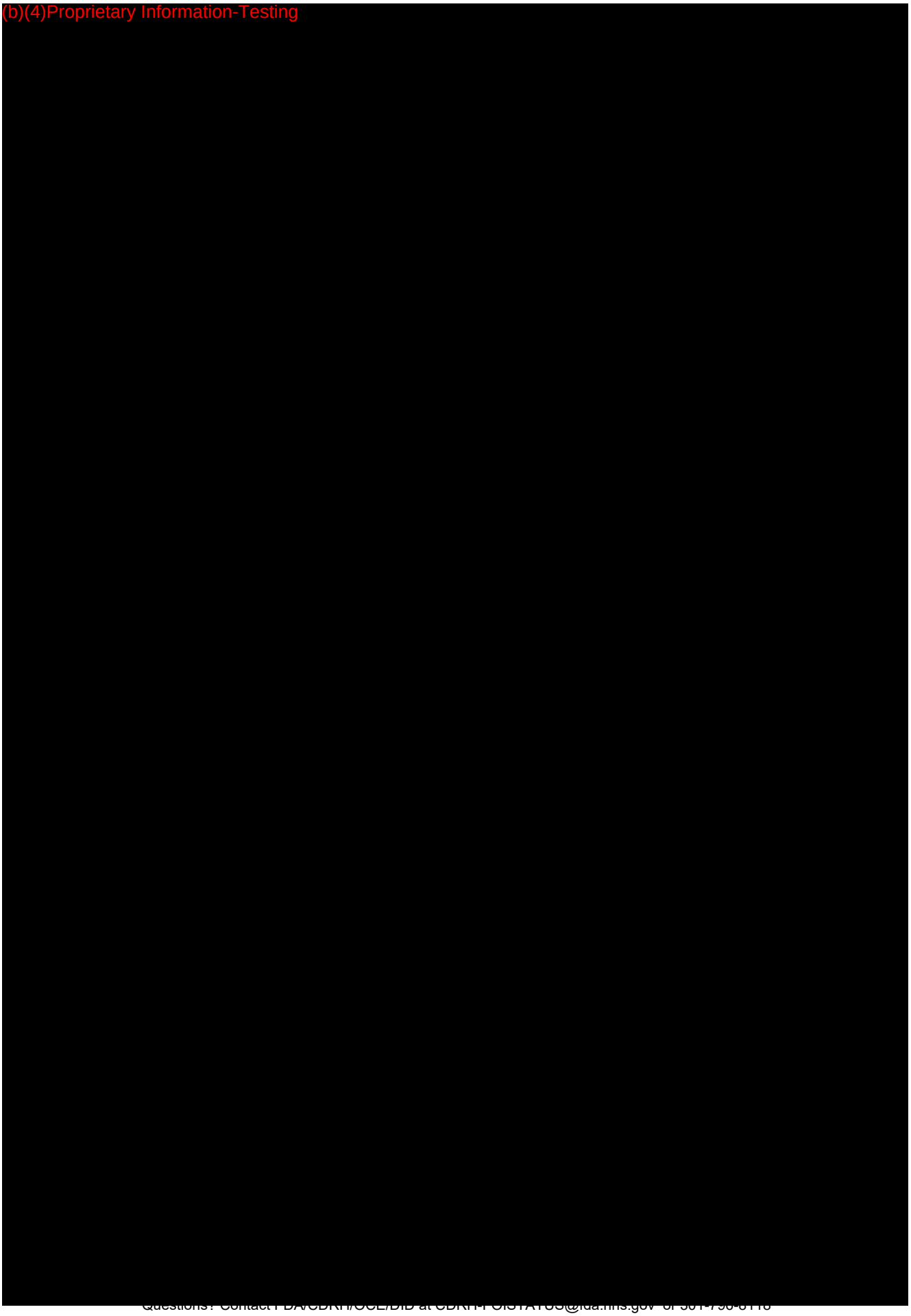
(b)(4)Proprietary Information-Testing



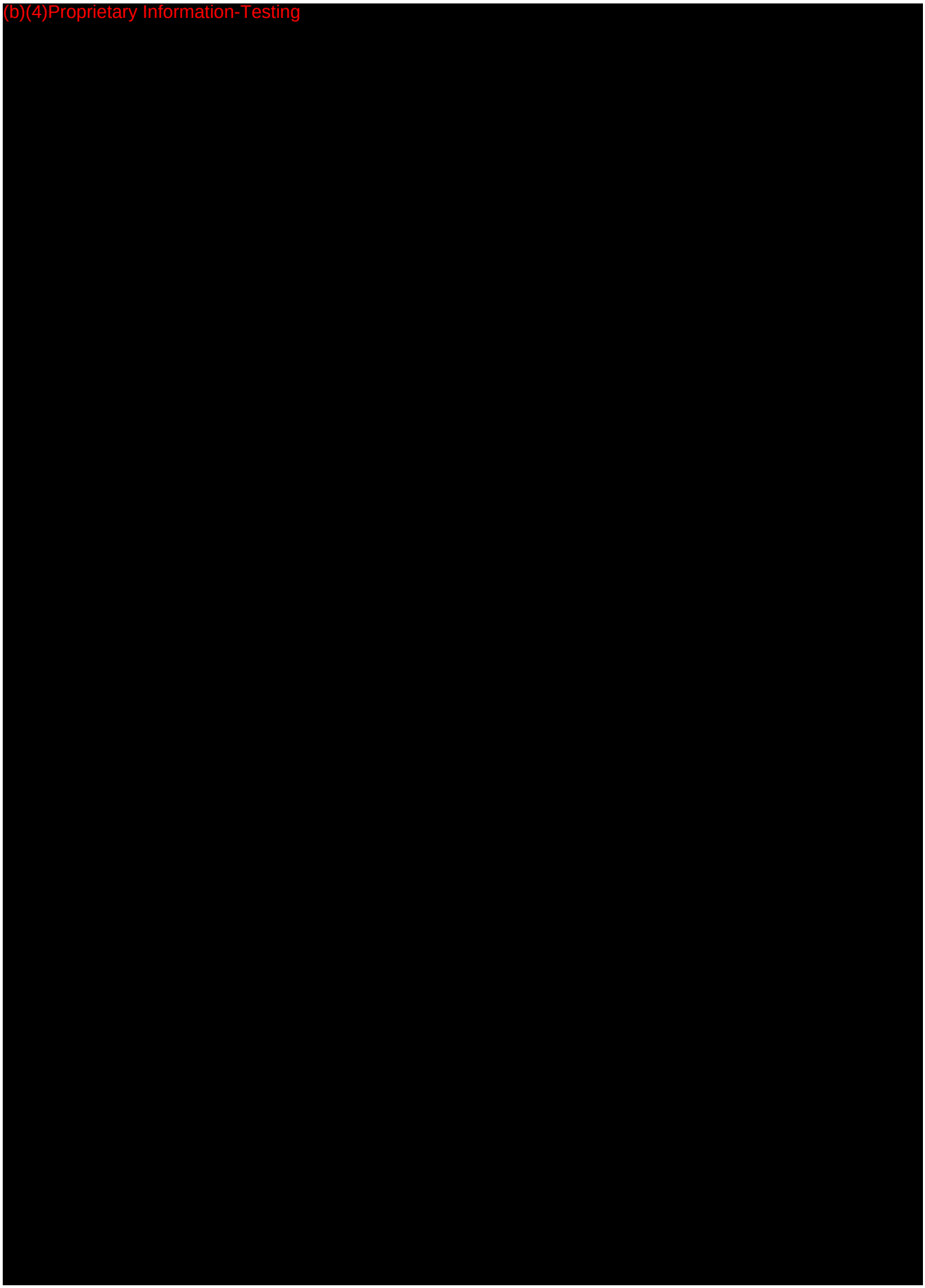
(b)(4)Proprietary Information-Testing



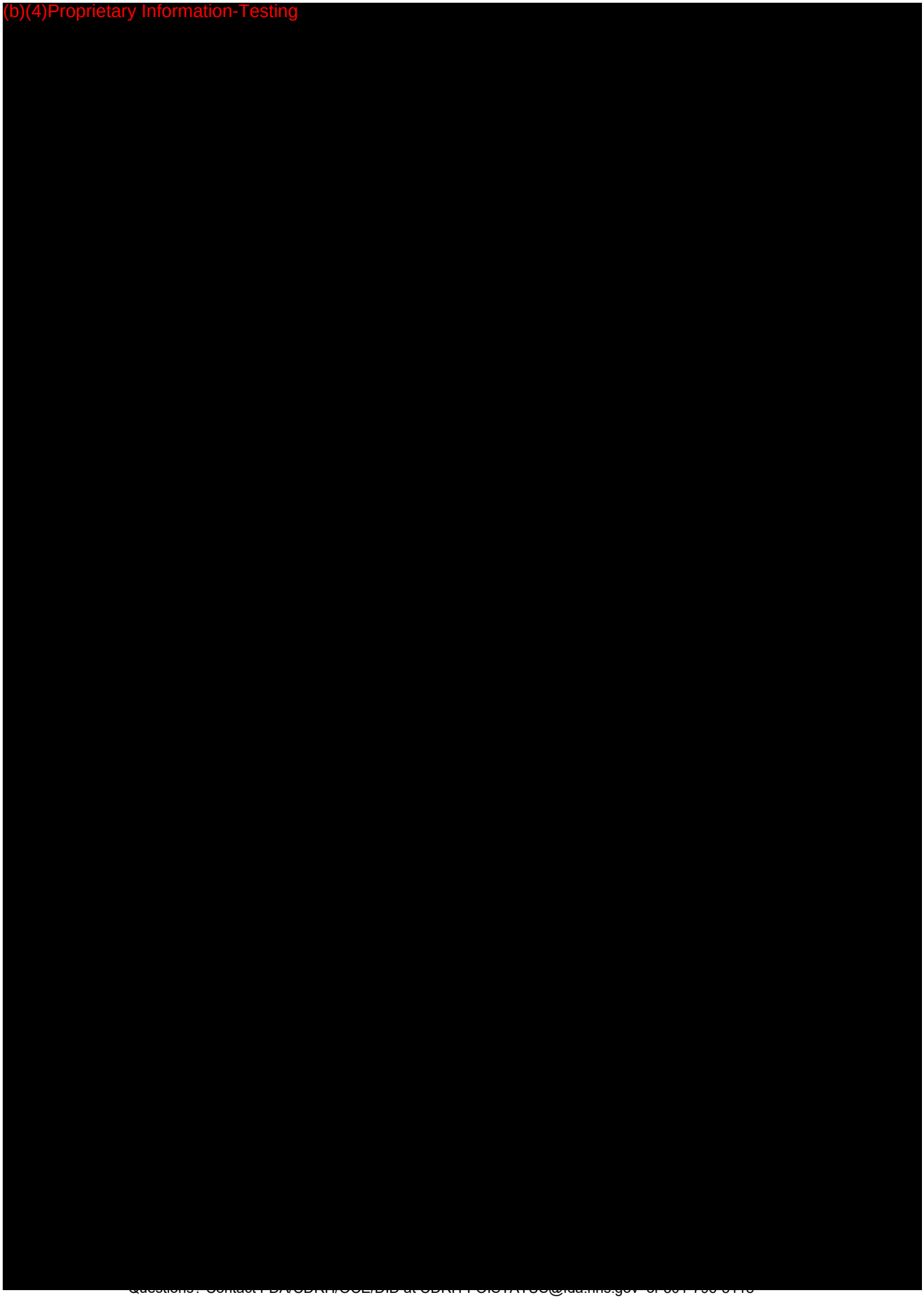
(b)(4)Proprietary Information-Testing



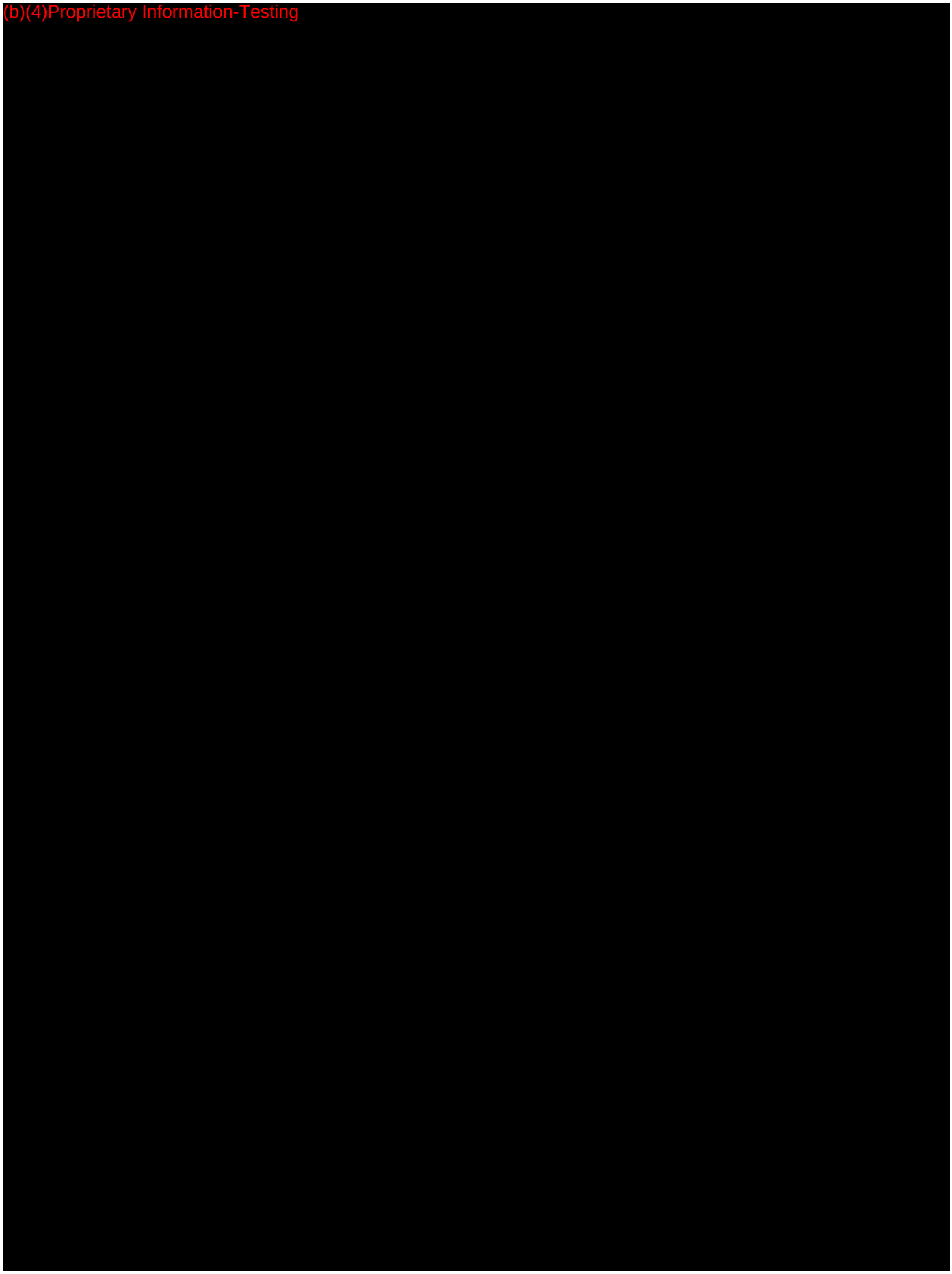
(b)(4)Proprietary Information-Testing



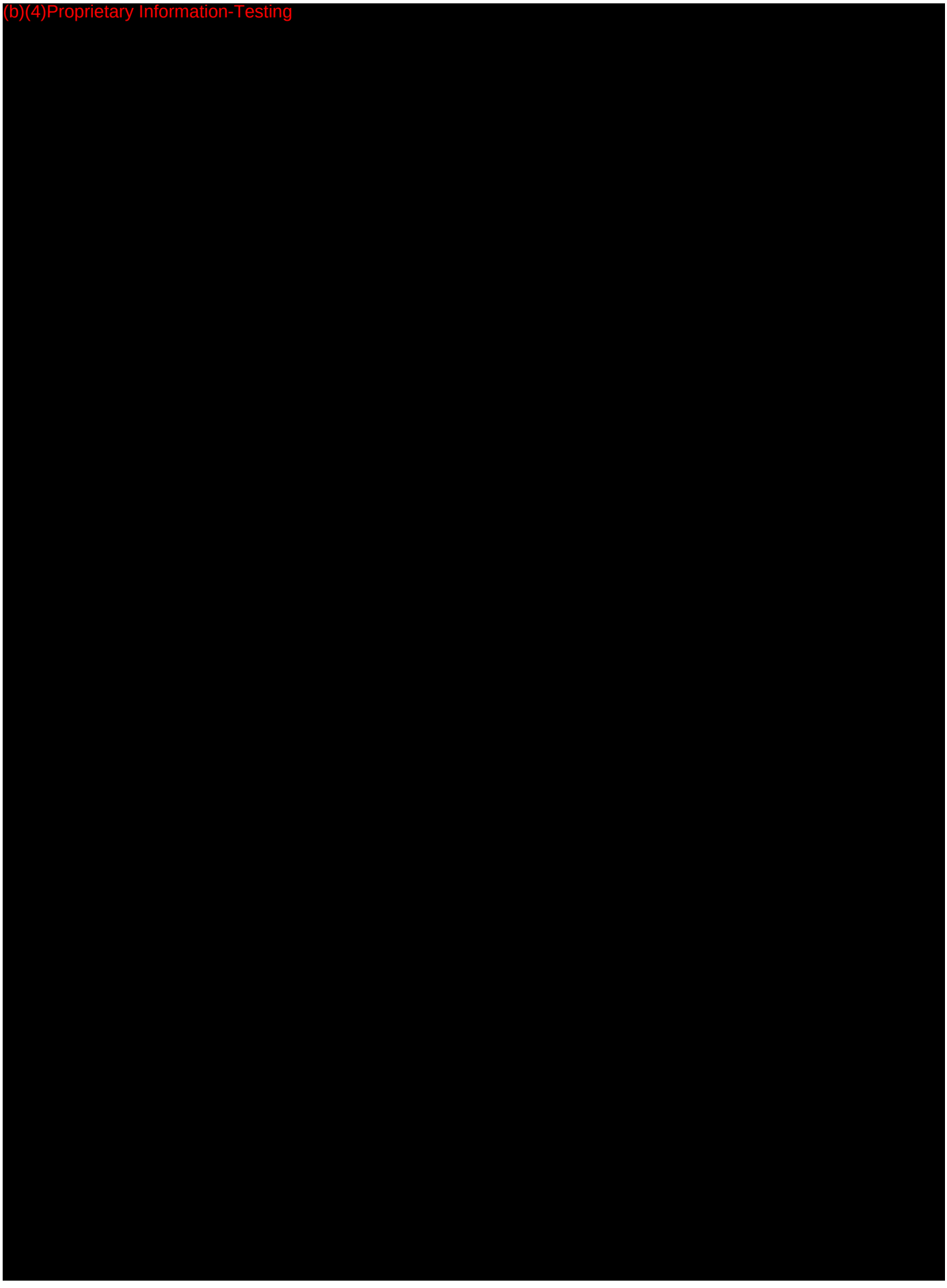
(b)(4)Proprietary Information-Testing



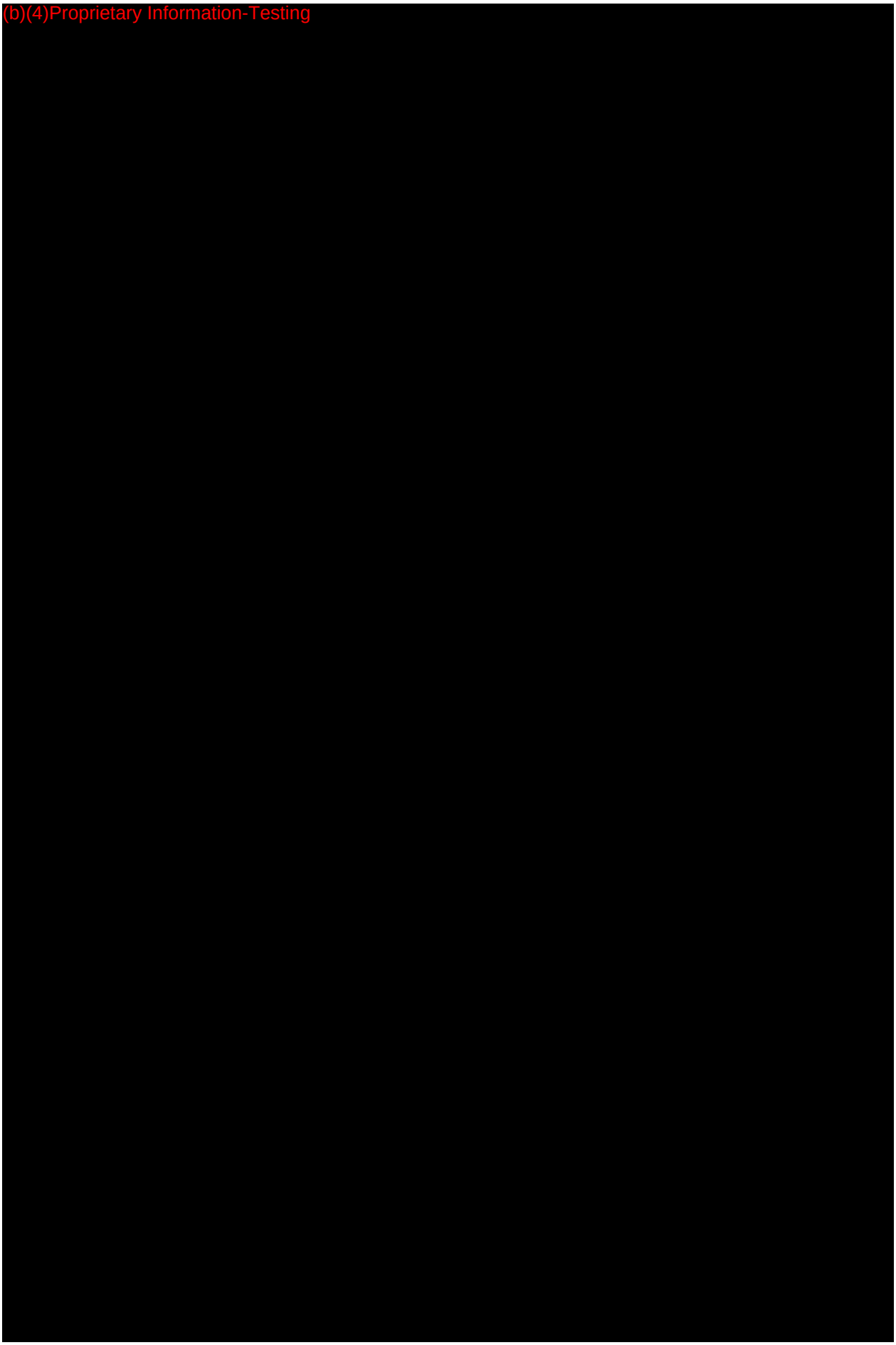
(b)(4)Proprietary Information-Testing



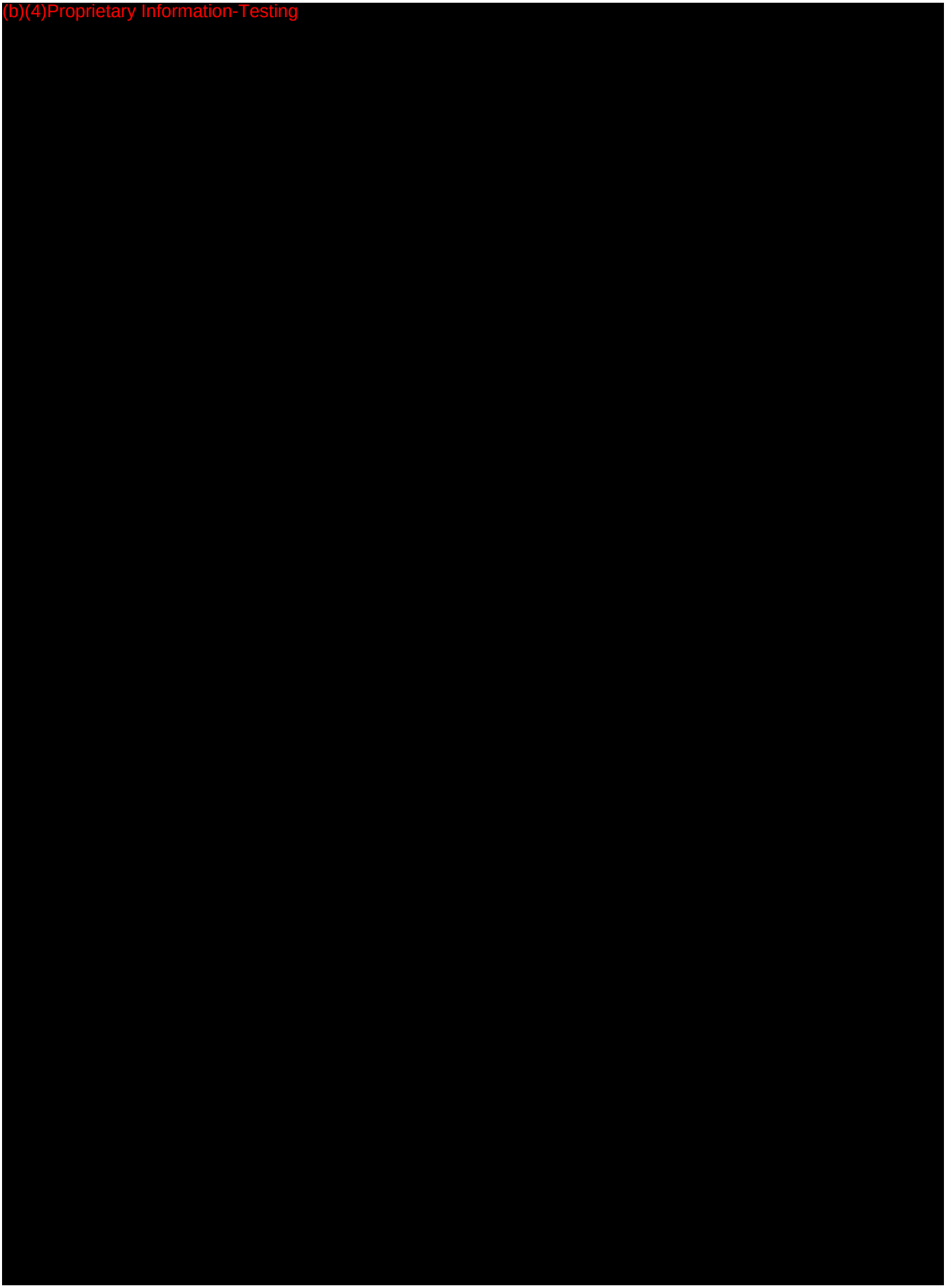
(b)(4)Proprietary Information-Testing



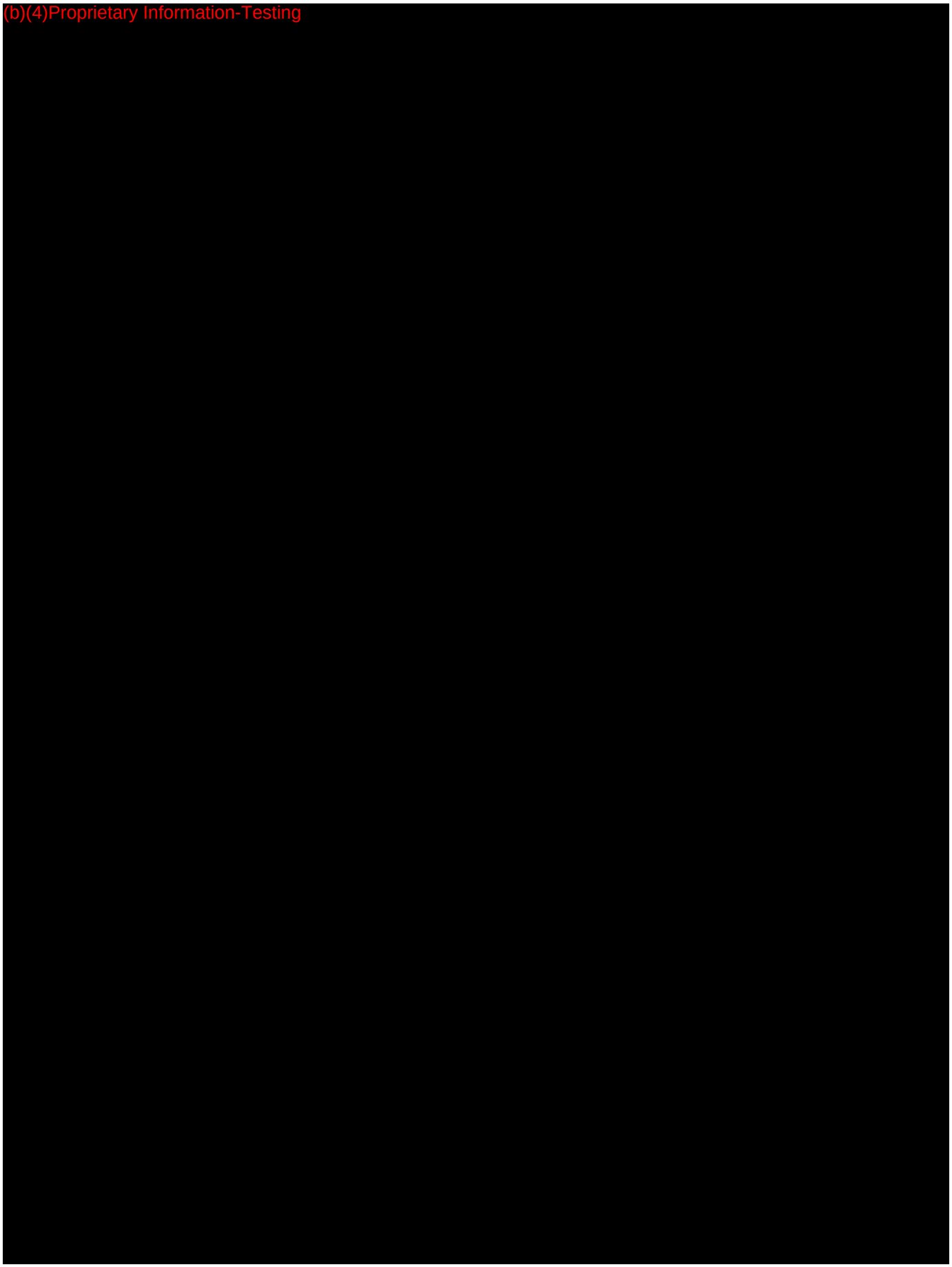
(b)(4)Proprietary Information-Testing



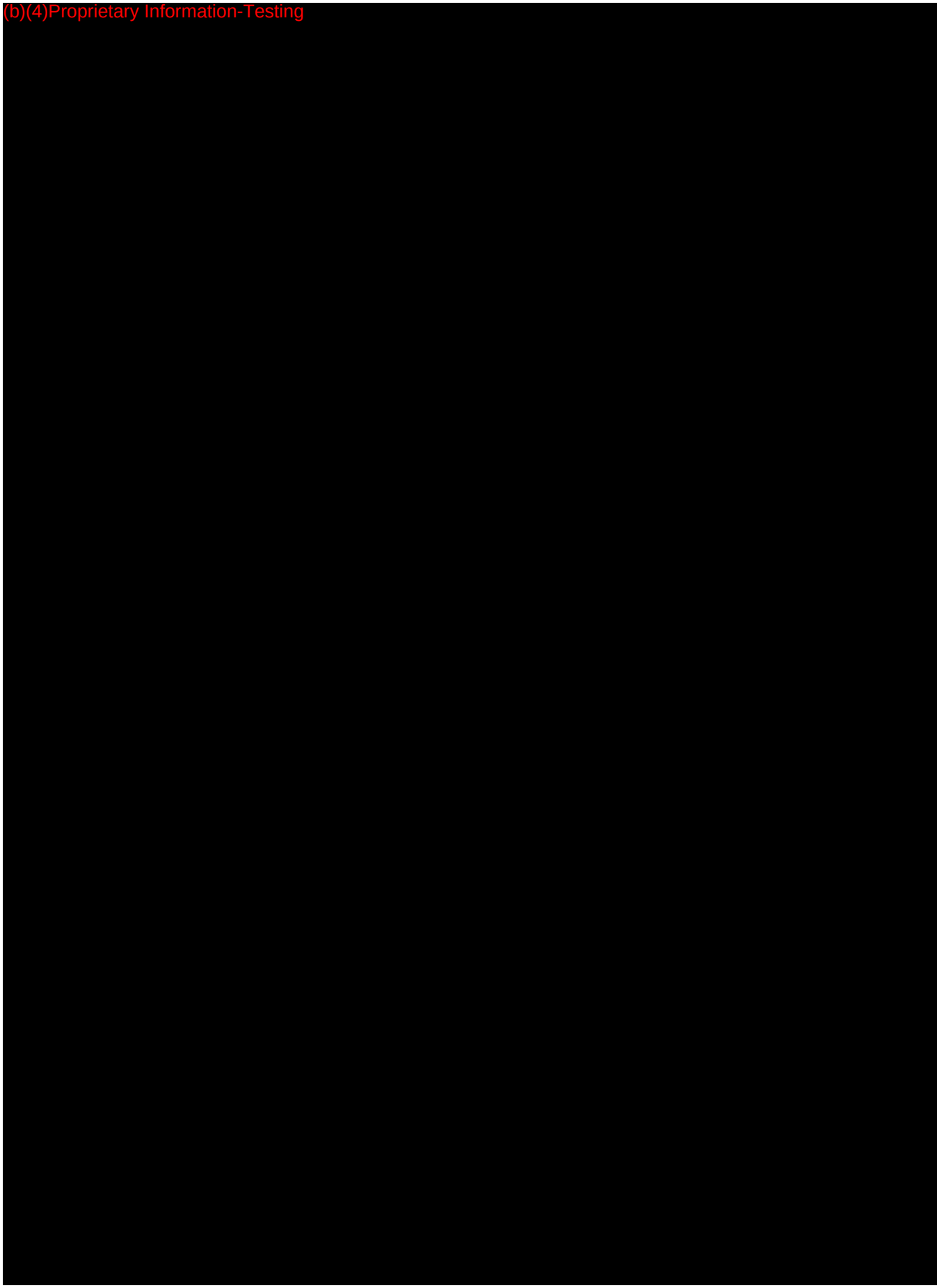
(b)(4)Proprietary Information-Testing



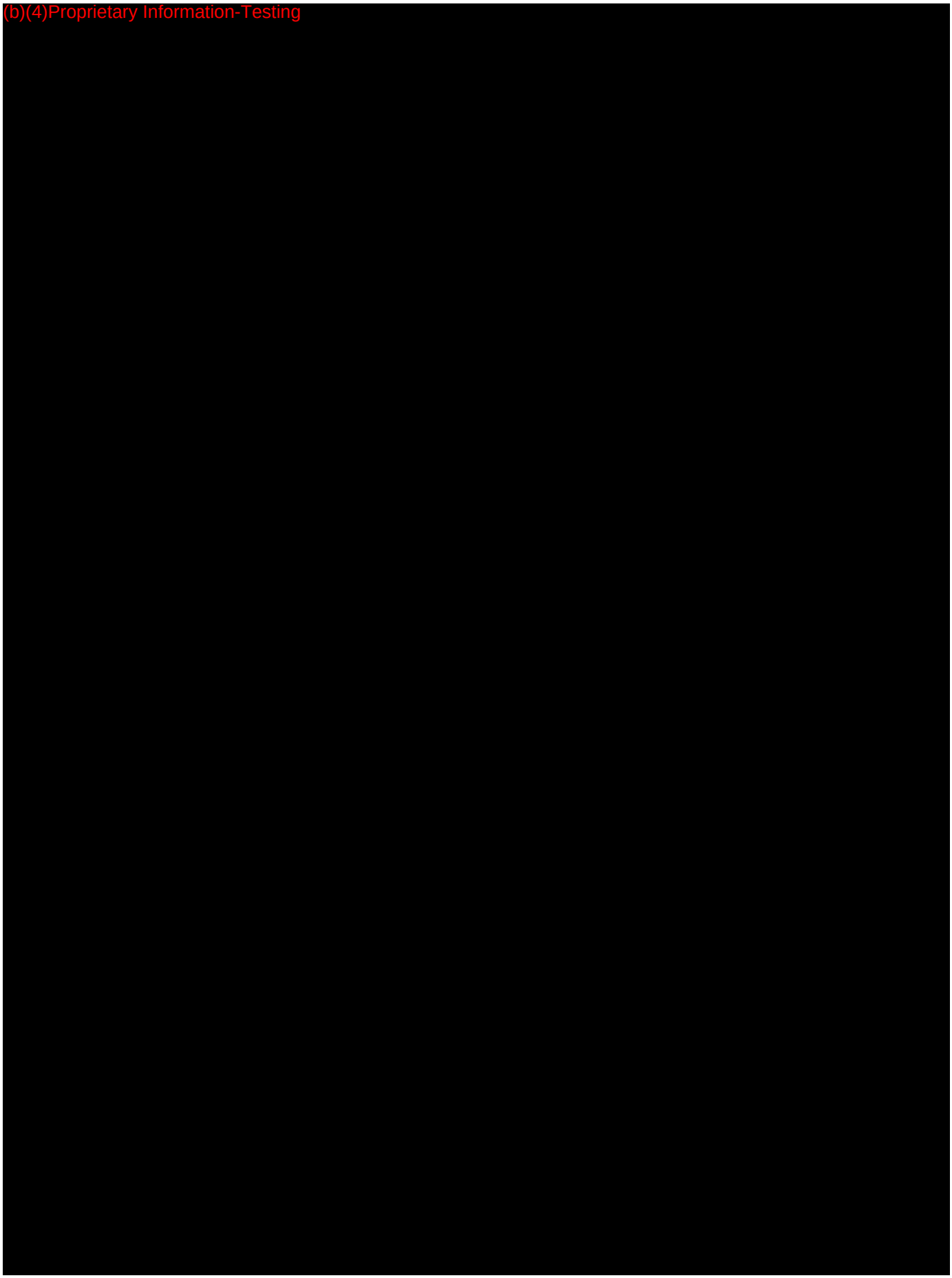
(b)(4)Proprietary Information-Testing



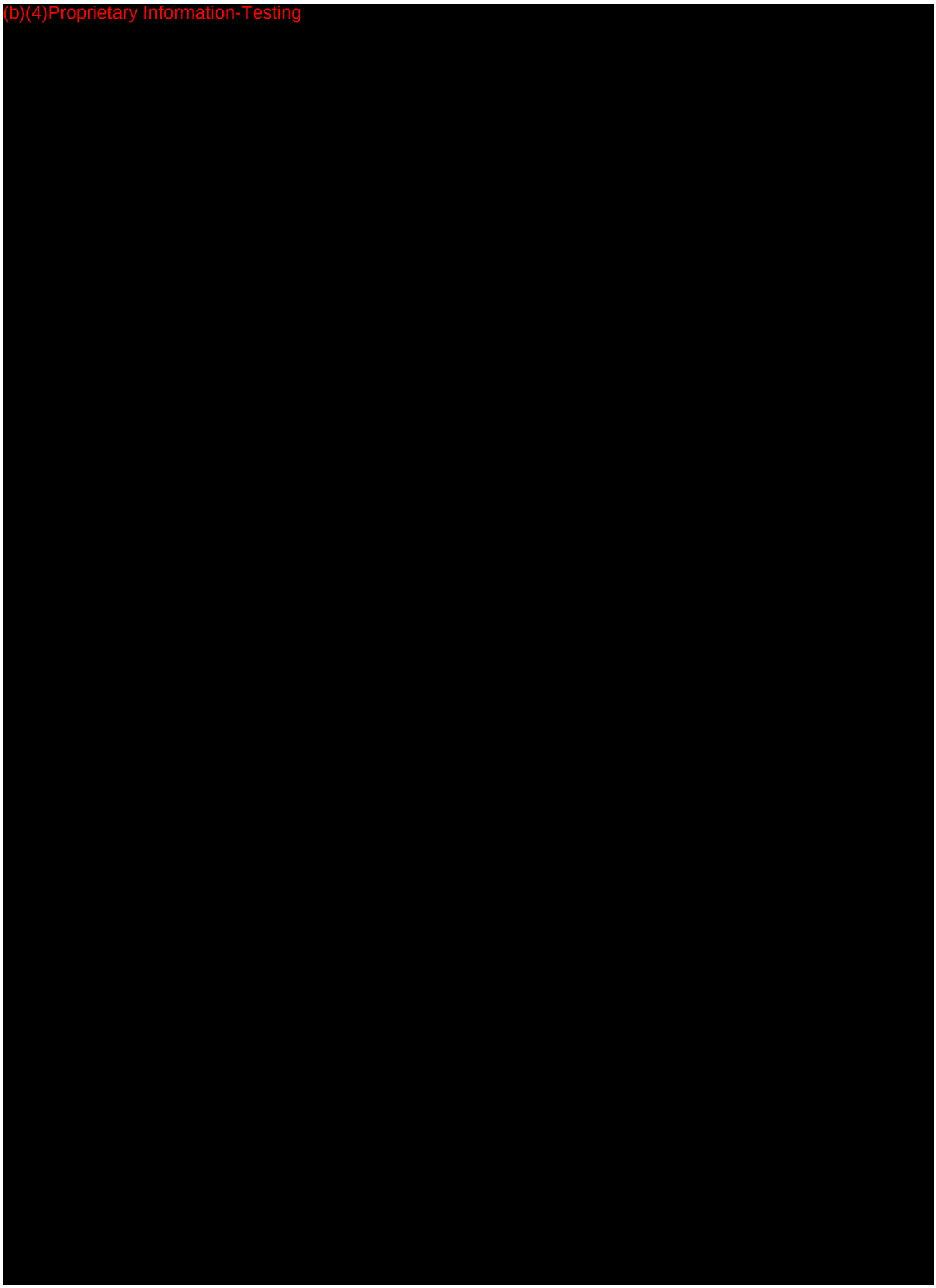
(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing

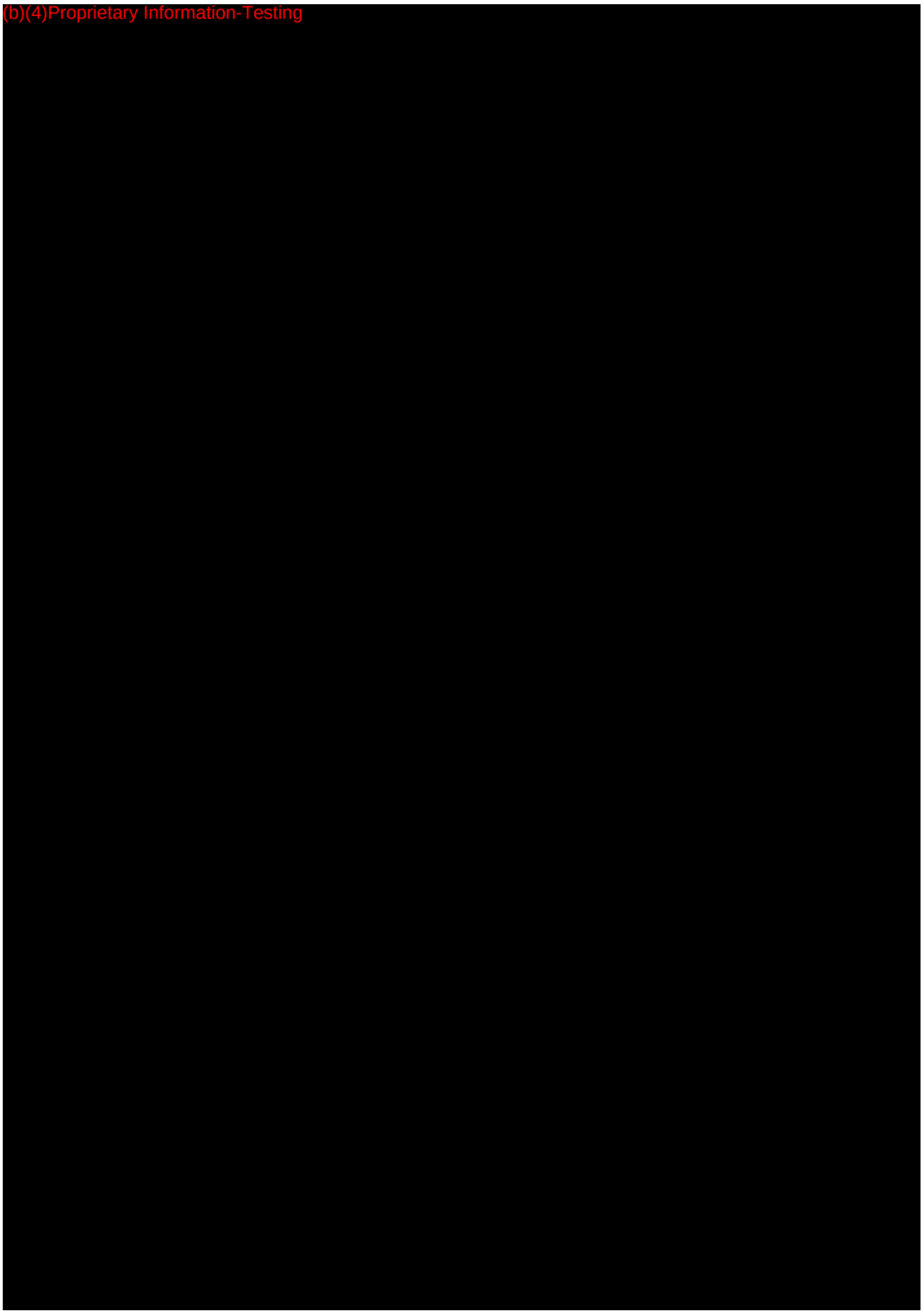


(b)(4)Proprietary Information-Testing

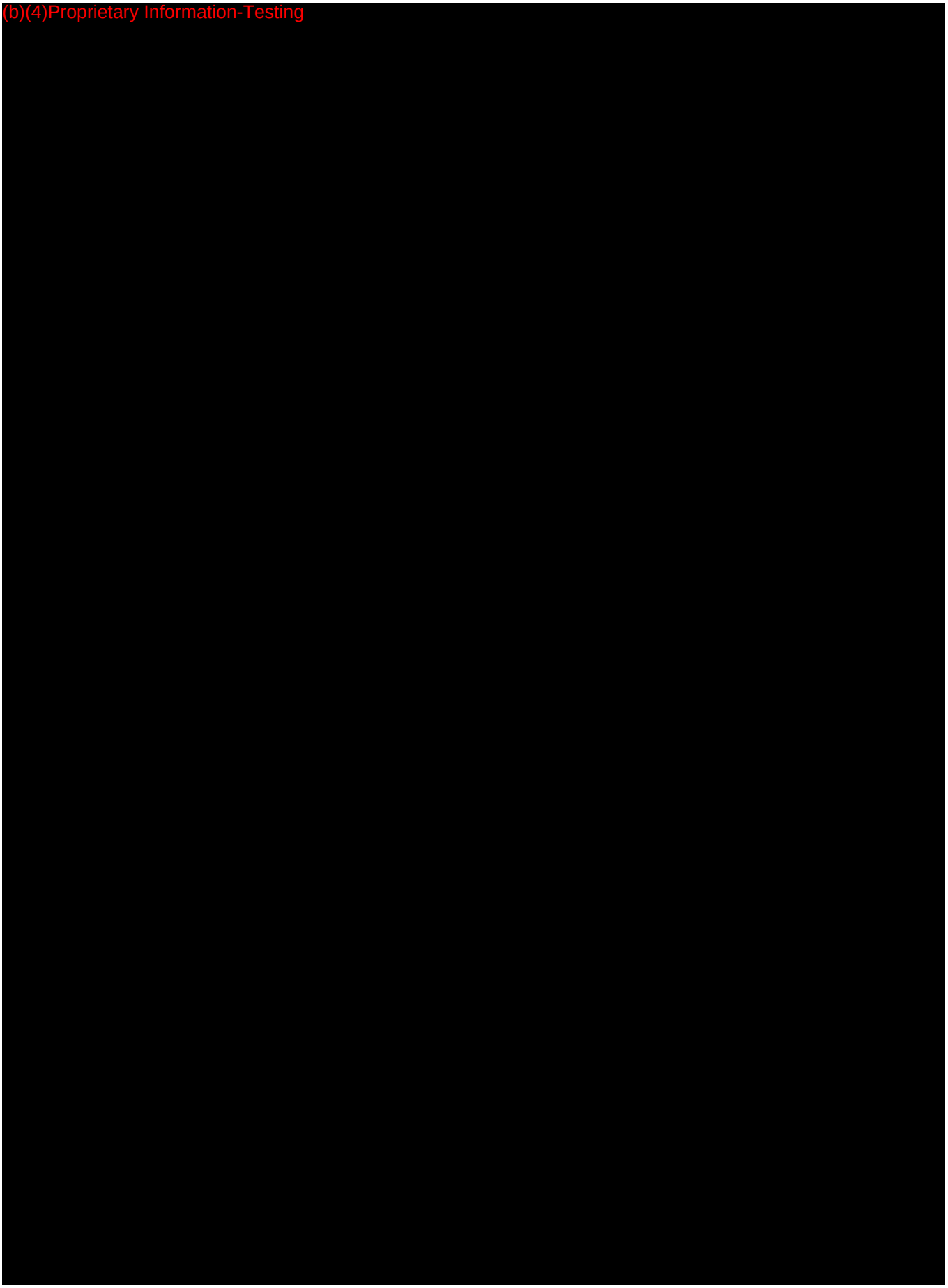


(b)(4)Proprietary Information-Testing

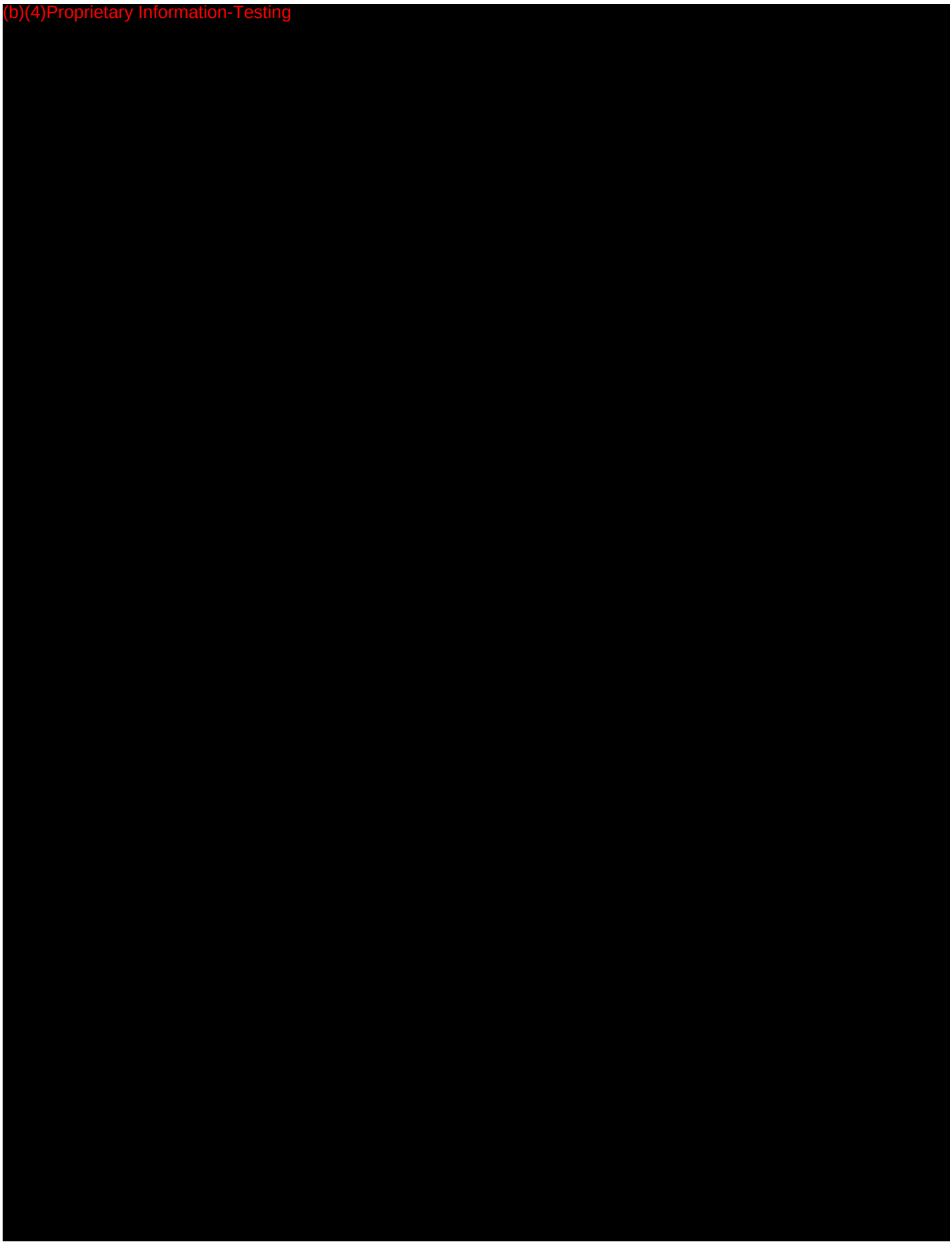
(b)(4)Proprietary Information-Testing



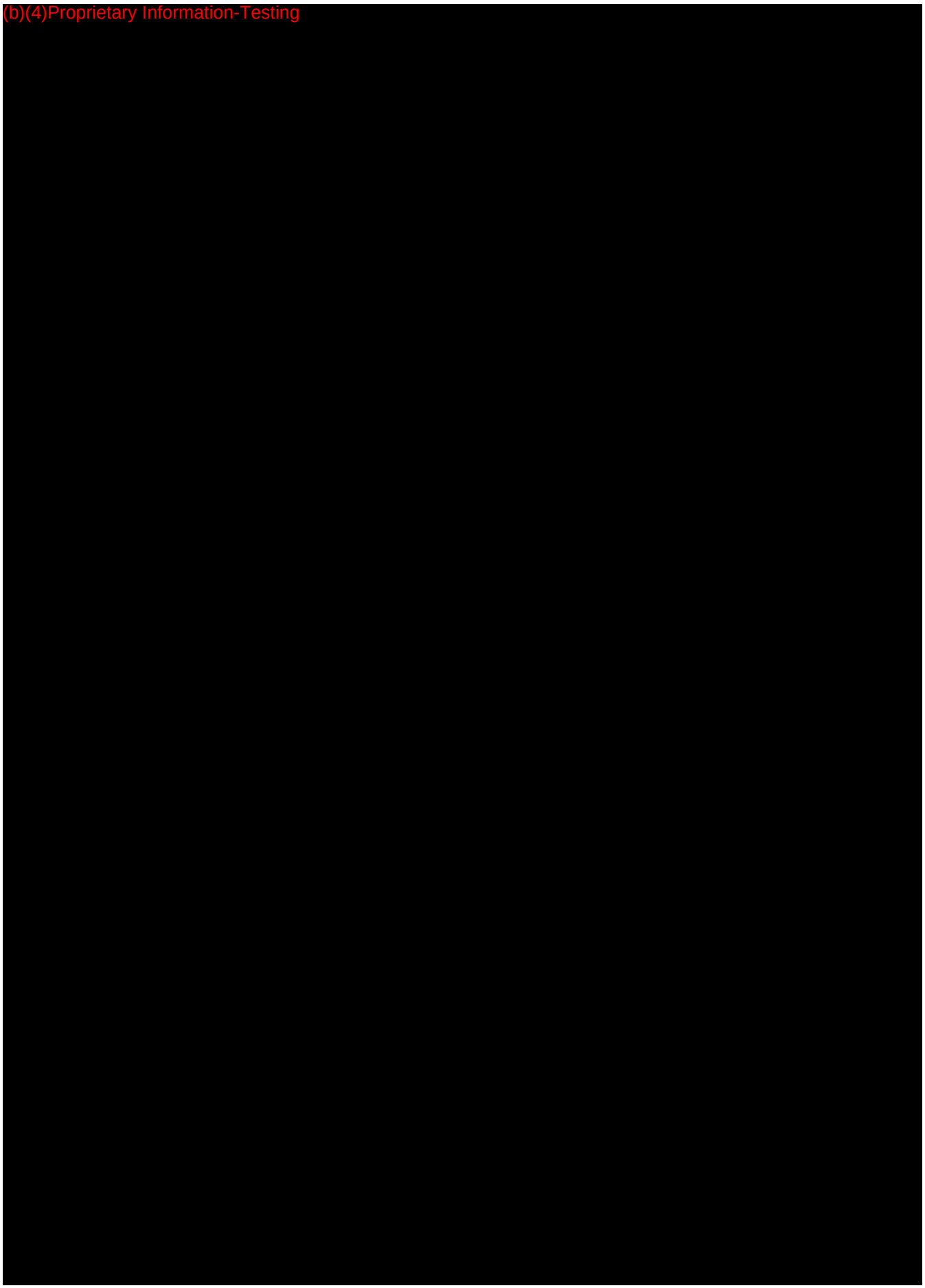
(b)(4)Proprietary Information-Testing



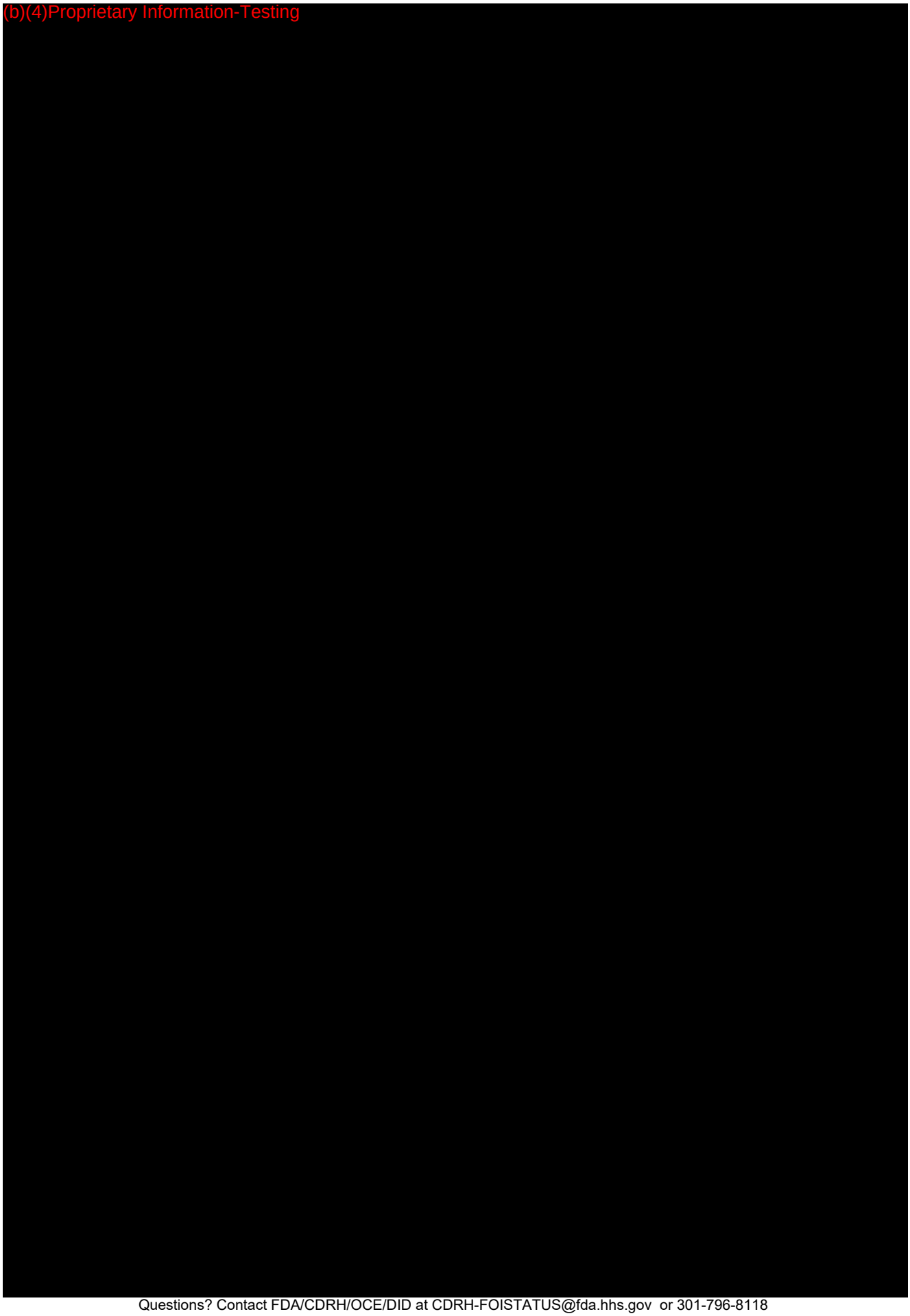
(b)(4)Proprietary Information-Testing



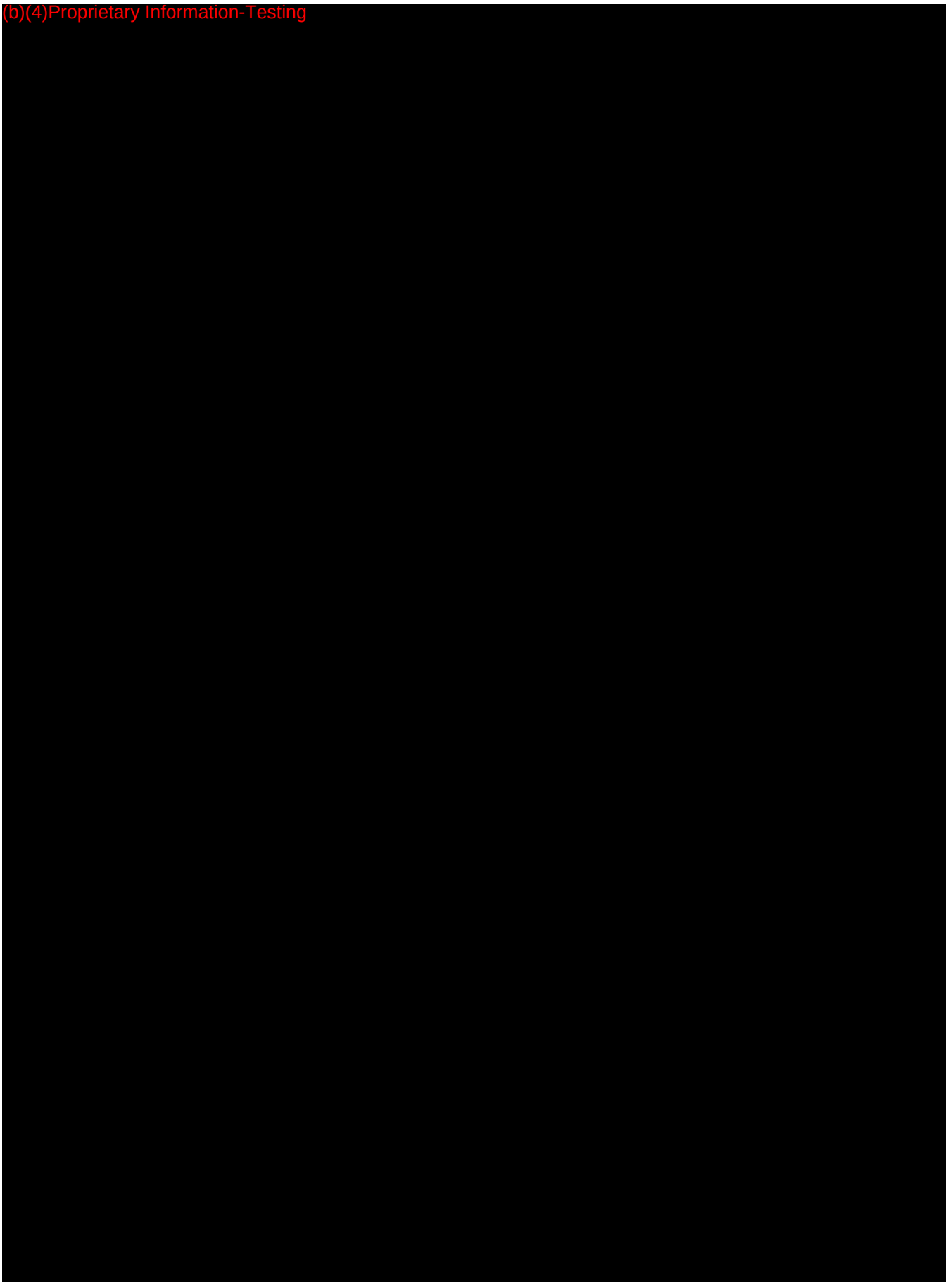
(b)(4)Proprietary Information-Testing



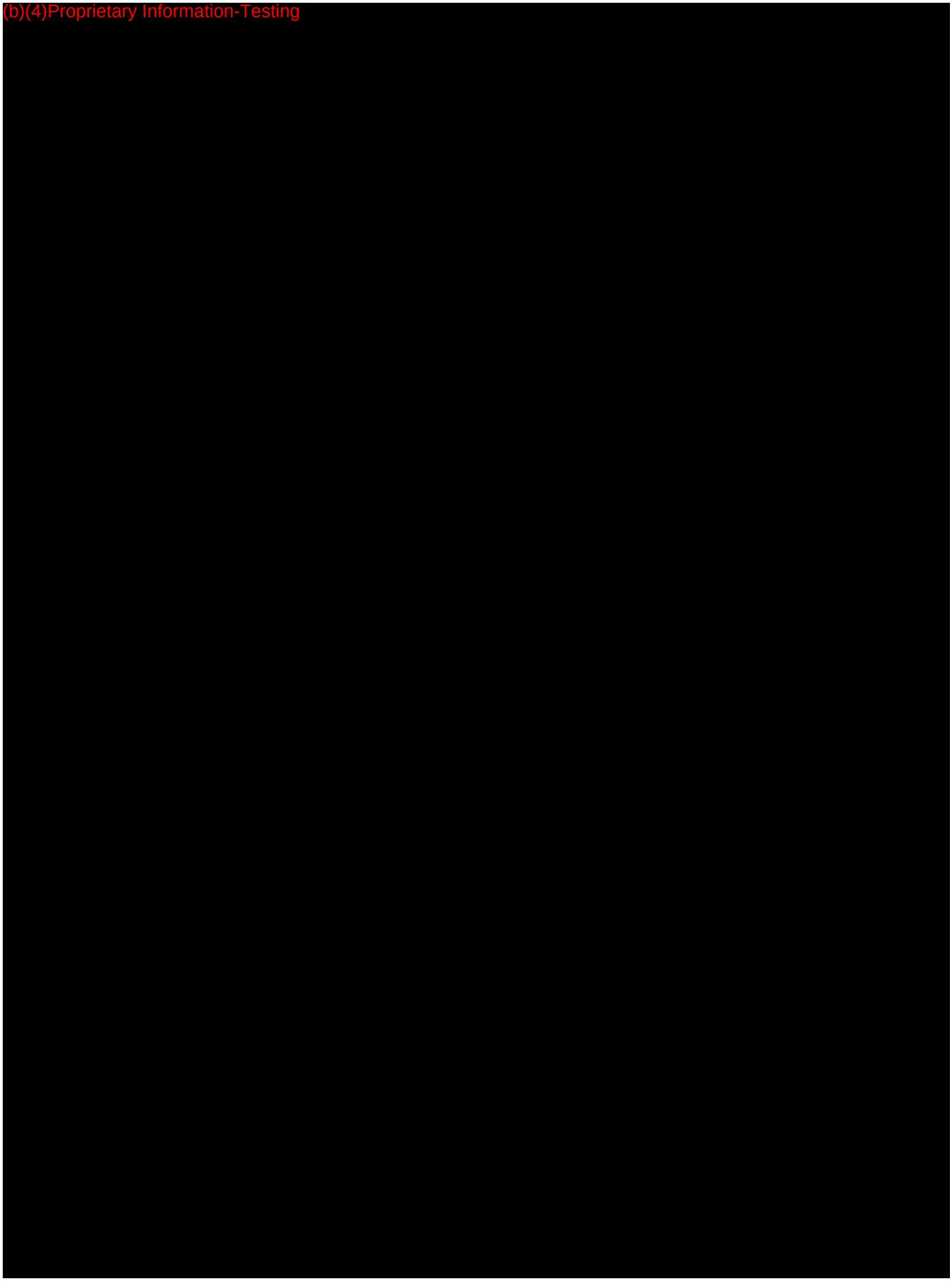
(b)(4)Proprietary Information-Testing



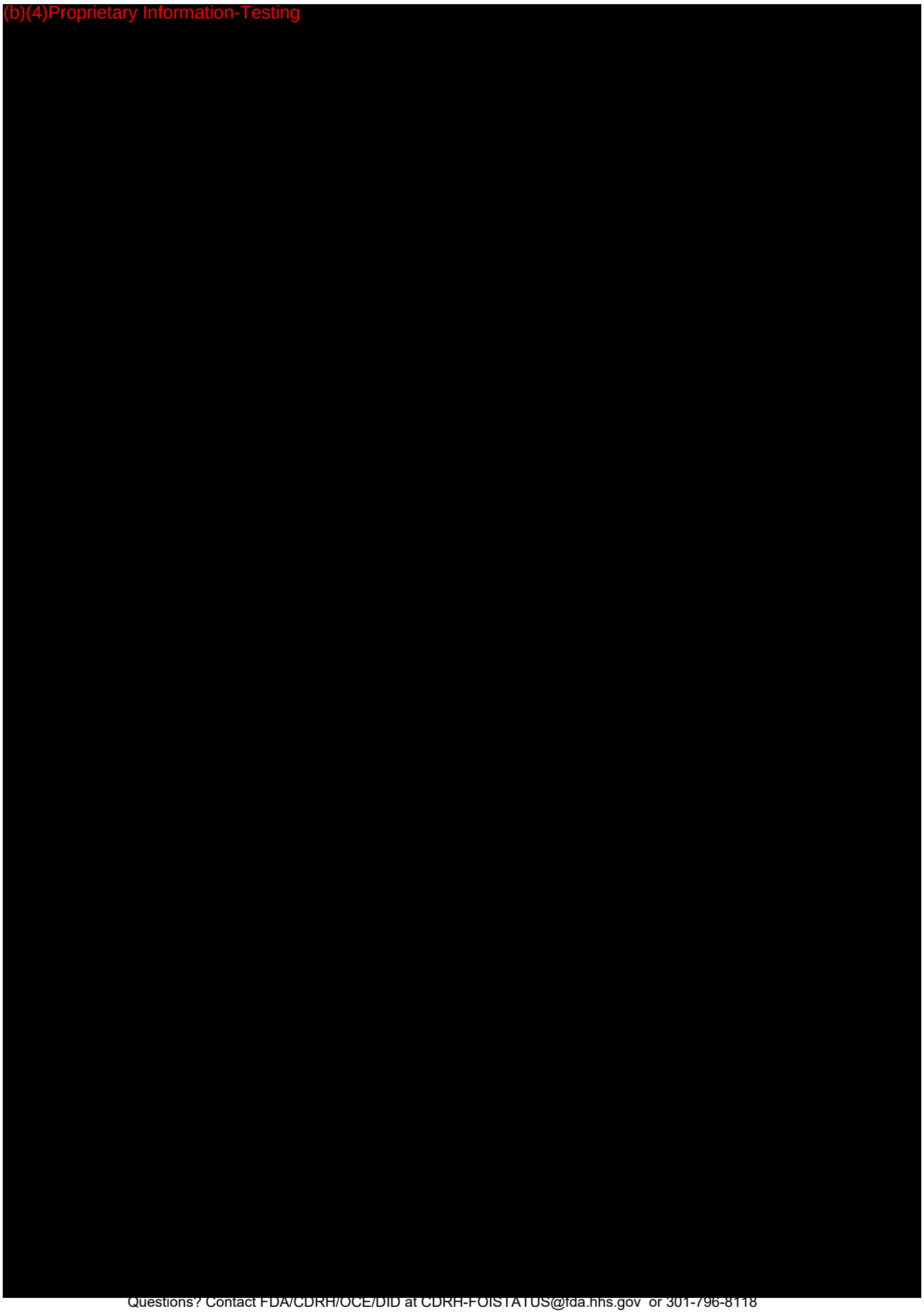
(b)(4)Proprietary Information-Testing



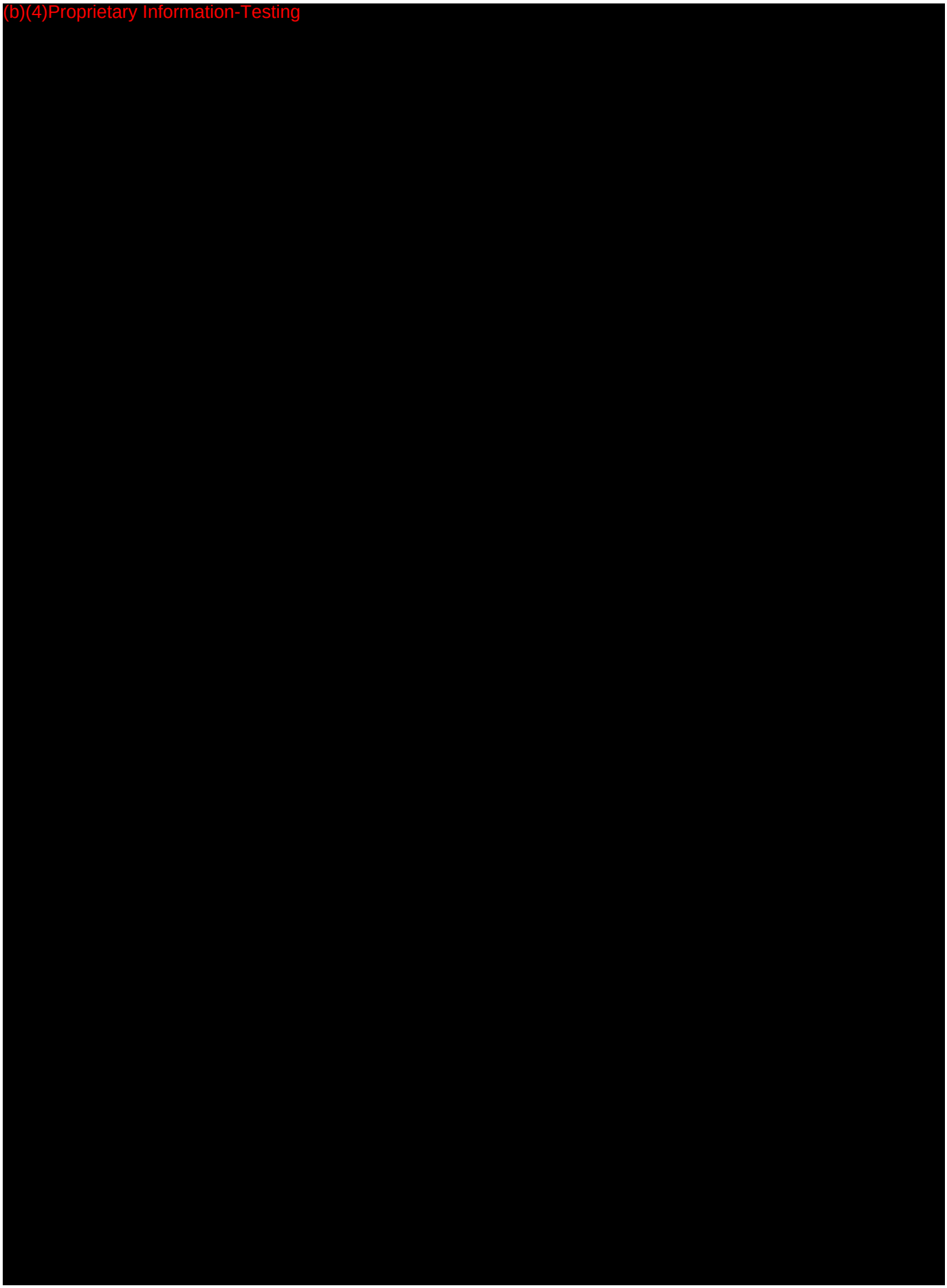
(b)(4)Proprietary Information-Testing



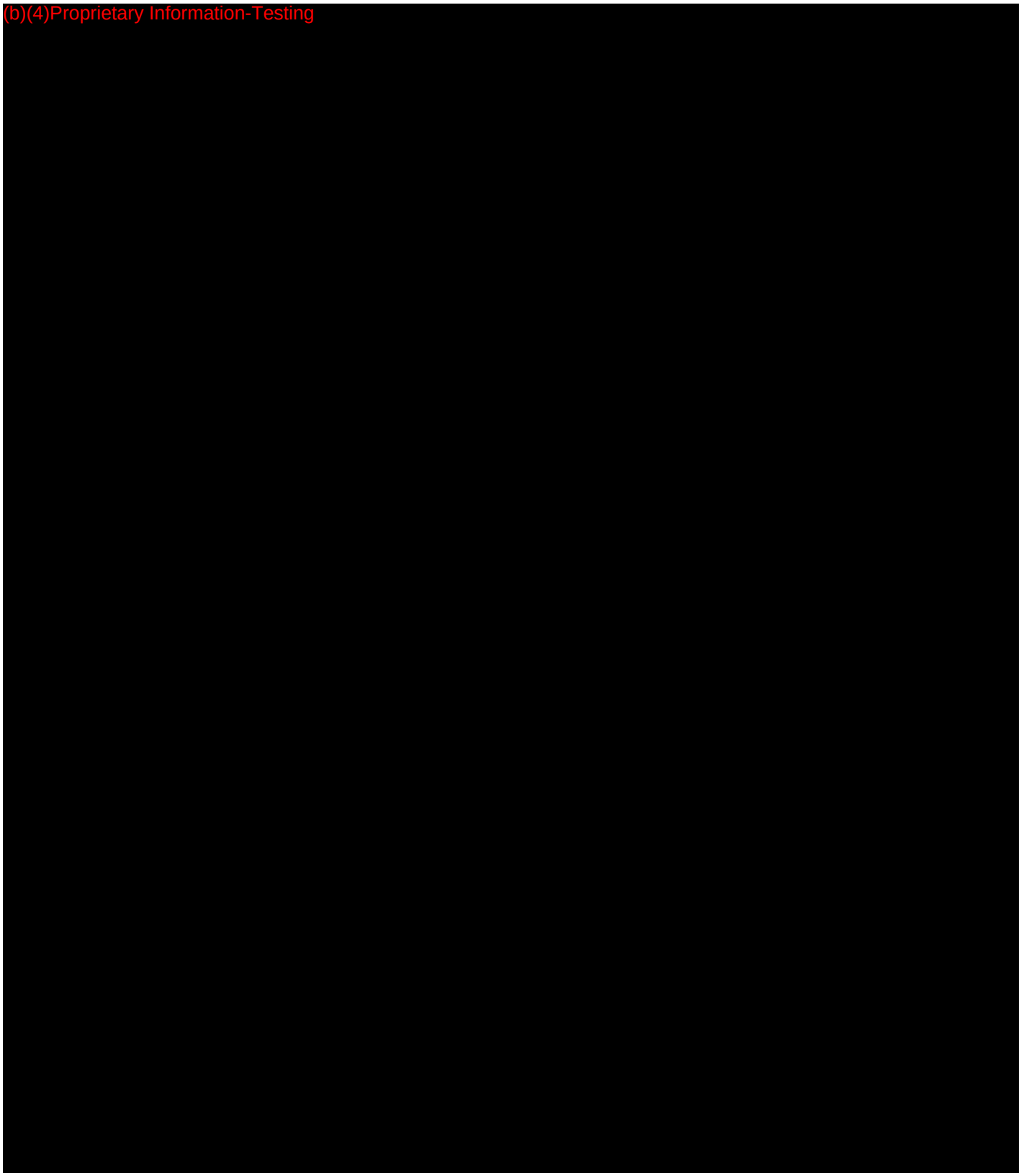
(b)(4)Proprietary Information-Testing



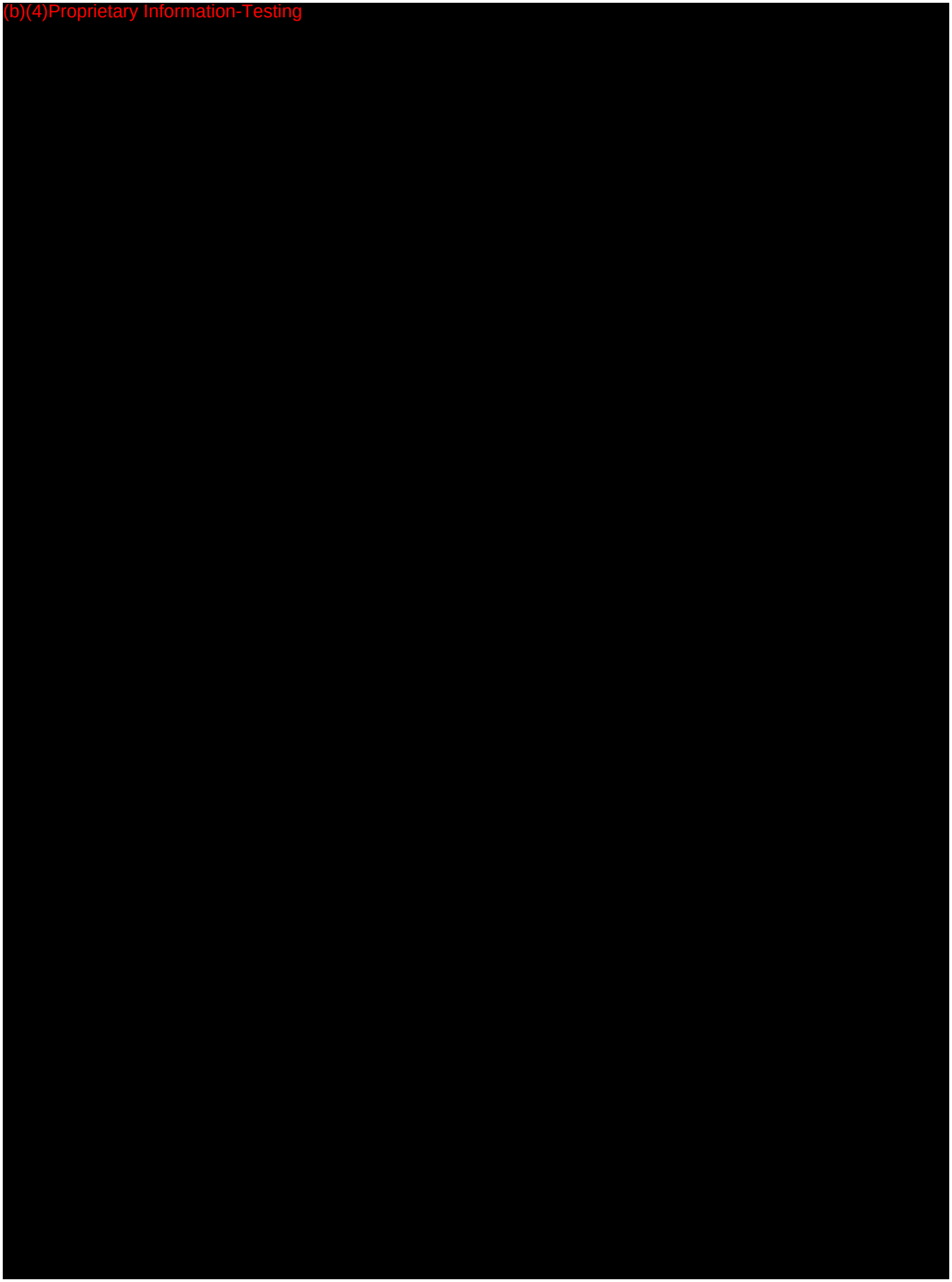
(b)(4)Proprietary Information-Testing



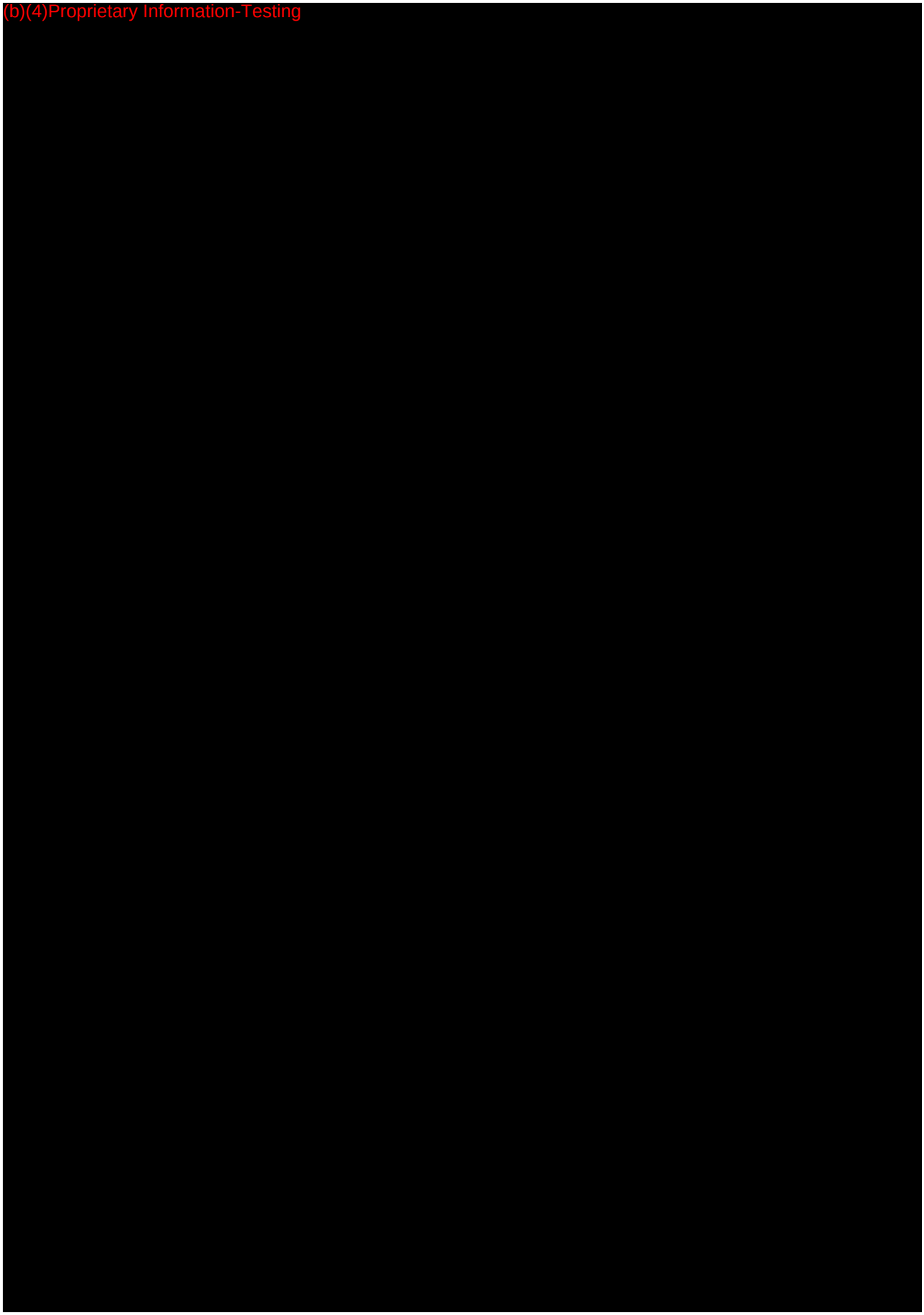
(b)(4)Proprietary Information-Testing



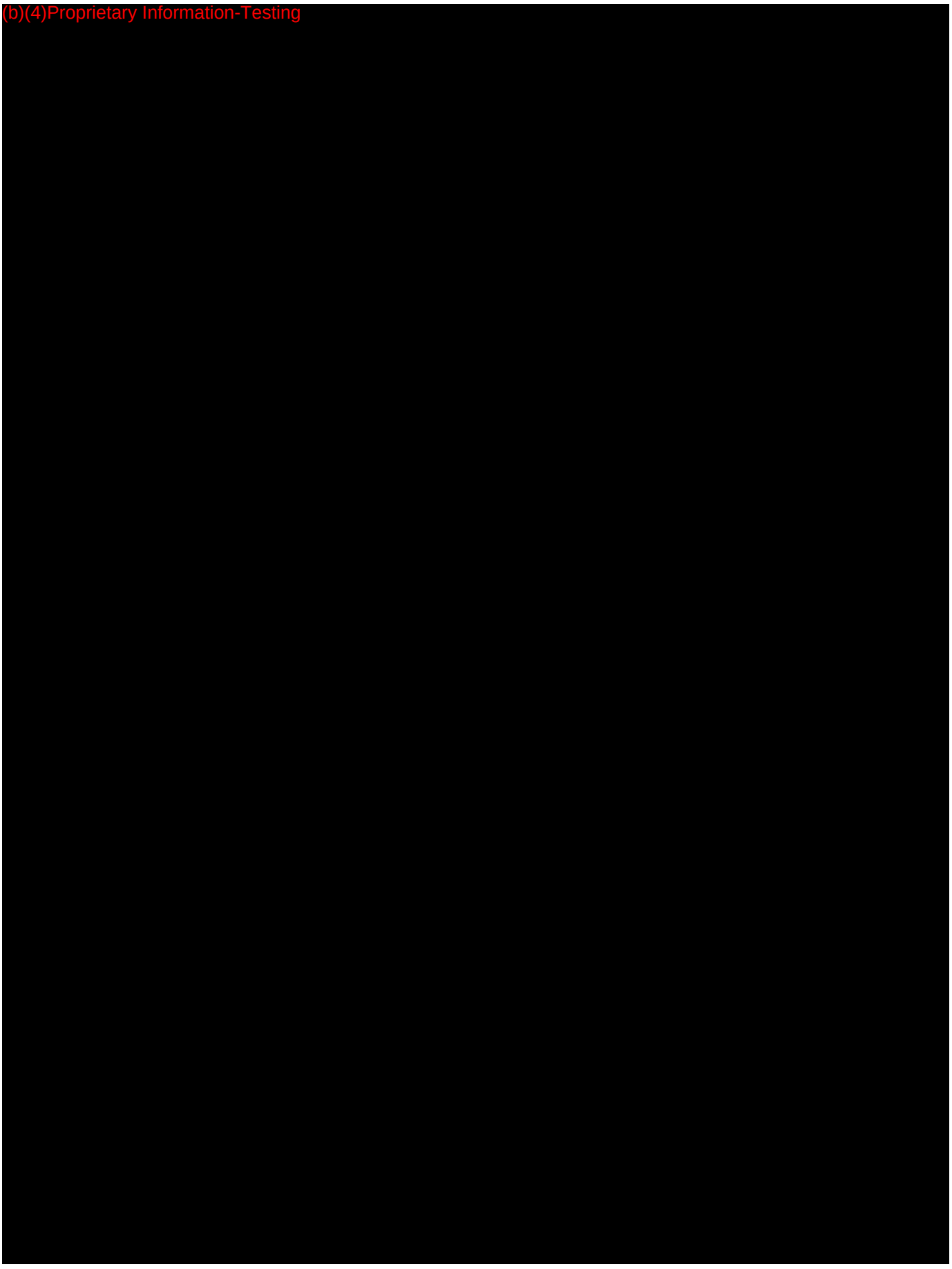
(b)(4)Proprietary Information-Testing



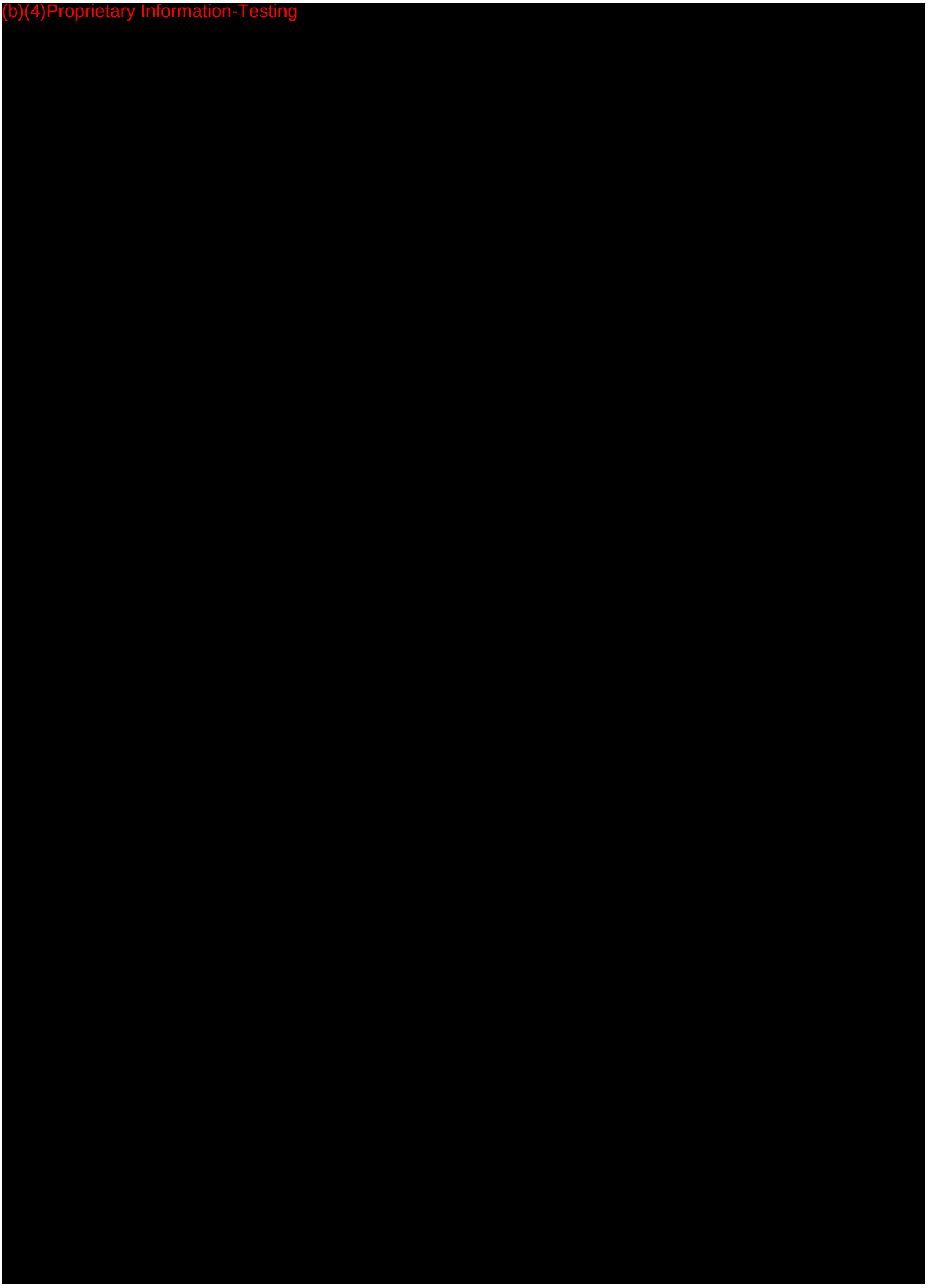
(b)(4)Proprietary Information-Testing



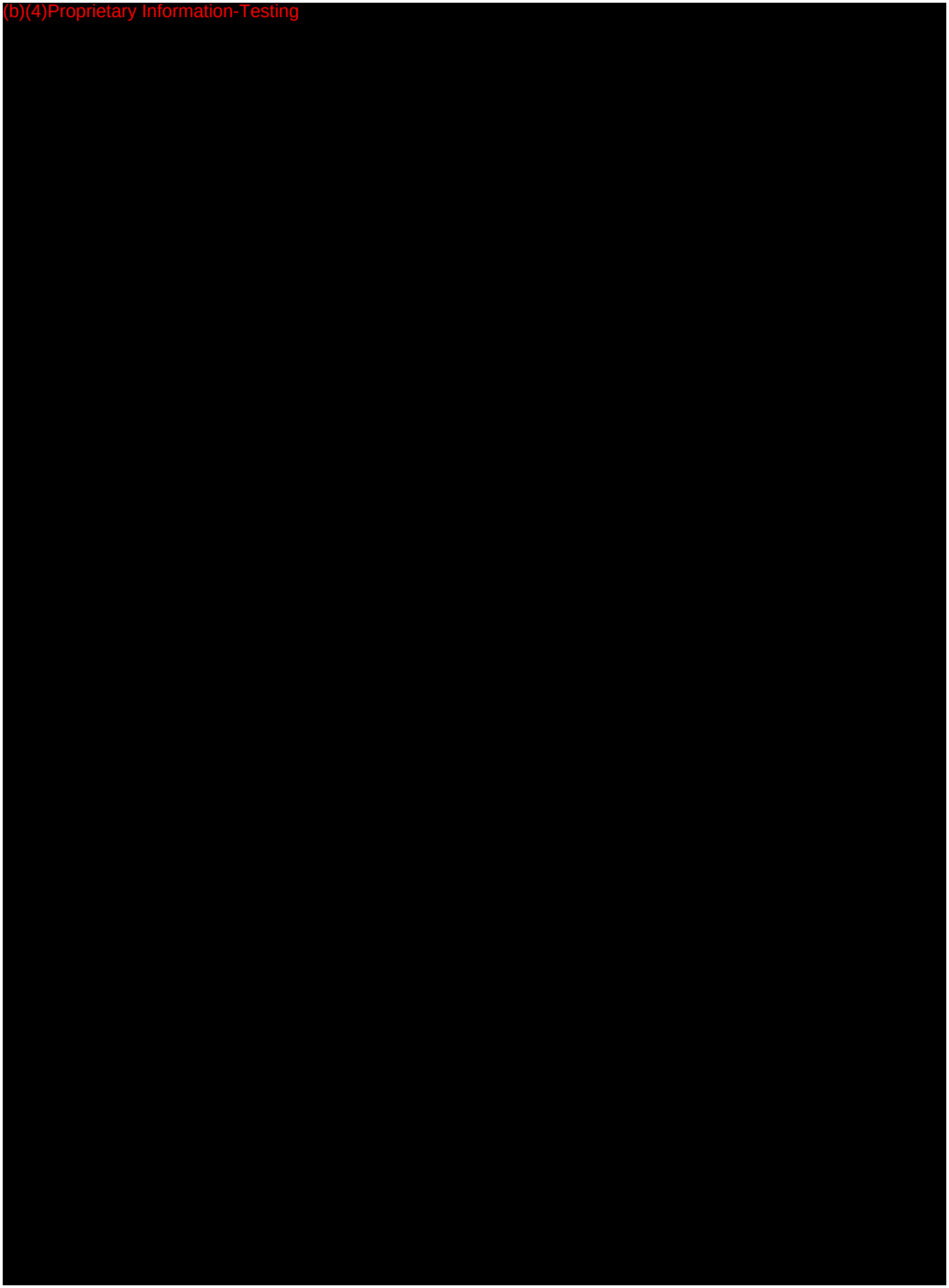
(b)(4)Proprietary Information-Testing



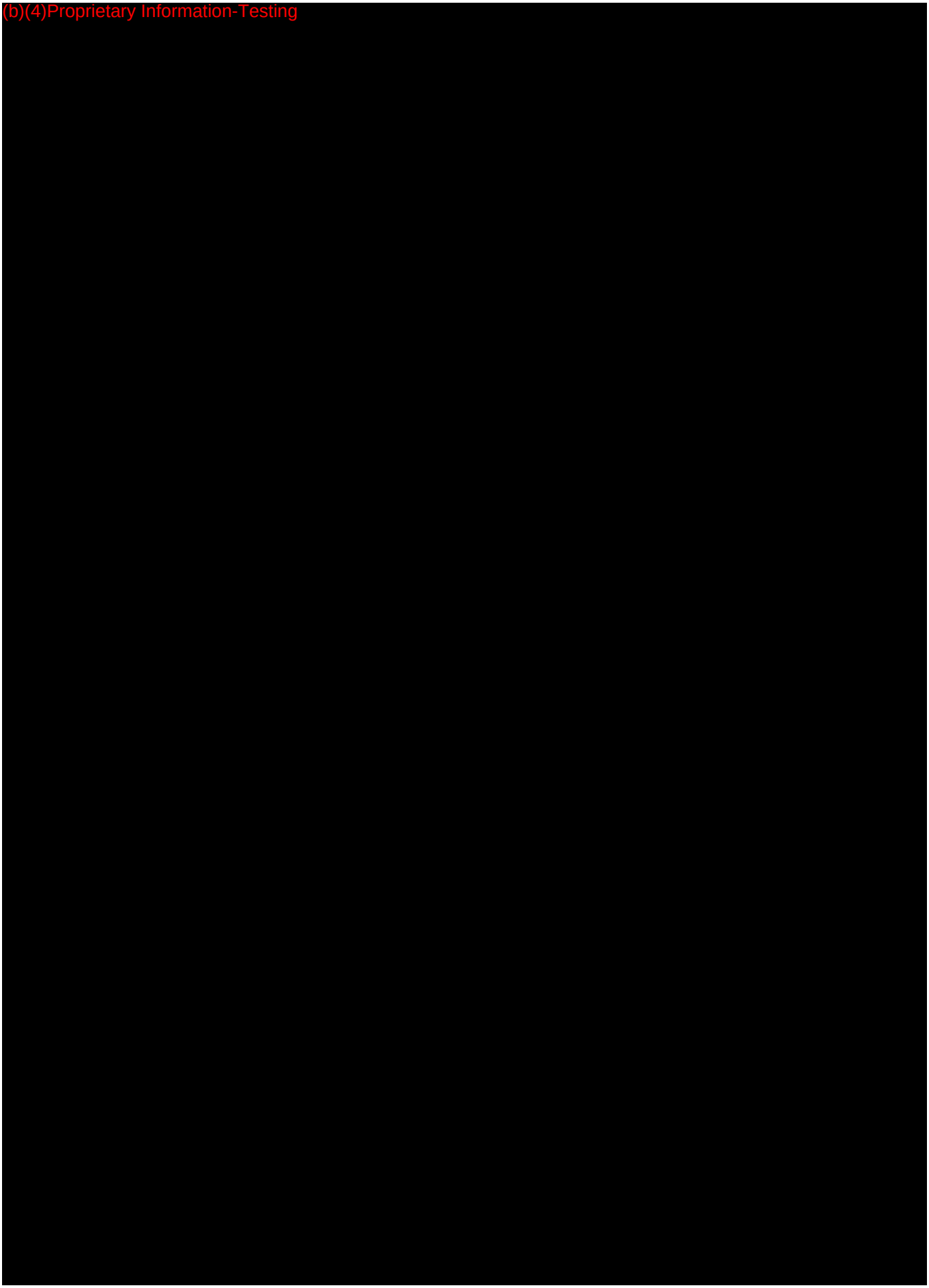
(b)(4)Proprietary Information-Testing



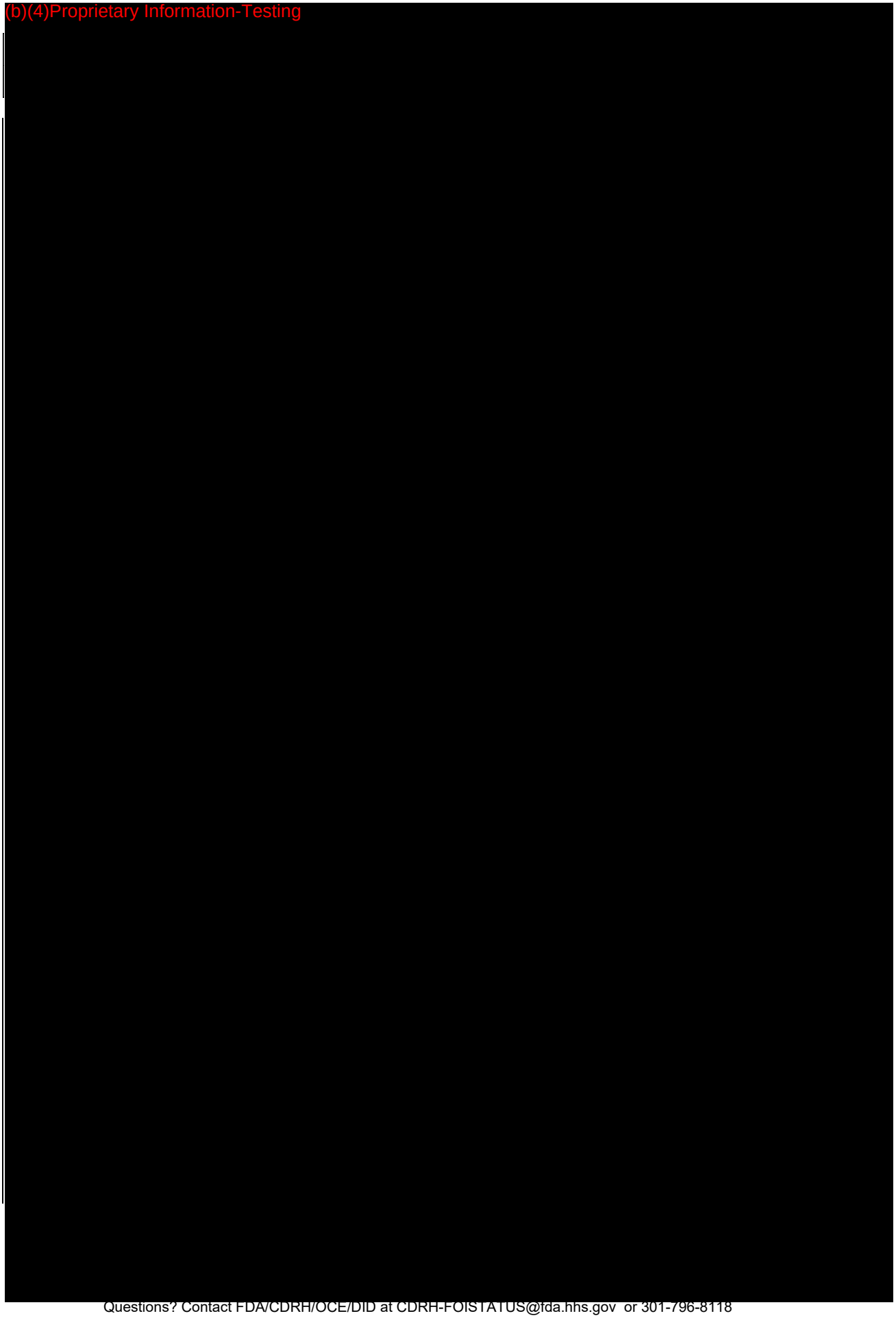
(b)(4)Proprietary Information-Testing



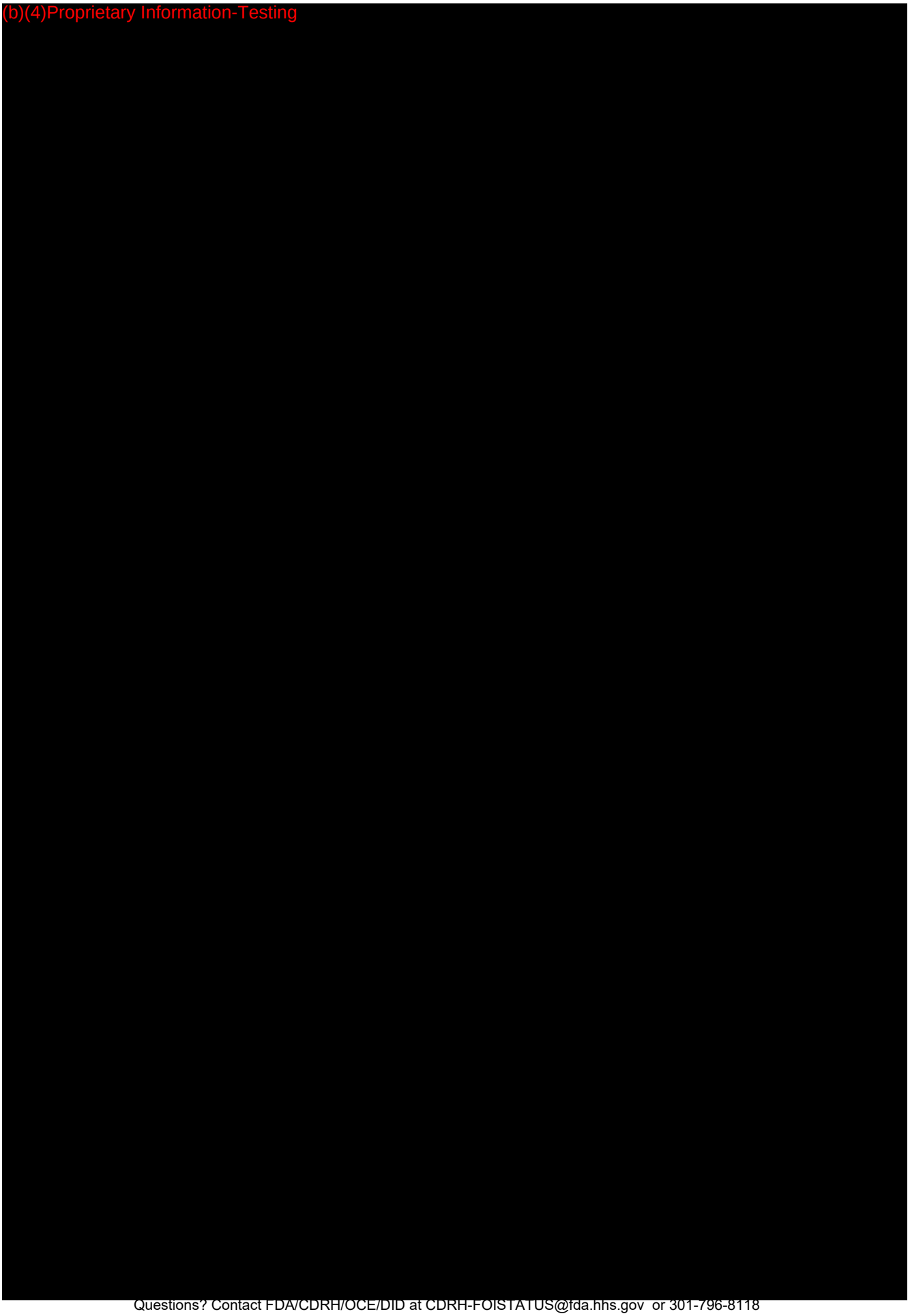
(b)(4)Proprietary Information-Testing



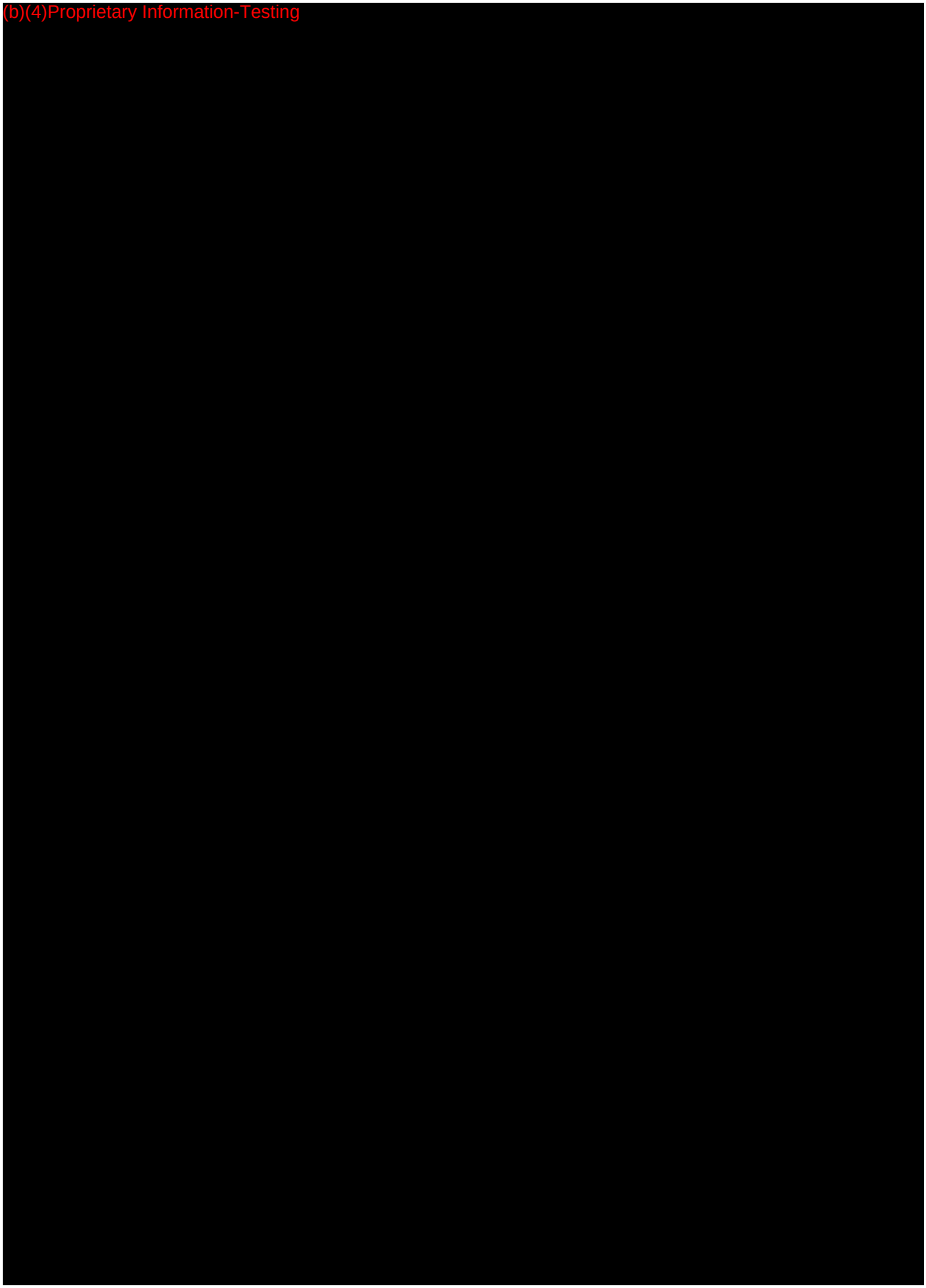
(b)(4)Proprietary Information-Testing



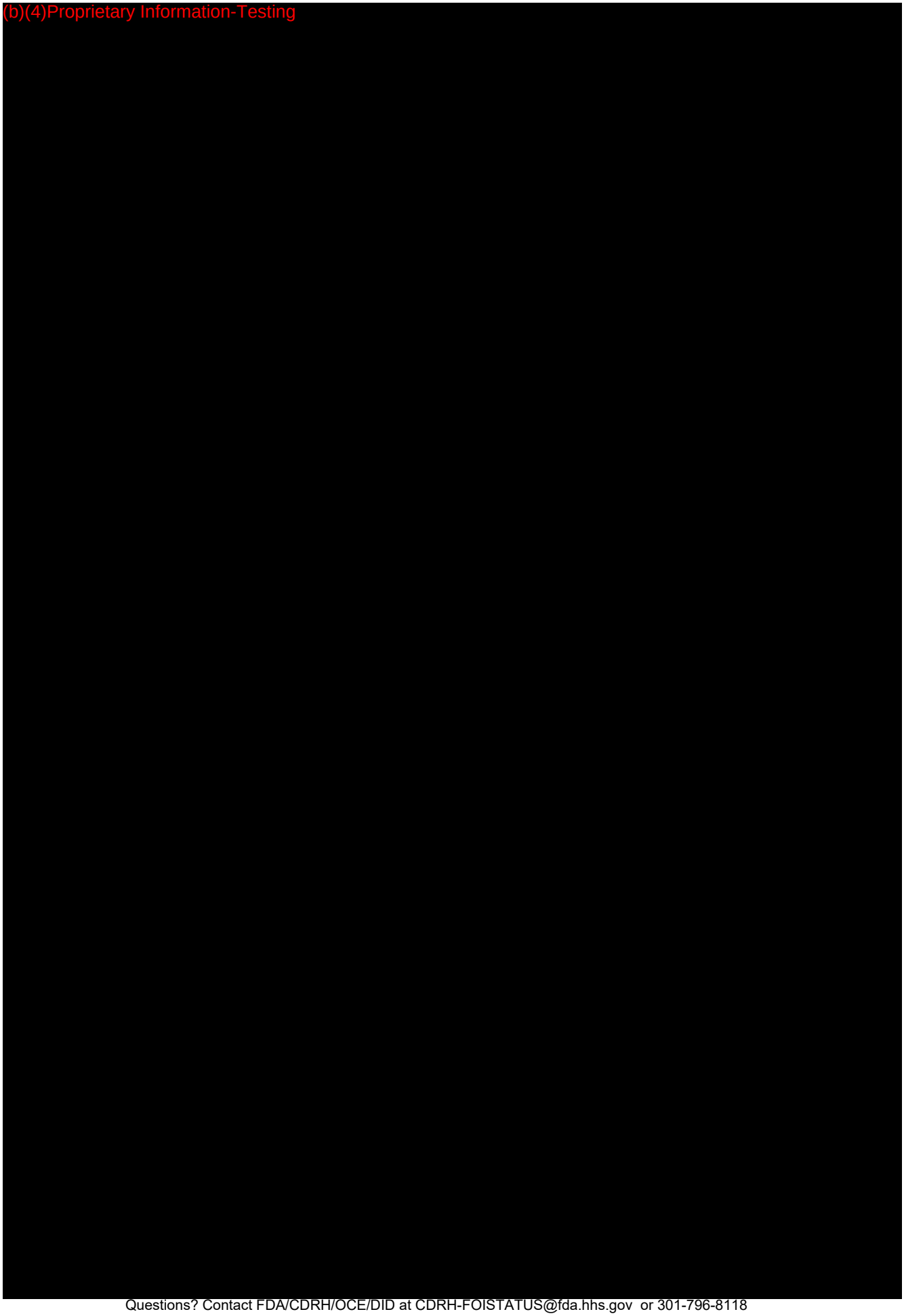
(b)(4)Proprietary Information-Testing



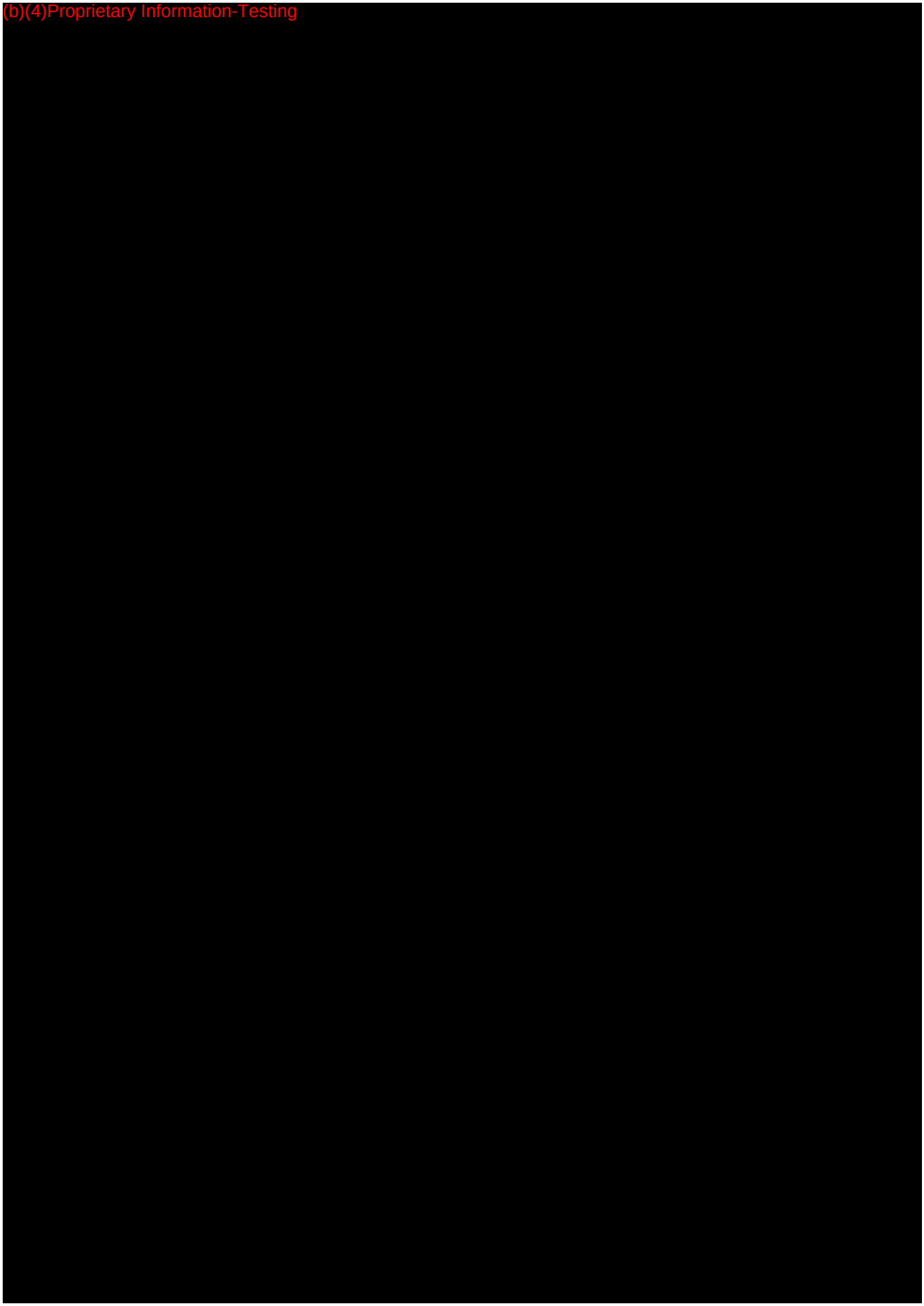
(b)(4)Proprietary Information-Testing



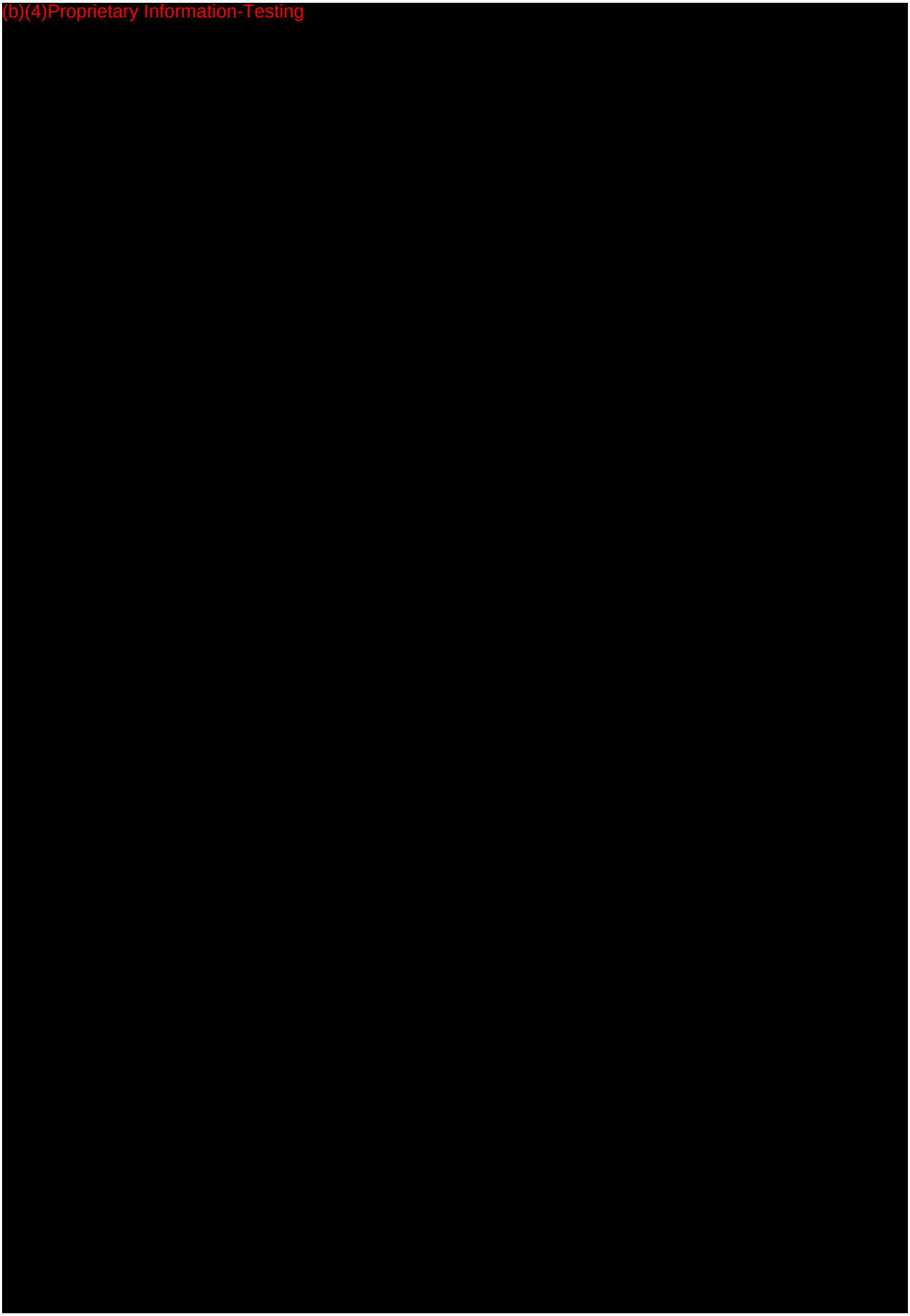
(b)(4)Proprietary Information-Testing



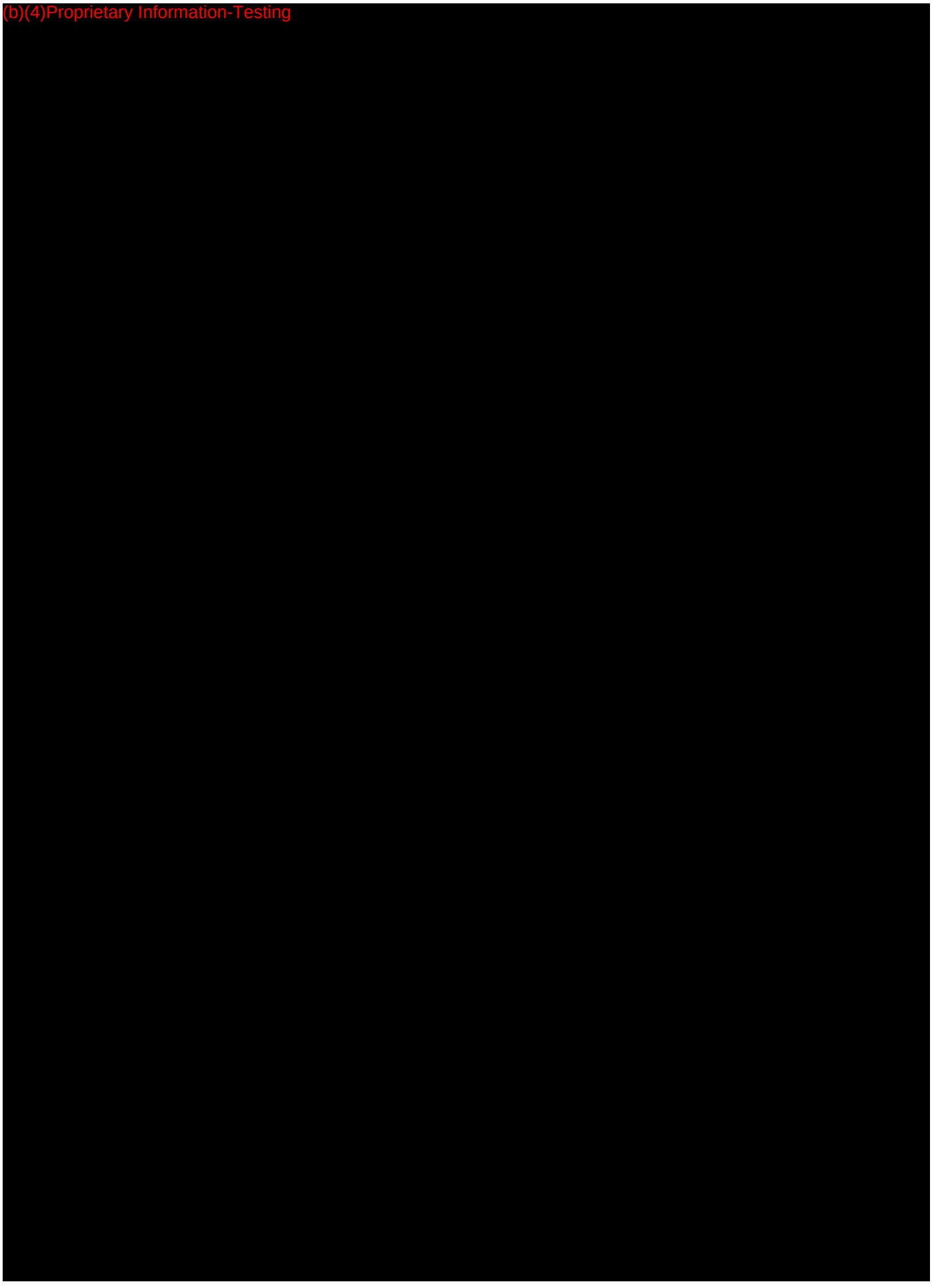
(b)(4)Proprietary Information-Testing



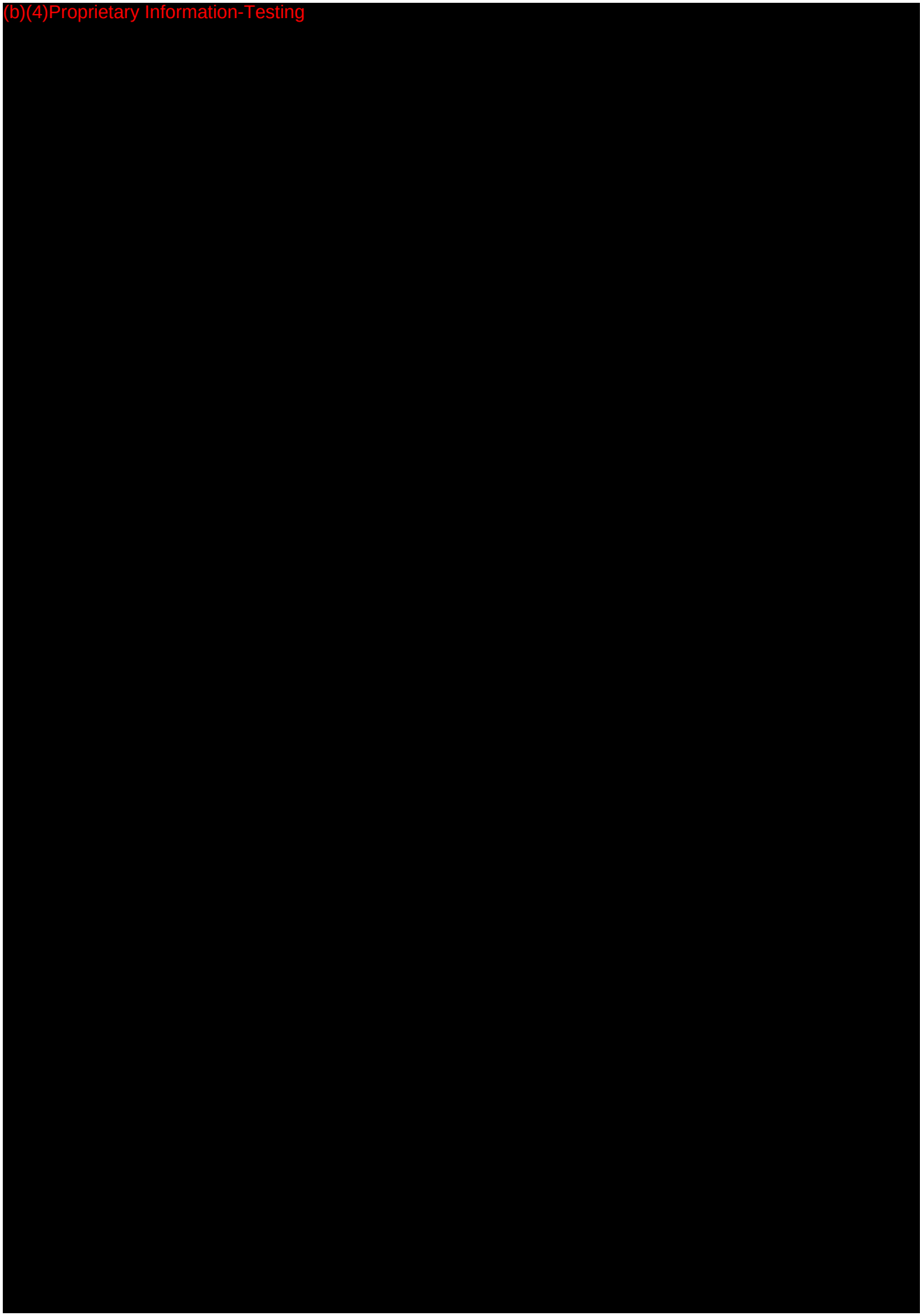
(b)(4)Proprietary Information-Testing



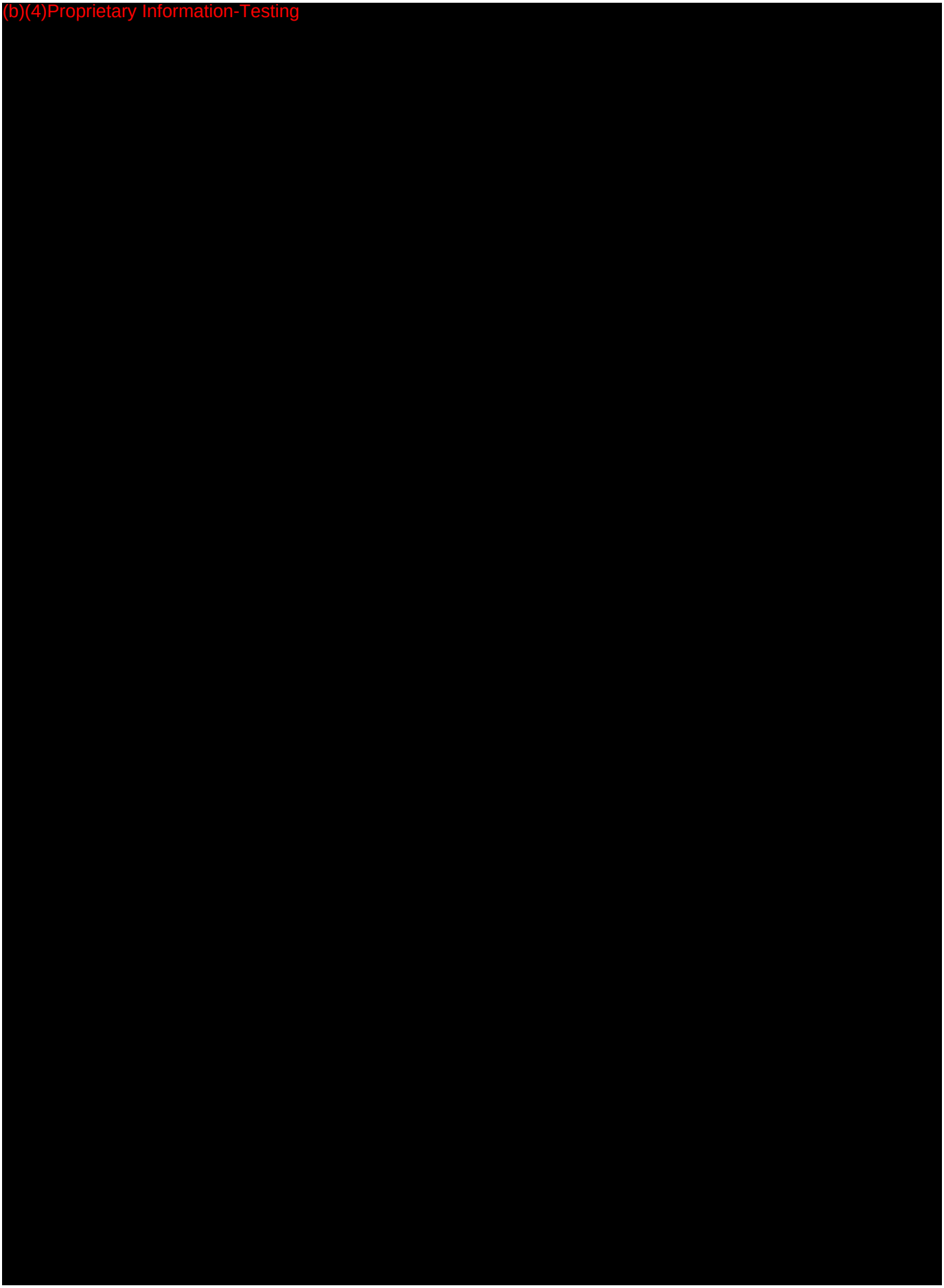
(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing

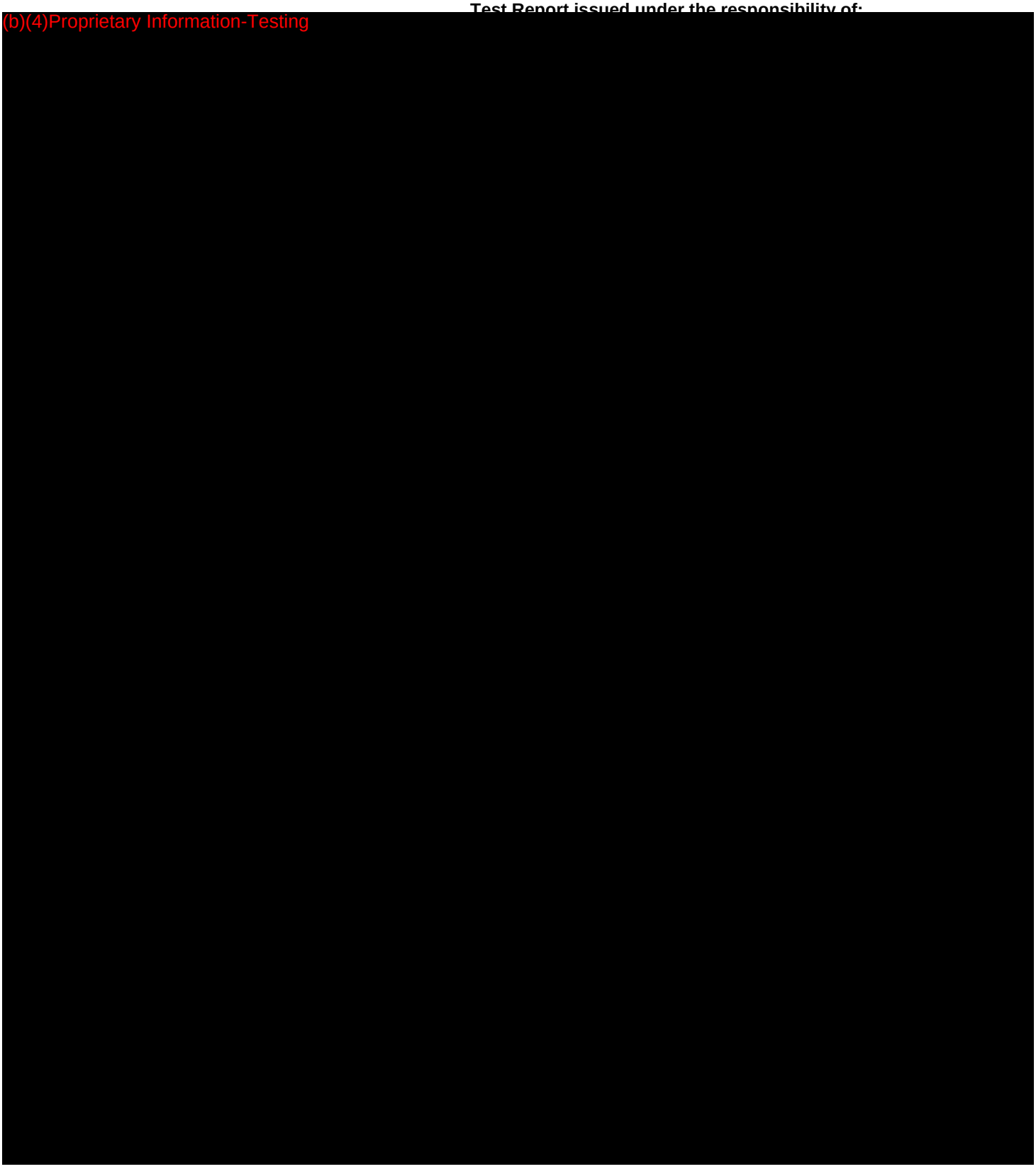


(b)(4)Proprietary Information-Testing

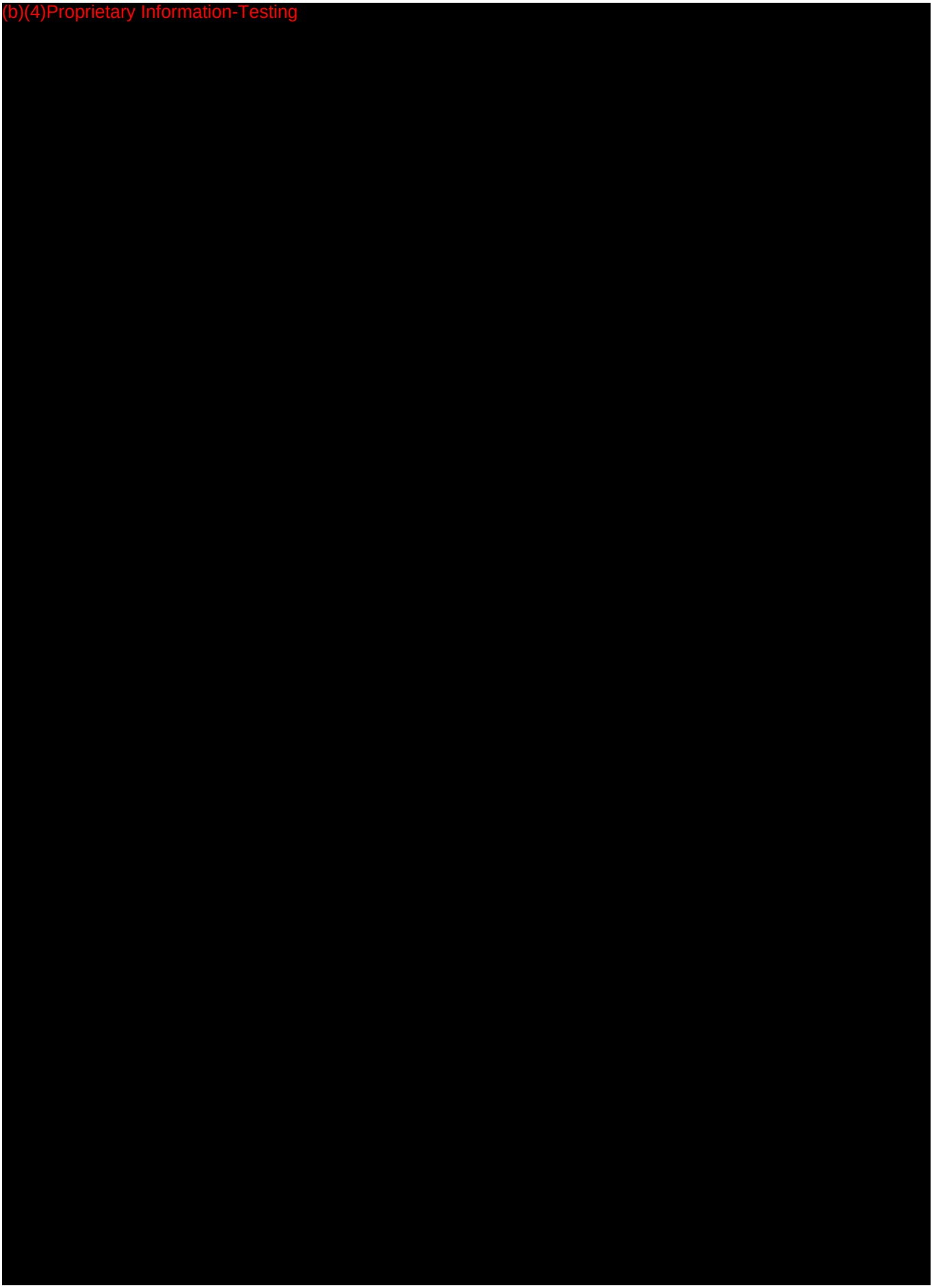


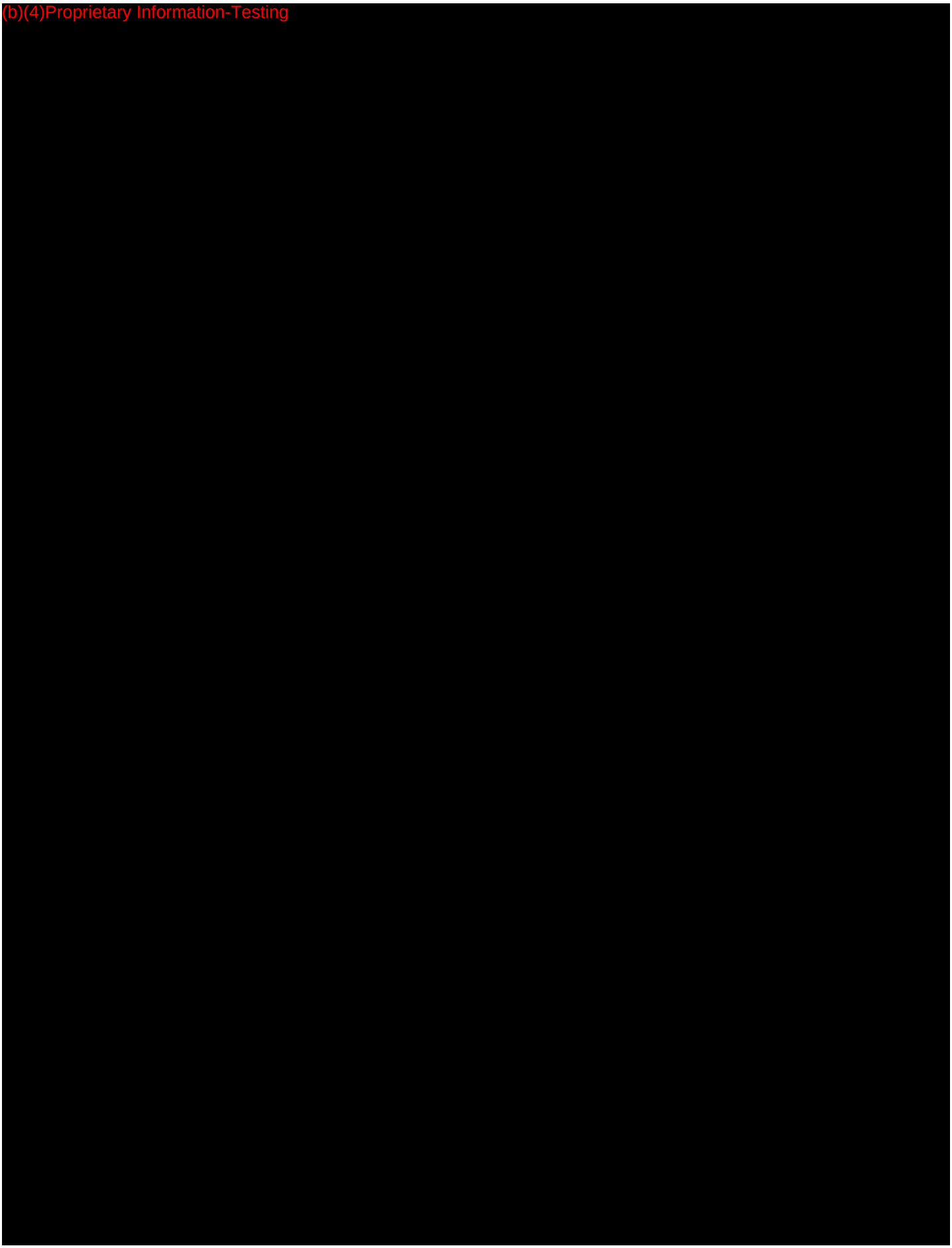
Test Report issued under the responsibility of:

(b)(4)Proprietary Information-Testing

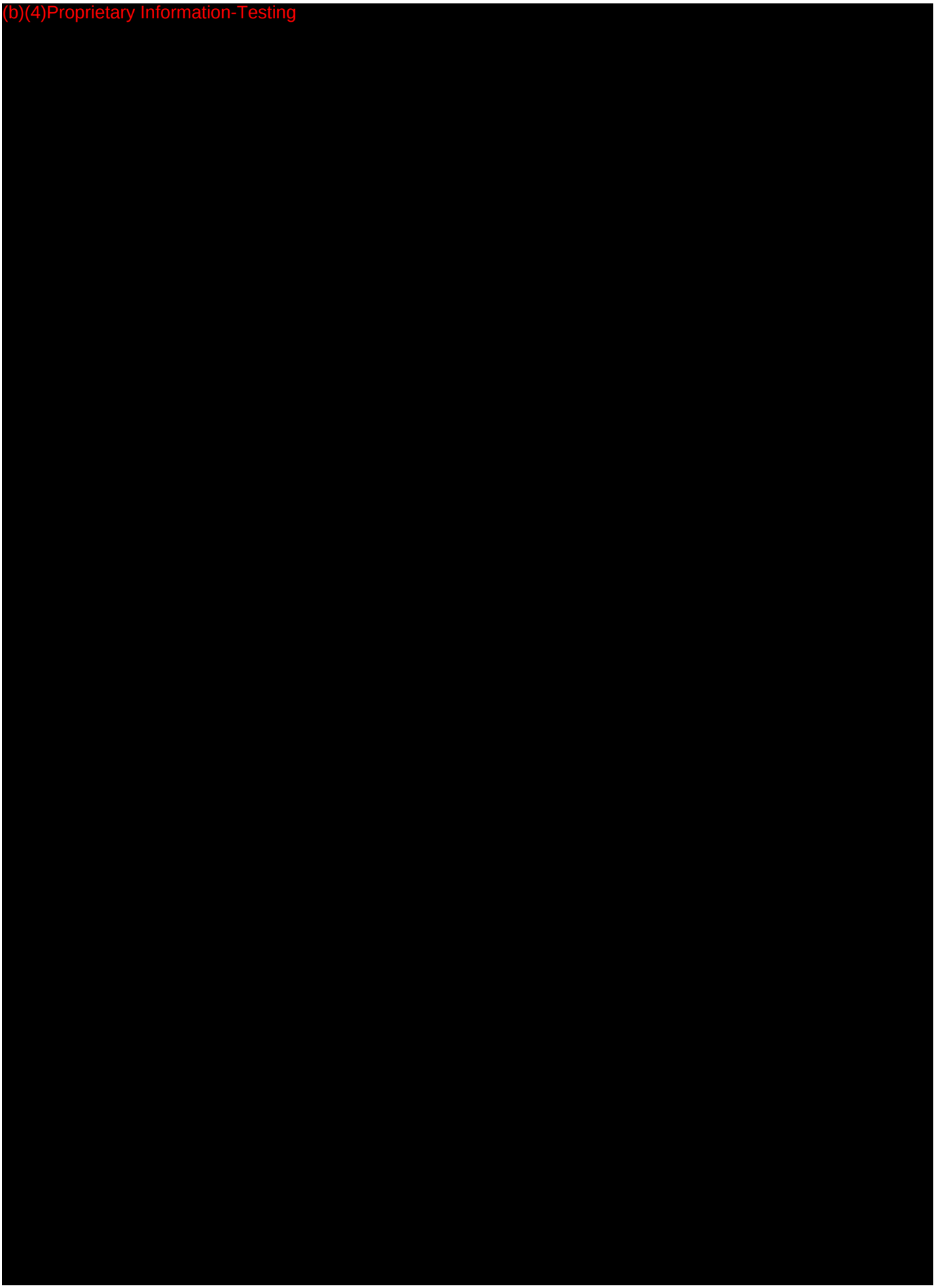


(b)(4)Proprietary Information-Testing

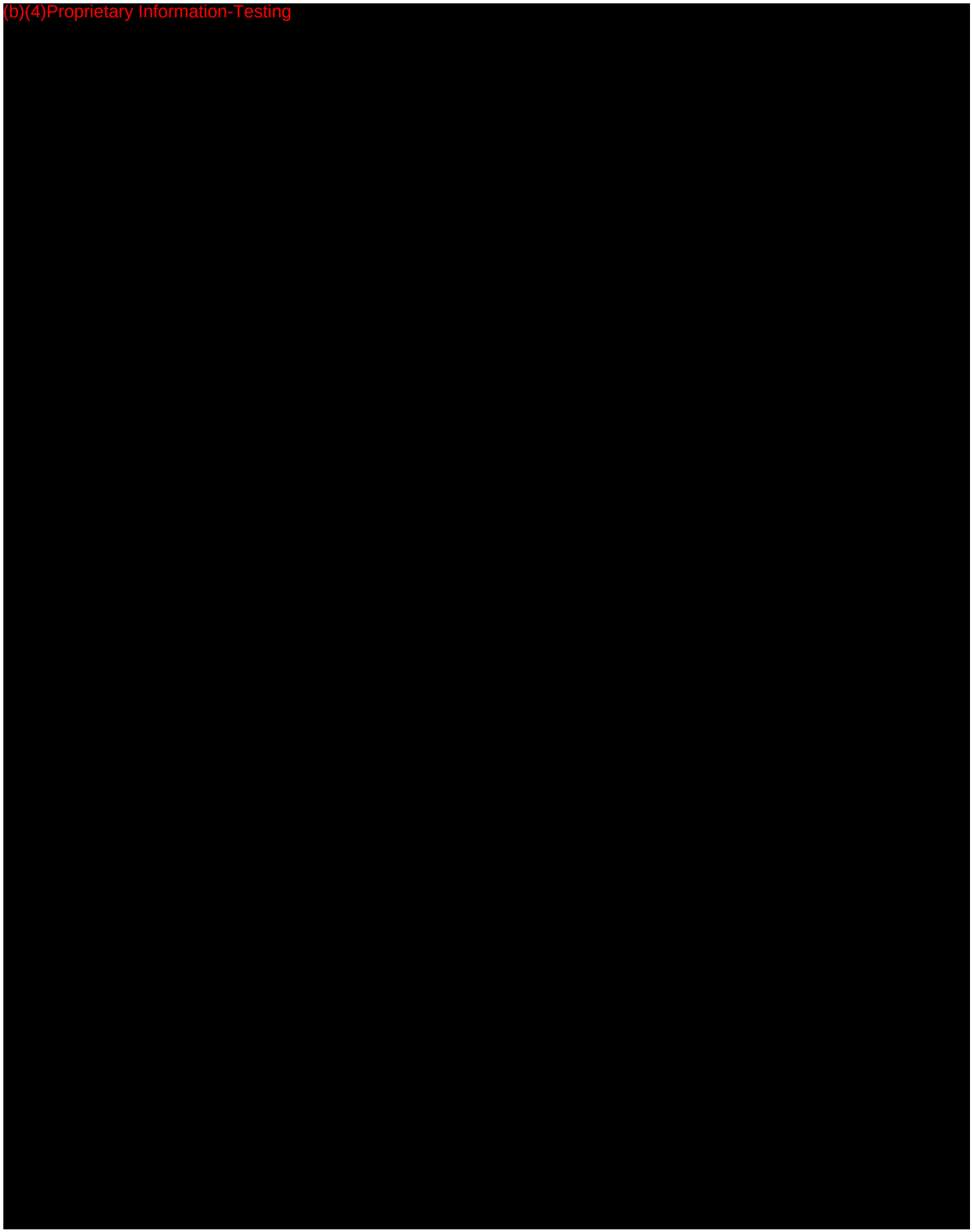




(b)(4)Proprietary Information-Testing



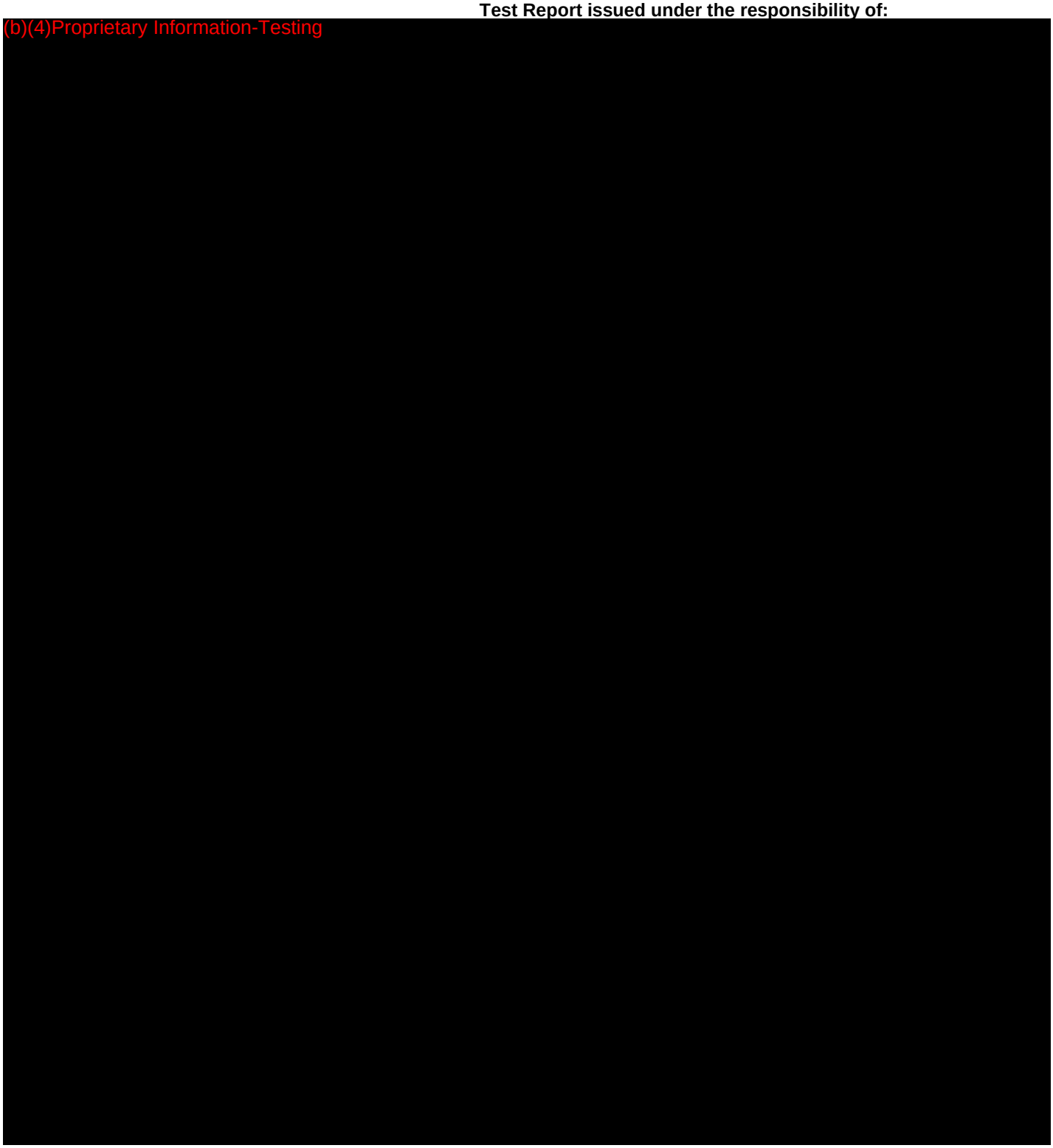
(b)(4)Proprietary Information-Testing



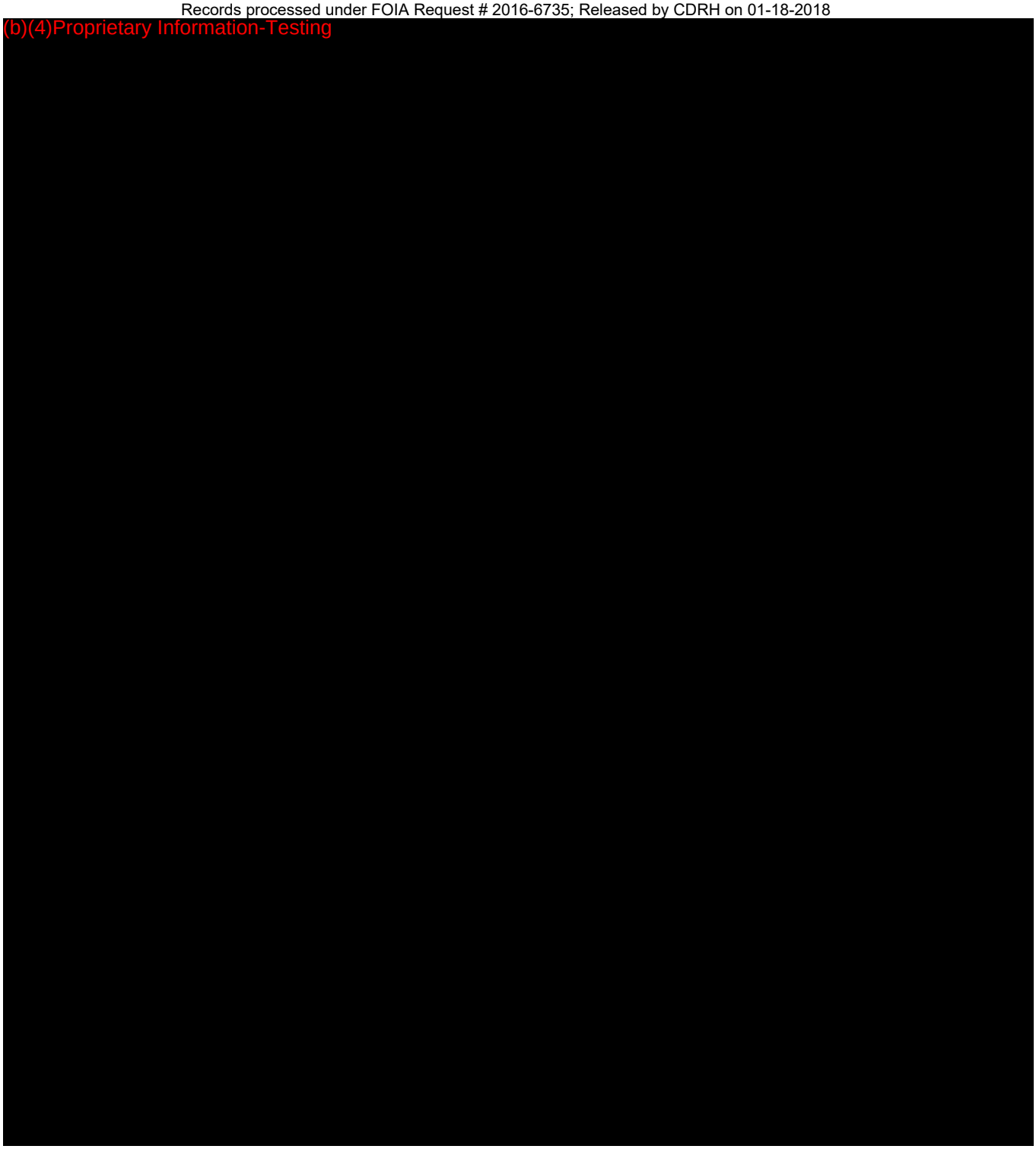
(b)(4)Proprietary Information-Testing

Test Report issued under the responsibility of:

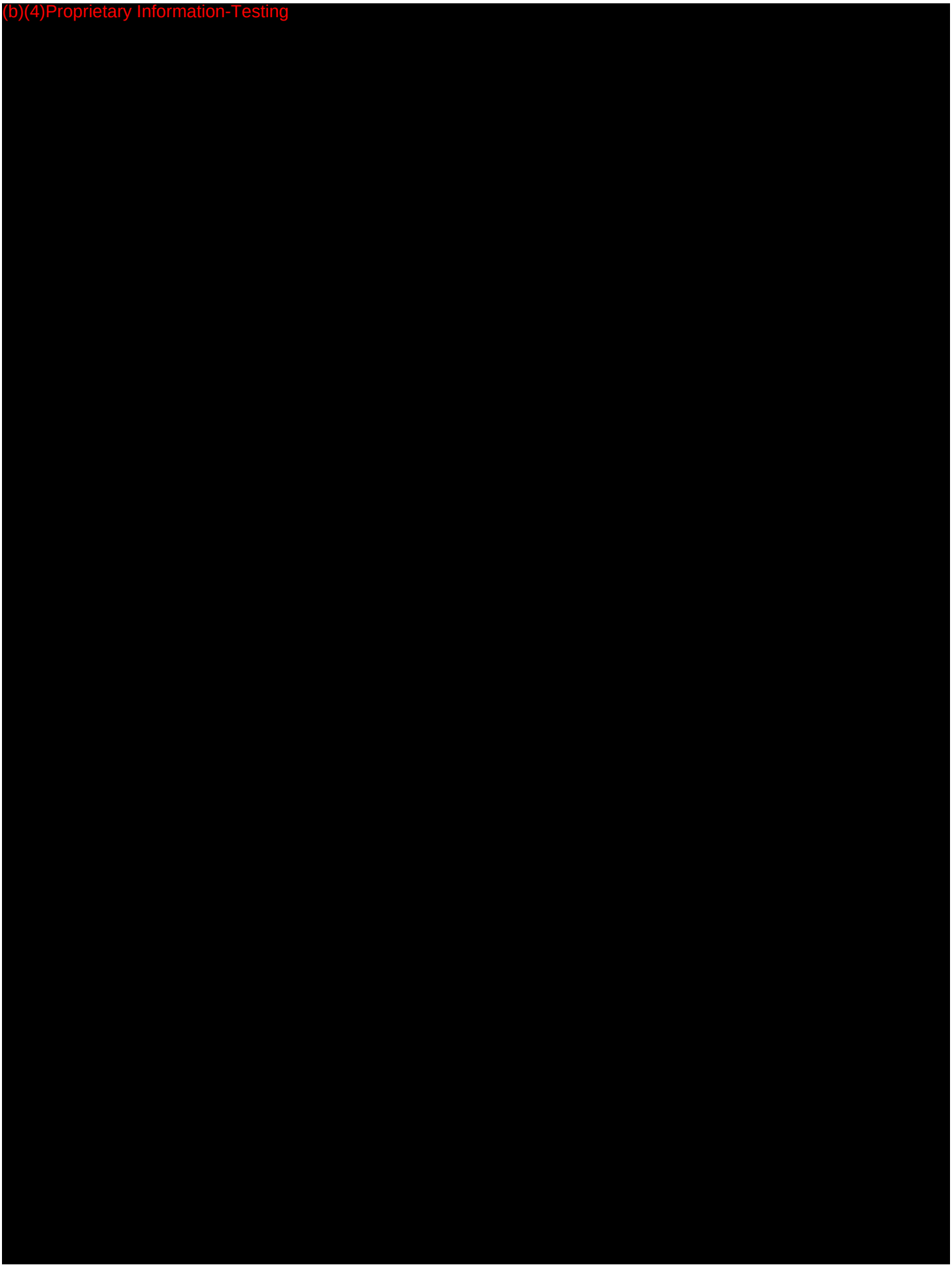
(b)(4)Proprietary Information-Testing



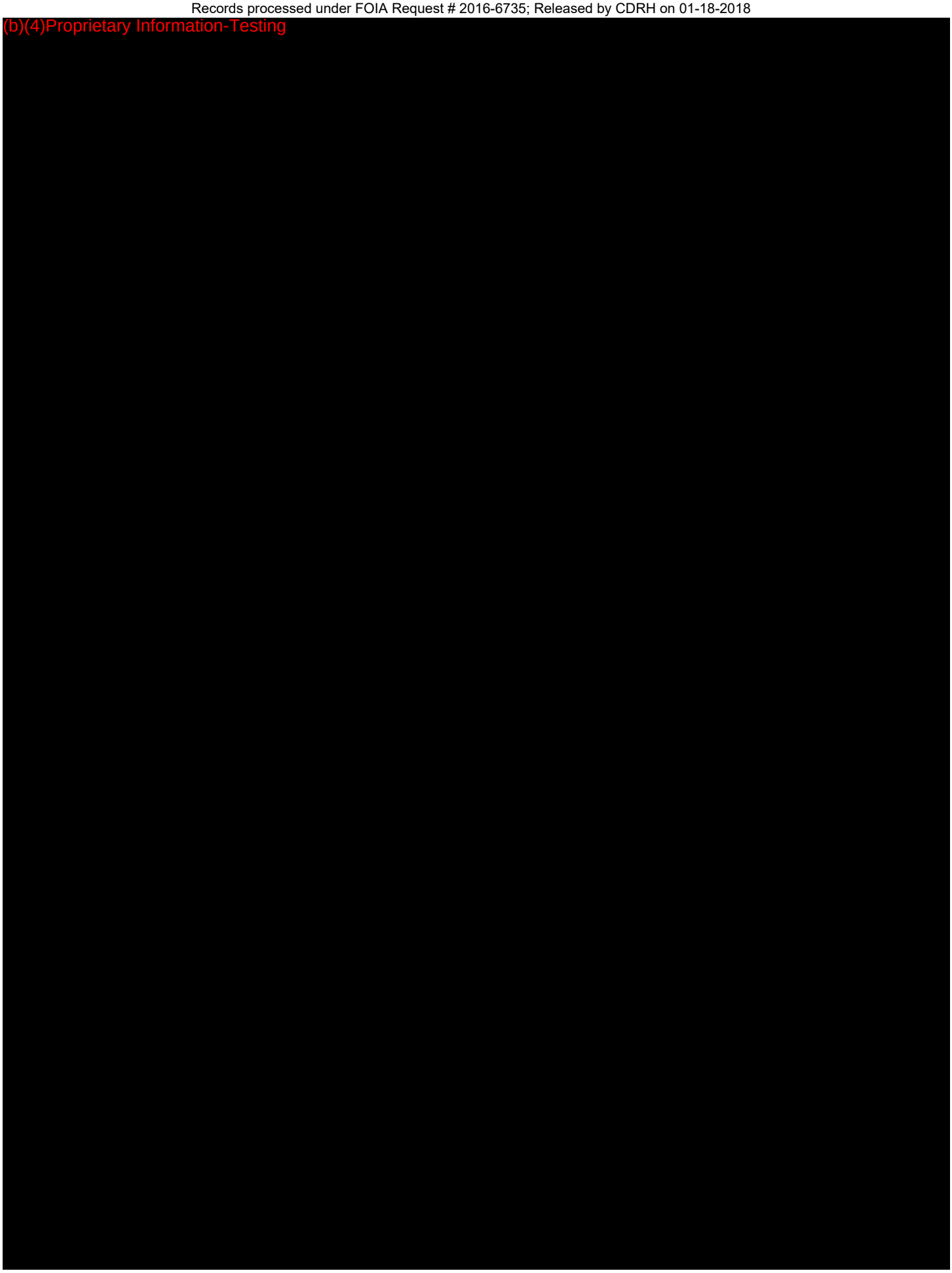
(b)(4)Proprietary Information-Testing



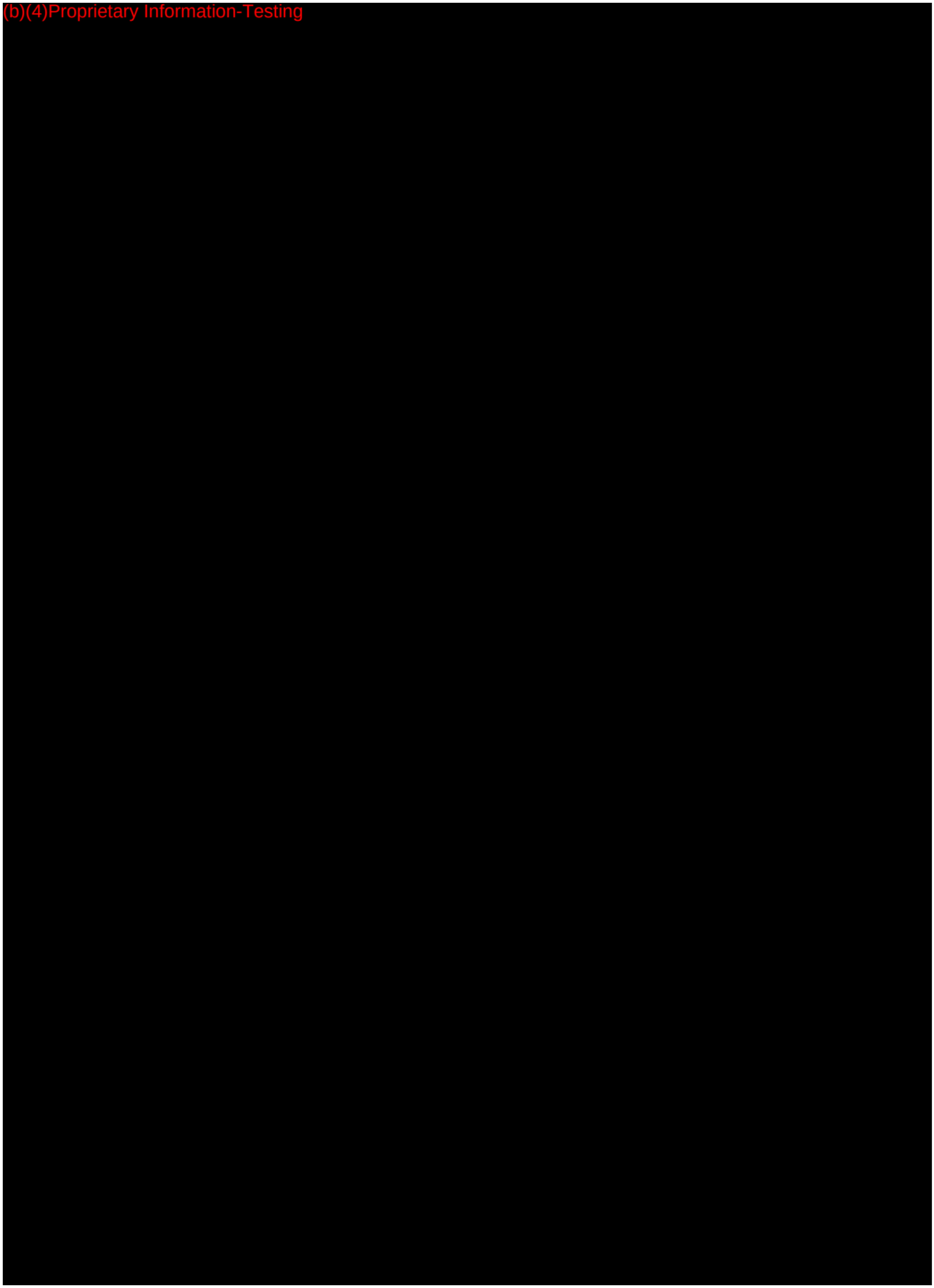
(b)(4)Proprietary Information-Testing



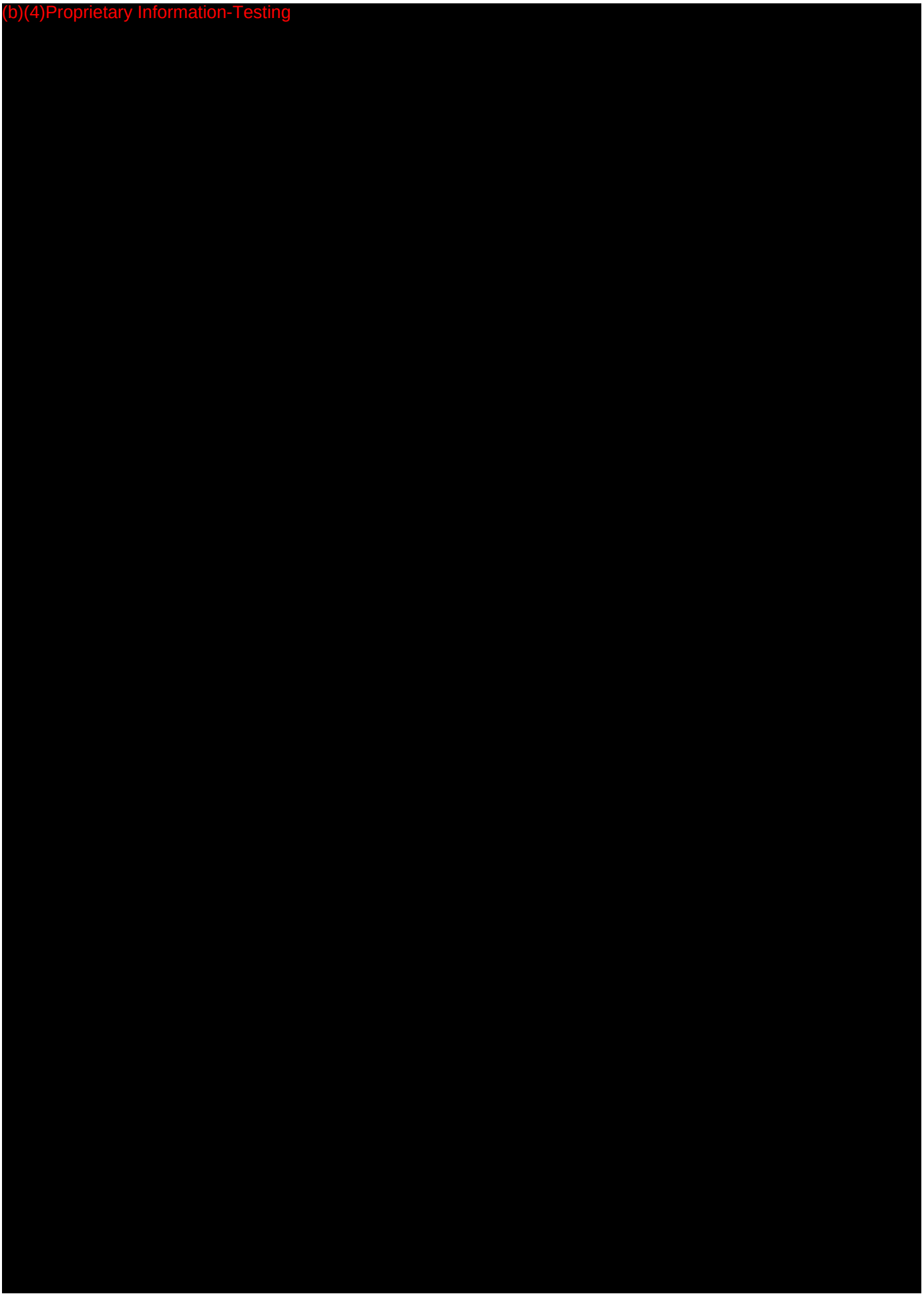
(b)(4)Proprietary Information-Testing



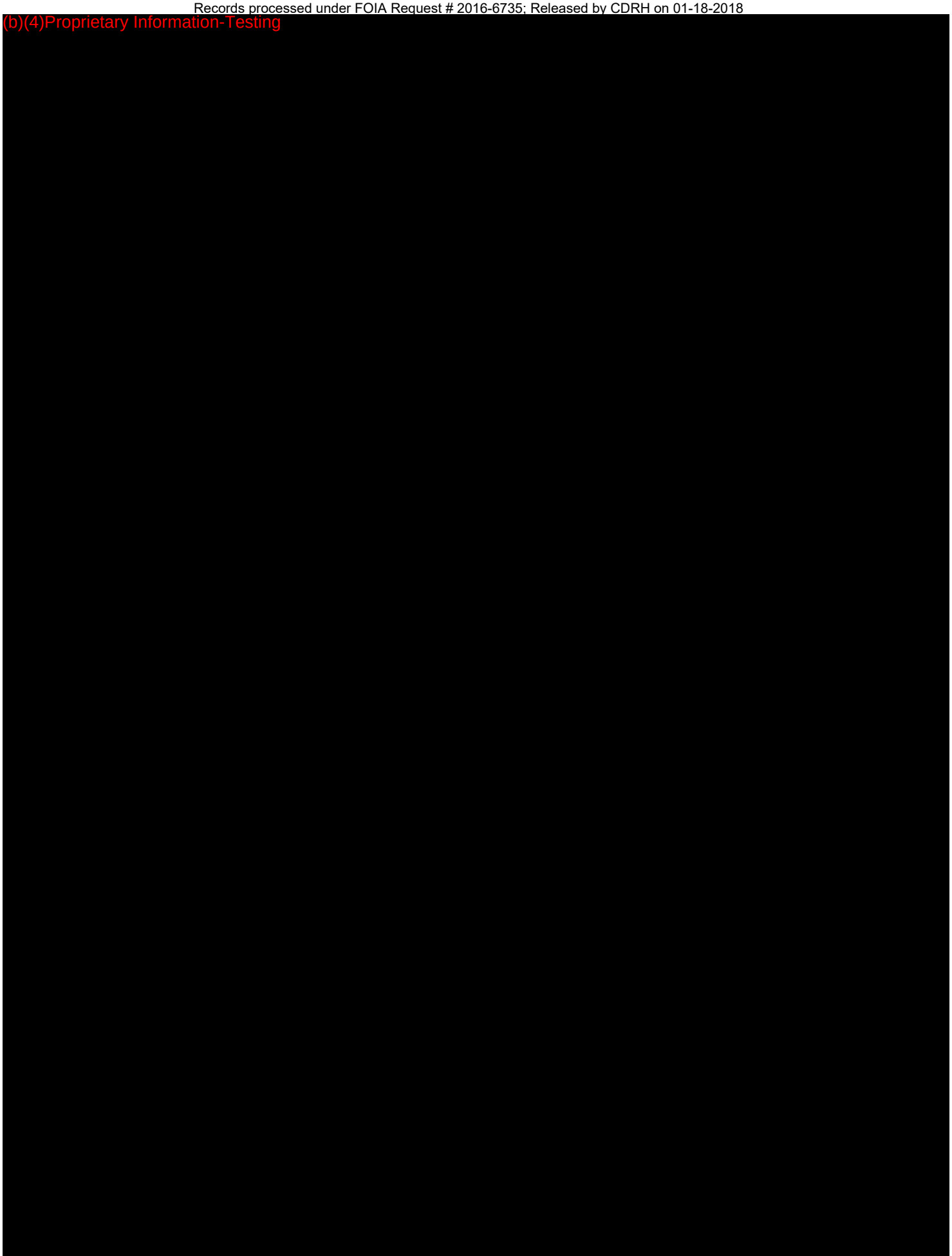
(b)(4)Proprietary Information-Testing



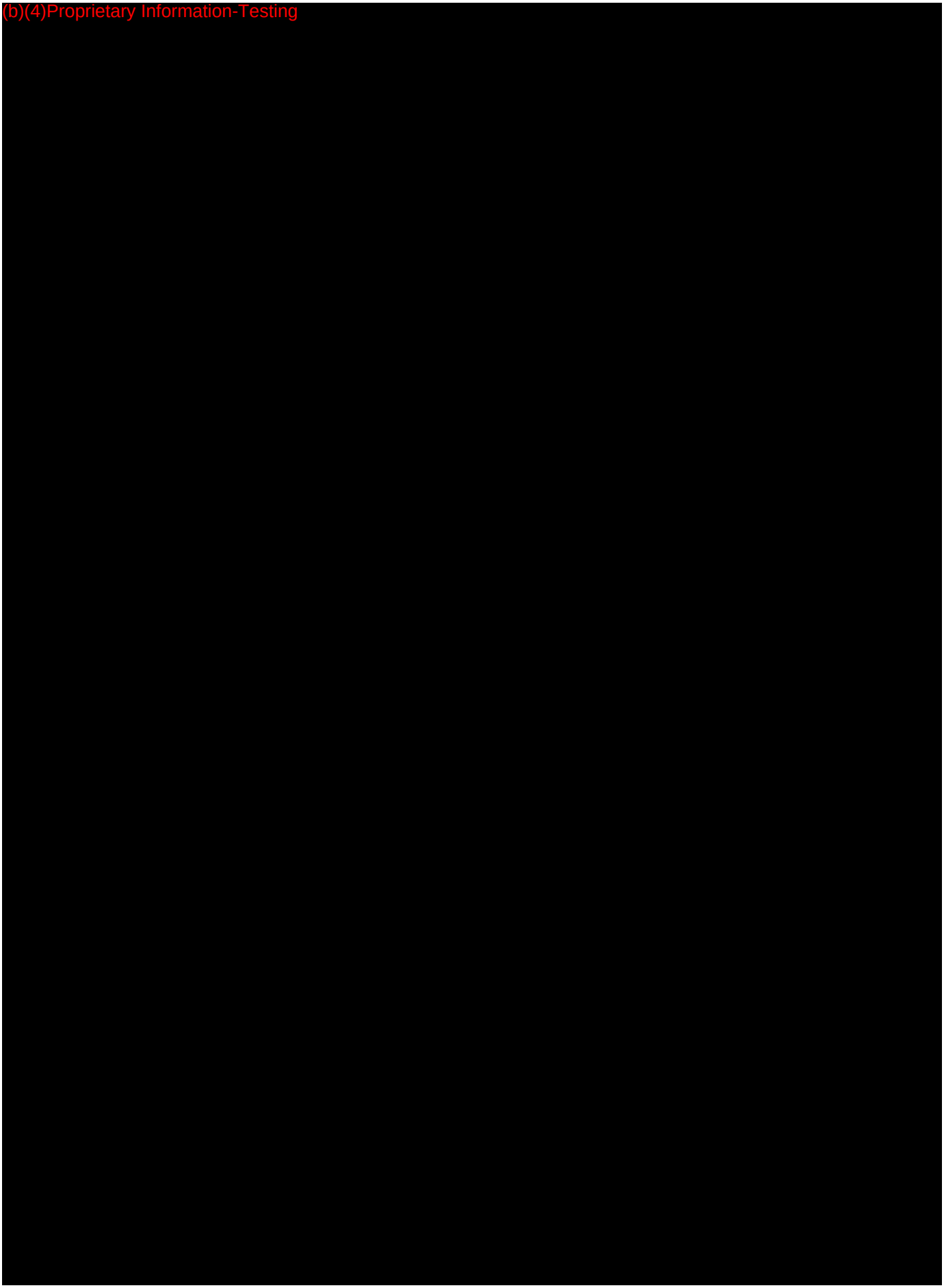
(b)(4)Proprietary Information-Testing



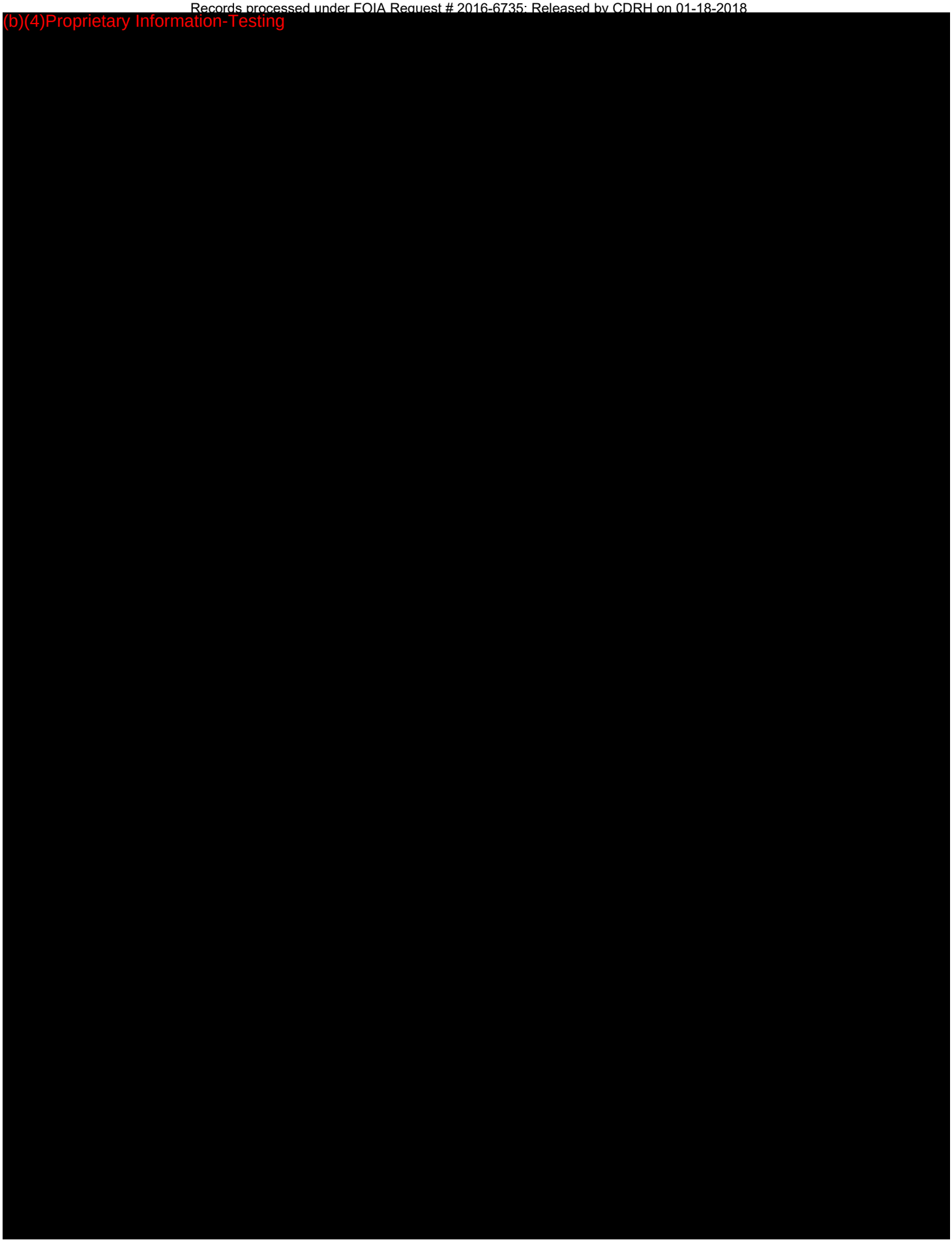
(b)(4)Proprietary Information-Testing



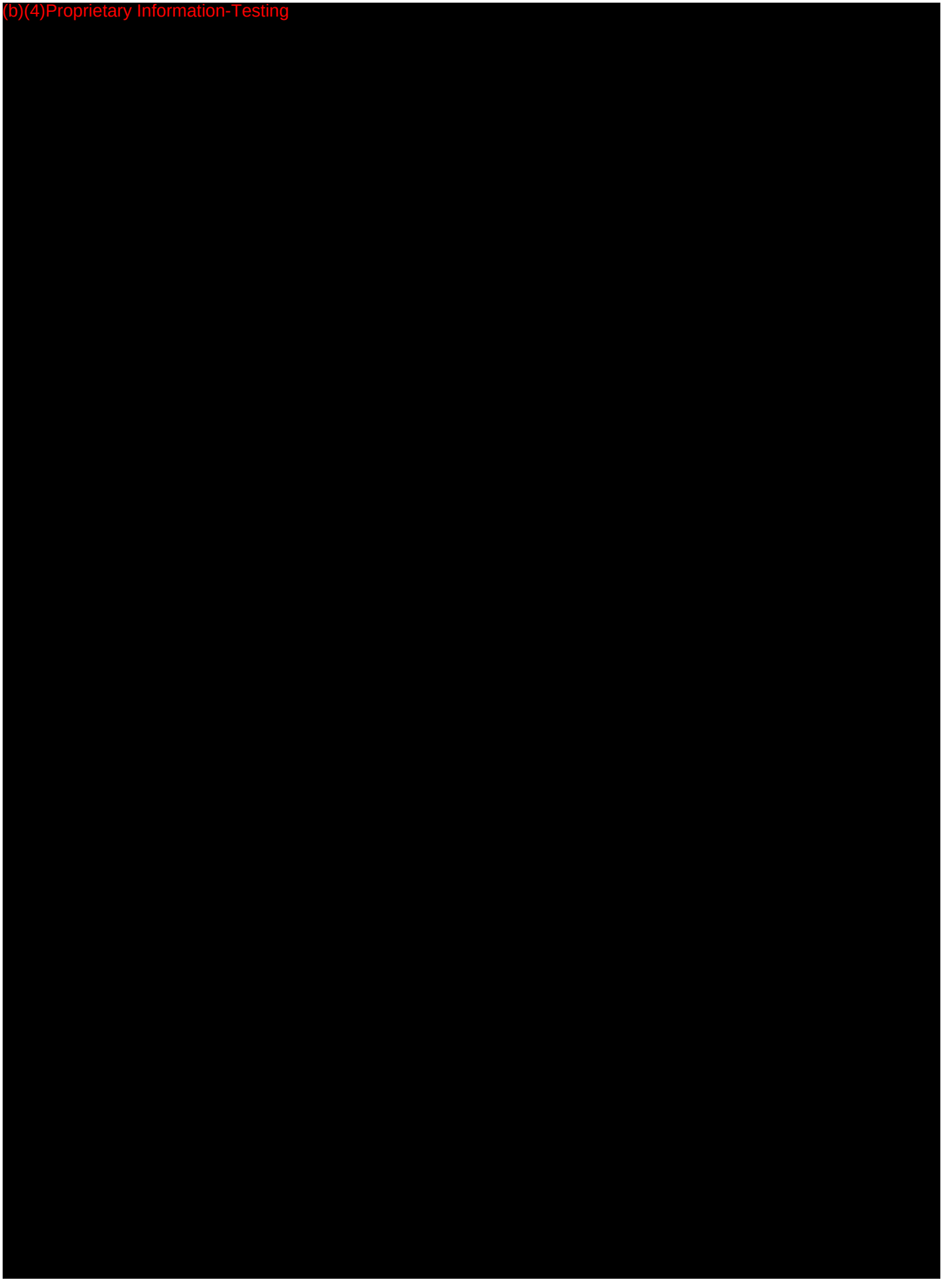
(b)(4)Proprietary Information-Testing



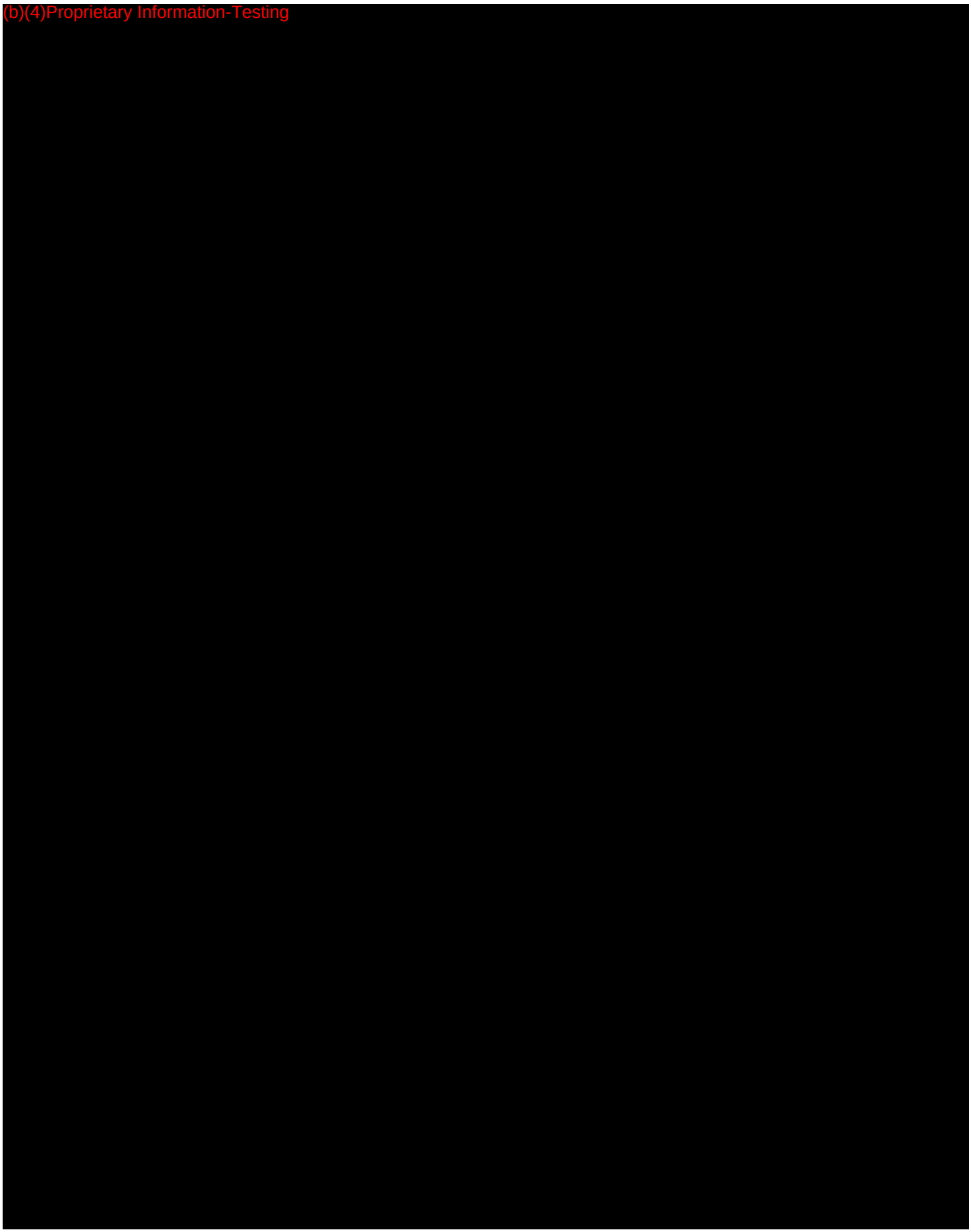
(b)(4)Proprietary Information-Testing



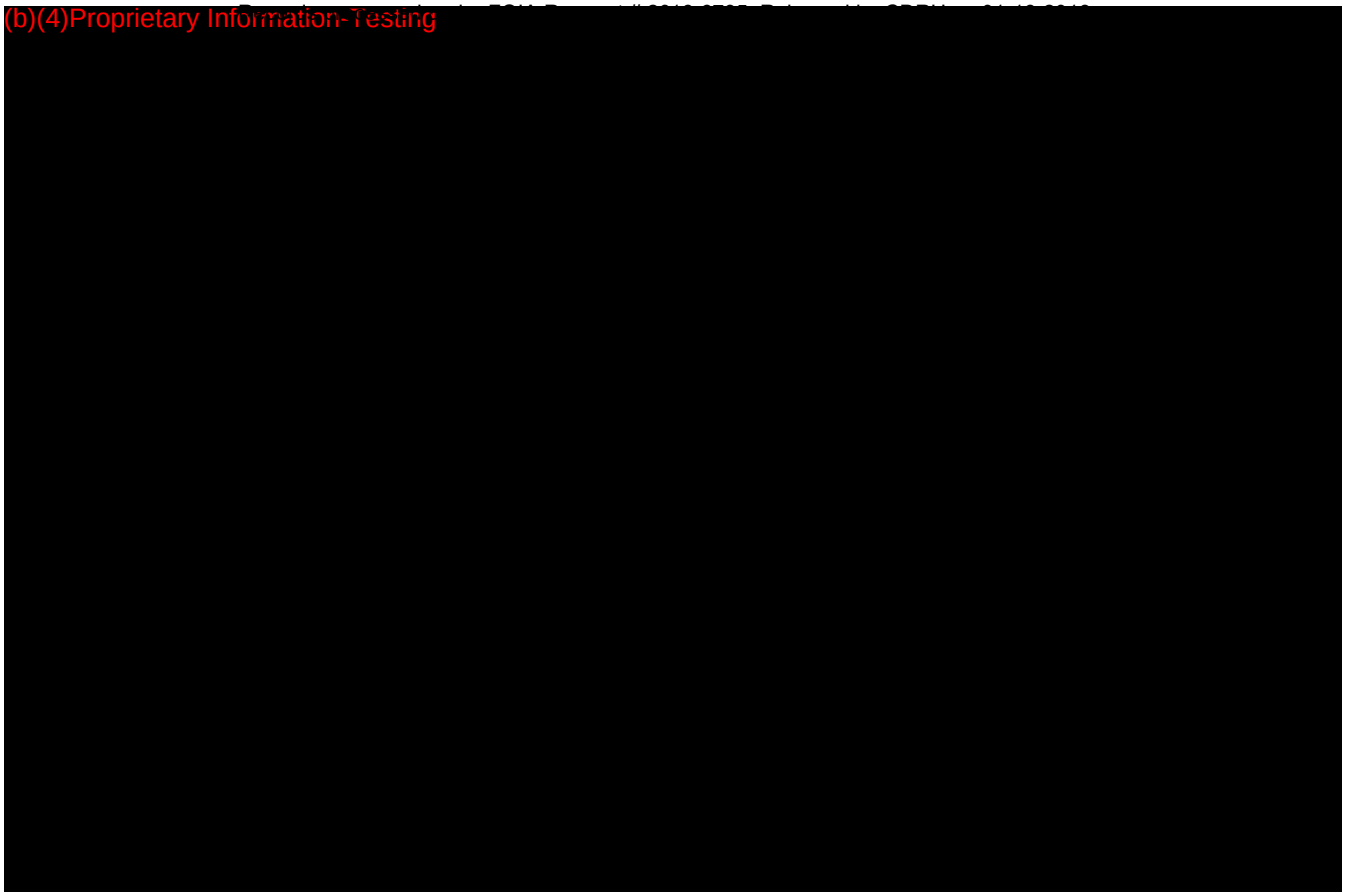
(b)(4)Proprietary Information-Testing



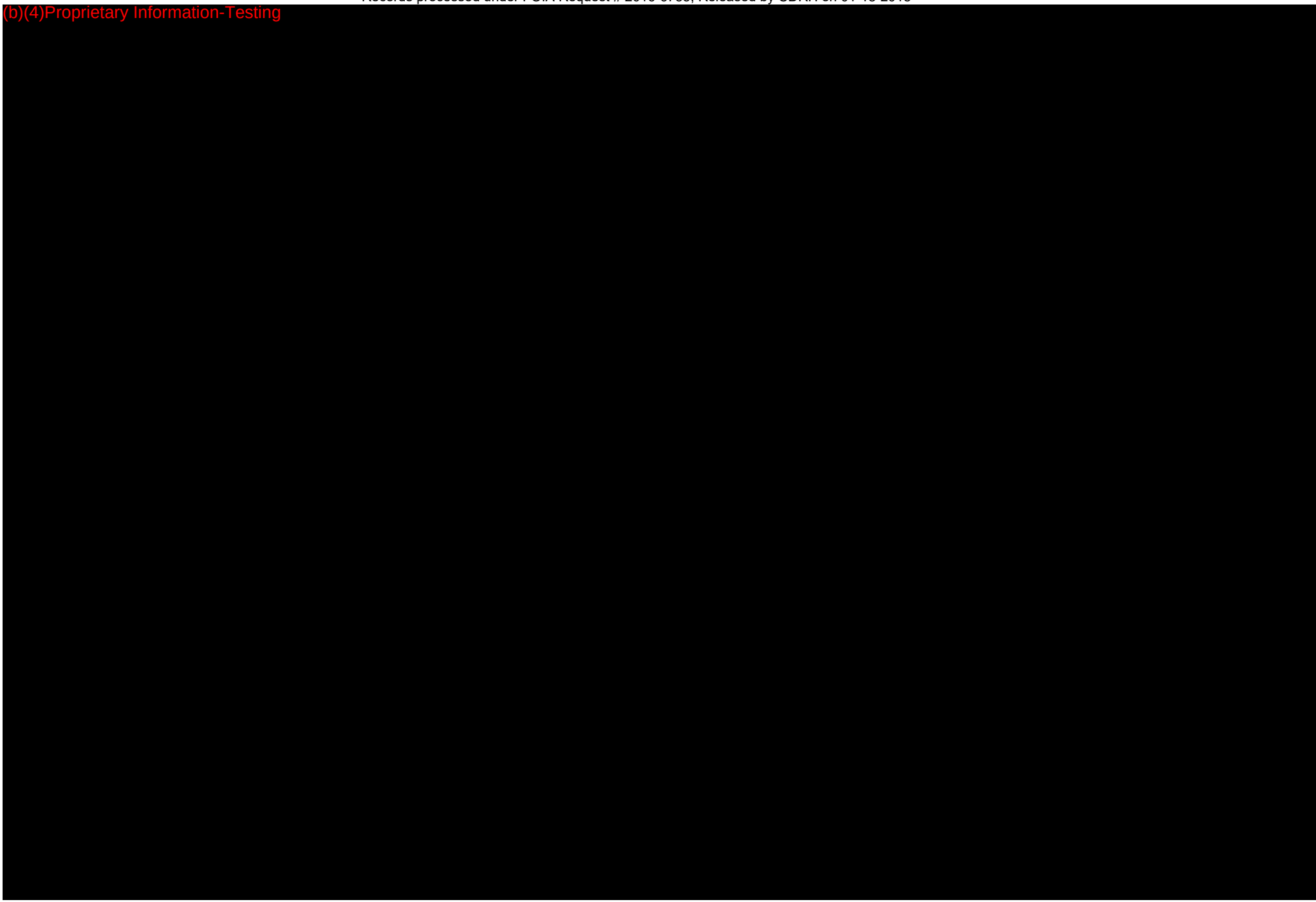
(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing

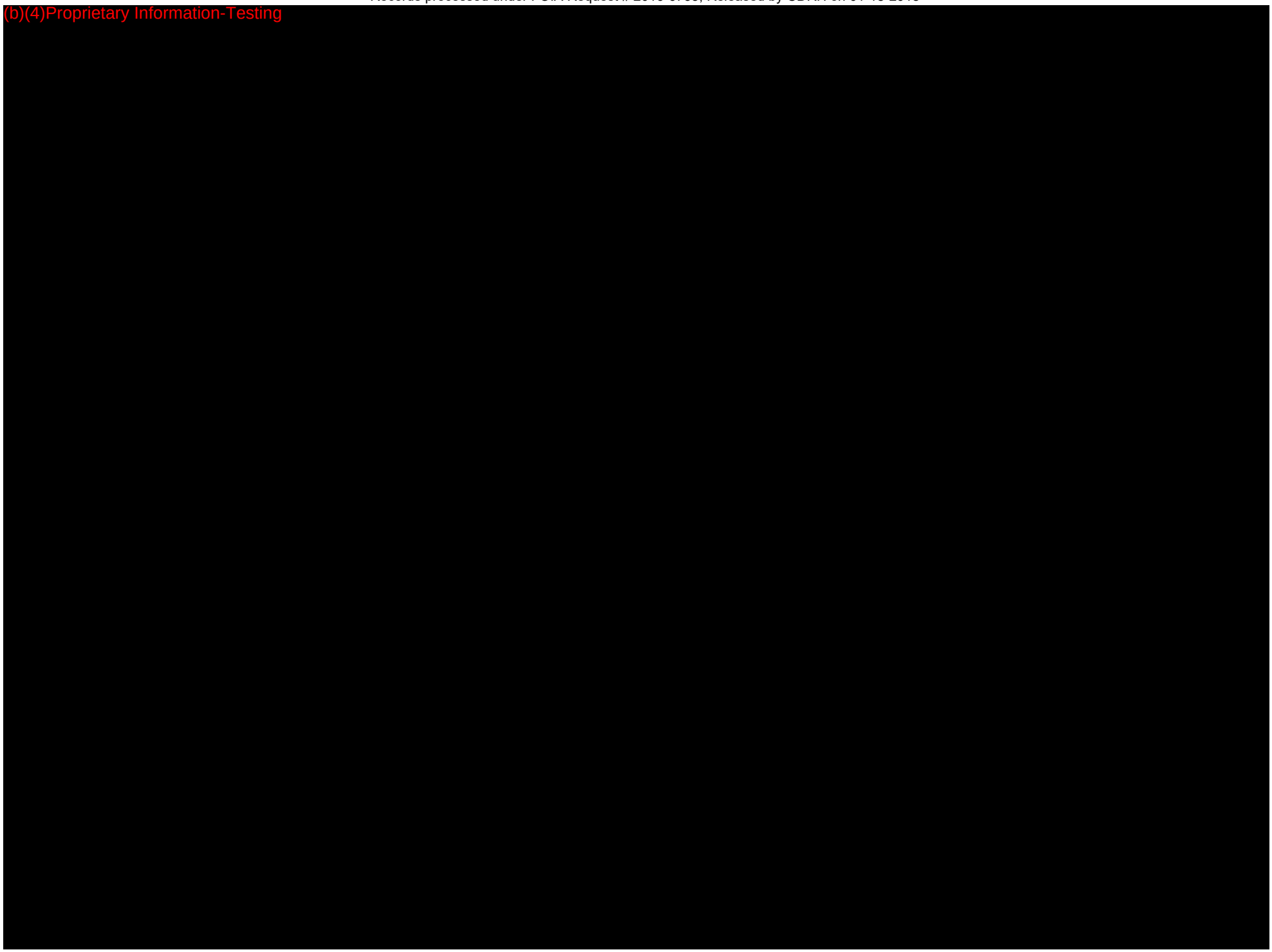


(b)(4)Proprietary Information-Testing

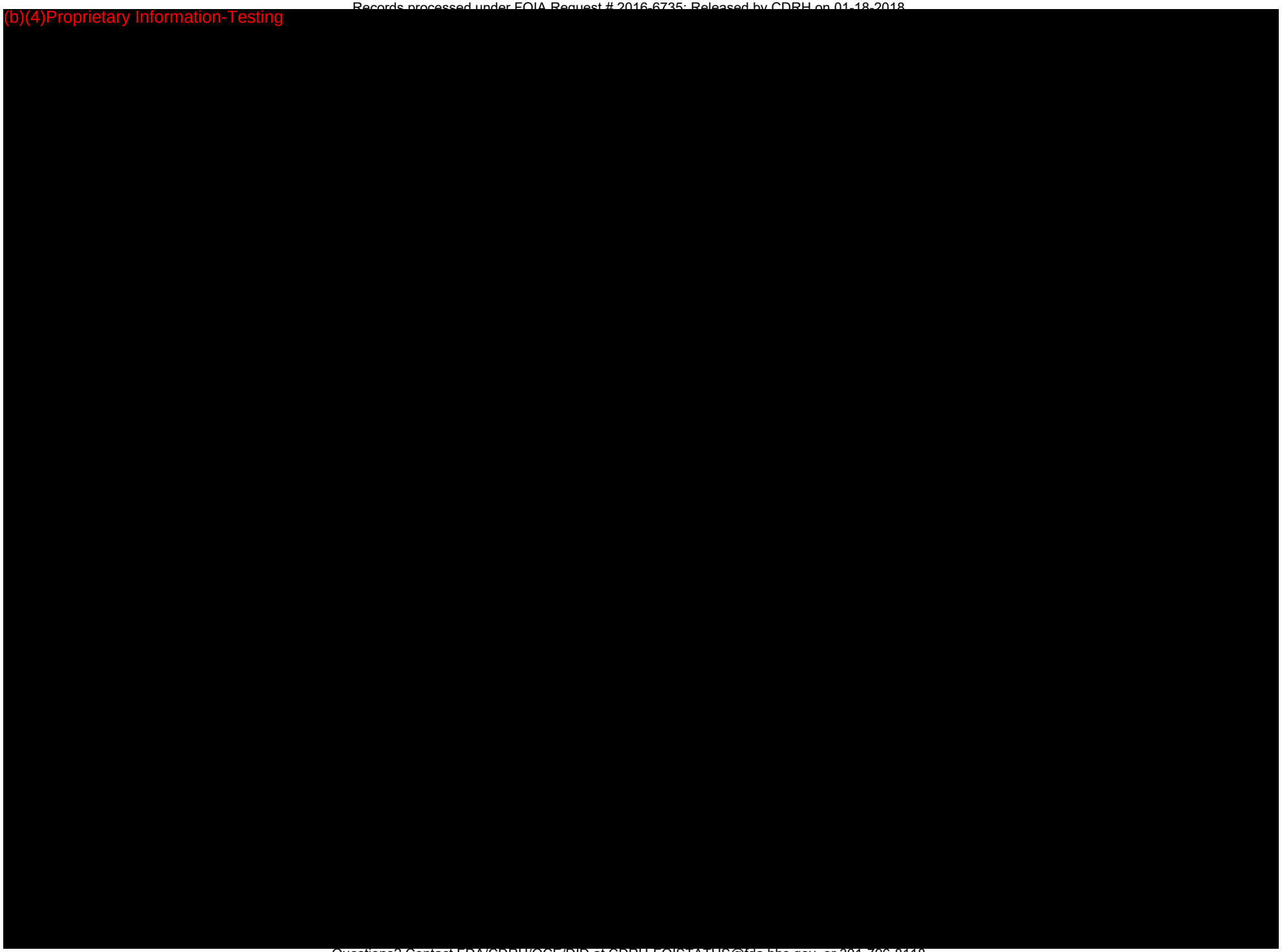


(b)(4)Proprietary Information-Testing

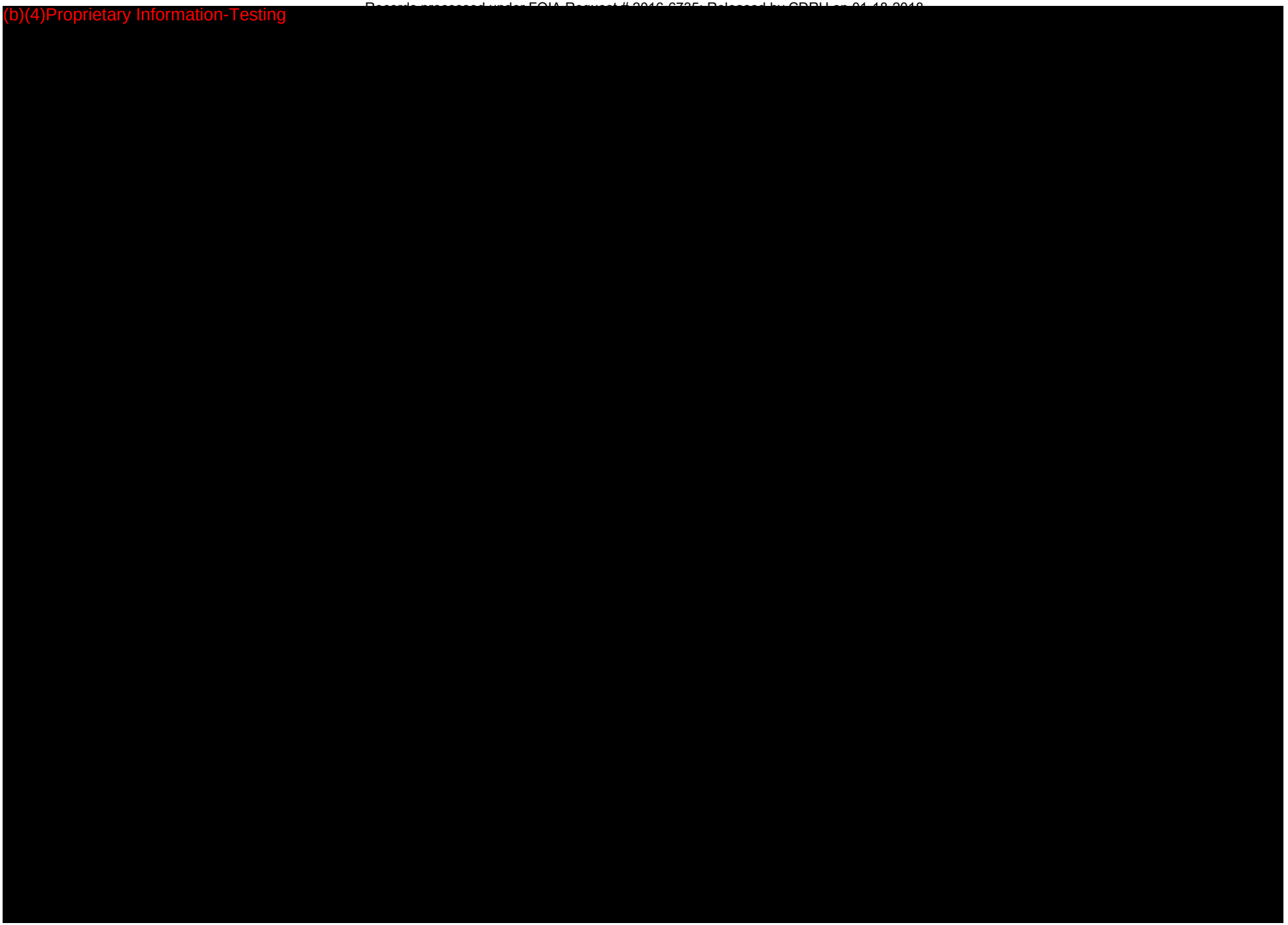
[redacted]



(b)(4)Proprietary Information-Testing



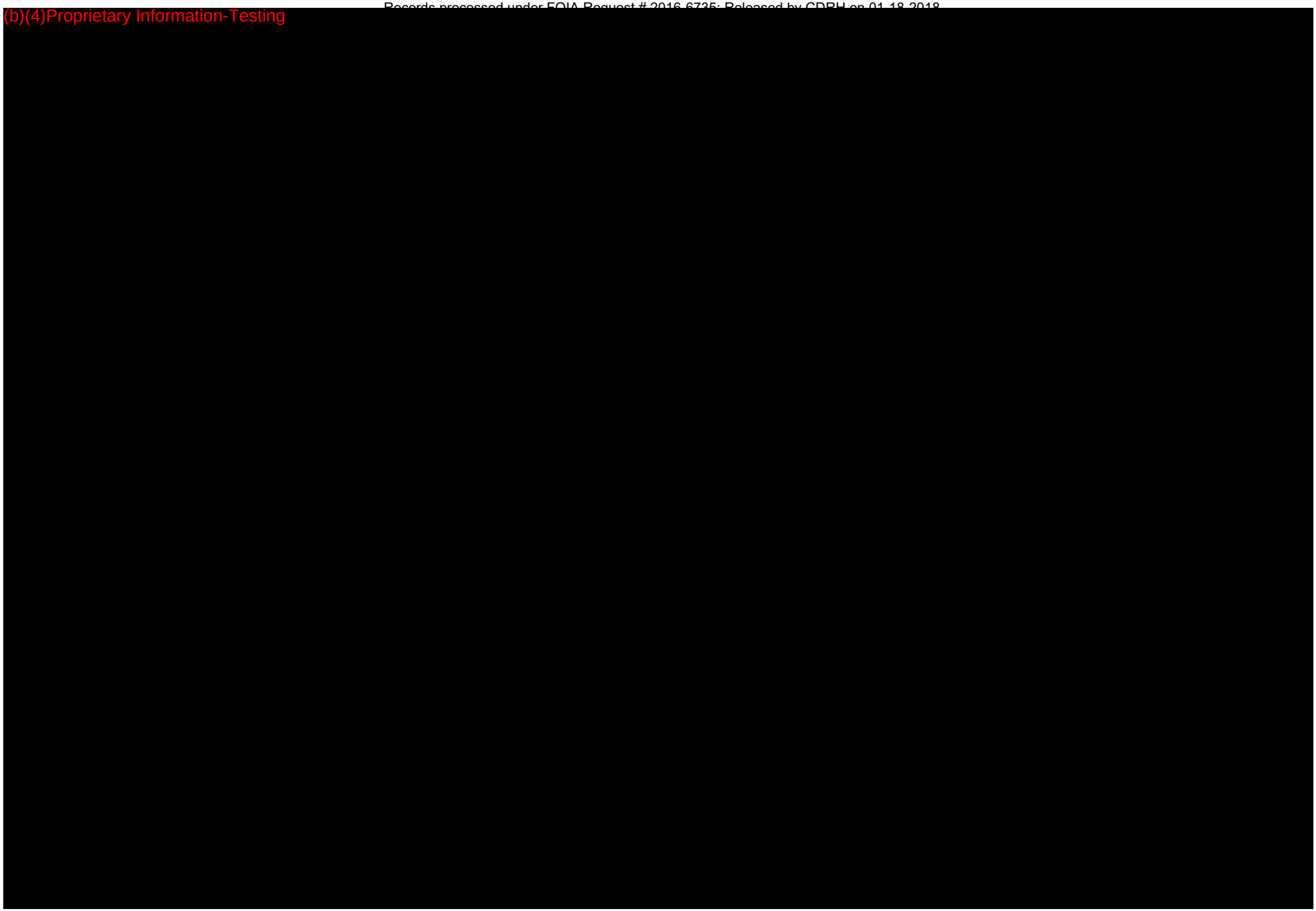
(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing

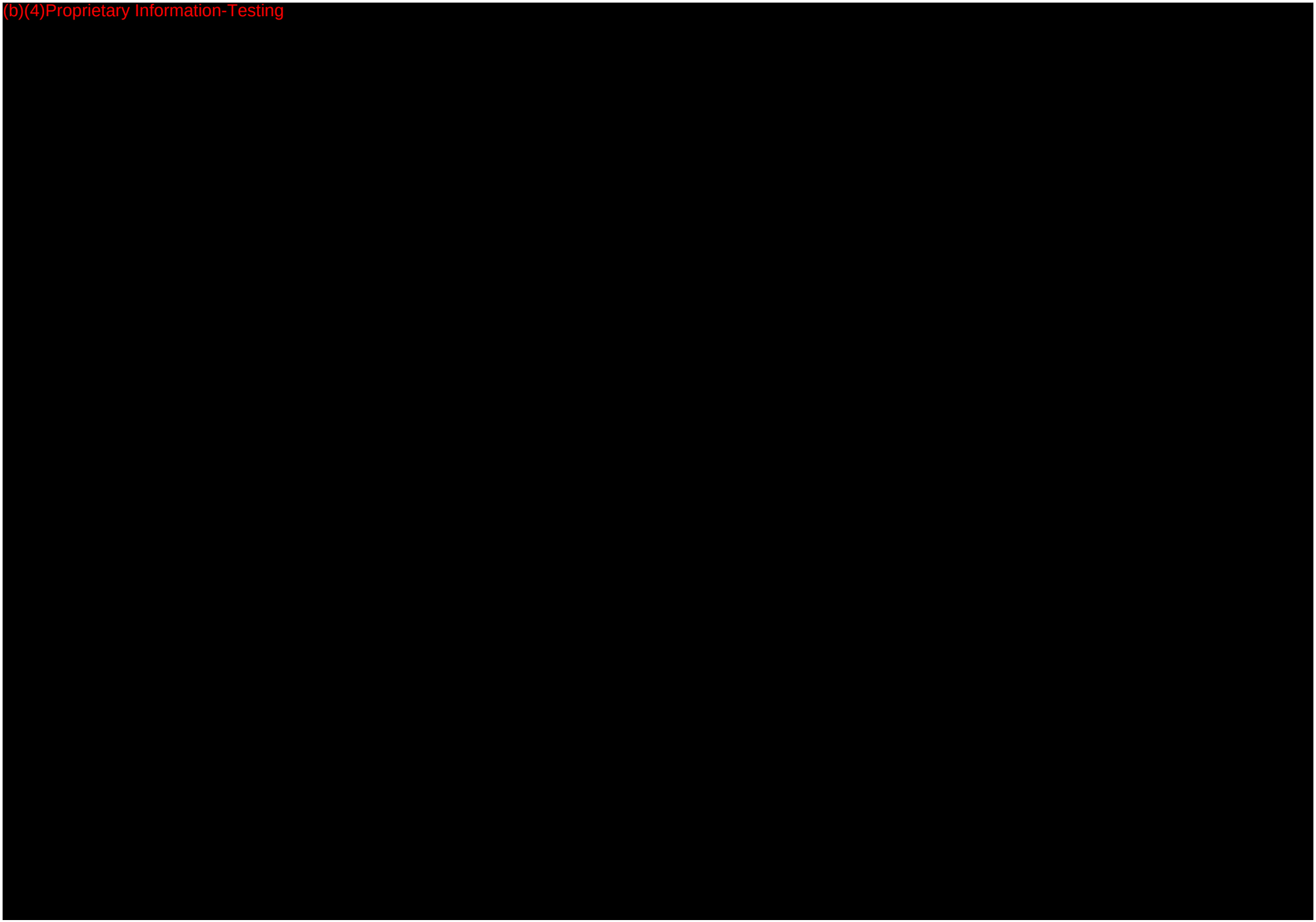
[redacted]

(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing

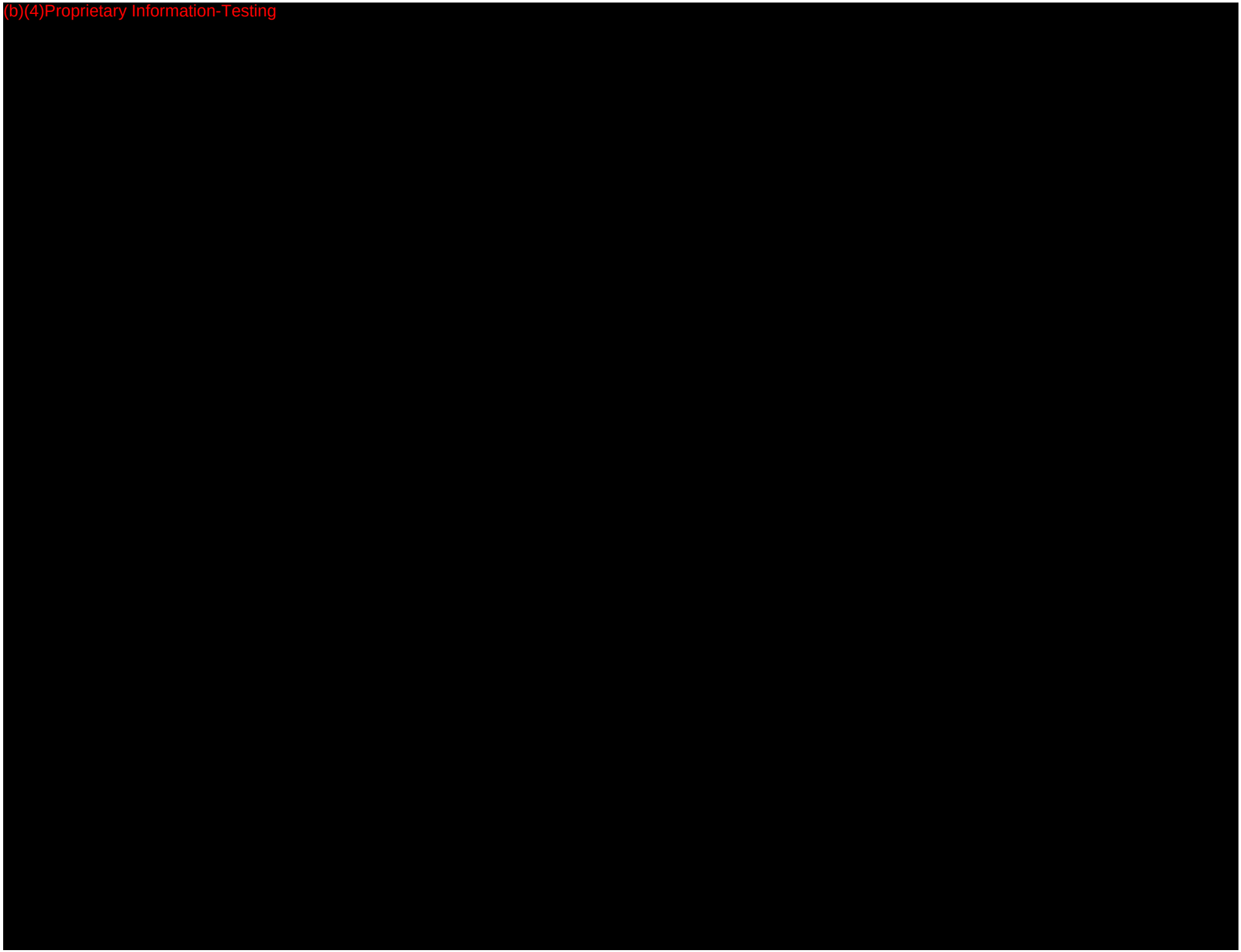
(b)(4)Proprietary Information-Testing



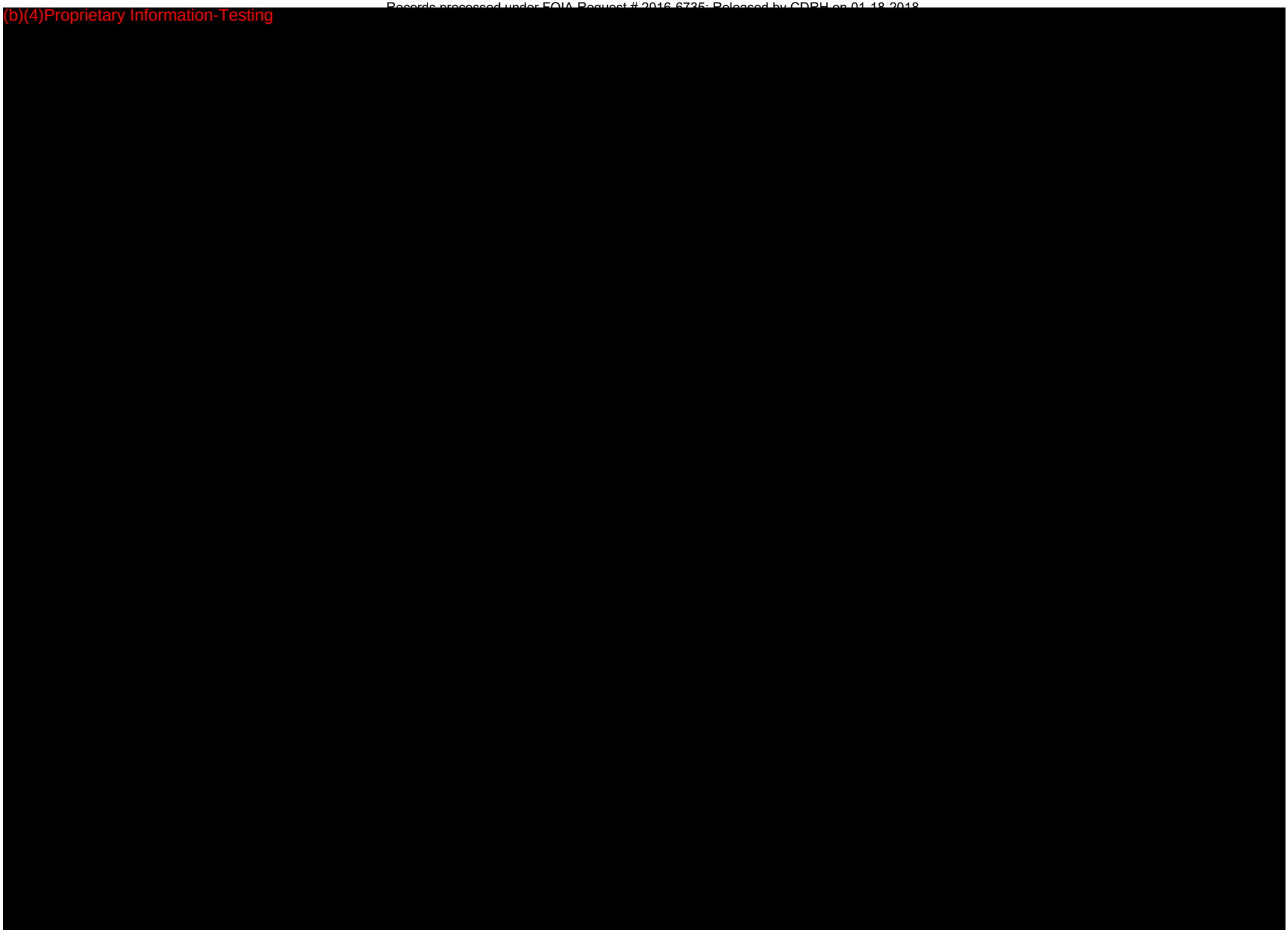
(b)(4)Proprietary Information-Testing

[redacted]

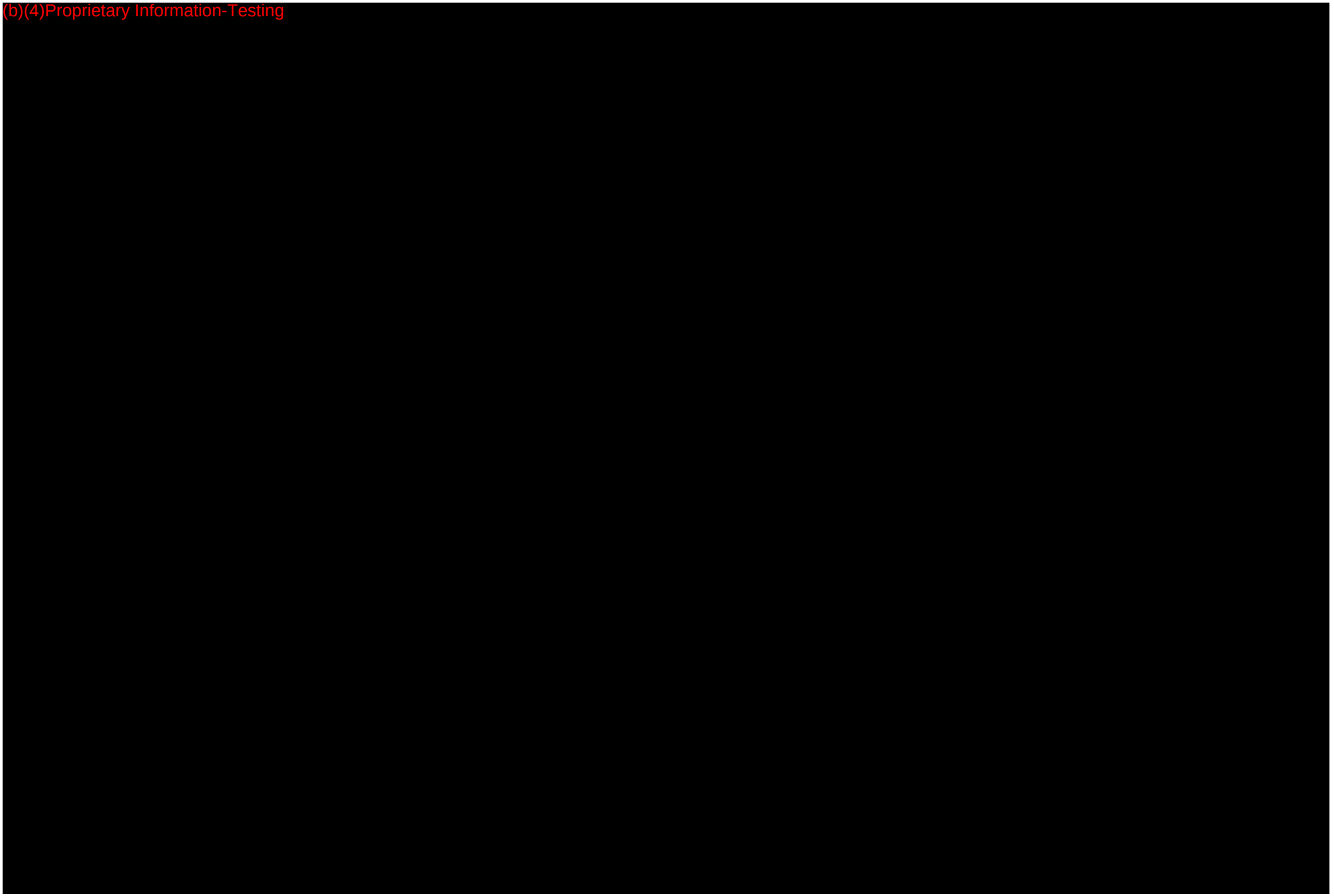
(b)(4)Proprietary Information-Testing



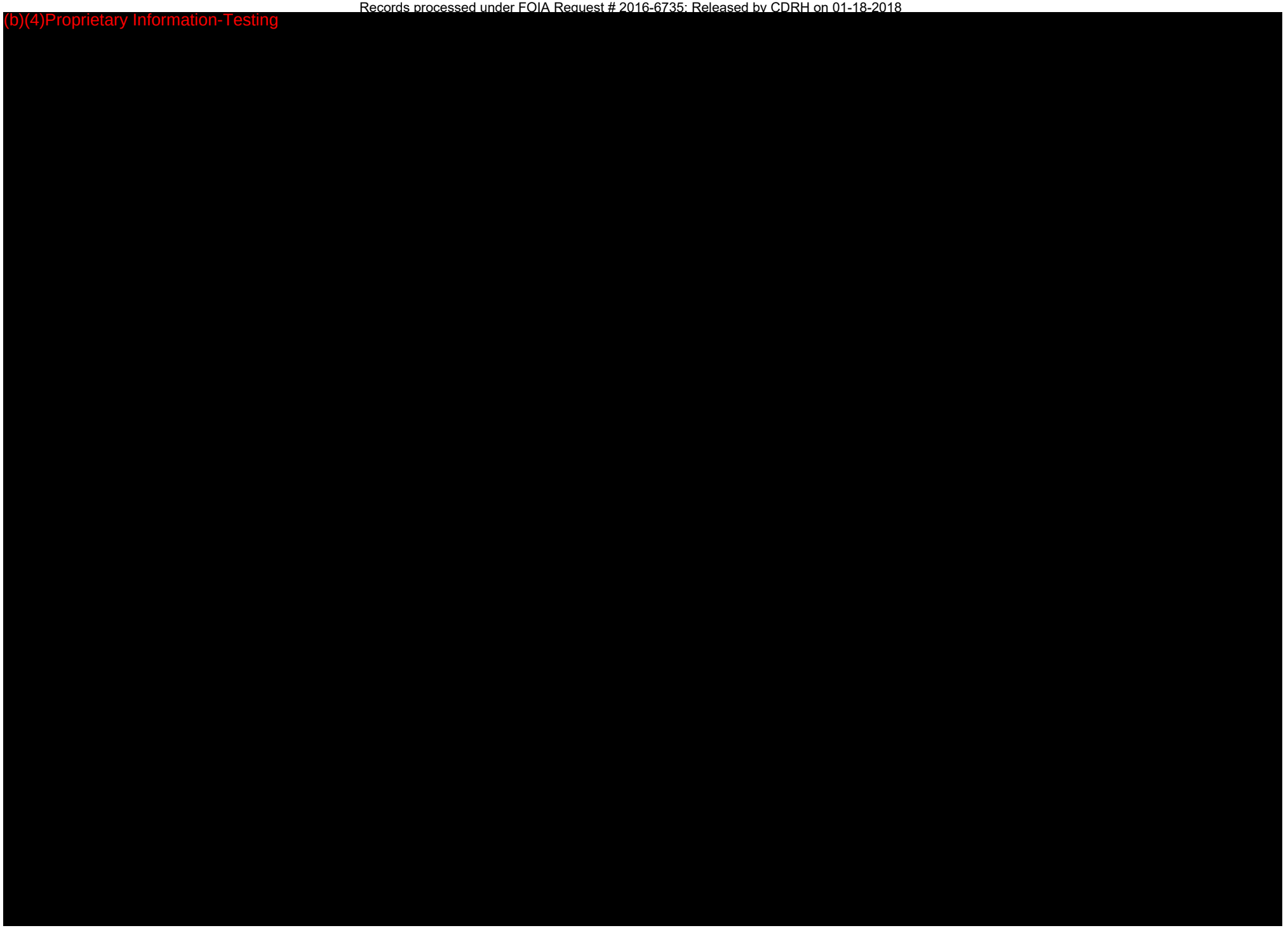
(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing



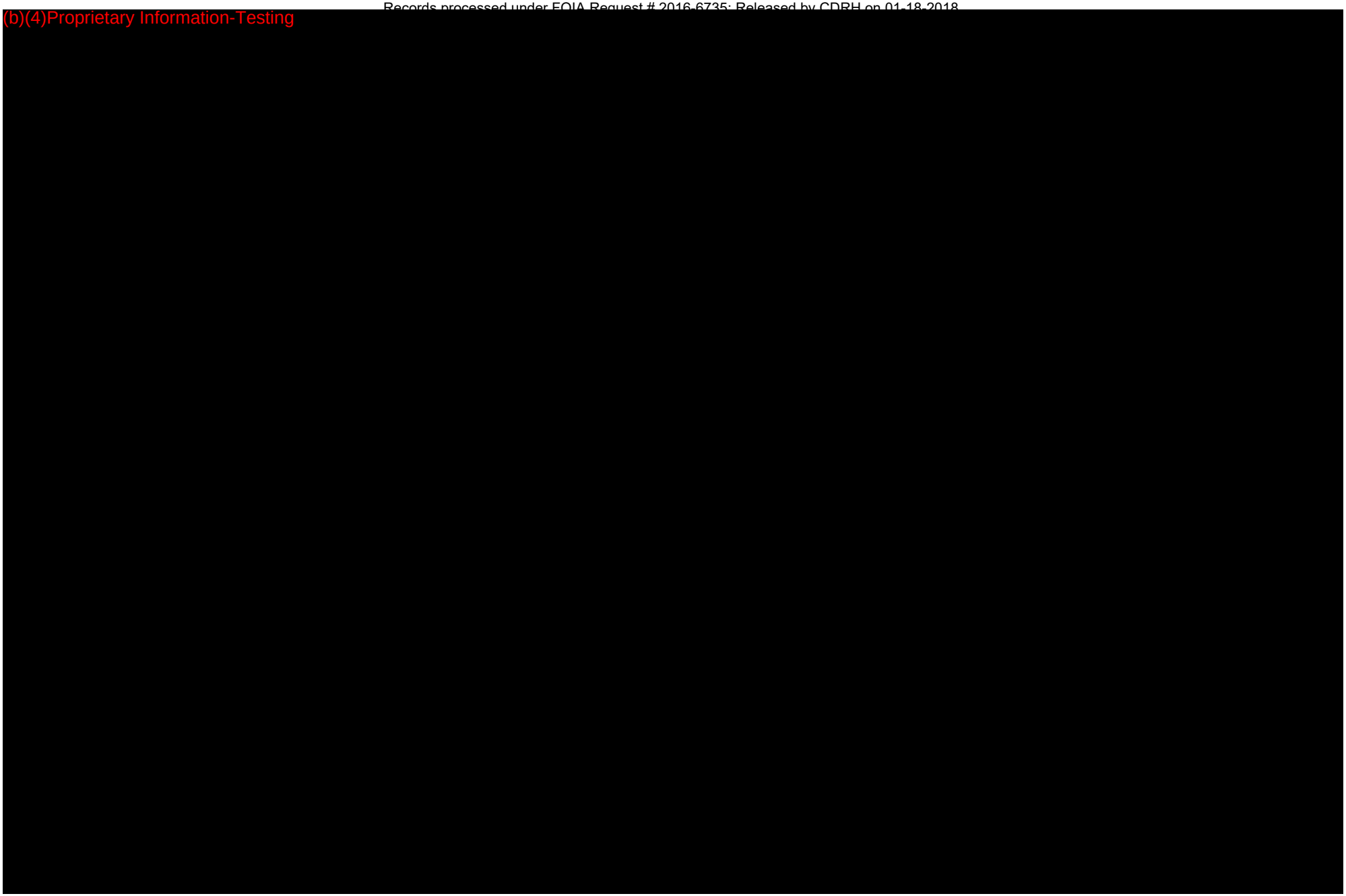
(b)(4)Proprietary Information-Testing



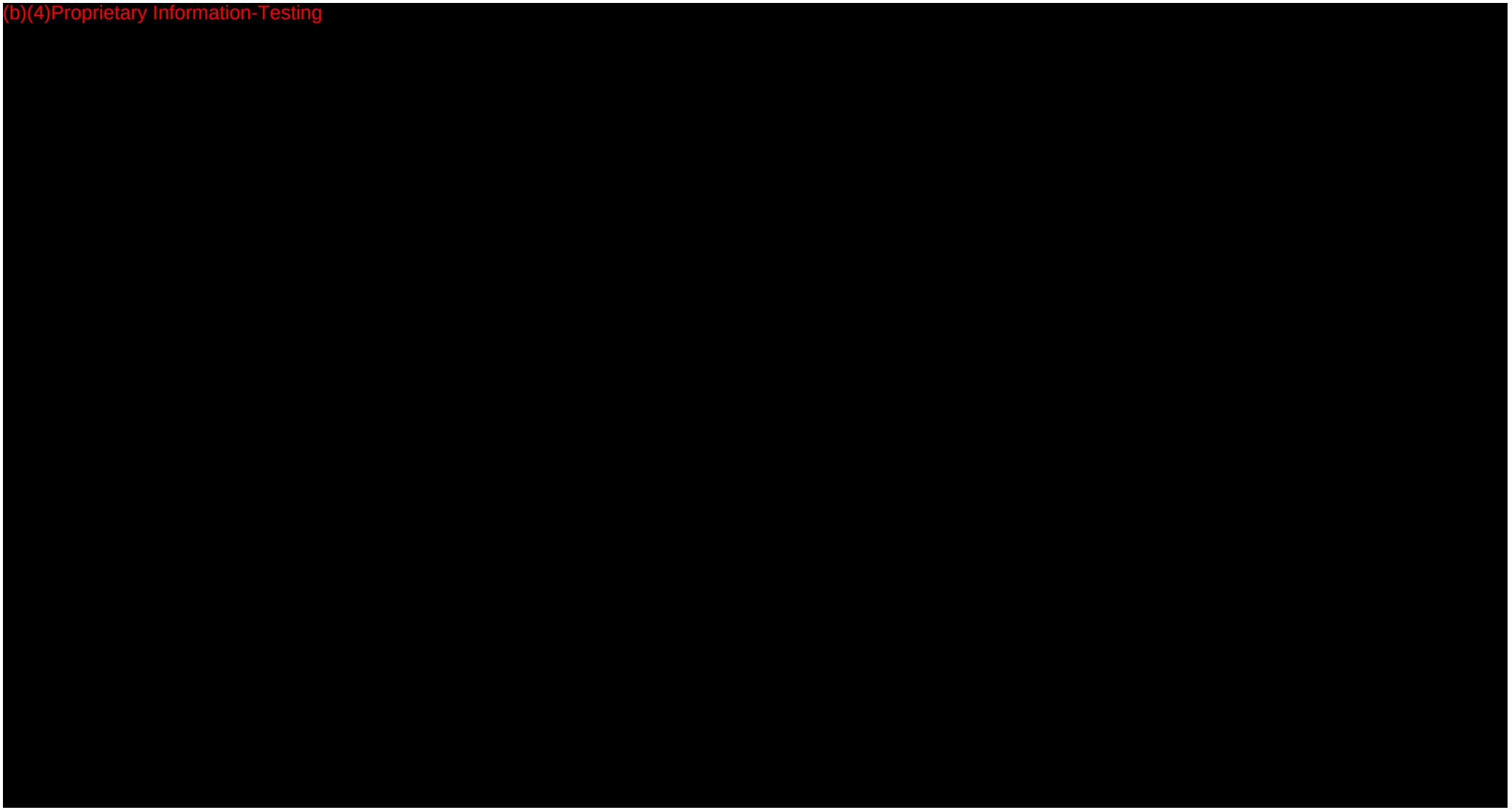
(b)(4)Proprietary Information-Testing

[redacted]

(b)(4)Proprietary Information-Testing



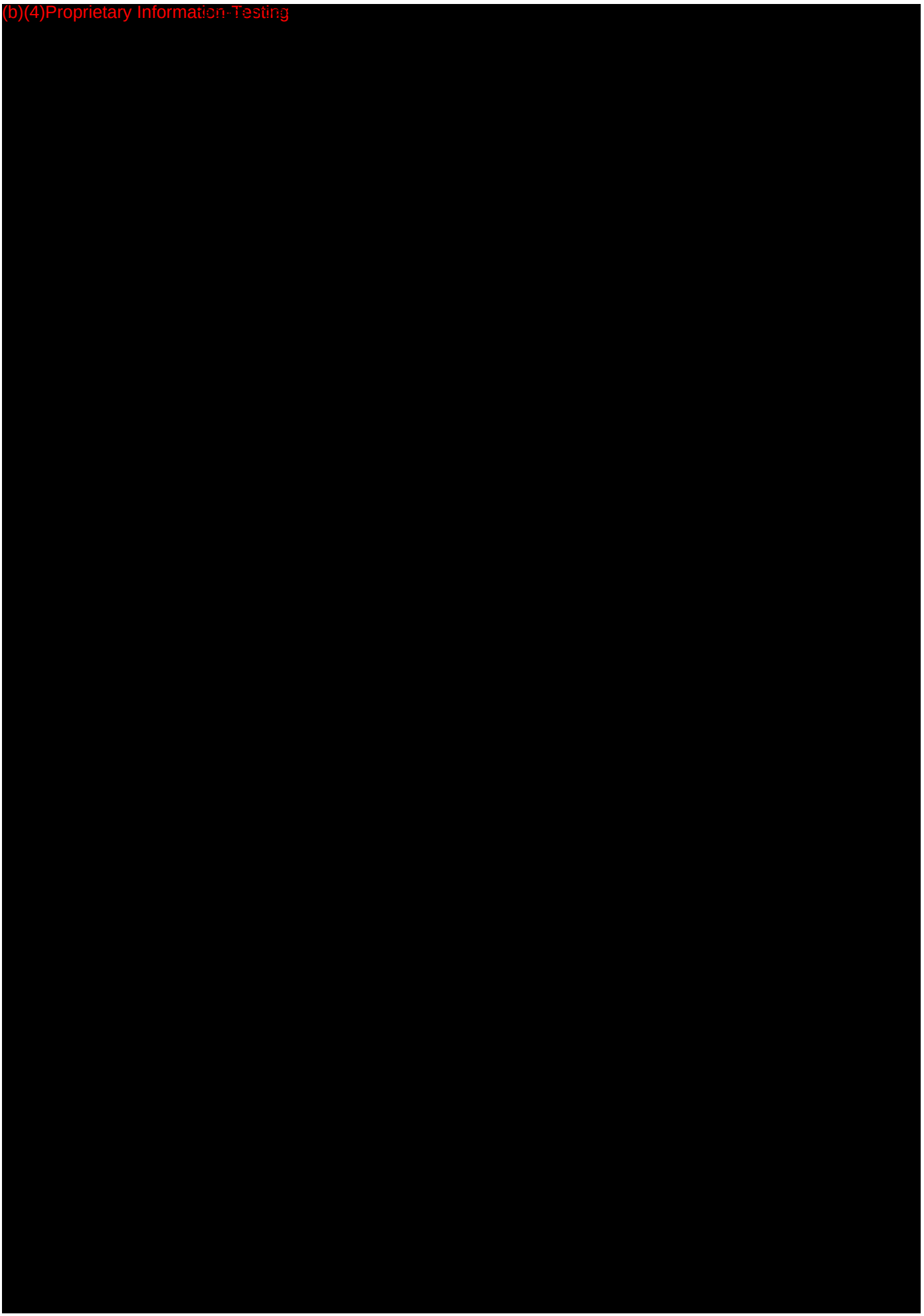
(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

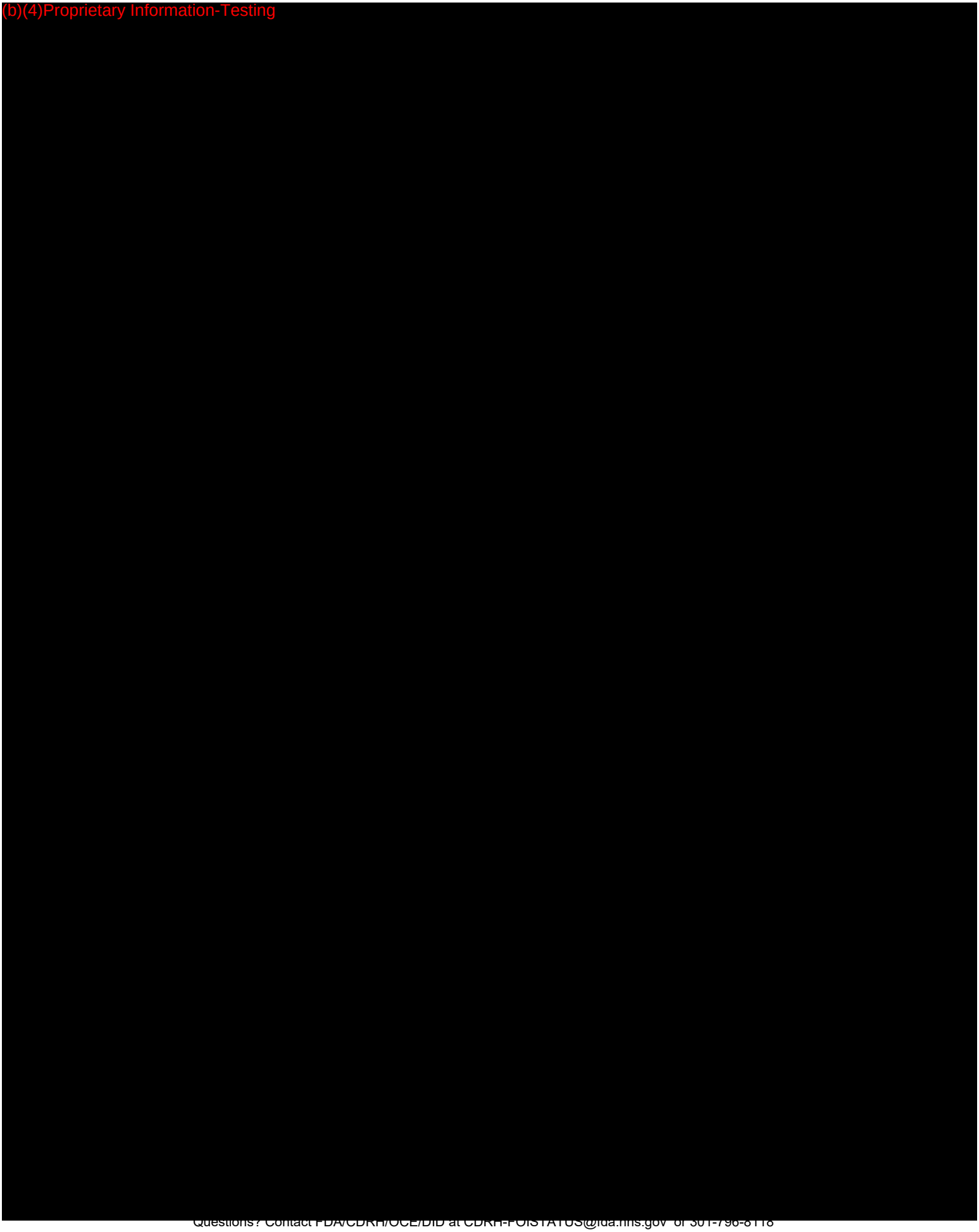
(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing

[redacted]

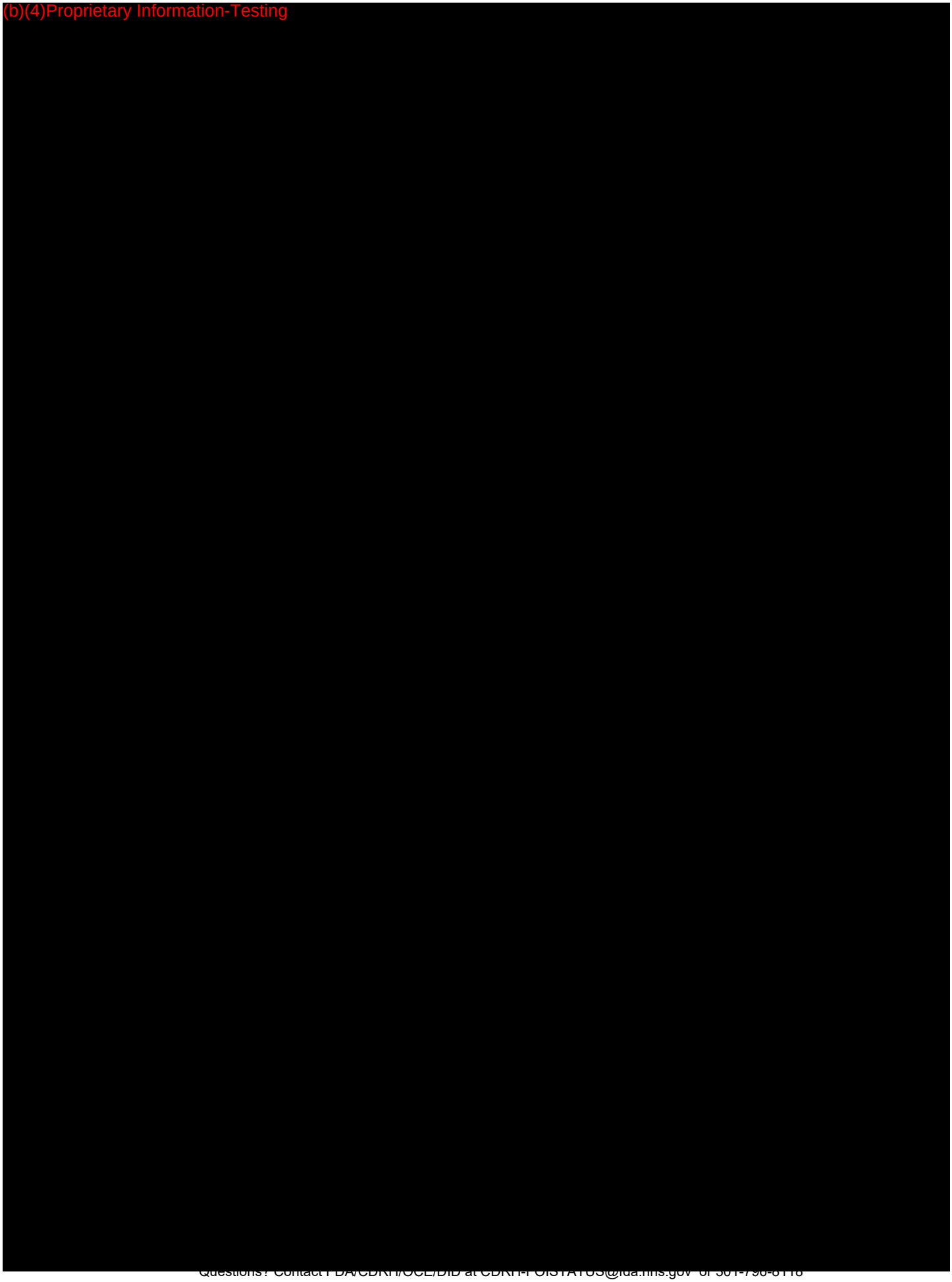
(b)(4)Proprietary Information-Testing



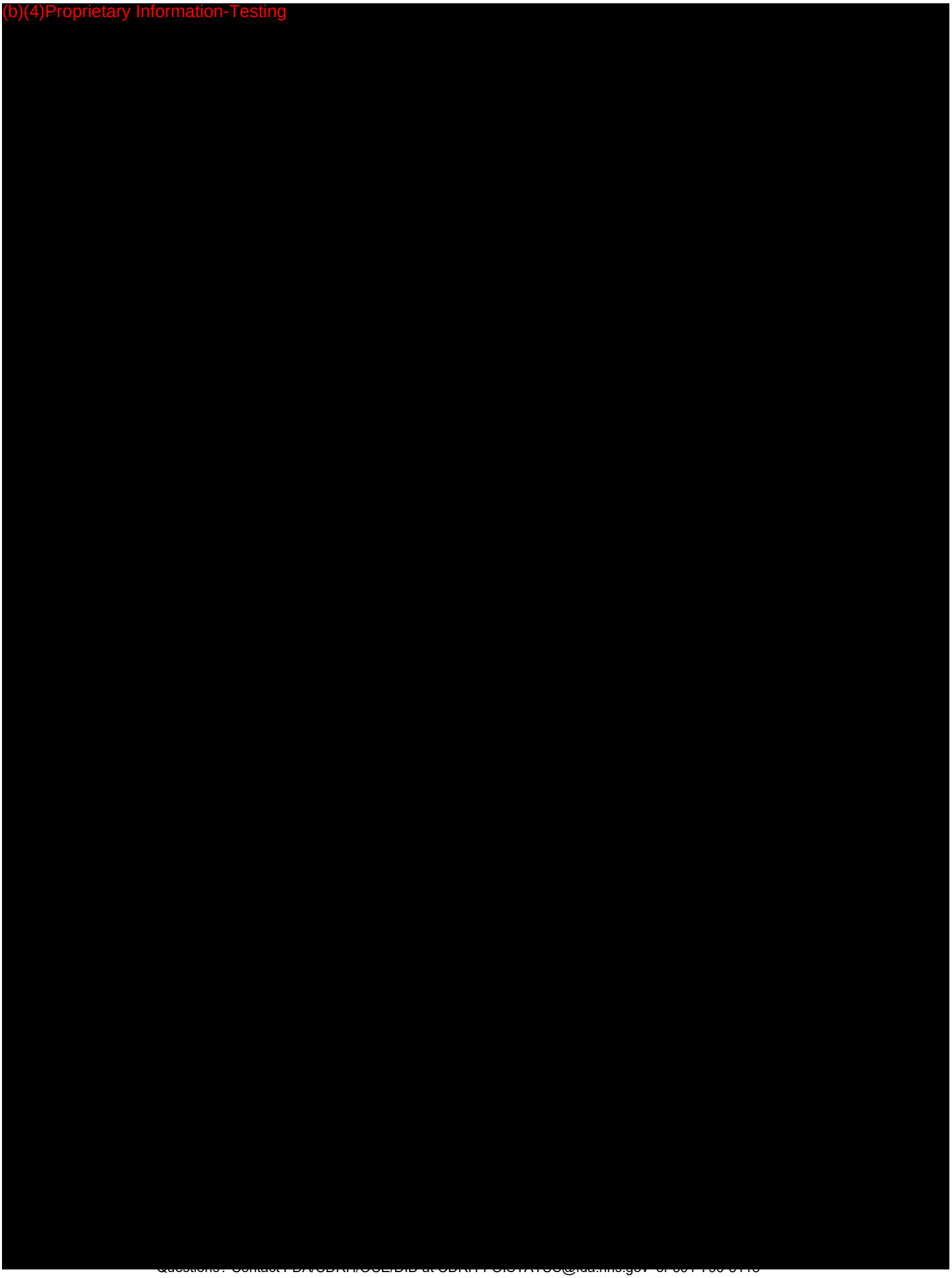
(b)(4)Proprietary Information-Testing

[redacted]

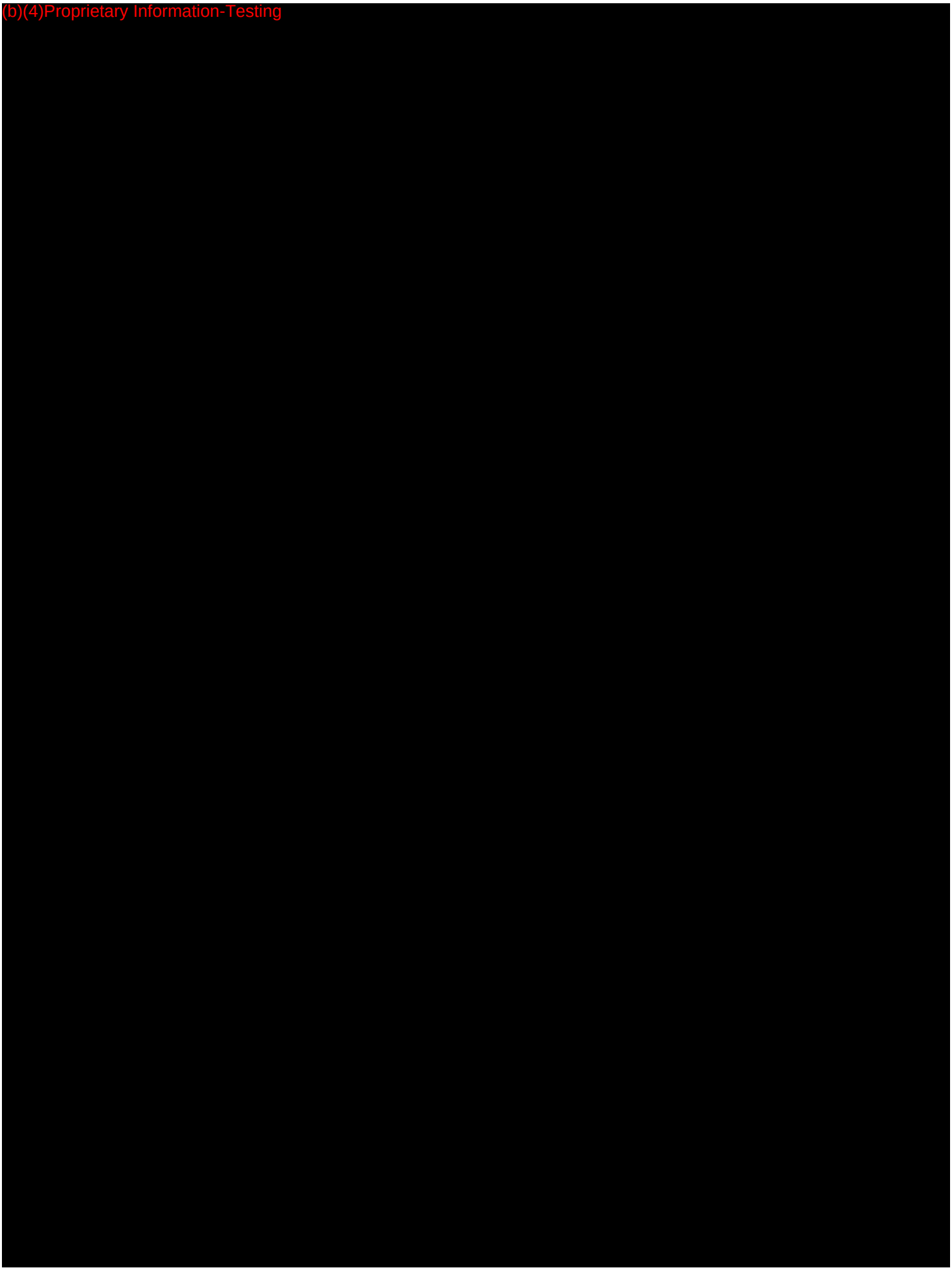
(b)(4)Proprietary Information-Testing

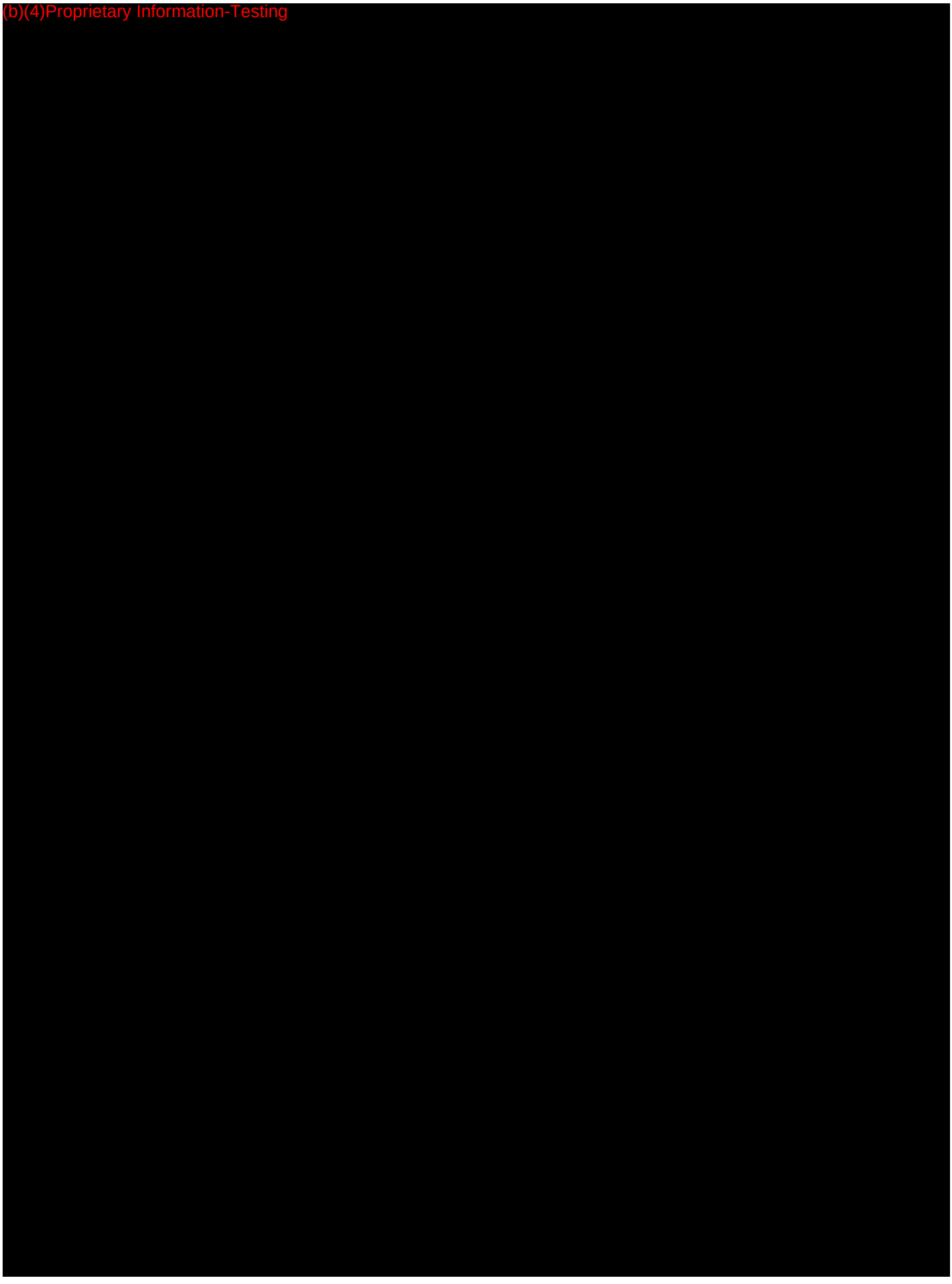


(b)(4)Proprietary Information-Testing



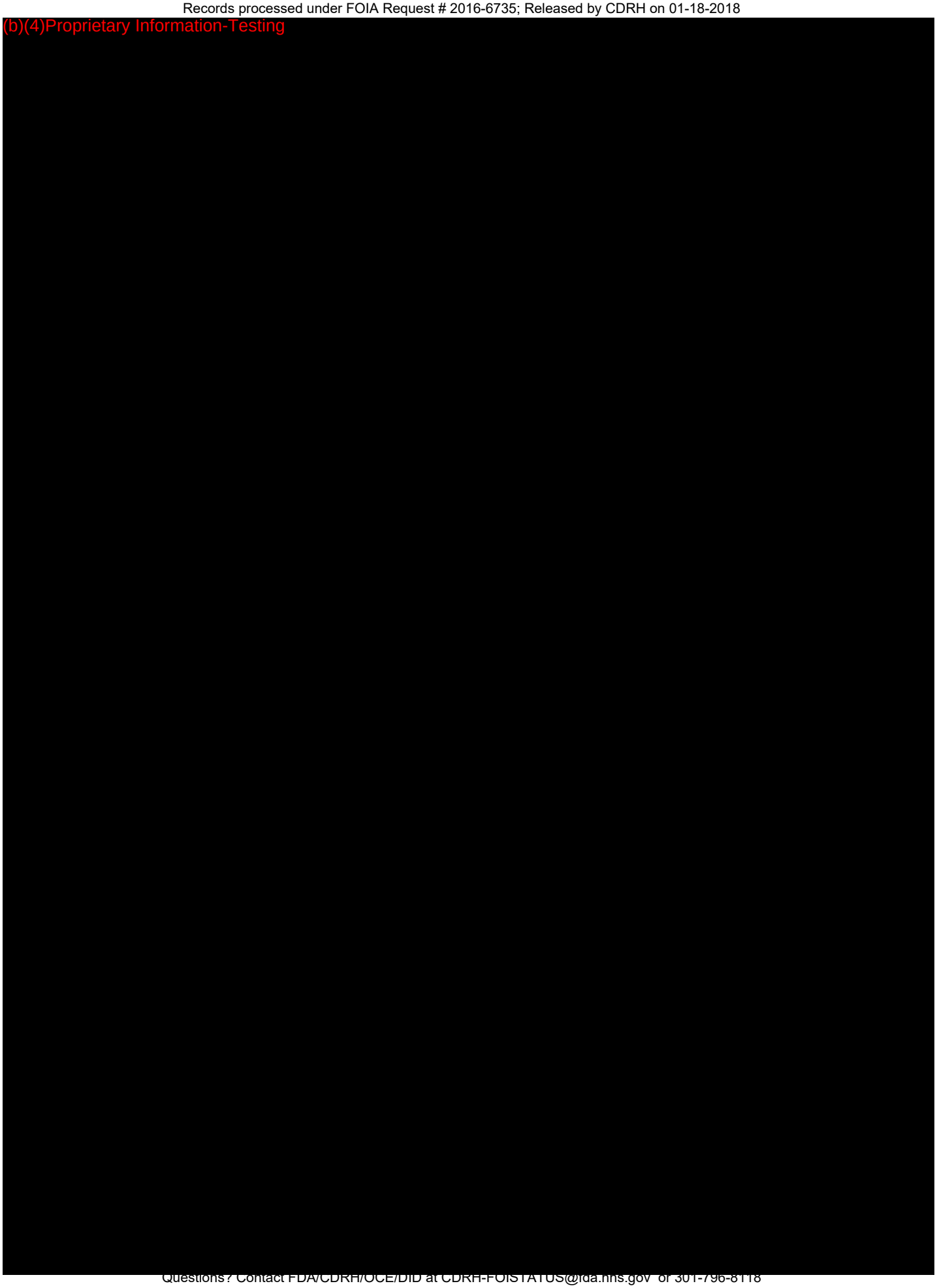
(b)(4)Proprietary Information-Testing



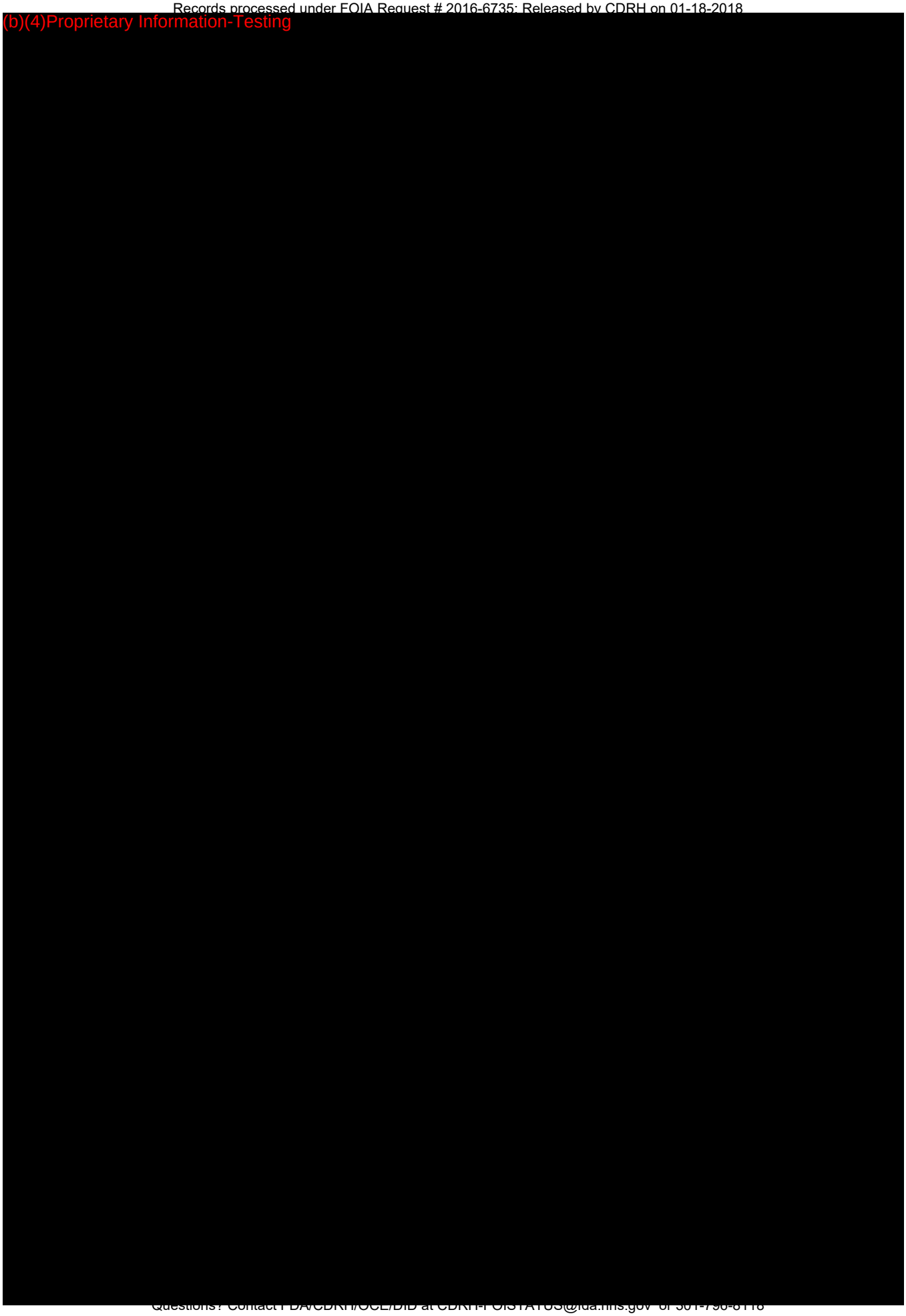


(b)(4)Proprietary Information-Testing

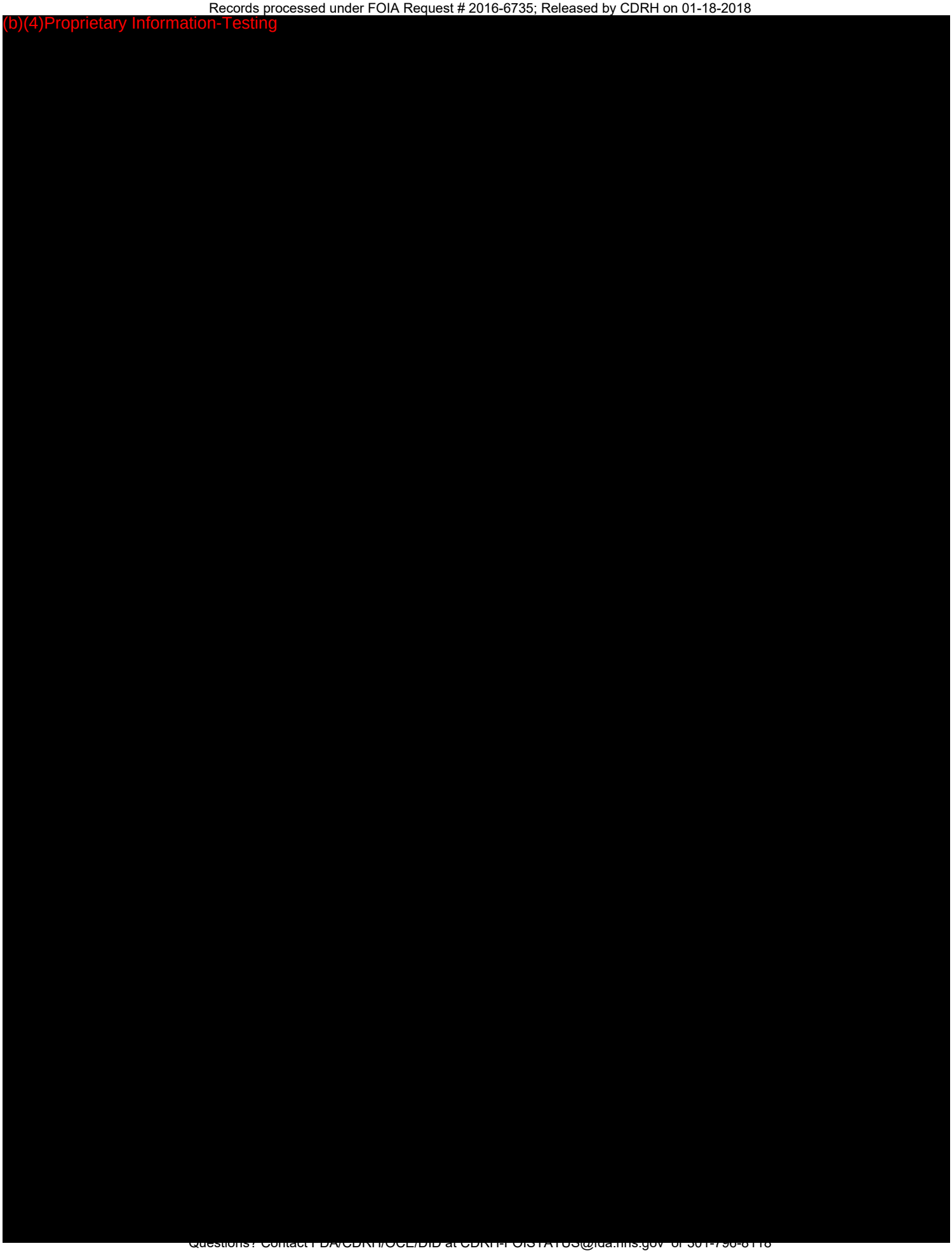
(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing



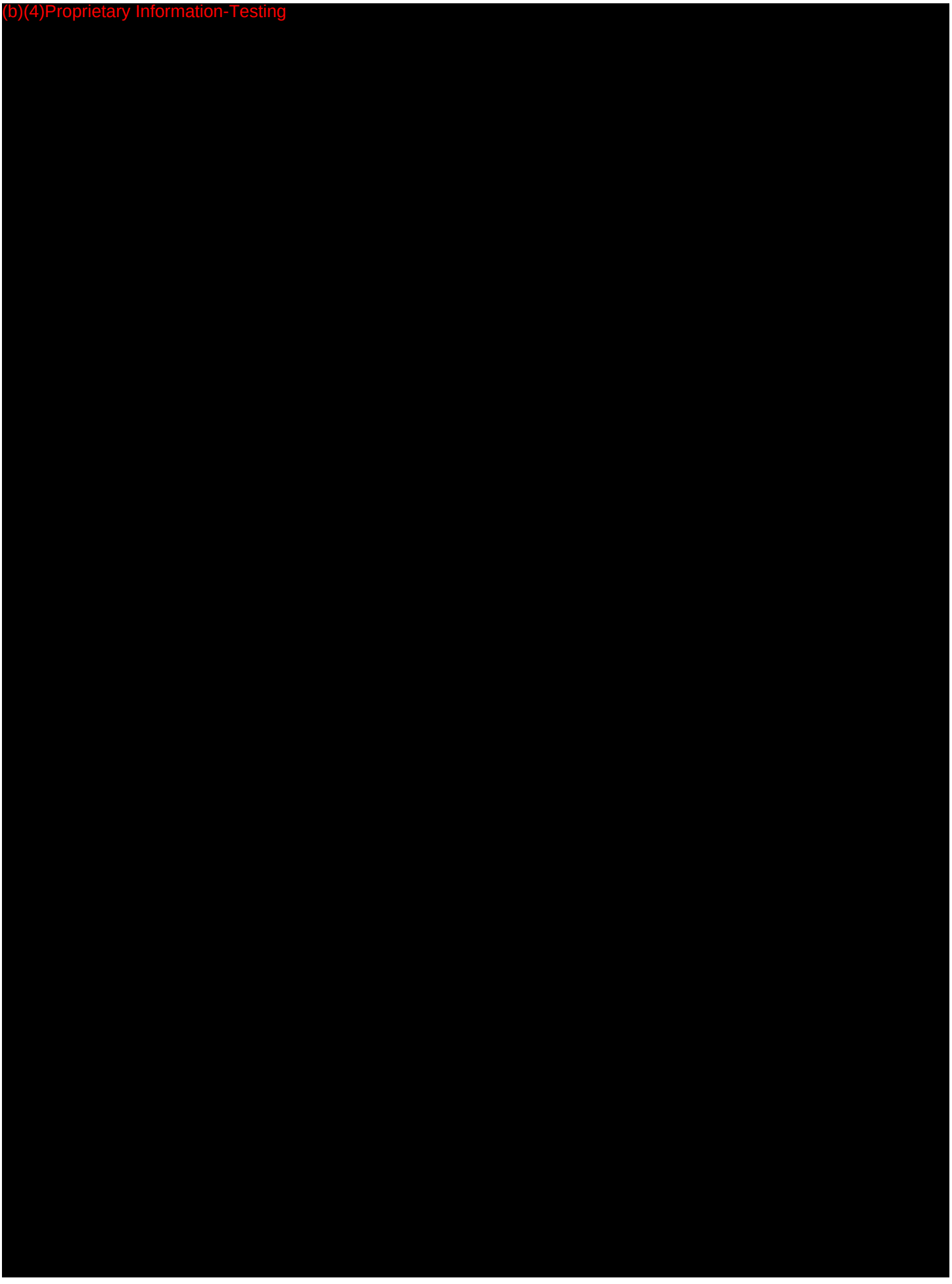
(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing

[redacted]

(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing

[redacted]

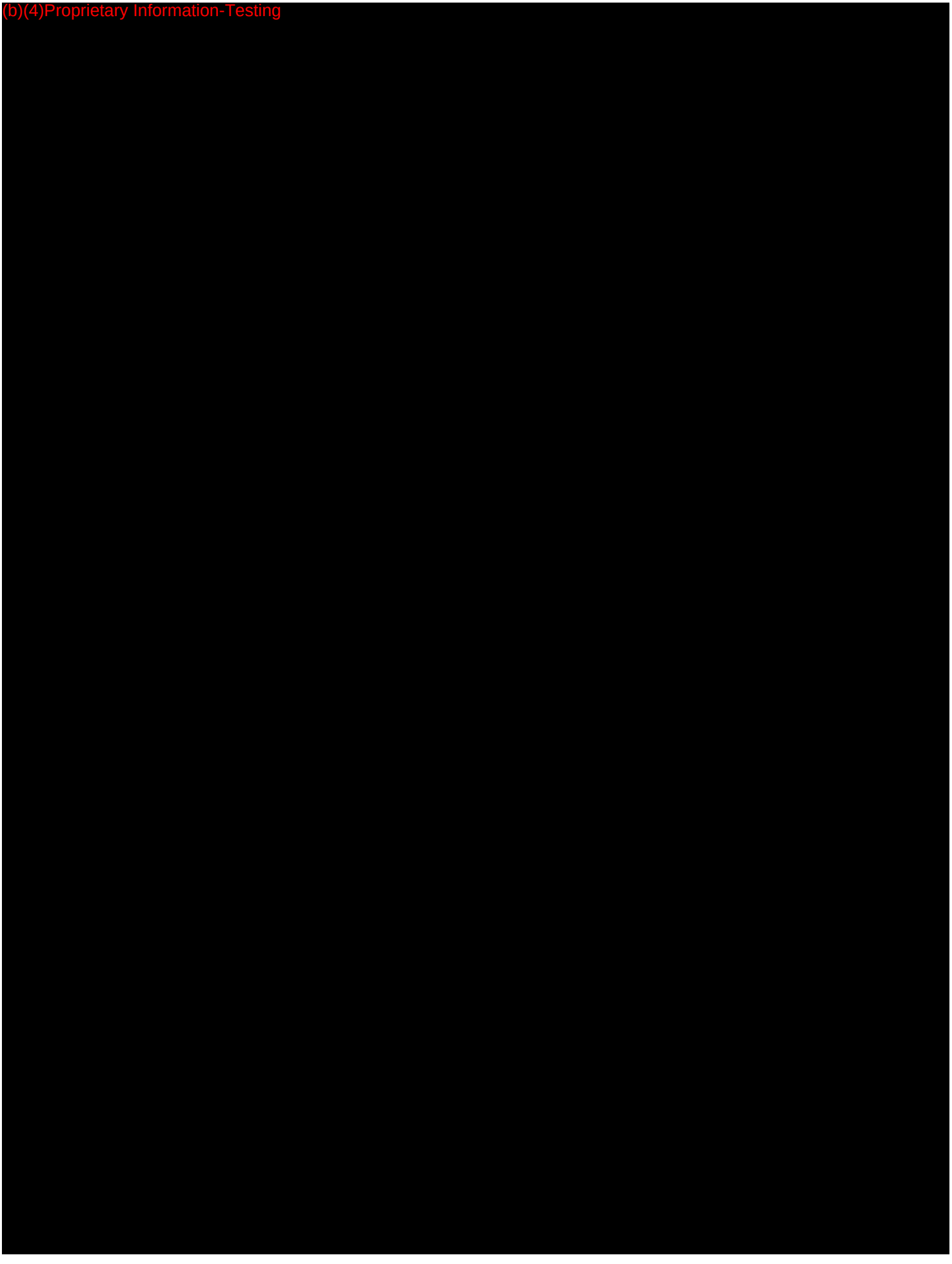
(b)(4)Proprietary Information-Testing

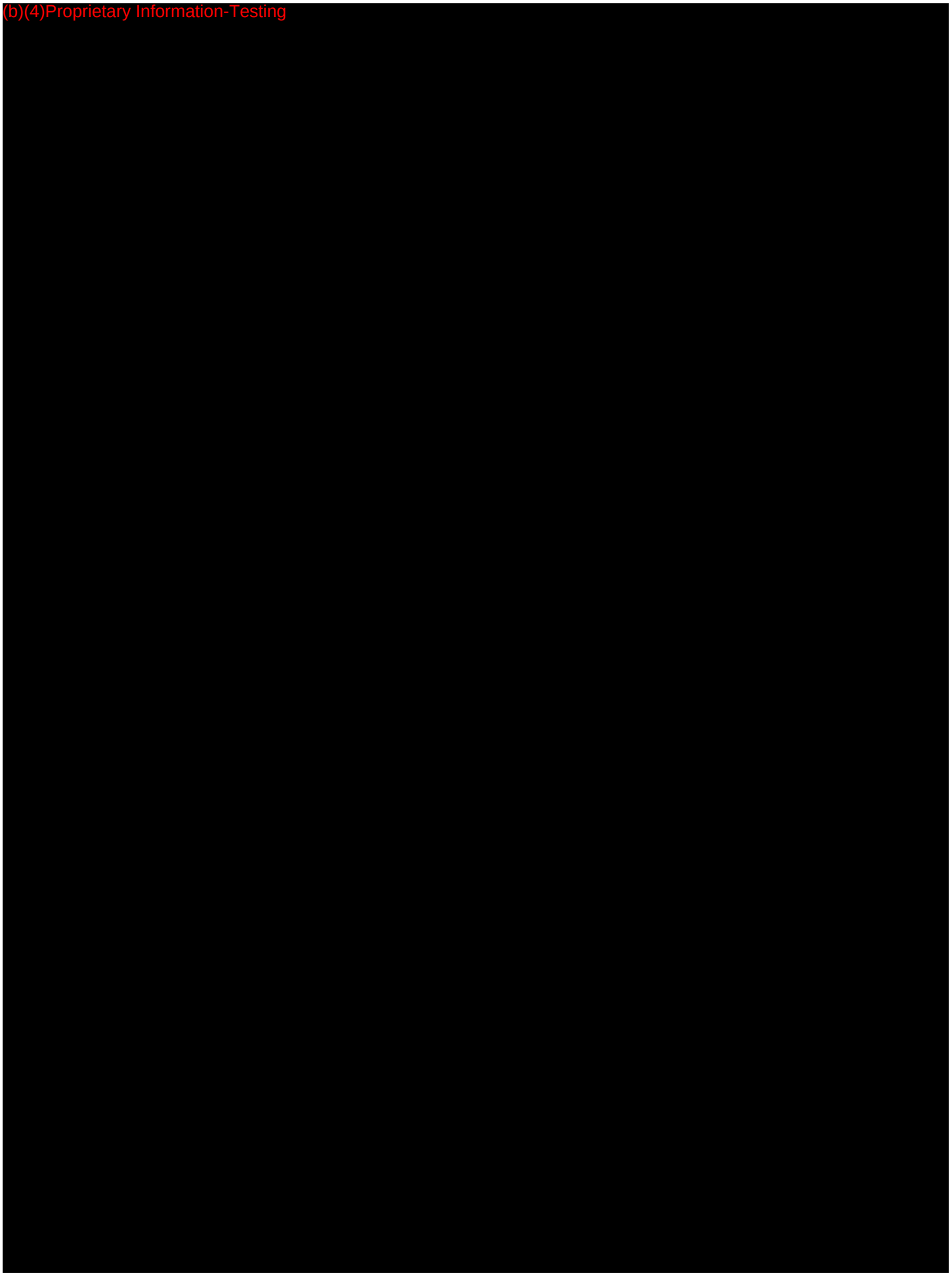
[redacted]

(b)(4)Proprietary Information-Testing

[redacted]

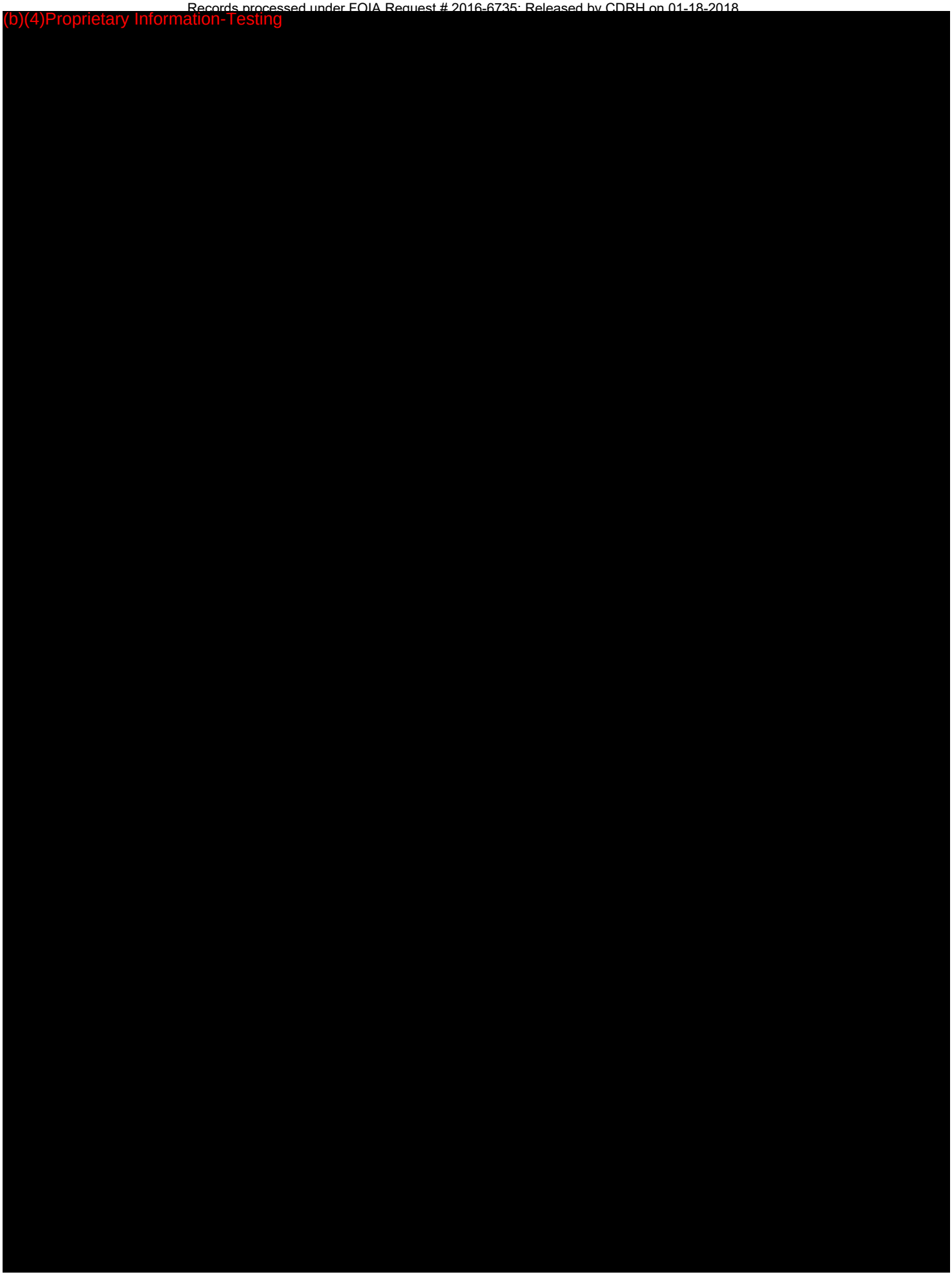
(b)(4)Proprietary Information-Testing



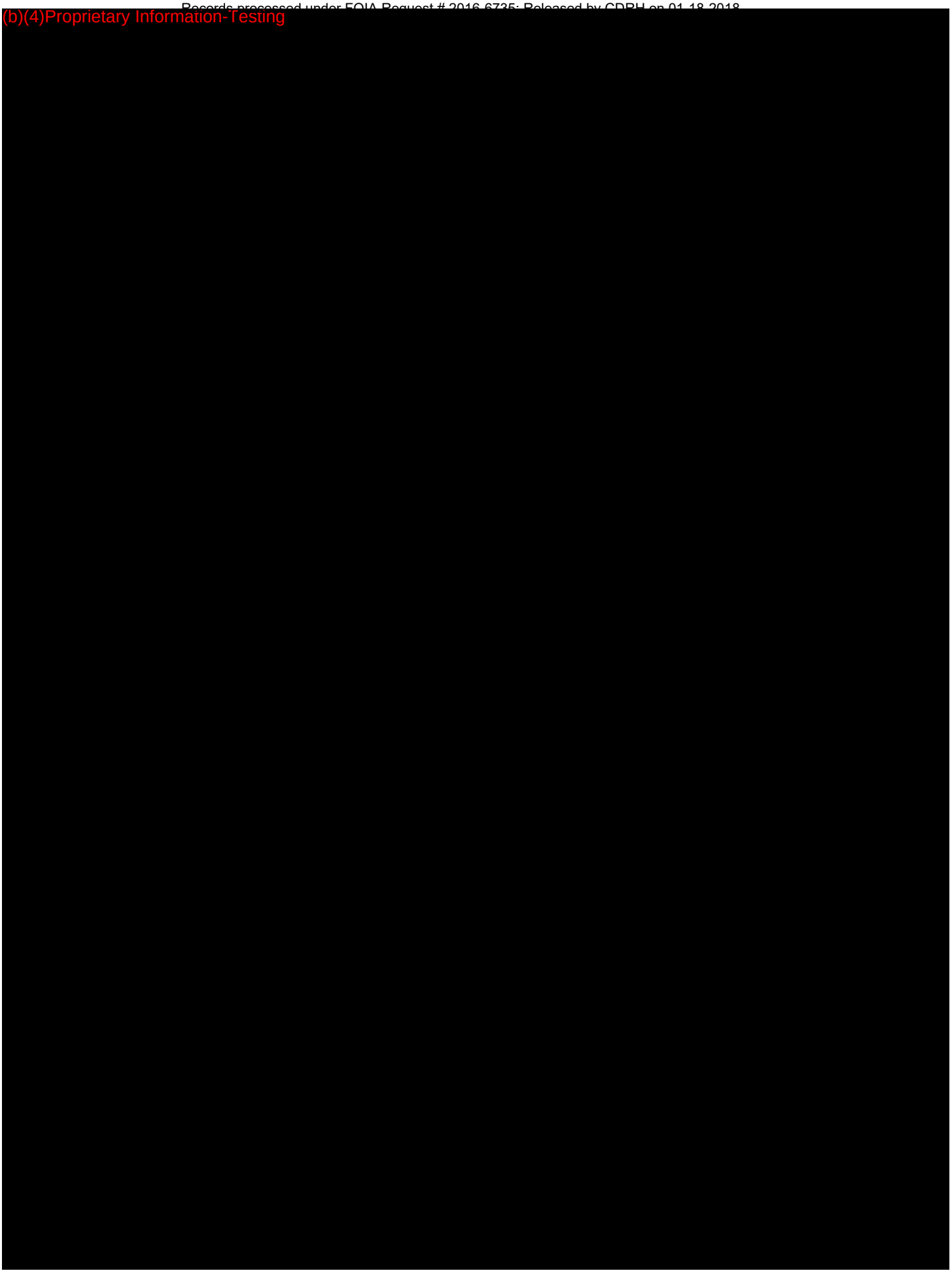


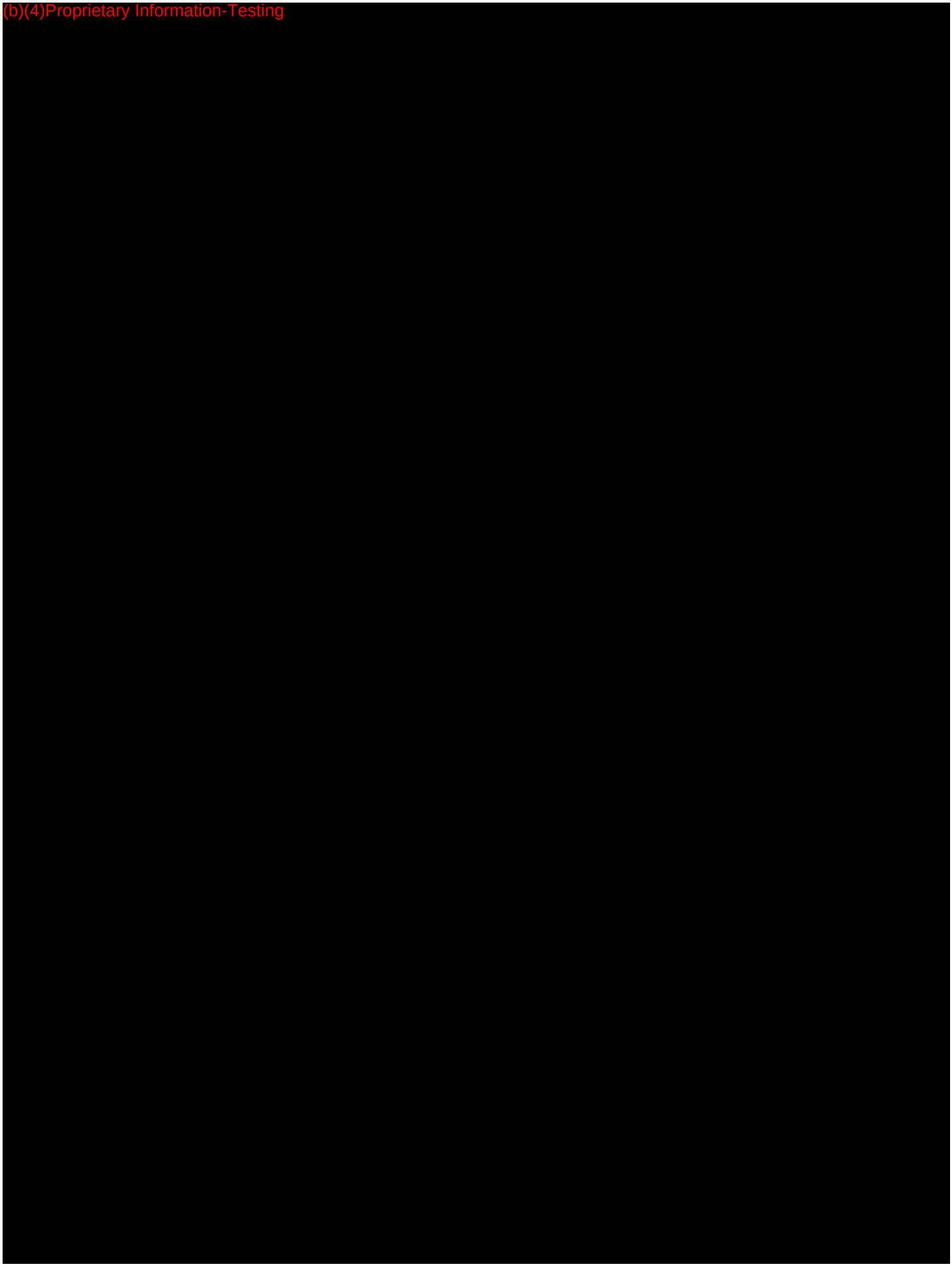
(b)(4)Proprietary Information-Testing

[redacted]

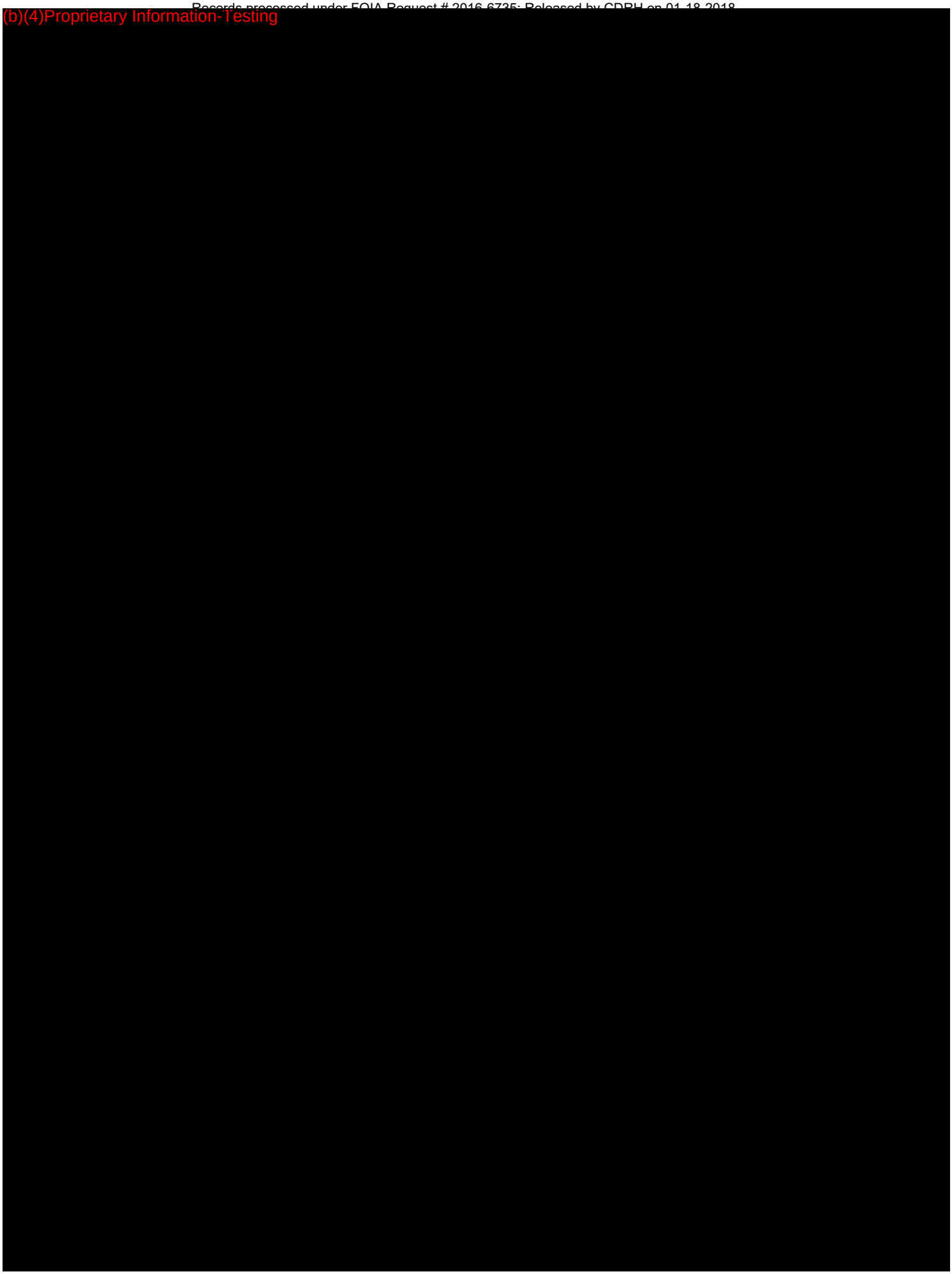


(b)(4)Proprietary Information-Testing





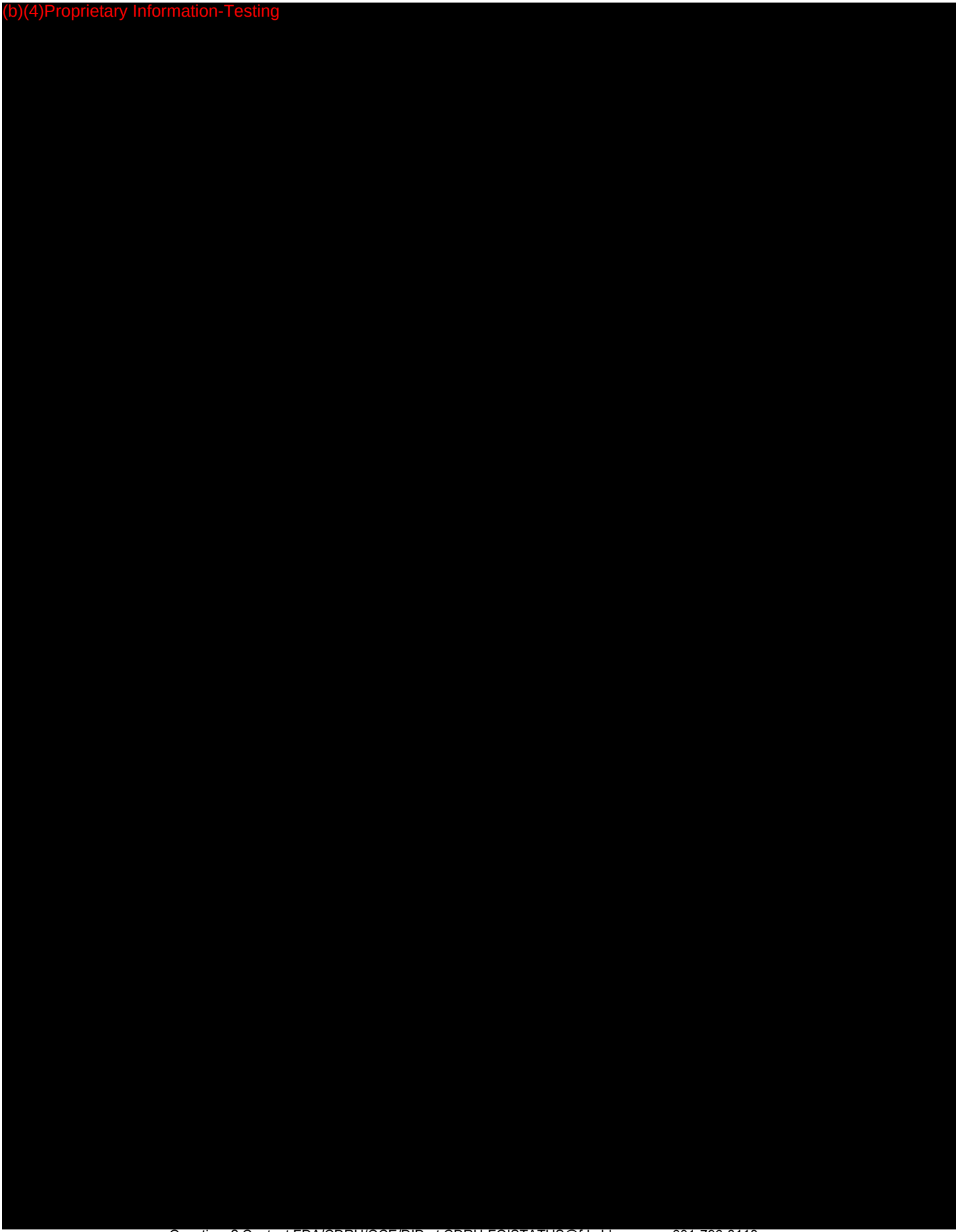
(b)(4)Proprietary Information-Testing



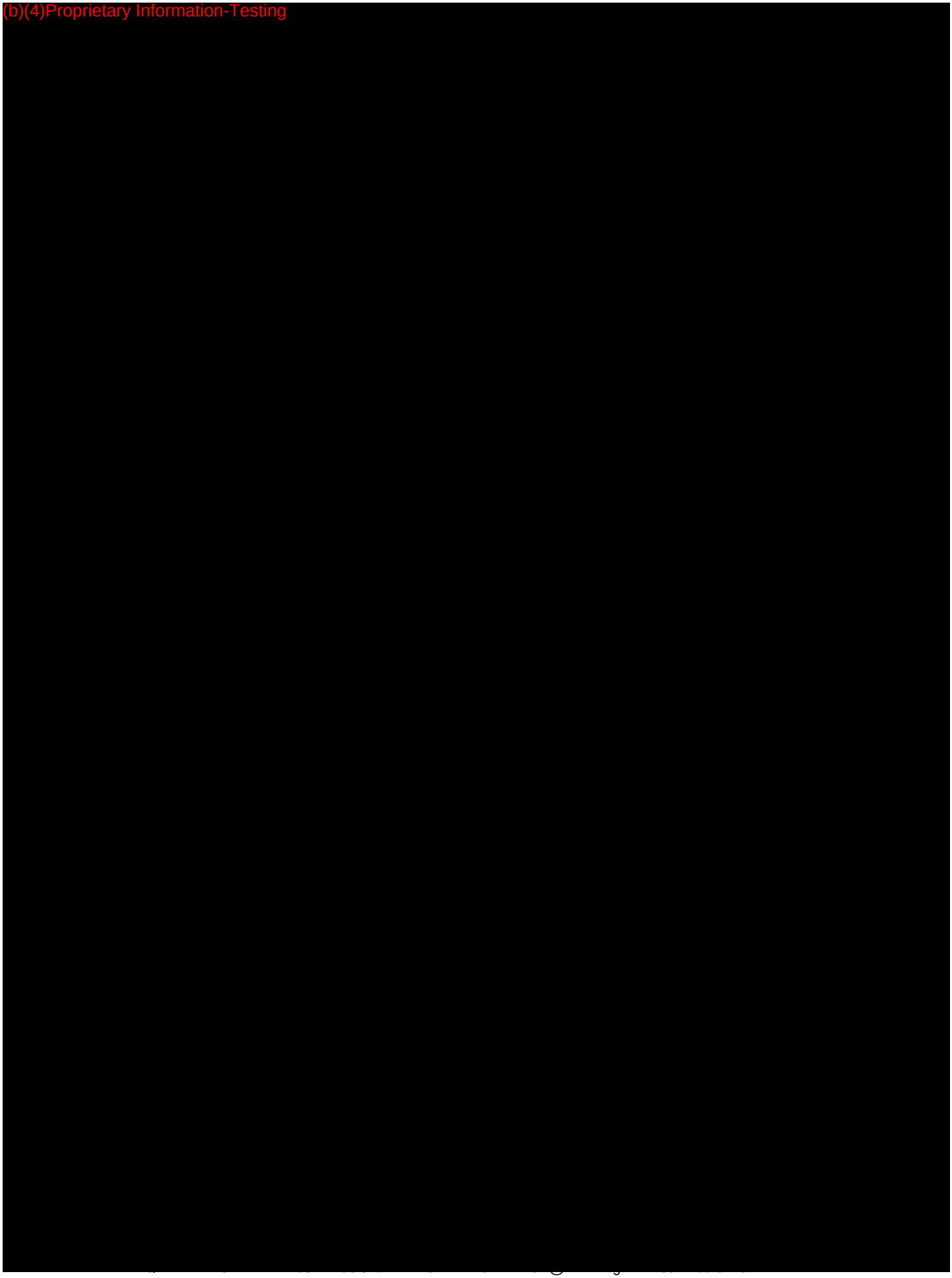
(b)(4)Proprietary Information-Testing

[redacted]

(b)(4)Proprietary Information-Testing



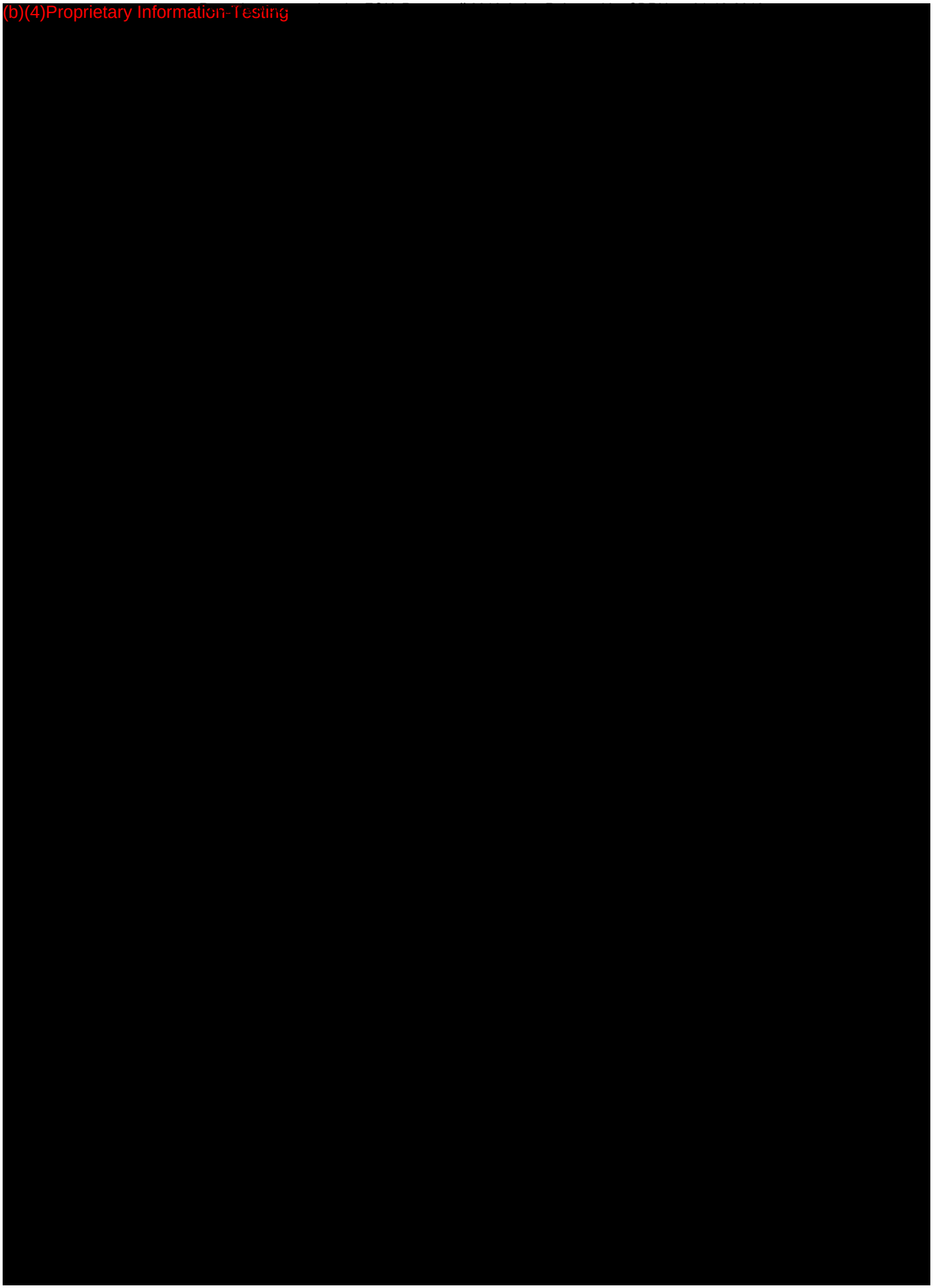
(b)(4)Proprietary Information-Testing



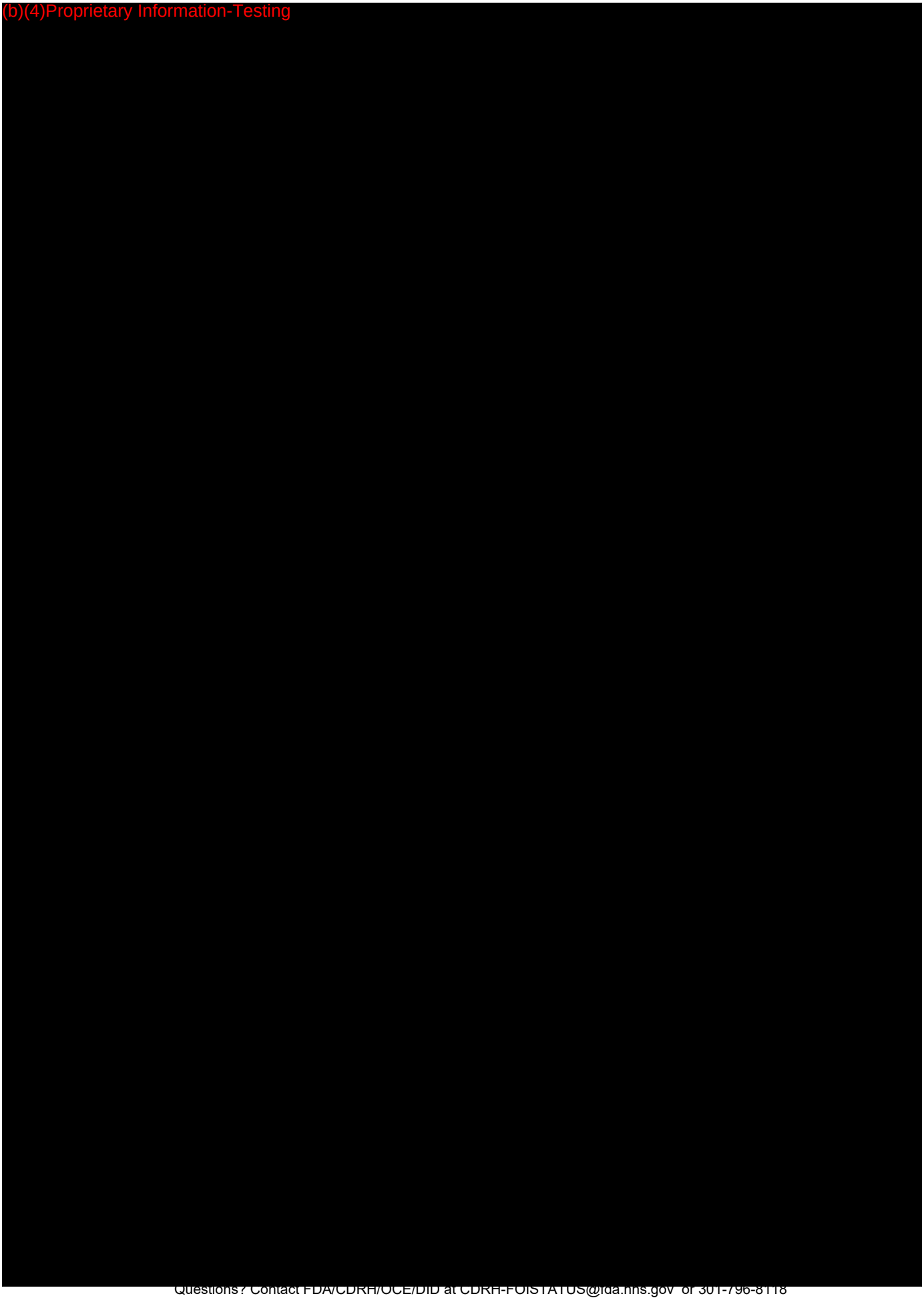
(b)(4)Proprietary Information-Testing

[redacted]

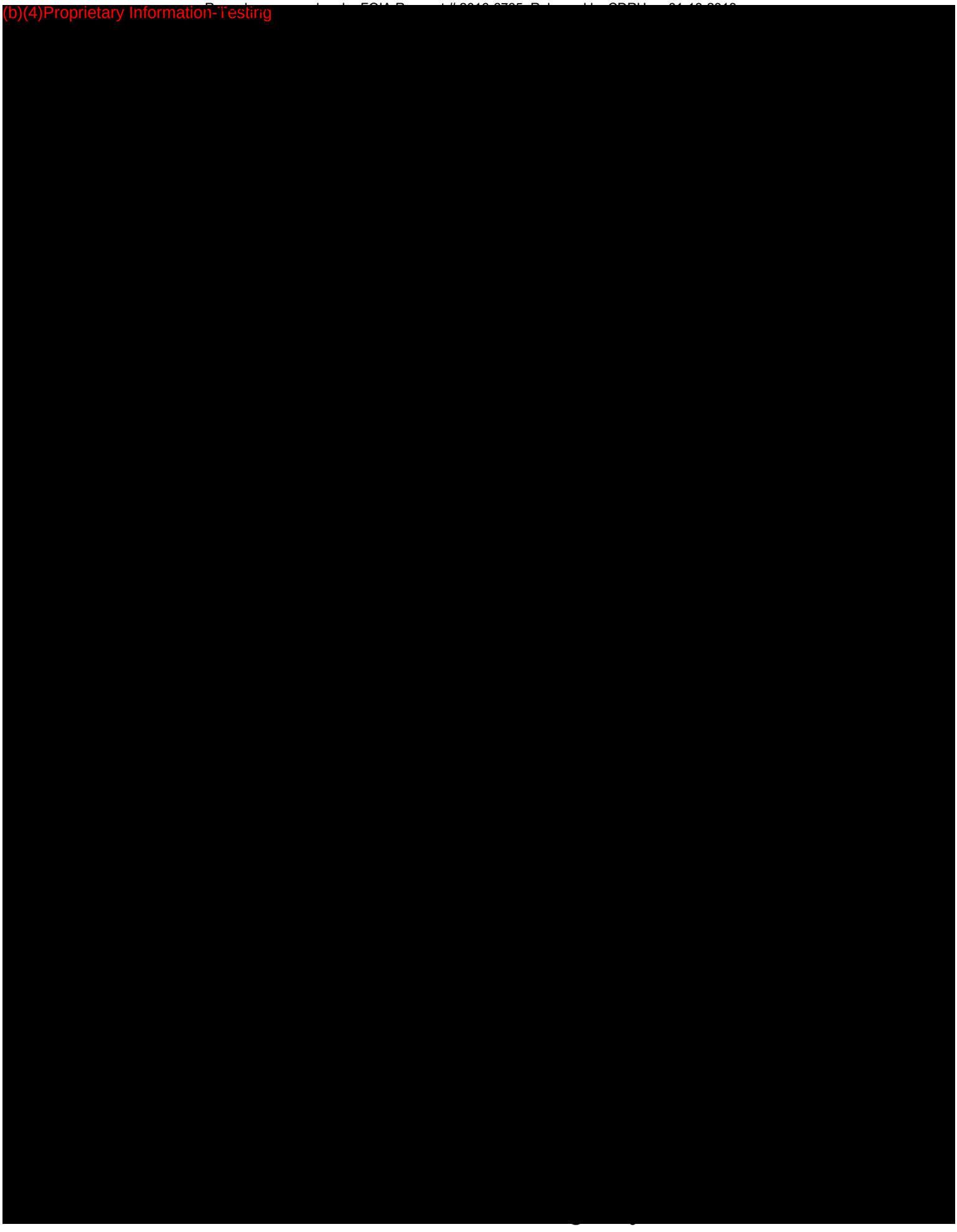
(b)(4)Proprietary Information-Testing



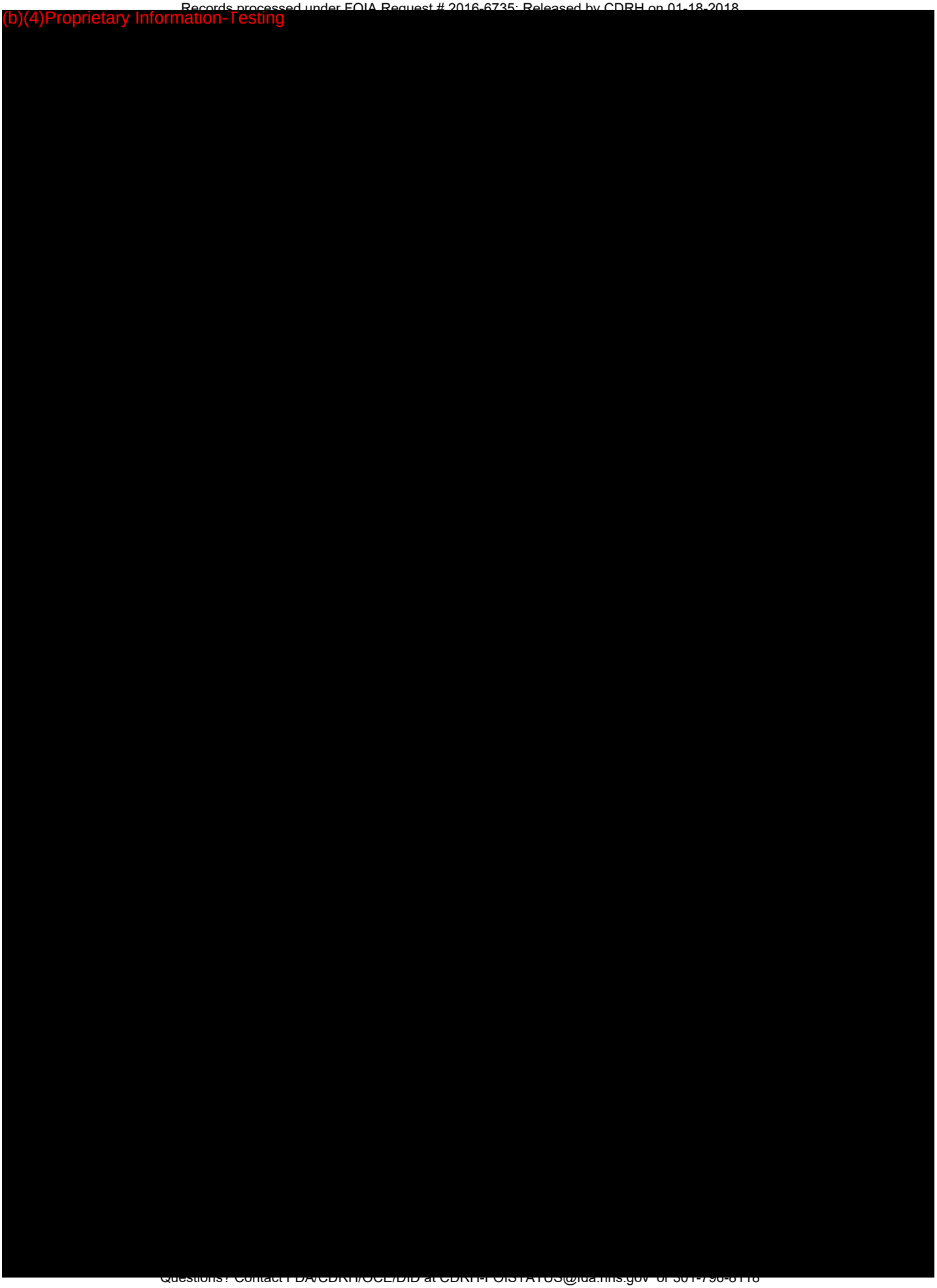
(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing



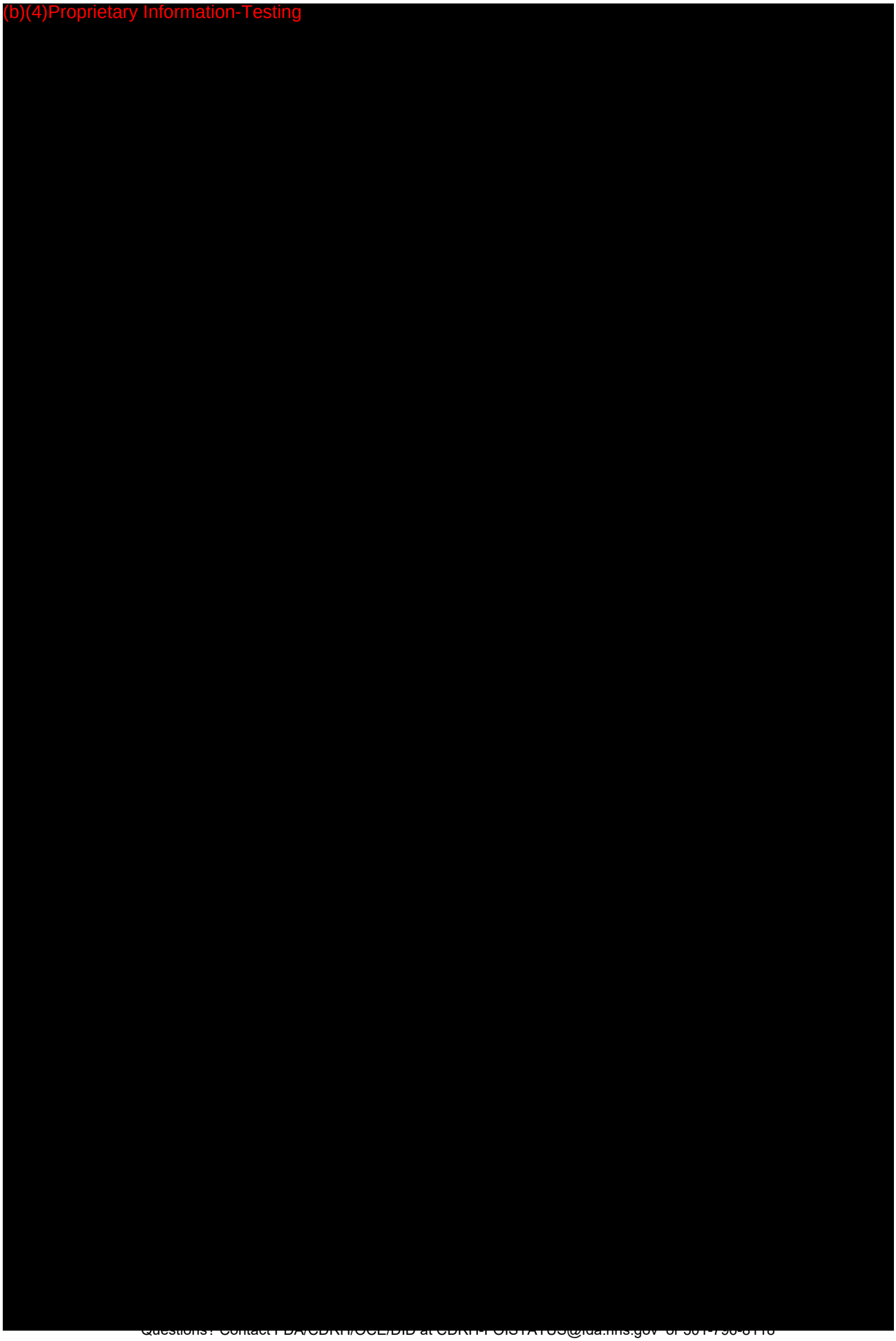
(b)(4)Proprietary Information- Testing



(b)(4)Proprietary Information-Testing

[redacted]

(b)(4)Proprietary Information-Testing



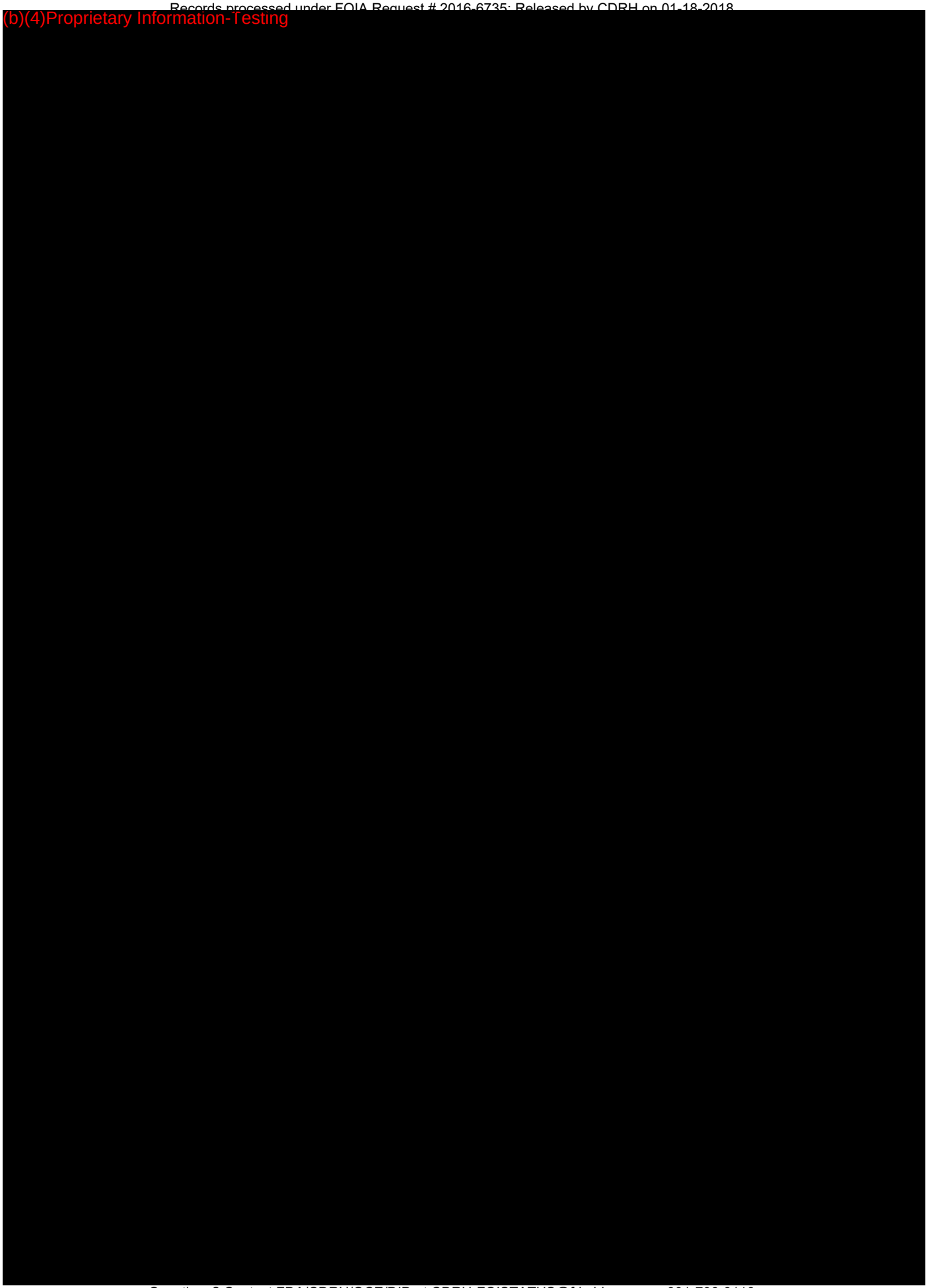
(b)(4)Proprietary Information-Testing

[redacted]

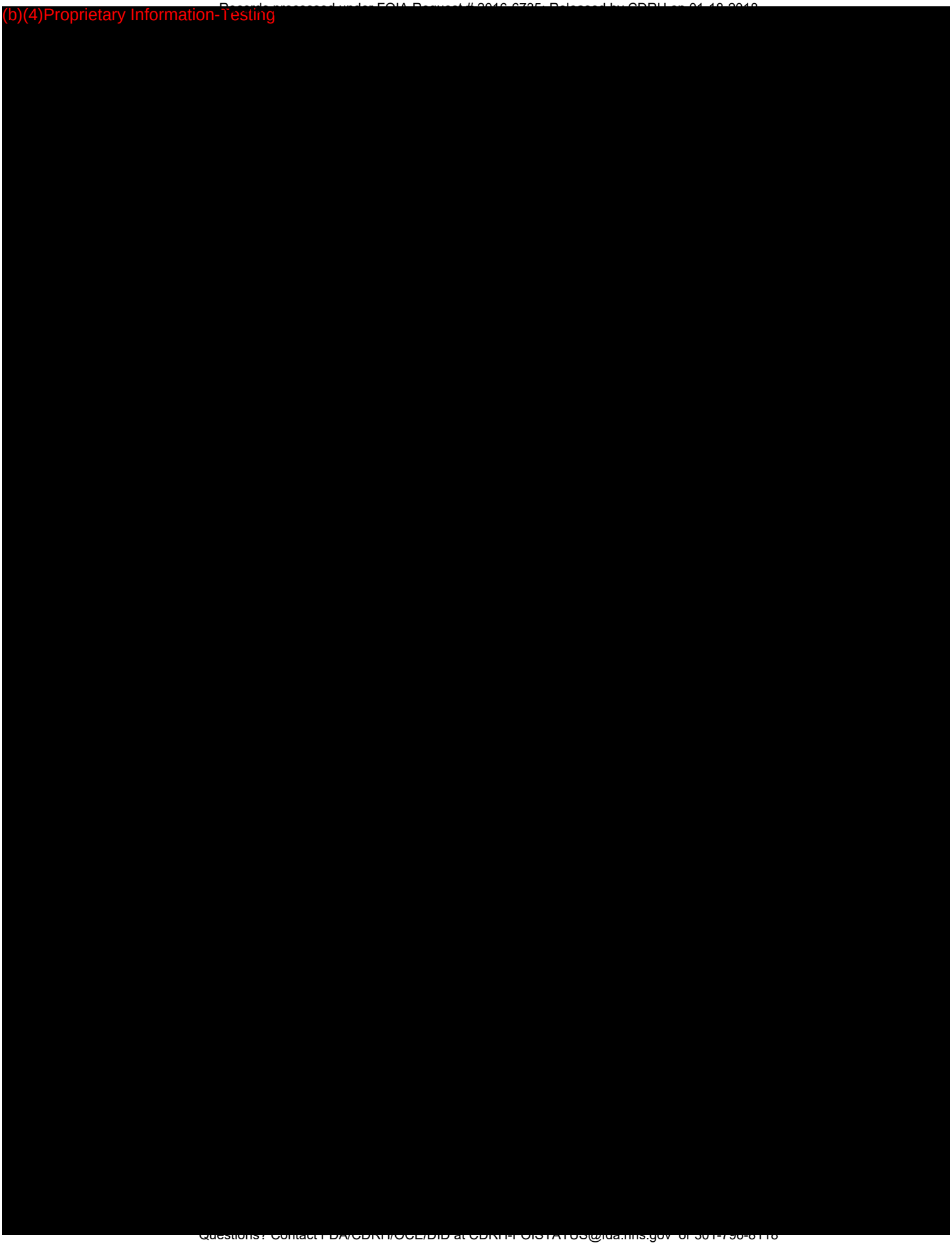
(b)(4)Proprietary Information-Testing

[redacted]

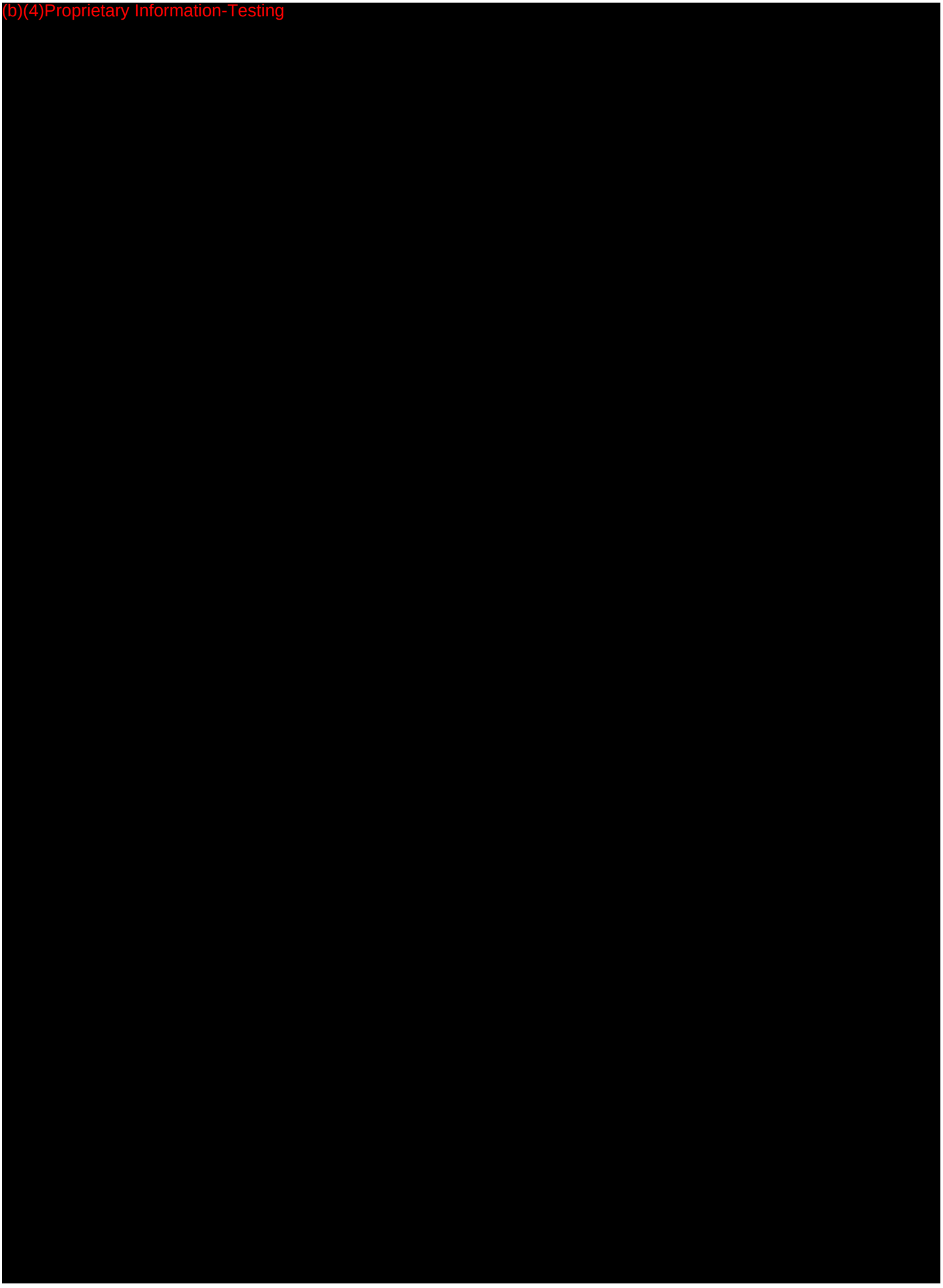
(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing

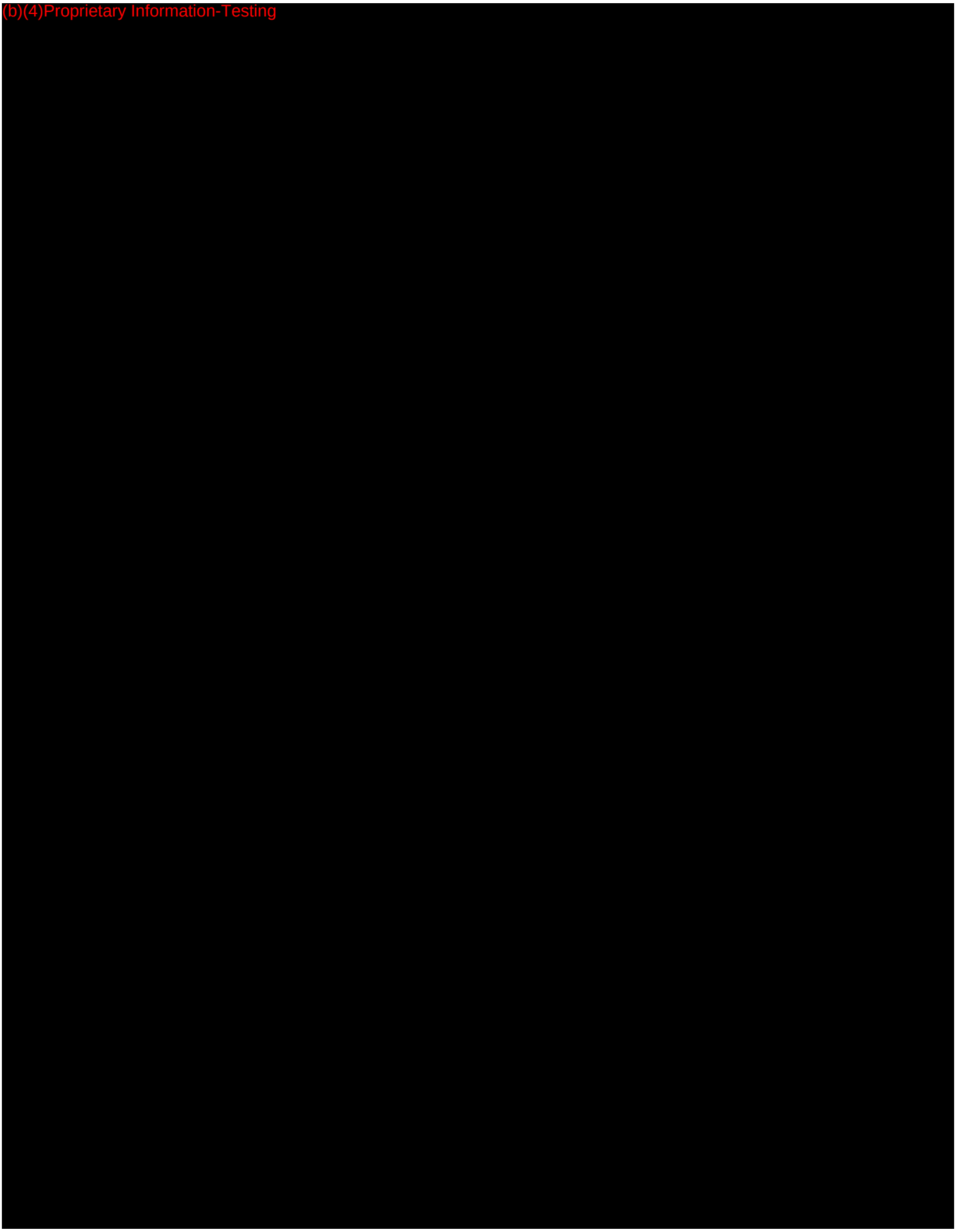


(b)(4)Proprietary Information-Testing

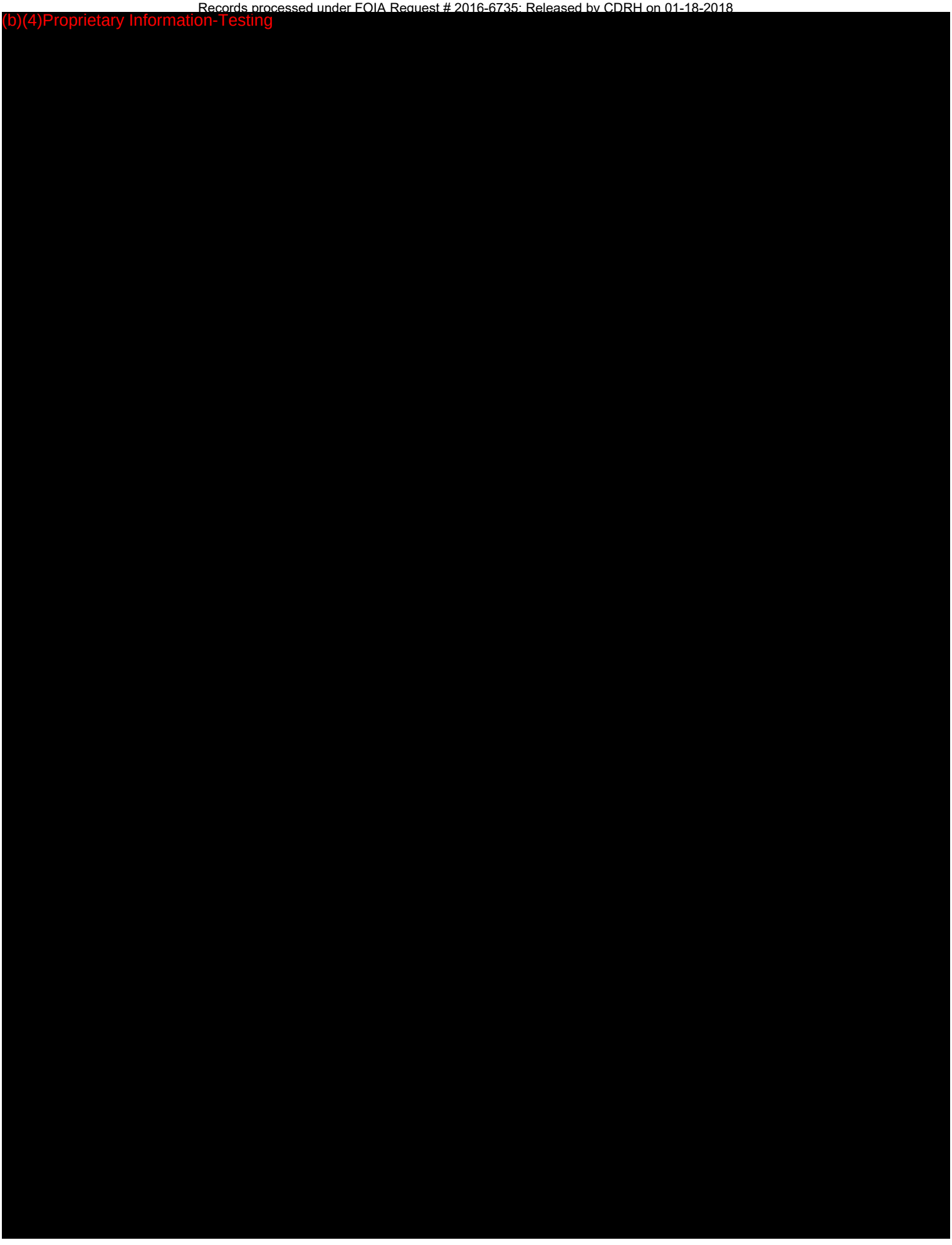
[redacted]

(b)(4)Proprietary Information-Testing

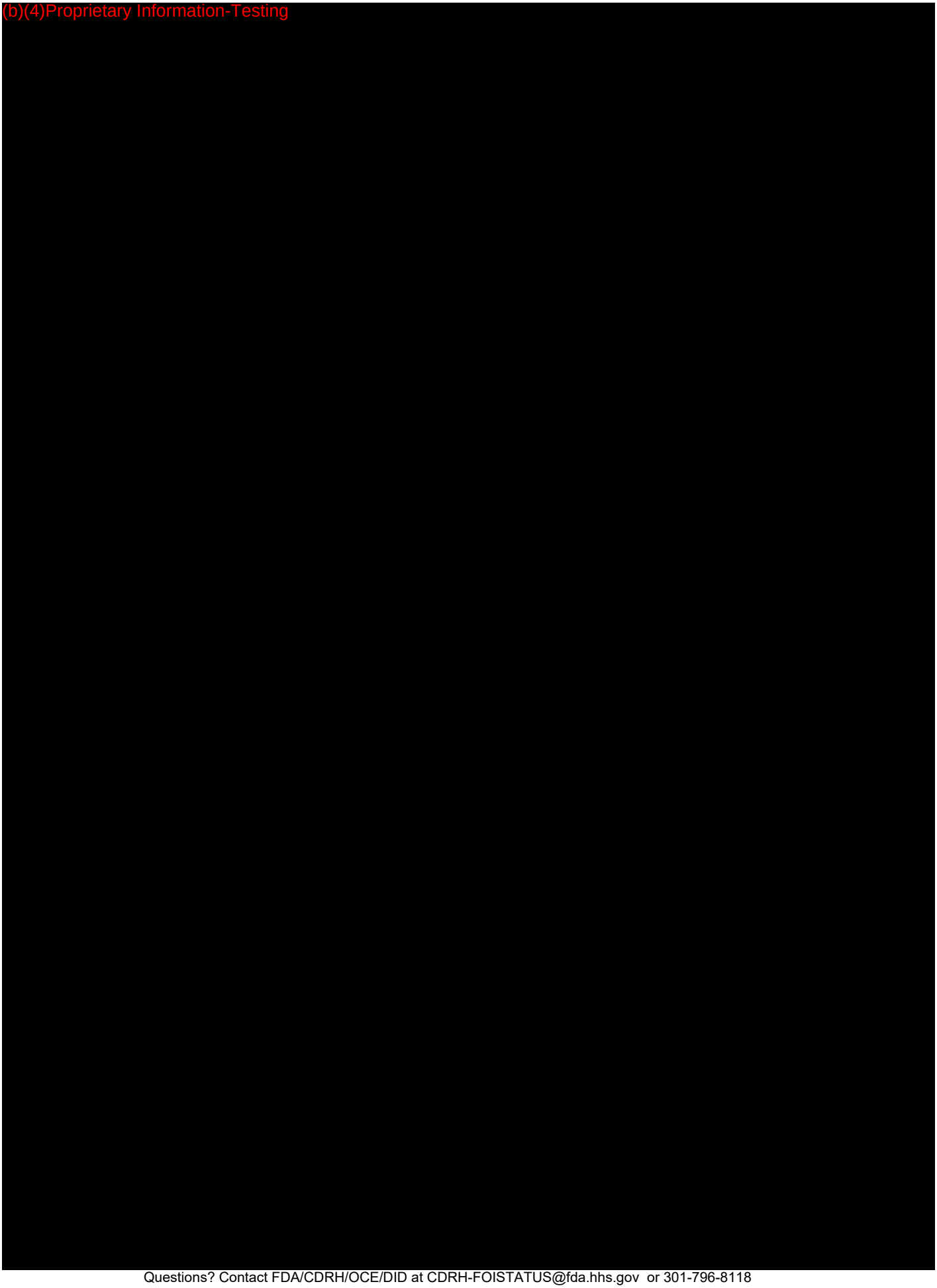
[redacted]



(b)(4)Proprietary Information-Testing



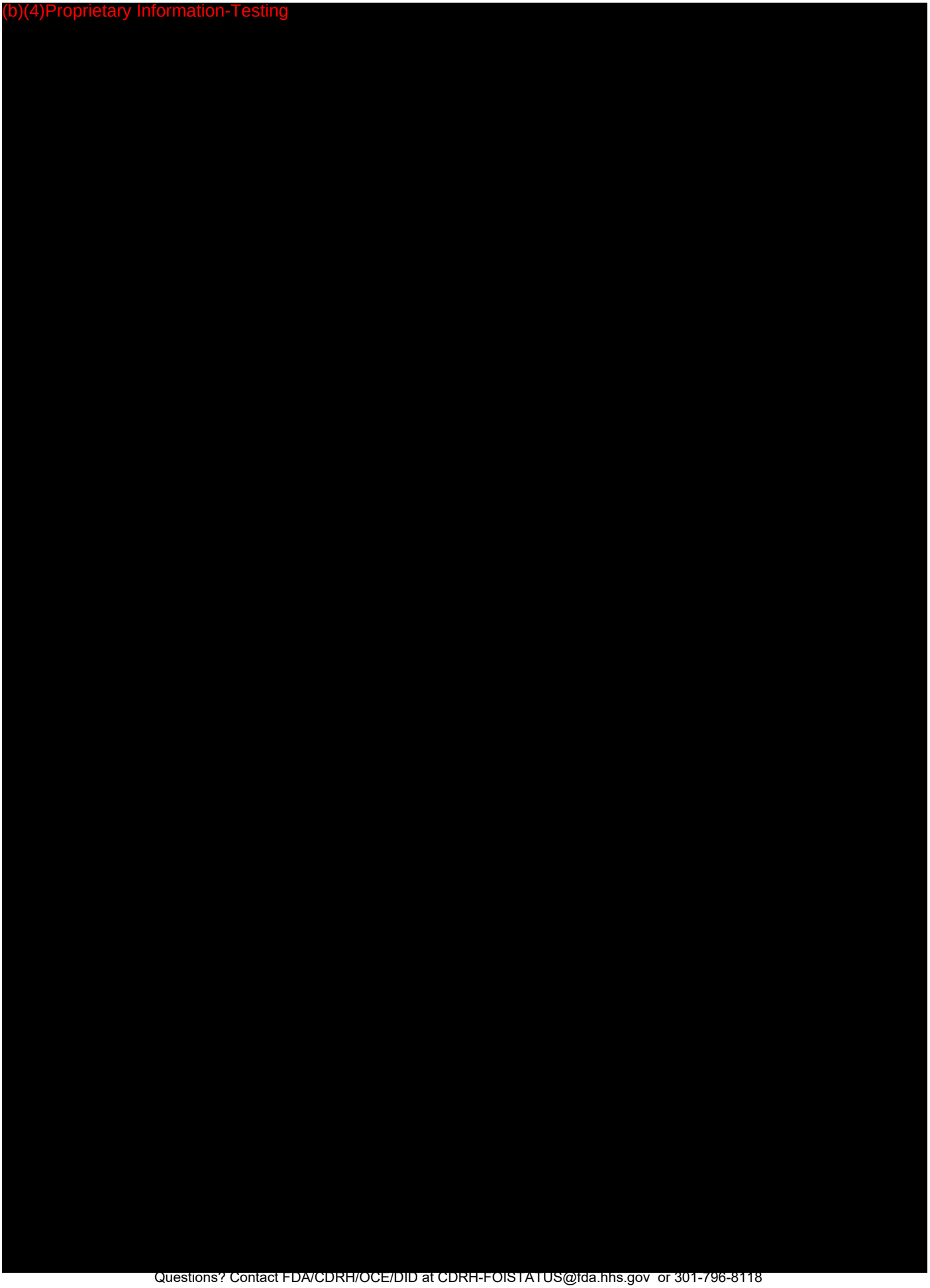
(b)(4)Proprietary Information-Testing



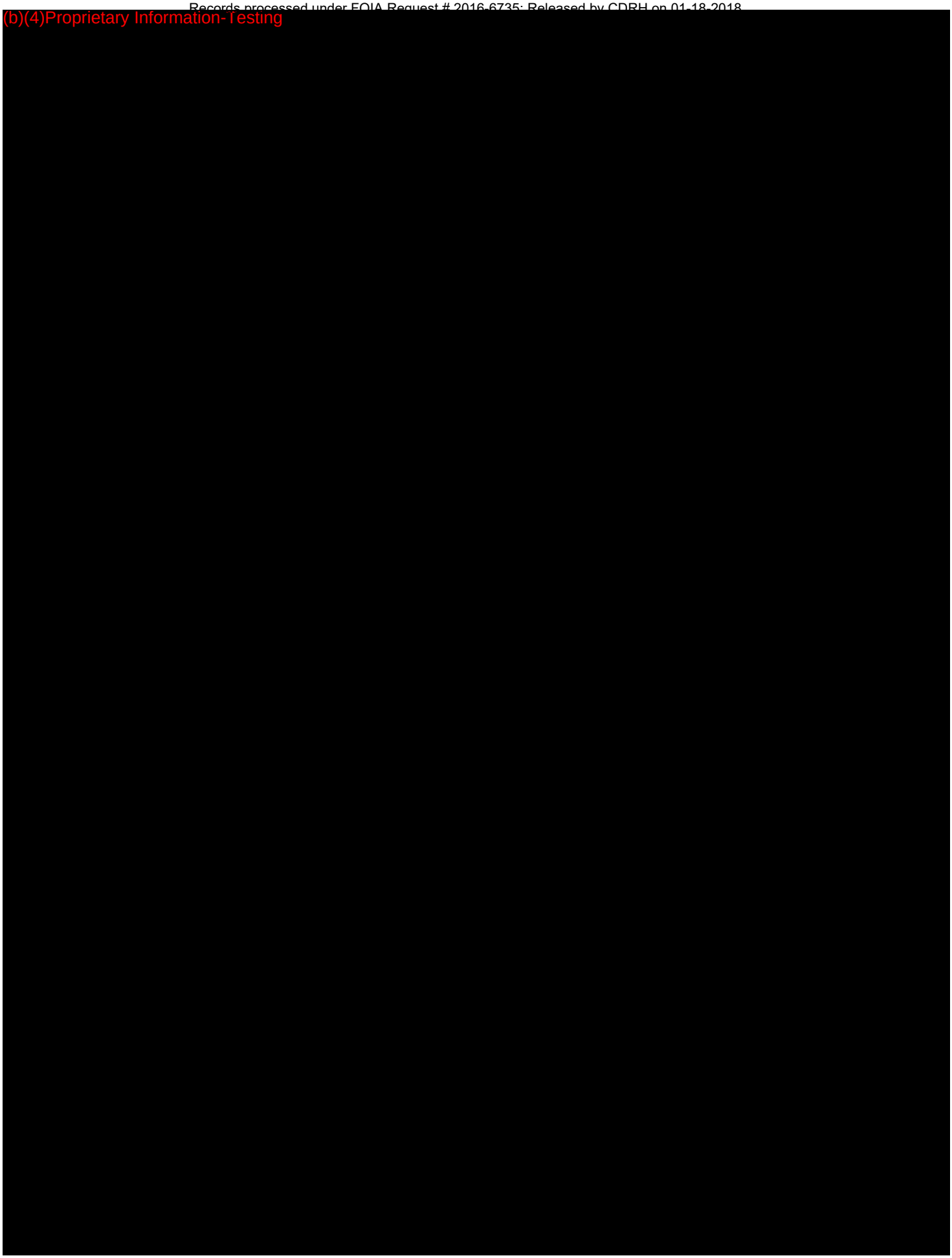
(b)(4)Proprietary Information-Testing

[redacted]

(b)(4)Proprietary Information-Testing

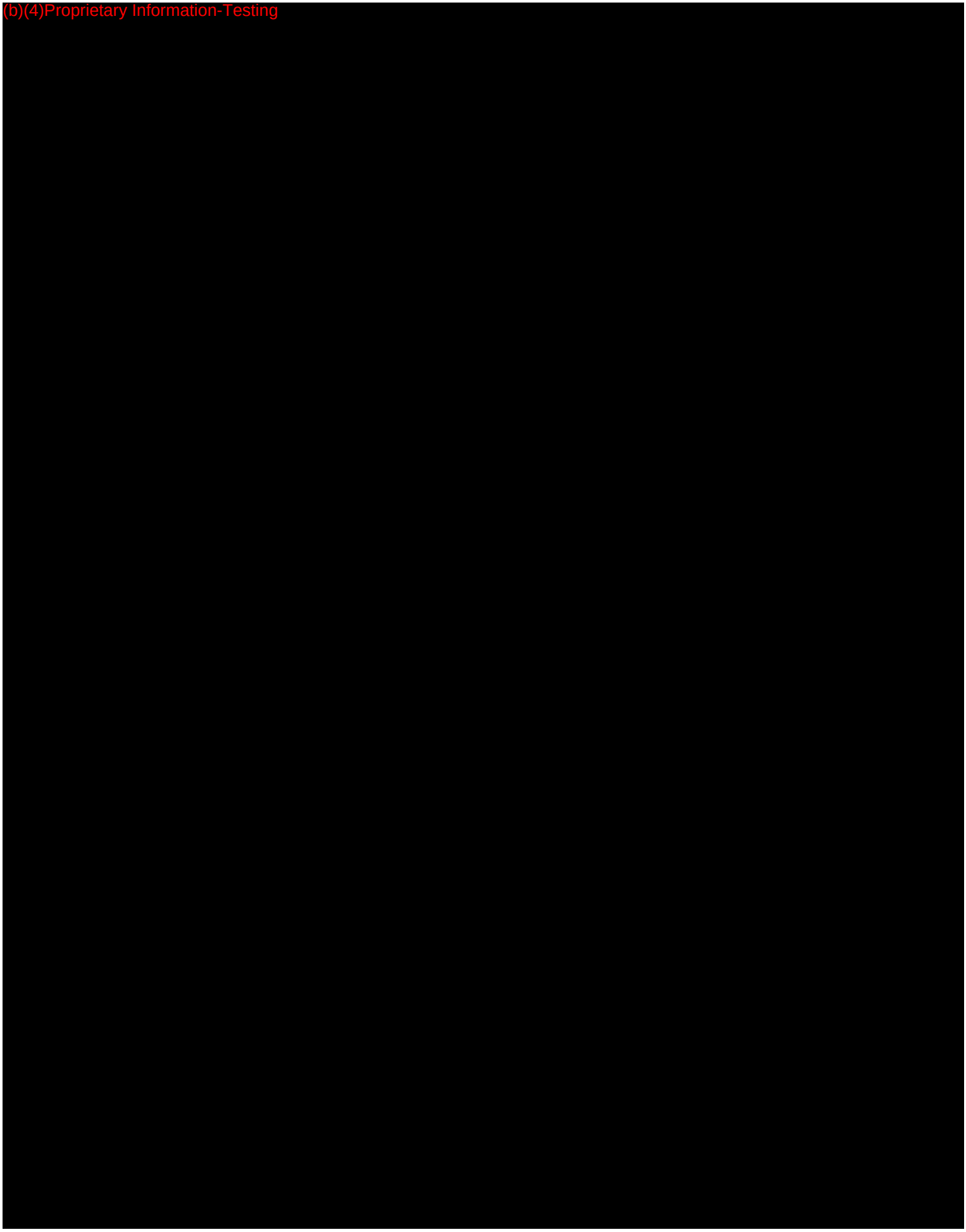


(b)(4)Proprietary Information- Testing

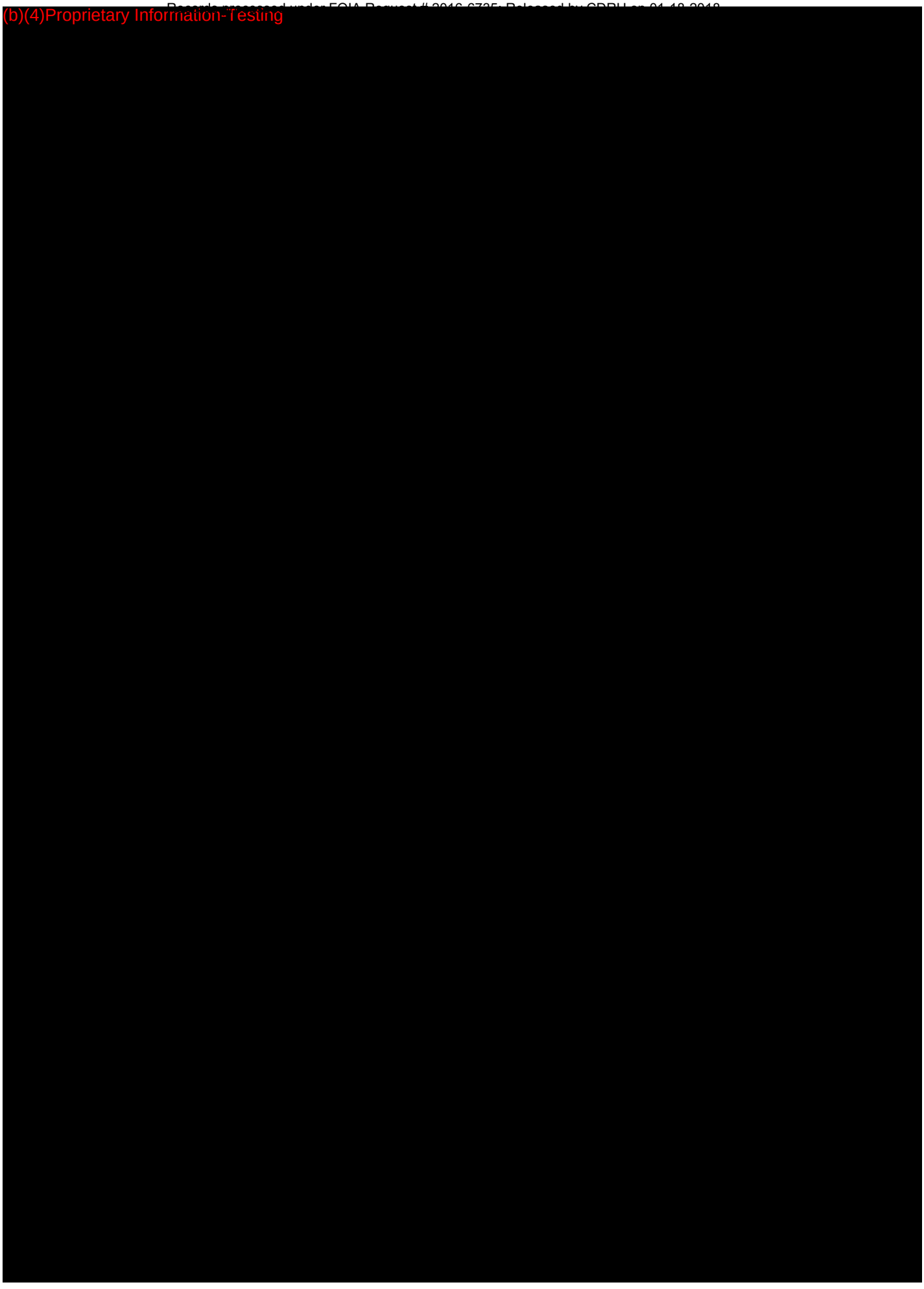


(b)(4)Proprietary Information-Testing

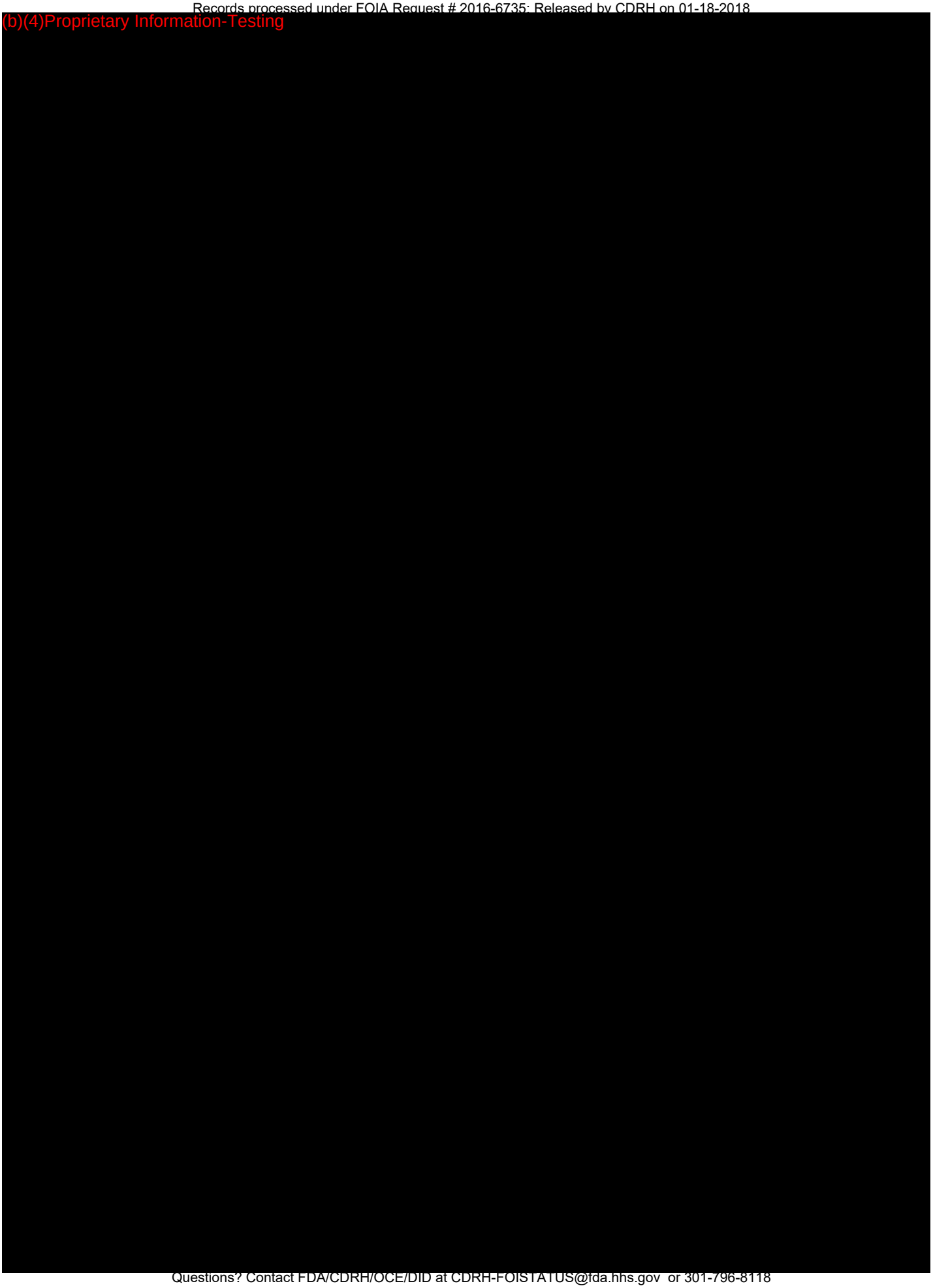
[redacted]



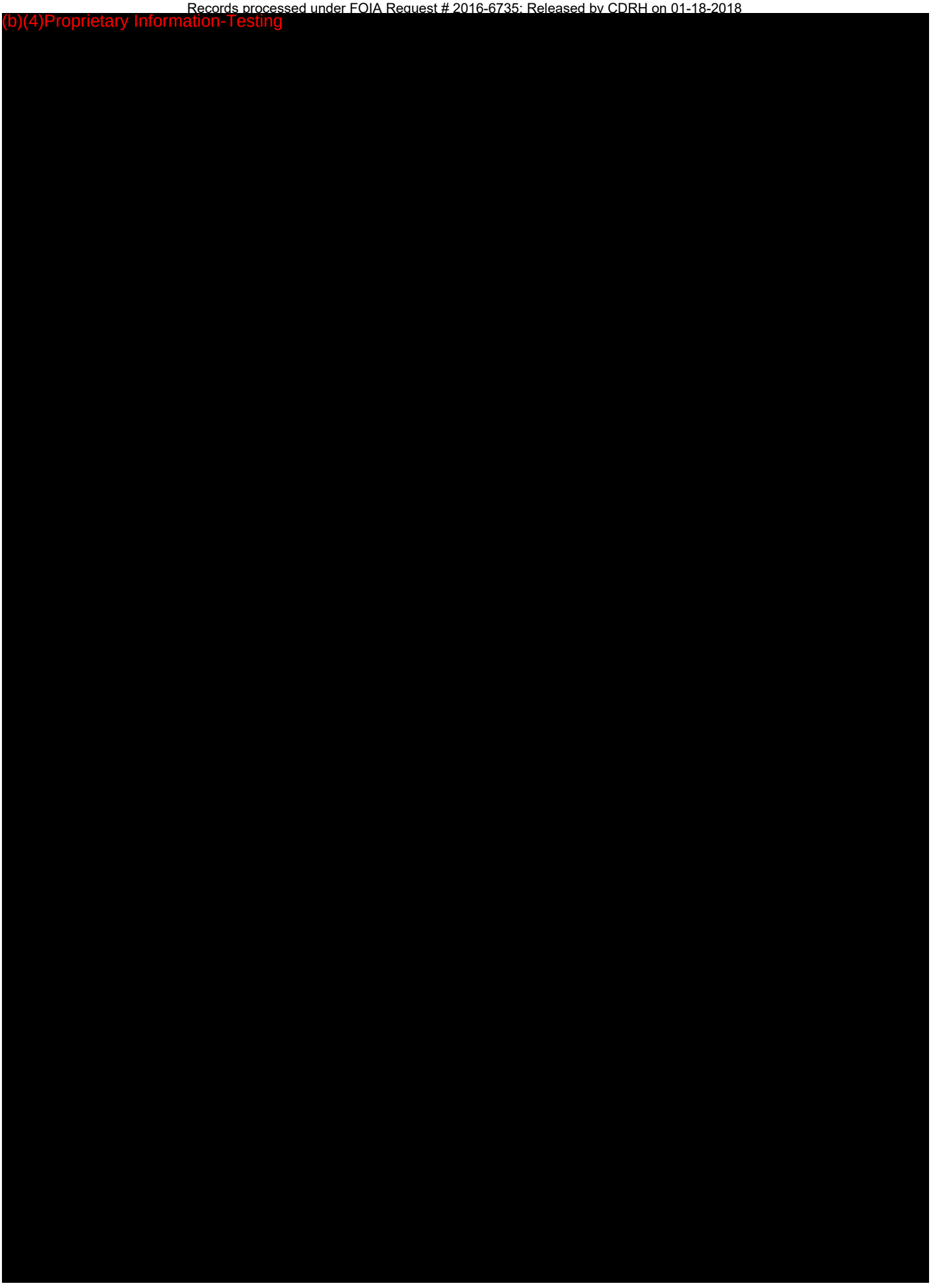
(b)(4)Proprietary Information - Testing



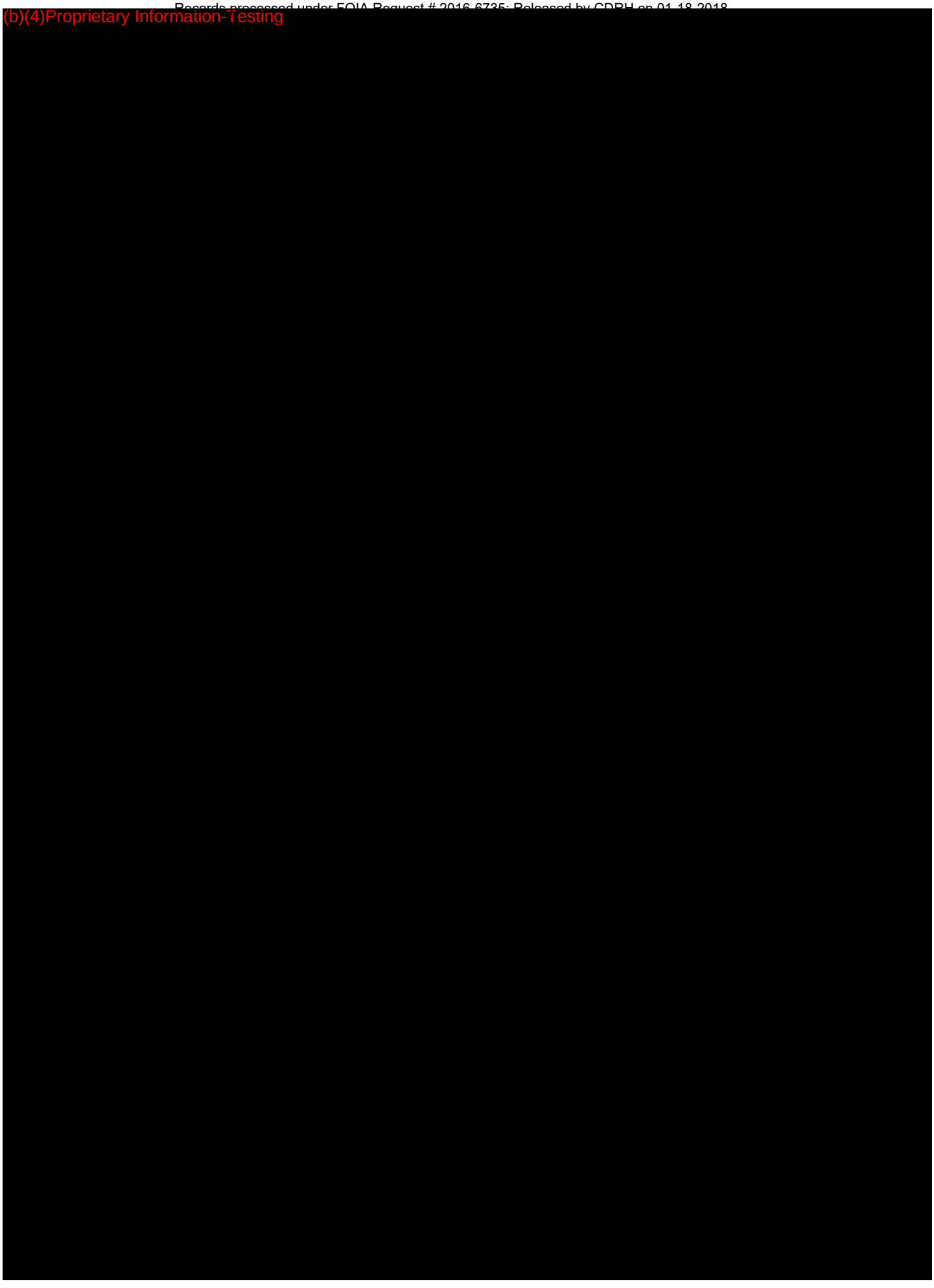
(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing



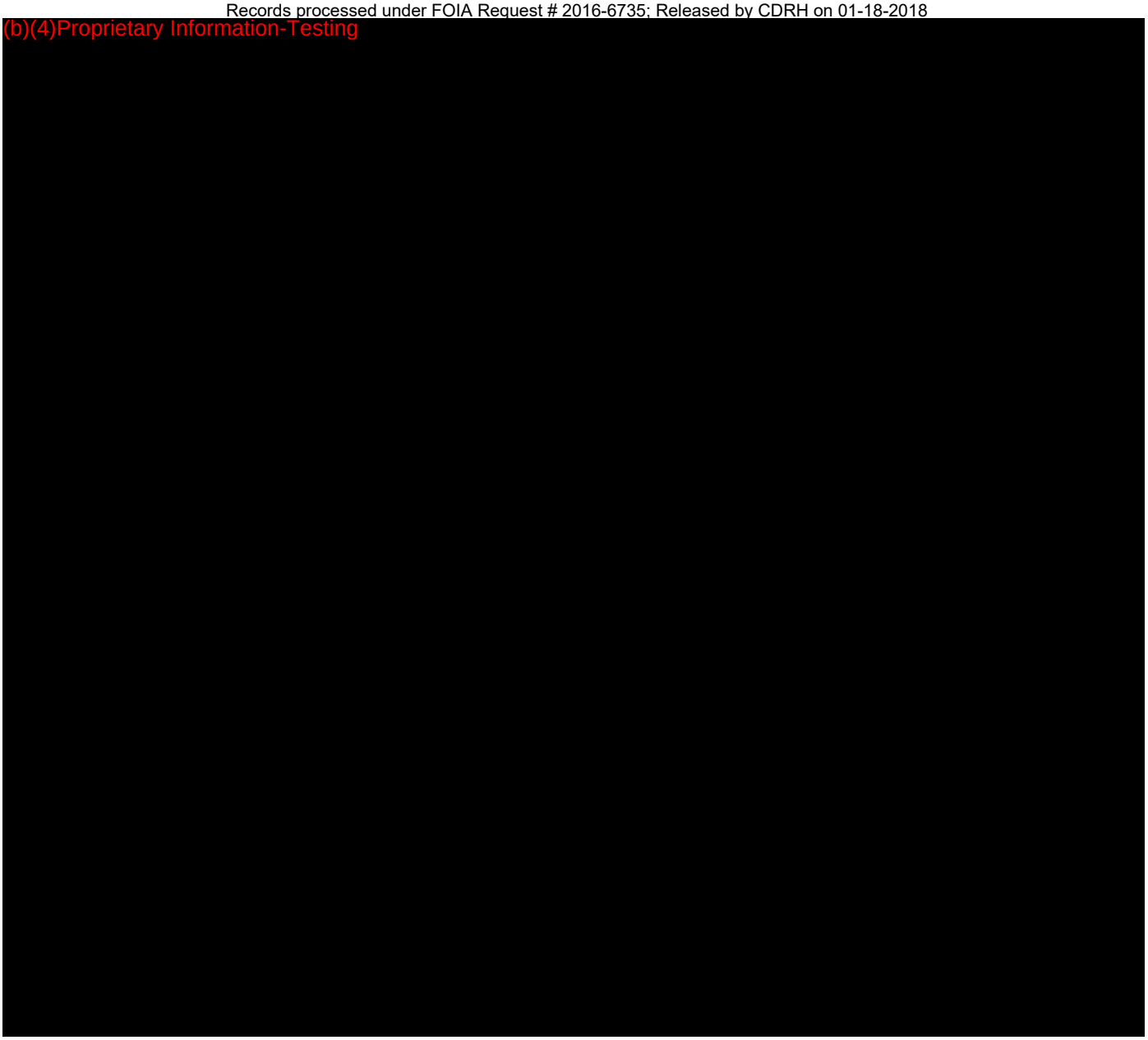
(b)(4)Proprietary Information-Testing

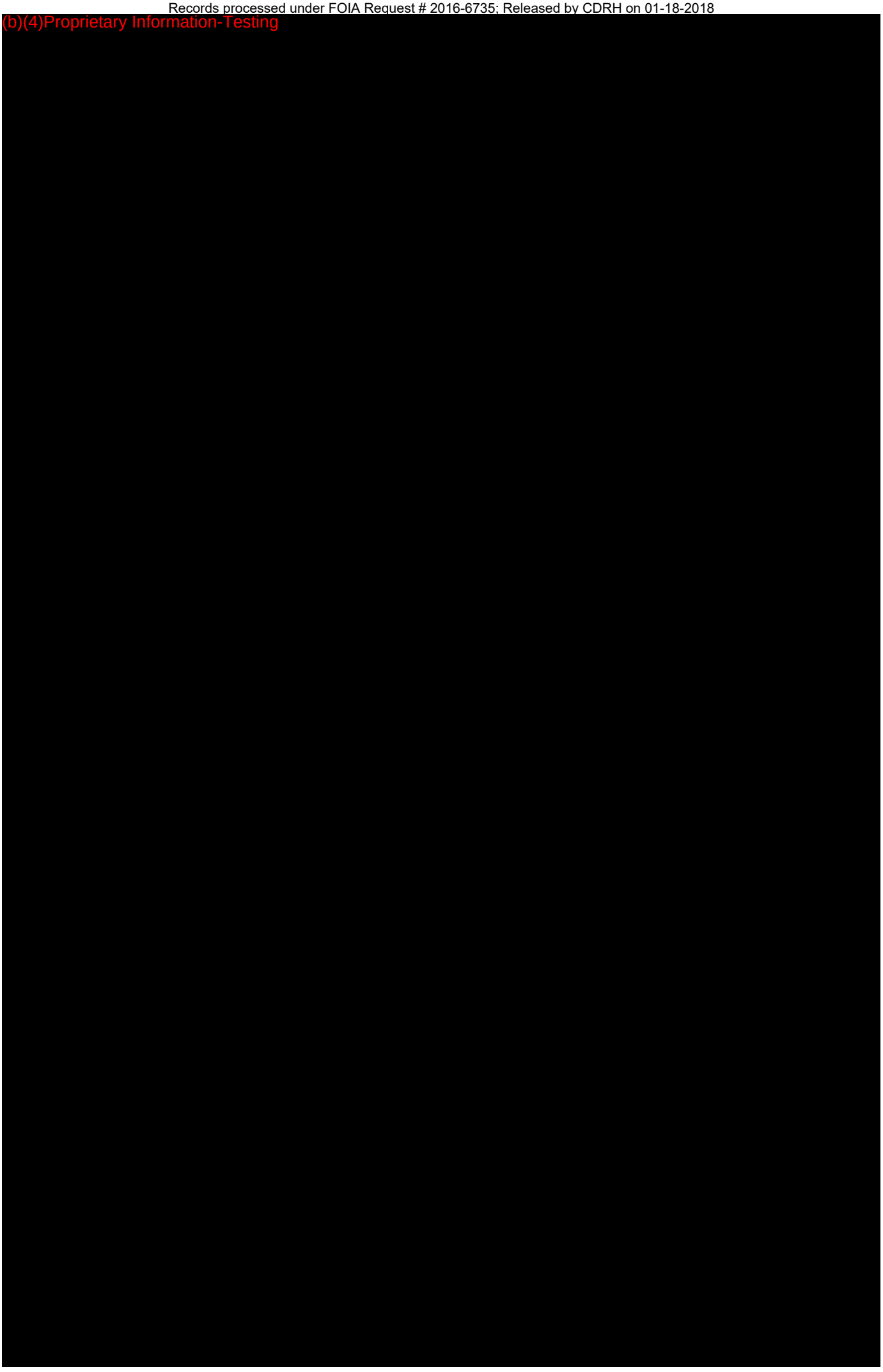
(b)(4)Proprietary Information-Testing

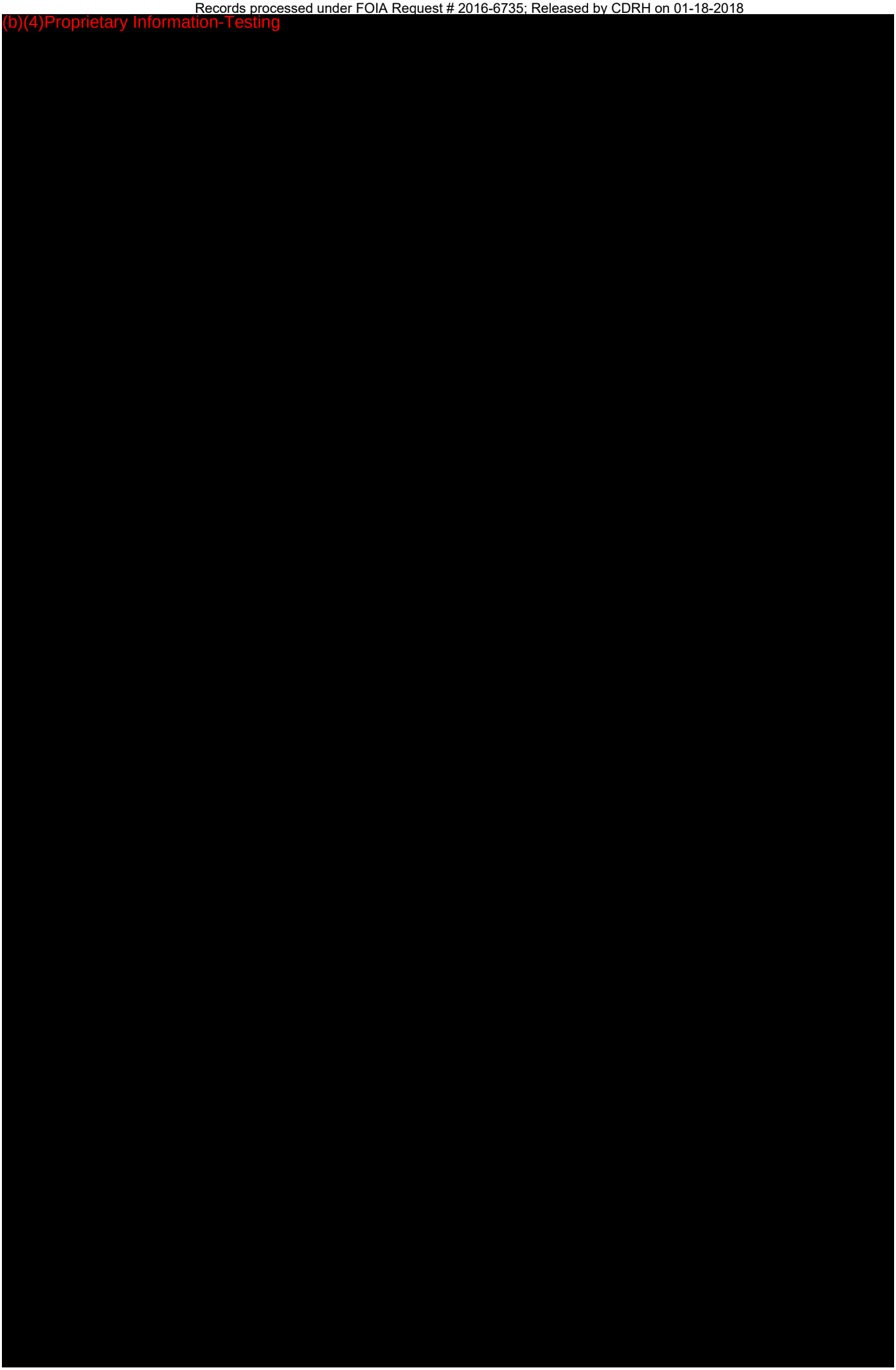
(b)(4)Proprietary Information-Testing

[redacted]

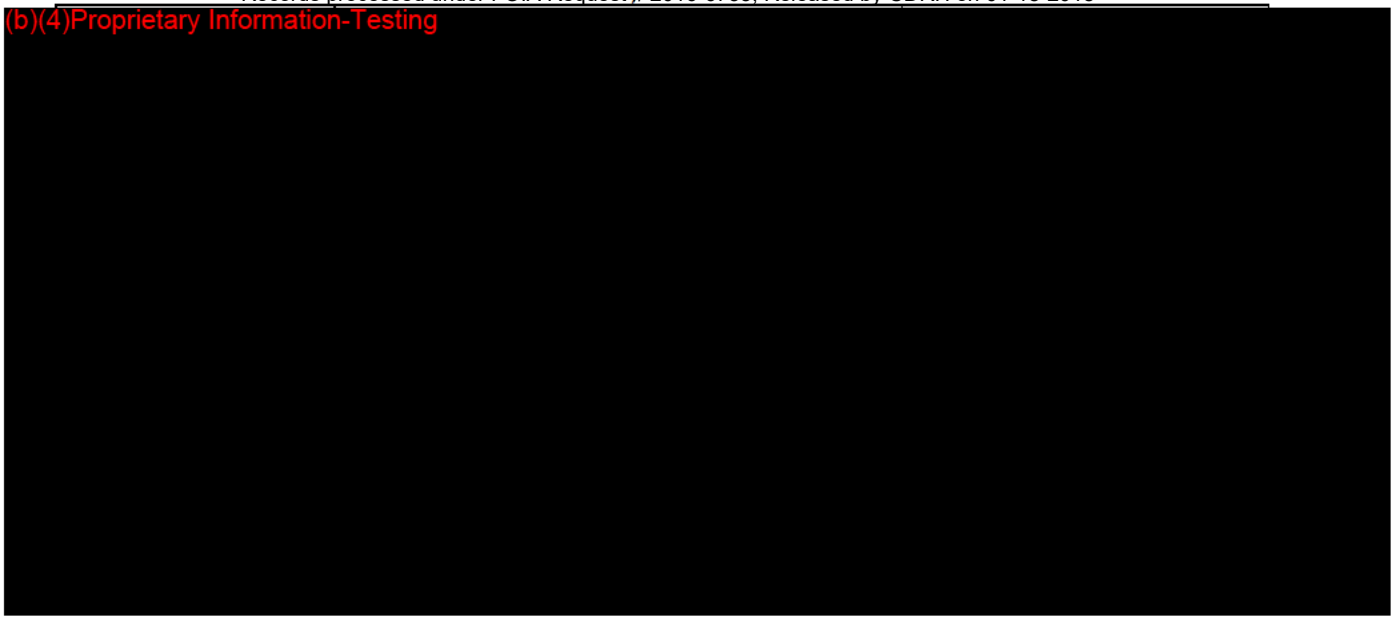
(b)(4)Proprietary Information-Testing







(b)(4)Proprietary Information-Testing

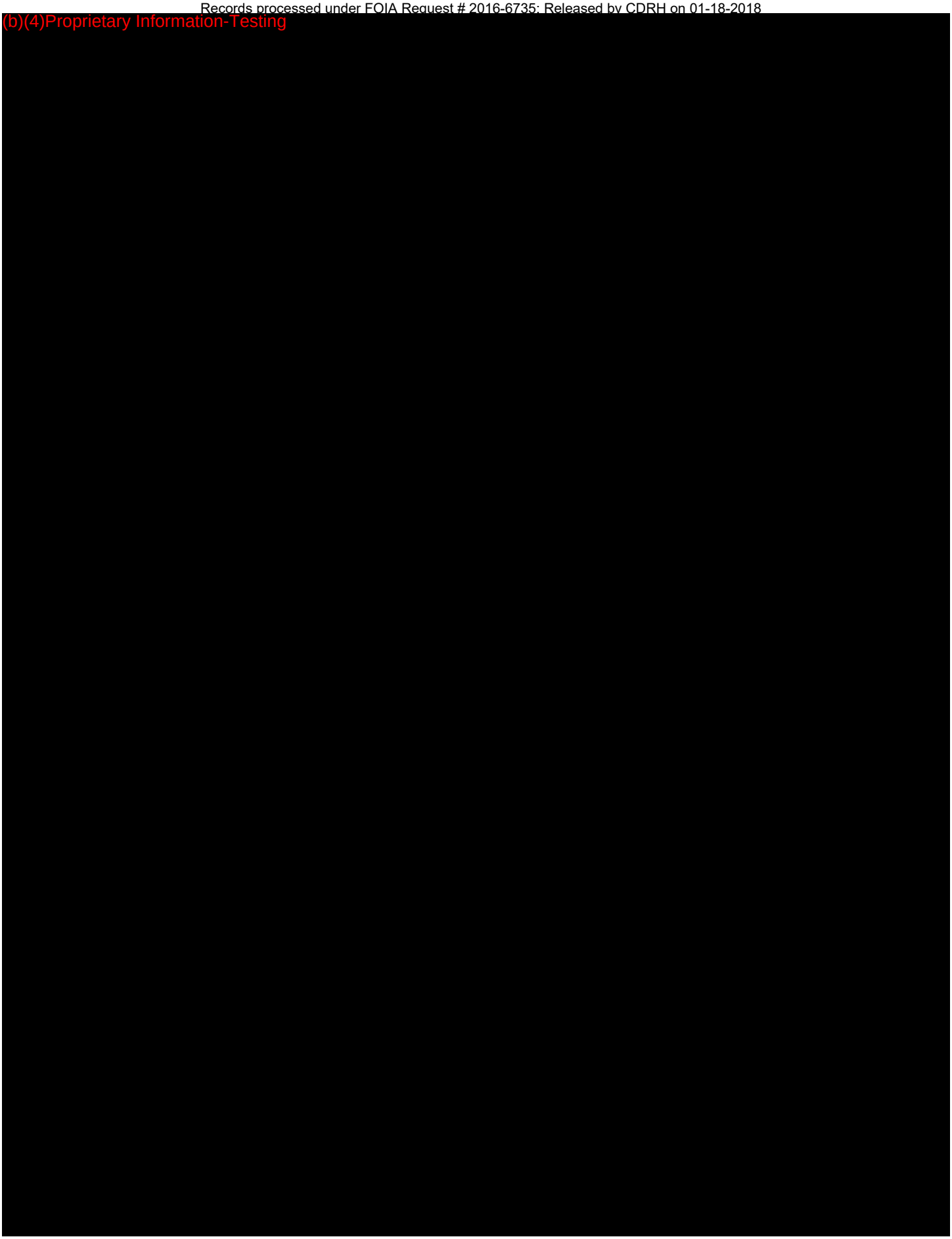


ATTACHMENT 27

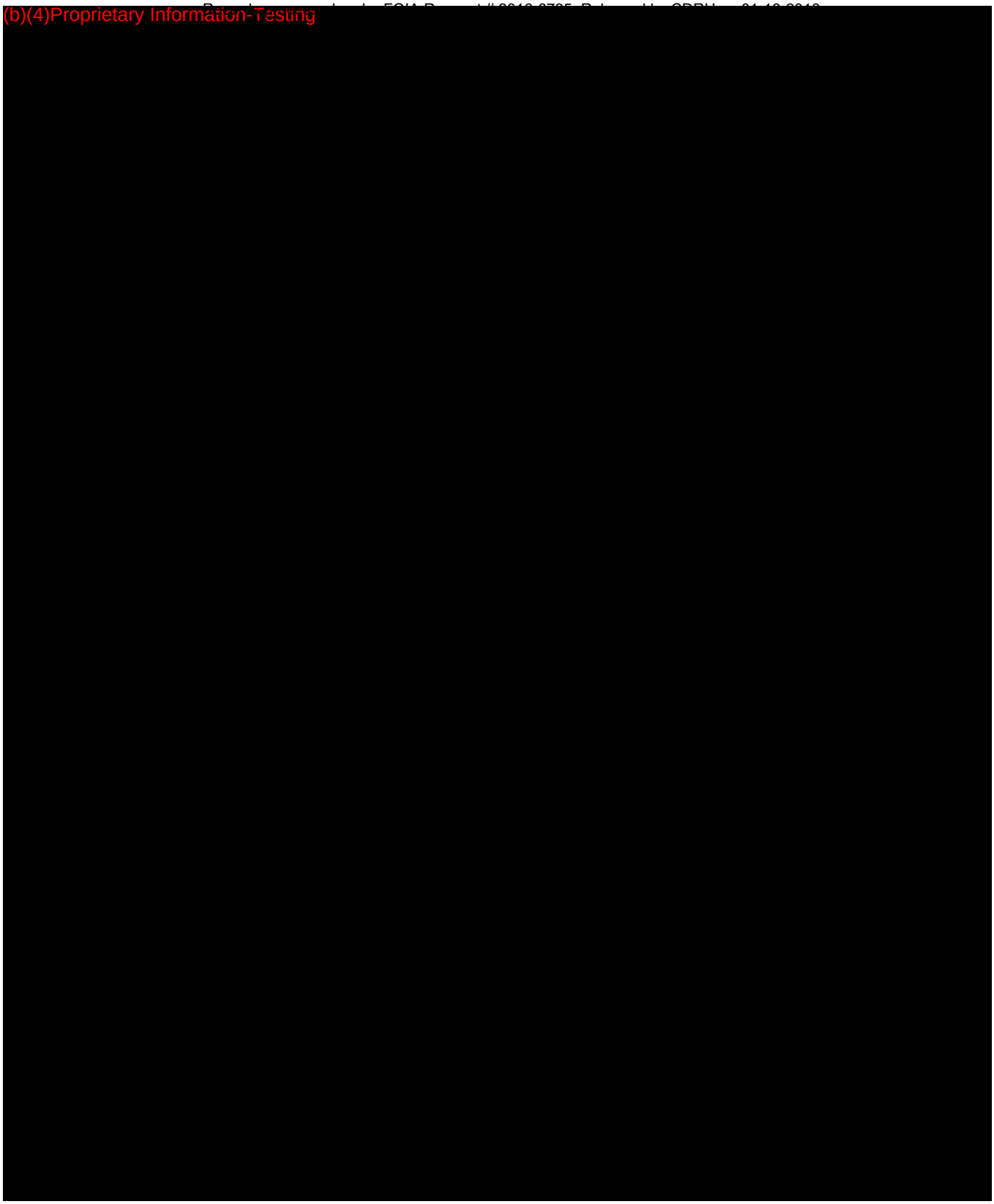
(b)(4)Proprietary Information-Testing

[redacted]

(b)(4)Proprietary Information-Testing

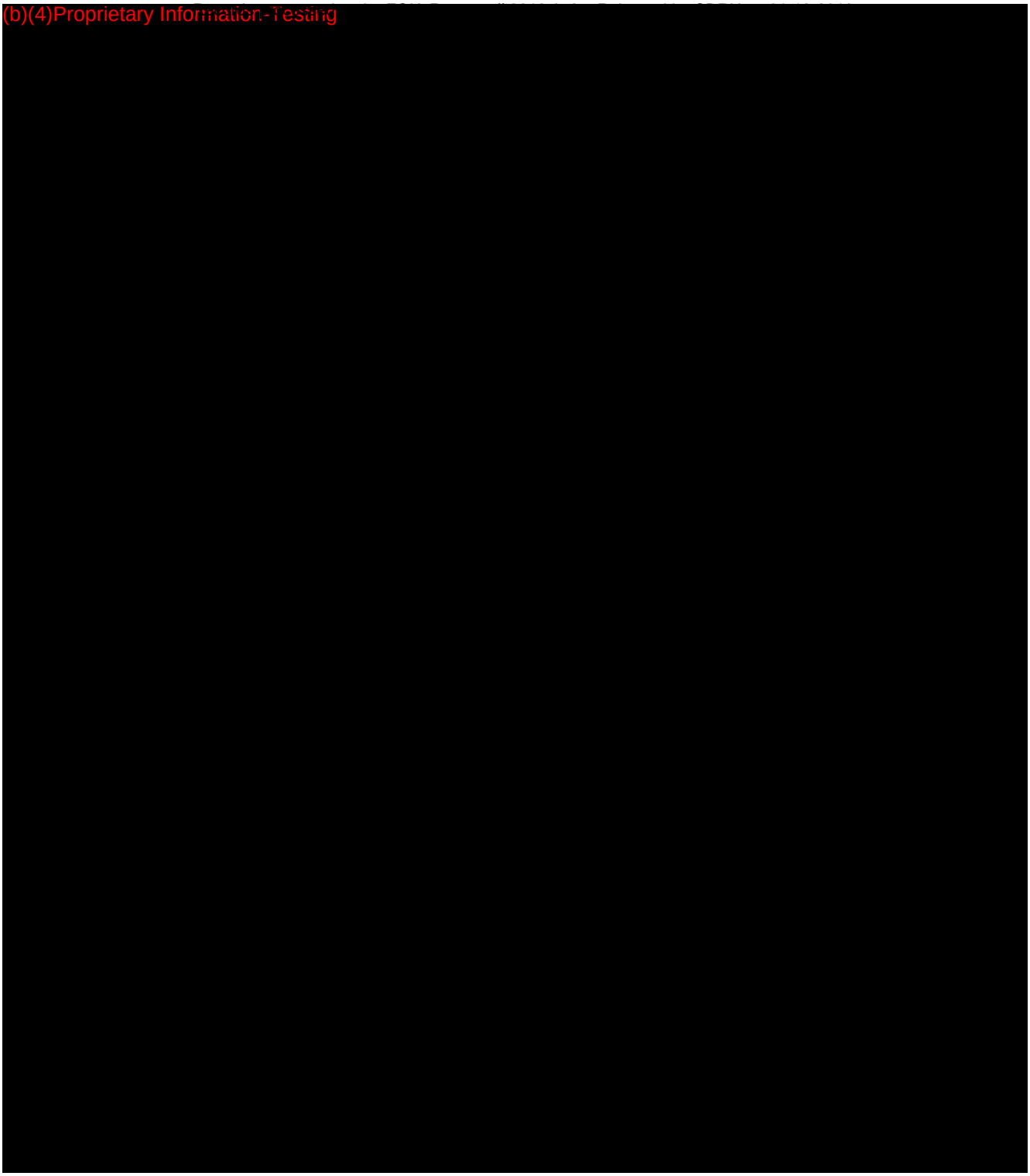


(b)(4)Proprietary Information-Testing

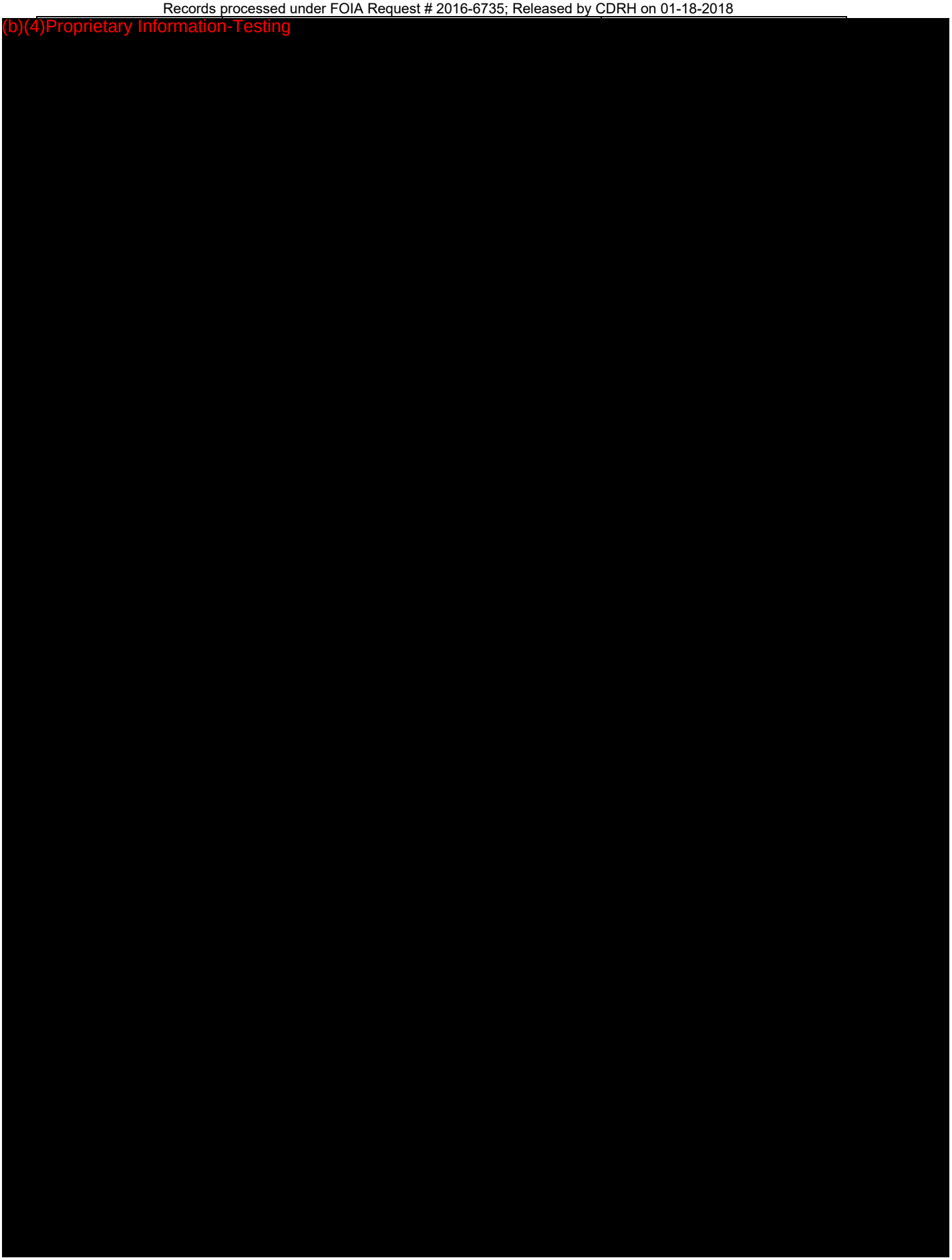


(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information-Testing



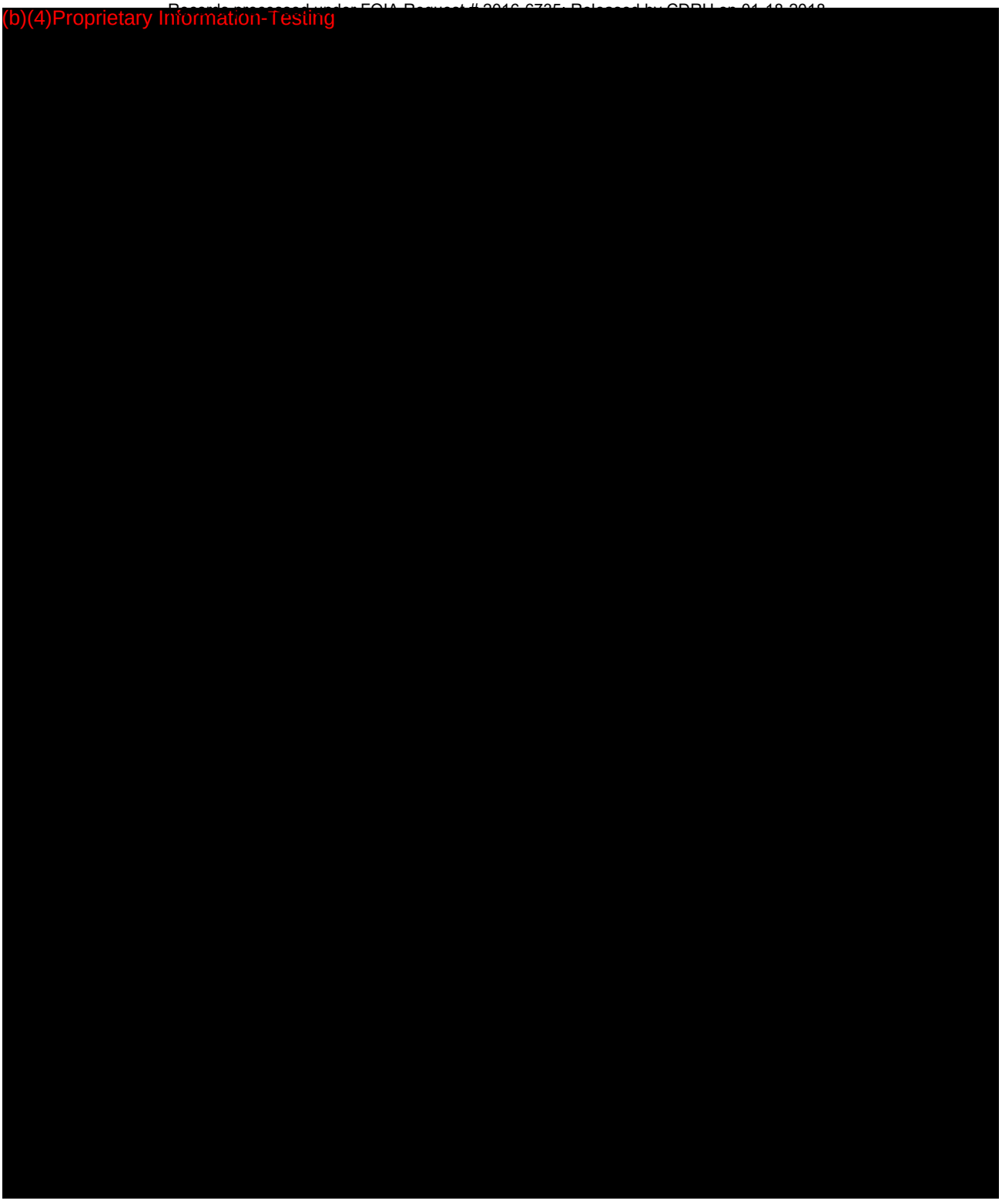
(b)(4)Proprietary Information-Testing



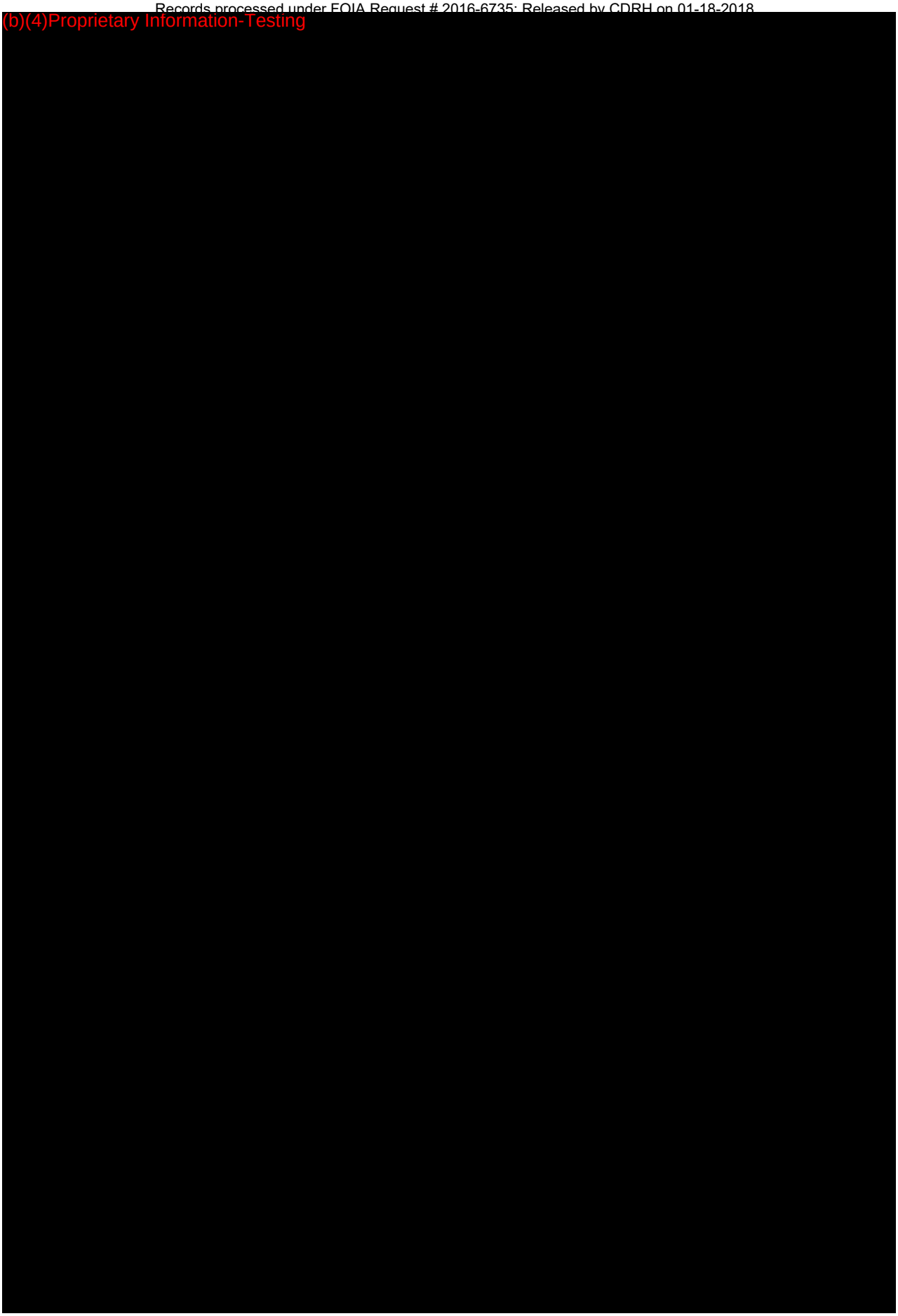
(b)(4)Proprietary information-Testing

[redacted]

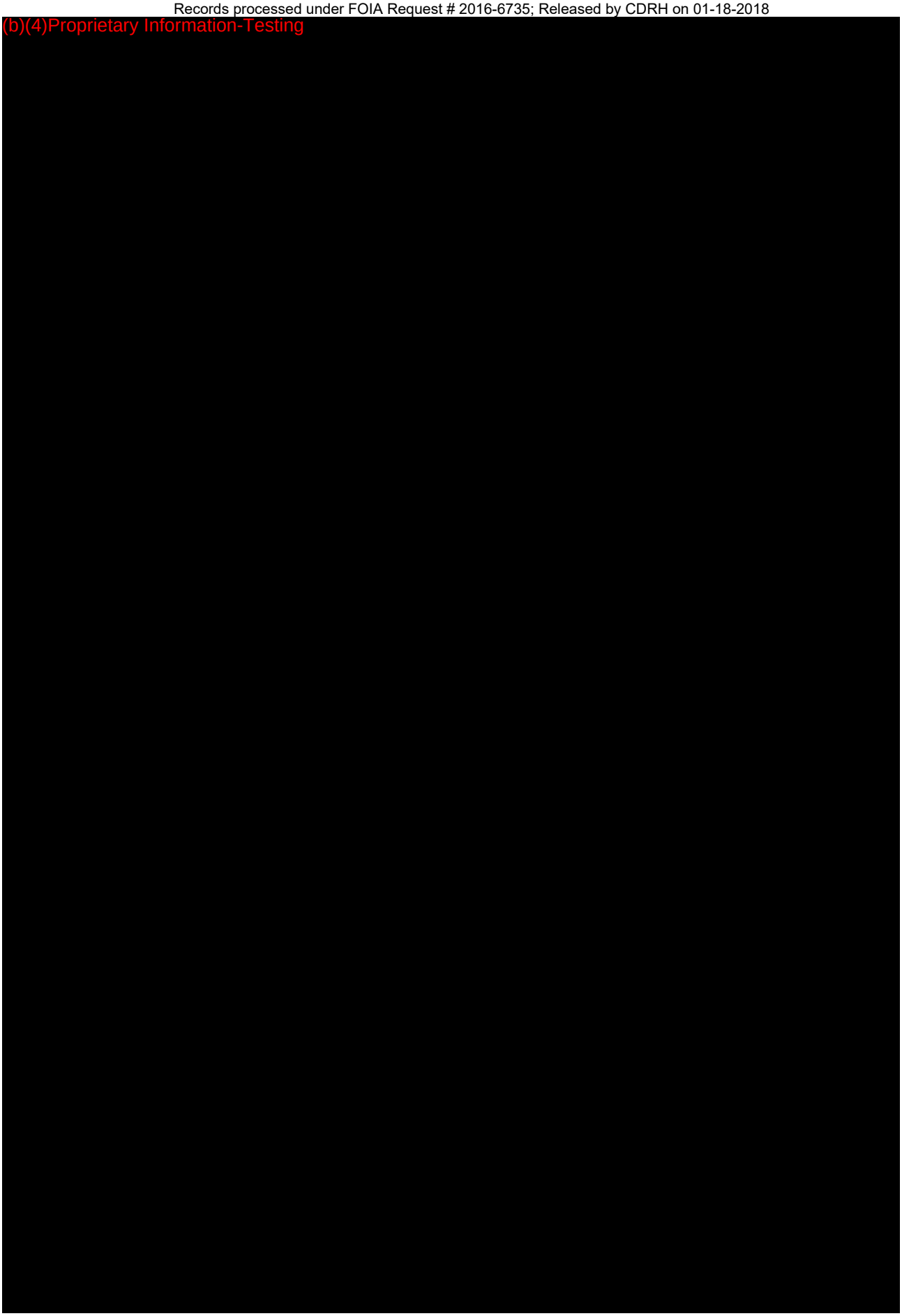
(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing



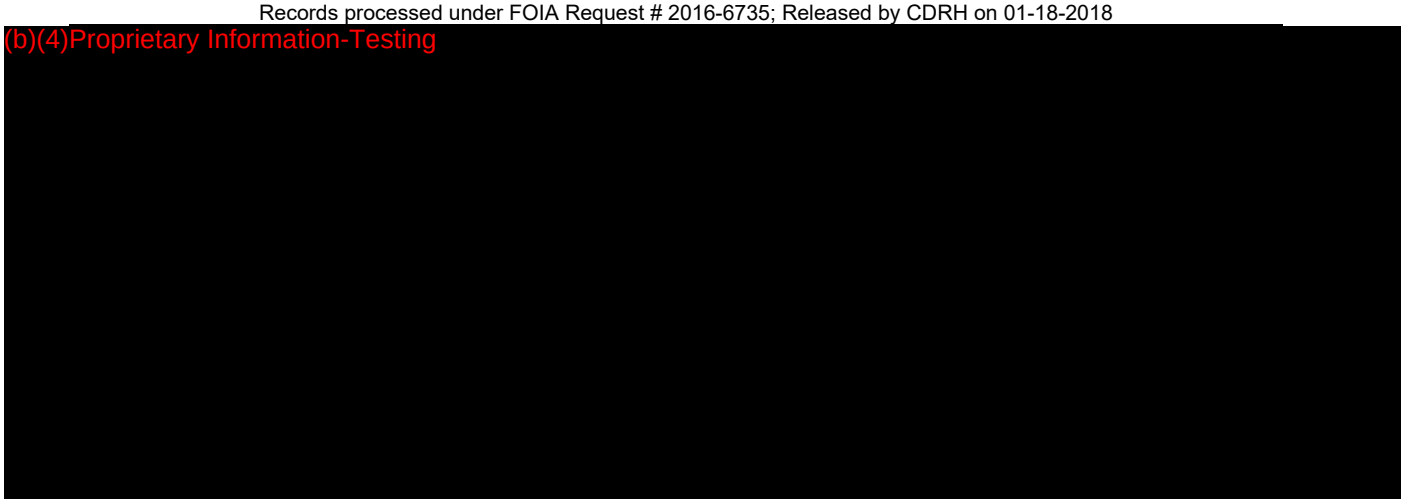
(b)(4)Proprietary Information-Testing

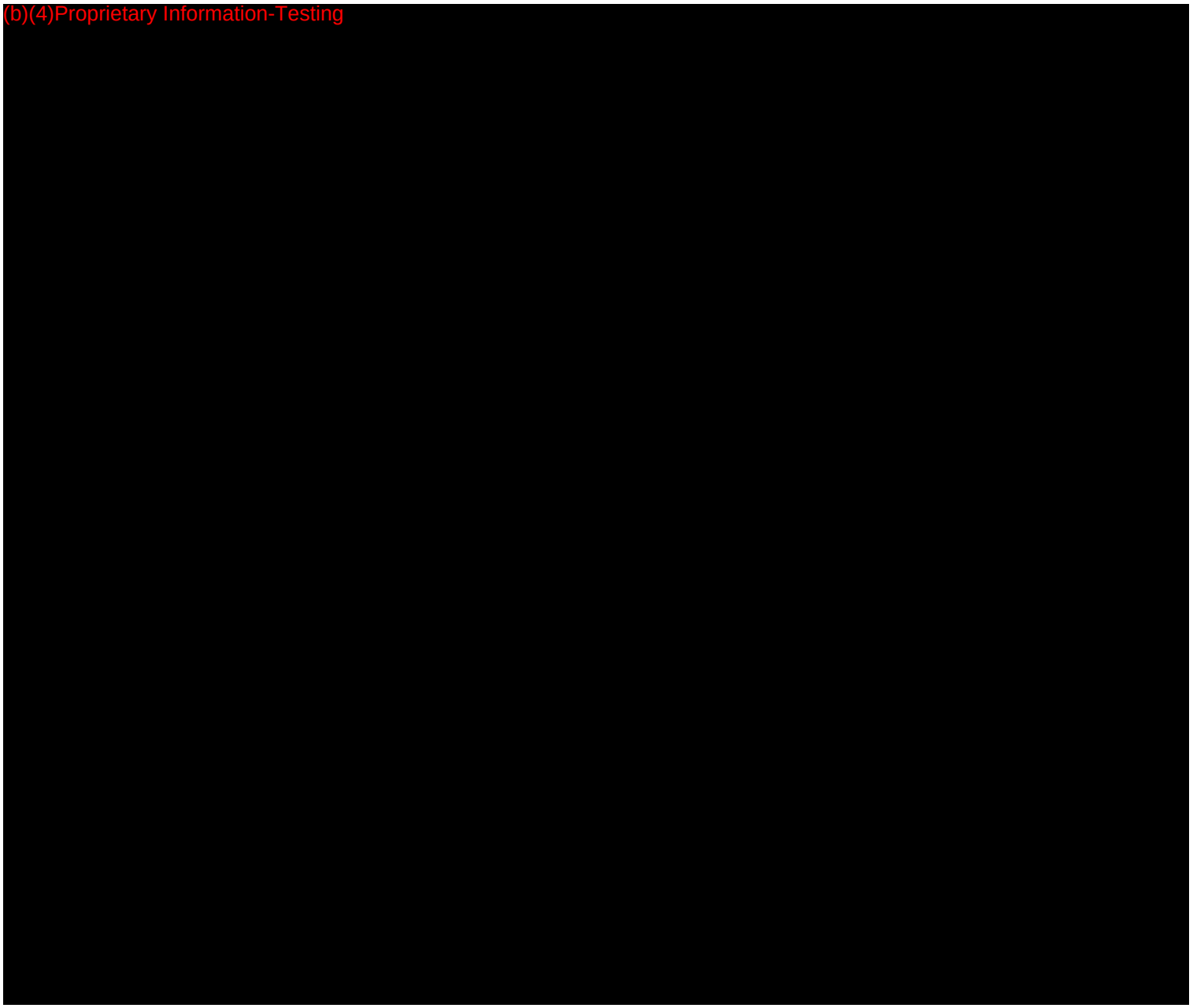


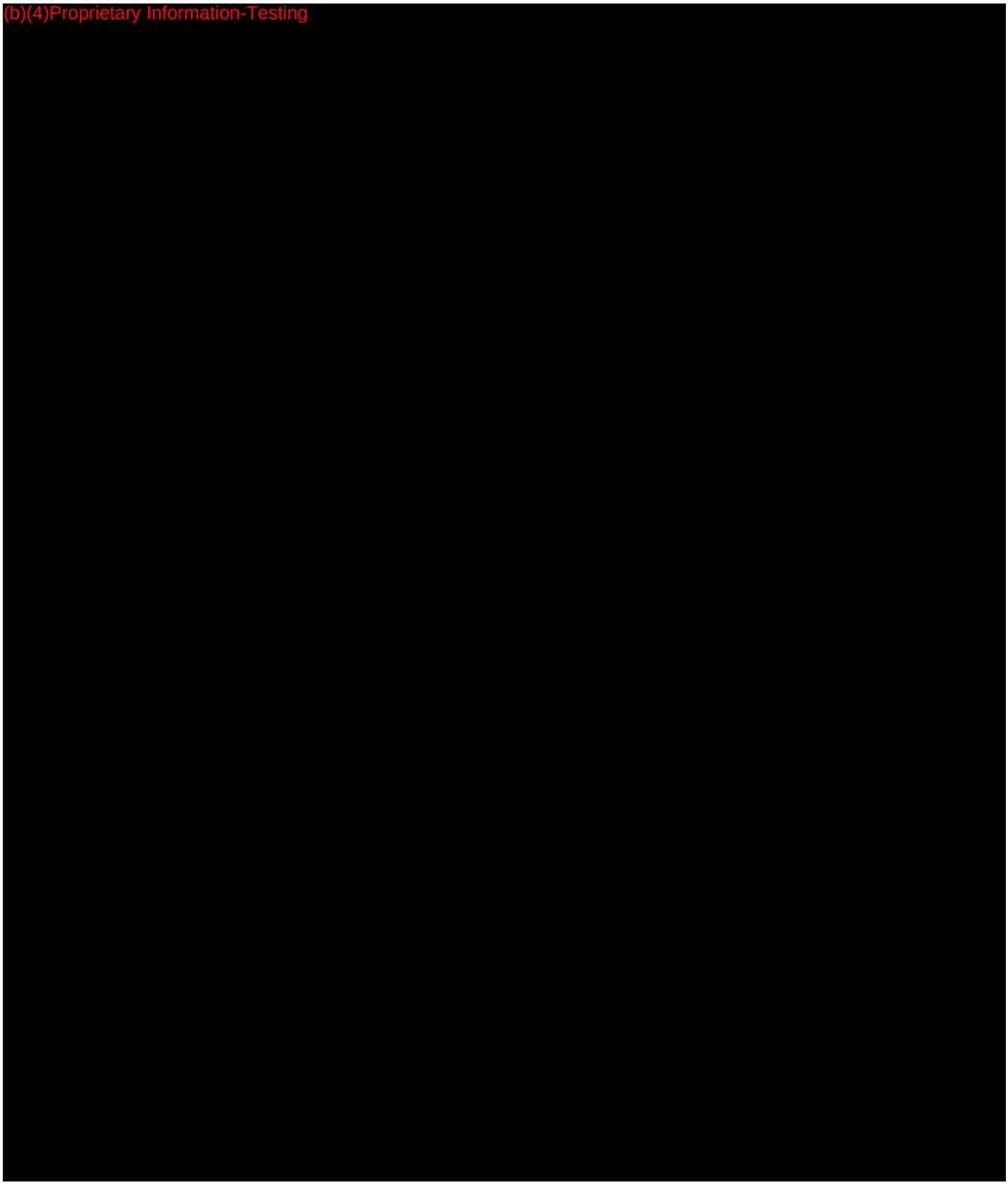
(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

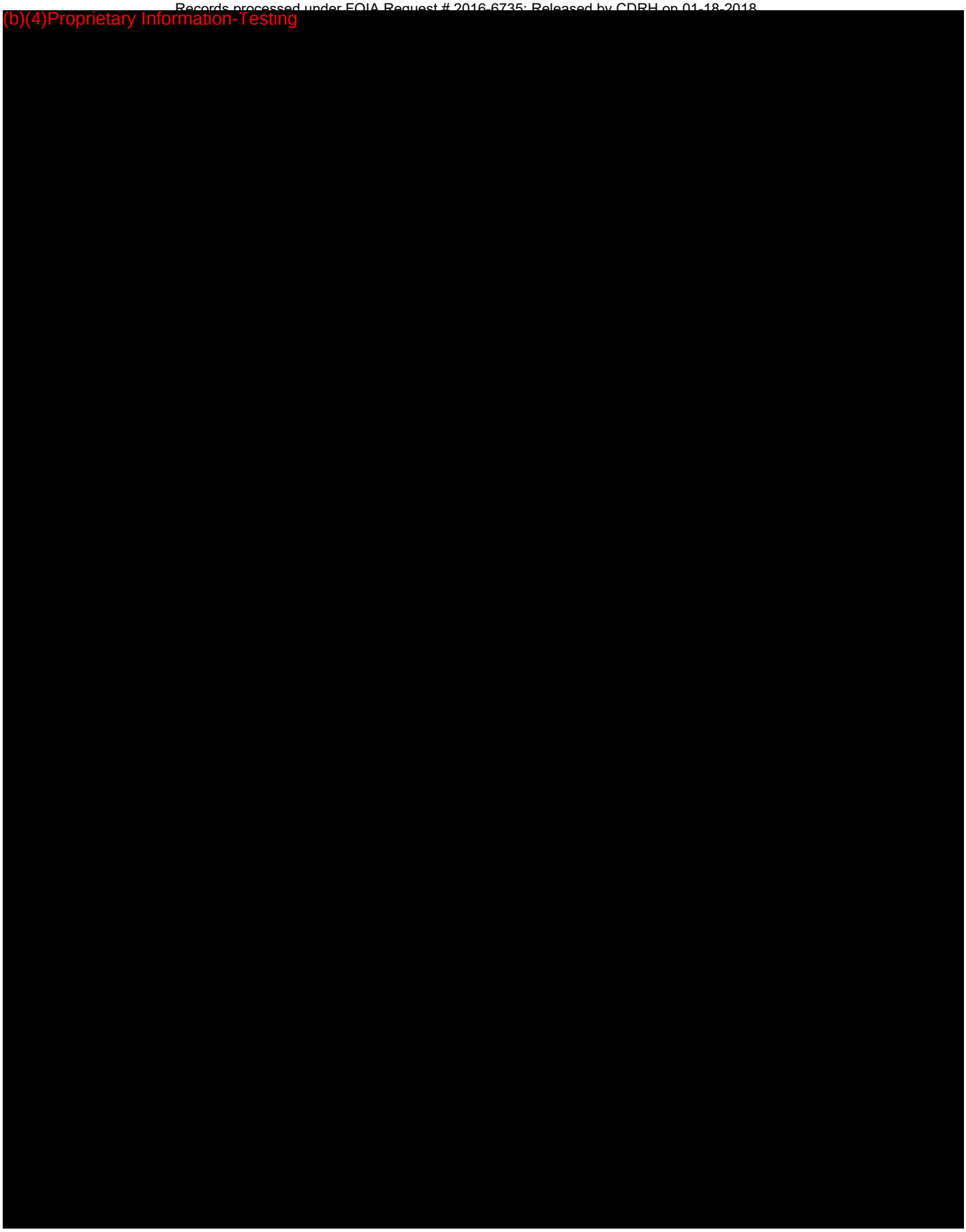
(b)(4)Proprietary Information-Testing



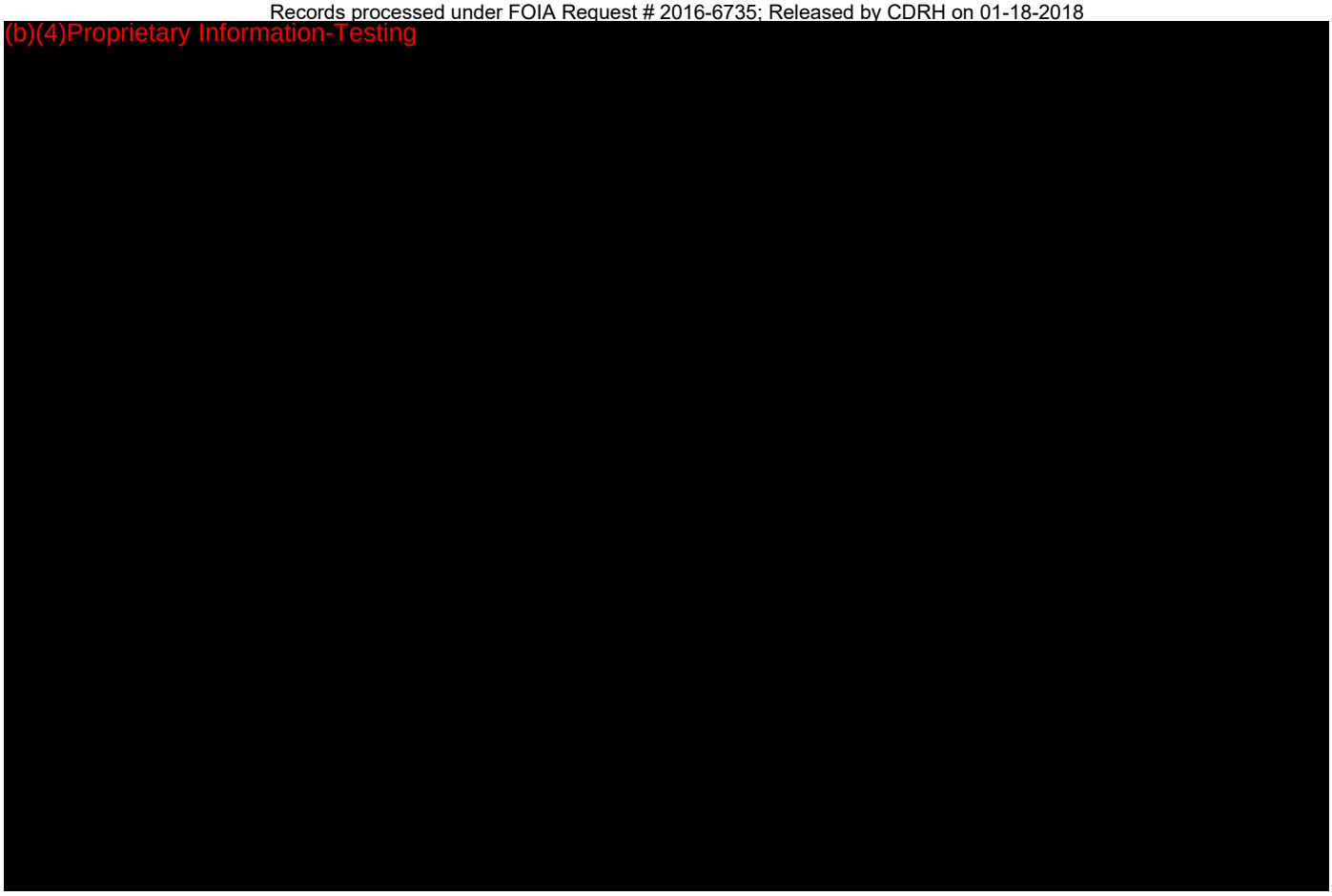




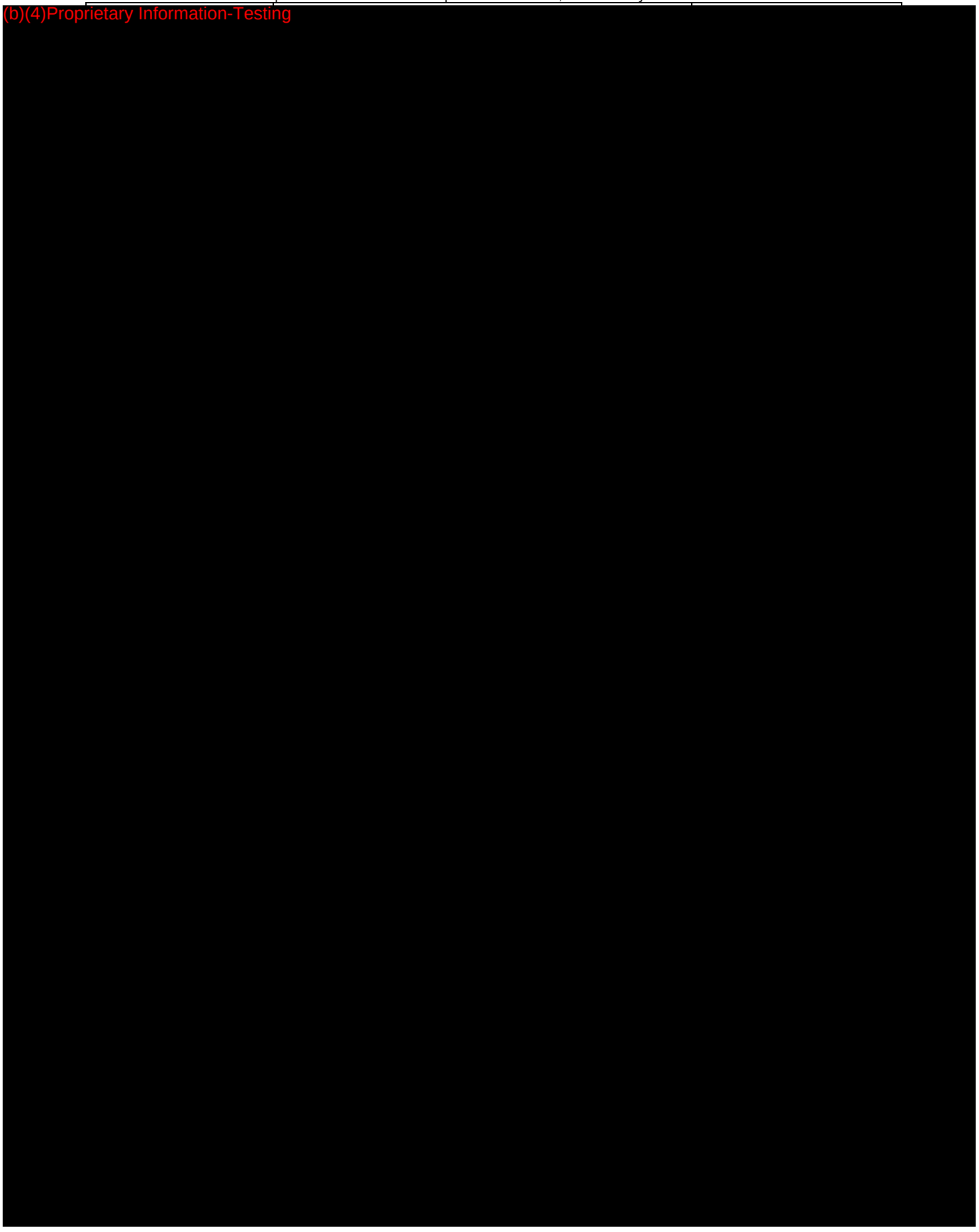
(b)(4)Proprietary Information-Testing



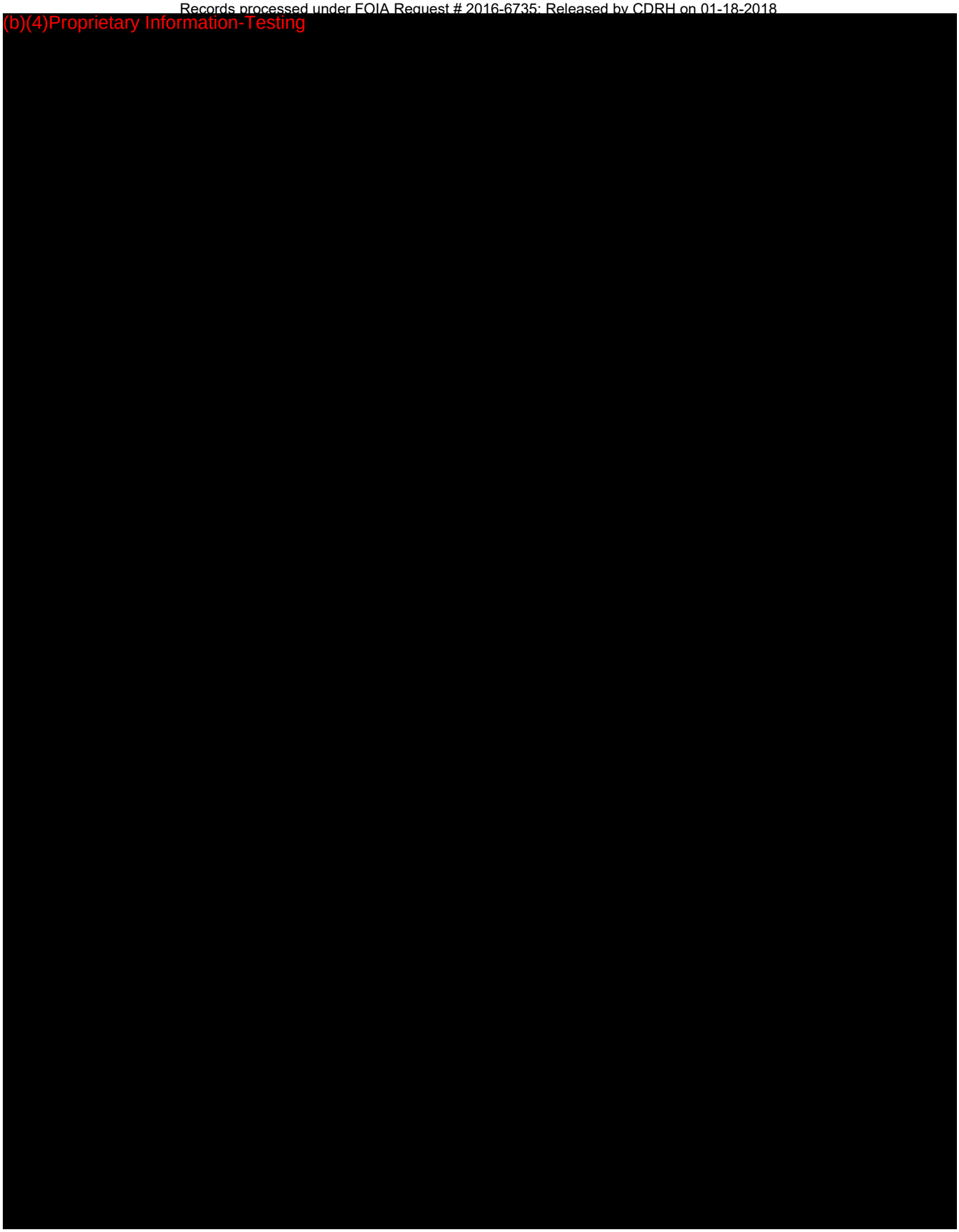
(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing



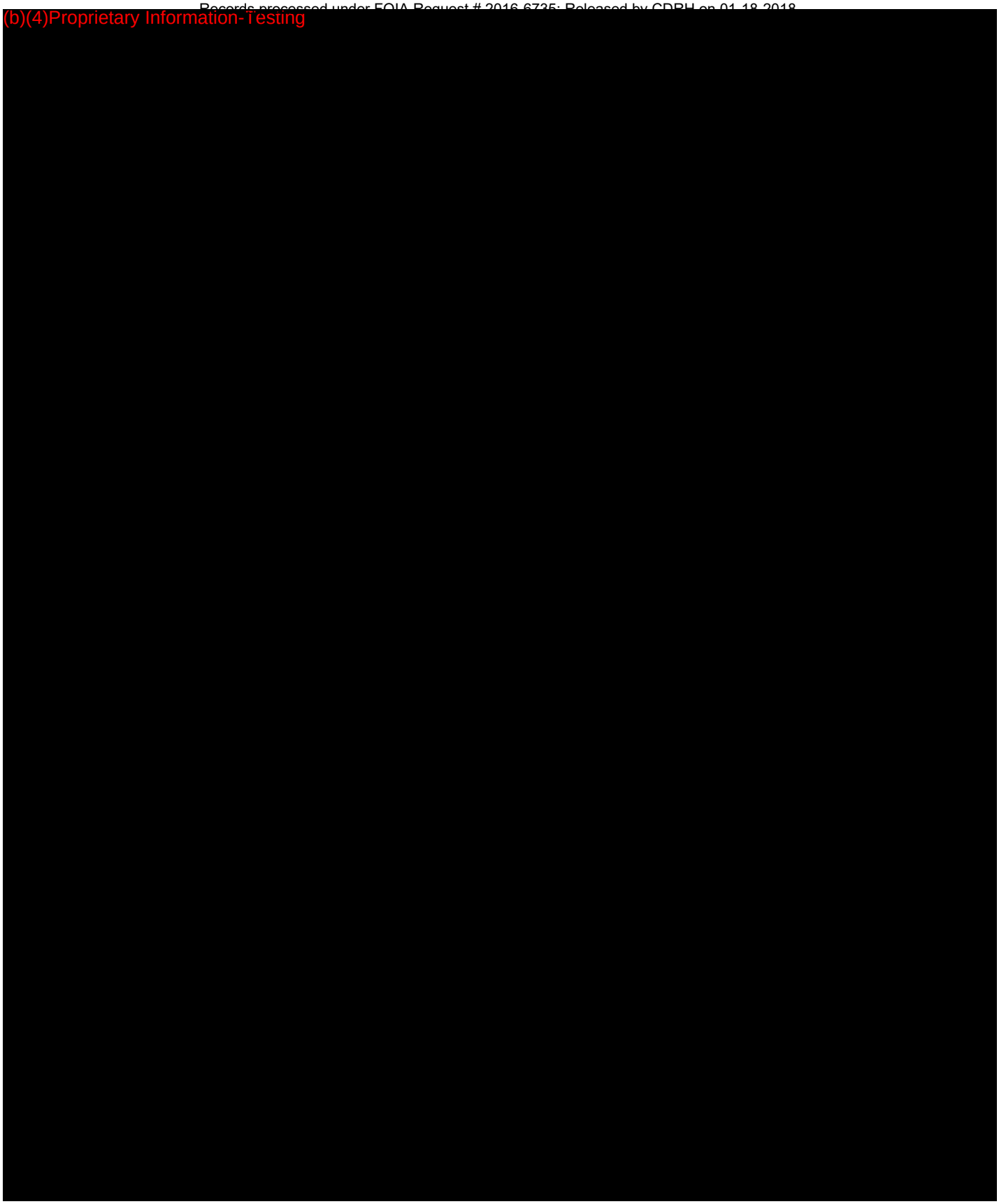
(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing

[redacted]

(b)(4)Proprietary Information-Testing

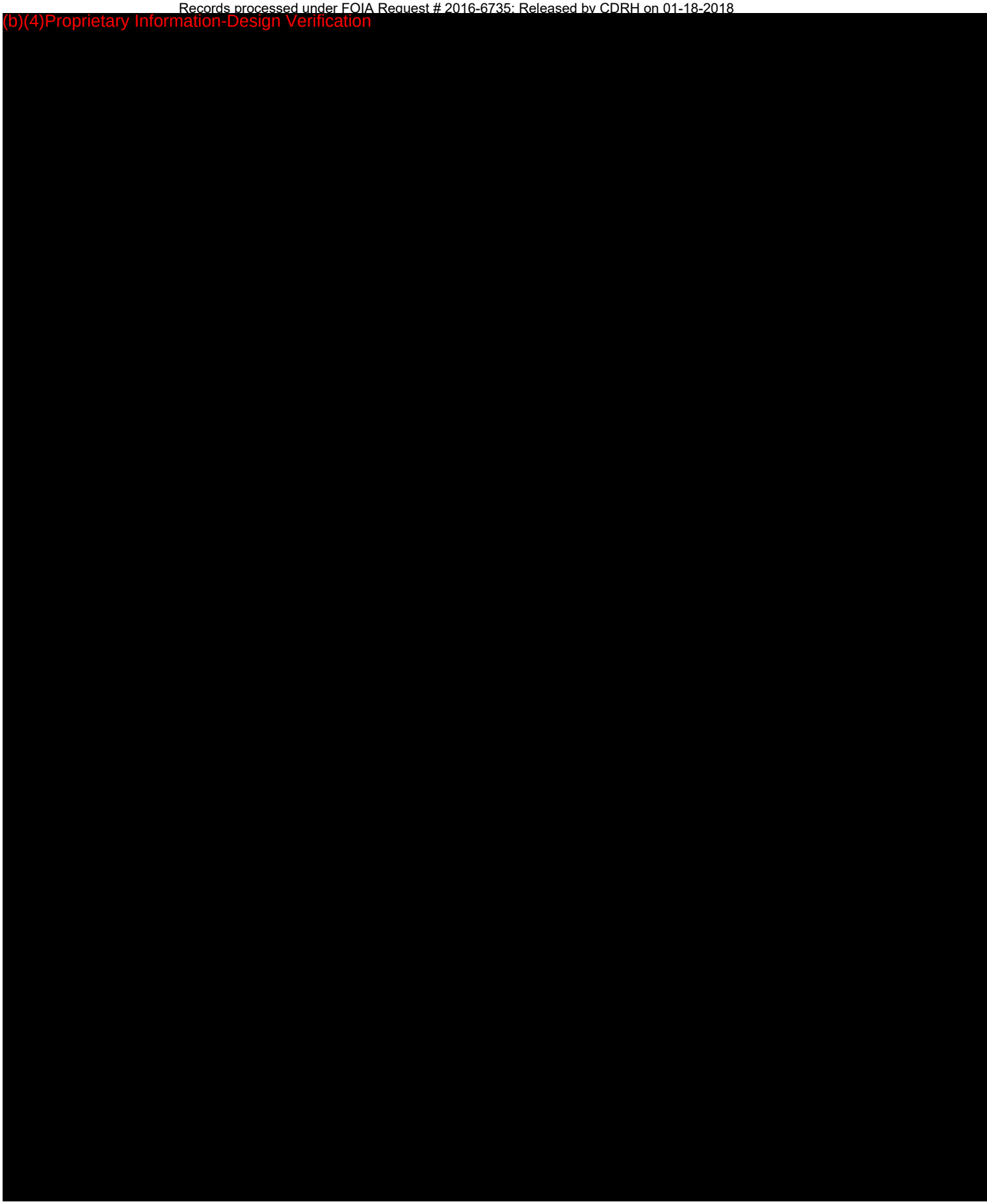


ATTACHMENT 28

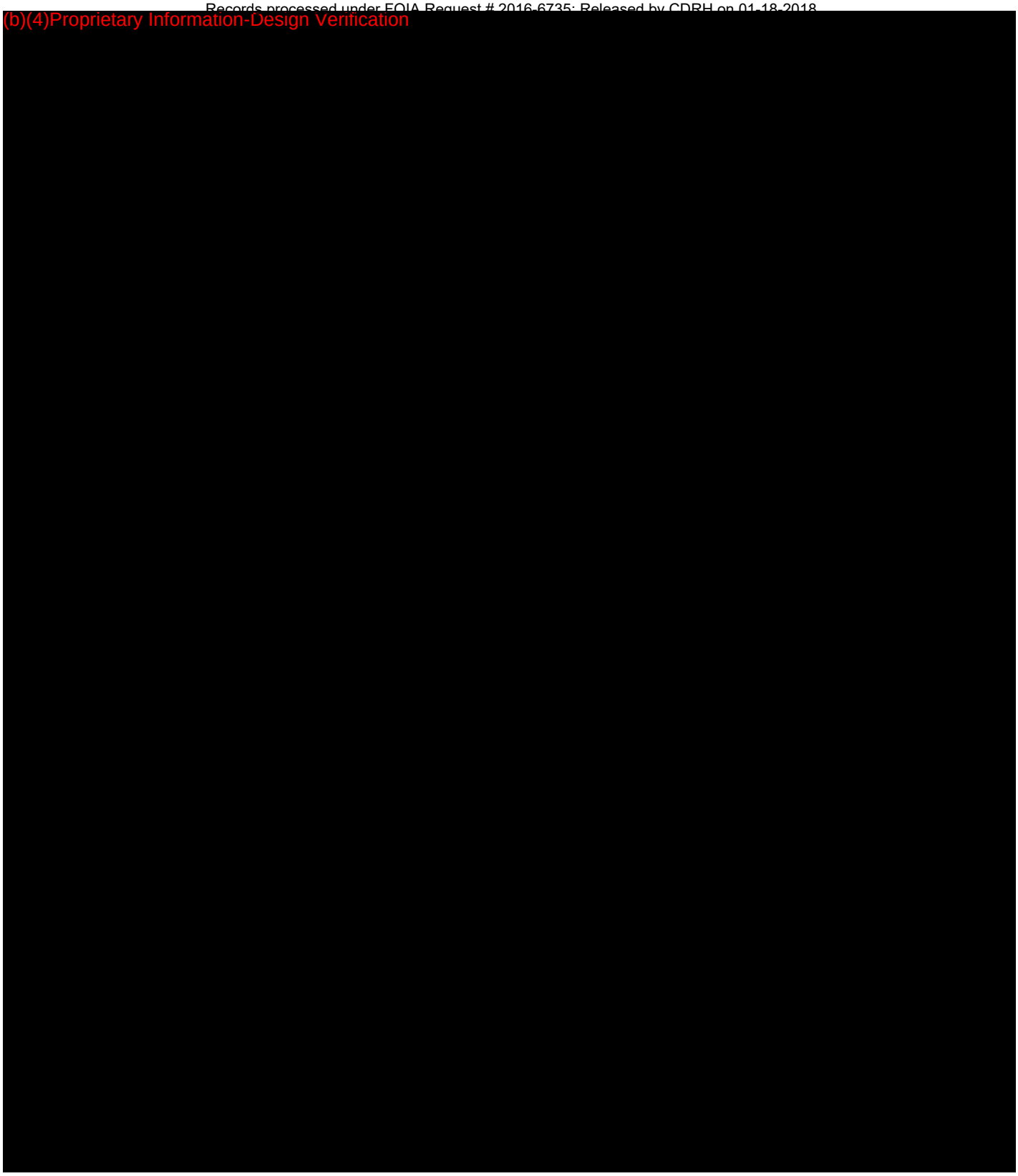
(b)(4)Proprietary Information-Design Verification

[redacted]

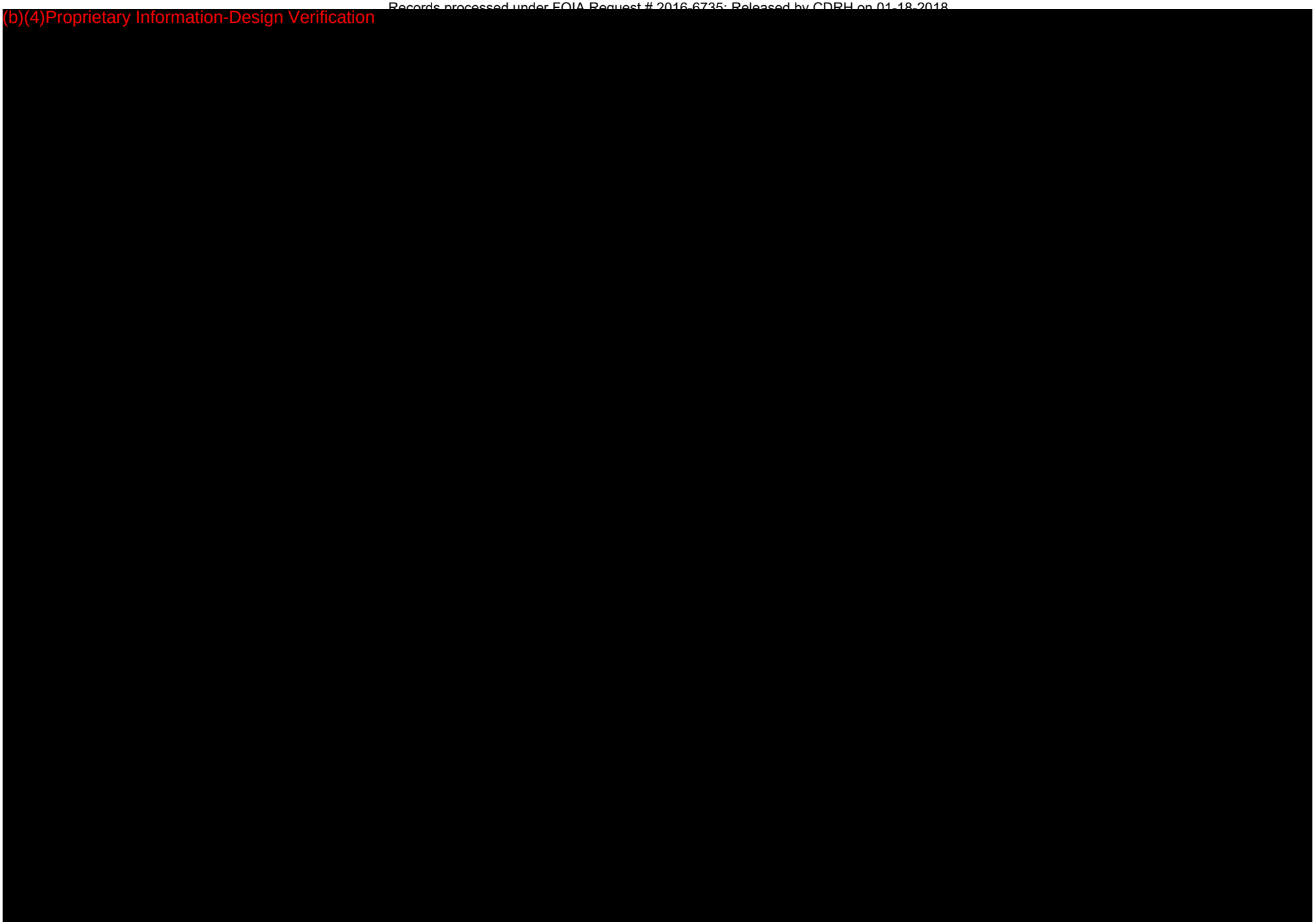
(b)(4)Proprietary Information-Design Verification



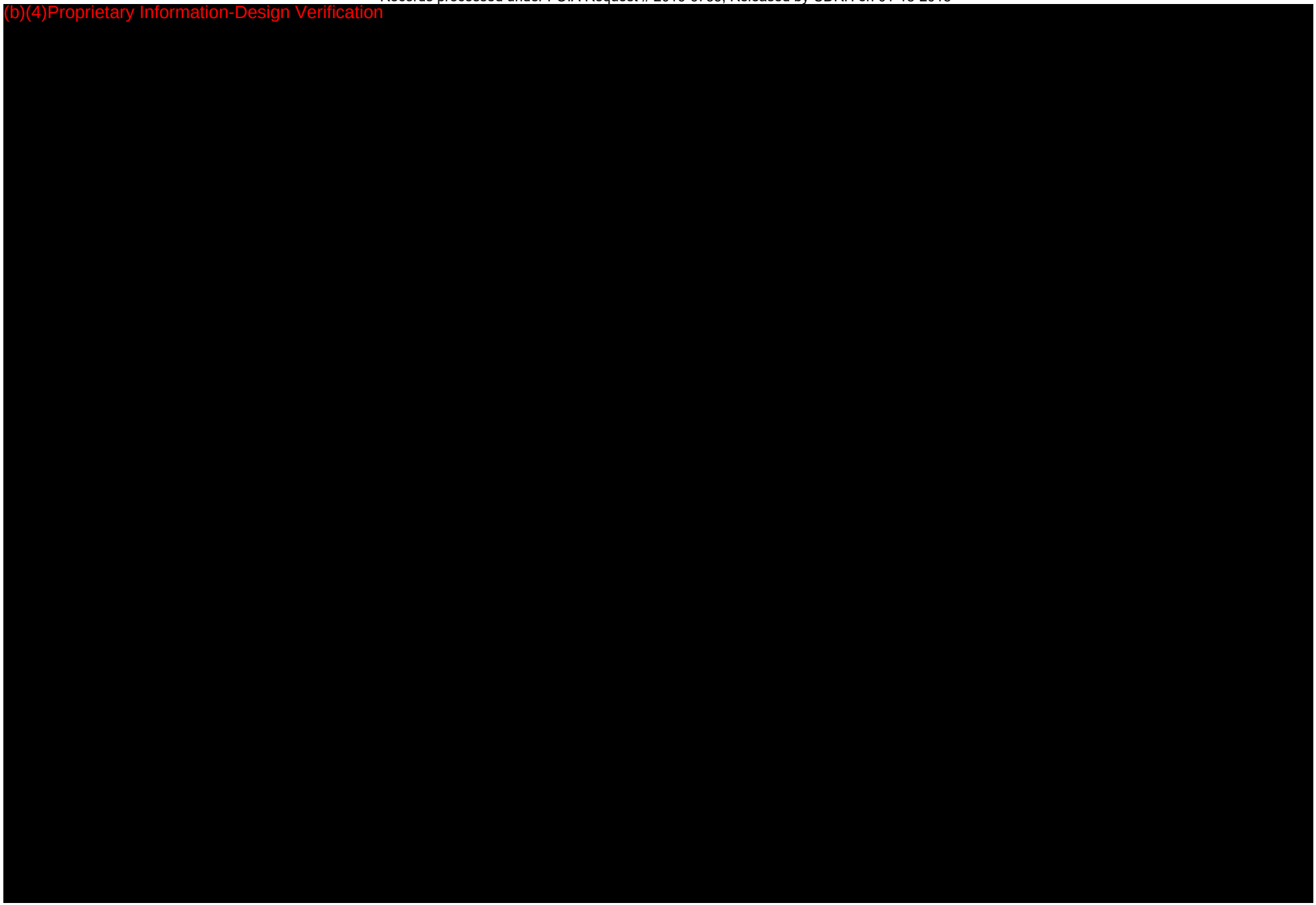
(b)(4)Proprietary Information-Design Verification



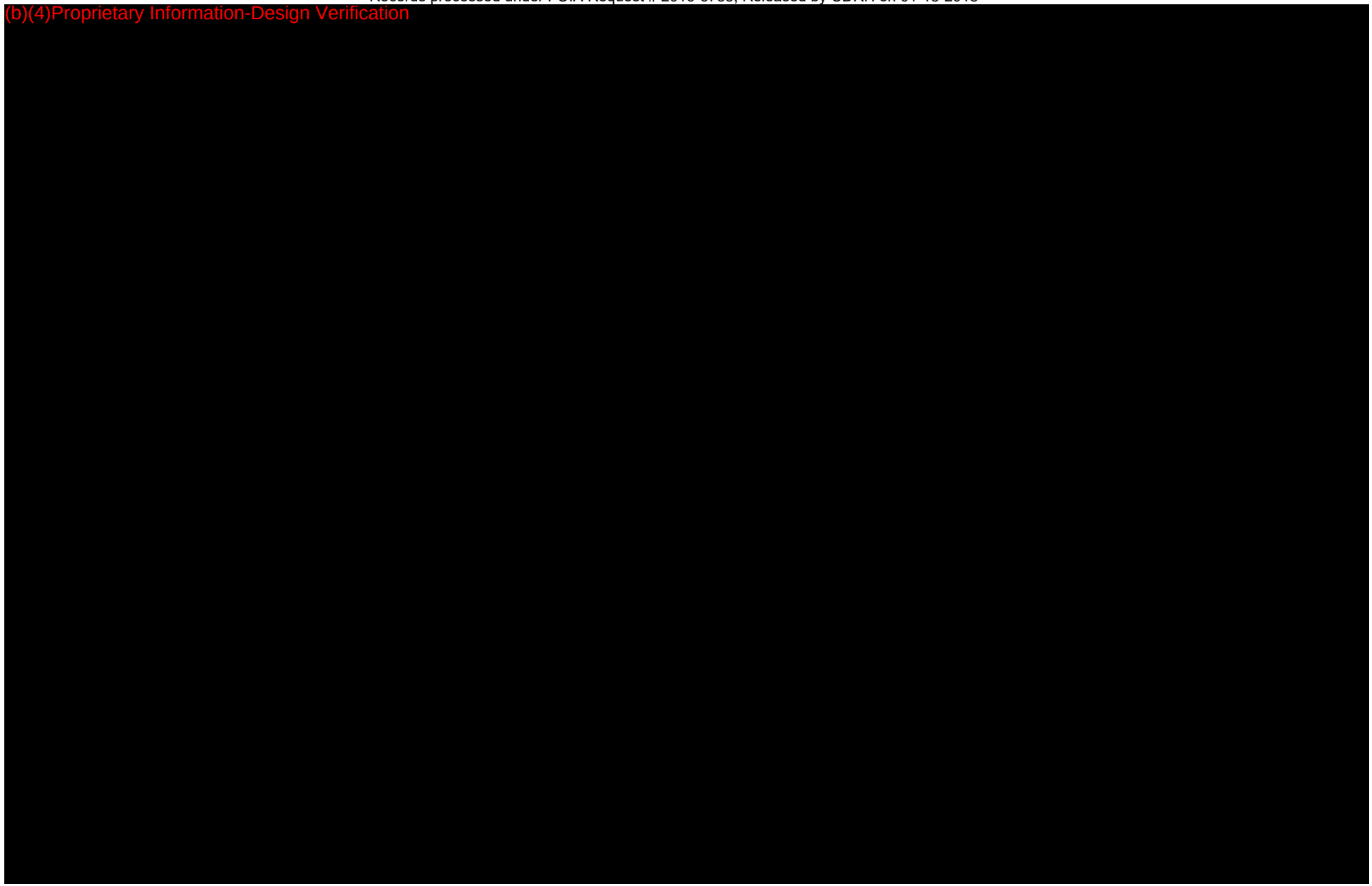
(b)(4)Proprietary Information-Design Verification



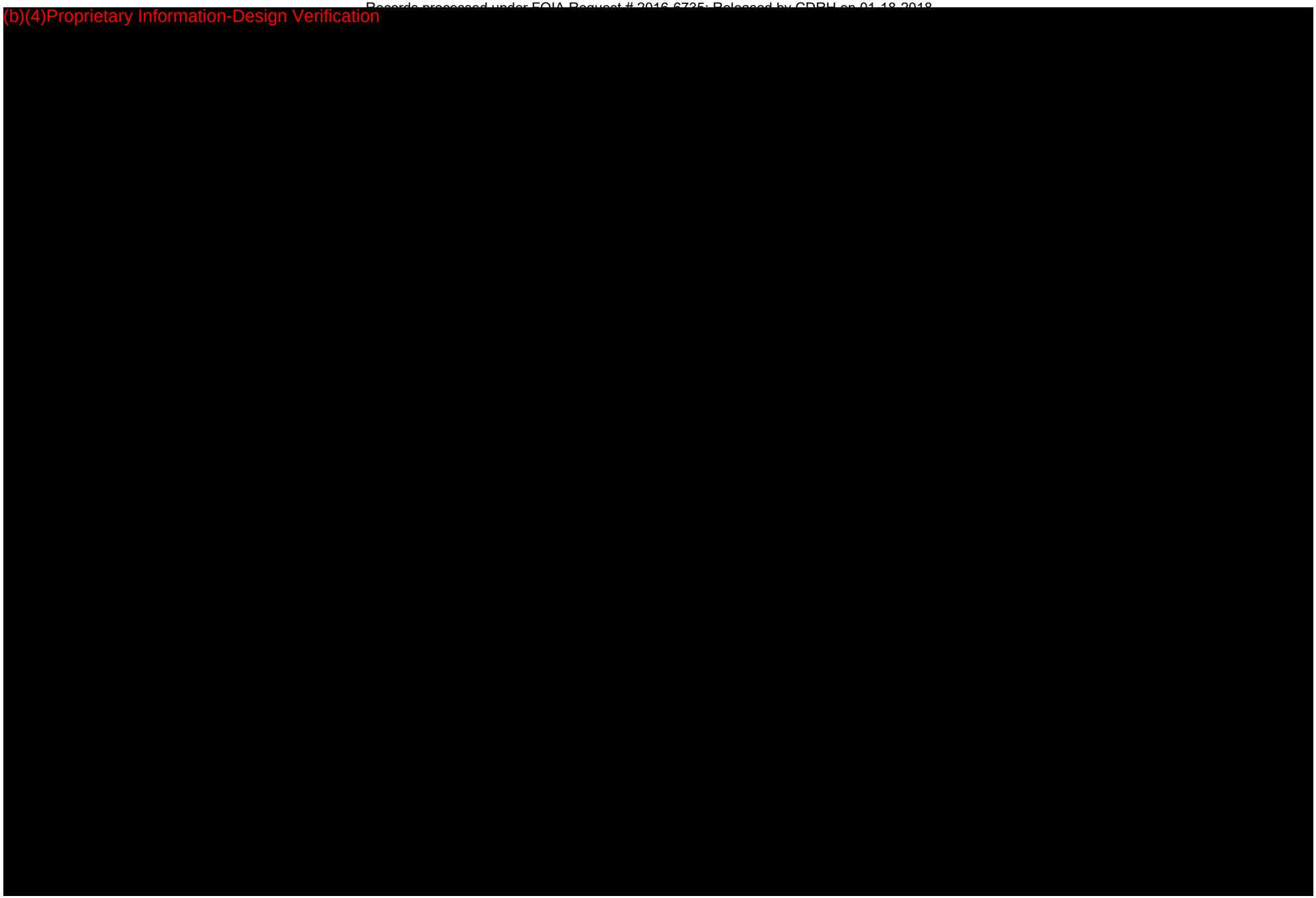
(b)(4)Proprietary Information-Design Verification



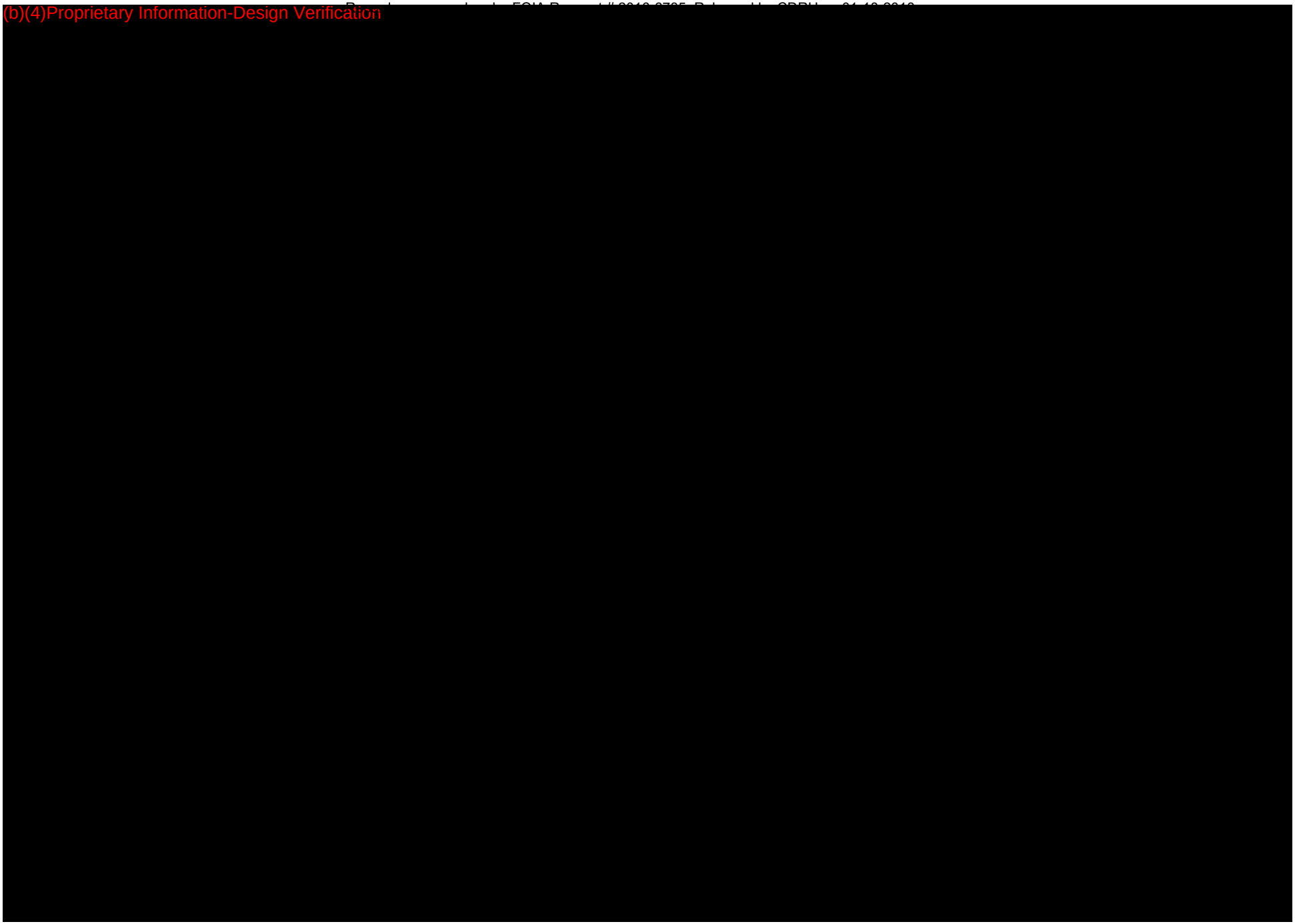
(b)(4)Proprietary Information-Design Verification



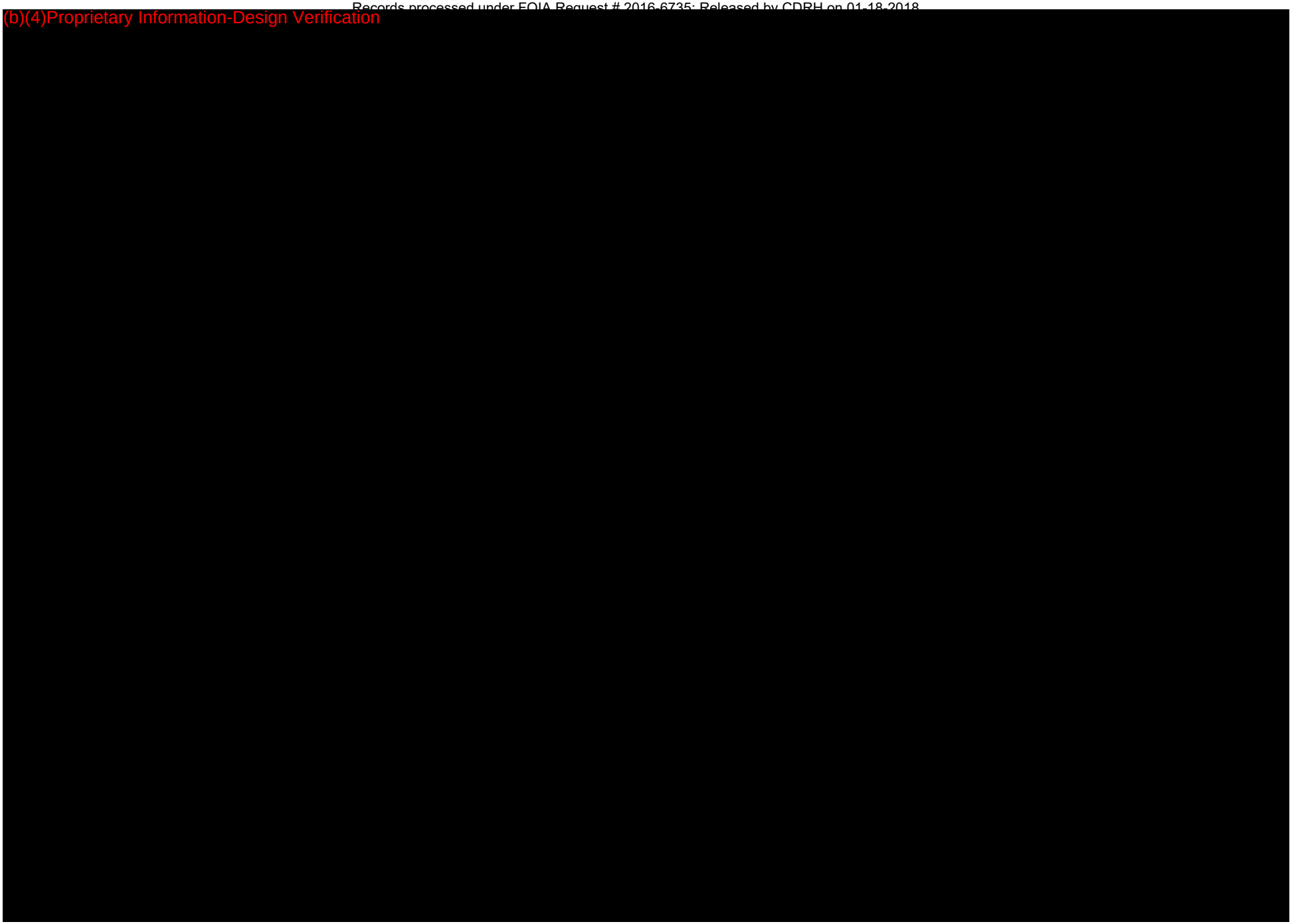
(b)(4)Proprietary Information-Design Verification



(b)(4)Proprietary Information-Design Verification



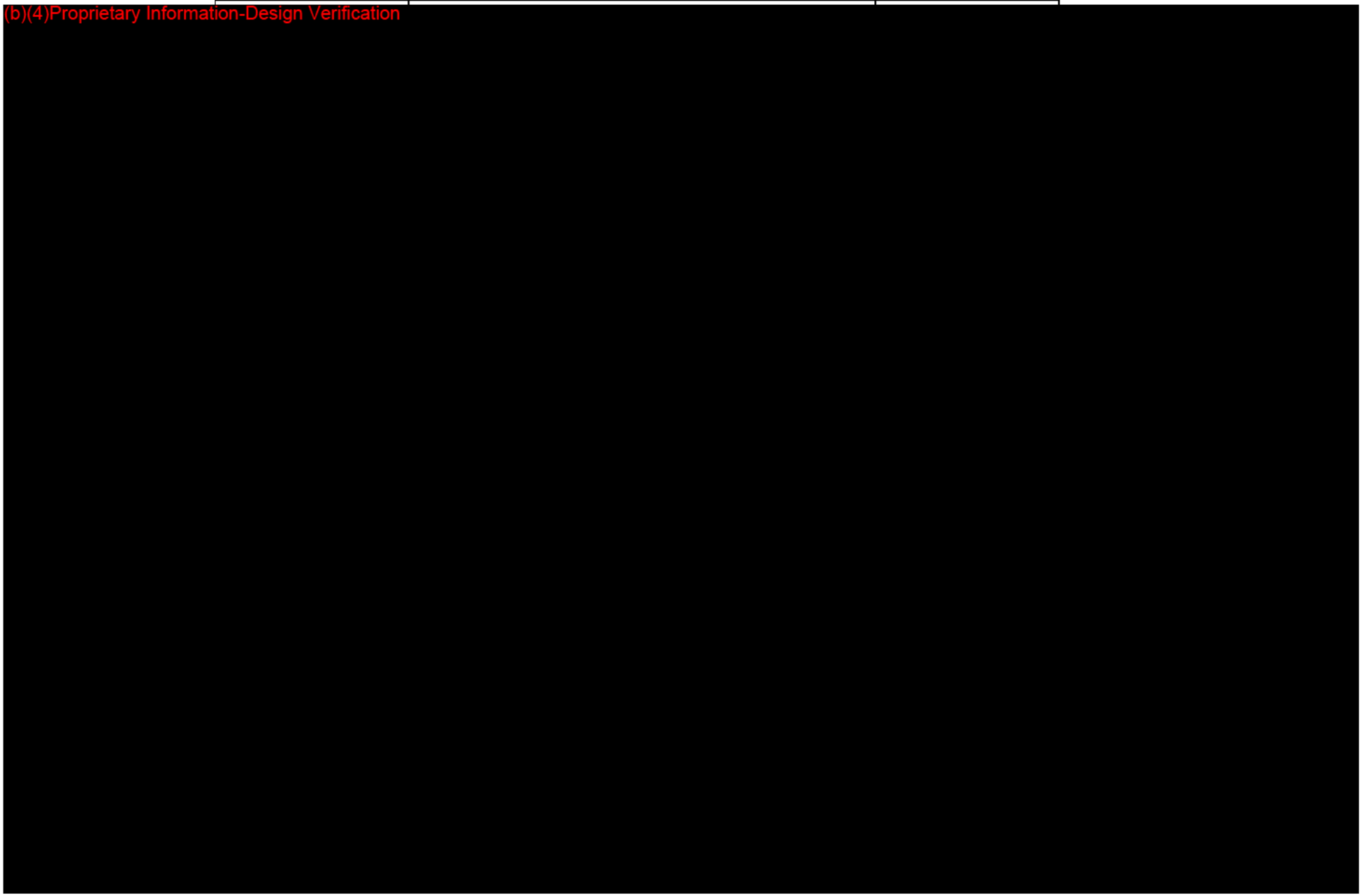
(b)(4)Proprietary Information-Design Verification



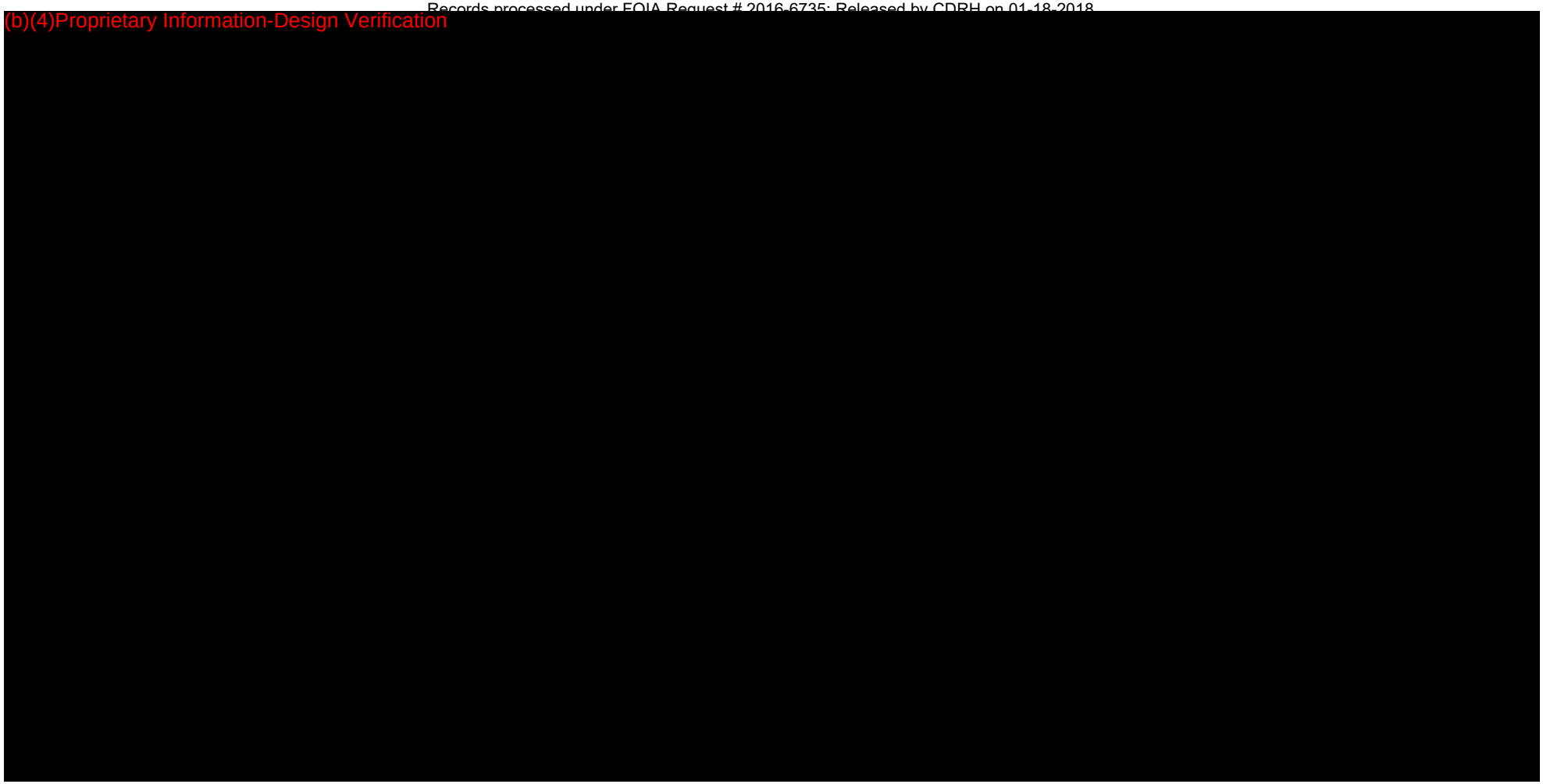
(b)(4)Proprietary Information-Design Verification

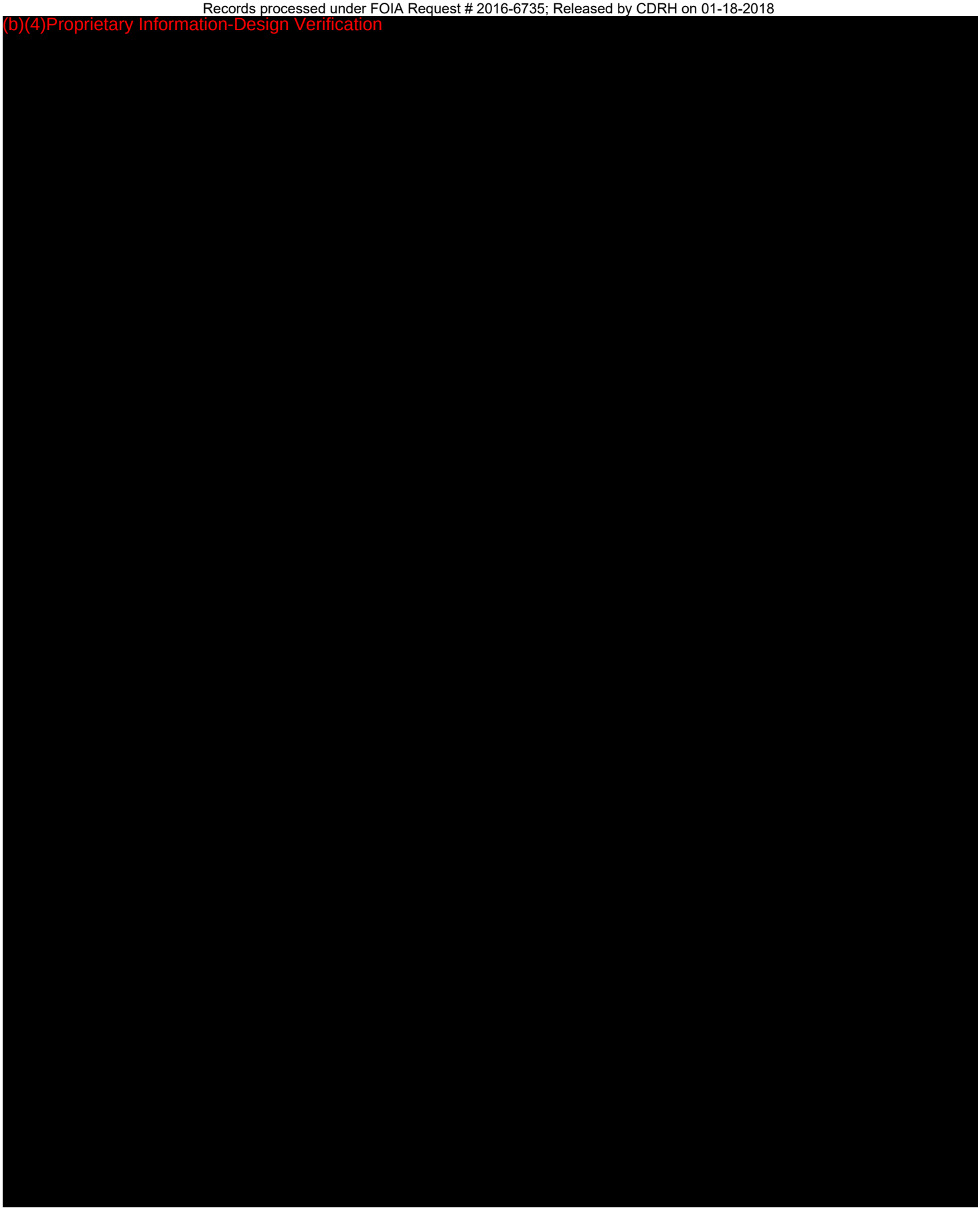
[redacted]

(b)(4)Proprietary Information-Design Verification

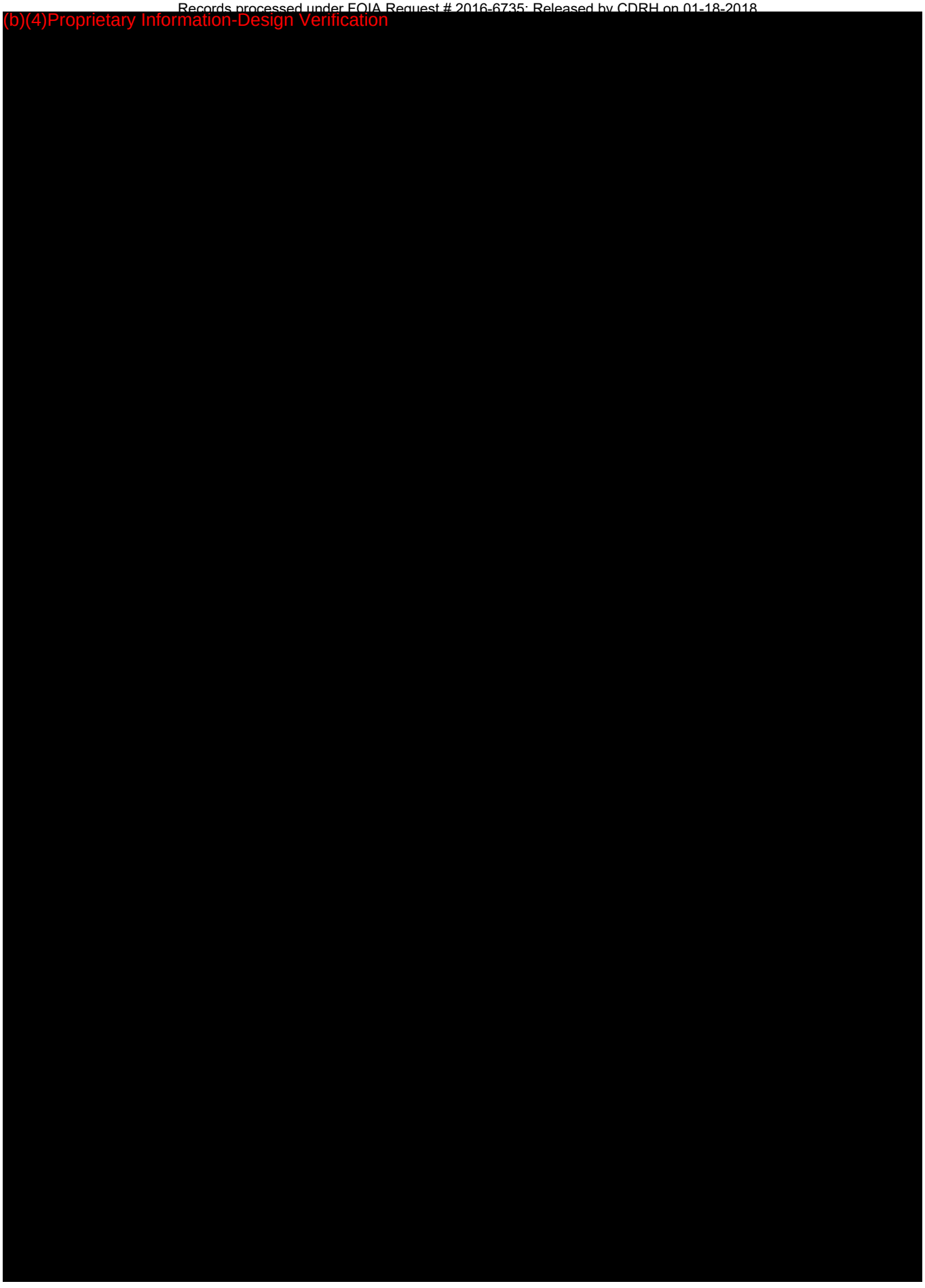


(b)(4)Proprietary Information-Design Verification

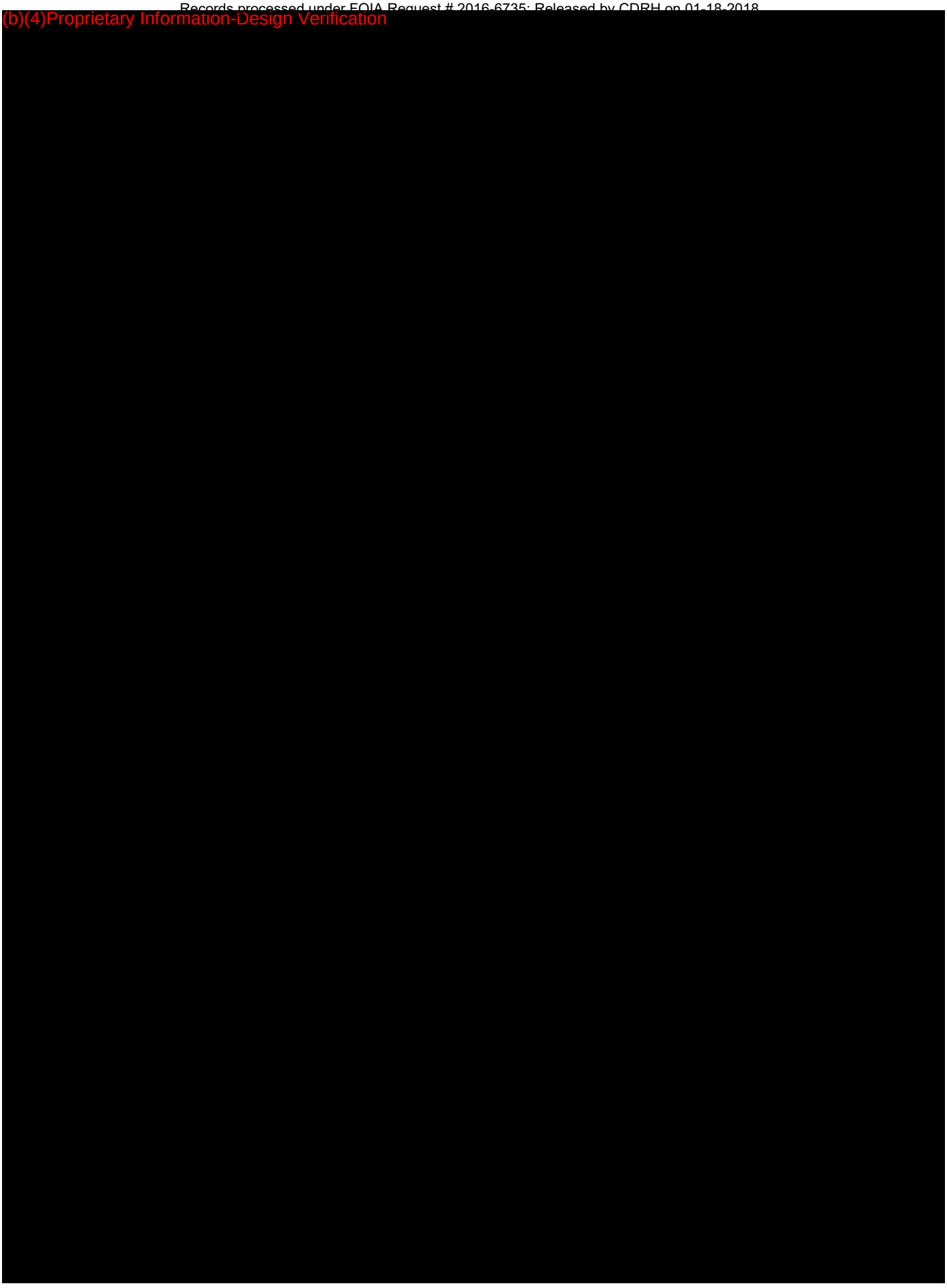




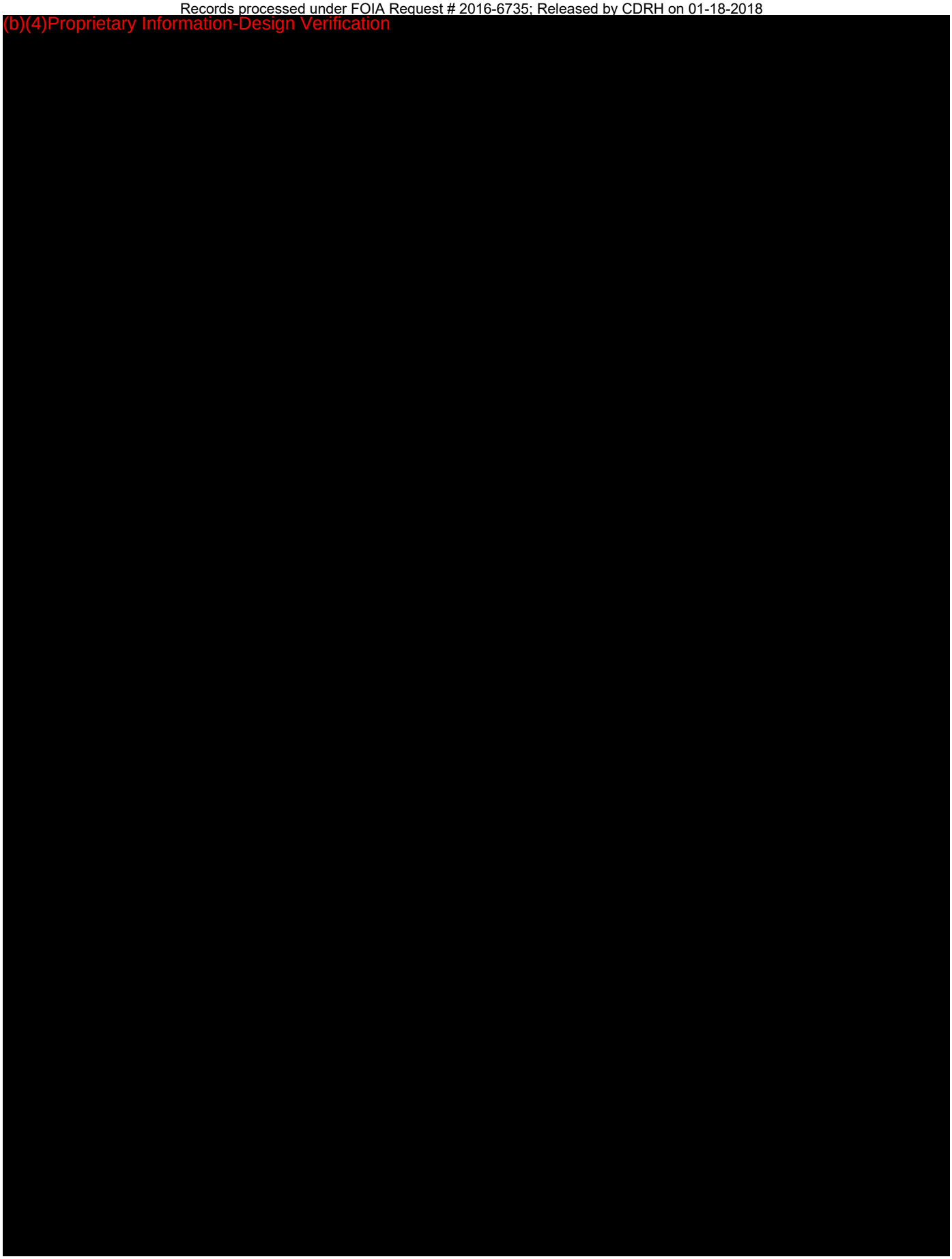
(b)(4)Proprietary Information-Design Verification



(b)(4)Proprietary Information-Design Verification



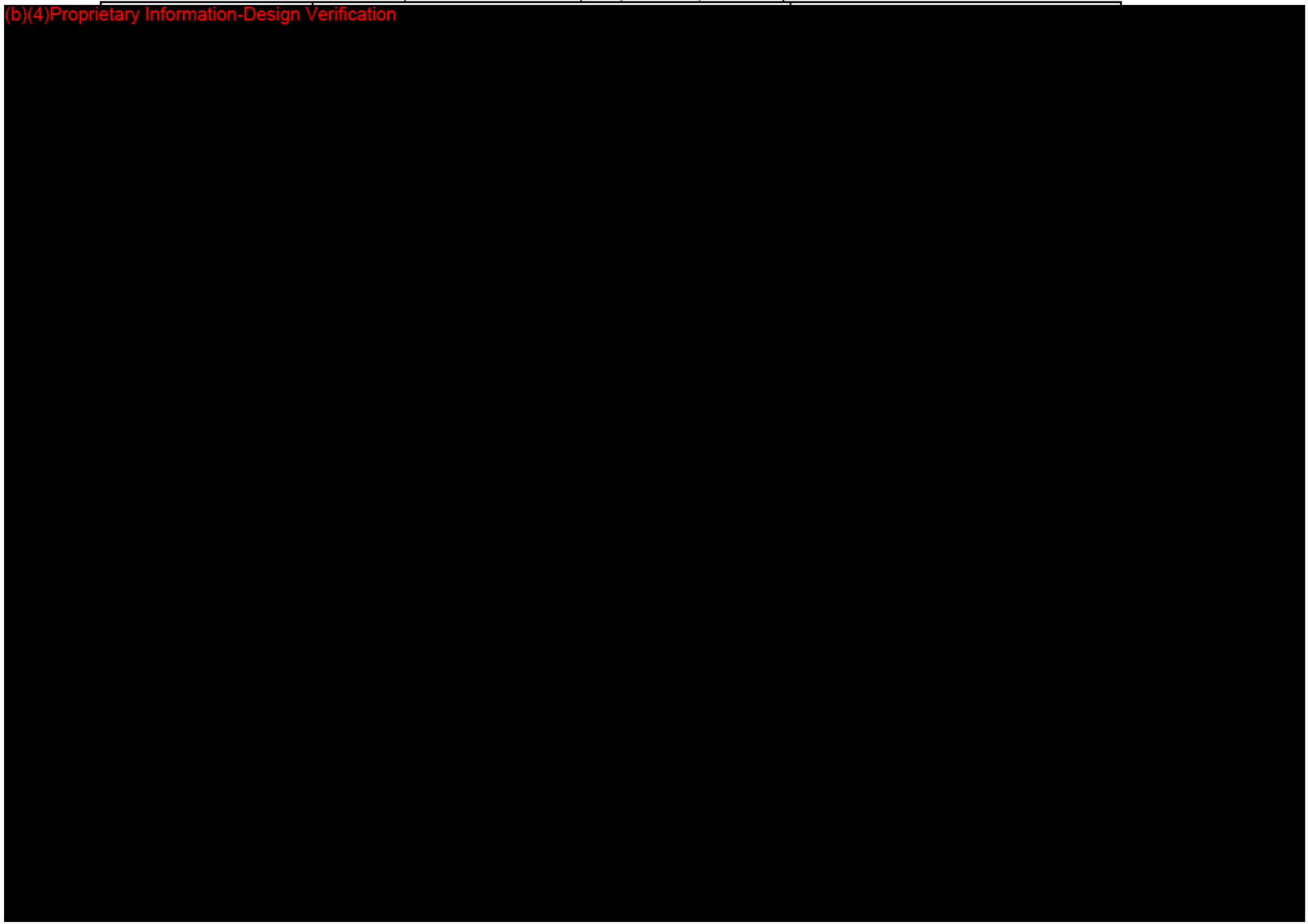
(b)(4)Proprietary Information-Design Verification



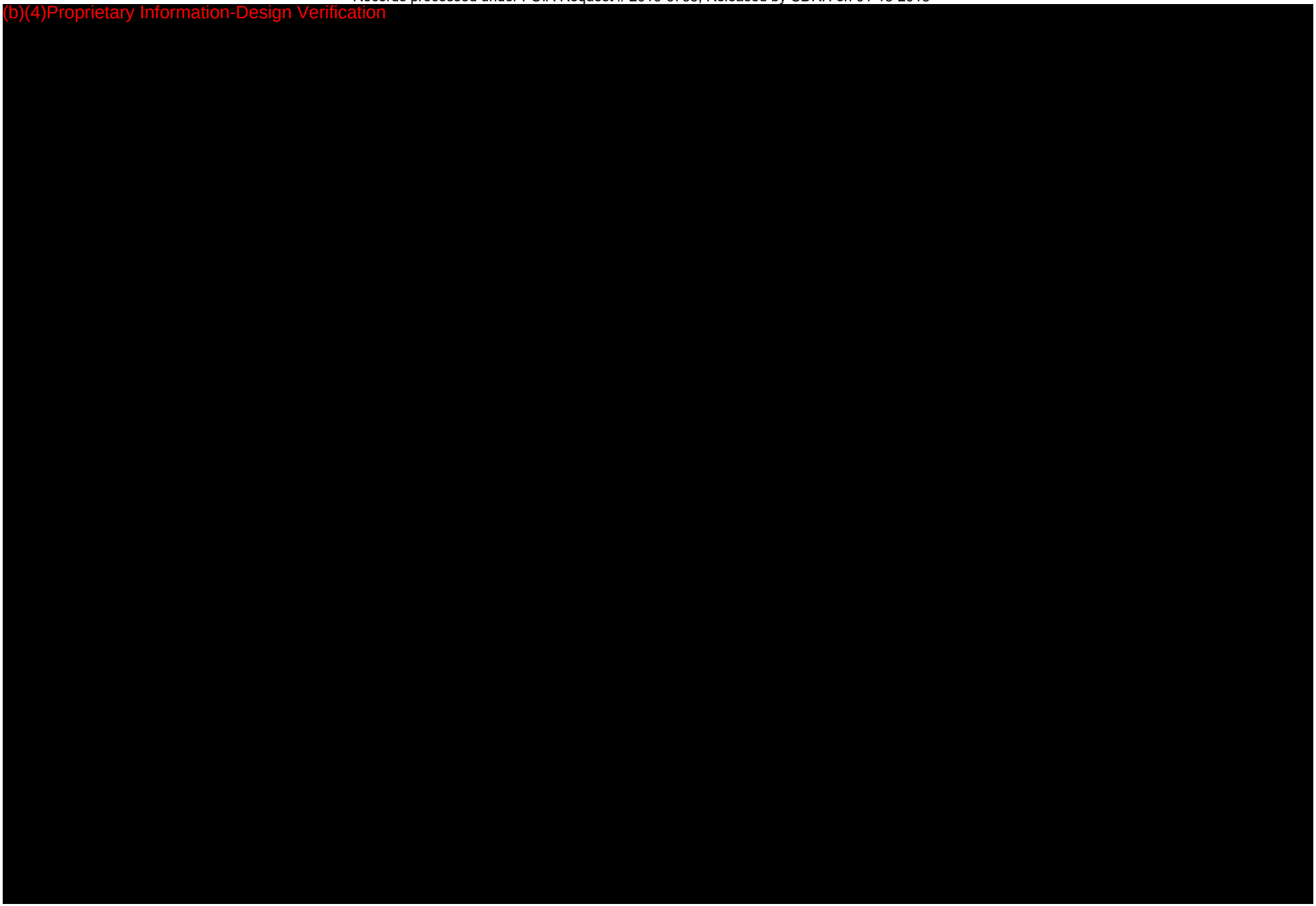
(b)(4)Proprietary Information-Design Verification

[redacted]

(b)(4)Proprietary Information-Design Verification



(b)(4)Proprietary Information-Design Verification

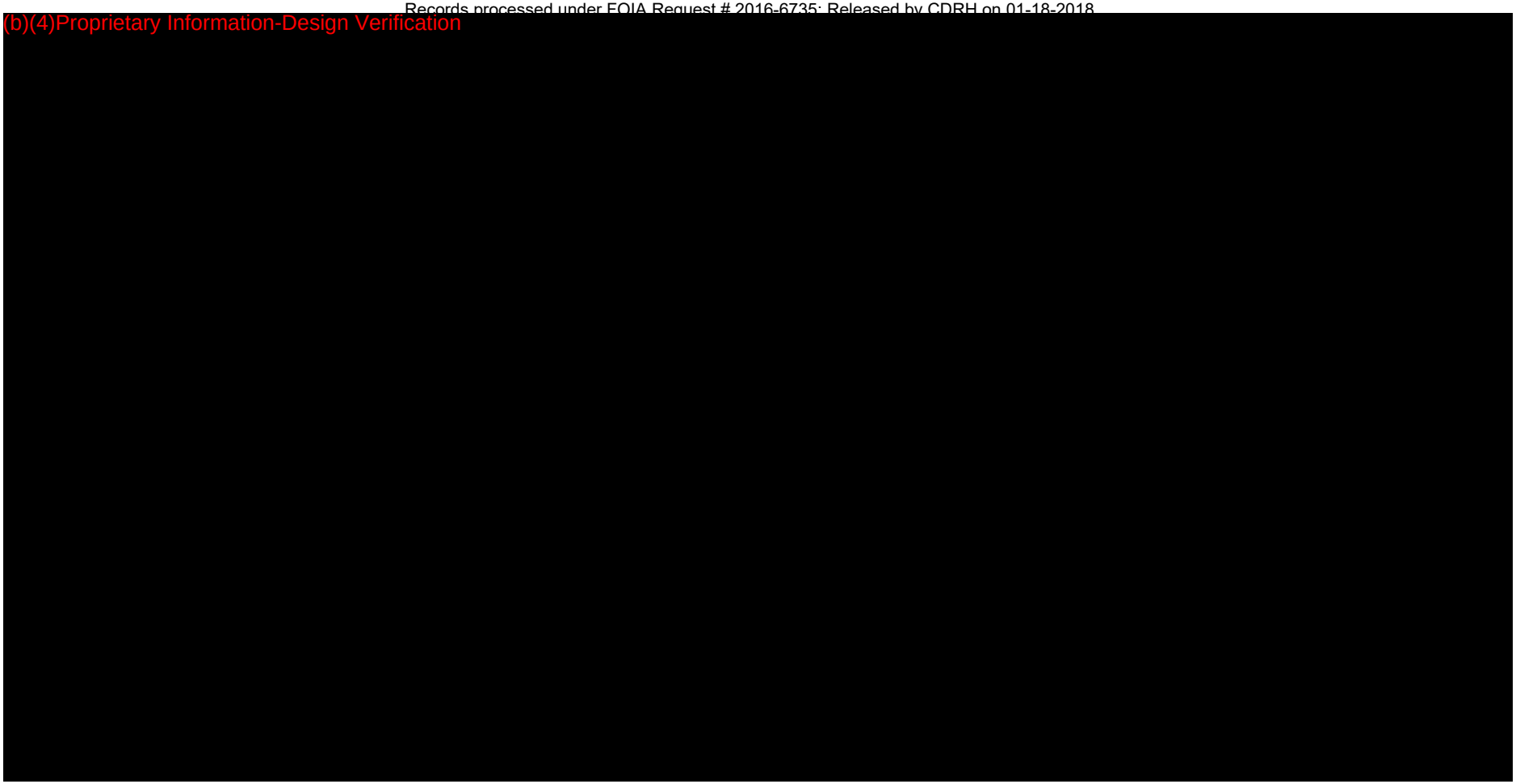


(b)(4)Proprietary Information-Design Verification

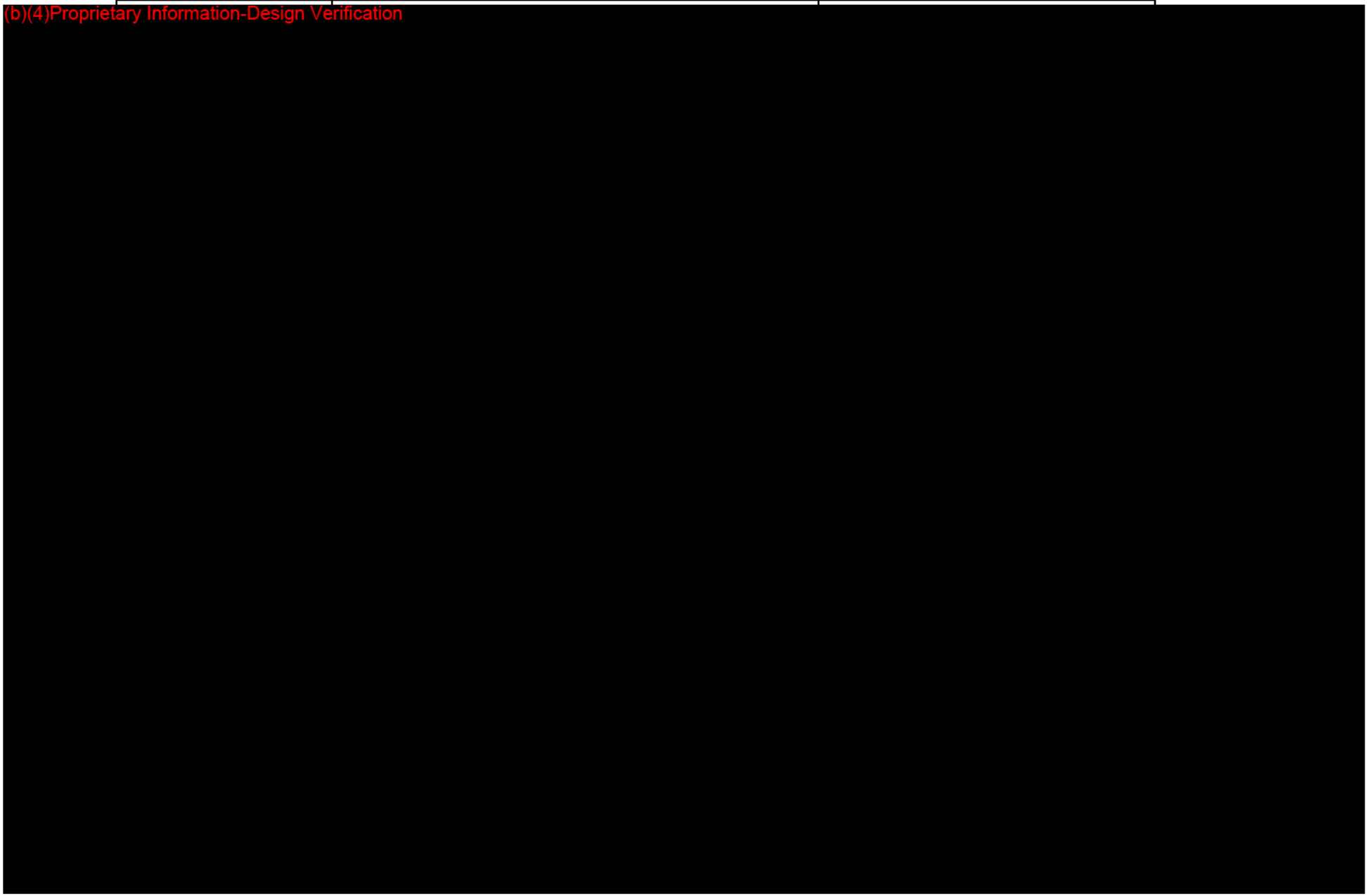
(b)(4)Proprietary Information-Design Verification

(b)(4)Proprietary Information-Design Verification

(b)(4)Proprietary Information-Design Verification



(b)(4)Proprietary Information-Design Verification

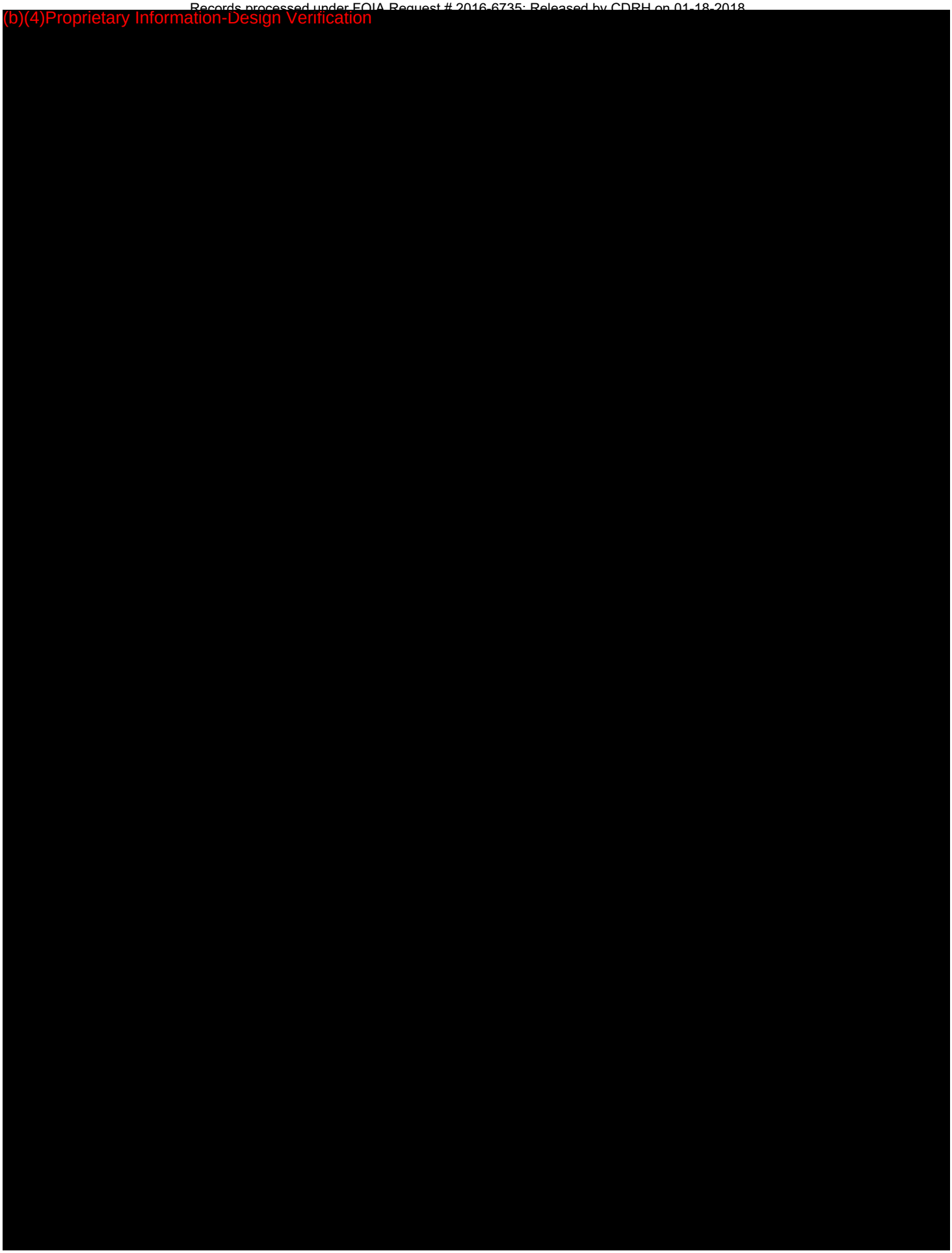


(b)(4)Proprietary Information-Design Verification

ATTACHMENT 29

ATTACHMENT 29

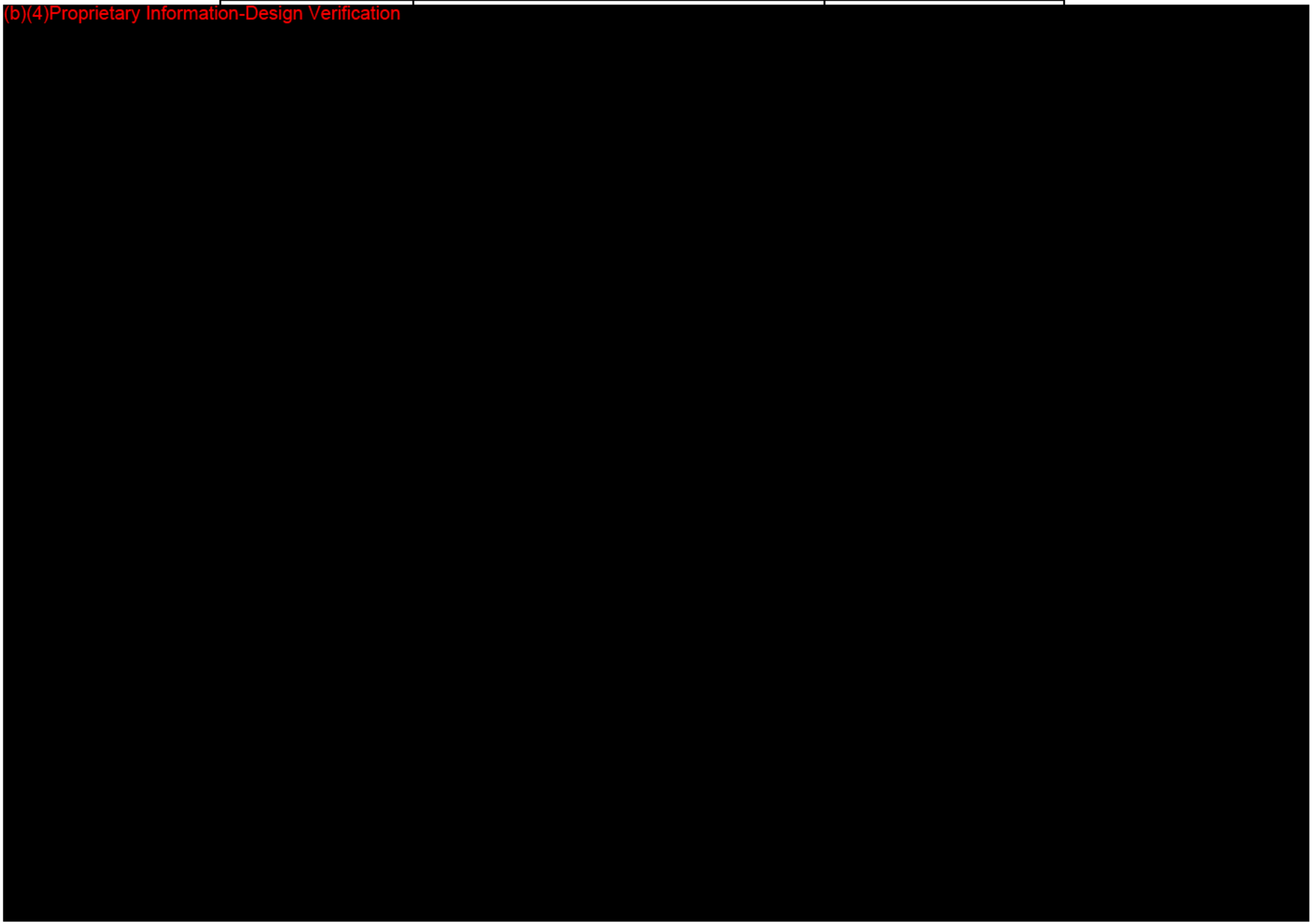
(b)(4)Proprietary Information-Design Verification



(b)(4)Proprietary Information-Design Verification

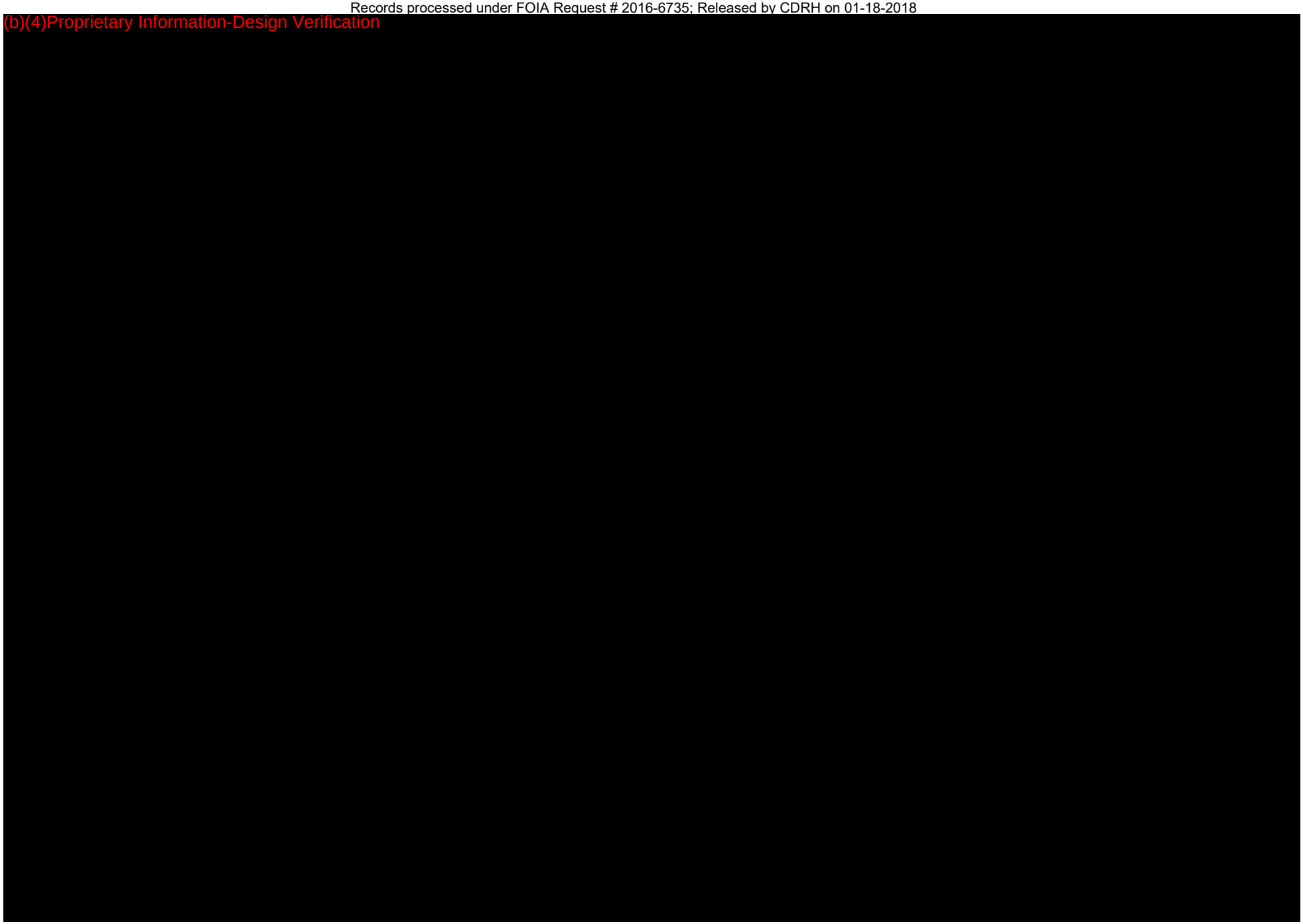
(b)(4)Proprietary Information-Design Verification

(b)(4)Proprietary Information-Design Verification

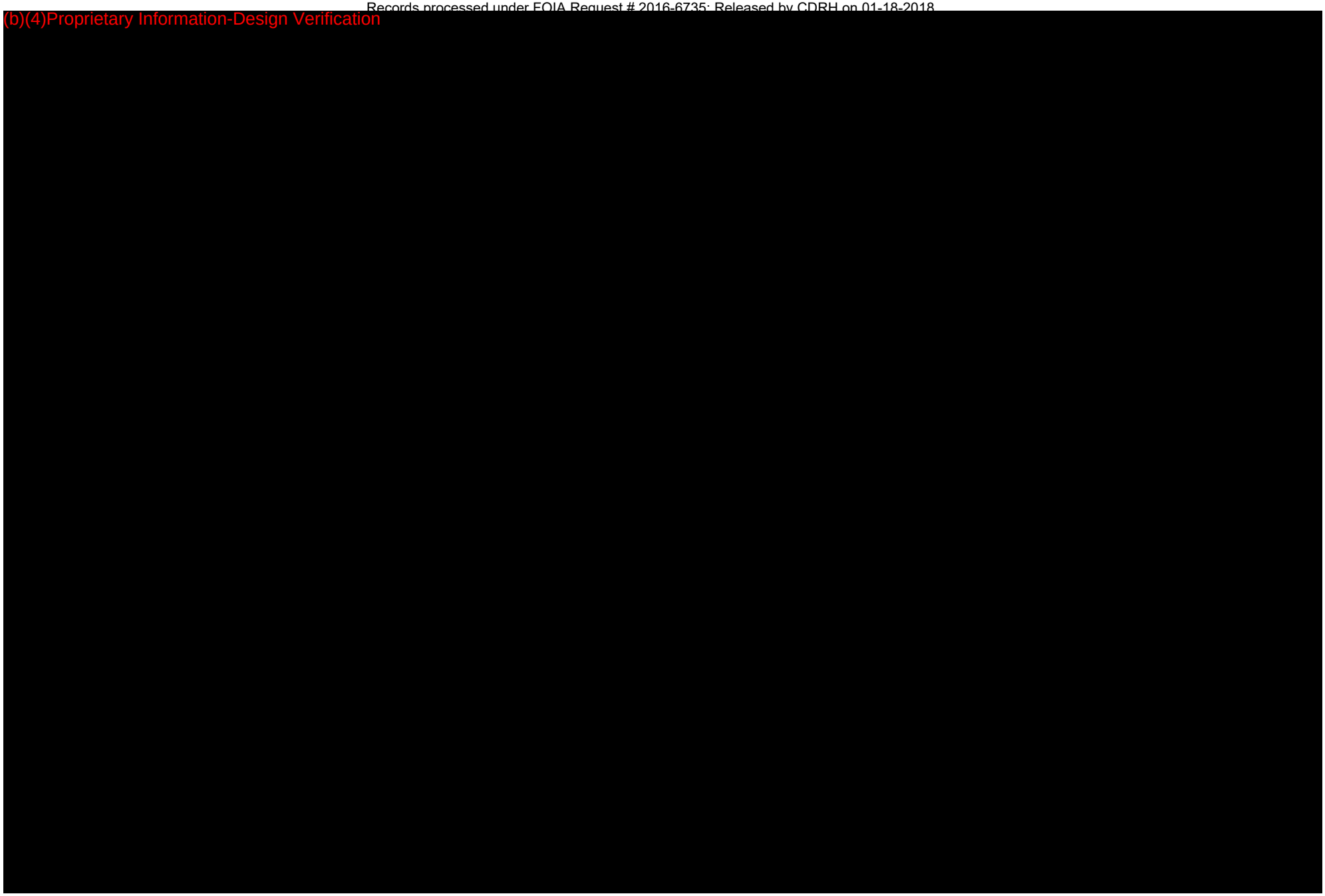


(b)(4)Proprietary Information-Design Verification

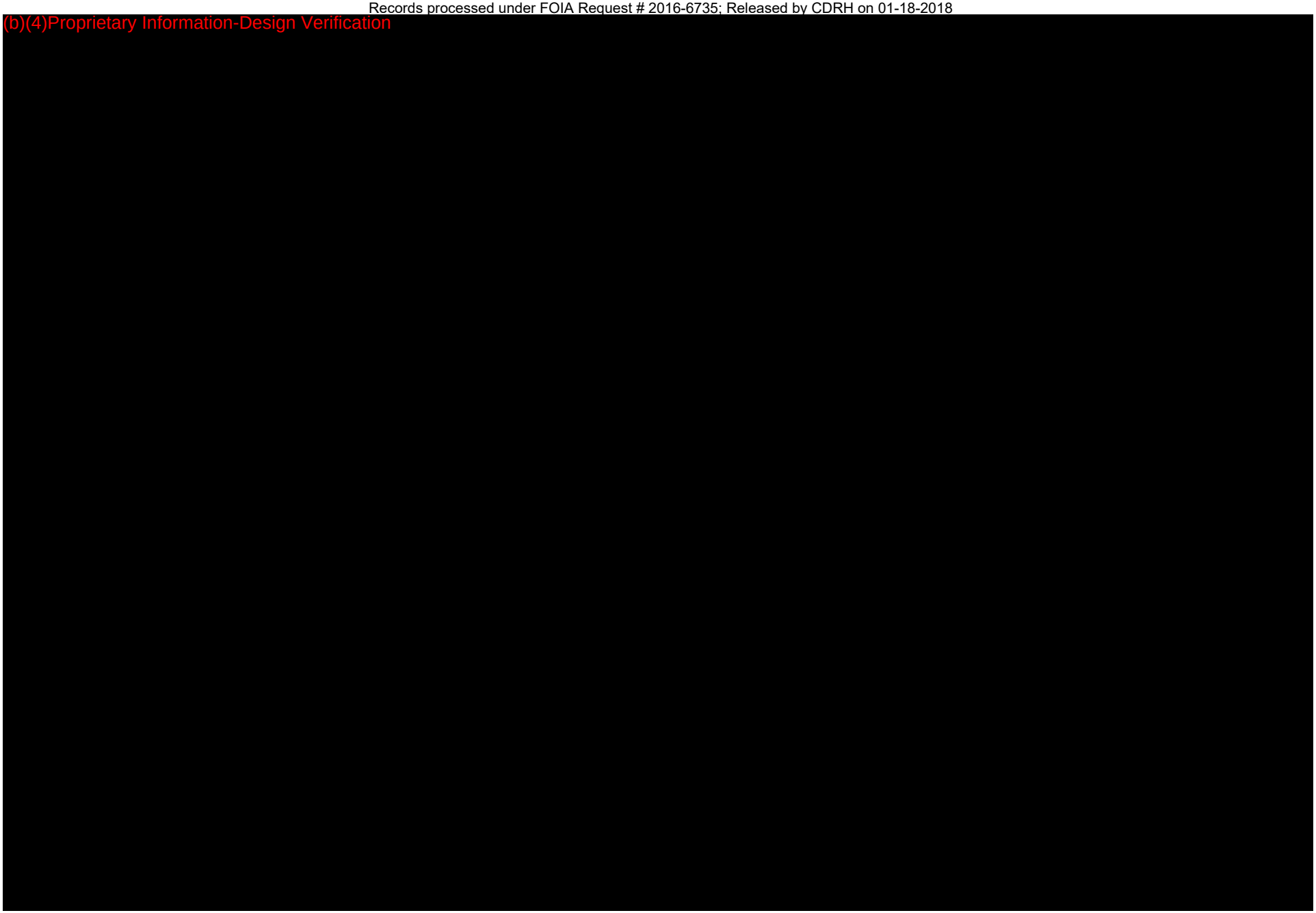
(b)(4)Proprietary Information-Design Verification



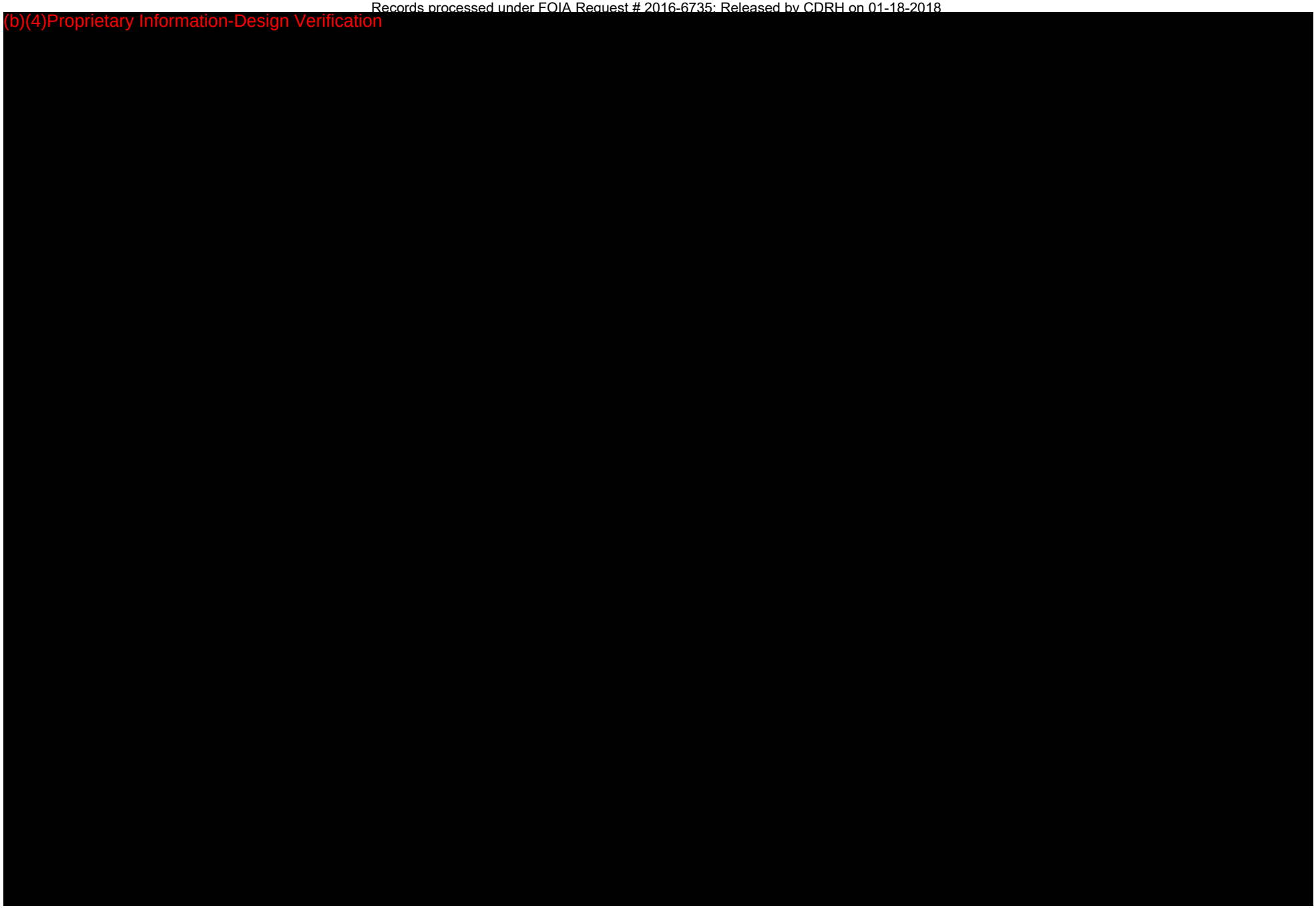
(b)(4)Proprietary Information-Design Verification



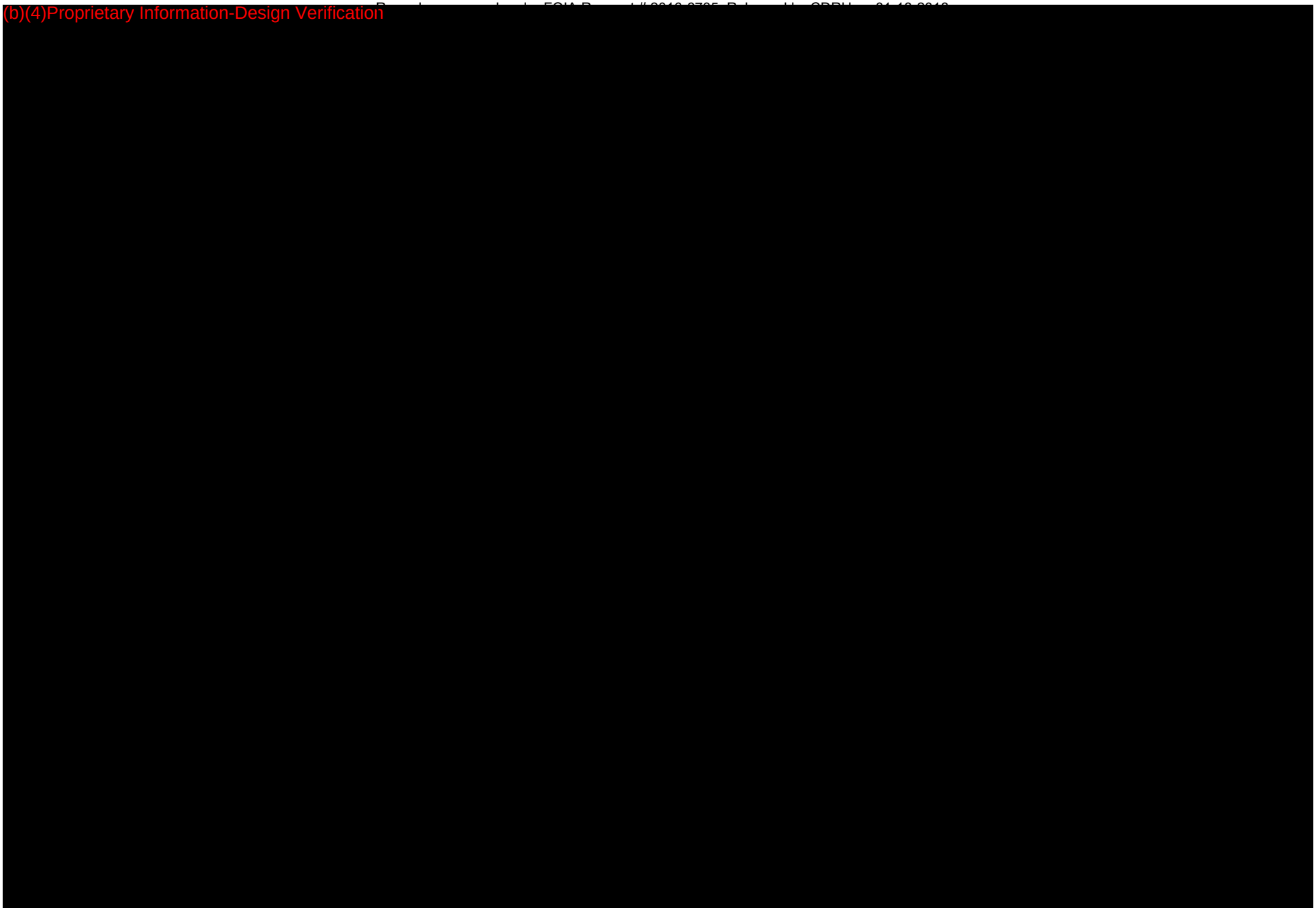
(b)(4)Proprietary Information-Design Verification



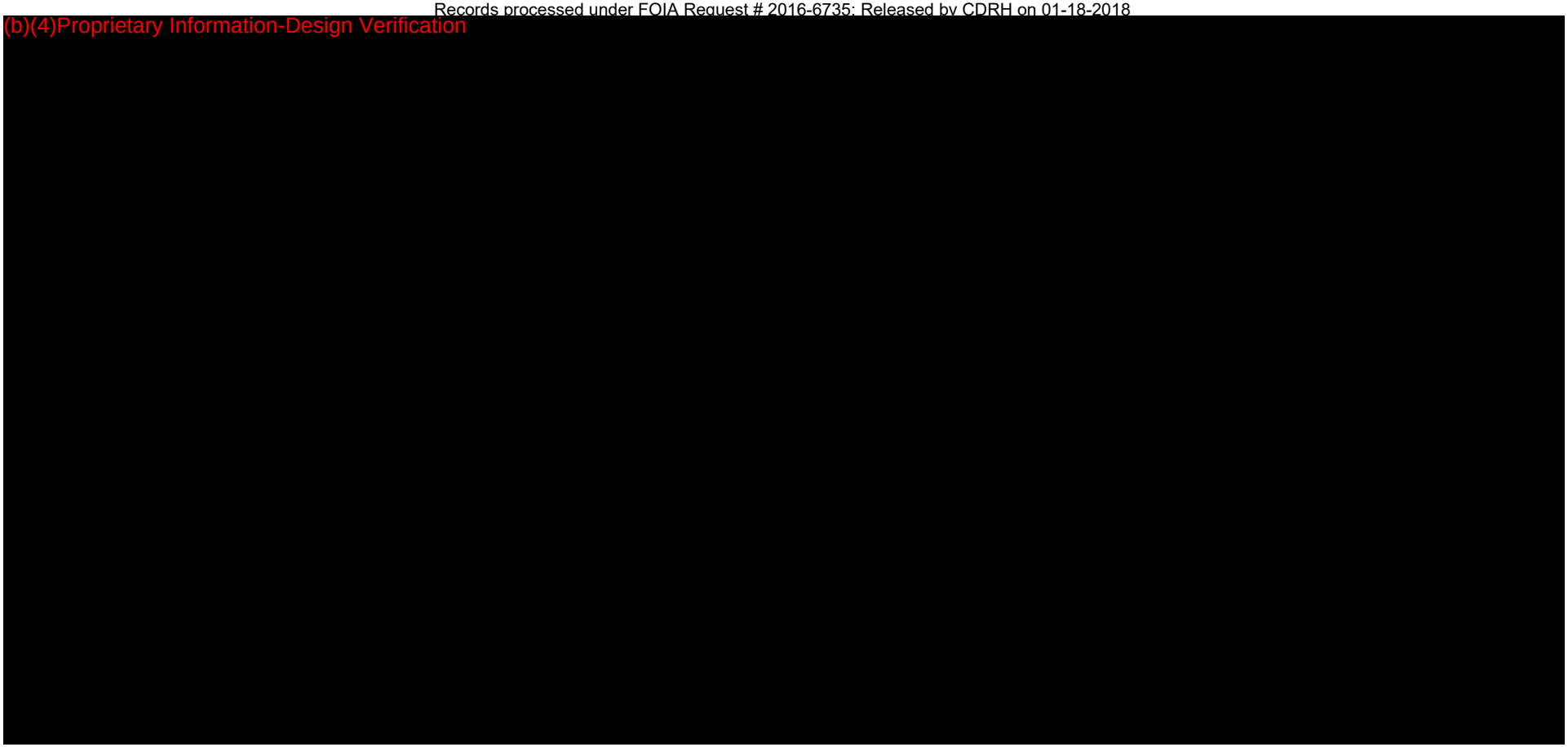
(b)(4)Proprietary Information-Design Verification



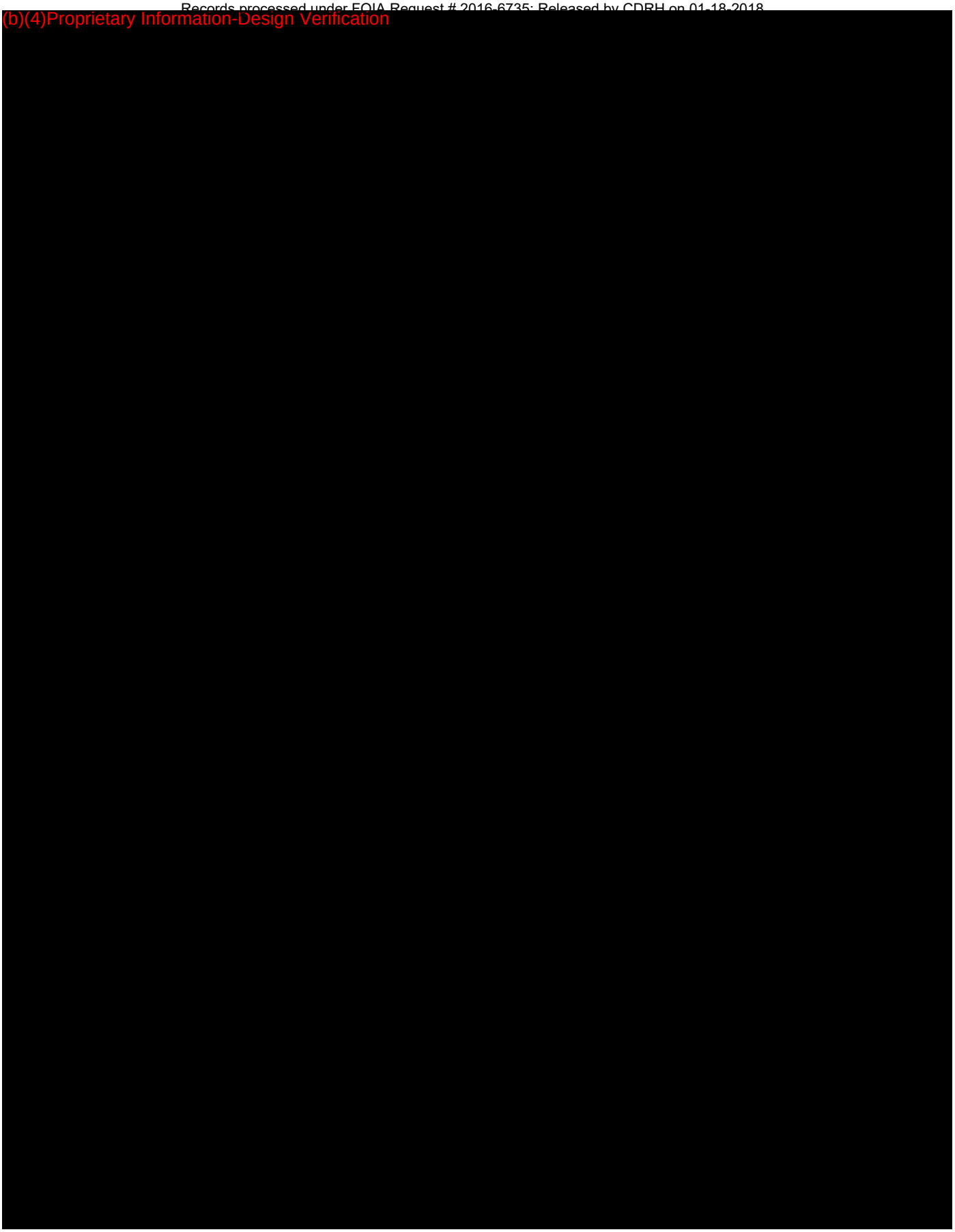
(b)(4)Proprietary Information-Design Verification



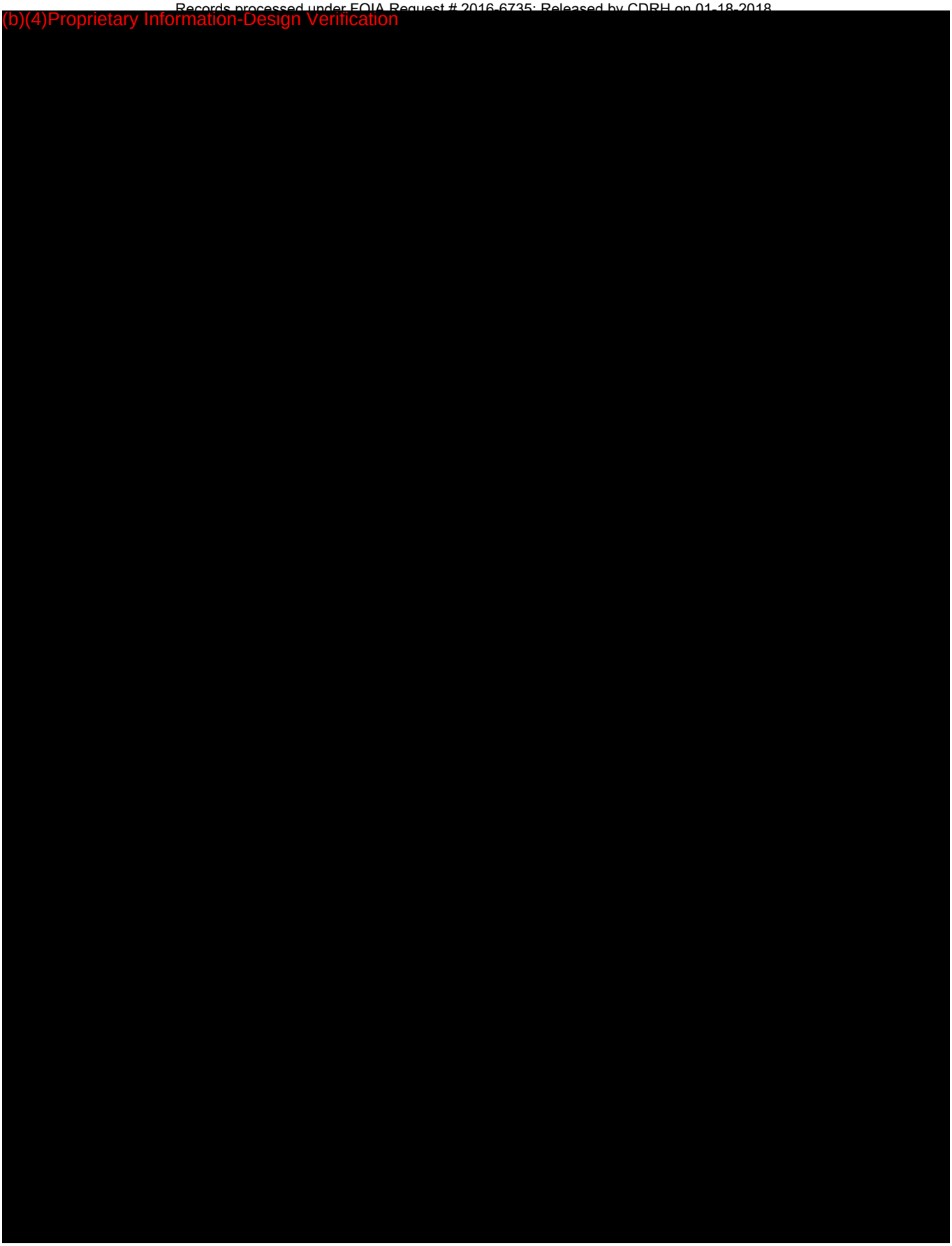
(b)(4)Proprietary Information-Design Verification



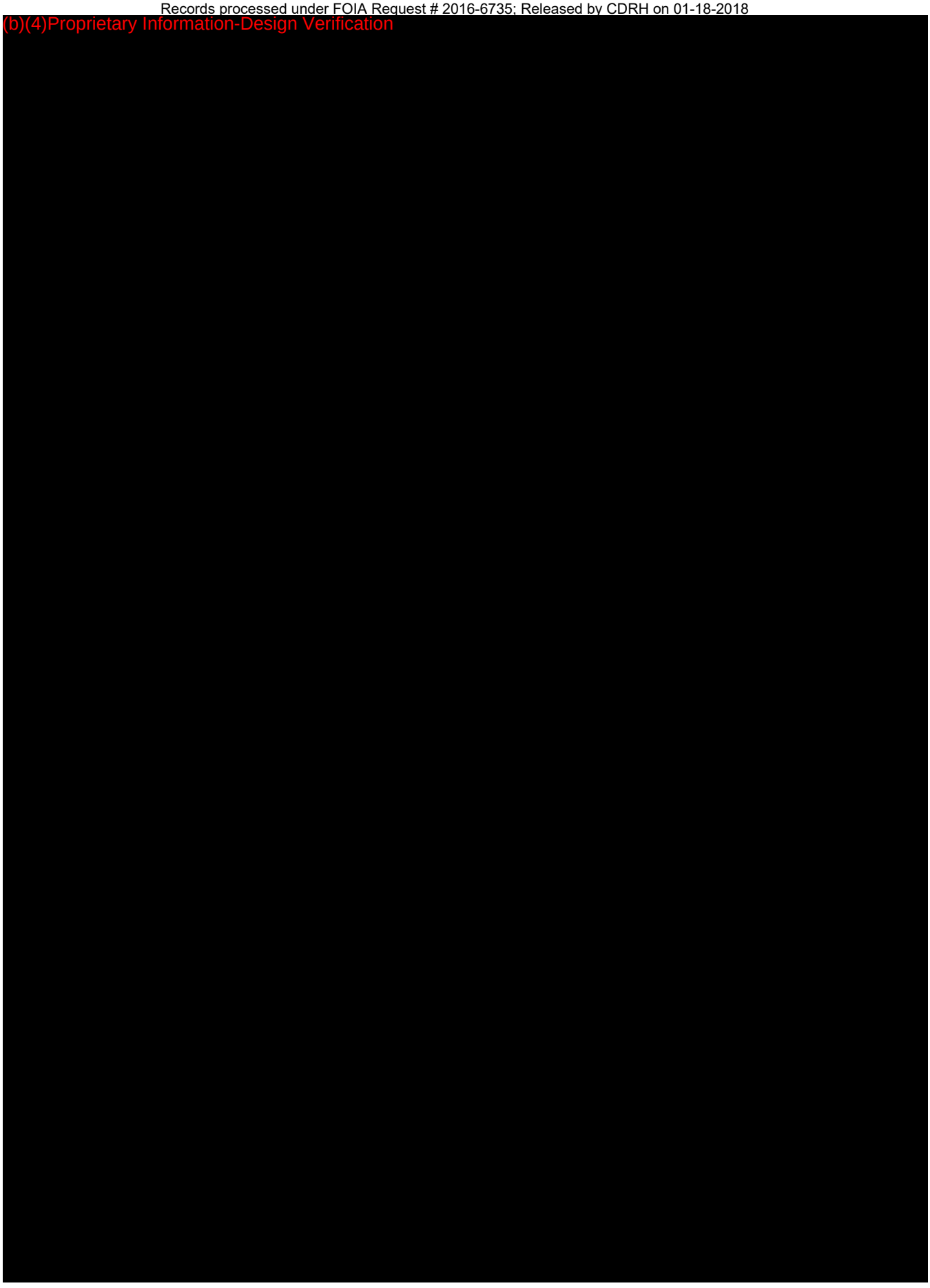
(b)(4)Proprietary Information-Design Verification



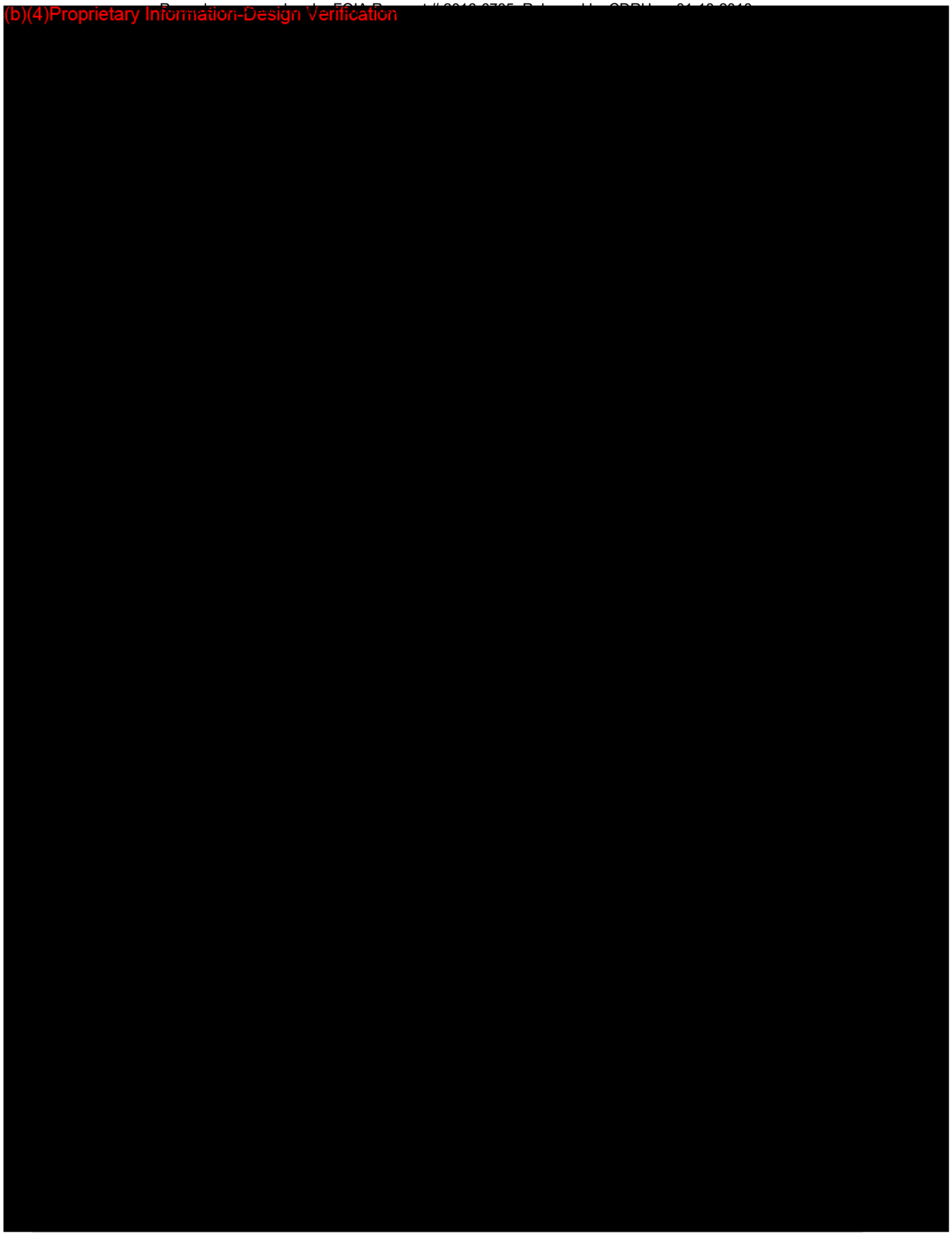
(b)(4)Proprietary Information-Design Verification



(b)(4)Proprietary Information-Design Verification



(b)(4)Proprietary Information-Design Verification



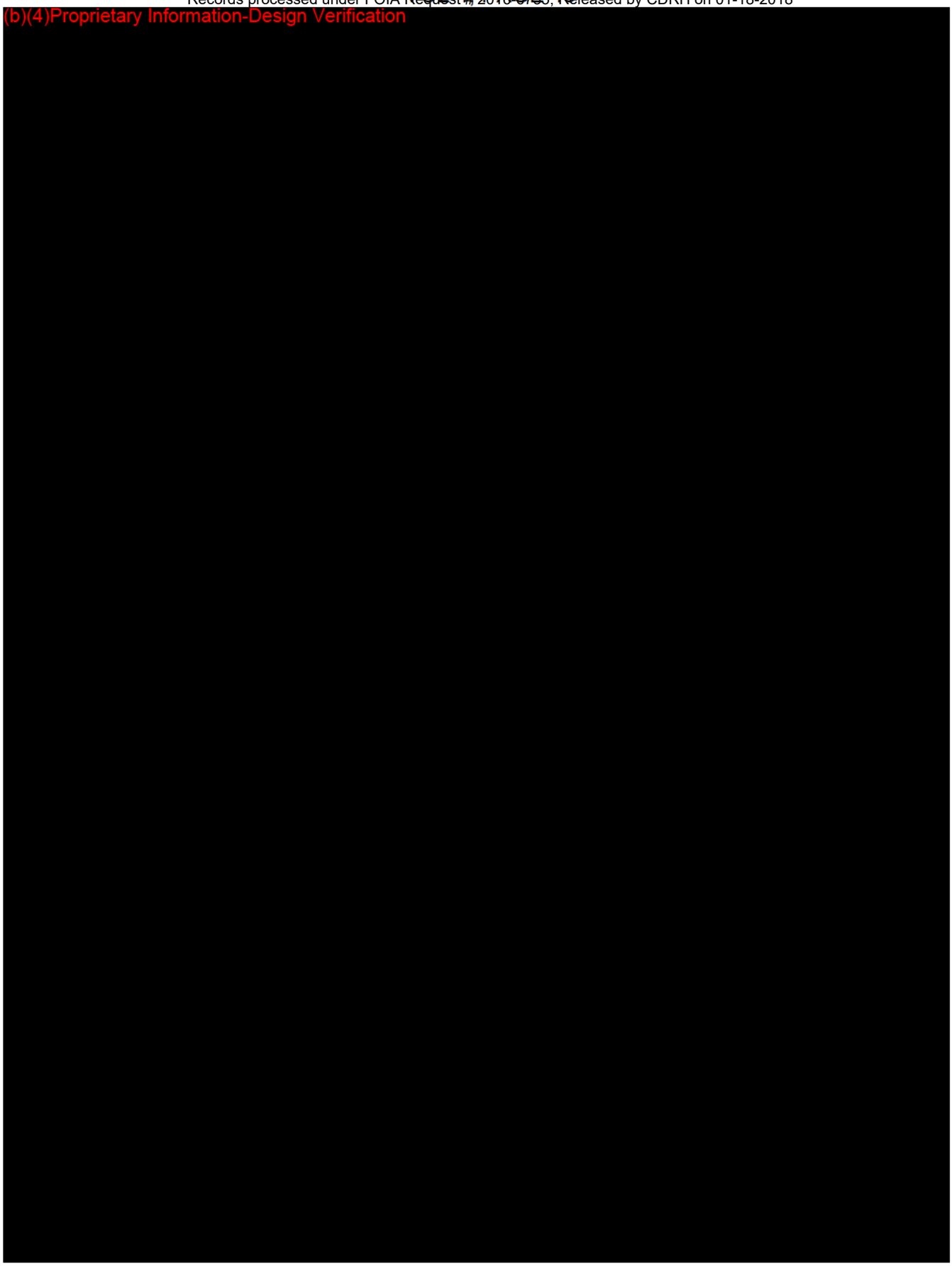
(b)(4)Proprietary Information-Design Verification

[redacted]

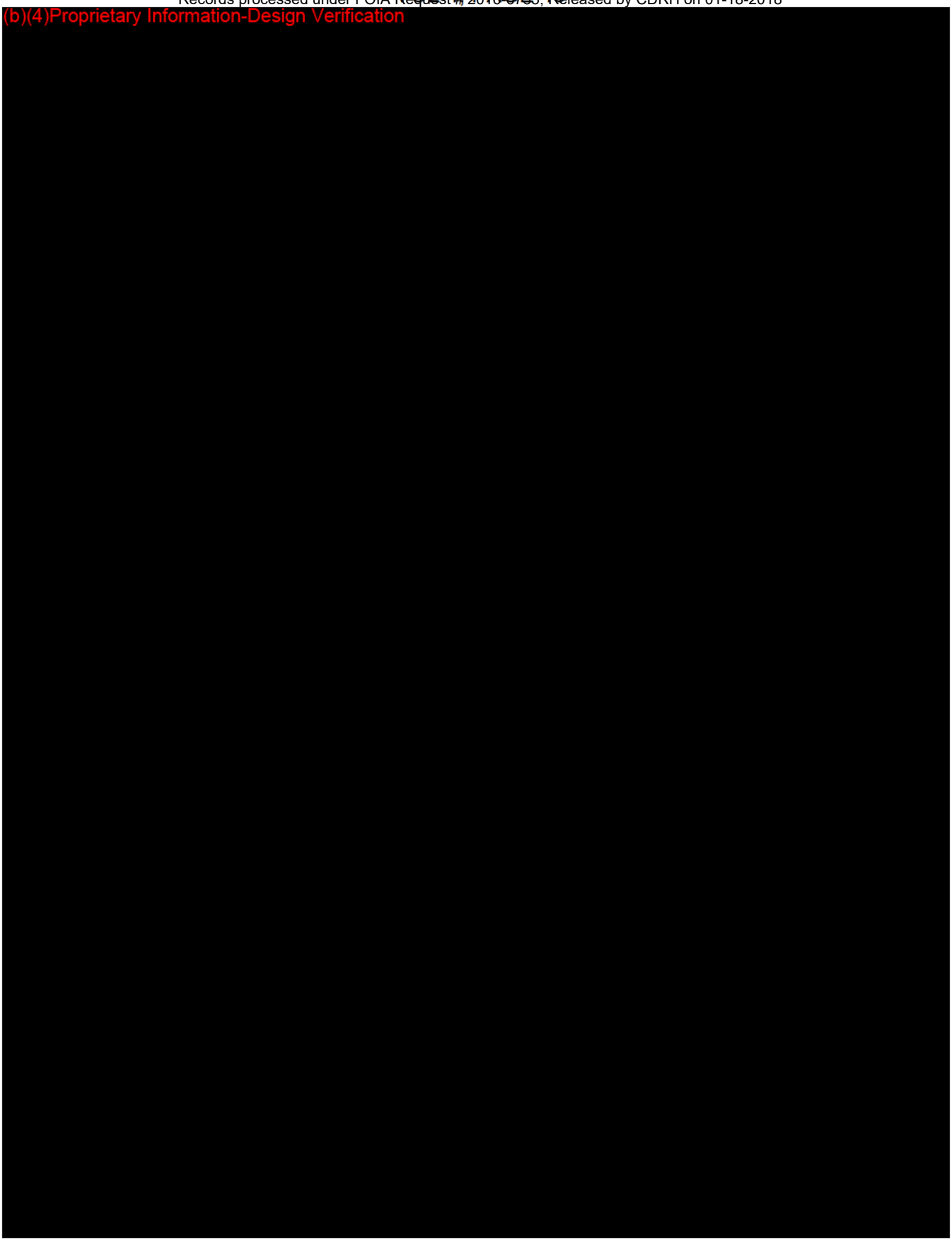
(b)(4)Proprietary Information-Design Verification

[redacted]

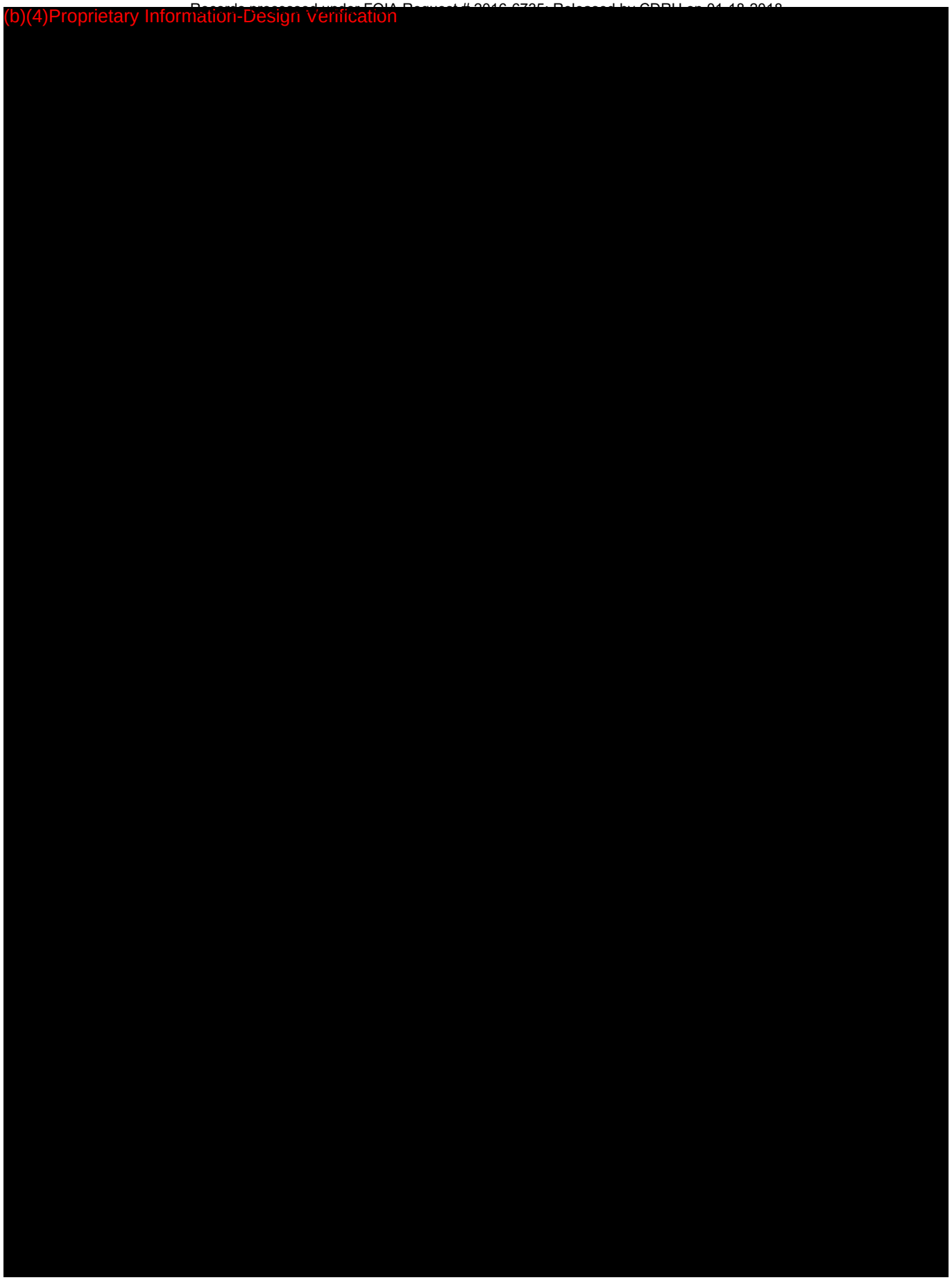
(b)(4)Proprietary Information-Design Verification



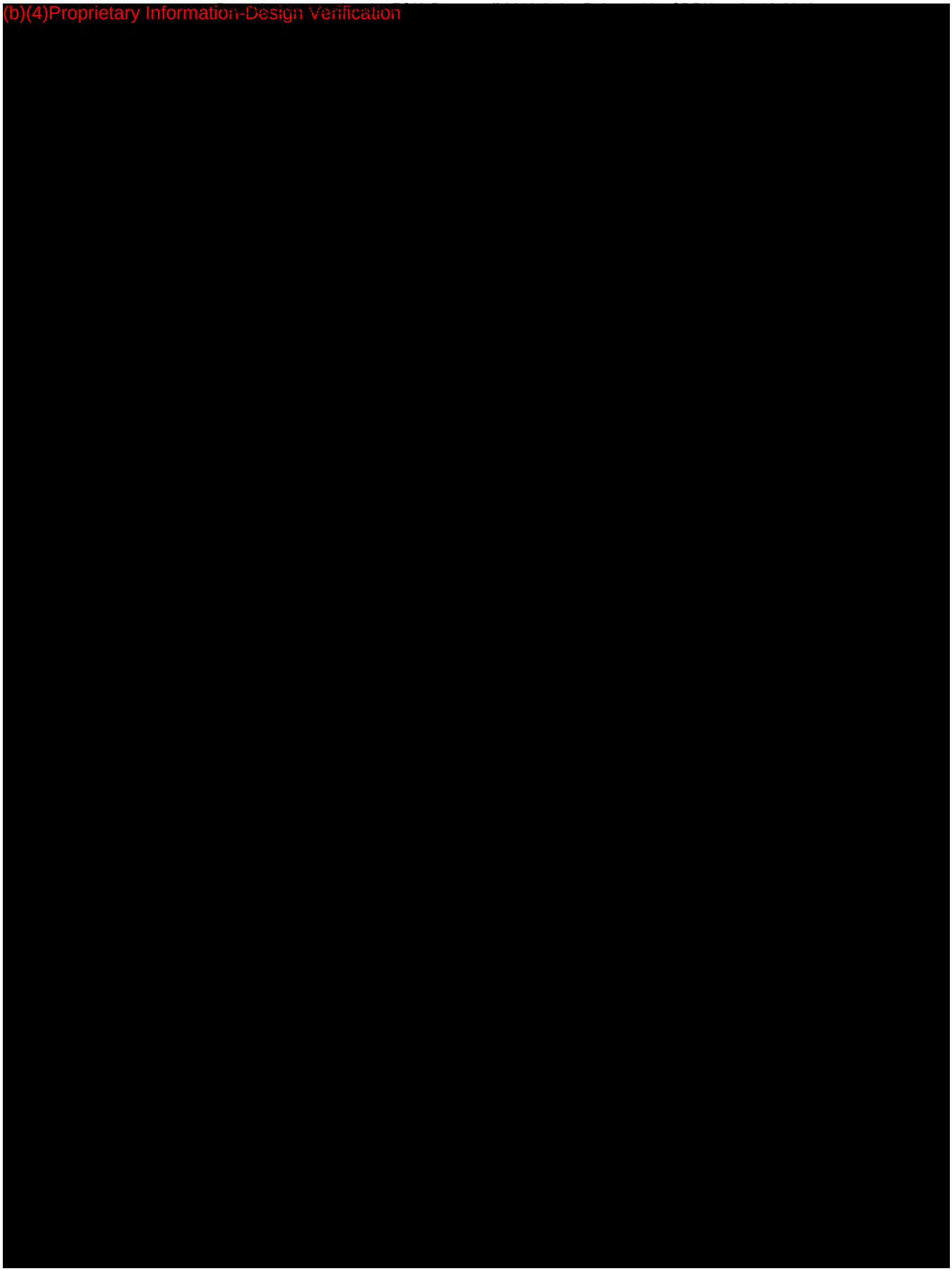
(b)(4)Proprietary Information-Design Verification



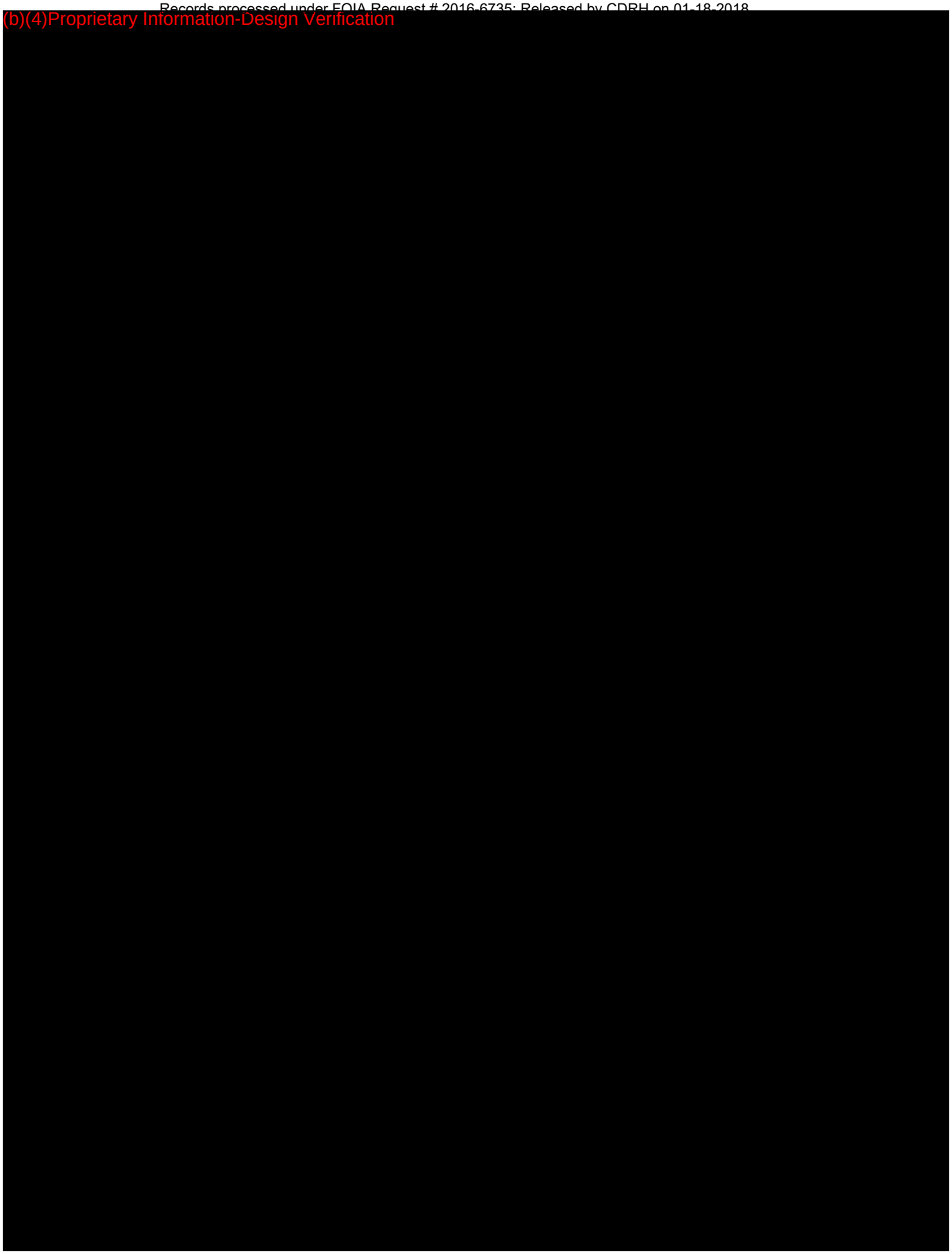
(b)(4)Proprietary Information-Design Verification



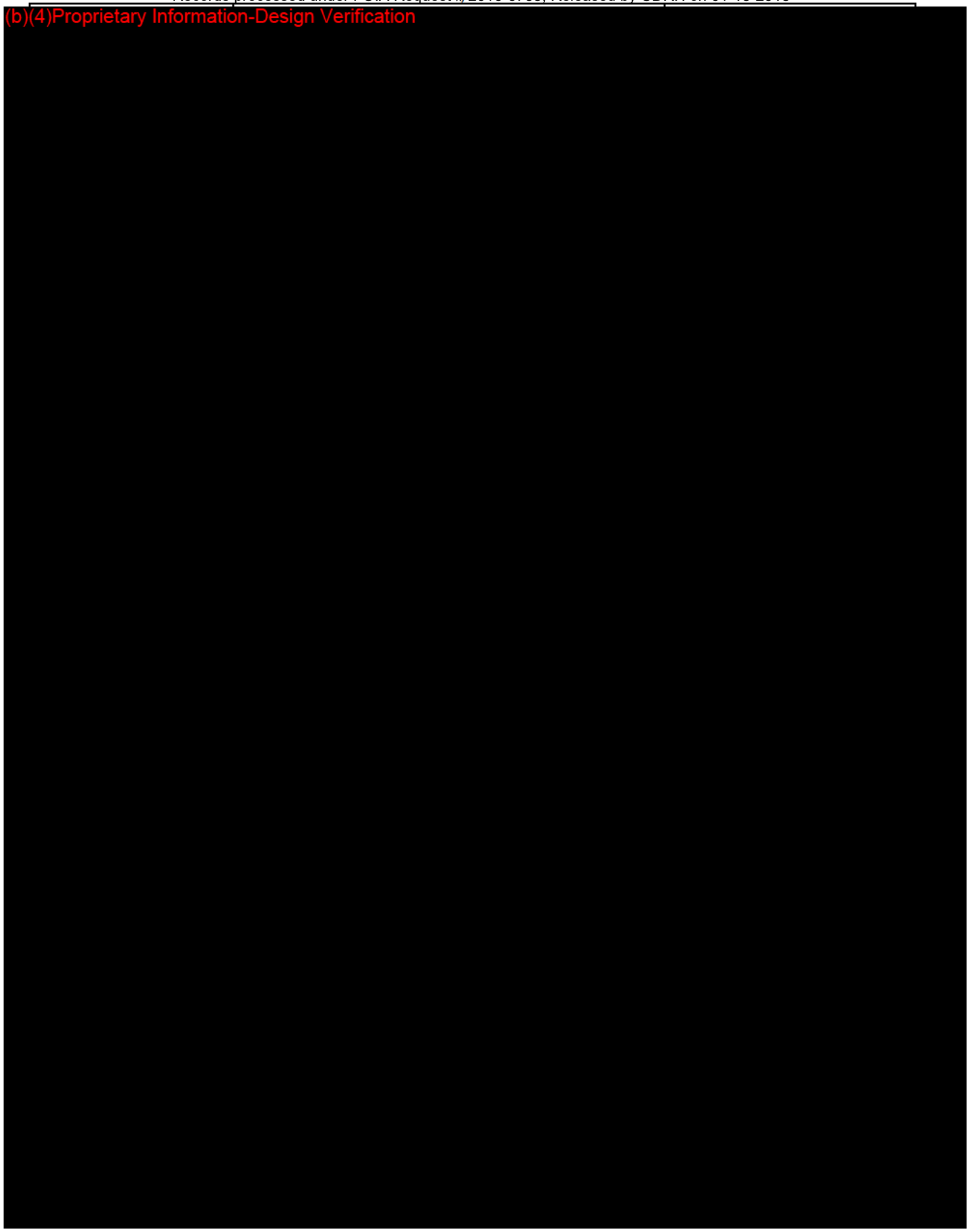
(b)(4)Proprietary Information-Design Verification



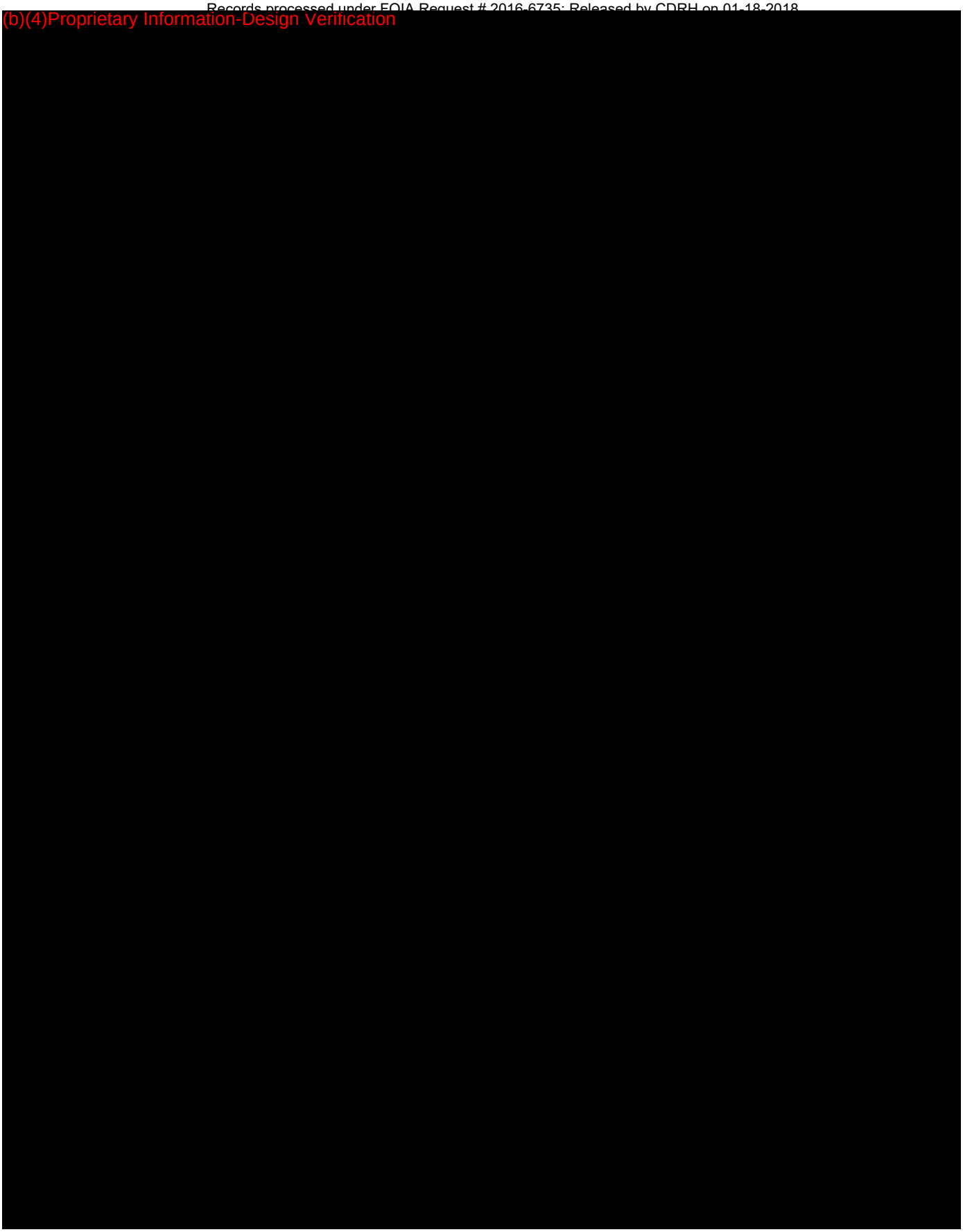
(b)(4)Proprietary Information-Design Verification



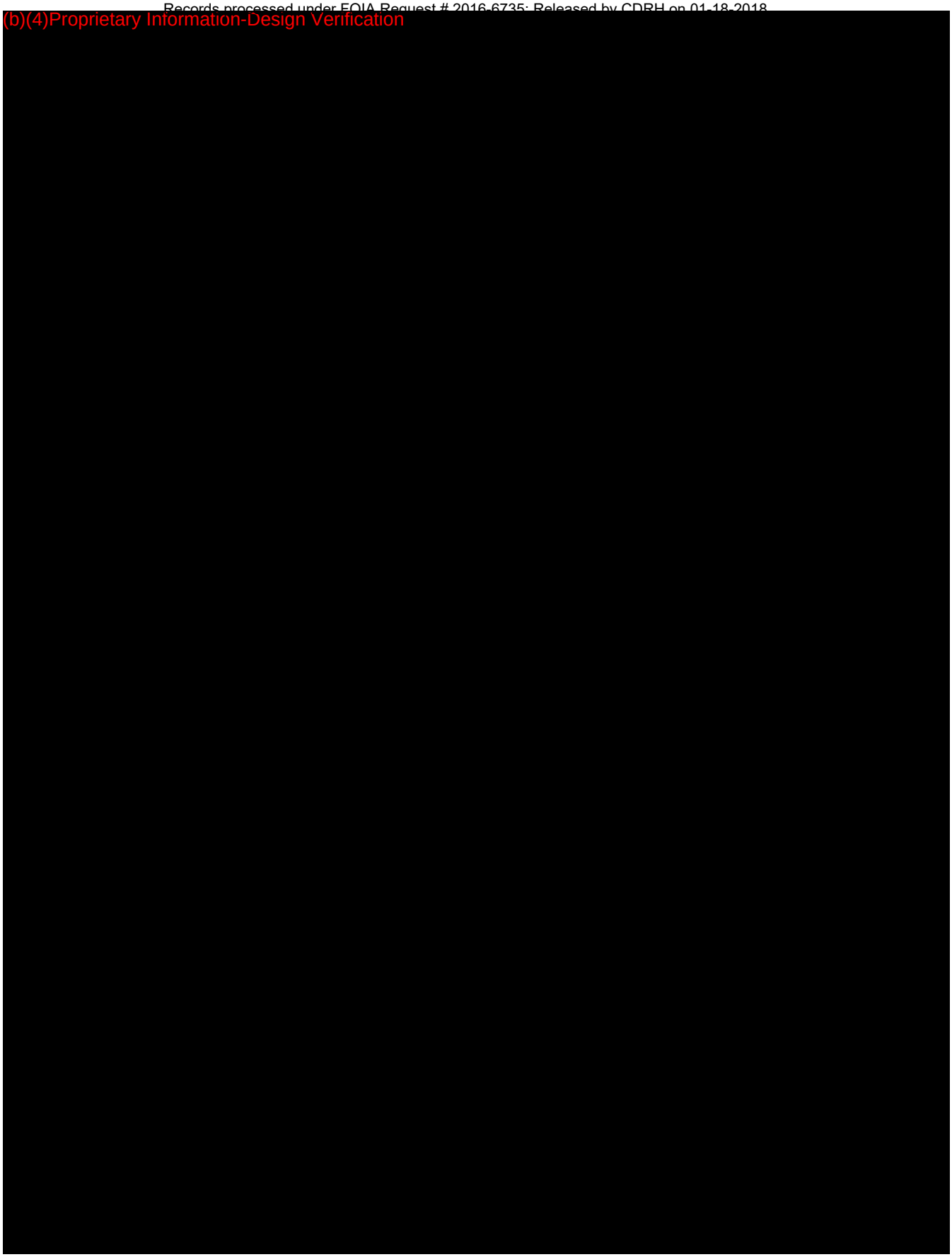
(b)(4)Proprietary Information-Design Verification



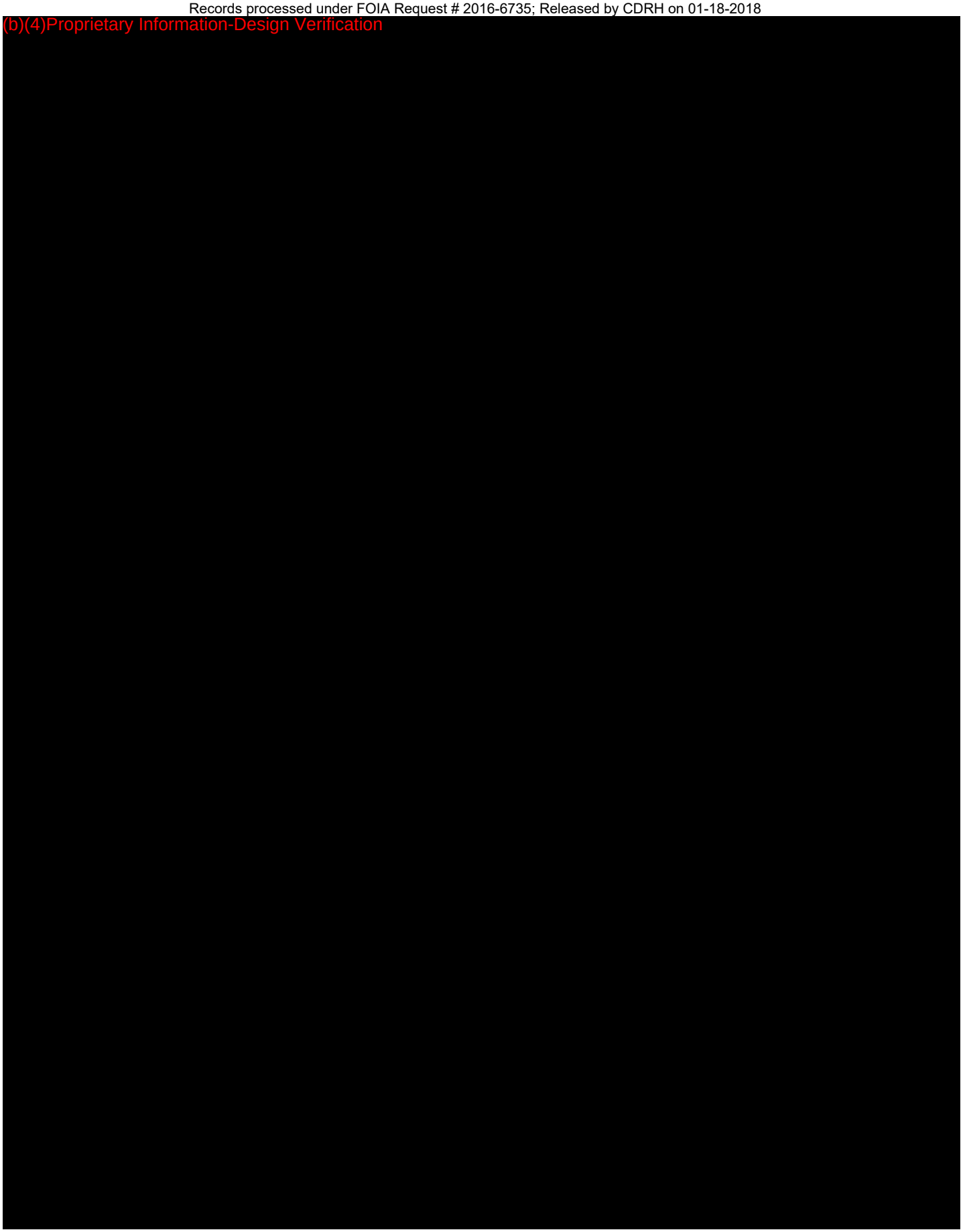
(b)(4)Proprietary Information-Design Verification



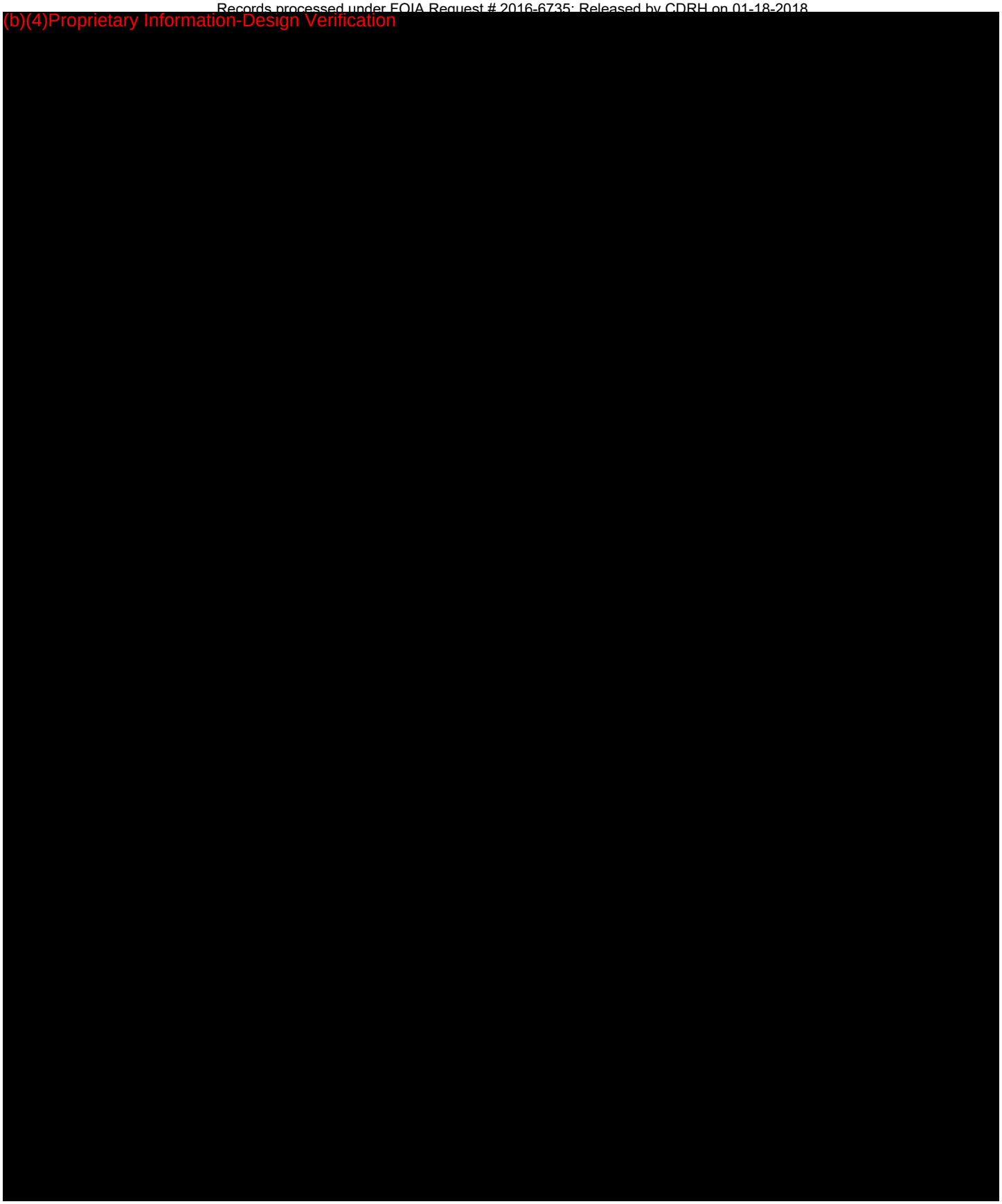
(b)(4)Proprietary Information-Design Verification



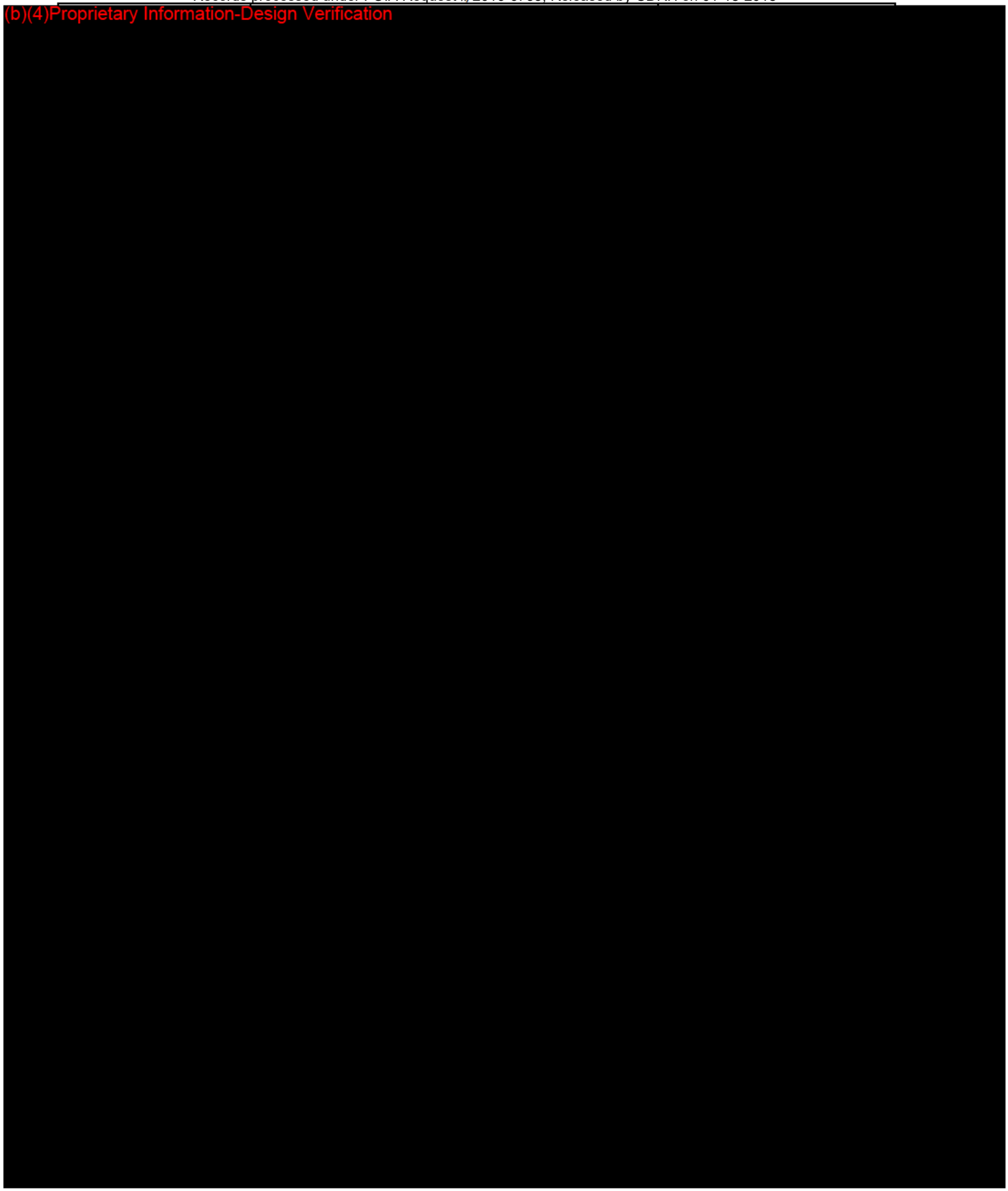
(b)(4)Proprietary Information-Design Verification



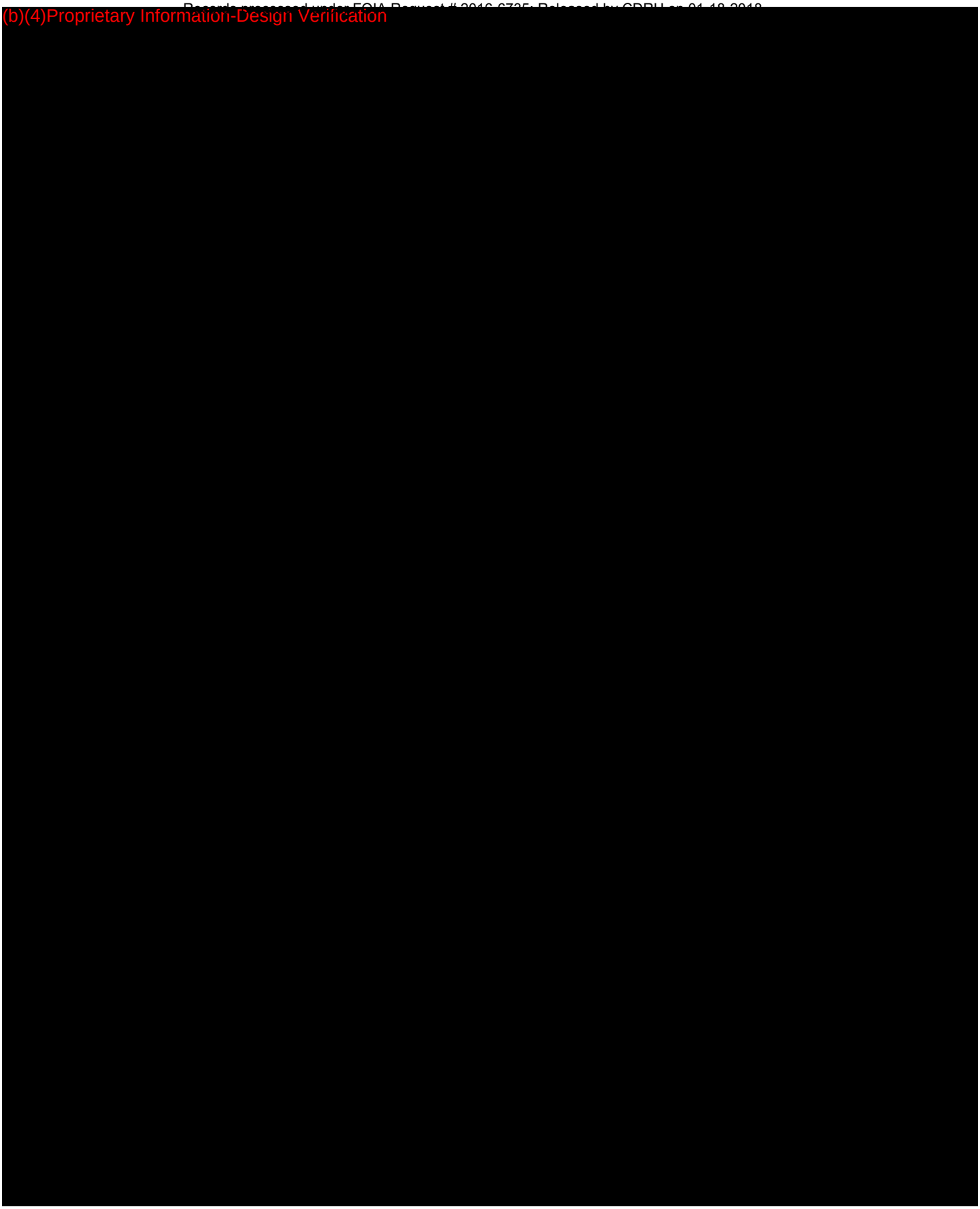
(b)(4)Proprietary Information-Design Verification



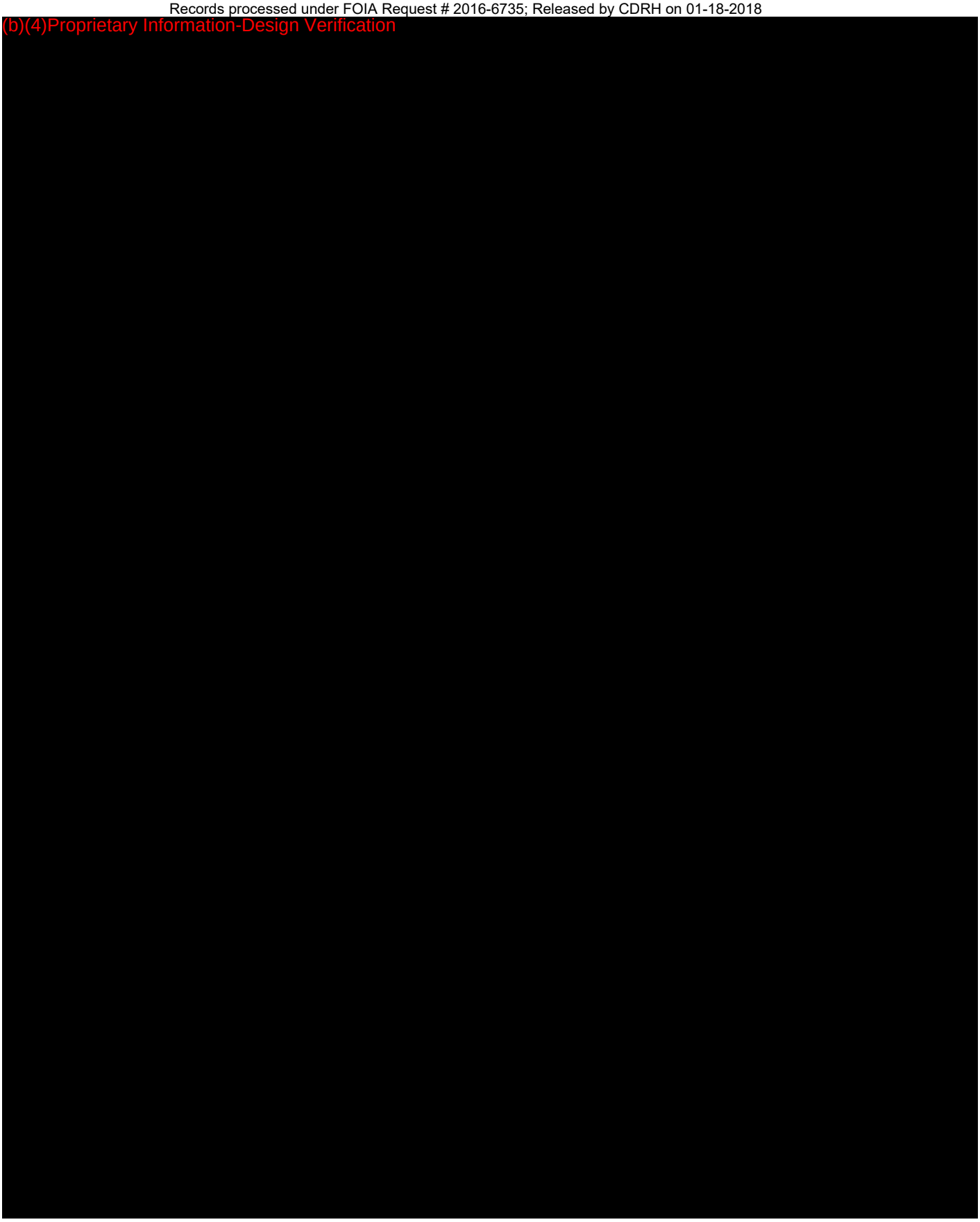
(b)(4)Proprietary Information-Design Verification



(b)(4)Proprietary Information-Design Verification



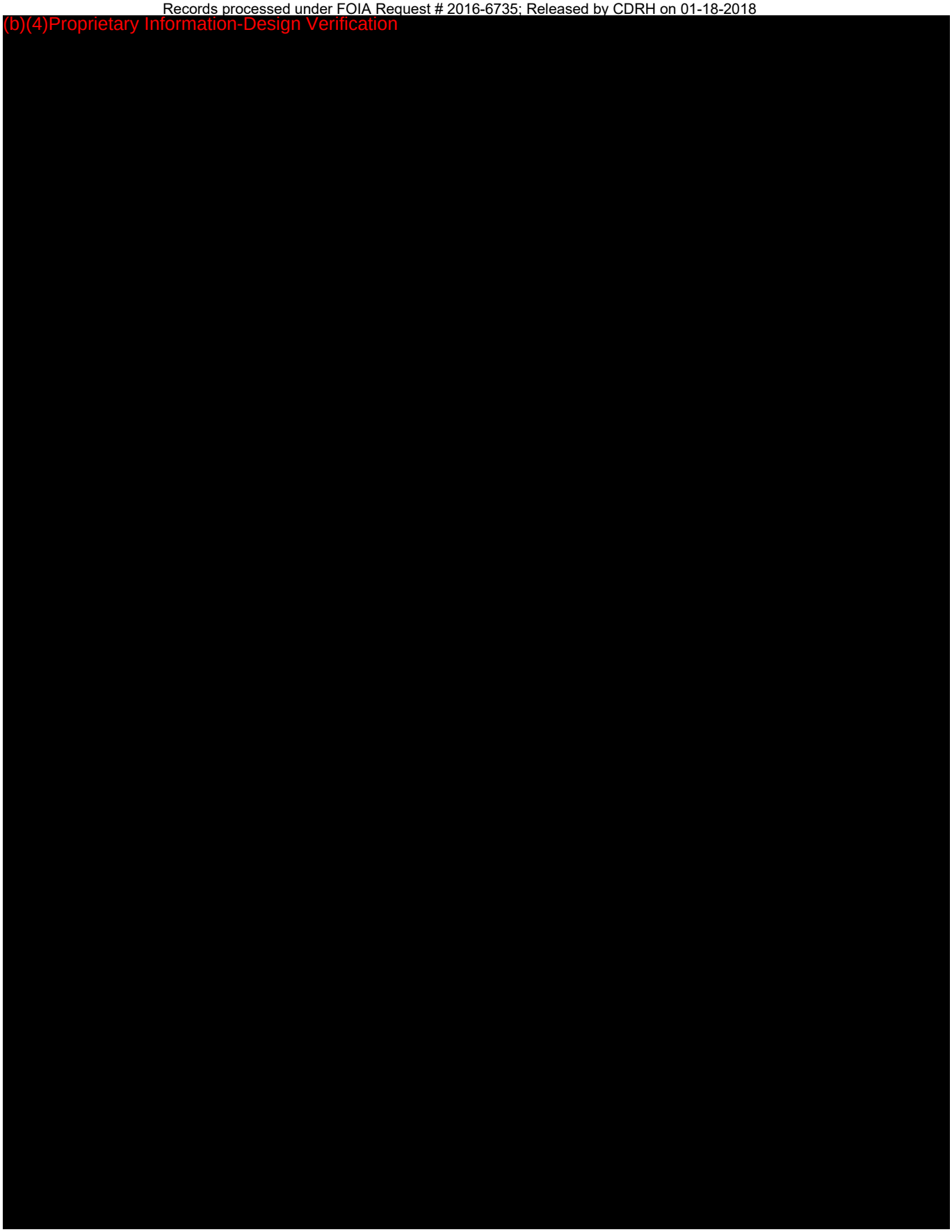
(b)(4)Proprietary Information-Design Verification



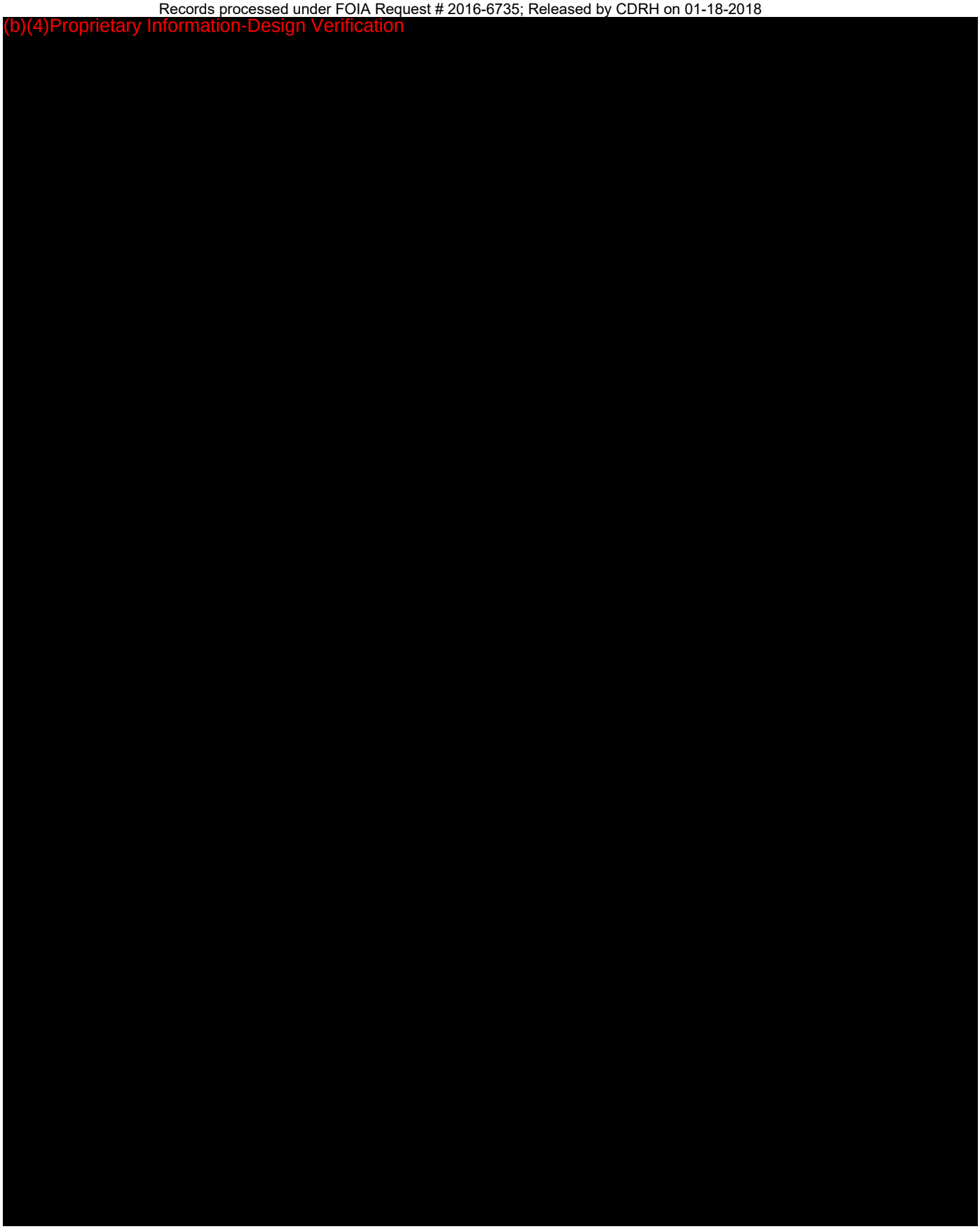
(b)(4)Proprietary Information-Design Verification

[redacted]

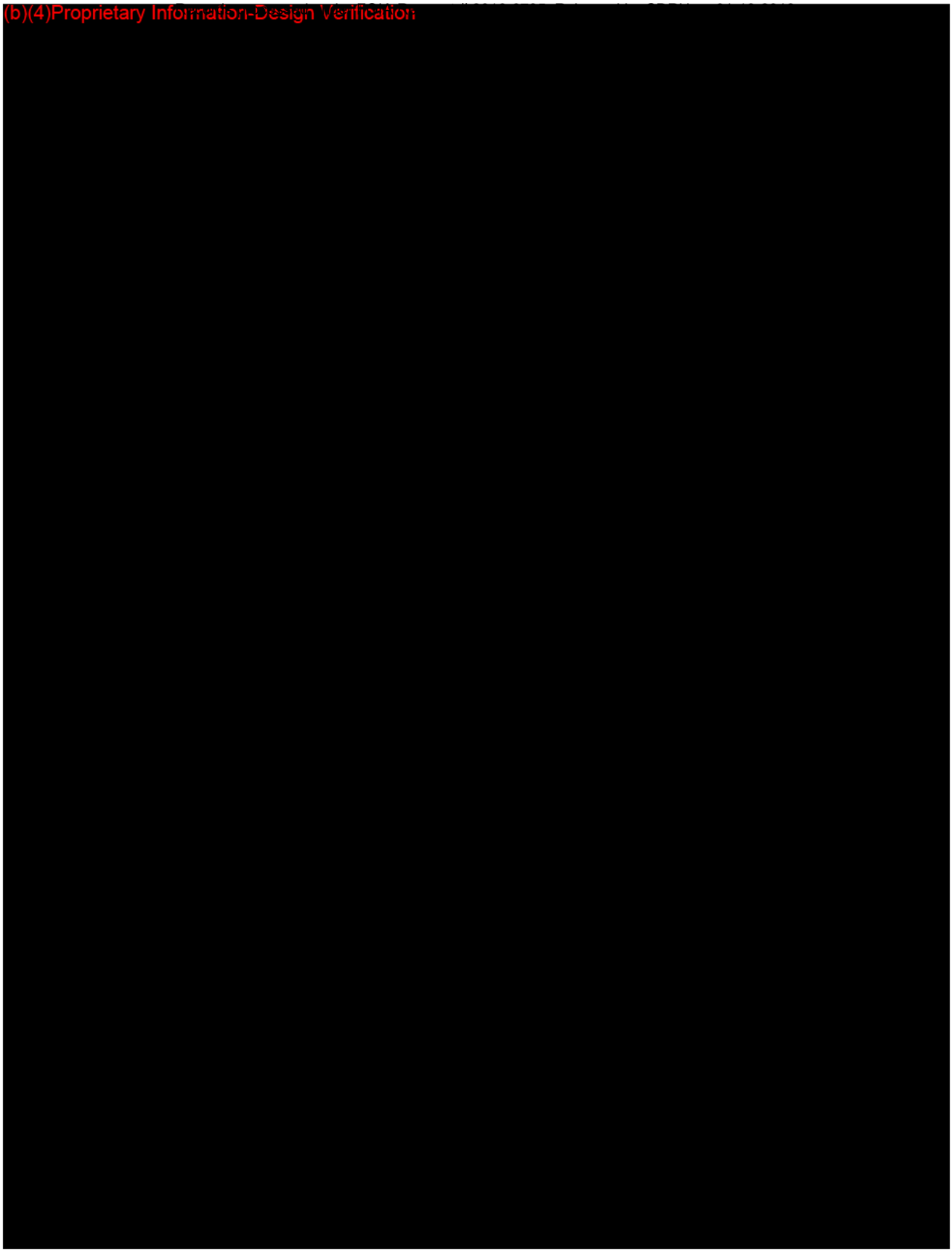
(b)(4)Proprietary Information-Design Verification



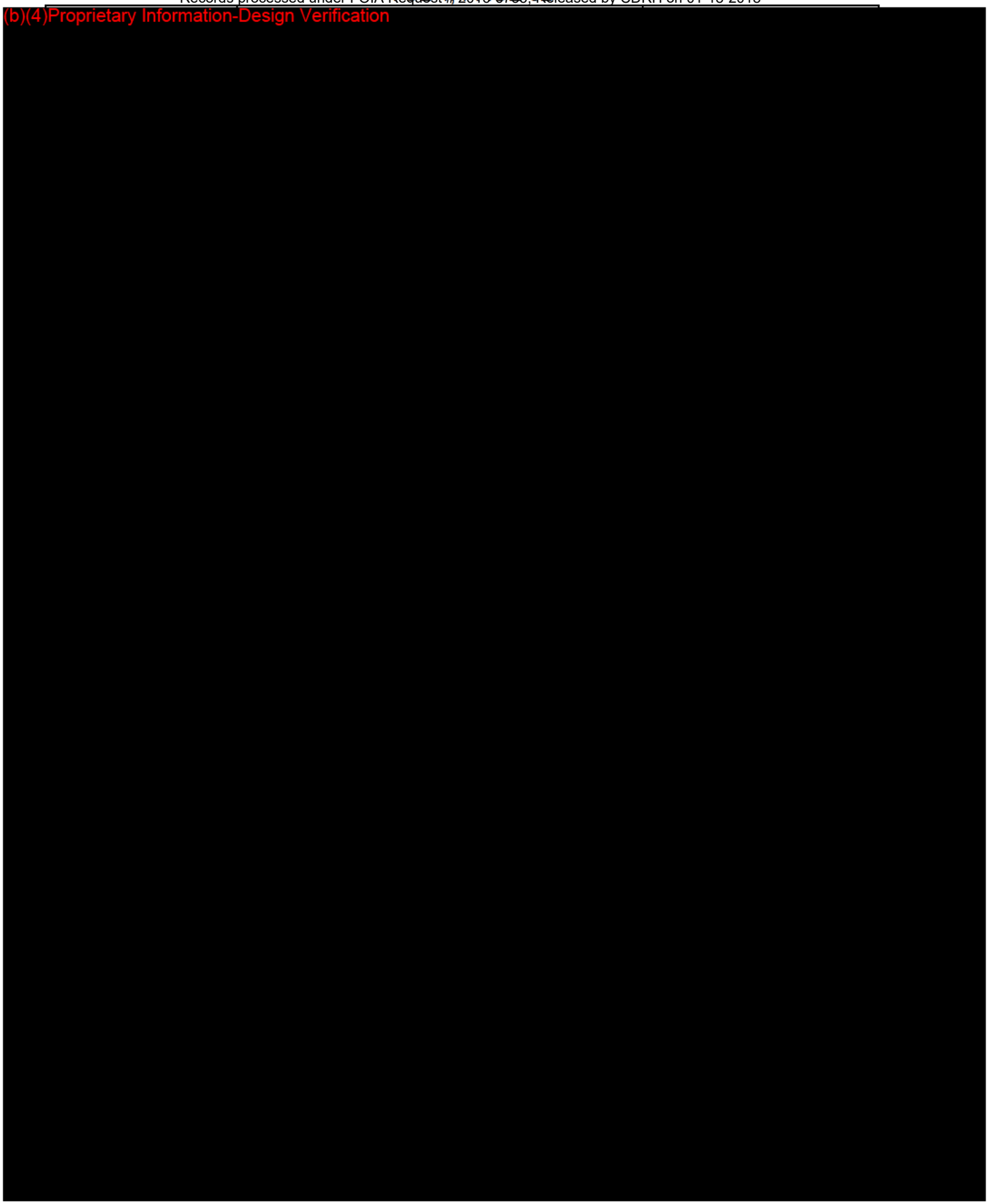
(b)(4)Proprietary Information-Design Verification



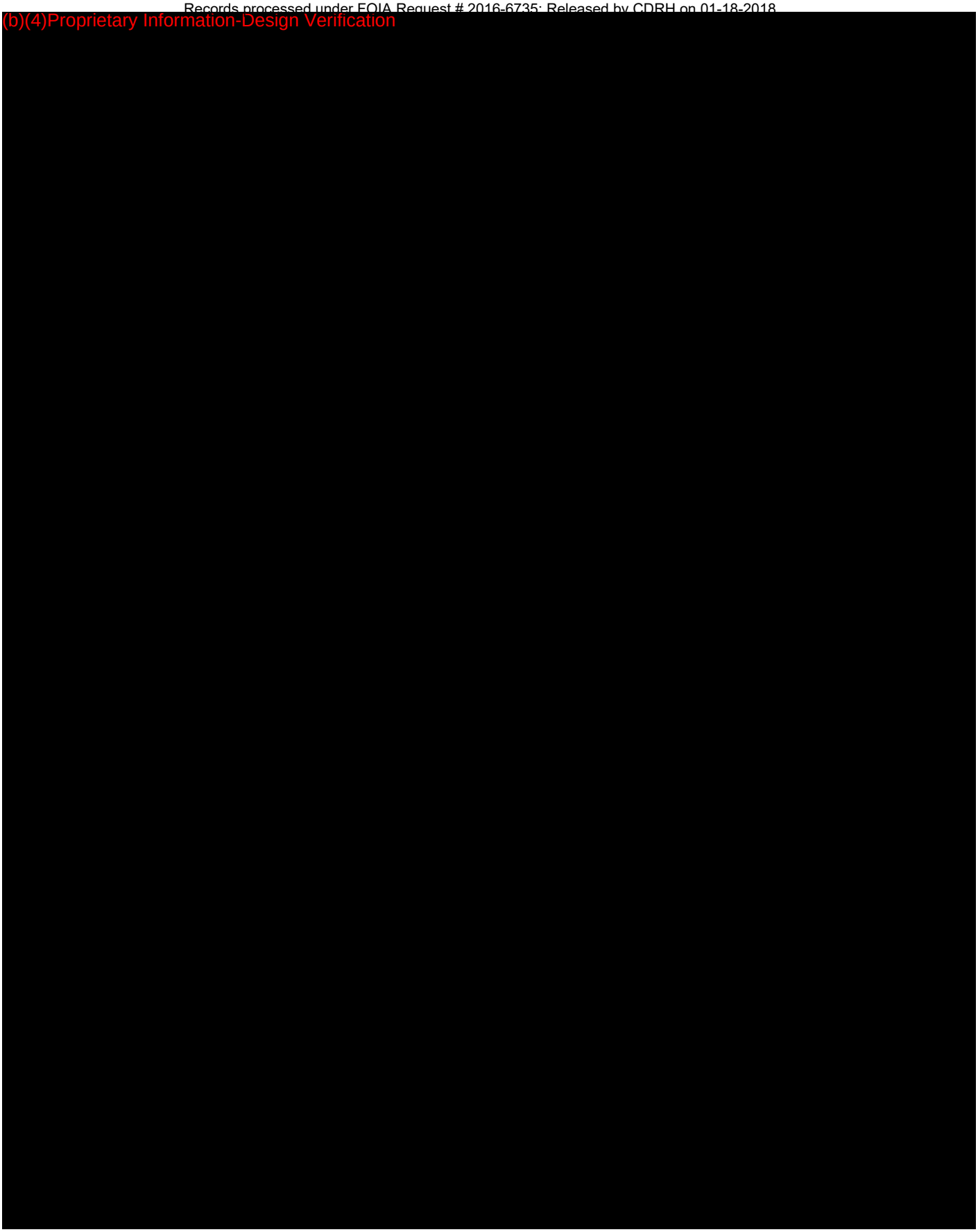
(b)(4)Proprietary Information-Design Verification



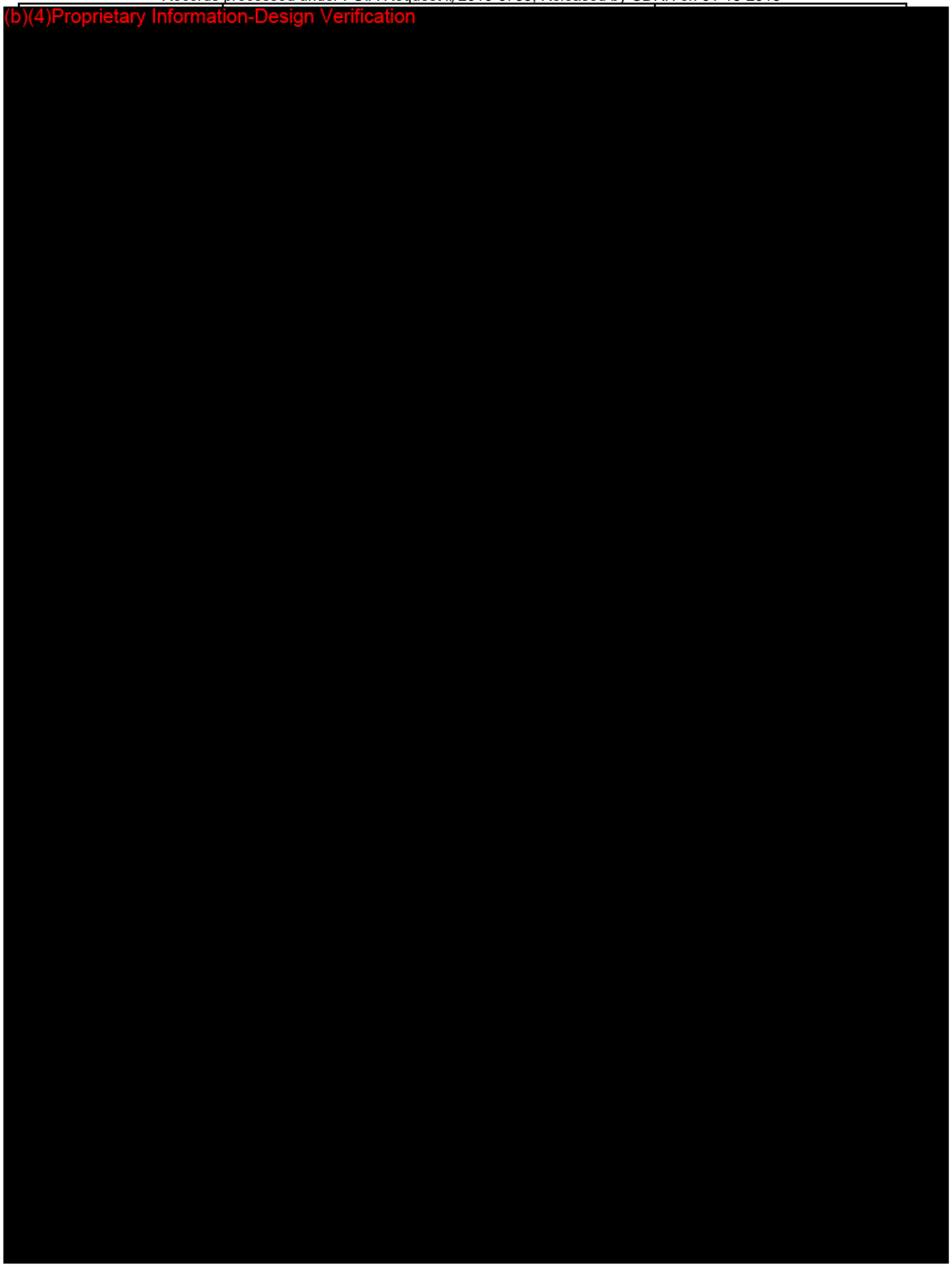
(b)(4)Proprietary Information-Design Verification



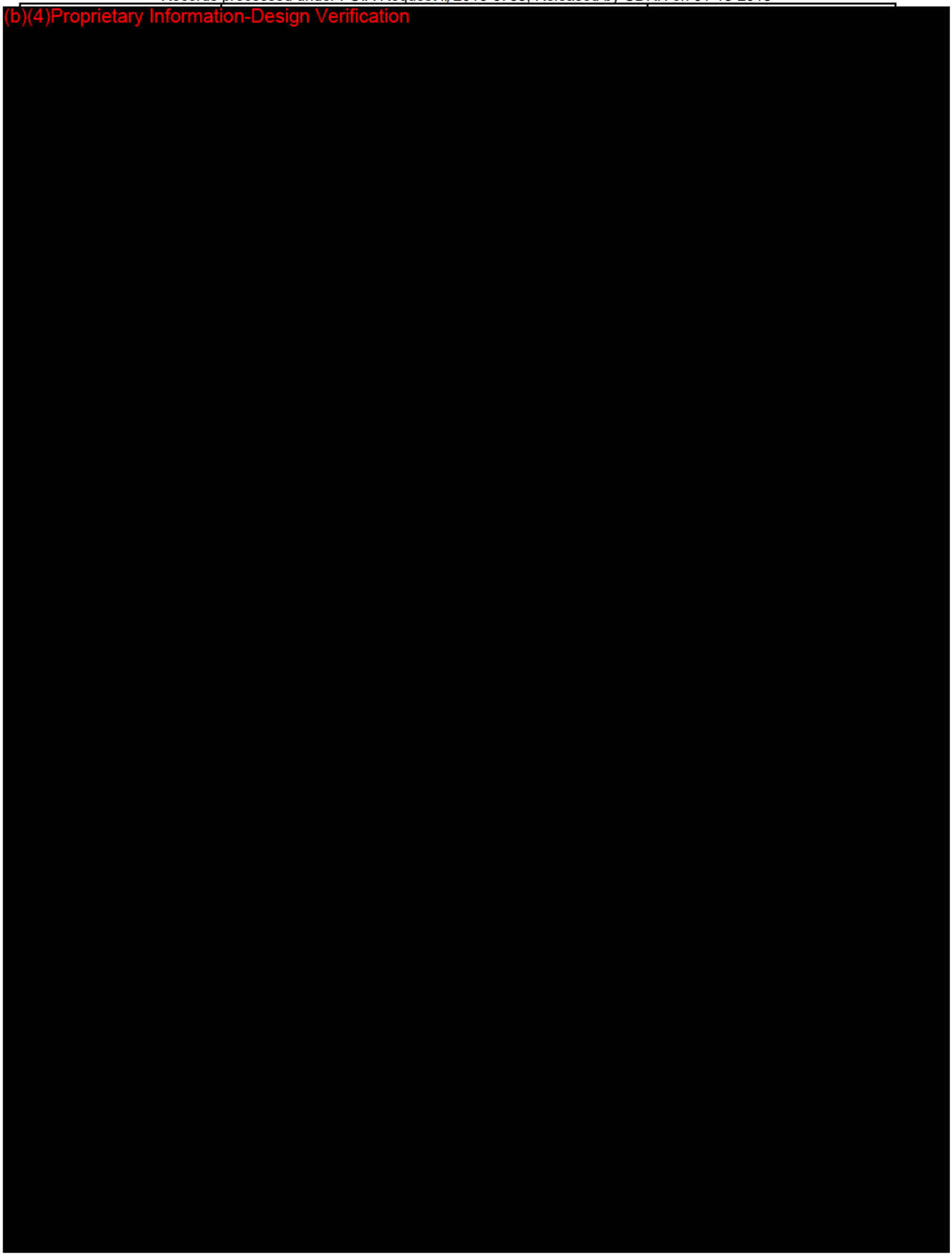
(b)(4)Proprietary Information-Design Verification



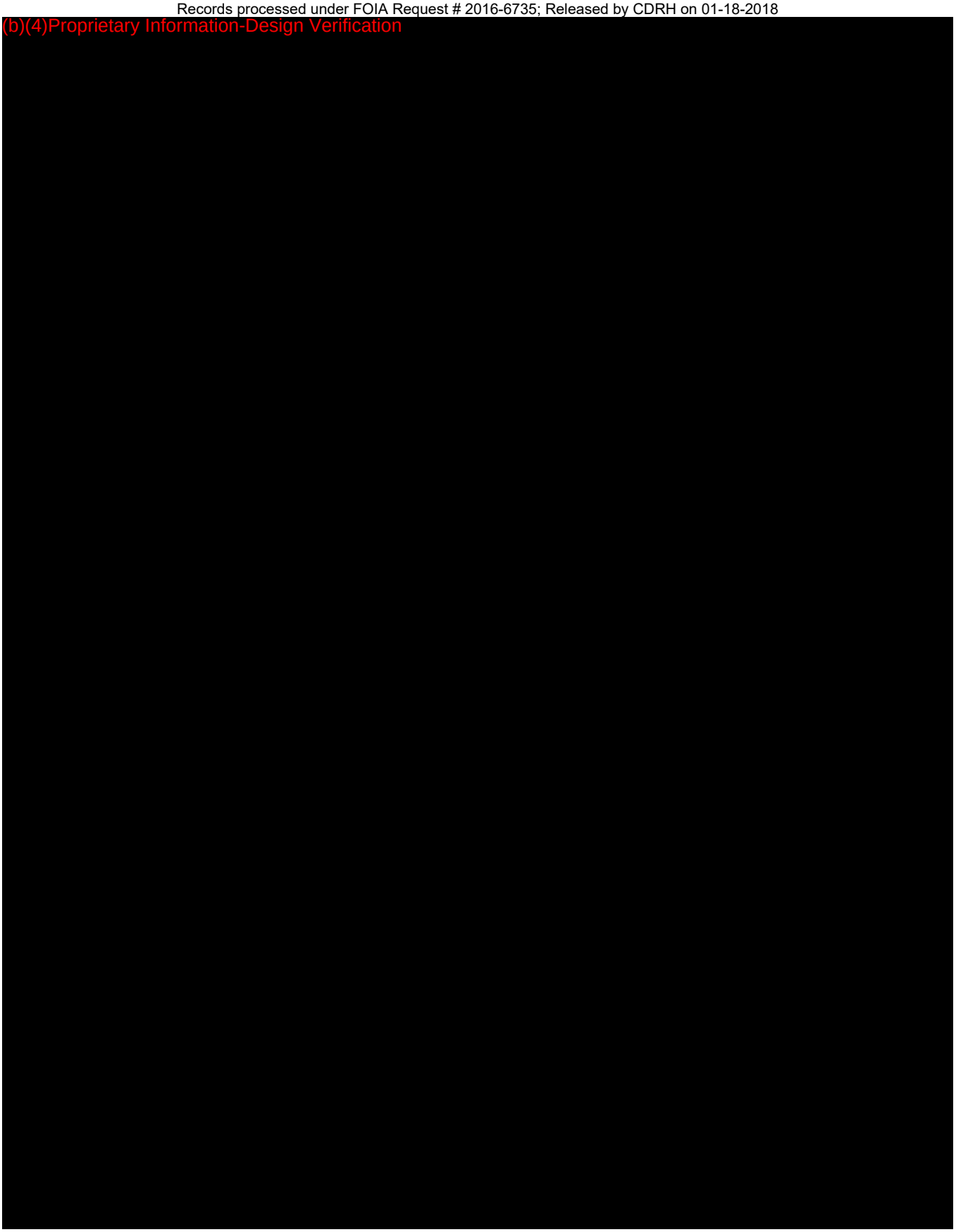
(b)(4)Proprietary Information-Design Verification



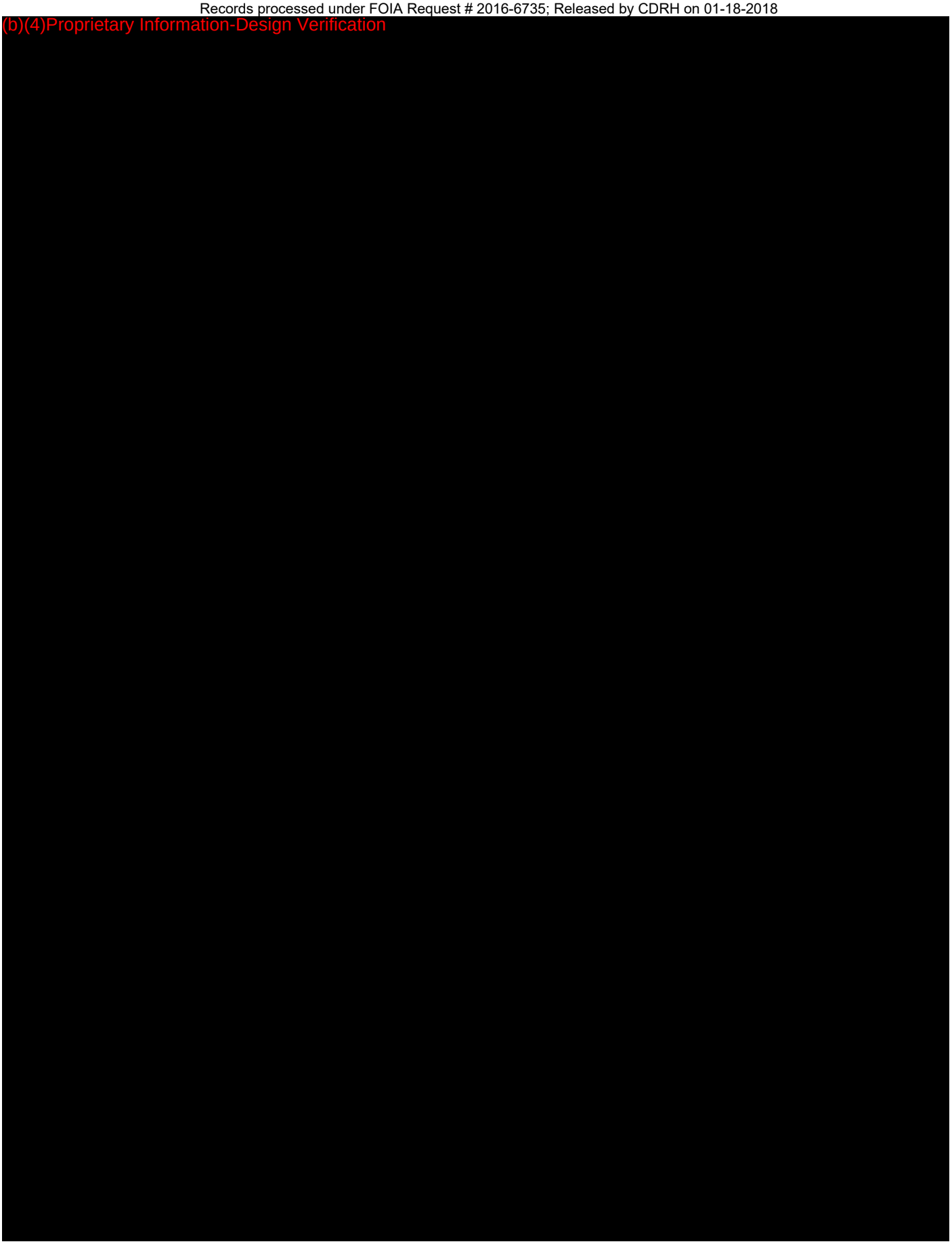
(b)(4)Proprietary Information-Design Verification



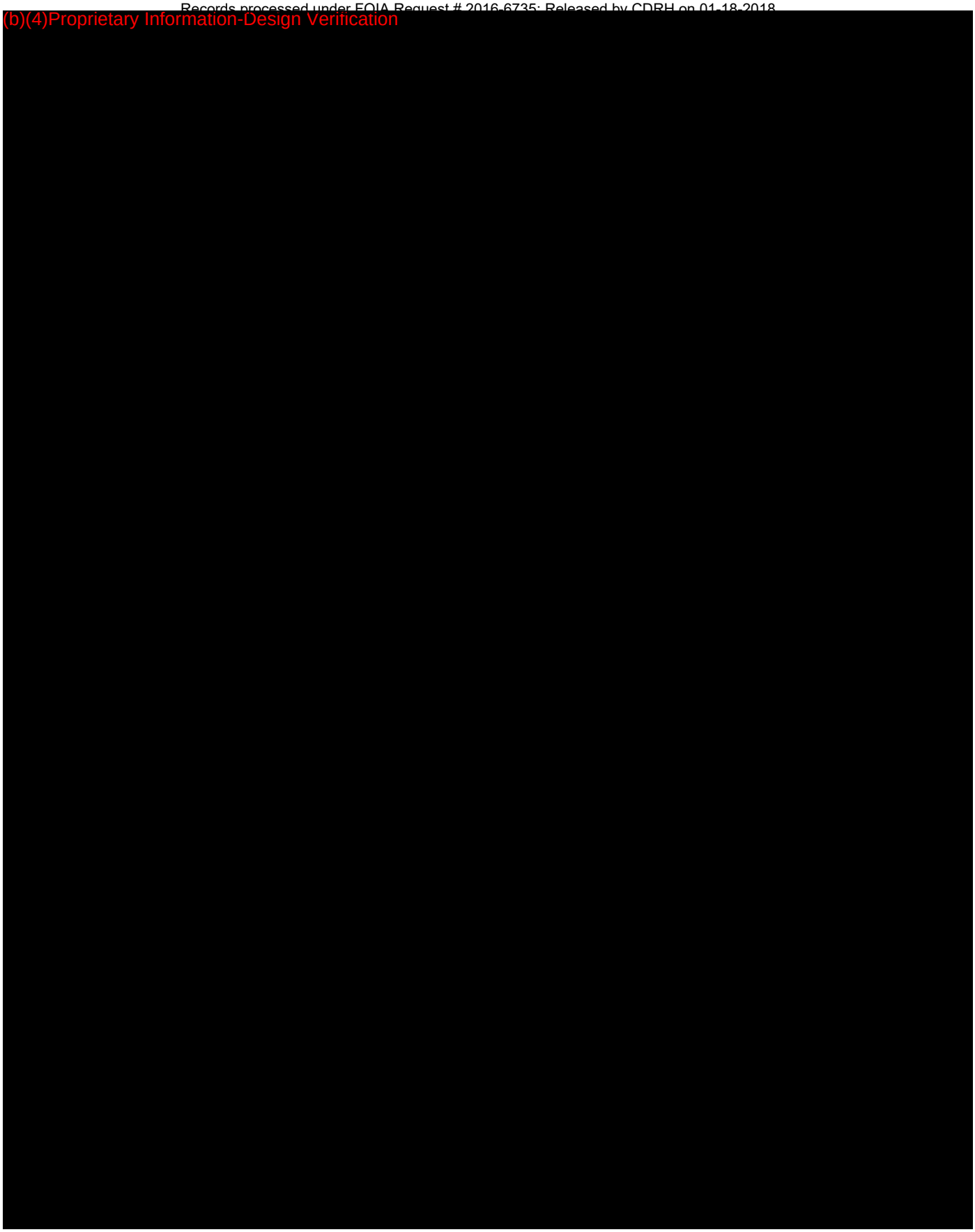
(b)(4)Proprietary Information-Design Verification



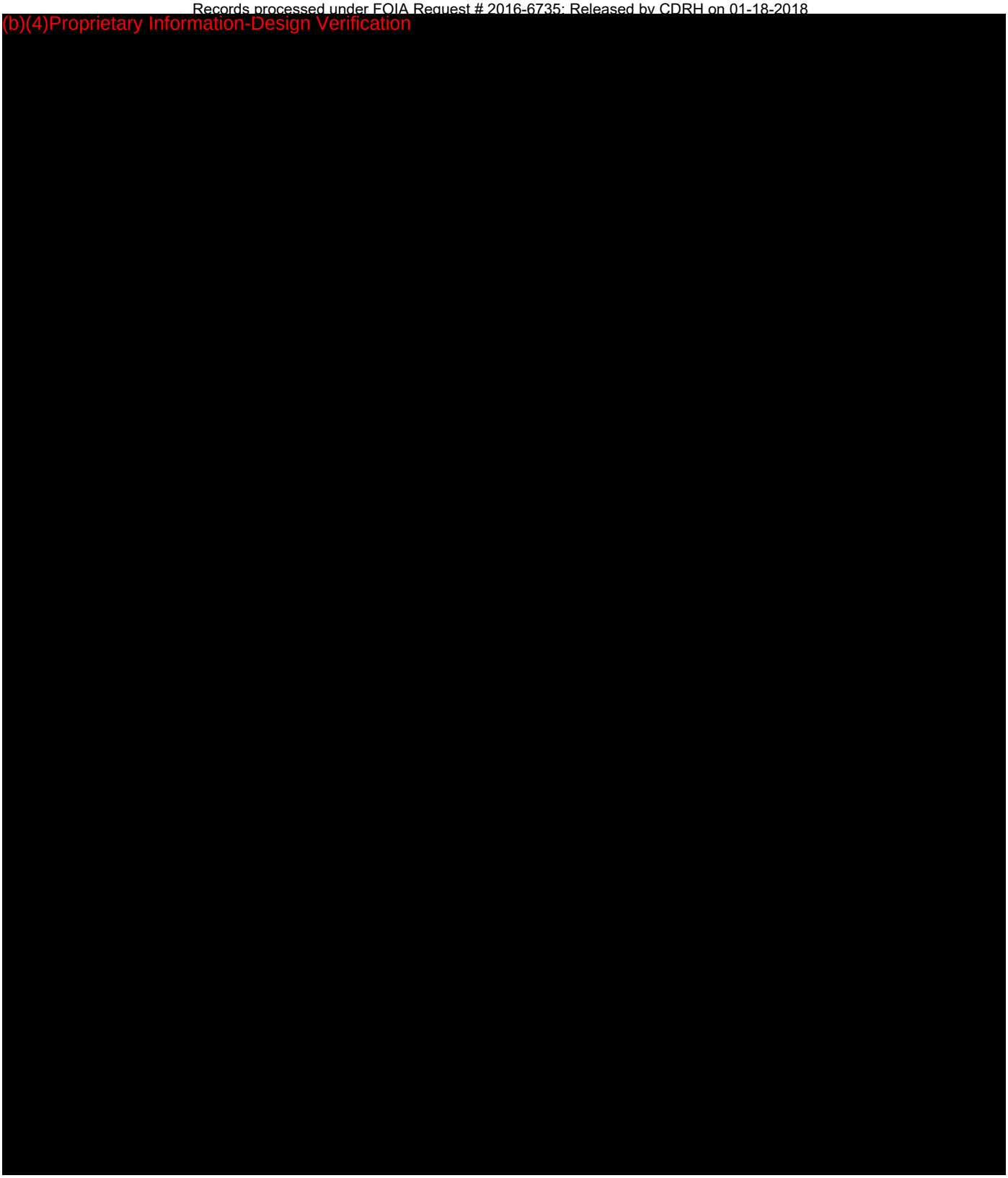
(b)(4)Proprietary Information-Design Verification



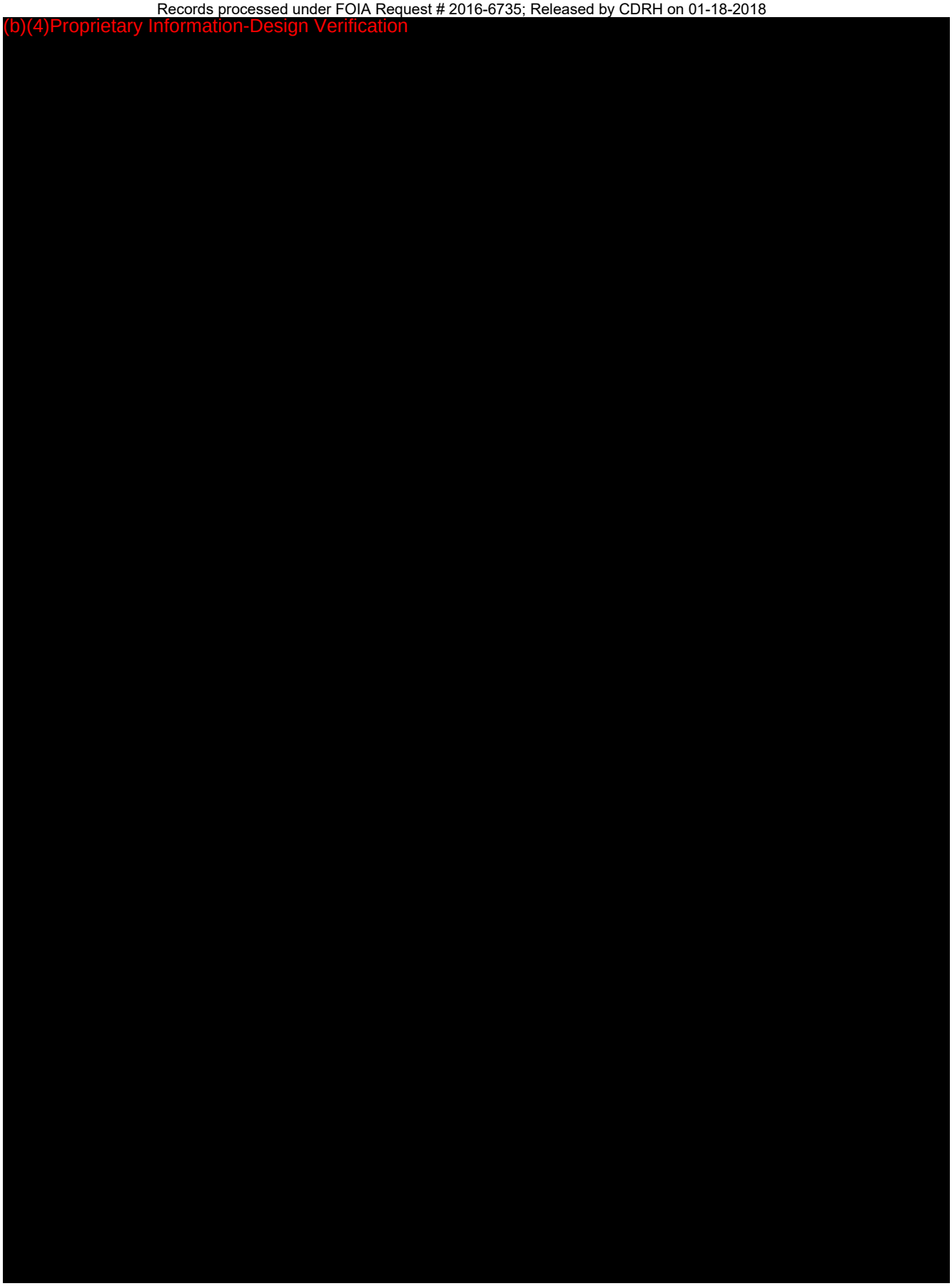
(b)(4)Proprietary Information-Design Verification



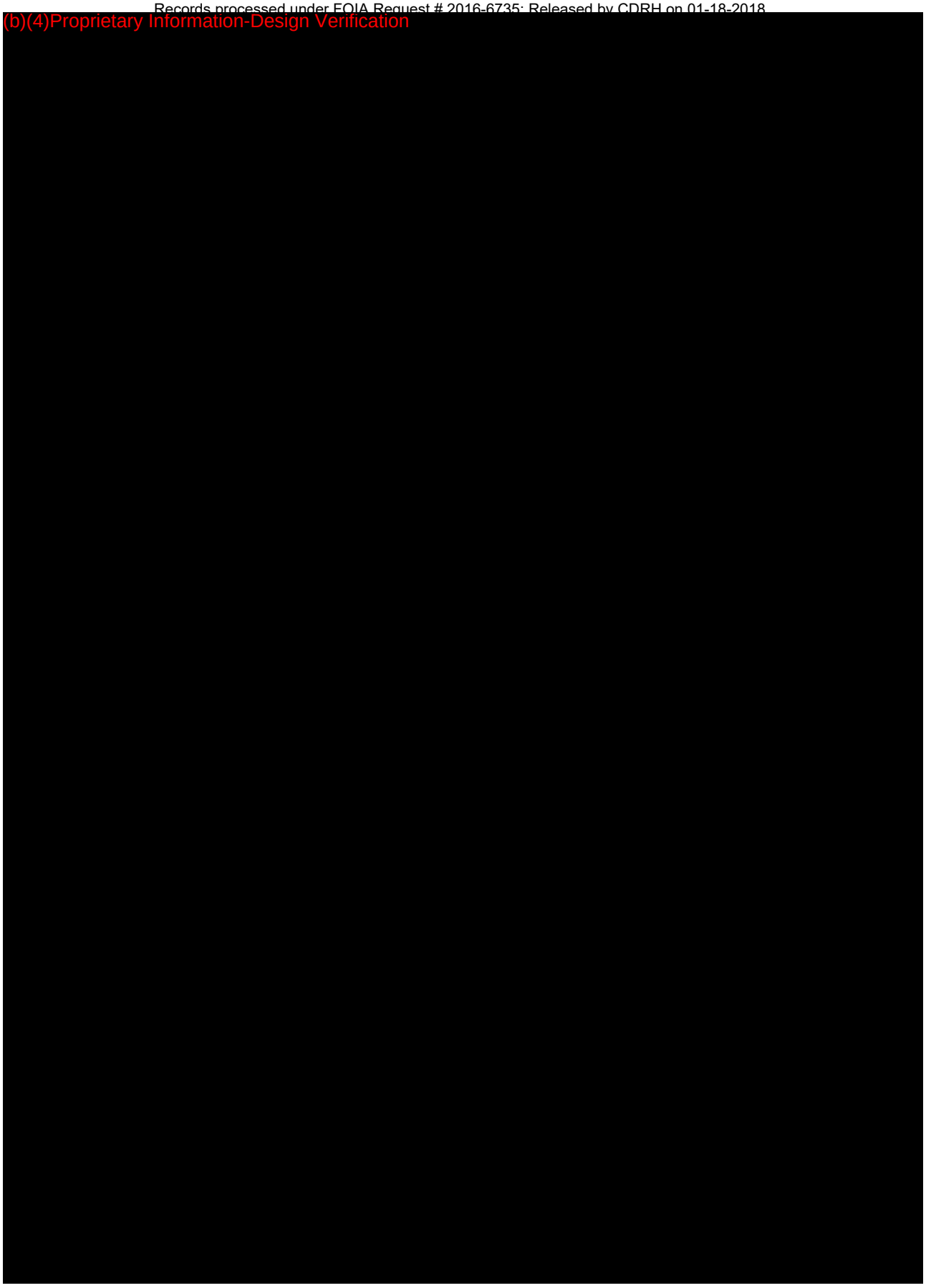
(b)(4)Proprietary Information-Design Verification



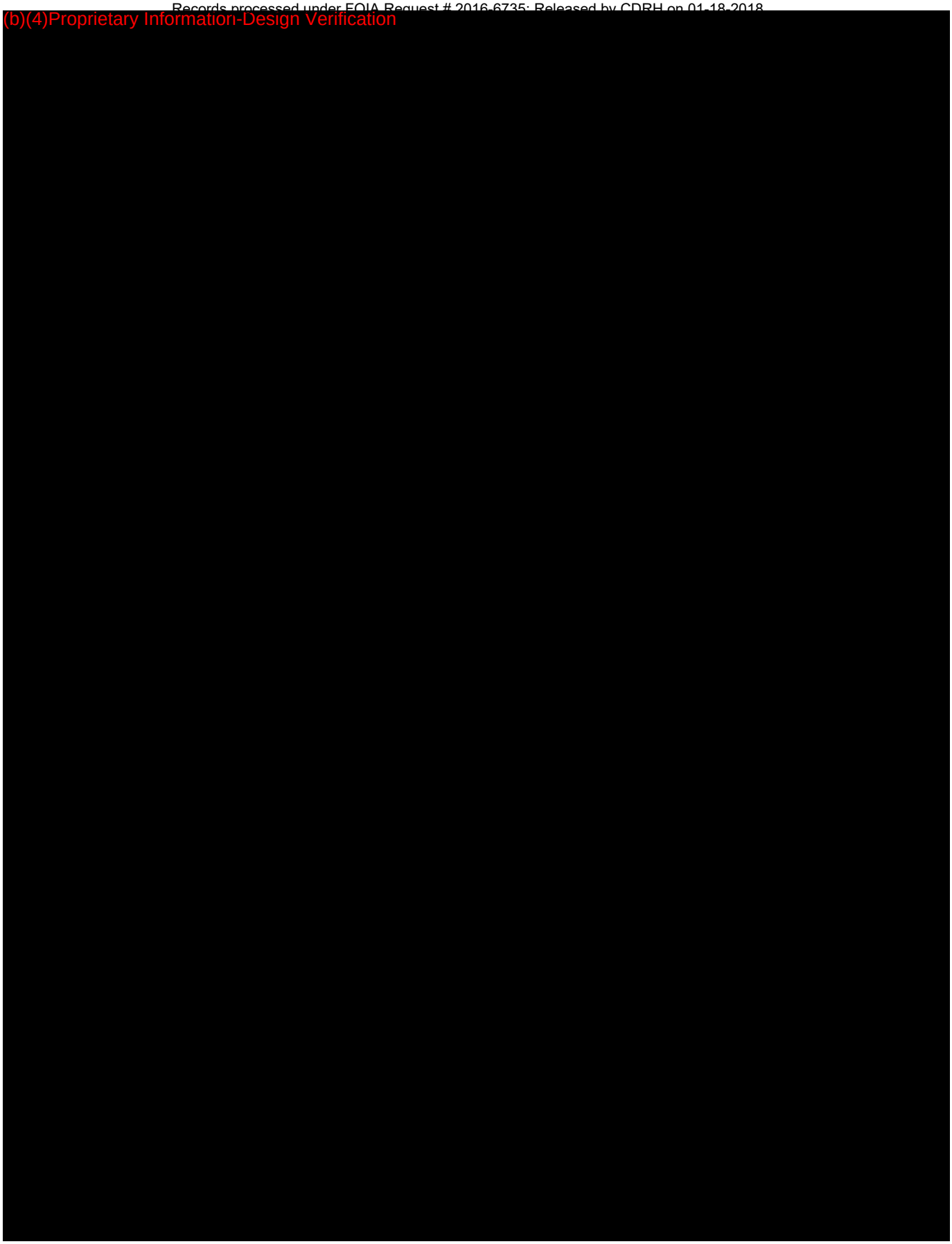
(b)(4)Proprietary Information-Design Verification



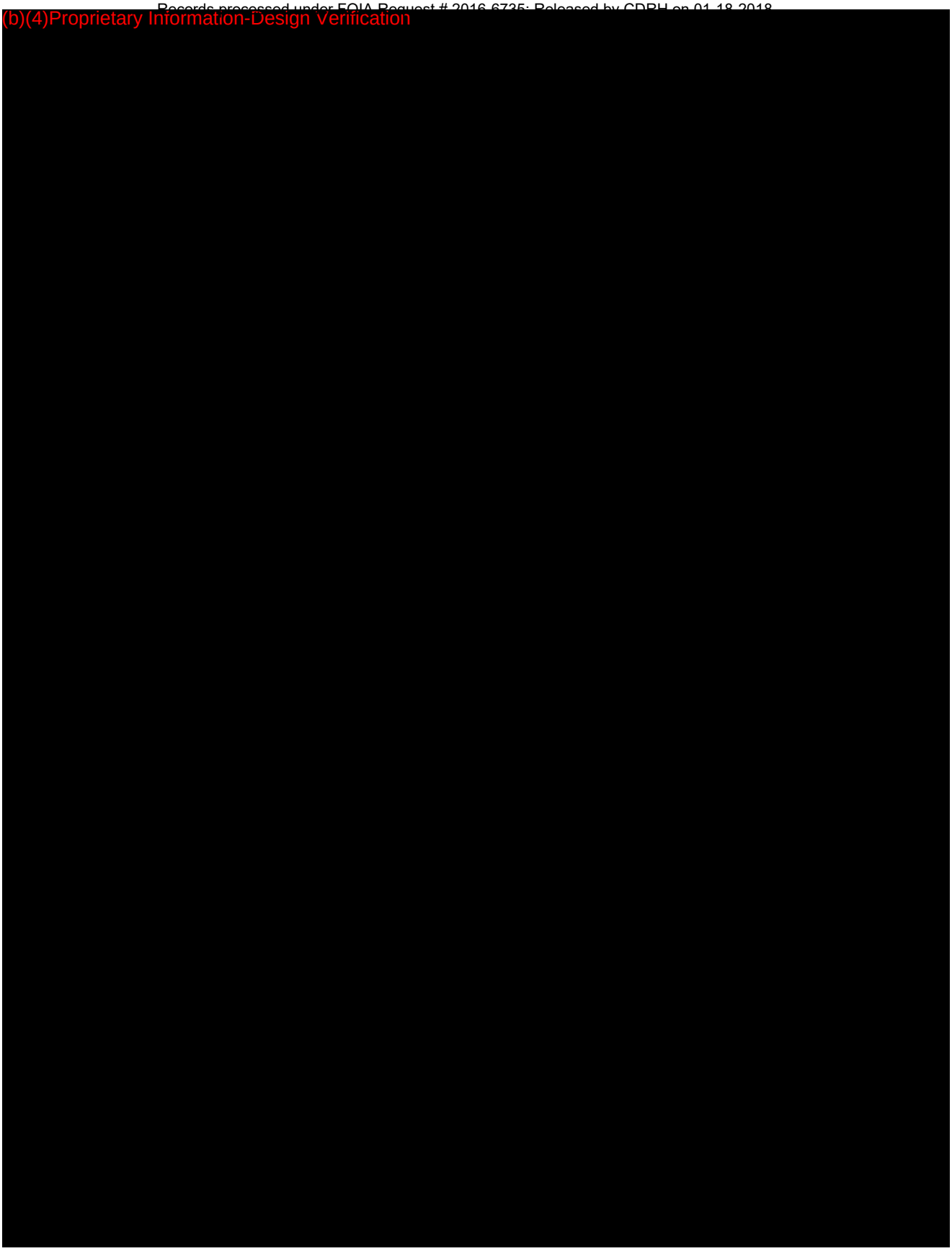
(b)(4)Proprietary Information-Design Verification



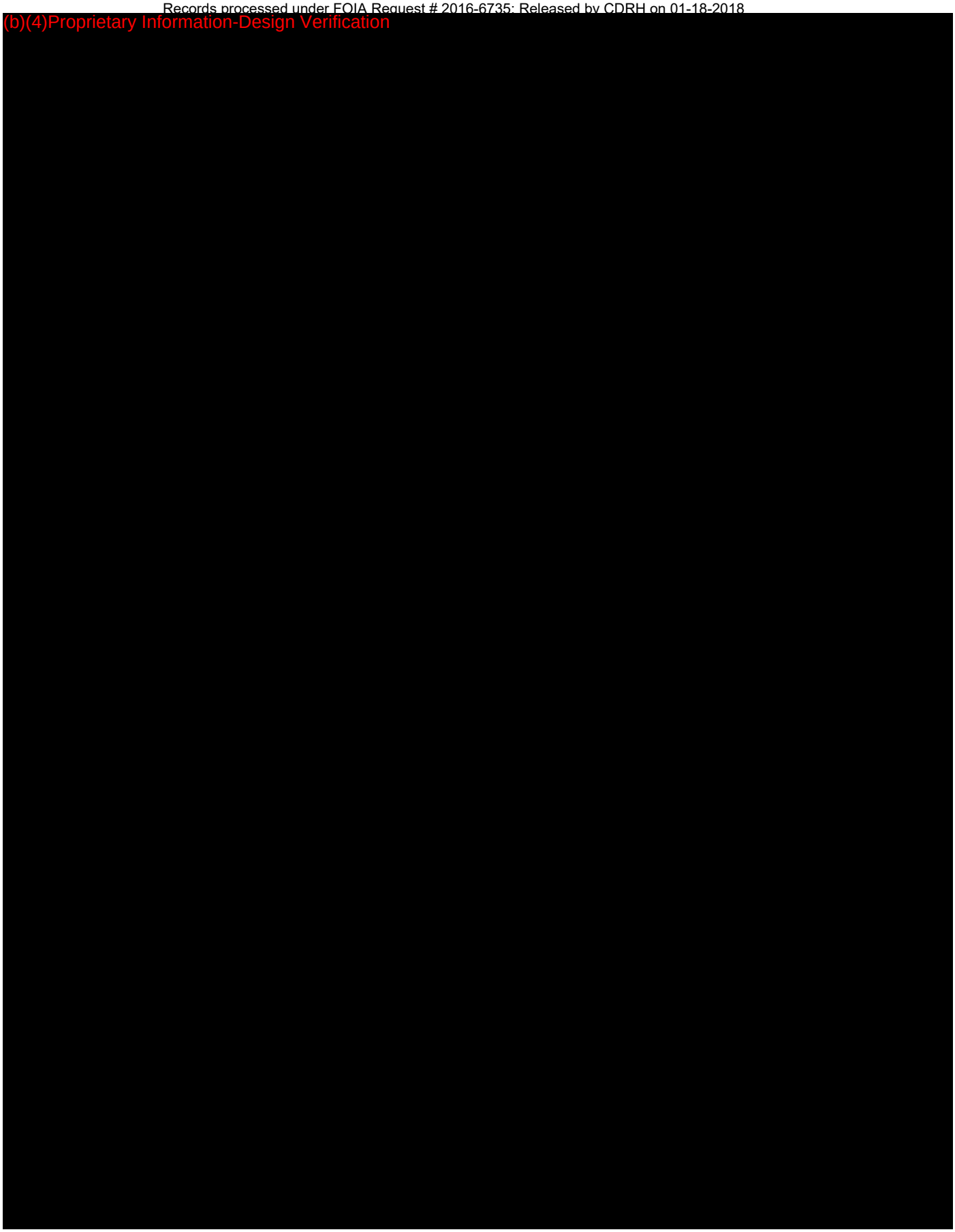
(b)(4)Proprietary Information-Design Verification



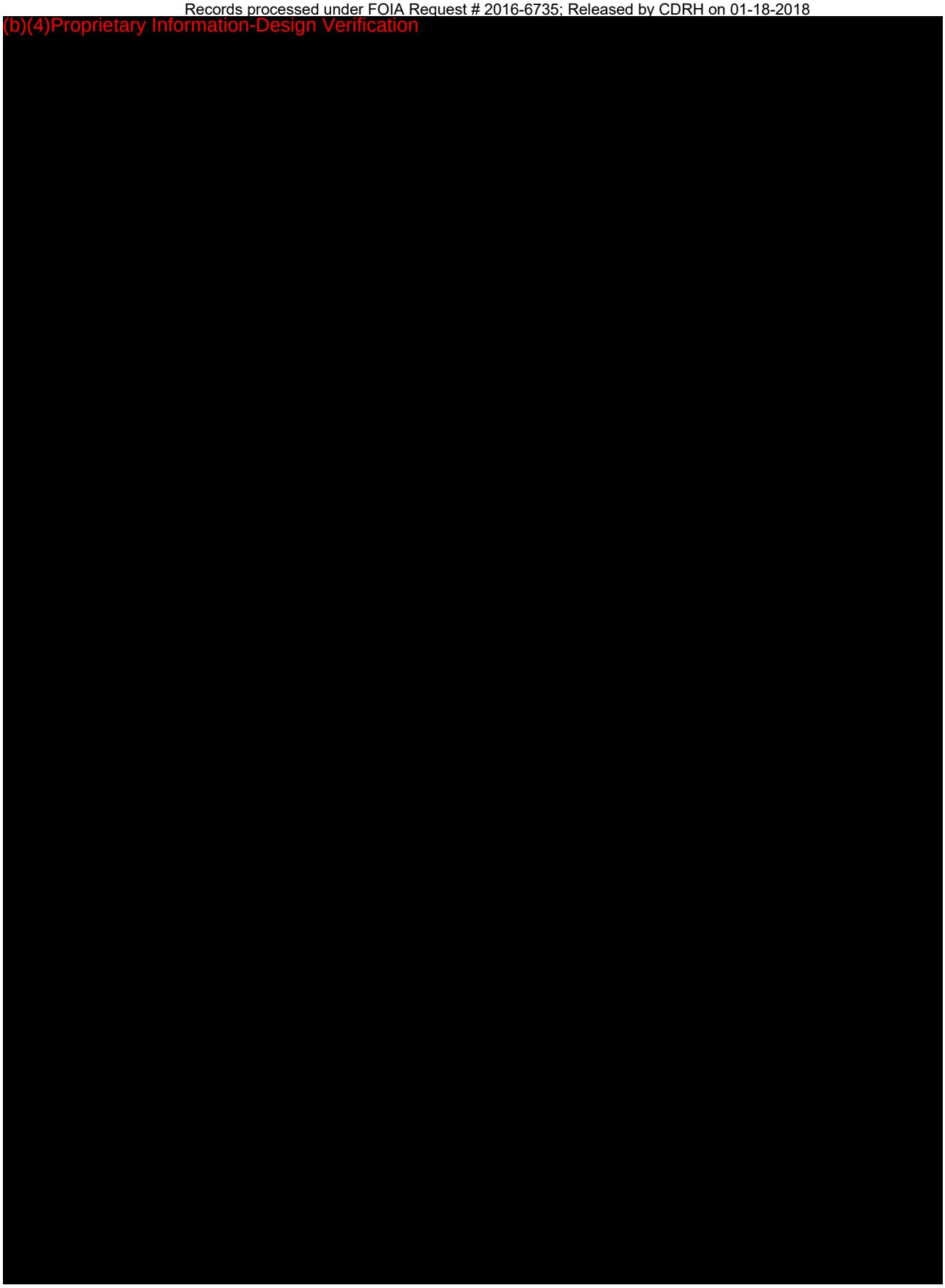
(b)(4)Proprietary Information-Design Verification



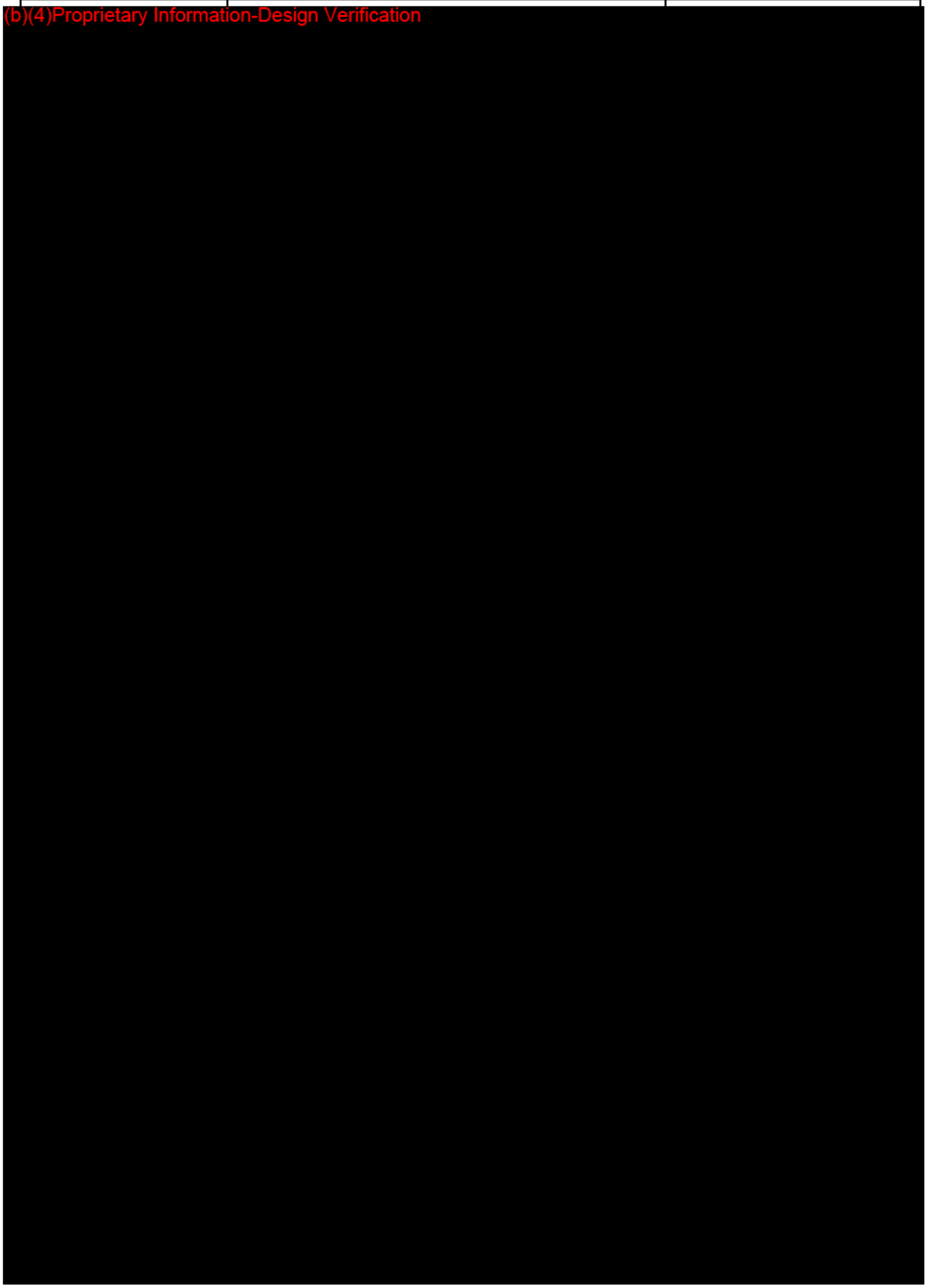
(b)(4)Proprietary Information-Design Verification



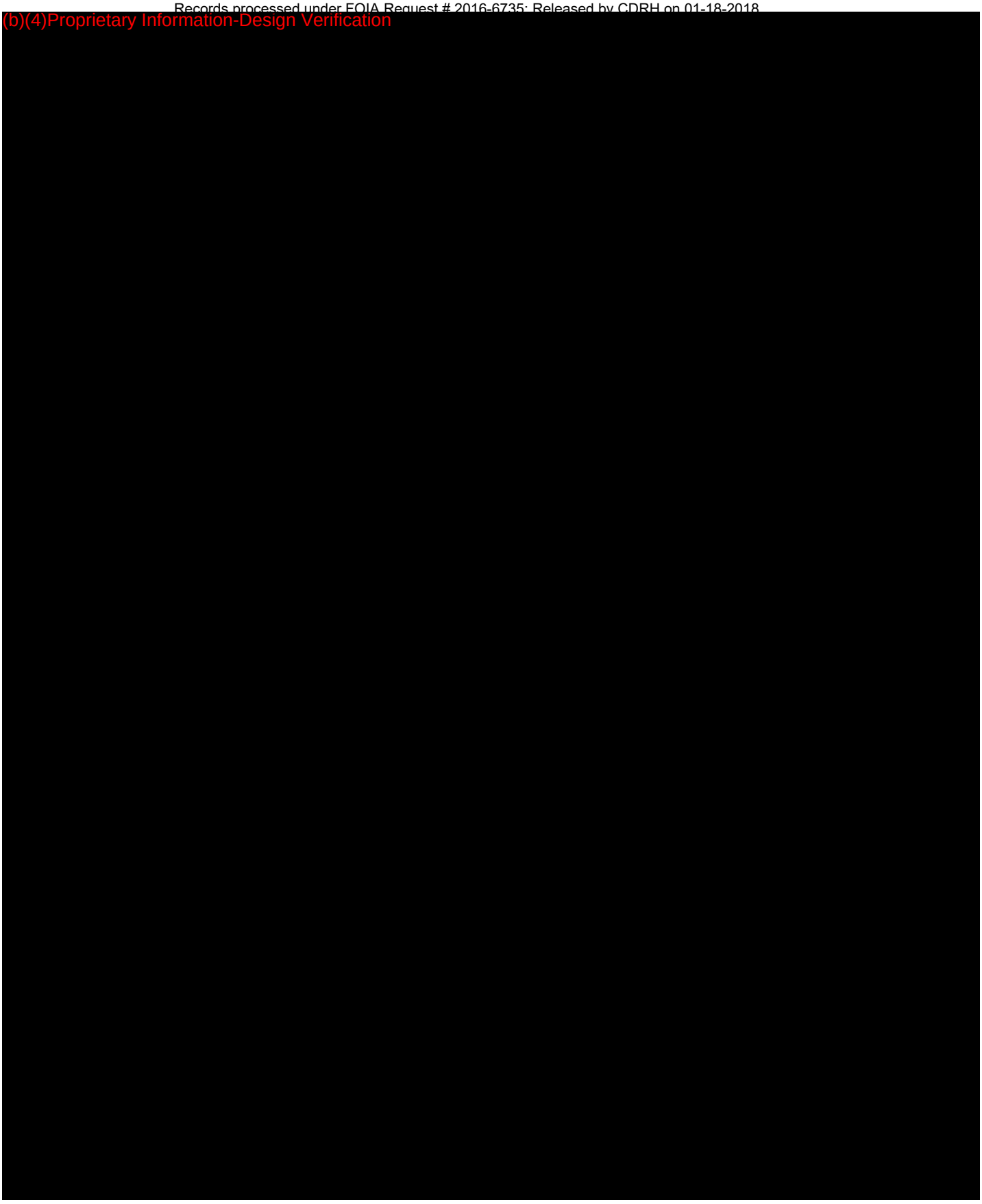
(b)(4)Proprietary Information-Design Verification



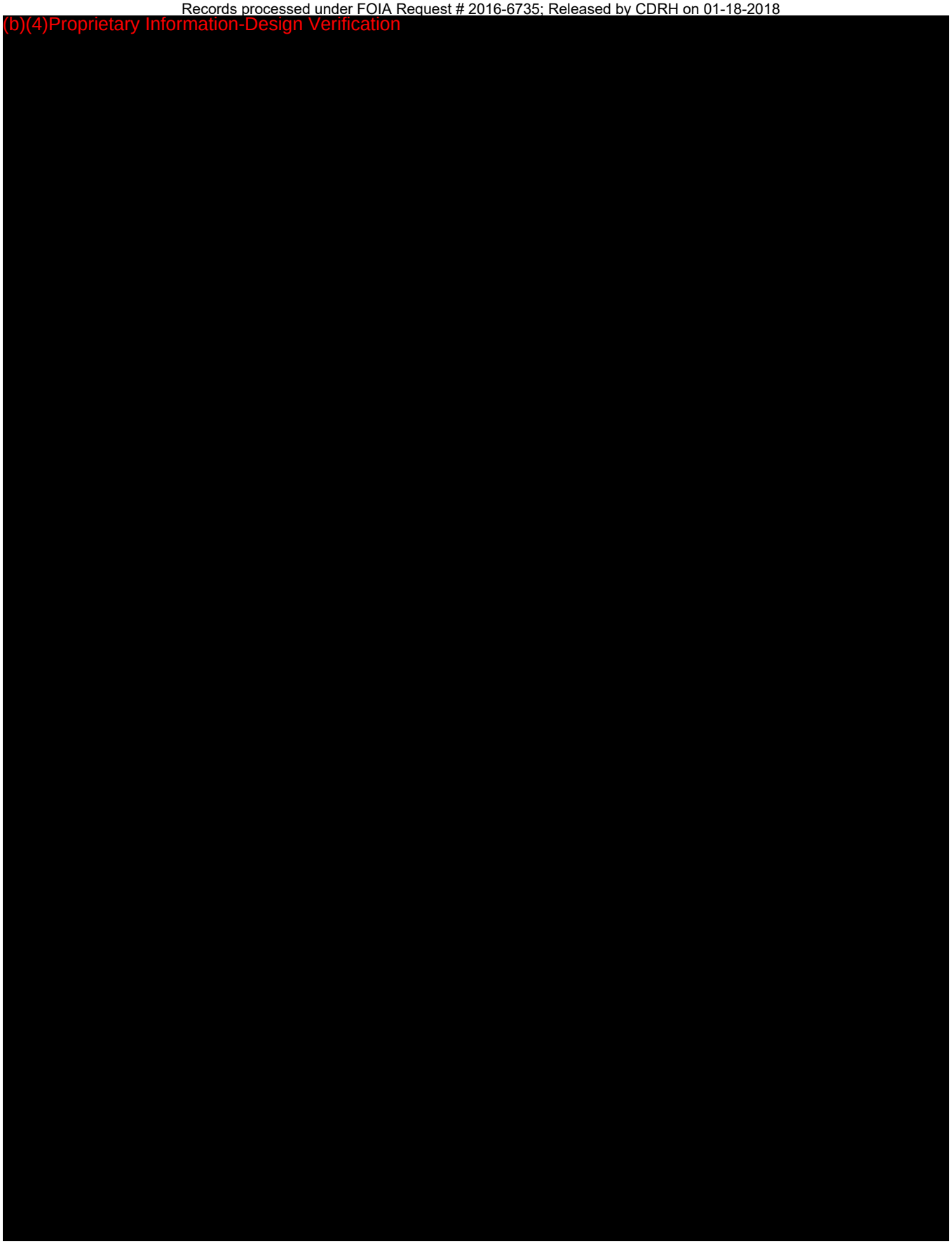
(b)(4)Proprietary Information-Design Verification



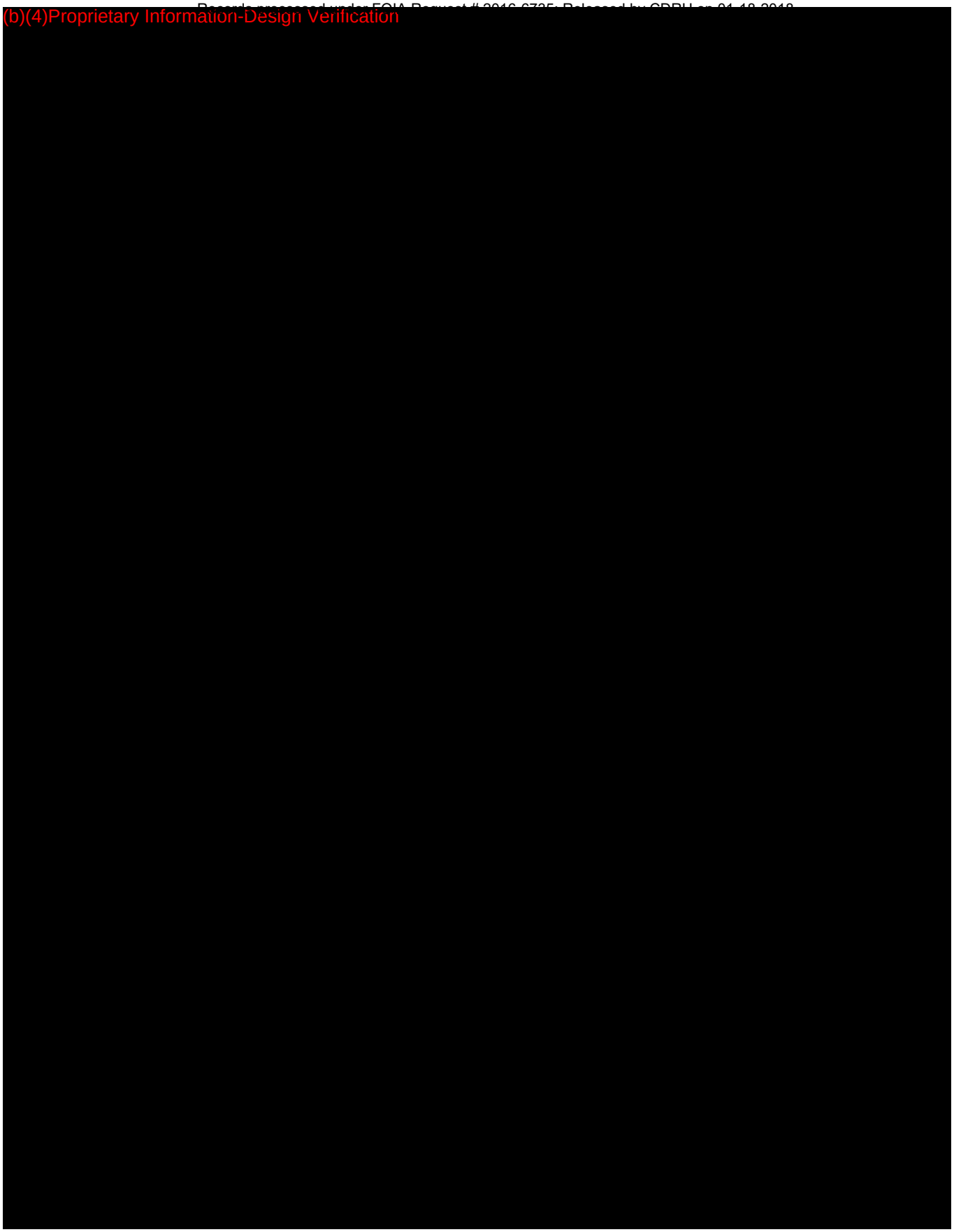
(b)(4)Proprietary Information-Design Verification



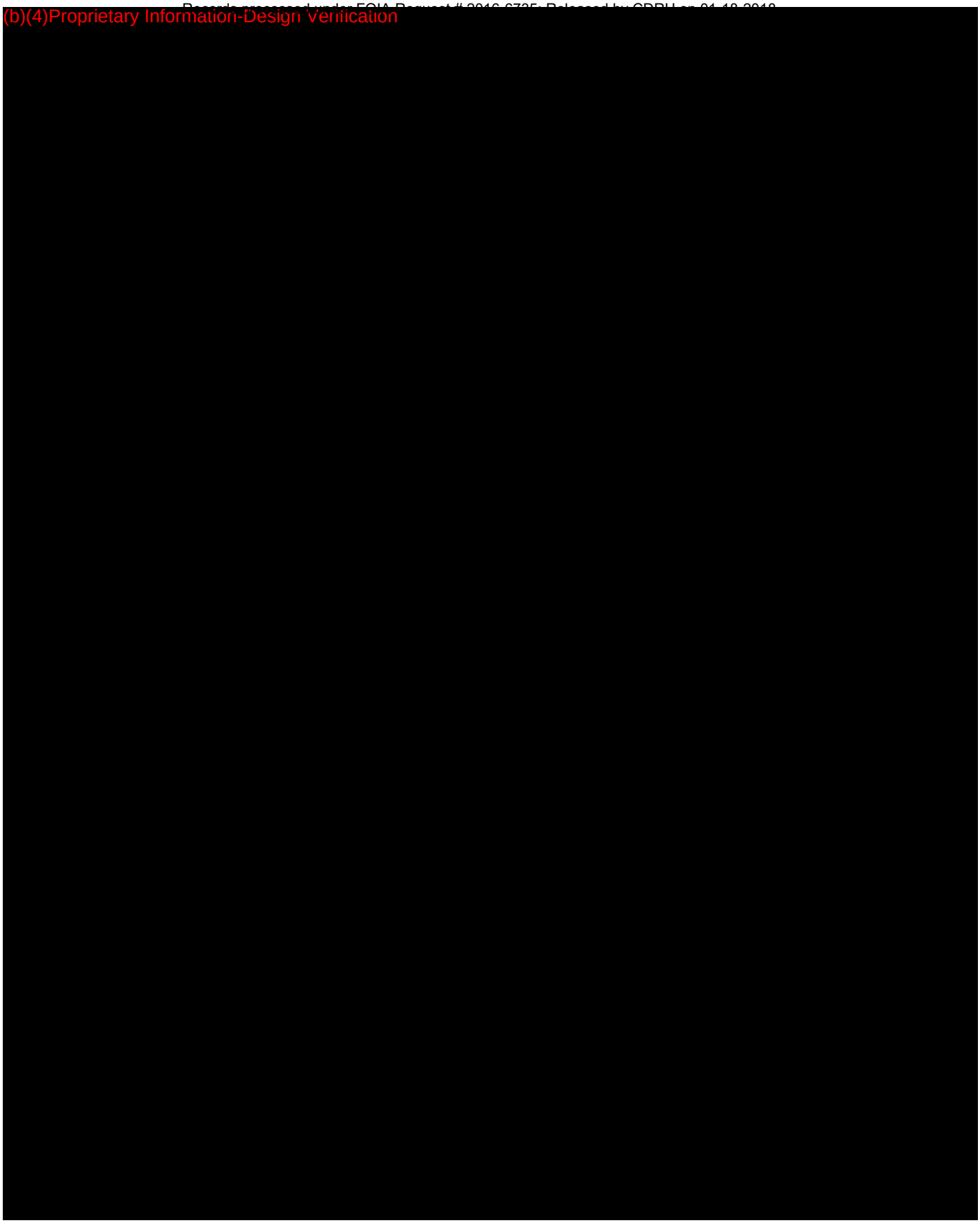
(b)(4)Proprietary Information-Design Verification



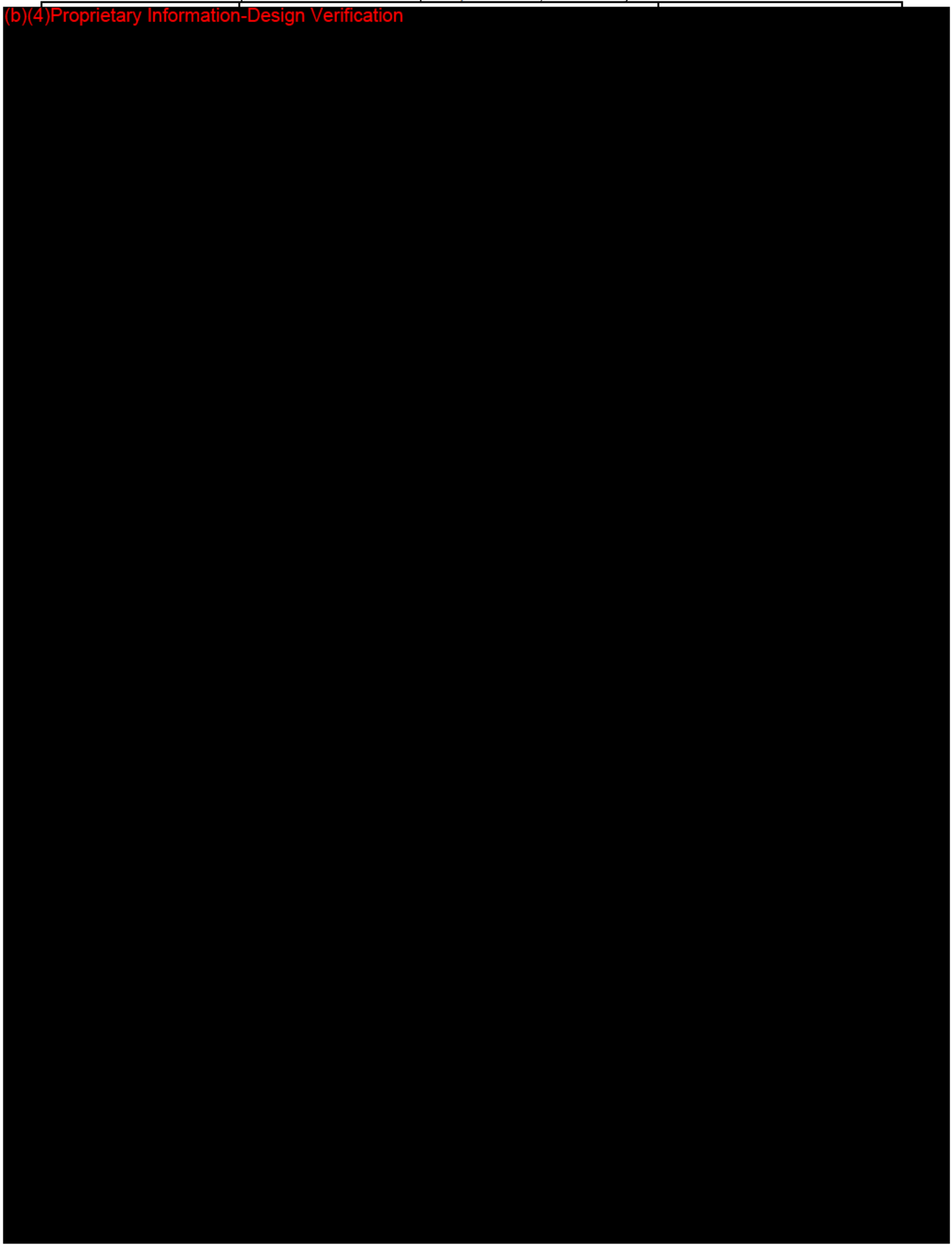
(b)(4)Proprietary Information-Design Verification



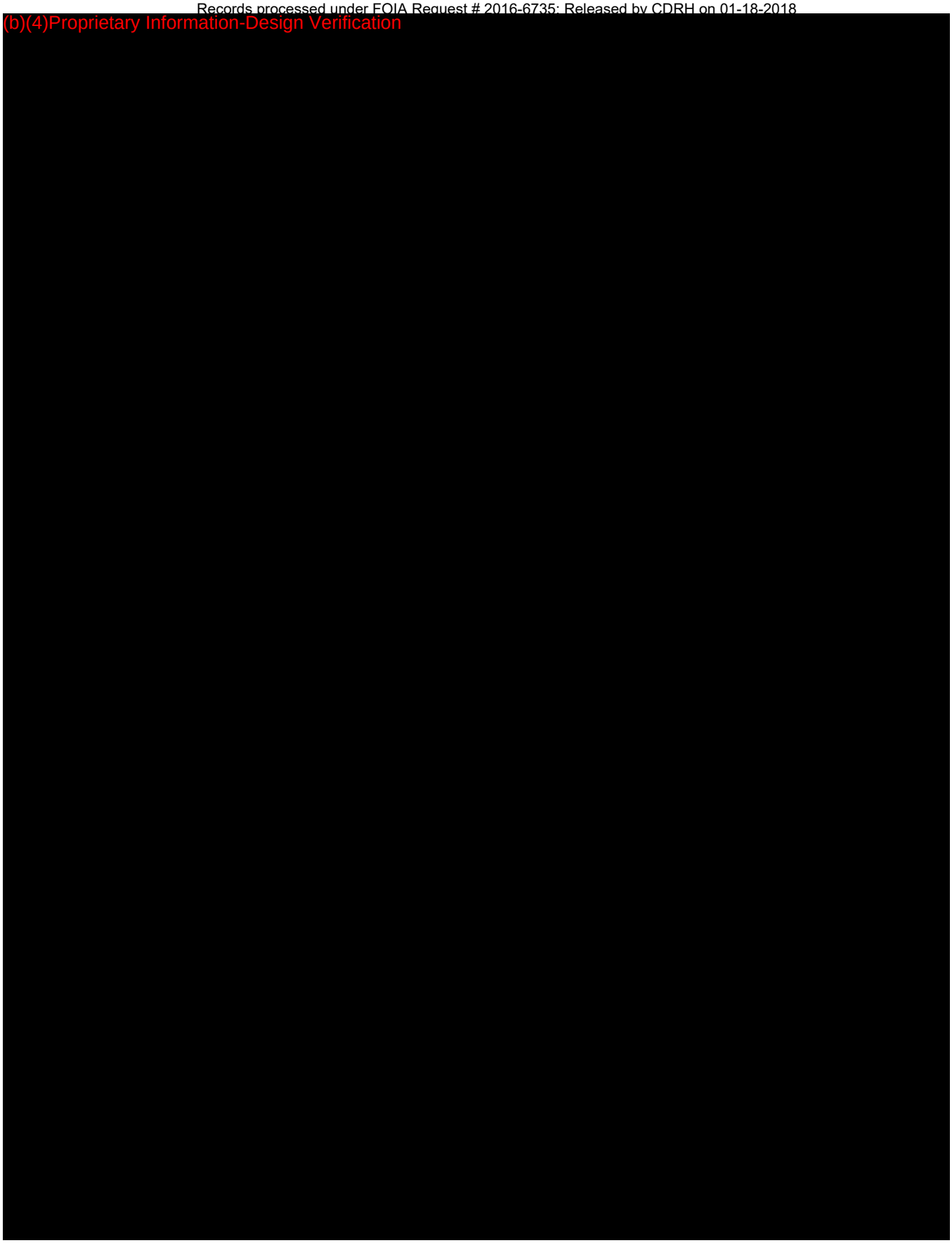
(b)(4)Proprietary Information-Design Verification



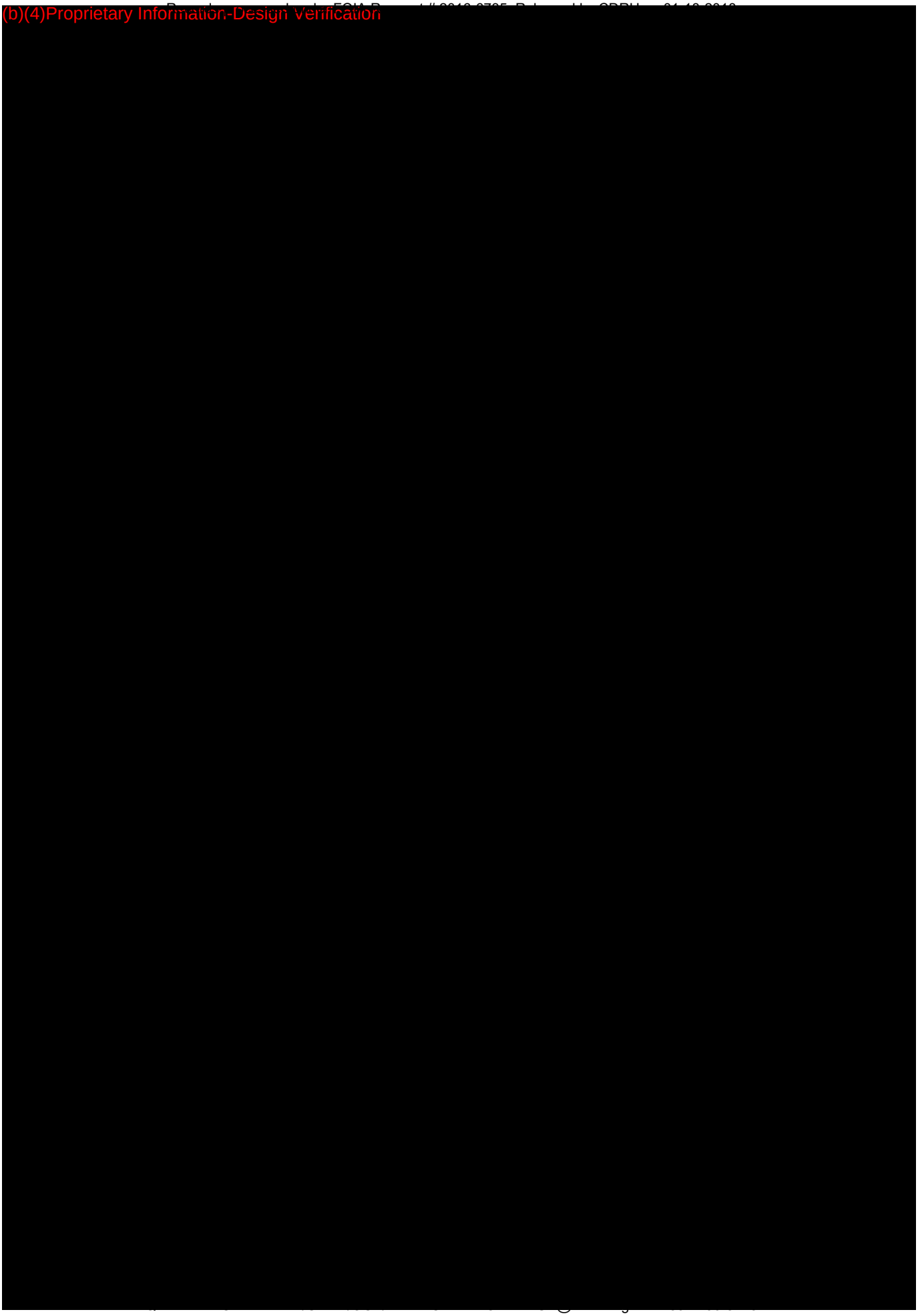
(b)(4)Proprietary Information-Design Verification



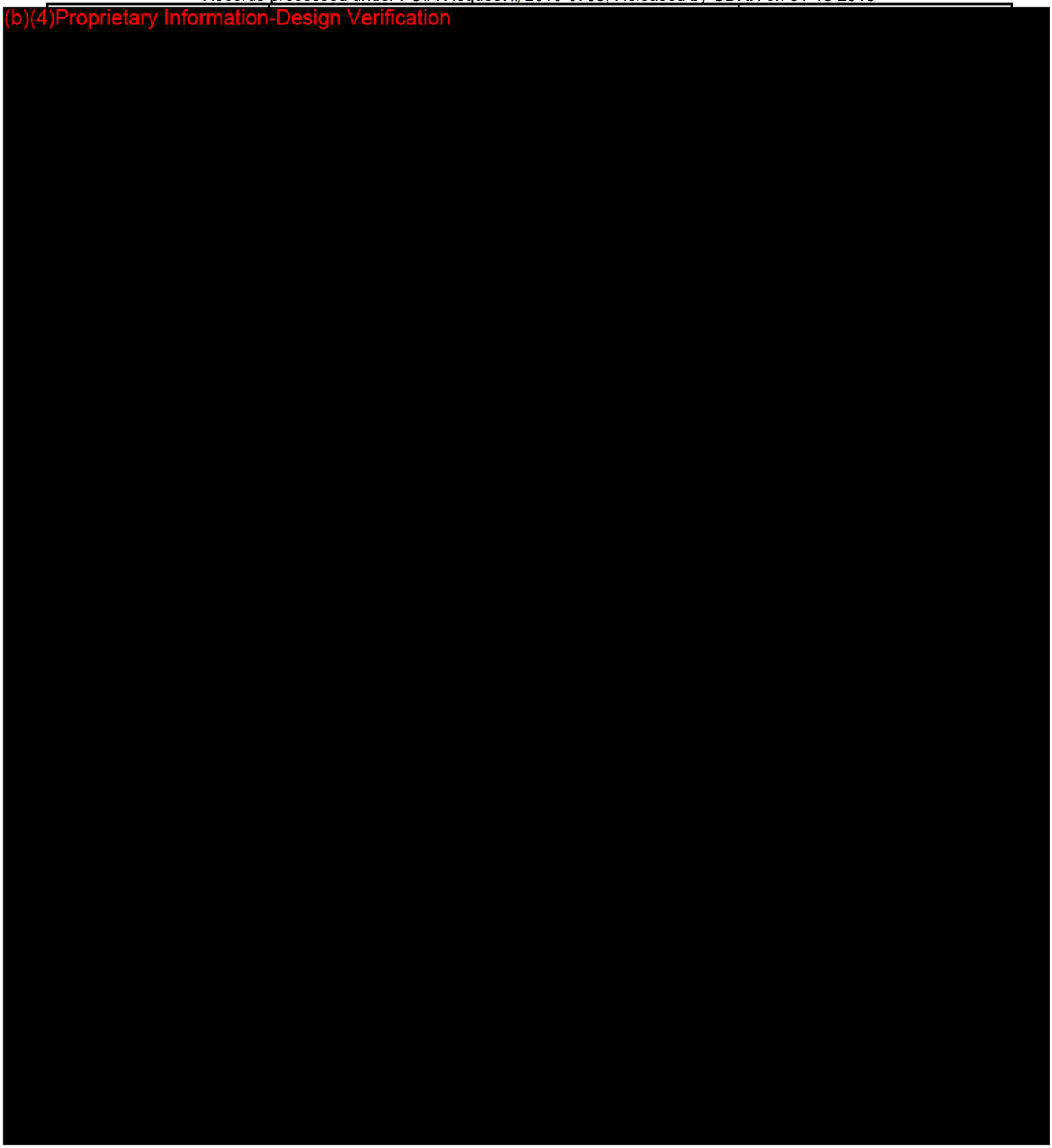
(b)(4)Proprietary Information-Design Verification

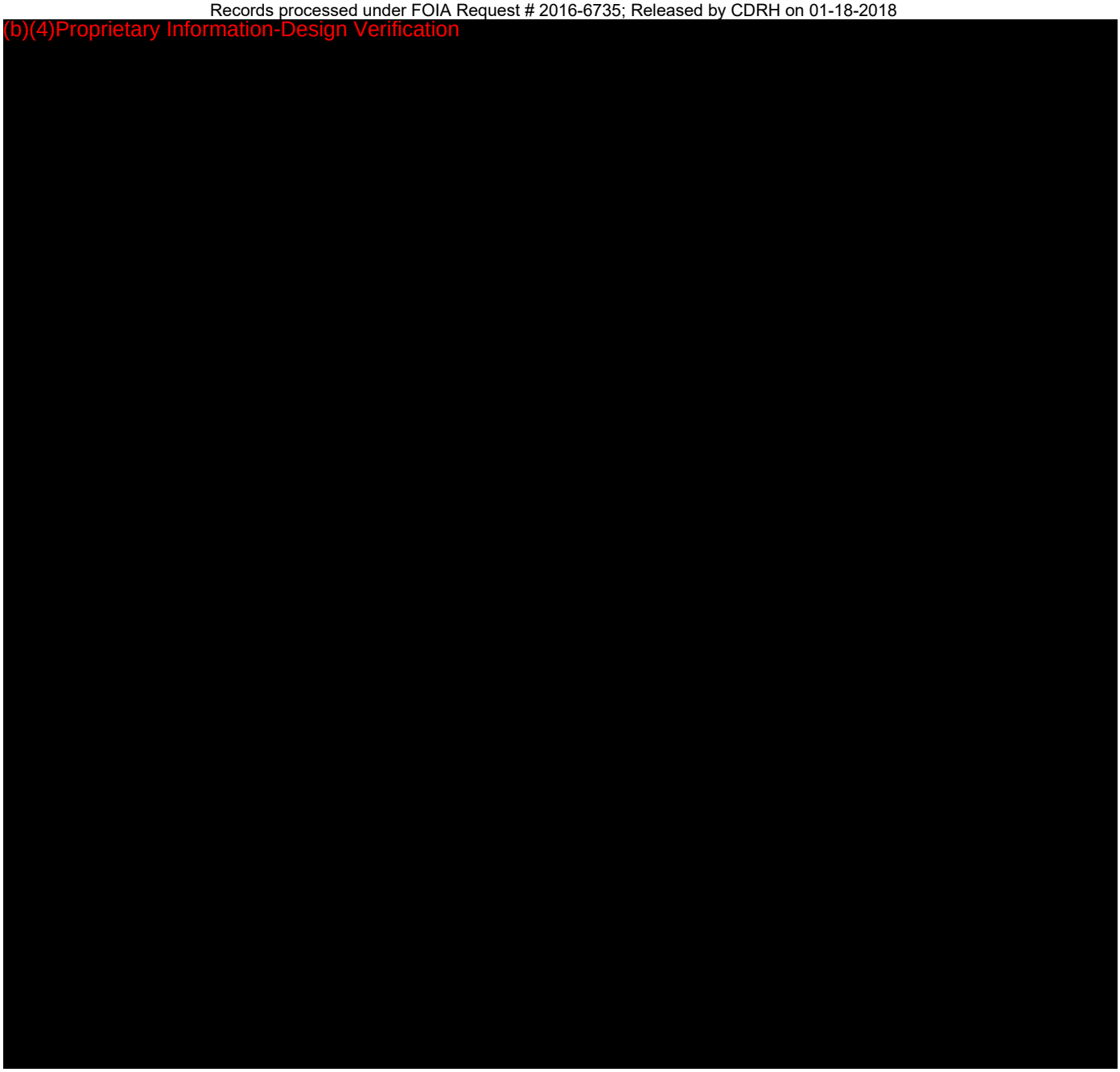


(b)(4)Proprietary Information-Design Verification

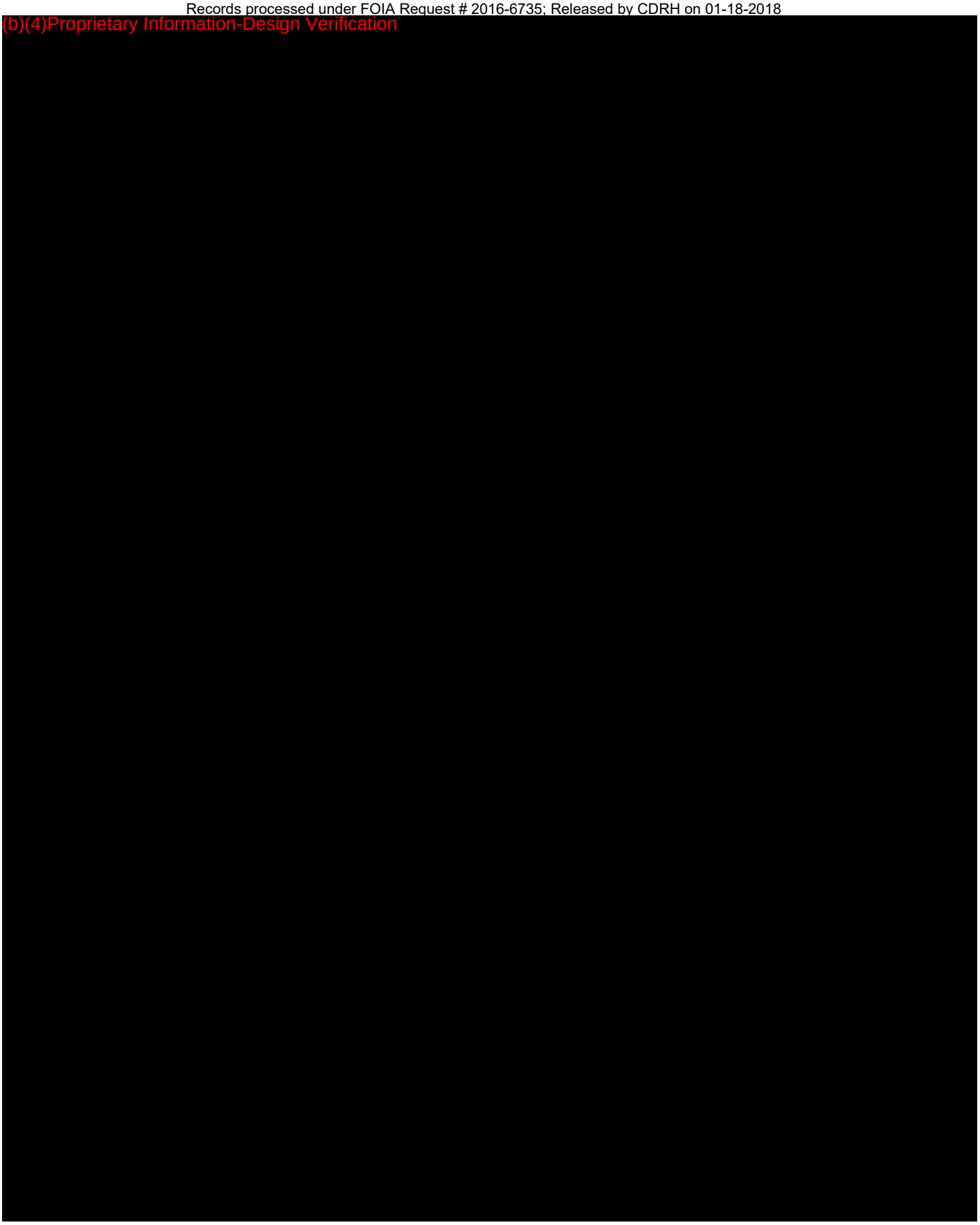


(b)(4)Proprietary Information-Design Verification



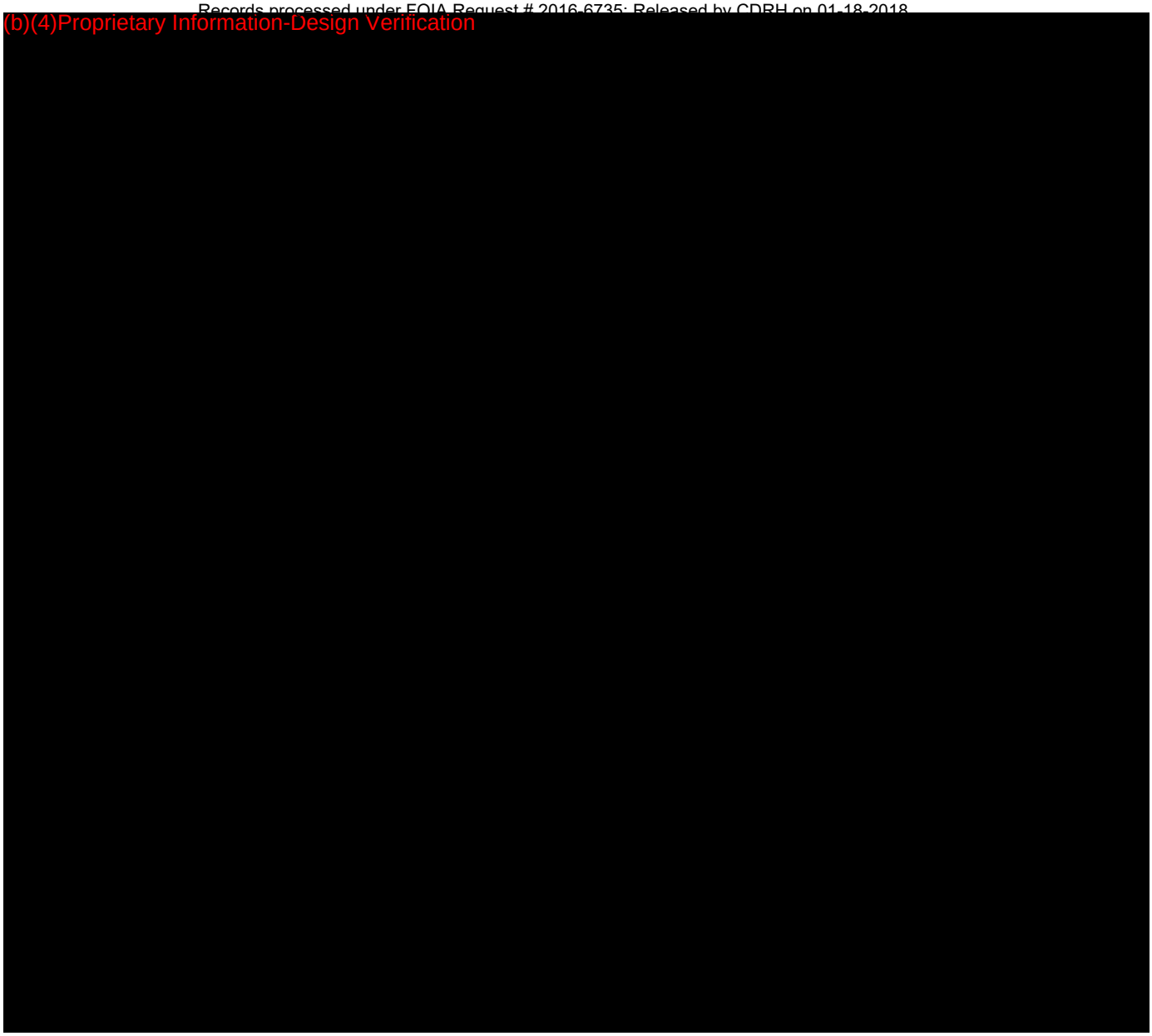


(b)(4)Proprietary Information-Design Verification

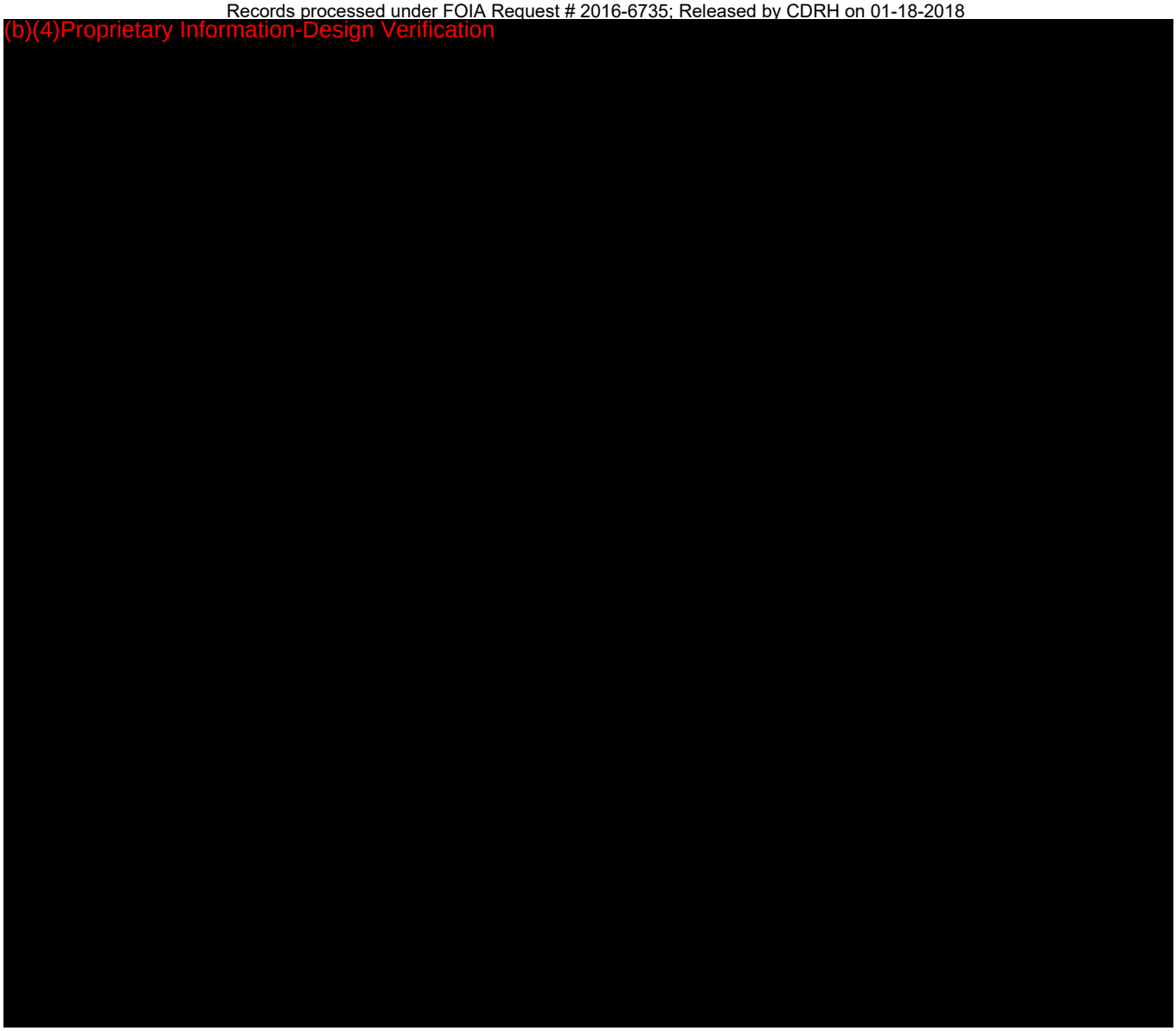


(b)(4)Proprietary Information-Design Verification

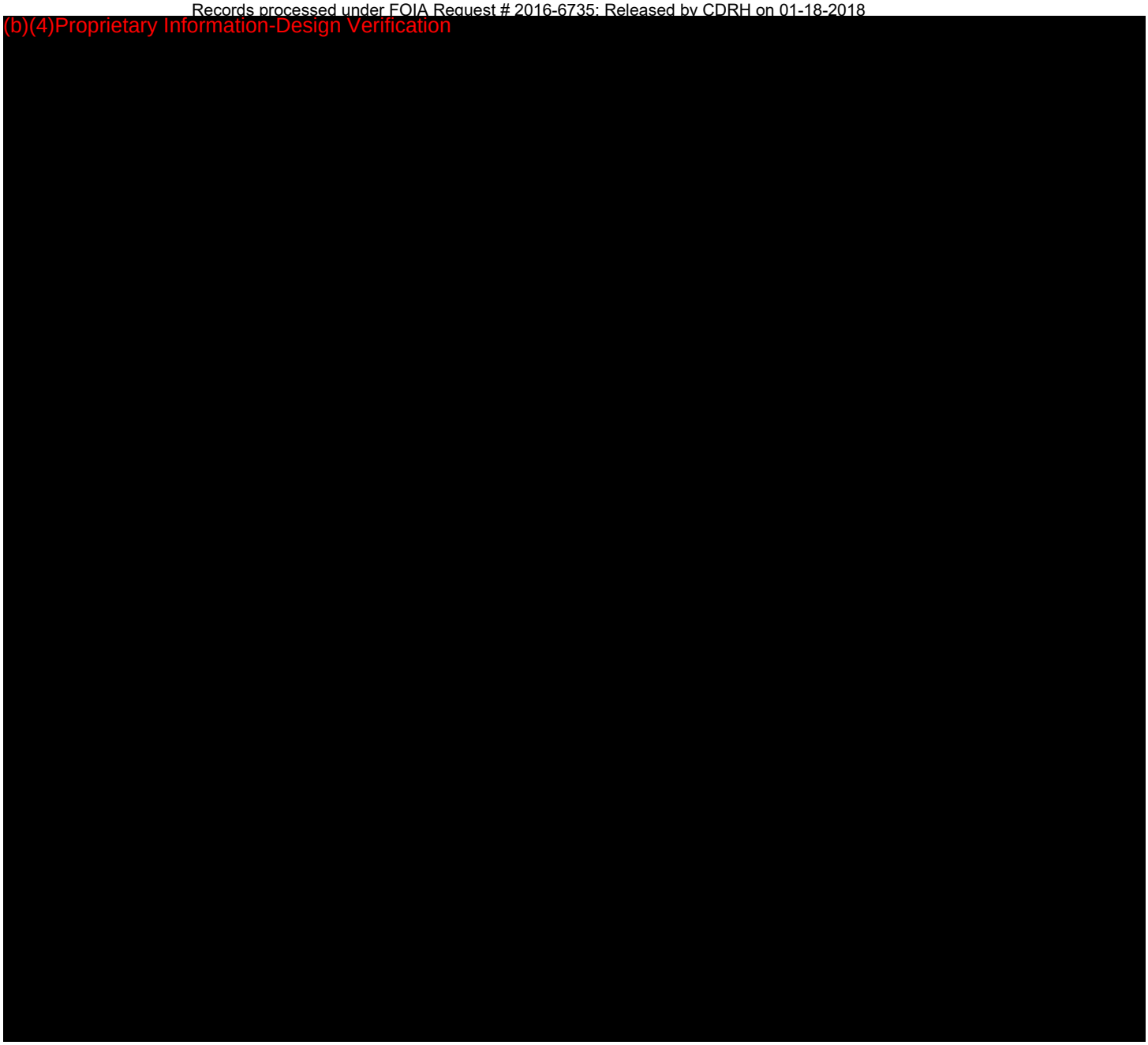
(b)(4)Proprietary Information-Design Verification



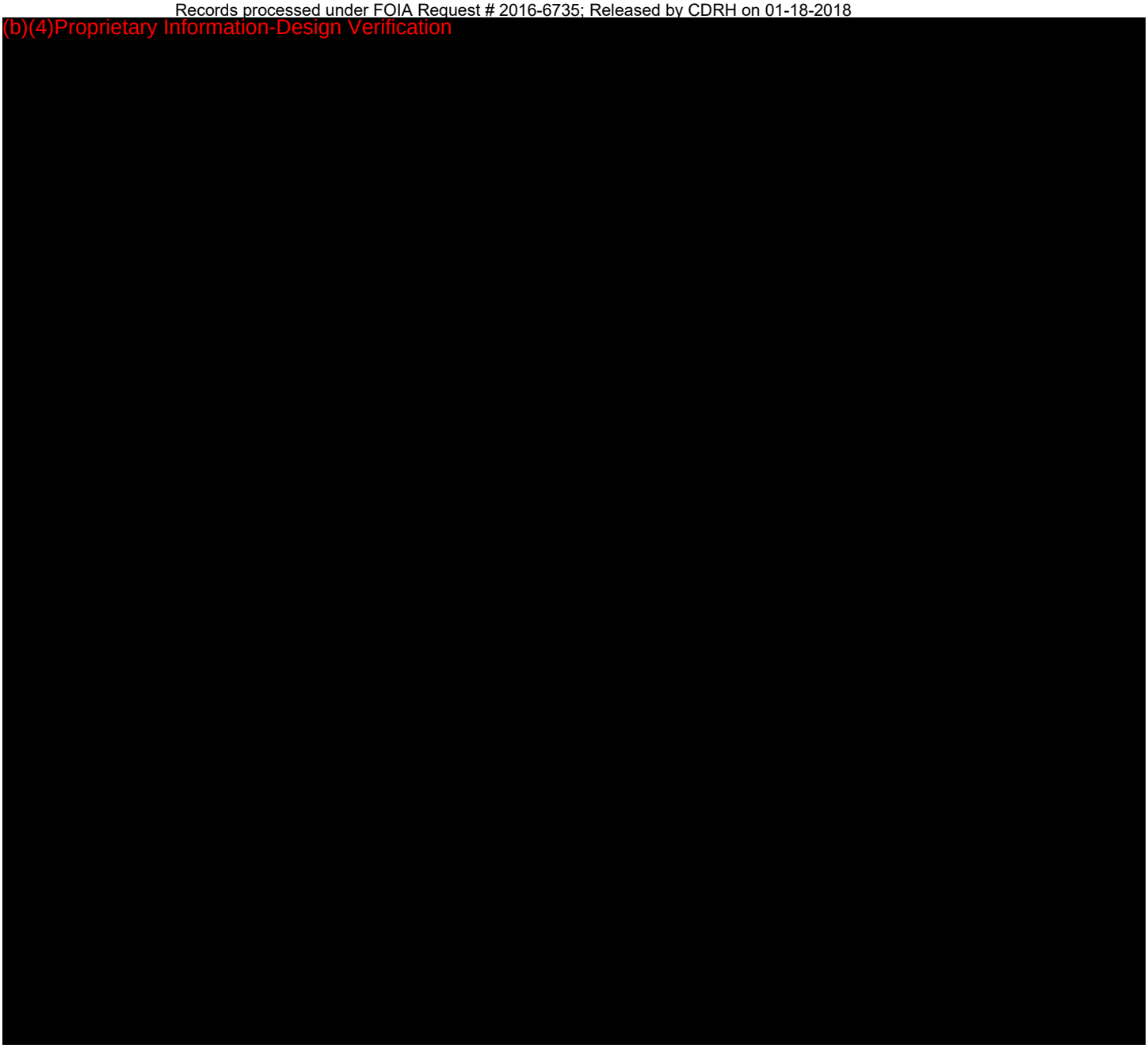
(b)(4)Proprietary Information-Design Verification



(b)(4)Proprietary Information-Design Verification

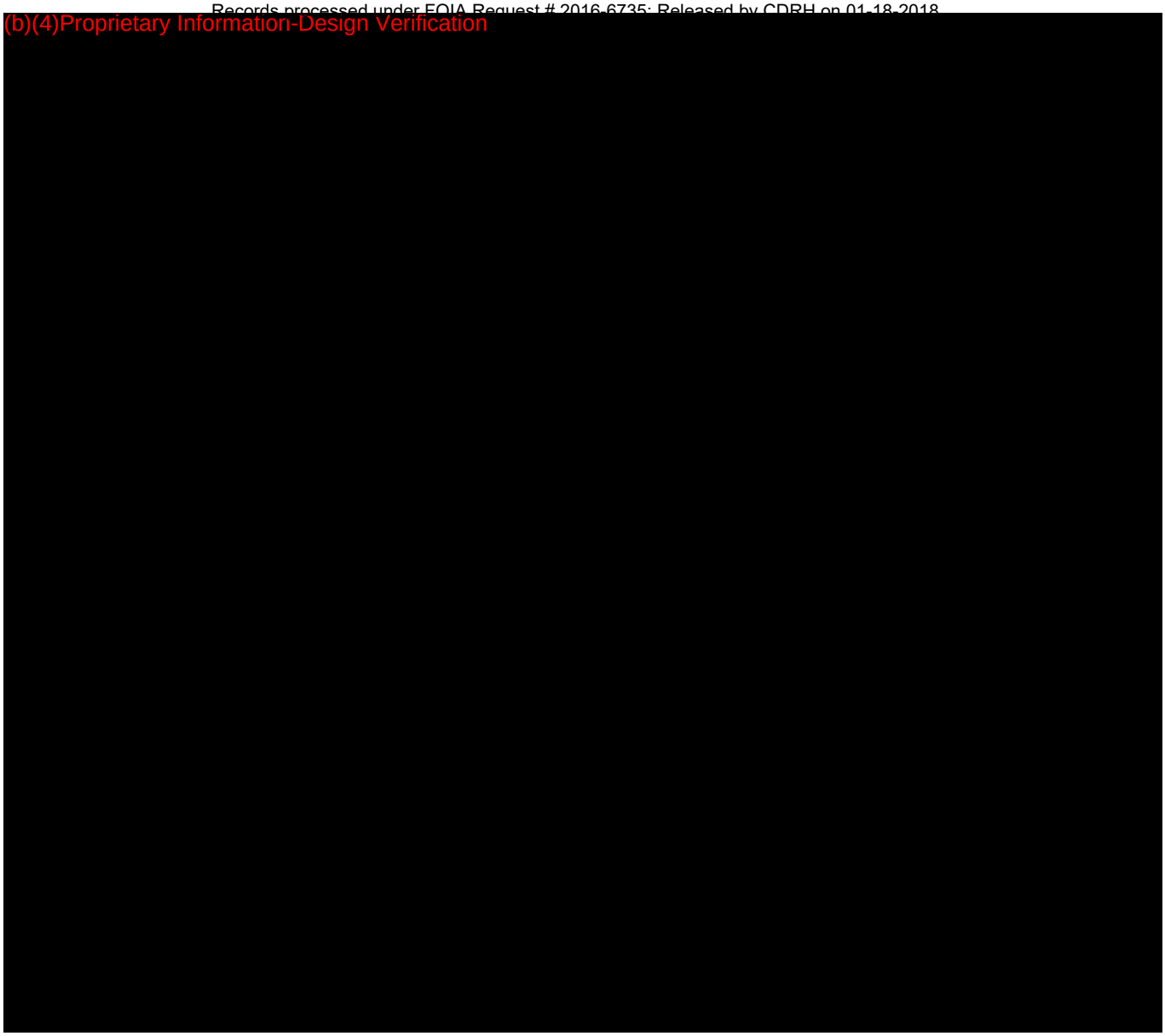


(b)(4)Proprietary Information-Design Verification

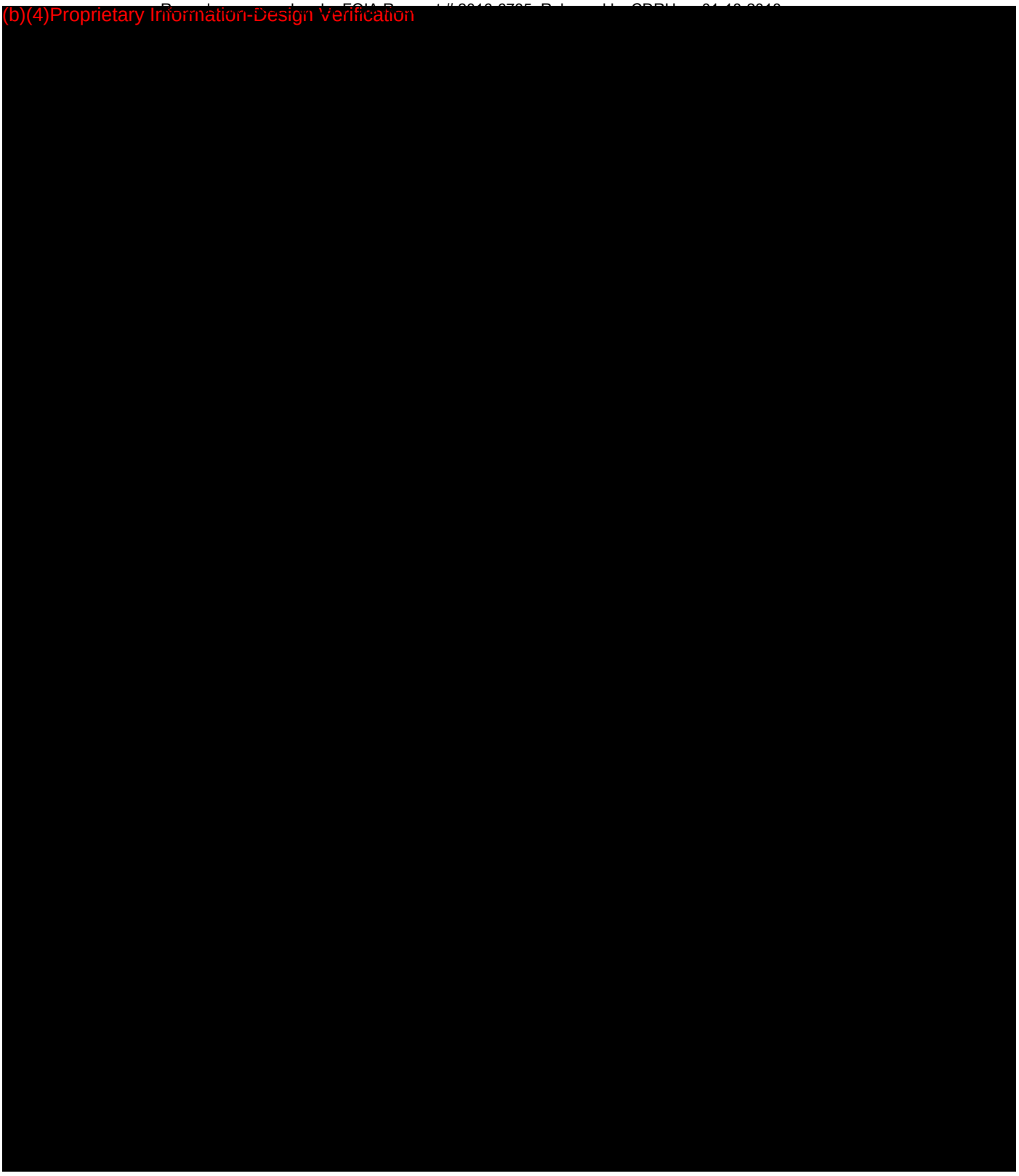


(b)(4)Proprietary Information-Design Verification

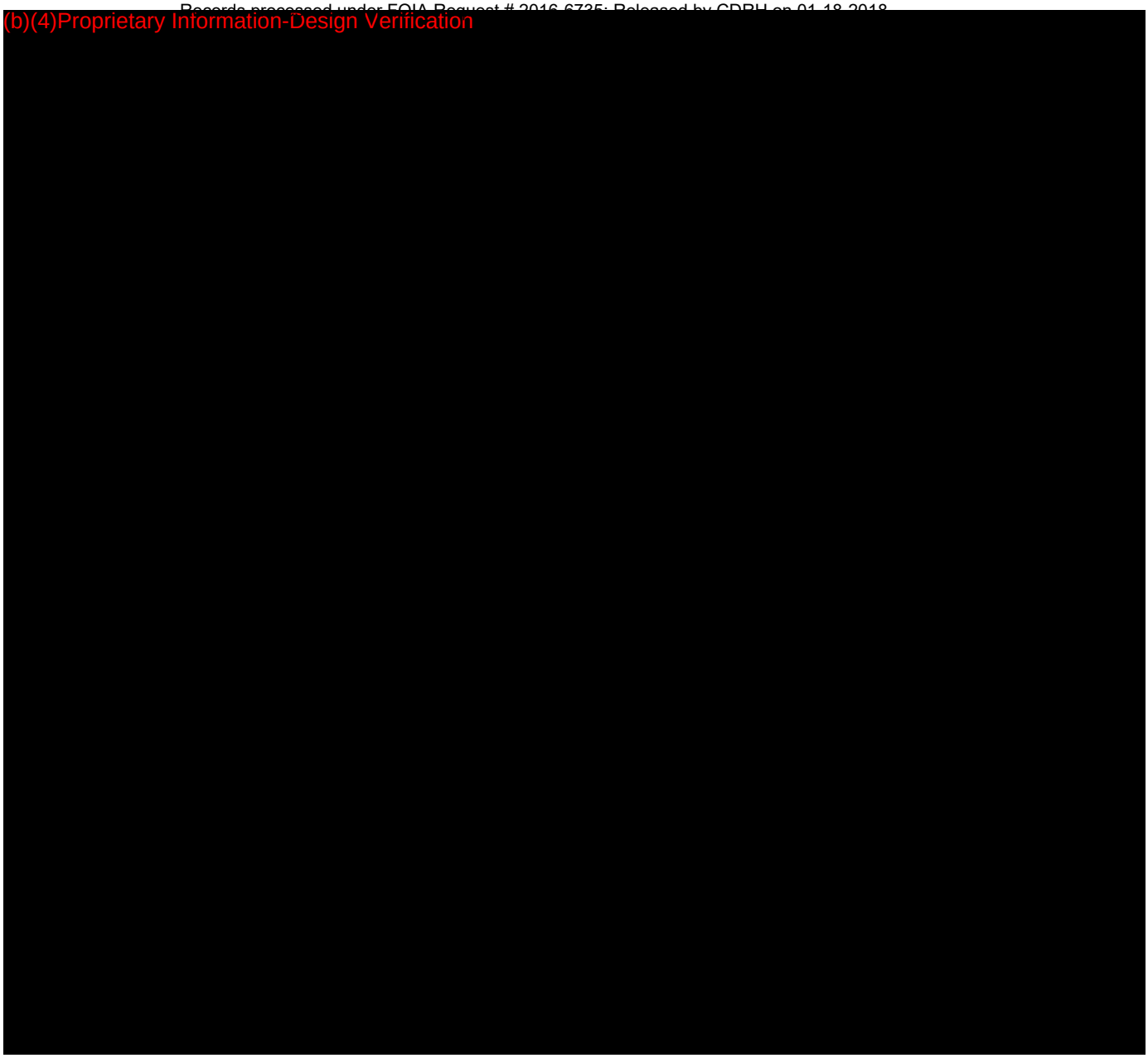
(b)(4)Proprietary Information-Design Verification



(b)(4)Proprietary Information-Design Verification

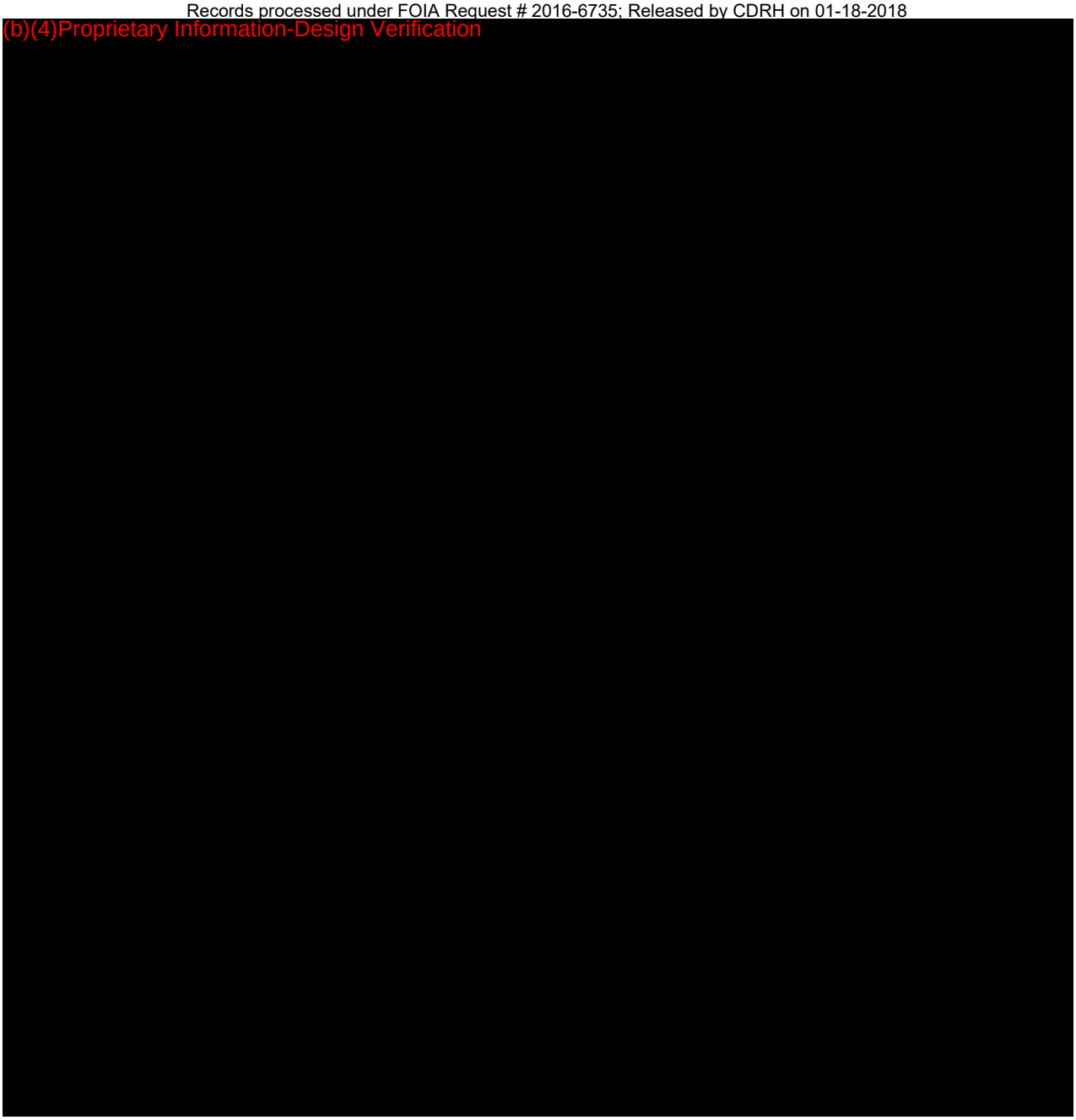


(b)(4)Proprietary Information-Design Verification

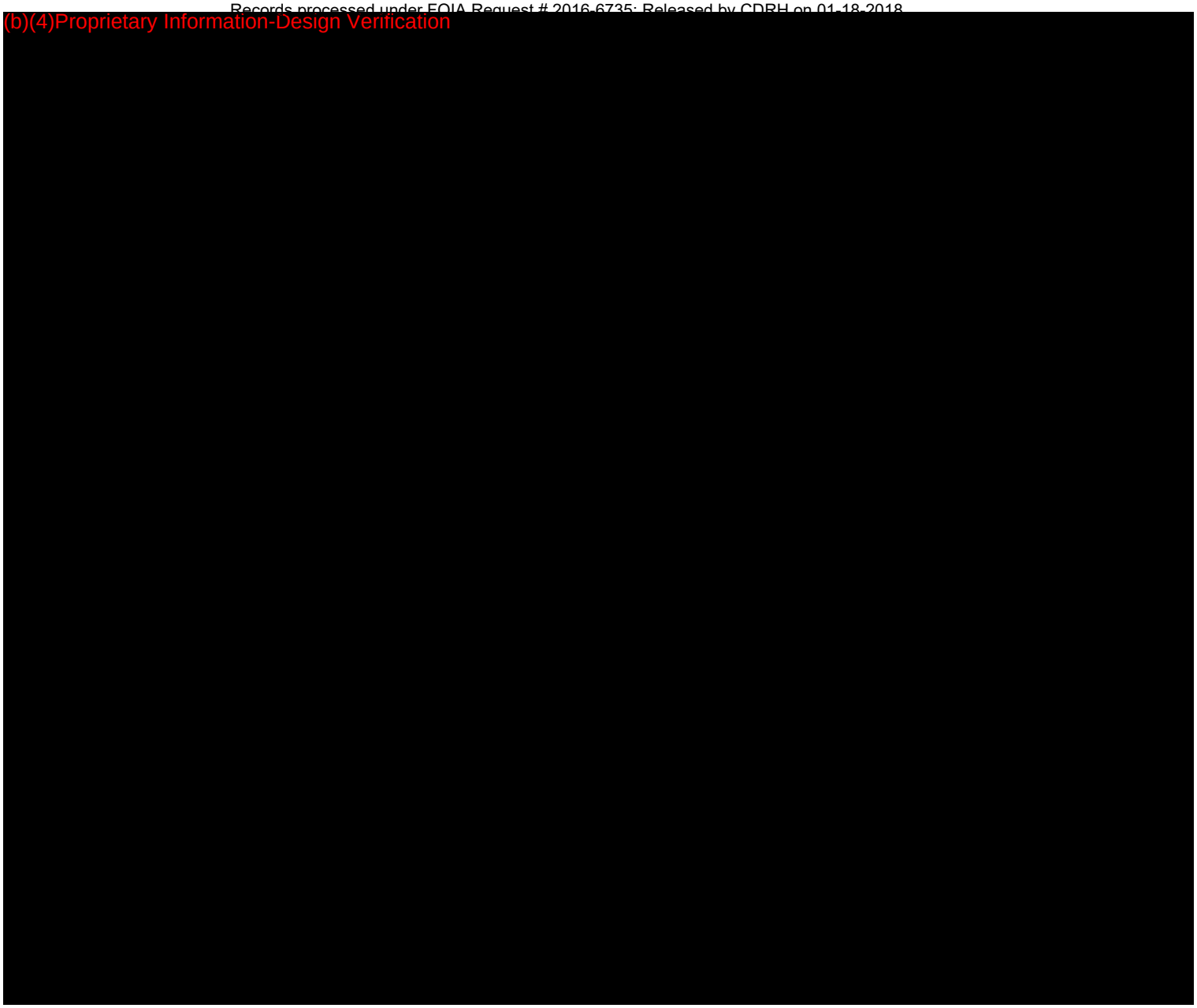


(b)(4)Proprietary Information-Design Verification

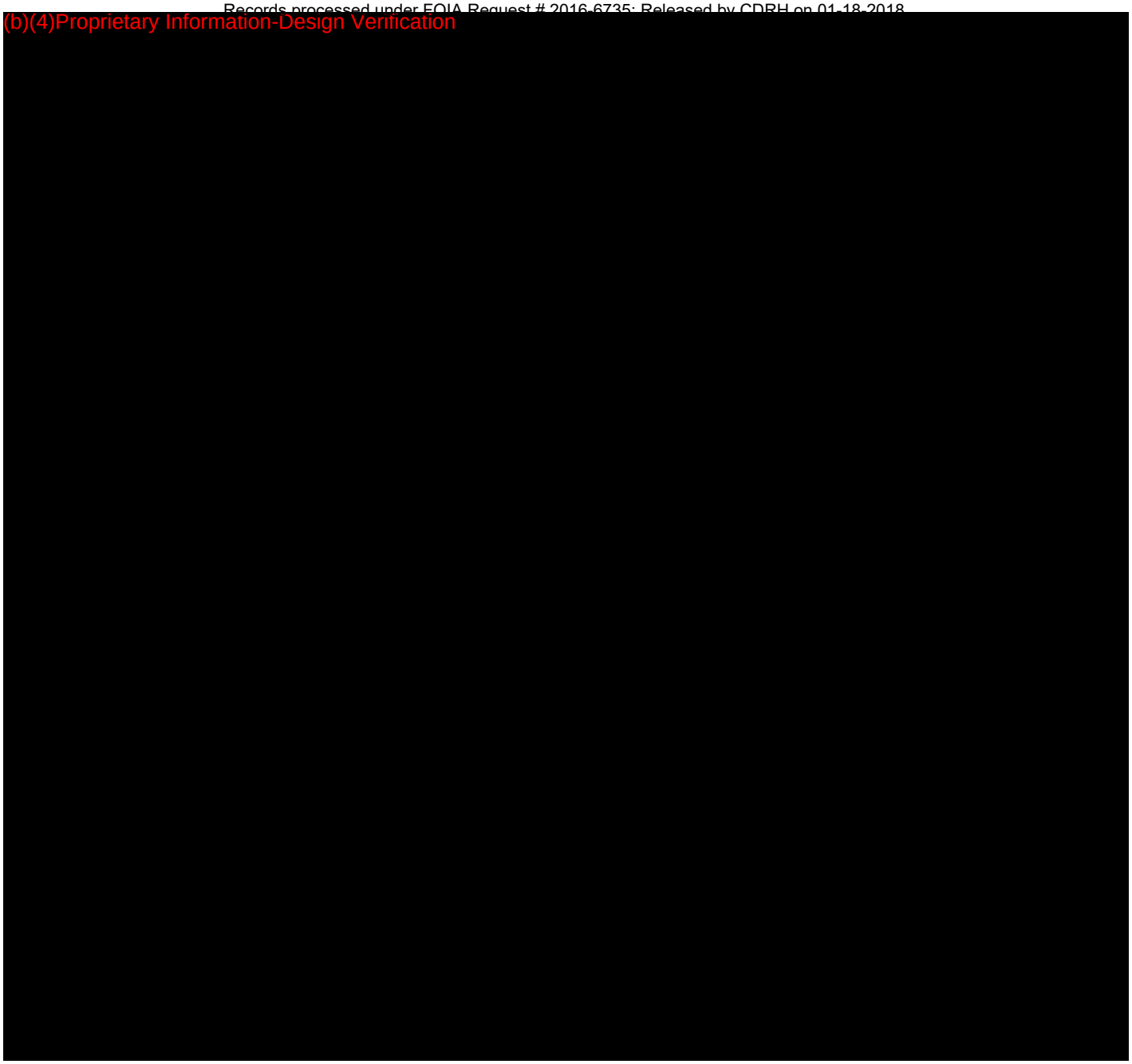
(b)(4)Proprietary Information-Design Verification



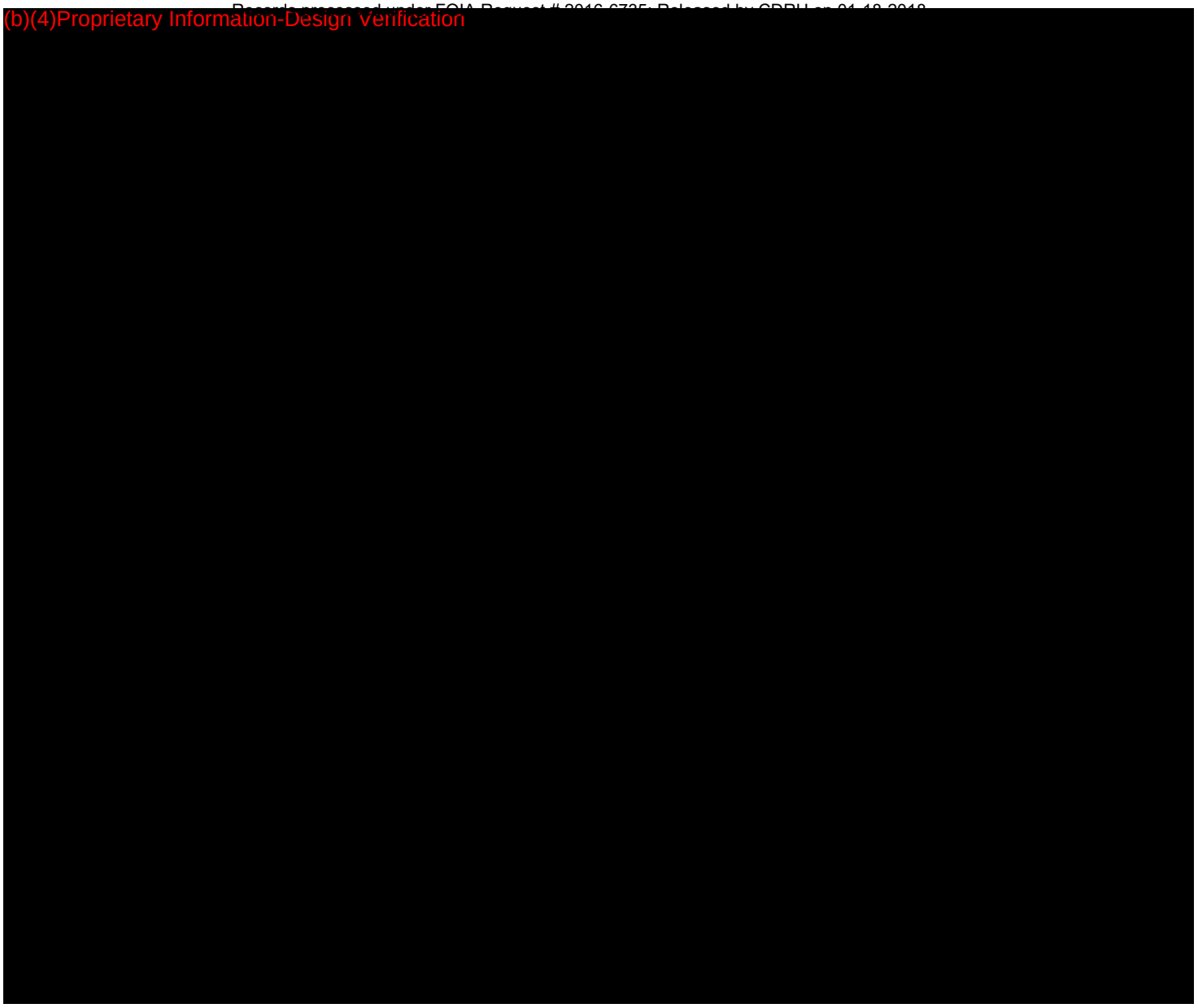
(b)(4)Proprietary Information-Design Verification



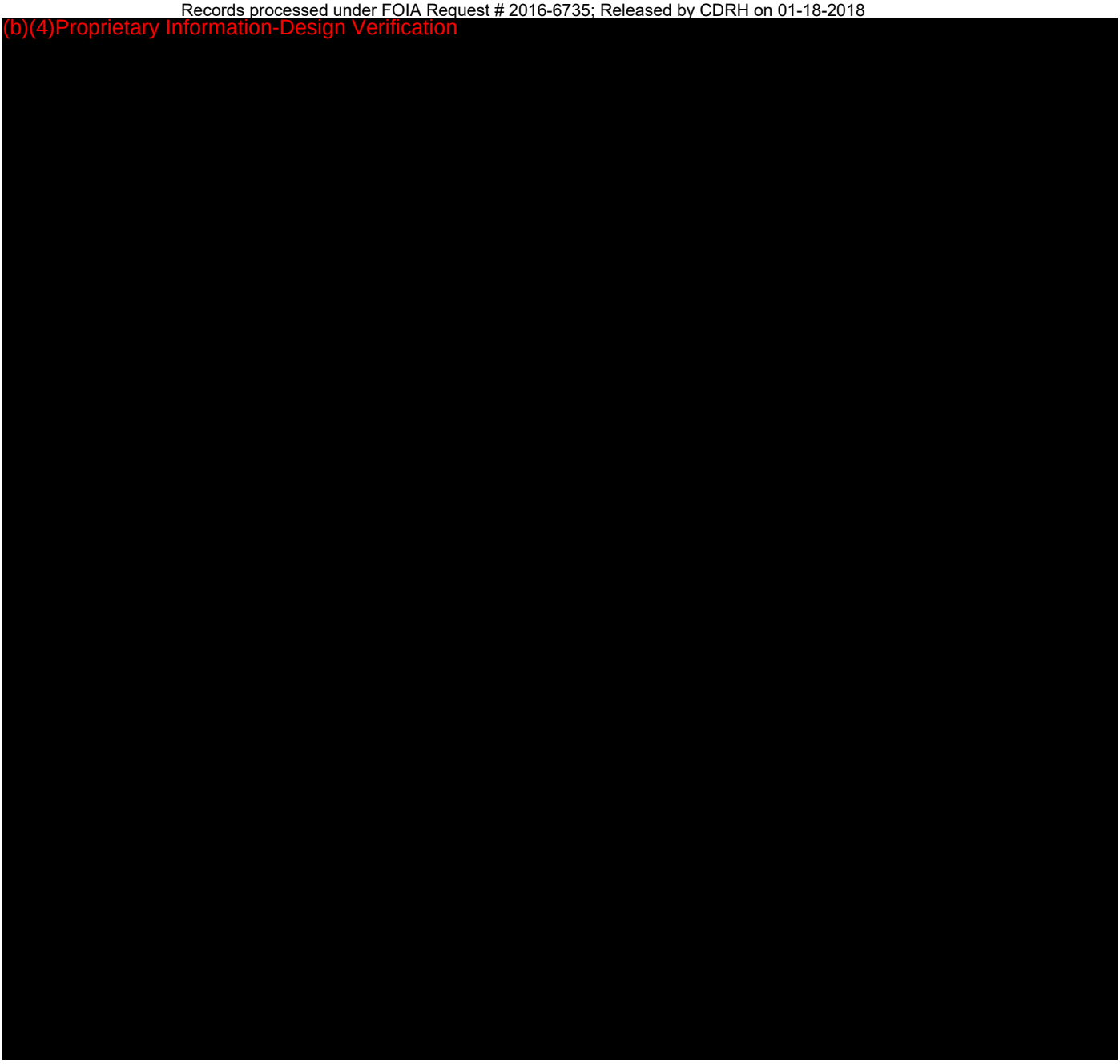
(b)(4)Proprietary Information-Design Verification



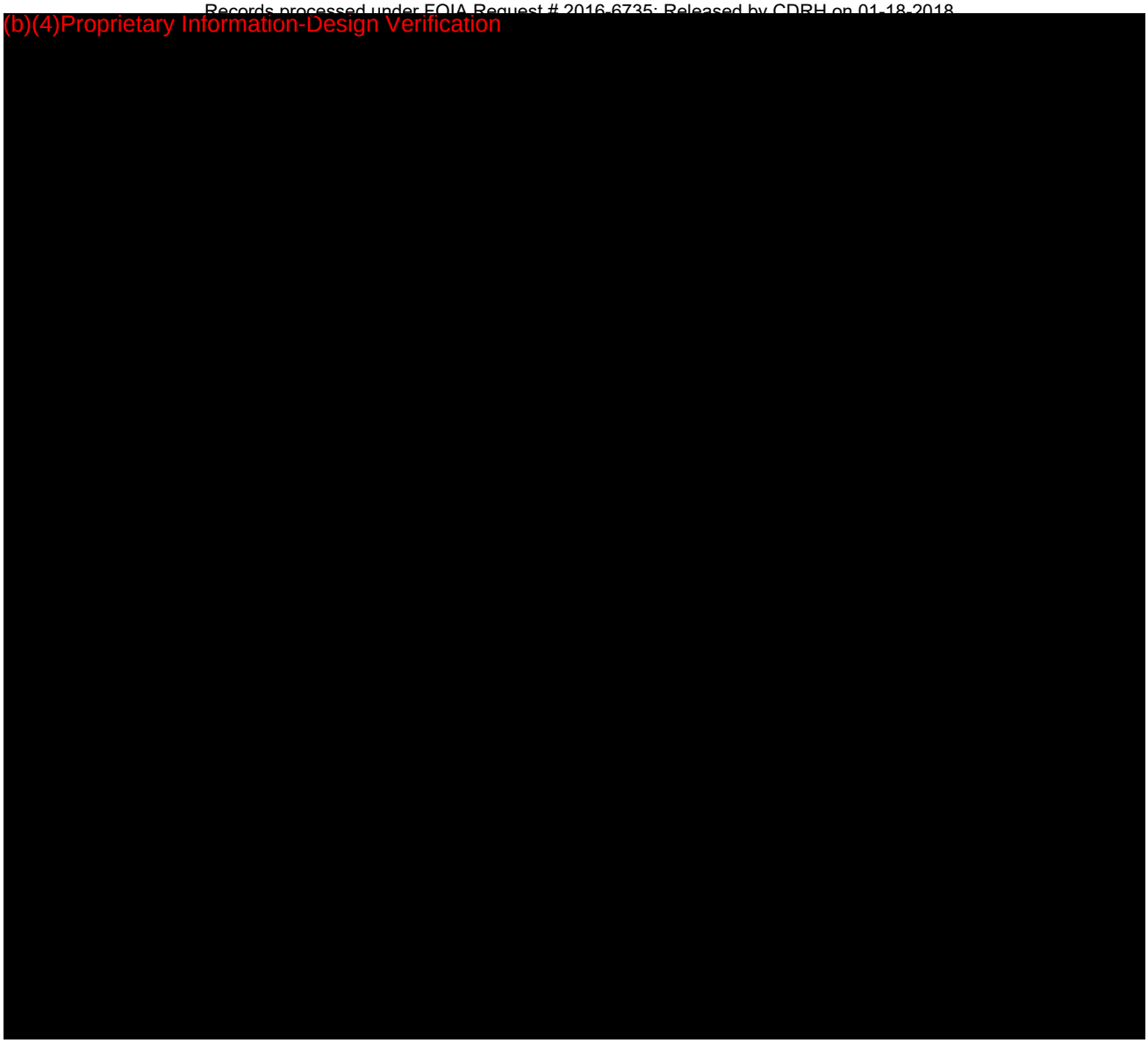
(b)(4)Proprietary Information-Design Verification



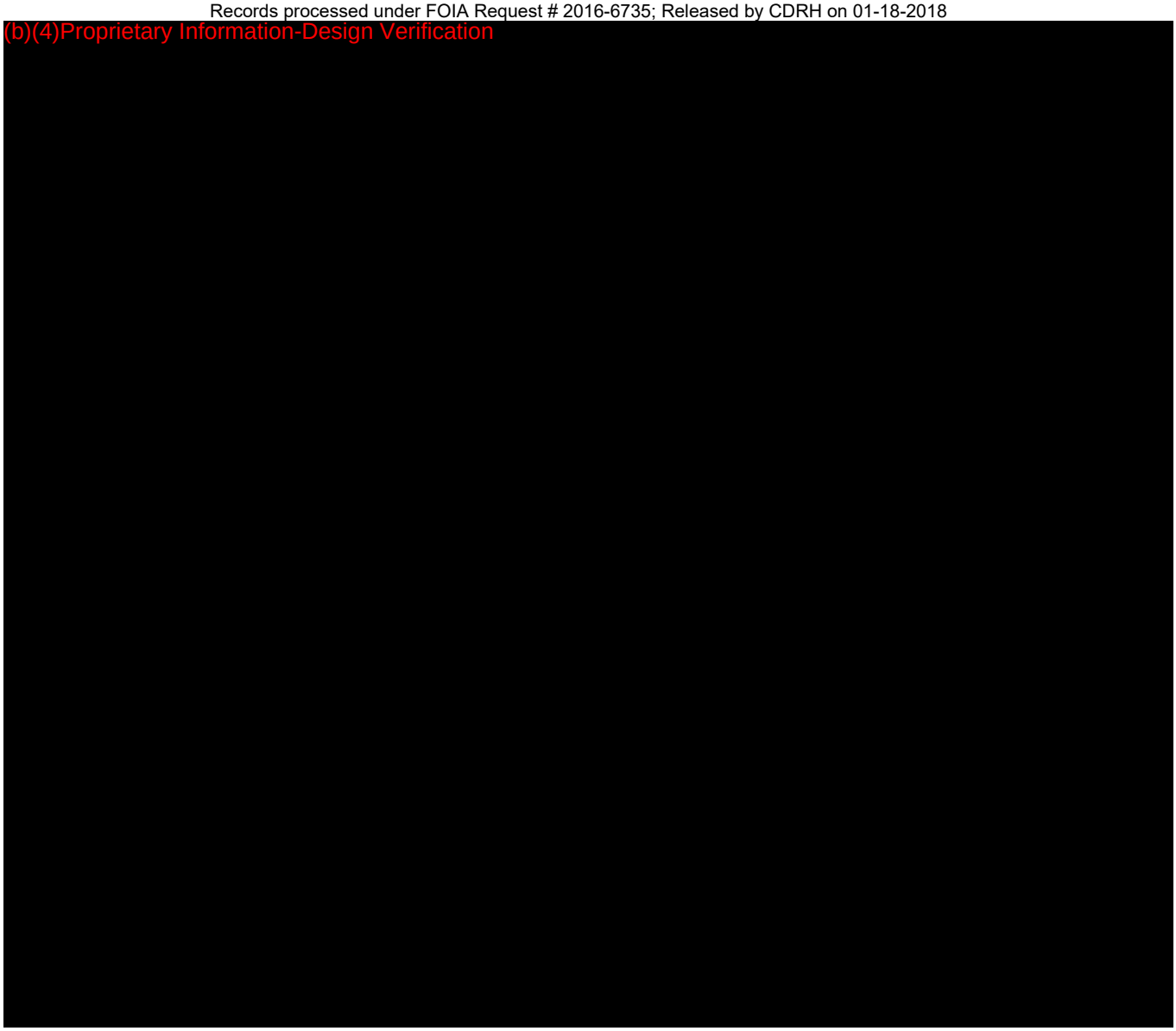
(b)(4)Proprietary Information-Design Verification



(b)(4)Proprietary Information-Design Verification

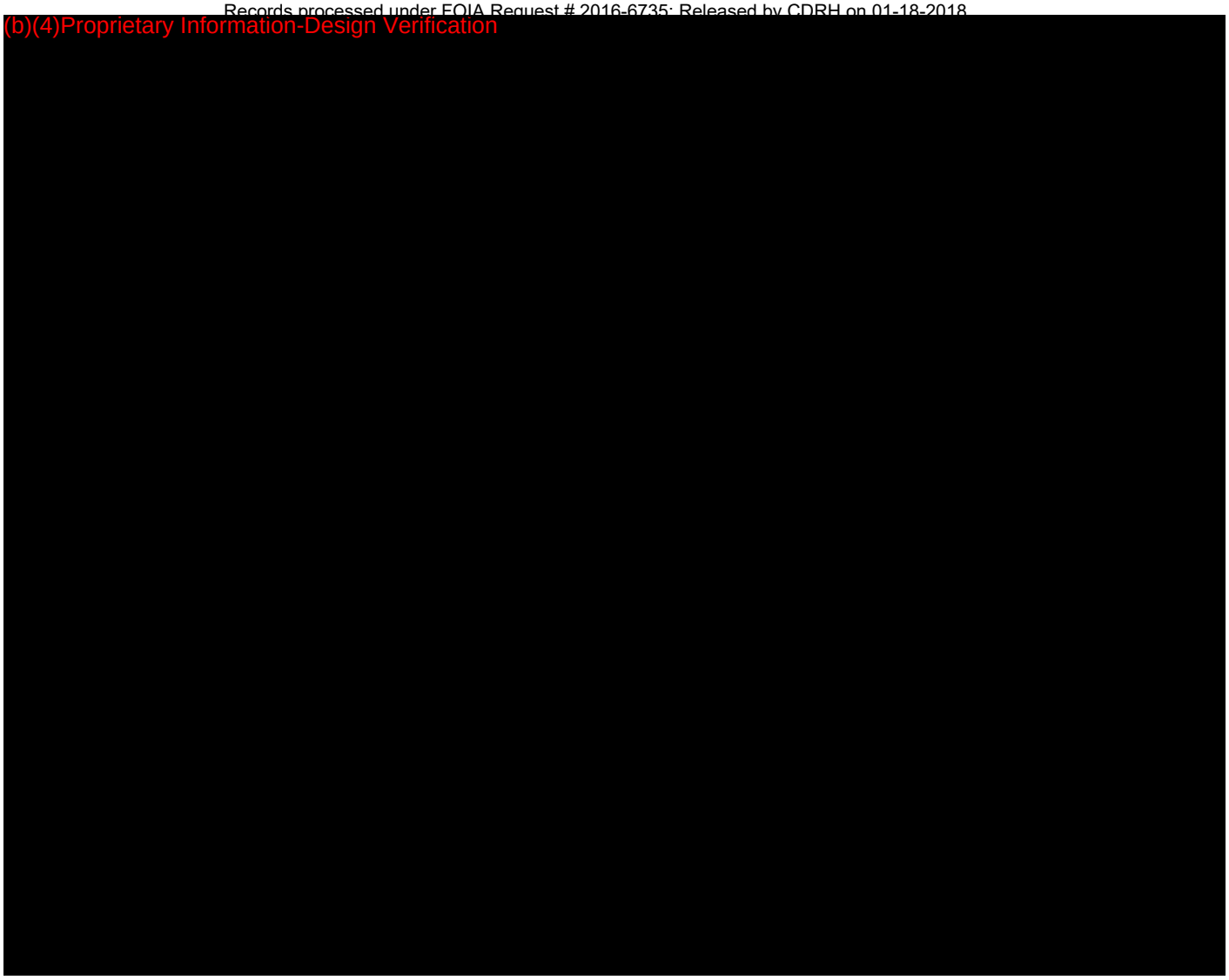


(b)(4)Proprietary Information-Design Verification



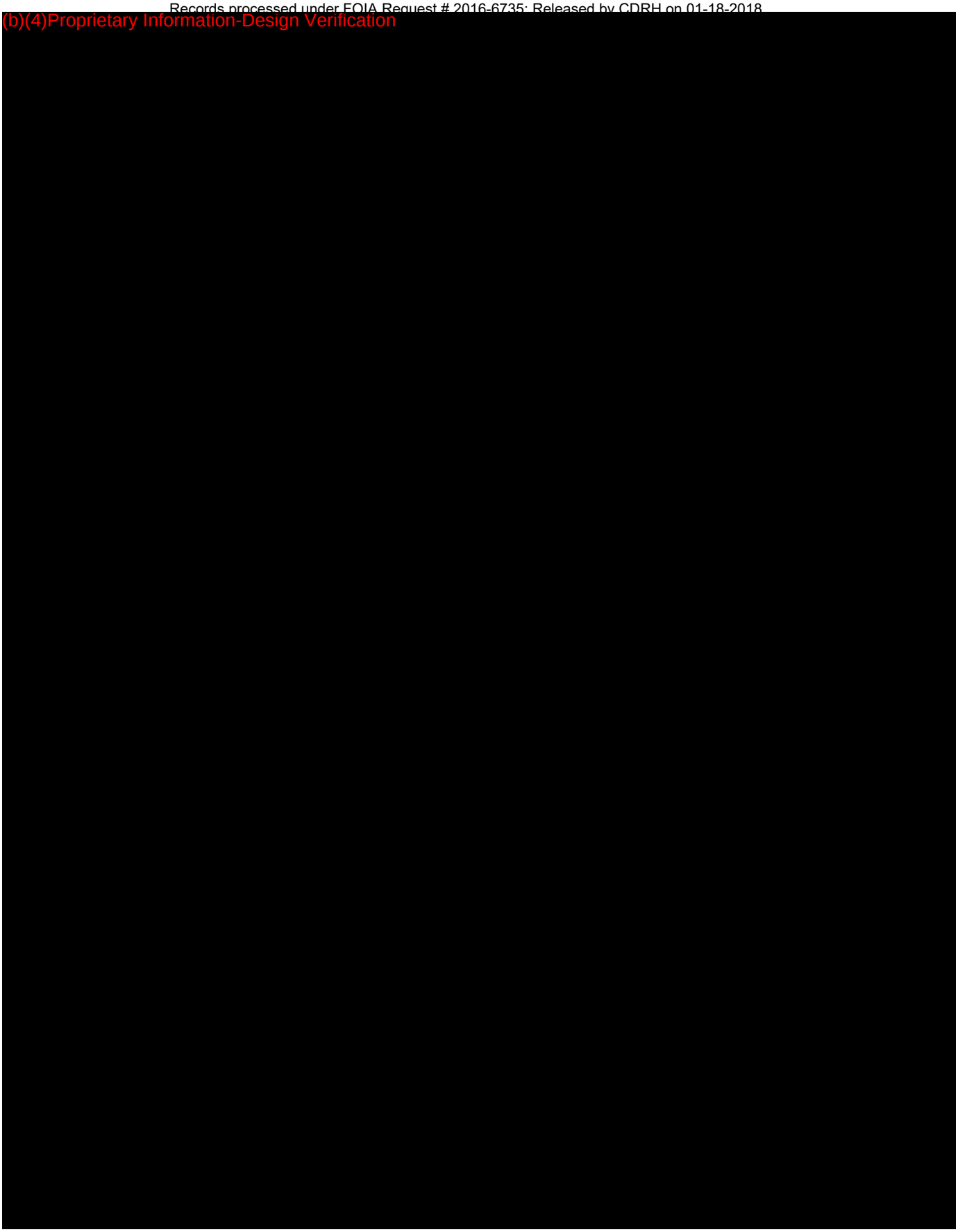
(b)(4)Proprietary Information-Design Verification

(b)(4)Proprietary Information-Design Verification

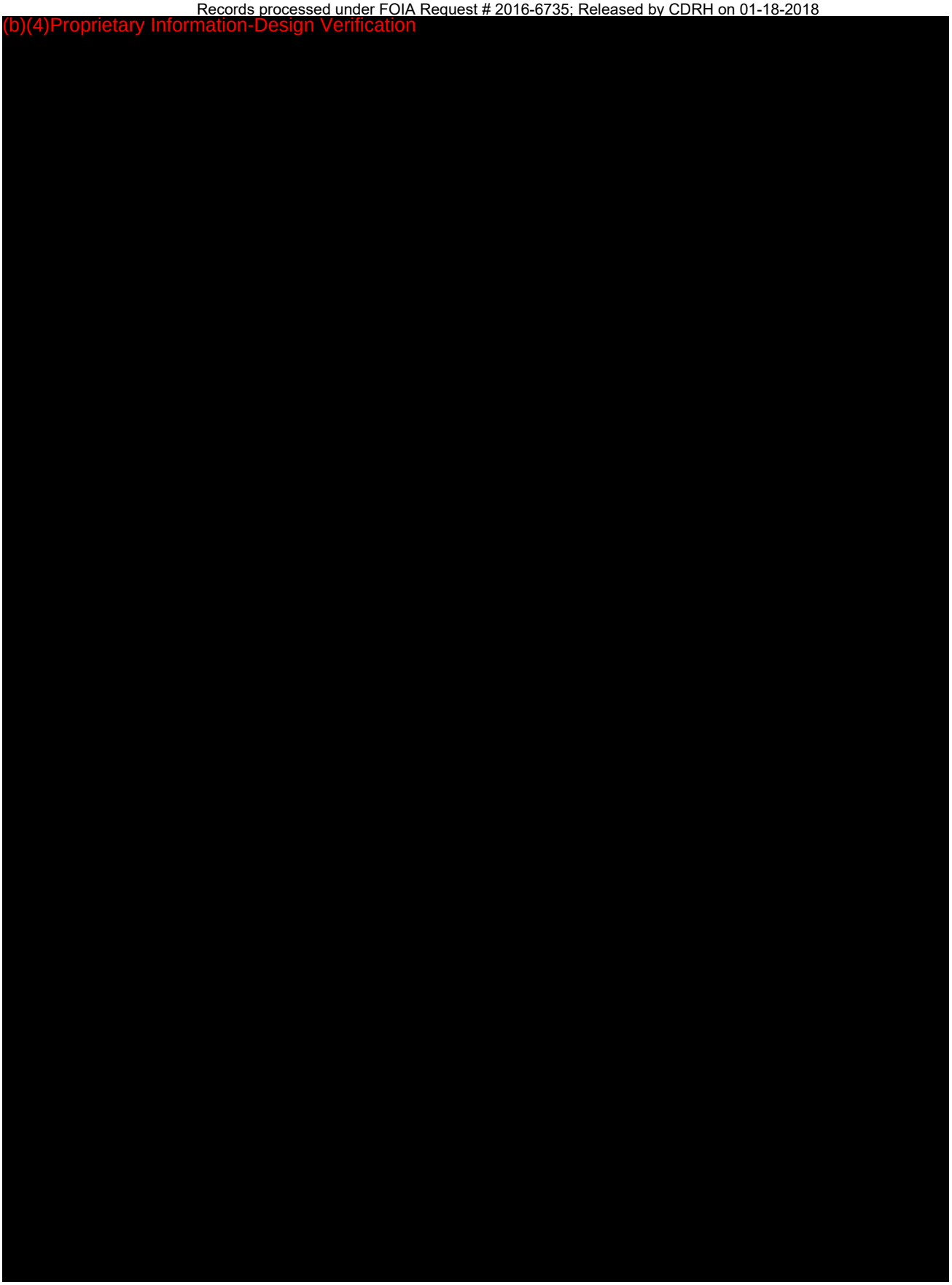


(b)(4)Proprietary Information-Design Verification

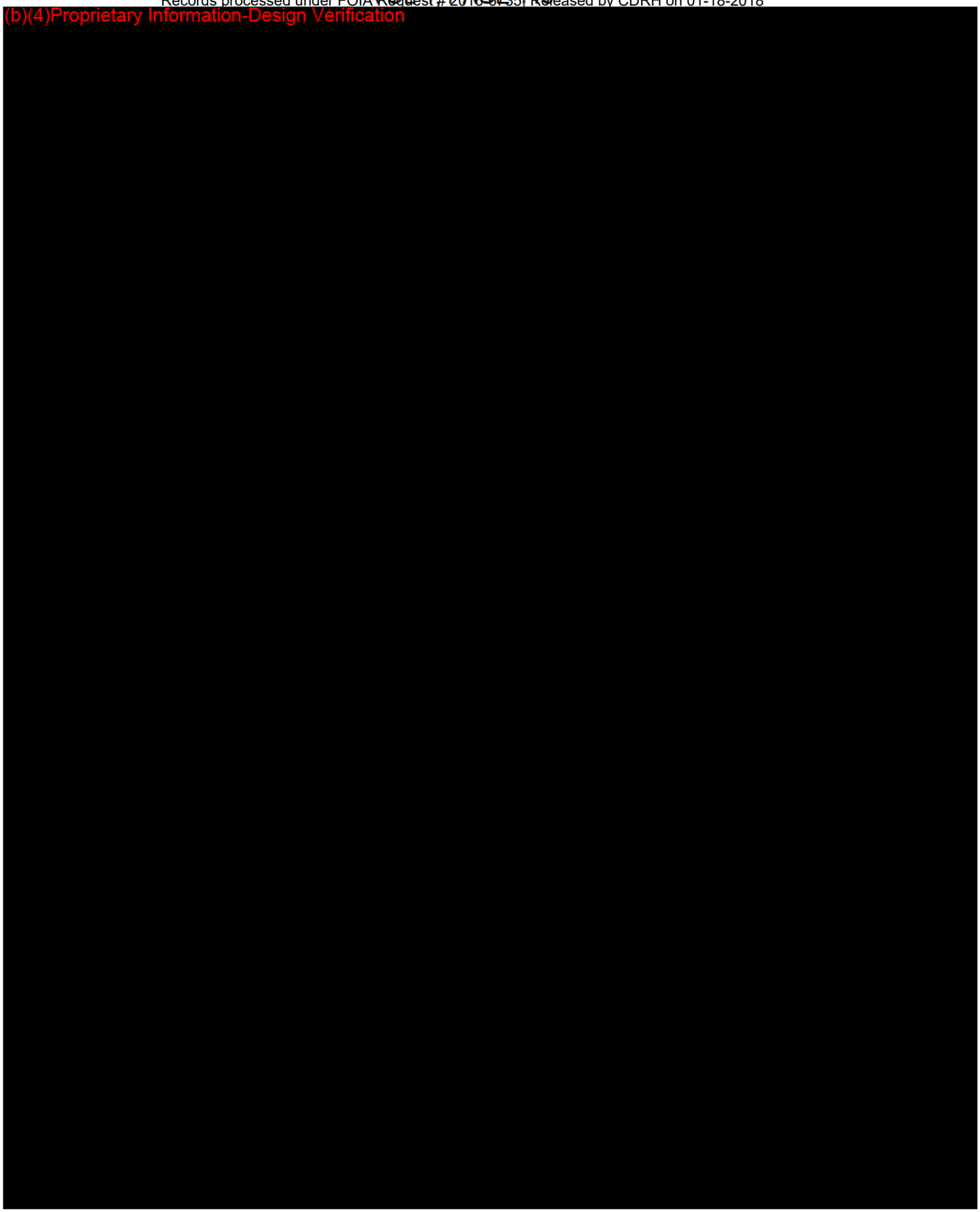
(b)(4)Proprietary Information-Design Verification



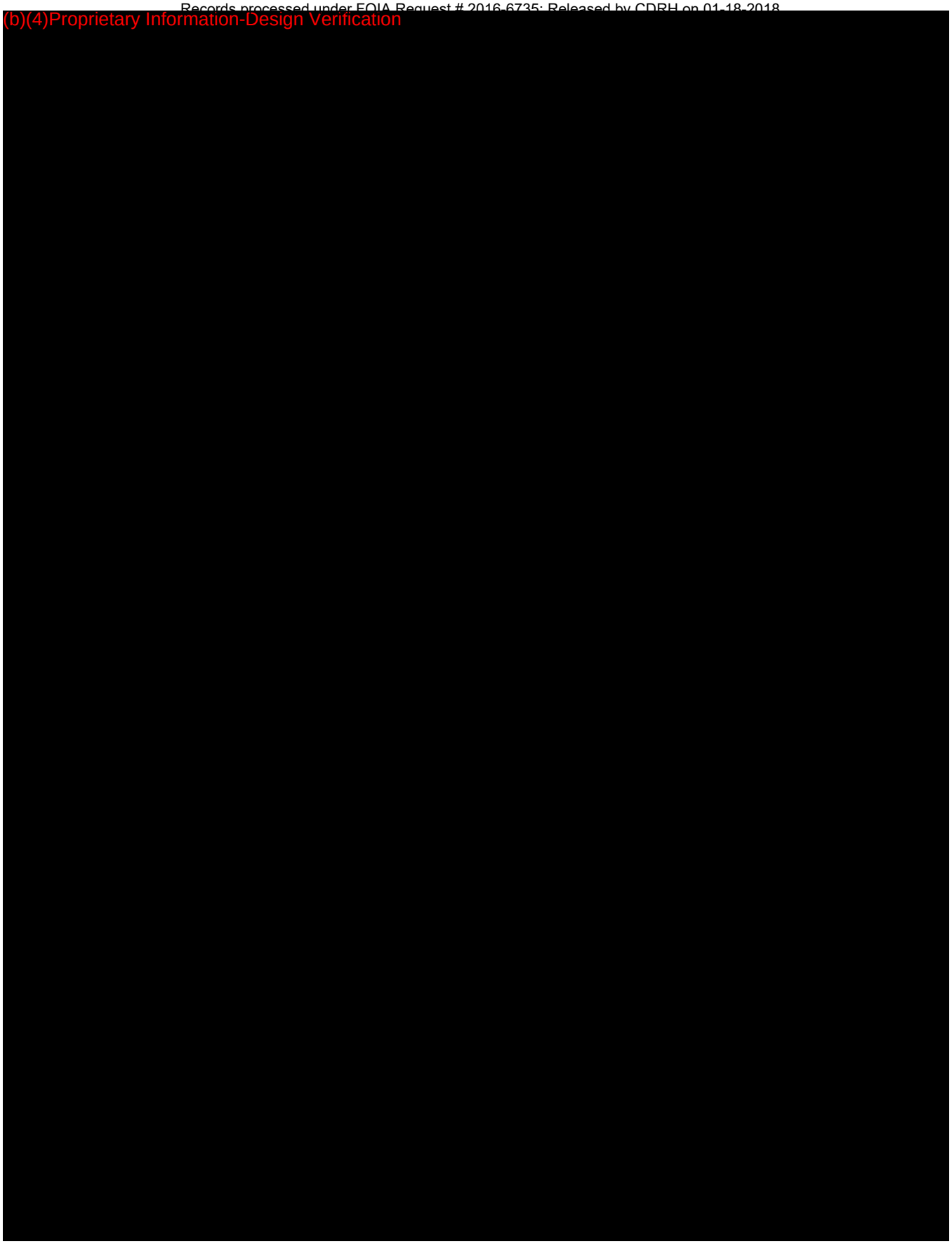
(b)(4)Proprietary Information-Design Verification



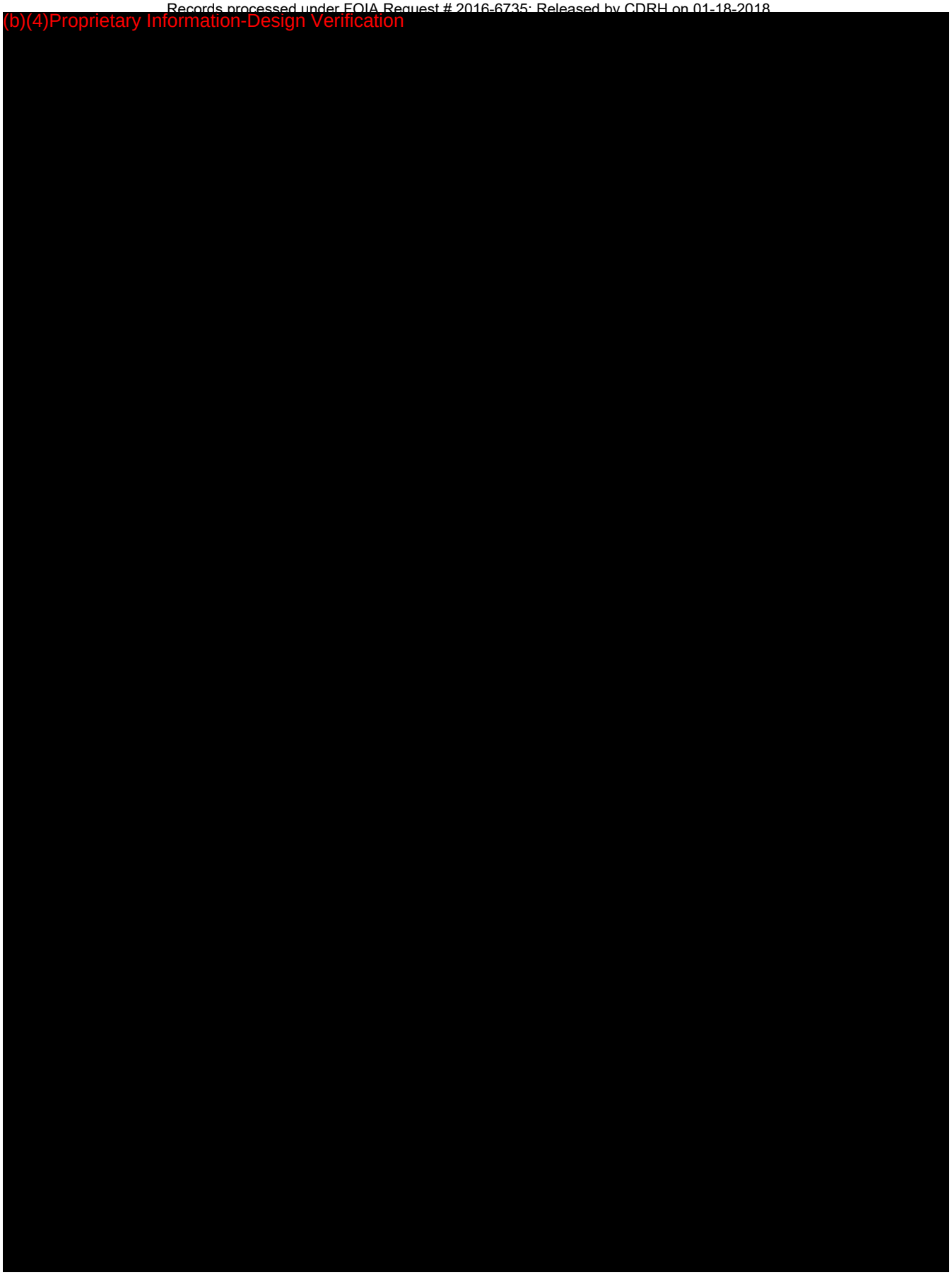
(b)(4)Proprietary Information-Design Verification



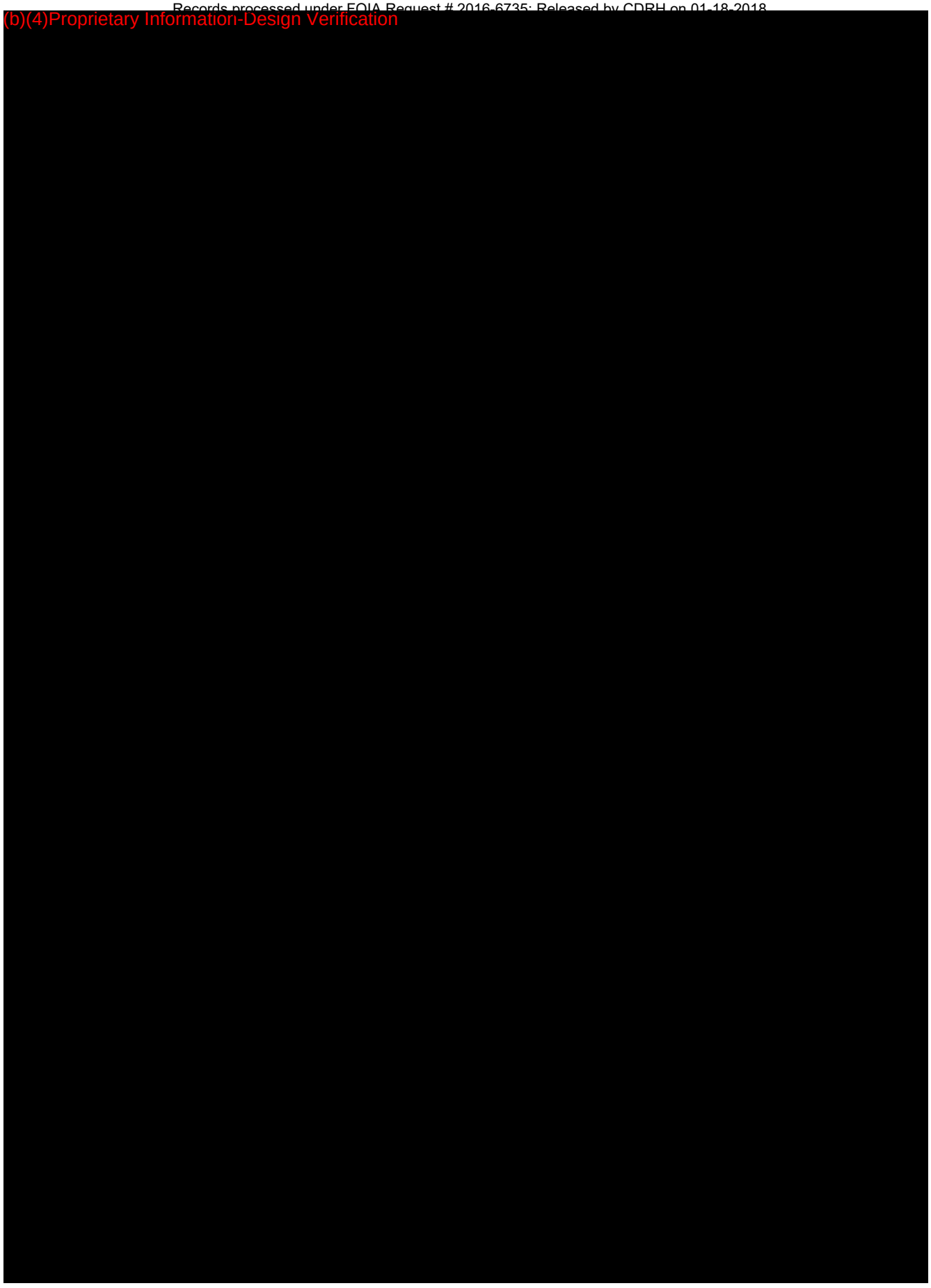
(b)(4)Proprietary Information-Design Verification



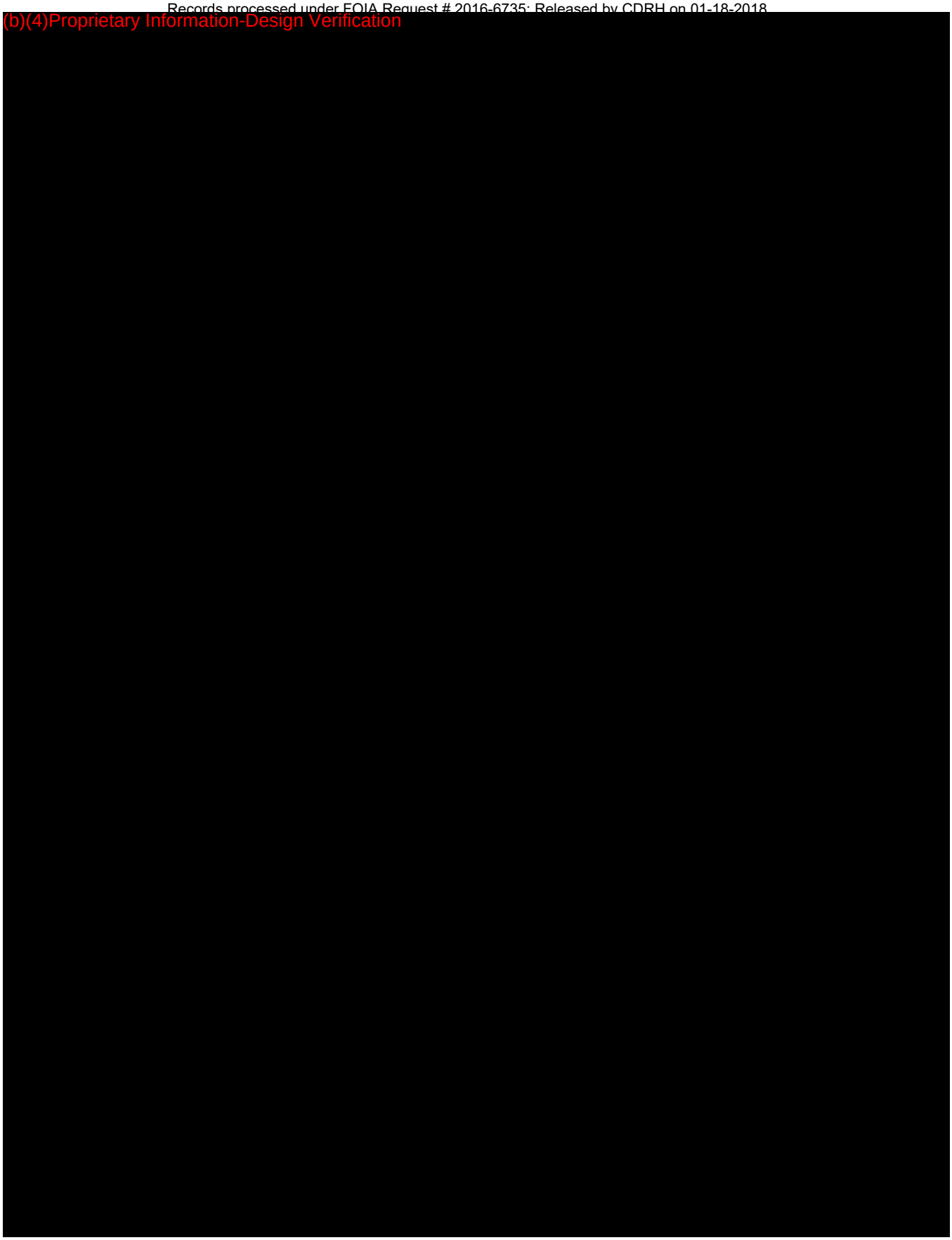
(b)(4)Proprietary Information-Design Verification



(b)(4)Proprietary Information-Design Verification



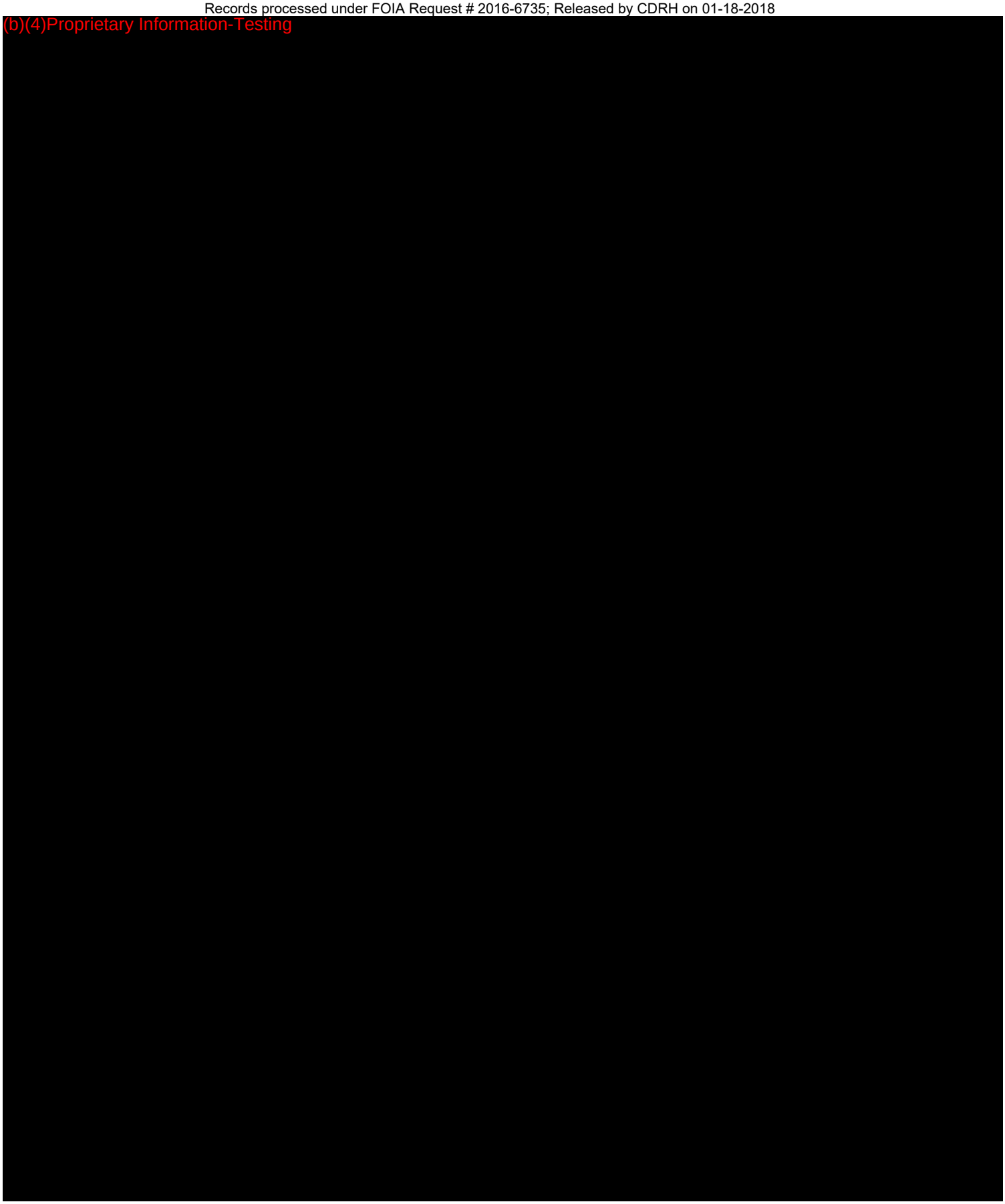
(b)(4)Proprietary Information-Design Verification



(b)(4)Proprietary Information-Design Verification

ATTACHMENT 30

(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing

[redacted]

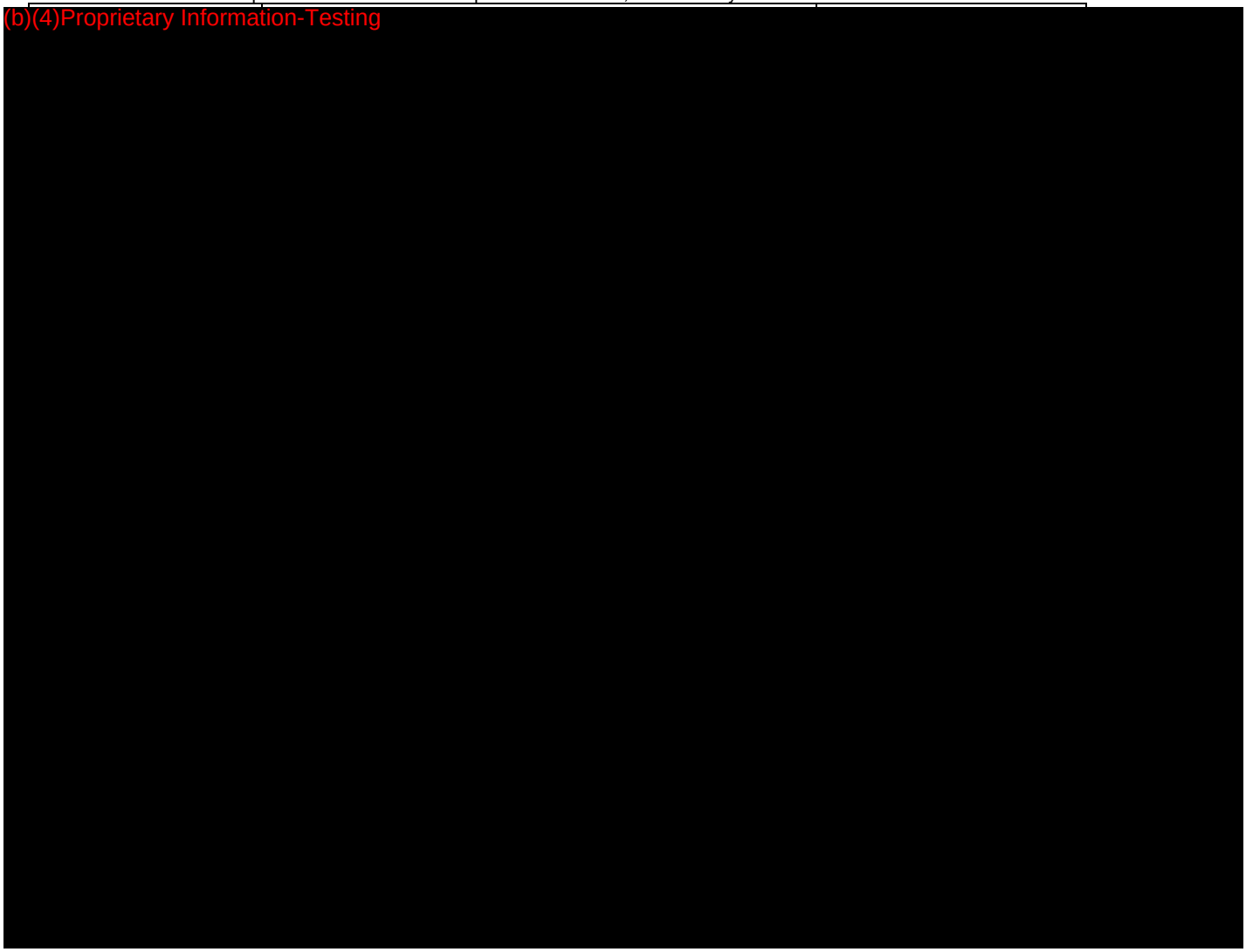
(b)(4)Proprietary Information-Testing

[redacted]

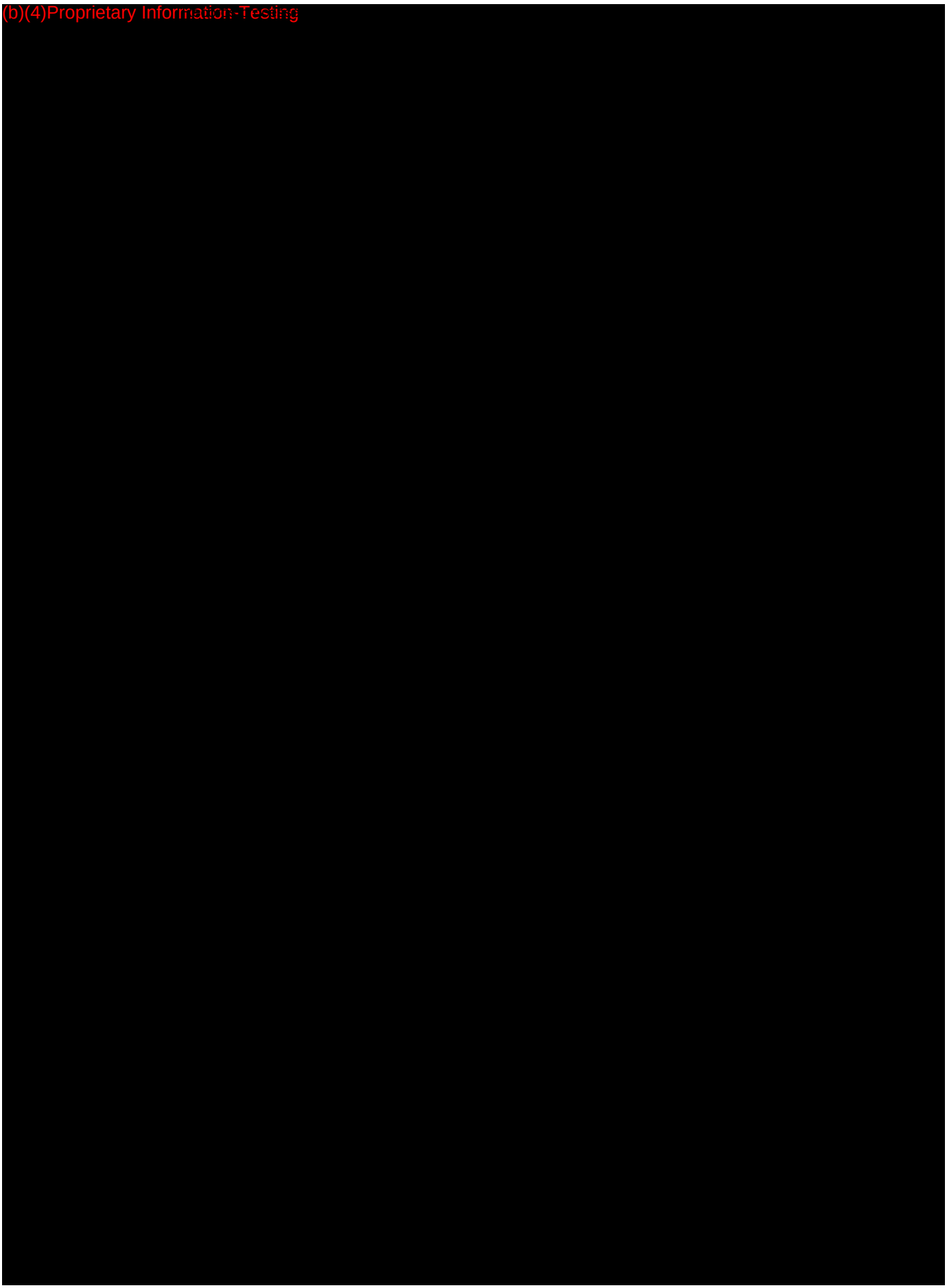
(b)(4)Proprietary Information-Testing

[redacted]

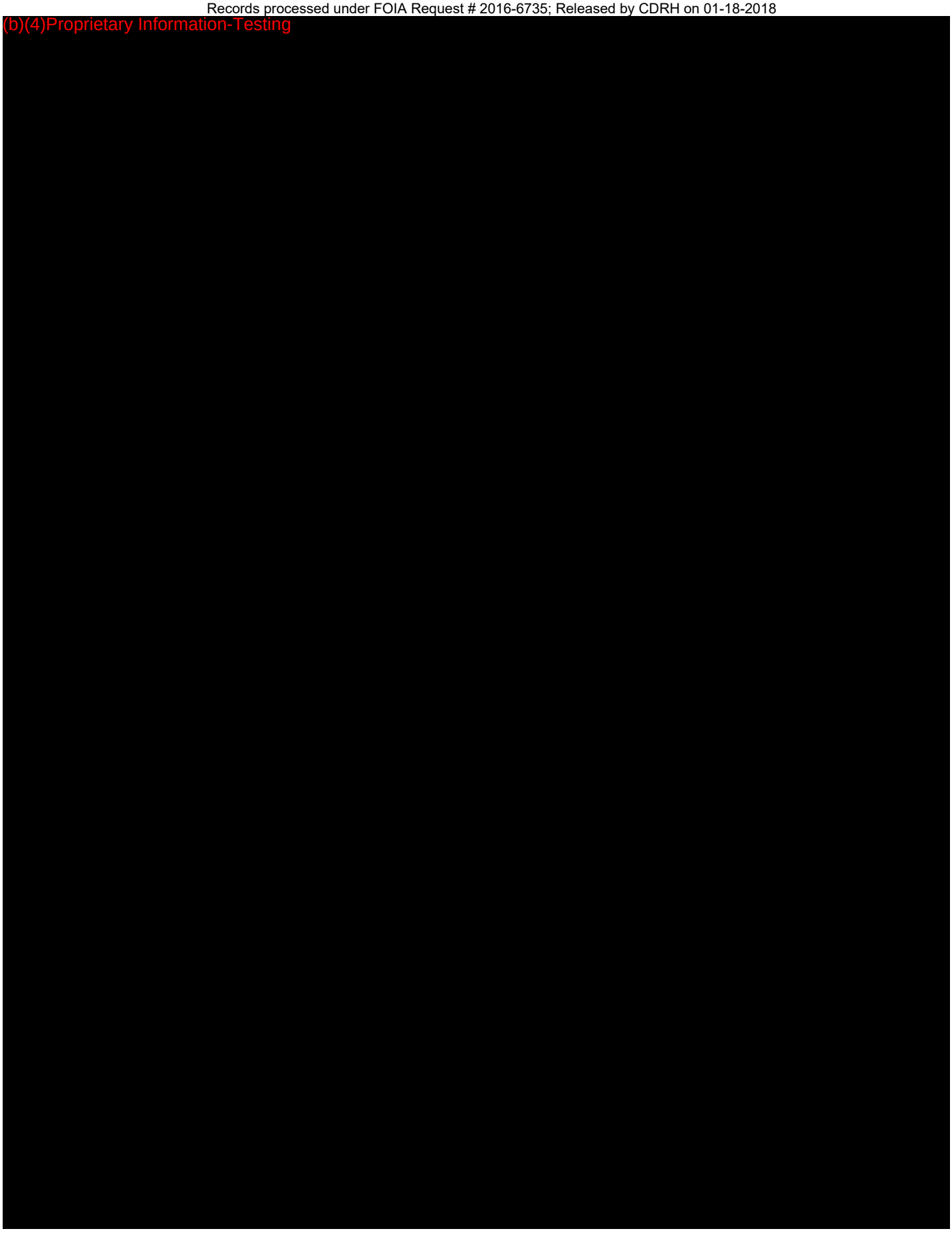
(b)(4)Proprietary Information-Testing



ATTACHMENT 31



(b)(4)Proprietary Information-Testing

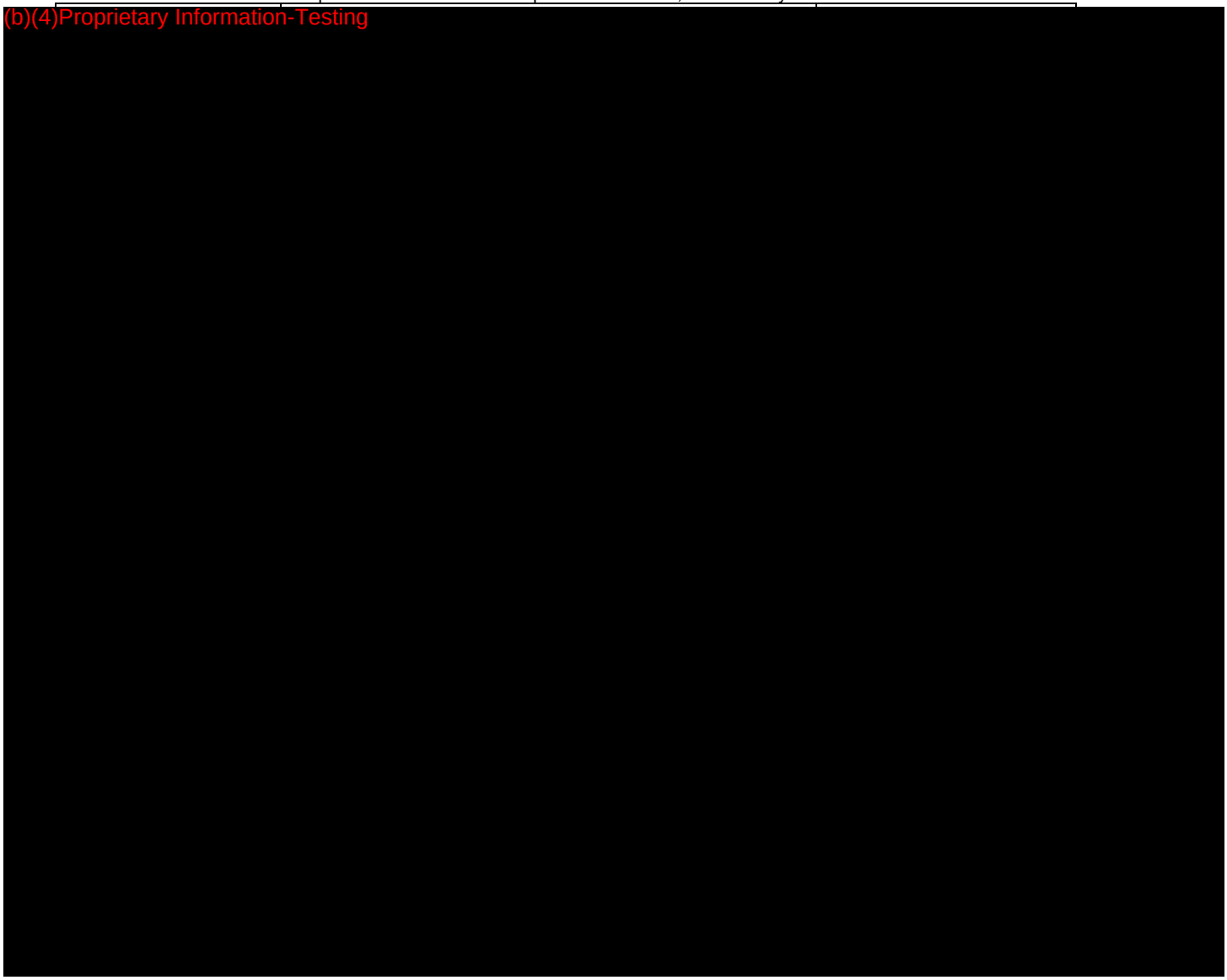


(b)(4)Proprietary Information-Testing

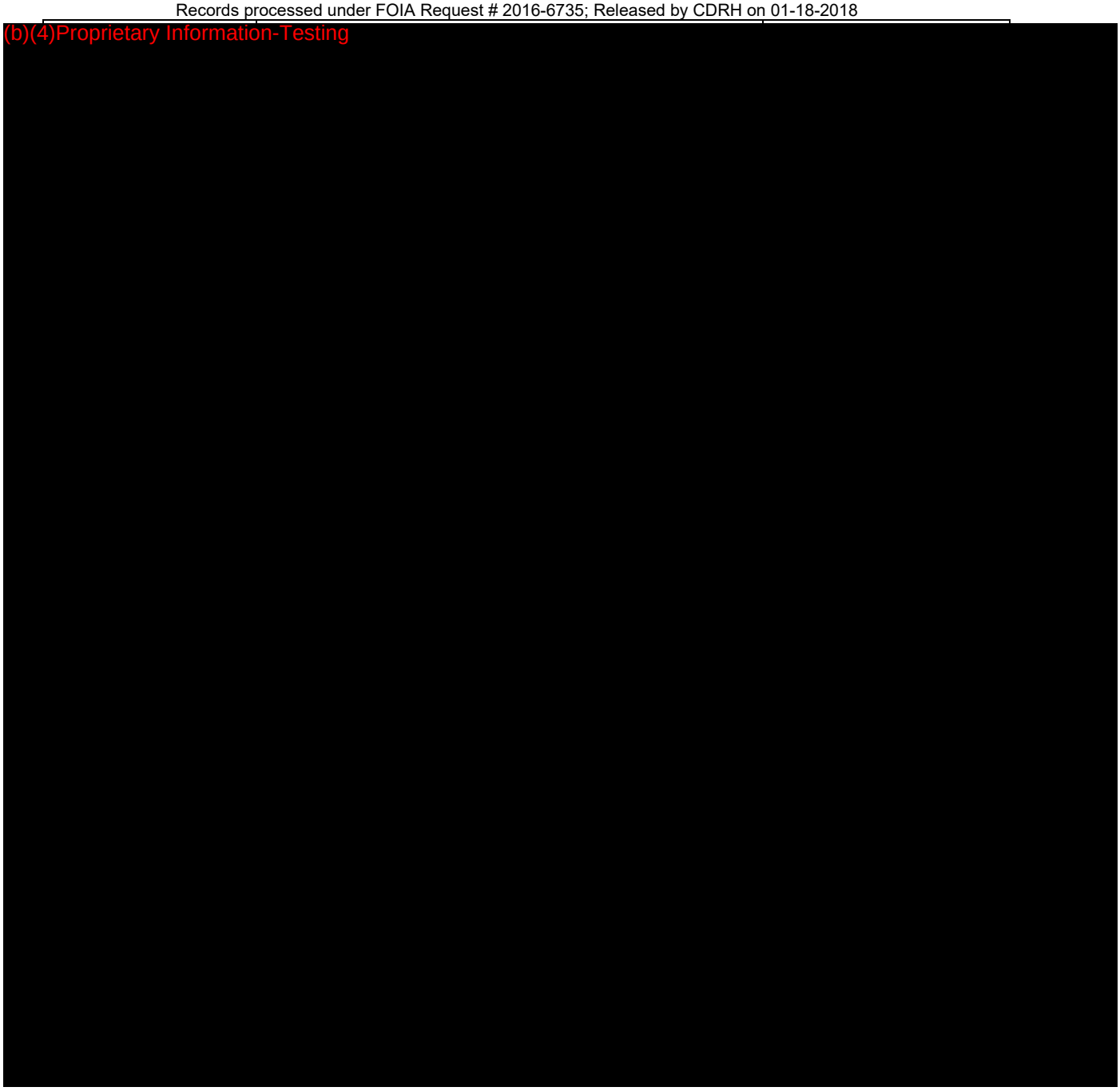
[redacted]

(b)(4)Proprietary Information-Testing

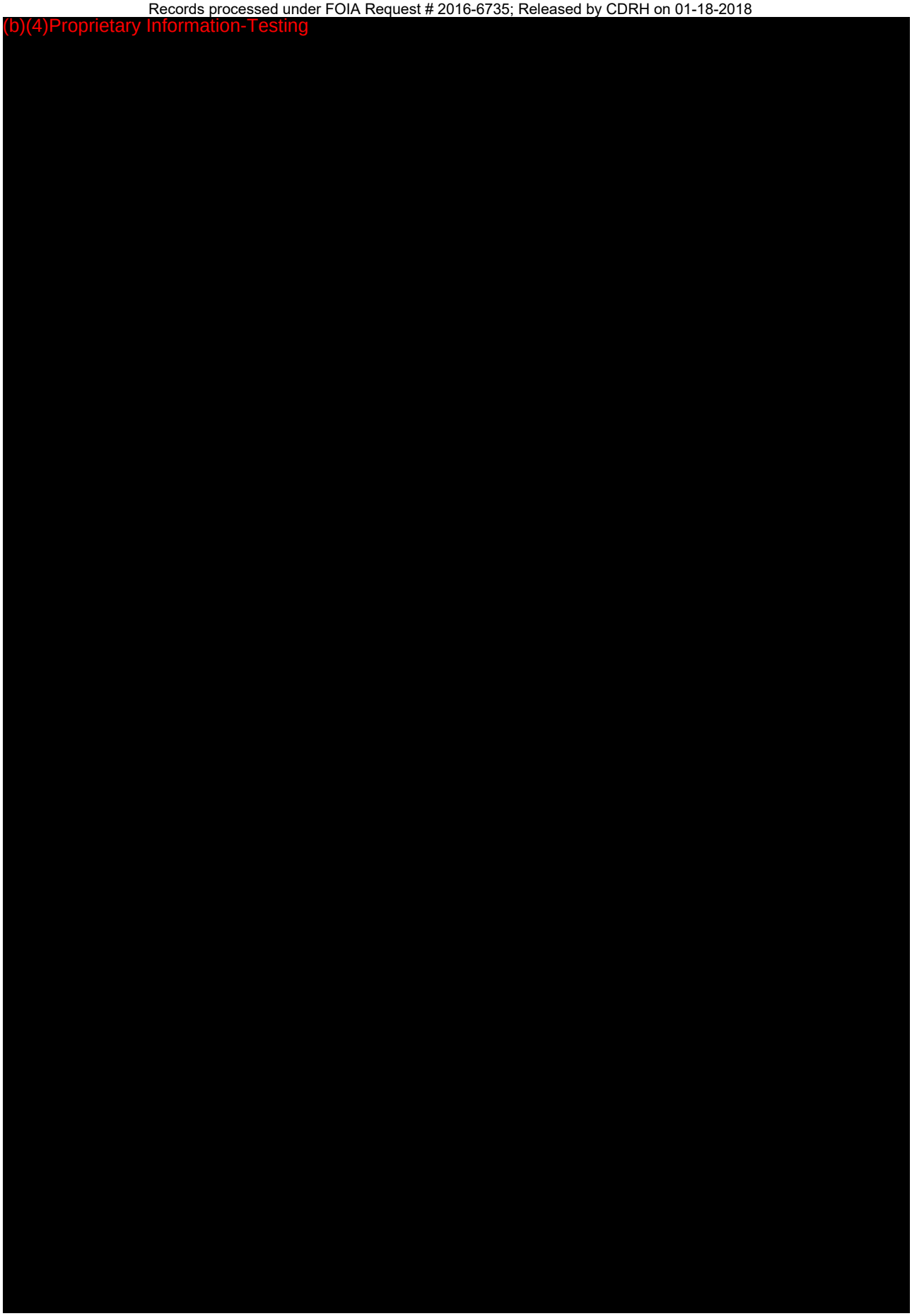
(b)(4)Proprietary Information-Testing



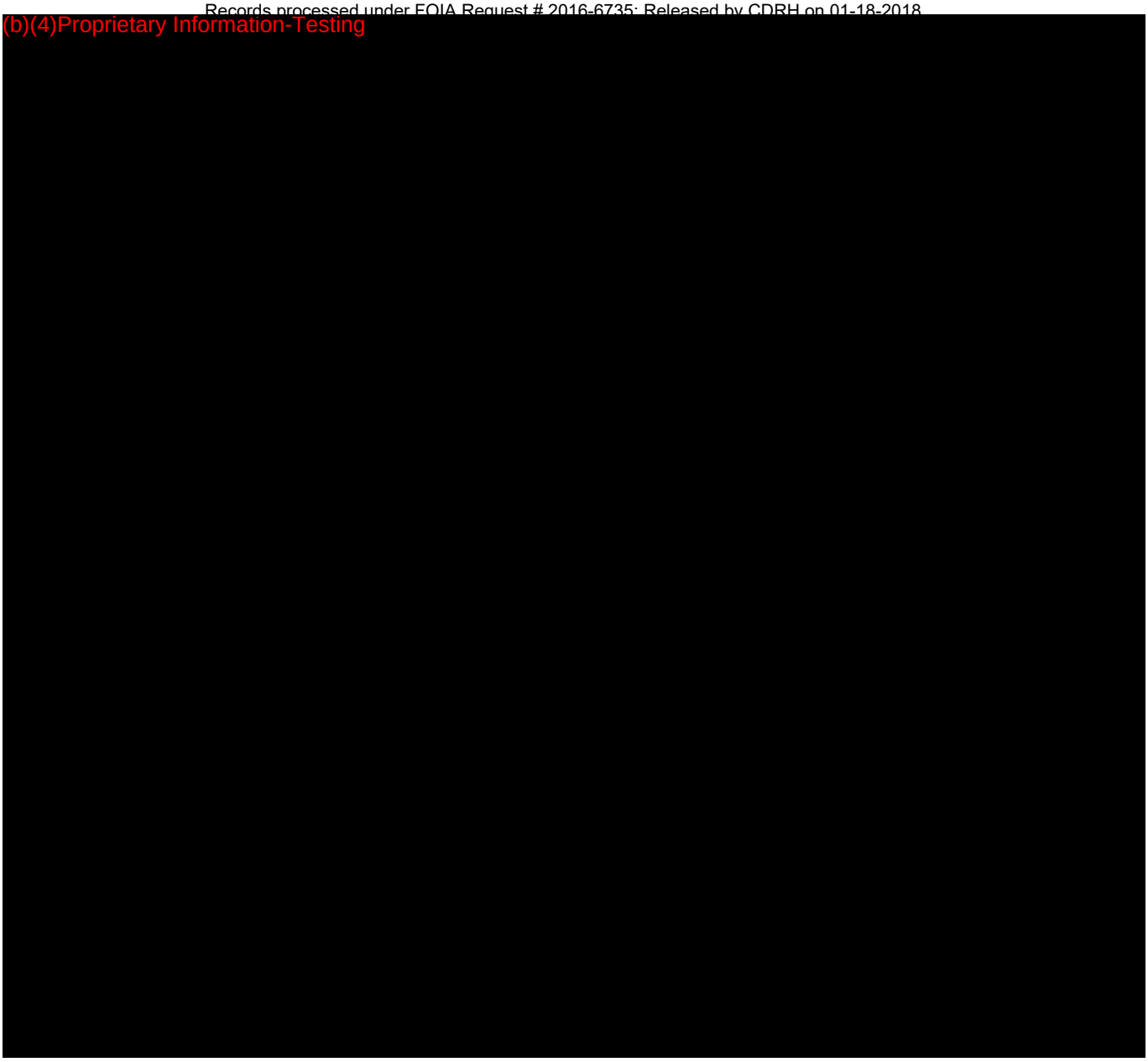
(b)(4)Proprietary Information-Testing



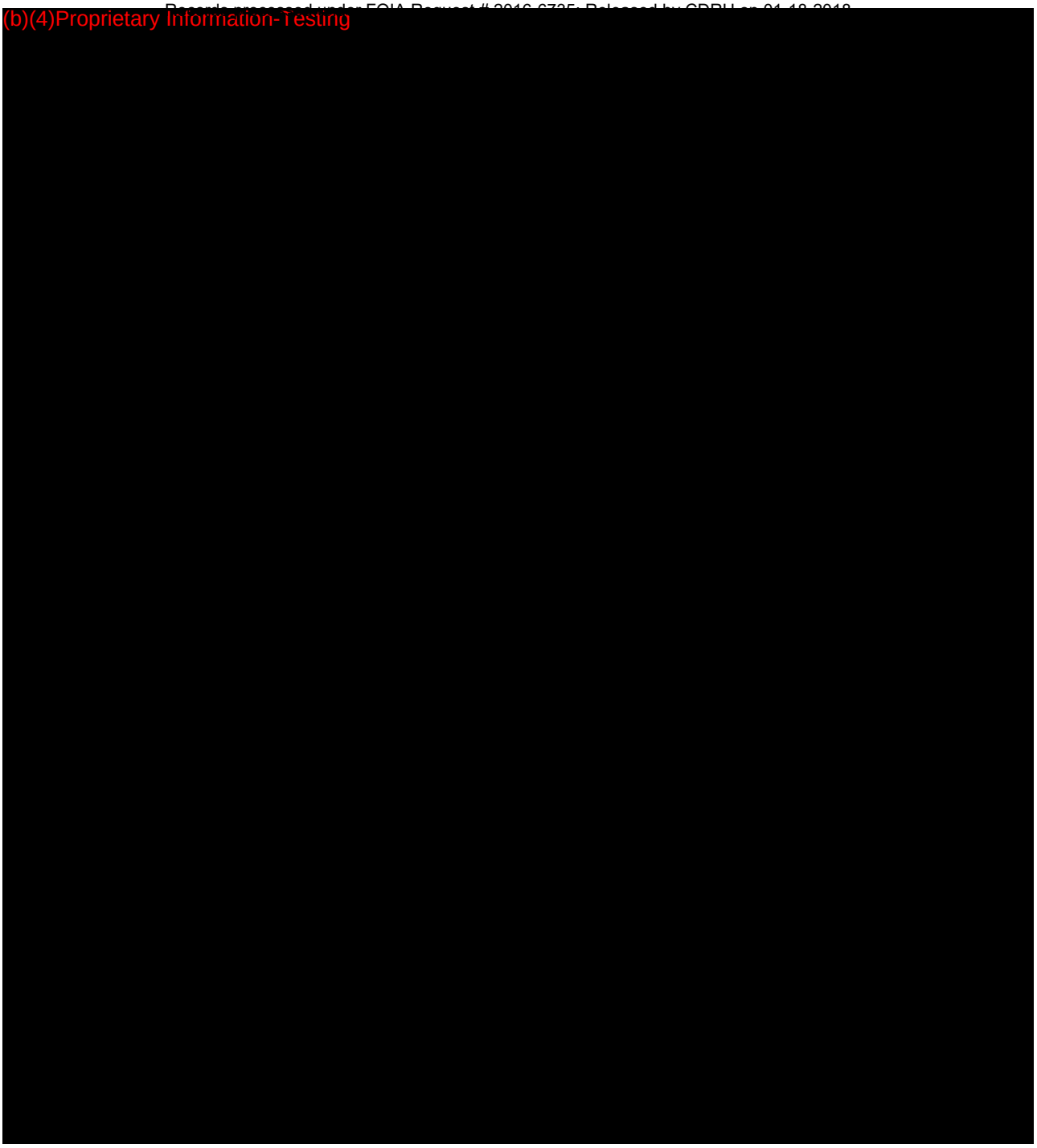
(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing



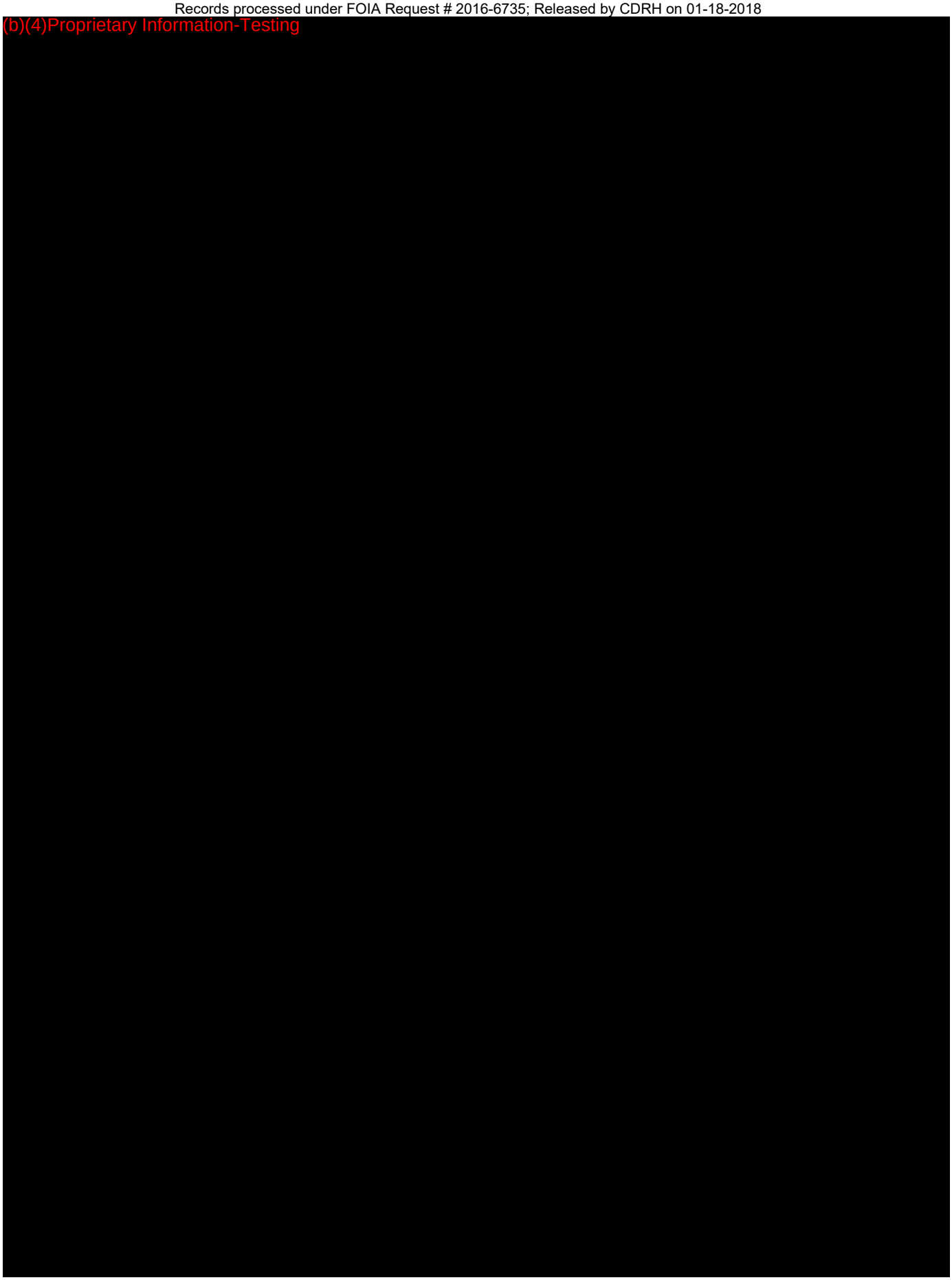
(b)(4)Proprietary Information-Testing



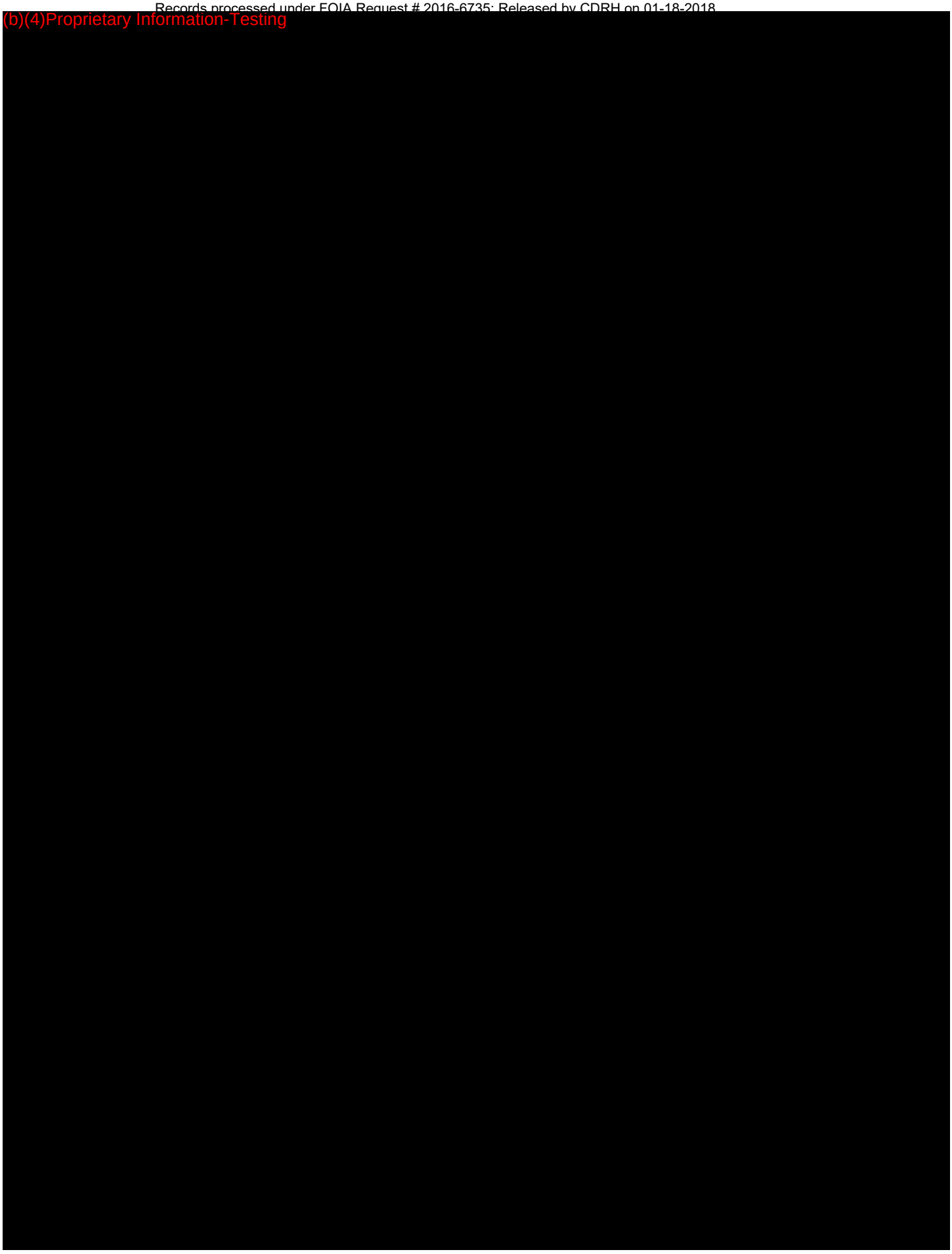
(b)(4)Proprietary Information-Testing

ATTACHMENT 32

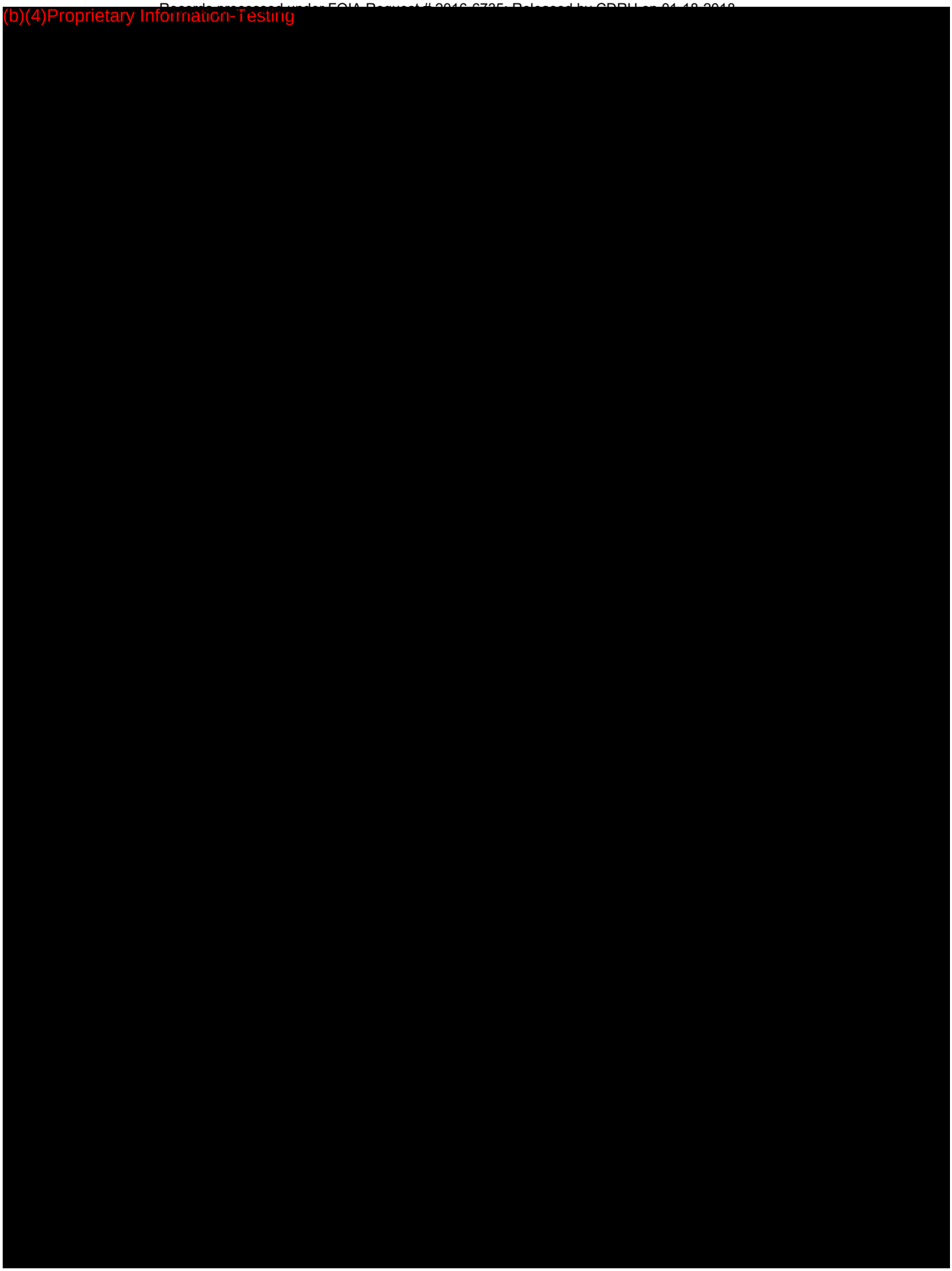
(b)(4)Proprietary Information-Testing



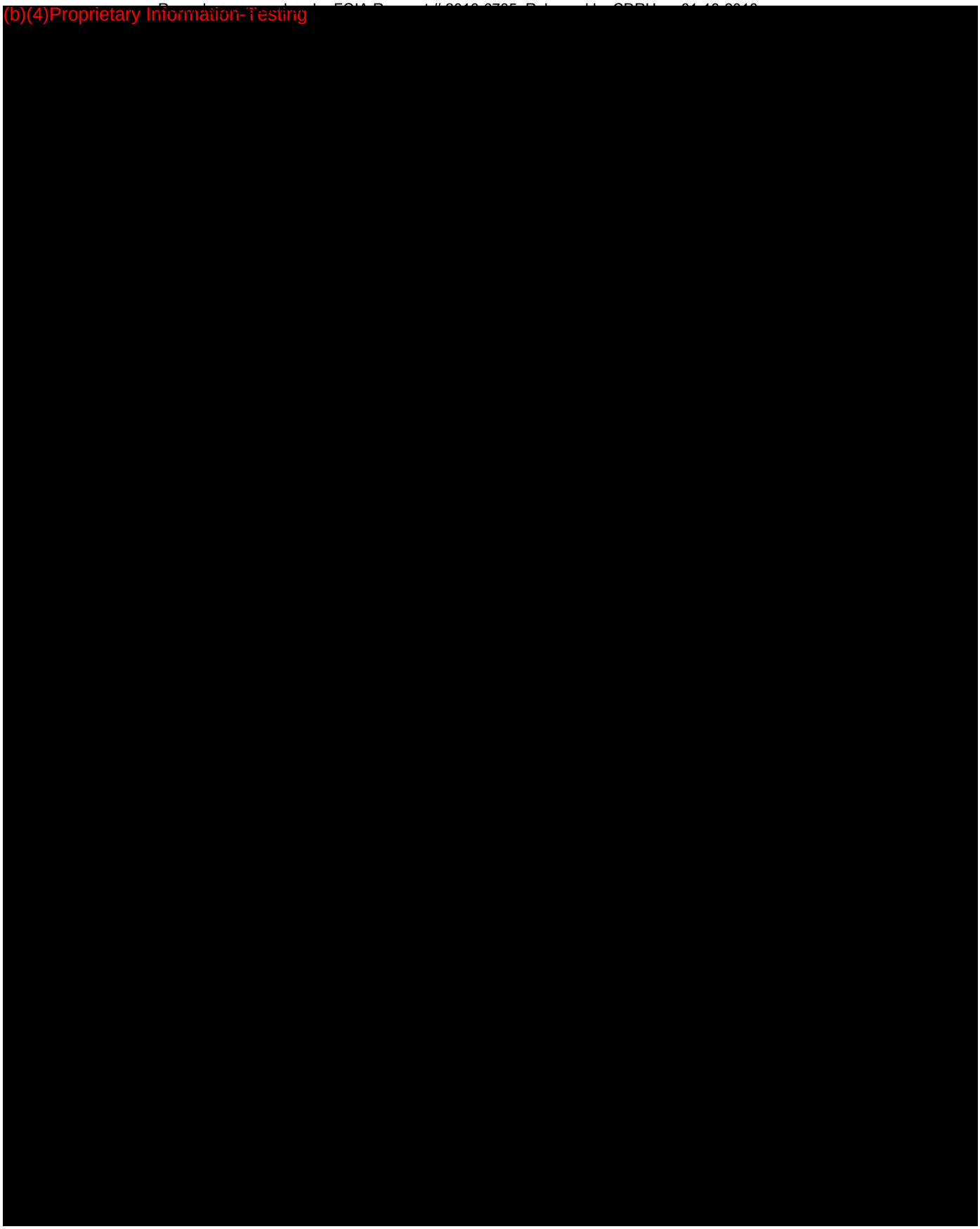
(b)(4)Proprietary Information-Testing



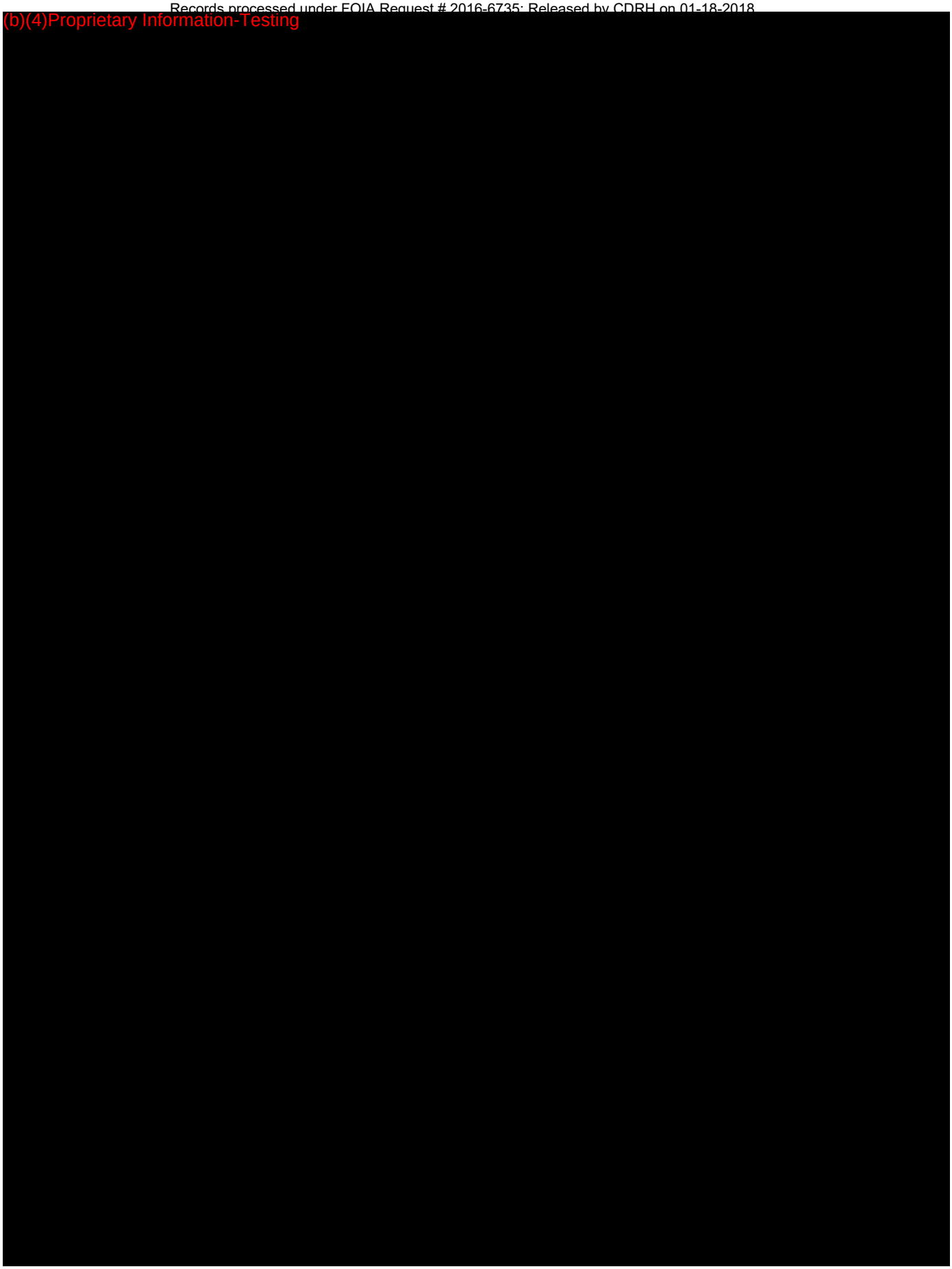
(b)(4)Proprietary Information-Testing



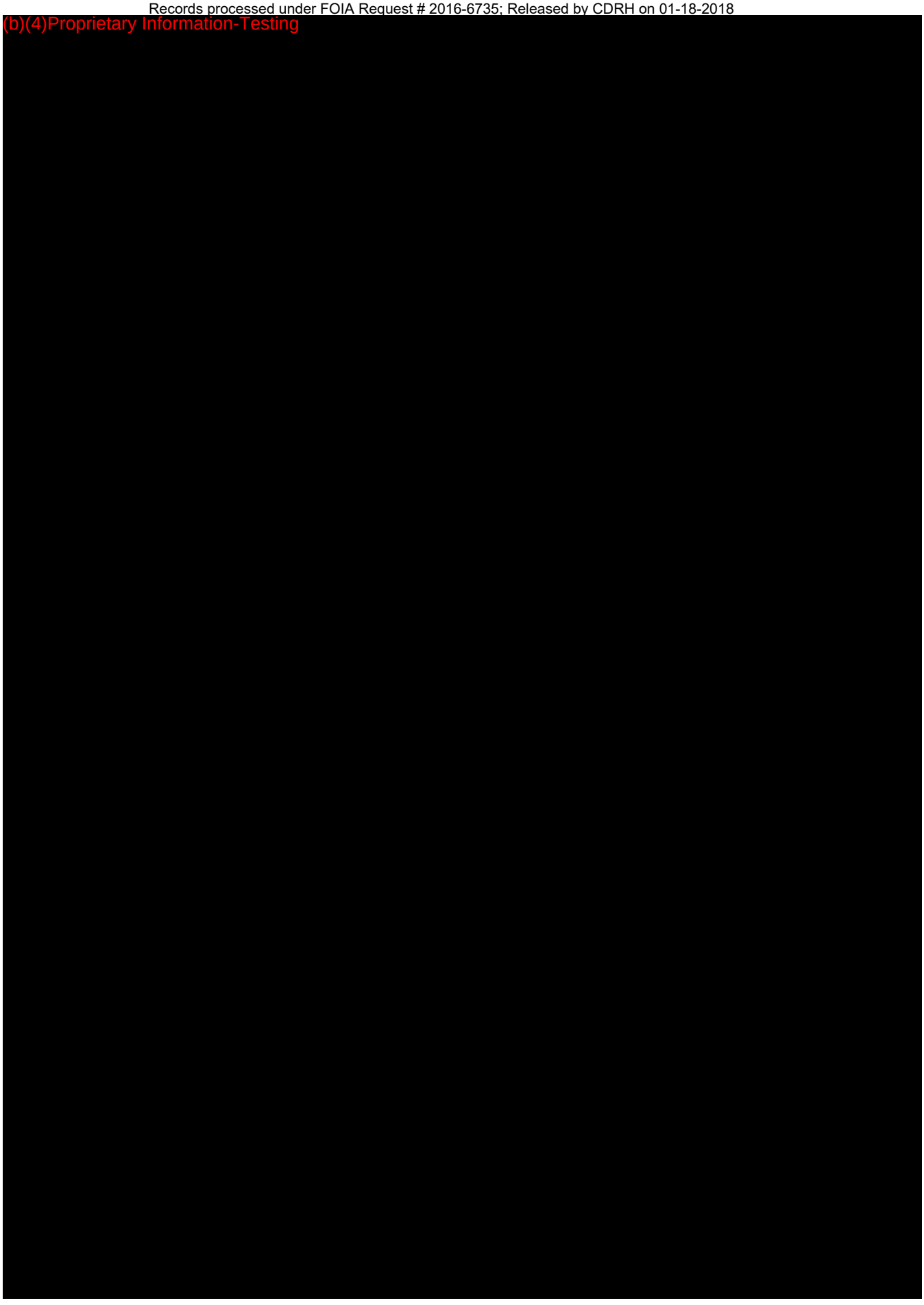
(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing

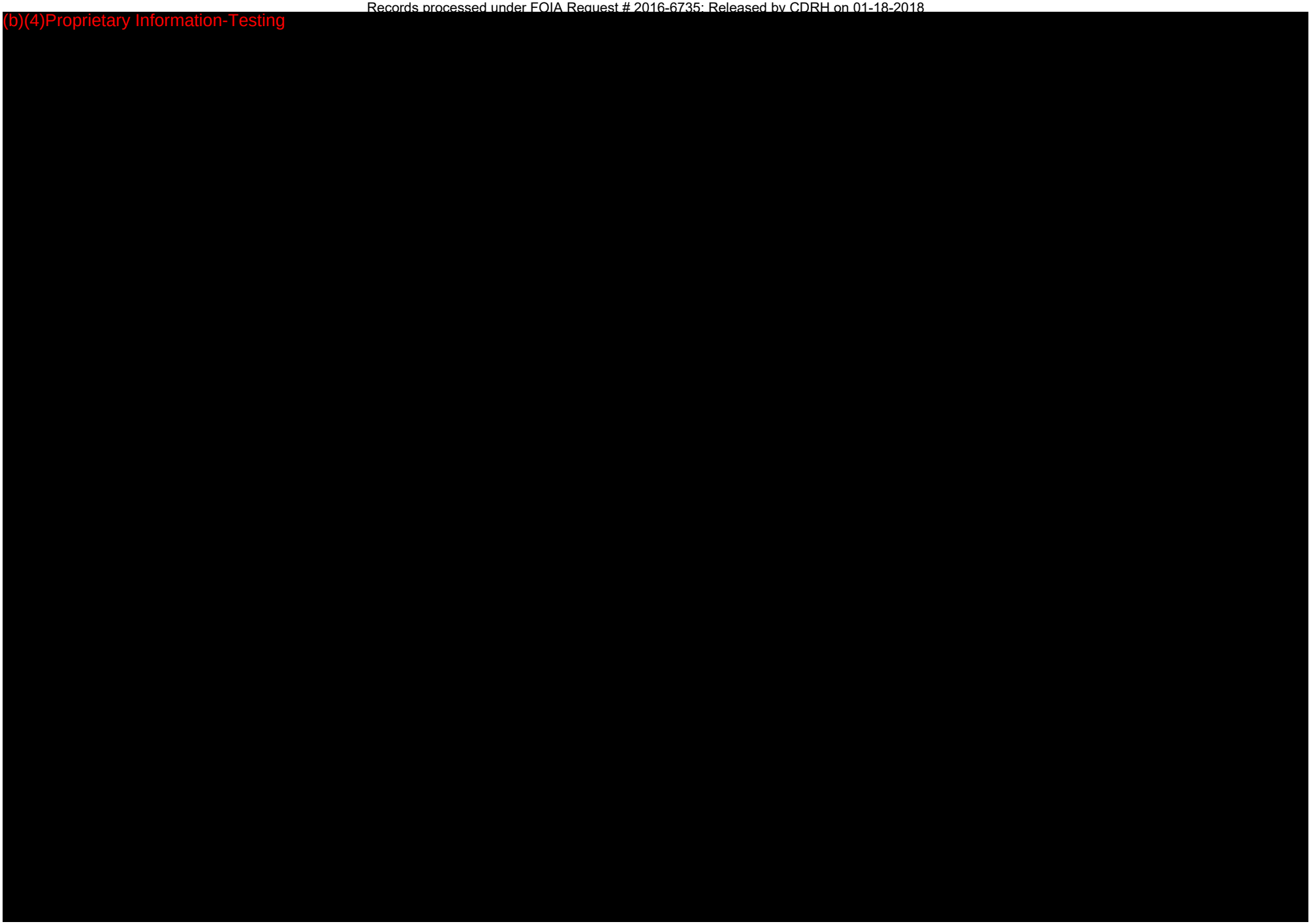


(b)(4)Proprietary Information-Testing



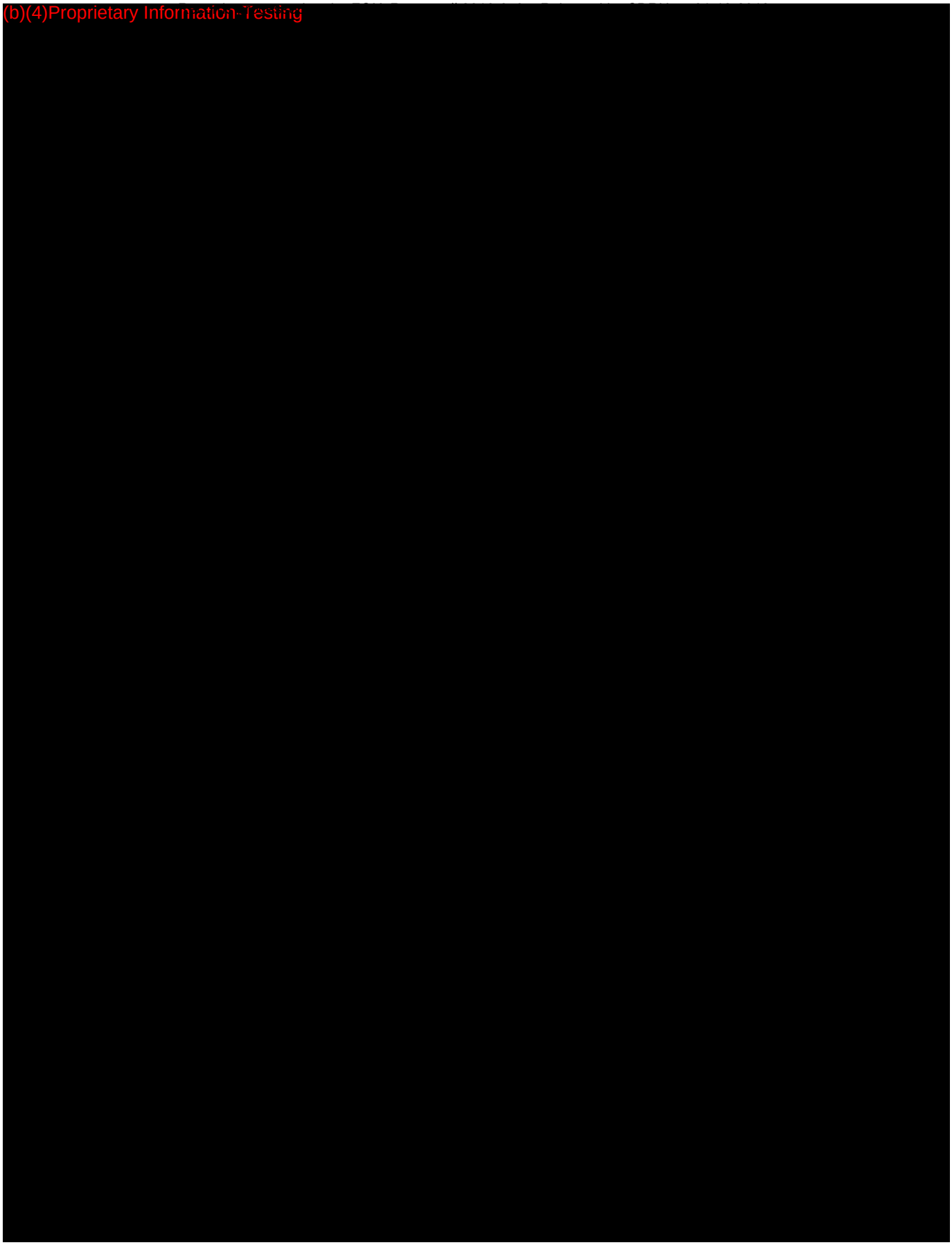
(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

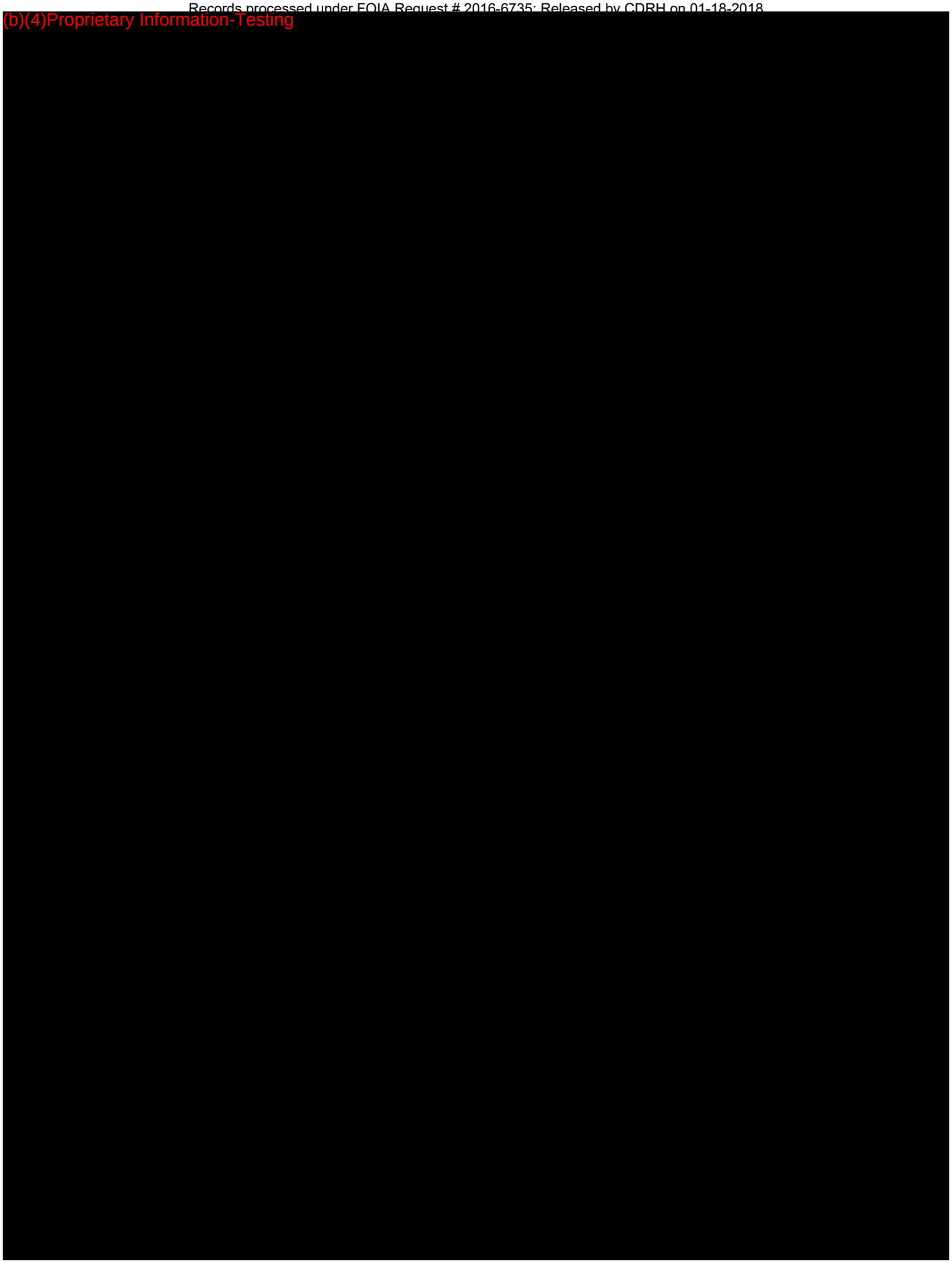


ATTACHMENT 30

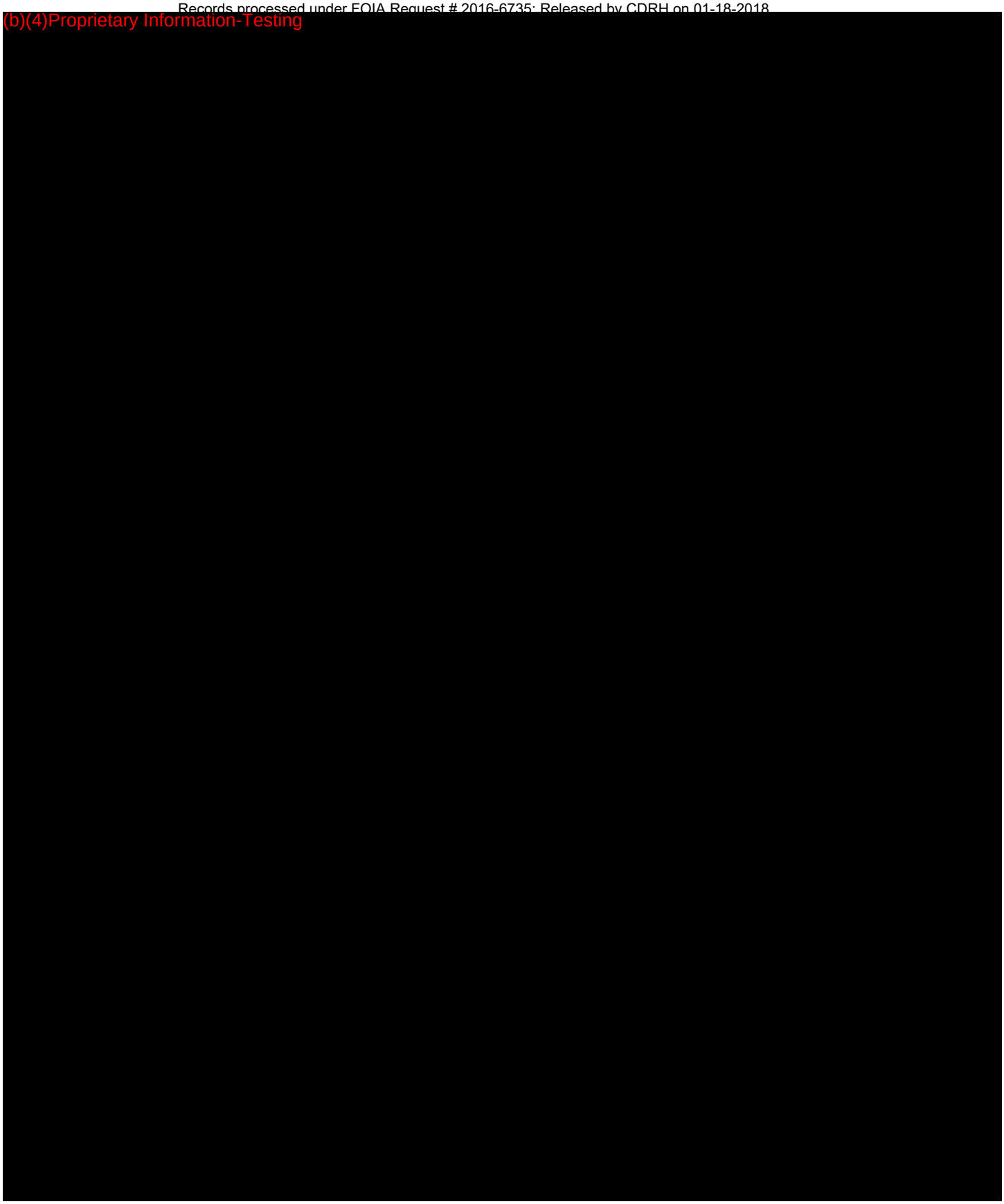
(b)(4)Proprietary Information-Testing



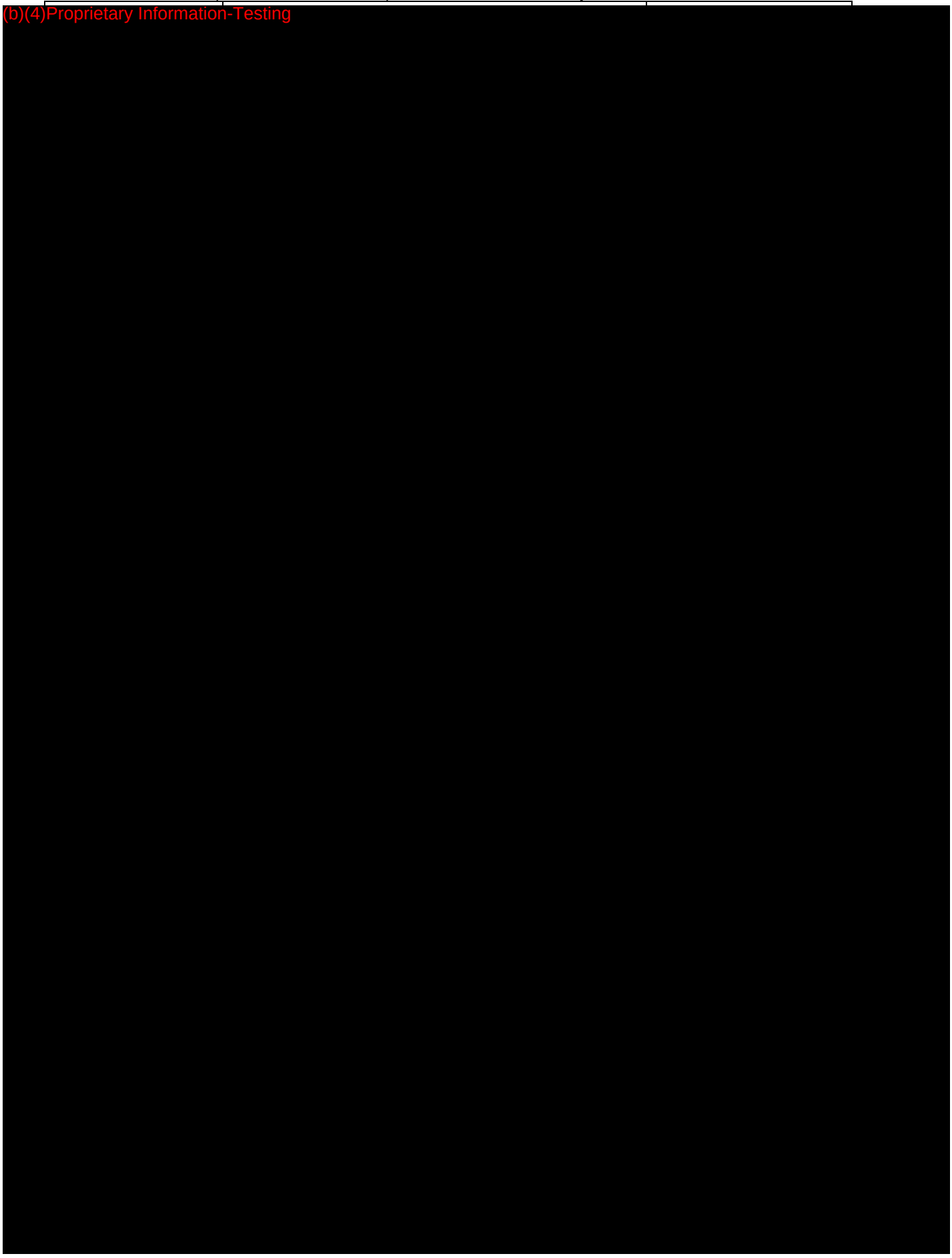
(b)(4)Proprietary Information-Testing



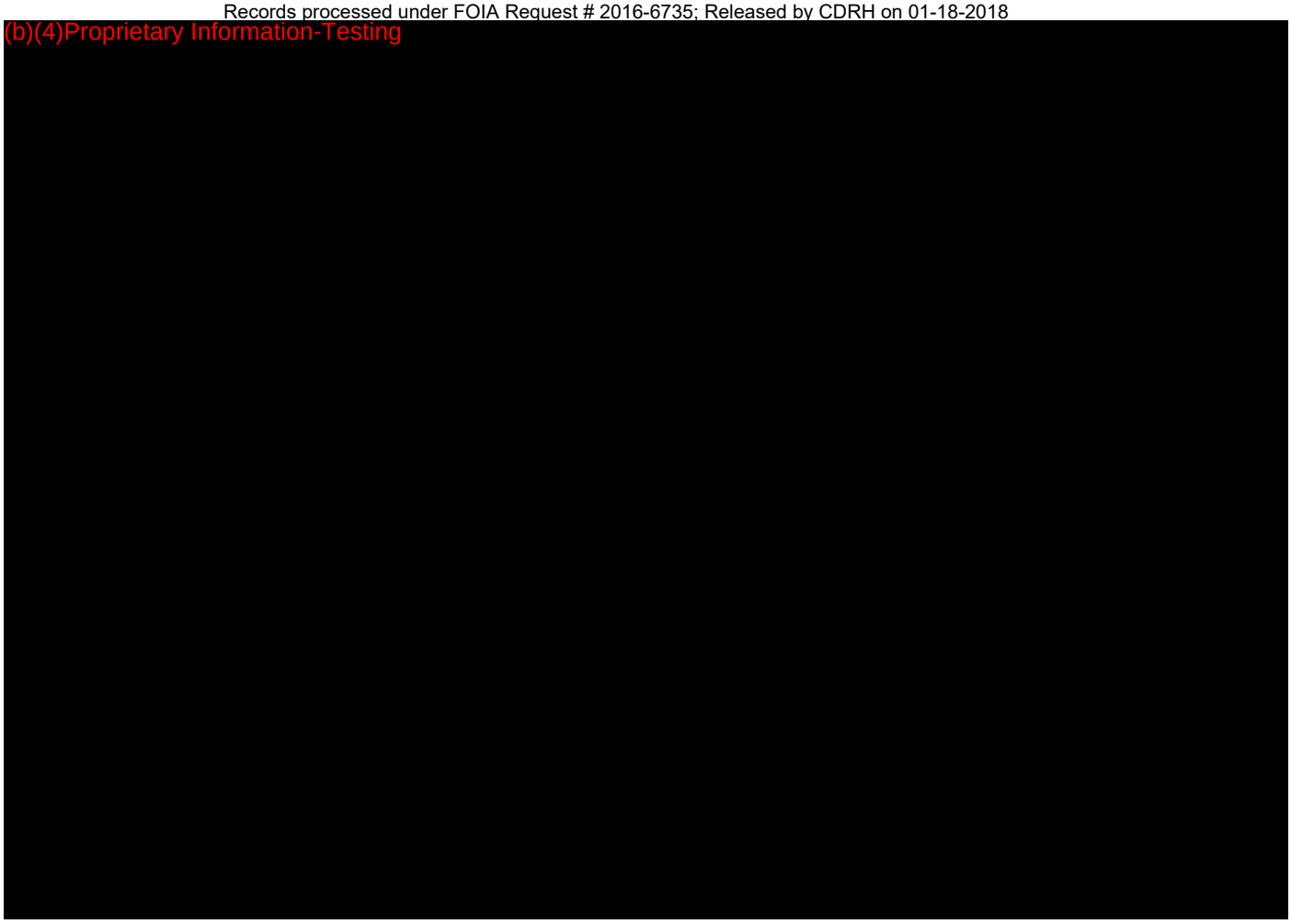
(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing

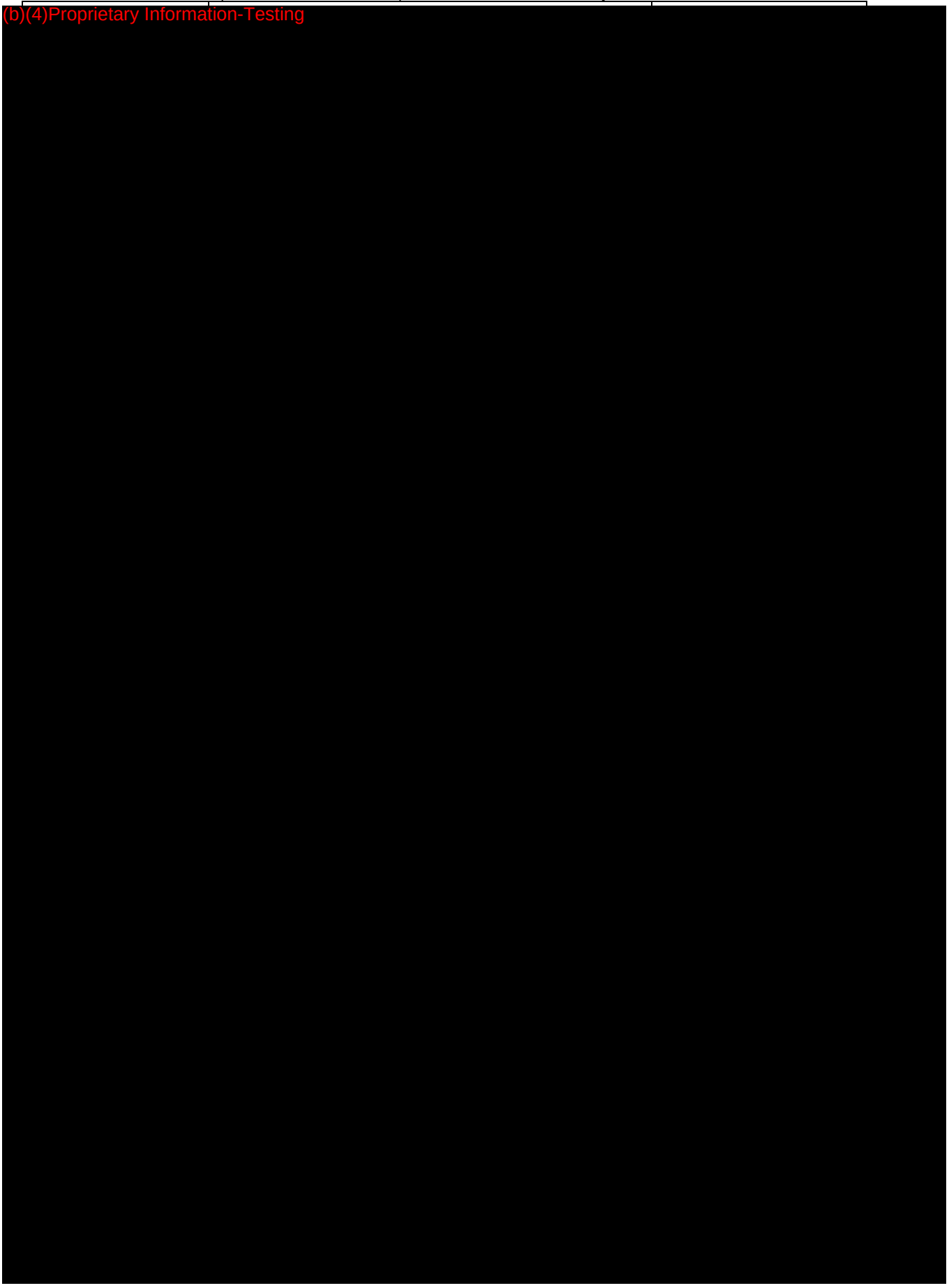


(b)(4)Proprietary Information-Testing



ATTACHMENT 31

(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing

[redacted]

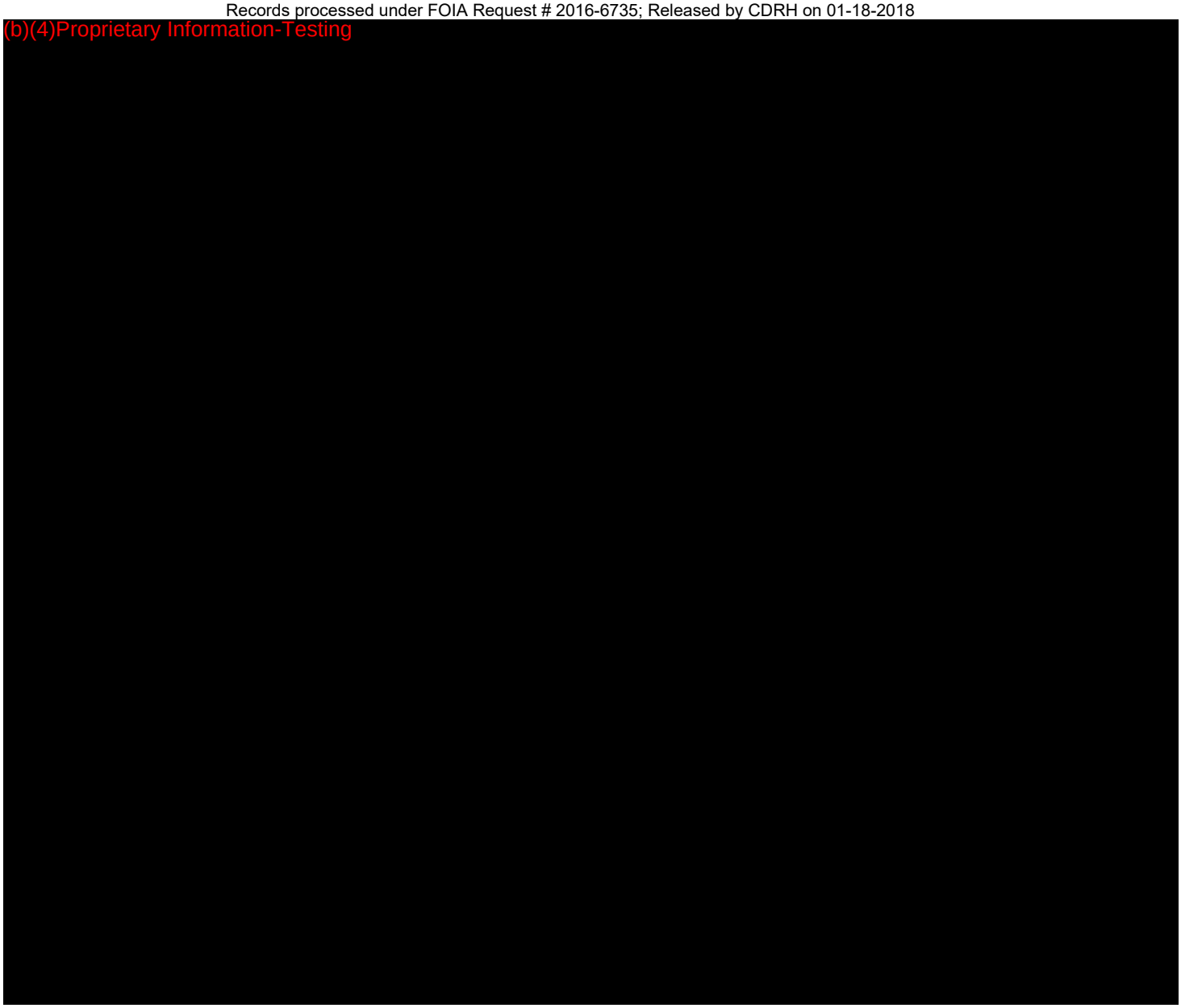
(b)(4)Proprietary Information-Testing

[redacted]

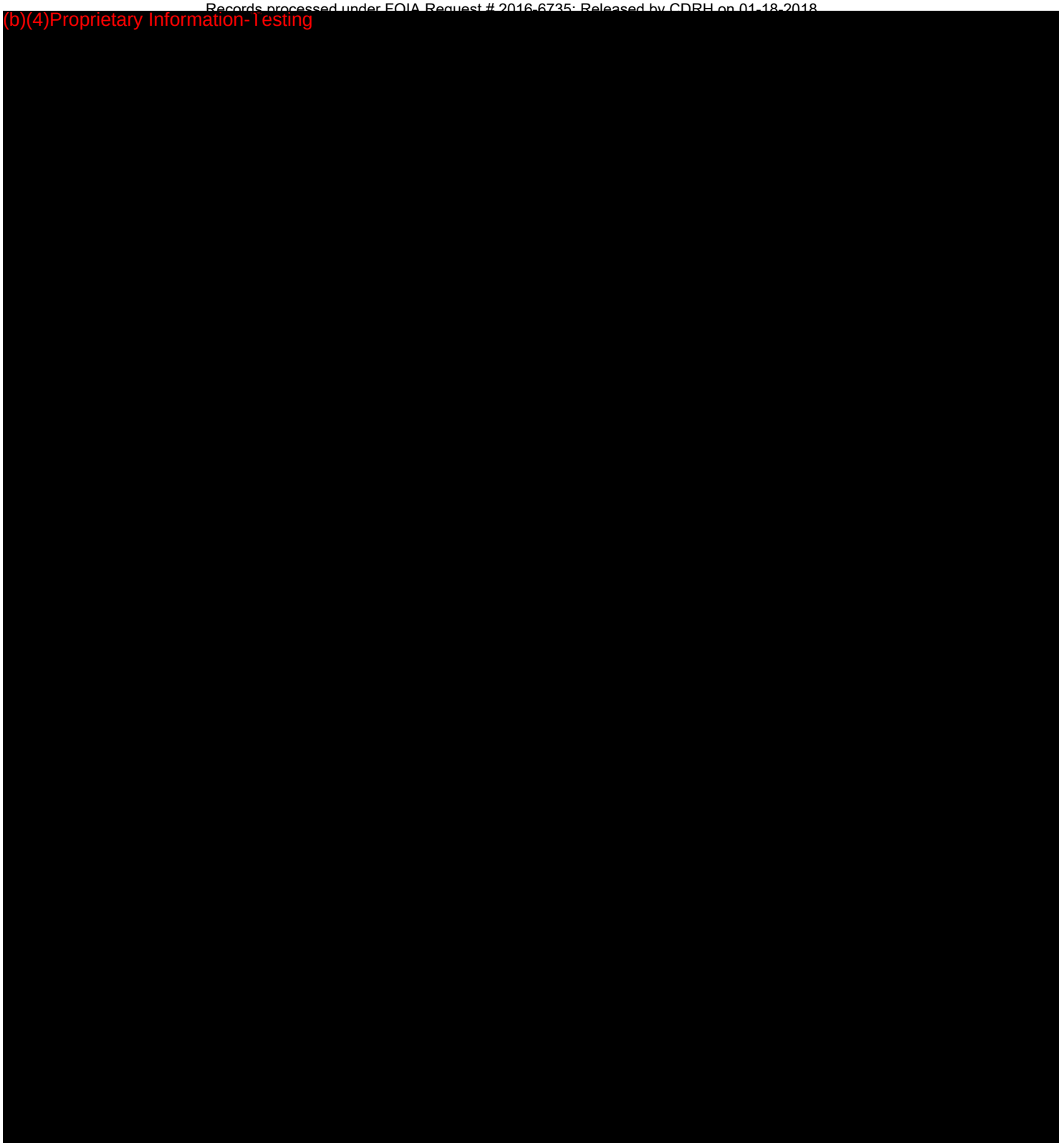
(b)(4)Proprietary Information-Testing

[redacted]

(b)(4)Proprietary Information-Testing



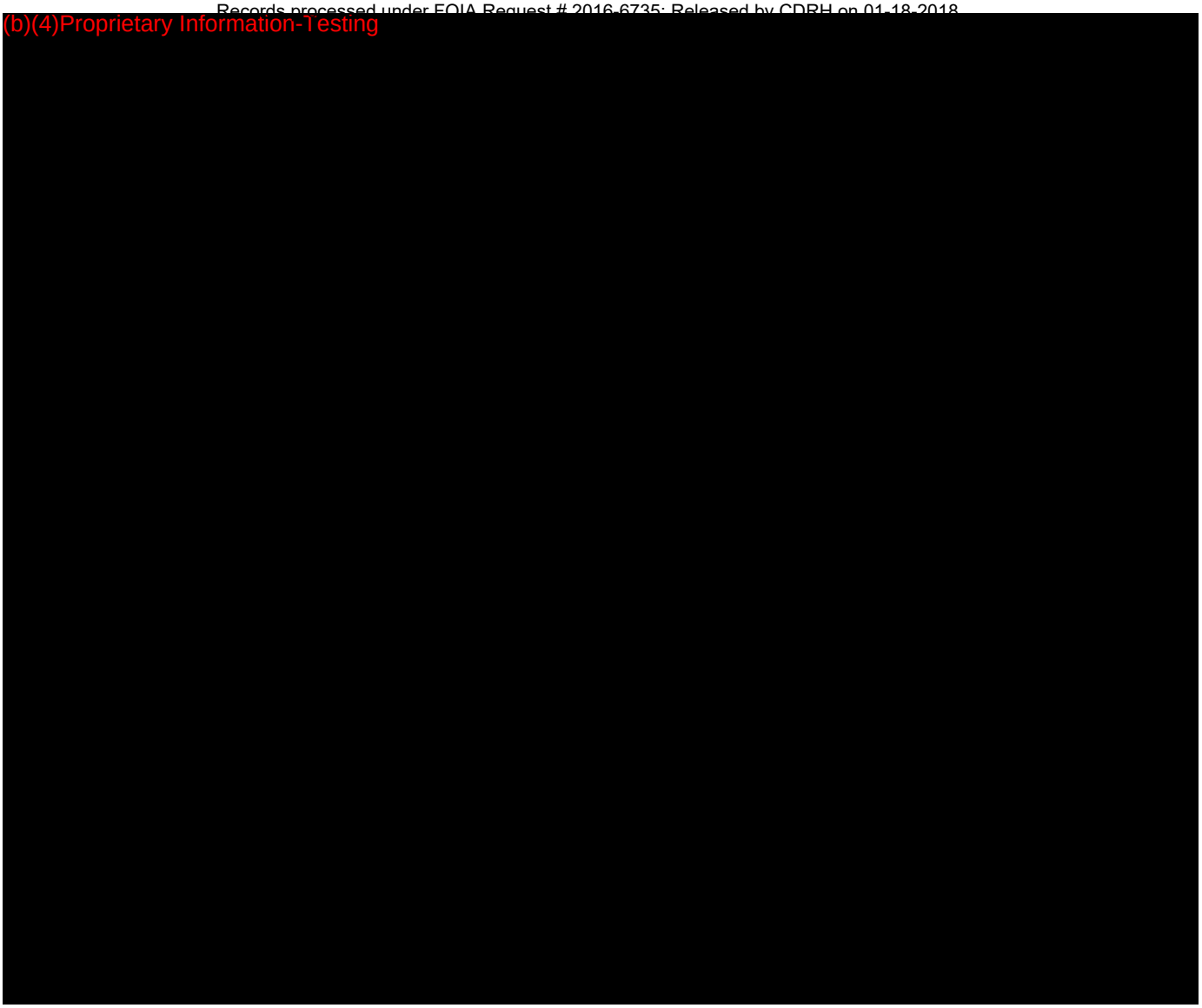
(b)(4)Proprietary Information-Testing



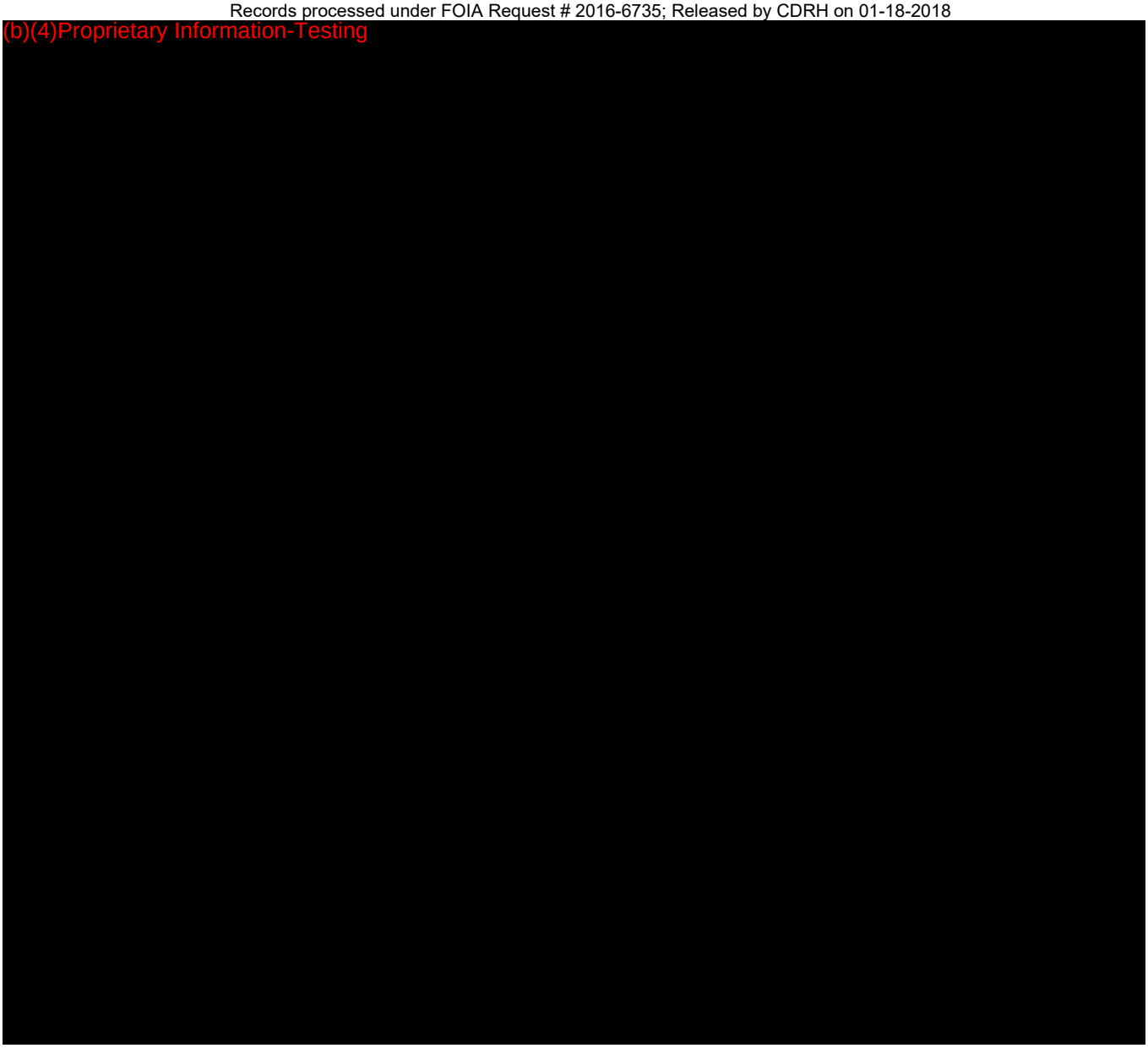
(b)(4)Proprietary Information-Testing

[redacted]

(b)(4)Proprietary Information-Testing



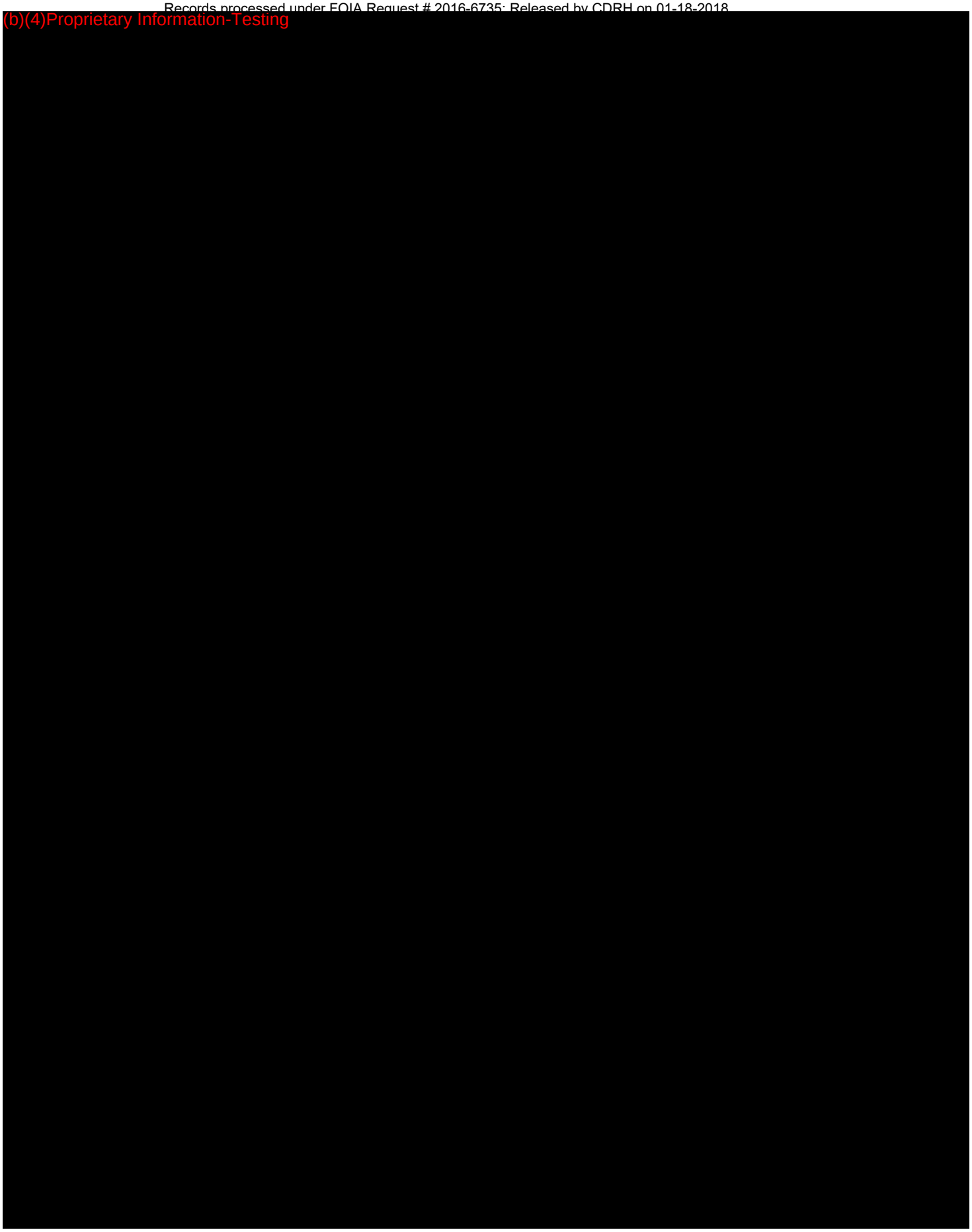
(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing

ATTACHMENT 32

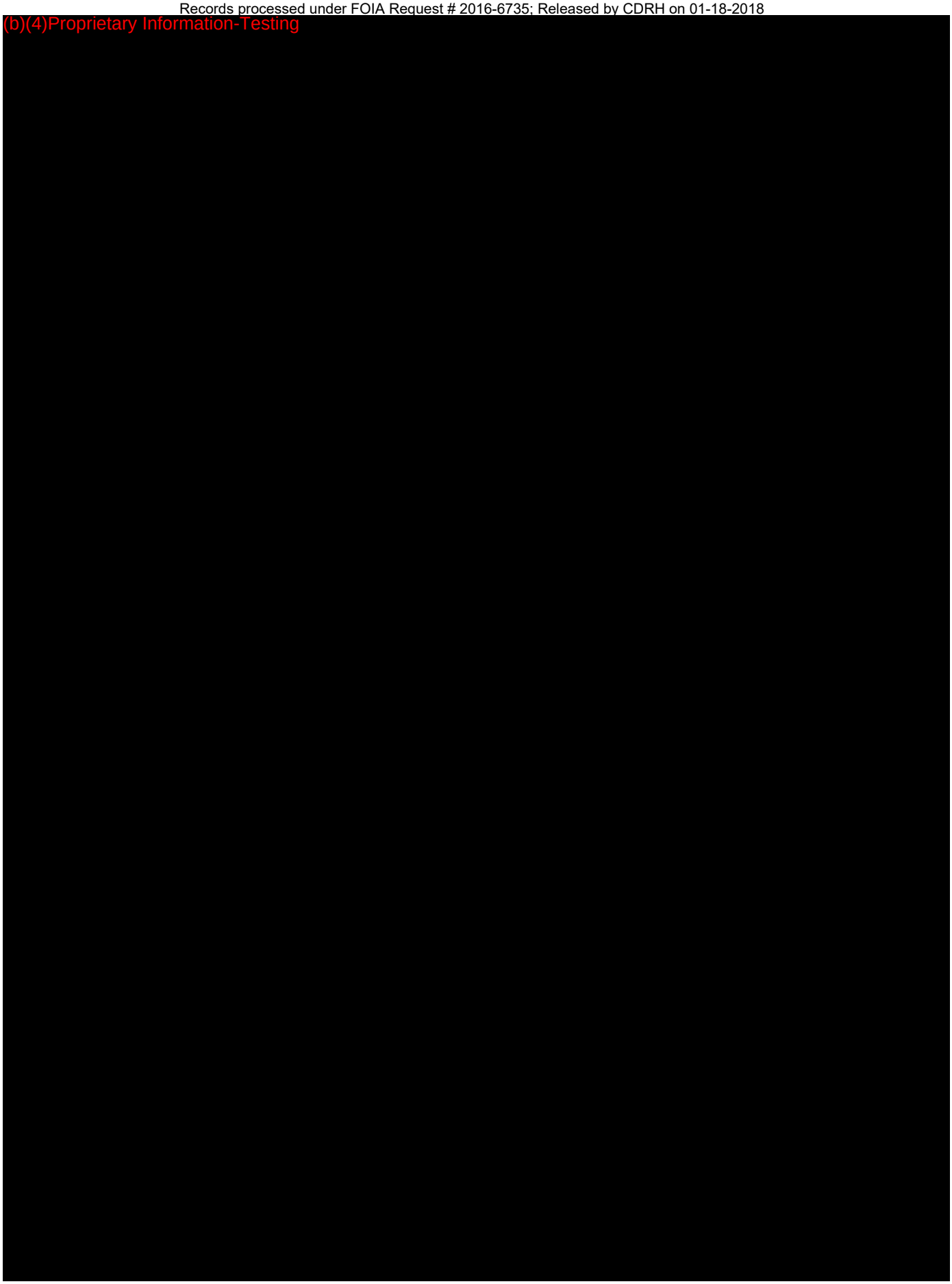
(b)(4)Proprietary Information-Testing



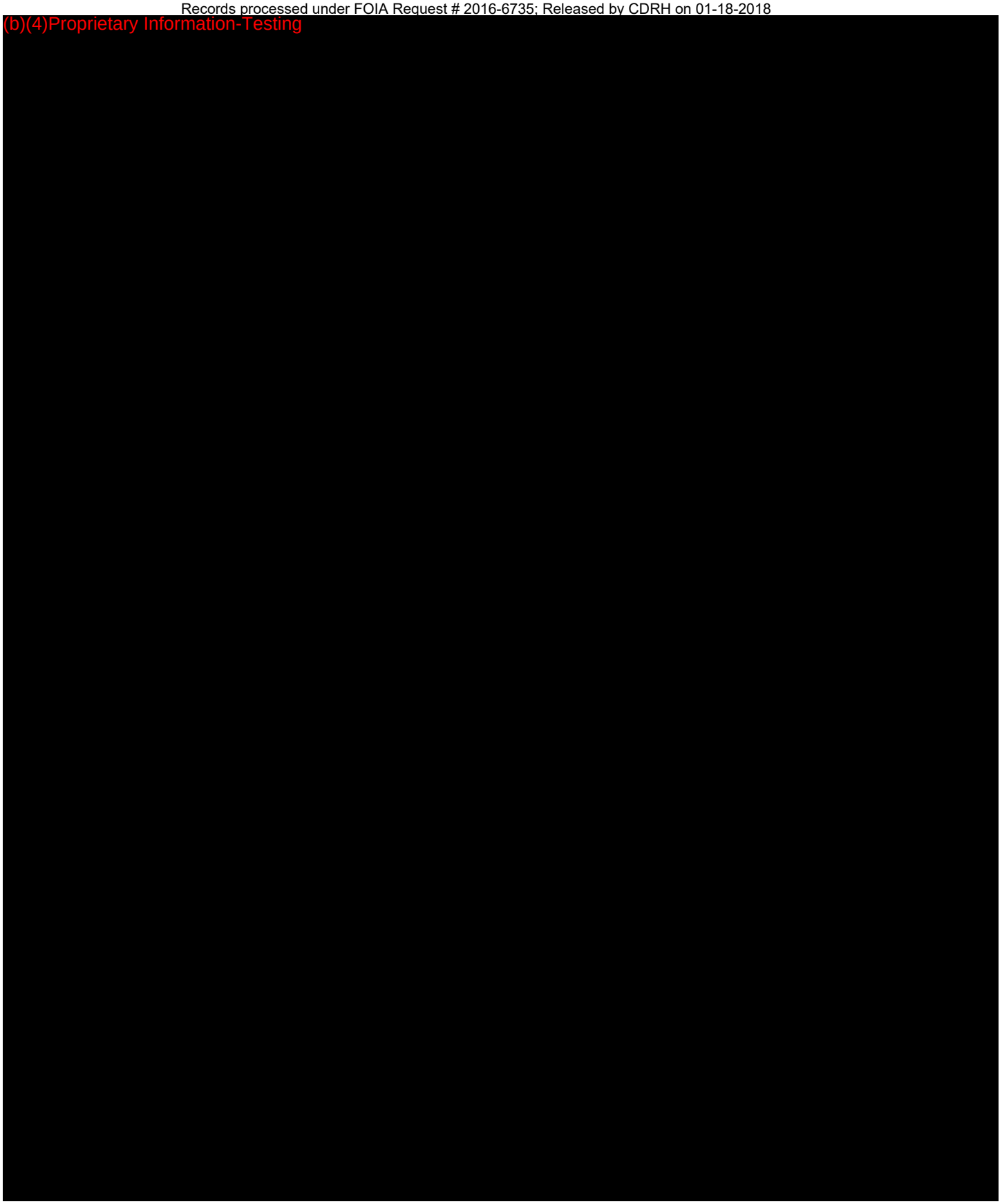
(b)(4)Proprietary Information-Testing

[redacted]

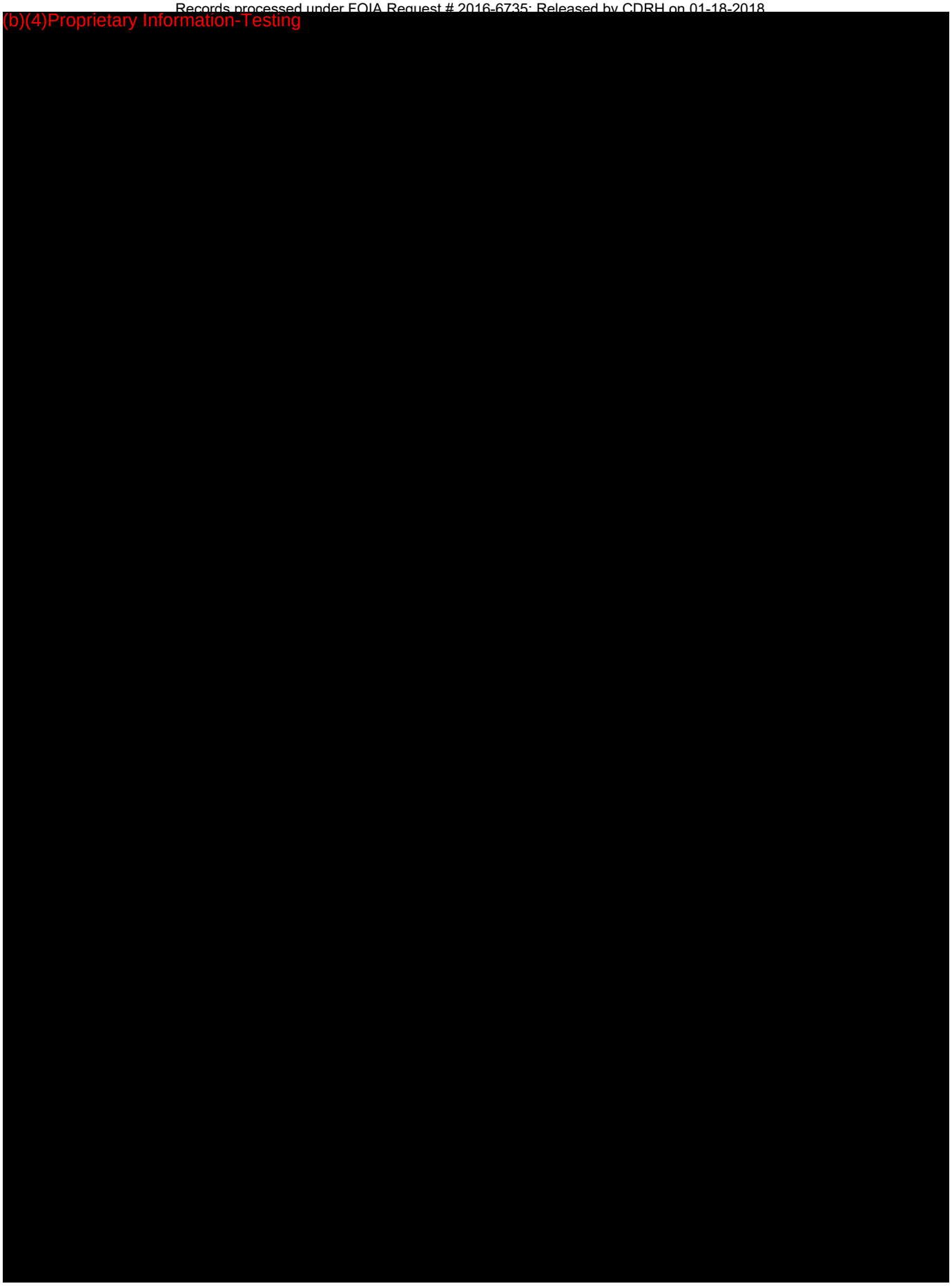
(b)(4)Proprietary Information-Testing



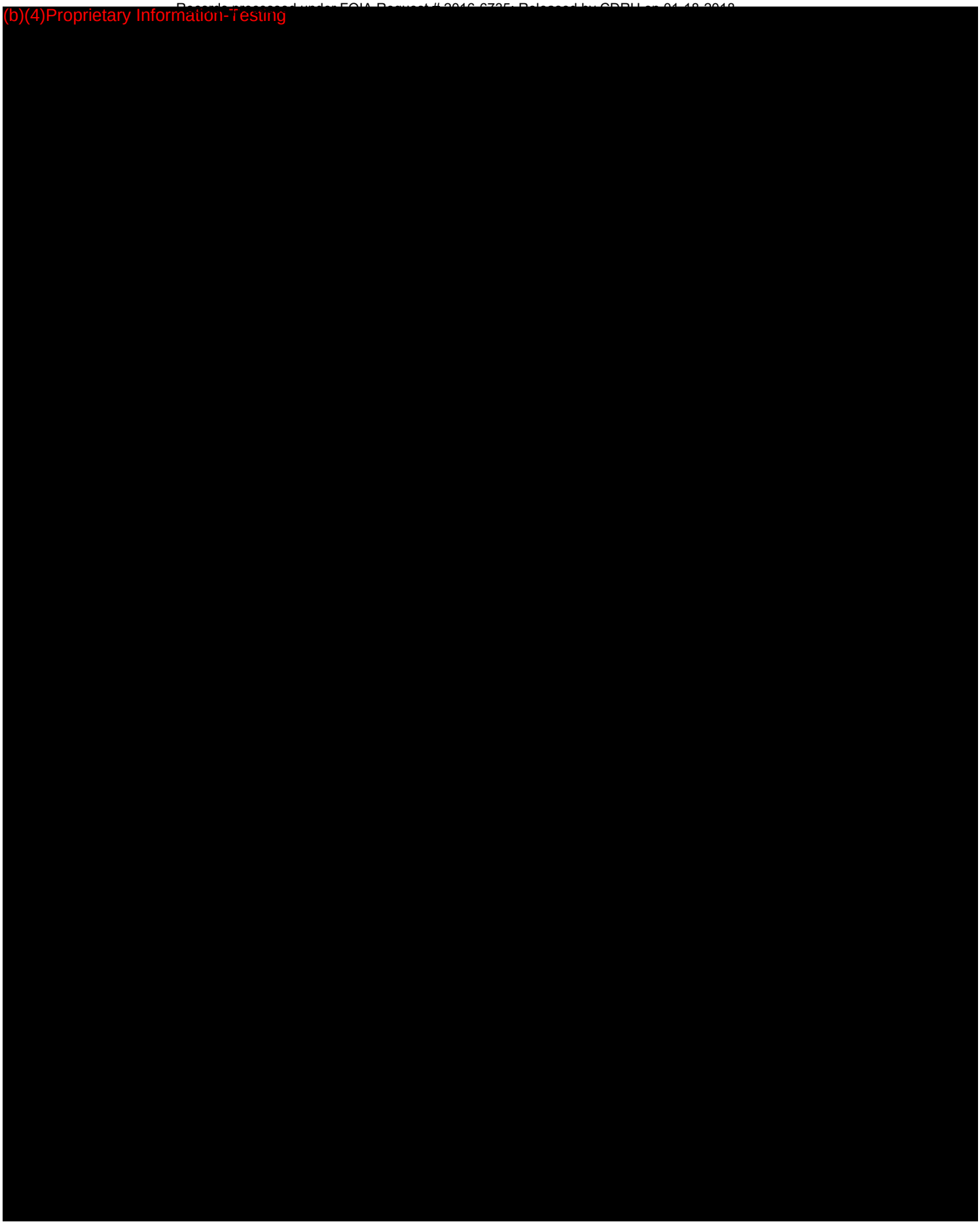
(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing

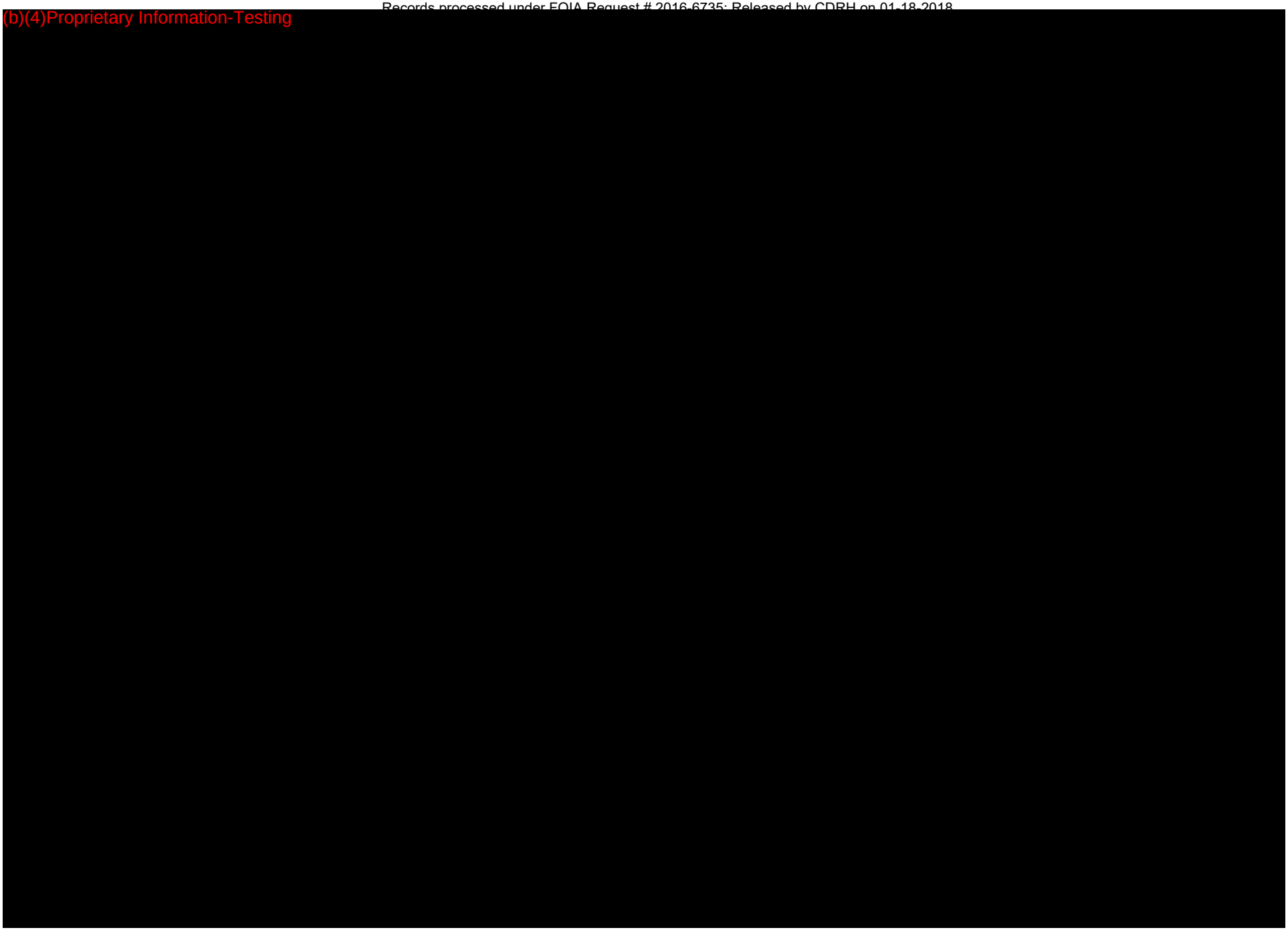


(b)(4)Proprietary Information-Testing

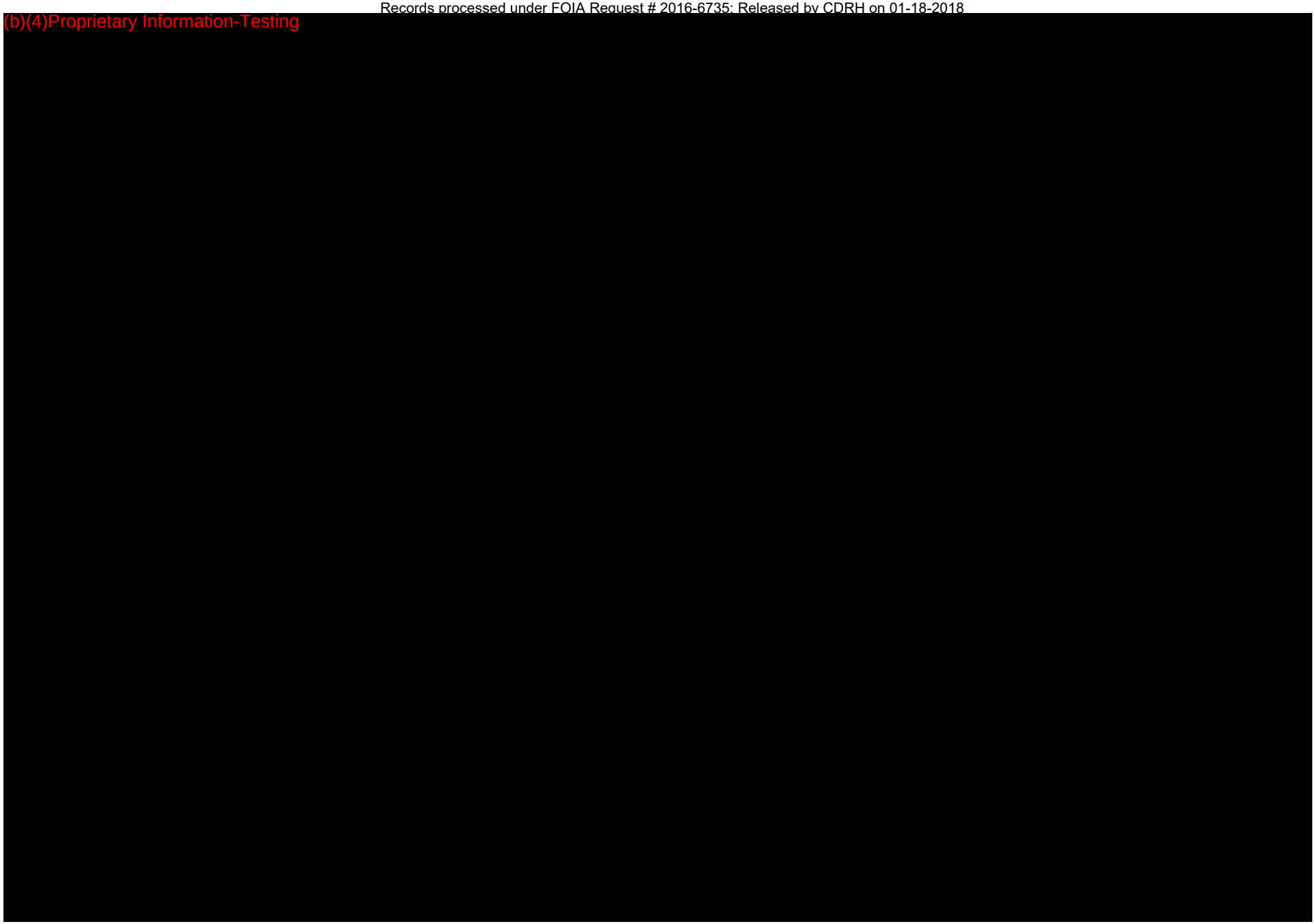


(b)(4)Proprietary Information-Testing

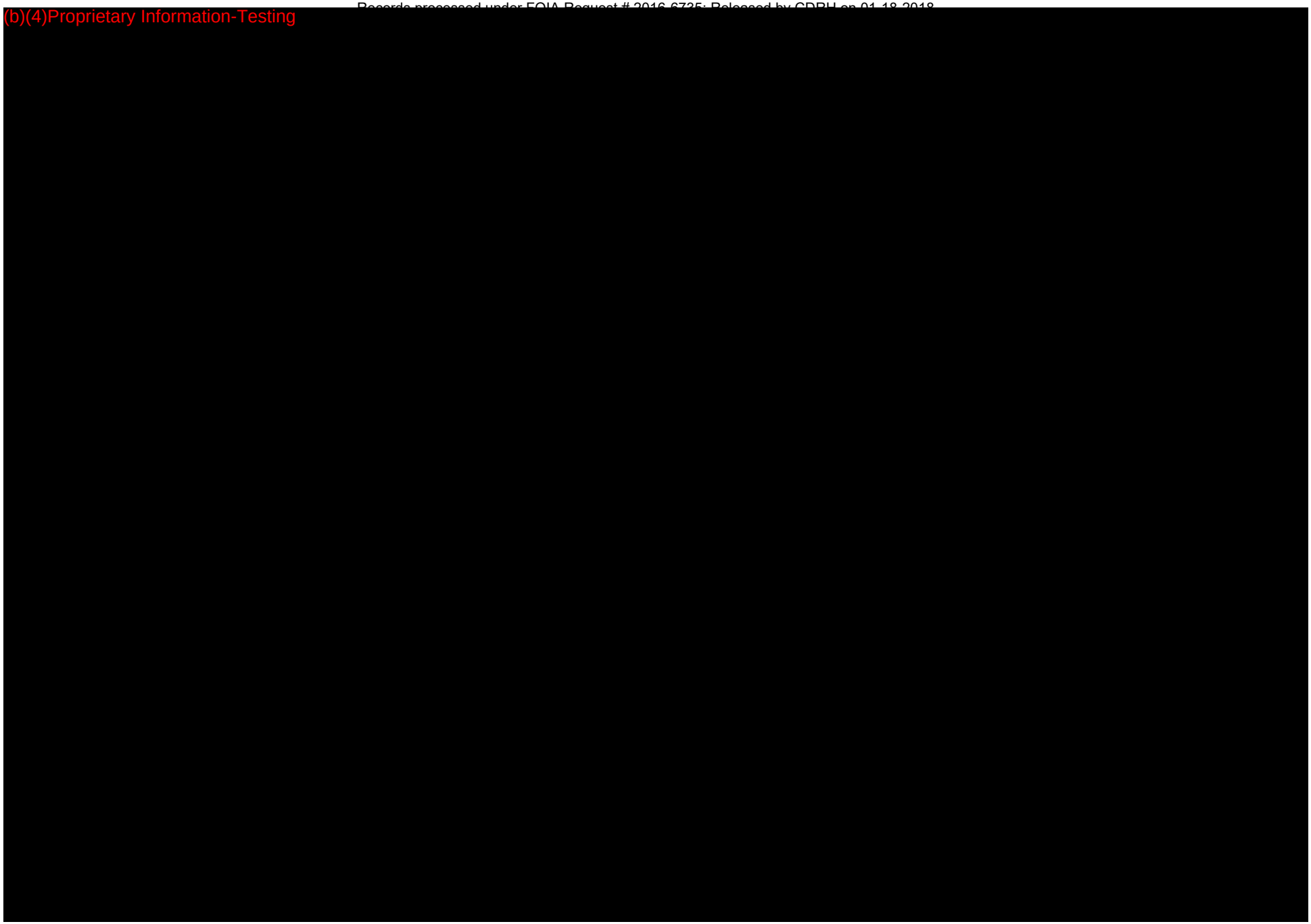
(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing



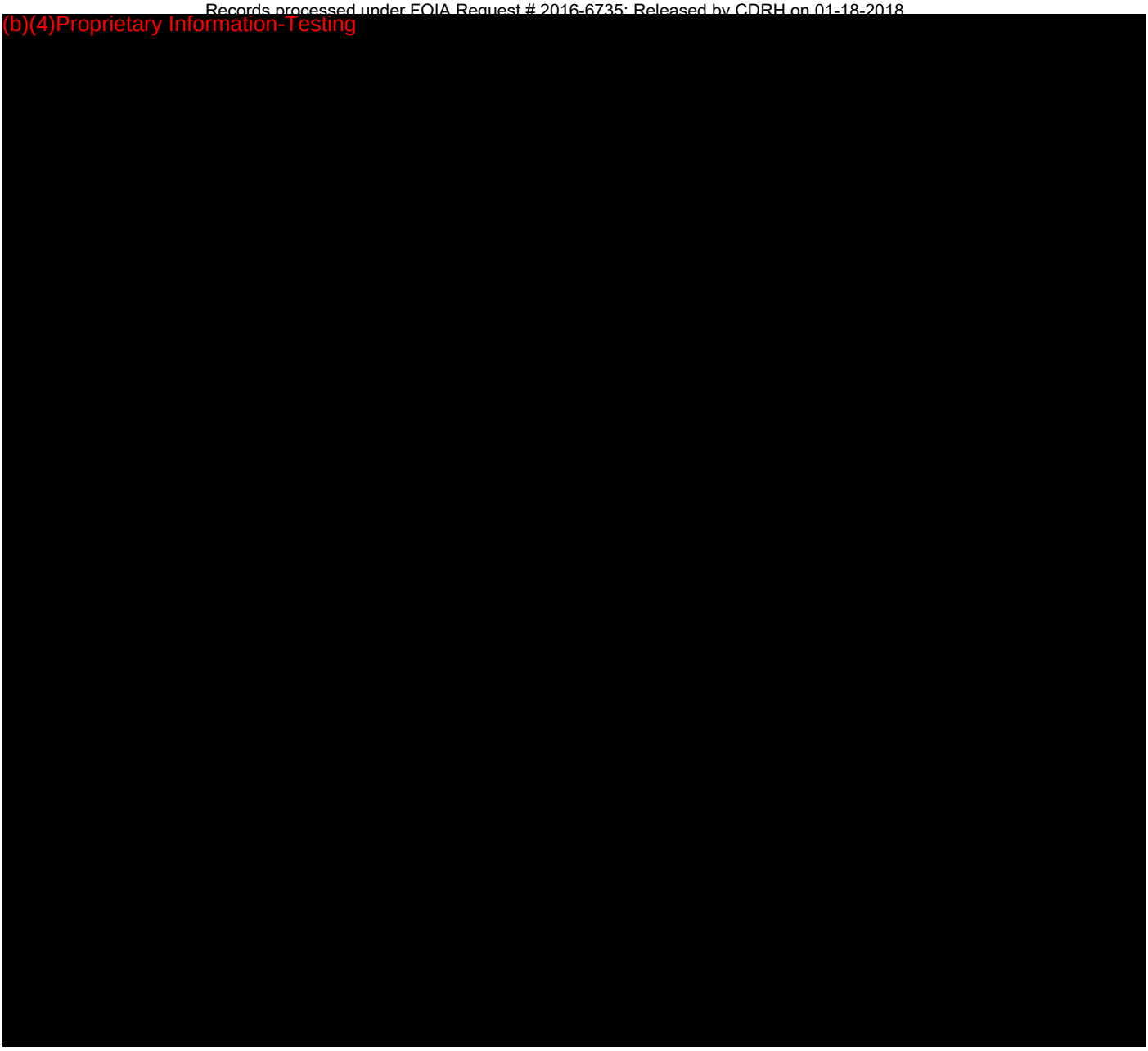
(b)(4)Proprietary Information-Testing



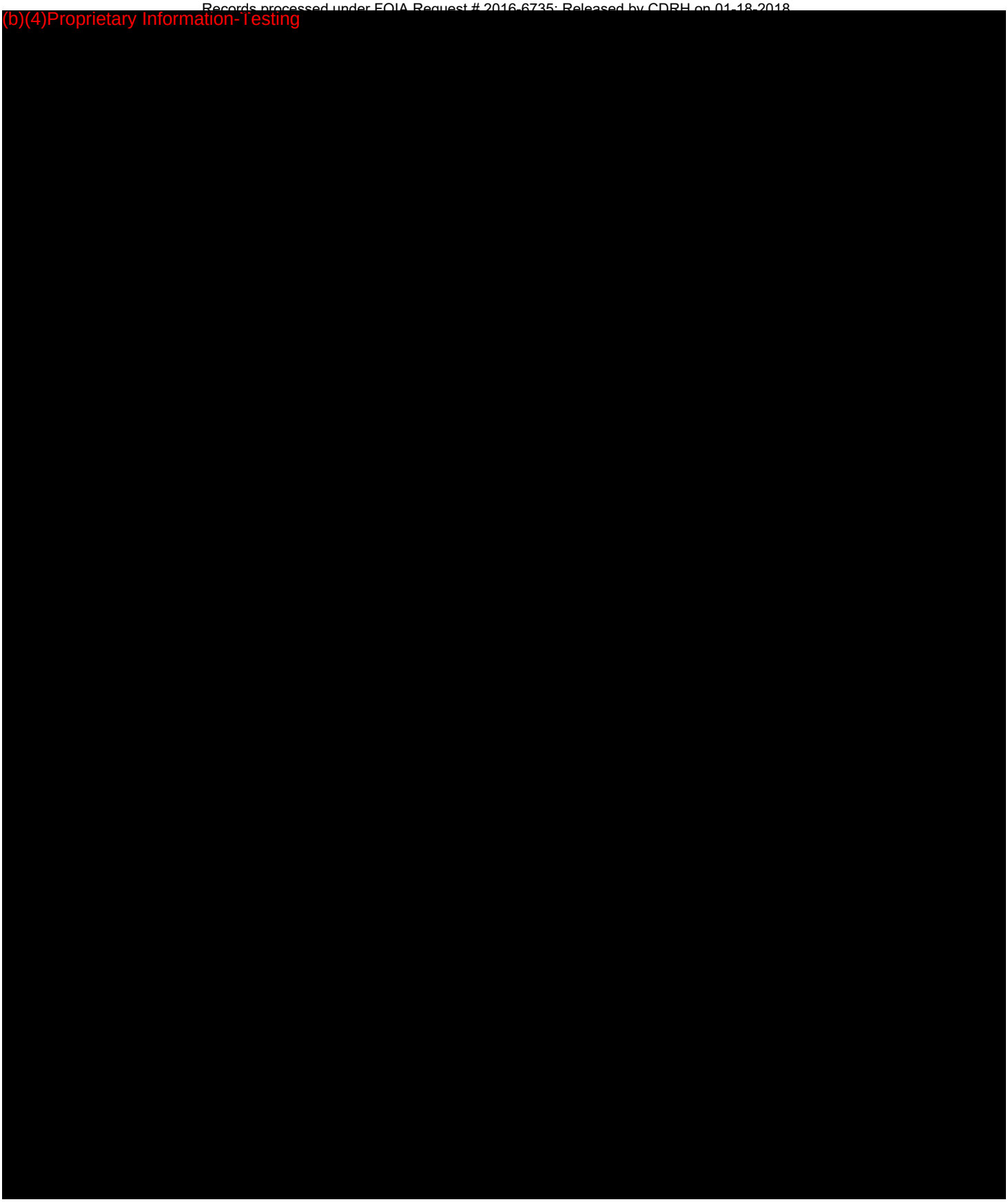
(b)(4)Proprietary Information-Testing

ATTACHMENT 33

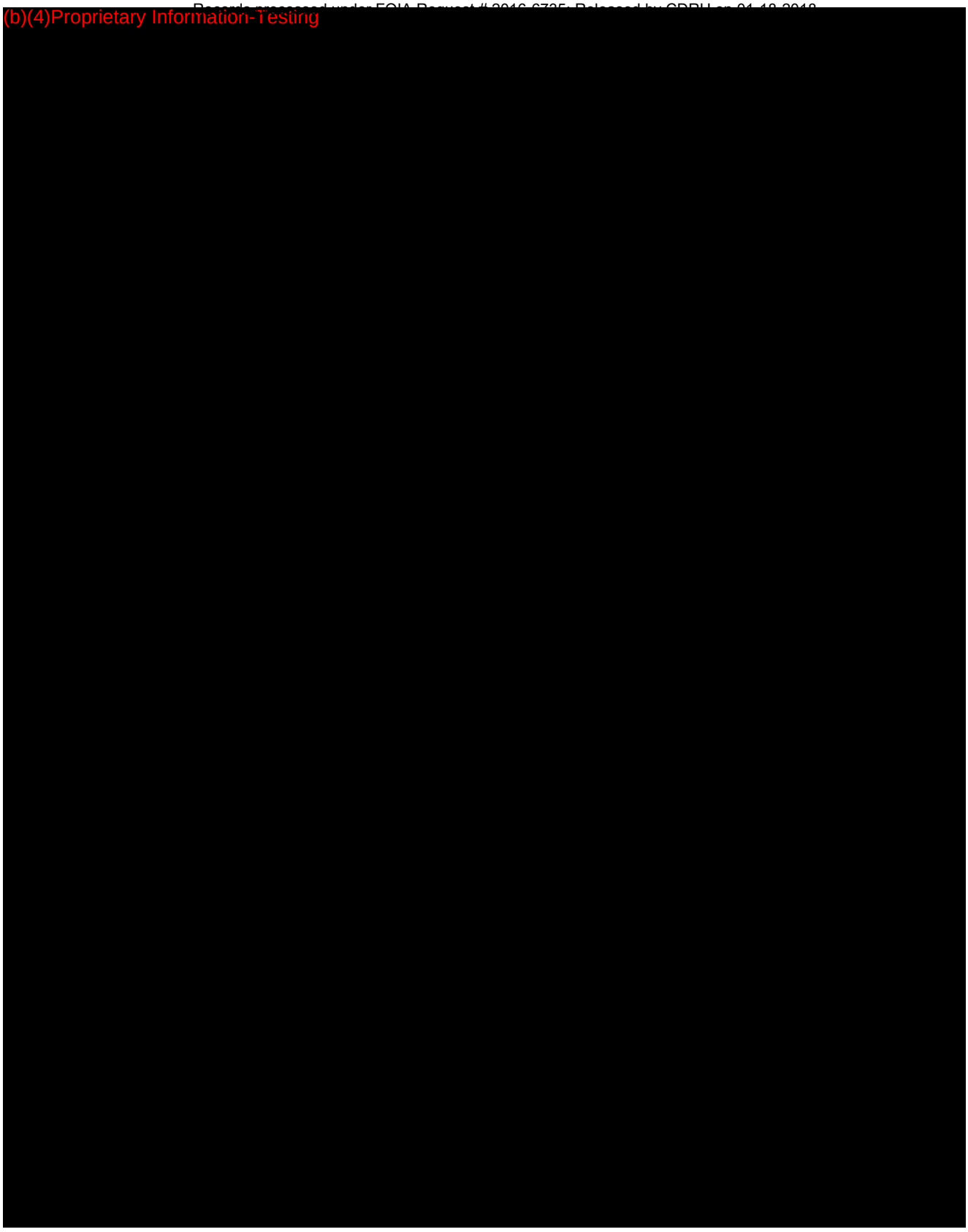
(b)(4)Proprietary Information-Testing



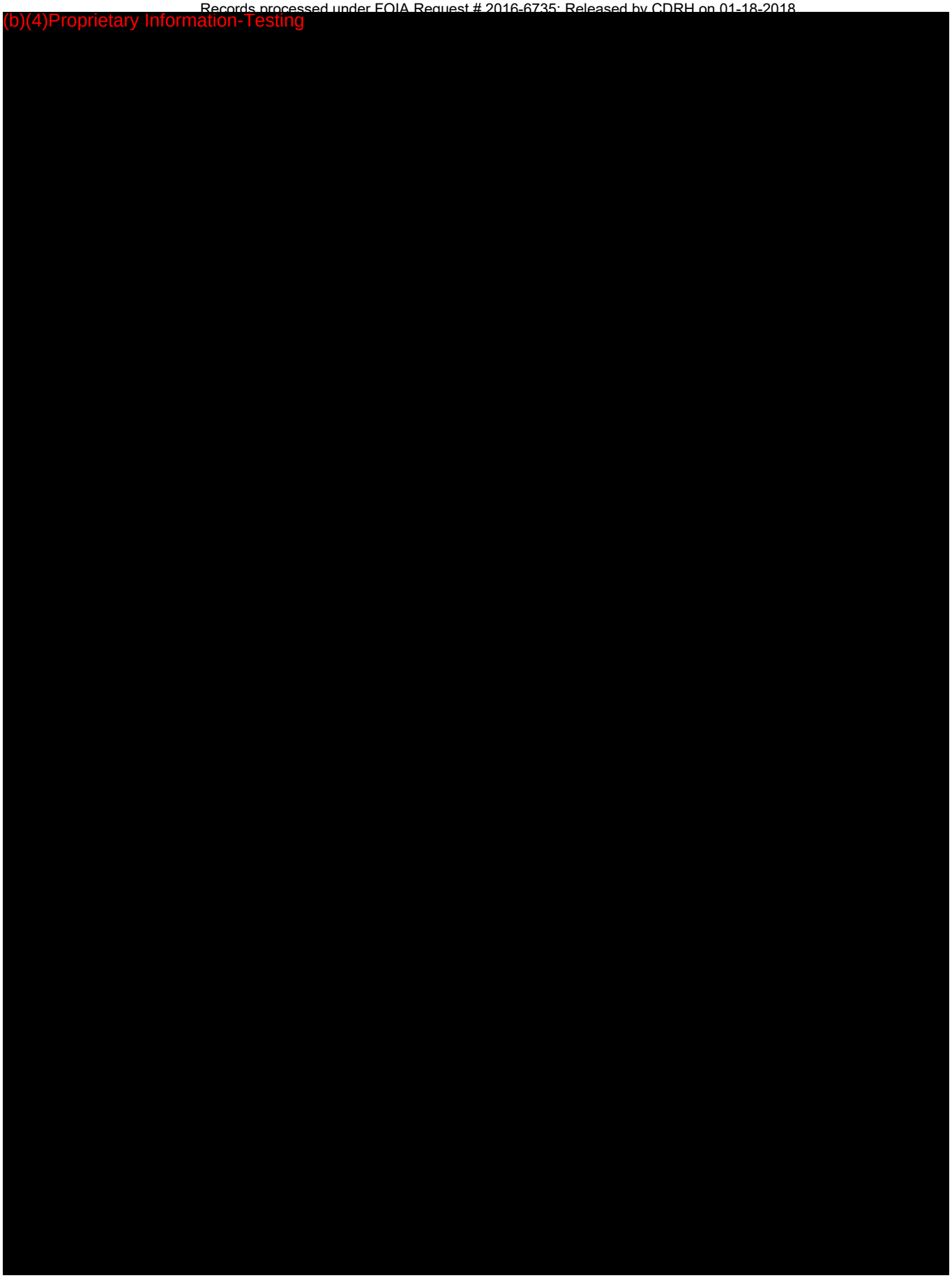
(b)(4)Proprietary Information-Testing



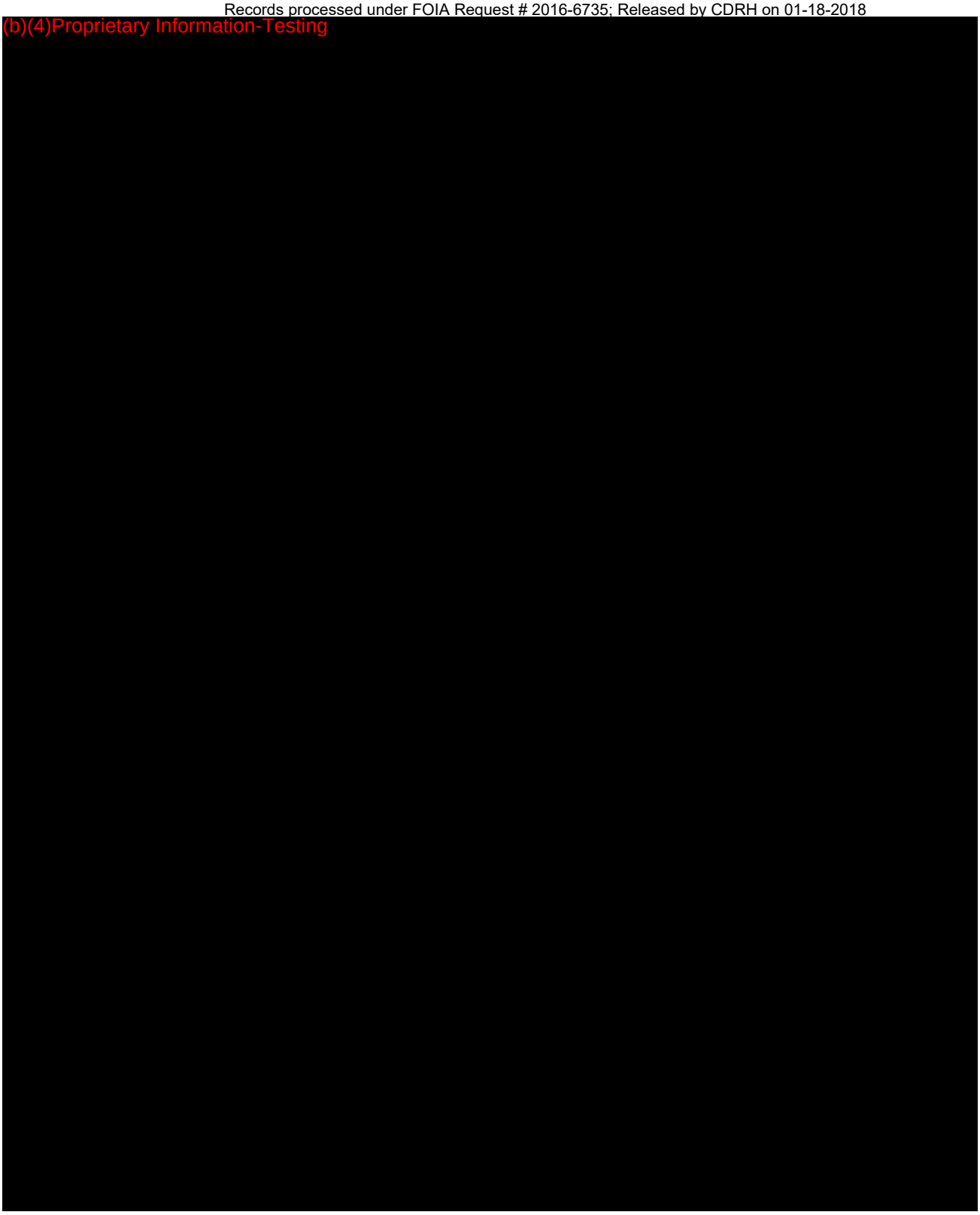
(b)(4)Proprietary Information-Testing



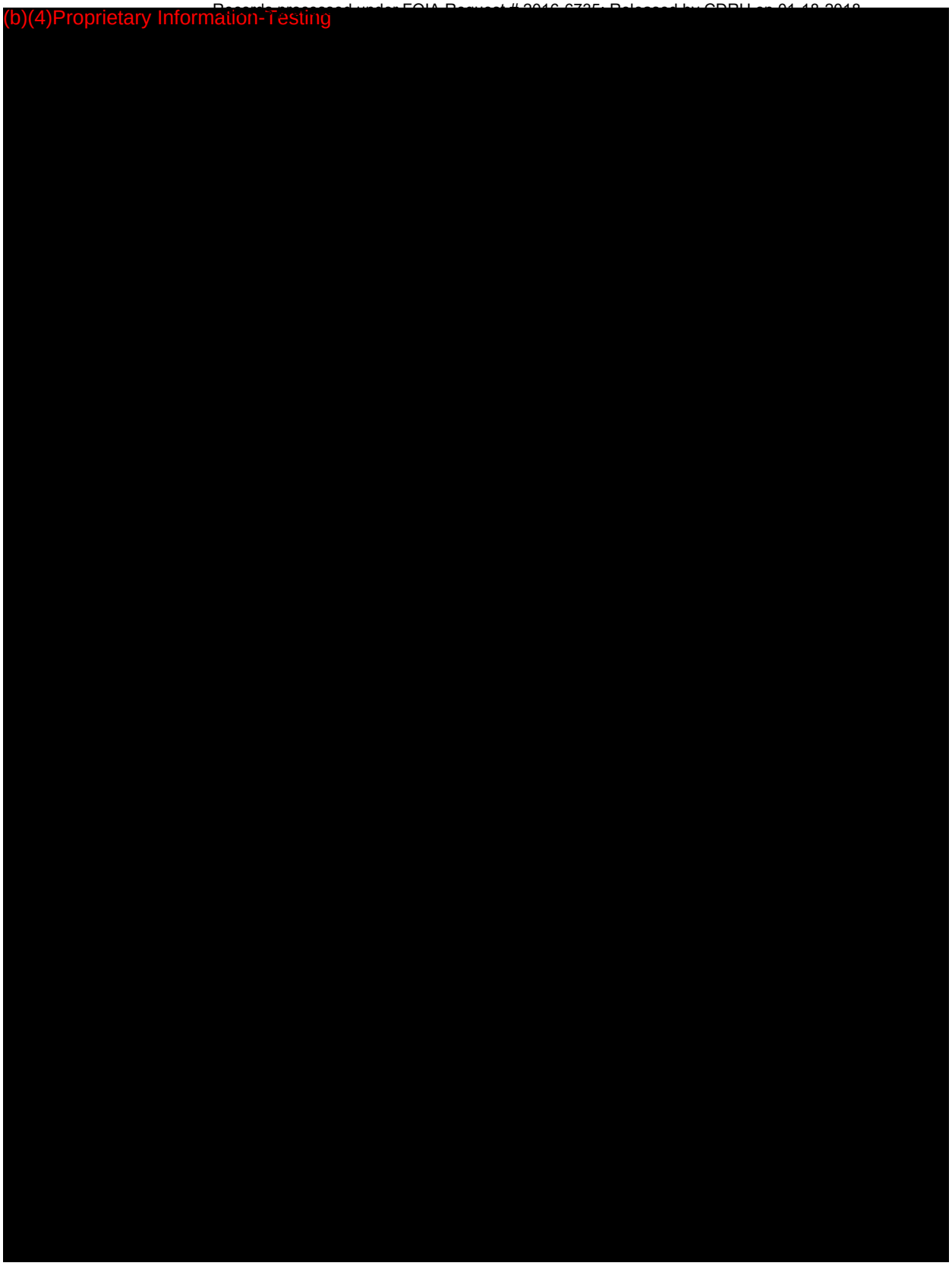
(b)(4)Proprietary Information-Testing



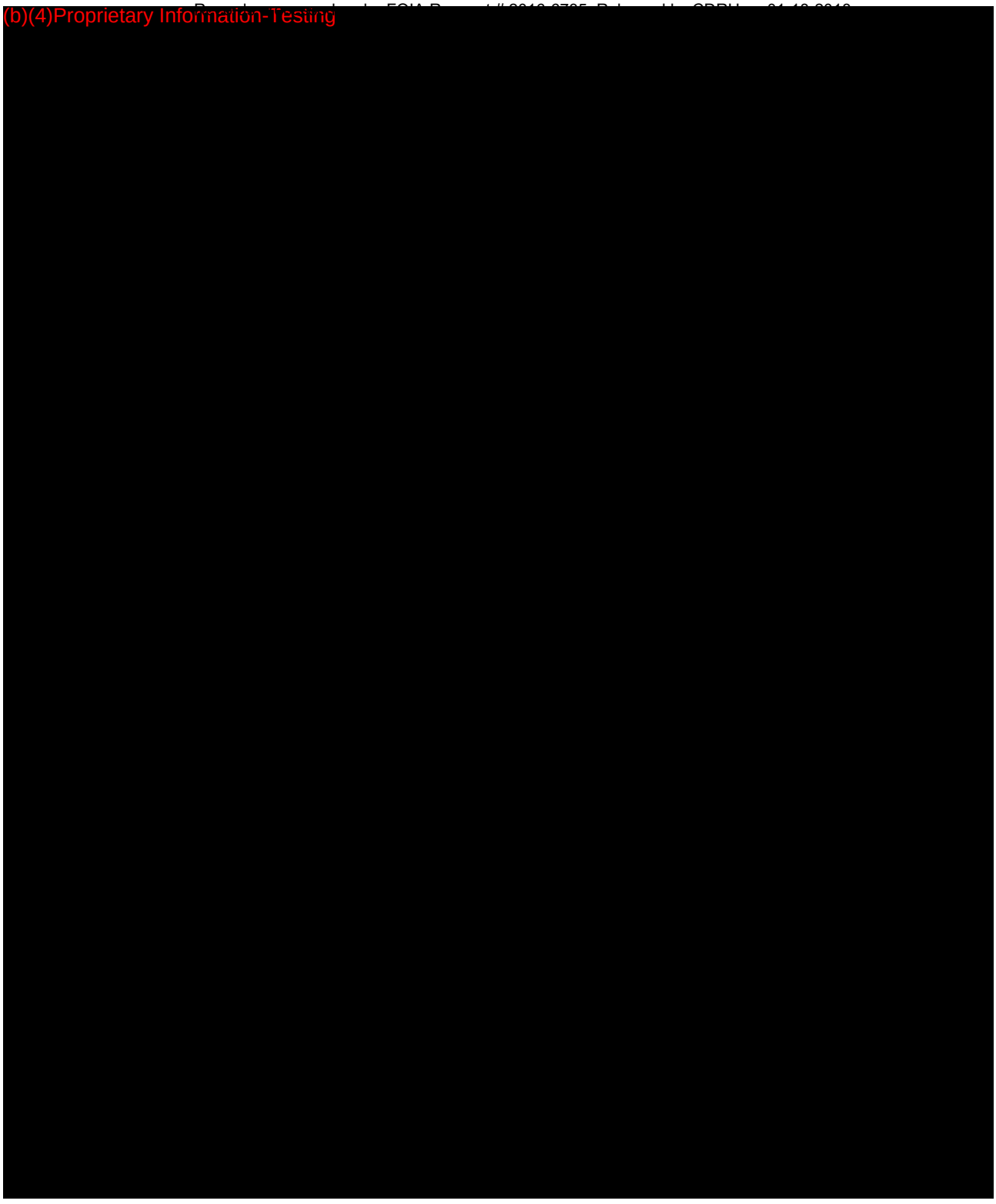
(b)(4)Proprietary Information-Testing



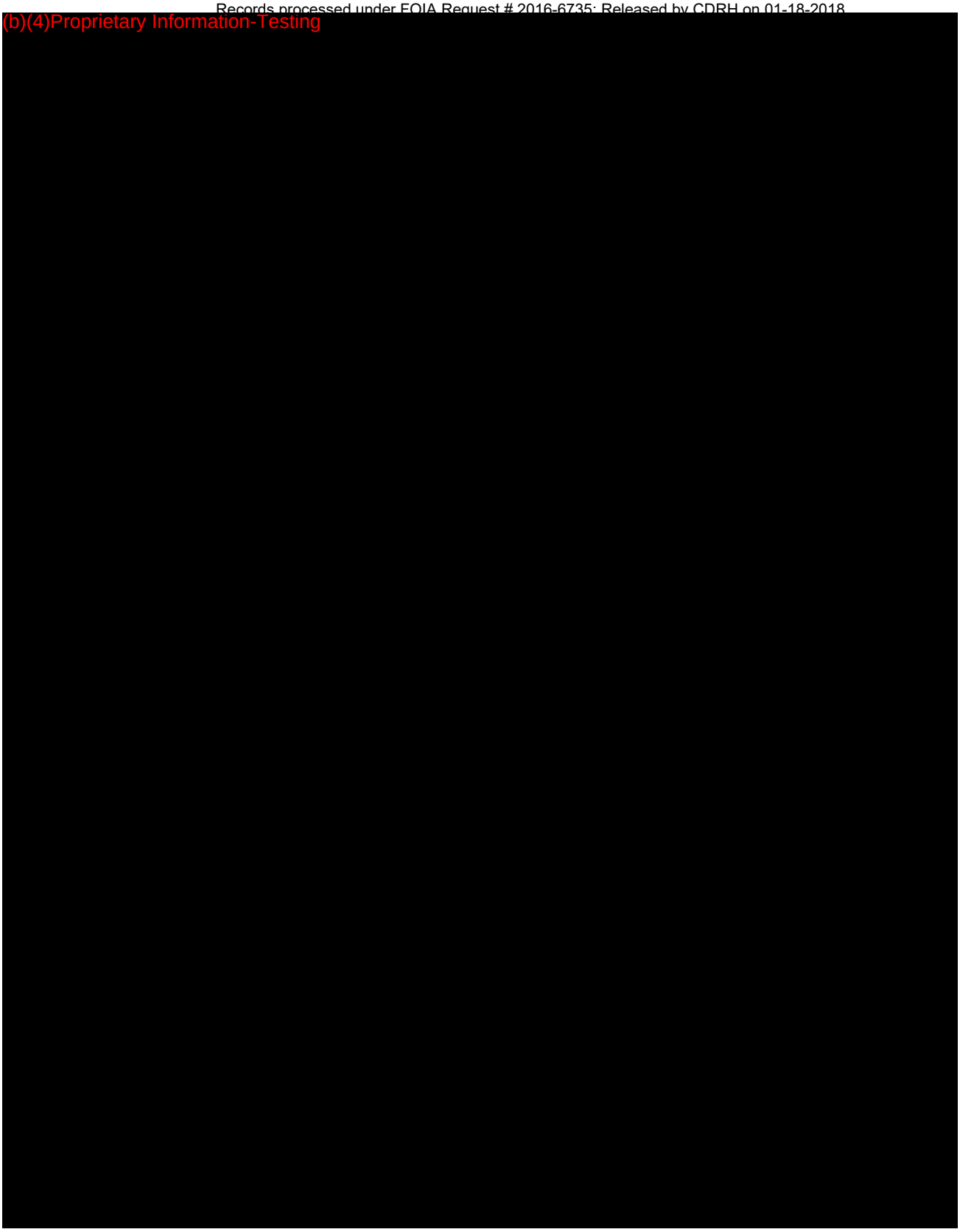
(b)(4)Proprietary Information-Testing



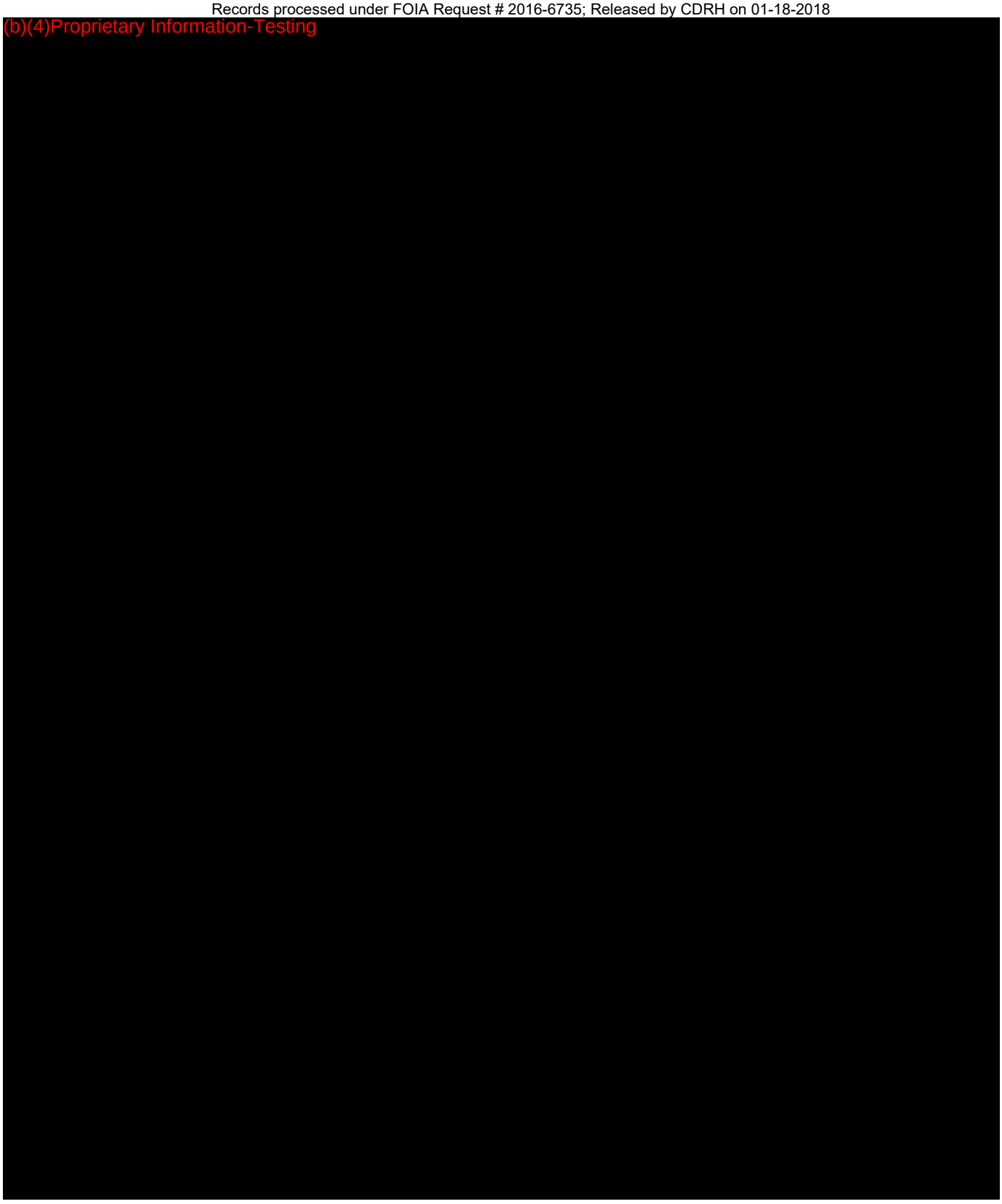
(b)(4)Proprietary Information-Testing



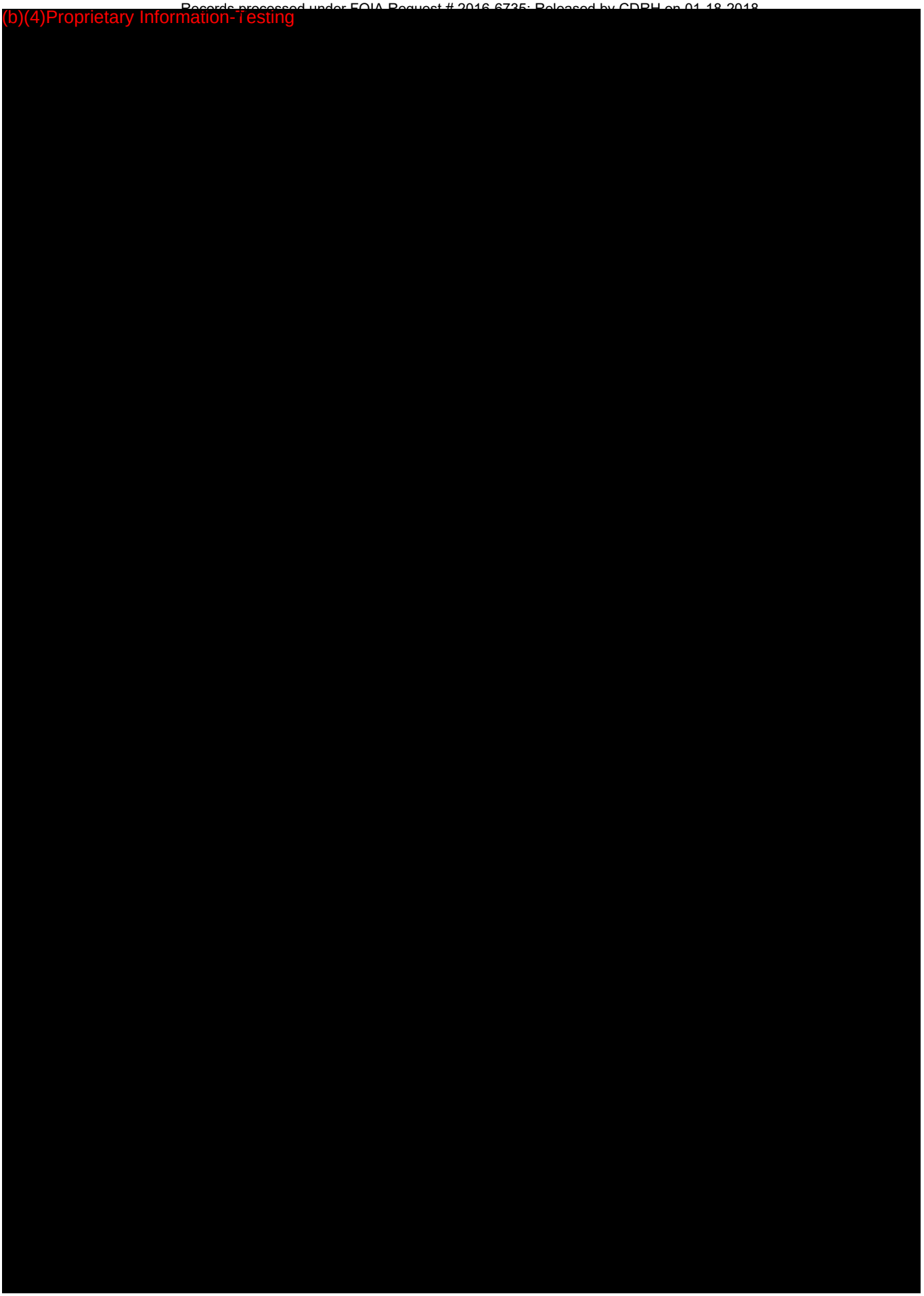
(b)(4)Proprietary Information-Testing



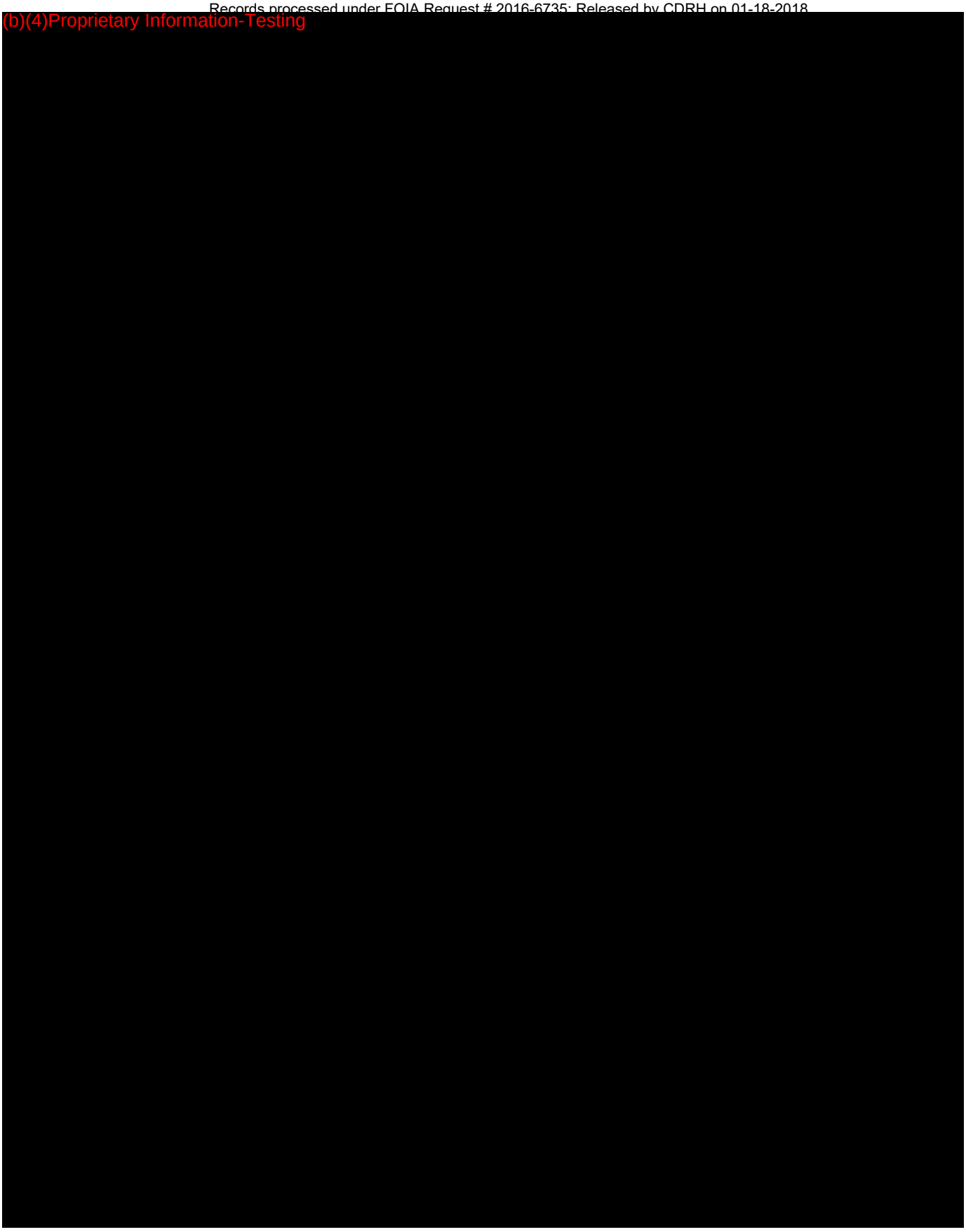
(b)(4)Proprietary Information-Testing



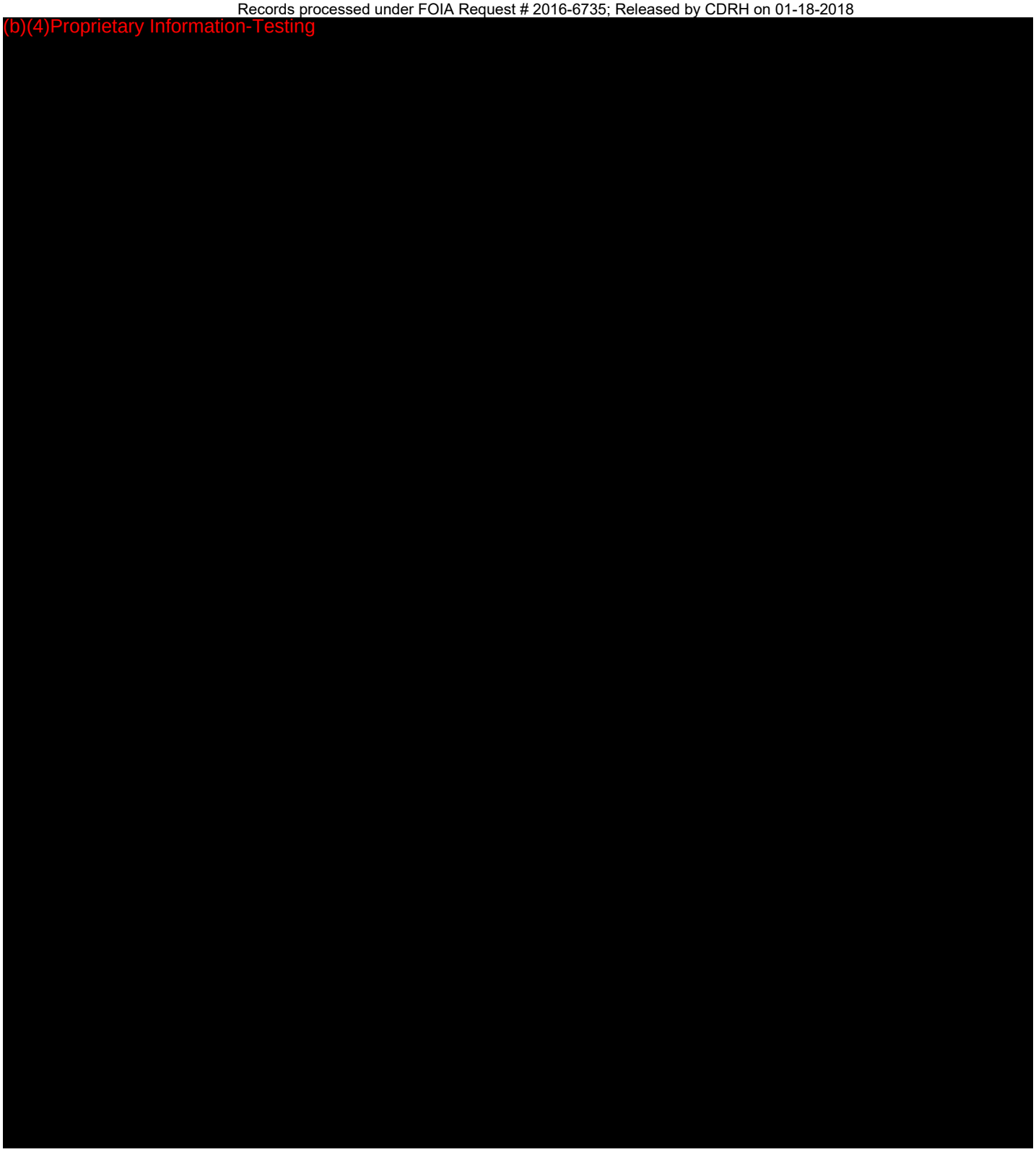
(b)(4)Proprietary Information-Testing



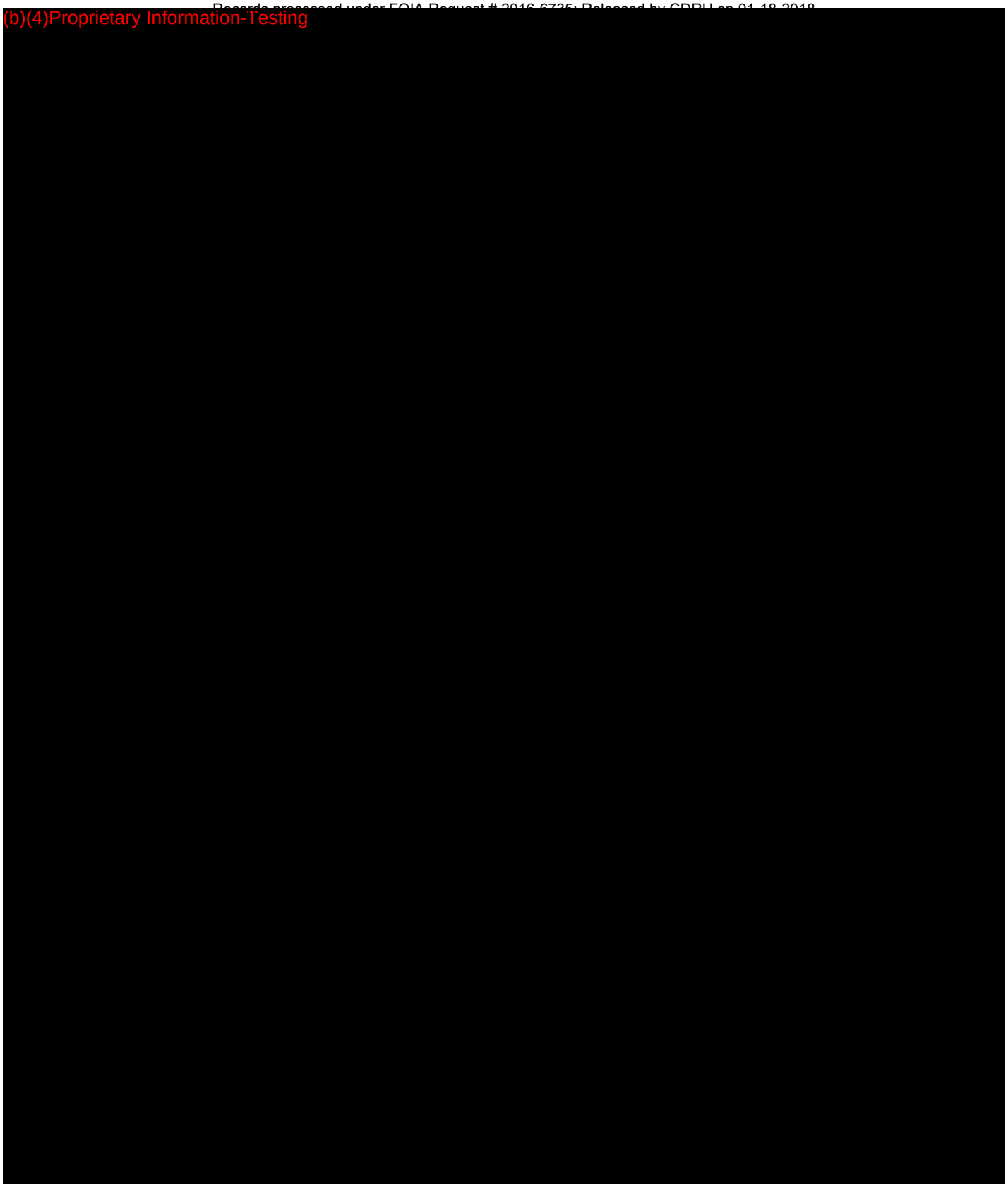
(b)(4)Proprietary Information-Testing



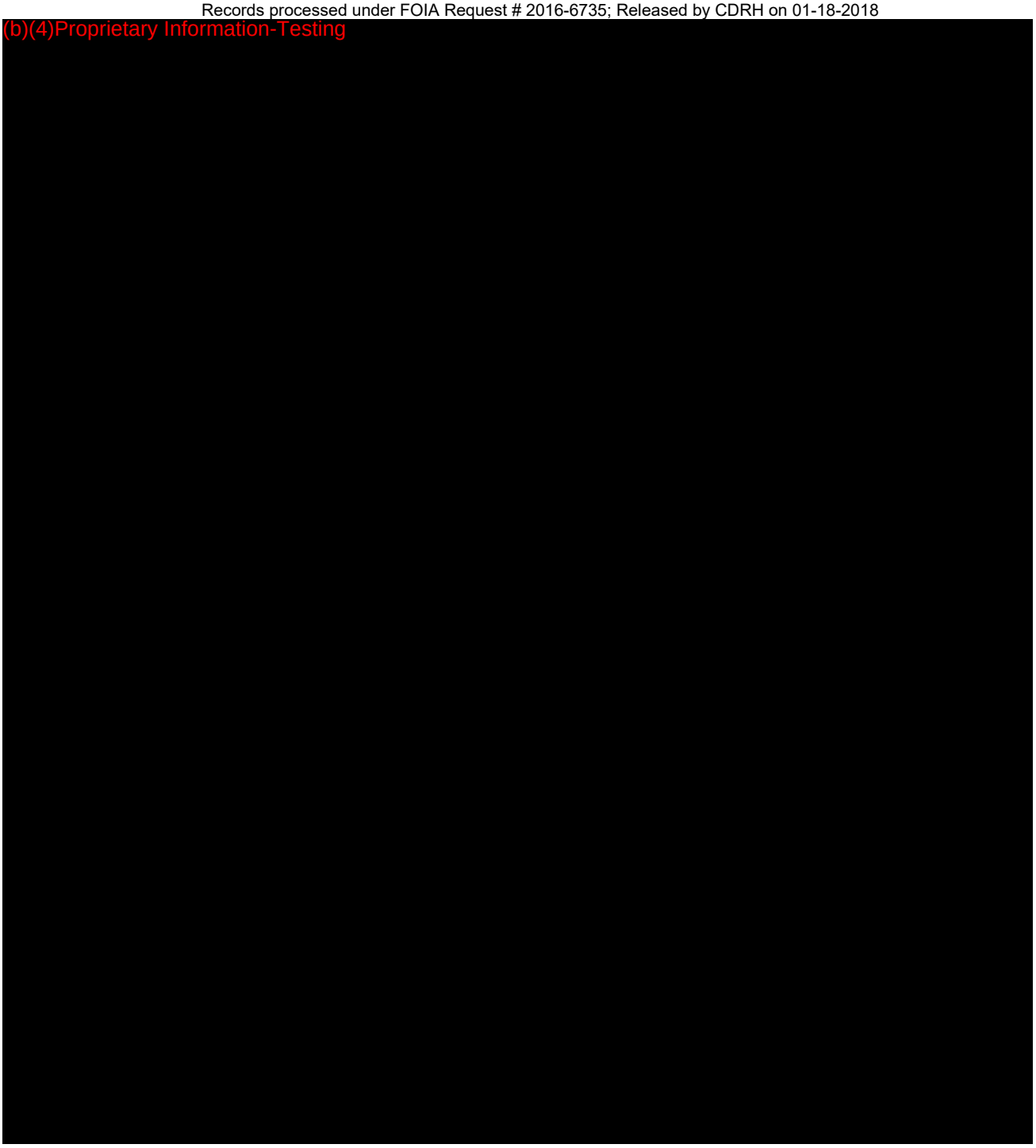
(b)(4)Proprietary Information-Testing



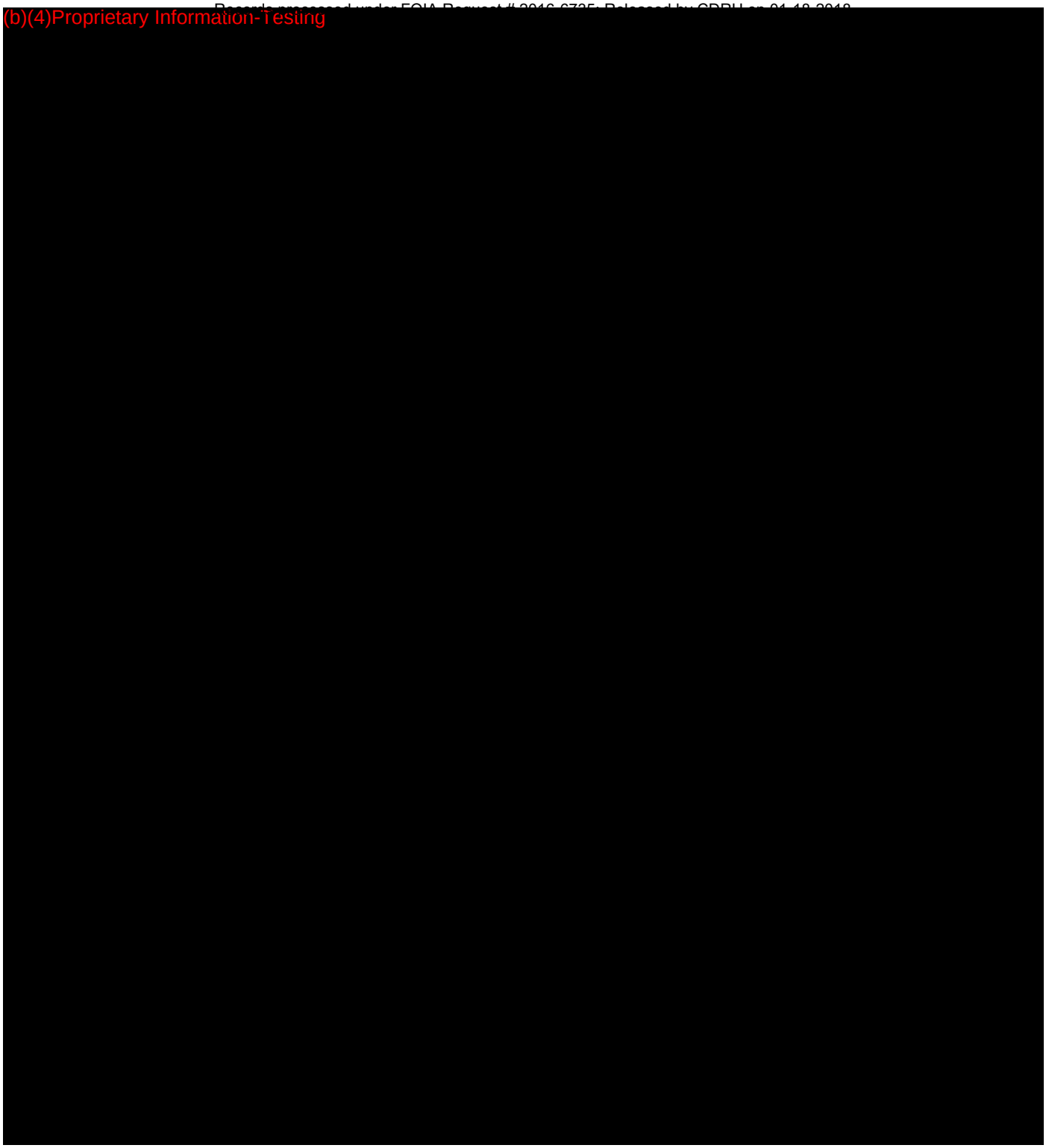
(b)(4)Proprietary Information-Testing



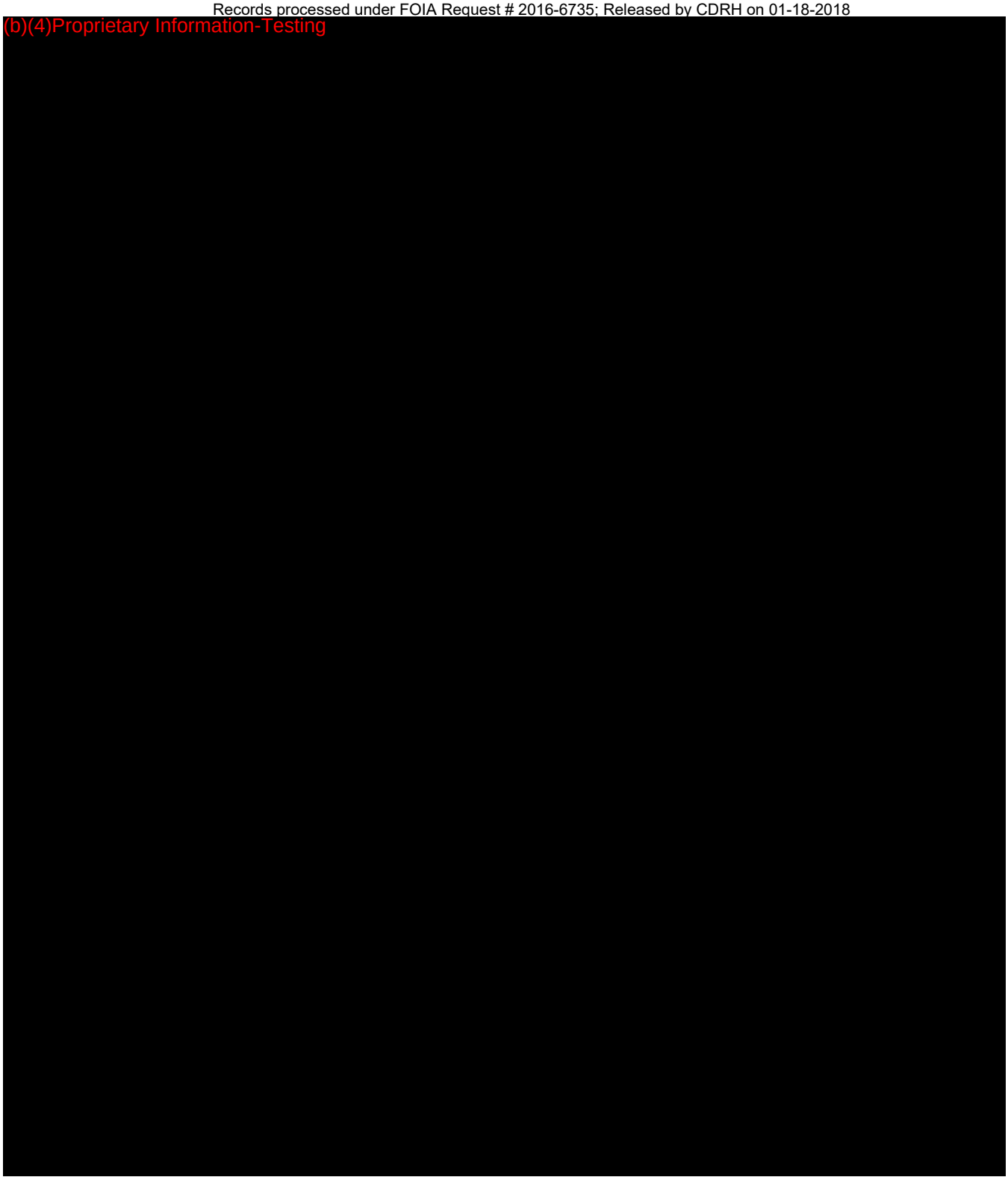
(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing

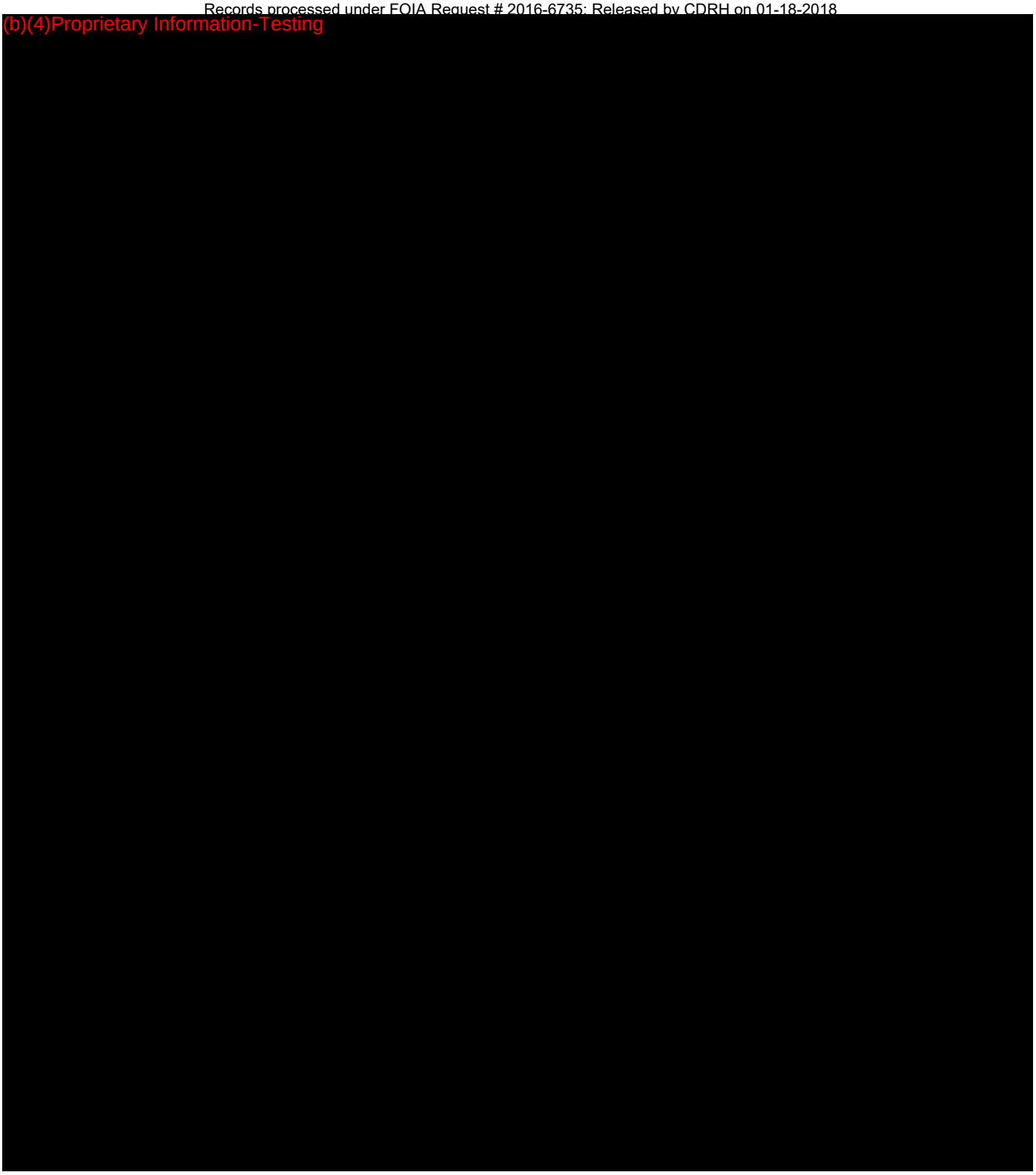


(b)(4)Proprietary Information-Testing

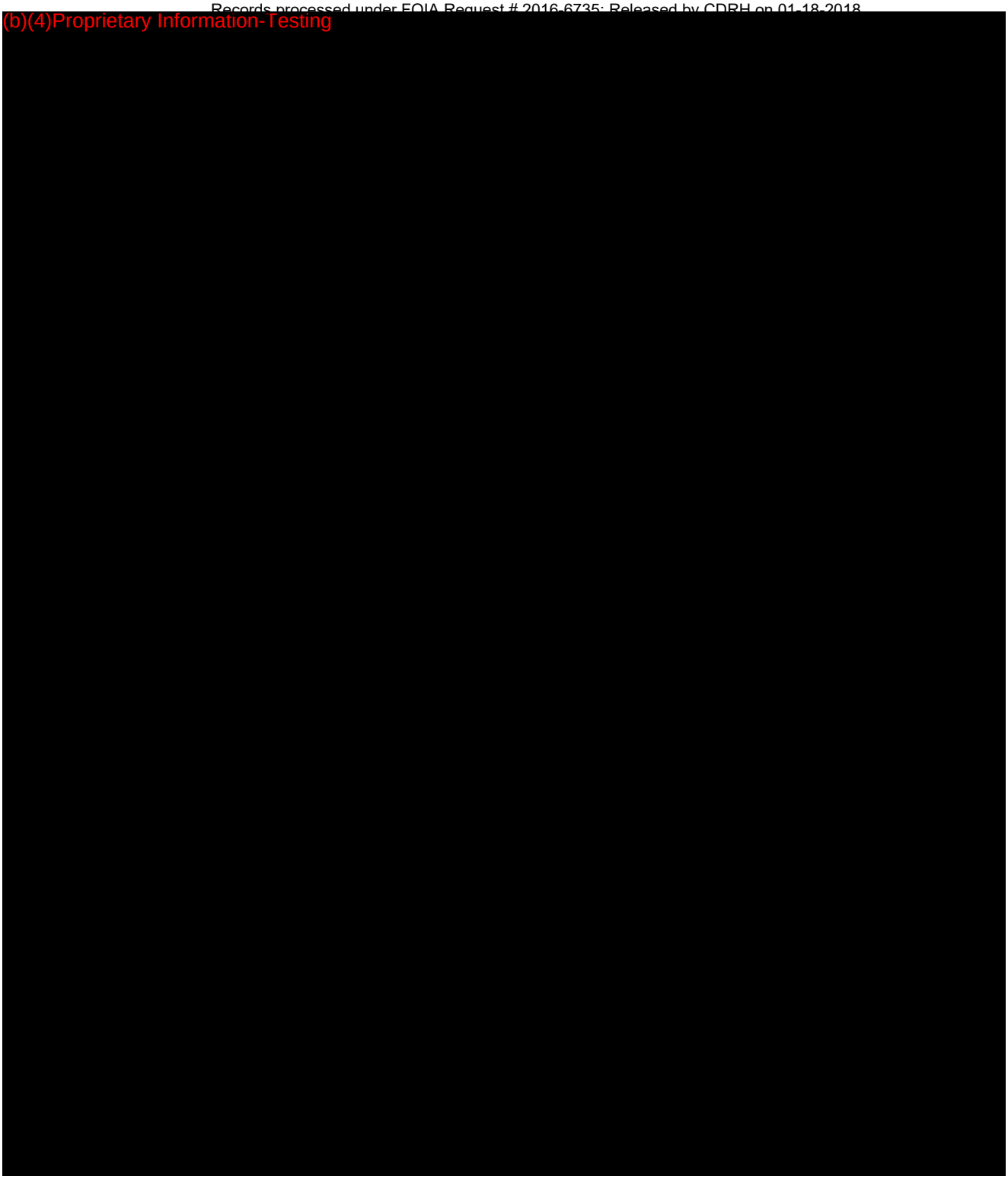


(b)(4)Proprietary Information-Testing

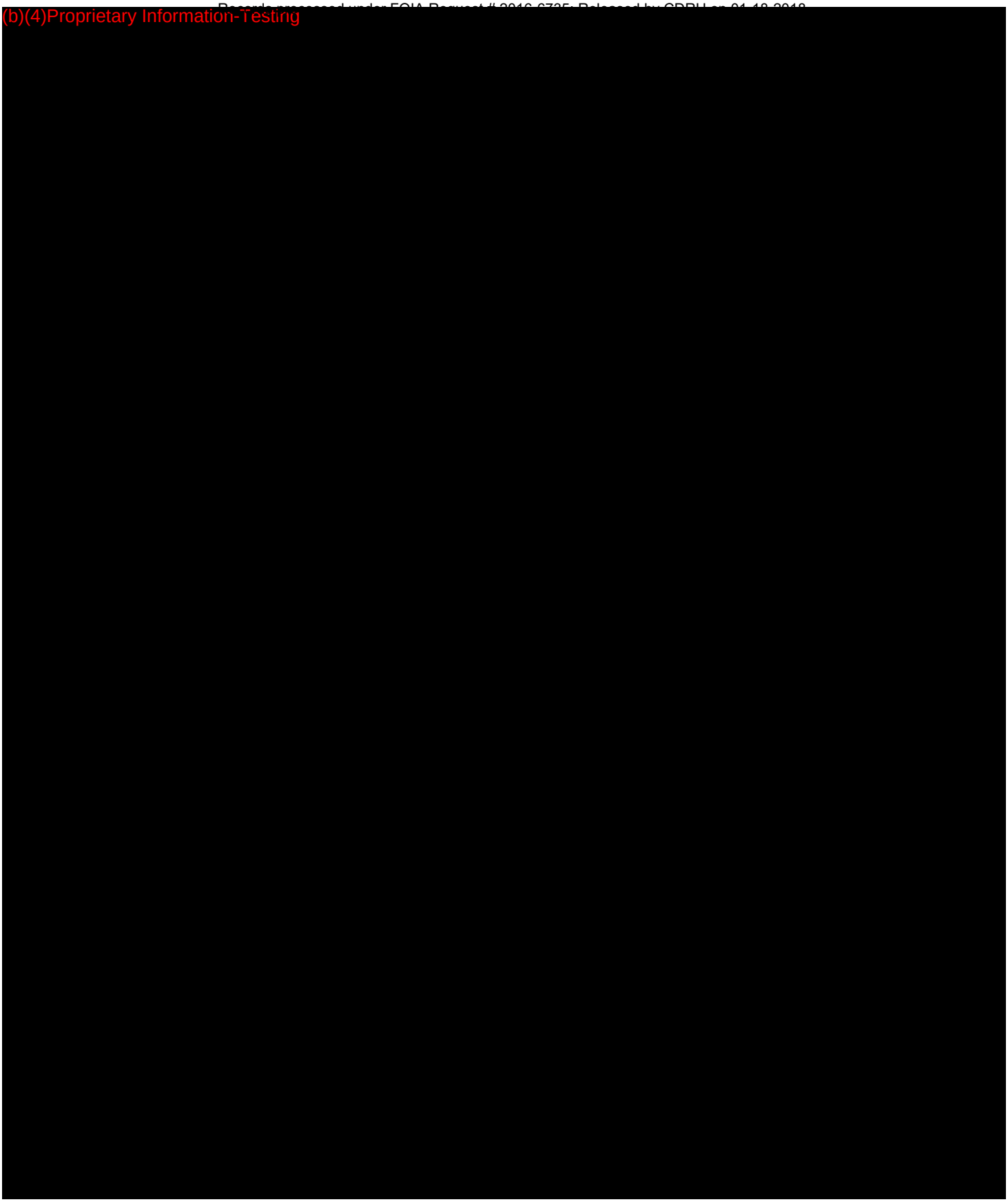
(b)(4)Proprietary Information-Testing



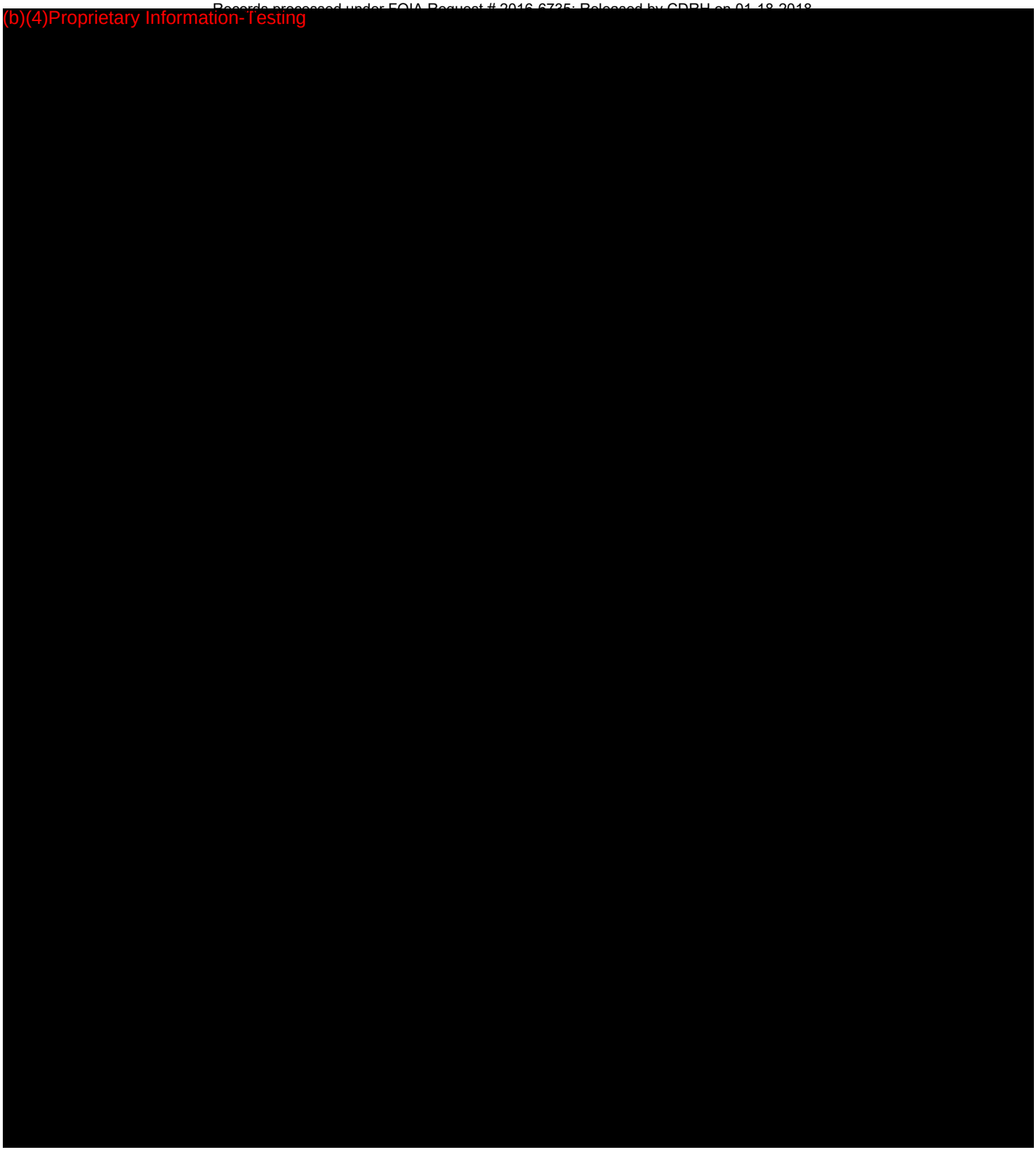
(b)(4)Proprietary Information- Testing



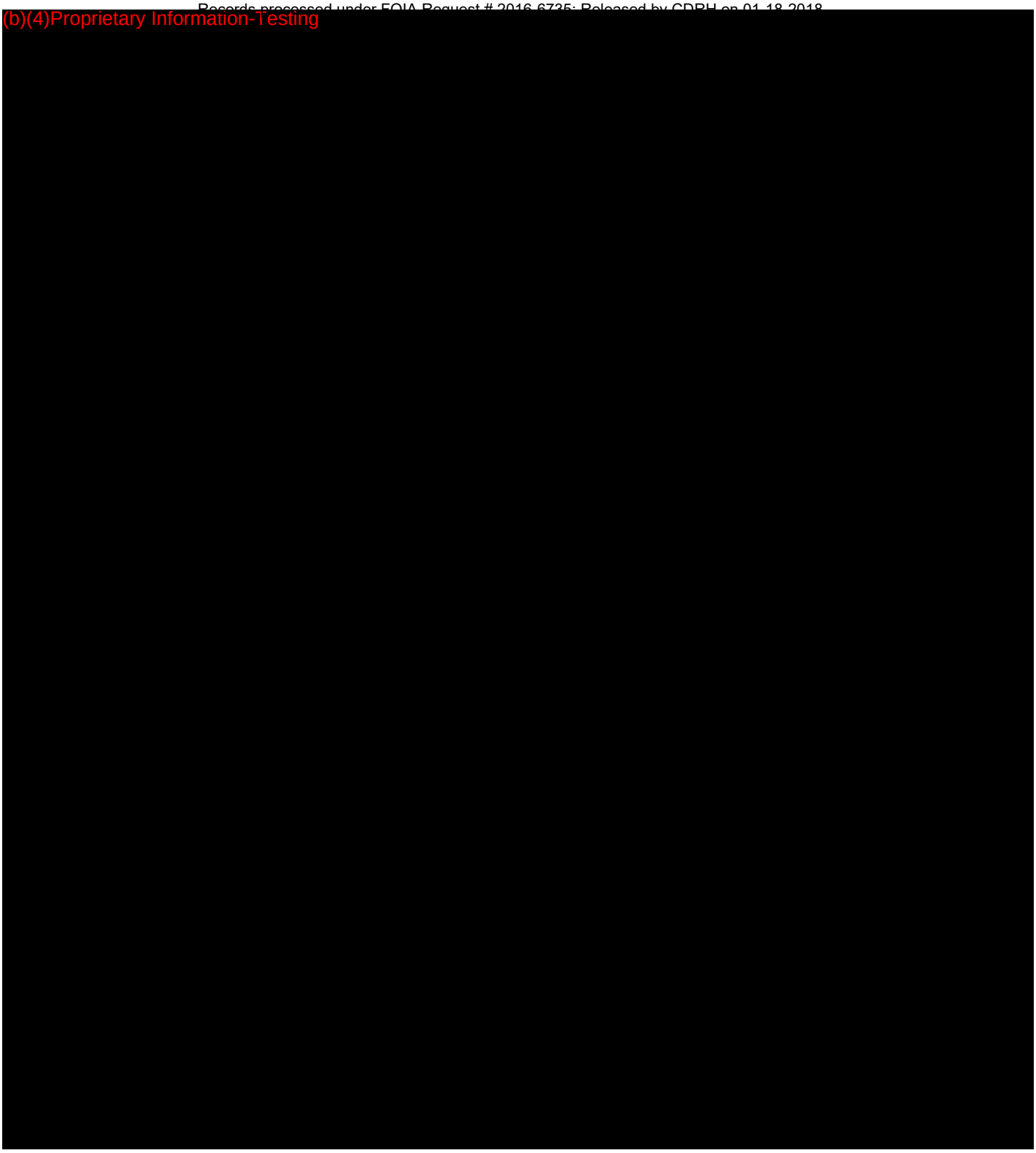
(b)(4)Proprietary Information-Testing



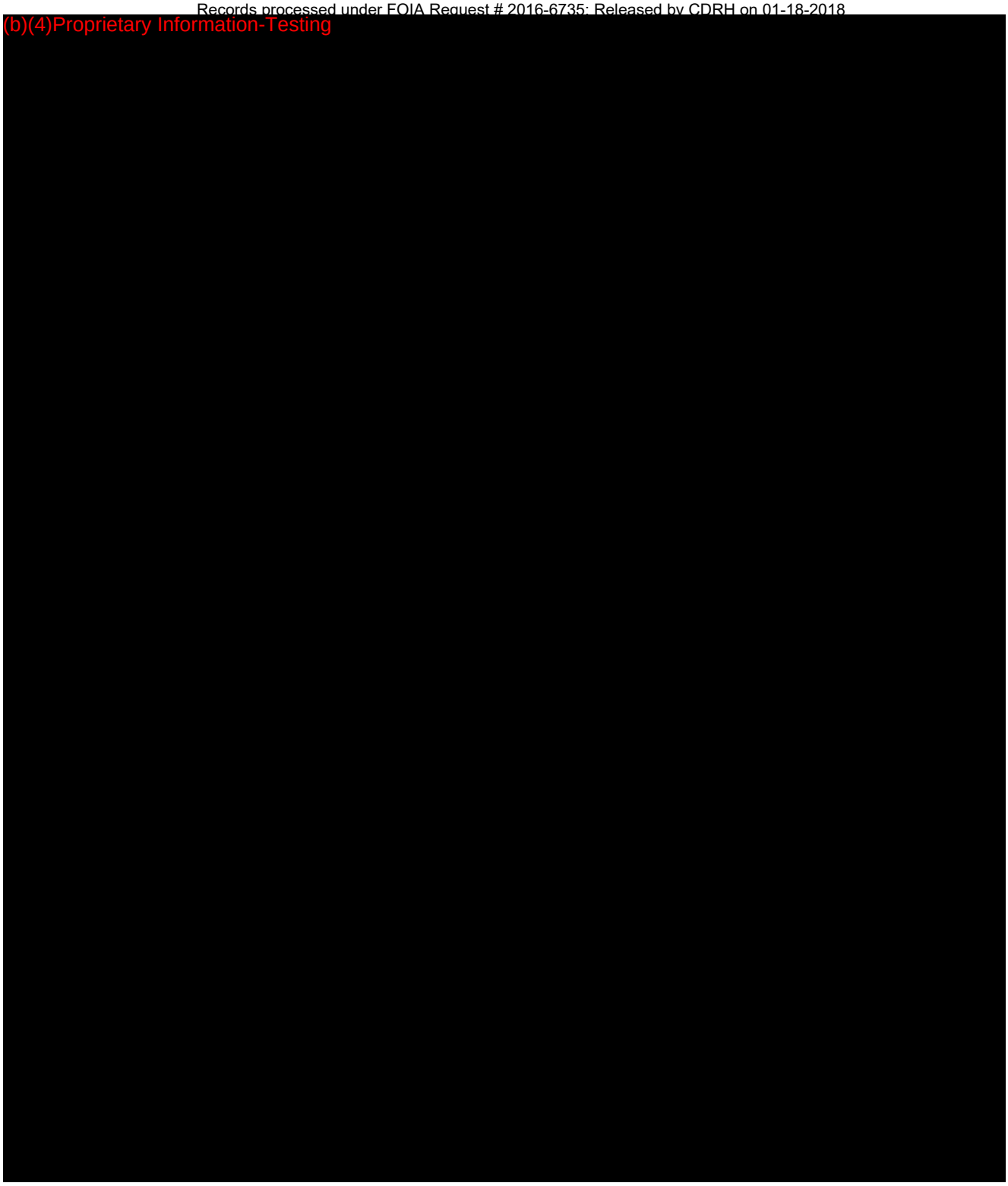
(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing

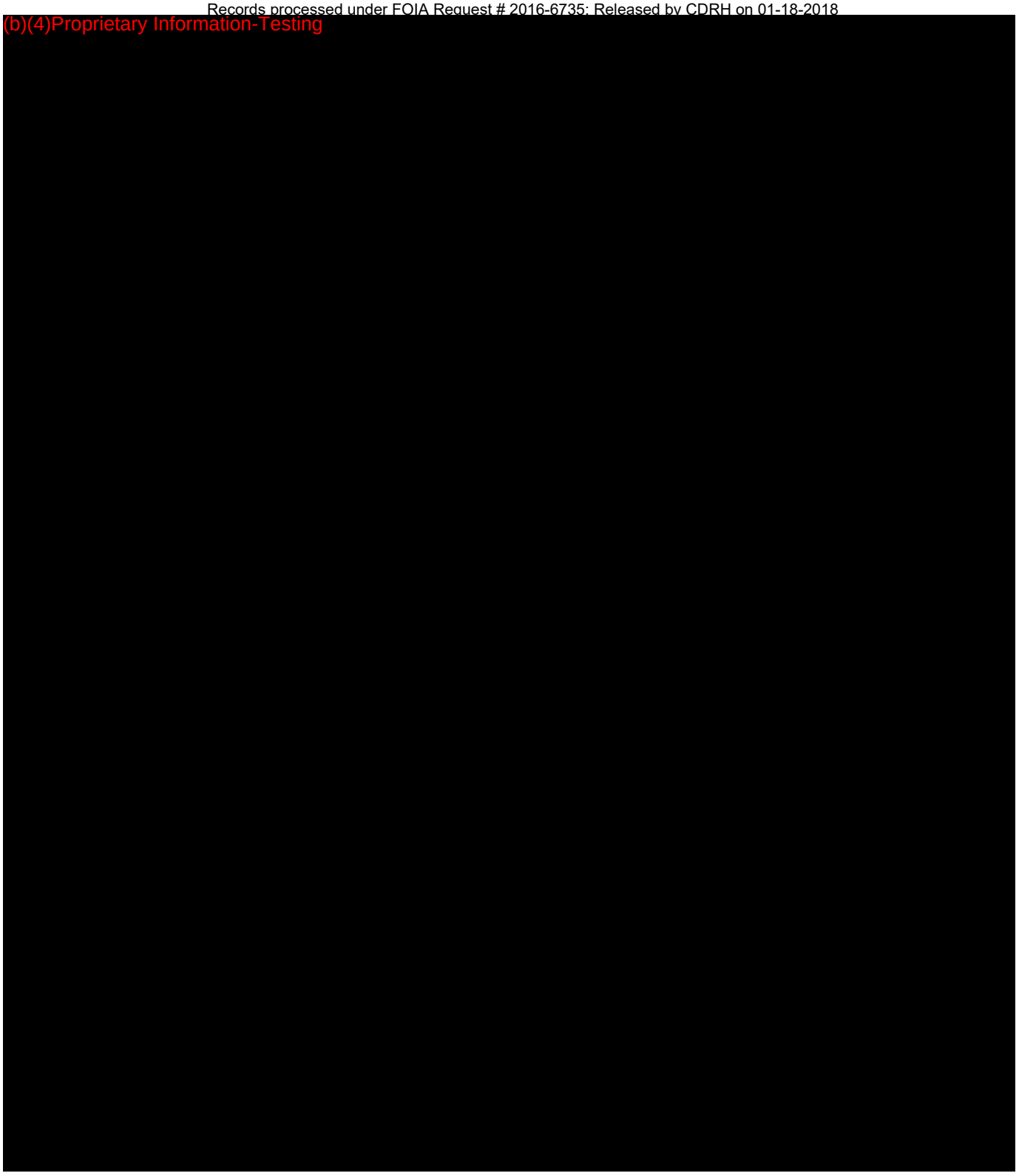


(b)(4)Proprietary Information-Testing



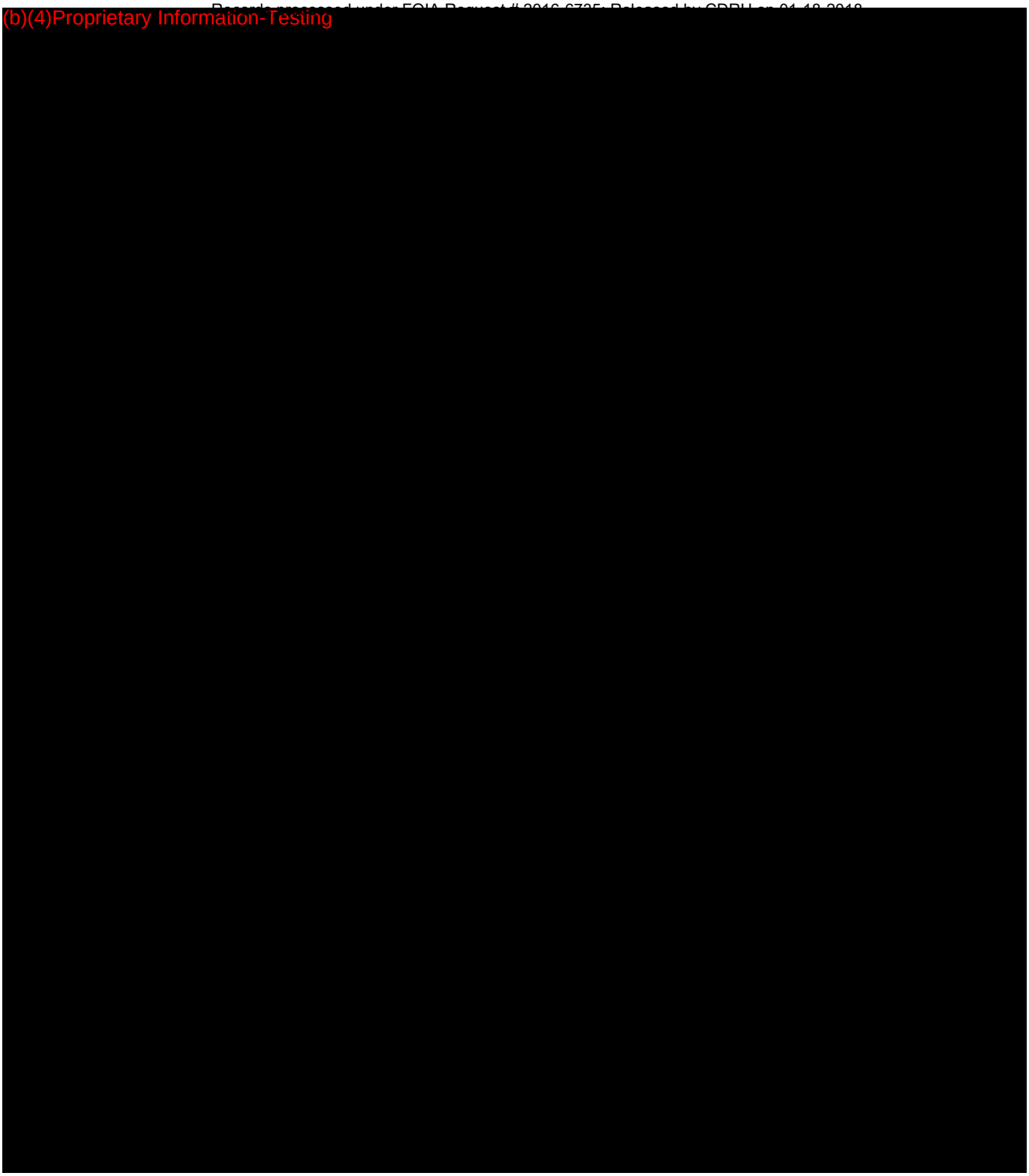
(b)(4)Proprietary Information- Testing

(b)(4)Proprietary Information-Testing

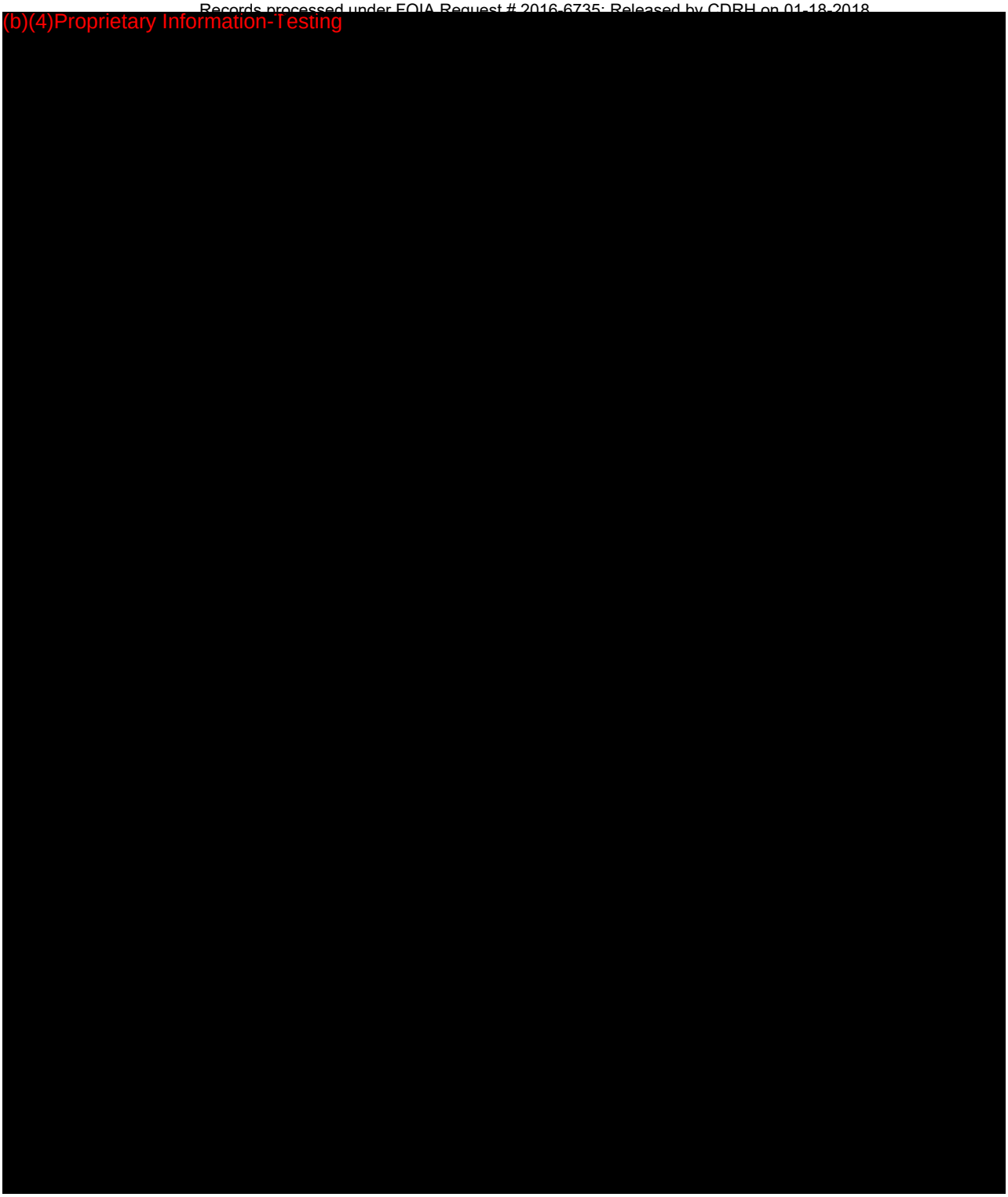


(b)(4)Proprietary Information-Testing

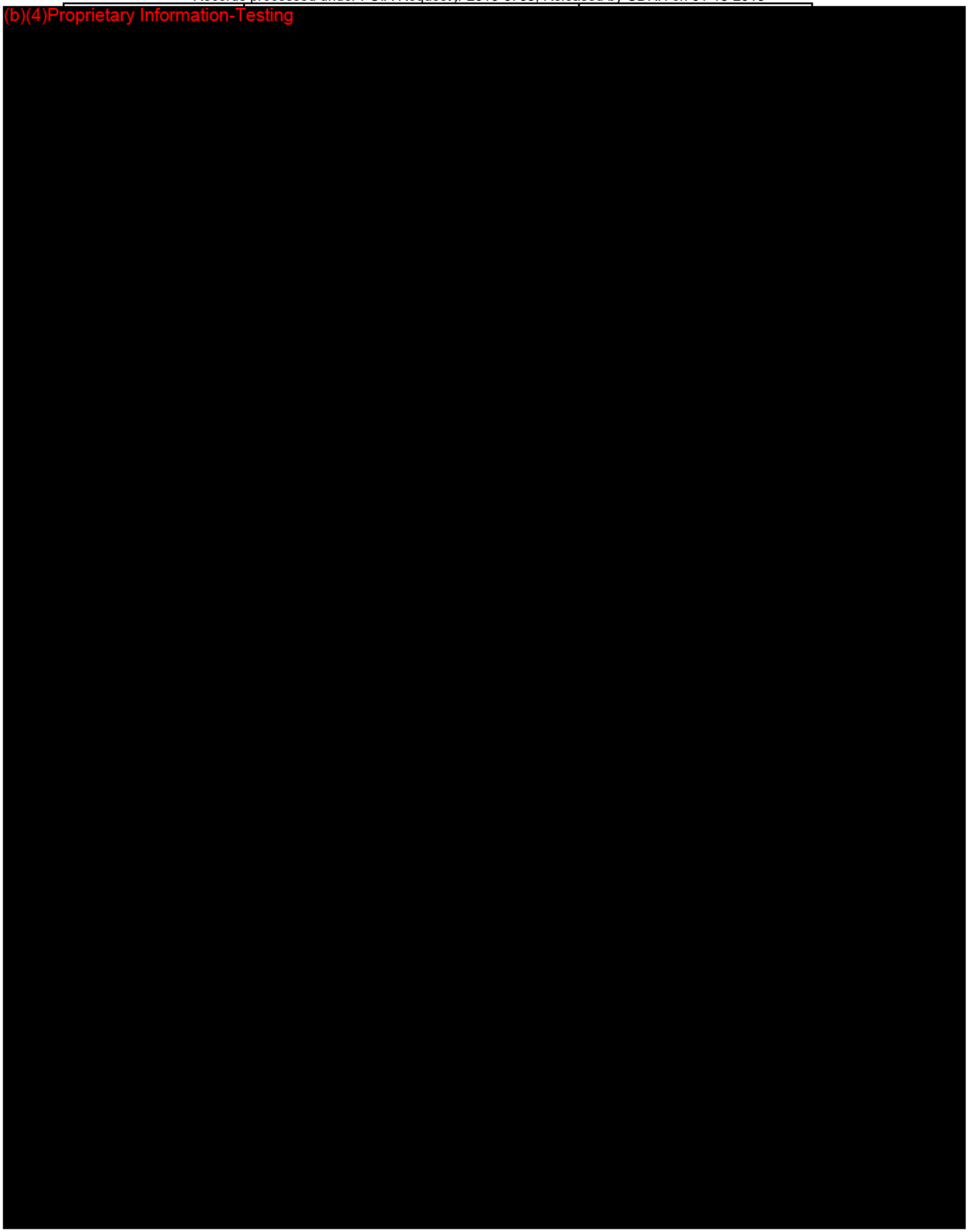
(b)(4)Proprietary Information-Testing



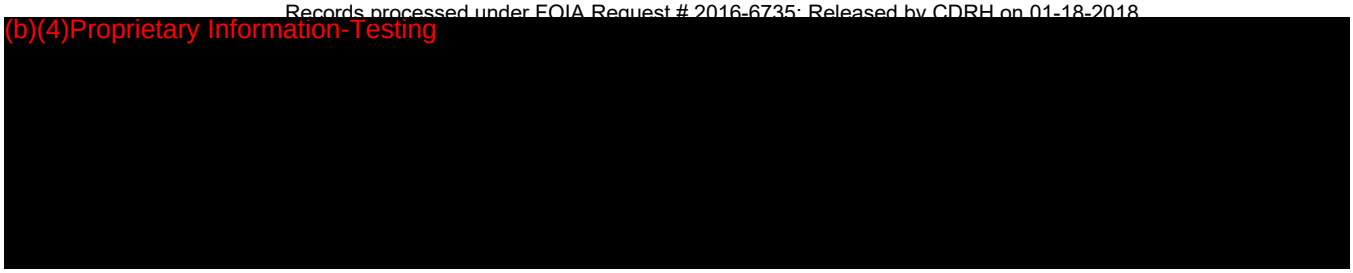
(b)(4)Proprietary Information-Testing



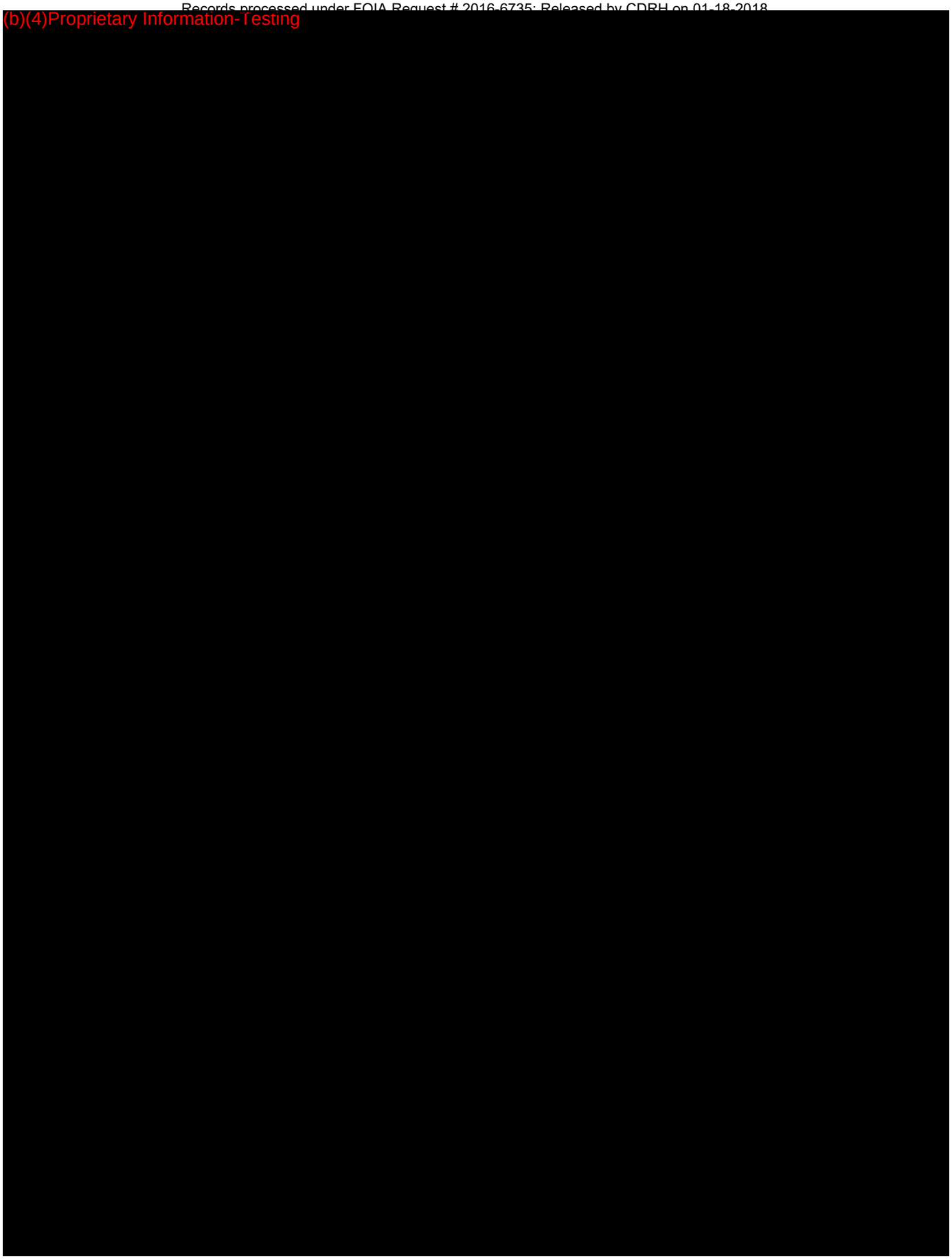
(b)(4)Proprietary Information-Testing



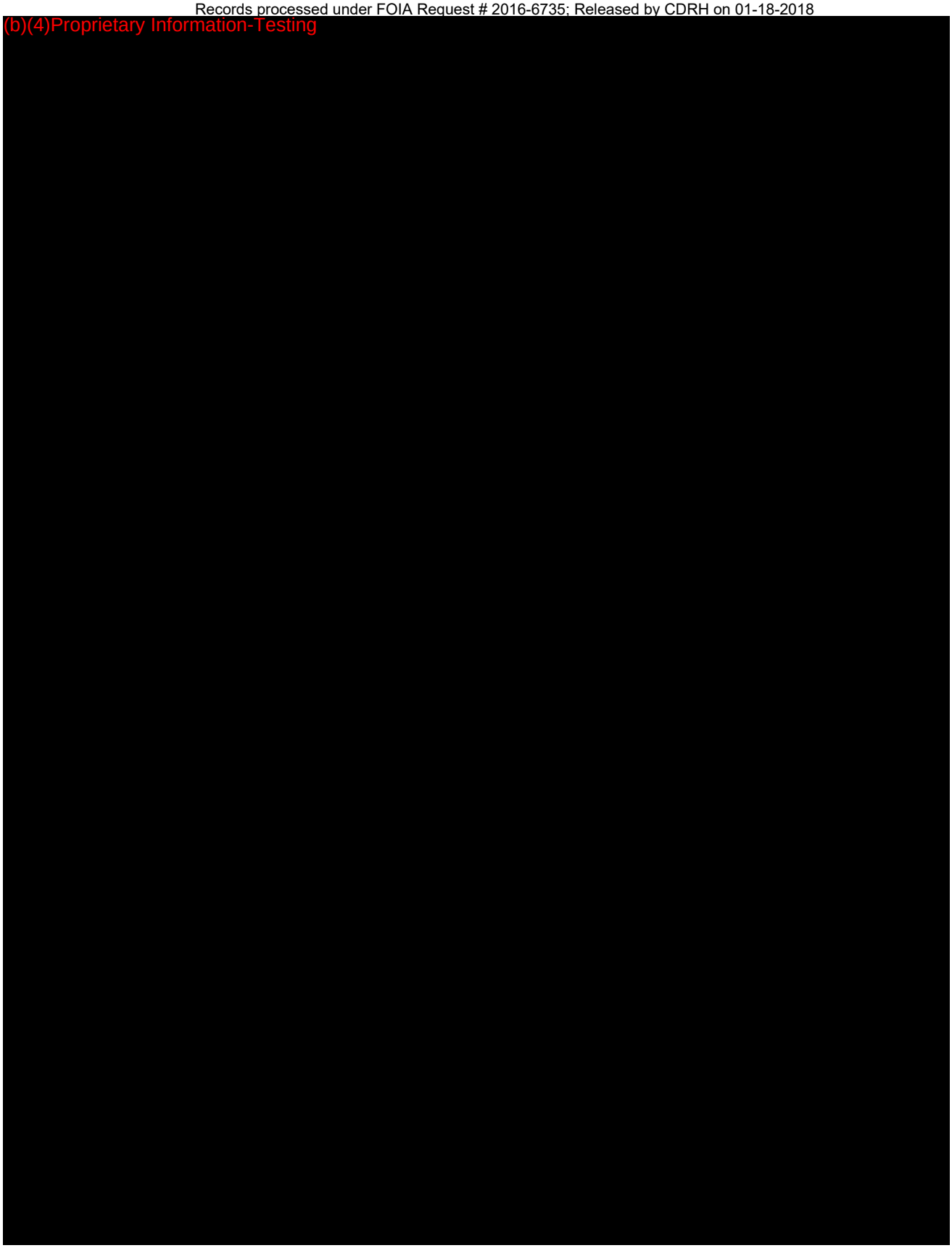
(b)(4)Proprietary Information-Testing



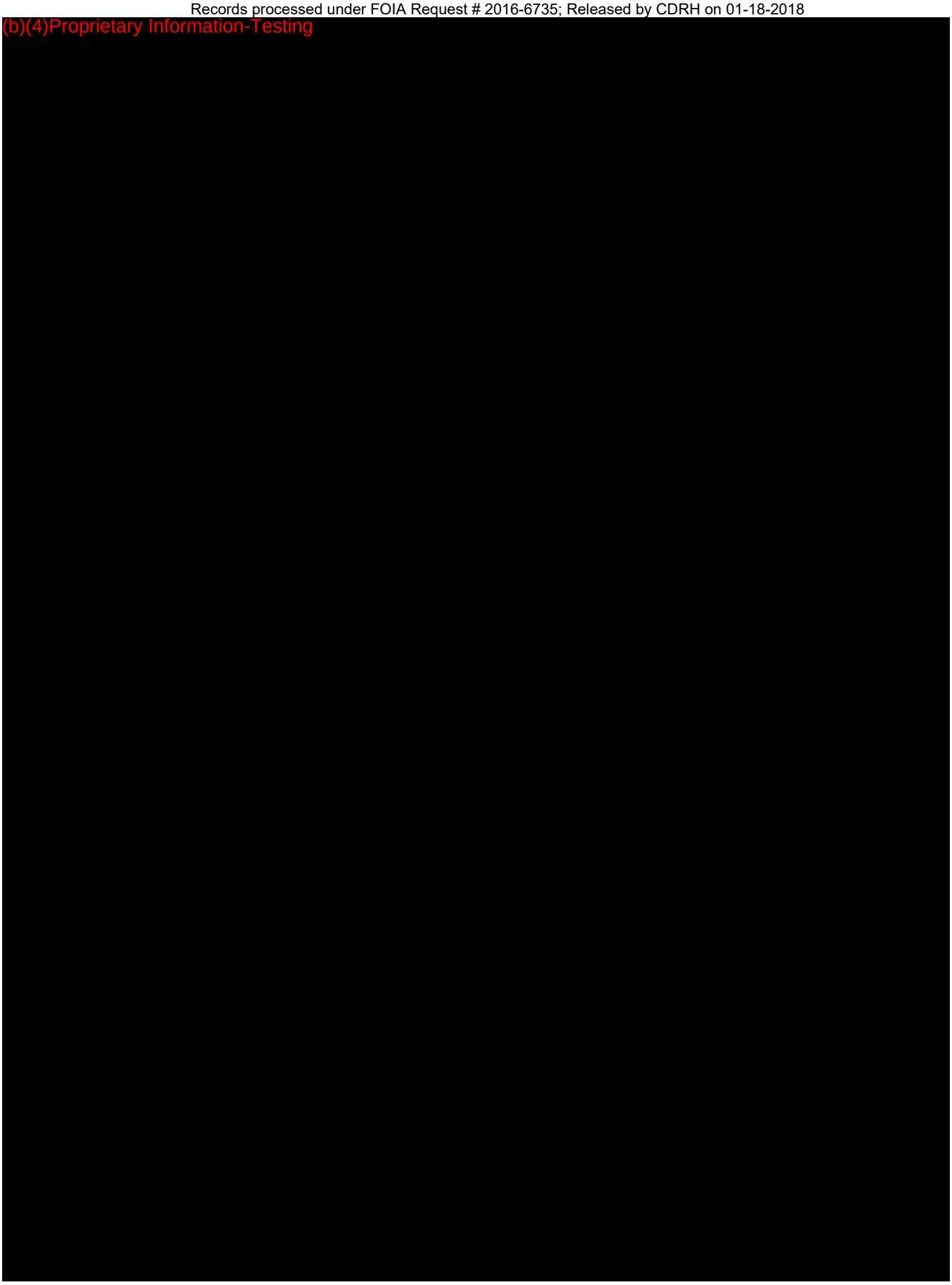
(b)(4)Proprietary Information- Testing



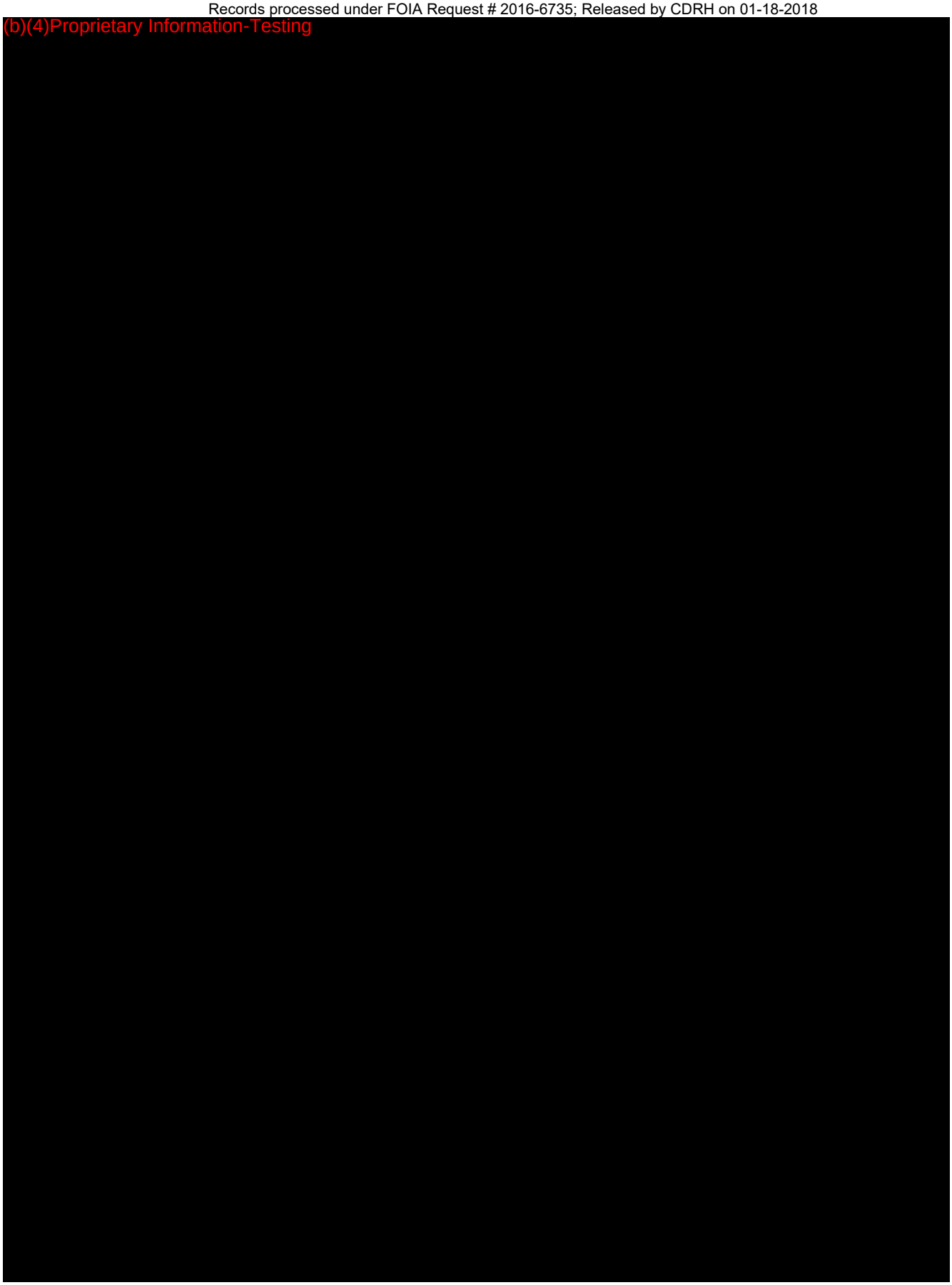
(b)(4)Proprietary Information-Testing



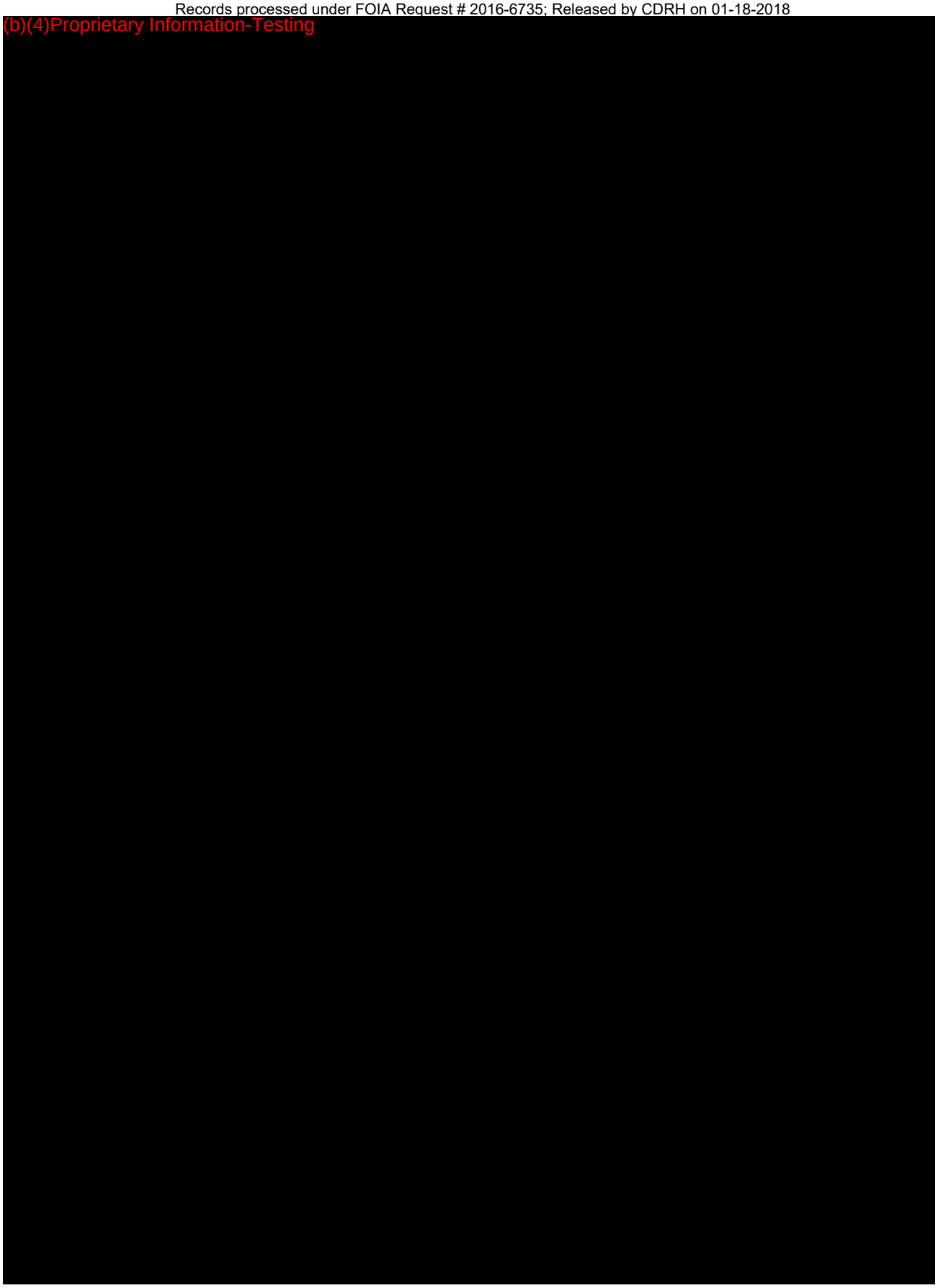
(b)(4)Proprietary Information-Testing



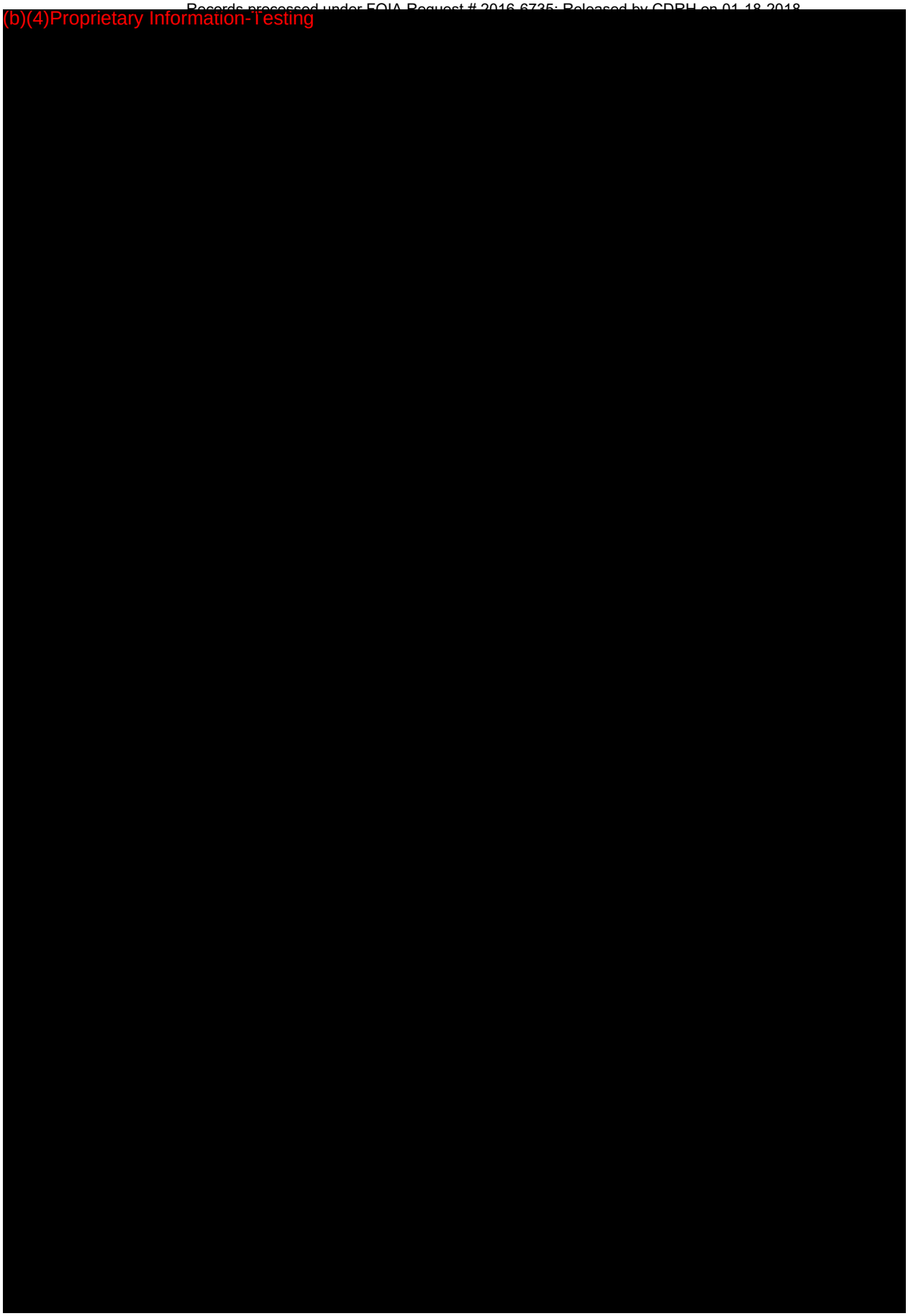
(b)(4)Proprietary Information-Testing



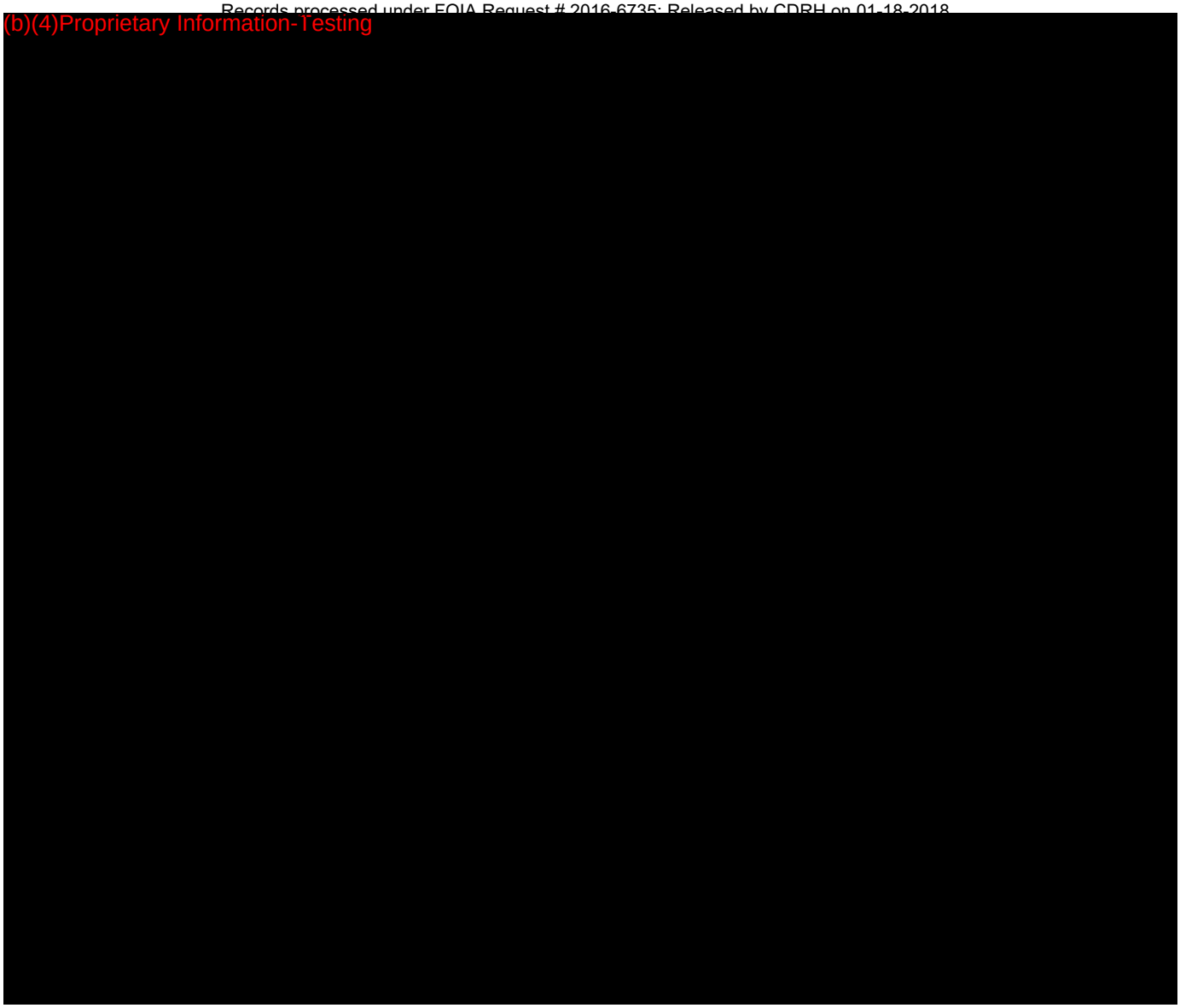
(b)(4)Proprietary Information-Testing



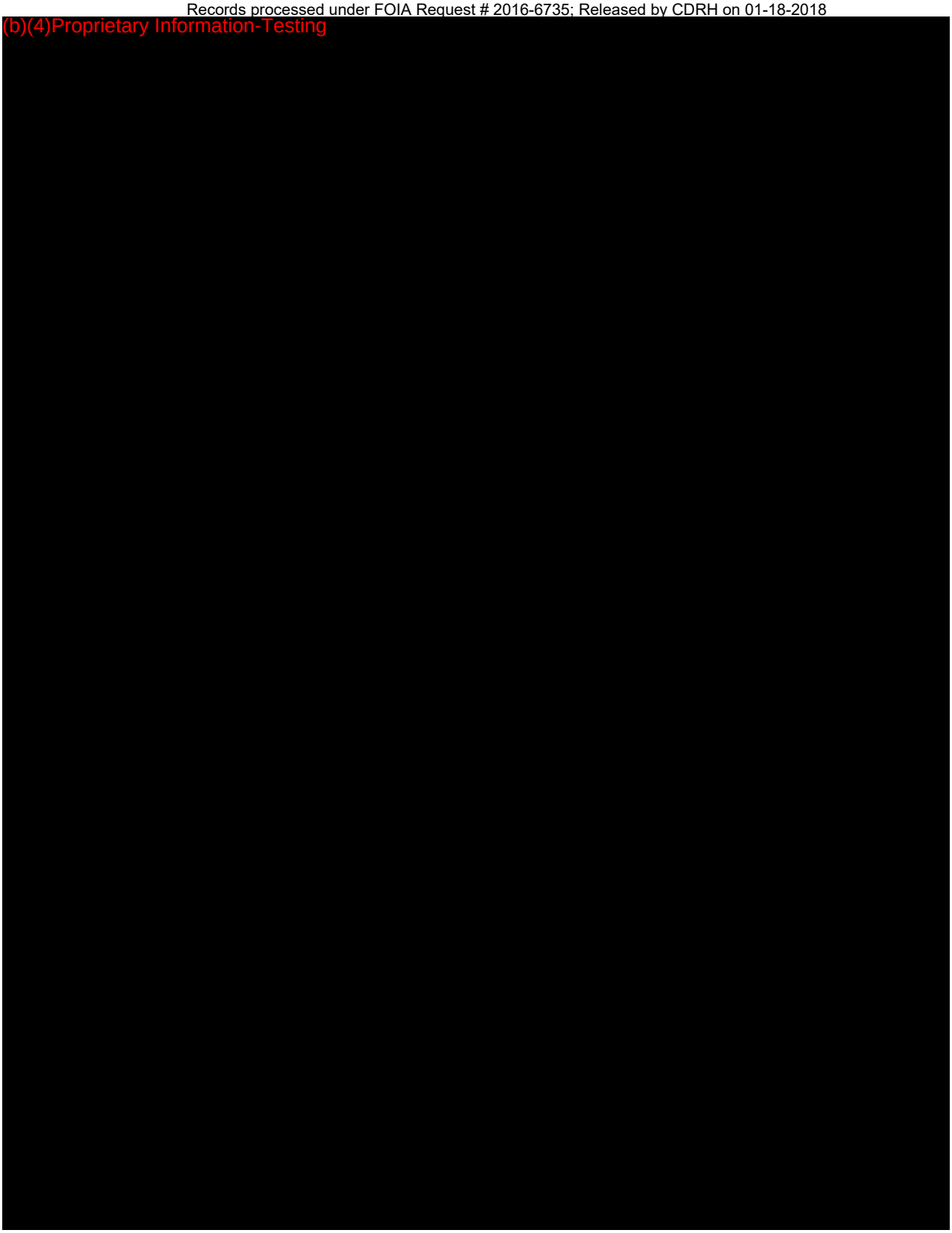
(b)(4)Proprietary Information-Testing



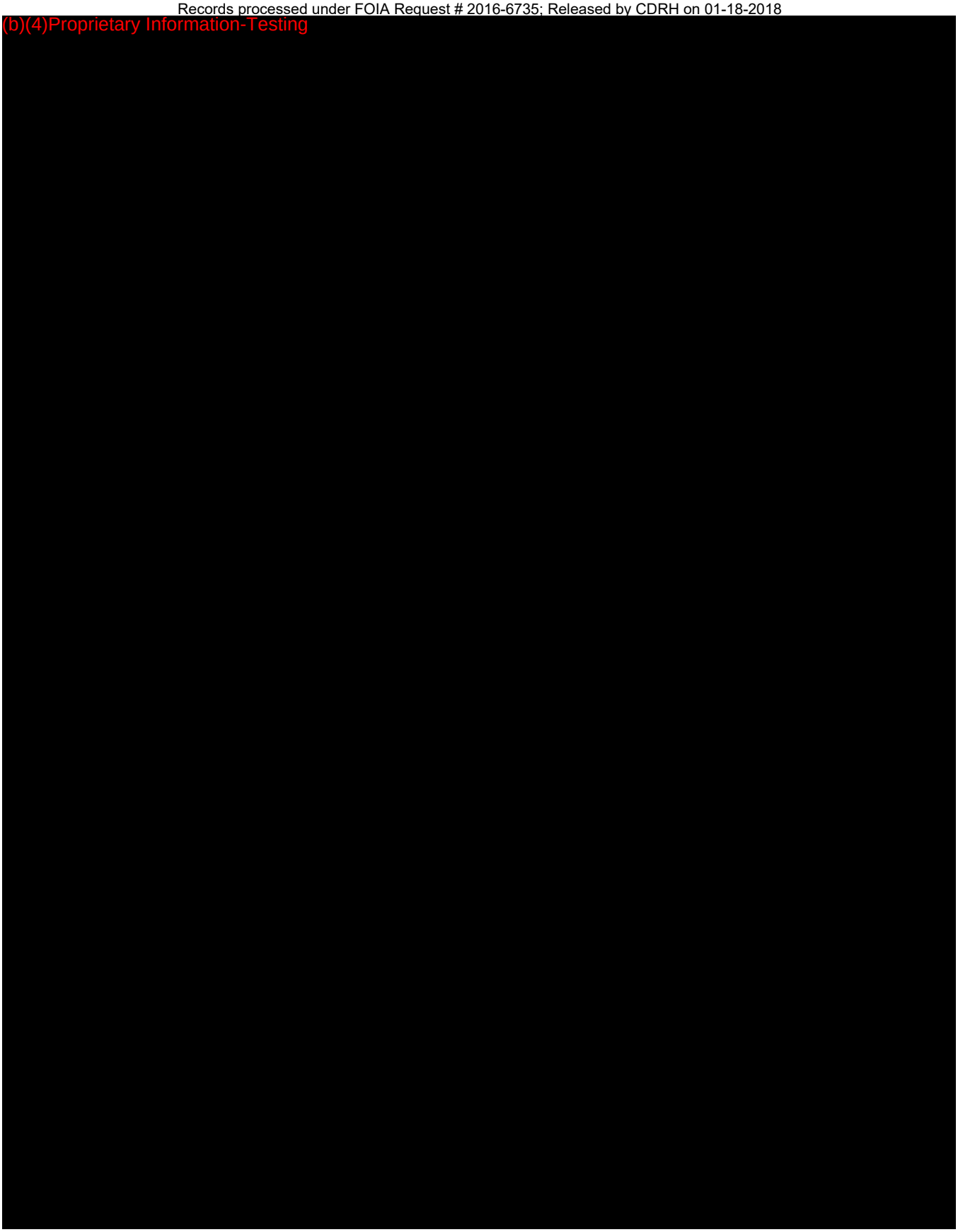
(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing

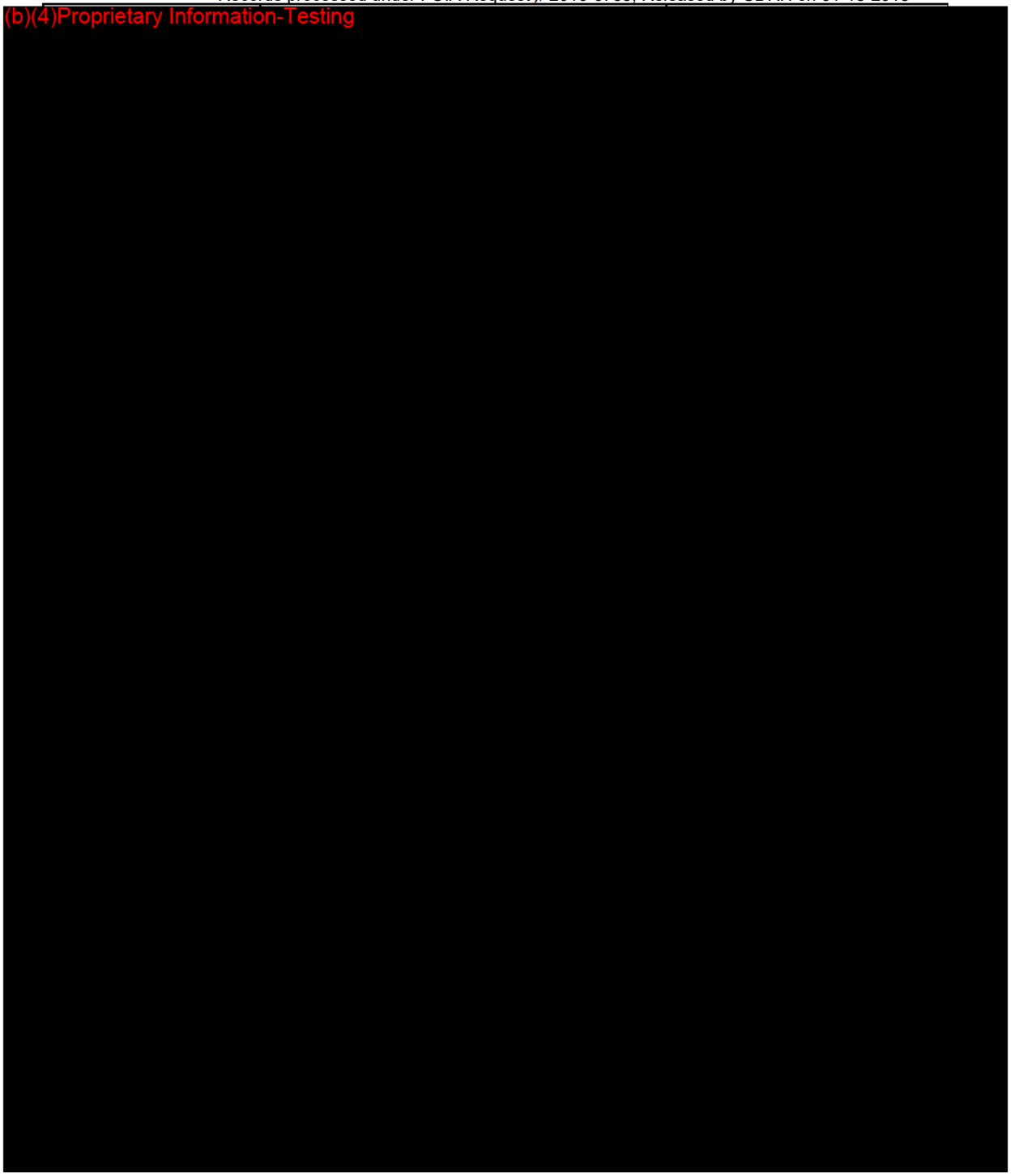


(b)(4)Proprietary Information-Testing

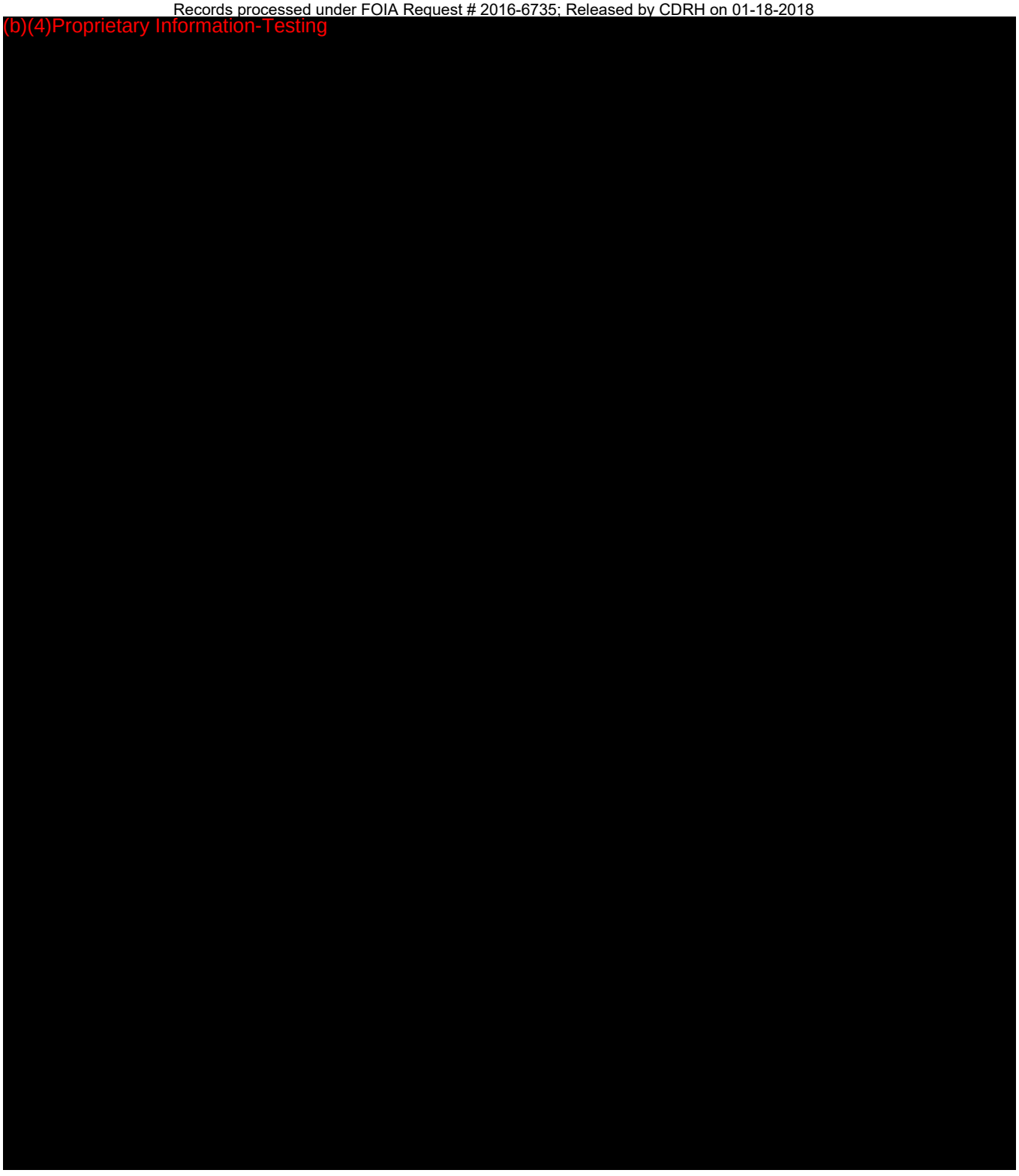


(b)(4)Proprietary Information-Testing

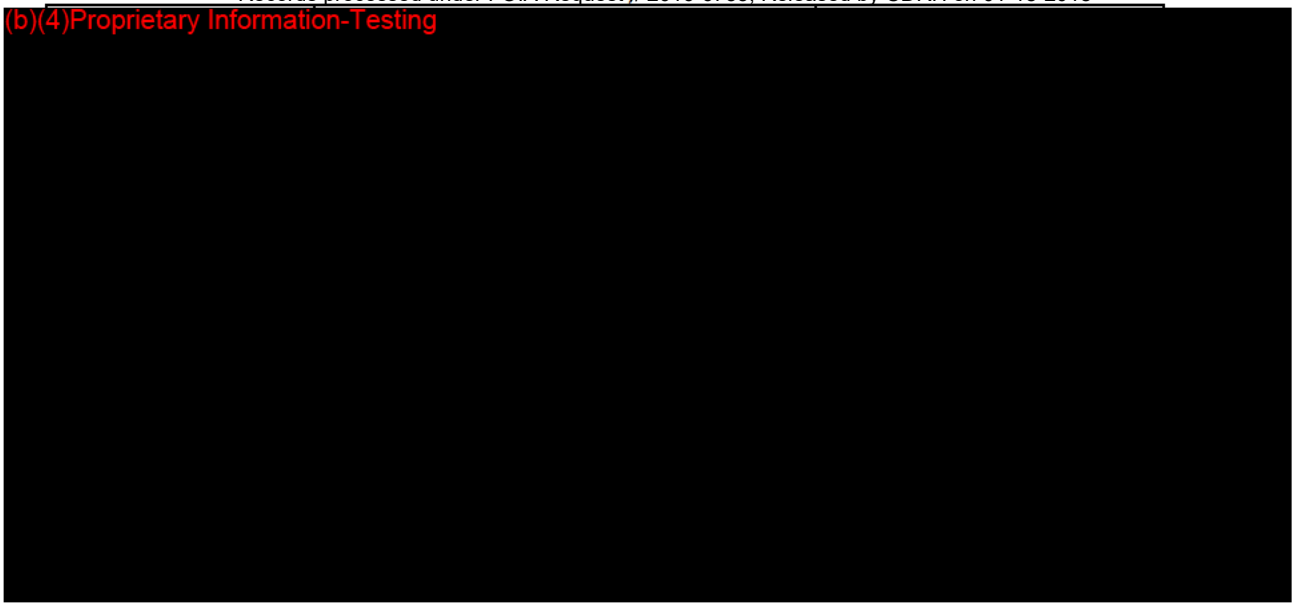
(b)(4)Proprietary Information-Testing



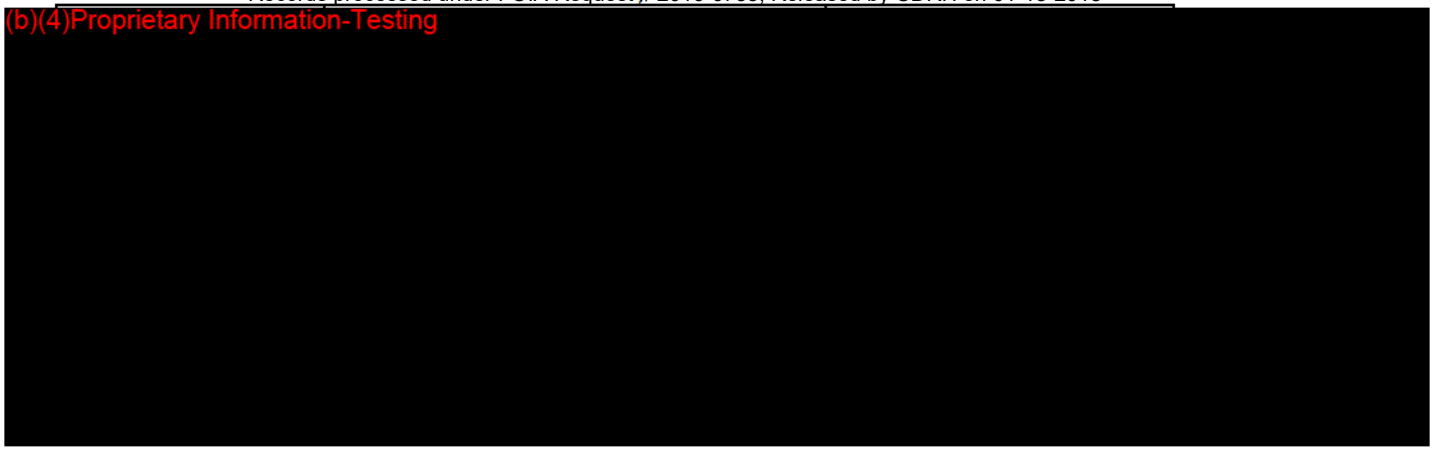
(b)(4)Proprietary Information-Testing



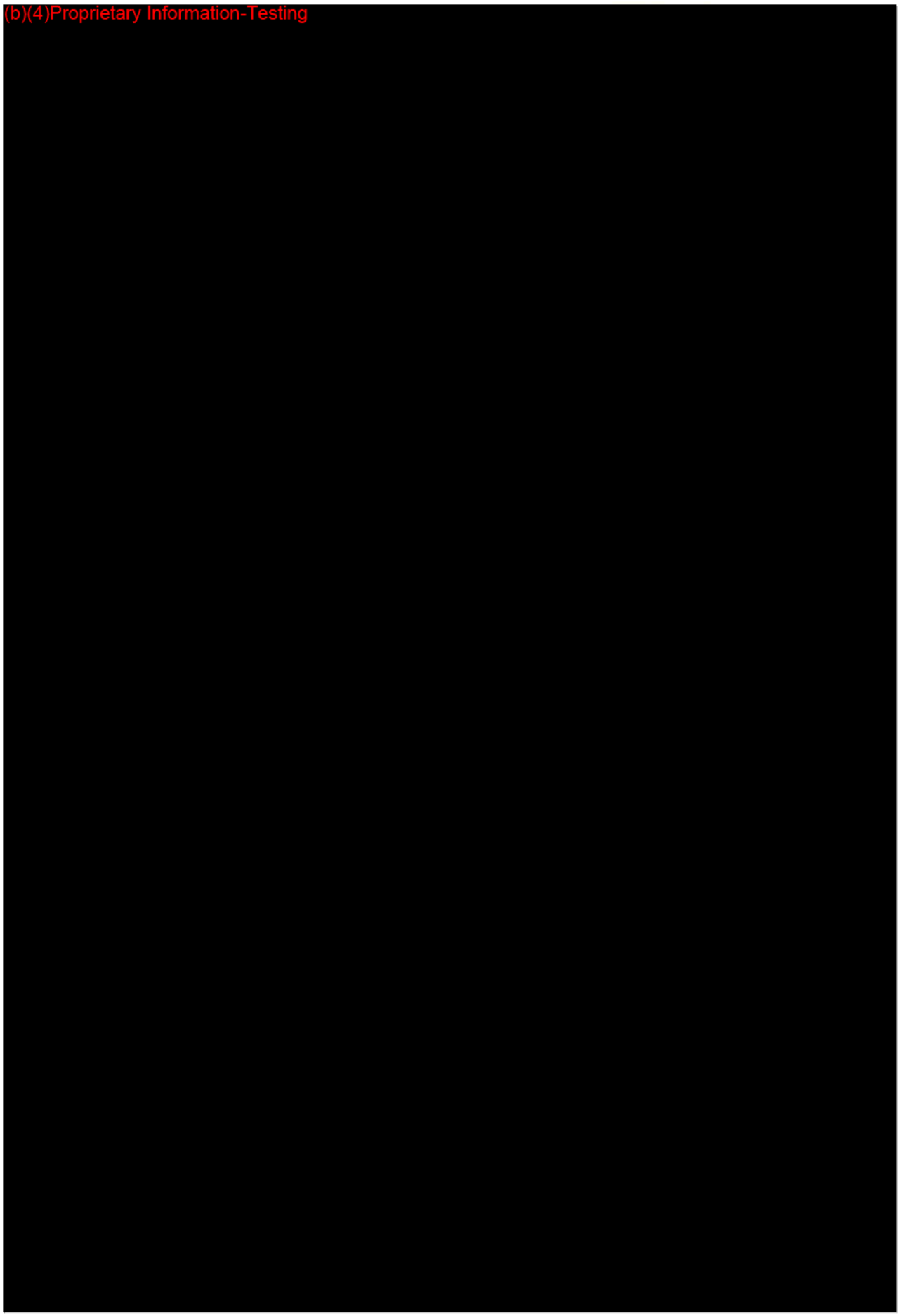
(b)(4)Proprietary Information-Testing



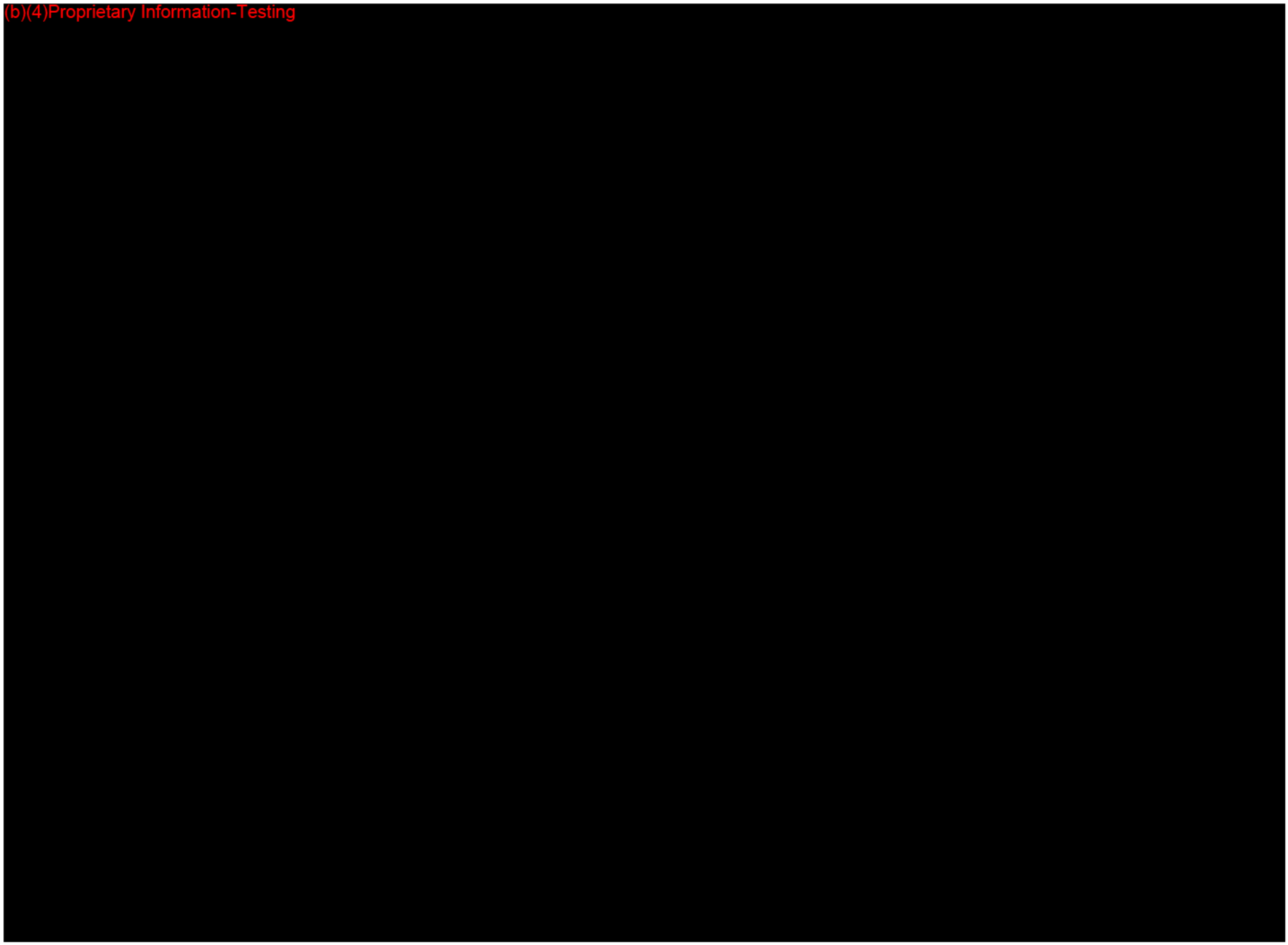
(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing



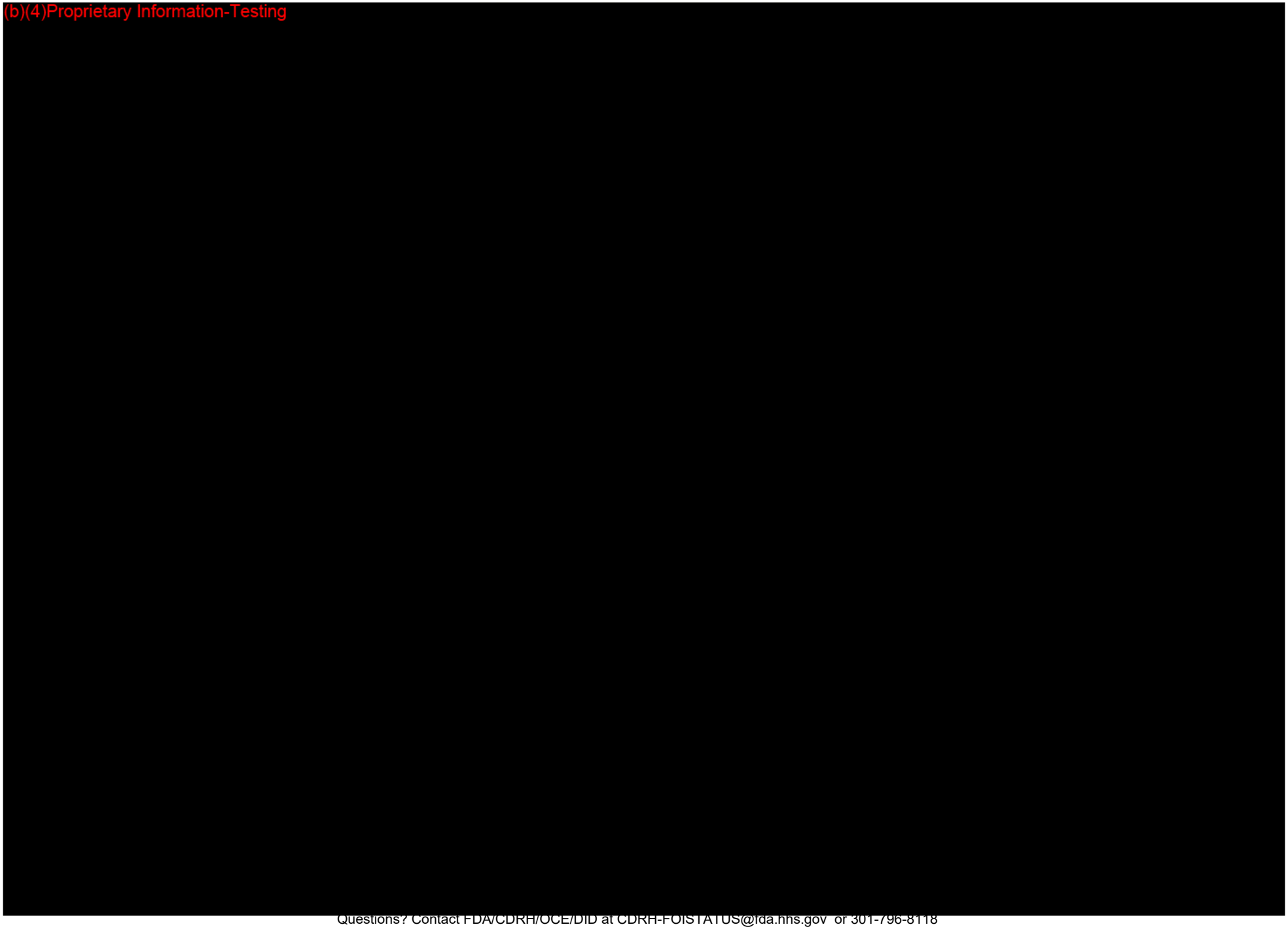
(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing

[redacted]

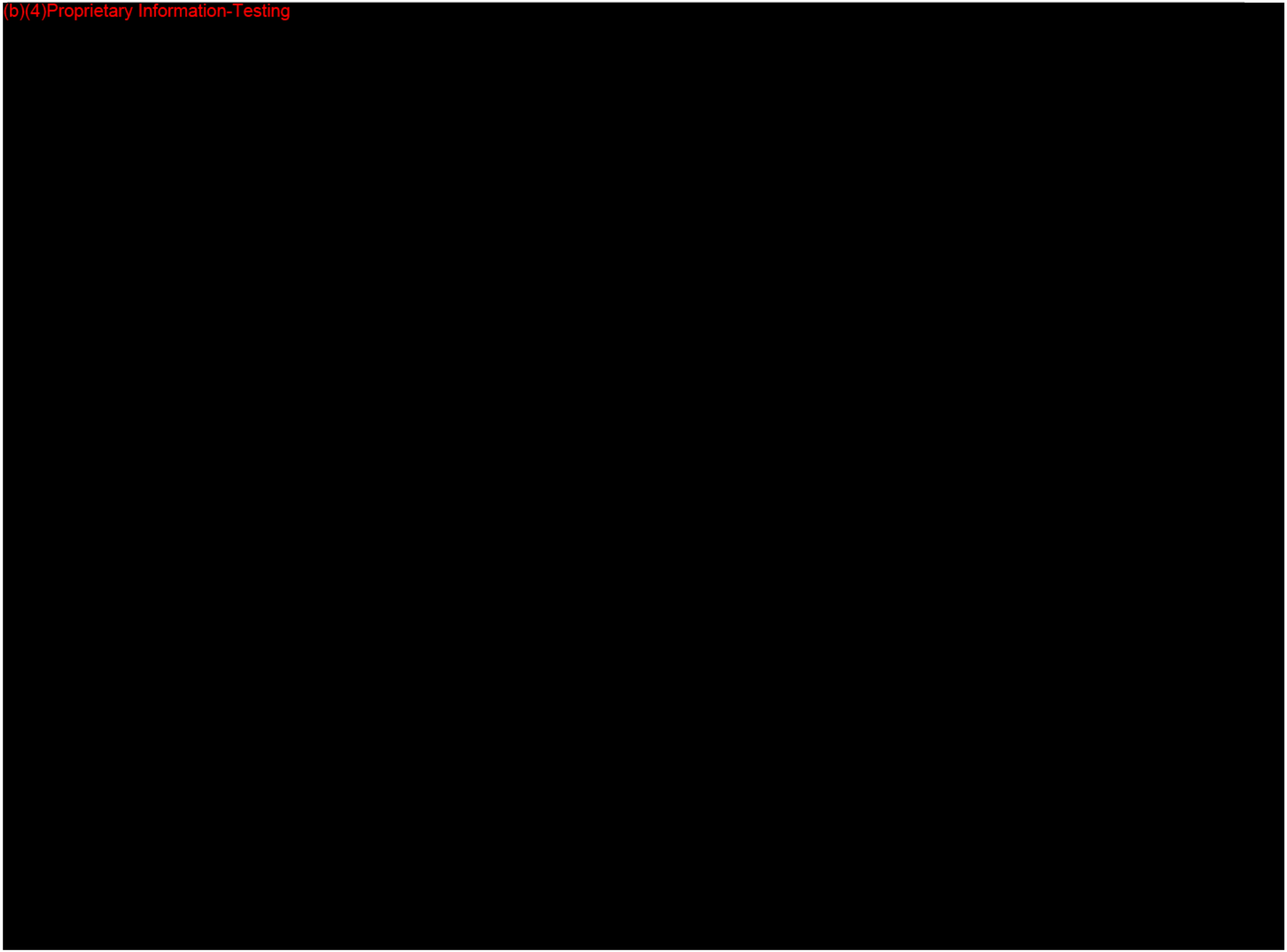
(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing

[redacted]

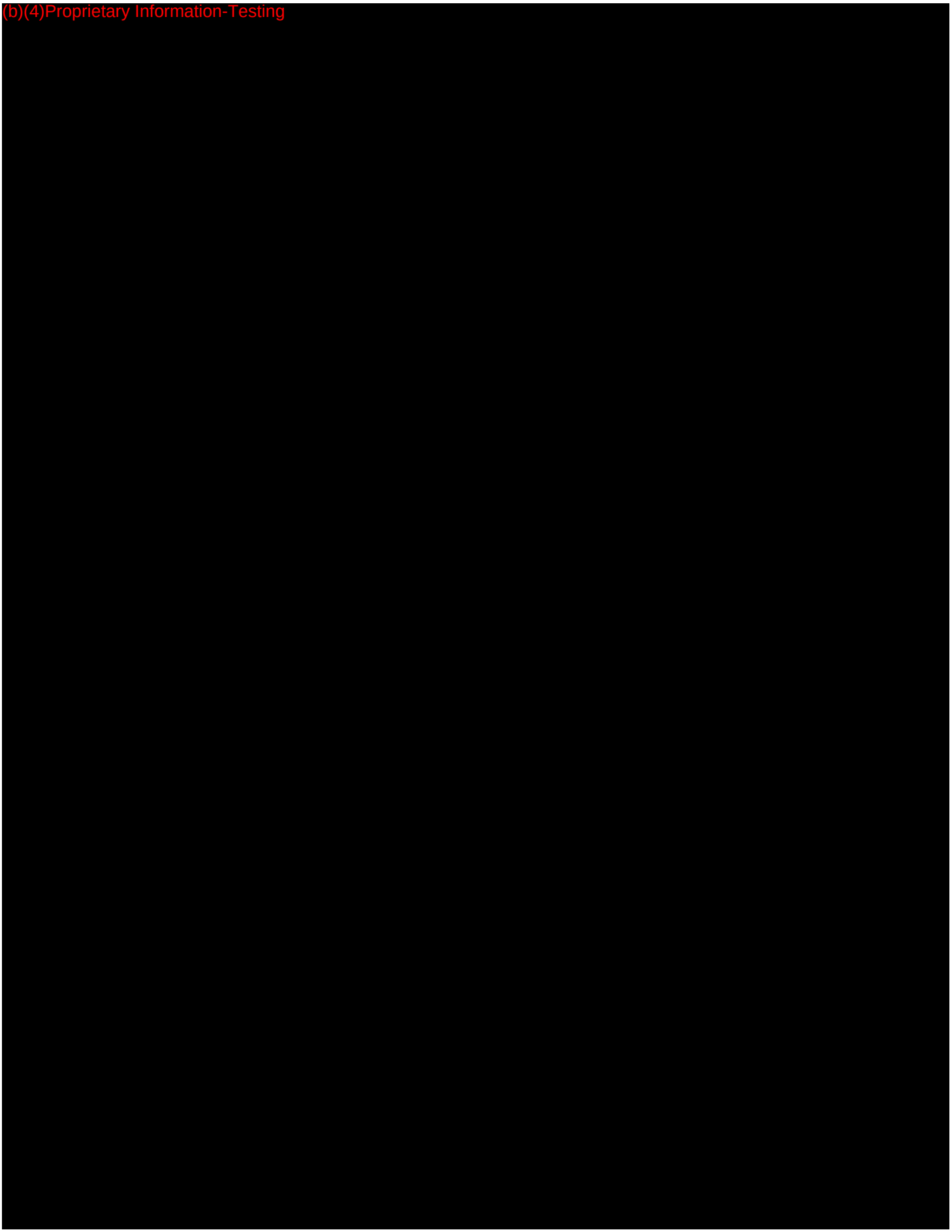
(b)(4)Proprietary Information-Testing



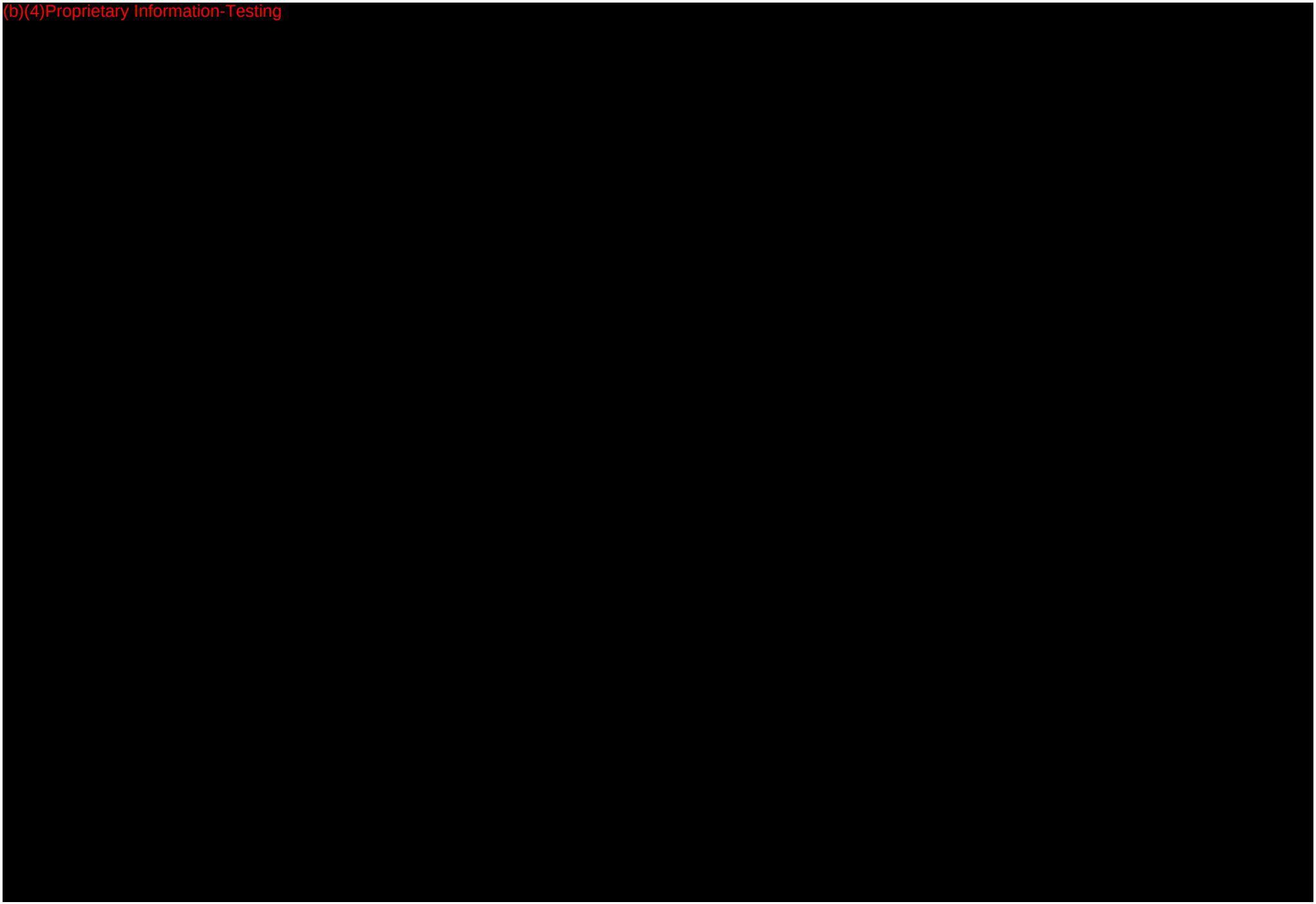
(b)(4)Proprietary Information-Testing

[redacted]

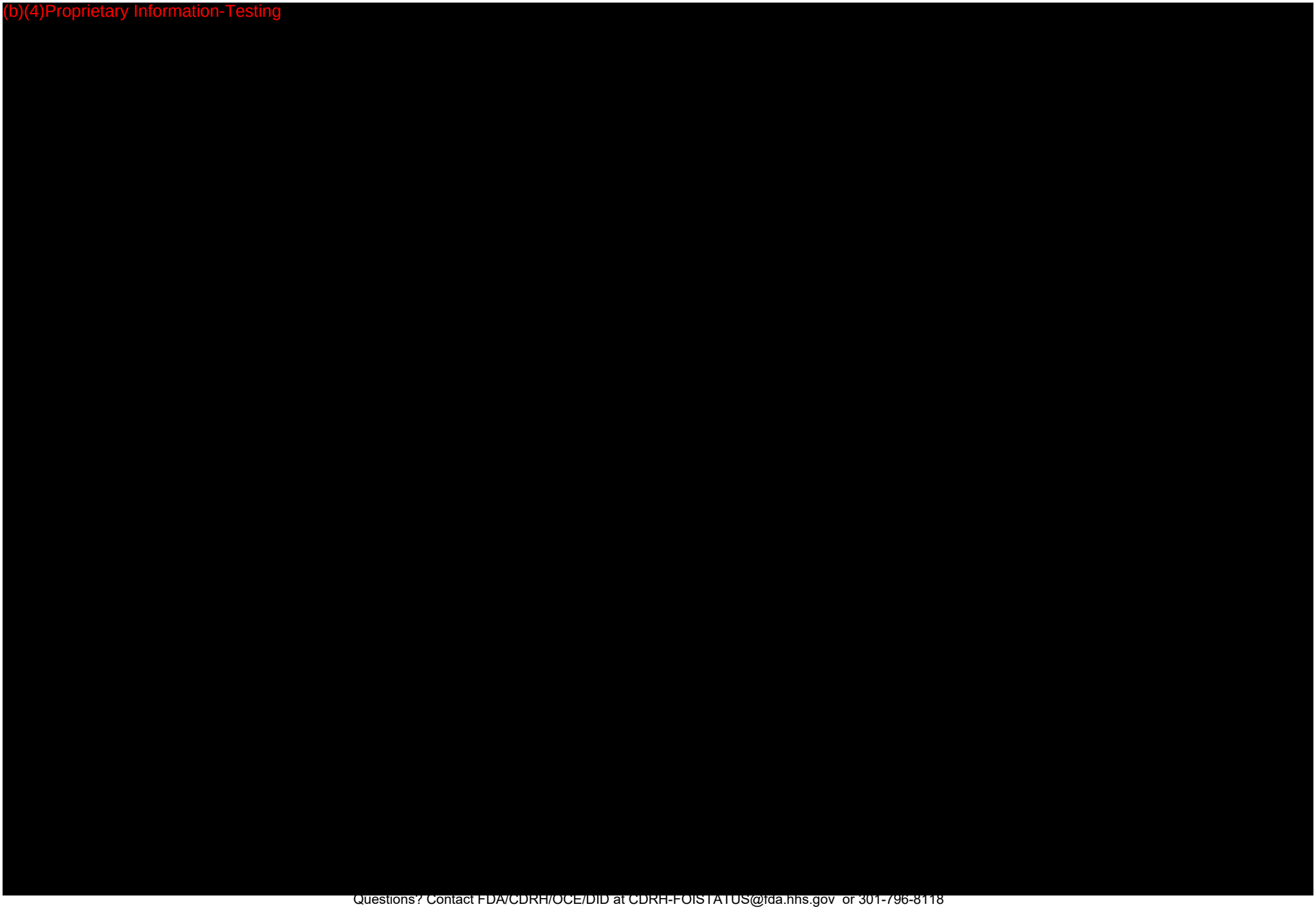
(b)(4)Proprietary Information-Testing

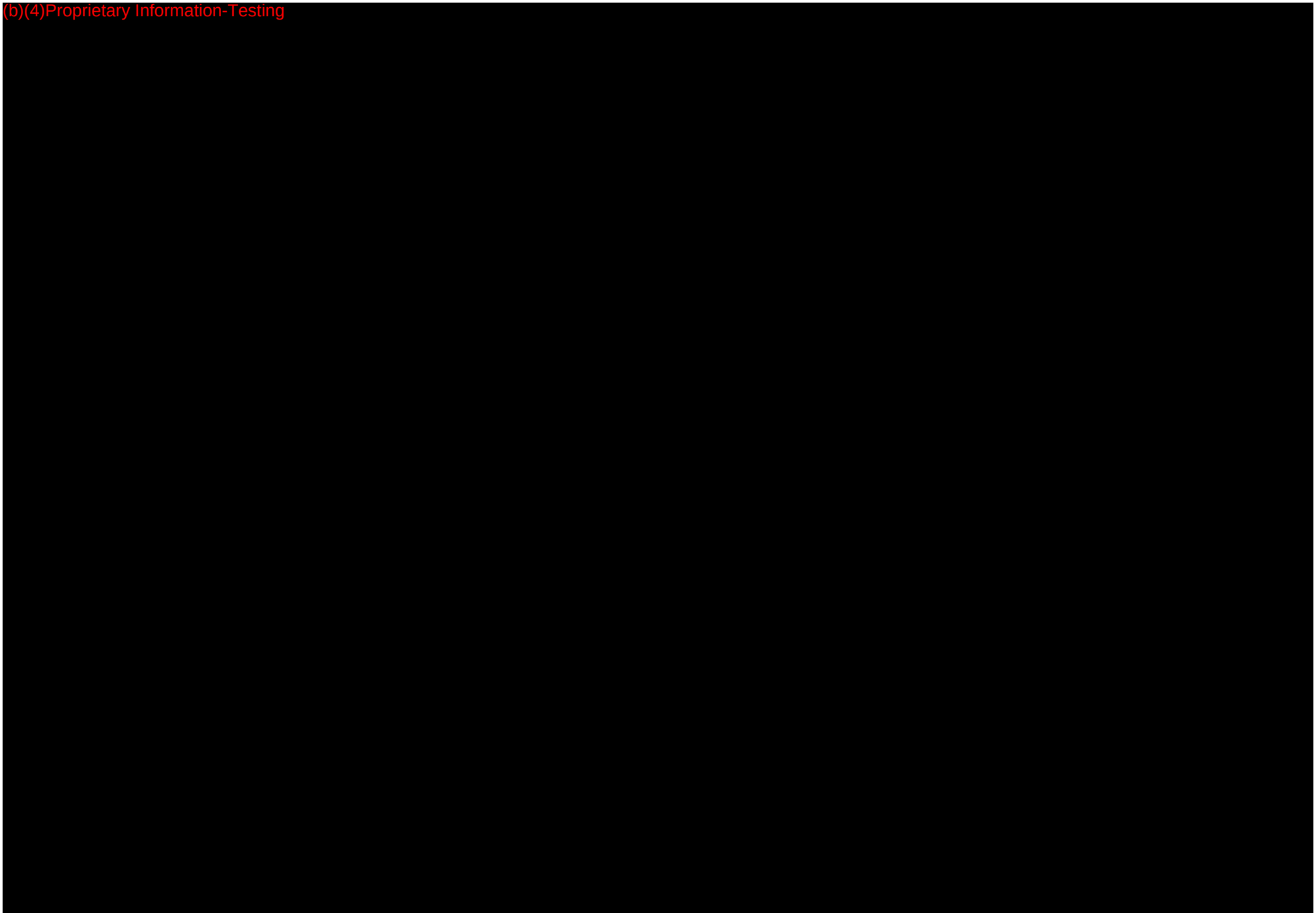


(b)(4)Proprietary Information-Testing

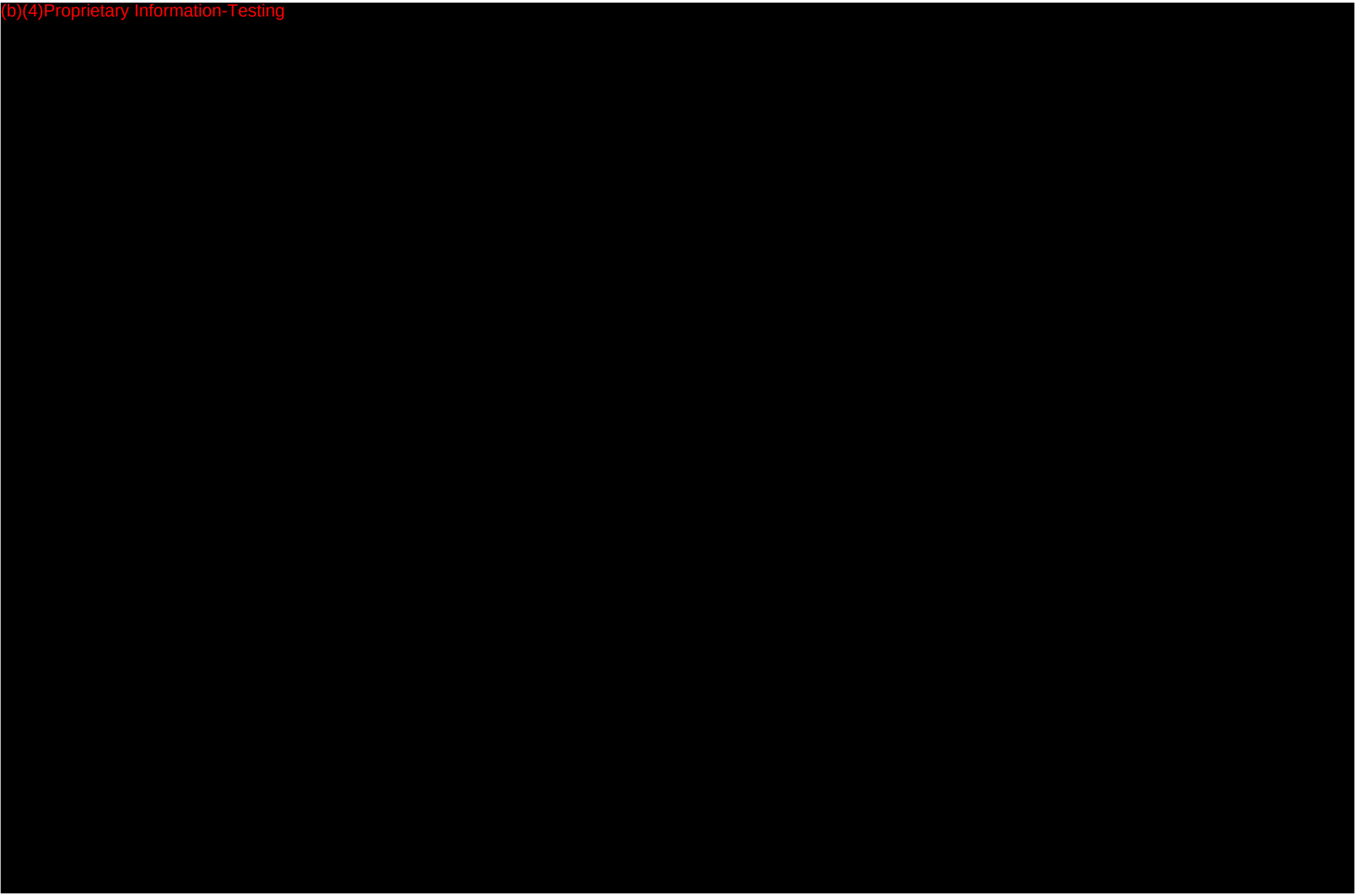


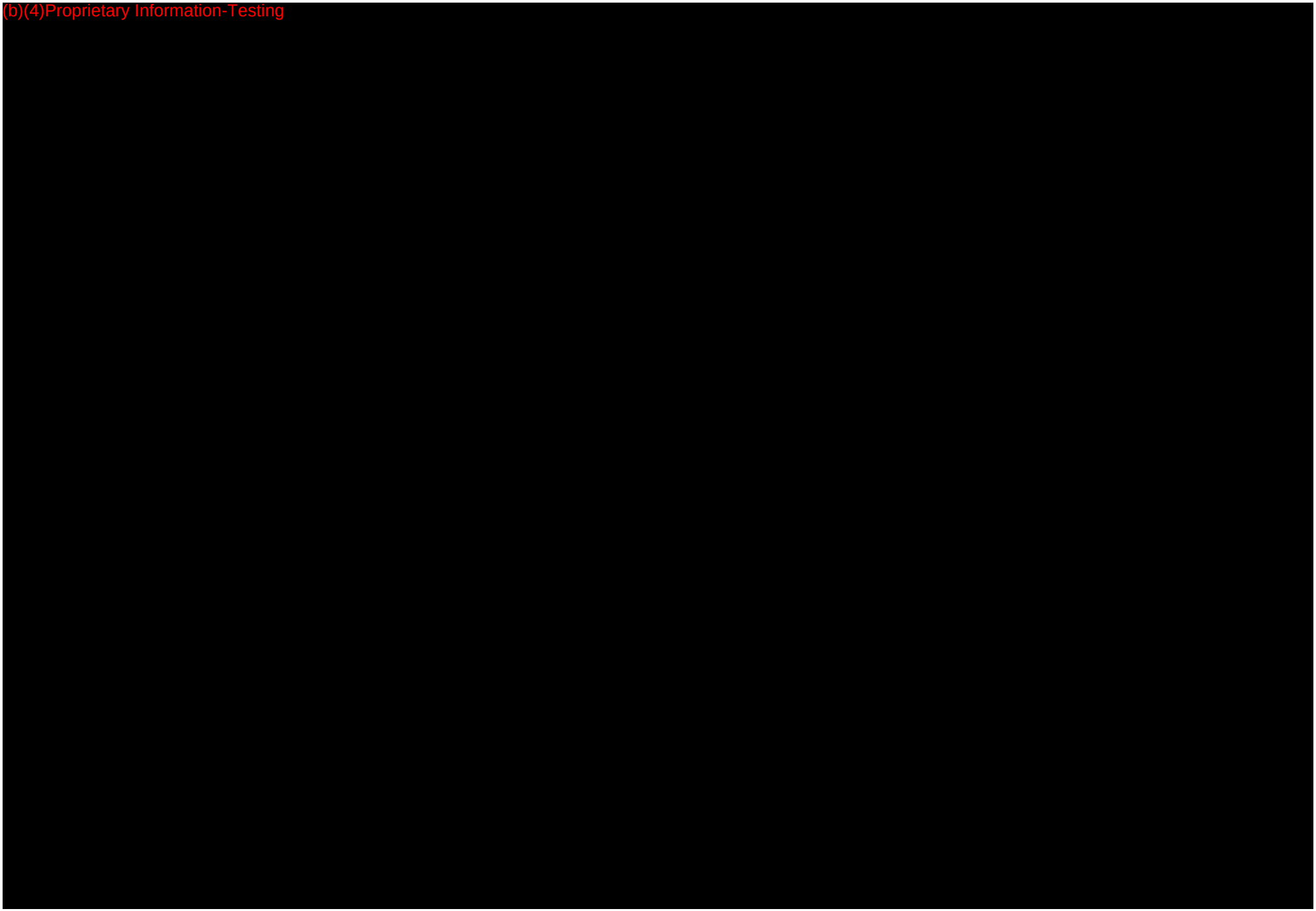
(b)(4)Proprietary Information-Testing



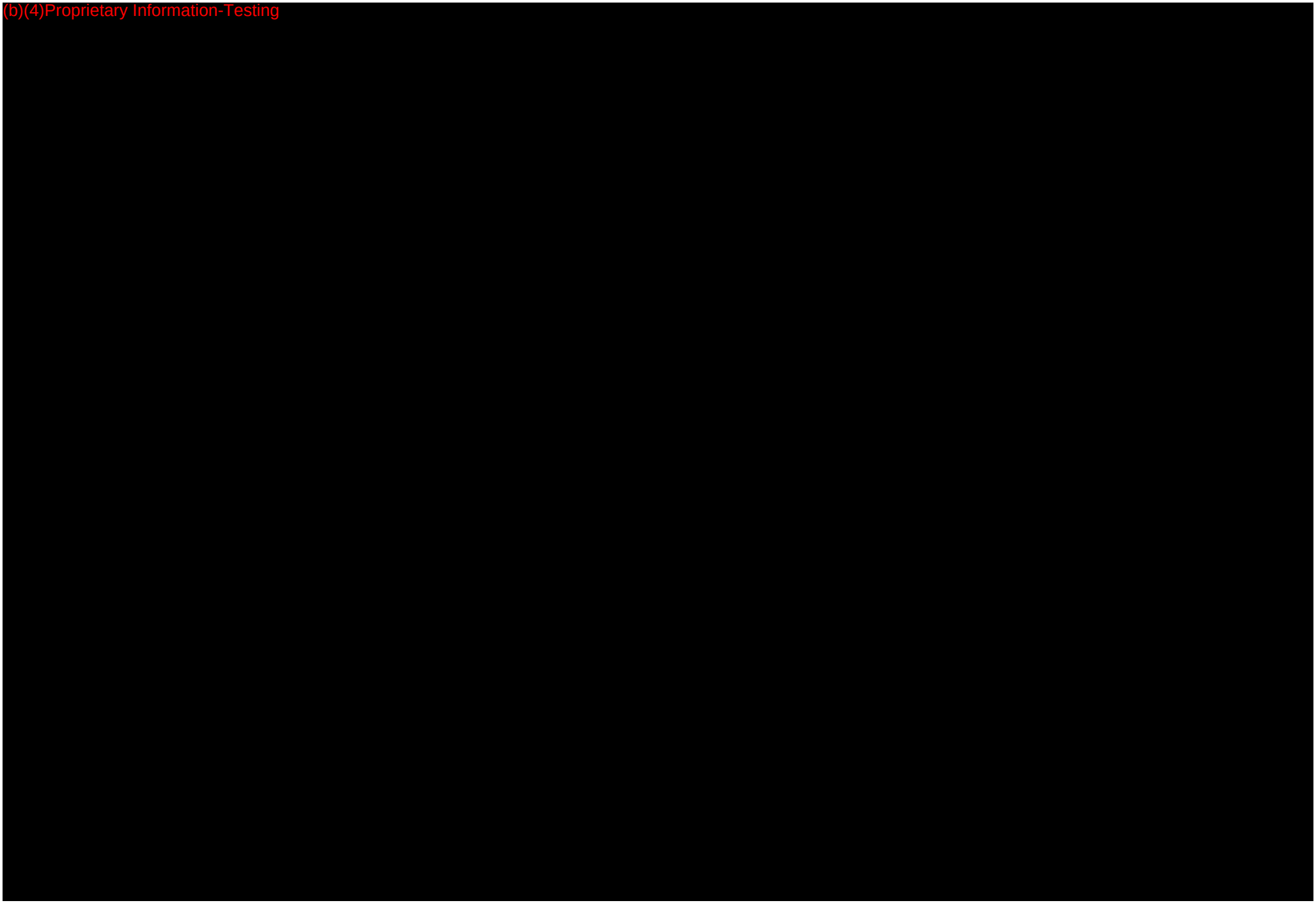


(b)(4)Proprietary Information-Testing

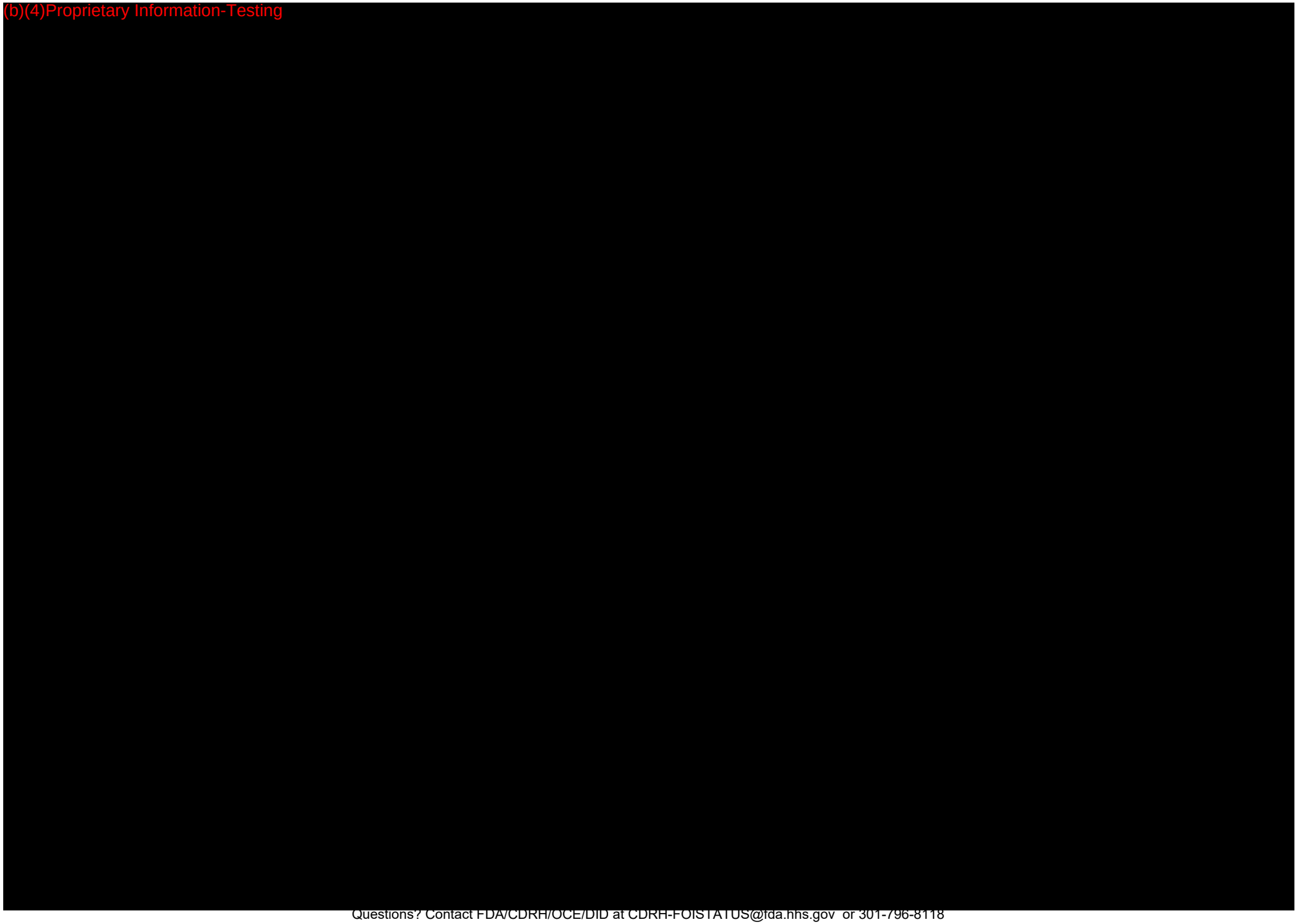




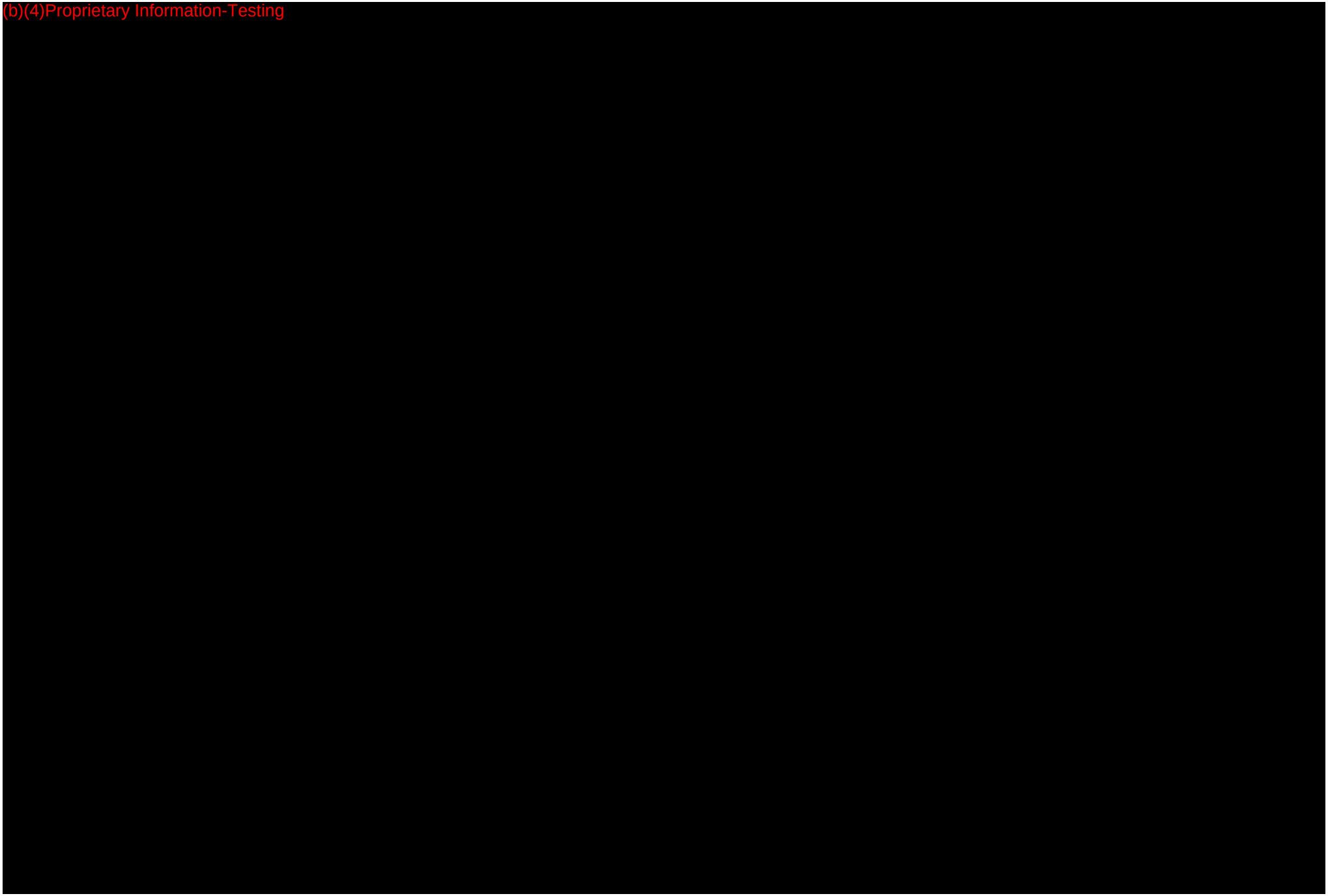
(b)(4)Proprietary Information-Testing



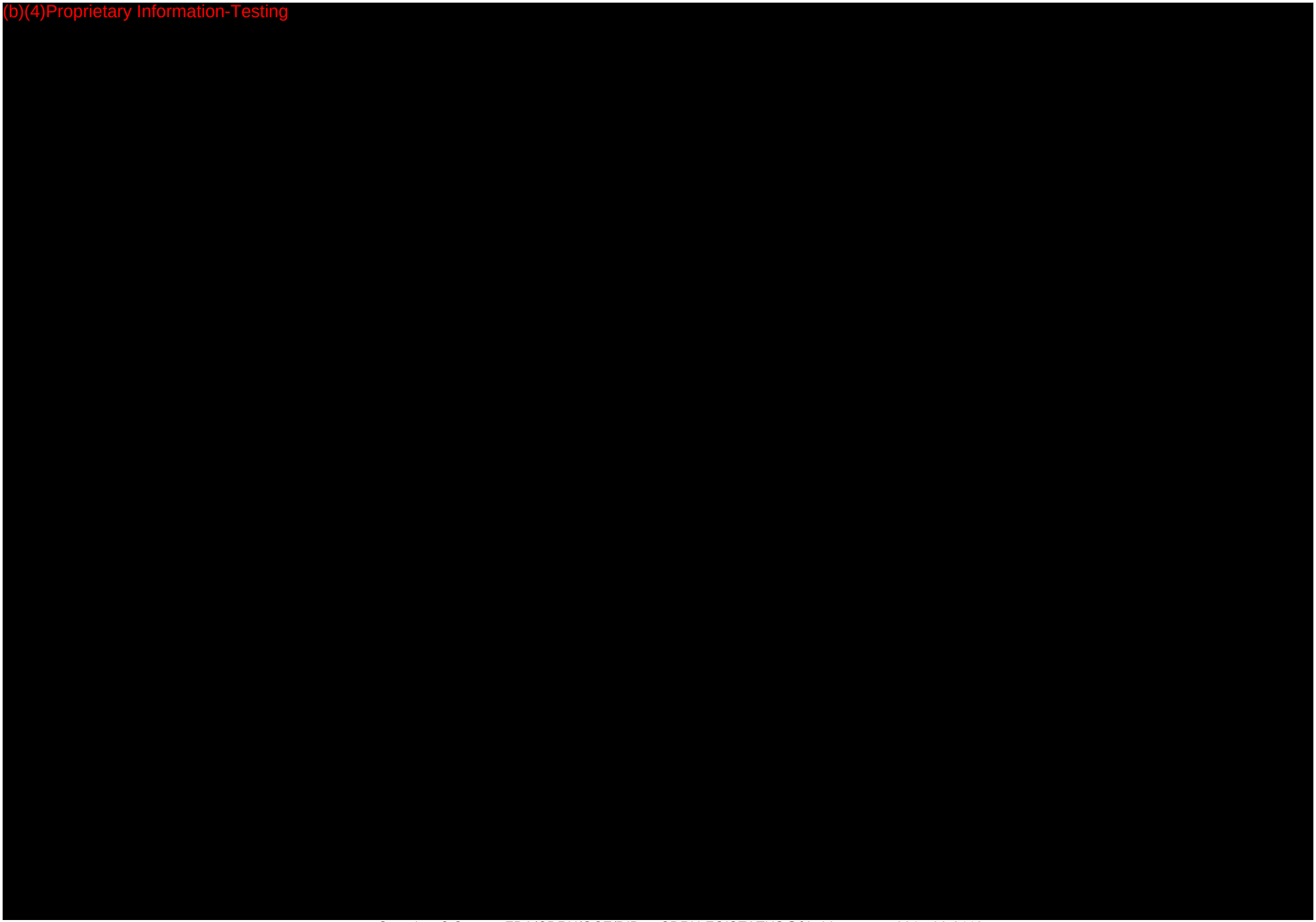
(b)(4)Proprietary Information-Testing



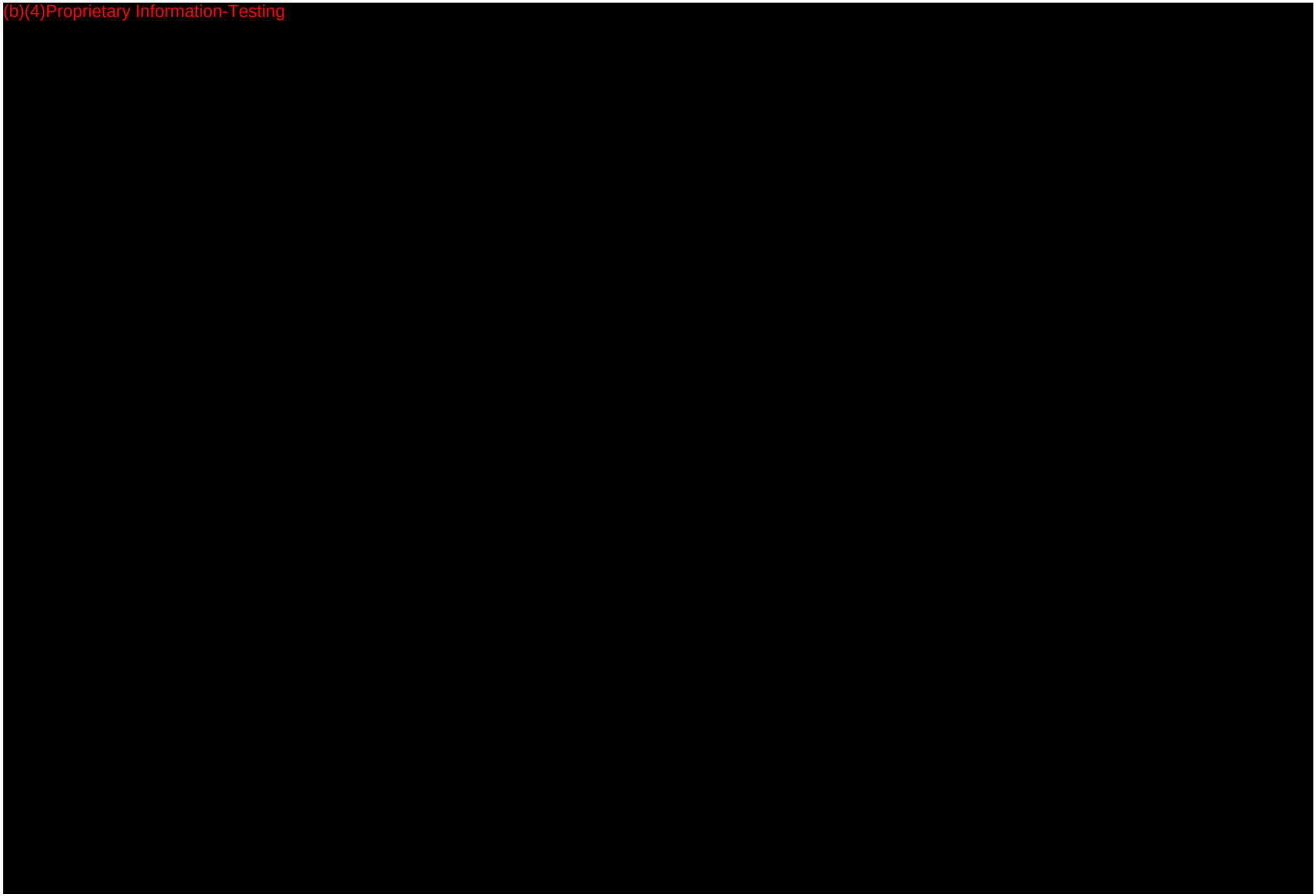
(b)(4)Proprietary Information-Testing

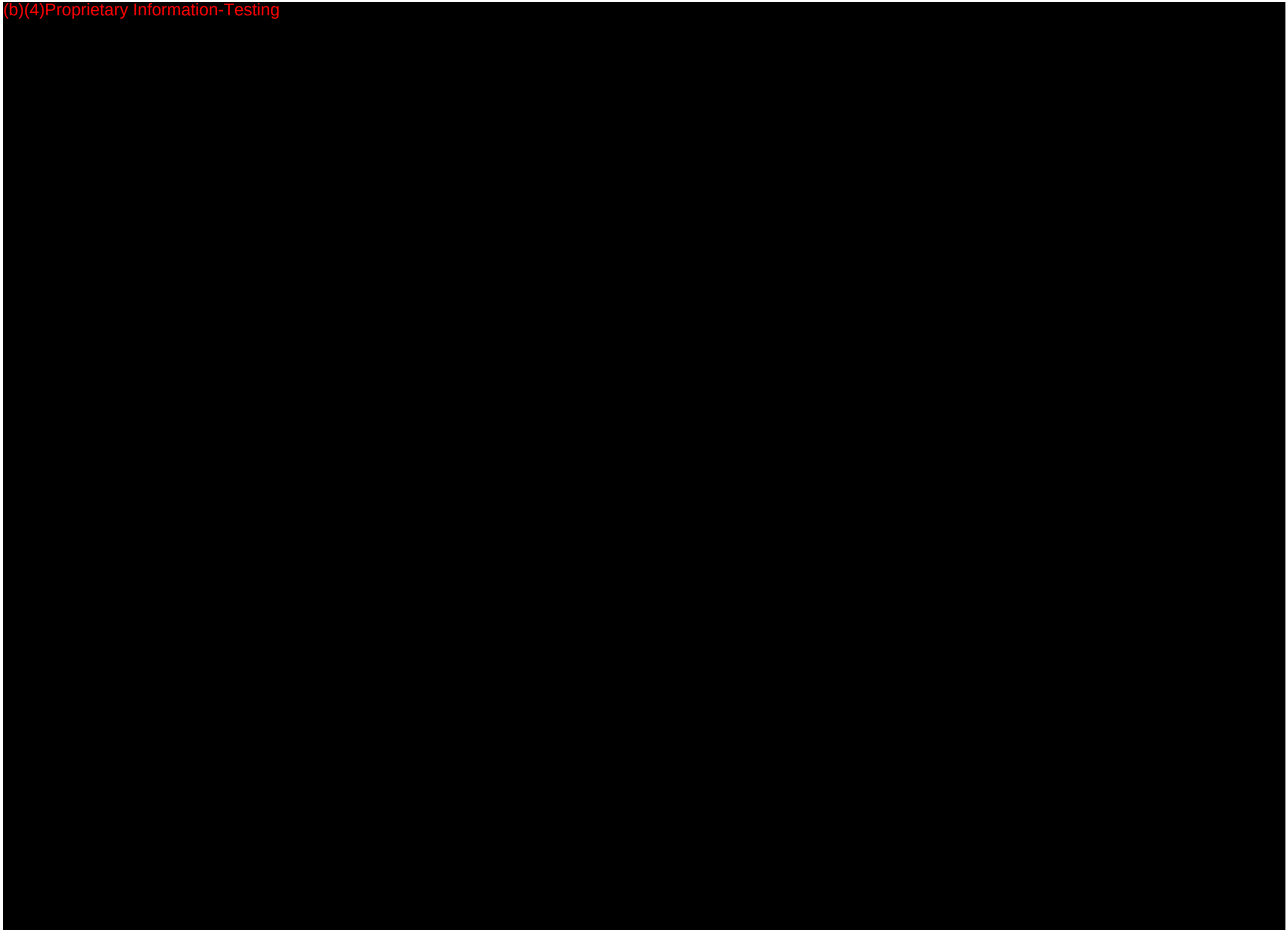


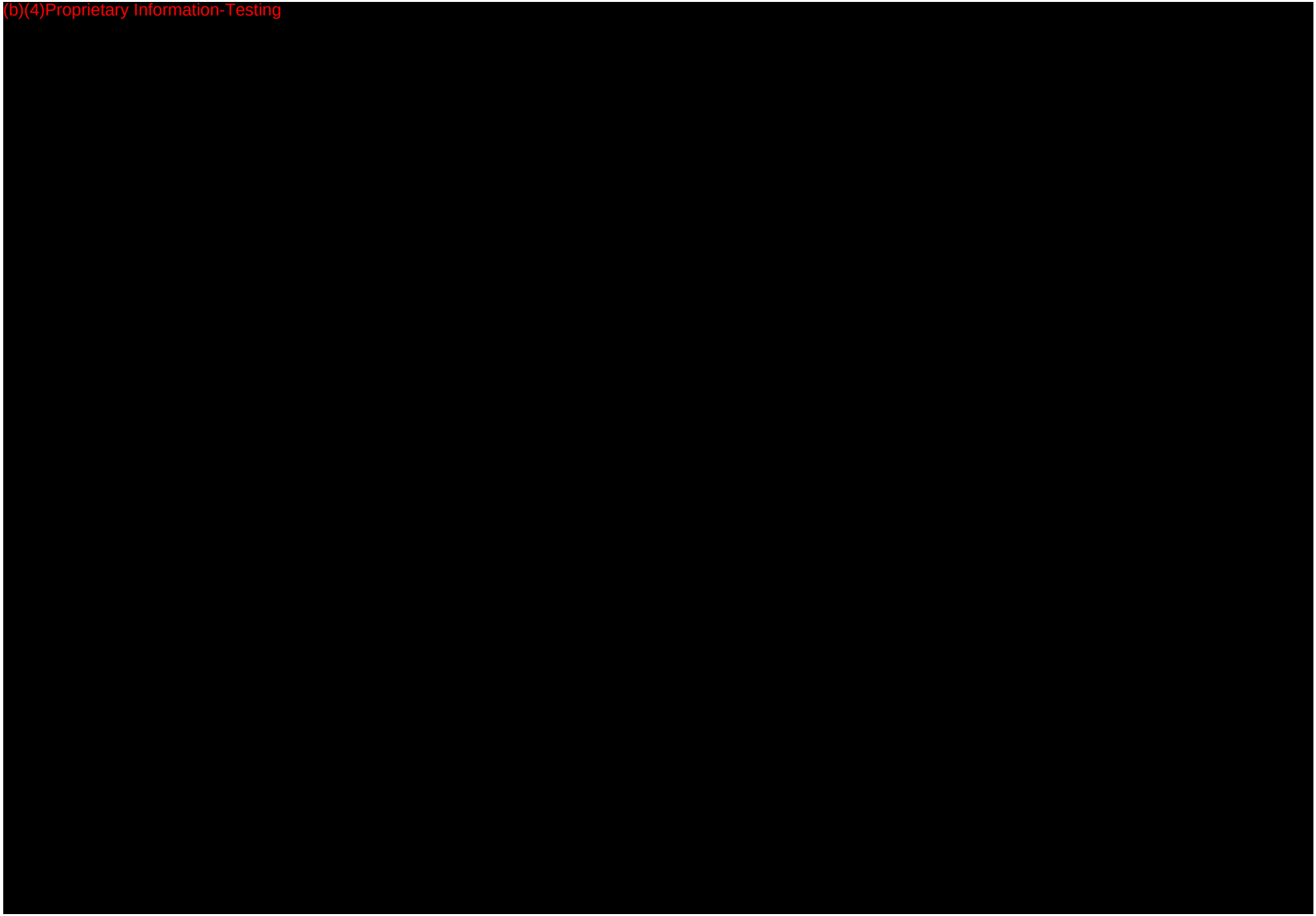
(b)(4)Proprietary Information-Testing

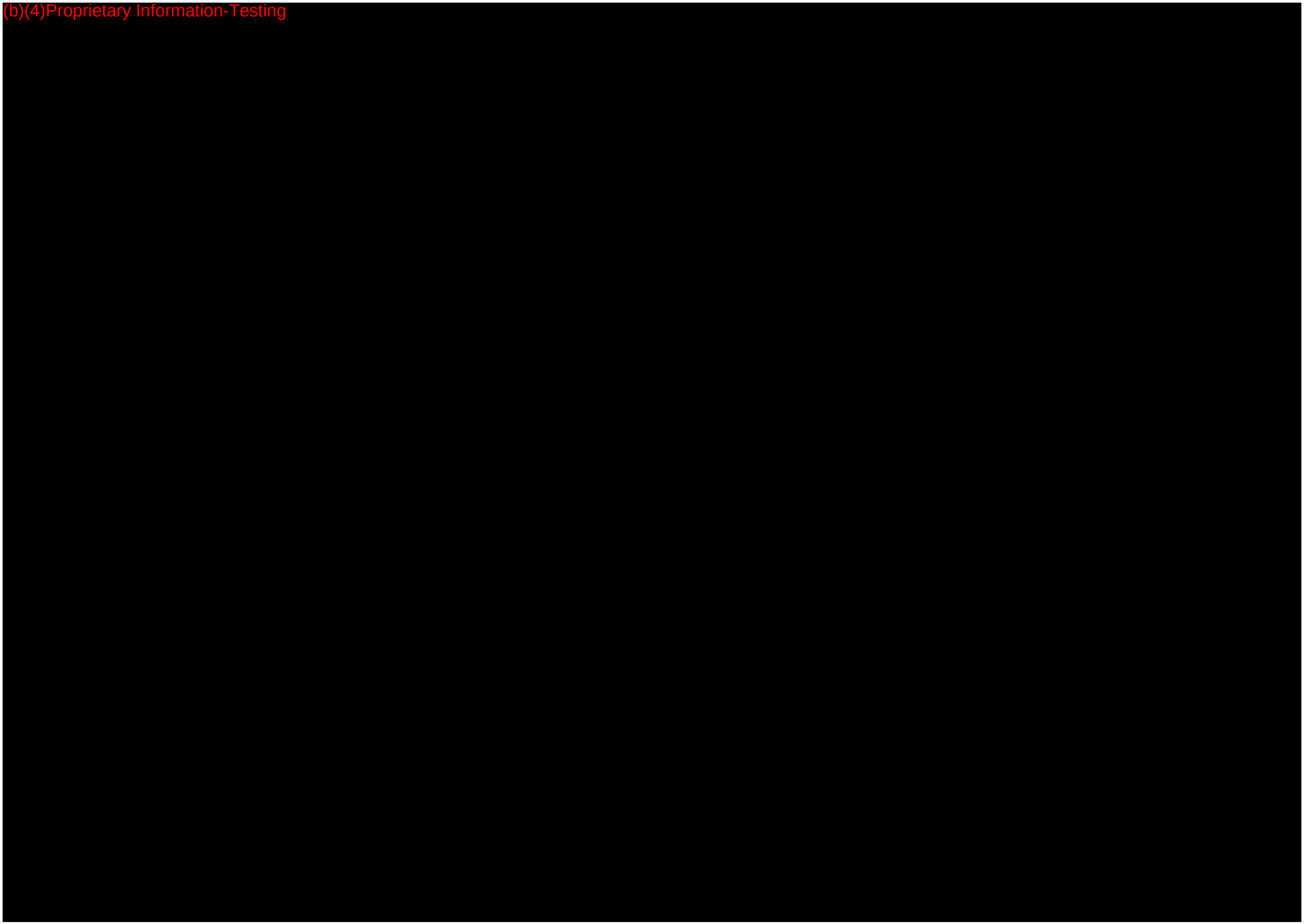


(b)(4)Proprietary Information-Testing

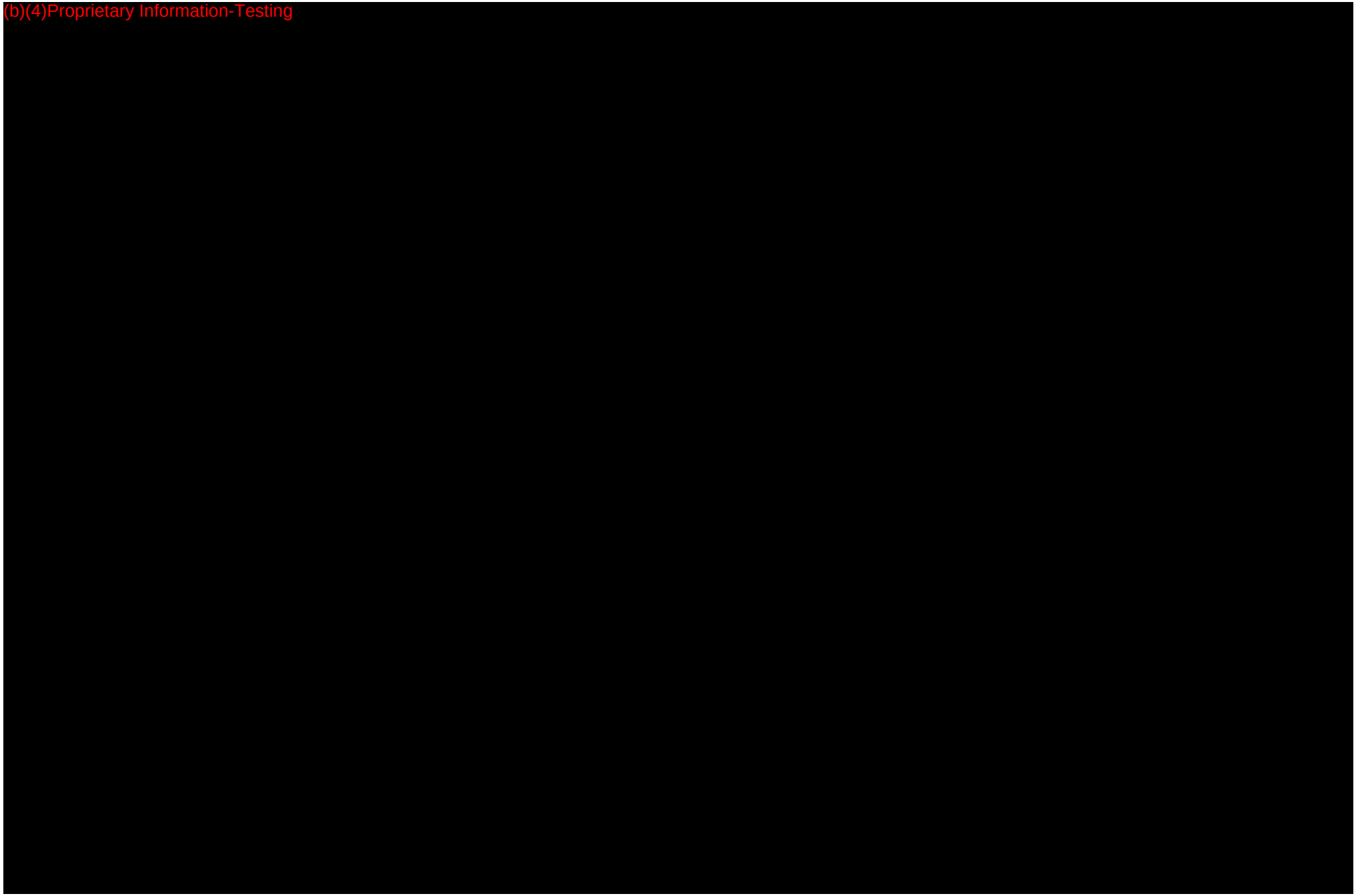




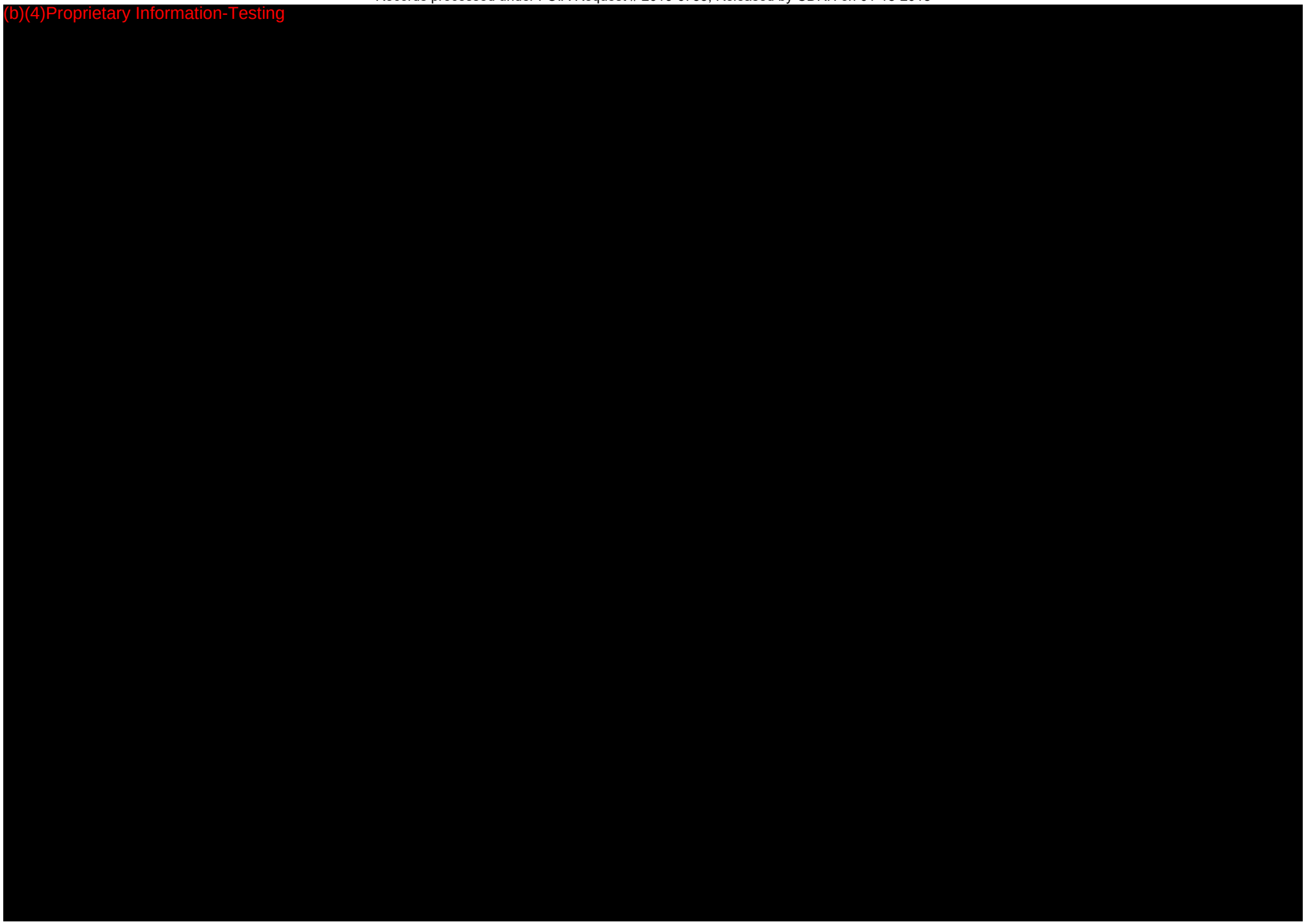


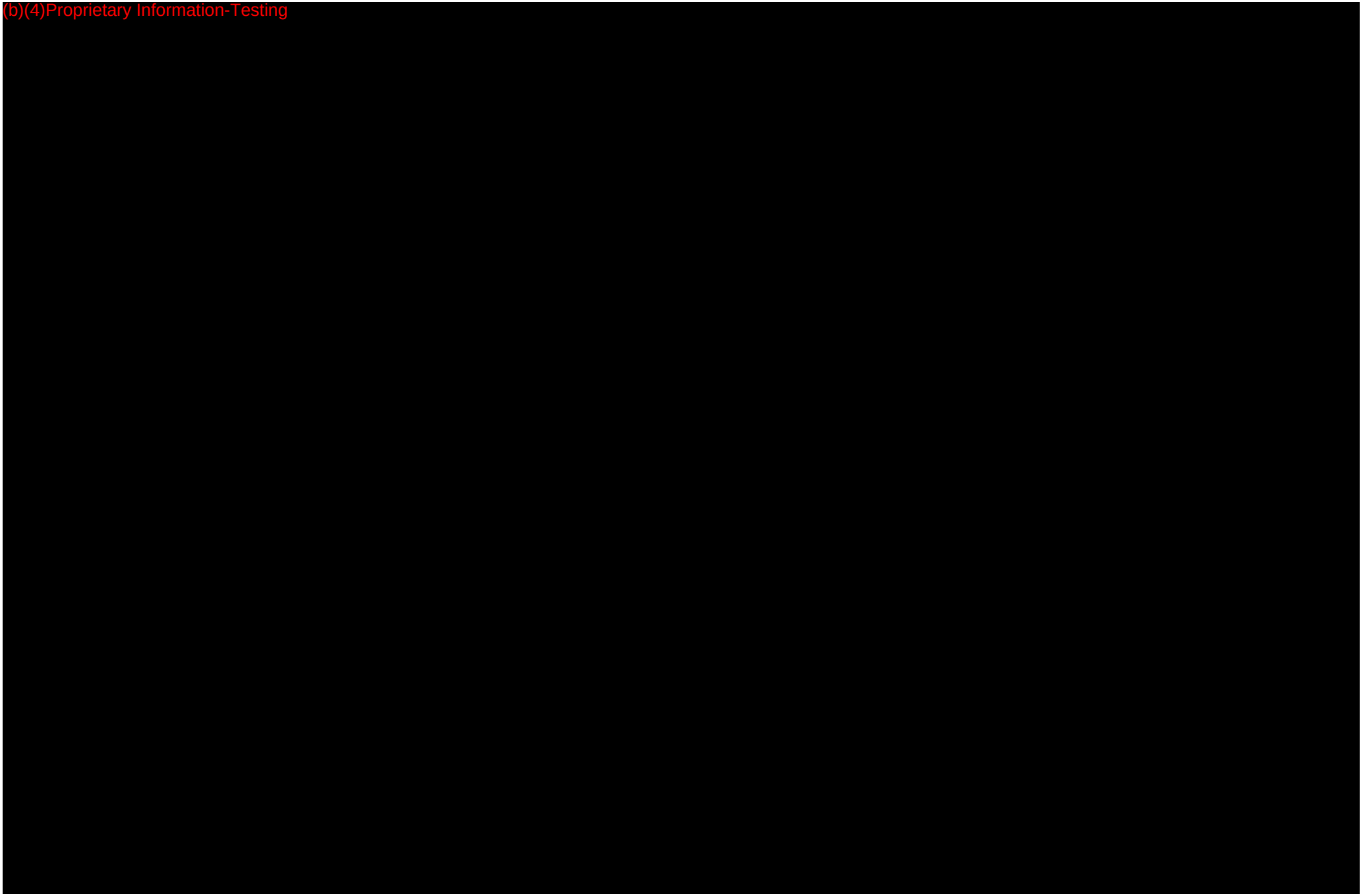


(b)(4)Proprietary Information-Testing



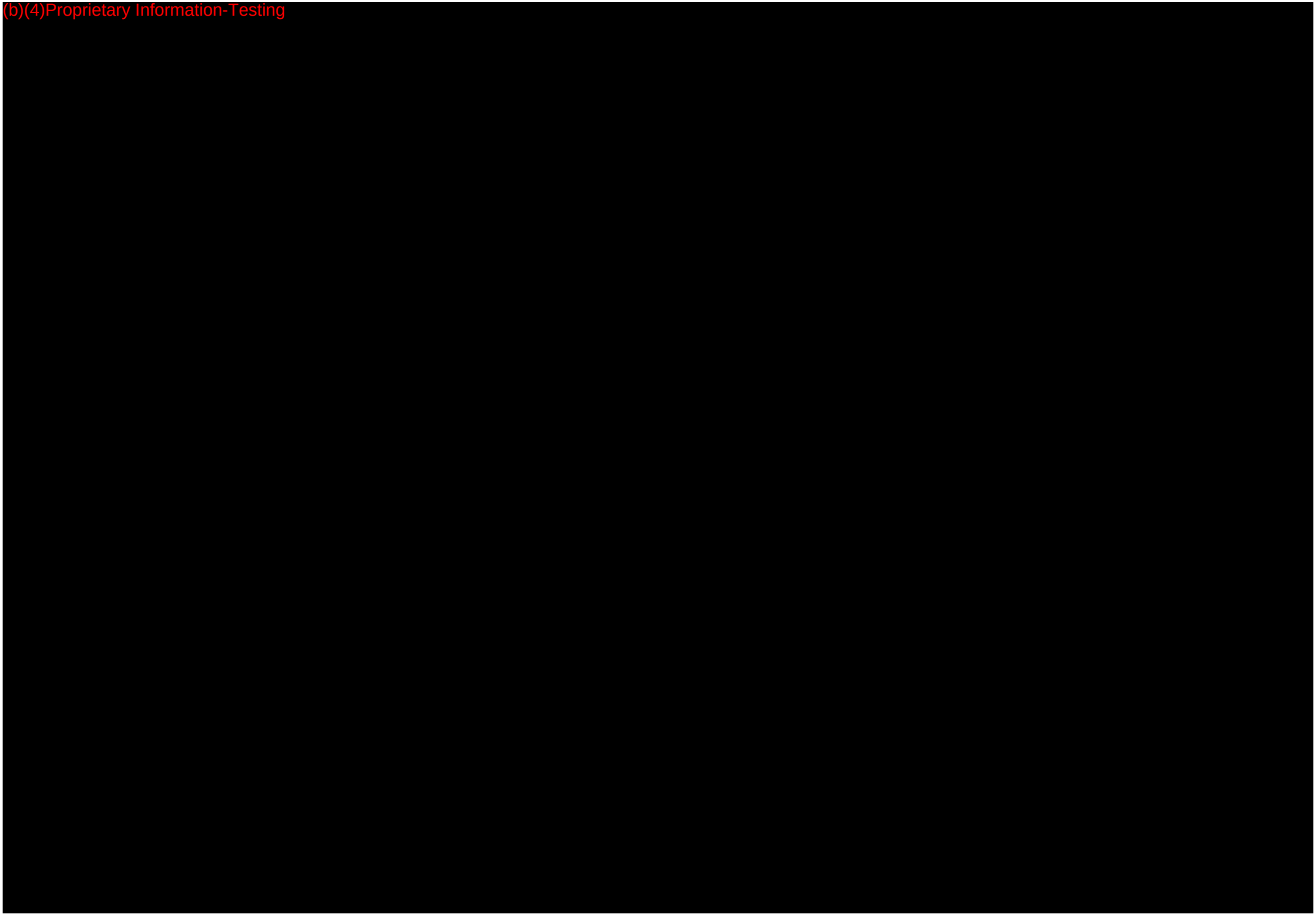
(b)(4)Proprietary Information-Testing

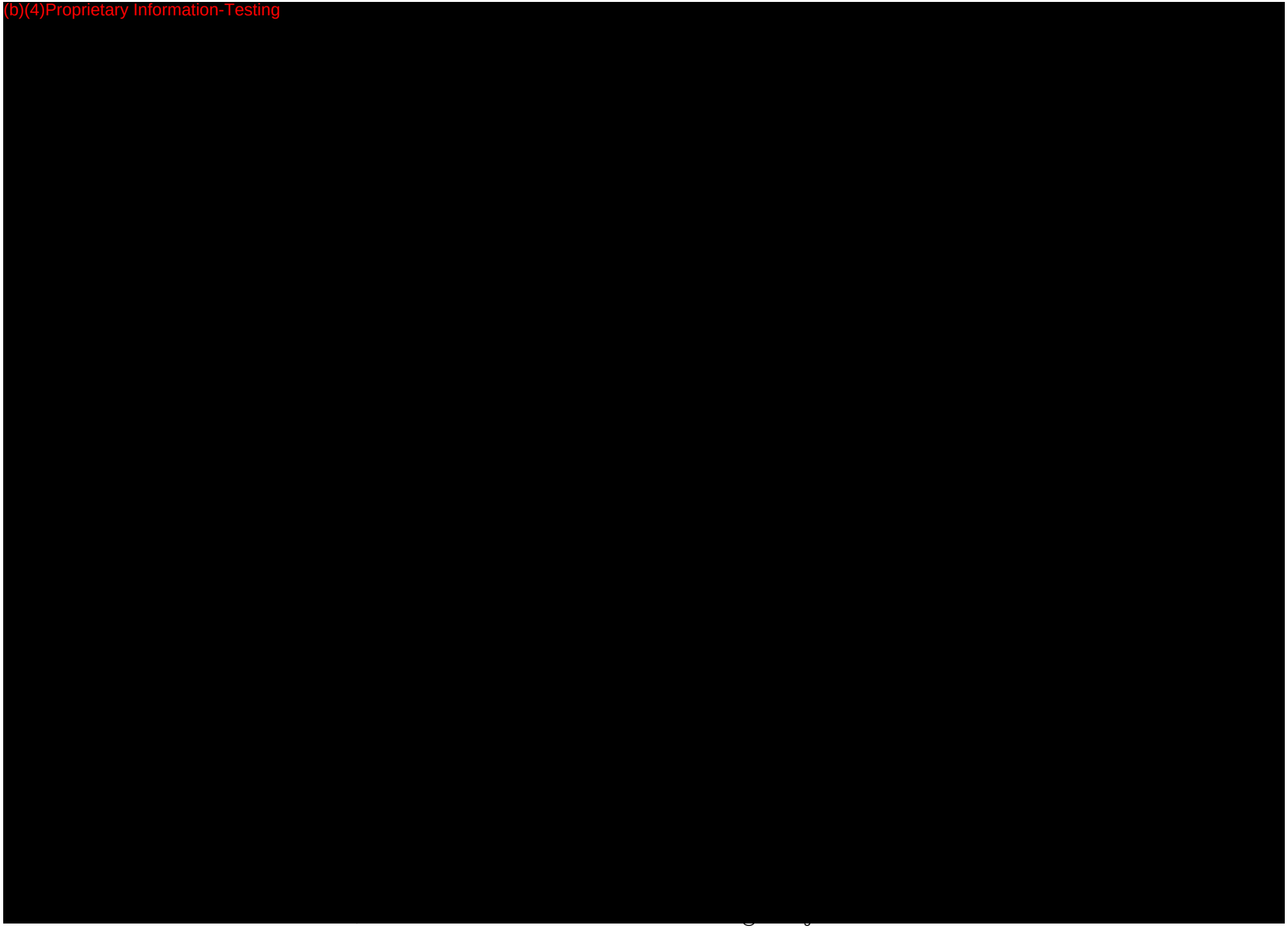




(b)(4)Proprietary Information-Testing

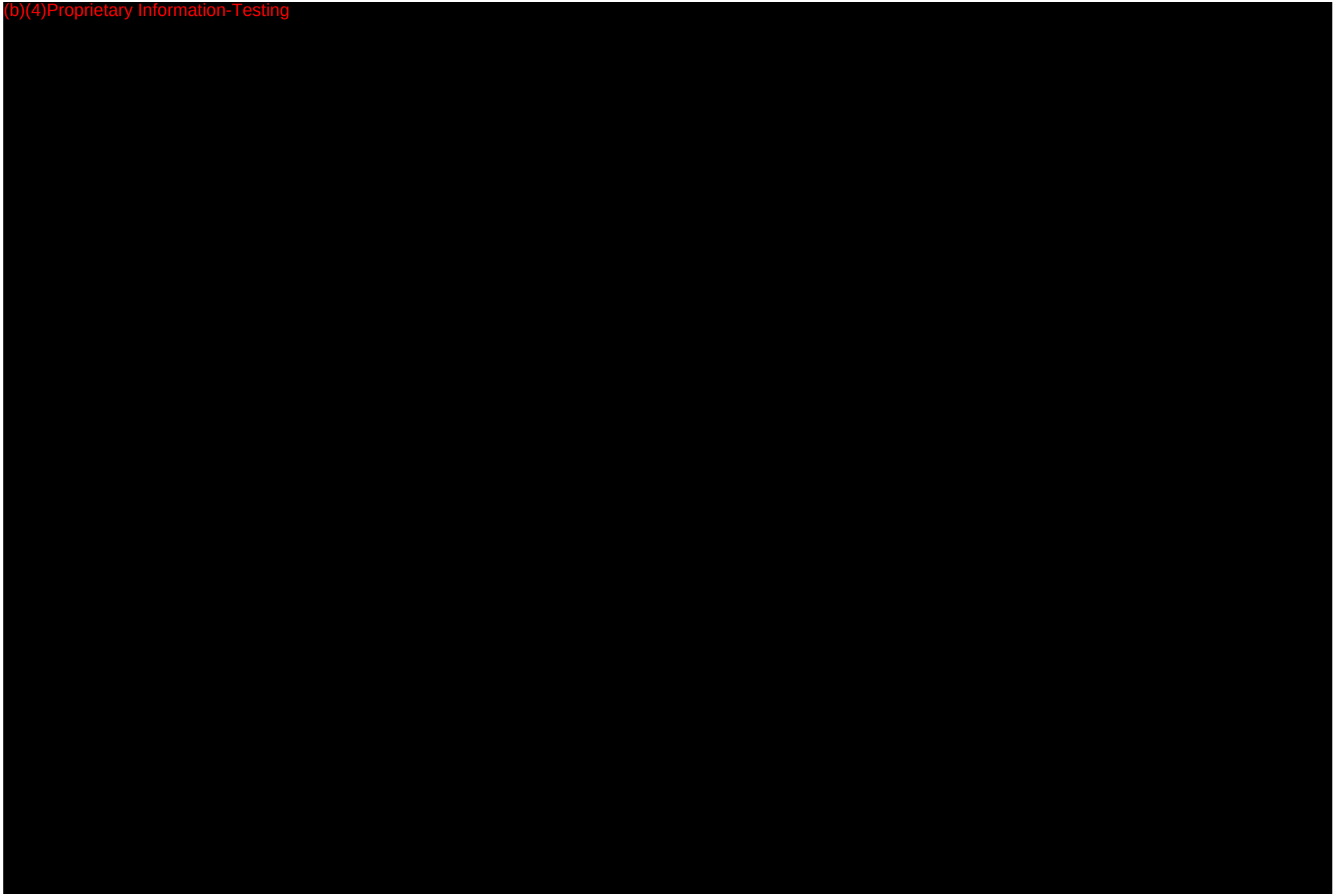
(b)(4)Proprietary Information-Testing

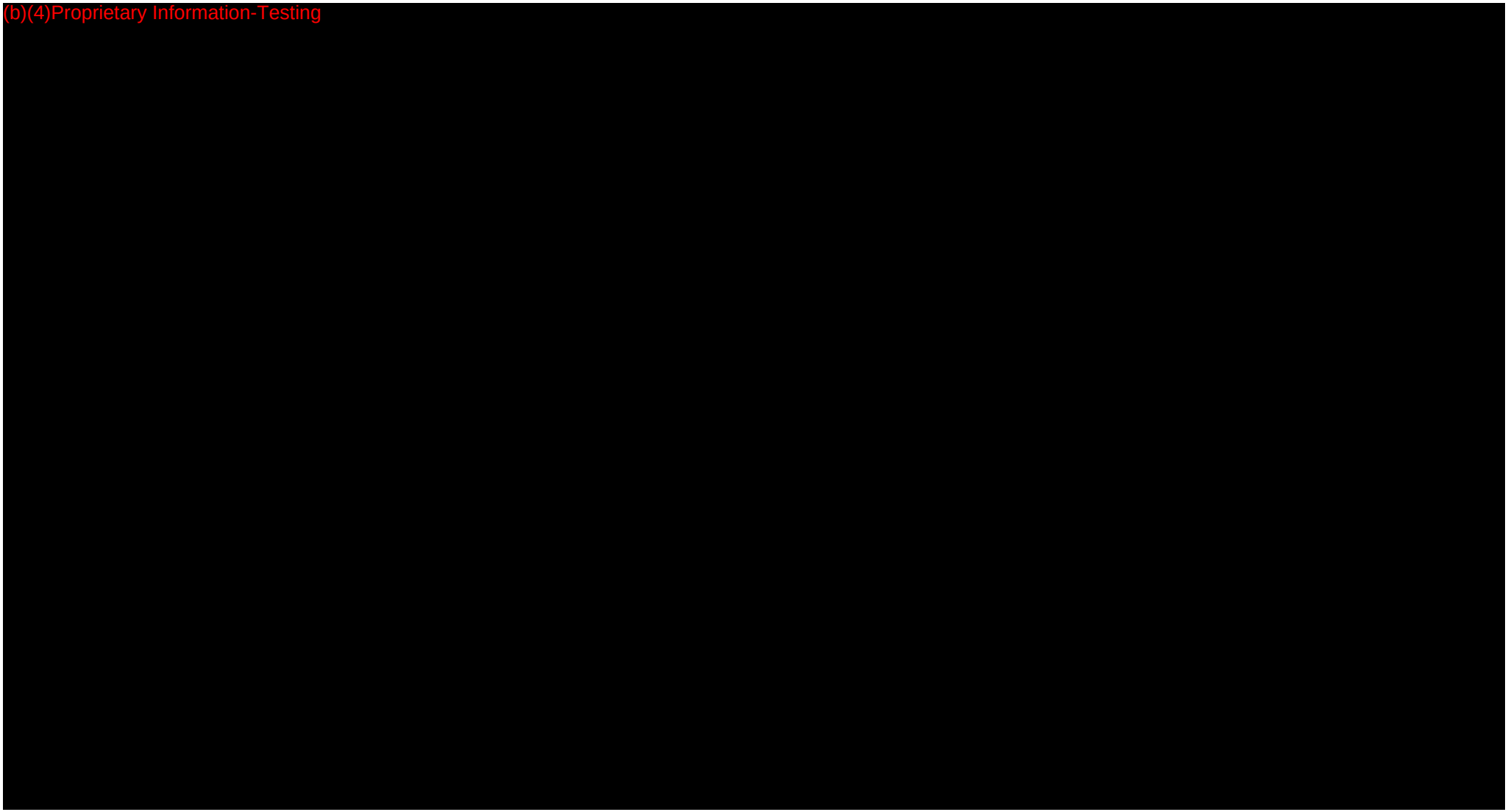


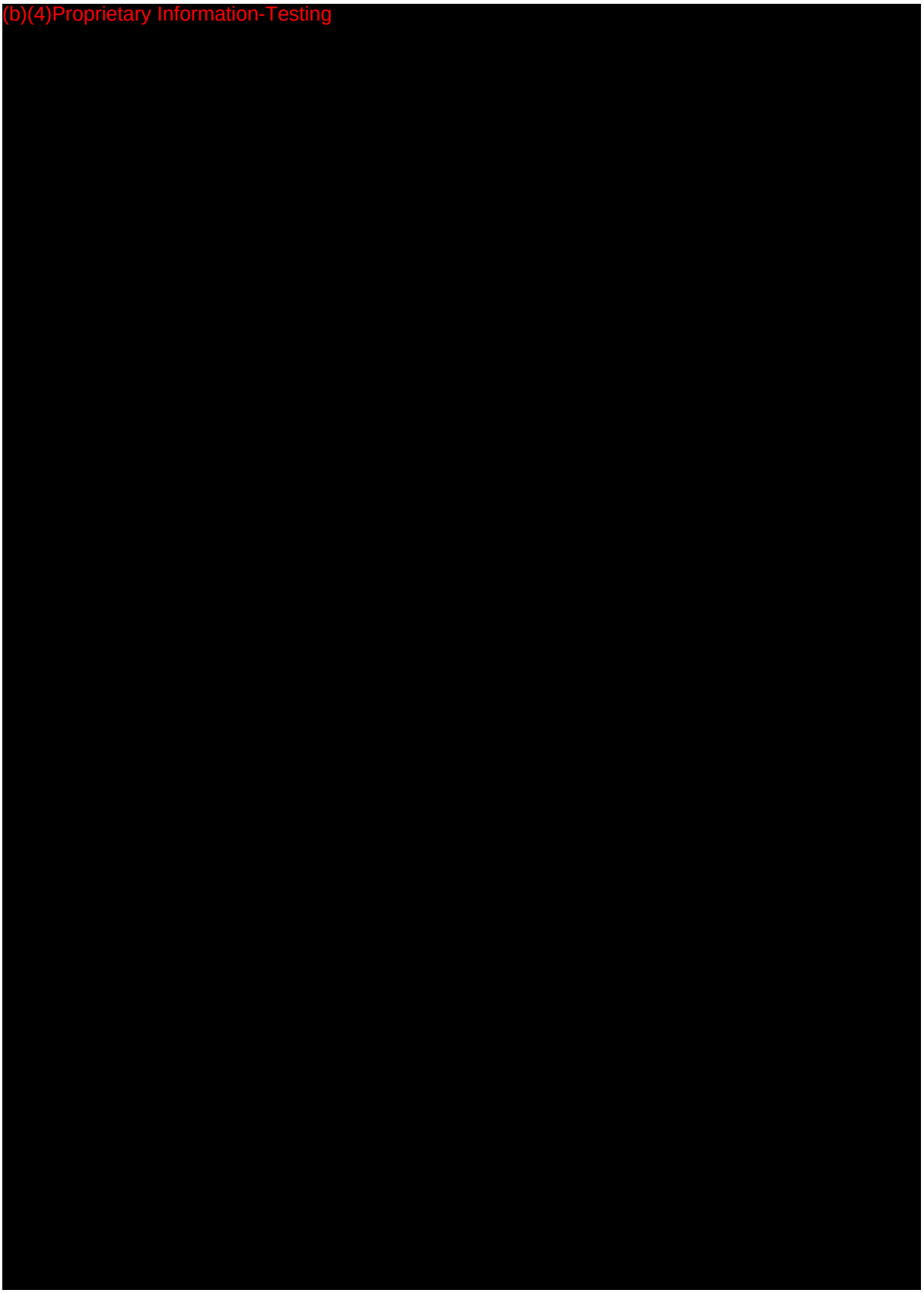


(b)(4)Proprietary Information-Testing

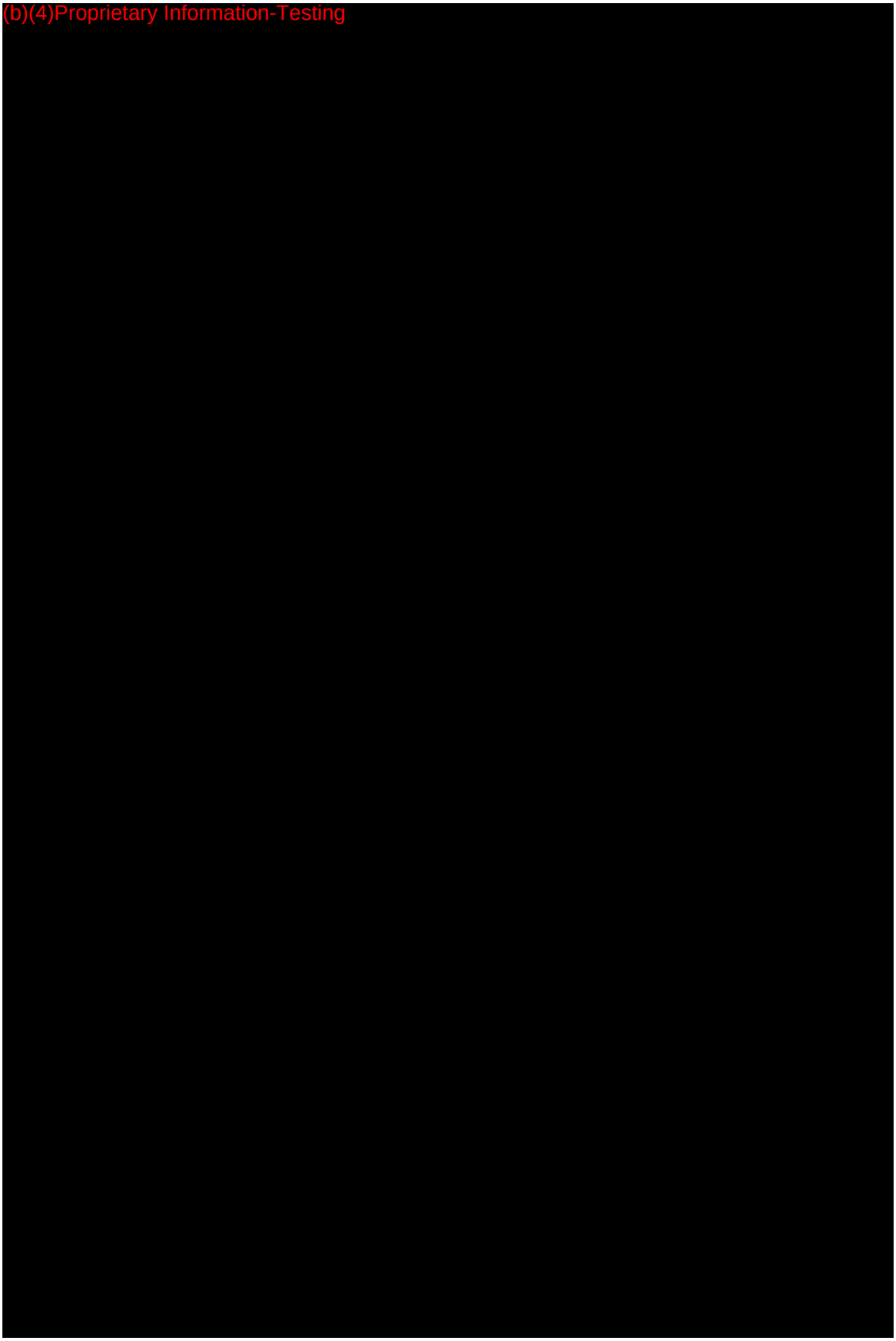
(b)(4)Proprietary Information-Testing



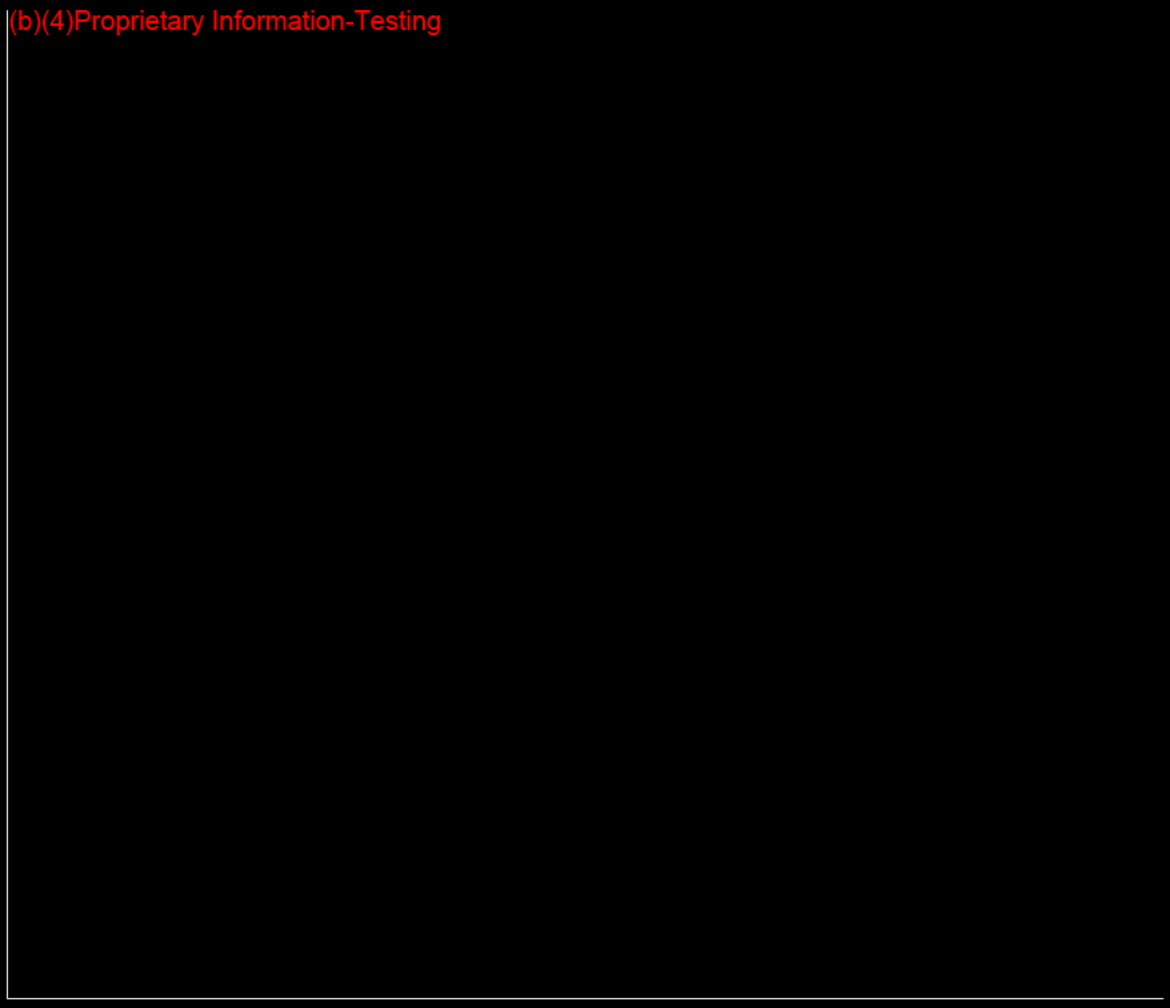




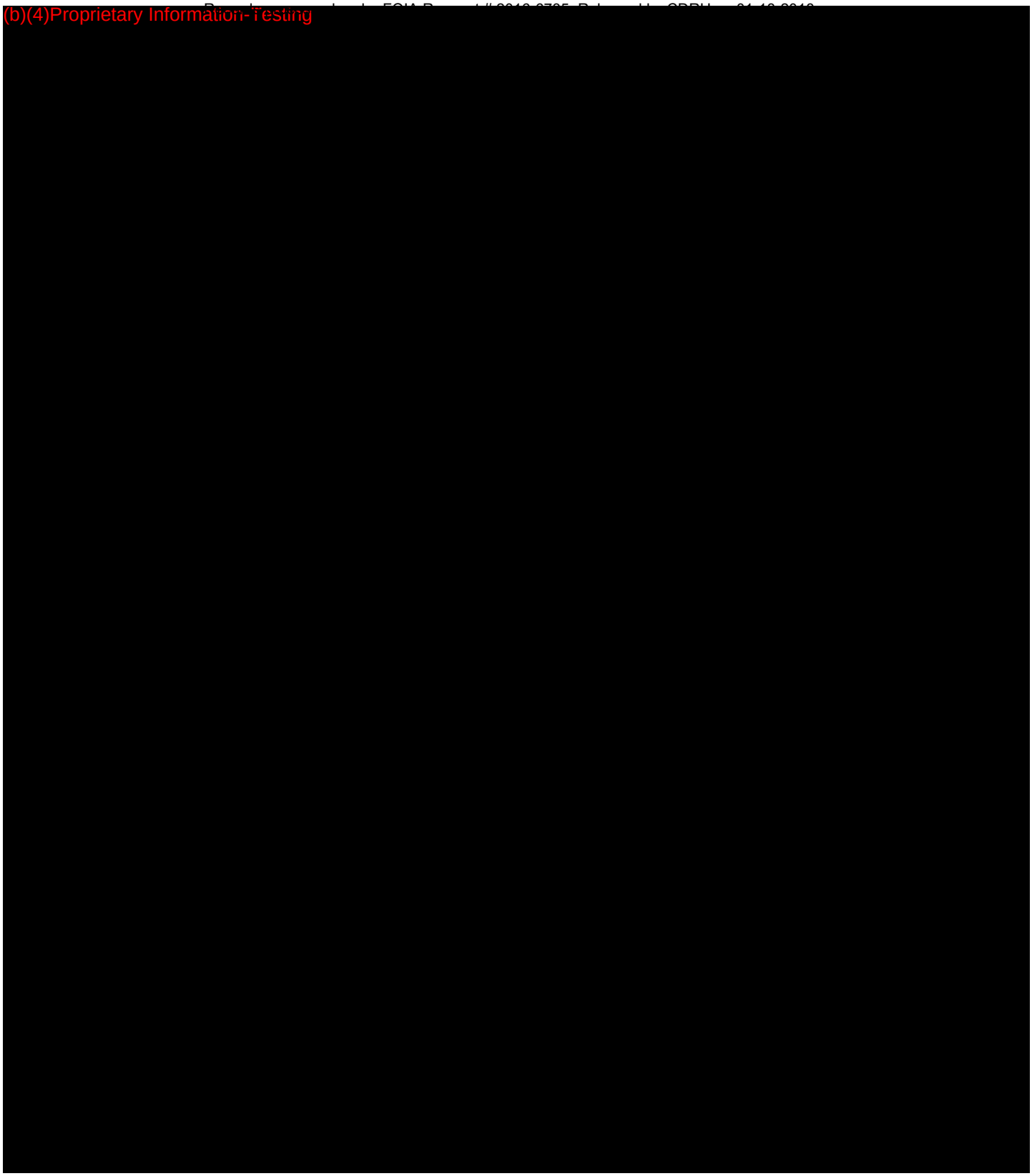
(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information- Testing



(b)(4)Proprietary Information-Testing

[redacted]

(b)(4)Proprietary Information-Testing

[redacted]

(b)(4)Proprietary Information-Testing

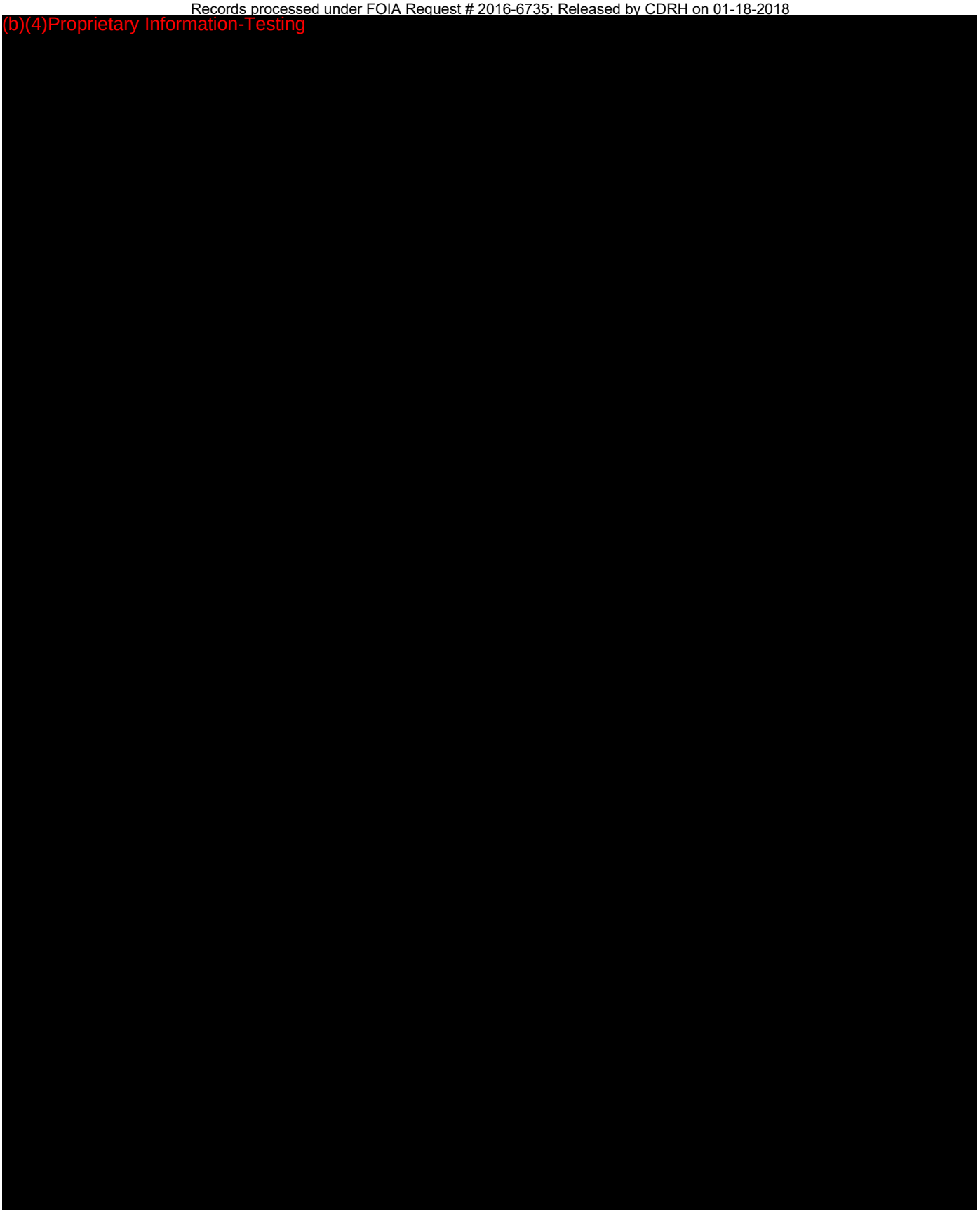
[redacted]

(b)(4)Proprietary Information-Testing

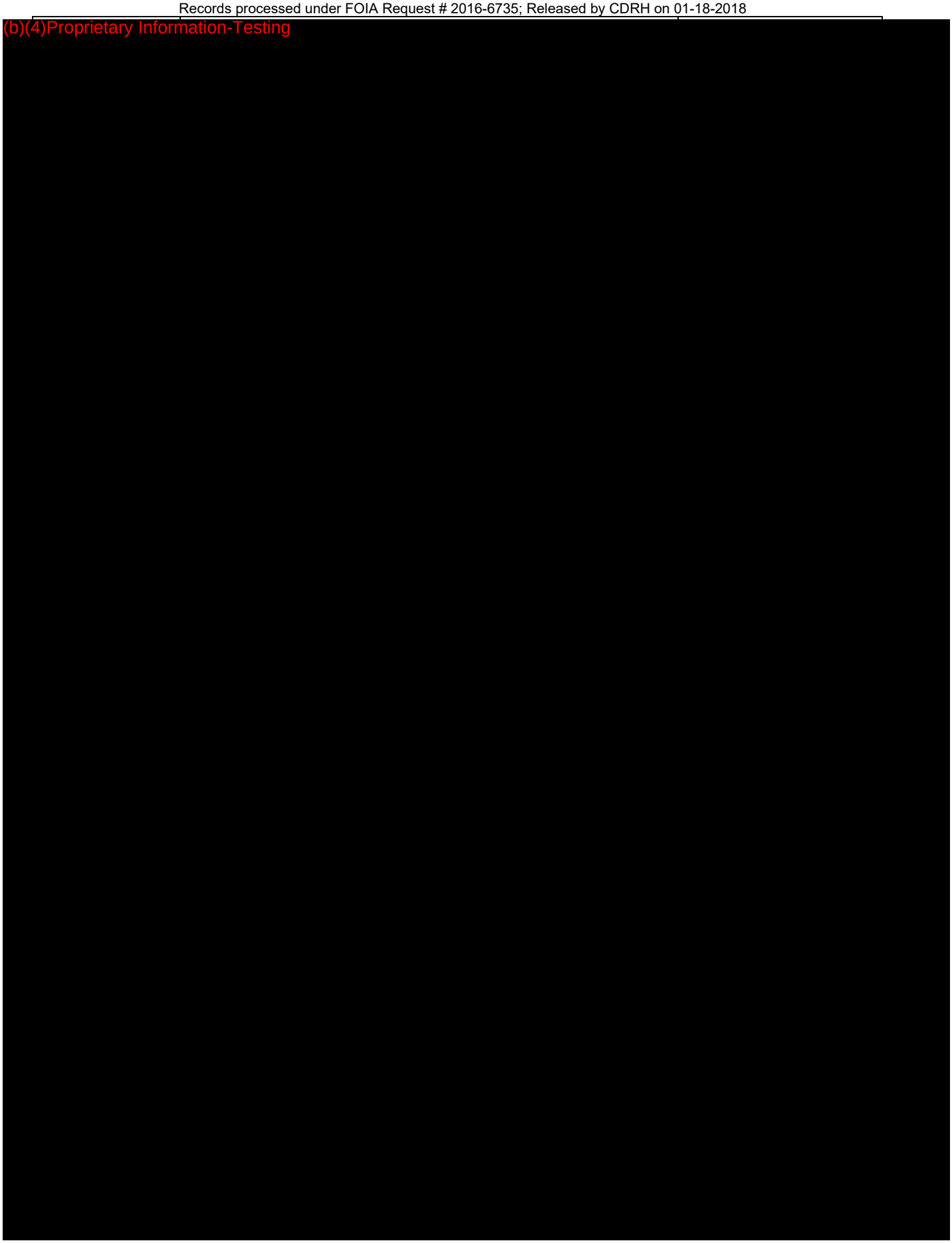
[redacted]

ATTACHMENT 34

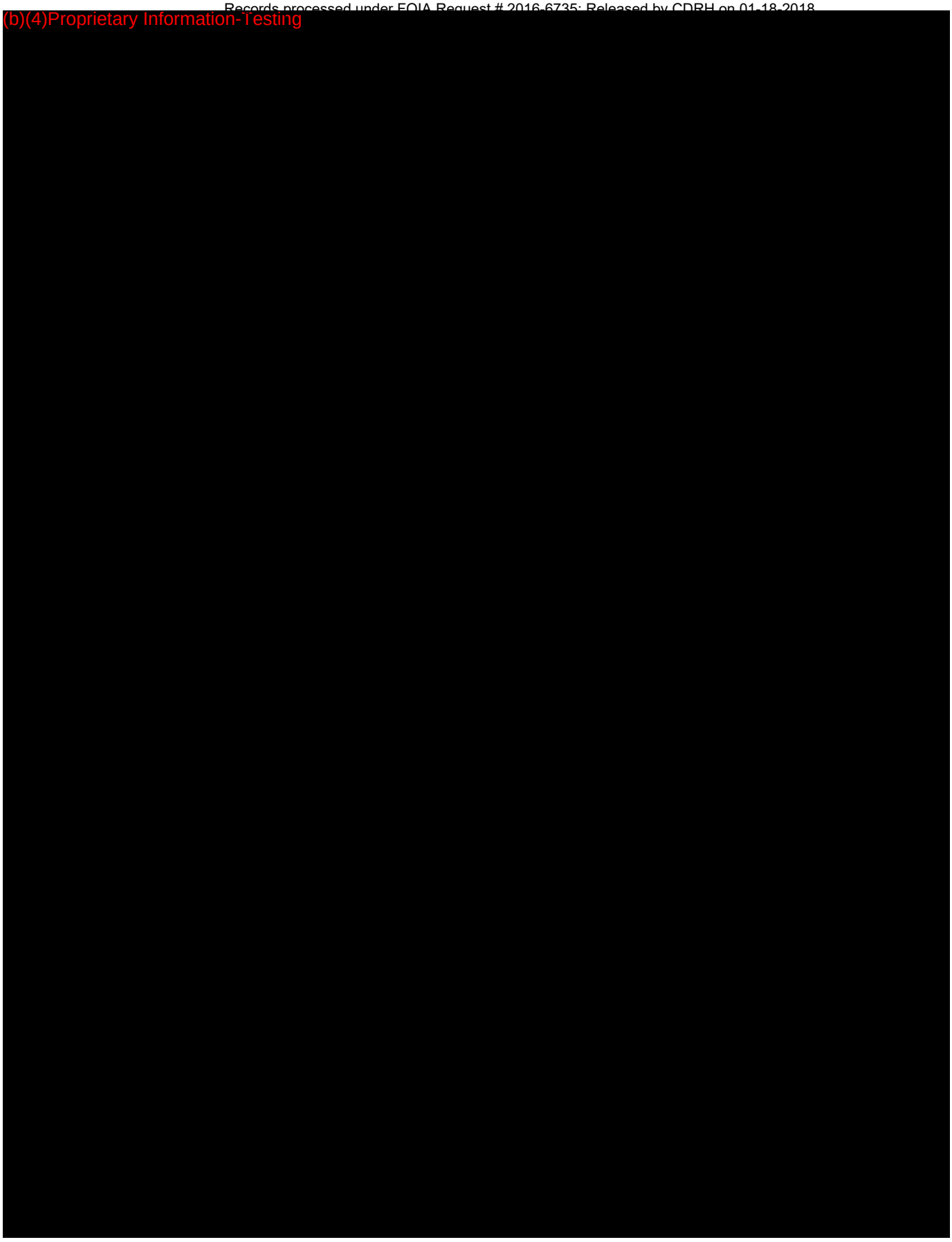
(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing



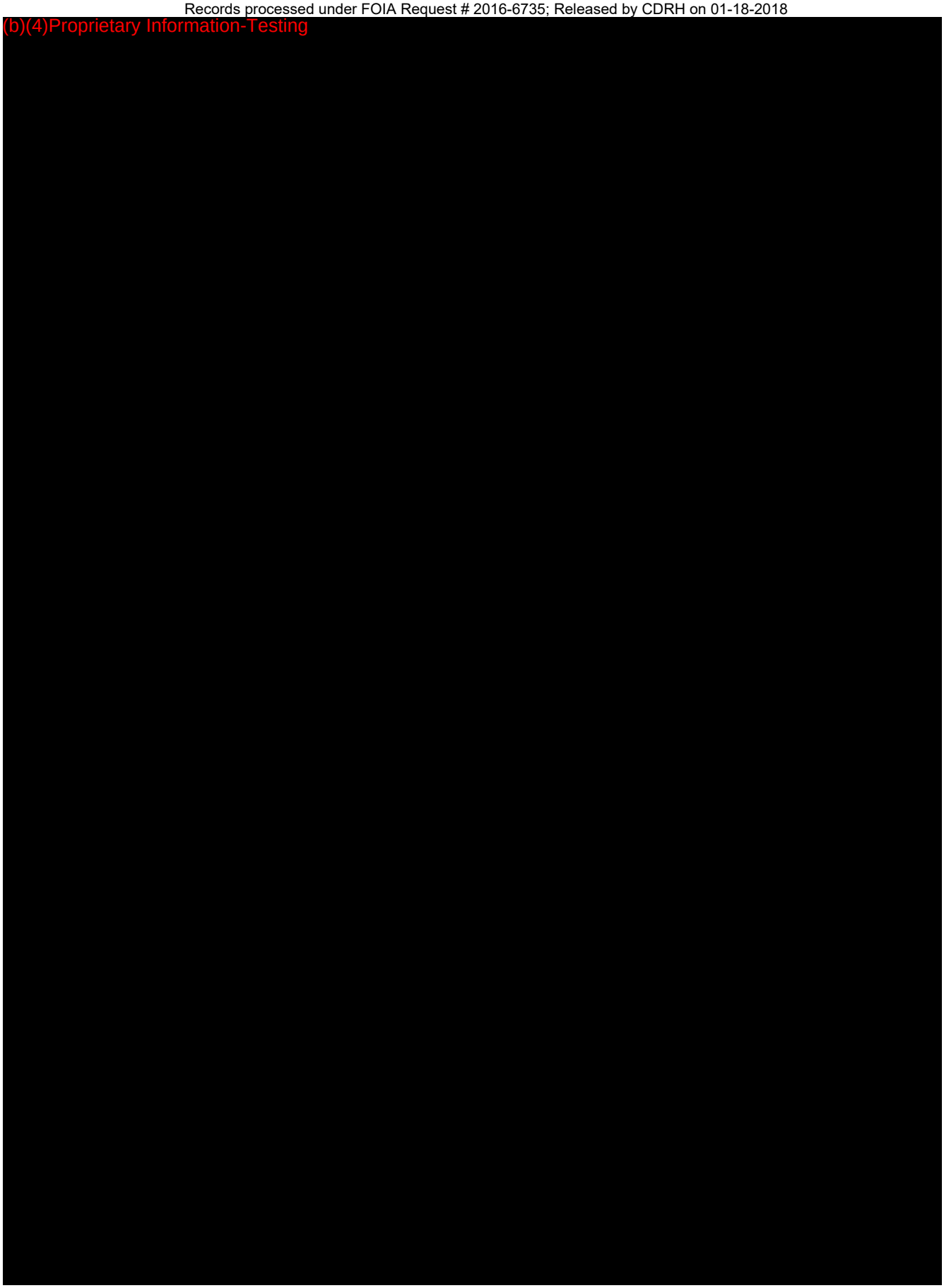
(b)(4)Proprietary Information-Testing

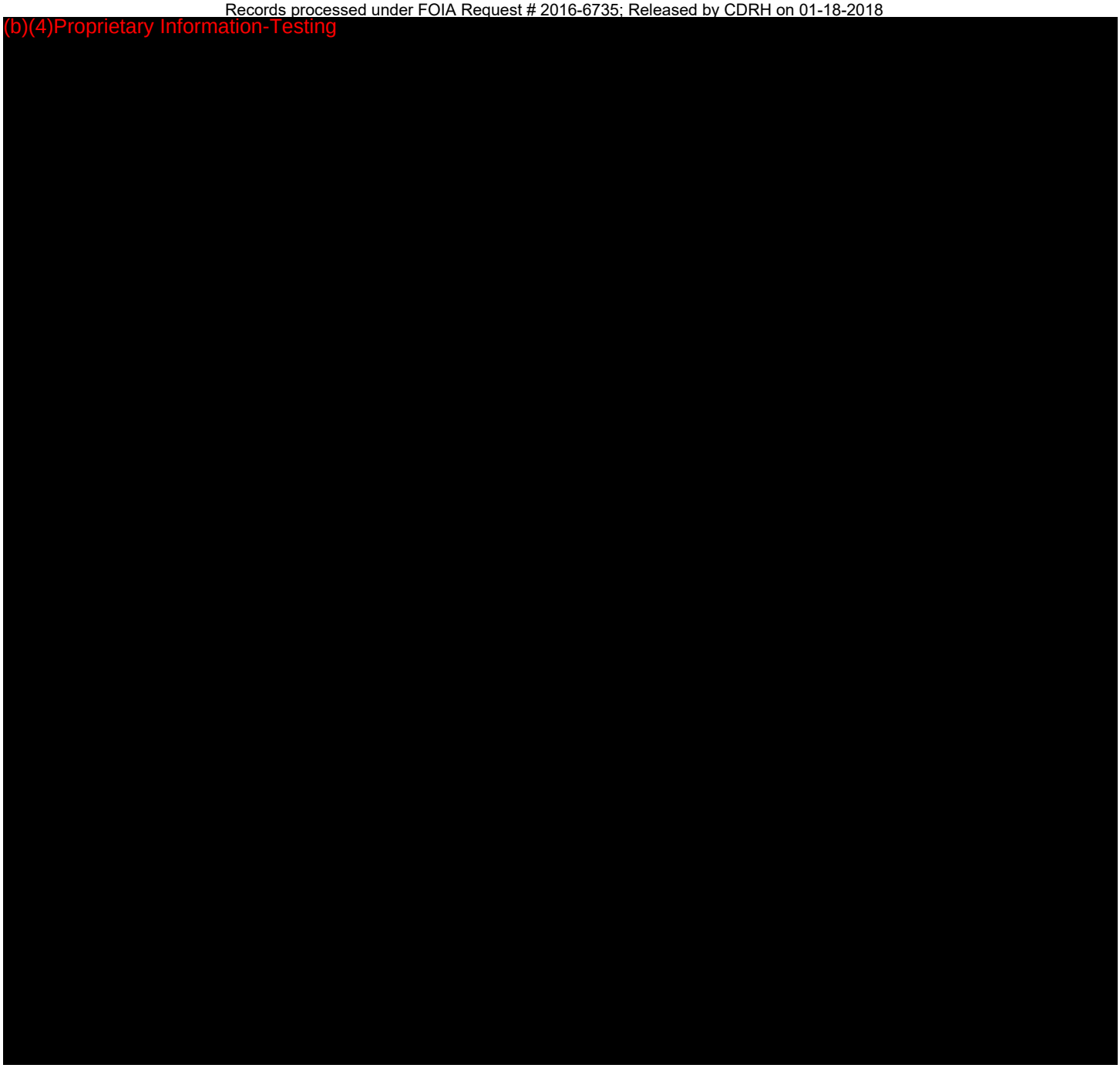


(b)(4)Proprietary Information-Testing

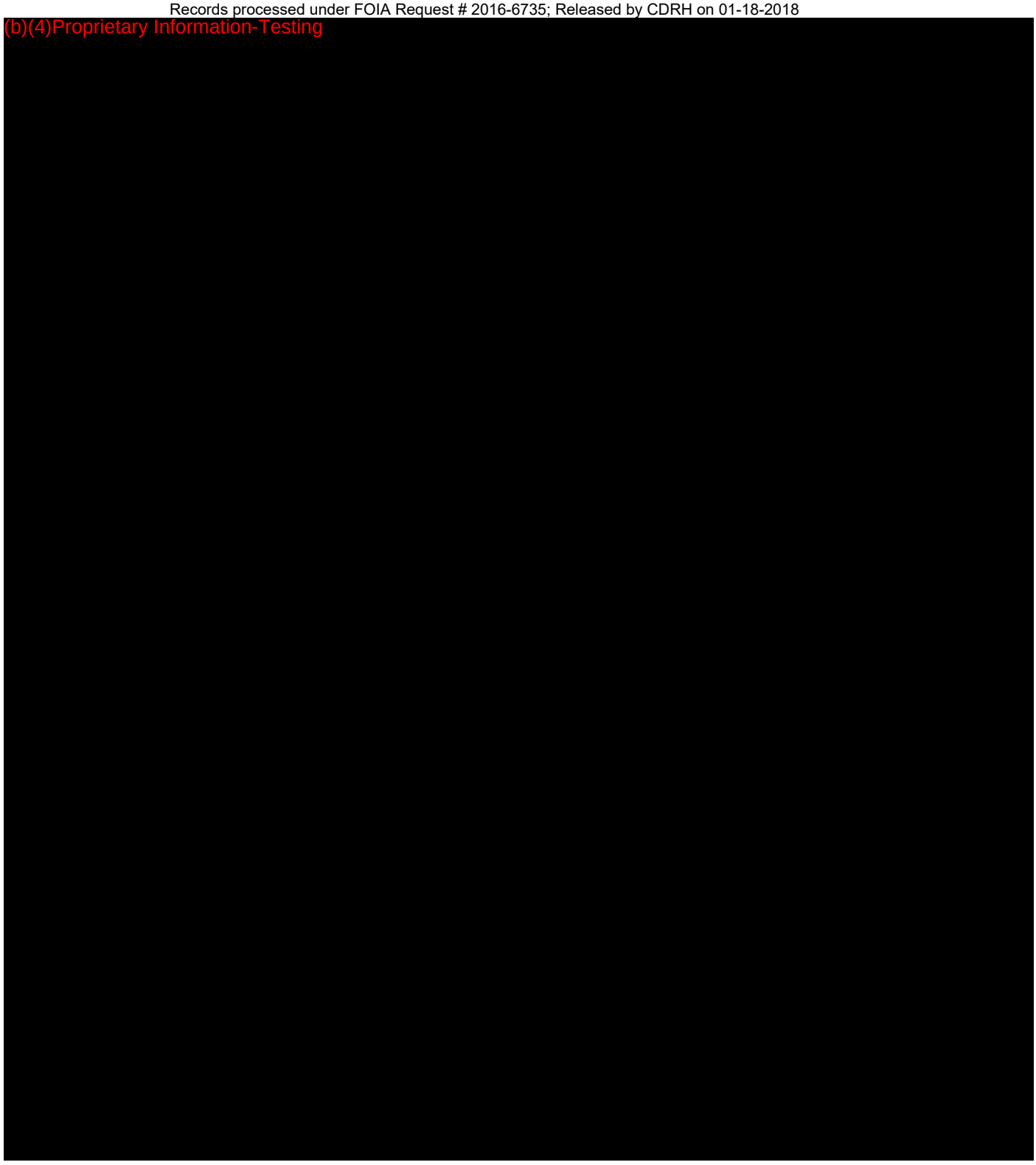
[redacted]

(b)(4)Proprietary Information-Testing

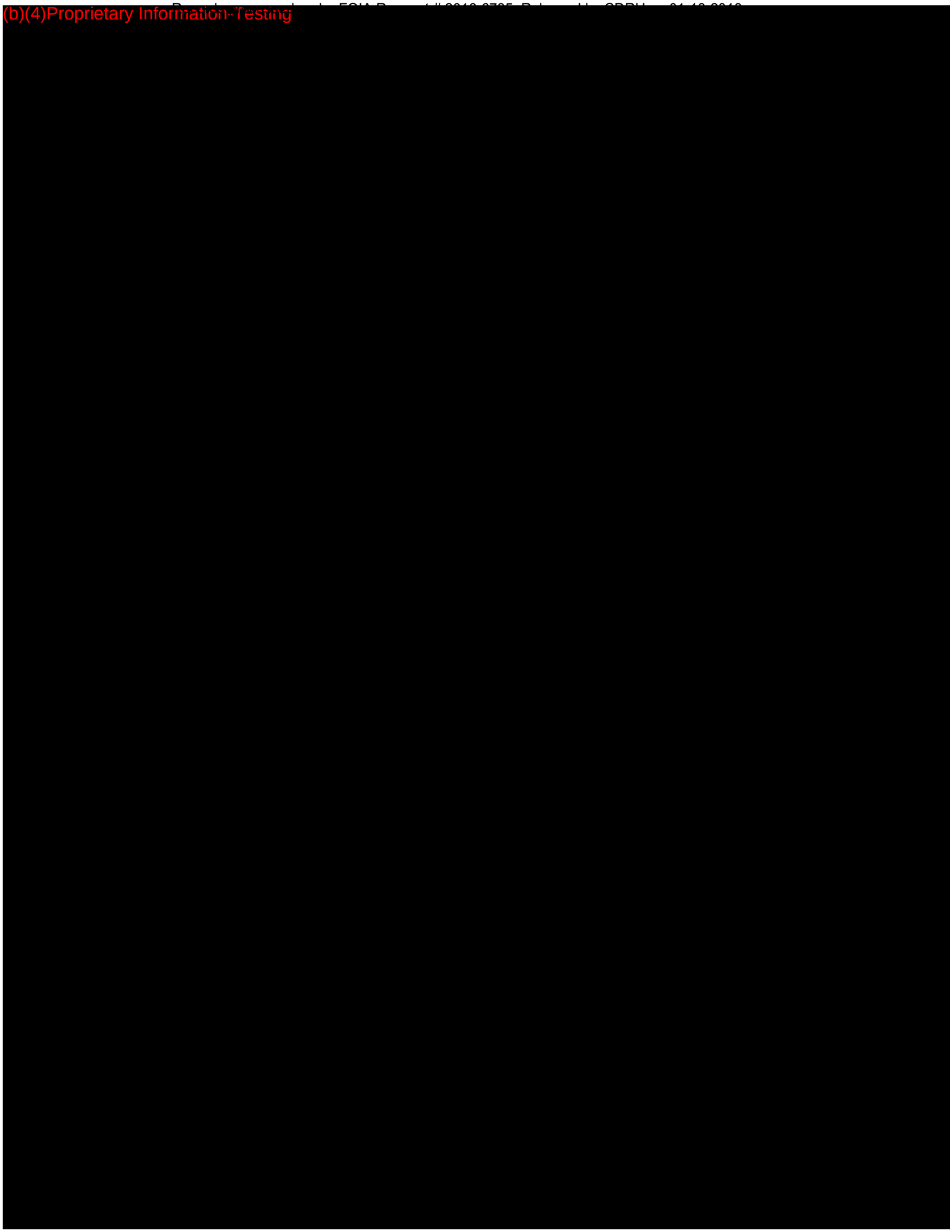




(b)(4)Proprietary Information-Testing



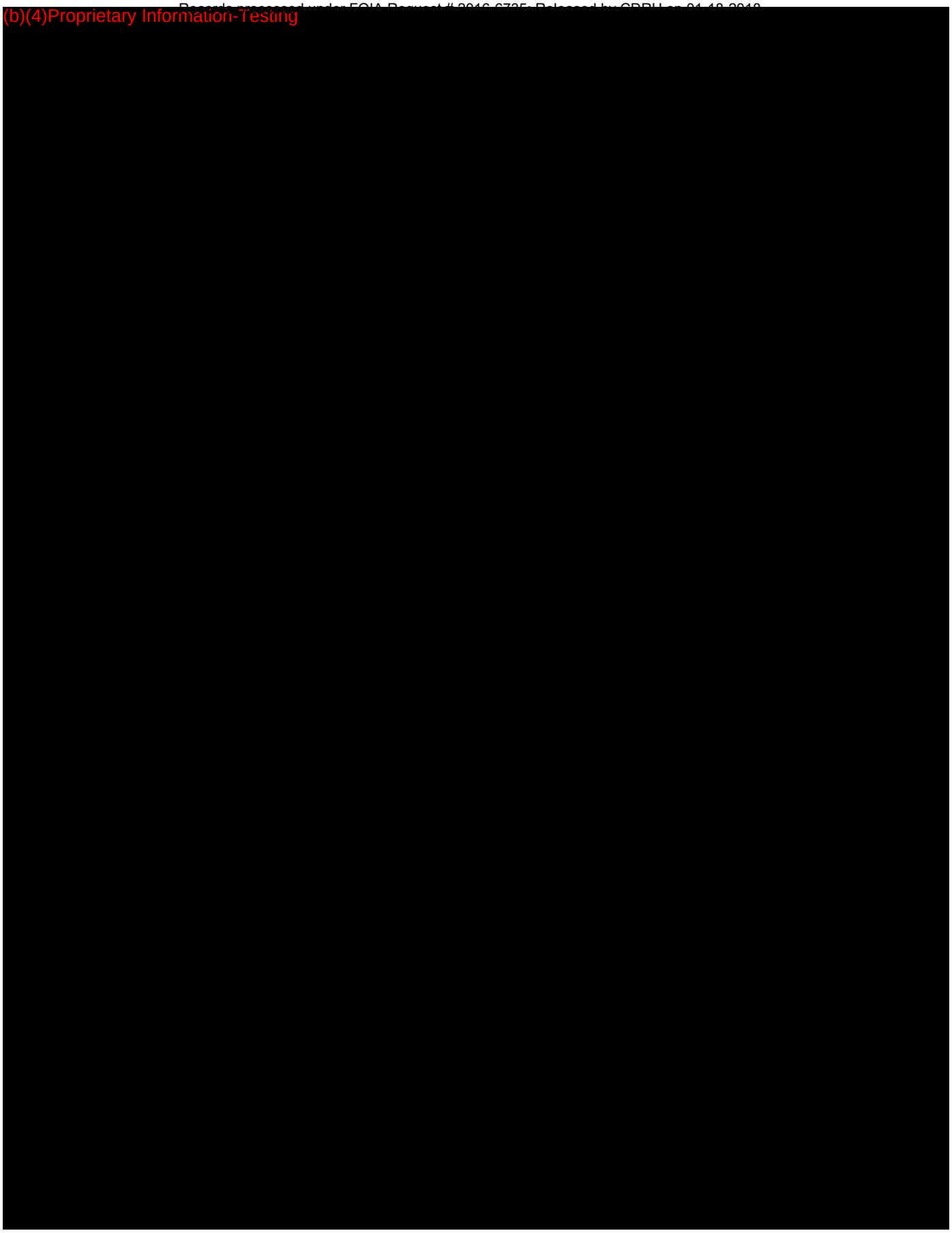
(b)(4)Proprietary Information - Testing



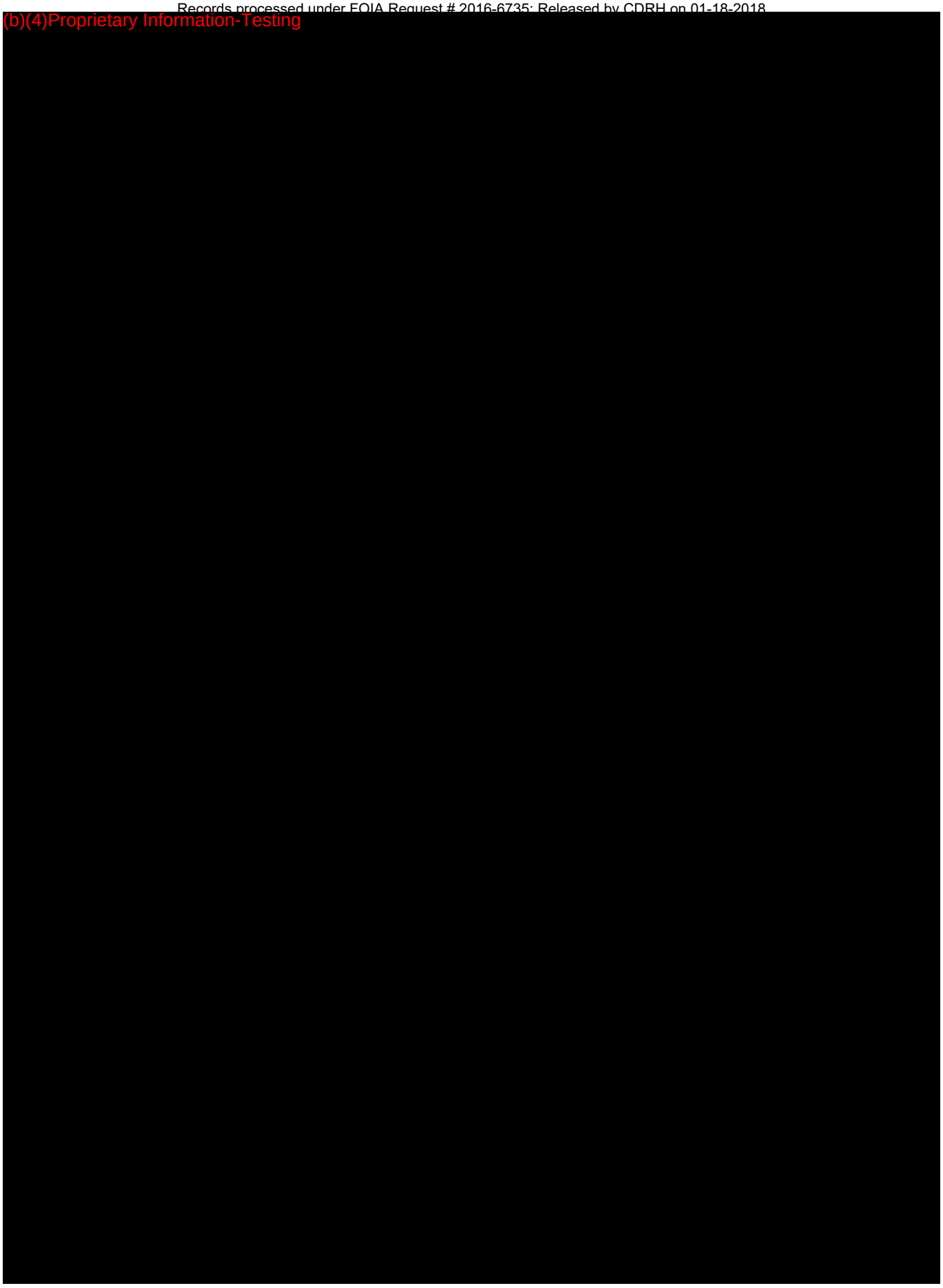
(b)(4)Proprietary Information-Testing

[redacted]

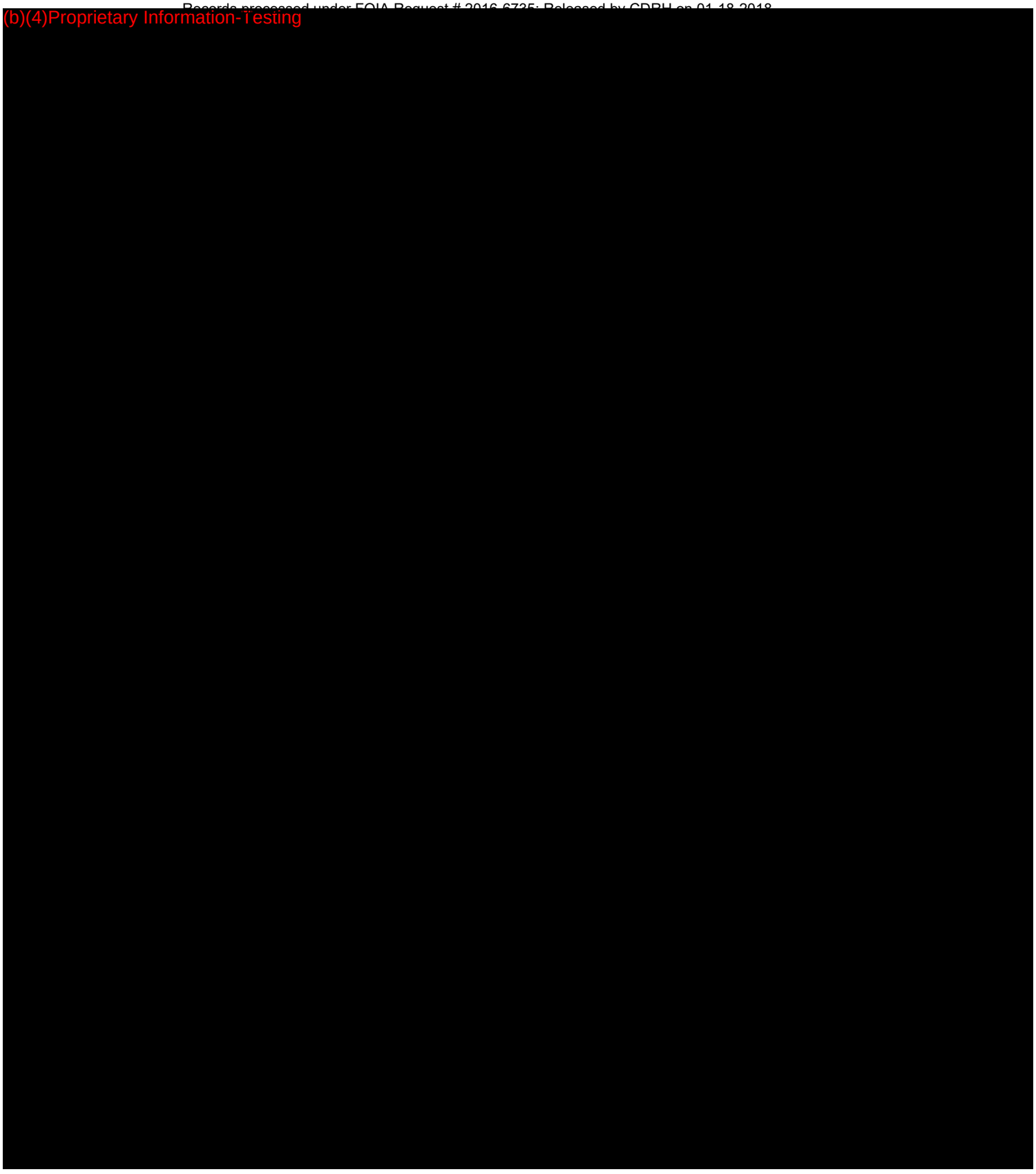
(b)(4)Proprietary Information-Testing



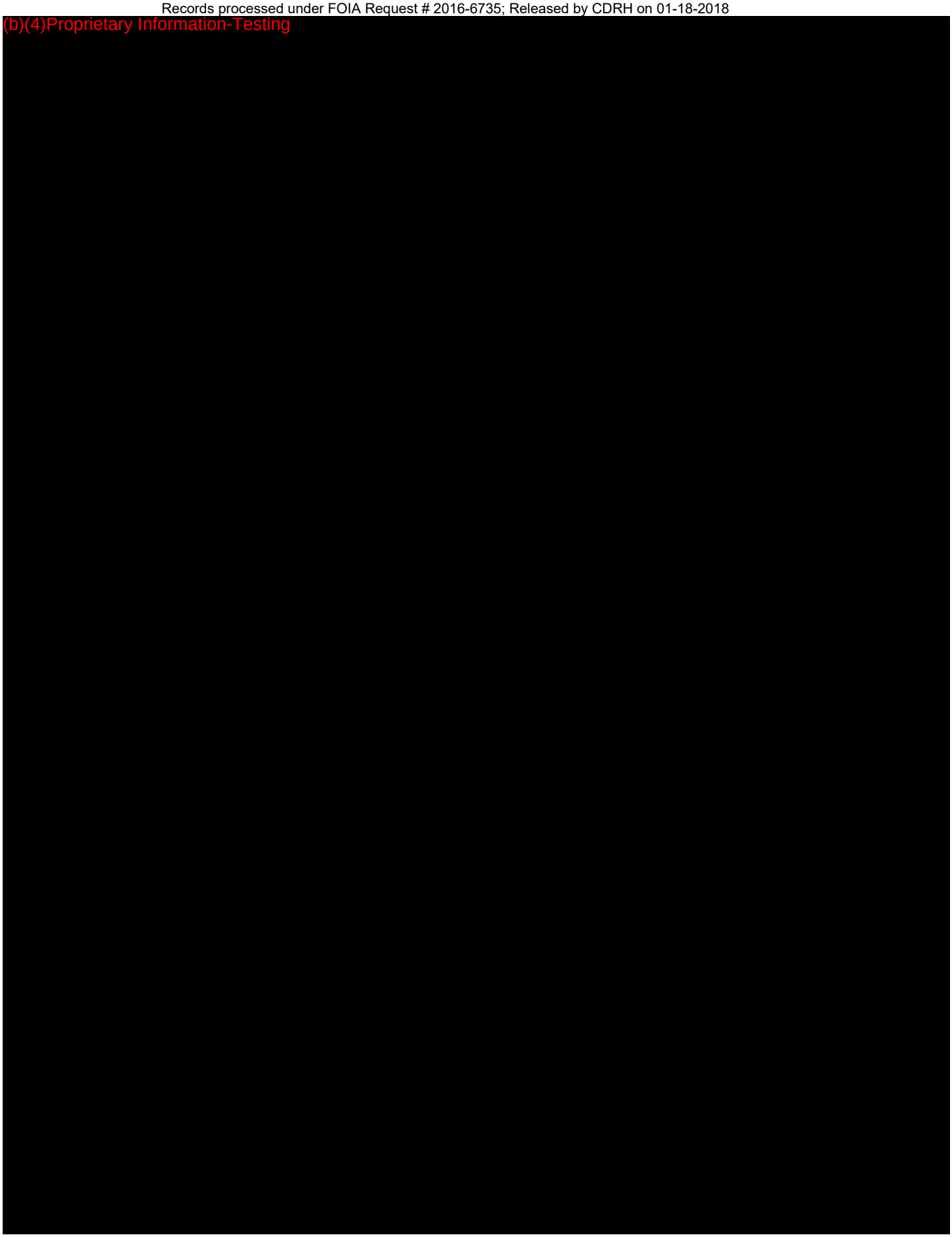
(b)(4)Proprietary Information-Testing



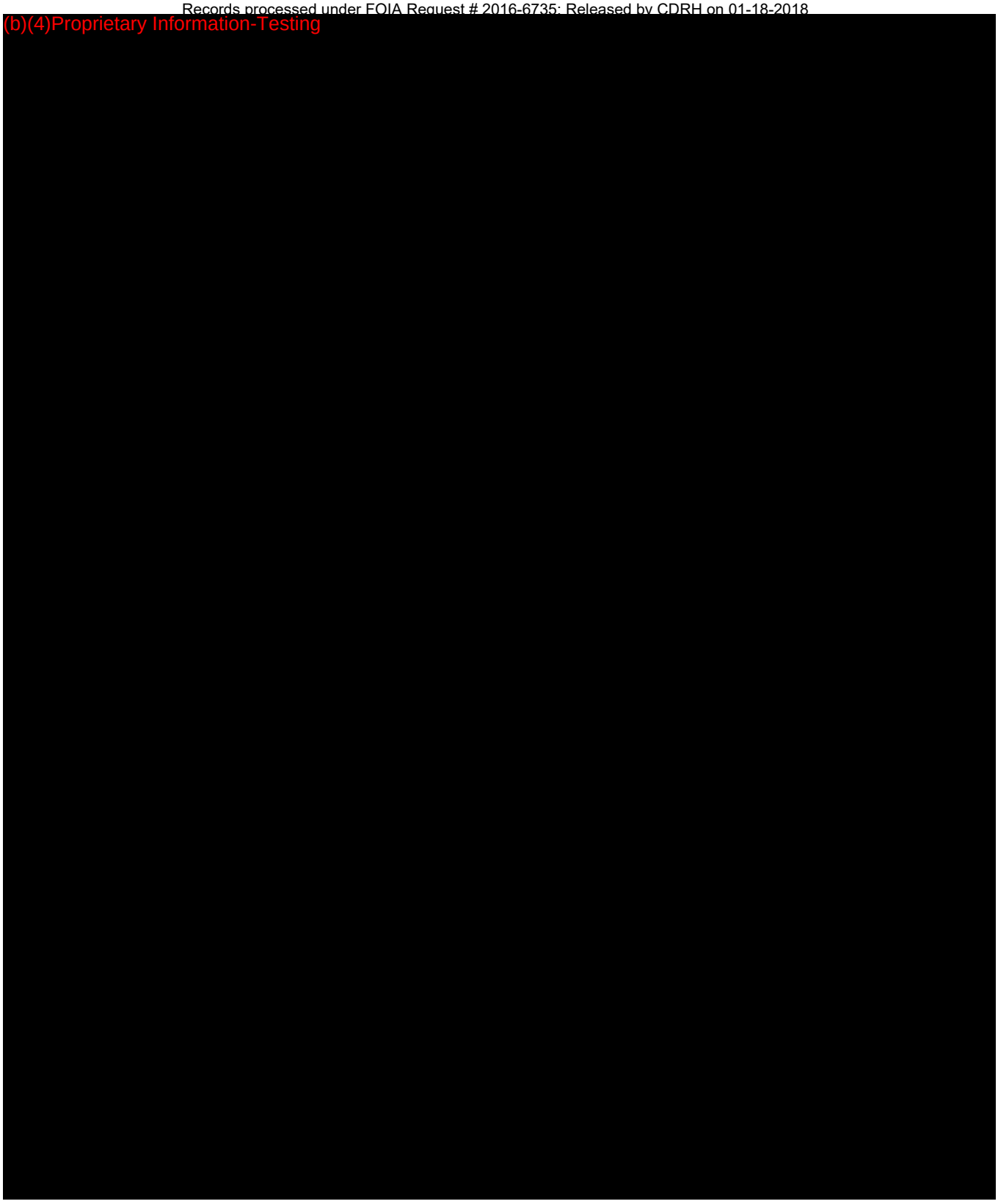
(b)(4)Proprietary Information-Testing



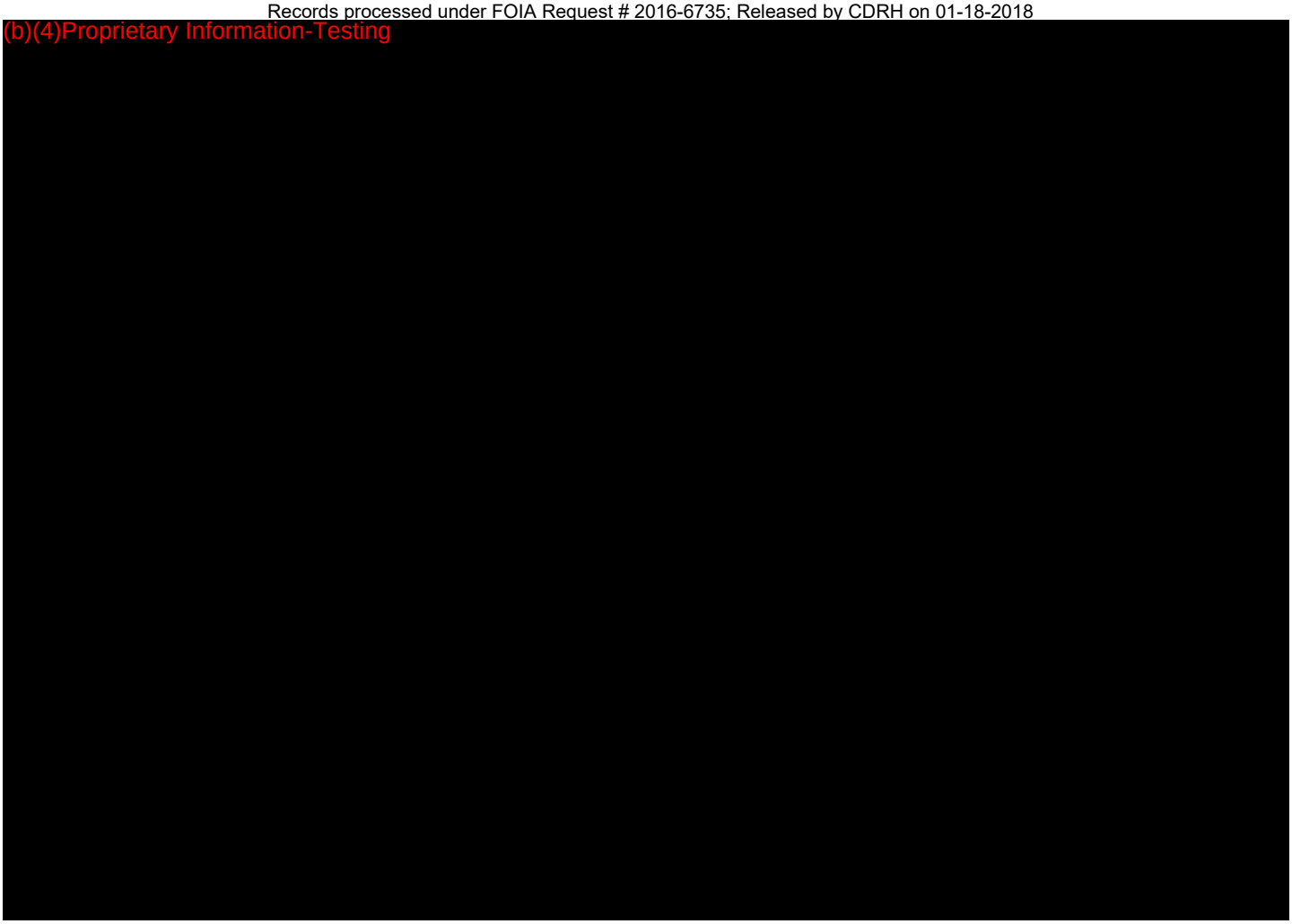
(b)(4)Proprietary Information-Testing

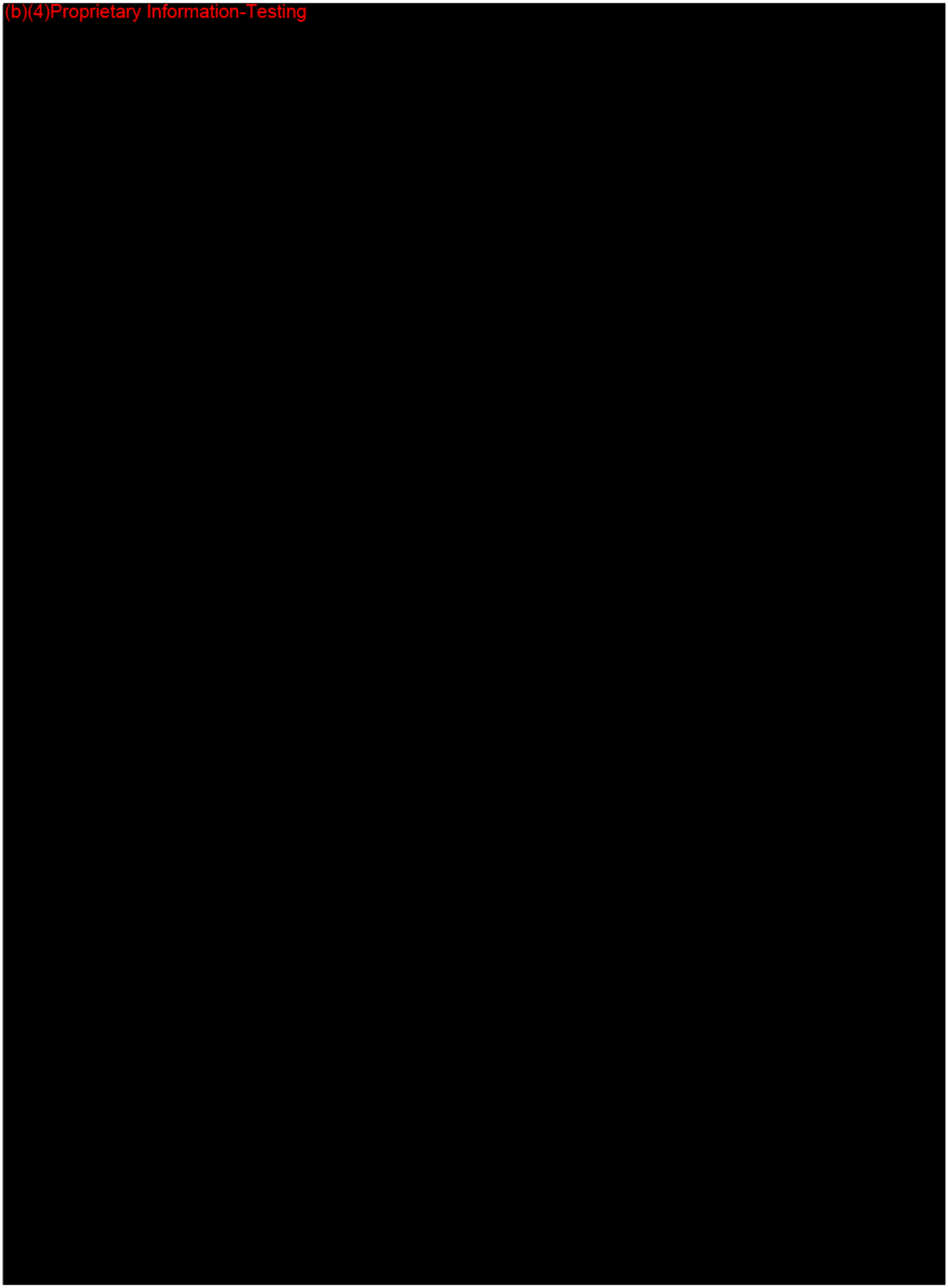


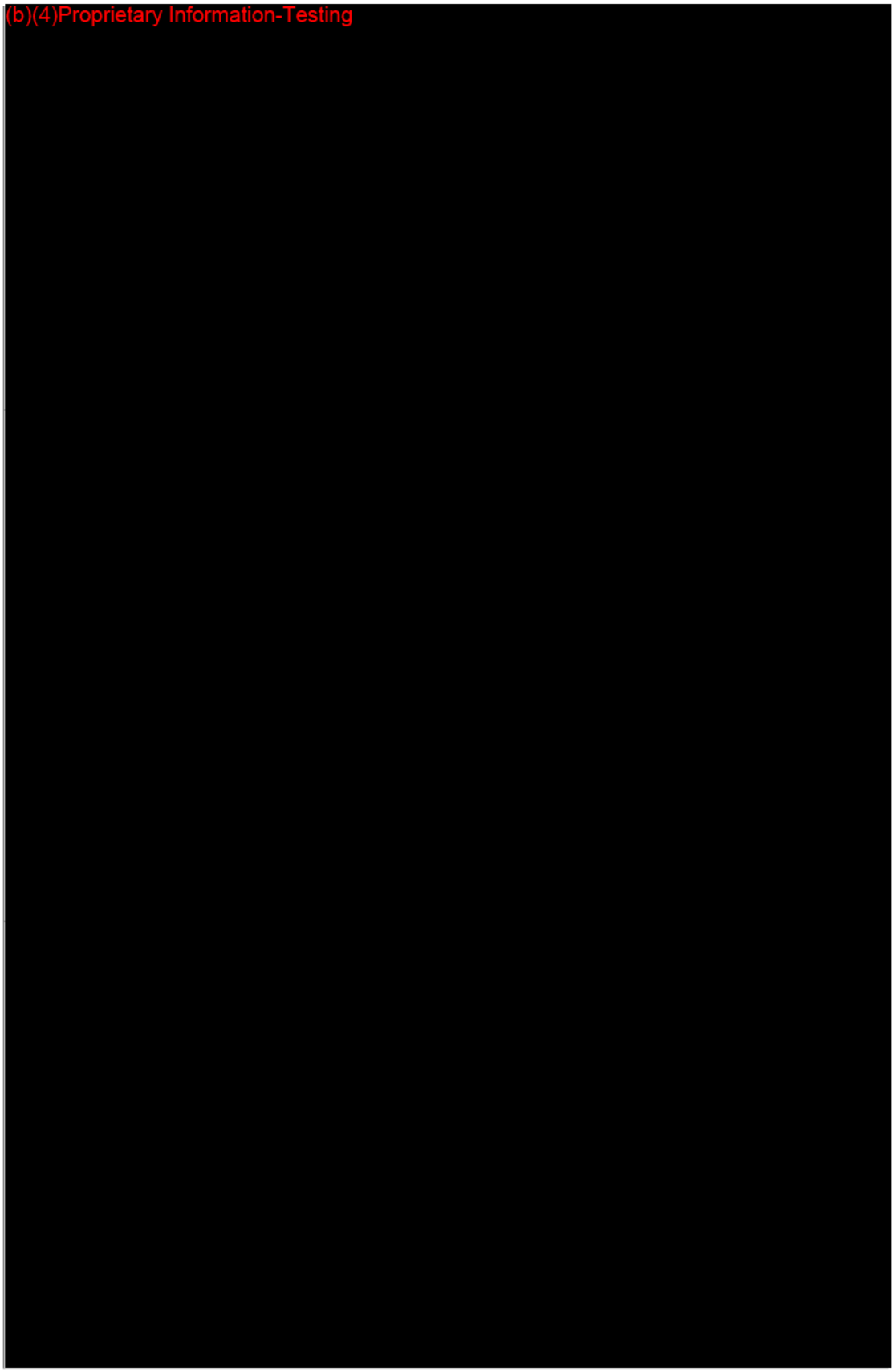
(b)(4)Proprietary Information-Testing



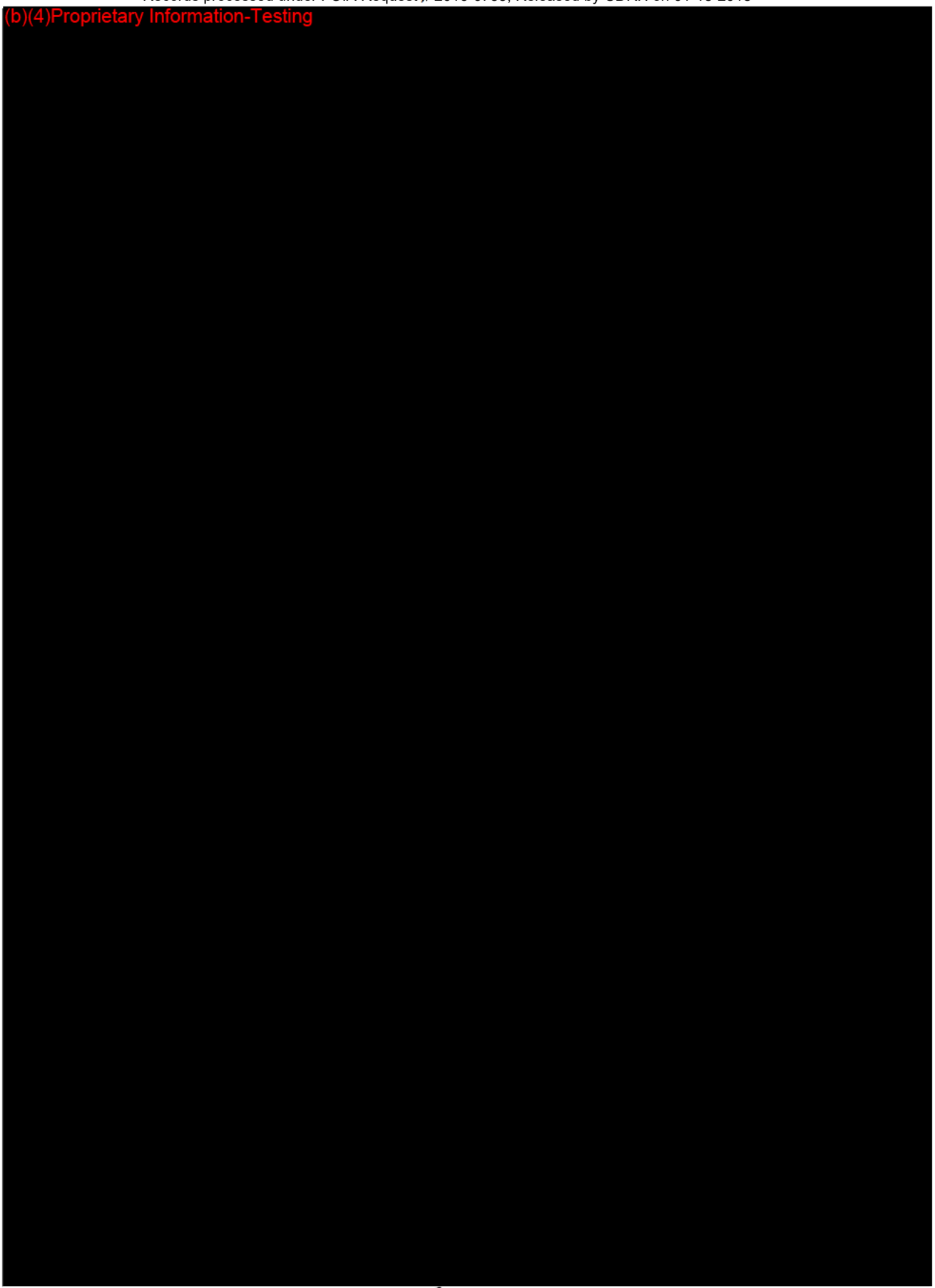
(b)(4)Proprietary Information-Testing



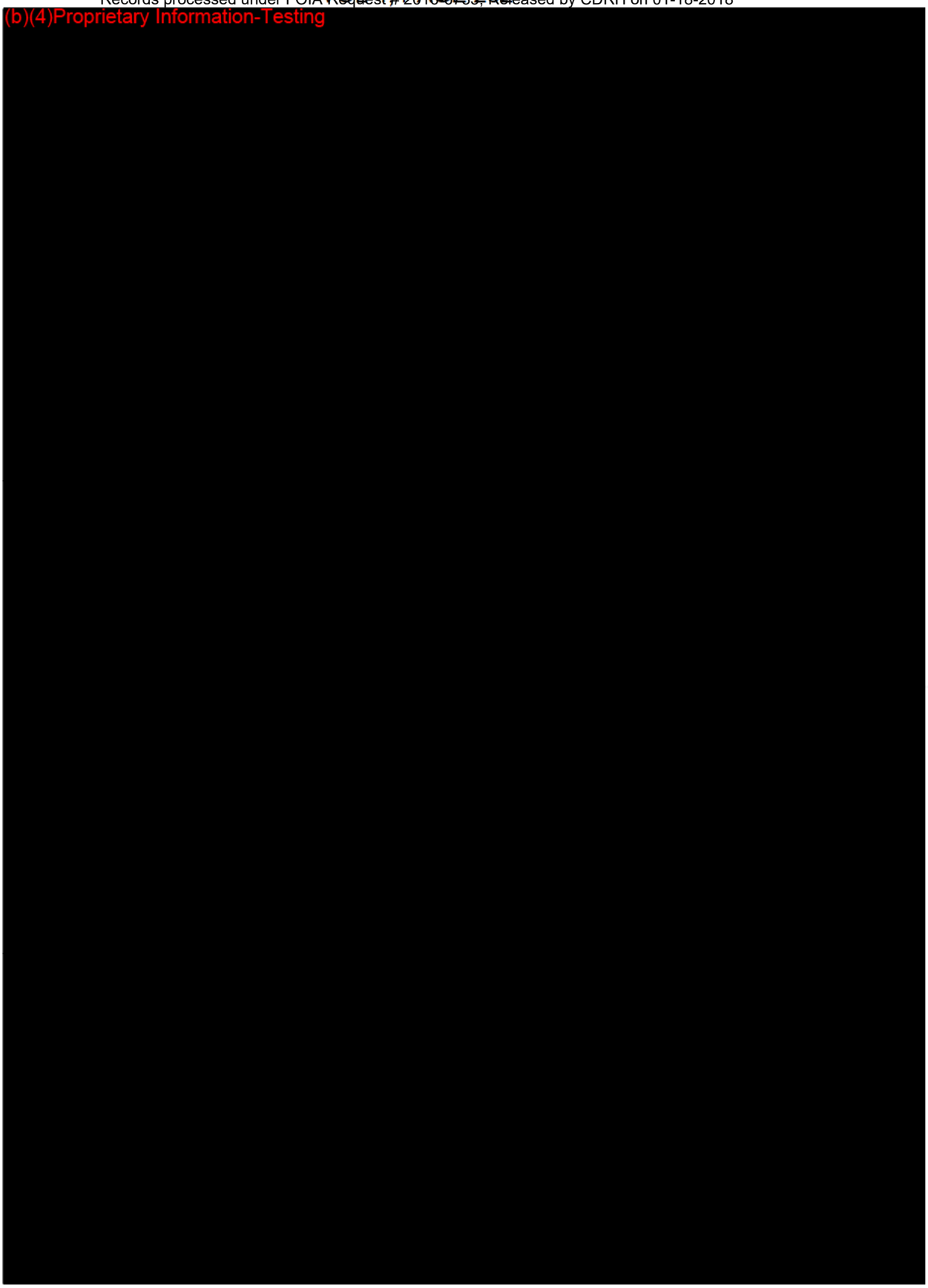




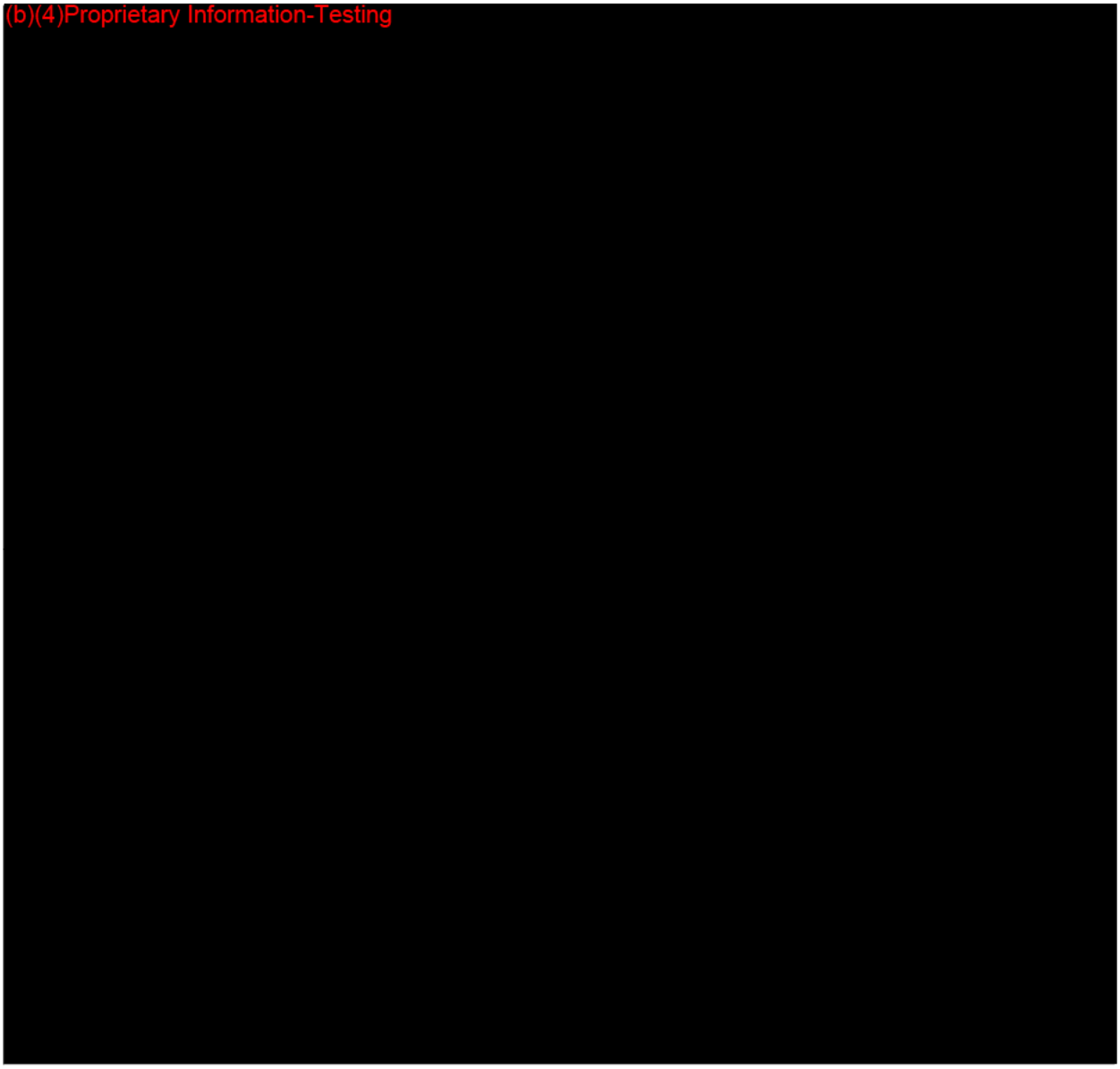
(b)(4)Proprietary Information-Testing



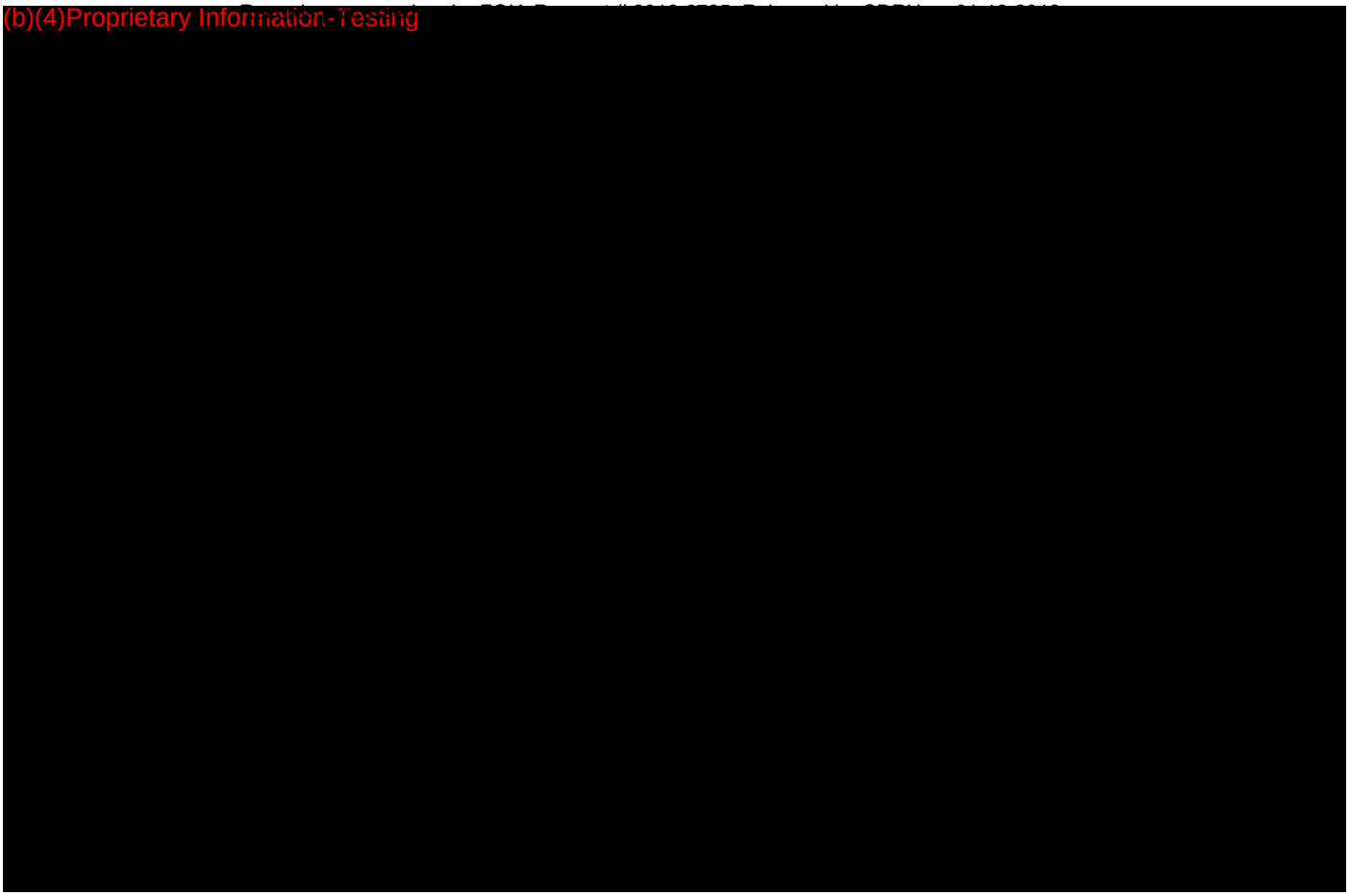
(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing



Data Recorder **Date**

CONFIDENTIAL

(b)(4)Proprietary Information-Testing

[redacted]

Data Recorder **Date**

CONFIDENTIAL

(b)(4)Proprietary Information-Testing

[redacted]

Data Recorder **Date**

CONFIDENTIAL

(b)(4)Proprietary Information-Testing

[redacted]

Data Recorder **Date**

CONFIDENTIAL

(b)(4)Proprietary Information-Testing

Data Recorder **Date**

CONFIDENTIAL

(b)(4)Proprietary Information-Testing

[redacted]

Data Recorder **Date**

CONFIDENTIAL

(b)(4)Proprietary Information-Testing

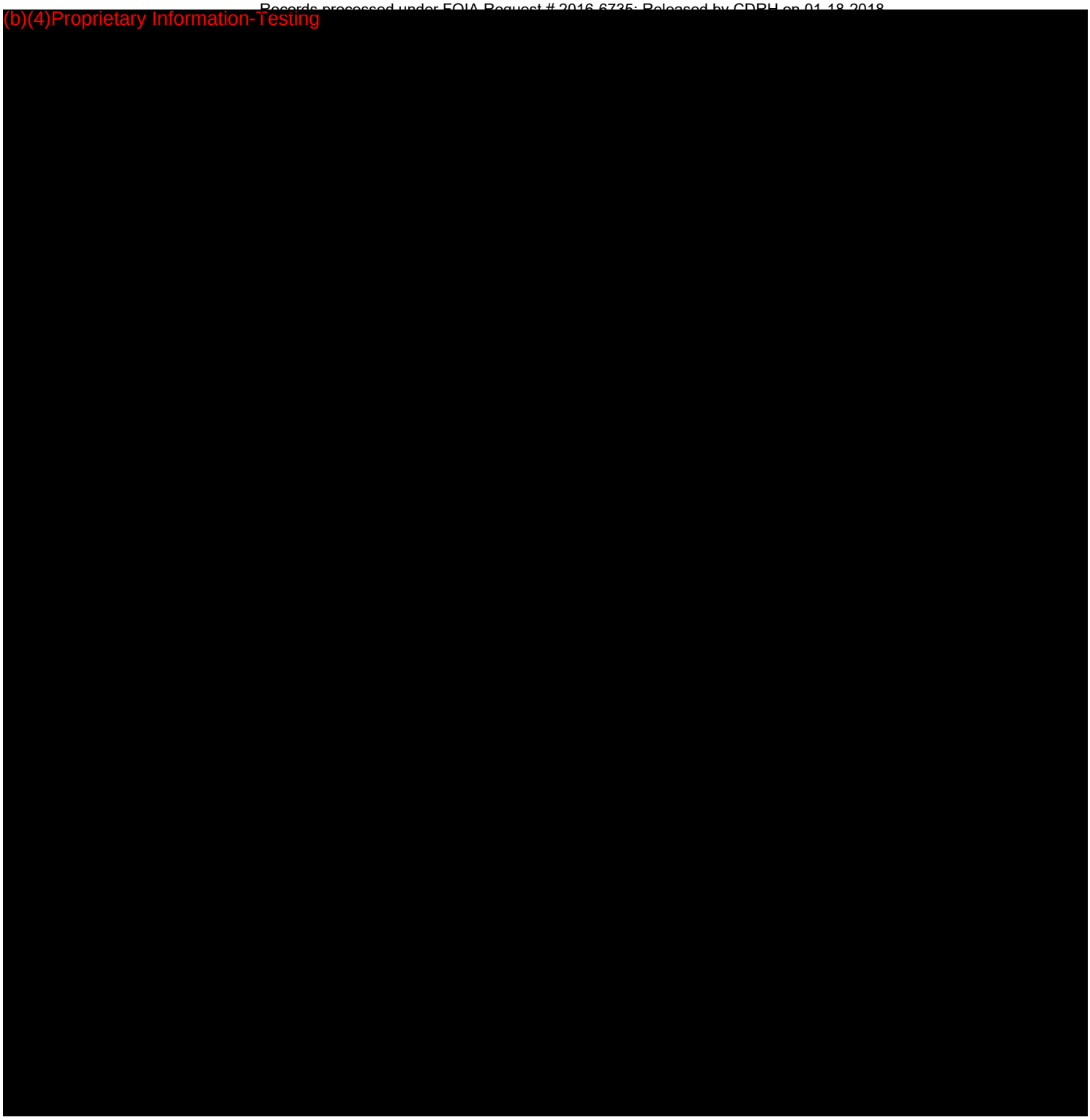
[redacted]

Data Recorder **Date**

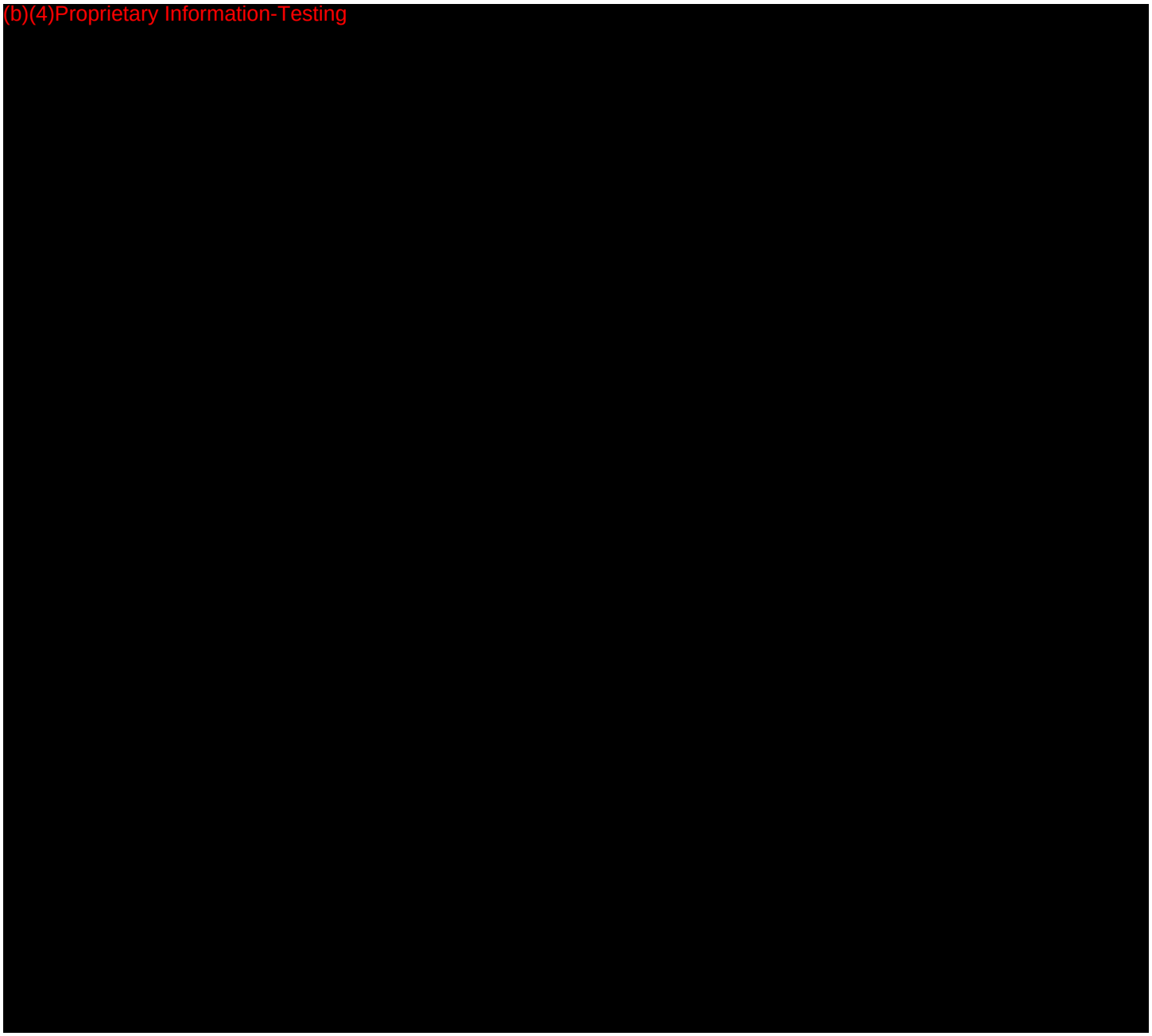
CONFIDENTIAL

ATTACHMENT 35

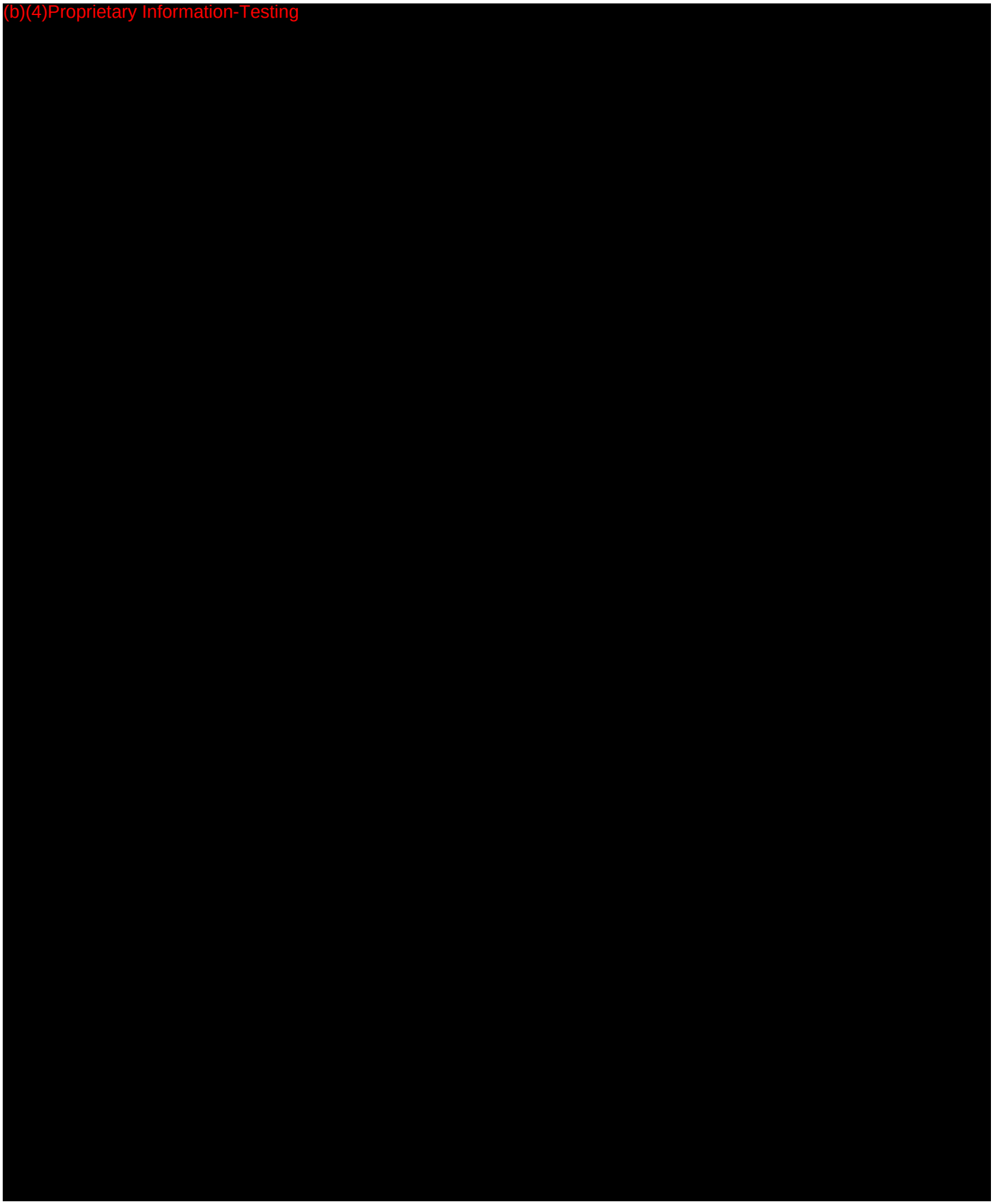
(b)(4)Proprietary Information-Testing



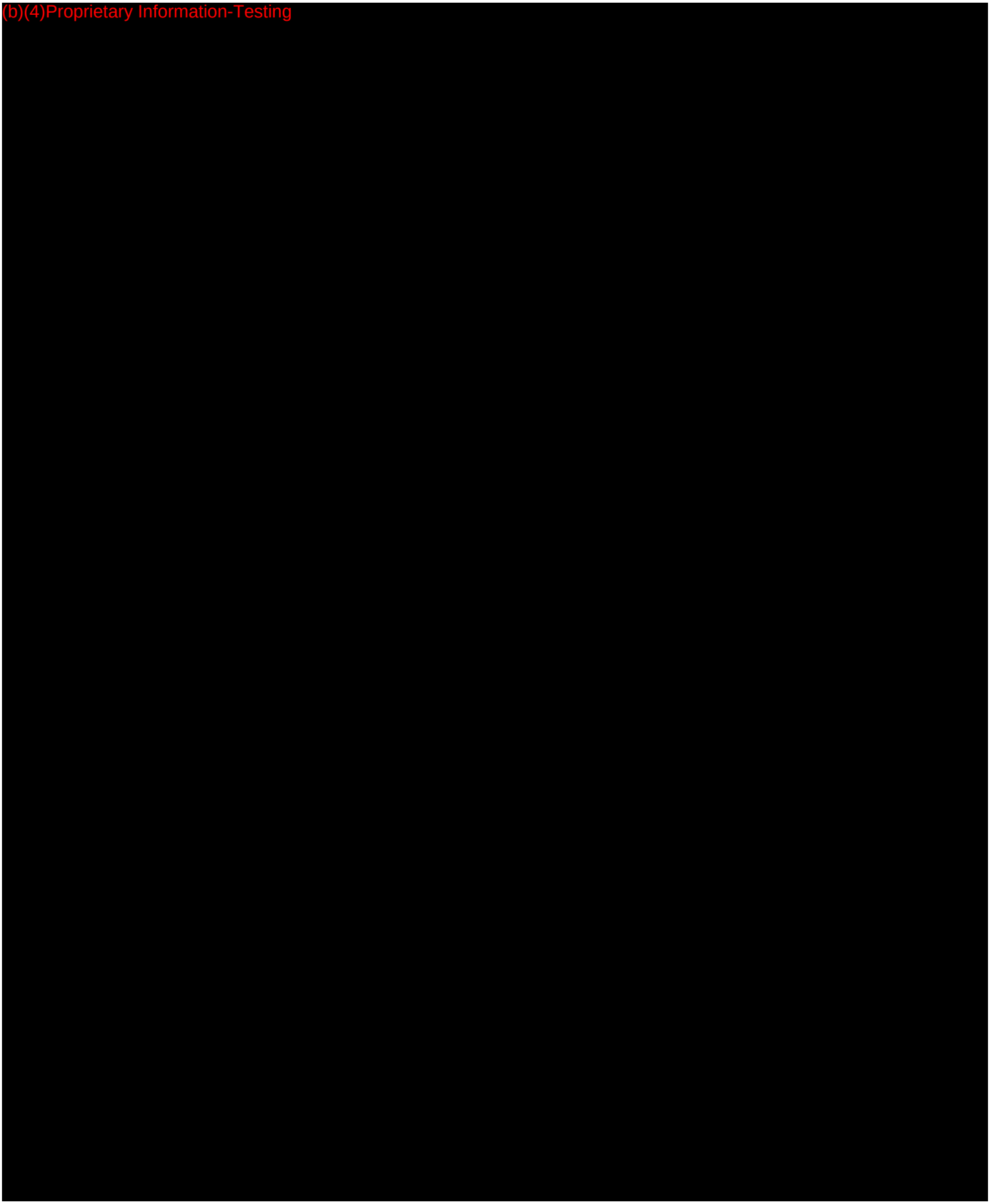
(b)(4)Proprietary Information-Testing



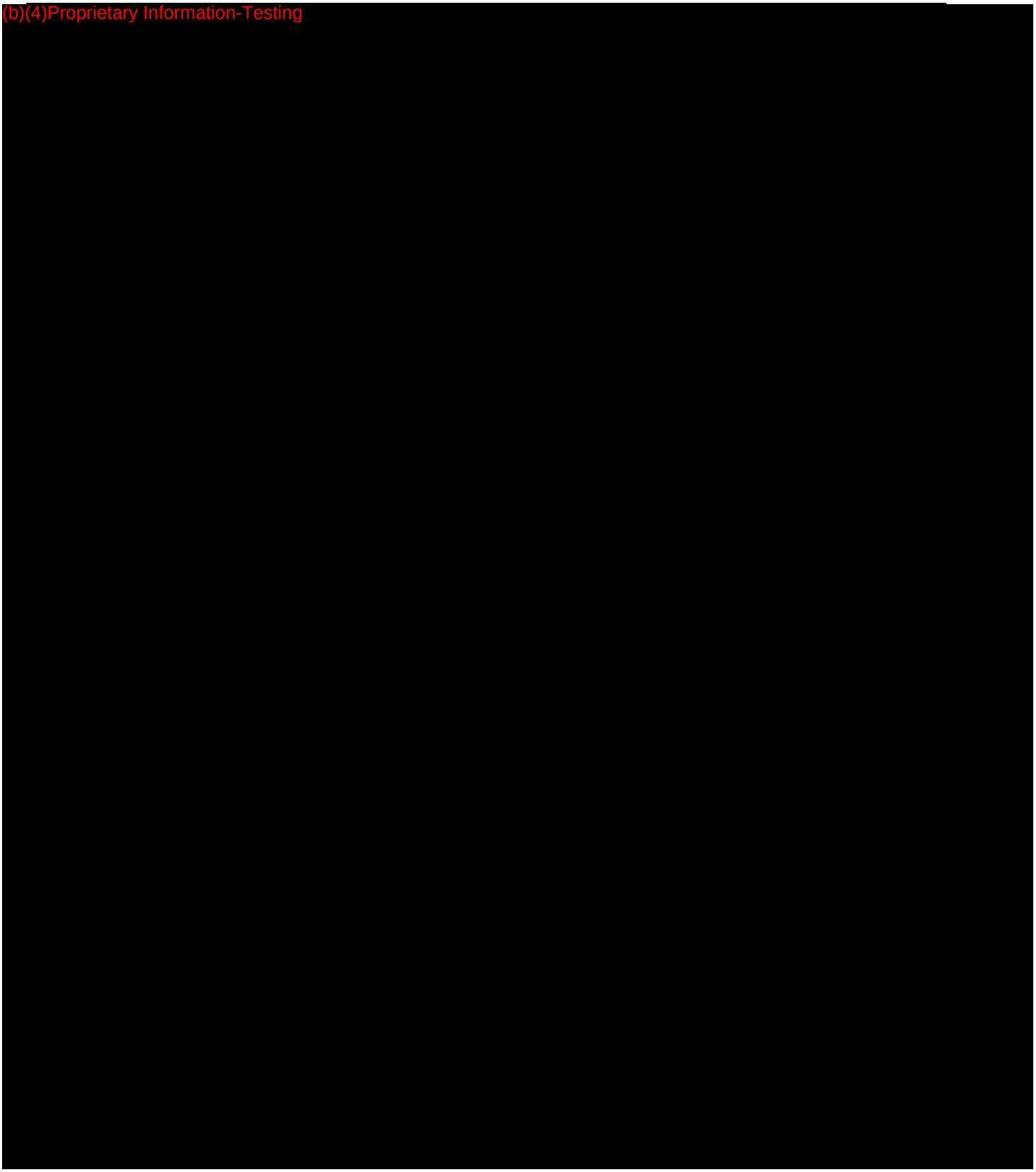
(b)(4)Proprietary Information-Testing



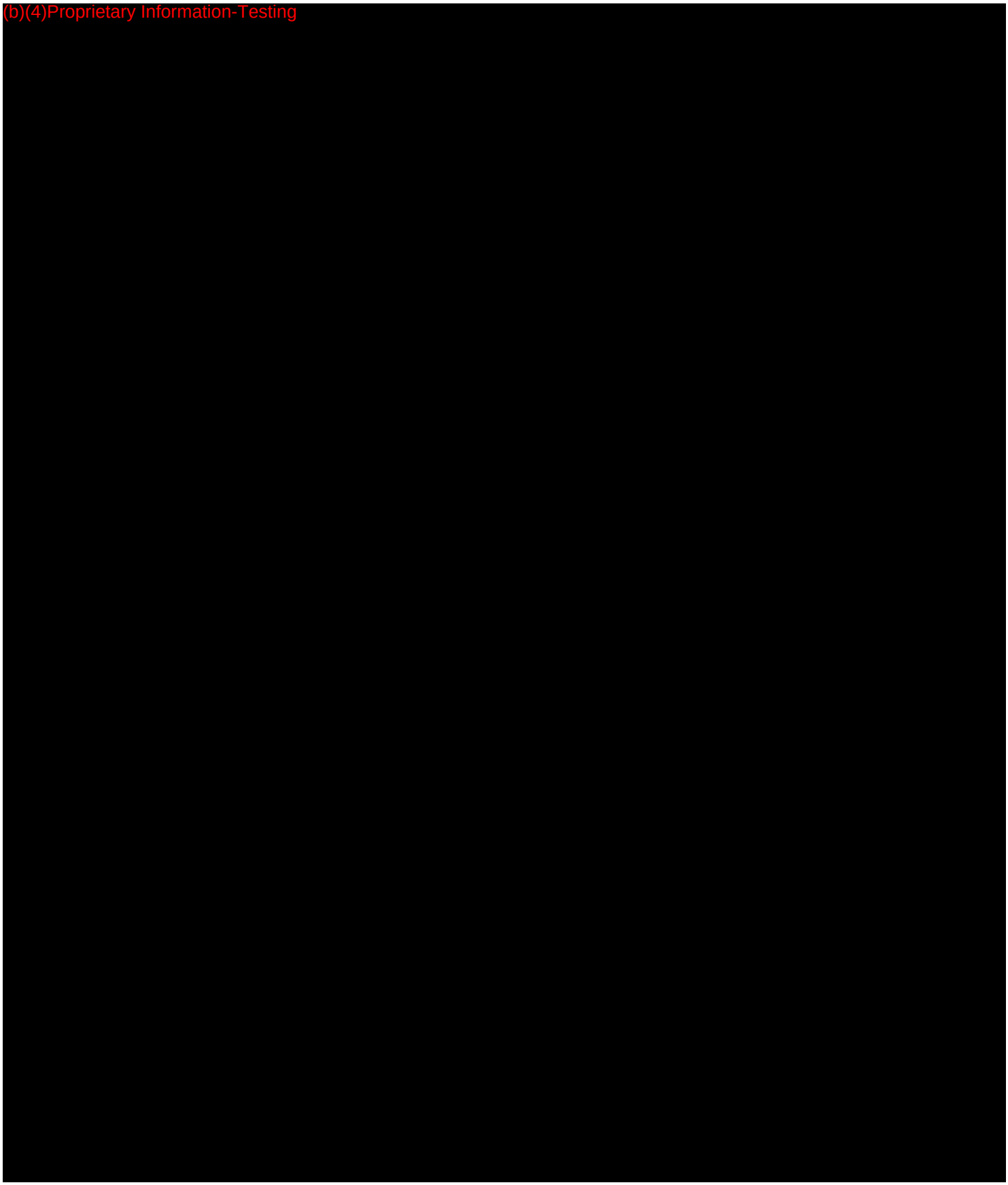
(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing

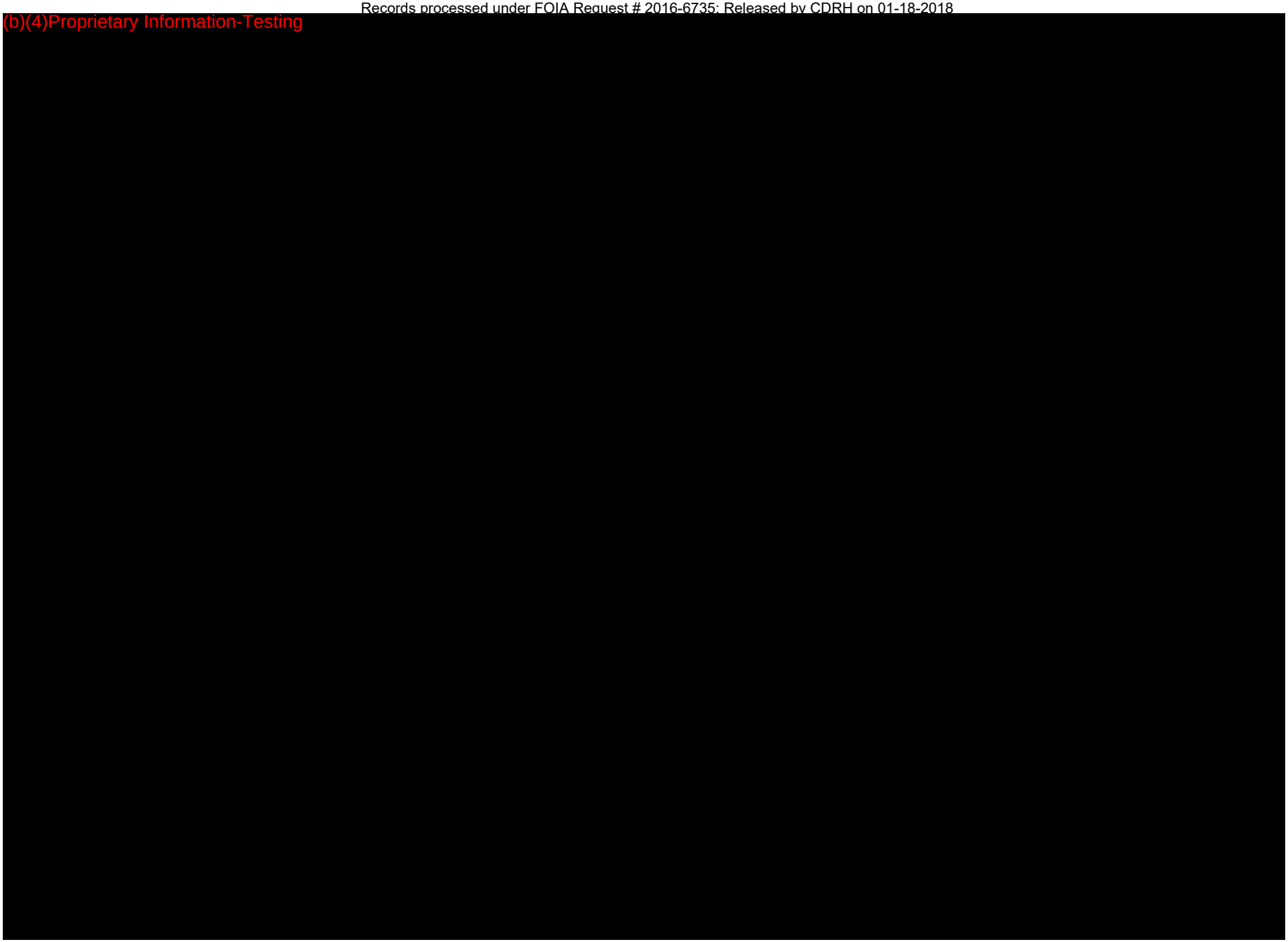


(b)(4)Proprietary Information-Testing



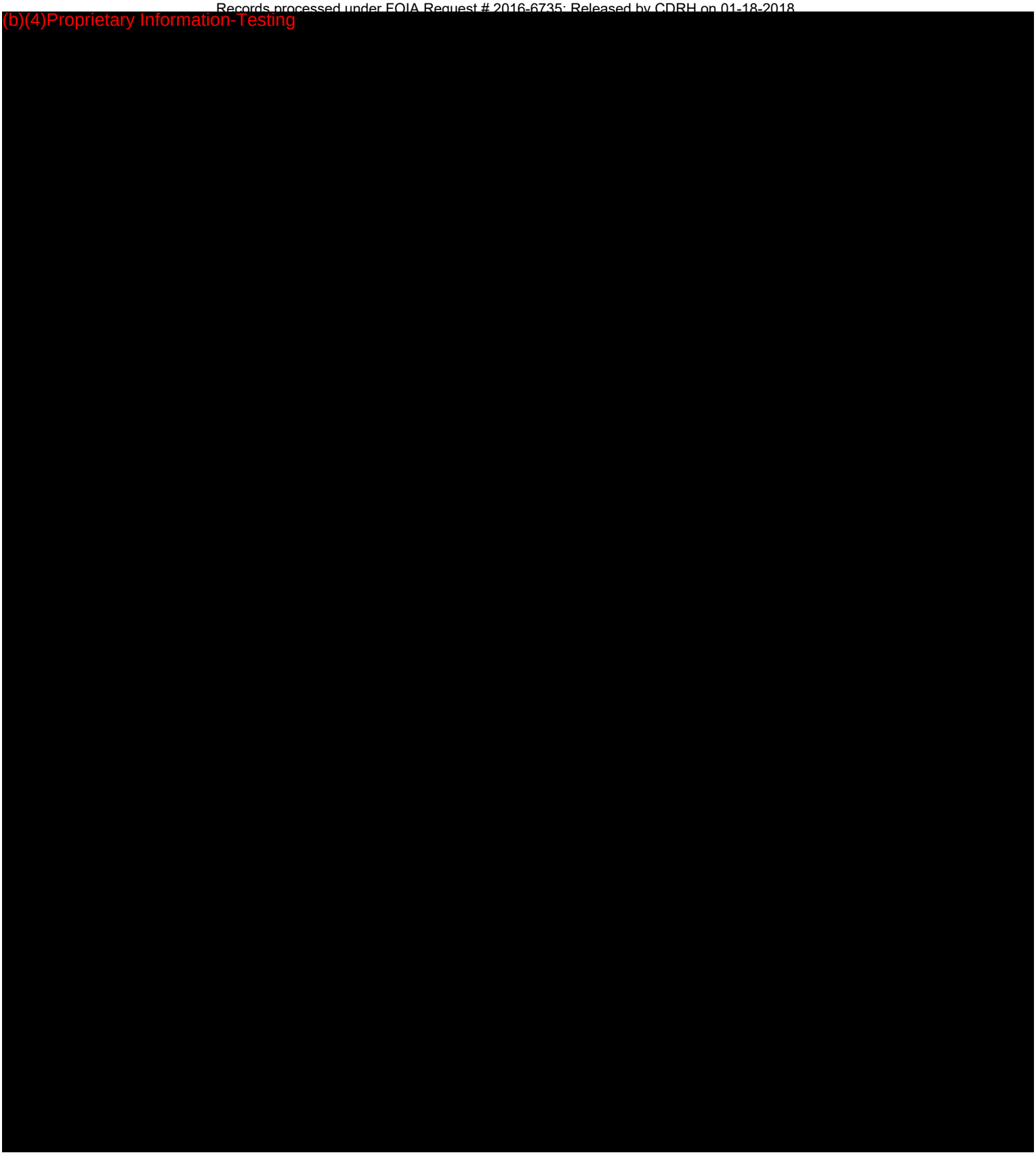
(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing

[redacted]

(b)(4)Proprietary Information- Testing

[redacted]

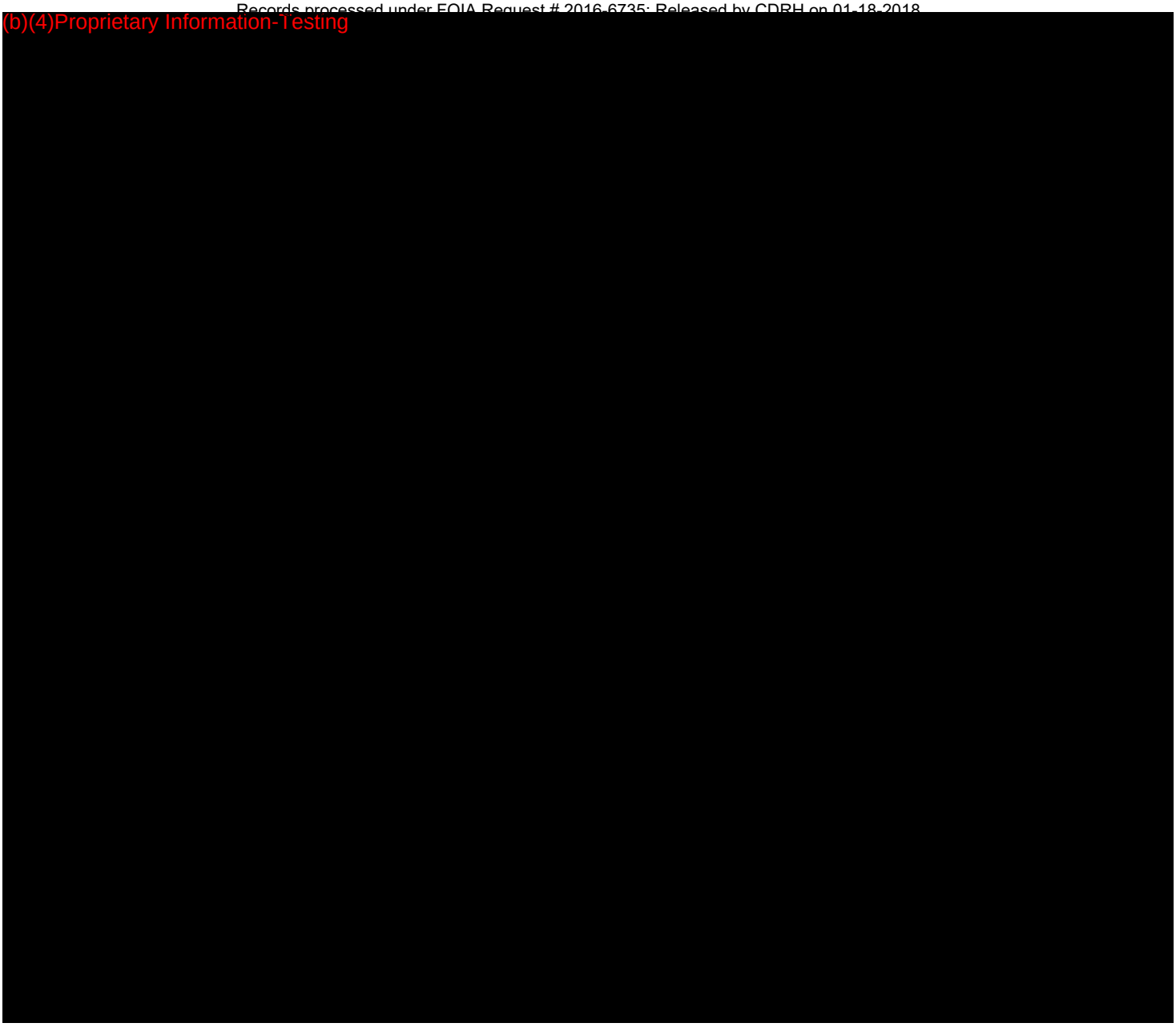
(b)(4)Proprietary Information-Testing

[redacted]

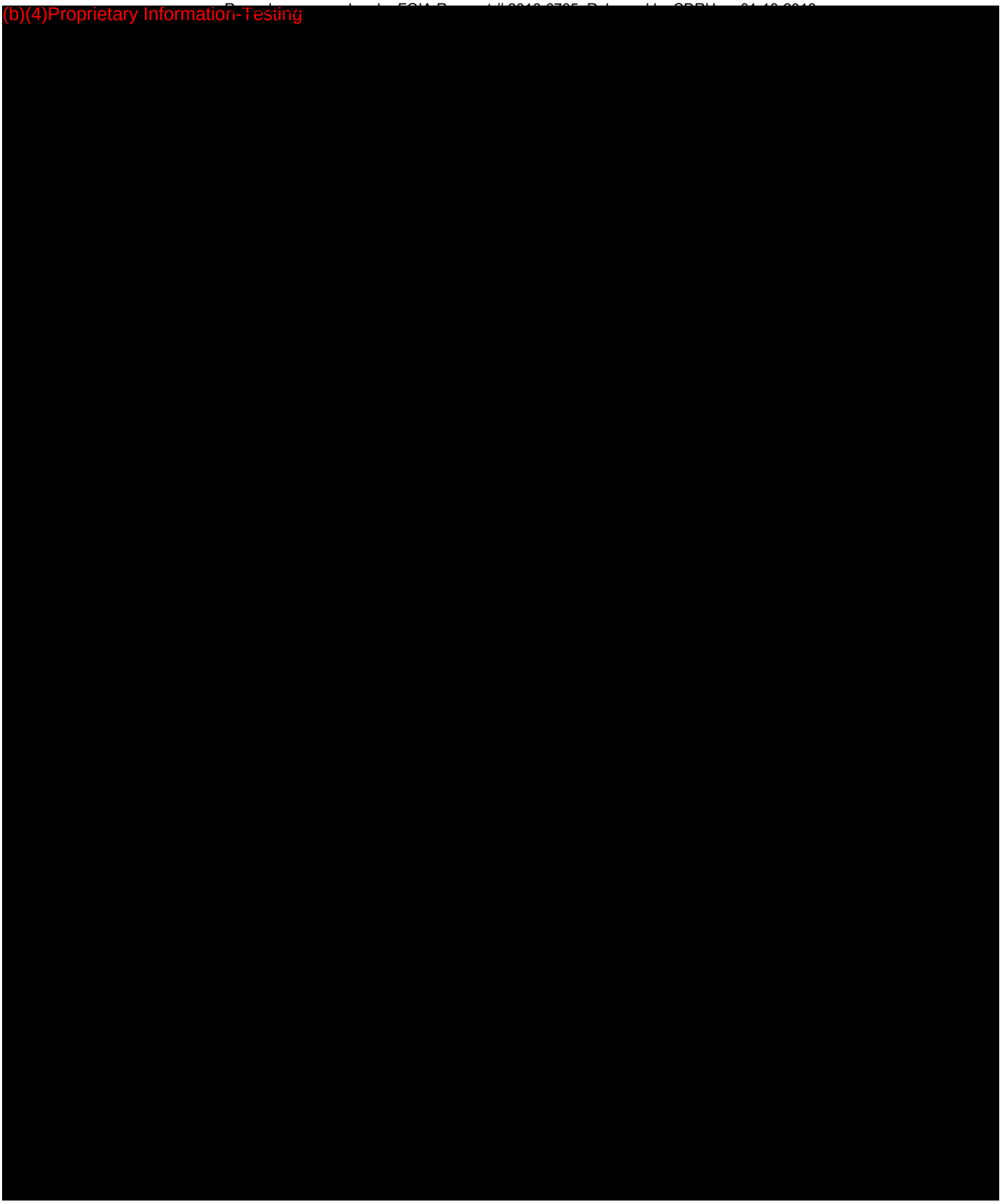
(b)(4)Proprietary Information-Testing

[redacted]

(b)(4)Proprietary Information-Testing

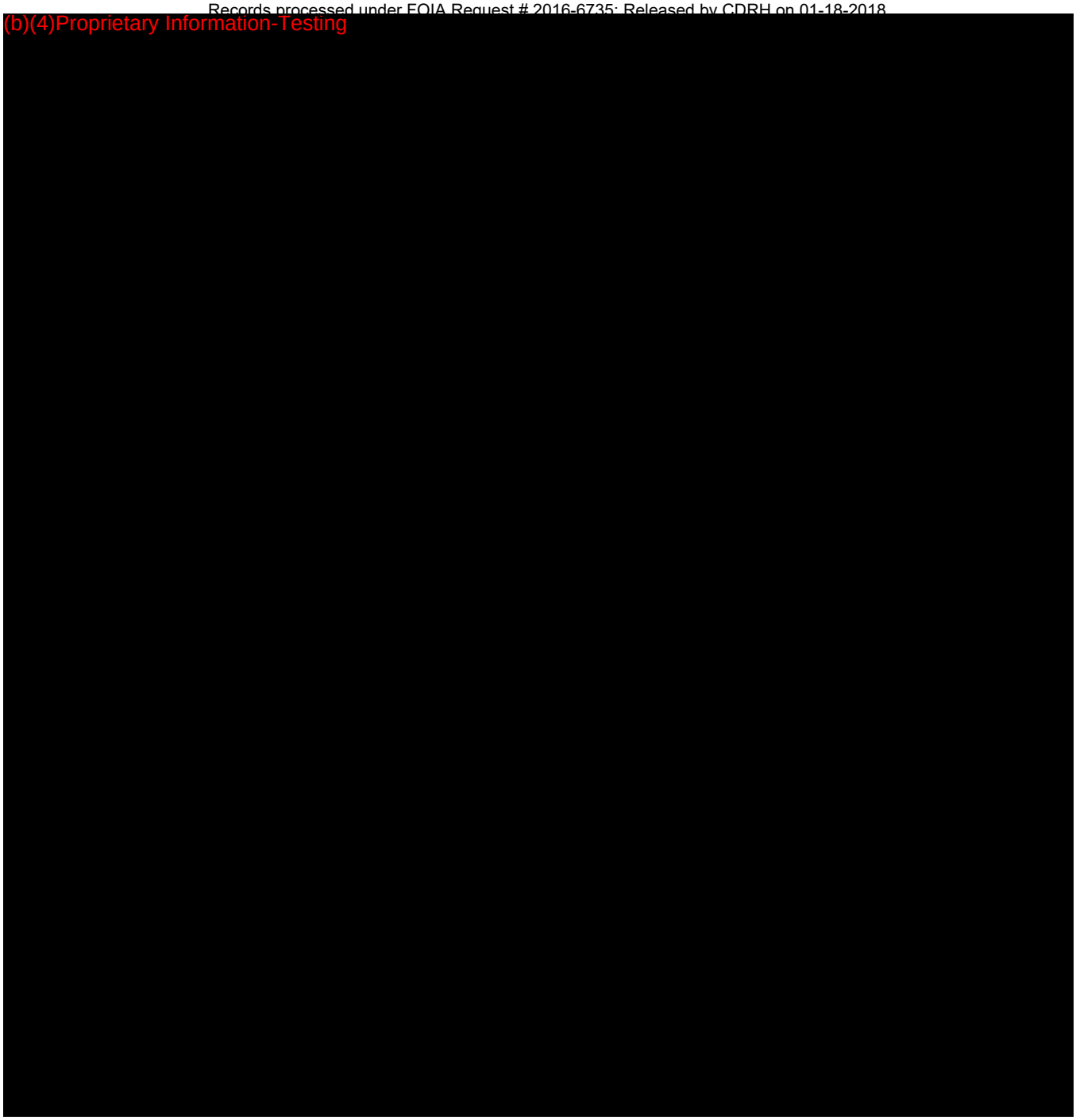


(b)(4)Proprietary Information-Testing

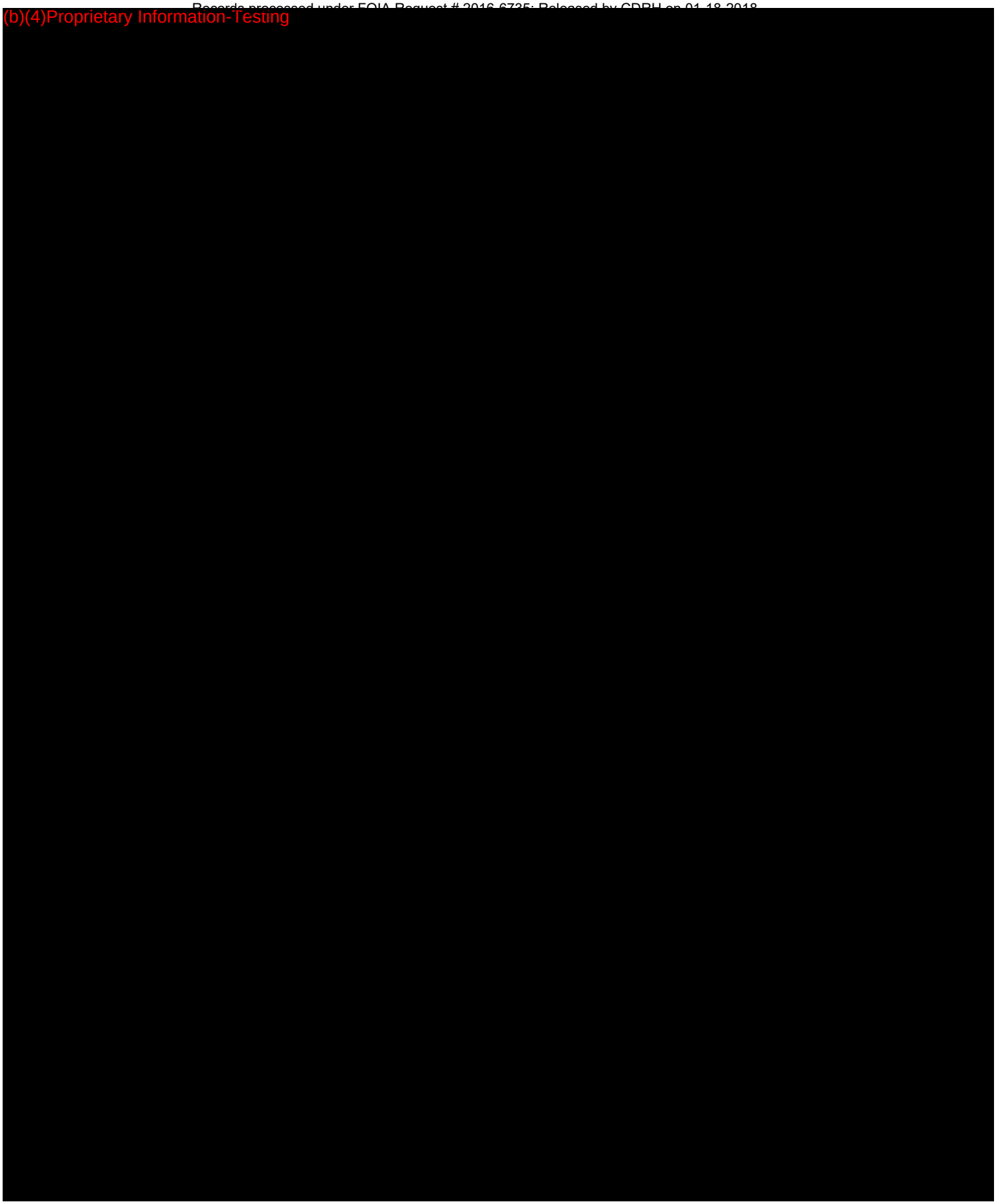


(b)(4)Proprietary Information-Testing

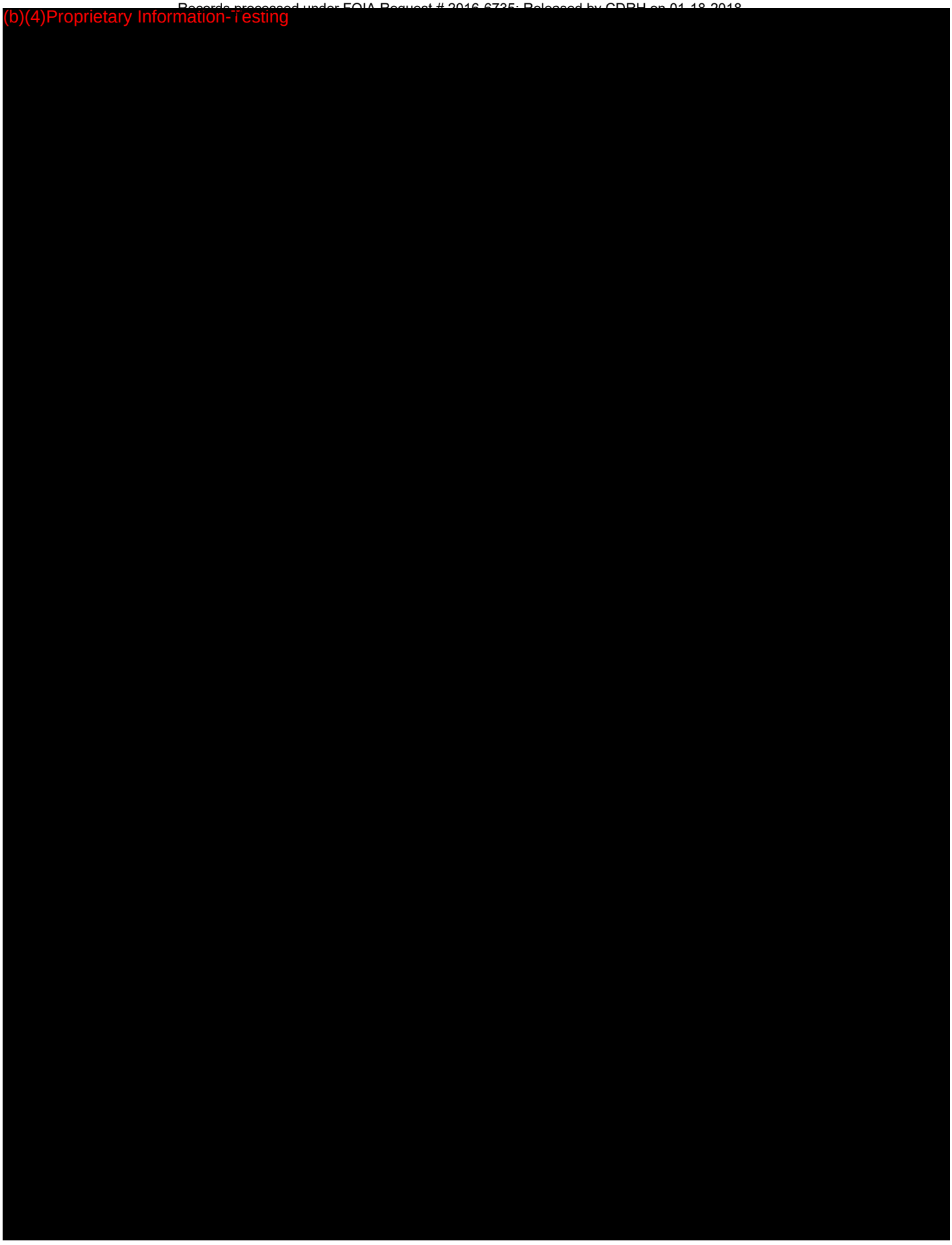
(b)(4)Proprietary Information-Testing



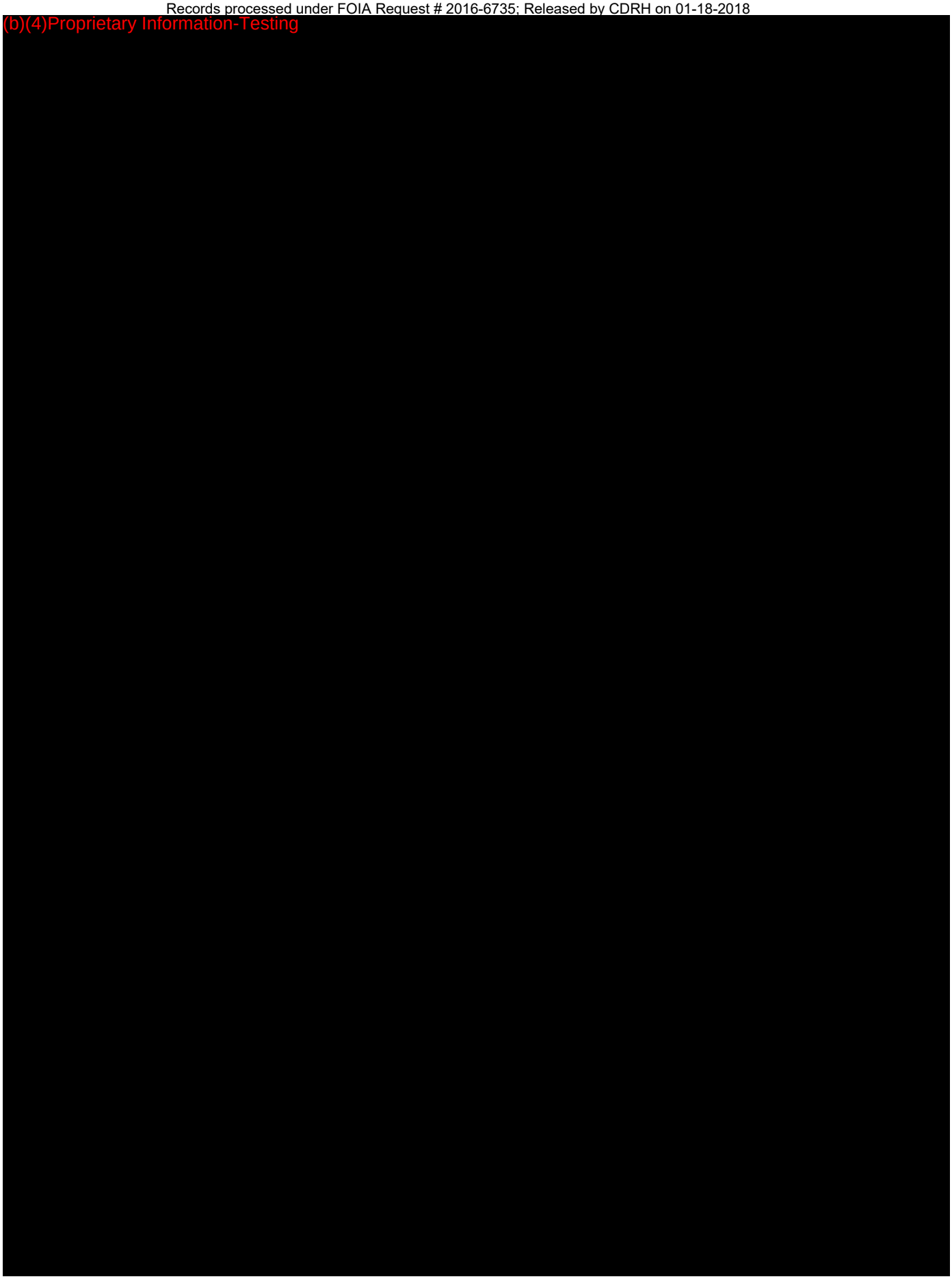
(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing

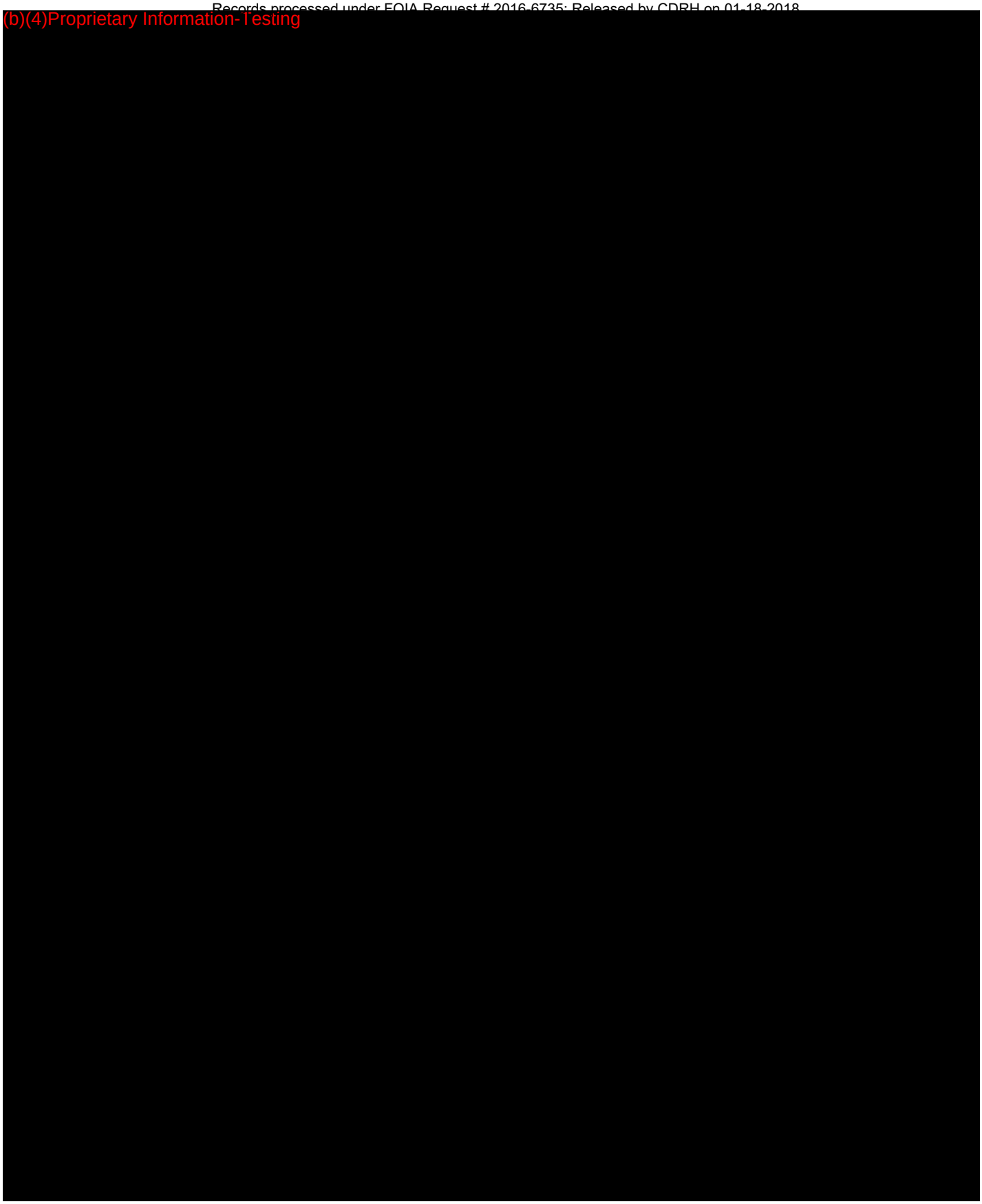


(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing

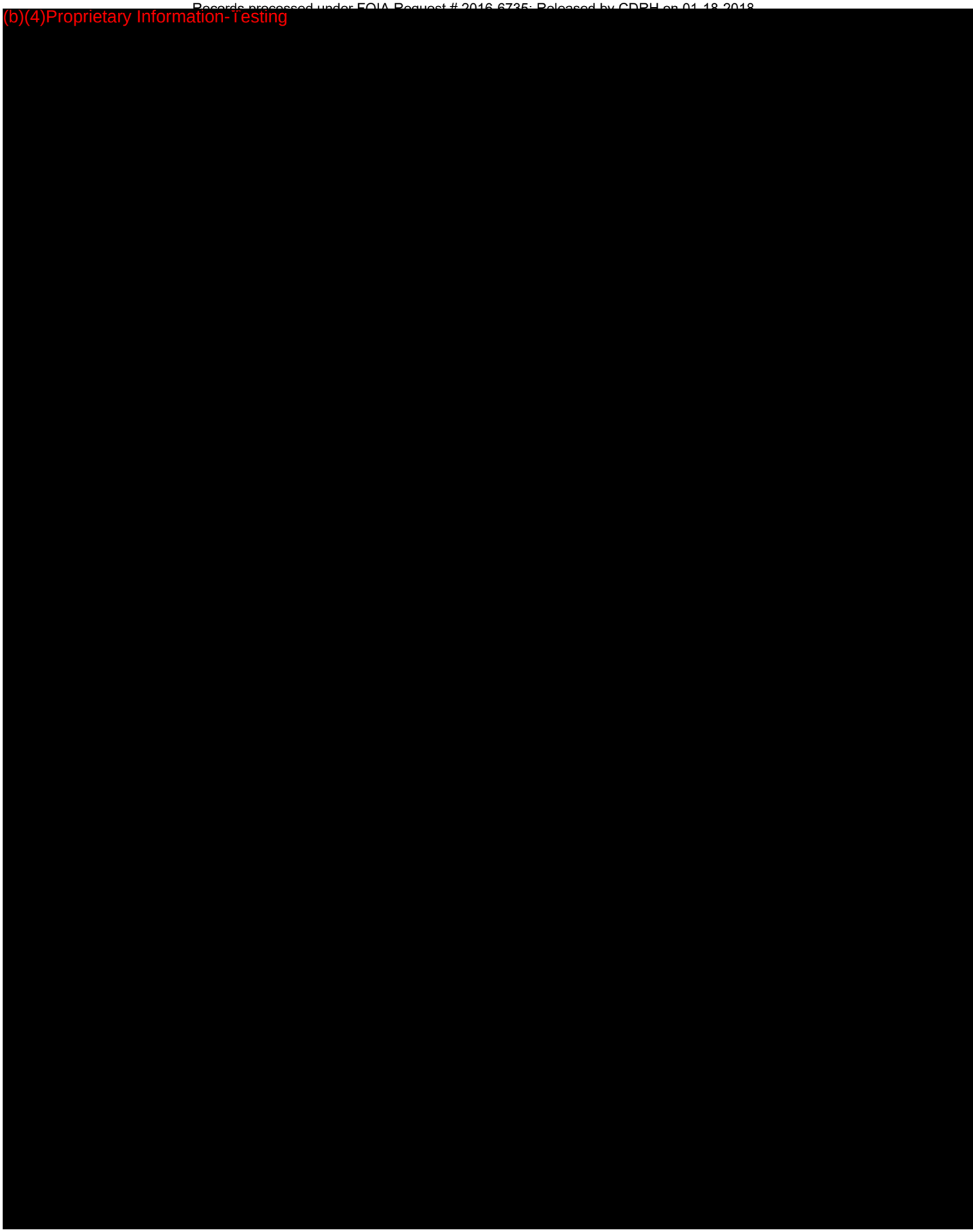
(b)(4)Proprietary Information-Testing



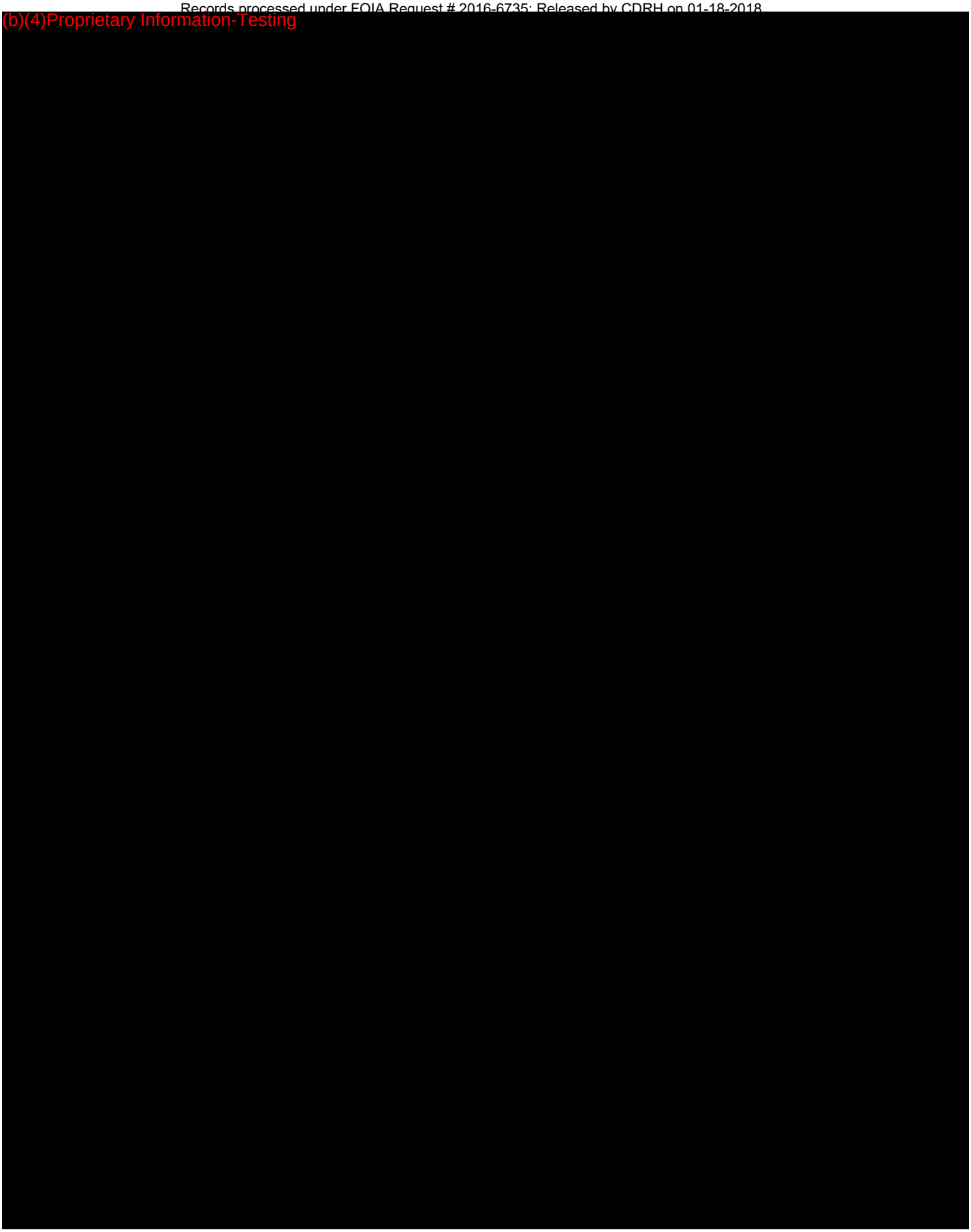
(b)(4)Proprietary Information-Testing

[redacted]

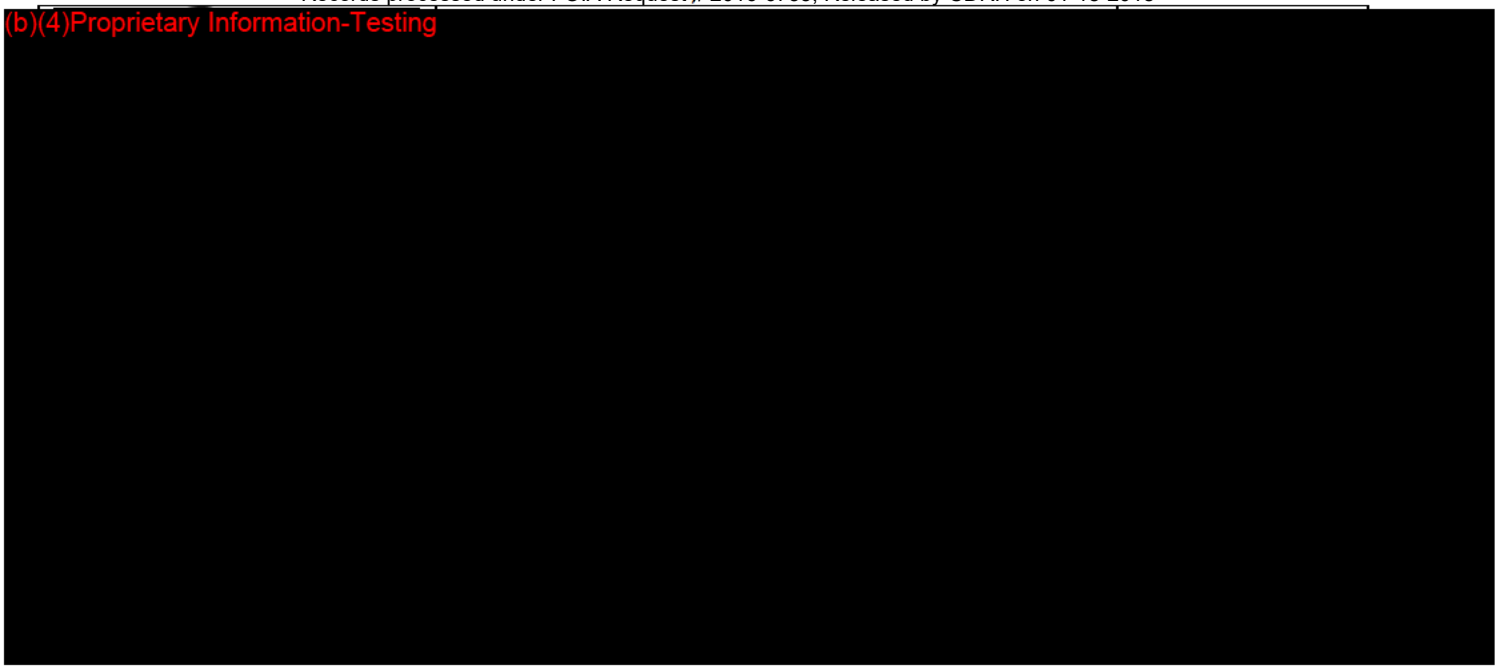
(b)(4)Proprietary Information-Testing

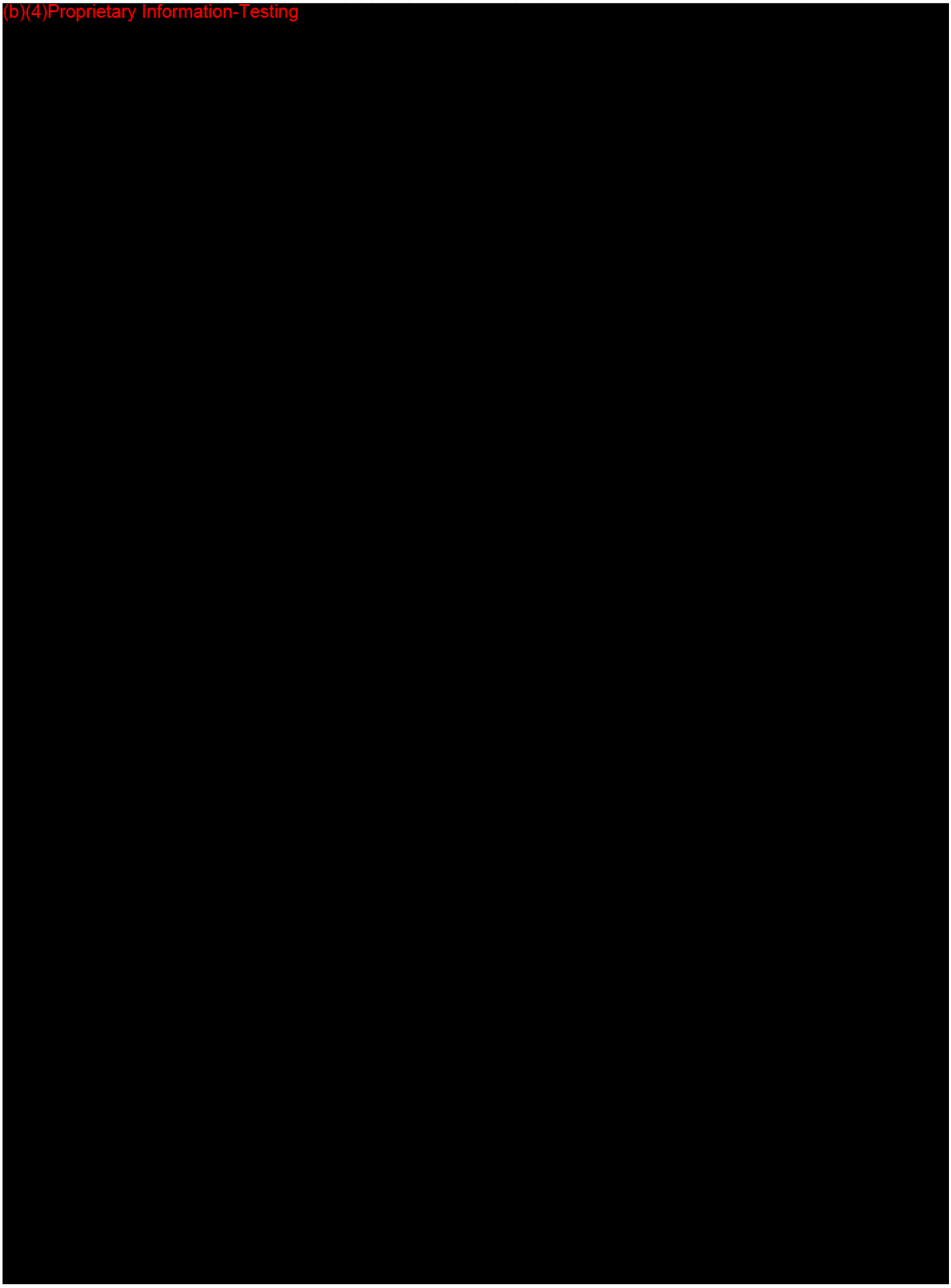


(b)(4)Proprietary Information-Testing



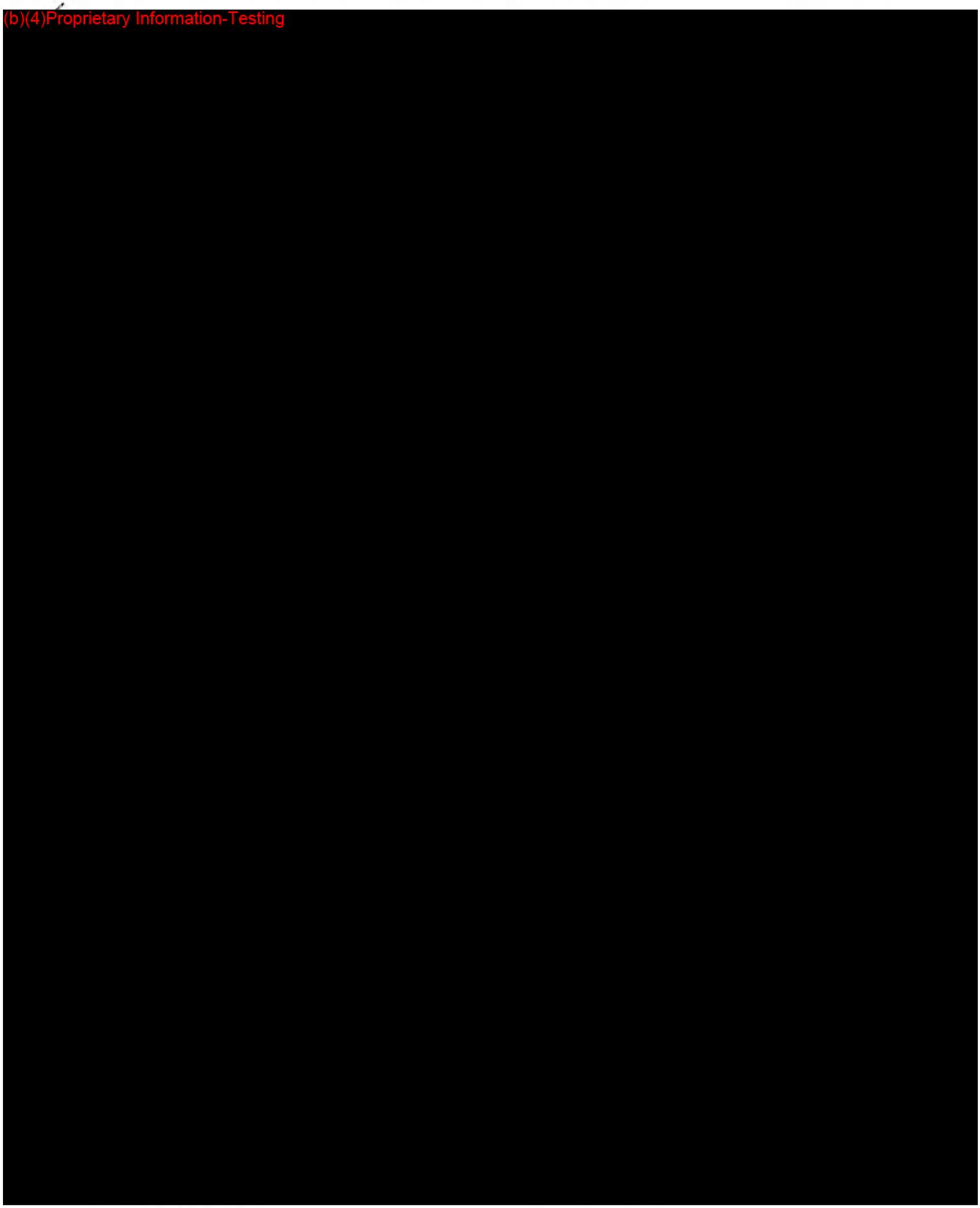
(b)(4)Proprietary Information-Testing



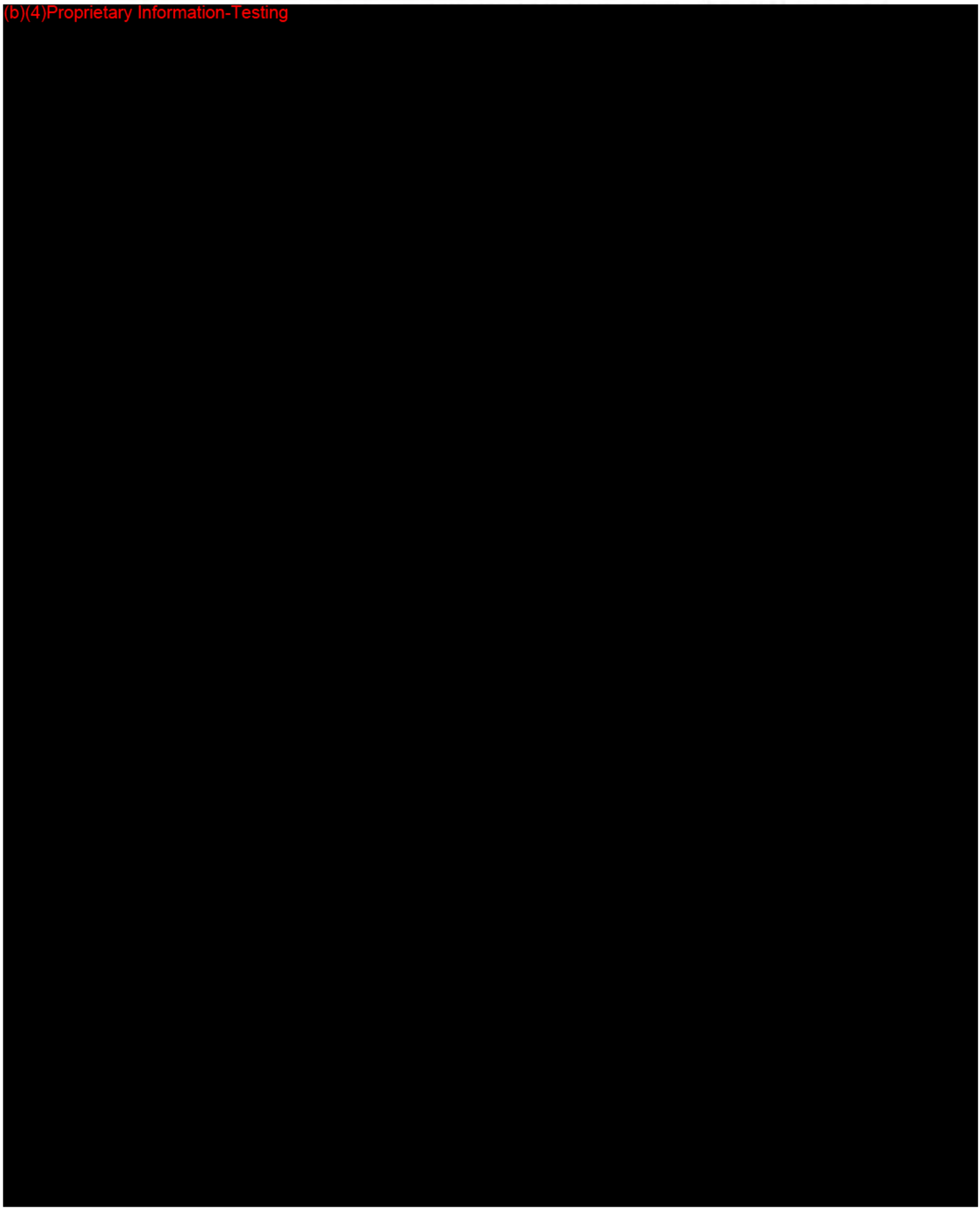


(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing



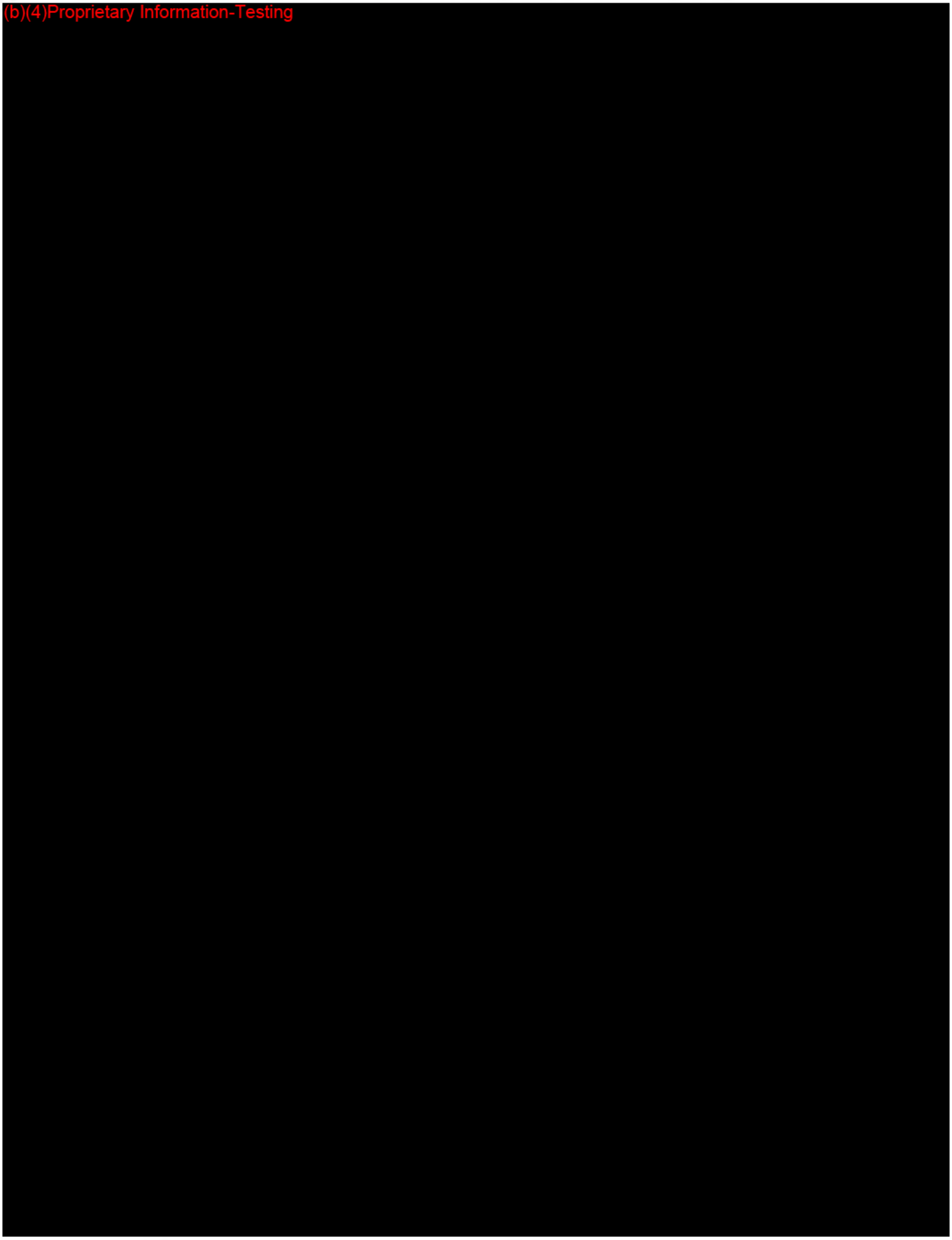
(b)(4)Proprietary Information-Testing



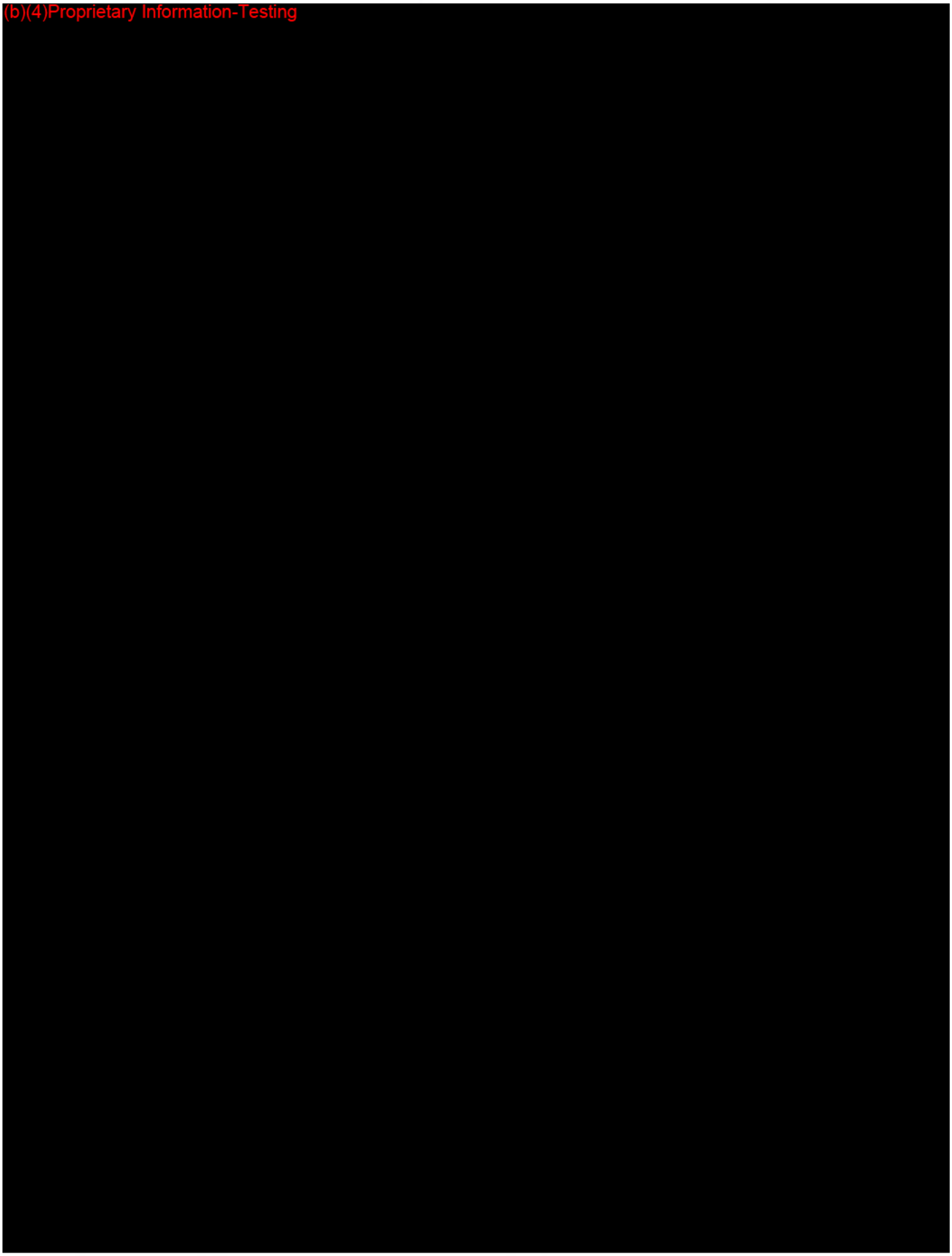
(b)(4)Proprietary Information-Testing

[redacted]

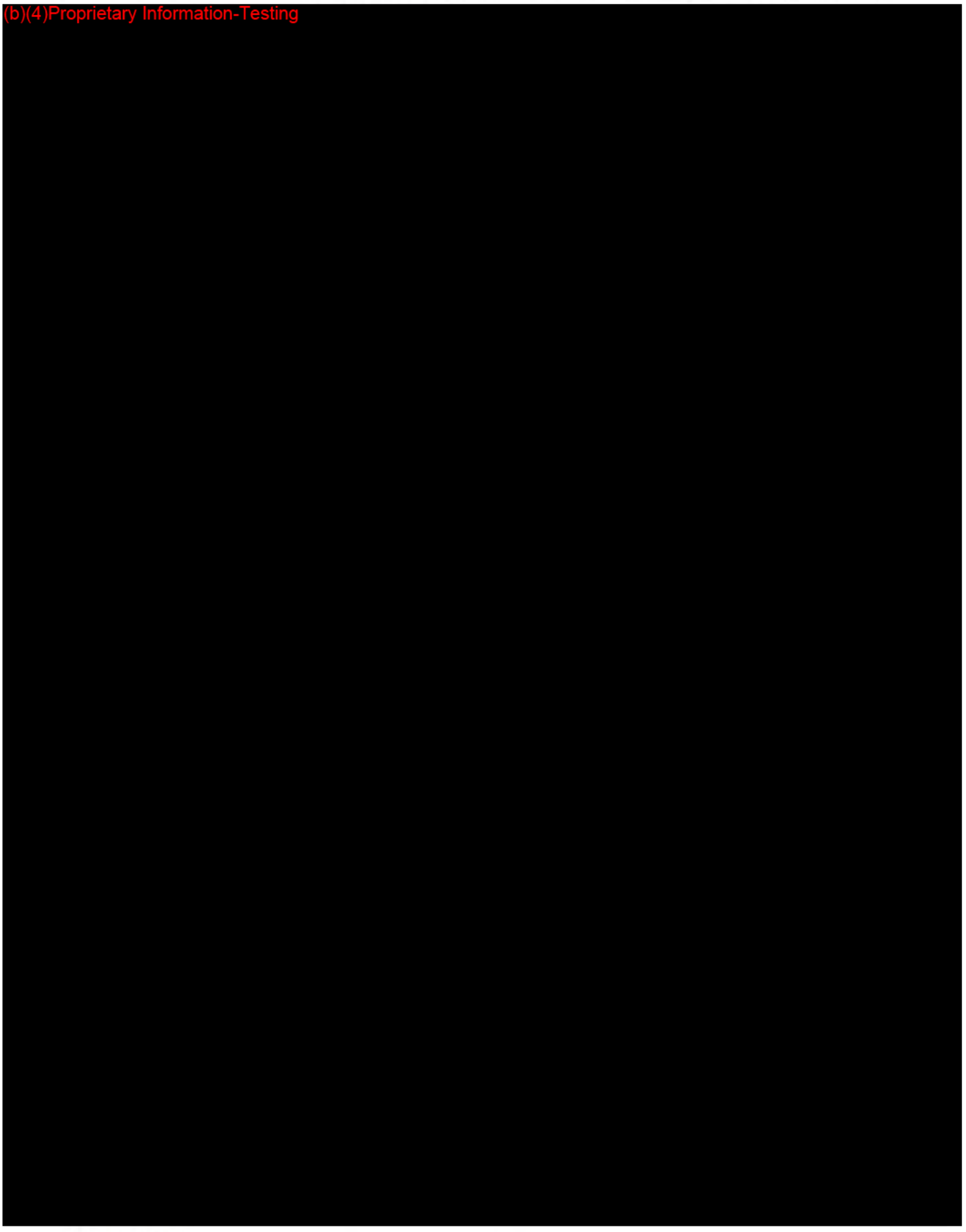
(b)(4)Proprietary Information-Testing



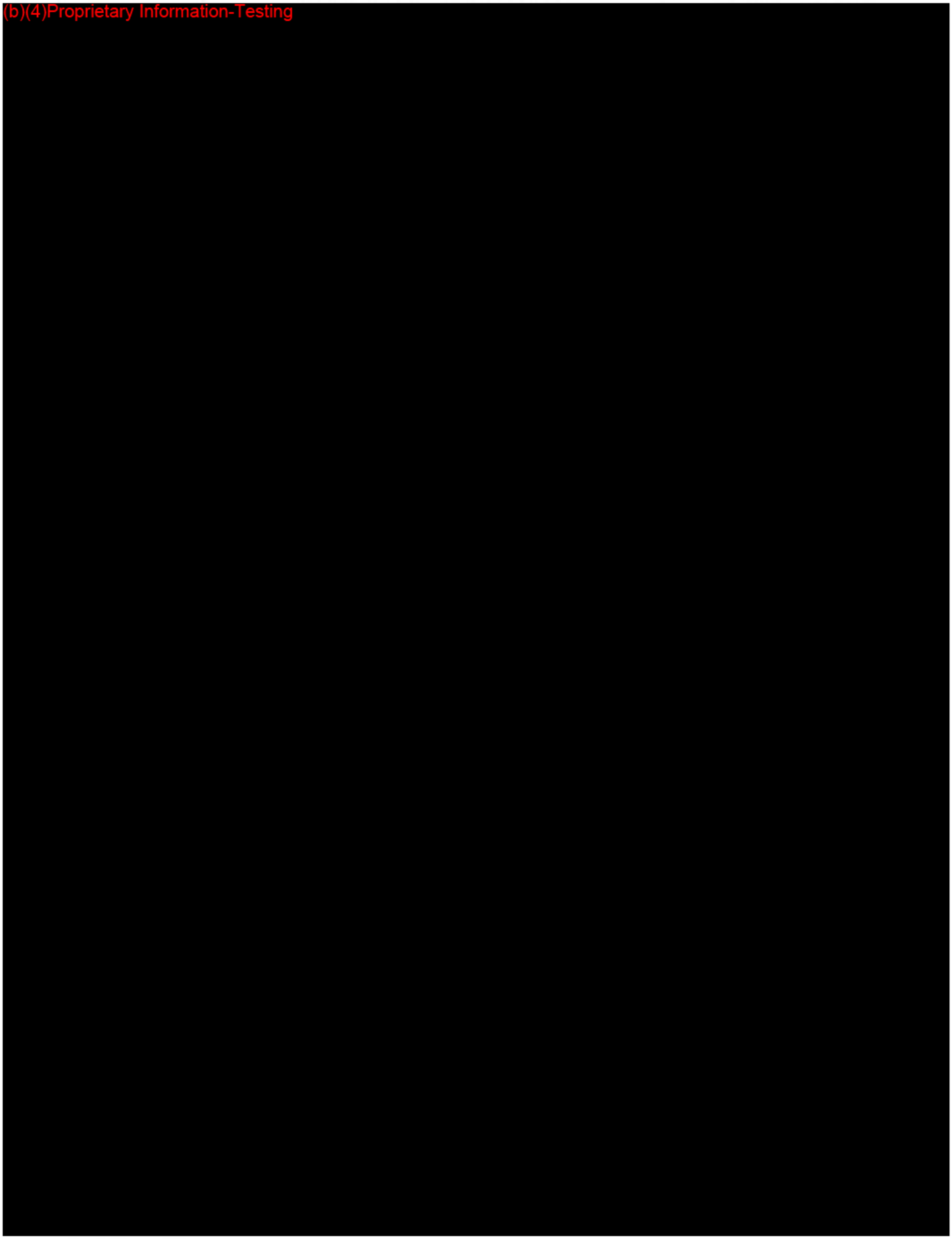
(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing



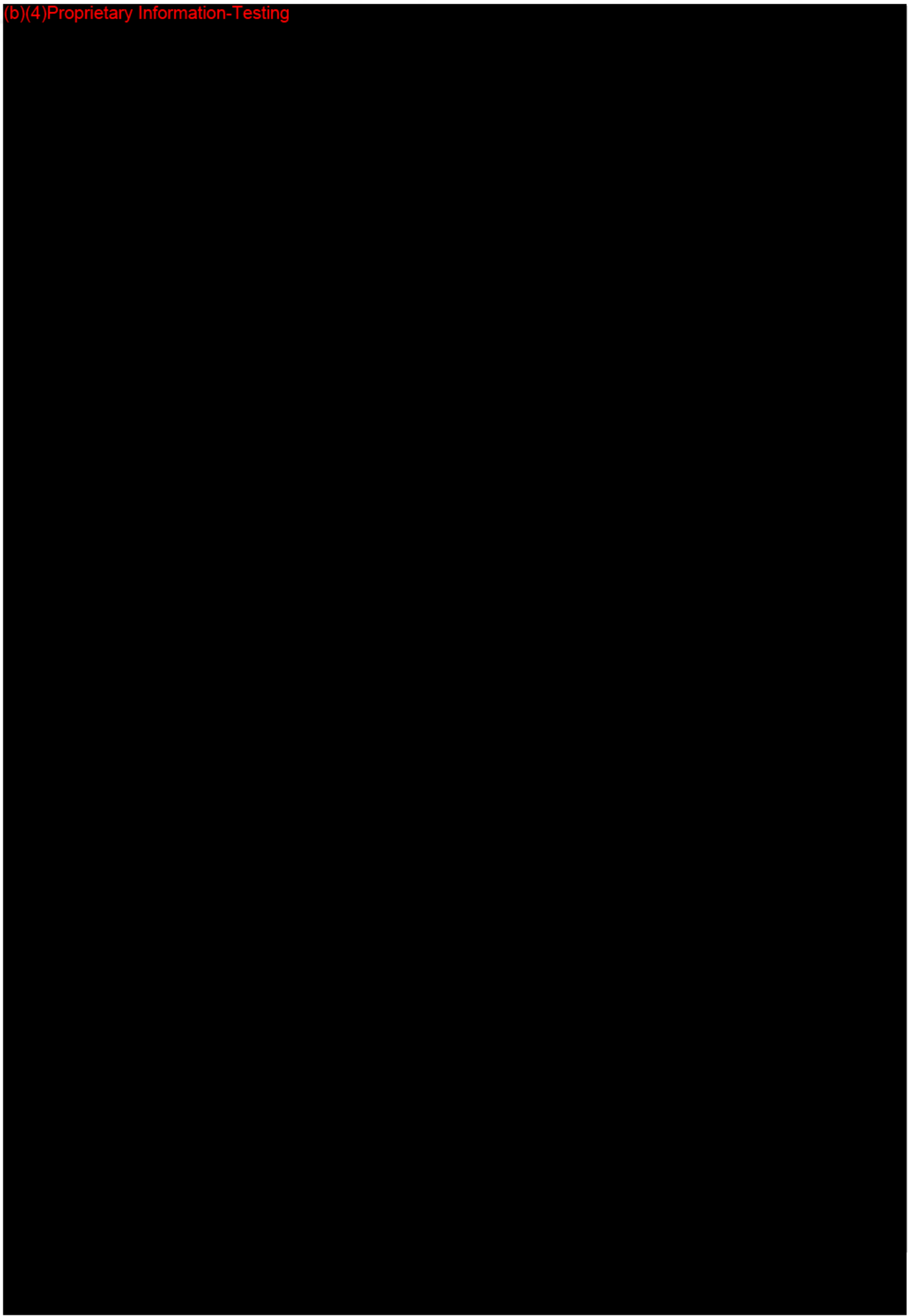
(b)(4)Proprietary Information-Testing



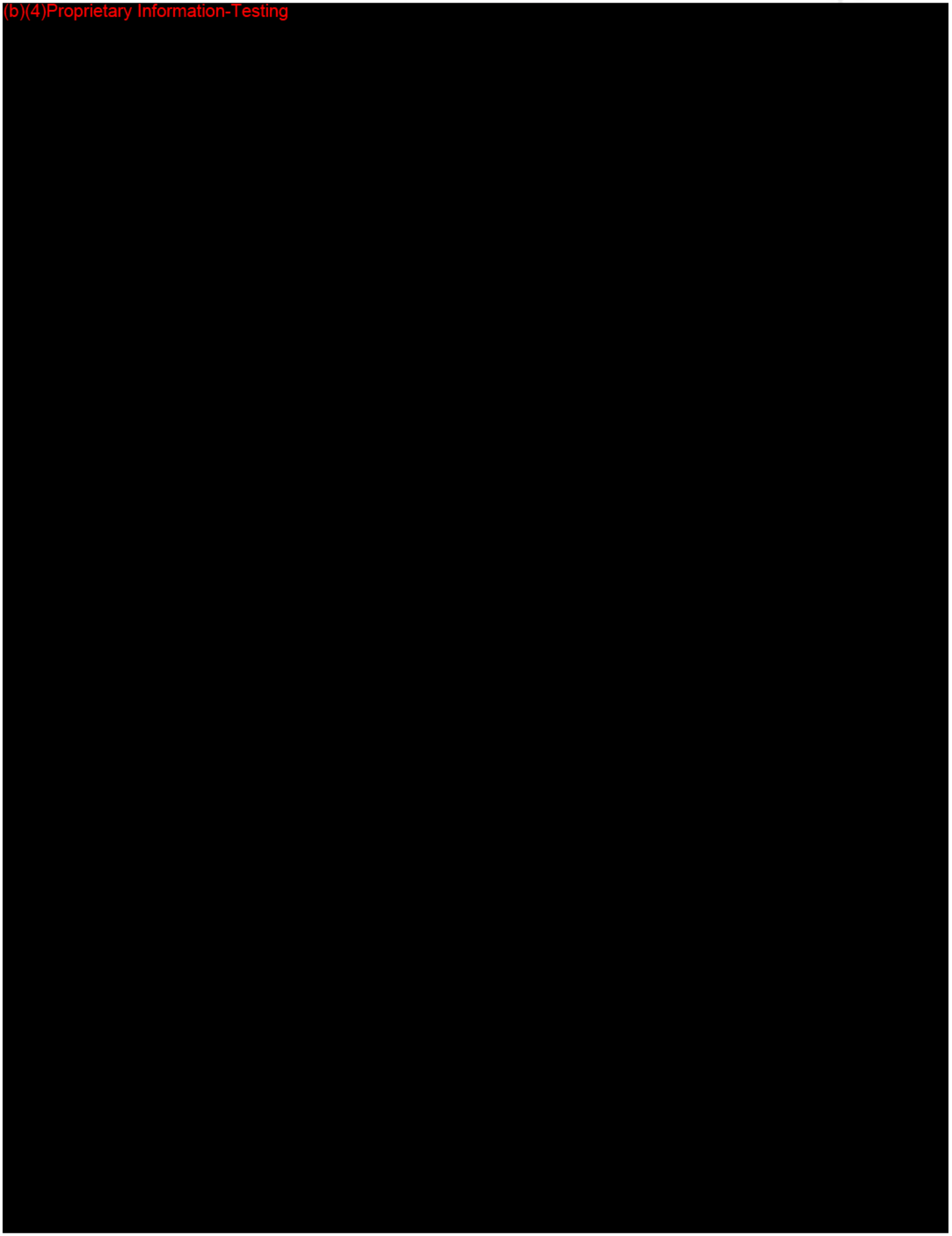
(b)(4)Proprietary Information-Testing

[redacted]

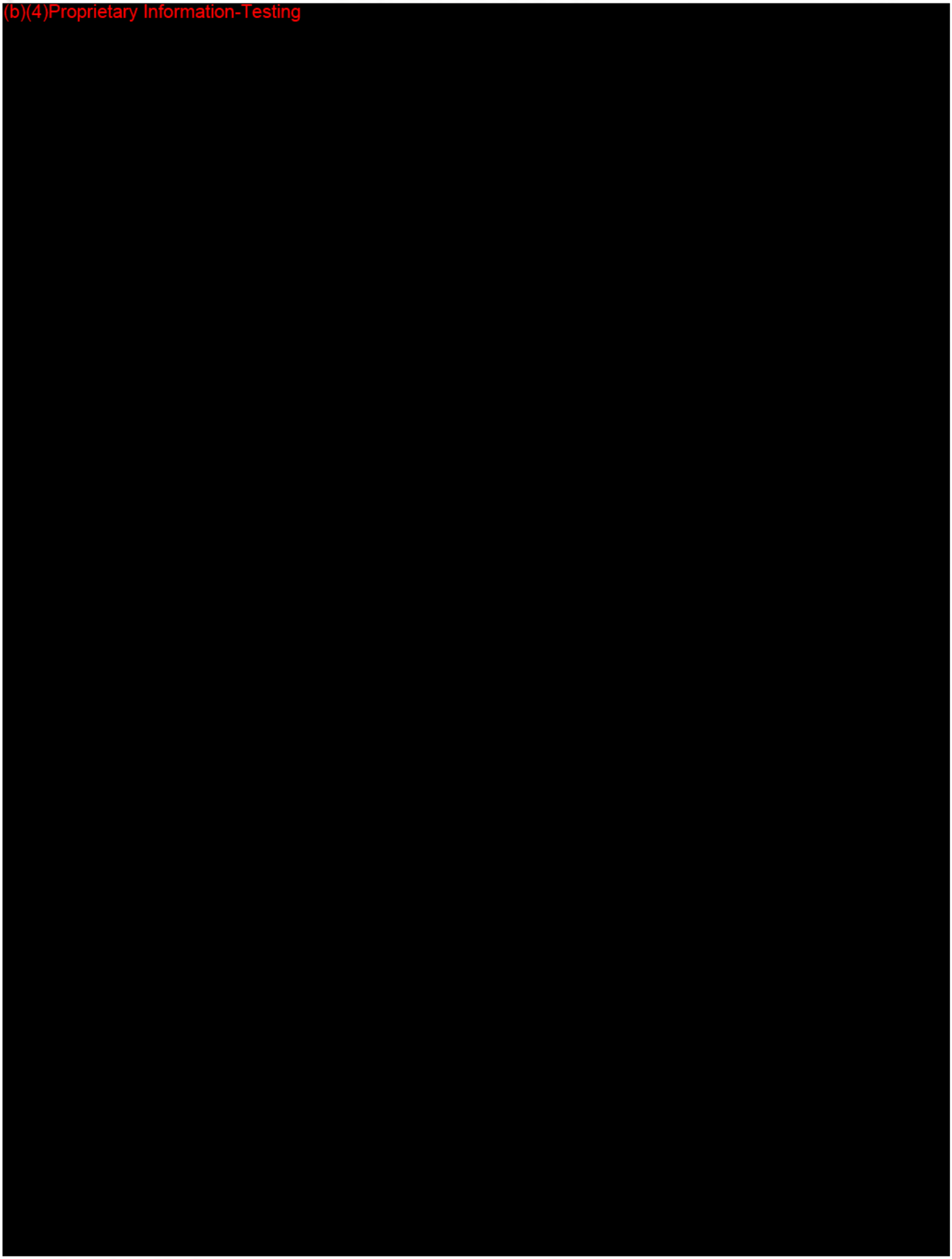
(b)(4)Proprietary Information-Testing



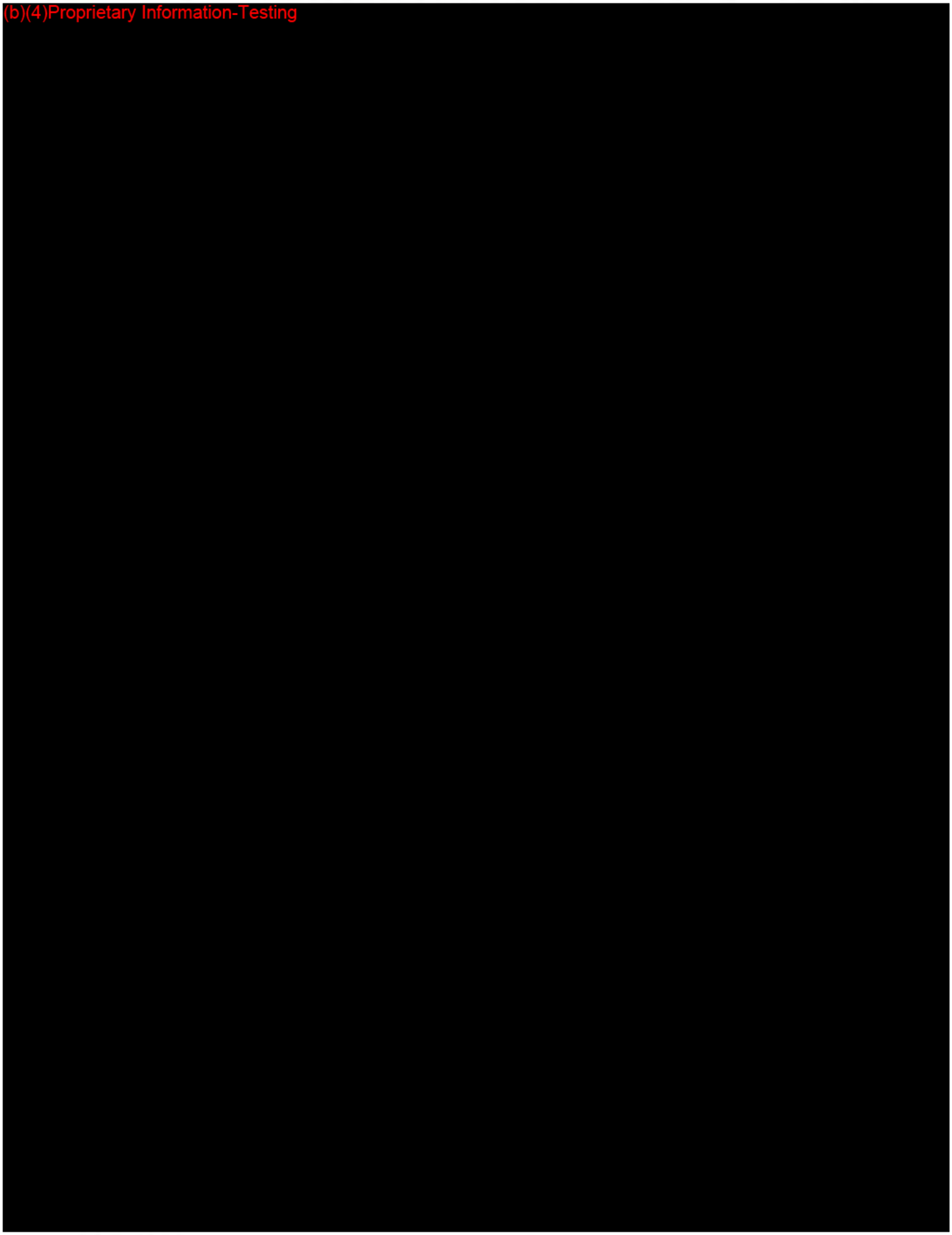
(b)(4)Proprietary Information-Testing



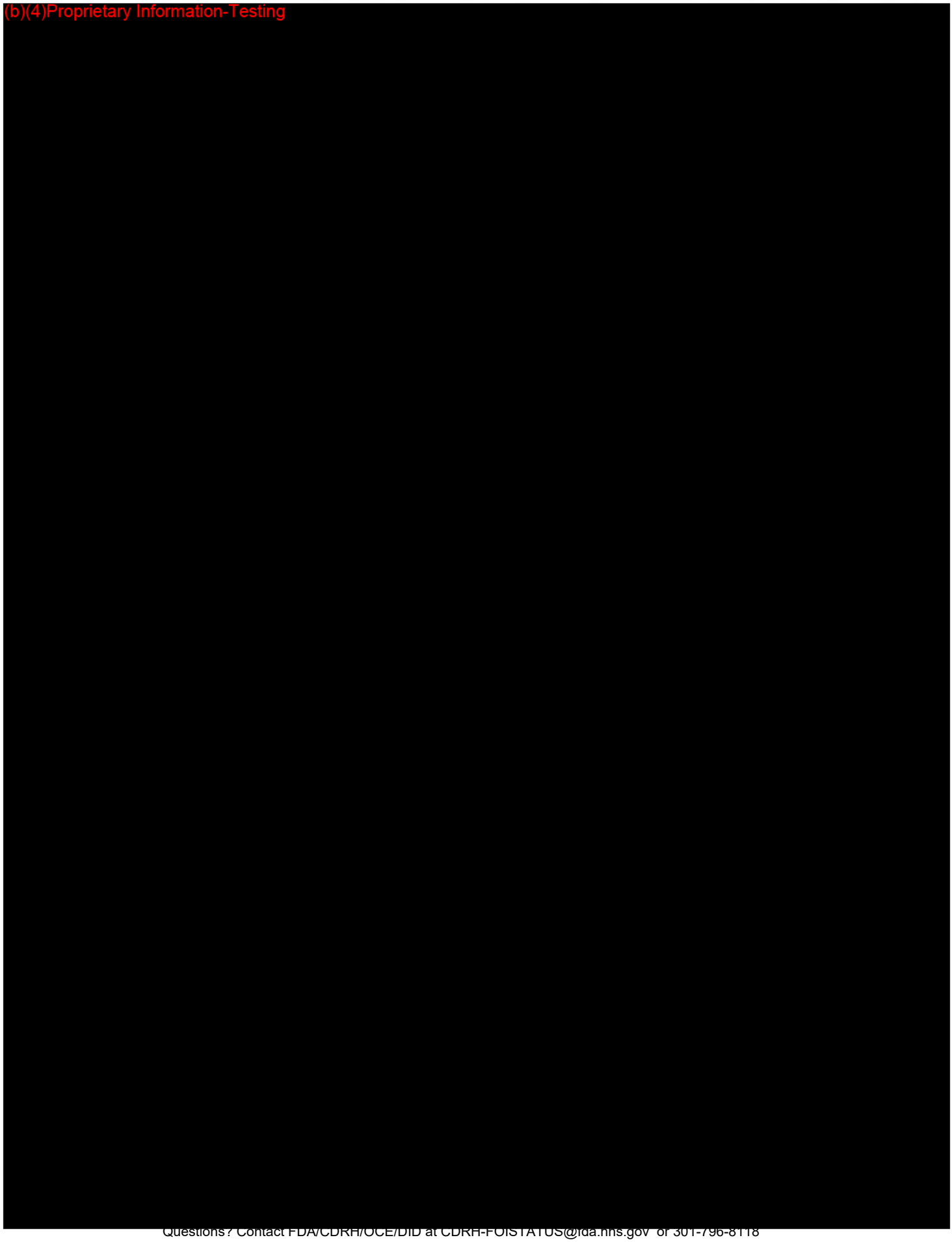
(b)(4)Proprietary Information-Testing



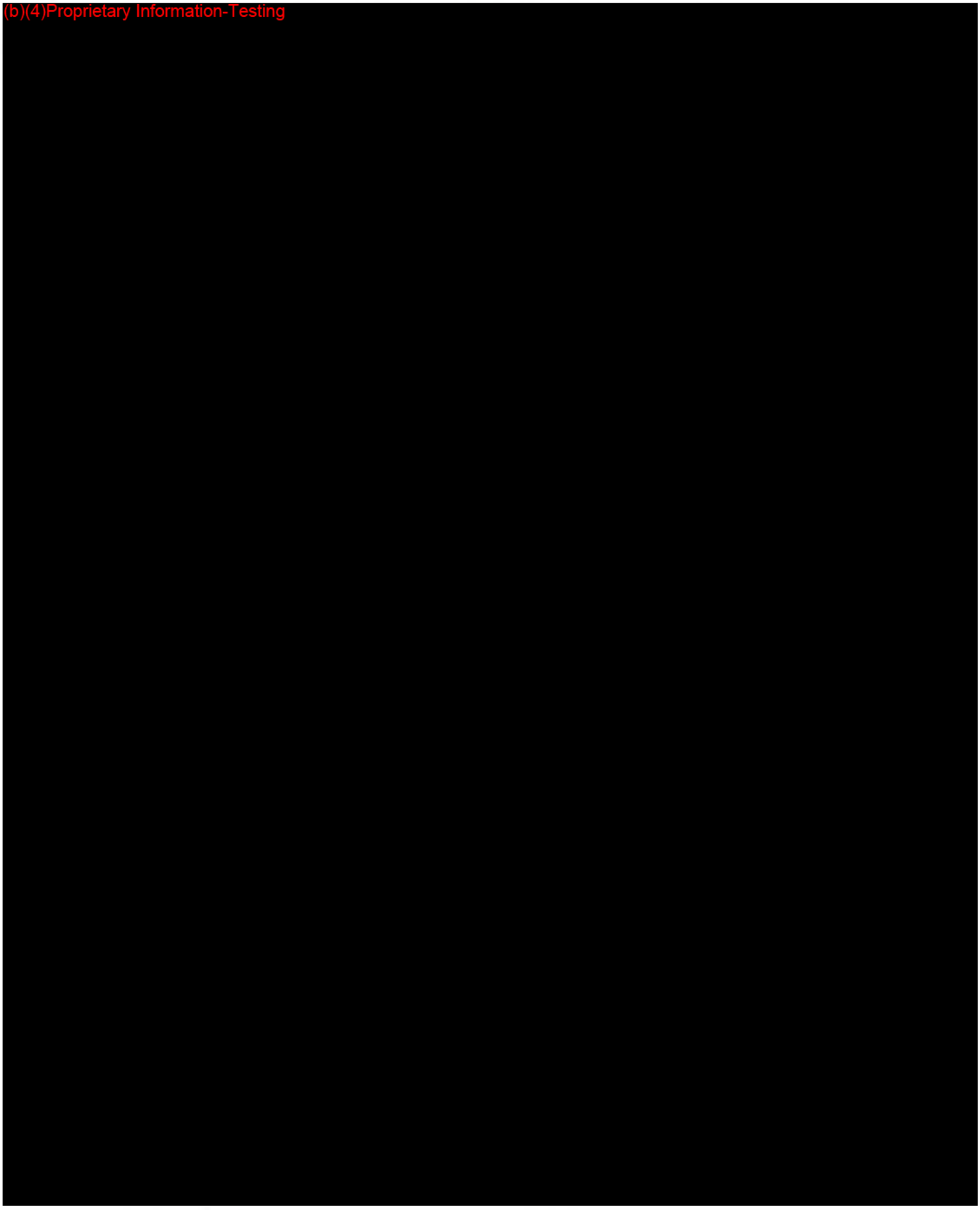
(b)(4)Proprietary Information-Testing



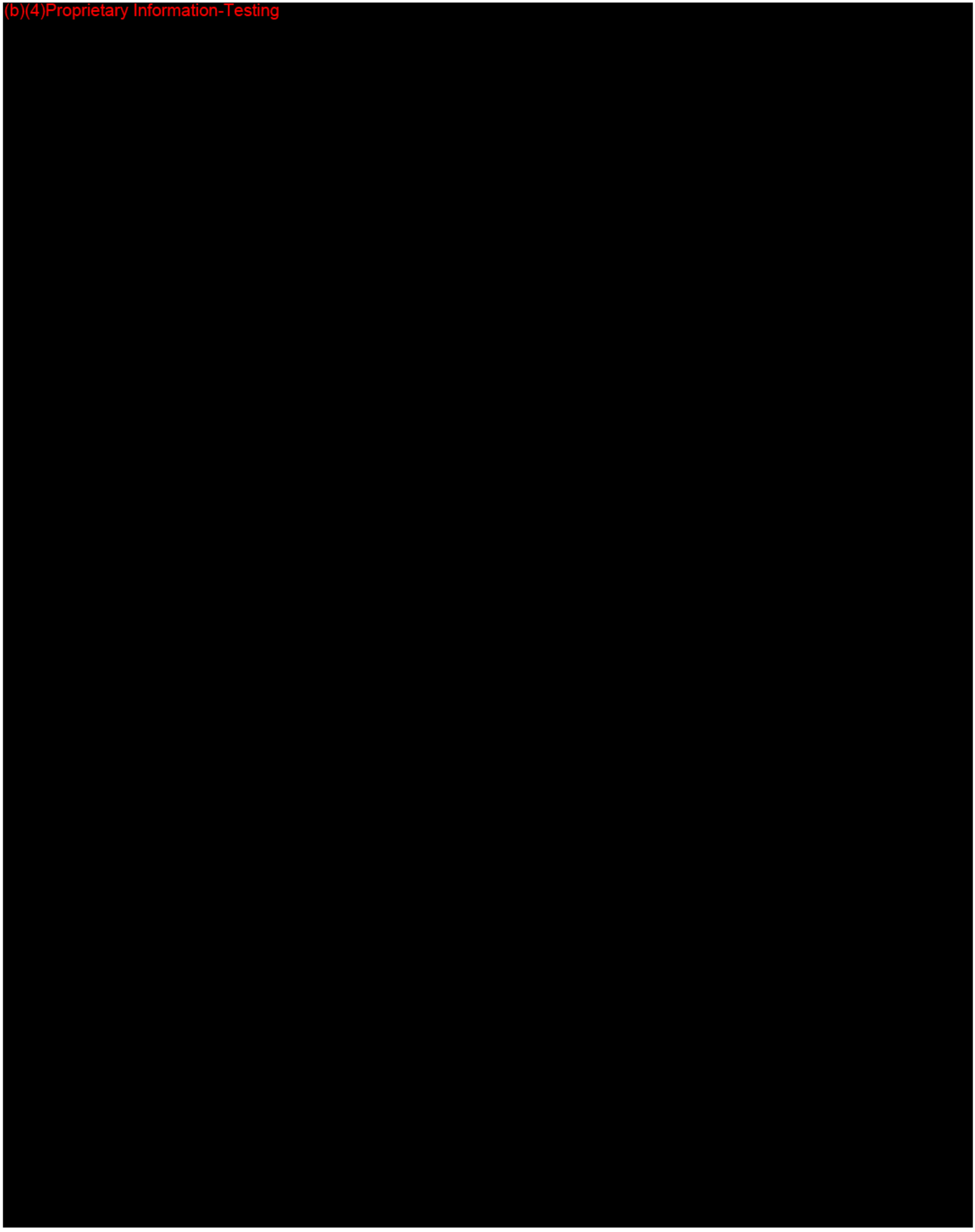
(b)(4)Proprietary Information-Testing

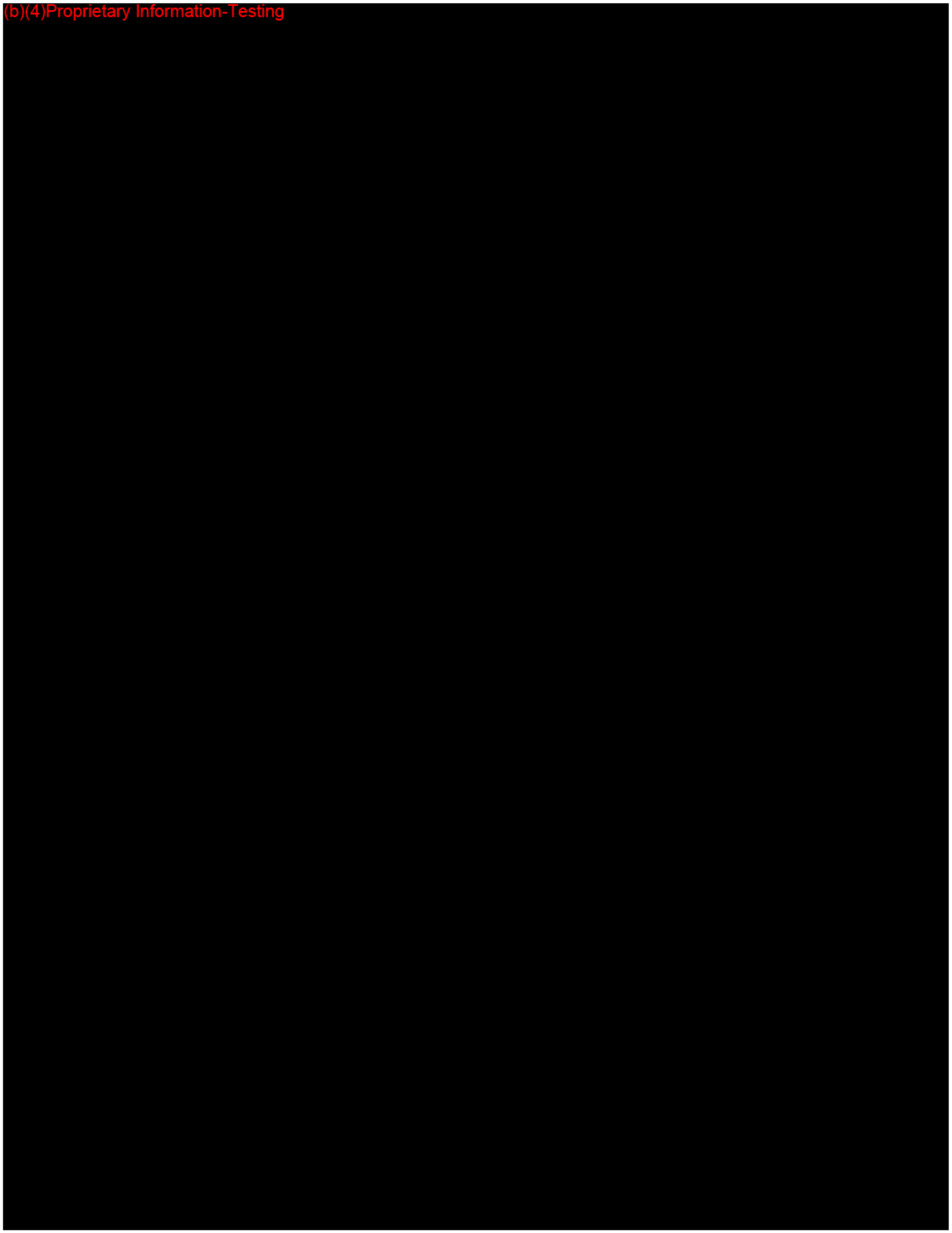


(b)(4)Proprietary Information-Testing

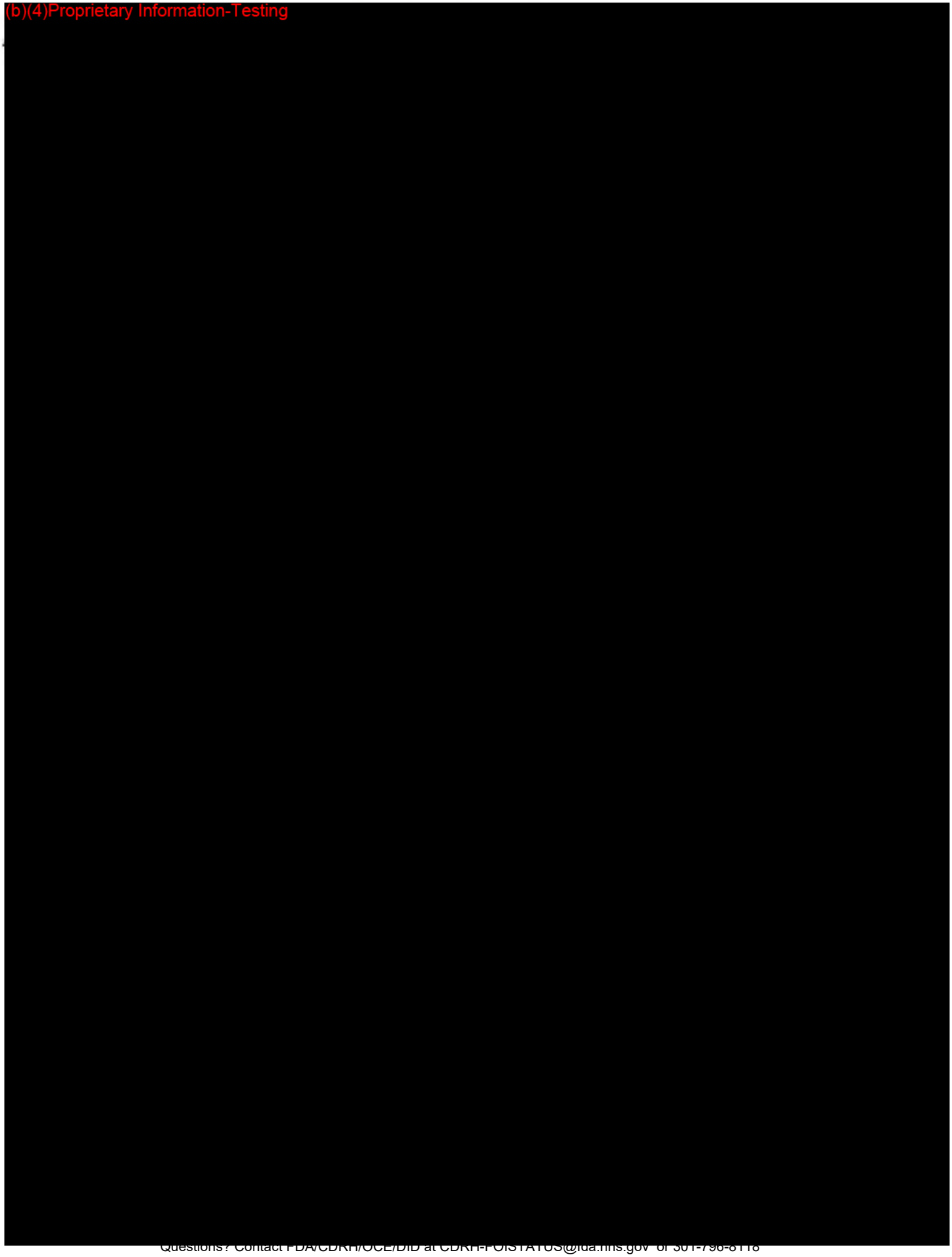


(b)(4)Proprietary Information-Testing

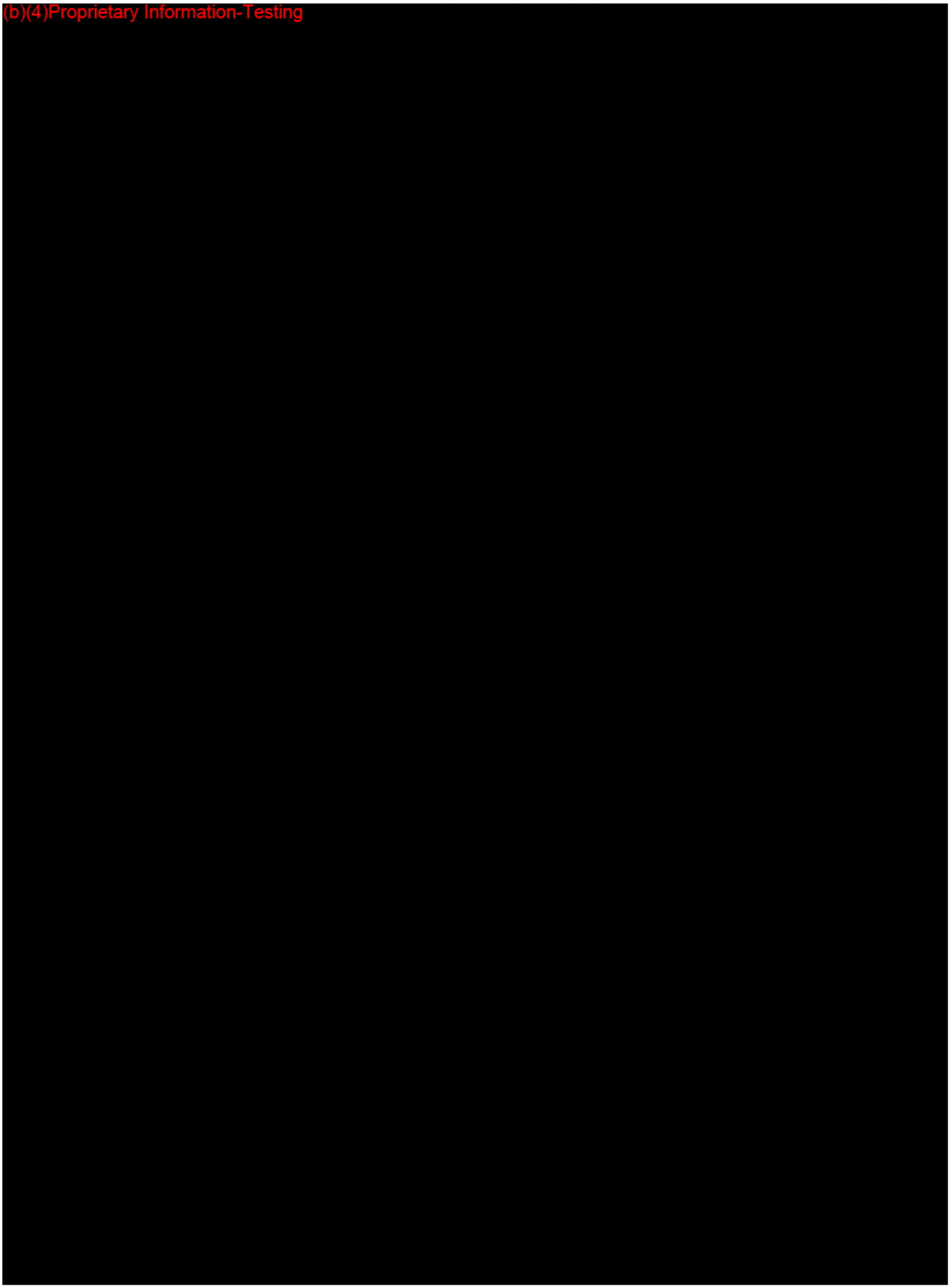


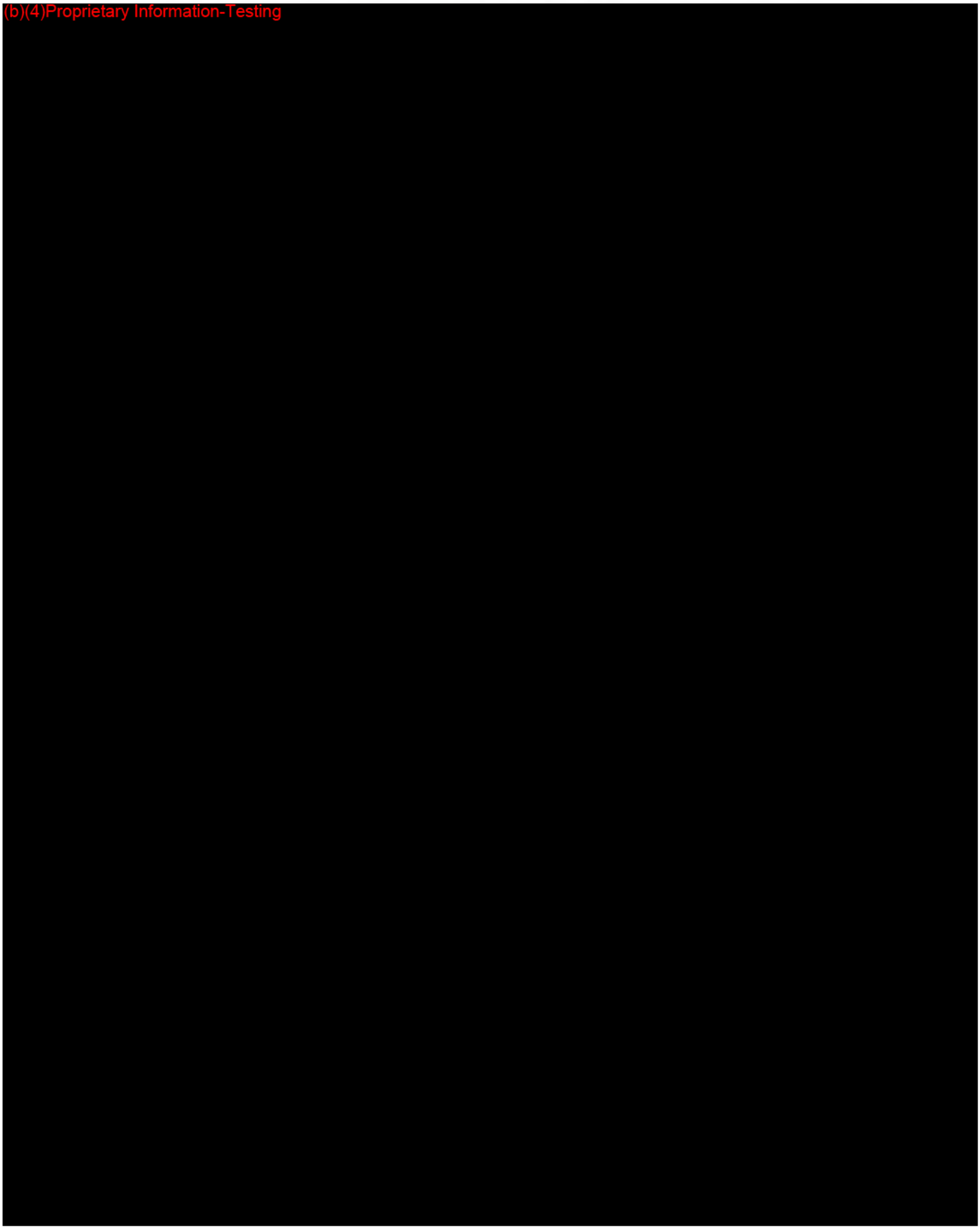


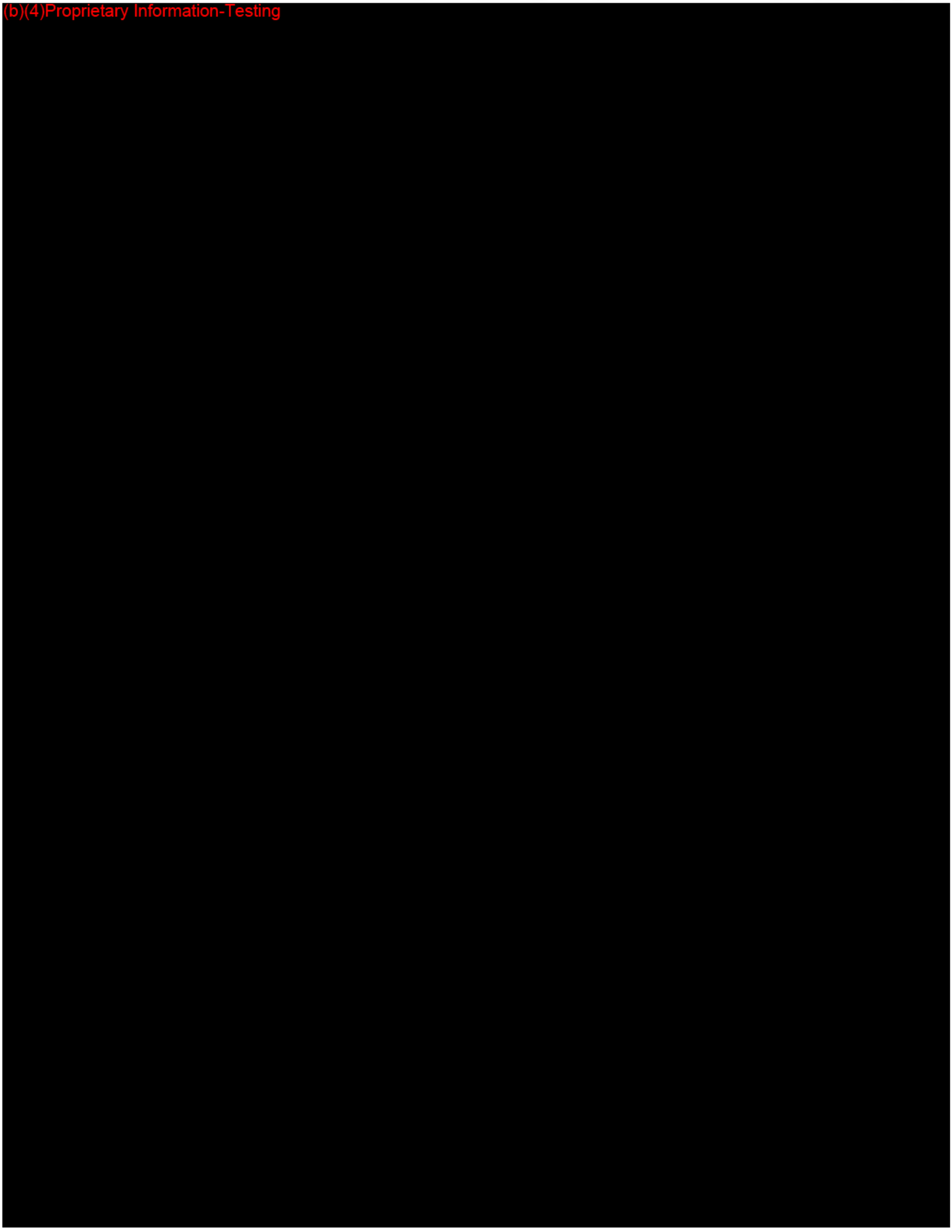
(b)(4)Proprietary Information-Testing



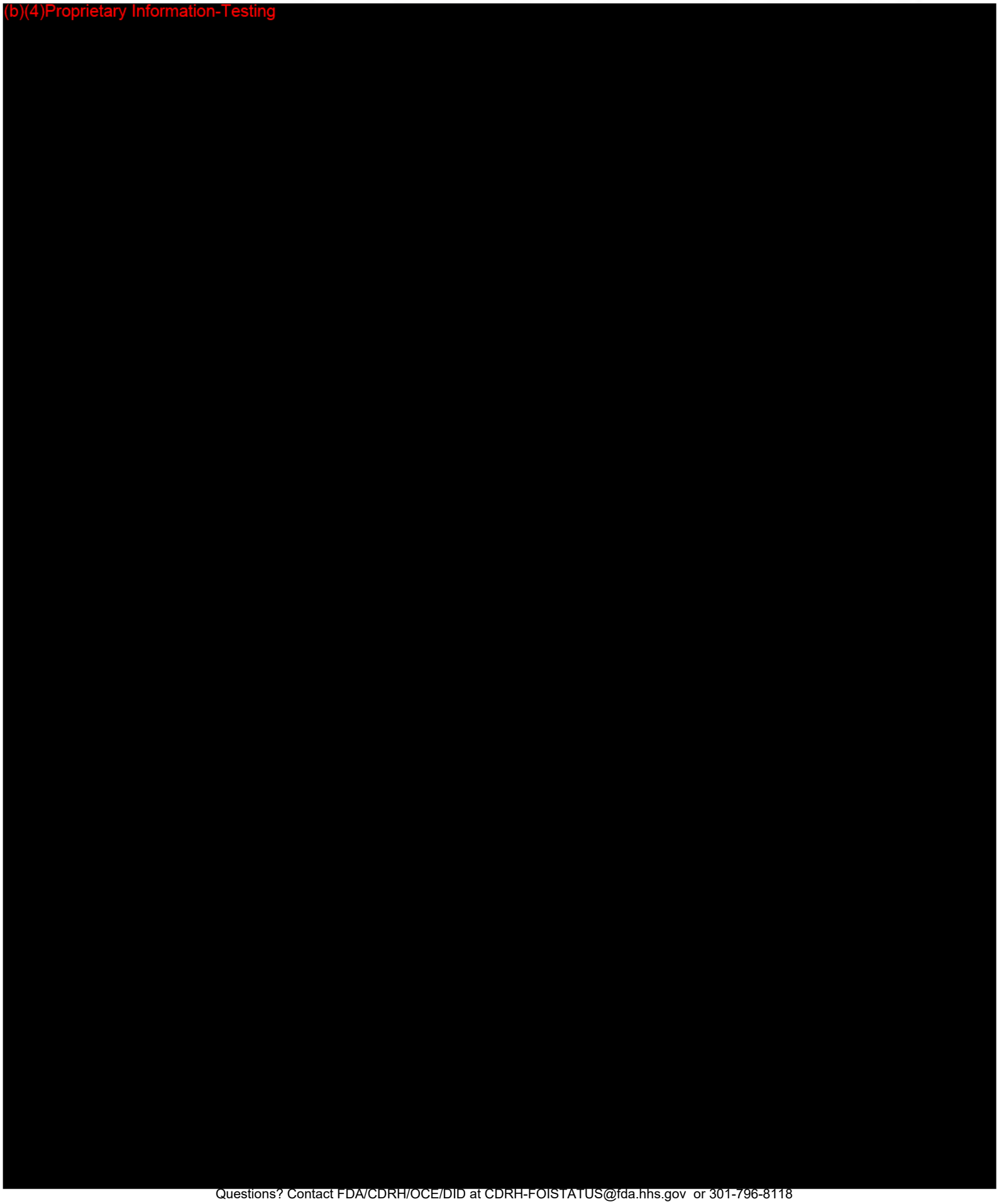
(b)(4)Proprietary Information-Testing



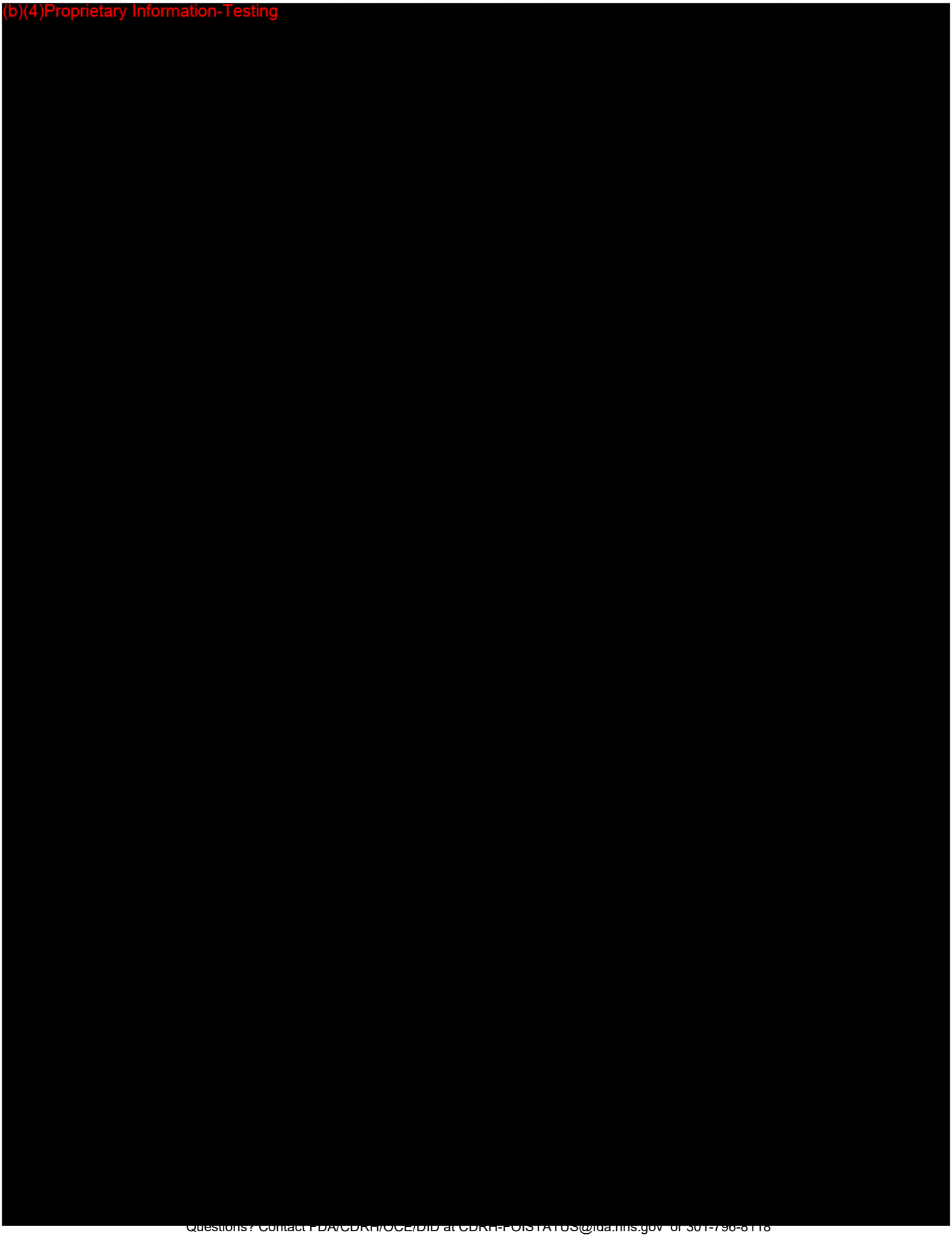




(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing

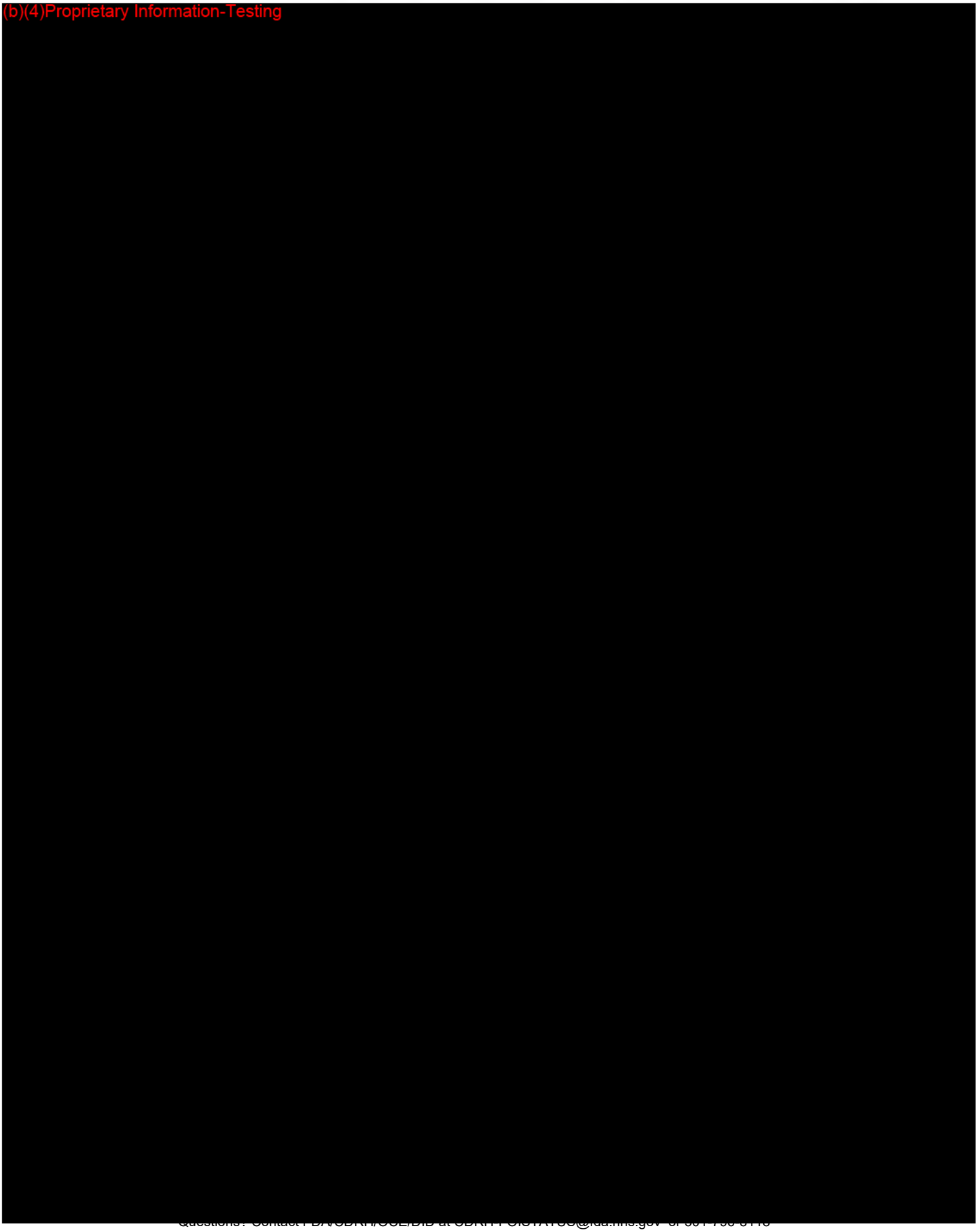
(b)(4)Proprietary Information-Testing

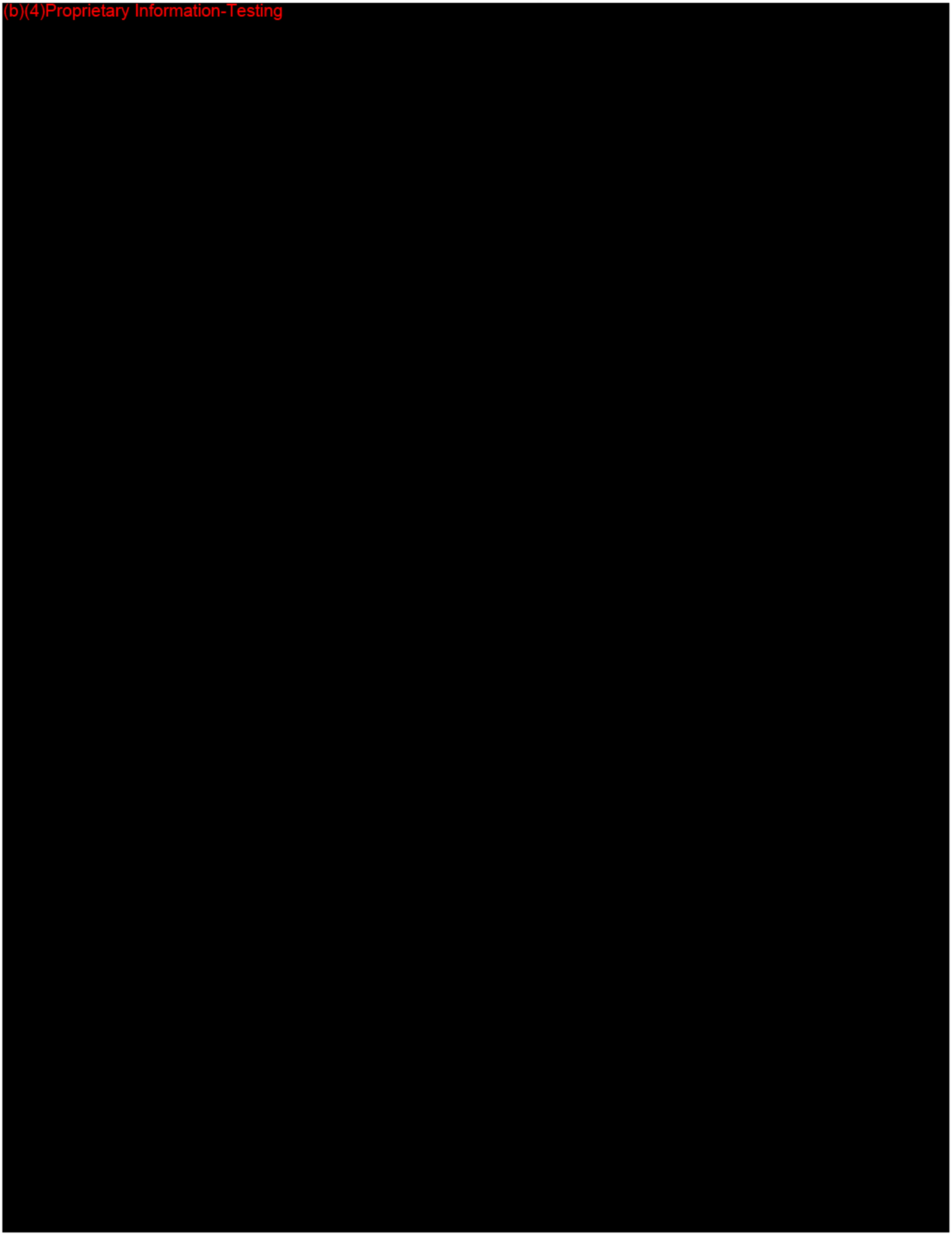
[redacted]

(b)(4)Proprietary Information-Testing

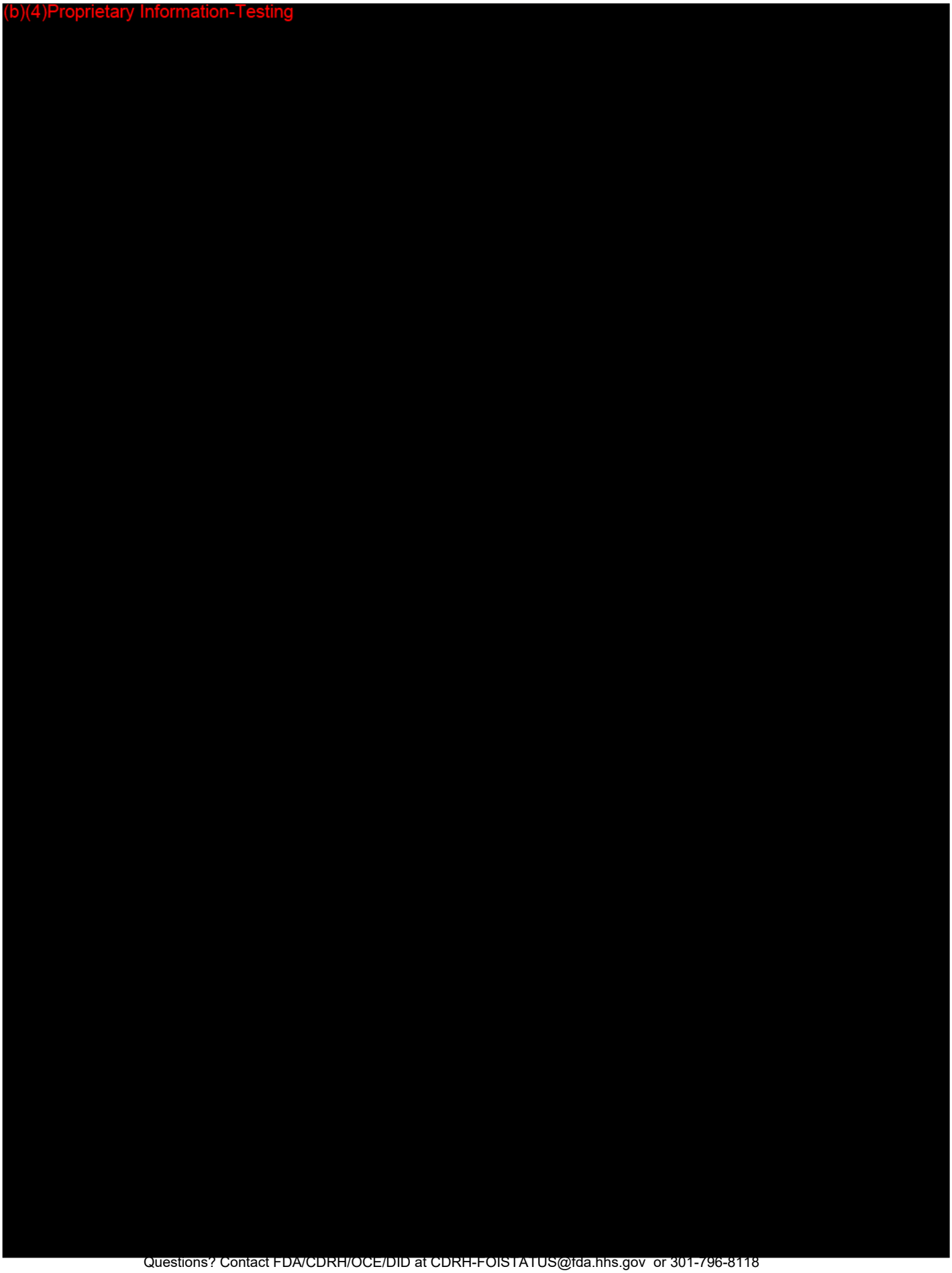
[redacted]

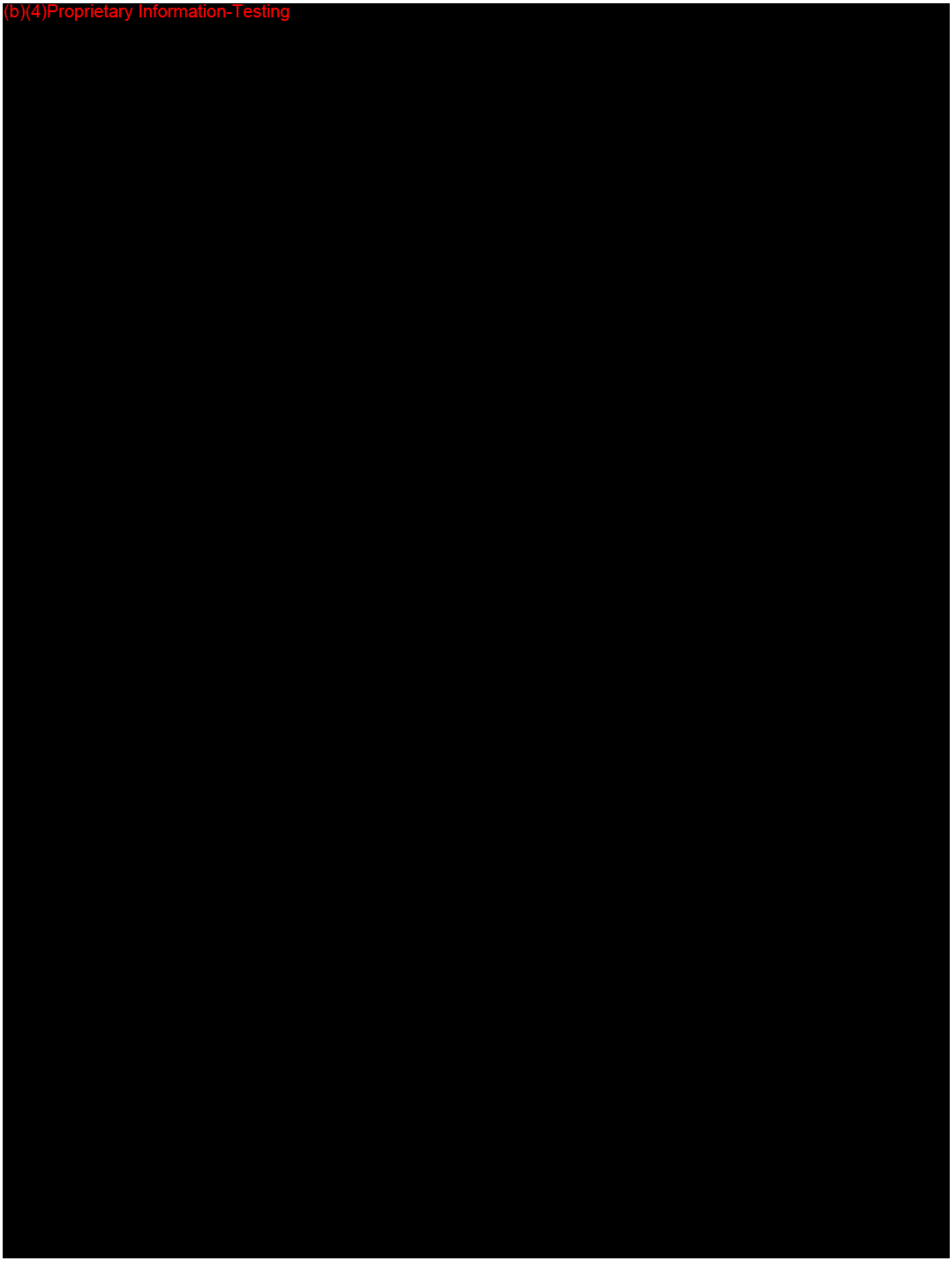
(b)(4)Proprietary Information-Testing



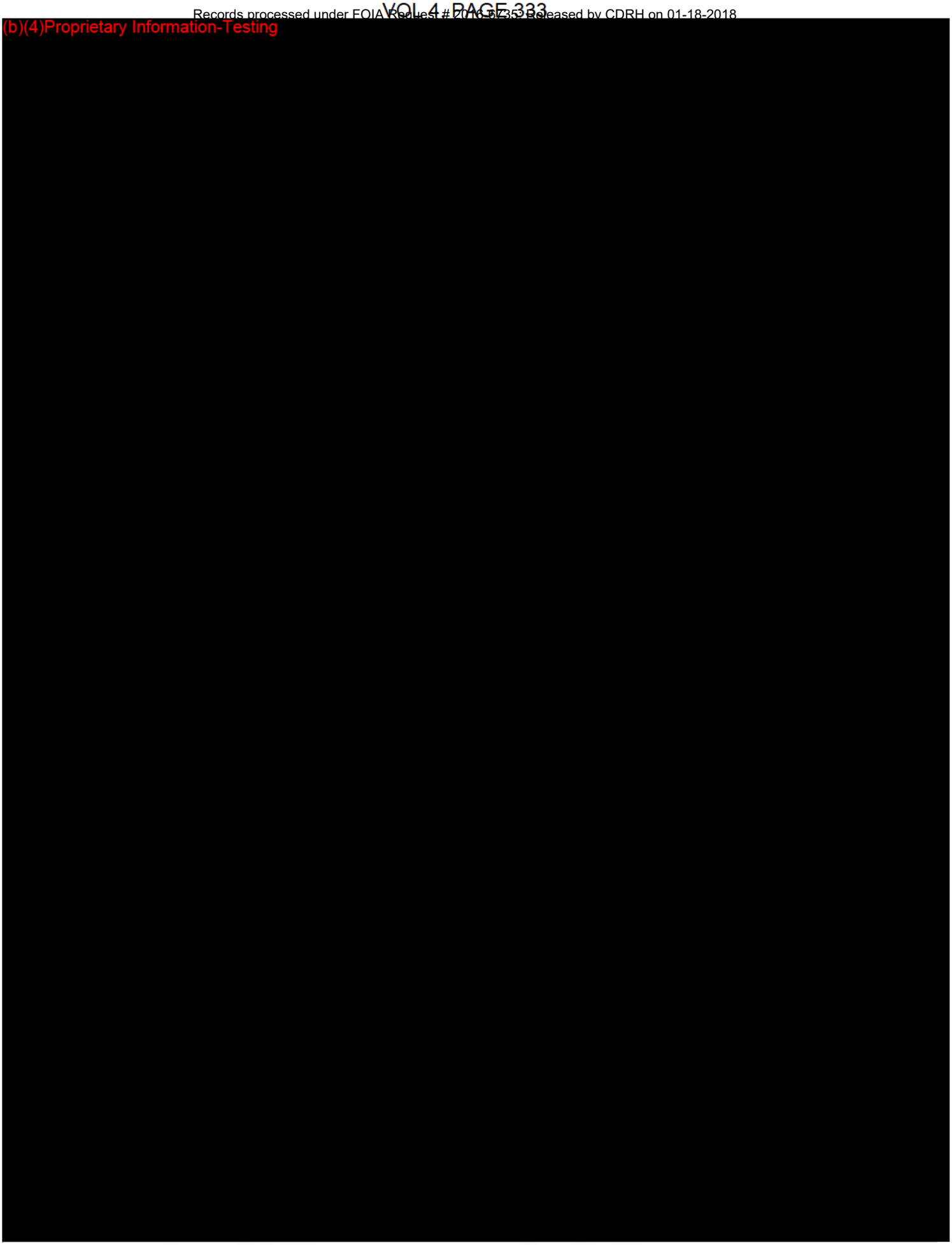


(b)(4)Proprietary Information-Testing

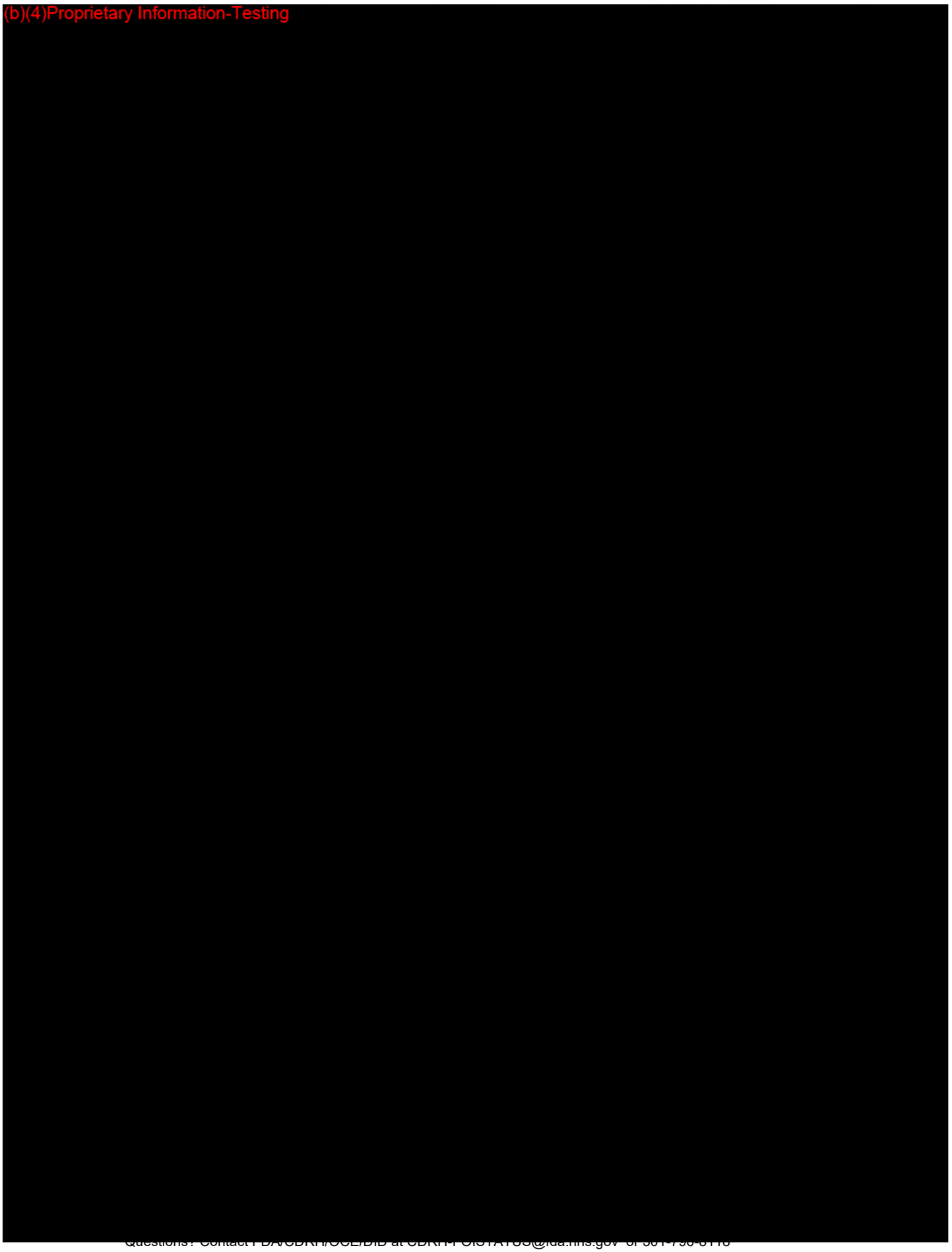


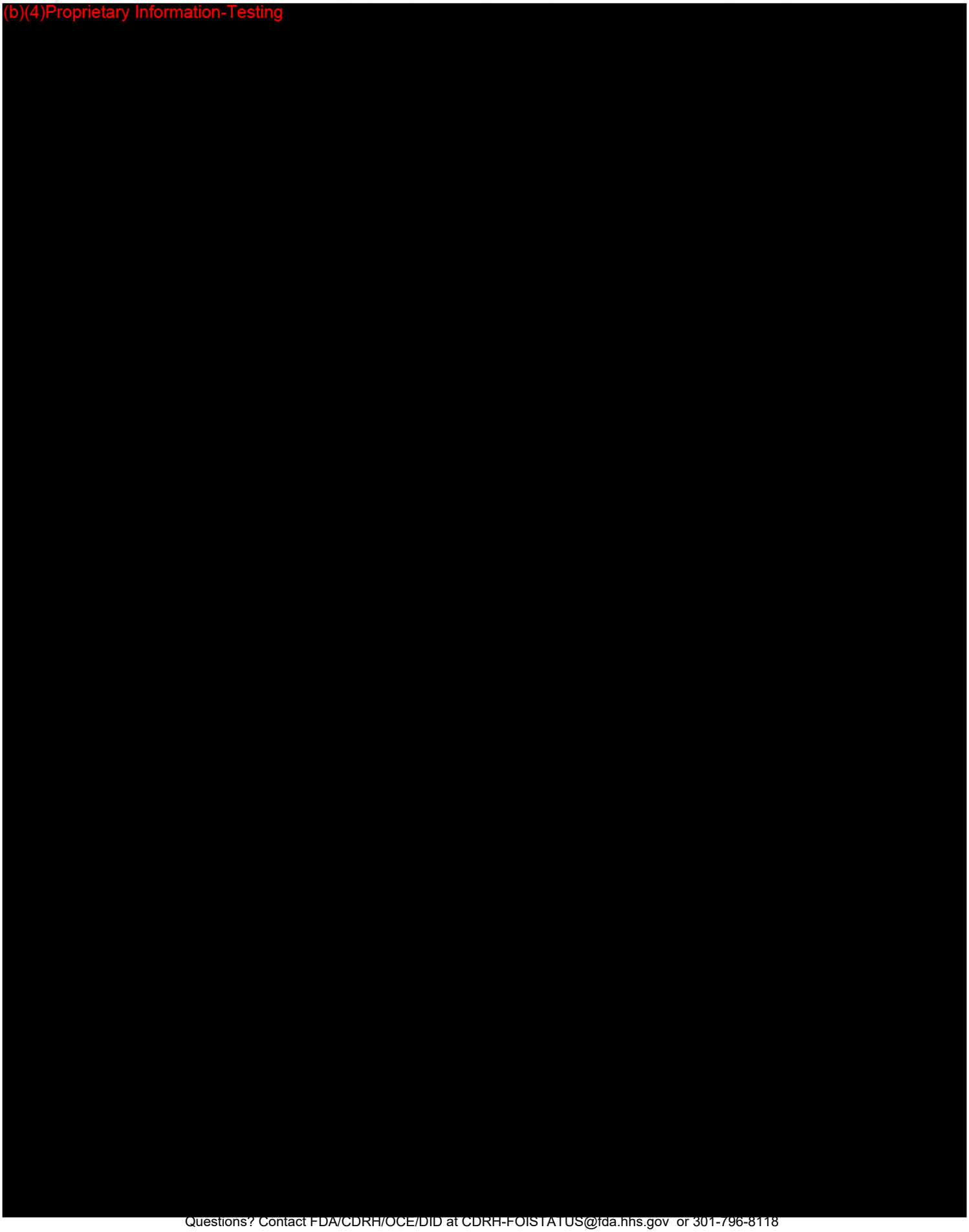


(b)(4)Proprietary Information-Testing

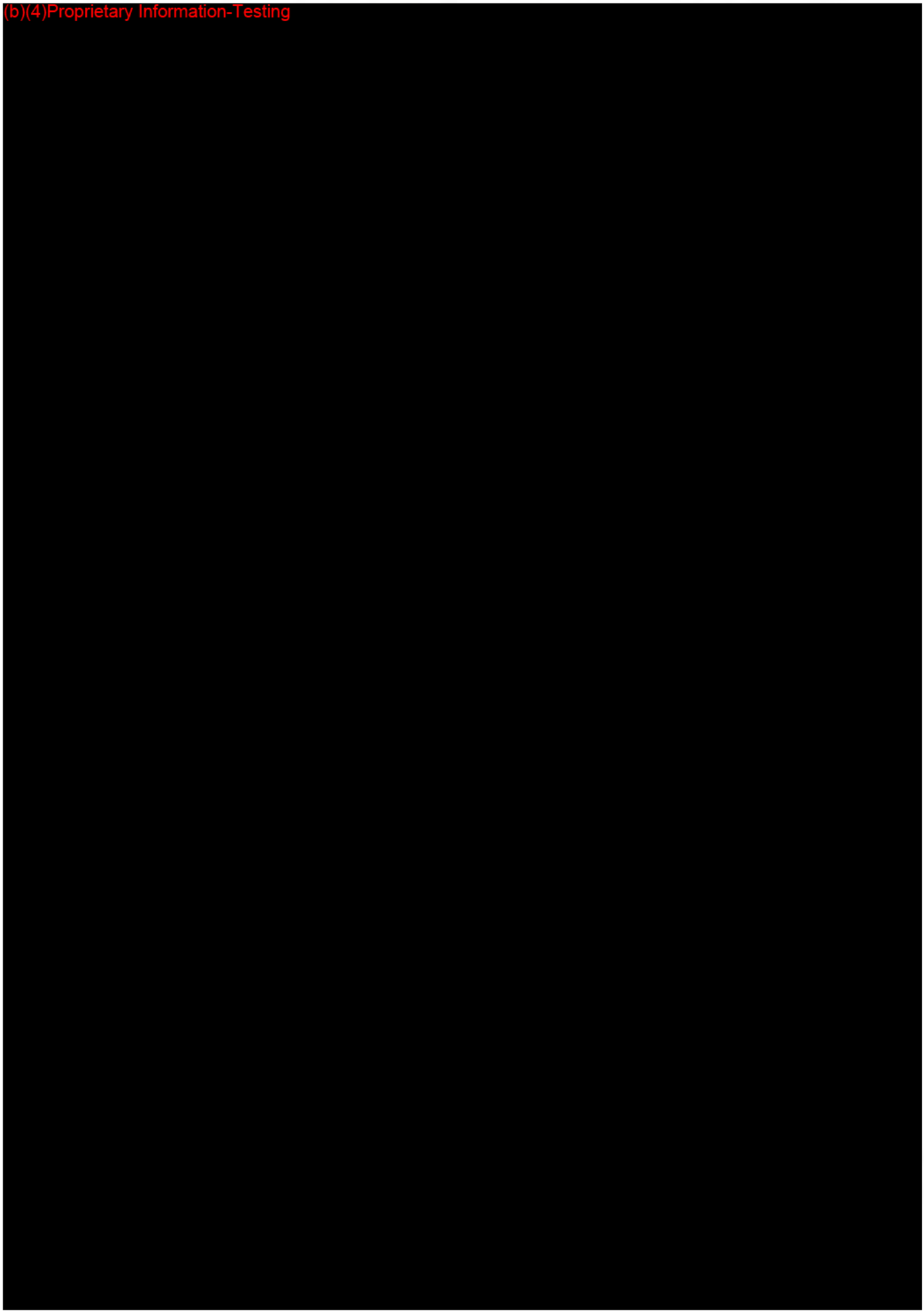


(b)(4)Proprietary Information-Testing





(b)(4)Proprietary Information-Testing



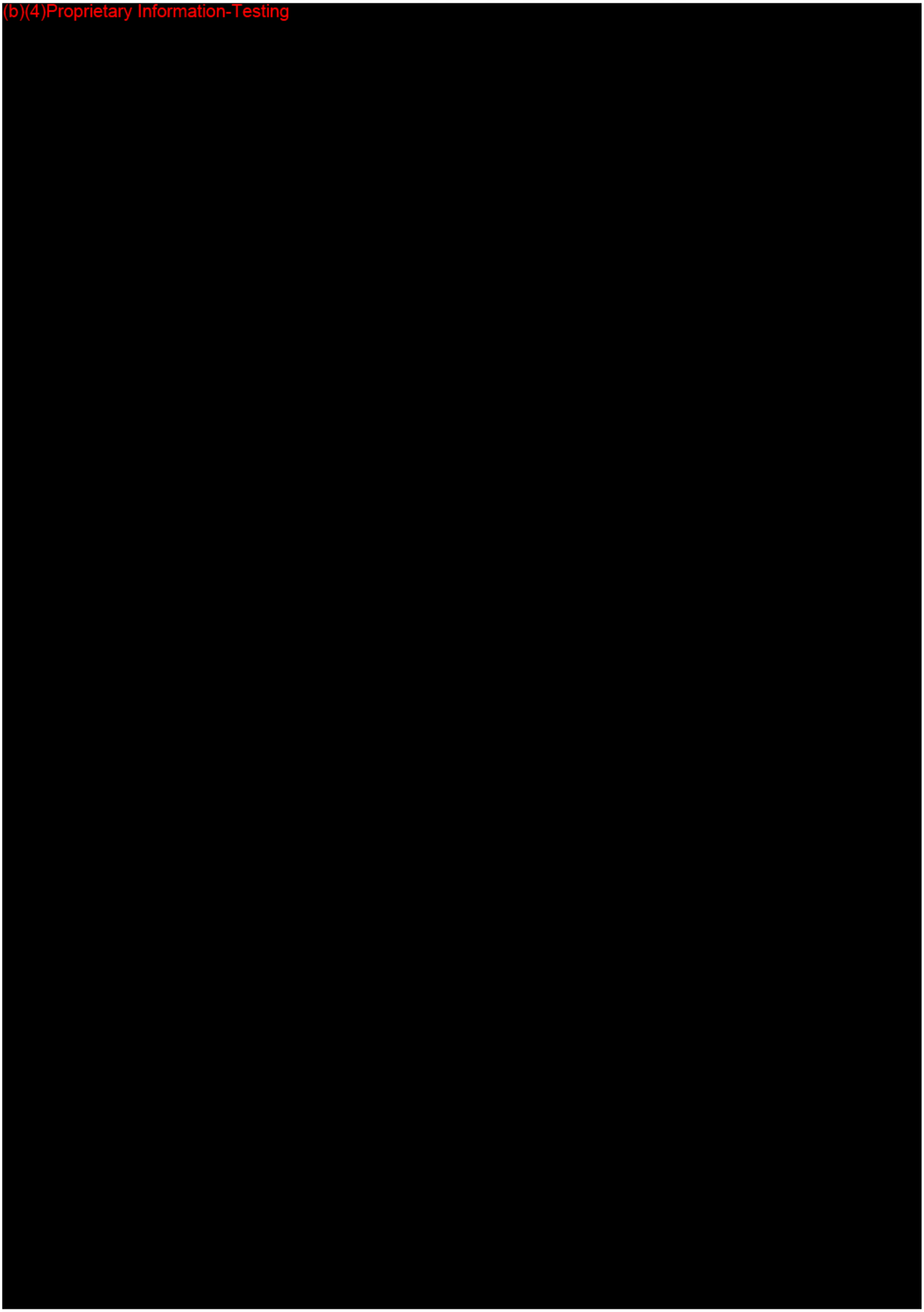
(b)(4)Proprietary Information-Testing

[redacted]

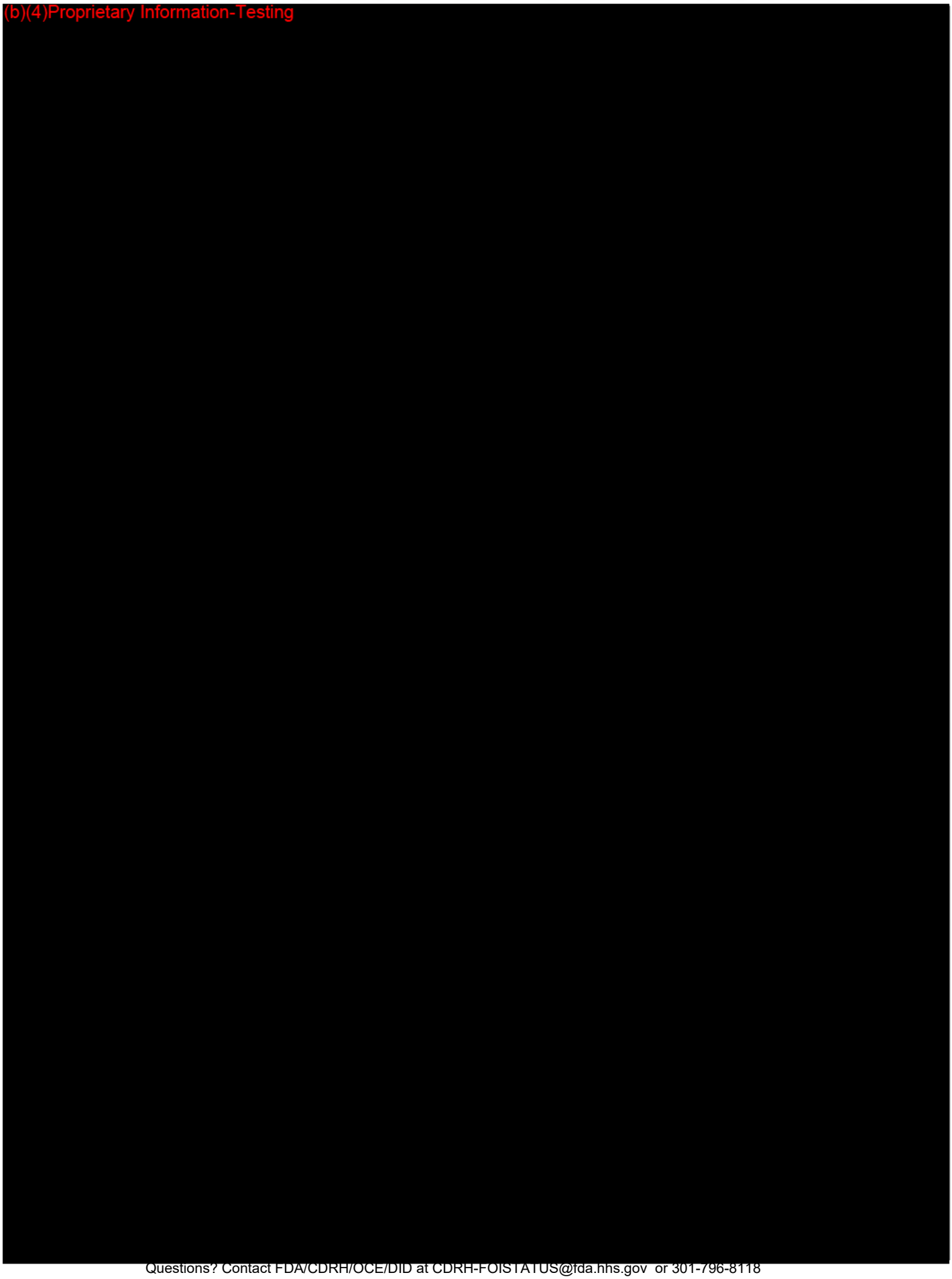
(b)(4)Proprietary Information-Testing

[redacted]

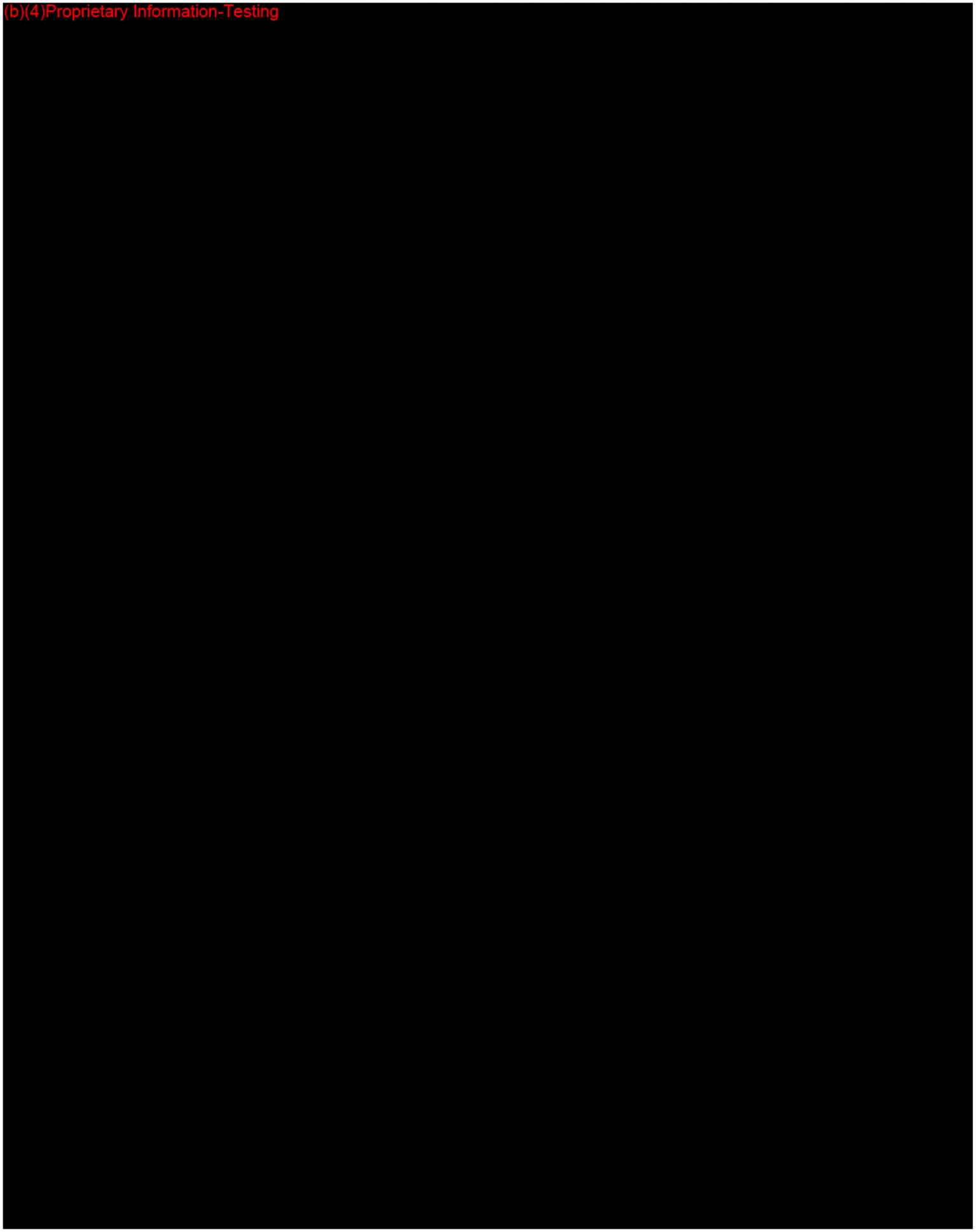
(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing

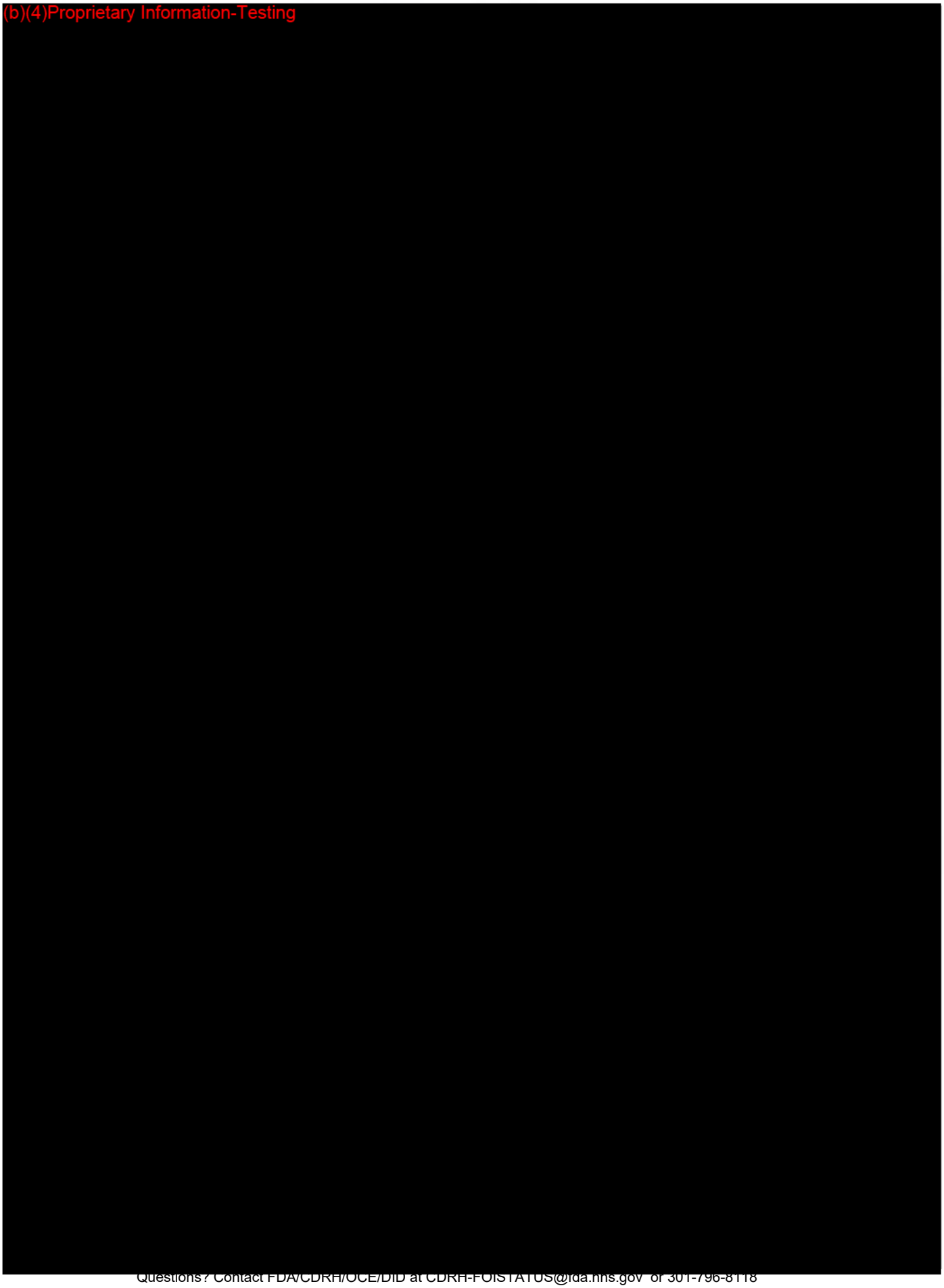


(b)(4)Proprietary Information-Testing



(b)(4)Proprietary Information-Testing

[redacted]



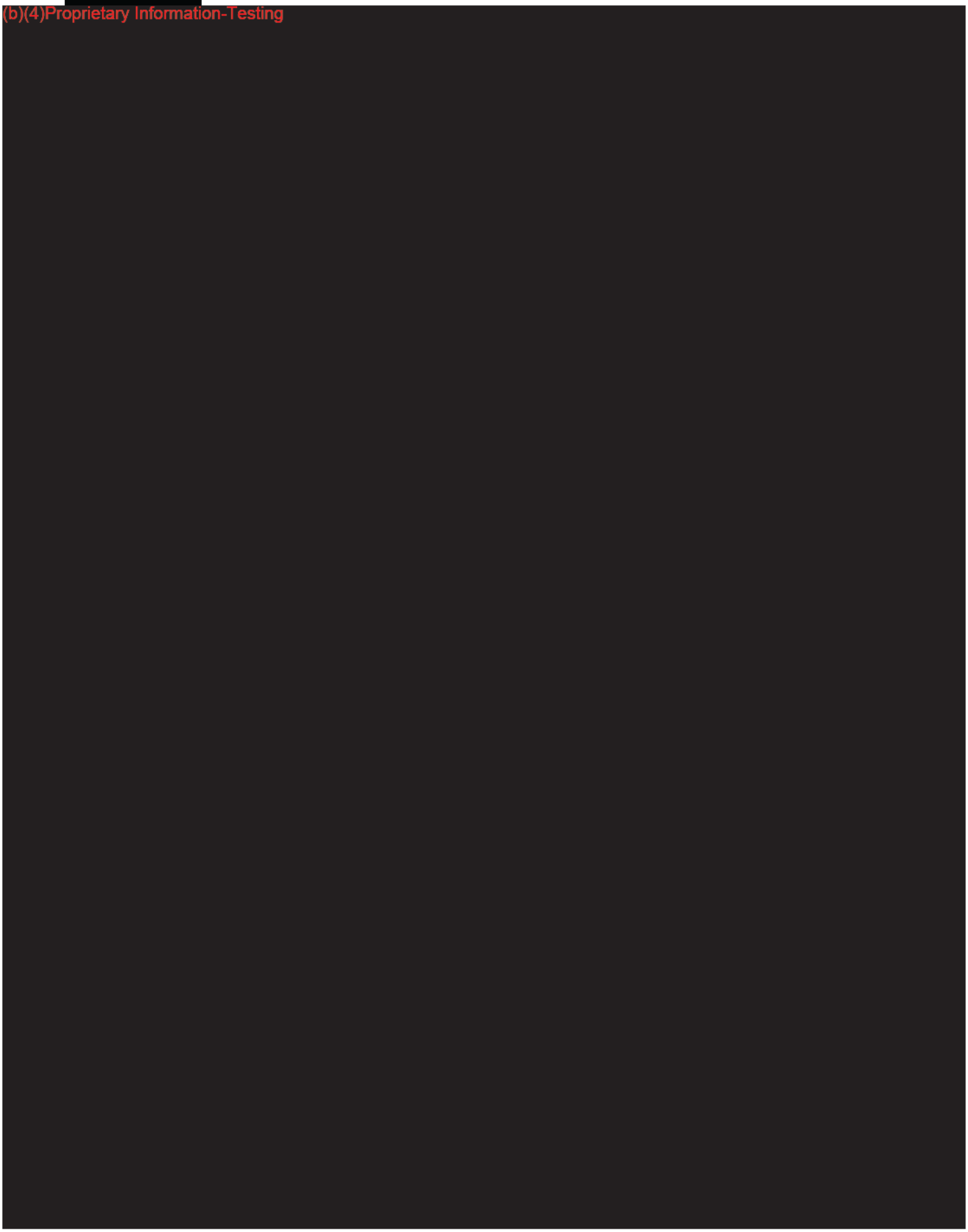
(b)(4)Proprietary Information-Testing

[redacted]

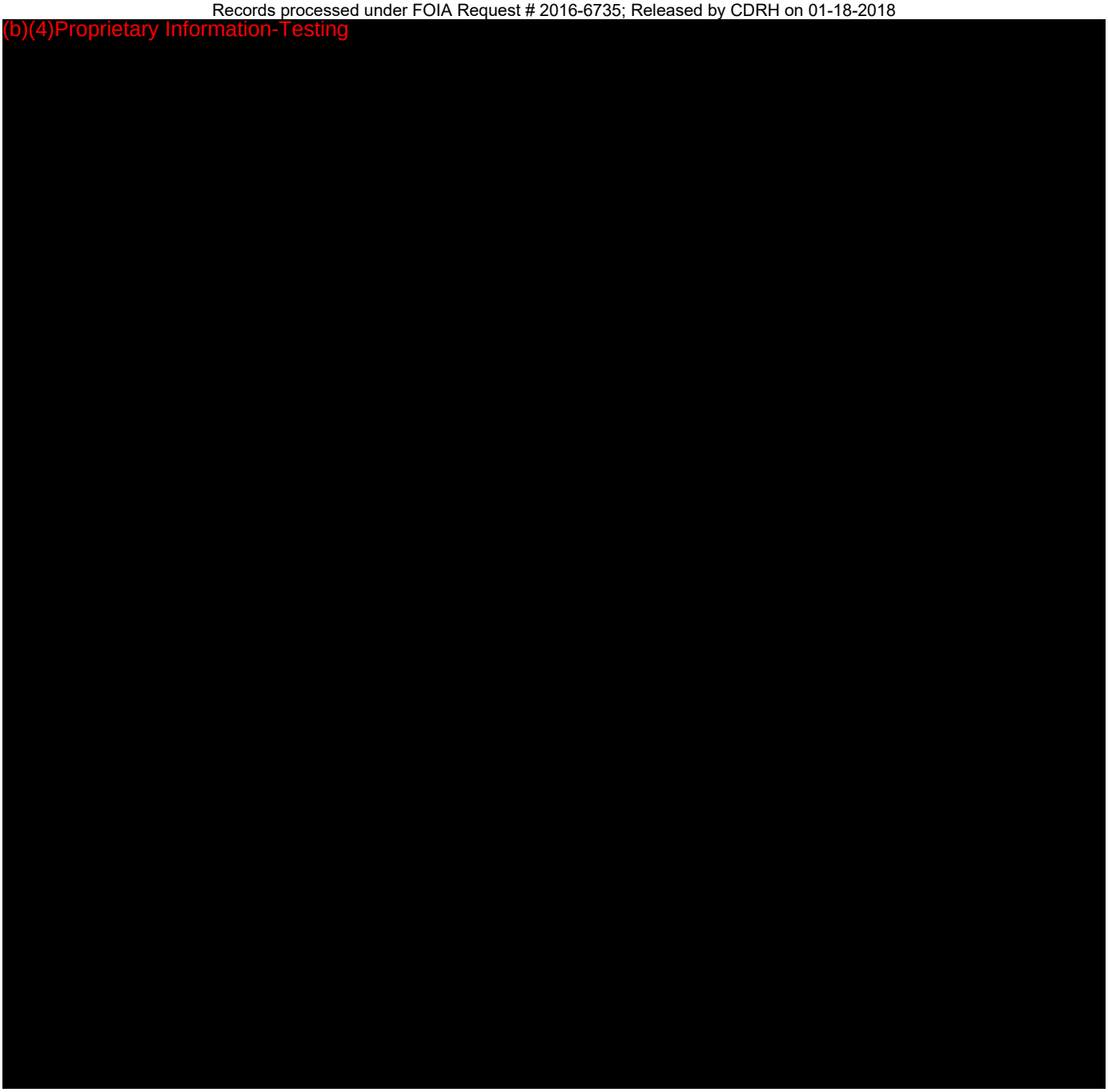
(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing



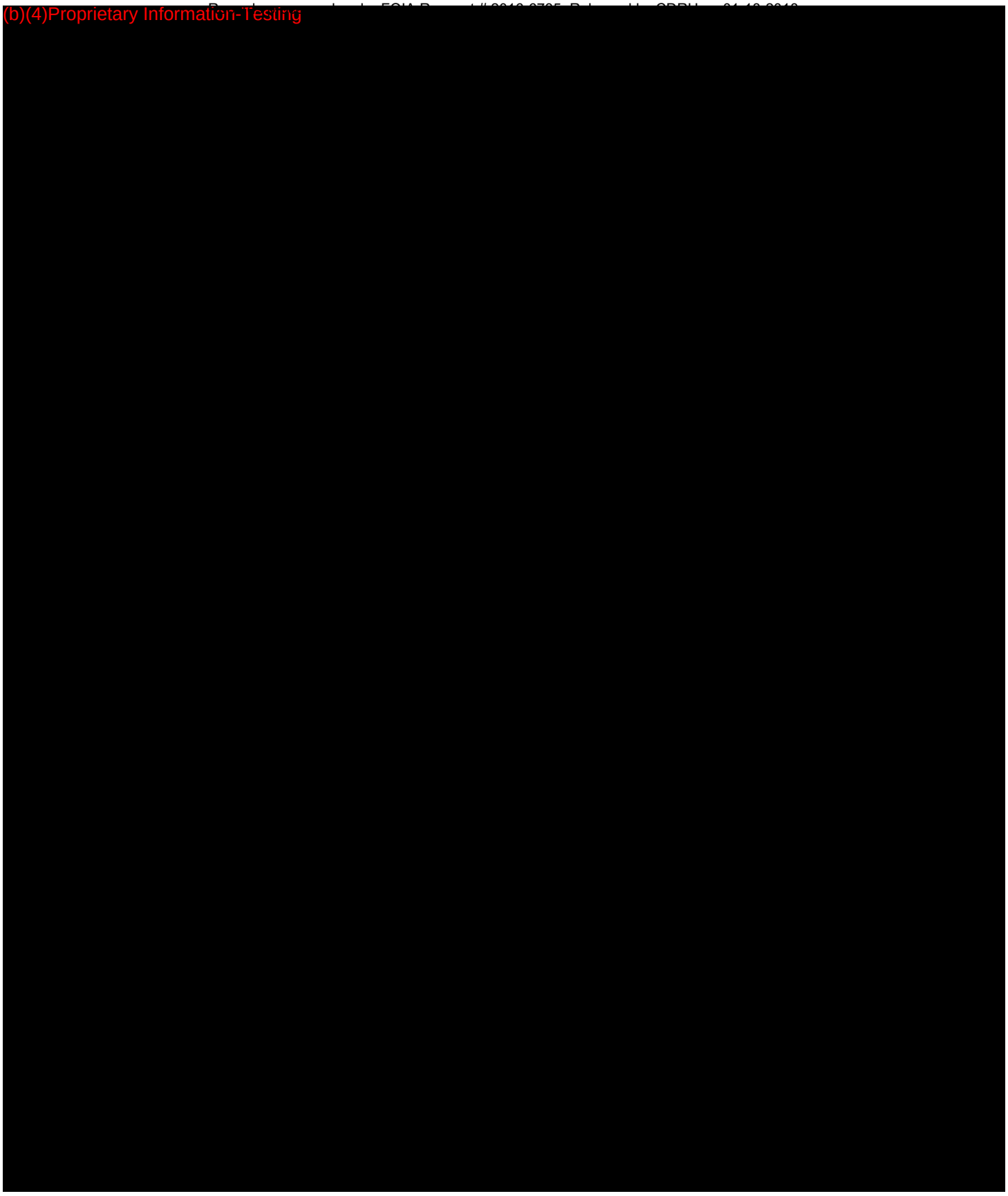
(b)(4)Proprietary Information-Testing



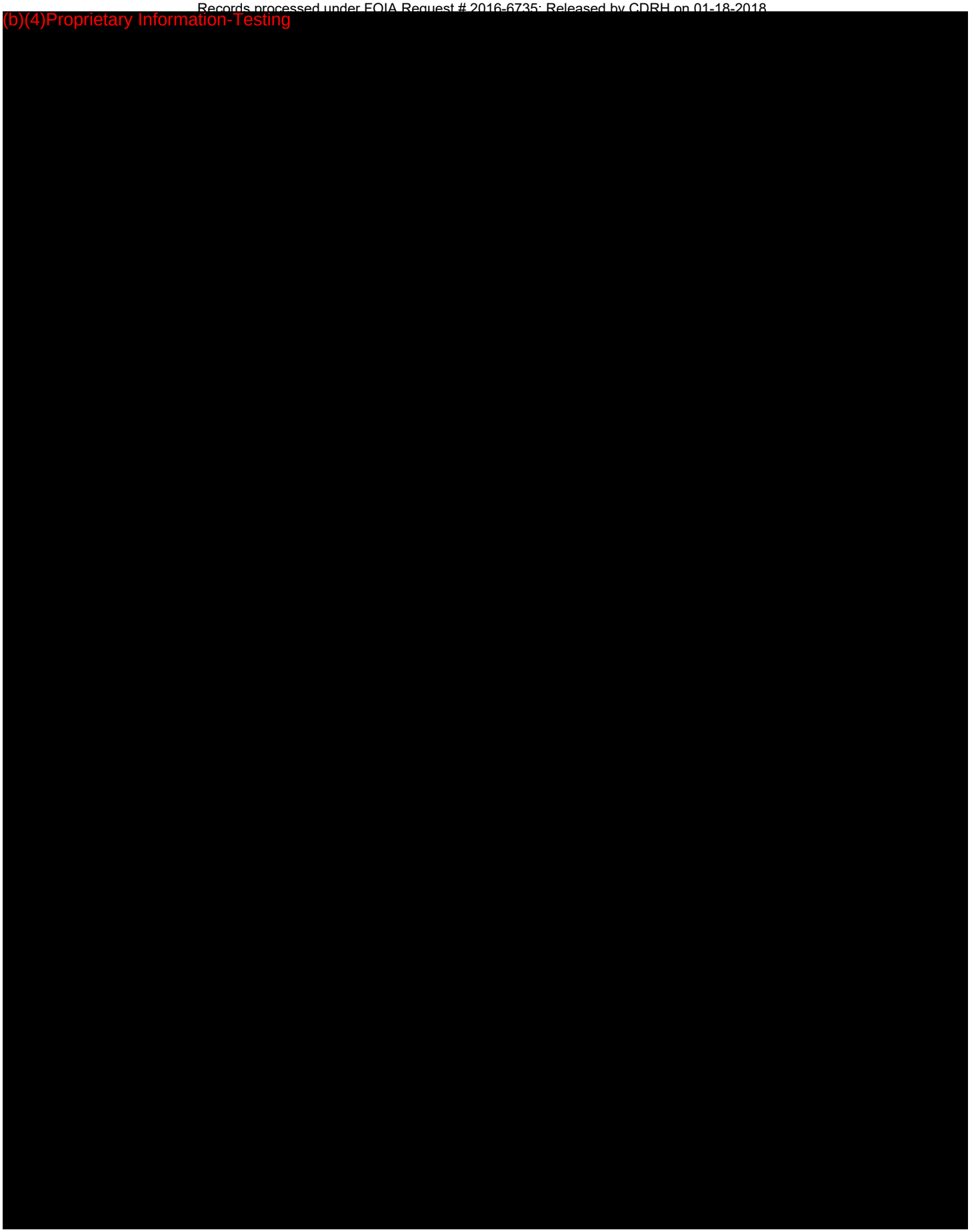
(b)(4)Proprietary Information-Testing

[redacted]

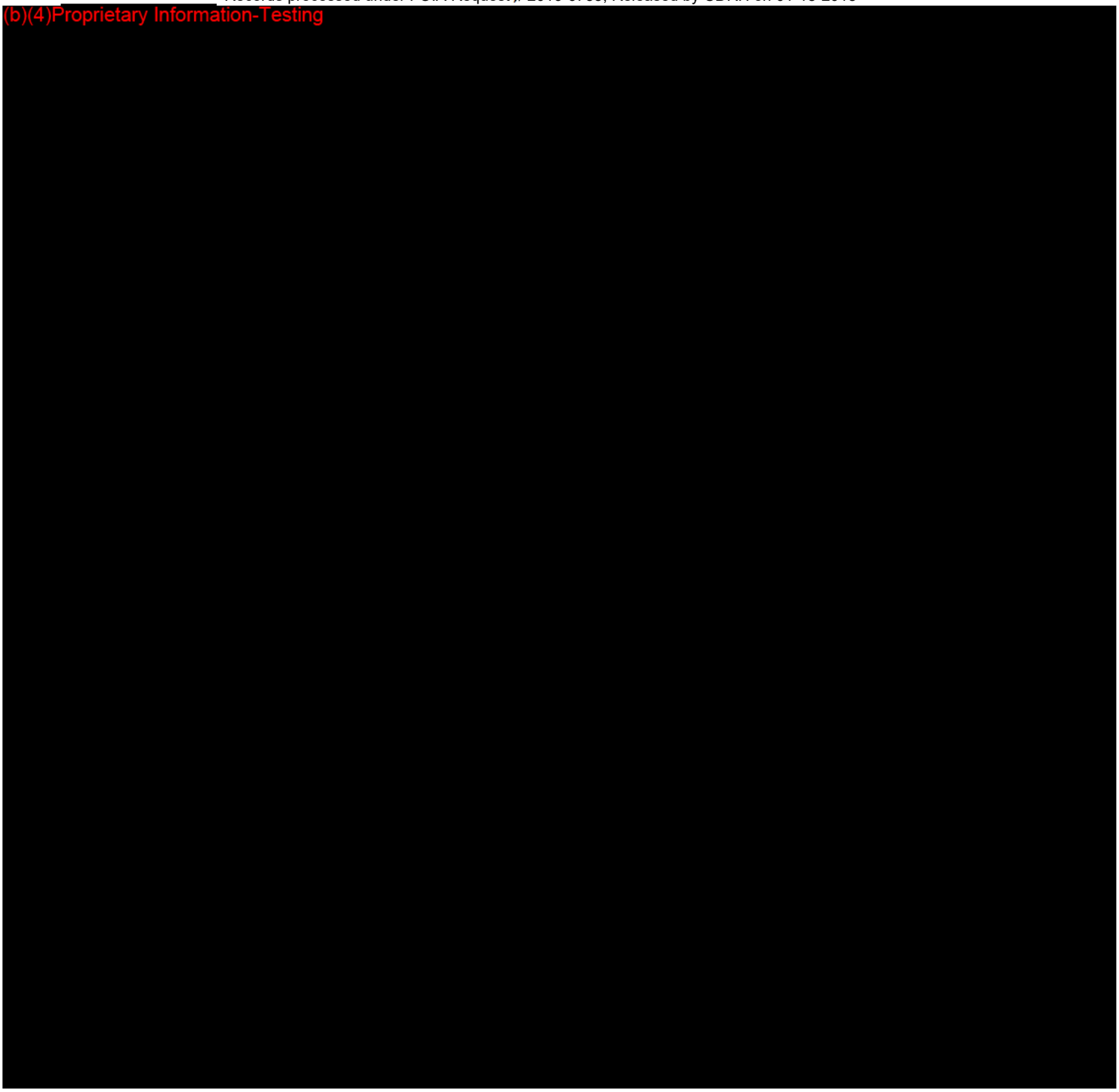
(b)(4)Proprietary Information-Testing



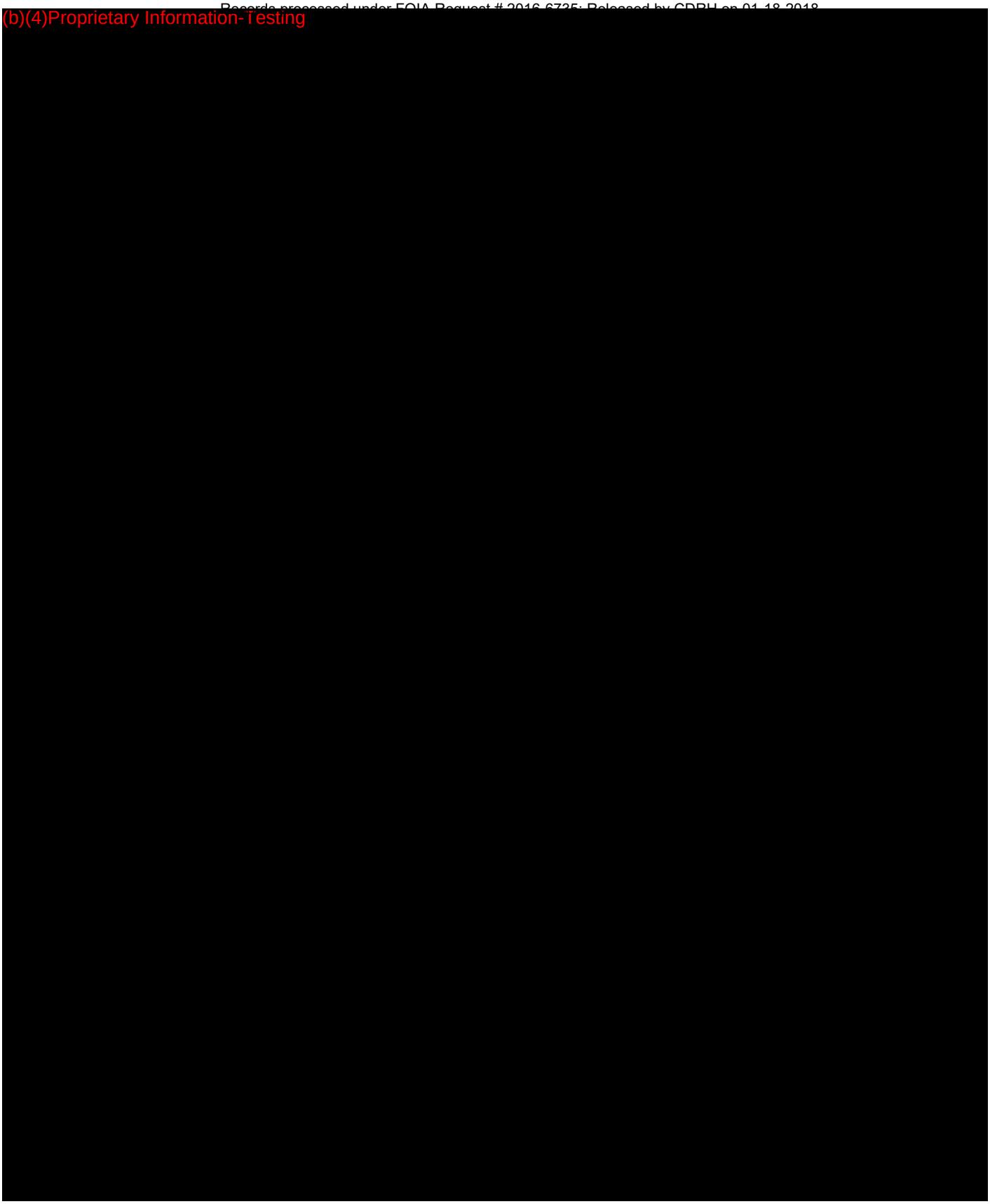
(b)(4)Proprietary Information-Testing



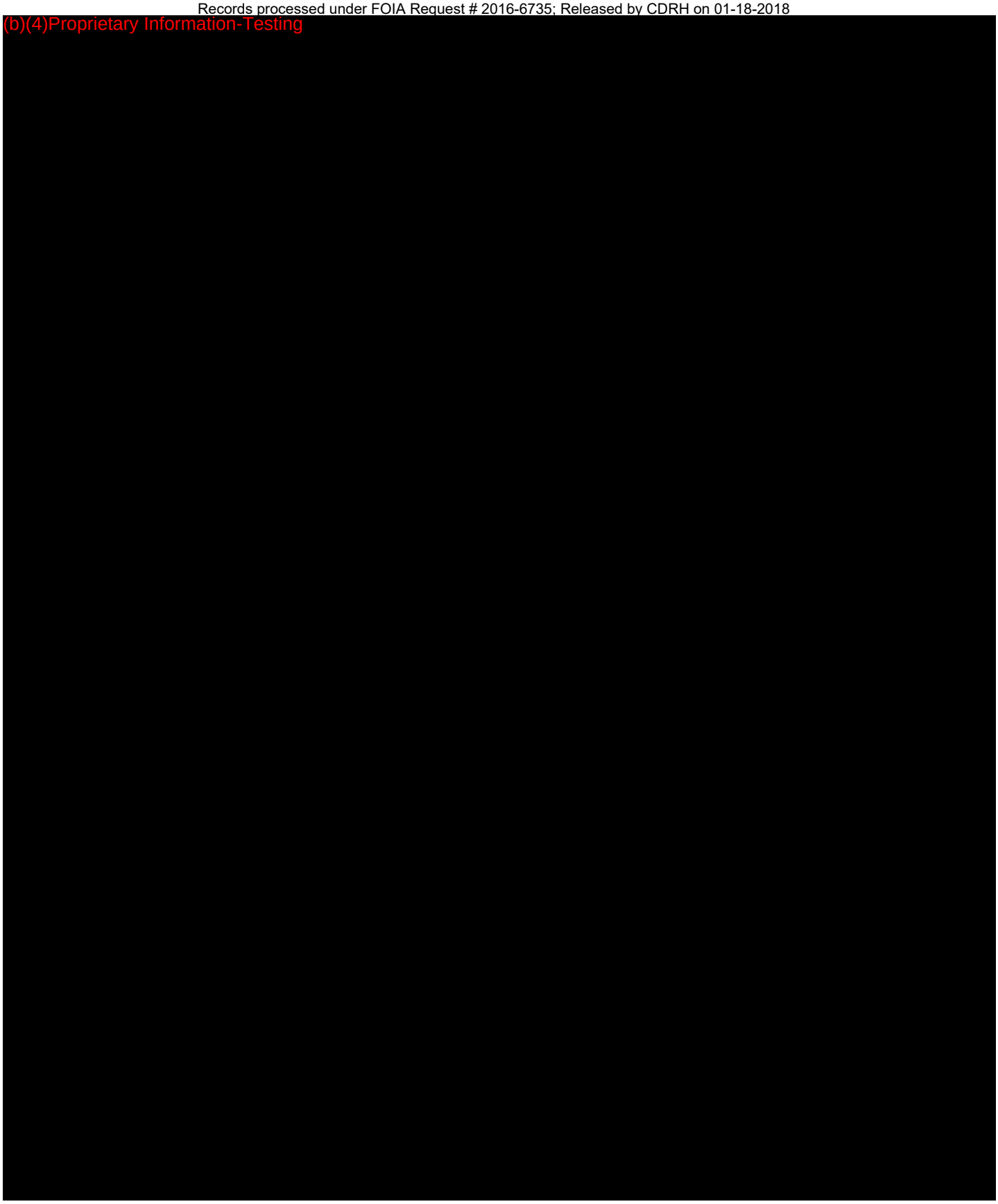
(b)(4)Proprietary Information-Testing



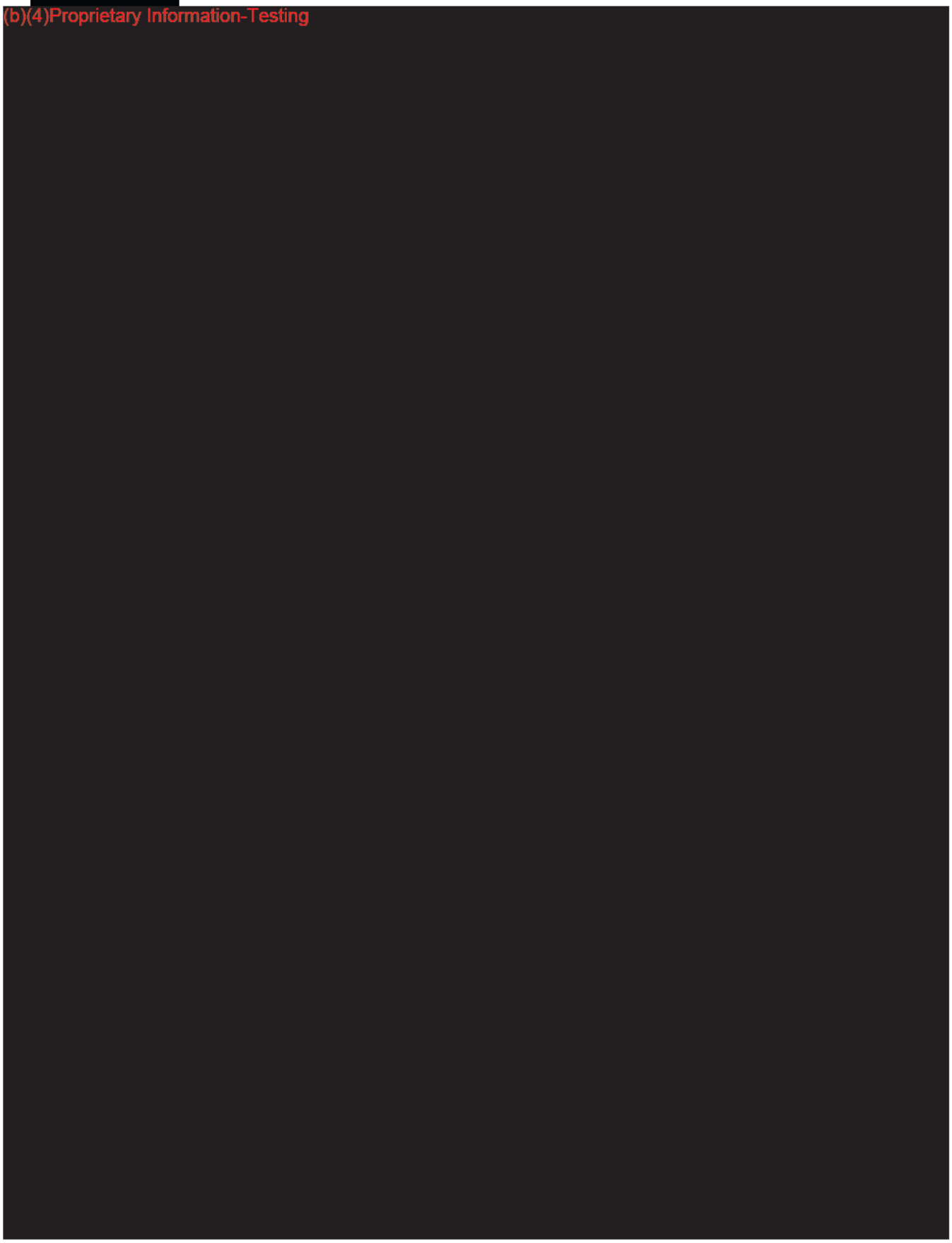
(b)(4)Proprietary Information- Testing



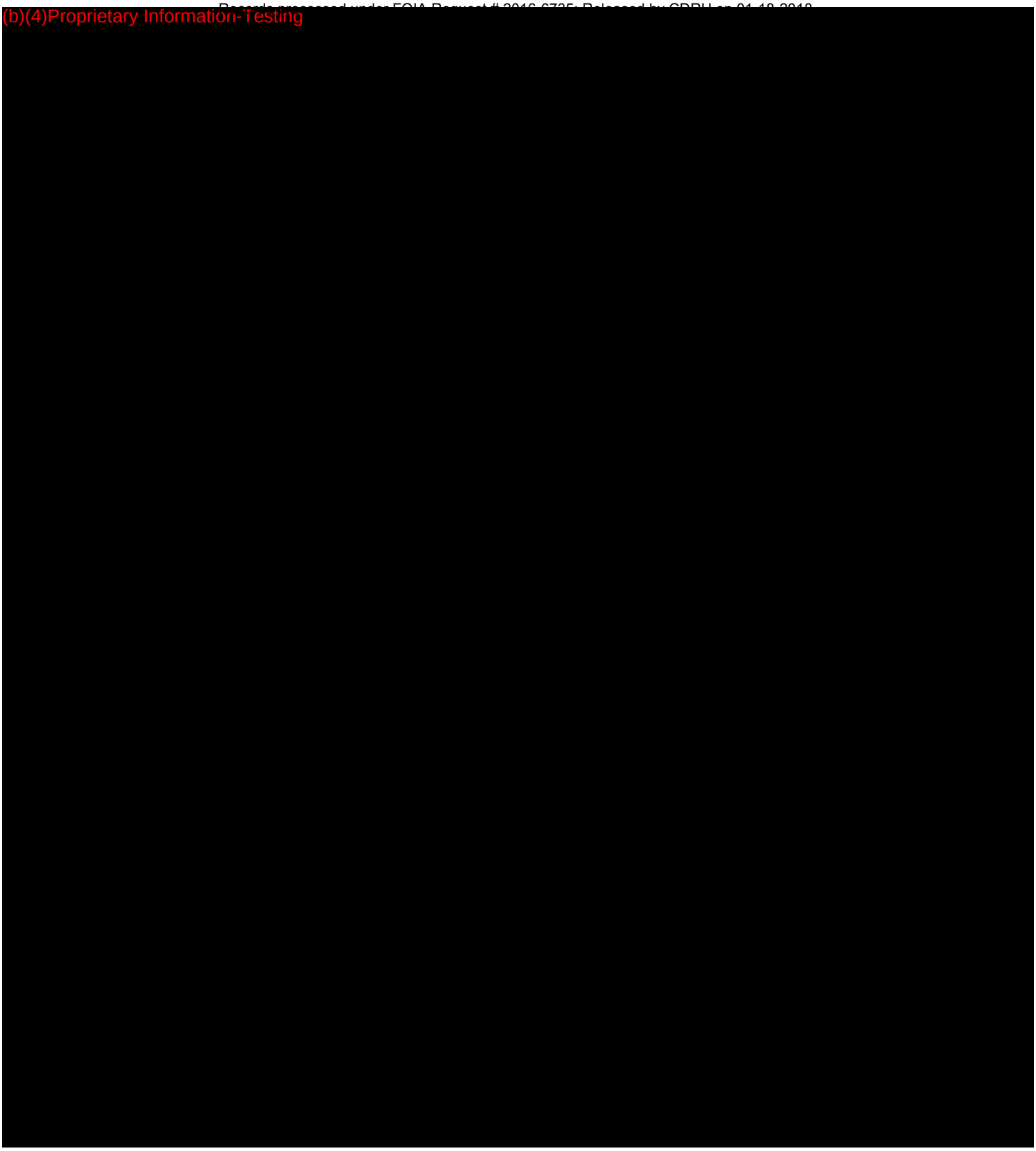
(b)(4)Proprietary Information-Testing



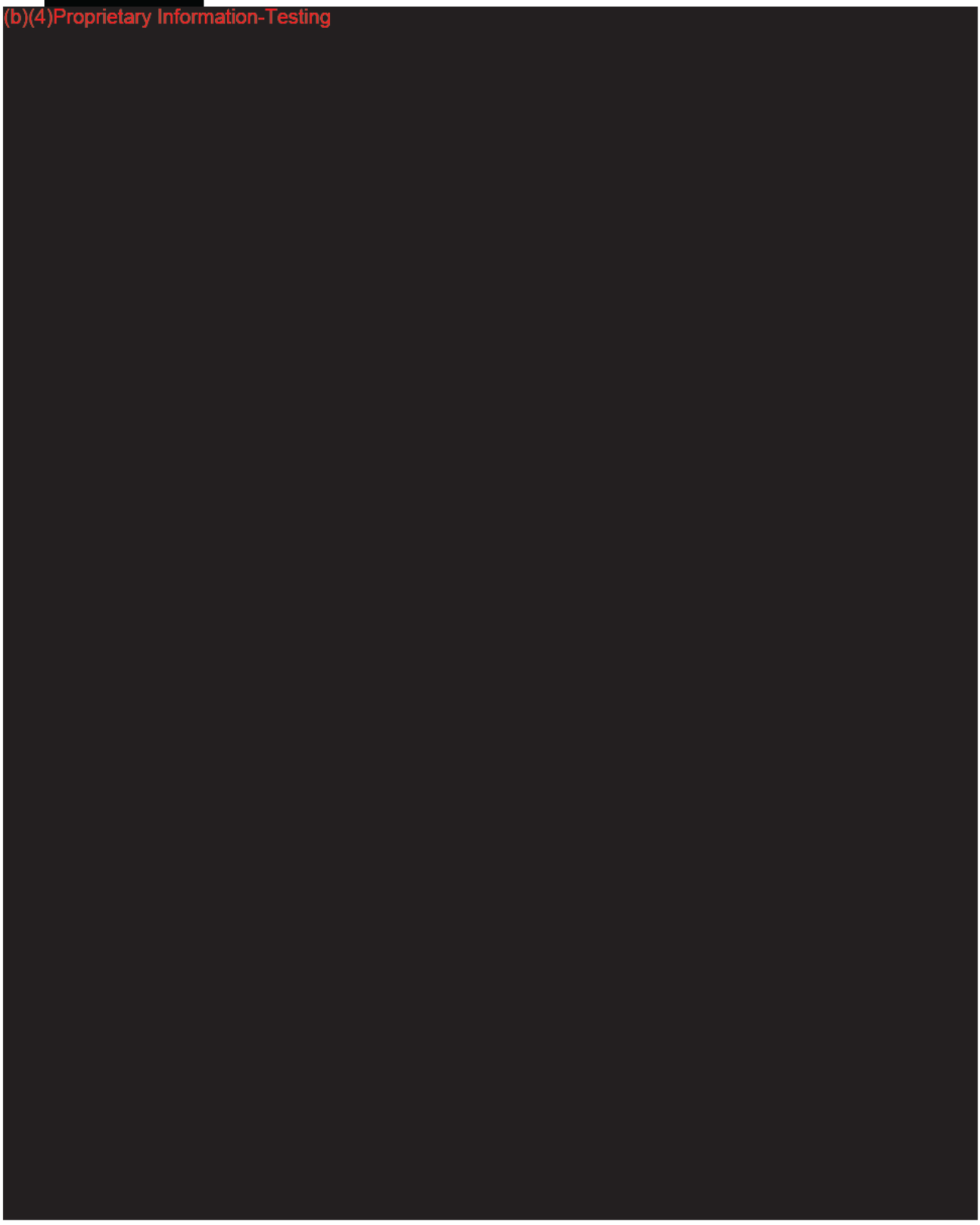
(b)(4)Proprietary Information-Testing



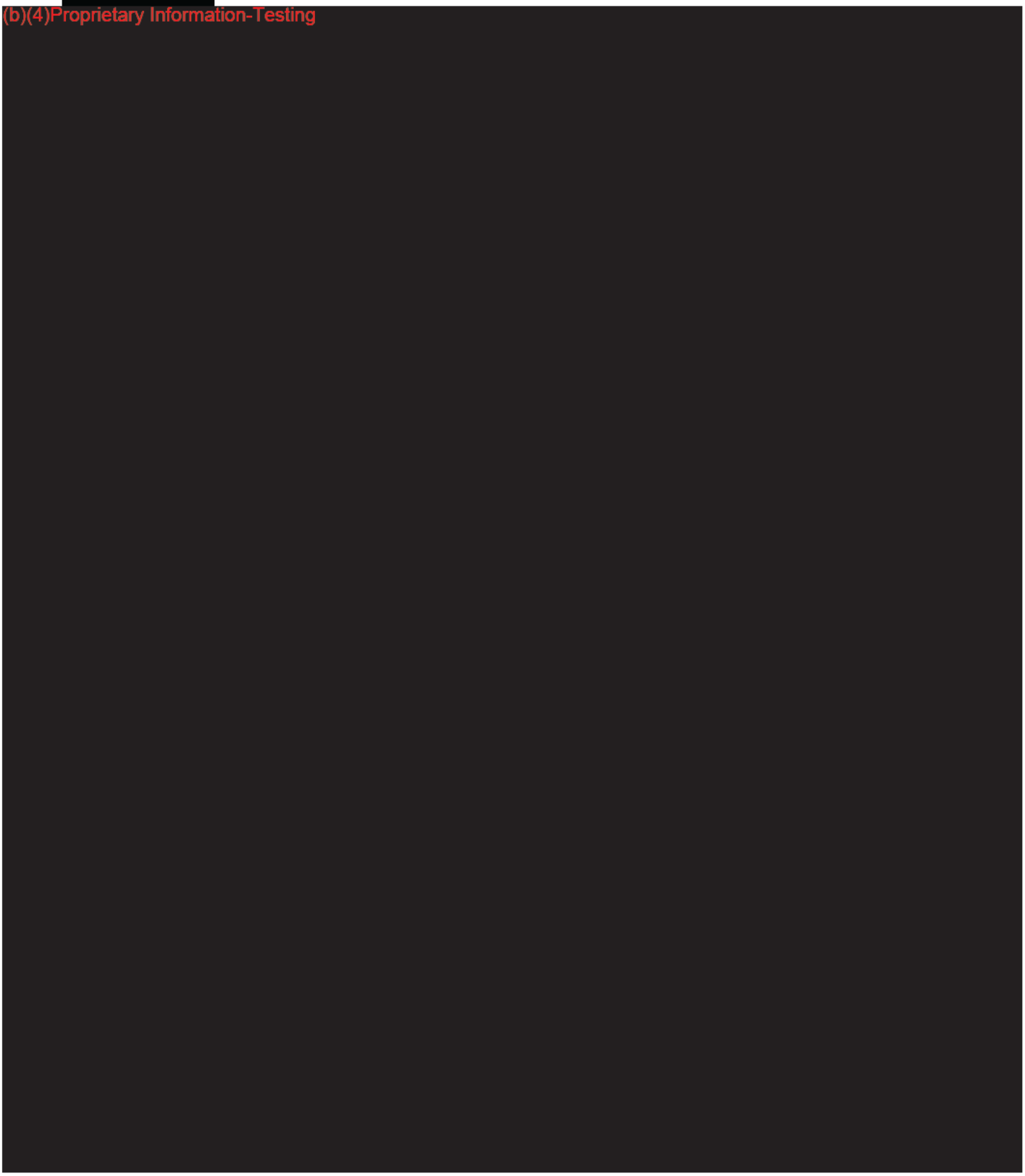
(b)(4)Proprietary Information- Testing



(b)(4)Proprietary Information-Testing

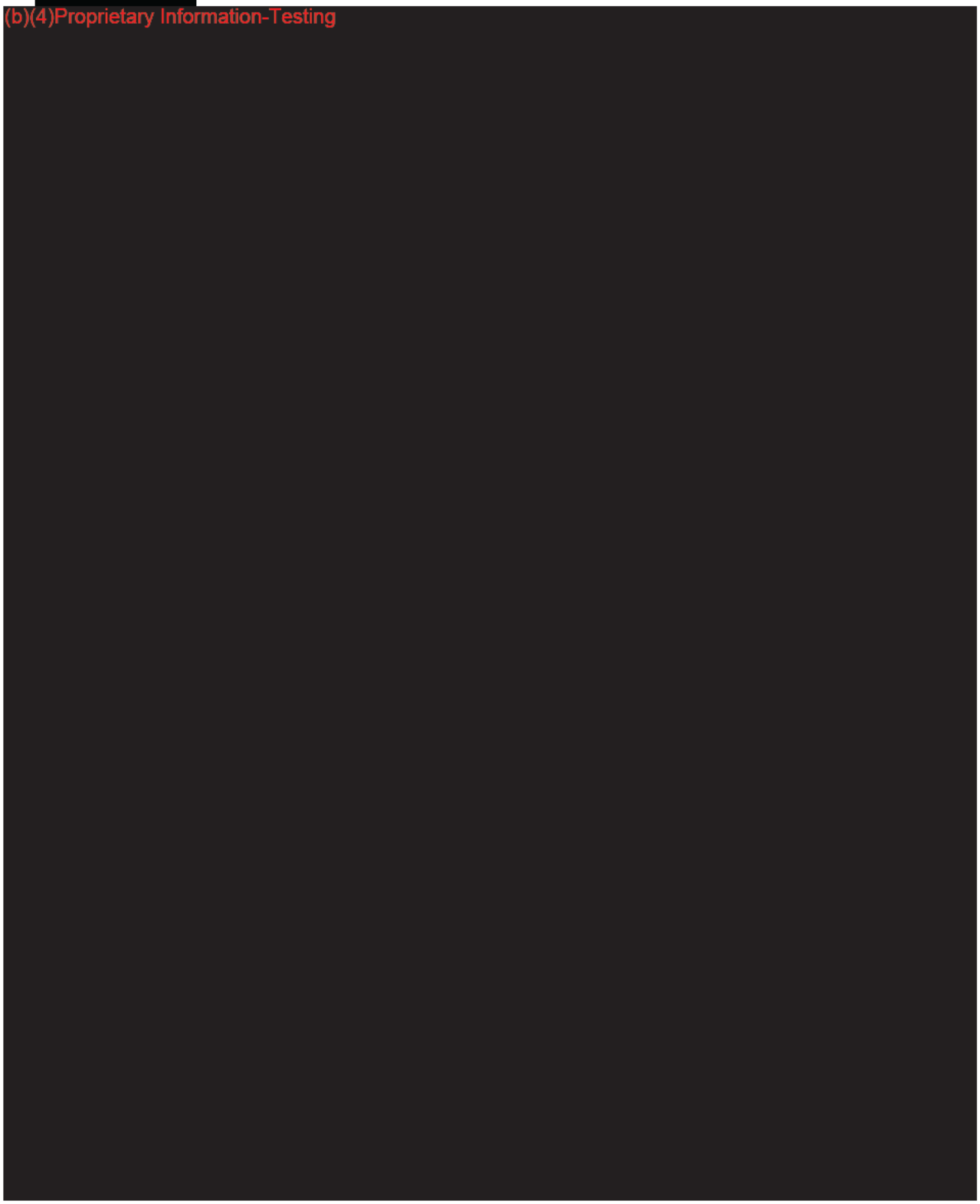


(b)(4)Proprietary Information-Testing

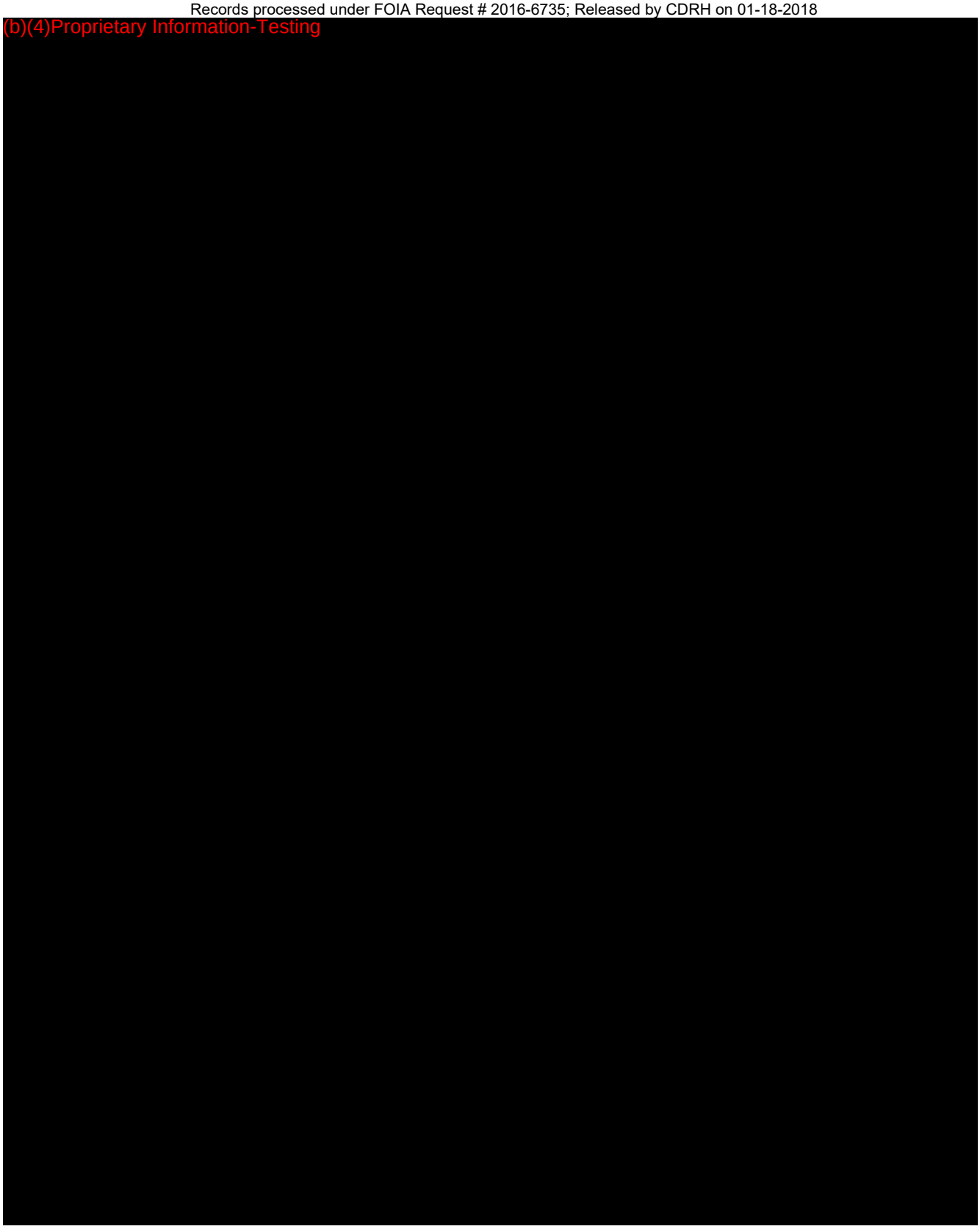


[redacted]

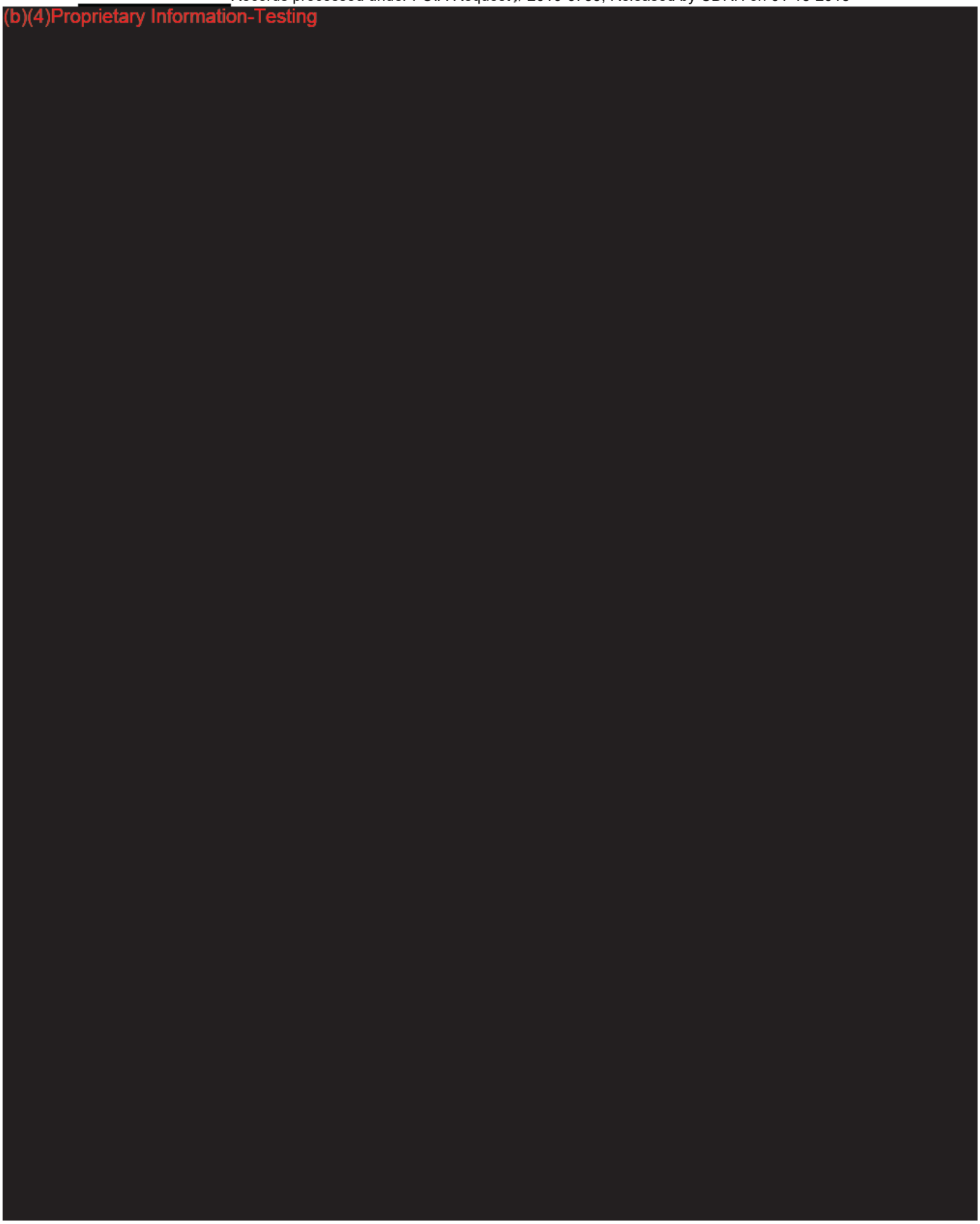
(b)(4)Proprietary Information-Testing



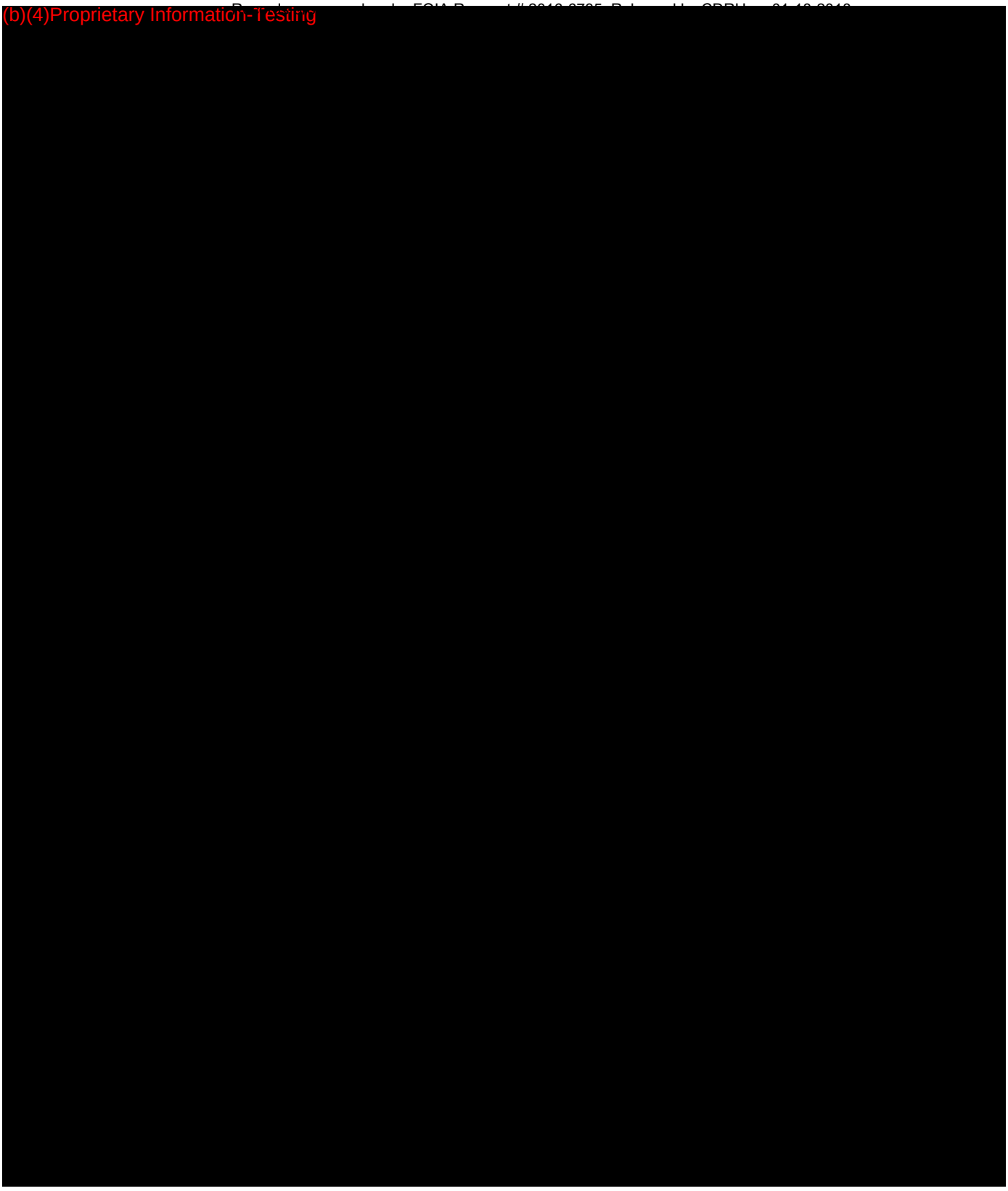
(b)(4)Proprietary Information-Testing



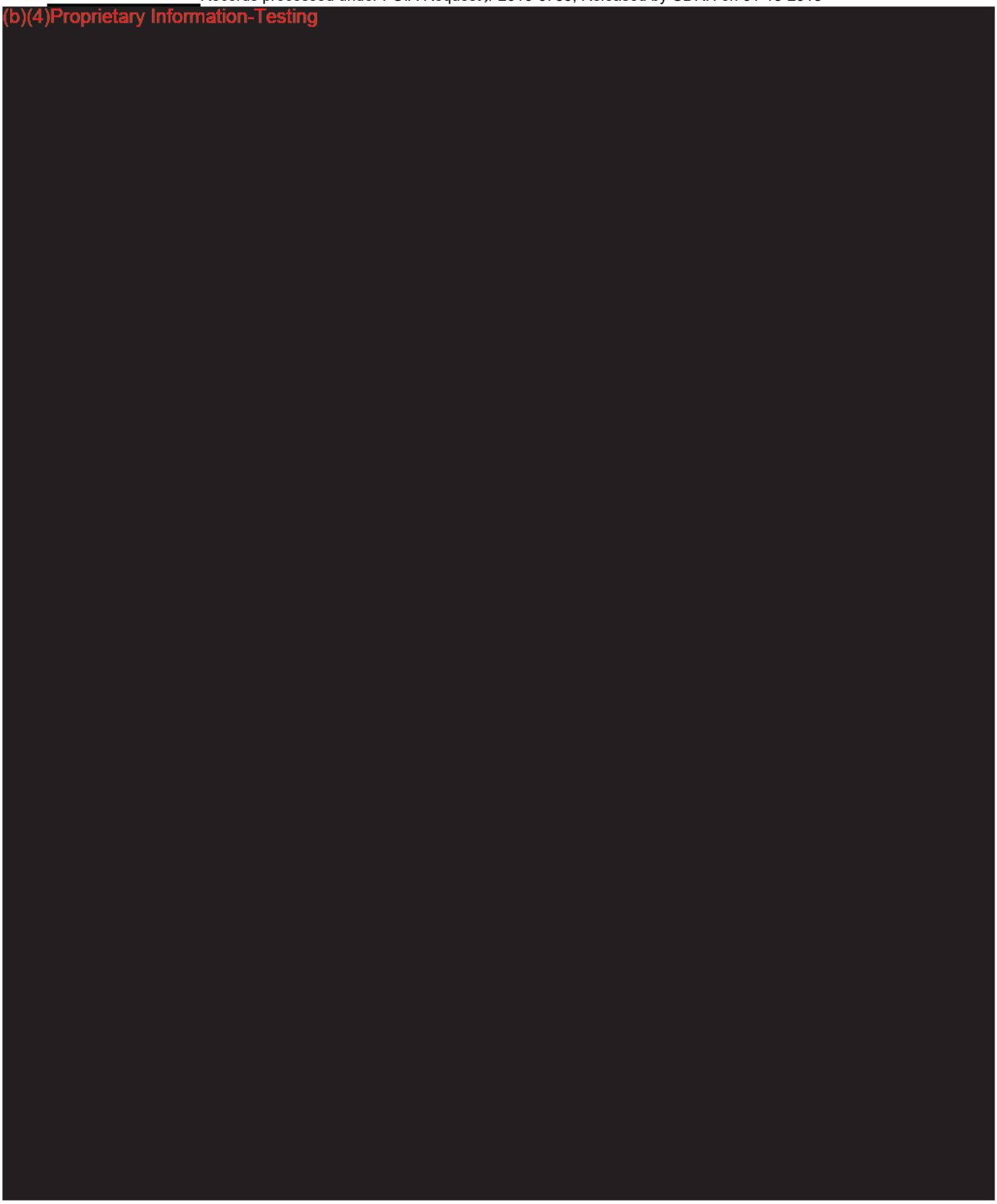
(b)(4)Proprietary Information-Testing



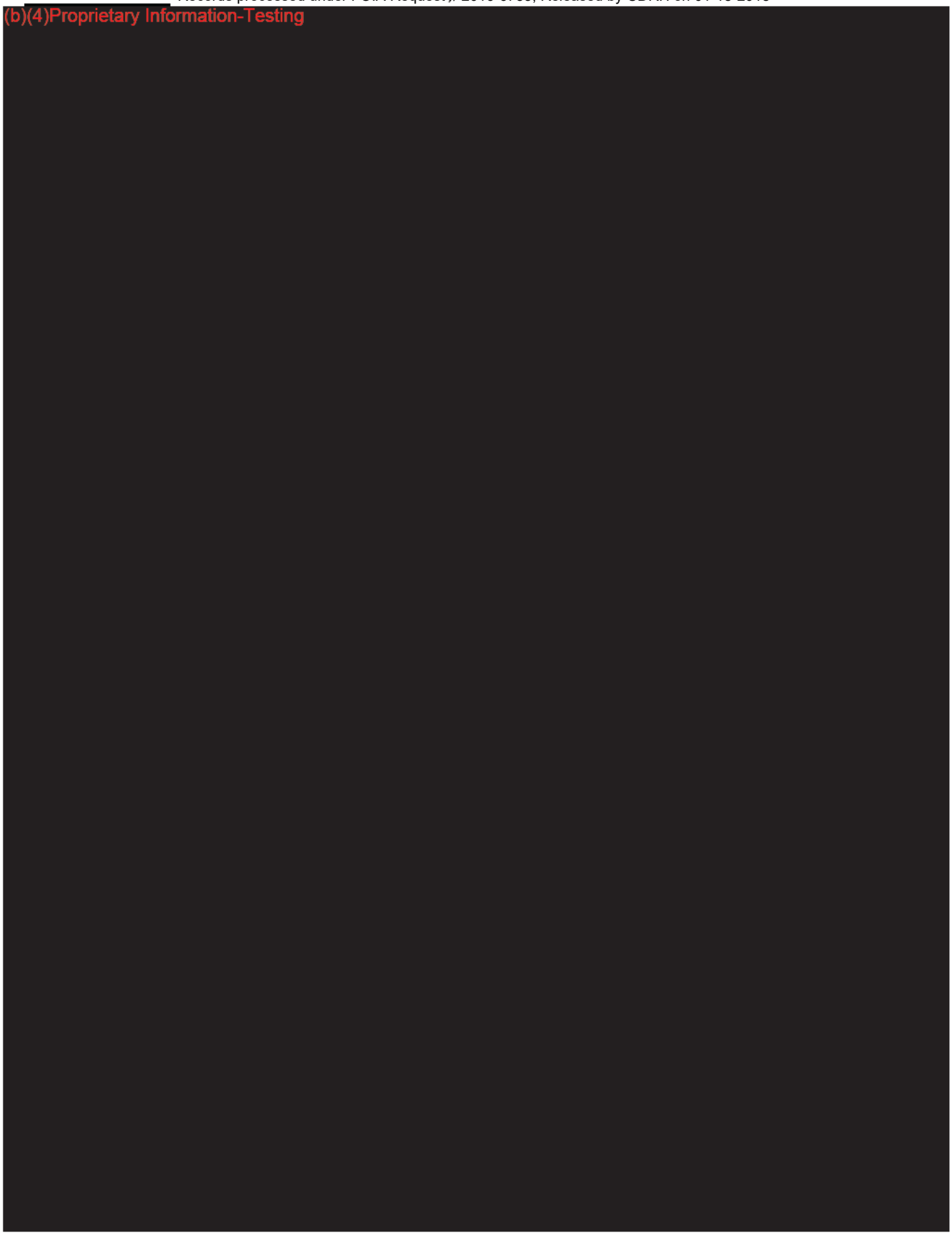
(b)(4)Proprietary Information-Testing



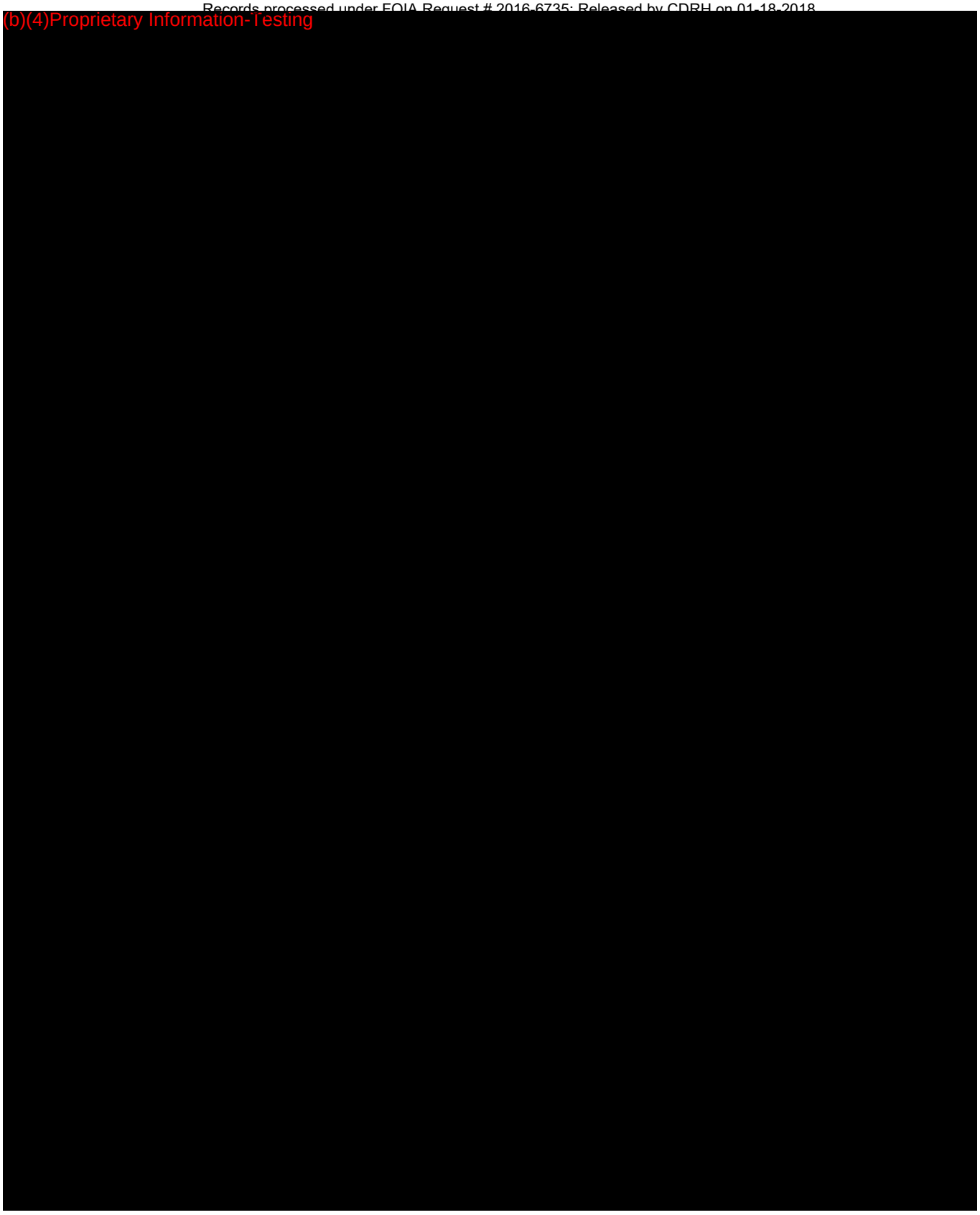
(b)(4)Proprietary Information-Testing

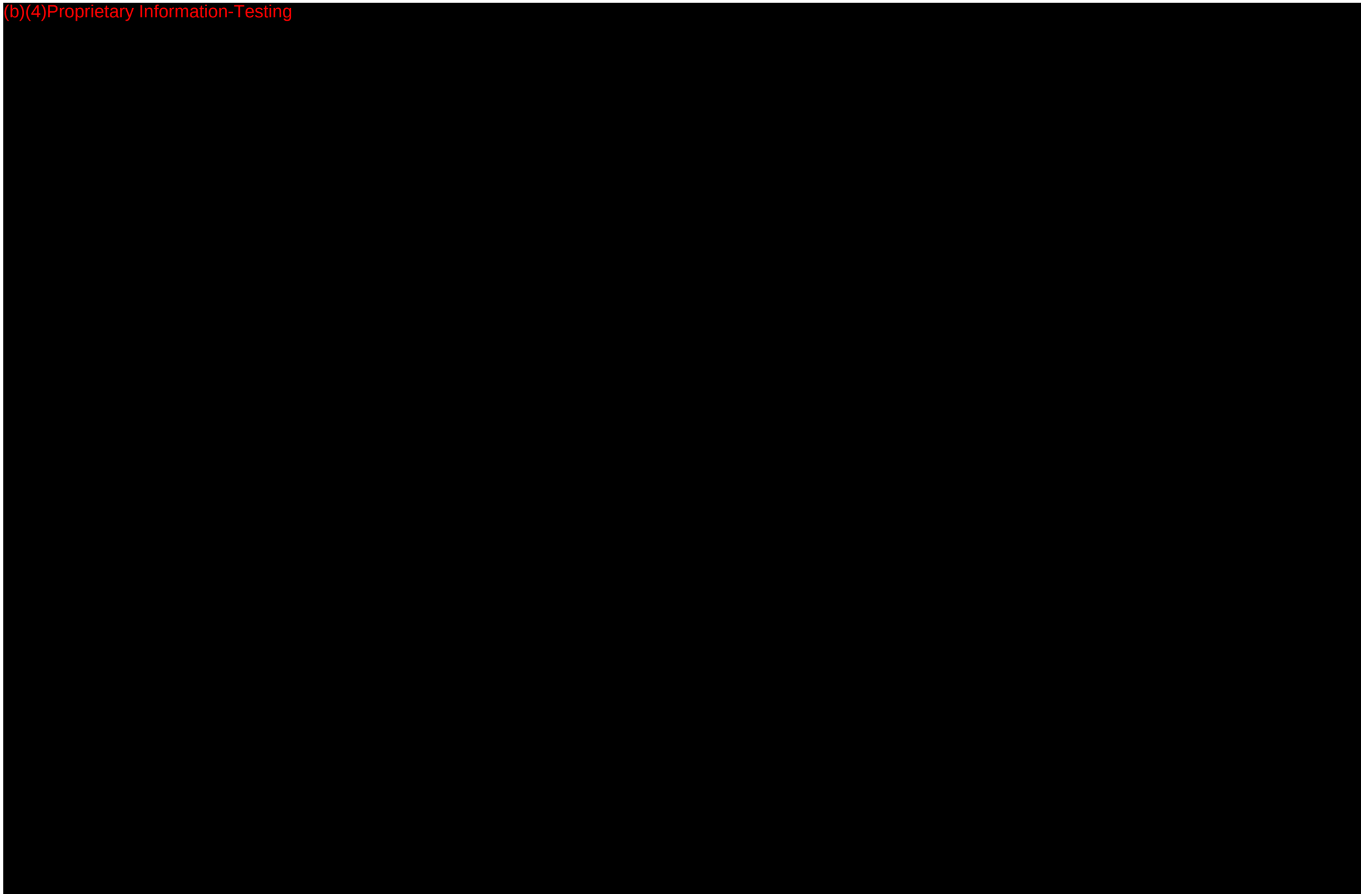


(b)(4)Proprietary Information-Testing



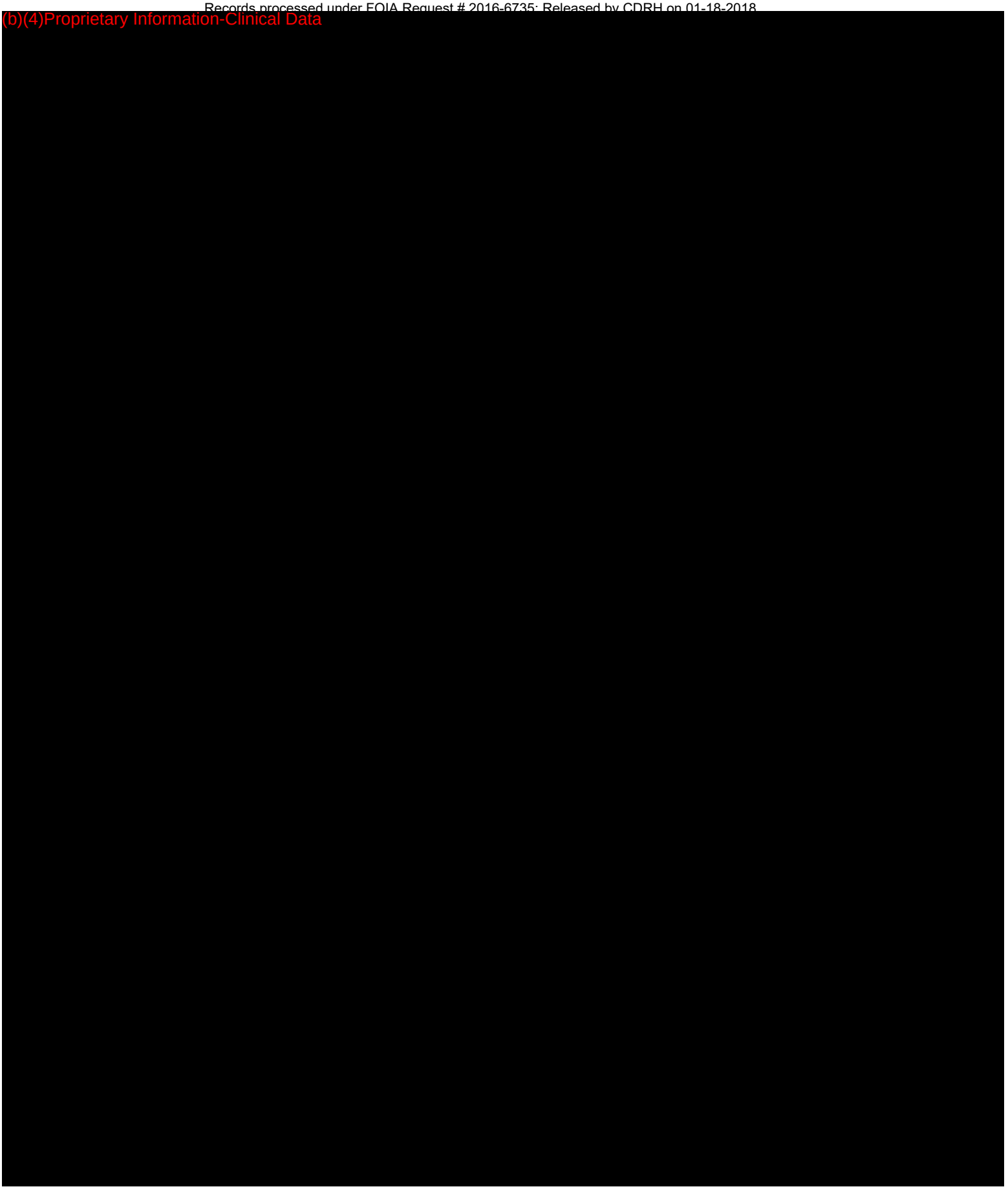
(b)(4)Proprietary Information-Testing



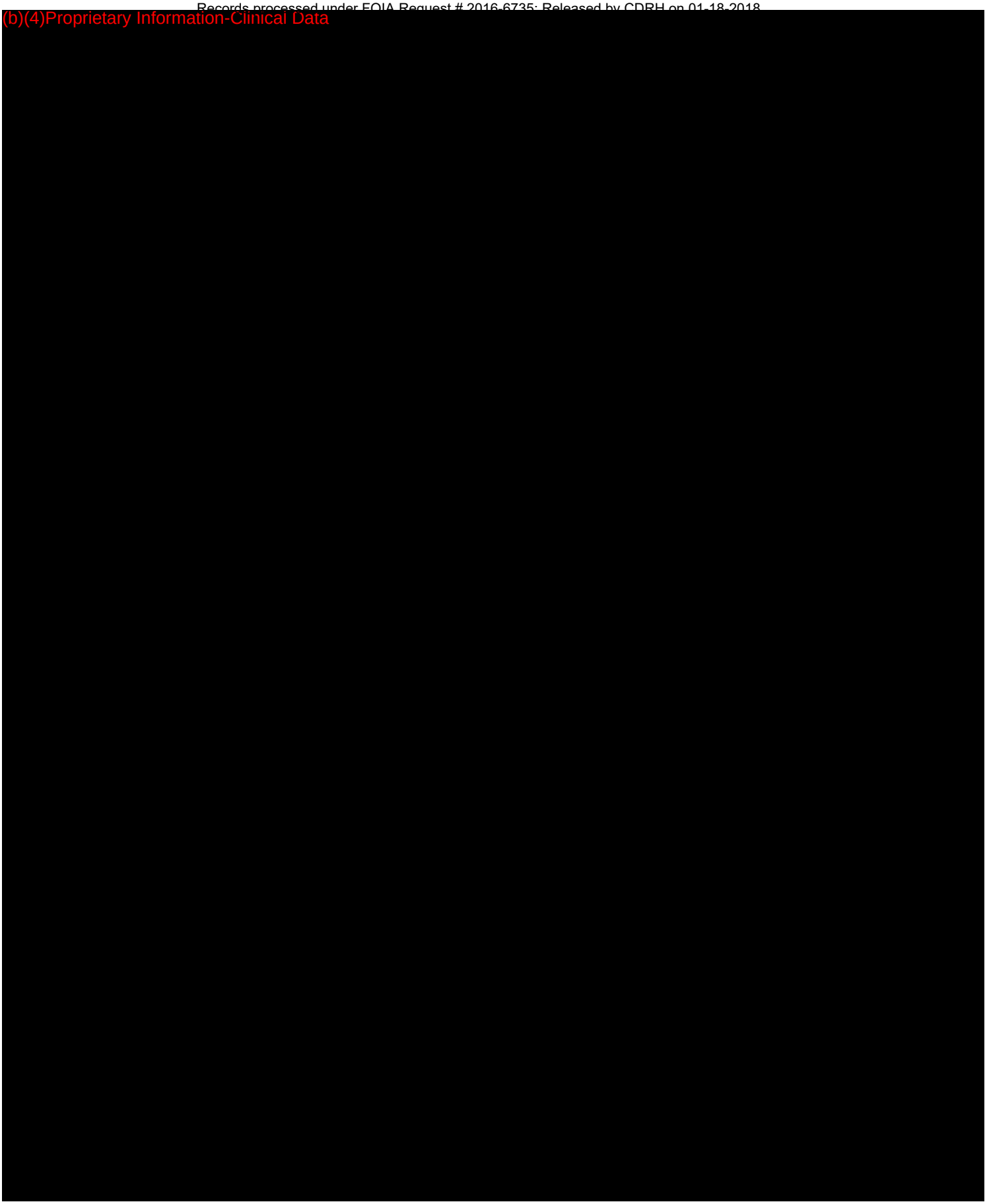


ATTACHMENT 36

(b)(4)Proprietary Information-Clinical Data



(b)(4)Proprietary Information-Clinical Data



(b)(4)Proprietary Information-Clinical Data

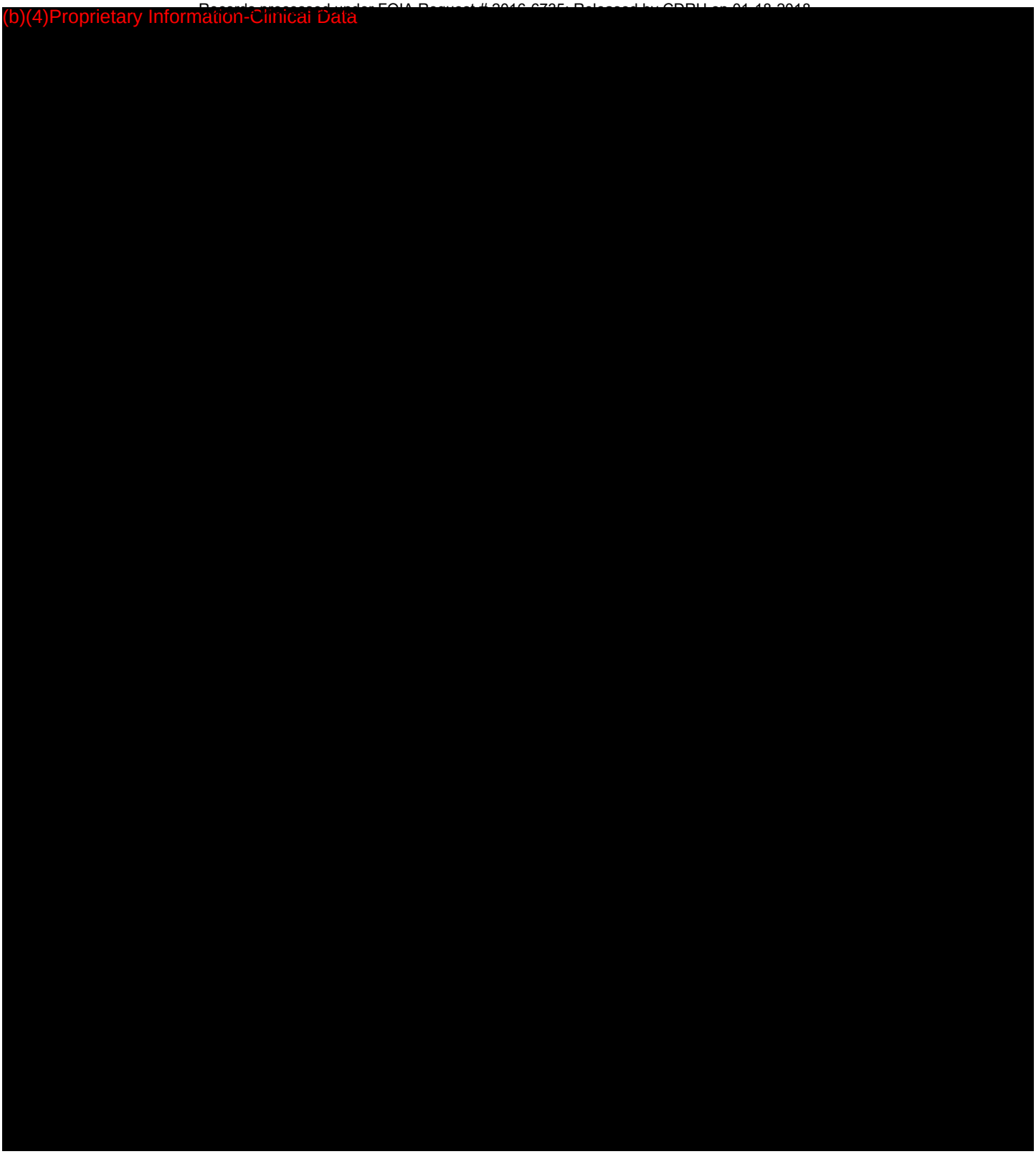
[redacted]

(b)(4)Proprietary Information-Clinical Data

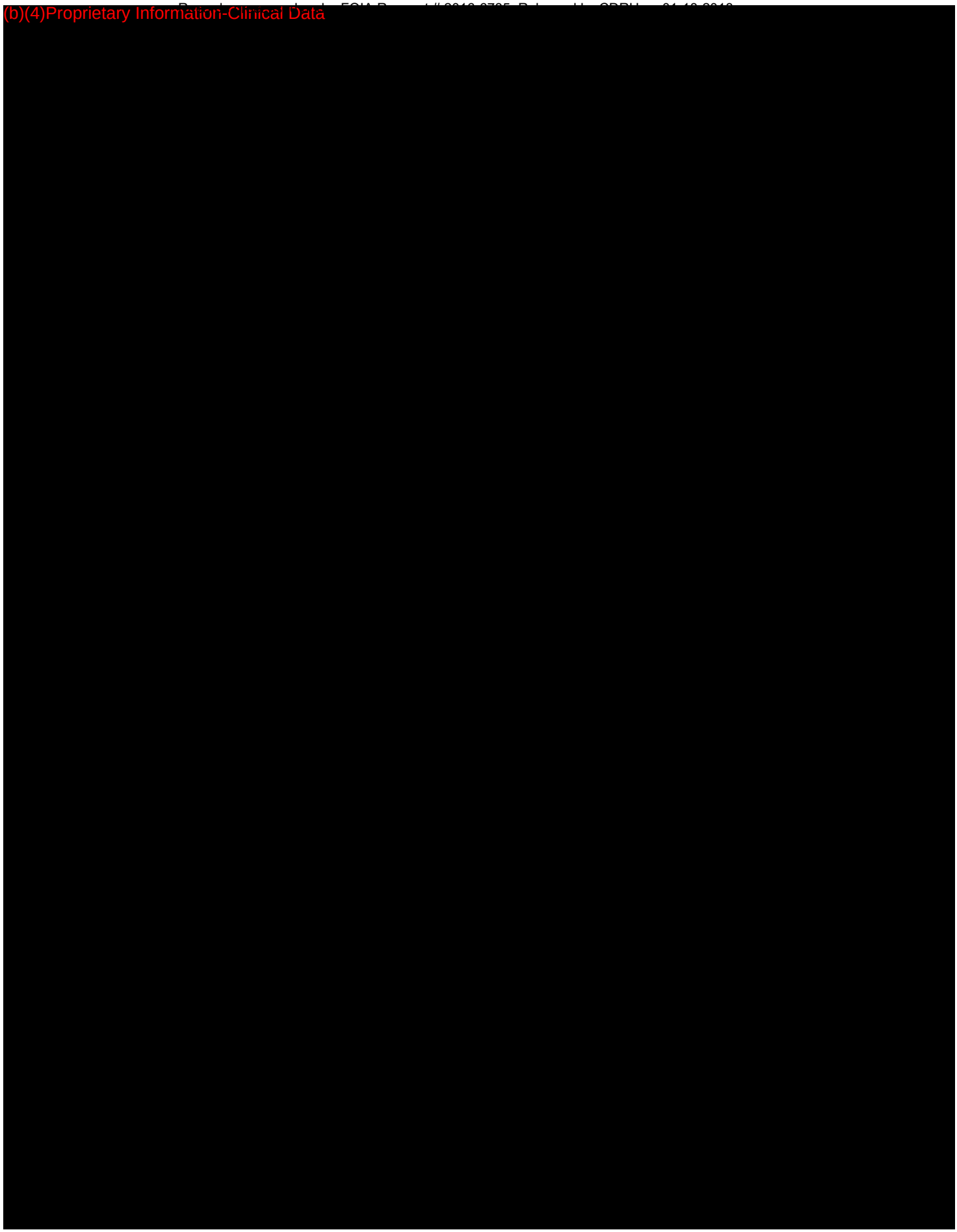
[redacted]

(b)(4)Proprietary Information-Clinical Data

(b)(4)Proprietary Information-Clinical Data



(b)(4)Proprietary Information-Clinical Data



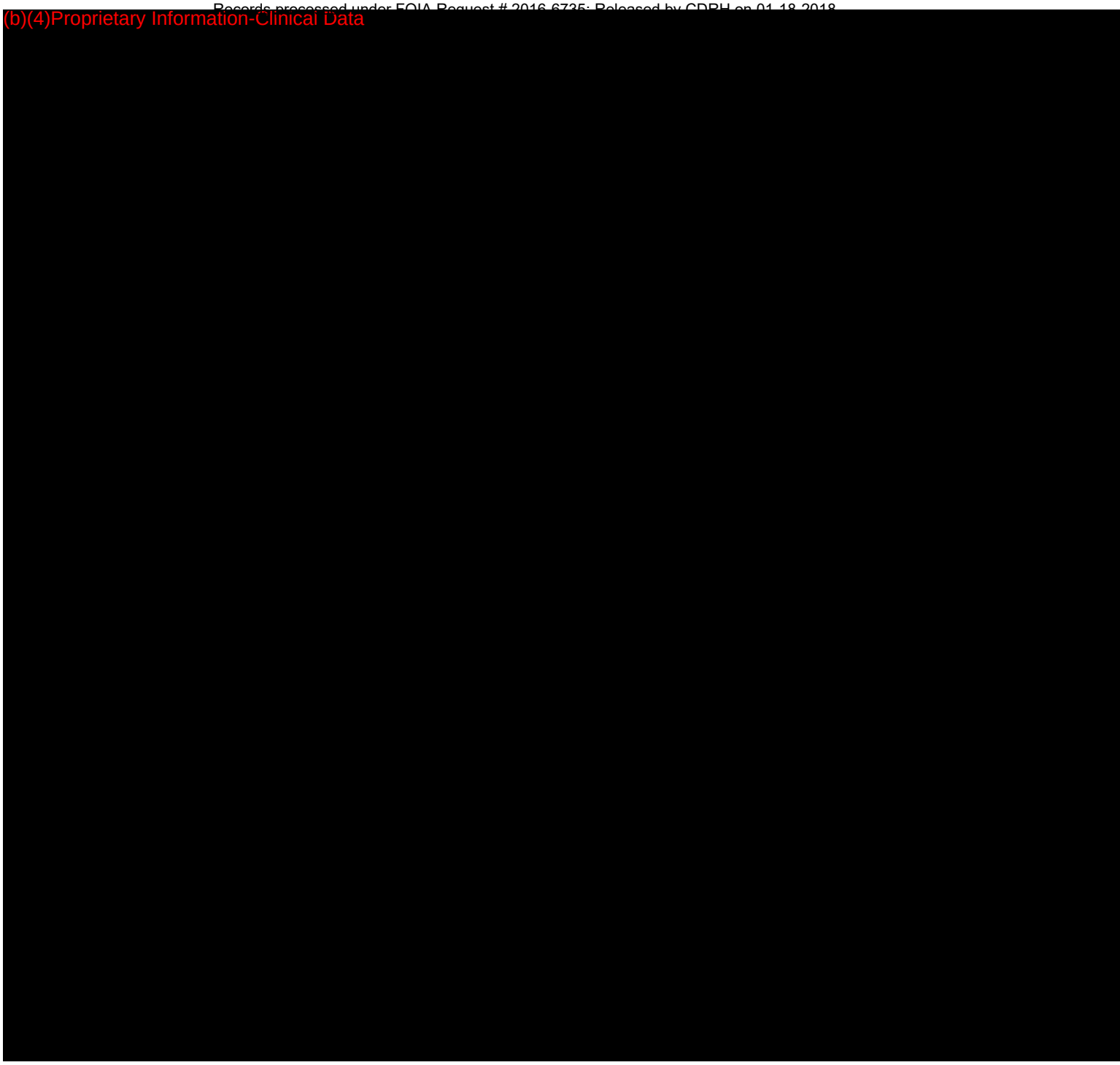
(b)(4)Proprietary Information-Clinical Data

[redacted]

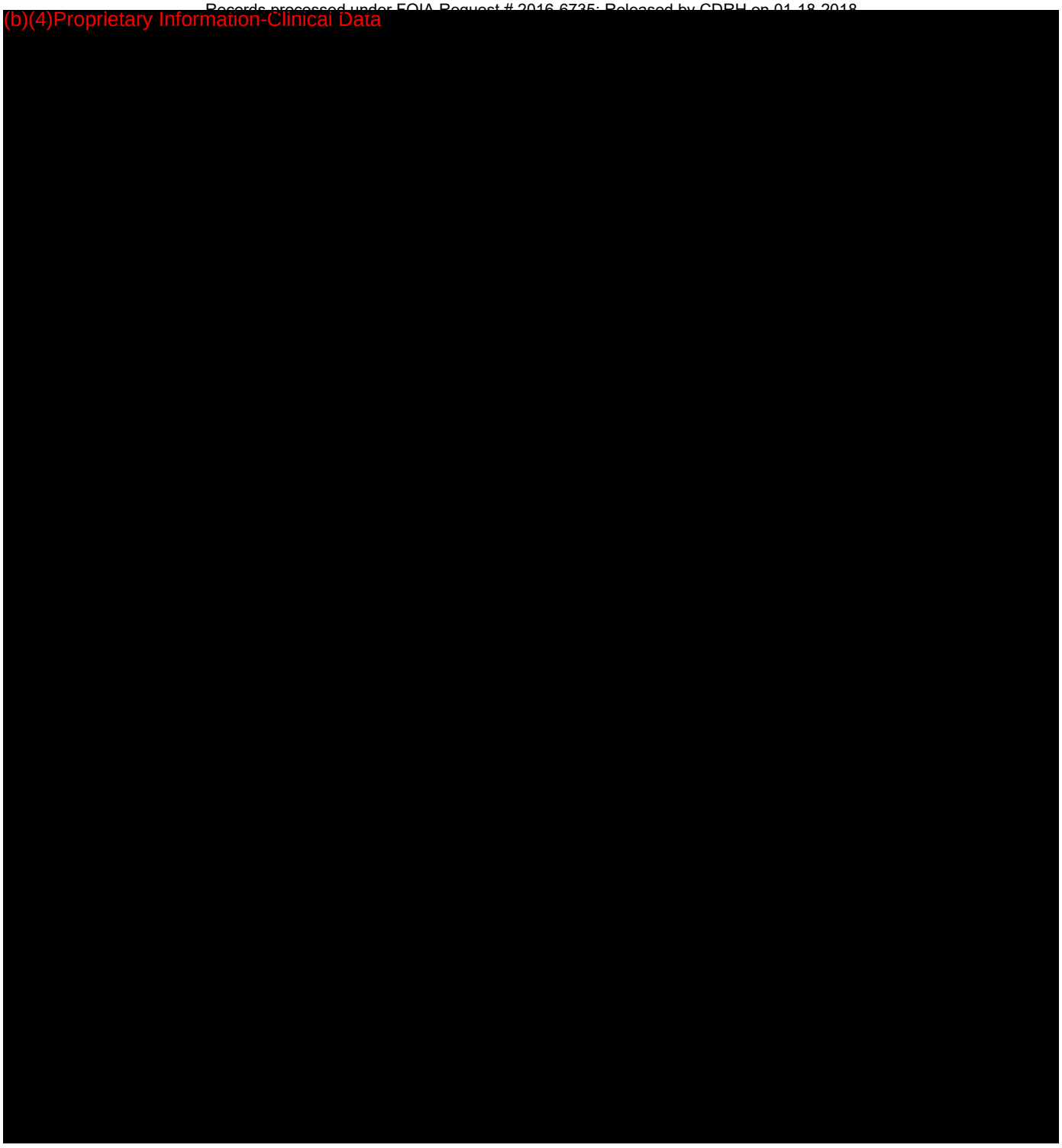
(b)(4)Proprietary Information-Clinical Data

[redacted]

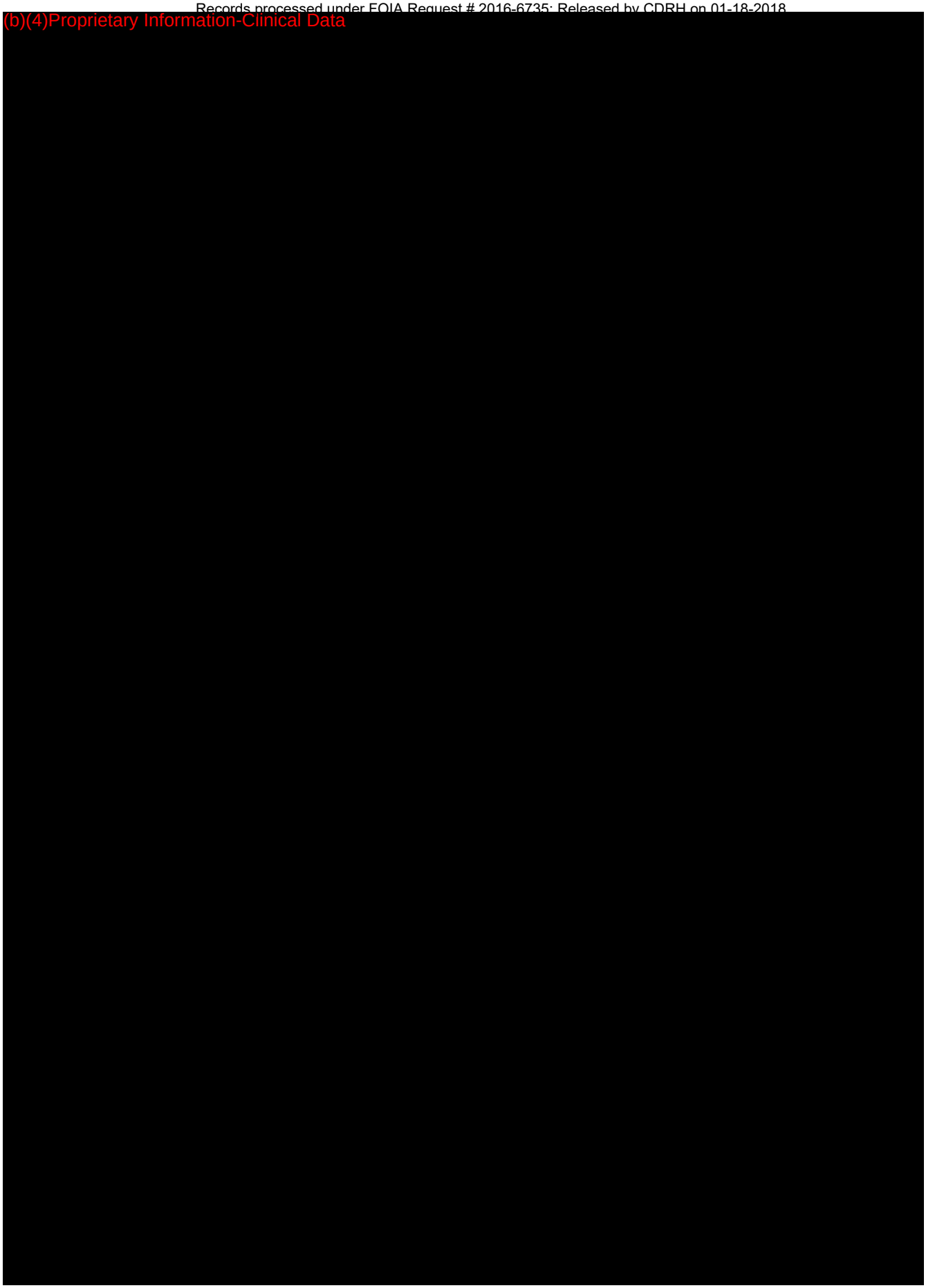
(b)(4)Proprietary Information-Clinical Data



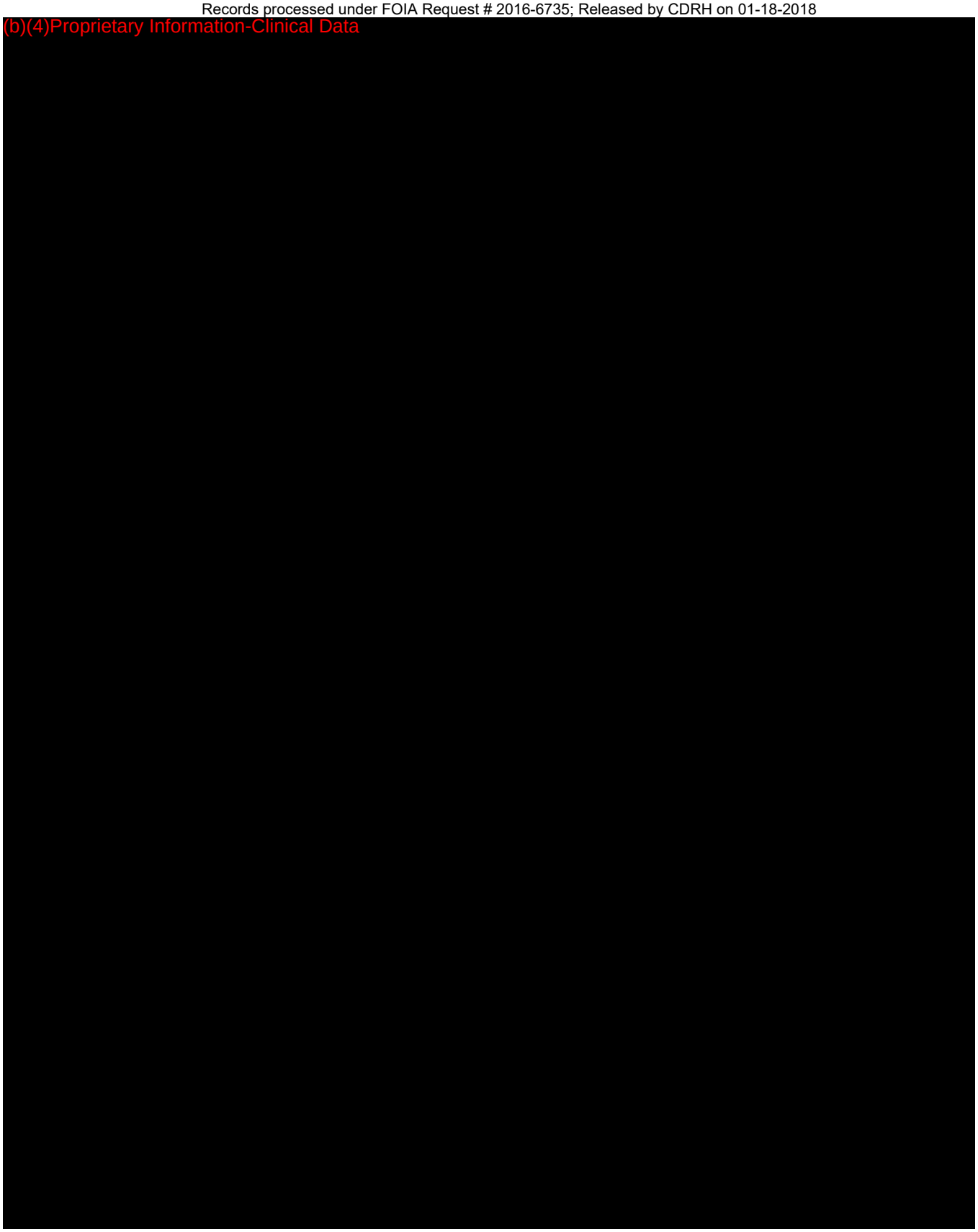
(b)(4)Proprietary Information-Clinical Data



(b)(4)Proprietary Information-Clinical Data



(b)(4)Proprietary Information-Clinical Data



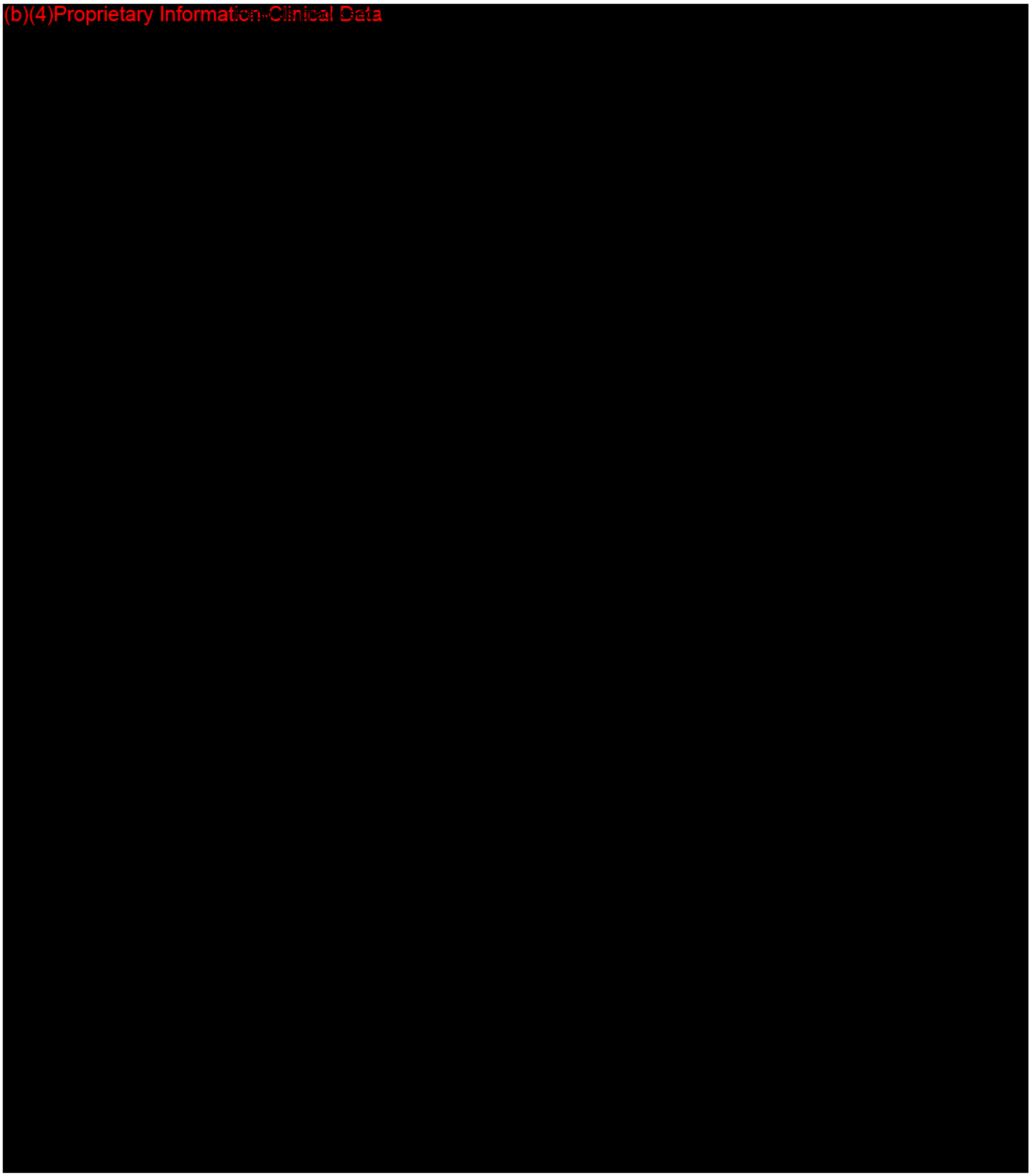
(b)(4)Proprietary Information-Clinical Data

[redacted]

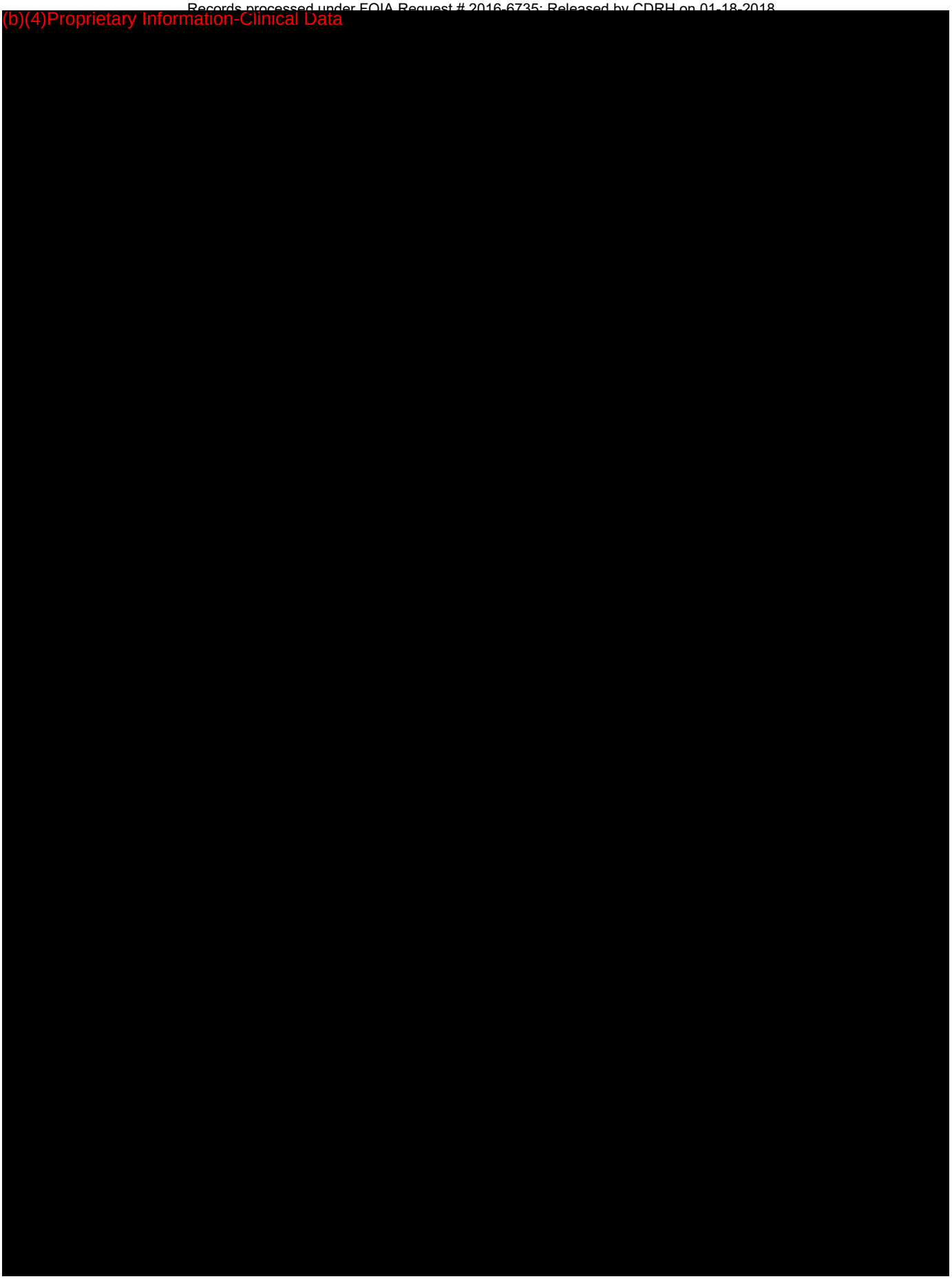
(b)(4)Proprietary Information-Clinical Data

[redacted]

(b)(4)Proprietary Information-Clinical Data



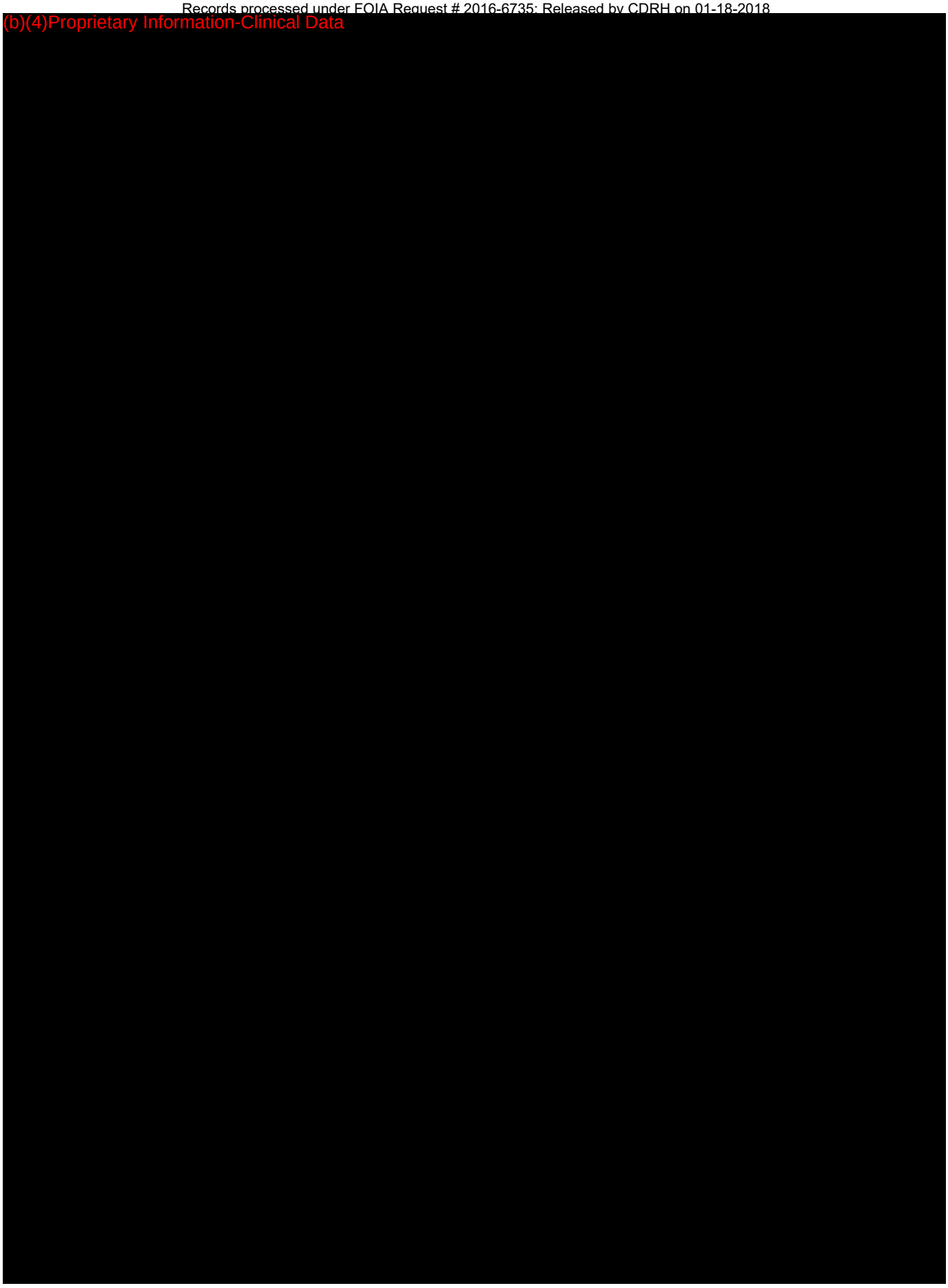
(b)(4)Proprietary Information-Clinical Data



(b)(4)Proprietary Information-Clinical Data

[redacted]

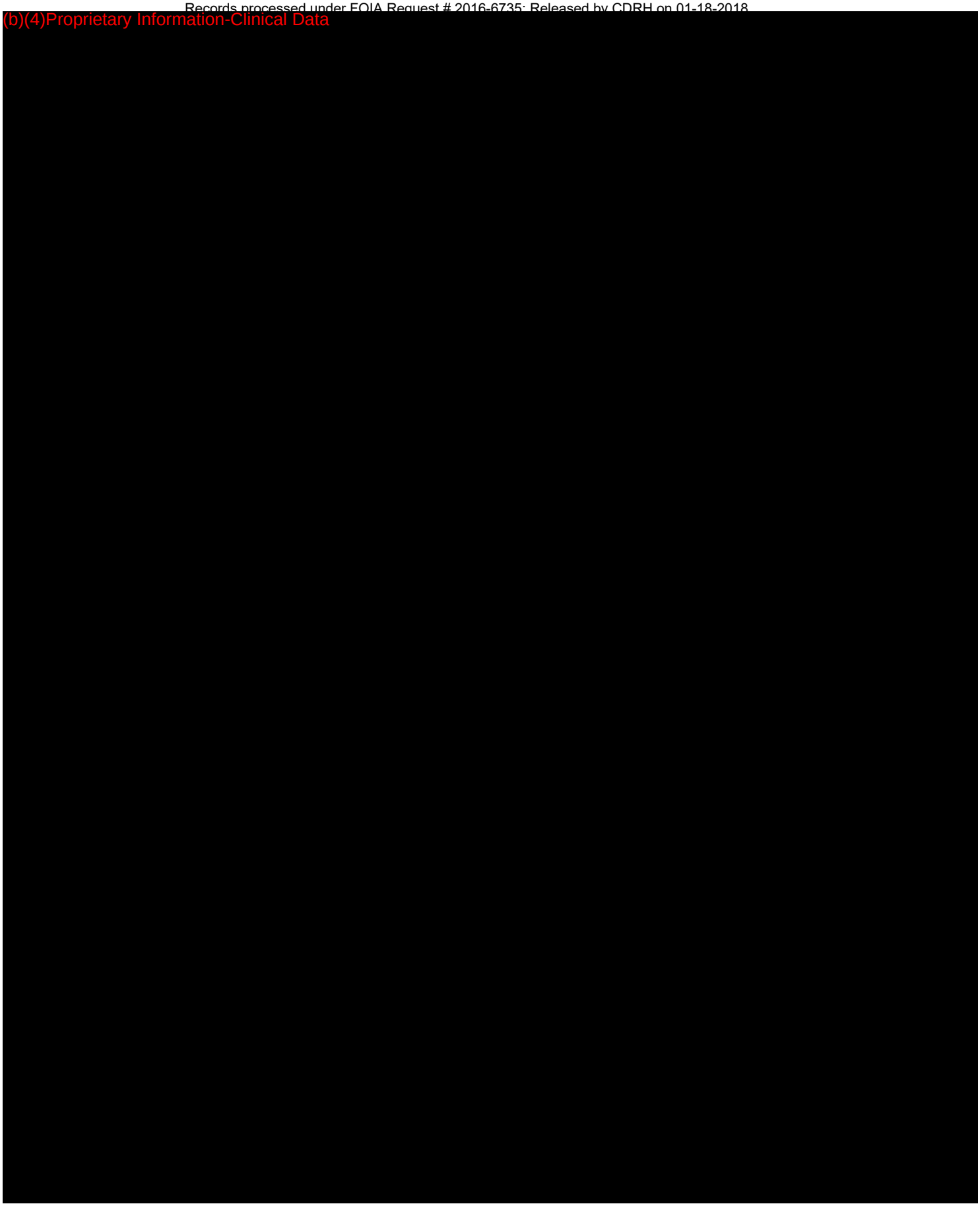
(b)(4)Proprietary Information-Clinical Data



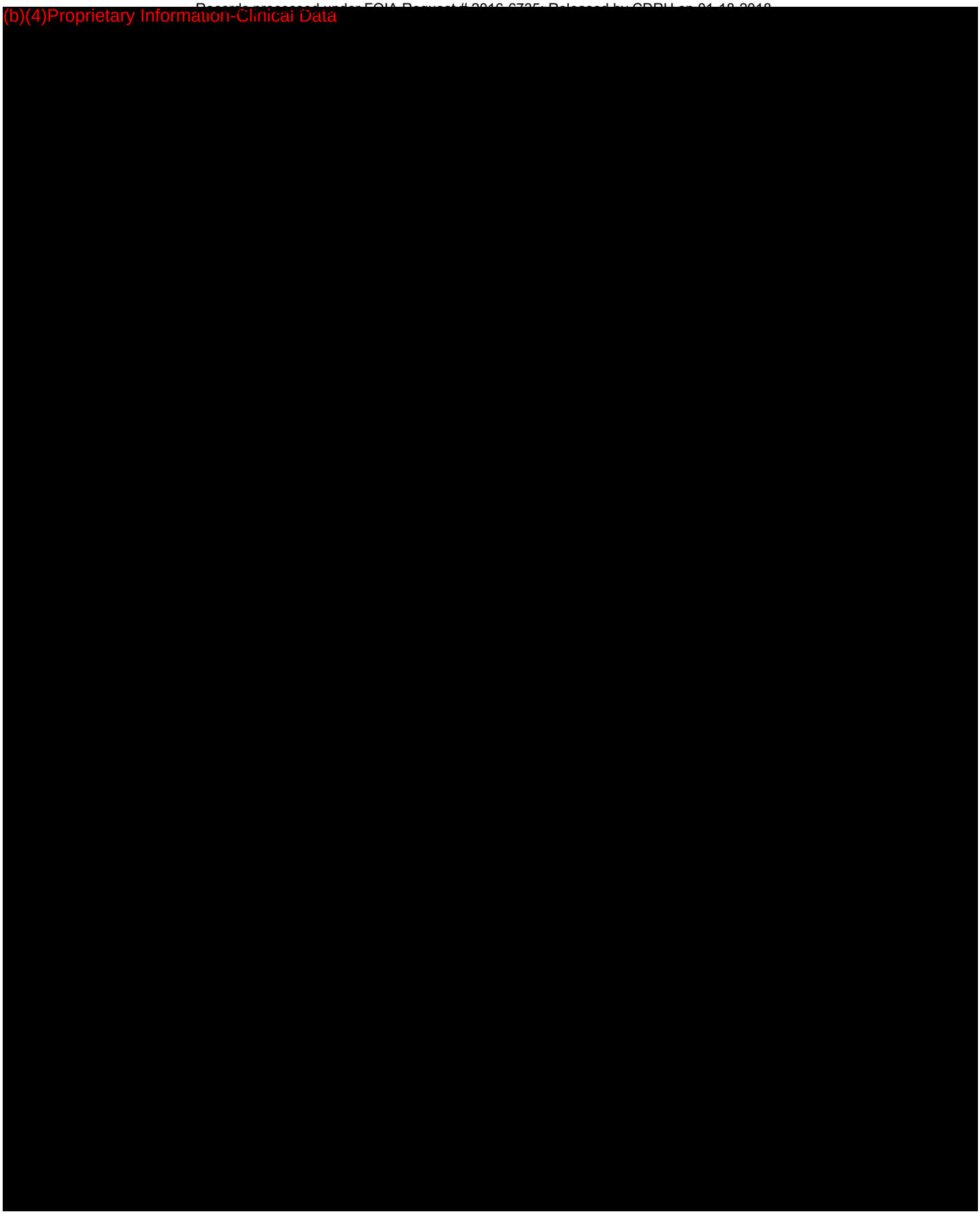
(b)(4)Proprietary Information-Clinical Data

[redacted]

(b)(4)Proprietary Information-Clinical Data



(b)(4)Proprietary Information-Clinical Data



(b)(4)Proprietary Information-Clinical Data

[redacted]

(b)(4)Proprietary Information-Clinical Data

[redacted]

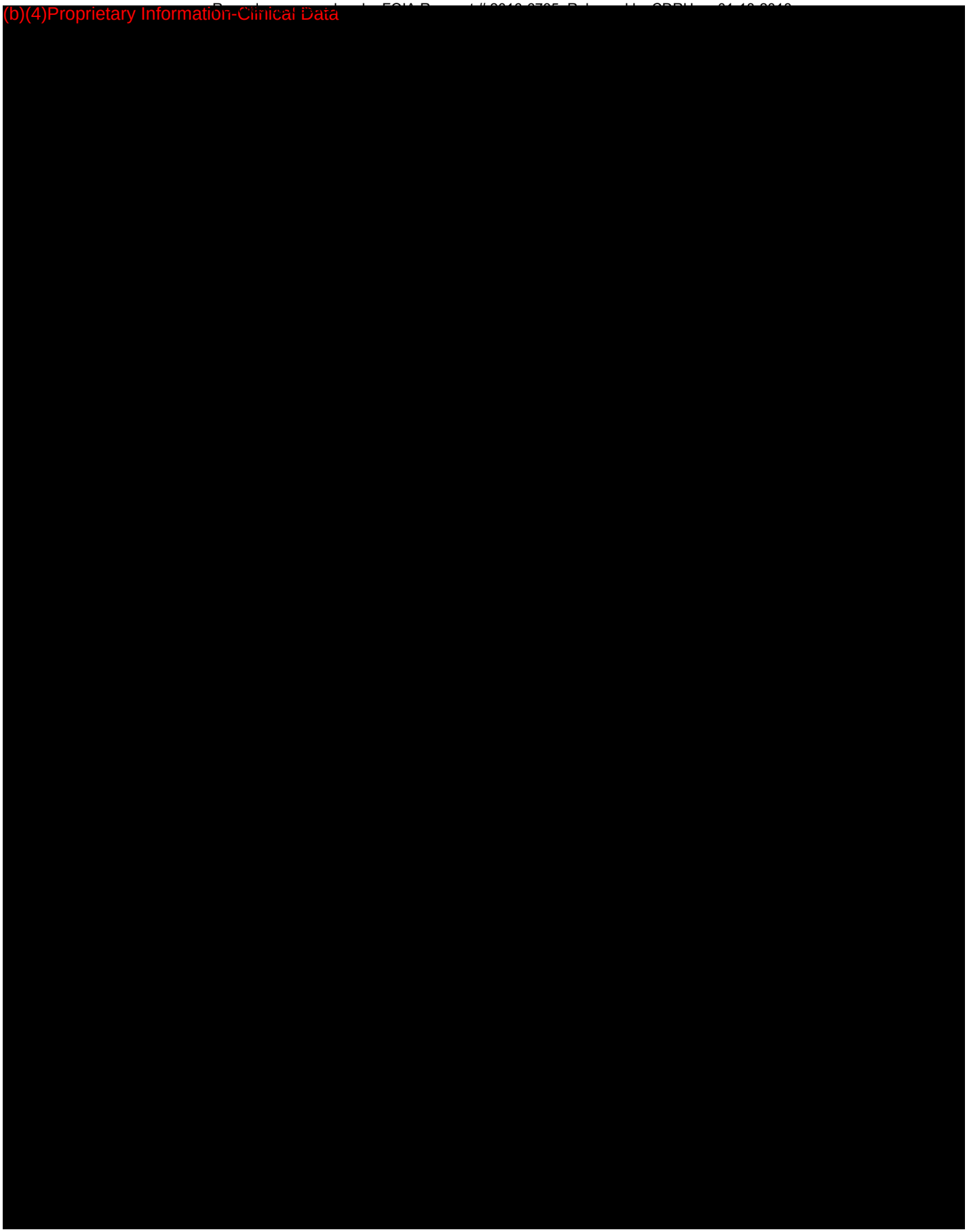
(b)(4)Proprietary Information-Clinical Data

[redacted]

(b)(4)Proprietary Information-Clinical Data

[redacted]

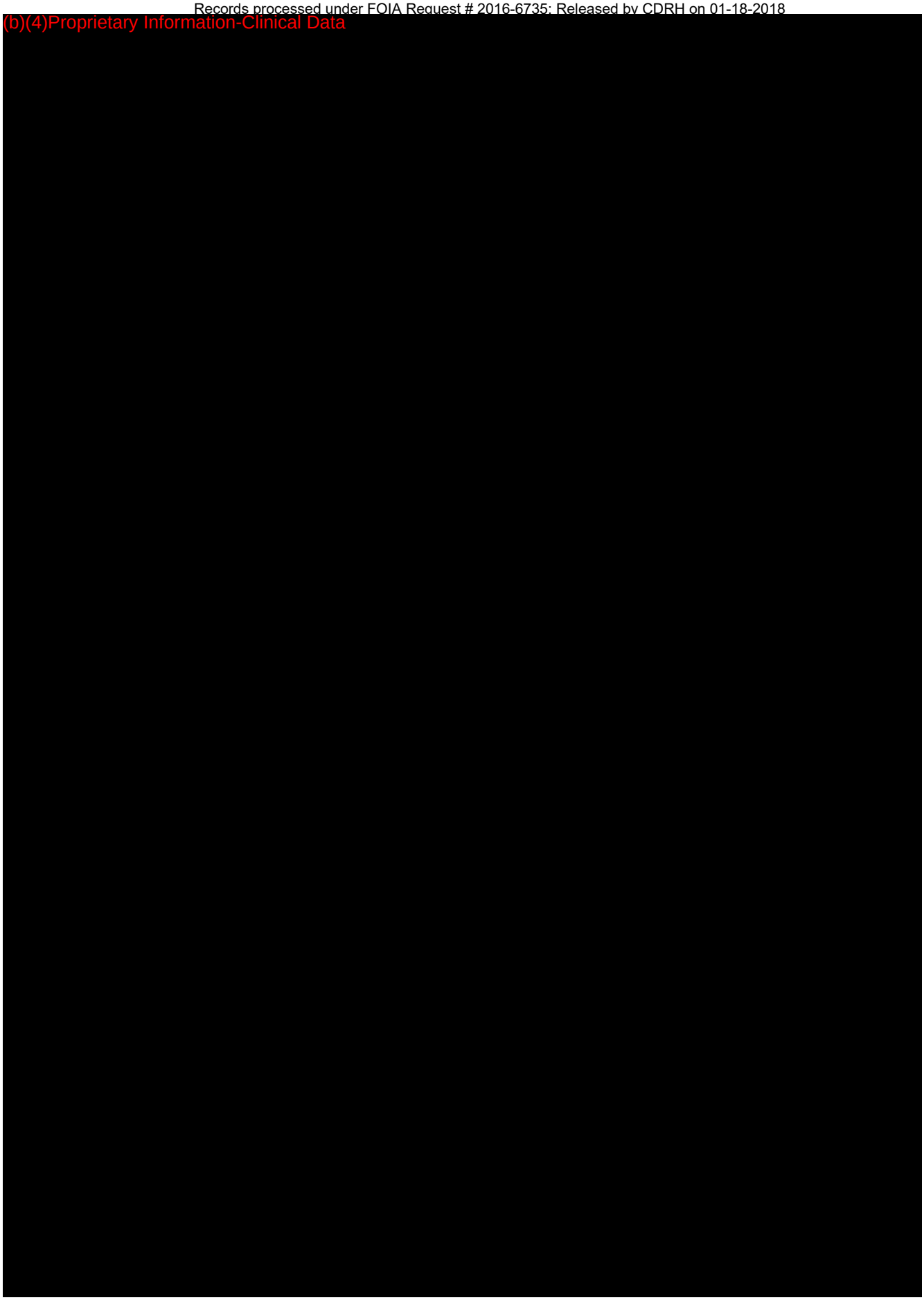
(b)(4)Proprietary Information-Clinical Data



(b)(4)Proprietary Information-Clinical Data

[redacted]

(b)(4)Proprietary Information-Clinical Data



(b)(4)Proprietary Information-Clinical Data

[redacted]

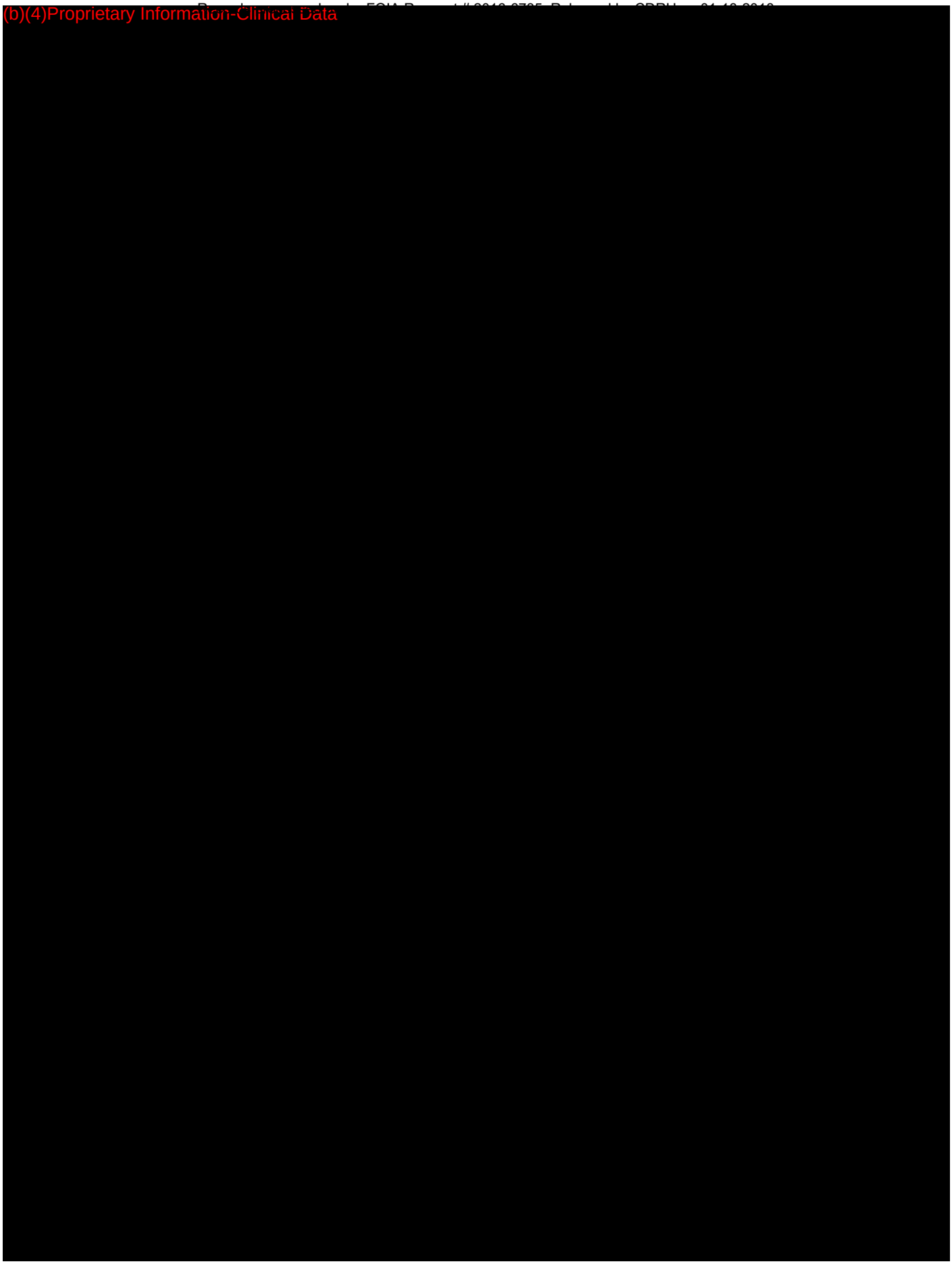
(b)(4)Proprietary Information-Clinical Data

[redacted]

(b)(4)Proprietary Information-Clinical Data

[redacted]

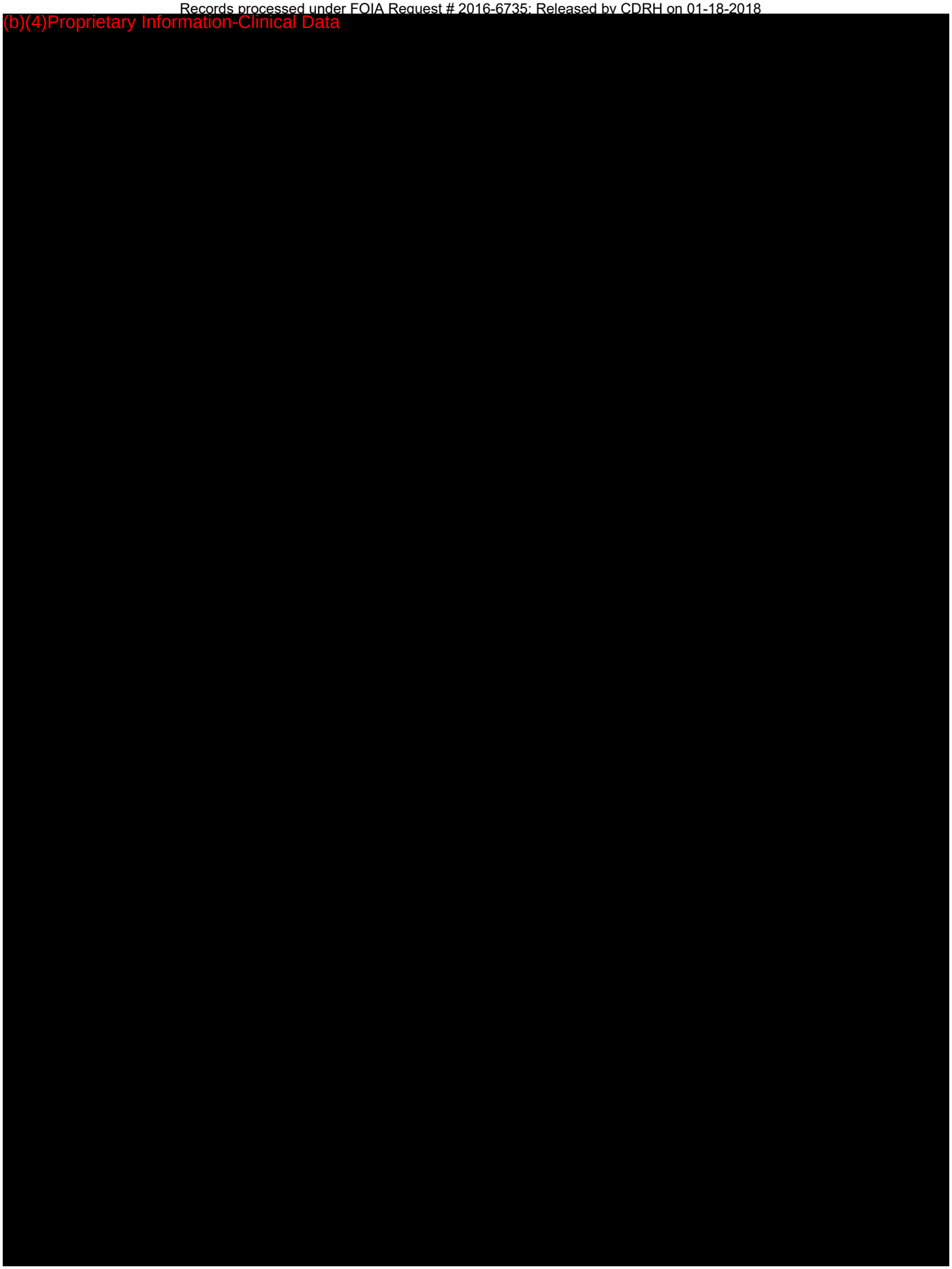
(b)(4)Proprietary Information-Clinical Data



(b)(4)Proprietary Information-Clinical Data

[redacted]

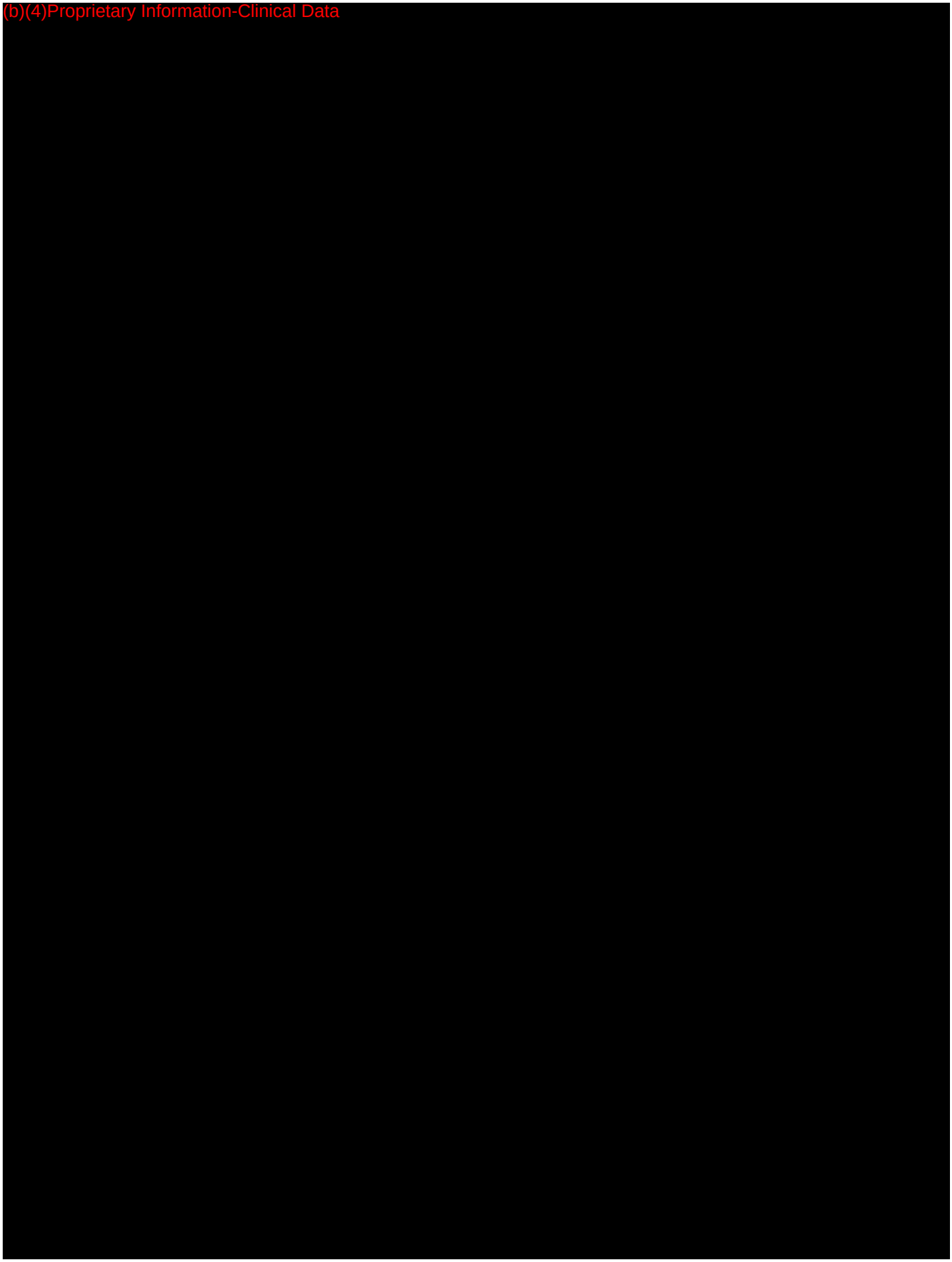
(b)(4)Proprietary Information-Clinical Data



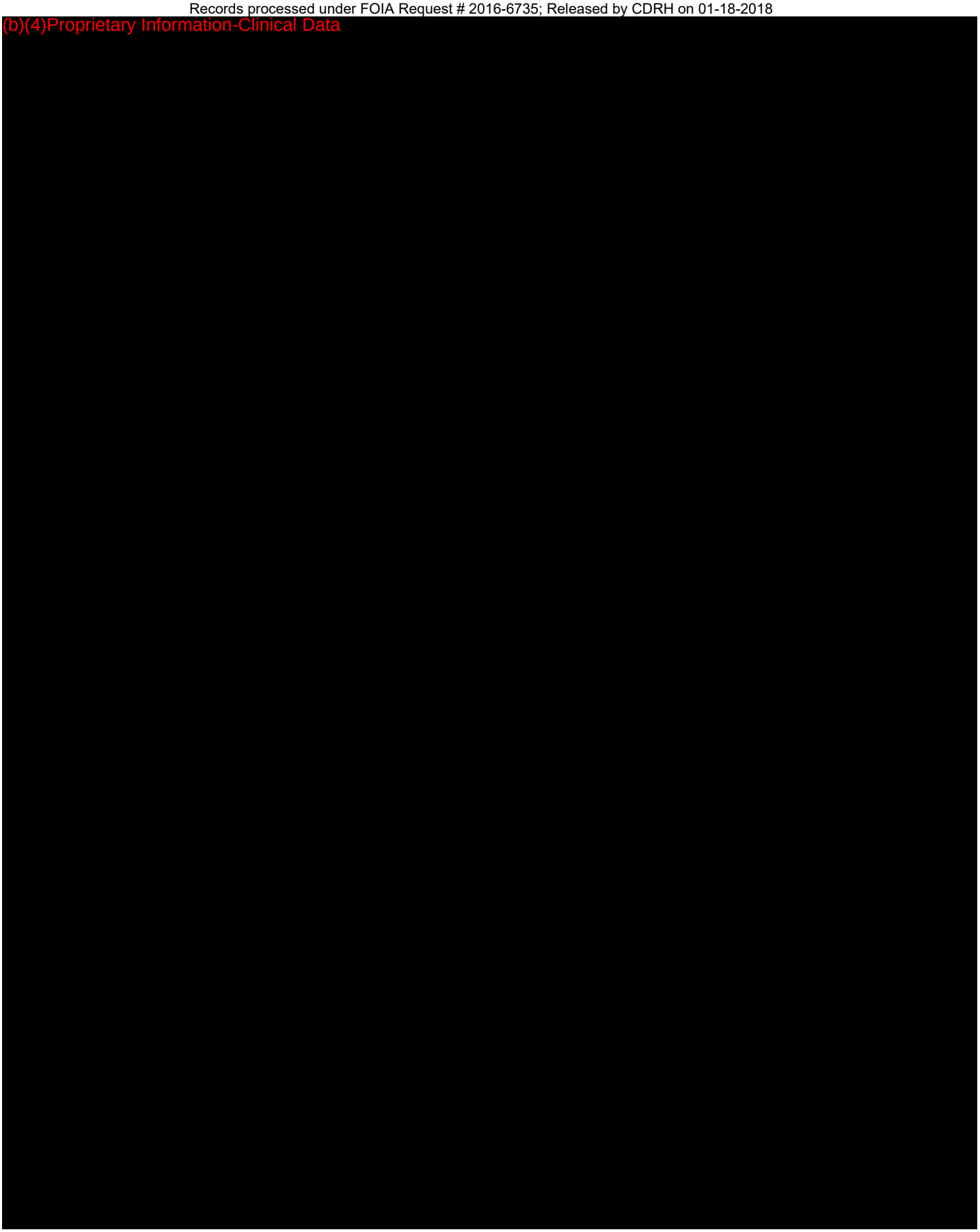
(b)(4)Proprietary Information-Clinical Data

[redacted]

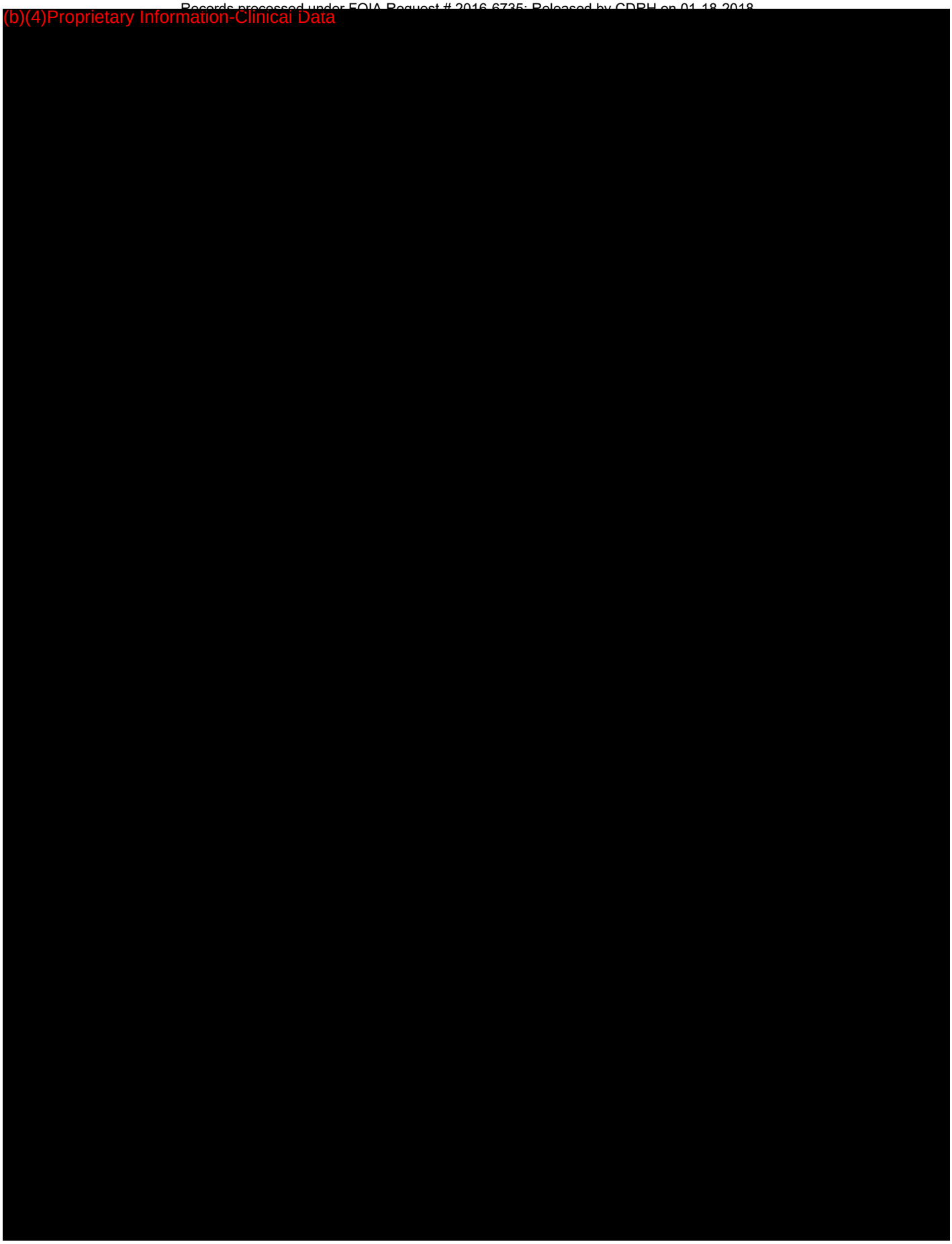
(b)(4)Proprietary Information-Clinical Data



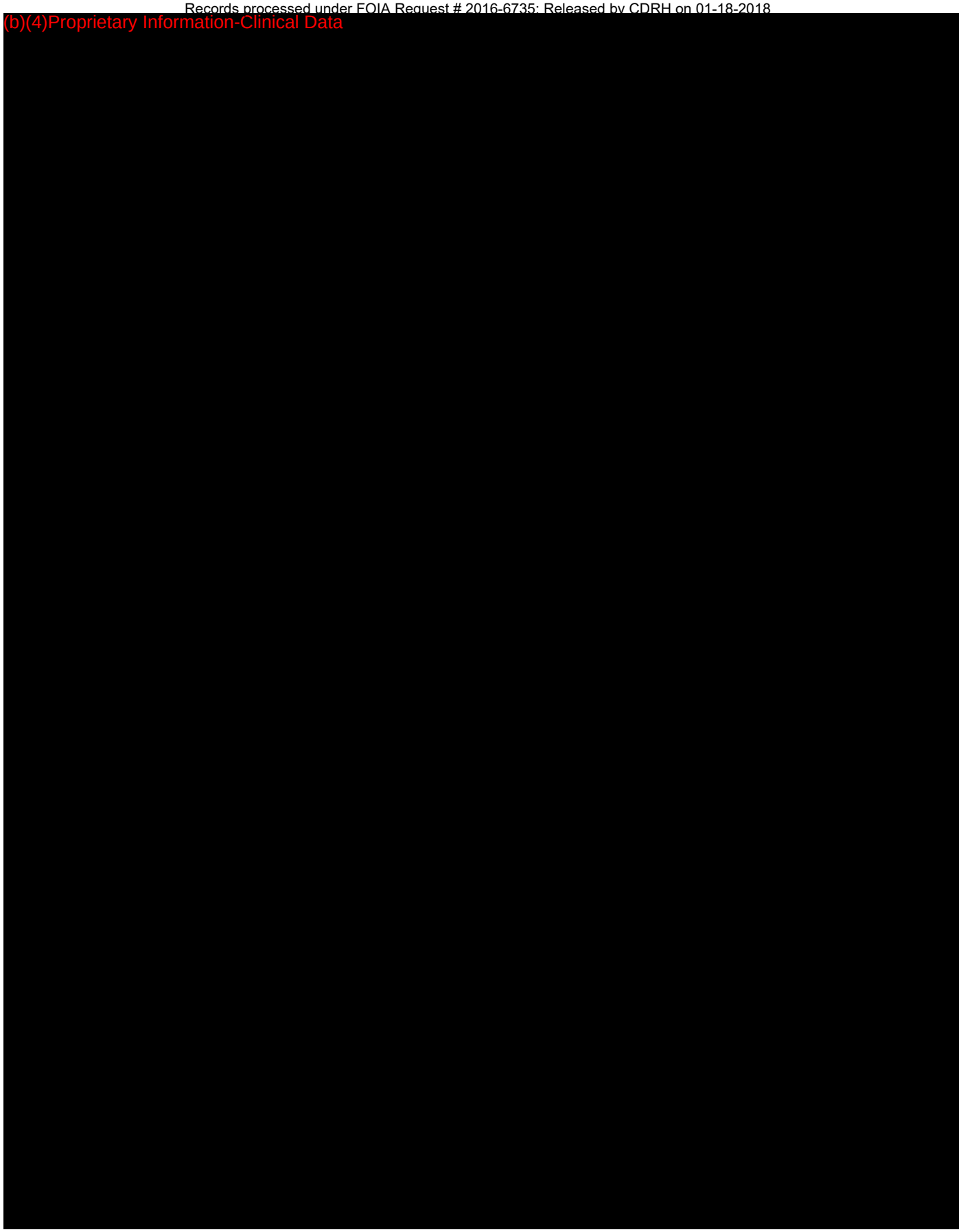
(b)(4)Proprietary Information-Clinical Data



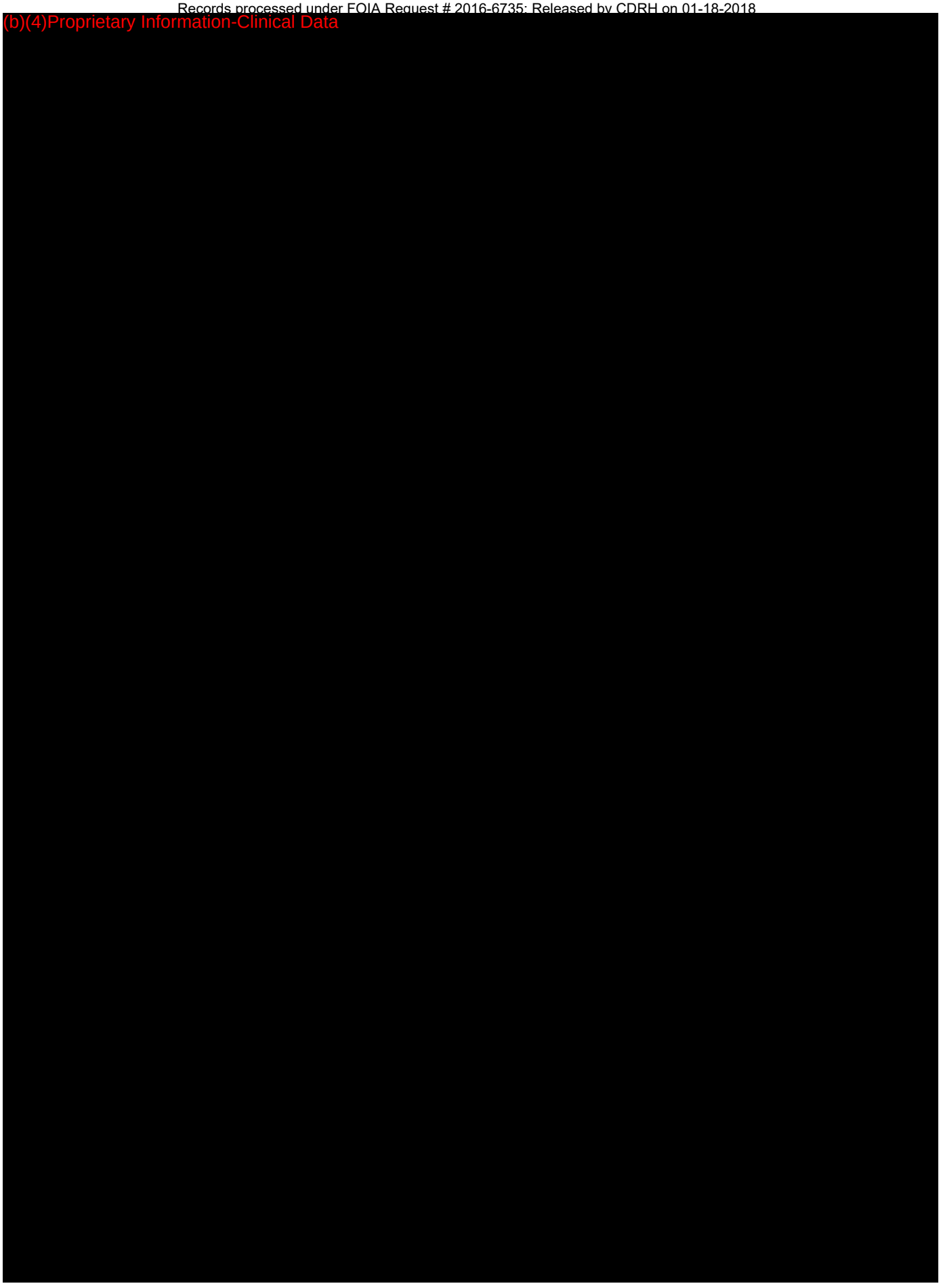
(b)(4)Proprietary Information-Clinical Data



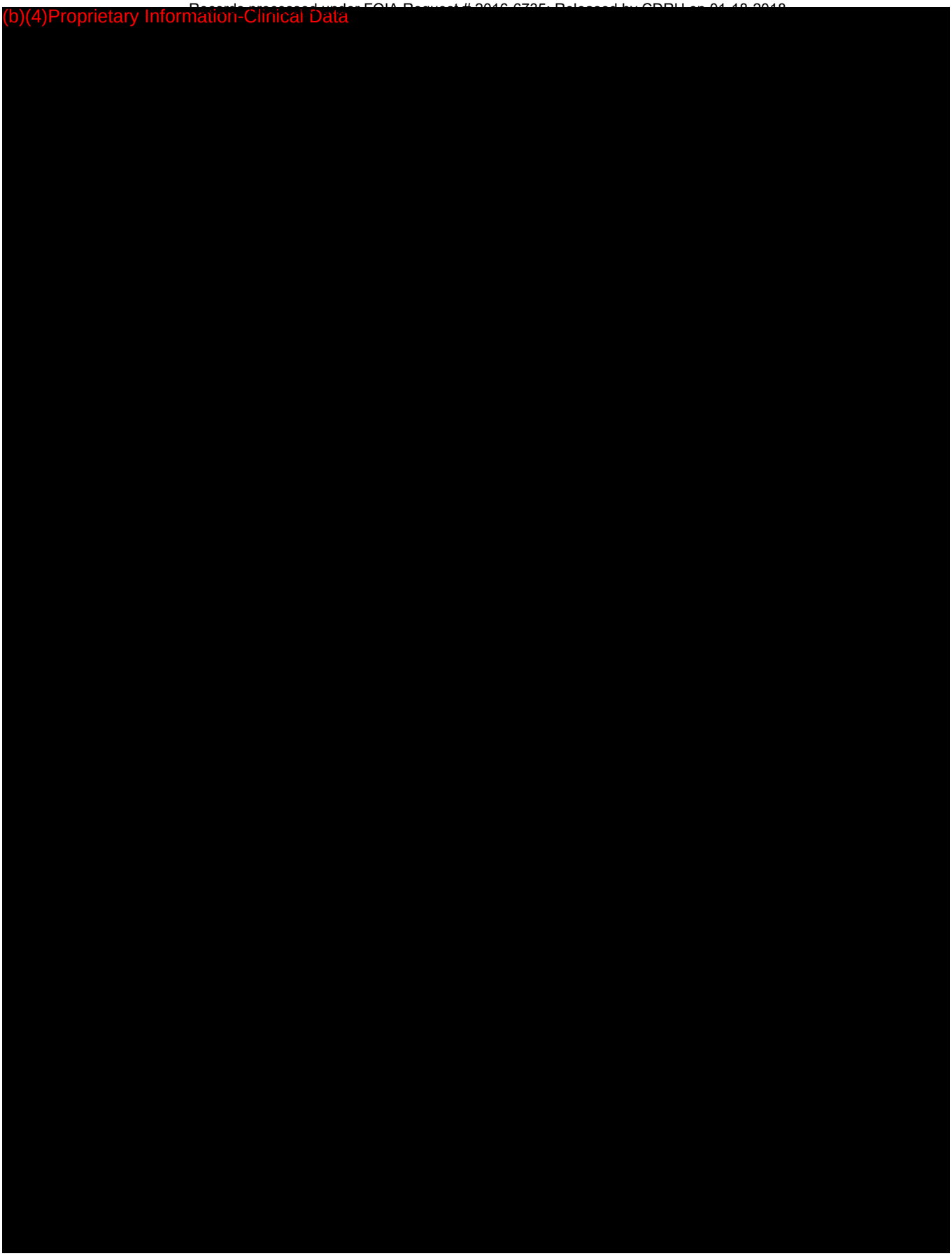
(b)(4)Proprietary Information-Clinical Data



(b)(4)Proprietary Information-Clinical Data



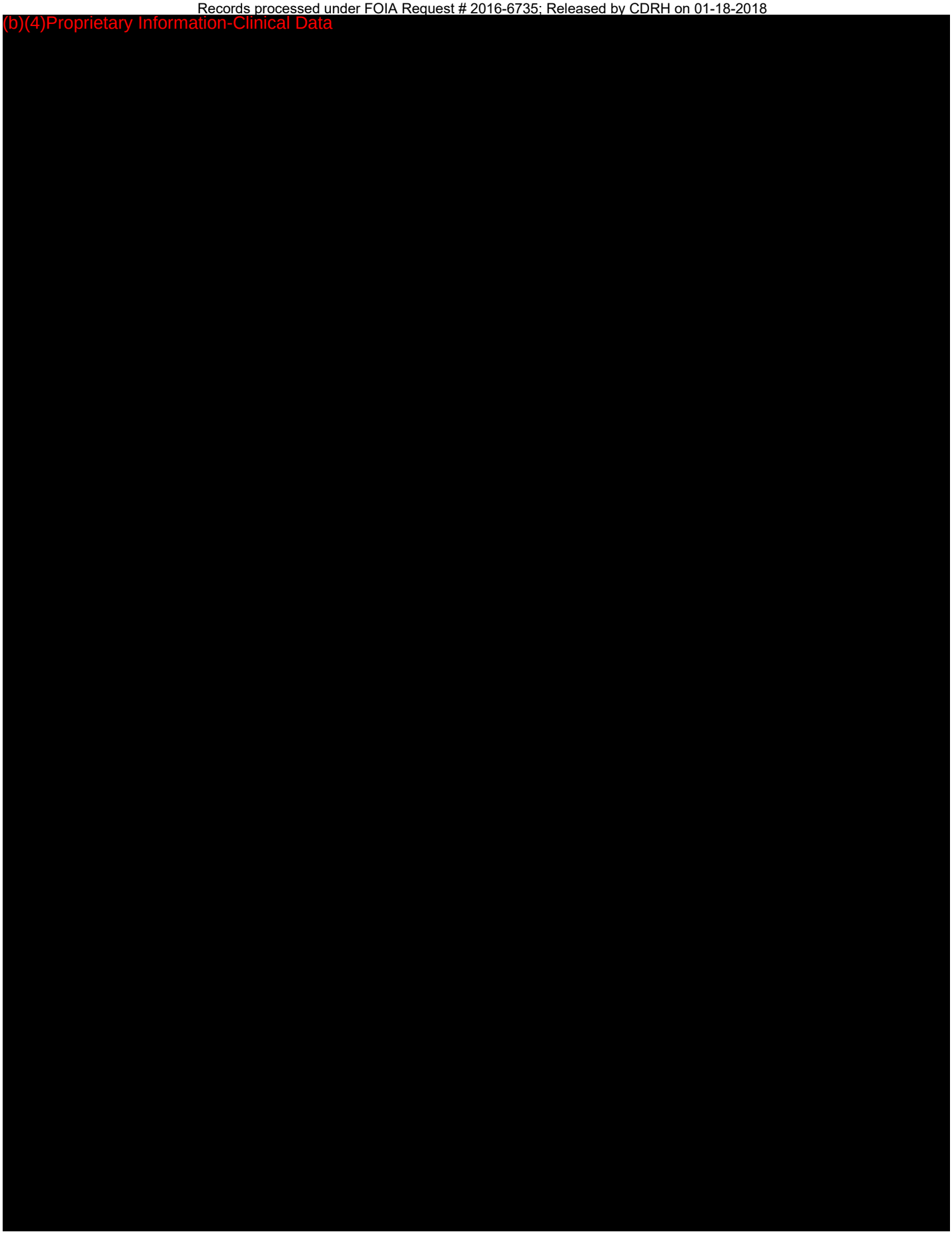
(b)(4)Proprietary Information-Clinical Data



(b)(4)Proprietary Information-Clinical Data

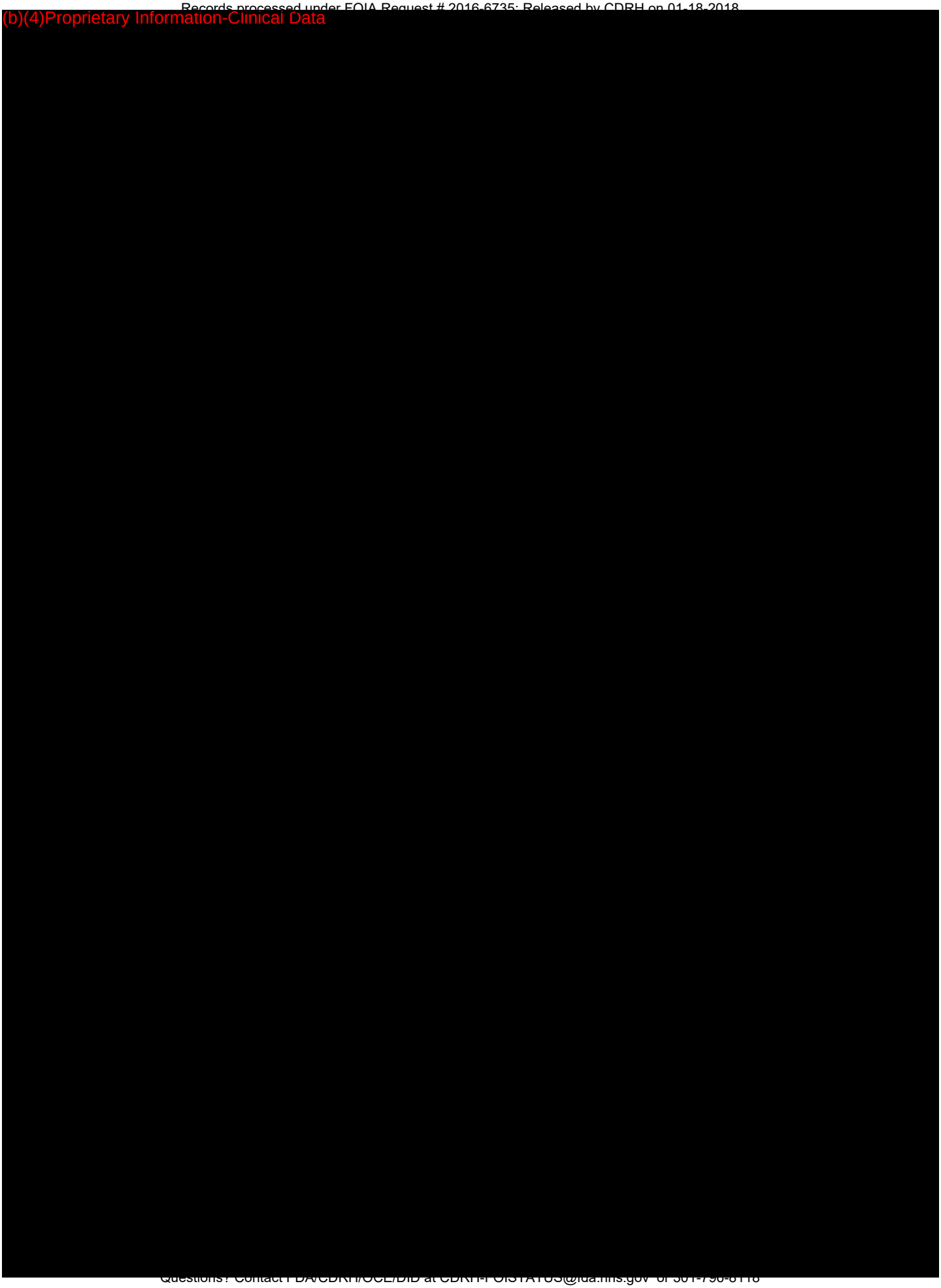
[redacted]

(b)(4)Proprietary Information-Clinical Data



(b)(4)Proprietary Information-Clinical Data

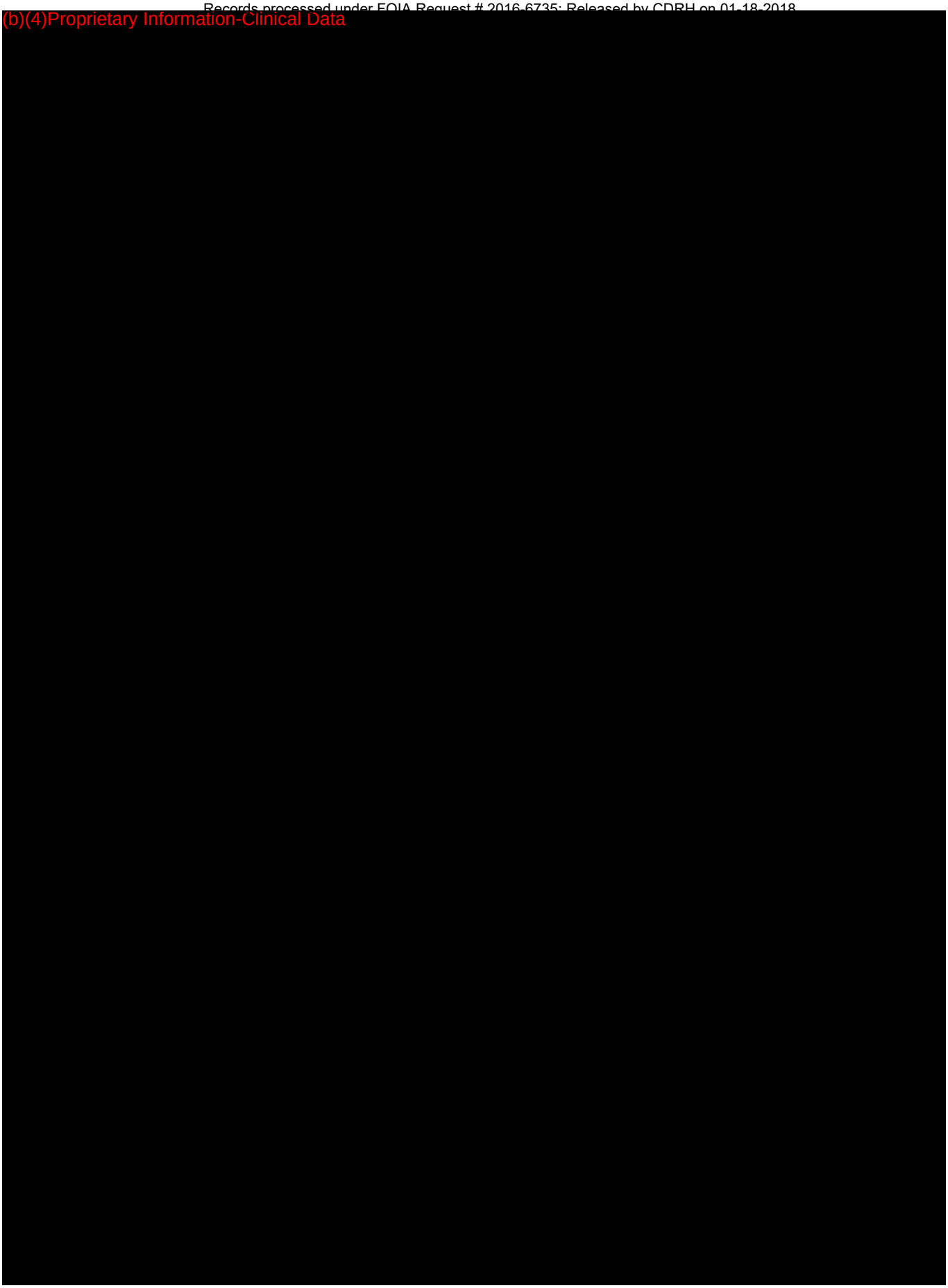
(b)(4)Proprietary Information-Clinical Data



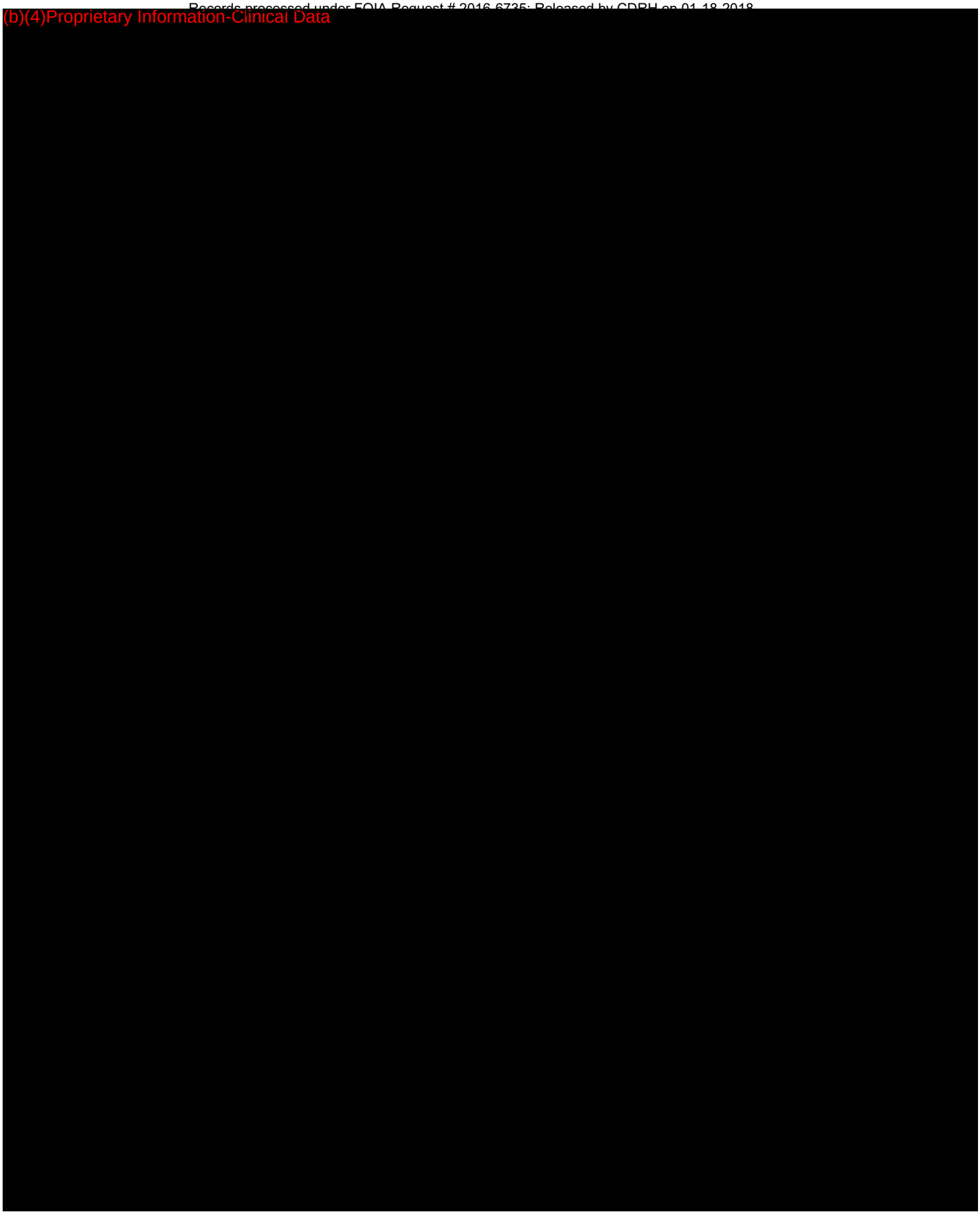
(b)(4)Proprietary Information-Clinical Data

[redacted]

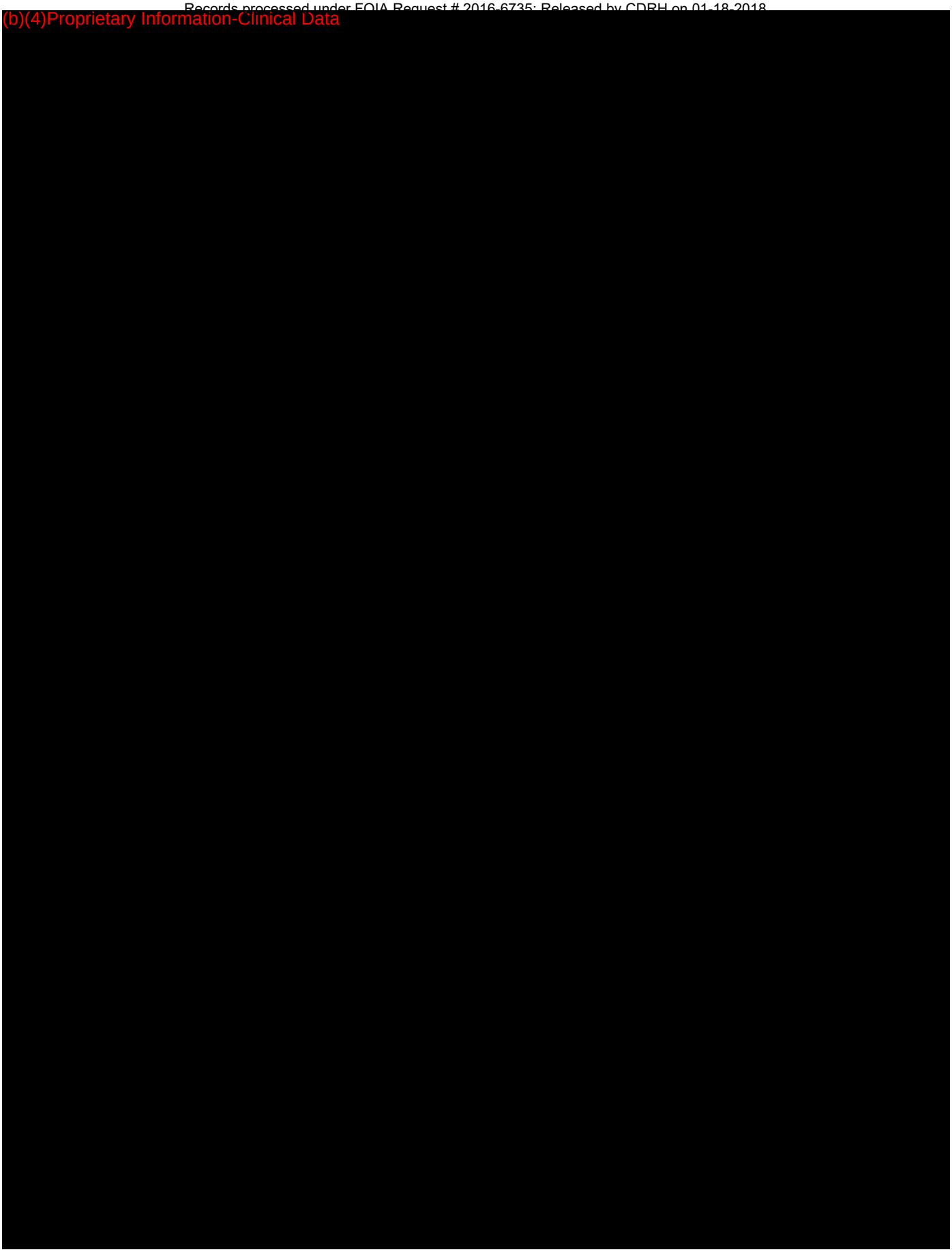
(b)(4)Proprietary Information-Clinical Data



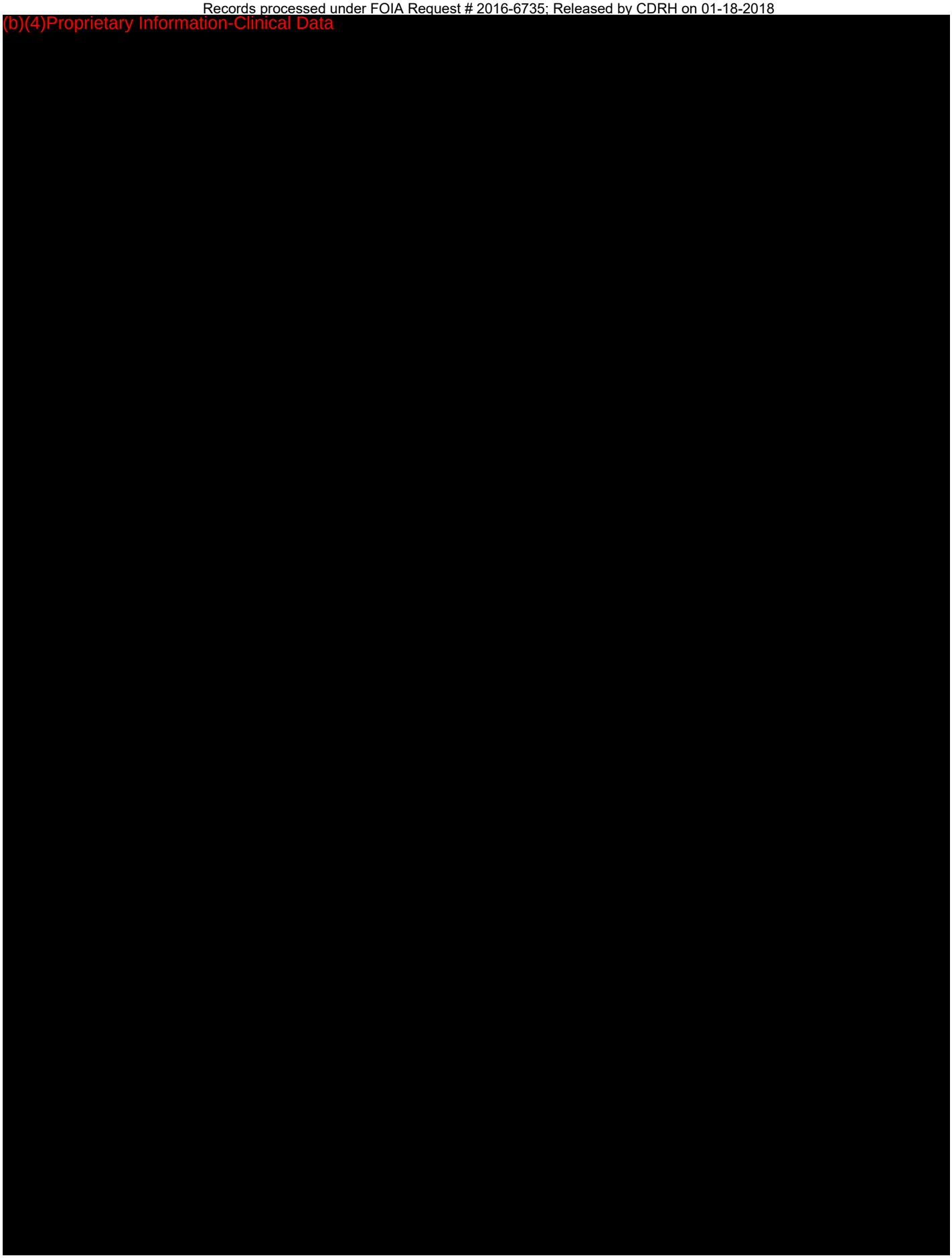
(b)(4)Proprietary Information-Clinical Data



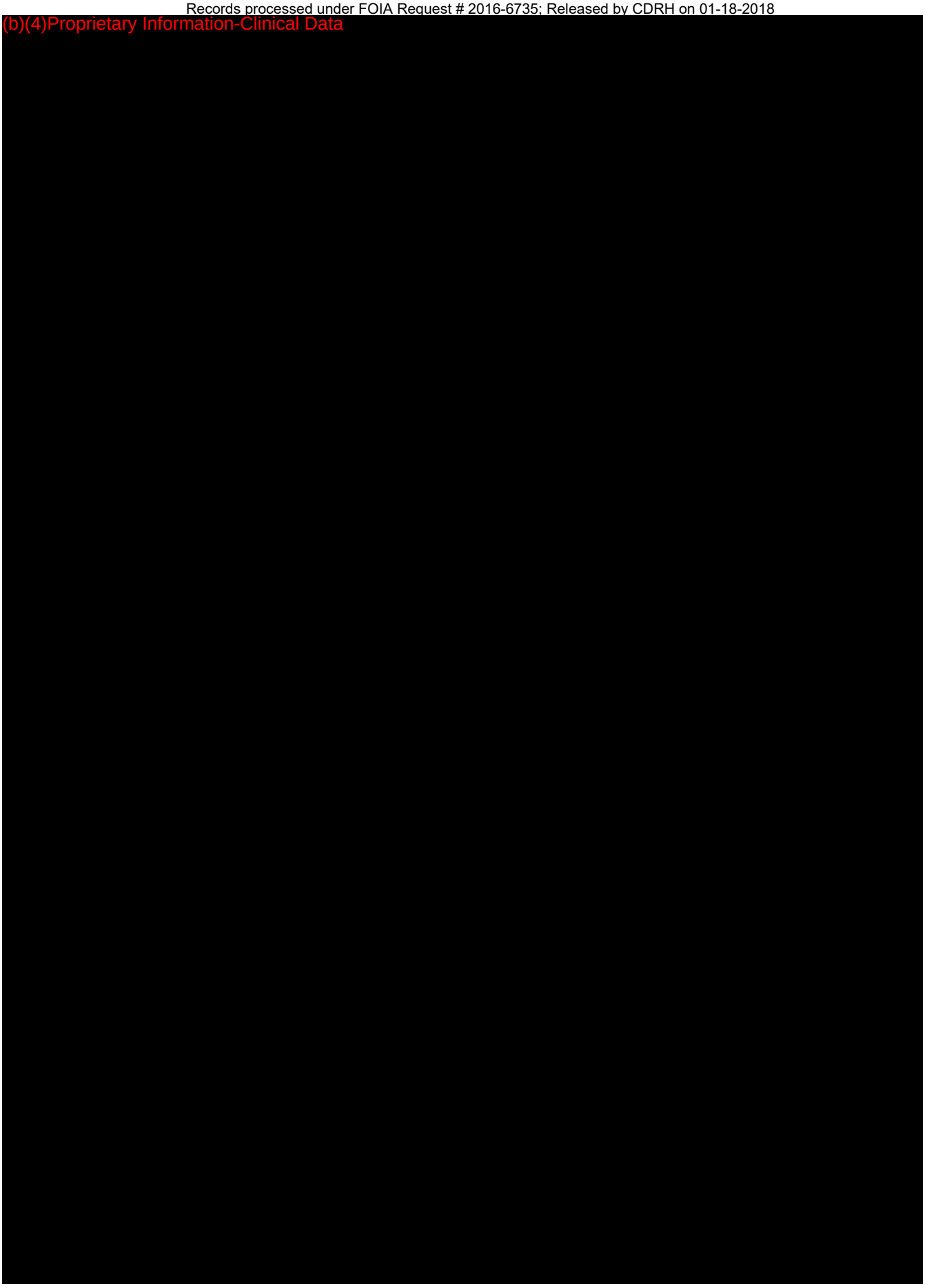
(b)(4)Proprietary Information-Clinical Data



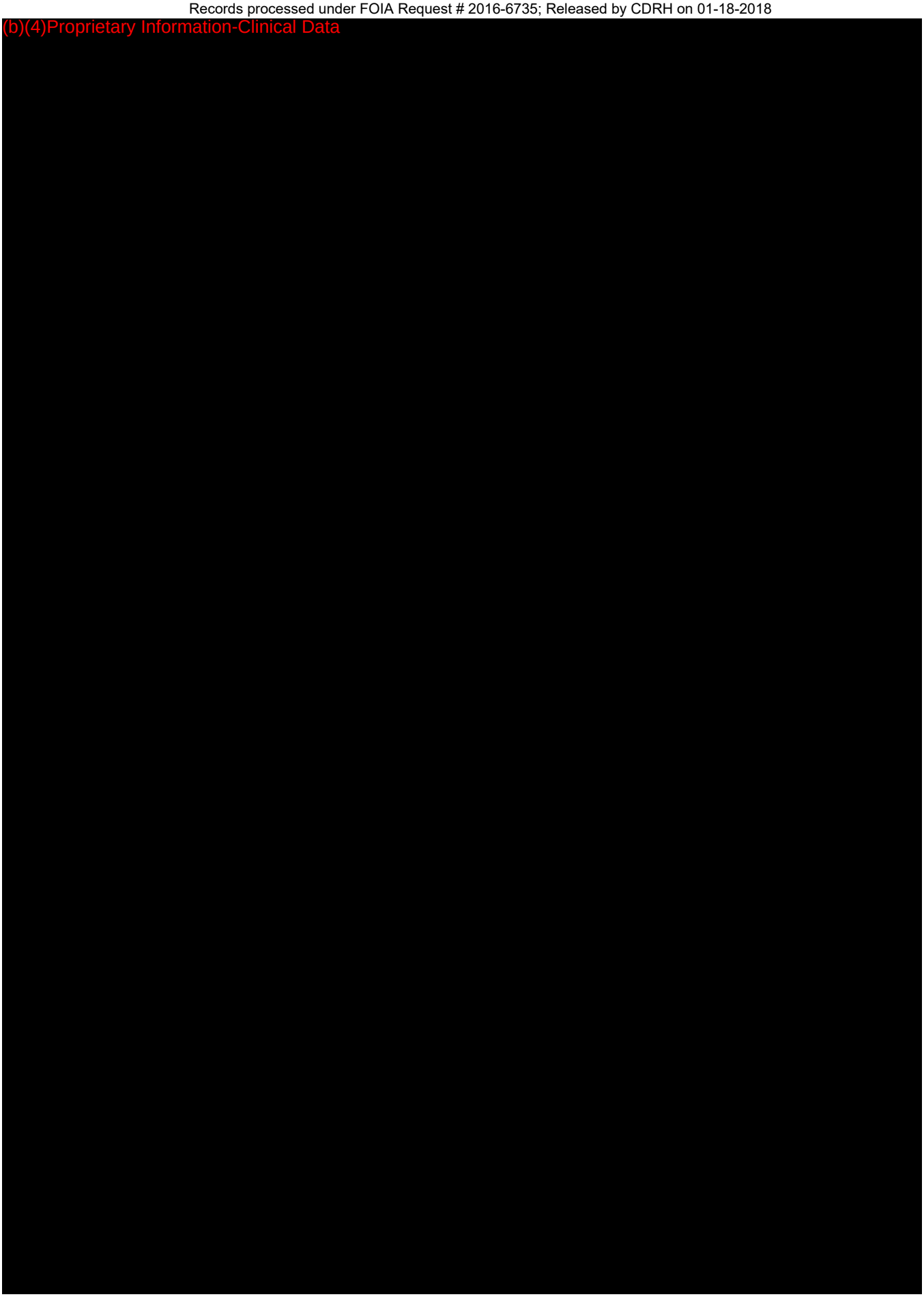
(b)(4)Proprietary Information-Clinical Data



(b)(4)Proprietary Information-Clinical Data



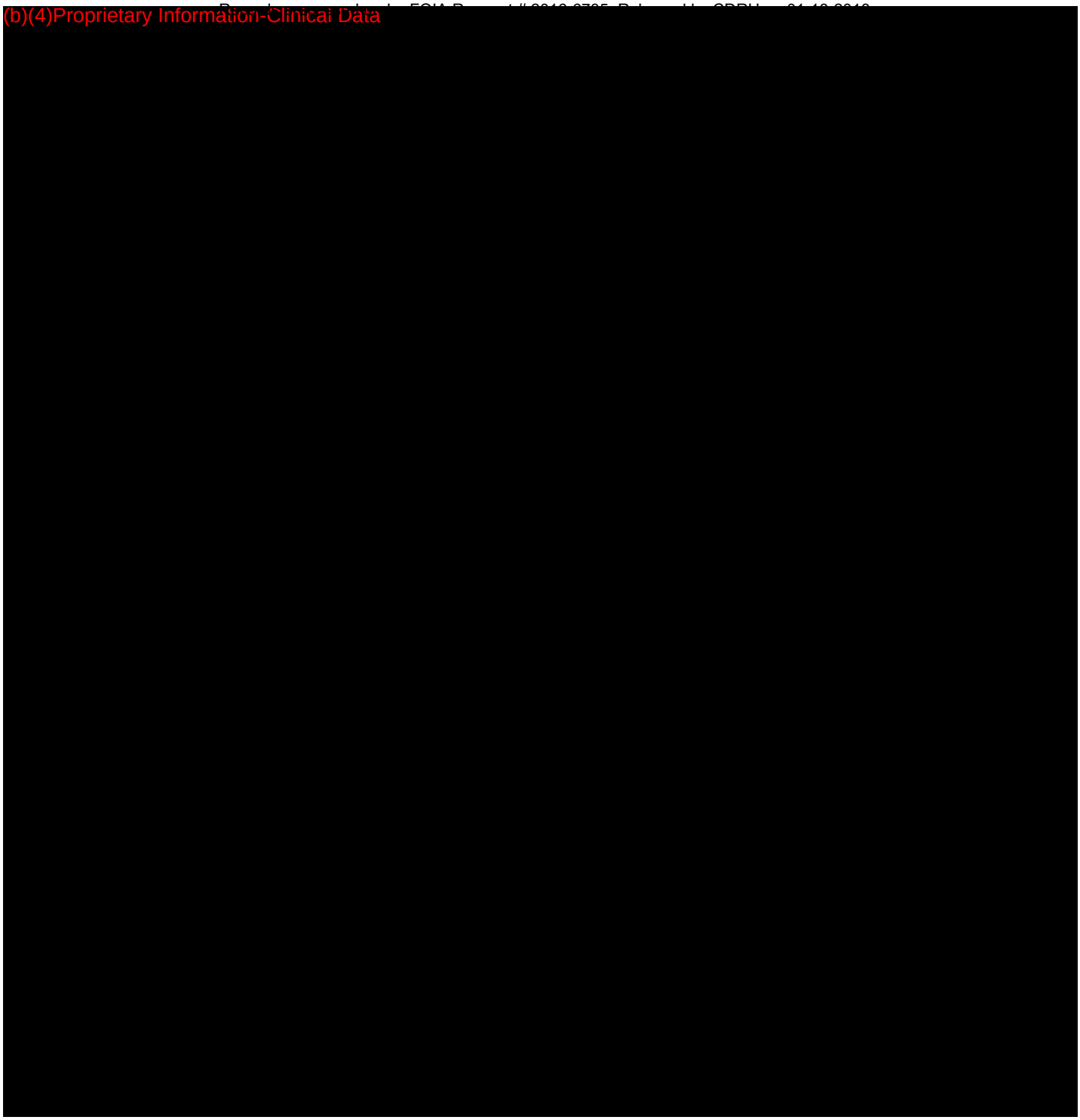
(b)(4)Proprietary Information-Clinical Data



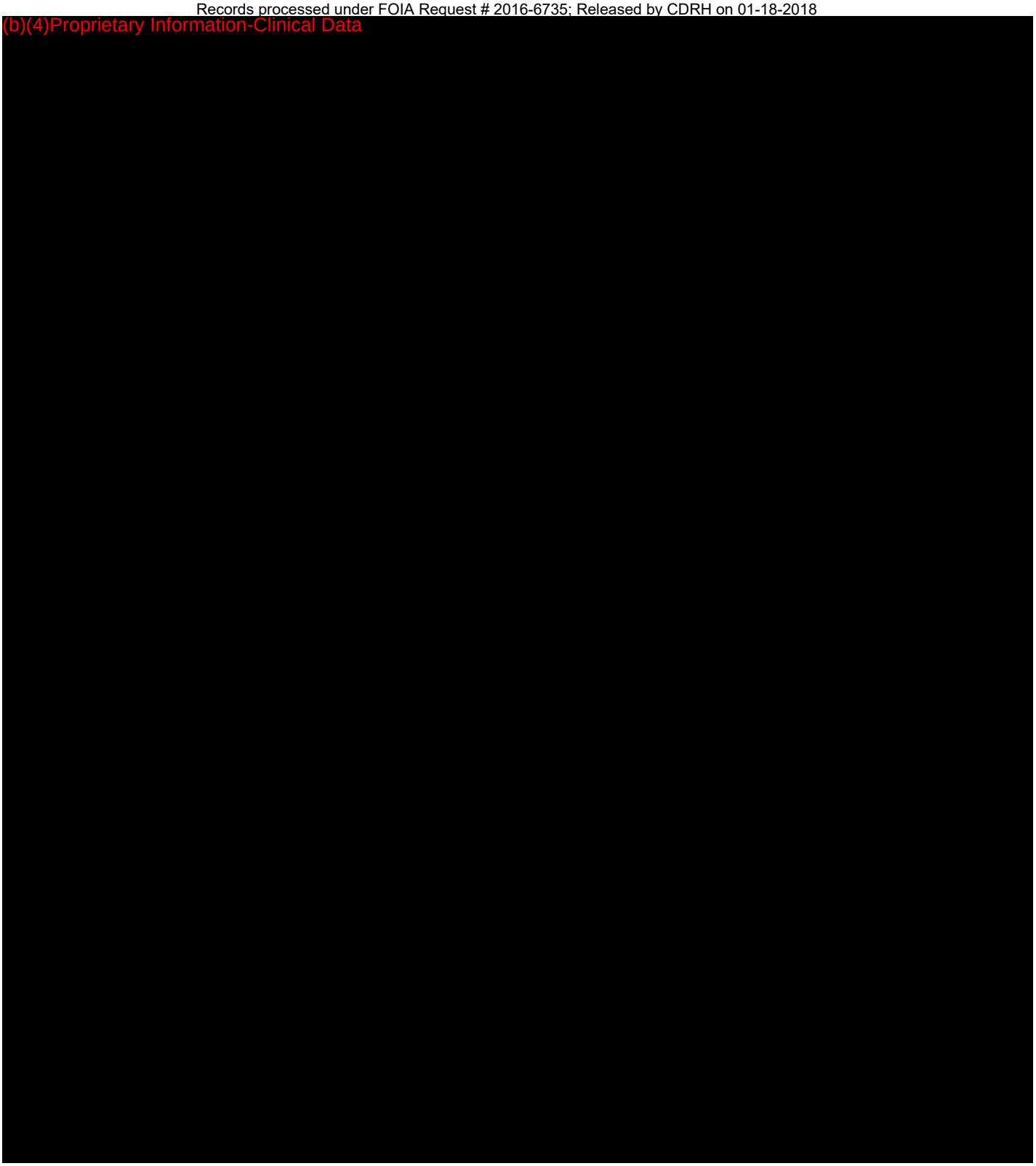
(b)(4)Proprietary Information-Clinical Data

[redacted]

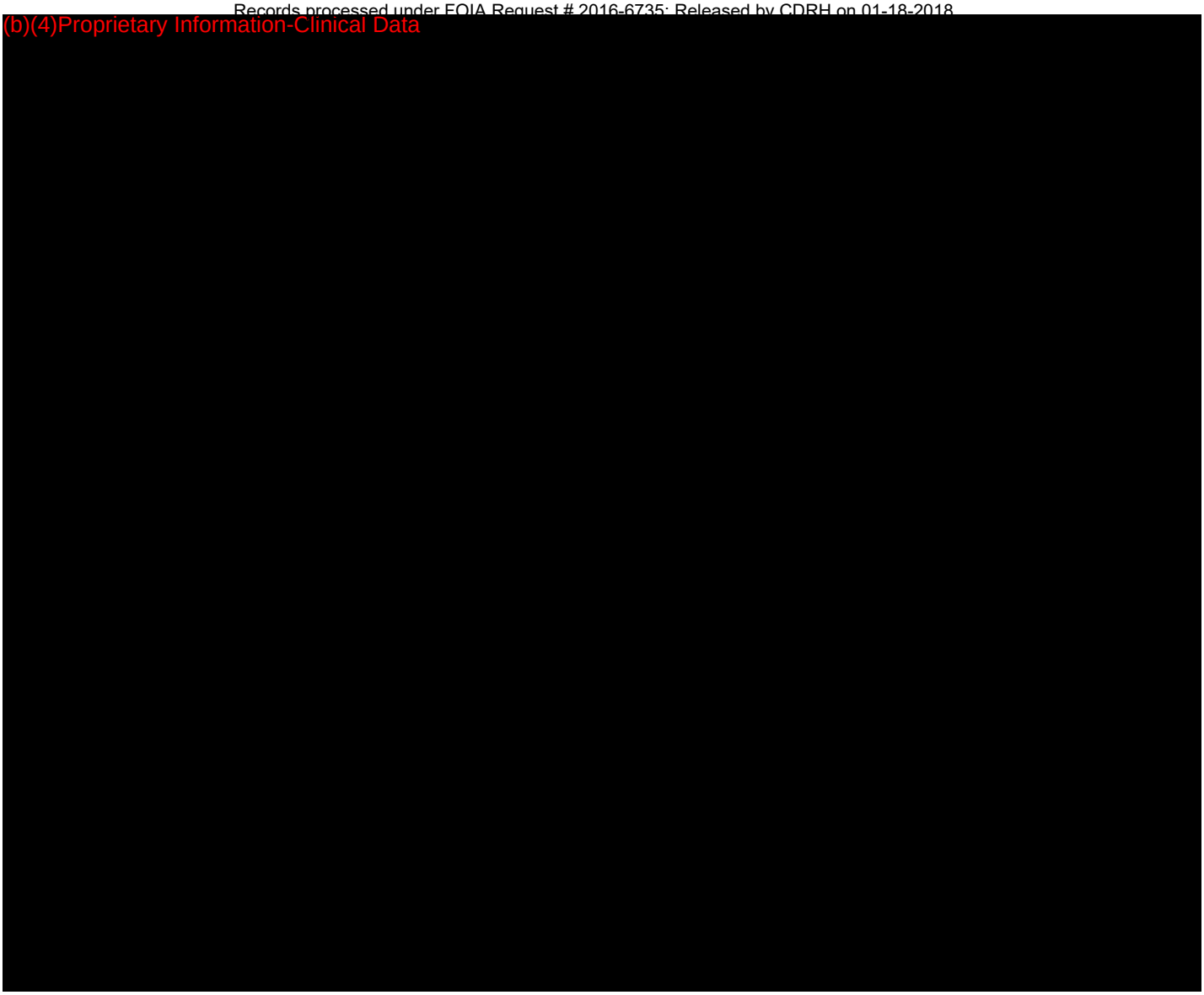
(b)(4)Proprietary Information-Clinical Data



(b)(4)Proprietary Information-Clinical Data

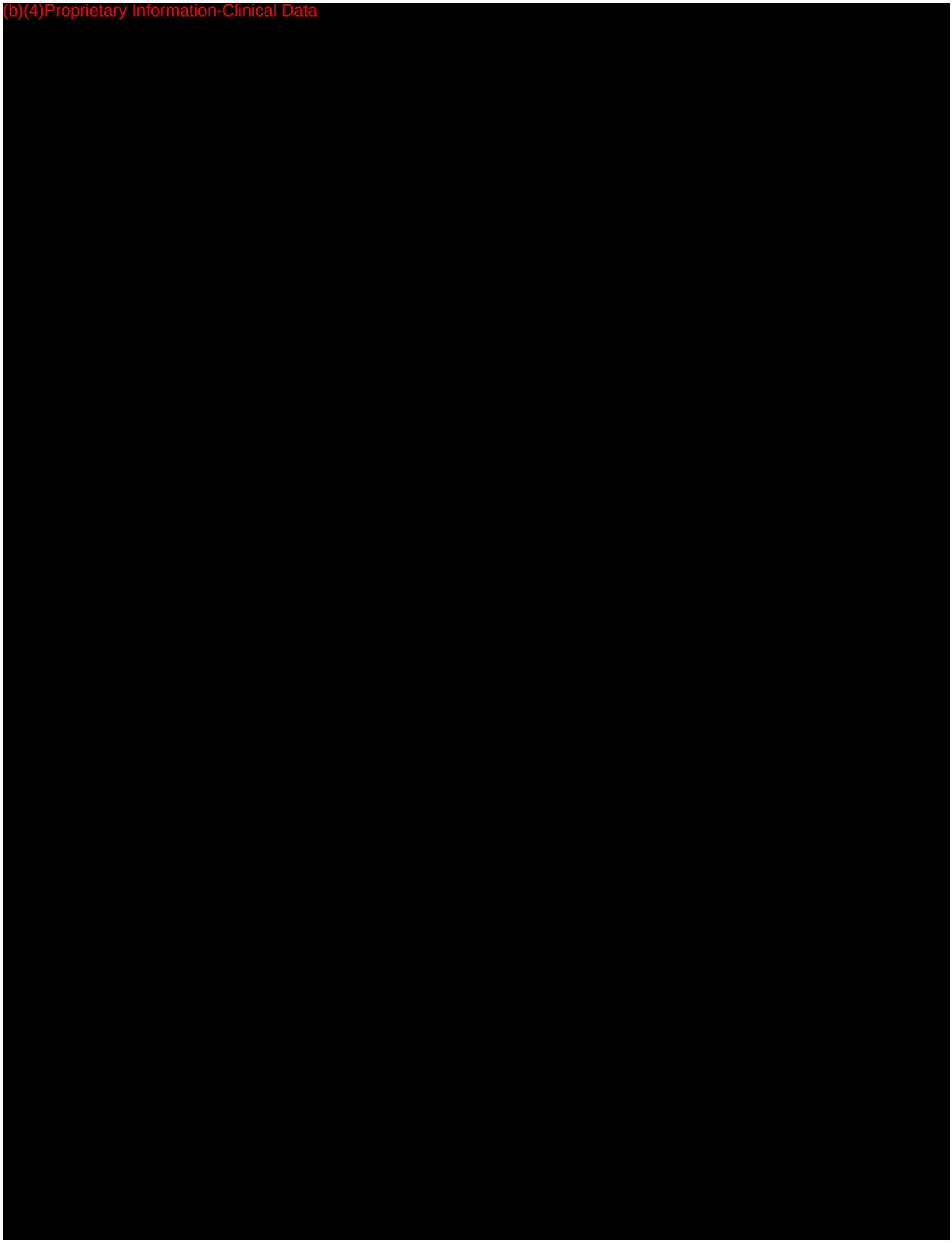


(b)(4)Proprietary Information-Clinical Data

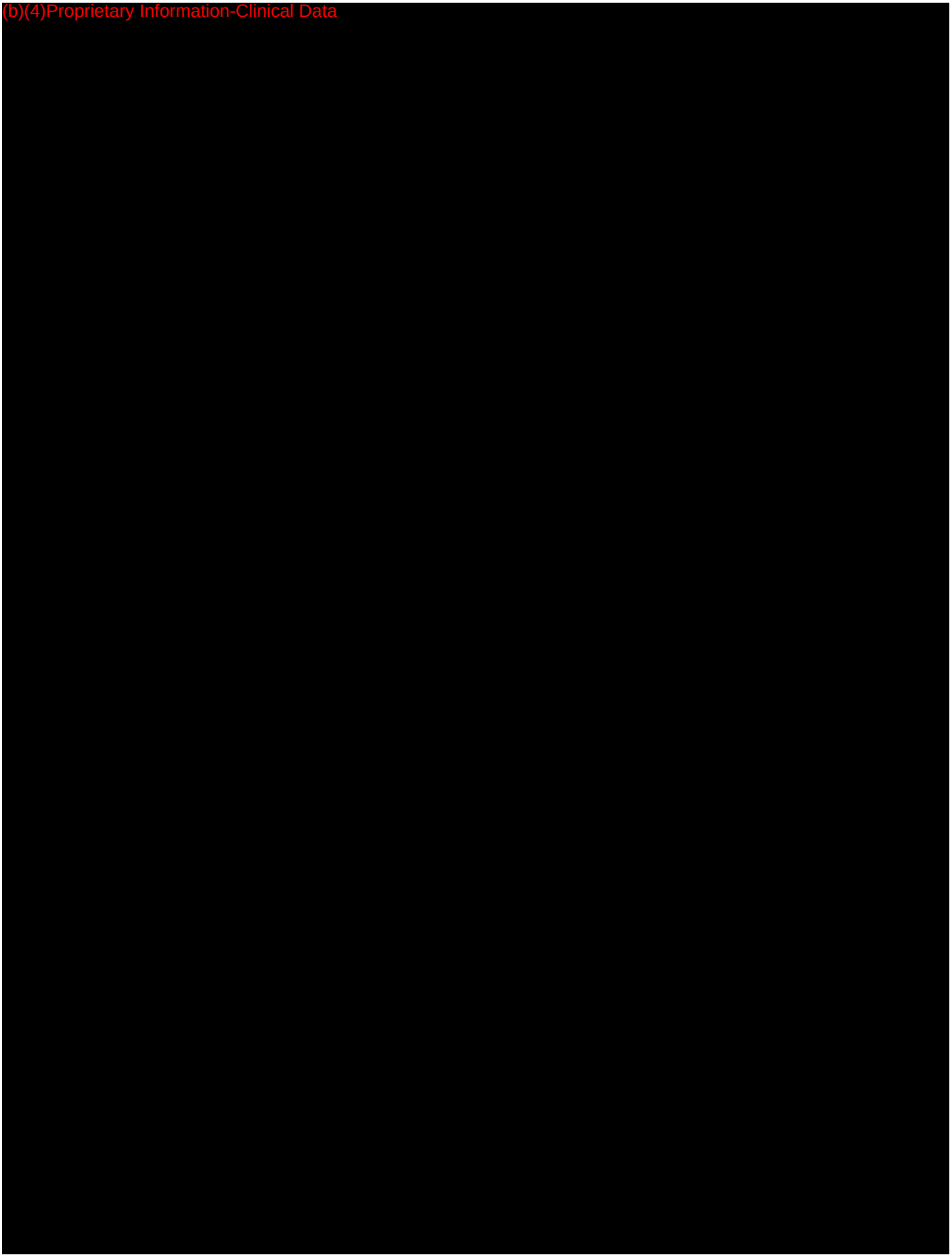


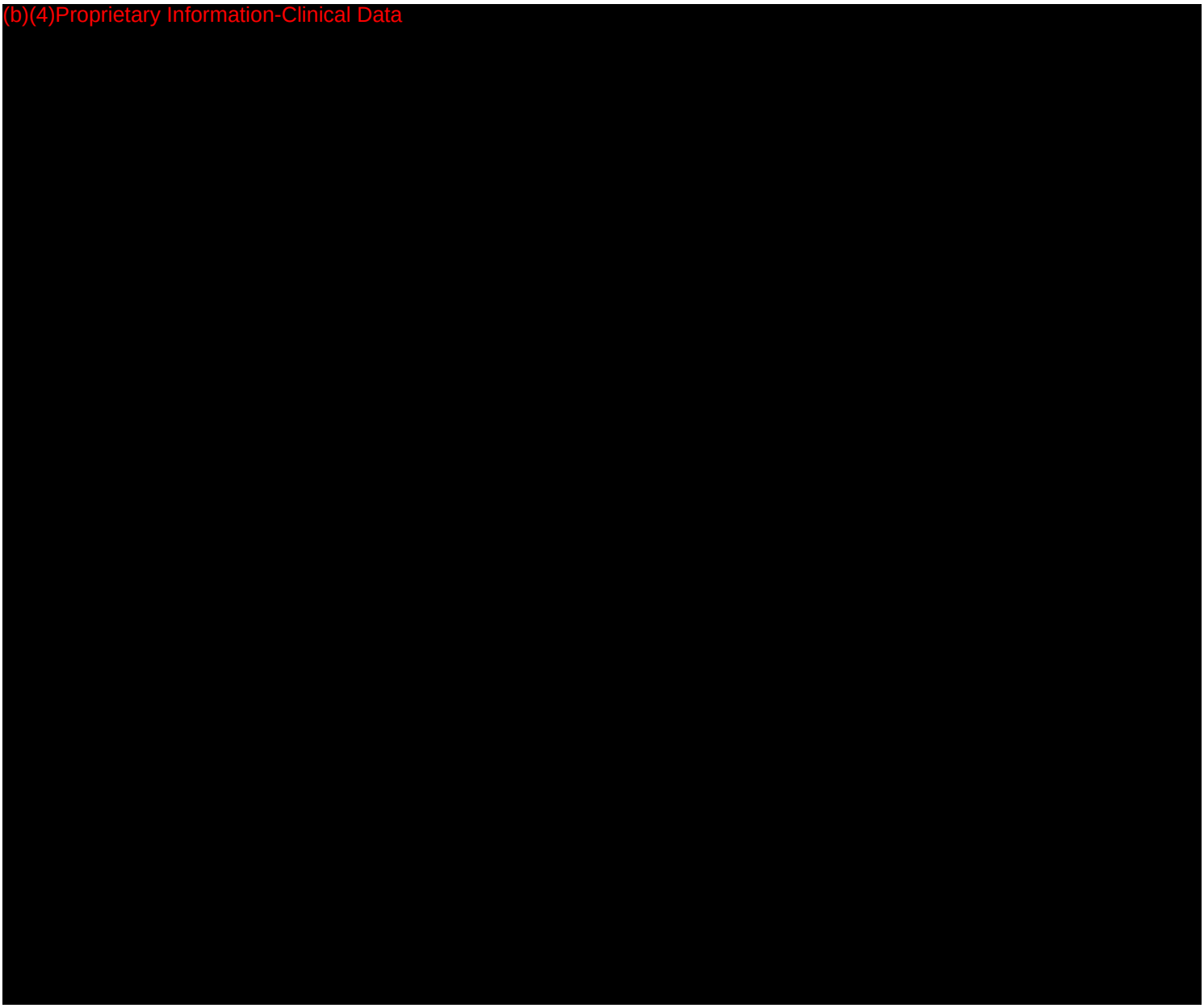
ATTACHMENT 37

(b)(4)Proprietary Information-Clinical Data

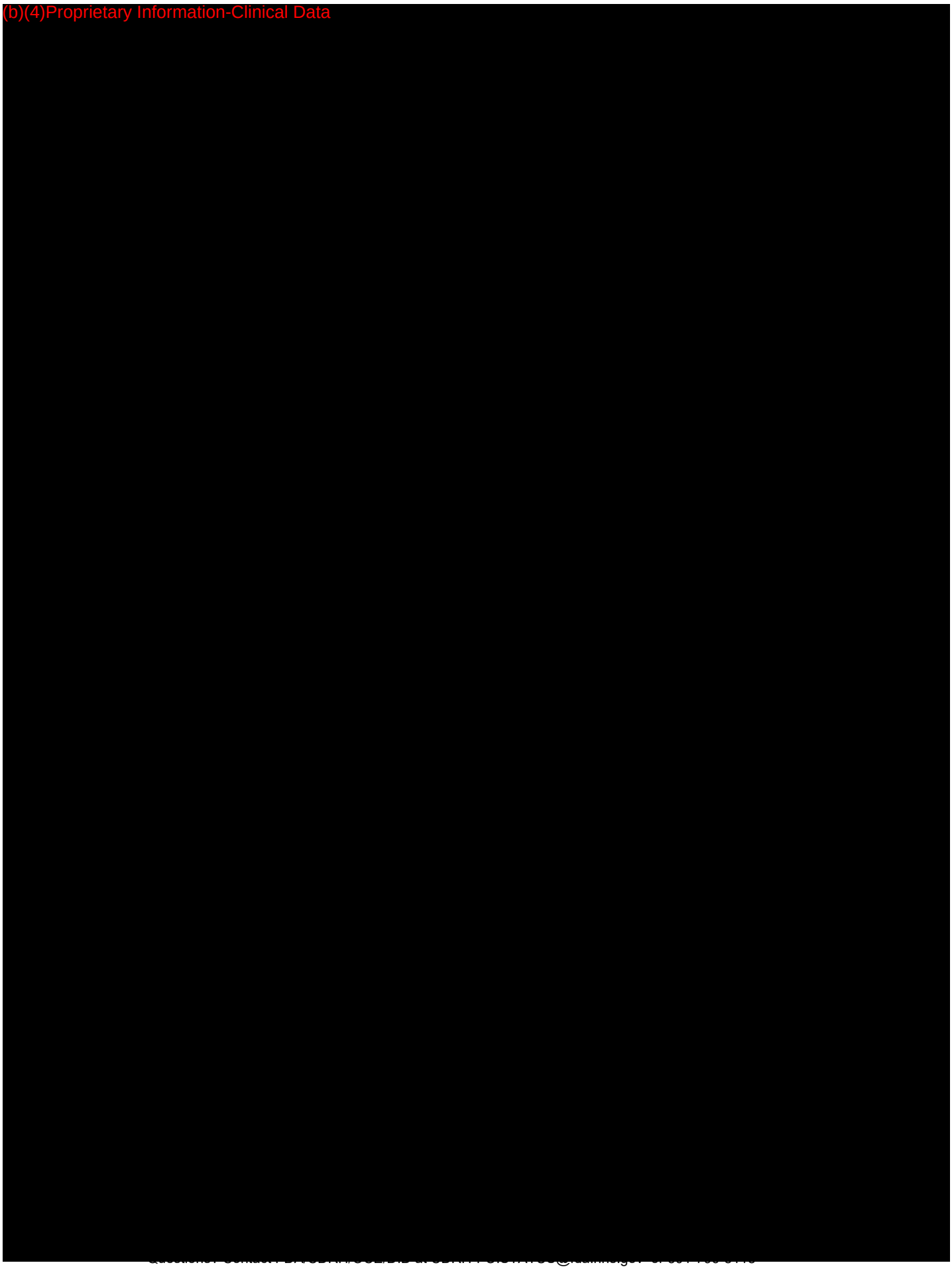


(b)(4)Proprietary Information-Clinical Data

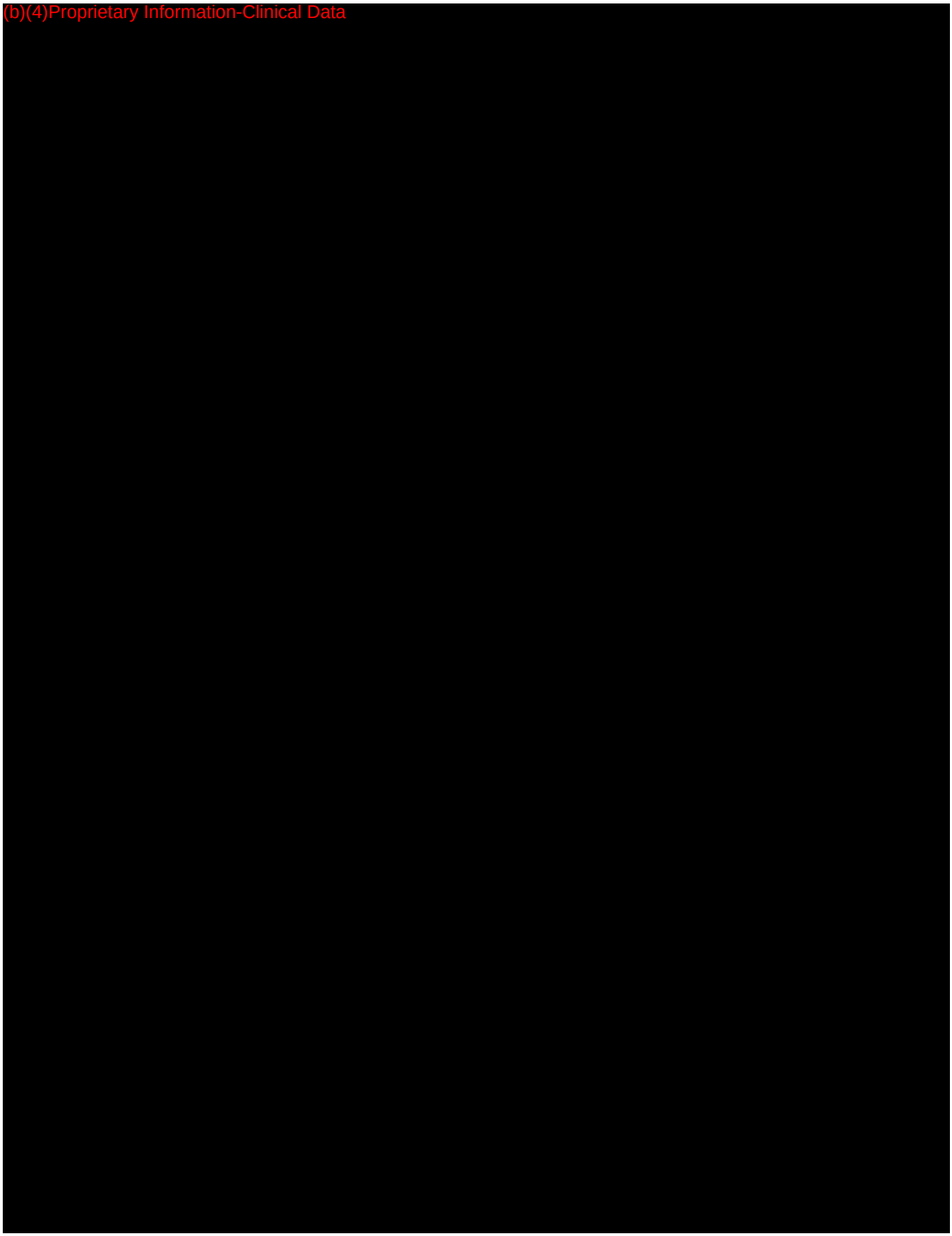


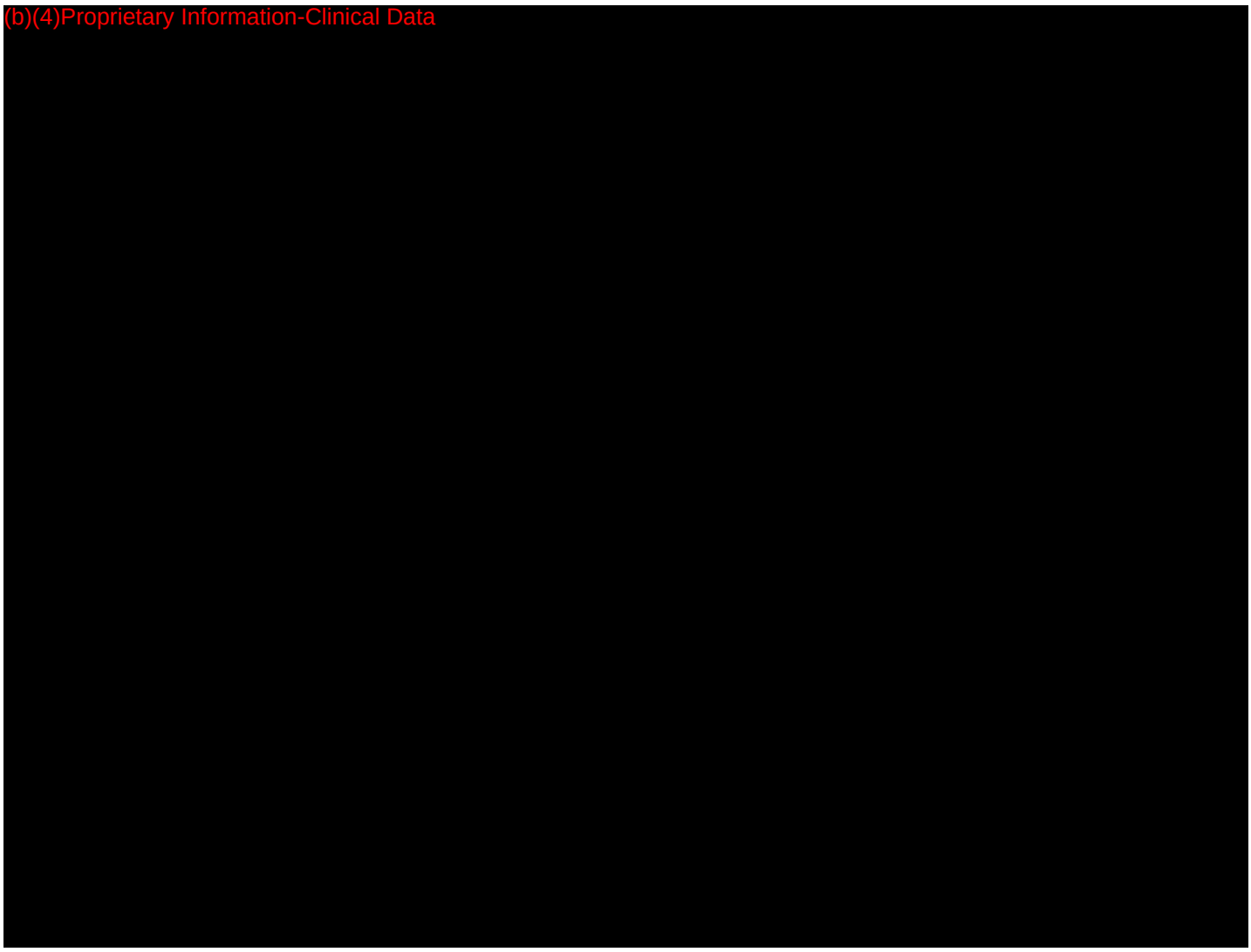


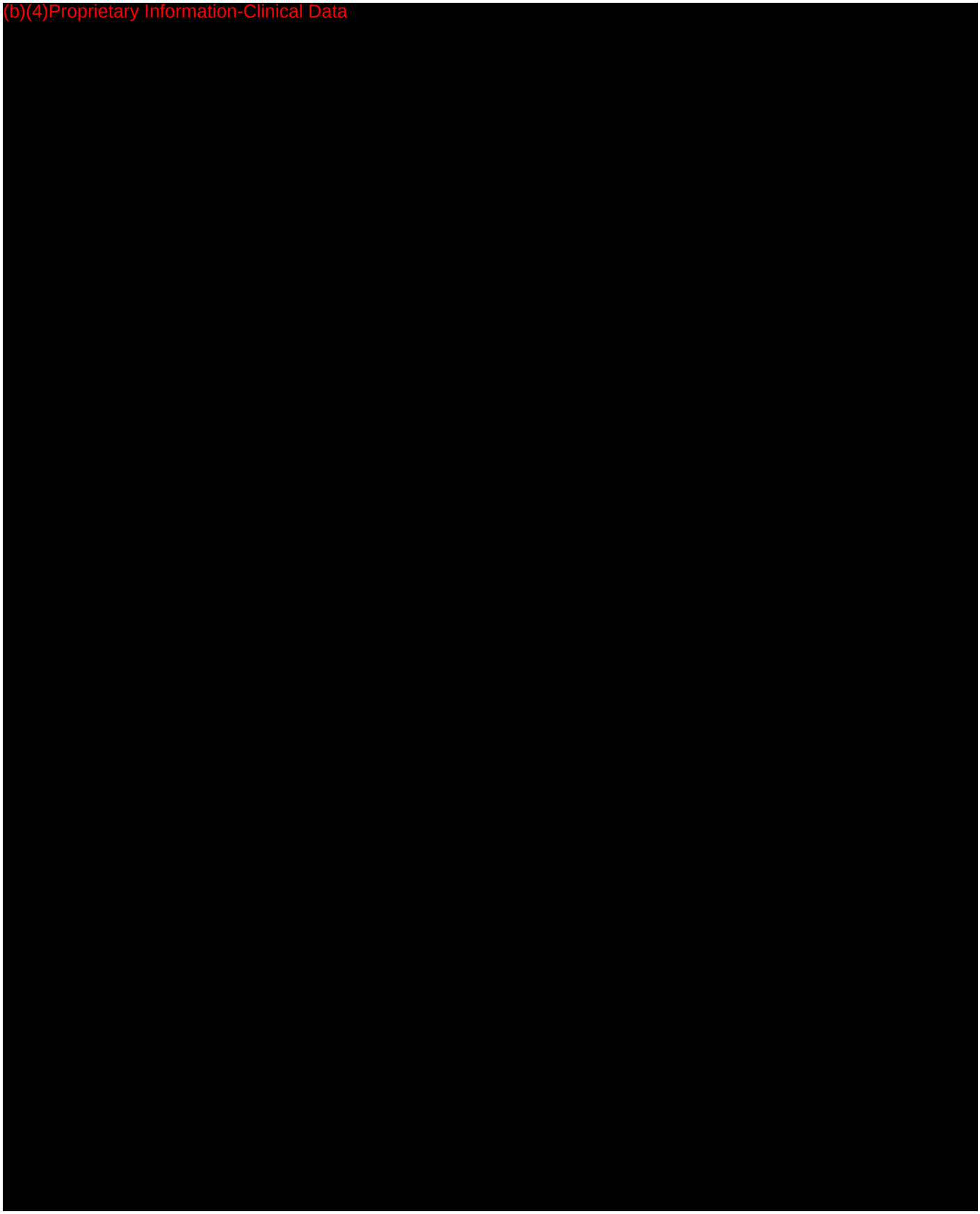
(b)(4)Proprietary Information-Clinical Data

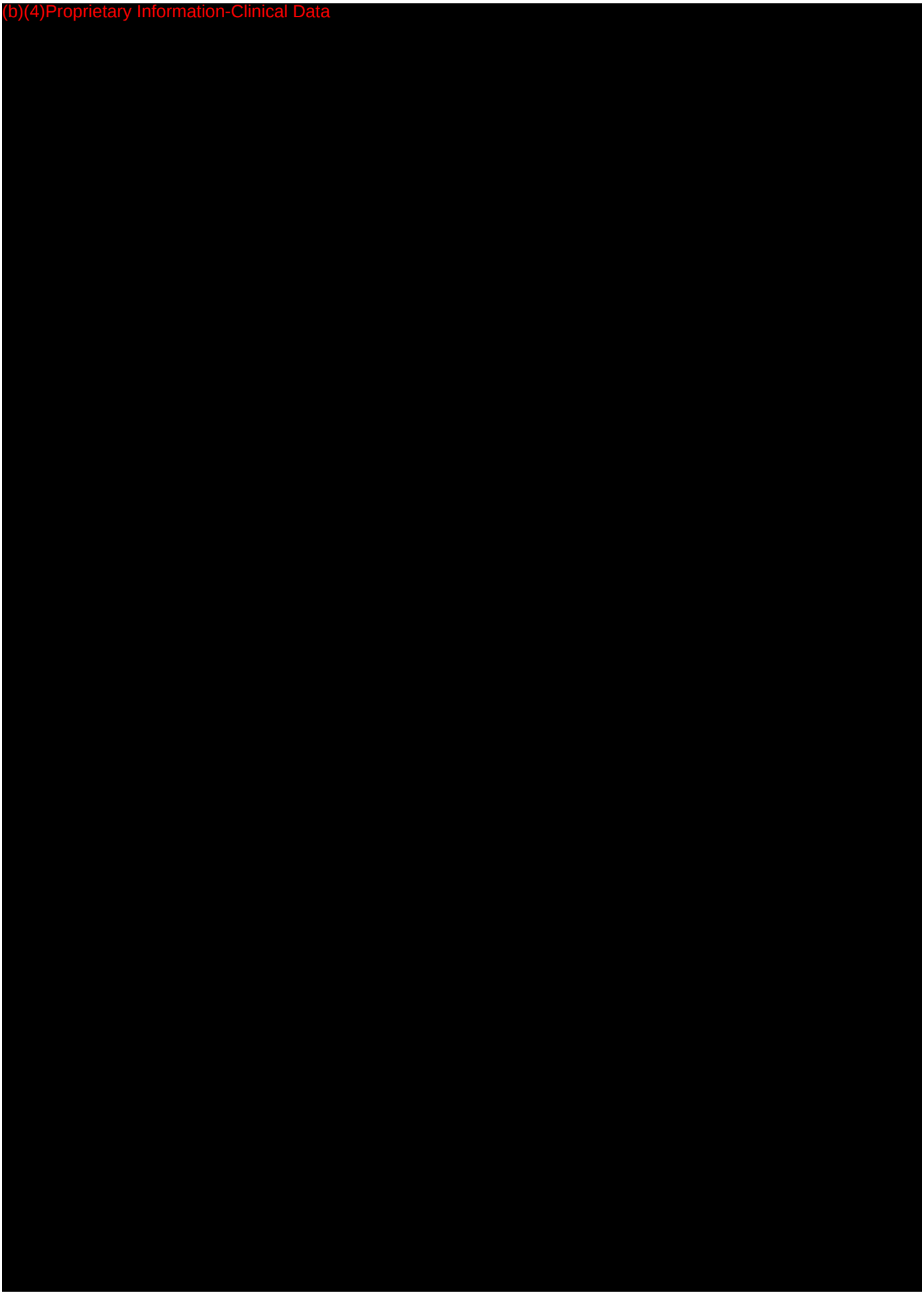


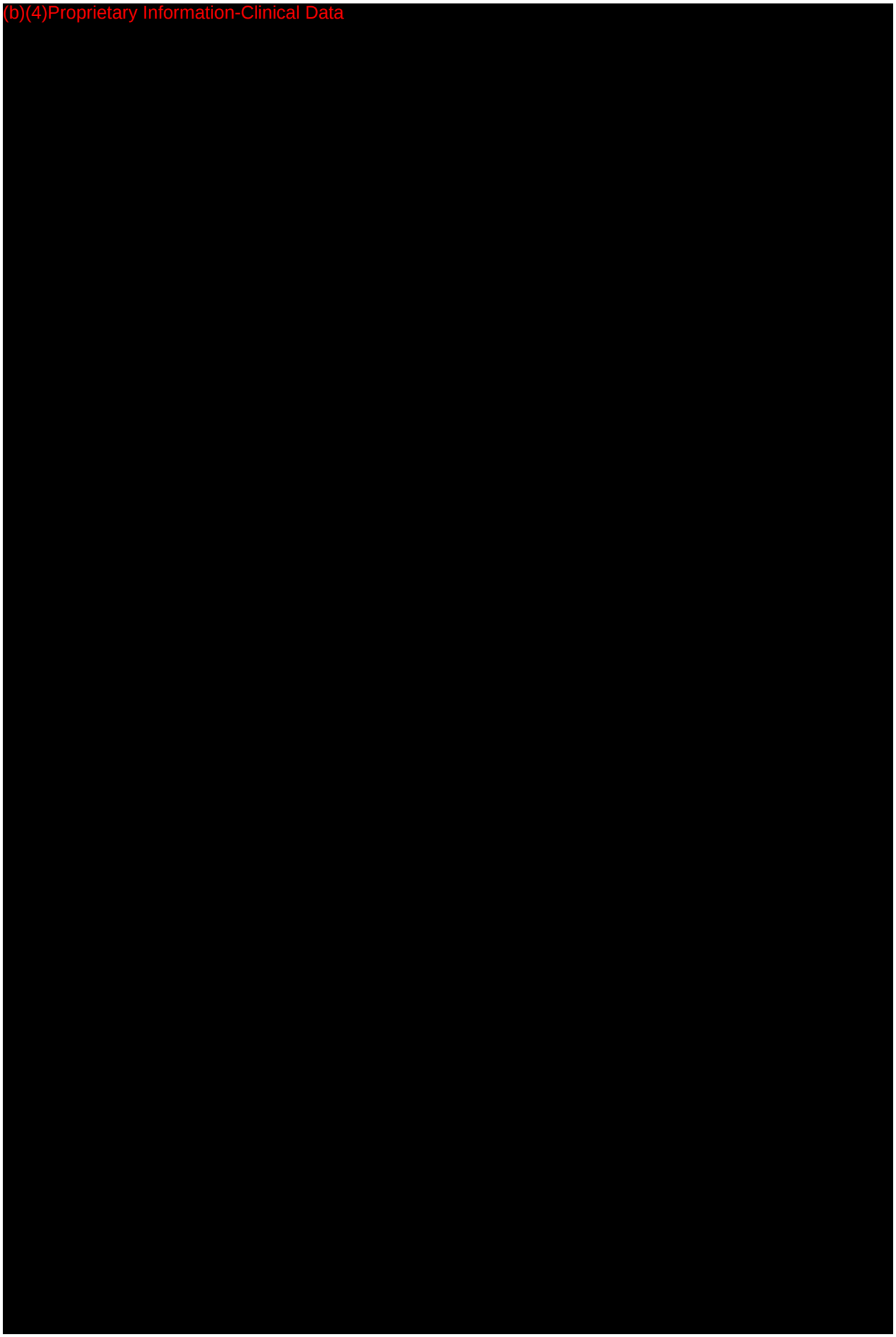
(b)(4)Proprietary Information-Clinical Data



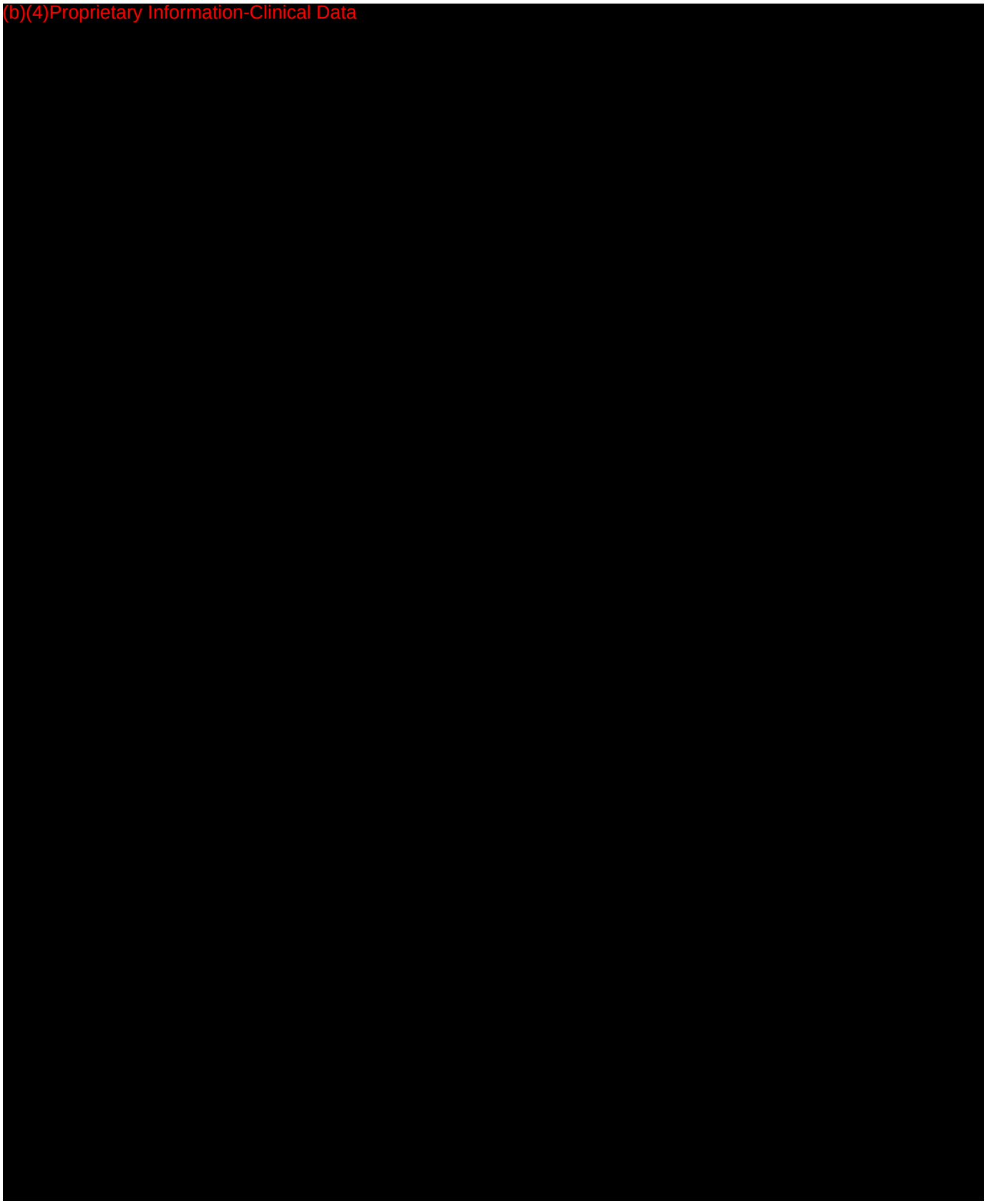


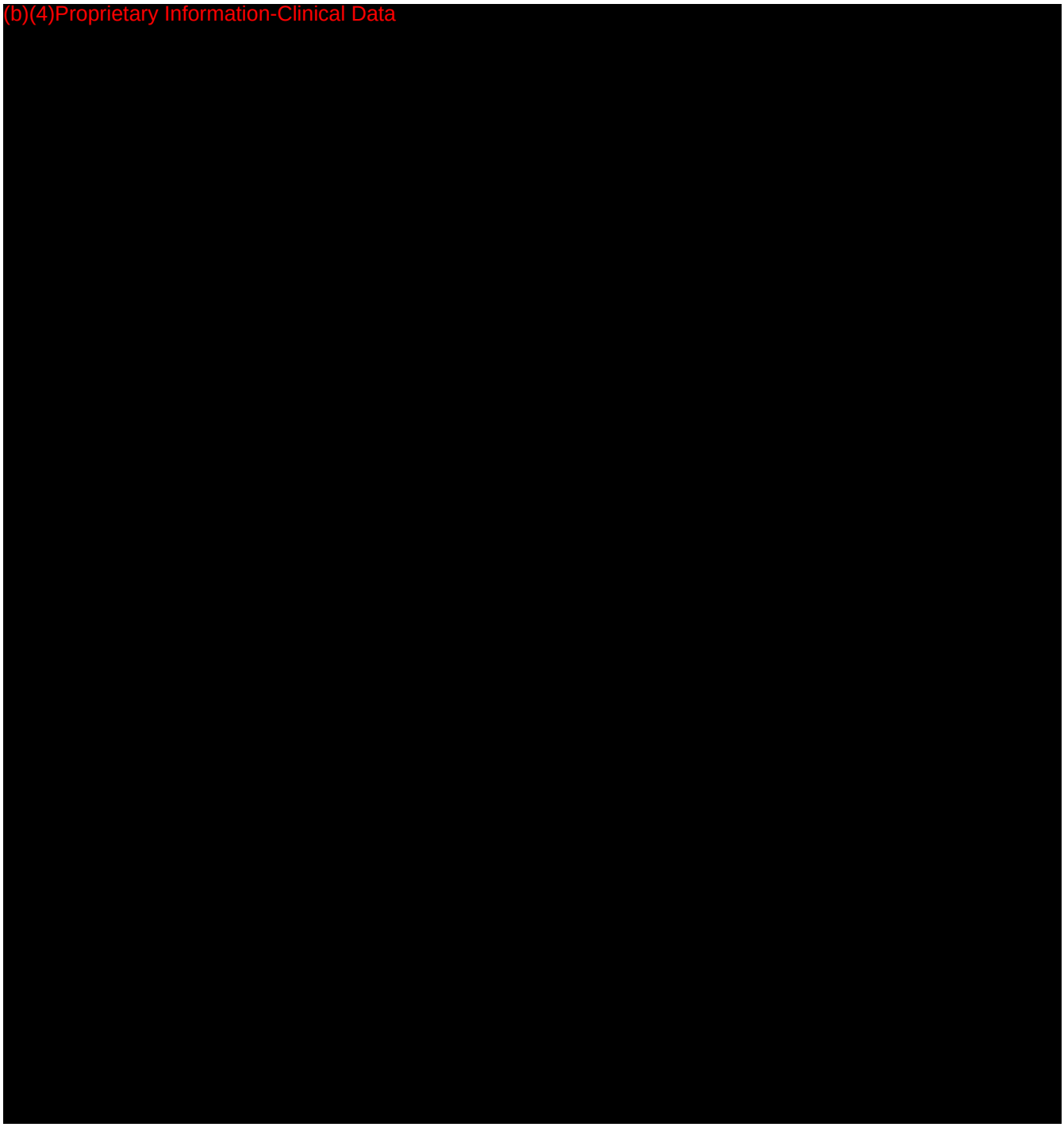


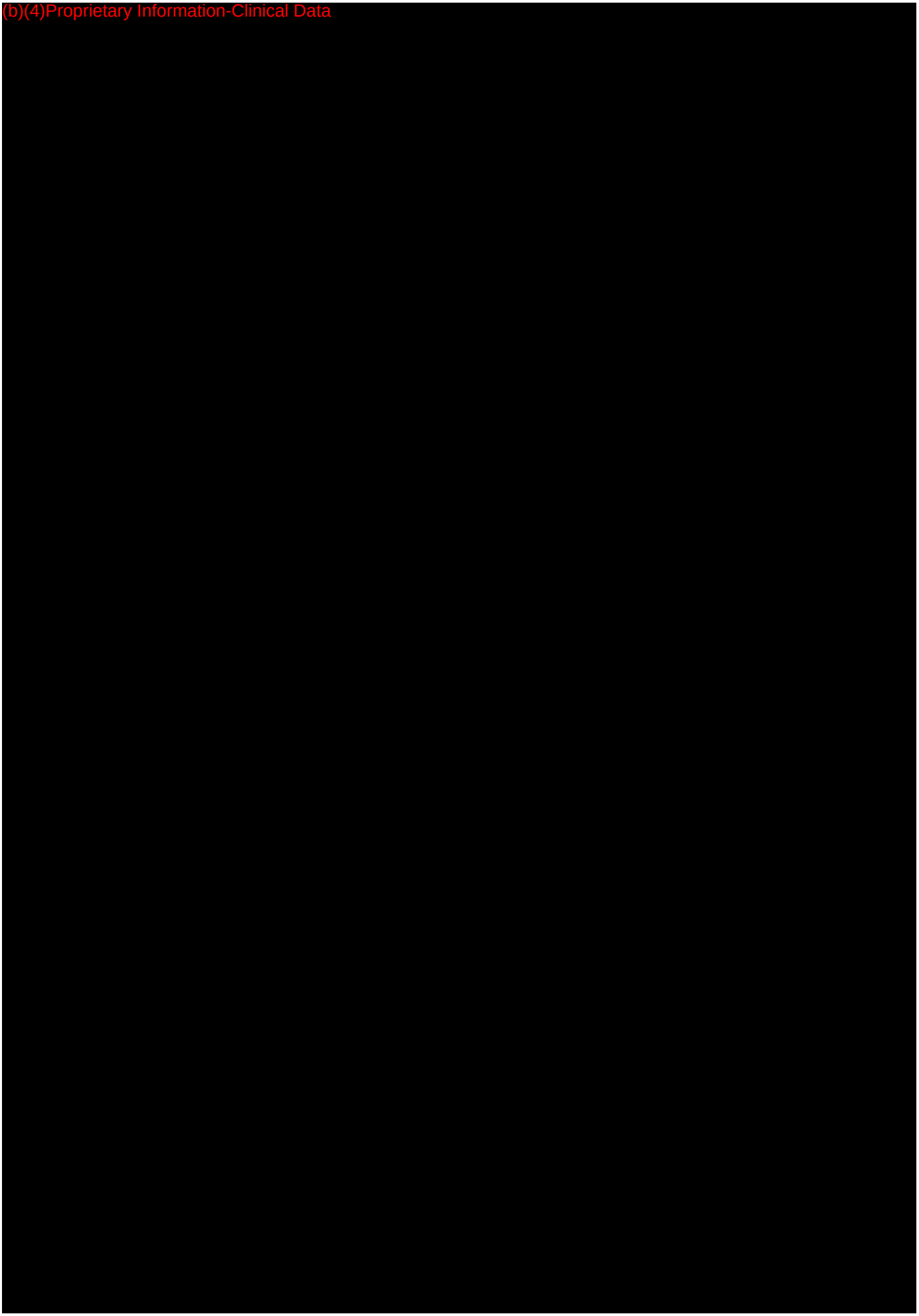


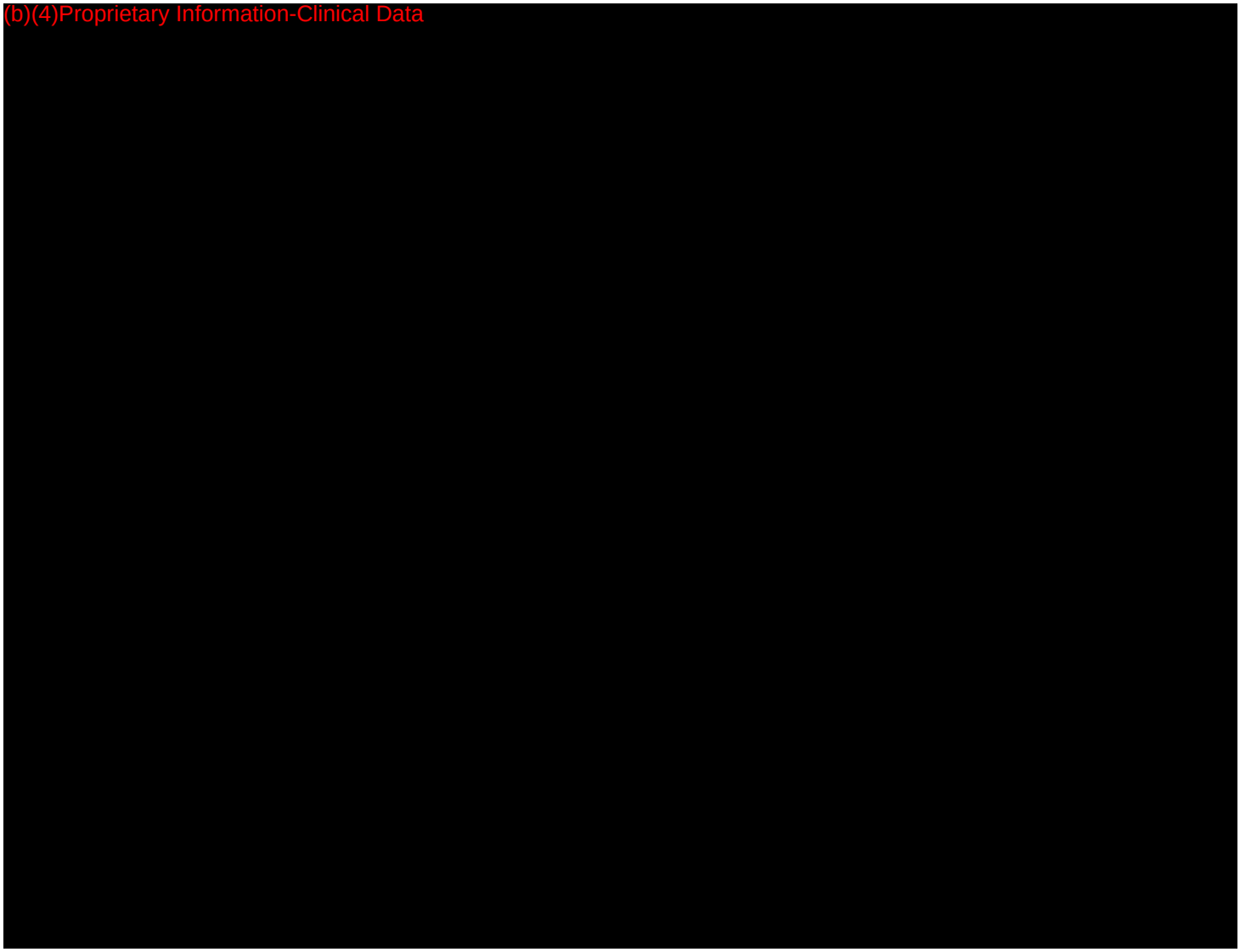


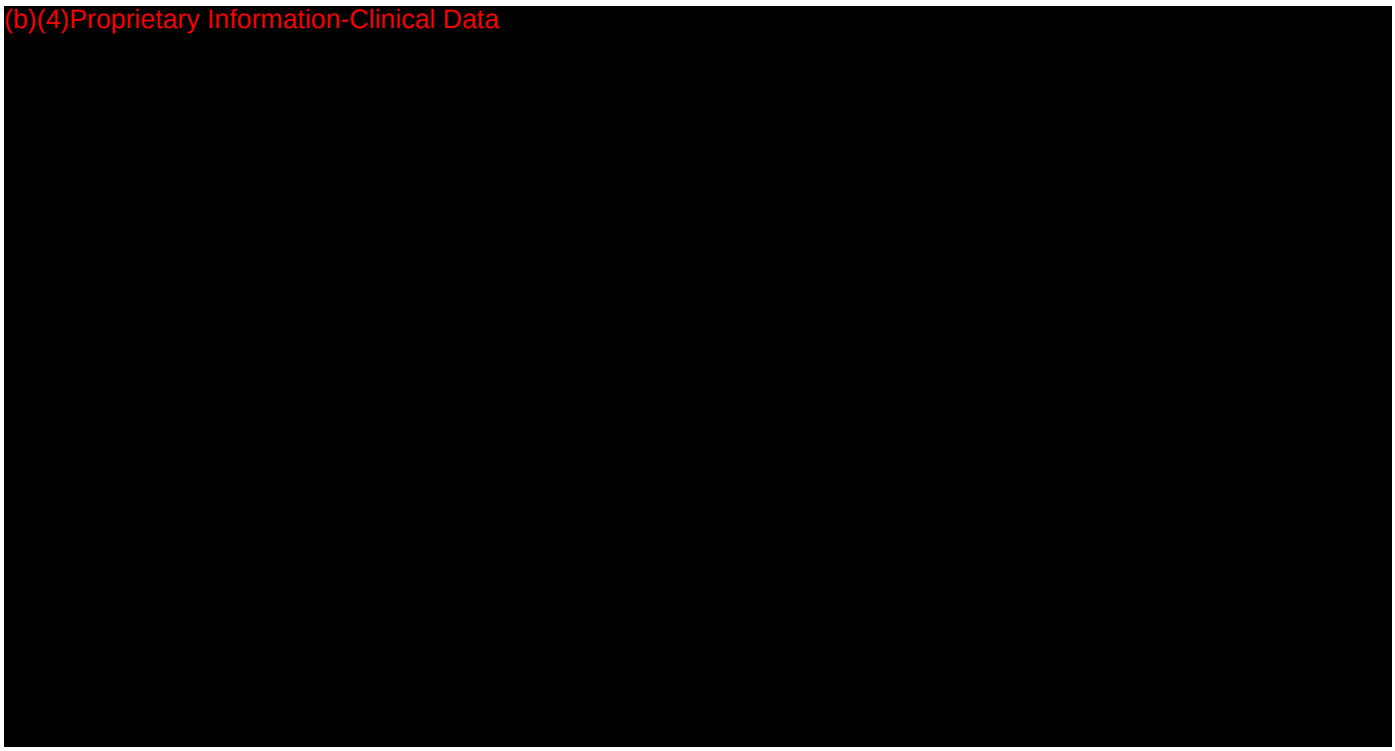
(b)(4)Proprietary Information-Clinical Data

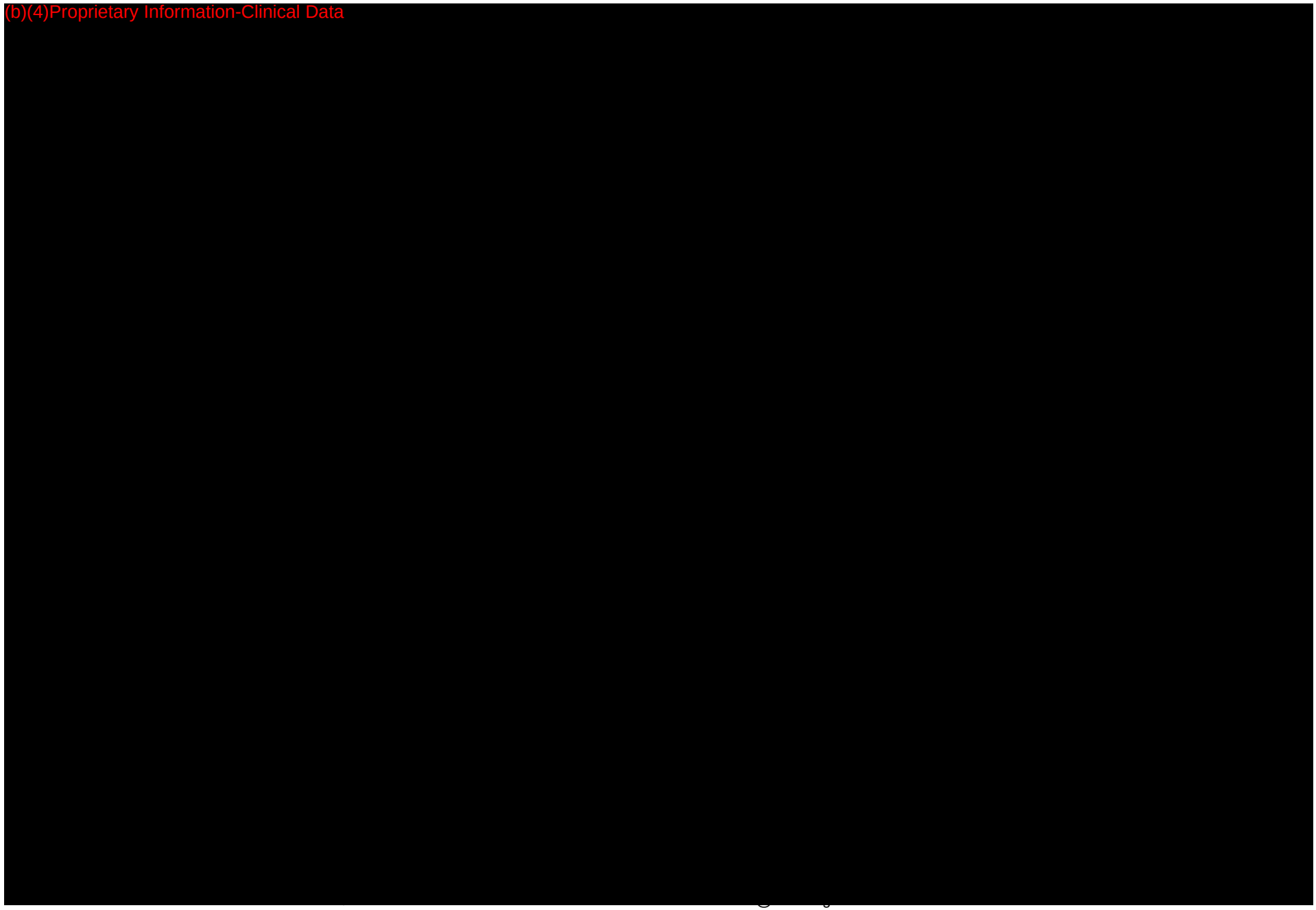


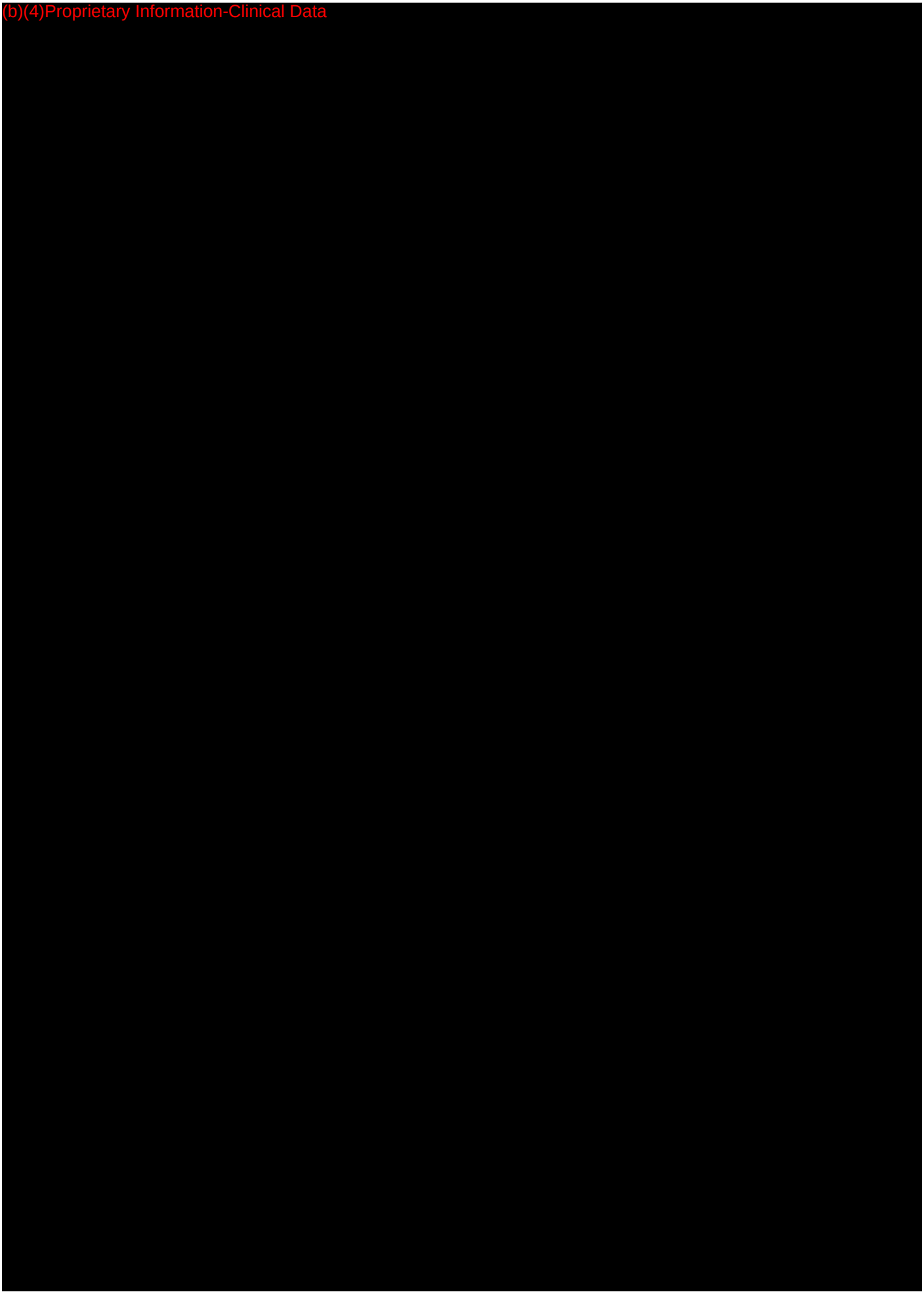




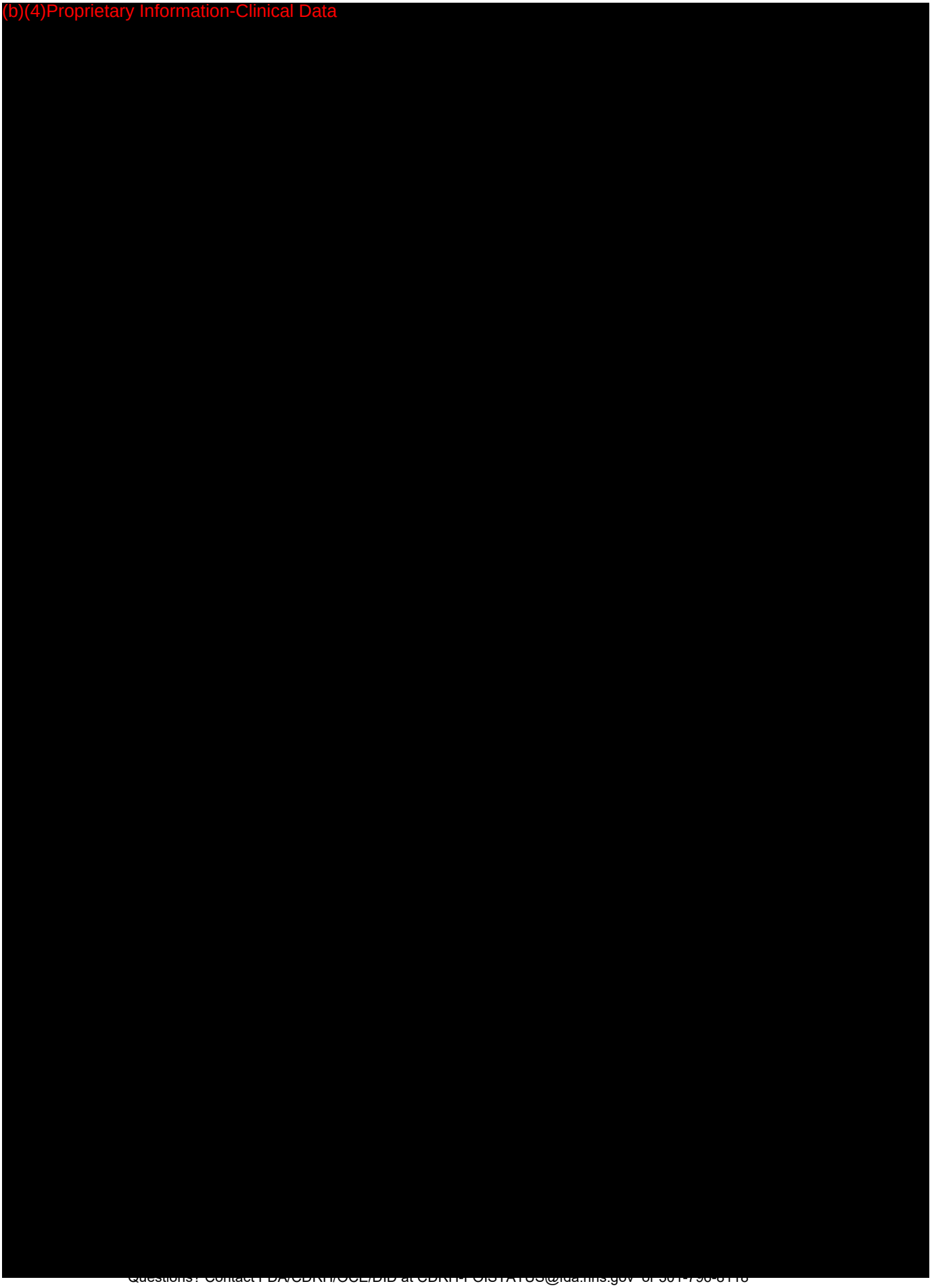


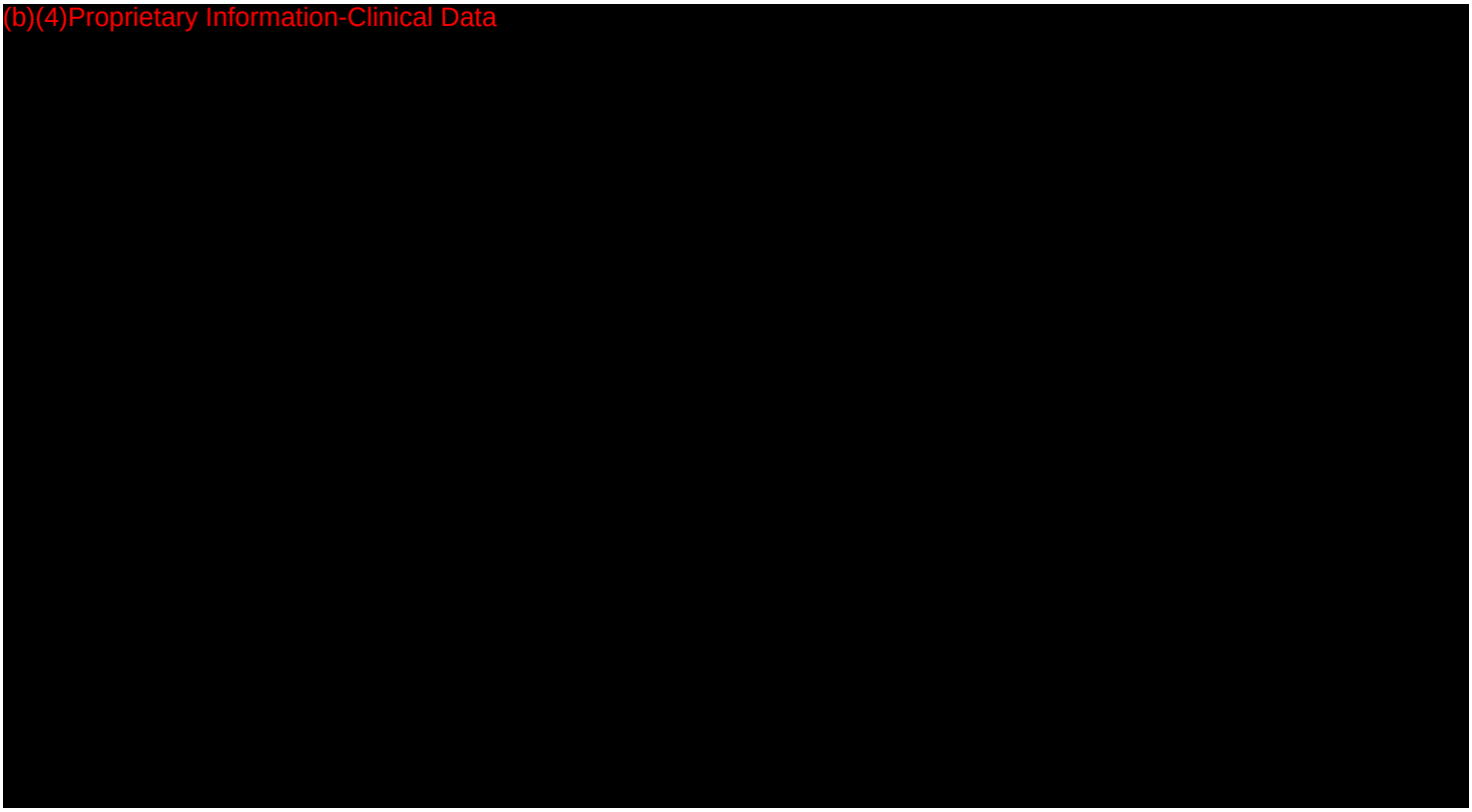




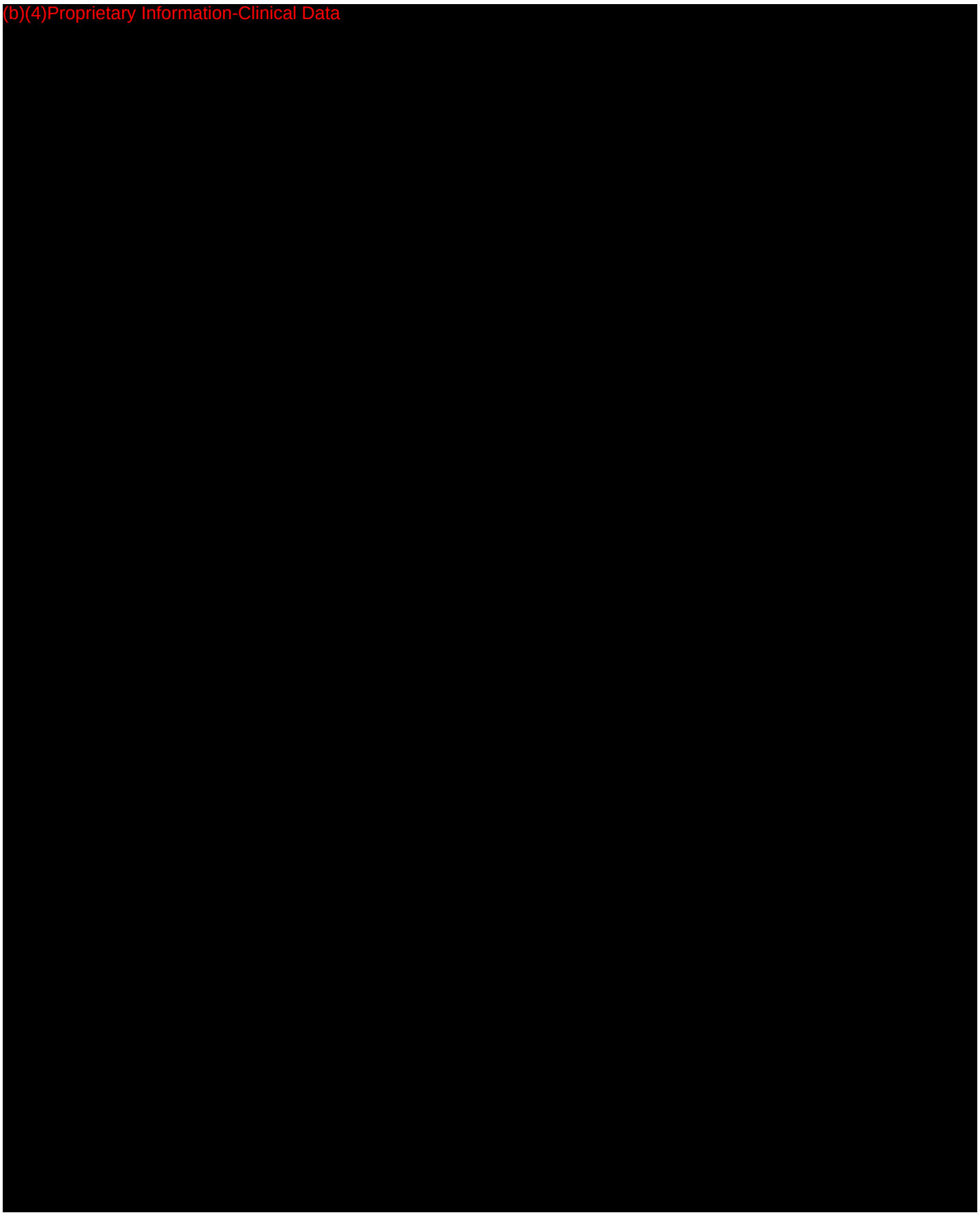


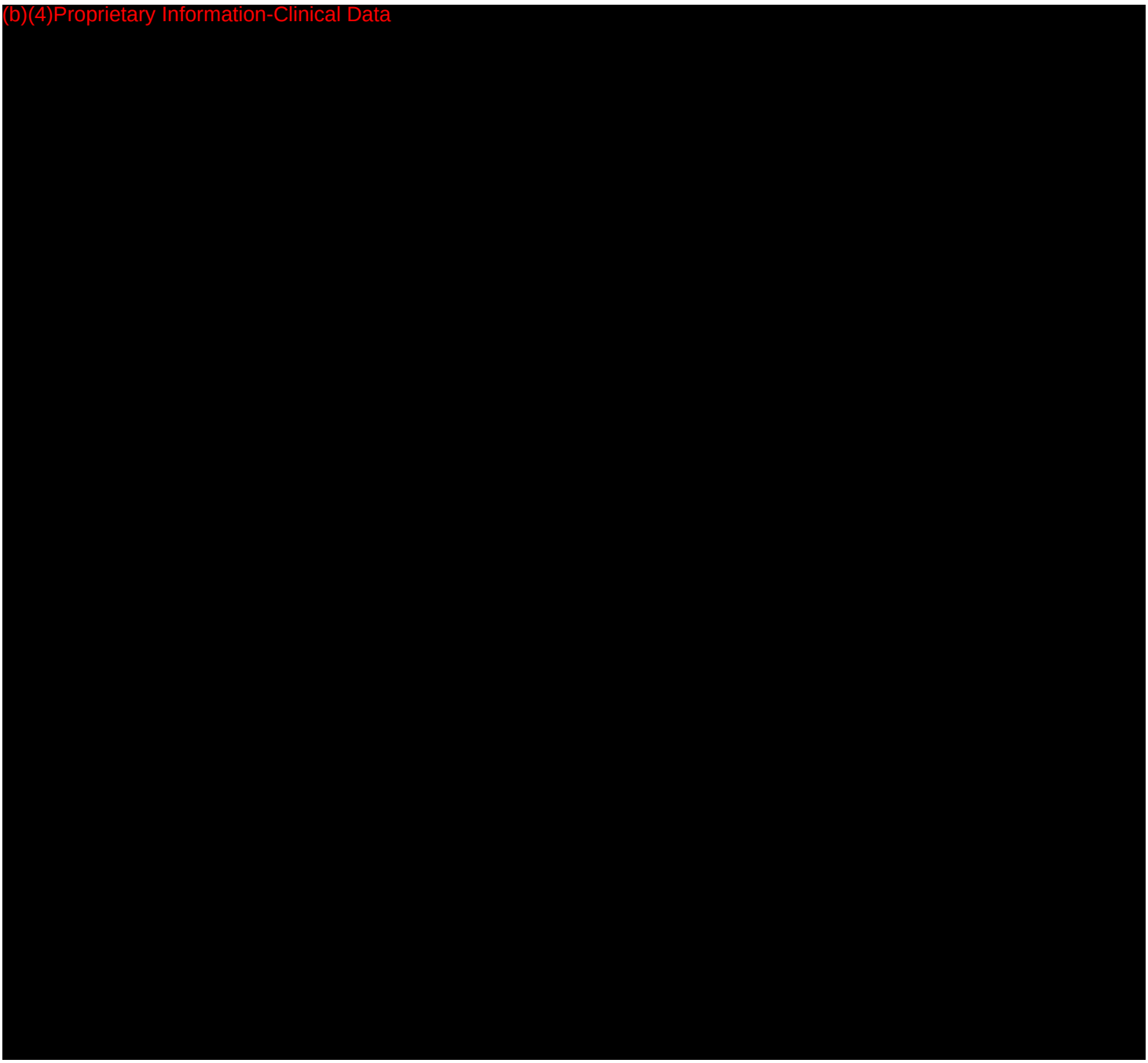
(b)(4)Proprietary Information-Clinical Data





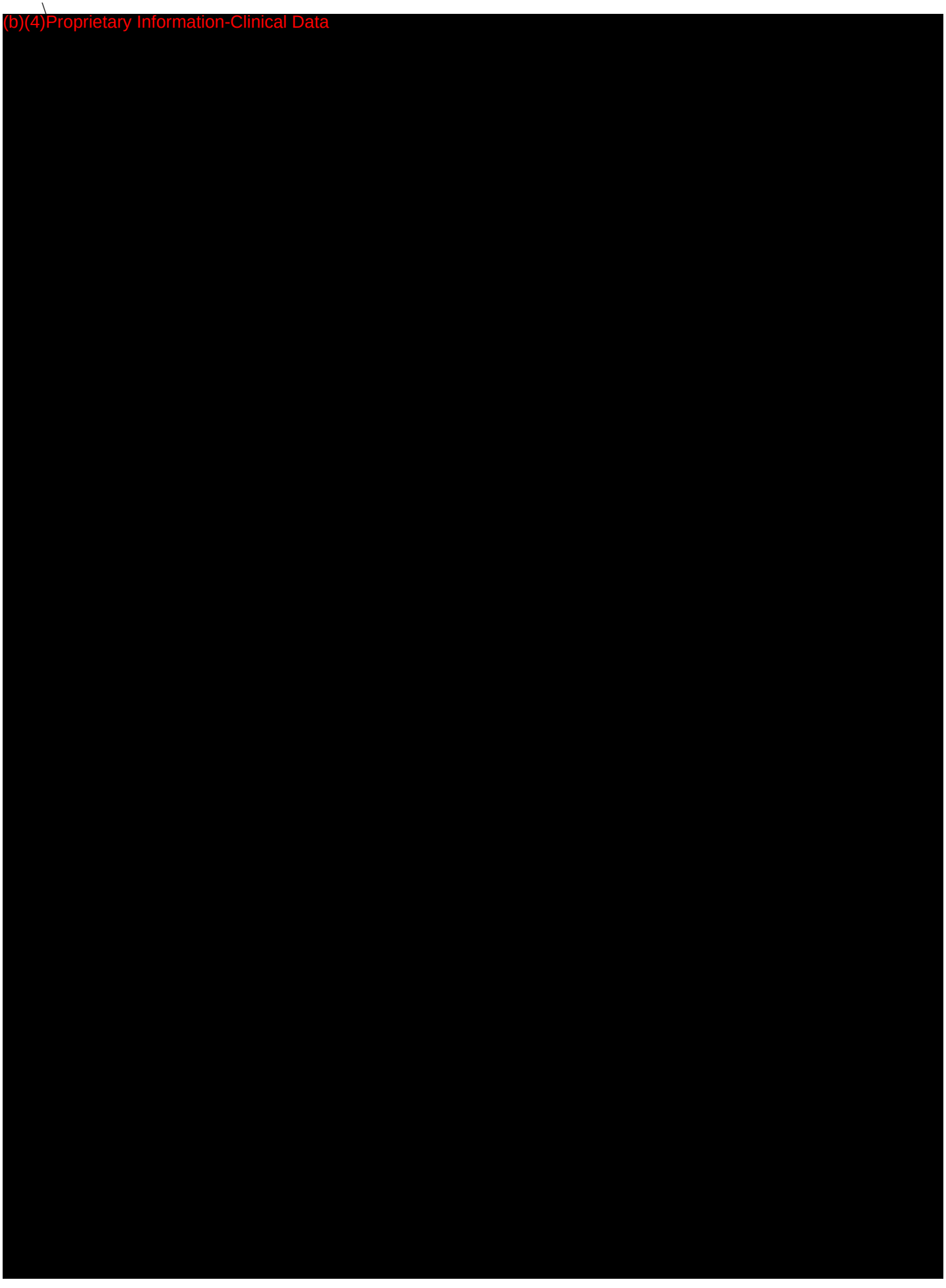
(b)(4)Proprietary Information-Clinical Data





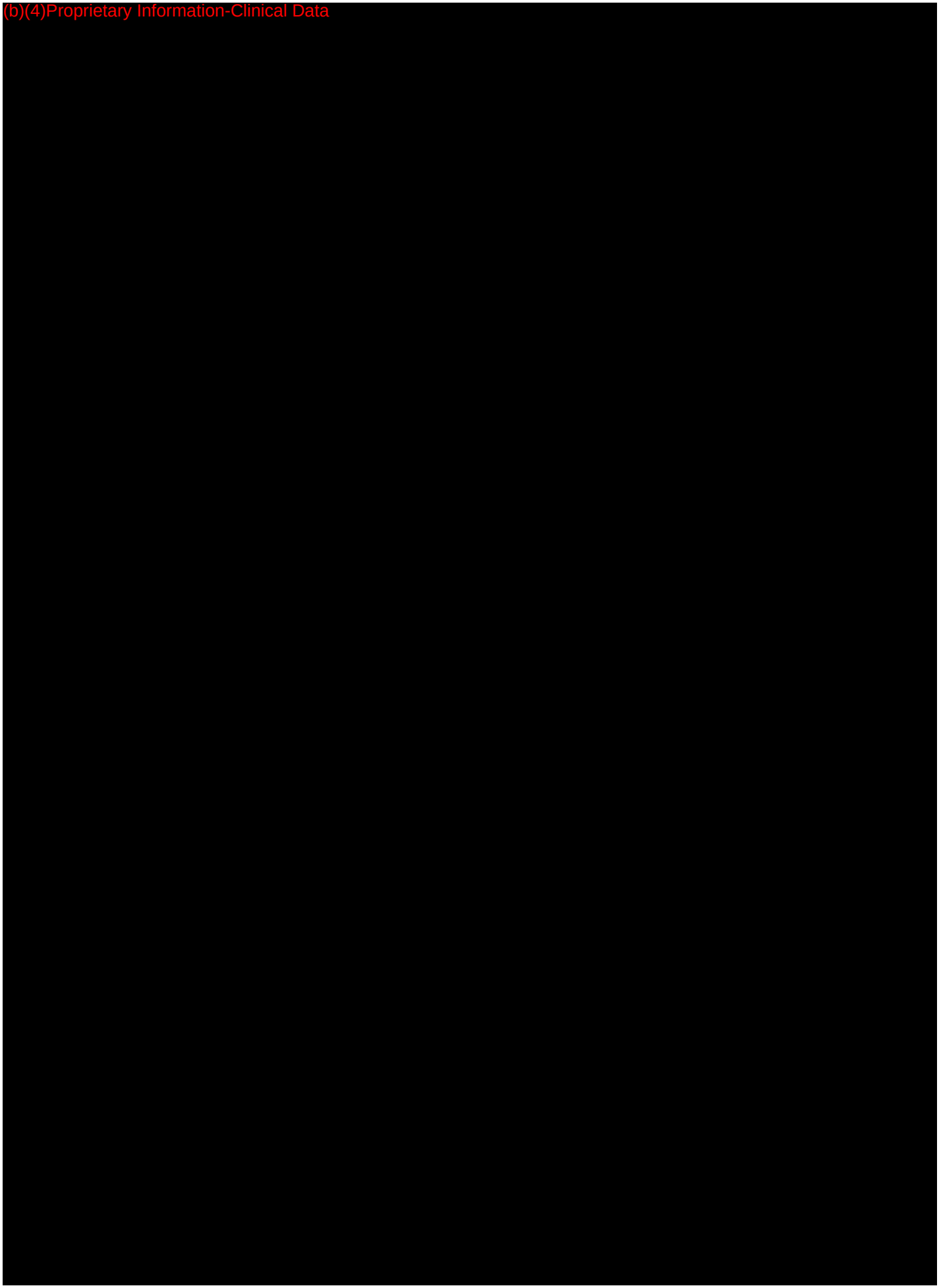
(b)(4)Proprietary Information-Clinical Data

(b)(4)Proprietary Information-Clinical Data



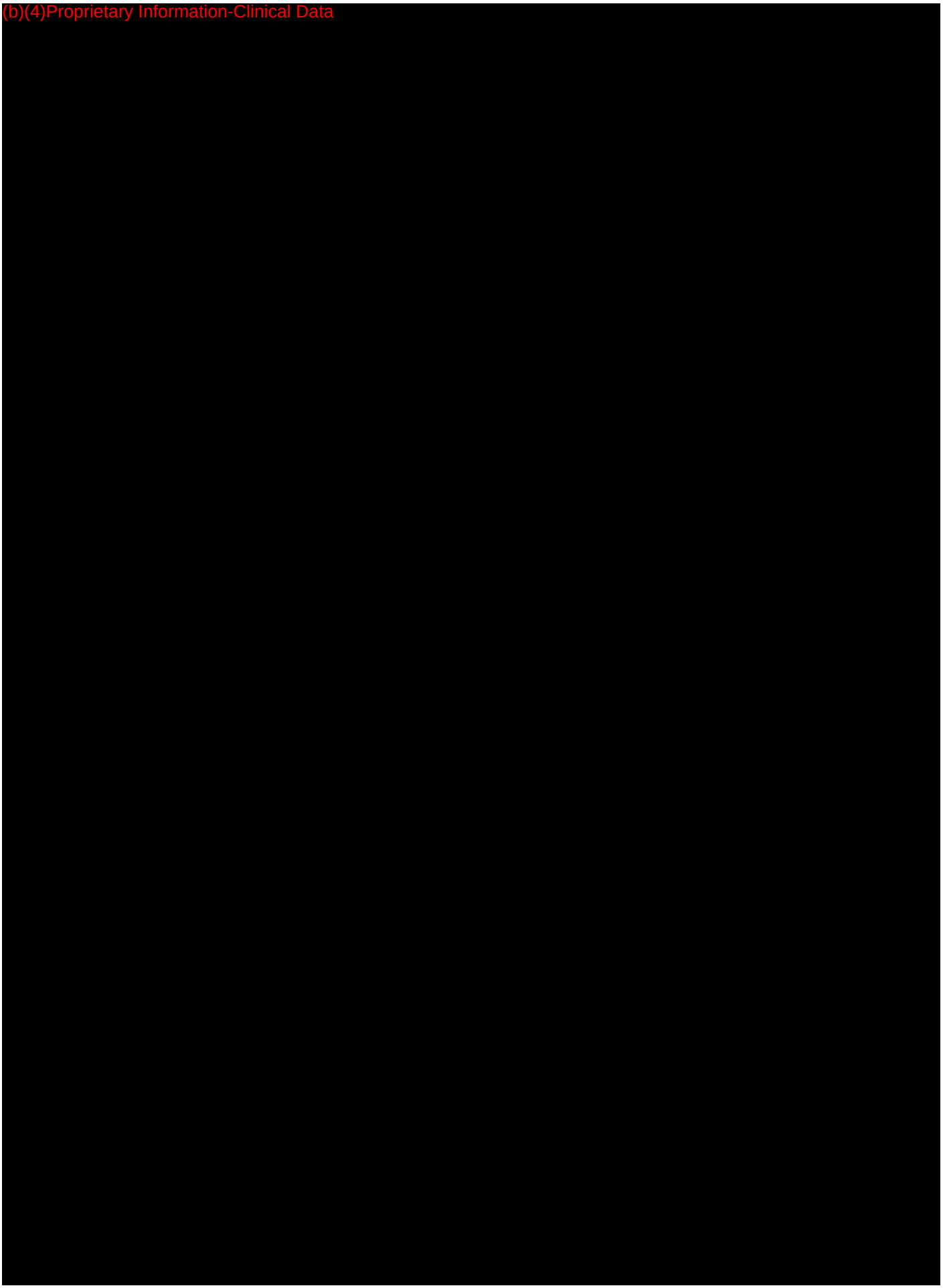
\

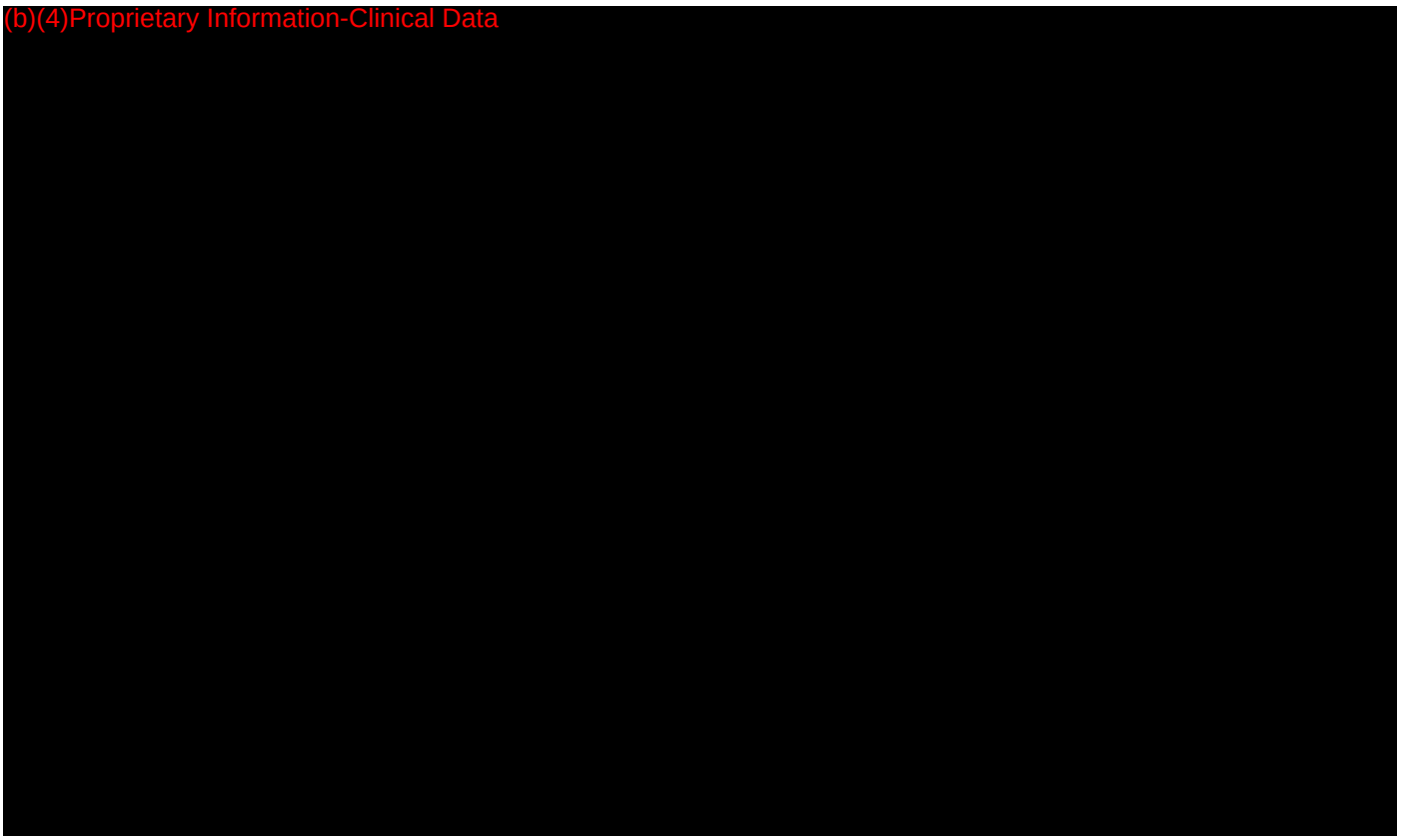
(b)(4)Proprietary Information-Clinical Data



\

(b)(4)Proprietary Information-Clinical Data

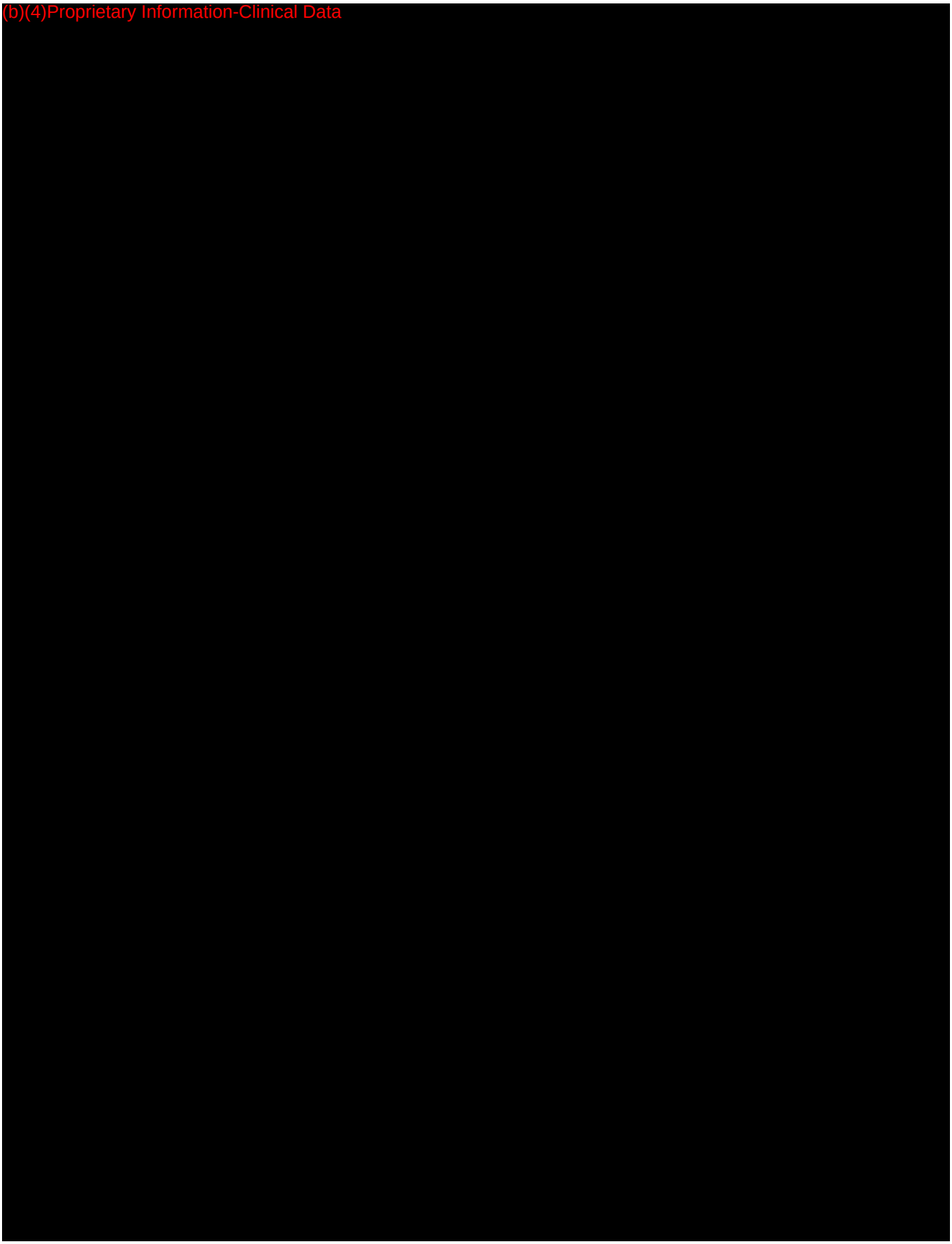




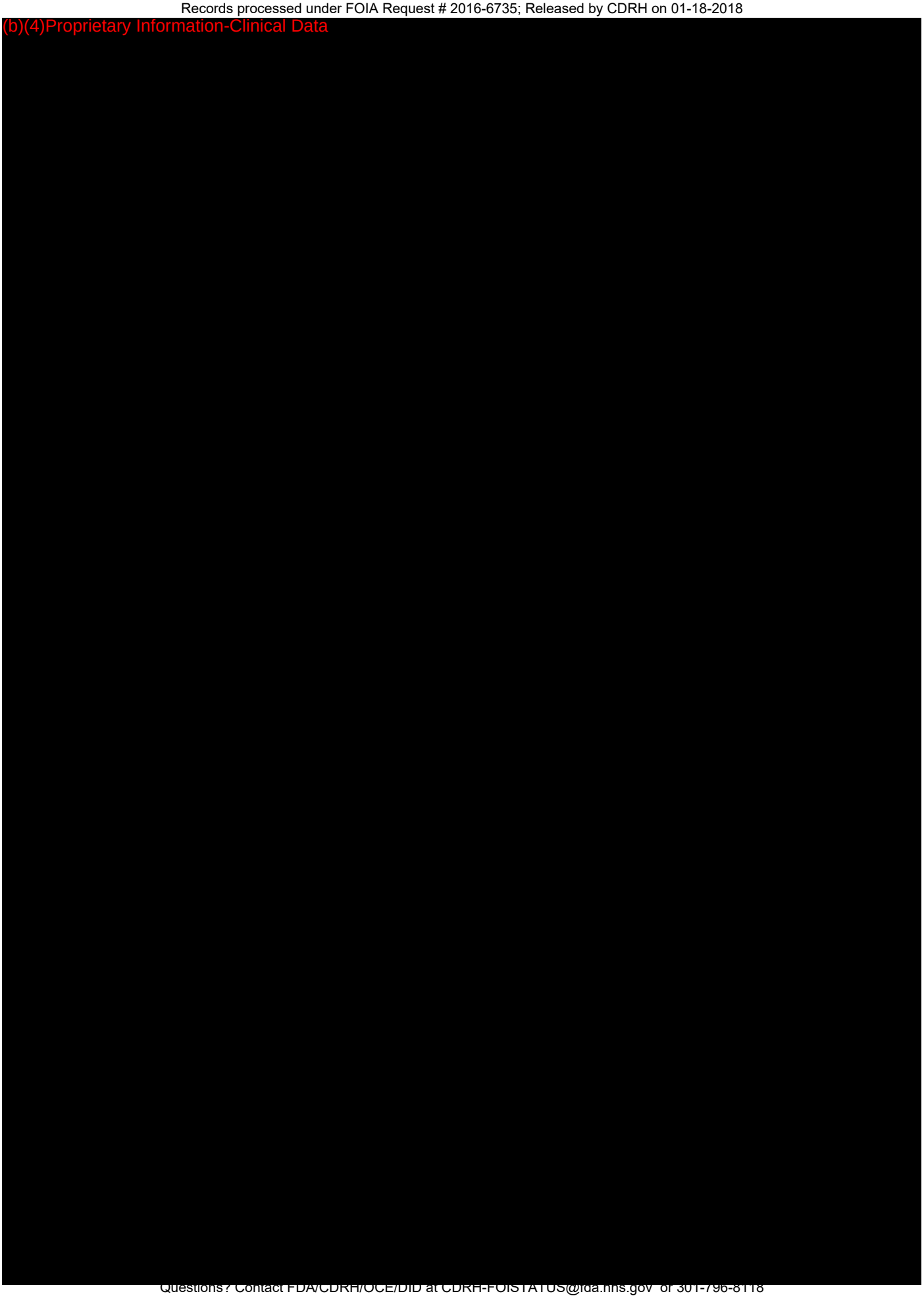
(b)(4)Proprietary Information-Clinical Data

[redacted]

(b)(4)Proprietary Information-Clinical Data



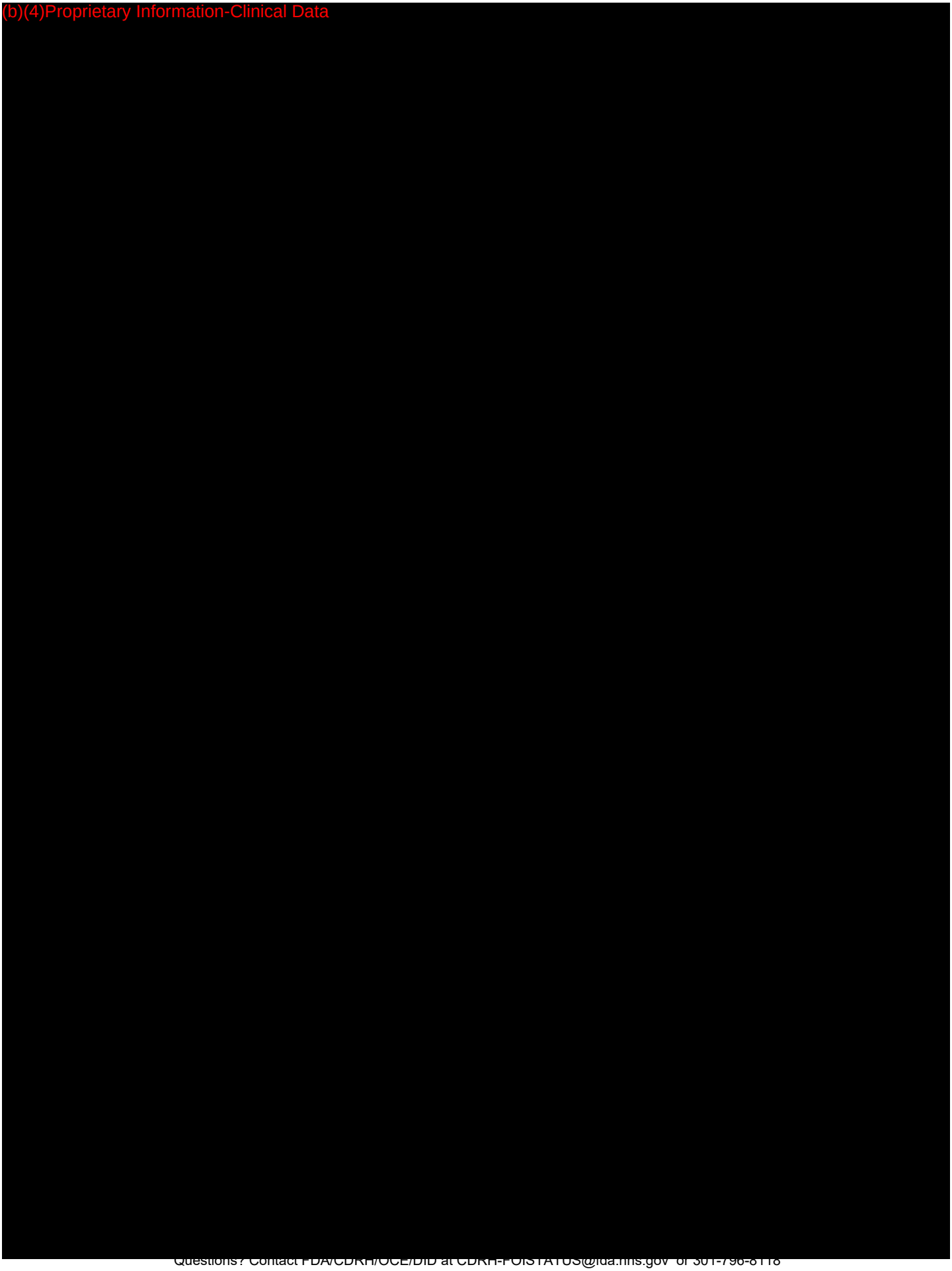
(b)(4)Proprietary Information-Clinical Data

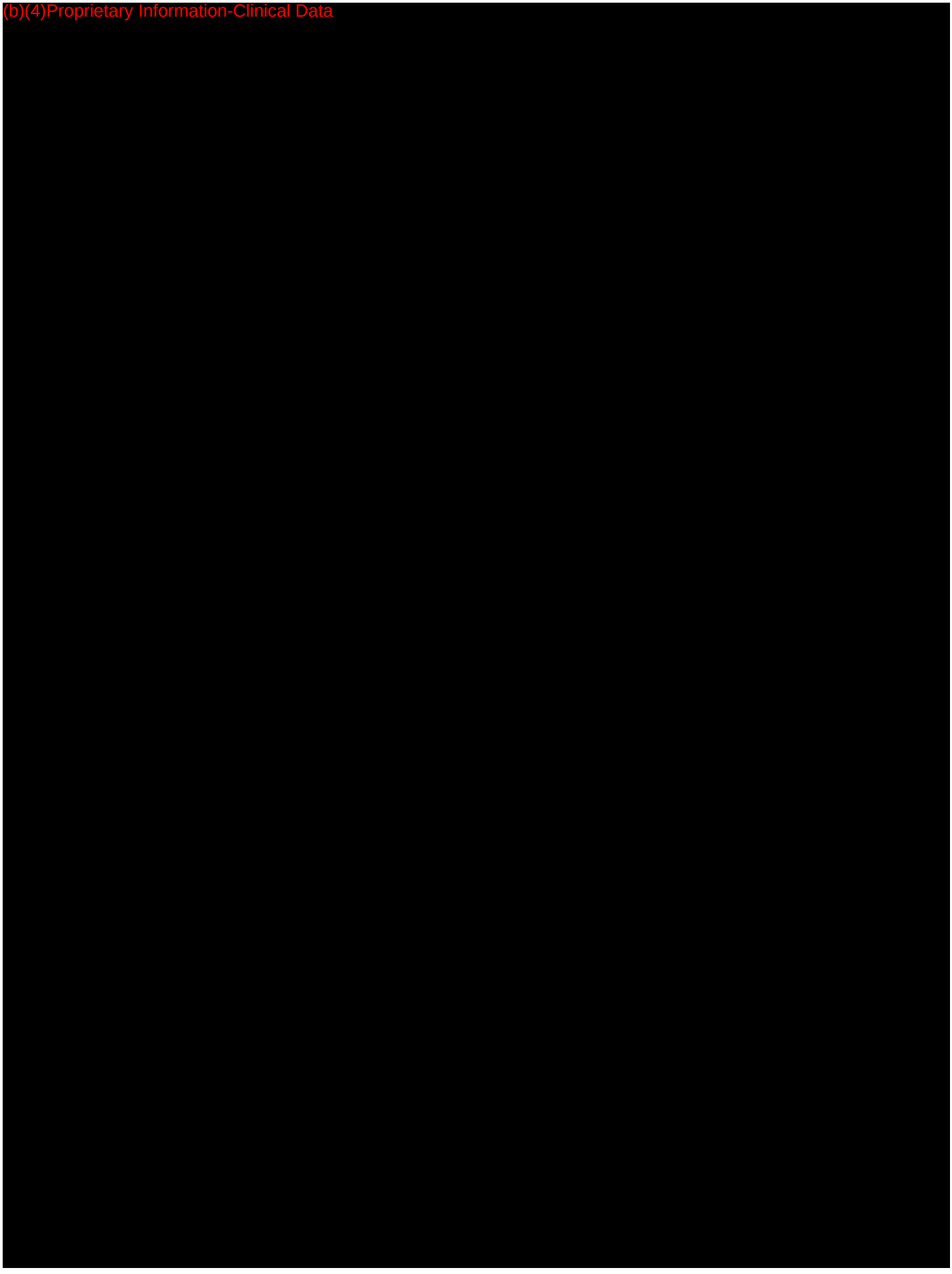


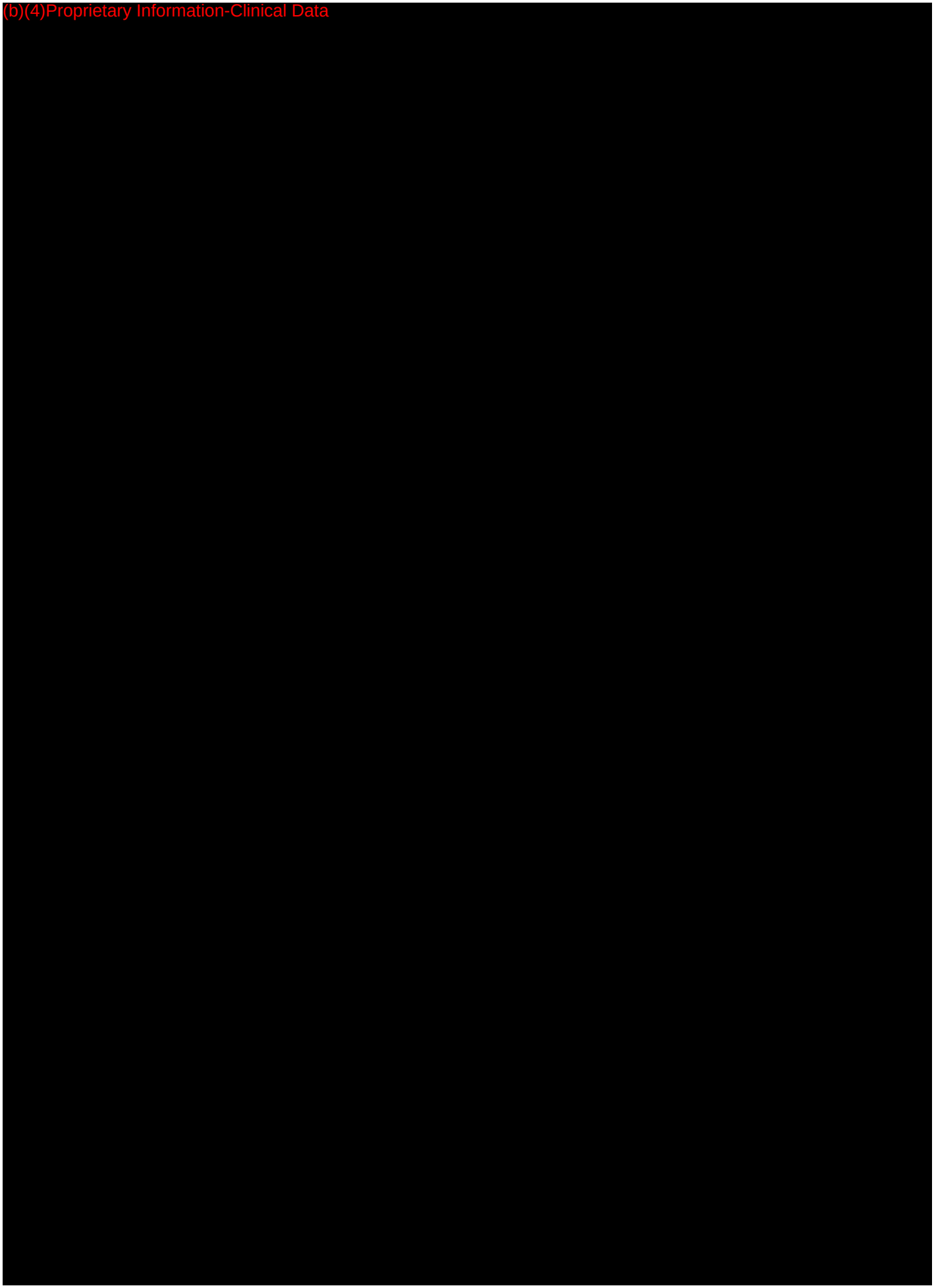
(b)(4)Proprietary Information-Clinical Data

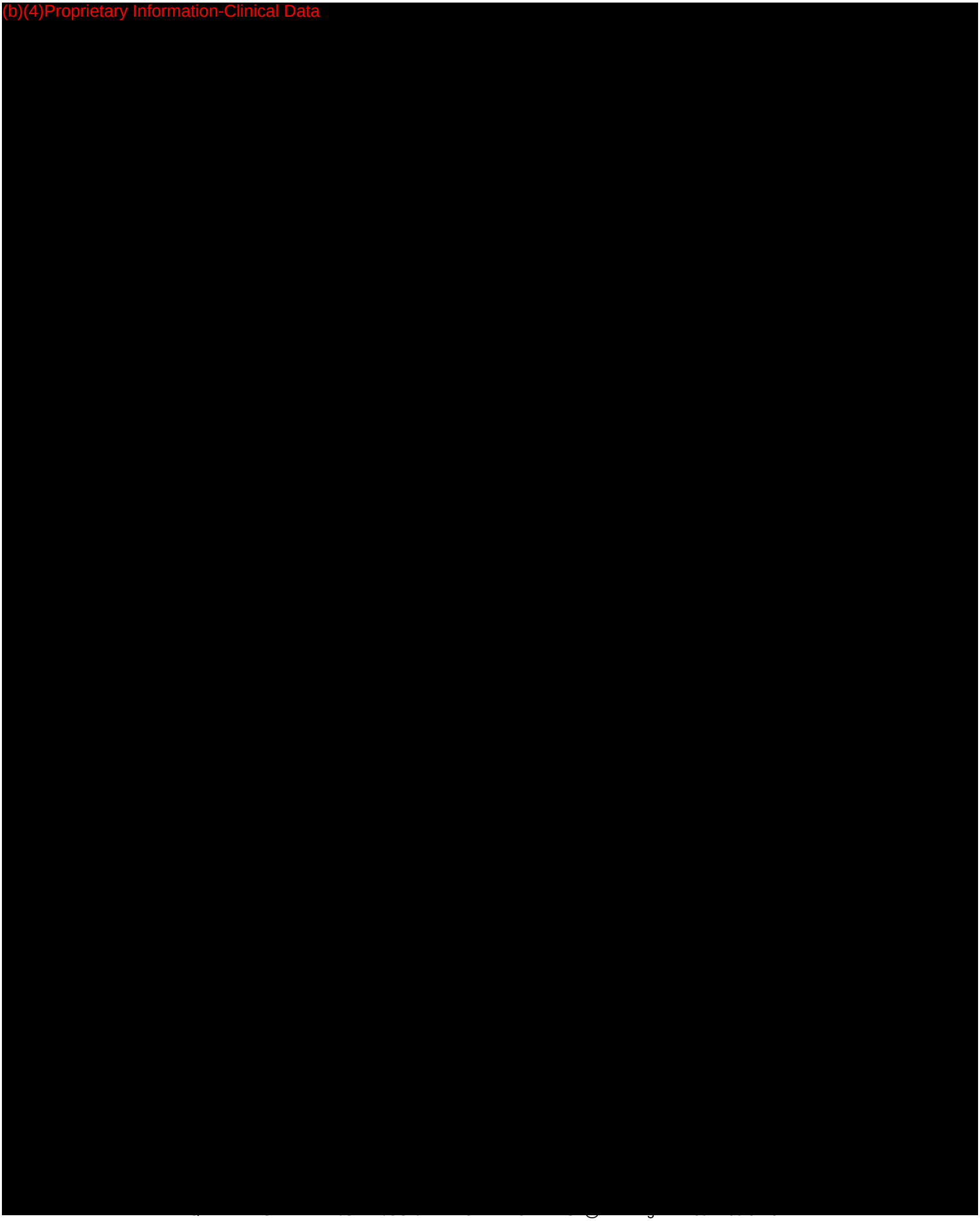
[redacted]

(b)(4)Proprietary Information-Clinical Data

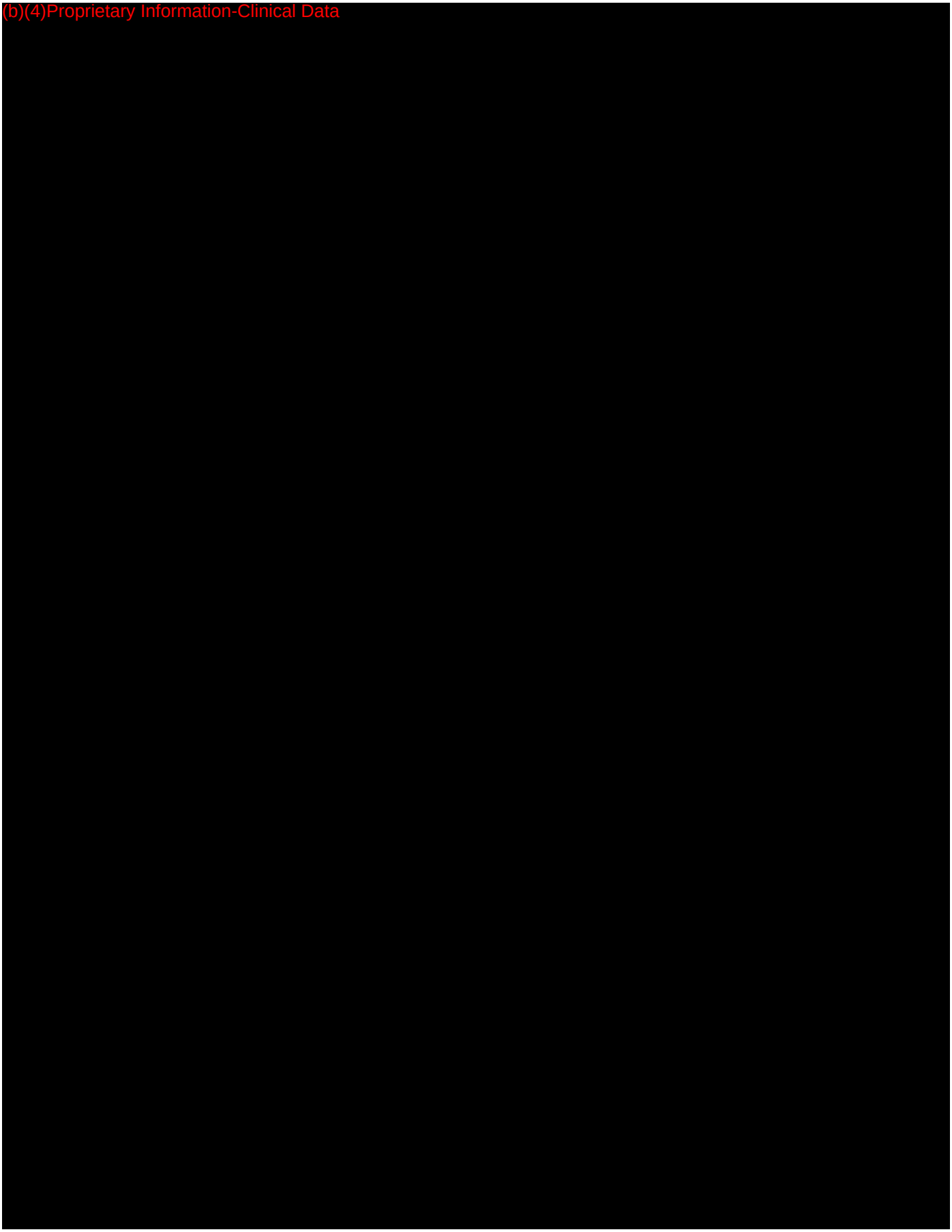


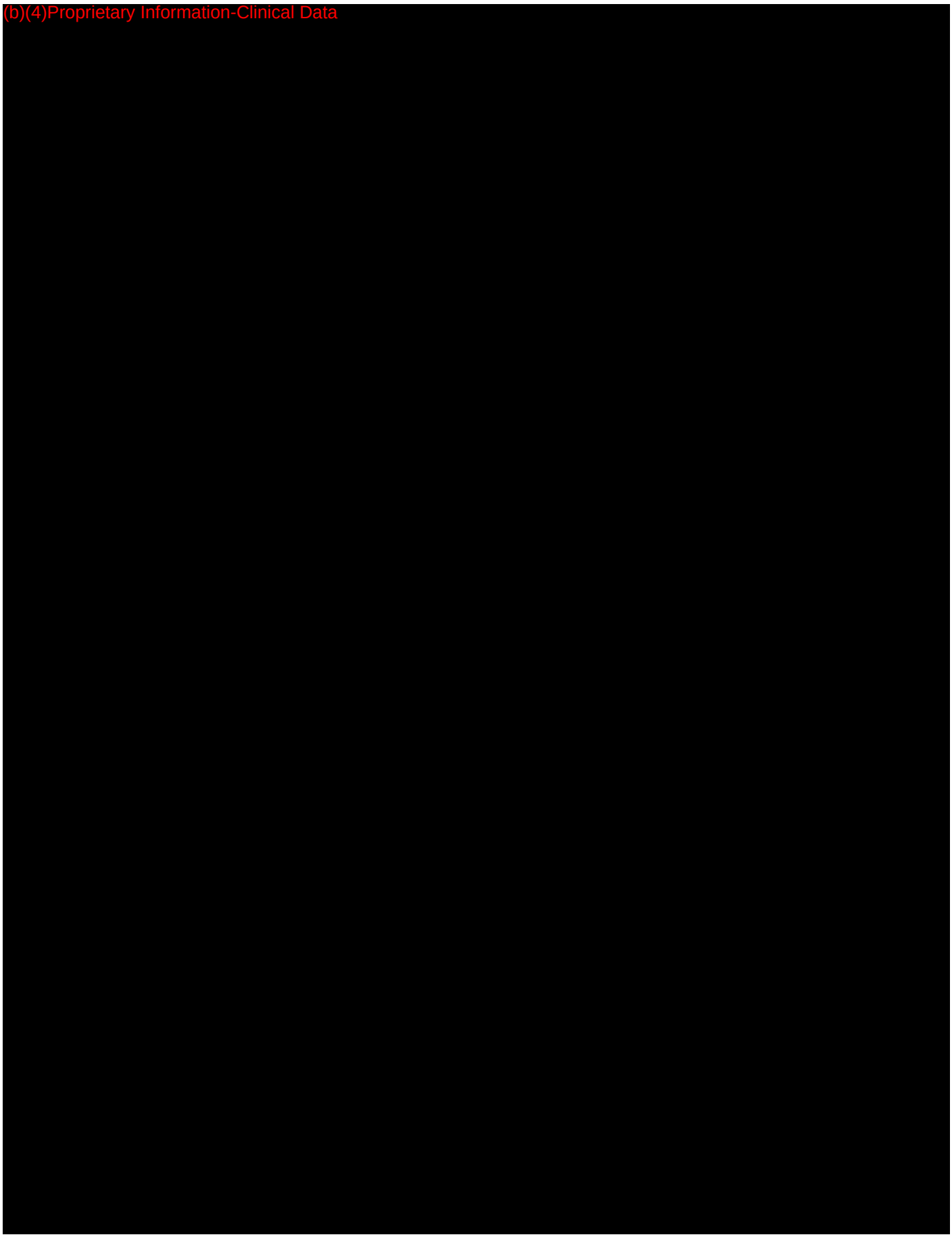


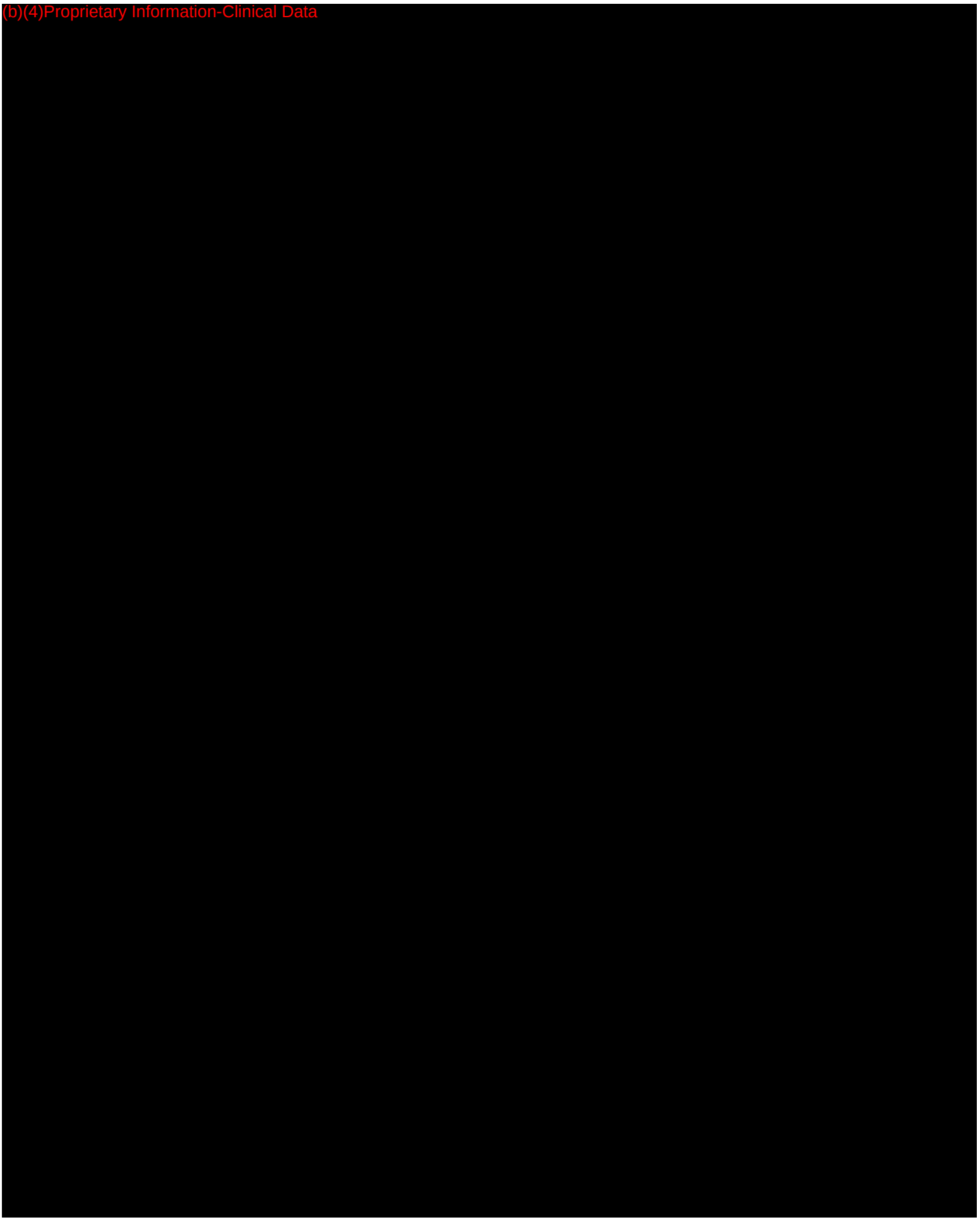


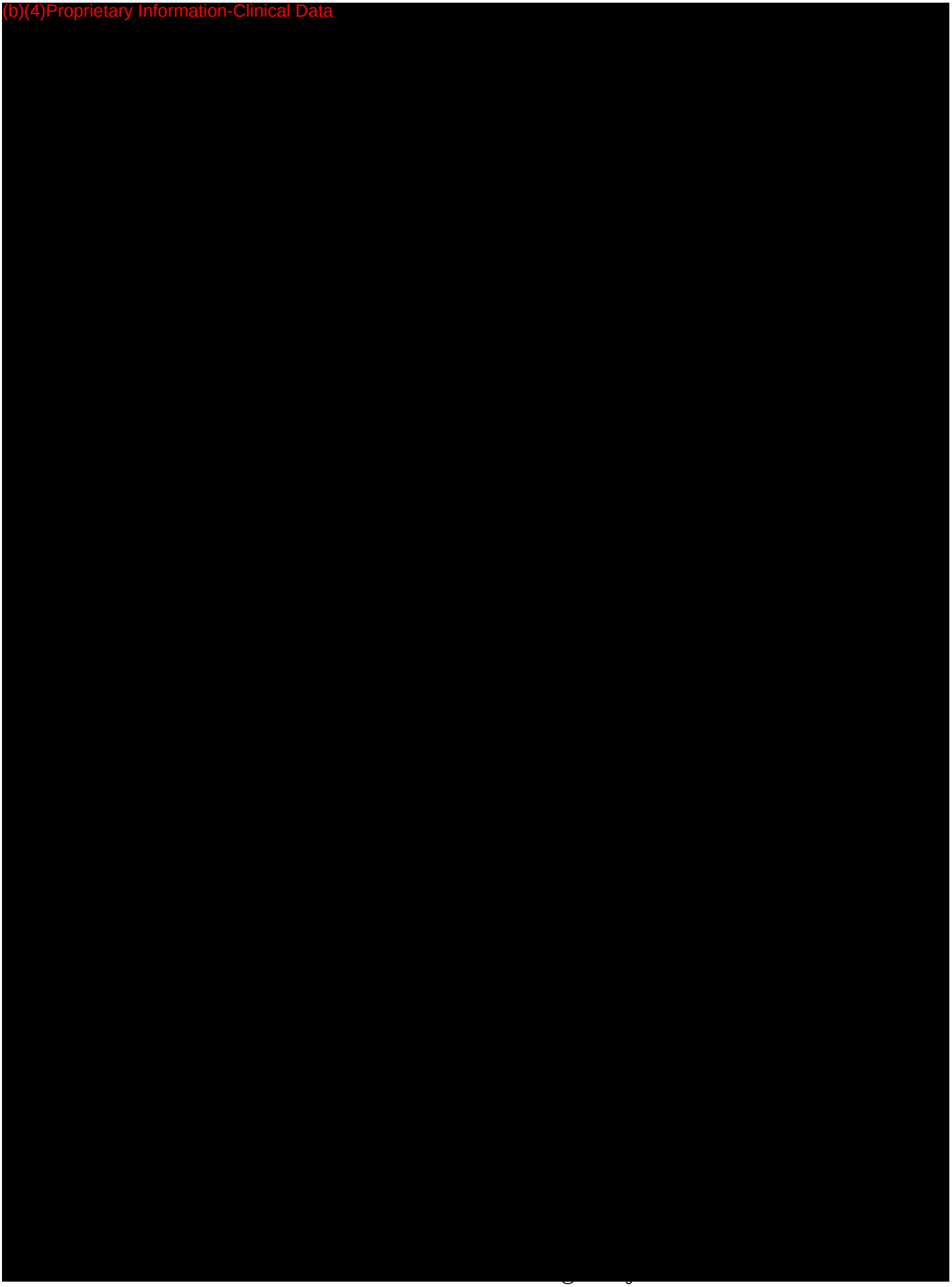


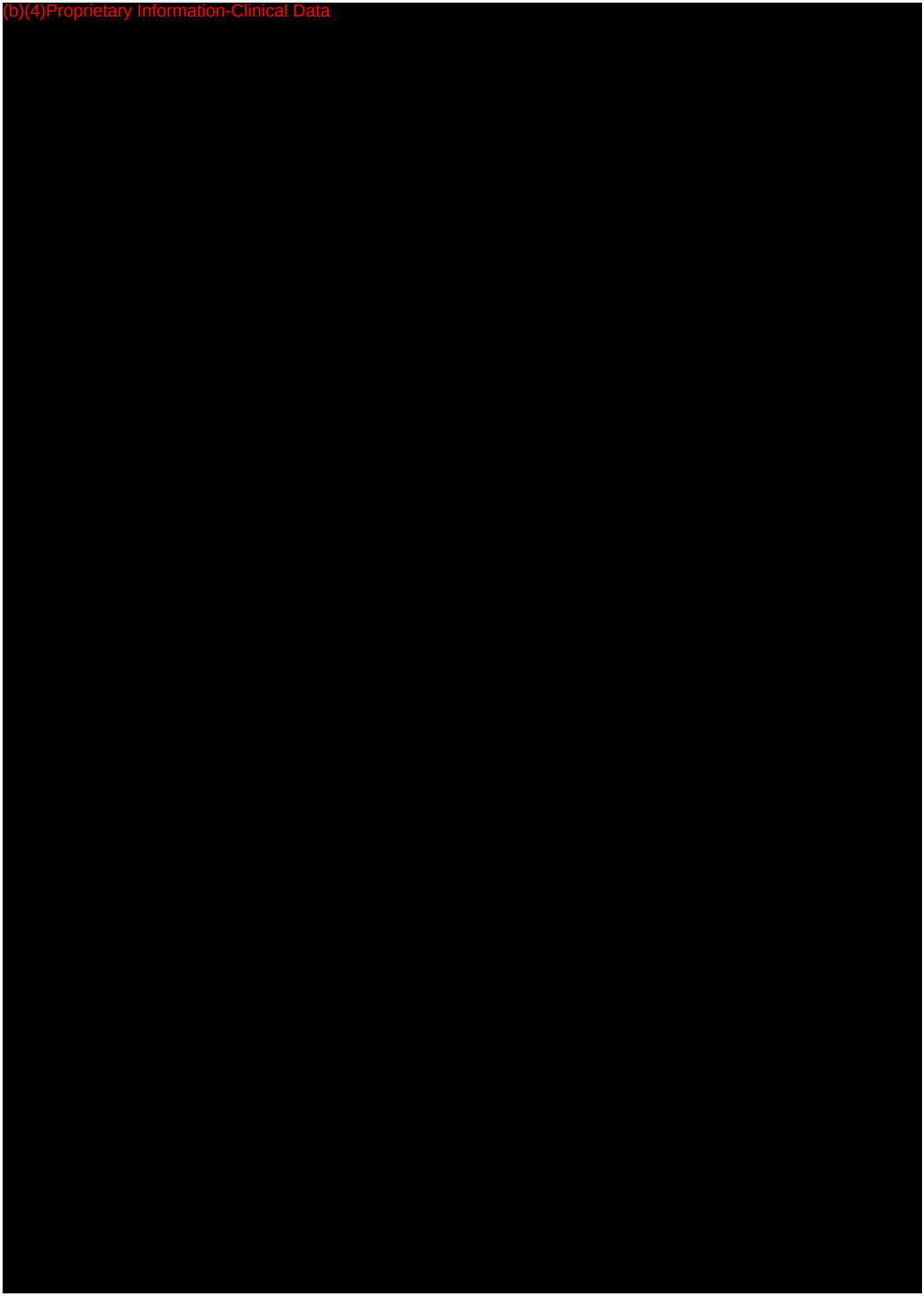
(b)(4)Proprietary Information-Clinical Data

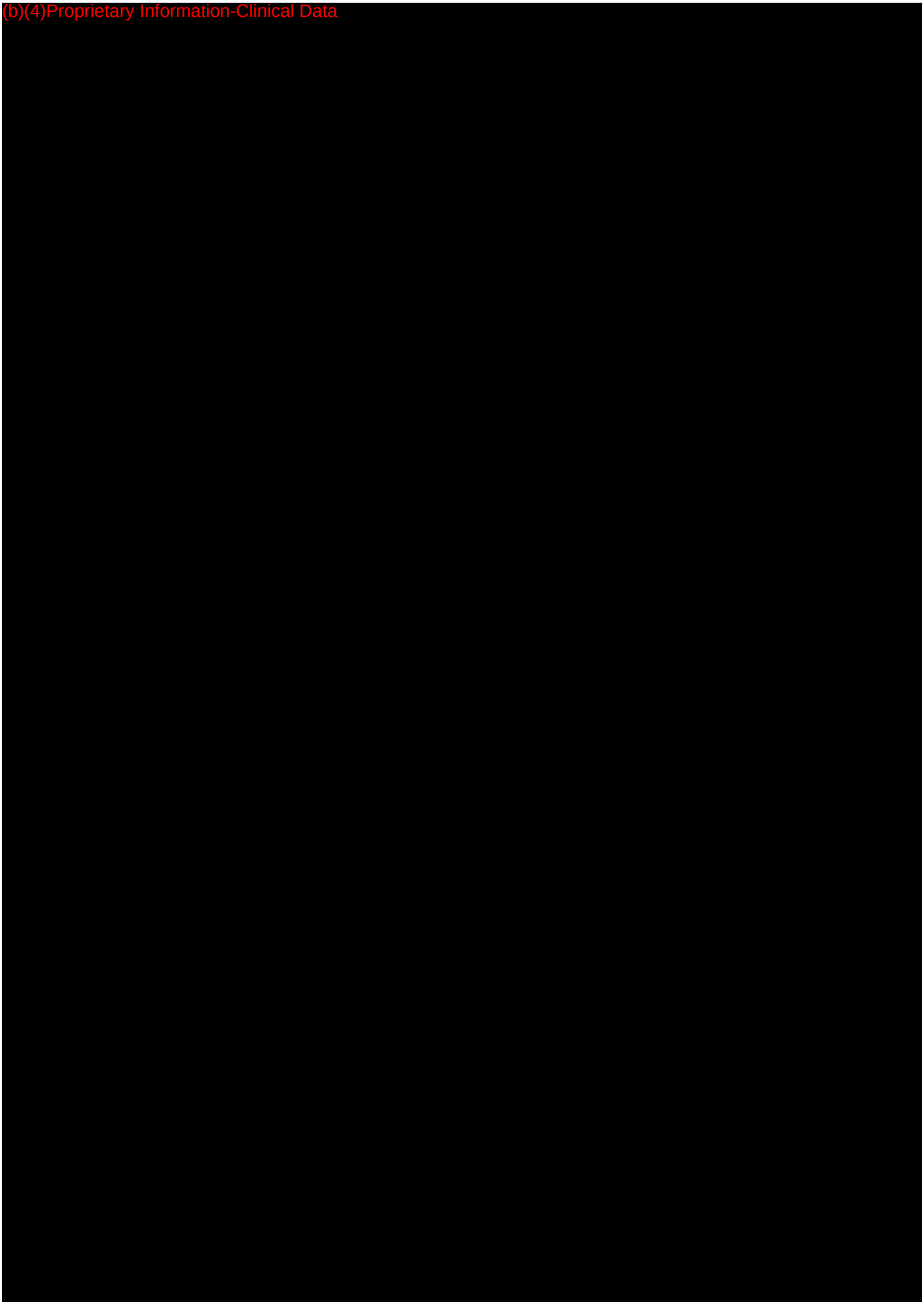




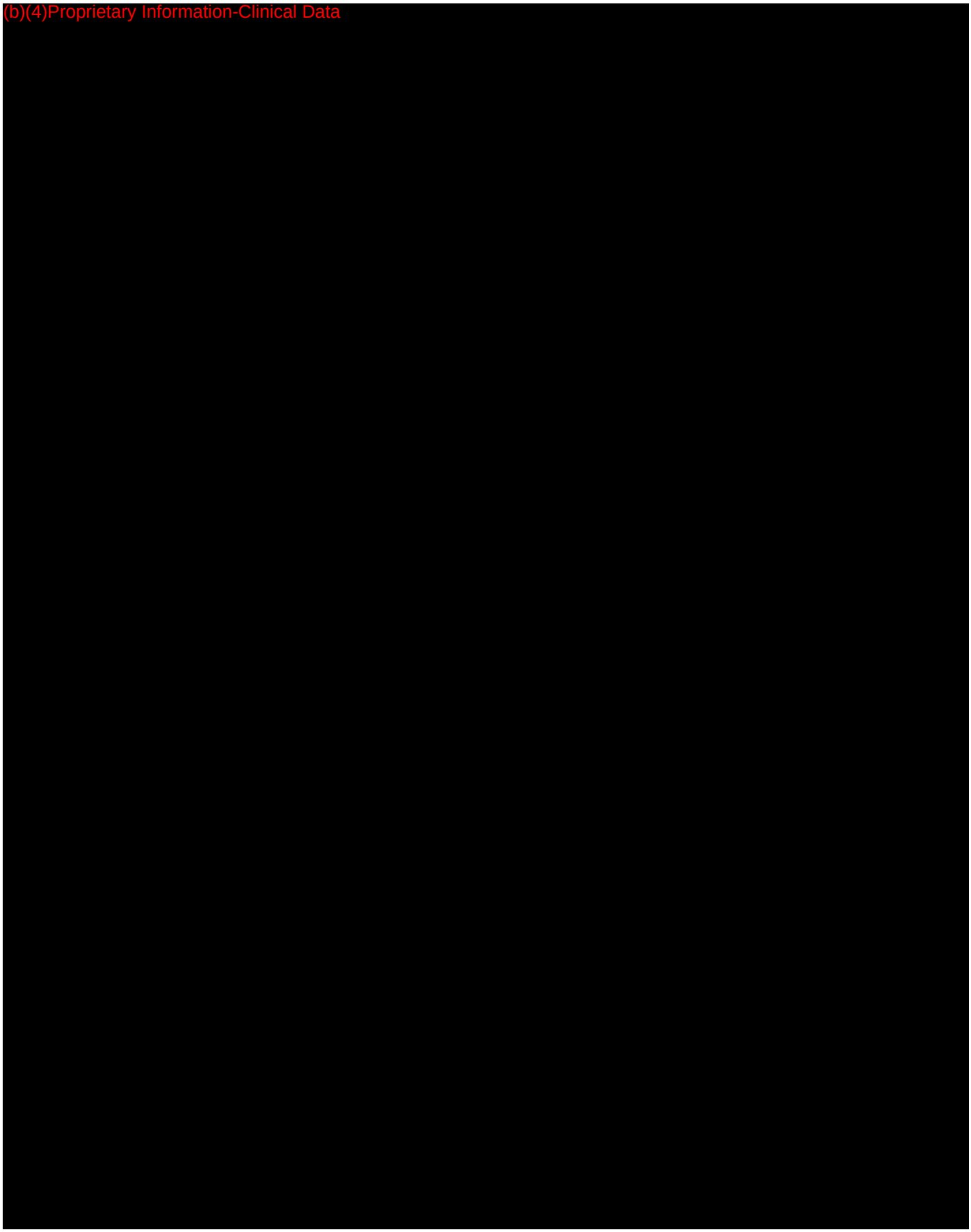




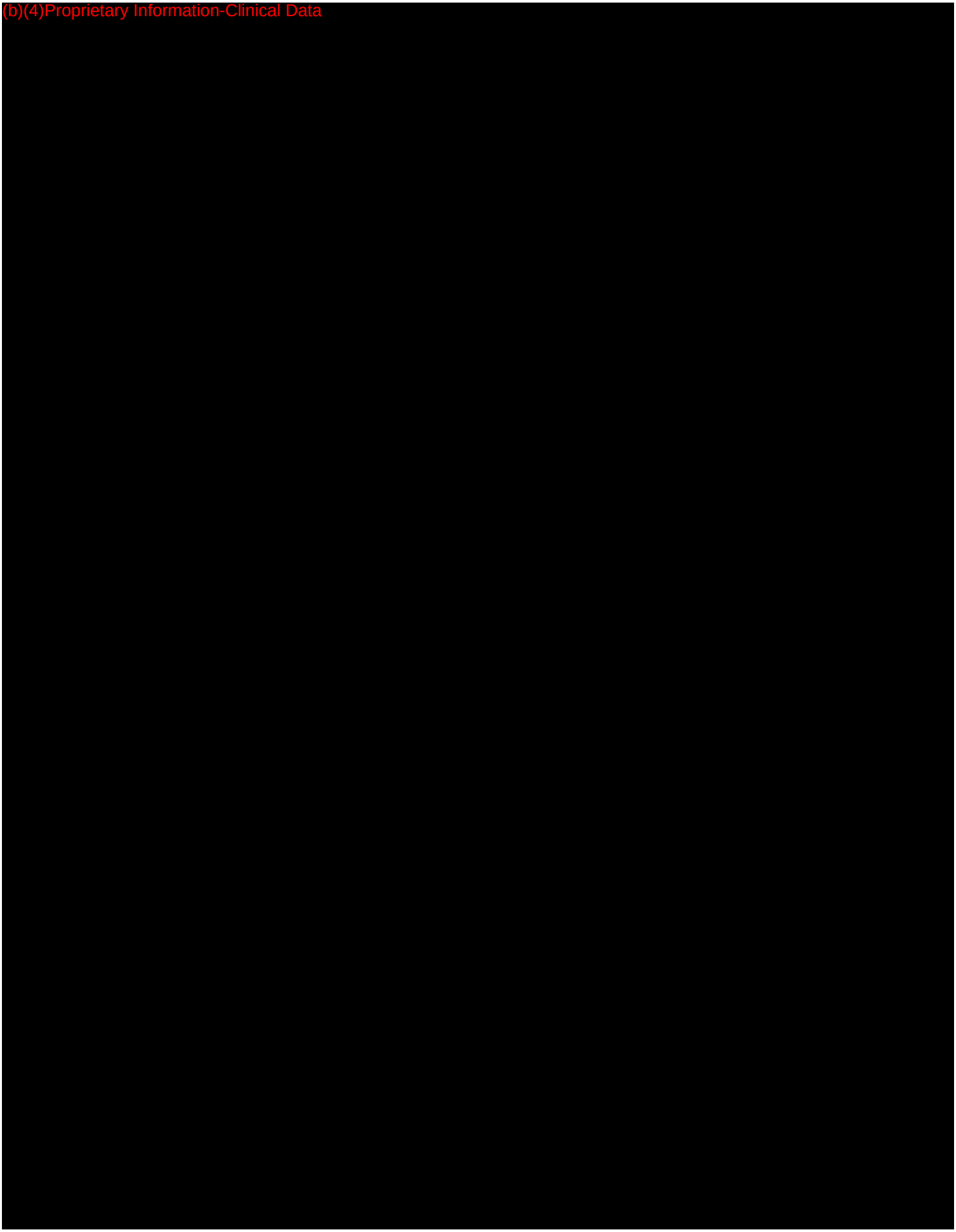




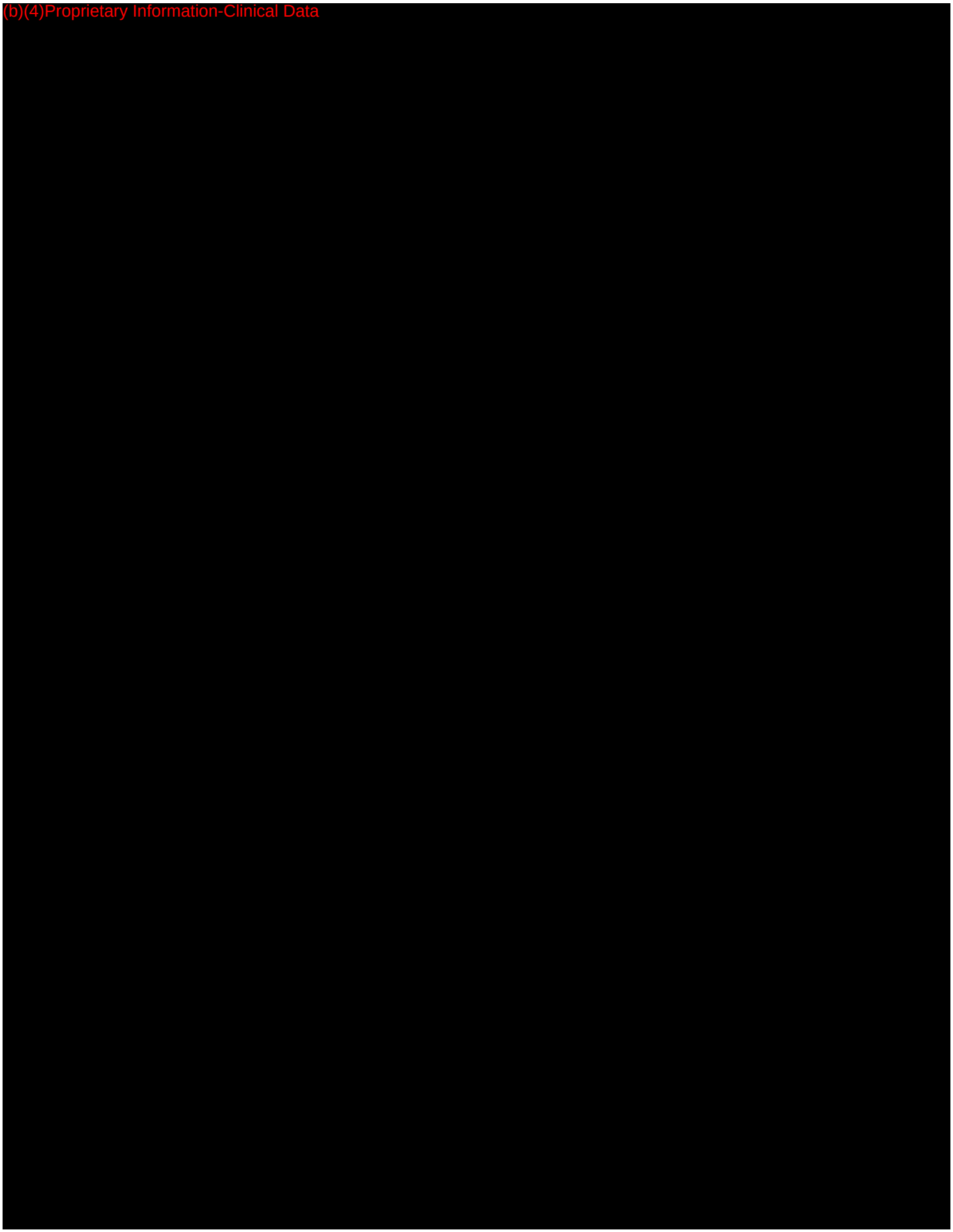
(b)(4)Proprietary Information-Clinical Data



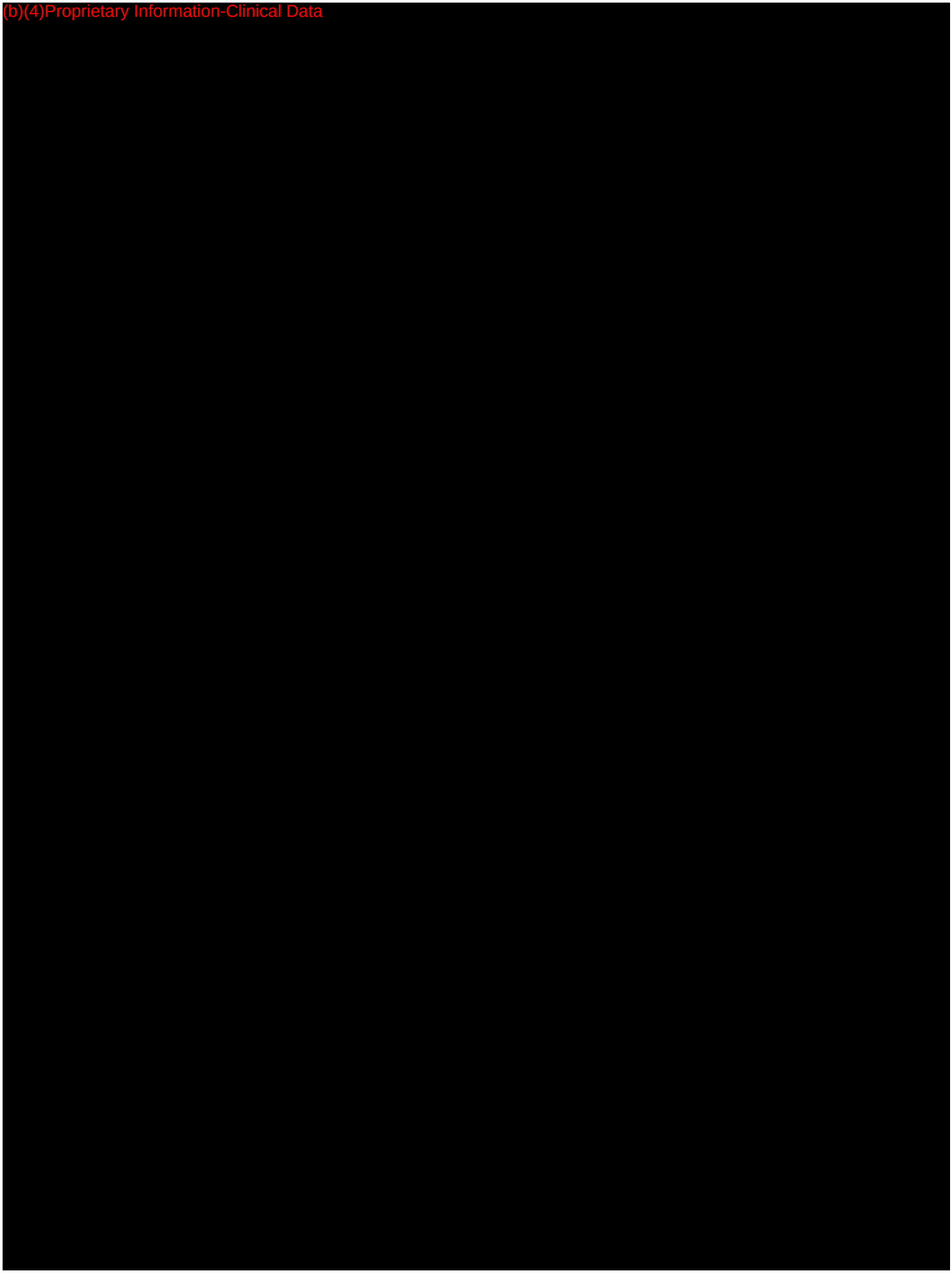
(b)(4)Proprietary Information-Clinical Data

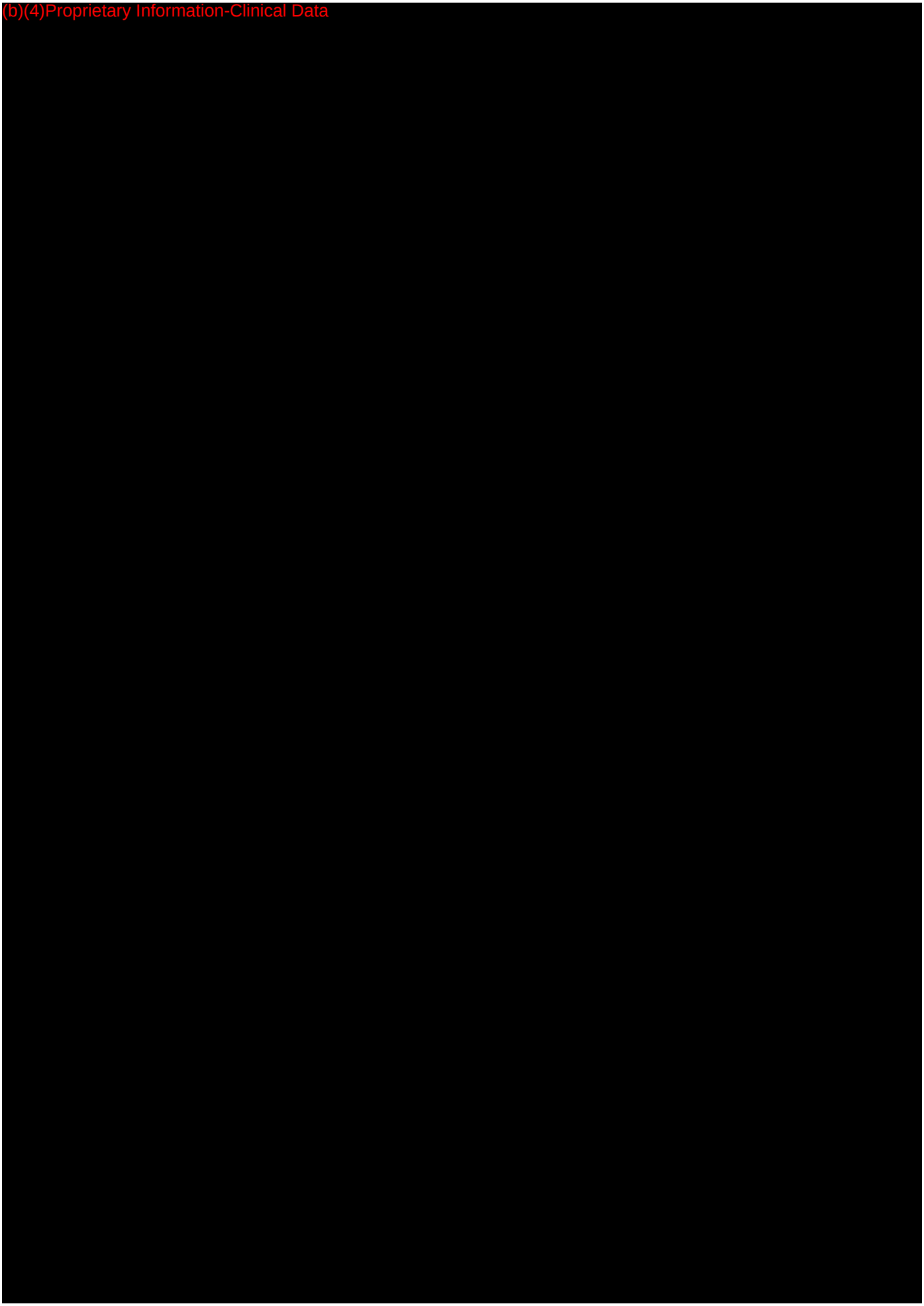


(b)(4)Proprietary Information-Clinical Data

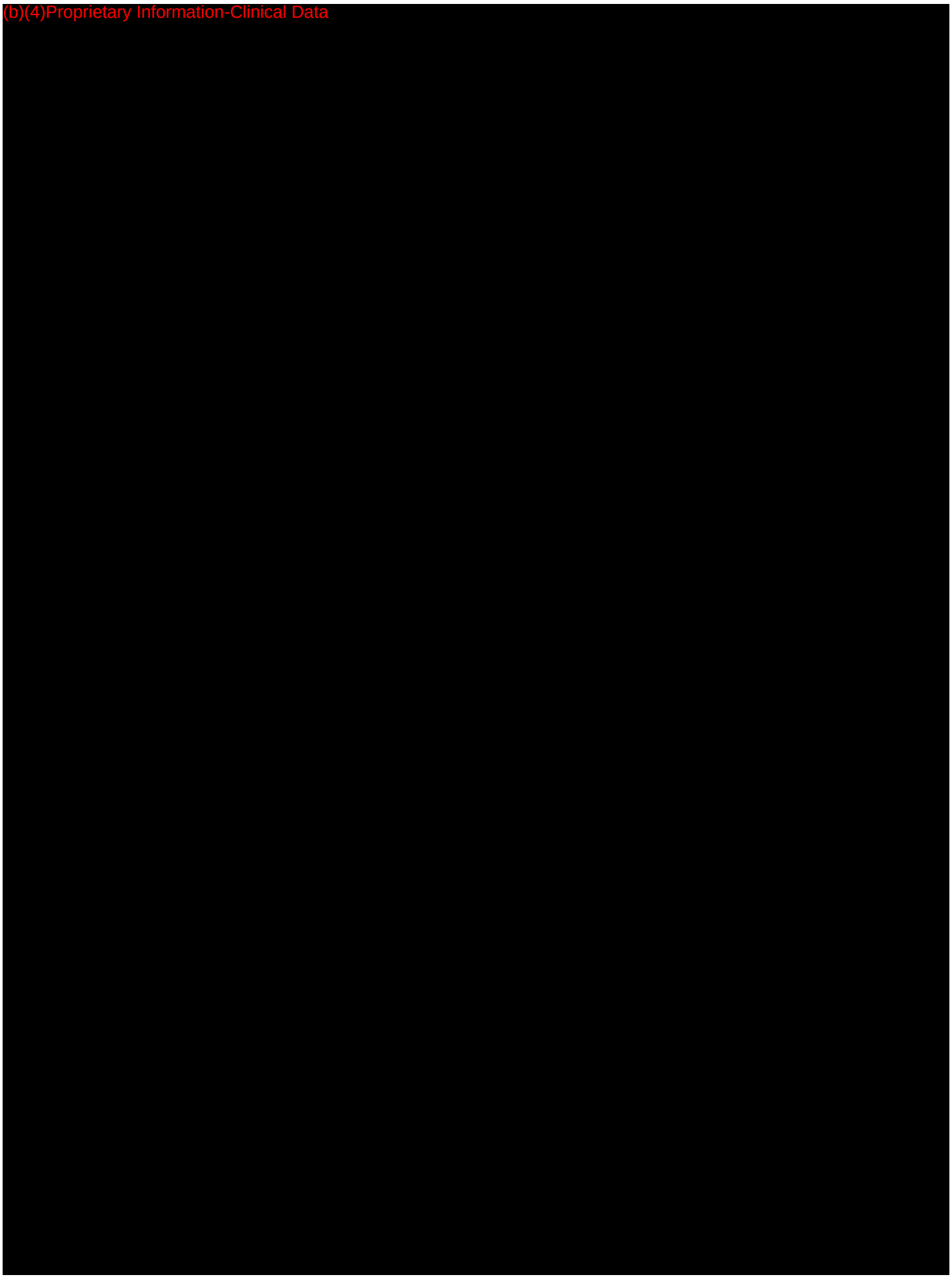


(b)(4)Proprietary Information-Clinical Data

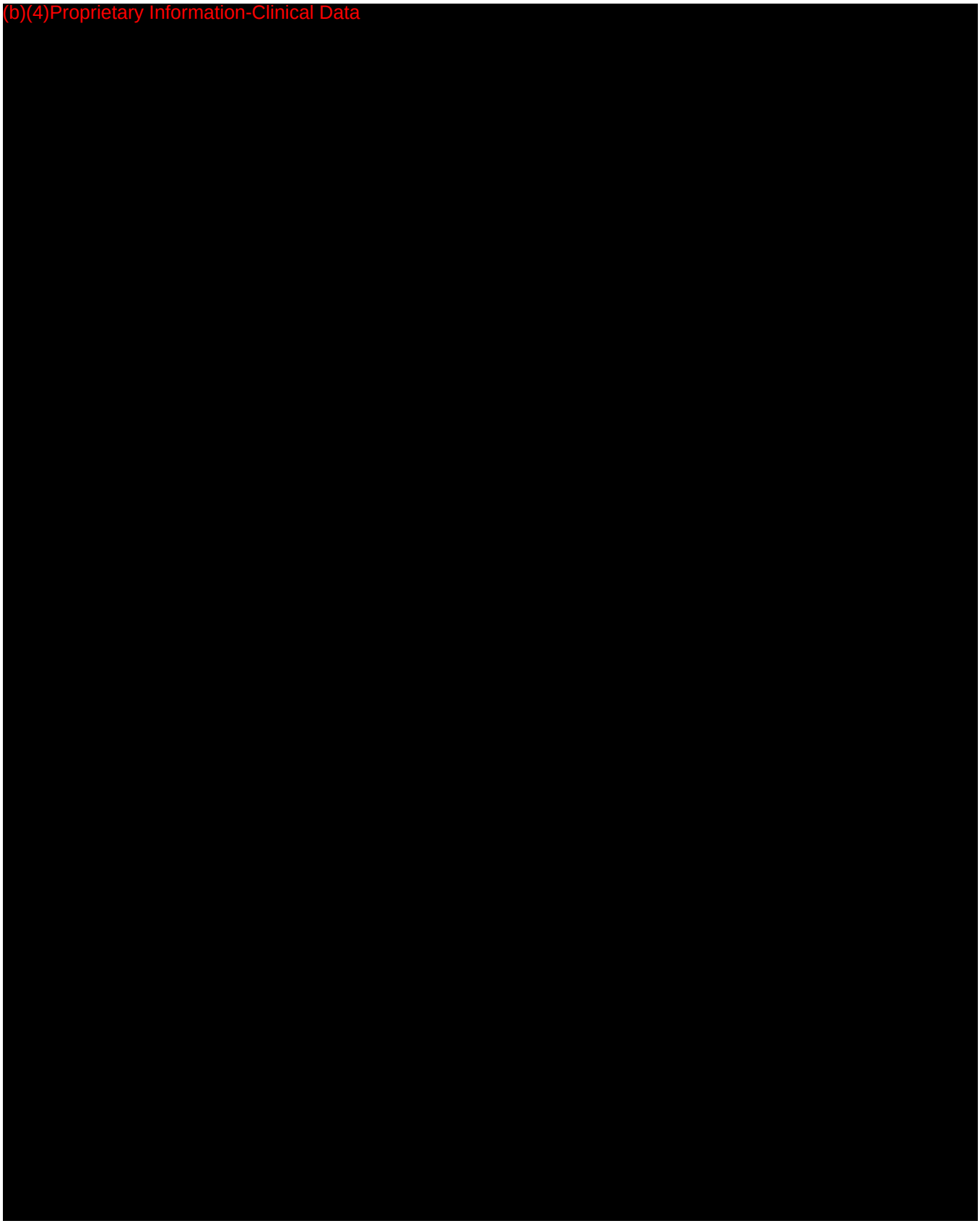


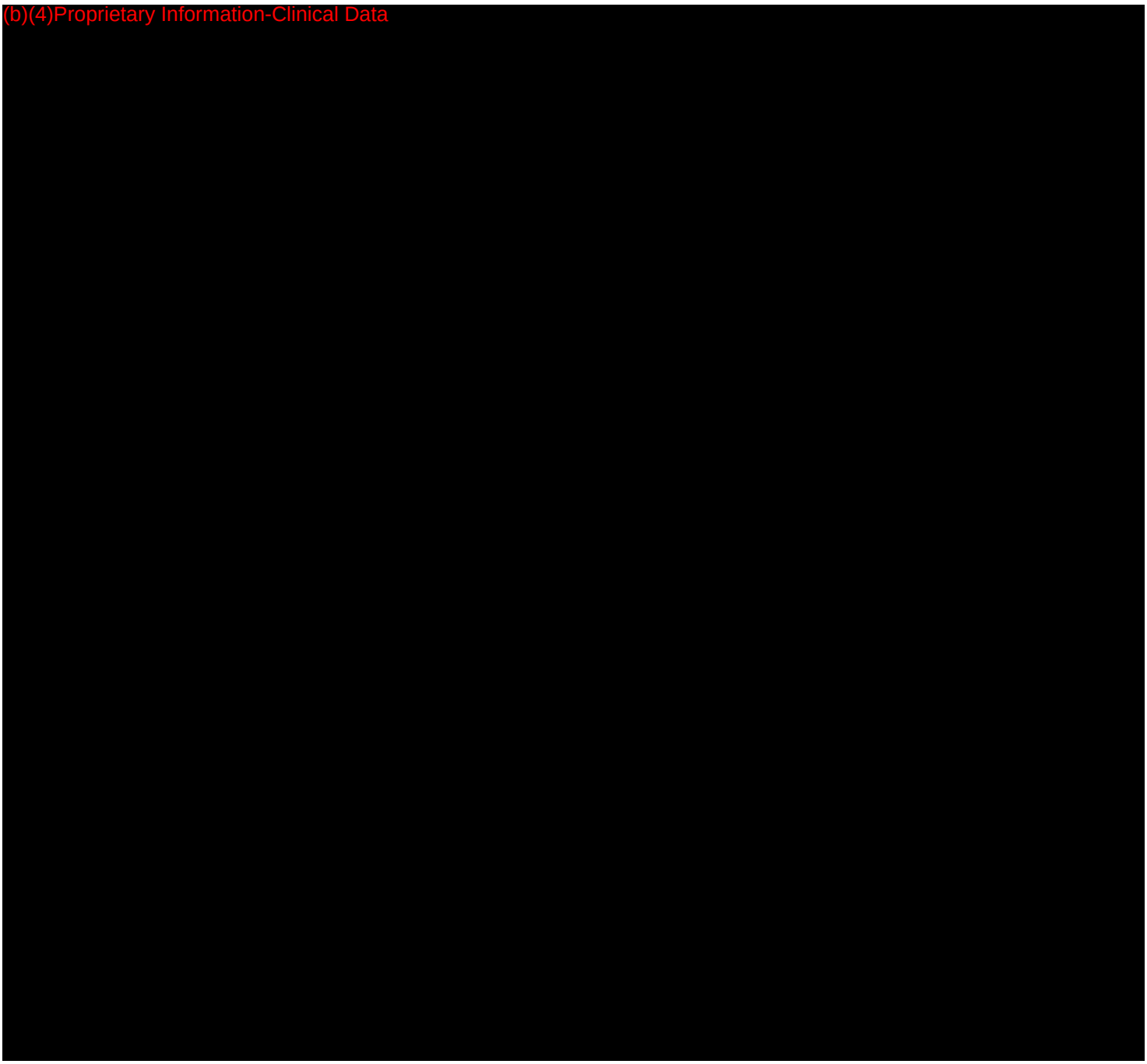


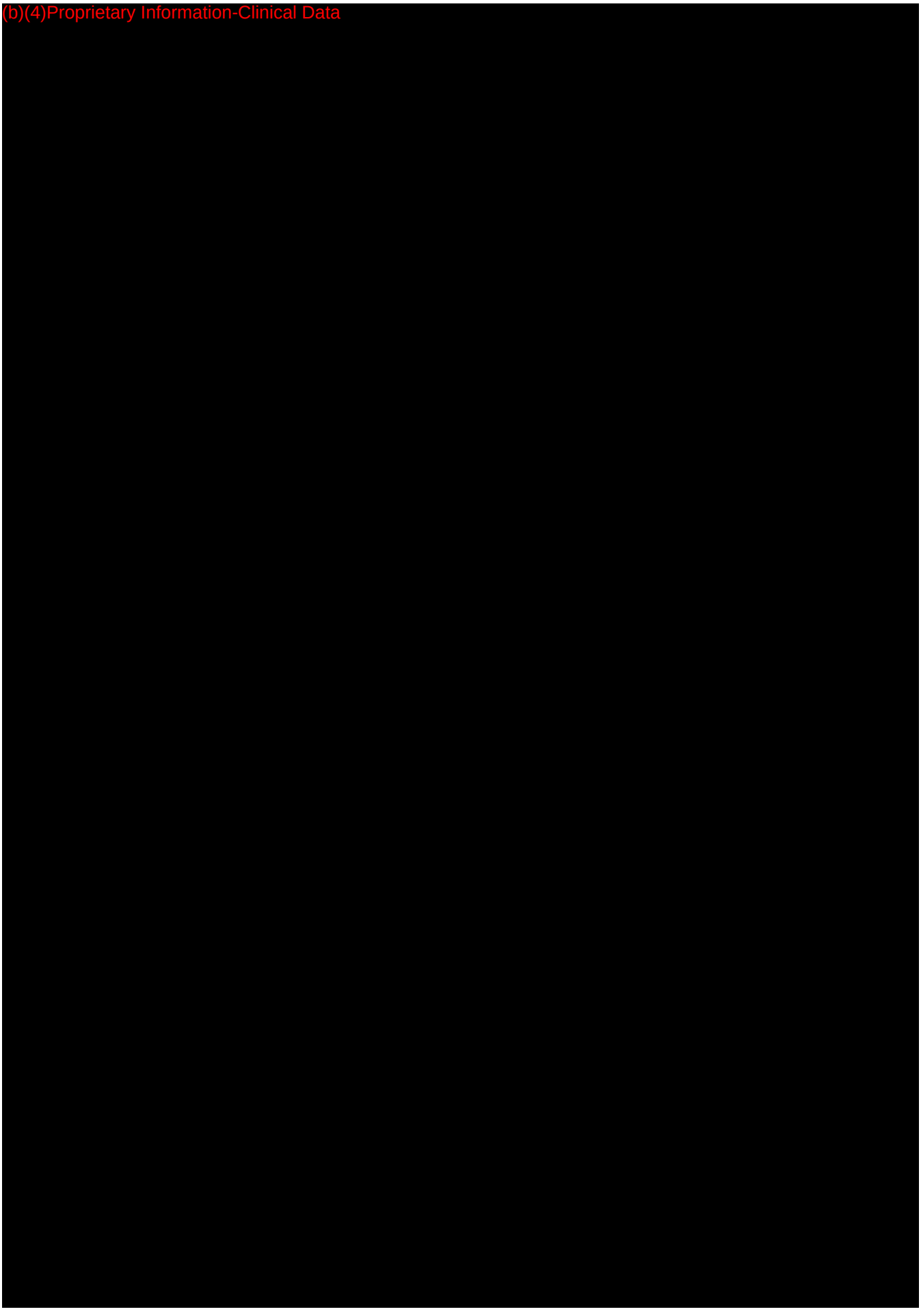
(b)(4)Proprietary Information-Clinical Data

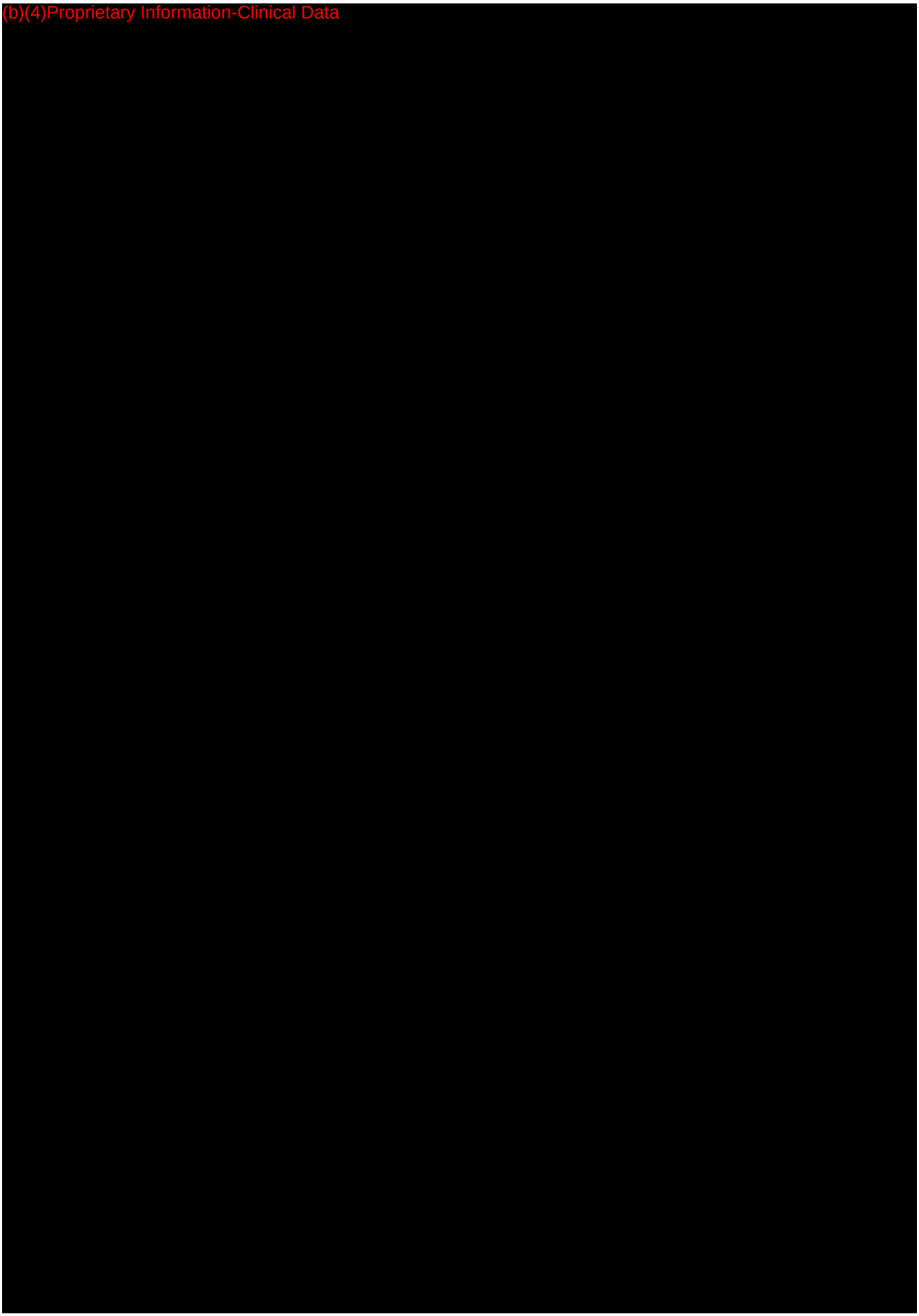


(b)(4)Proprietary Information-Clinical Data



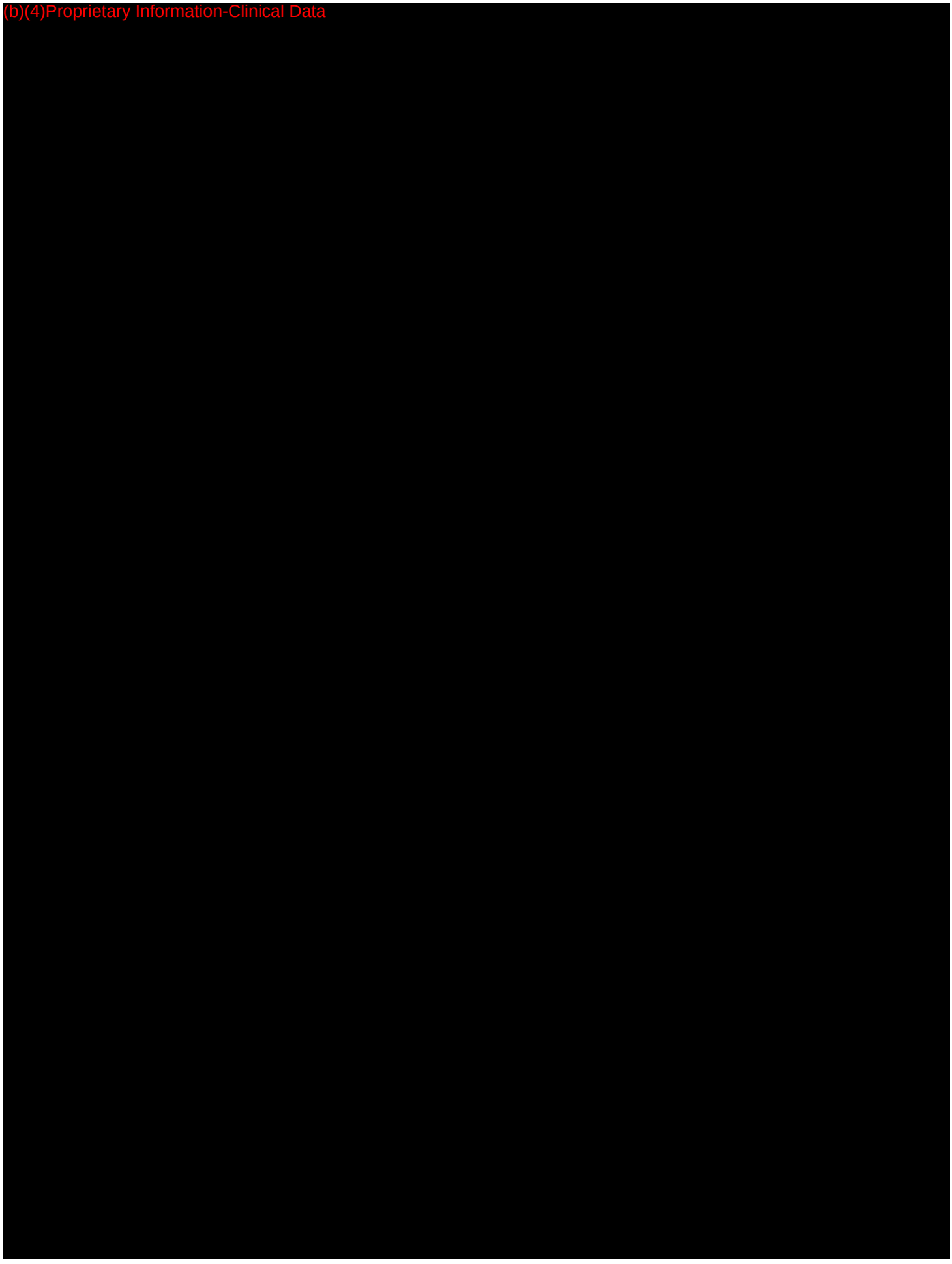




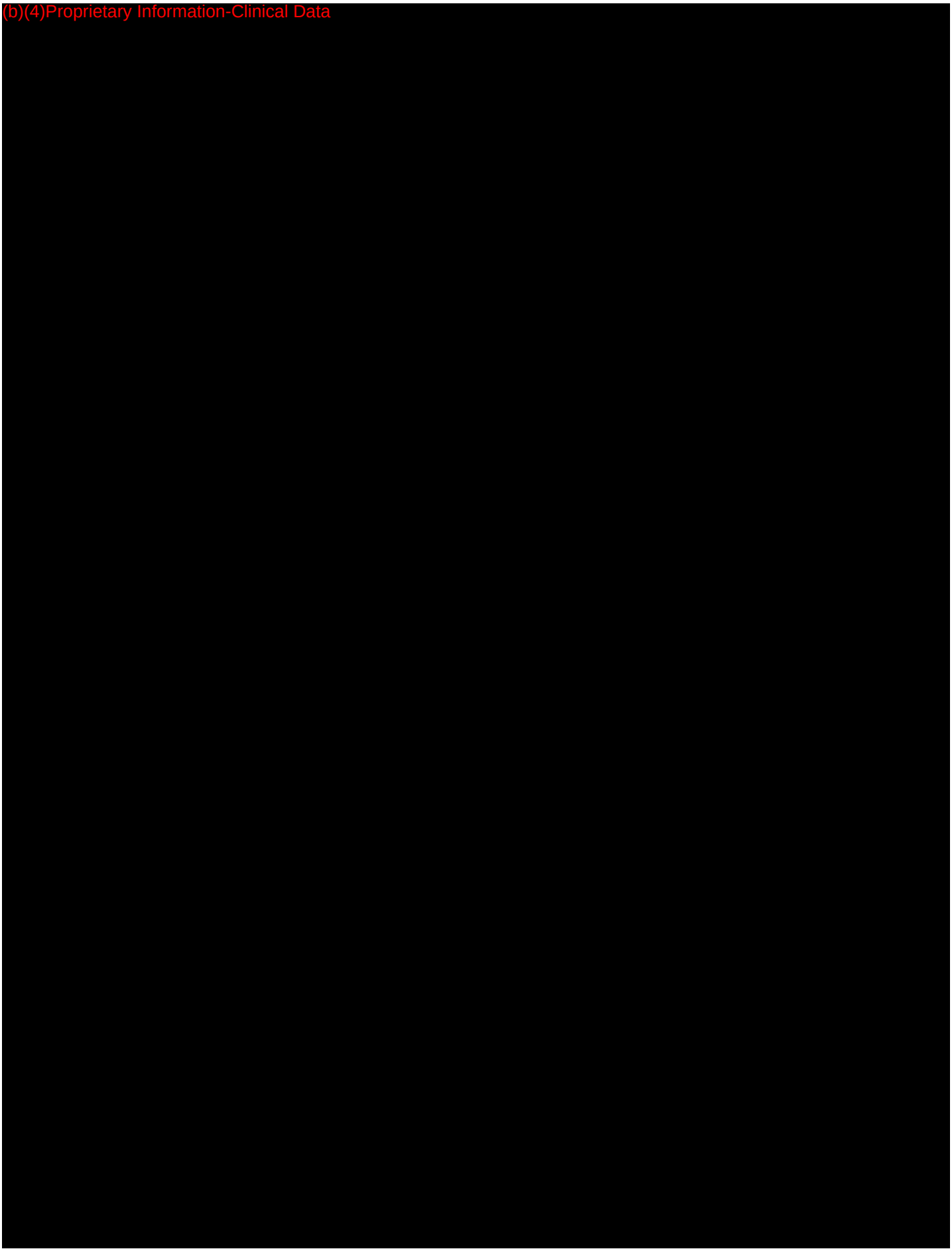


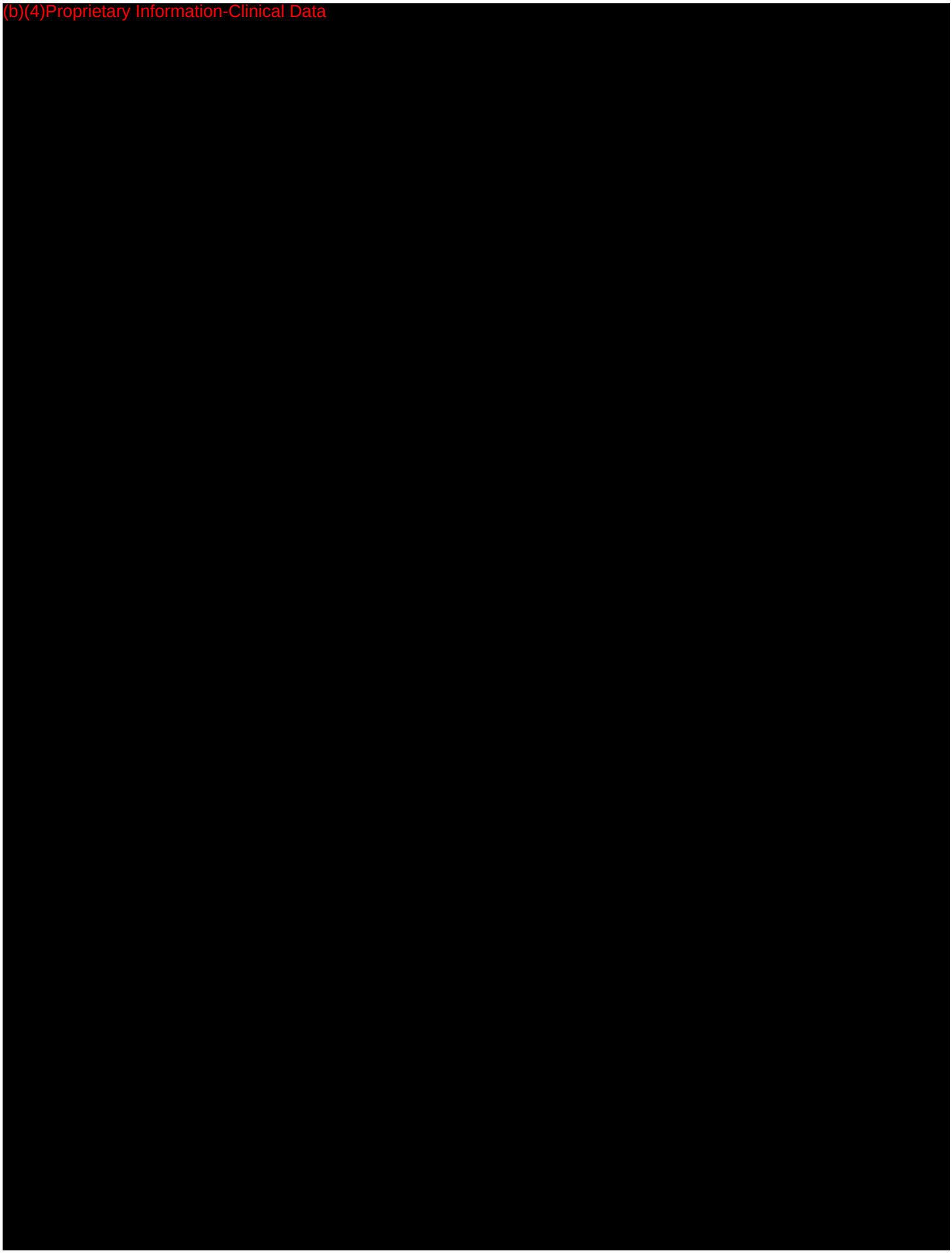
(b)(4)Proprietary Information-Clinical Data

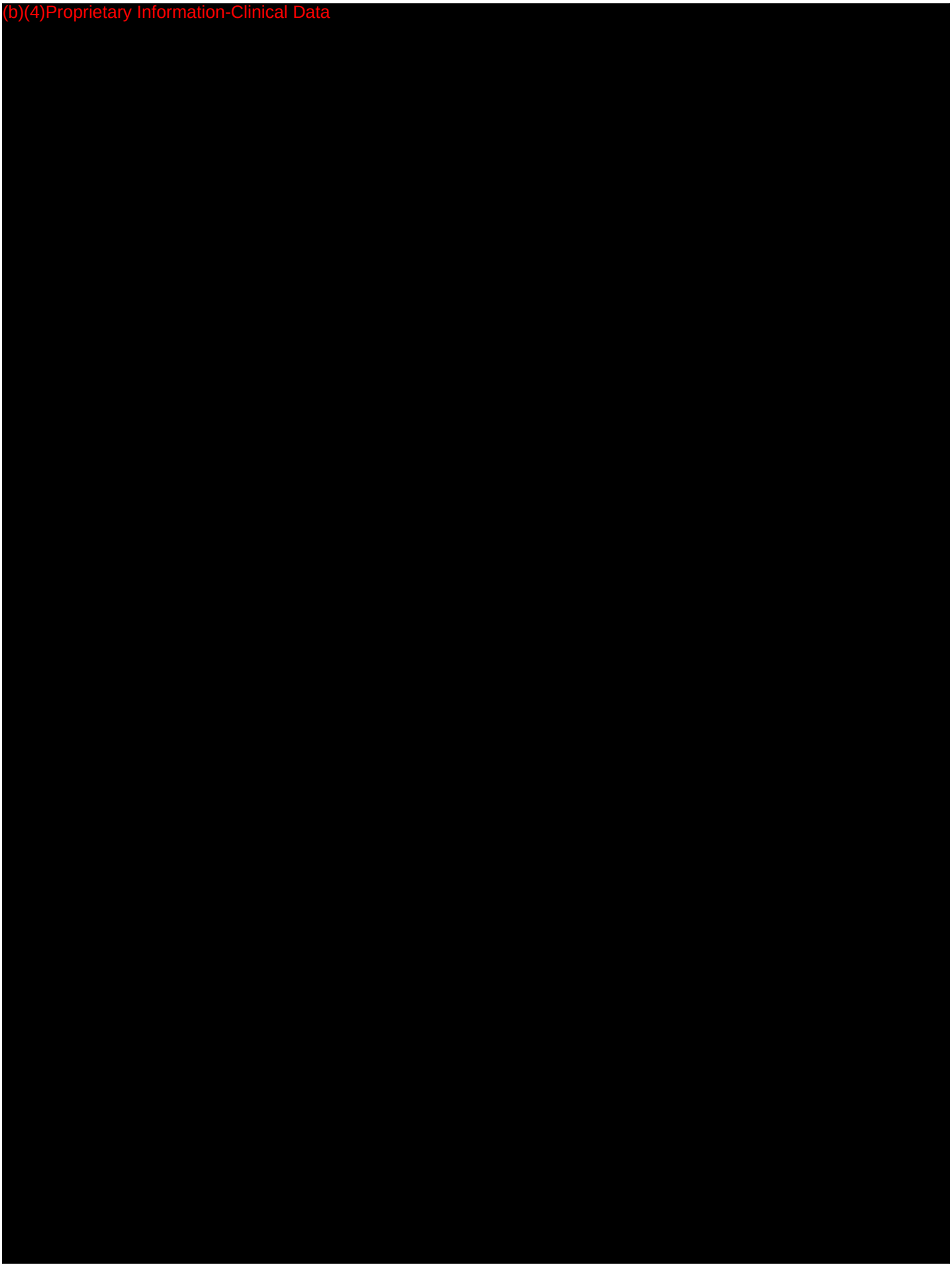
[redacted]

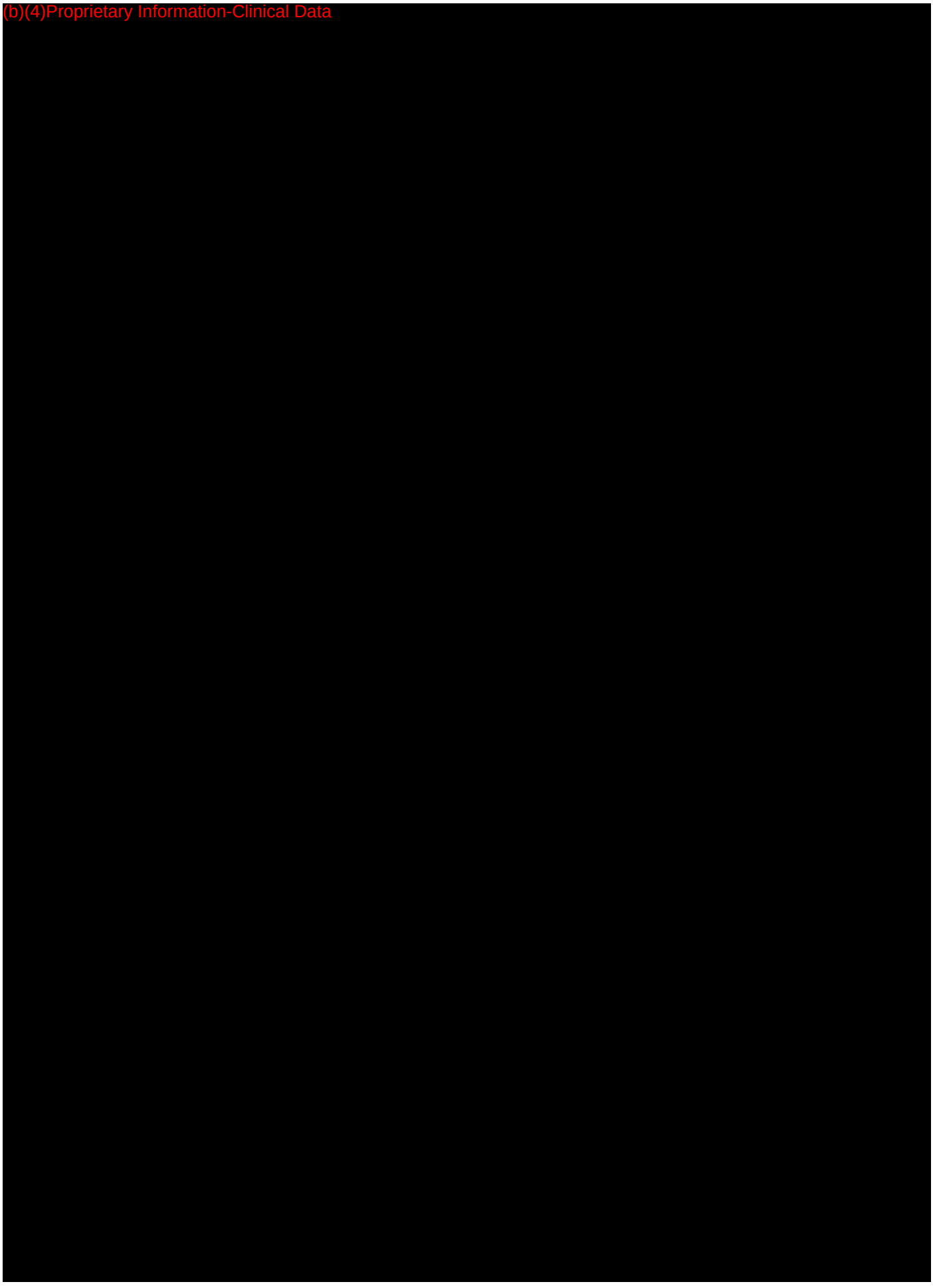


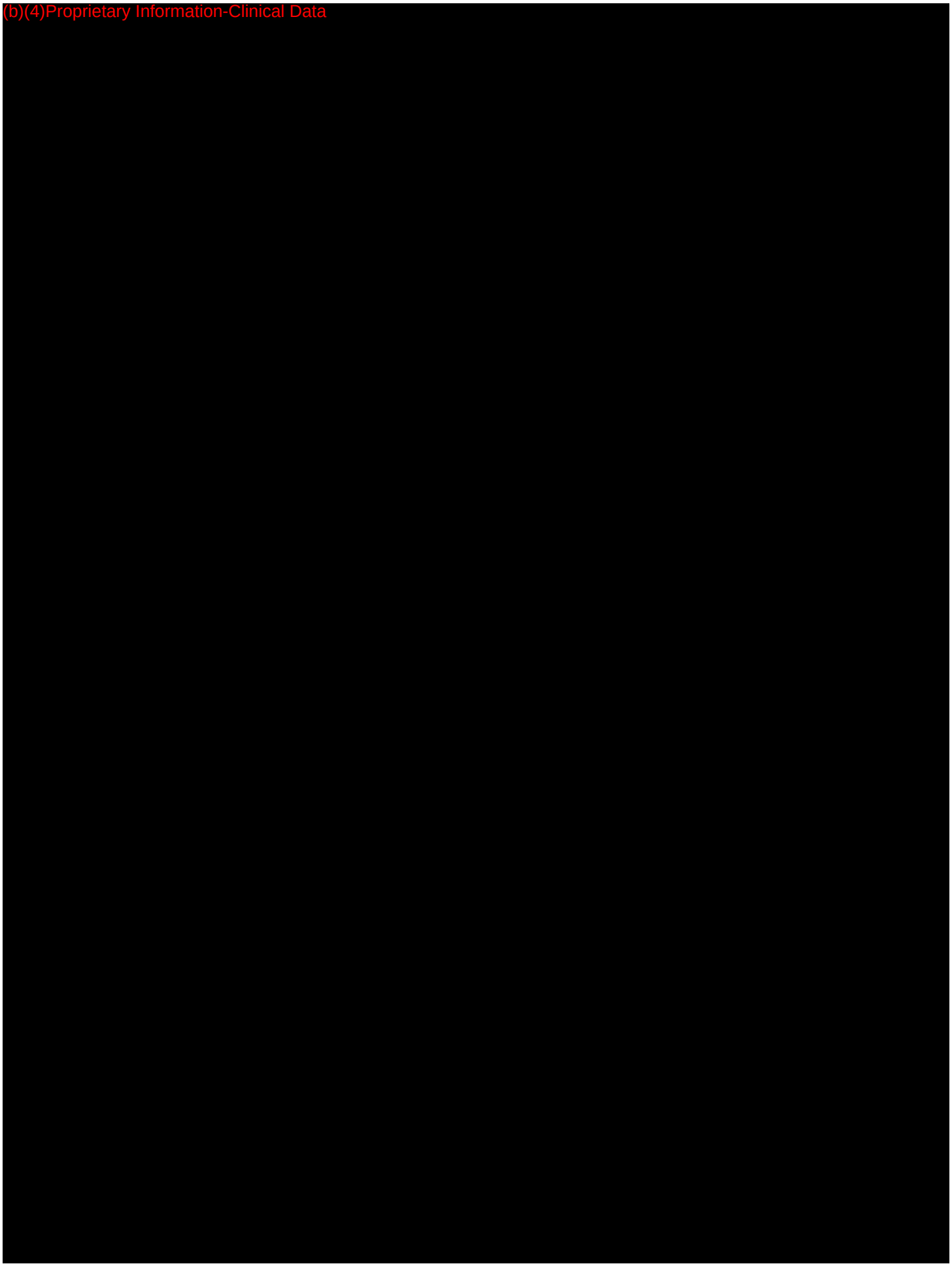
(b)(4)Proprietary Information-Clinical Data

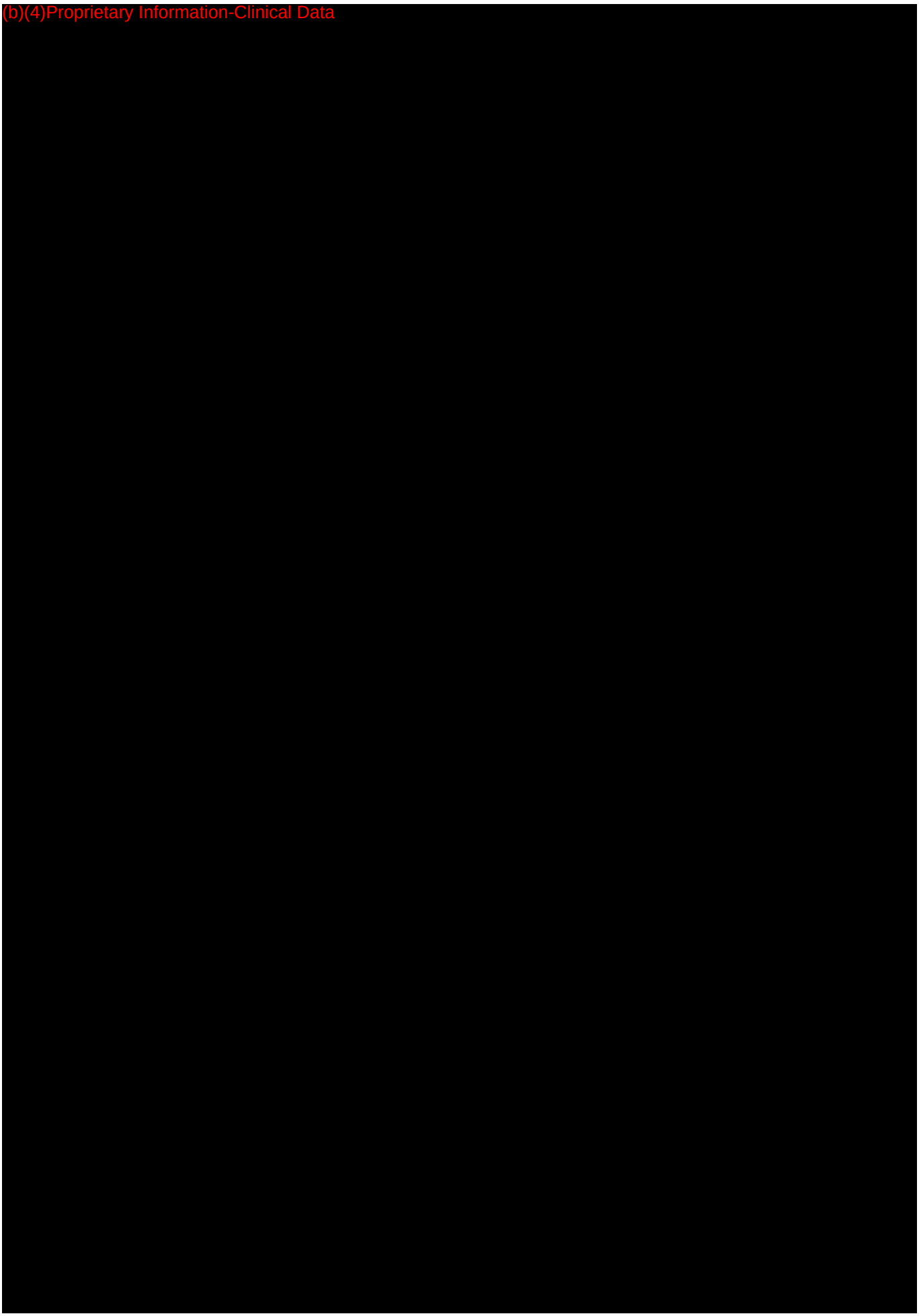


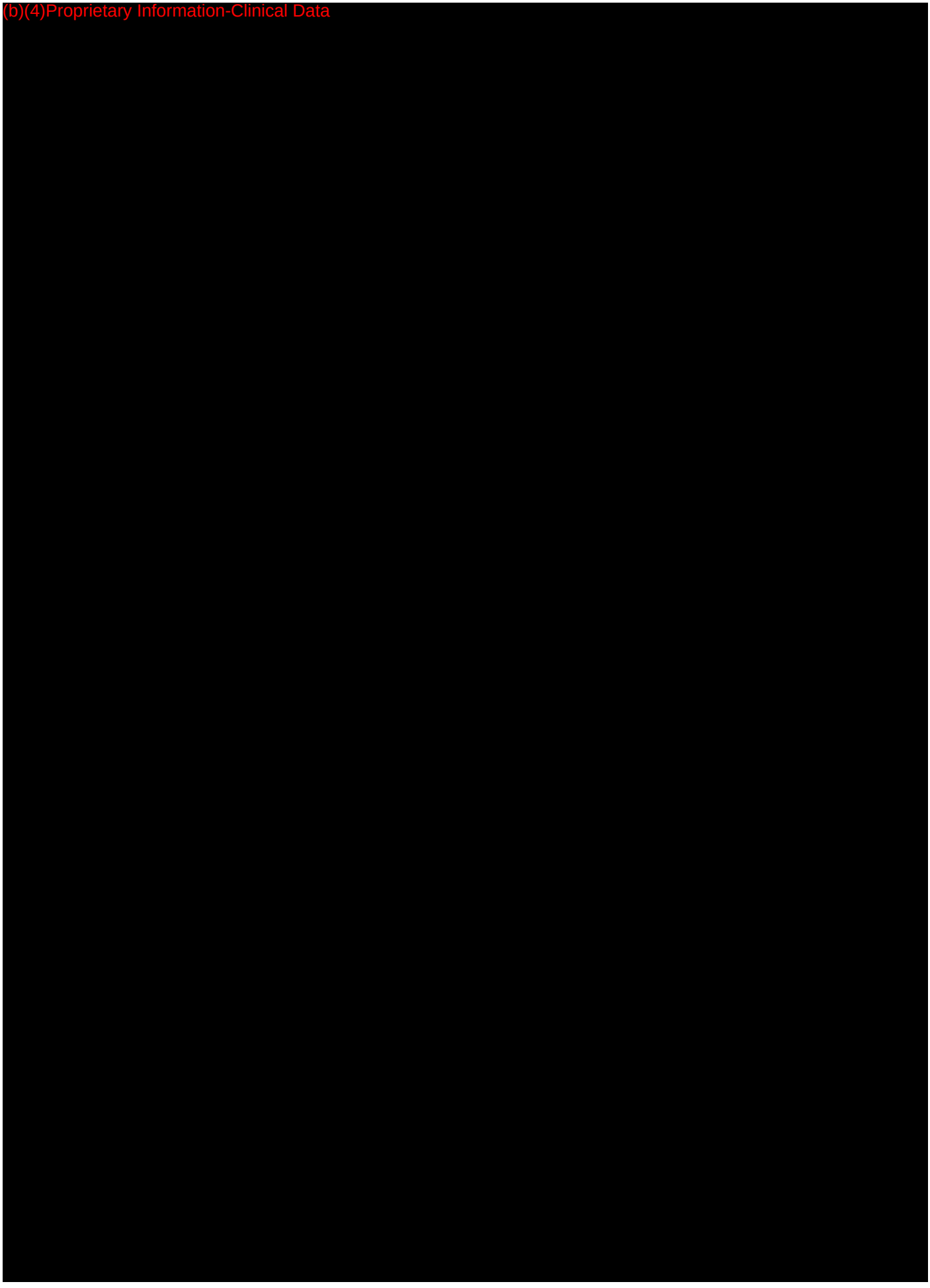


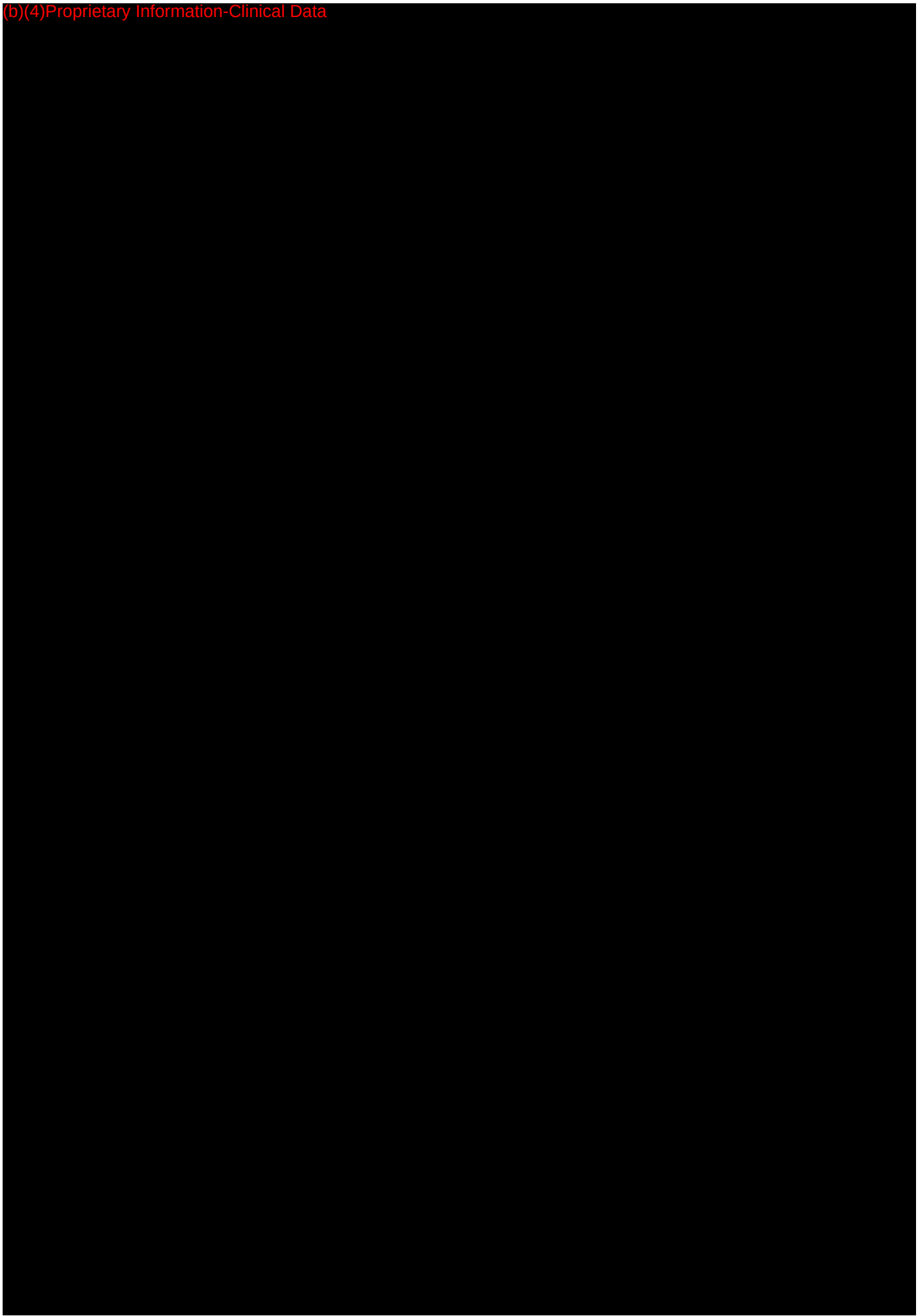


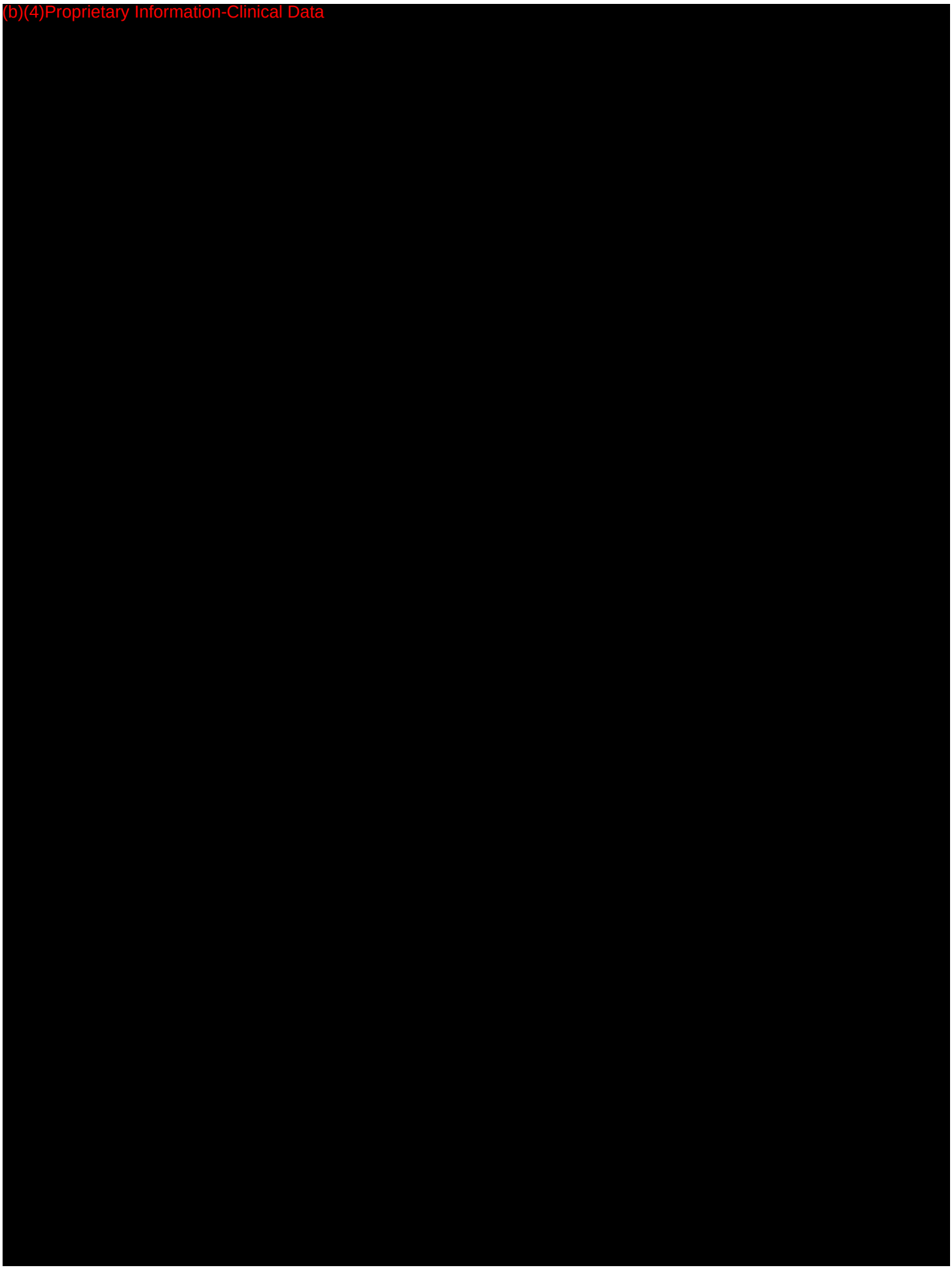


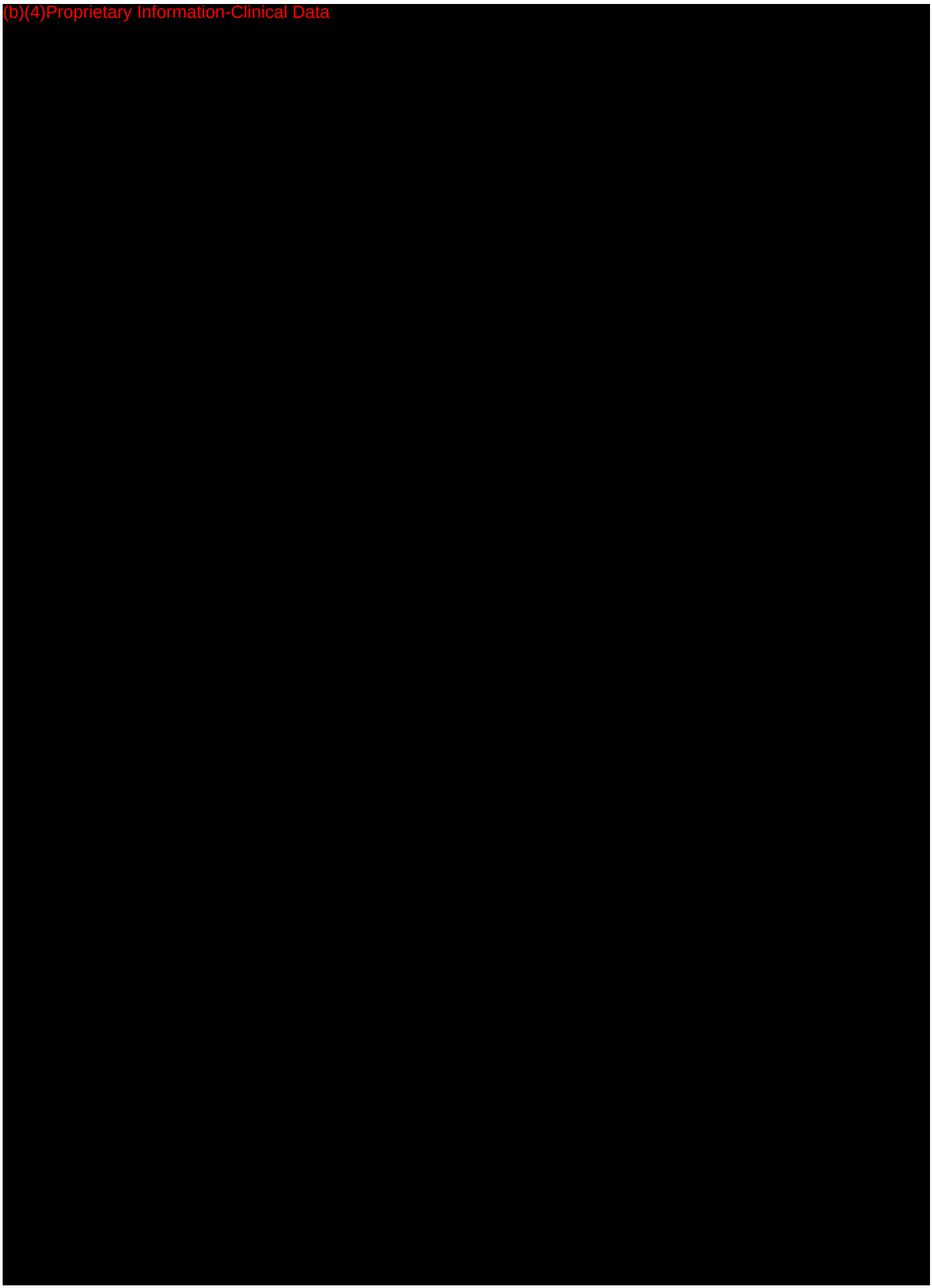


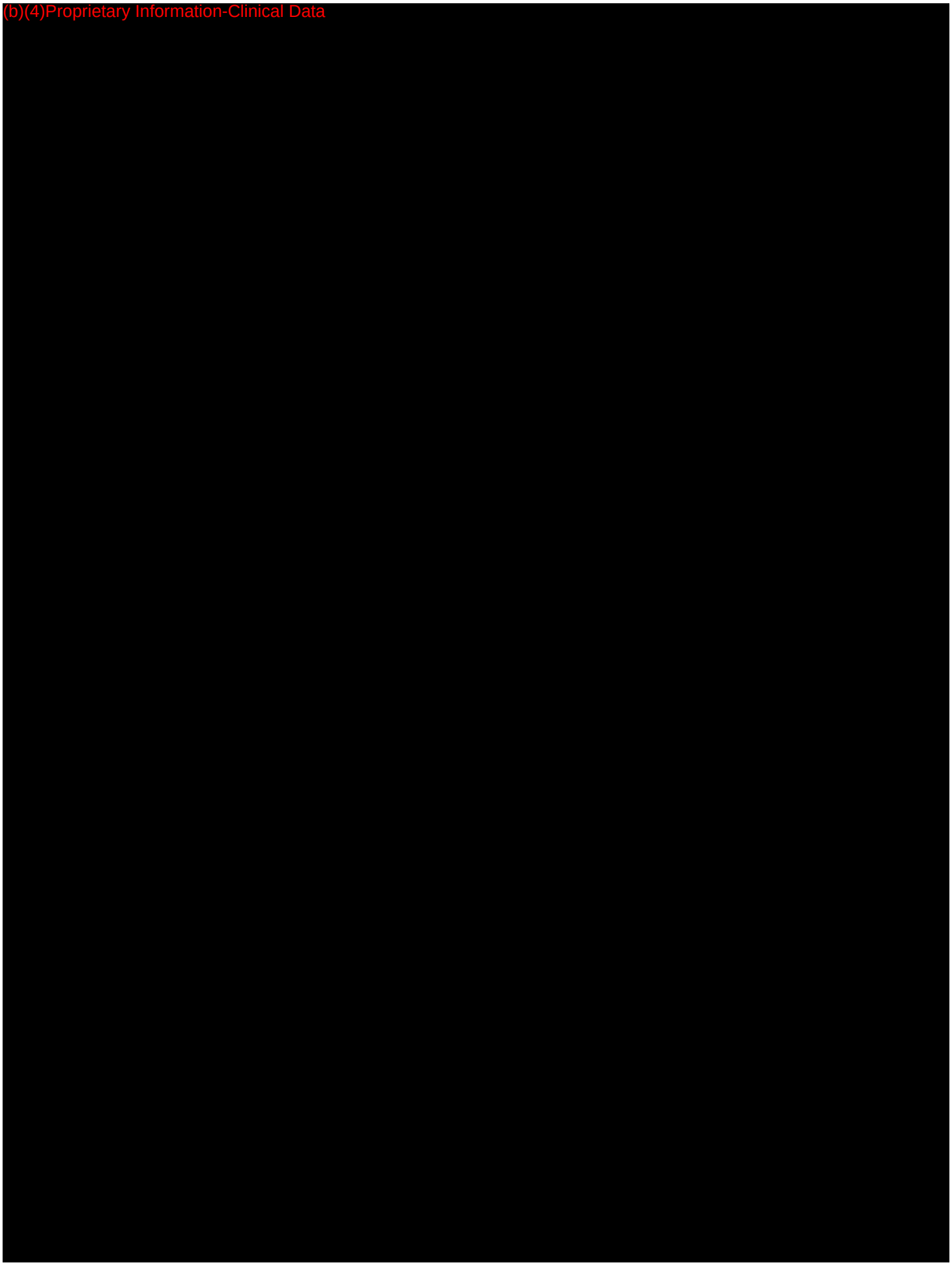




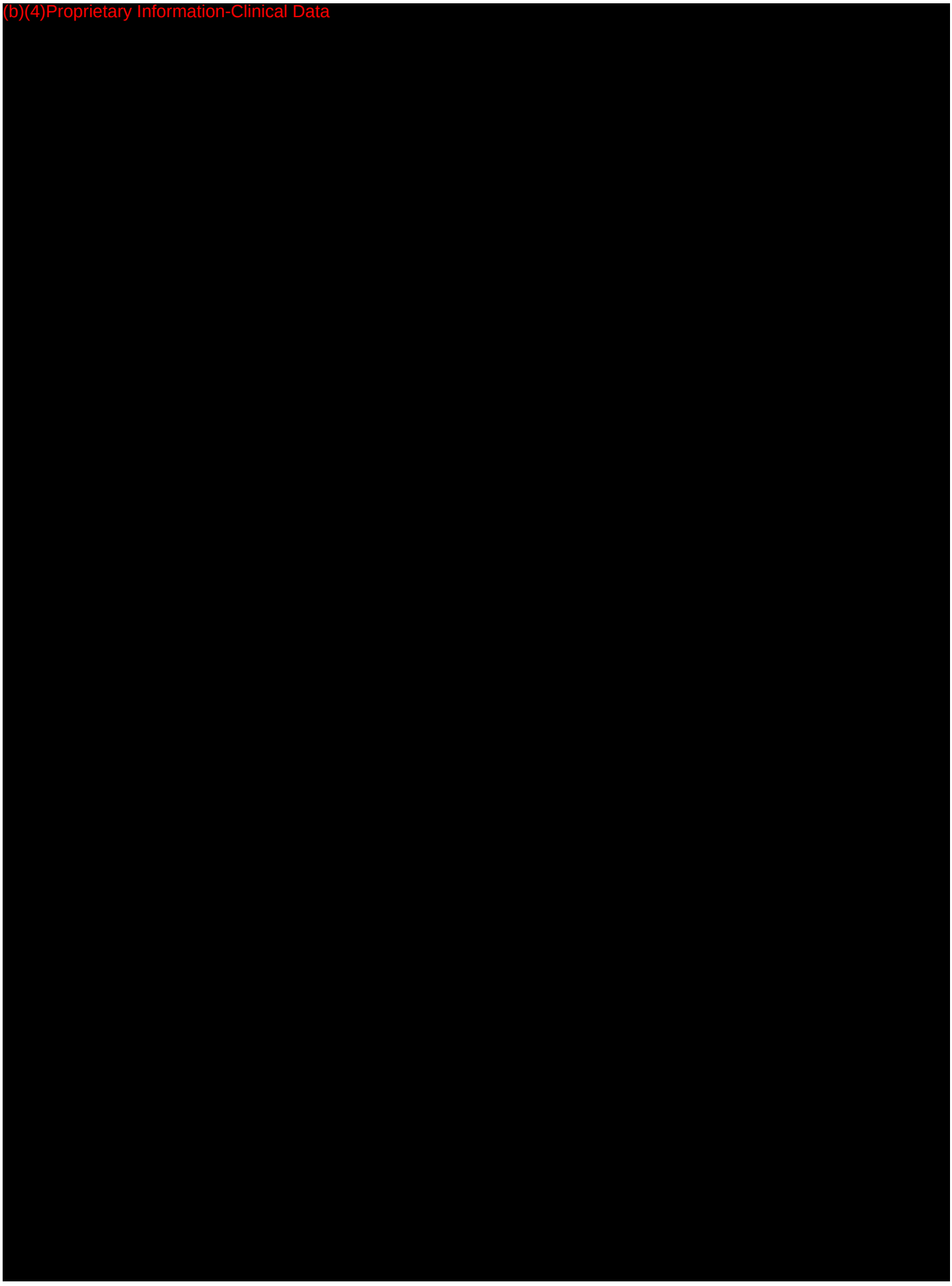




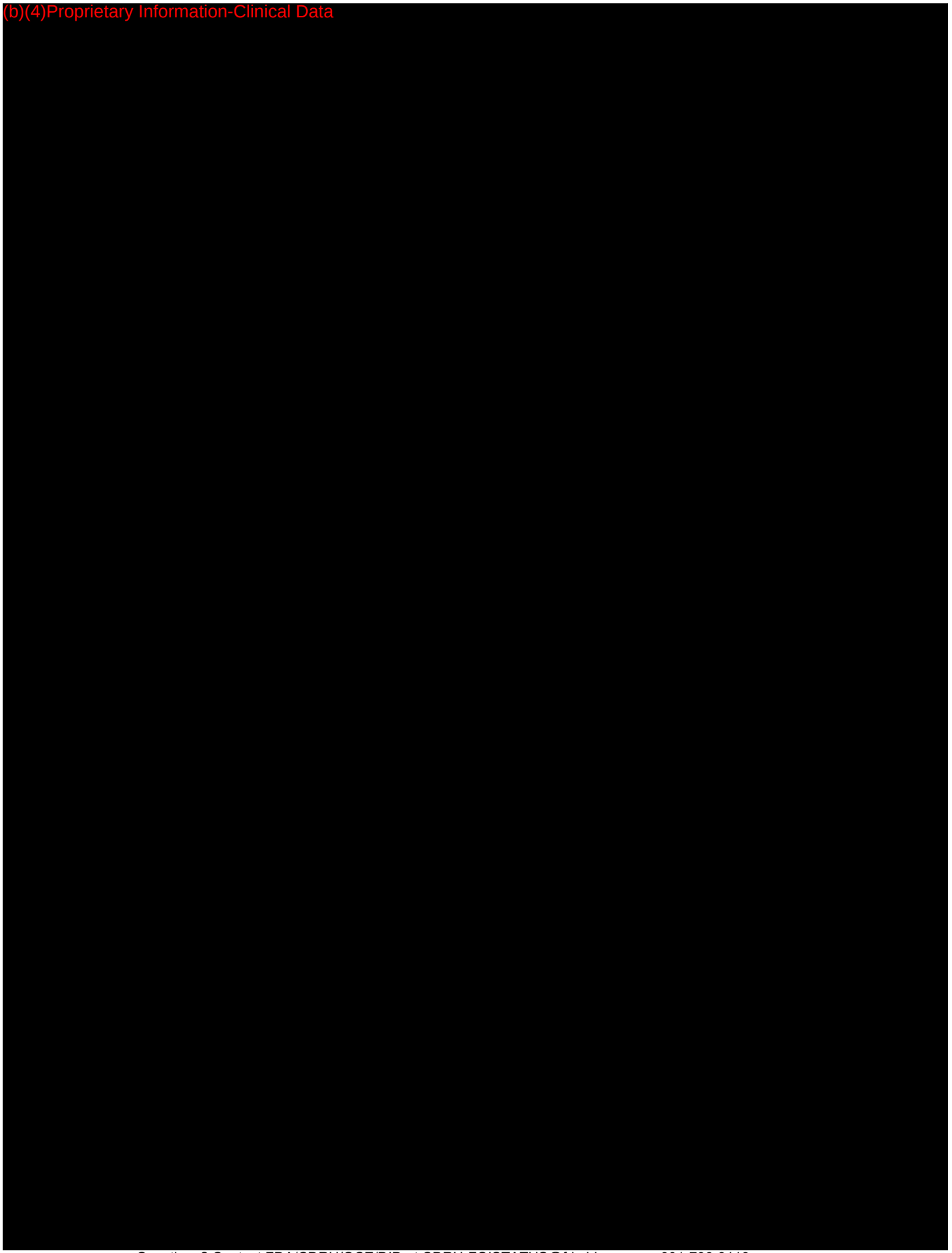


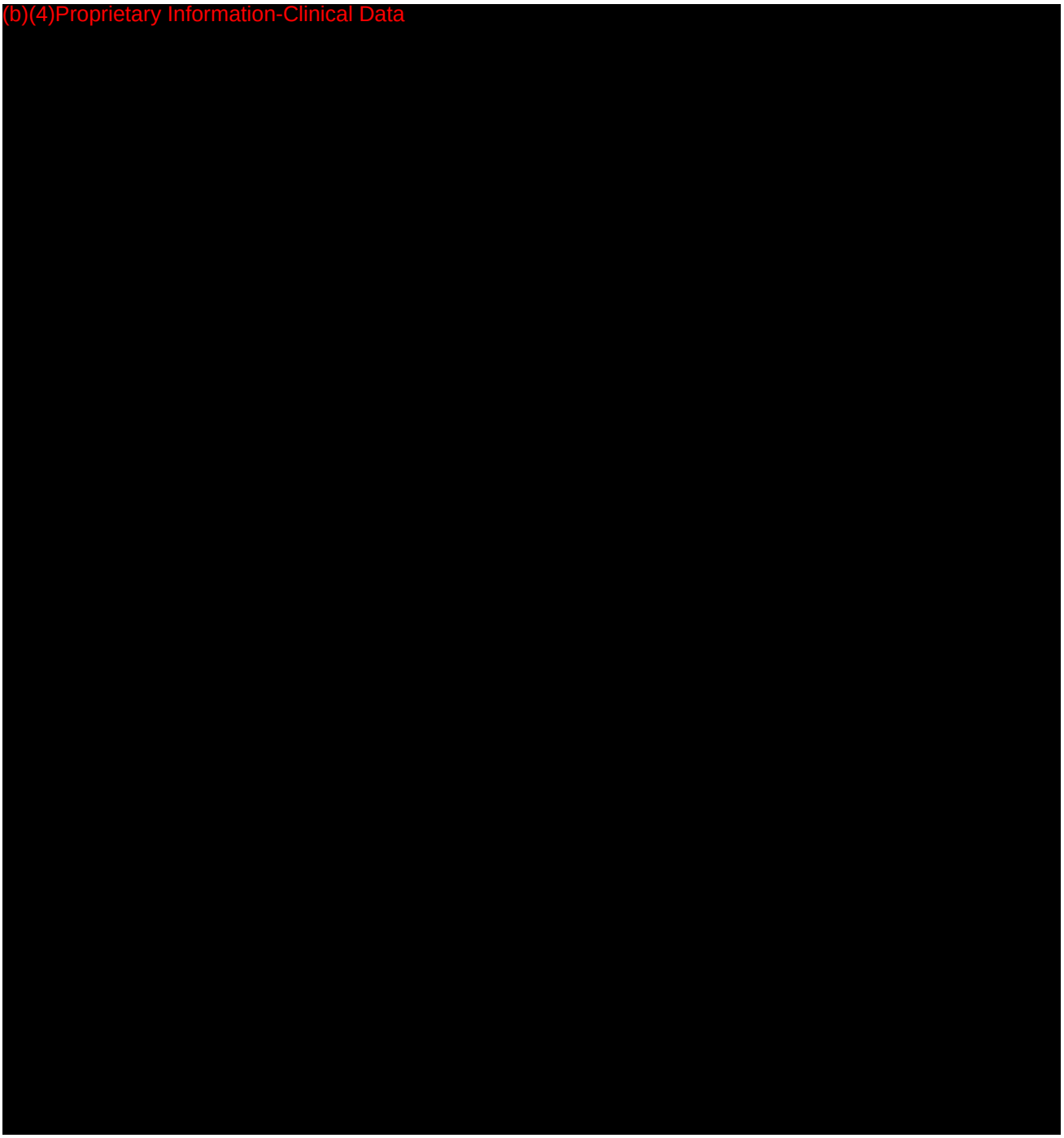


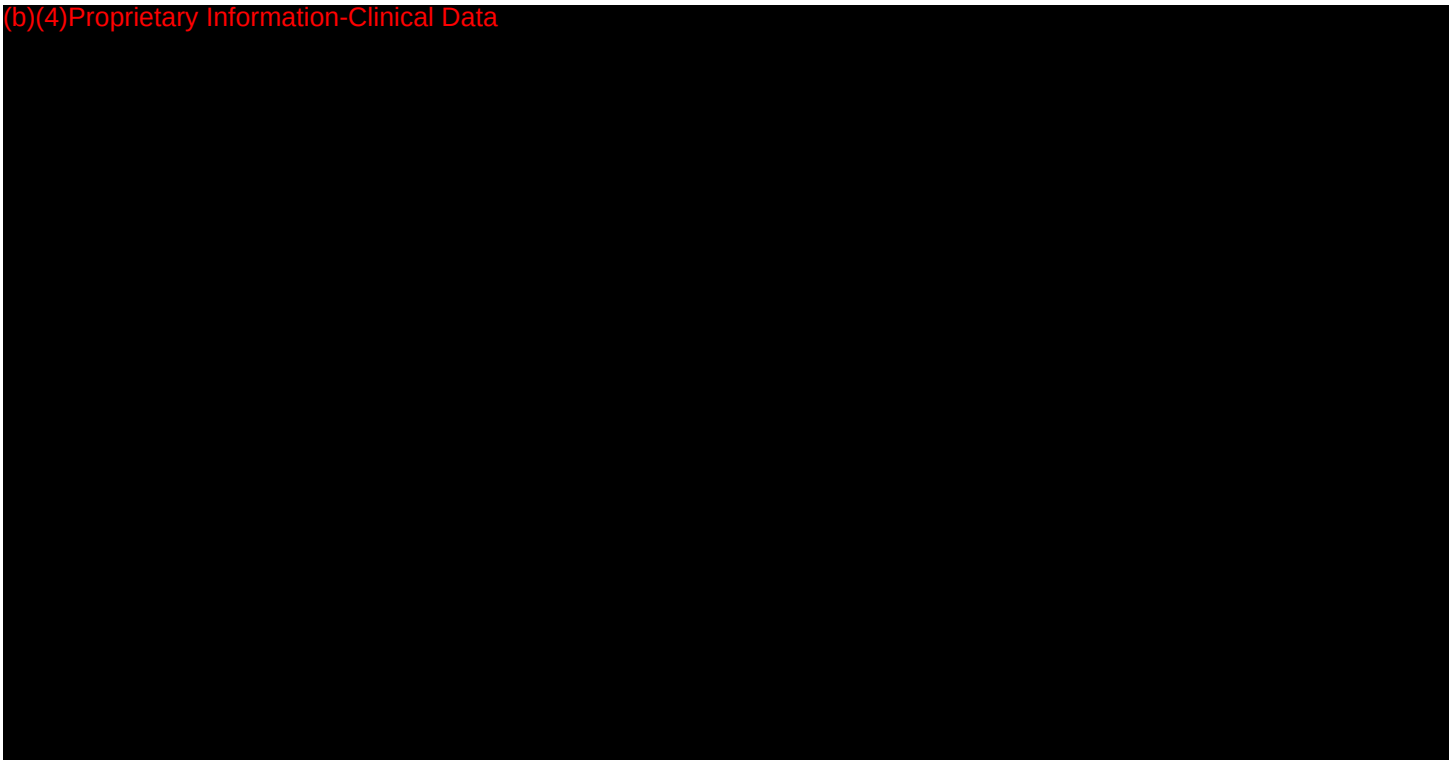
(b)(4)Proprietary Information-Clinical Data

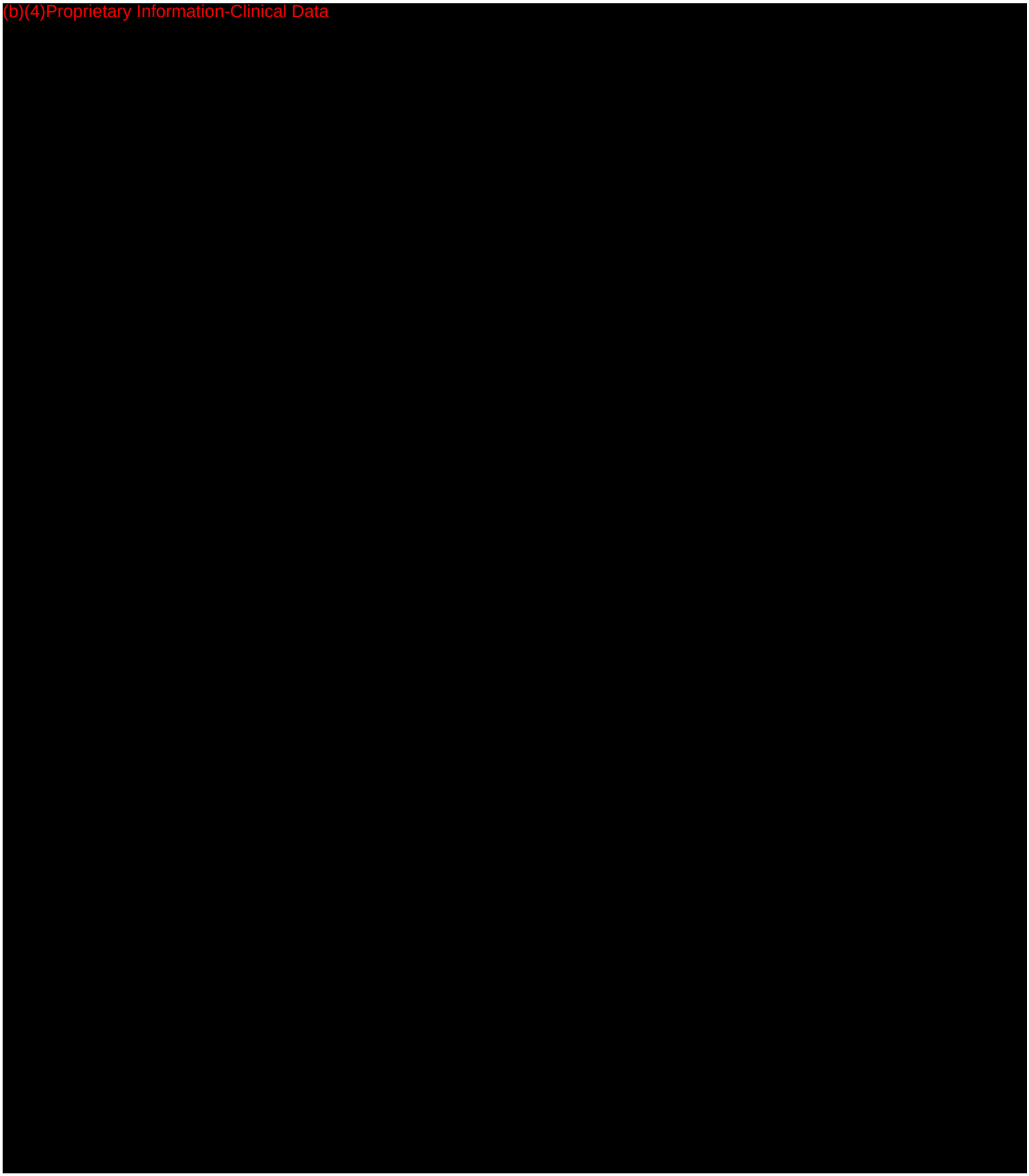


(b)(4)Proprietary Information-Clinical Data

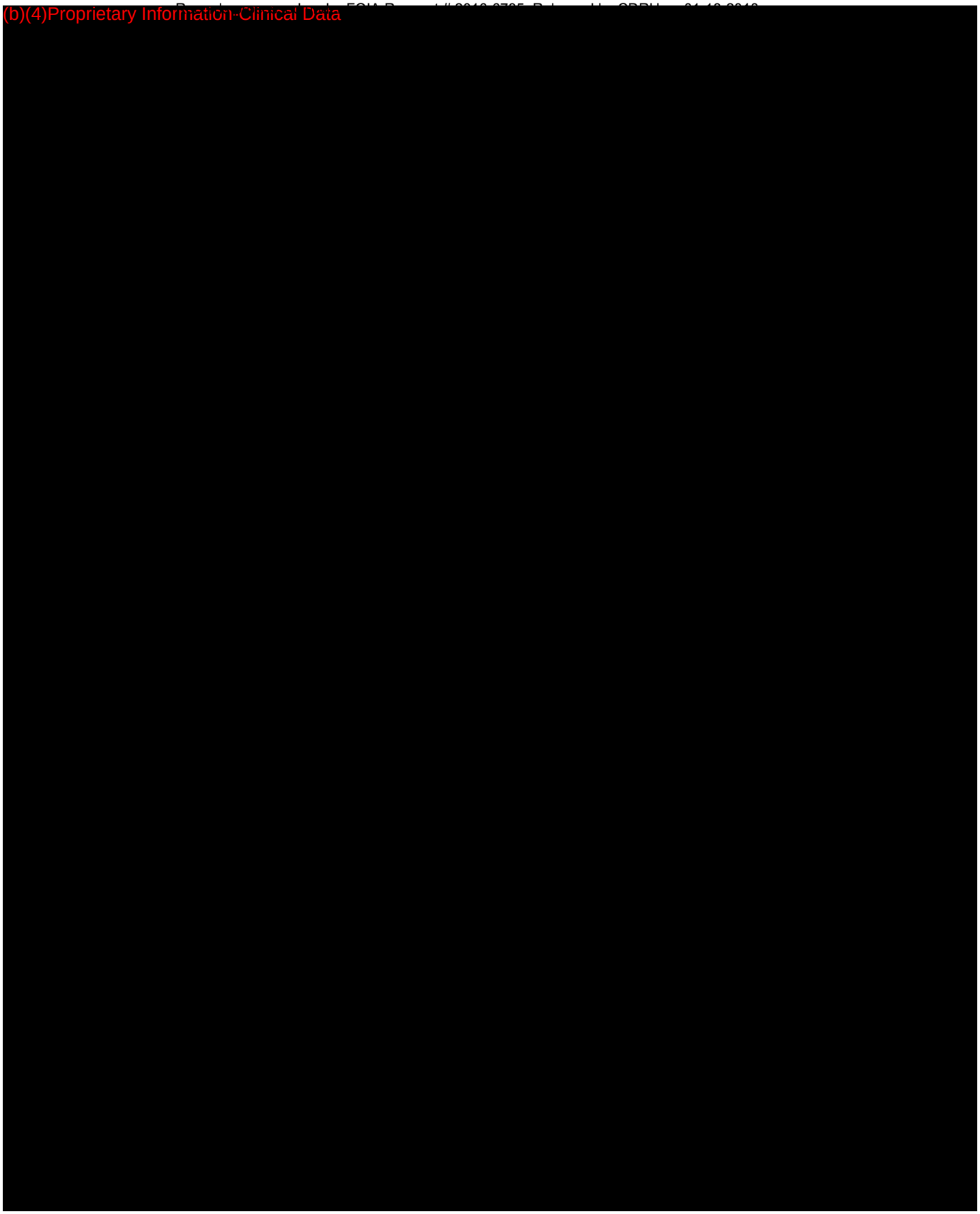








(b)(4)Proprietary Information-Clinical Data



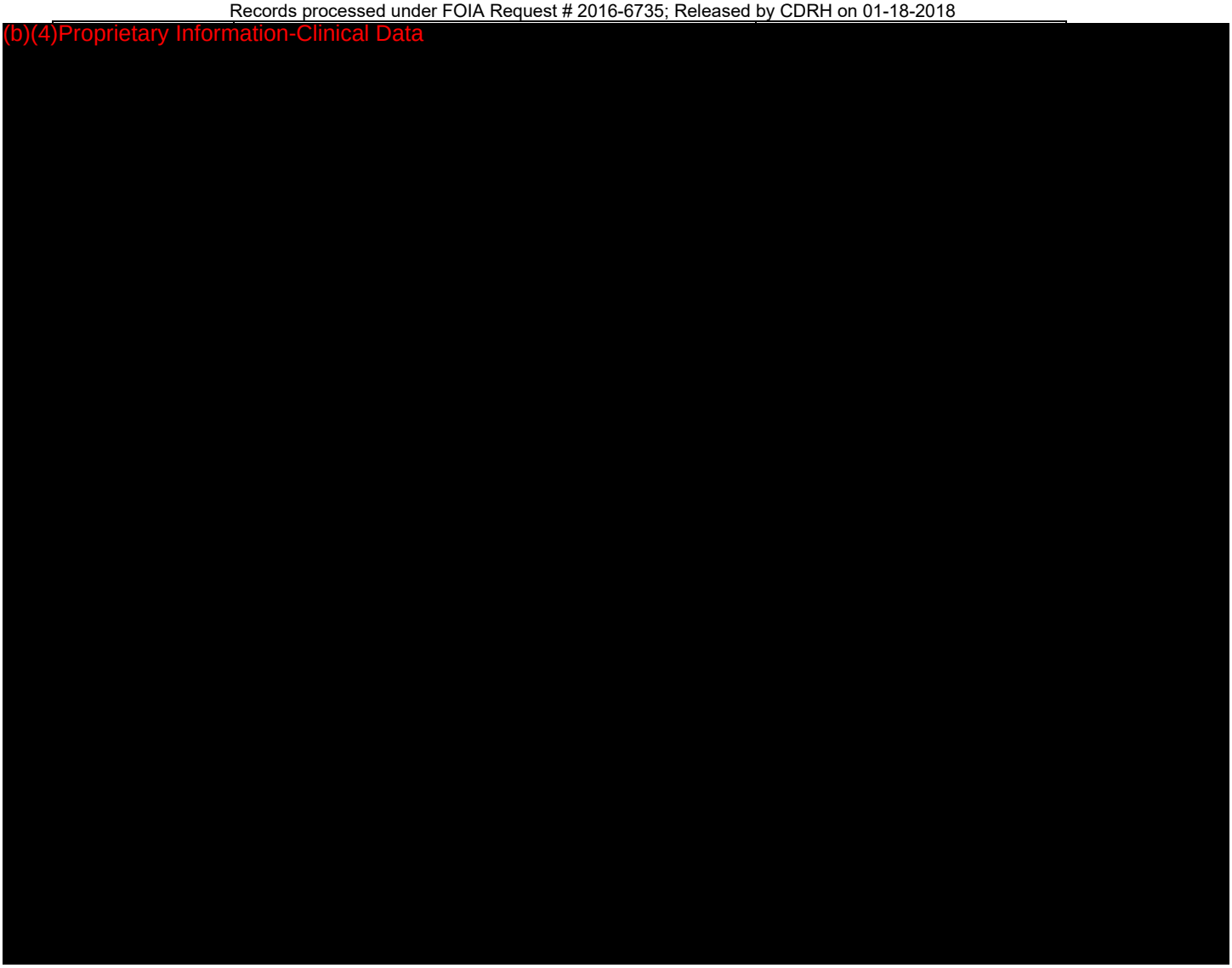
(b)(4)Proprietary Information-Clinical Data

[redacted]

(b)(4)Proprietary Information-Clinical Data

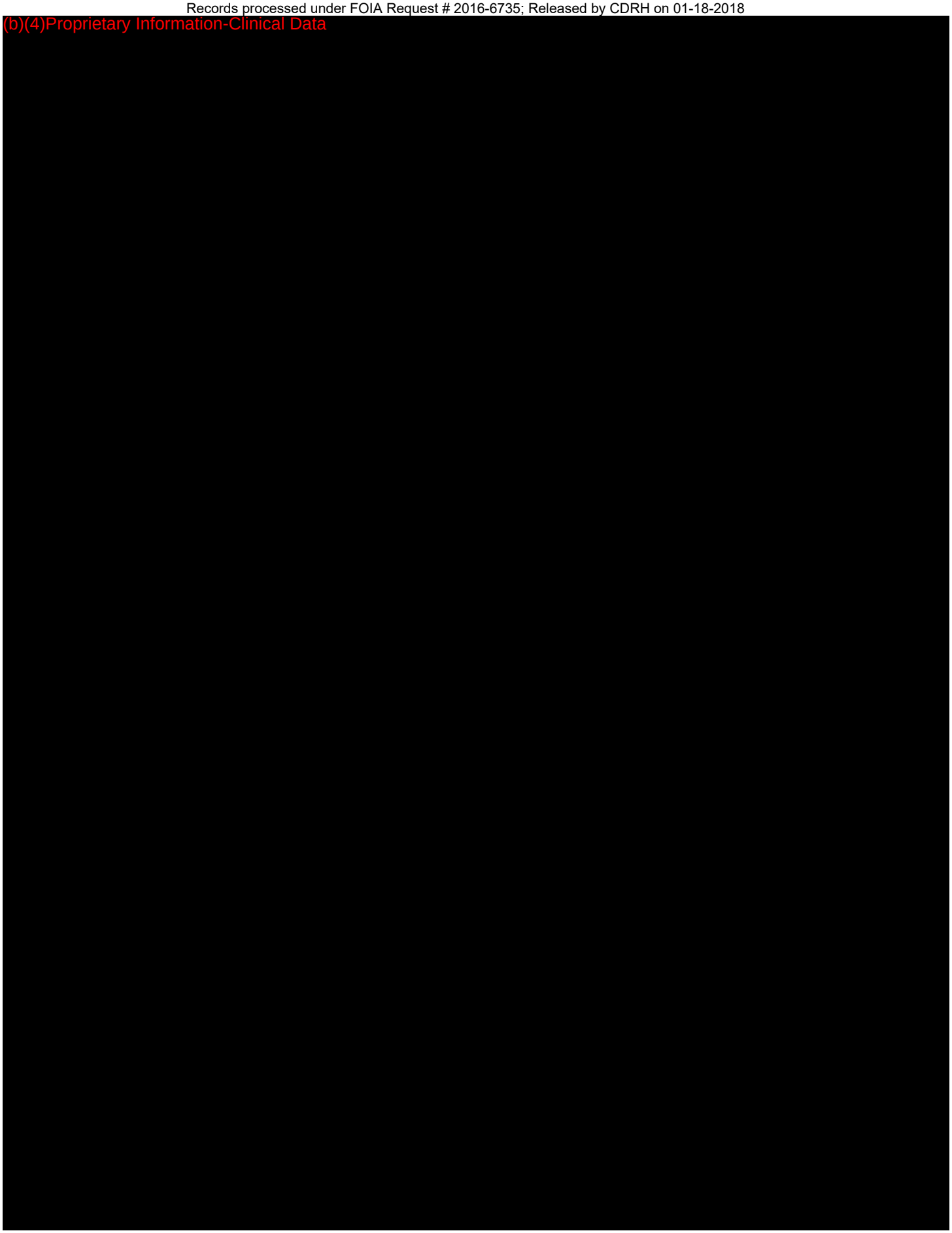
[redacted]

(b)(4)Proprietary Information-Clinical Data



(b)(4)Proprietary Information-Clinical Data

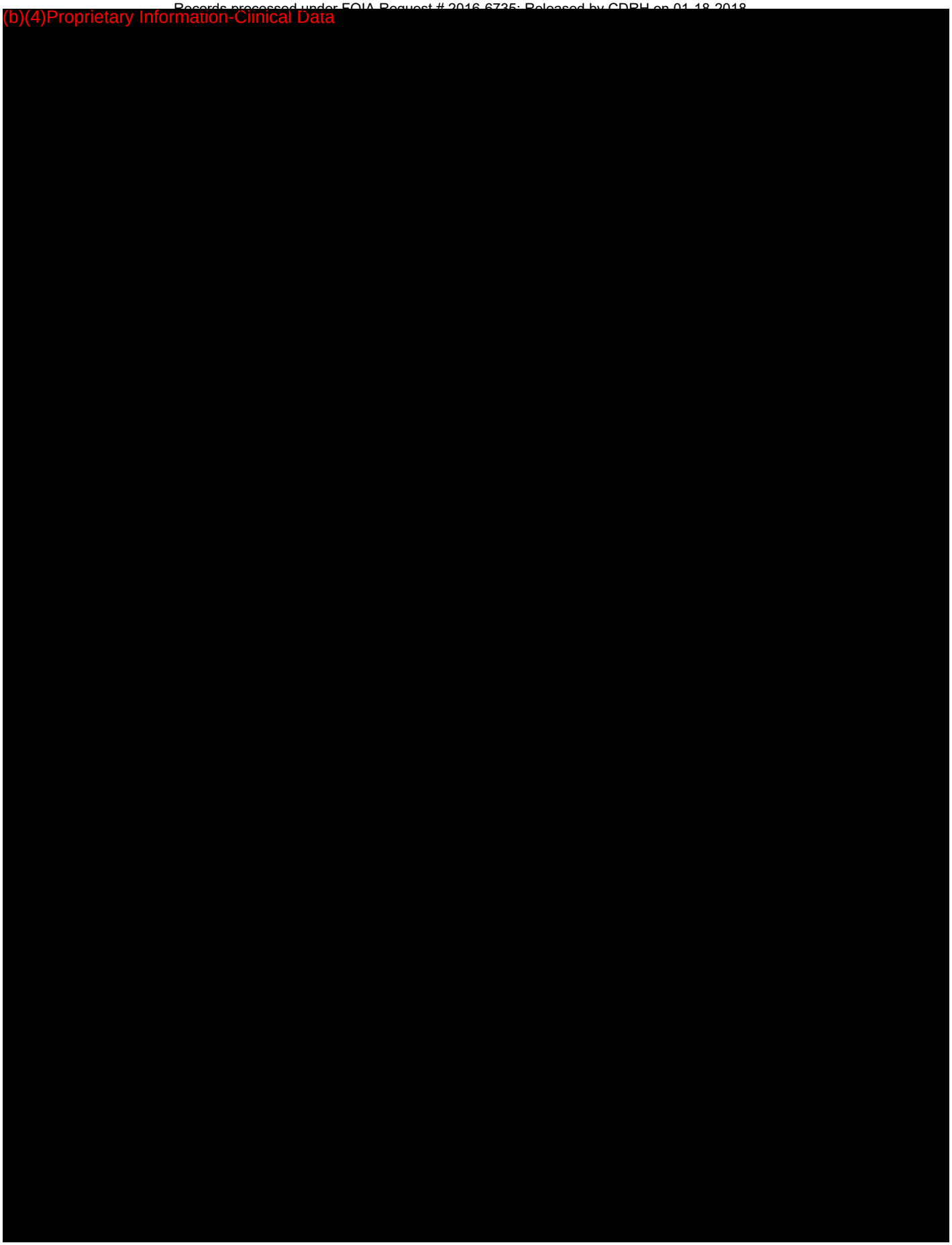
(b)(4)Proprietary Information-Clinical Data



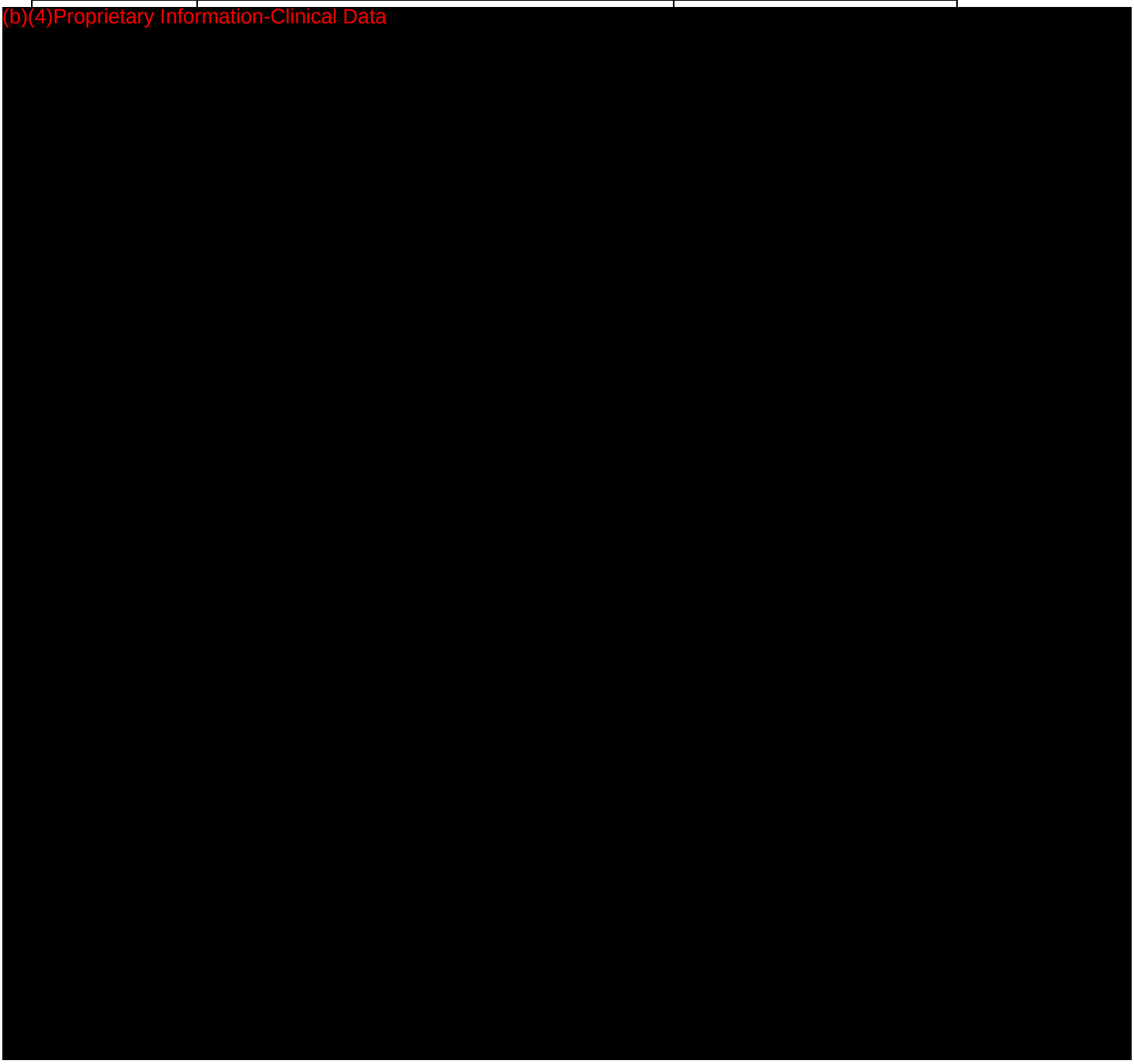
(b)(4)Proprietary Information-Clinical Data

[redacted]

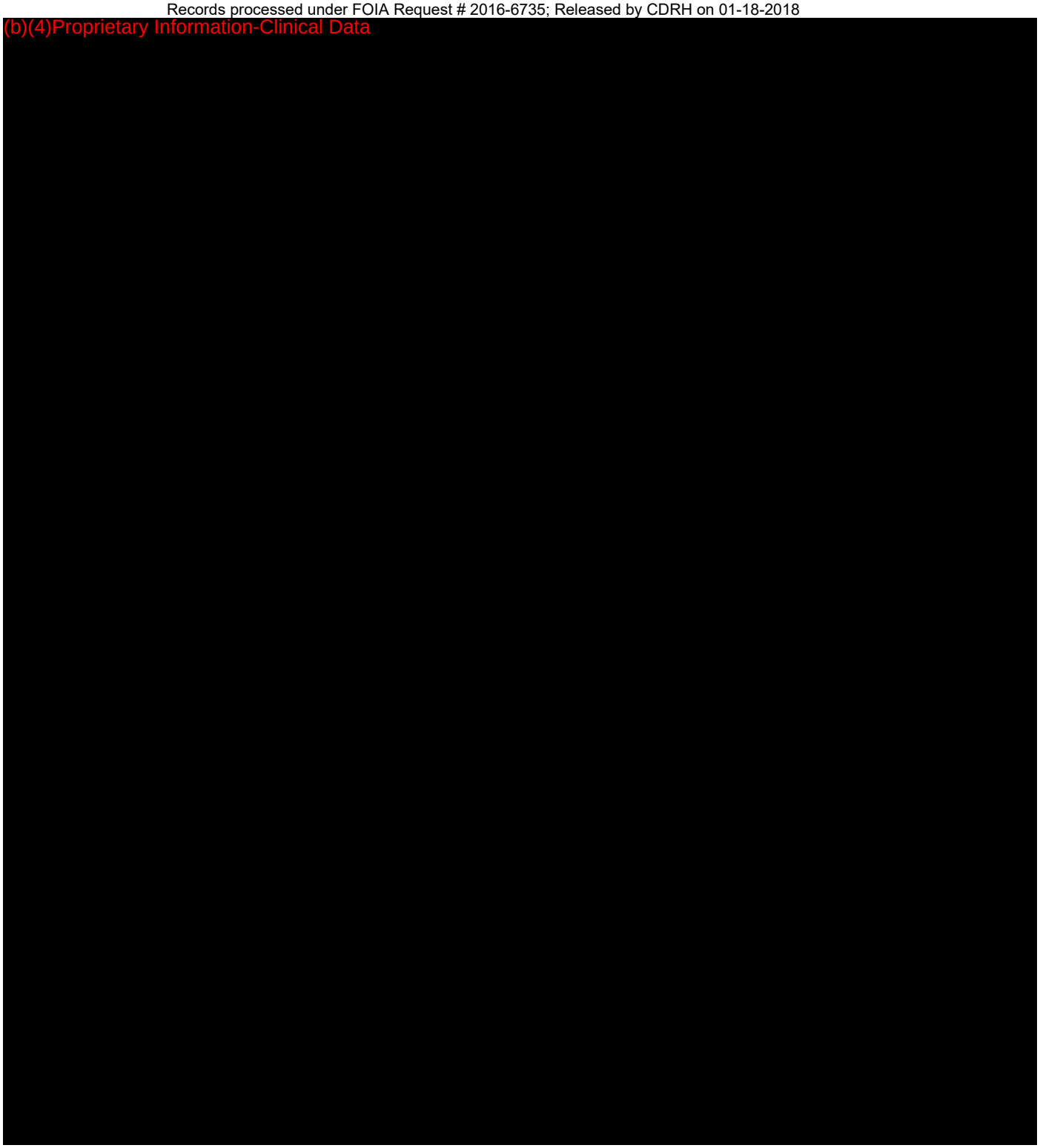
(b)(4)Proprietary Information-Clinical Data



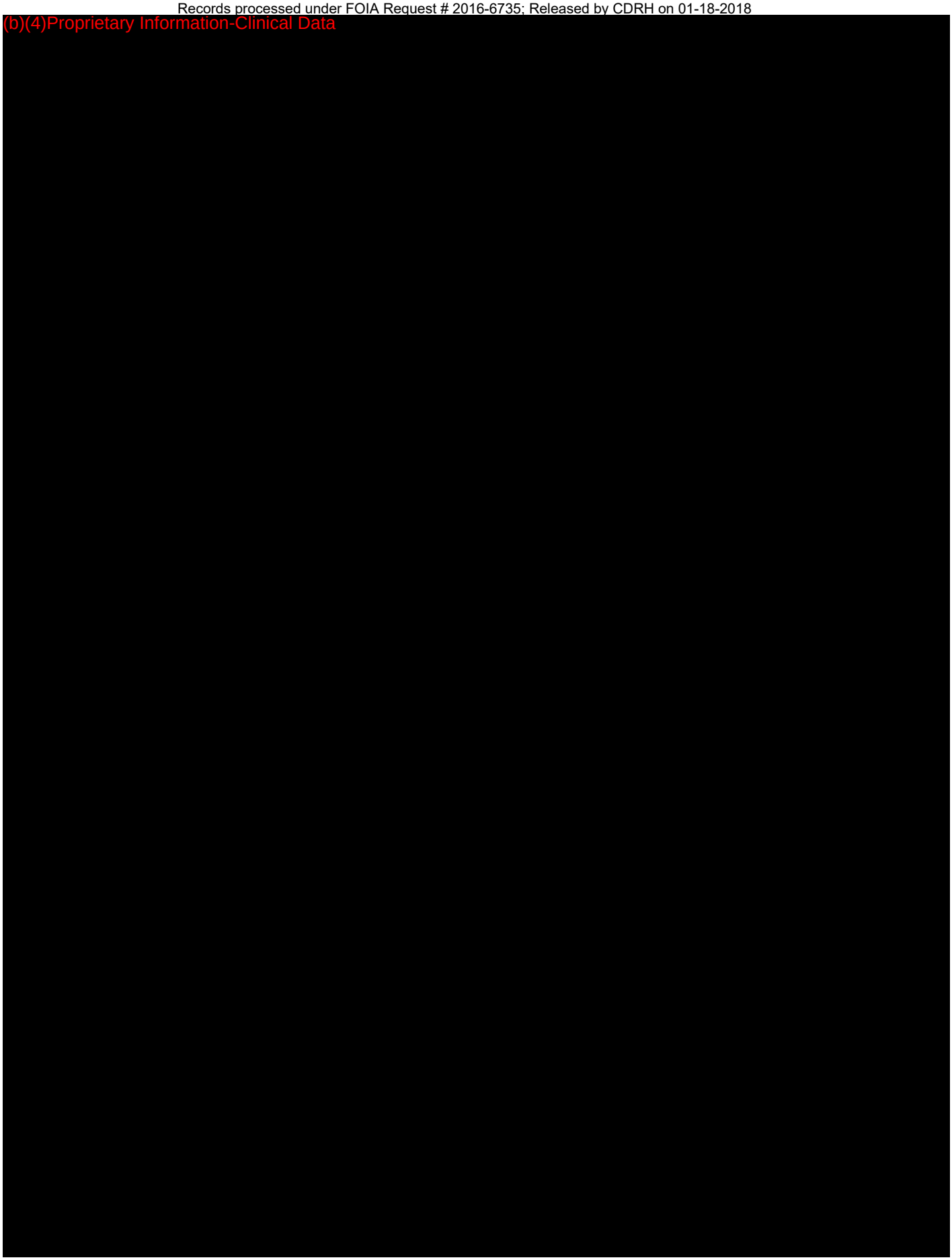
(b)(4)Proprietary Information-Clinical Data



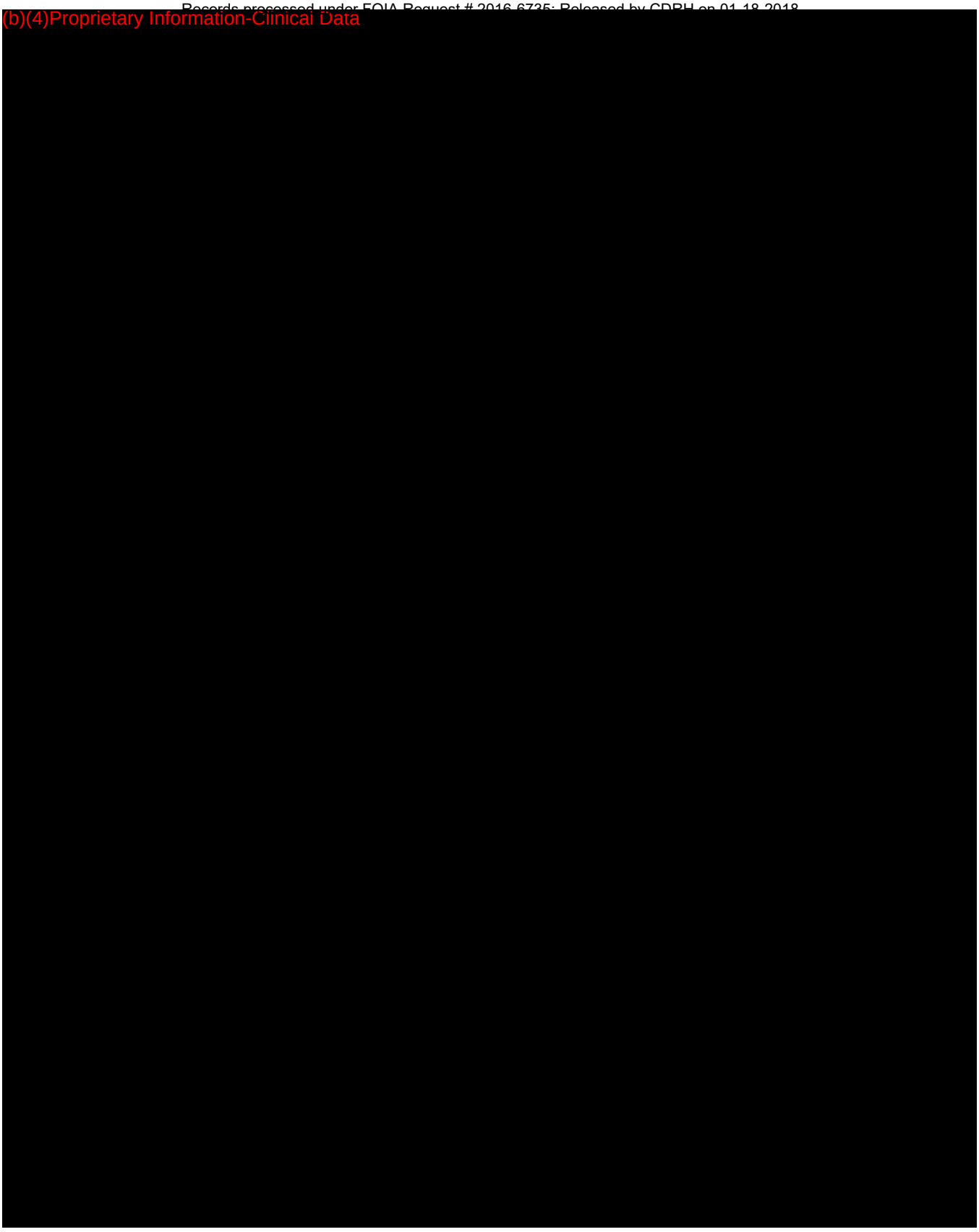
(b)(4)Proprietary Information-Clinical Data



(b)(4)Proprietary Information-Clinical Data



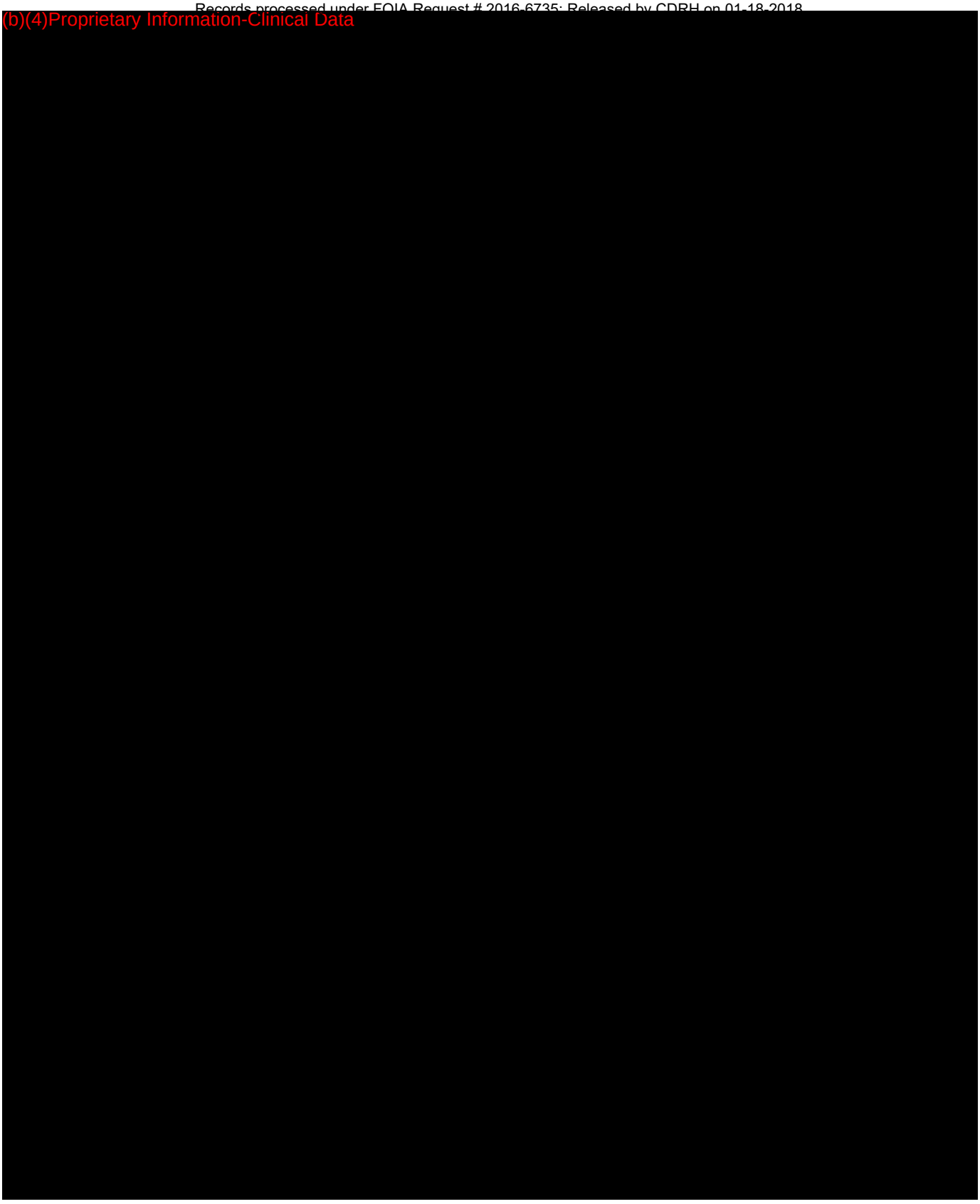
(b)(4)Proprietary Information-Clinical Data



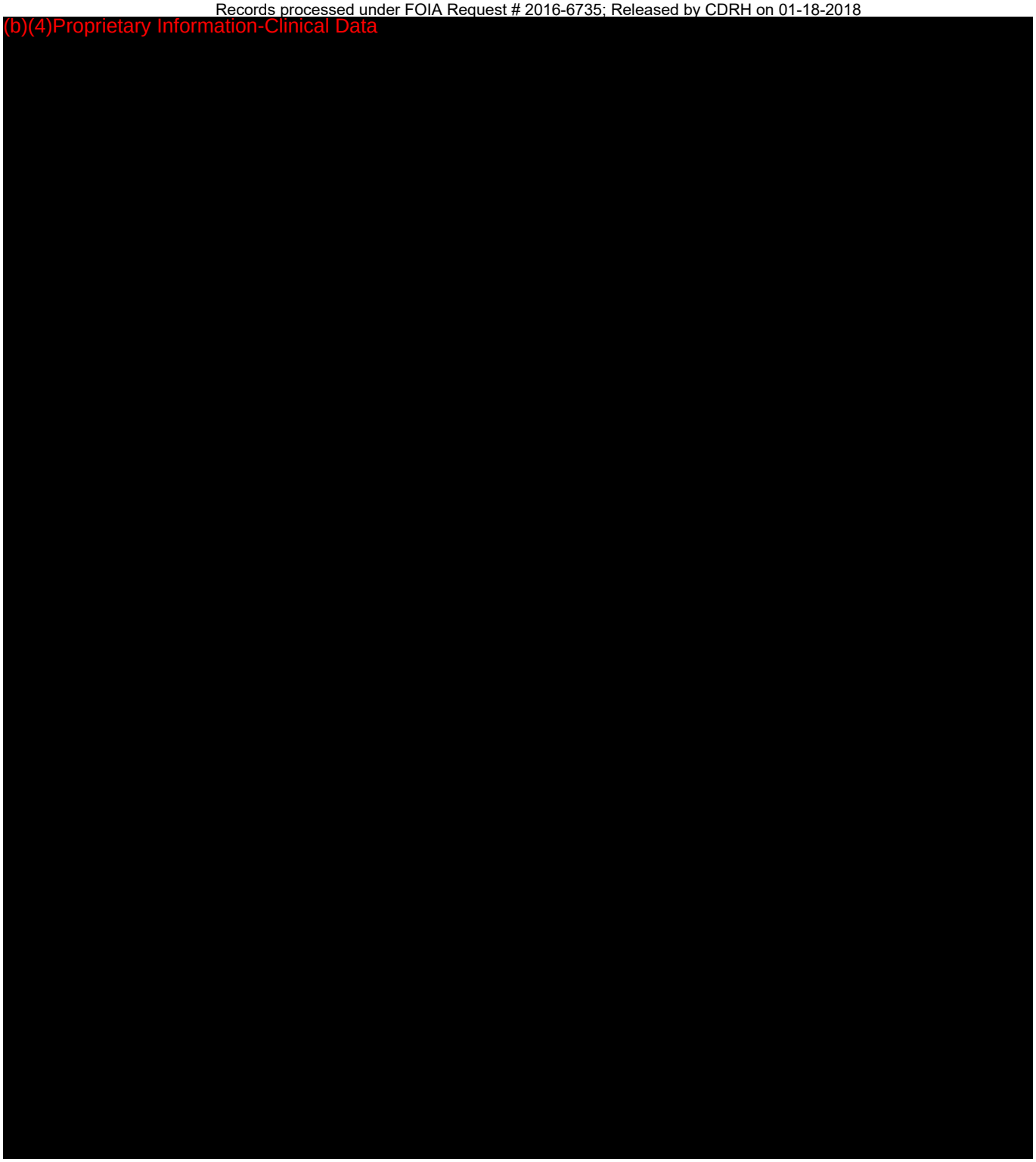
(b)(4)Proprietary Information-Clinical Data

[redacted]

(b)(4)Proprietary Information-Clinical Data



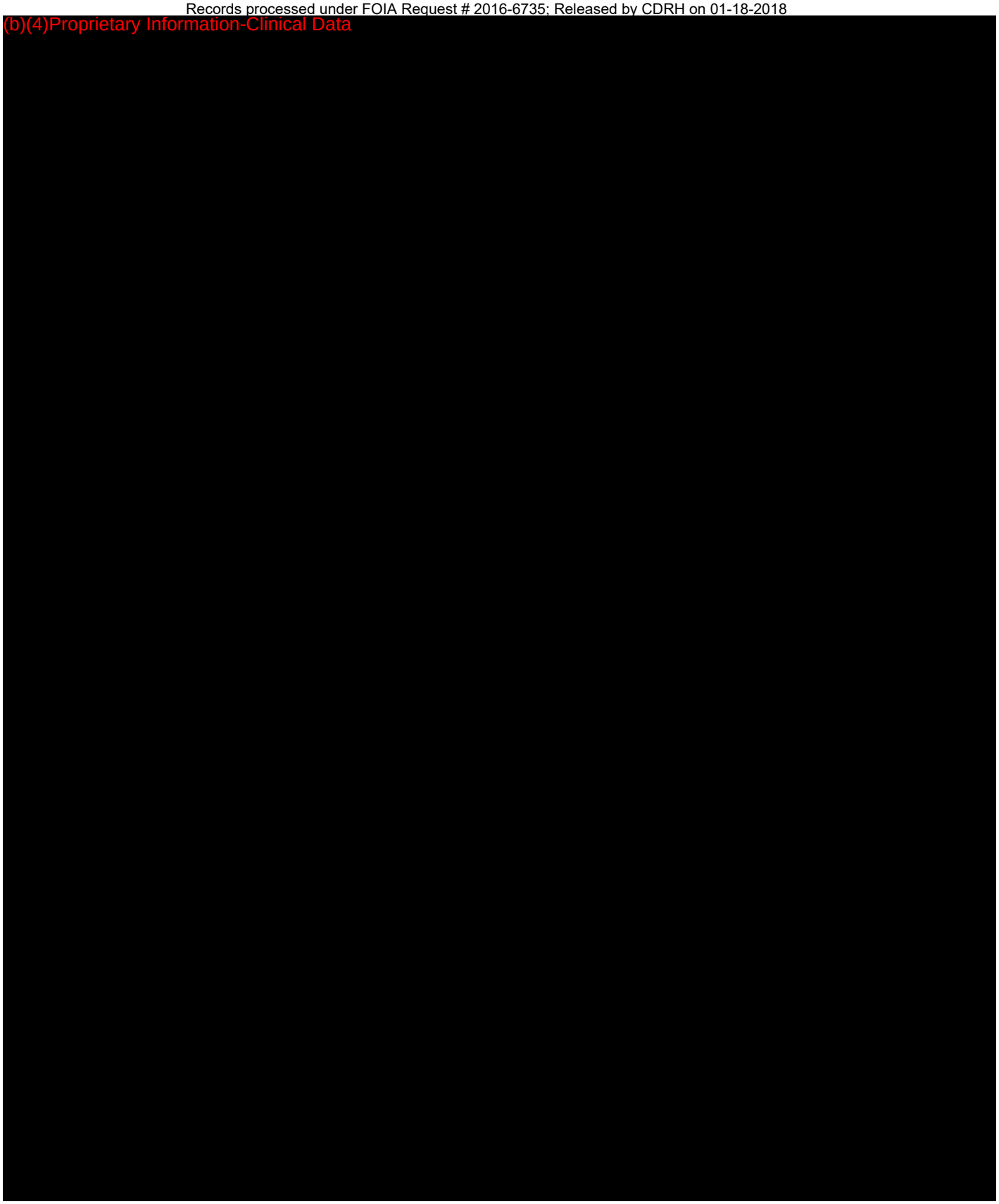
(b)(4)Proprietary Information-Clinical Data



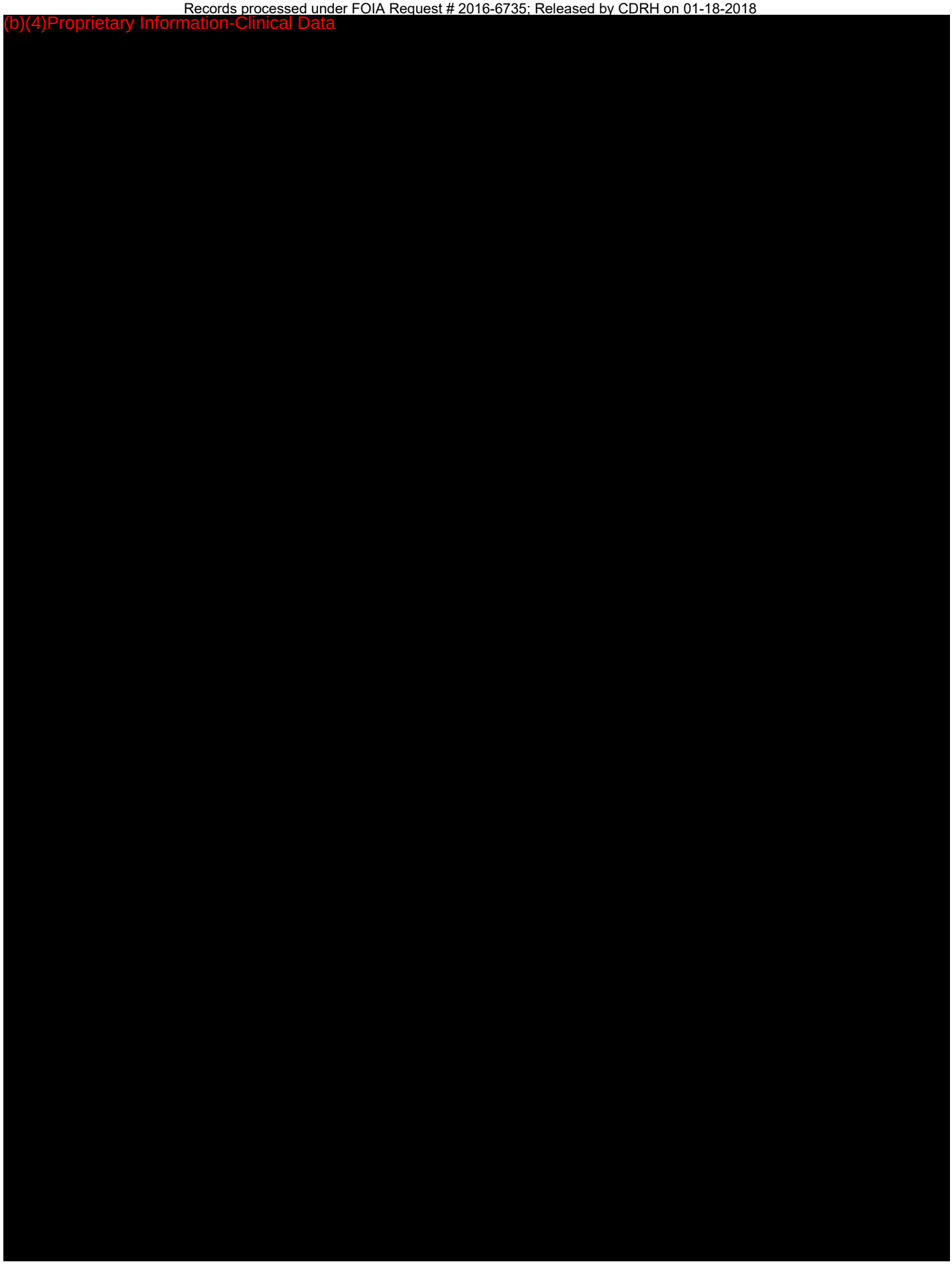
(b)(4)Proprietary Information-Clinical Data

[redacted]

(b)(4)Proprietary Information-Clinical Data



(b)(4)Proprietary Information-Clinical Data



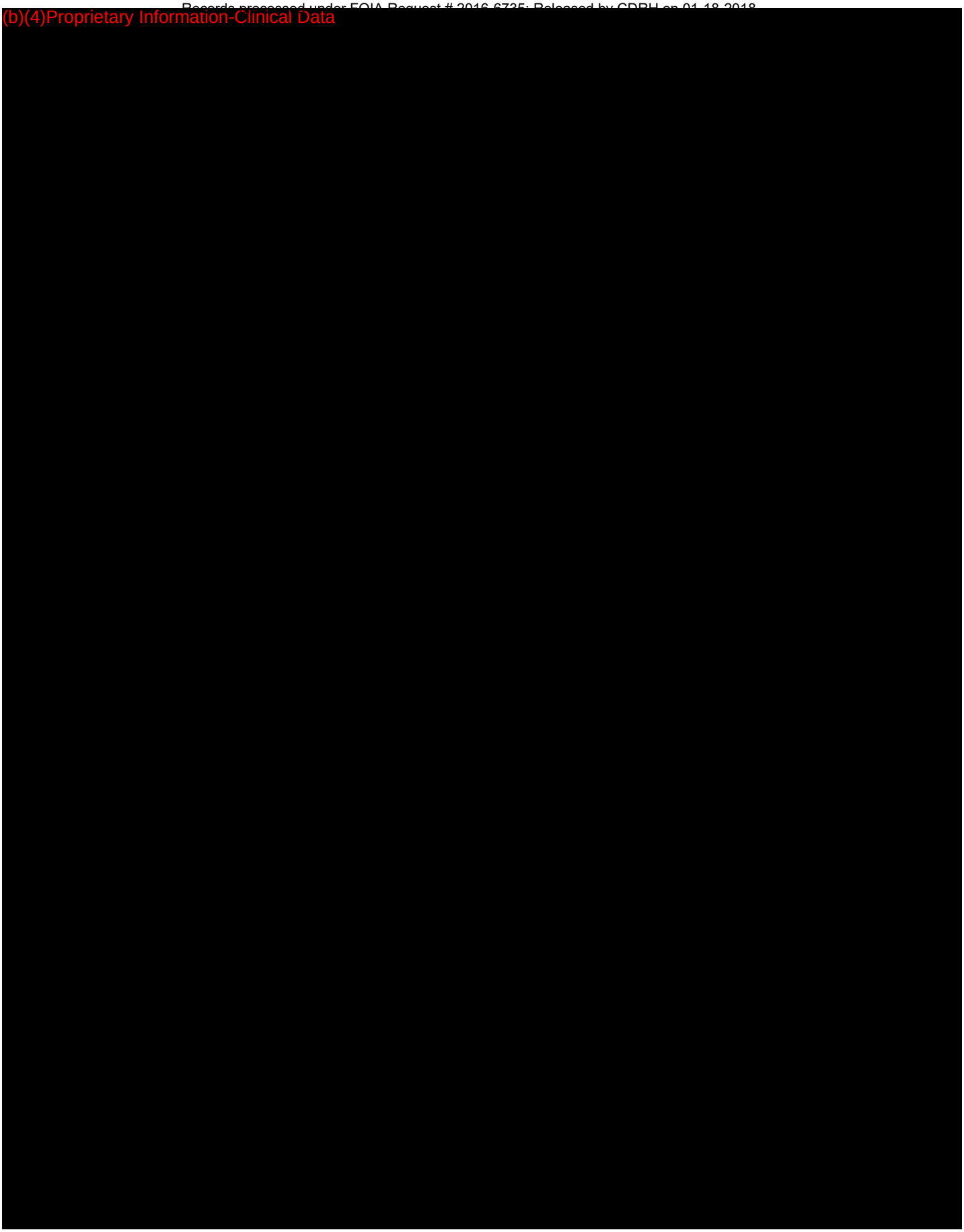
(b)(4)Proprietary Information-Clinical Data

[redacted]

(b)(4)Proprietary Information-Clinical Data

[redacted]

(b)(4)Proprietary Information-Clinical Data



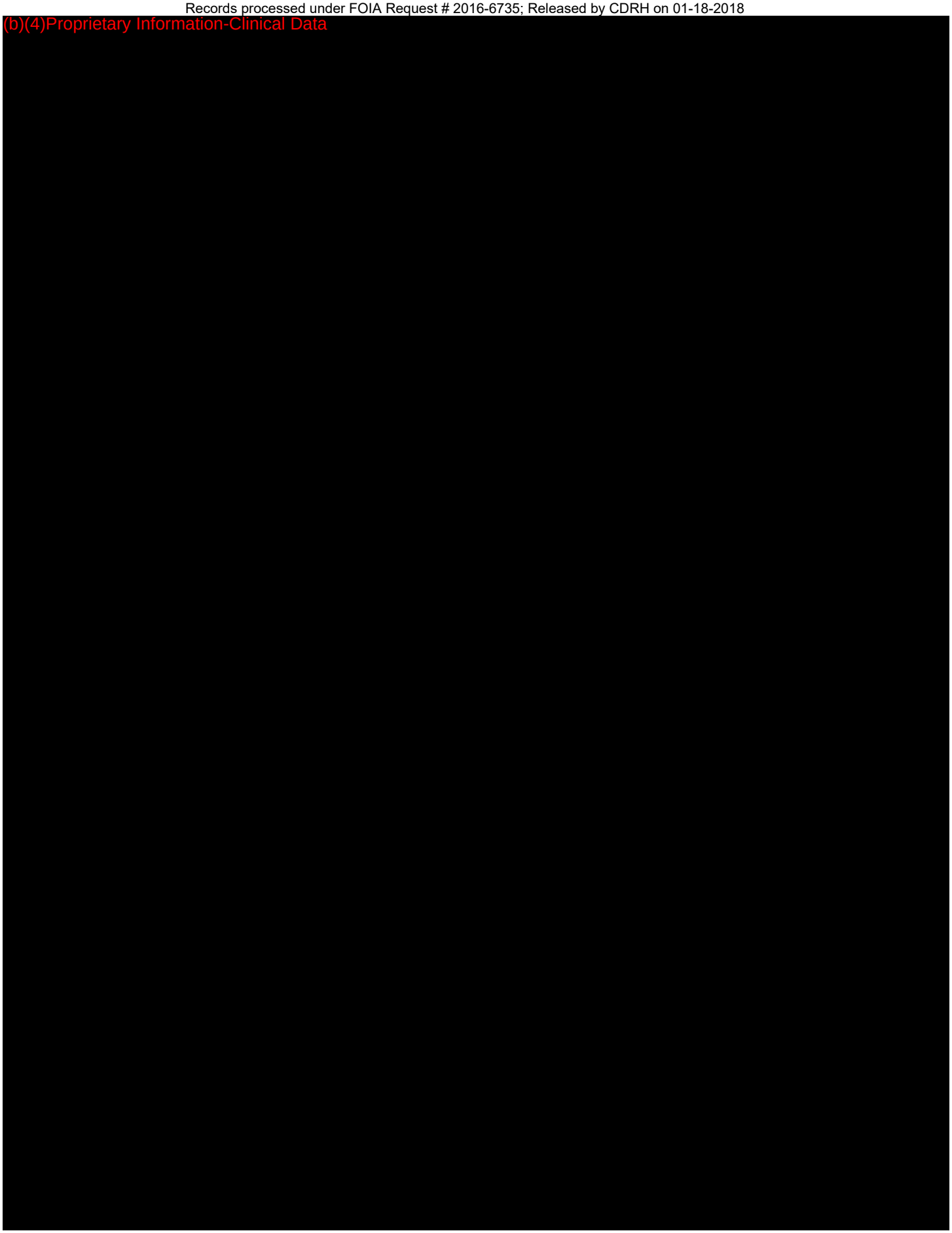
(b)(4)Proprietary Information-Clinical Data

[redacted]

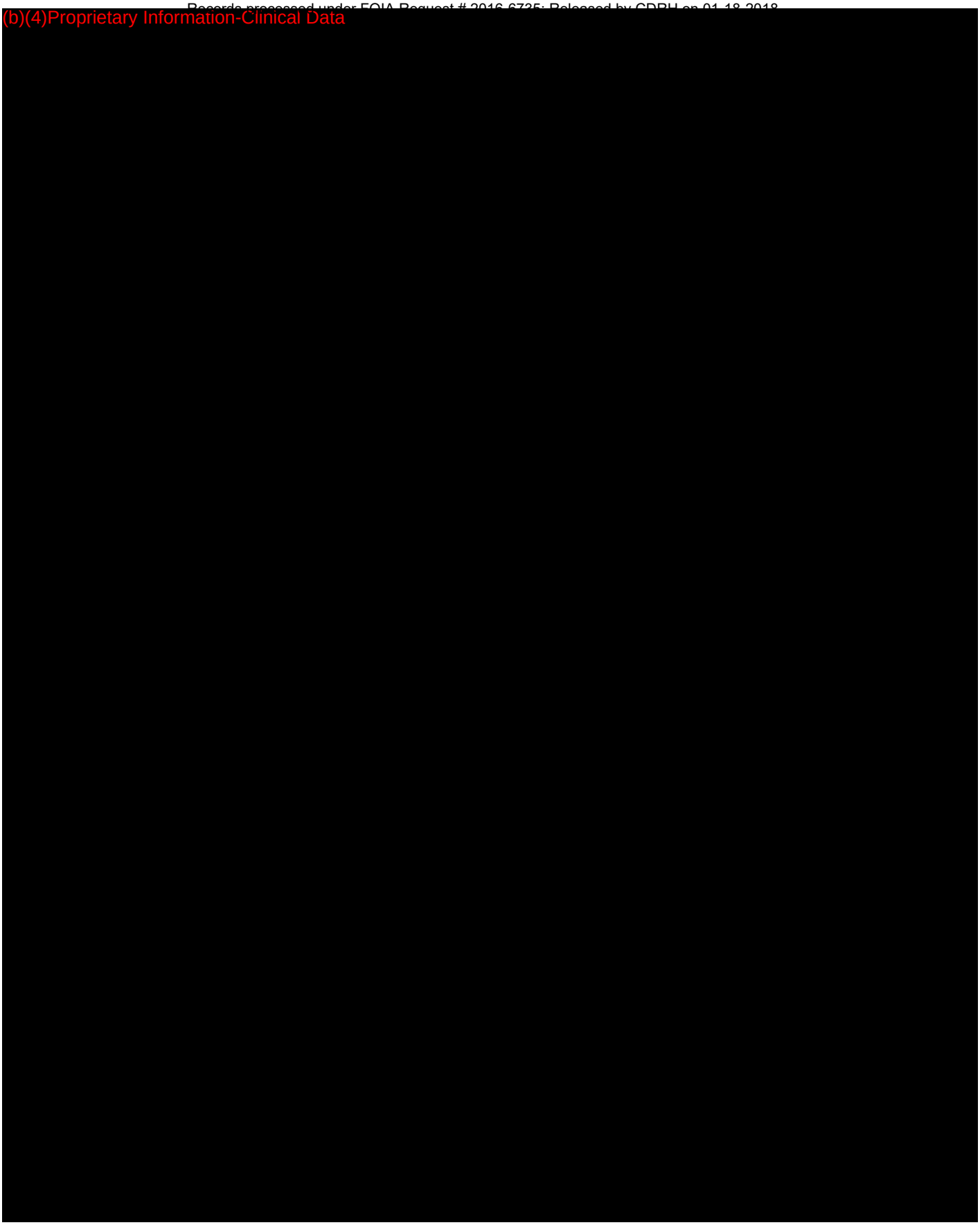
(b)(4)Proprietary Information-Clinical Data

[redacted]

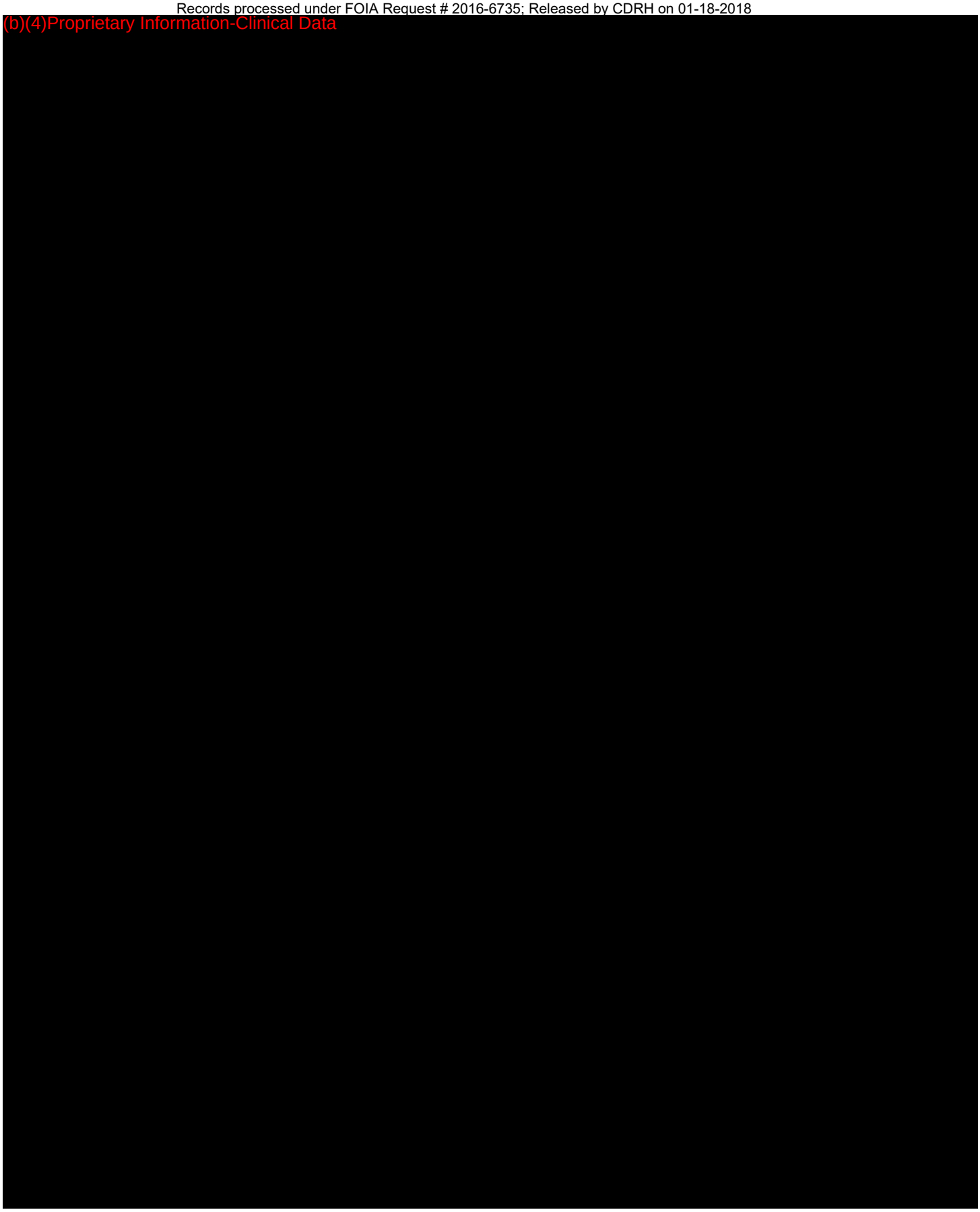
(b)(4)Proprietary Information-Clinical Data



(b)(4)Proprietary Information-Clinical Data



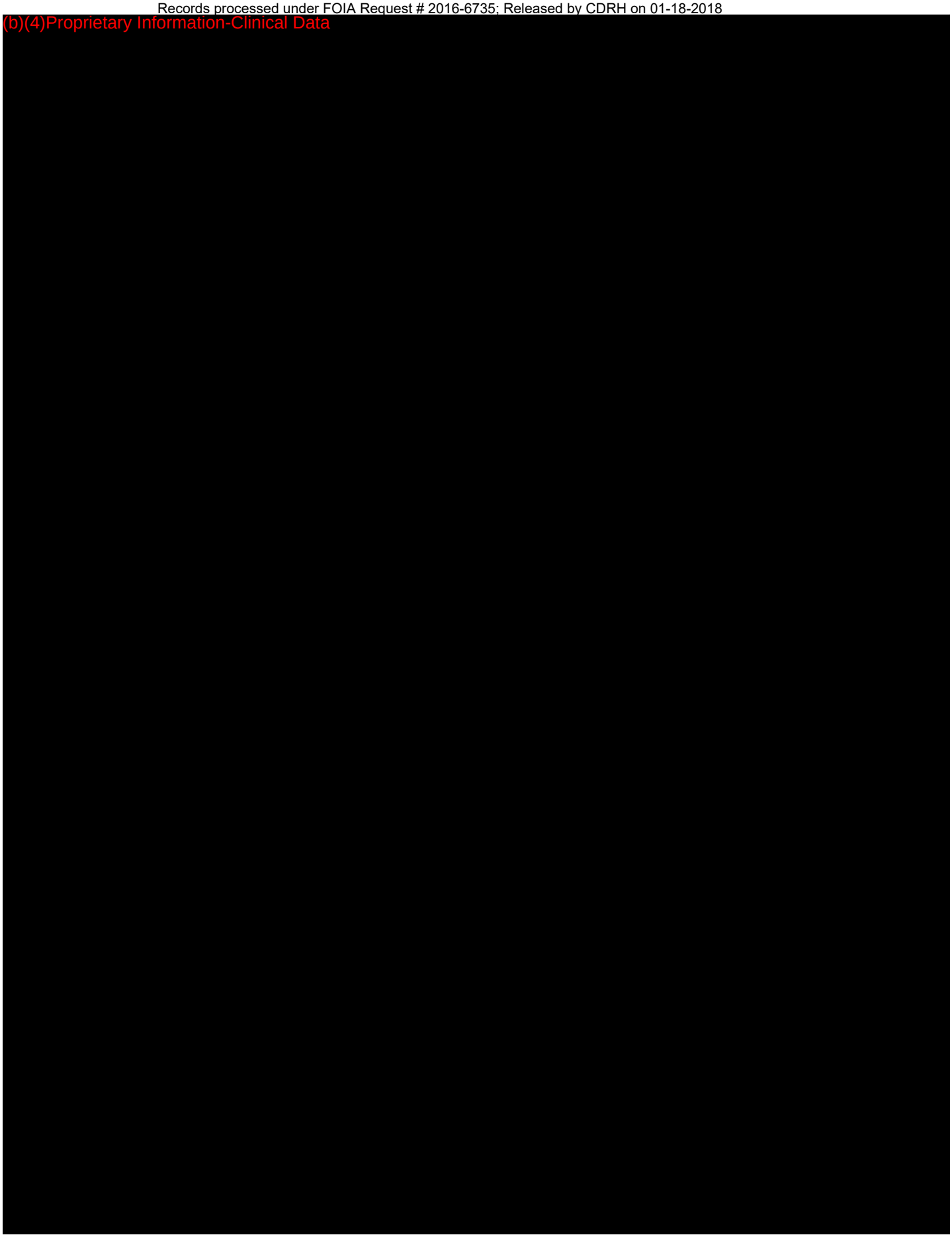
(b)(4)Proprietary Information-Clinical Data



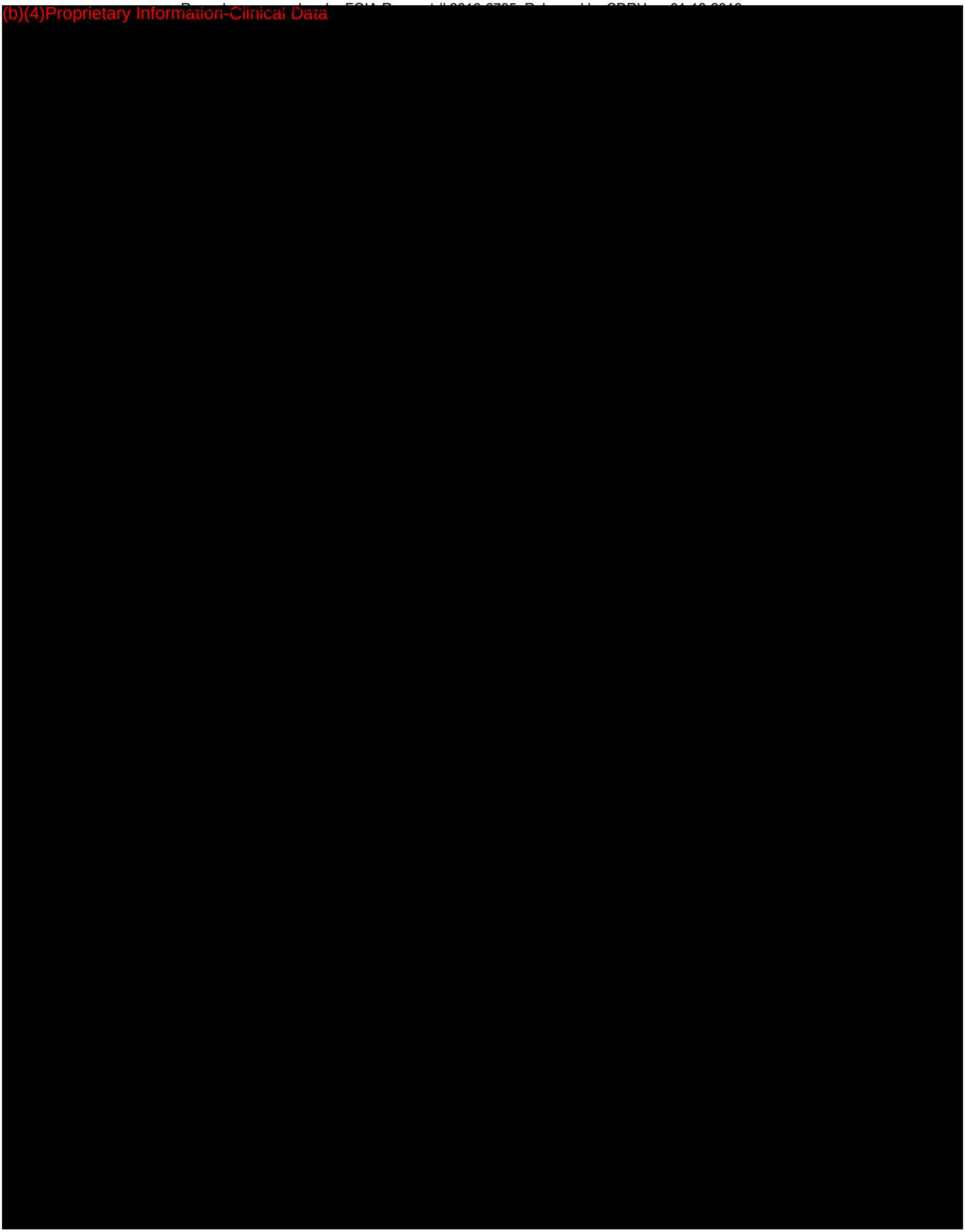
(b)(4)Proprietary Information-Clinical Data

[redacted]

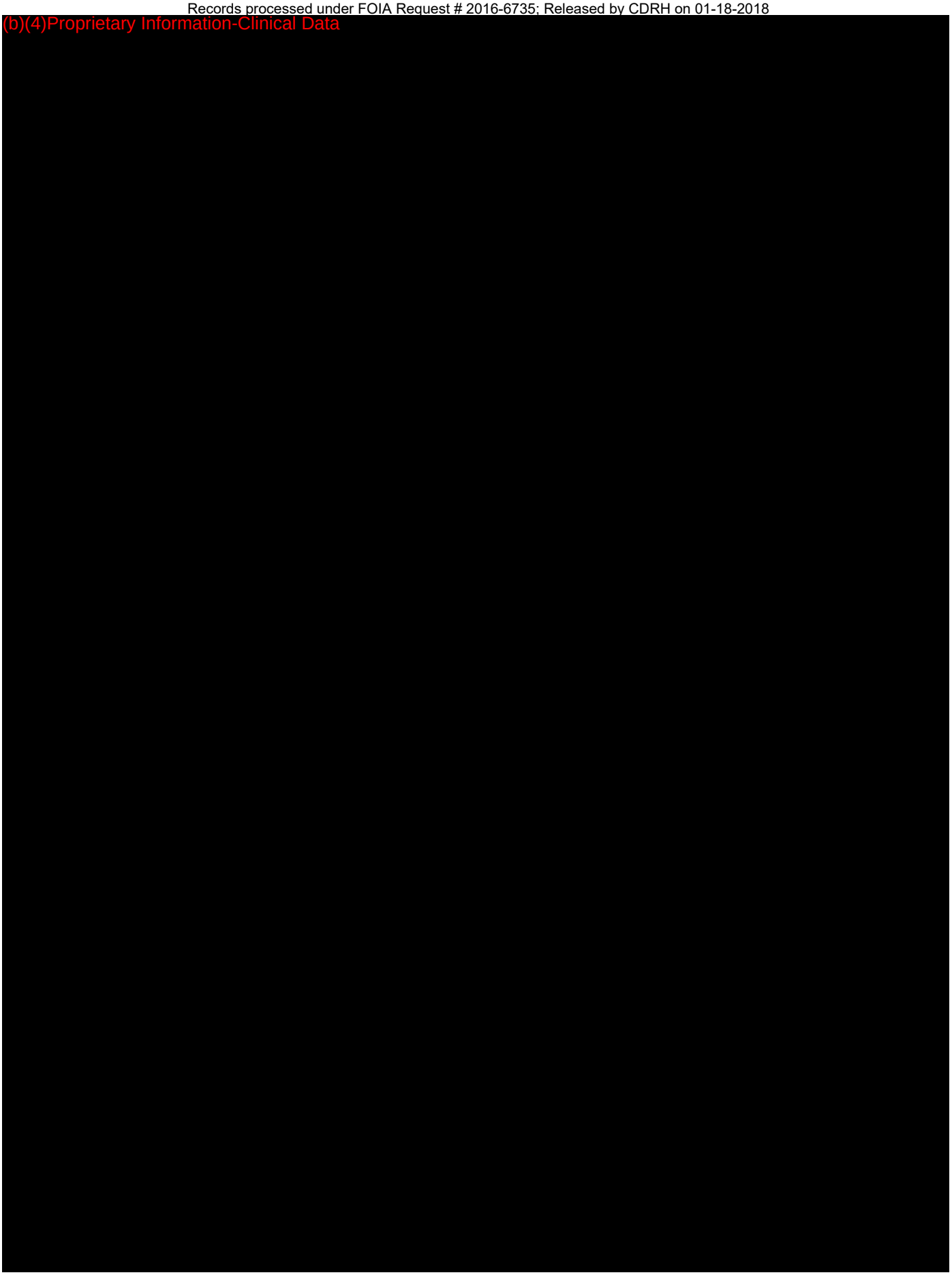
(b)(4)Proprietary Information-Clinical Data



(b)(4)Proprietary Information-Clinical Data



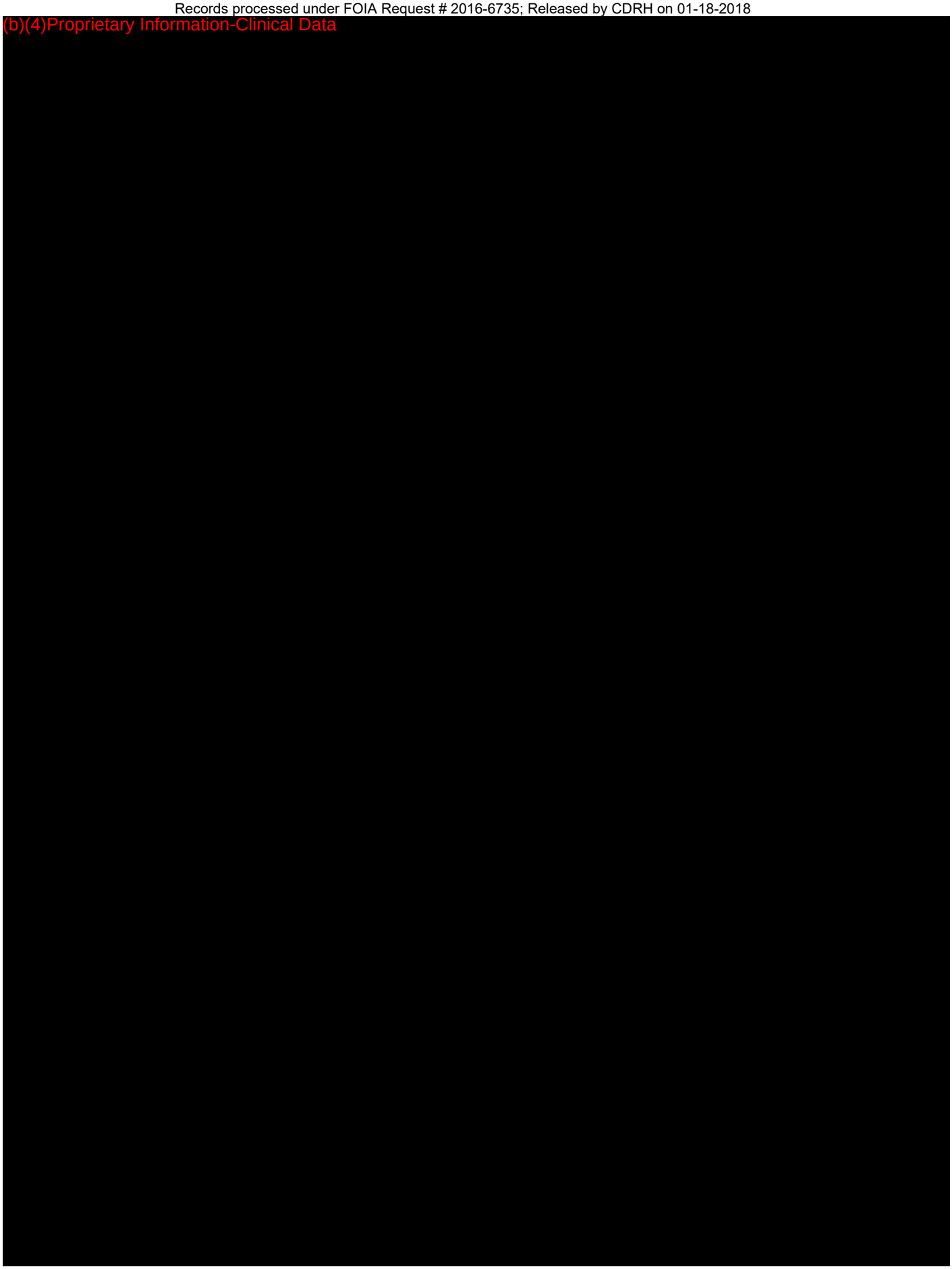
(b)(4)Proprietary Information-Clinical Data



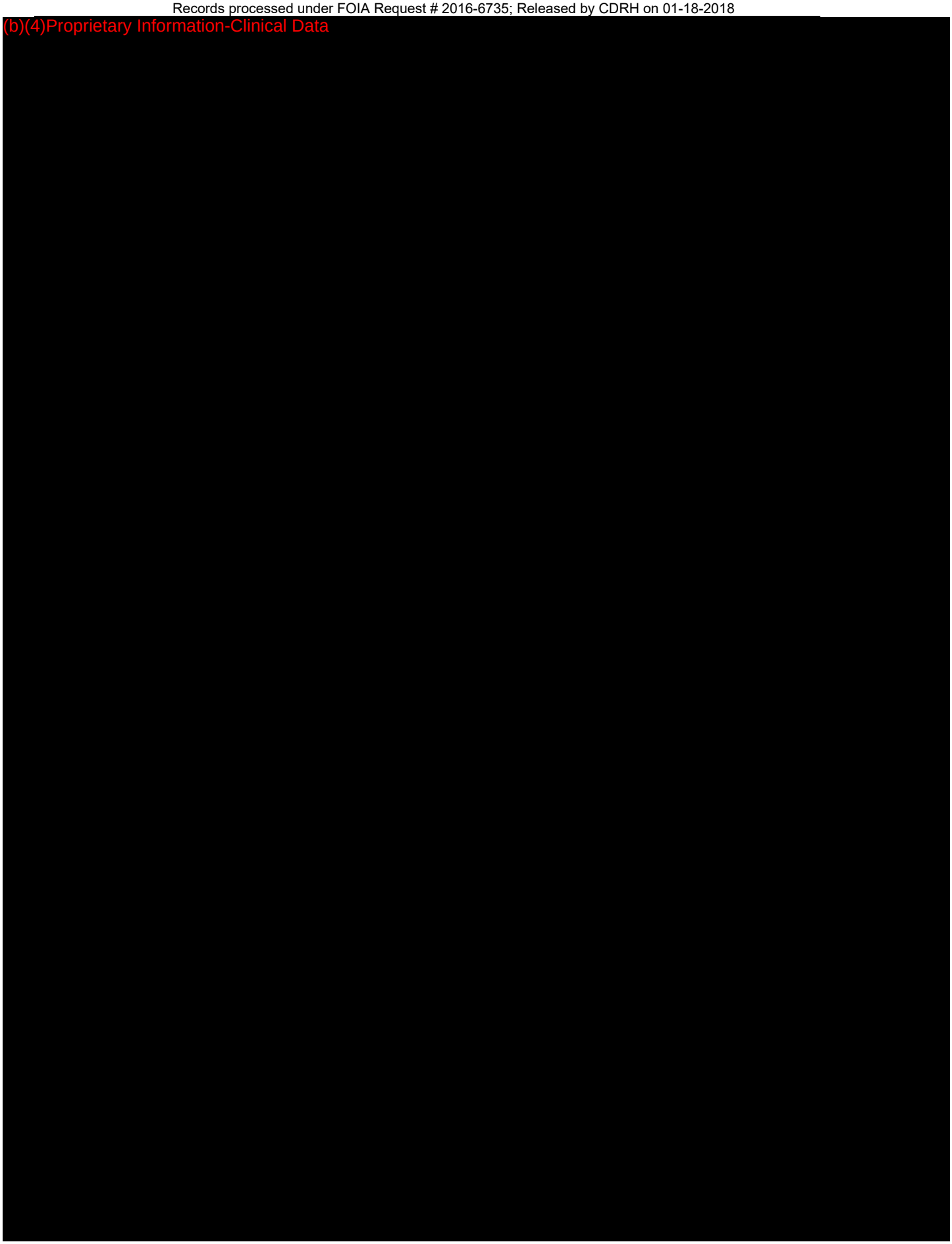
(b)(4)Proprietary Information-Clinical Data

[redacted]

(b)(4)Proprietary Information-Clinical Data



(b)(4)Proprietary Information-Clinical Data



(b)(4)Proprietary Information-Clinical Data

[redacted]

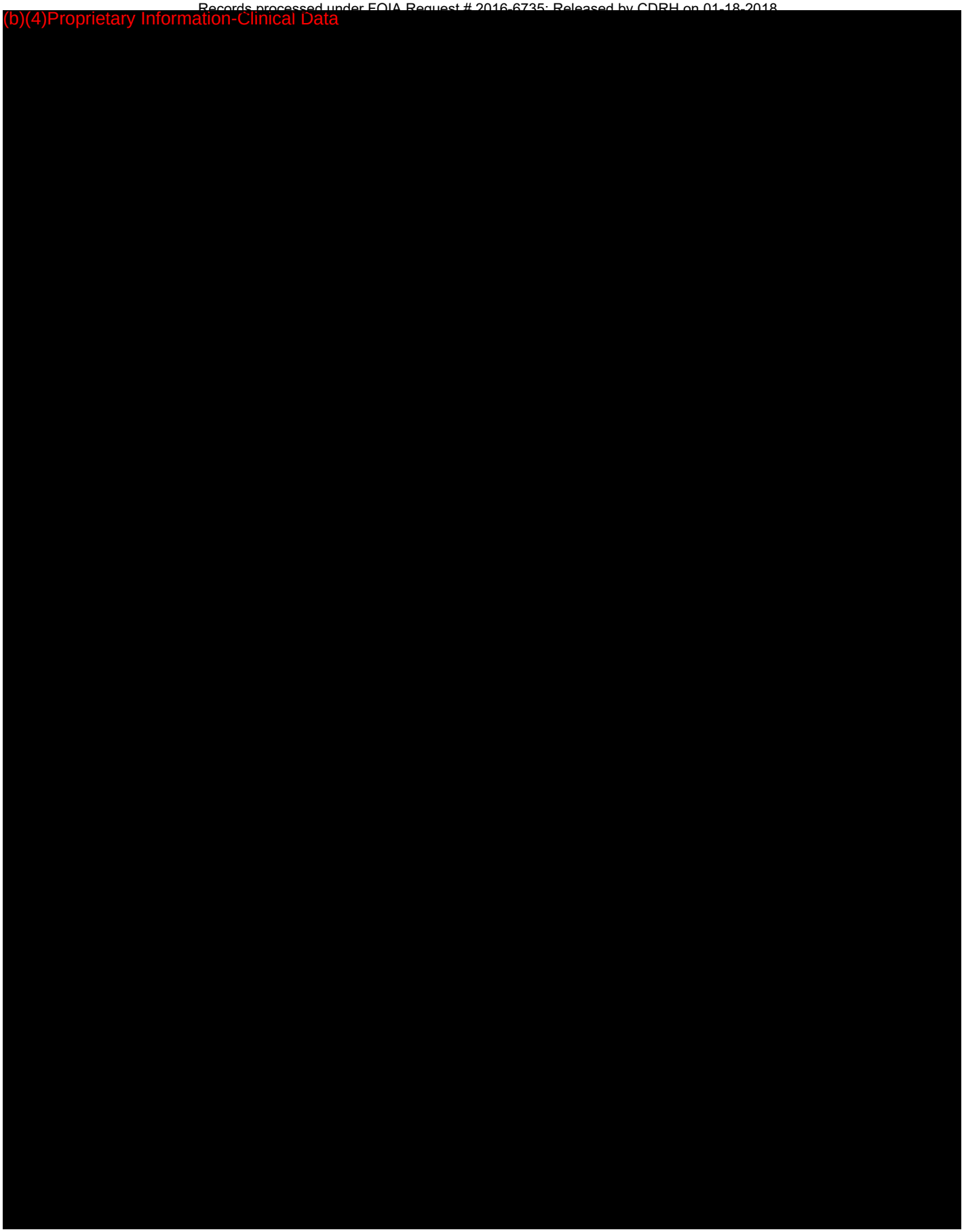
(b)(4)Proprietary Information-Clinical Data

[redacted]

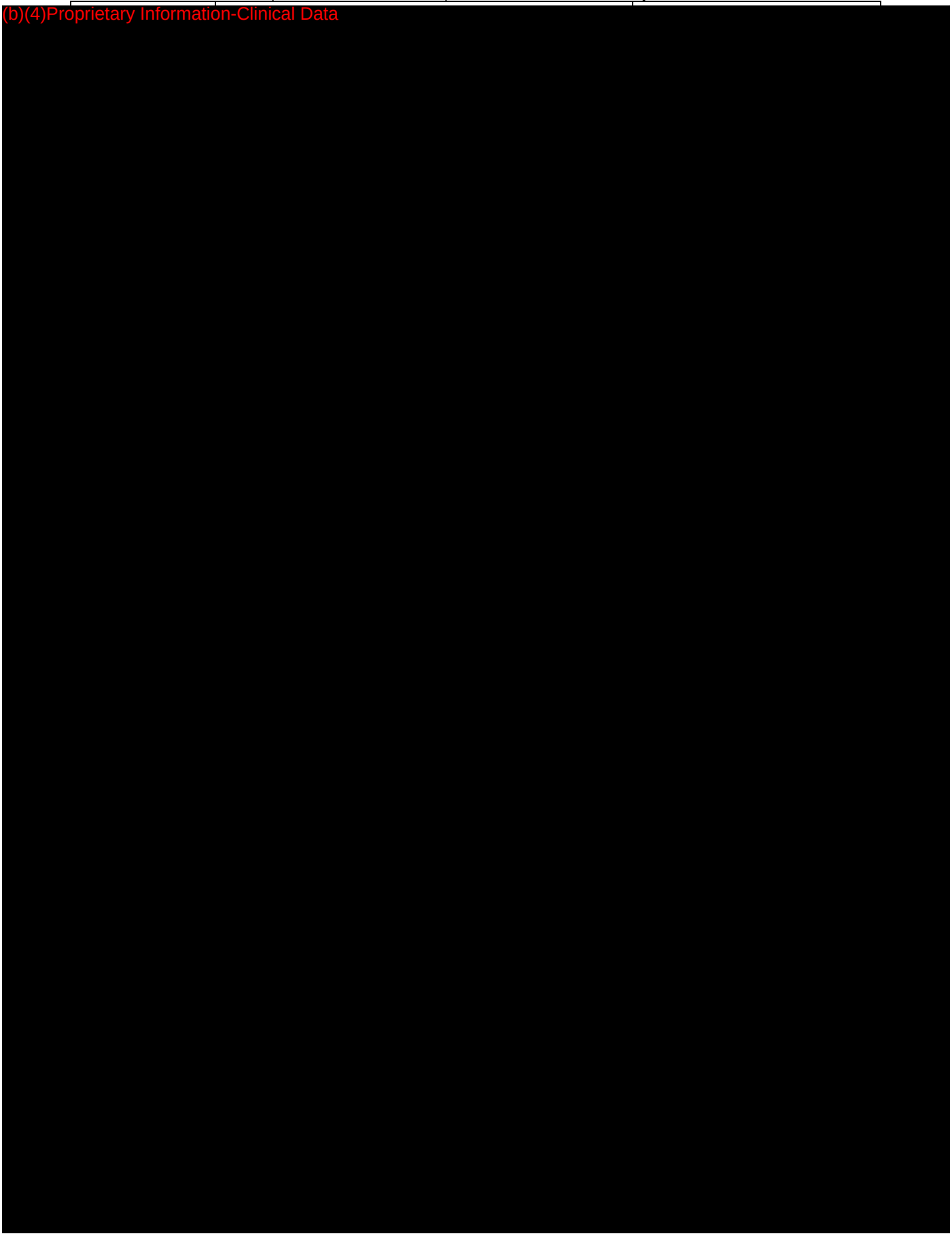
(b)(4)Proprietary Information-Clinical Data

[redacted]

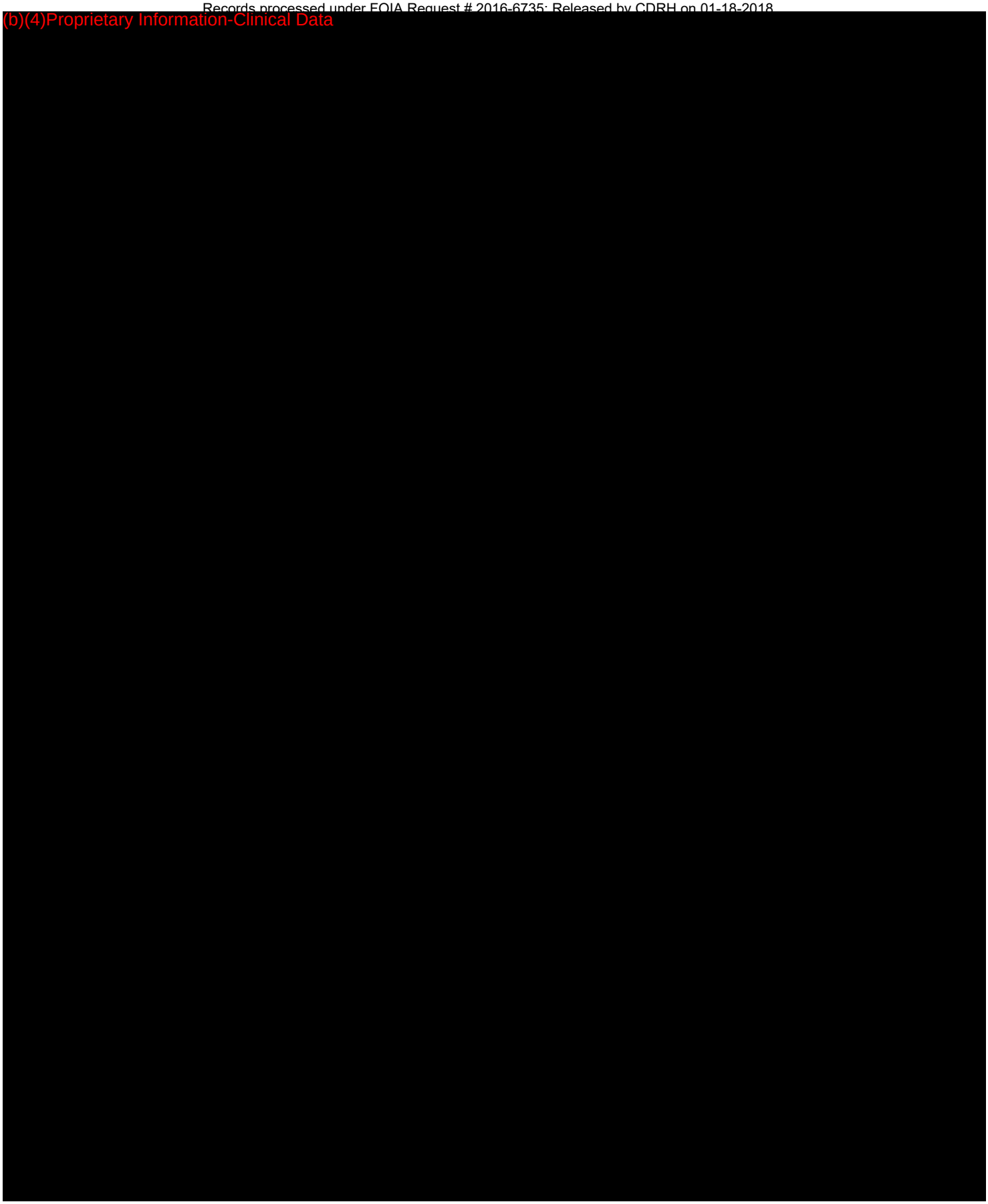
(b)(4)Proprietary Information-Clinical Data



(b)(4)Proprietary Information-Clinical Data



(b)(4)Proprietary Information-Clinical Data



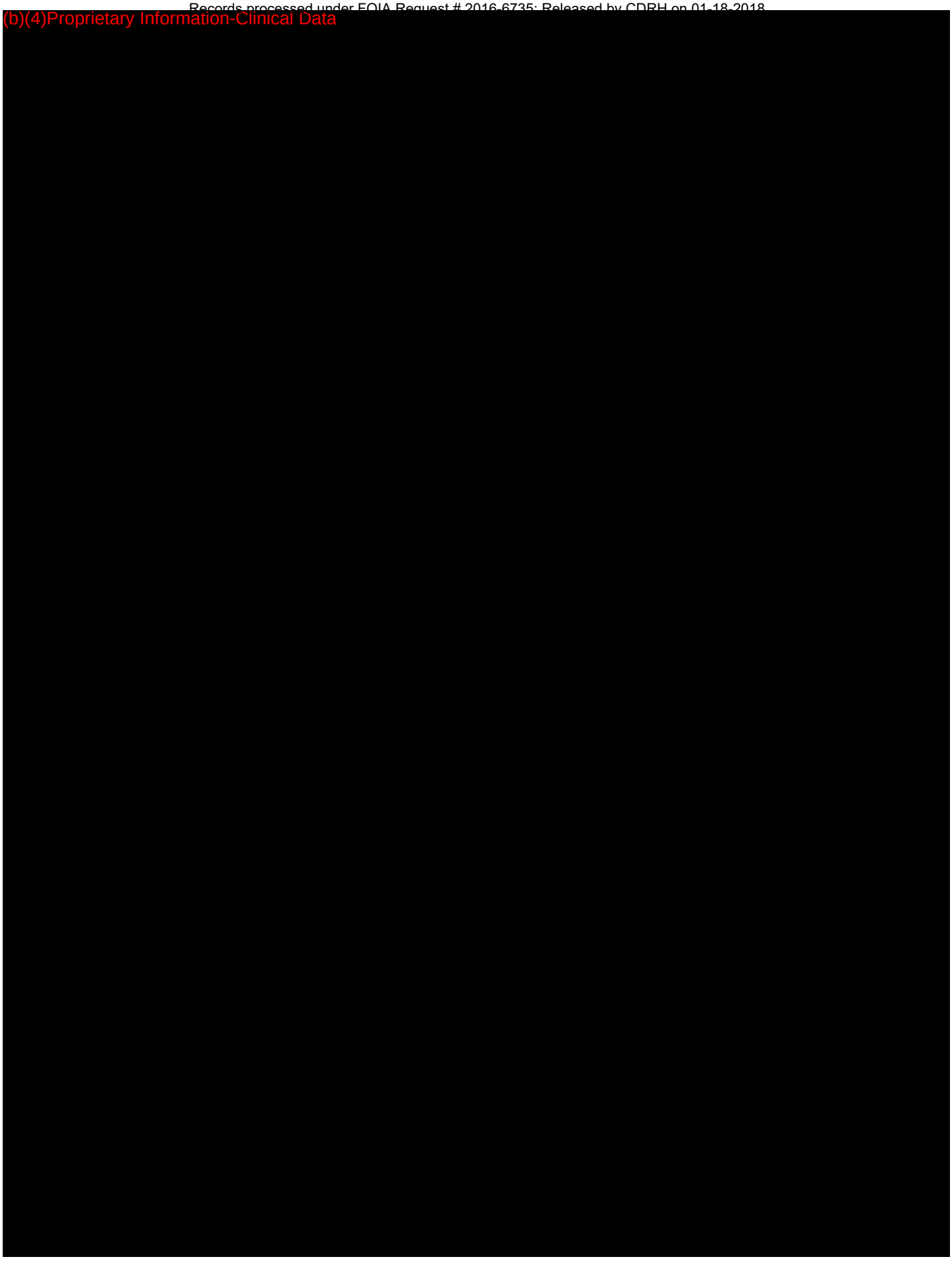
(b)(4)Proprietary Information-Clinical Data

[redacted]

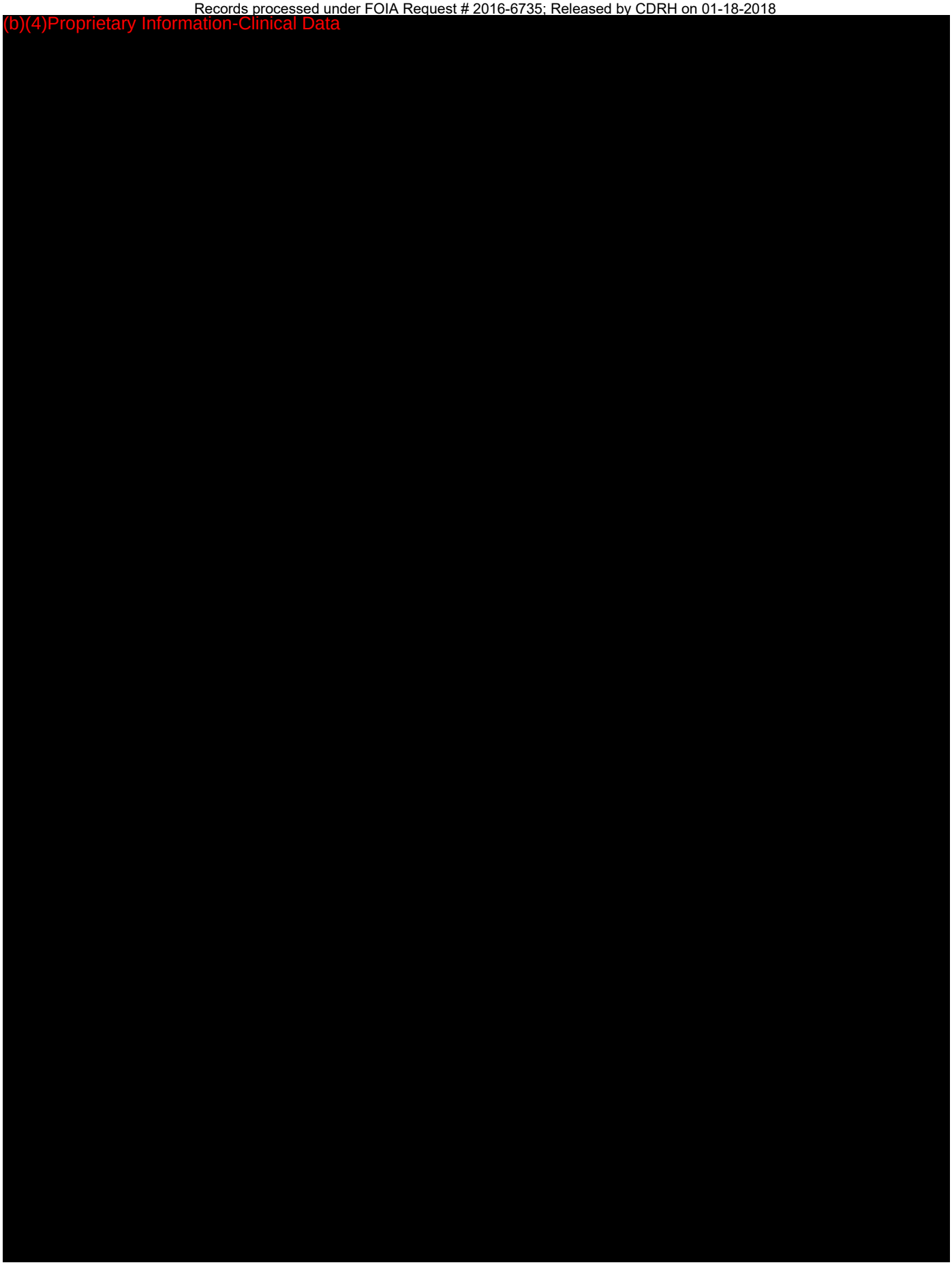
(b)(4)Proprietary Information-Clinical Data

[redacted]

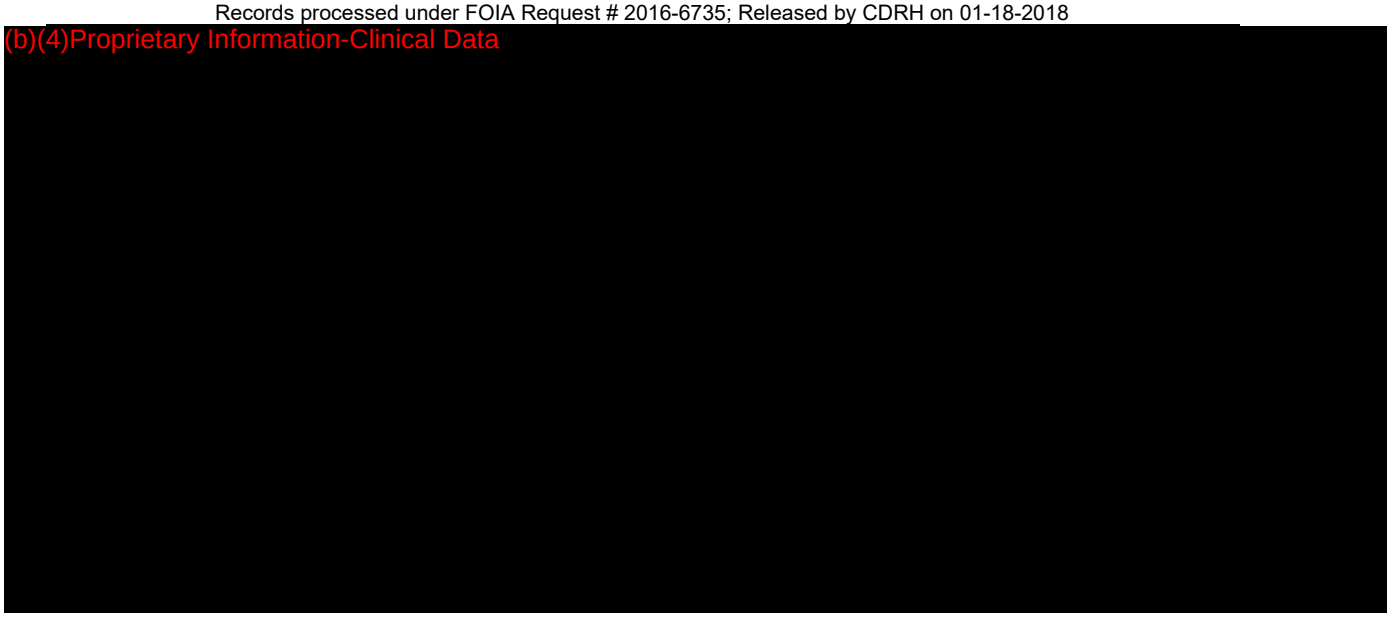
(b)(4)Proprietary Information-Clinical Data

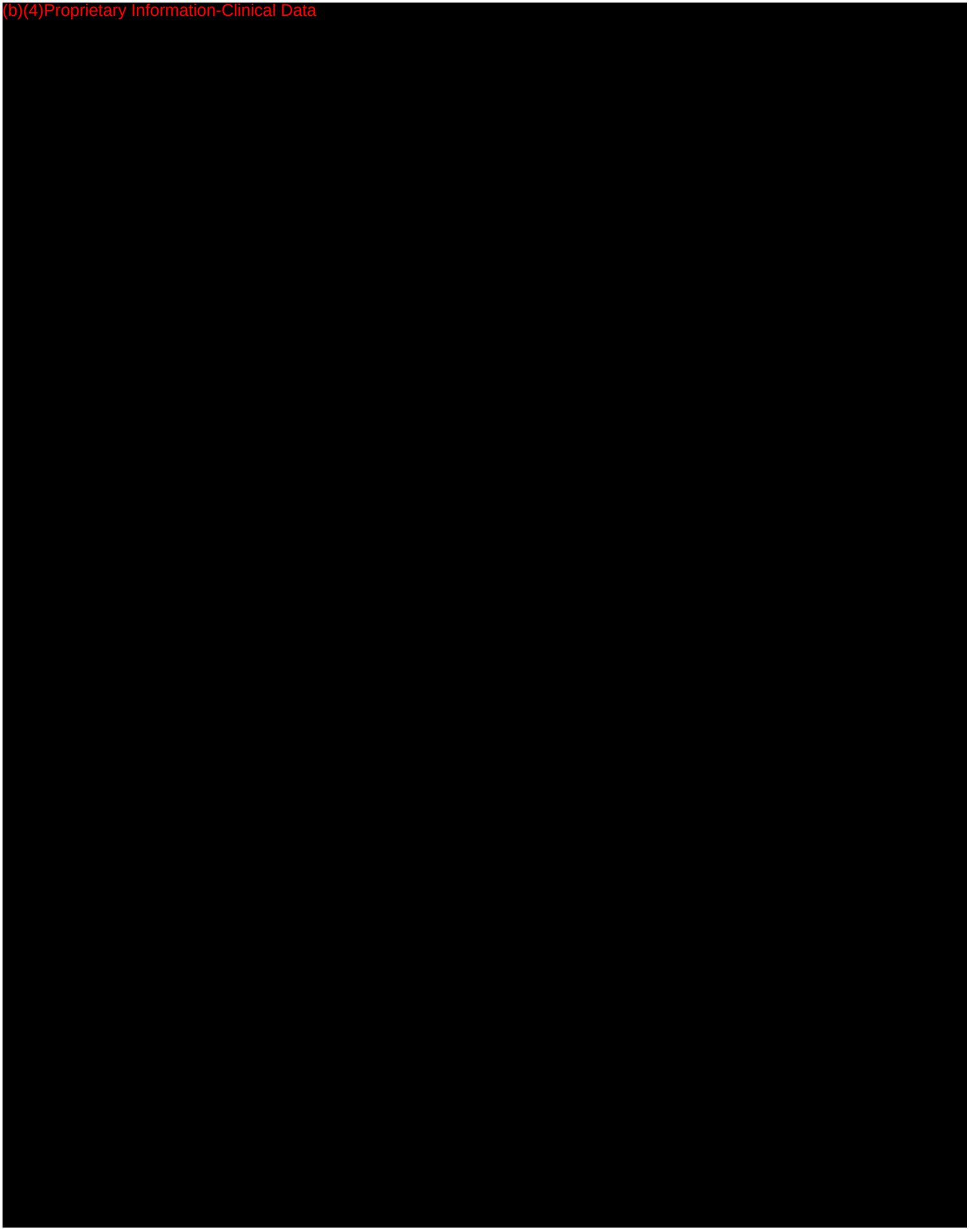


(b)(4)Proprietary Information-Clinical Data

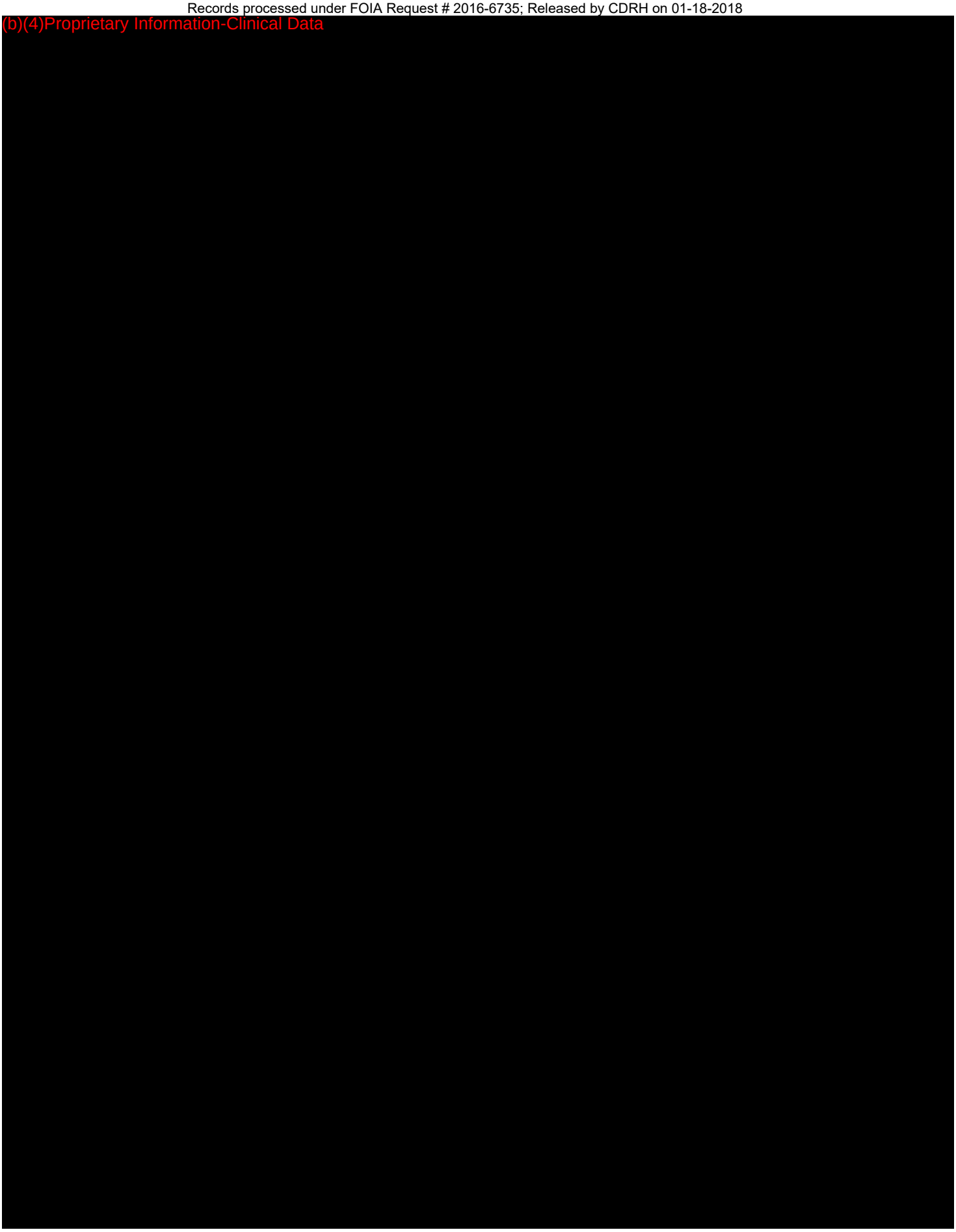


(b)(4)Proprietary Information-Clinical Data





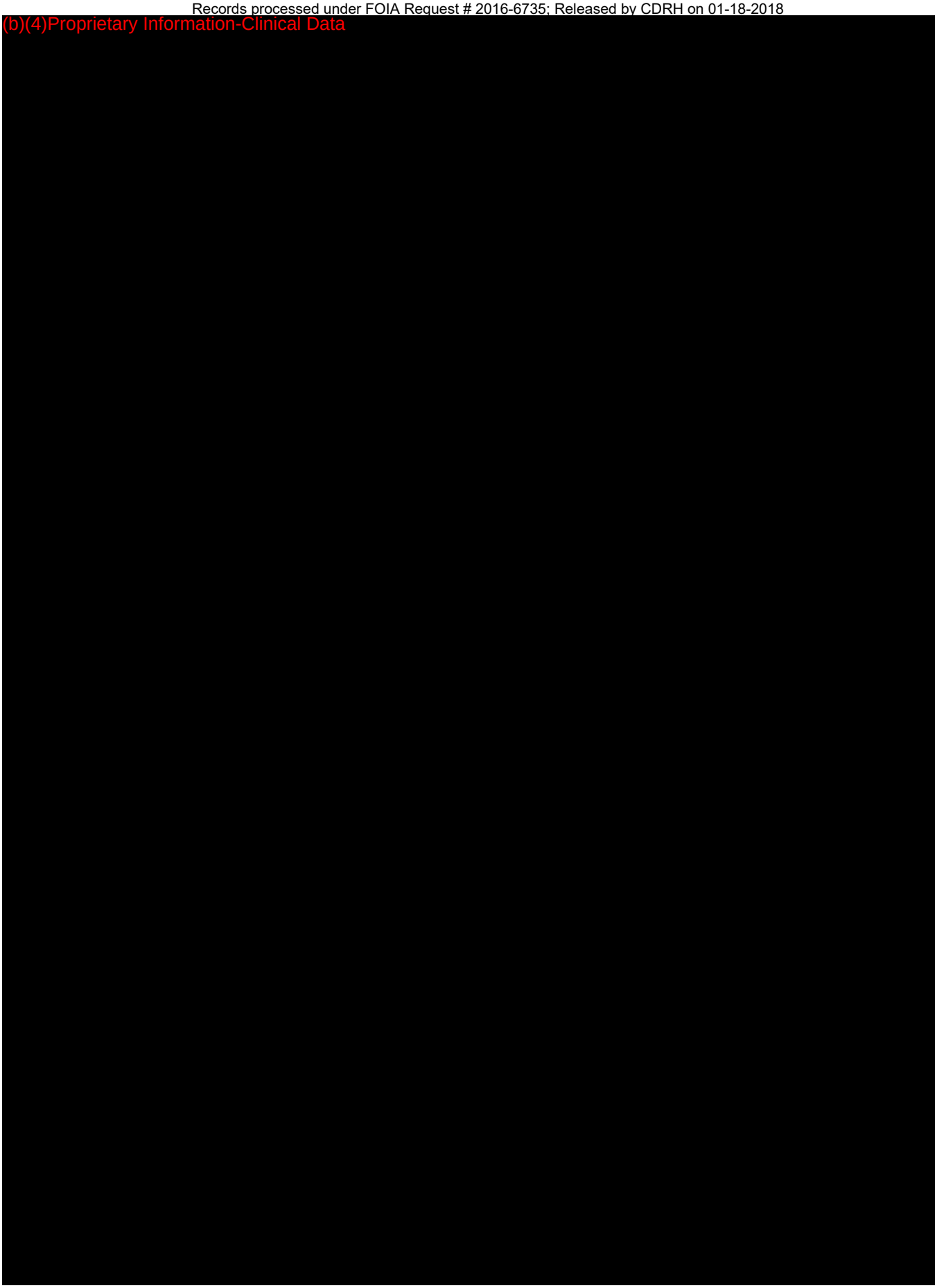
(b)(4)Proprietary Information-Clinical Data



(b)(4)Proprietary Information-Clinical Data

[redacted]

(b)(4)Proprietary Information-Clinical Data



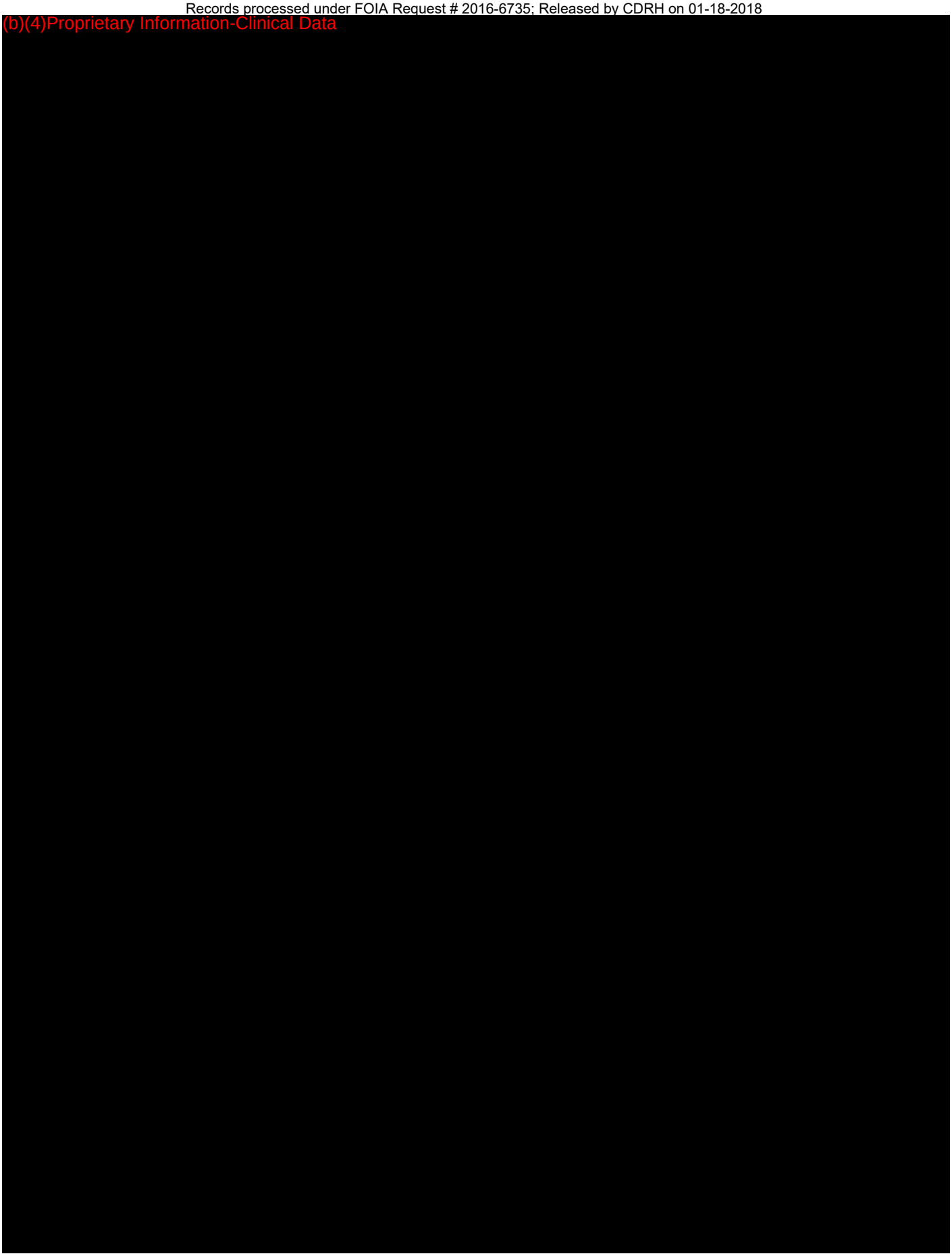
(b)(4)Proprietary Information-Clinical Data

[redacted]

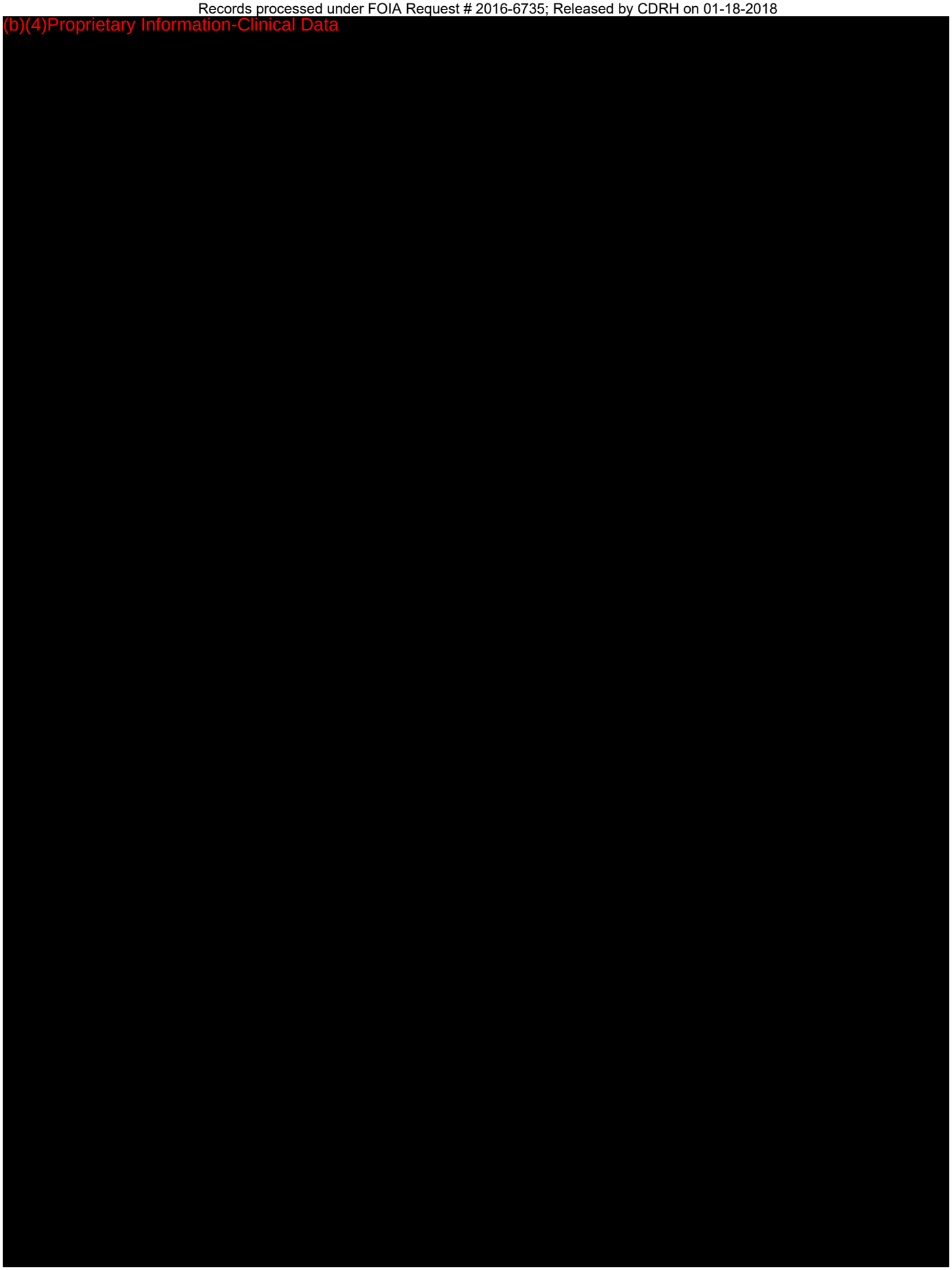
(b)(4)Proprietary Information-Clinical Data

[redacted]

(b)(4)Proprietary Information-Clinical Data



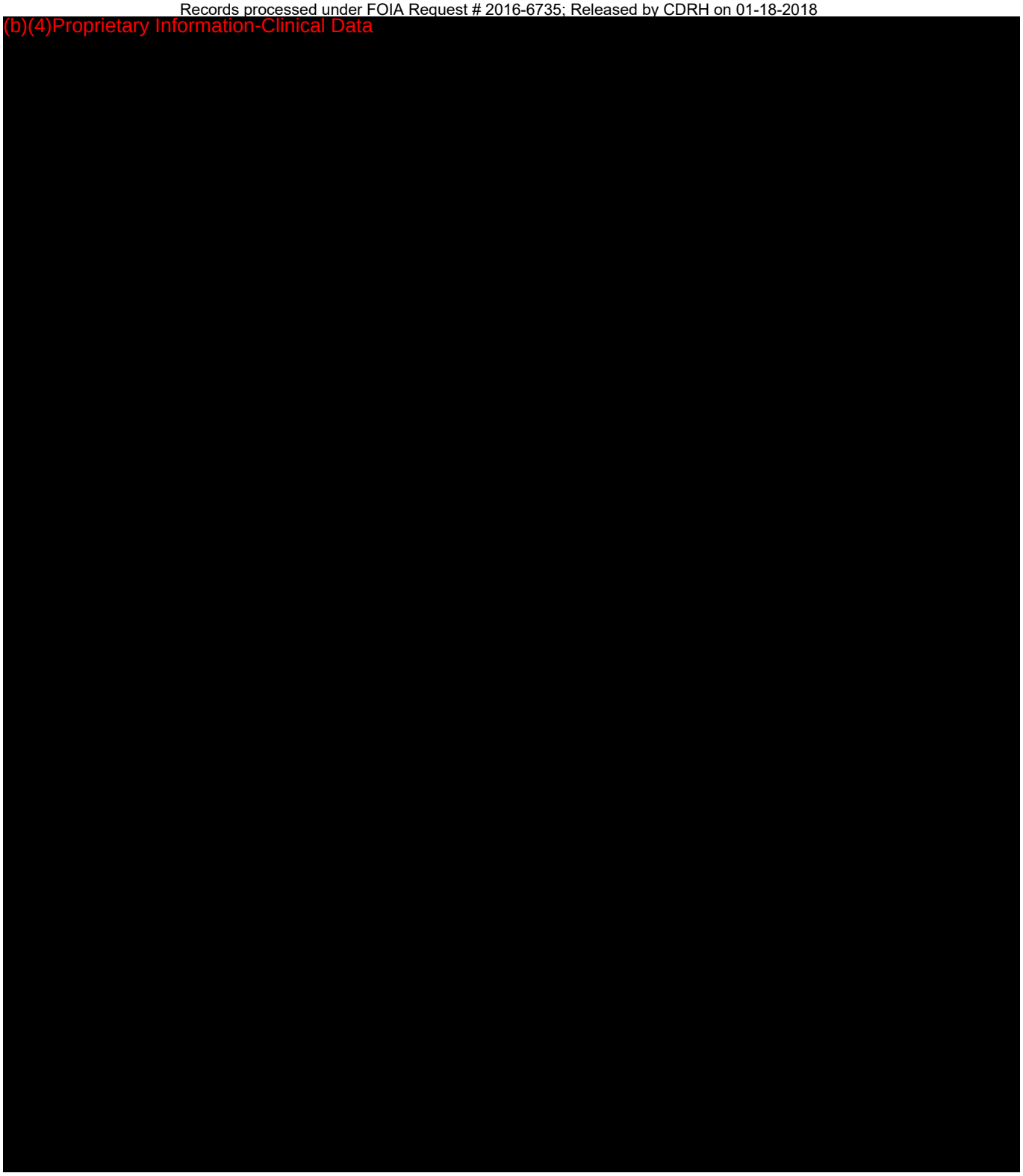
(b)(4)Proprietary Information-Clinical Data



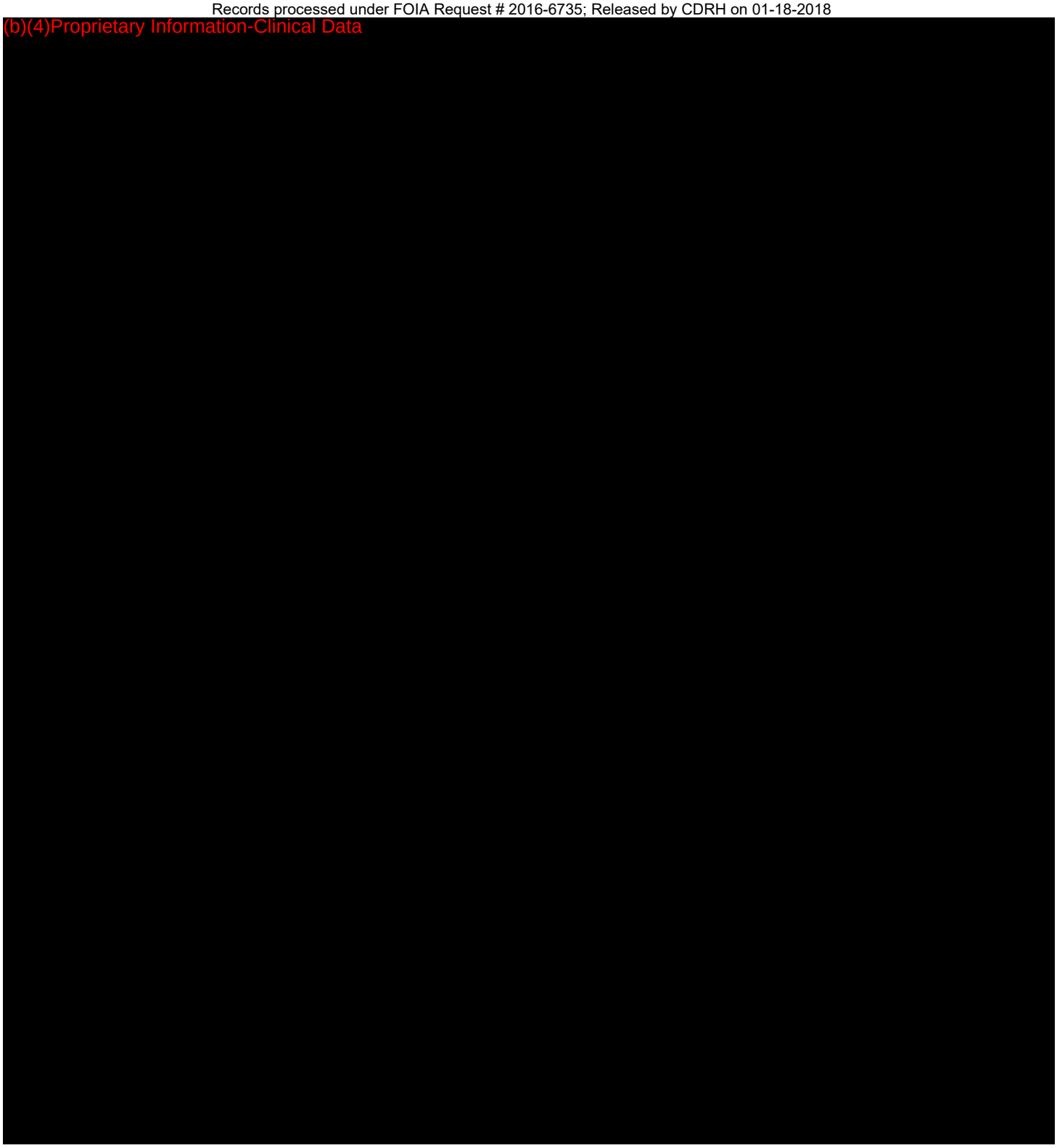
(b)(4)Proprietary Information-Clinical Data

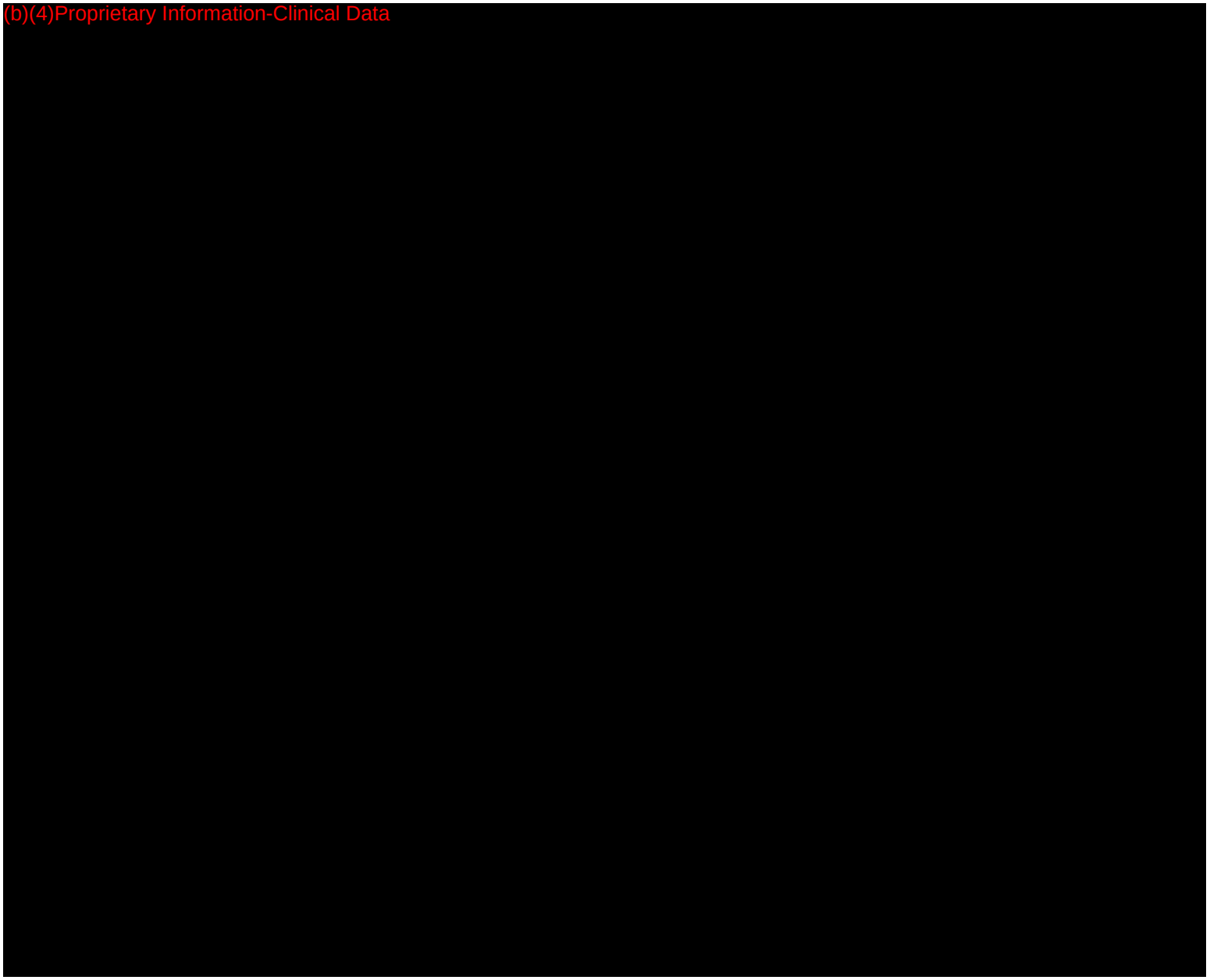
[redacted]

(b)(4)Proprietary Information-Clinical Data

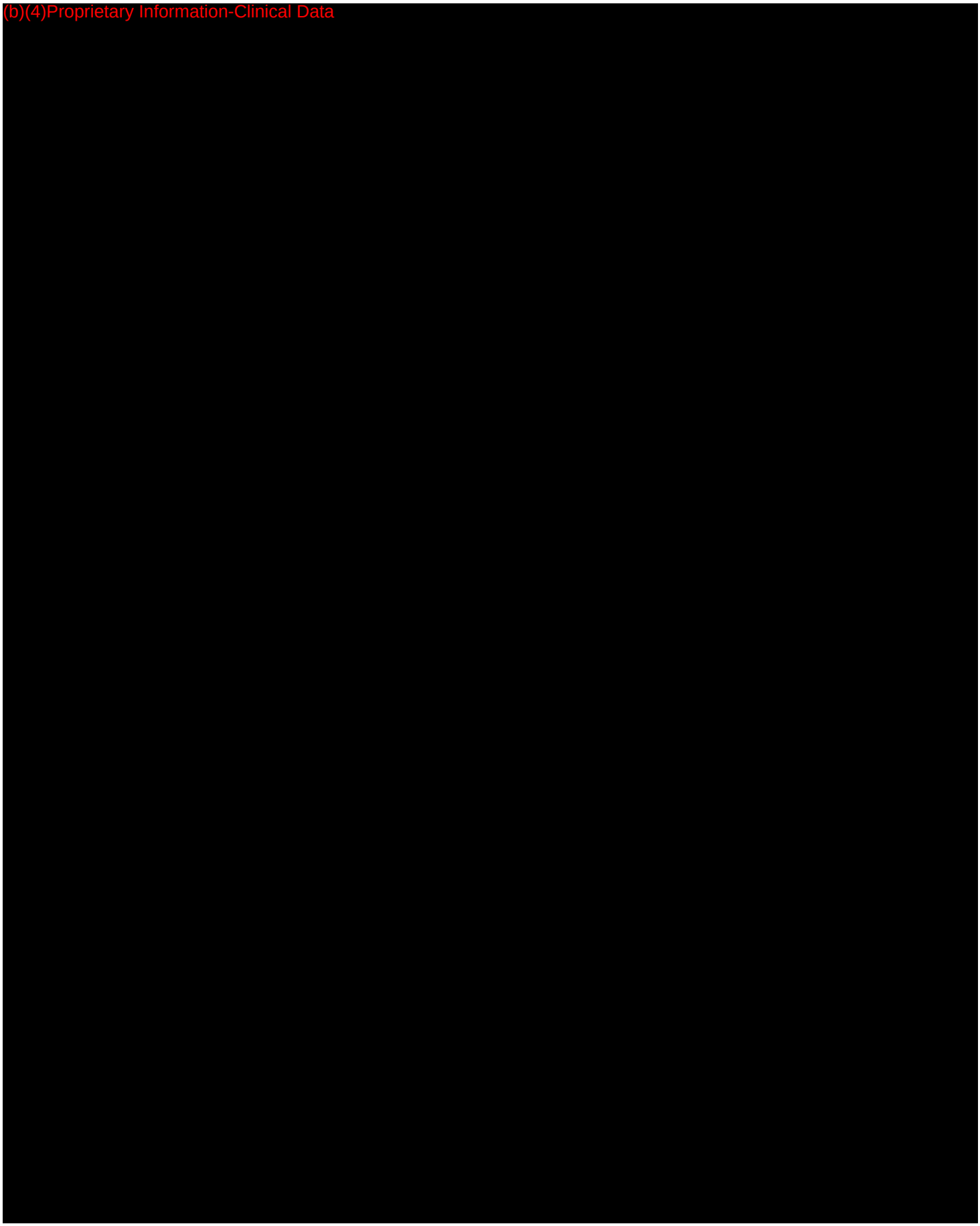


(b)(4)Proprietary Information-Clinical Data





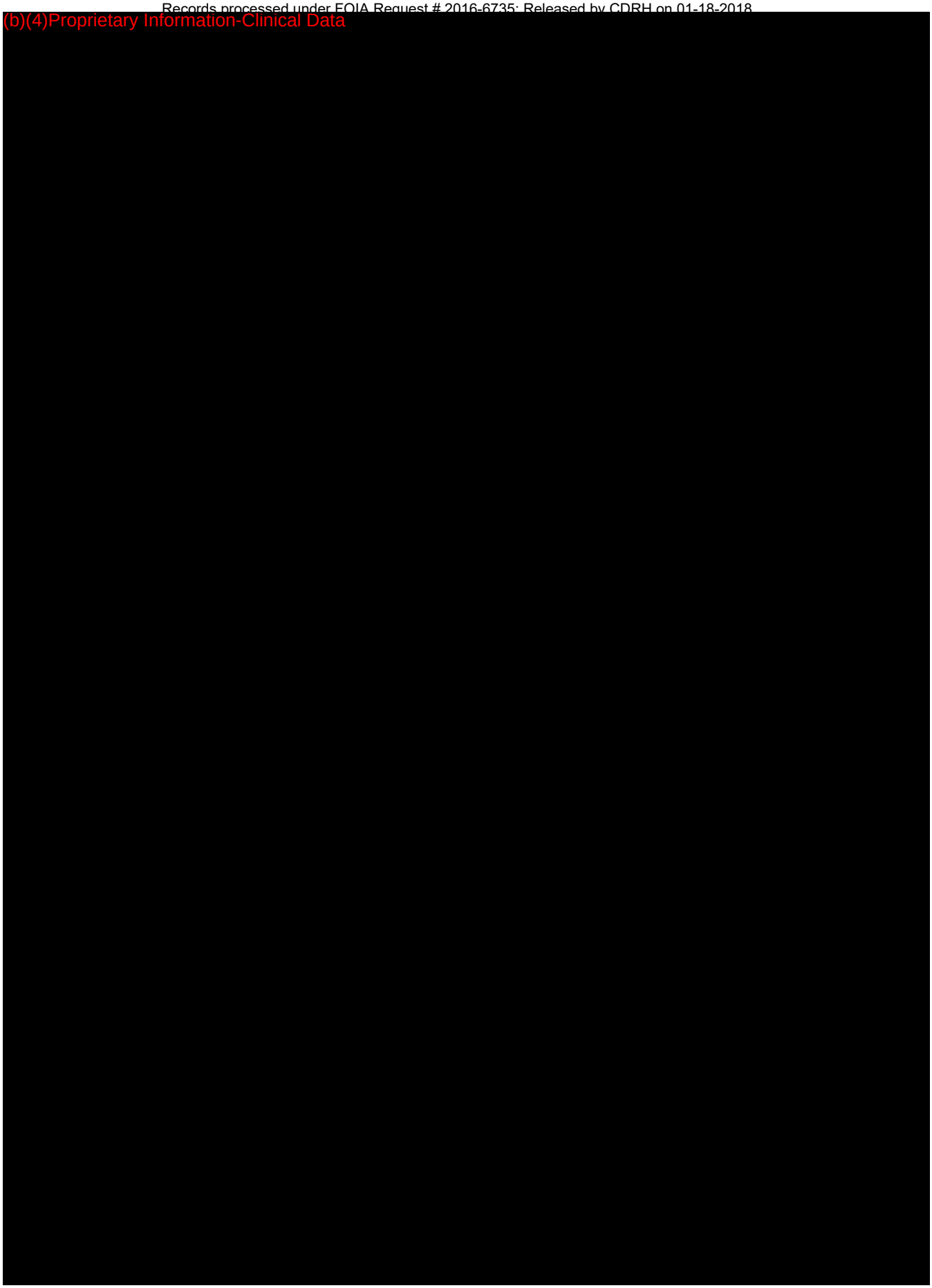
(b)(4)Proprietary Information-Clinical Data



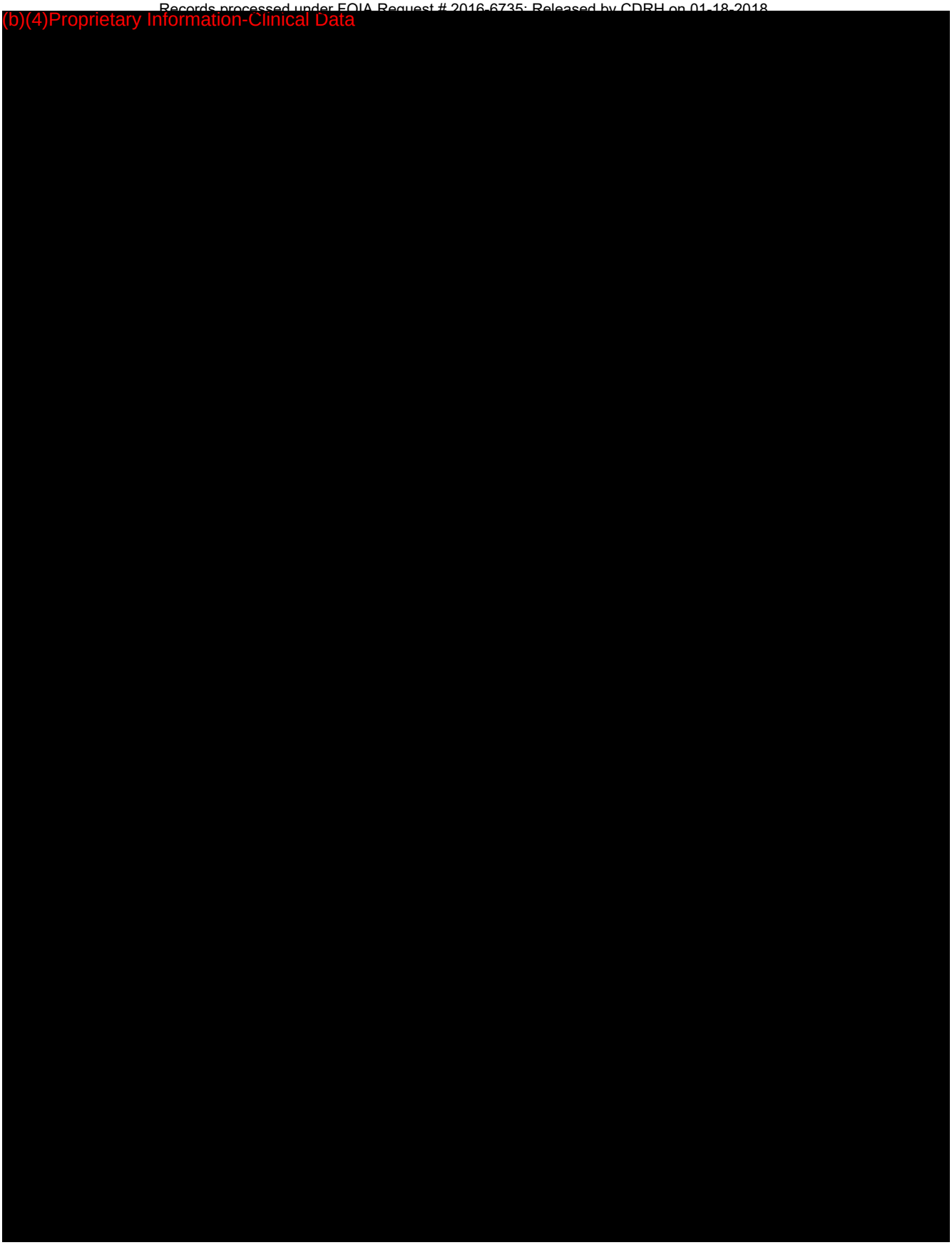
(b)(4)Proprietary Information-Clinical Data

[redacted]

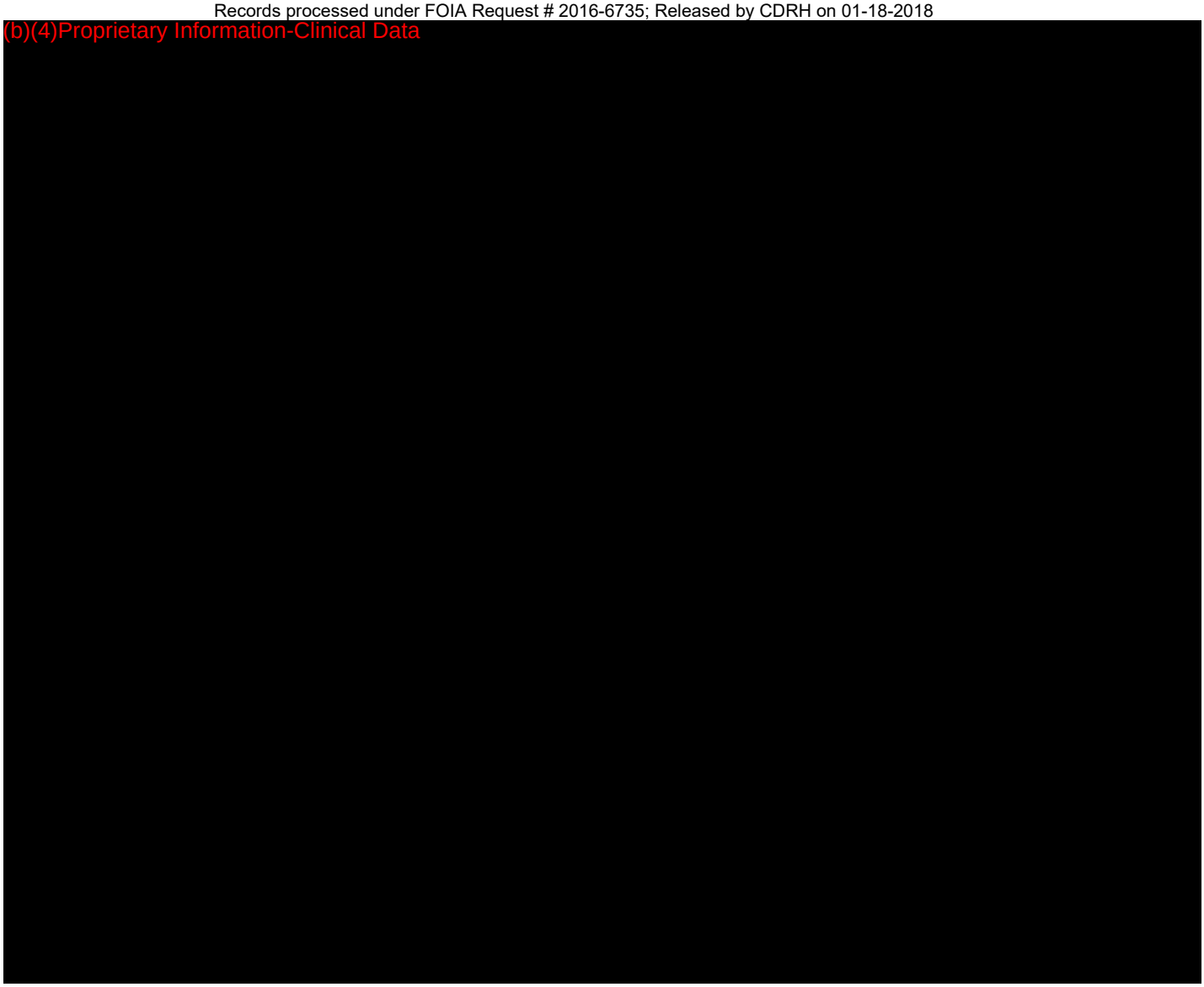
(b)(4)Proprietary Information-Clinical Data



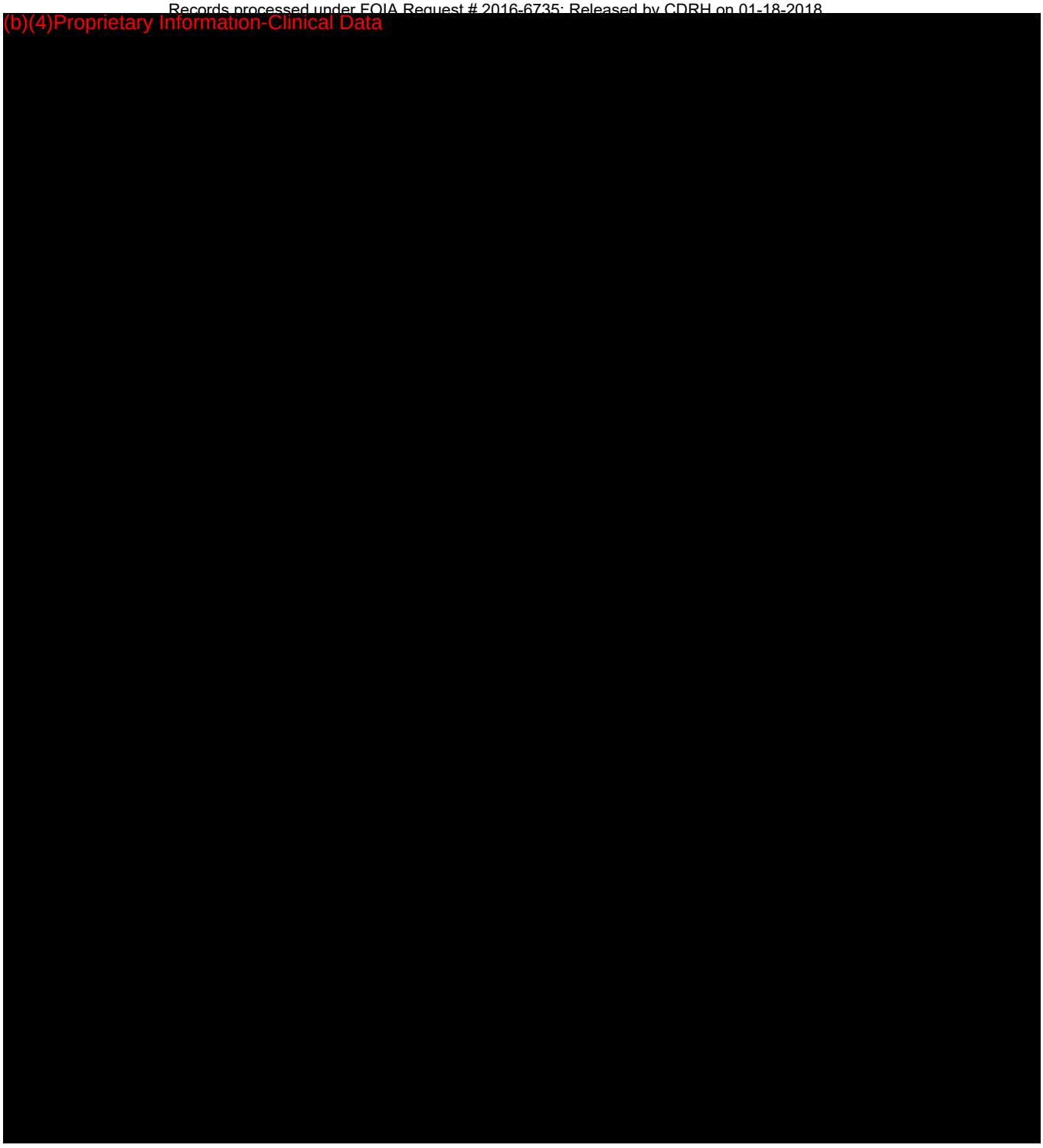
(b)(4)Proprietary Information-Clinical Data



(b)(4)Proprietary Information-Clinical Data



(b)(4)Proprietary Information-Clinical Data



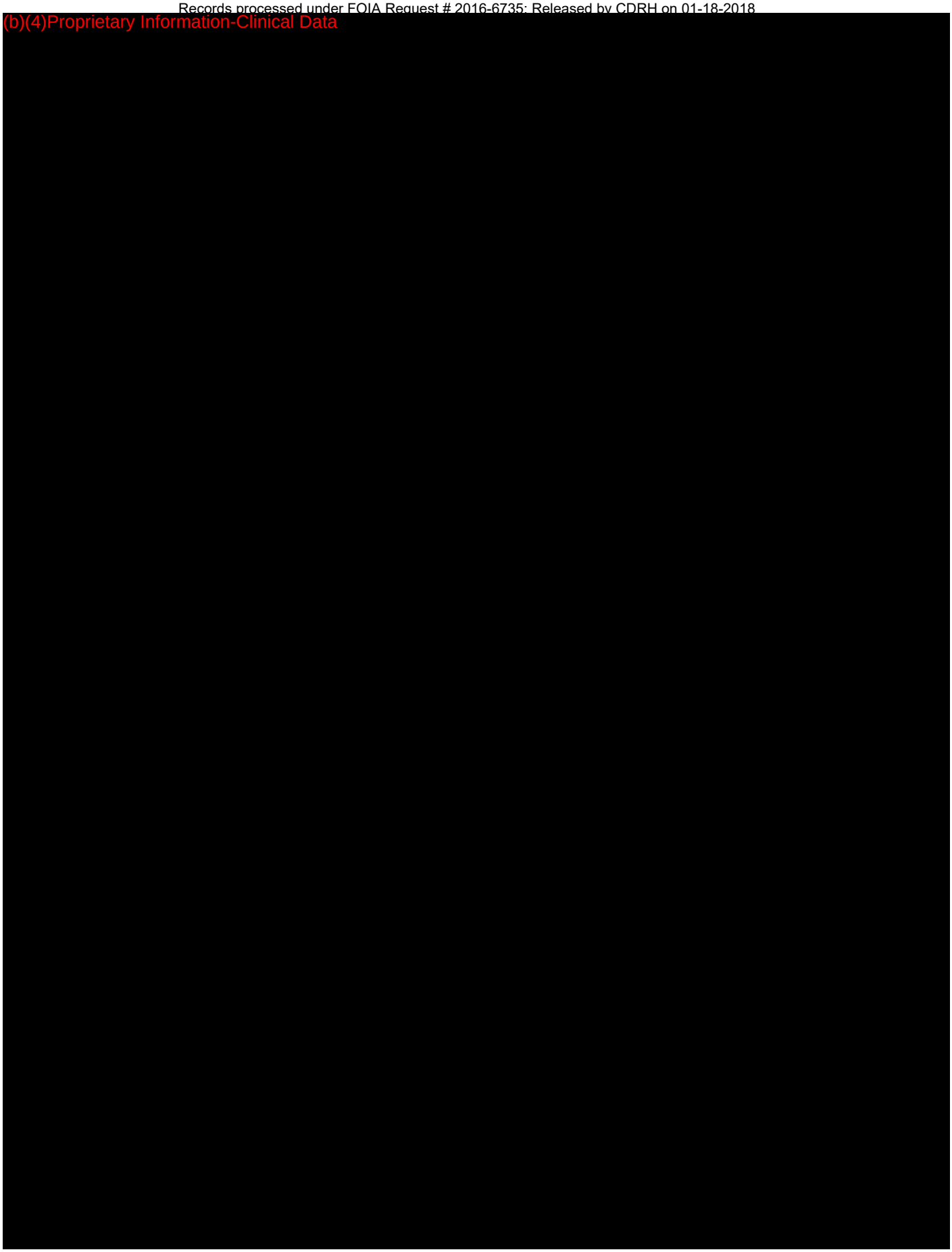
(b)(4)Proprietary Information-Clinical Data

[redacted]

(b)(4)Proprietary Information-Clinical Data

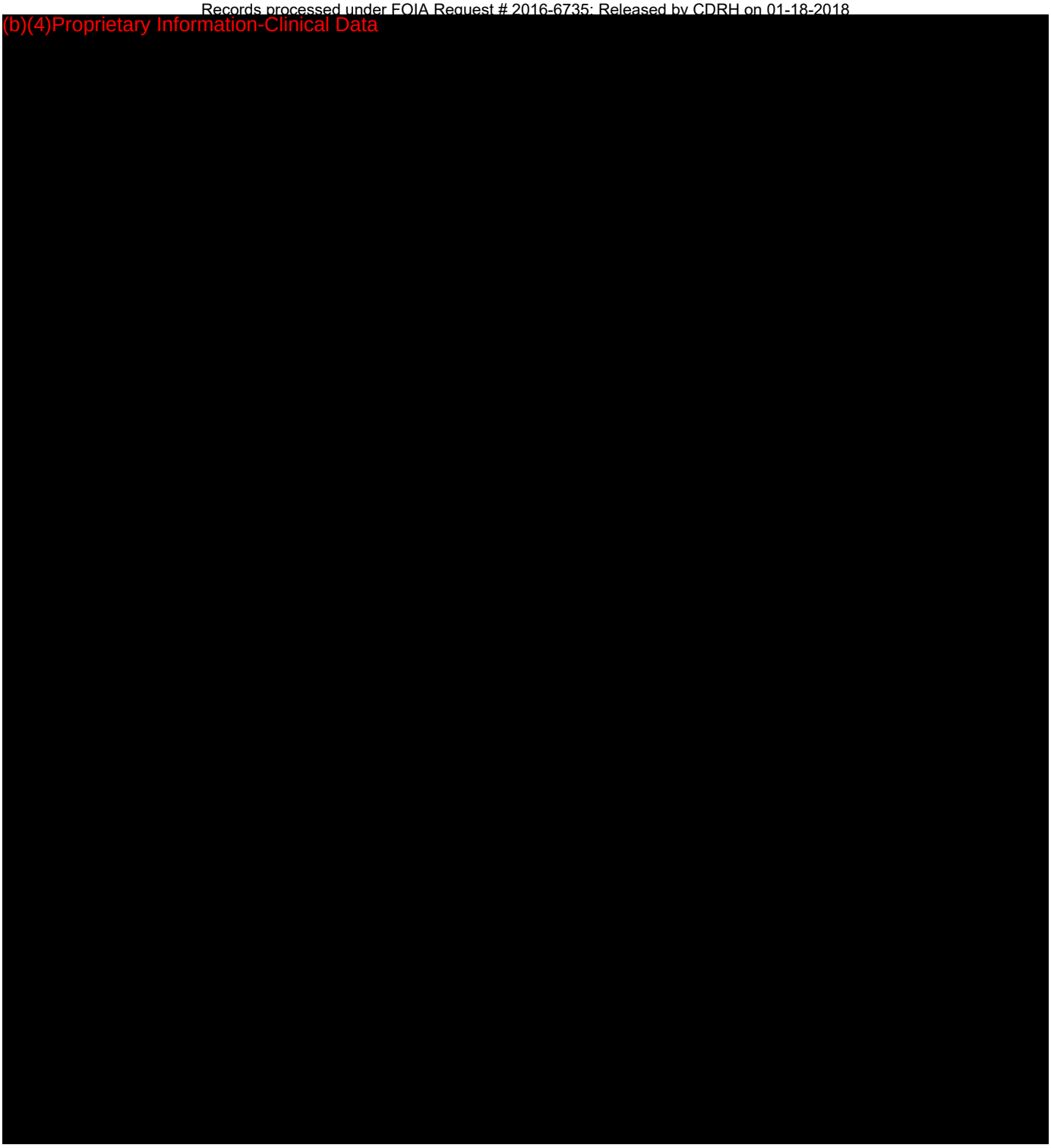
[redacted]

(b)(4)Proprietary Information-Clinical Data



(b)(4)Proprietary Information-Clinical Data

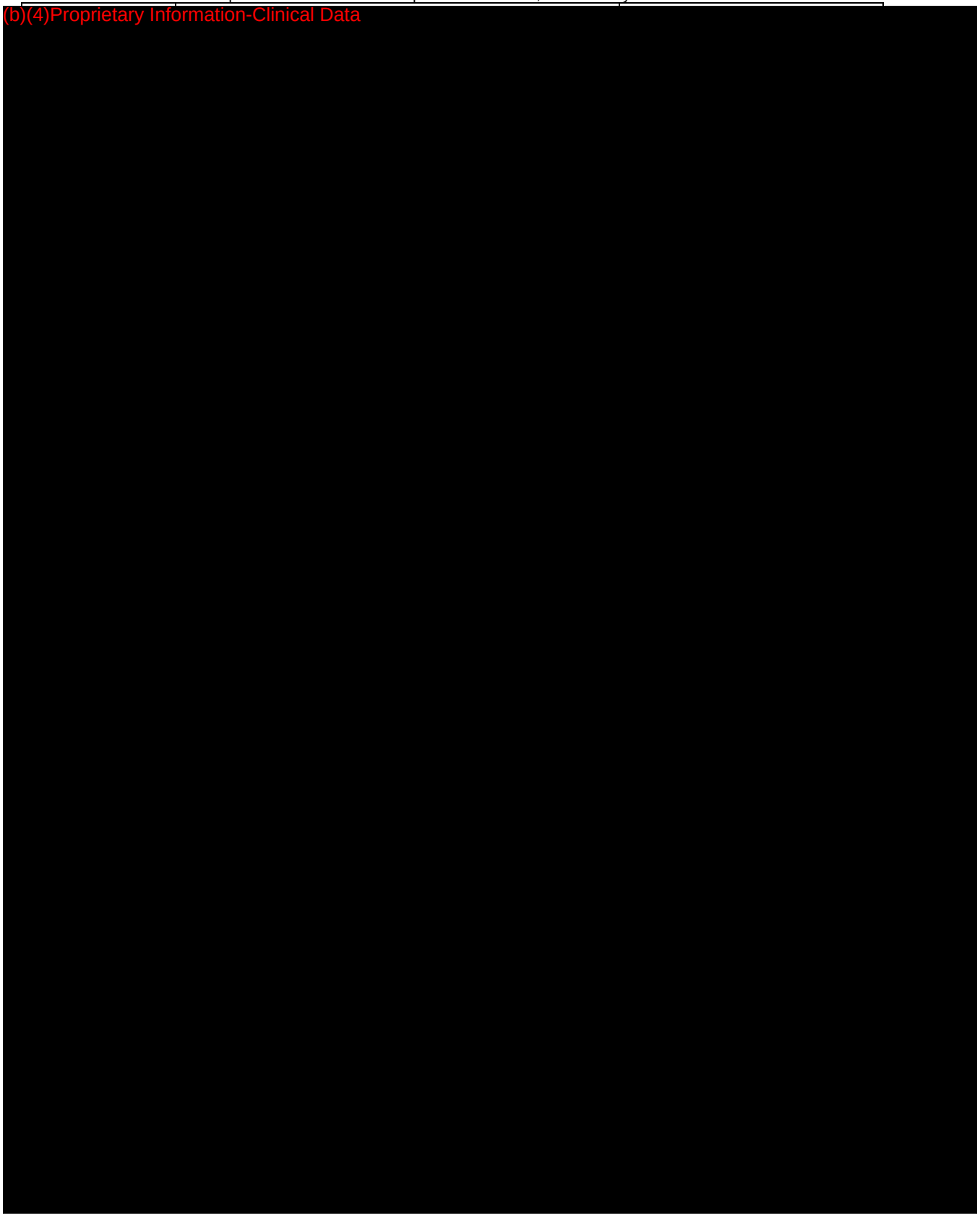
(b)(4)Proprietary Information-Clinical Data



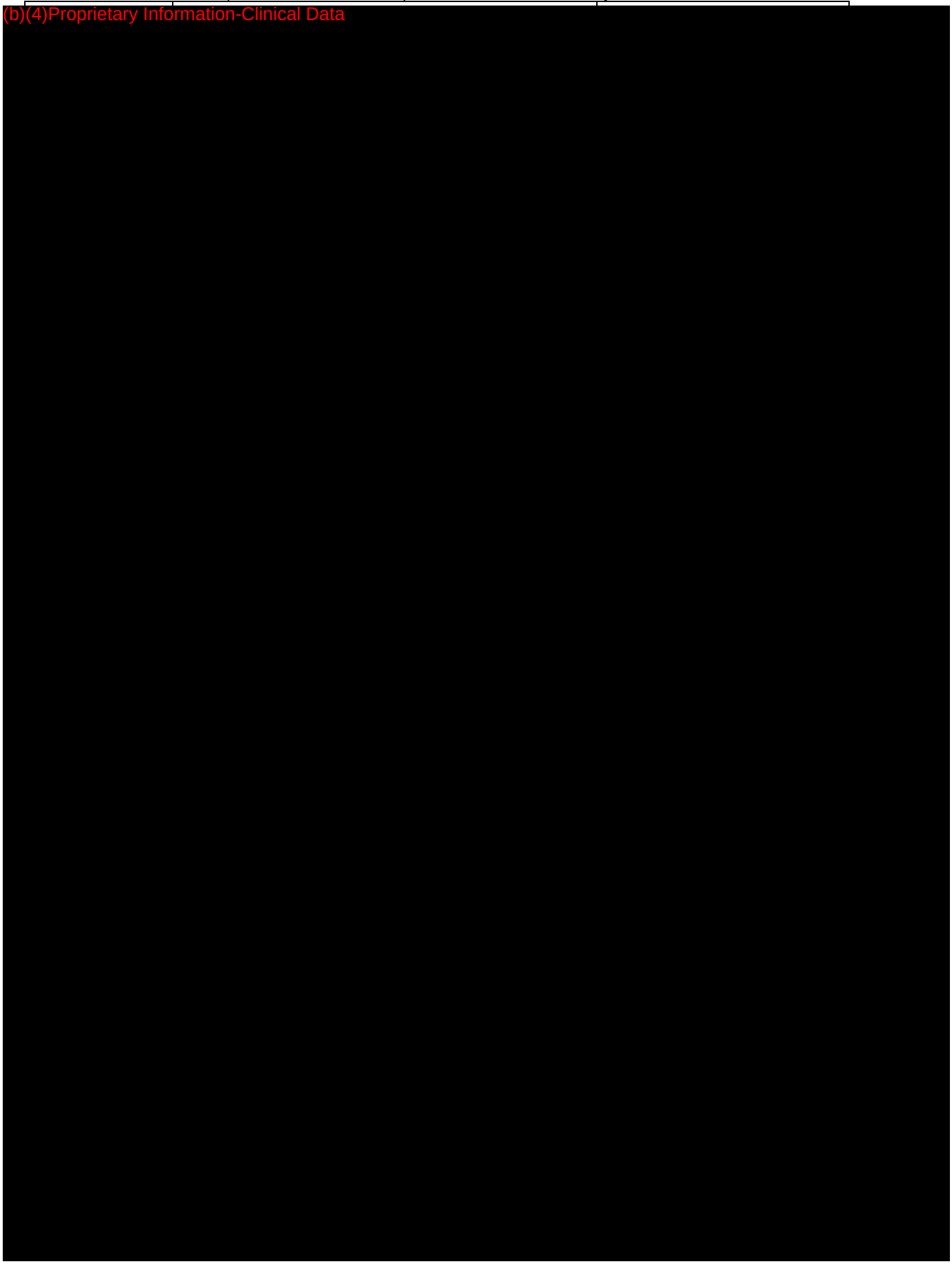
(b)(4)Proprietary Information-Clinical Data

[redacted]

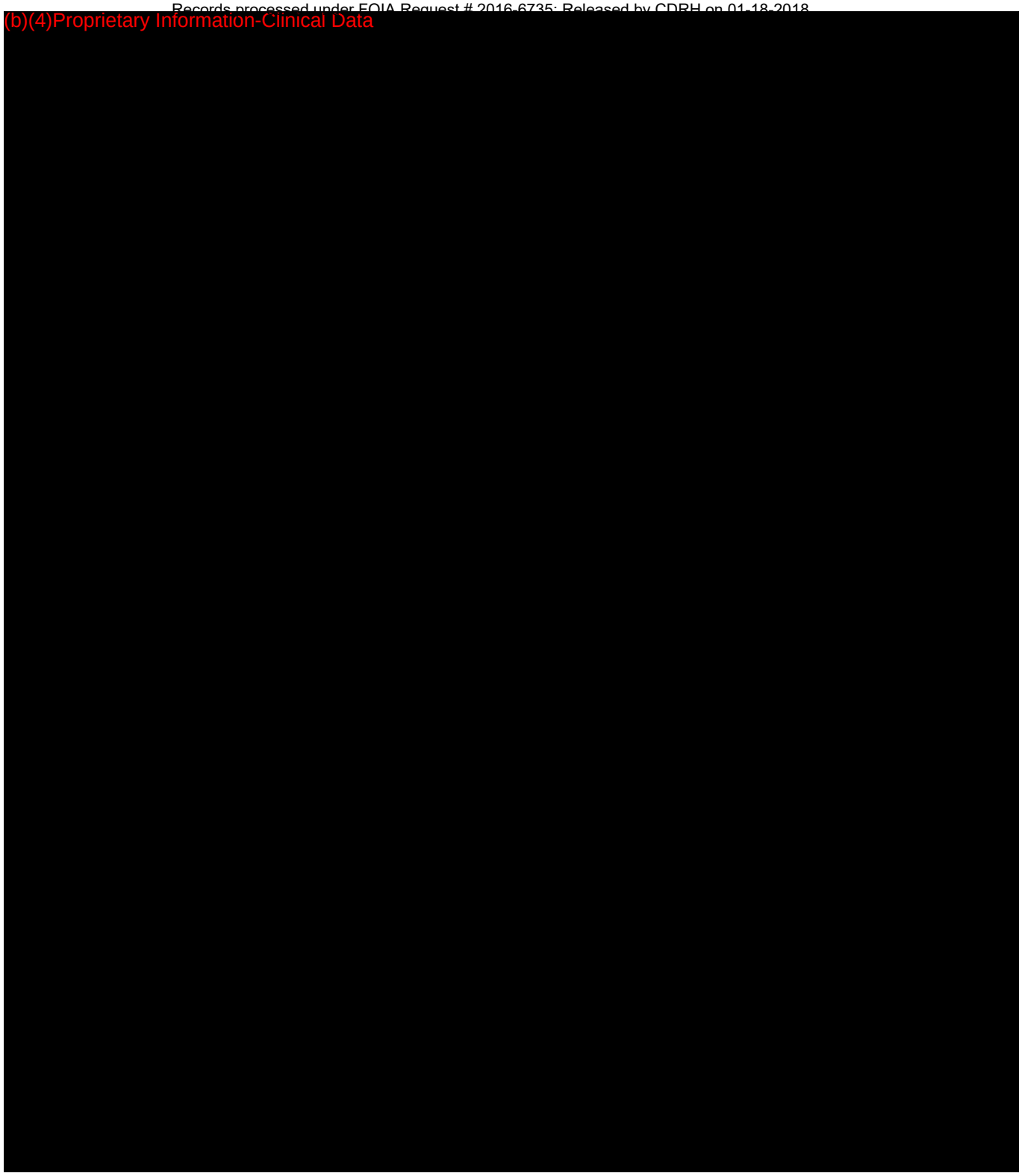
(b)(4)Proprietary Information-Clinical Data



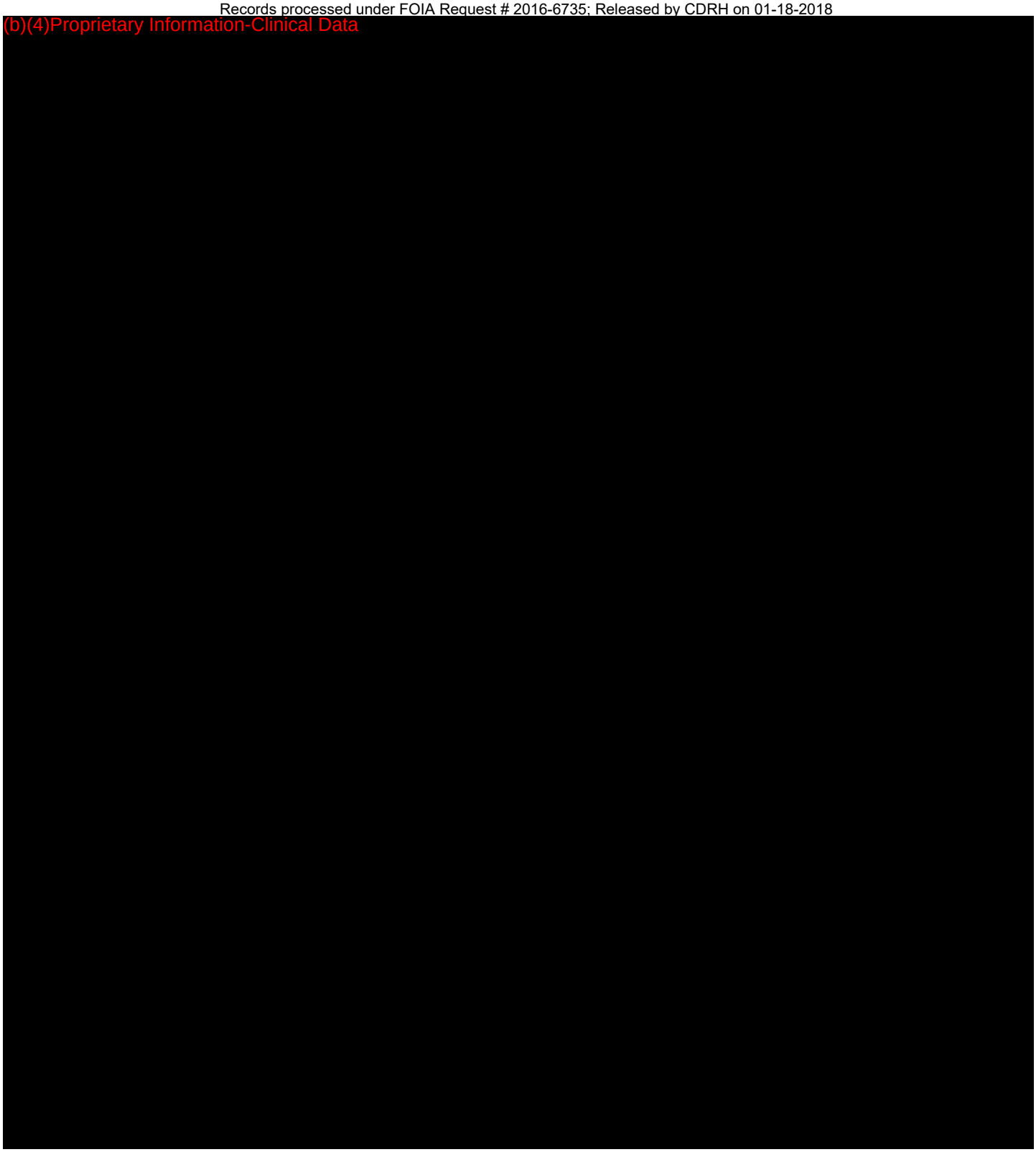
(b)(4)Proprietary Information-Clinical Data



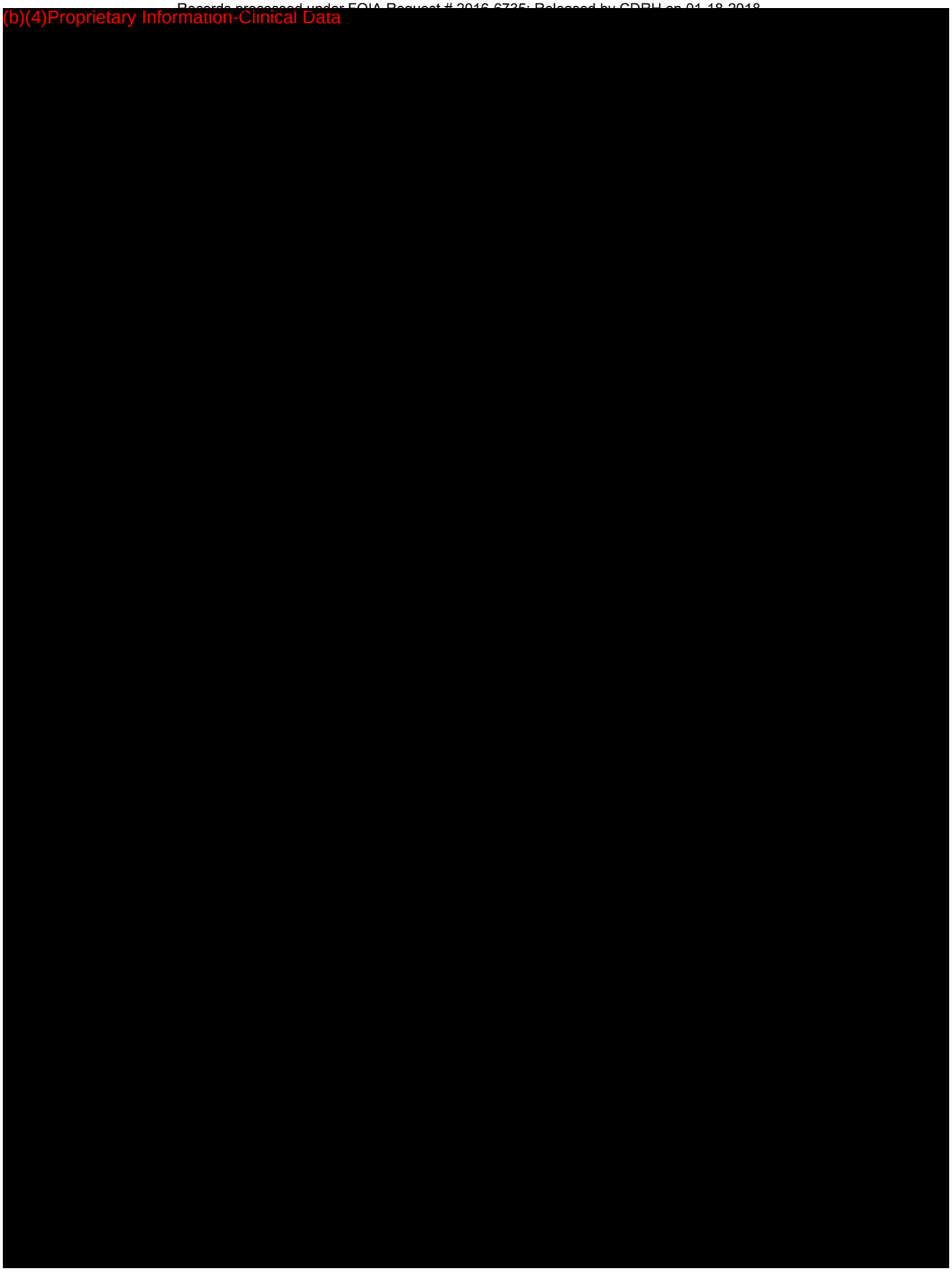
(b)(4)Proprietary Information-Clinical Data



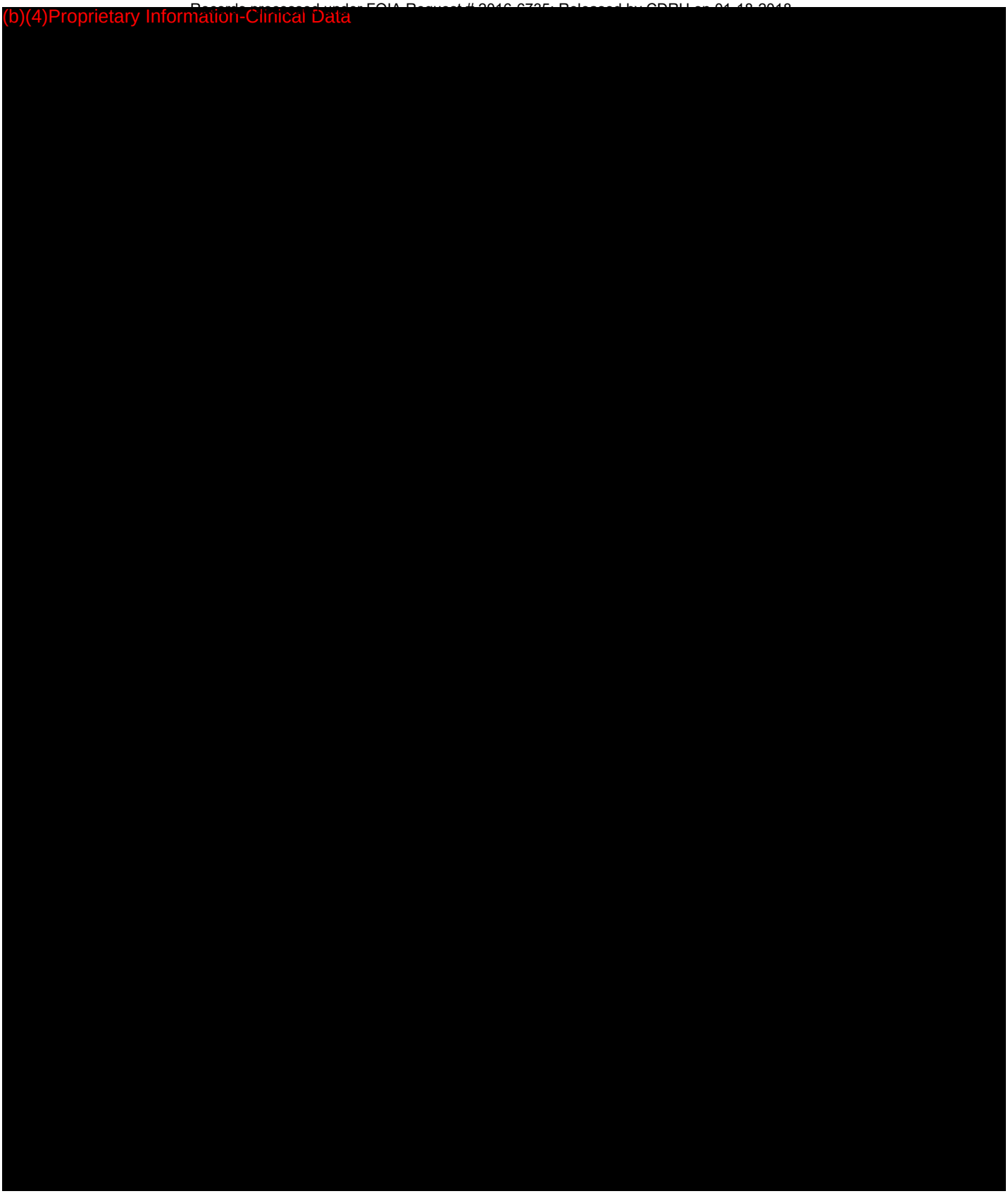
(b)(4)Proprietary Information-Clinical Data



(b)(4)Proprietary Information-Clinical Data



(b)(4)Proprietary Information-Clinical Data



(b)(4)Proprietary Information-Clinical Data

[redacted]

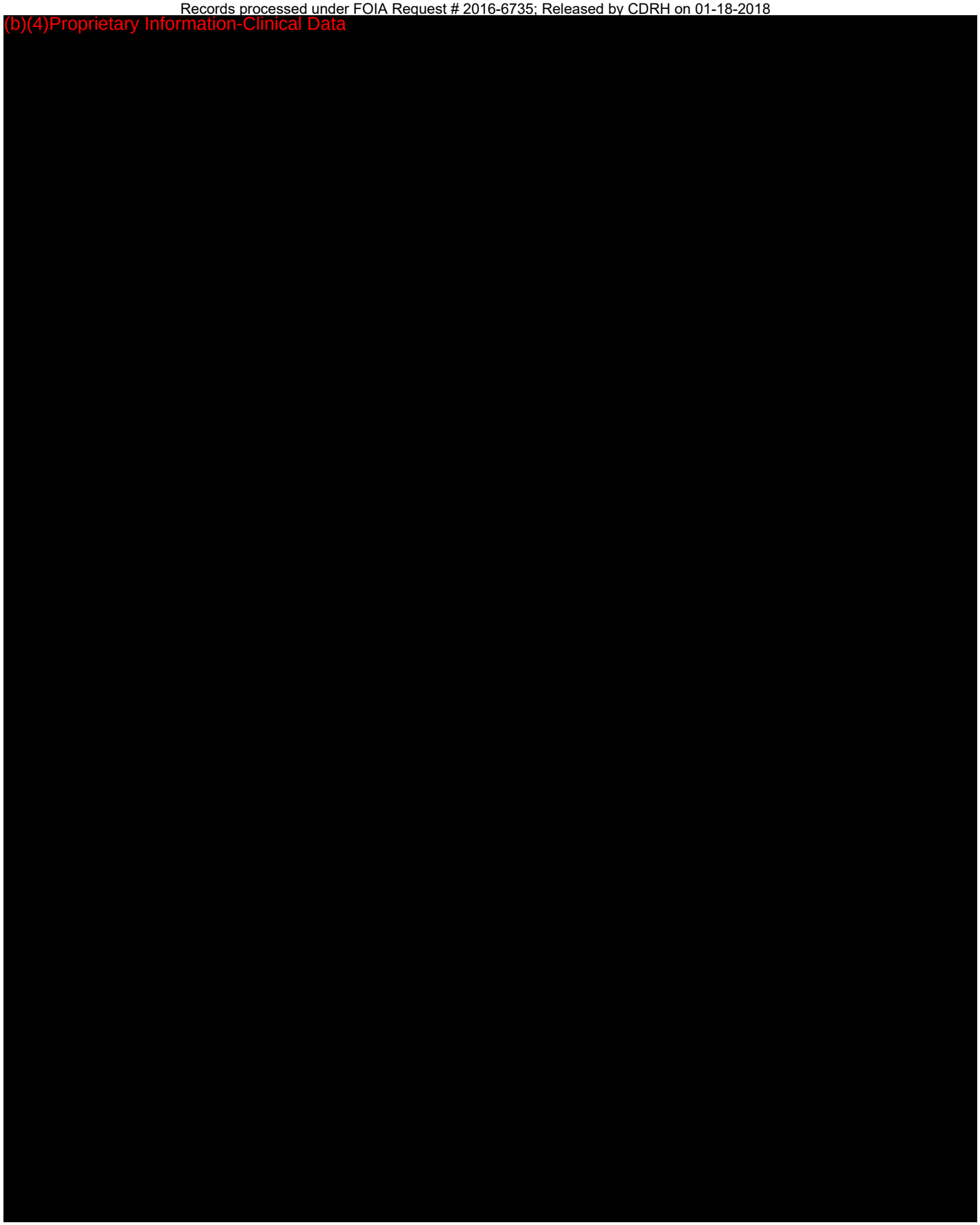
(b)(4)Proprietary Information-Clinical Data

[redacted]

(b)(4)Proprietary Information-Clinical Data

[redacted]

(b)(4)Proprietary Information-Clinical Data



(b)(4)Proprietary Information-Clinical Data

[redacted]

(b)(4)Proprietary Information-Clinical Data

[redacted]

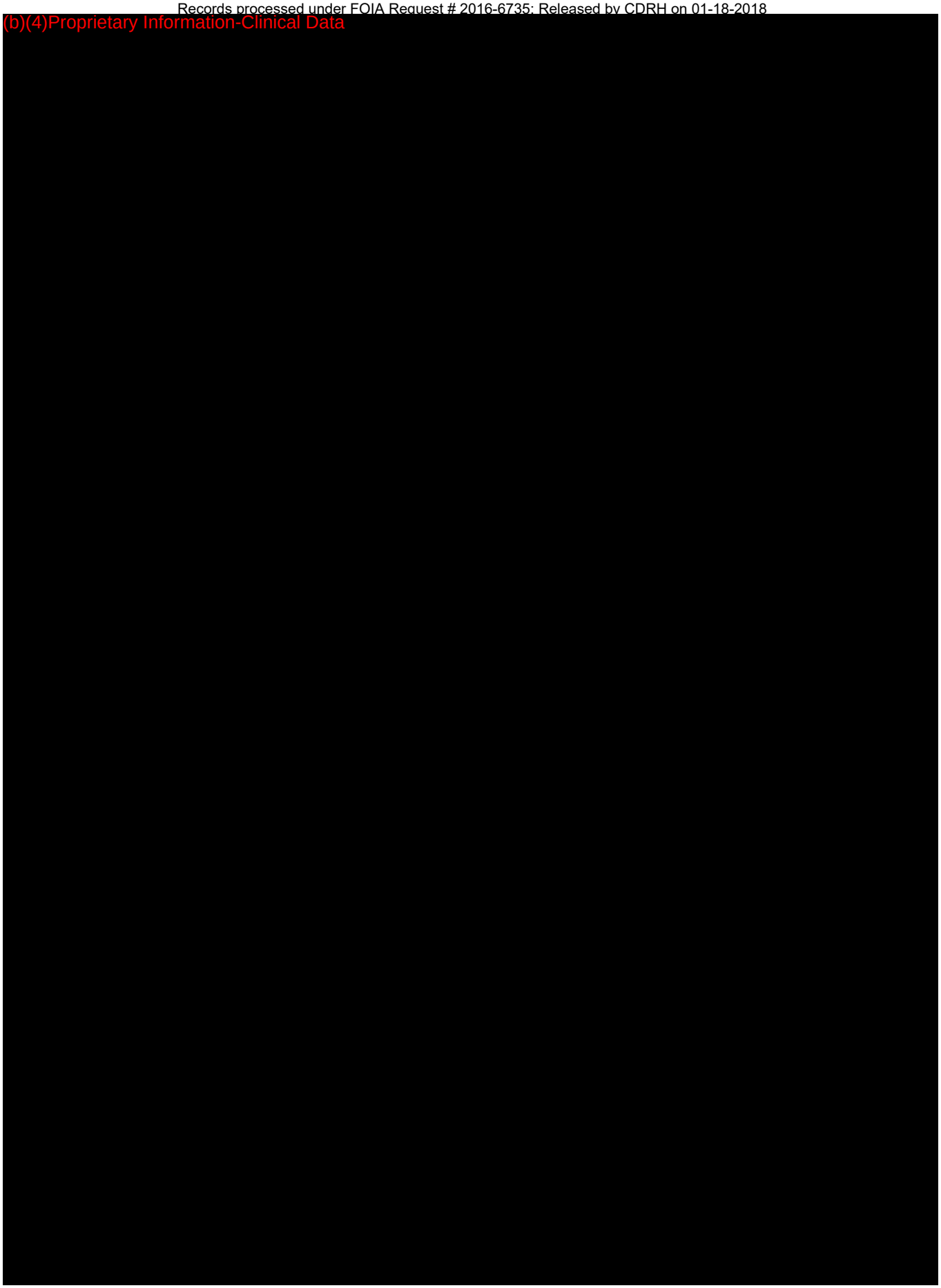
(b)(4)Proprietary Information-Clinical Data

[redacted]

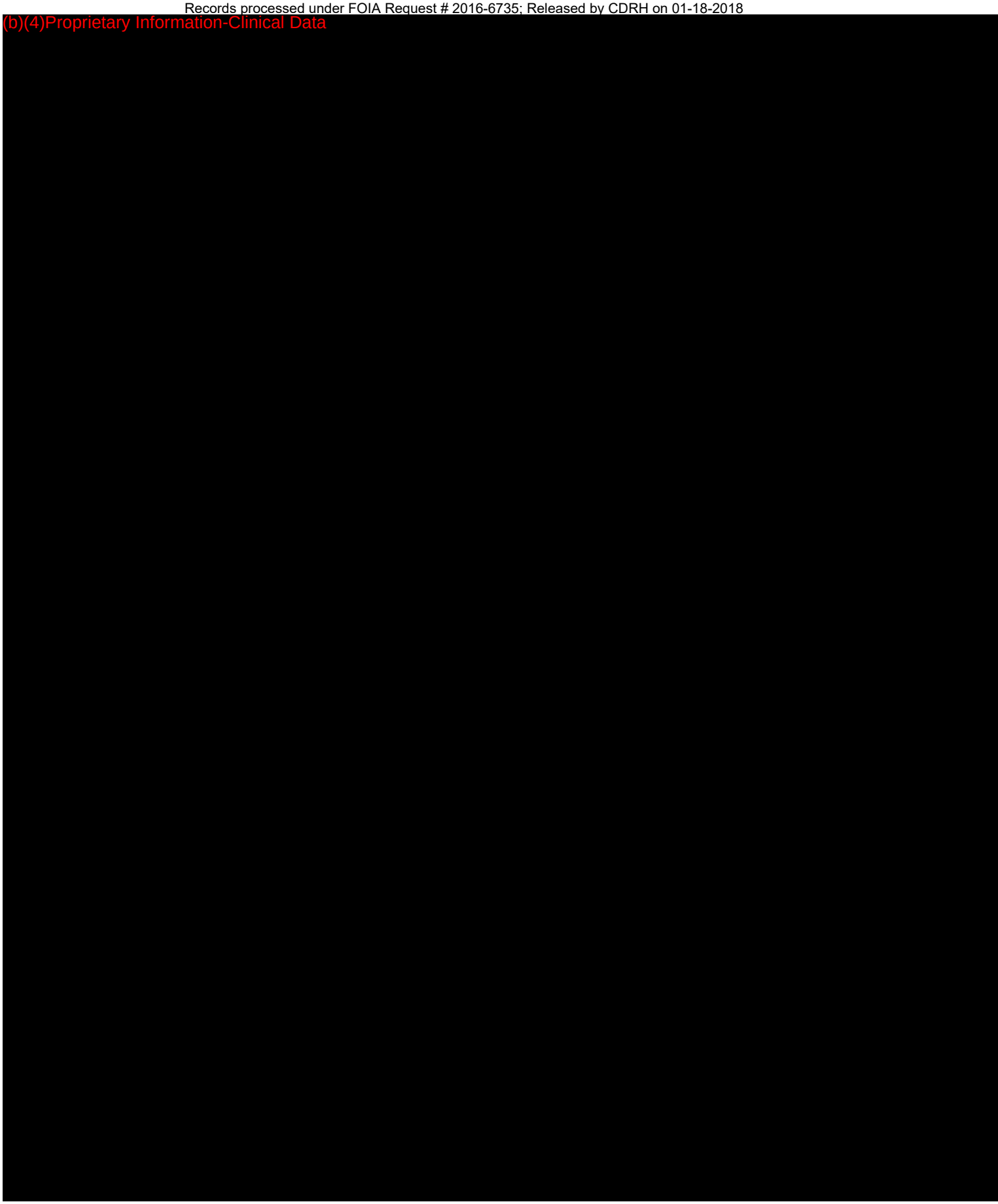
(b)(4)Proprietary Information-Clinical Data

[redacted]

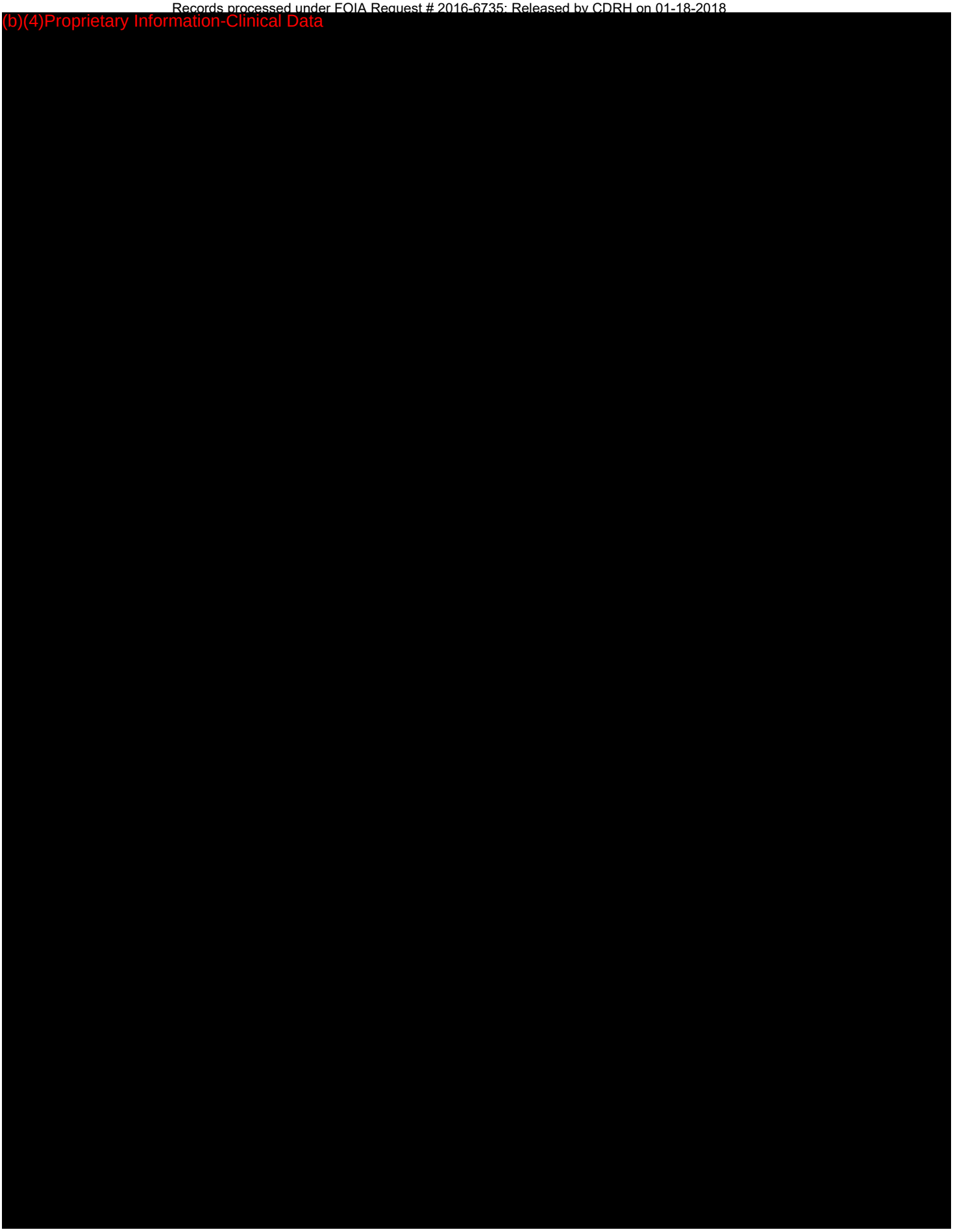
(b)(4)Proprietary Information-Clinical Data



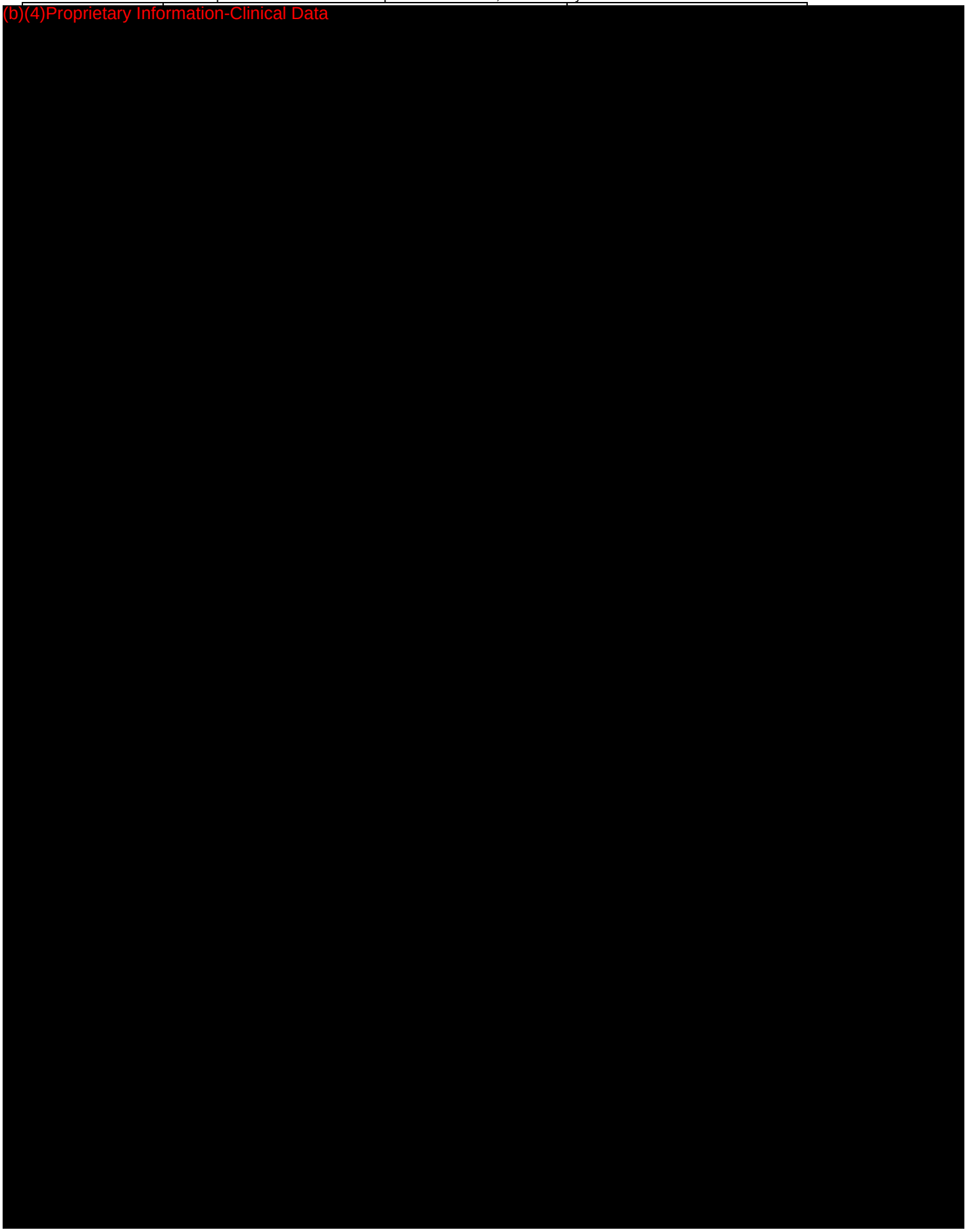
(b)(4)Proprietary Information-Clinical Data



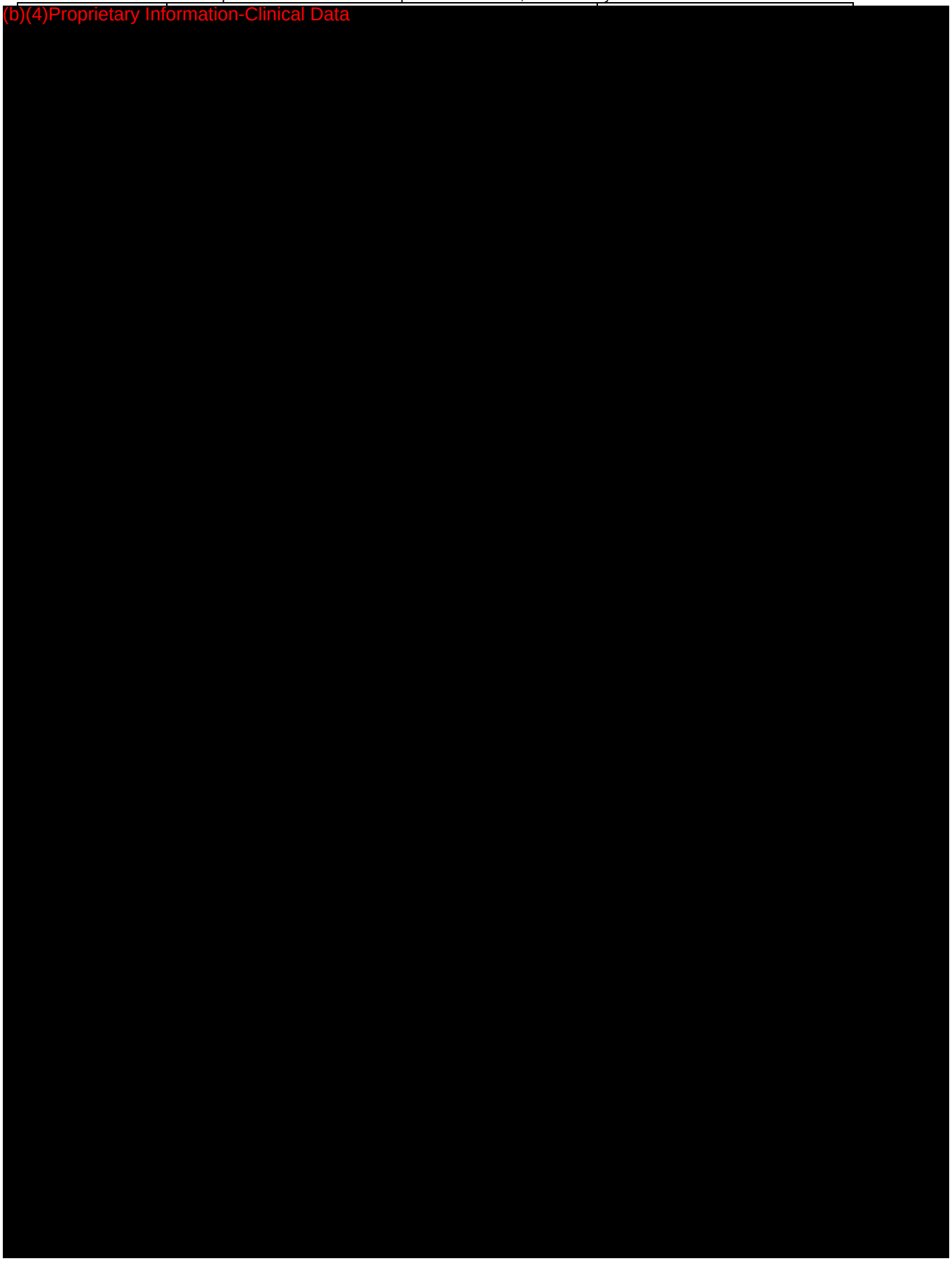
(b)(4)Proprietary Information-Clinical Data



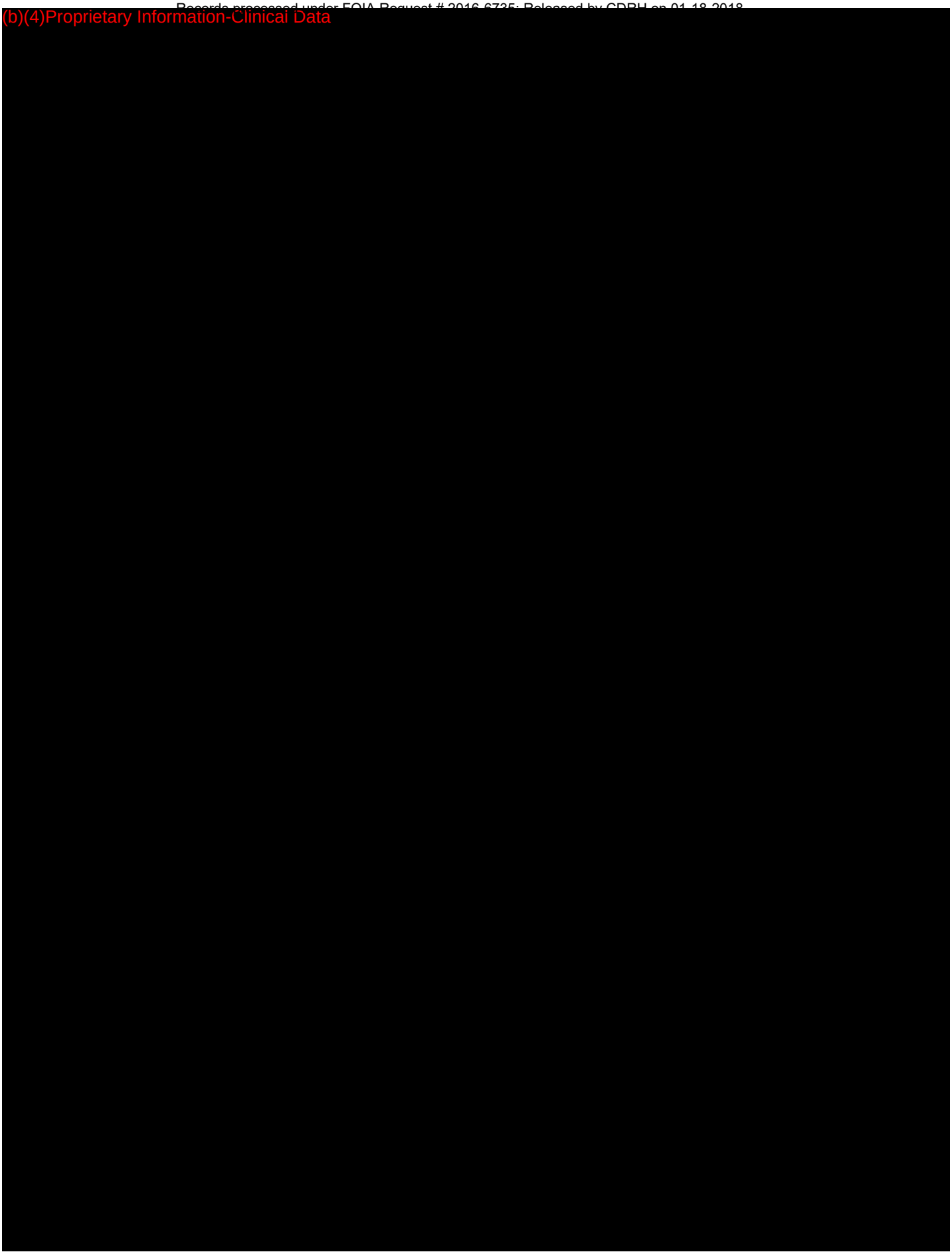
(b)(4)Proprietary Information-Clinical Data



(b)(4)Proprietary Information-Clinical Data



(b)(4)Proprietary Information-Clinical Data



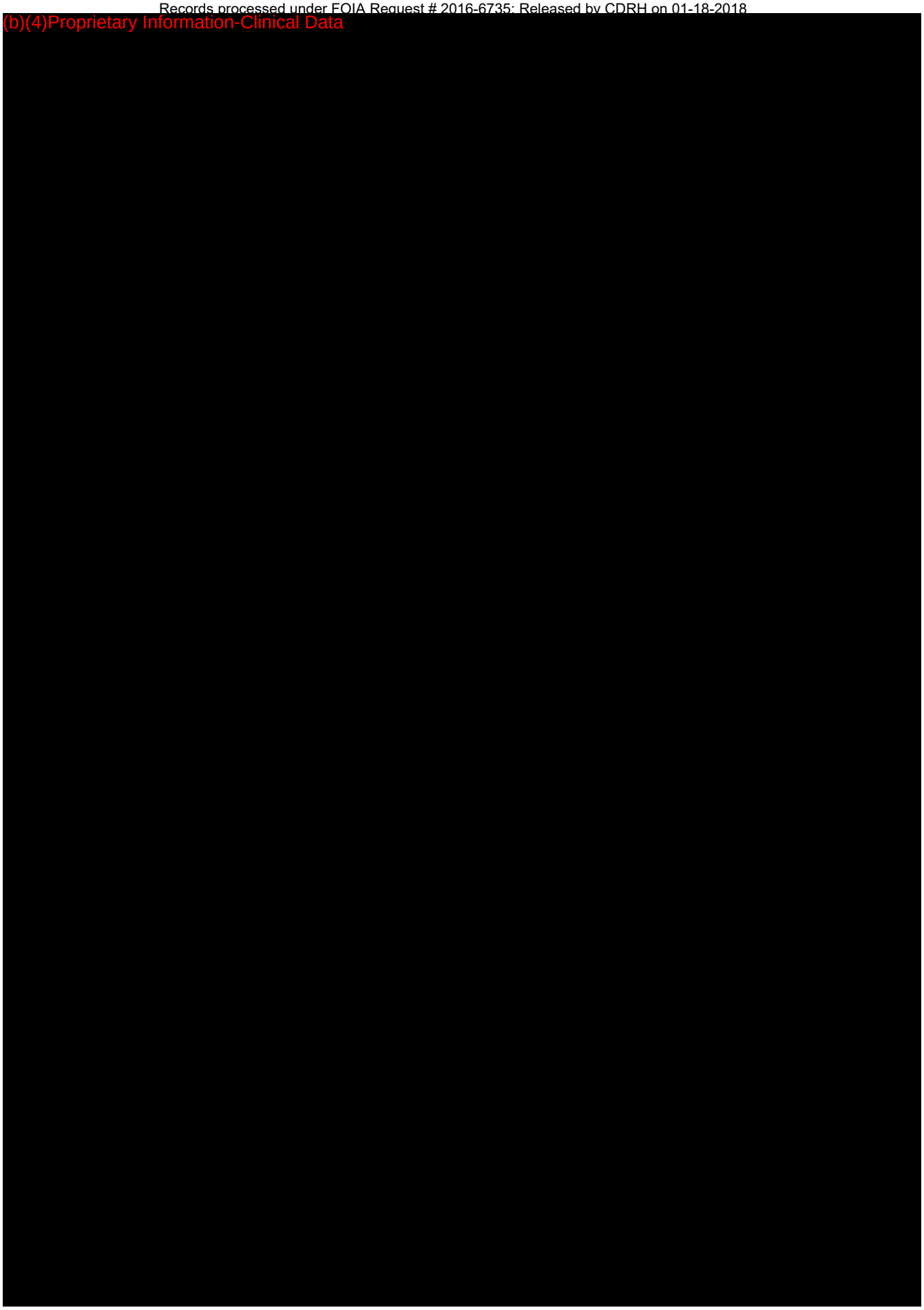
(b)(4)Proprietary Information-Clinical Data

[redacted]

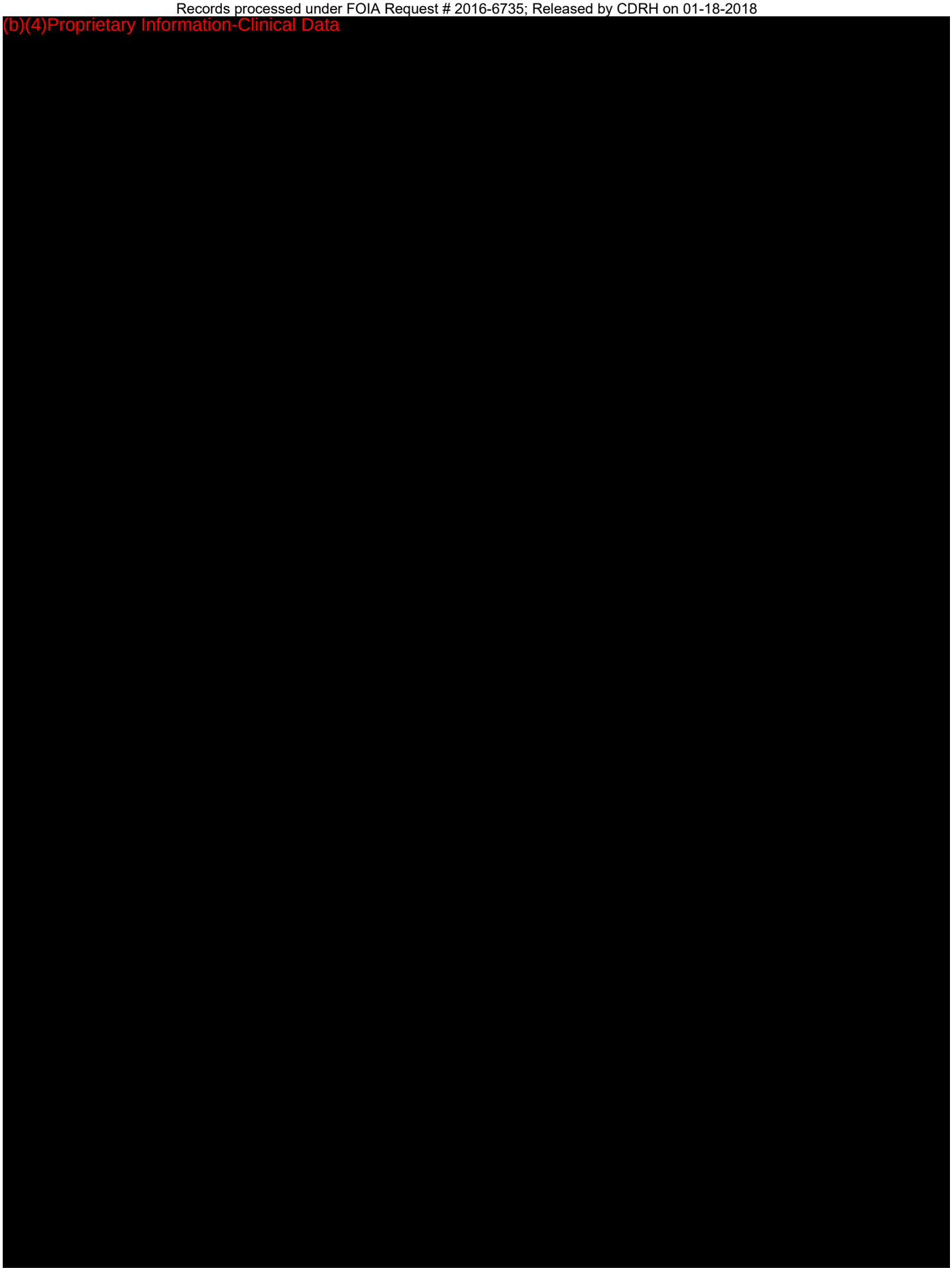
(b)(4)Proprietary Information-Clinical Data

[redacted]

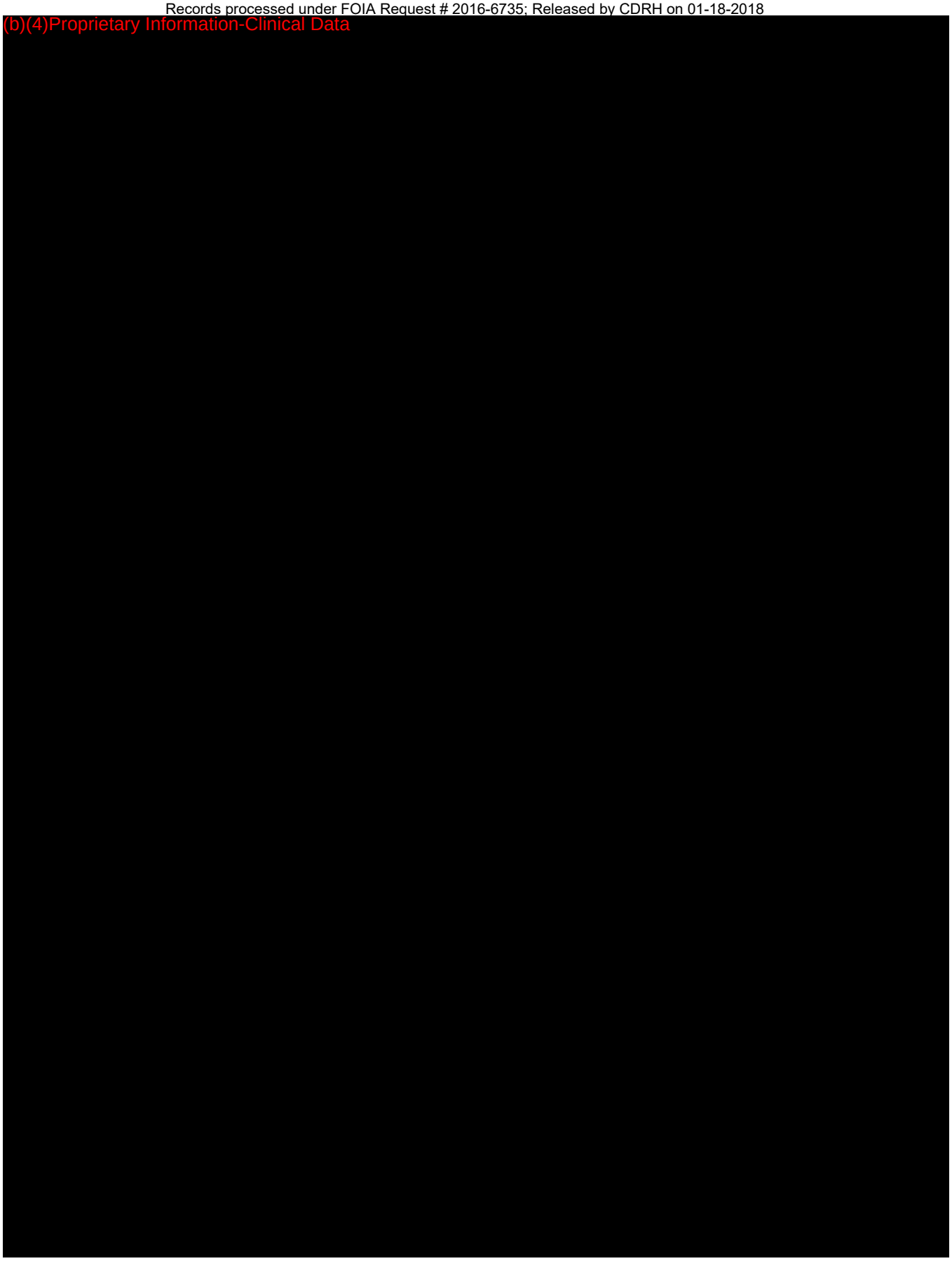
(b)(4)Proprietary Information-Clinical Data



(b)(4)Proprietary Information-Clinical Data



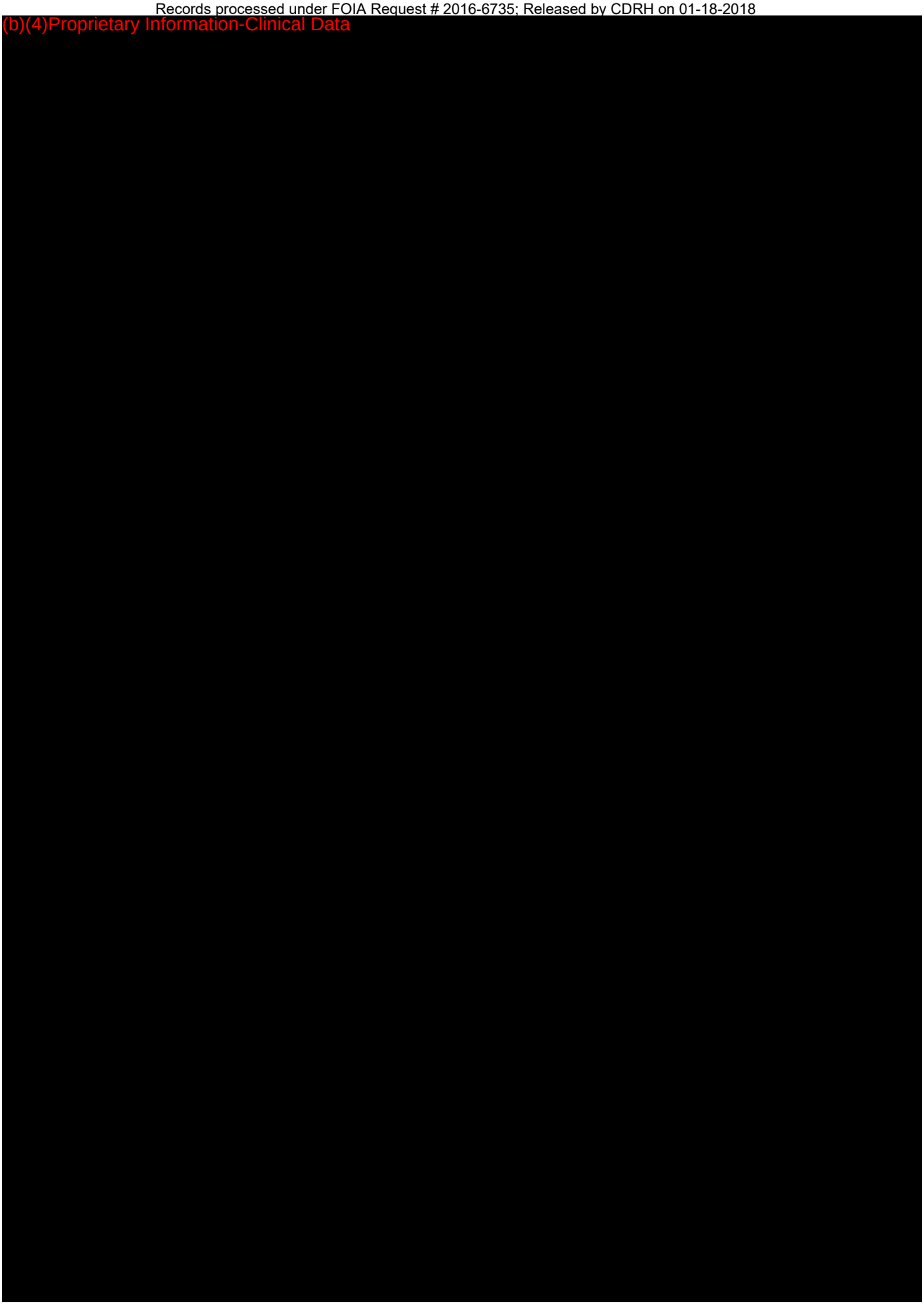
(b)(4)Proprietary Information-Clinical Data



(b)(4)Proprietary Information-Clinical Data

[redacted]

(b)(4)Proprietary Information-Clinical Data



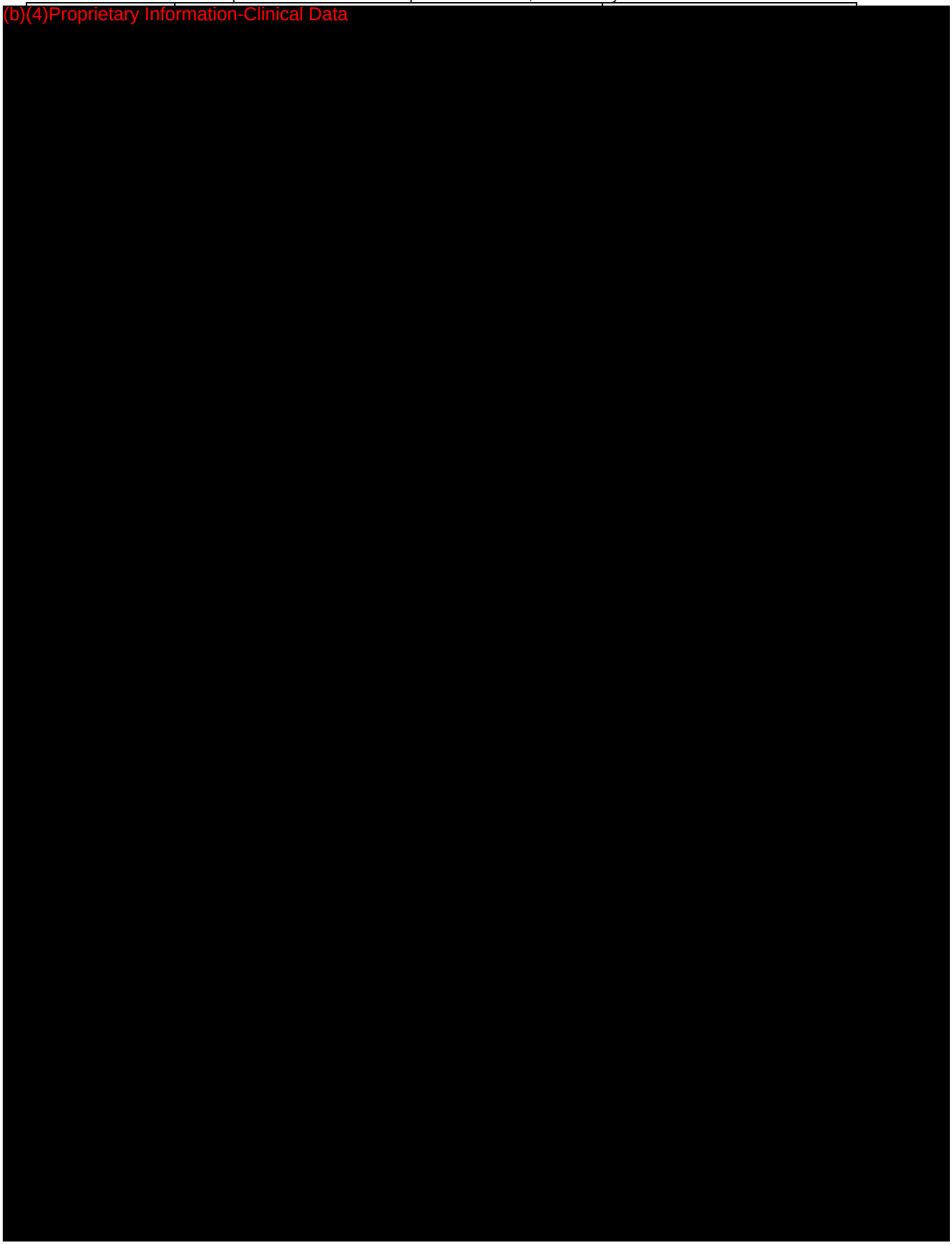
(b)(4)Proprietary Information-Clinical Data

[redacted]

(b)(4)Proprietary Information-Clinical Data

[redacted]

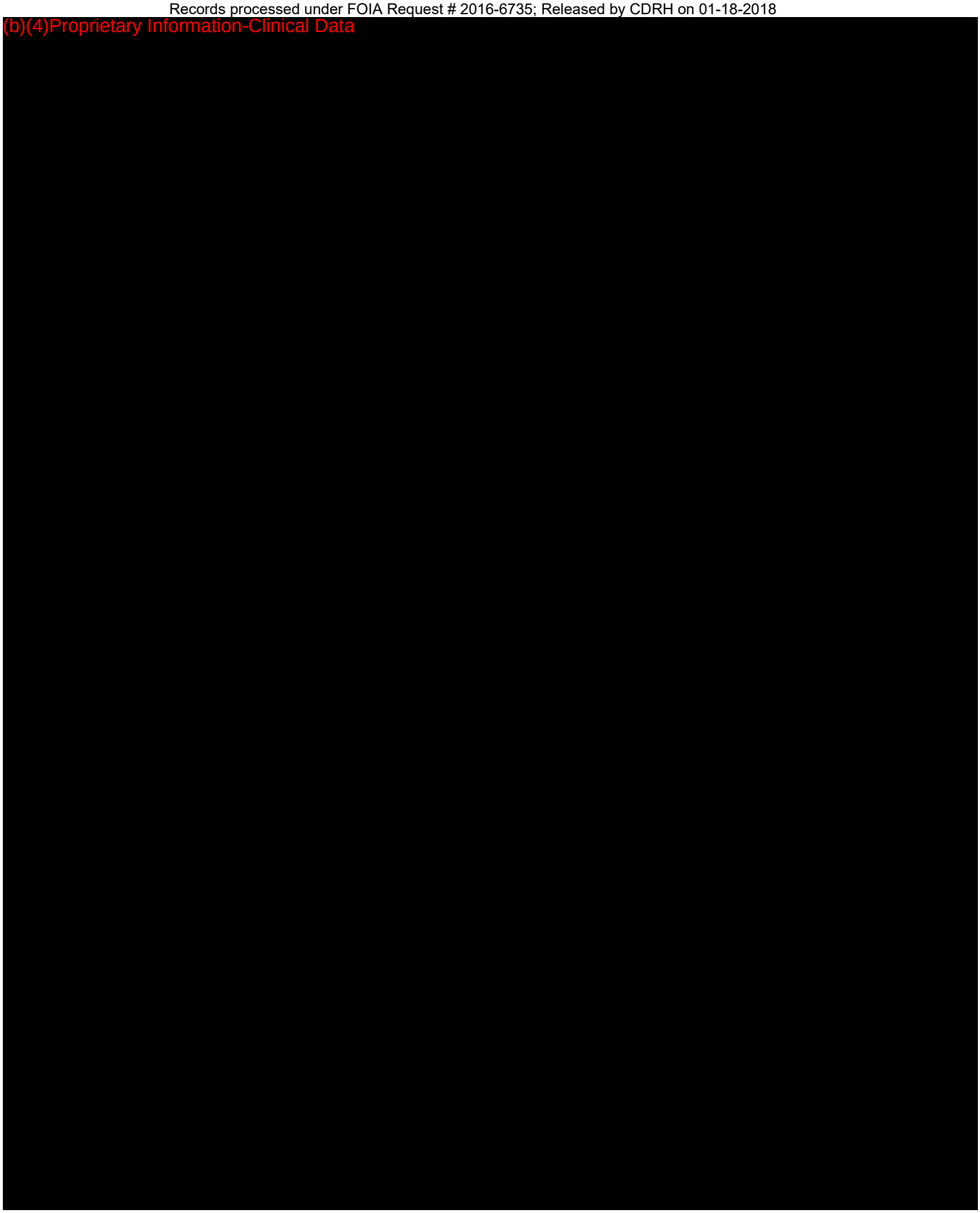
(b)(4)Proprietary Information-Clinical Data



(b)(4)Proprietary Information-Clinical Data

[redacted]

(b)(4)Proprietary Information-Clinical Data

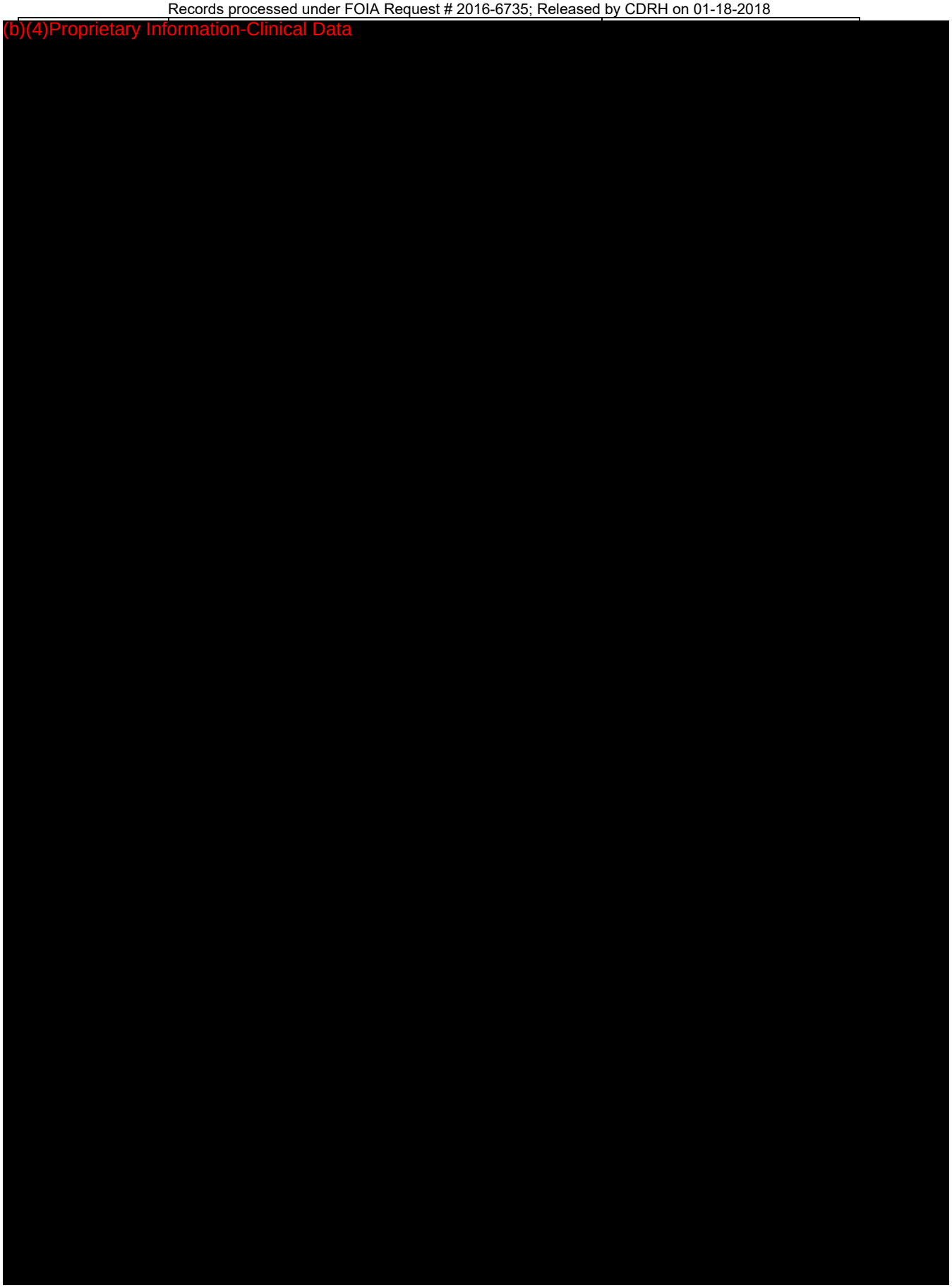


(b)(4)Proprietary Information-Clinical Data

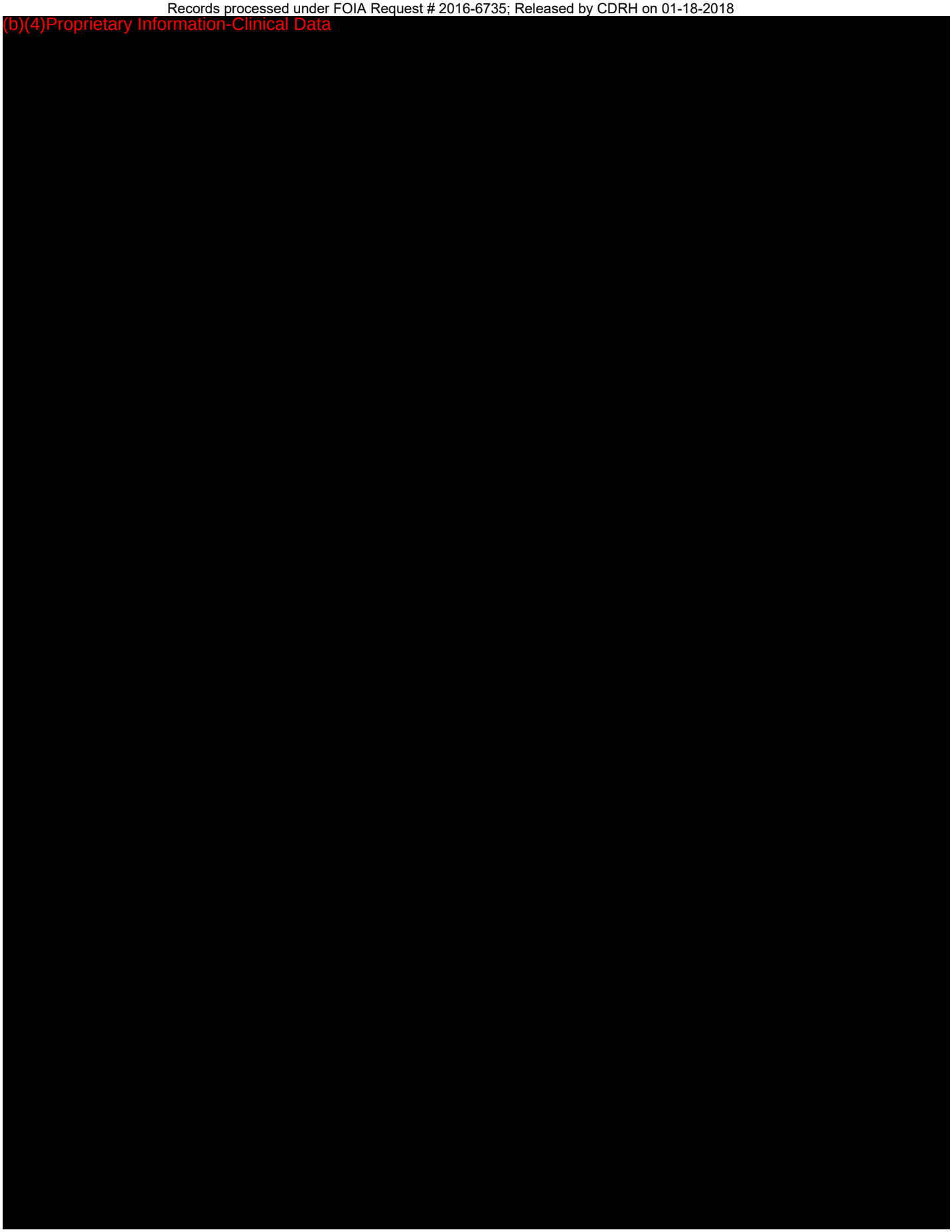
(b)(4)Proprietary Information-Clinical Data

[redacted]

(b)(4)Proprietary Information-Clinical Data



(b)(4)Proprietary Information-Clinical Data



(b)(4)Proprietary Information-Clinical Data

[redacted]

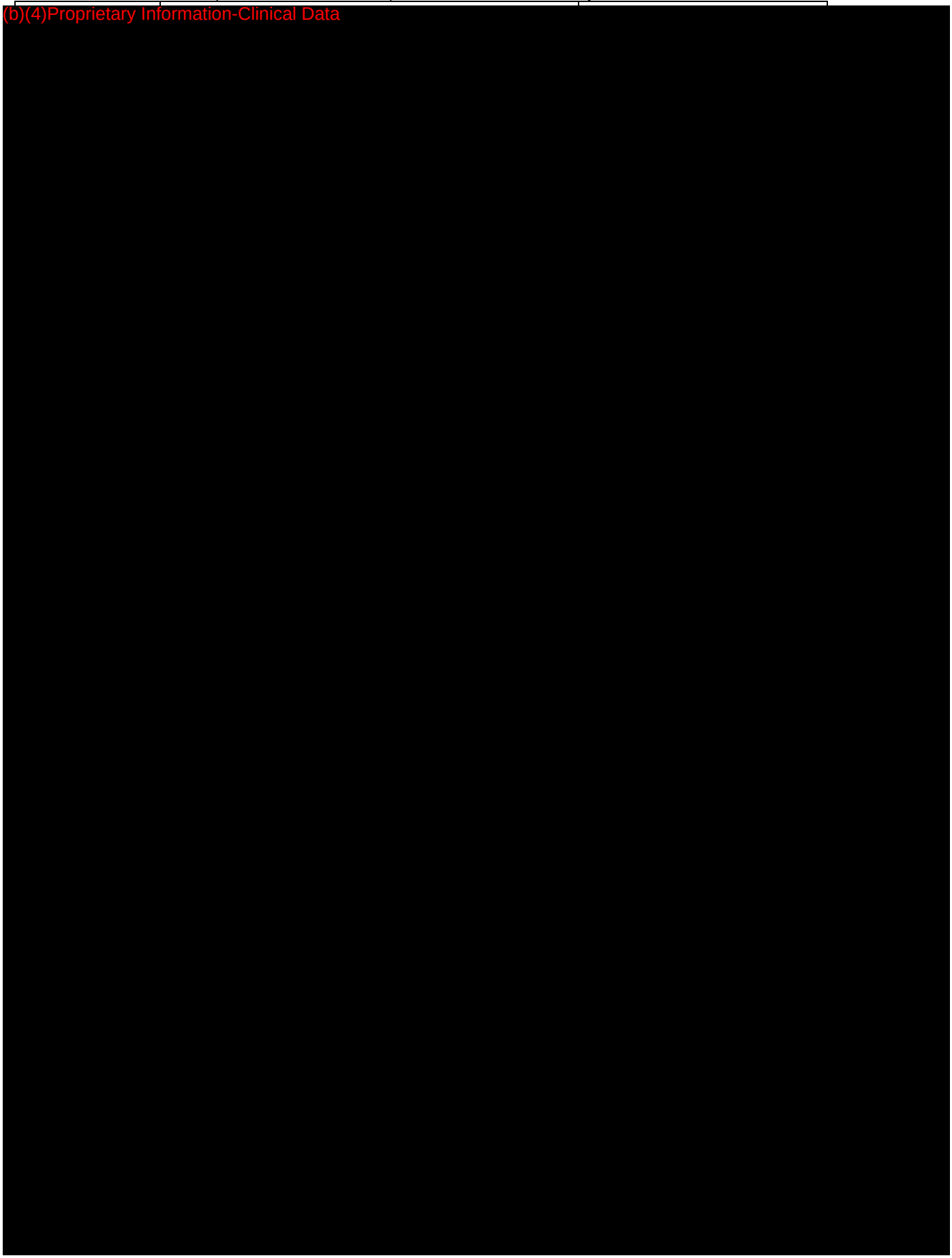
(b)(4)Proprietary Information-Clinical Data

[redacted]

(b)(4)Proprietary Information-Clinical Data

[redacted]

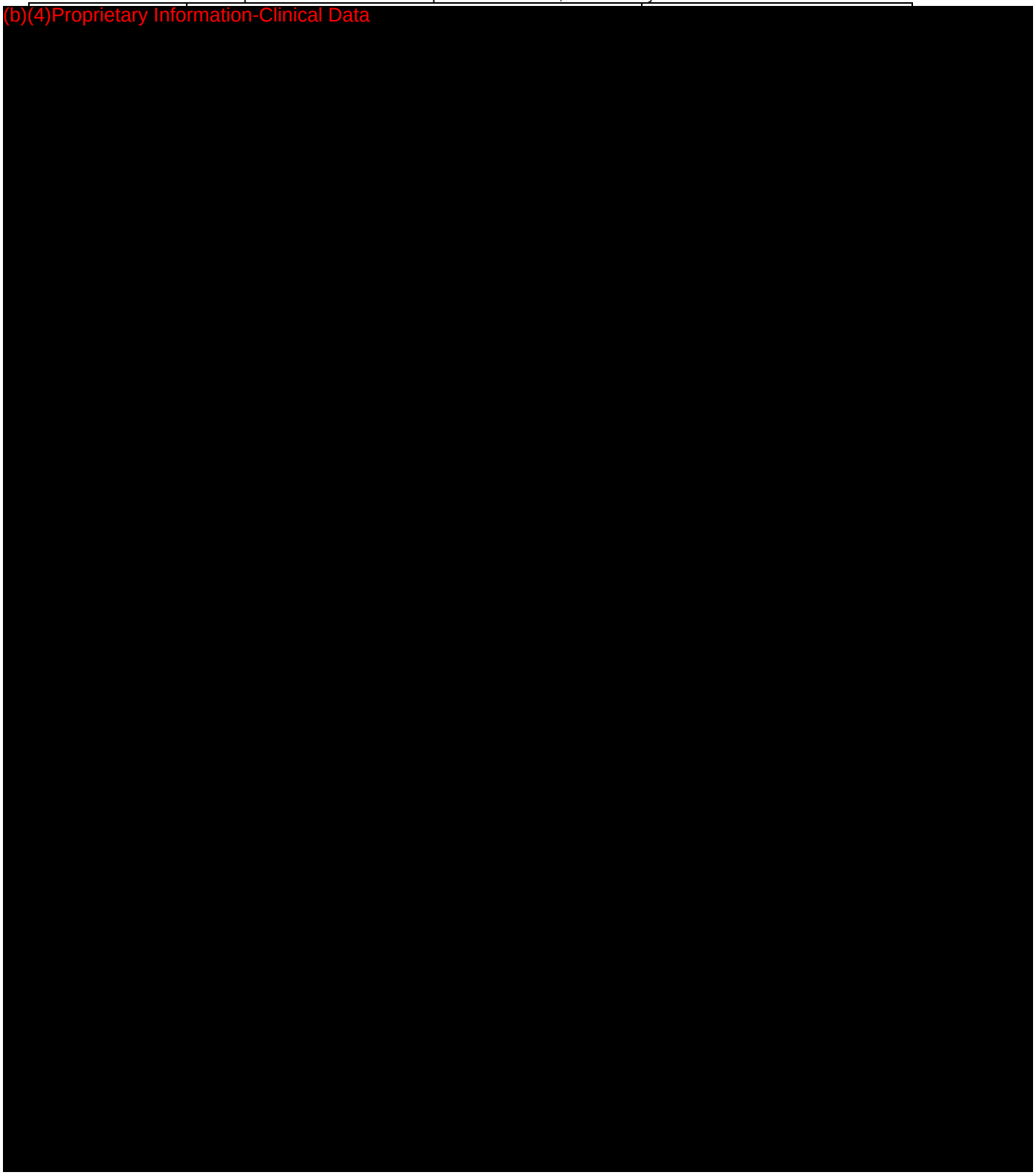
(b)(4)Proprietary Information-Clinical Data



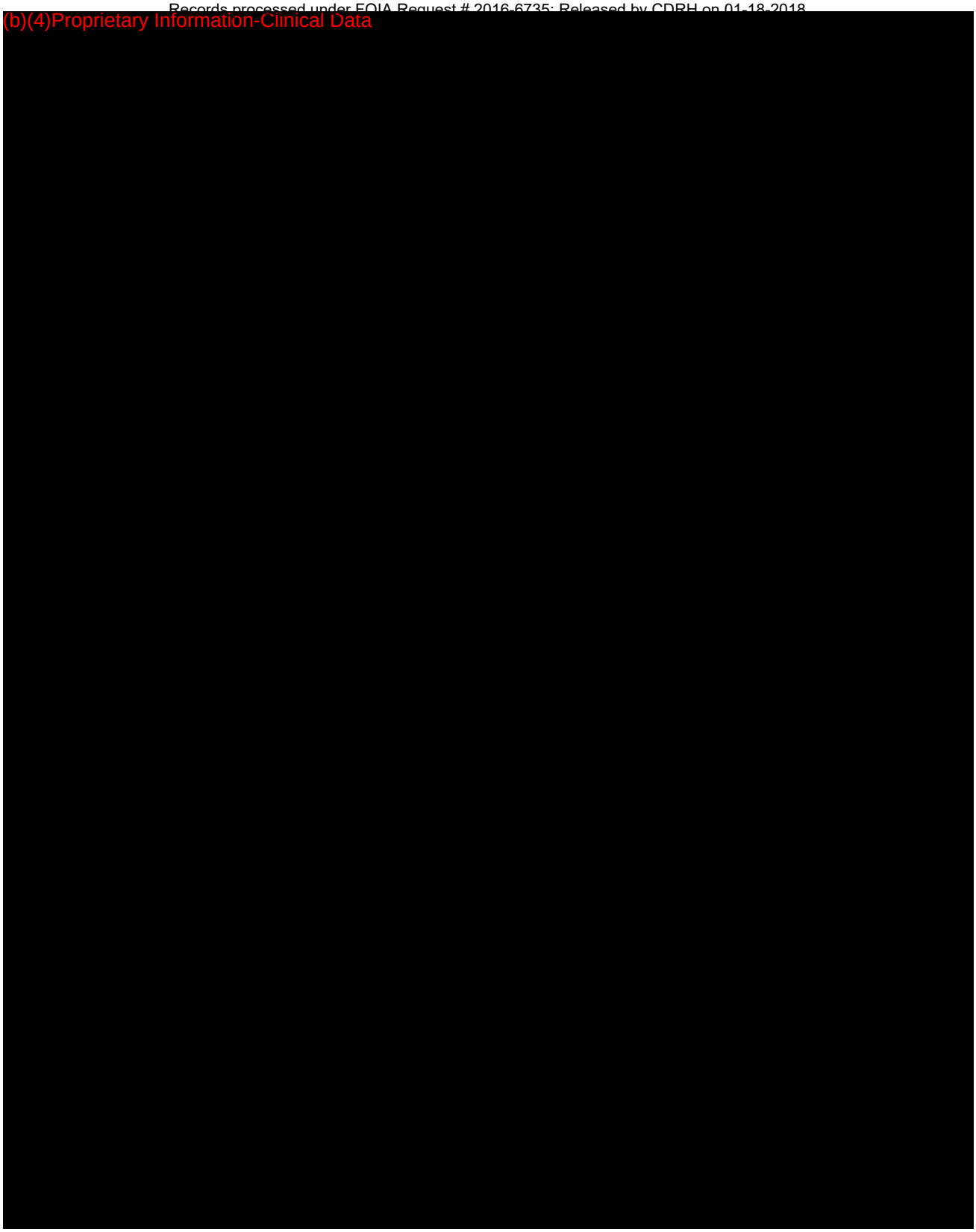
(b)(4)Proprietary Information-Clinical Data

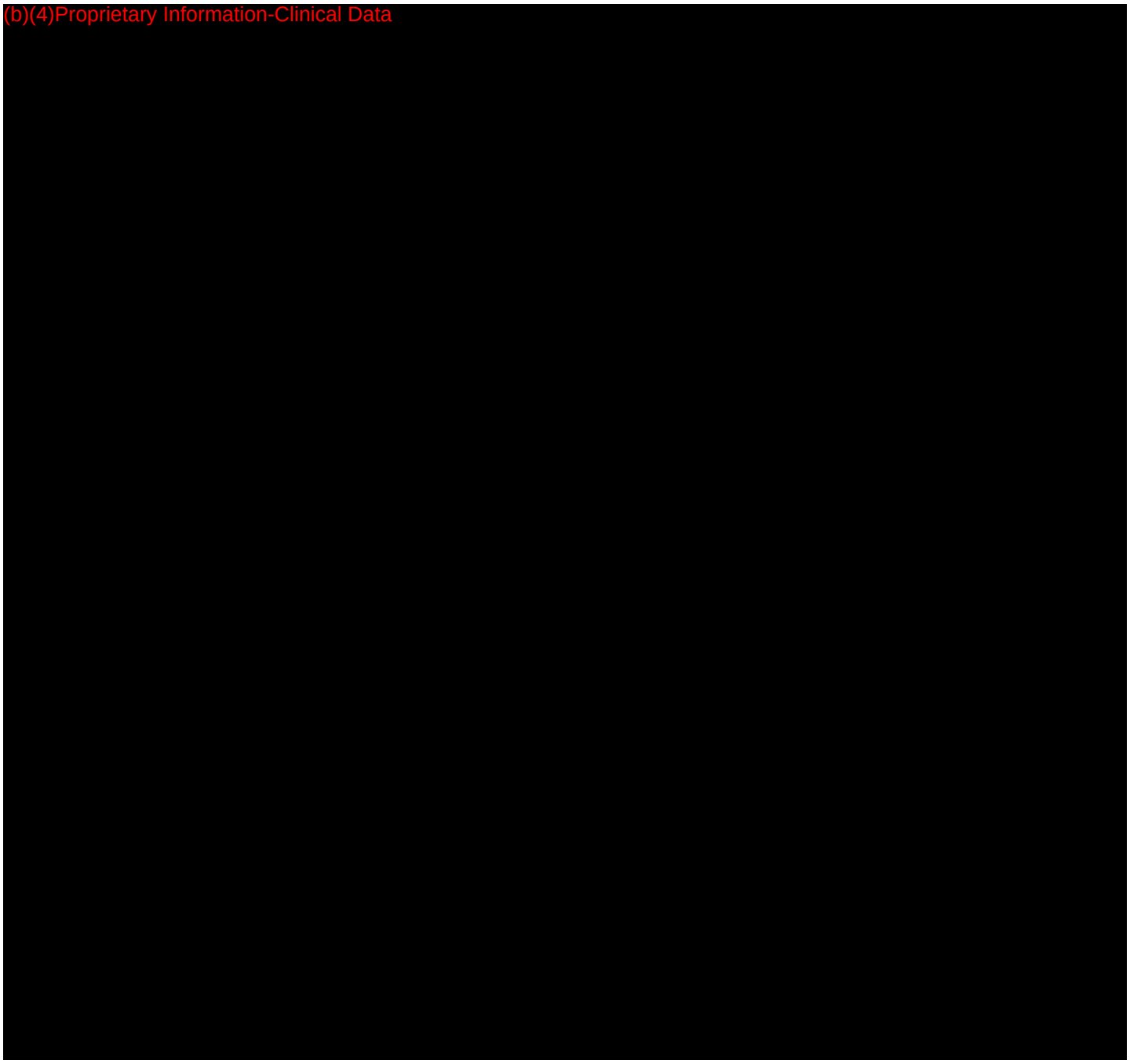
[redacted]

(b)(4)Proprietary Information-Clinical Data

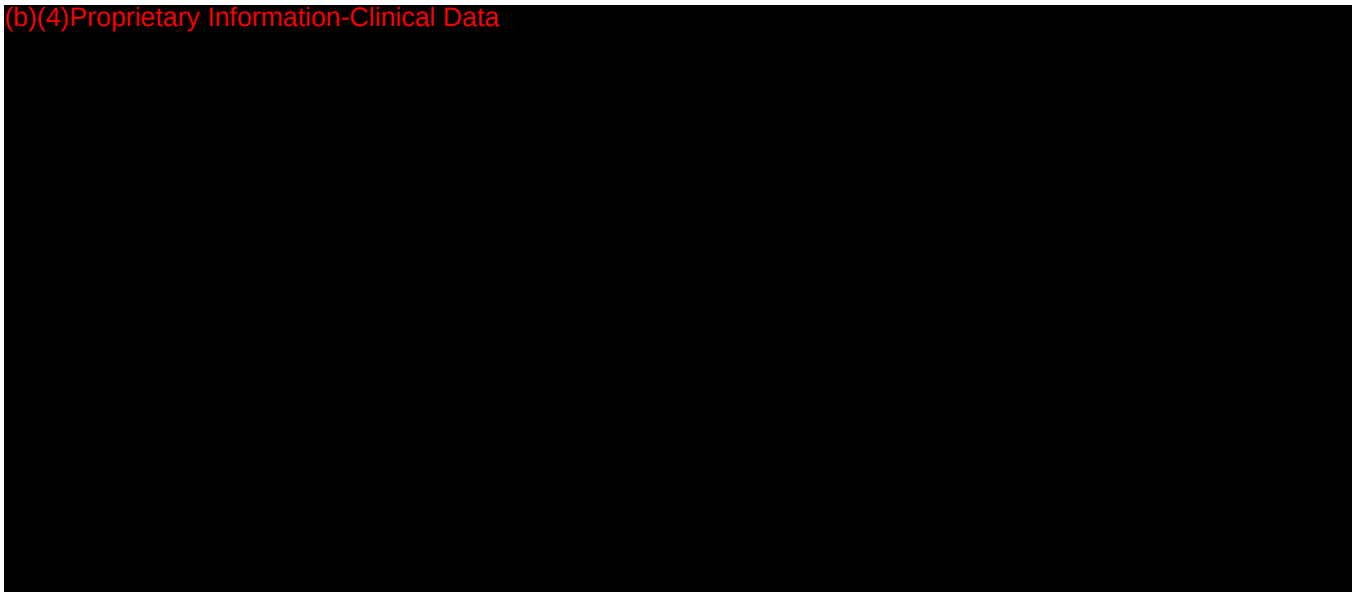


(b)(4)Proprietary Information-Clinical Data

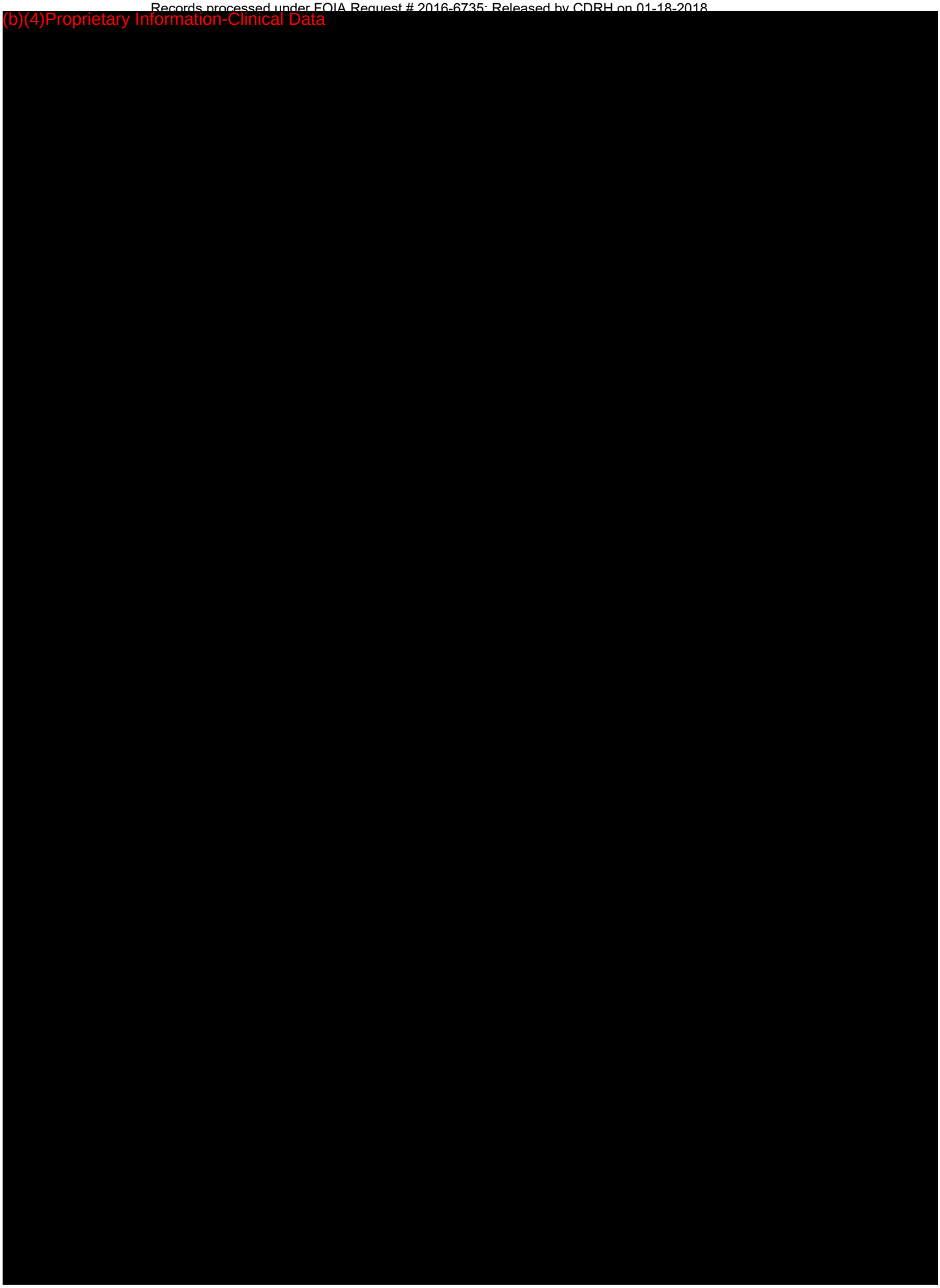




(b)(4)Proprietary Information-Clinical Data



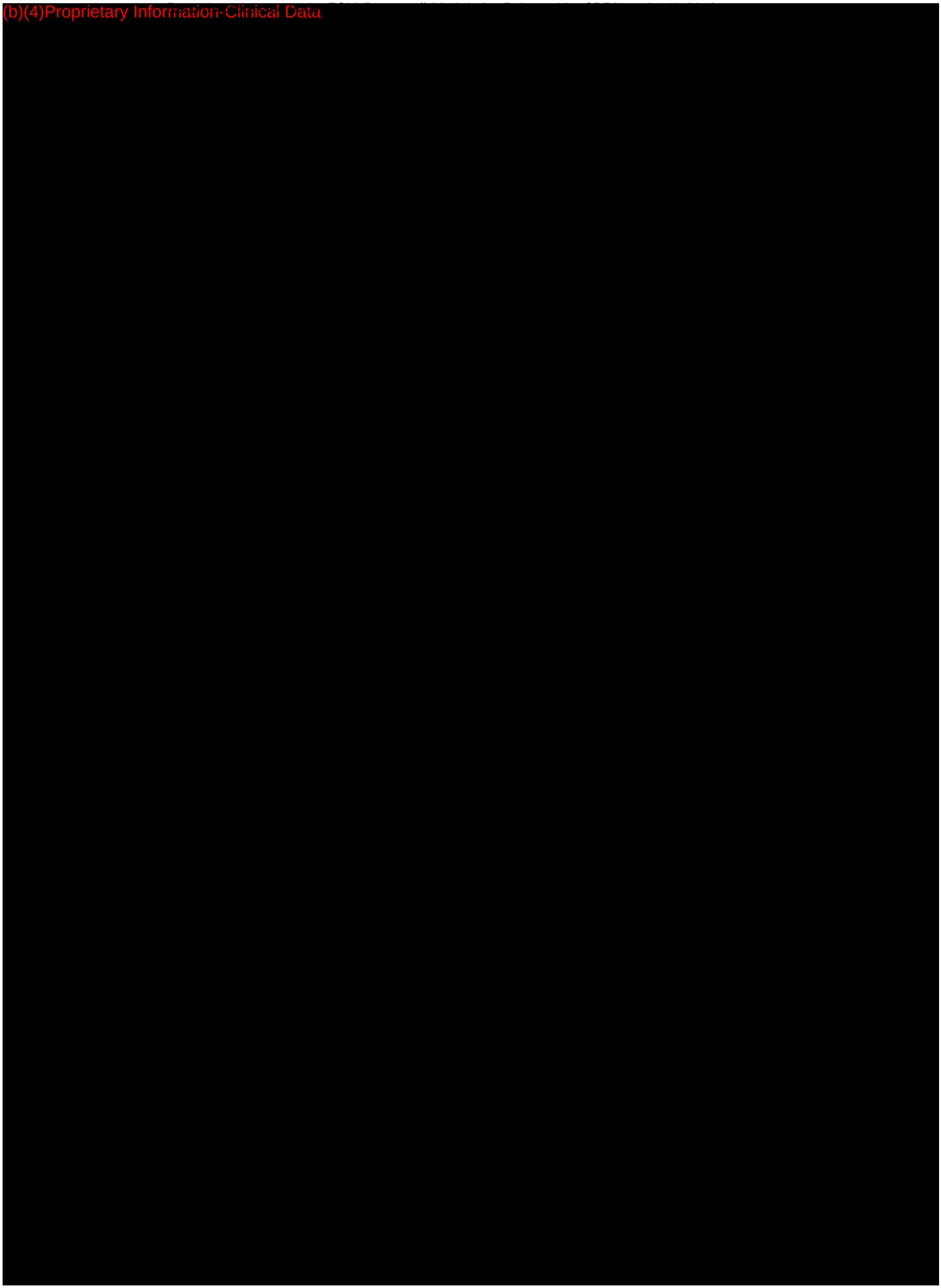
(b)(4)Proprietary Information-Clinical Data



(b)(4)Proprietary Information-Clinical Data

[redacted]

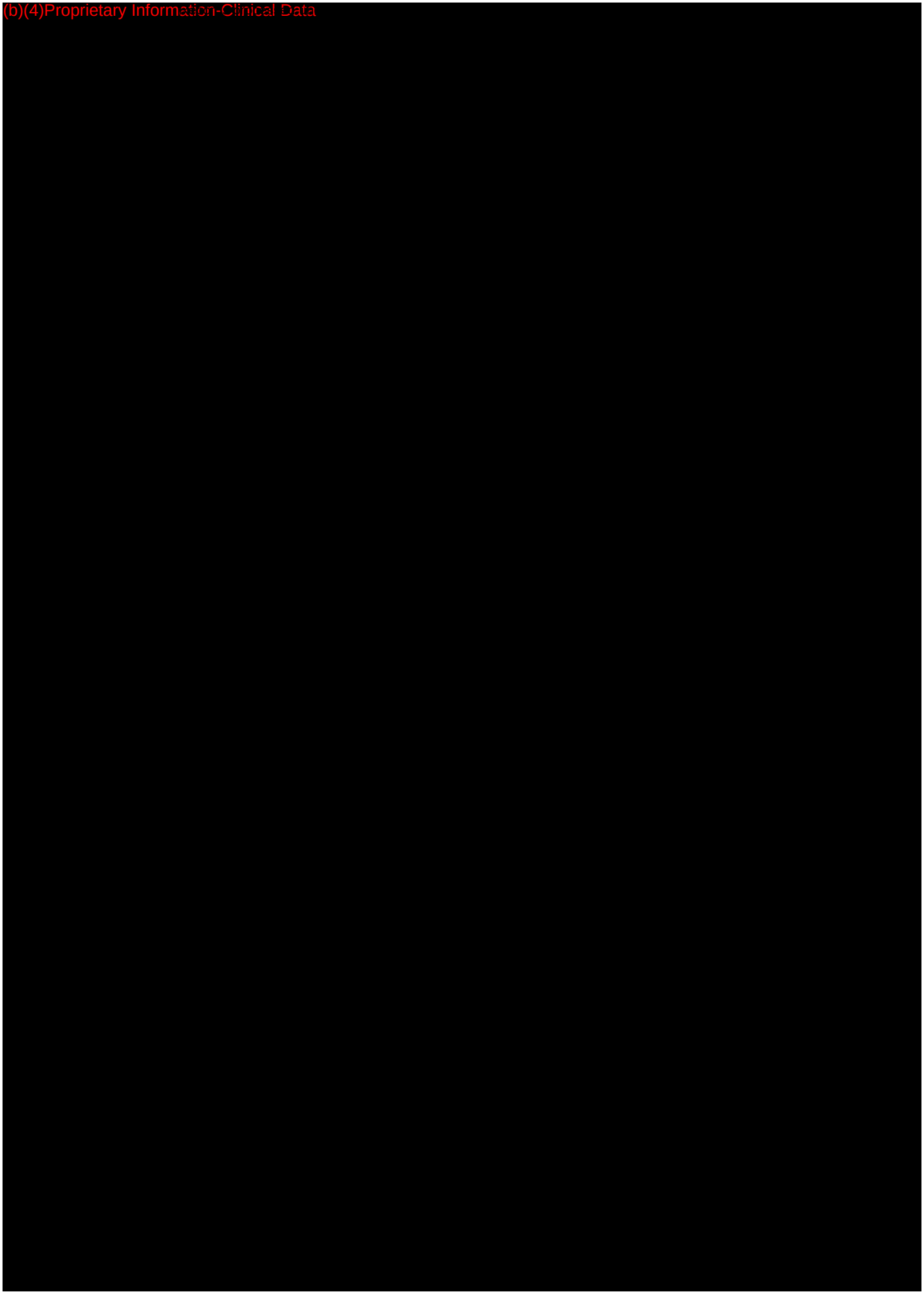
(b)(4)Proprietary Information-Clinical Data



(b)(4)Proprietary Information-Clinical Data

[redacted]

(b)(4)Proprietary Information-Clinical Data



(b)(4)Proprietary Information-Clinical Data

[redacted]

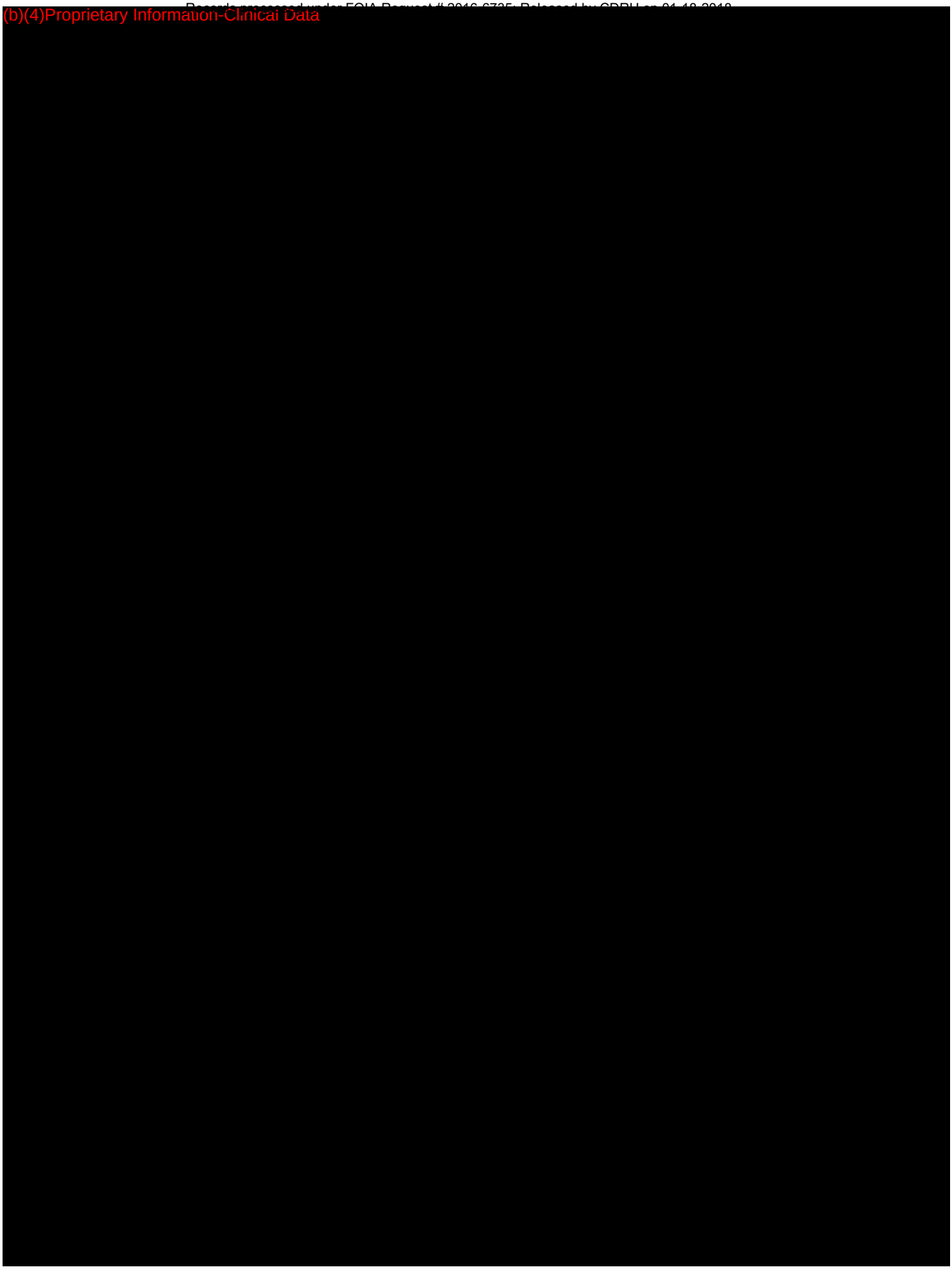
(b)(4)Proprietary Information-Clinical Data

[redacted]

(b)(4)Proprietary Information-Clinical Data

[redacted]

(b)(4)Proprietary Information-Clinical Data



(b)(4)Proprietary Information-Clinical Data

[redacted]

(b)(4)Proprietary Information-Clinical Data

[redacted]

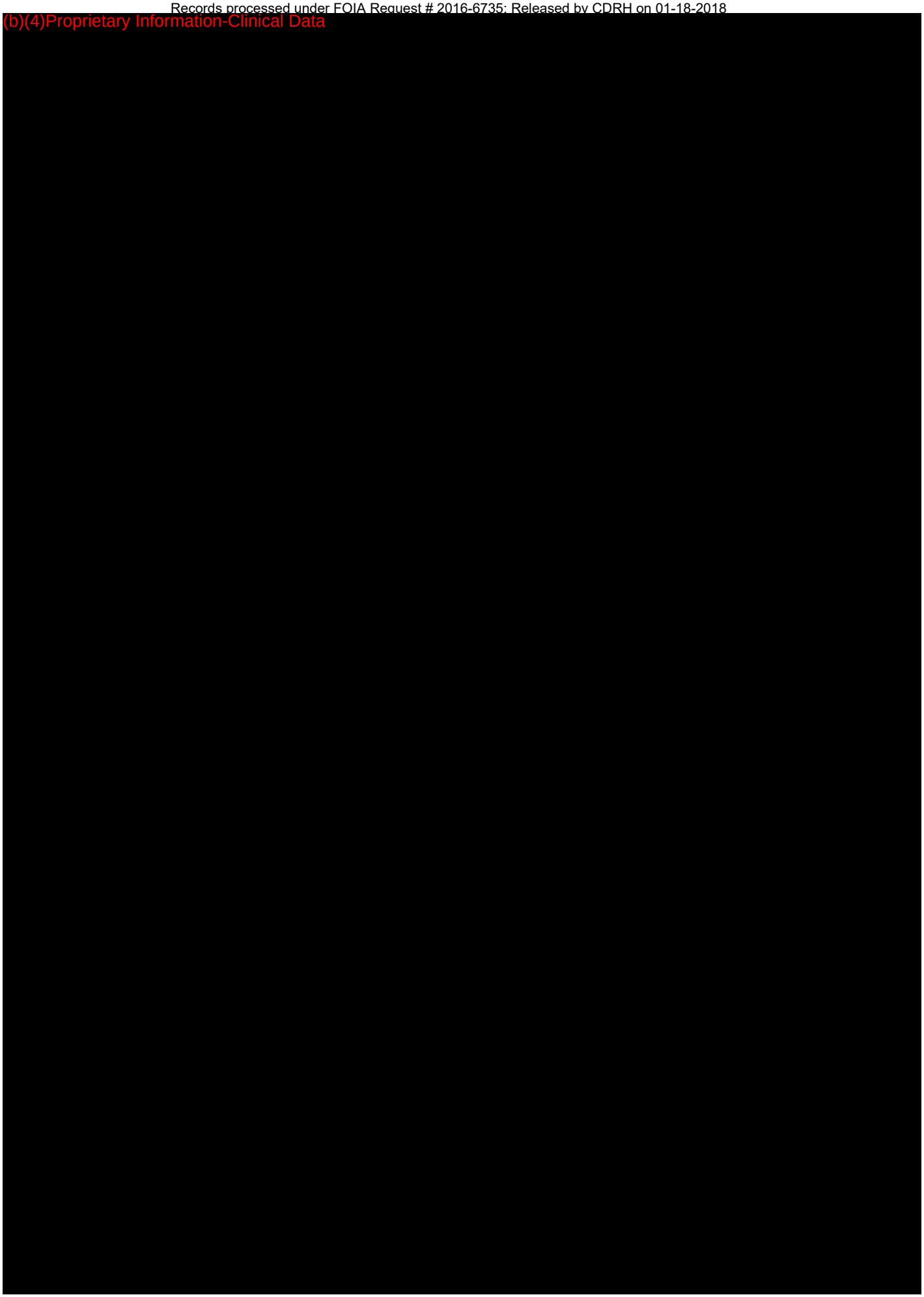
(b)(4)Proprietary Information-Clinical Data

[redacted]

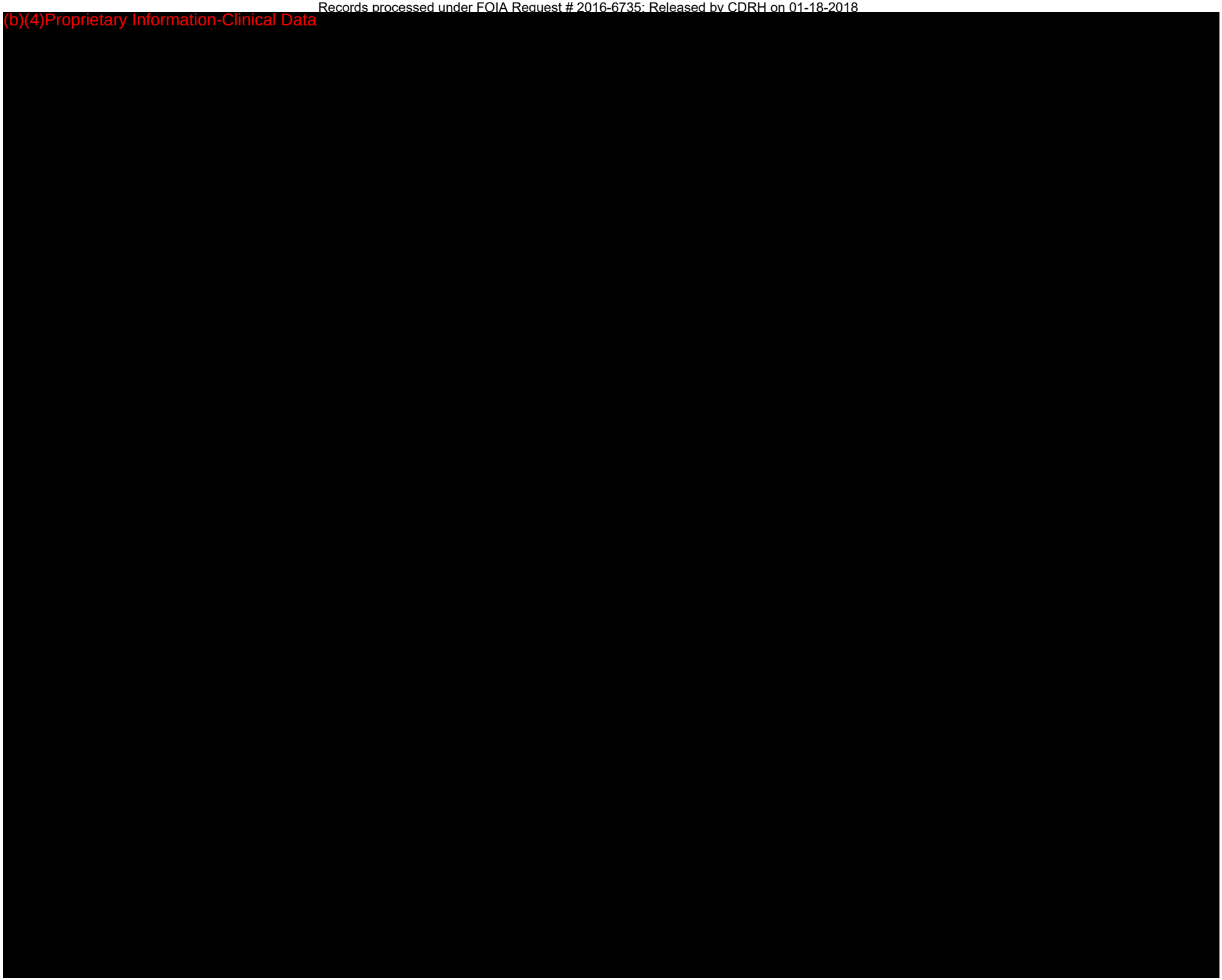
(b)(4)Proprietary Information-Clinical Data

[redacted]

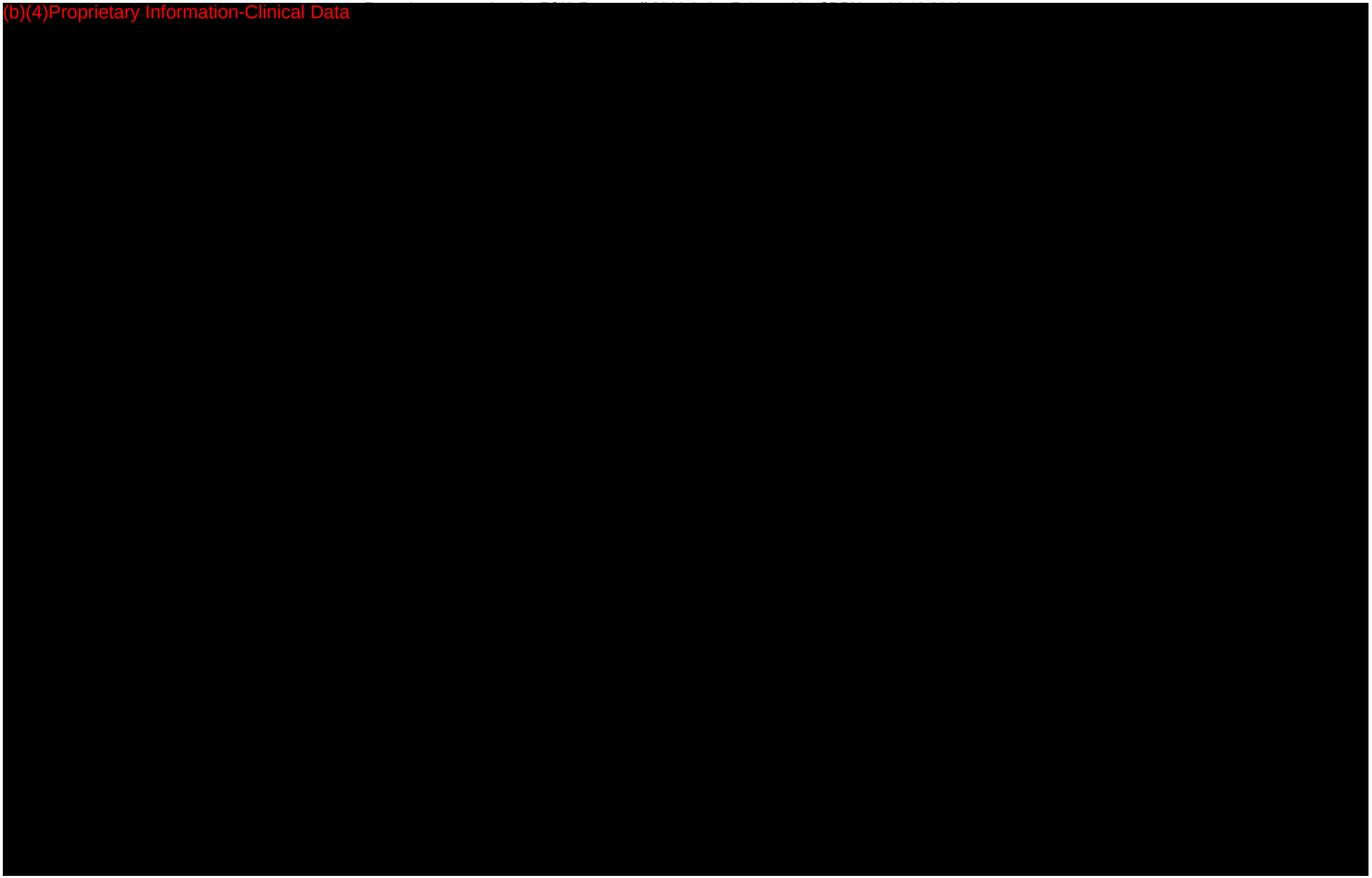
(b)(4)Proprietary Information-Clinical Data



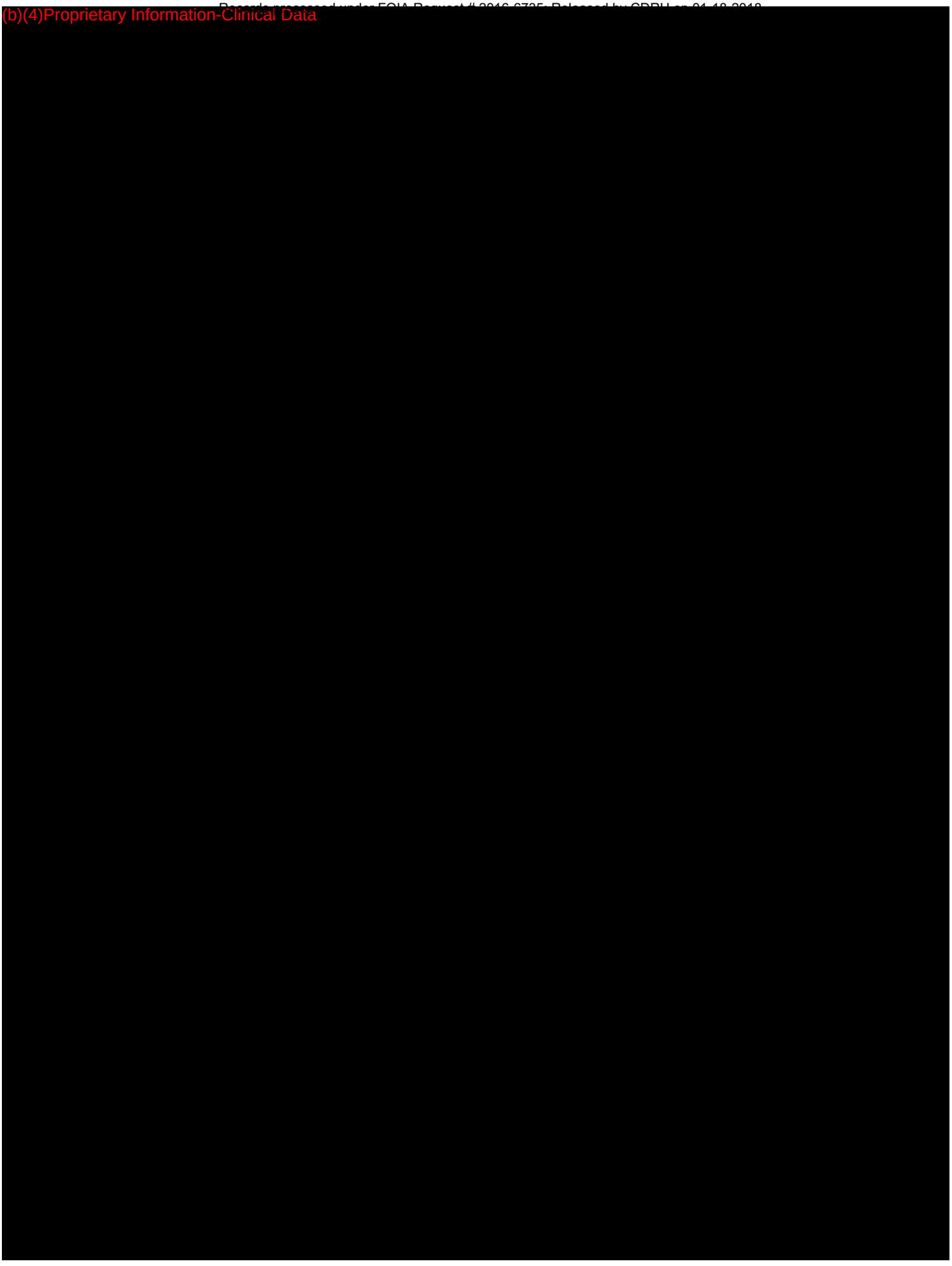
(b)(4)Proprietary Information-Clinical Data



(b)(4)Proprietary Information-Clinical Data



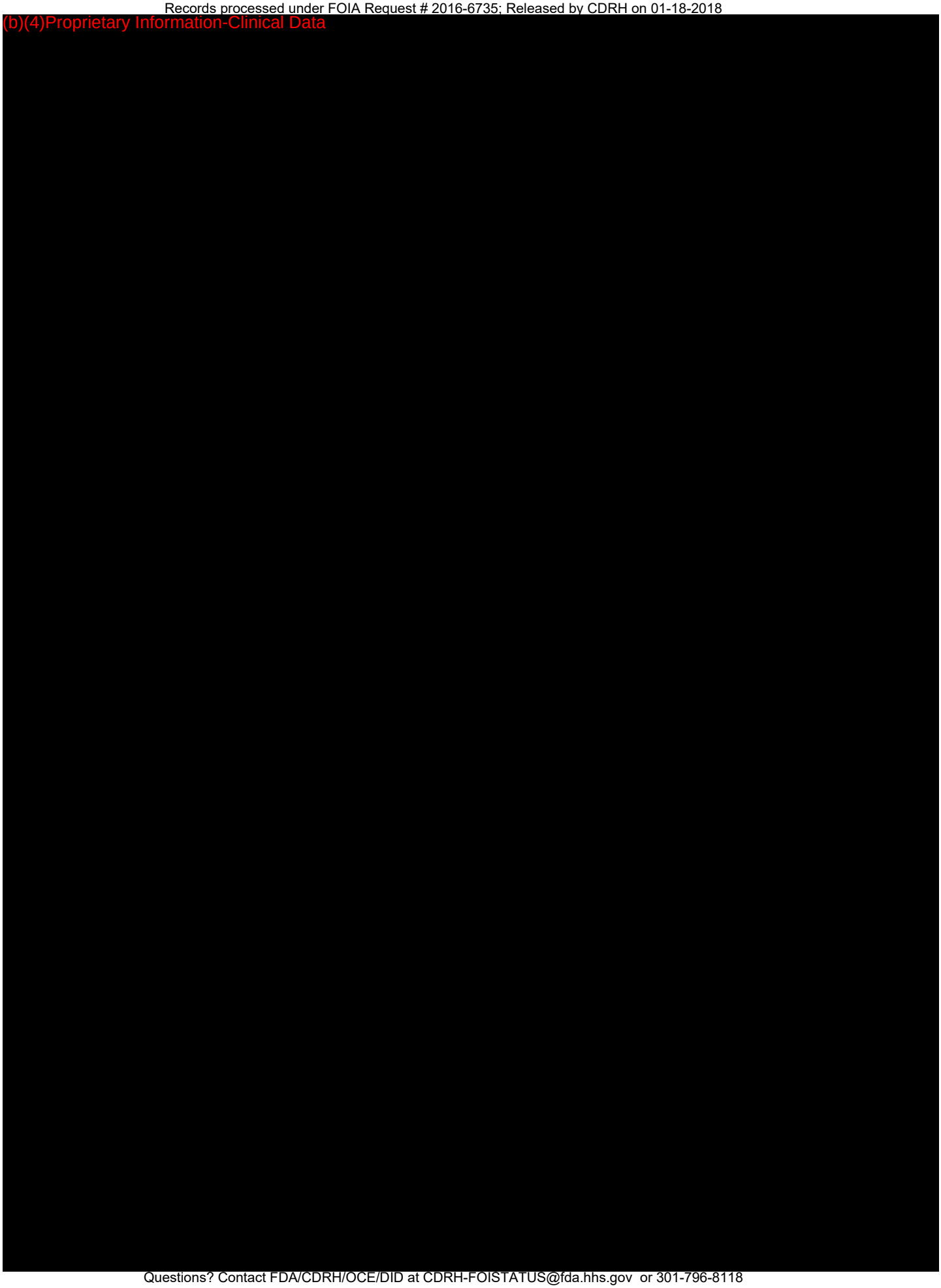
(b)(4)Proprietary Information-Clinical Data



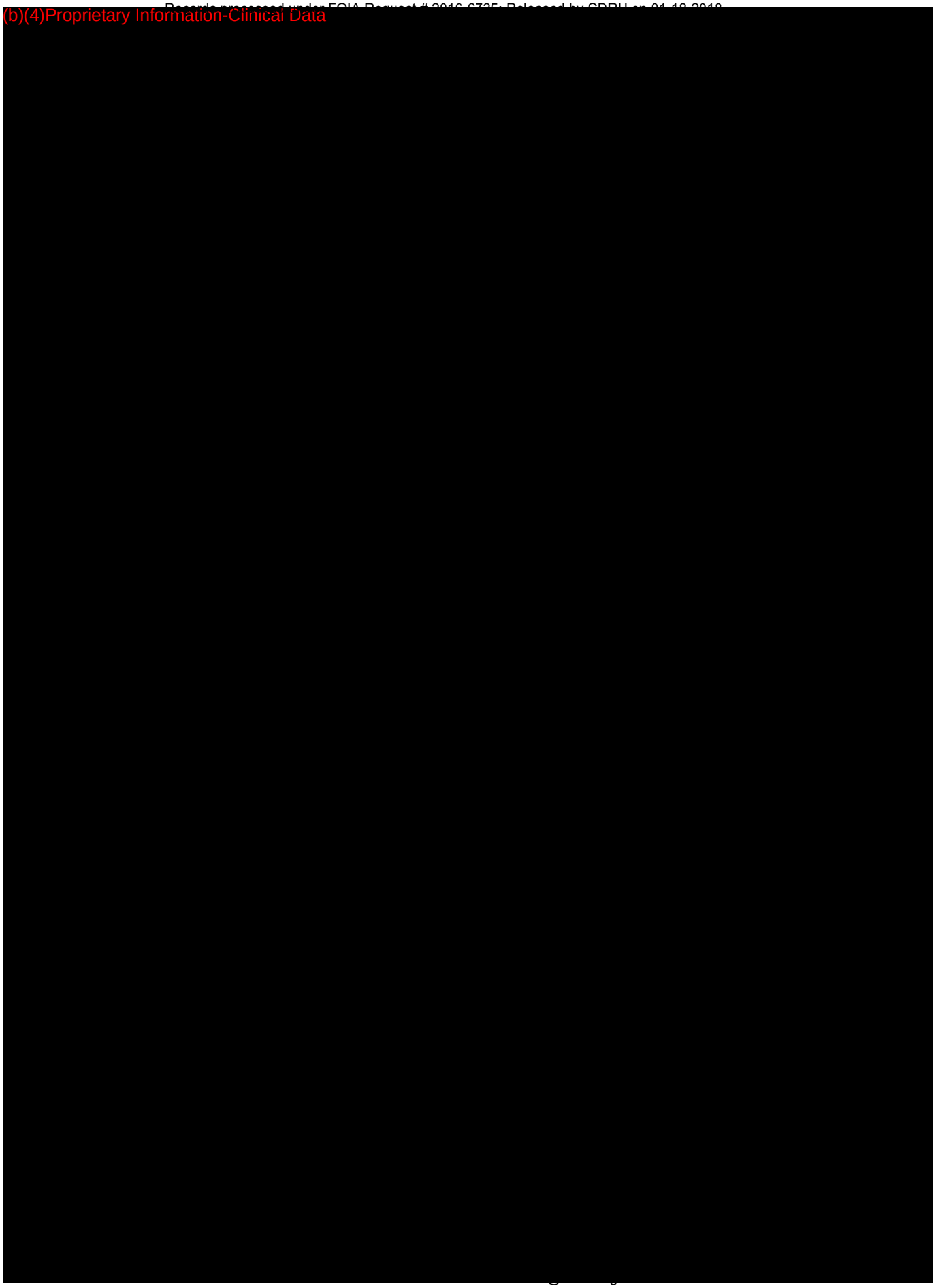
(b)(4)Proprietary Information-Ciinicai Data

[redacted]

(b)(4)Proprietary Information-Clinical Data



(b)(4)Proprietary Information-Clinical Data



(b)(4)Proprietary Information-Clinical Data

[redacted]

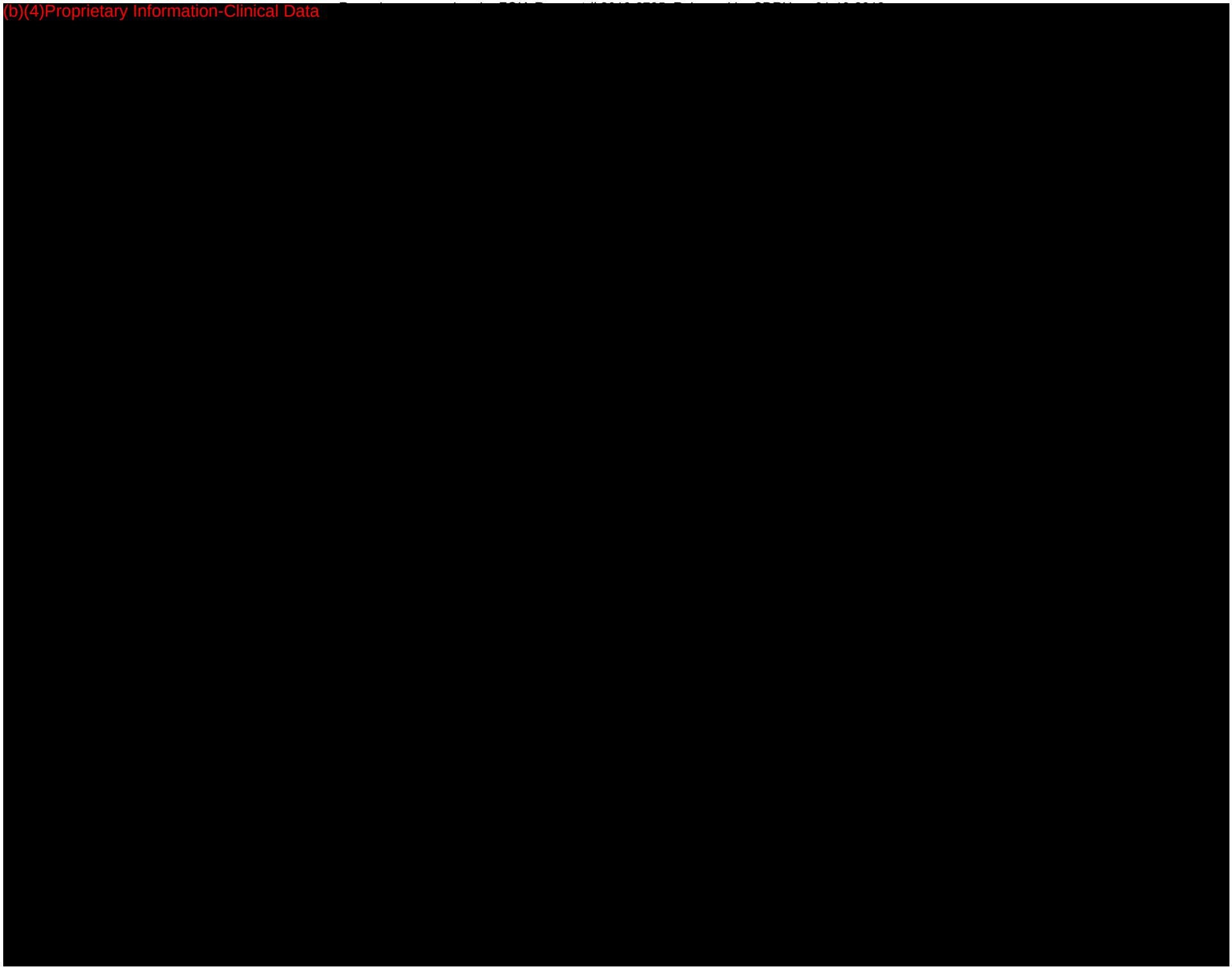
(b)(4)Proprietary Information-Clinical Data

[redacted]

(b)(4)Proprietary Information-Clinical Data

[redacted]

(b)(4)Proprietary Information-Clinical Data



(b)(4)Proprietary Information-Clinical Data

(b)(4)Proprietary Information-Clinical Data

[redacted]

(b)(4)Proprietary Information-Clinical Data

[redacted]

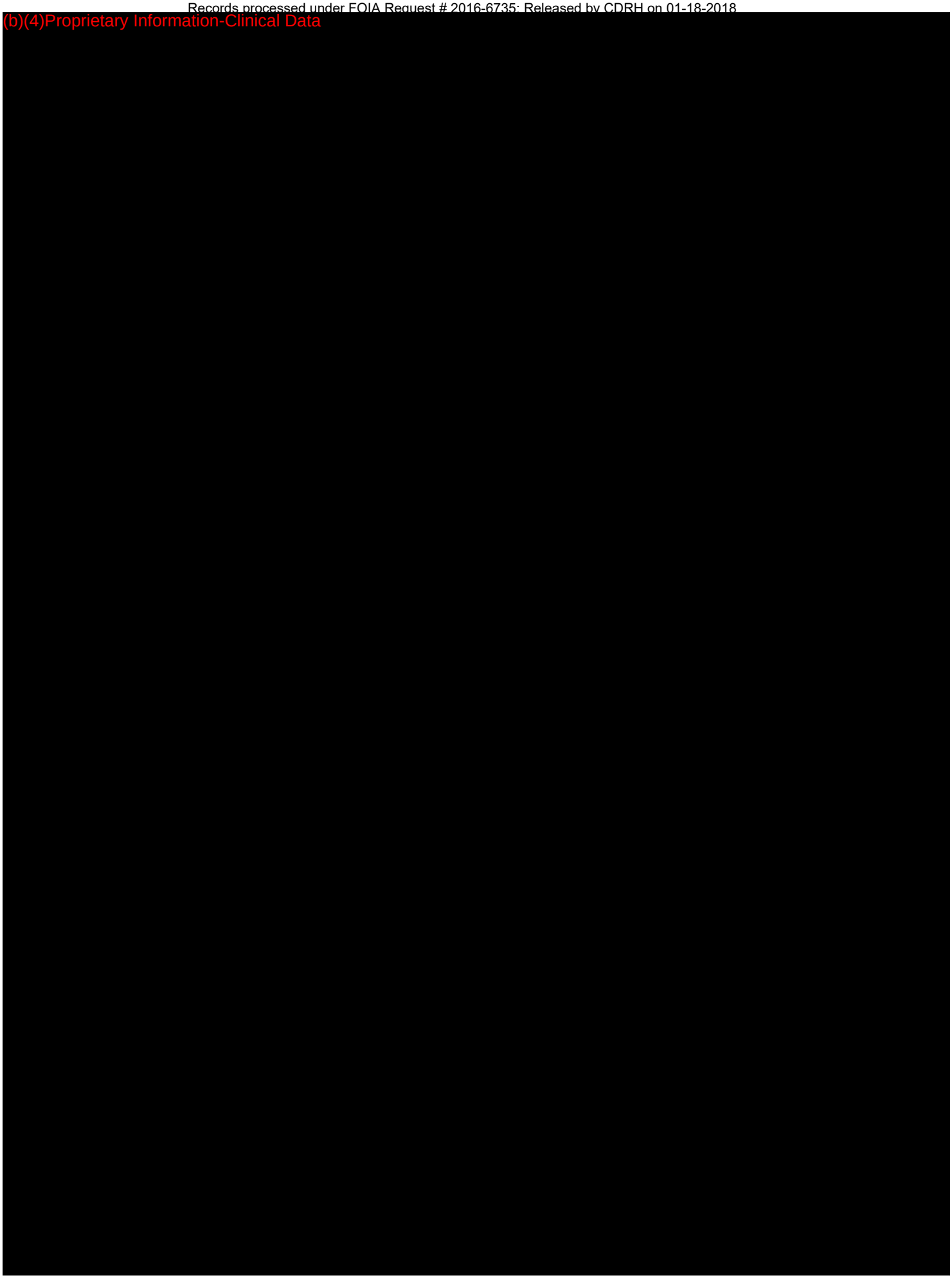
(b)(4)Proprietary Information-Clinical Data

[redacted]

(b)(4)Proprietary Information-Clinical Data

[redacted]

(b)(4)Proprietary Information-Clinical Data

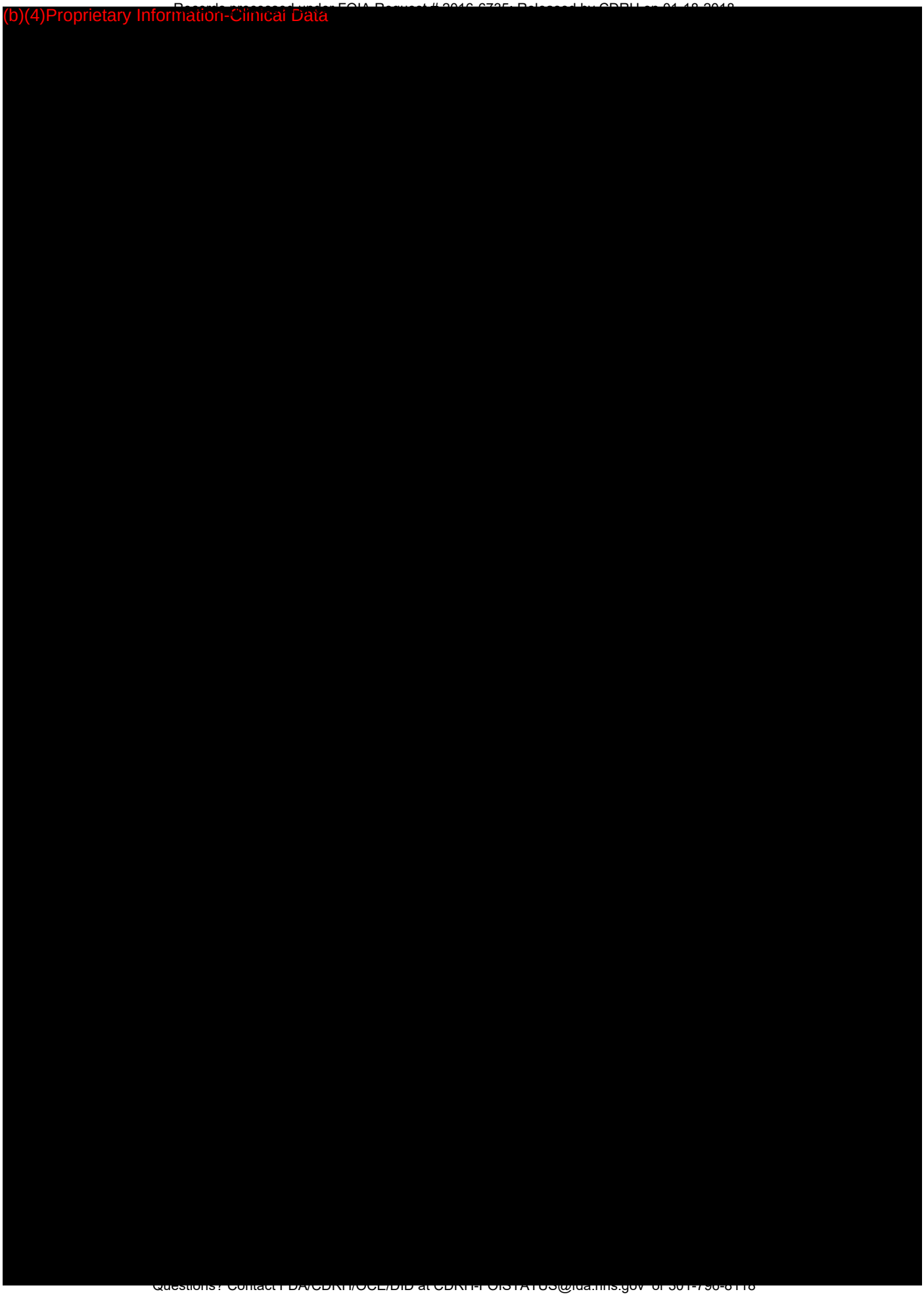


(b)(4)Proprietary Information-Clinical Data

(b)(4)Proprietary Information-Clinical Data

[redacted]

(b)(4)Proprietary Information-Clinical Data

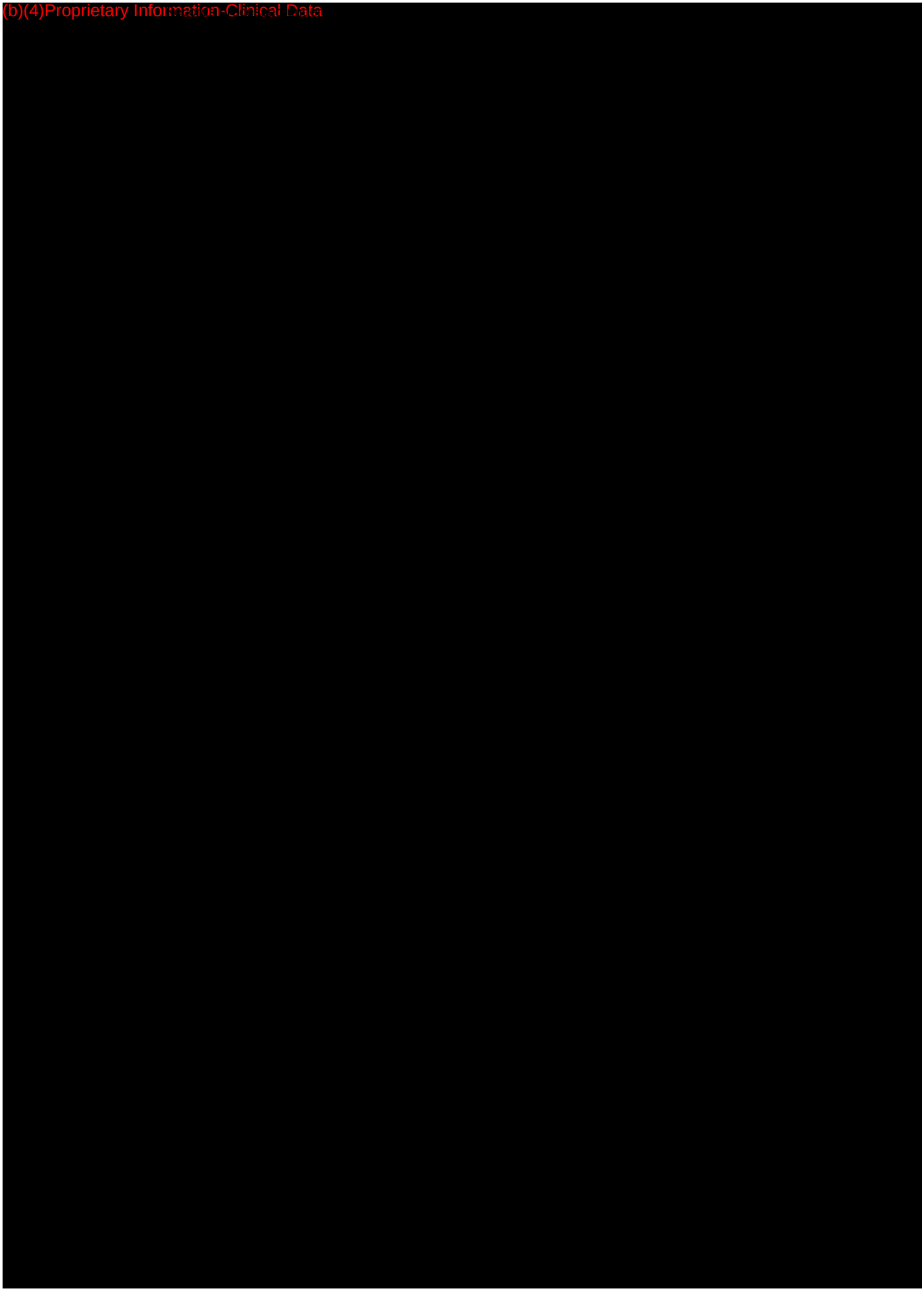


(b)(4)Proprietary Information-Clinical Data

(b)(4)Proprietary Information-Clinical Data

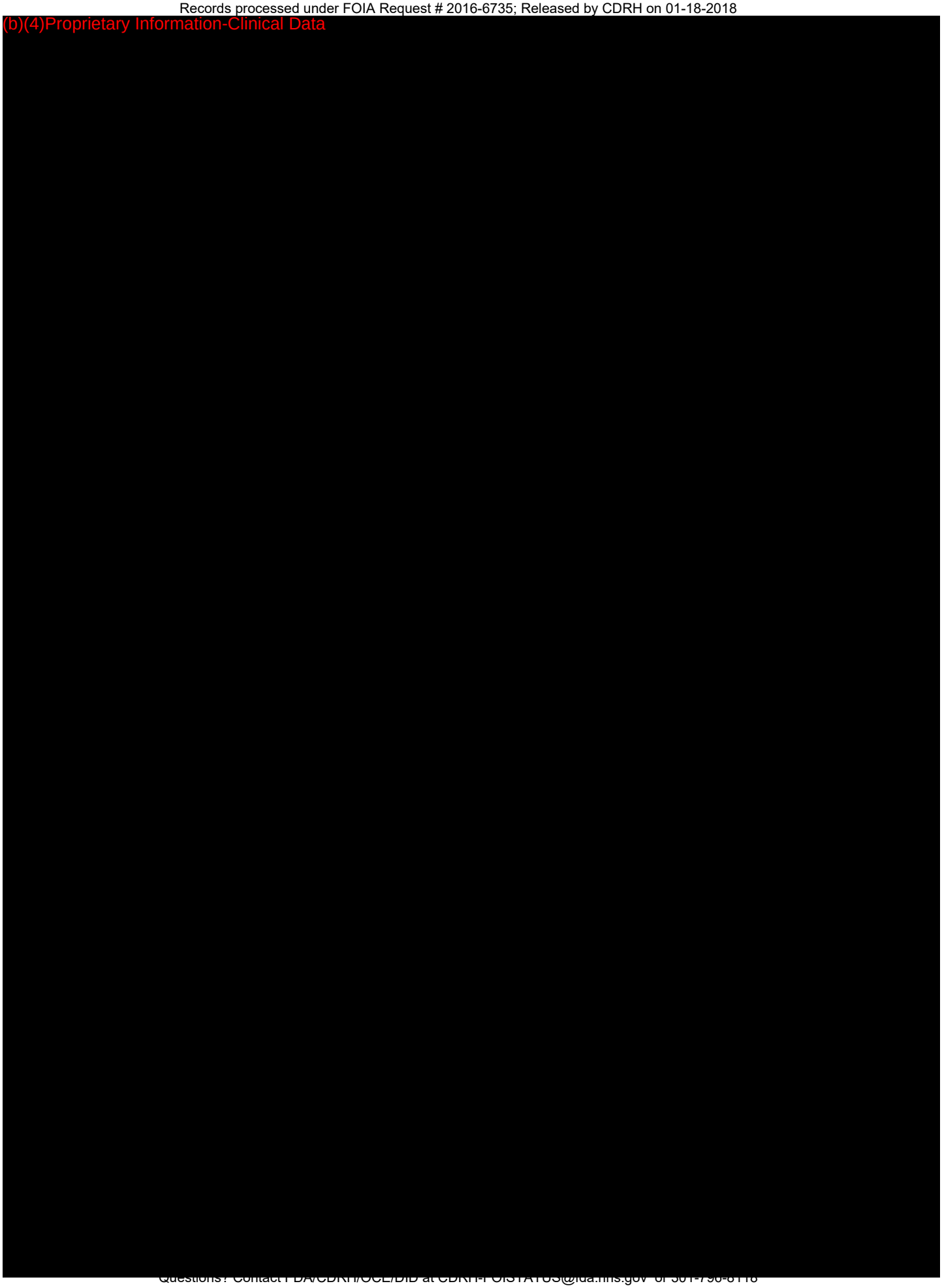
(b)(4)Proprietary Information-Clinical Data

[redacted]


(b)(4)Proprietary Information-Clinical Data

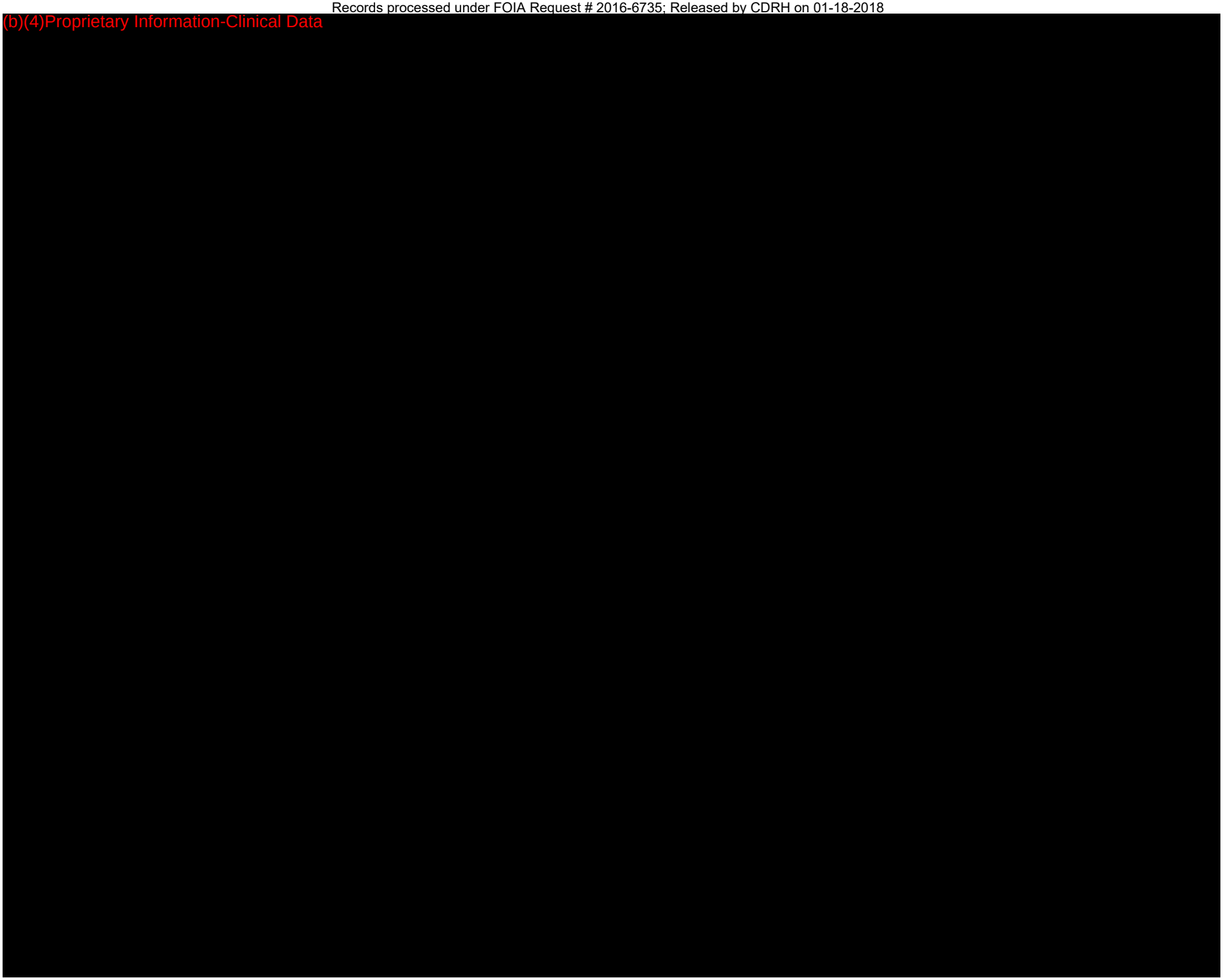
(b)(4)Proprietary Information-Clinical Data

[redacted]

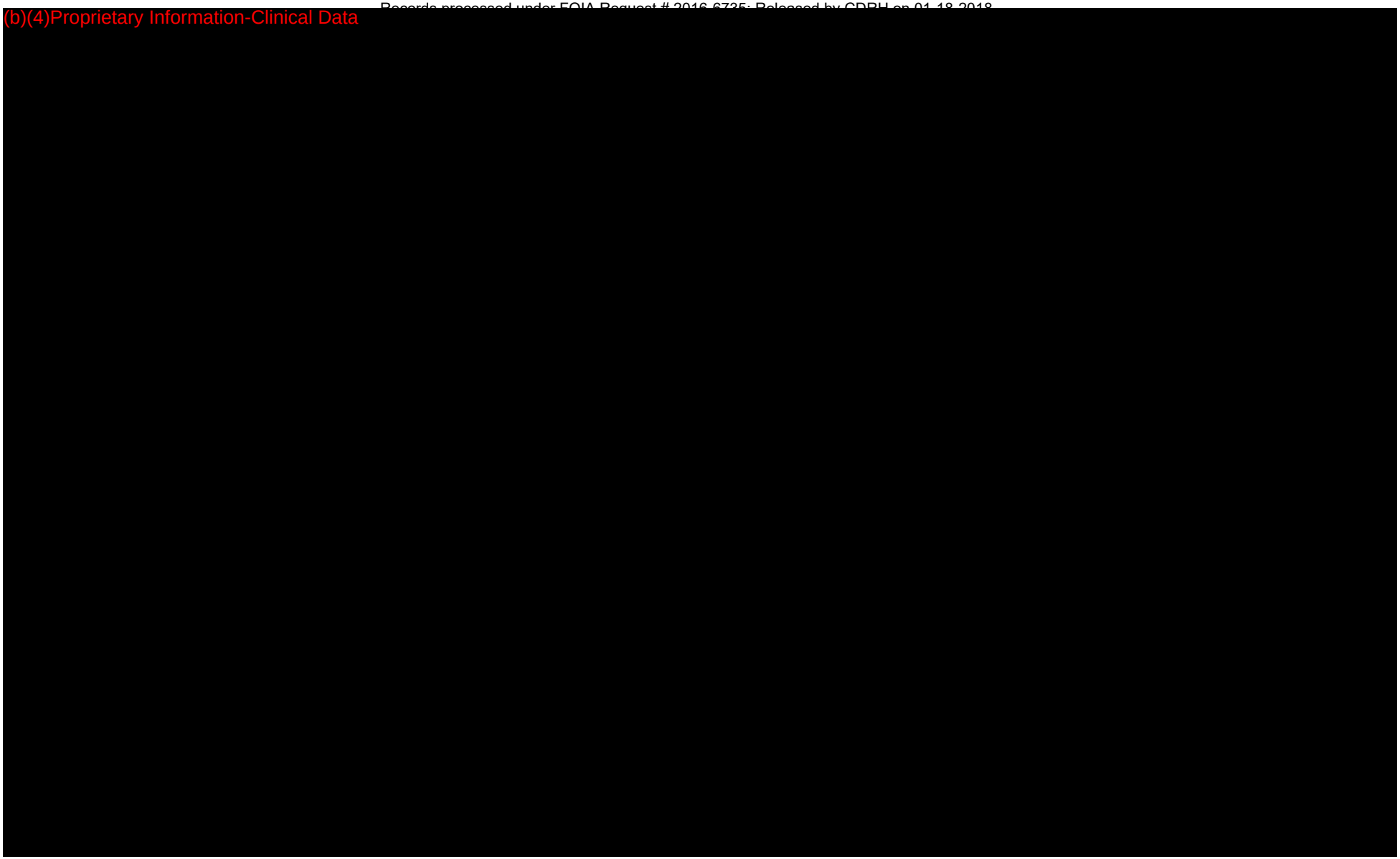
(b)(4)Proprietary Information-Clinical Data


(b)(4)Proprietary Information-Clinical Data

(b)(4)Proprietary Information-Clinical Data



(b)(4)Proprietary Information-Clinical Data



(b)(4)Proprietary Information-Clinical Data

[redacted]

(b)(4)Proprietary Information-Clinical Data

(b)(4)Proprietary Information-Clinical Data

[redacted]

(b)(4)Proprietary Information-Clinical Data

(b)(4)Proprietary Information-Clinical Data

[redacted]

(b)(4)Proprietary Information-Clinical Data

[redacted]

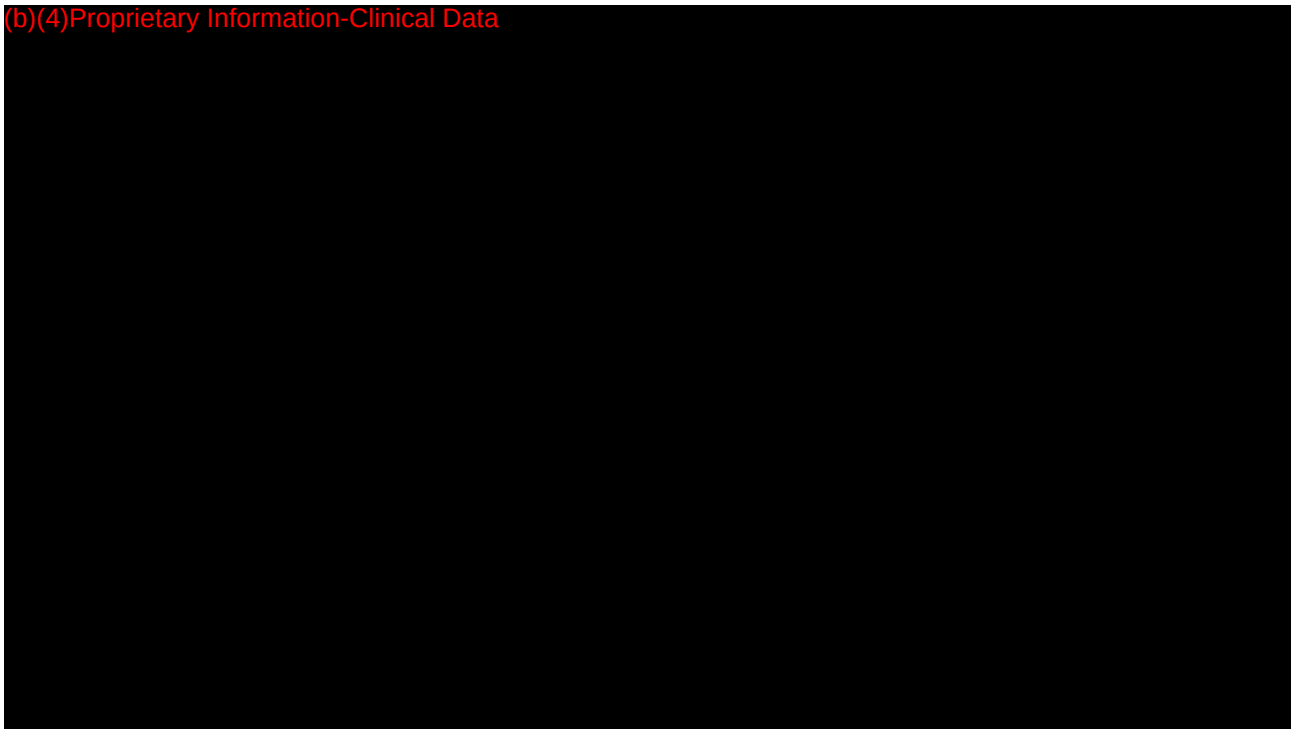
(b)(4)Proprietary Information-Clinical Data

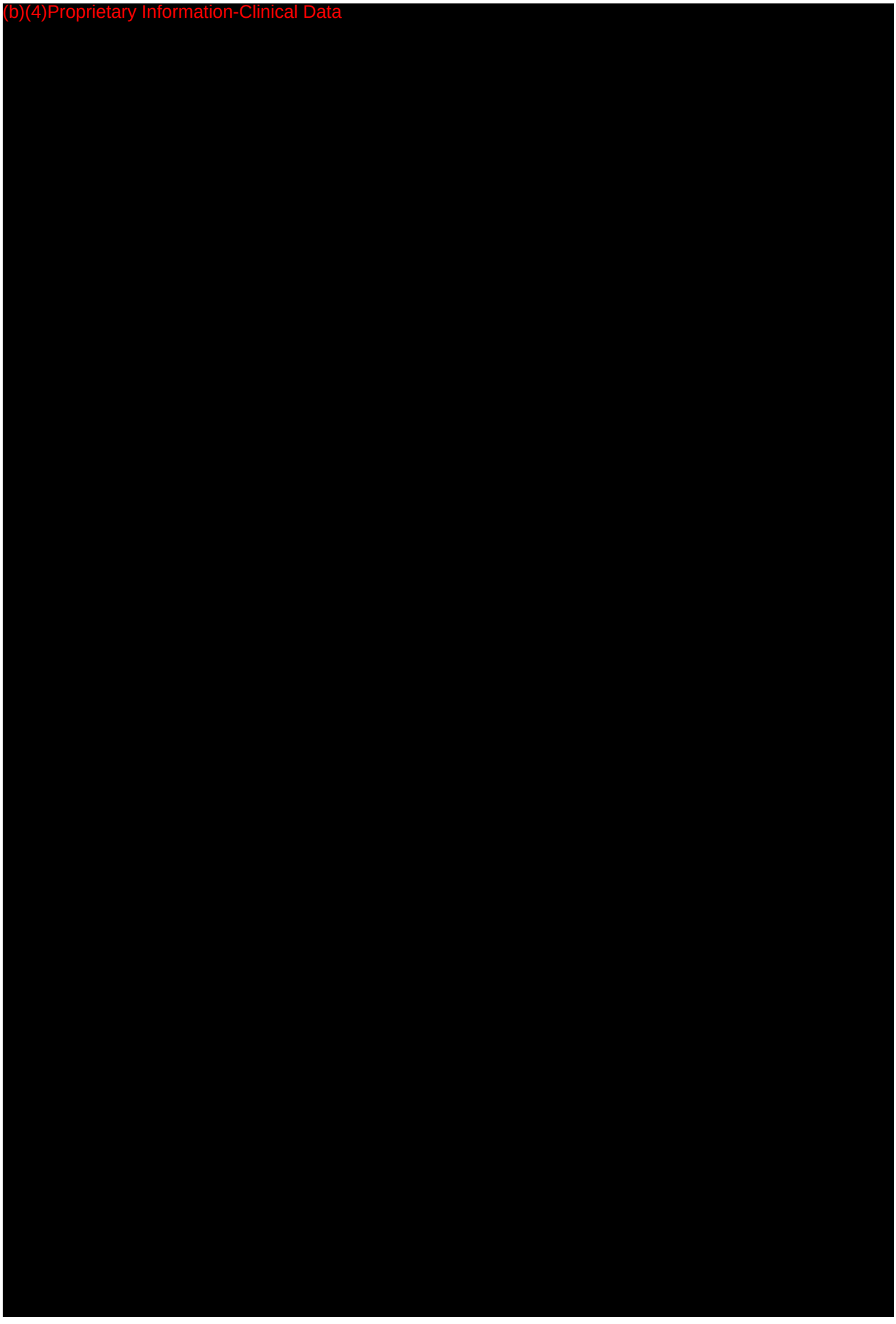
[redacted]

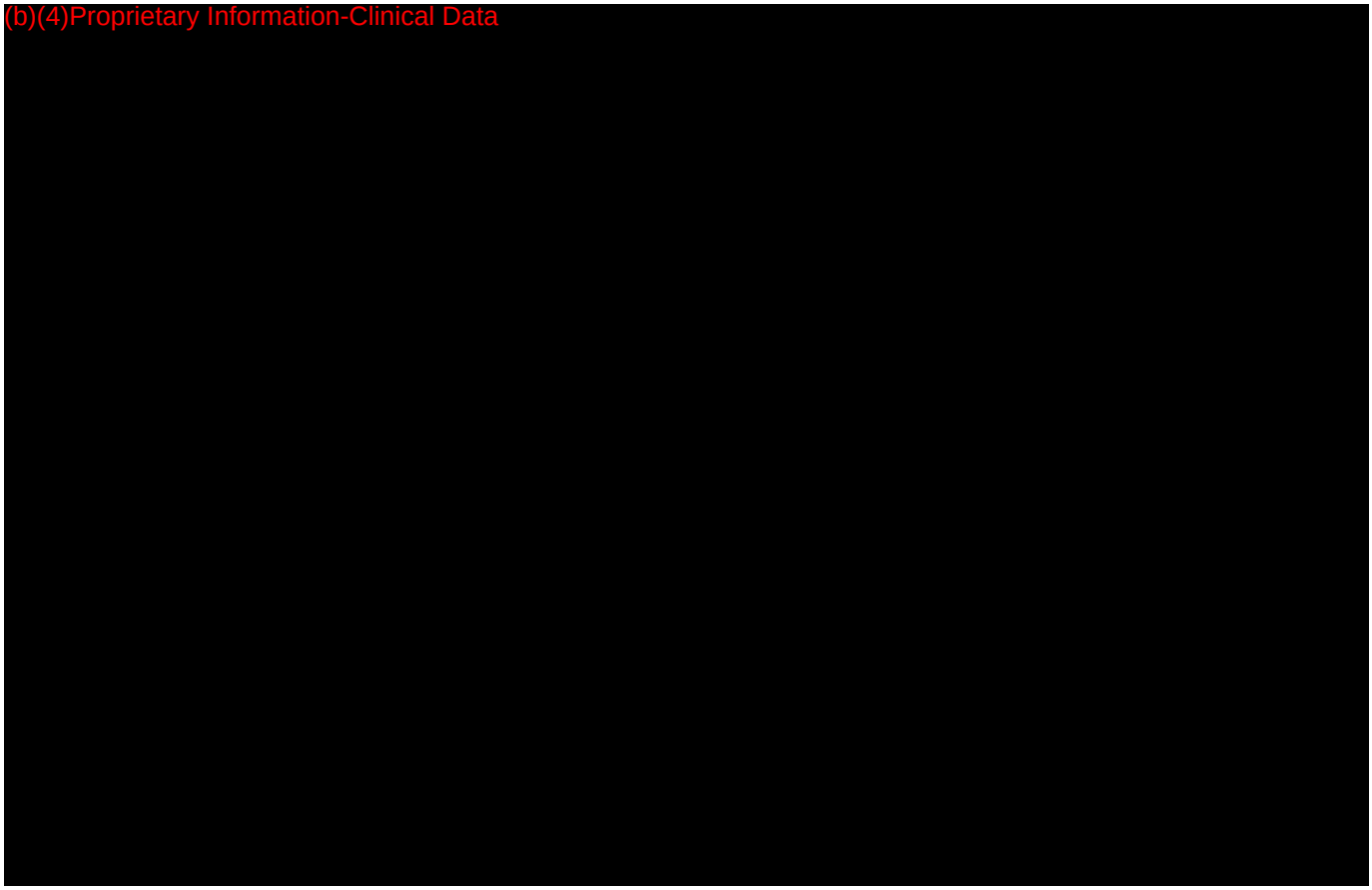
(b)(4)Proprietary Information-Clinical Data

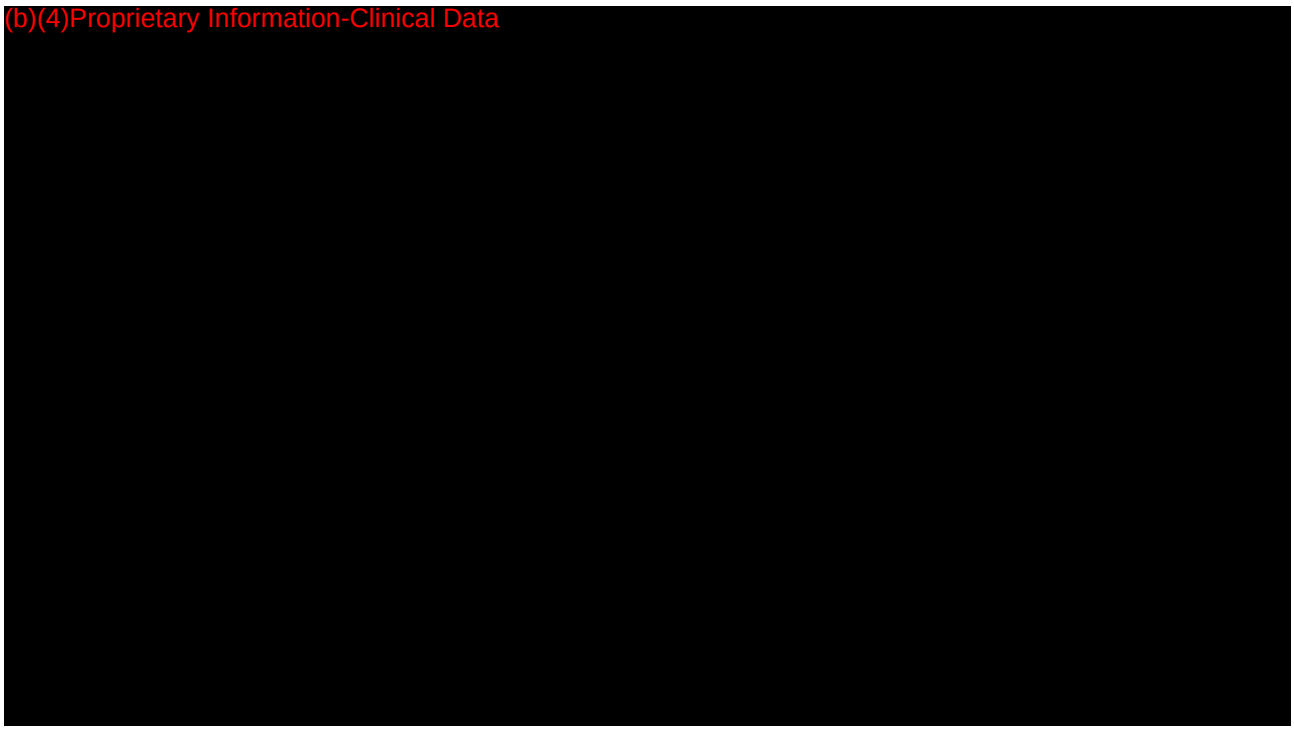
(b)(4)Proprietary Information-Clinical Data

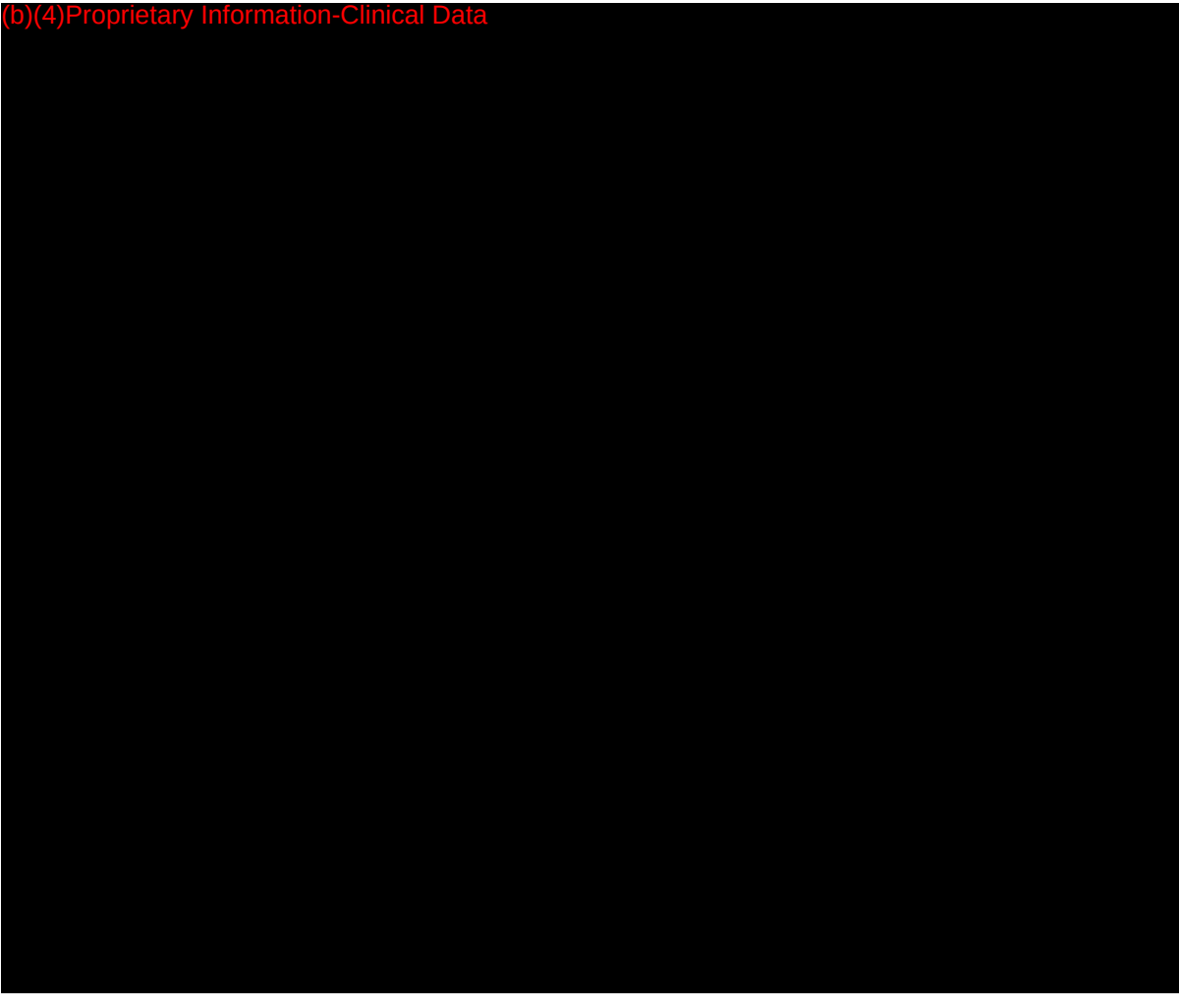
[redacted]



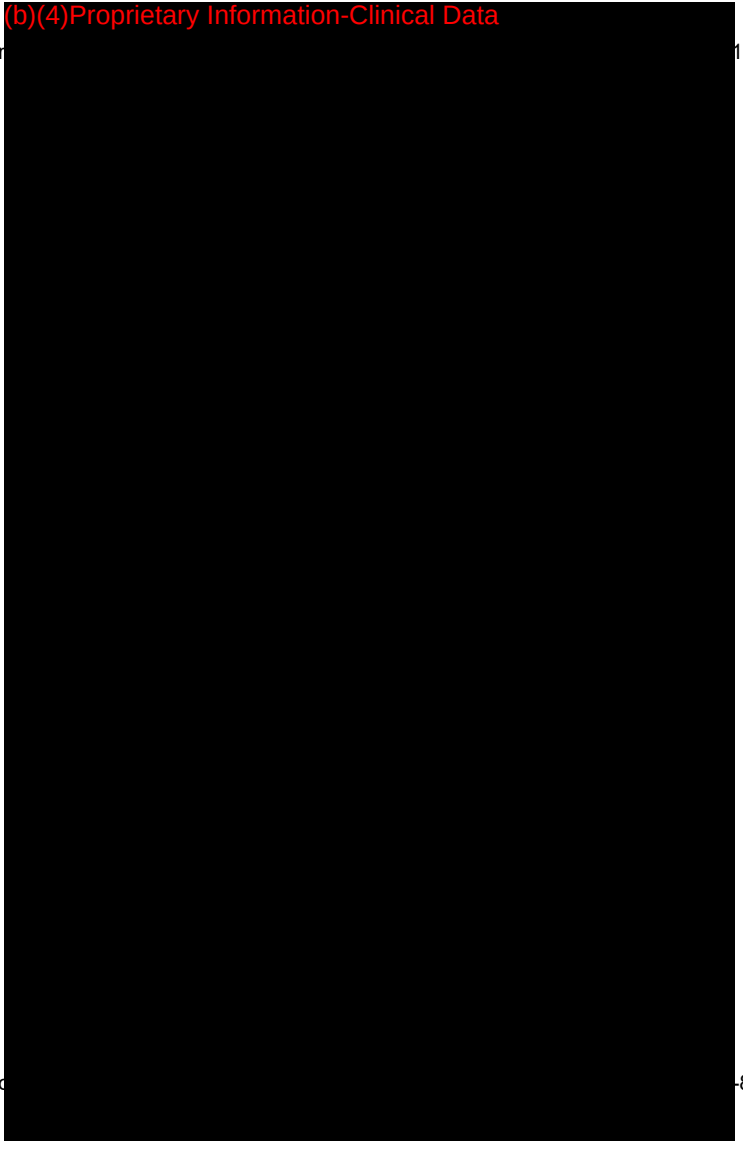




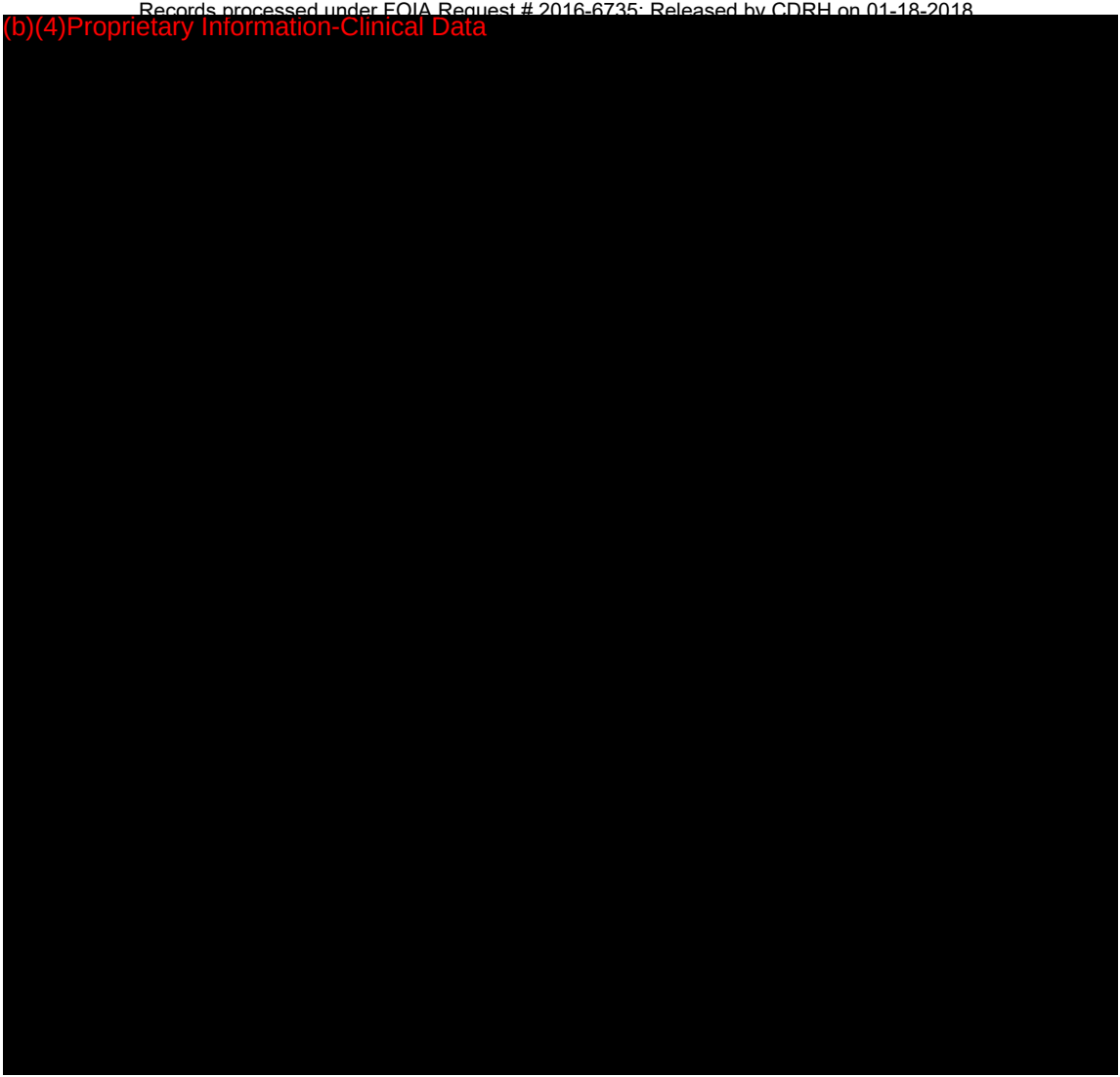




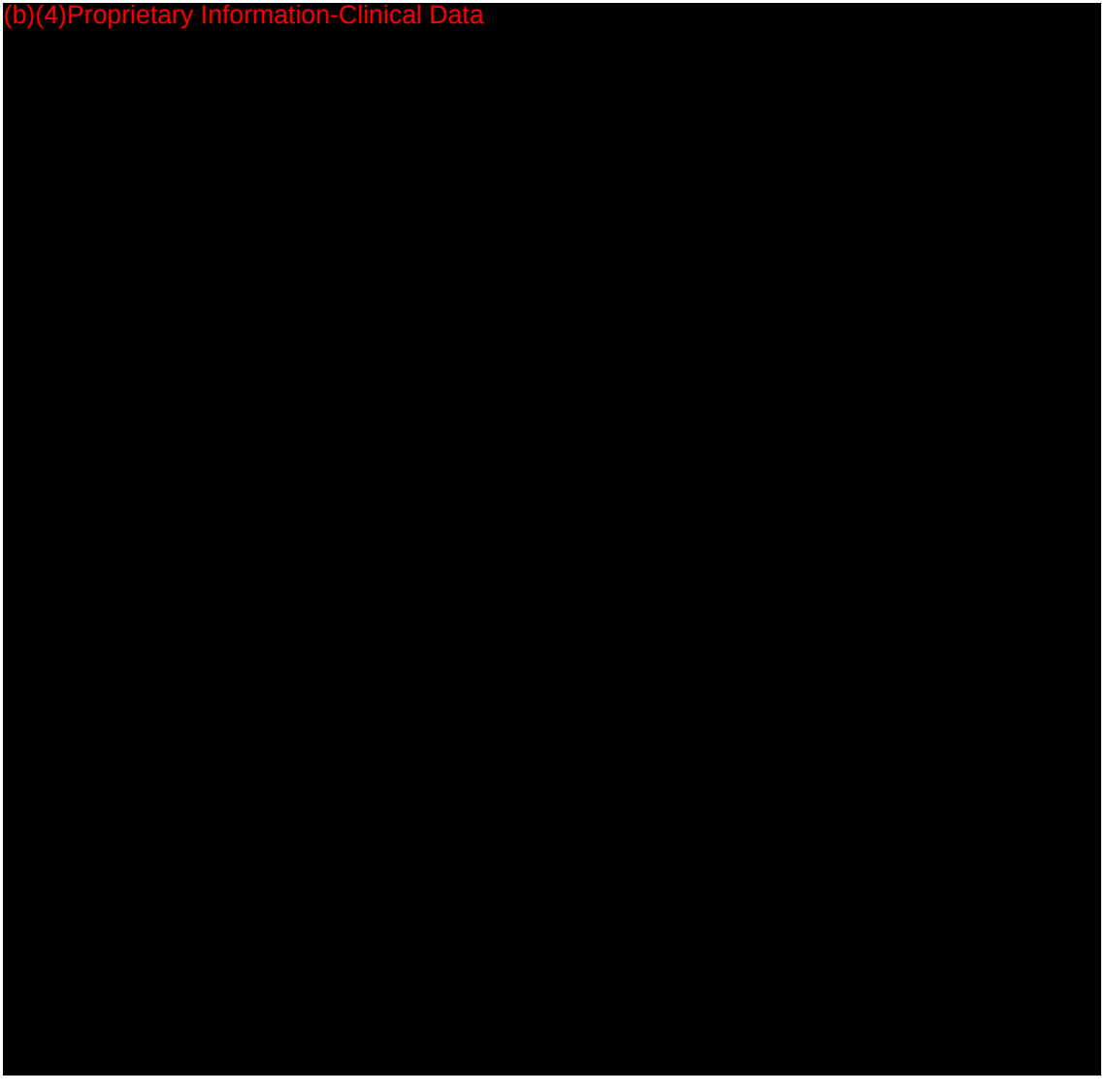
(b)(4)Proprietary Information-Clinical Data

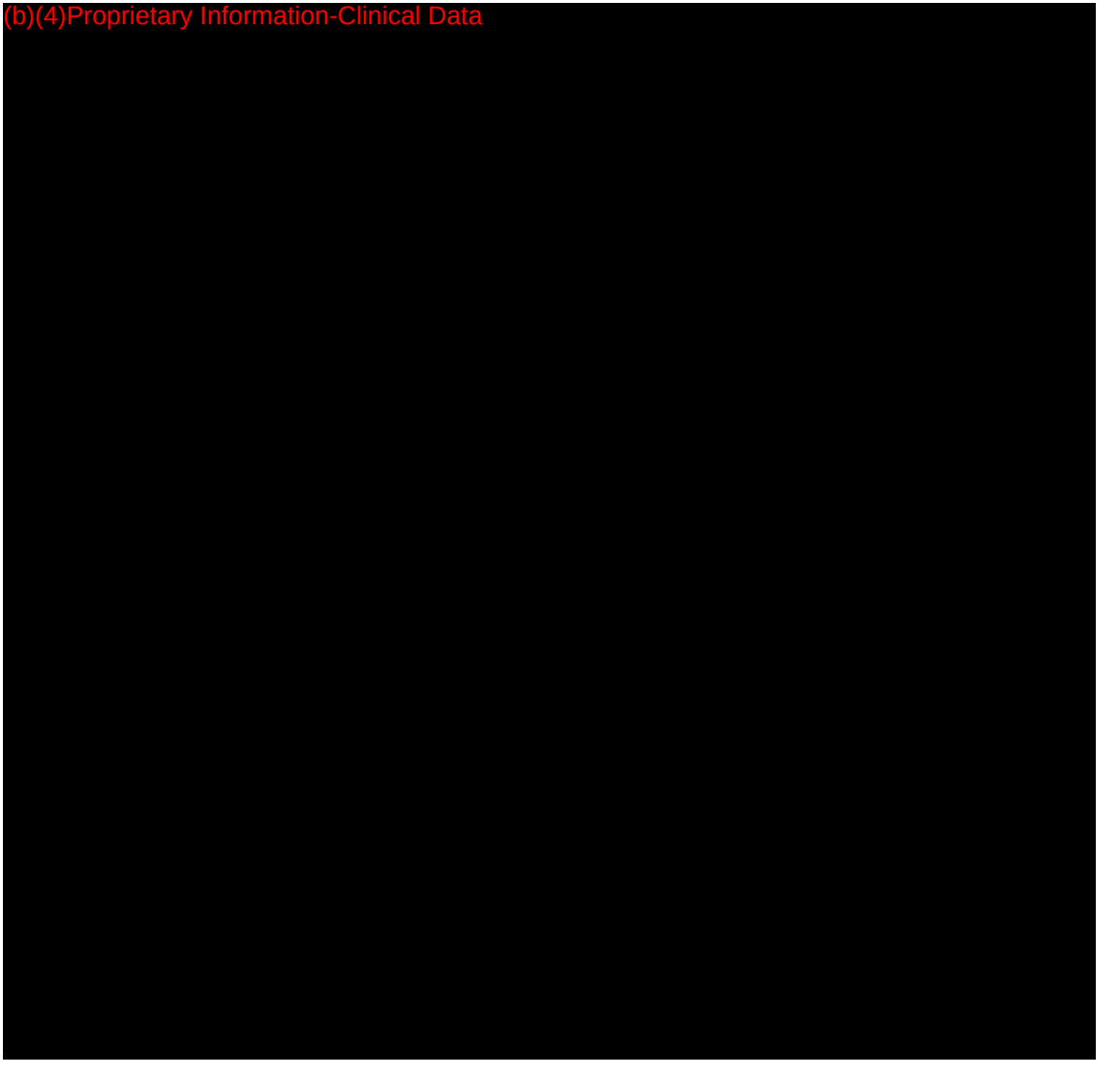


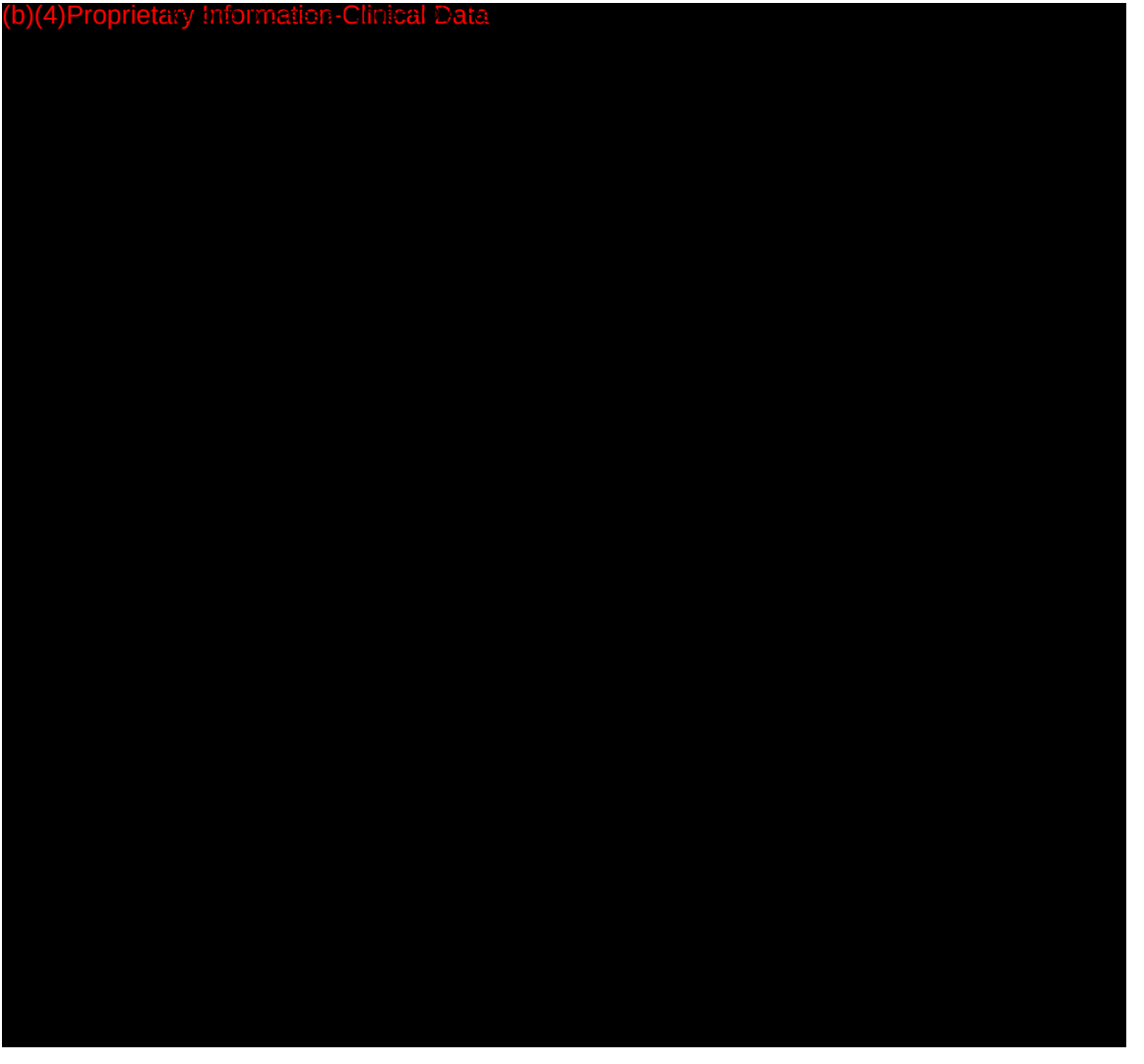
(b)(4)Proprietary Information-Clinical Data



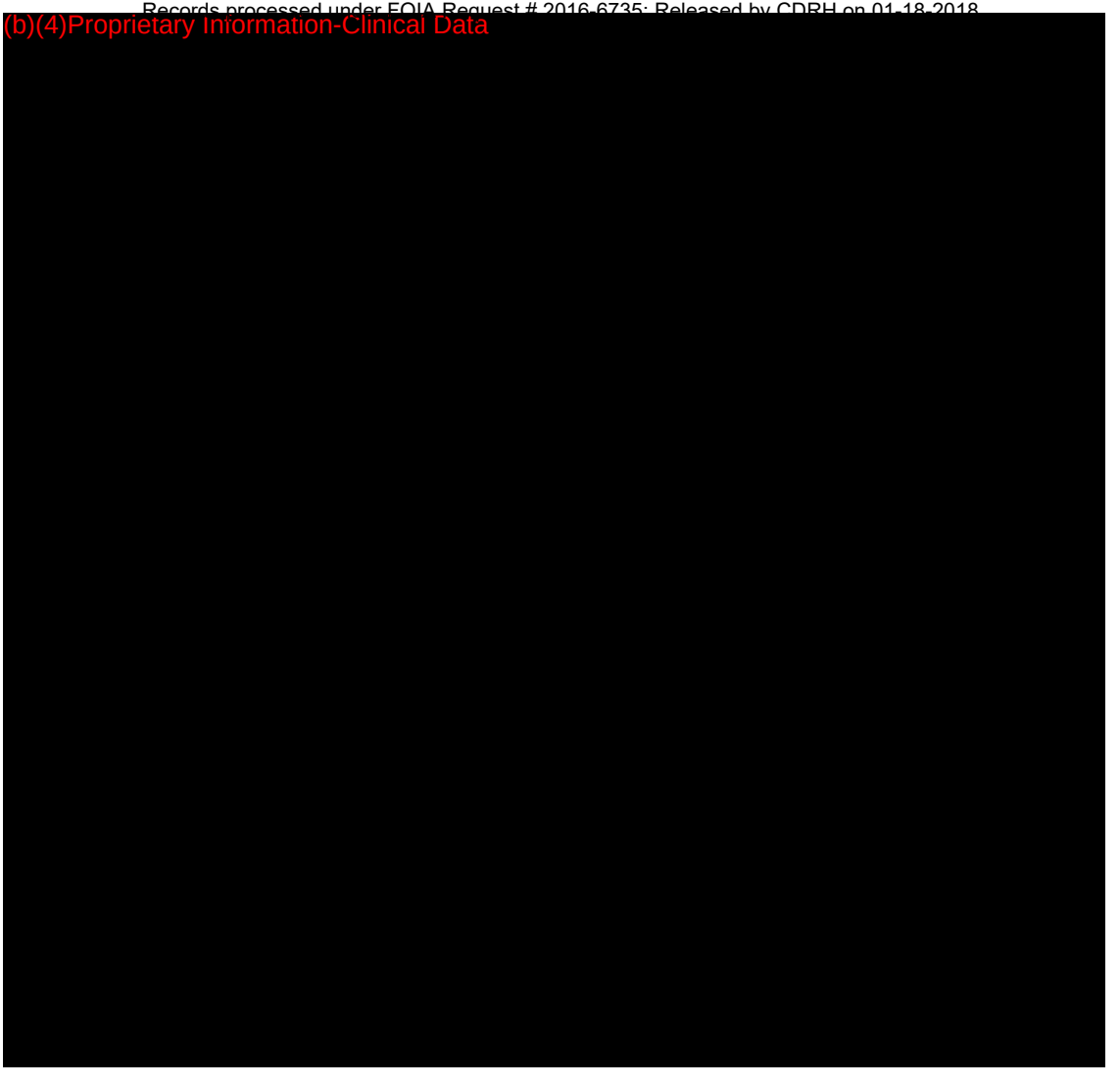
(b)(4)Proprietary Information-Clinical Data

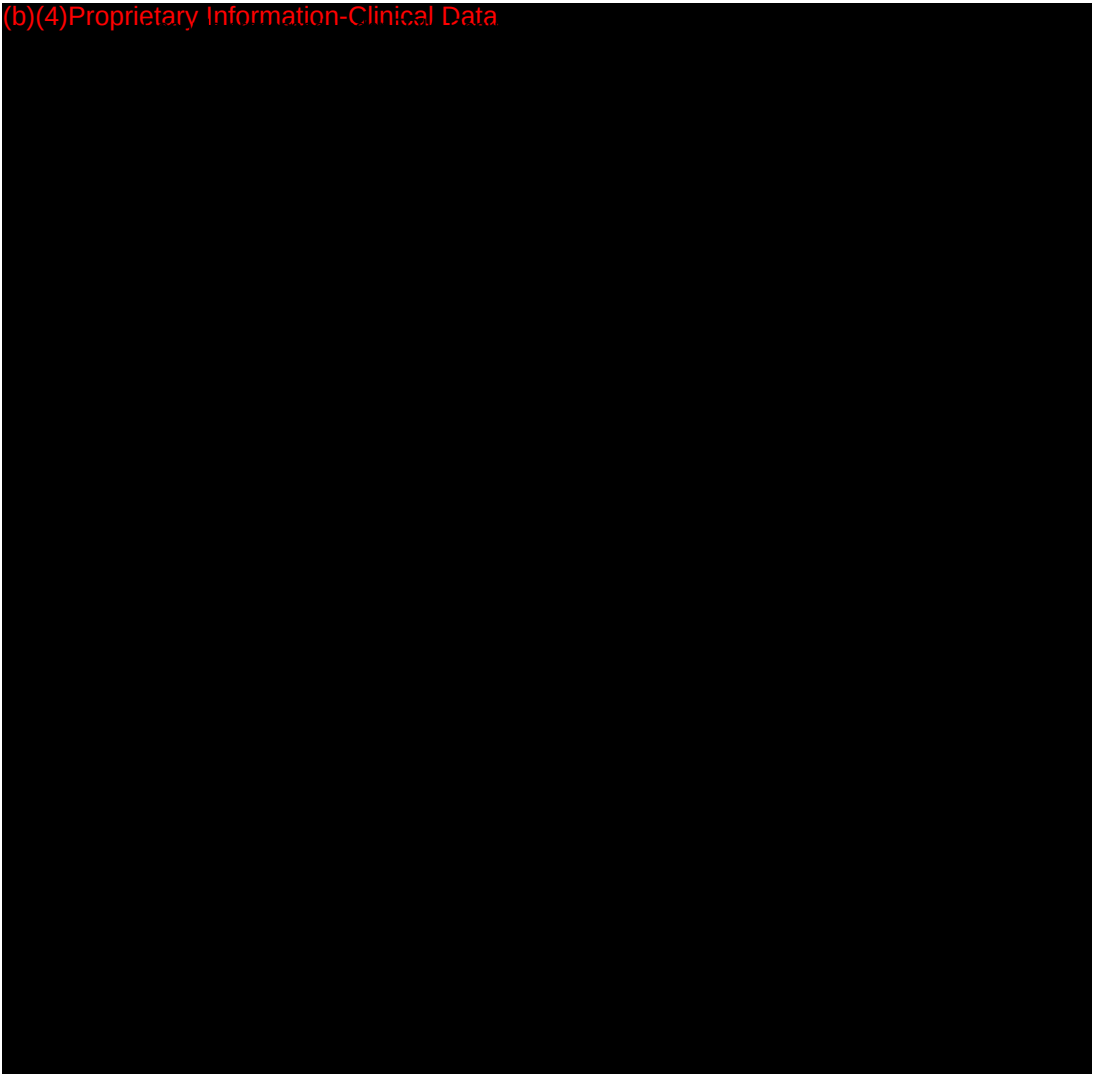

(b)(4)Proprietary Information-Clinical Data


(b)(4)Proprietary Information-Clinical Data

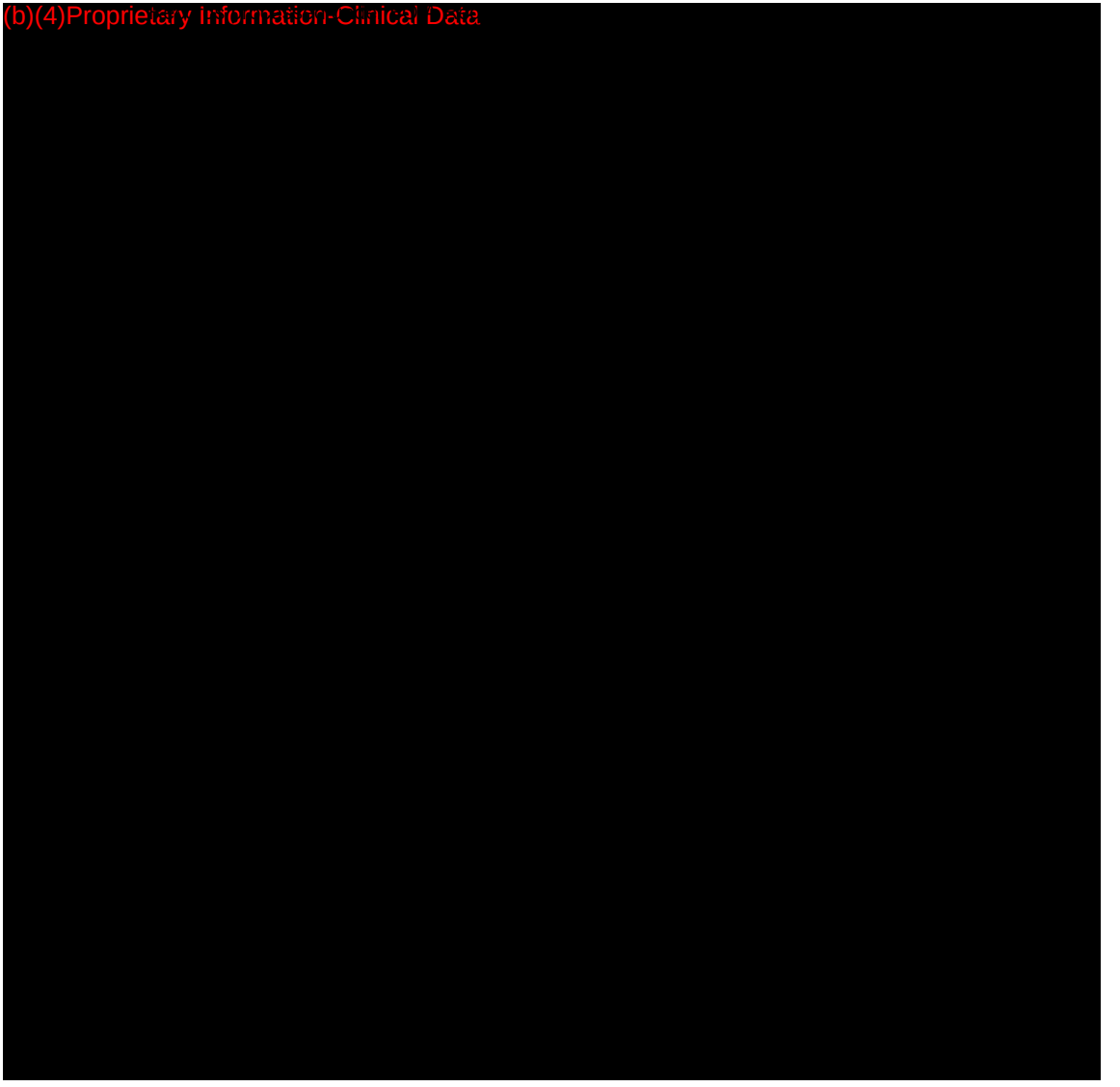

(b)(4)Proprietary Information-Clinical Data

(b)(4)Proprietary Information-Clinical Data



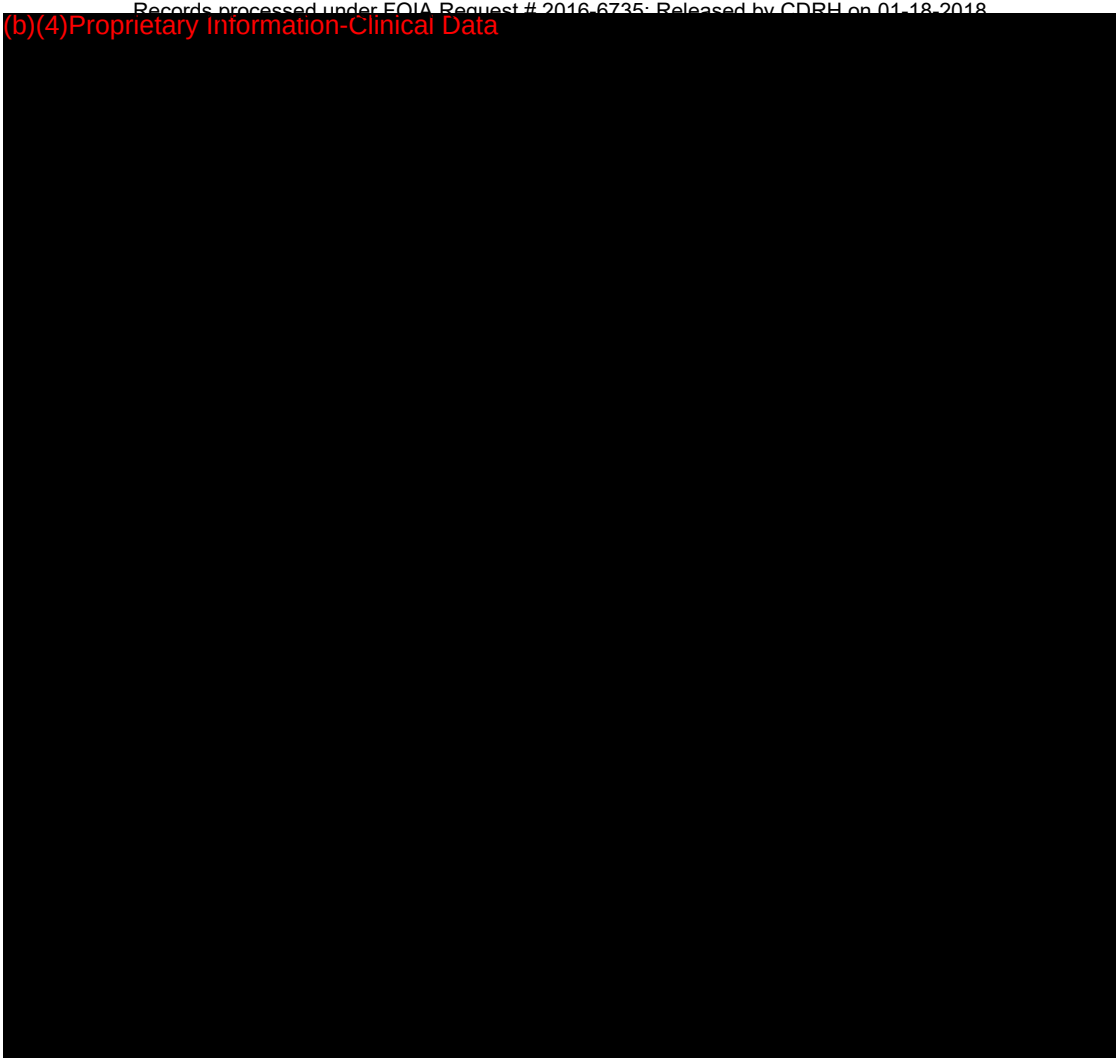

(b)(4)Proprietary Information-Clinical Data

(b)(4)Proprietary Information-Clinical Data

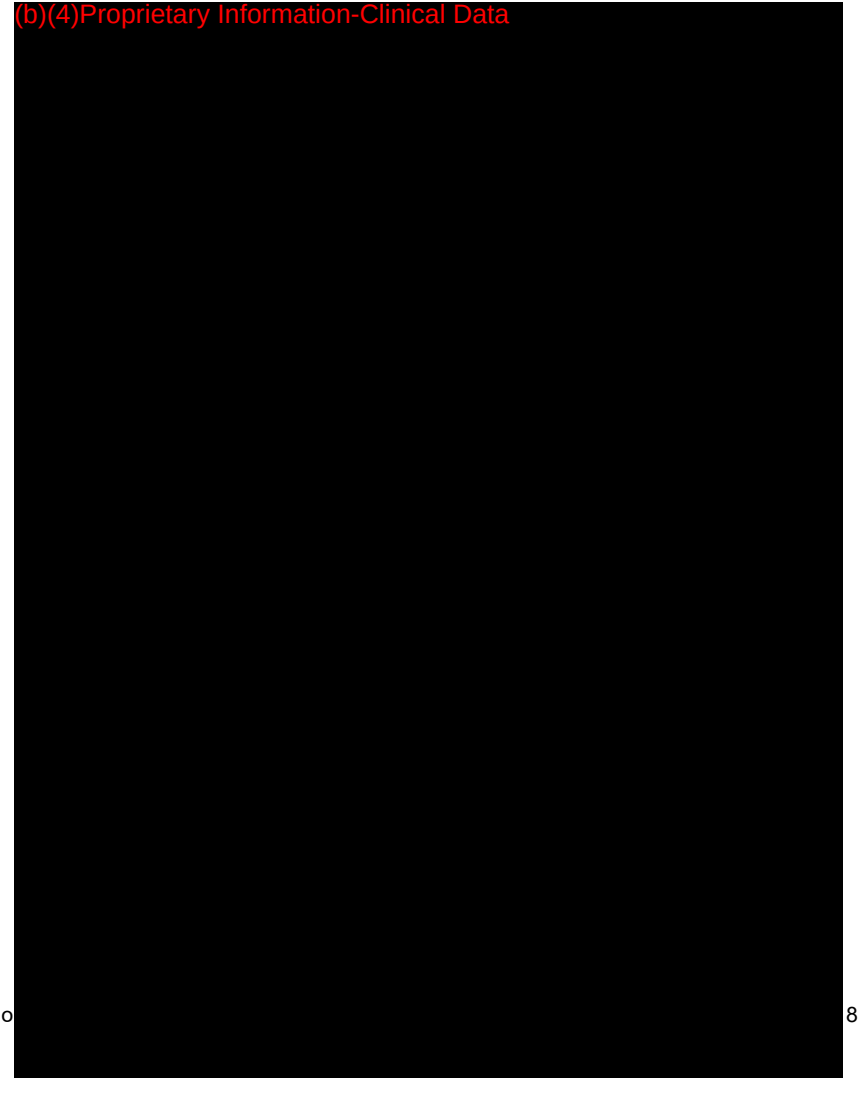



(b)(4)Proprietary Information-Clinical Data

(b)(4)Proprietary Information-Clinical Data

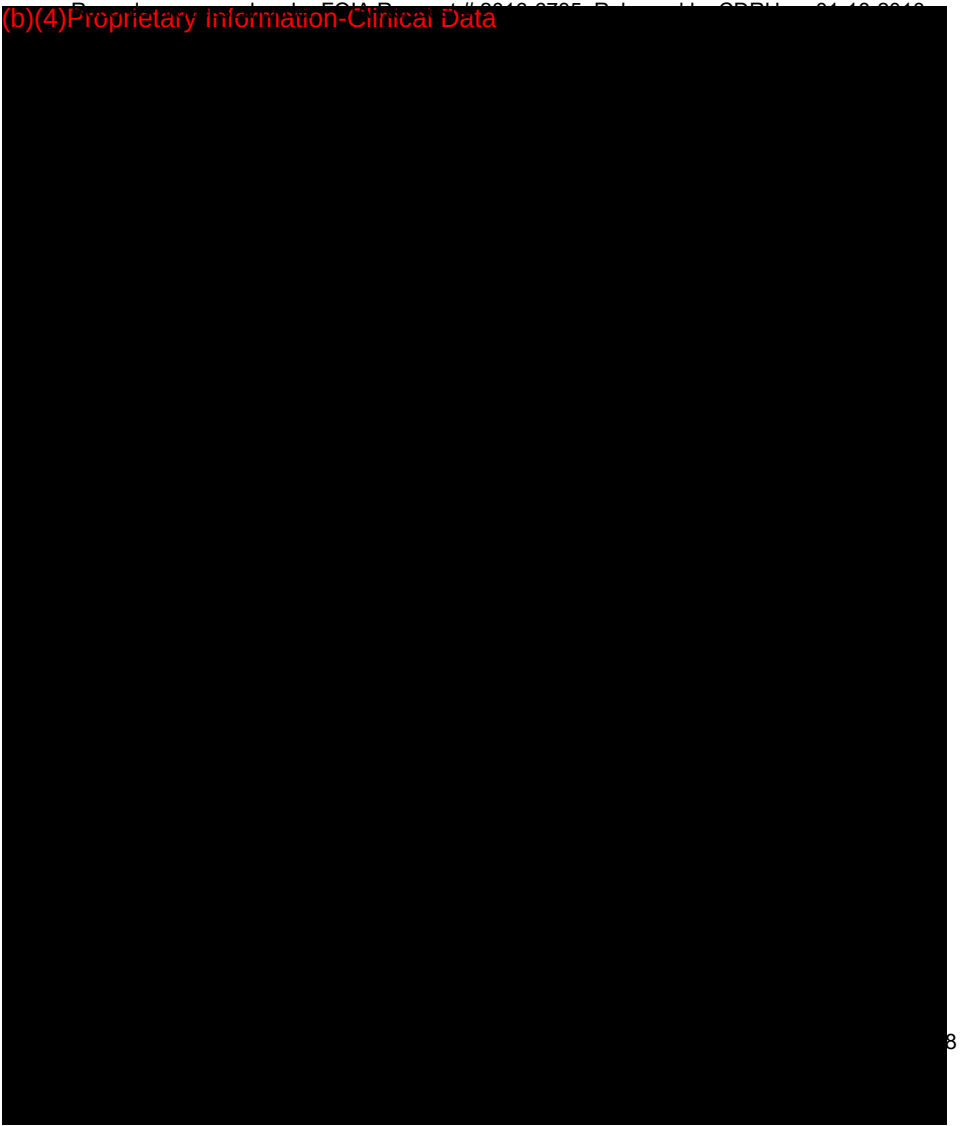


(b)(4)Proprietary Information-Clinical Data

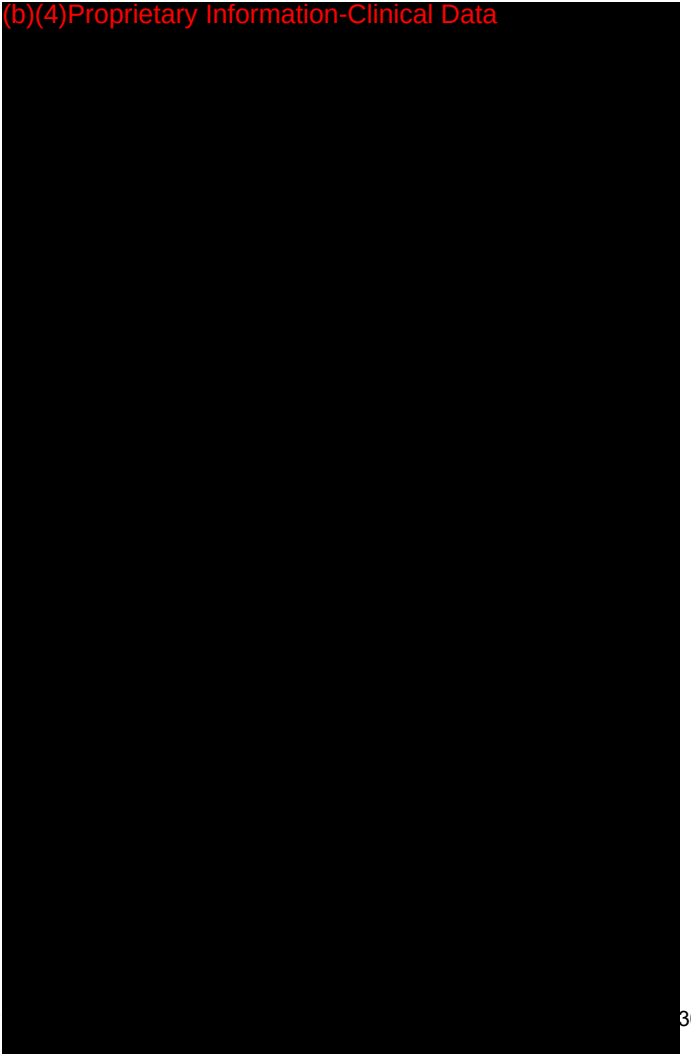


(b)(4)Proprietary Information-Clinical Data

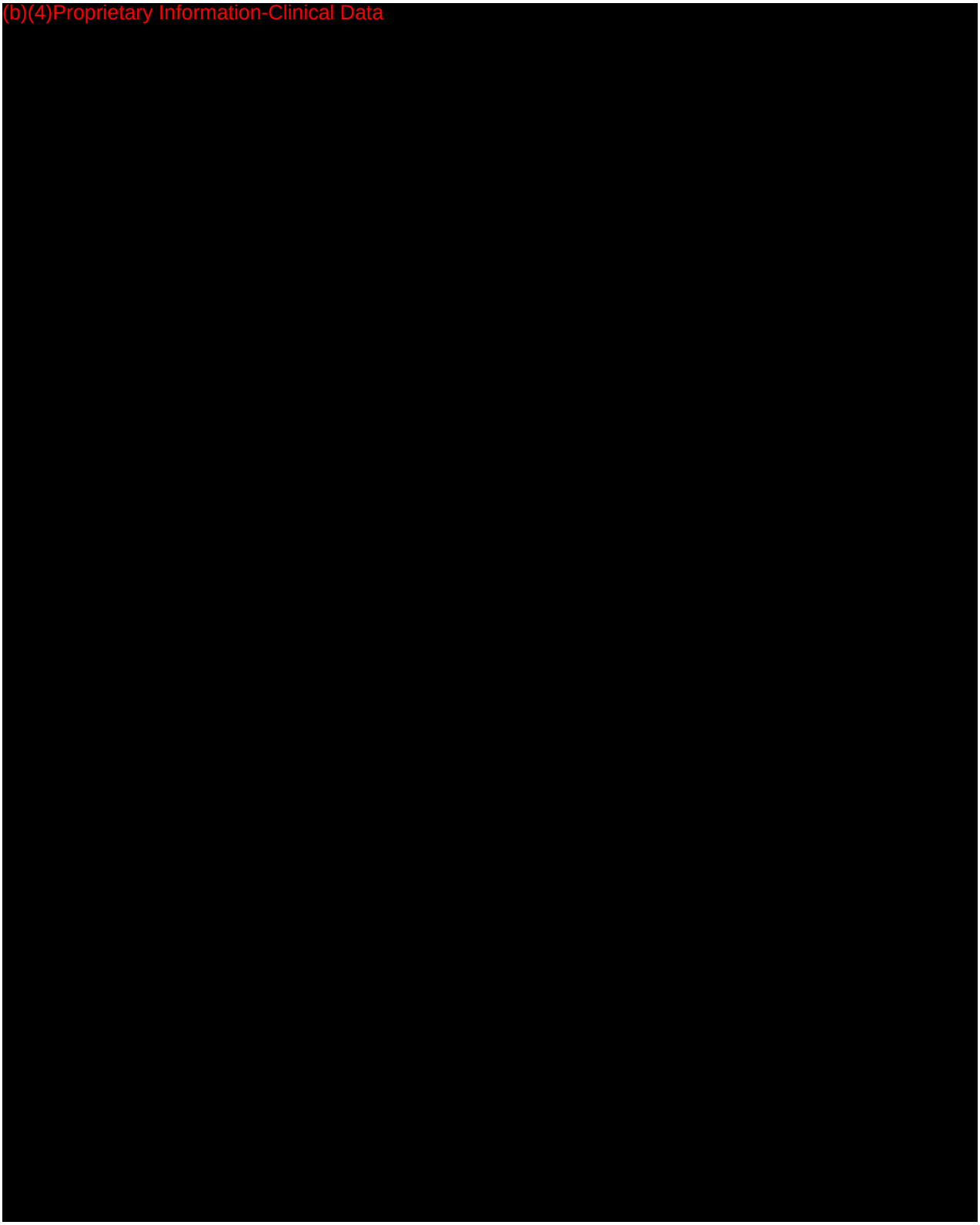
(b)(4)Proprietary Information-Clinical Data

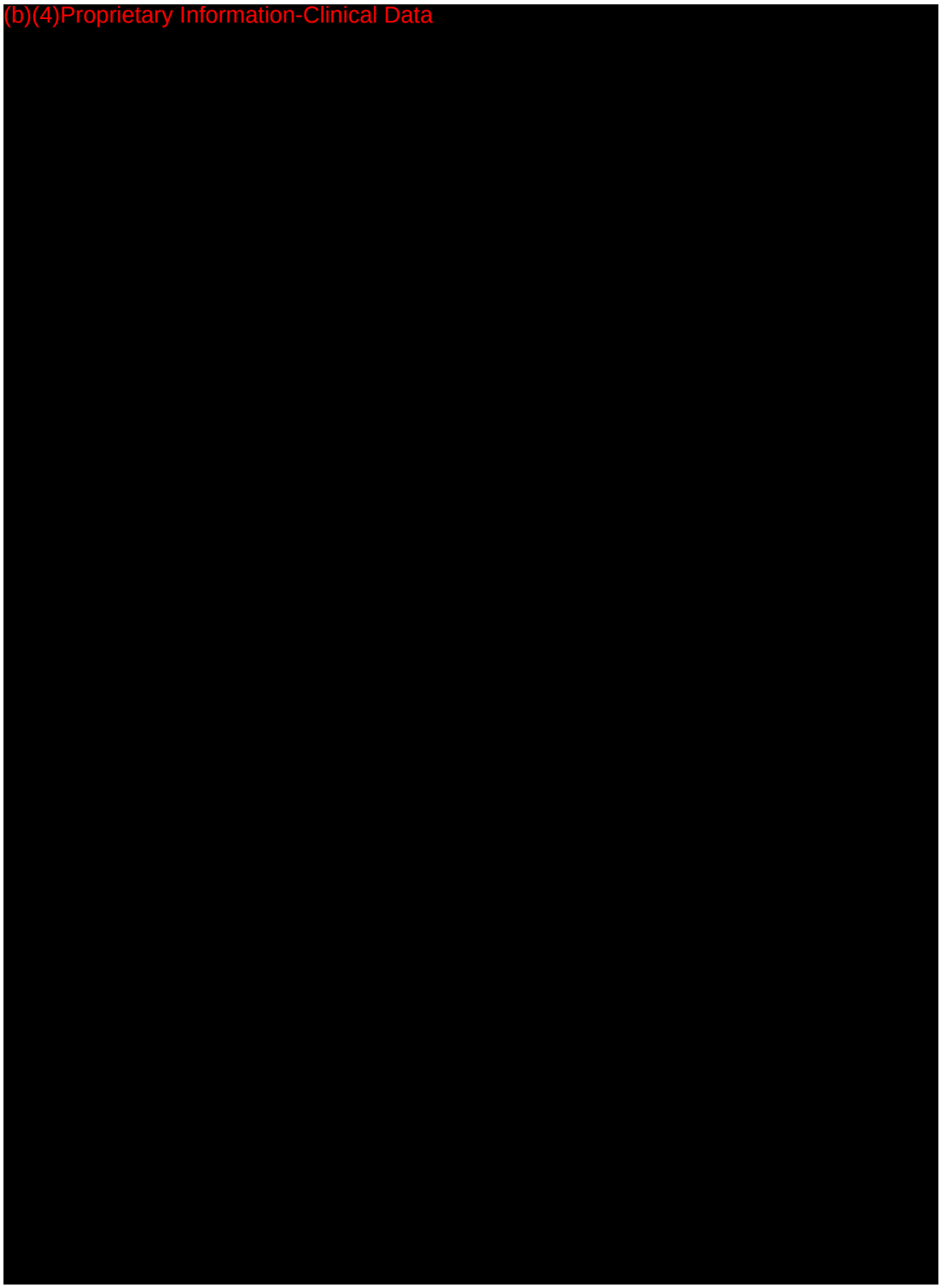


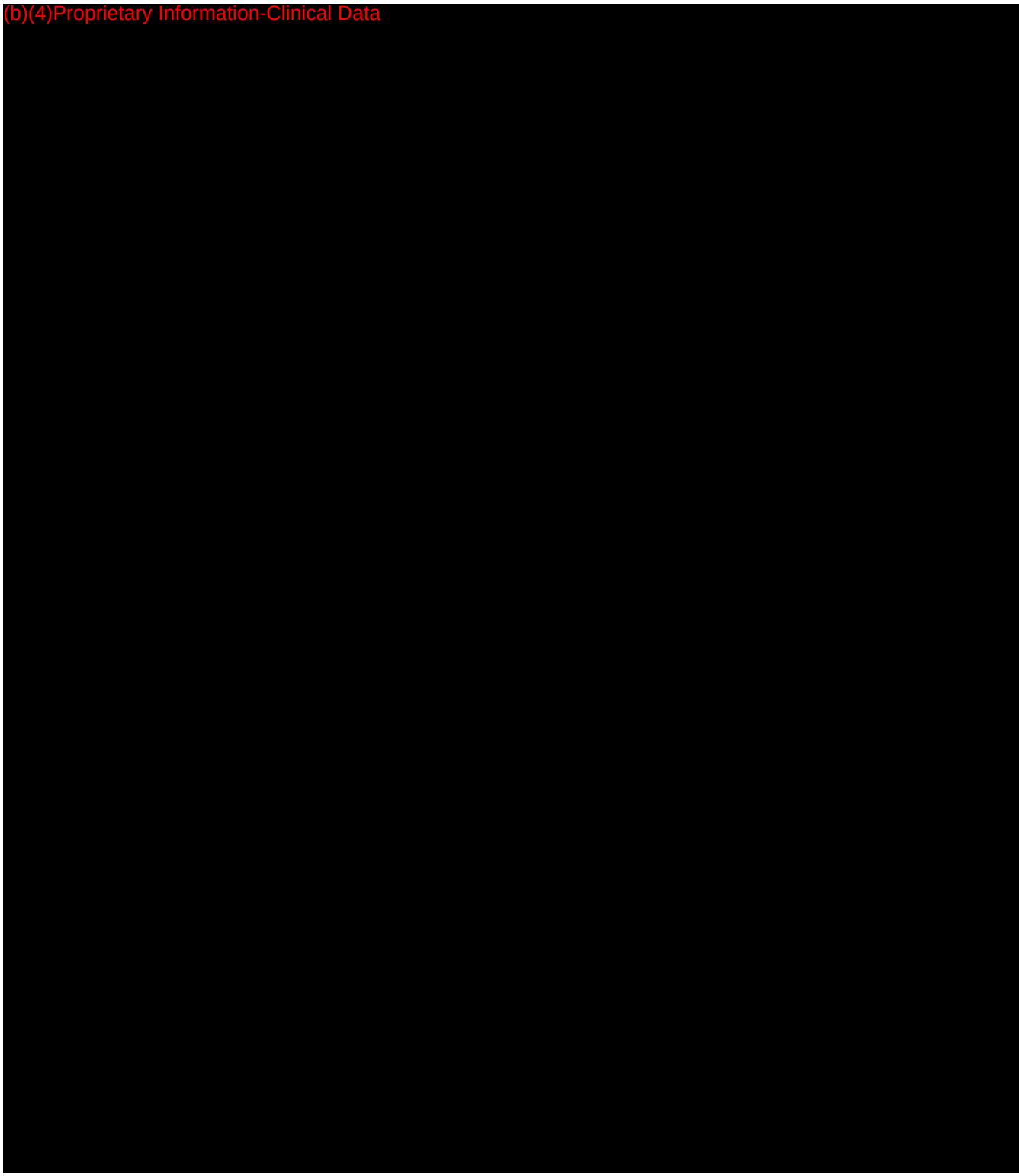
(b)(4)Proprietary Information-Clinical Data

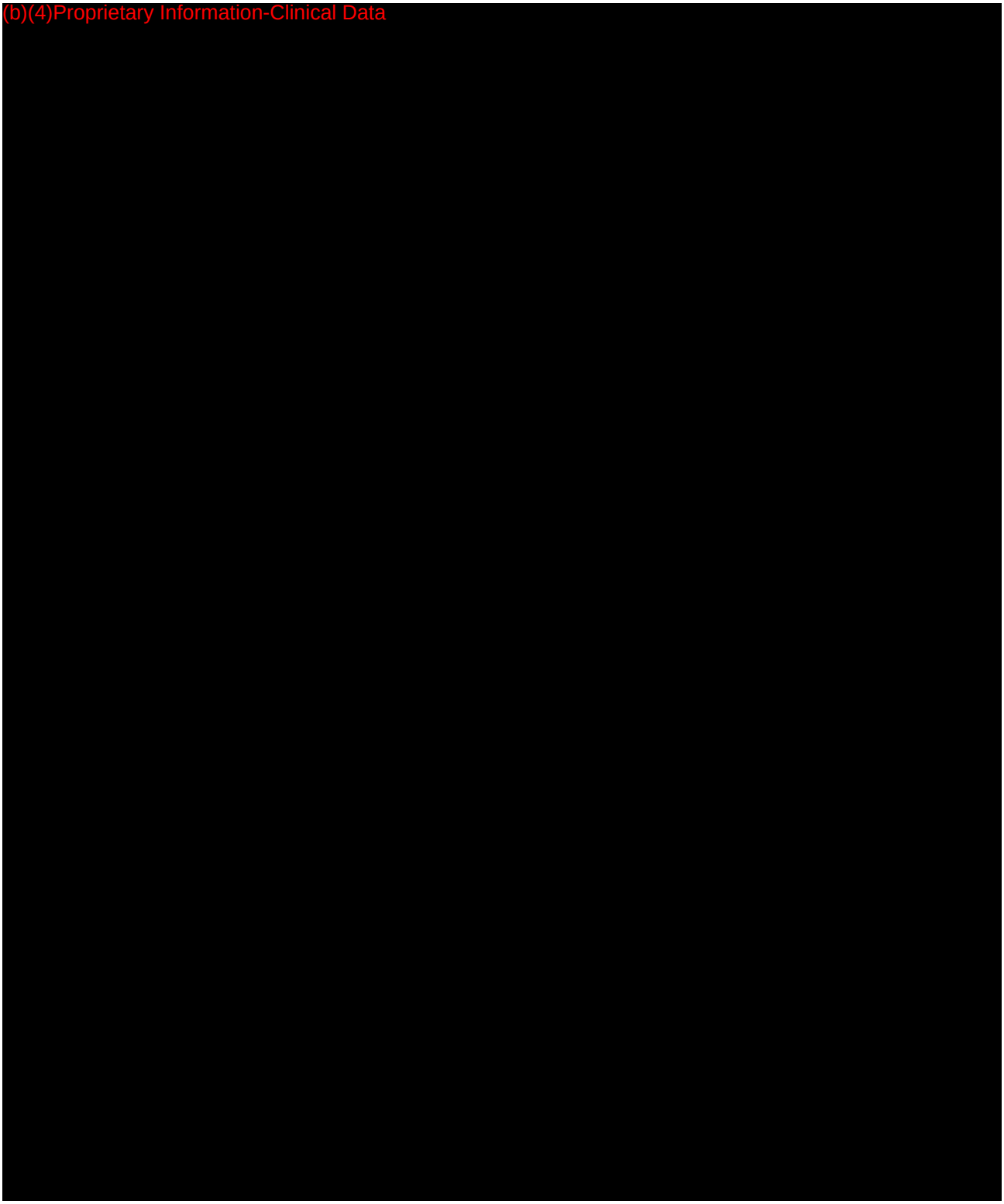


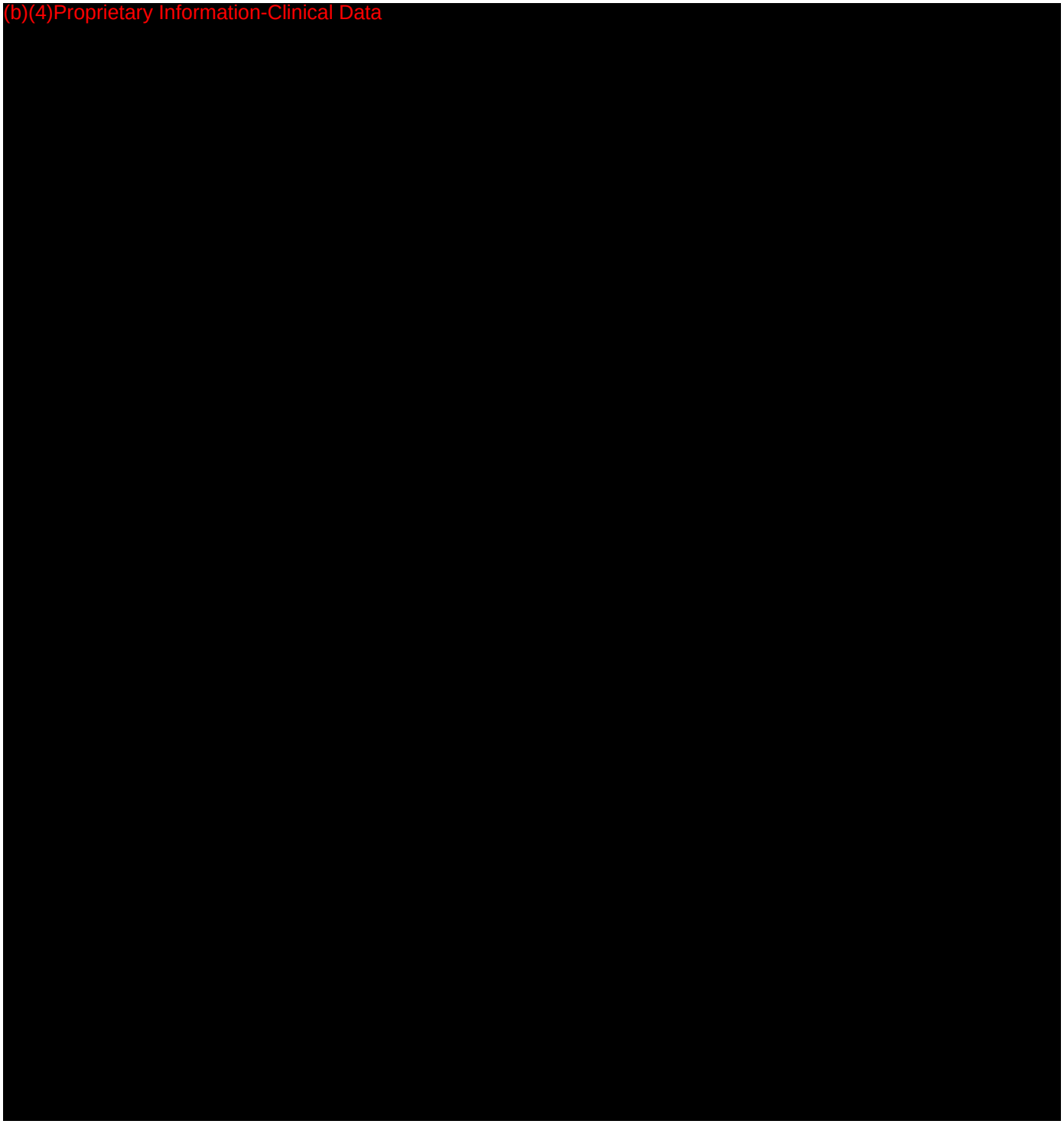
(b)(4)Proprietary Information-Clinical Data



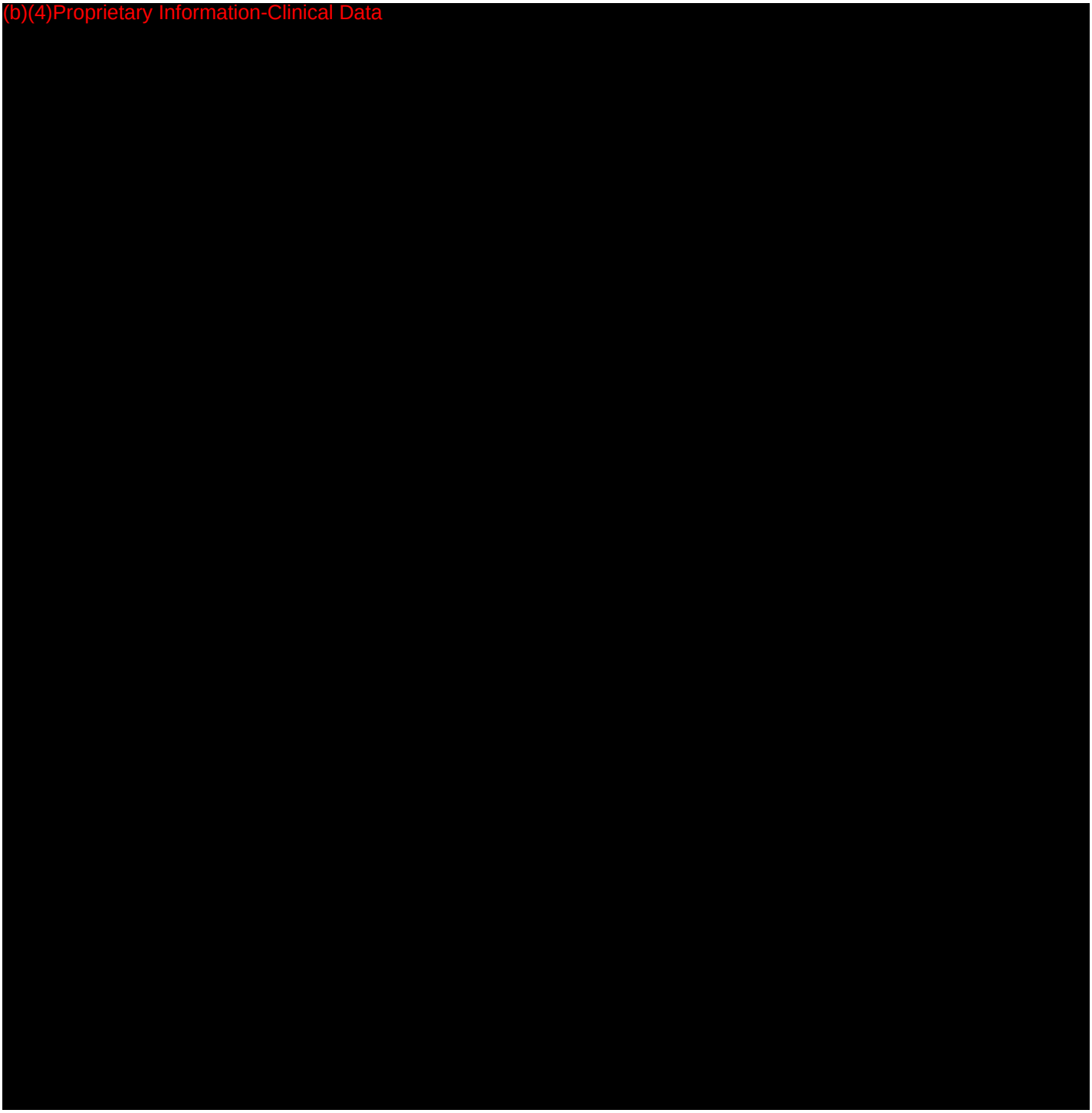


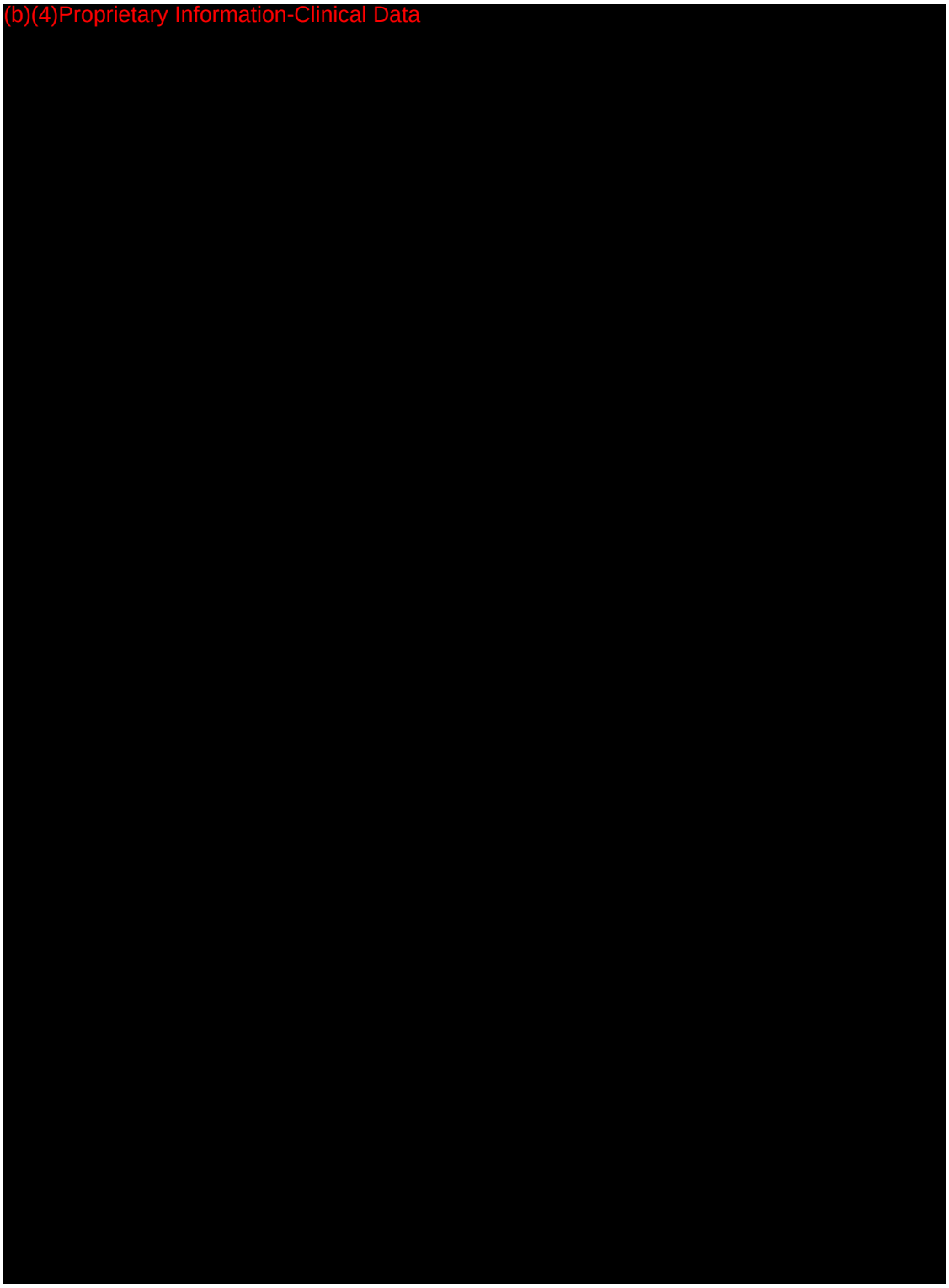


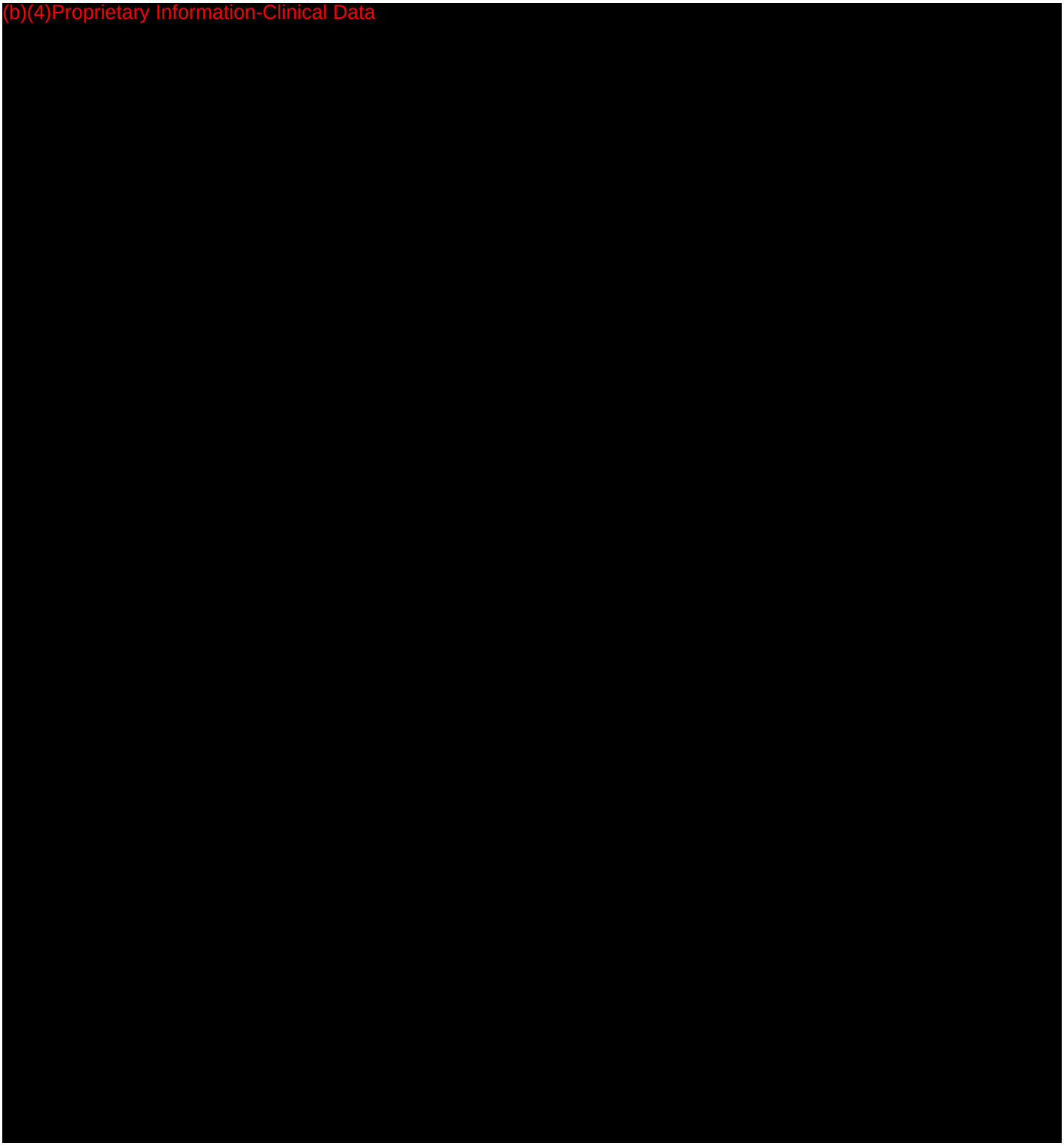




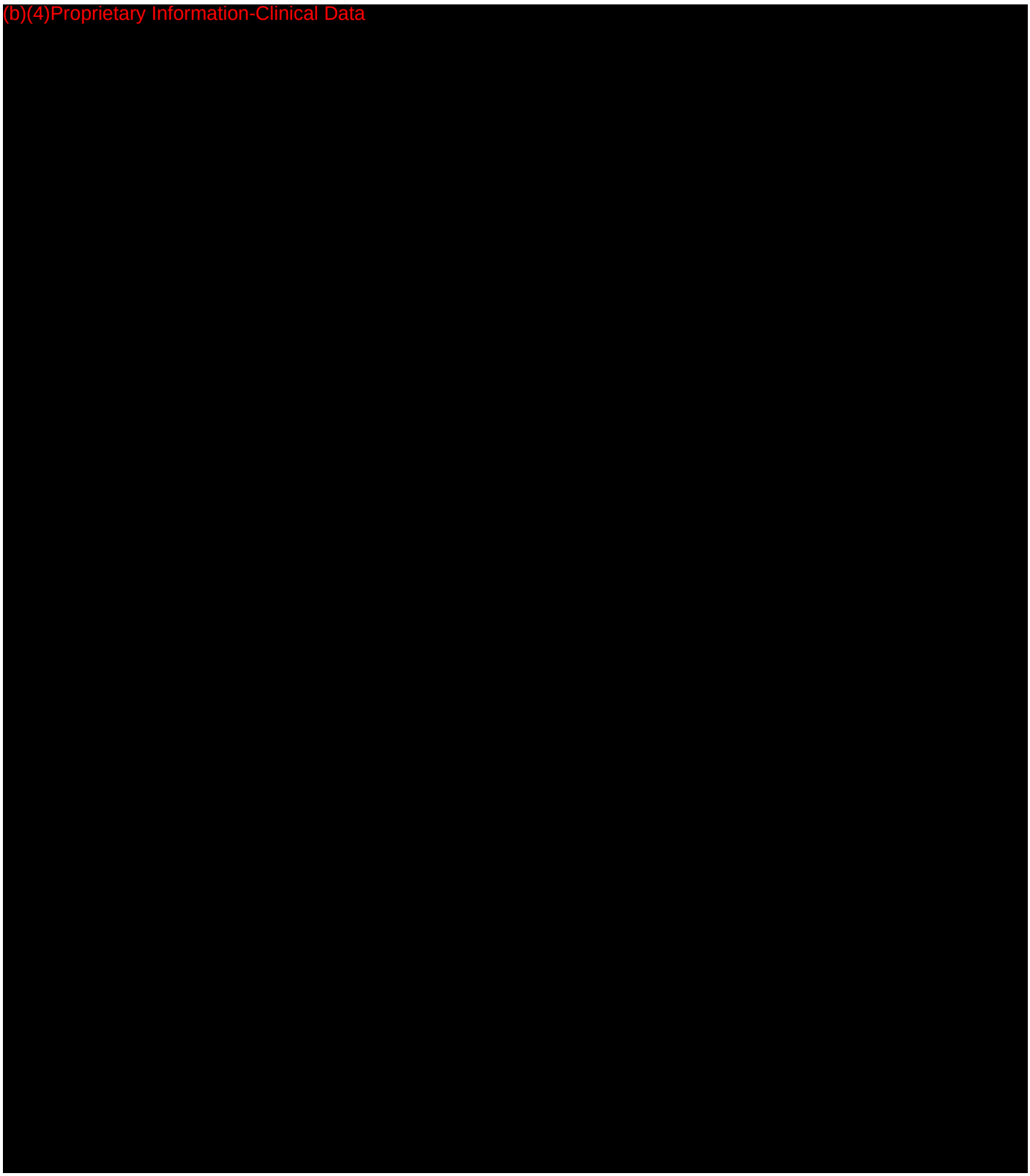
(b)(4)Proprietary Information-Clinical Data

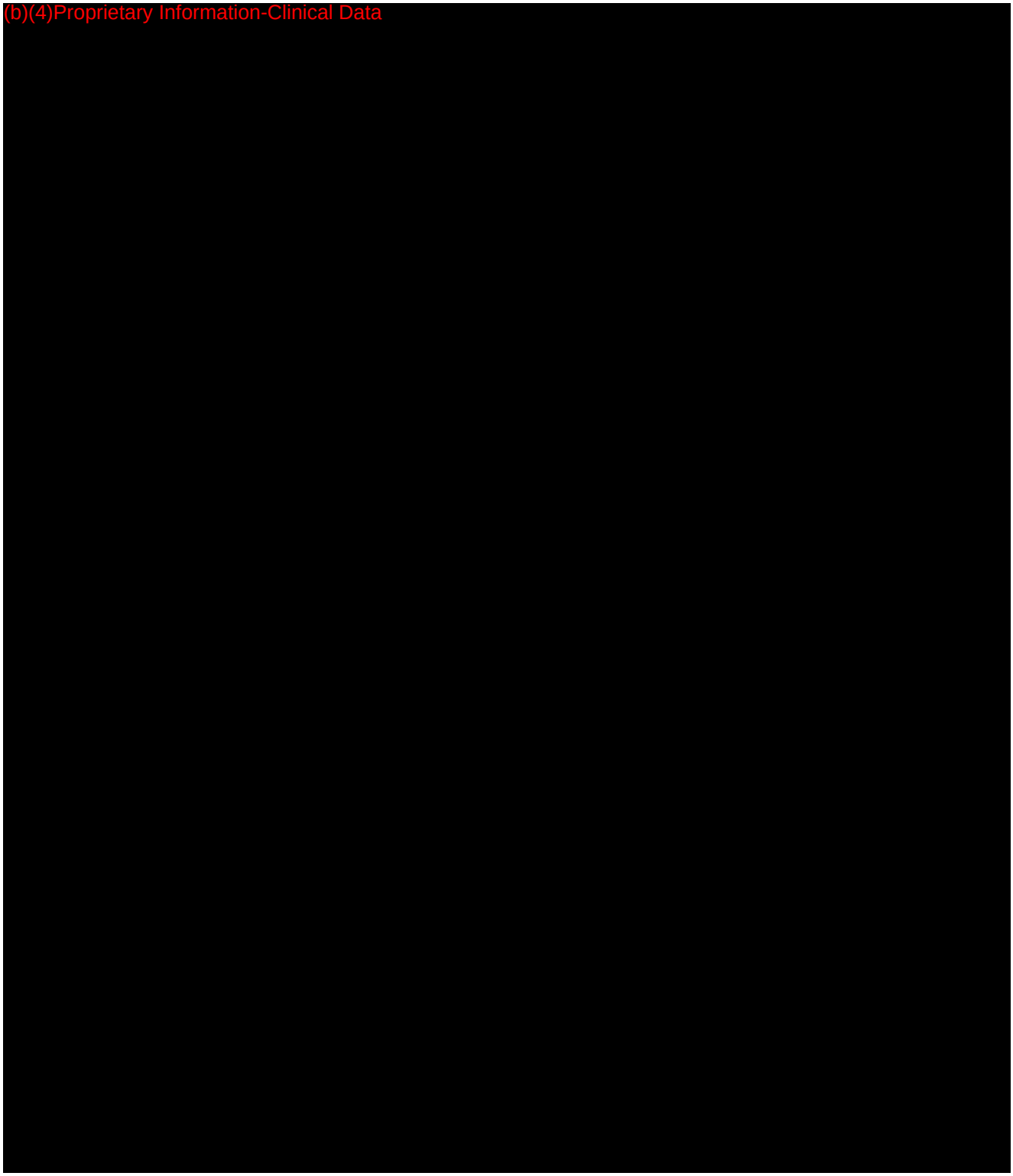


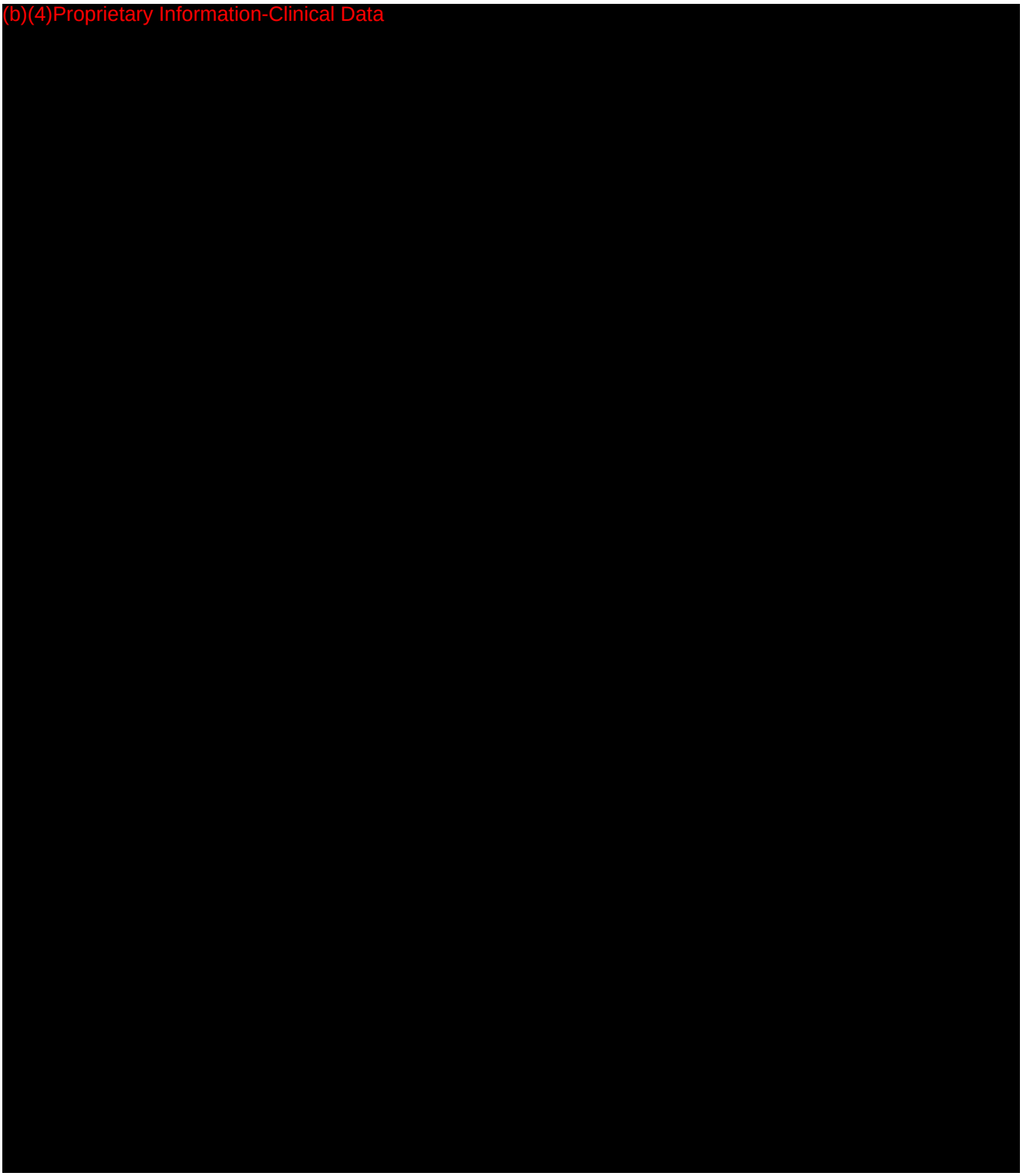


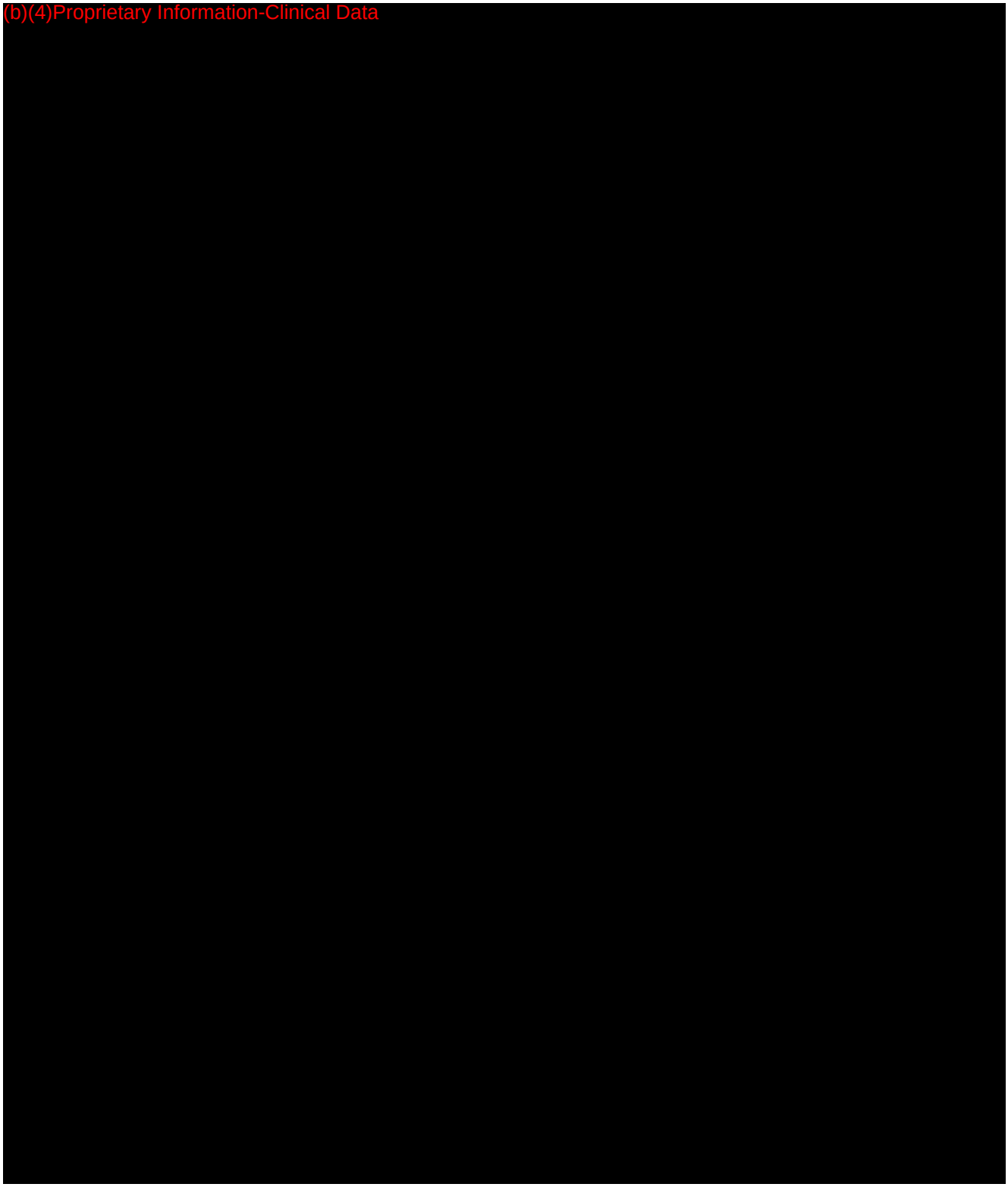


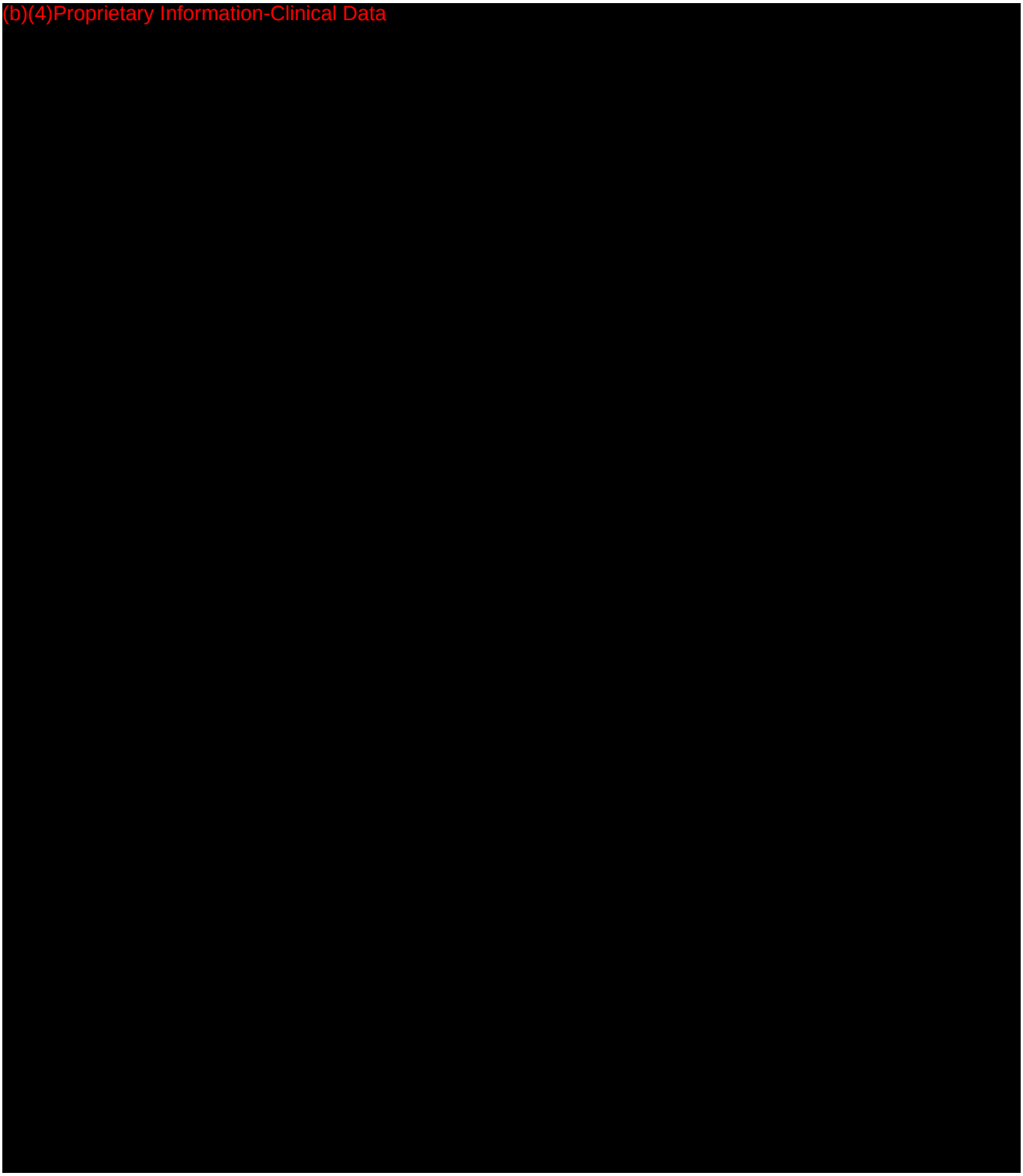
(b)(4)Proprietary Information-Clinical Data

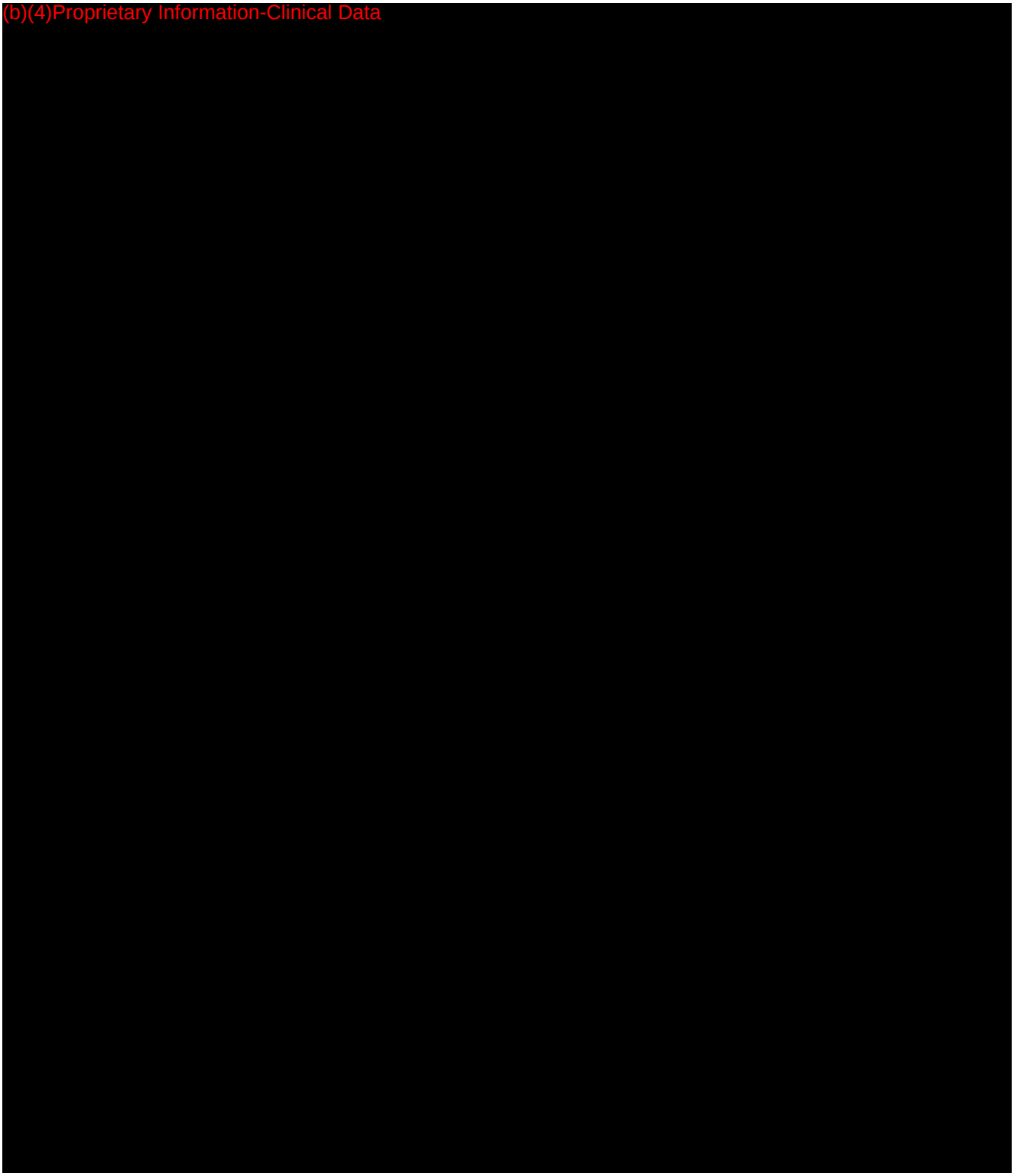


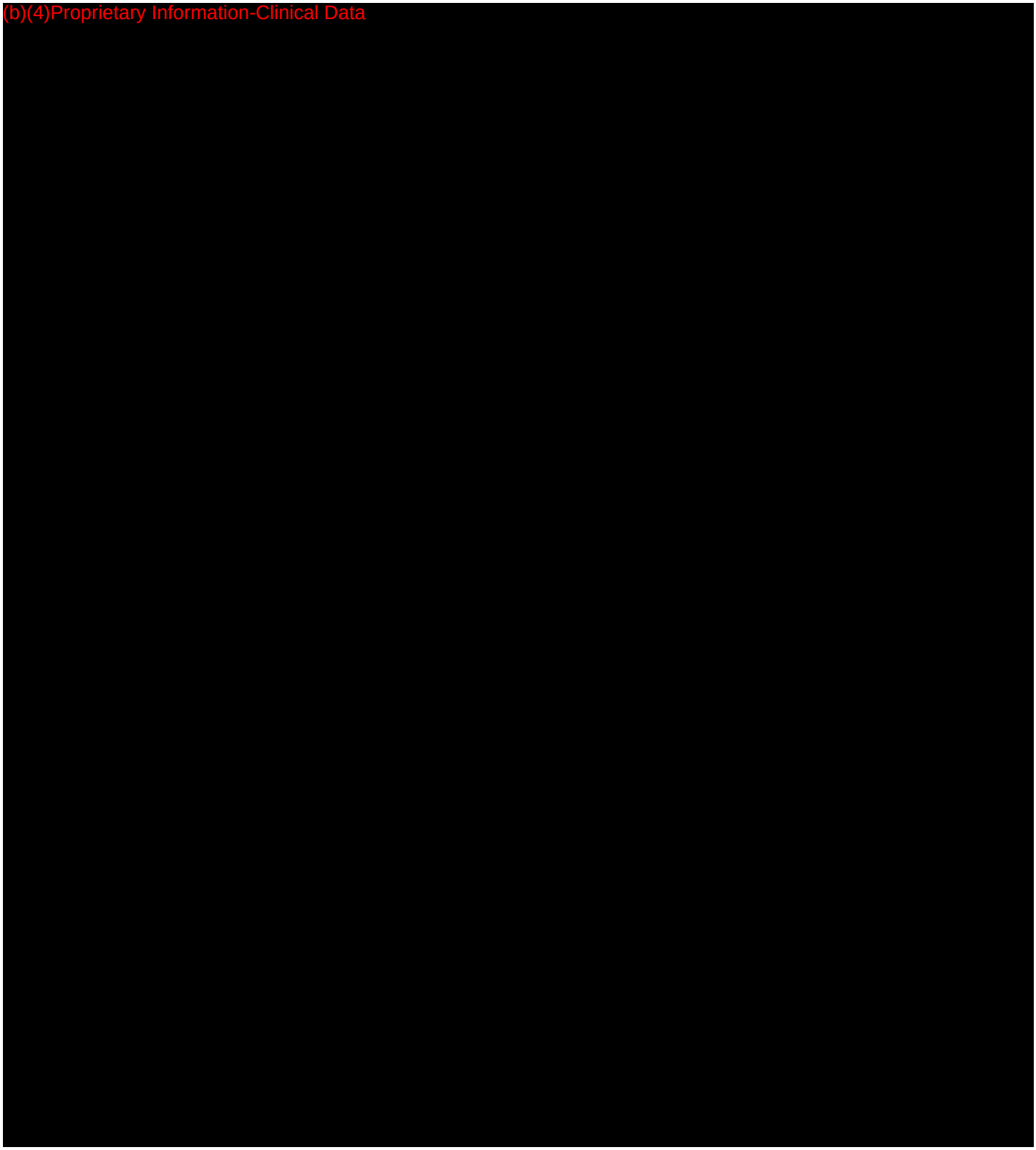


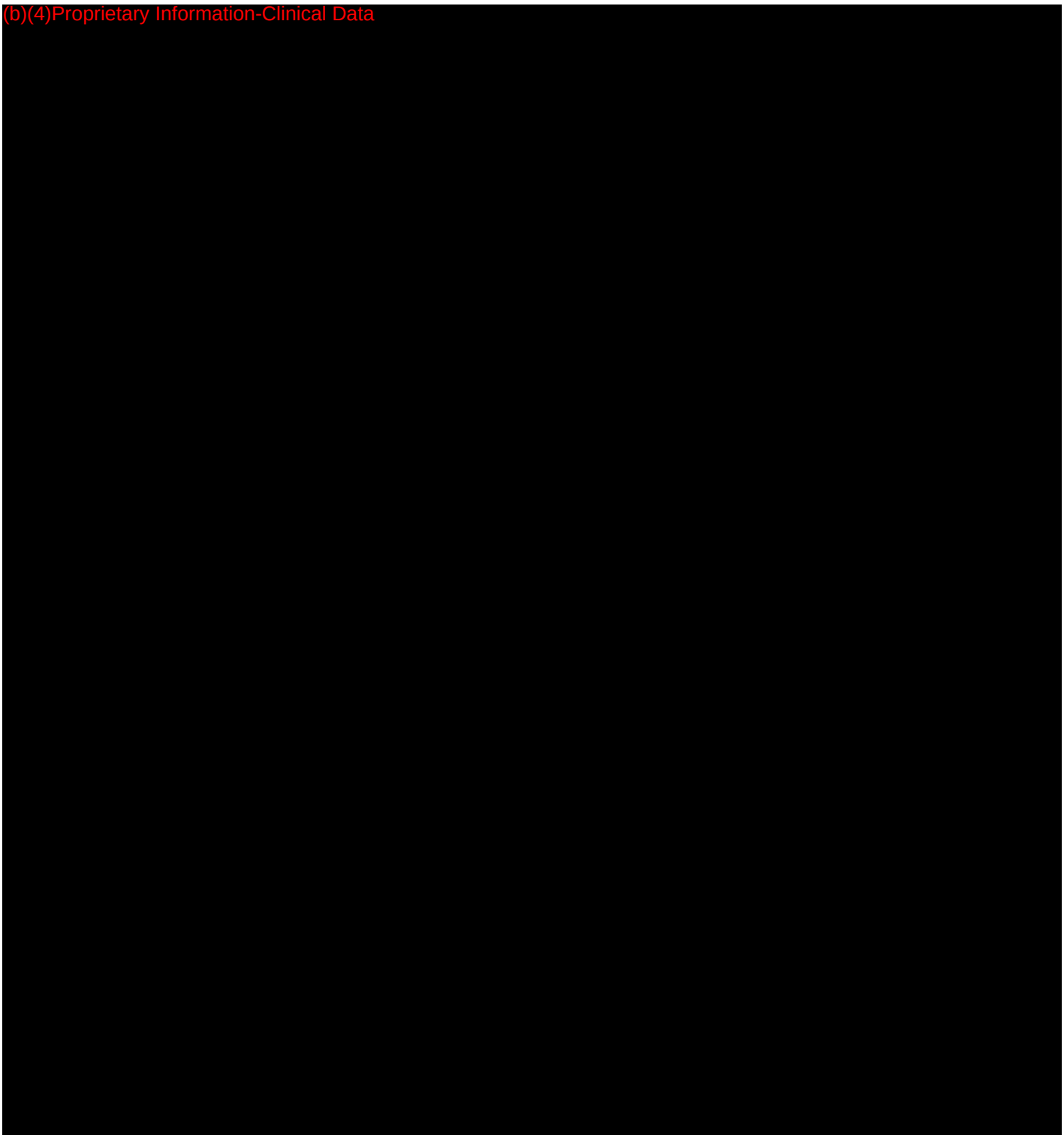




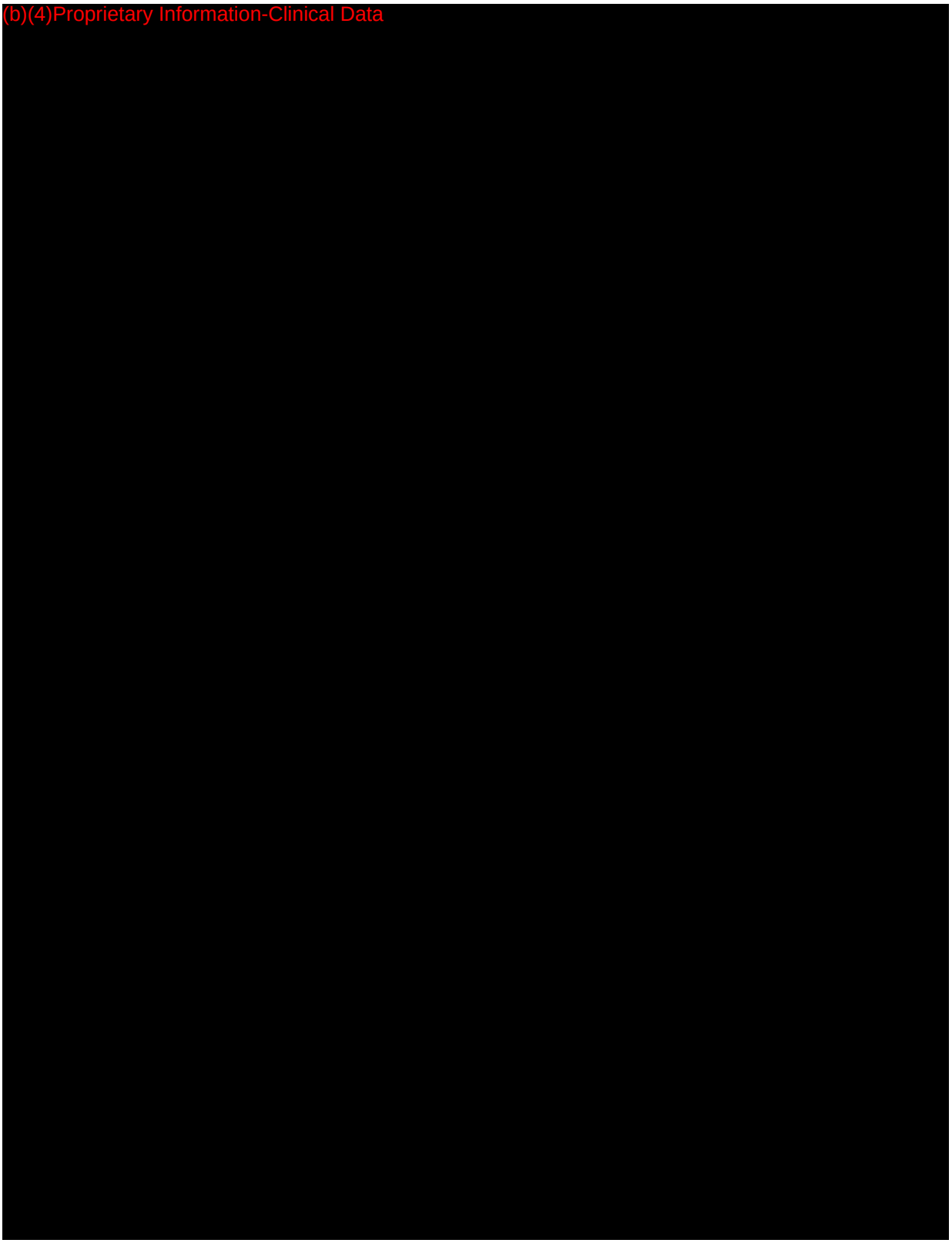


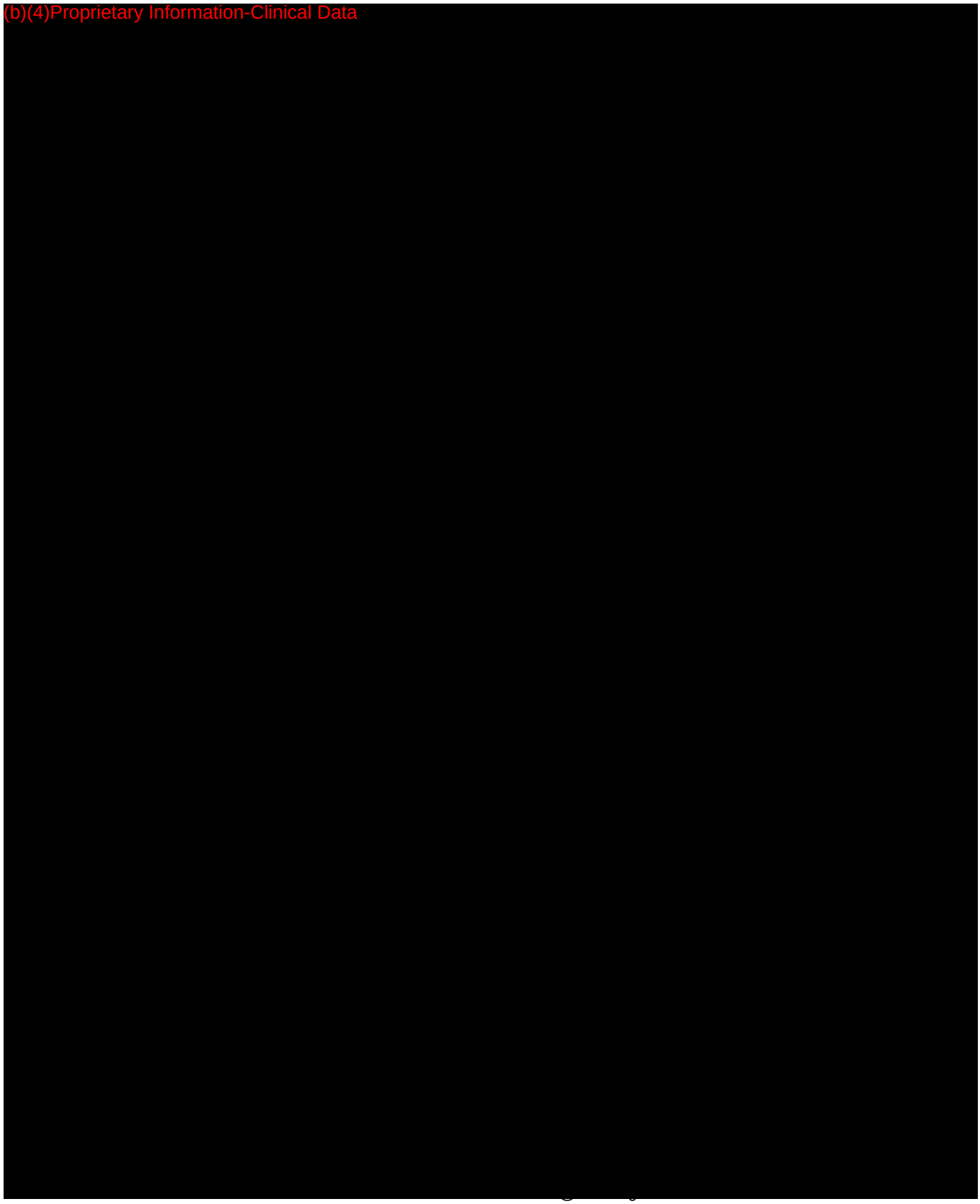


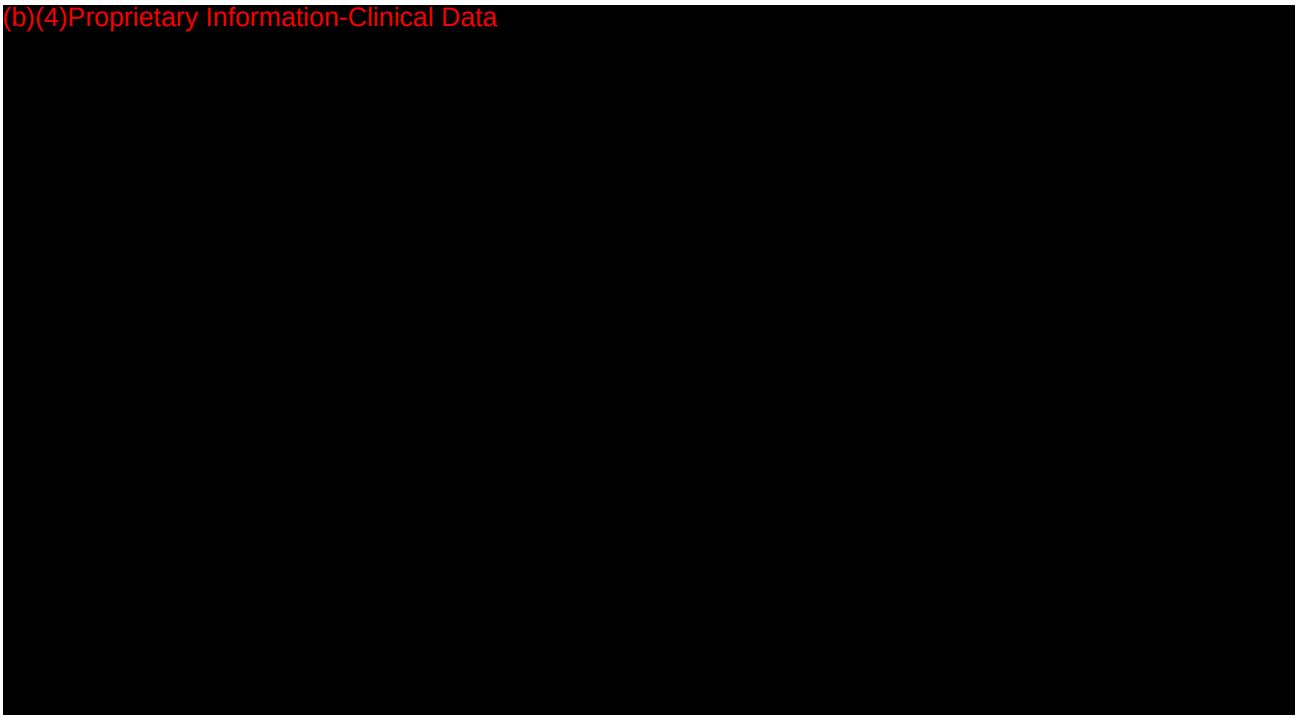


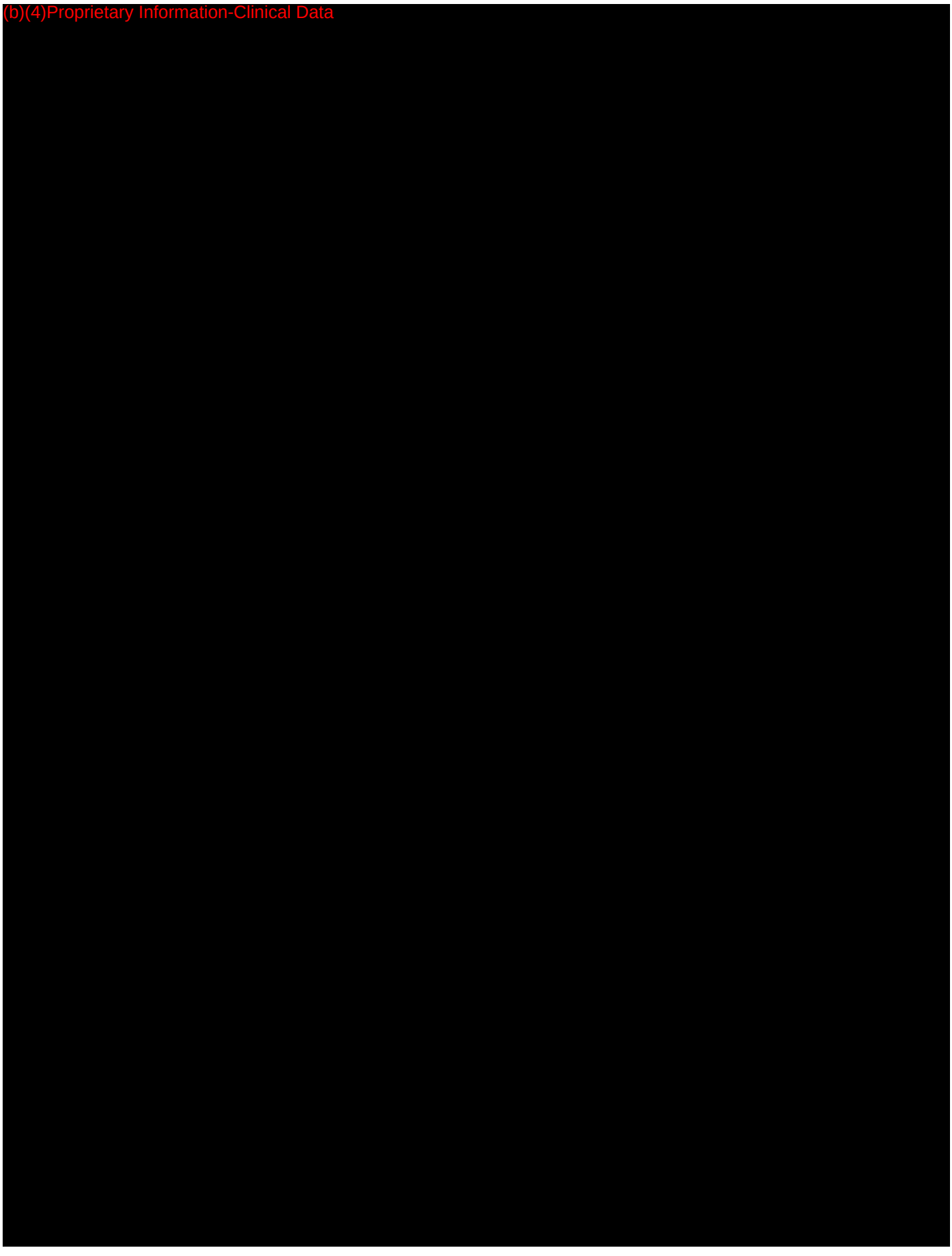


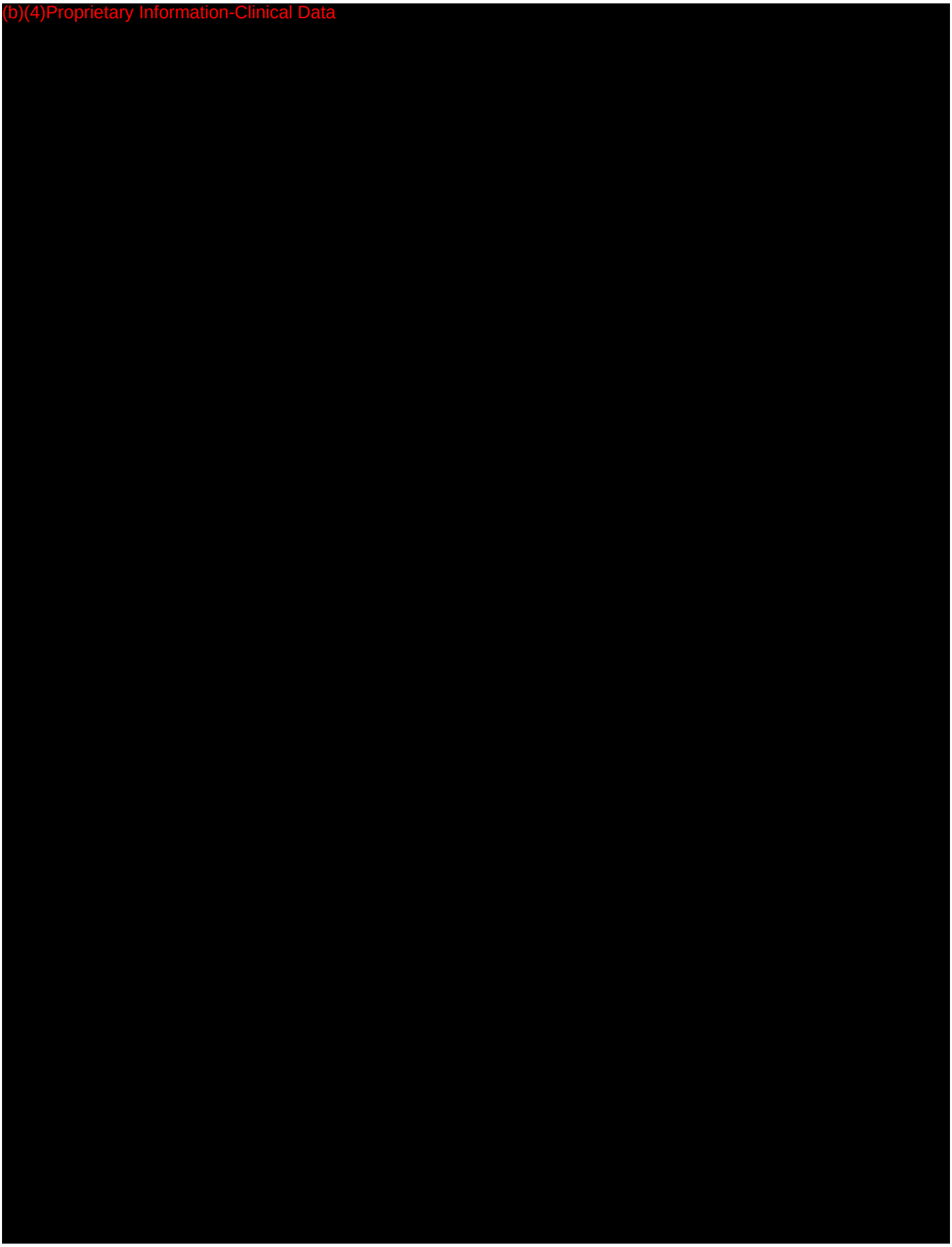
(b)(4)Proprietary Information-Clinical Data



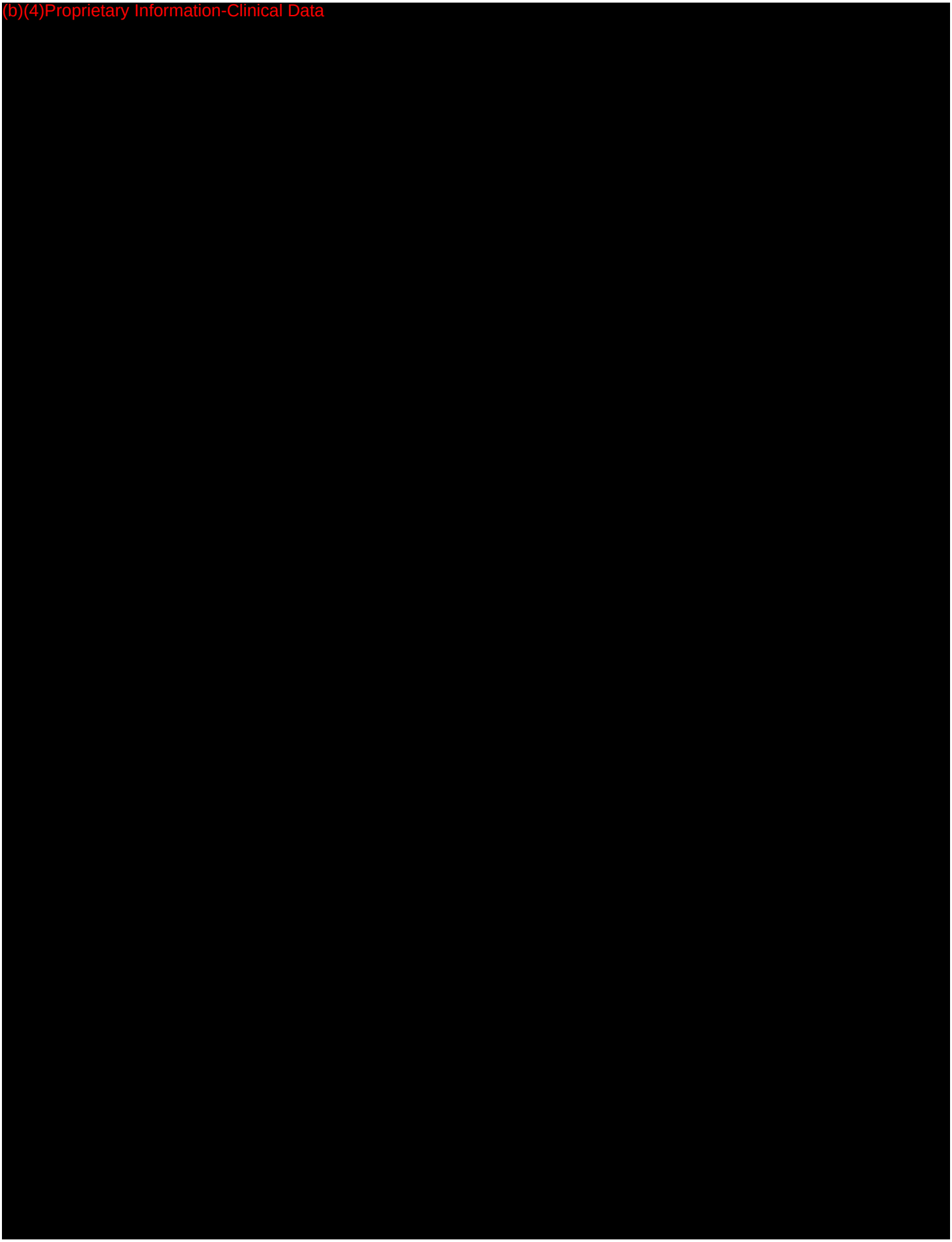


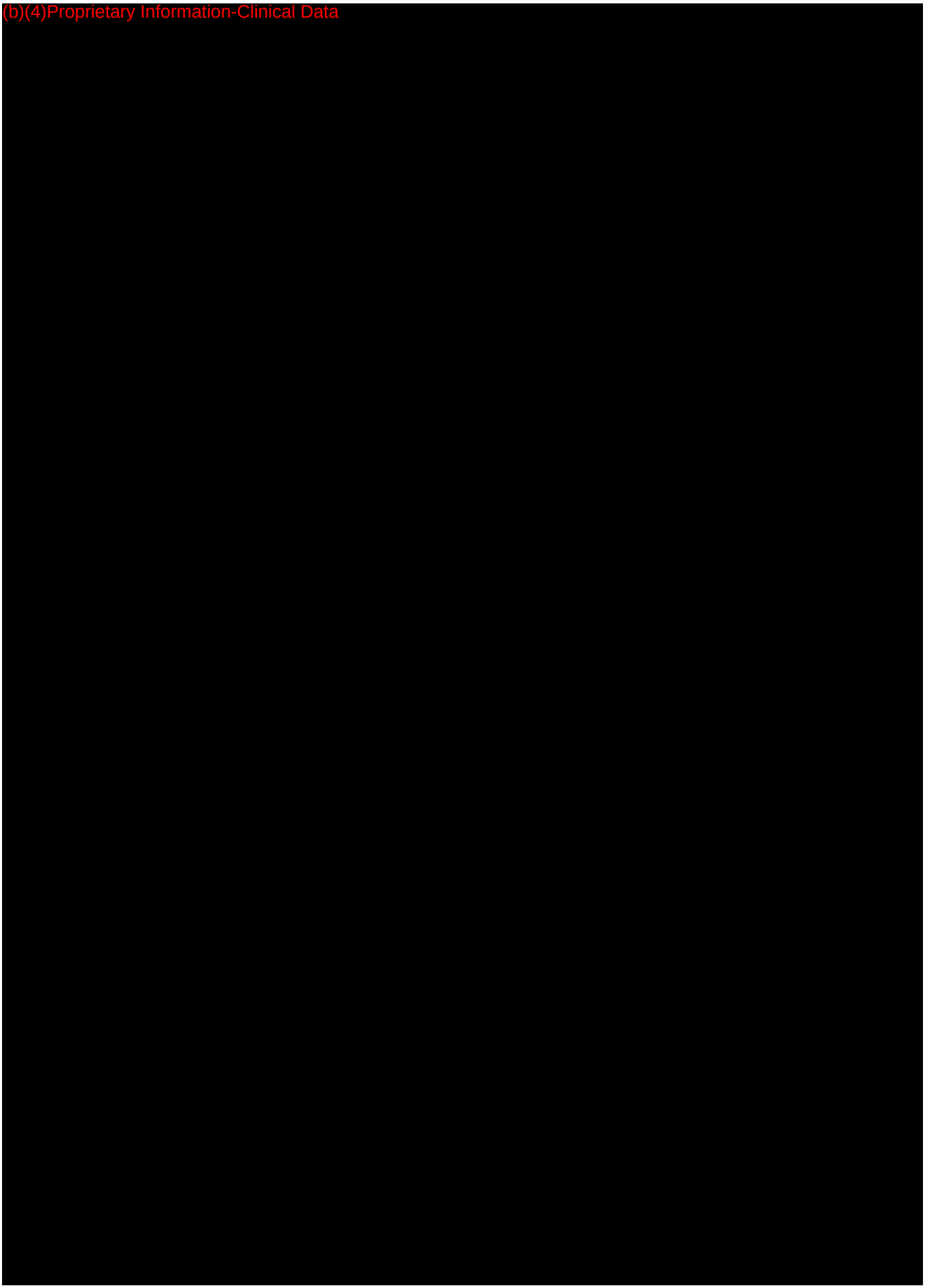


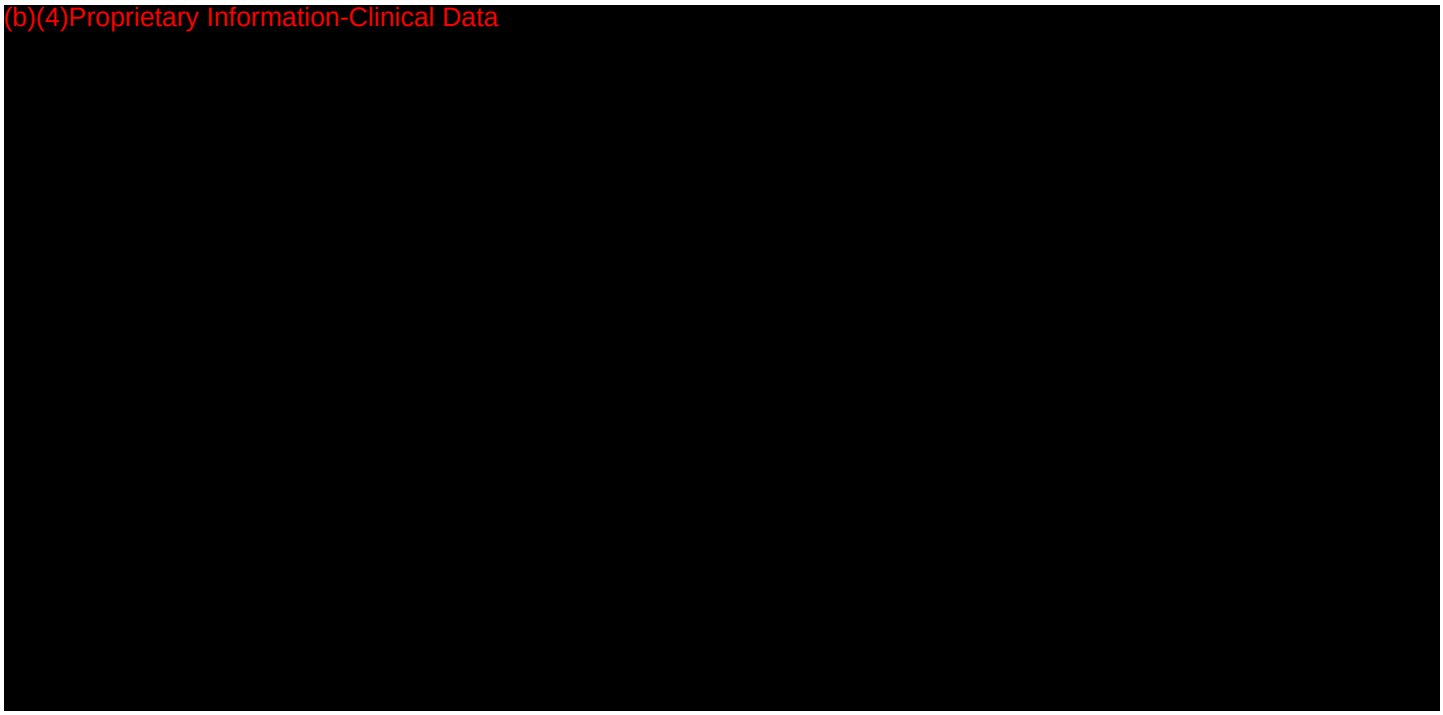


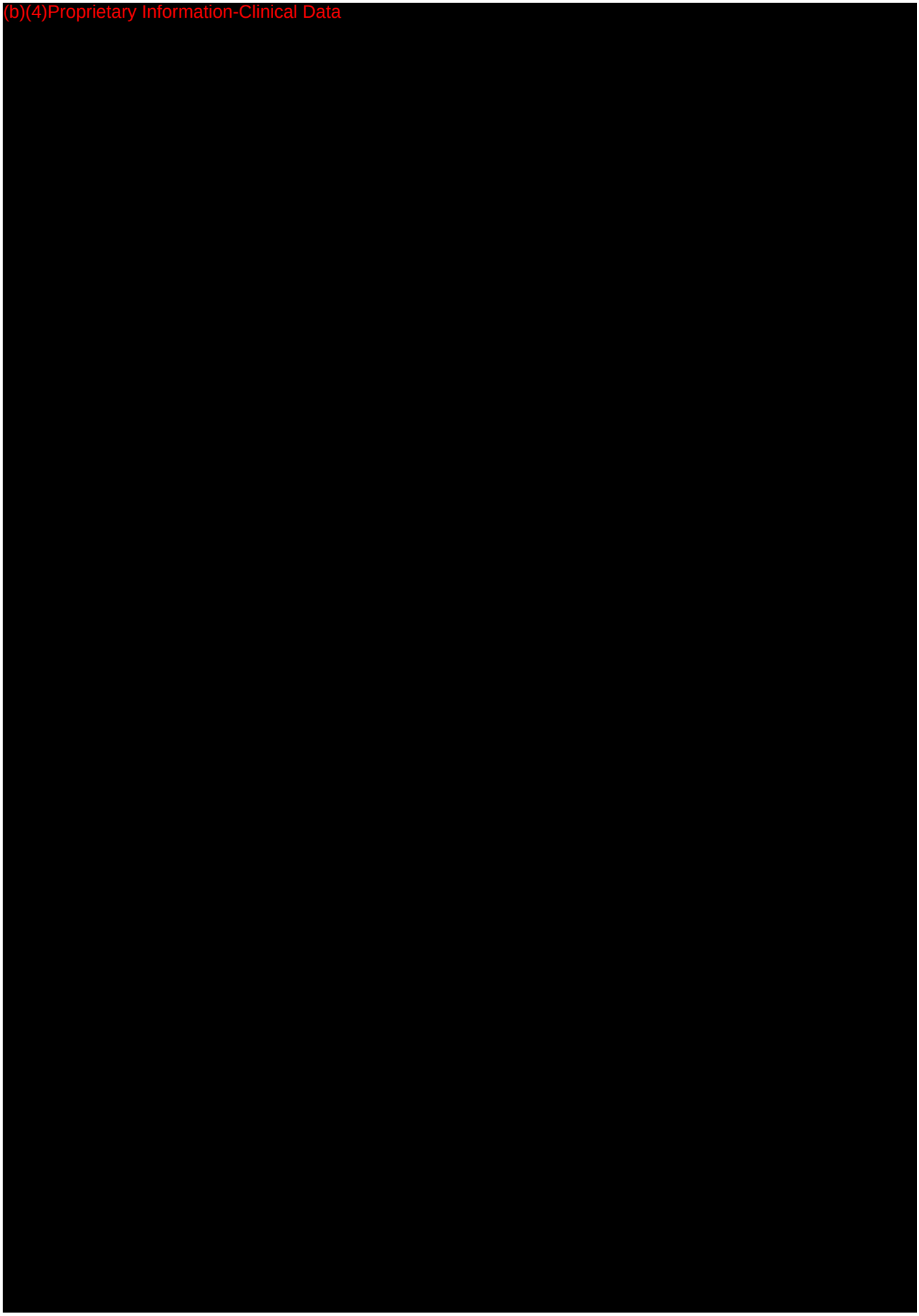


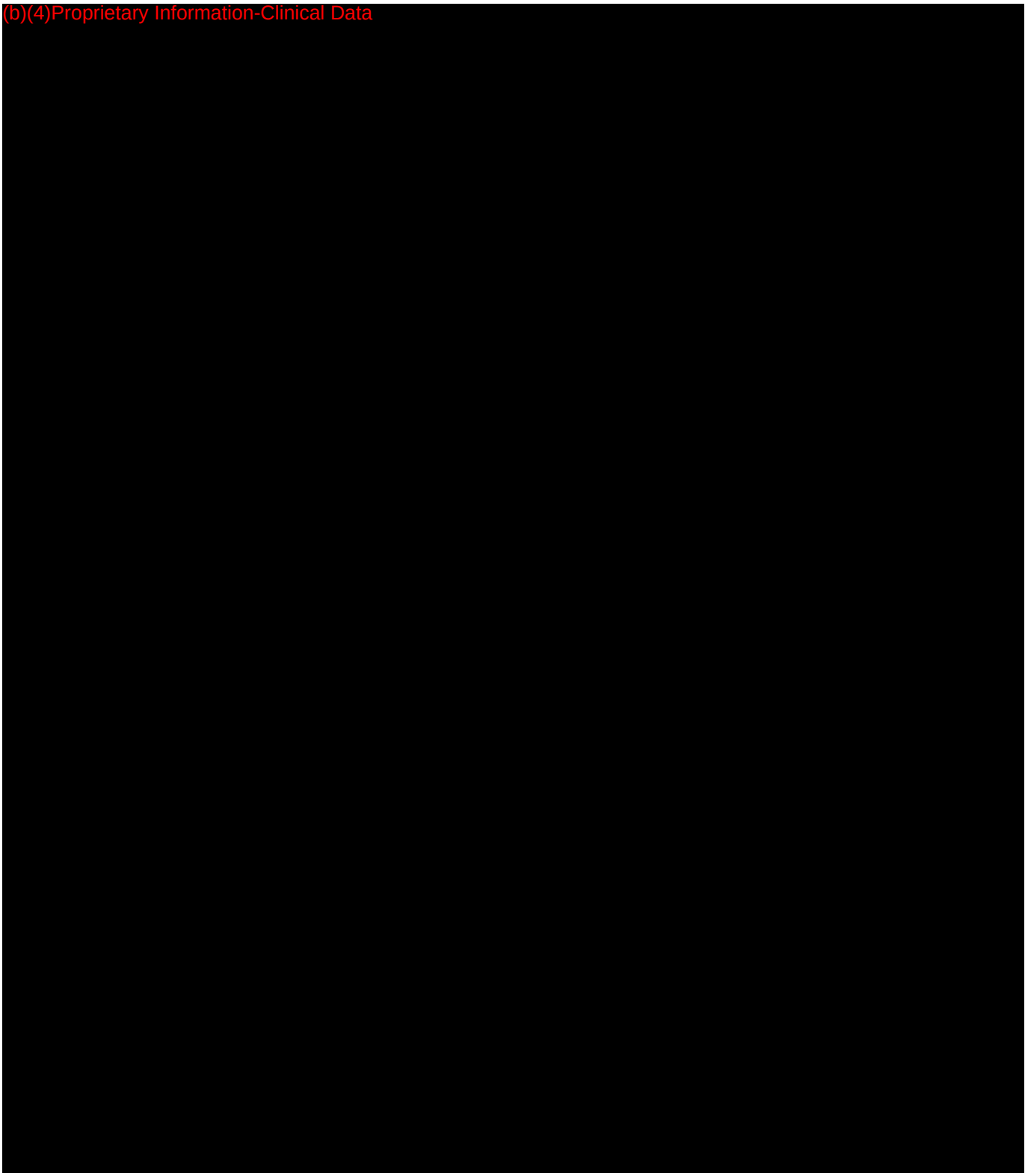
(b)(4)Proprietary Information-Clinical Data



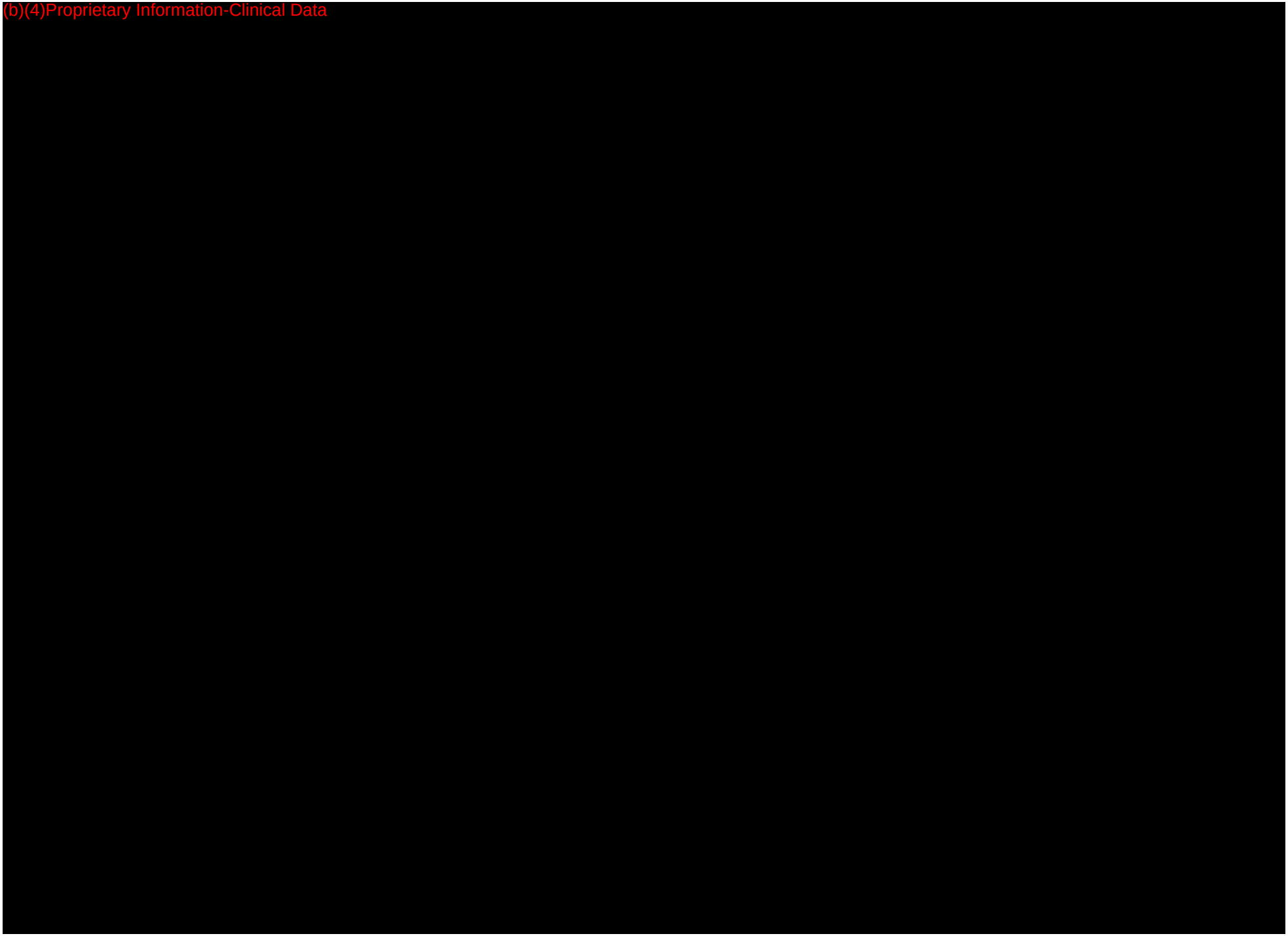


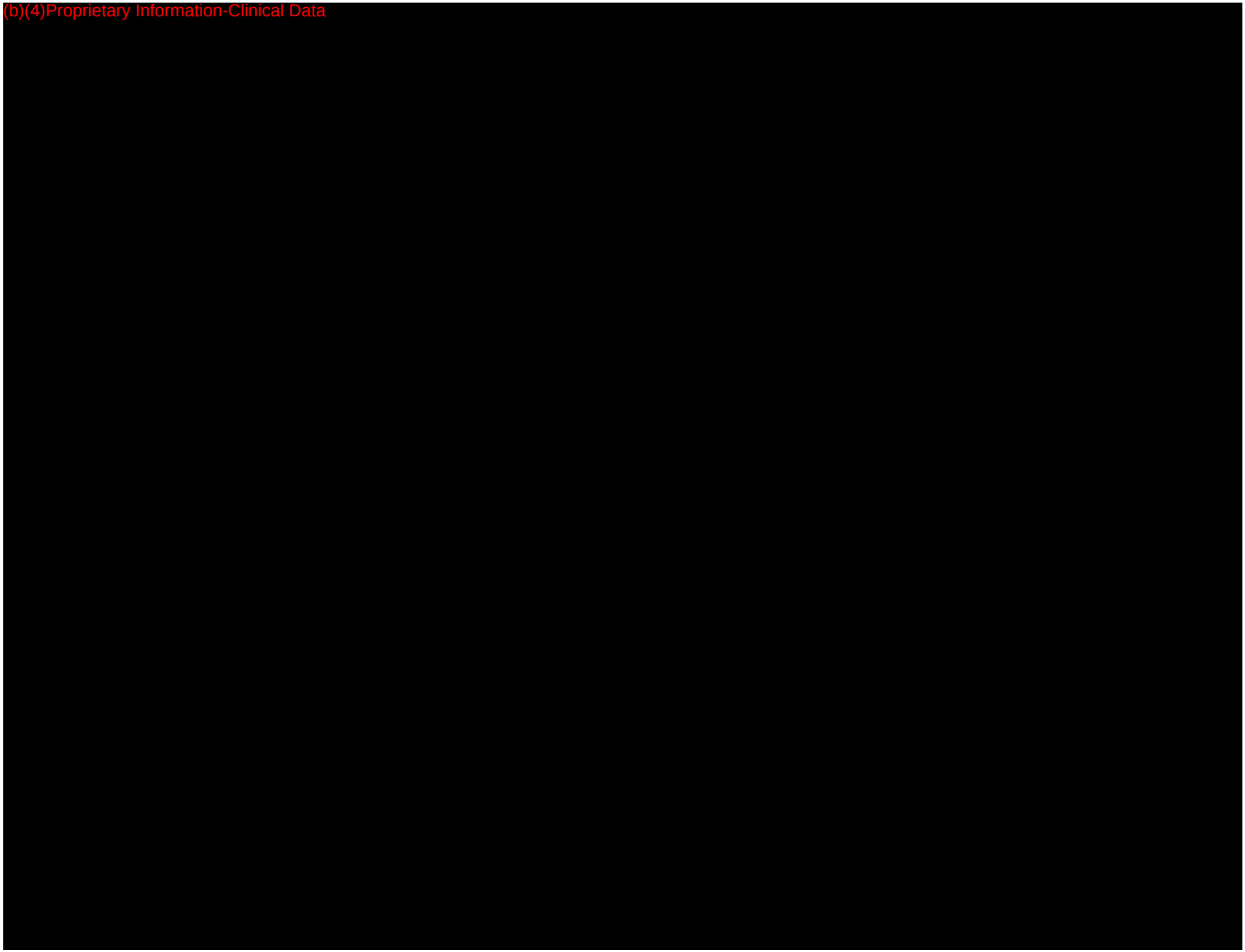


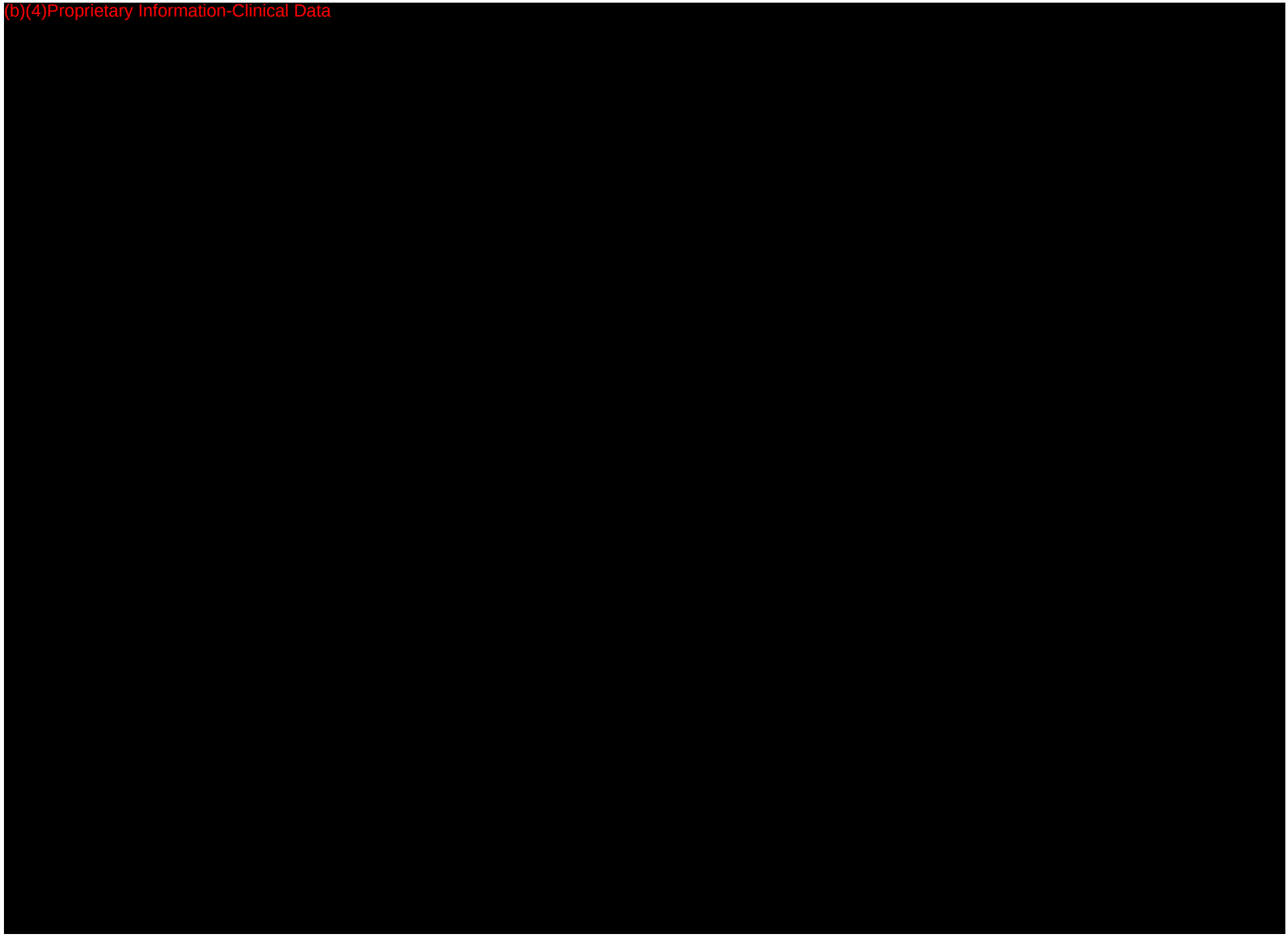


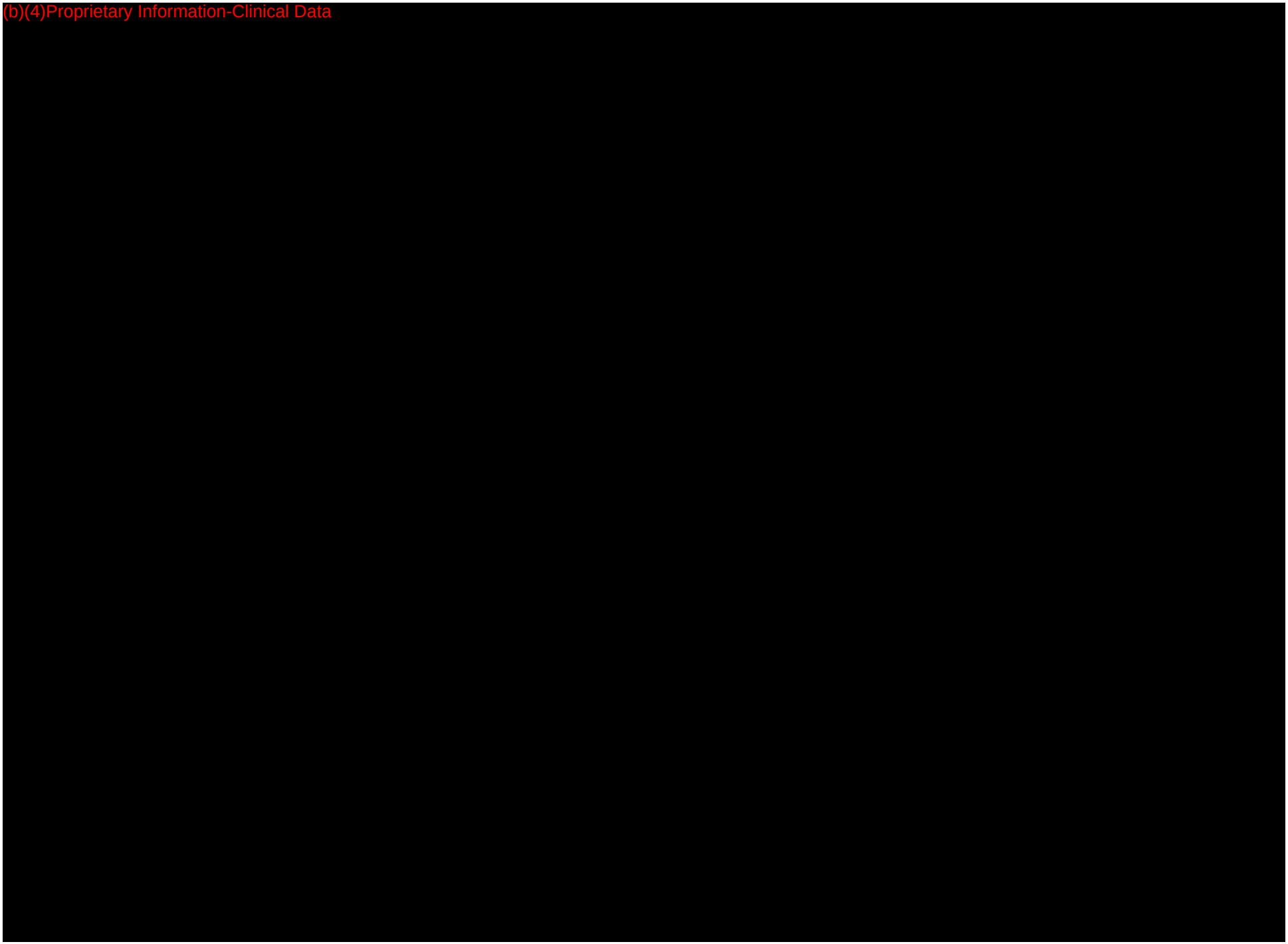


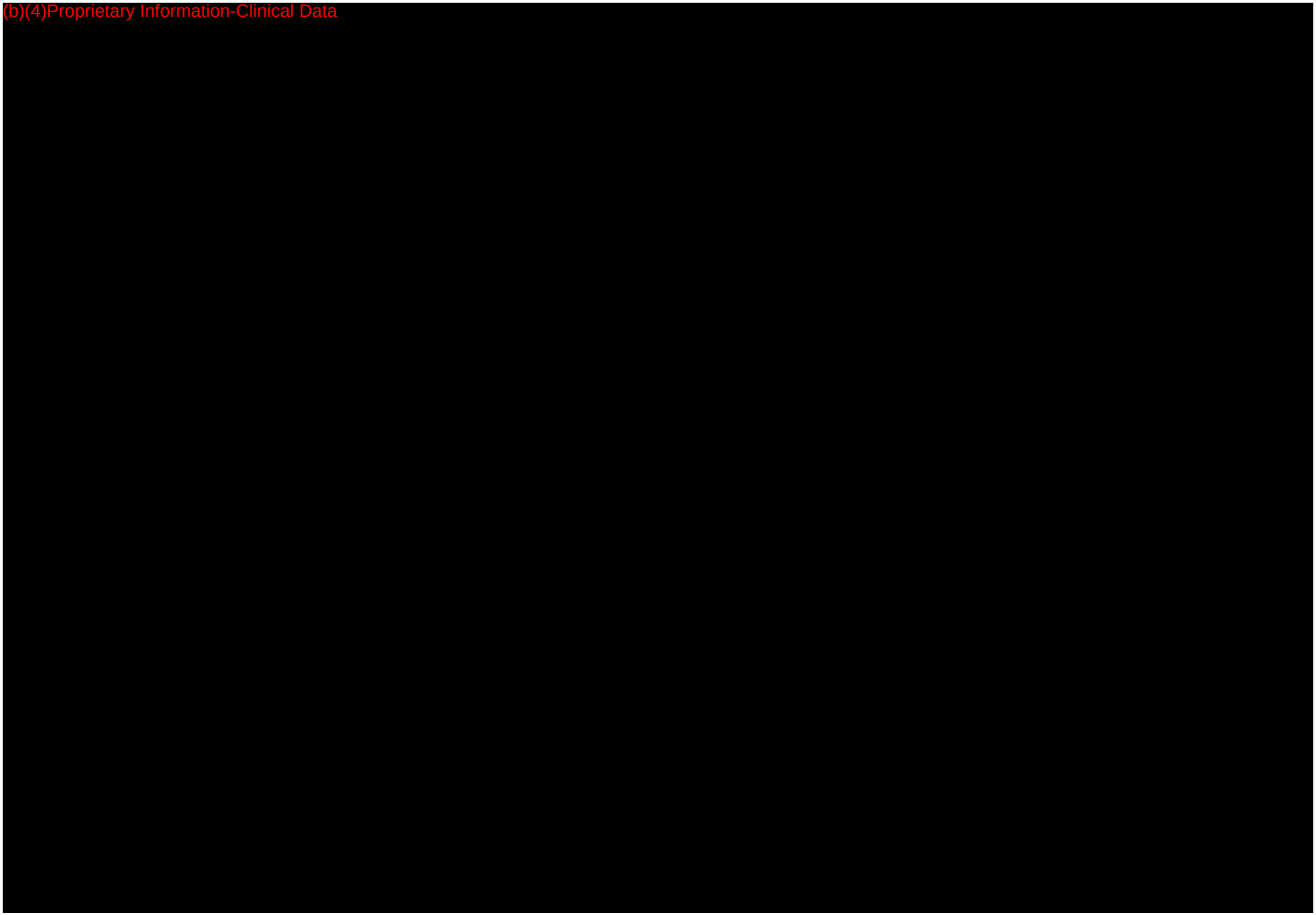
(b)(4)Proprietary Information-Clinical Data

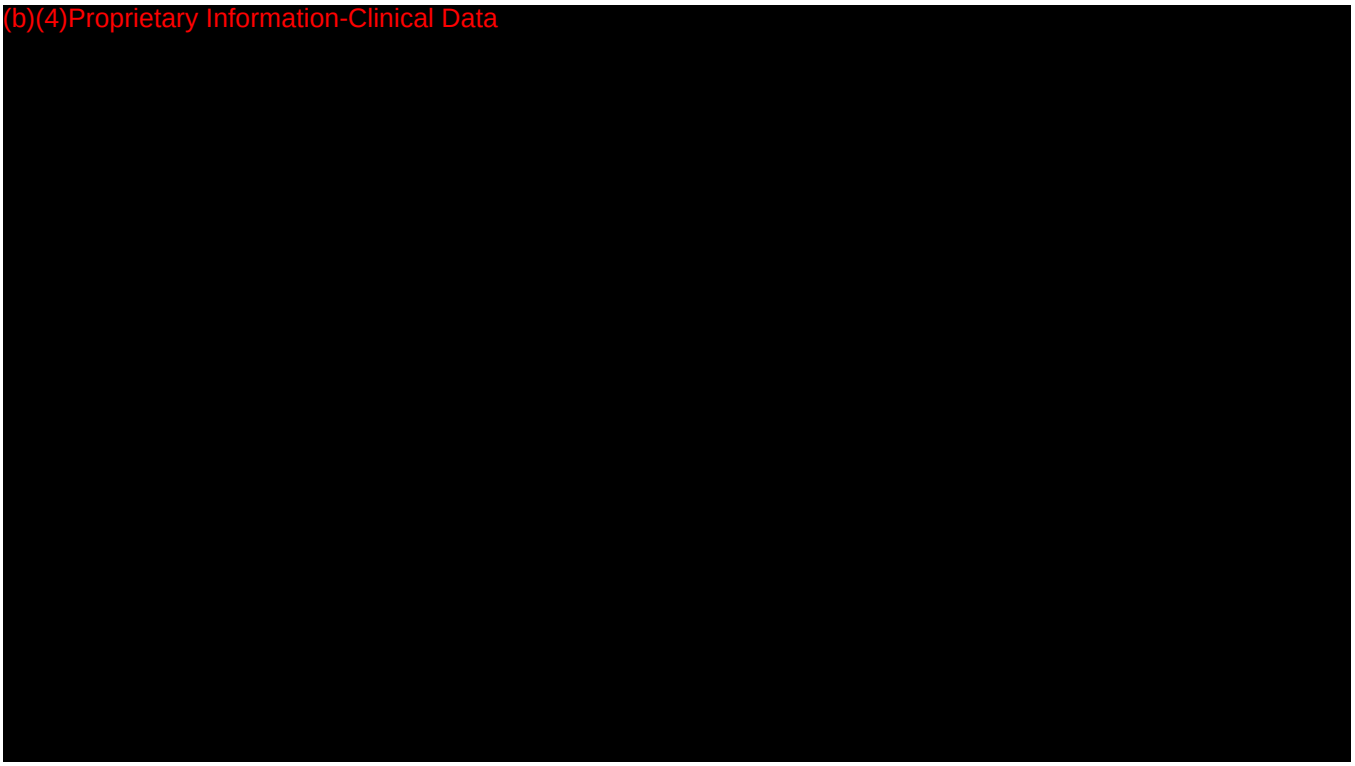




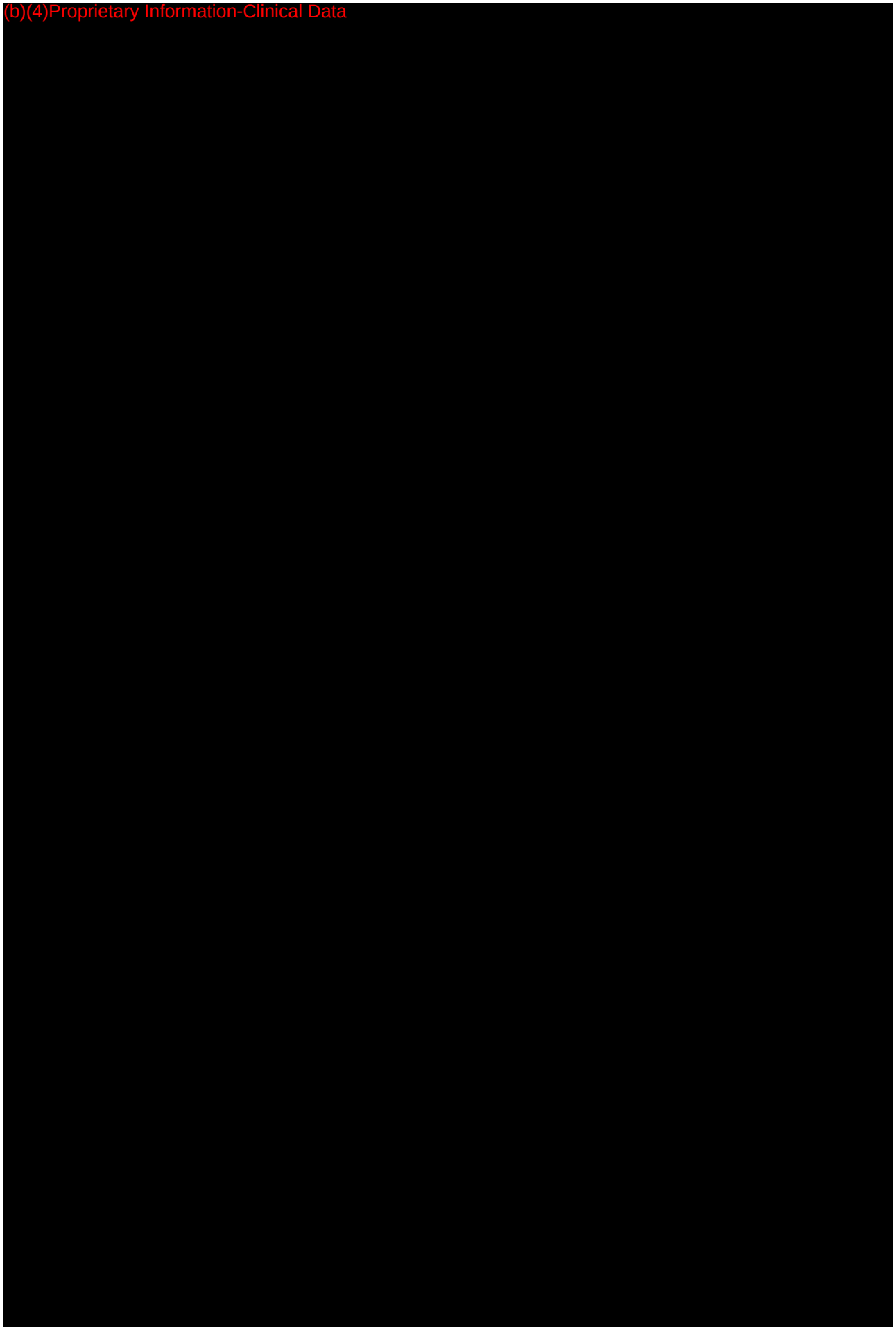




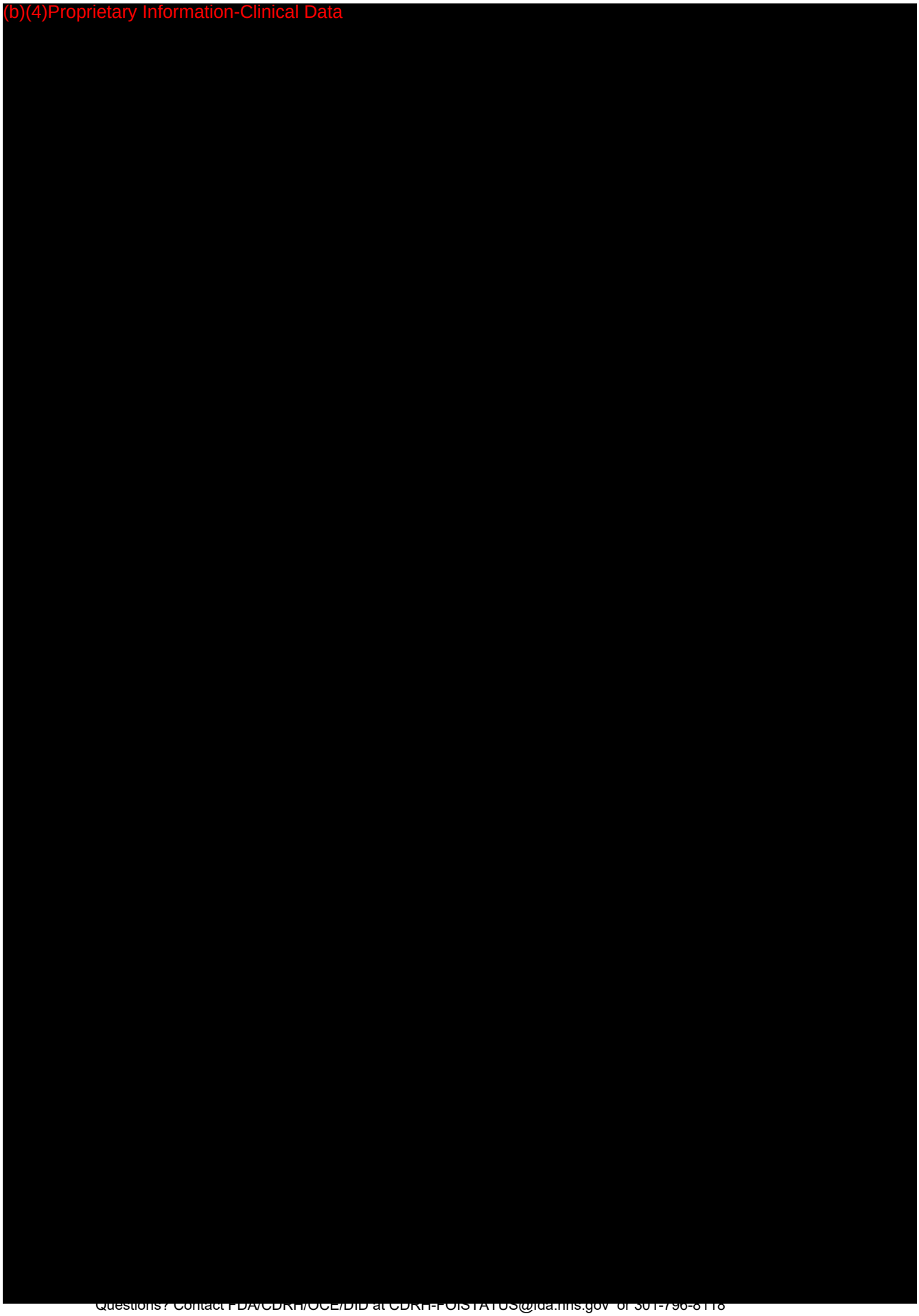


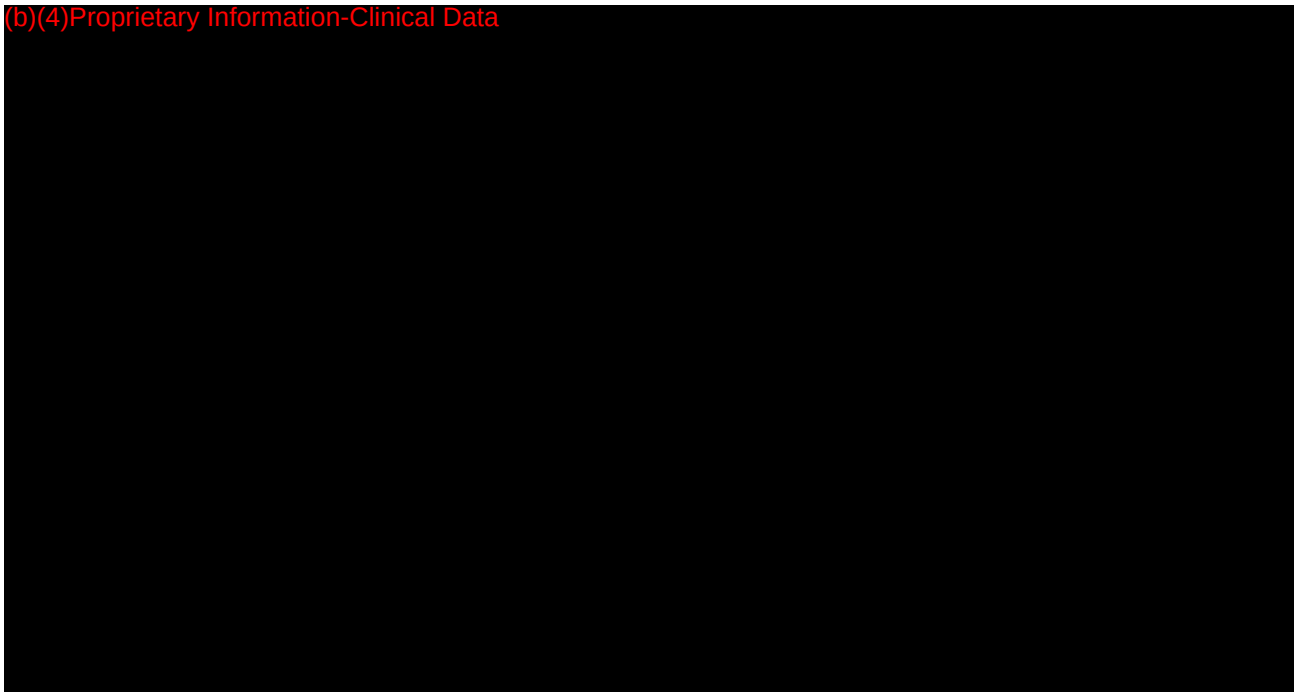


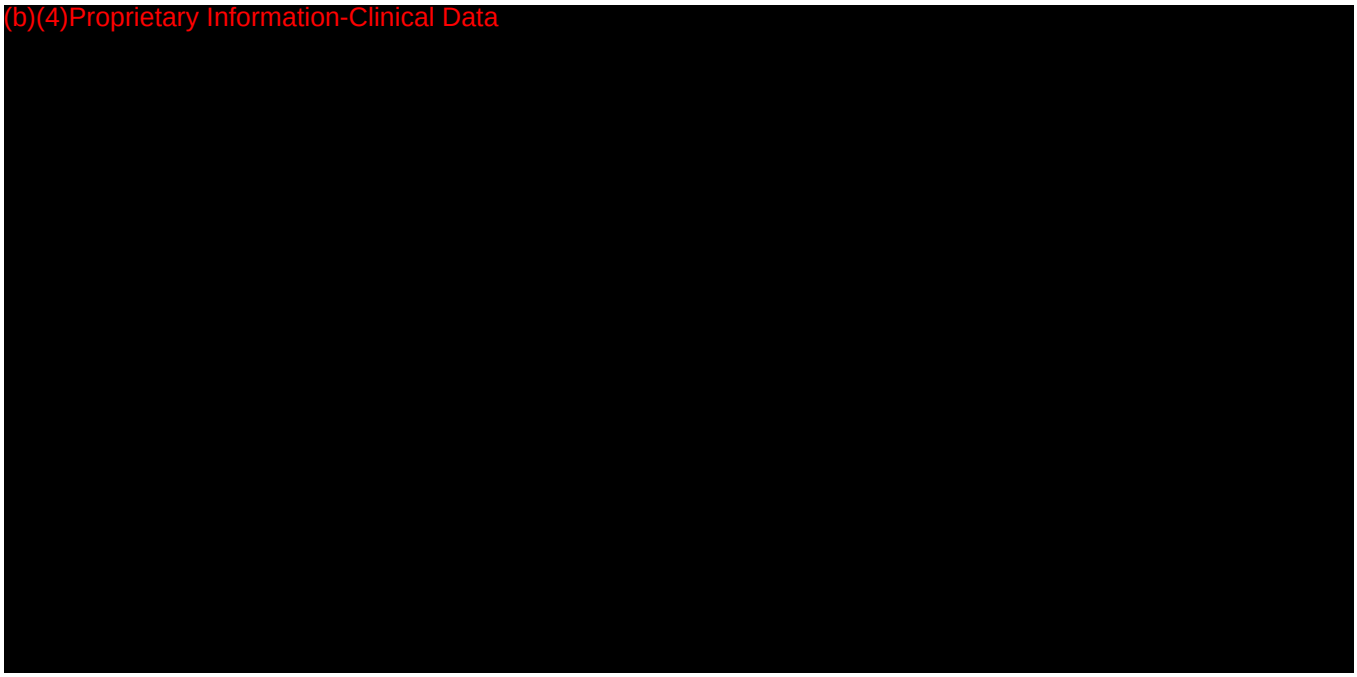
(b)(4)Proprietary Information-Clinical Data

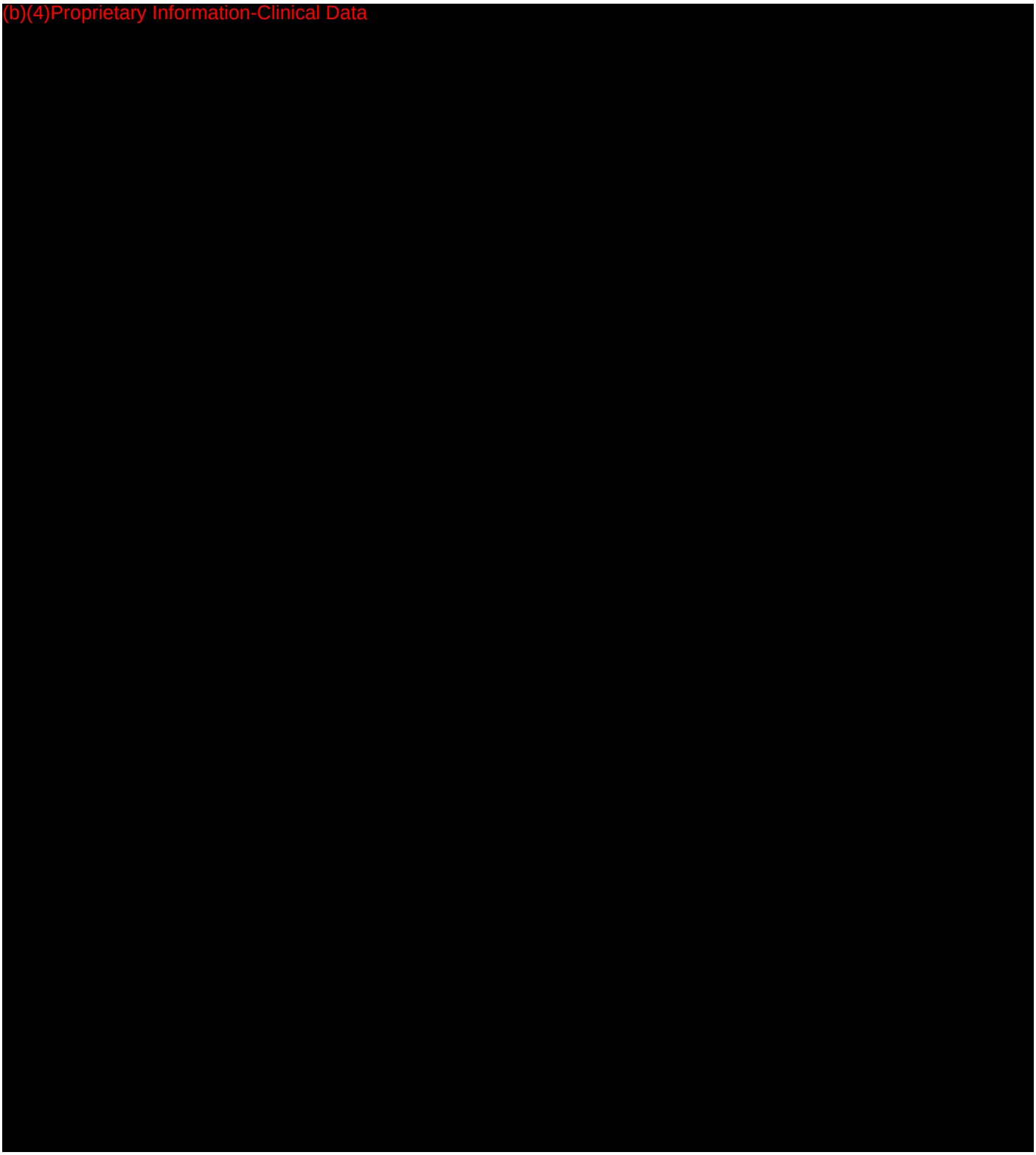


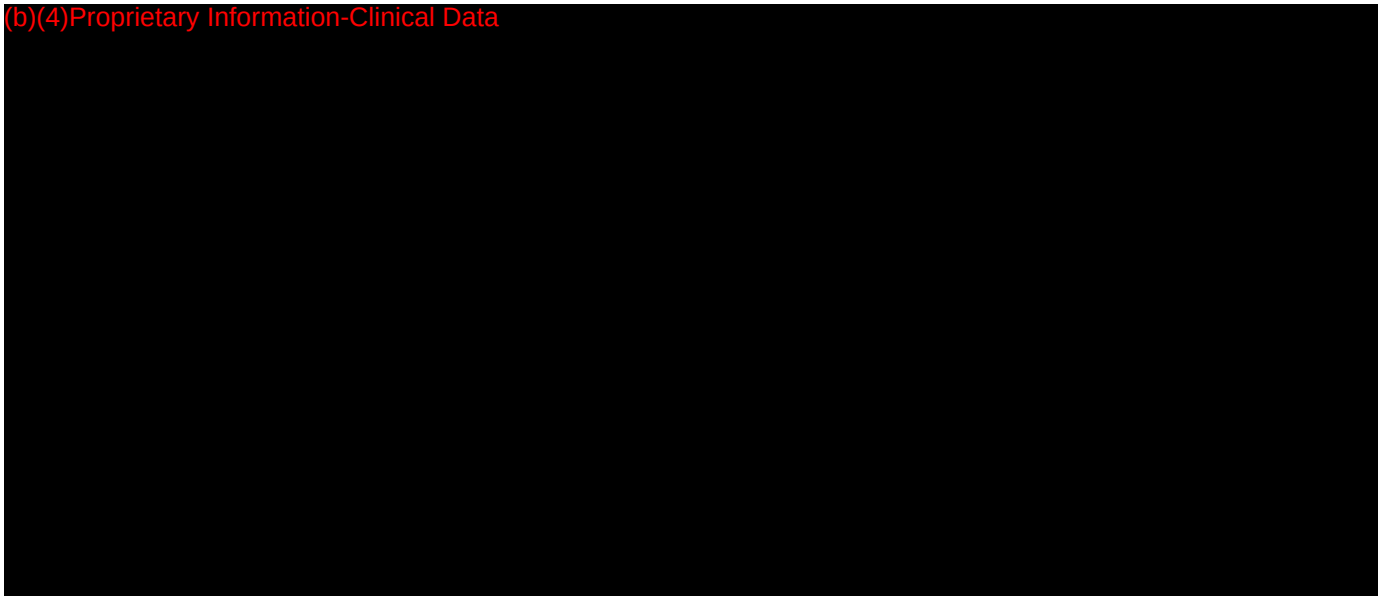
(b)(4)Proprietary Information-Clinical Data

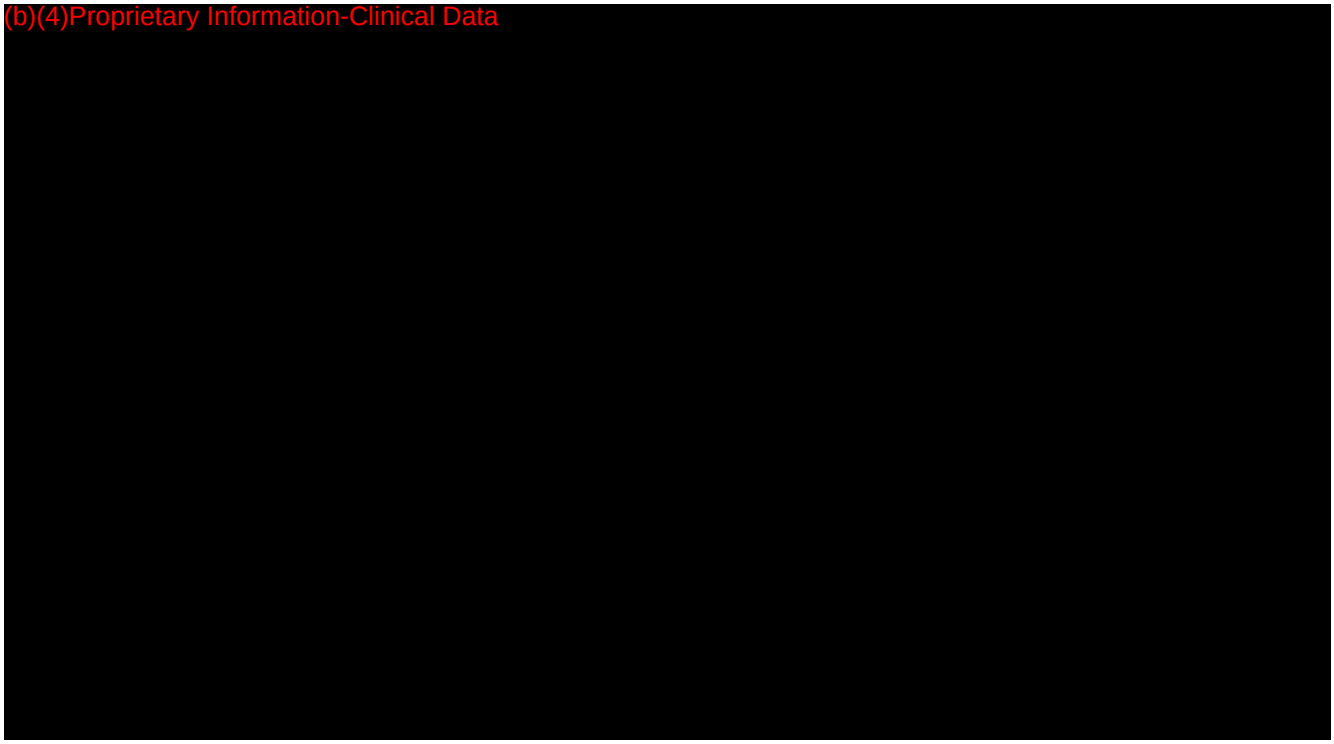


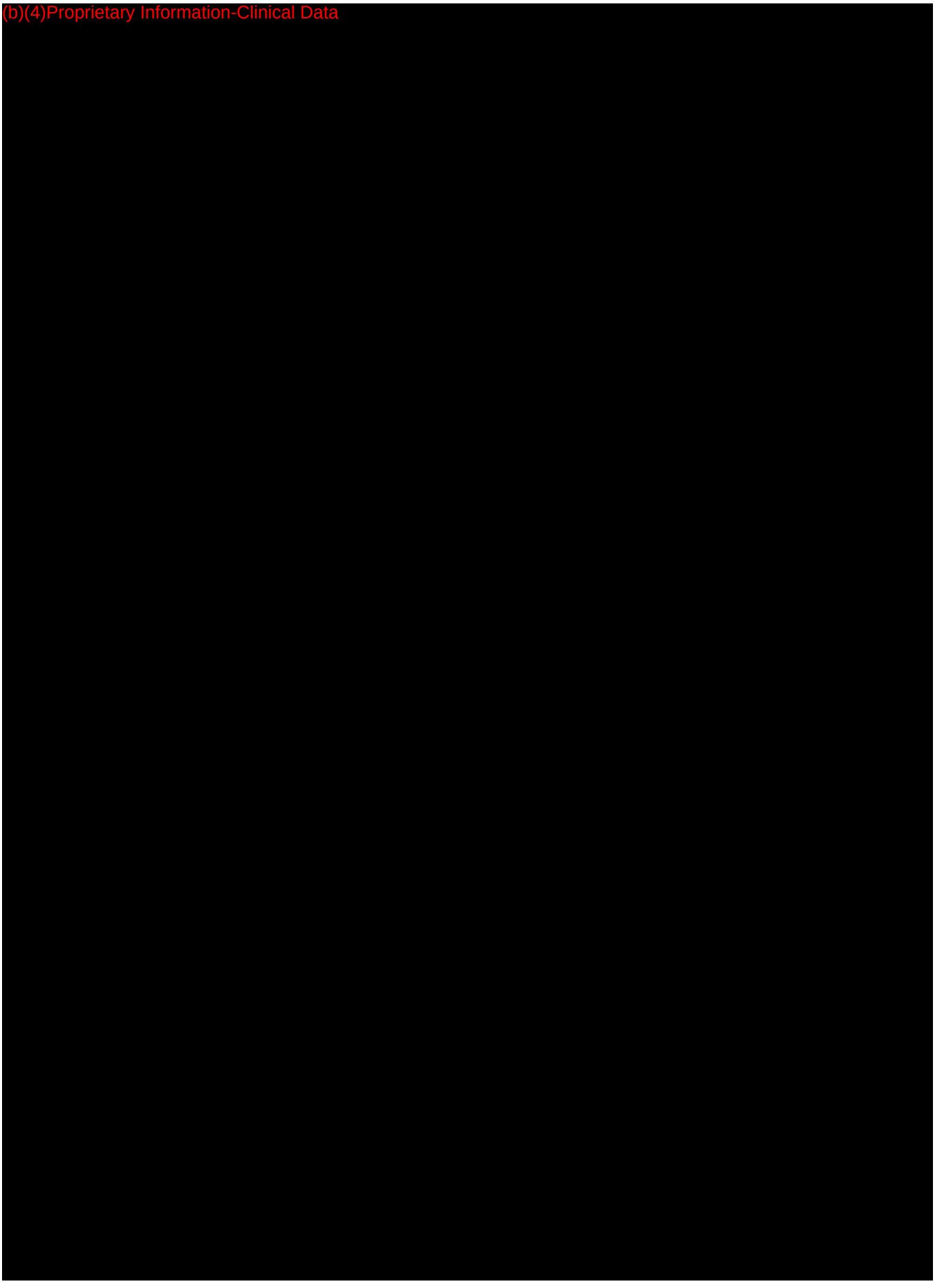




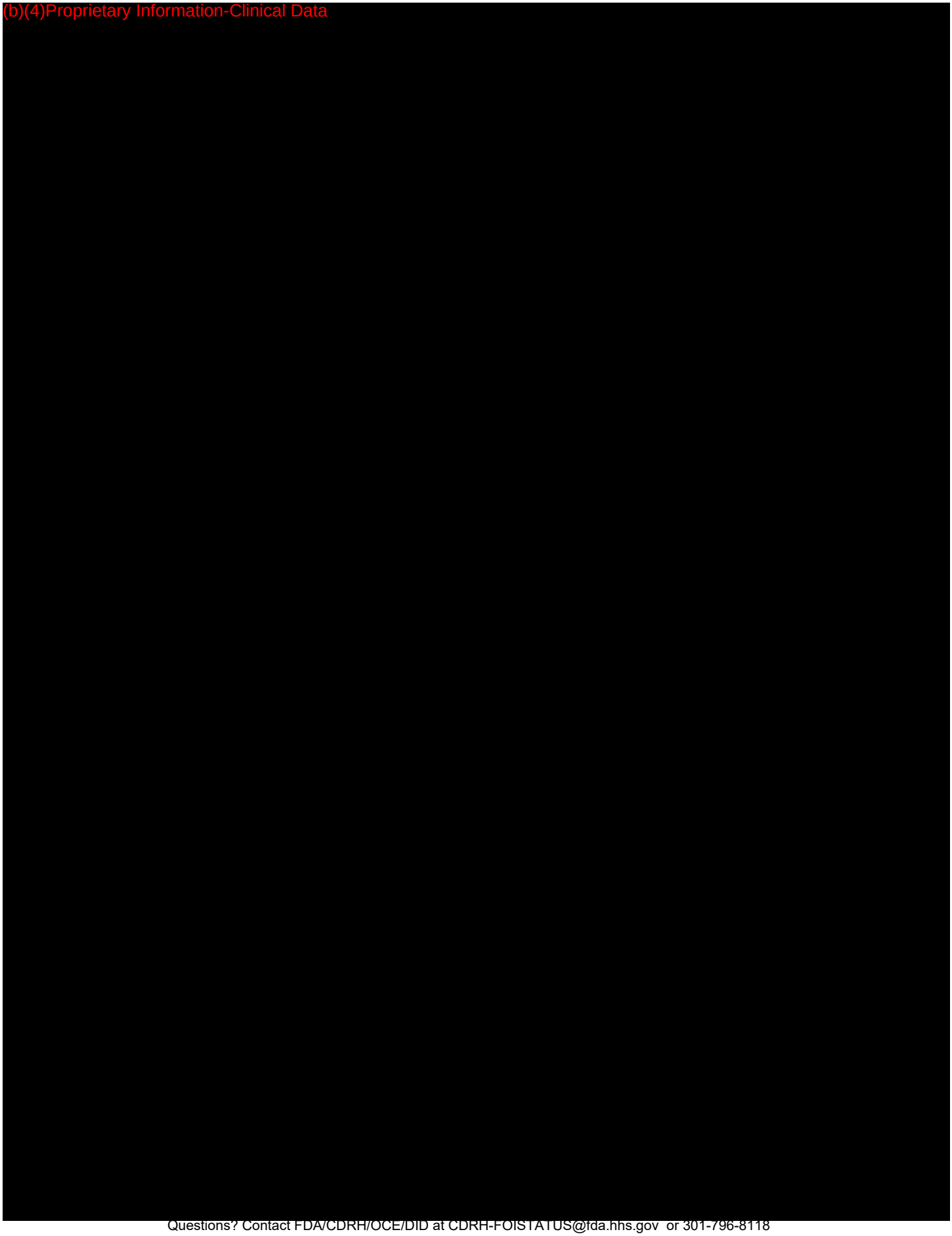




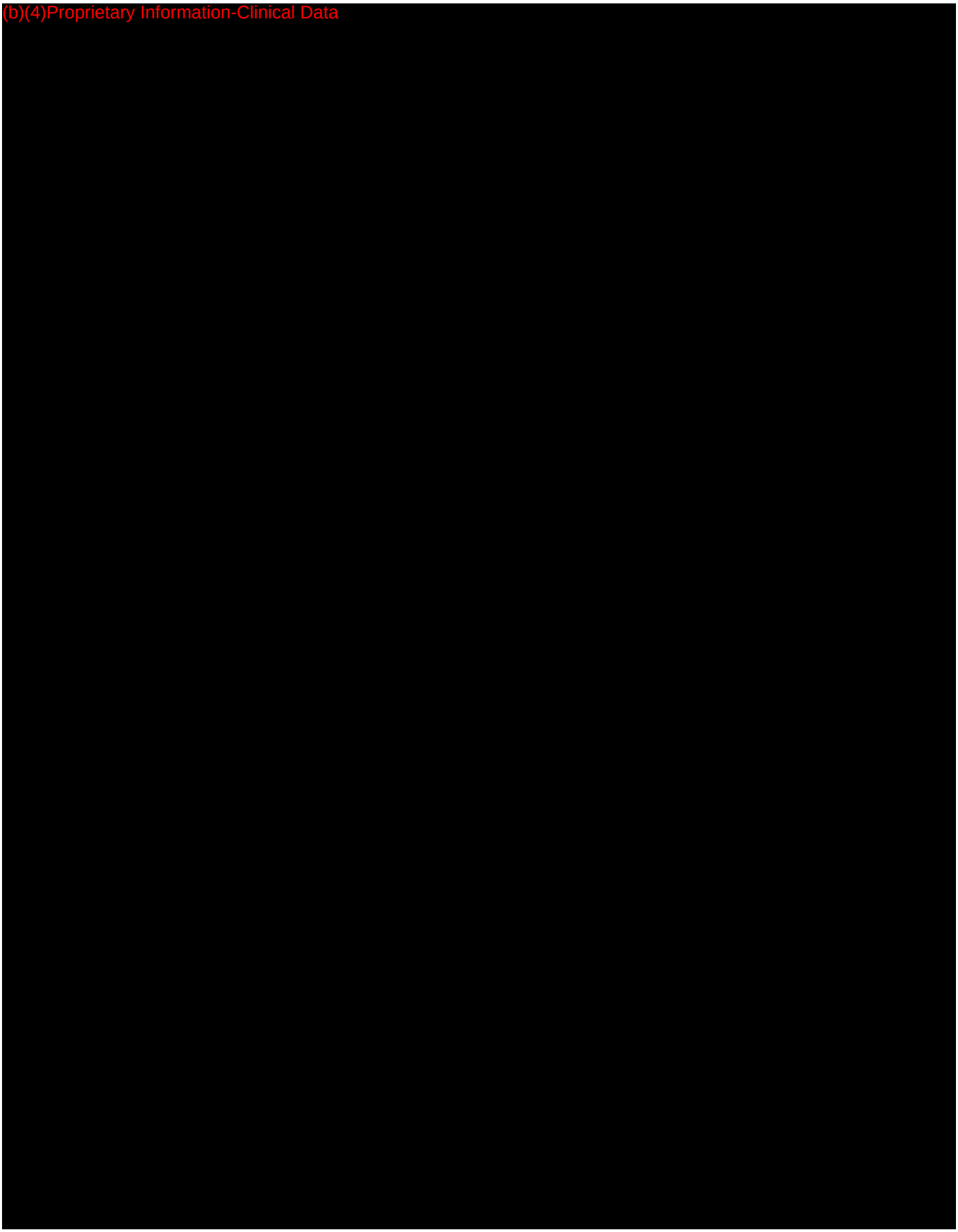


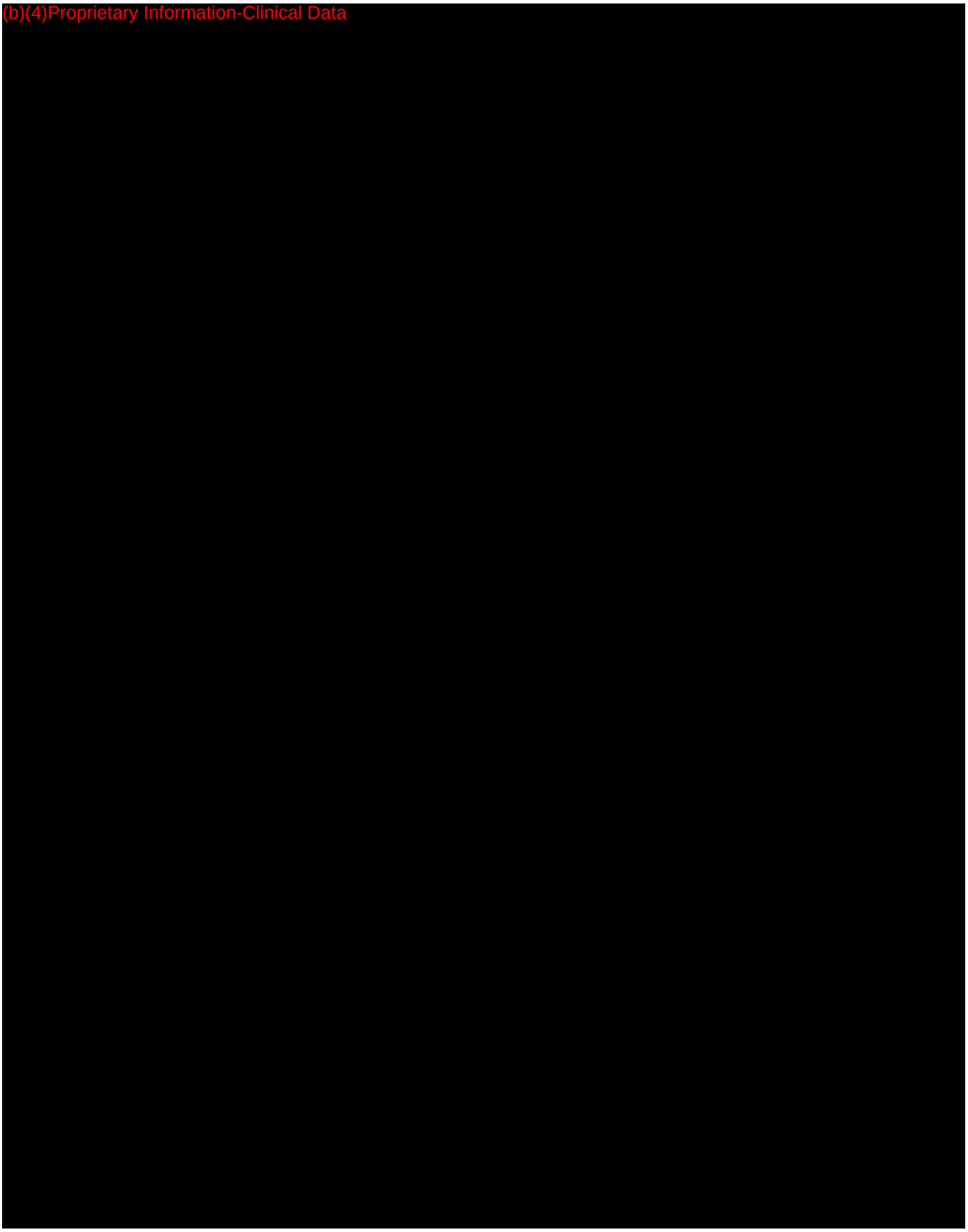


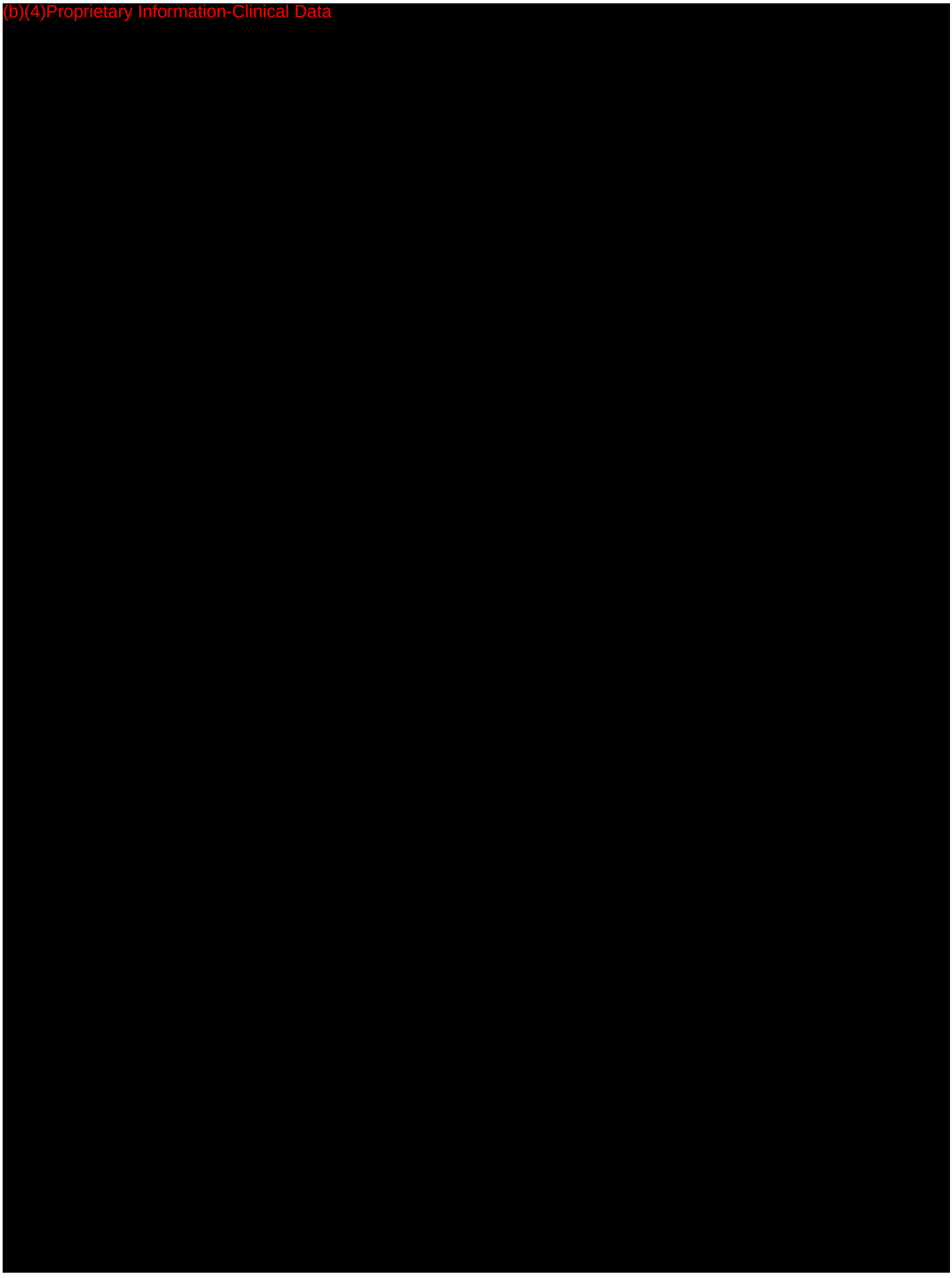
(b)(4)Proprietary Information-Clinical Data

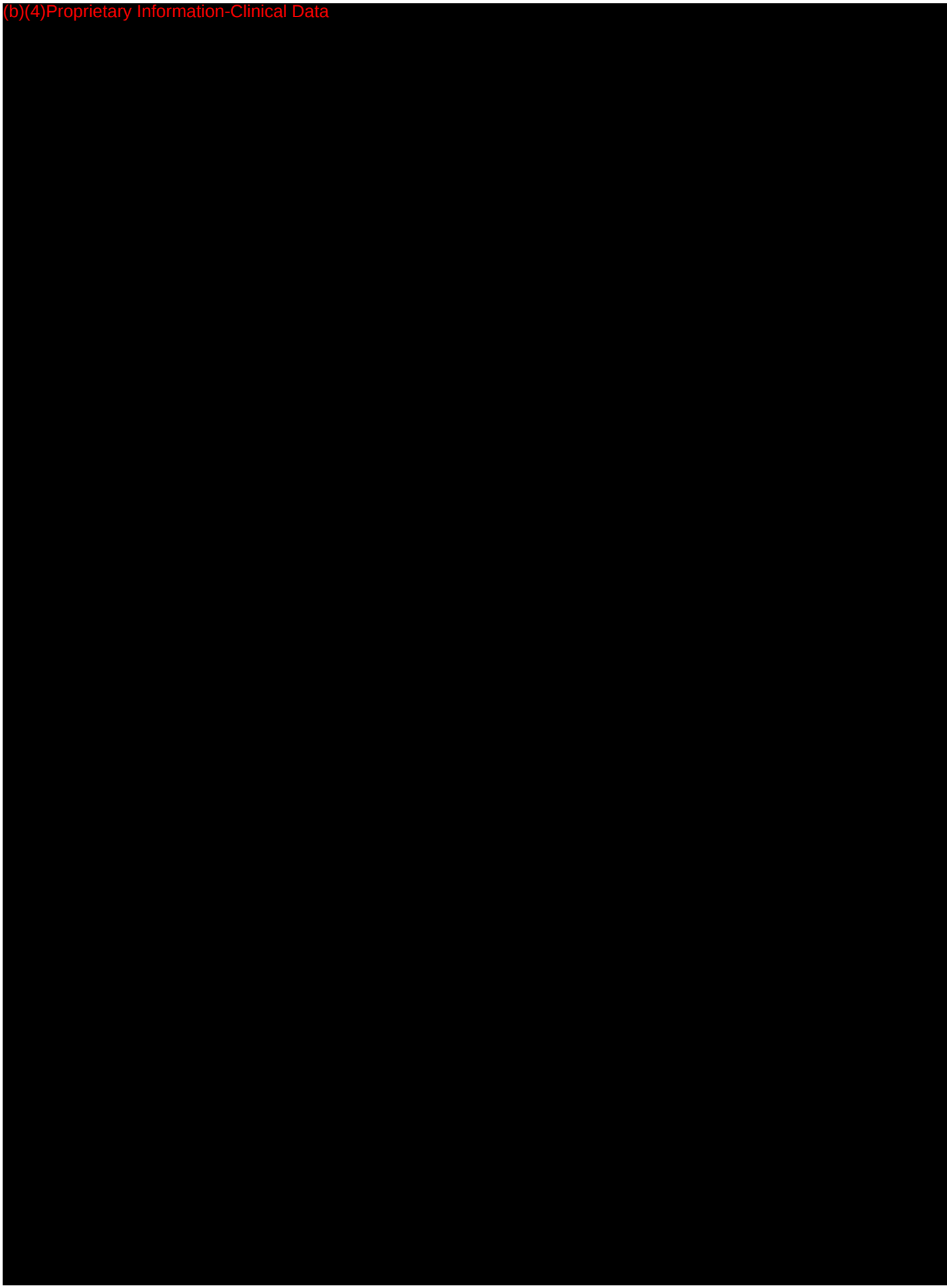


(b)(4)Proprietary Information-Clinical Data

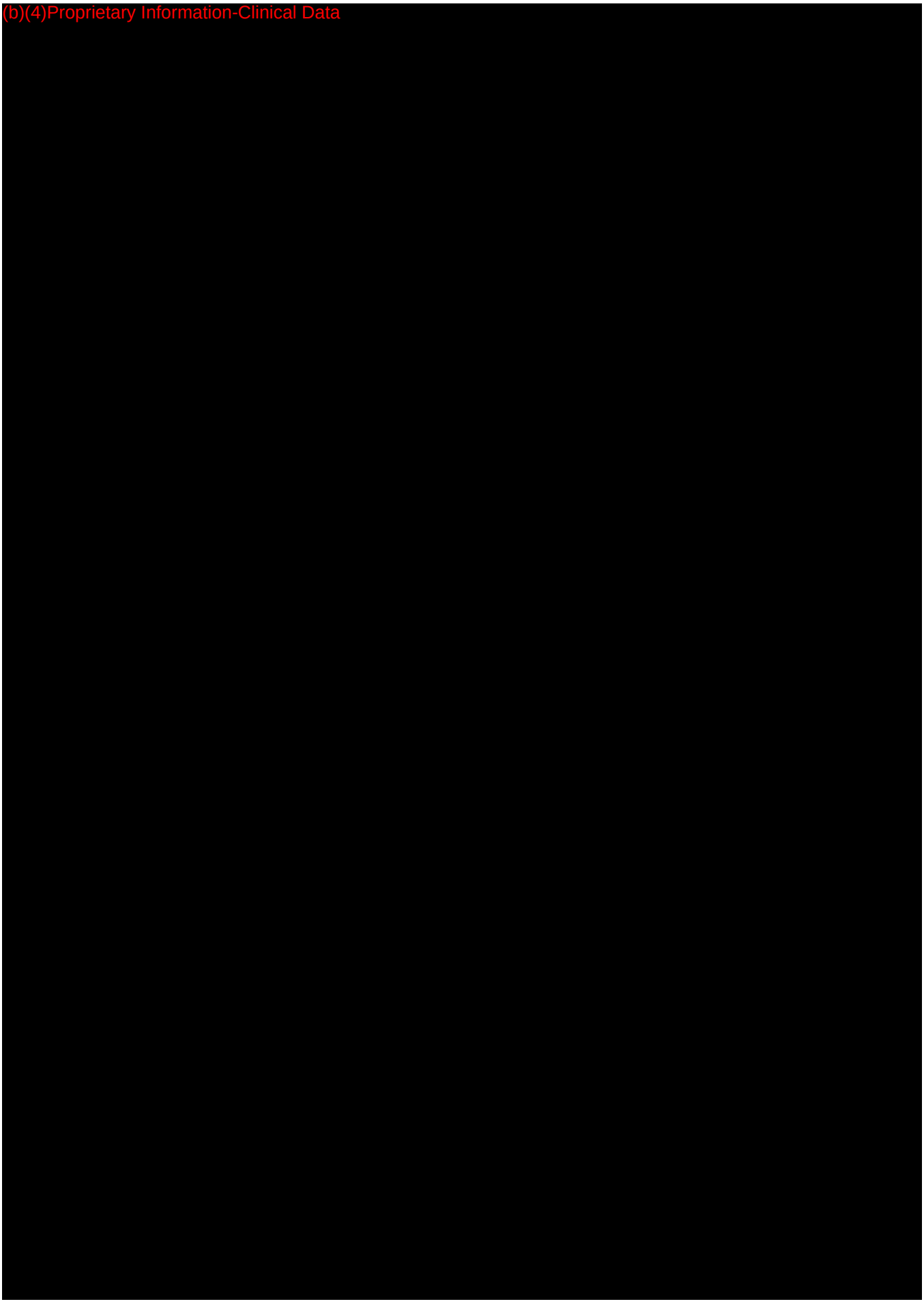


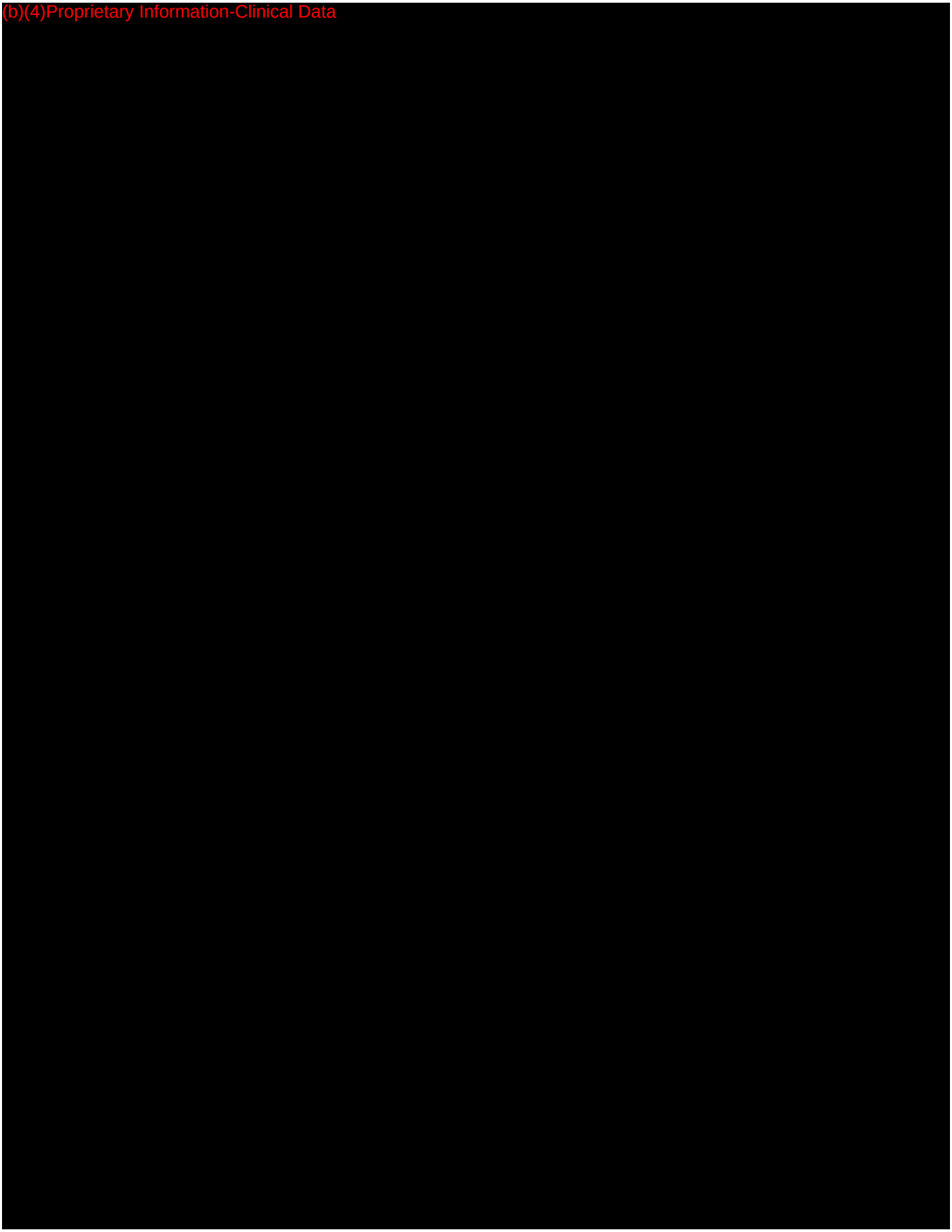




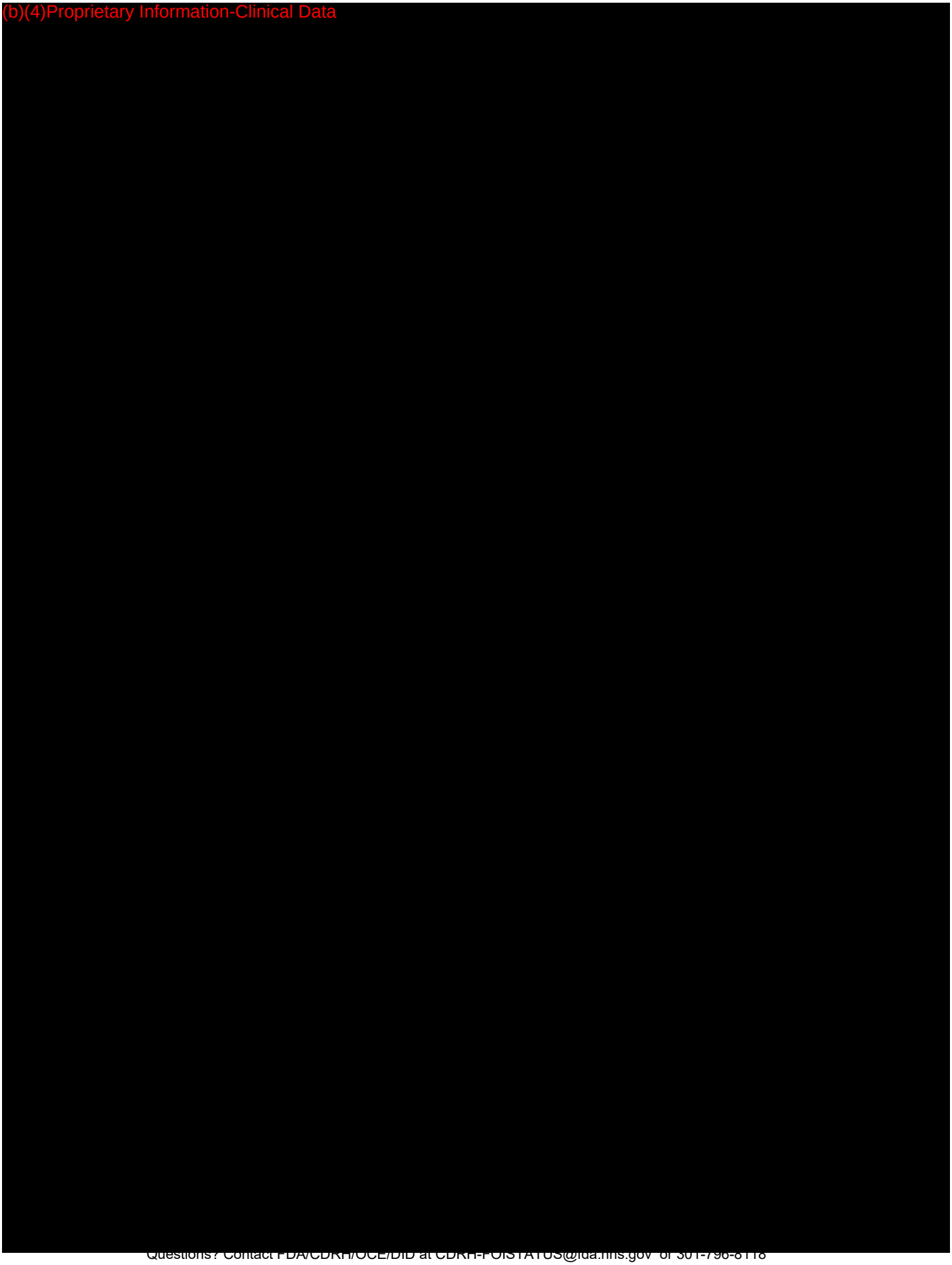


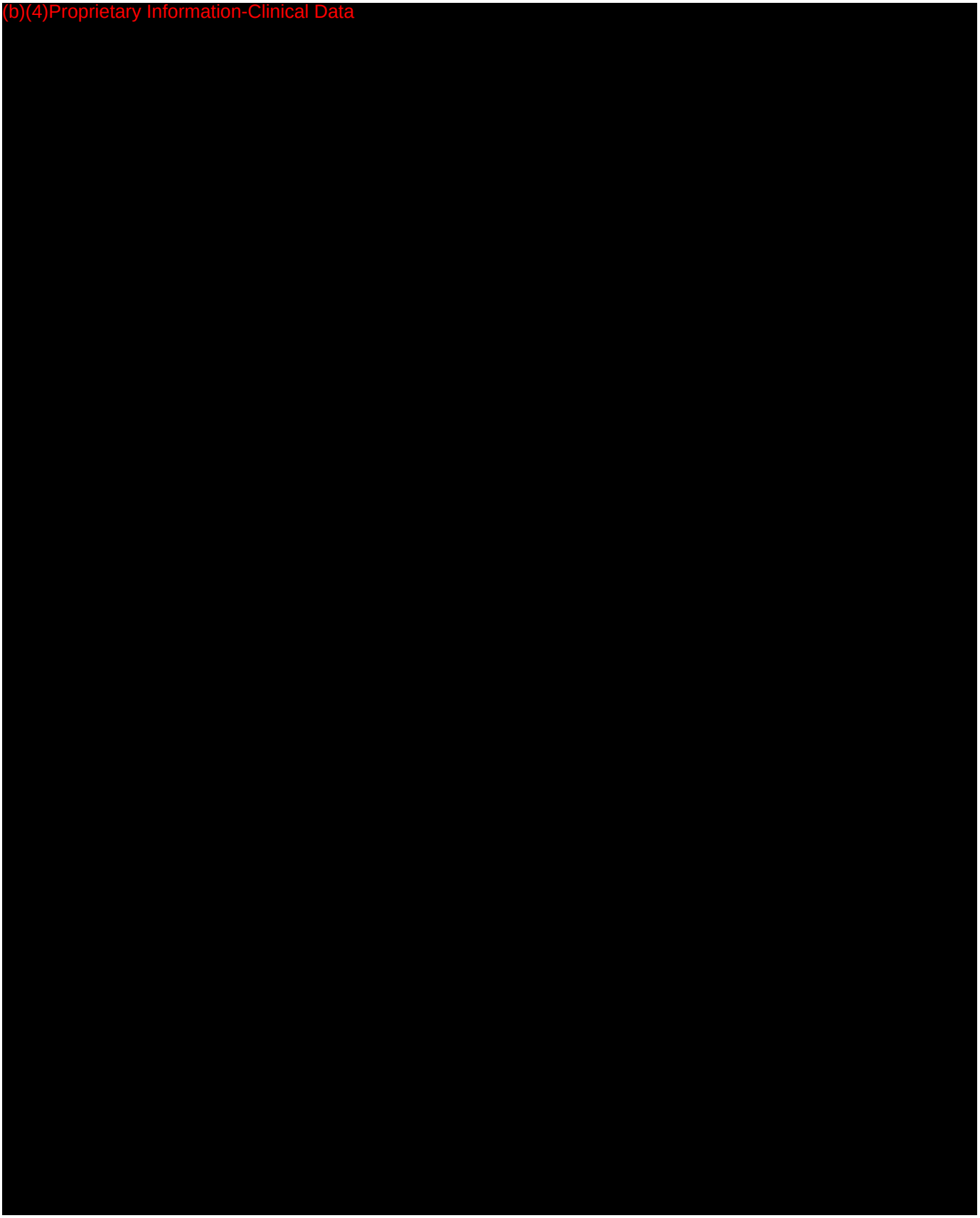
(b)(4)Proprietary Information-Clinical Data



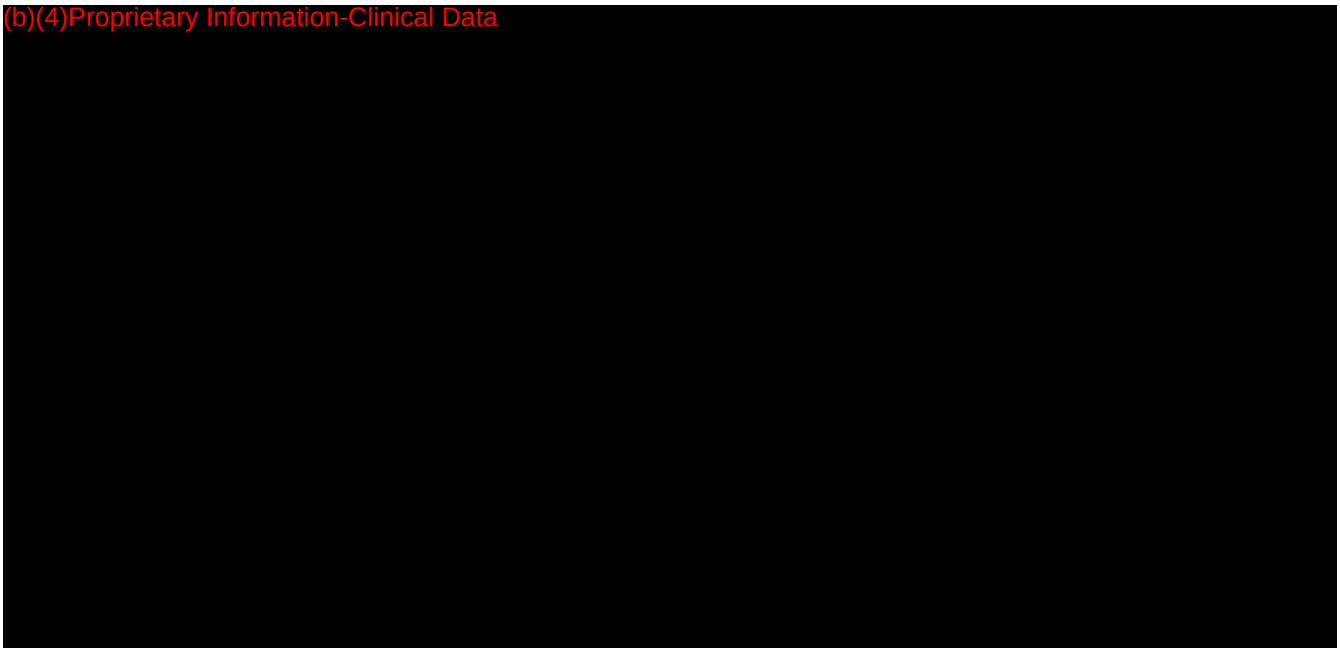


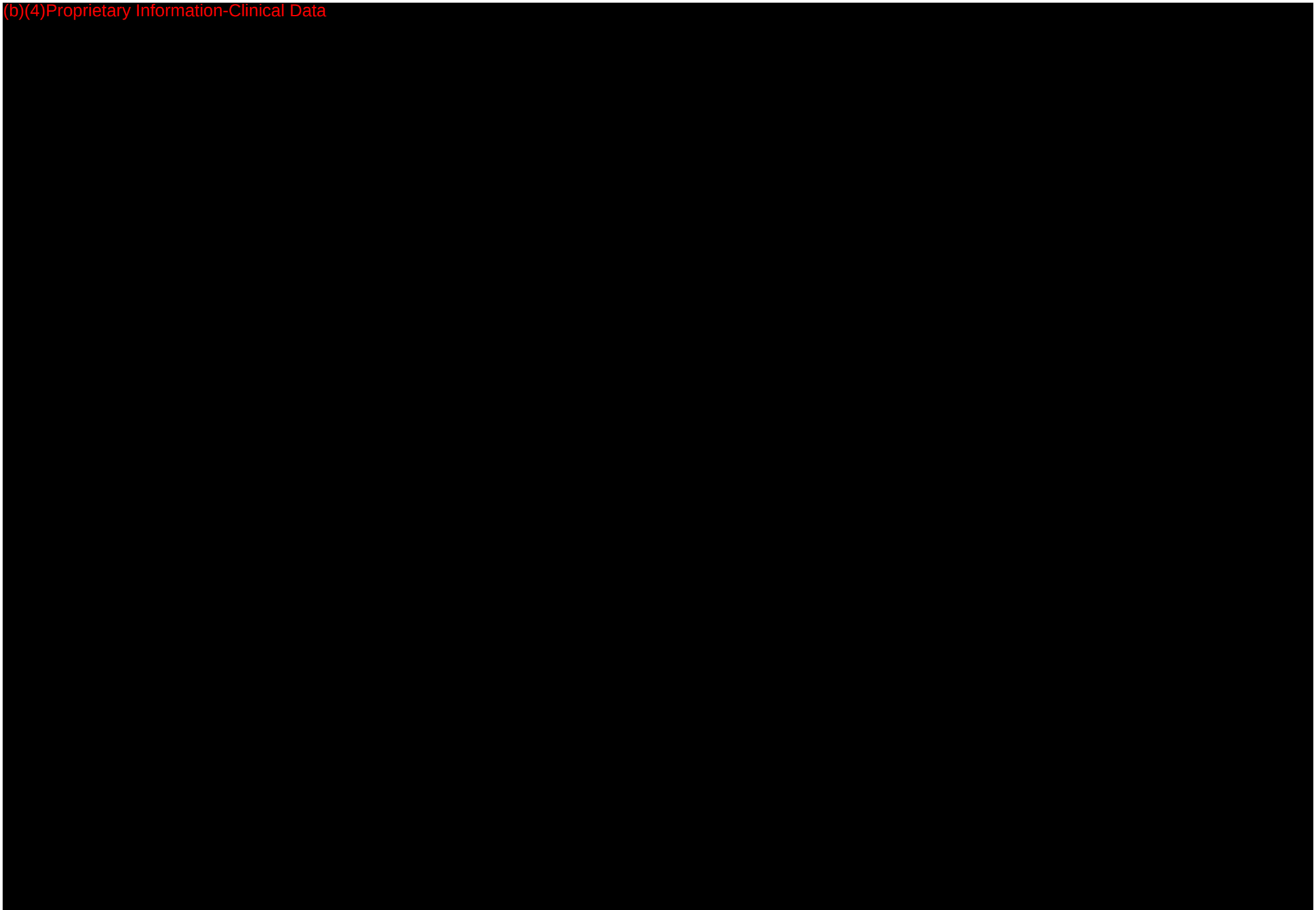
(b)(4)Proprietary Information-Clinical Data



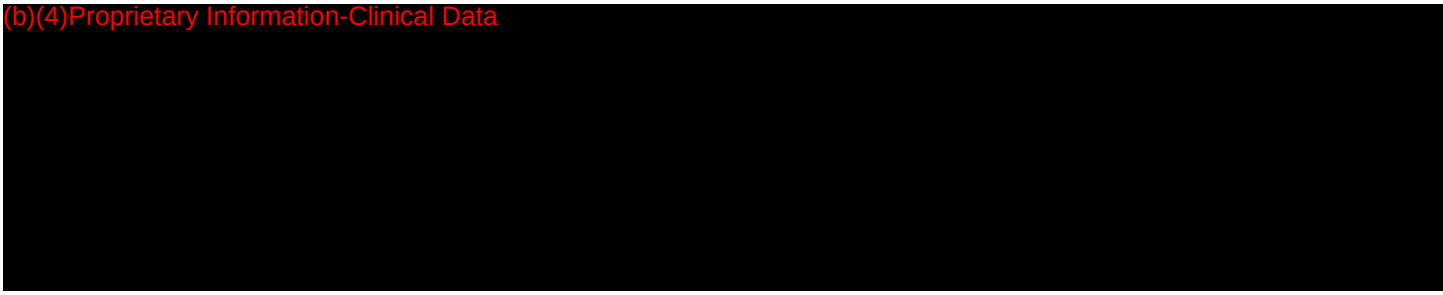


(b)(4)Proprietary Information-Clinical Data





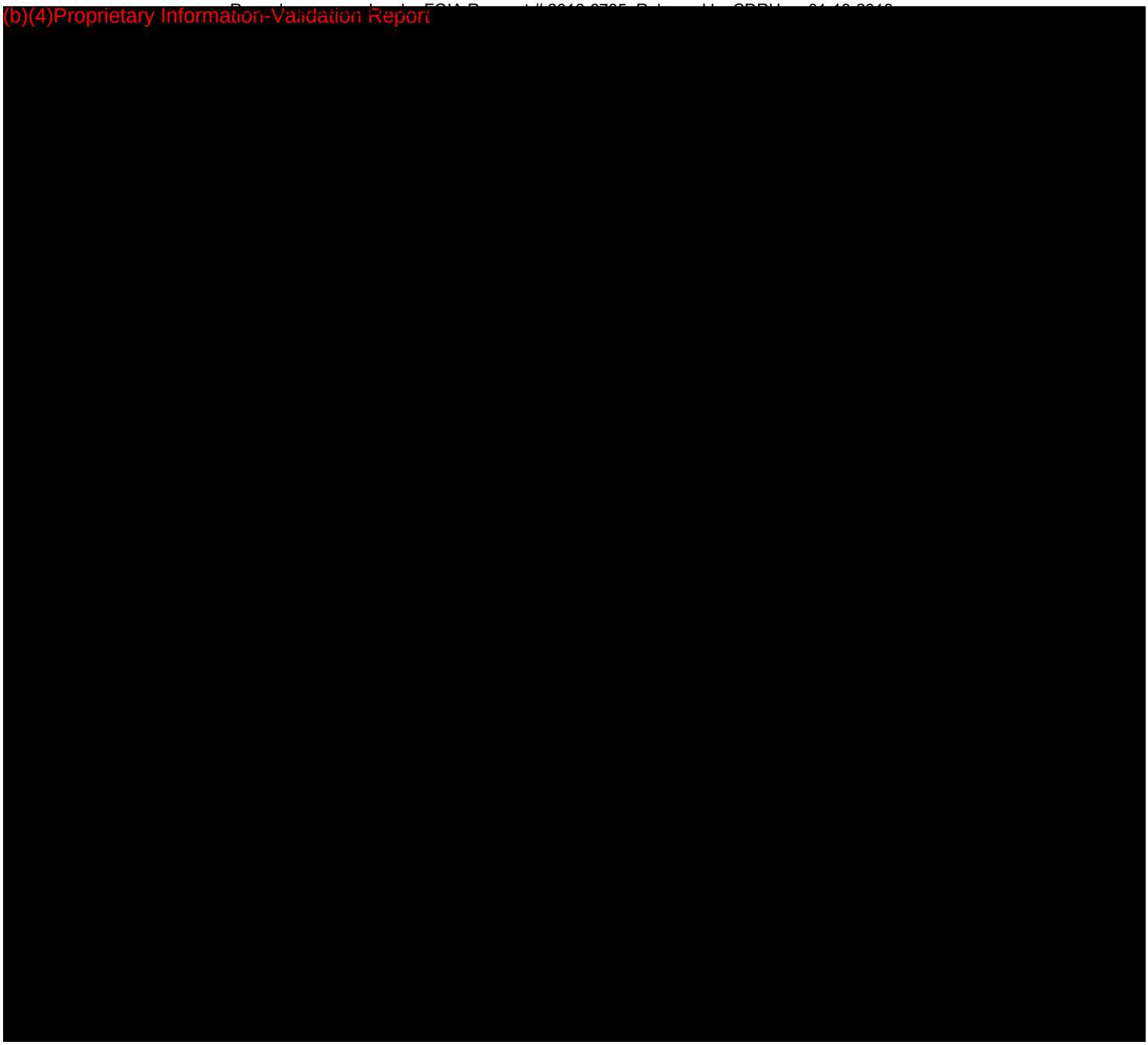
(b)(4)Proprietary Information-Clinical Data



ATTACHMENT 38

[redacted]

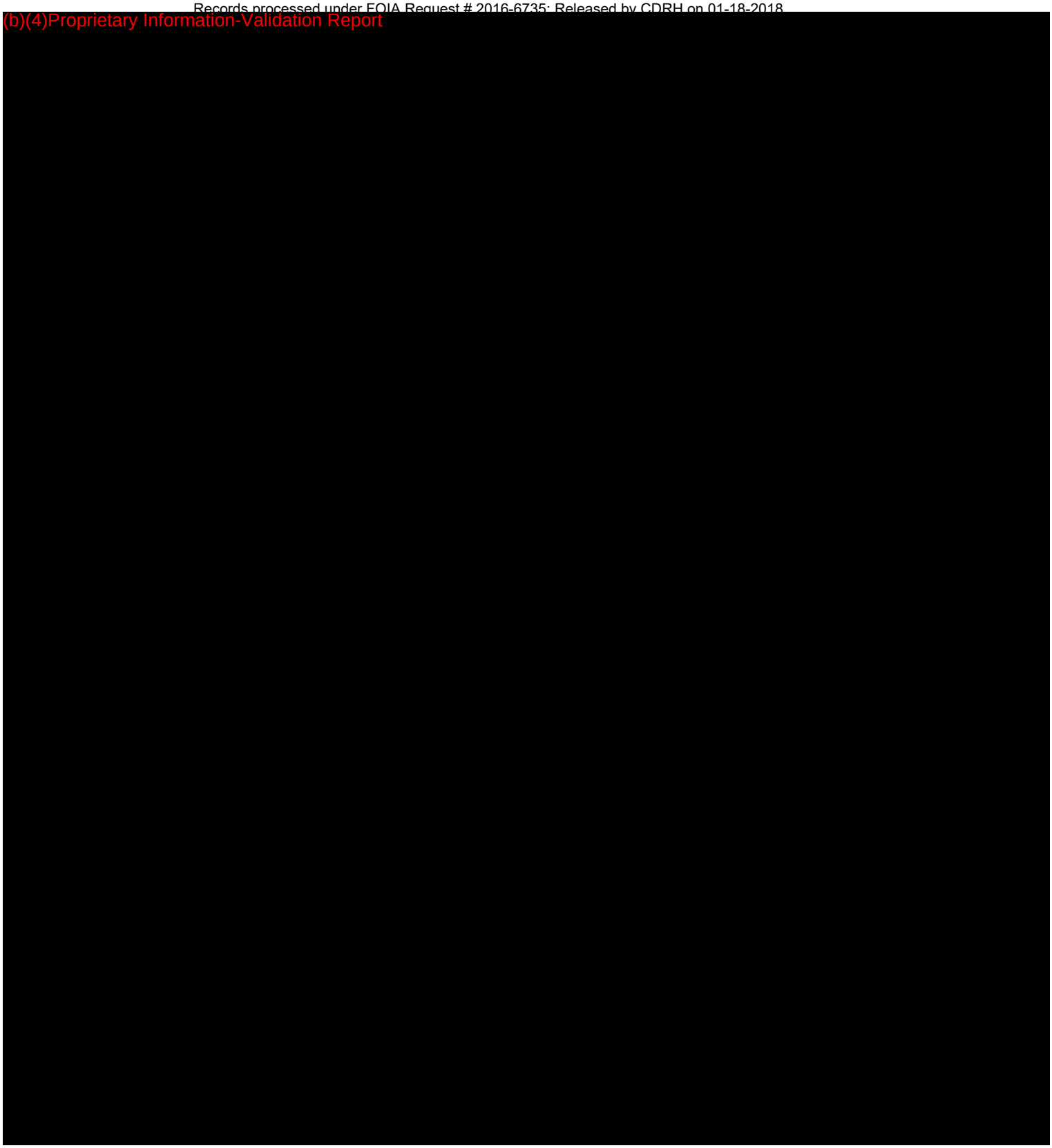
(b)(4)Proprietary Information-Validation Report



(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

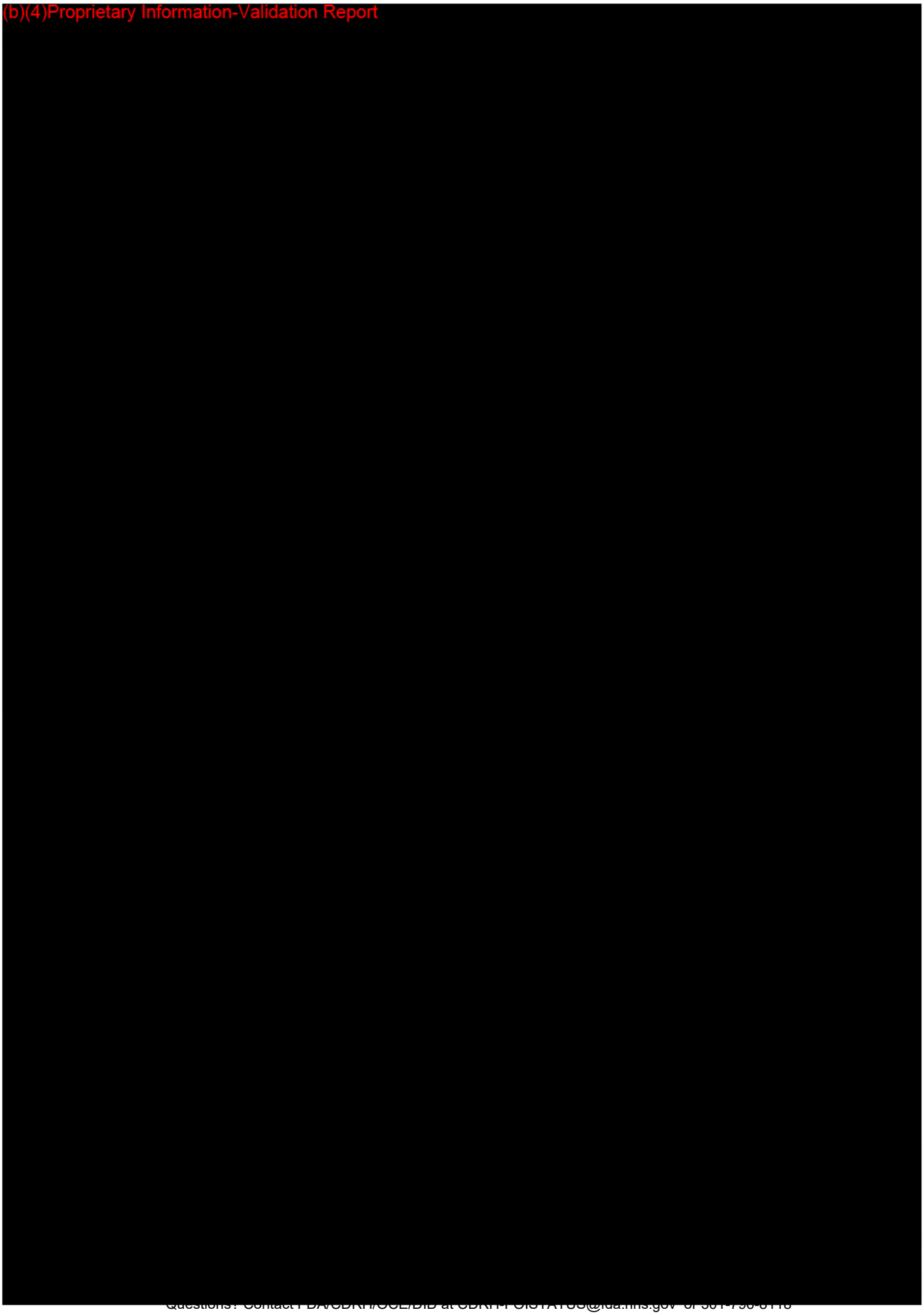


(b)(4)Proprietary Information-Validation Report

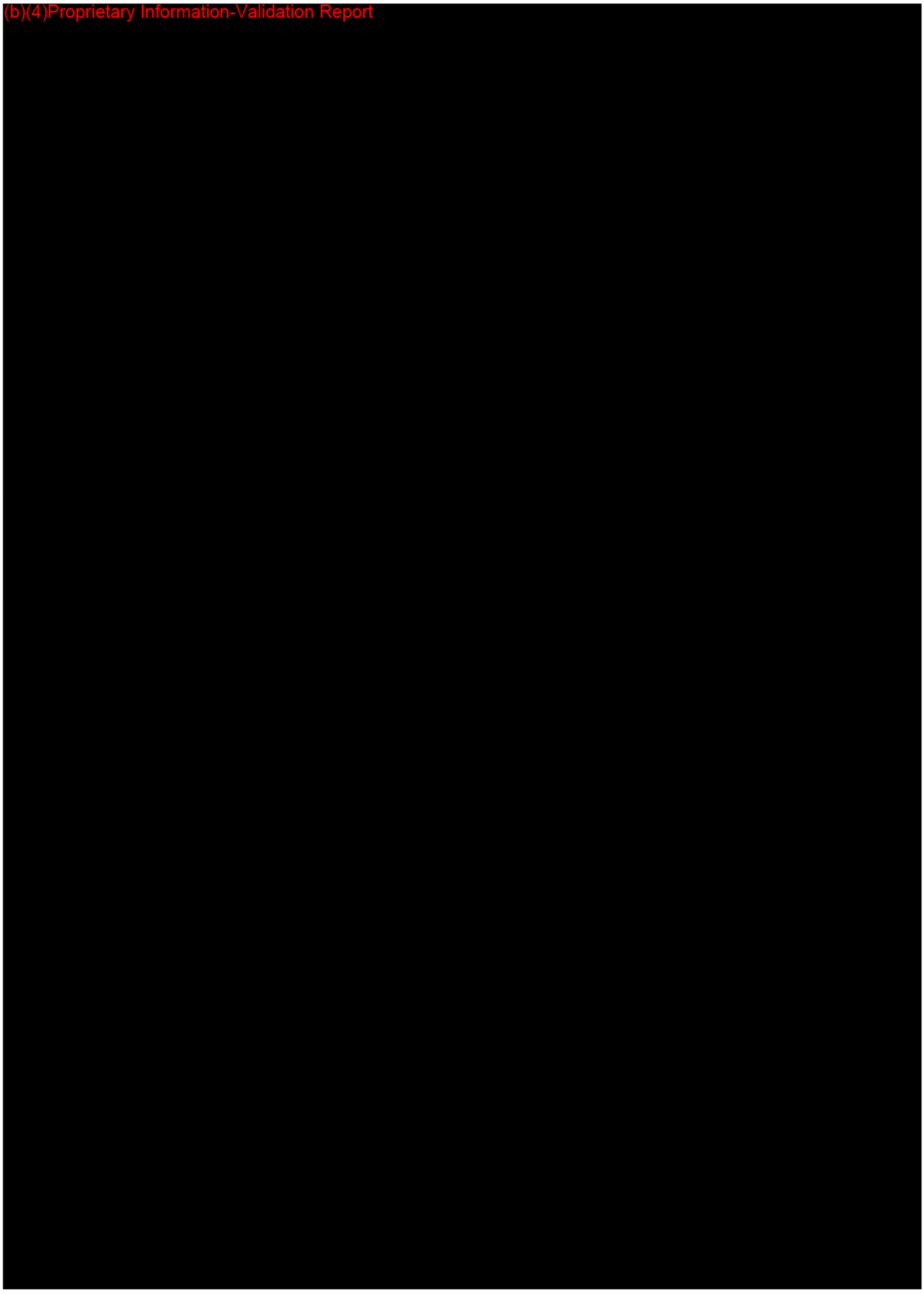
(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report



(b)(4)Proprietary Information-Validation Report



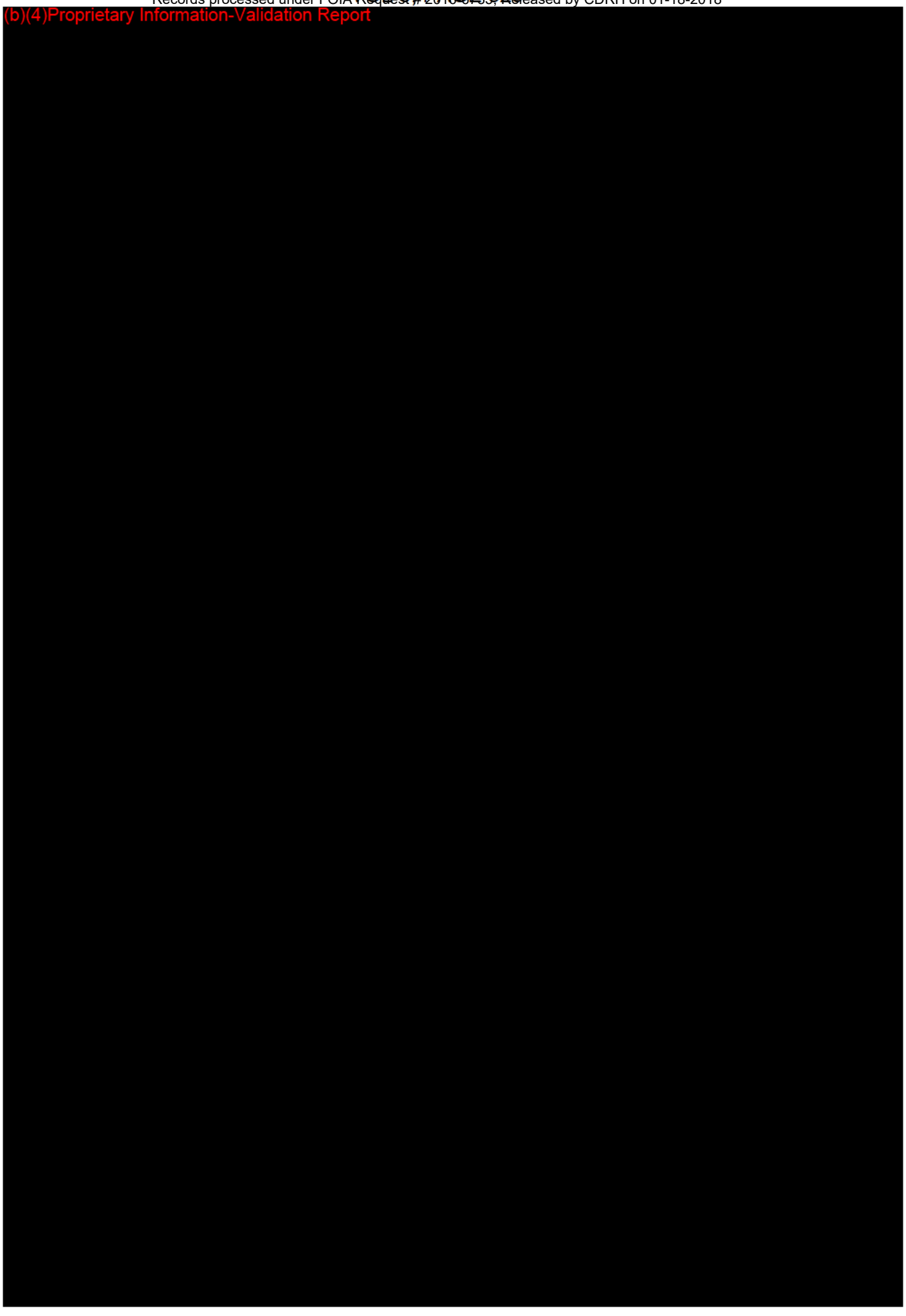
(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report



(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

(b)(4)Proprietary Information-Validation Report

[redacted]

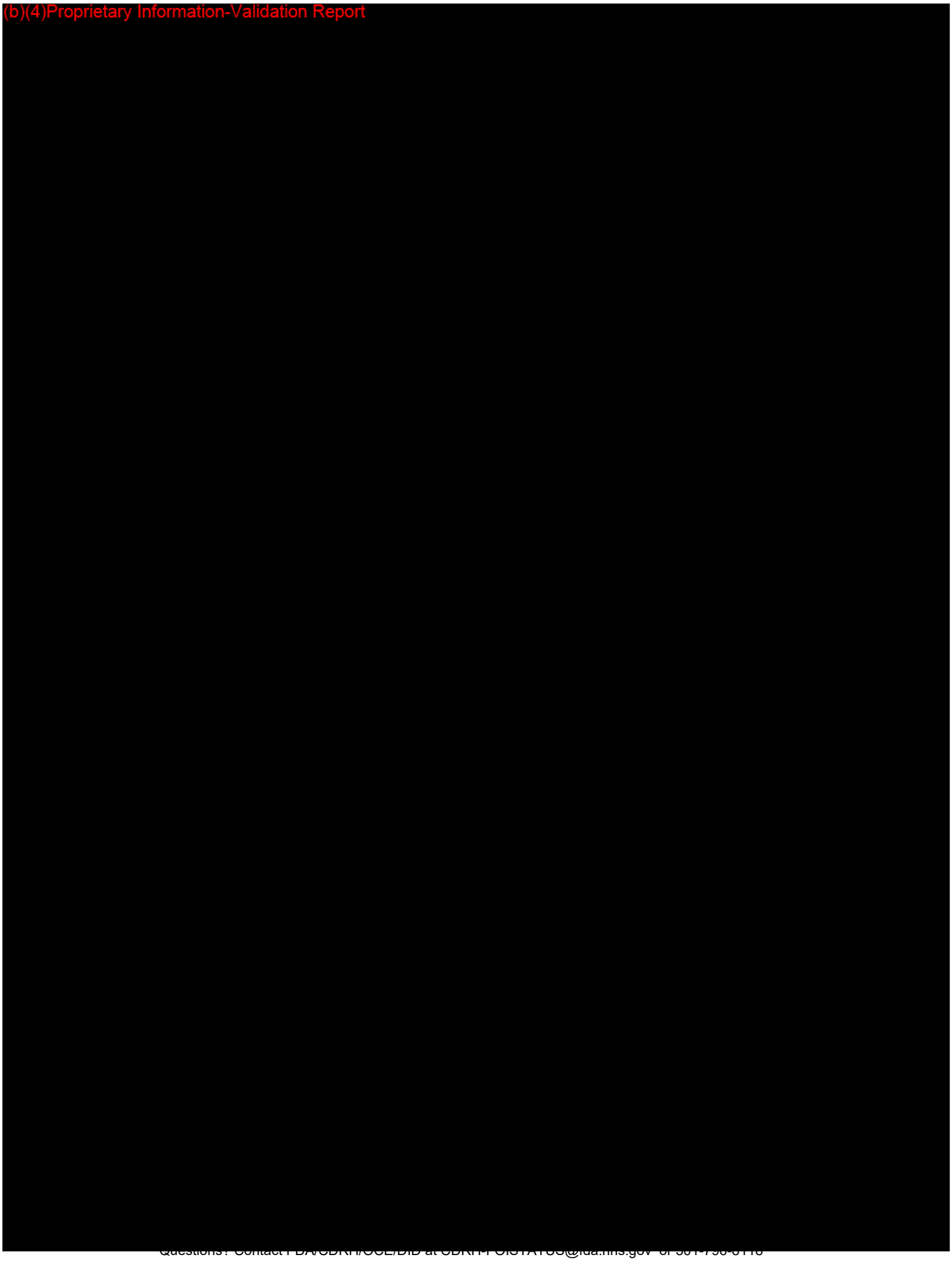
(b)(4)Proprietary Information-Validation Report

[redacted]

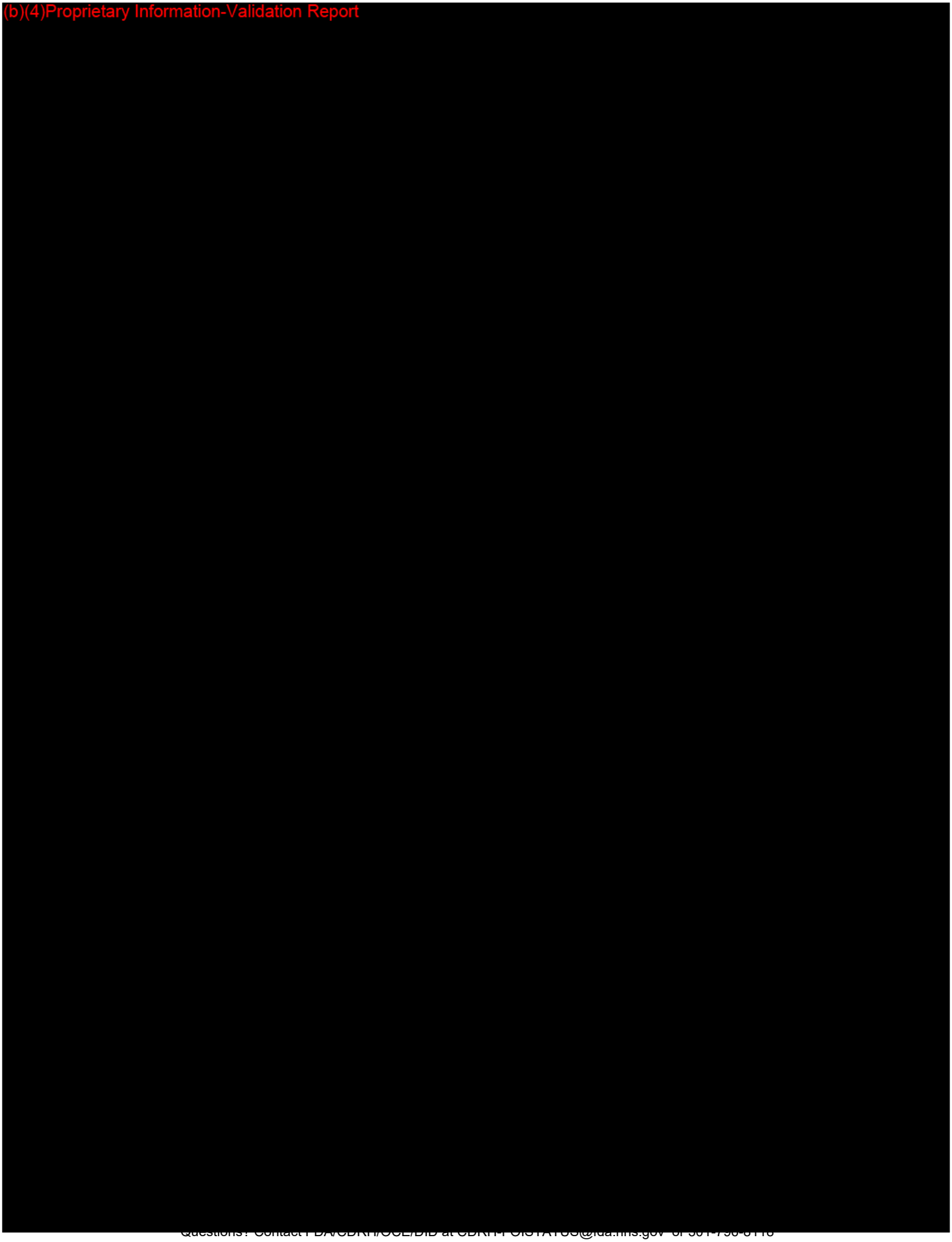
(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report



(b)(4)Proprietary Information-Validation Report



(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

[redacted]

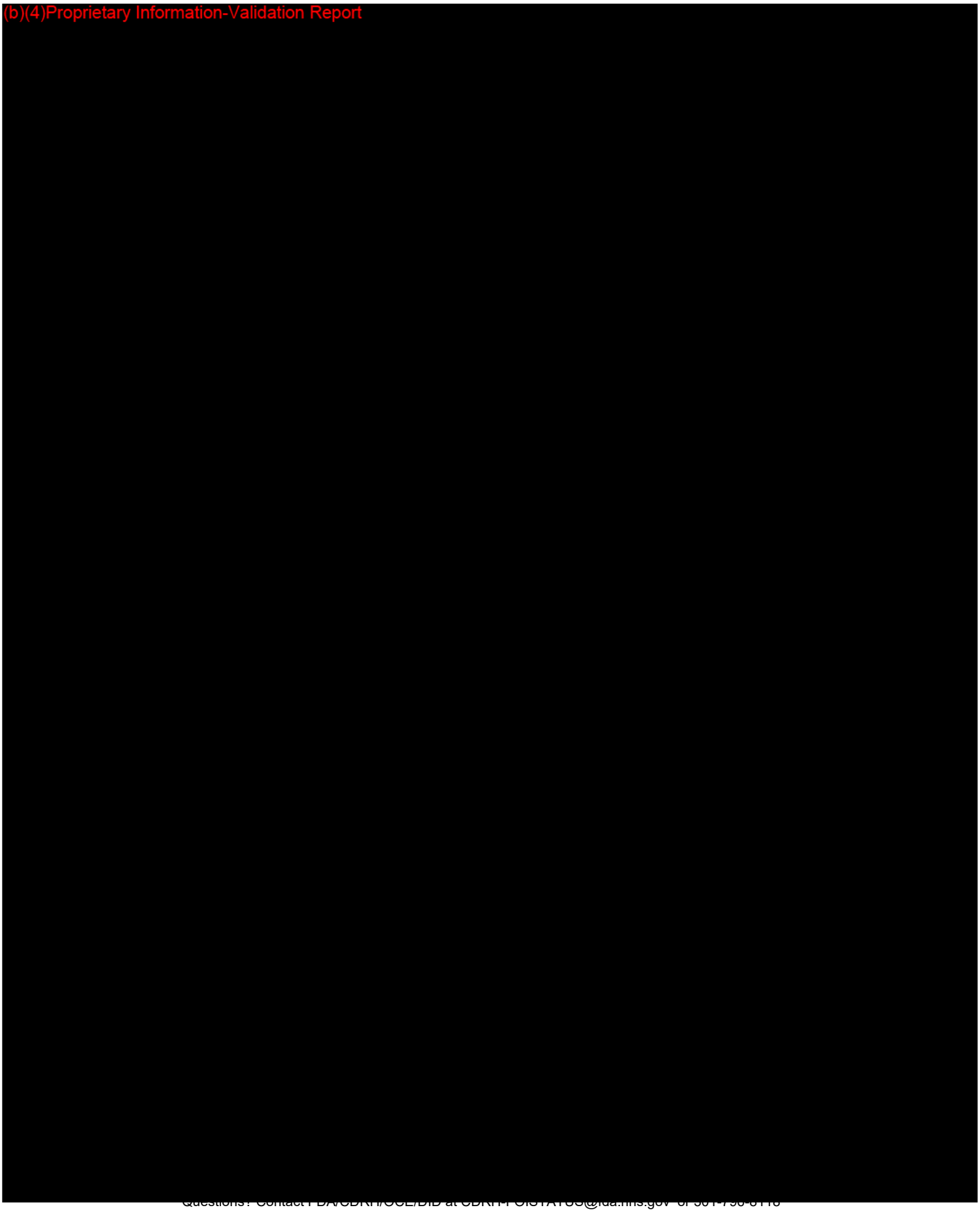
(b)(4)Proprietary Information-Validation Report

[redacted]

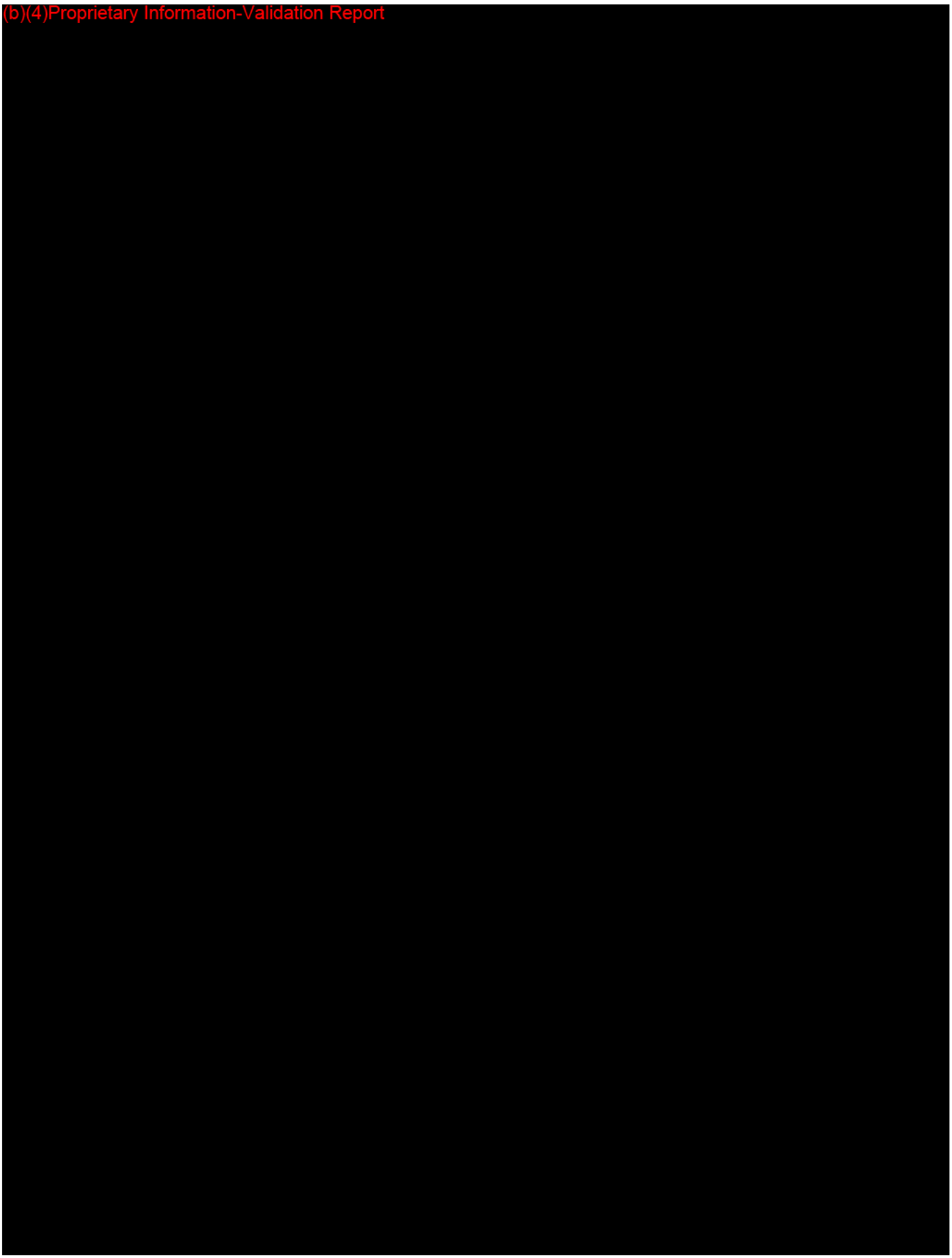
(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report



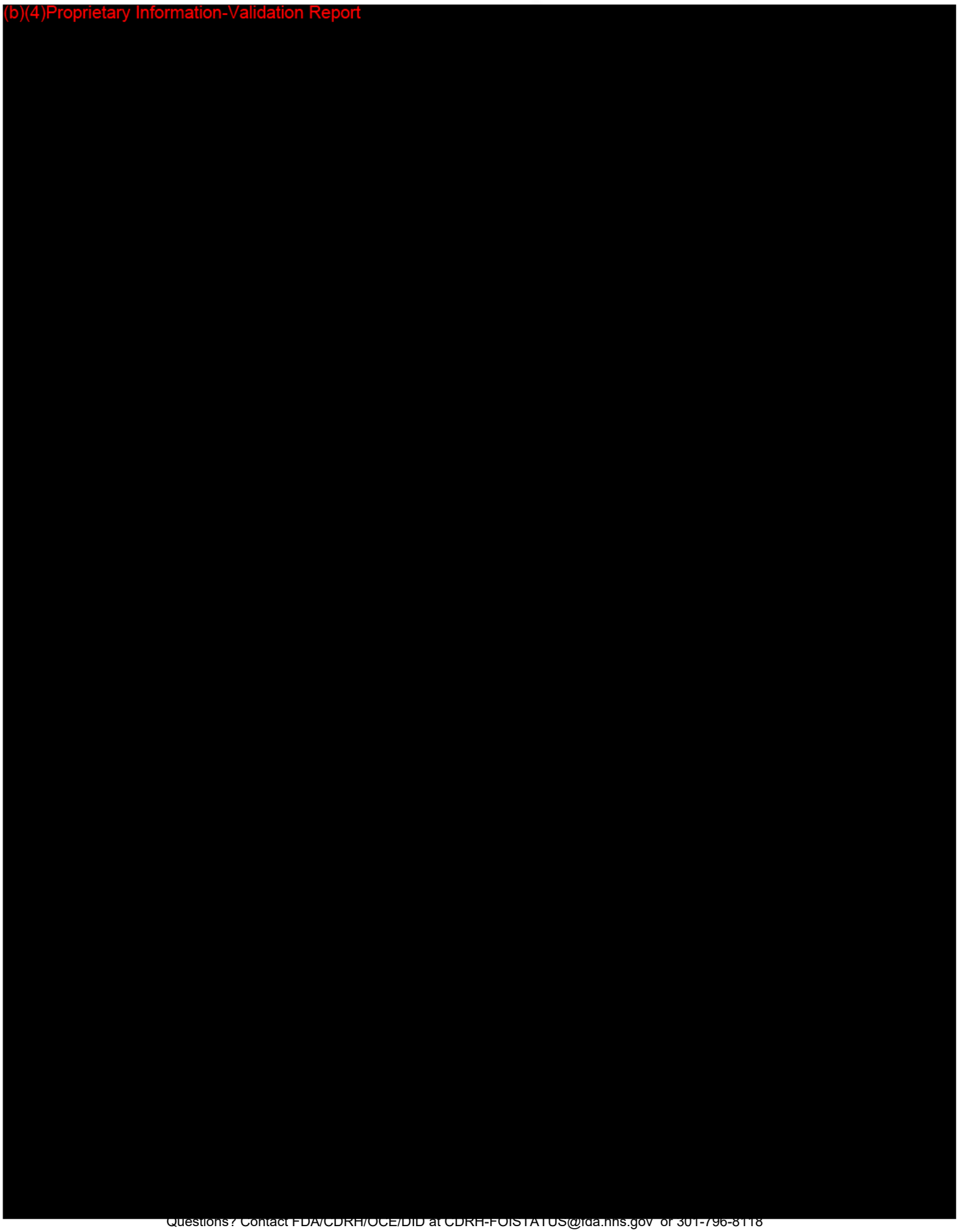
(b)(4)Proprietary Information-Validation Report



(b)(4)Proprietary Information-Validation Report

[redacted]

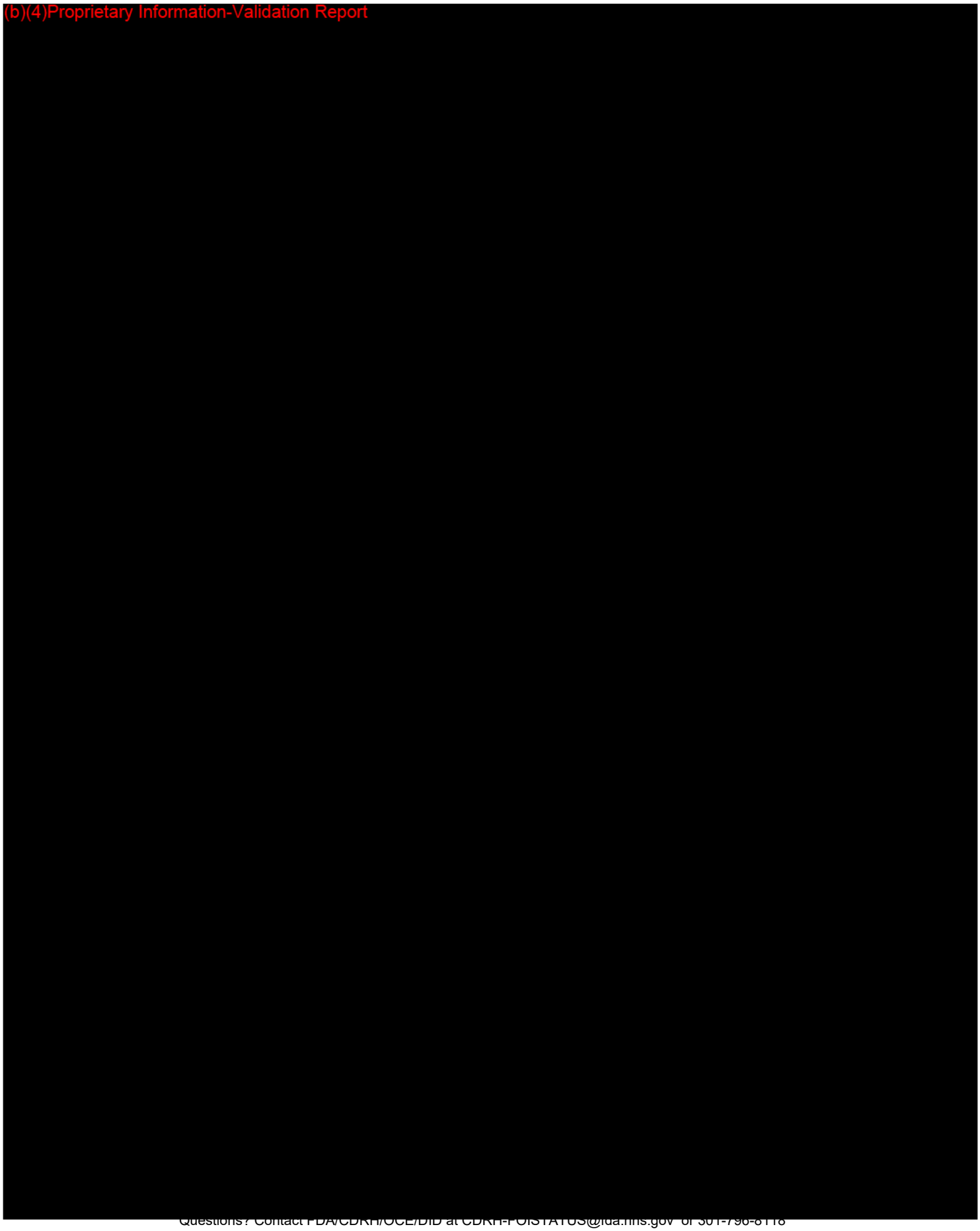
(b)(4)Proprietary Information-Validation Report



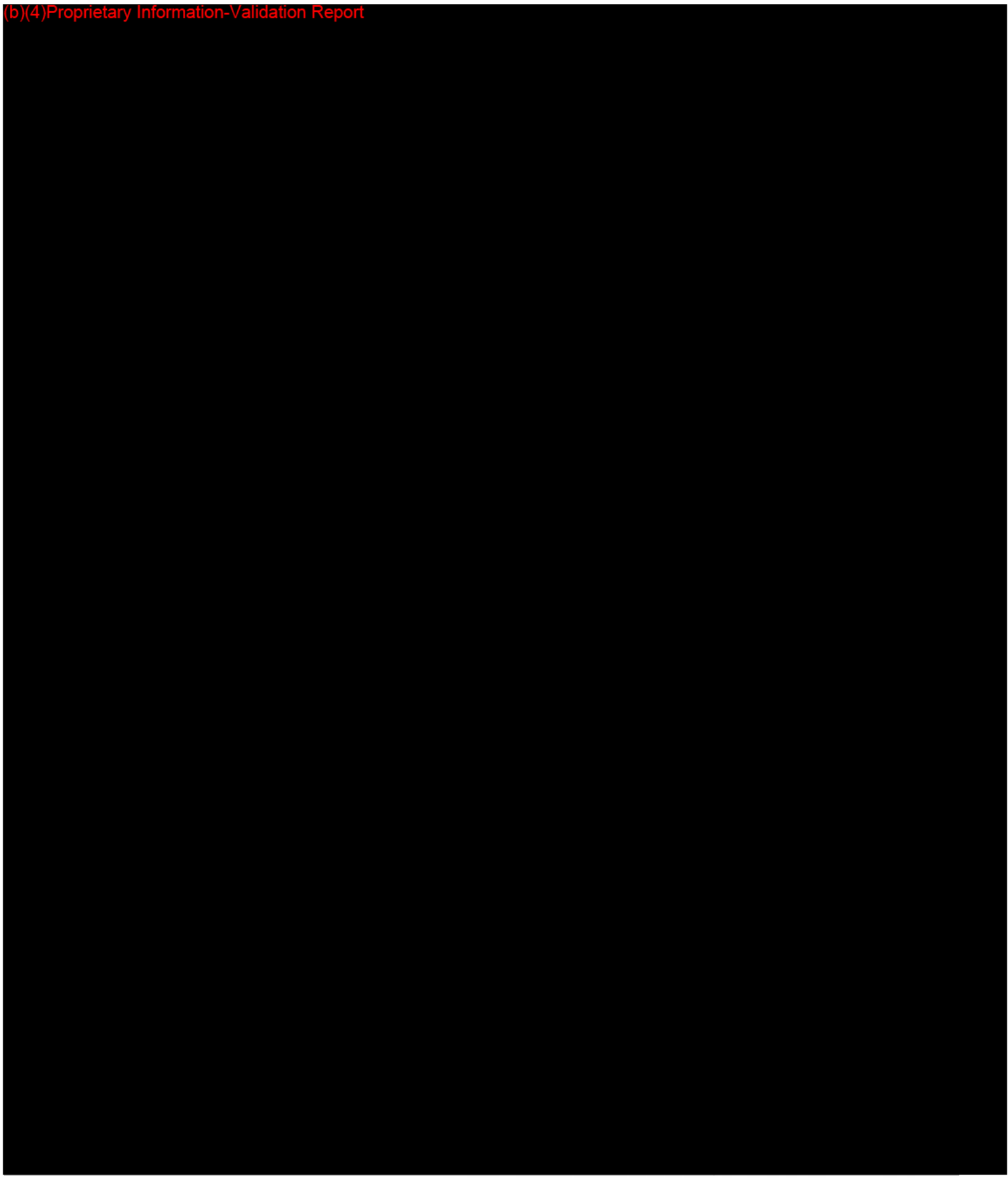
(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report



(b)(4)Proprietary Information-Validation Report



(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

[redacted]

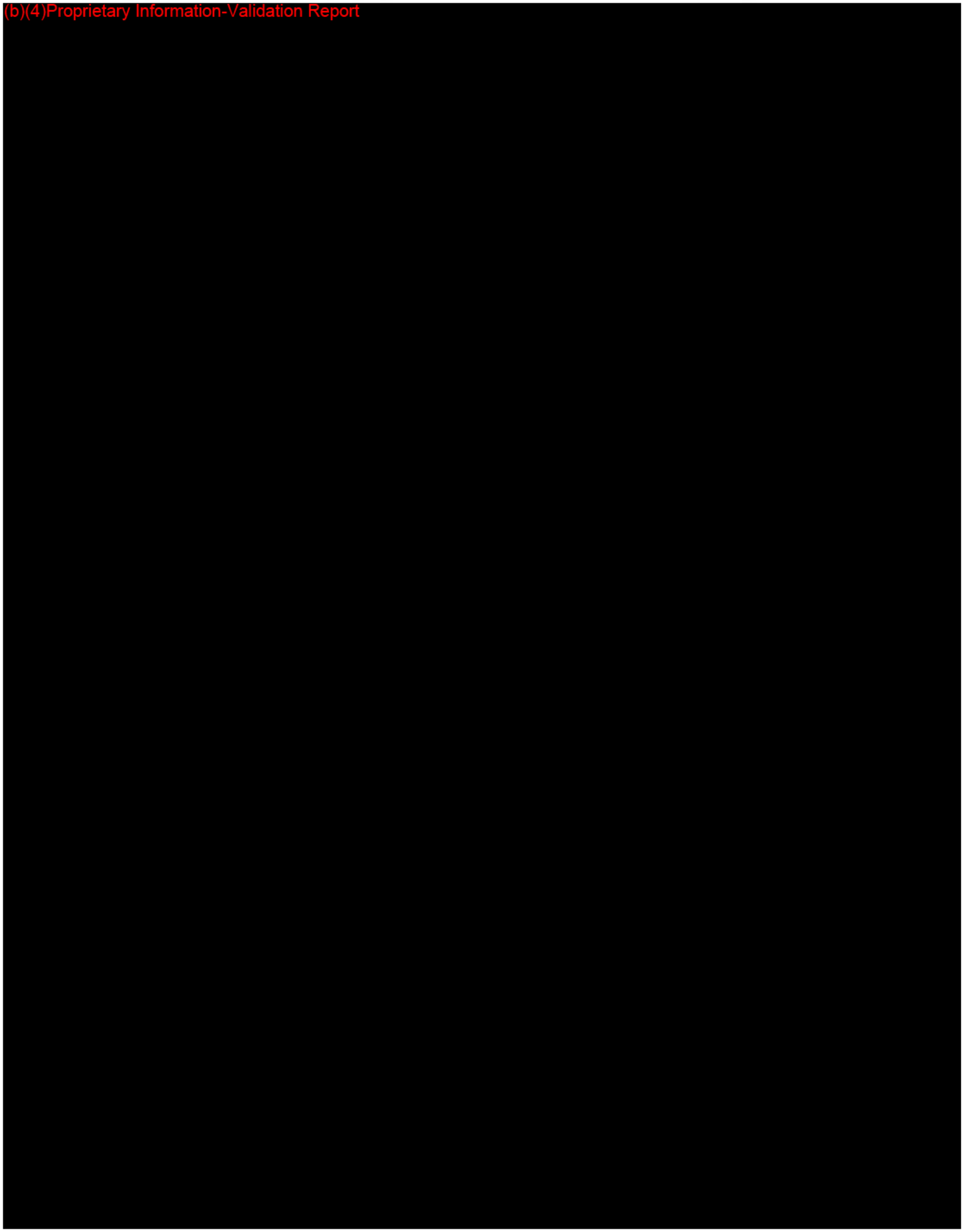
(b)(4)Proprietary Information-Validation Report

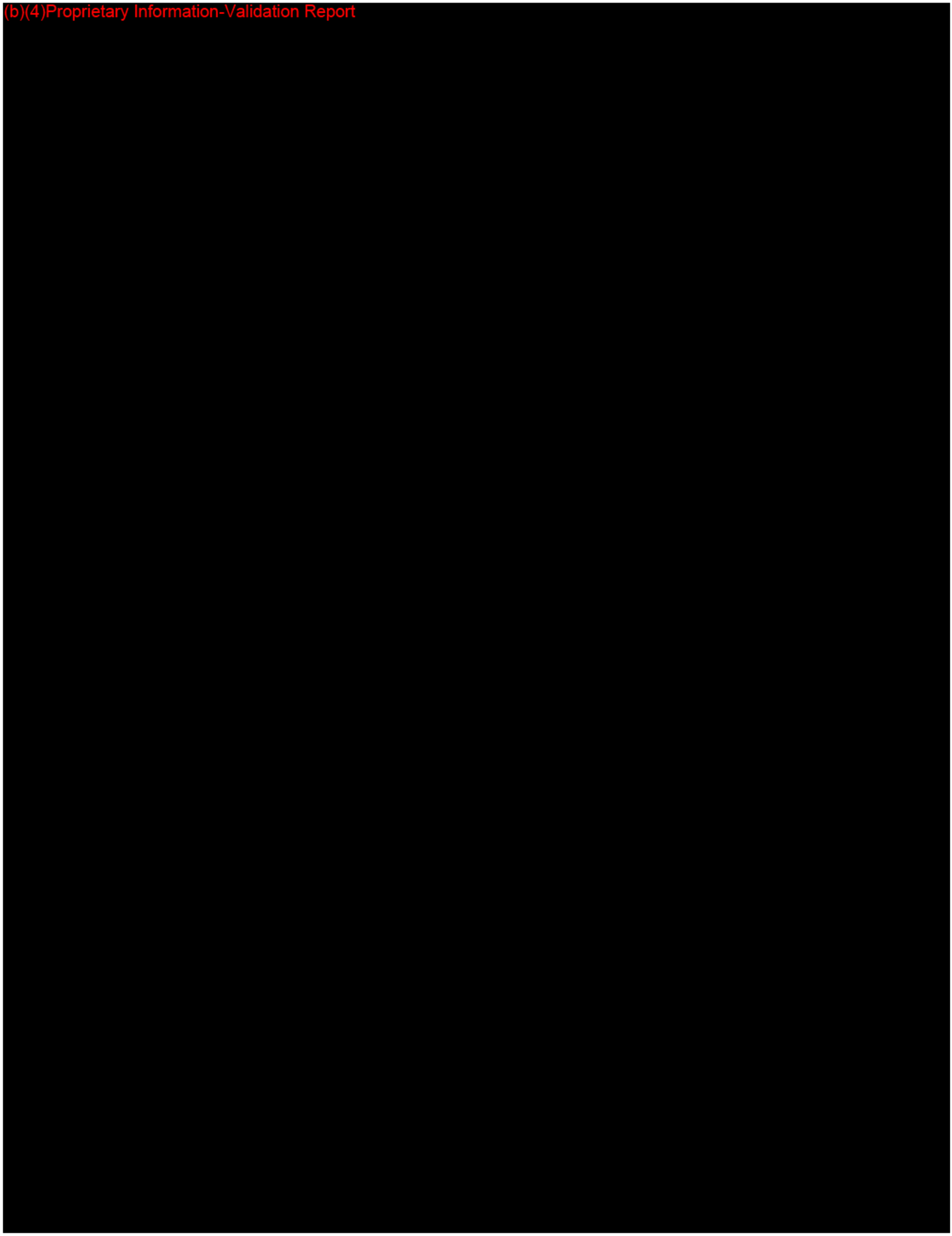
[redacted]

(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

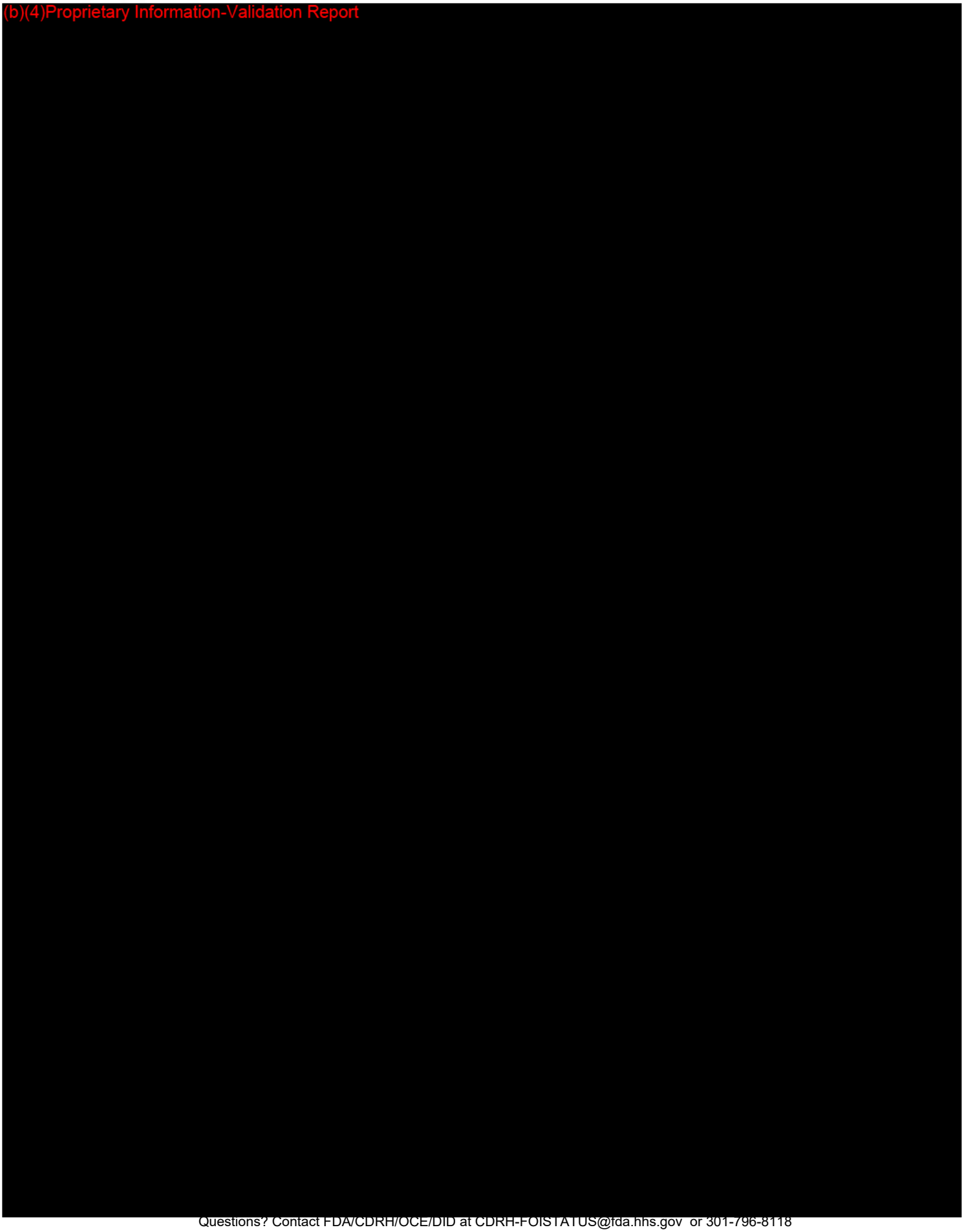




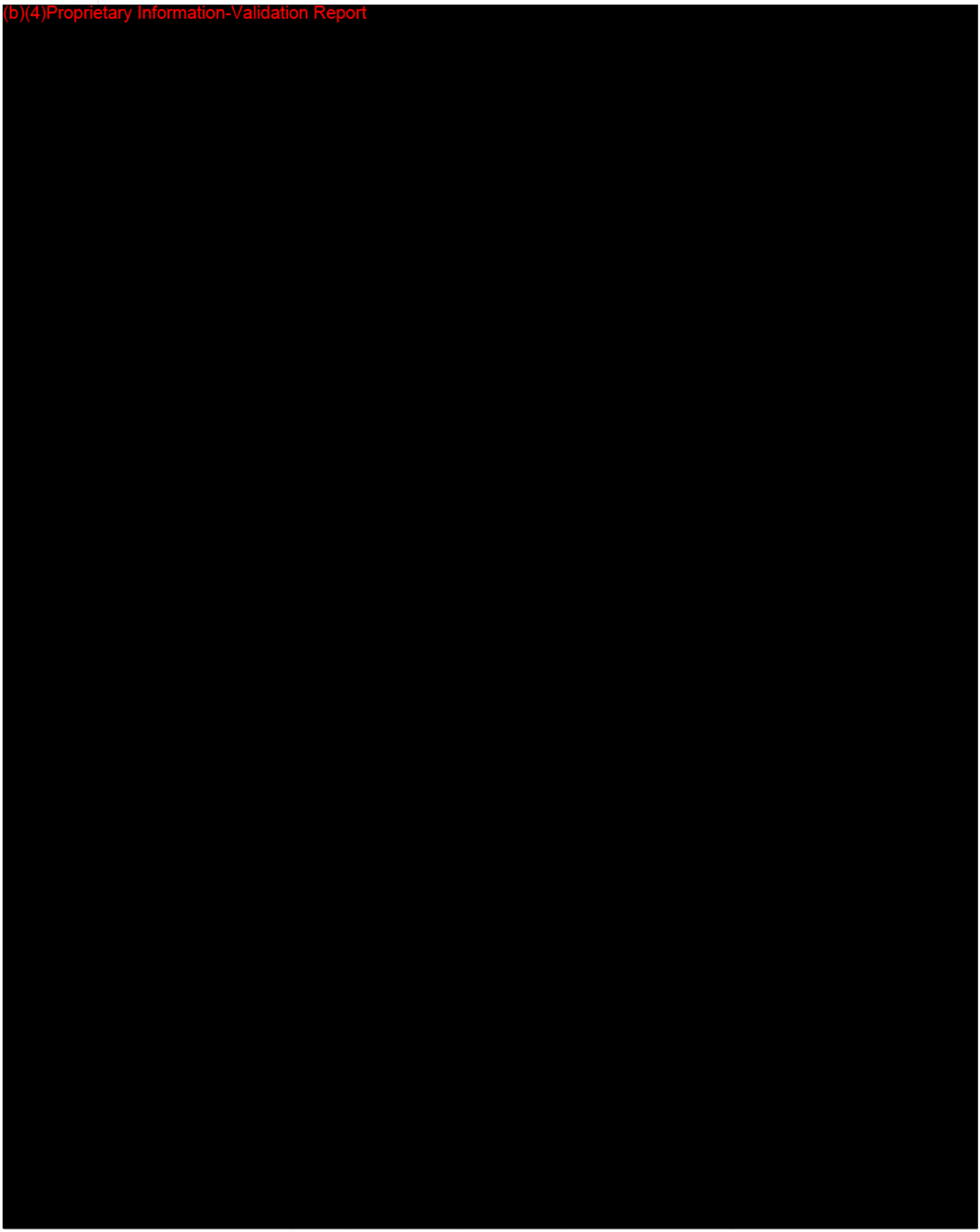
(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report



(b)(4)Proprietary Information-Validation Report



(b)(4)Proprietary Information-Validation Report

[redacted]

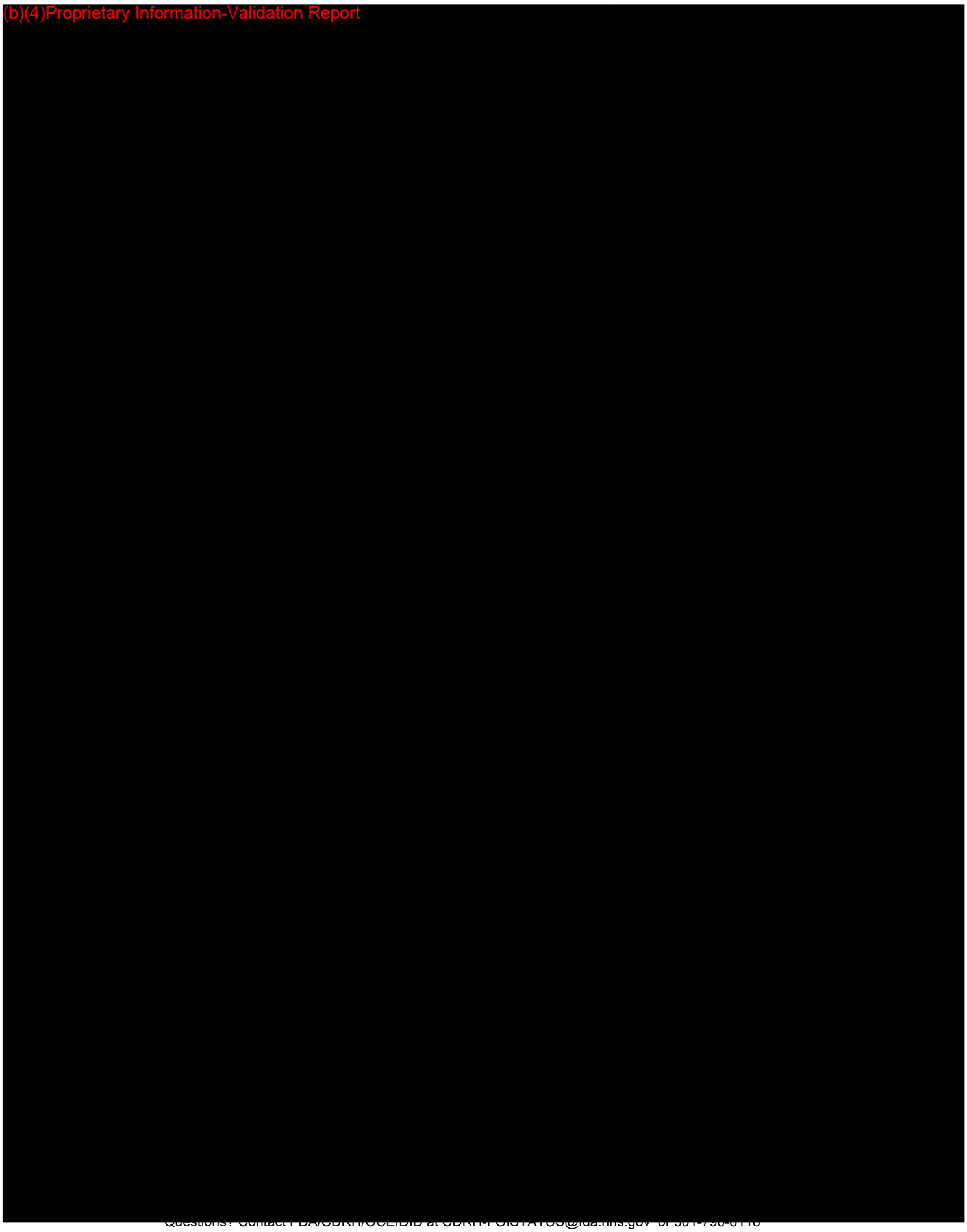
(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

[redacted]

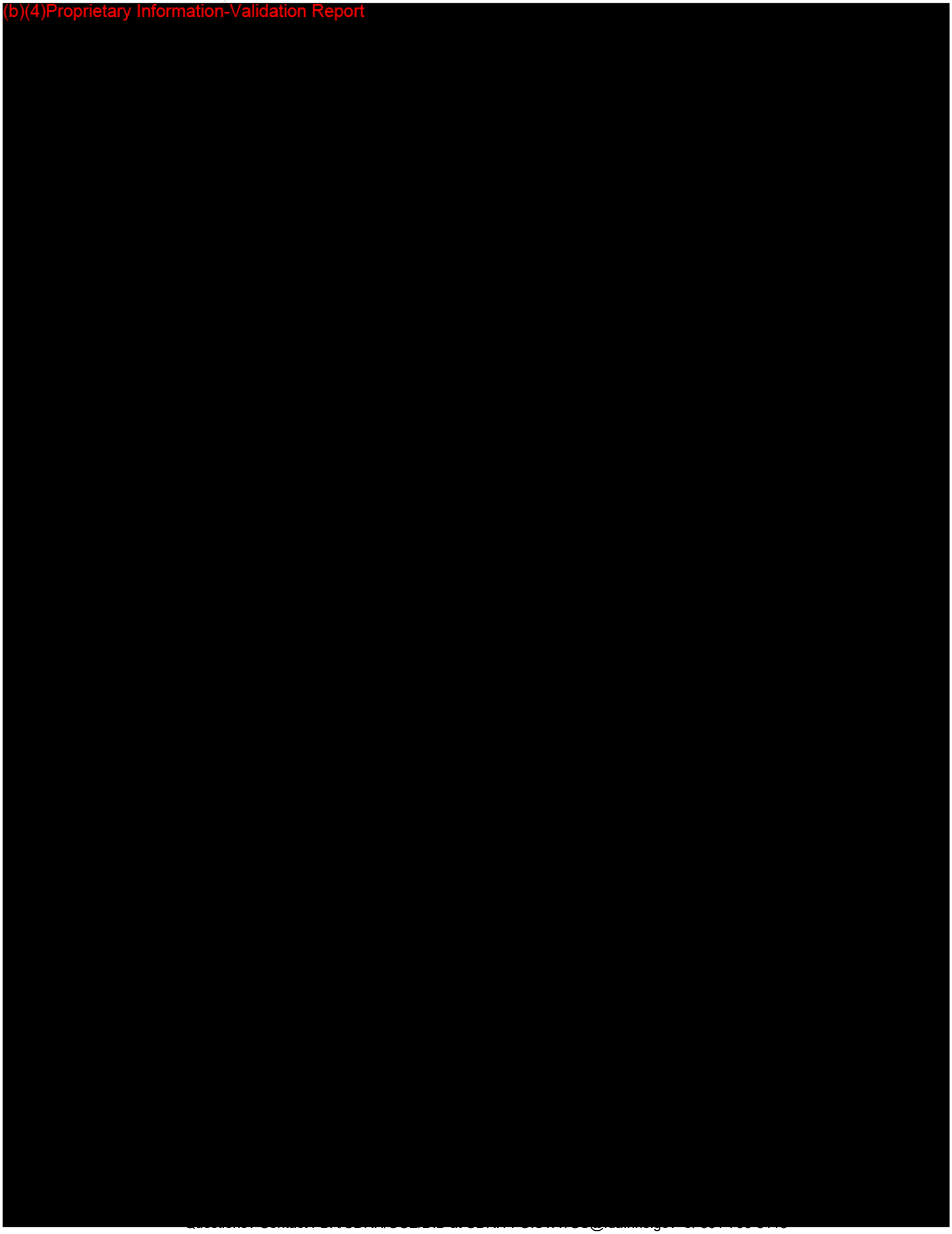
(b)(4)Proprietary Information-Validation Report



(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report



(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

[redacted]

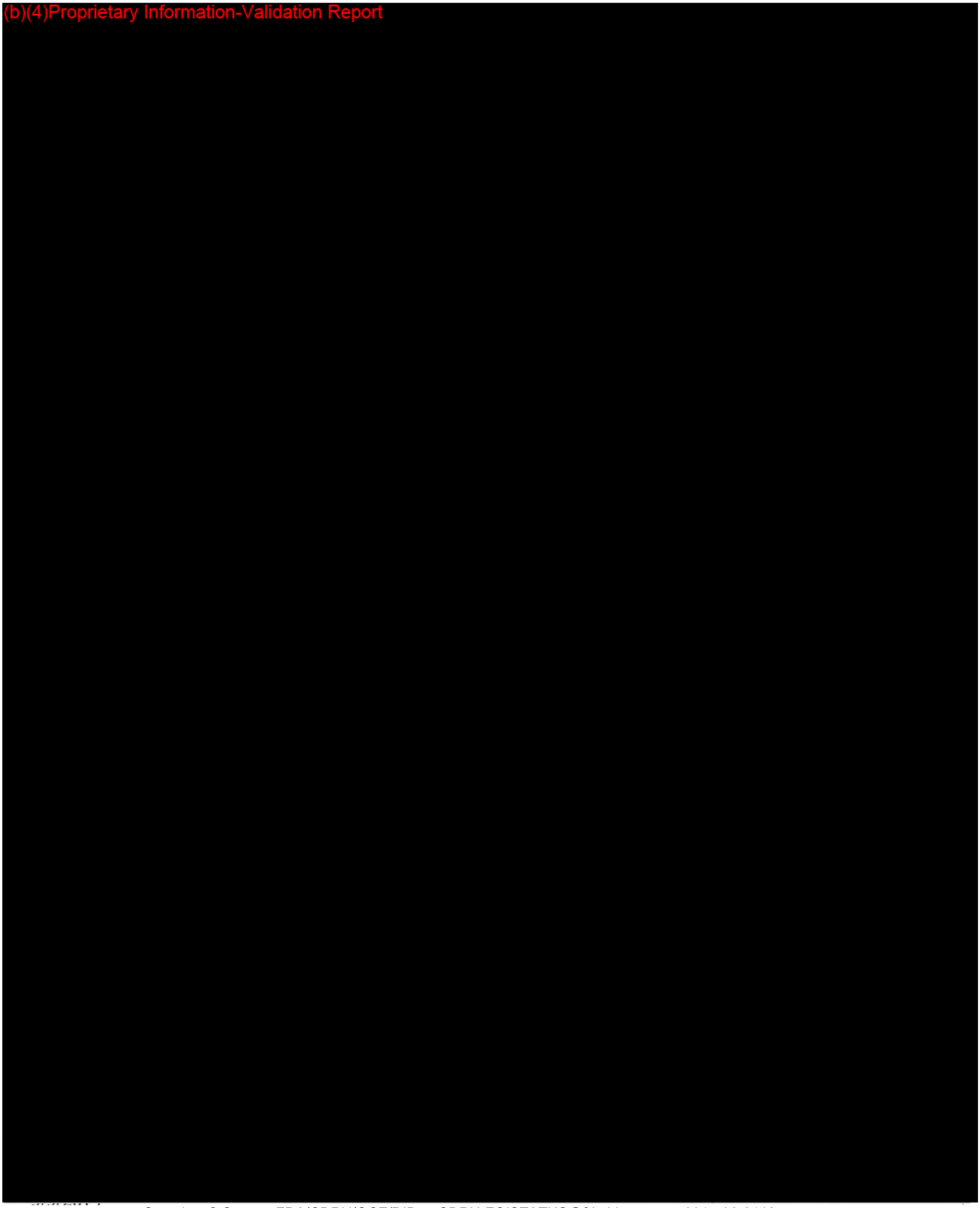
(b)(4)Proprietary Information-Validation Report

[redacted]

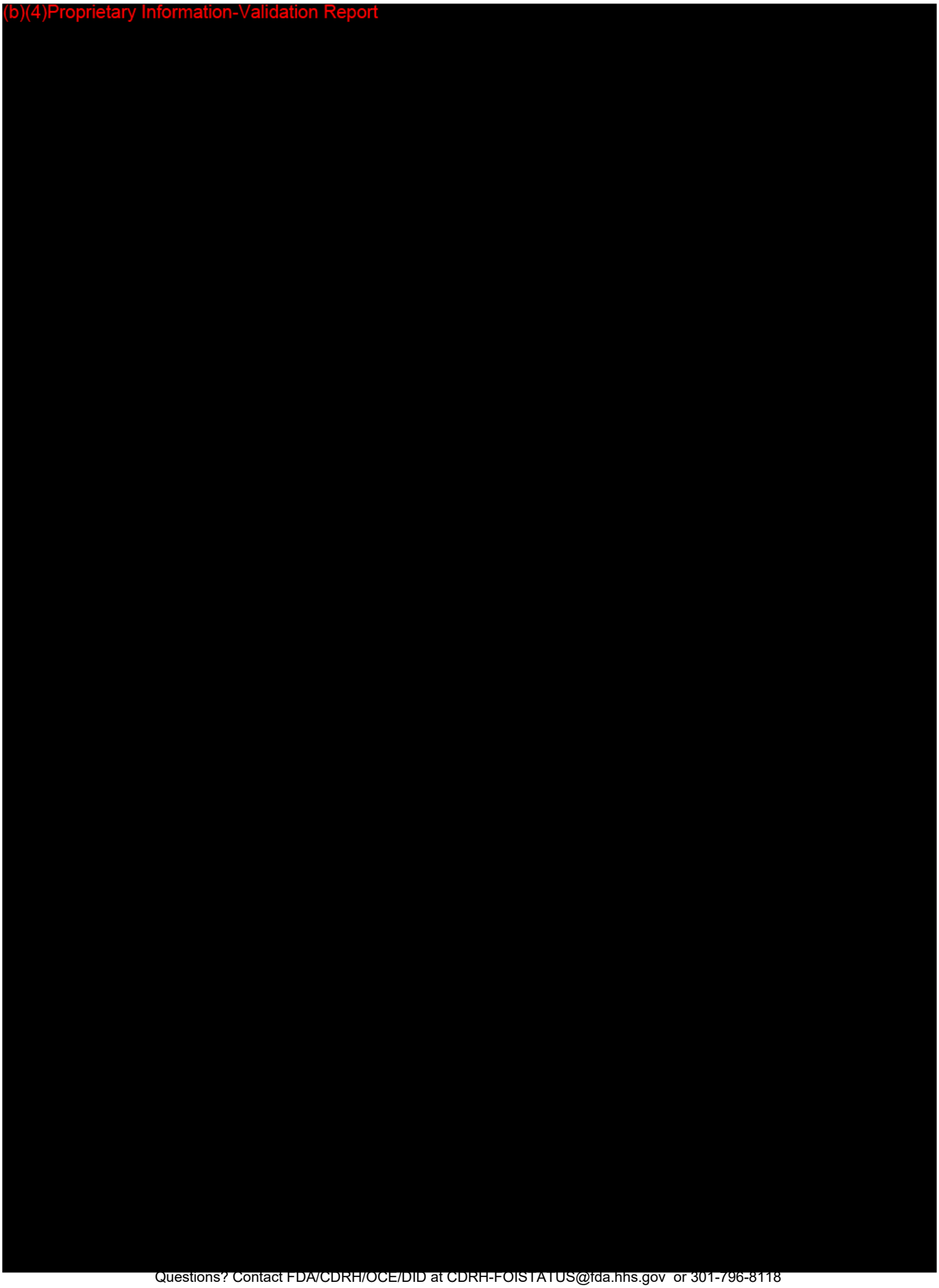
(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report



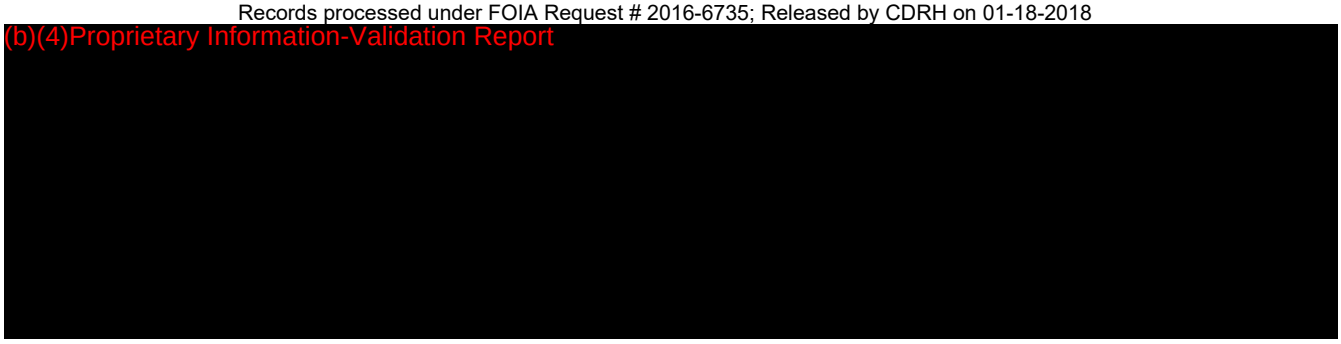
(b)(4)Proprietary Information-Validation Report



(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report



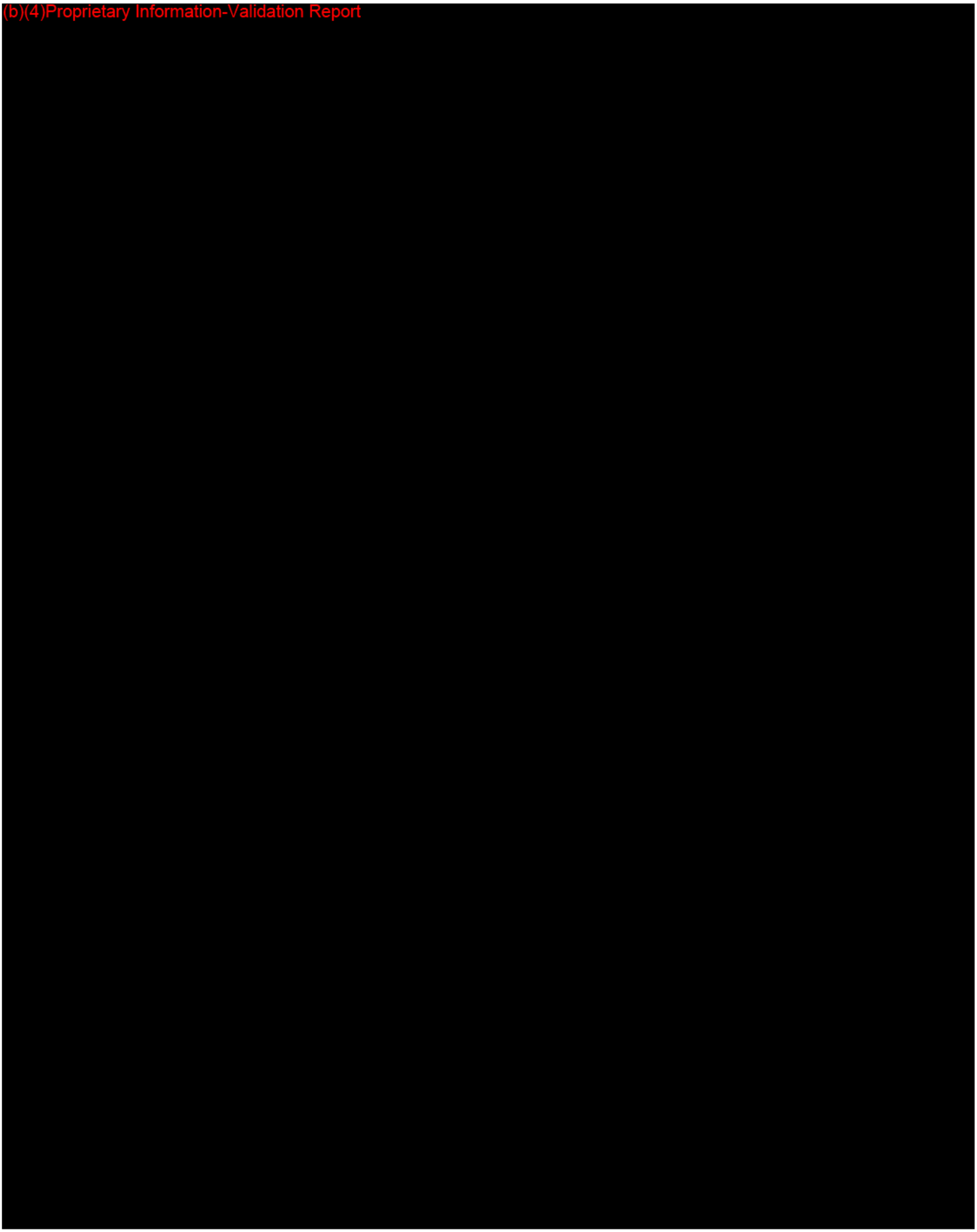
(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report



(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

[redacted]

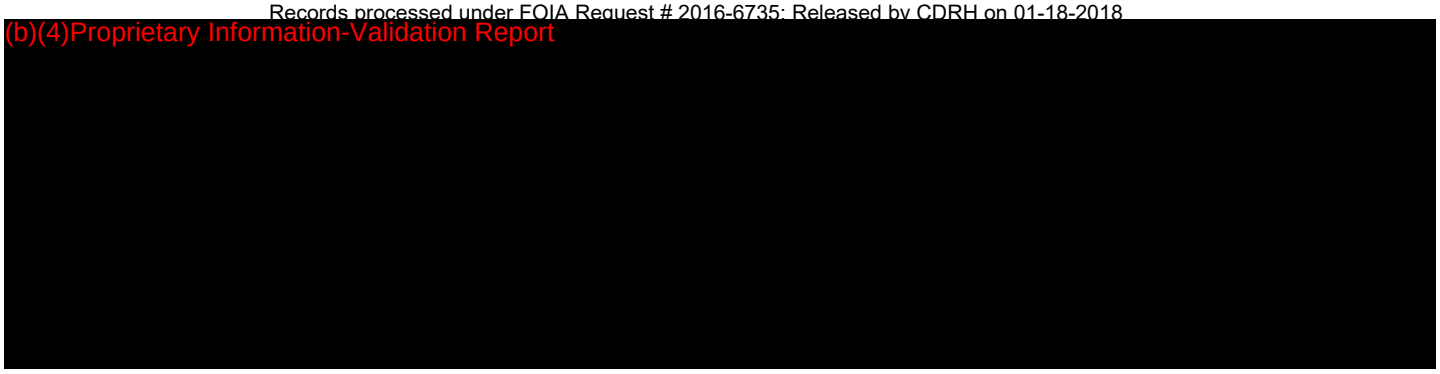
(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

[redacted]

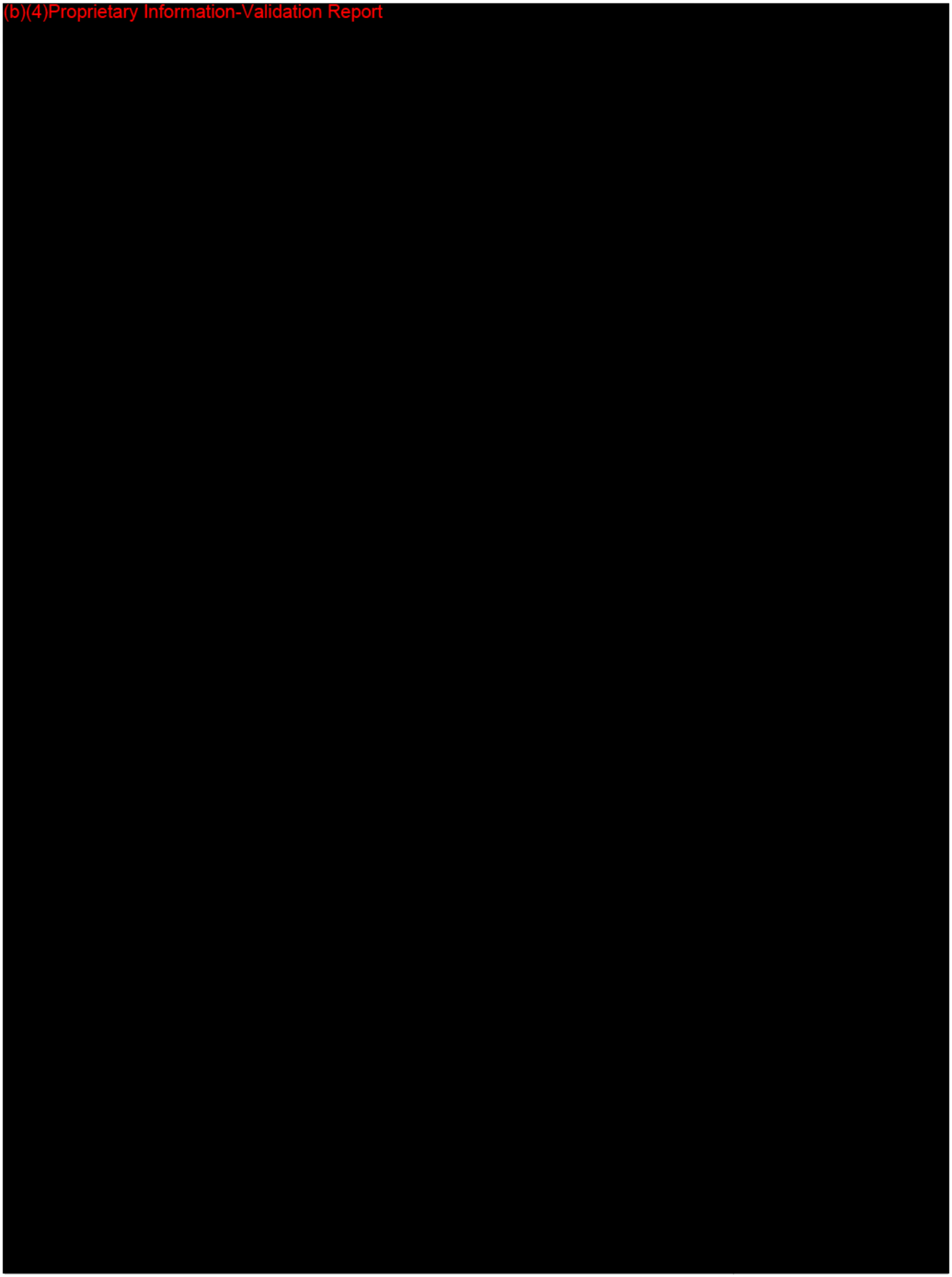
(b)(4)Proprietary Information-Validation Report



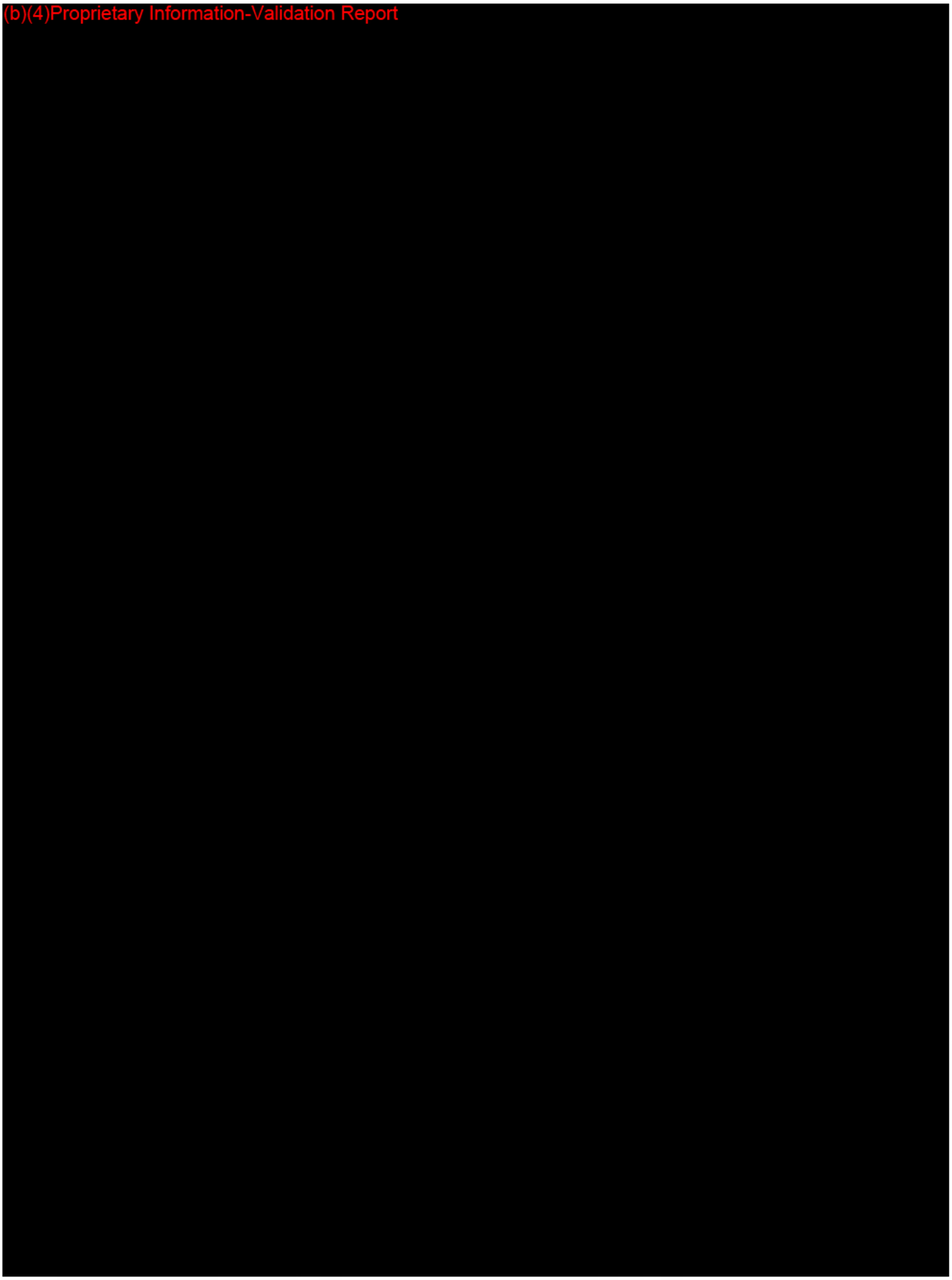
(b)(4)Proprietary Information-Validation Report

[redacted]

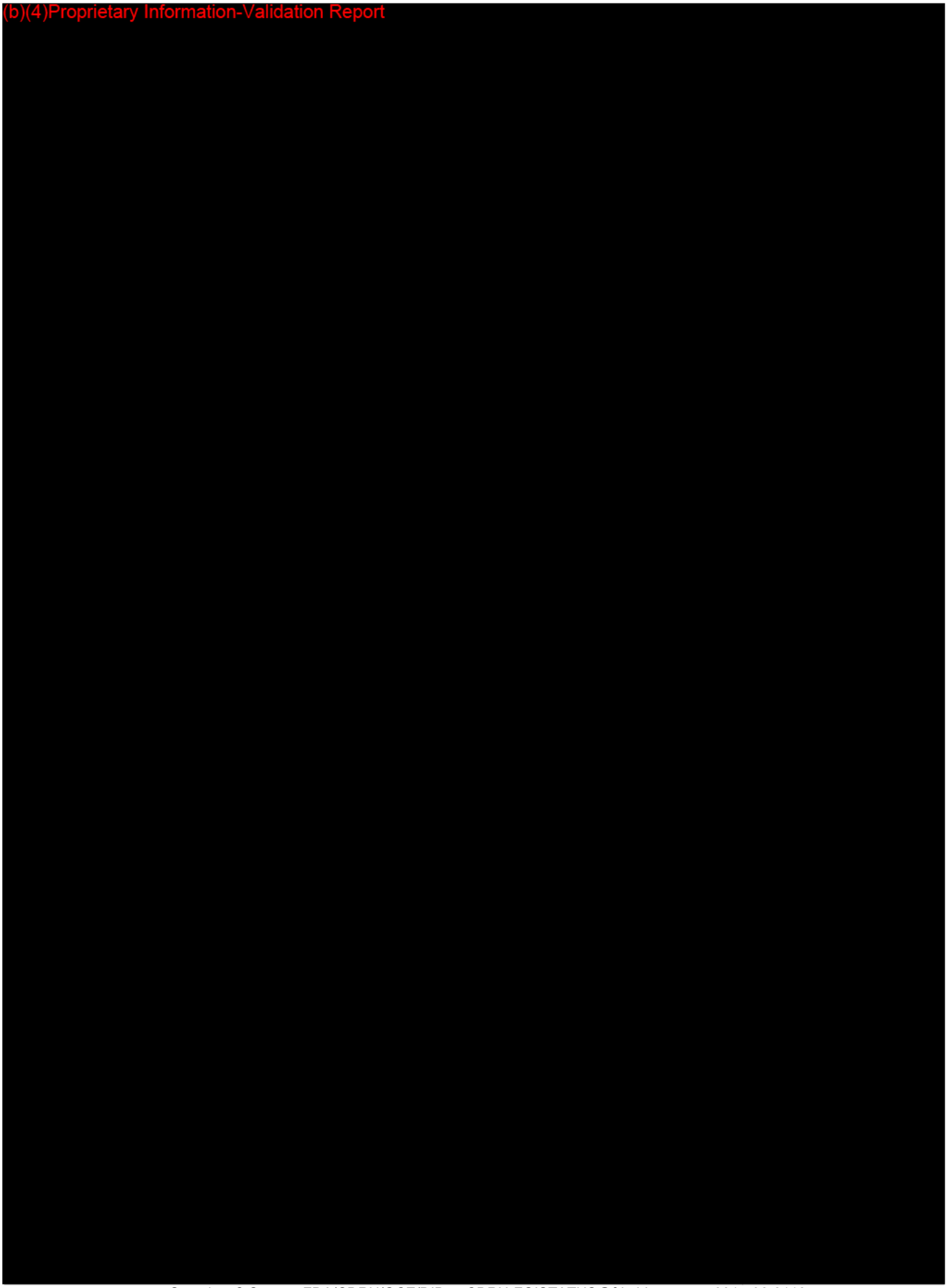
(b)(4)Proprietary Information-Validation Report



(b)(4)Proprietary Information-Validation Report



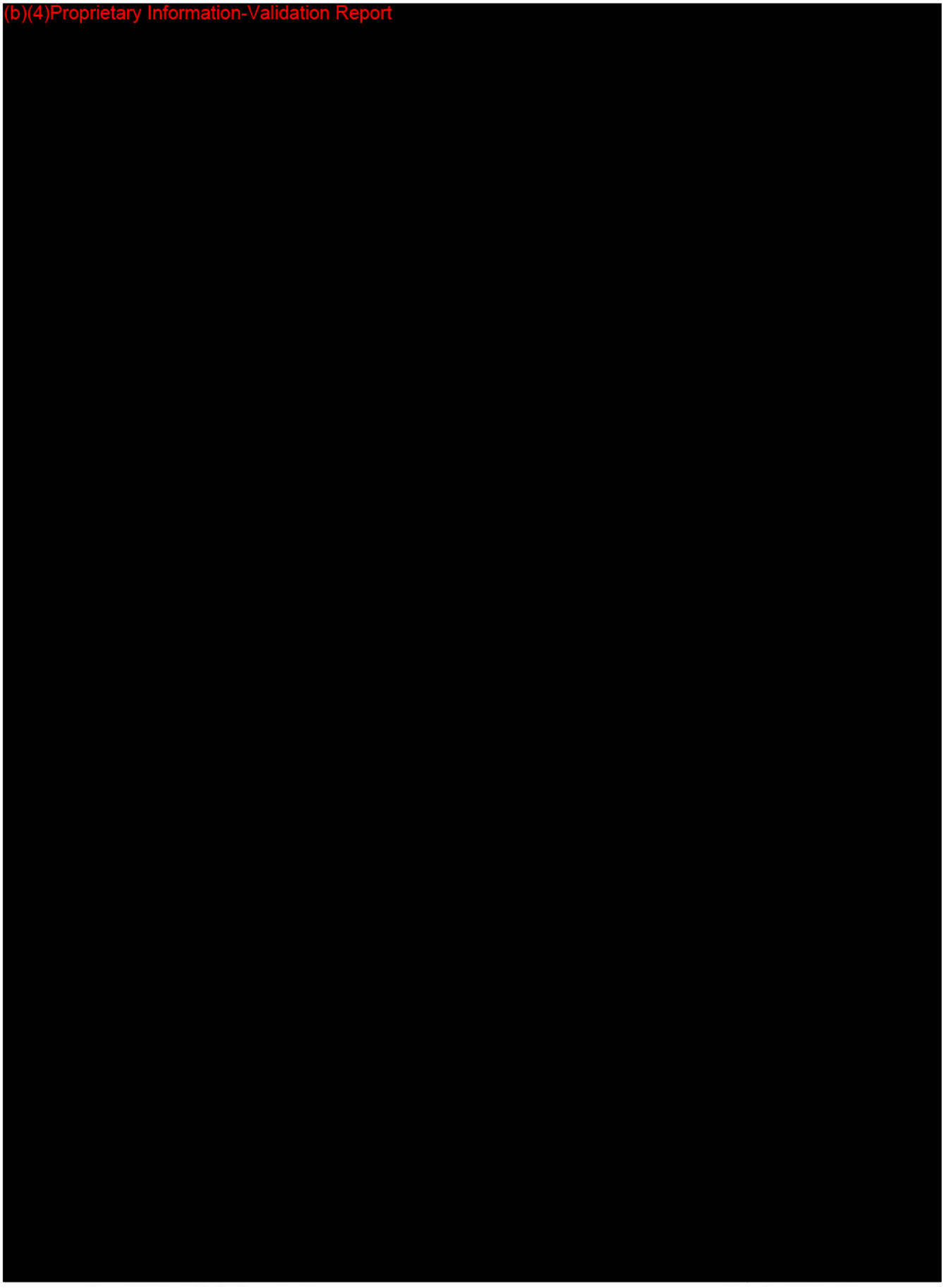
(b)(4)Proprietary Information-Validation Report



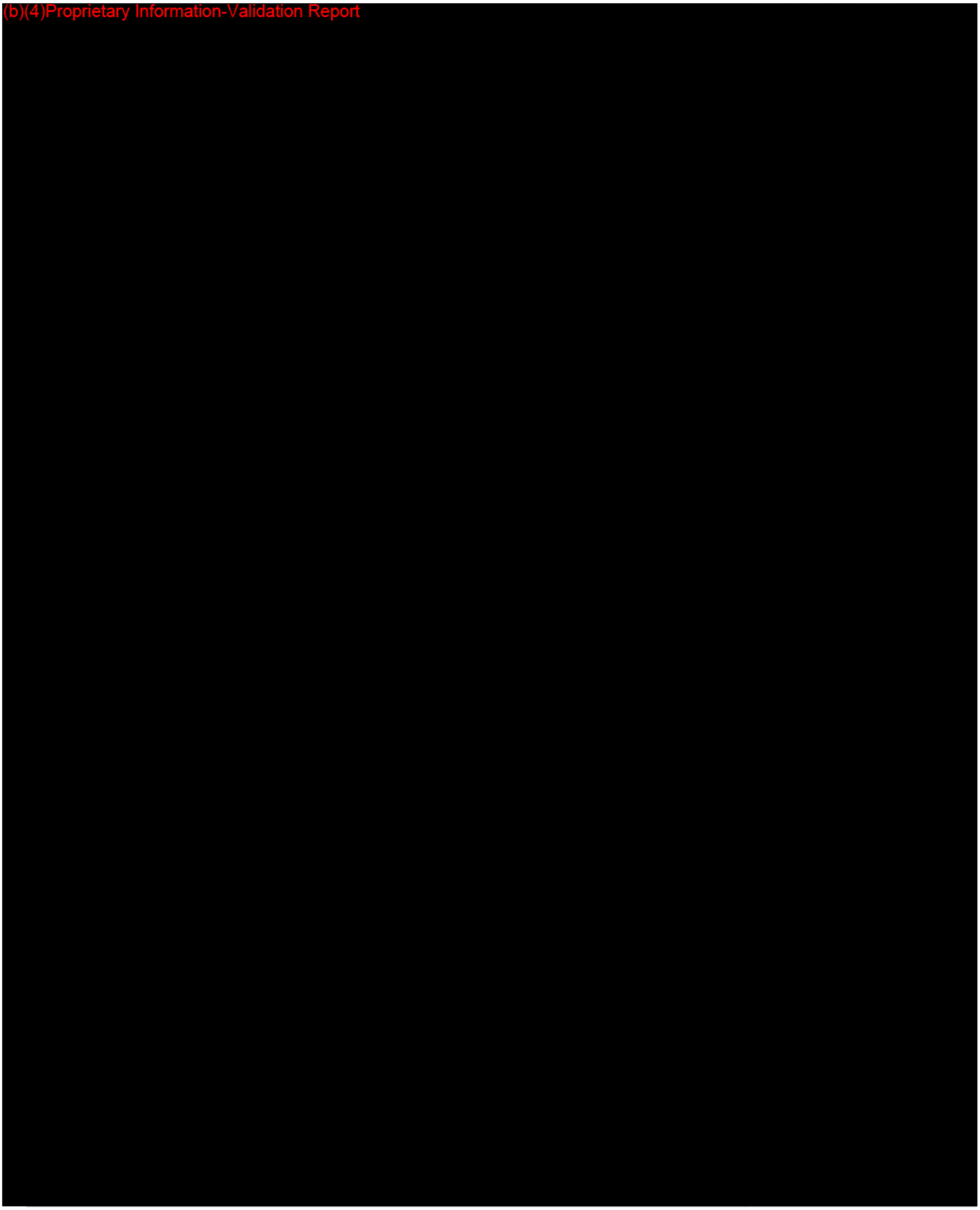
(b)(4)Proprietary Information-Validation Report

[redacted]

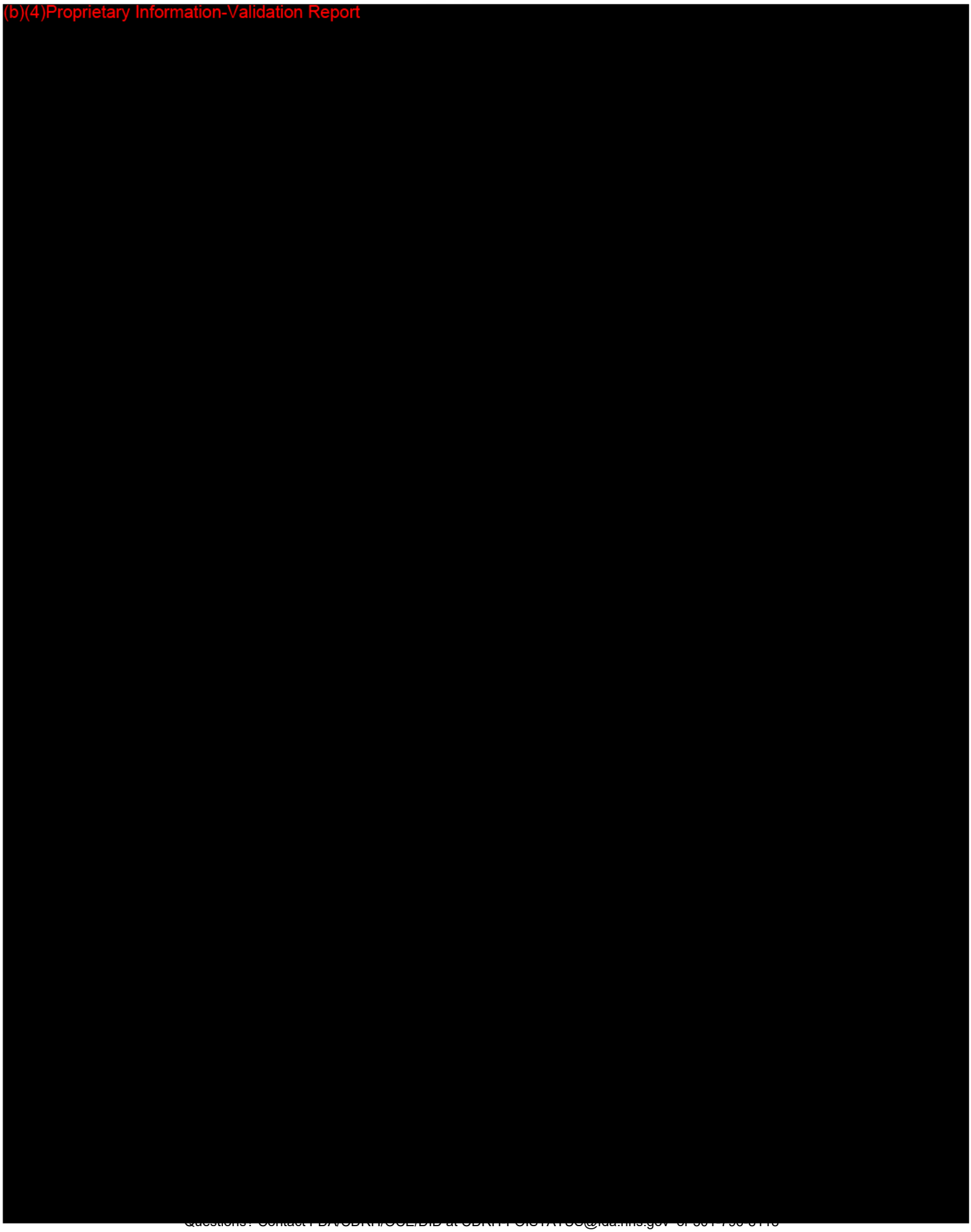
(b)(4)Proprietary Information-Validation Report



(b)(4)Proprietary Information-Validation Report



(b)(4)Proprietary Information-Validation Report



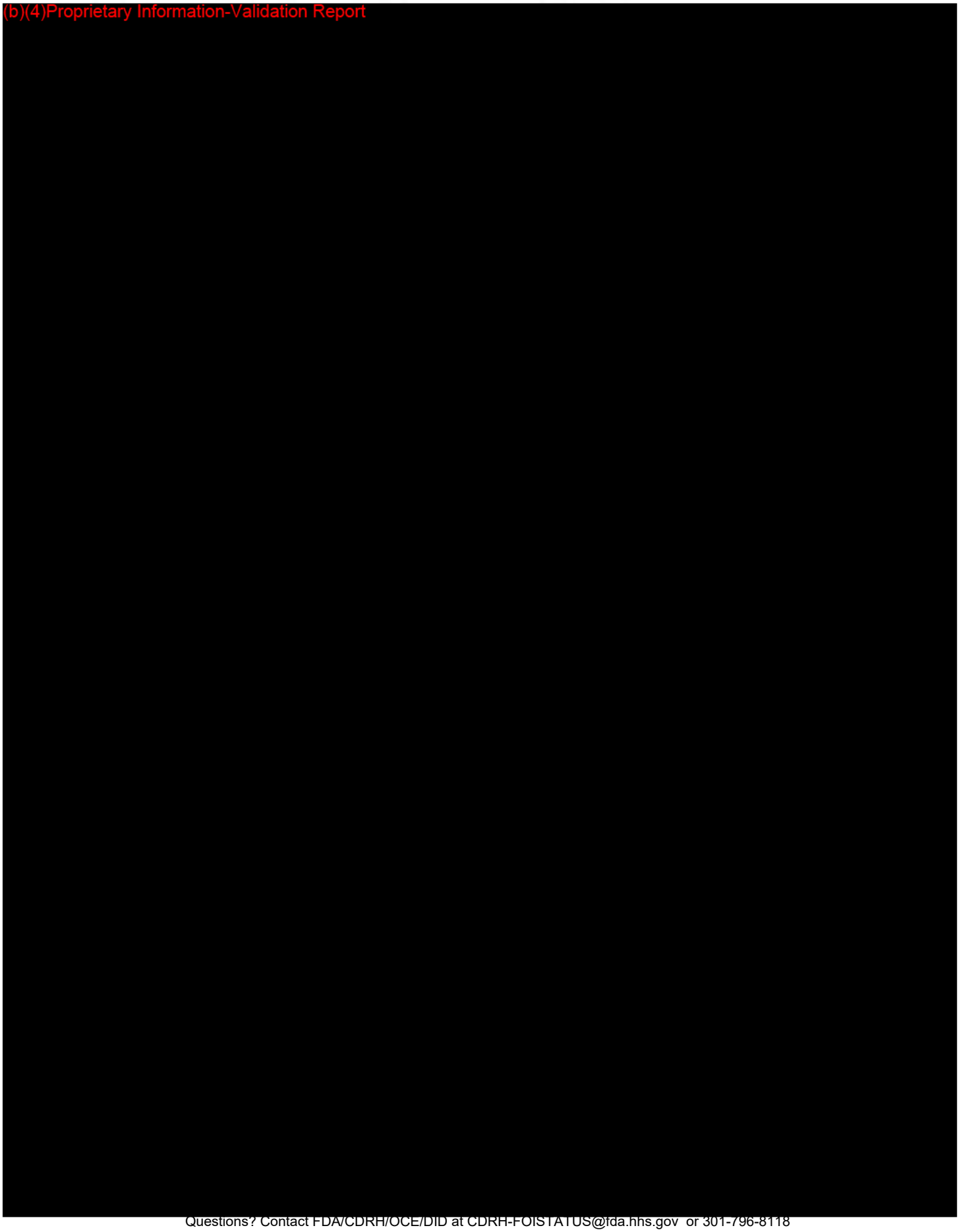
(b)(4)Proprietary Information-Validation Report

[redacted]

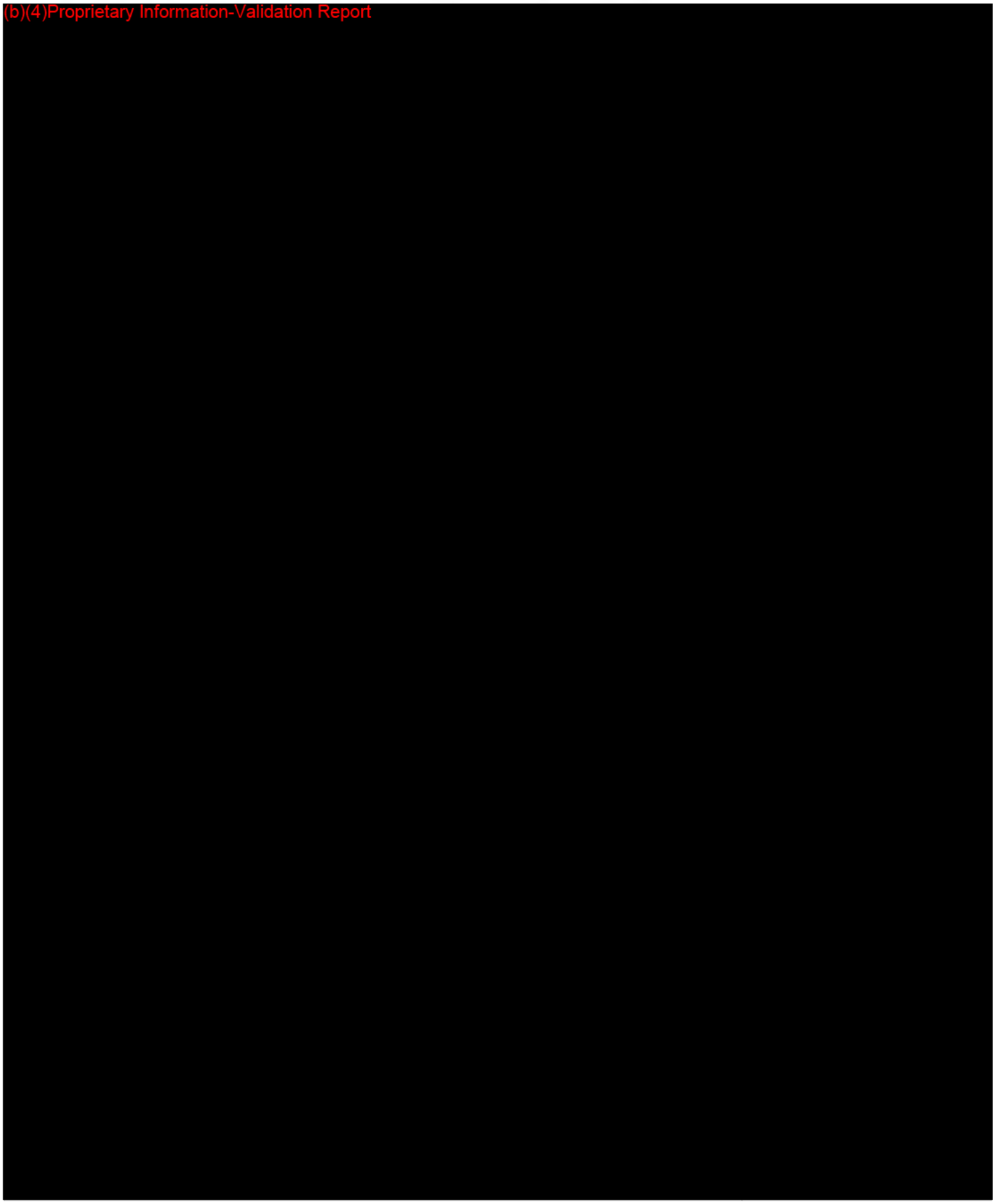
(b)(4)Proprietary Information-Validation Report

[redacted]

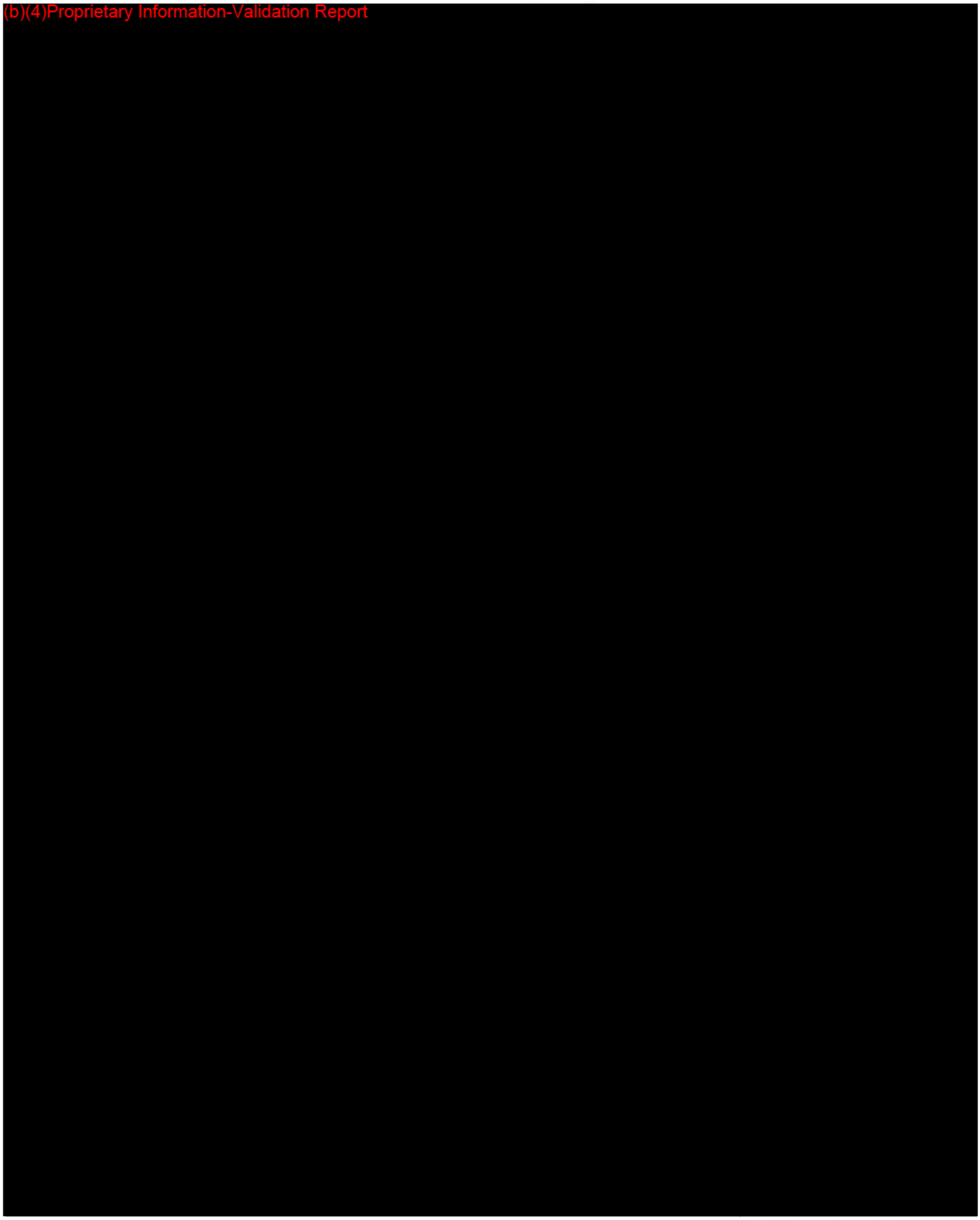
(b)(4)Proprietary Information-Validation Report



(b)(4)Proprietary Information-Validation Report



(b)(4)Proprietary Information-Validation Report



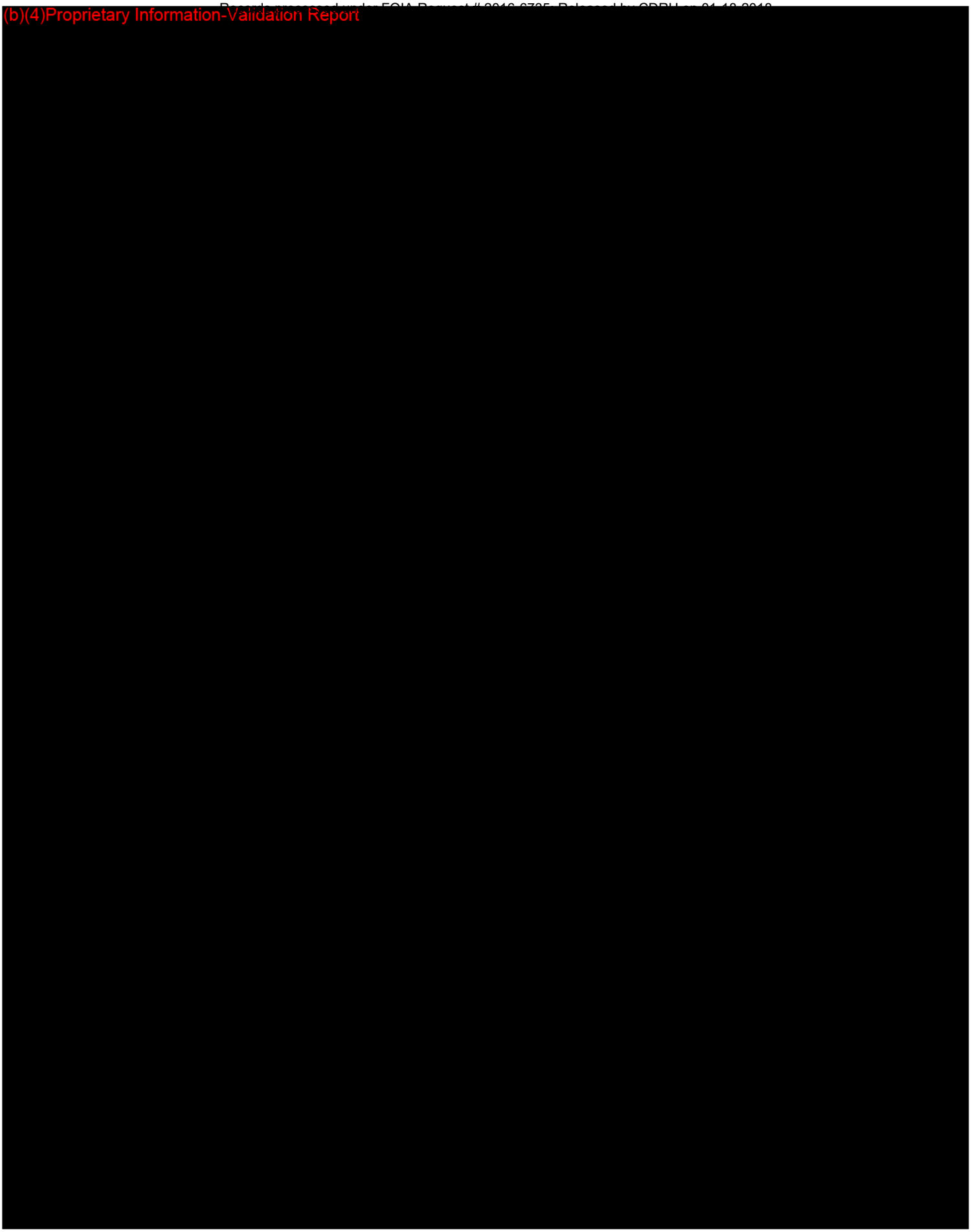
(b)(4)Proprietary Information-Validation Report

[redacted]

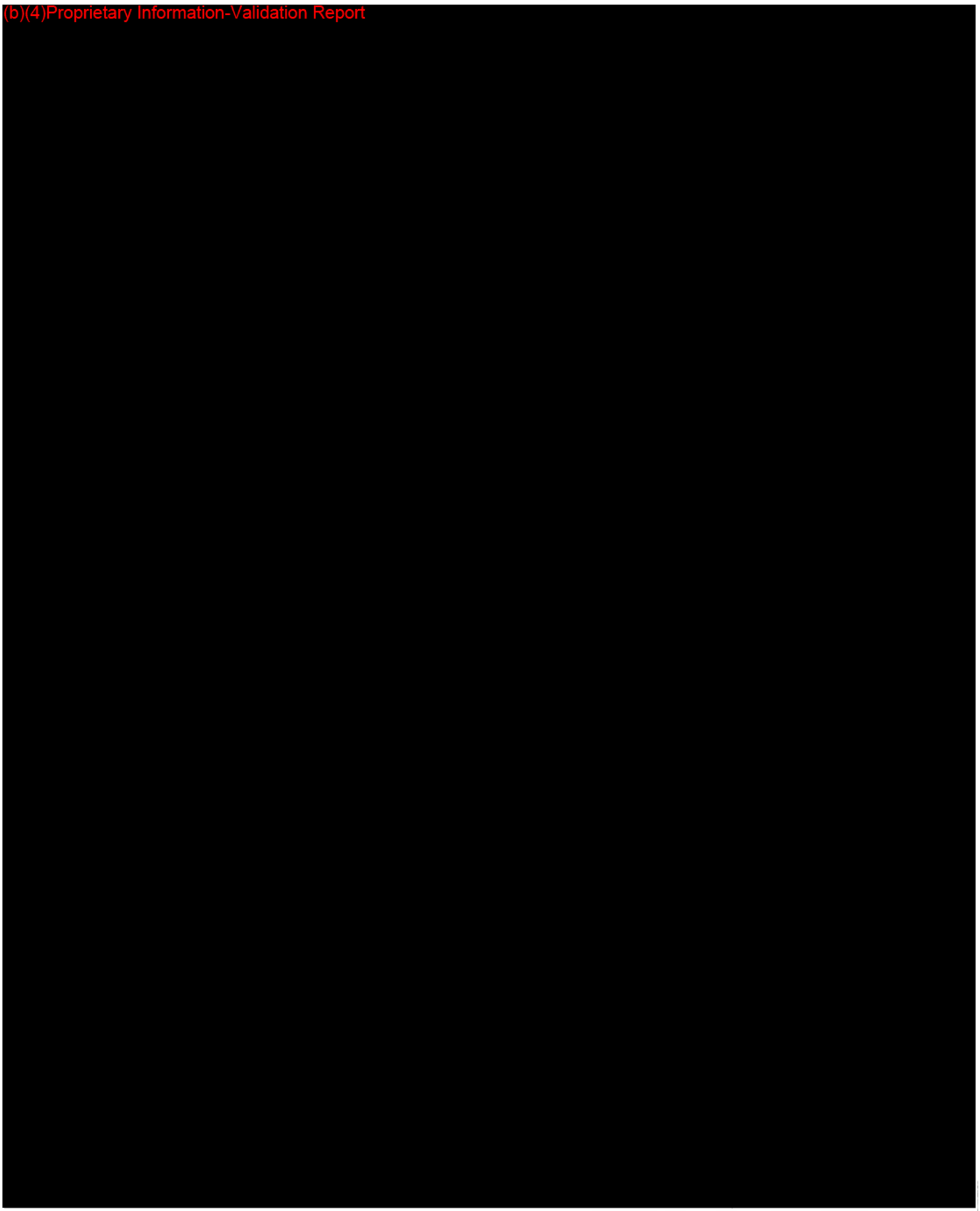
(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report



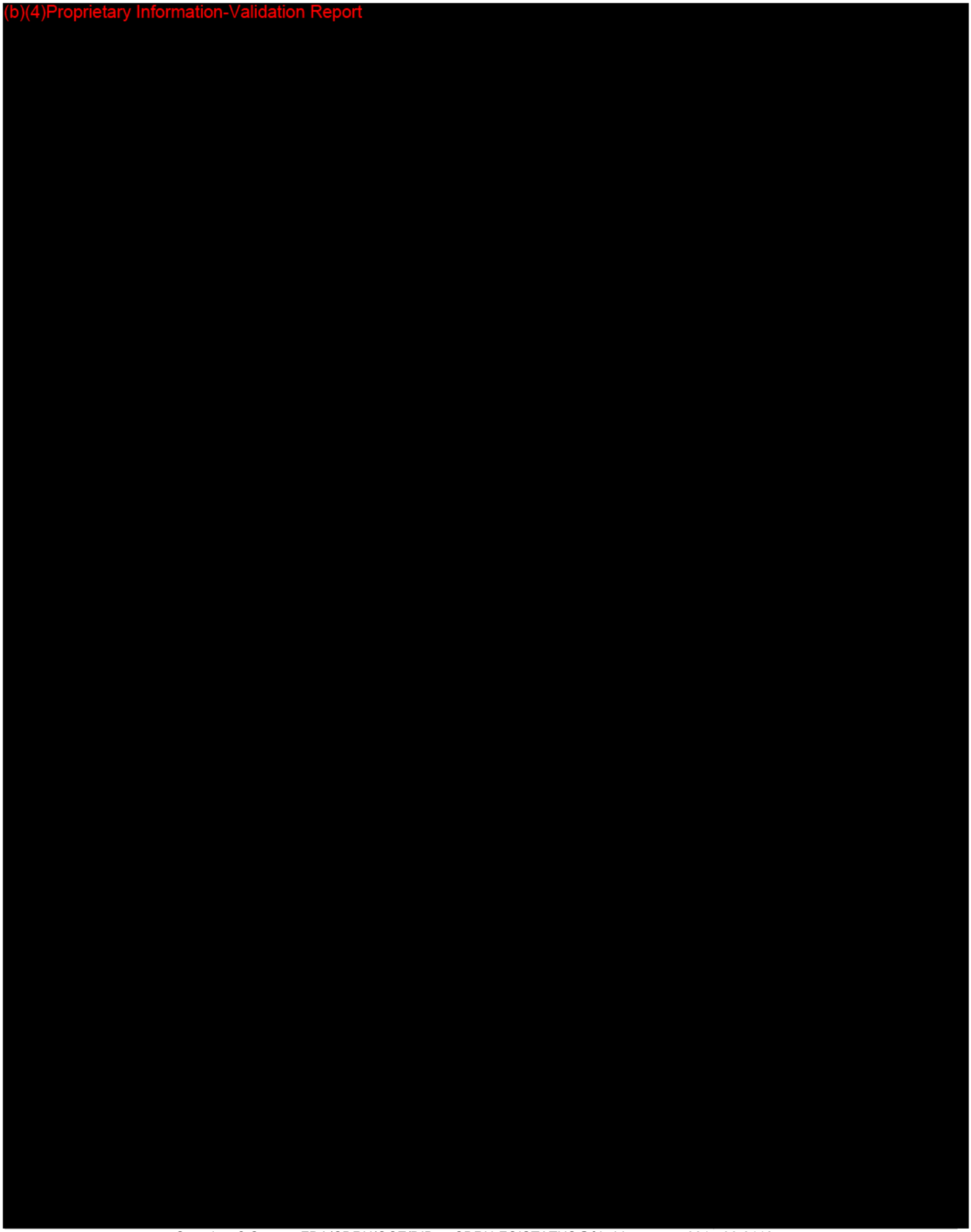
(b)(4)Proprietary Information-Validation Report



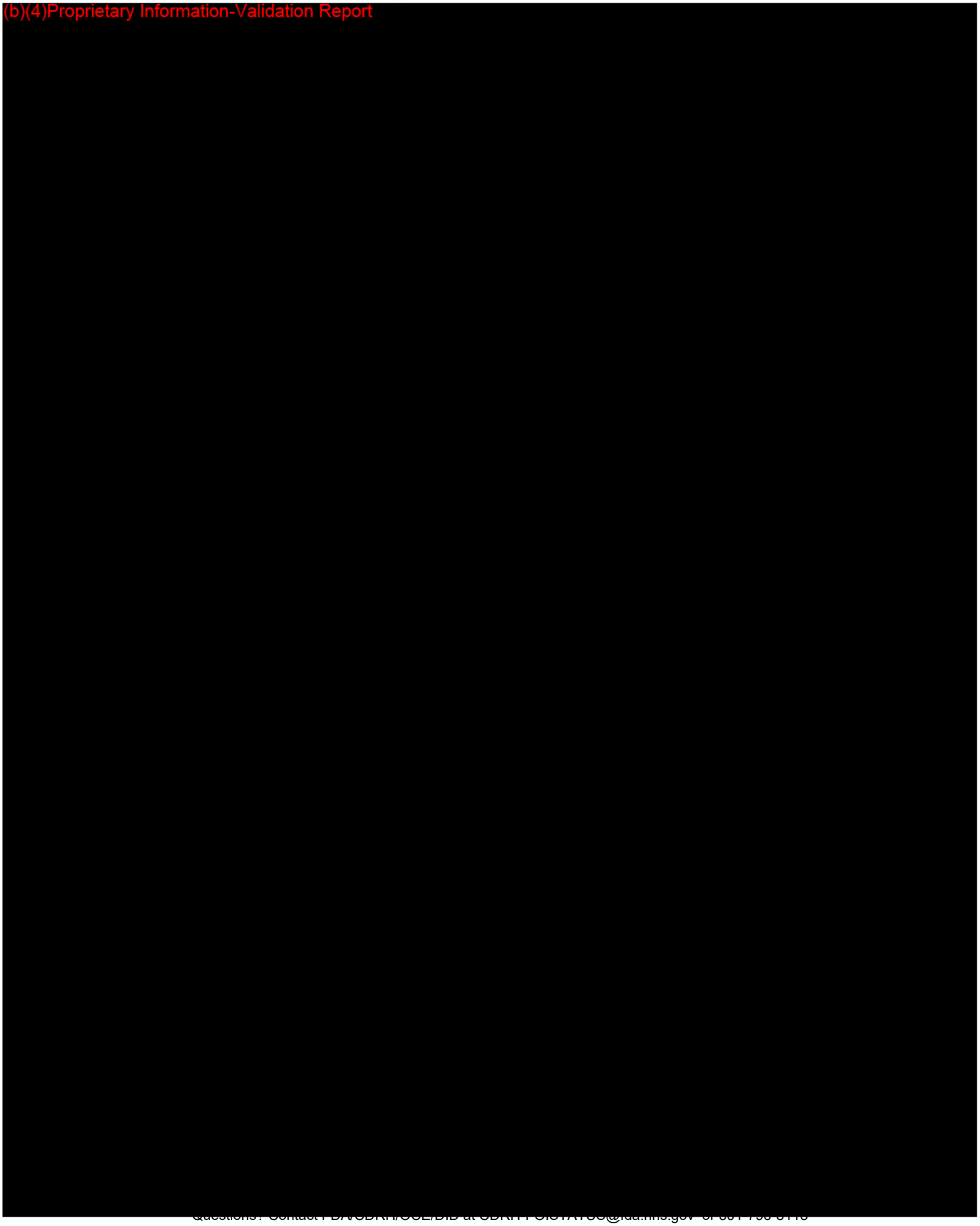
(b)(4)Proprietary Information-Validation Report

[redacted]

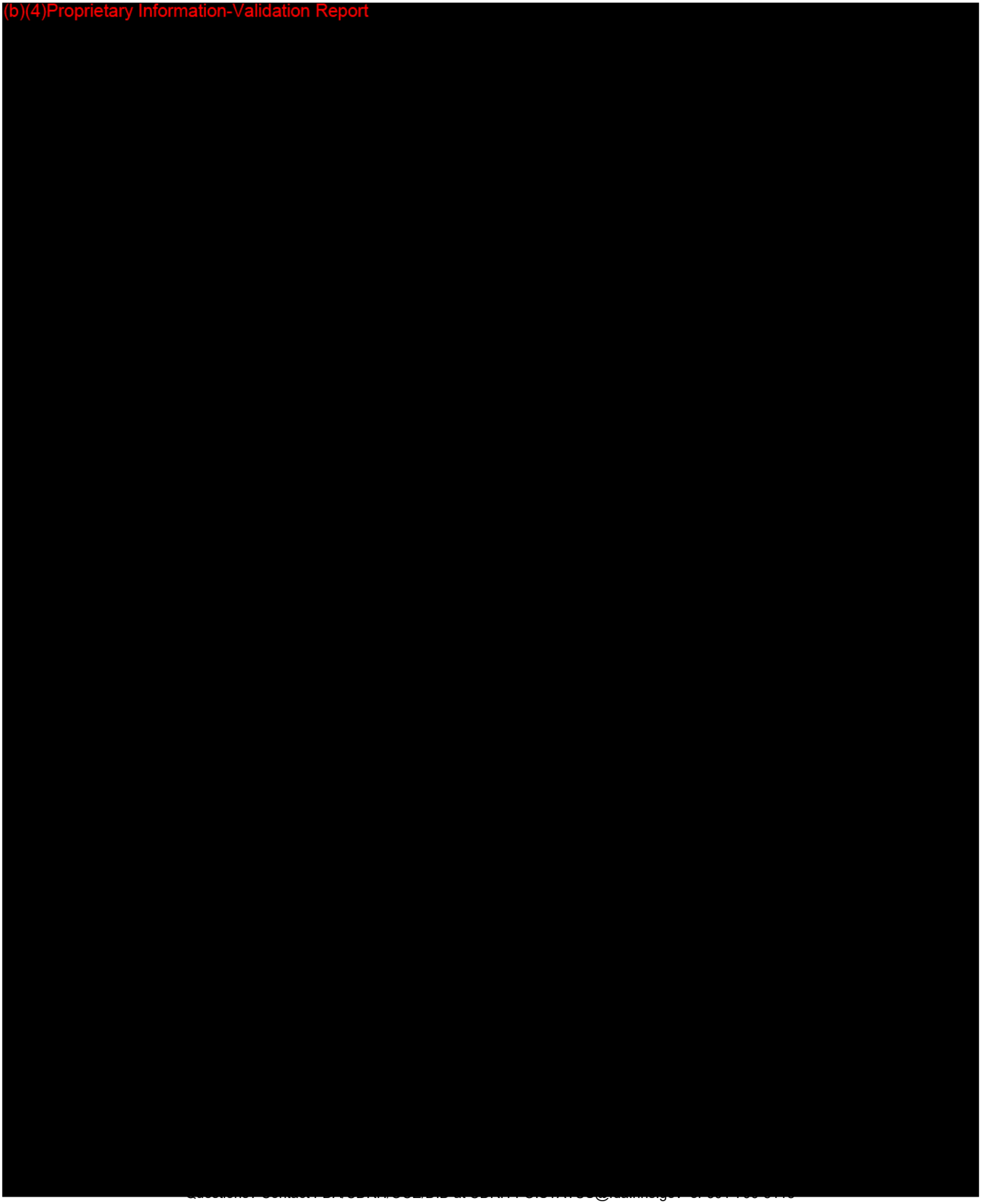
(b)(4)Proprietary Information-Validation Report



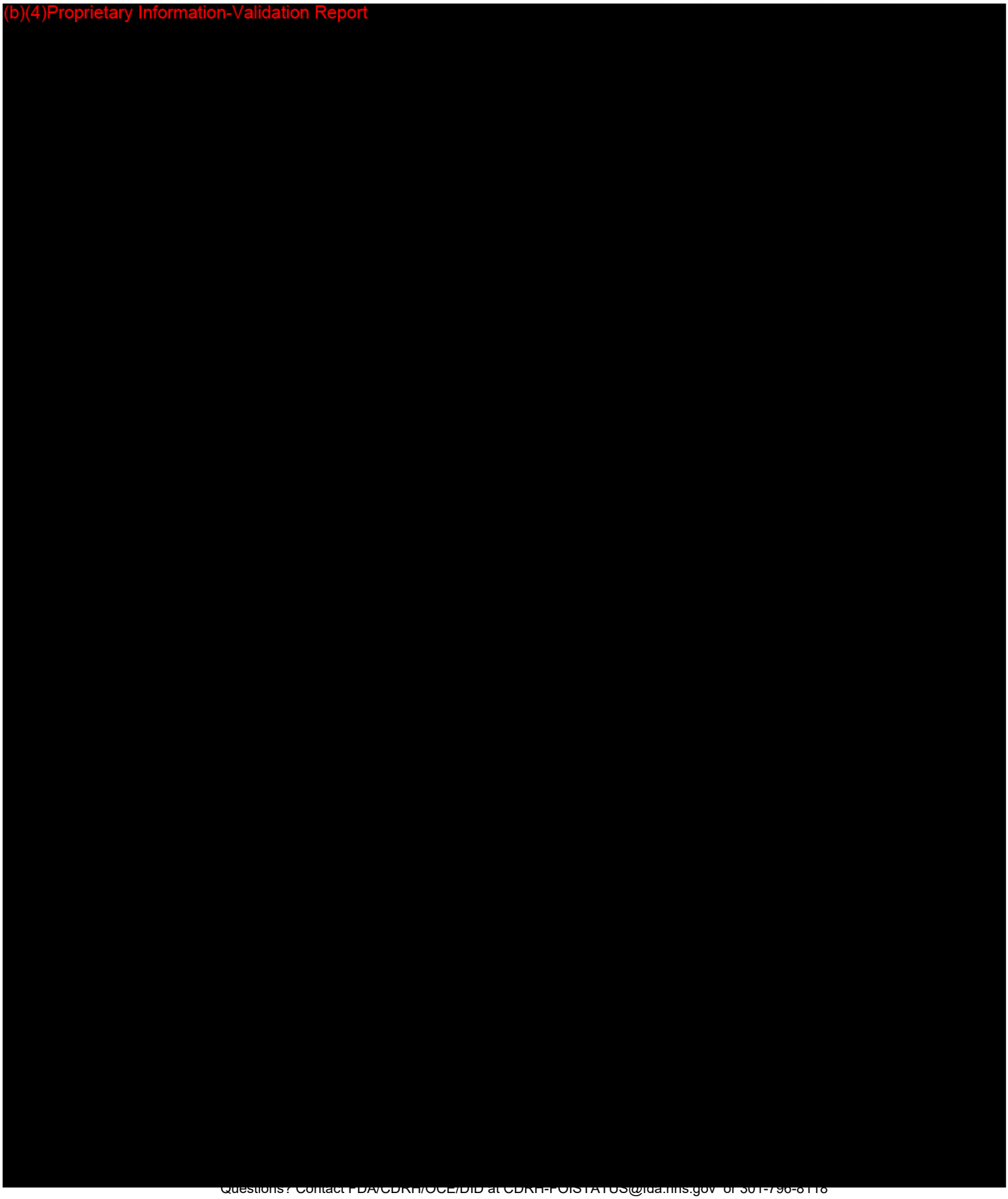
(b)(4)Proprietary Information-Validation Report



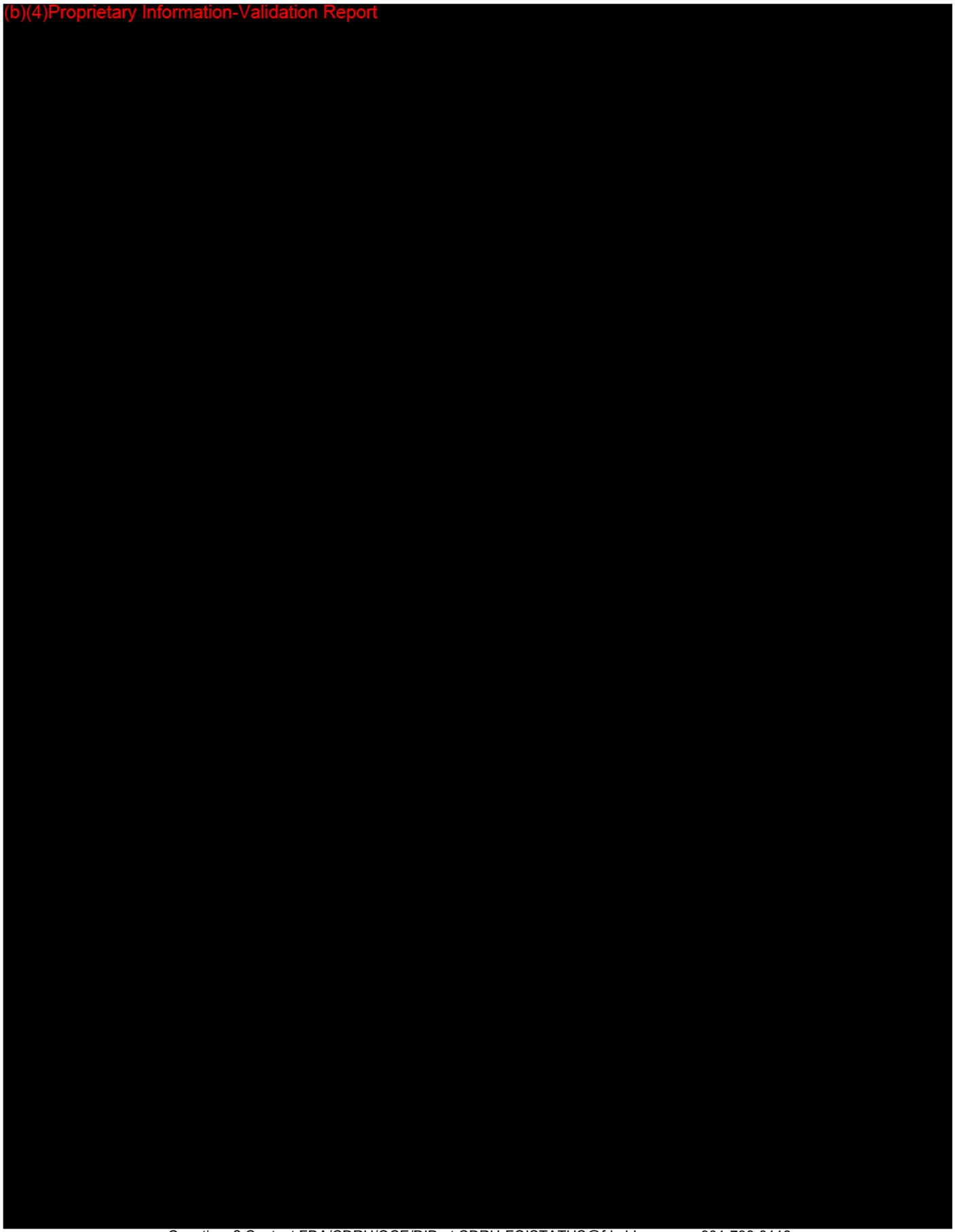
(b)(4)Proprietary Information-Validation Report



(b)(4)Proprietary Information-Validation Report



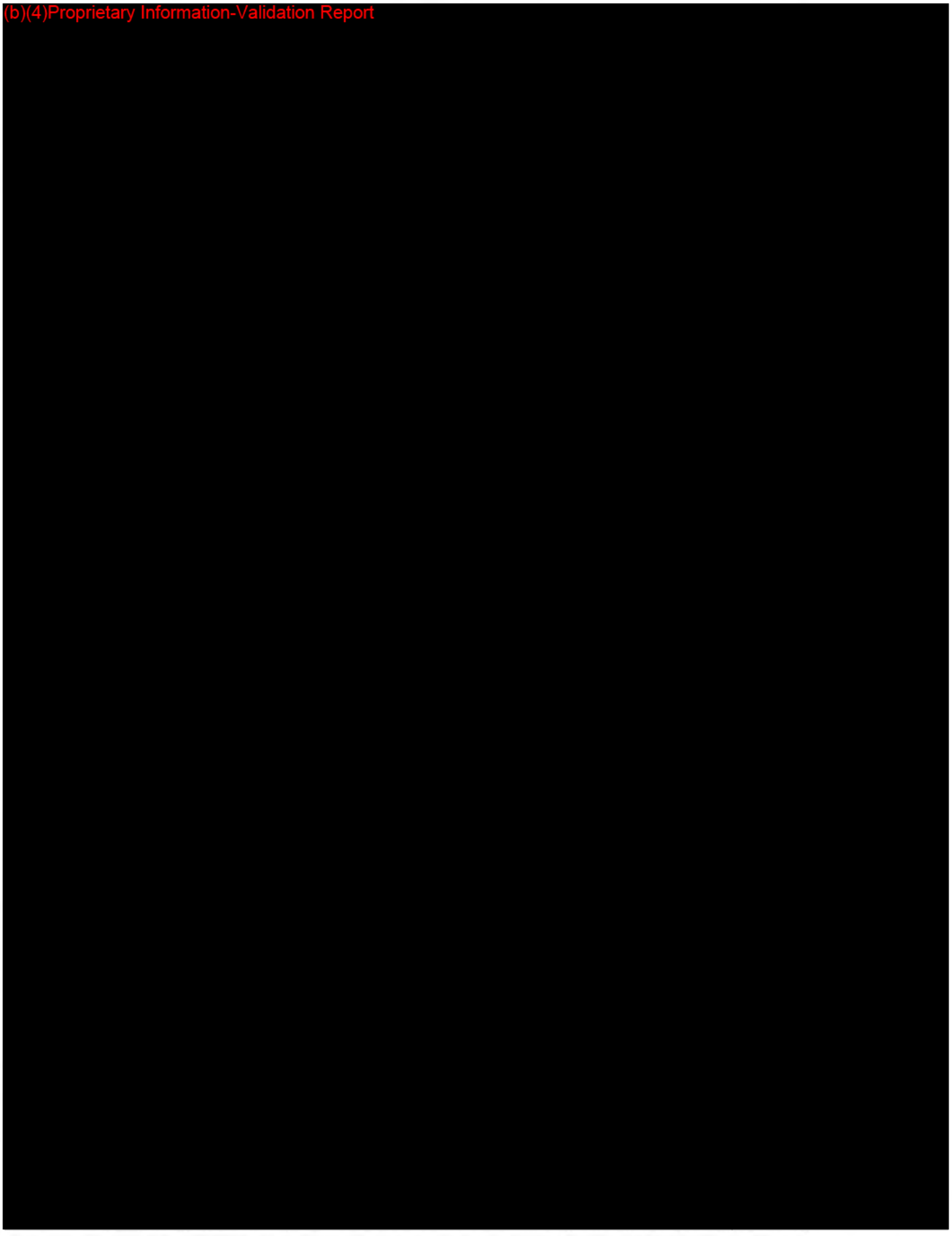
(b)(4)Proprietary Information-Validation Report

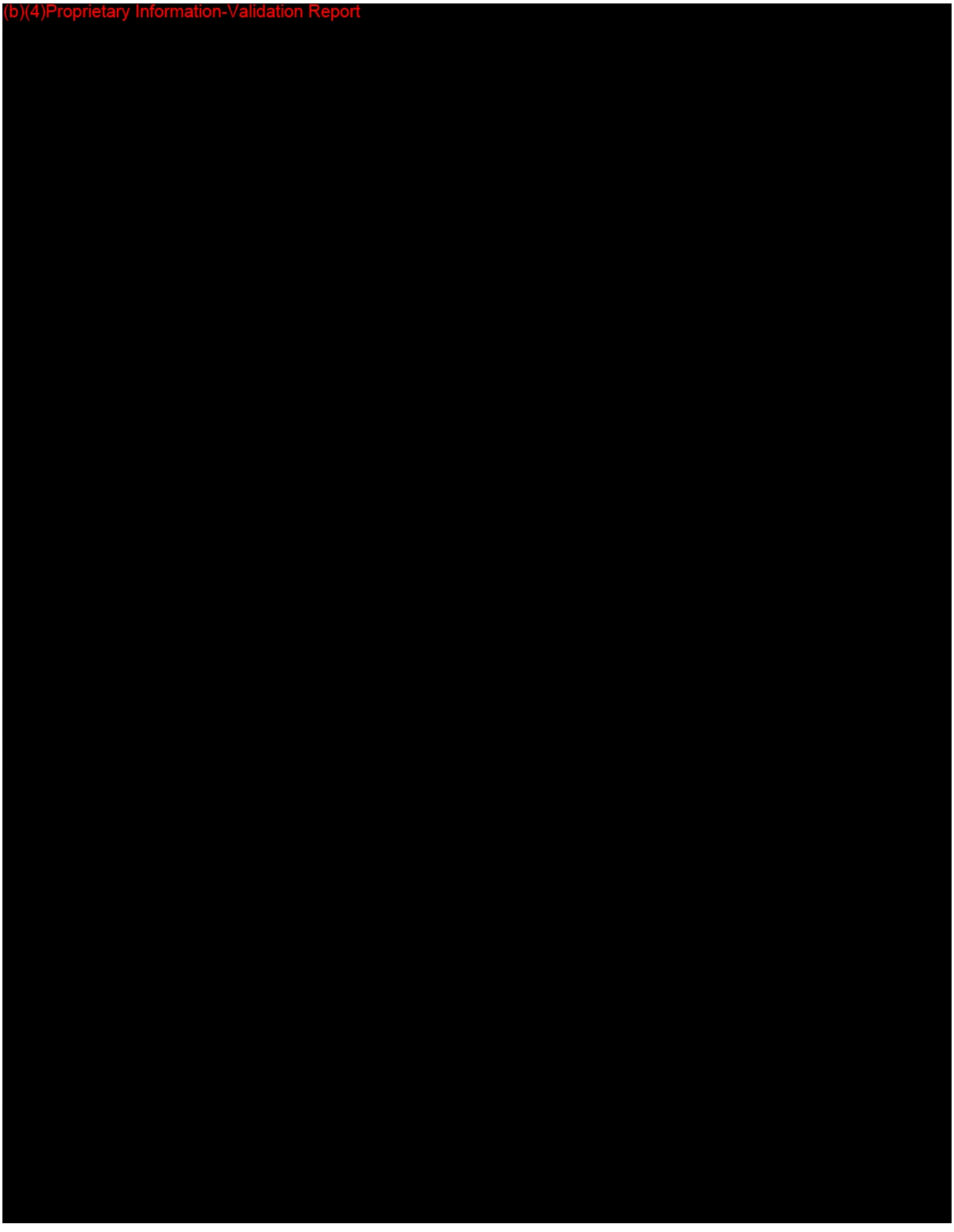


(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report





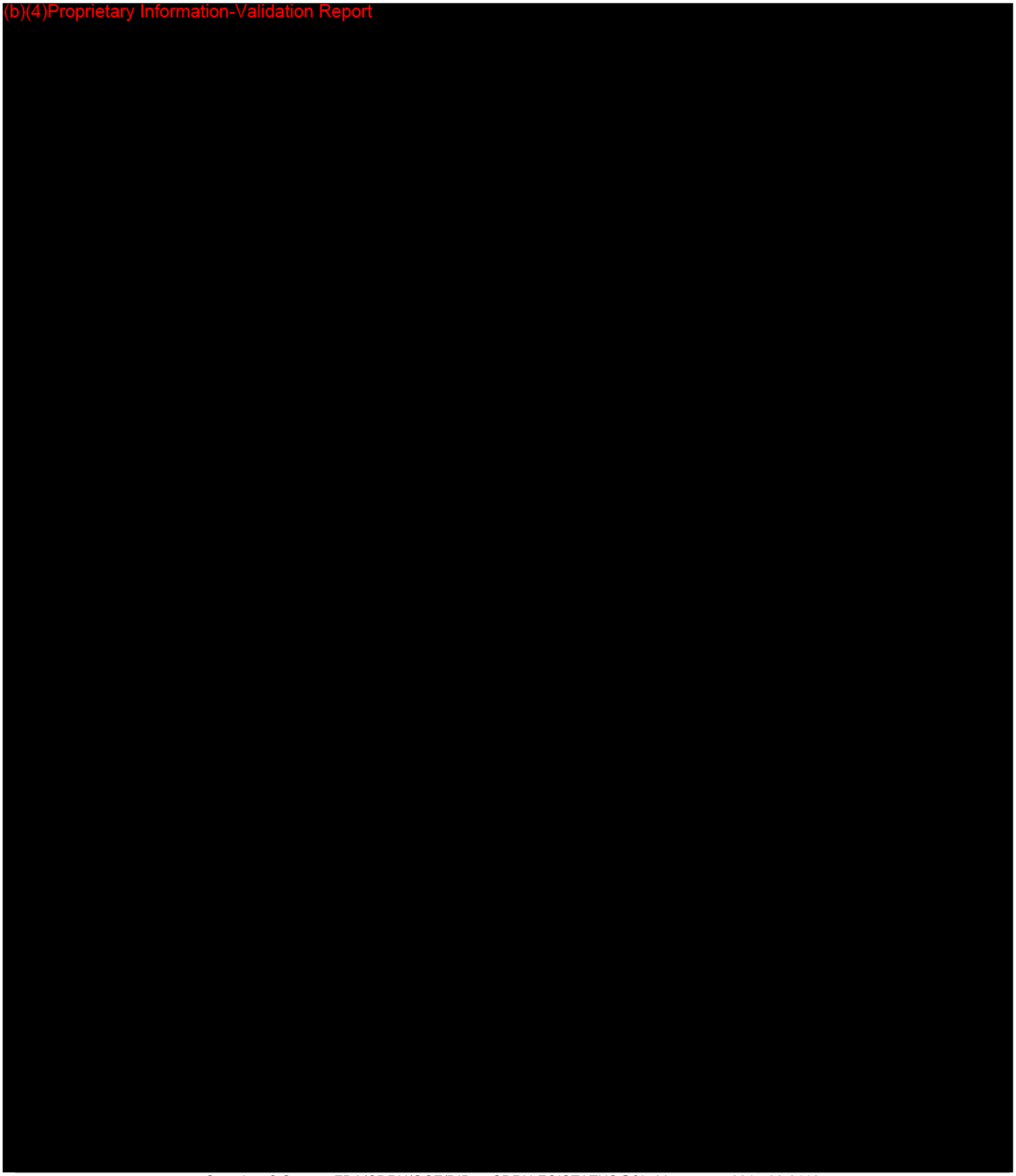
(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

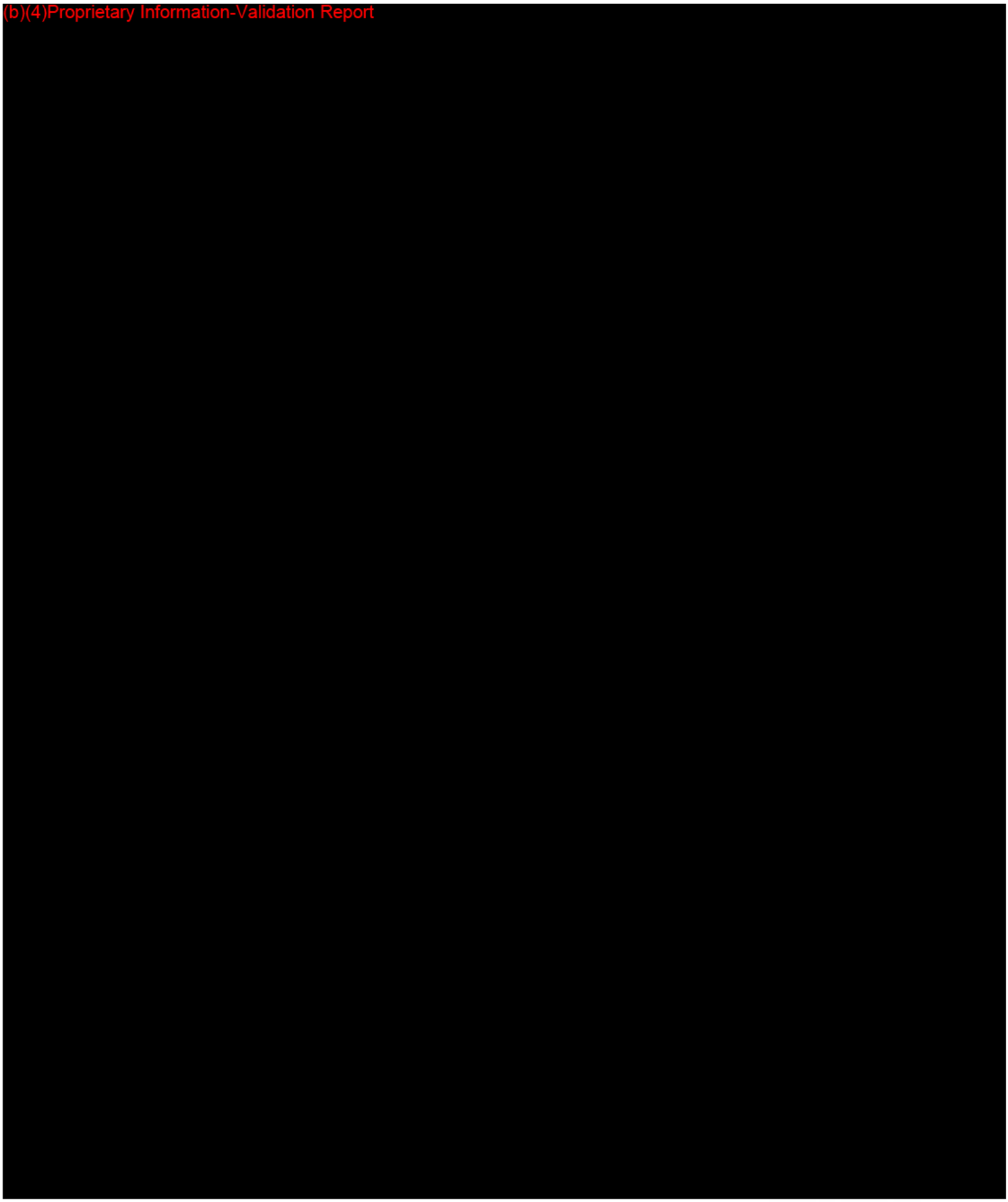


(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

[redacted]



(b)(4)Proprietary Information-Validation Report

[redacted]

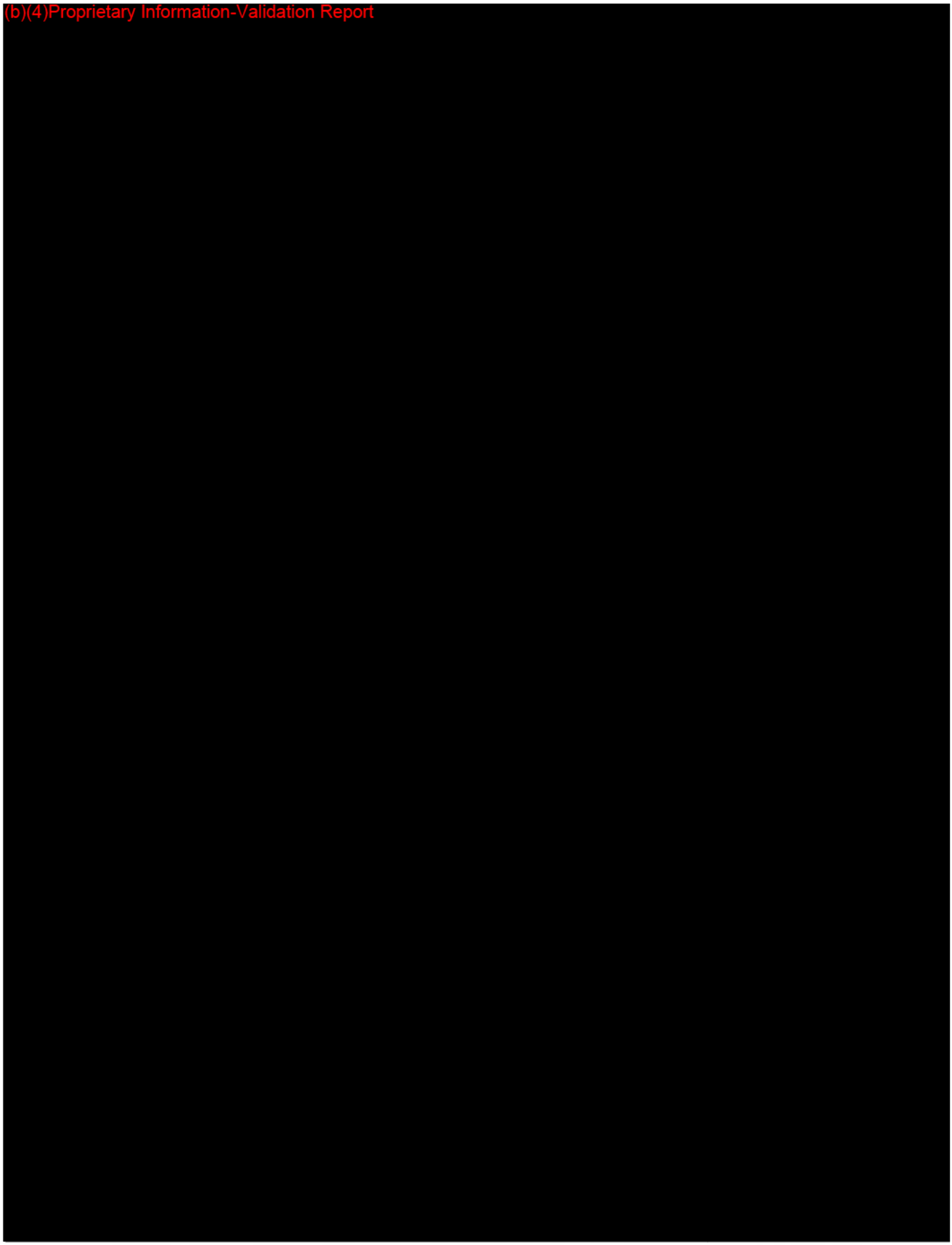
(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

[redacted]

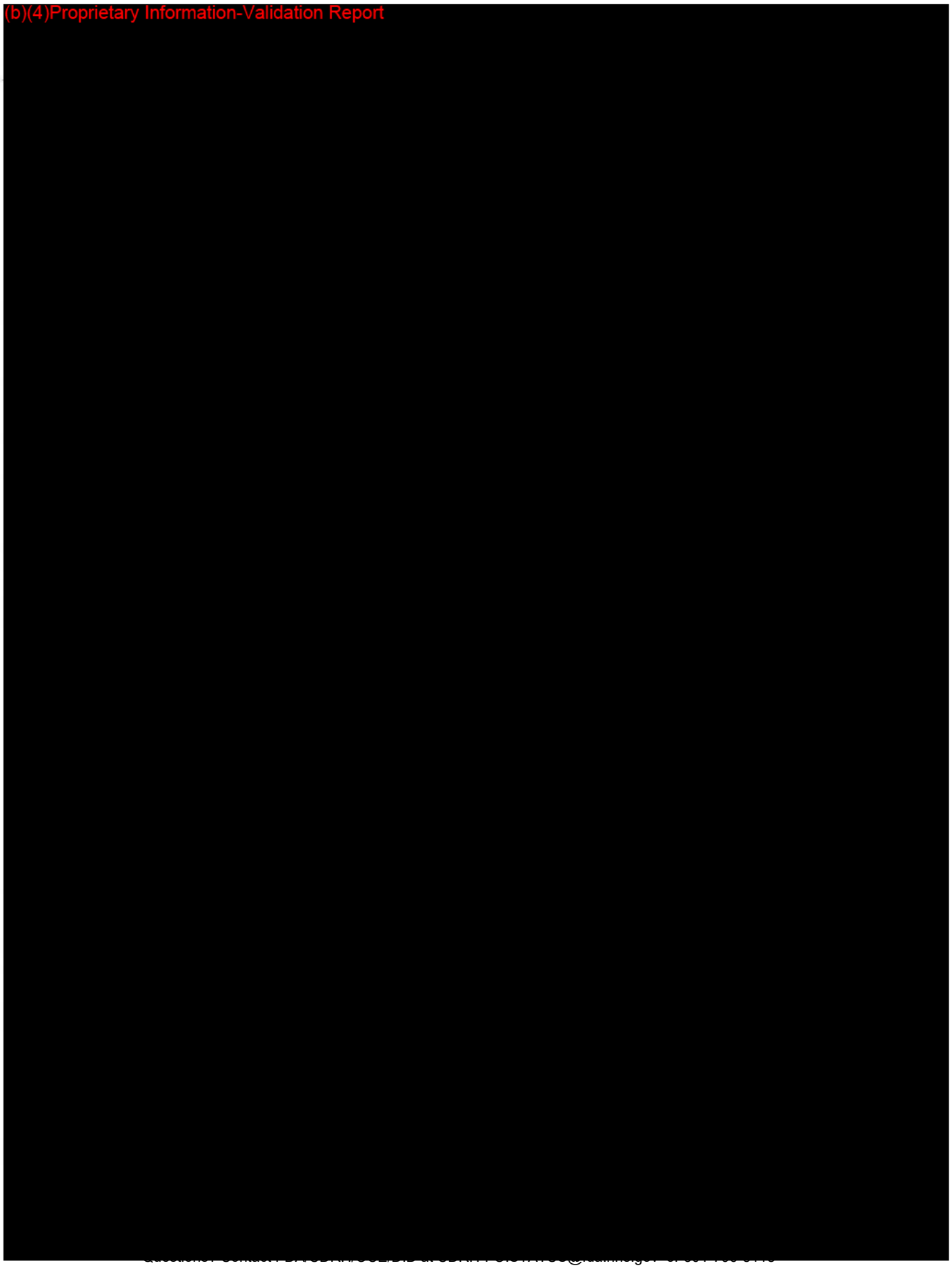
(b)(4)Proprietary Information-Validation Report



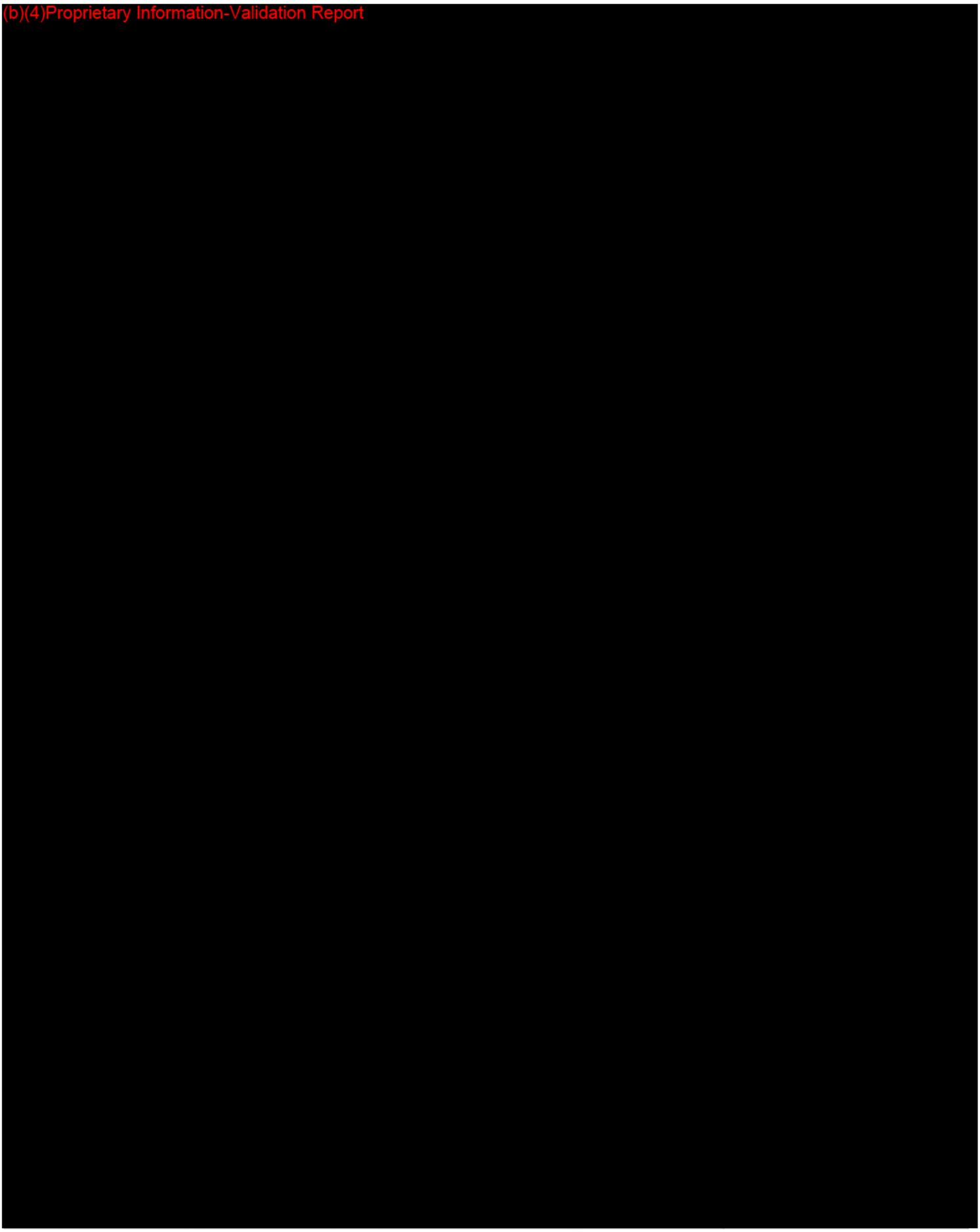
(b)(4)Proprietary Information-Validation Report

[redacted]

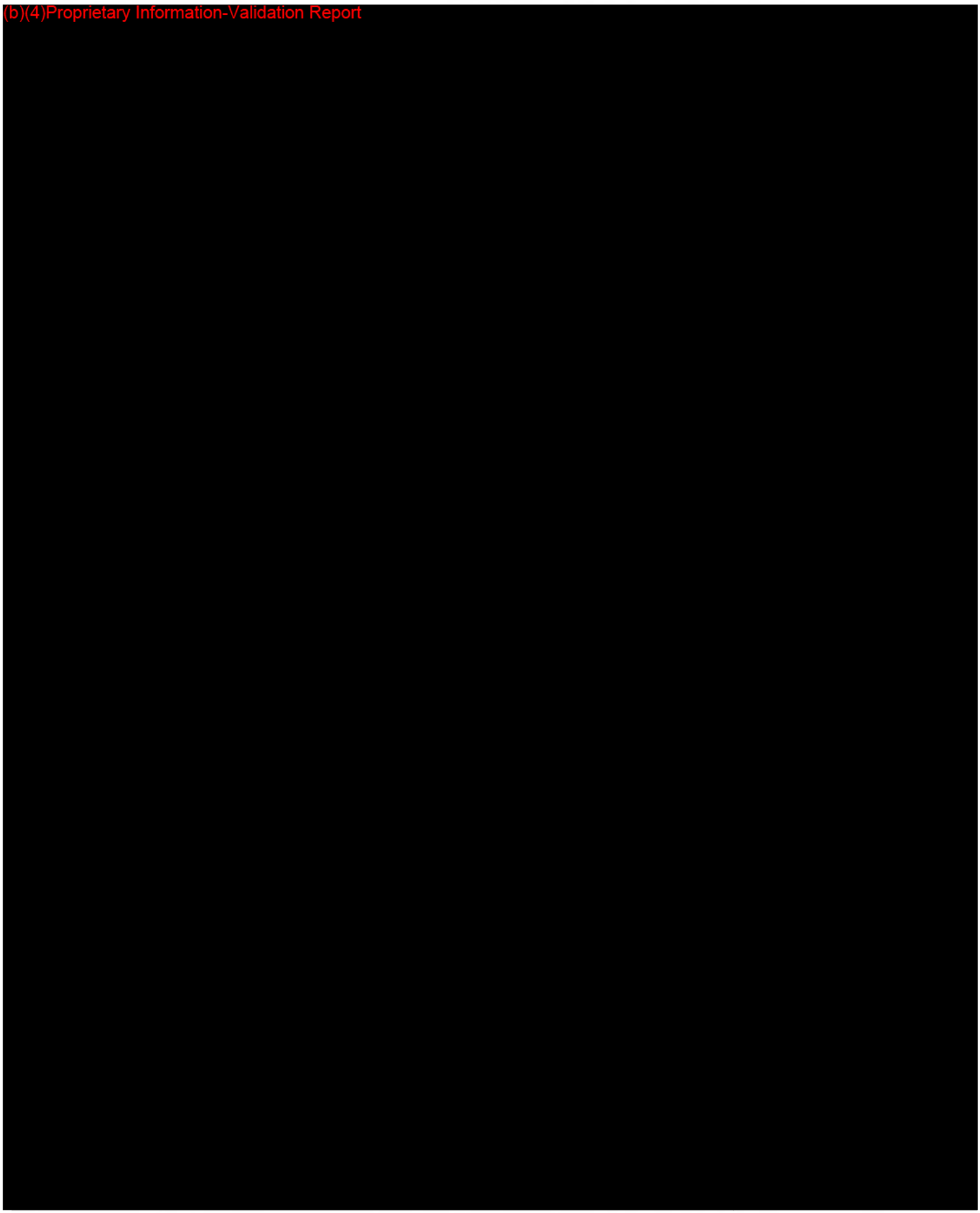
(b)(4)Proprietary Information-Validation Report



(b)(4)Proprietary Information-Validation Report



(b)(4)Proprietary Information-Validation Report



(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

[redacted]

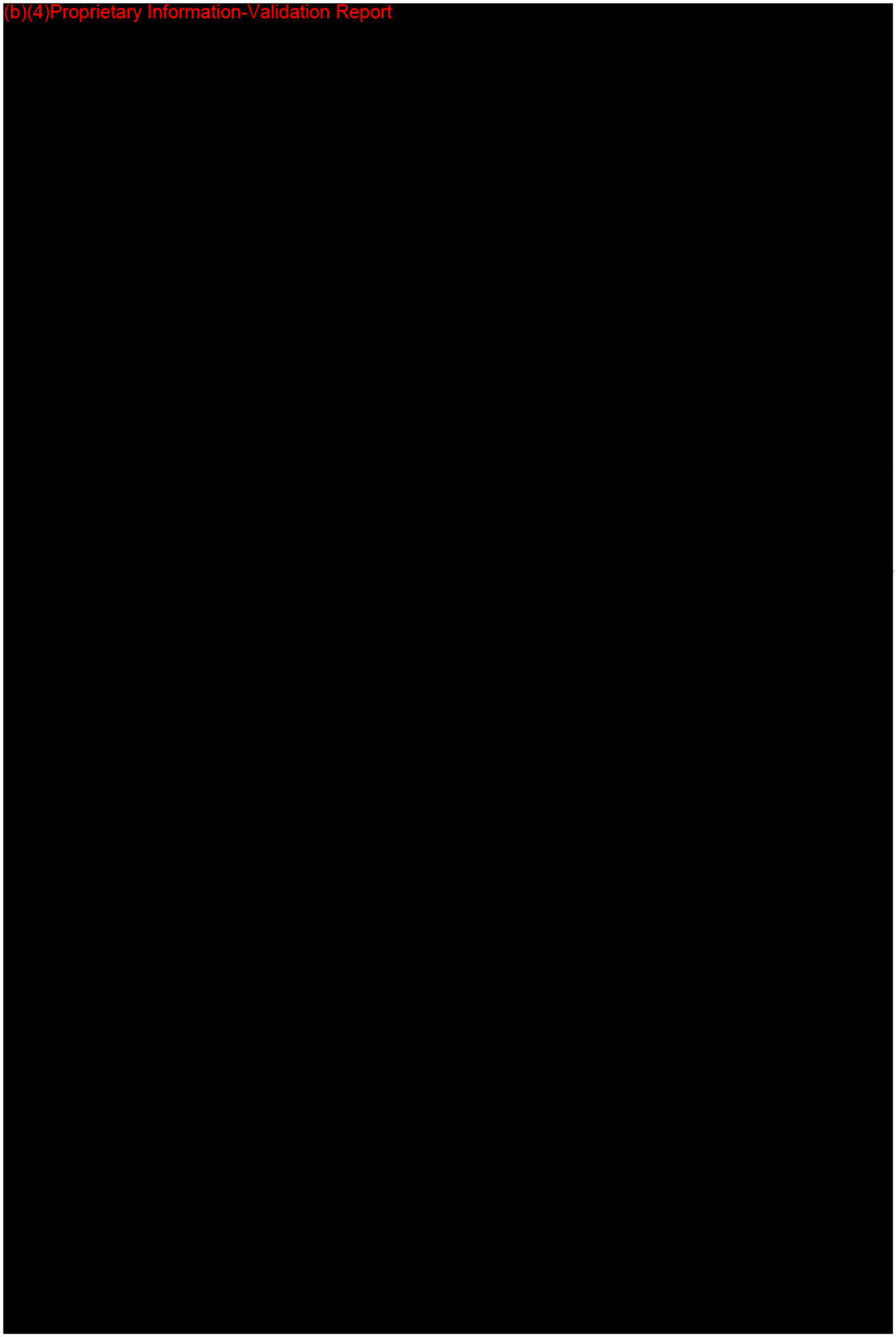
(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report



(b)(4)Proprietary Information-Validation Report

[redacted]

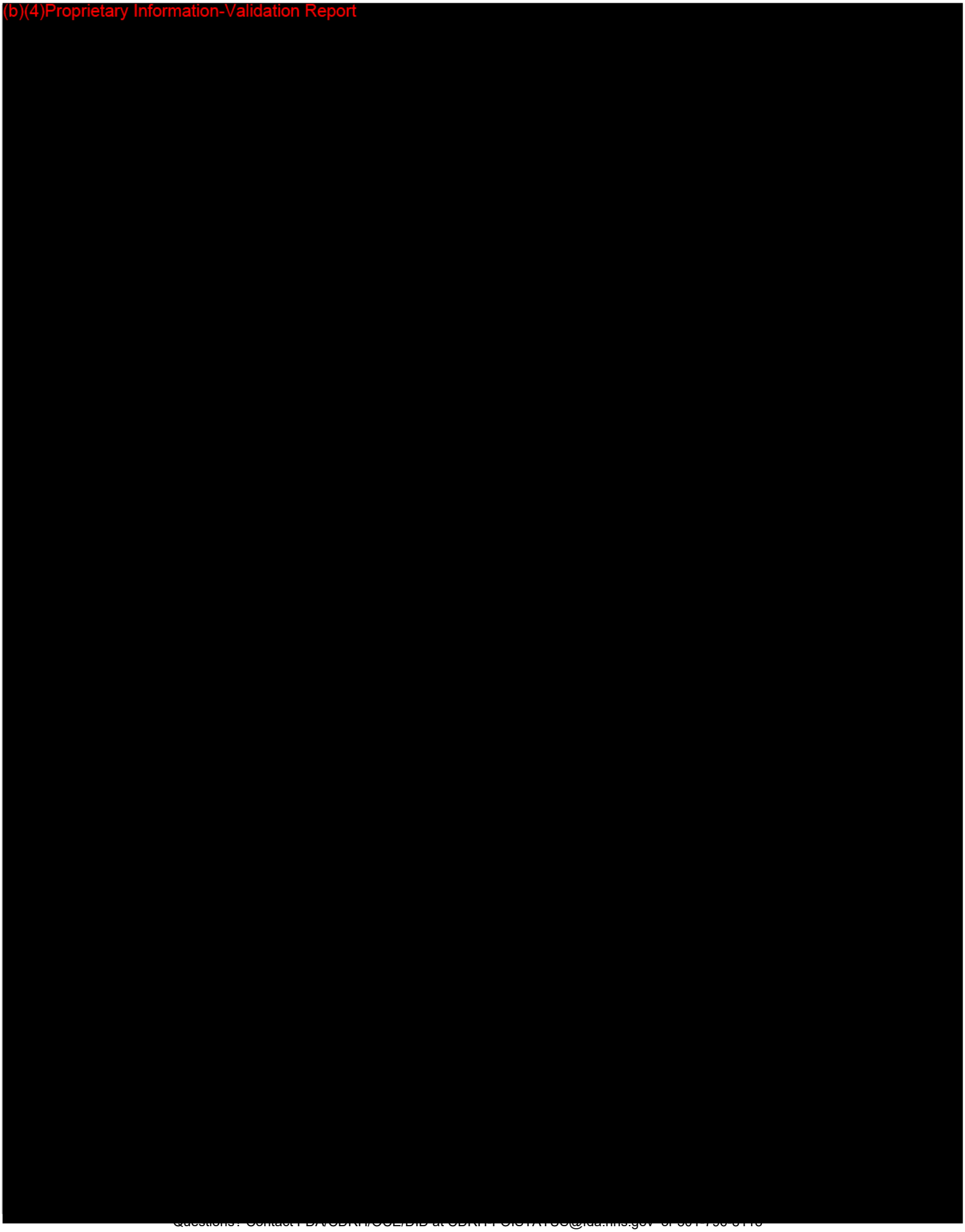
(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

(b)(4)Proprietary Information-Validation Report

(b)(4)Proprietary Information-Validation Report



(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

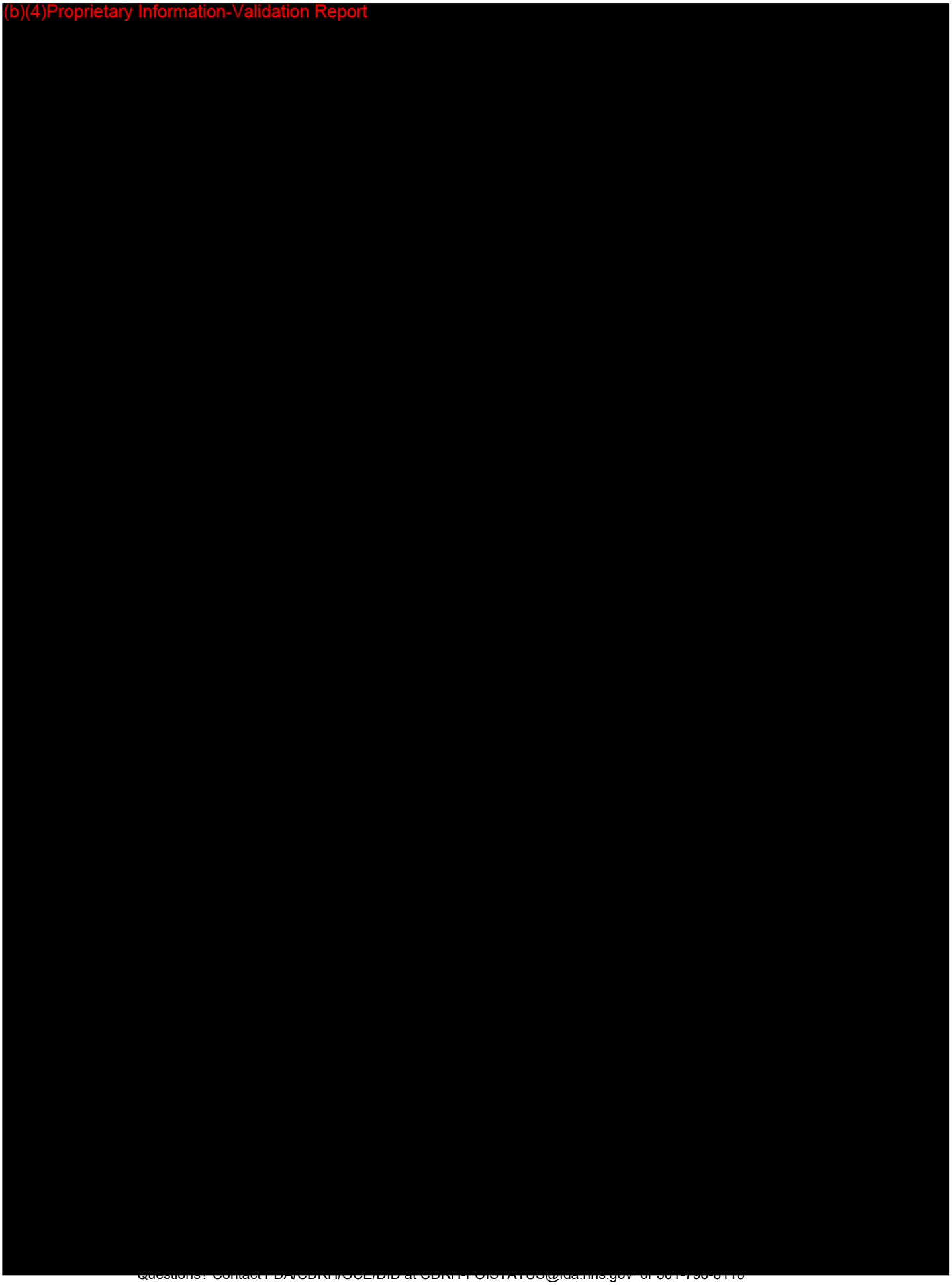
[redacted]

(b)(4)Proprietary Information-Validation Report

(b)(4)Proprietary Information-Validation Report

[redacted]

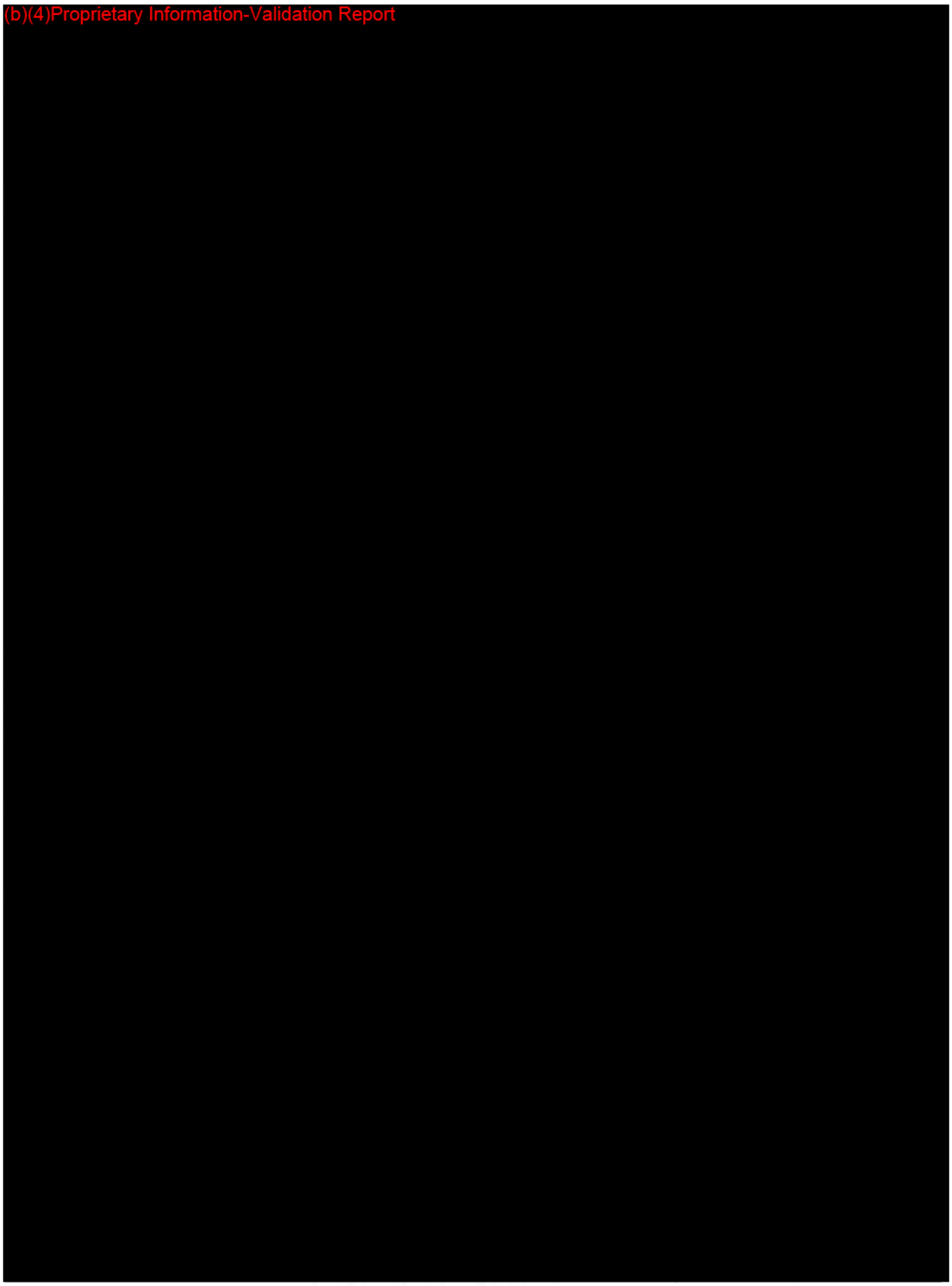
(b)(4)Proprietary Information-Validation Report



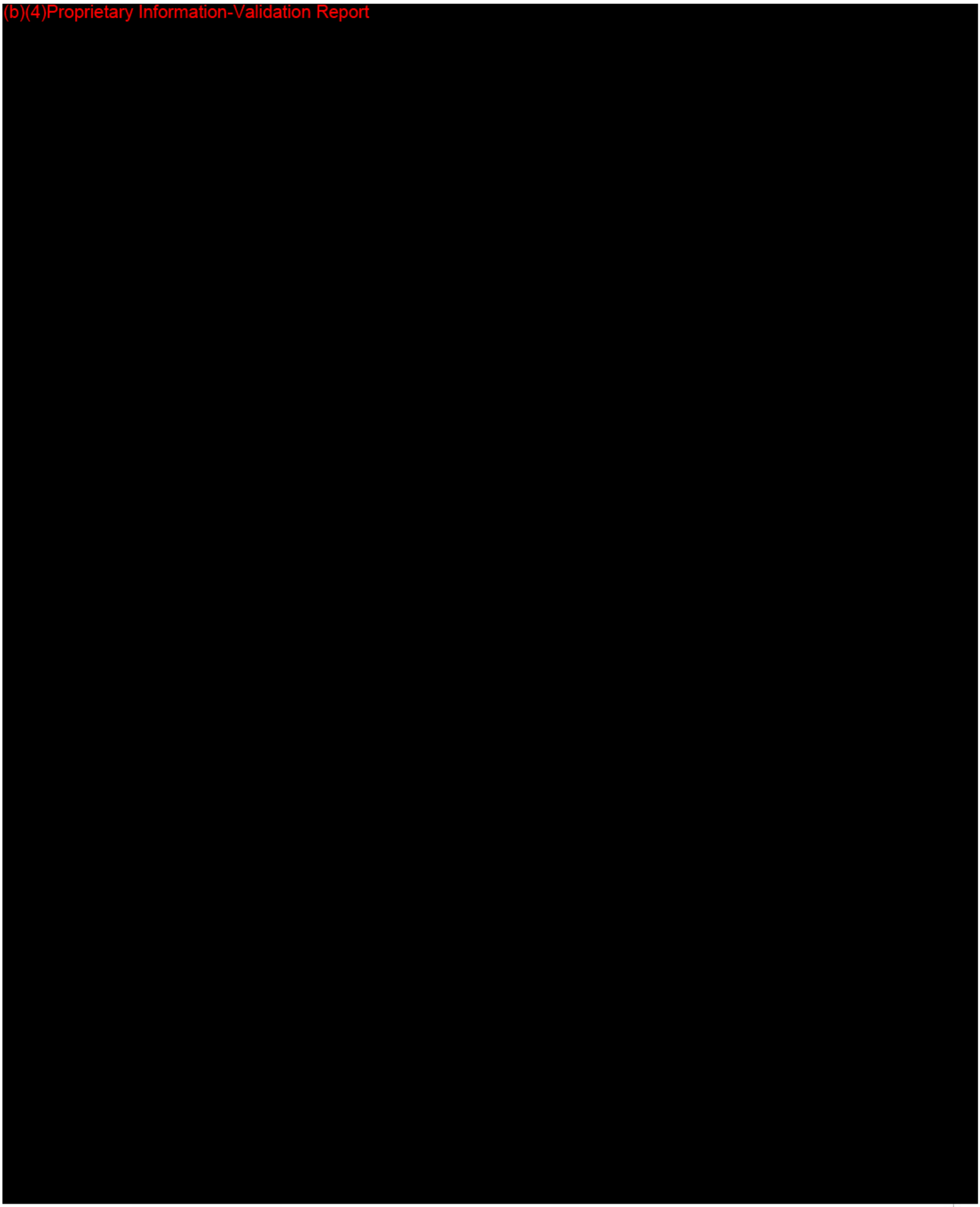
(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report



(b)(4)Proprietary Information-Validation Report



(b)(4)Proprietary Information-Validation Report

[redacted]

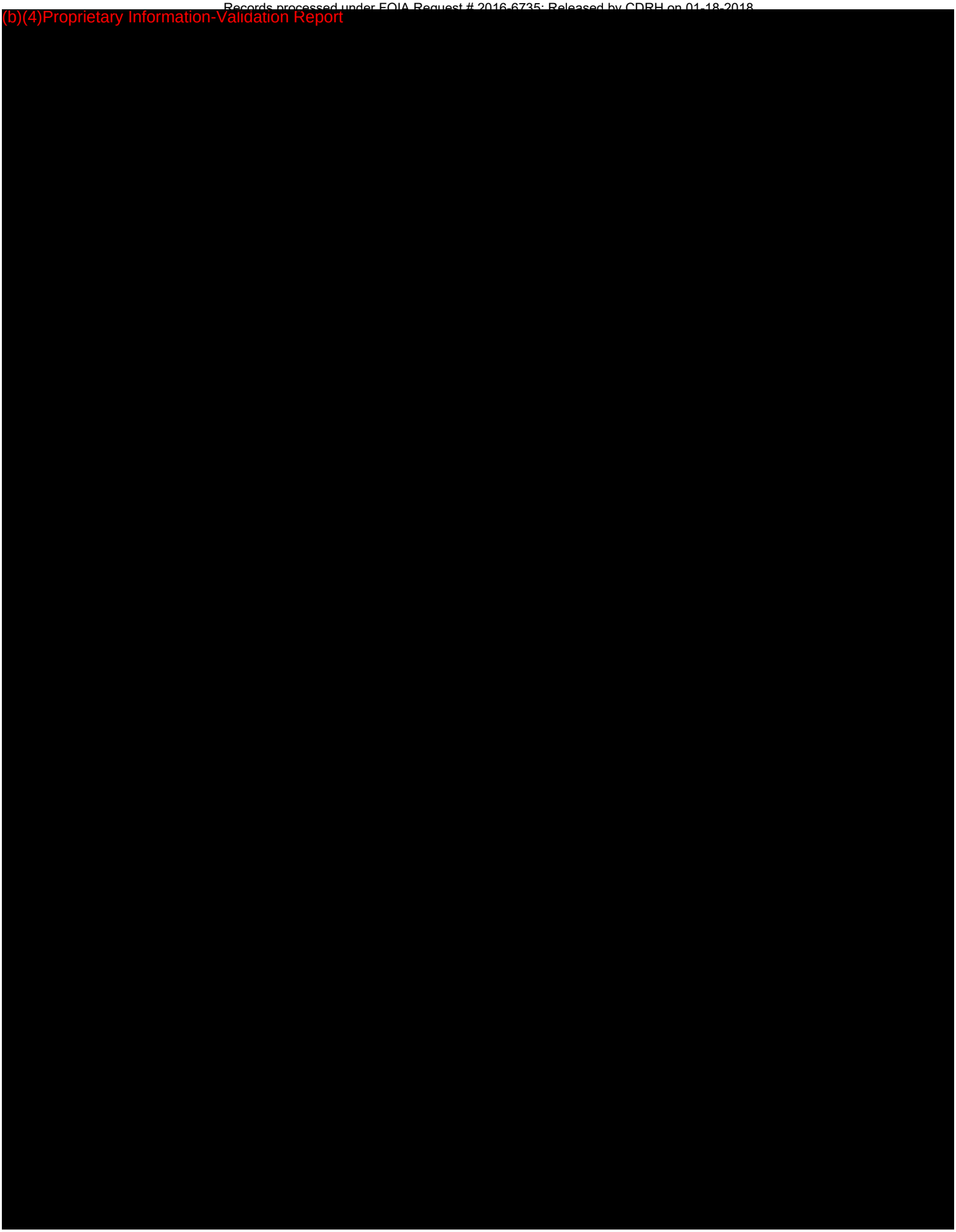
(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report



(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

[redacted]

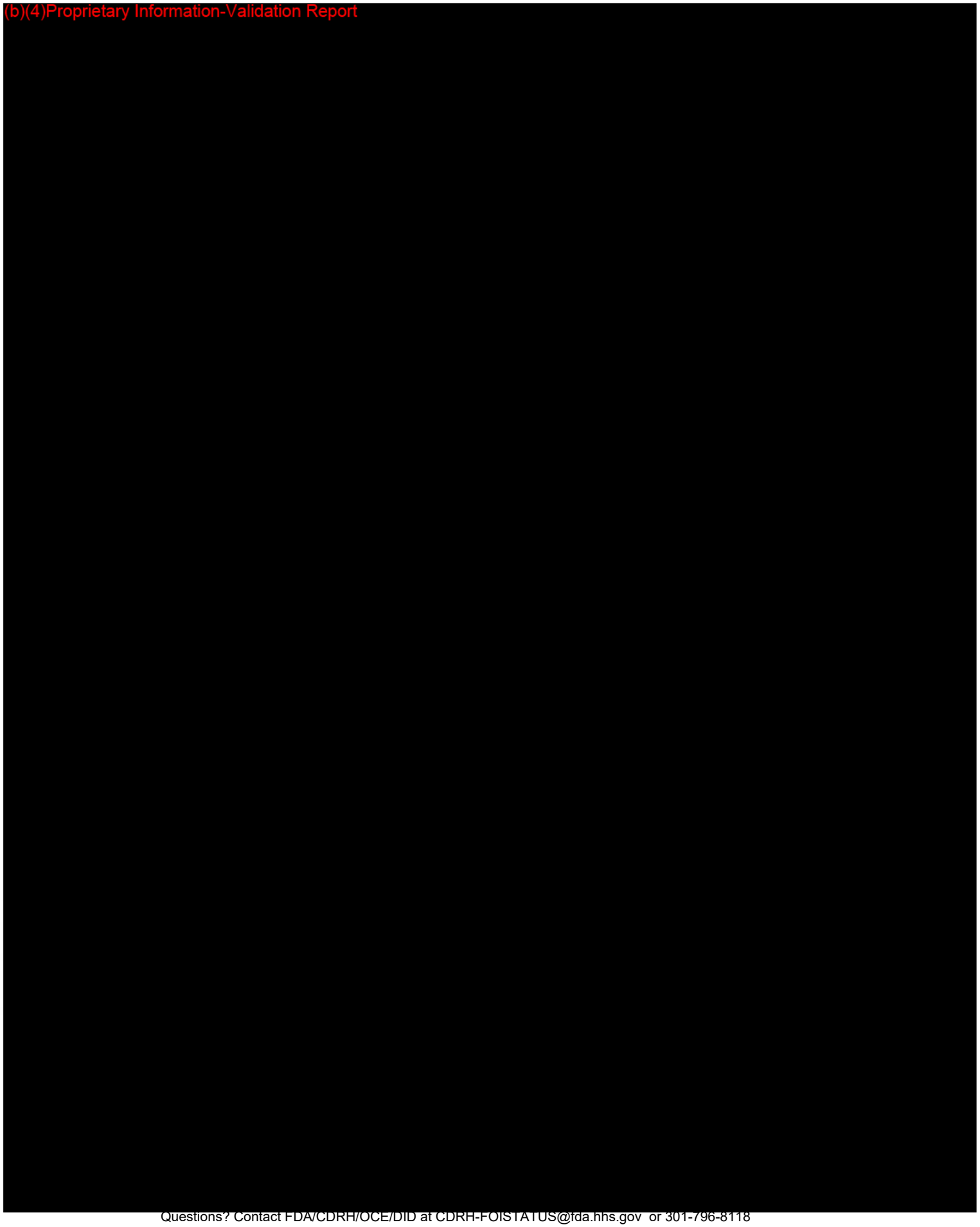
(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report



(b)(4)Proprietary Information-Validation Report

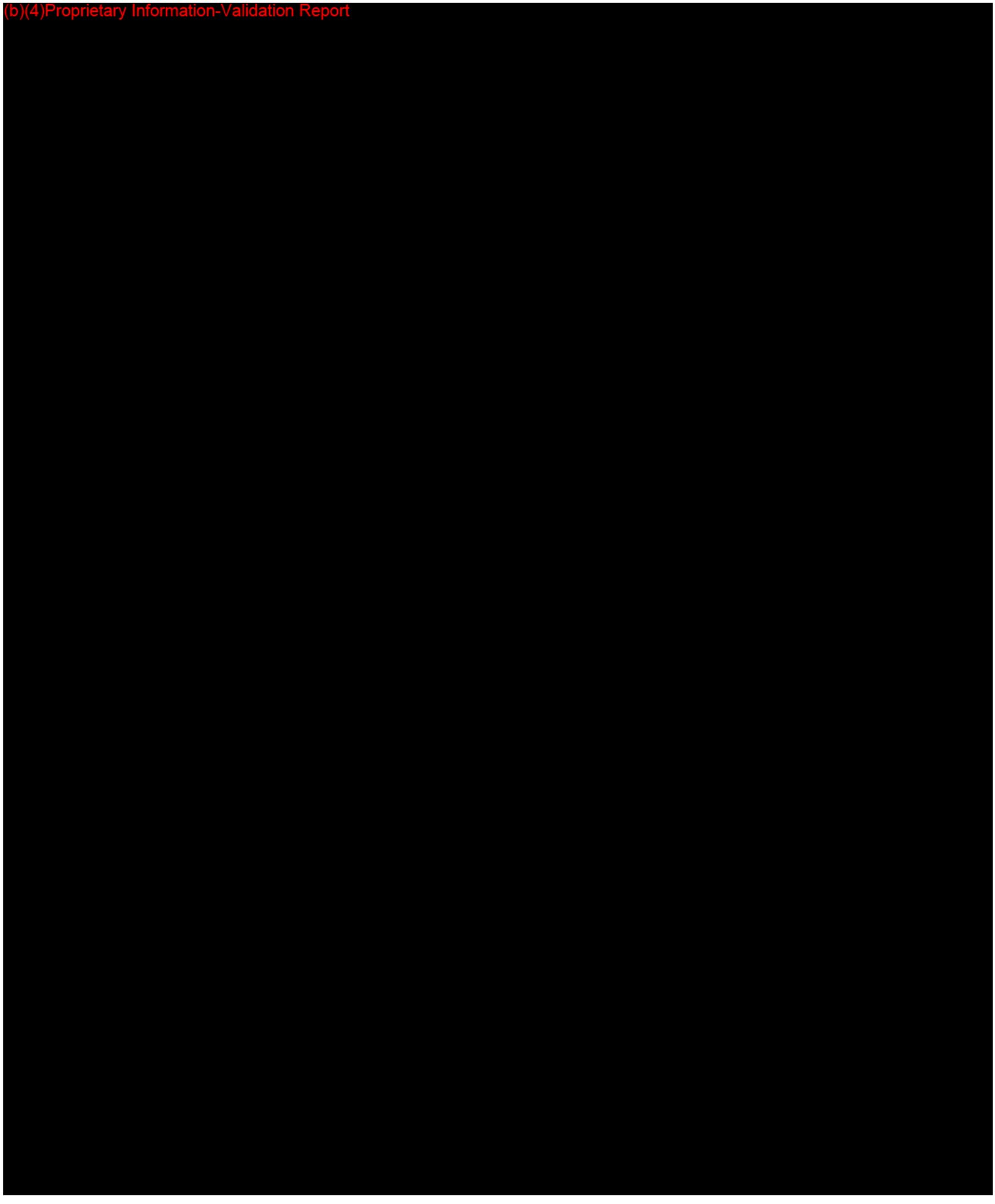
[redacted]

(b)(4)Proprietary Information-Validation Report

(b)(4)Proprietary Information-Validation Report

[redacted]

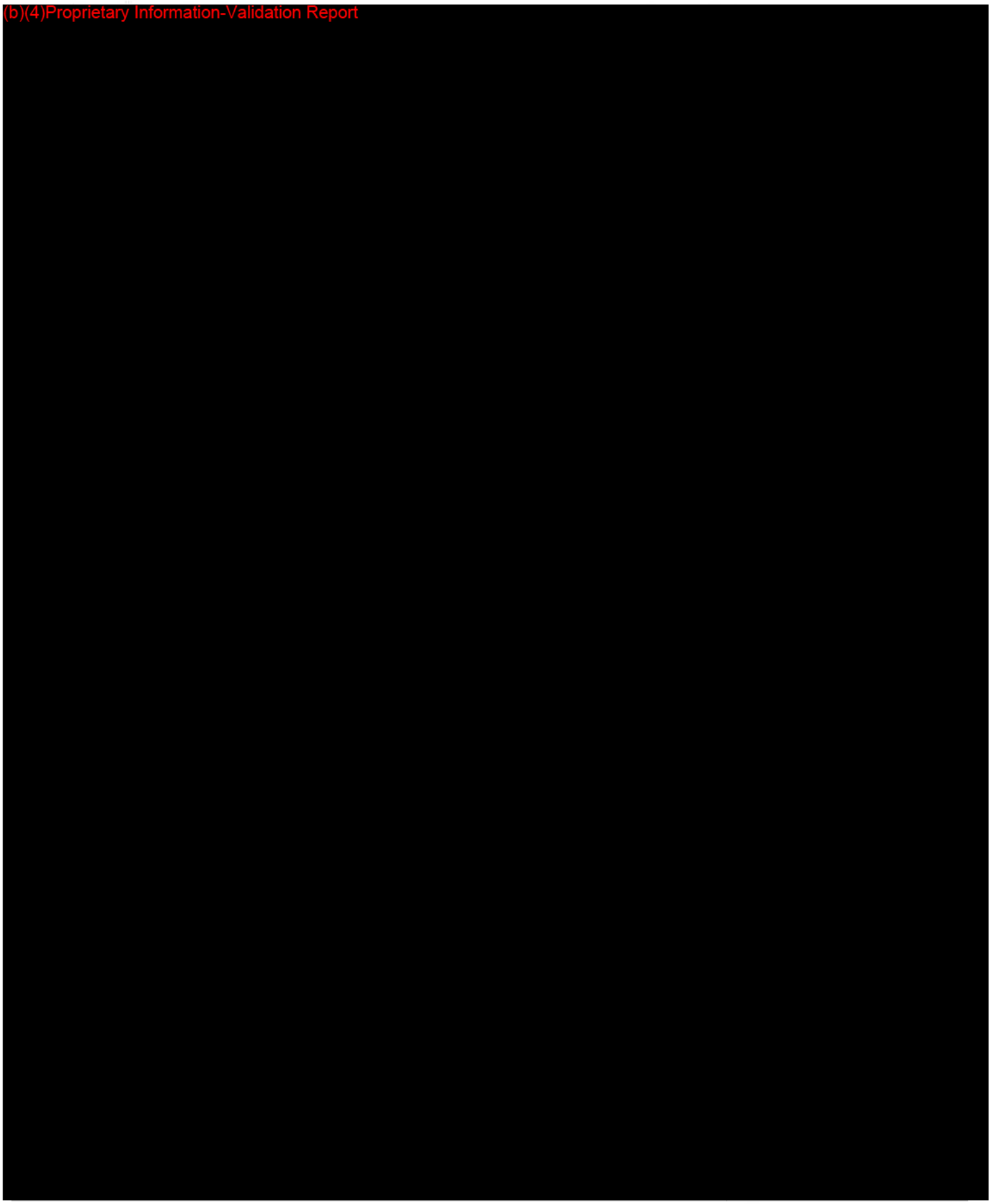
(b)(4)Proprietary Information-Validation Report



(b)(4)Proprietary Information-Validation Report

[redacted]

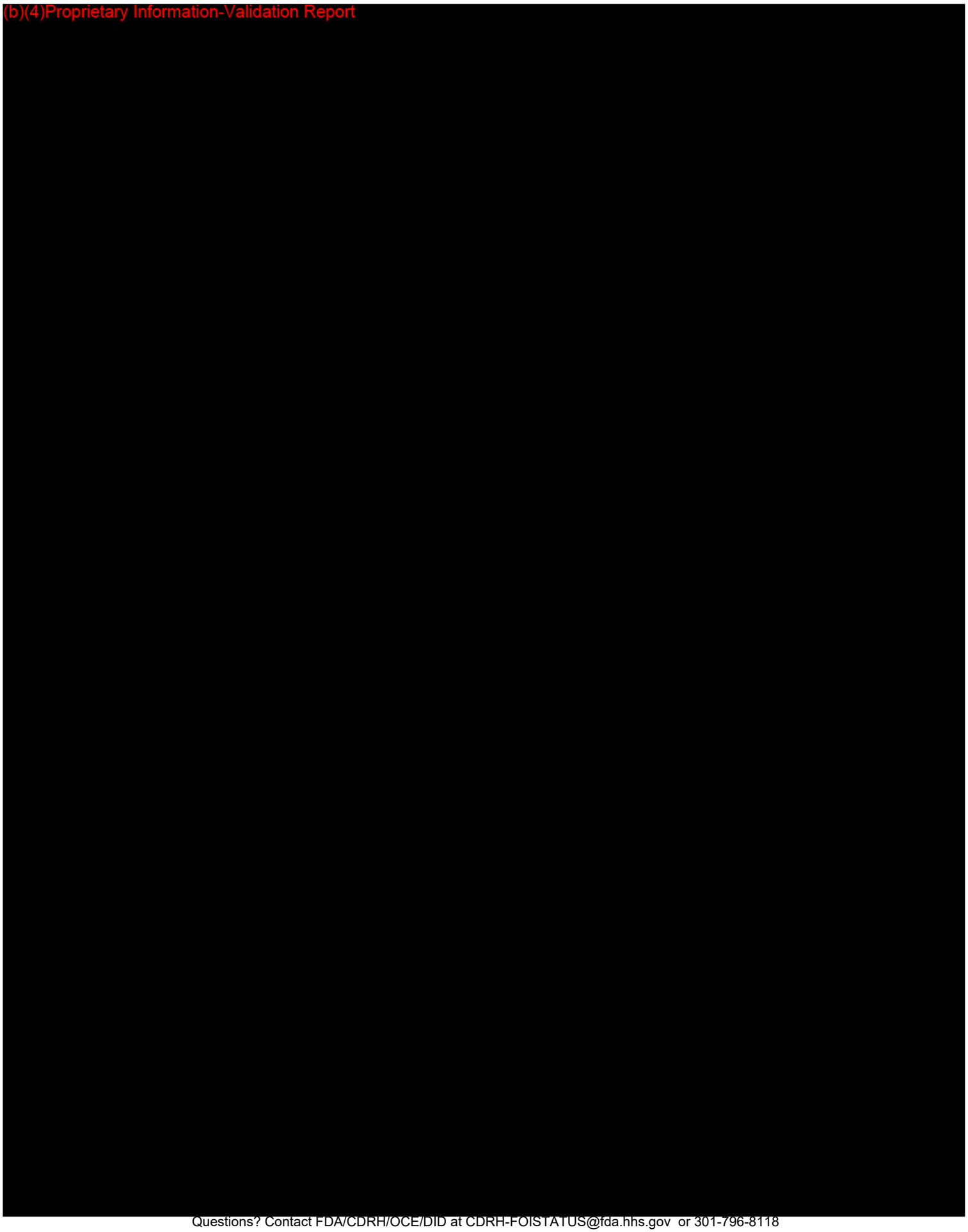
(b)(4)Proprietary Information-Validation Report



(b)(4)Proprietary Information-Validation Report

[redacted]

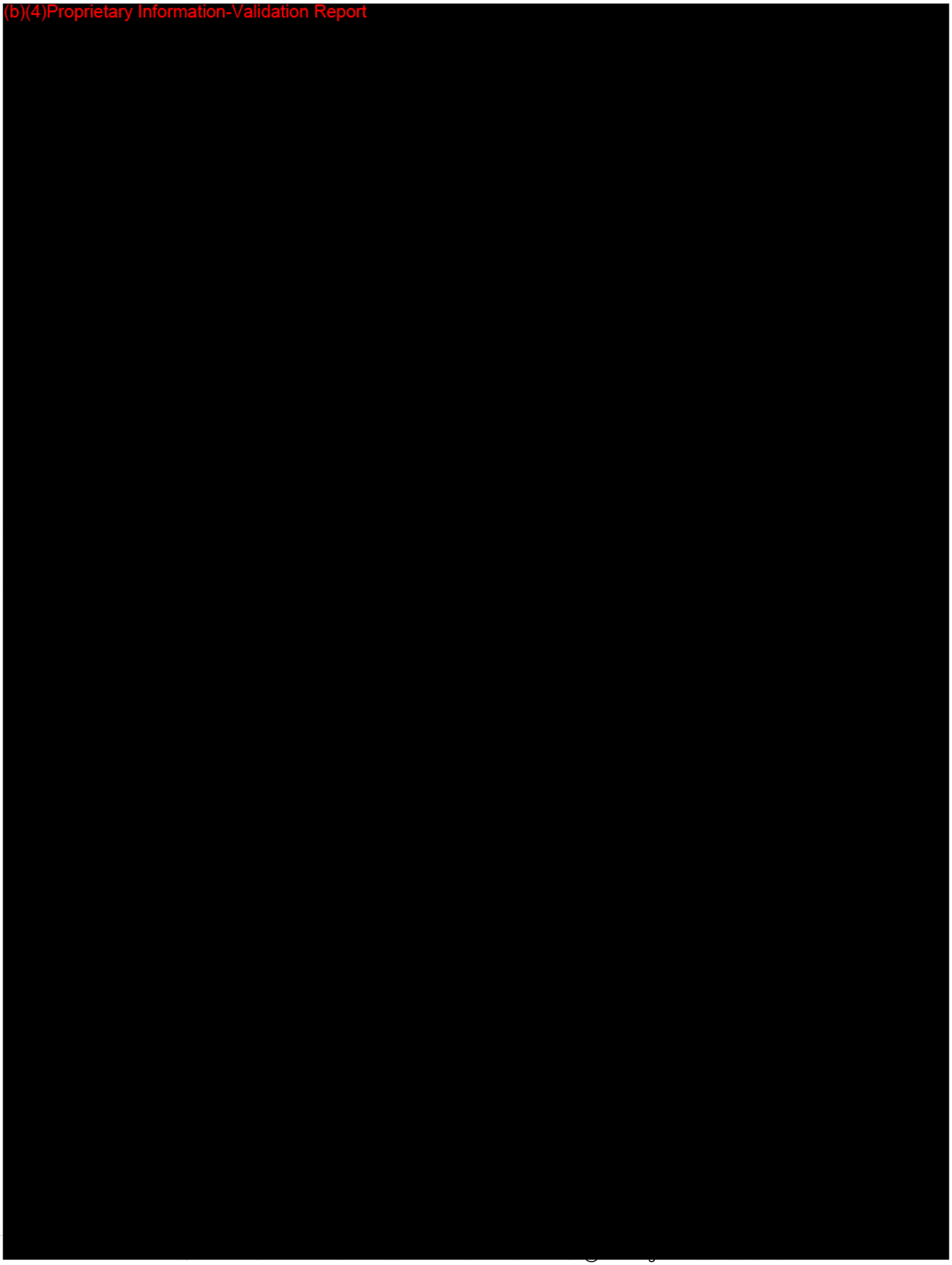
(b)(4)Proprietary Information-Validation Report



(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report



(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

[redacted]

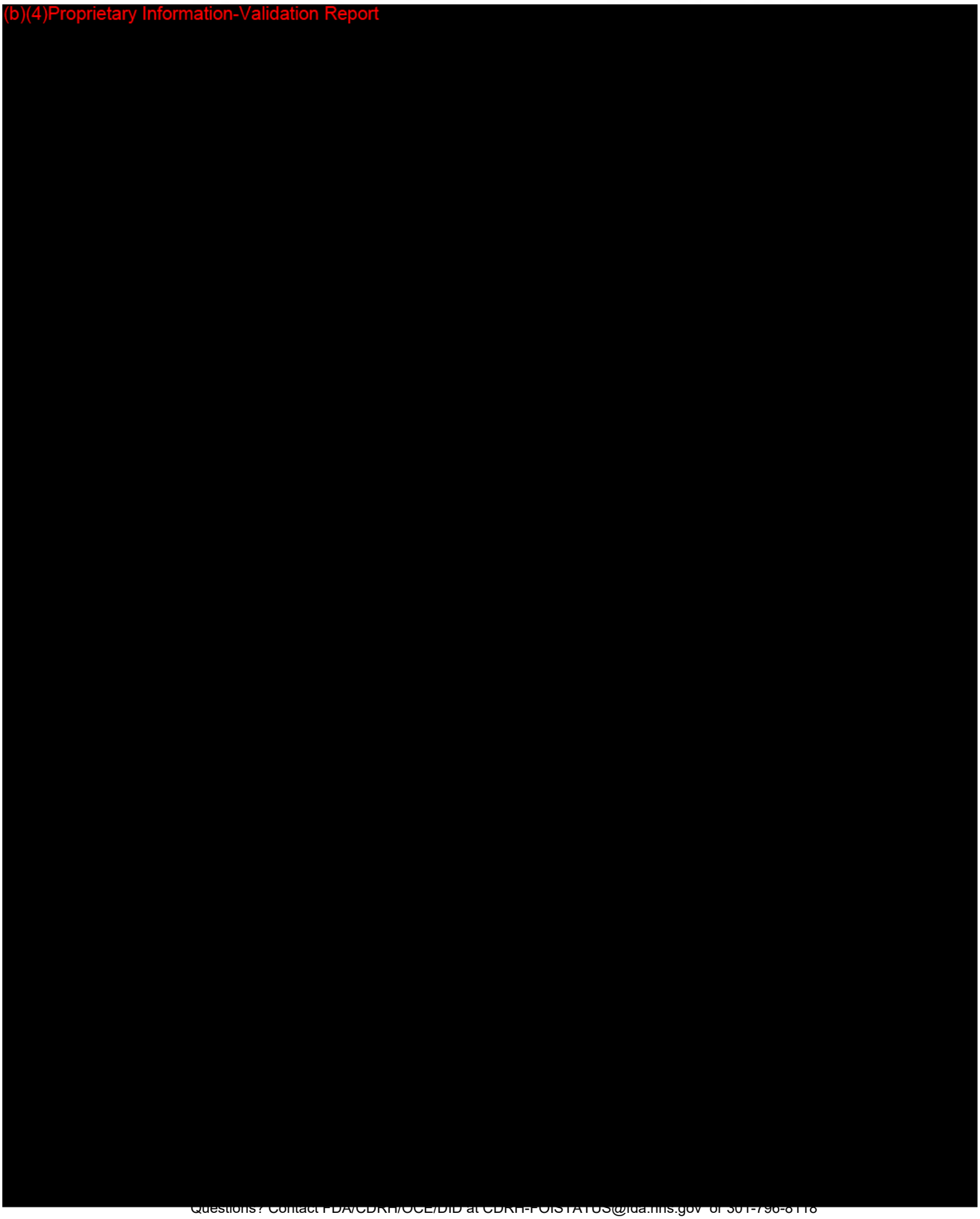
(b)(4)Proprietary Information-Validation Report

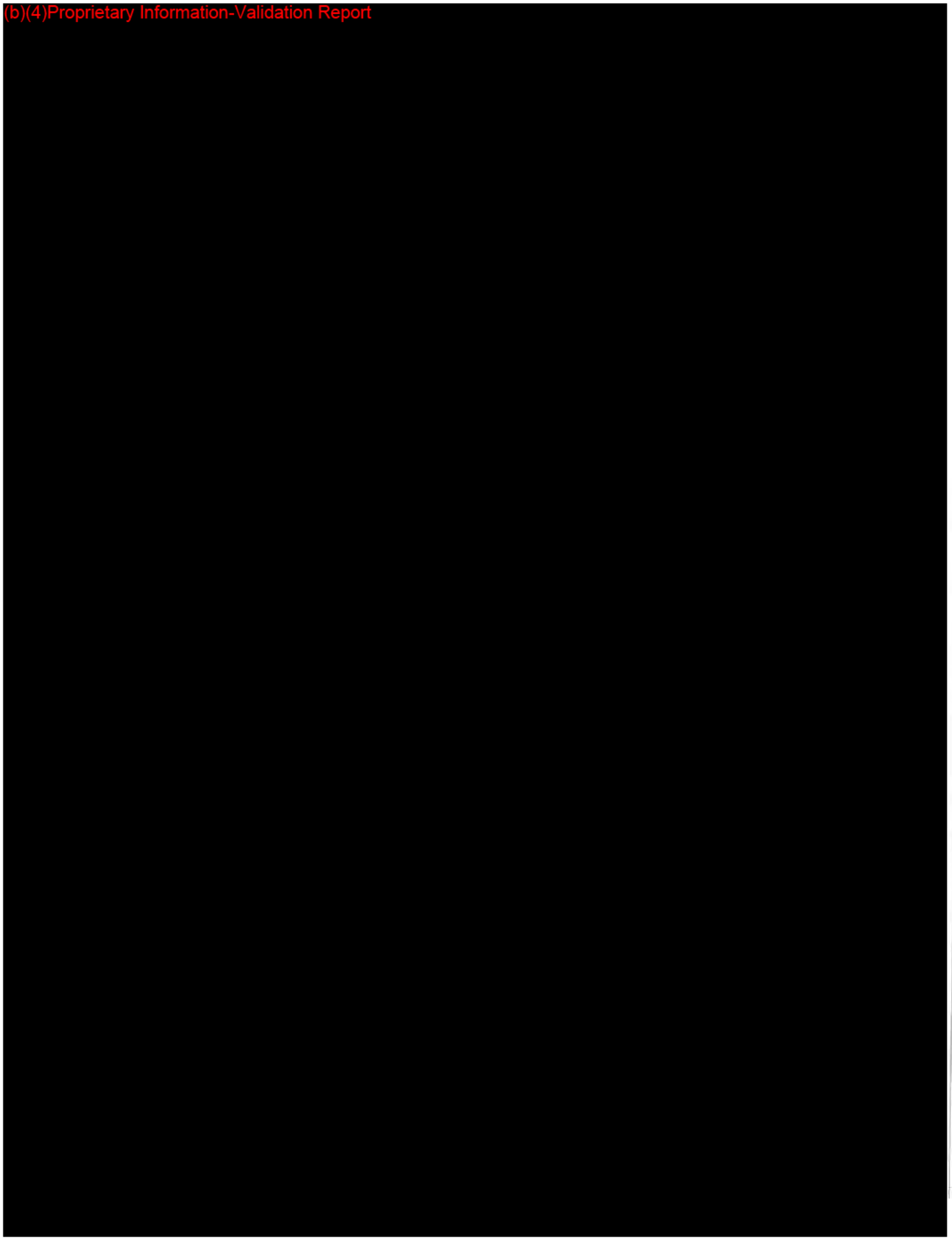
[redacted]

(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report





(b)(4)Proprietary Information-Validation Report

[redacted]

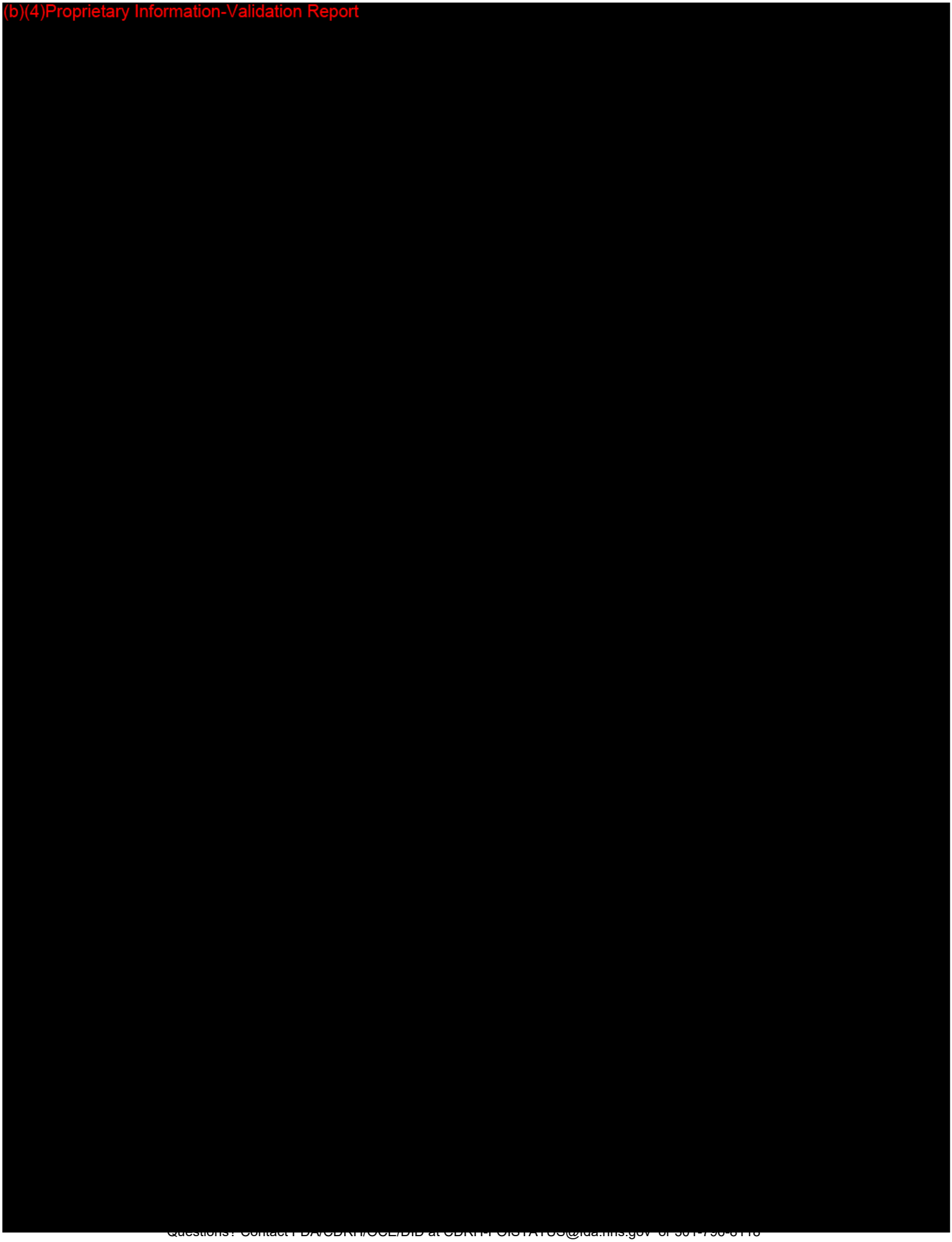
(b)(4)Proprietary Information-Validation Report

[redacted]

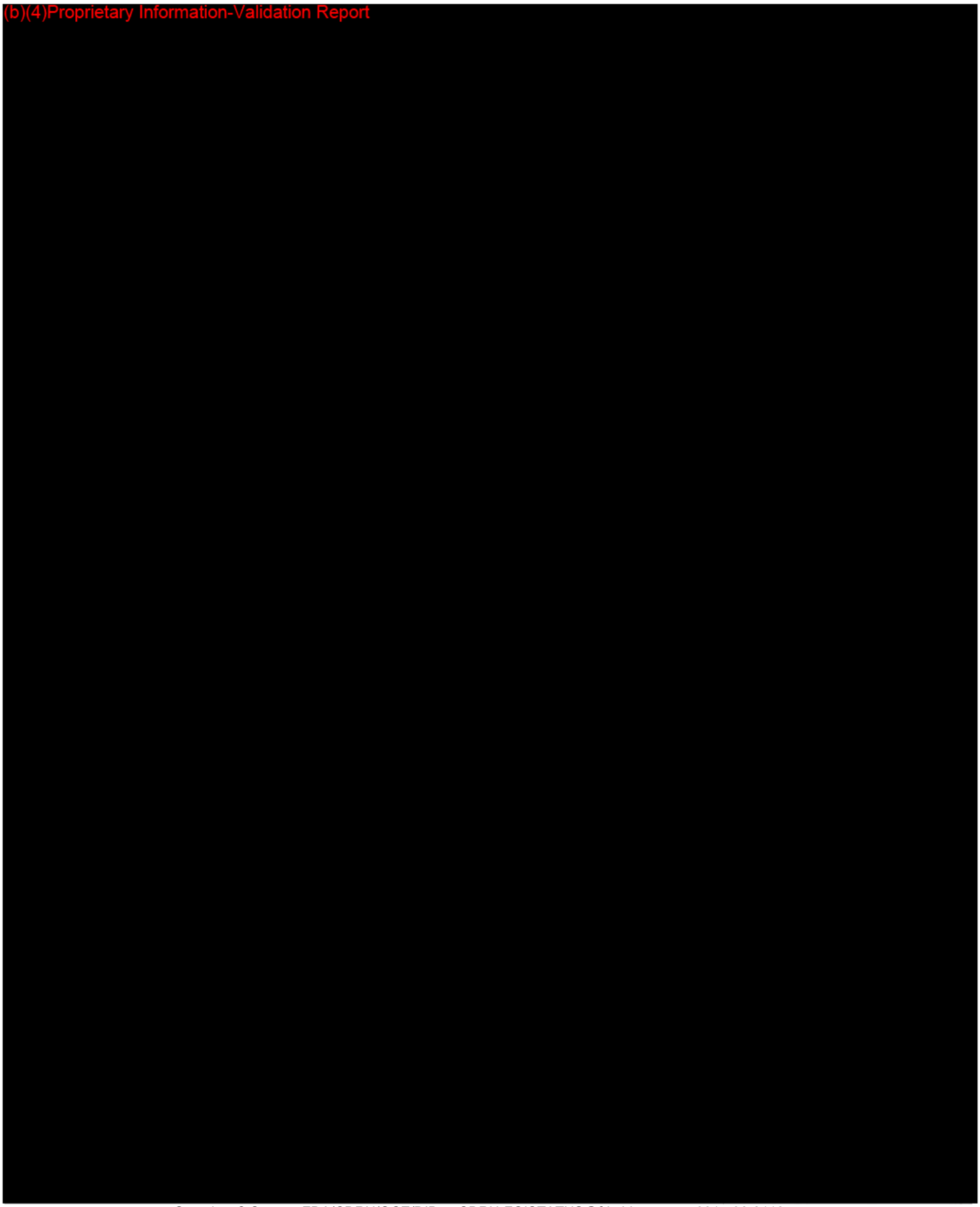
(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report



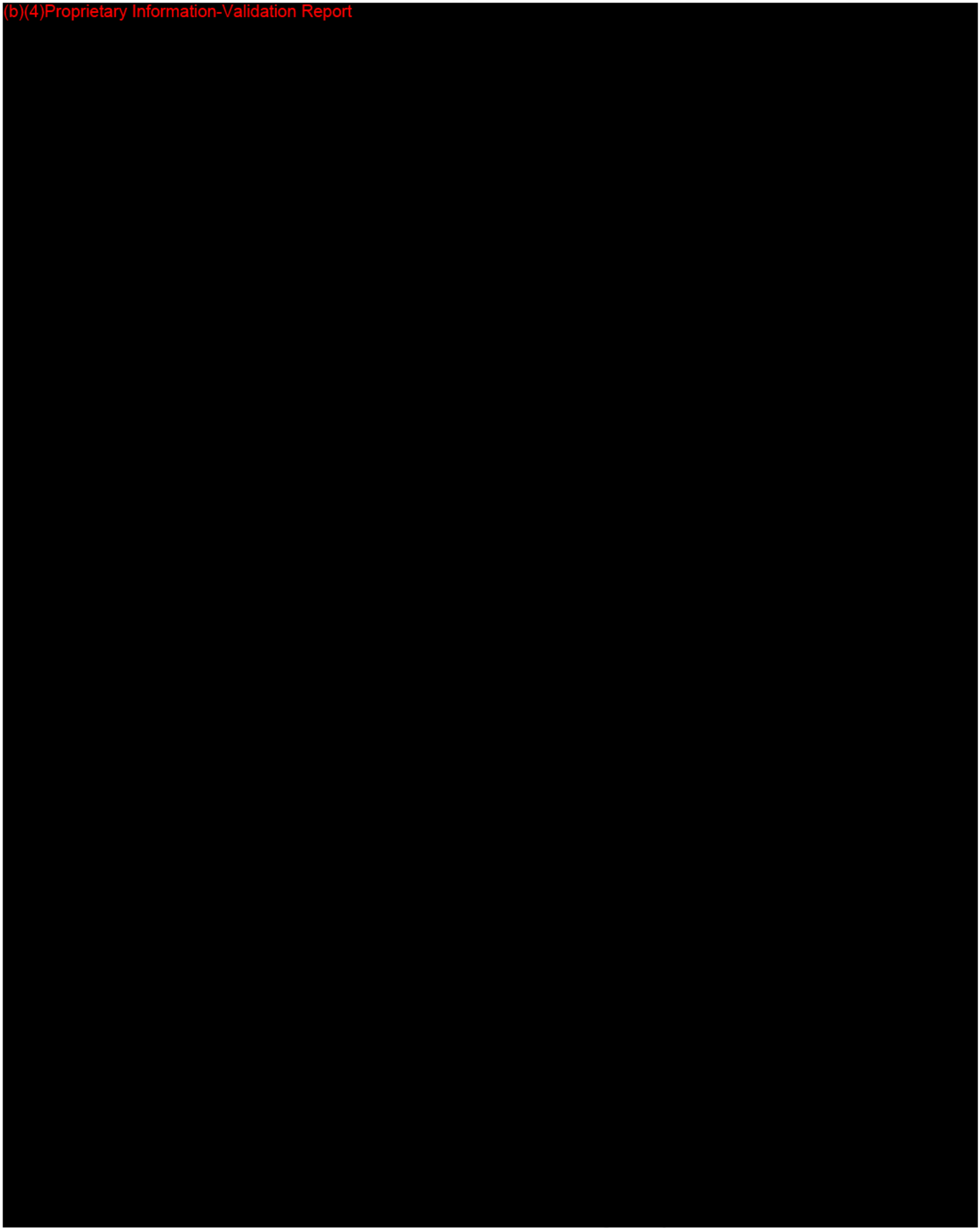
(b)(4)Proprietary Information-Validation Report



(b)(4)Proprietary Information-Validation Report

[redacted]

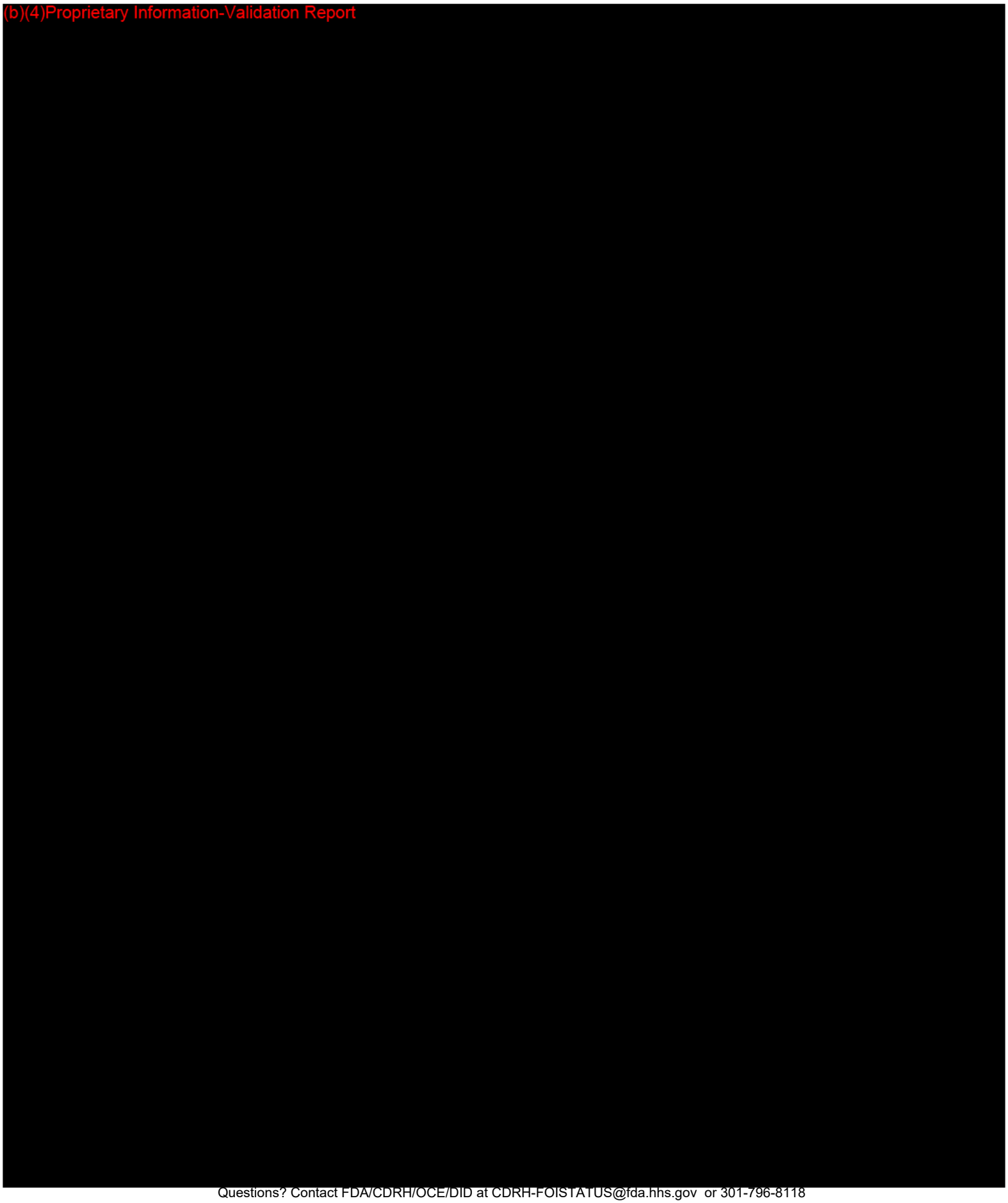
(b)(4)Proprietary Information-Validation Report



(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report



(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

[redacted]

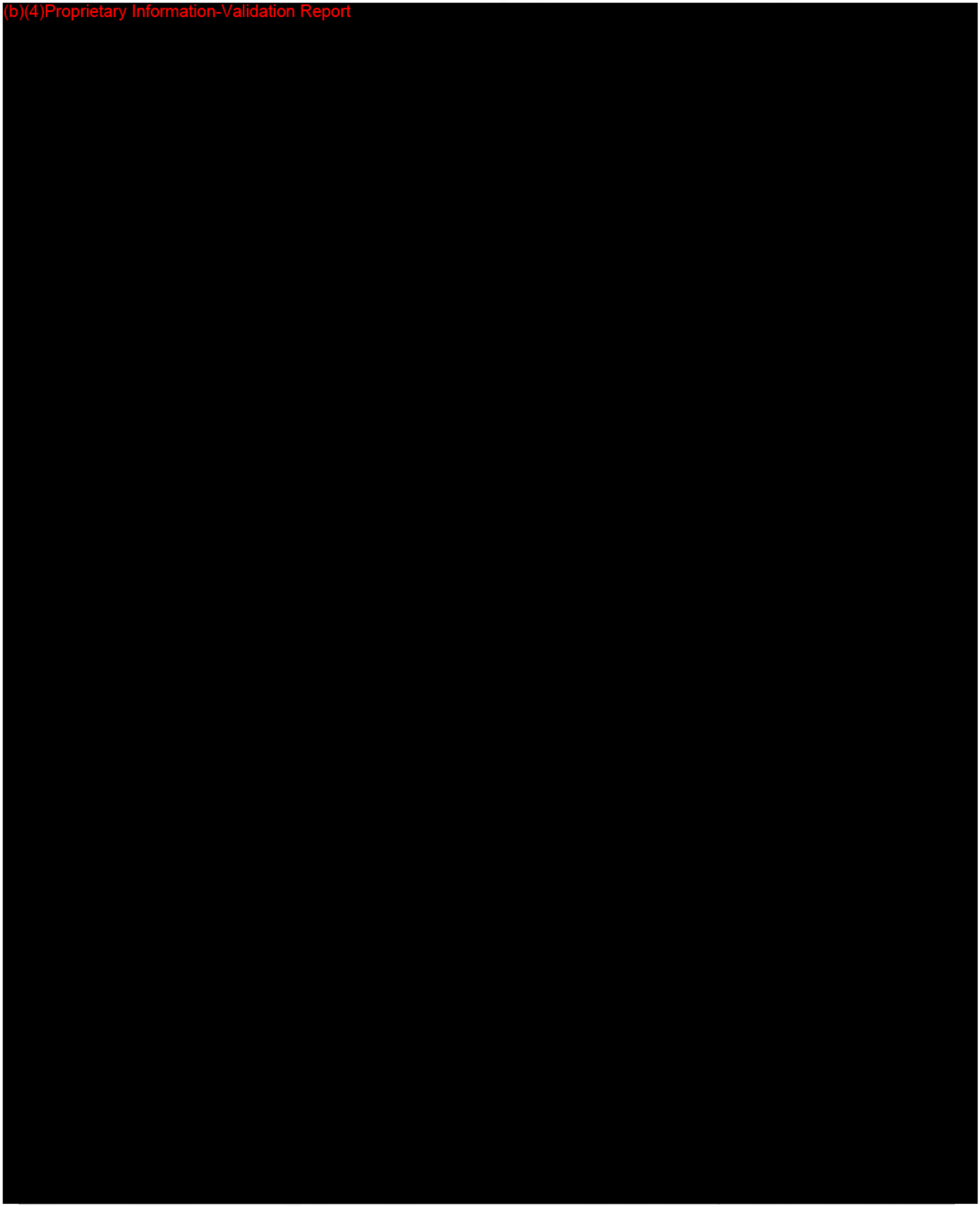
(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report



(b)(4)Proprietary Information-Validation Report

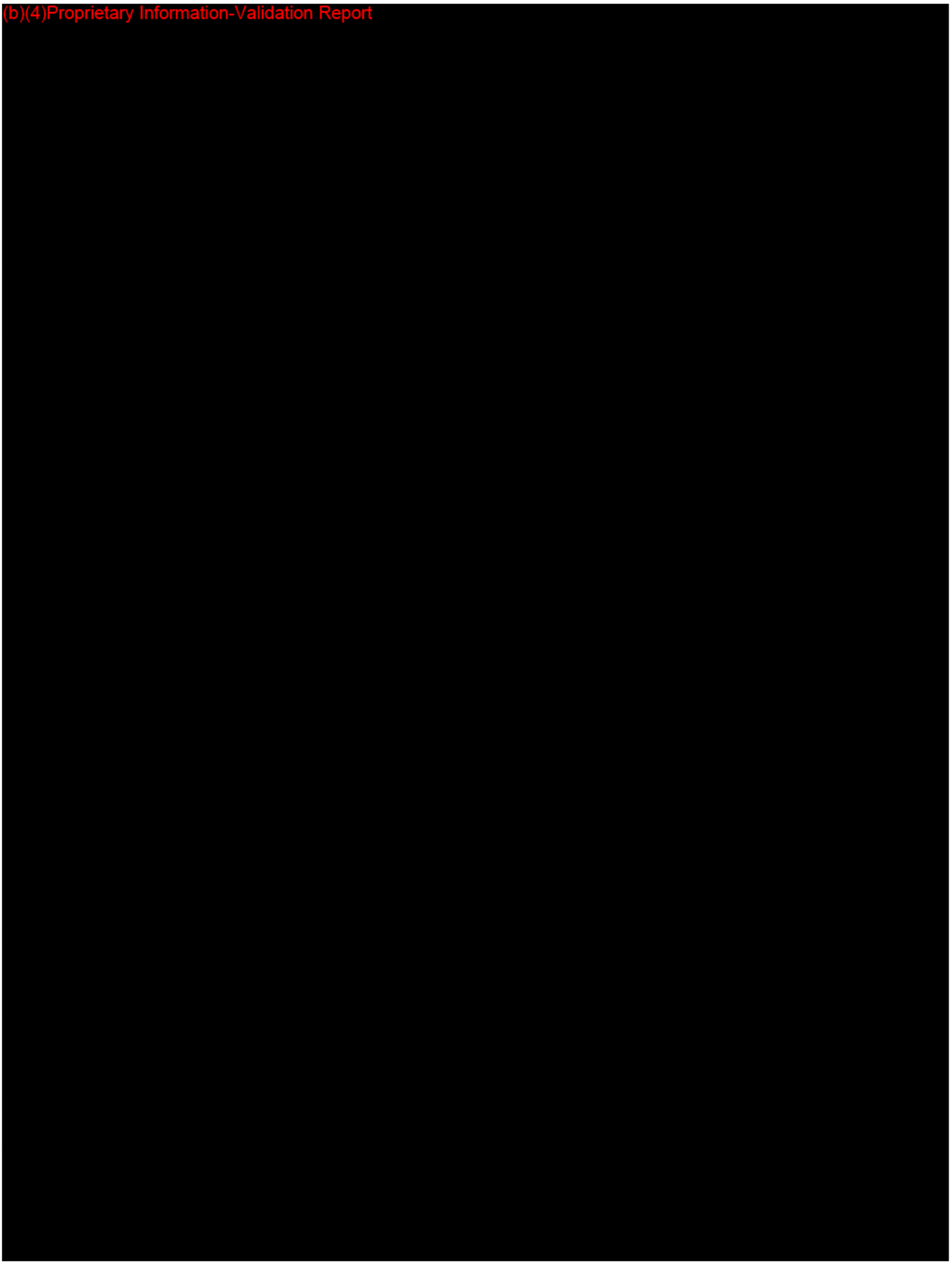
[redacted]

(b)(4)Proprietary Information-Validation Report

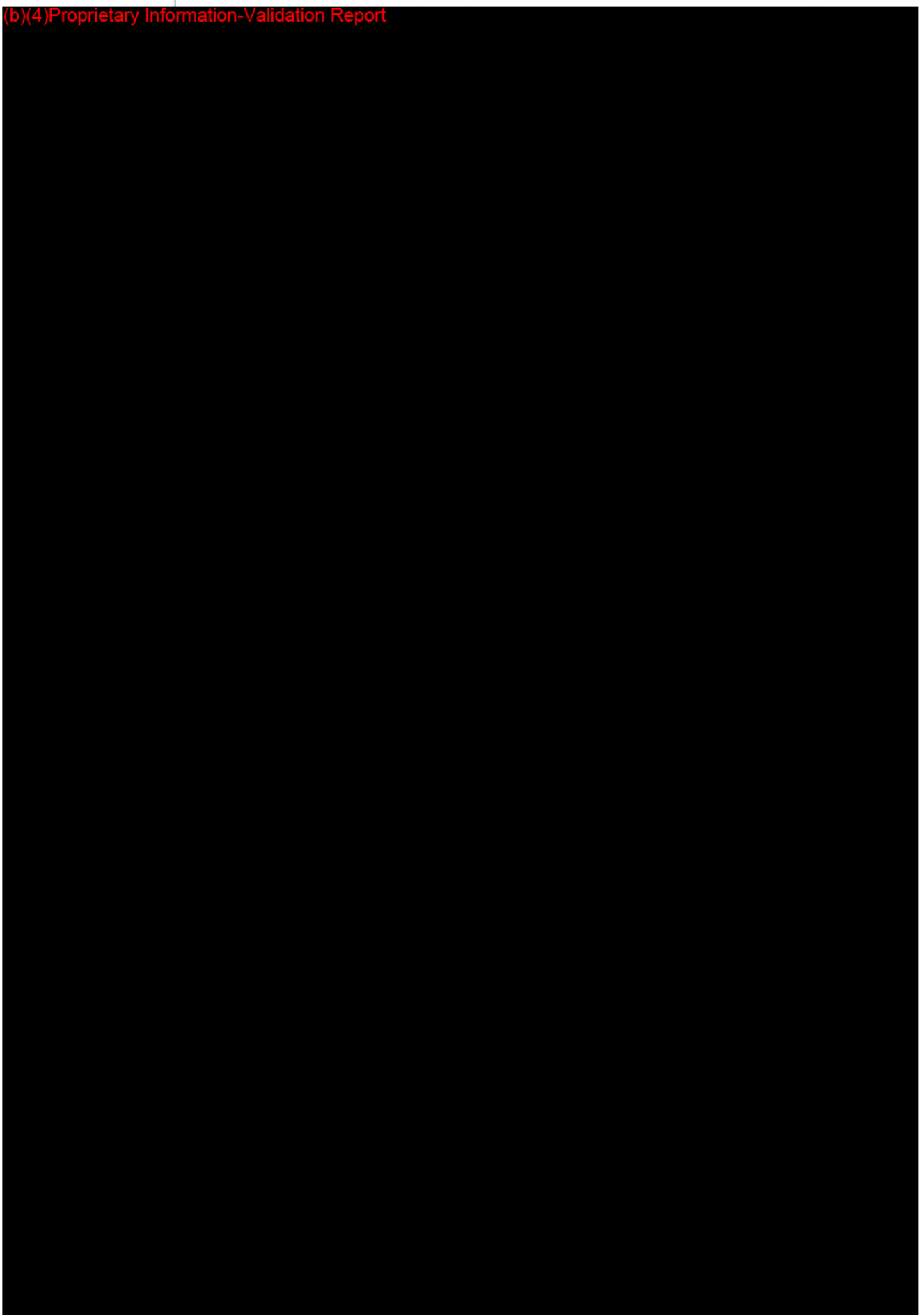
(b)(4)Proprietary Information-Validation Report

[redacted]

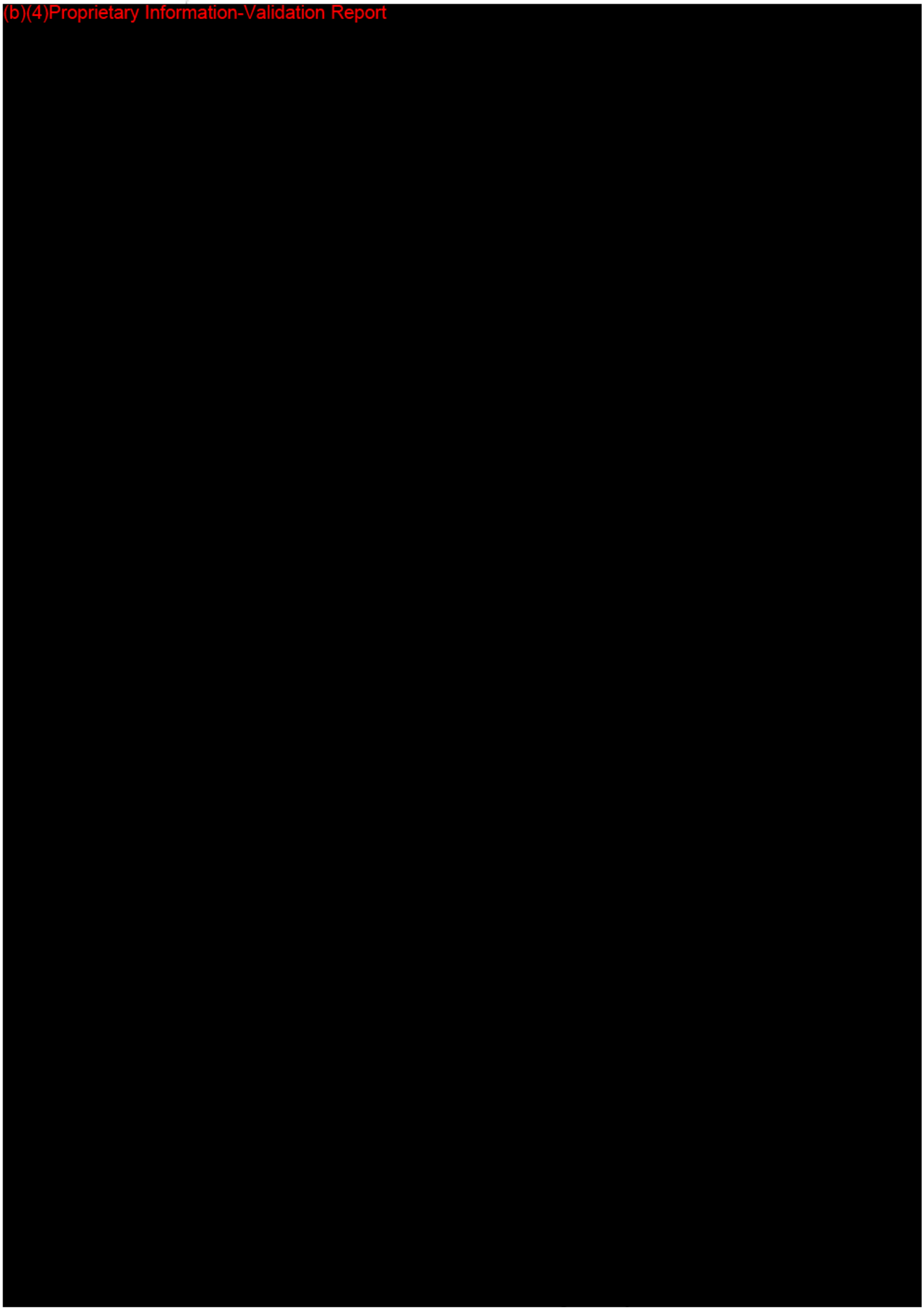
(b)(4)Proprietary Information-Validation Report



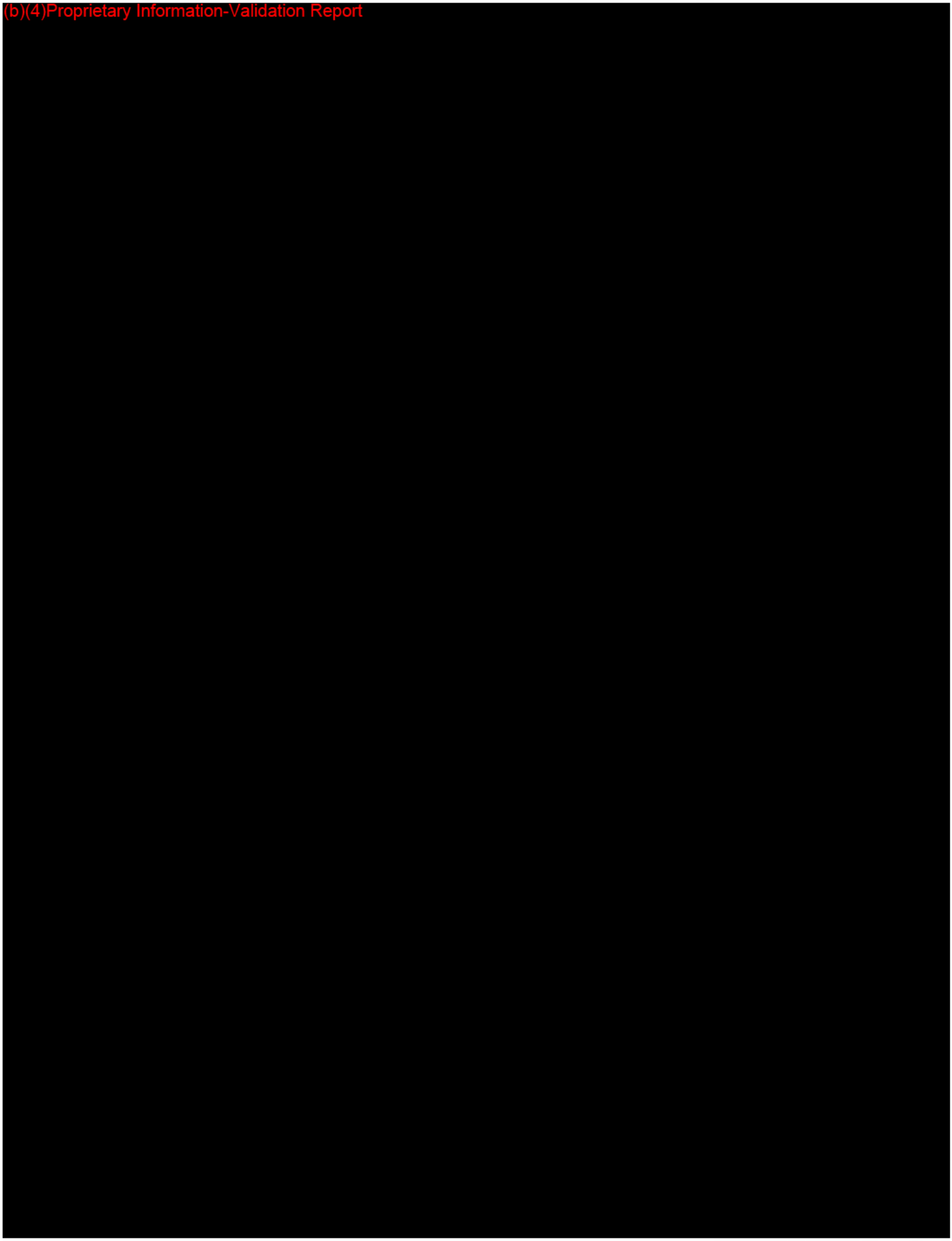
(b)(4)Proprietary Information-Validation Report



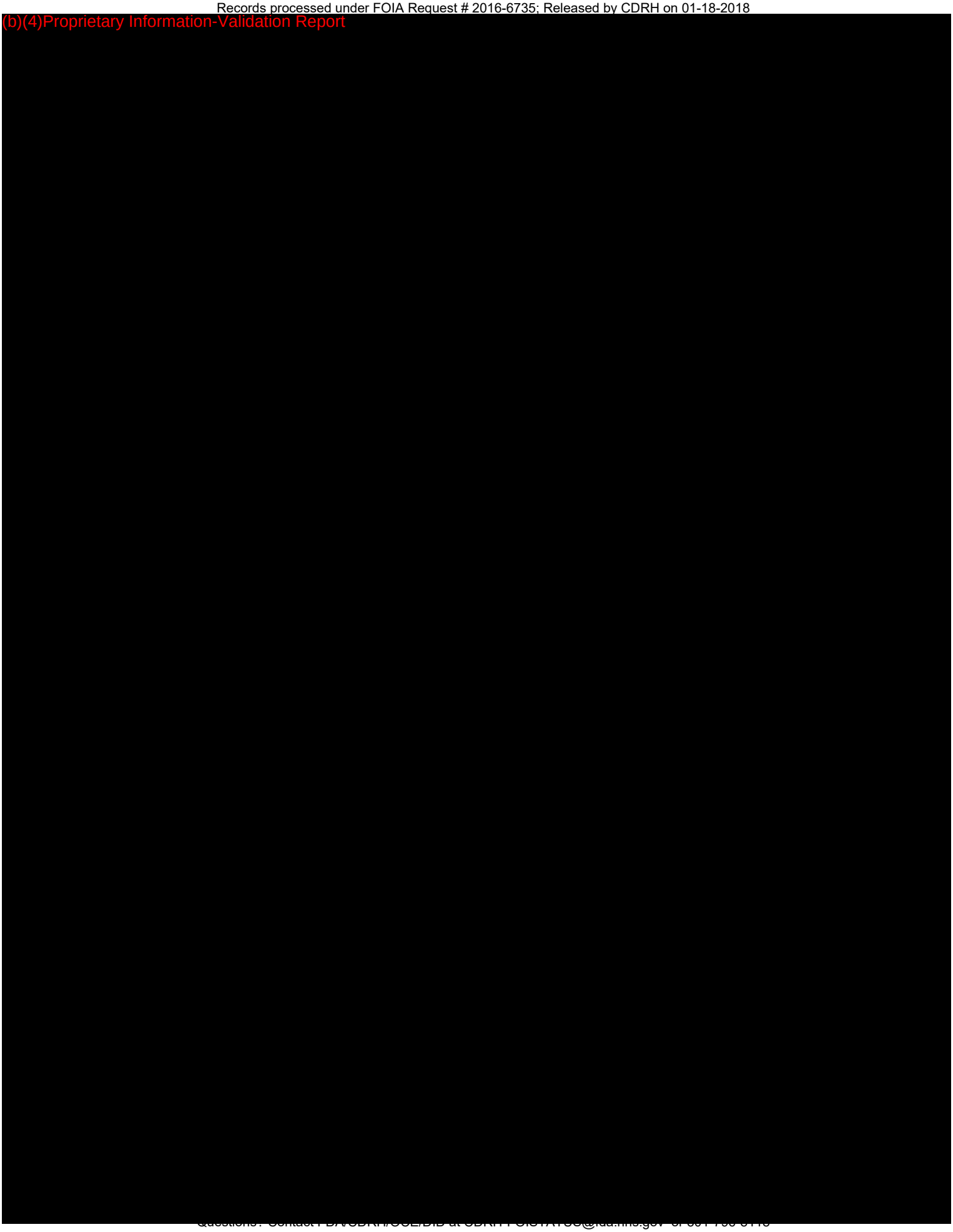
(b)(4)Proprietary Information-Validation Report



(b)(4)Proprietary Information-Validation Report



(b)(4)Proprietary Information-Validation Report



(b)(4)Proprietary Information-Validation Report

[redacted]

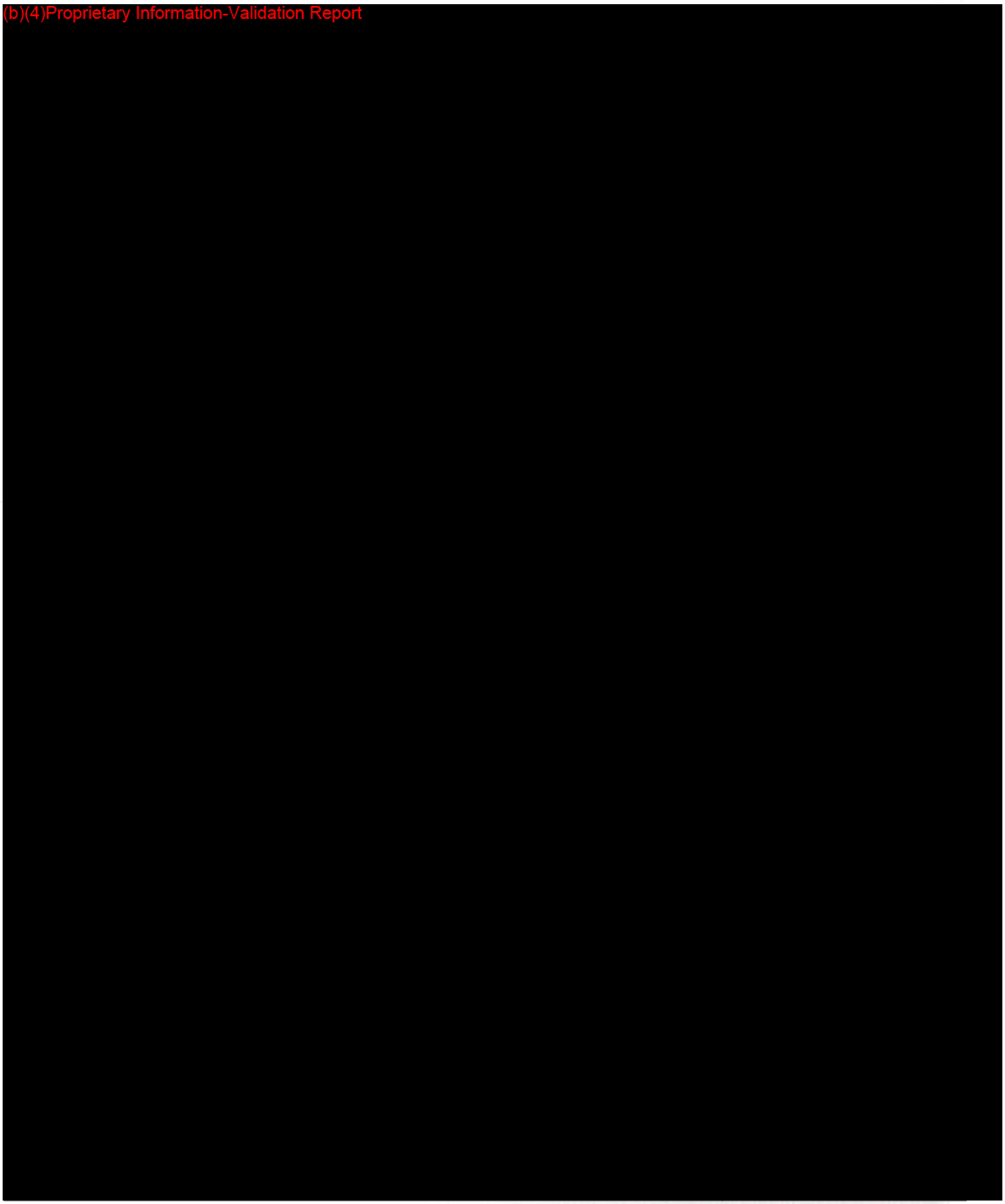
(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report



(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

[redacted]

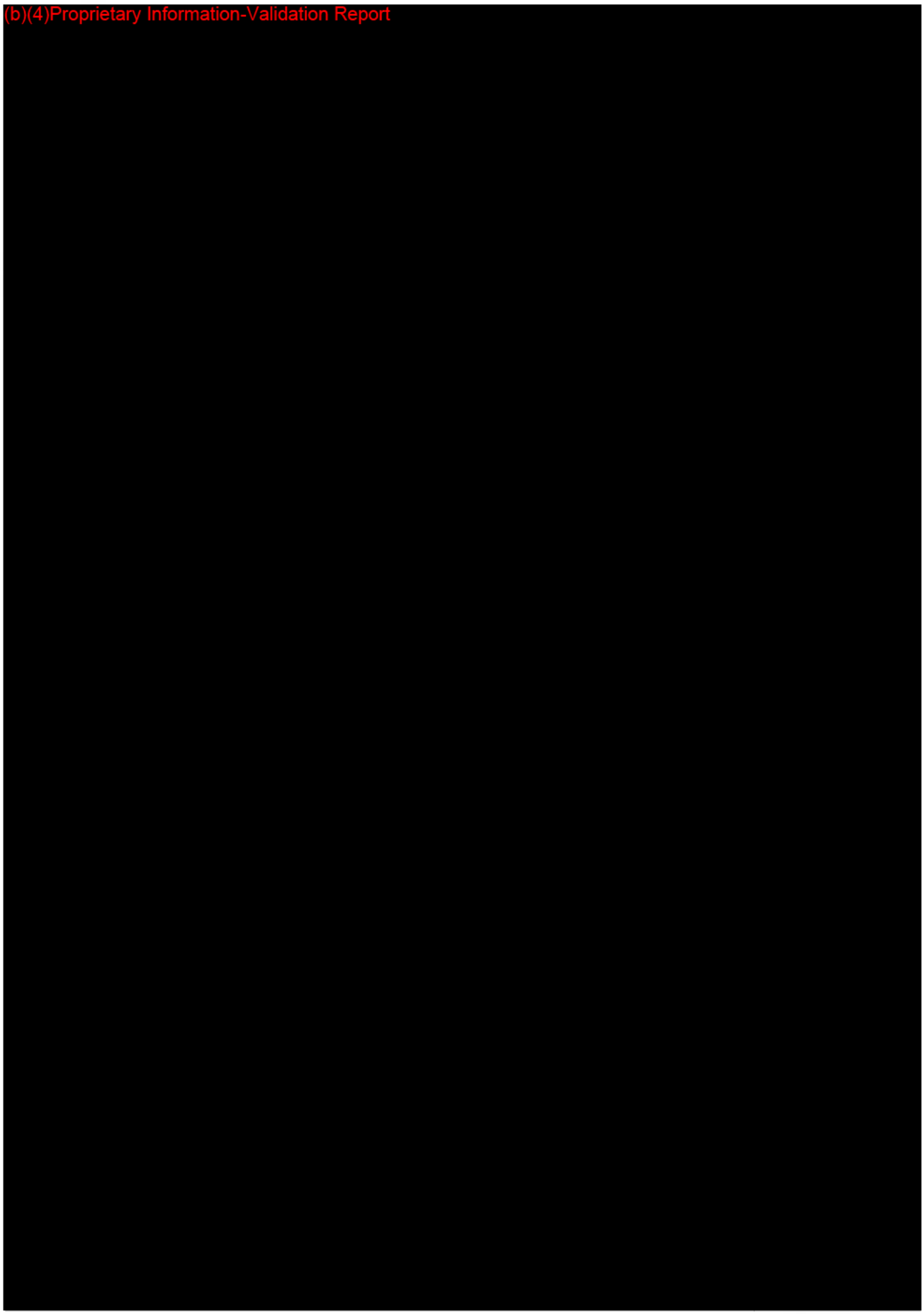
(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report



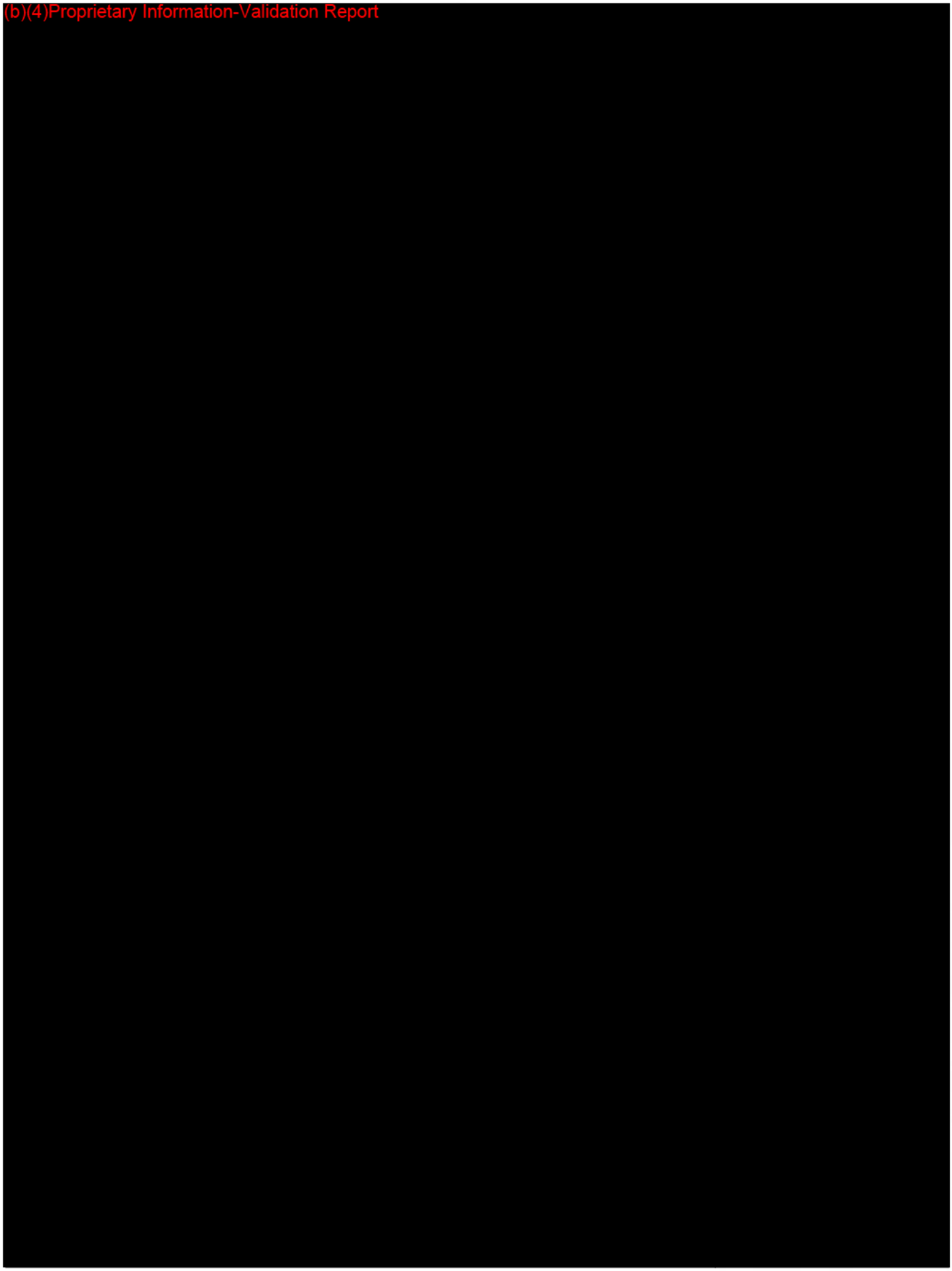
(b)(4)Proprietary Information-Validation Report

[redacted]

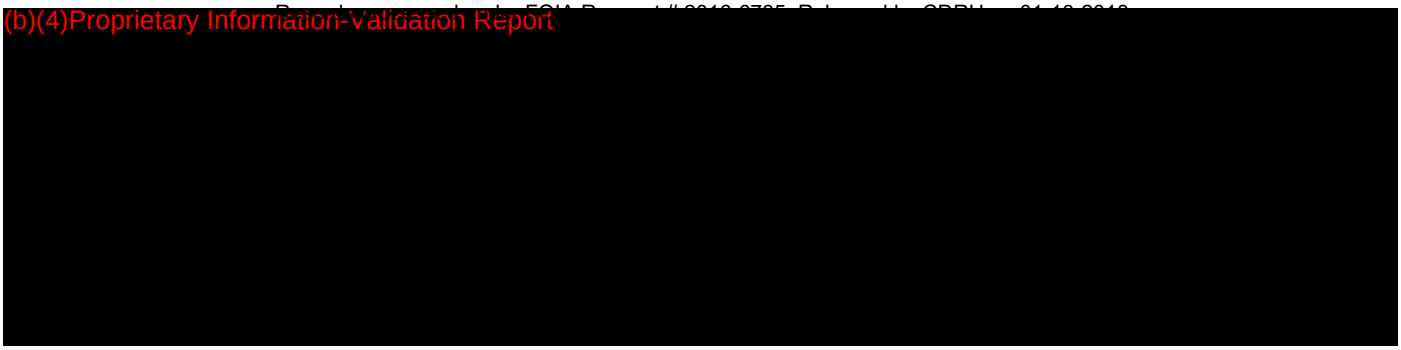
(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report



(b)(4)Proprietary Information-Validation Report



(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

[redacted]

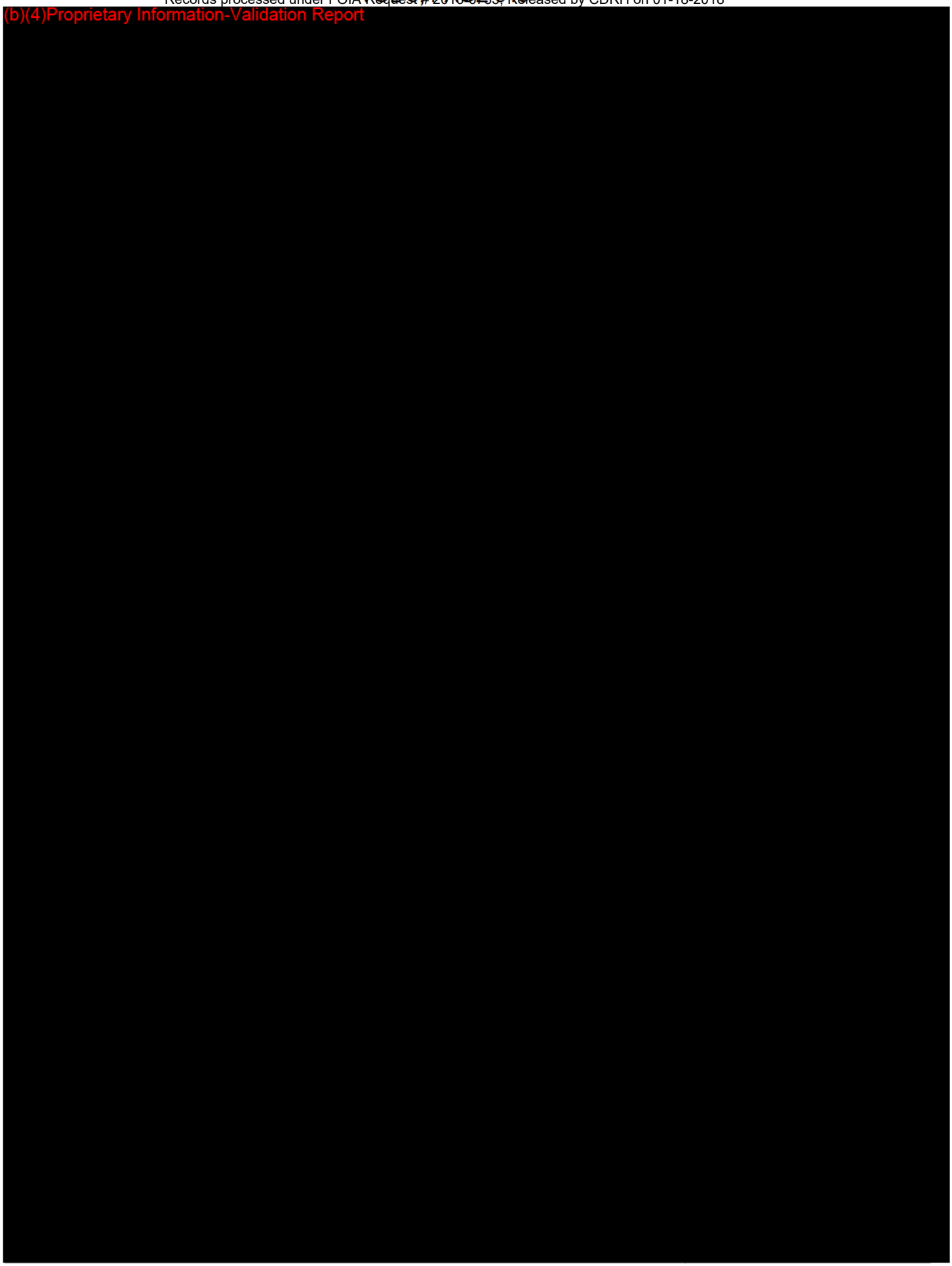
(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

[redacted]

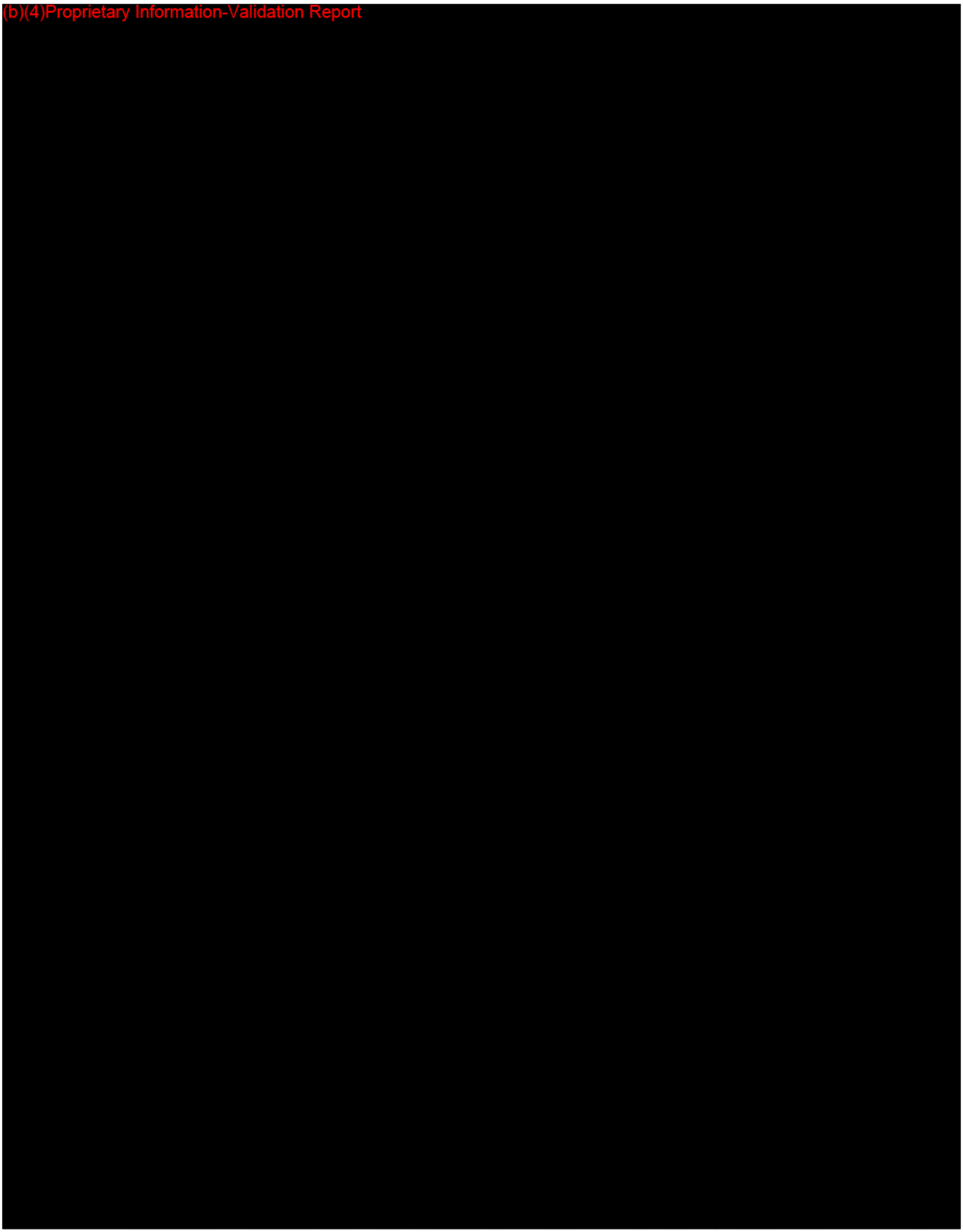
(b)(4)Proprietary Information-Validation Report



(b)(4)Proprietary Information-Validation Report

(b)(4)Proprietary Information-Validation Report

(b)(4)Proprietary Information-Validation Report



(b)(4)Proprietary Information-Validation Report

[redacted]

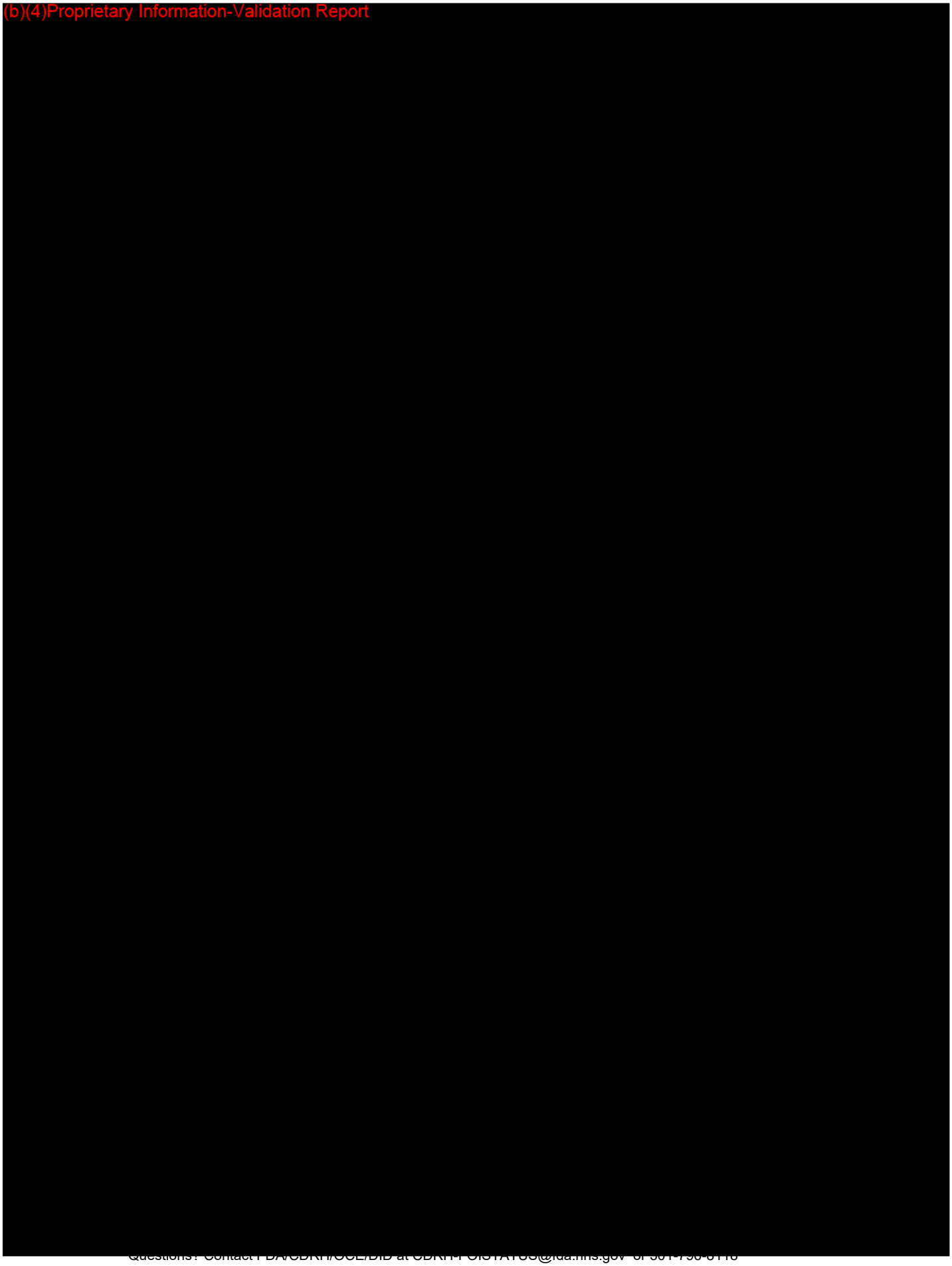
(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report



(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

[redacted]

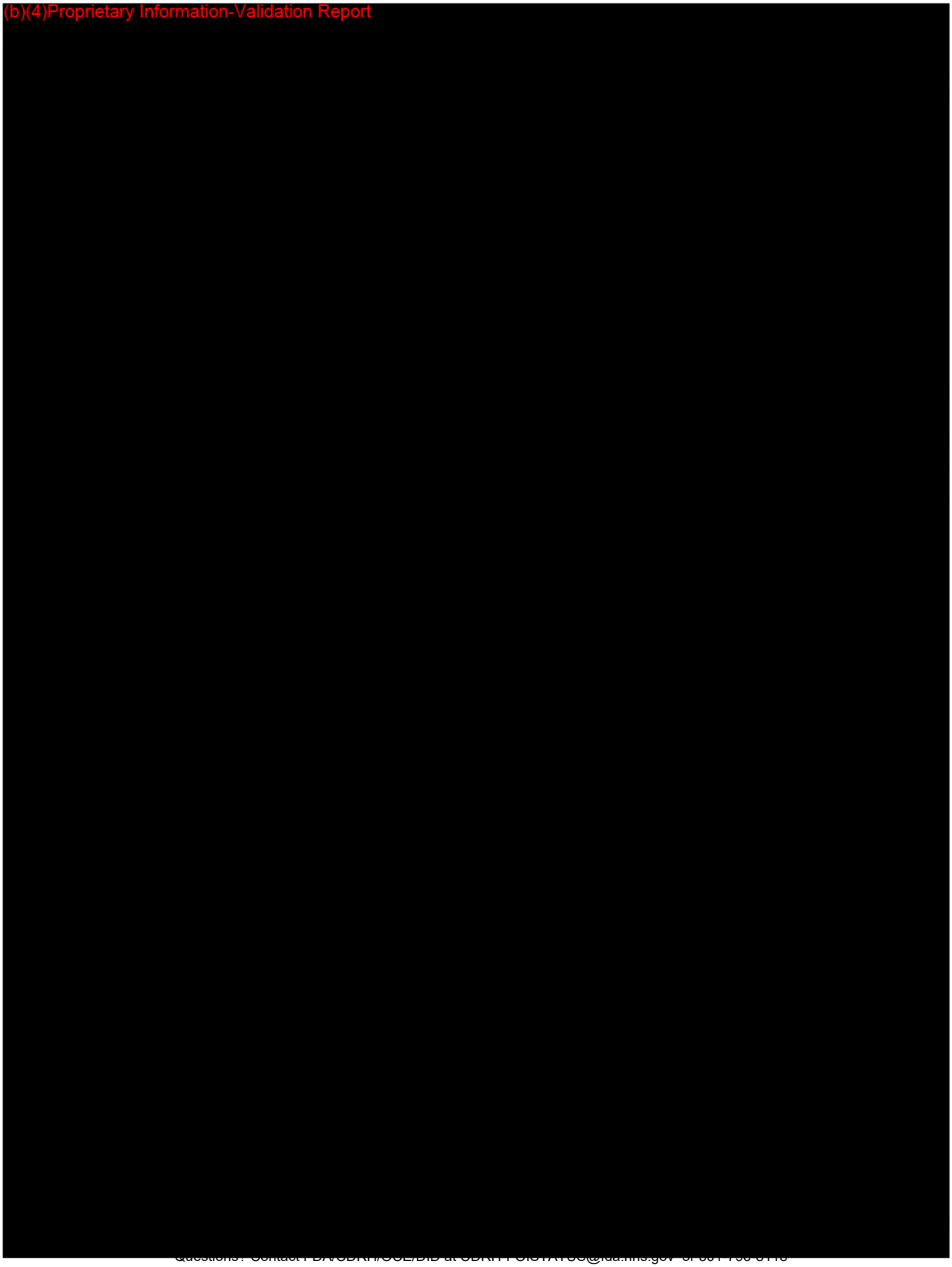
(b)(4)Proprietary Information-Validation Report

(b)(4)Proprietary Information-Validation Report

(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report



(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

[redacted]

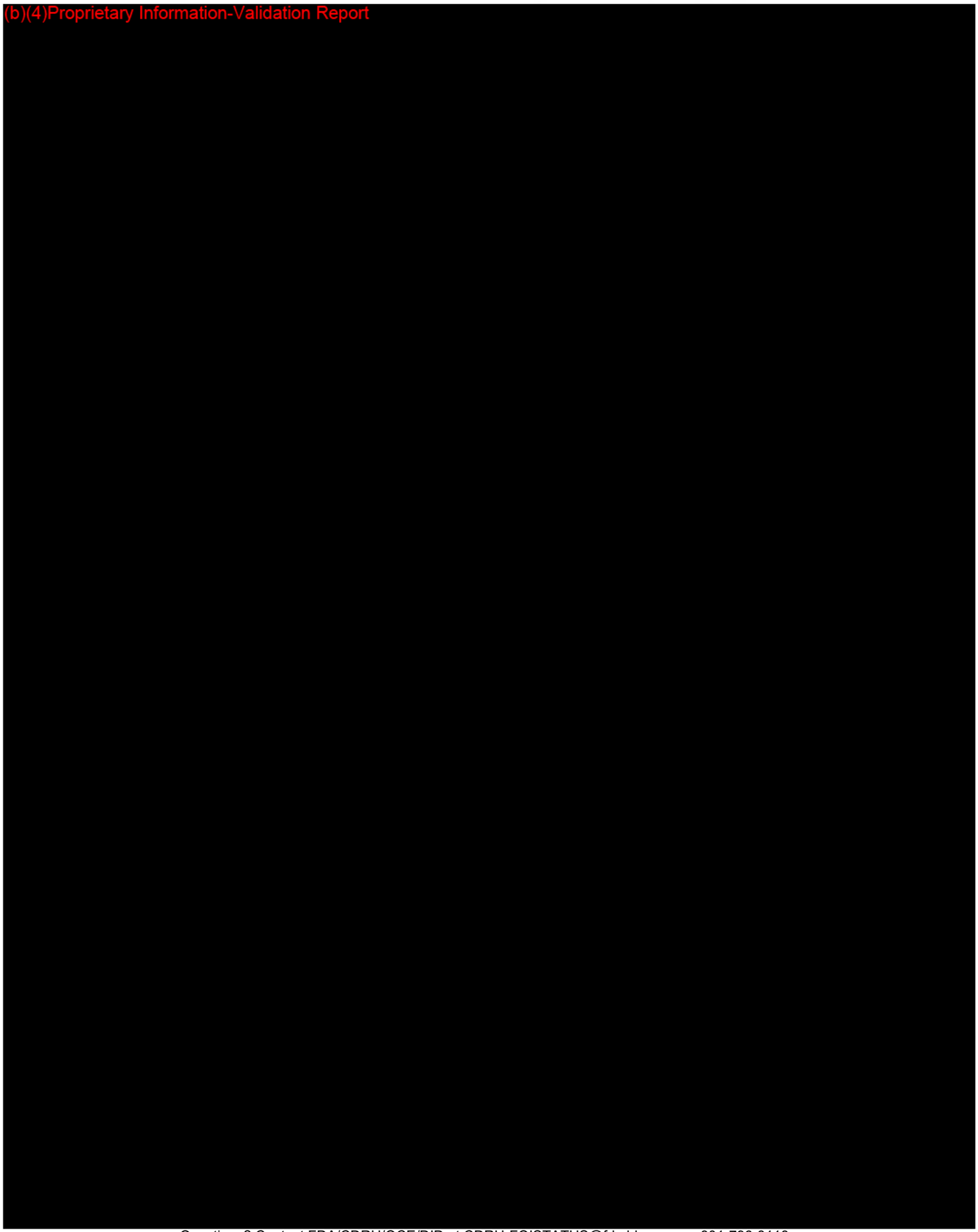
(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report



(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

[redacted]

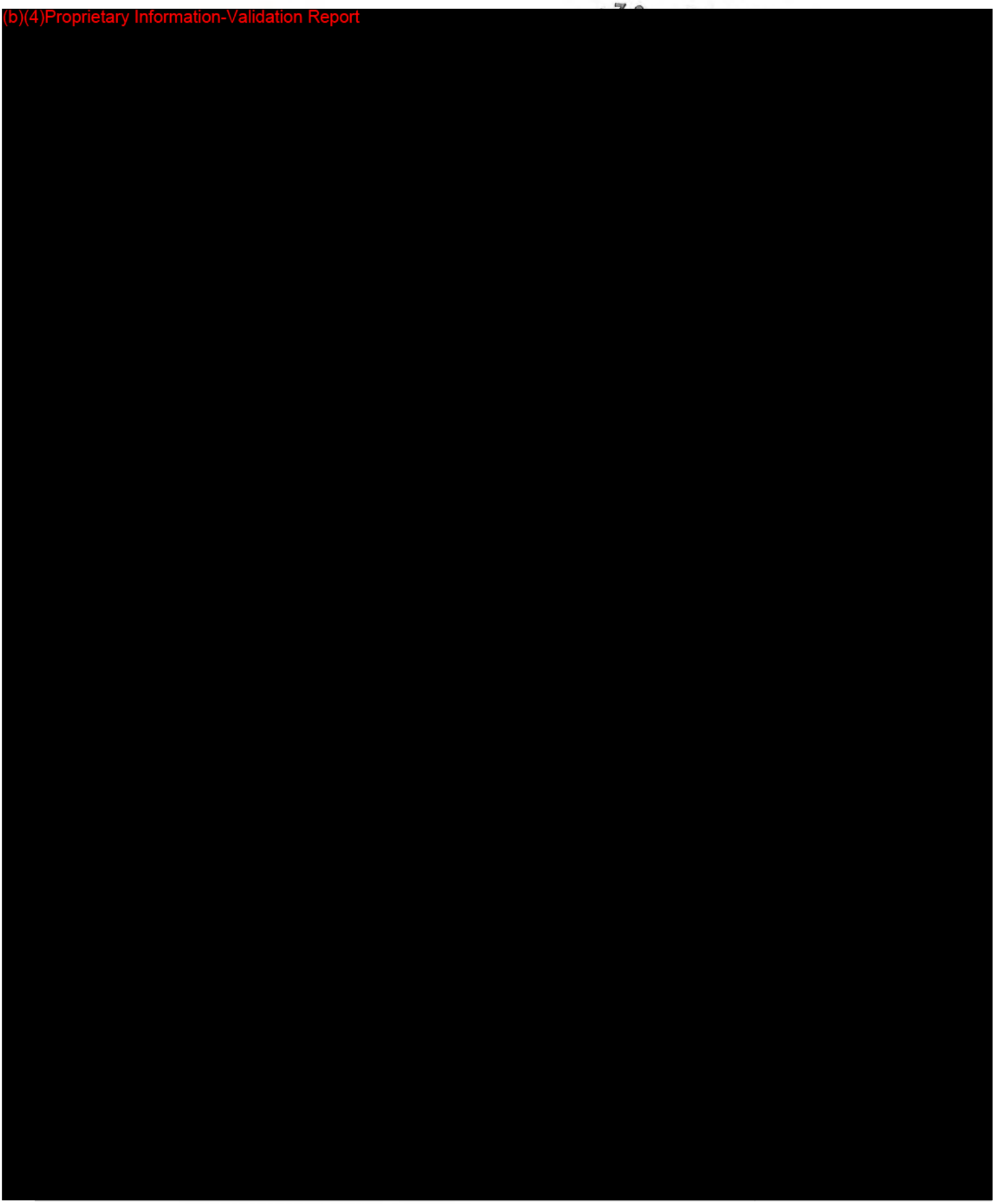
(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report



(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report

[redacted]

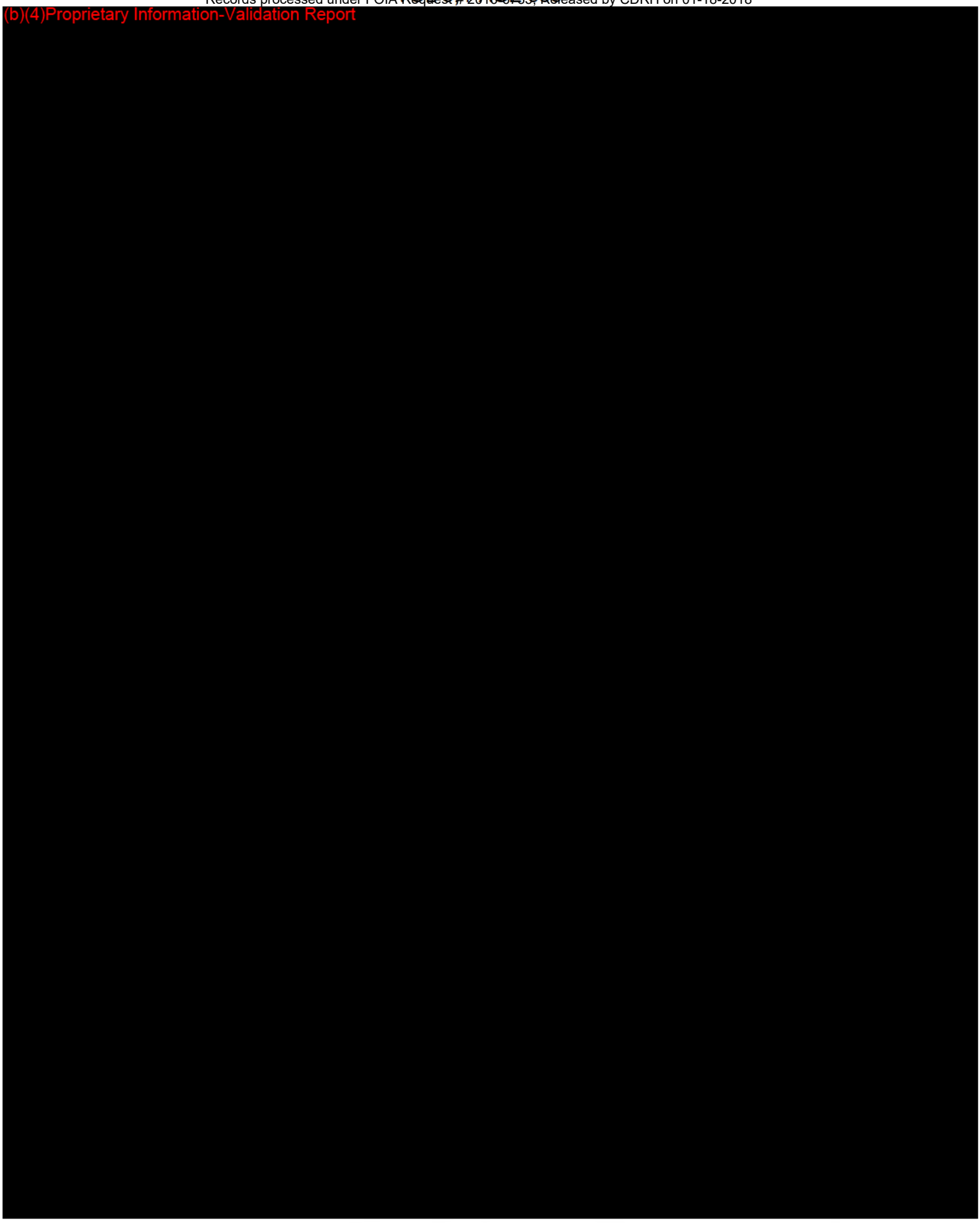
(b)(4)Proprietary Information-Validation Report

[redacted]

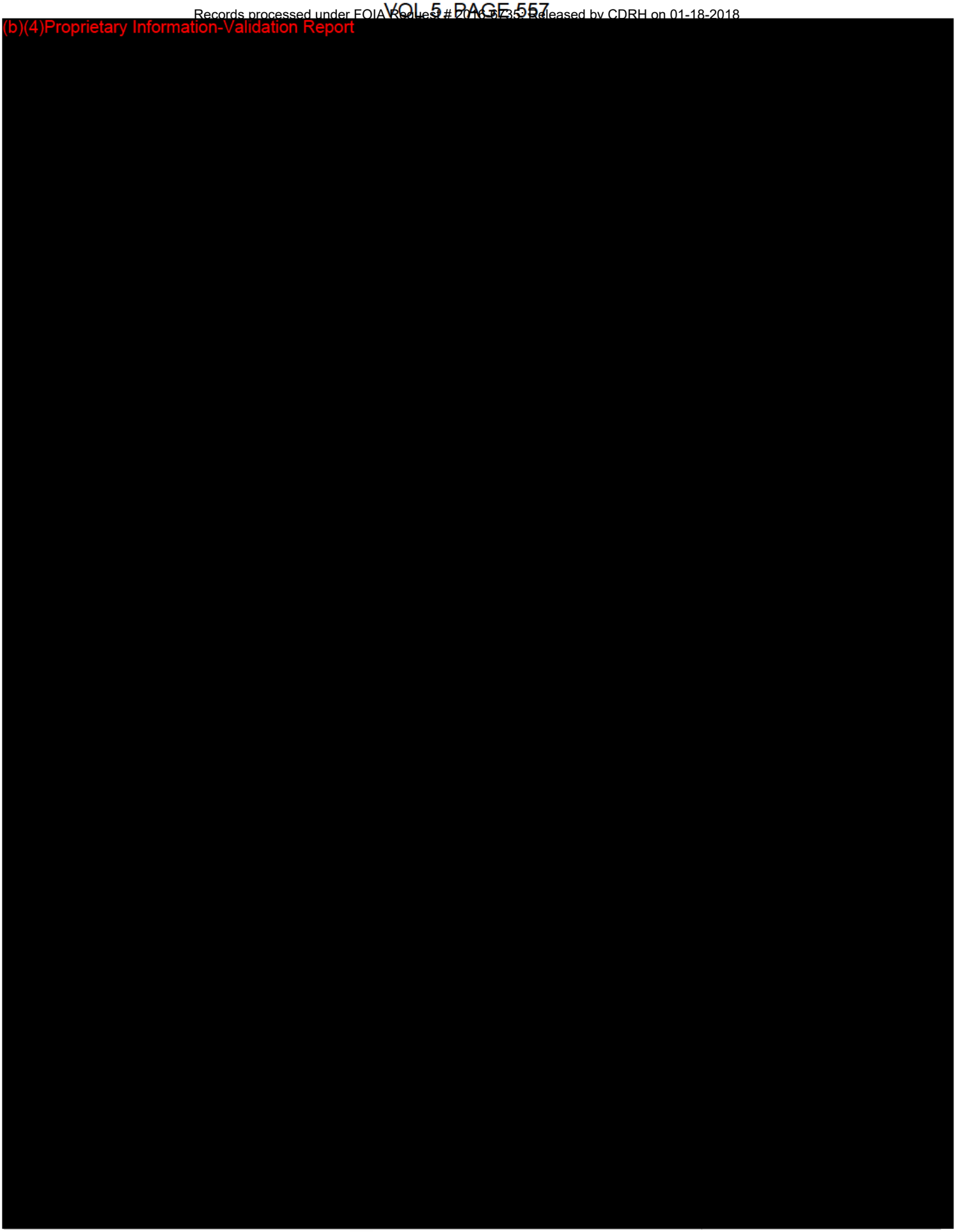
(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report



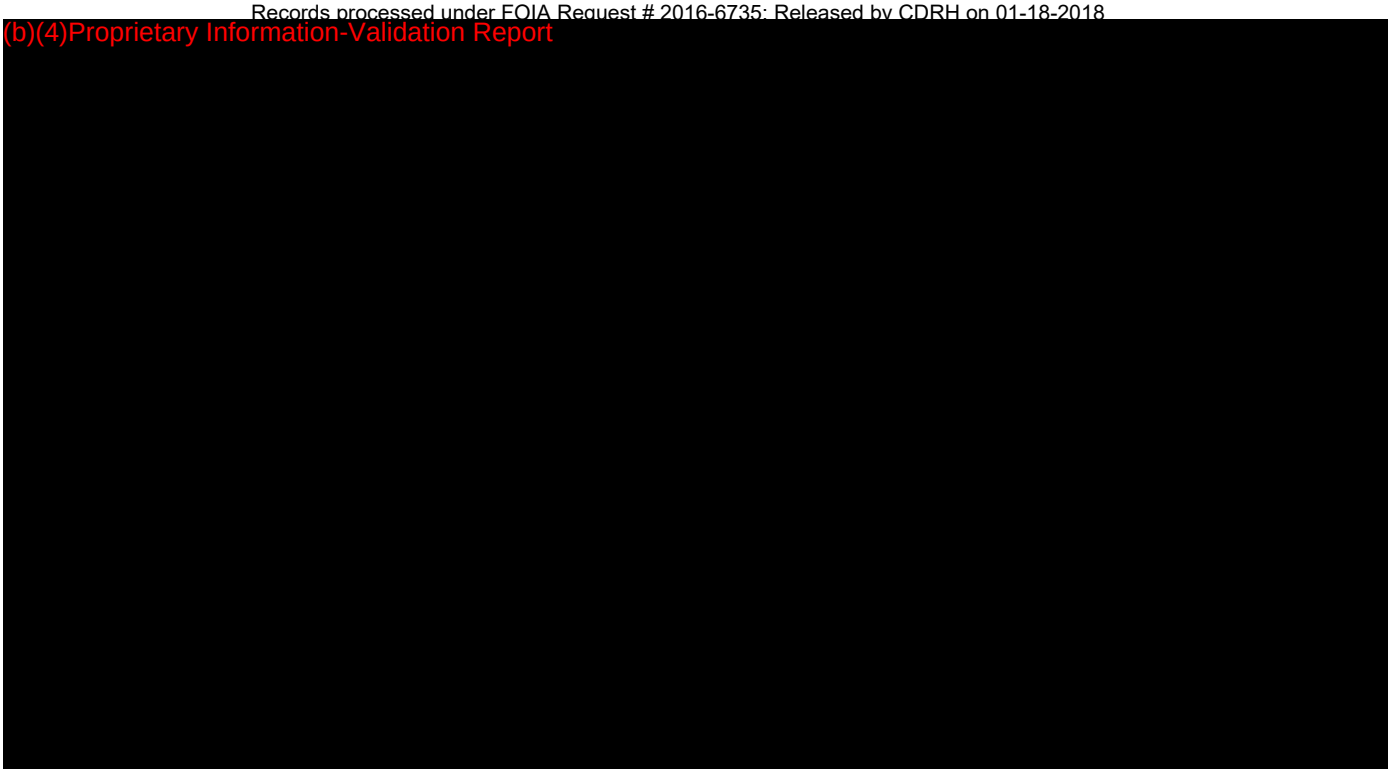
(b)(4)Proprietary Information-Validation Report



(b)(4)Proprietary Information-Validation Report

[redacted]

(b)(4)Proprietary Information-Validation Report



 K150692/S1

Boston Scientific

April 29, 2015

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center -WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: K150692 – Request for Additional Information (AI) via Email dated 5/1/2015
AXIOS Stent with Electrocautery Enhanced Delivery System

Dear Mr. Antonino,

Please accept this information in response to your request for additional information via email dated 5/1/2015.

Two copies of this 510(k) Response have been provided: one paper copy and one electronic copy (eCopy) prepared in accordance with CDRH's electronic copy program. The eCopy is an exact duplicate of the paper copy.

510(k) Submitter: Boston Scientific Corp.
453 Ravendale Drive, Suite H
Mountain View, CA 94043
Telephone: (650) 961-9900
Facsimile: (650) 961-9901

Contact: Carole Sykes, V.P. Clinical and Regulatory Affairs
(650) 868-4331 - cell
csykes@xlumena.com

Sincerely,

Carole Sykes

Carole Sykes
V.P. Clinical and Regulatory Affairs
Boston Scientific Corporation

48

K150692/S1

Boston Scientific

April 29, 2015

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center -WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: K150692 – Request for Additional Information (AI) via Email dated 5/1/2015
AXIOS Stent with Electrocautery Enhanced Delivery System

Dear Mr. Antonino,

Please accept this information in response to your request for additional information via email dated 5/1/2015.

Two copies of this 510(k) Response have been provided: one paper copy and one electronic copy (eCopy) prepared in accordance with CDRH's electronic copy program. The eCopy is an exact duplicate of the paper copy.

510(k) Submitter: Boston Scientific Corp.
453 Ravendale Drive, Suite H
Mountain View, CA 94043
Telephone: (650) 961-9900
Facsimile: (650) 961-9901

Contact: Carole Sykes, V.P. Clinical and Regulatory Affairs
(650) 868-4331 - cell
csykes@xlumena.com

Sincerely,

Carole Sykes

Carole Sykes
V.P. Clinical and Regulatory Affairs
Boston Scientific Corporation

Boston Scientific

April 29, 2015

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center -WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: K150692 – Request for Additional Information (AI) via Email dated 5/1/2015
AXIOS Stent with Electrocautery Enhanced Delivery System

Dear Mr. Antonino,

Please accept this information in response to your request for additional information via email dated 5/1/2015.

Two copies of this 510(k) Response have been provided: one paper copy and one electronic copy (eCopy) prepared in accordance with CDRH's electronic copy program. The eCopy is an exact duplicate of the paper copy.

510(k) Submitter: Boston Scientific Corp.
453 Ravendale Drive, Suite H
Mountain View, CA 94043
Telephone: (650) 961-9900
Facsimile: (650) 961-9901

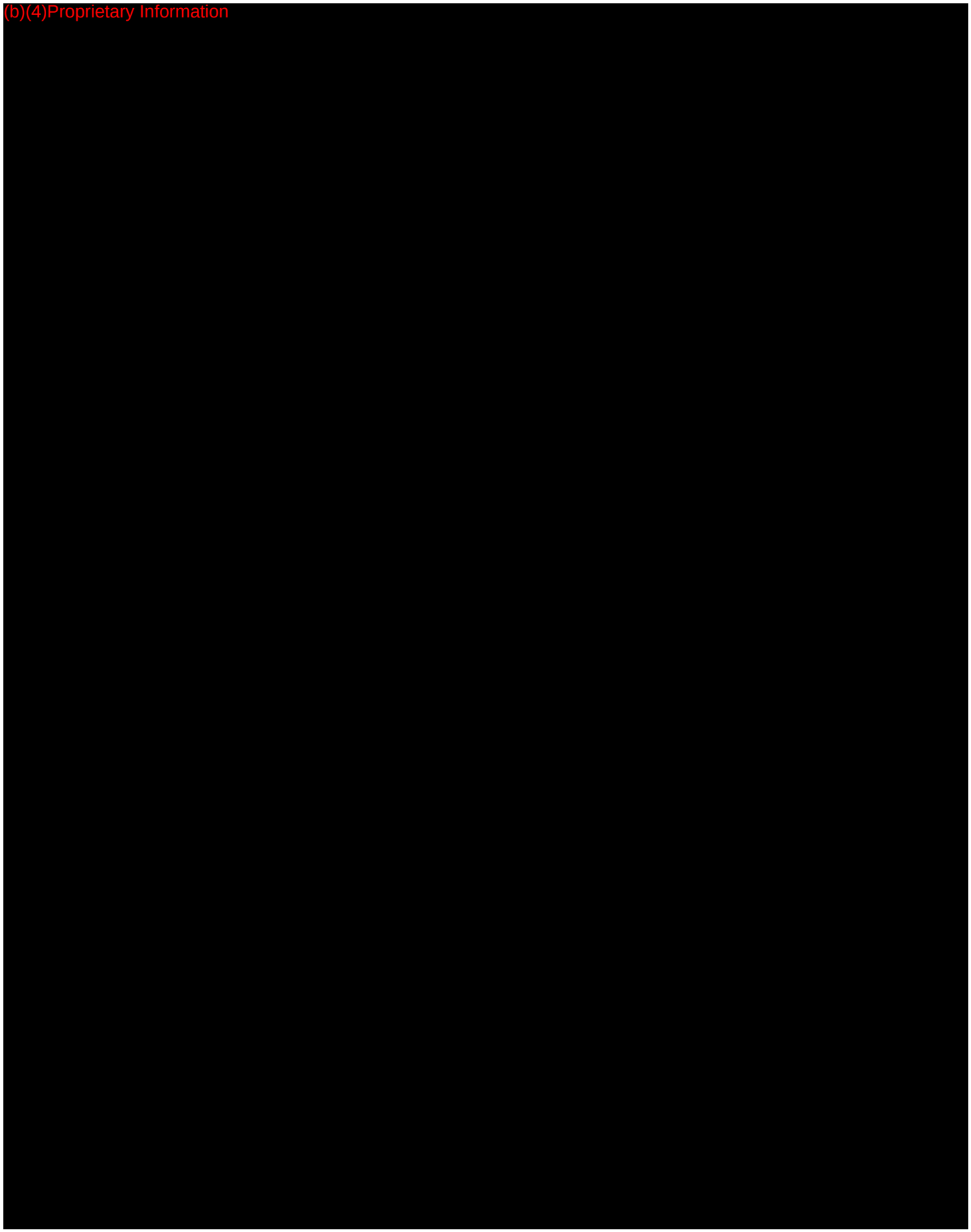
Contact: Carole Sykes, V.P. Clinical and Regulatory Affairs
(650) 868-4331 - cell
csykes@xlumena.com

Sincerely,

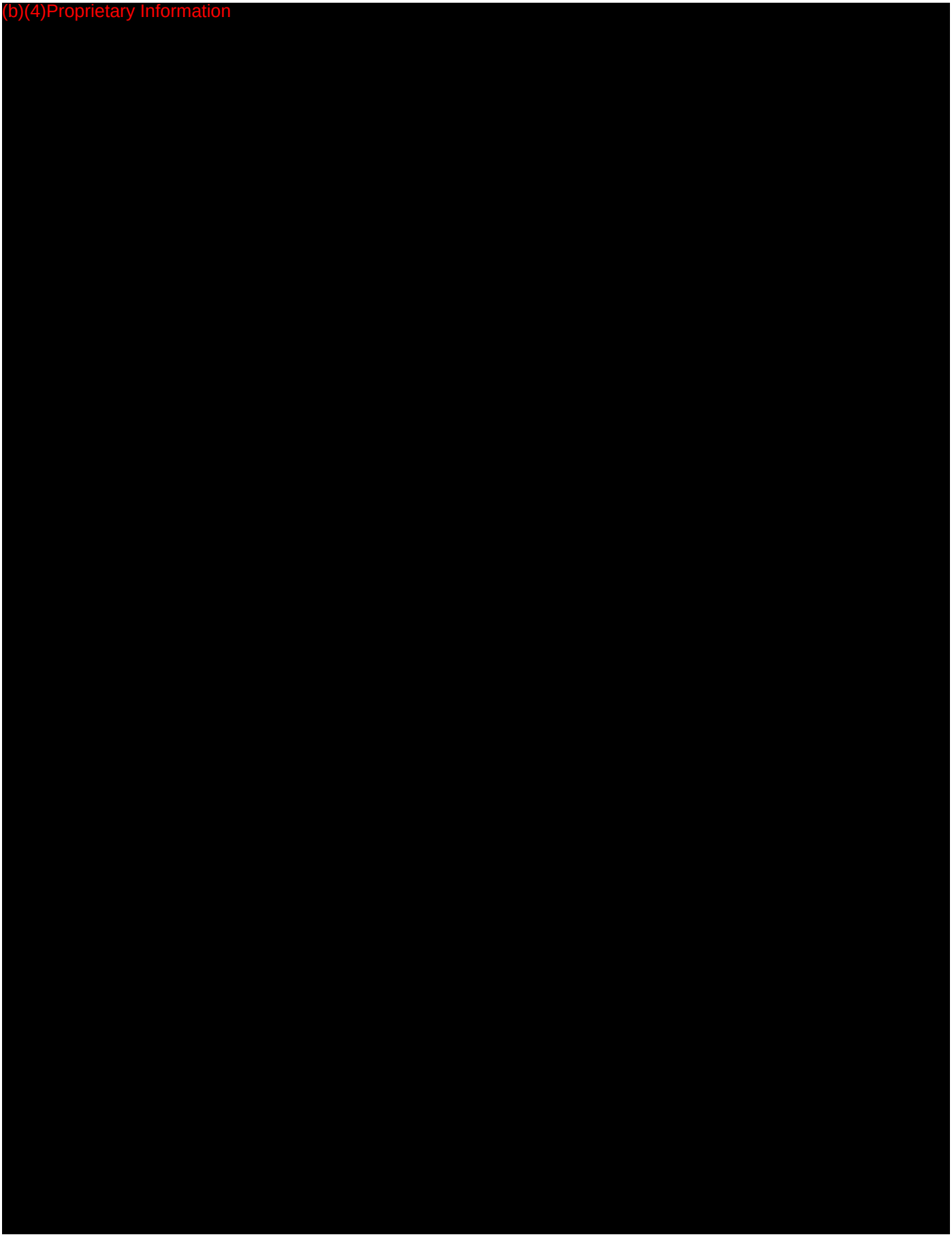
Carole Sykes

Carole Sykes
V.P. Clinical and Regulatory Affairs
Boston Scientific Corporation

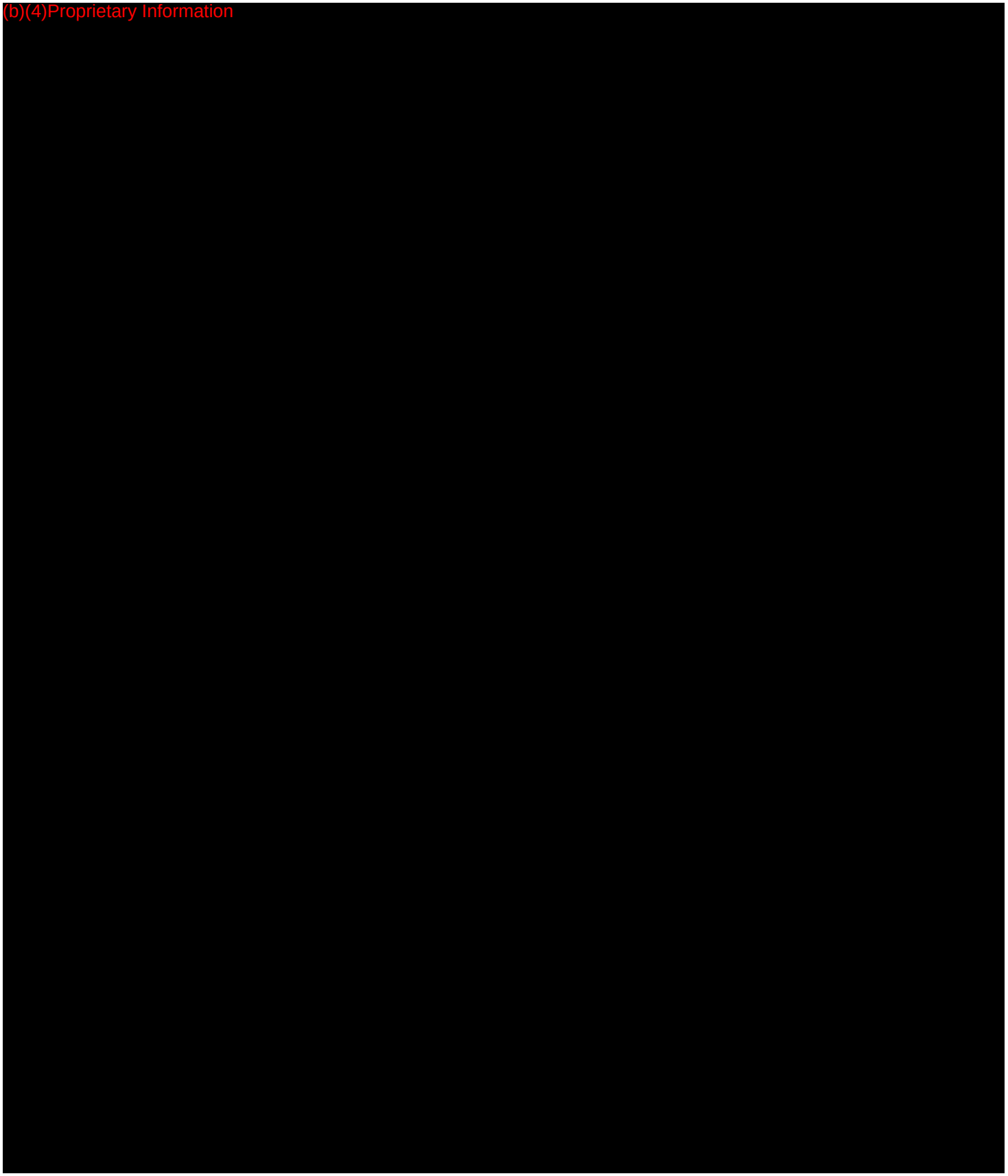
(b)(4)Proprietary Information



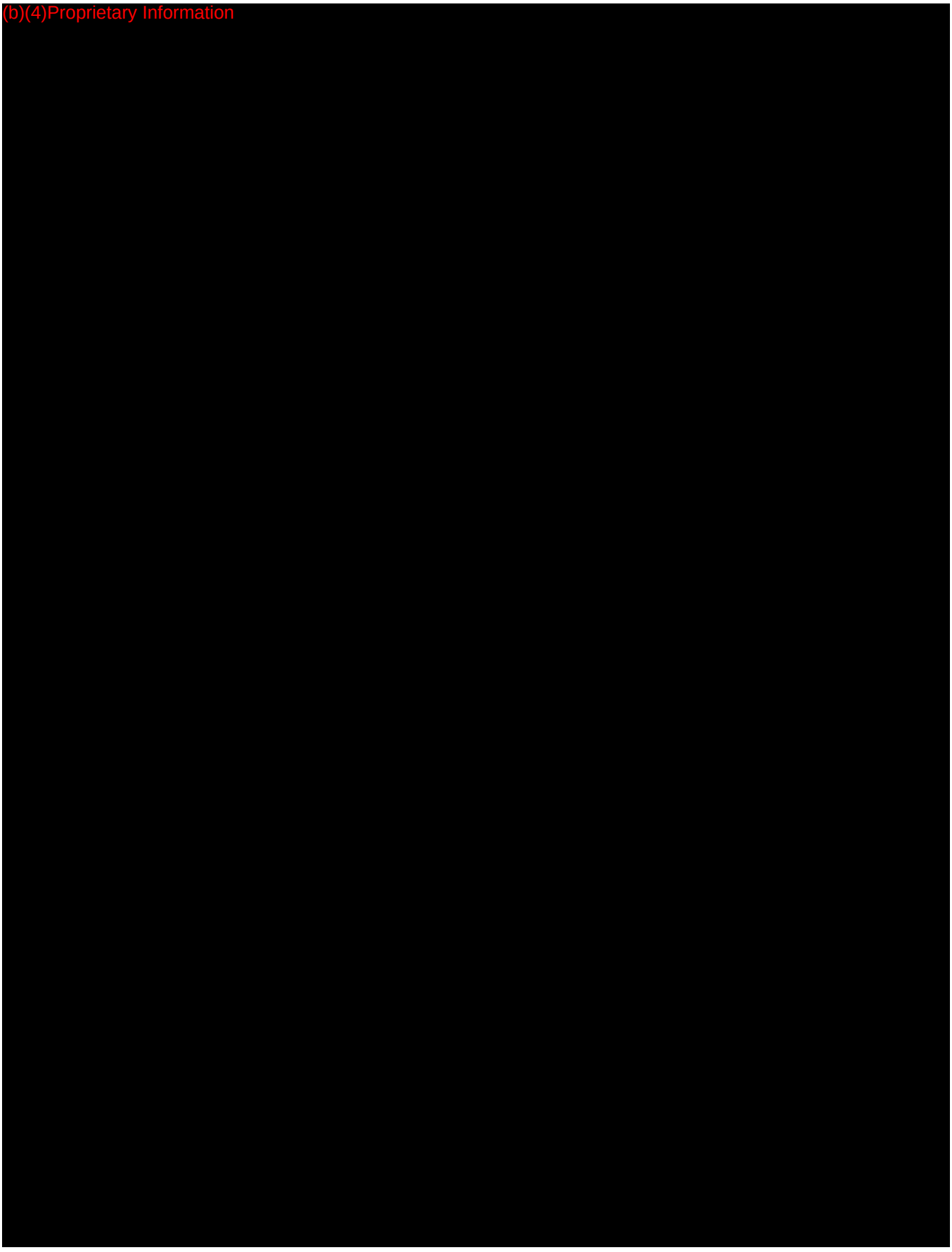
(b)(4)Proprietary Information



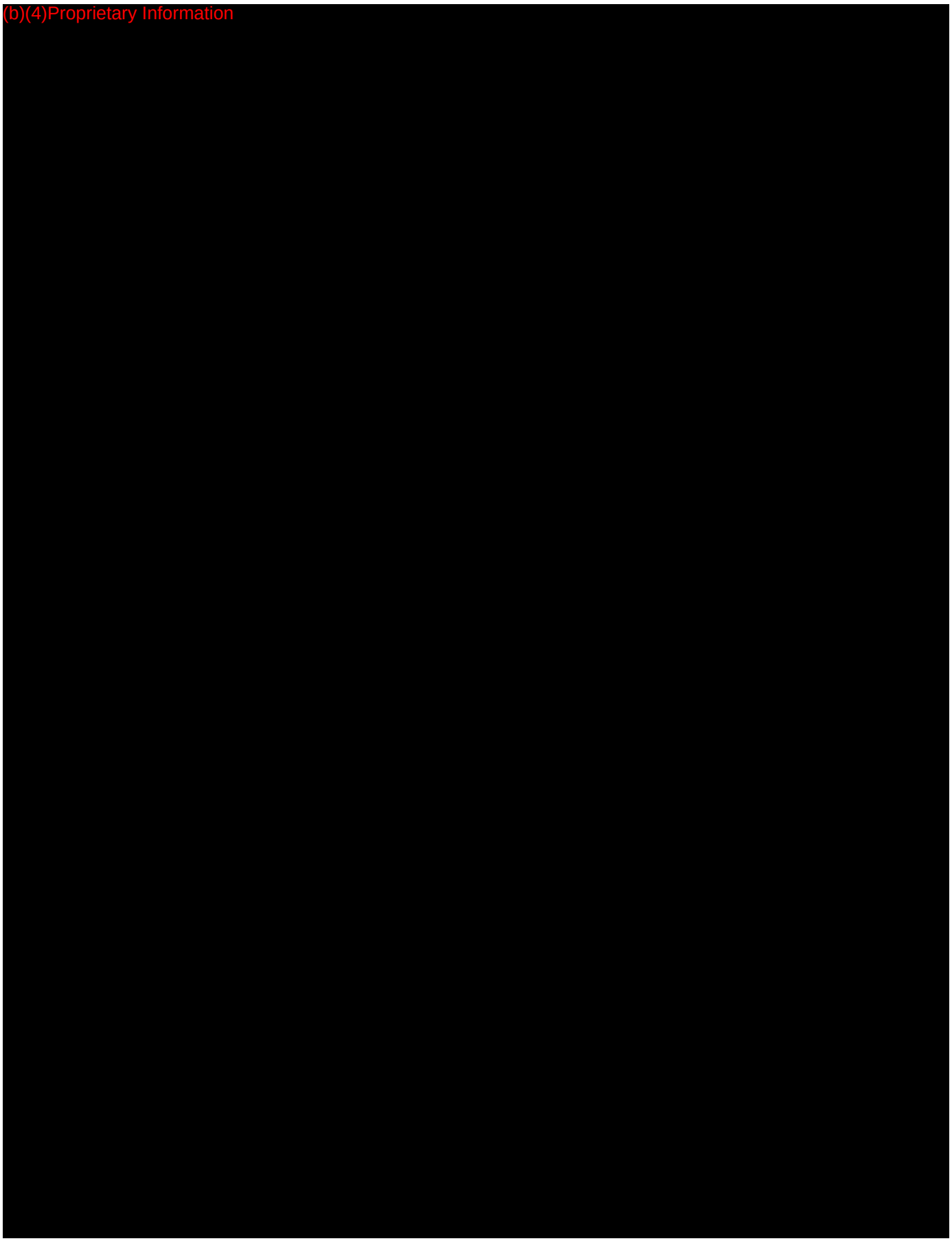
(b)(4)Proprietary Information



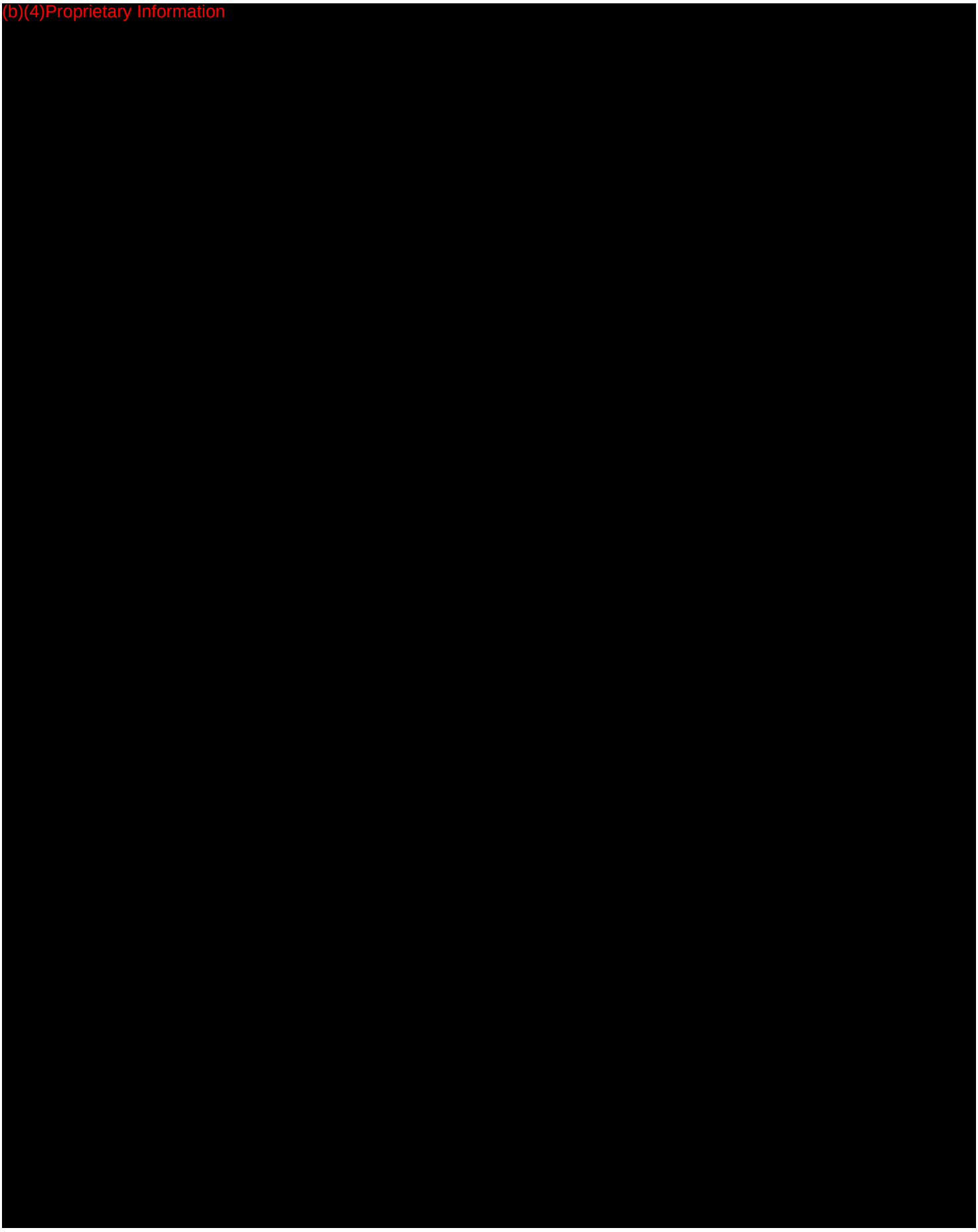
(b)(4)Proprietary Information



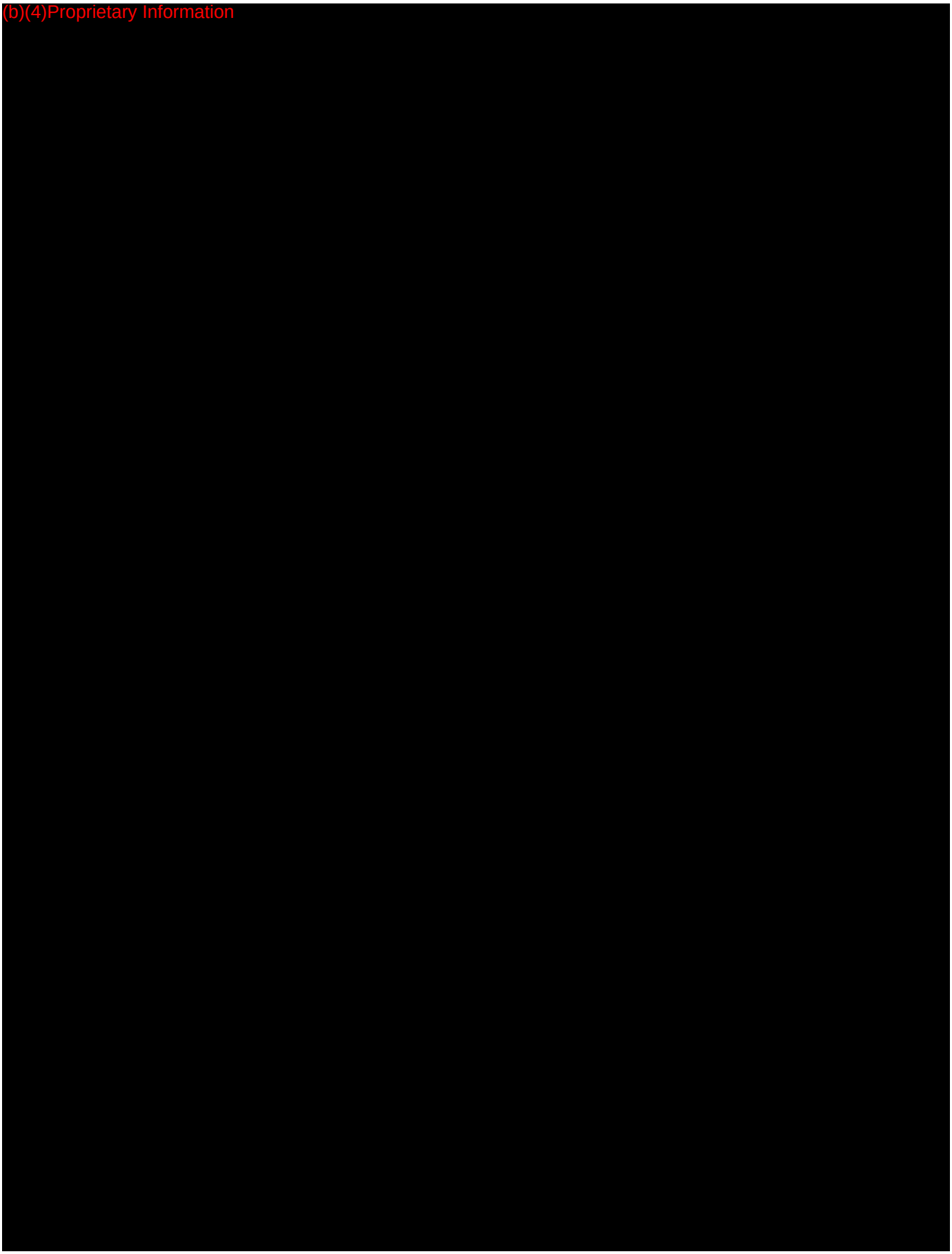
(b)(4)Proprietary Information

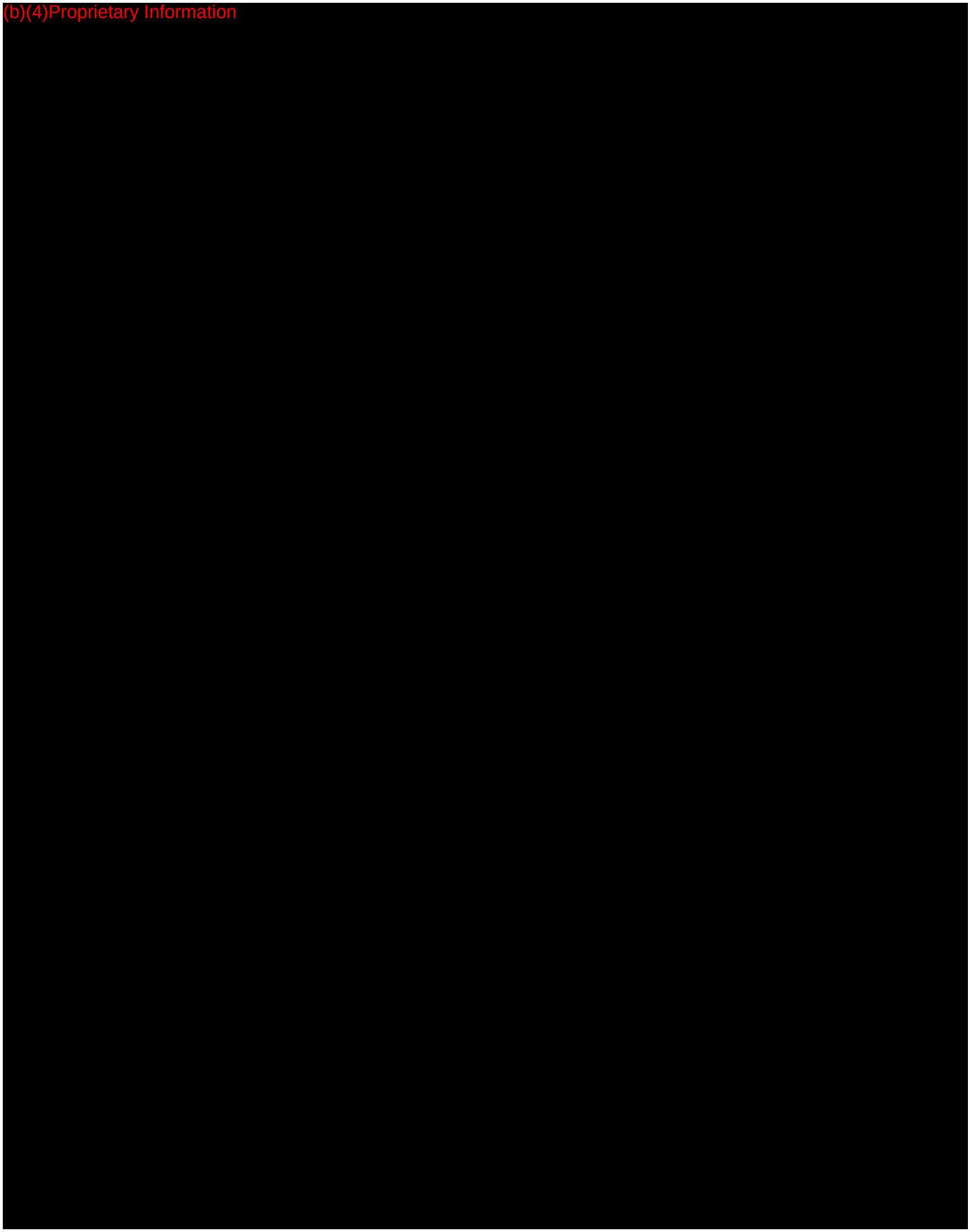


(b)(4)Proprietary Information

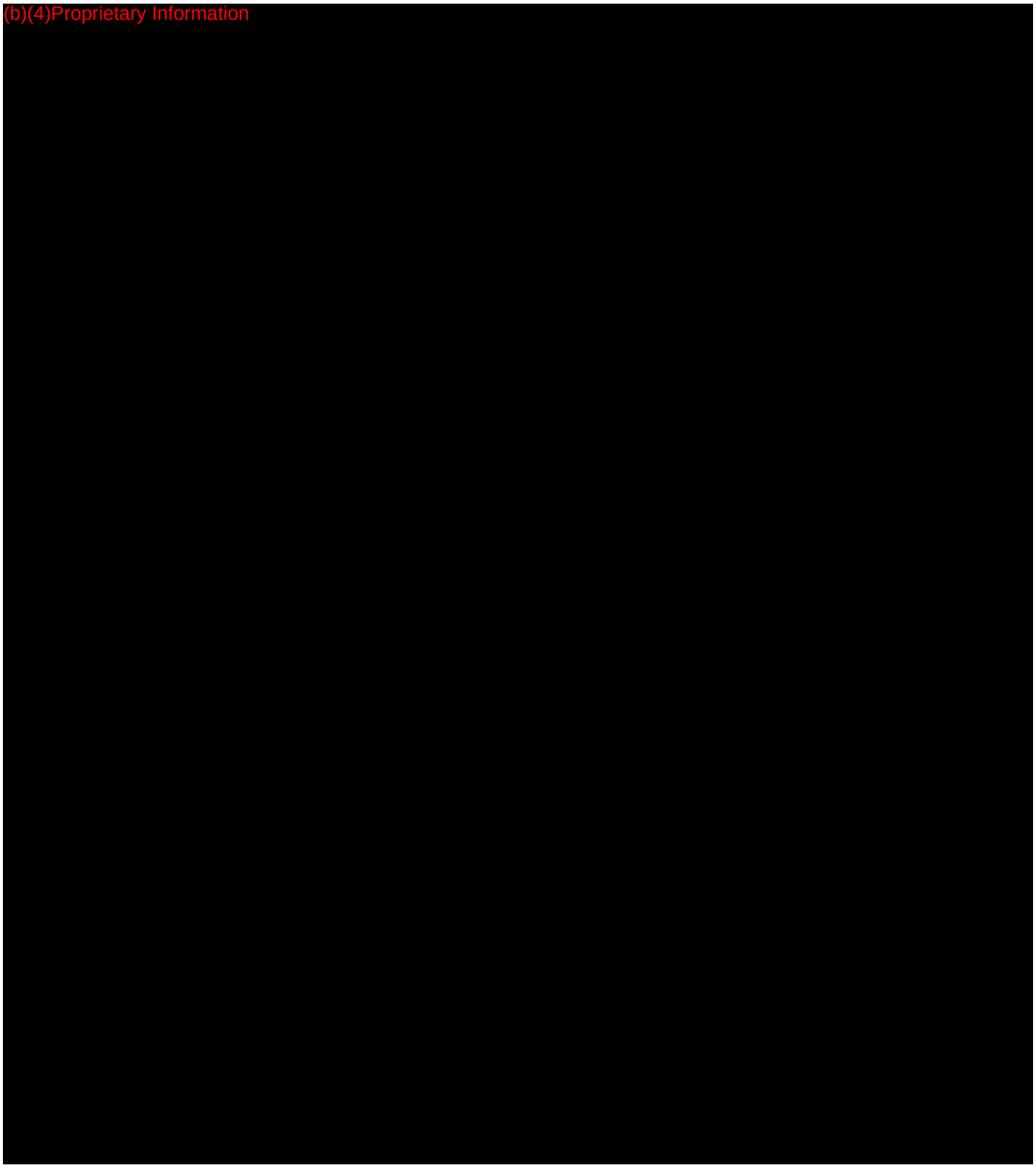


(b)(4)Proprietary Information



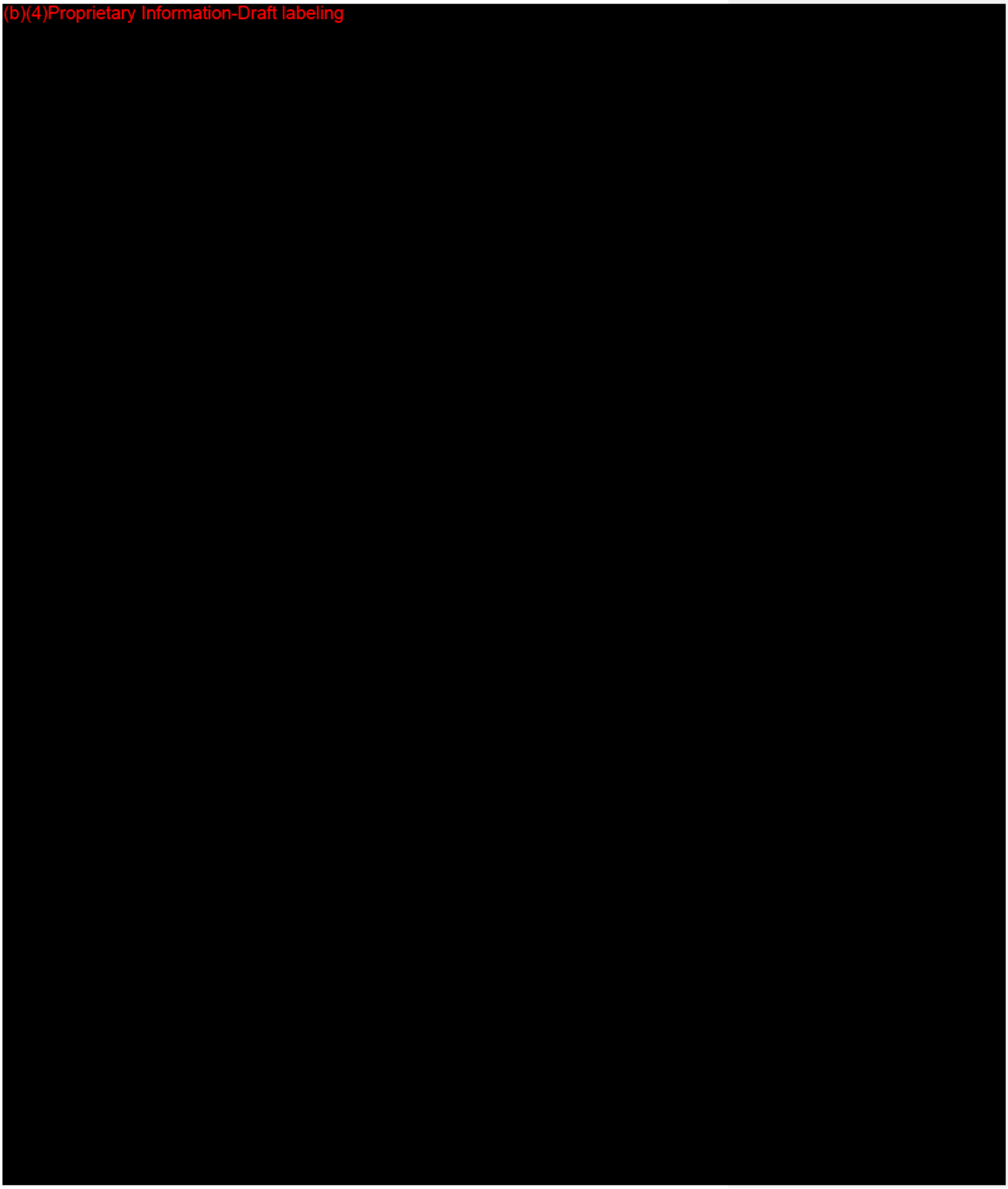


(b)(4)Proprietary Information

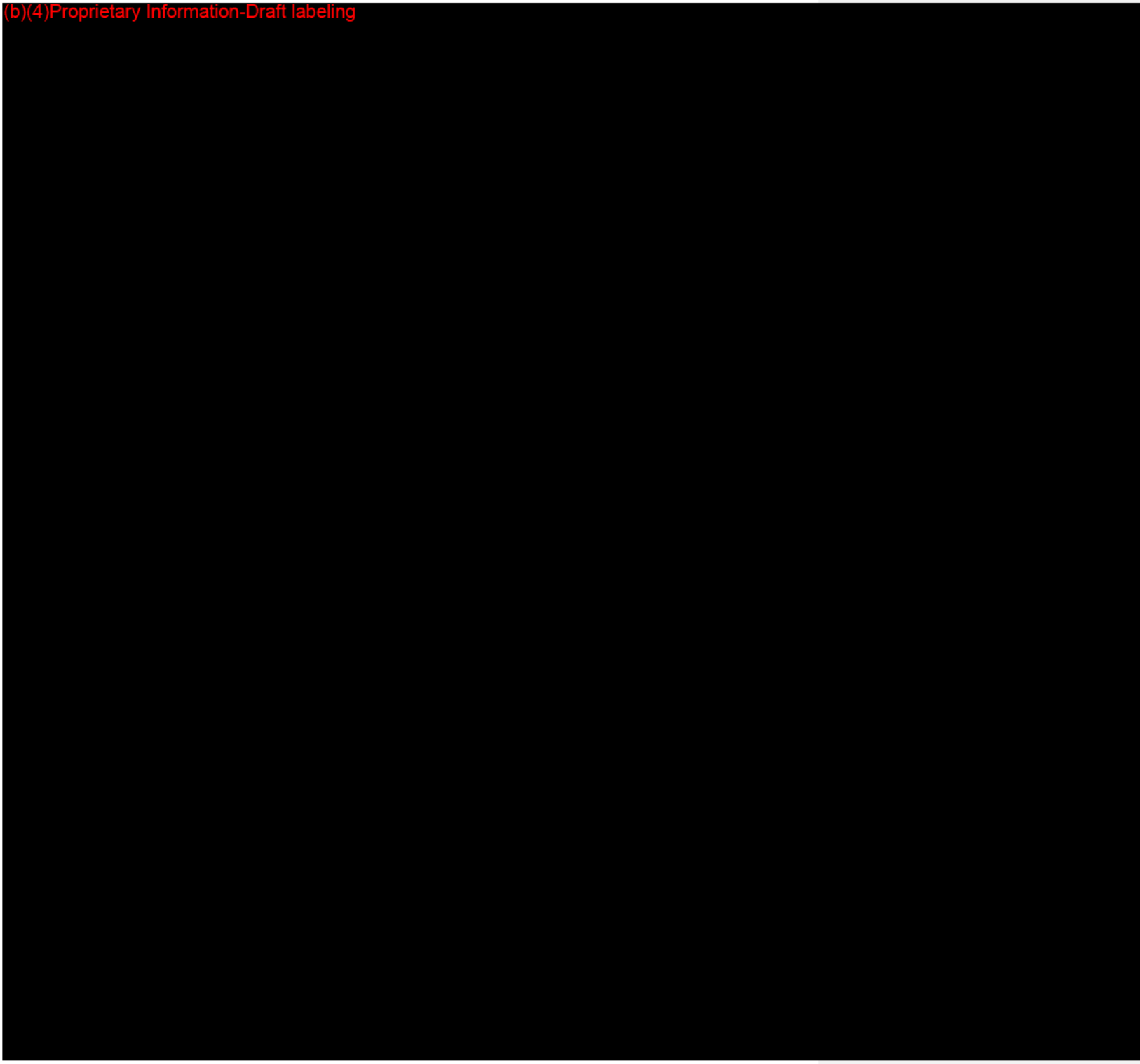


ATTACHMENT A

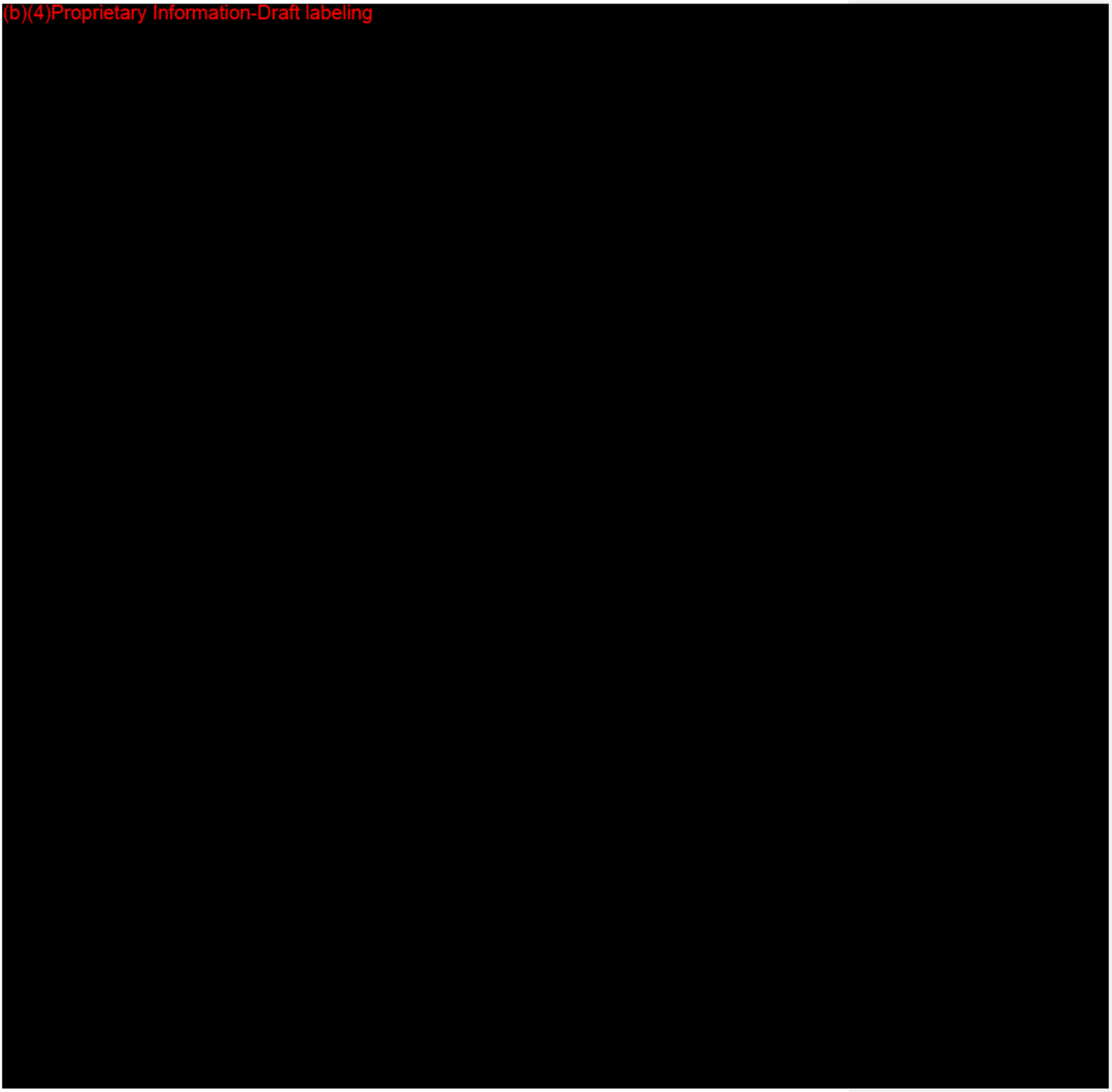
Redlined IFU



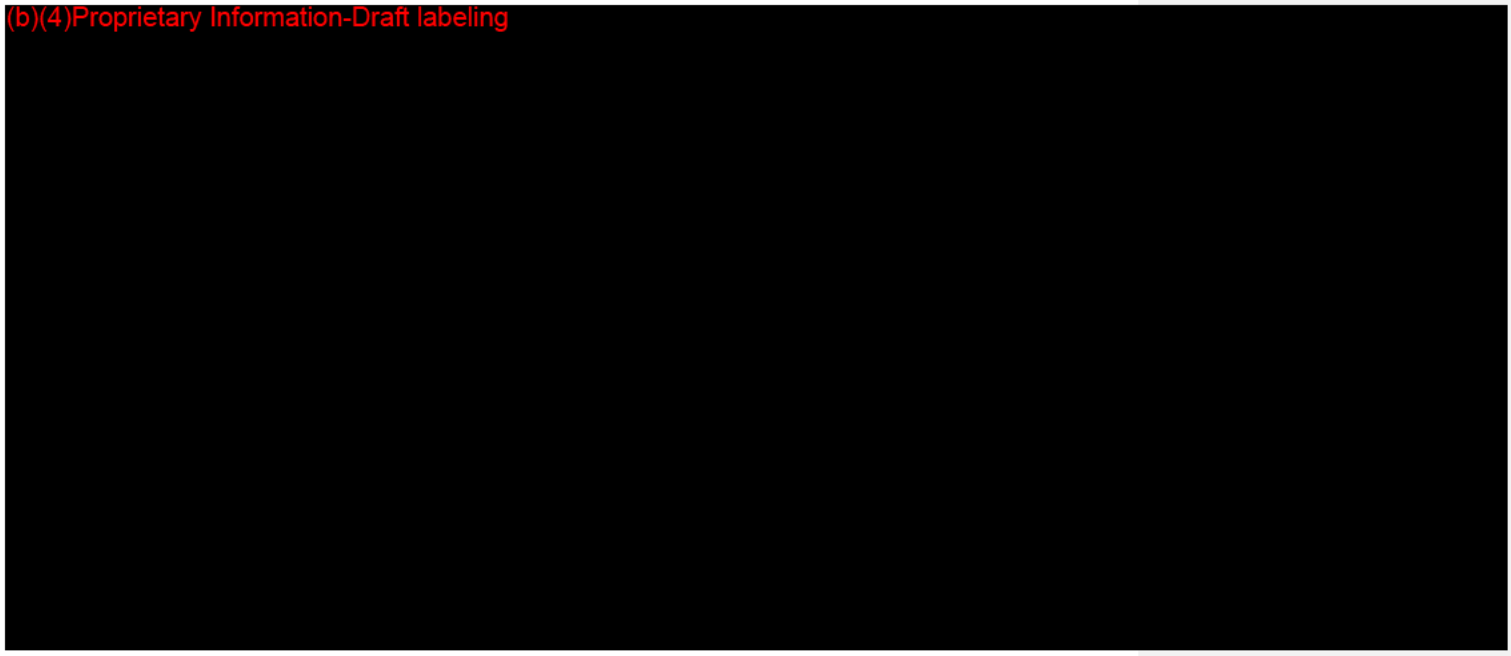
(b)(4)Proprietary Information-Draft labeling



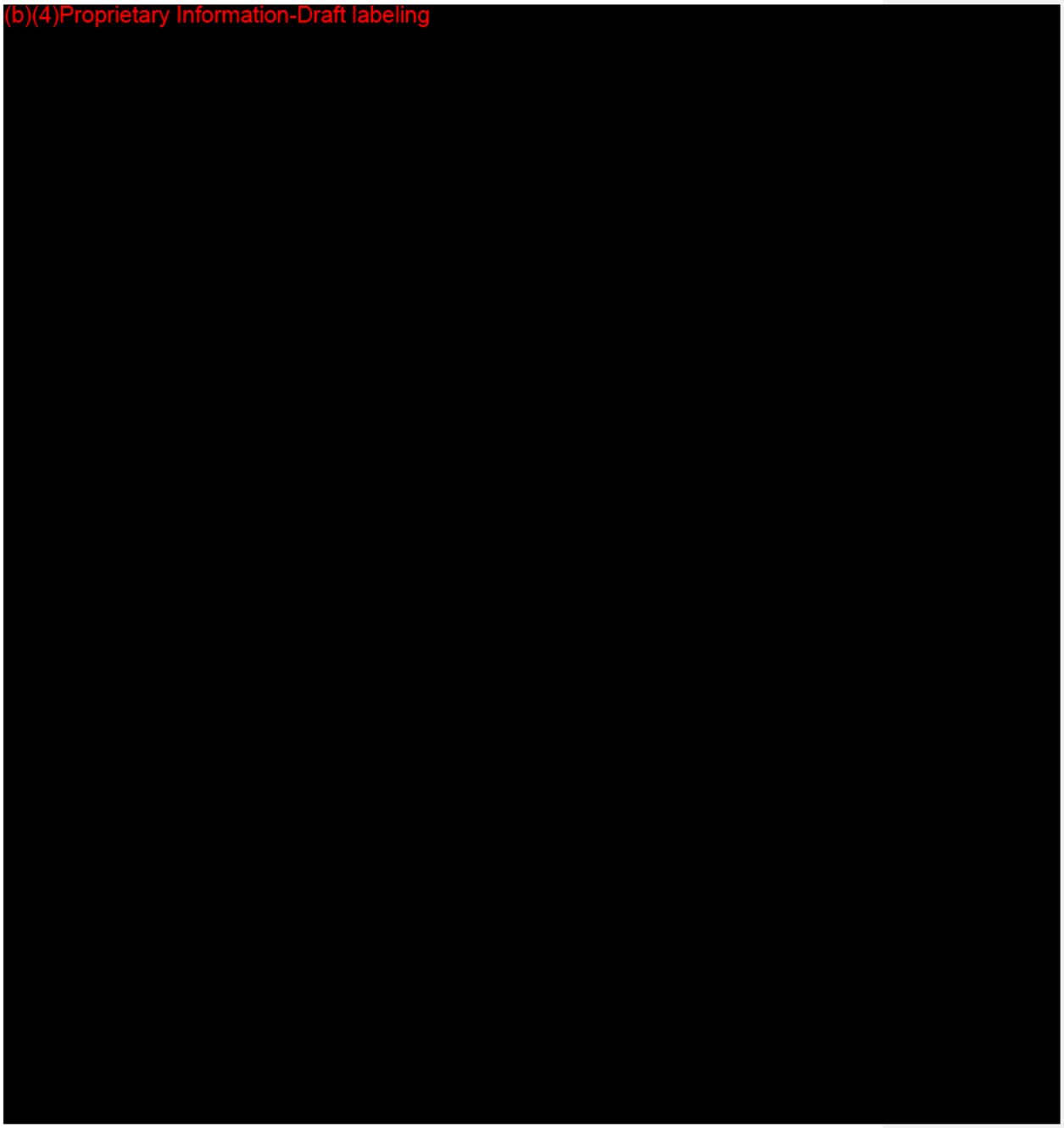
(b)(4)Proprietary Information-Draft labeling



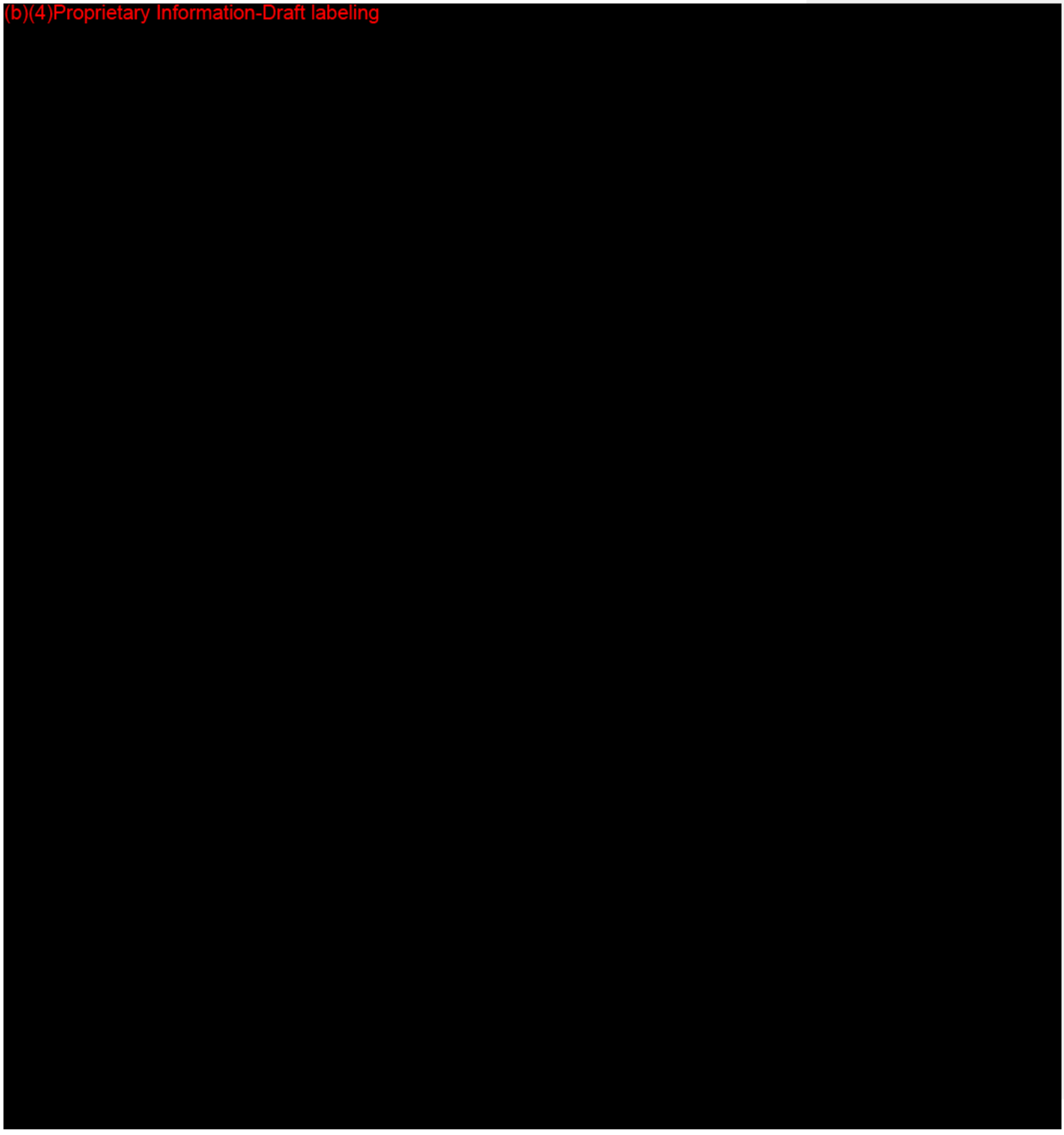
(b)(4)Proprietary Information-Draft labeling



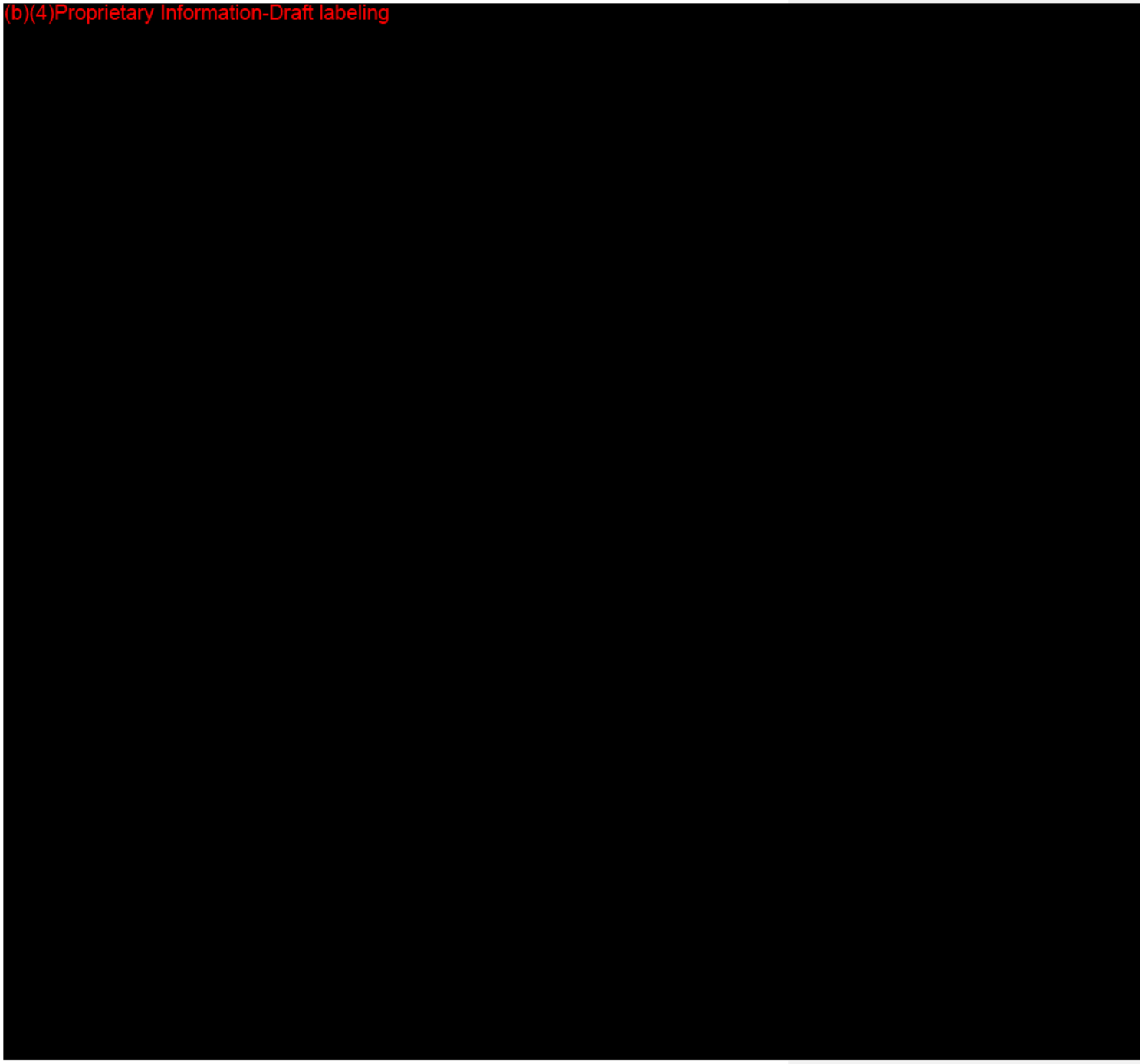
(b)(4)Proprietary Information-Draft labeling



(b)(4)Proprietary Information-Draft labeling

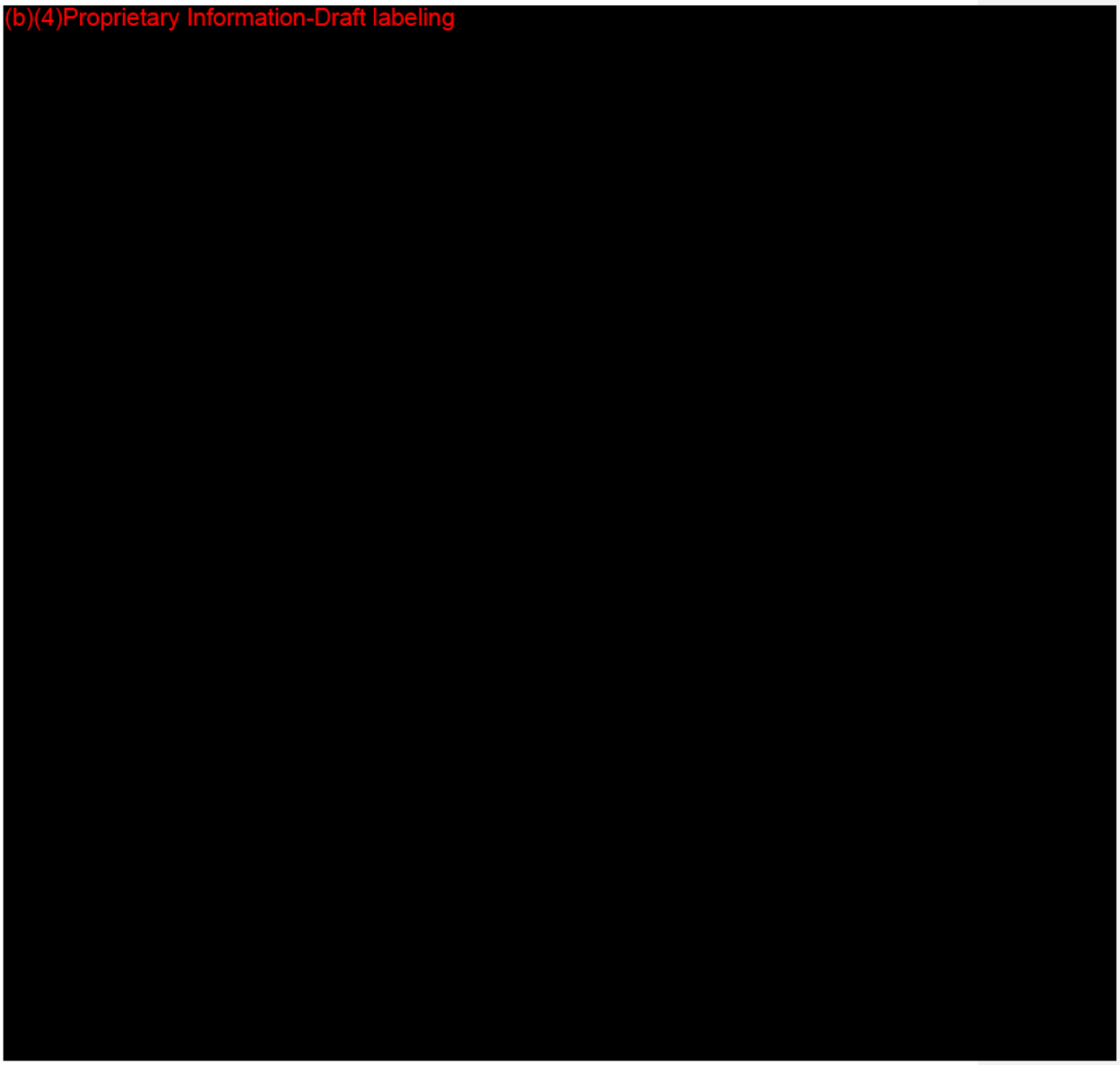


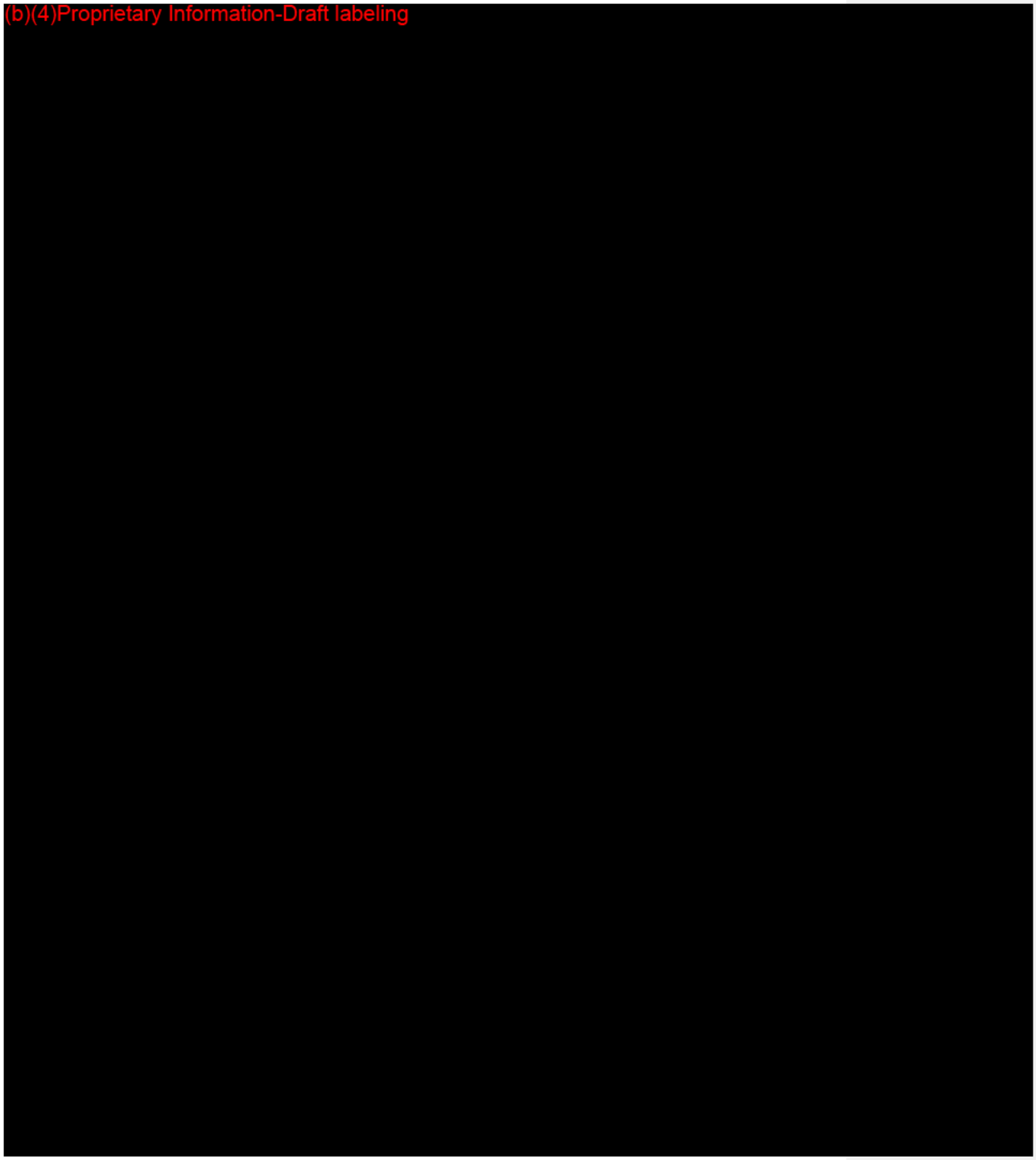
(b)(4)Proprietary Information-Draft labeling



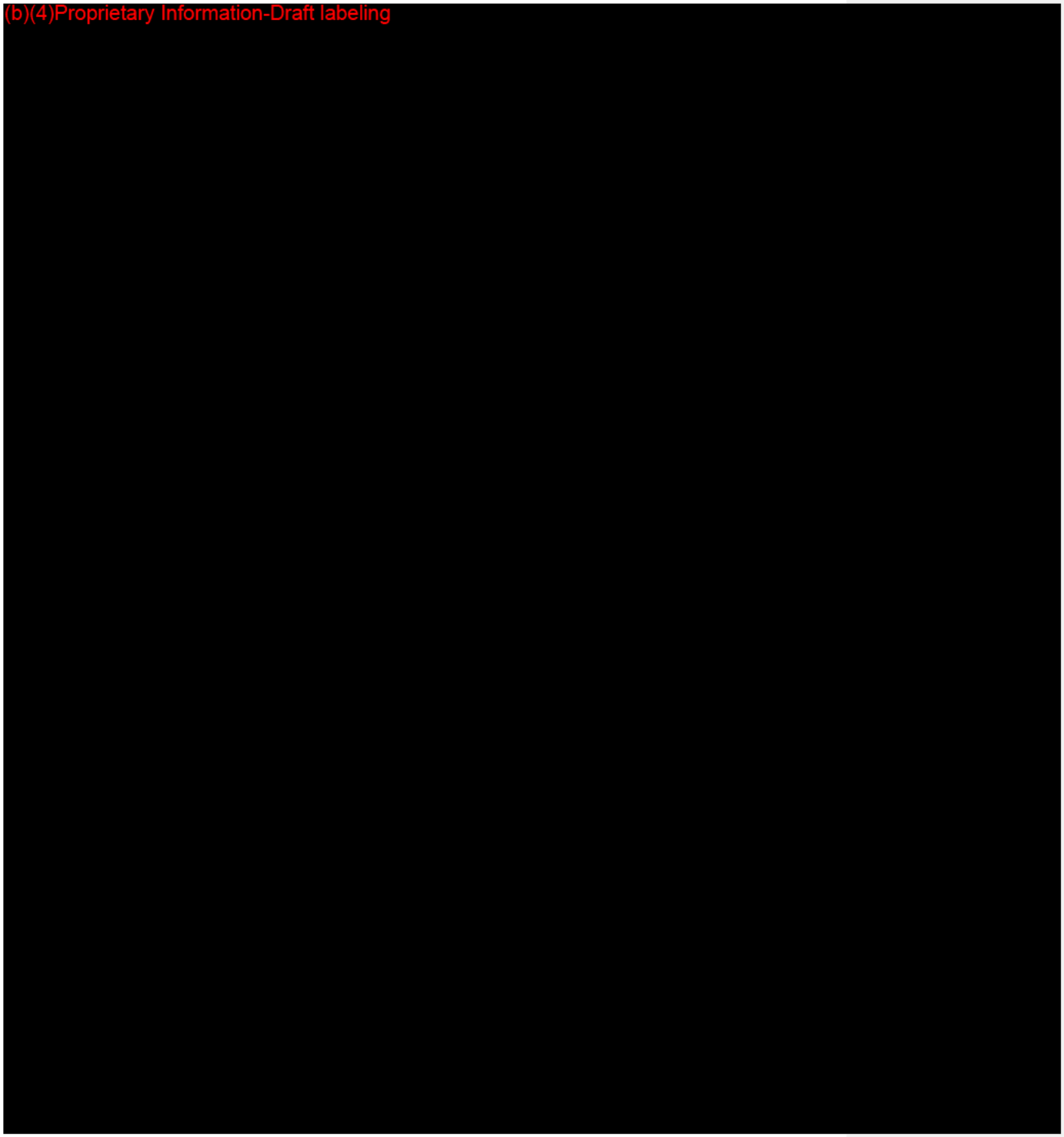
(b)(4)Proprietary Information-Draft labeling

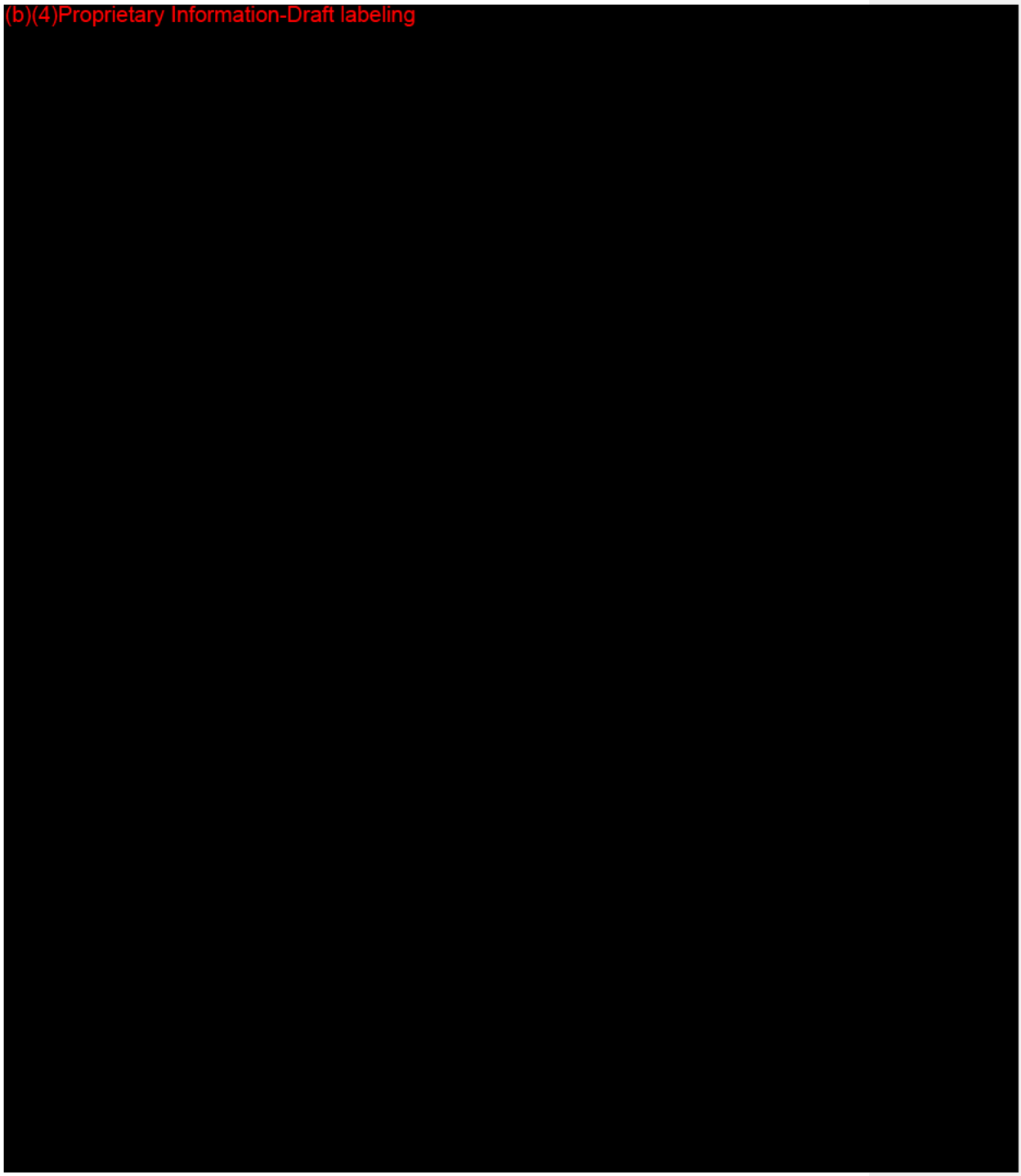
(b)(4)Proprietary Information-Draft labeling



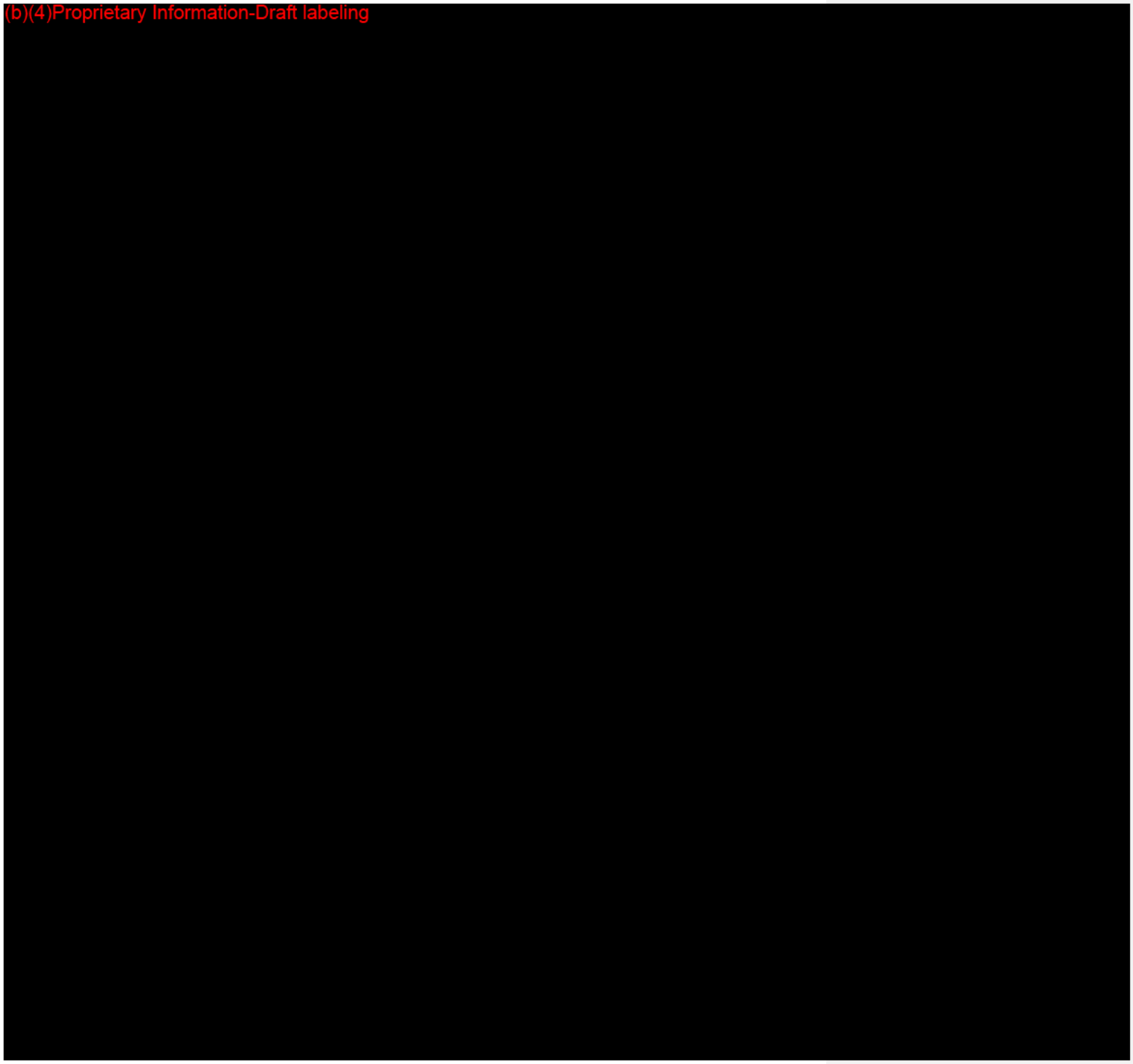


(b)(4)Proprietary Information-Draft labeling

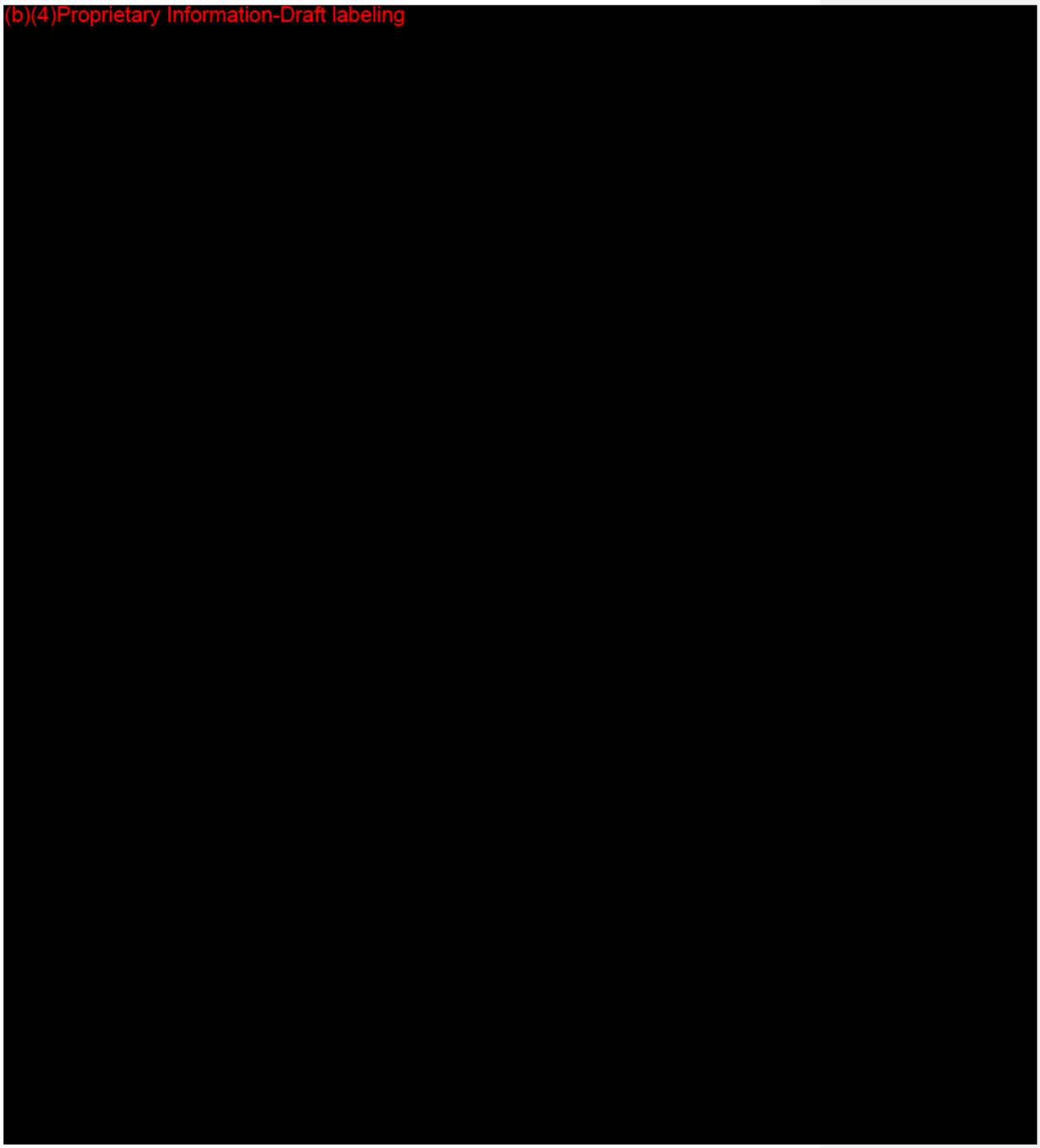




(b)(4)Proprietary Information-Draft labeling

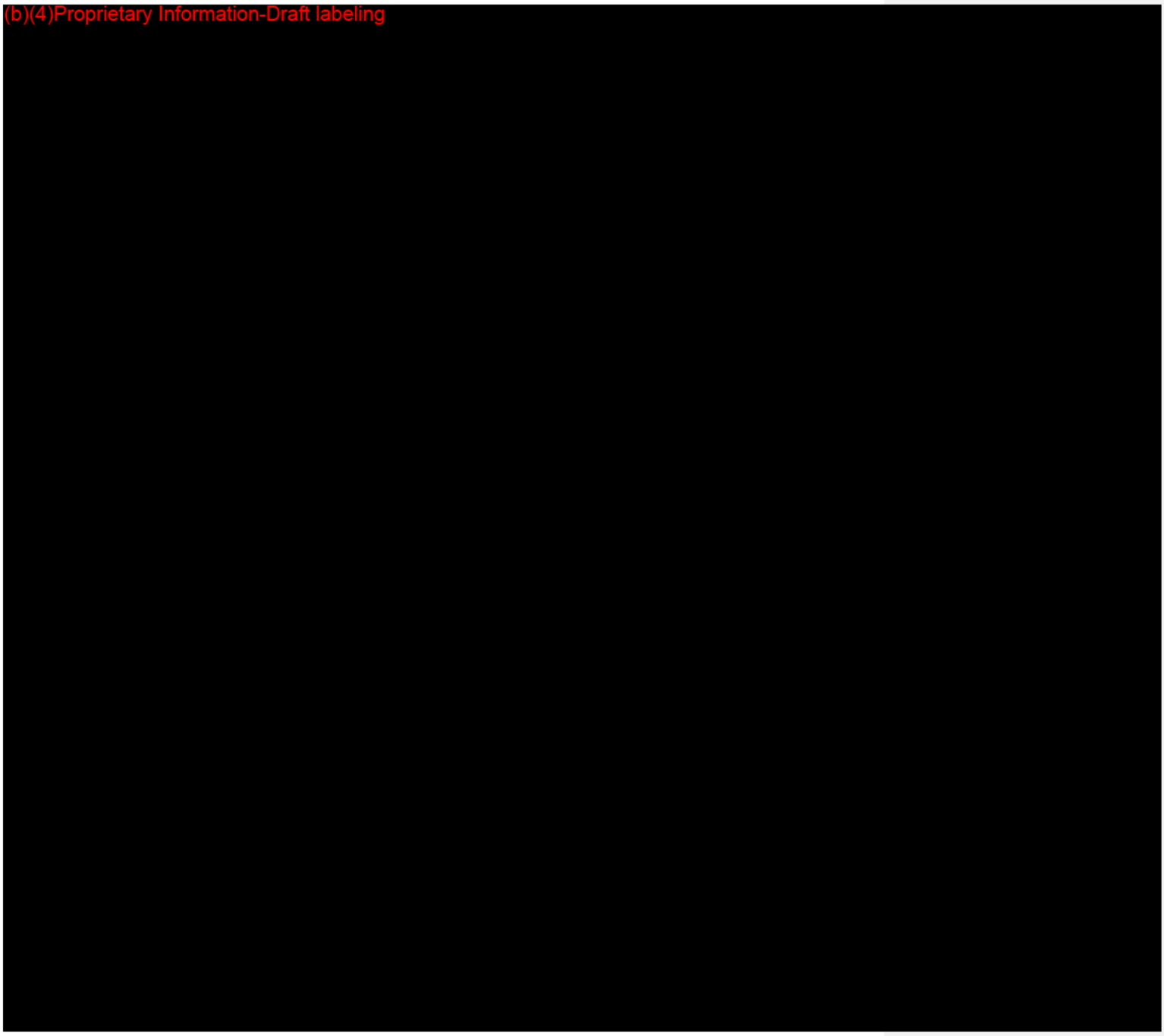


(b)(4)Proprietary Information-Draft labeling

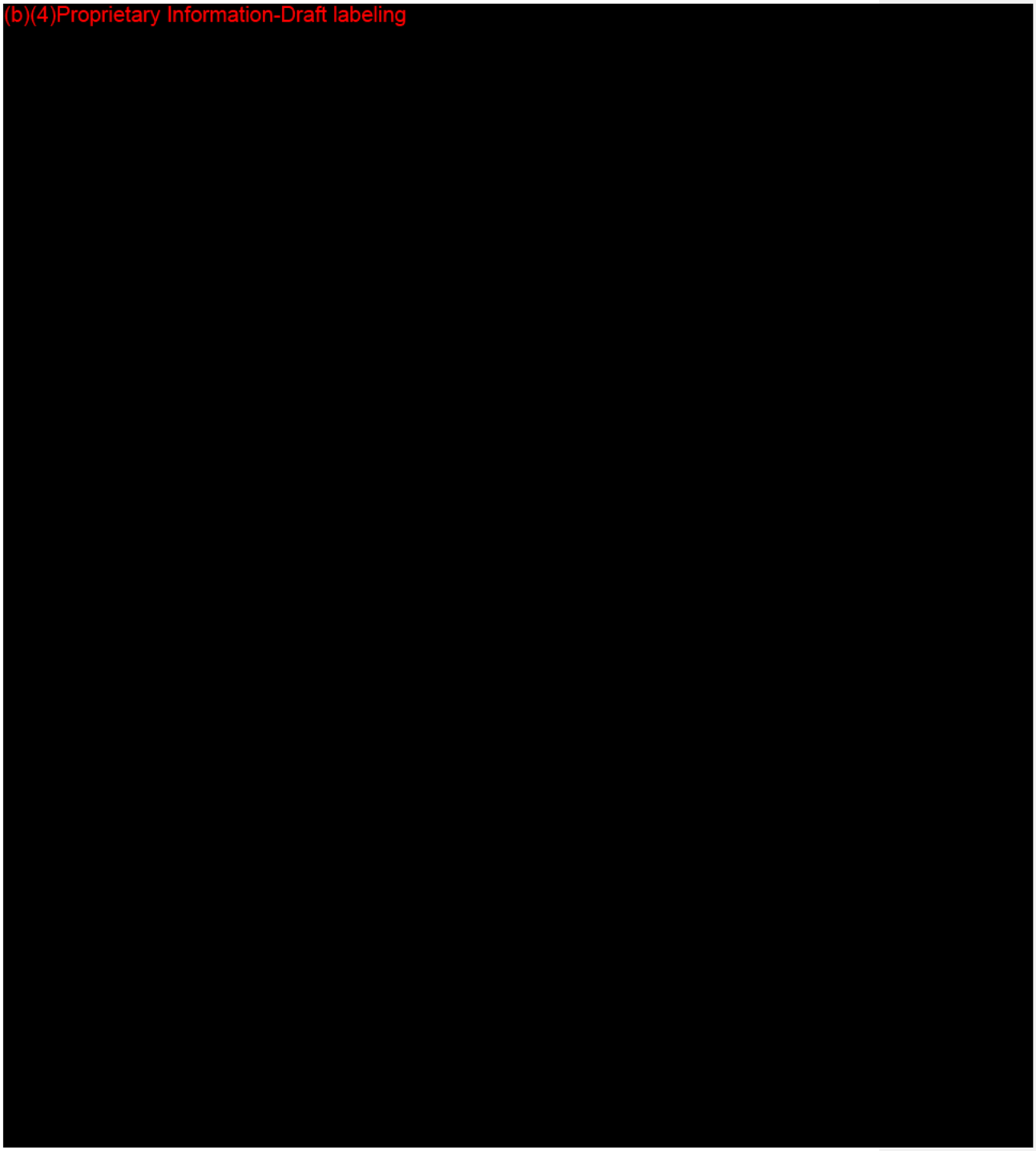


(b)(4)Proprietary Information-Draft labeling

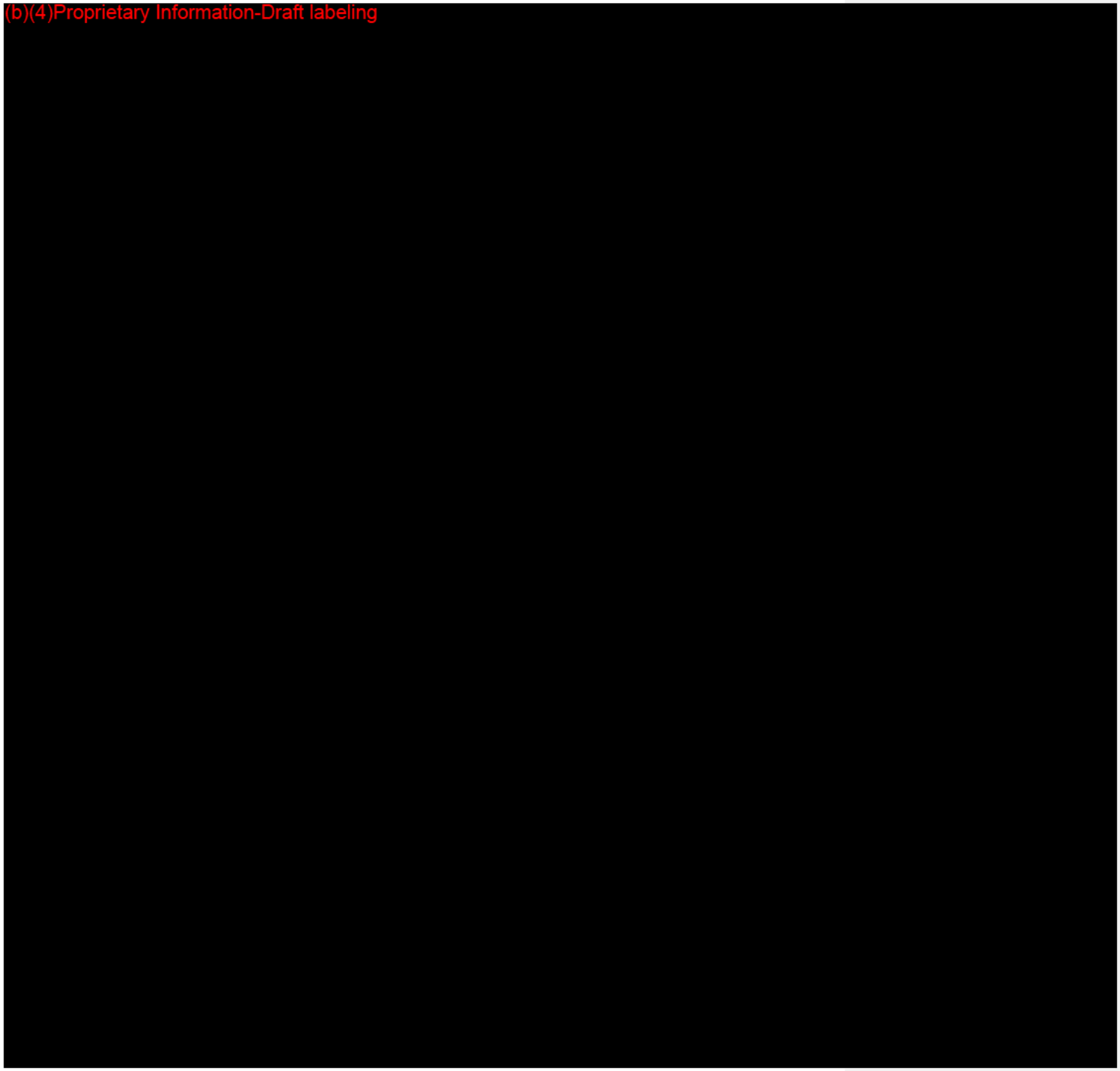
(b)(4)Proprietary Information-Draft labeling



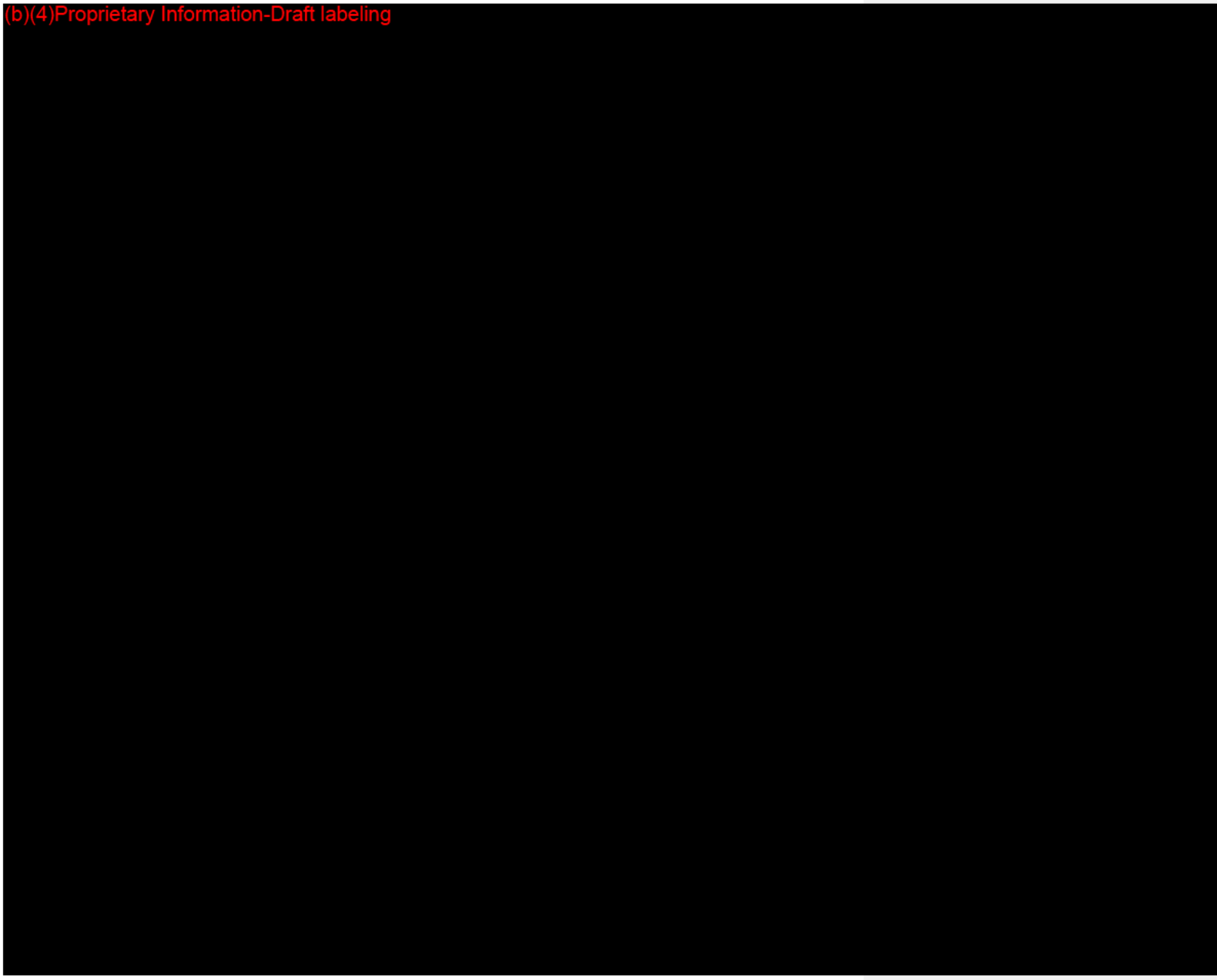
(b)(4)Proprietary Information-Draft labeling



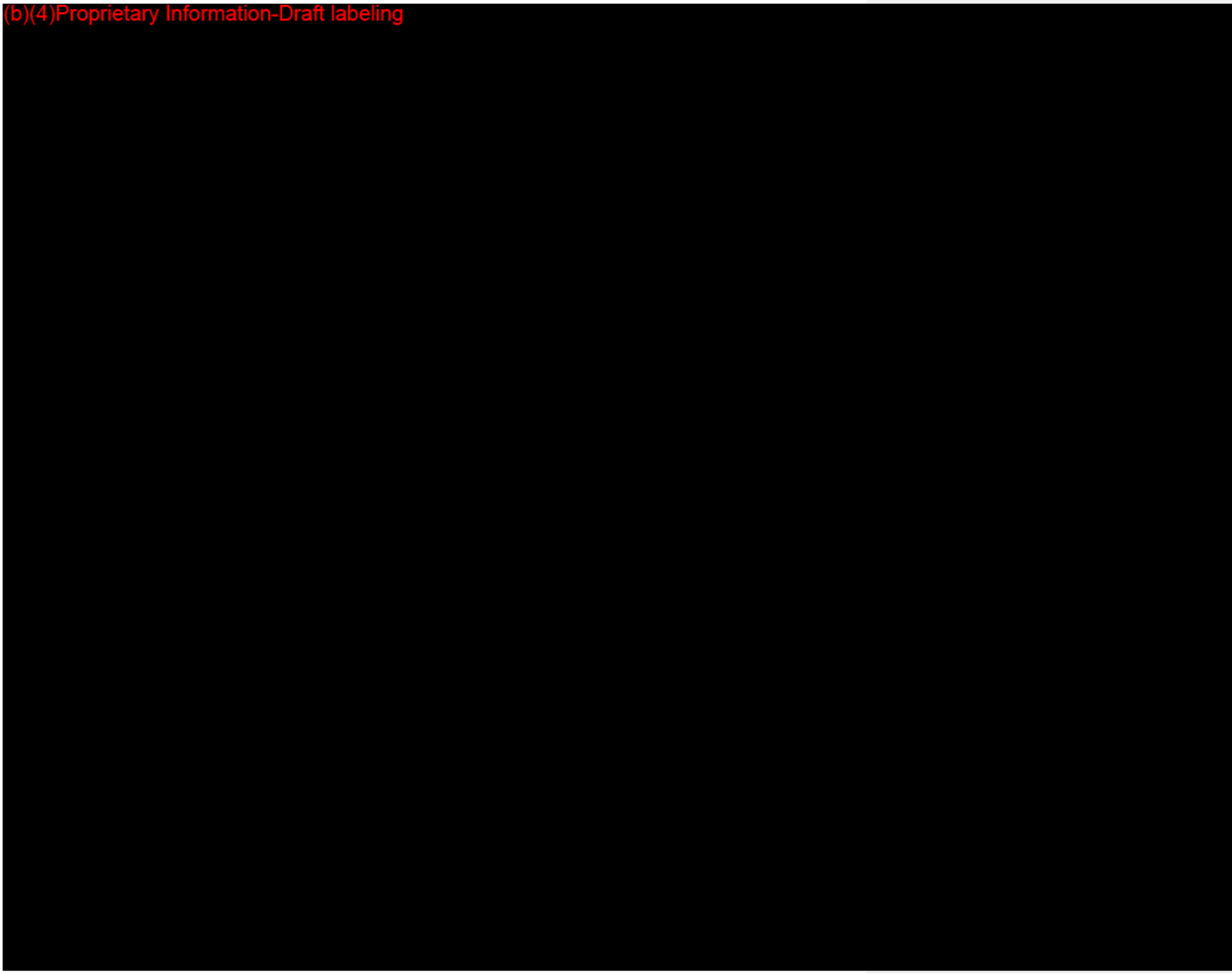
(b)(4)Proprietary Information-Draft labeling



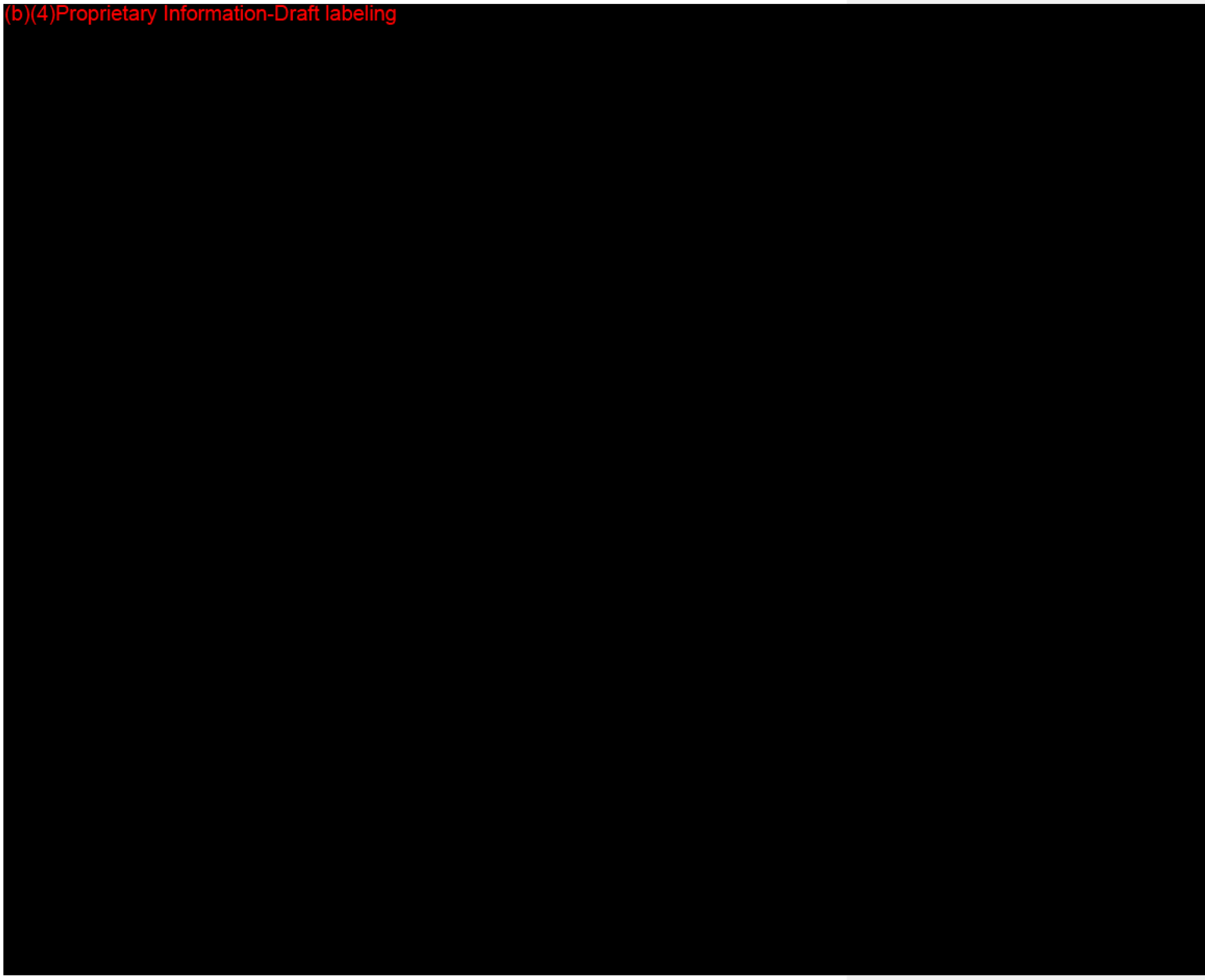
(b)(4)Proprietary Information-Draft labeling



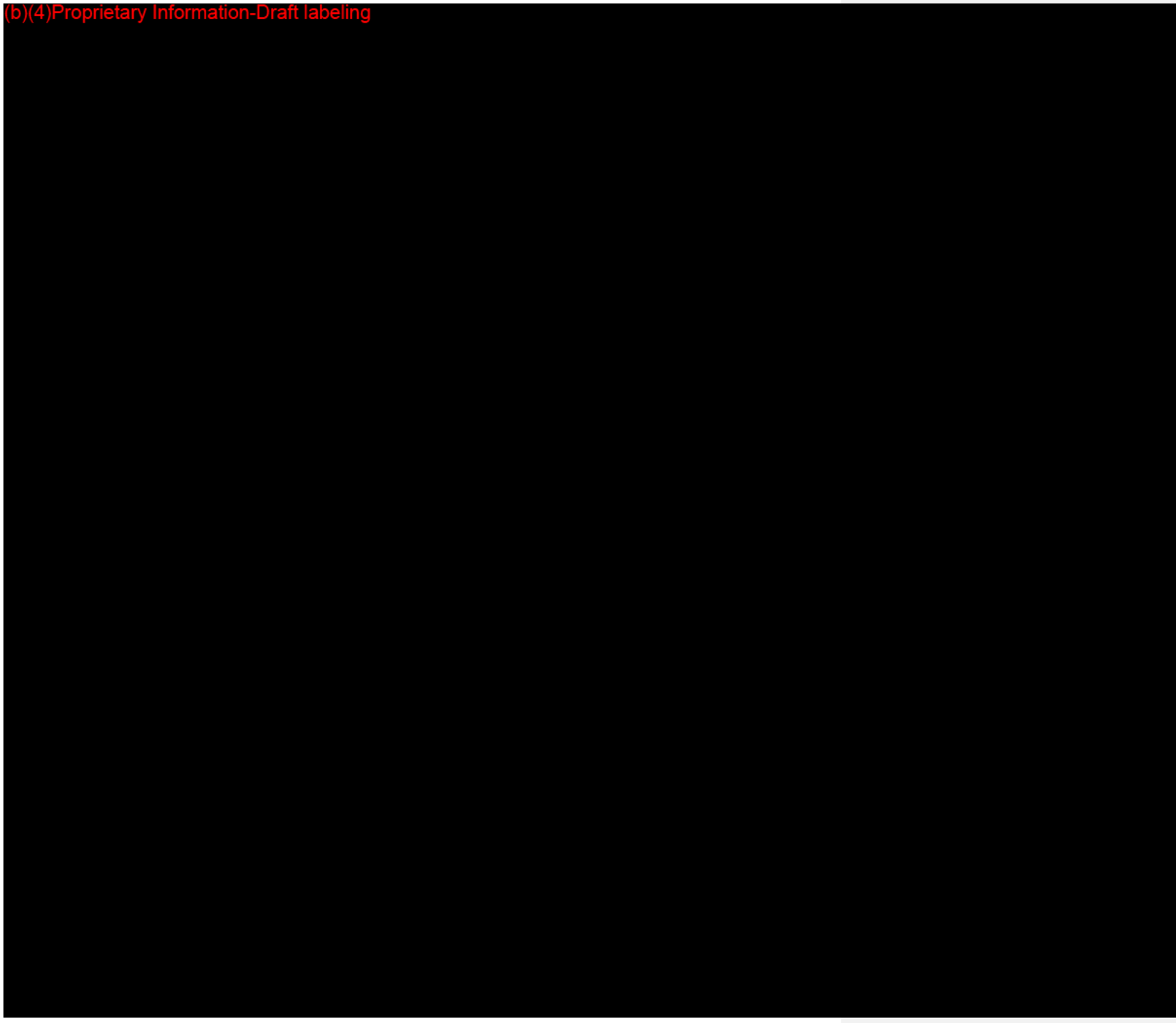
(b)(4)Proprietary Information-Draft labeling



(b)(4)Proprietary Information-Draft labeling



(b)(4)Proprietary Information-Draft labeling



ATTACHMENT B

Clean IFU

Boston Scientific

Axios™

Stent and Electrocautery-Enhanced Delivery System

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

TABLE OF CONTENTS

Axios™

Stent and Electrocautery-Enhanced Delivery System

Rx ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

WARNING

Contents supplied STERILE usingan ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative. For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient. After use, dispose of product and packaging in accordance with hospital, administrative and/ or local government policy.

DEVICE DESCRIPTION

The Axios™ Stent and Electrocautery-Enhanced Delivery System is an endoscopic device designed to enable the ultrasound trained interventional endoscopist to deliver a transenteric stent between the gastrointestinal tract and a pancreatic pseudocyst.

The AXIOS™ Stent is a flexible, fully-covered self-expanding nitinol stent that is preloaded within the Electrocautery-Enhanced Delivery System.

The Axios™ Electrocautery-Enhanced Delivery System is an electrocautery-enhanced delivery system that is compatible with therapeutic echoendoscopes having a working channel of 3.7 mm diameter or larger.

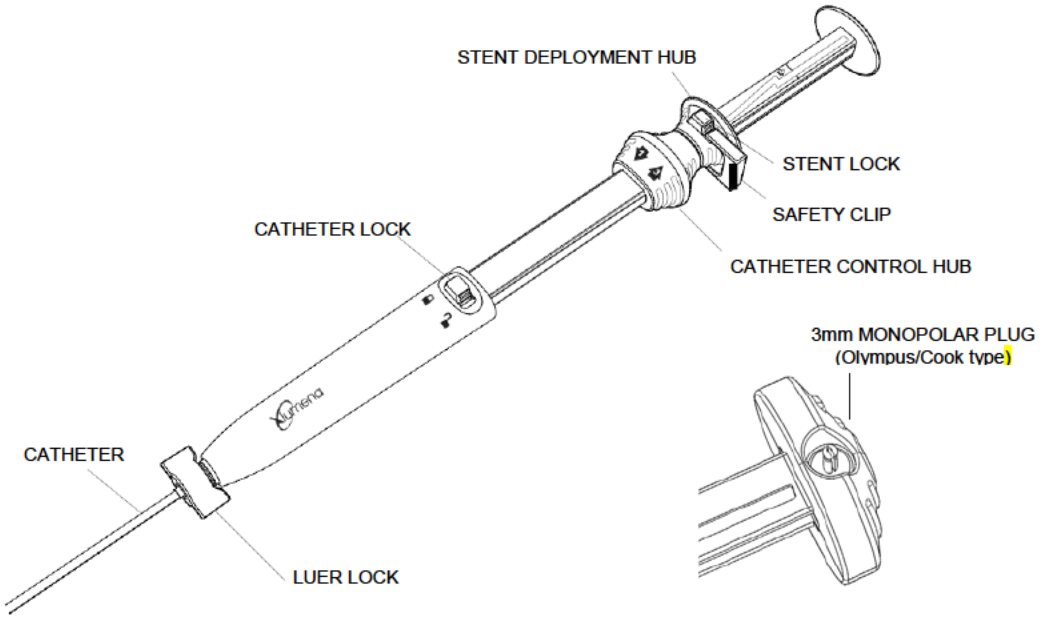


FIGURE 1. Axios™ Electrocautery- Enhanced Delivery System handle. The catheter control hub advances and retracts the catheter. The stent deployment hub releases the stent from the catheter. Monopolar plug for connection to electrosurgical generator.

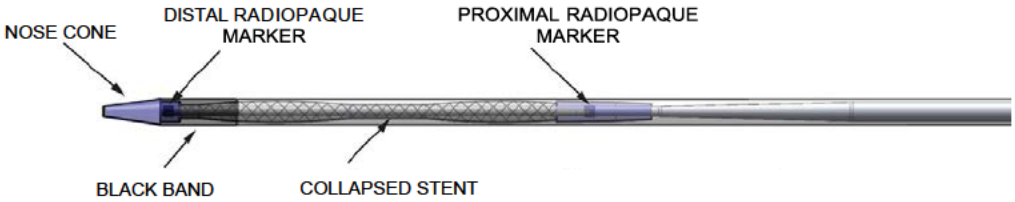


FIGURE 2. The collapsed stent is contained within the distal end of the catheter. A black band at the end of the catheter is used to position the stent second flange for deployment under direct visualization. Two radiopaque bands indicate the proximal and distal edges of the stent.

RECOMMENDED STENT SELECTION METHOD

Pseudocyst. Select the stent LUMEN diameter based on pseudocyst contents via endoscopic ultrasound (EUS) imaging. For example, select 15 mm in the presence of necrotic material and select 10 mm (or 15 mm) for 100% fluid contents.

The 10mm stent length can accommodate combined GI tract and pseudocyst wall thickness up to 10mm as assessed by EUS during the procedure..

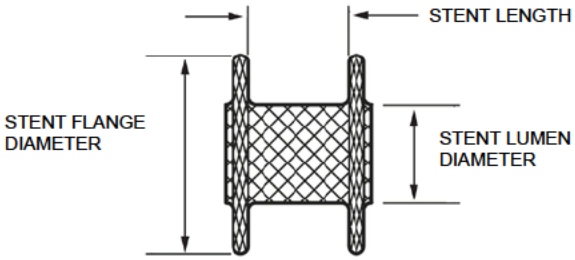


FIGURE 3. The stent is made of Nitinol wire and fully covered with silicone.

Description	Stent Size (nominal)			Delivery System Outer Diam.
	Flange Diameter	Lumen Diameter	Stent Length	
AXIOS Electrocautery-Enhanced Delivery System with 10x10 Stent	21 mm	10 mm	10 mm	10.8 Fr
AXIOS Electrocautery-Enhanced Delivery System with 15x10 Stent	24 mm	15 mm	10 mm	10.8 Fr

PACKAGE CONTENTS
One (1) Axios™ Stent and Electrocautery-Enhanced Delivery System

TRANSPORTATION CONDITIONS

Temperature	-29 to 60°C
Humidity	10 to 90%RH
Air pressure	70-106kPa

STORAGE & OPERATING CONDITIONS

Temperature	10 to 30°C
Humidity	10 to 75%RH
Air pressure	70 to 106kPa
General Environment:	Endoscopy Lab or Operating Suite within Hospital Buildings

INDICATIONS FOR USE
The Axios™ Stent and Electrocautery-Enhanced Delivery System is indicated for use to facilitate transgastric or transduodenal endoscopic drainage of symptomatic pancreatic pseudocysts ≥ 6cm in size, with ≥ 70% fluid content that are adherent to the gastric or bowel wall. Once placed, the AXIOS™ Stent functions as an access port allowing passage of standard and therapeutic endoscopes to facilitate debridement, irrigation and cystoscopy. The stent is intended for implantation up to 60 days and should be removed upon confirmation of pseudocyst resolution.

CONTRAINDICATIONS
This device is contraindicated for use in any and all cardiovascular applications.

Additional contraindica ions include:

- Cystic neoplasms.
- Pseudoaneurysms.
- Duplication cysts.
- Non-inflammatory fluid collections.
- Patients with abnormal coagulation or who require ongoing complete anticoagulation at the time of implantation and post stent placement have an increased possibility of bleeding
- Patients with altered anatomy that precludes the physician's ability to deliver he stent.
- Patients with intervening gastric varices or vessels within a one centimeter radius of the device insertion location.
- Patients that have allergies or are sensitive to any of the device materials.
- Patients with contraindications to use of electrical devices.

POTENTIAL COMPLICATIONS
Potential complications associated with the use of the Axios™ Stent and Electrocautery- Enhanced Delivery System may include those often associated with any endoscopic procedure. These complications include:

1. Anesthesia complications.
2. Improper AXIOS™ Stent placement; incomplete deployment; stent migration into the pseudocyst or, GI tract; separation of coating material from stent; stent fracture; coating material wear; coating material failure; puncture of coating material.
3. Tissue ingrowth or overgrowth leading to difficulty or a failure to remove stent.
4. Stent dislodgement.
5. Adverse reaction to implant materials and/or delivery system (e.g., abdominal or back pain, nausea, infection, fever, chronic inflammation or foreign body reaction).
6. Minor or excessive bleeding requiring interven ion.
7. Leakage of pseudocyst or bowel contents causing inflammation or peritonitis.
8. Stent occlusion.
9. Local infection at the implant site.
10. Tissue damage during stent implantation and/or removal.

11. Ulceration or erosion of mucosal or organ wall linings.
12. Pneumoperitoneum.
13. Sepsis (bacterial, endotoxin or fungal).
14. Perforation.
15. Surgical intervention (endoscopy, transfusion or surgery).
16. Persistent connection to the pseudocyst after removal (fistula).
17. Unintended electrical shock, muscle stimulation or burns.
18. Cardiac arrhythmia or arrest.
19. Death.

WARNINGS AND PRECAUTIONS

1. Placement of the AXIOS™ Stent should be performed by physicians familiar with endoscopic ultrasonography and who have received training for AXIOS™ Stent placement techniques.
2.
3. Before use, examine the outer surface of devices which are intended to be inserted into a patient or used during procedure. Do not use a device that has unintended rough surfaces, sharp edges or protrusions which may cause harm. Cut, burned or damaged device insulation may cause unsafe currents in either patient or operator.
4. Do not use this device in any echoendoscope with a working channel smaller than 3.7 mm.
5. Do not remove the stent from its delivery system prior to use.
6. This stent must only be placed using the delivery system provided.
7. No modification of this equipment is allowed.
8. Do not use this device for any purpose other than its stated intended use.
9. AXIOS™ Stent implantation should not exceed 60 days; performance beyond 60 days has not been established.
10. Long-term patency of the AXIOS™ Stent has not been established. Periodic evaluation of the stent is advised.
11. Do not use in patients who have electronic implants such as cardiac pacemakers without first consul ing a qualified professional (e.g., cardiologist). A possible hazard exists because interference with the action of the electronic implant may occur, or the implant may be damaged.
12. INSPECT the Axios™ Electrocautery-enhanced Delivery System, endoscope, and the connector cable for damage prior to use and, especially, the insulation of endoscopic instruments. This may be done visually under magnification or with a high voltage insulation testing device. Insulation failures may result in burns or other injuries to the patient or operator.
13. Interference of high frequency medical electrical equipment may adversely influence operation of other electronic equipment.
14. Before use, compa ibility with electrosurgical generators, accessories and other endoscopic equipment should be checked according to any criteria for safe use. Using incompatible equipment or equipment not specified by this Instruc ion for Use can result in patient injury or equipment damage. (see Technical Specifications)
15. Select cables, patient return electrodes and other medical electrical equipment that are Type BF applied parts. Use of medical electrical equipment other than those specified may result in increased emissions or decreased immunity of the generator.
16. Use caution with endoscopic equipment, accessories, and other medical / non-medical electrical equipment to avoid risks caused by their use together.
17. Any electrosurgical accessory constitutes a potential electrical hazard to the patient and operator. Safe and effective electrosurgery is dependent not only on equipment design but, to a large extent, on factors under the control of the operator.
18. Avoid high frequency output settings where the maximum output voltage may exceed rated accessory voltage (Axios™ Electrocautery-enhanced Delivery System rated accessory voltage is 750Vp or 1500Vp-p).
19. Patient risks may result from gas embolism caused by over-insufflation of air, inert gas prior to high frequency surgery, or laser assist gas.
20. Do not use in the presence of flammable anesthetics or oxidizing gases (such as nitrous oxide (N_2O) and oxygen) or in close proximity to volatile solvents (such as ether or alcohol), as explosion may occur.
21. Do not place instruments near or in contact with flammable materials (such as gauze or surgical drapes). Instruments that are activated or hot from use may cause a fire.

22. When energized endoscopes are used with energized endotherapy devices, patient leakage currents may be additive. When applying current, ensure the active tip of the AXIOS™ Electrocautery-enhanced Delivery System is completely outside the endoscope. Contact between the active element (located on the nose cone) and the echoendoscope may cause grounding, which can result in patient injury, operator injury, or damage to the endoscope.
23. Aspirate fluid from the area before activating the instrument. Conductive fluids (e.g., blood or saline) in direct contact with or in close proximity to an active electrode may carry electrical current or heat away from target tissues, which may cause unintended burns to the patient.
24. Do not activate the instrument when not in contact with target tissue, as this may cause injuries due to capacitive coupling.
25. The surface of the ac ive electrode may remain hot enough to cause burns after the RF current is turned off.
26. Ensure proper placement of return electrode on patient and connection to generator. Failure to do so could result in harm to patient including burns.
27. Temporary loss of EUS imaging may occur due to electromagnetic interference of the activated catheter tip. Normal EUS operation will resume immediately after deactivation of the catheter tip.
28. Use pure cut generator settings with Axios™ Electrocautery-enhanced Delivery System. Do not use blended or coagulation generator modes. Blended or coagulation modes may result in failure to access, prolonged time to access, tissue tenting or resistance.
29. Do not attempt to advance or retract the delivery system against resistance until the cause of resistance has been determined.
30. Care is required during dilation, debridement, irrigation, and cystoscopy procedures through he stent, to prevent air/fluid leak and/or stent dislodgement.
31. Ensure correct generator installation. The generator must be installed and put into service according to the EMC information provided in the generator manufacturer's guidance and declaration for electromagnetic compatibility. Refer to the Technical Specifications Table to confirm that this device is compatible with the equipment being used.
32. Connect the Axios™ Stent and Electrocautery-enhanced Delivery System to the electrosurgical unit only when the unit is off. Failure to do so may result in an injury or electrical shock to the patient or opera ing room personnel.
33. Due to concerns about the carcinogenic and infectious potential of electrosurgical by-products (such as tissue smoke plume and aerosols), protective eyewear, filtration masks, and effec ive smoke evacuation equipment should be used during the procedure.
34. Prior to increasing he intensity, check he adherence of the return electrode and its connections. Apparent low output or failure of the device to function correctly at the normal operating settings may indicate faulty application of the return electrode or poor contact in its connections.
35. If the electrosurgical device is operated in a mode without the CQM or a CQM compatible monitoring return electrode is not used, loss of safe contact between the return electrode and the patient will not result in an alarm.
36. Device must be used in conjunction with a Type BF or CF generator, see compatible electrosurgical unit or generator information.

TECHNICAL SPECIFICATIONS

Use:	Sterile, Single-Patient Use
Electrode Dimensions (nominal):	Keyhole diameter: 0.042 inches (1.1 mm) (3.1 F) Total Cut Length: 0.115 inches (2.9 mm) (8.8 F)
Energy:	Monopolar
Maximum Rated Input:	1.5 kV peak-to-peak (750Vp)
Recommended Generator Settings:	Pure cut mode, 80-120 Watts (400-500Vp).
Compatible Electrosurgical Unit or Generator:	Select an electrosurgical unit or generator that is compliant to IEC 60601-1-2 and IEC 60601-2-2: **ERBE VIO 300D** **ERBE I** **ERBE VIO 300S** **ERBE V**

	Power off the generator when not in use.
Minimum Electrosurgical Generator Requirements:	➢ Power Output > 50 Watts ➢ Peak Voltage (Vp) > 300Vp ➢ Pure Cut Mode
Electromagnetic Compatibility:	Refer to the generator manual for the manufacturer's guidance and declaration to electromagnetic compatibility.
Connectors:	Monopolar endoscopic cable, Olympus/Cook-Type, 3mm female plug. Select cables specified by generator manufacturer.
Dispersive Pad:	Select pad or return electrode specified by generator manufacturer.
Guidewire Compatibility:	0.035 inches (0.9 mm), insulated
Echoendoscope Compatibility:	Working channel of 3.7 mm diameter or larger.

INSTRUCTIONS FOR USE

Device Inspection

WARNING Do not use if the sterile barrier (inner packaging) is open or damaged.

1. **Remove from packaging**. Carefully remove the AXIOS™ Stent with Electrocautery-Enhanced Delivery System from its packaging.

2. **Inspect device**. Inspect the device for damage or defects.

   WARNING Before use, examine the outer surface of devices which are intended to be inserted into a patient or used during procedure. Do not use a device that has unintended rough surfaces, sharp edges or protrusions which may cause harm. Cut, burned or damaged device insulation may cause unsafe currents in either patient or operator.

3. **Inspect tip.** Check that the distal end of the catheter is not separated from the nose cone (Figure 4). Do not use if the distal end of the catheter is separated from the nose cone. Return the product to Xlumena.

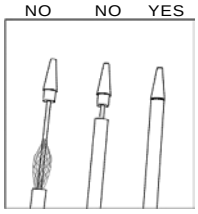


FIGURE 4. The two examples on the left ("NO") show separation of the nose cone from the catheter. The "YES" drawing illustrates the correct position of the nose cone as contiguous with the catheter.

Preparation

4. **Select electrosurgical generator**. The Axios™ Stent and Electrocautery-Enhanced Delivery System is an accessory device that is intended to be used in conjunction with an electrosurgical unit or generator that is compliant to EC 60601-1-2 and IEC 60601-2-2. See Technical Specifications Table for generator requirements and compatibility.

5. **Connect 3mm monopolar cable to generator**. Select Olympus / Cook type electrosurgical cable with a 3mm female monopolar plug on the end that will connect to the Axios™ Stent and Electrocautery-Enhanced Delivery System. Connect the cable to the generator, ensuring it fits securely. Do not yet attach cable to AXIOS™ catheter to avoid unintended delivery of energy.

   CAUTION: Electrosurgical cables with 4mm plugs are not compatible with the Axios™ Stent and Electrocautery-Enhanced Delivery System.

6. **Apply return electrode to patient**. Follow recommendations provided by the manufacturer of the electrosurgical generator for the proper preparation, placement and utilization of the patient return electrode. Ensure that a proper path from the patient return electrode to the electrosurgical unit is maintained throughout the procedure.

7. **Power on the generator and check settings.** Power on the generator and ensure the correct settings (see recommended settings in Technical Specification Table). ONLY pure cut settings should be used (80-120 Watts, 400-500Vp). Using the ERBE

electrosurgical generators, the "Autocut" setting corresponds to the pure cut setting. Do not use ERBE "Endocut" setting.

CAUTION: DO NOT USE blended or coagulation electrosurgical generator modes with the Axios™ Stent and Electrocautery-Enhanced Delivery System. Blended or coagulation modes may result in failure to access, prolonged time to access, tissue tenting or resistance.

8. **Identify site for AXIOS™ stent placement**. Using EUS, survey the stomach and duodenum for a good site for AXIOS™ stent placement. Select a site that is clear of intervening blood vessels, where the pseudocyst is close to the GI tract (within 10mm), and where the pseudocyst has a large enough diameter to accommodate insertion of the AXIOS™ delivery catheter (catheter should pass 3-4cm into the pseudocyst).

9. **Insert guidewire (optional).** If using over-the-wire technique (see Procedure instruction 1), ensure that a 0.035 inch (0.9 mm) insulated guidewire has been placed through the echoendoscope working channel and into the target structure.

10. **Lower elevator.** Ensure that the echoendoscope elevator is in the lowered (open) position (Figure 5).

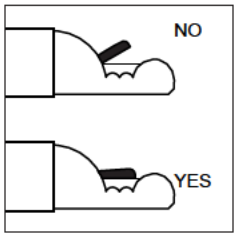


FIGURE5. Ensure the elevator is in the lowered (open) position. The up (closed) elevator position is incorrect and will inhibit catheter advancement.

Procedure

1. **Determine approach and position echoendoscopes**. There are two approaches you can use for Axios™ stent placement into the target structure: over-the-wire (Seldinger technique) or freestyle. In the over-the-wire technique, access is obtained to the pseudocyst using standard methods (e.g., using an FNA needle) and a guidewire is placed into the pseudocyst. The Axios™ delivery catheter is front loaded over the guidewire. In freestyle, the Axios™ electrocautery-enhanced catheter tip is aimed and passed direc ly hrough the GI and pseudocyst walls into the pseudocyst without a guidewire.

    a. Using your echoendoscope, select an access location that is free from intervening blood vessels, where the wall between the GI tract and pseudocyst is 10mm or less, and where the pseudocyst diameter is large enough to accommodate 3-4cm of AXIOS™ catheter insertion.

        i. If using over-the wire technique, pass your chosen access device into the collection such that .035" insulated guidewire can be placed into he collection, then remove access device. Continue to Procedure instruction 2.

        ii. If using freestyle technique, continue directly to Procedure instruction 2.

2. **Wet and insert the AXIOS™ catheter**. Wet the entire length of the Axios™ delivery catheter with sterile water or normal saline. Carefully insert the catheter into the working channel of the therapeutic echoendoscope and advance it until the handle Luer lock aligns and fits into the working channel fitting. If using the over-the wire technique, the AXIOS™ delivery catheter should be placed over the guidewire before inserting it into the working channel. Be careful not to bend or kink the catheter during insertion. Rotate the winged Luer lock clockwise to secure the delivery system handle to the echoendoscope (Figure 6).

NOTE: After fitting the AXIOS™ delivery catheter into the echoendoscope, the catheter tip will not be visible under endoscopic ultrasound (EUS) or endoscopic view. It will be visible only when the catheter is advanced as described in Procedure instruction 4.

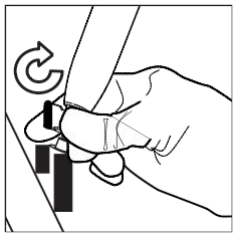


FIGURE 6. Align the handle with the echoendoscope and attach it by rotating the Luer lock fitting clockwise.

3. **Connect to generator.** Connect the AXIOS™ Electrocautery Enhanced Delivery System to the 3mm monopolar electrosurgical active cable so that the 3.0mm plug fits securely. Ensure the generator is at desired settings (Use pure cut mode, 80-120 Watts, 400-500Vp).

4. **Confirm position, unlock and visualize.** Using EUS imaging, re-confirm your posi ion for stent delivery. Unlock the catheter lock (Figure 7) and advance the (black) catheter control hub (Figure 8) until the distal catheter position is visible.

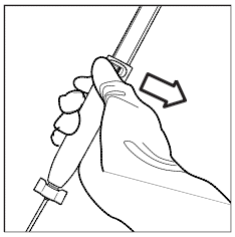


FIGURE 7. Push the catheter lock to the right to unlock the catheter and to the left to relock it.

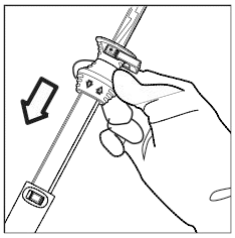


FIGURE 8. With the catheter unlocked, carefully advance the catheter control hub (in the direction indicated by the "1" arrow on the hub) so that the distal end of the catheter moves towards and into the target structure.

5. **If necessary adjust echoendoscope elevator.** Under EUS imaging, adjust the echoendoscope elevator to the desired angle. The angle of approach should be as perpendicular to the pseudocyst wall as possible.

6. **Energize and advance.** Advance the AXIOS™ delivery catheter tip using the catheter control hub to tent the tissue for visualization on EUS. Power-On the electrosurgical generator using the foot pedal and advance carefully into the target structure. After entry into the target structure, Power-Off the generator and disconnect the monopolar electrosurgical cable. Typically, the electrosurgery energy is applied from 1-3 seconds to gain access into the target structure.

7.

WARNING: Apply only enough energy to enter the target structure, prolonged energy delivery may cause unintended damage to issues or perforation.

CAUTION: Temporary EUS imaging artifact may occur due to electromagnetic interference of the activated catheter tip. Normal EUS operation will resume immediately after deactivation of the catheter tip.

8. **Confirm AXIOS™ delivery catheter tip within target structure, lock catheter.** Using EUS imaging, ensure that the tip of he AXIOS™ delivery catheter is positioned at least 3-4 cm within the inner margin of the target structure. Lock the catheter lock to ensure that the delivery catheter does not move during deployment of the stent first flange.

CAUTION: The stent cannot be resheathed after the stent first flange has been deployed.

9. **Deploy the stent first flange.** Press down on the yellow safety clip to remove it from the stent deployment hub. Under EUS imaging, deploy the stent first flange by unlocking the stent lock (Figure 9) and retracting the stent deployment hub to the halfway point indicated on the handle (Figure 10). A "click" will be heard as the stent deployment hub automatically locks into place (at the "2" arrow line). Verify with EUS imaging that the stent first flange is deployed inside the target structure (do not proceed to next step until verified).

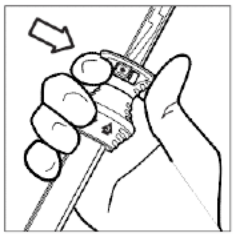


FIGURE 9. Push the stent lock to the right to unlock the stent deployment hub. The lock automatically relocks when the hub reaches he stent first flange deployment stop.

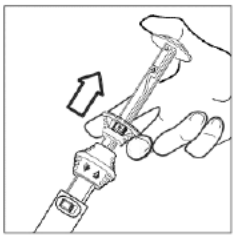


FIGURE 10. Holding the handle and stent deployment hub like a syringe, retract the hub to release the stent first flange. The hub will "click" and lock into place at the "2" arrow line.

10. **Deploy the stent second flange.** There are two approaches you can use for deploying the second flange: under endoscopic visualization or under EUS guidance.

    a. **Endoscopic visualization:**

        i. **Switch to endoscopic view.** Retract the echoendoscope until the delivery catheter shaft is visible passing through the gastric or duodenal wall.

            WARNING: Excessive retrac ion may pull the stent out of the target structure or result in poor positioning of the stent first flange.

        ii. **Visualize the black band.** Confirm at least 2-3mm of the black band is visible in the gastrointestinal tract (Figure 11). This indicates that the catheter is correctly positioned for deployment of the stent second flange. If 2-3mm is not visible, follow step 9aiii. Otherwise, proceed to 9aiv.

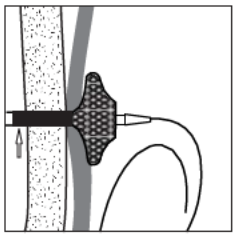


FIGURE 11. Under endoscopic view, confirm that at least 2-3 mm of he black band is visible in GI tract (see arrow). This indicates hat the stent first flange is correctly positioned against the lumen wall.

            WARNING: Confirm at least 2-3mm of the black band is visible. If insufficient shaft length is visible, the second flange may be deployed into he collection or peritoneal space

        iii. **If 2-3mm of the black band is not visible,** unlock he catheter lock and retract the catheter control hub (Figure 12) until 2-3mm is visible. Then re-lock the catheter lock to ensure the catheter does not move during deployment of the stent second flange.

            WARNING: Failure to re-lock the catheter lock will result in the incorrect deployment of the second flange inside the collection.

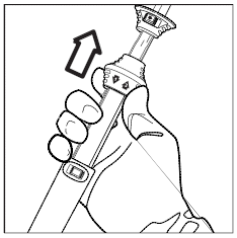


FIGURE 12. If necessary, carefully retract the catheter control hub (as indicated by the "3" arrow on the hub). Under endoscopic view, position the catheter for deployment of the second flange by confirming at least 2-3 mm of the black band is visible in the GI tract.

iv. Deploy the stent second flange. Unlock the stent lock and retract the stent deployment hub to the top of the handle in the direction indicated by the "4" arrow (Figure 13).

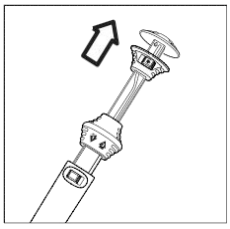


FIGURE 13. Under endoscopic view, deploy the stent second flange by retracting the stent deployment hub in the direction indicated by the "4" arrow on the handle.

v. Verify correct deployment. Under direct endoscopic visualization, verify that the stent second flange is deployed within the gastrointestinal tract.

b. <u>EUS guidance</u>.

i. **Position the catheter for second flange delivery.** With he first flange in EUS view, unlock the catheter lock and retract the catheter control hub so hat the first flange approaches he inner wall of the target structure. Retract the first flange gently against he inner wall of the structure until it changes shape from a flat or disk-like shape (no load) to an oval shape (small load).

WARNING: Do not retract the first flange forcefully against the inner wall. Excessive retraction may pull the stent out of the target structure or result in poor positioning of the stent first flange.

ii. **Re-lock catheter.** Maintaining the first flange against the inner wall with an oval shape, re-lock the catheter lock.

WARNING: Failure to re-lock the catheter lock will result in he incorrect deployment of second flange inside the collec ion.

iv. **Deploy the stent second flange.** Unlock the stent lock and retract the stent deployment hub to the top of the handle in the direction indicated by the "4" arrow (Figure 14). The second flange of the stent is now released but may remain in the working channel. If the second flange remains in the working channel of the echoendoscope, while ensuring that the first flange remains correctly in position, advance the catheter control hub while retracting the scope in a 1-to-1 fashion until he second flange releases from the scope and is visualized on endoscopy or EUS.

WARNING: If you do not advance the catheter control hub and retract the scope in a 1-to-1 fashion, there is a risk that the stent may deploy into the collection or the first flange may be pulled into the GI tract.

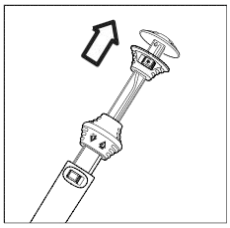


FIGURE 14. Under EUS view, deploy the stent second flange by retracting the stent deployment hub.

Delivery System Removal from Echoendoscope
Following deployment of the AXIOS Stent, rotate the Luer lock at the base of the handle counterclockwise. Remove the delivery catheter by pulling it upward and out of the working channel. If desired, maintain the insulated guidewire position across the target structure as the catheter is removed.

Dispose of the delivery system in accordance with institutional guidelines for biohazardous medical waste.

AXIOS™ Stent Dilation
If desired, place a balloon catheter over the insulated guidewire and into the central lumen of the stent. Dilate the stent up to the nominal diameter. Post-dilation allows the AXIOS stent flanges to fully expand, which secures the stent in place and optimizes transenteric drainage.

Additional Procedures
The AXIOS™ stent bi-flange design and large diameter provides a secure conduit for additional diagnostic and therapeutic interventions. Once placed, the AXIOS™ stent functions as a port allowing passage of standard and therapeutic endoscopes to facilitate debridement, irrigations and cystoscopy.

> **WARNING:** Care is required during dilation, debridement, irrigation, and cystoscopy procedures through the stent, to prevent air/fluid leak and/or stent dislodgement.

Stent Removal
Under endoscopic visualization, place a standard endoscopic snare over the stent flange. Tighten the snare until the stent lumen collapses. Pull the snare away from the gastrointestinal wall until the stent is removed from the tract. Remove the endoscope to extract the stent.

NOTE: The snare must be large enough to fit over the flange of the AXIOS stent (which can be up to 24 mm in diameter, see Stent Size table at beginning of document).

Stent removal may also be performed with endoscopic forceps. The stent is braided in such a way that it will not unravel if a wire is broken.

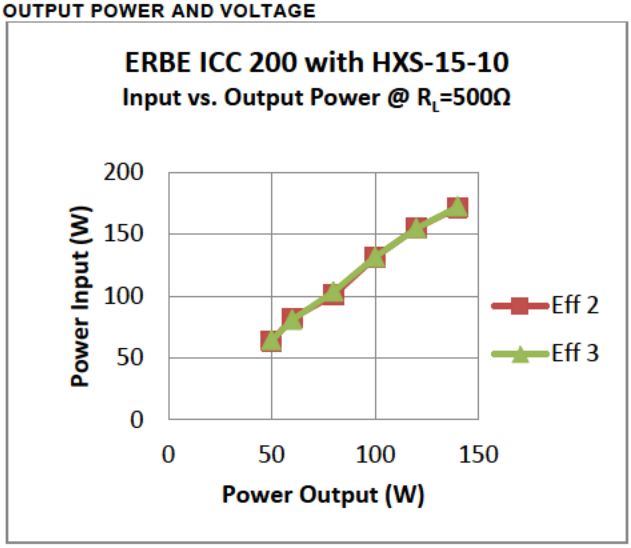
Once removed, the stent must be disposed of according to institutional guidelines for biohazardous medical waste.

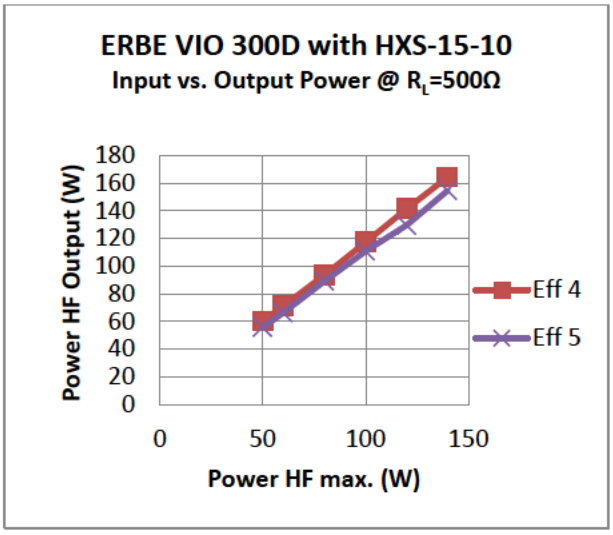
TROUBLESHOOTING
Some echoendoscope and elevator positions result in excess friction between the catheter and the working channel. Friction can produce length-wise compression (shortening) of the catheter as it is advanced through the working channel and conversely, extension (lengthening) when the catheter is retracted. Friction impacts the performance of the AXIOS Electrocautery Enhanced Delivery System; therefore the solutions below include both lowering (opening) the elevator and straightening the echoendoscope.

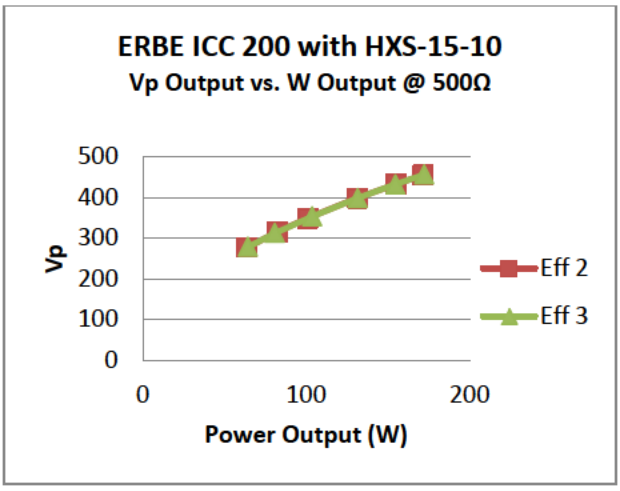
PROBLEM	POTENTIAL SOLUTION(S)
There is excessive resistance when trying to pass the catheter through the working channel.	• If the catheter is less than 2 cm from full insertion, lower (open) the echoendoscope elevator and straighten he distal end of the echoendoscope. • If the catheter is less than 10 cm from full insertion, straighten the echoendoscope. • If the catheter is more than 10 cm from full insertion, remove it from the echoendoscope. Pass another tool to see if the working channel is obstructed.
The catheter cannot be advanced from its post-insertion position.	• Make sure he catheter is unlocked. • Ensure the echoendoscope elevator is lowered (open). • Straighten the echoendoscope position. • Remove the catheter from the working channel and confirm hat it is not kinked or damaged and that the nose cone is contiguous with the catheter. • Wet he entire working length of the catheter and reinsert it into the working channel.
The catheter can be advanced but it does not enter the target structure.	• Under EUS imaging, ensure that the insulated guidewire is visible. Confirm that the nose cone and catheter are coaxially aligned with the insulated guidewire at the target structure. • Adjust/realign the echoendoscope position. • Ensure proper electrical connection between the electrosurgical generator and he Axios™ Electrocautery Enhanced Delivery System. • Ensure that the patient is properly grounded in accordance with manufacturers recommenda ions for the return electrode. • Check generator to ensure appropriate settings.
Resistance makes it difficult to retract the stent deployment hub.	• Ensure the echoendoscope elevator is lowered (open). • Straighten the echoendoscope as much as possible. • Exchange the device for a new one.
The stent first flange is not deployed even though the stent deployment hub has clicked into position (at the "2" arrow line).	• Ensure the echoendoscope elevator is lowered (open). • Straighten the echoendoscope position. • Unlock the catheter lock, raise the elevator, advance he catheter control hub, and confirm the stent first flange deployment. Retract and advance the catheter control hub as necessary. Relock the catheter lock. • To limit deployment hub travel, grasp the handle at 5-10 mm above the "2" arrow line. Unlock the stent lock and carefully retract the stent deployment hub while closely monitoring the EUS image. Stop retrac ing the hub immediately when the stent first flange has deployed. DO NOT RETRACT MORE THAN 1 CM. **WARNING:** Retracting the deployment hub too far may result in the en ire stent deploying inside the target structure.

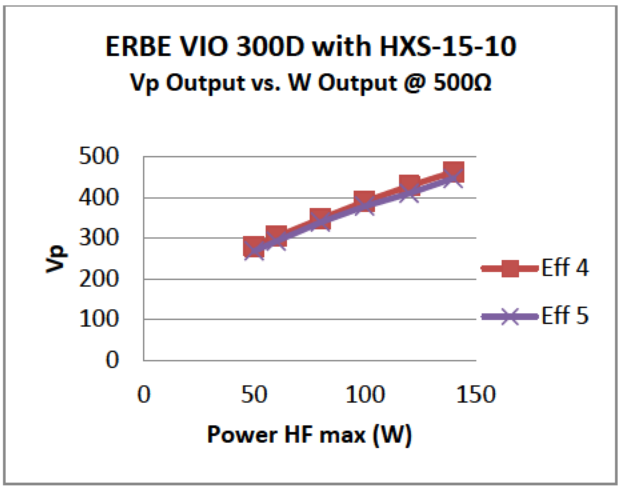
PROBLEM	POTENTIAL SOLUTION(S)
The catheter cannot be seen (or is seen with difficulty) on the endoscopic view when attempting to deploy the stent second flange.	Under EUS imaging, retract the catheter control hub so that the stent first flange is seen tugging against the inner target wall. Deploy the stent second flange in accordance with Instructions for Use.
The stent second flange does not deploy even though the stent deployment hub has been retracted to the top of the handle.	Unlock the catheter lock and slowly advance the catheter control hub to push the stent second flange out of the echoendoscope working channel.
There is excessive resistance and the catheter lock has not been released when trying to pass the catheter through the working channel. **After the catheter is advanced into endoscopic view, there is an observed separation between the tip (nose cone) and the outer sheath. The stent may or may not be partially visible.**	• Unlock the catheter lock and advance the catheter 2-3 cm beyond the echoendoscope elevator. Lock the catheter lock. • Lock the echoendoscope elevator in the up (closed) position to hold the outer catheter sheath. • Withdraw the catheter by unlocking the catheter lock and pulling the handle until either: - the sheath and tip are in contact and the tip is resheathed, or - the sheath or tip is near the echoendoscope elevator. • Ensure the echoendoscope elevator is lowered (open) and advance the catheter. • If the catheter tip can be reset to Figure 4 “yes” position without dislodging the stent then, continue with the procedure as normal. • If resheathing procedure is unsuccessful, withdraw the device and return it to Xlumena.
After positioning the first flange, the catheter has moved retrograde into the echoendoscope working channel and the second flange is deployed in the working channel.	To complete the second flange deployment, keep the EUS image of the first flange in view and apply gentle traction to the echoendoscope. • Maintain the first flange image on EUS to guide the echoendoscope retraction. Do not retract such that the first flange changes shape beyond an ‘American football’ shape. • With this mild traction in place, open catheter lock and slowly move the catheter out of the echoendoscope to expel the second flange from the echoendoscope working channel.
The catheter is unable to be removed from the echoendoscope after the stent has been deployed.	• Method 1 – Position the echoendoscope tip in the full down and gently tug on the catheter to remove it from the scope. If this does not work proceed to method 2. • Method 2 – While maintaining slight tension on the catheter, move the elevator lever to the fully closed position, then open the elevator while tugging gently on the catheter. The movement of the elevator will allow the back shoulder of the ceramic nose cone to slip into the channel and be removed. • Method 3 - Move the stent deployment hub back to its original position by moving the gray stent deployment hub downward to the number 2 marker on the handle. Then, either break off the plastic leg just below the #2 line, or push the leg in while moving the deployment hub below the #2 line toward its original position. The tip of the delivery catheter should be visible on the endo view, confirm that the nose cone and the catheter are flush. If not, pull the elevator lever downward and pull the catheter back. This maneuver should snug up the two components and allow the easy removal of the AXIOS™ delivery catheter.

OUTPUT POWER AND VOLTAGE









WARRANTY

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose**. Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments**.

MRI SAFETY INFORMATION

MR Conditional

Non-clinical testing demonstrated that the AXIOS Stent is MR Conditional. A patient with this device can be scanned safely in an MR system immediately after placement under the following conditions:

- Static magnetic field of 1.5-Tesla and 3-Tesla, only
- Maximum spatial gradient magnetic field of 4,000-Gauss/cm (extrapolated) or less

MRI-Related Heating
Under the scan conditions defined above, the AXIOS™ Stent is expected to produce a maximum temperature rise of 1.2°C after 15-minutes of continuous scanning (i.e., per pulse sequence).

Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode.

Artifact Information
The delivery system has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of delivery system in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

In non-clinical testing, the image artifact caused by the AXIOS Stent extends approximately 10-mm from the AXIOS Stent when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

DEFINITIONS OF SYMBOLS

	CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician		
	Consult Instructions for Use		MR Conditional
	Lot Number		Catalogue/Model number
	Use By Date		Keep Dry
	Do Not Use if Package is Damaged		Humidity Limitation
	Do Not Re-use		Pressure Limitation
			Temperature Limitation
	Sterilized Using Ethylene Oxide		Legal Manufacturer
	Do Not Re-sterilize		

Xlumena, Inc., a Boston Scientific Company
453 Ravendale Drive, Suite H
Mountain View, CA 94043
United States of America
Phone: 1-888-958-6362

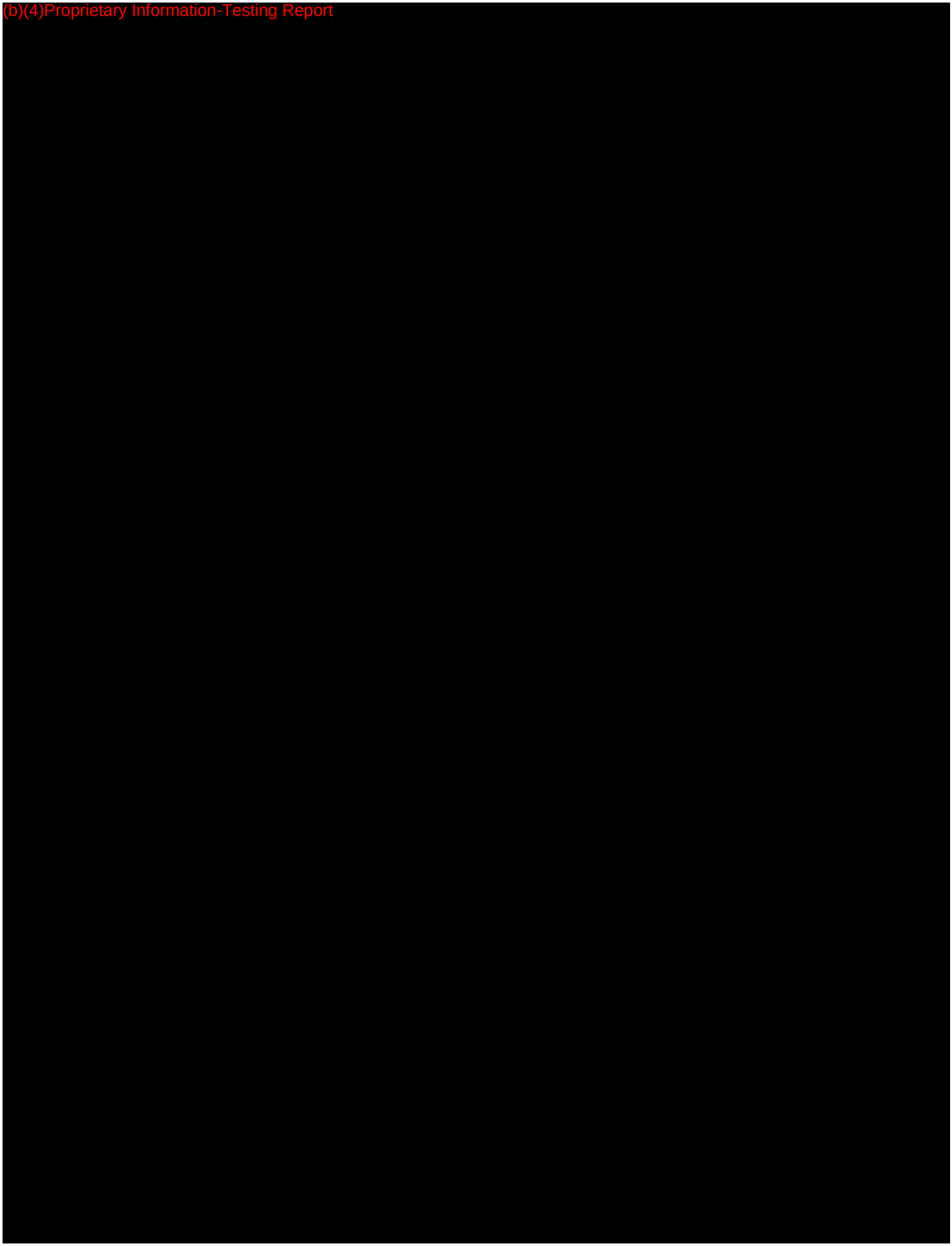
ATTACHMENT C

MRI Report Dated May 15, 2015

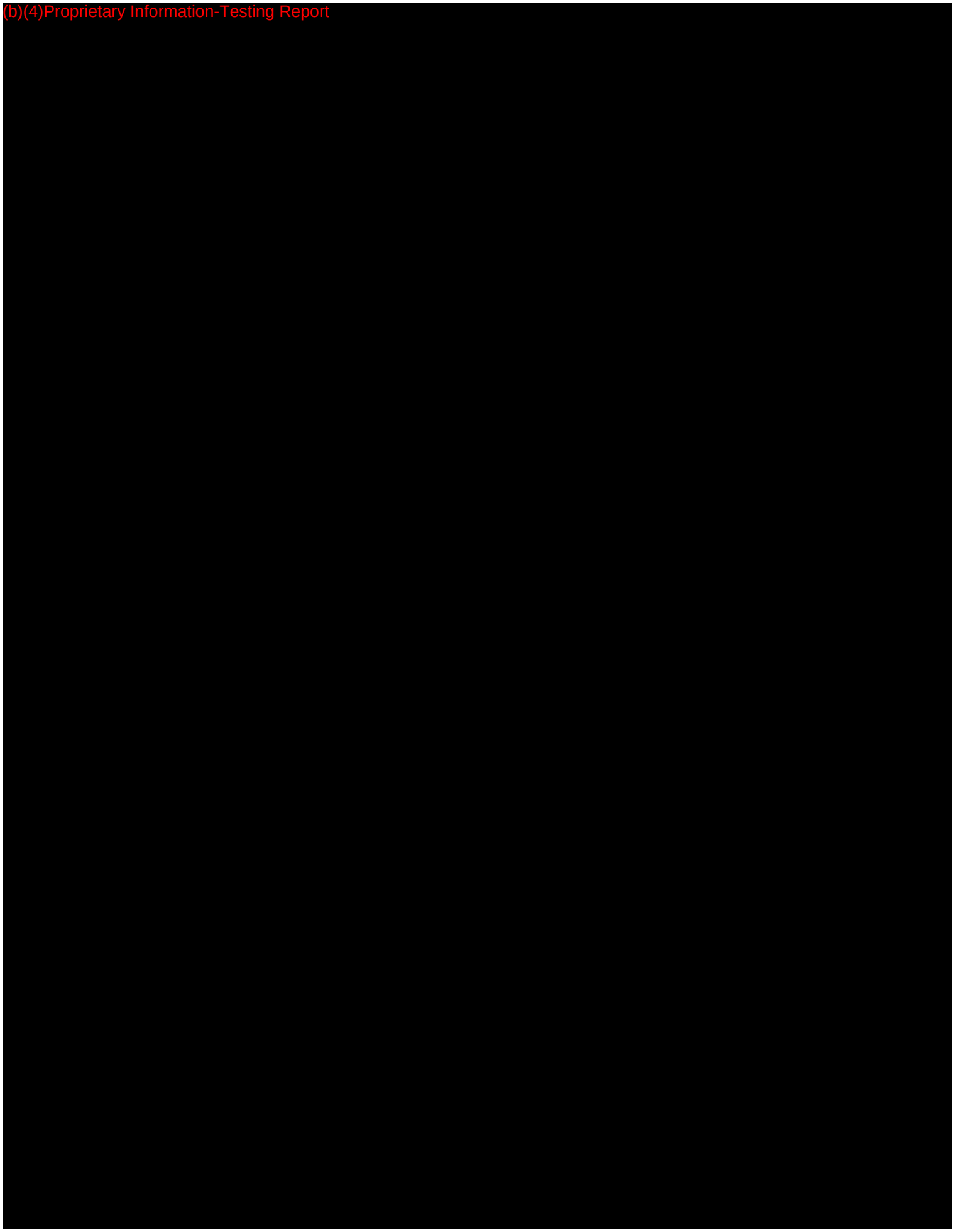
(b)(4)Proprietary Information-Testing Report

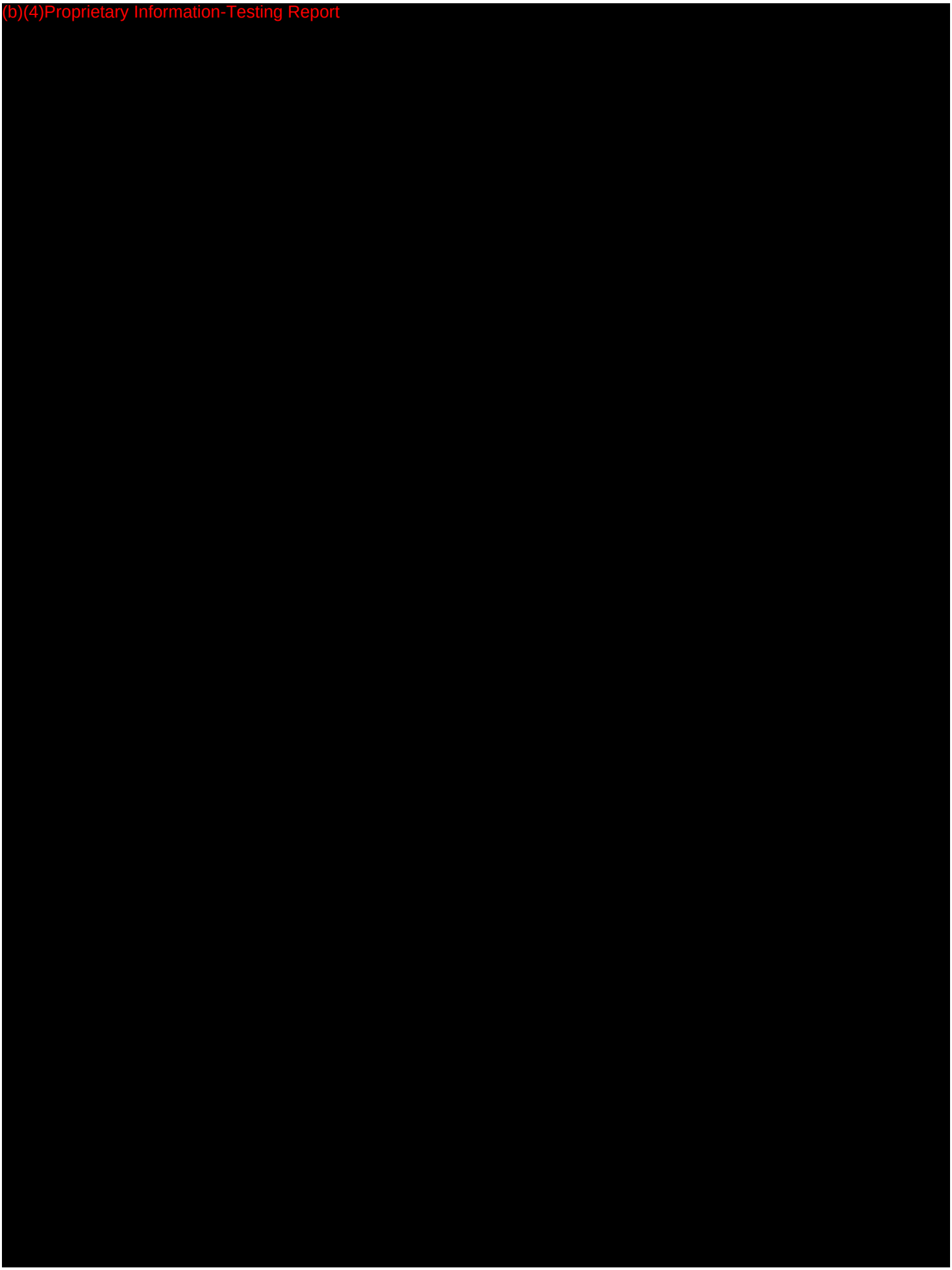
[redacted]

(b)(4)Proprietary Information-Testing Report



(b)(4)Proprietary Information-Testing Report

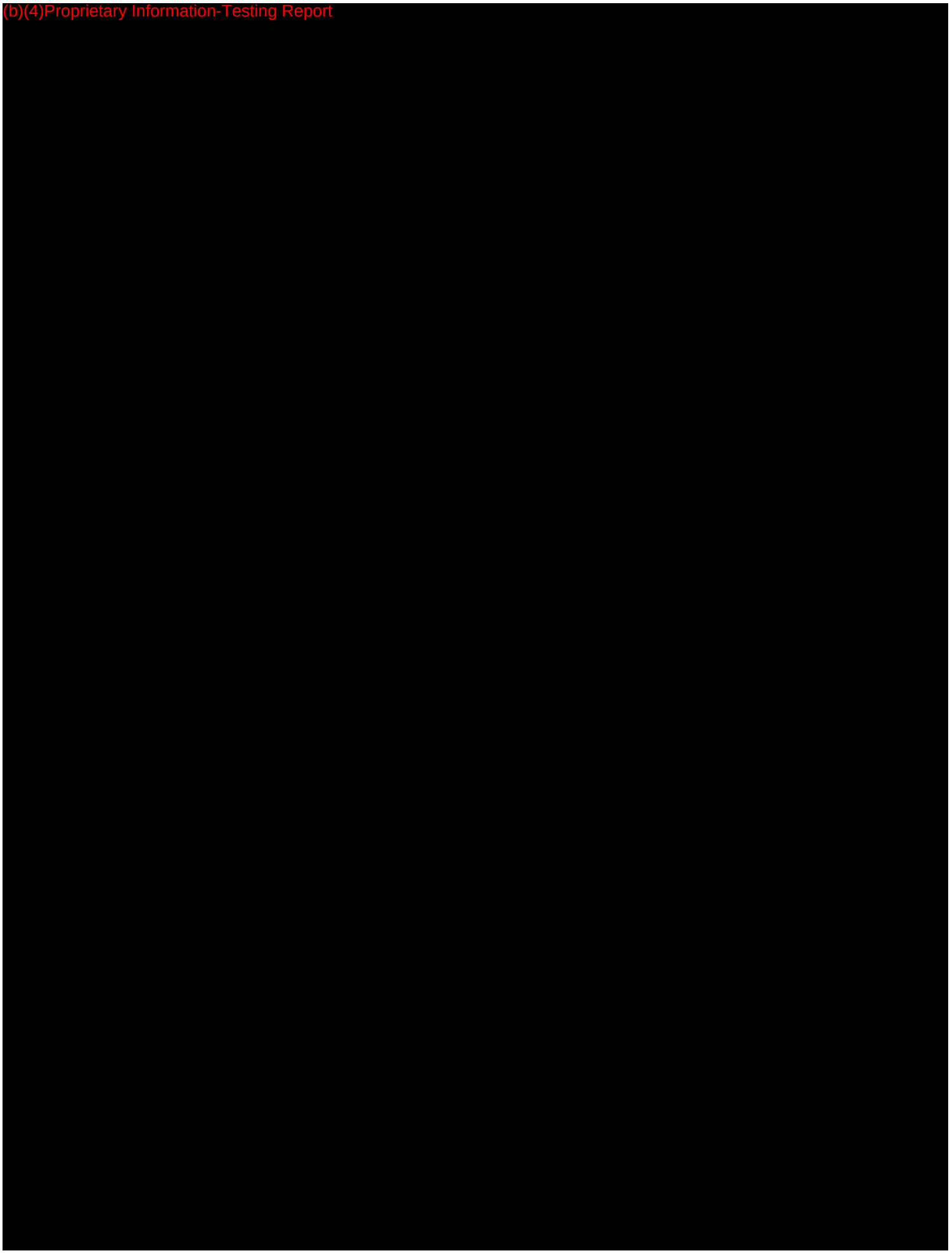


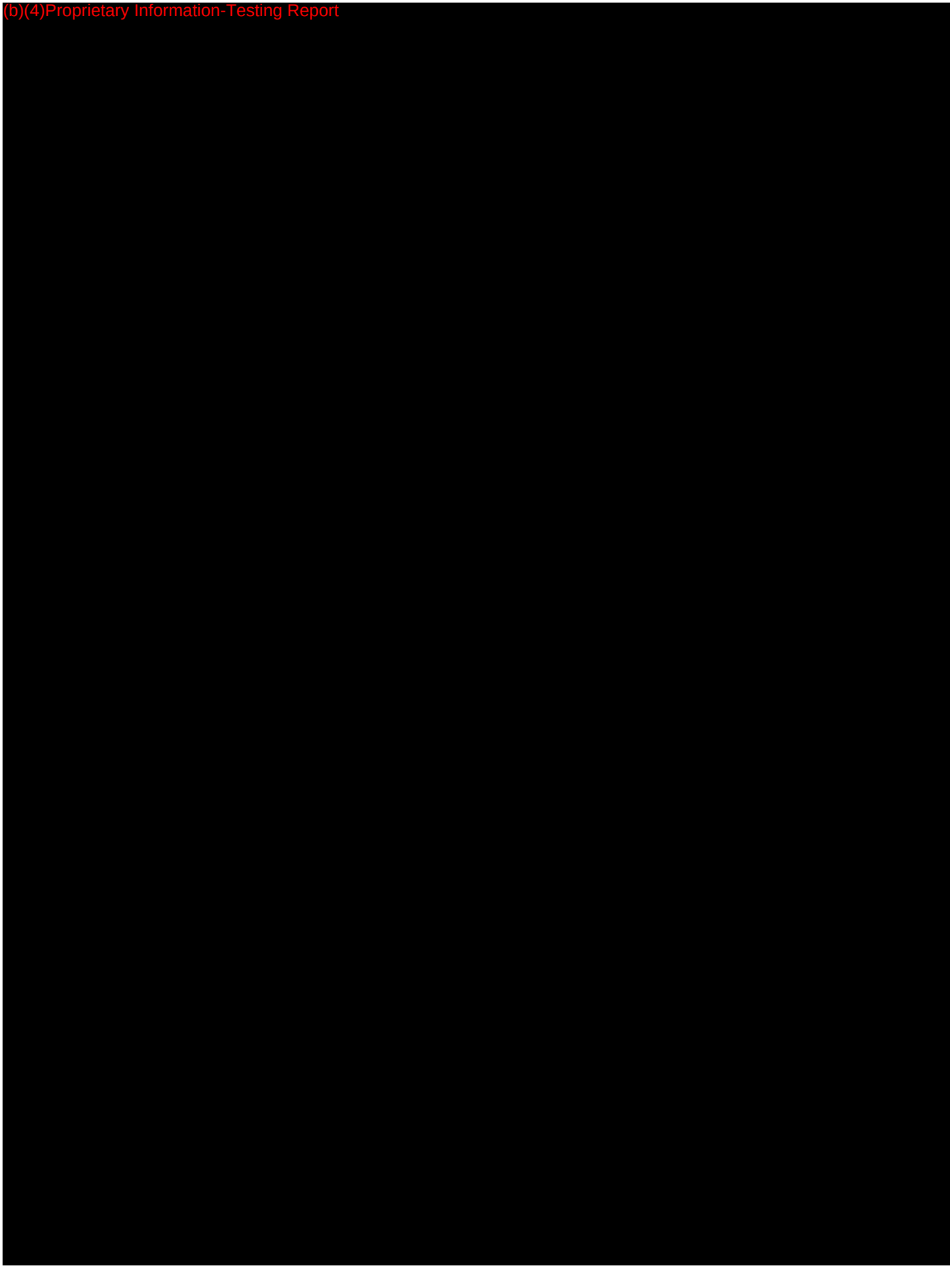


(b)(4)Proprietary Information-Testing Report

[redacted]

(b)(4)Proprietary Information-Testing Report





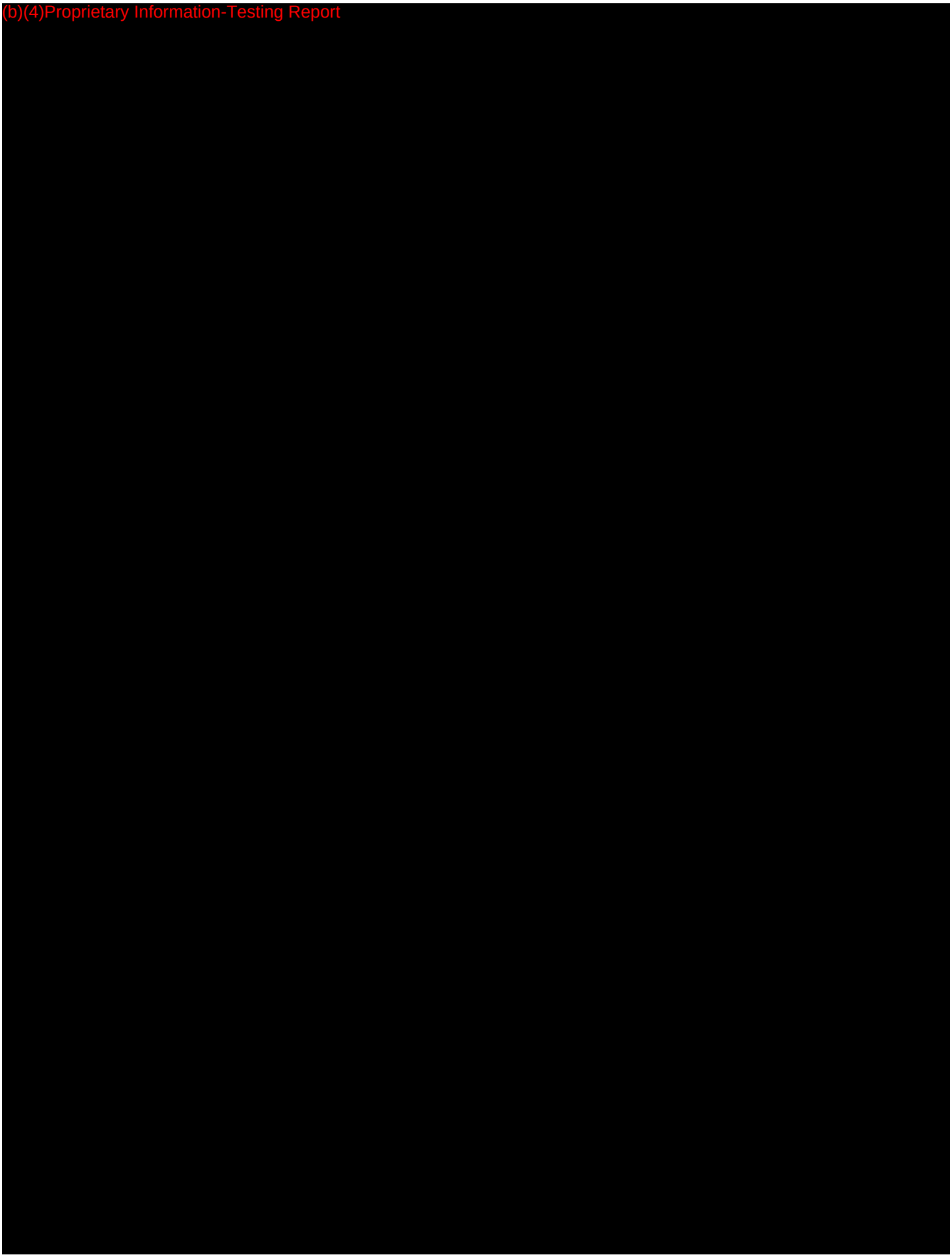
(b)(4)Proprietary Information-Testing Report

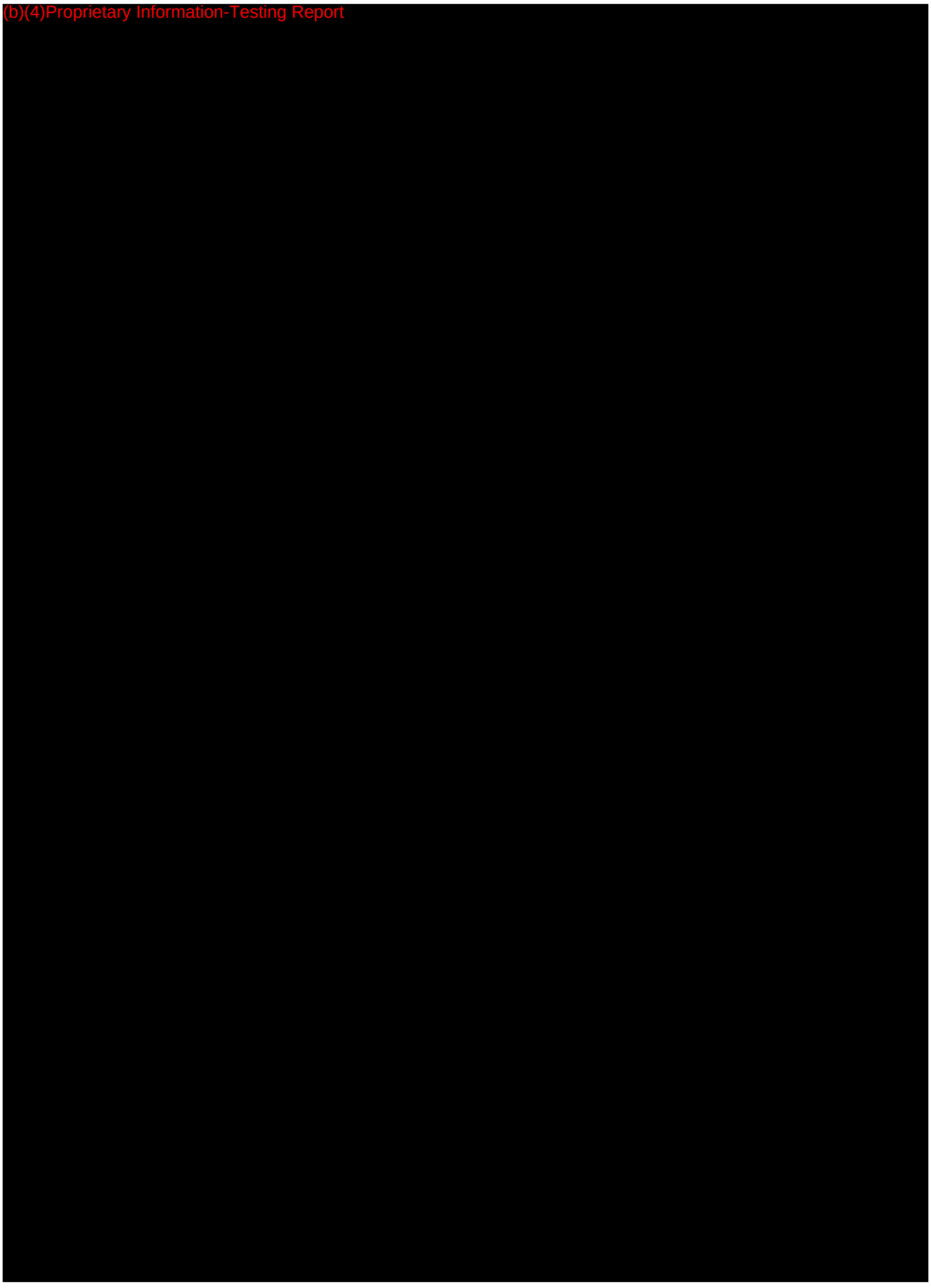
[redacted]

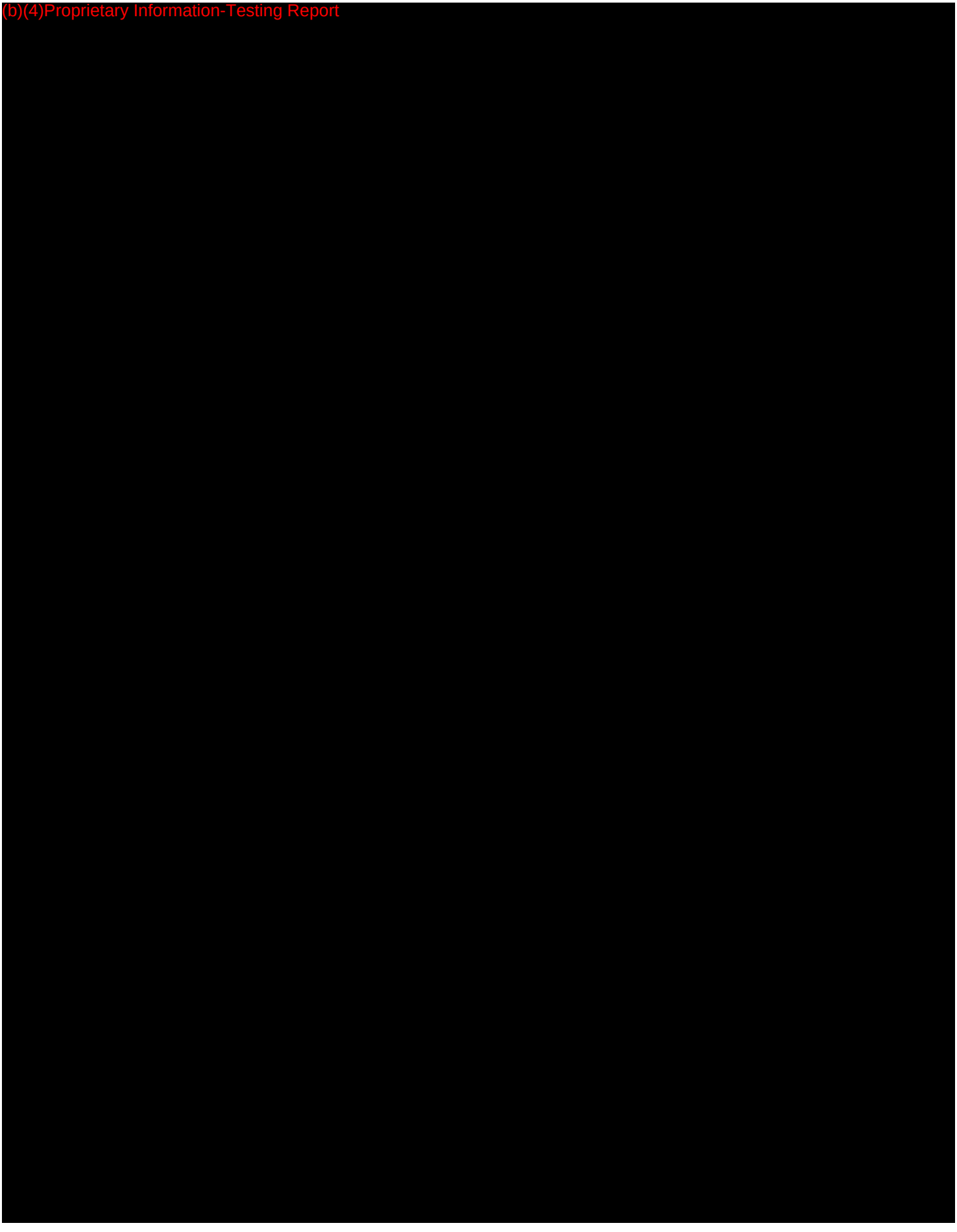
(b)(4)Proprietary Information-Testing Report

[redacted]

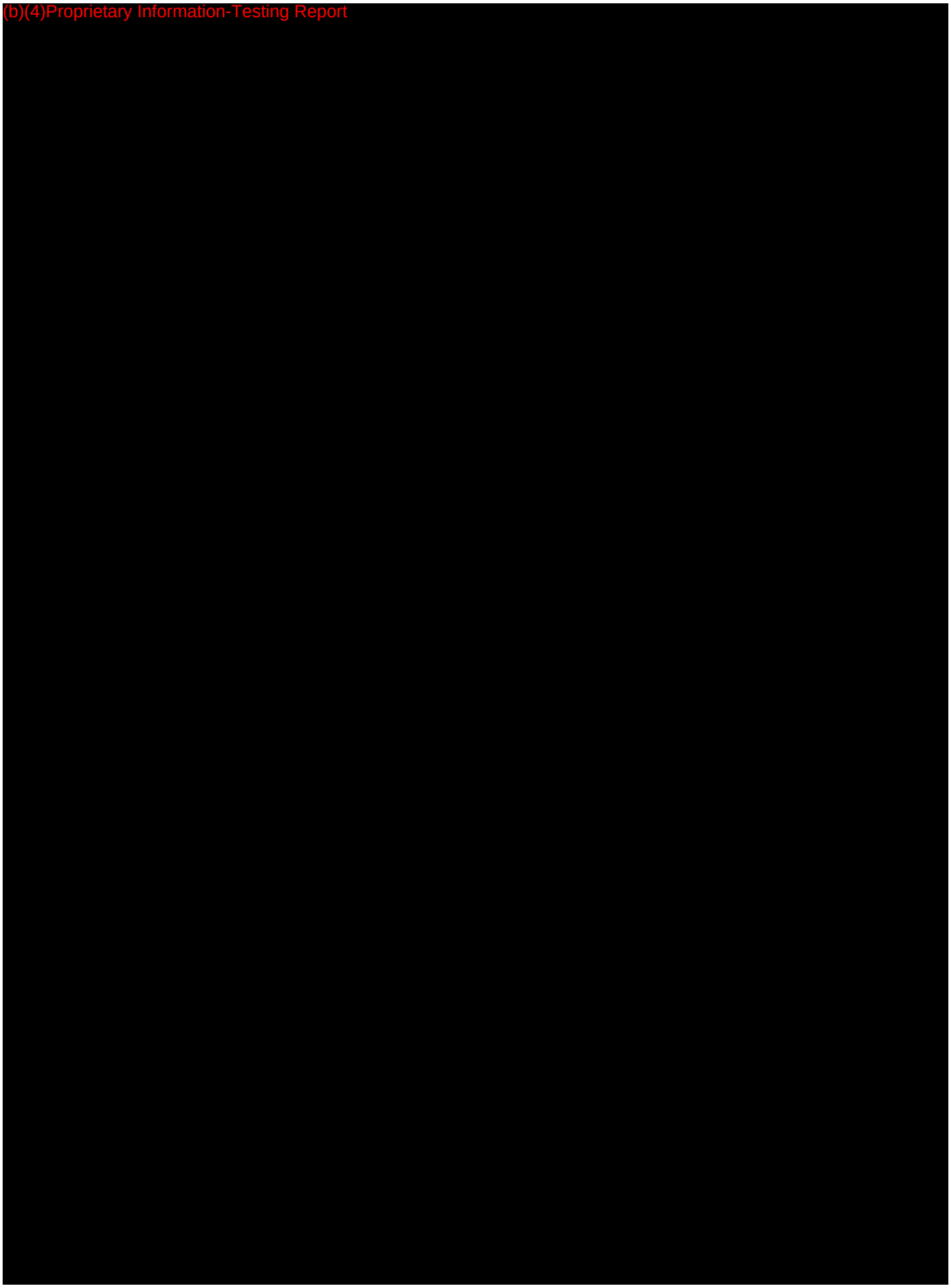
(b)(4)Proprietary Information-Testing Report

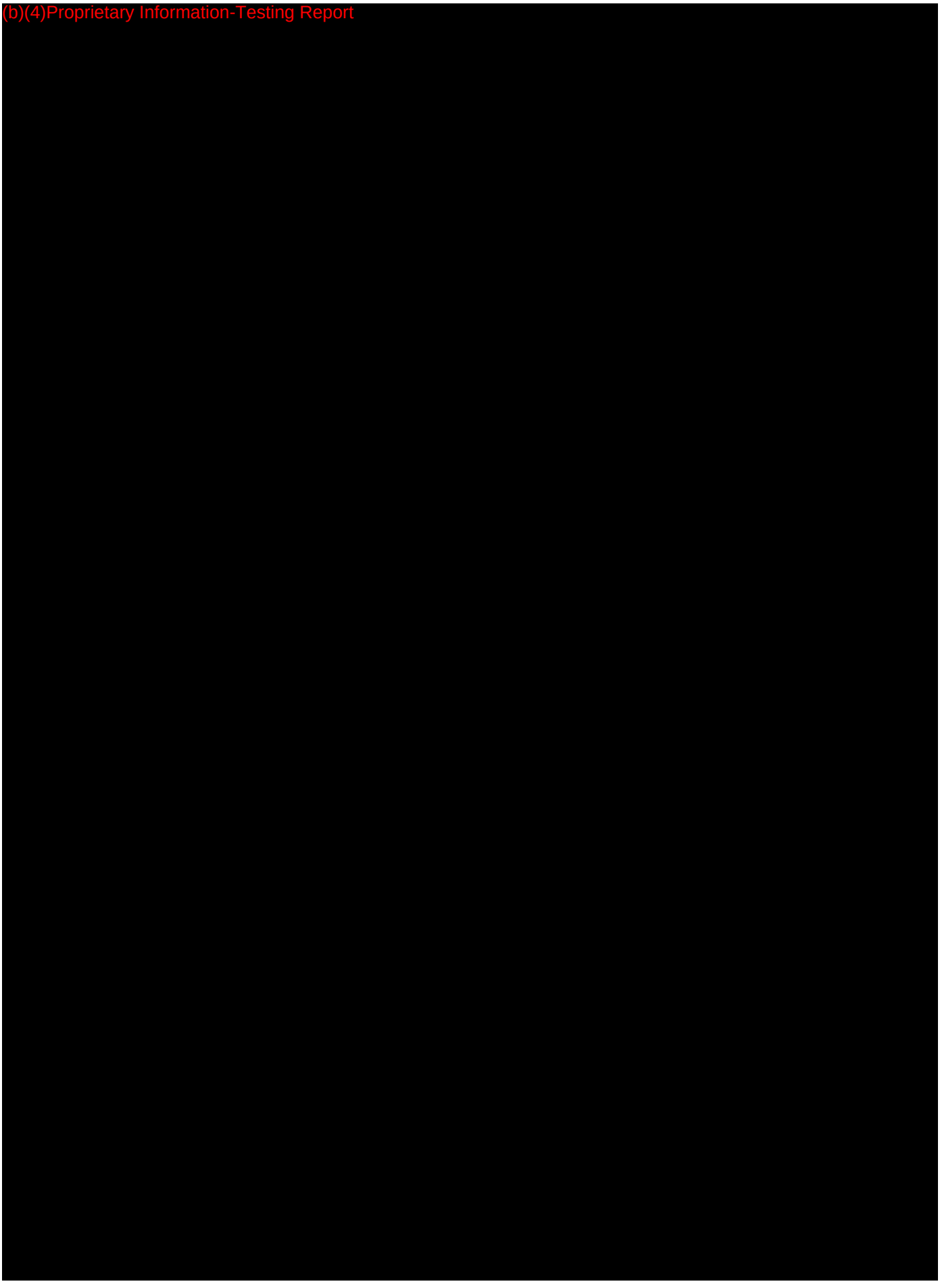


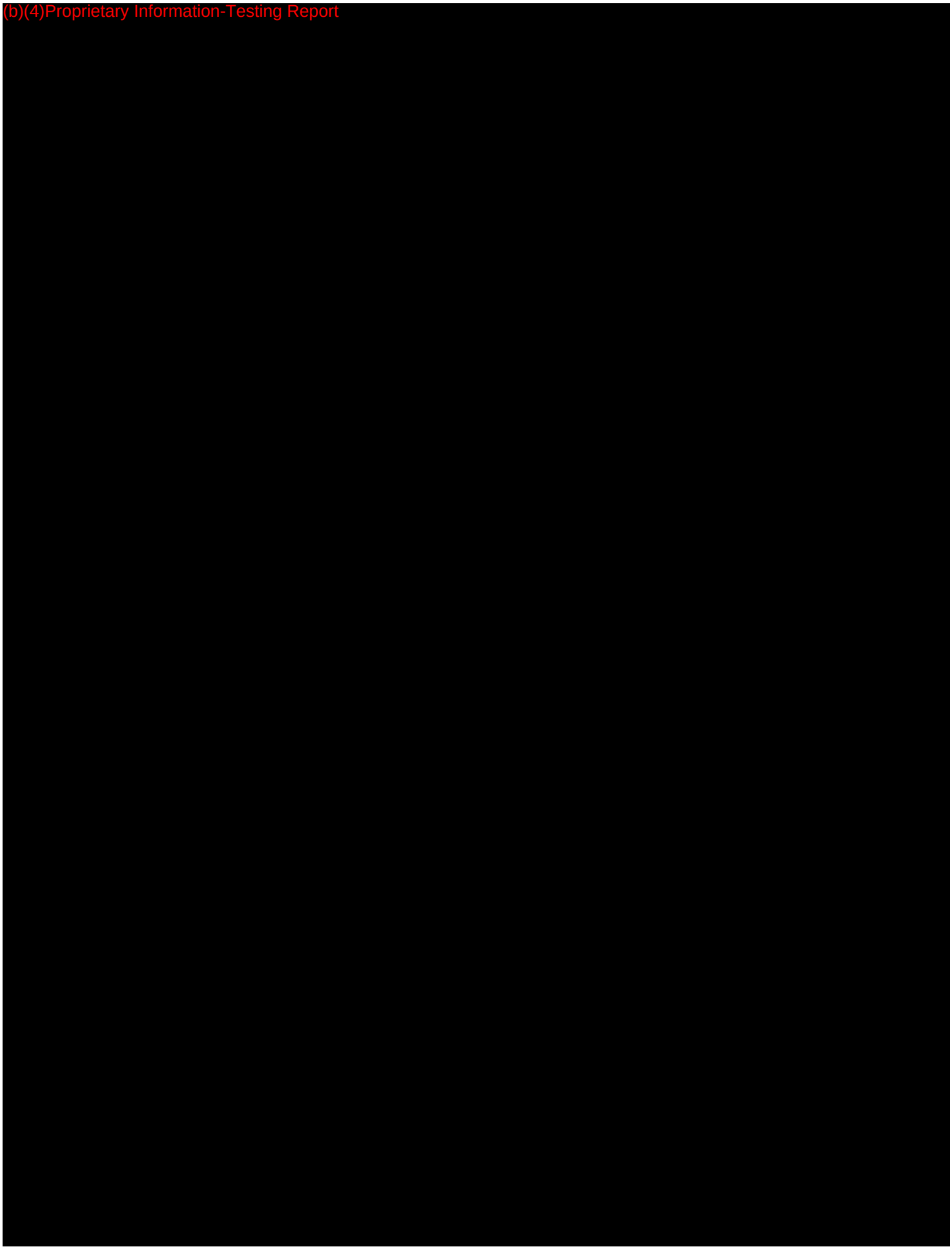


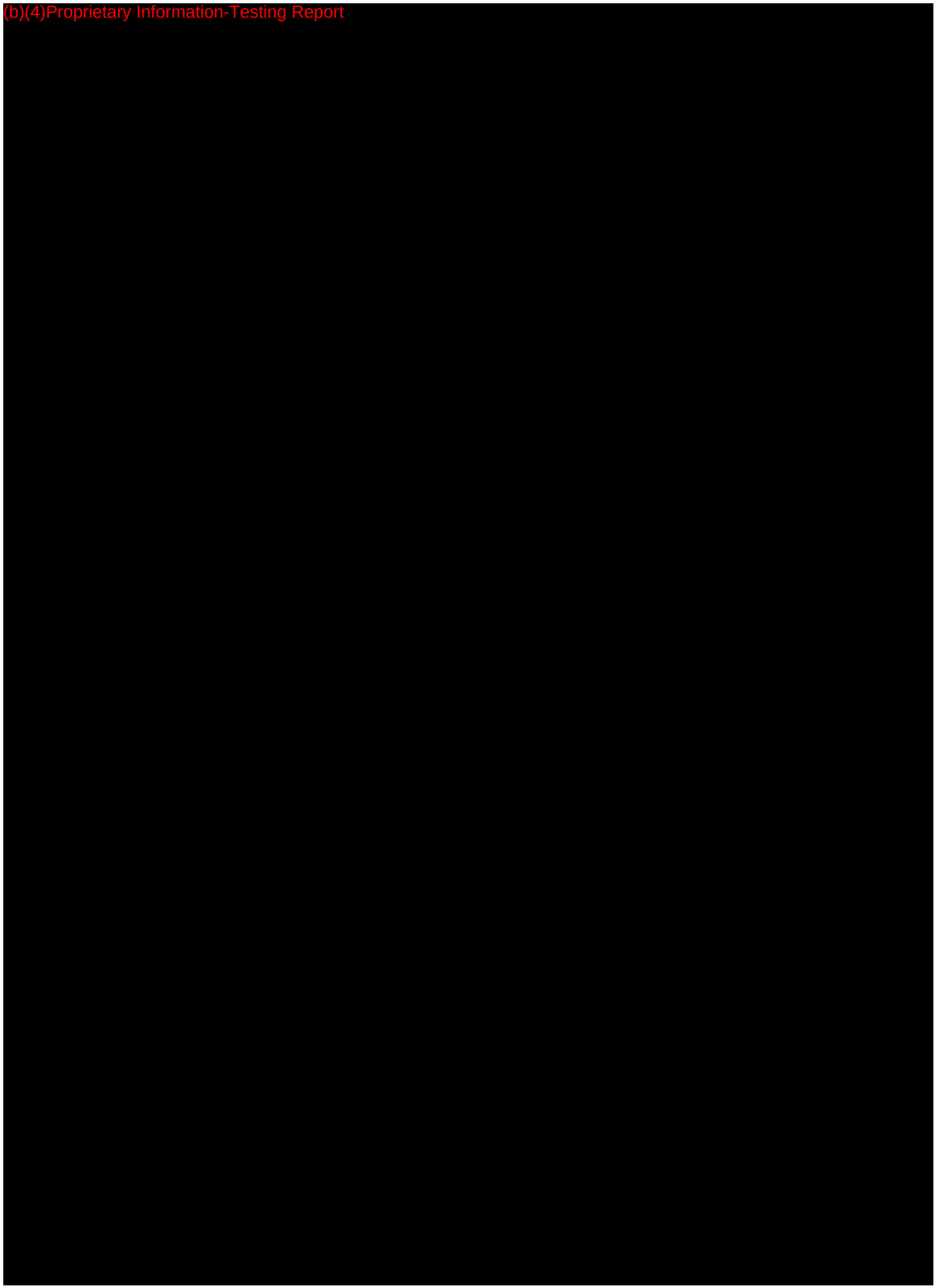


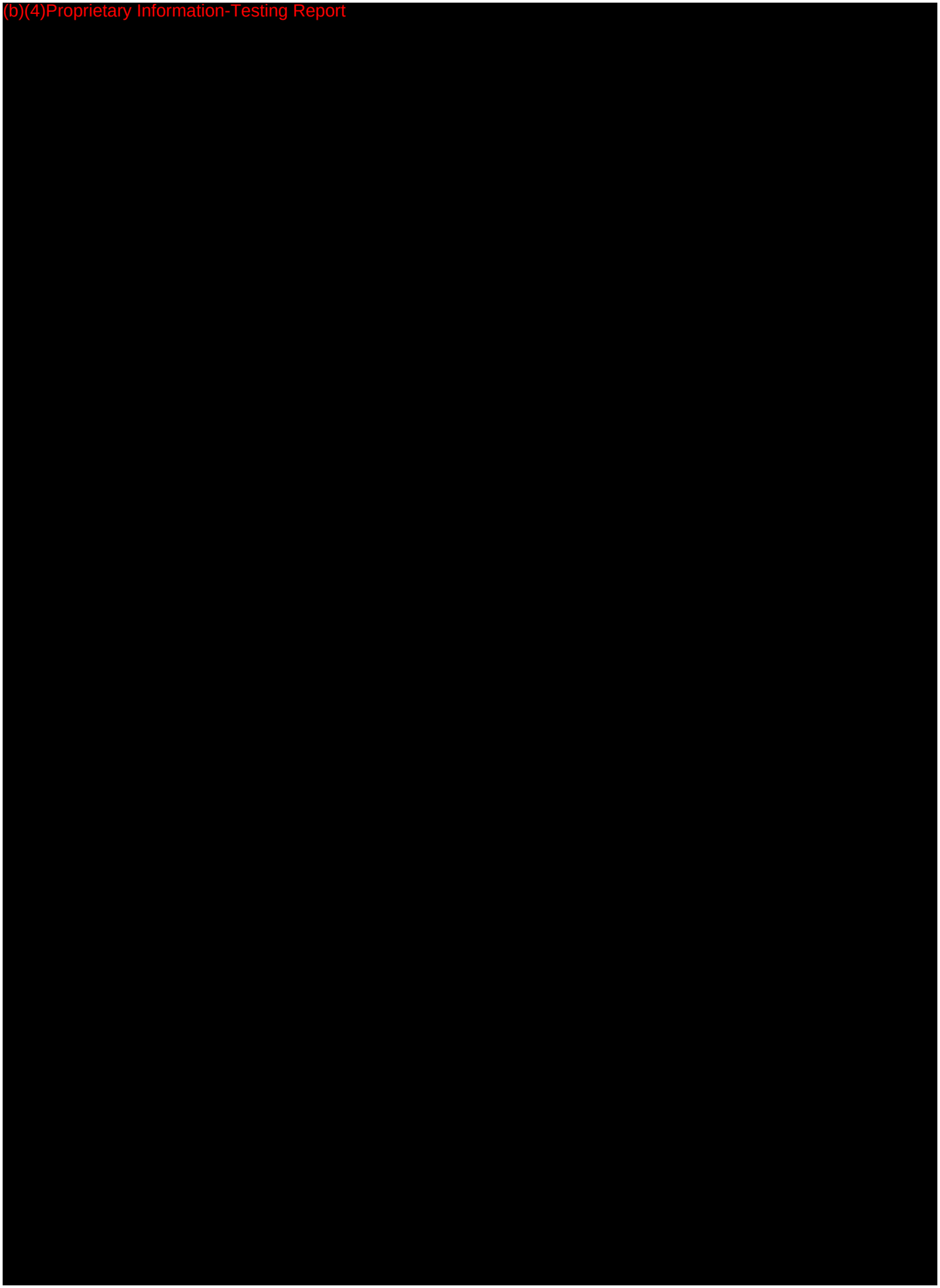
(b)(4)Proprietary Information-Testing Report

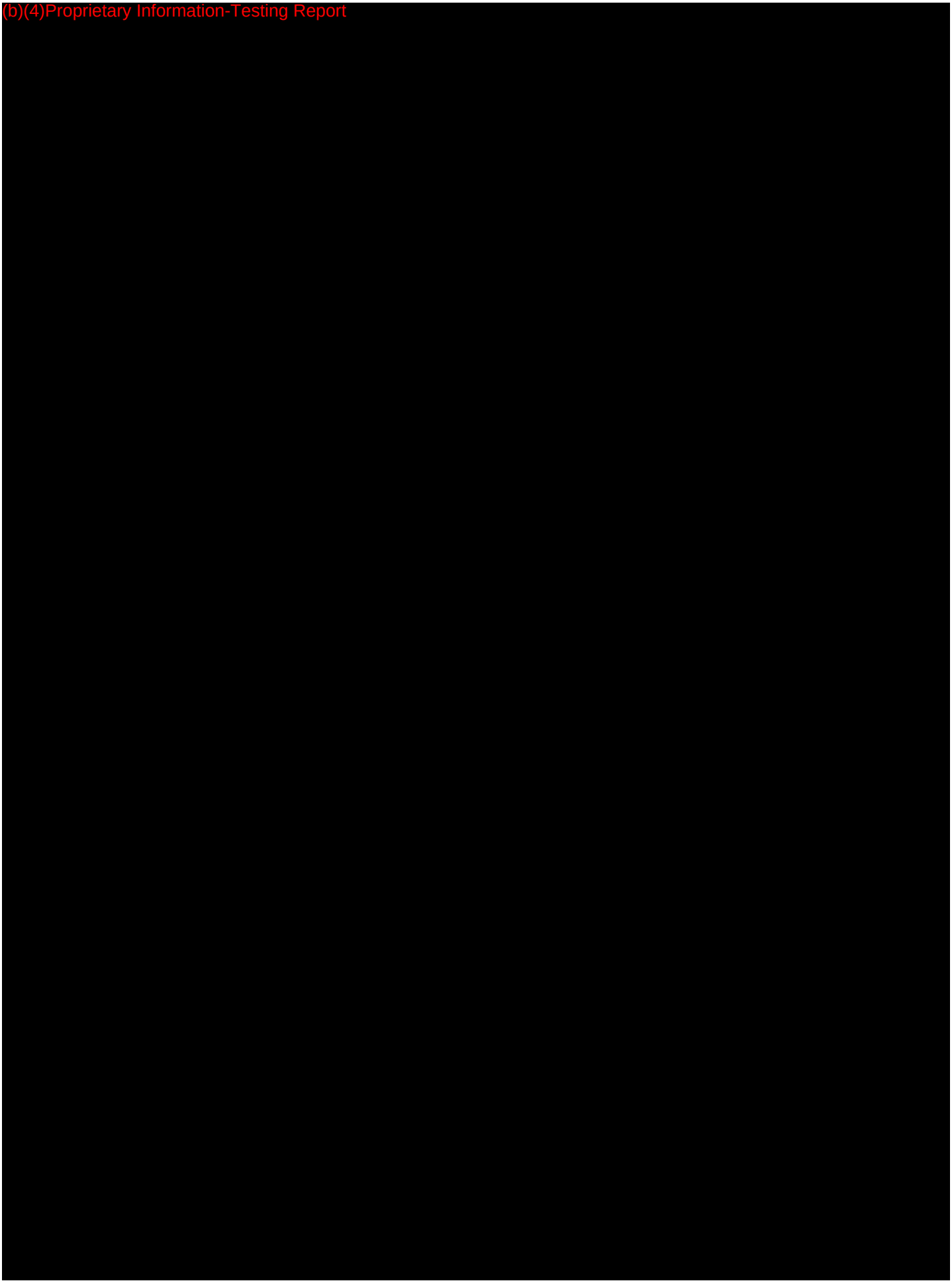




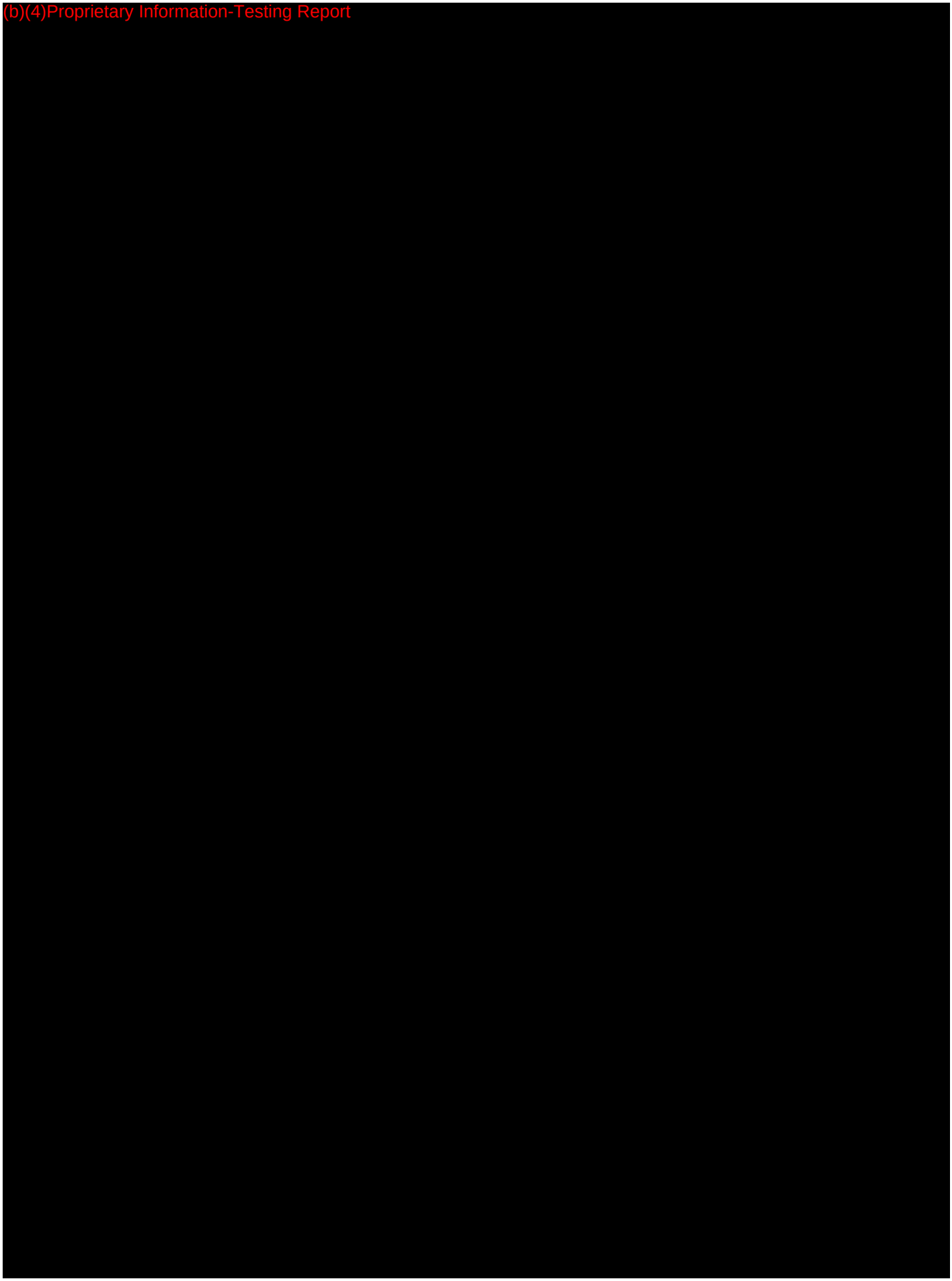




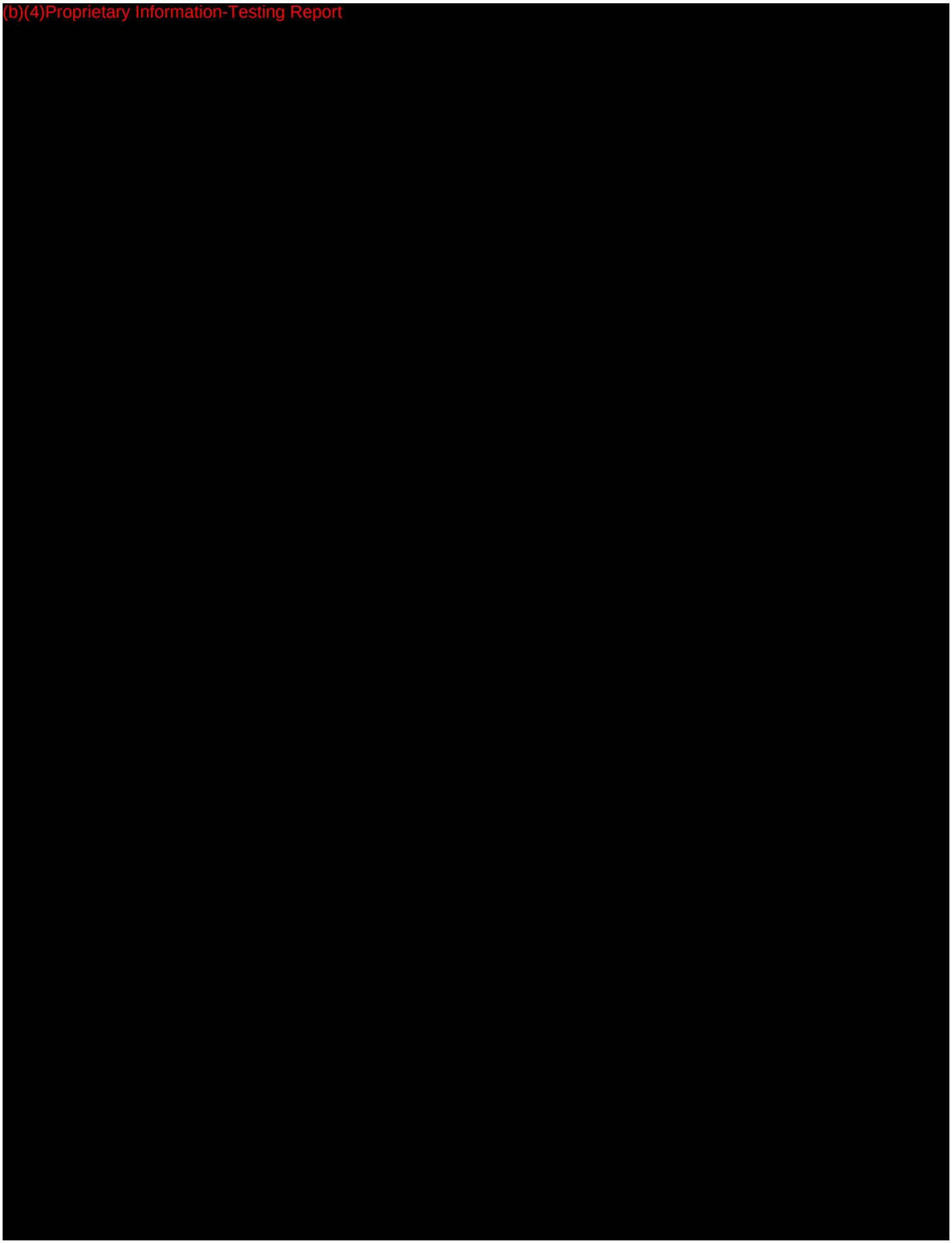




(b)(4)Proprietary Information-Testing Report



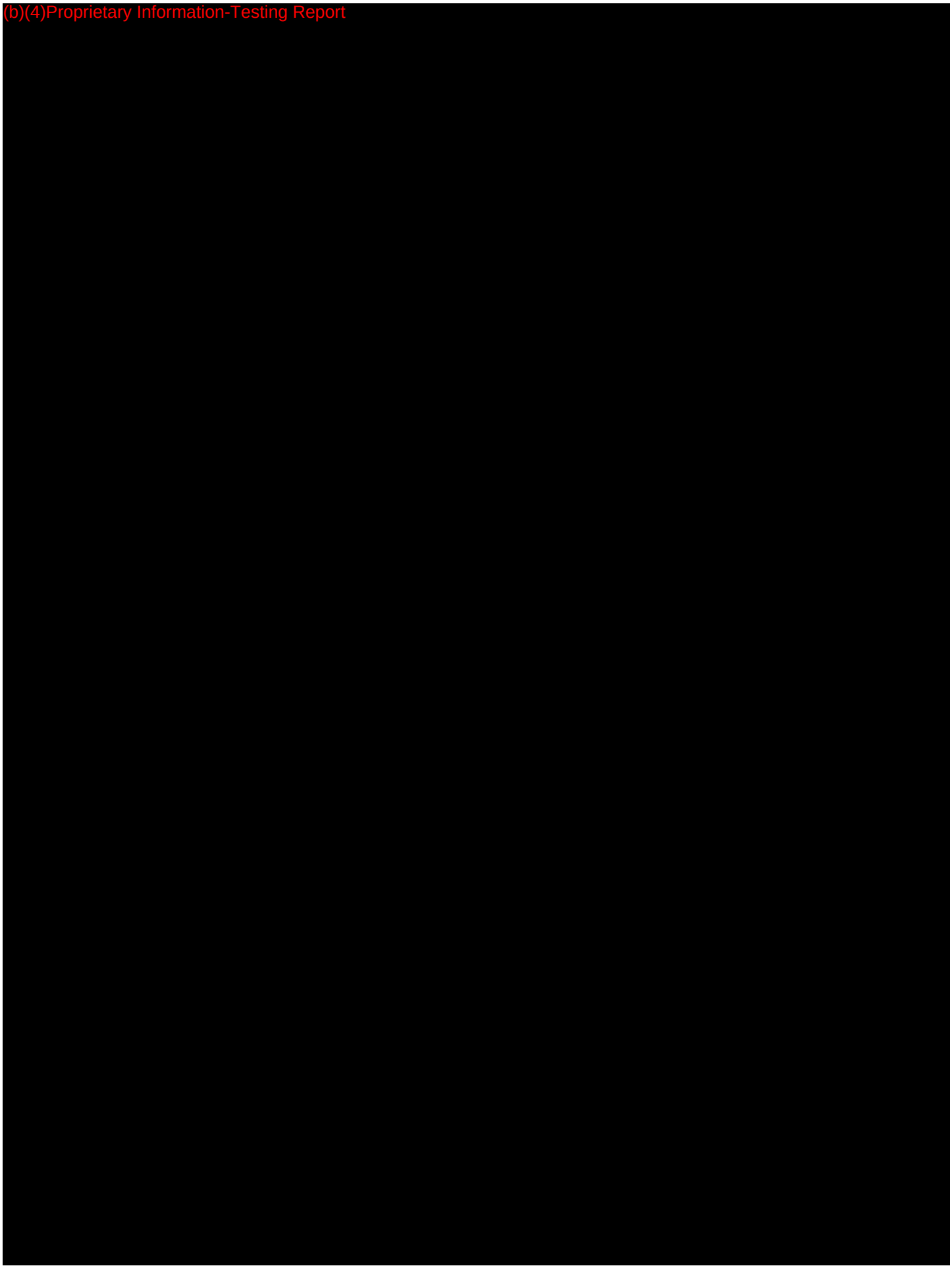
(b)(4)Proprietary Information-Testing Report



(b)(4)Proprietary Information-Testing Report

[redacted]

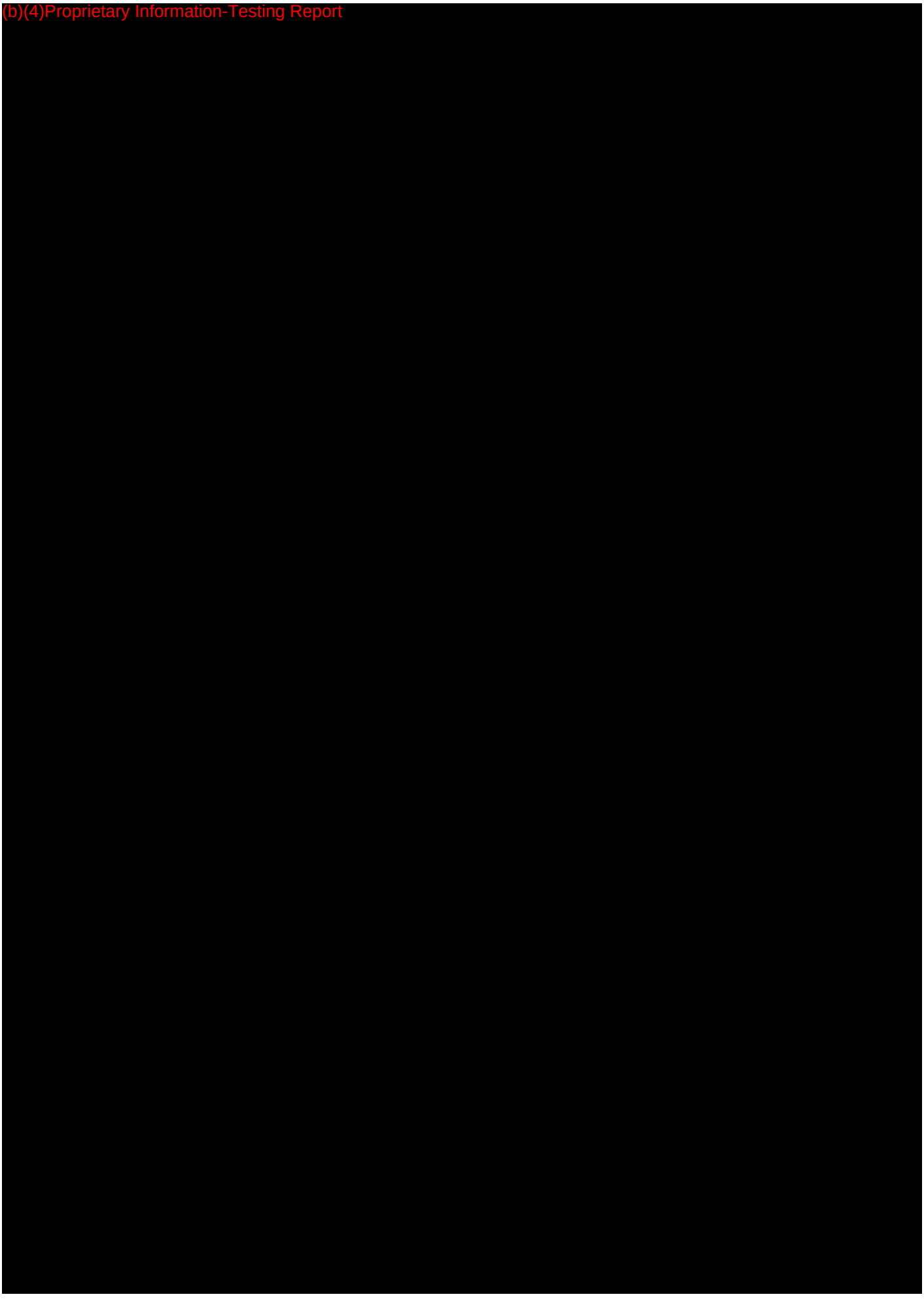
(b)(4)Proprietary Information-Testing Report



(b)(4)Proprietary Information-Testing Report

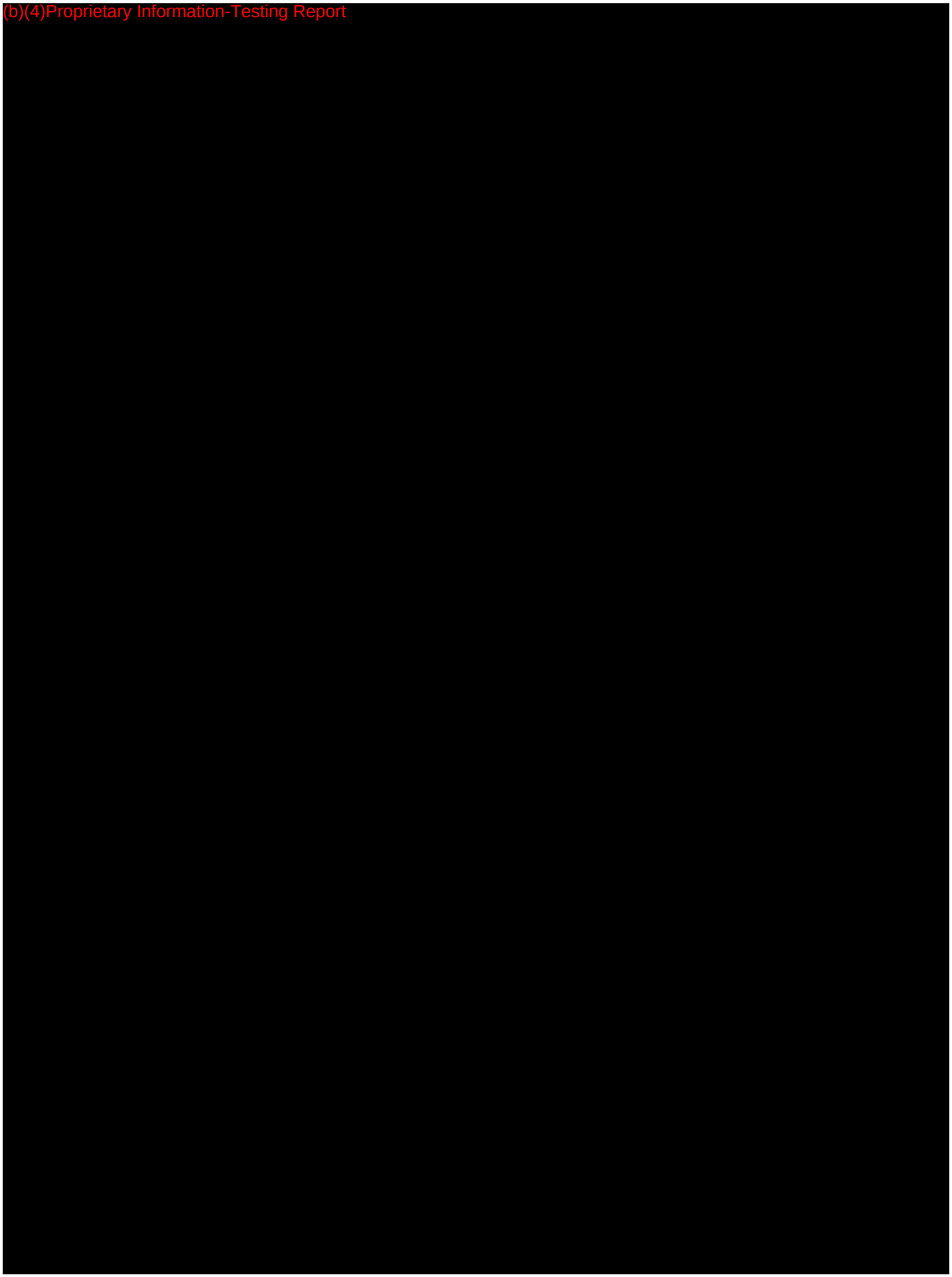
[redacted]

(b)(4)Proprietary Information-Testing Report

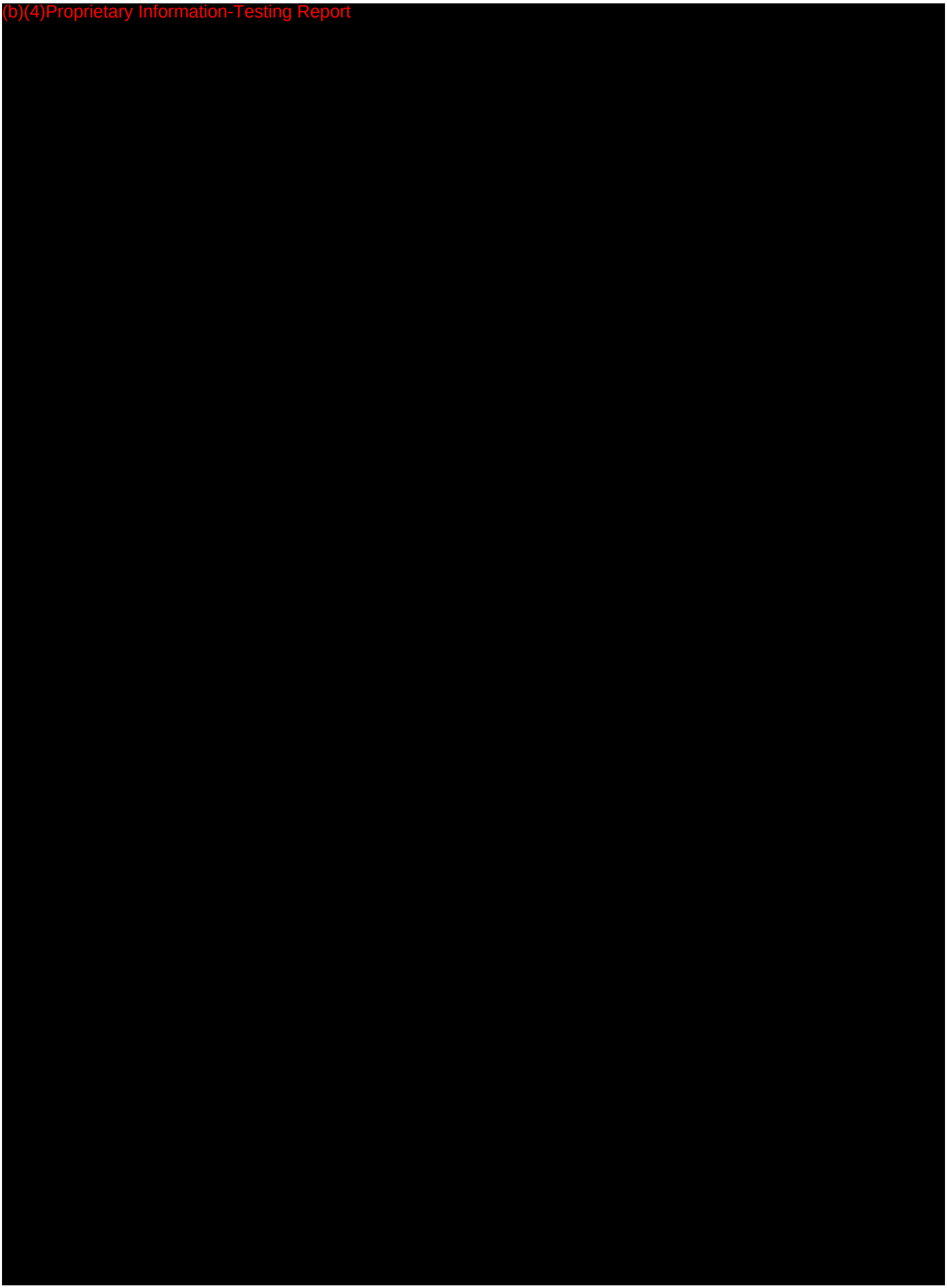


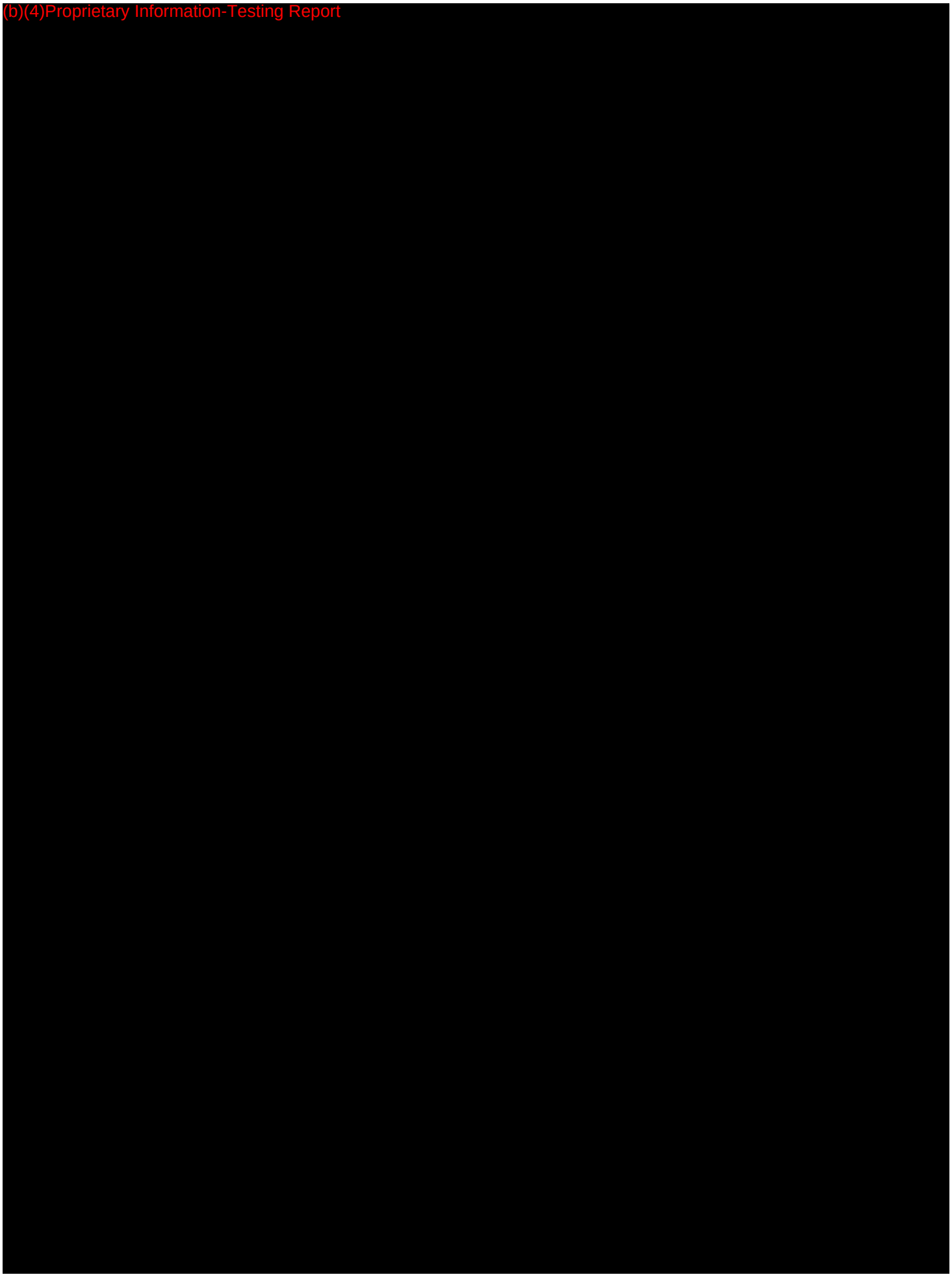
(b)(4)Proprietary Information-Testing Report

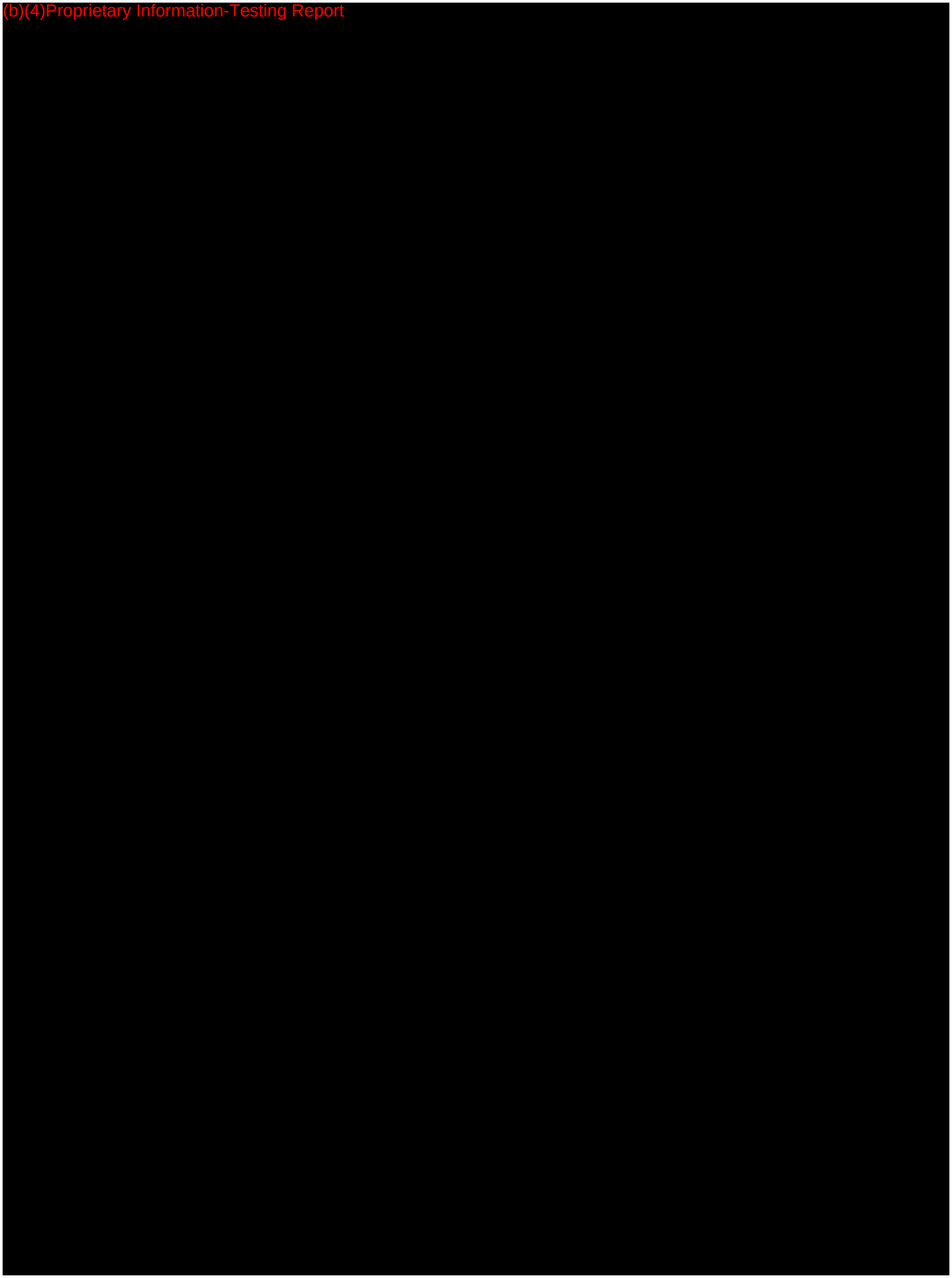
[redacted]



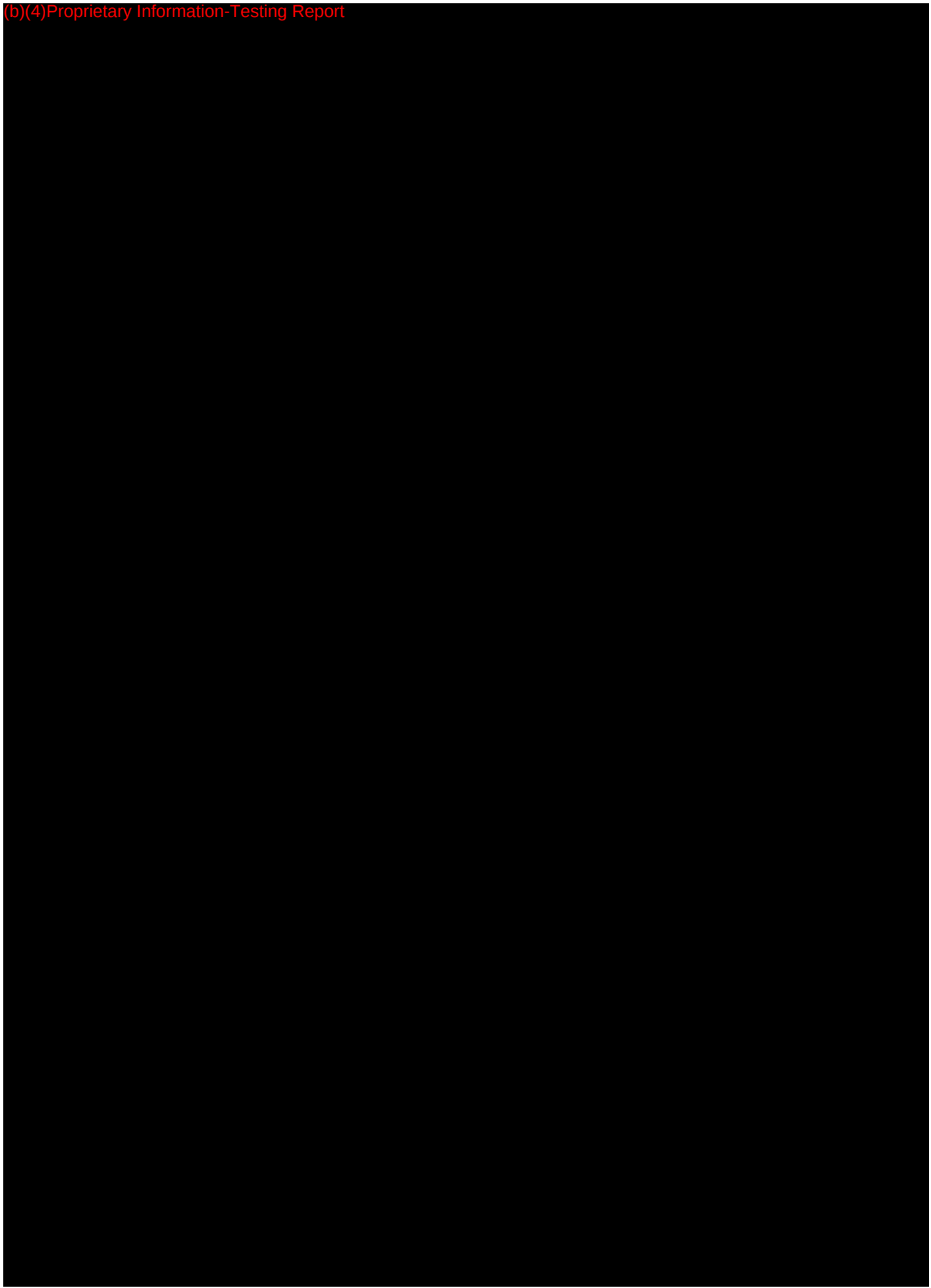
(b)(4)Proprietary Information-Testing Report





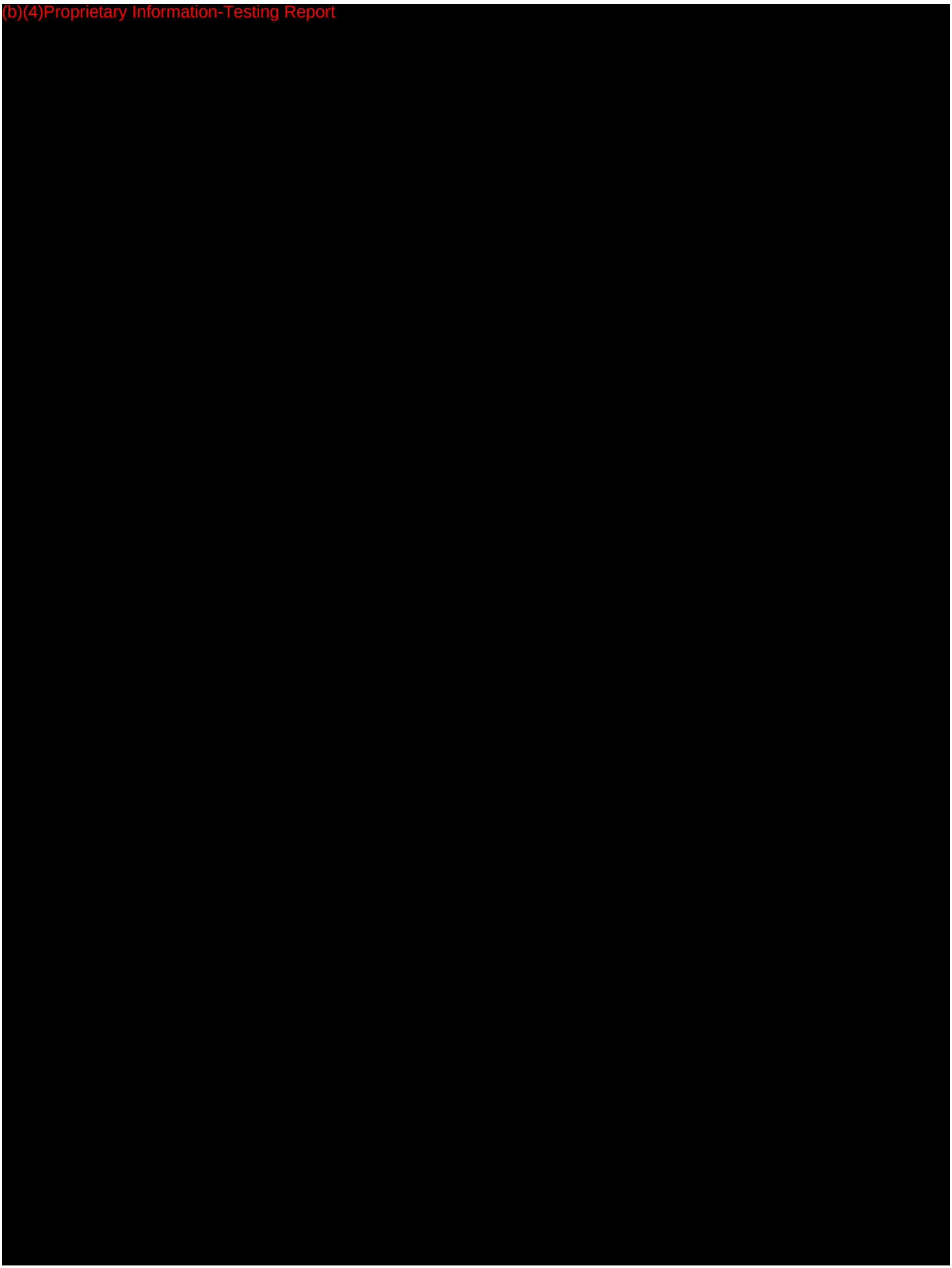


(b)(4)Proprietary Information-Testing Report

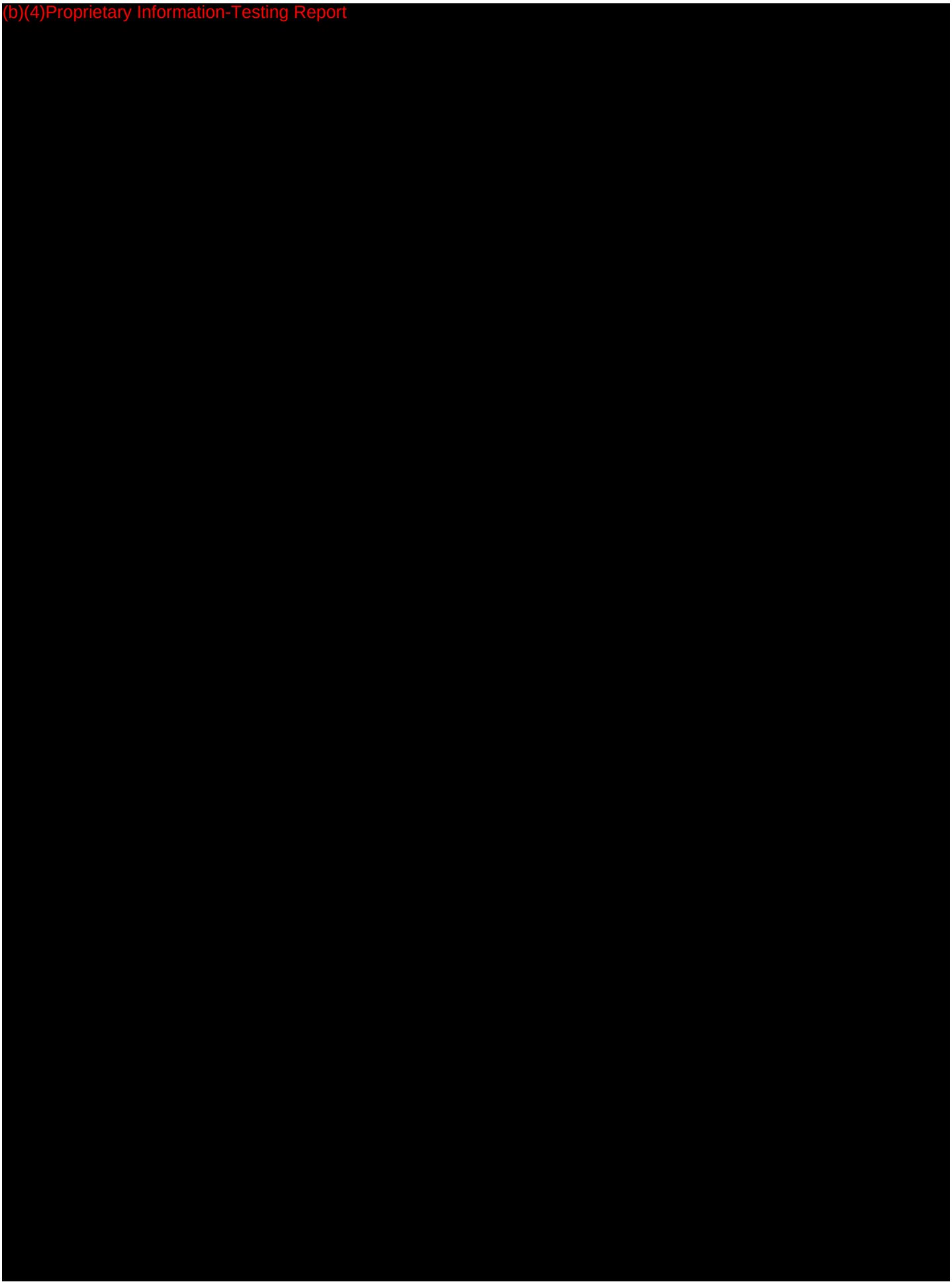


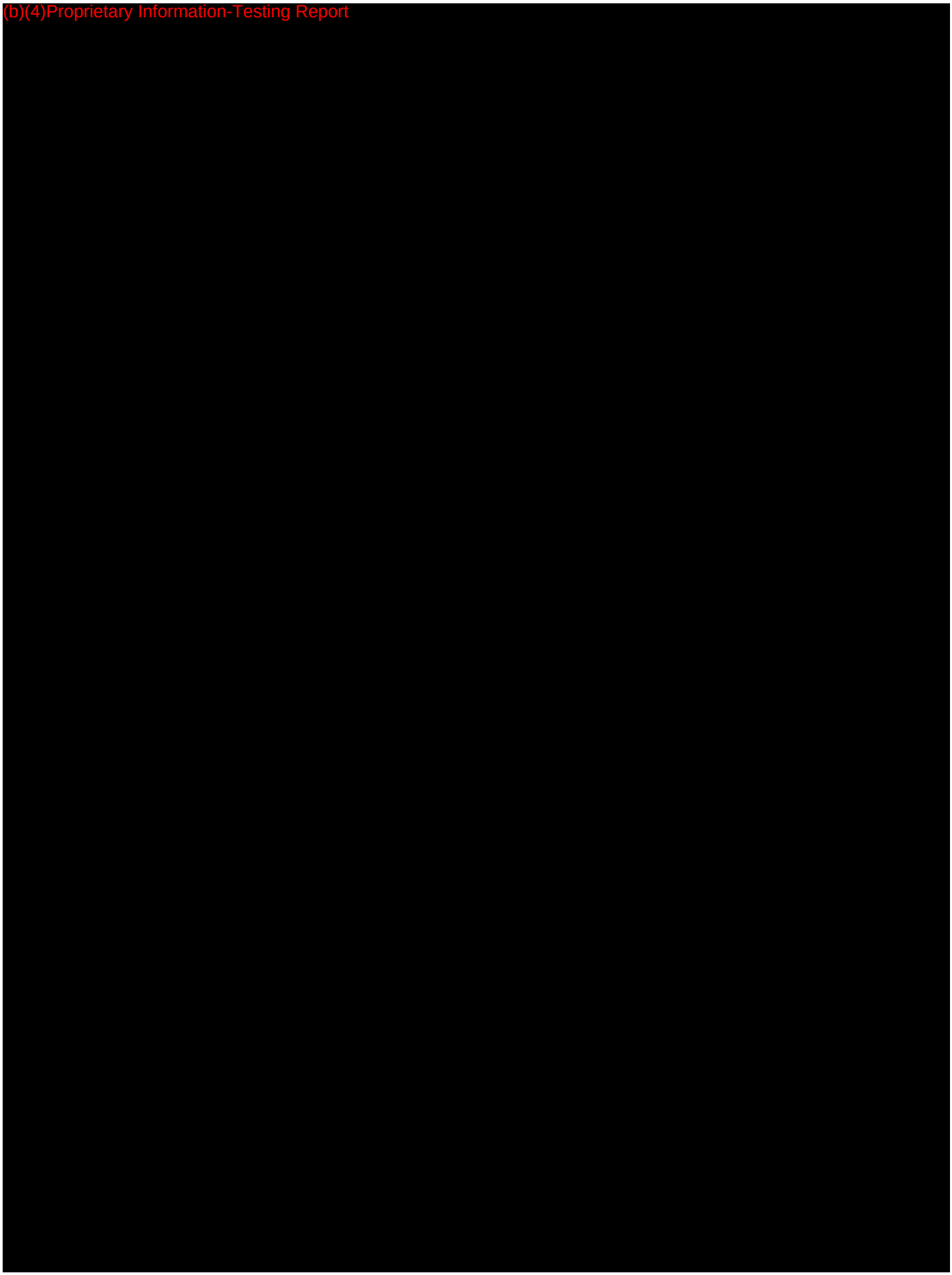
(b)(4)Proprietary Information-Testing Report

[redacted]

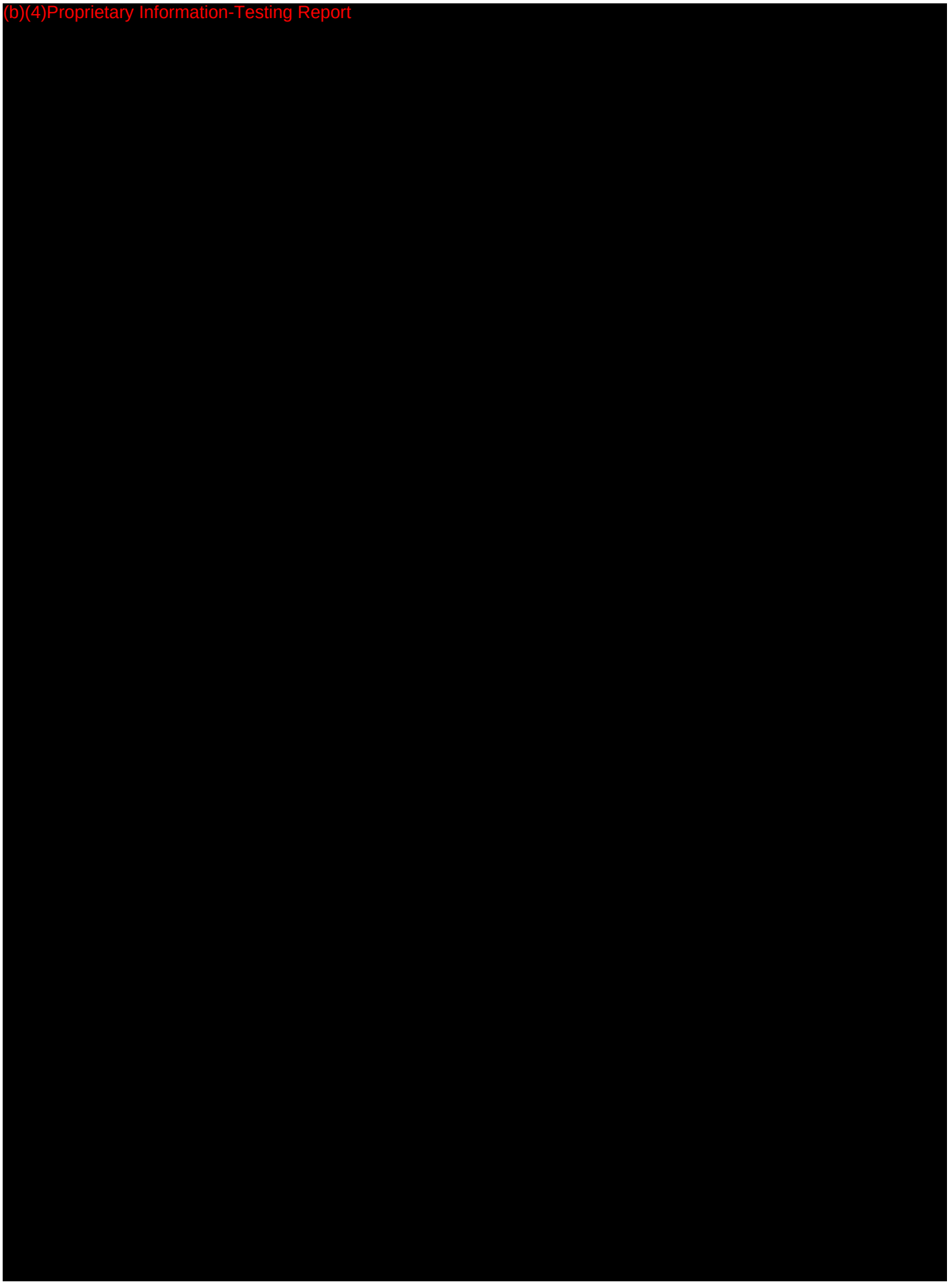


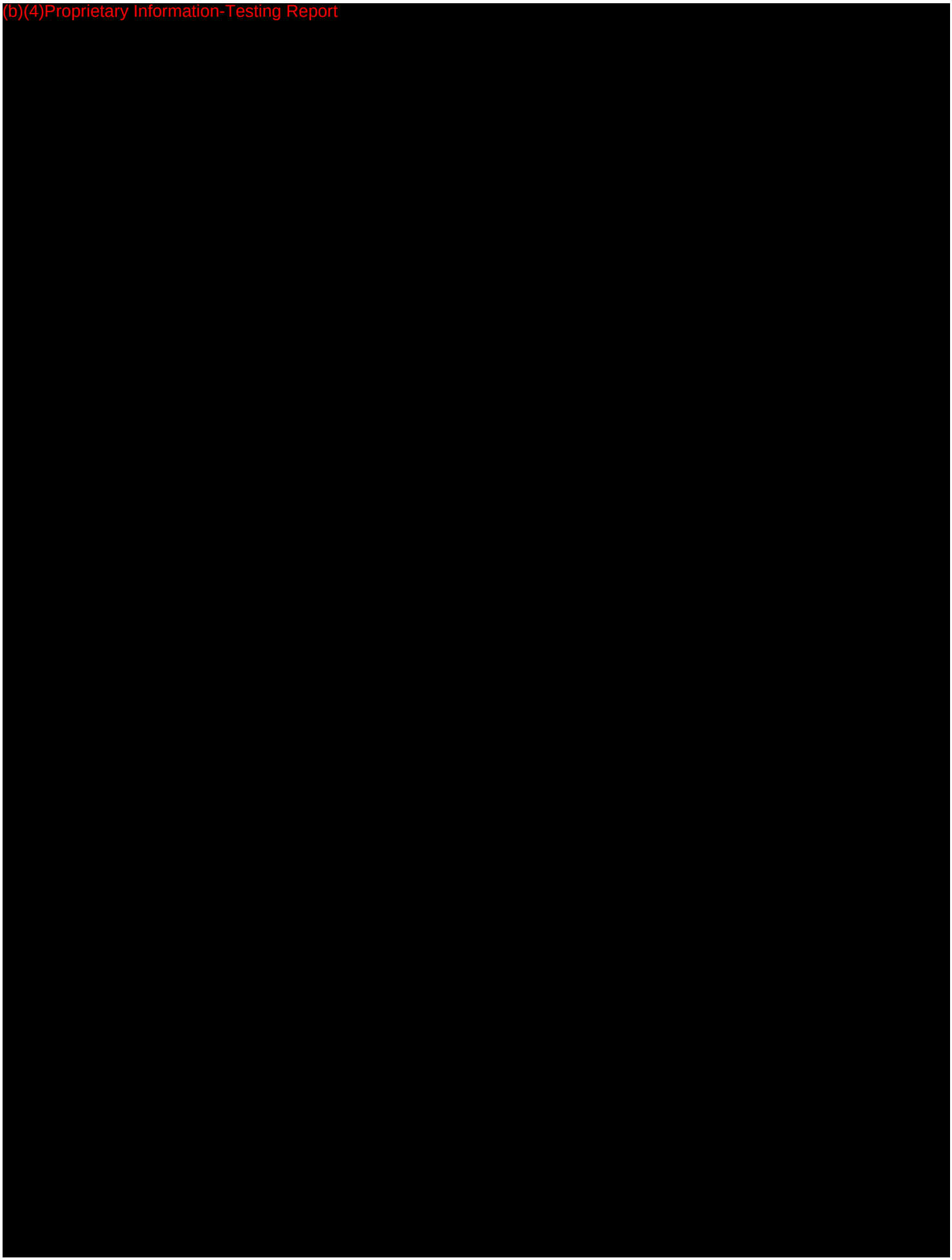
(b)(4)Proprietary Information-Testing Report





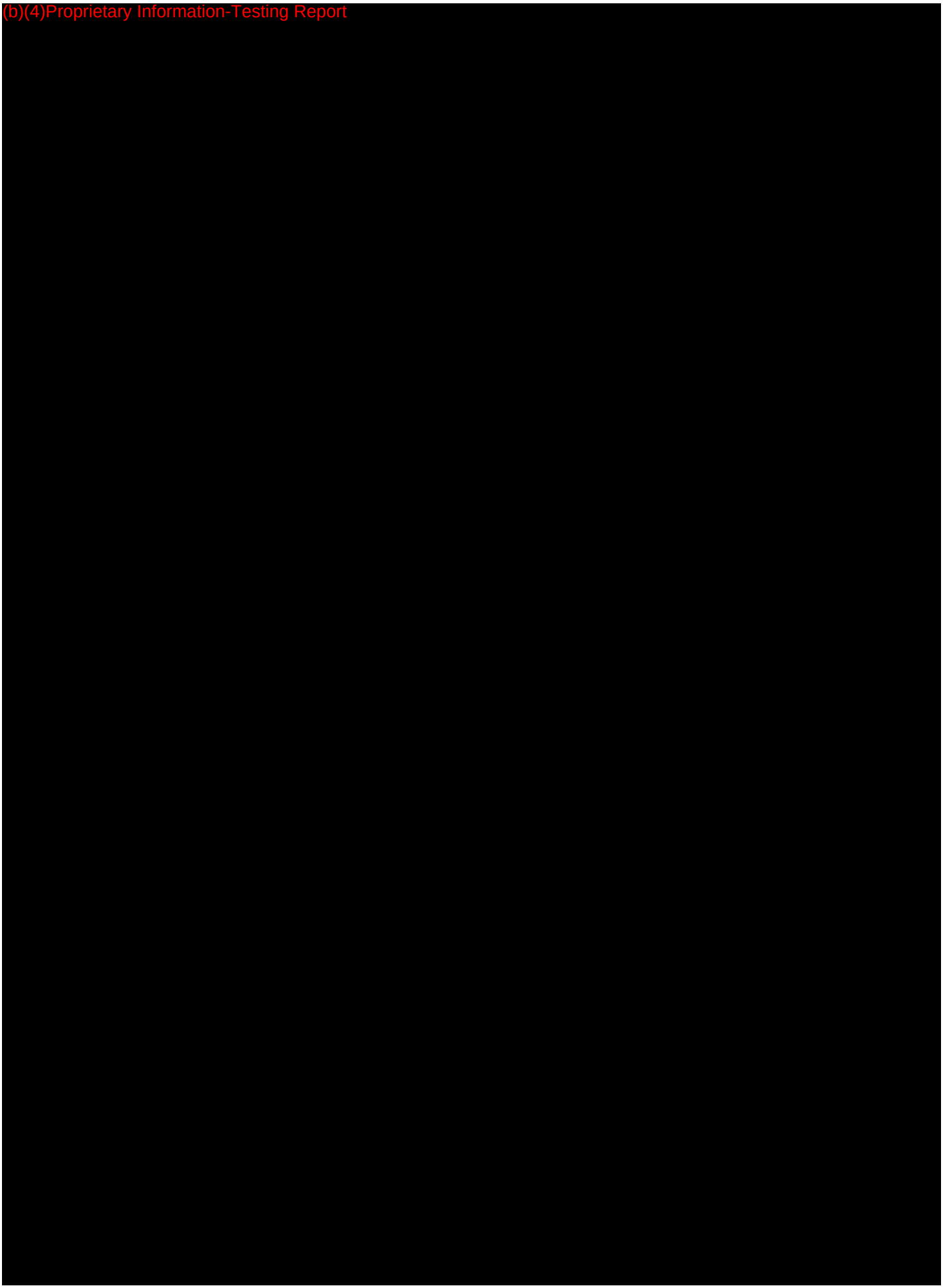
(b)(4)Proprietary Information-Testing Report





(b)(4)Proprietary Information-Testing Report

[redacted]



ATTACHMENT D

MSDS

(b)(4)Proprietary Information-Material Data

(b)(4)Proprietary Information-Material Data

(b)(4)Proprietary Information-Material Data

(b)(4)Proprietary Information-Material Data

(b)(4)Proprietary Information-Material Data

(b)(4)Proprietary Information-Material Data

(b)(4)Proprietary Information-Material Data

(b)(4)Proprietary Information-Material Data

(b)(4)Proprietary Information-Material Data

(b)(4)Proprietary Information-Material Data

(b)(4)Proprietary Information-Material Data

(b)(4)Proprietary Information-Material Data

(b)(4)Proprietary Information-Material Data

(b)(4)Proprietary Information-Material Data

(b)(4)Proprietary Information-Material Data

(b)(4)Proprietary Information-Material Data

(b)(4)Proprietary Information-Material Data

(b)(4)Proprietary Information-Material Data

(b)(4)Proprietary Information-Material Data

(b)(4)Proprietary Information-Material Data

(b)(4)Proprietary Information-Material Data

(b)(4)Proprietary Information-Material Data

(b)(4)Proprietary Information-Material Data

(b)(4)Proprietary Information-Material Data

(b)(4)Proprietary Information-Material Data

(b)(4)Proprietary Information-Material Data

(b)(4)Proprietary Information-Material Data