U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(kml)
FOLDER:	K132560 - 487 pages
COMPANY:	RNK PRODUCTS, INC. (RNKPRODA)
PRODUCT:	STETHOSCOPE, ELECTRONIC (DQD)
SUMMARY:	Product: PCP-USB STETHOSCOPE
DATE REQUESTED:	Nov 2, 2015
DATE PRINTED:	Nov 2, 2015
Note:	Printed

RNK Products

510(k) SUMMARY
RNK Products
PCP-USB Stethoscope

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K132560

Submitter Information

Submitter: RNK Products
8247 Devereux Drive
Suite 101
Viera, FL 32940
Telephone: (321) 610-3980
Facsimile: (321) 610-3979

Contact Person: Charles R. Abbruscato
RNK Products
Telephone: (321) 610-3980
Facsimile: (321) 610-3979

Date Prepared: October 9, 2013

Device Information

Name of Device	RNK PCP-USB Stethoscope
Common or Usual Name	Electronic Stethoscope
Classification Name	Electronic Stethoscope
Predicate Devices	RNK Products PCP/PC Stethoscope (K102893)

Device Description

The PCP-USB Stethoscope consists of a hardware element, the PCP-Chest Piece, and software elements consisting of some audio signal processing in the Streaming Stethoscope Over IP (sSOIP) Anywhere software on the end station PCs, communications software on the end station PCs (sSOIP Anywhere), and communications networking software on the Telemedicine Communications Server (TMCS), Relay Server and Stethoscope User Data (SUD) Server. It provides remote auscultation between a patient at one location and a clinician at another location.

The PCP-USB Chest Piece contains an embedded piezo sensor, audio amplifier Analog to Digital Converter (ADC) and Encoder to create a digitized stream, plus a USB interface to send that data to the PC. The PCP-USB Chest Piece derives its operating voltage from the 5v lead of the USB interface to the PC.

Under direction of the sSOIP Anywhere program in the PC, the digitized signal is formatted in the PC into IP packets for transport. Both the transmit end station (i.e. patient end) and the receive end station (i.e. clinician end) log into the TMCS, which indicates their availability for a connection.

In the sSOIP Anywhere program, the clinician at the receive end, selects a patient from a list of available patients and initiates a connection request to the TMCS, which passes on the request to the patient station. When the patient accepts the incoming connection request in the sSOIP Anywhere program, the TMCS facilitates a direct (peer-to-peer) connection between the two parties. If a direct connection is not possible, the TMCS facilitates a relay connection between the two parties through a Relay Server. No patient stethoscope data passes through the TMCS.

At the receive end PC, the sSOIP Anywhere program directs the acceptance of the IP packets, conversion of the digitized signal back to analog and presentation of the analog signal to the Headset port of the PC.

The TMCS receives information on users that are permitted to use the TMCS services from a SUD Server. That information would be entered into the SUD Server by the health care provider responsible for those users.

Intended Use

The PCP-USB Stethoscope is intended to transmit auscultation sound data, whereby a clinician at one location on an IP network can listen to the auscultation sounds of a patient at a different location on the IP network with the signal carried on an IP connection between the two locations.

Substantial Equivalence

The PCP-USB Chest Piece includes the same piezo sensor and the same audio amplifier as the predicate PCP/PC Chest Piece. But whereas the PCP/PC Stethoscope uses the Analog to Digital Converter (ADC) and Encoder of the PC's audio circuitry, the PCP-USB Chest Piece embeds those circuit elements within the chest piece head itself. Whereas the PCP/PC Chest Piece derives its operating voltage from the phantom voltage on the Microphone port of the PC, the PCP-USB derives its operation voltage from the 5v lead of the USB interface to the PC. The PCP-USB Stethoscope is substantially equivalent to the RNK Products, Inc. PCP/PC Stethoscope. Bench testing and clinical testing were performed to verify specifications and performance.

The sSOIP Anywhere software is an enhancement of the predicate sSOIP software such that working with the TMCS, SUD Server and Relay Server, IP connections can be accomplished

across Network Address Translation (NAT) boundaries, whereas sSOIP could only make IP connections between static IP addresses.

Both the PCP-USB Stethoscope and the predicate device successfully demonstrated conformance to IEC60601-1:2005 3rd Edition Medical Electrical Equipment Part 1: General Requirement for Safety and to EN60601-1-2, 2007/03, EMC Immunity Requirements for Medical Electrical Equipment Part 1: General Requirements for Safety, 2. Collateral Standard – Electromagnetic Compatibility Requirements and Tests. Since both devices use the same materials that a patient or clinician might touch, the biocompatibility analysis is the same. The PCP-USB Stethoscope passed the same auscultation performance tests as the predicate device both in bench testing and by clinicians.

The RNK PCP-USB Stethoscope has the same intended use, principles of operation and technological characteristics as the predicate devices. There are no new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

October 11, 2013

Rnk Products, Inc.
c/o Mr. Charles Abbruscato
C.E.O.
8247 Devereux Dr Ste 101
Melbourne, FL 32940 US

Re: K132560
Trade/Device Name: PCP-USB Stethoscope
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: DQD
Dated: August 4, 2013
Received: August 15, 2013

Dear Mr. Charles Abbruscato:

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.

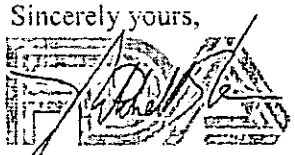
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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



for Bram D. Zuckerman, Ph.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K132560

Indications for Use

510(k) Number (if known): K_____

Device Name: PCP-USB Stethoscope

Indications for Use:

The RNK PCP-USB Stethoscope is intended to transmit auscultation sound data, whereby a clinician at one location on an IP network can listen to the auscultation sounds of a patient at a different location on the IP network with the signal carried on an IP connection between the two locations.

Prescription Use: X OR Over-the-Counter Use _____
(Part 21 CRF 801 Subpart D) (Part 21 CRF 801 Subpart C)

(Please Do Not Write Below This Line – Continue On Another Page If Needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 1-2-96)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

October 11, 2013

Rnk Products, Inc.
c/o Mr. Charles Abbruscato
C.E.O.
8247 Devereux Dr Ste 101
Melbourne, FL 32940 US

Re: K132560
Trade/Device Name: PCP-USB Stethoscope
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: DQD
Dated: August 4, 2013
Received: August 15, 2013

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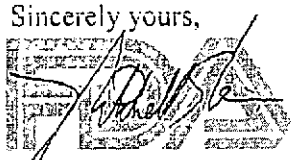
Sincerely yours,



for Bram D. Zuckerman, Ph.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K132560

Indications for Use

510(k) Number (if known): K_____

Device Name: PCP-USB Stethoscope

Indications for Use:

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Prescription Use: X OR Over-the-Counter Use _____
(Part 21 CRF 801 Subpart D) (Part 21 CRF 801 Subpart C)

(Please Do Not Write Below This Line – Continue On Another Page If Needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 1-2-96)

RNK Products, Inc. K132560

August 14, 2013

Food and Drug Administration
Center for Devices and Radiological Health
510(k) Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver spring, MD 20993-0002

Re: Premarket Notification for RNK Products' PCP-USB Stethoscope

Dear Sir or Madam:

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act 21 U.S.C. § 351(k), RNK Products, Inc. ("RNK") is submitting the enclosed premarket notification for RNK's PCP-USB Stethoscope, an electronic stethoscope. The PCP-USB Stethoscope is intended for use as a remote monitoring device, whereby a clinician at one location can listen to the auscultation sounds of a patient at a different location, with the signal carried over a data communication channel between the two locations. The PCP-USB Stethoscope is a Class II medical device pursuant to 21 C.F.R. § 870.1875, "Stethoscope."

The PCP-USB Stethoscope is substantially equivalent to other marketed devices that have received premarket clearance, specifically the RNK Products PCP/PC Stethoscope (K102893). As explained in greater detail in the attached submission, the PCP-USB Stethoscope has the same intended use and principles of operations and technological characteristics as a combination of the predicate PCP/PC Stethoscope. The differences of the PCP-USB Stethoscope from the predicate do not raise any new questions of safety or effectiveness. The eCopy of the submitted material is an exact duplicate of the paper copy.

We trust that the information in the enclosed 510(k) notice will be sufficient to enable the Food and Drug Administration ("FDA") to find that the PCP-USB Telephonic Stethoscope is substantially equivalent to the PCP/PC Stethoscope. Please direct any questions or requests for information concerning this submission to the undersigned at (321) 610-3980. Upon a finding of substantial equivalence, please send me a copy of the signed substantial equivalence letter by facsimile at (321) 610-3979.

Sincerely,

Charles R. Abbruscato

Charles R. Abbruscato
RNK Products, Inc.
8247 Devereux Drive, Suite 101
Viera, FL 32940
(321) 610-3980

SI

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

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)

RNK PRODUCTS INC
8247 Devereux Drive
Suite 101
Viera
Brevard
FL 32940
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
(b)(4)

2. CONTACT NAME
Charles Abbruscato
2.1 E-MAIL ADDRESS
abbruscato@rnkproducts.com
2.2 TELEPHONE NUMBER (include Area code)
321-6267717
2.3 FACSIMILE (FAX) NUMBER (Include Area code)
321-3055983

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)
[X] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number: SBD135077

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, 1350 Piccard Drive, 4th Floor Rockville, MD 20850
[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) 03-Jul-2013

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

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)*

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)*		
RNK Products, Inc.	3004595287		
Division Name *(if applicable)*	Phone Number *(including area code)*		
	321.610.3980		
Street Address	FAX Number *(including area code)*		
8247 Devereux Drive, Suite 101	321.910.3979		
City	State / Province	ZIP/Postal Code	Country
Viera, FL 32940	FL	32940	USA
Contact Name			
Charles R. Abbruscato			
Contact Title	Contact E-mail Address		
CEO	abbruscato@rnkproducts.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

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

- ☐ Response to FDA correspondence:

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

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

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

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

- ☐ 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)*:

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	DQD	2		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	K102893	1	PCP/PC Telephonic Stethoscope	1	RNK Products, Inc.
2		2		2	
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

	Trade or Proprietary or Model Name for This Device		Model Number
1	PCP-USB Stethoscope	1	
2		2	
3		3	
4		4	
5		5	

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

1	2	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
DQD	21 CFR 870.1875	☐ Class I ☒ Class II
Classification Panel		☐ Class III ☐ Unclassified
Cardiovascular		

Indications *(from labeling)*

The RNK PCP-USB Stethoscope is intended to transmit auscultation sound data, whereby a clinician at one location on an IP network can listen to the auscultation sounds of a patient at a different location on the IP network with the signal carried on an IP connection between the two locations.

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: 3004595287	☒ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name: RNK Products, Inc.		Establishment Registration Number: 3004595287	
Division Name *(if applicable)*		Phone Number *(including area code)*: 321.610.3980	
Street Address: 8247 Devereux Drive, Suite 101		FAX Number *(including area code)*: 321.610.3979	
City: Viera	State / Province: FL	ZIP Code: 32940	Country: USA
Contact Name: Charles R. Abbruscato	Contact Title: CEO	Contact E-mail Address: abbruscato@rnkproducts.com	

☐ 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 *(i)*	
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	

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	IEC 60601-1	IEC/EN	Medical Electrical Equipment Part 1: General Requirement for Safety	3rd Edition	01/01/2005
2	IEC 60601-1-2	IEC/EN	EMC Immunity Requirements for Medical Electrical Equipment Part 1: General Requirements for Safety, 2. Collateral Standard – Electromagnetic Compatibility Requirements and Tests		01/01/2007
3					
4					
5					
6					
7					

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.

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

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RNK Products, Inc.

August 14, 2013

Food and Drug Administration
Center for Devices and Radiological Health
510(k) Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver spring, MD 20993-0002

Re: Premarket Notification for RNK Products' PCP-USB Stethoscope

Dear Sir or Madam:

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act 21 U.S.C. § 351(k), RNK Products, Inc. ("RNK") is submitting the enclosed premarket notification for RNK's PCP-USB Stethoscope, an electronic stethoscope. The PCP-USB Stethoscope is intended for use as a remote monitoring device, whereby a clinician at one location can listen to the auscultation sounds of a patient at a different location, with the signal carried over a data communication channel between the two locations. The PCP-USB Stethoscope is a Class II medical device pursuant to 21 C.F.R. § 870.1875, "Stethoscope."

The PCP-USB Stethoscope is substantially equivalent to other marketed devices that have received premarket clearance, specifically the RNK Products PCP/PC Stethoscope (K102893). As explained in greater detail in the attached submission, the PCP-USB Stethoscope has the same intended use and principles of operations and technological characteristics as a combination of the predicate PCP/PC Stethoscope. The differences of the PCP-USB Stethoscope from the predicate do not raise any new questions of safety or effectiveness. The eCopy of the submitted material is an exact duplicate of the paper copy.

We trust that the information in the enclosed 510(k) notice will be sufficient to enable the Food and Drug Administration ("FDA") to find that the PCP-USB Telephonic Stethoscope is substantially equivalent to the PCP/PC Stethoscope. Please direct any questions or requests for information concerning this submission to the undersigned at (321) 610-3980. Upon a finding of substantial equivalence, please send me a copy of the signed substantial equivalence letter by facsimile at (321) 610-3979.

Sincerely,

Charles R. Abbruscato
RNK Products, Inc.
8247 Devereux Drive, Suite 101
Viera, FL 32940
(321) 610-3980

PCP-USB Stethoscope 510(k) Premarket Notification Checklist

	ITEM	COMMENT
1.	Device trade or proprietary name	See 510(k) section II – RNK PCP-USB Stethoscope.
2.	Device common or usual name or classification name	See 510(k) section II – Electronic Stethoscope.
3.	Establishment registration number (only applies if establishment is registered)	See 510(k) section III. - 3004595287
4.	Class into which the device is classified	See 510(k) section IV - This device is a class II device, pursuant to 21 C.F.R. § 870.1875.
5.	Classification Panel	See 510(k) section IV - Cardiovascular Panel.
6.	Action taken to comply with Section 514 of the Act	See 510(k) section V - Not applicable - no performance standards developed and no applicable special controls.
7.	Proposed labels, labeling and advertisements (if available) that describe the device, its intended use, and directions for use	See Attachments 1 and 2.
8.	A 510(k) summary of safety and effectiveness or a 510(k) statement that safety and effectiveness information will be made available to any person upon request	See Attachment 11.
9.	For class III devices only, a class III certification and a class III summary	Not applicable - this device is a class II device.
10.	Photographs and engineering drawings of the device	See Attachment 6 for engineering drawings.
11.	The marketed device(s) to which equivalence is claimed including labeling and description of the device	See 510(k) section VII; Attachment 3.
12.	Statement of similarities and/or differences with marketed devices(s)	See 510(k) section VII: Attachment 4.
13.	Data to show consequences and effects of a modified device	Not applicable.
14.	Submitter's name and address	See 510(k) section XI.
15.	Contact person, telephone number and fax number	See 510(k) section XII.
16.	Representative/Consultant if applicable	Not applicable.
17.	Table of Contents with pagination	See 510(k) page iv.

18. Address of manufacturing facility/facilities and, if appropriate, sterilization site(s)	See 510(k) section III.
19. Comparison table of the new device to the marketed device(s)	See Attachment 4.
20. Action taken to comply with voluntary standards	See 510(k) section VIII.
21. Performance data	--
a. marketed device	--
1. bench testing	n/a
2. animal testing	n/a
3. clinical data	n/a
b. new device	--
1. bench testing	None.
2. animal testing	None.
3. clinical data	None.
22. Sterilization information	Not applicable.
23. Software Information	See Attachment 7.
24. Hardware information	Not applicable.
25. Is this device subject to issues that have been addressed in specific guidance document(s)?	No.
26. Indications for Use Statement	See 510(k) section XIV; Attachment 12.
27. Truthful and Accurate Statement	See 510(k) section XV; Attachment 13.
28. Other (specify)	None.

RNK Products

RNK PCP-USB Stethoscope

510(k) Premarket Notification

RNK Products, Inc.
8247 Devereux Drive
Suite 101
Viera, FL 32940
(321) 610-3980

TABLE OF CONTENTS

LIST OF ATTACHMENTS

I. INTRODUCTION

The purpose of this 510(k) notice is to obtain clearance from the Food and Drug Administration ("FDA") for RNK Products ("RNK") PCP-USB Stethoscope.

The only custom hardware element of the PCP-USB Stethoscope is a PCP-USB Chest Piece assembly that plugs into a USB port of a generic PC. (b) (4) [redacted] Operating power is derived from the 5v on the USB interface.

The sSOIP Anywhere program puts the digitized audio stream into IP communications format for transmission over an IP connection to another PC. A network server called the Telemedicine Communications Server (TMCS) is used to facilitate connections between Transmit End stations and Receive End stations through the use of industry standards called ICE, STUN and TURN. Network information on the users at the Transmit End stations and Receive End stations is entered by healthcare Providers into a Stethoscope User Data (SUD) server which then forwards that information to the TMCS. There may be multiple SUD servers each controlled by a separate healthcare Provider, but only one TMCS is needed to service connection requests from all of them. This network connection service working in conjunction with sSOIP Anywhere can be referred to by the trade name Auscultation Anywhere.

At the receive end of the IP connection, sSOIP Anywhere software on the receive end PC accepts the streaming audio signal and feeds it to the PC's audio circuitry where it is converted back to analog, amplified and presented to the Headset port. The audio stethoscope sounds can be heard at the Headset output port of the receive end PC.

The RNK PCP-USB Stethoscope with sSOIP Anywhere and the network service provided by the TMCS is substantially equivalent to the PCP/PC Stethoscope with sSOIP software.

II. NAME OF DEVICE

A. Trade or Proprietary Name: **RNK PCP-USB Stethoscope**

B. Common Name: **Electronic Stethoscope**

C. Classification Name: **Stethoscope**

(21 C.F.R. § 870.1875)

D. Product Code: **DQD**

III. ESTABLISHMENT REGISTRATION NUMBER AND ADDRESS OF MANUFACTURING FACILITY

Establishment Reg. No.: 3004595287

RNK Products
8247 Devereux Drive
Suite 101
Viera, FL 32940
Telephone: (321) 610-3980
Facsimile: (321) 610-3979

IV. DEVICE CLASSIFICATION/CLASSIFICATION PANEL

Pursuant to 21 C.F.R. §870.1875, FDA has classified electronic stethoscopes as Class II devices. Electronic stethoscopes are reviewed by the Cardiovascular Panel.

V. PERFORMANCE STANDARDS

No performance standards or special controls have been developed under Section 514 of the FDC Act for electronic stethoscopes.

VI. LABELING

Draft labeling for the PCP-USB Stethoscope is provided in **Attachment 1** of this submission. Draft promotional material for the PCP-USB Stethoscope is provided in **Attachment 2**.

VII. SUBSTANTIAL EQUIVALENCE

The RNK PCP-USB Stethoscope is substantially equivalent to the RNK PCP/PC Stethoscope (K102893). Labeling for the predicate device is provided in **Attachment 3** of this submission.

In summary, there are two areas of difference between the PCP-USB Stethoscope and the predicate PCP/PC Stethoscope – one area is hardware related and the other is network connectivity software related.

Hardware: (b) (4) [redacted]

(b) (4) [redacted]

Software: The sSOIP software with the PCP/PC Stethoscope could only make IP connections to static IP addresses and could not cross Network Address Translation (NAT) boundaries. In comparison, the sSOIP Anywhere software on the PC to which the PCP-USB is attached can use the services of the TMCS and Relay Server to establish IP connections across NAT boundaries.

(b) (4) [redacted]

(b) (4) [redacted]

The predicate software Streaming Stethoscope Over IP (sSOIP) used with the PCP/PC can only make IP connections to static IP addresses. The software with the PCP-USB includes an enhancement to sSOIP called **sSOIP Anywhere** software that working with the software on a network server called the Telemedicine Communications Server (TMCS), a Stethoscope User Data (SUD) Server and a Relay Server, can accomplish IP connections across Network Address Translation (NAT) boundaries.

The NAT feature is very common in most business facilities and homes because it allows many PC workstations with individual local IP addresses to share much fewer or even only one public IP address. When a PC accesses the Internet through the local network's router, the NAT feature in the router maps the internal IP address to the public IP address by assigning a port number to be used for that connection. Another PC accessing the Internet through the router at the same time would use a different port number which the router would keep track of. The NAT feature is important because it enables multiple PCs each with their own local IP address to

use the same public IP address for outgoing calls. However, this feature doesn't help for incoming calls trying to find a specific PC workstation on the local, internal network. On the contrary, it creates a barrier to incoming calls.

Fortunately, there are industry standards developed by the Internet Engineering Task Force to solve the NAT traversal challenge. The Interactive Connectivity Establishment (ICE) technique can work with the Session Traversal Utilities for NAT (STUN) standard and the Traversal Using Relay NAT (TURN) standard to reliably traverse NAT boundaries. STUN is used to create direct connections where possible and TURN is used to create relay connections where direct connections are not allowed (e.g. with symmetrical NATs).

The TMCS is used to facilitate connections between Transmit End stations and Receive End stations through the use of ICE, STUN and TURN. Network information on the users at the Transmit End stations and Receive End stations is entered into a Stethoscope User Data (SUD) Server that then forwards the information to the TMCS. There may be multiple SUD Servers each controlled by a separate healthcare provider, but only one TMCS is needed to service connection requests from all of them. No user auscultation data passes through the TMCS or SUD Server during an auscultation connection.

There are certain NATs that won't allow a direct connection to be established by TMCS. In those cases, the services of the TURN standard and a Relay Server are employed. The TMCS will indicate to the sSOIP-TX Anywhere at the transmit end and sSOIP-RX Anywhere at the receive end to connect to a Relay Server. Once that is accomplished the Relay Server will take the auscultation data stream received over the connection to the transmit end station and relay it onto the connection to the receive end station, thus establishing a relay connection.

It is important to note that however an IP connection is established - either direct using static IP addresses, direct using STUN or via relay using TURN and a Relay Server - the content of the auscultation data stream is unaltered and unaffected.

As explained in greater detail below, the PCP-USB Stethoscope has the same intended use and principles of operation and technological characteristics as the predicate device. **Attachment 4** contains a Substantial Equivalence Chart setting forth the similarities and differences between the PCP-USB Stethoscope and the predicate device. There are no new questions of safety or effectiveness.

A. Intended Use

The RNK PCP-USB Stethoscope and the PCP/PC Stethoscope predicate device are intended for use as remote auscultation monitoring devices, whereby a clinician at one location can listen to the auscultation sounds of a patient at a different location, with the signal carried over an IP data communication channel between the two locations.

B. Principles of Operation

The principles of operation can be broken down into three categories: the chest piece sensor technology, the signal processing technology and the communications technology.

(b) (4)

[redacted]

.

(b) (4)

[redacted]

The communications function performs two core tasks. First it converts the digital audio signal to a streaming format and puts the streaming signal into IP packets for transmission over an IP network. This streaming methodology is widely used for sending audio and video over the Internet. This function is identical for the predicate sSOIP used with the PCP/PC Stethoscope and for sSOIP Anywhere used with the PCP-USB Stethoscope.

The second core task is to set up an IP connection from the Transmit End station to the Receive End station then send the streaming data between the stations. The predicate sSOIP can only establish IP connections using static IP addresses and cannot traverse NAT boundaries. Using the connection facilitating services of the TMCS and Relay Server, as needed, sSOIP Anywhere can establish connections across NAT boundaries. Once a connection is established,

there is no difference in the data flow for an auscultation session with sSOIP Anywhere compared to one with sSOIP. Prior to a connection attempt, the network information on both the Transmit End station and the Receive End station must be entered into the SUD Server which forwards that information to the TMCS.

Typical operation of the PCP-USB Stethoscope is as follows:

1. At the patient's location, install the sSOIP Anywhere software on a PC connected to an IP network and configure it as a Transmit End station. Finish the installation of the transmit end station by plugging the PCP-USB Chest Piece assembly into a USB port of the PC. Open the sSOIP-TX Anywhere program and log in as a user already entered into the SUD Server.

2. At the clinician's location, install the sSOIP Anywhere software on a PC connected to an IP network and configure it as a Receive End station. Plug a headset into the Headset jack. Open the sSOIP-RX Anywhere program and log in as a clinician user already entered into the SUD Server.

Both the patient and clinician are now logged in to the TMCS, thus establishing what is referred to as presence.

3. On the sSOIP-RX Anywhere window at the clinician's location, the clinician would select the patient he/she wishes to make a connection to from the "Connect To" drop down list box. The clinician would click on the Connect button to initiate an IP connection to that party. This request goes to the TMCS, which then send a message to the patient station indicating that there is a call request.

4. On the sSOIP-TX Anywhere window at the patient's location, a window will pop up indicating an incoming call. The patient would click on the button to answer the call. This goes to the TMCS, which then facilitates a connection between the two parties. The connection may be direct or through a Relay Server. The clinician then guides the patient in the placement of the chest piece over the desired locations on the body. The audio level to the headset may be adjusted using the PC's Volume control feature.

C. Technological Characteristics

As described above and shown in the substantial equivalence chart at **Attachment 4**, the PCP-USB Stethoscope has the same operational technological characteristics as the predicate PCP/PC Stethoscope. (b) (4) [redacted]

(b) (4) [redacted]

One of the functions both sSOIP Anywhere and the predicate sSOIP use is the same technology is to convert the digital audio signal to a streaming format and put it into IP packets for transmission over an IP network. This streaming methodology is widely used for sending streaming audio and video over the Internet.

NAT traversal is an enhanced capability of the PCP-USB Stethoscope compared to the PCP/PC Stethoscope. The software technology used to accomplish NAT traversal includes ICE, STUN and TURN networking capabilities commonly used in Internet communications for video conferencing and audio (VOIP) applications. While certain code or program routines may be different between Internet applications or instantiations for streaming data, they all use technology from the body of technology used in Internet networking and communications. **Attachment 7** provides detail on the software used with the PCP-USB Stethoscope.

D. Conclusion

Based on the intended use, principles of operation and technological characteristics, the RNK PCP-USB Stethoscope does not raise any new questions of safety or effectiveness.

VIII CERTIFICATION OF COMPLIANCE WITH STANDARDS

As described at **Attachment 8**, the RNK PCP-USB Stethoscope complies with the appropriate tests/standards and has passed the following tests:

- IEC60601-1:2005 3rd Edition Medical Electrical Equipment Part 1: General Requirement for Safety
- EN60601-1-2, 2007/03, EMC Immunity Requirements for Medical Electrical Equipment Part 1: General Requirements for Safety, 2. Collateral Standard – Electromagnetic Compatibility Requirements and Tests
- EN61000-4-2 Part 2: Electrostatic Discharge Requirements
- EN61000-4-3 Part 3: Radiated Electromagnetic Field Requirements
- EN61000-4-4 Part 4: Electrical Fast Transient/Burst Requirements

- EN61000-4-6 Part 6: Conducted Immunity Requirements
- EN61000-4-8 Part 8: Power Frequency Magnetic Field Requirements
- EN6100-4-11 Part 11: Voltage Dips, Interrupts, and Fluctuations Requirements

A signed certification of compliance is contained in **Attachment 9**. Charles R. Abbruscato, CEO of RNK Products has signed the certification.

IX HAZARD ANALYSIS

The RNK PCP-USB Stethoscope is comprised of a chest piece assembly, software that runs locally on a PC and software that runs on certain network communications servers. Should any function fail whether it be the chest piece assembly, hardware on the PC, a software function on the PC, the PC itself, networking services, or the IP network (i.e. the Internet) connecting the transmit end PC to the receive end PC, the RNK PCP-USB Stethoscope could not be used for an auscultation exam. Denial of the use of the RNK PCP-USB Stethoscope will not cause injury to a patient. Clinicians are trained in the use of stethoscopes and would recognize the failure of the equipment. There is no safety hazard presented by the RNK PCP-USB Stethoscope.

Attachment 5 provides a risk analysis for the PCP-USB Stethoscope. Following is a hazard chart summary.

Hazard Chart for PCP-USB Stethoscope

Undesirable Effect	Potential Cause	Mode of Control	Minimum Requirements/ Description of Control
Electrical Safety	The internal operating voltage shorts to part of the case that the user can touch	Design	By satisfying the safety requirements of EN 60601-1-1, no part that the user can touch will have a hazardous voltage level.
Electrical EMI and EMC	Electro-magnetic interference to the devoice or by the device	Design	By satisfying the EMI and EMC requirements of EN 60601-1-2, such risks are negligible.
Adverse Biocompatibil-ity Reaction	Unsafe materials used for the PCP-USB chest piece (the only physical component other than the generic PC)	Design	The PCP-USB chest piece is made from the identical safe materials as the previously cleared PCP/PC and Piezo Electronic Stethoscopes.
Inability to use device because of hardware or component failure	Failure of a hardware component inside the PCP-USB chest piece or failure of a hardware component in the PC or server running PCP-USB Stethoscope software.	Clinical Training/ Operation Instructions	Clinicians are trained in the use of stethoscopes and would recognize the failure of the equipment. The PCP-USB Stethoscope is intended to be used to listen to auscultation sounds remotely as a supplement to in-person care. Should a clinician not be able to conduct the remote auscultation and feel that an auscultation exam is needed, the clinician would instruct the person to see a clinician in person.
Inability to use device because of software failure	Failure of a PCP-USB Stethoscope software component including: • Inability to process analog audio signal at the patient end. • Inability to process digitized audio signals at the patient end. • Inability to transport digitized signals from the patient end location to the clinician end location. • Inability to process digitized audio signals at the patient end. • Inability to process analog audio signal at the patient end.	Clinical Training/ Operation Instructions	Clinicians are trained in the use of stethoscopes and would recognize the failure of the equipment. The PCP-USB Stethoscope is intended to be used to listen to auscultation sounds remotely as a supplement to in-person care. Should a clinician not be able to conduct the remote auscultation and feel that an auscultation exam is needed, the clinician would instruct the person to see a clinician in person.
Unauthorized Use	Non-authorized person using the stethoscope	Design	No physical harm can come to someone using the stethoscope.
Misuse by User	Clinician fails to use the stethoscope properly	Clinical Training/ Operation Instructions	Clinicians are trained in auscultation as part of their clinical education. The PCP-USB Stethoscope presents the same auscultation sounds as a traditional acoustic stethoscope, but amplified. The Operation Instructions informs the clinician and patient how to use the PCP-USB Stethoscope.

X. 510(K) SUMMARY

The 510(k) summary for the RNK PCP-USB Stethoscope is provided in **Attachment 11**.

XI. SUBMITTER'S NAME AND ADDRESS

RNK Products
8247 Devereux Drive
Suite 101
Viera, FL 32940
Telephone: (321) 610-3980
Facsimile: (321) 610-3979

XII CONTACT PERSONS AND TELEPHONE/FACSIMILE NUMBERS

Mr. Charles R. Abbruscato
RNK Products
8247 Devereux Drive
Suite 101
Viera, FL 32940
Telephone: (321) 610-3980
Facsimile: (321) 610-3979

XIII. CONFIDENTIALITY

RNK Products, Inc. considers information on the RNK PCP-USB Stethoscope to be confidential commercial information. 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 is trade secret or confidential commercial 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 you consult with the company as provided in 21 C.F.R. § 20.45 before making any part of this submission publicly available.

XIV. INDICATIONS FOR USE STATEMENT

The company's Indications for Use Statement for the RNK PCP-USB Stethoscope is provided in **Attachment 12**.

XV. TRUTHFUL AND ACCURATE STATEMENT

A certification of the truthfulness and accuracy of this submission, as required by 21 C.F.R. § 807.87(j), is provided in **Attachment 13**. Charles R. Abbruscato, CEO of RNK Products, Inc. has signed the certification.

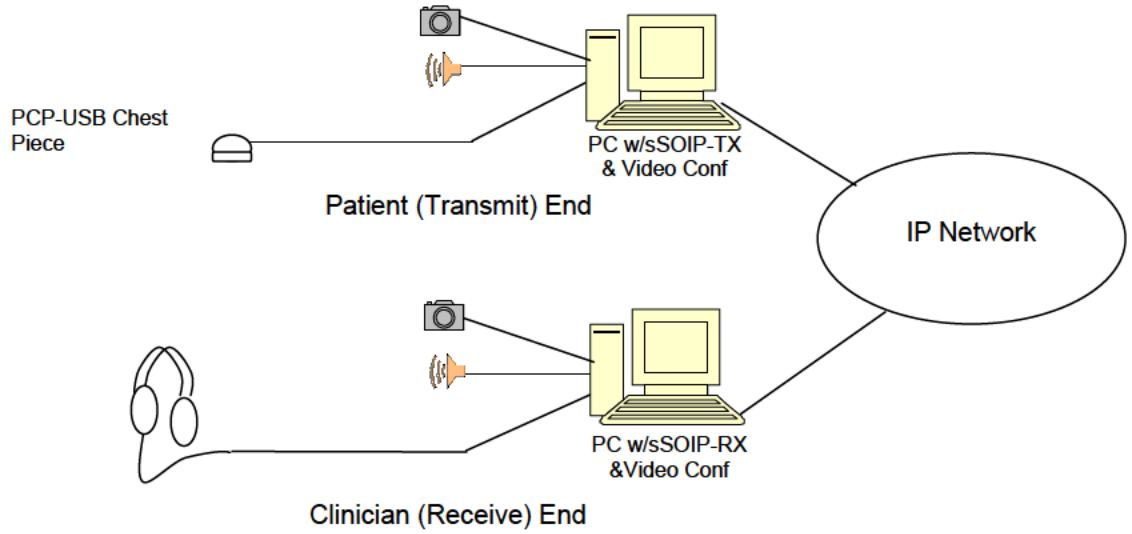
PCP-USB Stethoscope with sSOIP-TX Anywhere
Patient User Operation Instructions

Rev 1.0

This document provides the Patient operating instructions for the PCP-USB Stethoscope with sSOIP-TX Anywhere Software.

1. Introduction

The typical application for a telephonic stethoscope is in conjunction with a video conference session for telemedicine. The stethoscope sounds will go over a separate connection from the video conferencing.



The PCP-USB Chest Piece can be used with a generic PC on an IP network (e.g. the Internet) running (sSOIP-TX Anywhere software. The sSOIP-TX Anywhere client software operates on the transmit (Patient) end of an sSOIP Anywhere network remote auscultation connection. When the Patient user at the sSOIP-TX Anywhere station logs in to the Telemedicine Communications Server (TMCS), the TMCS sends a list of all the authorized sSOIP Anywhere users that have logged in to the consulting Clinicians at the sSOIP-RX Anywhere stations. From that list, the Clinicians can request a connection to any party on the list. The TMCS would then facilitate that connection. The Clinician at the receive end is in control of the connection and will Start or Stop the stethoscope exam from the receive end PC.

The SOIP-TX Anywhere program also provides the capability for recording stethoscope sound streams and playing them back.

The typical application for a telephonic stethoscope is in conjunction with a video conference session for telemedicine. The stethoscope sounds will go over a separate connection from the video conferencing.

2. Installation, Setup and Login

Installation of the PCP-USB Stethoscope is comprised of plugging the PCP-USB Chest Piece into the Microphone port of the PC and installing the sSOIP-TX Anywhere program (following the sSOIP Anywhere Installation Instructions).

Open the sSOIP-TX Anywhere program using the desktop icon or directly from the folder with the sSOIP-TX Anywhere executable file. The main window shown in Figure 1 will display when the program is opened.

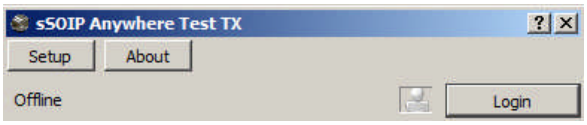


Figure 1: Main Window for sSOIP-TX.

Clicking on the Setup button brings up a new window for selecting the stethoscope input source, audio compression and adjustment of the microphone level shown in Figure 2. Typically, the features under Setup will have been set by the installer during installation of sSOIP-TX Anywhere.

By clicking on the Setup button, a Stethoscope Properties window will appear and give the user at the transmit end the following options

Stethoscope input: This is a drop down list showing the available audio inputs. If there is more than one, be sure that the input to which the PCP-USB is connected is selected.

Audio Compression: This is a drop down list from which you can select u-Law PCM (64 Kb/s), ADPCM (32 Kb/s), Speex or Opus. Note that sampling is always at 8 K samples per second.

Mic level: Use the slider to adjust the microphone level. Note that applying to much Mic gain can cause distortion of the stethoscope data stream.

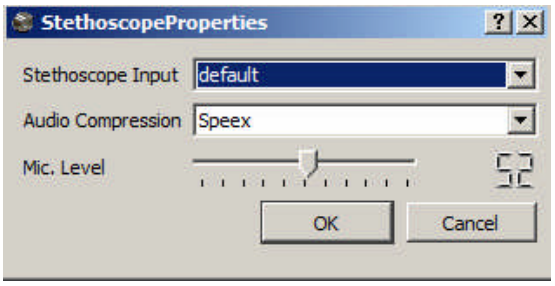
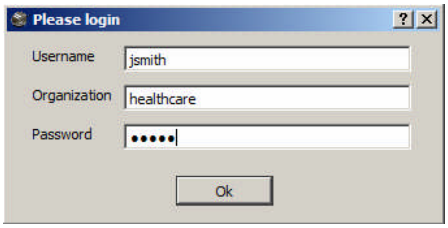


Figure 2: sSOIP-TX Stethoscope Properties Window

Typically, the features under Setup will have been set by the installer during installation of sSOIP-TX Anywhere. If there are any questions, contact the sSOIP-TX Anywhere installer for assistance.

The Patient must Log in to the TMCS by clicking on the Login box which will bring up the login screen shown in Figure 3.



Type in your username, organization and password. Make sure they are exactly the same as provided by your Administrator. Note that they are case sensitive.

Figure 3: Login Window

3. Auscultation Sessions

Before starting an sSOIP Anywhere auscultation session, the video conferencing session would be established to enable the Patient and Clinician to see and talk to each other. The Clinician at the receive end initiates stethoscope session following the sSOIP-RX Anywhere Operation Instructions.

The Patient at the sSOIP-TX Anywhere end would be prompted to accept the connection (See Figure 4). Click on Yes to enable the connection. Then the clinician at the receive location would be able to hear the sounds coming from the PCP-USB Chest Piece.

The Clinician would conduct the auscultation exam by directing the Patient over video to place the PCP-USB Chest Piece in the desired locations and listening to the sounds. When the auscultation session is over, the Clinician or Patient would Hang Up to end the connection.

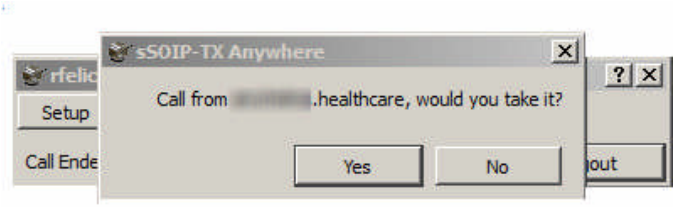


Figure 4: Accepting a call on Patient / transmit end

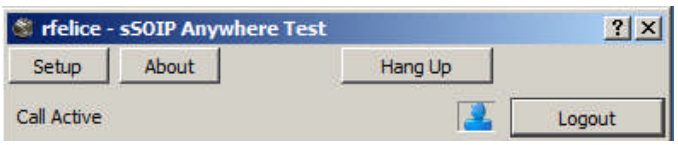


Figure 5: Main window for sSOIP-TX with an active call connection

4. Cleaning, Preventive Inspection, Maintenance and Calibration

The PCP-USB Chest Piece requires no preventive inspection, no preventive or routine maintenance, and it does not have to be calibrated.

The PCP-USB Chest Piece is not a sterile device and does not require sterilization or disinfection. It can be cleaned, as deemed necessary, by wiping with a moist cloth, alcohol or a sanitizing towelette.

5. Trouble Shooting

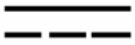
If a connection cannot be established or if no stethoscope sounds are heard at the receiving end after the connection is established, check the following:

- Ensure the PCP-USB Chest Piece is fully plugged into a UCB port of the PC.
- Ensure the transmit end sSOIP-TX Anywhere application is open and ready to transmit.
- Ensure the transmit end PC is connected to the internet.

Service personnel from the company that provided the PCP-USB Chest Piece and installed the sSOIP-TX software may be needed to assist in resolving any PCP-USB Chest Piece failures or sSOIP-TX Anywhere software failure.

6. Safety

This product meets the safety requirements of IEC/EN 60601-1 Medical Electrical Equipment Part 1: General Requirements for Safety for Type BF protection using a power source providing 5 vdc. The device providing power should satisfy IEC 60950.

Vdc: 

Type BF applied part: 

Class II protection against electrical shock: 

This product is classified as medical electronic equipment and thus needs special precautions regarding EMC and needs to be installed in accordance with the instructions in this Manual. Portable and mobile RF communications equipment can affect medical electrical equipment.

If interference from other equipment is heard from the PCP-USB during a stethoscope session, the problem may be resolved by relocating other equipment so that it is farther from the PCP-USB. The provider of the PCP-USB Chest Piece will assist in resolving any interference problems. If the interference problems cannot be resolved and the interference does not permit auscultation sounds from being heard, then the PCP-USB should not be used in that location.

The PCP-USB Stethoscope Chest Piece is intended for use within the electromagnetic environment specified below. The user of the PCP-USB Chest Piece should assure that it is used in such an environment. Portable and mobile RF communications equipment should be used no closer to any part of the PCP-USB Chest Piece than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

This product may be used in continuous operation.

This product is not a defibrillation-proof applied part. This product is not suitable for use in the presence of a flammable anesthetic mixture with air or with continuous oxygen or nitrous oxide.

Normal use for this product is at an ambient temperature range of +5° to +40°C, a relative humidity range of 15% to 93%, an atmospheric pressure range of 700 hPa to 1,065 hPa. It may be transported and stored at temperatures from -25°C to +70°C and relative humidity of up to 93%.

The expected life of this device exceeds five years. It contains electronic components and disposal of it should in accordance with all federal and local laws.

Local laws may take priority over the above requirements. If in doubt, consult your local representative or the technical service department.

WARNING: No modification of this equipment is allowed.

Caution: Federal law restricts this device for sale by or on the order of a (licensed healthcare practitioner).

For questions or comments in Europe, contact EC Authorized Representative Emergo Europe, Molenstraat 15, 2513 BH, The Hague, The Netherlands.

In North America, contact RNK Products, Inc., 8247 Devereux Drive, Viera, FL 32940.

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Molenstraat 15
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The Netherlands

Label for PCP-USB Chest Piece

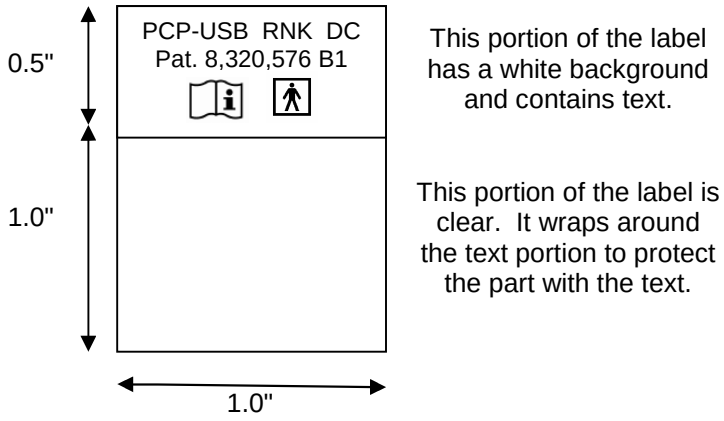
June 11, 2013
Rev 1.0

The PCP-USB Chest Piece is a chest piece with a permanently attached cable. There is no convenient surface on the PCP-USB Chest Piece to apply a label. (This is a similar situation for the PCP Chest Piece and the PCP-USB1 Chest Piece.) For these products, a small water resistant label is wrapped around the cable to identify the product. Other pertinent information is in the Operator's Manual.

Label material: Polyester with adhesive backing.
Style: Wrap-around, self-laminating.

Label Spec

CL10A Label from Cable Labels USA



PCP-USB is the product name.
RNK denotes RNK Products, Inc.
DC is the two character hexadecimal date code denoting month and year of manufacture.

telehealth technologies

PCP-USB Stethoscope Over IP Networks

PCP-USB Chest Piece and sSOIP Anywhere Software and Auscultation Anywhere Networking

PCP-USB Chest Piece:

- Single piece assembly.
- 20 Hz – 2,000 Hz bandwidth.
- Plugs into USB port of PC.

PCP-USB Chest Piece

PC with sSOIP Anywhere

IP Channel:

- Traverses NAT Boundaries
- AES 128-Bit encryption.
- UDP protocol.

sSOIP-TX - Transmit End:

- Creates packets for IP channel.
- Accepts IP connection.
- Selection of audio filters for monitoring stethoscope session.

IP Network

PC with sSOIP Anywhere

Telemedicine Communications Server

sSOIP-RX - Receive End:

- Selection of patient (transmit end).
- Initiates IP connection.
- Converts incoming digital signal to analog.
- Selection of audio filters for monitoring stethoscope session.
- Record and playback stethoscope sessions.

Manufactured by RNK Products, Inc.

8247 Devereux Drive, Suite 101, Viera, FL 32940 321.610.3980 www.rnkproducts.com

telehealth technologies

RNK Products, Inc.
Phone 321-610-3980
www.rnkproducts.com

Auscultation Anywhere

A telemedicine cloud solution for traversing NAT boundaries.

A low cost cloud solution for securely streaming stethoscope sound over IP, allowing a Value Added Reseller to enter new markets such as the home or work place.

Cloud Technology

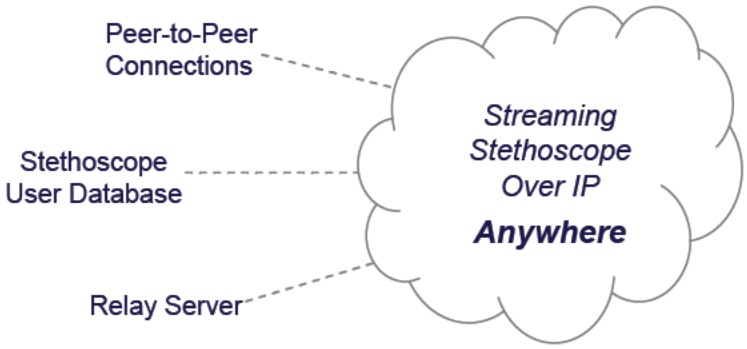
High Performance

Cost Effective

Recurring Revenue

Global Compliance

Advancing Auscultation



The PCP-USB Stethoscope is designed specifically for telemedicine and has the high performance expected from high-end stethoscopes.

Seamlessly connecting clinicians to patients, the Auscultation Anywhere solution opens up possibilities in the telehealth industry once thought impossible due to cost and technology.

Features:

User friendly. The patient only has to plug the stethoscope chest piece into the computer.

Convenience for the clinician. Only headphones are needed. Easy volume adjustments and selectable audio filters aid in diagnosing.

HIPPA compliant. Encrypted connections. Patient data can reside solely on the health care provider's network.

Easily integrates. With little effort, the sSOIP software could be integrated with the telemedicine workstation.

PCP-1 Stethoscope Operation Instructions and sSOIP-TX Software User Manual

Rev 4.0.a

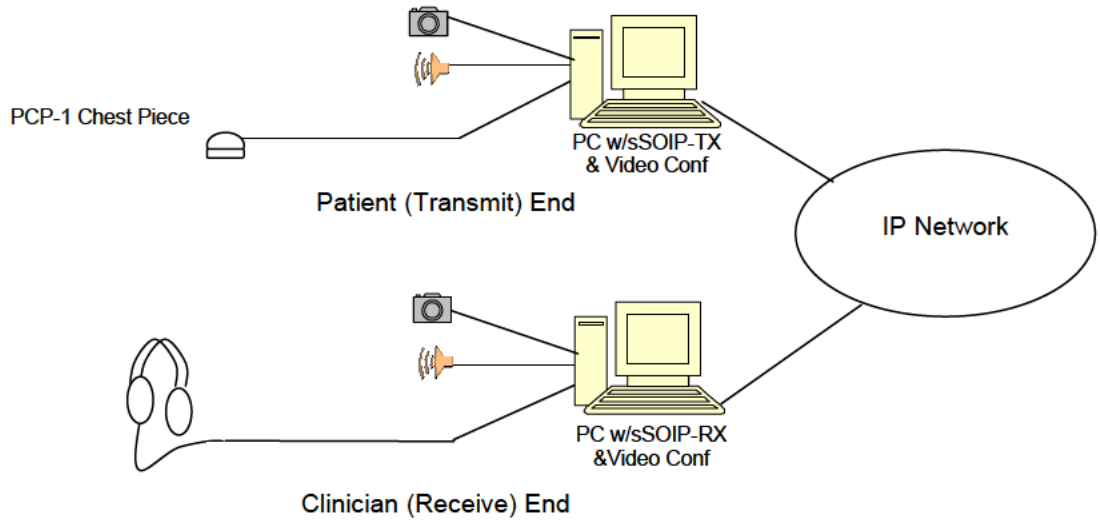
This document provides the patient operating instructions for the PCP-1 Stethoscope with sSOIP Software.

I. Introduction

The PCP-1 Chest Piece can be used with a generic PC on an IP network (e.g. the Internet) running streaming Stethoscope Over IP (sSOIP) software to establish a communications channel between the two sites. This provides remote auscultation between a patient at one location and a clinician at another location.

The clinician at the receive end is in control of the connection and will Start or Stop the stethoscope exam from the receive end PC. When the clinician clicks on Connect, an IP connection between the two PCs will be established. When Disconnect is clicked, the exam stops and the connection breaks so that no stethoscope data is transmitted.

The typical application for a telephonic stethoscope is in conjunction with a video conference session for telemedicine. The stethoscope sounds will go over a separate connection from the video conferencing.



II. Installation and Setup

Installation of the PCP-1 Stethoscope is comprised of installing the sSOIP-TX program (following the sSOIP Installation Instructions) and plugging the PCP-1 Chest Piece into the Microphone port of the PC.

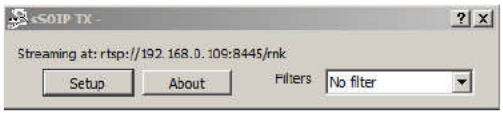


Figure 1: Main Window for sSOIP-TX.

Open the SOIP-TX program using the desktop icon or directly from the folder with the sSOIP-TX executable file. The main window for transmit shown in Figure 1 will display when the program is opened.

Clicking on the Setup button brings up a new window for selecting the stethoscope input source, the port assignment, adjustment of the microphone level, selecting Local Test mode and QoS dialog box as shown in Figure 2.

Stethoscope input: The sSOIP-TX program will detect the PCP-1 Chest Piece and display the stethoscope input sources This is a drop down list showing the available audio inputs. If there is more than one, be sure that the input to which the PCP-1 is connected is selected.

Mic level: Use the slider to adjust the microphone level. Note that applying to much mic gain can cause distortion of the stethoscope data stream.

Port: The sSOIP-RX must know and use the IP Port specified for use by sSOIP-TX. Port 8445 is used as default.

Local test: Selecting this check box puts sSOIP-TX into local loopback mode so that whatever is presented to the Mic input port is fed to the local speaker port. This enables convenient testing of the PCP-1 chest piece and sSOIP-TX signal processing. When in local test mode, sSOIP will not accept connection request.

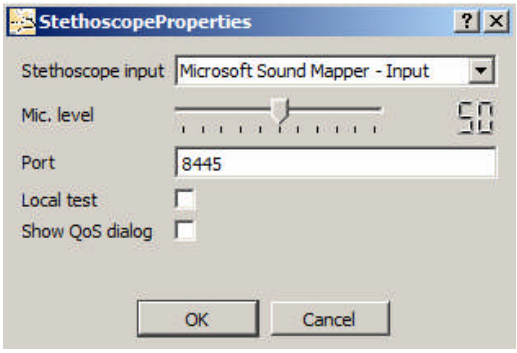


Figure 2: Setup Window sSOIP-TX.

Show QoS dialog: Selecting this check box causes a QoS TX dialog box to be displayed showing several performance measures. A key field related to the CODEC selected is the InstantBitRate showing the bit rate in Bytes per second. This should be used only by your Information Technology representative for IT purposes.

If QoS Dialog box is checked, the window in Figure 3 will open up and remain attached to the right of the main window at all times:

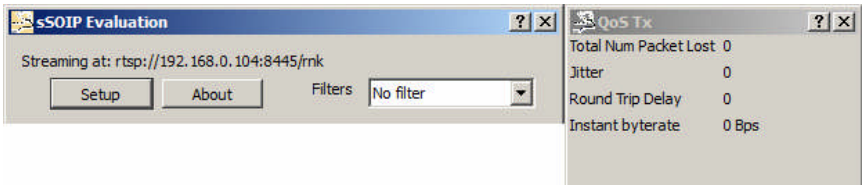


Figure 3: QoS TX Dialog Box.

III. Operation

First the video conferencing session would be established to enable the patient and clinician to see and talk to each other. Then the communications channel for the stethoscope session would be set up from the clinician end (receive end) following the sSOIP-RX Operation Instructions. At that point, the clinician at the receive location would be able to hear the sounds coming from the PCP-1 Chest Piece.

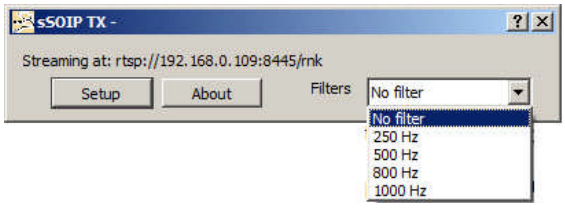


Figure 4: Main Window sSOIP-TX. Filter Selection.

While a connection is established, the user at the transmit end will be able to hear the stethoscope sound stream at the local headset port and will be able to select an audio low pass filter for local listening.

The clinician would conduct the auscultation exam by directing the patient over video to place the PCP-1 Chest Piece in the desired locations and listening to the sounds. When the auscultation session is over, the clinician would take down and end the connection of the communications channel. The communications channel set up and take down is controlled from the receive end by the clinician.

IV. Cleaning, Preventive Inspection, Maintenance and Calibration

The PCP-1 Chest Piece requires no preventive inspection, no preventive or routine maintenance, and it does not have to be calibrated.

The PCP-1 Chest Piece is not a sterile device and does not require sterilization or disinfection. It can be cleaned, as required, by wiping with a moist cloth, alcohol or a sanitizing towelette.

V. Trouble Shooting

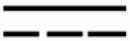
If an IP connection cannot be established or if no stethoscope sounds are heard at the receiving end after the IP connection is established, the first step should be to verify that the IP connection was properly setup. Service personnel from the company that provided the PCP-1 Chest Piece may be needed to assist in checking the following:

- Insure the transmit end sSOIP-TX application is open and ready to transmit.
- Insure the transmit end PC is connected to the IP network and can access the IP network.
- Insure there is a License File (ending in .lic) in the same directory as the sSOIP-TX program.
- Insure the assigned IP address and port number of the transmit end is properly entered into the received end sSOIP-RX application.
- Insure the receive end PC is connected to the IP network and can access the IP network.
- Insure there is a License File (ending in .lic) in the same directory as the sSOIP-RX program.
- If patient on the Transmit end can hear stethoscope sounds and they are not supposed to, please refer to the sSOIP-TX Installation Instructions.
- If patient on the Transmit end does not hear stethoscope sounds and they should, please refer to the sSOIP-TX Installation Instructions.
- Check for a failed PCP-1 Chest Piece by testing it in Local Mode (see Section II.)
- Check for a failed PCP-1 Chest Piece by substituting it with a replacement PCP-1 Chest Piece.
- Check for an improperly operating sSOIP-TX or sSOIP-RX by reloading it.

In addition to using the Local Test mode of sSOIP-TX, operation of the PCP-1 Chest Piece itself can be verified on the local PC by going to the Sound window in Control Panel to set the Microphone signal to be fed to the local Speaker. After doing that and setting the volume levels to a nominal setting, if sounds from the PCP-1 Chest Piece are heard on the Speakers, then the PCP-1 Chest Piece is working properly. If the PC local audio setup is correct and sounds are not heard from the PCP-1 Chest Piece, then the PCP-1 Chest Piece may be faulty. Contact your provider of the PCP-1 Chest Piece for assistance and product resolution.

VI. Safety

This product meets the safety requirements of EN 60601-1 Medical Electrical Equipment Part 1: General Requirements for Safety for Type BF protection using a power source providing 2 - 5 vdc. The device providing power should satisfy IEC 60950.

Vdc:  Type BF applied part:  Class II protection against electrical shock: 

This product meets the EMC Emissions and Immunity requirements of EN 60601-1-2 Medical Electrical Equipment Part 2 Collateral Standard: Electromagnetic Compatibility Requirements and Tests:

This product is classified as medical electronic equipment and thus needs special precautions regarding EMC and needs to be installed in accordance with the instructions in this Manual. Portable and mobile RF communications equipment can affect medical electrical equipment.

If interference from other equipment is heard from the PCP-1 during a stethoscope session, the problem may be resolved by relocating other equipment so that it is farther from the PCP-1. The provider of the PCP-1 Chest Piece will assist in resolving any interference problems. If the interference problems cannot be resolved and the interference does not permit auscultation sounds from being heard, then the PCP-1 should not be used in that location.

The PCP-1 Stethoscope Chest Piece is intended for use within the electromagnetic environment specified below. The user of the PCP-1 Chest Piece should assure that it is used in such an environment. Portable and mobile RF communications equipment should be used no closer to any part of the PCP-1 Chest Piece than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Immunity Test	IEC 60601 Test Level	Electromagnetic Environment Recommended Separation Distance
Conducted RF IEC 61000-4-6	3 Vrms 150 KHz to 80 MHz	d = [3.5/3V]√P
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	d = [3.5/3V]√P for 80 MHz to 800 MHz d = [7.0/3V]√P for 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts according to the manufacturer and d is the recommended separation in meters. Interference may occur in the vicinity of equipment marked with the antenna symbol.

Antenna Symbol

This product may be used in continuous operation.

This product is not a defibrillation-proof applied part. This product is not suitable for use in the presence of a flammable anesthetic mixture with air or with continuous oxygen or nitrous oxide.

Normal use for this product is at an ambient temperature range of +10° to +40°C, a relative humidity range of 30% to 75%, an atmospheric pressure range of 700 hPa to 1,065 hPa. It may be transported and stored at temperatures from 0°C to 50°C and relative humidity of 10% to 95%.

The device contains electronic components and disposal of it should in accordance with all federal and local laws.

Local laws may take priority over the above requirements. If in doubt, consult your local representative or the technical service department.

Caution: Federal law restricts this device for sale by or on the order of a (licensed healthcare practitioner).

For questions or comments in Europe, contact EC Authorized Representative Emergo Europe, Molenstraat 15, 2513 BH, The Hague, The Netherlands.

In North America, contact RNK Products, Inc., 8247 Devereux Drive, Viera, FL 32940.

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Molenstraat 15
2513 BH, The Hague
The Netherlands

sSOIP-RX Software
Operation Instructions
for use with PCP-1 Stethoscope

Rev 2.0

I. Introduction

The PCP-1 Stethoscope can be used with a generic PC on an IP network (e.g. the Internet) running streaming Stethoscope Over IP (sSOIP-TX software at the transmit end and sSOIP-RX software at the receive end) to establish a communications channel between the two sites. This provides remote auscultation between a patient at one location and a clinician at another location.

The clinician at the receive end is in control of the connection and will Start or Stop the stethoscope exam from the receive end PC. When the clinician clicks on Connect, an IP connection between the two PCs will be established. When Disconnect is clicked, the exam stops and the connection breaks at the transmit end so that no stethoscope data is sent over the IP network.

The SOIP-RX program also provides the capability for recording stethoscope sound streams and playing them back.

II. Installation

Installation of the sSOIP-RX should be completed following the directions provided in the sSOIP Software Installation Instructions.

III. Setup

Figure 1 shows the main sSOIP-RX screen. From this screen the user can access the address book, initiate and terminate connections, start and stop recordings, access the recorded stethoscope files and apply filters to the audio presented to the headset port.

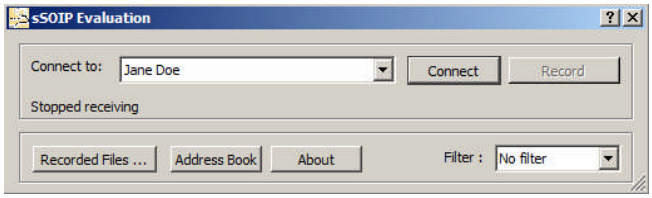


Figure 1: Main Screen for sSOIP-RX

A. IP Address Book

Since the receive end (RX) initiates all connections, it is necessary to know the IP address of the transmit end (TX). Multiple transmit end locations are handled through the IP Address Book, which allows the creation and storage of a list of IP addresses where the transmit end PCP-1 Stethoscope stations are located. Open the IP Address Book by clicking on the Address Book button.

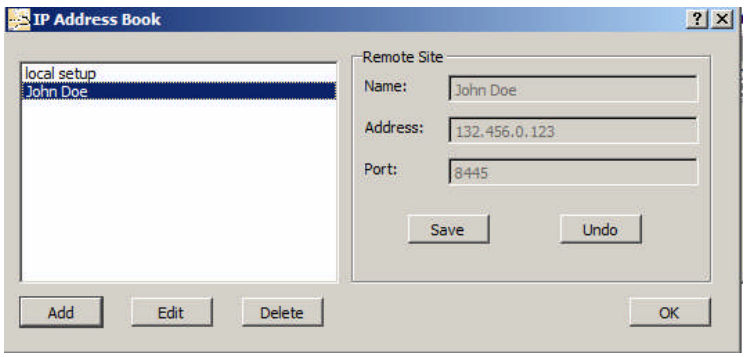


Figure 2: Address Book

To add a new location, click on Add, then enter a user friendly name you want to give for that location, the IP address and the port number. You can then either Save the address information or Undo it. Figure 2 shows Remote Station 2 in the IP Address Book.

An IP address can be edited by clicking on the name in the box on the left to highlight it, then clicking on Edit. Changes can be saved with Save or cancelled with Undo.

The sSOIP-RX must know and use the IP Port specified for use by sSOIP-TX. Port 8445 is used as the default in the TX.

IV. Operation

A. Receiving Stethoscope Sound Stream

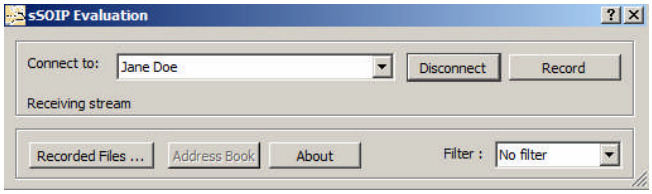


Figure 3: Main Screen while Receiving Data

Connections are initiated from the receive end where the consulting clinician is located. In the main screen, select a patient location by clicking on the down arrow in the "Connect to" list box, then select the desired patient location. (If the desired patient location is not on the list, then go back to the Main screen and use the Address Book to enter the information for the desired patient location.) After selecting the patient location, click on the Connect button to initiate the IP connection. Once the connection is made, the Status will change to Receiving Stream as shown in Figure 3. If a connection cannot be made, the connection attempt will time out and Status will return to readv.

While a connection is established, the clinician at the receive end can select an audio low pass filter as shown in figure 4 for local listening.

The clinician would conduct the auscultation exam by directing the patient to place the PCP-1 Chest Piece in the desired locations and listening to the sounds. As described in the next section, the clinician can record the stethoscope sound stream.

When the auscultation session is over, the clinician would take down the communications channel by clicking on the Disconnect button.

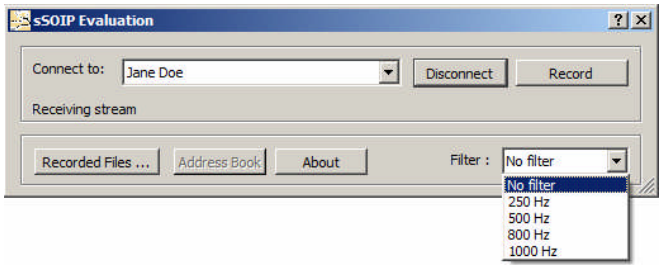


Figure 4: Selecting a Filter

B. Recording Stethoscope Sounds

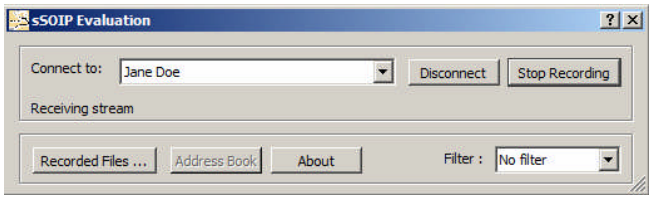


Figure 5: Main Screen while Recording Data

While sSOIP-RX is receiving stethoscope data, click on Record to start recording. When recording, the Record button changes to Stop Recording as shown in Figure 5.

To stop recording, Click on the Stop Recording button. A new screen will pop up to allow the recording to be saved. Figure 6 shows the screen with Play Time and Creation Date entered automatically by sSOIP-RX.

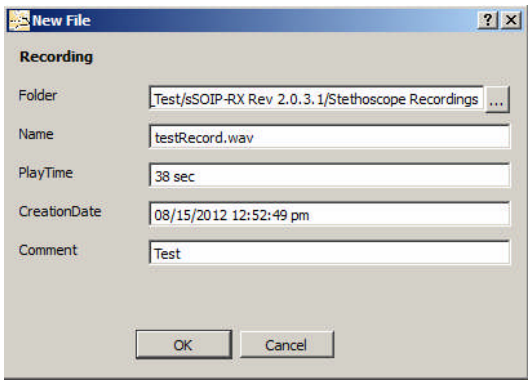


Figure 6: Adding a New Stethoscope File

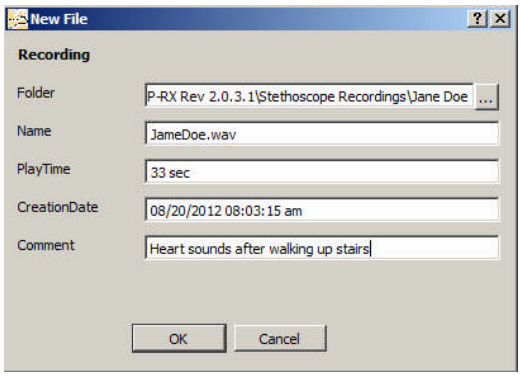


Figure 7: Example of New Stethoscope File

Click on the fields next to Name and Comment to enter the patient's name and a comment, respectively. Click on the field next to Folder, and then click on the down arrow to display the list of folders available. Figure 7 shows an example where "Jane Doe" was entered in the Name field and "Heart sounds after walking up stairs" was entered in the Comment field. There is the opportunity to create a new folder through this window.

Clicking on the OK button saves the file, closes the window and goes back to the Main window as shown in Figure 1.

When the stethoscope session is over, the clinician would click on Disconnect to terminate the connection.

C. Stethoscope Files

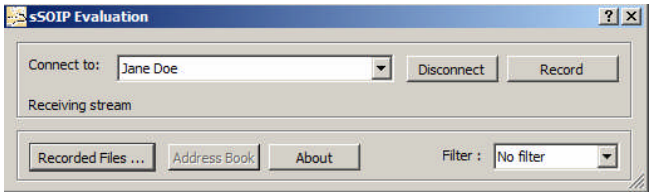


Figure 8: sSOIP Main window to access Recorded Files

To access the stethoscope file management functions or to playback a file, click on the Recorded Files button.

To add a new folder for a patient, click on the New Folder button, then next to Name and Description fields enter appropriate information on that patient. Figure 9 shows an example where a Folder for Jane Doe that was previously created.

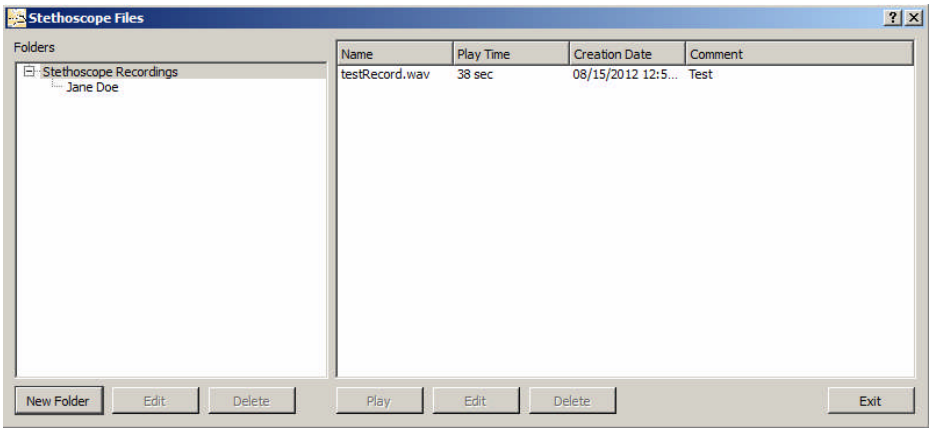


Figure 9: Stethoscope Files Window

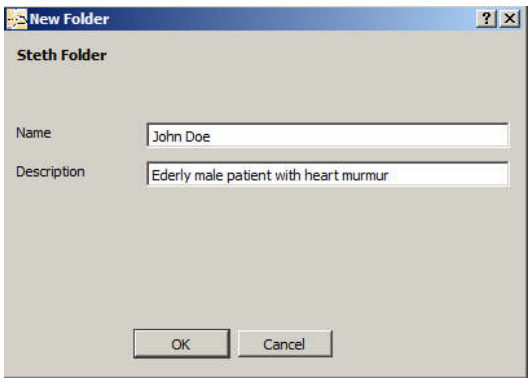
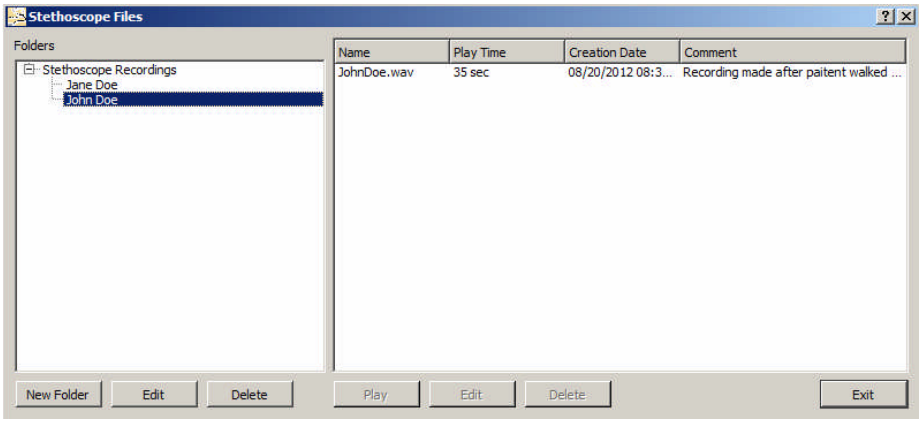


Figure 10: Create New Patient Folder

Click on OK to finish the creation of the folder. A folder can be edited by clicking on the folder to highlight it, then clicking on Edit. That brings up the Stethoscope Folder window again. Make the desired changes then click on OK. To delete a folder, click on the folder to highlight it, and then click on Delete. A window will pop up to confirm that you want to delete the folder. If you are sure, click on Yes, otherwise click on No.



To access files for any patient, click on the folder name on the right side of the Stethoscope Files window shown in Figure 11. Be sure to expand or collapse folders as necessary as files are structured with parent/child relationships.

Figure 11: Stethoscope Files Screen Showing Files

To play back a saved file, click on the desired file to highlight it, and then click on Play which brings up the window shown in Figure 12.

If desired, use the drop down box next to Cutoff Frequency to apply an audio filter.

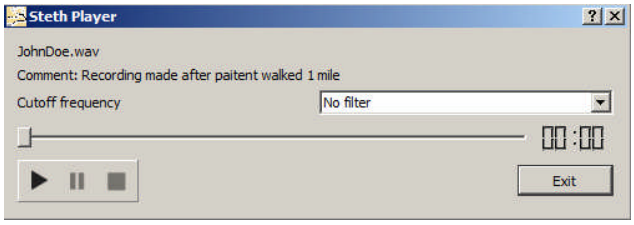


Figure 12: Stethoscope Player Screen

Using the standard audio player symbols, the clinician can play, pause or stop the stethoscope sound file. The stethoscope sound file will playback through the attached Headset. The clinician can also select an audio filter to be used with the playback. Clicking on Exit goes back to the screen of Figure 11.

The information for a stethoscope file can be edited by selecting the file to highlight it, then clicking on the Edit button. Make the desired changes to either the Name or Comment field, then click on Save. A file can be deleted by selecting the file to highlight it, then clicking on the Delete button. A window will pop up to confirm that you want to delete the file. If you are sure, click Yes, otherwise click No.

To close the Stethoscope Files window, click on the Exit button.

V. Trouble Shooting

If an IP connection cannot be established to the transmit end station, service personnel from the company that provided the PCP-1 and sSOIP-RX program should check the following:

- Insure the assigned IP address of the transmit end is properly entered into the receive end sSOIP-RX Address Book.
- Insure the Port number (default 8445) is properly entered into the receive end of sSOIP-RX.
- Insure the receive end PC is connected to the Internet and can access the Internet.
- Insure the transmit end sSOIP-TX application is open and ready to transmit.
- Insure the transmit end PC is connected to the Internet and can access the Internet.
- Insure there is a License File (ending in .lic) in the same directory as the sSOIP-RX program.
- Check for an improperly operating sSOIP-RX by reloading sSOIP-RX.
- Check for a failed PCP-1 Chest Piece by substituting it with a replacement PCP-1 Chest Piece.

If taking the above steps does not remedy the problem, contact your provider of the PCP-1 Stethoscope and sSOIP-RX program for assistance and product resolution.

For questions or comments, contact RNK Products, Inc., 8247 Devereux Drive, Suite 101, Viera, FL 32940.

telehealth technologies

PCP-1 Stethoscope Over IP Networks

PCP-1 Chest Piece and sSOIP Software Running on Generic PC

PCP-1 Chest Piece:

- Single piece assembly.
- 20 Hz – 2,000 Hz bandwidth.
- Plugs into Mic port of PC.
- Uses PC's audio capability.

PCP-1 Chest Piece

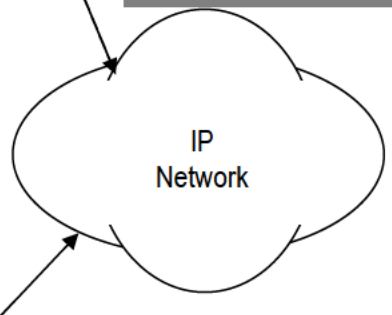
PC with sSOIP

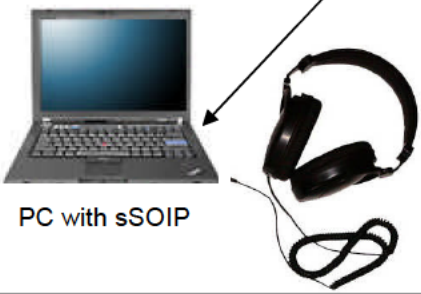
IP Channel:

- Static IP addresses.
- AES 128-Bit encryption.
- UDP protocol.

sSOIP-TX - Transmit End:

- Converts analog auscultation signal to digital and encodes into PCM.
- Creates UDP packets for IP channel.
- Sets up IP communications channel.
- Selection of audio filters for monitoring stethoscope session.





PC with sSOIP

sSOIP-RX - Receive End:

- Selection of patient (transmit end) location from Address Book.
- Initiates IP connection.
- Converts digital signal to analog.
- Selection of audio filters for monitoring stethoscope session.
- Record and playback stethoscope sessions.

Manufactured by RNK Products, Inc.

8247 Devereux Drive, Suite 101, Viera, FL 32940 • 321.610.3980 • www.rnkproducts.com

Substantial Equivalence Chart for PCP-USB Stethoscope

	PCP-USB Stethoscope	**PCP/PC Stethoscope** (K102893)
Intended use:	Remote monitoring device, whereby a clinician at one location can listen to the auscultation sounds of a patient at a different location with the signal carried over a data communication channel between the two locations.	Remote monitoring device, whereby a clinician at one location can listen to the auscultation sounds of a patient at a different location with the signal carried over a data communication channel between the two locations.
Components:	• Detachable Chest Piece. • Detachable Headset. • Chest Piece and Headset connect to generic PC. • Audio handling control and communications software on PC.	• Detachable Chest Piece. • Detachable Headset. • Chest Piece and Headset connect to generic PC. • Audio handling control and communications software on PC.
Technical Characteristics – PCP-USB Chest Piece	PCP-USB Chest Piece converts body auscultation signals to analog signal.	PCP/PC Chest Piece converts body auscultation signals to analog signal.
Power Source – PCP-USB Chest Piece	5 vdc provided in the USB cable from the PC. Safety isolation is provided within the PCP-USB Chest Piece.	2 -5 vdc provided from the PC. Safety isolation is provided within the PCP/PC Chest Piece.
Technical Characteristics – Audio/Digital processing	Analog signal from Chest Piece amplified in PC. Analog signal is converted and encoded to a digital signal by audio circuitry within the PCP-USB Chest Piece. Then sSOIP-TX Anywhere puts the digitized signal into IP data format in the PC. At receive end PC, sSOIP-RX accepts the IP data stream, decodes the digital signal converting it back to analog then amplifies the analog signal and presents it to Headset port.	Analog signal from Chest Piece amplified in PC. Under the direction of sSOIP software, the analog signal is converted and encoded to a digital signal using the PC's audio circuitry. Then sSOIP puts the digitized signal into IP data format in the PC. At receive end PC, sSOIP accepts the IP data stream, decodes the digital signal converting it back to analog then amplifies the analog signal and presents it to Headset port.

Technical Characteristics - Data Communications:	sSOIP-TX Anywhere software in the PC puts signal into IP format. Connections across NAT boundaries can be established using network services offer by TMCS, Relay Server and SUD Server. sSOIP-TX Anywhere at the transmit end and sSOIP-RX at the receive end log into the TMCS to establish presence. When the receive end requests a connection, the TMCS facilitates a direct connection or a relay connection through the Relay Server. Once a connection is established, sSOIP-TX Anywhere in the transmit end PC transmits streaming data to the receive end over the connection established in the IP network. At receive end, sSOIP-RX Anywhere in the PC accepts IP data stream.	sSOIP software in the PC puts signal into IP format. Only static IP addresses can be used in establishing IP connections. Connections cannot be established across NAT boundaries. Once a connection is established, sSOIP-TX in the transmit end PC transmits streaming data to the receive end over the connection established in the IP network. At receive end, sSOIP-RX in the PC accepts the IP data stream.
Auscultation Bandwidth:	20 Hz to 2,000 Hz	20 Hz to 2,000 Hz
Controls:	• No controls on PCP-USB Chest Piece. • Volume Control to Headset using PC audio controls.	• No controls on PCP/PC Chest Piece. • Volume Control to Headset using PC audio controls.

See Section VII Substantial Equivalence in the 510(k) body for more detail.

Risk Analysis – PCP-USB Stethoscope

Rev. 0.0

April 15, 2013

I. Scope

This Risk Analysis applies to the PCP-USB Stethoscope which is comprised of the PCP-USB Chest Piece Assembly and software that resides on the PC to which the PCP-USB Chest Piece attaches.

II. Responsibilities

As part of his role as head of engineering and head of operations, C. R. Abbruscato conducted this Risk Analysis for the PCP-USB Stethoscope.

III. Intended Use and Identification of Characteristics Related to Safety

The PCP-USB Stethoscope is intended to be used for remote auscultation where a clinician at one location can hear the heart and lung sounds of a patient at another location. The patient or a care giver with the patient holds the PCP-USB chest piece to the part of the body as requested by the clinician and the clinician listens to the sounds via the headset.

The essential performance requirement of the PCP-USB chest piece is to provide pickup of body sounds from a patient and present that signal to a PC based telemedicine station, then transport that signal across the communications network to a PC based telemedicine station at another location. That station would then present the auscultation signal in audio form to a listener.

The PCP-USB Chest Piece plugs into a USB port of a generic PC and derives its power from the approximately 5 vdc provided on the USB interface.

The expected service life of the PCP-USB stethoscope is five years.

A stethoscope is a tool used by clinicians who are trained in the use of a stethoscope for auscultation. Some clinicians are better at it than others. The PCP-USB Stethoscope is subject to misuse by a clinician without adequate skills in stethoscope use.

IV. Identification of Hazards

Hazards for the PCP-USB Chest Piece are:

1. Electrical safety associated with the dc power.
2. Other potential safety issues.
3. Electromagnetic interference (EMI).
4. Electromagnetic compatibility (EMC).
5. Biocompatibility.
6. Component failure.
7. Network failure.

8. Misuse by the clinician due to poor usability associated with identification, labeling or documents.
9. Misuse by the clinician due to poor usability associated with arrangement of controls and indicators.
10. Misuse by the clinician due to lack of skills.

Hardware hazards within the PC to which the PCP-USB Chest Piece is connected are:

1. Failure of the PC's internal power supply.
2. Failure of the PC's USB circuitry or USB software drivers.
3. Headset circuitry failure.
4. Any other internal failure which causes the PC to stop performing.

Software hazards within the PC to which the PCP-USB Chest Piece is connected are:

- Failure of software in the PC or within the communications network can occur at many points – control of USB interface function, control of headset function, digitization of the stethoscope signal, formatting of the stethoscope signal, and network connection and control anywhere along the path of the connection from the patient site to the clinician site.

V. Estimation of Risks for Each Hazardous Situation

Following is an estimation of each PCP-USB Chest Piece hazard:

1. Electrical safety and energy hazards are addressed and verified through the pertinent testing specified in EN 60601-1:2005 3rd Edition Medical electrical equipment - Part 1 General Requirements for Safety. Once the tests are successfully performed, then the covered risks are negligible.
2. The issue with potential safety is that the PCP-USB Chest Piece must have adequate isolation from power, ground and signal from the PC to provide adequate protection to the user per EN 60601-1:2005 3rd Edition Medical electrical equipment - Part 1 General Requirements for Safety. The design of the PCP-USB Chest Piece addresses these requirements and is explained in PCP-USB Creepage, Air Gap and Insulation Analysis 4/15/2013.
3. Electromagnetic interference (EMI) is addressed and verified through the pertinent testing specified in EN 60601-1-2:2007 3rd Edition Medical Electrical Equipment - Collateral Standard; Electromagnetic Compatibility Requirements and Tests. Once the tests are successfully performed, then the covered risks are negligible and remote in frequency of occurrence.
4. Electromagnetic compatibility (EMC) is addressed and verified through the pertinent testing specified in EN 60601-1-2:2007 3rd Edition Medical Electrical Equipment - Collateral Standard; Electromagnetic Compatibility Requirements and Tests. Once the tests are successfully performed, then the covered risks are negligible and remote in frequency of occurrence.
5. Biocompatibility hazards have been addressed through the use of safe materials for those parts of the PCP-USB Stethoscope that can be touched by the patient or clinician. The

Bottom part of the PCP-USB Chest Piece enclosure is made from Tairilac ABS AG15A1 plastic and Materials Testing reports are available with copies retained in the DHF. The Top part of the PCP-USB Chest Piece is made from inert SUS304 Stainless Steel. There is a covering that goes over the piezo element in the PCP-USB Chest Piece that is made of inert Silicone. The coverings on the cables of the Headset and Chest Piece Assembly are PVC. The Headset is an off-the-shelf consumer product and biocompatibility has been addressed by the manufacturer. All these materials are the same as used in the previously FDA cleared PCP-1 Stethoscope and Piezo Precordial Stethoscope.

6. Failure of an electrical component within the PCP-USB Chest Piece can result in the unavailability of the PCP-USB Stethoscope to perform its normal functions. Such a failure inherently causes no harm. Since the stethoscopes are used for monitoring purposes, the net effect is an inconvenience and would be infrequent in frequency of occurrence.
7. Telephonic stethoscopes are accessory devices that provide remote auscultation as part of a telemedicine system. Full and effective usage is dependent upon things outside of RNK's control, in particular having a properly functioning communications network between the two sites in a remote auscultation exam. Should the network function improperly, then the remote auscultation capability would not be available. Such a failure causes no direct harm to a patient or clinician.
8. Misuse by the clinician due to poor usability associated with identification, labeling or documents is addressed and verified through the pertinent testing specified in IEC 60601-1:2005 3rd Edition Medical electrical equipment - Part 1 General Requirements for Safety. Once the tests are successfully performed, then the covered risks are negligible and remote in frequency of occurrence. Further, should an operator fail to understand any of this, then the remote auscultation capability may not be available, which presents no risk of direct harm to the patient.
9. Misuse by the clinician due to poor usability associated with arrangement of controls and indicators is addressed and verified through the pertinent testing specified in IEC 60601-1:2005 3rd Edition Medical electrical equipment - Part 1 General Requirements for Safety. Once the tests are successfully performed, then the covered risks are negligible and remote in frequency of occurrence. Further, should an operator fail to use the controls or indications properly, then the remote auscultation capability may not be available, which presents no risk of direct harm to the patient.
10. Misuse or the PCP-USB Stethoscope or any stethoscope by the clinician due to lack of skills is a possibility. It is expected that clinicians will receive the necessary training in auscultation to perform their jobs. If they don't that is roughly equivalent to not having the stethoscope available for use. Such unavailability inherently causes no harm. Since the stethoscopes are used for monitoring purposes, the net effect is an inconvenience and infrequent in frequency of occurrence.

Following is an estimation of each PC hardware hazard:

1. Failure of the power supply in the PC is a possibility. PCs to which the PCP-USB Chest Piece is connected use ITE power supplies conforming to IEC 60950-1. Per IEC 60601-1:2005 3rd Edition Medical electrical equipment - Part 1 General Requirements for

Safety, the design of the PCP-USB Chest Piece provides adequate protection for any specified failures of the PC's power supply.

2. Failure of the USB interface or headset circuitry in the PC results in the unavailability of the stethoscope. Such unavailability inherently causes no harm. Since the stethoscopes are used for monitoring purposes, the net effect is an inconvenience and infrequent in frequency of occurrence.
3. Failure of any other hardware component with the PC results in the unavailability of the stethoscope. Such unavailability inherently causes no harm. Since the stethoscopes are used for monitoring purposes, the net effect is an inconvenience and infrequent in frequency of occurrence.

Following is an estimation of PC software hazards:

1. Failure of software in the PC or within the communications network can occur at many points – control of USB interface function, control of headset function, digitization of the stethoscope signal, formatting of the stethoscope signal, and network connection and control anywhere along the path of the connection from the patient site to the clinician site.

Overall, of all the single-point failures that could occur in a remote auscultation setup, the worst result is that the remote auscultation capability would not be available. There is no single-point failure that could directly cause harm to a patient or clinician.

VI. Risk Evaluation

The risk estimation meets the risk criteria described in the Risk Management Plan – PCP-USB Stethoscope. Therefore, no risk reduction is required and there is no residual risk.

VII. Risk Controls Required

No risk controls are required.

VIII. Conclusions

All the hazards for the PCP-USB Stethoscope have been identified and the evaluation for those hazards shows that the risk criteria described in the Risk Management Plan – PCP-USB Stethoscope are satisfied. No risk reduction is required, no risk controls are required and there is no residual risk

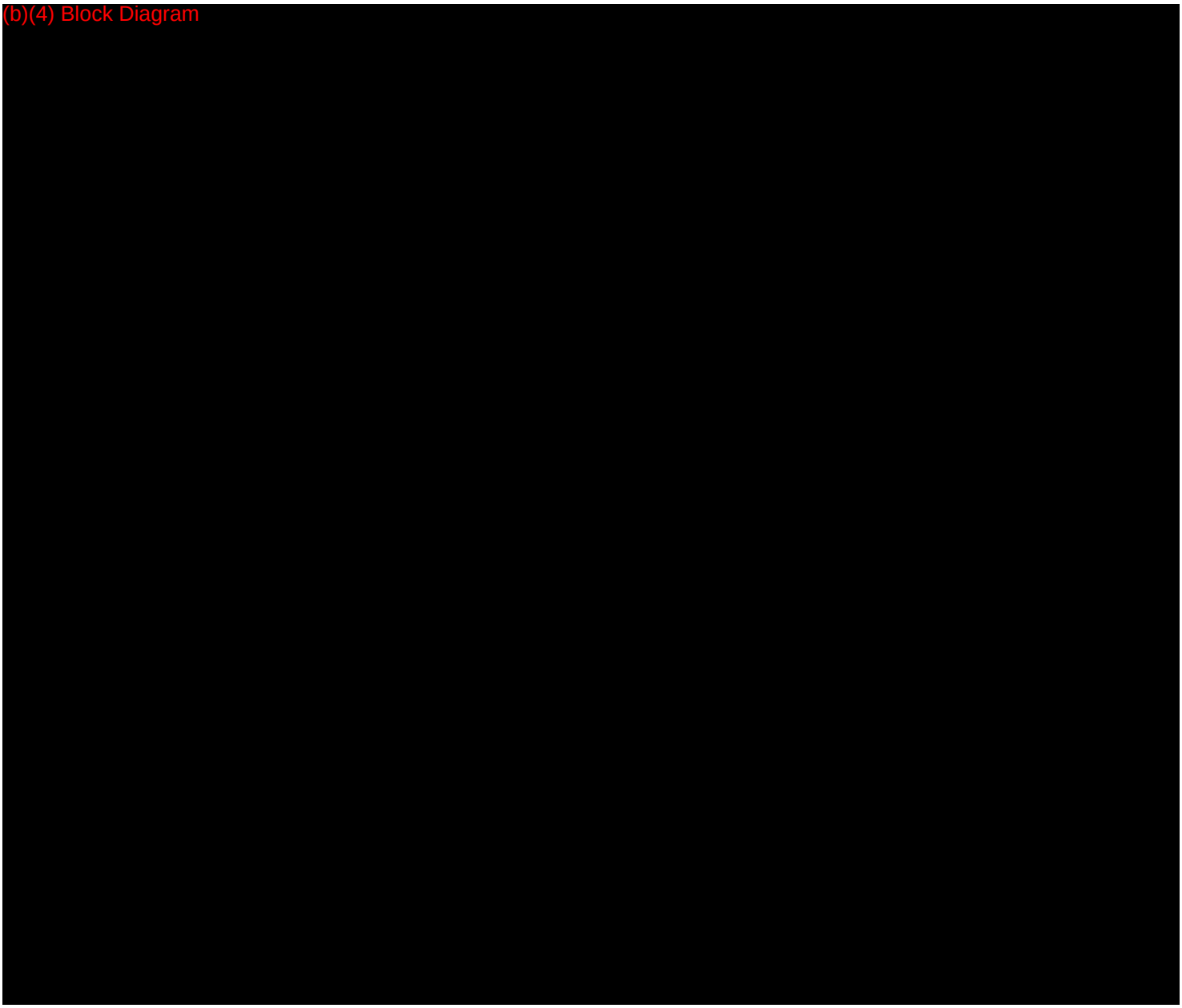
(b)(4) Testing

(b)(4) Testing

Hazard Chart for PCP-USB Stethoscope

Undesirable Effect	Potential Cause	Mode of Control	Minimum Requirements/ Description of Control
Electrical Safety	The internal operating voltage shorts to part of the case that the user can touch	Design	By satisfying the safety requirements of EN 60601-1-1, no part that the user can touch will have a hazardous voltage level.
Electrical EMI and EMC	Electro-magnetic interference to the devoice or by the device	Design	By satisfying the EMI and EMC requirements of EN 60601-1-2, such risks are negligible.
Adverse Biocompatibil-ity Reaction	Unsafe materials used for the PCP-USB chest piece (the only physical component other than the generic PC)	Design	The PCP-USB chest piece is made from the identical safe materials as the previously cleared PCP/PC and Piezo Electronic Stethoscopes.
Inability to use device because of hardware or component failure	Failure of a hardware component inside the PCP-USB chest piece or failure of a hardware component in the PC or server running PCP-USB Stethoscope software.	Clinical Training/ Operation Instructions	Clinicians are trained in the use of stethoscopes and would recognize the failure of the equipment. The PCP-USB Stethoscope is intended to be used to listen to auscultation sounds remotely as a supplement to in-person care. Should a clinician not be able to conduct the remote auscultation and feel that an auscultation exam is needed, the clinician would instruct the person to see a clinician in person.
Inability to use device because of software failure	Failure of a PCP-USB Stethoscope software component including: • Inability to process analog audio signal at the patient end. • Inability to process digitized audio signals at the patient end. • Inability to transport digitized signals from the patient end location to the clinician end location. • Inability to process digitized audio signals at the patient end. • Inability to process analog audio signal at the patient end.	Clinical Training/ Operation Instructions	Clinicians are trained in the use of stethoscopes and would recognize the failure of the equipment. The PCP-USB Stethoscope is intended to be used to listen to auscultation sounds remotely as a supplement to in-person care. Should a clinician not be able to conduct the remote auscultation and feel that an auscultation exam is needed, the clinician would instruct the person to see a clinician in person.
Unauthorized Use	Non-authorized person using the stethoscope	Design	No physical harm can come to someone using the stethoscope.
Misuse by User	Clinician fails to use the stethoscope properly	Clinical Training/ Operation Instructions	Clinicians are trained in auscultation as part of their clinical education. The PCP-USB Stethoscope presents the same auscultation sounds as a traditional acoustic stethoscope, but amplified. The Operation Instructions informs the clinician and patient how to use the PCP-USB Stethoscope.

(b)(4) Block Diagram



(b)(4) Testing

(b)(4) Schematics

(b)(4) Trade Secret Process- Engineering Drawing

(b)(4) Trade Secret Process- Engineering Drawing

(b)(4) Trade Secret Process- Engineering Drawing

Level of Concern (b)(4) Testing

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June 4, 2013

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Software Design Specification

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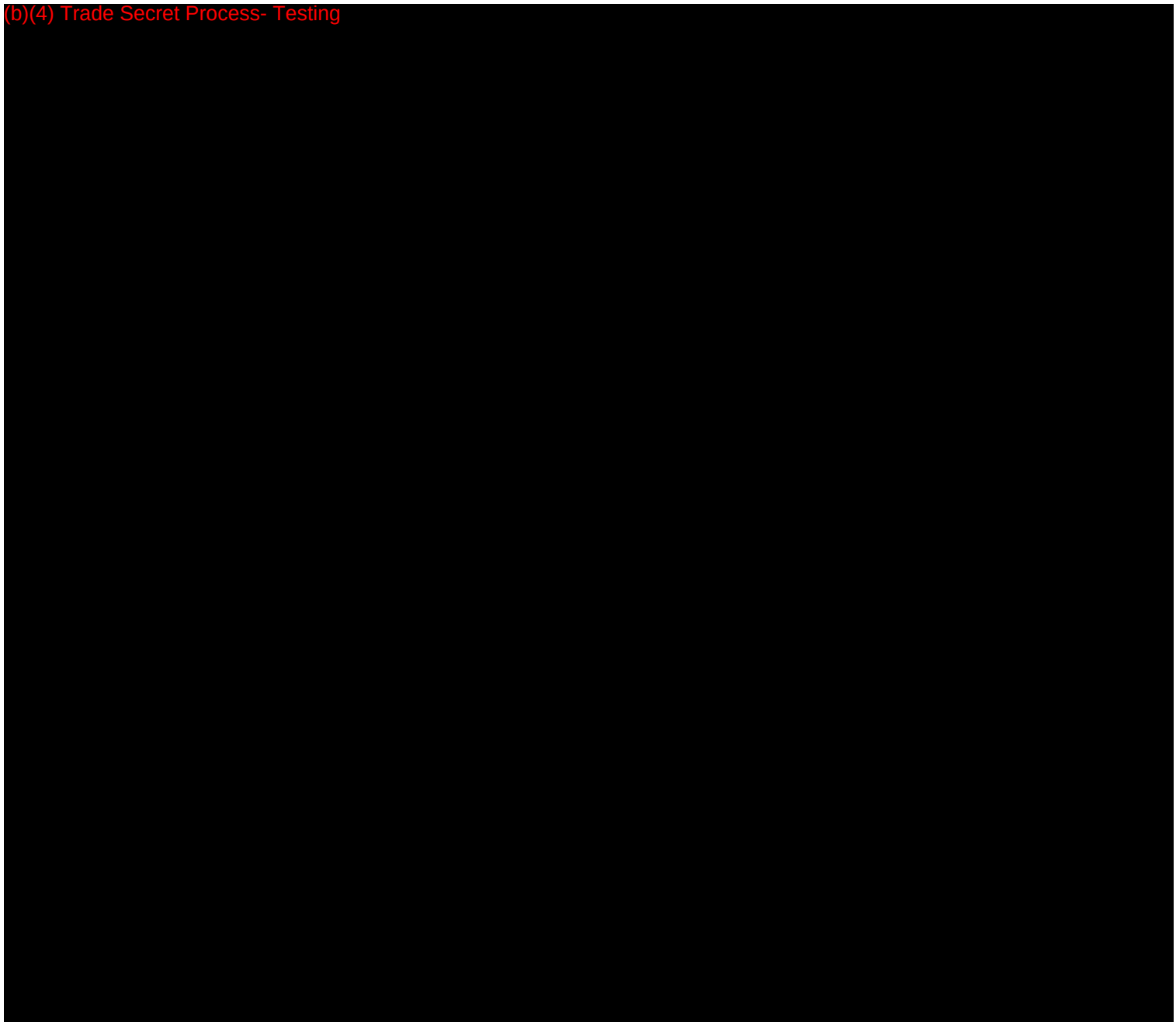

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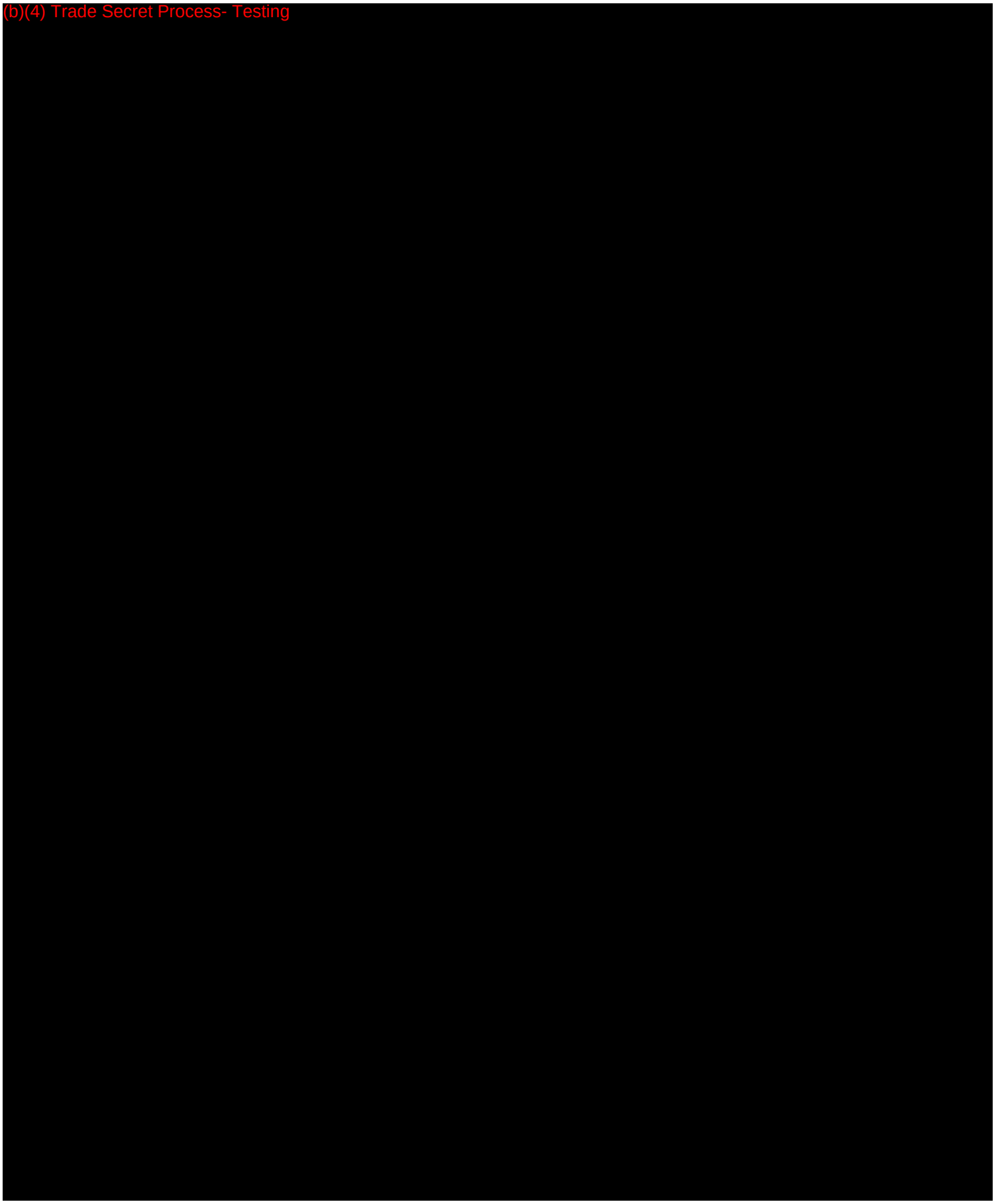

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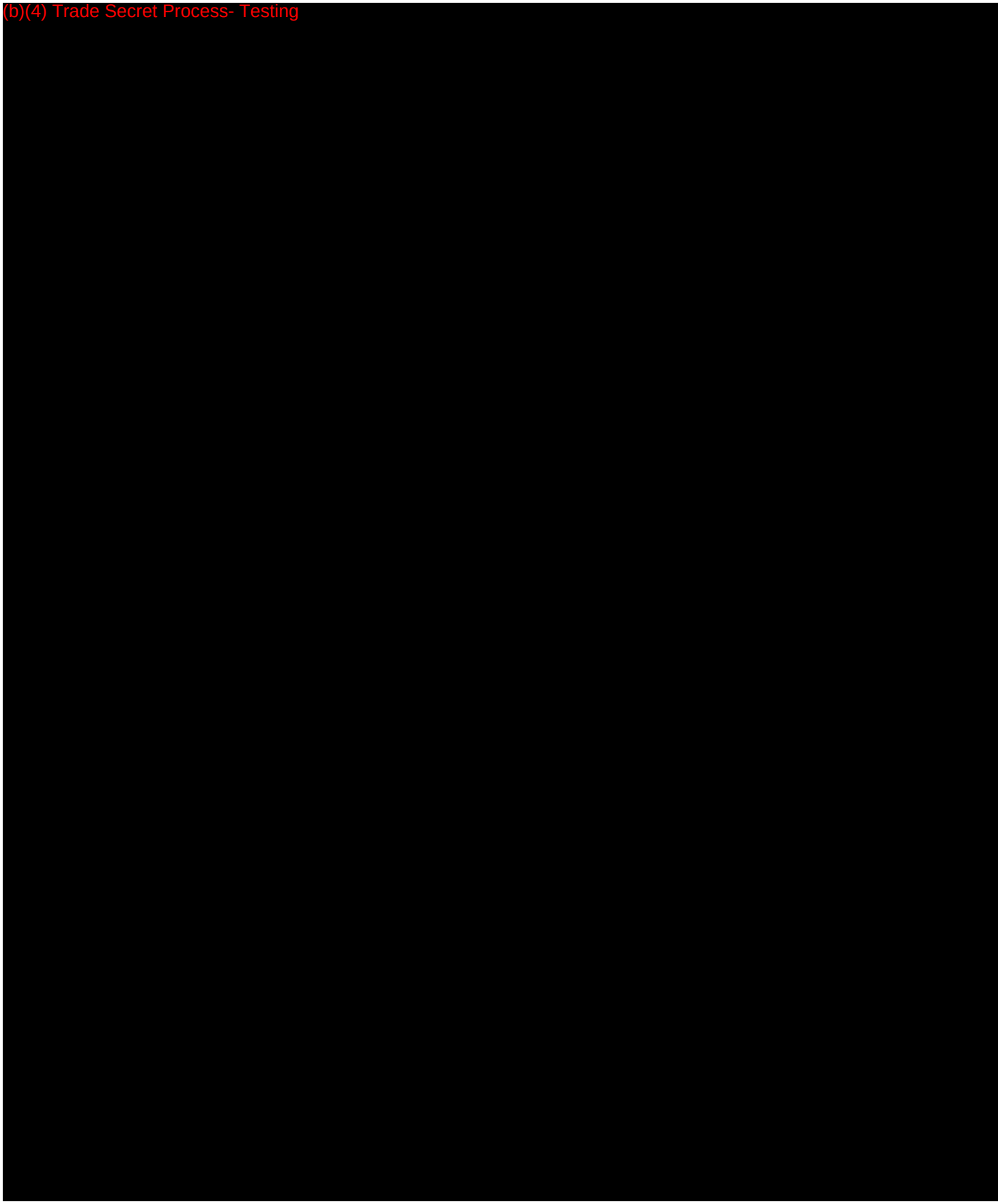

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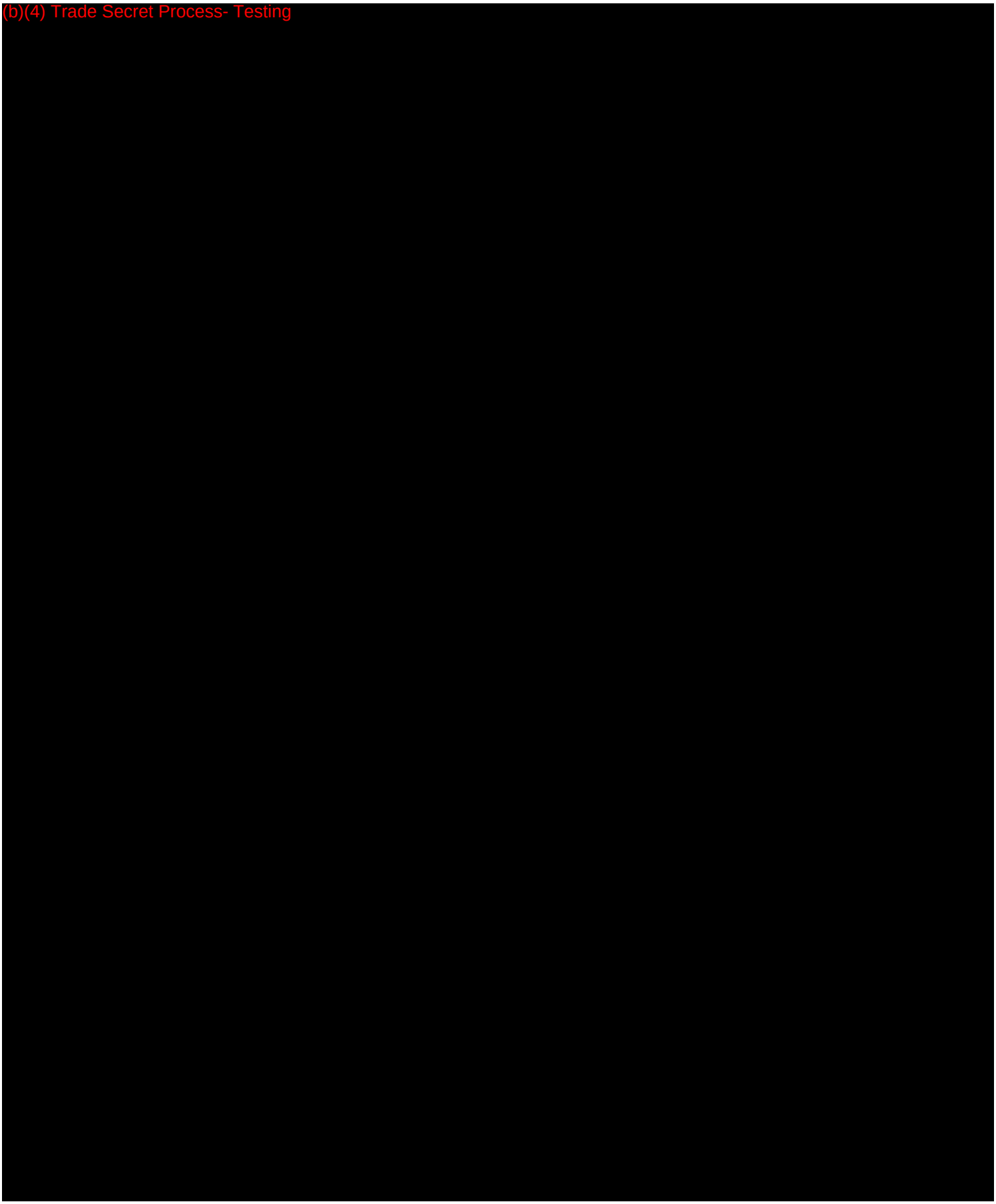

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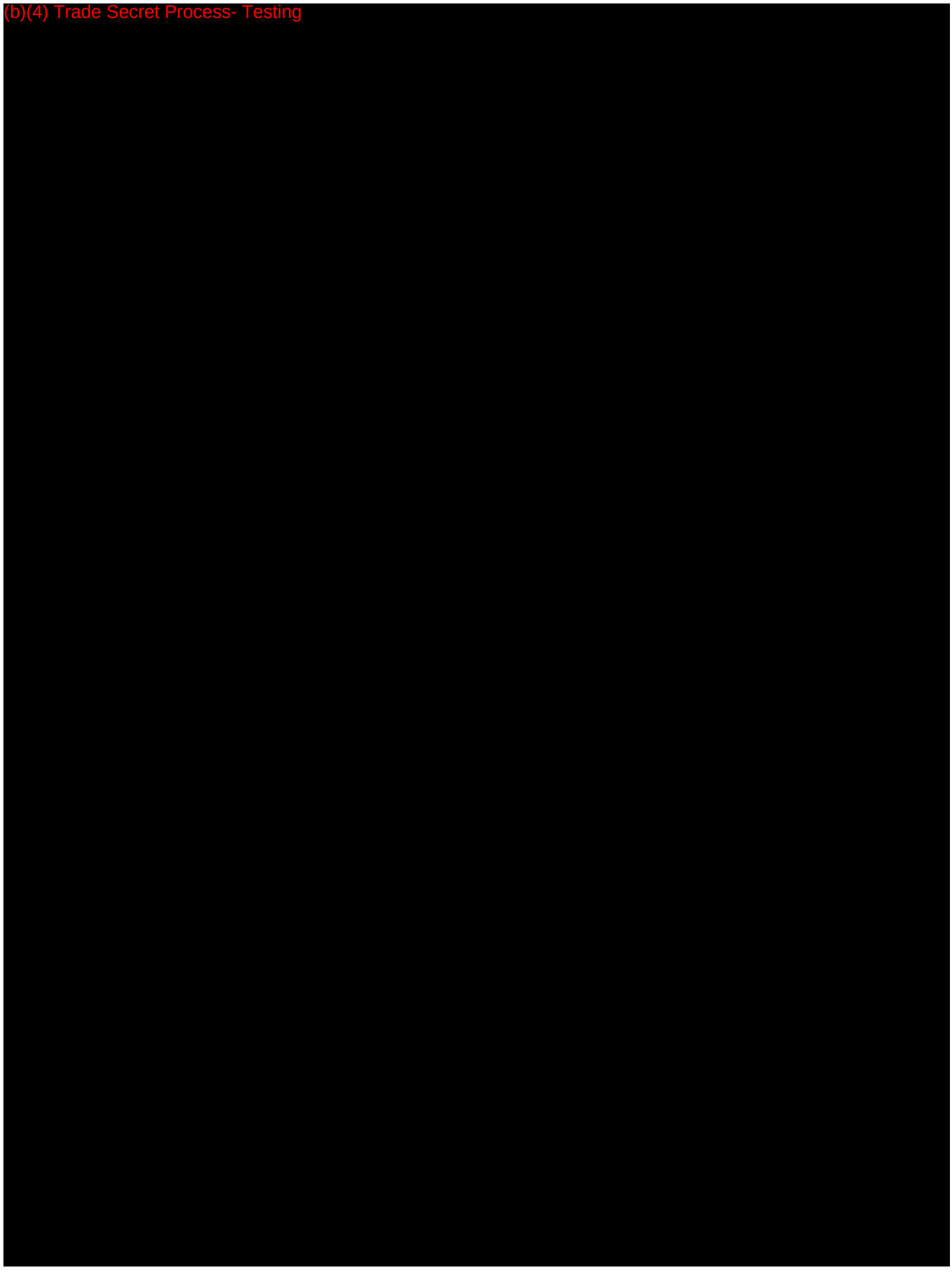
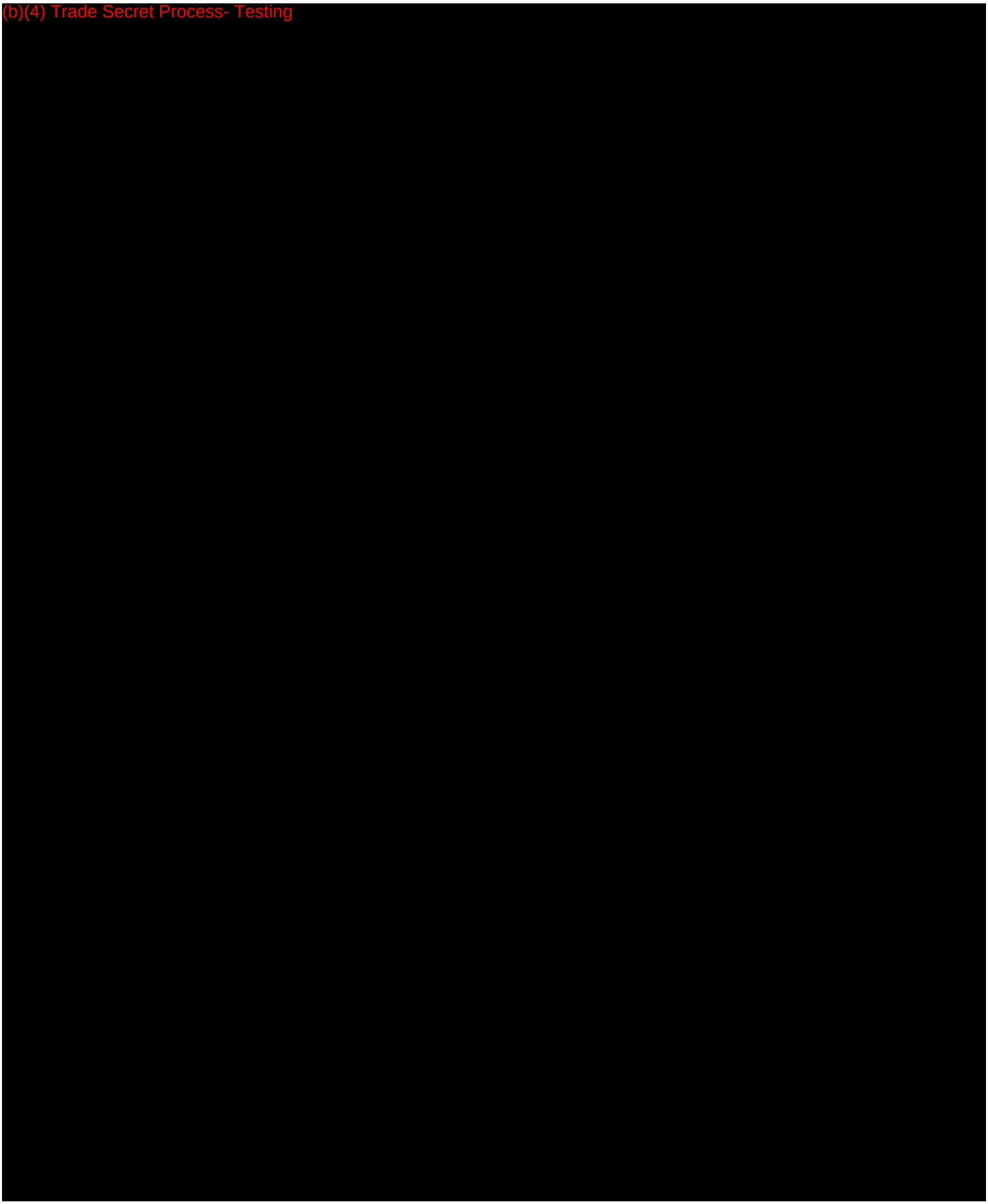


(b)(4) Trade Secret Process- Testing



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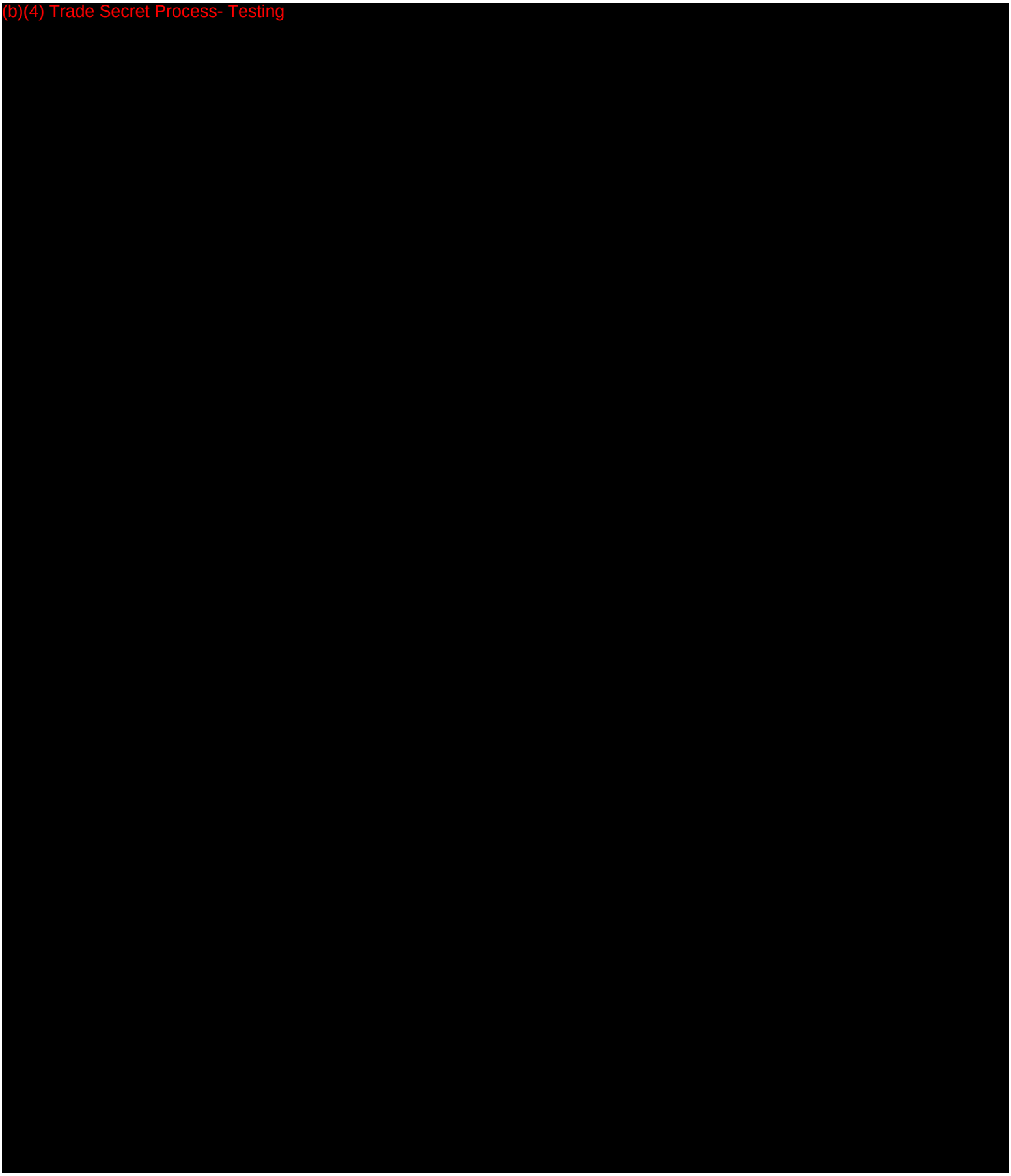

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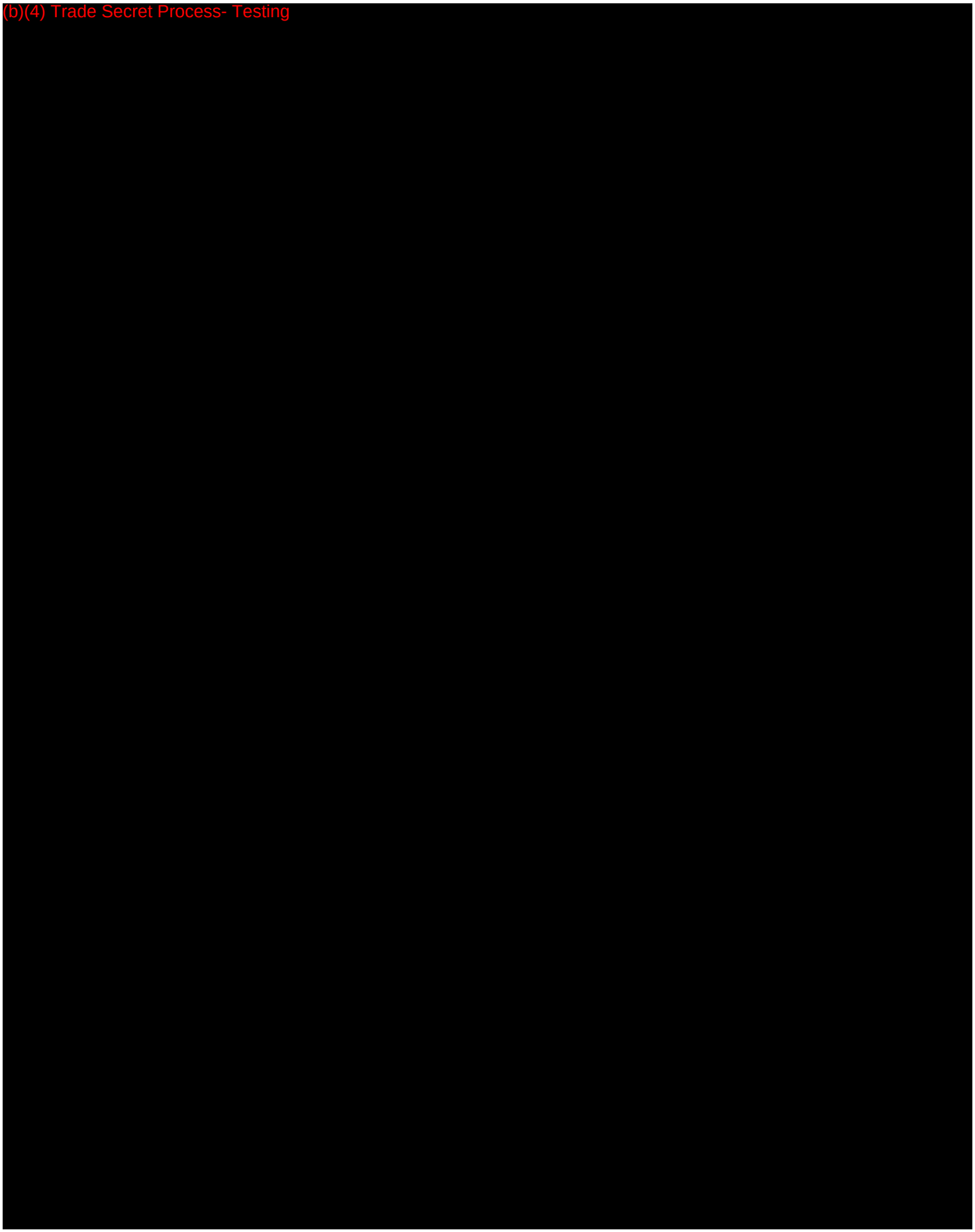

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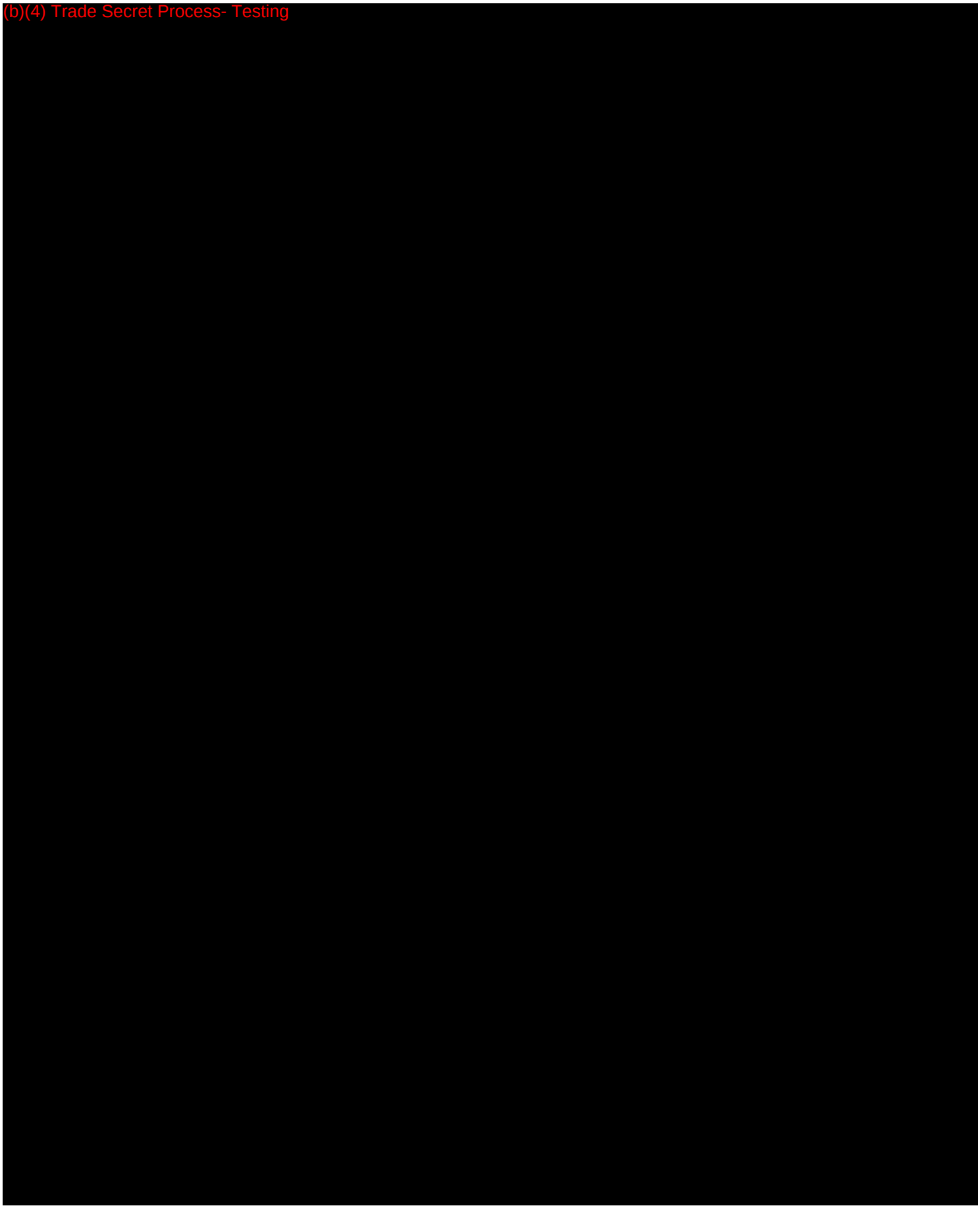

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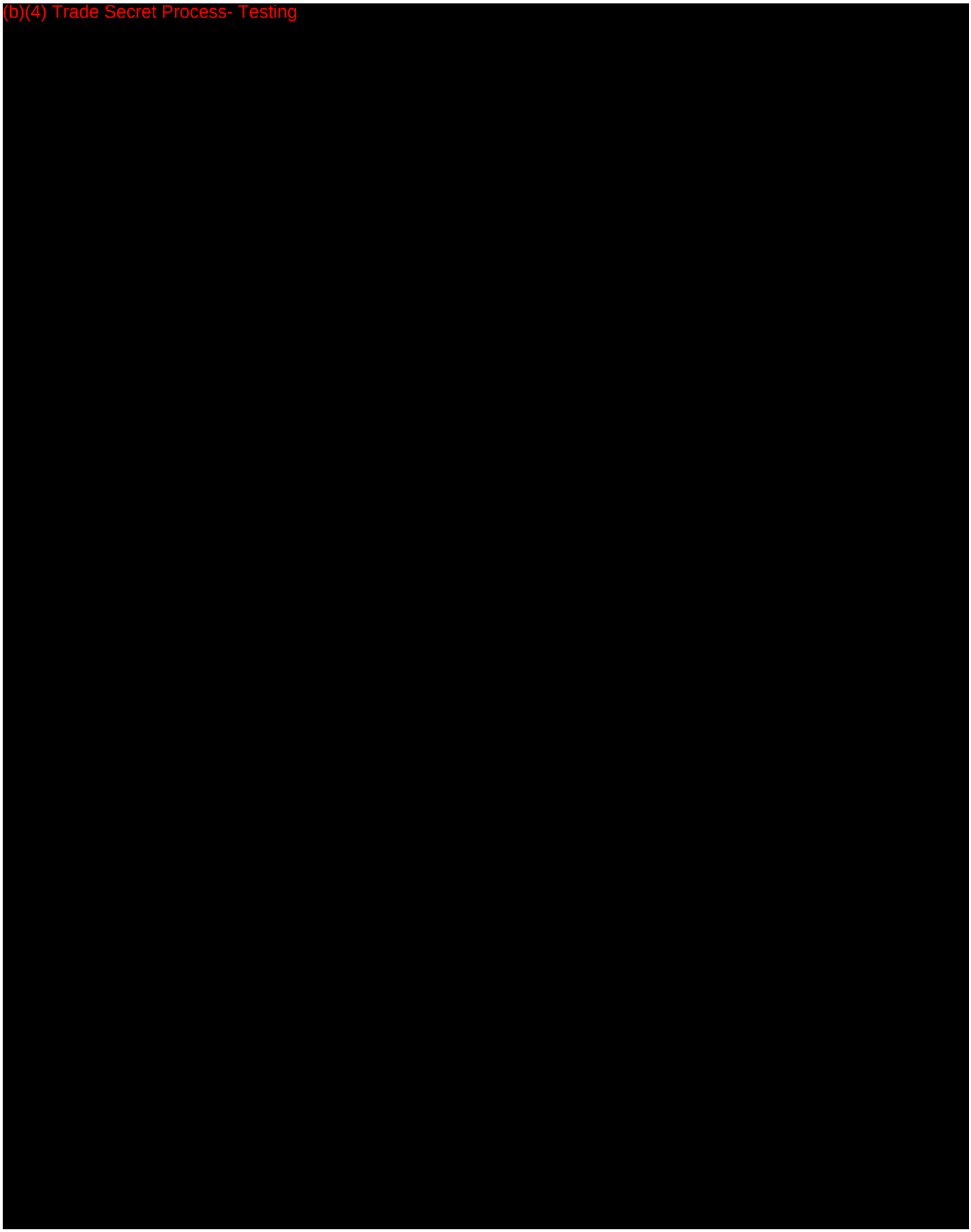

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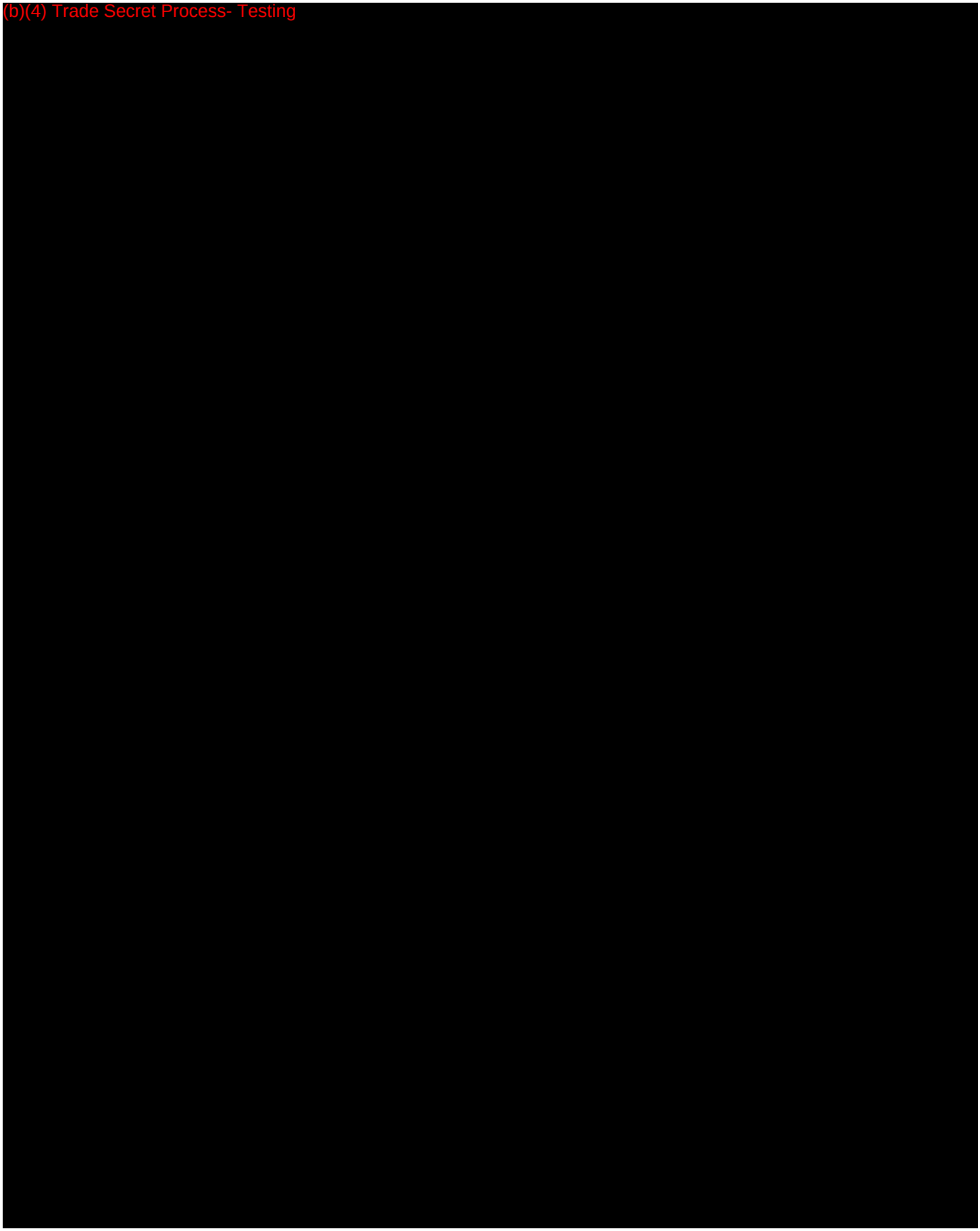

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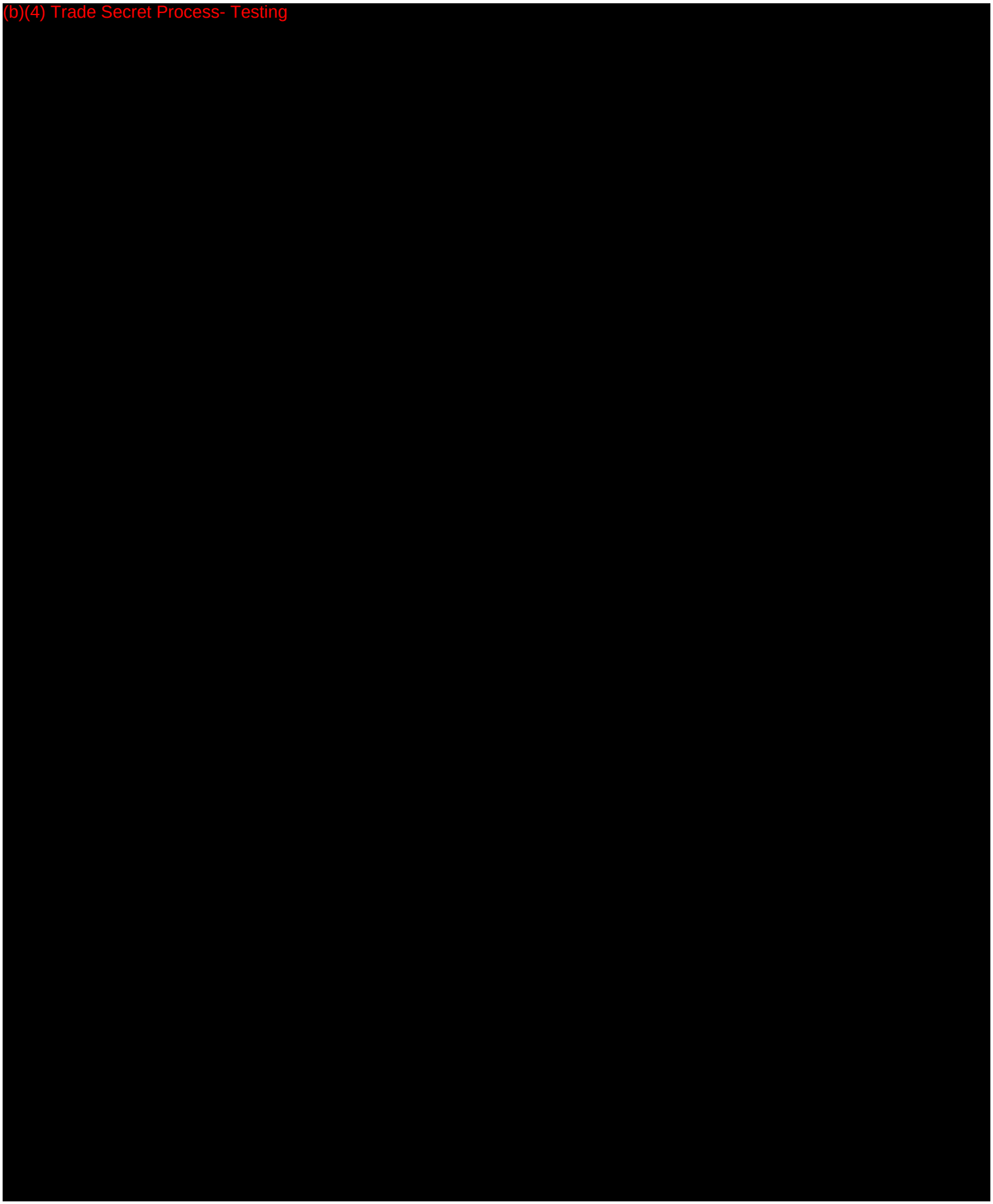

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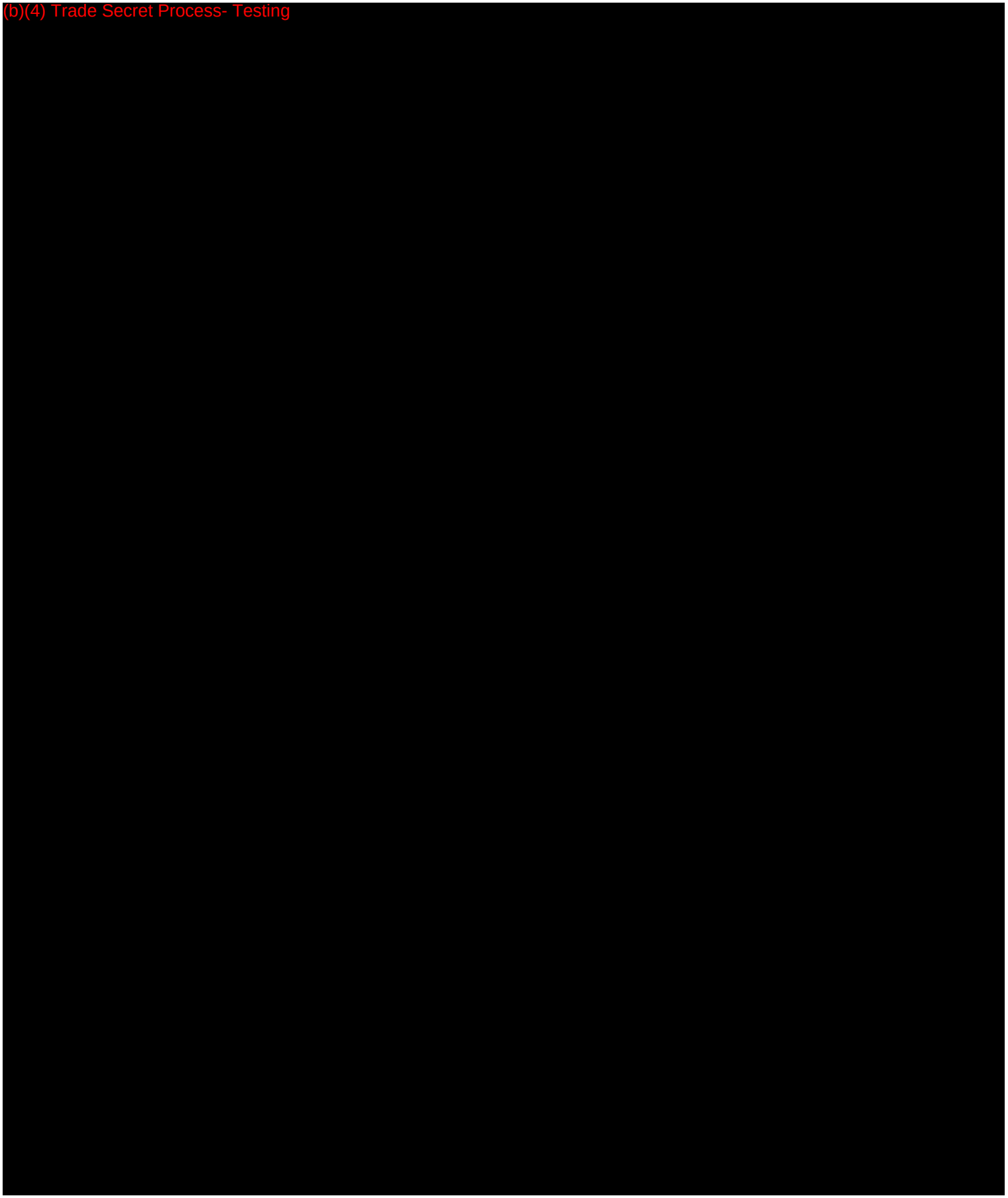

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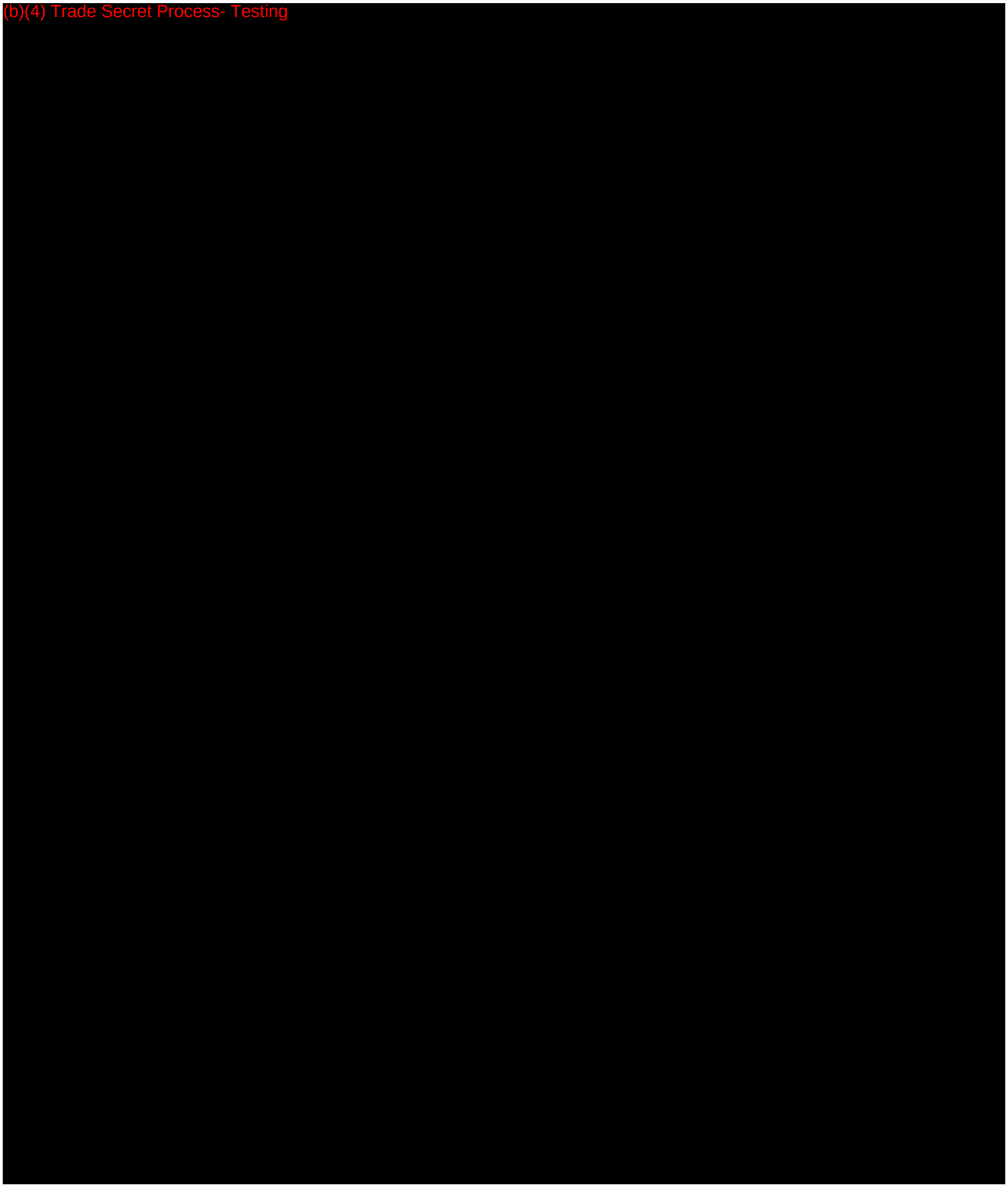

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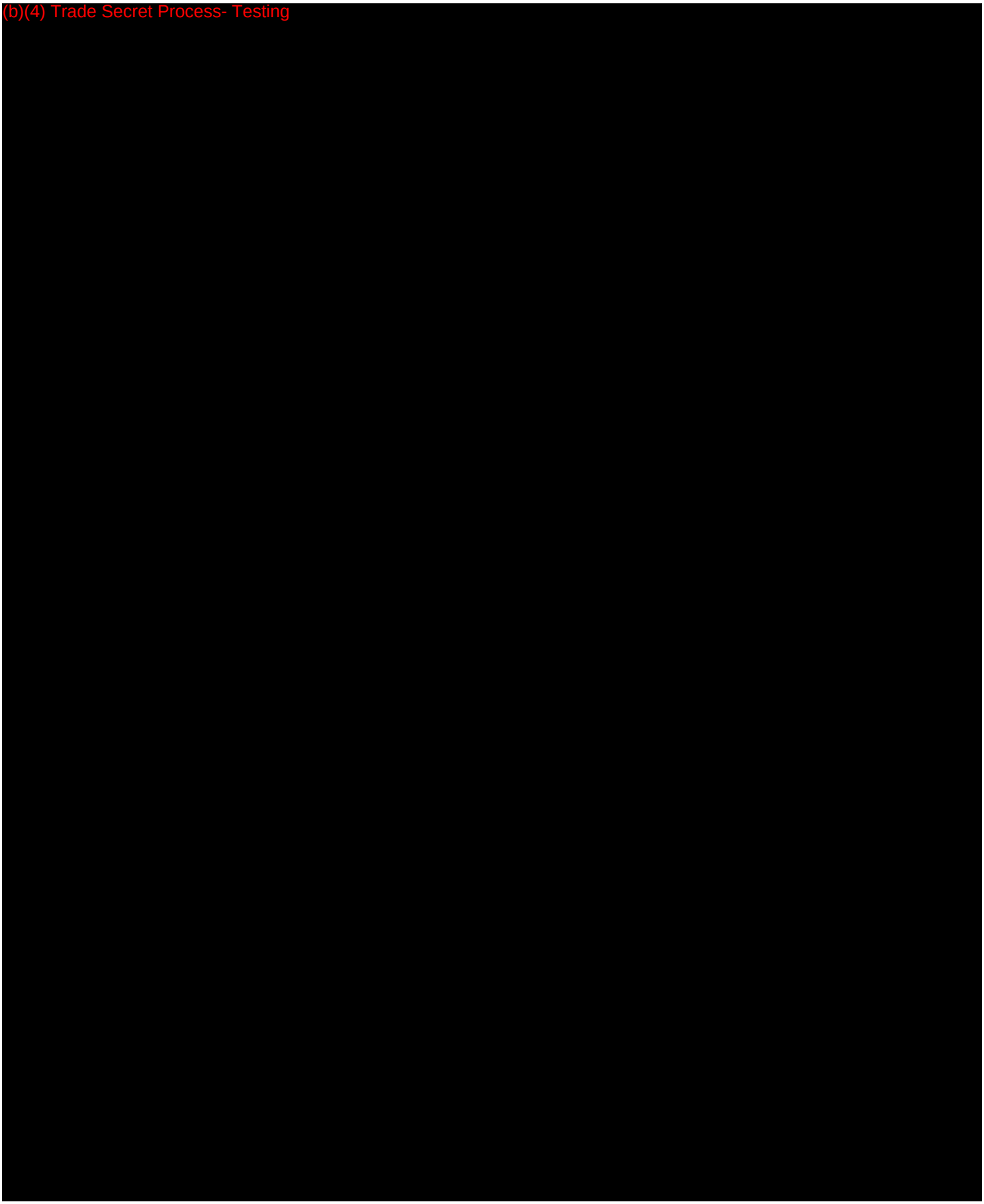

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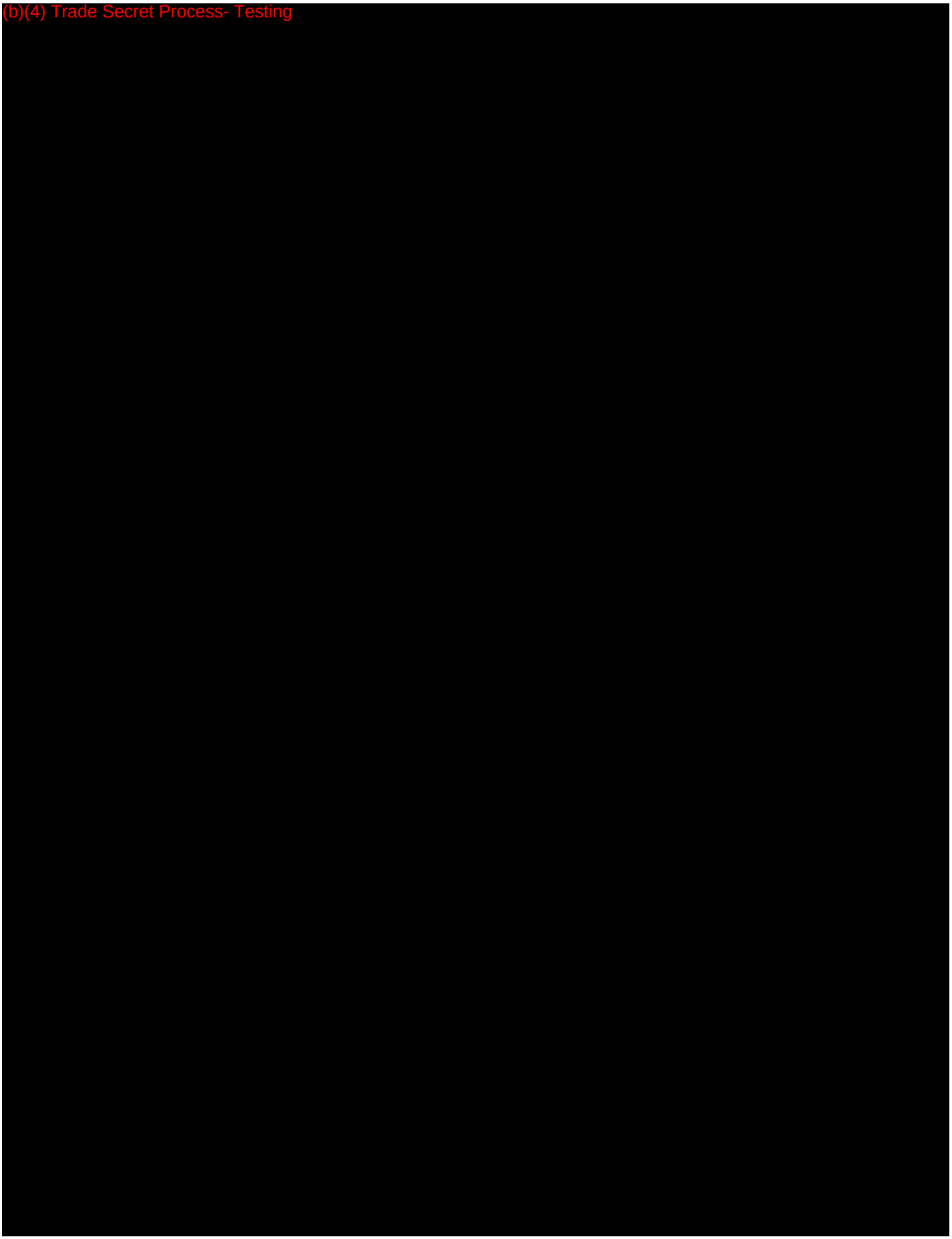

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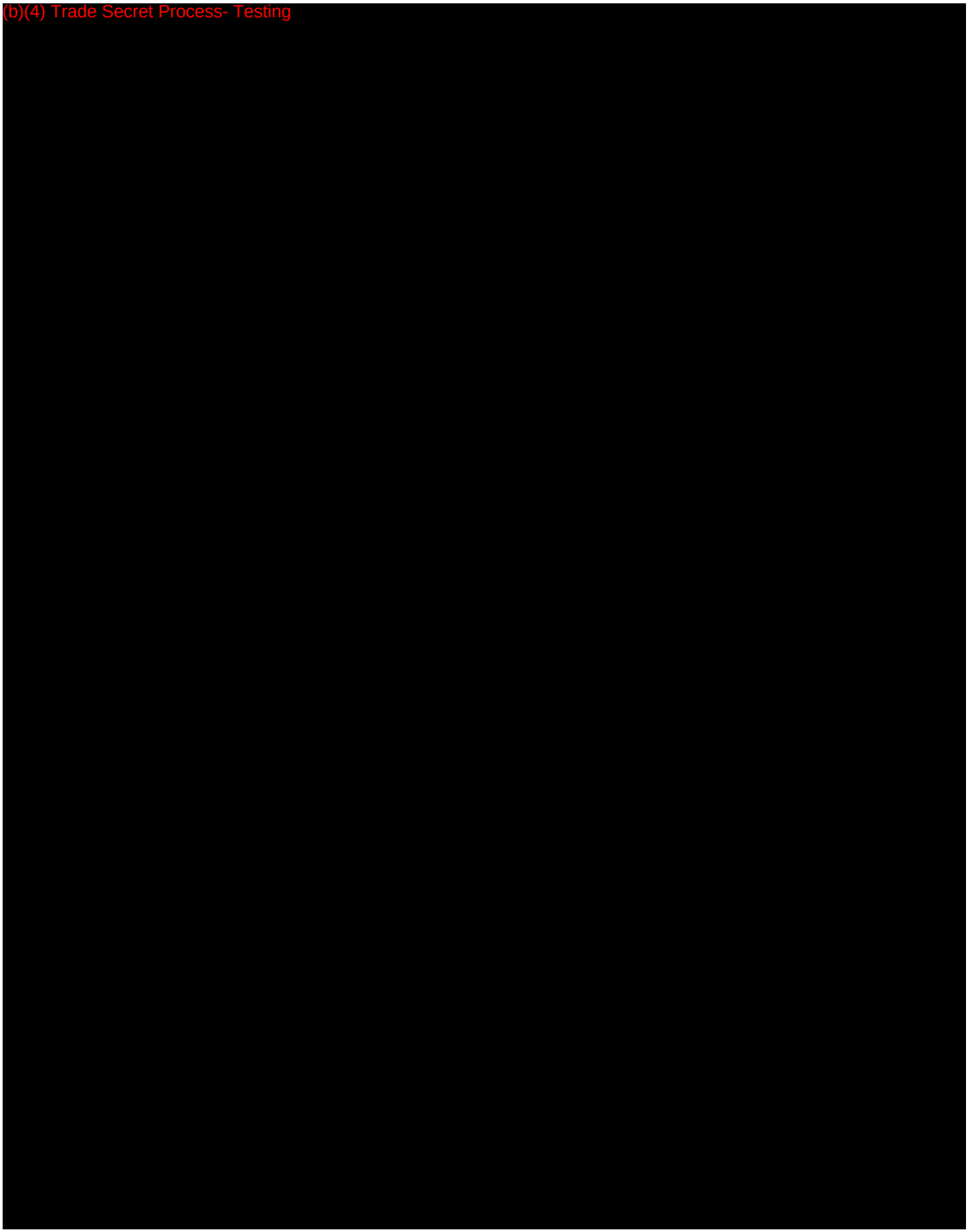

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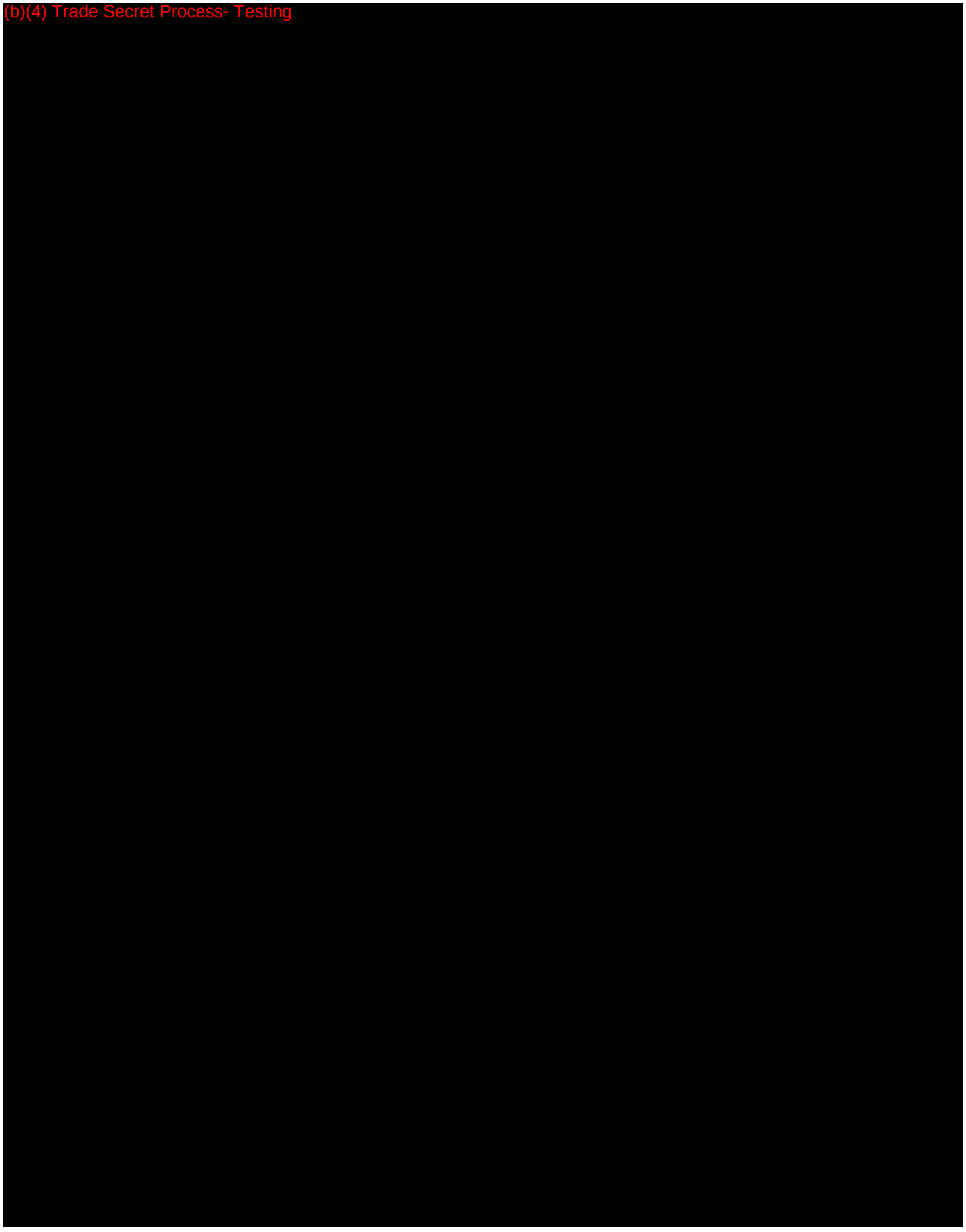

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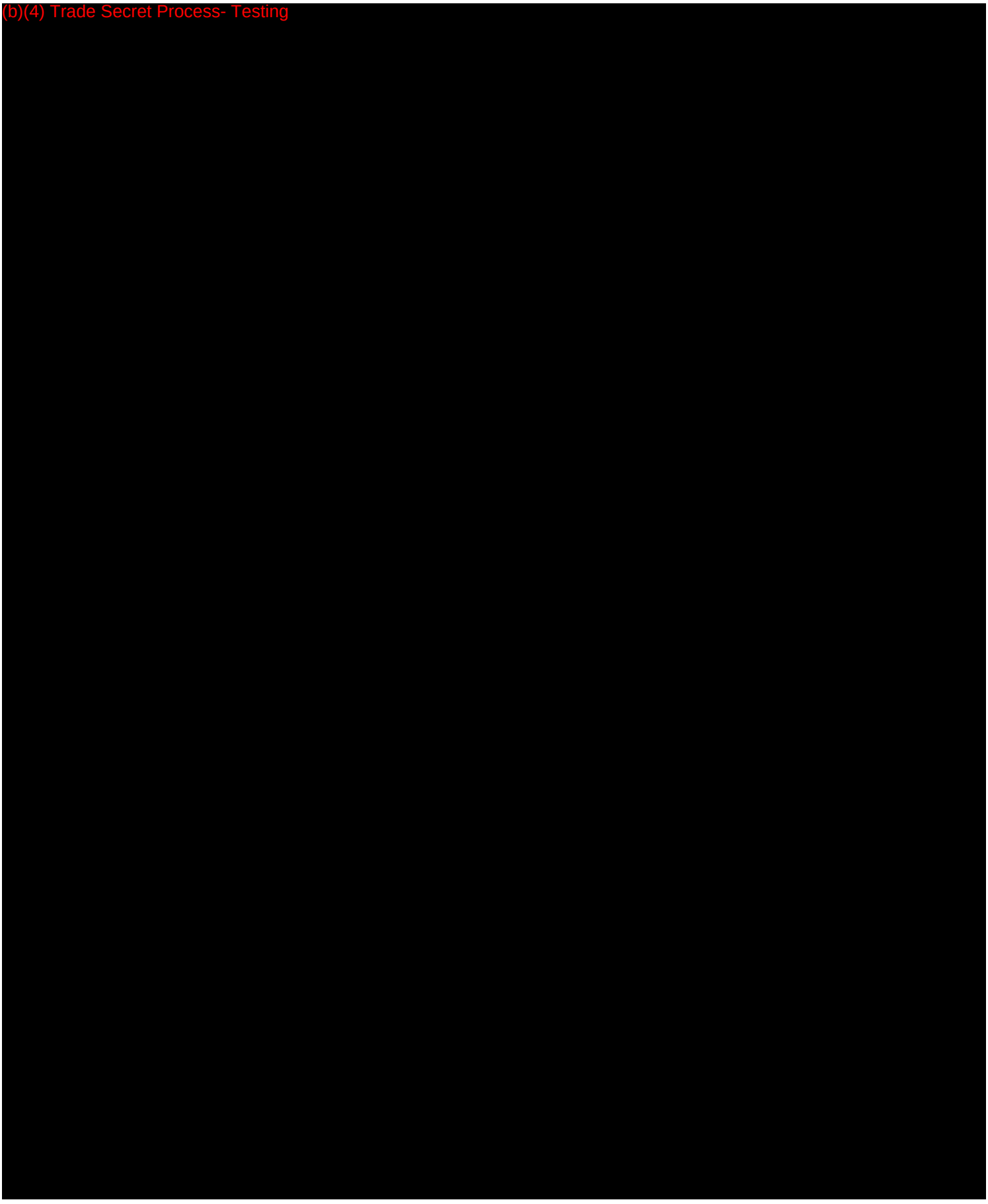

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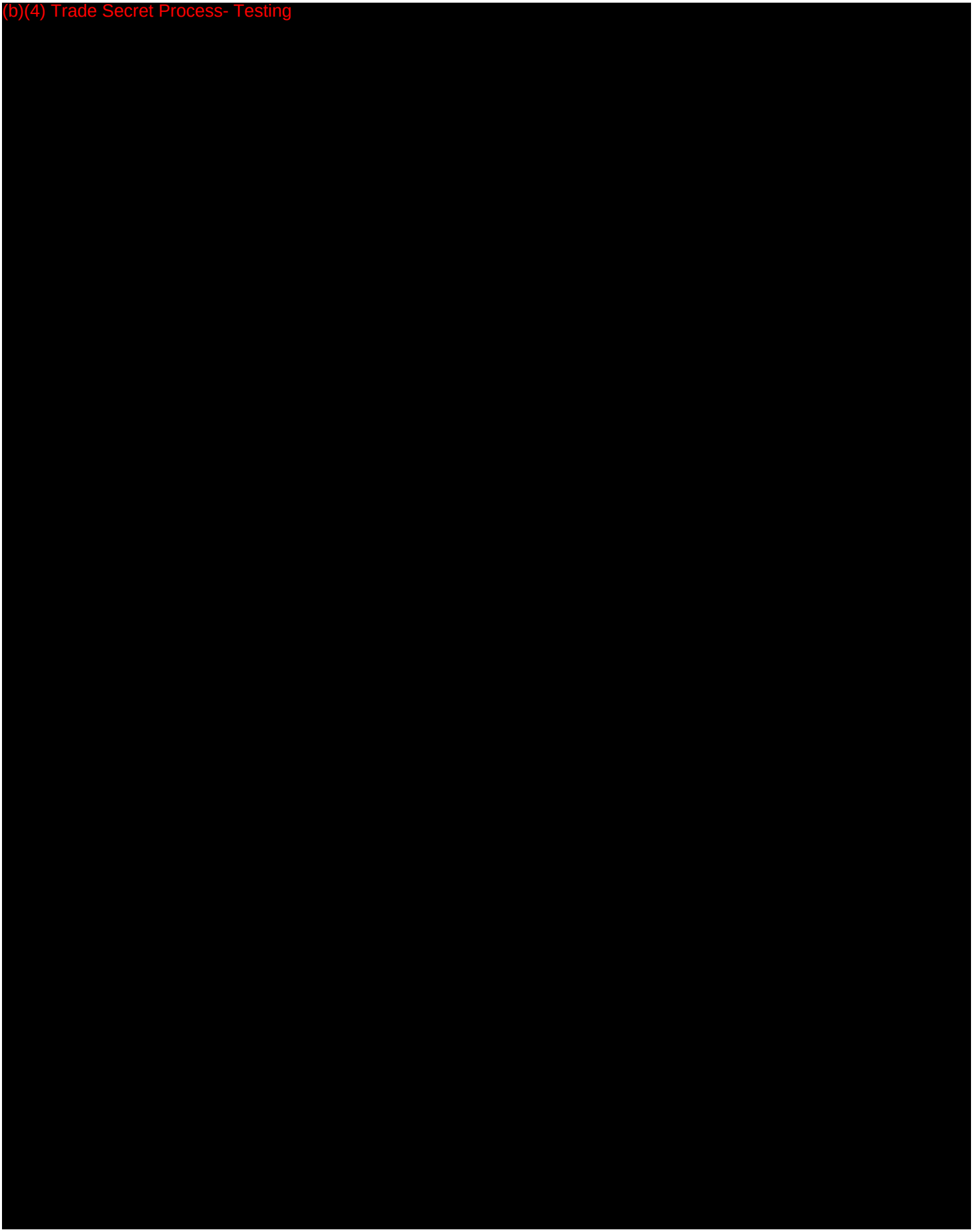

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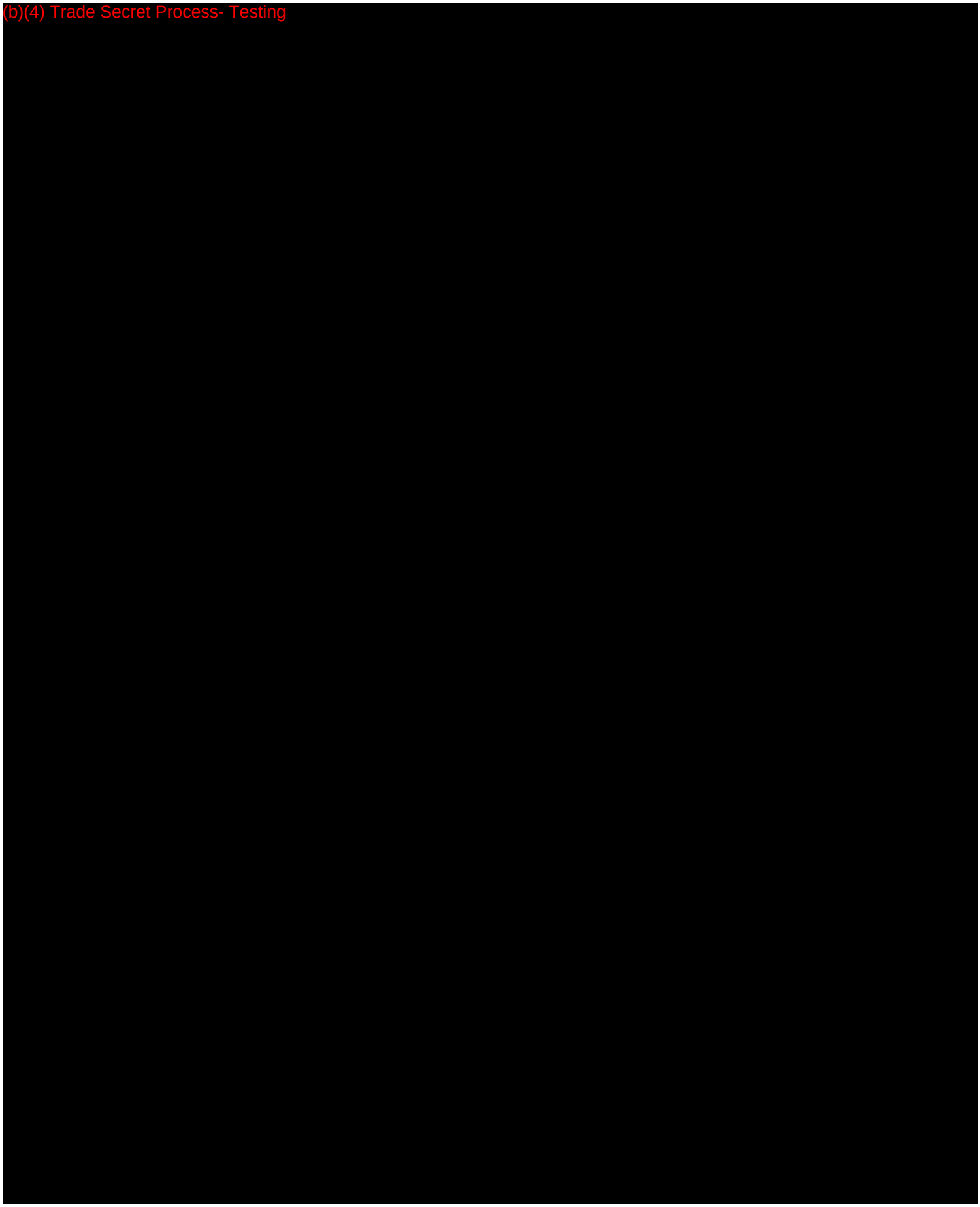

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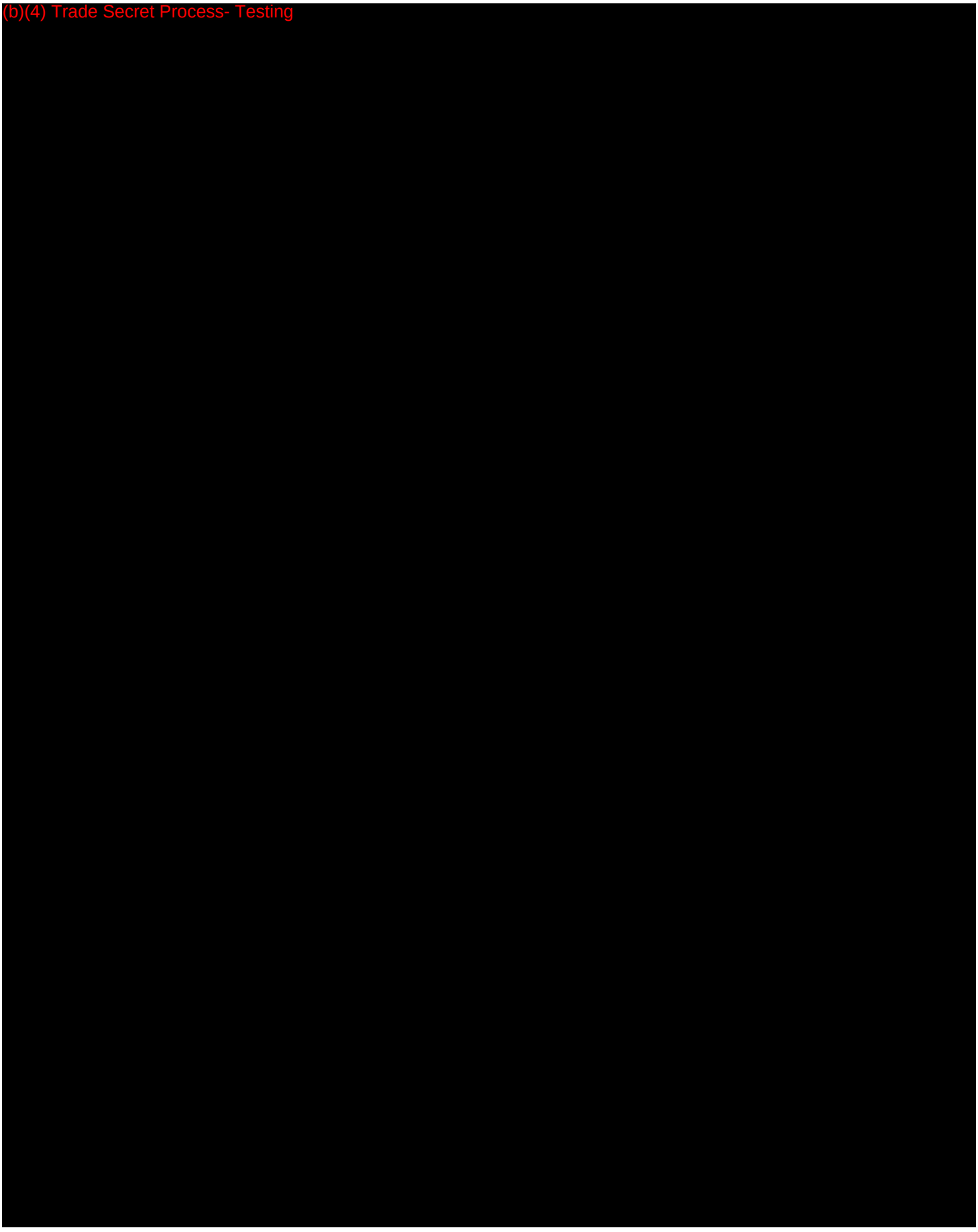

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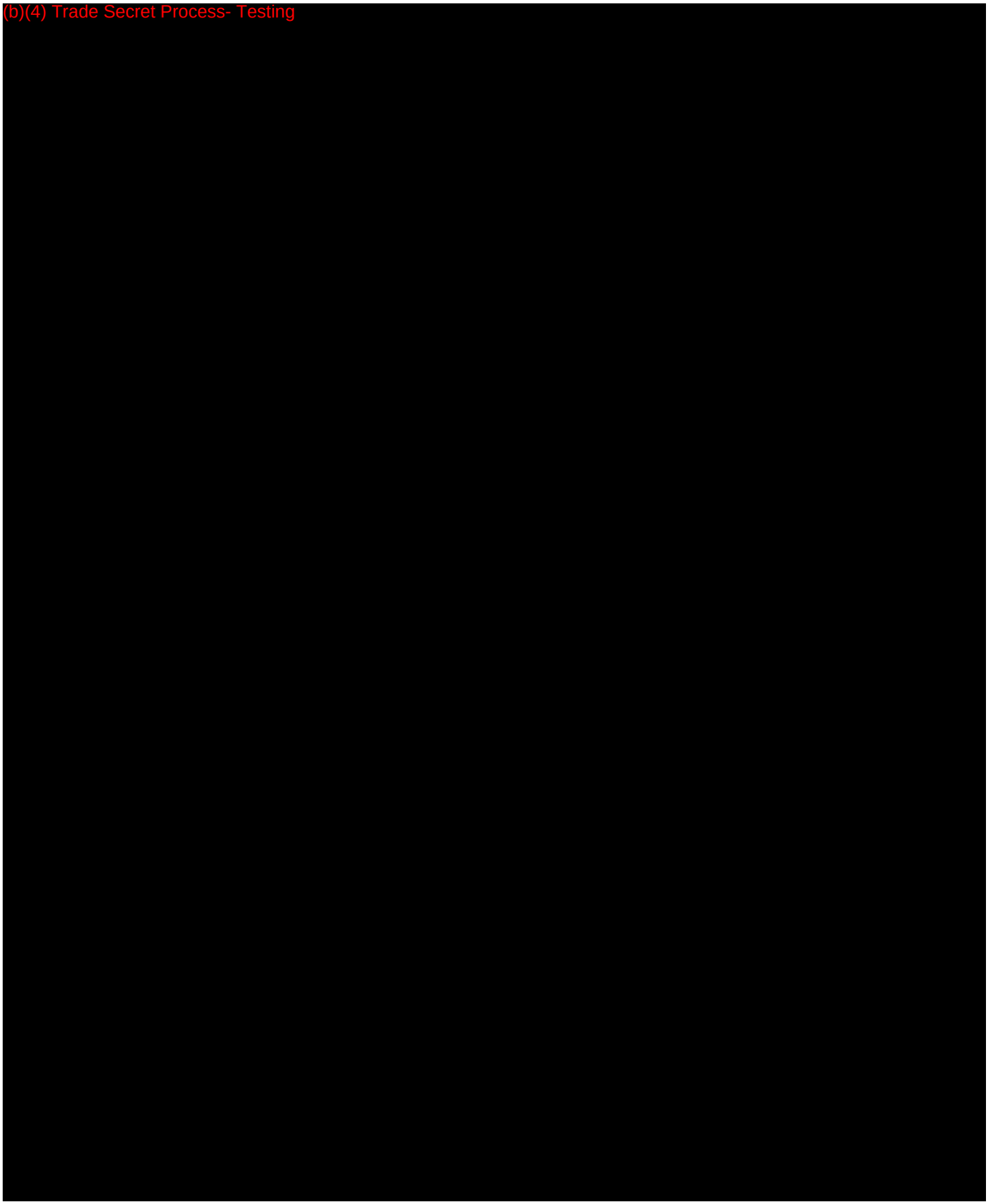

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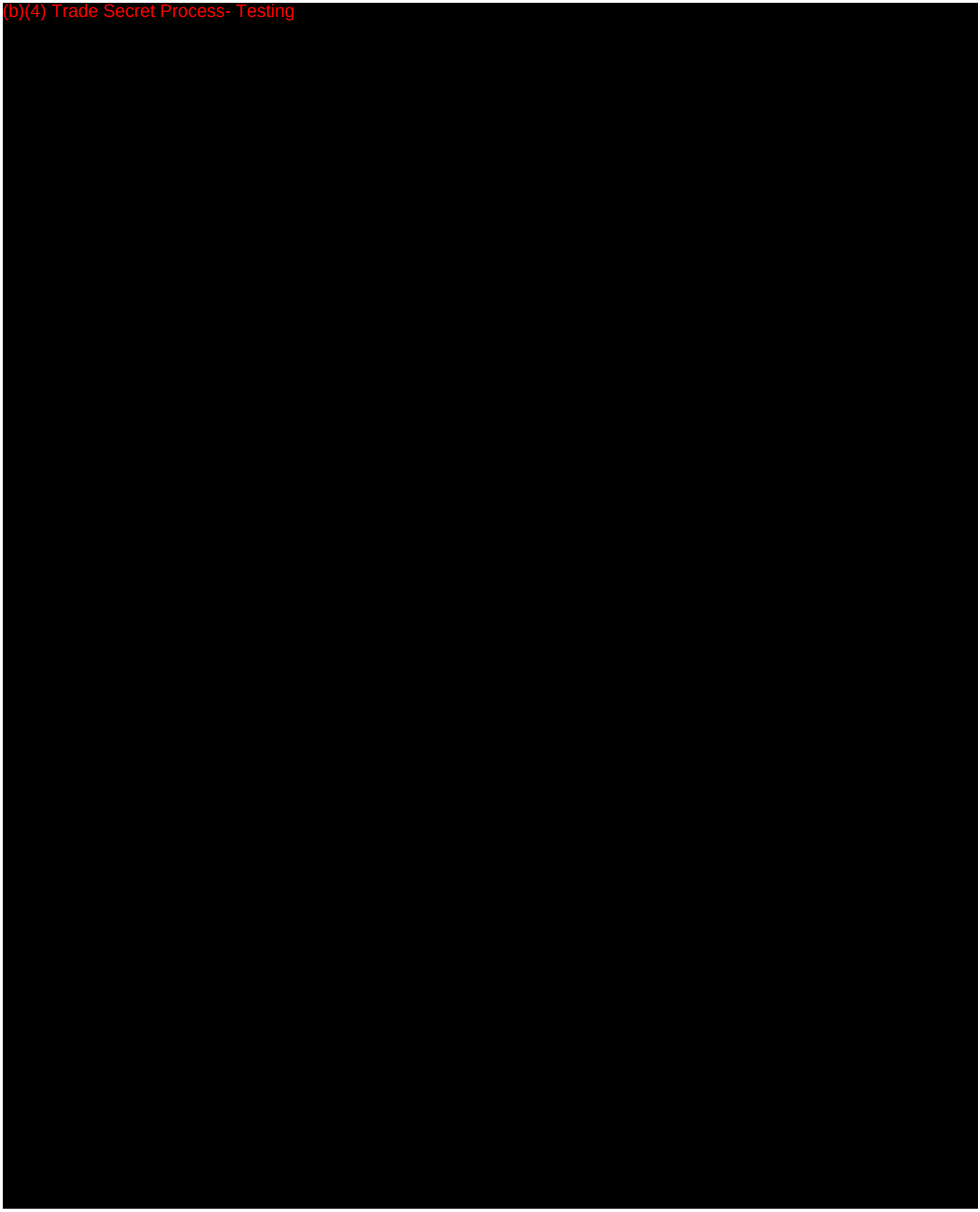

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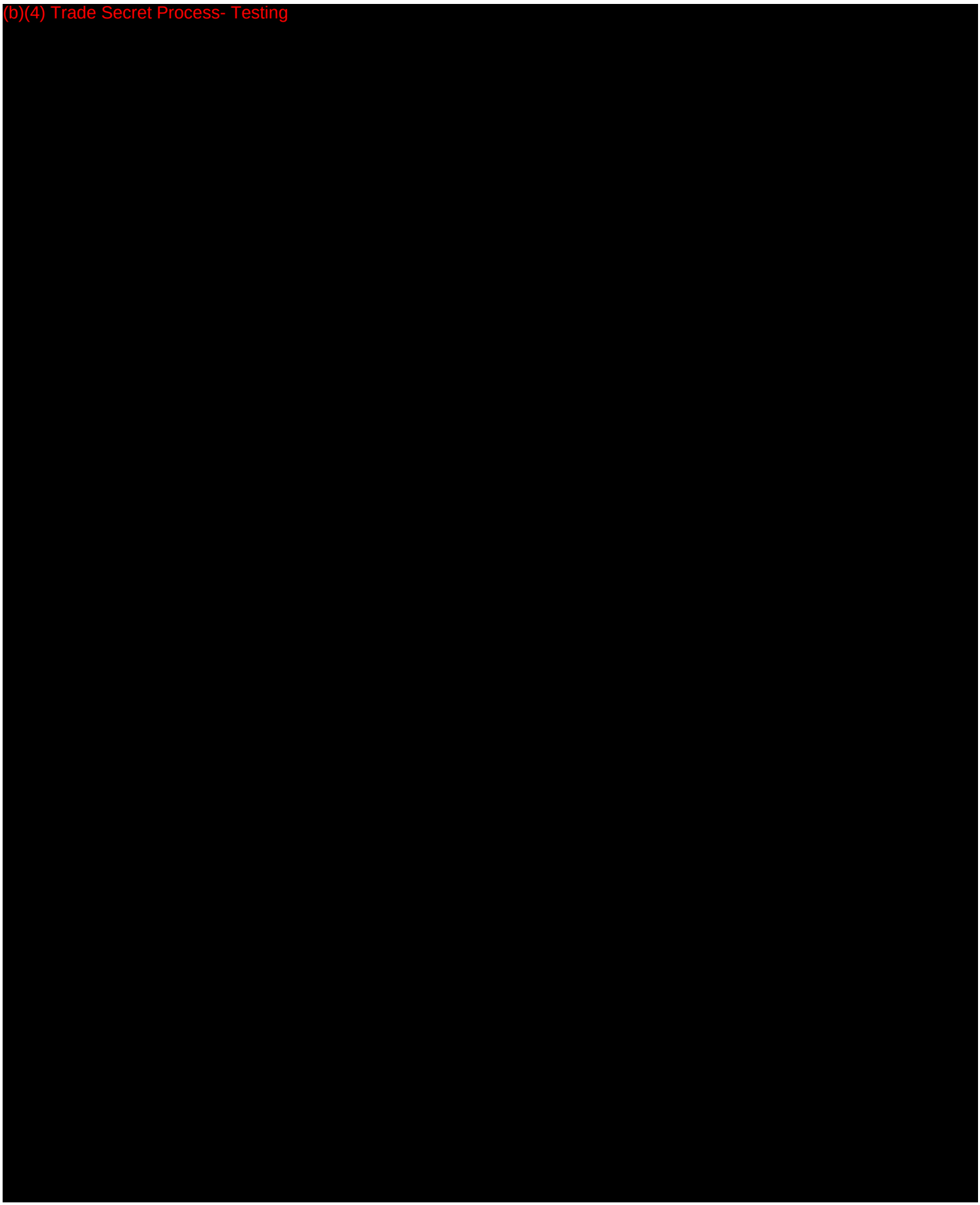

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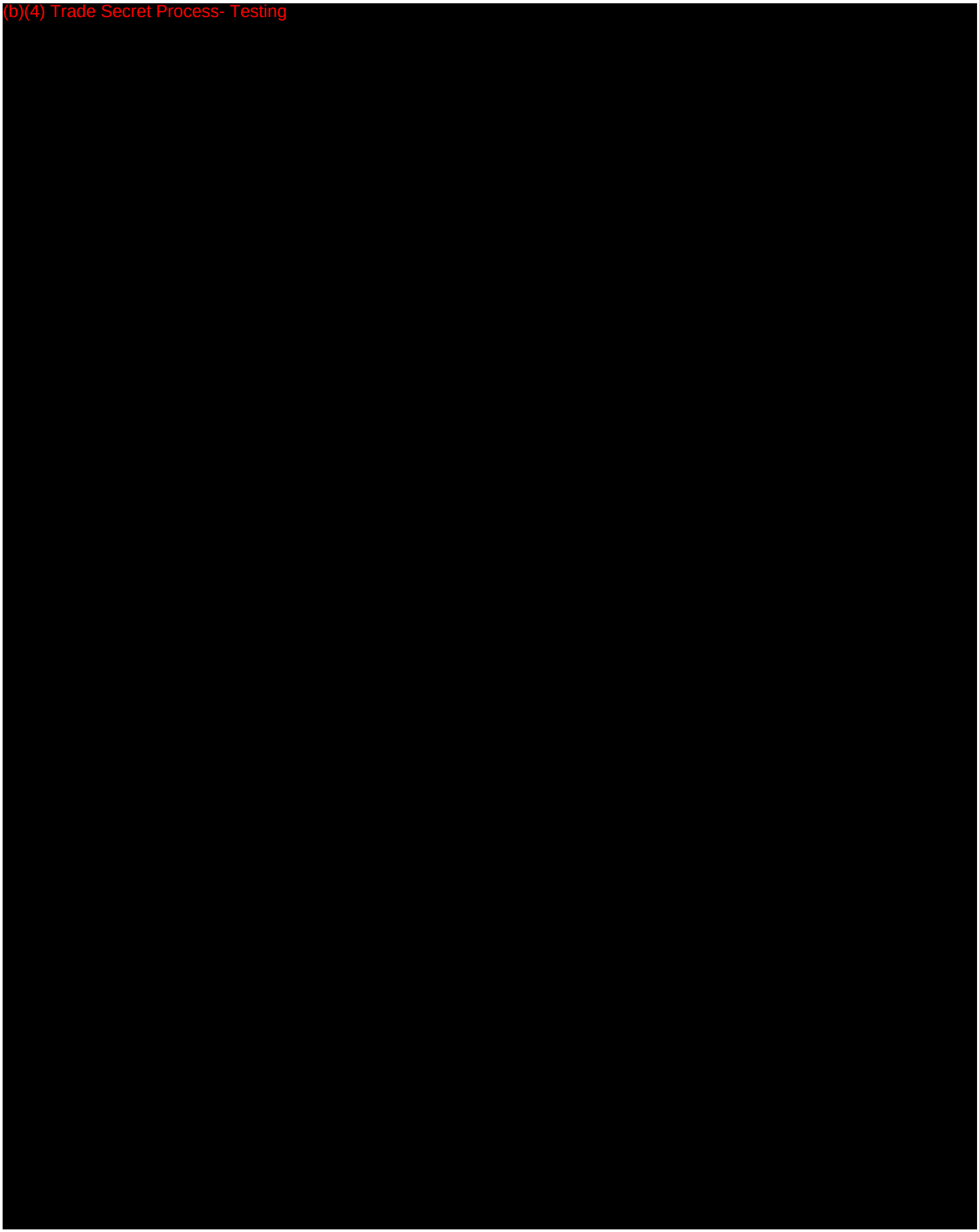

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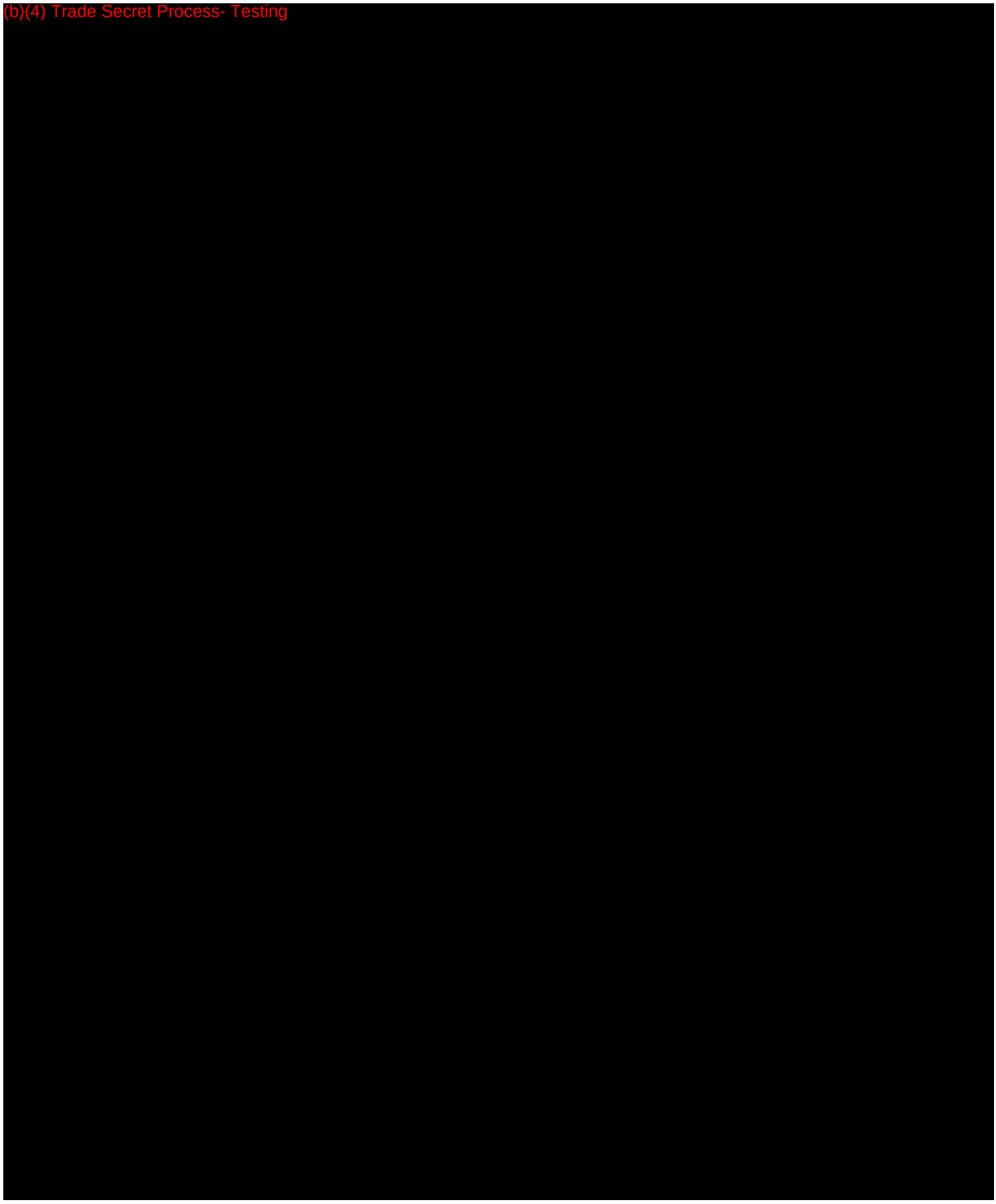

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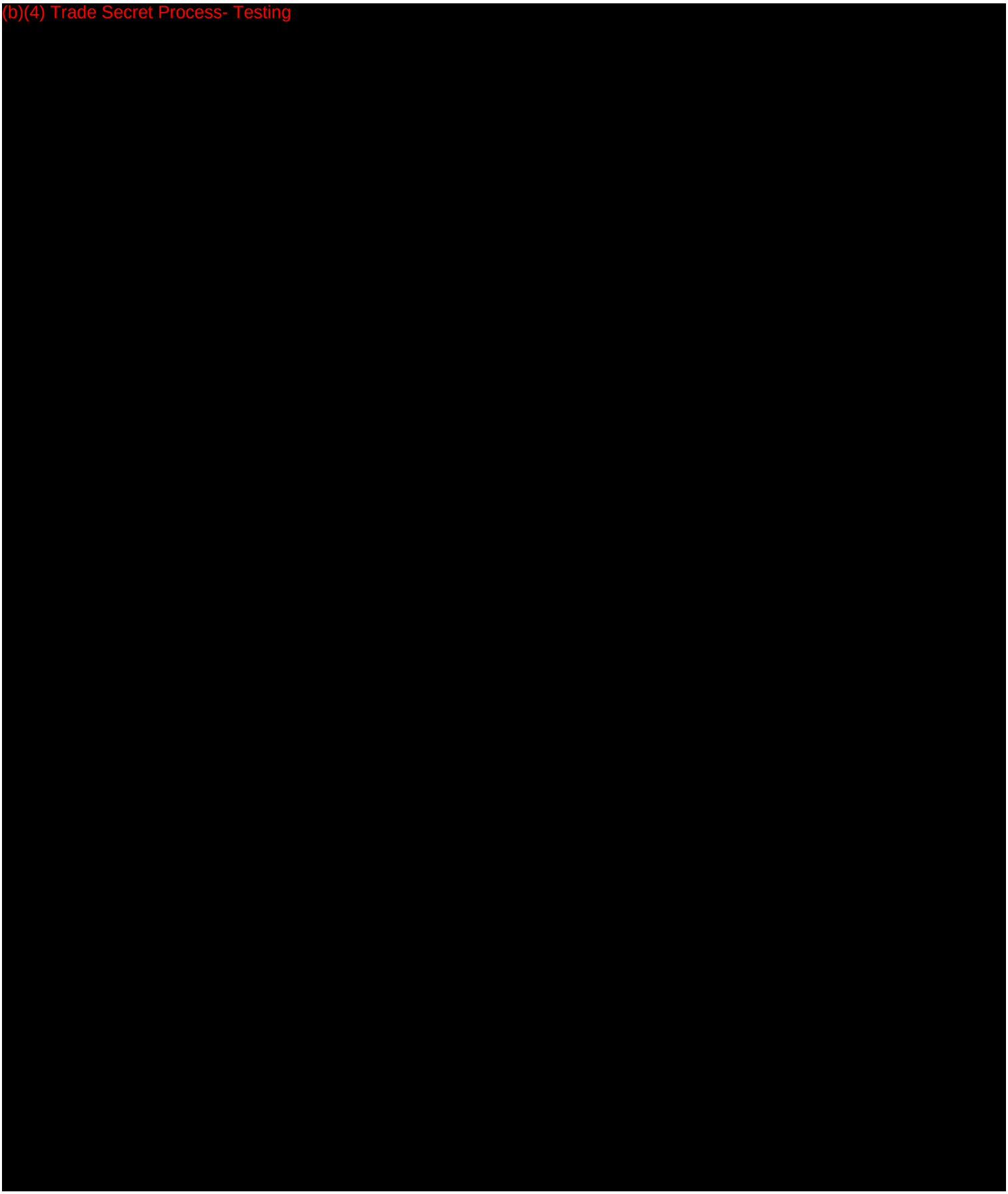

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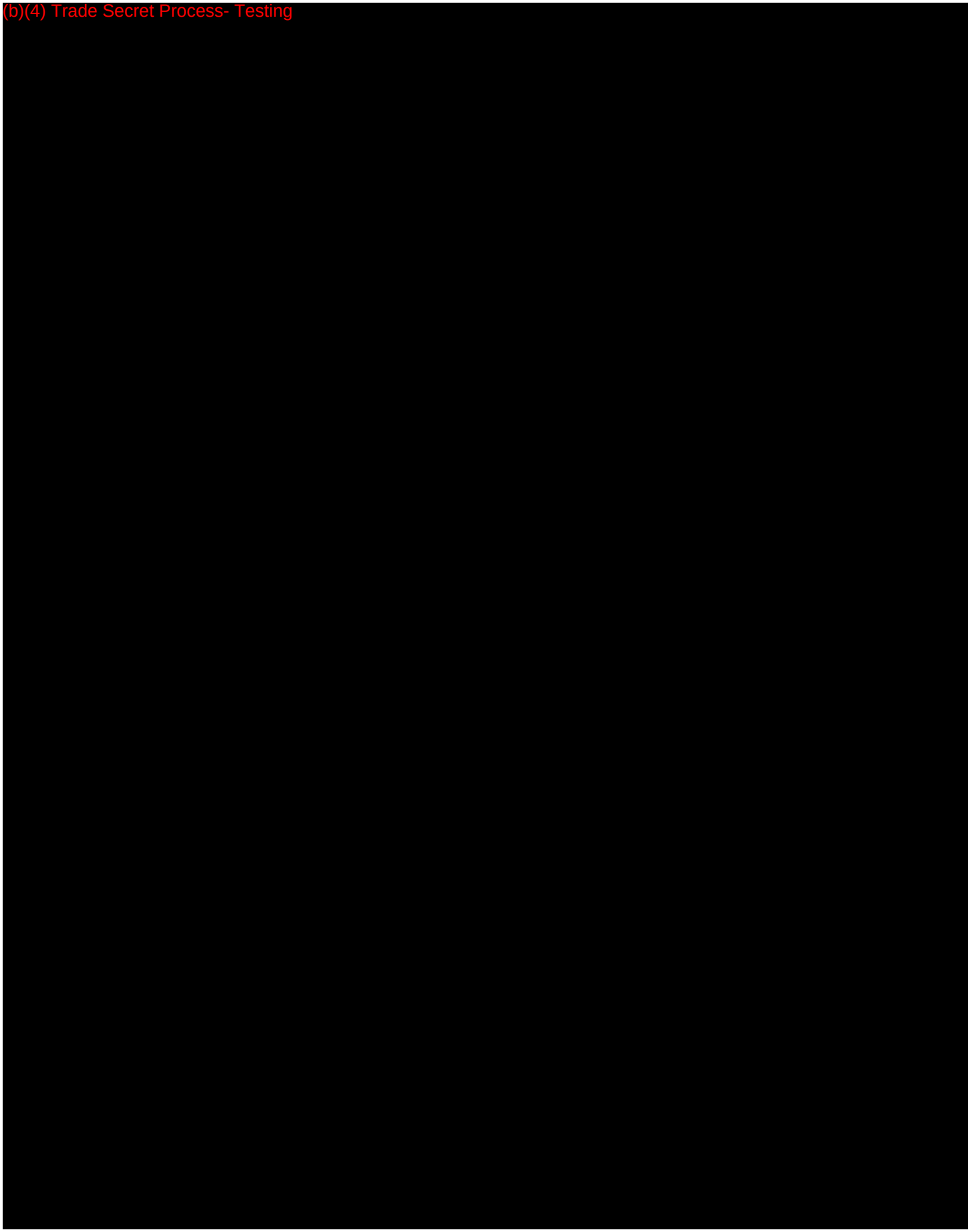

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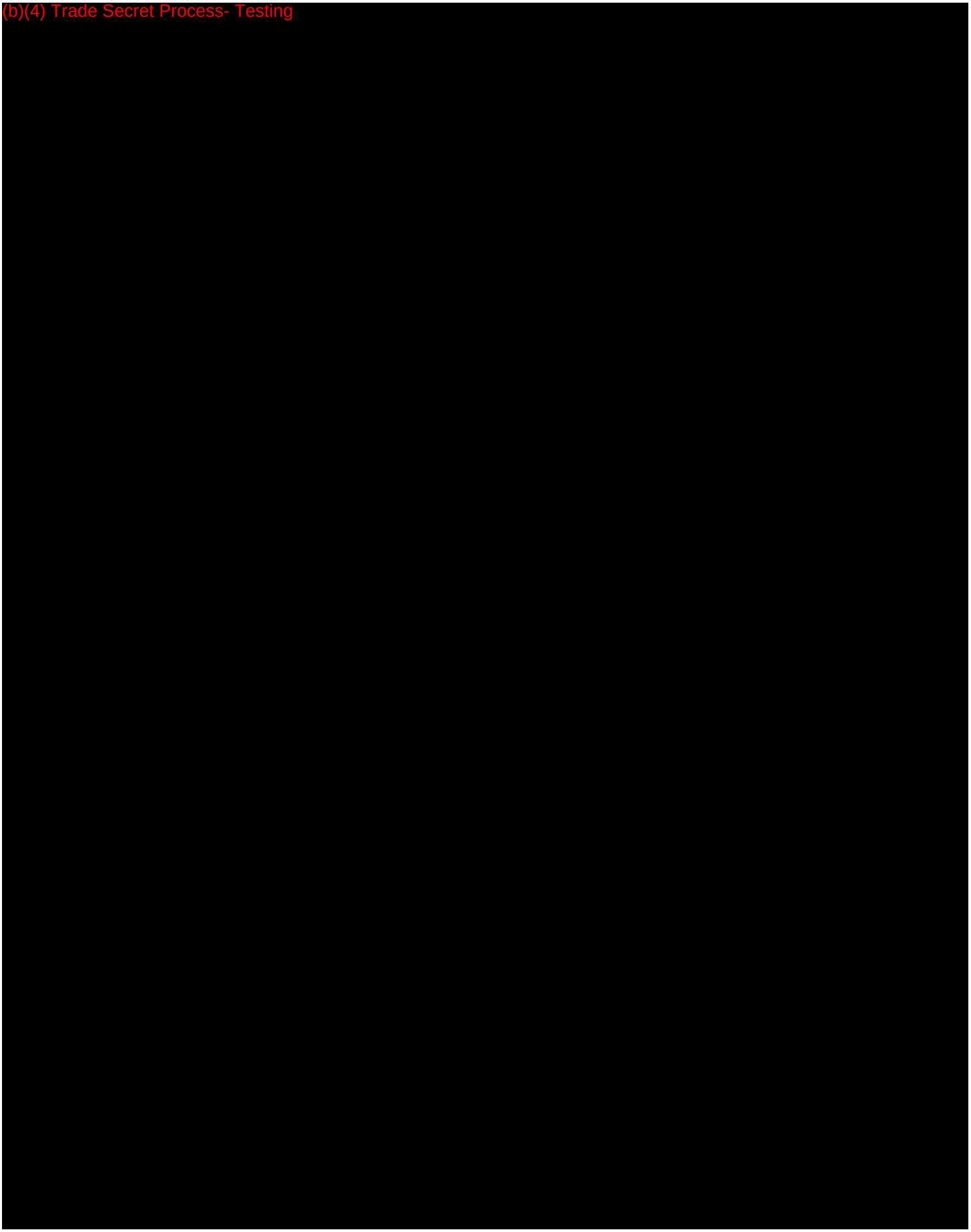

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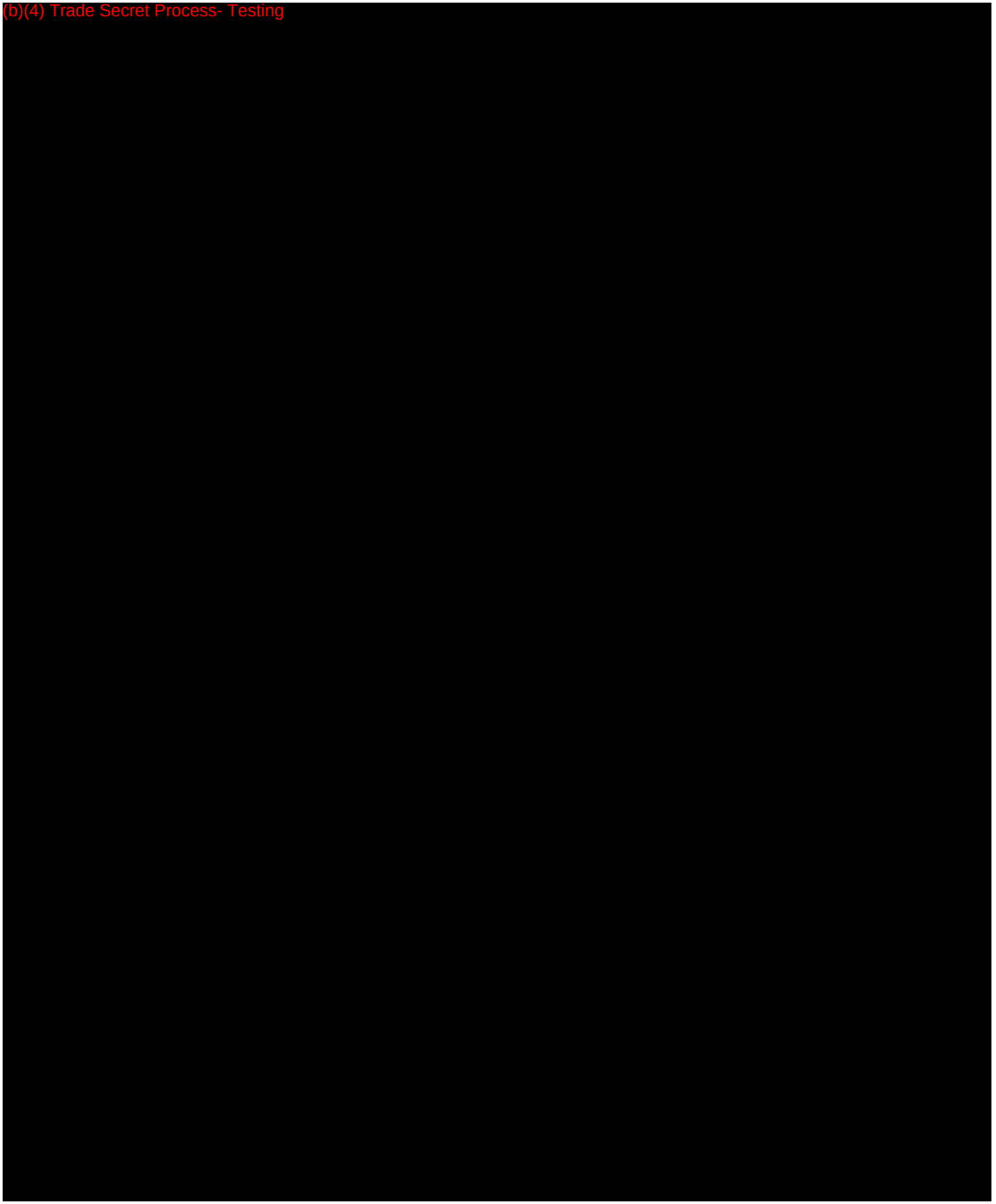

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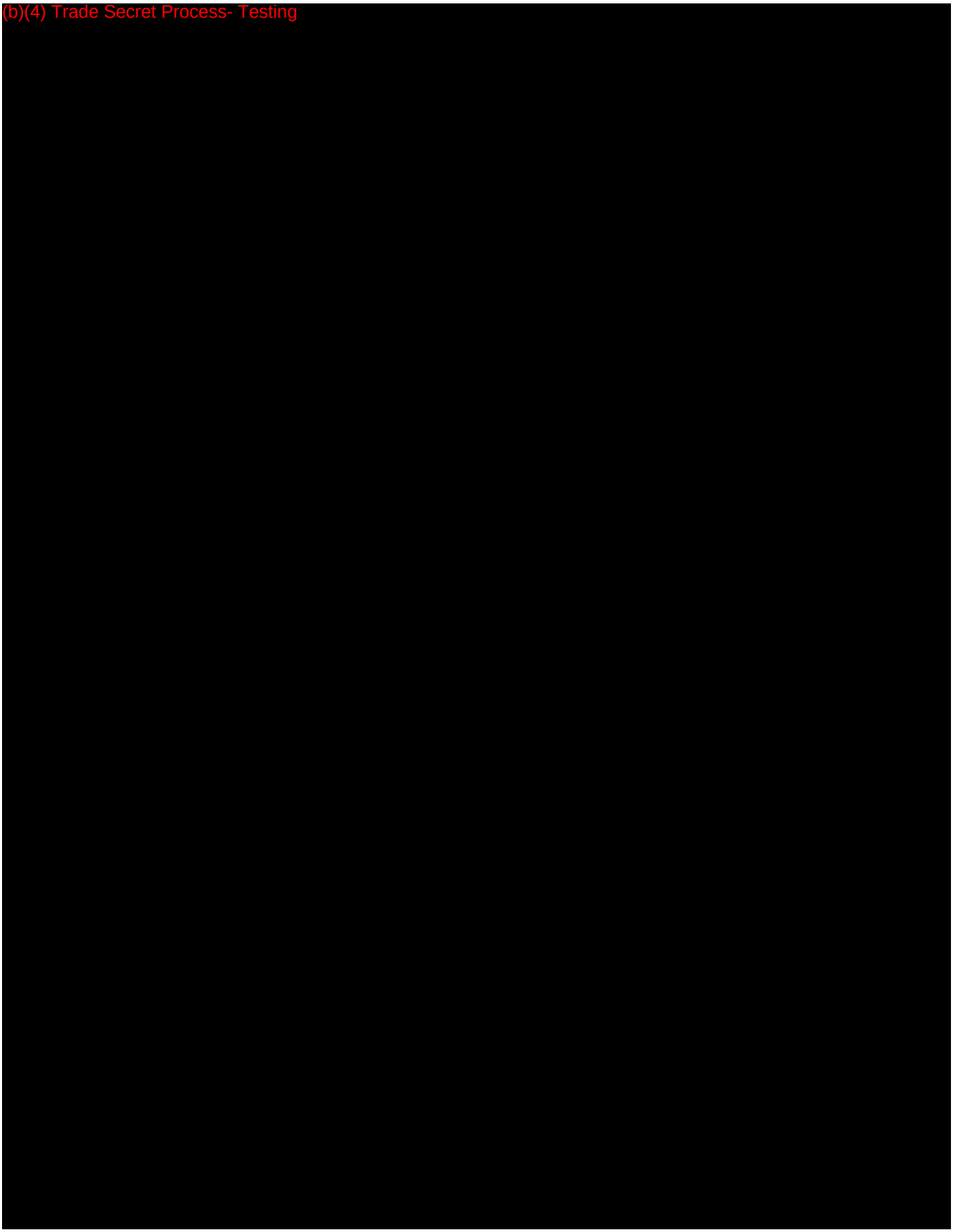

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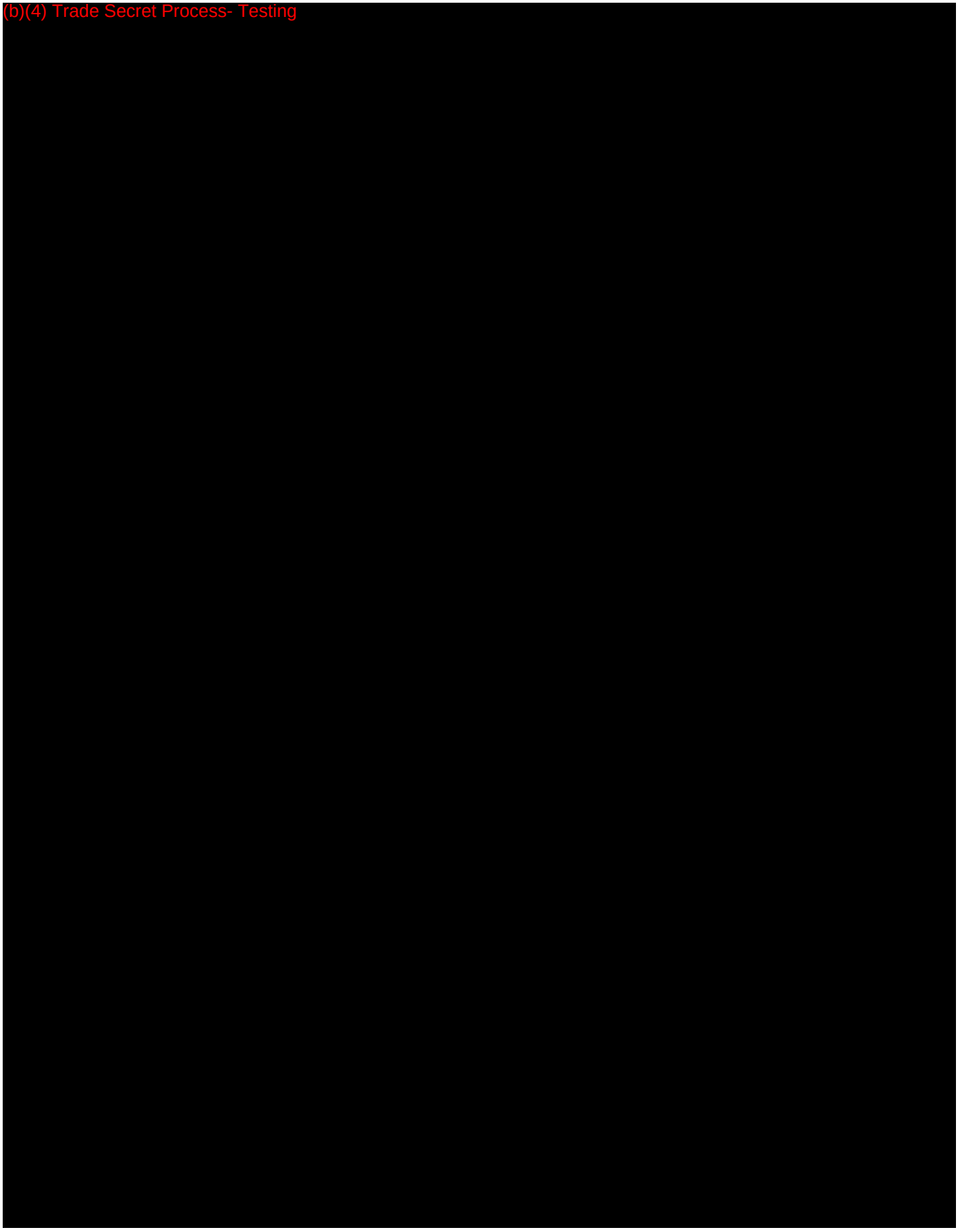

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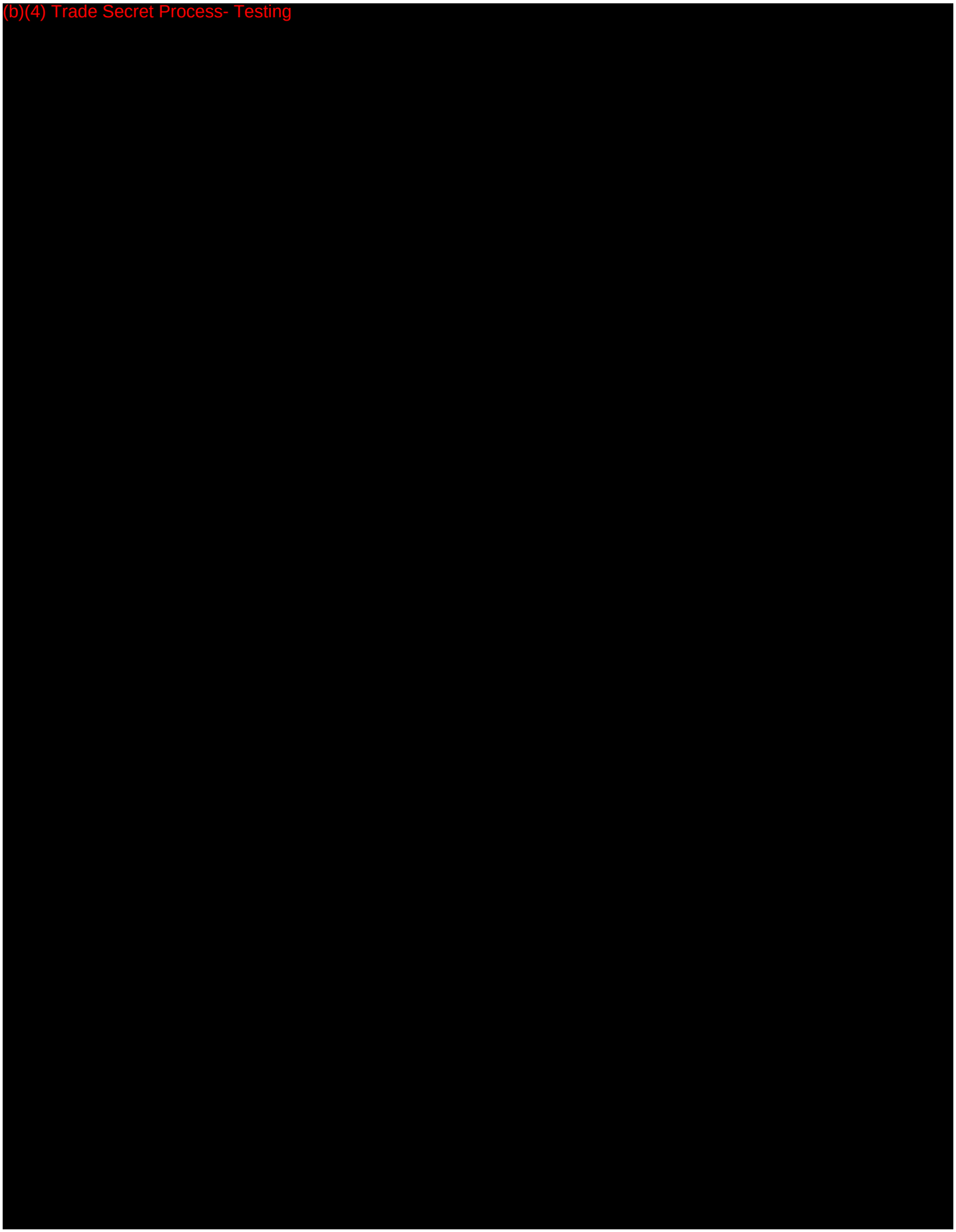

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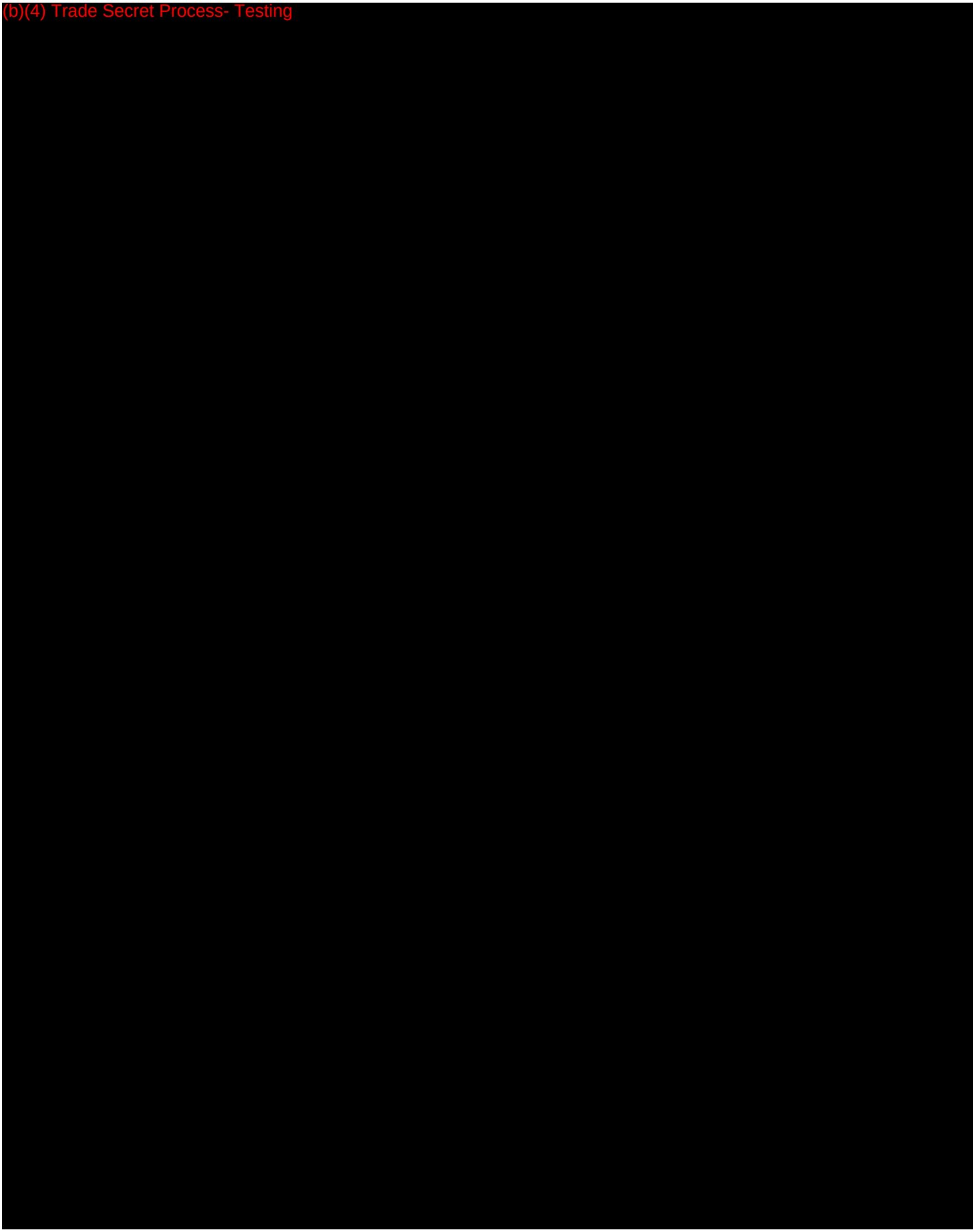

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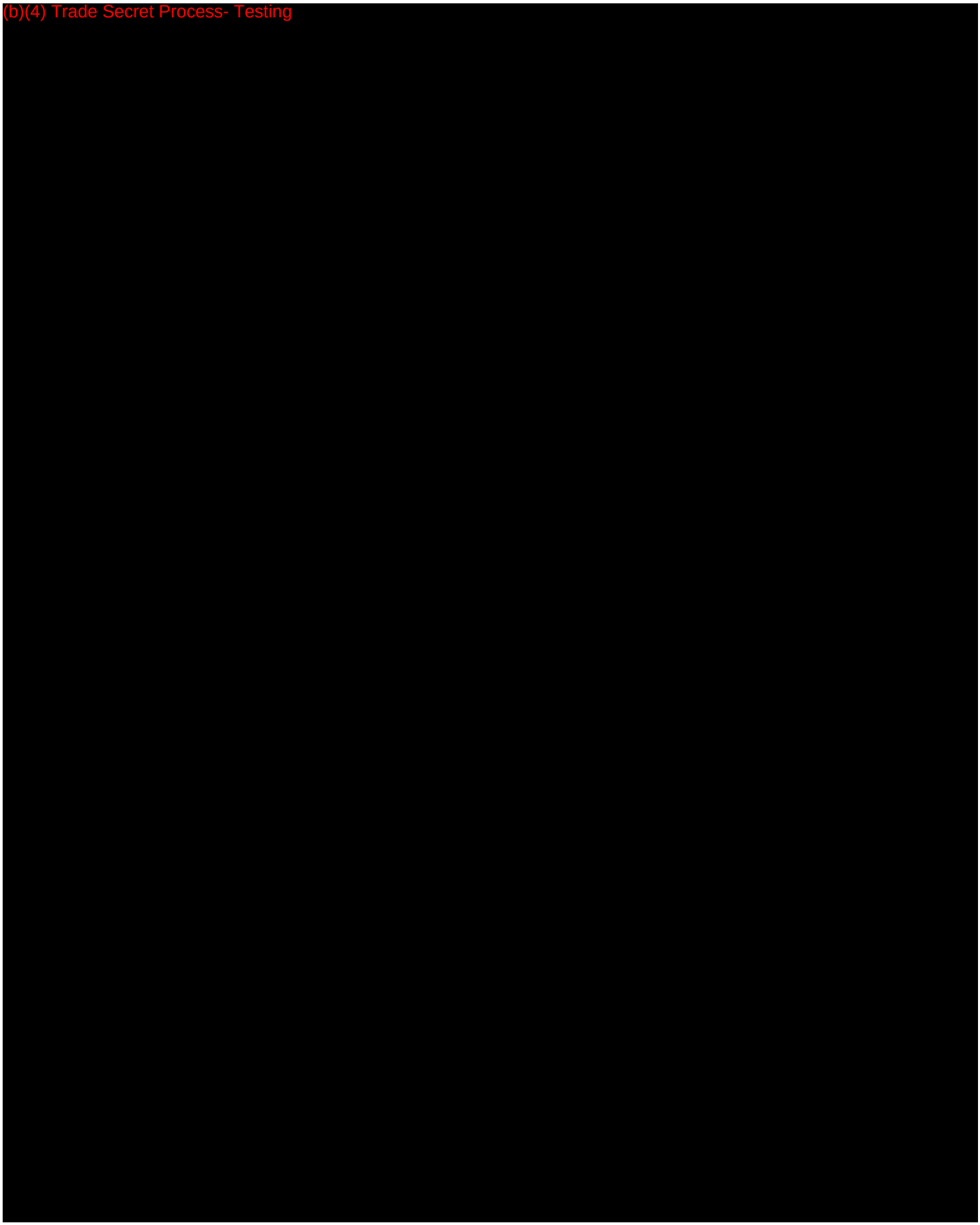

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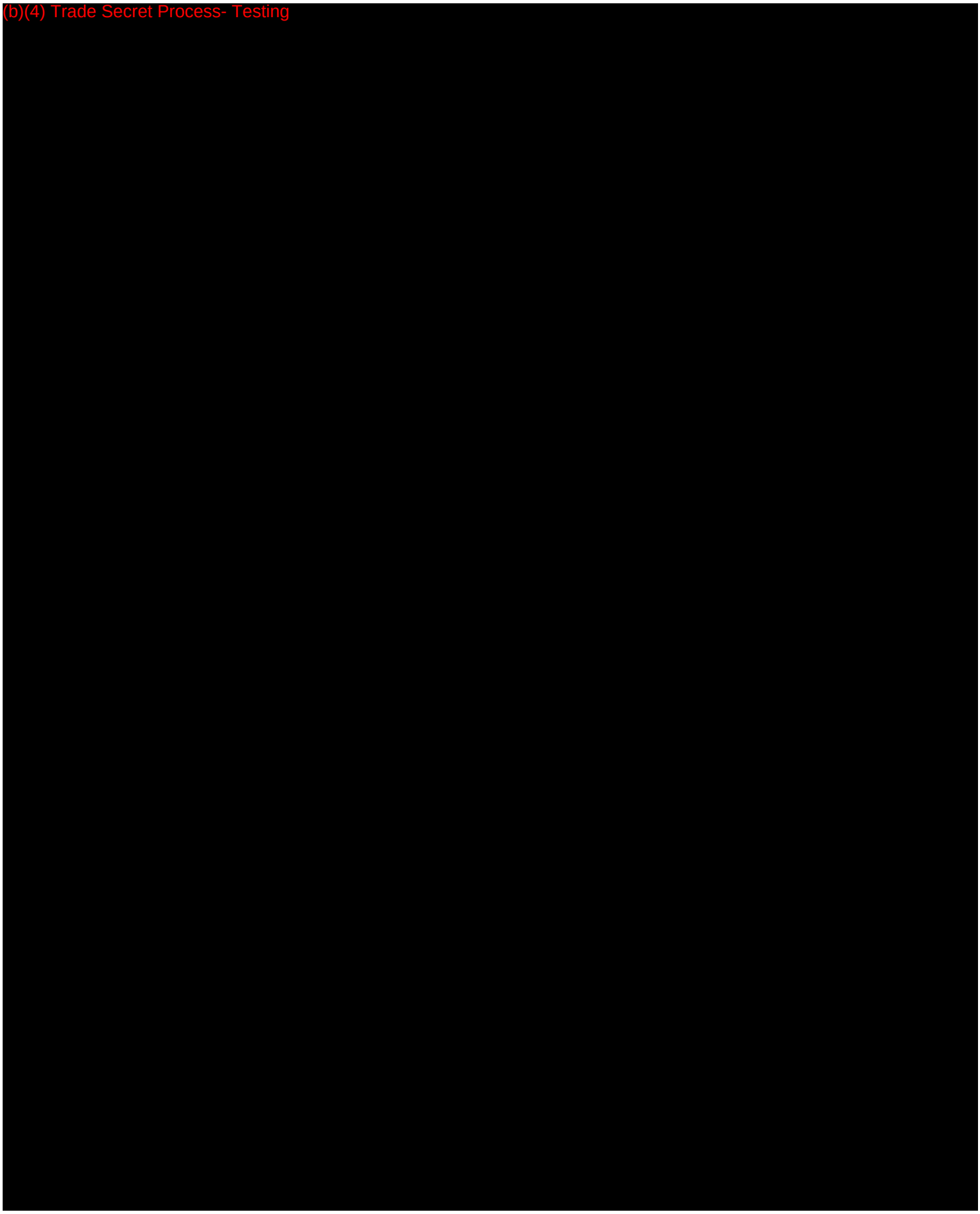

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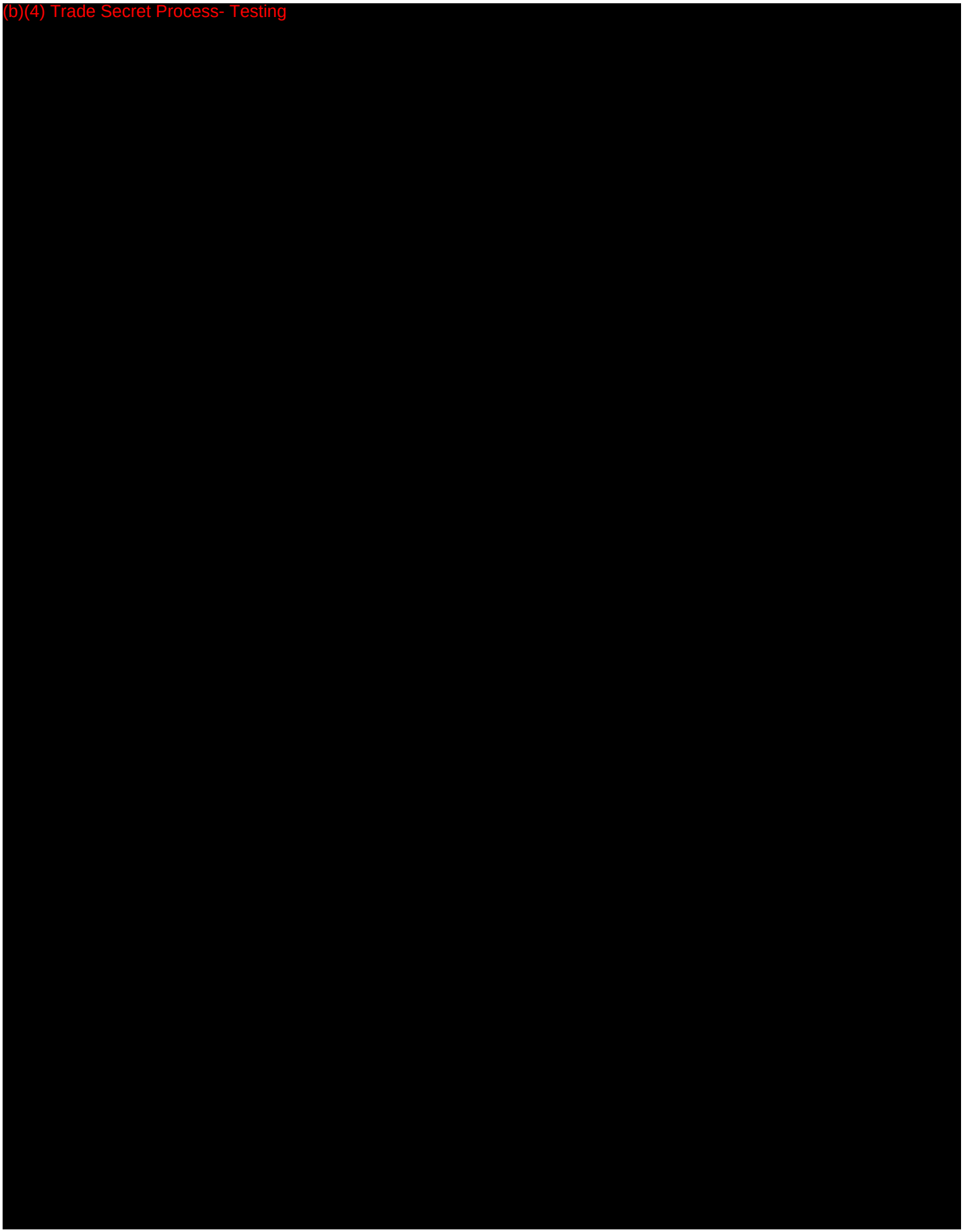

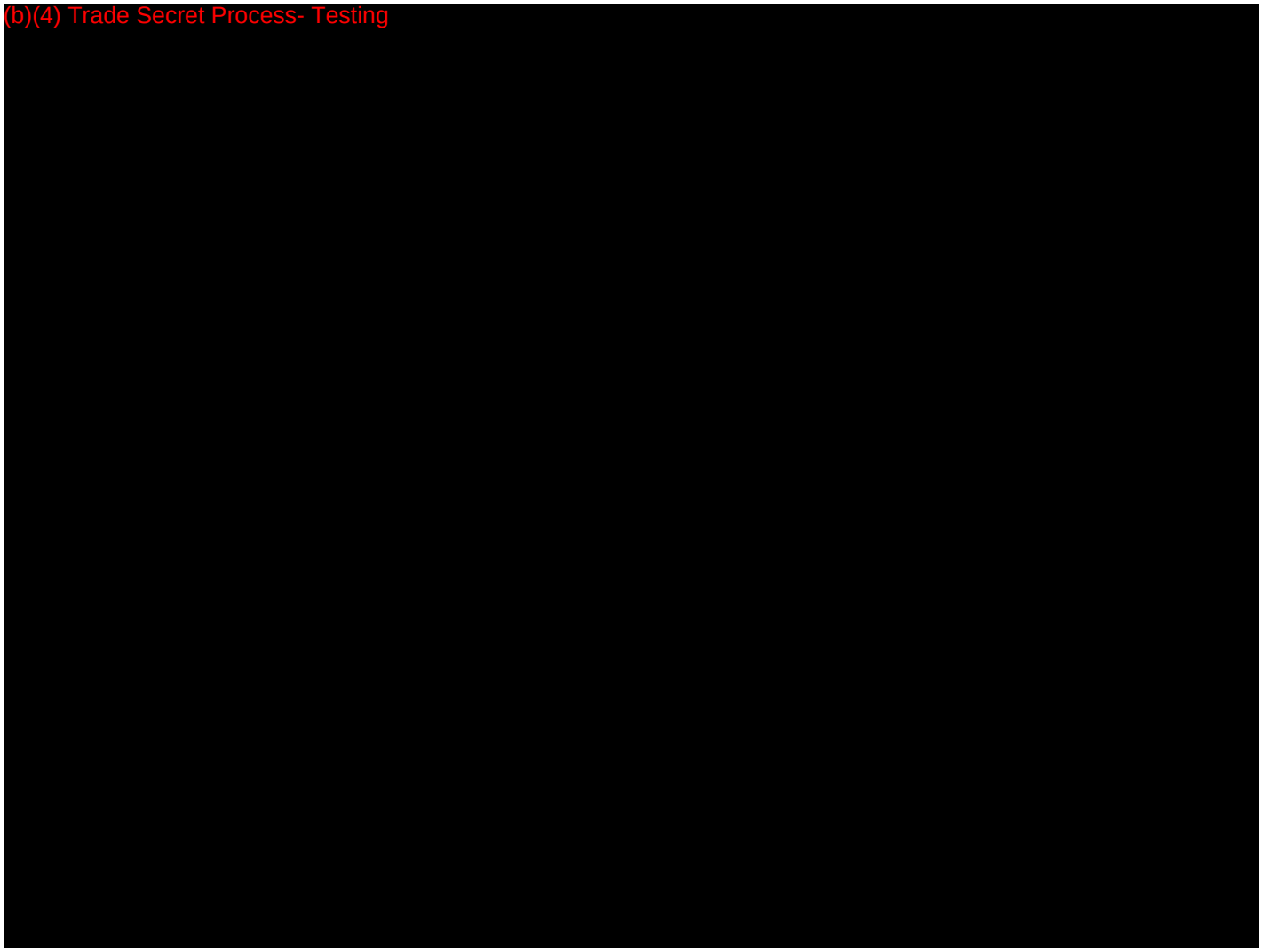
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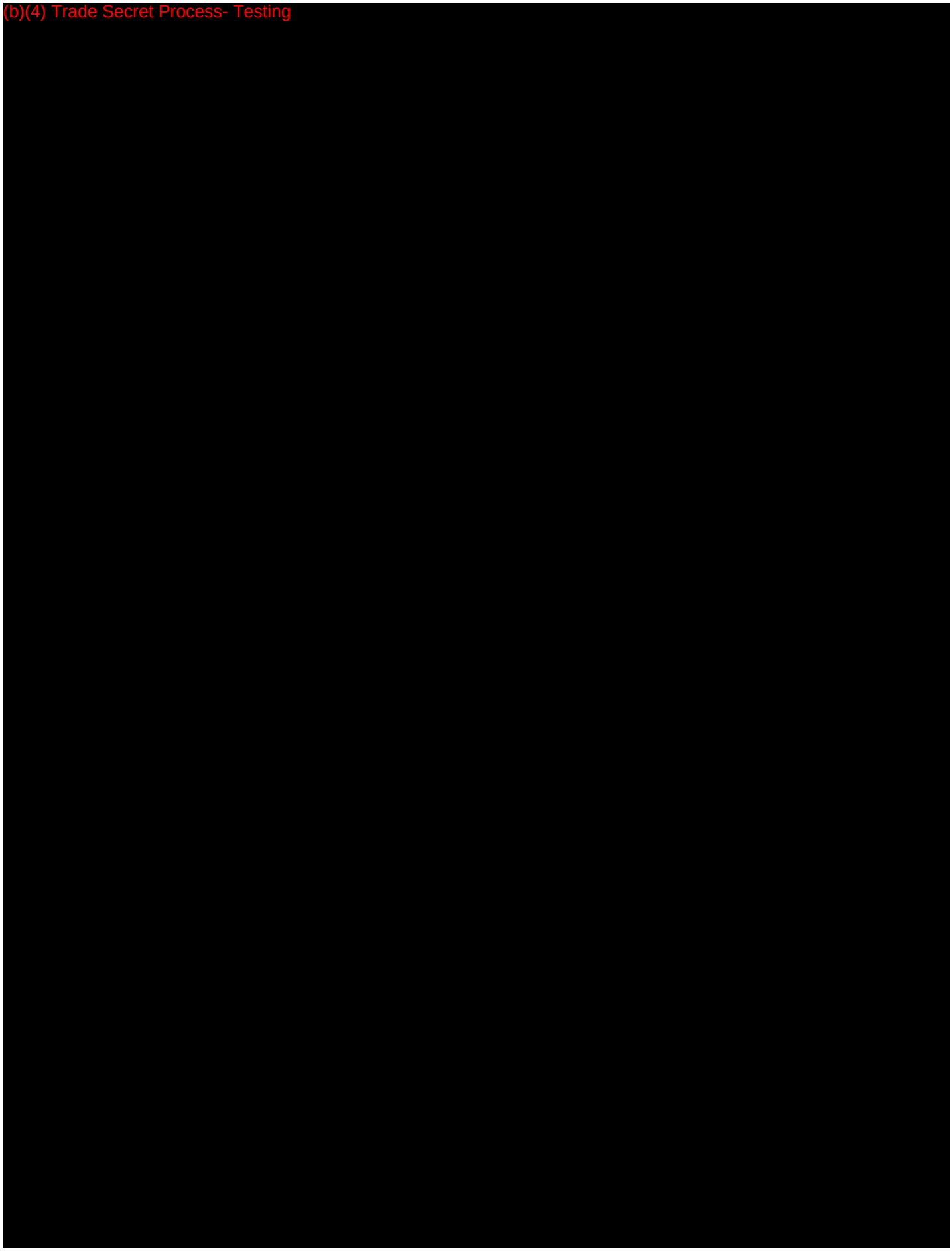

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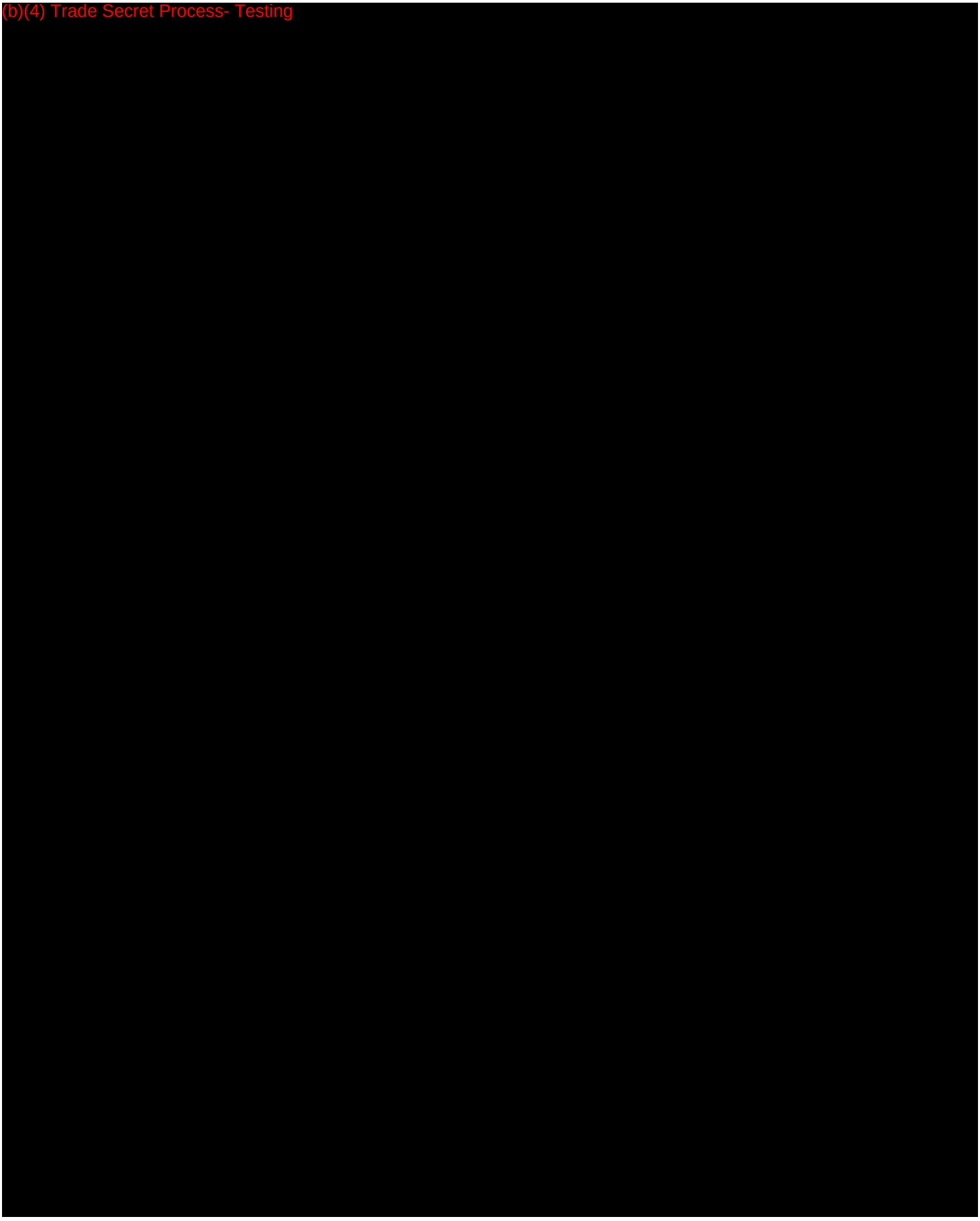

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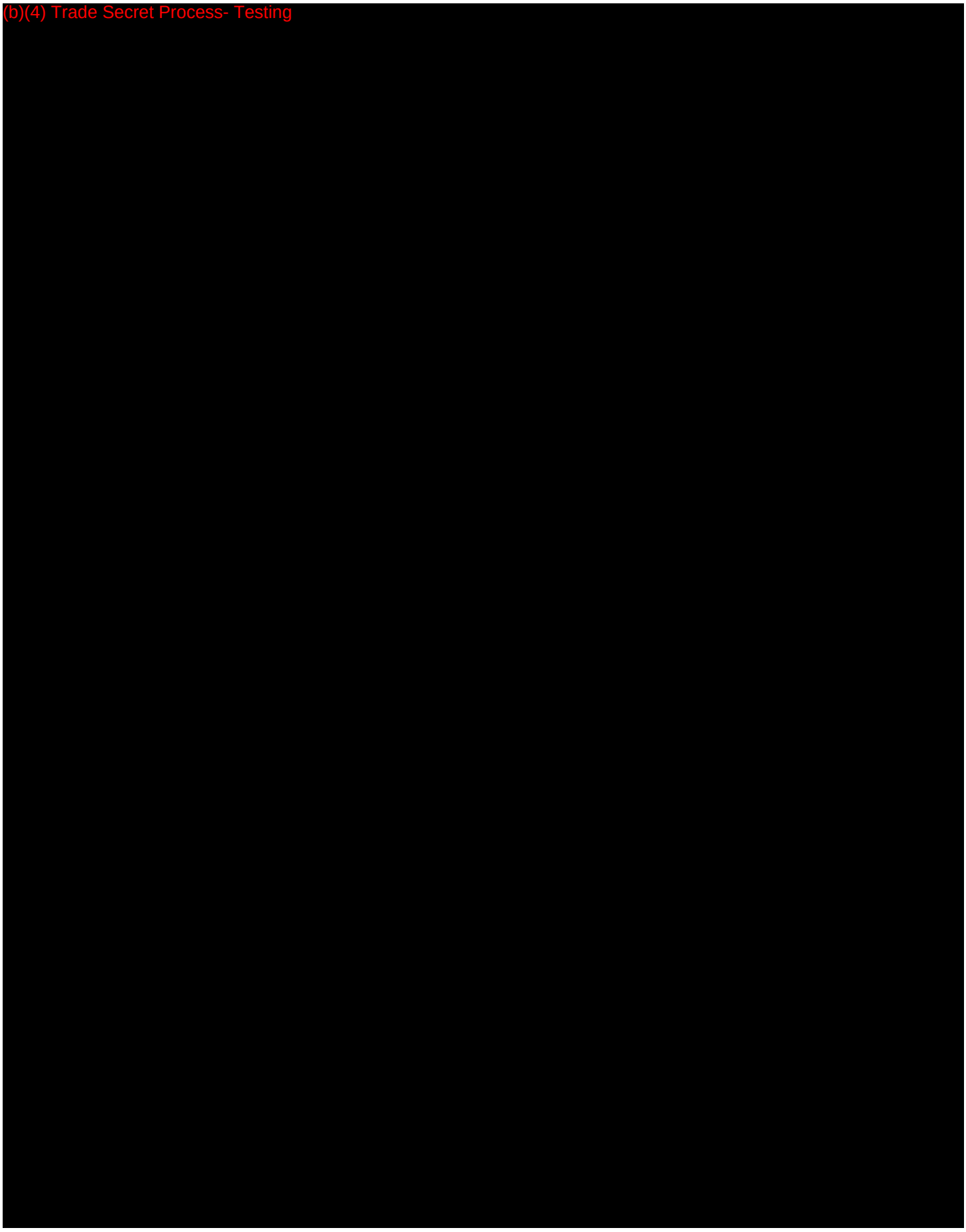

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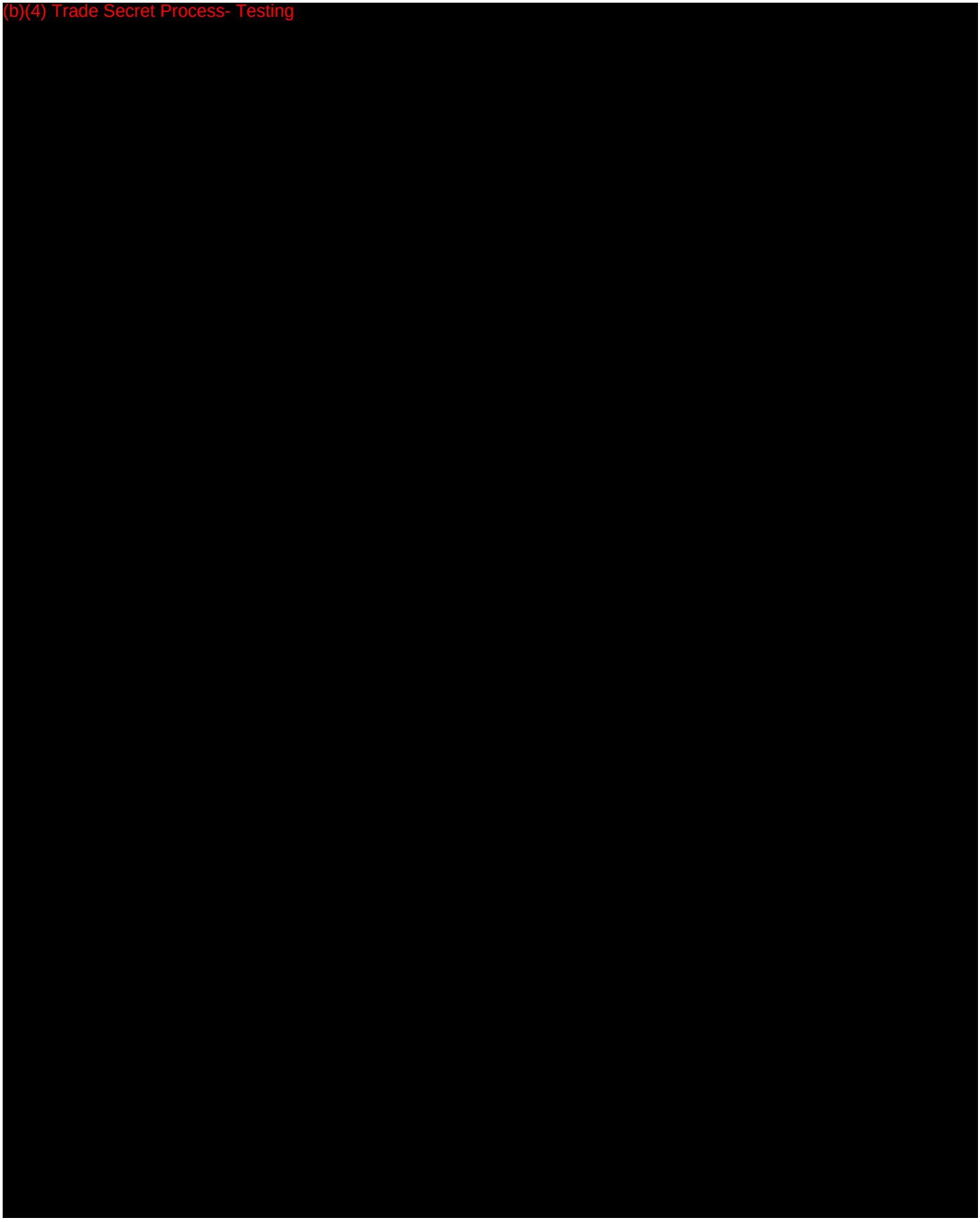

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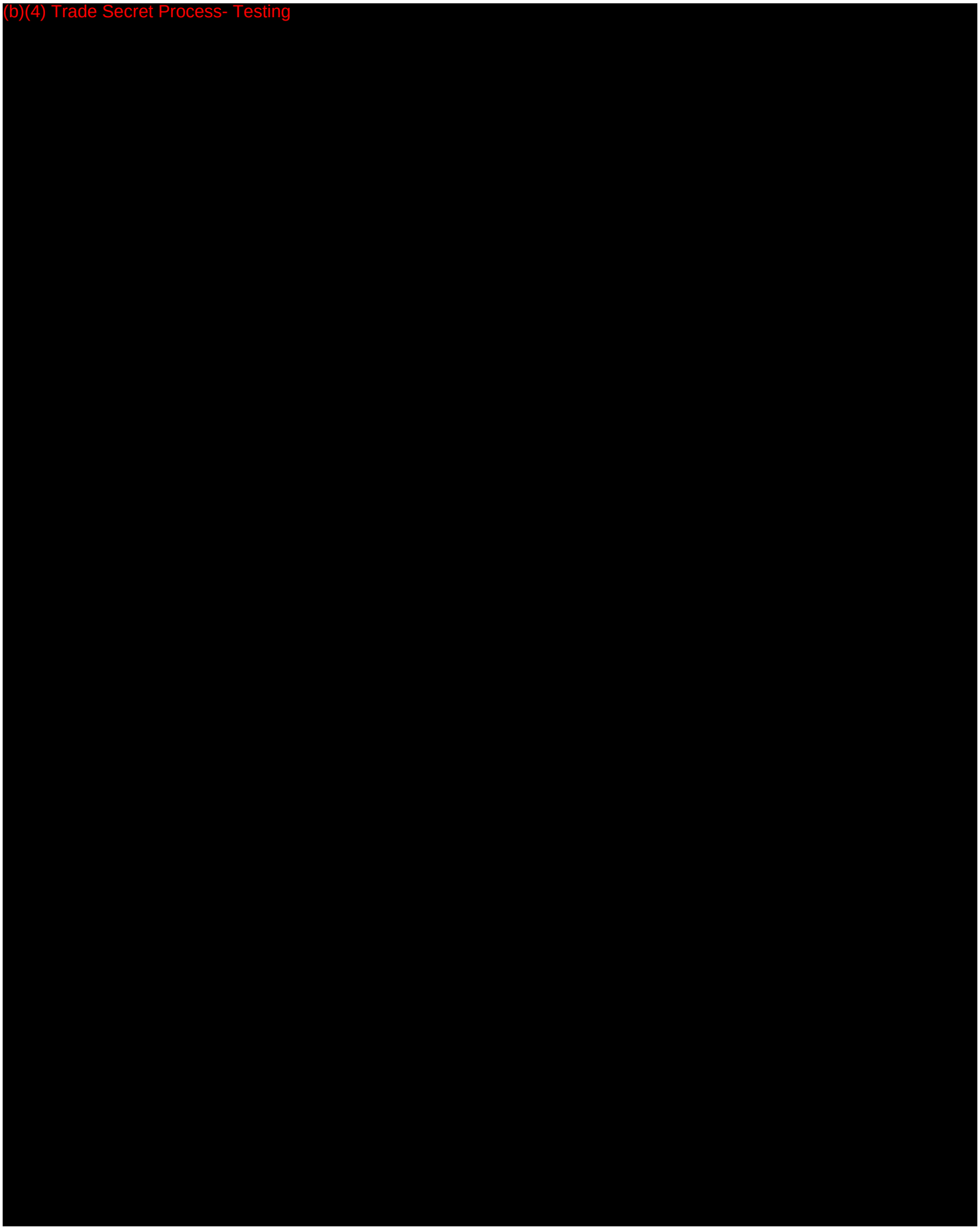

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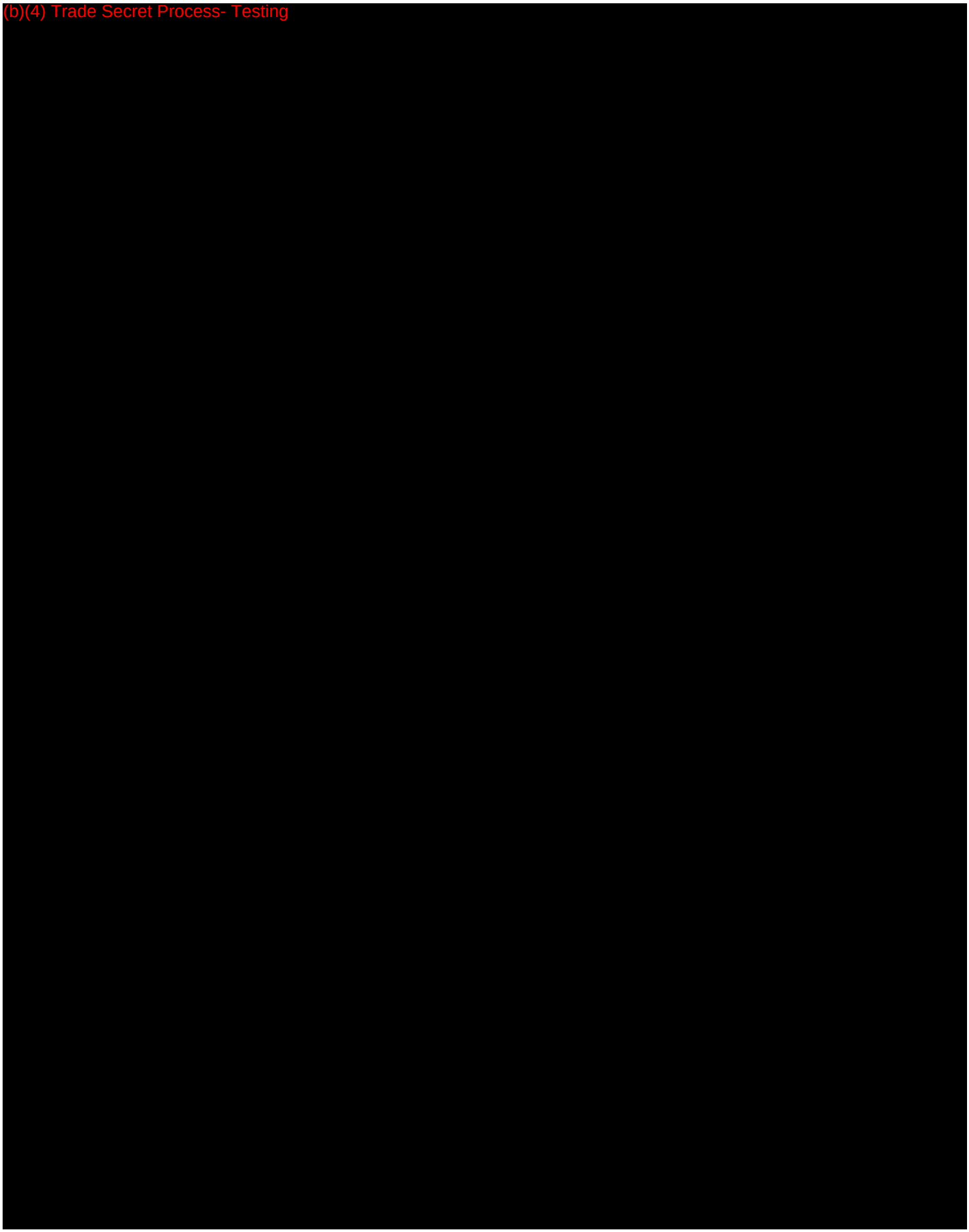

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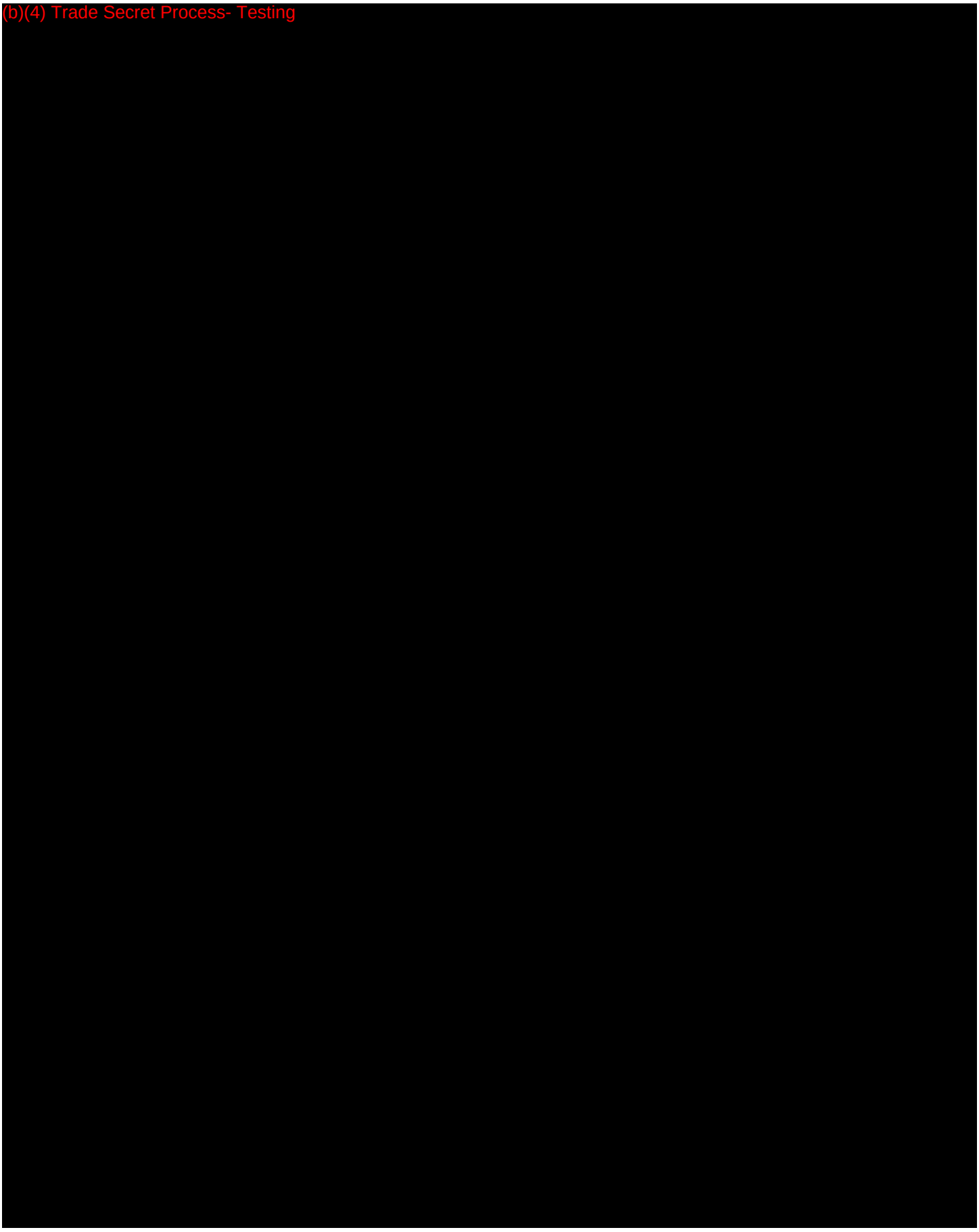

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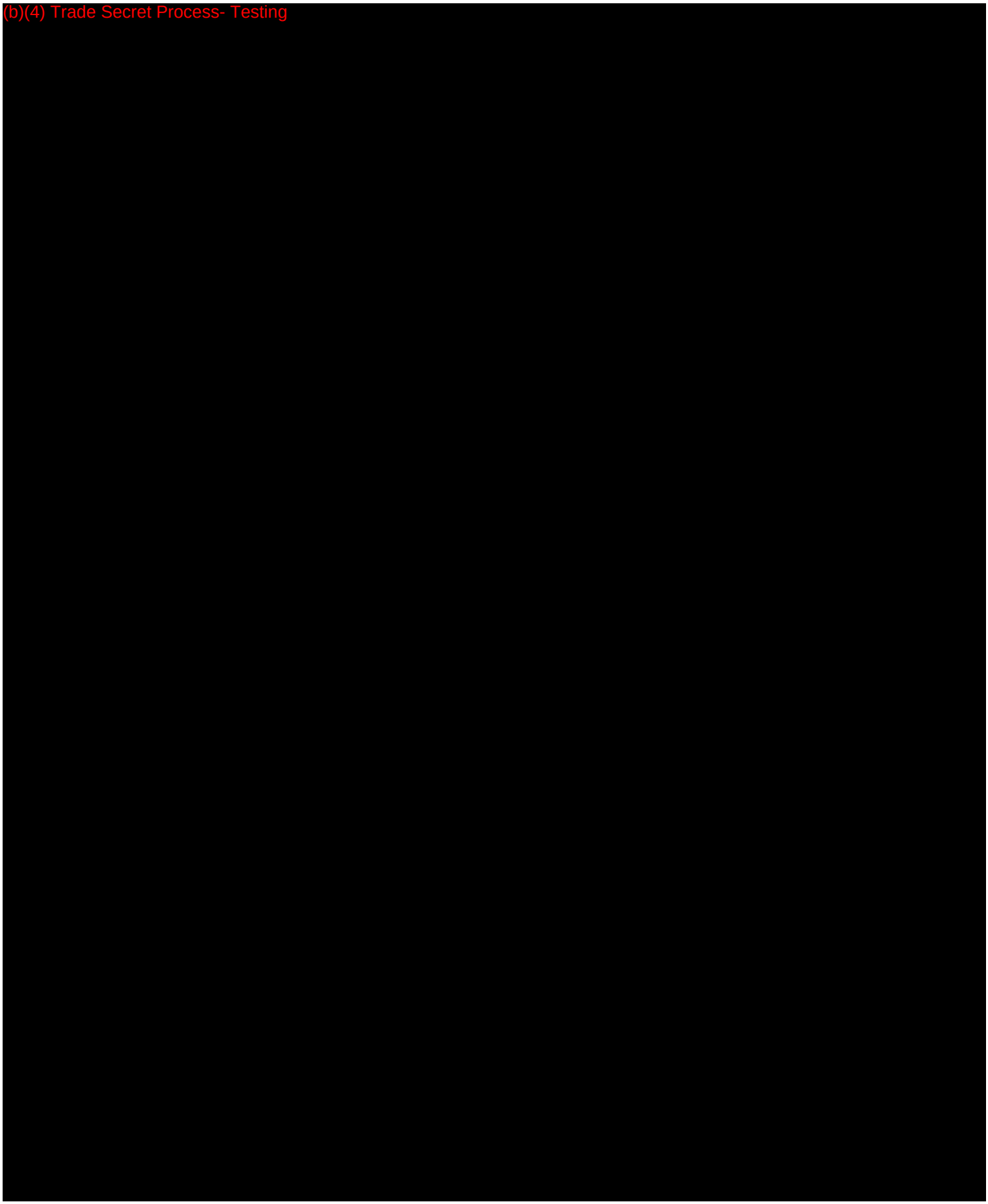

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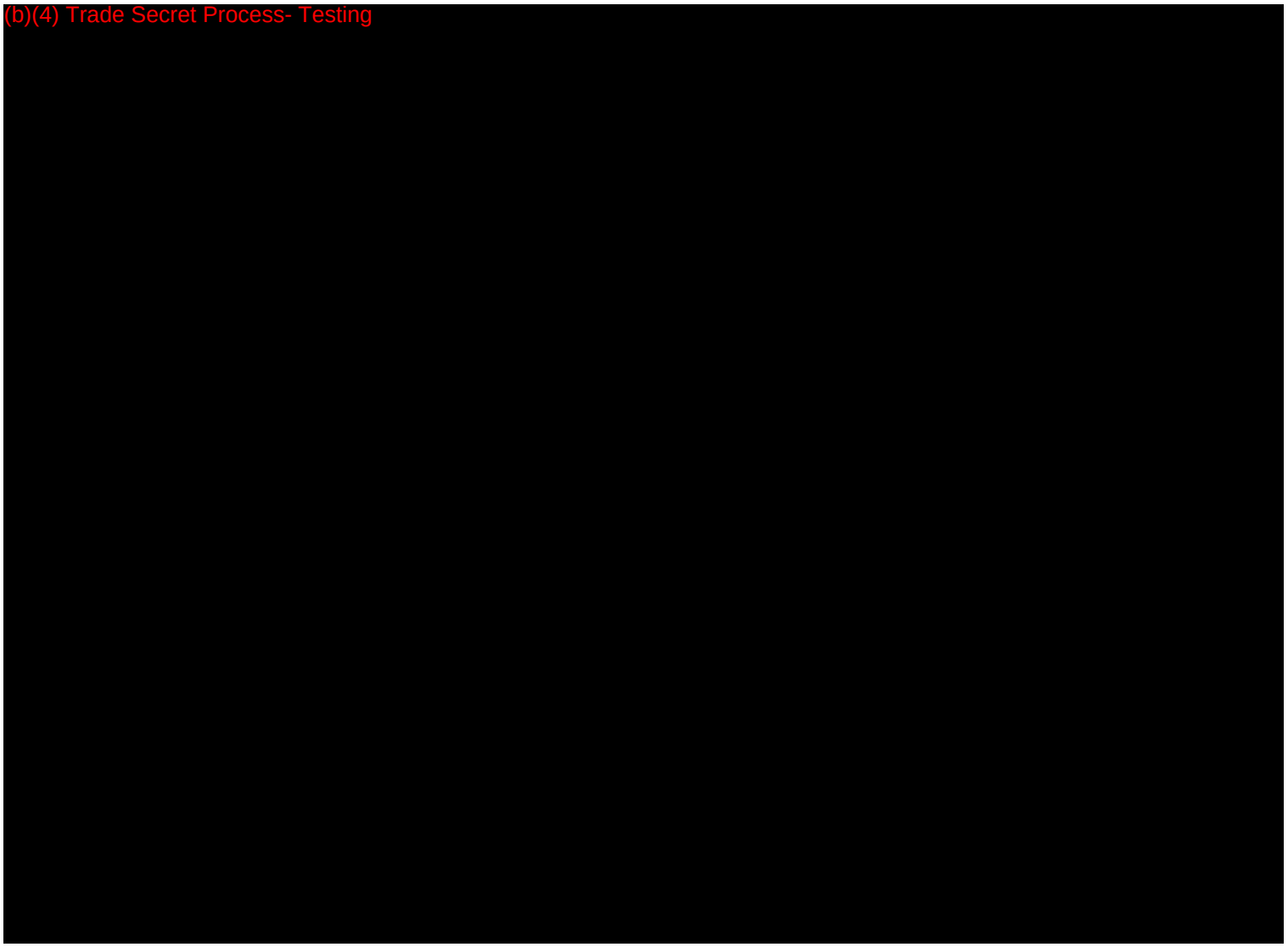

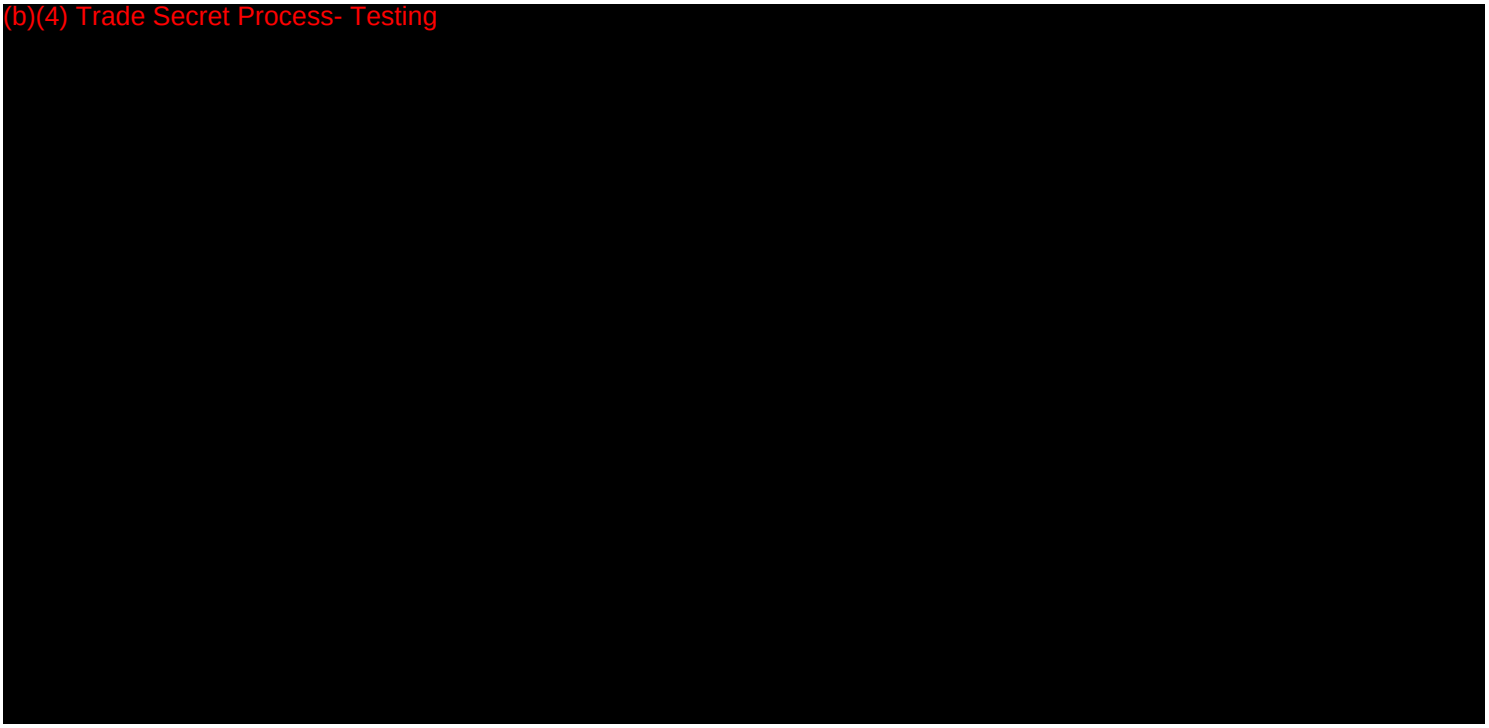
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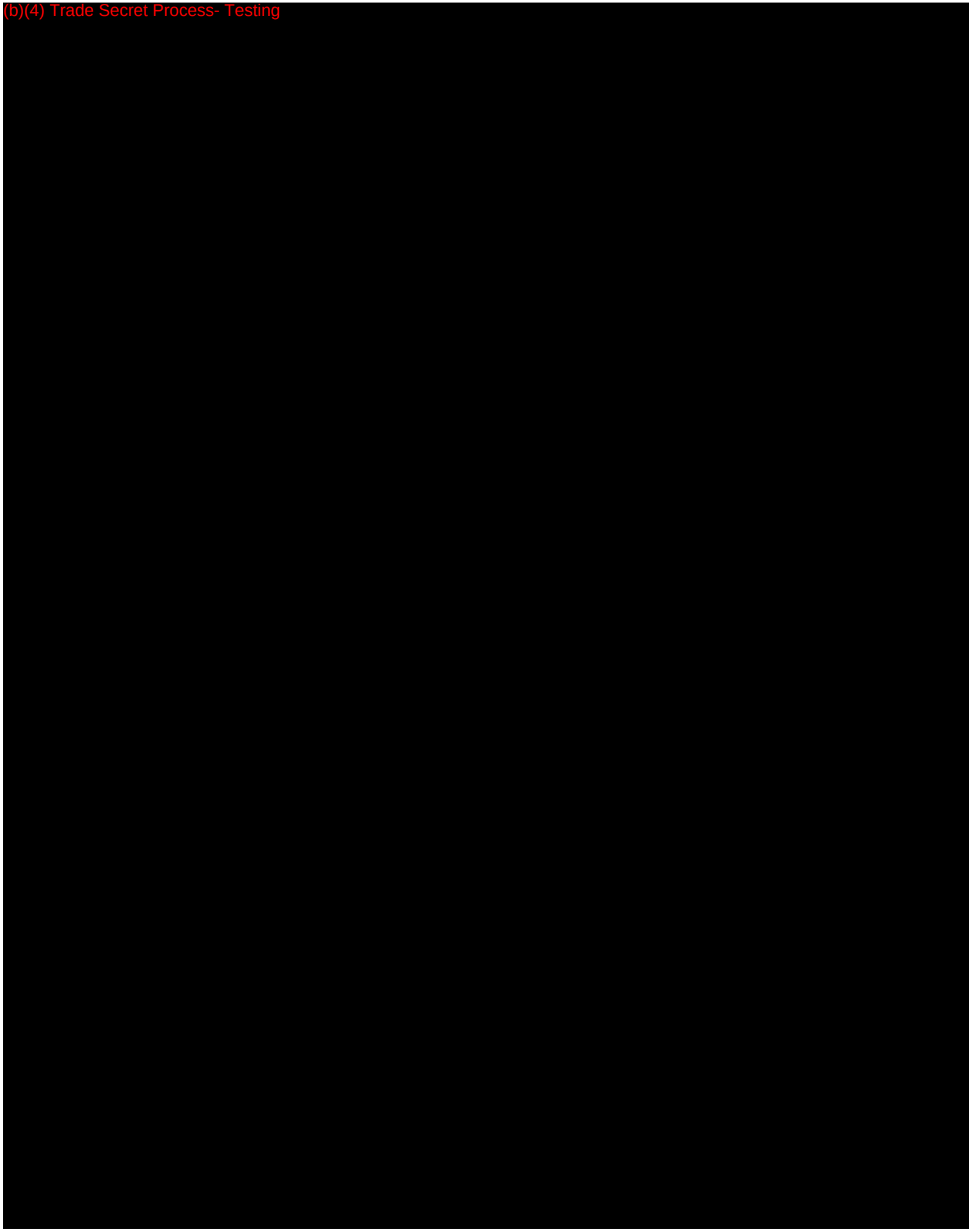

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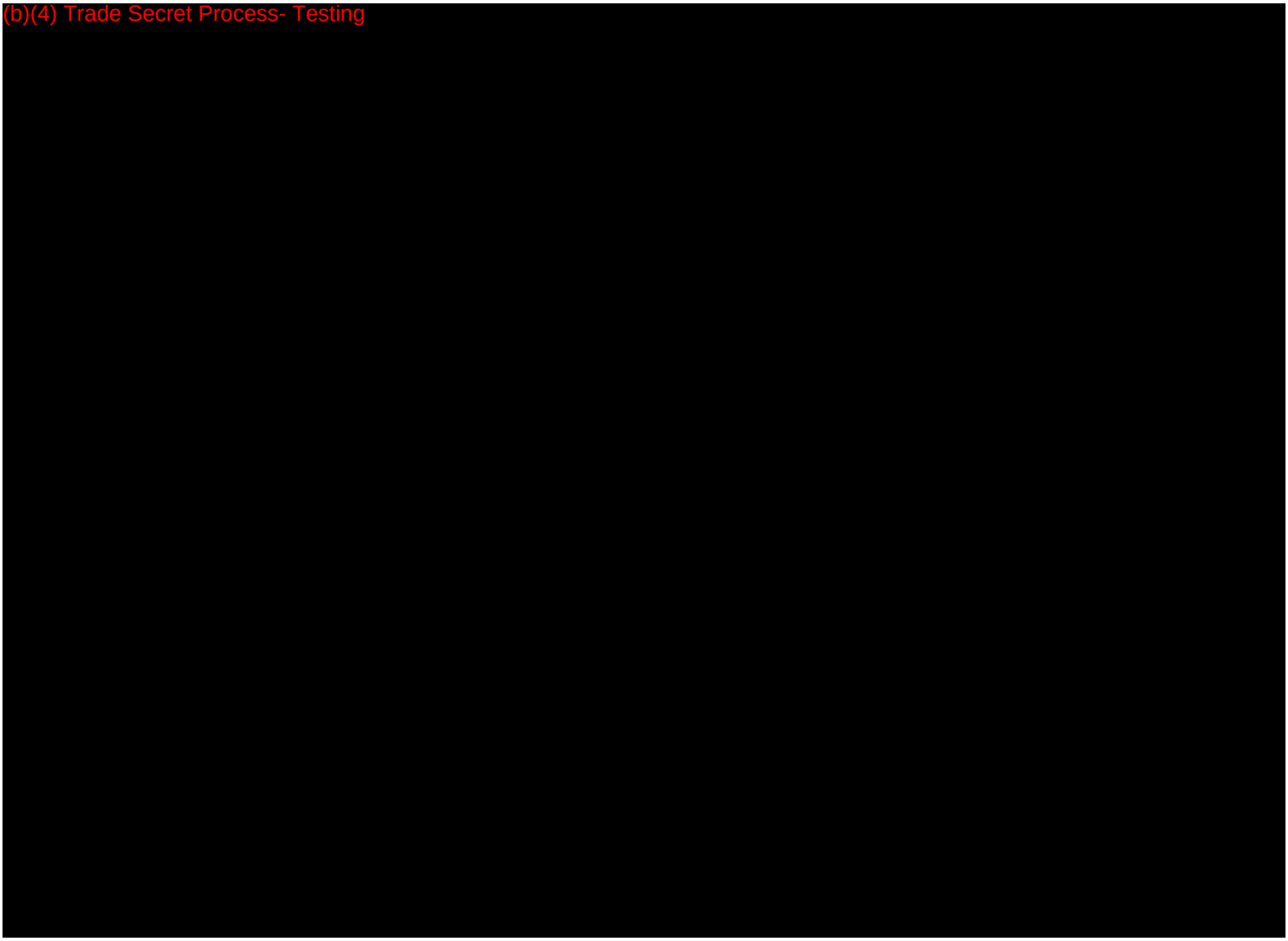

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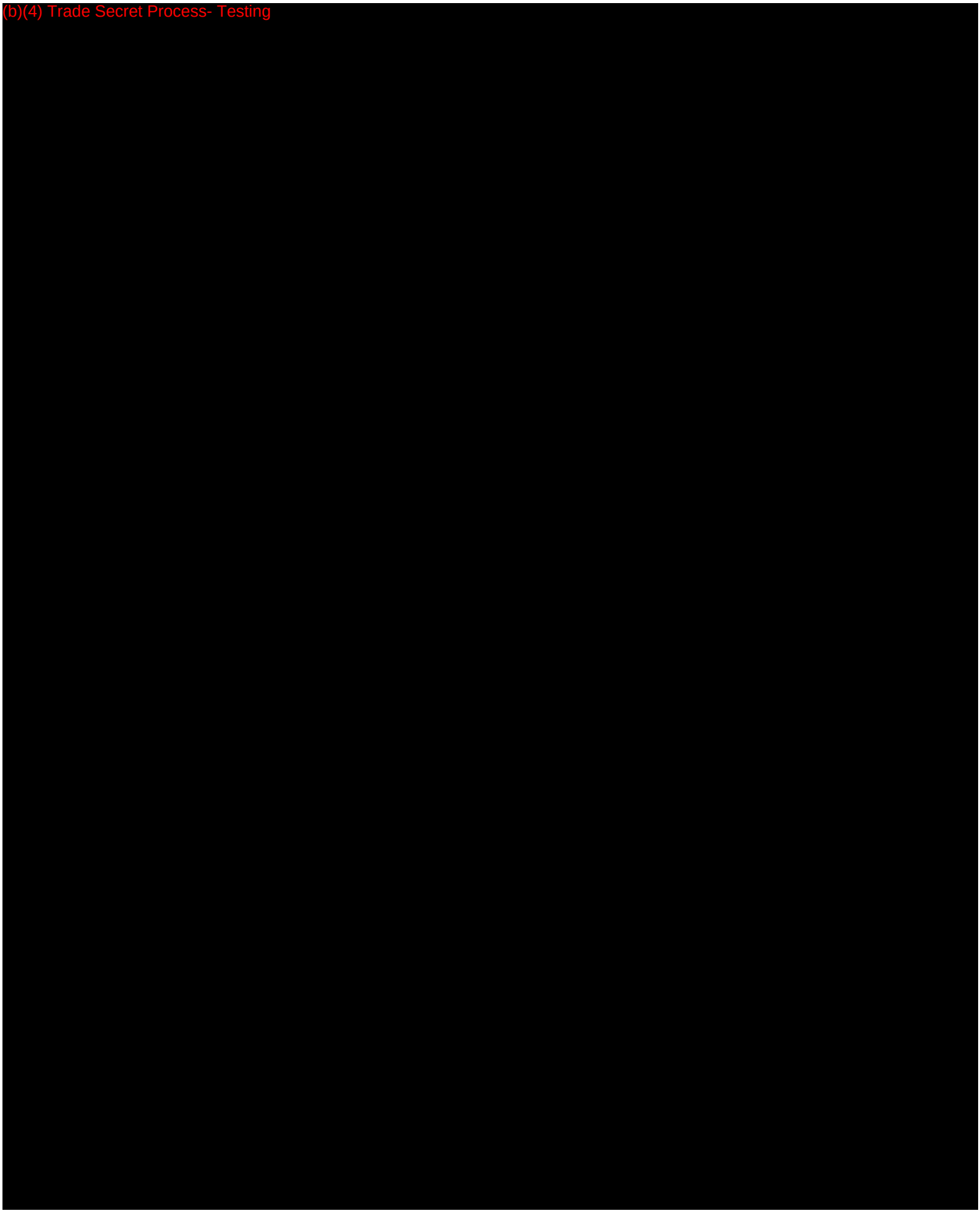

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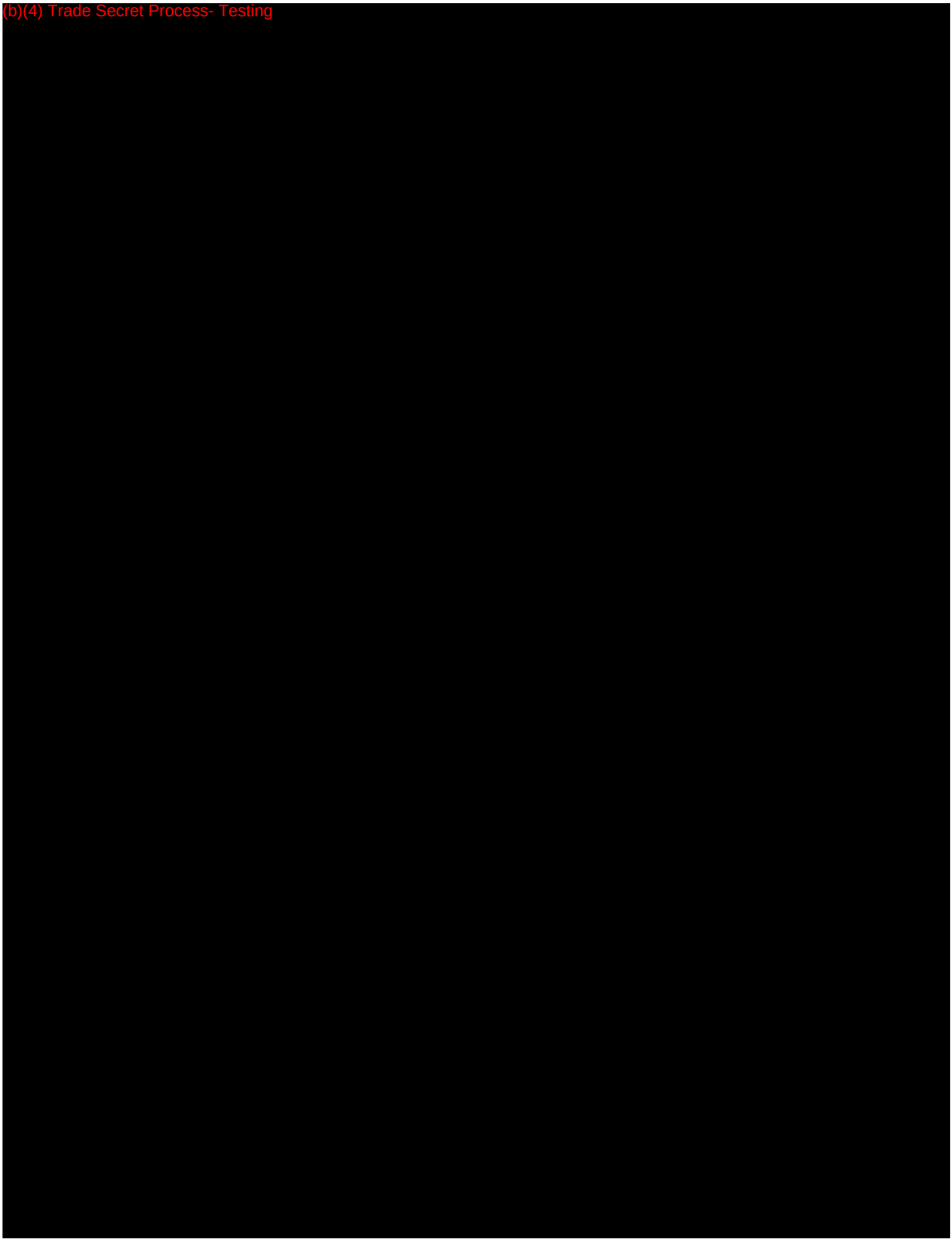

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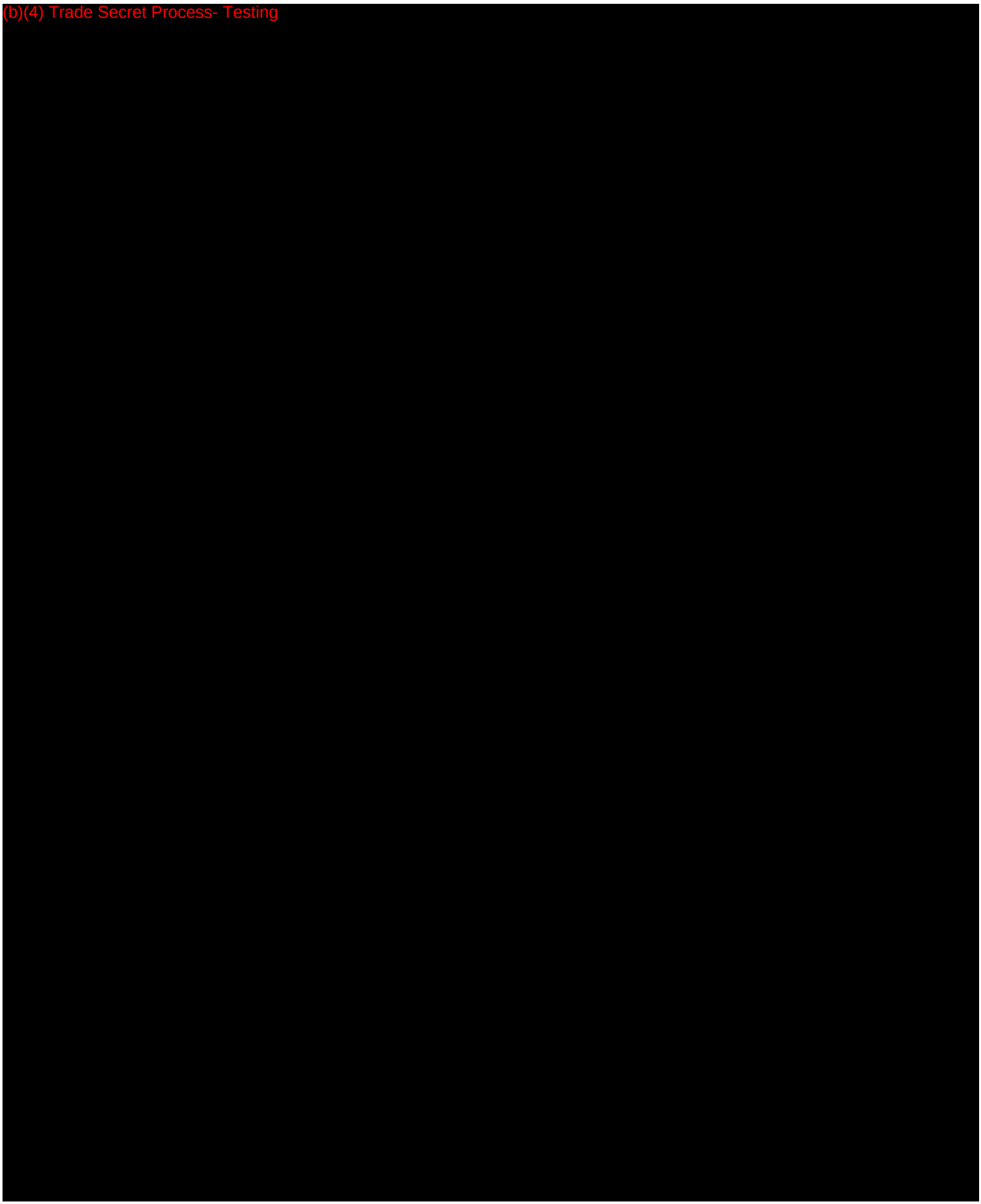

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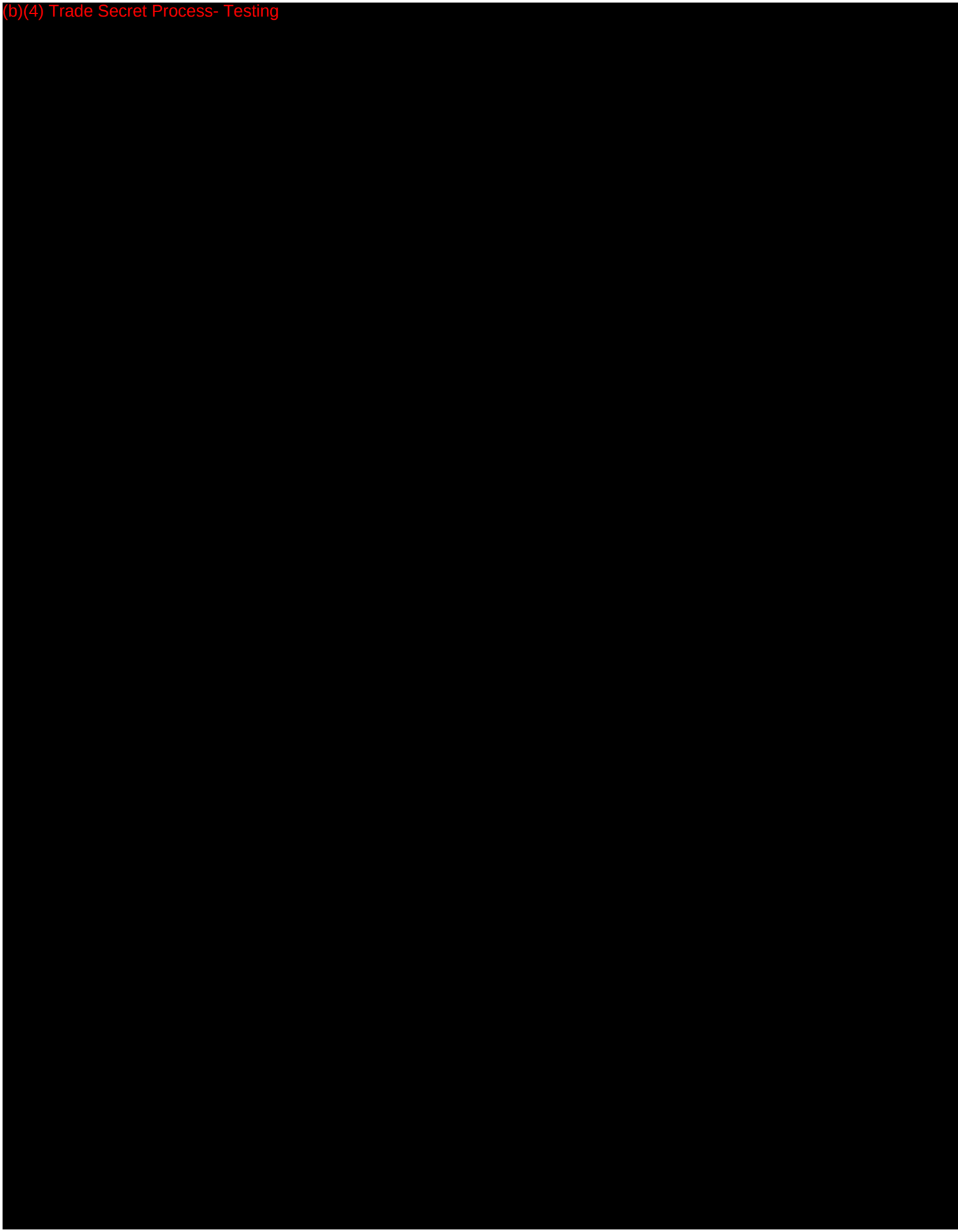

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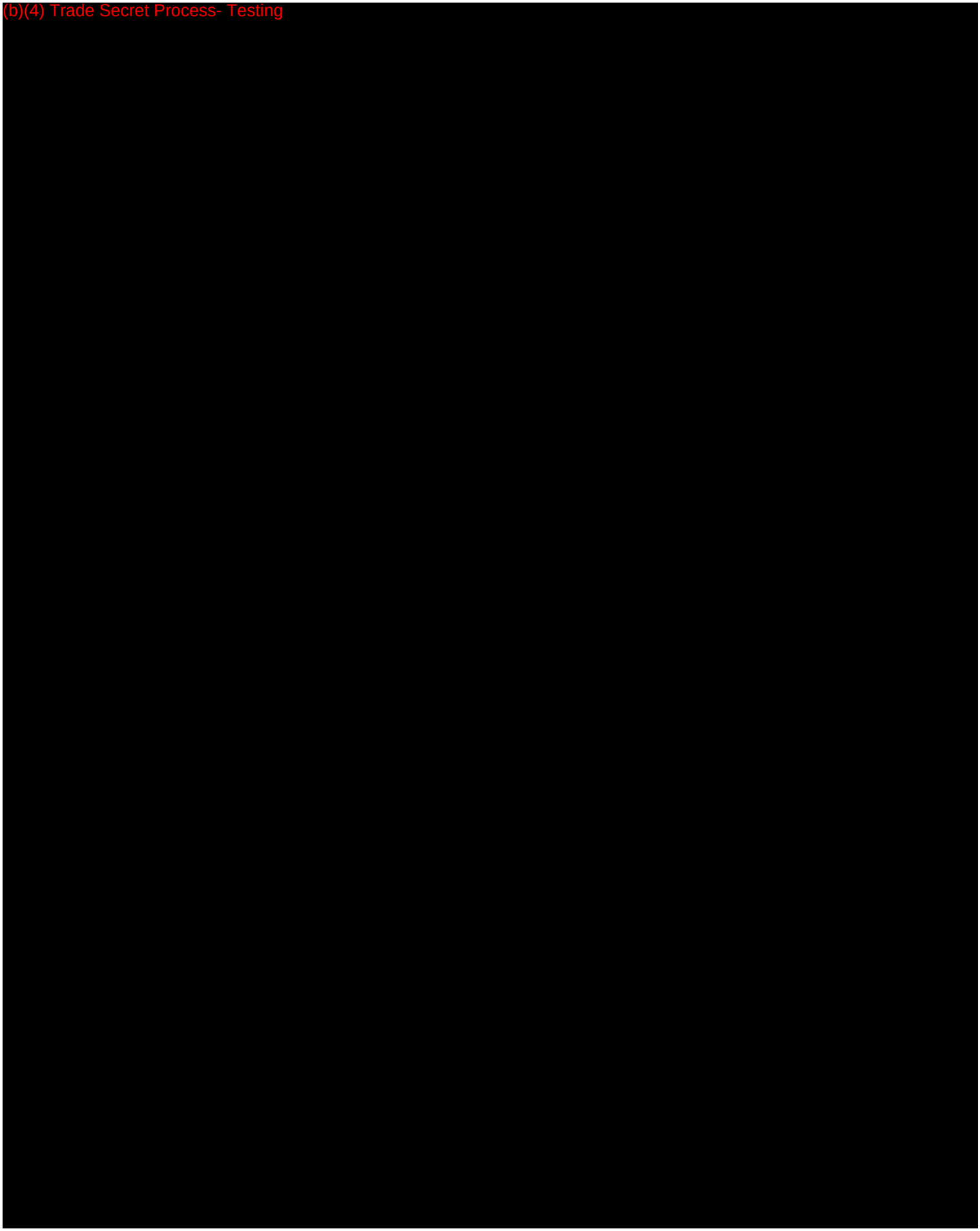

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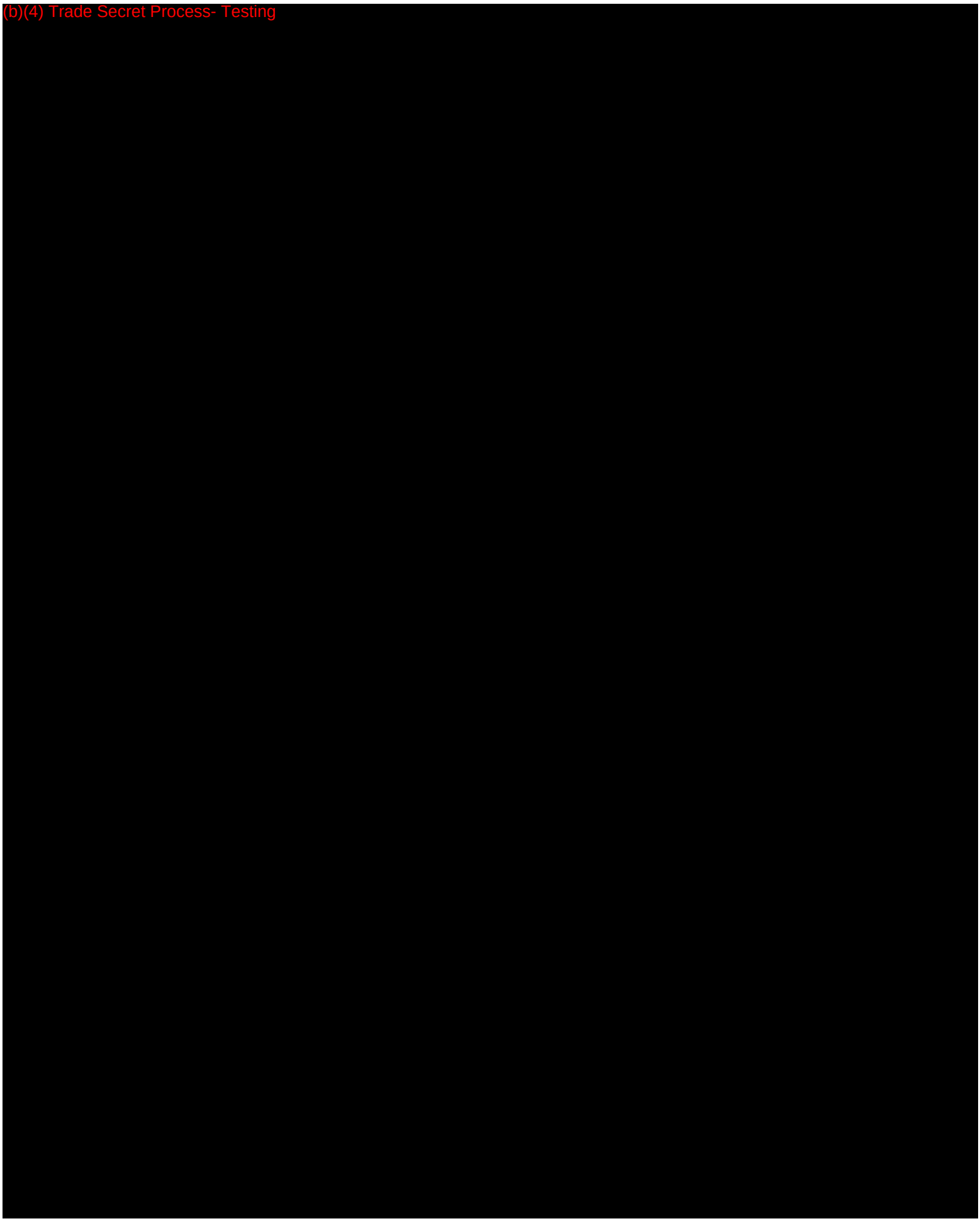

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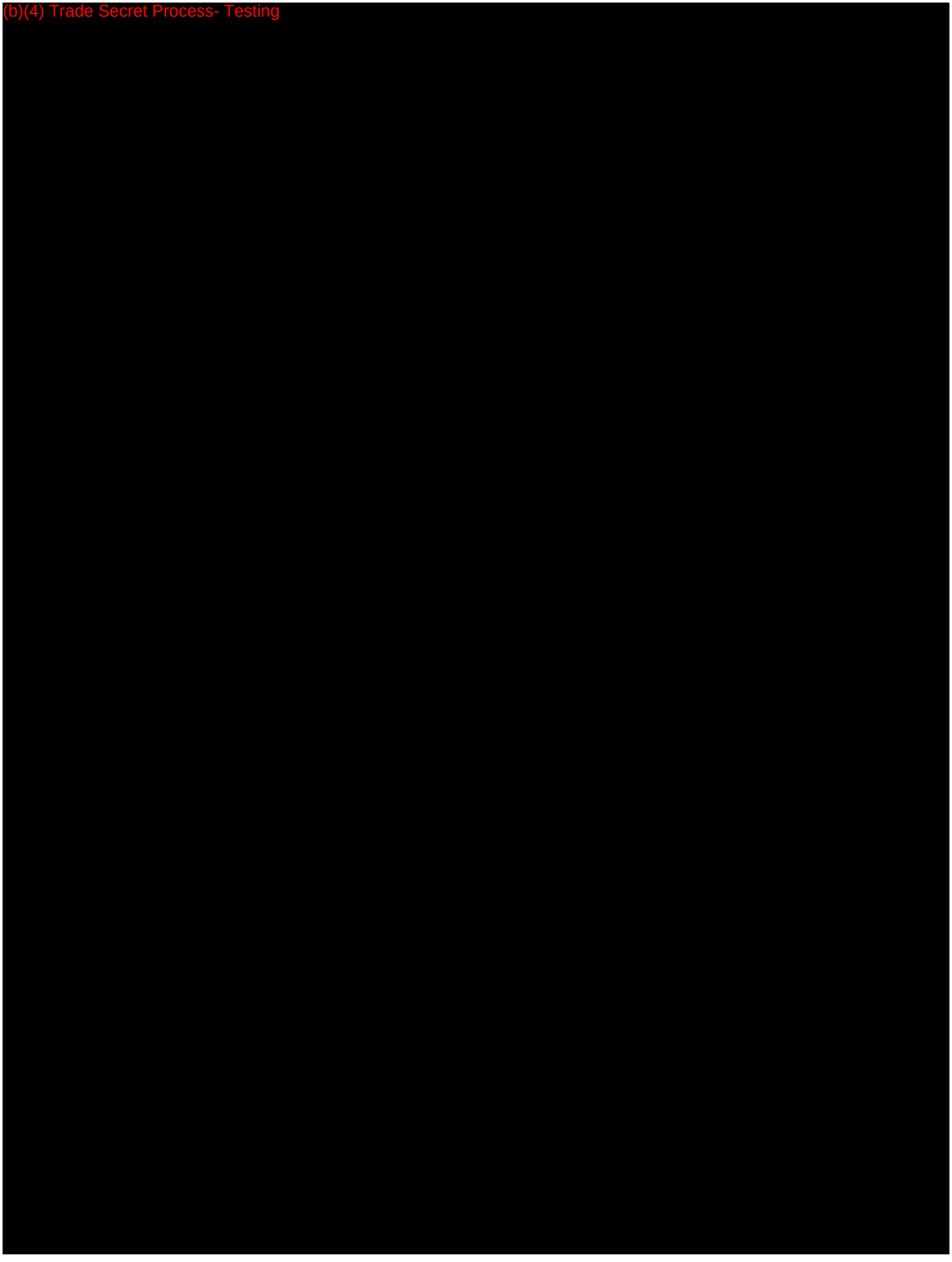

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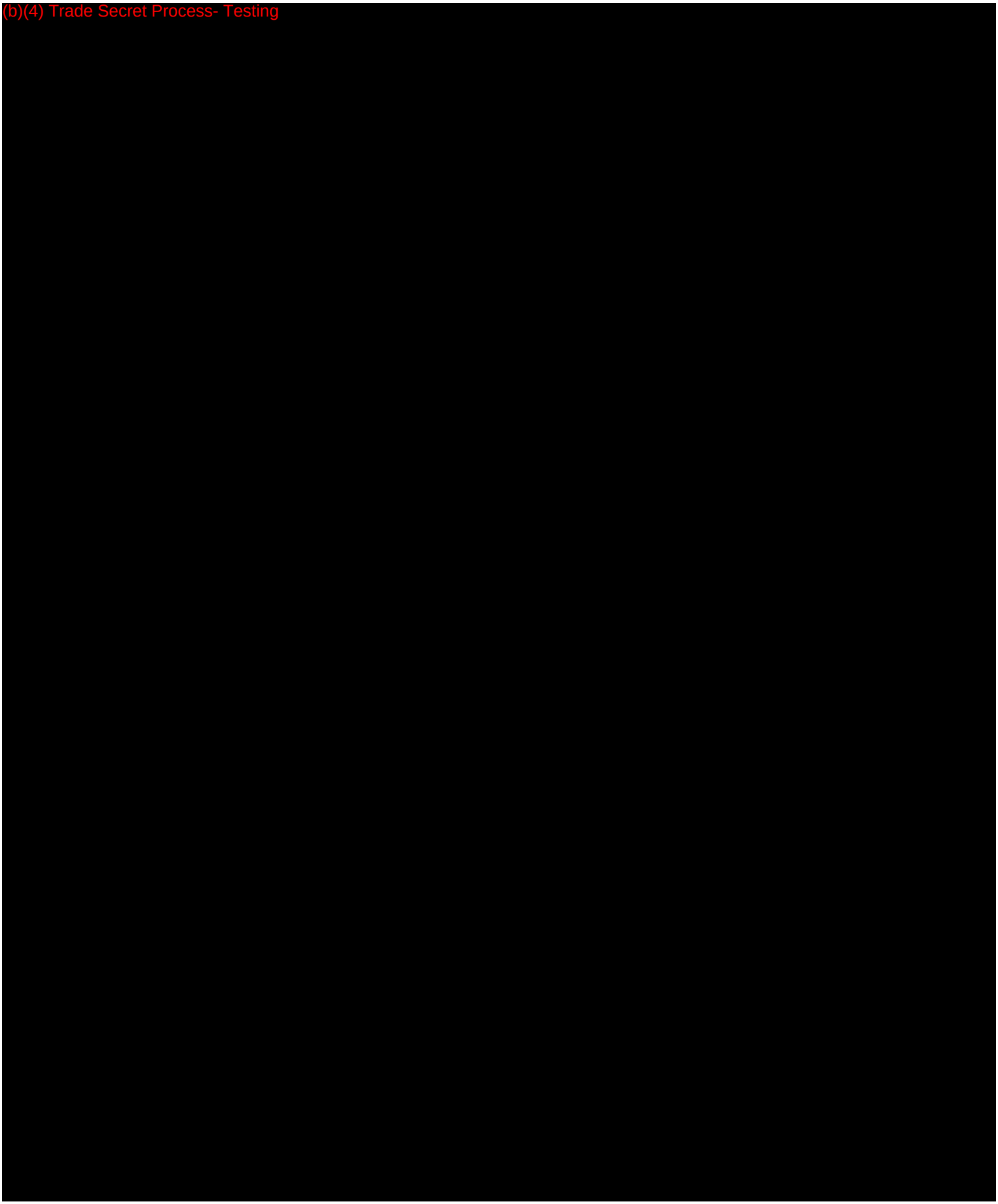

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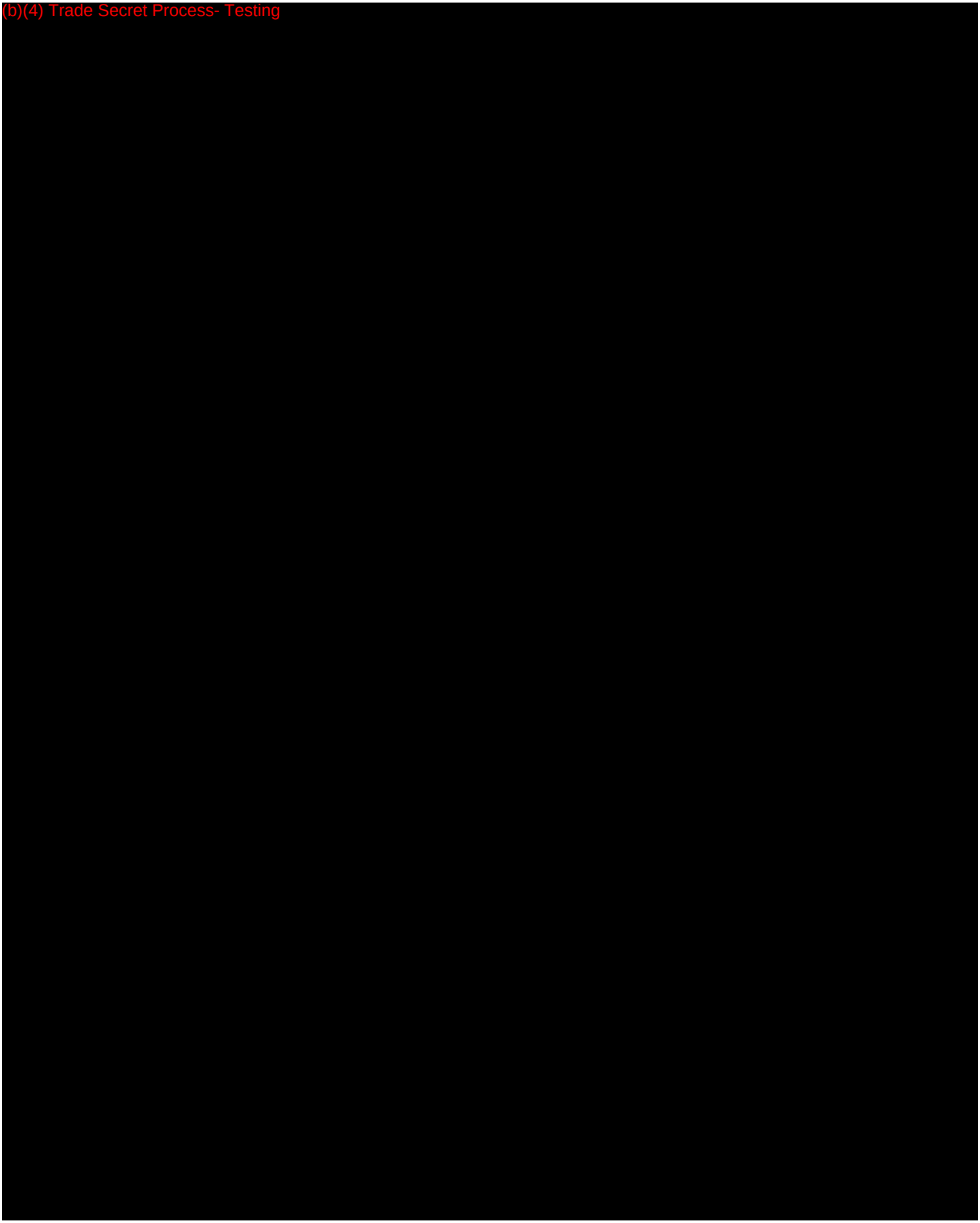

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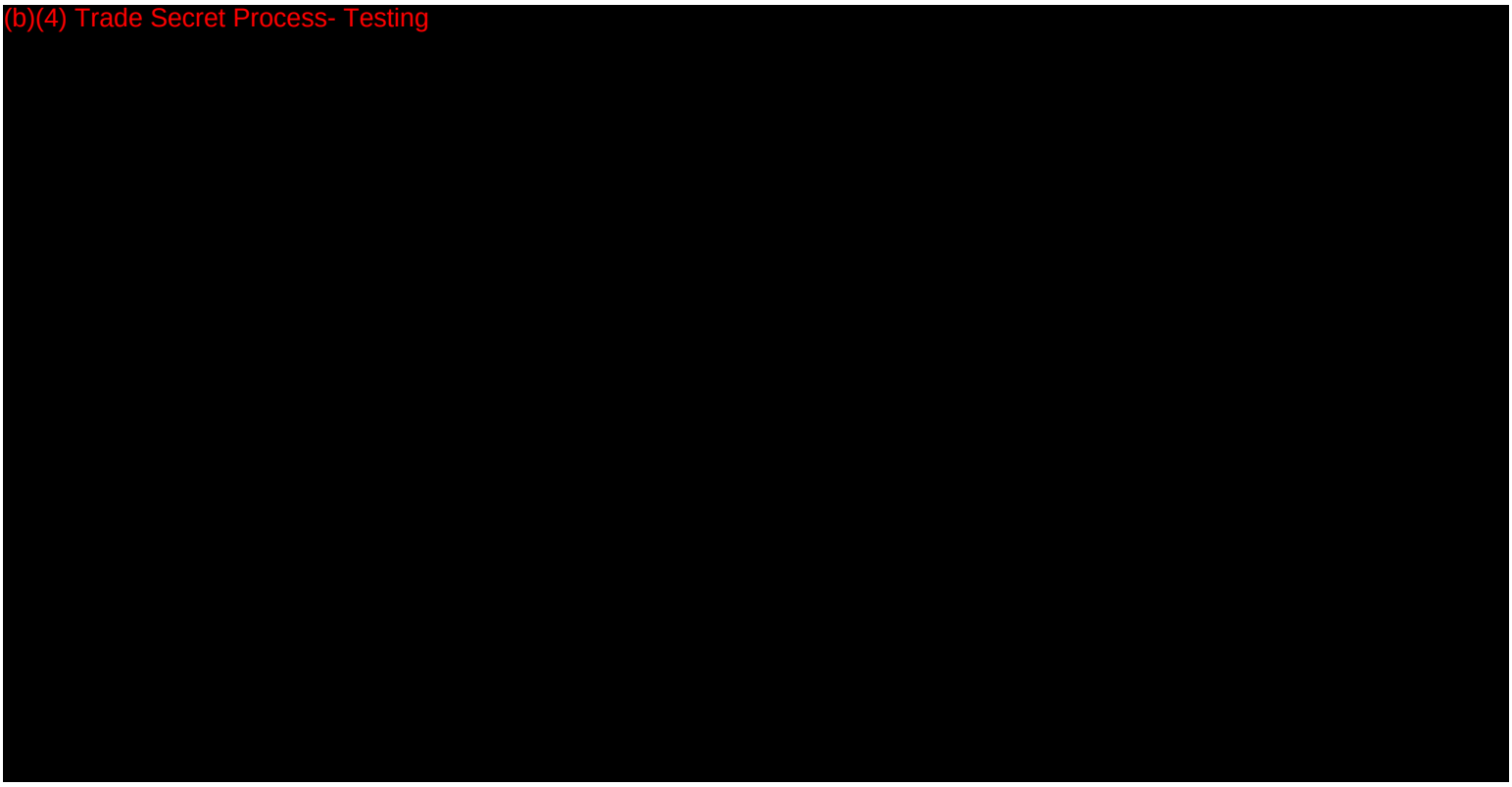

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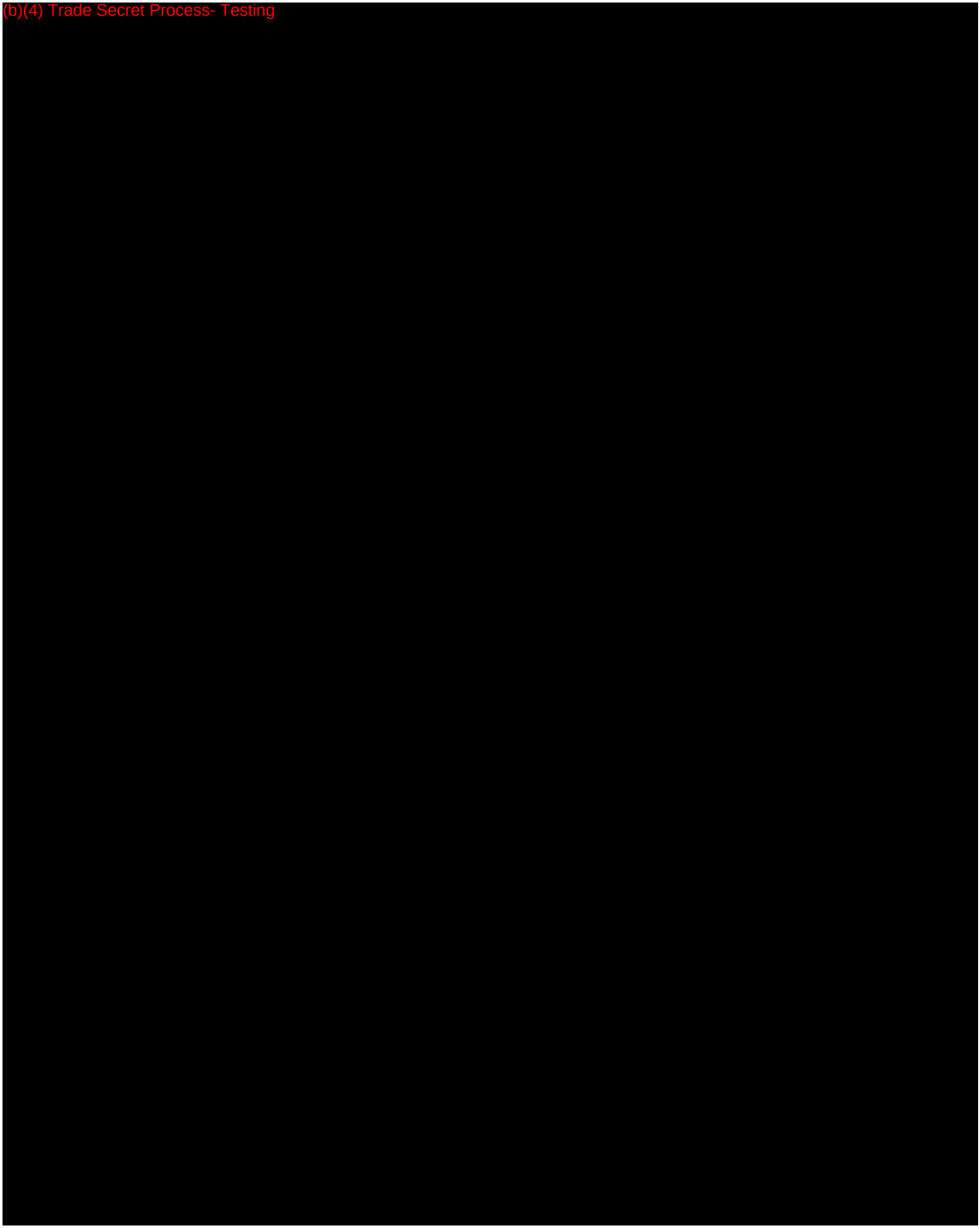

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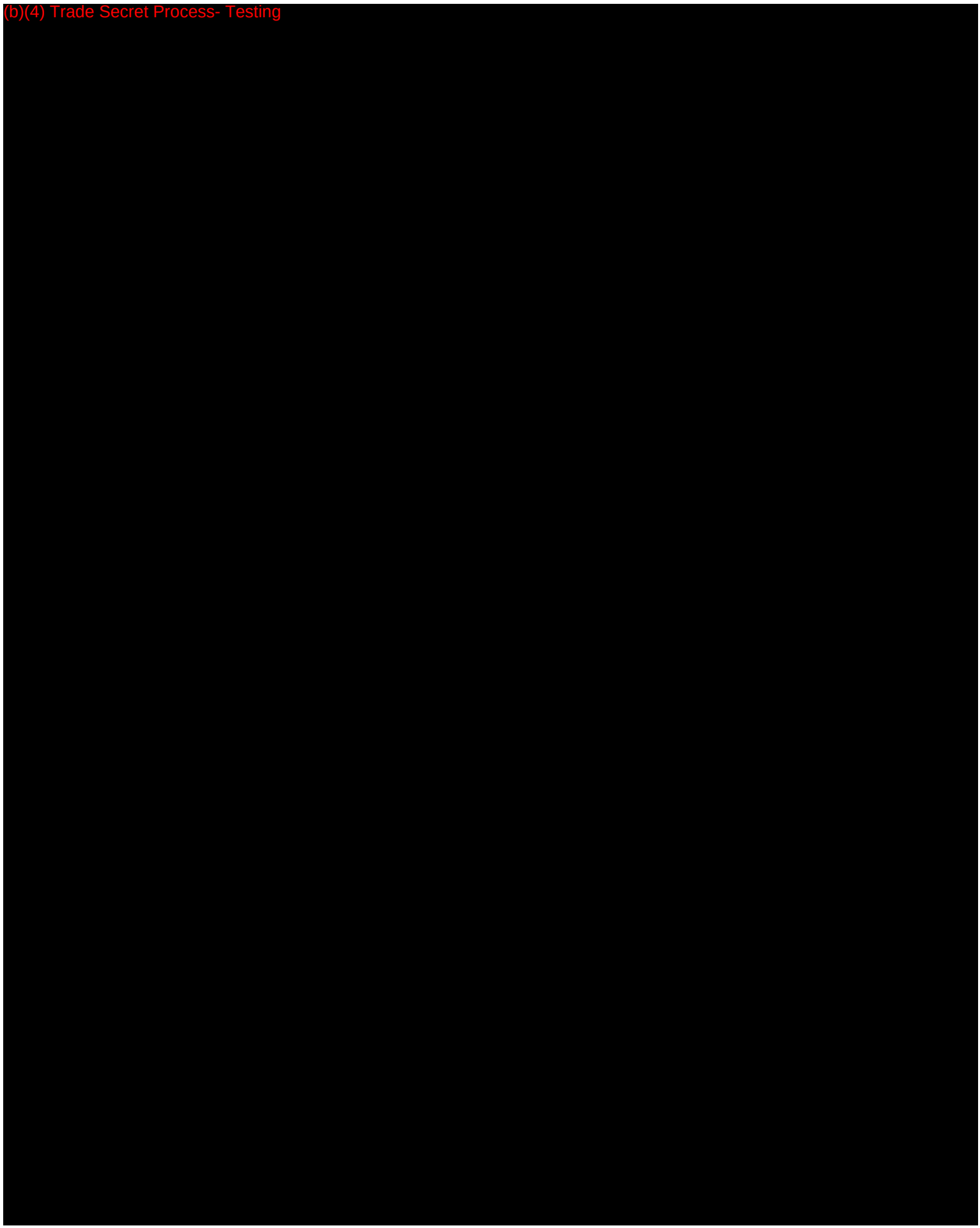

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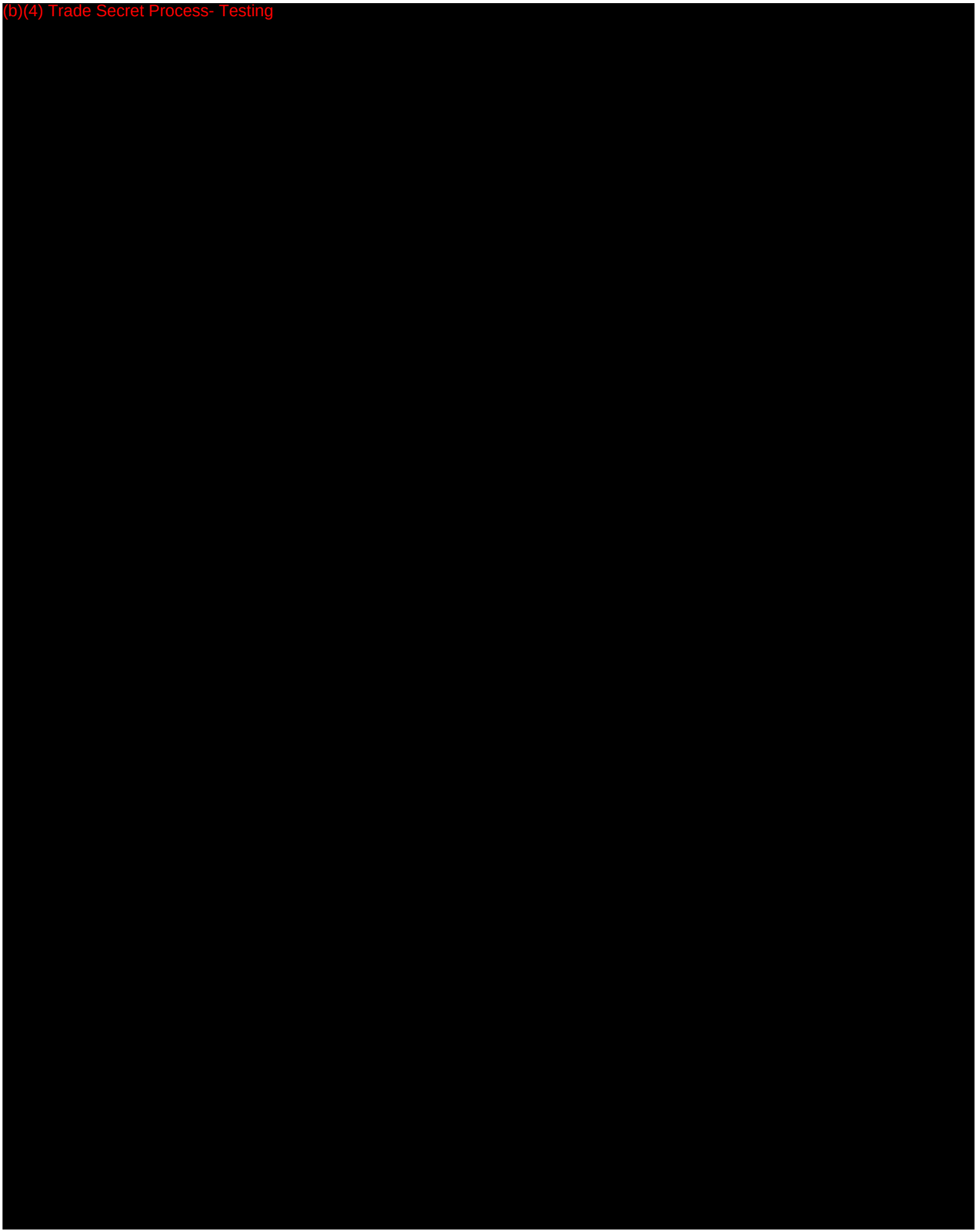

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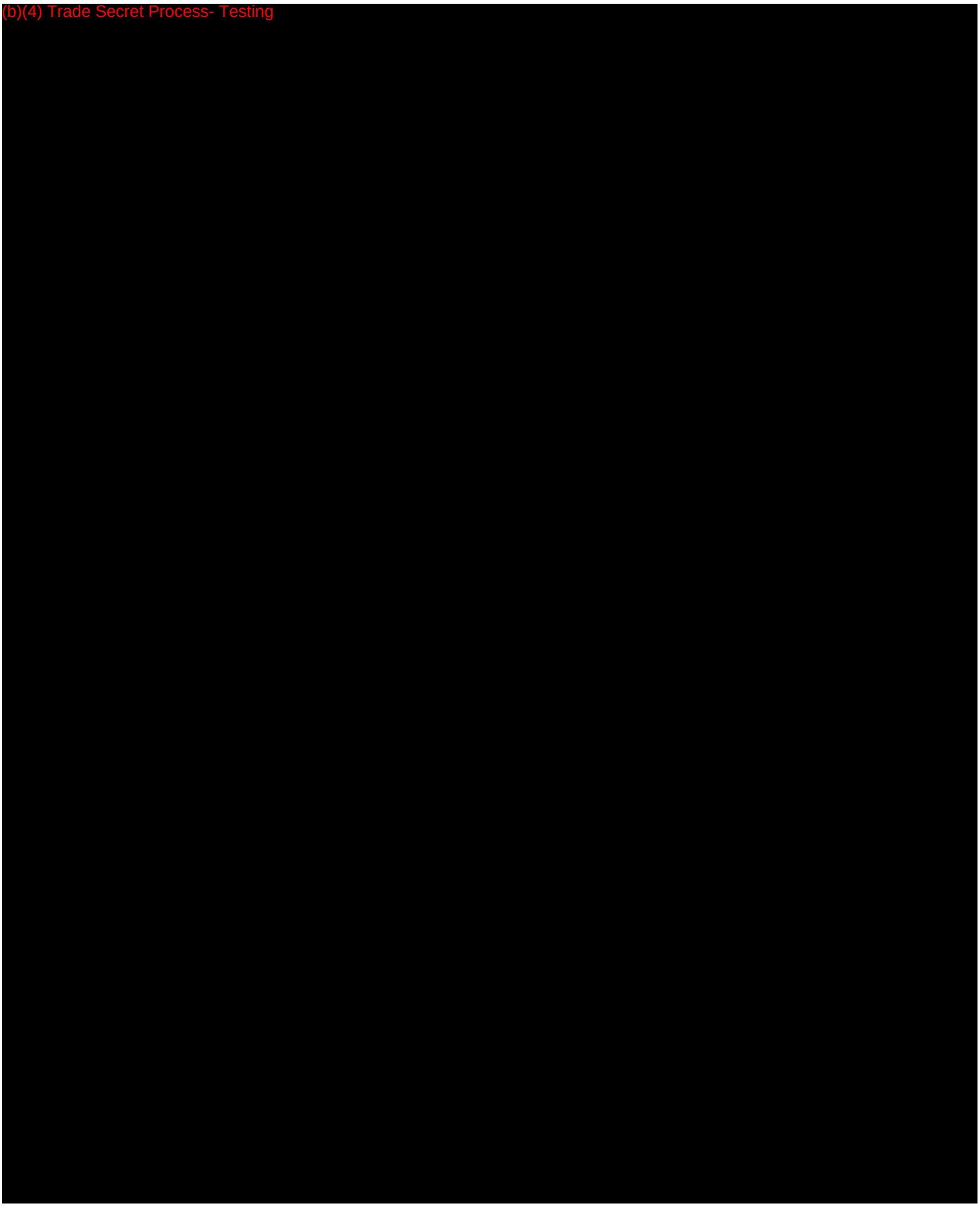

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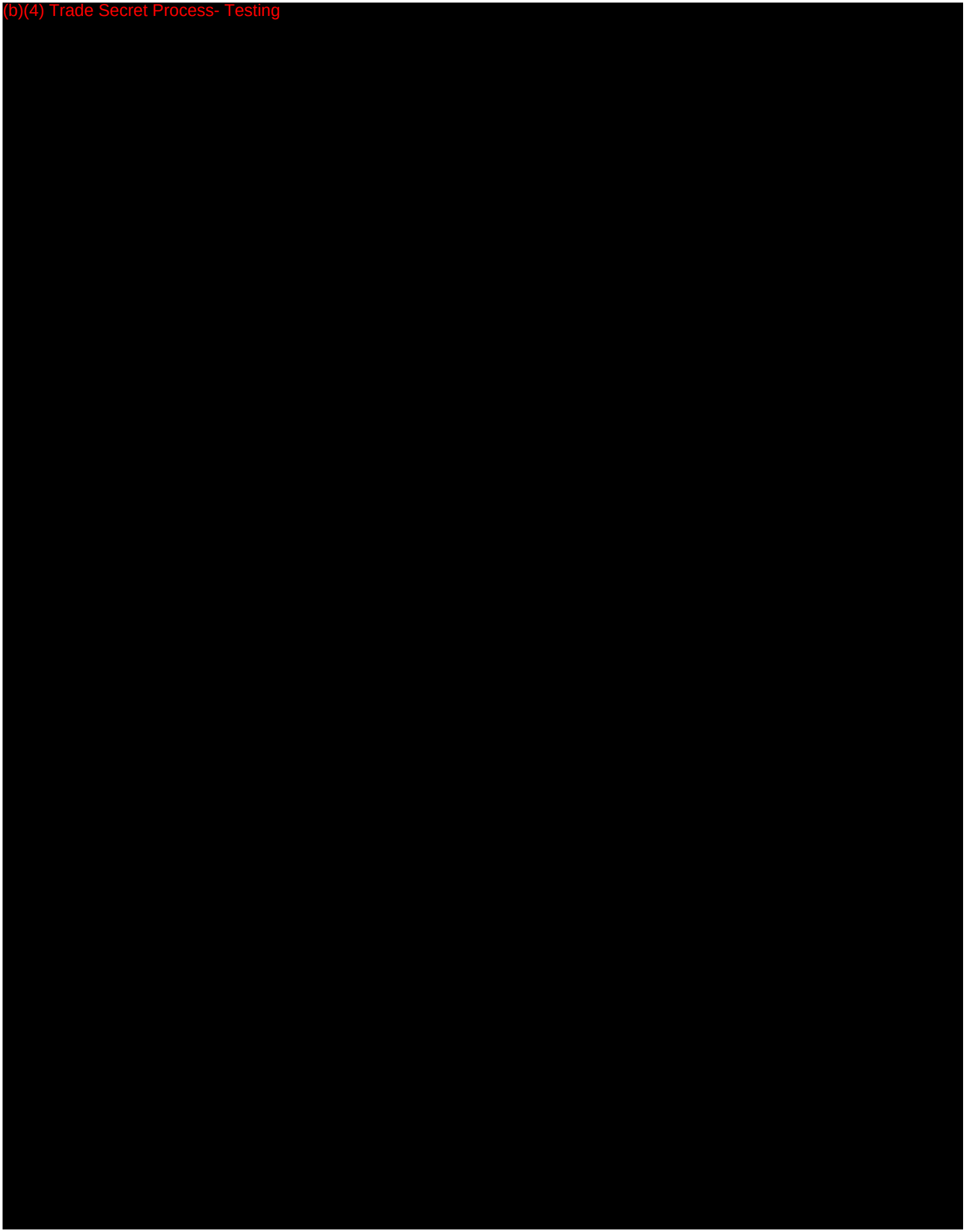

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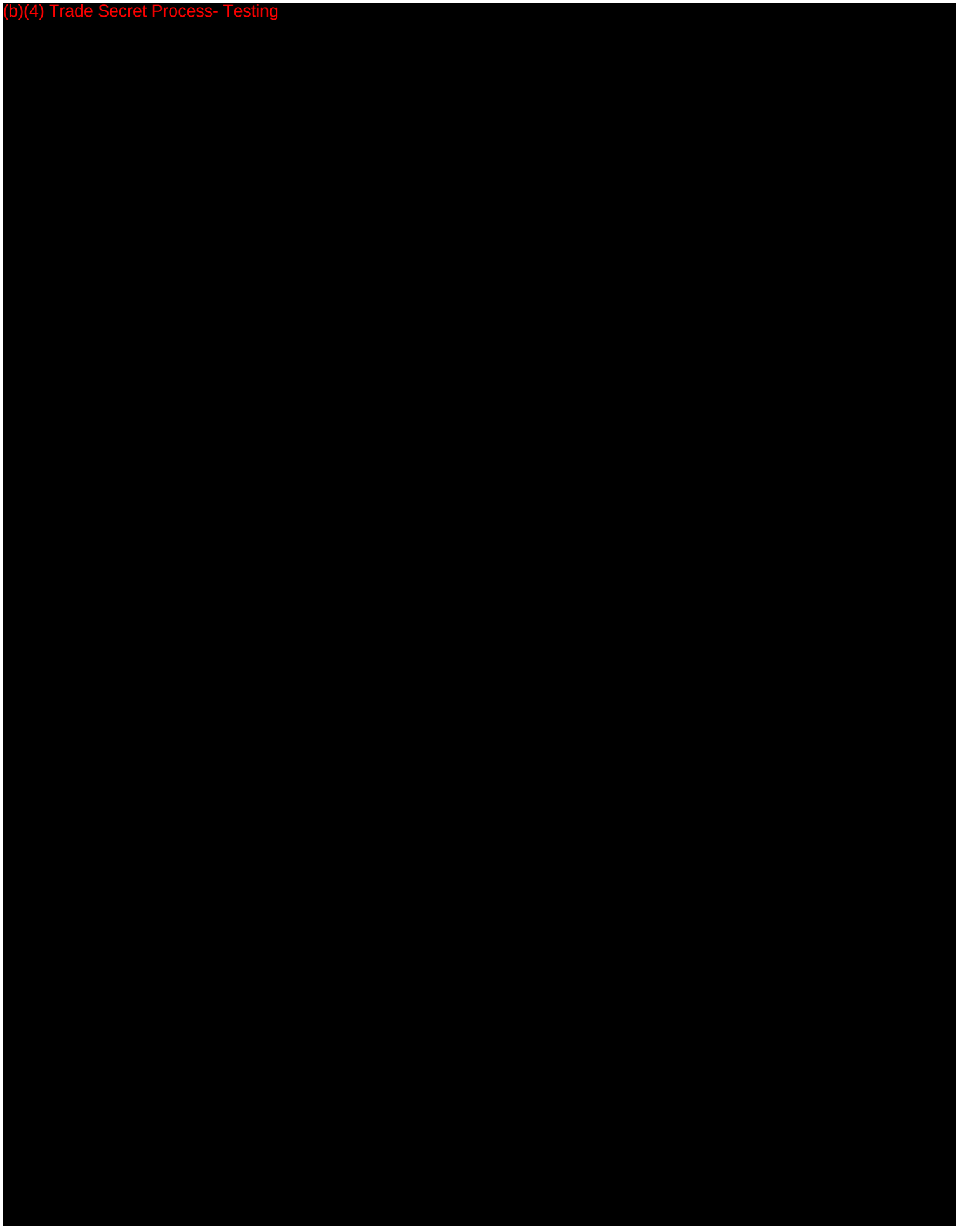

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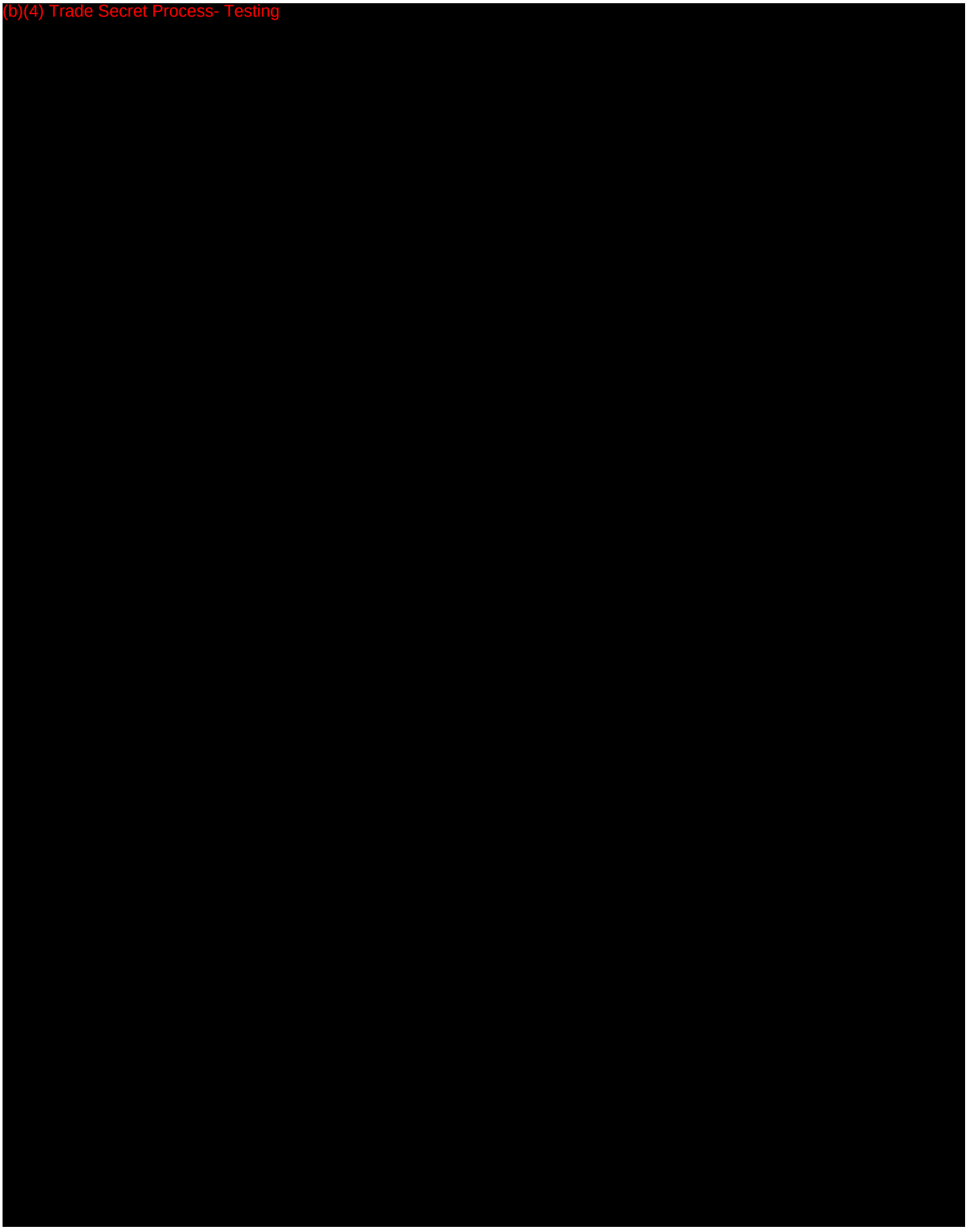

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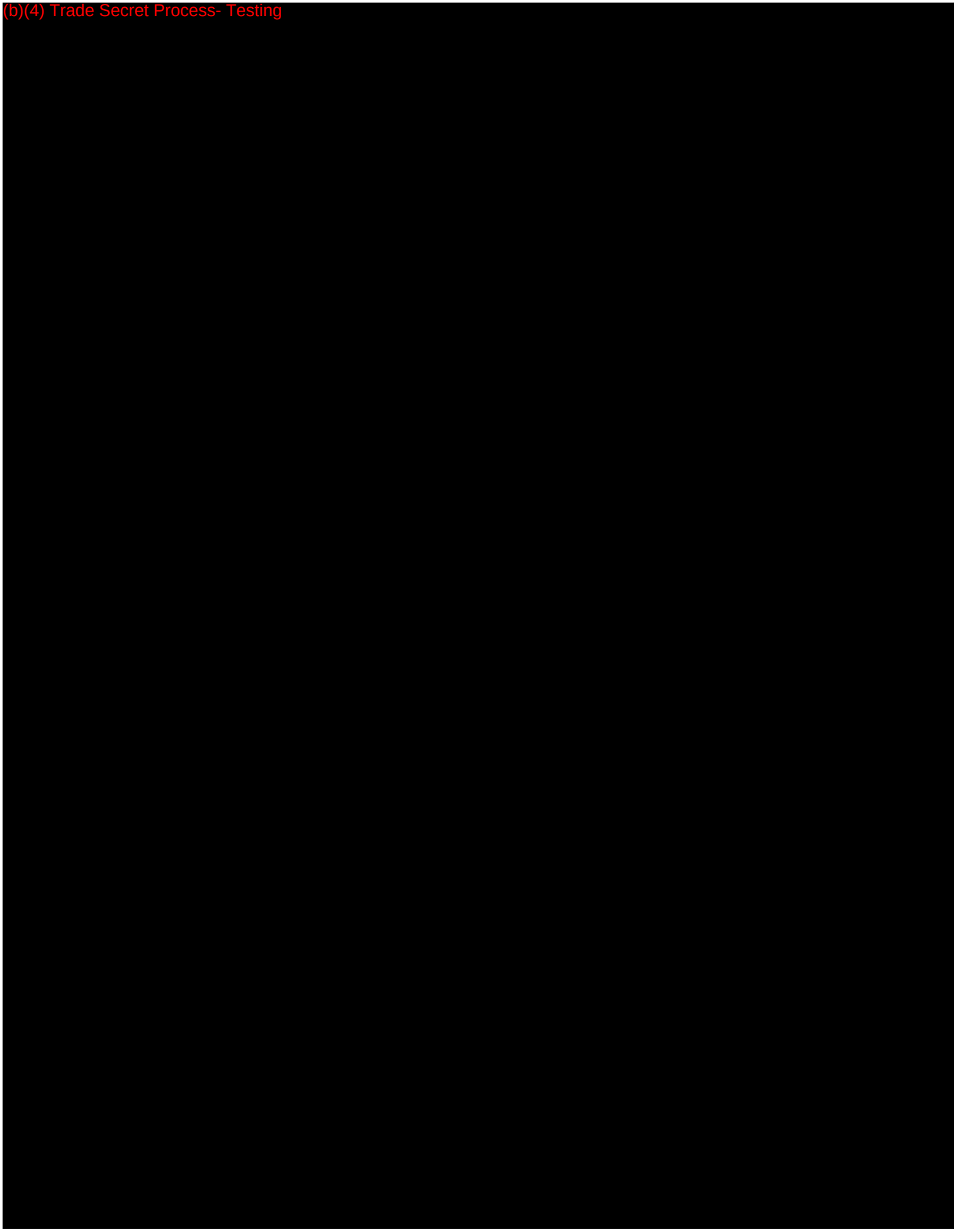

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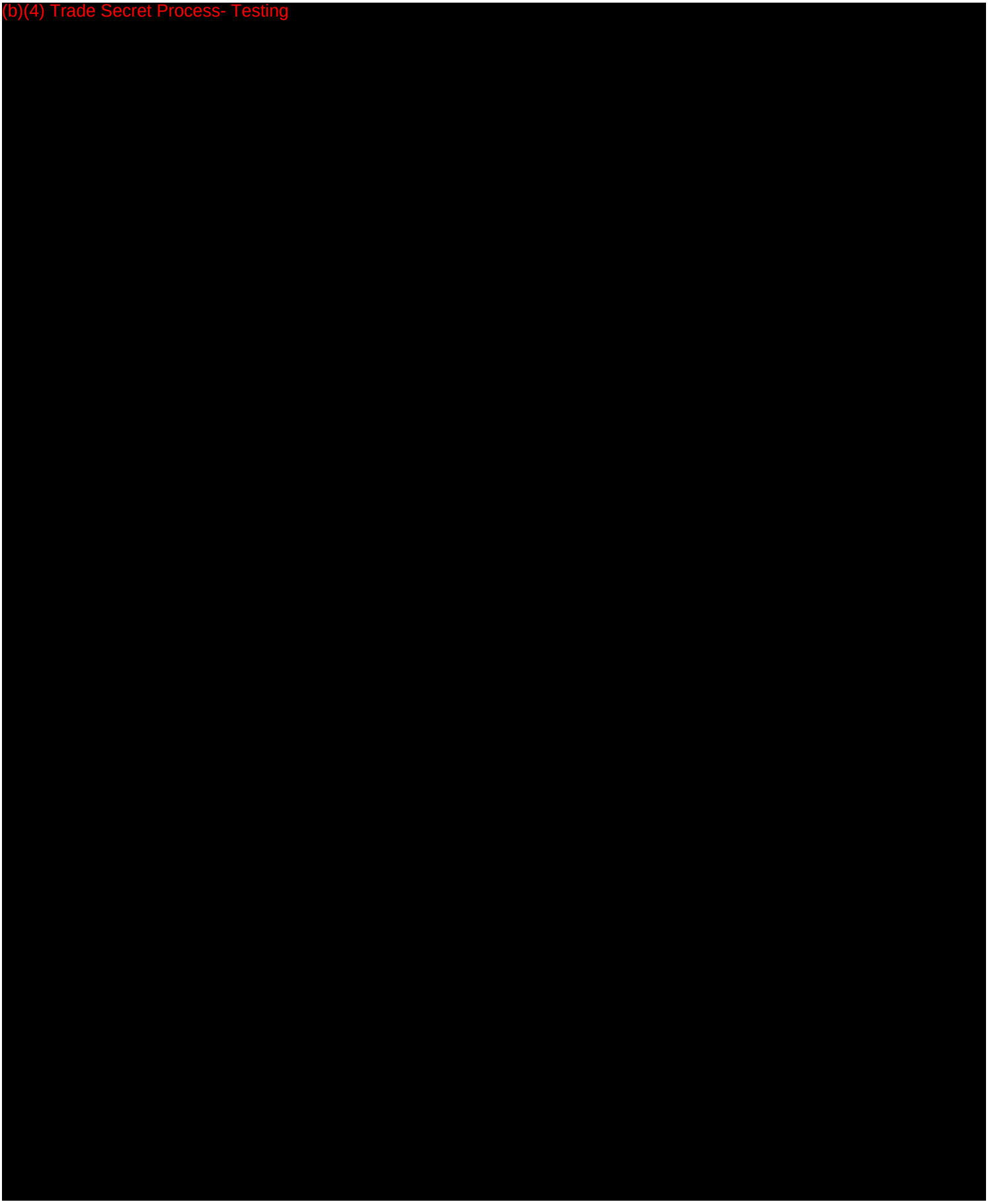

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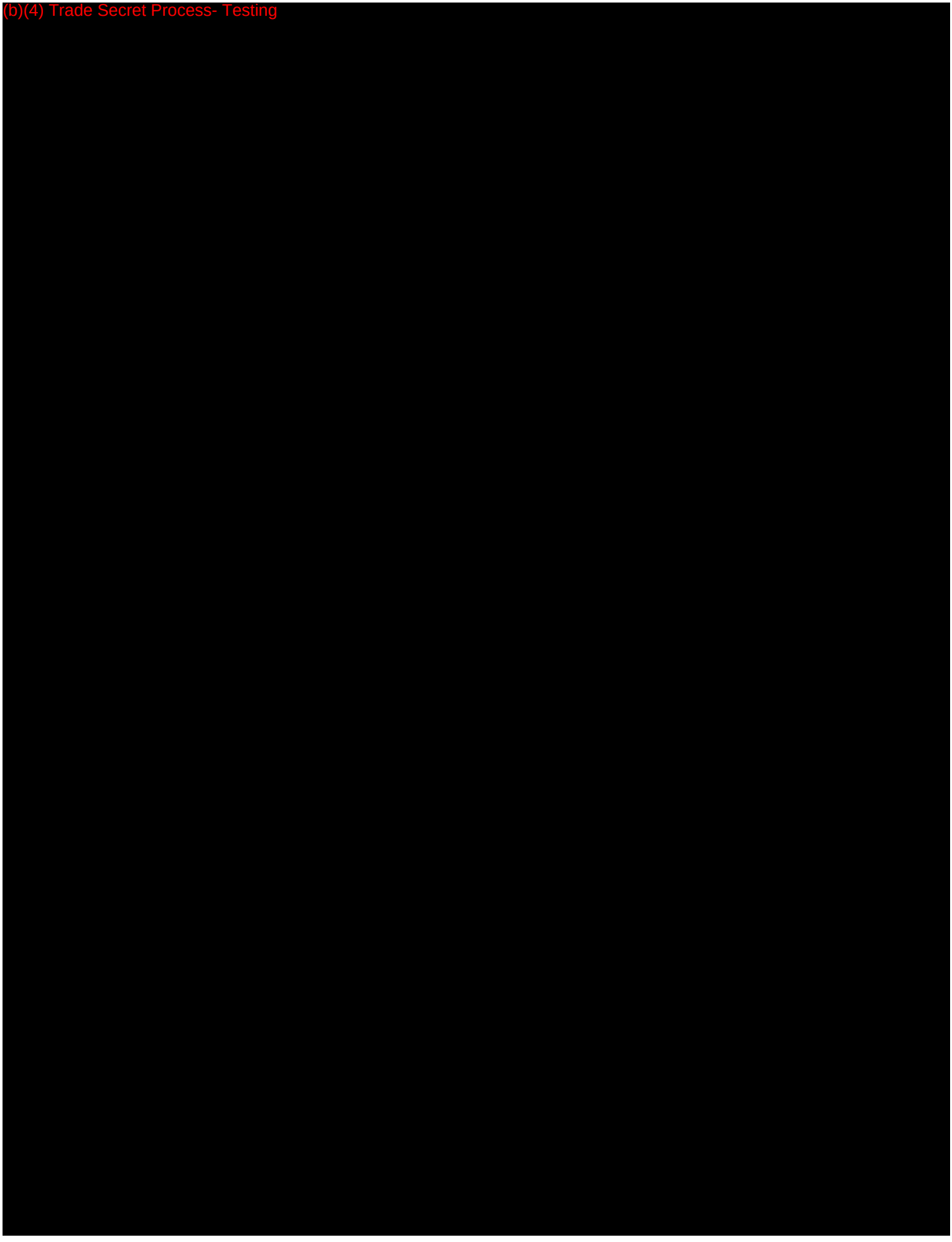

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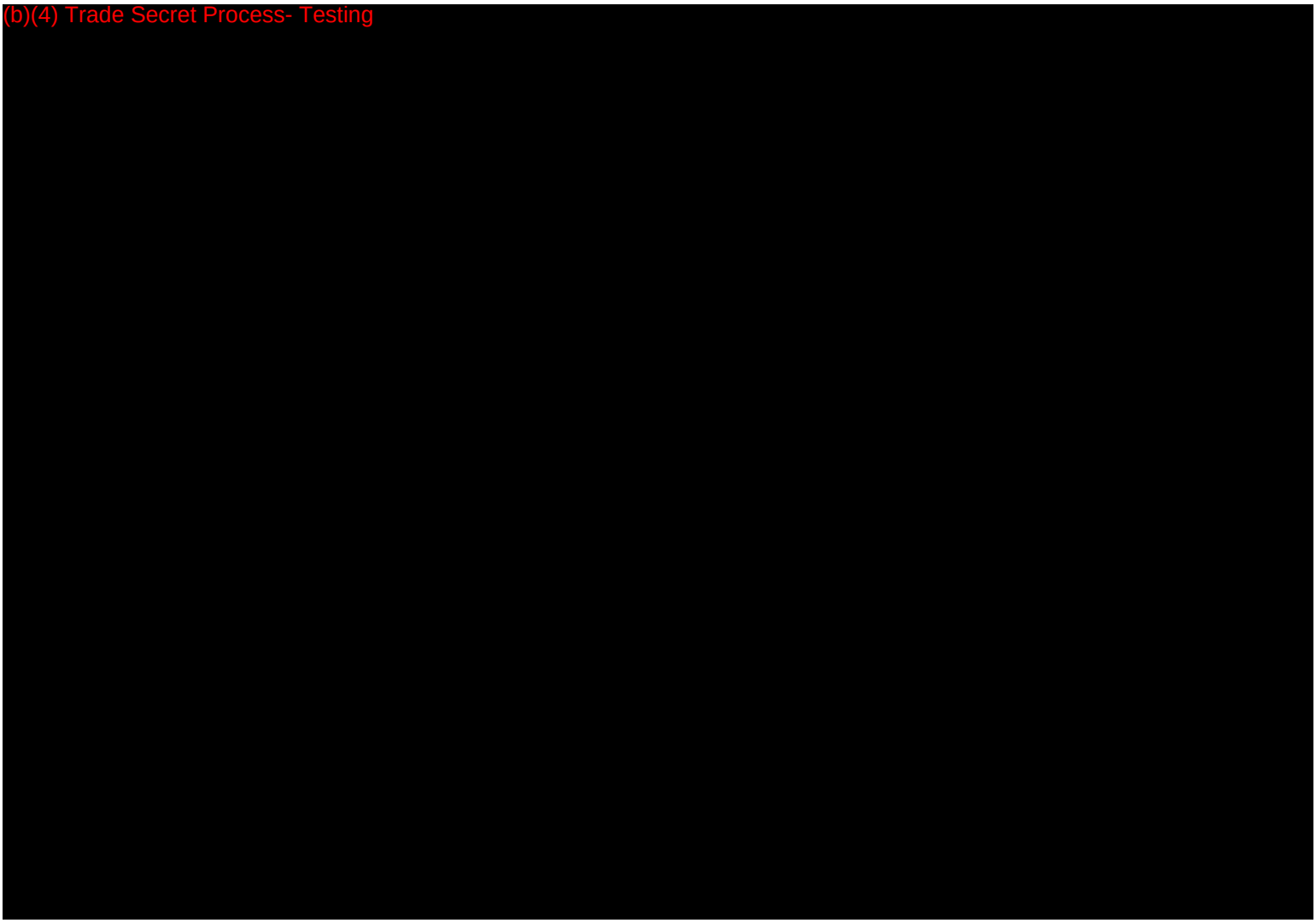

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Software Design Specification

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PCP-USB Stethoscope
with
sSOIP Anywhere, TMCS, SUDS and Relay Server Software

PCP-USB Stethoscope Overview

The PCP-USB Stethoscope consists of a hardware element, the PCP-USB Chest Piece, and software elements consisting of some audio signal processing in the Streaming Stethoscope Over IP (sSOIP) Anywhere software on the end station PCs, communications software on the end station PCs (sSOIP Anywhere), and communications networking software on the Telemedicine Communications Server (TMCS), Relay Server and Stethoscope User Data (SUD) Server. It provides remote auscultation between a patient at one location and a clinician at another location.

The PCP-USB Stethoscope is a medical device with a moderate level of concern, so the software elements associated with it are also a moderate level of concern. Unless otherwise noted in the table below, the following documentation items are addressed in this **Attachment 7 for Software**.

Topic	Document
Level of Concern	"Level of Concern – PCP-USB Stethoscope with sSOIP Anywhere and Auscultation Anywhere Software"
Software Description	Section III of "PCP-USB Stethoscope with NAT Traversal Requirements"
Device Hazard Analysis	"Hazard Chart for PCP-USB Stethoscope". See Attachment 5 Risk Management "Risk Analysis - PCP-USB Stethoscope". See Attachment 5 Risk Management
Software Requirements Specification	Section III of "PCP-USB Stethoscope with NAT Traversal Requirements"
Architecture Design Chart	"sSOIP Anywhere with Auscultation Anywhere Software Design Specification" "ICE Call Establishment"
Software Design Specification sSOIP Anywhere	"sSOIP Anywhere with Auscultation Anywhere Software Design Specification"
Software Design Specification TMCS	"TMCS Software Design Specification"
Software Design Specification SUD	"Stethoscope User Database (SUD) Software Design Specification"

Software Design Specification Relay Server	"Relay Server (TURN/STUN) Software Design Specification"
Traceability Analysis	Performance at all stages are compared back to: "PCP-USB Stethoscope with NAT Traversal Requirements" "sSOIP Anywhere with Auscultation Anywhere Software Design Specification" "TMCS Software Design Specification" "Stethoscope User Database (SUD) Software Design Specification" "Relay Server (TURN/STUN) Software Design Specification"
Software Development Environment Description	Section II of each Software Design Specification"
Verification and Validation Documentation	"PCP-USB Stethoscope Alpha Test". See Attachment 10. "PCP-USB Stethoscope Clinical Test". See Attachment 10. TMCS Test Reports (Documents 006 – 012) SUD Test Reports (Documents 013 – 025) Relay Server Test Report (Document 027)
Revision Level History	Standard MRI
Unresolved Anomalies (Bugs or Defects)	No known software anomalies that prevent the product from satisfying requirement or that adversely affect safety or effectiveness.

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Attachment 3
PCP-USB with sSOIP Anywhere Patient User Operation Manual

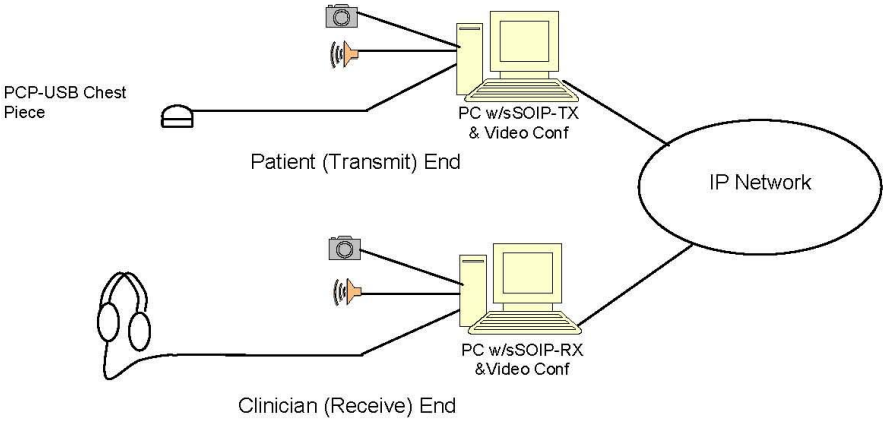
PCP-USB Stethoscope with sSOIP-TX Anywhere
Patient User Operation Instructions

Rev 1.0

This document provides the Patient operating instructions for the PCP-USB Stethoscope with sSOIP-TX Anywhere Software.

1. Introduction

The typical application for a telephonic stethoscope is in conjunction with a video conference session for telemedicine. The stethoscope sounds will go over a separate connection from the video conferencing.



The PCP-USB Chest Piece can be used with a generic PC on an IP network (e.g. the Internet) running (sSOIP-TX Anywhere software. The sSOIP-TX Anywhere client software operates on the transmit (Patient) end of an sSOIP Anywhere network remote auscultation connection. When the Patient user at the sSOIP-TX Anywhere station logs in to the Telemedicine Communications Server (TMCS), the TMCS sends a list of all the authorized sSOIP Anywhere users that have logged in to the consulting Clinicians at the sSOIP-RX Anywhere stations. From that list, the Clinicians can request a connection to any party on the list. The TMCS would then facilitate that connection. The Clinician at the receive end is in control of the connection and will Start or Stop the stethoscope exam from the receive end PC.

The SOIP-TX Anywhere program also provides the capability for recording stethoscope sound streams and playing them back.

The typical application for a telephonic stethoscope is in conjunction with a video conference session for telemedicine. The stethoscope sounds will go over a separate connection from the video conferencing.

2. Installation, Setup and Login

Installation of the PCP-USB Stethoscope is comprised of plugging the PCP-USB Chest Piece into the Microphone port of the PC and installing the sSOIP-TX Anywhere program (following the sSOIP Anywhere Installation Instructions).

Open the sSOIP-TX Anywhere program using the desktop icon or directly from the folder with the sSOIP-TX Anywhere executable file. The main window shown in Figure 1 will display when the program is opened.

Figure 1: Main Window for sSOIP-TX.

Clicking on the Setup button brings up a new window for selecting the stethoscope input source, audio compression and adjustment of the microphone level shown in Figure 2. Typically, the features under Setup will have been set by the installer during installation of sSOIP-TX Anywhere.

By clicking on the Setup button, a Stethoscope Properties window will appear and give the user at the transmit end the following options

Stethoscope input: This is a drop down list showing the available audio inputs. If there is more than one, be sure that the input to which the PCP-USB is connected is selected.

Audio Compression: This is a drop down list from which you can select u-Law PCM (64 Kb/s), ADPCM (32 Kb/s), Speex or Opus. Note that sampling is always at 8 K samples per second.

Mic level: Use the slider to adjust the microphone level. Note that applying to much Mic gain can cause distortion of the stethoscope data stream.

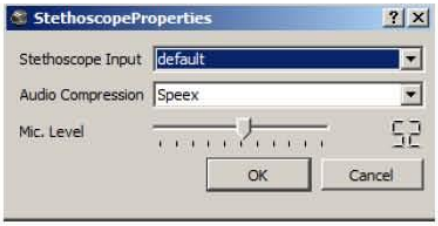


Figure 2: sSOIP-TX Stethoscope Properties Window

Typically, the features under Setup will have been set by the installer during installation of sSOIP-TX Anywhere. If there are any questions, contact the sSOIP-TX Anywhere installer for assistance.

The Patient must Log in to the TMCS by clicking on the Login box which will bring up the login screen shown in Figure 3.

Type in your username, organization and password. Make sure they are exactly the same as provided by your Administrator. Note that they are case sensitive.

Figure 3: Login Window

3. Auscultation Sessions

Before starting an sSOIP Anywhere auscultation session, the video conferencing session would be established to enable the Patient and Clinician to see and talk to each other. The Clinician at the receive end initiates stethoscope session following the sSOIP-RX Anywhere Operation Instructions.

The Patient at the sSOIP-TX Anywhere end would be prompted to accept the connection (See Figure 4). Click on Yes to enable the connection. Then the clinician at the receive location would be able to hear the sounds coming from the PCP-USB Chest Piece.

The Clinician would conduct the auscultation exam by directing the Patient over video to place the PCP-USB Chest Piece in the desired locations and listening to the sounds. When the auscultation session is over, the Clinician or Patient would Hang Up to end the connection.

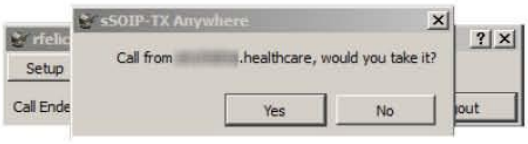


Figure 4: Accepting a call on Patient / transmit end

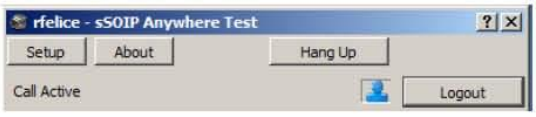


Figure 5: Main window for sSOIP-TX with an active call connection

4. Cleaning, Preventive Inspection, Maintenance and Calibration

The PCP-USB Chest Piece requires no preventive inspection, no preventive or routine maintenance, and it does not have to be calibrated.

The PCP-USB Chest Piece is not a sterile device and does not require sterilization or disinfection. It can be cleaned, as deemed necessary, by wiping with a moist cloth, alcohol or a sanitizing towelette.

5. Trouble Shooting

If a connection cannot be established or if no stethoscope sounds are heard at the receiving end after the connection is established, check the following:

- Ensure the PCP-USB Chest Piece is fully plugged into a UCB port of the PC.
- Ensure the transmit end sSOIP-TX Anywhere application is open and ready to transmit.
- Ensure the transmit end PC is connected to the internet.

Service personnel from the company that provided the PCP-USB Chest Piece and installed the sSOIP-TX software may be needed to assist in resolving any PCP-USB Chest Piece failures or sSOIP-TX Anywhere software failure.

6. Safety

This product meets the safety requirements of IEC/EN 60601-1 Medical Electrical Equipment Part 1: General Requirements for Safety for Type BF protection using a power source providing 5 vdc. The device providing power should satisfy IEC 60950.

Vdc:  Type BF applied part:  Class II protection against electrical shock: 

This product is classified as medical electronic equipment and thus needs special precautions regarding EMC and needs to be installed in accordance with the instructions in this Manual. Portable and mobile RF communications equipment can affect medical electrical equipment.

If interference from other equipment is heard from the PCP-USB during a stethoscope session, the problem may be resolved by relocating other equipment so that it is farther from the PCP-USB. The provider of the PCP-USB Chest Piece will assist in resolving any interference problems. If the interference problems cannot be resolved and the interference does not permit auscultation sounds from being heard, then the PCP-USB should not be used in that location.

The PCP-USB Stethoscope Chest Piece is intended for use within the electromagnetic environment specified below. The user of the PCP-USB Chest Piece should assure that it is used in such an environment. Portable and mobile RF communications equipment should be used no closer to any part of the PCP-USB Chest Piece than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

This product may be used in continuous operation.

This product is not a defibrillation-proof applied part. This product is not suitable for use in the presence of a flammable anesthetic mixture with air or with continuous oxygen or nitrous oxide.

Normal use for this product is at an ambient temperature range of +5° to +40°C, a relative humidity range of 15% to 93%, an atmospheric pressure range of 700 hPa to 1,065 hPa. It may be transported and stored at temperatures from -25°C to +70°C and relative humidity of up to 93%.

The expected life of this device exceeds five years. It contains electronic components and disposal of it should in accordance with all federal and local laws.

Local laws may take priority over the above requirements. If in doubt, consult your local representative or the technical service department.

WARNING: No modification of this equipment is allowed.

Caution: Federal law restricts this device for sale by or on the order of a (licensed healthcare practitioner).

For questions or comments in Europe, contact EC Authorized Representative Emergo Europe, Molenstraat 15, 2513 BH, The Hague, The Netherlands.

In North America, contact RNK Products, Inc., 8247 Devereux Drive, Viera, FL 32940.

CE 0123

RNK Products, Inc.
Devereux Dr, Ste 101
Viera, FL 32940 USA

EC REP
Emergo Group
Molenstraat 15
2513 BH, The Hague
The Netherlands

CERTIFICATION OF COMPLIANCE WITH STANDARDS
BY RNK PRODUCTS INC. PCP-USB STETHOSCOPE

I certify that RNK Products, Inc. PCP-USB Stethoscope complies with appropriate tests/standards:

- IEC60601-1:2005 3rd Edition Medical Electrical Equipment Part 1: General Requirement for Safety
- EN60601-1-2, 2007/03, EMC Immunity Requirements for Medical Electrical Equipment Part 1: General Requirements for Safety, 2. Collateral Standard – Electromagnetic Compatibility Requirements and Tests
- EN61000-4-2 Part 2: Electrostatic Discharge Requirements
- EN61000-4-3 Part 3: Radiated Electromagnetic Field Requirements
- EN61000-4-4 Part 4: Electrical Fast Transient/Burst Requirements
- EN61000-4-6 Part 6: Conducted Immunity Requirements
- EN61000-4-8 Part 8: Power Frequency Magnetic Field Requirements
- EN6100-4-11 Part 11: Voltage Dips, Interrupts, and Fluctuations Requirements

Signature

Charles R. Abbruscato	CEO
Typed Name	Title
RNK Products, Inc.	July 1, 2013
Company	Date

Verification and Validation Plan

(b)(4) Trade Secret Process-Verification & Validation Plan

[redacted]

(b)(4) Trade Secret Process-Verification & Validation Plan

(b)(4) Trade Secret Process-Verification & Validation Plan

RNK Products

PCP-USB Stethoscope
Alpha Test
Rev 0.0
March 4, 2013

Tested By:
C. R. Abbruscato

Signature: C R Abbruscato

Date: May 20, 2013

(b)(4) Trade Secret Process-Testing

(b)(4) Trade Secret Process-Testing

(b)(4) Trade Secret Process-Testing

RNK Products

(b)(4) Trade Secret Process-Testing

(b)(4) Trade Secret Process-Testing Test

(b)(4) Trade Secret Process-Testing

Tested By:

C. R. Abbruscato

Signature:

Date: July 15, 2013

(b)(4) Trade Secret Process-Testing

(b)(4) Trade Secret Process-Testing

(b)(4) Trade Secret Process-Testing

(b)(4) Trade Secret Process-Testing

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(b)(4) Trade Secret Process-Testing

(b)(4) Trade Secret Process-Testing

(b)(4) Trade Secret Process-Testing

RNK Products

510(k) SUMMARY
RNK Products
PCP-USB Stethoscope

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is:

Submitter Information

Submitter:
RNK Products
8247 Devereux Drive
Suite 101
Viera, FL 32940
Telephone: (321) 610-3980
Facsimile: (321) 610-3979

Contact Person:
Charles R. Abbruscato
RNK Products
Telephone: (321) 610-3980
Facsimile: (321) 610-3979

Date Prepared: August 14, 2013

Device Information

Name of Device	RNK PCP-USB Stethoscope
Common or Usual Name	Electronic Stethoscope
Classification Name	Electronic Stethoscope
Predicate Devices	RNK Products PCP/PC Stethoscope (K102893)

Device Description

The PCP-USB Stethoscope consists of a hardware element, the PCP-Chest Piece, and software elements consisting of some audio signal processing in the Streaming Stethoscope Over IP (sSOIP) Anywhere software on the end station PCs, communications software on the end station PCs (sSOIP Anywhere), and communications networking software on the Telemedicine Communications Server (TMCS), Relay Server and Stethoscope User Data (SUD) Server. It provides remote auscultation between a patient at one location and a clinician at another location.

The PCP-USB Chest Piece contains an embedded piezo sensor, audio amplifier Analog to Digital Converter (ADC) and Encoder to create a digitized stream, plus a USB interface to send that data to the PC. The PCP-USB Chest Piece derives its operating voltage from the 5v lead of the USB interface to the PC.

Under direction of the sSOIP Anywhere program in the PC, the digitized signal is formatted in the PC into IP packets for transport. Both the transmit end station (i.e. patient end) and the receive end station (i.e. clinician end) log into the TMCS, which indicates their availability for a connection.

In the sSOIP Anywhere program, the clinician at the receive end, selects a patient from a list of available patients and initiates a connection request to the TMCS, which passes on the request to the patient station. When the patient accepts the incoming connection request in the sSOIP Anywhere program, the TMCS facilitates a direct (peer-to-peer) connection between the two parties. If a direct connection is not possible, the TMCS facilitates a relay connection between the two parties through a Relay Server. No patient stethoscope data passes through the TMCS.

At the receive end PC, the sSOIP Anywhere program directs the acceptance of the IP packets, conversion of the digitized signal back to analog and presentation of the analog signal to the Headset port of the PC.

The TMCS receives information on users that are permitted to use the TMCS services from a SUD Server. That information would be entered into the SUD Server by the health care provider responsible for those users.

Intended Use

The PCP-USB Stethoscope is intended to transmit auscultation sound data, whereby a clinician at one location on an IP network can listen to the auscultation sounds of a patient at a different location on the IP network with the signal carried on an IP connection between the two locations.

Substantial Equivalence

The PCP-USB Chest Piece includes the same piezo sensor and the same audio amplifier as the predicate PCP/PC Chest Piece. But whereas the PCP/PC Stethoscope uses the Analog to Digital Converter (ADC) and Encoder of the PC's audio circuitry, the PCP-USB Chest Piece embeds those circuit elements within the chest piece head itself. Whereas the PCP/PC Chest Piece derives its operating voltage from the phantom voltage on the Microphone port of the PC, the PCP-USB derives its operation voltage from the 5v lead of the USB interface to the PC. The PCP-USB Stethoscope is substantially equivalent to the RNK Products, Inc. PCP/PC Stethoscope. Bench testing and clinical testing were performed to verify specifications and performance.

The sSOIP Anywhere software is an enhancement of the predicate sSOIP software such that working with the TMCS, SUD Server and Relay Server, IP connections can be accomplished across Network Address Translation (NAT) boundaries, whereas sSOIP could only make IP connections between static IP addresses.

The RNK PCP-USB Stethoscope has the same intended use, principles of operation and technological characteristics as the predicate devices. There are no new questions of safety or effectiveness.

510(k) Number (if known): K

Device Name: PCP-USB Stethoscope

Indications for Use:

The RNK PCP-USB Stethoscope is intended to transmit auscultation sound data, whereby a clinician at one location on an IP network can listen to the auscultation sounds of a patient at a different location on the IP network with the signal carried on an IP connection between the two locations.

Prescription Use: **X** OR Over-the-Counter Use _____
(Part 21 CRF 801 Subpart D) (Part 21 CRF 801 Subpart C)

(Please Do Not Write Below This Line – Continue On Another Page If Needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT
(As Required by 21 C.F.R. § 807.87(j))

I certify that, in my capacity as CEO of RNK Products, Inc. I believe, to the best of my knowledge, that all data and information submitted in this premarket notification for the RNK PCP-USB Stethoscope is truthful and accurate and that no material fact has been omitted.

Signature

August 14, 2013
Date

Charles R. Abbruscato
Name

CEO
Title

Barlow, Lenny *

From: Barlow, Lenny *
Sent: Friday, October 18, 2013 11:45 AM
To: 'abbruscato@rnkproducts.com'
Subject: FW: k132560 Correspondence
Attachments: k132560.pdf

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name _____Frank Lacy_____

Subject: 510(k) Number _____K132560/S1_____

To: The Record

Please list CTS decision code ____SE_____

- o Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
- o Hold (Additional Information or Telephone Hold).
- X Final Decision (**SE**, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

o	NO	NSE for lack of predicate
o	NI	NSE for new intended use
o	NQ	NSE for new technology that raises new questions of safety and effectiveness
o	NU	NSE for new intended use AND new technology raising new questions of safety and effectiveness
o	NP	NSE for lack of performance data
o	NS	NSE no response
o	NL	NSE for lack of performance data AND no response
o	NM	NSE pre-amendment device call for PMAs (515i)
o	NC	NSE post-amendment device requires PMAs
o	NH	NSE for new molecular entity requires PMA
o	TR	NSE for transitional device

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	X	
510(k) Summary /510(k) Statement	*Attach Summary*	X	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	X	
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		X
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		X	
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			X
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			X
Is this device intended for pediatric use only?			X
Is this a prescription device? (If both prescription & OTC, check both boxes.)		X	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			✠
Is clinical data necessary to support the review of this 510(k)? For United States-based clinical studies **only**: Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If study was			✠

conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			X
All Pediatric Patients age<=21			
Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			
Nanotechnology			X
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		X

Regulation Number	**Class***	**Product Code**
21 CFR 870.1875	II(two)	74 DQD

(*If unclassified, see 510(k) Staff)

Additional Product Codes: _____

Review: Linda J. Ricci -S 2013.10.08 14:46:41 -04'00'

(Branch Chief) (Branch Code) (Date)

Final Review: Date: 2013.10.11 08:57:18 -04'00'

(Division Director) (Date)

RNK Products, Inc.

K132560/S1

FDA CDRH DMC

AUG 29 2013

Received

August 28, 2013

Food and Drug Administration
Center for Devices and Radiological Health
510(k) Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver spring, MD 20993-0002

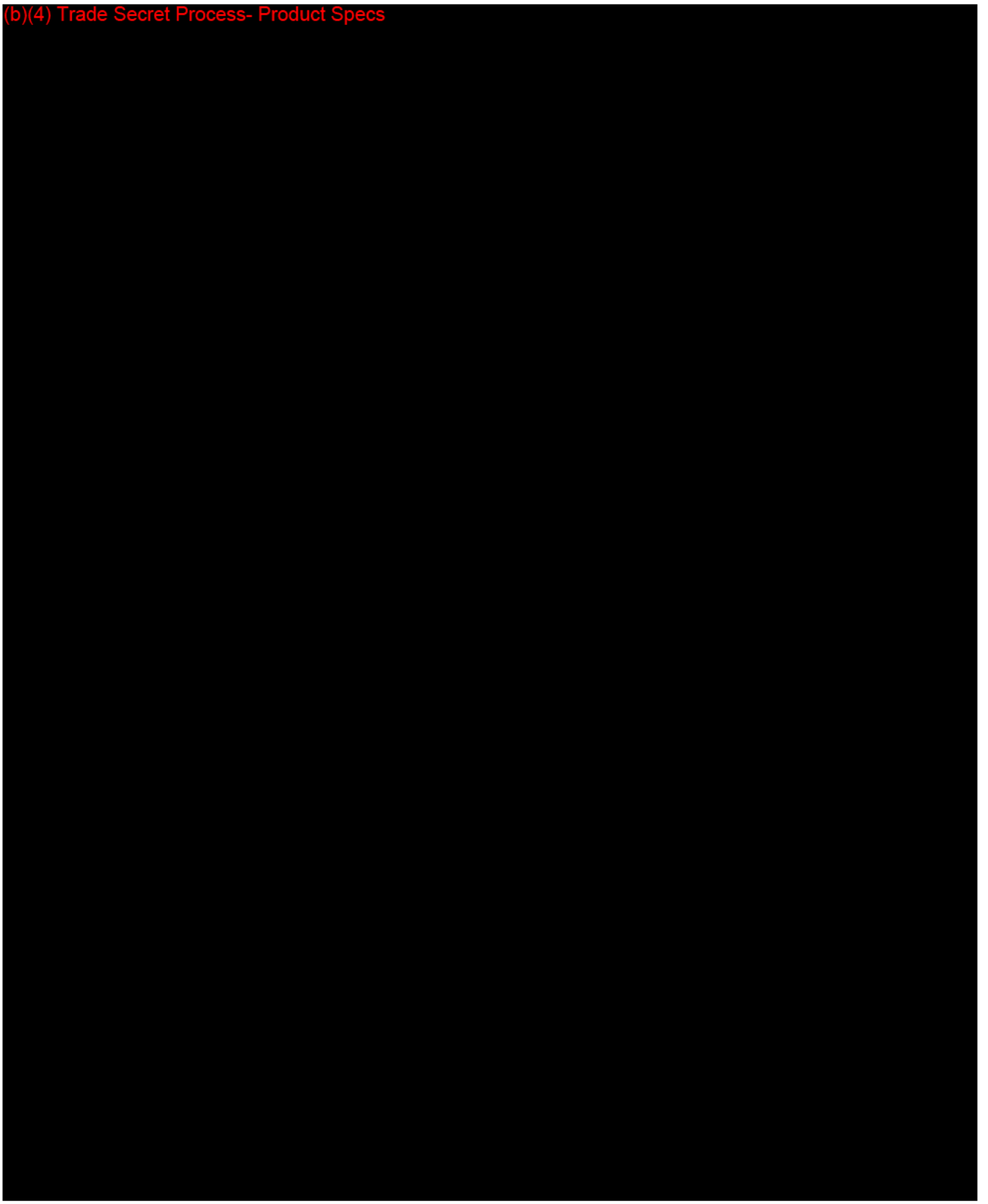
(b)(4) Trade Secret Process- Product Specs

Dear Sir or Madam:

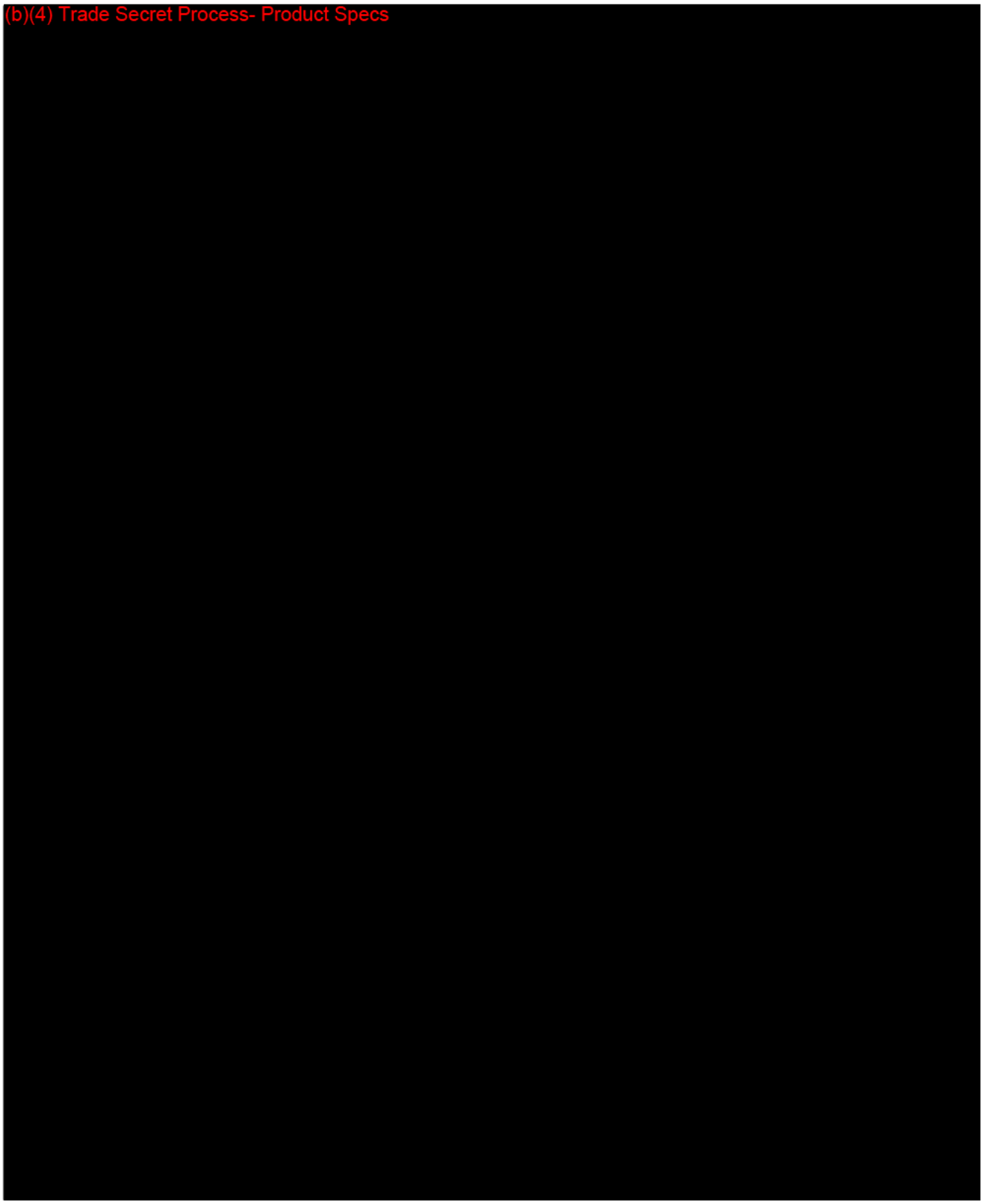
(b)(4) Trade Secret Process- Product Specs

S2

(b)(4) Trade Secret Process- Product Specs



(b)(4) Trade Secret Process- Product Specs



(b)(4) Trade Secret Process- Product Specs

[redacted]

Regards,

Charles R. Abbruscato
RNK Products, Inc.
8247 Devereux Drive
Suite 101
Viera, FL 32940
(321) 610.3980

RNK Products, Inc.

August 28, 2013

Food and Drug Administration
Center for Devices and Radiological Health
510(k) Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver spring, MD 20993-0002

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(b)(4) Trade Secret Process- Product Specs

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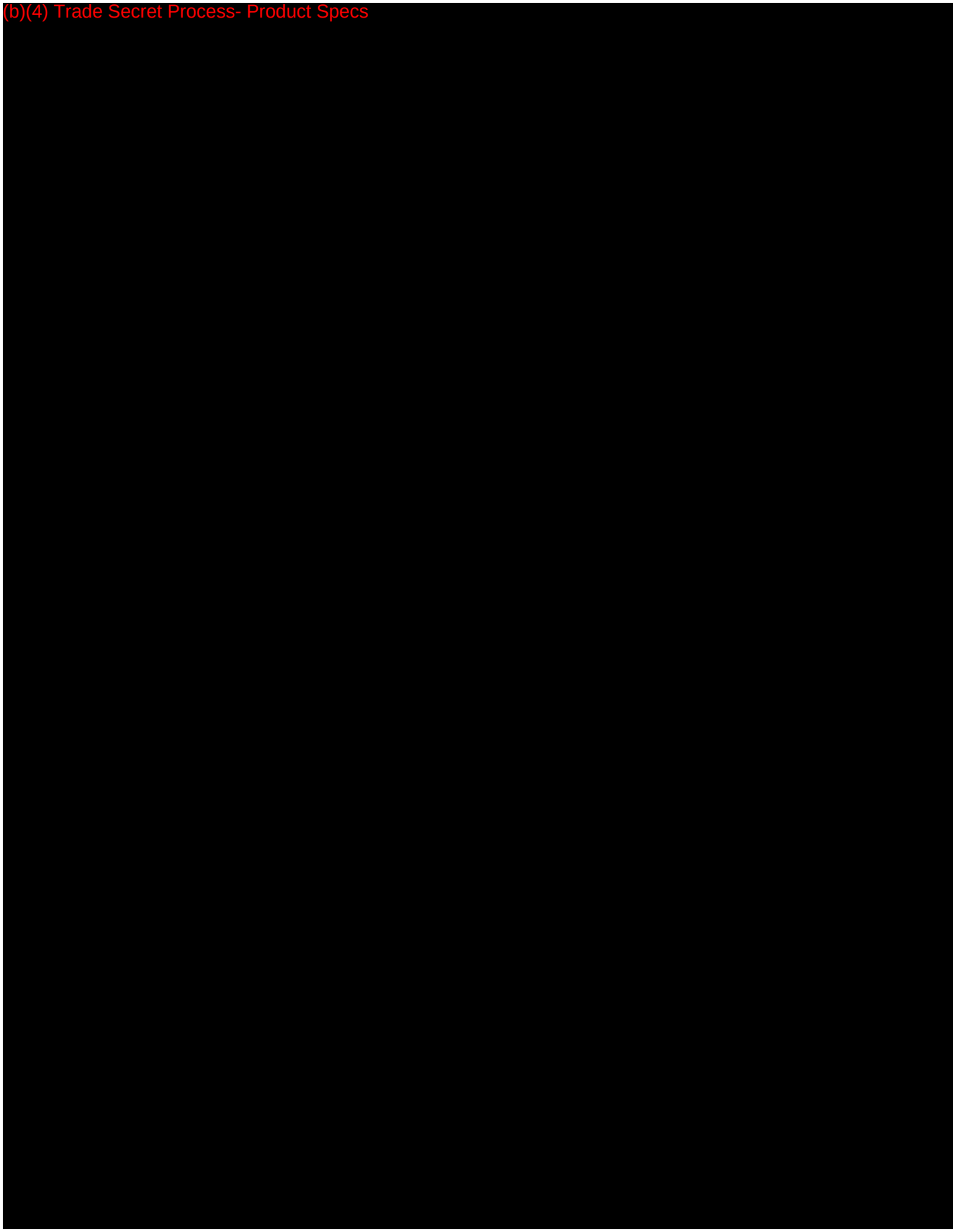
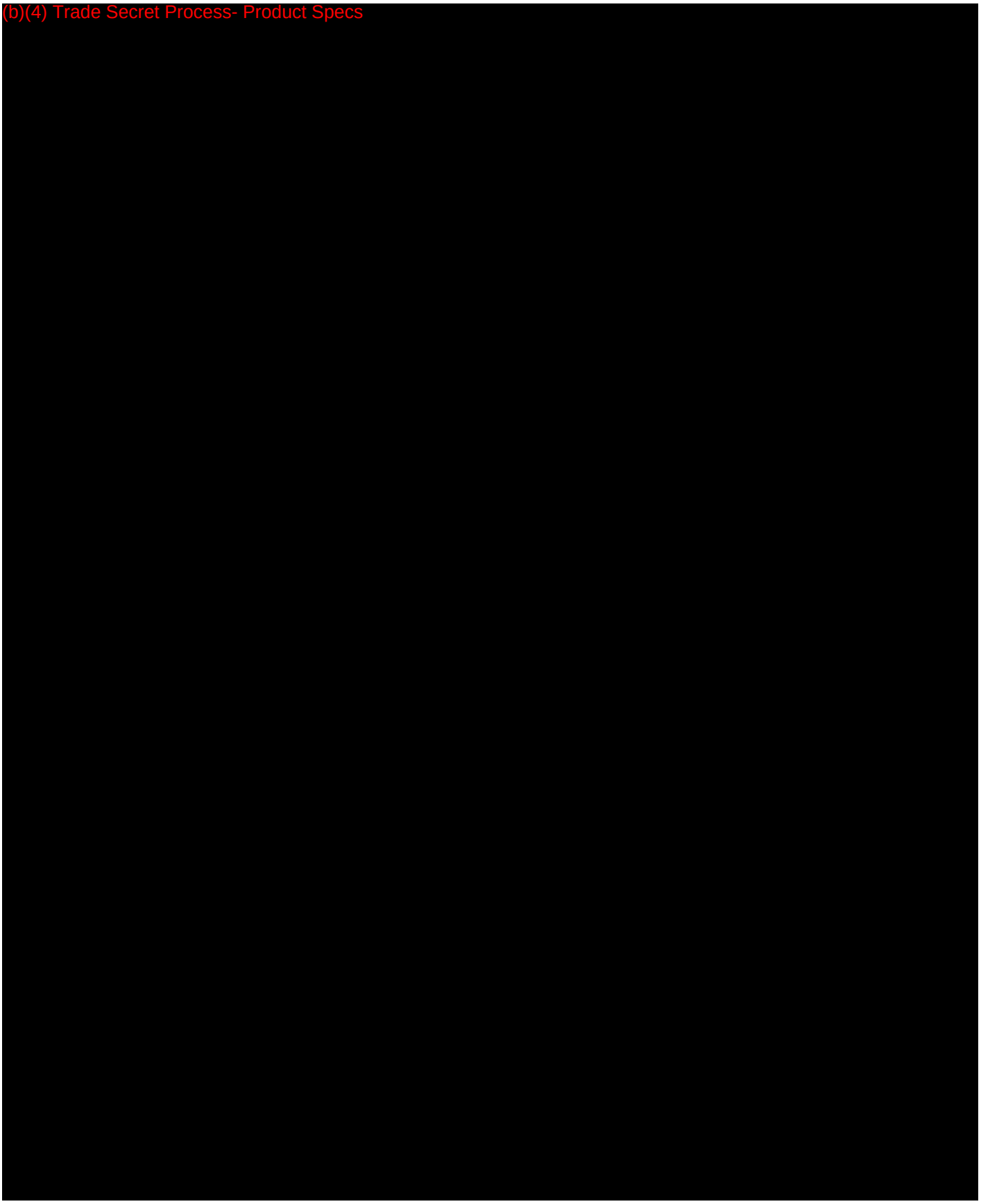


(b)(4) Trade Secret Process- Product Specs



(b)(4) Trade Secret Process- Product Specs

[redacted]

Regards,

Charles R. Abbruscato
RNK Products, Inc.
8247 Devereux Drive
Suite 101
Viera, FL 32940
(321) 610.3980

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

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]

IEC 60601-1:2005 Medical Electrical Equipment - Part 1: General Requirements for Safety

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 5-4	
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], www.fda.gov/cdrh/stdsprog.html

[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 descr bed; 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 www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

* 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.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour 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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
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.

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-1-2:2007 Medical Electrical Equipment - Part 1: General Req. for Safety 2. Collateral Standard: EMC Req. and Tests

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 5-54	
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?	☒	☐
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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.	☐	☒
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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], www.fda.gov/cdrh/stdsprog.html

[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 descr bed; 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 www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

* 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.

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(b)(4) Trade Secret Process- Software Specs

Software Description

Rev 1.0

(b)(4) Trade Secret Process- Software Specs

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