K090224

510(k) Summary

ADMINISTRATIVE INFORMATION

JUL 30 2009

Manufacturer Name:	X-spine Systems, Inc. 452 Alexandersville Rd. Miamisburg, OH 45342 Telephone (937) 847-8400 FAX (937) 847-8410
Official Contact:	David Kirschman, MD Chief Medical Officer

DEVICE NAME

Classification Names:	Orthosis, Spondylolisthesis Spinal Fixation Orthosis, Pedicle Spinal Fixation
Trade/Proprietary Name:	Fortex Pedicle Screw System
Common Name:	Pedicle Screw Spinal System

ESTABLISHMENT REGISTRATION NUMBER

X-spine Systems, Inc. has submitted an Establishment Registration to FDA. The Establishment Registration number is 3005031160. The owner/operator number for X-spine Systems, Inc. is 9063903.

DEVICE CLASSIFICATION

FDA has classified pedicle screw spinal systems as Class II devices (21 CFR 888.3070). The product code for Orthosis, Spondylolisthesis Spinal Fixation is (MNH). The product code for Orthosis, Spinal Pedicle Fixation is (MNI). These device classifications are reviewed by the Orthopedic Devices Branch.

INTENDED USE

The Fortex Pedicle Screw System is indicated for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

The Fortex Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the

following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

DEVICE DESCRIPTION

Fortex Rod

Fortex rods are 5.5 mm diameter solid cylinders with spherically rounded ends, provided in 40 mm, 60 mm, 70 mm, 80 mm, 100 mm, 120 mm, 140 mm, 160 mm, 180 mm, 200 mm, and 300 mm lengths.

Fortex Pedicle Screw Assembly

Each Fortex pedicle screw assembly consists of a pedicle screw, yoke, and screw cap. Self-tapping pedicle screw assemblies are provided in diameters of 4.75mm, 5.5 mm, 6.5 mm, 7.5 mm and 8.25mm. All screw assemblies are provided in lengths of 30 mm, 35 mm, 40 mm, 45 mm, 50 mm, and 55 mm. Screws are provided in canulated and non-canulated configurations.

Fortex Cross Bar Assembly

The Fortex cross bar assembly is an optional component and can be used for additional stabilization. Cross bar assemblies are available in lengths from 25 mm to 81 mm.

Material composition

The rods, pedicle screws and cross bars of the Fortex Pedicle Screw System are made of titanium alloy conforming to ASTM F136.

STATEMENT OF TECHNOLOGICAL COMPARISON

X-spine Systems, Inc. has submitted information to demonstrate that, for the purposes of FDA's regulation of medical devices, the Fortex Pedicle Screw System is substantially equivalent in indications and design principles to the predicate Capless Pedicle Screw System (K052847) and Capless LI Pedicle Screw System (K072282).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

X-Spine Systems, Inc.
c/o Dr. David Kirschman, M.D.
Chief Medical Officer
452 Alexandersville Rd
Miamisburg, OH 45342

JUL 30 2009

Re: K090224
Trade/Device Name: Fortex™ Pedicle Screw System
Regulation Number: 21 CFR 888. 3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNH, MNI
Dated: June 26, 2009
Received: June 30, 2009

Dear Dr. Kirschman:

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

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

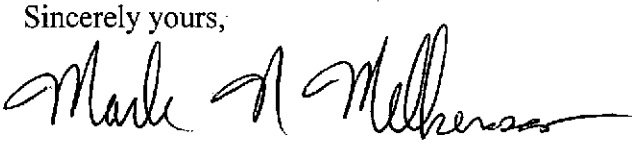
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark M. Melkerson
Director
Division of Surgical, Orthopaedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090224

Device Name: Fortex™ Pedicle Screw System

Indications for Use:

The Fortex Pedicle Screw System is indicated for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

In addition, the Fortex Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(EXT for M&M)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090224

page 1 of 1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

X-Spine Systems, Inc.
c/o Dr. David Kirschman, M.D.
Chief Medical Officer
452 Alexandersville Rd
Miamisburg, OH 45342

JUL 30 2009

Re: K090224
Trade/Device Name: Fortex™ Pedicle Screw System
Regulation Number: 21 CFR 888. 3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNH, MNI
Dated: June 26, 2009
Received: June 30, 2009

Dear Dr. Kirschman:

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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

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Sincerely yours,

Mark M. Melkerson
Director
Division of Surgical, Orthopaedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090224

Device Name: Fortex™ Pedicle Screw System

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(EXT for M&M)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090224

page 1 of 1

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

May 19, 2009

X-SPINE SYSTEMS, INC.
452 ALEXANDERSVILLE RD.
MIAMISBURG, OHIO 45342
UNITED STATES
ATTN: DAVID KIRSCHMAN

510k Number: K090224

Product: FORTEX PEDICLE SCREW SYSTEM

Extended Until: 06/30/2009

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

X-spine Systems, Inc.
452 Alexandersville Rd.
Miamisburg, OH 45342
Phone: (800) 903-0640
Direct: (937) 847-8400
Fax: (937) 847-8410
www.x-spine.com

David Kirschman, M.D
President & Chief Medical Officer
(b)(4)

May 15, 2009

Marjorie Schulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
Food and Drug Administration
9200 Corporate Blvd.
Rockville MD, 20850

FDA CDRH DMC

MAY 18 2009

Received

RE: K090224, Fortex Pedicle Screw System

Ms. Schulman,

This letter is to notify you of our request to extend to June 30 our response time to provide additional information requested by the Office of Device Evaluation regarding our above-referenced Premarket Notification.

If you have any questions, please feel free to contact me.

Sincerely yours,

David Kirschman, M.D.
President and Chief Medical Officer
X-spine Systems, Inc.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

March 24, 2009

X-SPINE SYSTEMS, INC.
452 ALEXANDERSVILLE RD.
MIAMISBURG, OHIO 45342
UNITED STATES
ATTN: DAVID KIRSCHMAN

510k Number: K090224
Product: FORTEX PEDICLE SCREW SYSTEM

Extended Until: 05/26/2009

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

X-spine Systems, Inc.
452 Alexandersville Rd.
Miamisburg, OH 45342
Phone: (800) 903-0640
Direct: (937) 847-8400
Fax: (937) 847-8410
www.x-spine.com

David Kirschman, M.D
President & Chief Medical Officer
(b)(4)

March 19, 2009

Marjorie Schulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
Food and Drug Administration
9200 Corporate Blvd.
Rockville MD, 20850

RE: K090224, Fortex Pedicle Screw System

Ms. Schulman,

This letter is to notify you of our request to extend for a period of 60 days our response time to provide additional information requested by the Office of Device Evaluation regarding our above-referenced Premarket Notification.

If you have any questions, please feel free to contact me.

Sincerely yours,

David Kirschman MD

David Kirschman, M.D.
President and Chief Medical Officer
X-spine Systems, Inc.

K41

X-spine™

X-spine Systems, Inc.
452 Alexandersville Rd.
Miamisburg, OH 45342
Phone: (800) 903-0640
Direct: (937) 847-8400
Fax: (937) 847-8410
www.x-spine.com

David Kirschman, M.D
President & Chief Medical Officer
(b)(4)

March 19, 2009

Marjorie Schulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
Food and Drug Administration
9200 Corporate Blvd.
Rockville MD, 20850

RE: K090224, Fortex Pedicle Screw System

Ms. Schulman,

This letter is to notify you of our request to extend for a period of 60 days our response time to provide additional information requested by the Office of Device Evaluation regarding our above-referenced Premarket Notification.

If you have any questions, please feel free to contact me.

Sincerely yours,

David Kirschman MD

David Kirschman, M.D.
President and Chief Medical Officer
X-spine Systems, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

February 24, 2009

510k Number: K090224
Product: FORTEX PEDICLE SCREW SYSTEM

X-SPINE SYSTEMS, INC.
452 ALEXANDERSVILLE RD.
MIAMISBURG, OHIO 45342
UNITED STATES
ATTN: DAVID KIRSCHMAN

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

January 30, 2009

X-SPINE SYSTEMS, INC.
452 ALEXANDERSVILLE RD.
MIAMISBURG, OHIO 45342
UNITED STATES
ATTN: DAVID KIRSCHMAN

510k Number: K090224
Received: 1/30/2009
Product: FORTEX PEDICLE SCREW SYSTEM

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at http://www.fda.gov/cdrh/mdufma/index.html for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3674.pdf) accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007" (http://www.fda.gov/oc/initiatives/fdaaa/guidance_certifications.html). According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1655.pdf. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/elecsub.html. In addition, the 510(k) Program Video is now available for viewing on line at www.fda.gov/cdrh/video/510k.wmv .

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice www.fda.gov/cdrh/devadvice/". If you have questions on the status of your submission, please contact DSMICA at (240) 276-3150 or the toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsma/dsmastaf.html. If you have procedural questions, please contact the 510(k) Staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

K090224

Special 510(k): Device Modification

Fortex™
Pedicle Screw System

X-spine Systems, Inc.
452 Alexandersville Road
Miamisburg, OH 45342
Telephone (937) 847-8400
FAX (937) 847-8410

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K10

Table of Contents

1. Medical Device User Fee Cover Sheet

Form Approved: OMB No. 0910-511 Expiration Date: January 31, 2010. 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)

X SPINE SYSTEMS INC
X SPINE SYSTEMS INC
452 ALEXANDERSVILLE RD
Miamisburg OH 45342
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
421631333

2. CONTACT NAME
David Kirschman

2.1 E-MAIL ADDRESS
(b)(4)

2.2 TELEPHONE NUMBER (include Area code)
937-847-8400

2.3 FACSIMILE (FAX) NUMBER (Include Area code)
937-847-8410

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/oc/mdufma

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)
[ ] Annual Fee for Periodic Reporting (APR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application
Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?
[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)
[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).
[ ] YES [X] NO

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
(b)(4)
23-Jan-2009

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

2. CDRH Premarket Review Submission Cover Sheet

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: August 31, 2010.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
01/26/2009	(b)(4)	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☑ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☐ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☑ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ 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)*		
X-spine Systems, Inc.	3005031160		
Division Name *(if applicable)*	**Phone Number *(including area code)***		
	(937) 847-8400		
Street Address	**FAX Number *(including area code)***		
452 Alexandersville Rd	(937) 847-8410		
City	**State / Province**	**ZIP/Postal Code**	**Country**
Miamisburg	OH	45429	USA
Contact Name			
David Kirschman, MD			
Contact Title	**Contact E-mail Address**		
Chief Medical Officer	(b)(4)		

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/Postal Code**	**Country**
Contact Name			
Contact Title	**Contact E-mail Address**		

PSC Graphics: (301) 443-1090 EF

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

- ☐ 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
  - ☐ Sterilization
  - ☐ Packaging
  - ☐ 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
  - ☐ 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

- ☐ Repose 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	MNH	2	MNI	3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- [x] 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	K052847	1	Capless Pedicle Screw System	1	X-spine Systems, Inc.
2	K072282	2	Capless LI Pedicle Screw System	2	X-spine Systems, Inc.
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

	Trade or Proprietary or Model Name for This Device		Model Number
1	Fortex Pedicle Screw System	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
MNH, MNI	21 CFR 888.3070	[ ] Class I [x] Class II
Classification Panel		[ ] Class III [ ] Unclassified
Orthopedic Devices Branch		

Indications *(from labeling)*

The Fortex Pedicle Screw System is indicated for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion. The Fortex Pedicle Screw System is also intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

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

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

☑ Original ☐ Add ☐ Delete	Facility Establishment Identifer (FEI) Number: 3005031160	☑ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name: X-spine Systems, Inc.		Establishment Registration Number: 3005031160	
Division Name *(if applicable)*		Phone Number *(including area code)*: (937) 847-8400	
Street Address: 452 Alexandersville Rd.		FAX Number *(including area code)*: (937) 847-8410	
City: Miamisburg	State / Province: OH	ZIP/Postal Code: 45342	Country: USA
Contact Name: David Kirschman, MD	Contact Title: Chief Medical Officer	Contact E-mail Address: (b)(4)	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifer (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/Postal Code	Country
Contact Name	Contact Title	Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifer (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/Postal Code	Country
Contact Name	Contact Title	Contact E-mail Address	

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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	F 136	ASTM	Standard Specifications for Wrought Titanium 6-Aluminum 4-Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications	02	11/01/2002
2	F 1717	ASTM	Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model	04	04/01/2004
3					
4					
5					
6					
7					

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

3. 510(k) Cover Letter

X-spine Systems, Inc.
452 Alexandersville Rd.
Miamisburg, OH 45342
Phone: 800/903-0640
Direct: 937/847-8400
Fax: 937/847-8410
www.x-spine.com

David Kirschman, M.D
Chief Medical Officer
dk@x-spine.com

January 29, 2009

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

Reference: K052847, Capless Pedicle Screw System, 12/12/2005

Dear Madam/Sir:

X-spine Systems, Inc. hereby submits this **Special 510(k): Device Modification** to request a modification to our Capless and Capless LI Pedicle Screw Systems (K052847 and K072282). The modified device shall be called the Fortex Pedicle Screw System. The modifications are to (b)(4) [redacted]. We believe these modifications are eligible for the Special 510(k) process since they have the same fundamental scientific technology and intended use as the predicate device. The product code for Orthosis, Spondylolisthesis Spinal Fixation is (MNH). The product code for Orthosis, Spinal Pedicle Fixation is (MNI). These device classifications are reviewed by the Orthopedic Devices Branch.

We consider our intent to market this device as confidential commercial information and requests that it be treated as such by FDA. We have taken precautions to protect the confidentiality of these devices. We understand that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).

Thank you in advance for your consideration of our application. If there are any questions, please feel free to contact me at 937-847-8400.

Sincerely,

David Kirschman, M.D.
Chief Medical Officer

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4. Indications for Use Statement

Indications for Use

510(k) Number (if known): _____

Device Name: Fortex™ Pedicle Screw System

Indications for Use:

The Fortex Pedicle Screw System is indicated for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

In addition, the Fortex Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

Prescription Use (Part 21 CFR 801 Subpart D)	X	AND/OR Over-The-Counter Use (21 CFR 801 Subpart C)	_____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

5. 510(k) Summary

510(k) Summary

ADMINISTRATIVE INFORMATION

Manufacturer Name:	X-spine Systems, Inc. 452 Alexandersville Rd. Miamisburg, OH 45342 Telephone (937) 847-8400 FAX (937) 847-8410
Official Contact:	David Kirschman, MD Chief Medical Officer

DEVICE NAME

Classification Names:	Orthosis, Spondylolisthesis Spinal Fixation Orthosis, Pedicle Spinal Fixation
Trade/Proprietary Name:	Fortex Pedicle Screw System
Common Name:	Pedicle Screw Spinal System

ESTABLISHMENT REGISTRATION NUMBER

X-spine Systems, Inc. has submitted an Establishment Registration to FDA. The Establishment Registration number is 3005031160. The owner/operator number for X-spine Systems, Inc. is 9063903.

DEVICE CLASSIFICATION

FDA has classified pedicle screw spinal systems as Class II devices (21 CFR 888.3070). The product code for Orthosis, Spondylolisthesis Spinal Fixation is (MNH). The product code for Orthosis, Spinal Pedicle Fixation is (MNI). These device classifications are reviewed by the Orthopedic Devices Branch.

INTENDED USE

The Fortex Pedicle Screw System is indicated for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

The Fortex Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the

following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

DEVICE DESCRIPTION

Fortex Rod

Fortex rods are 5.5 mm diameter solid cylinders with spherically rounded ends, provided in 40 mm, 60 mm, 70 mm, 80 mm, 100 mm, 120 mm, 140 mm, 160 mm, 180 mm, 200 mm, and 300 mm lengths.

Fortex Pedicle Screw Assembly

Each Fortex pedicle screw assembly consists of a pedicle screw, yoke, and screw cap. Self-tapping pedicle screw assemblies are provided in diameters of 4.75mm, 5.5 mm, 6.5 mm, 7.5 mm and 8.25mm. All screw assemblies are provided in lengths of 30 mm, 35 mm, 40 mm, 45 mm, 50 mm, and 55 mm. Screws are provided in canulated and non-canulated configurations.

Fortex Cross Bar Assembly

The Fortex cross bar assembly is an optional component and can be used for additional stabilization. Cross bar assemblies are available in lengths from 25 mm to 81 mm.

Material composition

The rods, pedicle screws and cross bars of the Fortex Pedicle Screw System are made of titanium alloy conforming to ASTM F136.

STATEMENT OF TECHNOLOGICAL COMPARISON

X-spine Systems, Inc. has submitted information to demonstrate that, for the purposes of FDA's regulation of medical devices, the Fortex Pedicle Screw System is substantially equivalent in indications and design principles to the predicate Capless Pedicle Screw System (K052847) and Capless LI Pedicle Screw System (K072282).

6. Device Name

Device Name

The device trade names and Common/Classification names are:

Device Trade Name	**Common/Classification Name**
Fortex Pedicle Screw System	Pedicle Screw Spinal System

7. Address and Registration Number

Address and registration number

X-spine Systems, Inc.
452 Alexandersville Rd.
Miamisburg, OH 45342

FDA Registration # 3005031160

8. Device Class

Device Class

FDA has classified pedicle screw spinal systems as Class II devices (21 CFR 888.3070). The product code for Orthosis, Spondylolisthesis Spinal Fixation is (MNH). The product code for Orthosis, Spinal Pedicle Fixation is (MNI). These device classifications are reviewed by the Orthopedic Devices Branch.

9. Predicate Device Information

Predicate Device Information

The predicate devices are the Capless Pedicle Screw System

510(k) Number: K052847

Occurrence Date: 12/12/2005

and

Capless LI Pedicle Screw System

510(k) Number: K072282

Occurrence Date: 9/14/2007

10. Labeling and Intended Use

Labeling and Instructions for Use

Draft labels and Instructions for Use can be found in Attachment A.

Labeling has been changed to reflect the new name of the product. The Instructions for Use have been modified to address the addition of a threaded setscrew to the system.

Intended Use

The Fortex Pedicle Screw System is indicated for the treatment of severe spondylolisthesis (Grade 3and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

The Fortex Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

This is the **same intended use** as previously cleared for the Capless Pedicle Screw System K052847 and Capless LI Pedicle Screw System K072282.

11. Device Description and Comparison

Device Description and Comparison

DEVICE DESCRIPTION

Fortex Rod

Fortex rods are 5.5 mm diameter solid cylinders with spherically rounded ends, provided in 40 mm, 50mm, 60 mm, 70 mm, 80 mm, 90mm, 100 mm, 120 mm, 140 mm, 160 mm, 180 mm, 200 mm, and 300 mm lengths. These rods are identical to those previously cleared for the Capless and Capless LI systems.

Fortex Pedicle Screw Assembly

Each Fortex pedicle screw assembly consists of a pedicle screw, yoke, screw top, and threaded setscrew. The screw top is 12.7 mm in diameter. Self-tapping pedicle screw assemblies are provided in diameters of 4.75mm, 5.5 mm, 6.5 mm, 7.5 mm and 8.25mm. All screw assemblies are provided in lengths of 30 mm, 35 mm, 40 mm, 45 mm, 50 mm, and 55 mm. Screws are provided in canulated and non-canulated configurations. The screw housing diameter of 12.7mm is identical between the Capless LI and Fortex systems. The screw shafts and screw retention yoke are identical to those previously cleared for the Capless and Capless LI systems.

Fortex Cross Bar Assembly

The Fortex cross bar assembly is an optional component and can be used for additional stabilization. Cross bar assemblies are available in lengths from 25 mm to 81 mm. These assemblies are identical to those previously cleared for the Capless and Capless LI systems.

Material composition

The rods, pedicle screws and transverse links of the Fortex Pedicle Screw System are made of titanium alloy conforming to ASTM F136. The material is identical to that of previously cleared Capless and Capless LI systems.

DEVICE COMPARISON

The modification made, compared to the Capless and Capless LI Pedicle Screw Systems (K052847 and K072282), is the addition of a threaded set-screw to the upper portion of the screw housing. Compared to the prior systems the rod and screw are locked using the same mechanism of direct mechanical compression of the rod onto the screw shaft. See comparison in Table 1 below.

Technology	*Original Device* Capless and Capless LI Pedicle Screw Systems (K052847 and K072282)	*Modified Device* Fortex Pedicle Screw System
Material	Titanium alloy 6Al 4V	identical
Screw overall diameter	12.7mm (LI)	identical
Screw shaft sizing	4.75-8.25mm x 30-55mm	identical
Screw threading	Modified buttress, conical inner diameter	identical
Cross-bar system	25-81mm	identical
Rod diameter	5.5 mm	identical
Sterility	Provided non-sterile	identical
Locking vector	Downward rod compression	identical
Rod loading direction	Top	identical
Set-screw	No	yes

TABLE 1: Technology comparison between original device (Capless) and modified device (Fortex)

12. Substantial Equivalence

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Substantial Equivalence

The Fortex Pedicle Screw system has the following similarities to the Capless and Capless LI Pedicle Screw Systems which have previously received 510(k) clearance:

- It has the same indicated use,
- It uses the same operating principle,
- It incorporates the same basic screw design,
- It incorporates the same materials,
- It is provided in the same sterility level (non-sterile)

In summary, the Fortex Pedicle Screw System described in this submission is, in our opinion, substantially equivalent to the predicate device.

13. Summary of Design Control Activities

Summary of Design Control Activities

The risk analysis method used to assess the impact of the modifications was a (b)(4) (b)(4) The design verification tests that were performed as a result of this risk analysis assessment are listed in Table 2 below.

TABLE 2- Verification Tests

Modification	Test Performed	Acceptance Criteria
(b)(4)		

The test methods used are the same as those submitted in the original submissions.

A declaration of conformity with design controls is included in the following section.

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14. Declaration of Conformity with Design Controls

Declaration of Conformity with Design Controls

Verification Activities

To the best of my knowledge, the verification activities, as required by the risk analysis, for the modification were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.

David Kirschman, MD
Chief Medical Officer
X-spine Systems, Inc.

1/24/09
Date

Manufacturing Facility

The manufacturing facility, X-spine Systems, Inc. is in conformance with the design control requirements as specified in 21 CFR 820. 30 and the records are available for review.

(b)(6)

[redacted]
X-spine Systems, Inc.

1/29/09
Date

15. Truthful and Accuracy Certification

Truthful and Accuracy Statement

I certify that, in my capacity as Chief Medical Officer of X-spine Systems, Inc., I believe to the best of my knowledge that all data and information in this Special 510(k) Device Modification - Fortex Pedicle Screw System are truthful and accurate and that no material fact has been omitted.

David Kirschman, MD
Chief Medical Officer

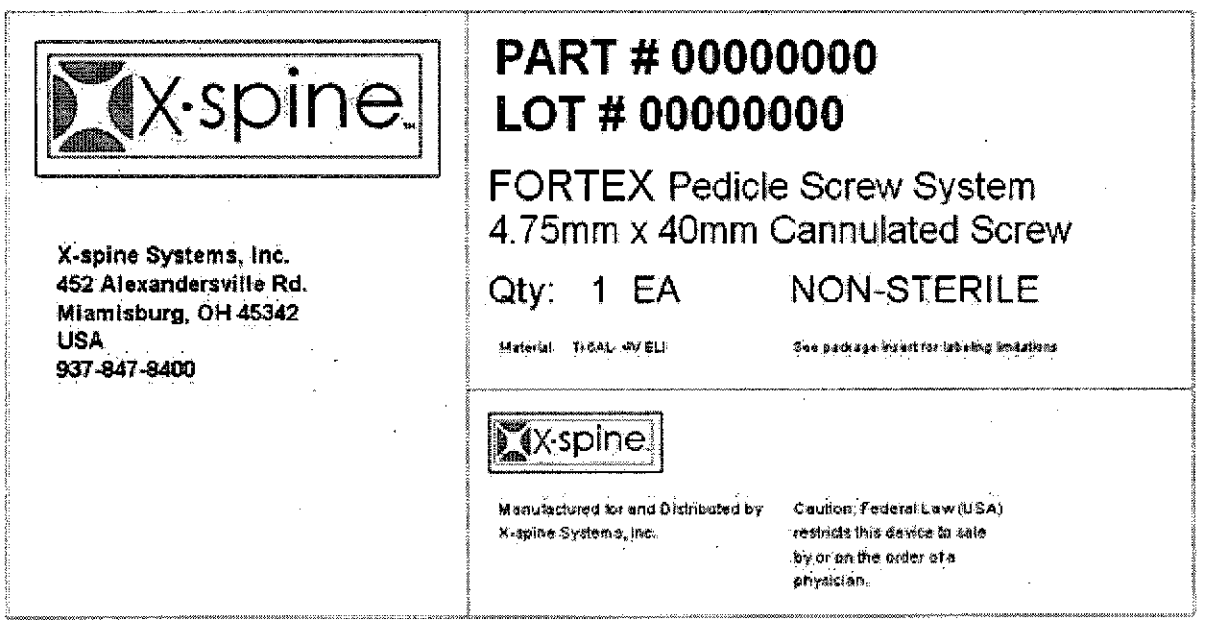
Date 1/29/09

NB

Appendix A

Draft Label and Instructions for Use

Draft Label



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Draft Instructions for Use/Package Insert

X-Spine Systems Fortex Pedicle Screw System

Important Note

The users acknowledge that they have read and agreed on the conditions in this insert, which are to be considered as contractual.

Basic Structure
The Fortex Pedicle Screw System consists of rods, pedicle screws, cross bar connectors and hand instruments. Various forms and sizes of these implants are available, so that adaptations can always be made to take into account the pathology and anatomy of an individual patient.

Material
All components are made of Ti6Al4V ELI, a titanium based alloy which complies with ASTM F136.

Indications for Use
The Fortex Pedicle Screw System is indicated for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

In addition, the Fortex Pedicle Screw system is intended to provide immobilization and stabilization of the spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

Levels of Fixation
Levels of fixation are for the thoracic, lumbar and sacral spine.

General Conditions of Use
The implants must be implanted only by experienced surgeons having undergone appropriate training in spinal surgery. Their use in implantation must be decided upon with regard to the surgical and medical indications, the potential risks, and limitations related to this type of surgery. The surgeon and patient should demonstrate knowledge of the contraindications, side effects, precautions, metallurgic and biological characteristics of the implants to be used. Fortex implants must not be used together with implants from a different source, a different manufacturer or made from a different material. Under no circumstances may the implants be reused.

Contraindications
Contraindications for the Fortex Pedicle Screw System are similar to those of other systems of similar design, and include, but are not limited to:

1. Active infectious process in the patient, particularly in or adjacent to the spine or spinal structures
2. Morbid obesity.
3. Pregnancy.
4. Grossly distorted anatomy due to congenital abnormalities.
5. Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery.
6. Rapid joint disease, bone absorption, osteopenia, osteomalcia, or osteoporosis. Osteopenia or osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction and/or the amount of mechanical fixation.
7. Suspected or documented metal allergy or intolerance.
8. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
9. Use of these implants is relatively contraindicated in patients whose activity, mental capacity, mental illness, alcohol or drug abuse, occupation or life-style may interfere with their ability to follow post-operative instructions.

10. Any time implant utilization would interfere with anatomical structures or expected physiological performance.
11. Any case not needing a bone graft and fusion or where fracture healing is not required.
12. Other medical or surgical conditions which would preclude the potential benefit of spinal implant surgery such as the presence of tumors, congenital abnormalities, elevation of white blood cell count(WBC), or a left shift in the WBC differential count.

Potential Complications and Adverse Side Effects:

Potential complications and adverse effects for this system are similar to those of other spinal instrumentation systems, and include, but are not limited to:

1. Early or late loosening of the components
2. Disassembly, bending or breakage of any or all of the components
3. Foreign body (allergic) reaction to the implants
4. Infection
5. Non-union (pseudarthrosis)
6. Loss of neurological function, including paralysis (complete or incomplete), radiculopathy, dysesthesia, hyperesthesia, anesthesia, paresthesia, development or continuation of pain, numbness, neuroma, tingling sensation, dural tears, neuropathy, neurological deficits (transient, permanent, or delayed), reflex deficits, bilateral paraplegia, and/or arachnoiditis
7. Hemorrhage, hematoma, seroma, embolism, edema, stroke, excessive bleeding, phlebitis, wound necrosis, or wound dehiscence
8. Misalignment of anatomical structures or loss of spinal mobility
9. Bone graft donor complications including pain, fracture or wound healing problems
10. Atelectasis
11. Cessation of any potential growth of the operated portion of the spine
12. Vascular damage resulting in excessive bleeding.
13. Loss or impairment of bowel, sexual, and/or bladder function and other types of urological compromise.
14. Fracture, damage, degenerative changes or instability of any bone above and/or below the level or surgery.
15. Gastrointestinal system compromise
16. Bone loss due to resorption or stress shielding
17. Death

Precautions:

The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Knowledge of surgical techniques, proper reduction, selection and placement of implants, and pre and post-operative patient management are consideration essential to a successful surgical outcome. Appropriate selection, placement and fixation of the spinal system components are critical factors which affect implant service life. As in the case of all prosthetic implants, the durability of these components is affected by numerous biologic, biomechanics and other extrinsic factors, which limit their service life. Accordingly, strict adherence to the indications, contra-indications, precautions, and warnings for this product is essential to potentially maximize service life. (Note: While proper implant selection can minimize risks, the size and shape of human bones present limitations on the size, shape, and strength of the implants).

Patients who smoke have been shown to have an increased incidence of pseudoarthrosis. Such patients should be advised of this fact and warned of the potential consequences.

If the patient is involved in an occupation or activity which applies inordinate stress upon the implant (e.g. substantial walking, running, lifting, or muscle strain) resultant forces can cause failure of the device. In some cases, progression of degenerative disease may be so advanced at the time of implantation that the expected useful life of the appliance may be substantially decreased. In such cases, orthopedic devices may be considered only as a delaying technique or to provide temporary relief. Patients should be instructed in detail about the limitations of the implants, including, but not limited to the impact of excessive

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loading through patient weight or activity, and be taught to govern their activities accordingly. The patient should understand that a metallic implant is not as strong as normal, healthy bone and will bend: loosen or fracture if excessive demands are placed on it. An active, debilitated, or demented patient who cannot properly use weight supporting devices may be particularly at risk during postoperative rehabilitation.

Care must be taken to protect the components from being marred, nicked or notched as a result of contact with metal or abrasive objects. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant.

⚠ Warnings:

The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar and sacral spine secondary to severe spondylolisthesis (grade 3 and 4) of L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthorosis).

The safety and effectiveness of these devices for any other condition are unknown. Benefits of spinal fusion utilizing any pedicle screw fixation system has not been adequately established in patients with stable spine. Potential risks associated with the use of this system, which may require additional surgery, include; device component neurological injury, and vascular or visceral injury. Discard all damaged or mishandled implants. Never reuse an implant, even though it may appear undamaged.

Internal fixation devices cannot withstand activity and load levels equal to those placed on normal healthy bone. Until maturation of the fusion mass is confirmed, do not subject this device to the stress of full weight bearing, or implant failure may result.

Contouring and bending of a system component may reduce its fatigue strength and cause failure under load. If spinal screws are bent or otherwise damaged during insertion or adjustment, they must not be implanted and must be replaced. Rods should only be contoured with the proper contouring instruments. Incorrectly contoured rods or rods which have been repeatedly or excessively contoured must not be implanted.

Mixing Metal; some degree of corrosion occurs on all implanted metal and alloys. Contact of dissimilar metals, however, may accelerate this corrosion process. The presence of corrosion may accelerate fatigue fracture of implants, and the amount of metal compounds released into the body system will also increase. Internal fixation devices, such as rods, hooks, screws, etc., which come in contact with other metal objects, must be made from like or compatible metals. Because different manufactures employ different materials, varying tolerances and manufacturing specifications, and differing design parameters. The components of Fortex should not be used in conjunction with components from any other manufacturer's spinal system.

Removal of an unloosened spinal screw may require the use of special instruments to disrupt the interface at the implant surface. This technique may require practice in the laboratory before attempted clinically. Any decision by a surgeon to remove the internal fixation device should take into consideration such factors as the risk to the patient of the additional surgical procedure as well as the difficulty of removal. Implant removal should be followed by adequate postoperative management to avoid fracture.

Packaging, Labeling and Storage

The implants are supplied NON-STERILE. They must be cleaned and sterilized (see below). The implants are delivered in packages. These must be intact at the time of receipt. All the legal information required for this type of implants is given on the label of each package. The implants may be delivered as a complete set: Implants and instruments are contained within specially designed trays or in boxes which can be sterilized directly. Use care in handling and storage of the implant

components. Cutting, sharply bending, or scratching the surface can significantly reduce the strength and fatigue resistance of the implant system. This, in turn, could induce cracks and/or non-visible internal stresses that could lead to fracture of the implants. Implants and instruments in storage should be protected from corrosive environments such as salt, air, moisture, etc. Inspection and trial assembly are recommended prior to surgery to determine if instruments or implants have been damaged during the storage processes.

Sterilization Procedures:

Ultrasound clean for five minutes using distilled water.

⚠ Caution: Use of sodium hydroxide (NaOH) is prohibited. Use of corrosive products and/or instruments including abrasive sponges and metal brushes should be avoided. Verify that the instruments are in operation condition.

Sterilization: Recommended method to achieve a degree of sterility equal to at least 10^{-6}. Sterilize by autoclaving procedure regularly used in the hospital. Suggested method: Steam, Wrapped Gravity Cycle at 132° C (270° F) for 45 minutes

Instructions for Use

A successful result is not achieved in every surgical case, especially in spinal surgery where many extenuating circumstances may compromise results. Preoperative planning and operating procedures, including knowledge of surgical techniques, proper reduction, and proper selection and placement of the implant are critical considerations in achieving a successful result. Use of the X-Spine Fortex Pedicle Screw System should only be considered when the following preoperative, intraoperative and postoperative conditions exist.

Preoperative

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and/or predispositions such as those mentioned in the contraindications should be avoided.
3. Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage especially from corrosive environments.
4. The type of construct to be assembled for the case should be determined prior to beginning the surgery. An adequate inventory of sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used.
5. Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify that all parts and necessary instruments are present before the surgery begins. The X-Spine Fortex system components are not to be combined with the components from another manufacturer. Different metal types should not be used together.
6. All components and instruments should be cleaned and sterilized prior to use. Additional sterile components should be available in case of unexpected need.

Intraoperative

1. Patient Positioning
   The patient is positioned on the operating table in the prone position. The patient should be positioned to minimize intra-abdominal pressure to avoid venous congestion and excess intra-operative bleeding and allow adequate ventilation under anesthesia. The patient's hips should be extended to preserve lumbar lordosis for fusion and instrumentation of the lumbosacral junction.
2. Exposure
   The surgical approach is carried out though a standard midline incision to the spinal column over the anatomic position of the spinous process. The exposure of the spinous process should extend one additional level. The spinal column is then exposed in routine fashion by the surgeon and decompression is carried out as needed.
3. Decortication and Fusion
   Vertebral decortication and placement of bone grafts are usually done after pedicle screw preparation just prior to insertion of the pedicle screw. Meticulous fusion techniques are critical for success of the procedure. Anterior column support with intervertebral structural bone graft or fixation device (i.e. cage) is strongly recommended.
4. Pedicle Probing

After conformation of the position of the pedicle canal via radiography and creation of a cortical defect using the bone awl, the pedicle probe is gently pressed into the pedicle canal. The pedicle entry point is intersected by the vertical line that connects the lateral edges of bony crest extension of the pars inter-articularis, and the horizontal line that bisects the middle of the transverse process. Anatomical variation in individual patients may cause slight differences in the entry site. These differences should be considered carefully and noted on the pre-operative radiographic images and on the intra-operative images. A small rongeur or a burr may be used to decorticate the pedicle entry point. The bone awl may be used to make an entry hole through the cortex at the pedicle entry point. The probe is passed through the pedicle canal until the probe is 2/3rds of the distance to the anterior cortex of the vertebral body. The pedicle probe incorporates centimeter gradations and is used to determine the appropriate screw length. The length of the pedicle screw to be used can be determined relative to this measurement. Caution should be taken not to violate the anterior wall of the vertebral body or cortical walls.

5. Pedicle Testing
   After use of the probe, the curved tester is used to confirm continuity of the cortical walls of the pedicle. The straight tester can also be used to palpate the inner surface of the pedicle canal to check for defects of perforations of the cortical walls.
6. Screw Driving
   The pedicle screws are inserted using the Fortex screw driver assembly. The screw driver head is inserted into the hexagonal opening and secured to the driver by engaging the locking slide into the screw head. The pedicle screw is inserted into the vertebral body to the desired depth. The pedicle screw should parallel the endplates and extend 50% to 80% into the vertebral body when fully seated. The distal tip of the Fortex pedicle screw has a self-tapping flute and generally does not require tapping. Bone taps with quick connect capabilities are included for time when tapping may be required due to high bone density.
7. Rod Selection
   After the pedicle screws have been placed in the pedicles, the correct length of the rod is selected. The rods are provided in various pre-cut lengths. The rod should extend approximately 5 mm beyond the outer edges of the proximal screw bodies of the most superior and the most inferior pedicle screws.
8. Rod Bending
   After the appropriate length of rod has been selected, lordosis may be bent into the rod via the rod bender. A simple lordosis bend is typically sufficient and the amount of lordosis is based on the patient's anatomy and the amount of reduction to be achieved.
9. Rod Placement and loose capture
   After insertion of the Fortex screws and rod bending, the rod is placed in the Fortex screw housing. A rod gripper is provided for this purpose. The setscrew is placed by rotating clockwise using the cap-introducer tool.
10. Rod Persuasion
    A rod persuader instrument is included to assist in rod replacement into the Fortex screw housing. The persuader instrument contains a forked head which slides medially or laterally under a corresponding collar of the Fortex screw housing. Clockwise rotation of the persuader handle directs the rod downward into the Fortex screw housing.
11. Distraction and Compression
    Distraction is accomplished using the distractor, and compression is accomplished using the compressor. The spreader or compressor fit onto the rod adjacent to one or more loosely captured Fortex Screws. When the desired amount of distraction or compression has been achieved, final tightening of the Fortex screw housing is performed. Screw unlocking, if desired, is the reversal of the locking procedure.
12. Final Tightening and Counter Torque
    After desired compression or distraction has been performed, the anti-torque sleeve is used to stabilize the screw housing while rotating the setscrew clockwise using locking torque wrench. Tightening should be confirmed by audible clicking of the torque handle.
13. Cross Bar Connector Placement
    After final tightening of the Fortex screws, a cross bar connector is used if desired. The cross bar connector assembly consists of one jointed transverse body and two integrated rod locking clamps. There are multiple sizes of cross bar connectors provided to allow for anatomic variation. Once the desired location of the cross bar has been determined, the appropriate cross bar connector size is selected. The connector is placed with each clamp pressed lightly onto each rod. The cross bar connector hex driver and anti-torque sleeve, rotated clock-wise, is used to tighten each locking clamp onto the rods.

Postoperative

The physician's post-operative directions and warnings to the patient and the corresponding patient compliance are extremely important.

1. Detailed instructions on the use and limitations of the device should be given to the patient. The patient should be instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. Patients should be advised of their inability to bend at the point of spinal fusion and taught to compensate for this permanent restriction in body motion. The patient should be advised not to smoke or consume alcohol during the bone graft healing process.
2. External orthosis should be used during the postoperative period until radiographic and clinical evidence of solid fusion has been achieved.
3. If a non-union develops or the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed or nonunion of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue these stresses can cause eventual bending, loosening or breakage of the device(s).
4. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, none of the X-Spine Fortex components should ever be reused under any circumstances.

X-Spine Systems, Inc.
7081 Corporate Way
Dayton, OH 45459-4288
Telephone: 800/903-0640
Fax: 937/432-6390

⚠ Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

Appendix B

Engineering Drawings

(b)(4) Engineering Drawings

(b)(4) Engineering Drawings

(b)(4) Engineering Drawings

(b)(4) Engineering Drawings

(b)(4) Engineering Drawings

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

COVER SHEET MEMORANDUM

From: Reviewer Name Jonatha Peck

Subject: 510(k) Number K090224/S1

To: The Record

Please list CTS decision code SE

☐ 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)

☐ Hold (Additional Information or Telephone Hold).

☒ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	✓	
510(k) Summary /510(k) Statement	*Attach Summary*	✓	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	✓	
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		✓
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		✓	
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			✓
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)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	
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)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			✓
Does this device include an Animal Tissue Source?			✓
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			✓
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		✓

Regulation Number	**Class***	**Product Code**
888.3070	II	MNH, MNI

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

Additional Product Codes: _____

Review: _____ (Branch Chief) OSDB (Branch Code) 7/29/09 (Date)

Final Review: _____ (Division Director) 7/30/09 (Date)

SPECIAL 510(k) MEMORANDUM

To:	K090224/S1
From:	Jonathan H. Peck, Mechanical Engineer ODE/DGRND/Orthopedic Devices Branch
Date:	July 27, 2009
Subject:	Fortex Pedicle Screw System
Regulation:	888.3070 Product Code: MNH, MNI
Firm:	X-Spine Systems, Inc. 452 Alexandersville Rd. Miamisburg, OH 45342
Contact:	David Kirschman Phone: (937) 847-8400
Decision:	**SE**

JP 7/29/09

Recommendation:
I recommend the screws that are the subject of this 510(k) be found substantially equivalent to previously cleared predicate components.

Summary:
This submission seeks clearance of a (b)(4) [redacted]. All other components are identical. The sponsor has addressed my concerns related to the (b)(4) [redacted]. There was, in (b)(4) [redacted]. Therefore, I recommend the screws that are the subject of this 510(k) be found substantially equivalent to predicate components.

Attached: Email from Dan McGunagle containing recall information.

Deficiencies:
(b)(4) [redacted]

Sponsor's Response (S1):
(b)(4) [redacted]

Modification	Possible Risks	Verification Activities	Acceptance Criteria	Results
(b)(4) [redacted]				

(b)(4)

Reviewer Comments:

(b)(4) *(provide for reference below).*

Early Bird Values:

Test	Comparative Parameters	Comparative Values
(b)(4)		

(b)(4)

Sponsor's Response (S1):

(b)(4)

(b)(4)

[redacted]

Reviewer Comments:

(b)(4)

[redacted]

Administrative Requirements:
This submission contains a Truthful and Accurate Statement, a 510(k) Summary and an Indications for Use page.

Internal Administrative Form:

	YES	NO
1. Did the firm request expedited review?		X
2. Did we grant expedited review?		N/A
3. Have you verified that the Document is labeled Class III for GMP purposes?		N/A
4. If, not, has POS been notified?		N/A
5. Is the product a device?	X	
6. Is the device exempt from 510(k) by regulation or policy?		X
7. Is the device subject to review by CDRH?	X	
8. Are you aware that this device has been the subject of a previous NSE decision?		X
9. If yes, does this new 510(k) address the NSE issue(s). (e.g., performance data)?		N/A
10. Are you aware of the submitter being the subject of an integrity investigation?		X
11. If, yes, consult the ODE Integrity Officer.		N/A
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		N/A

Substantial Equivalence Decision Making Checklist:

	YES	NO	
1. Is the product a device?	X		NO then Stop
2. Is the device subject to 510(k)?			NO then Stop
3. Is the indication statement the same?	X		YES then Go To 5
4. Do differences in the indication statement raise new issues of safety and effectiveness?			YES then NSE
5. Does the device have the same technological characteristics?	X		YES then Go To 7
6. Could the new characteristics affect safety and effectiveness?			YES then Go To 8

7.	Are the descriptive characteristics precise enough?		X	NO then Go To 10 YES then SE
8.	Are there new types of safety and effectiveness questions?			YES then NSE
9.	Do accepted scientific methods exist to test the impact of the new characteristics?			NO then NSE
10.	Is performance data available?	X		NO then Request Data
11.	Does the performance data demonstrate substantial equivalence?	X		FINAL DECISION: SE

The (b)(4) provided by the sponsor is sufficient to determine substantially equivalent performance of the subject components.

Previous Review (Original Submission):

Predicate Submissions:
The predicate submission referenced by the sponsor is the X-Spine – Capless Pedicle Screw System (K052847 and K072282).

Indications:
The Fortex Pedicle Screw System is indicated for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

In addition, the Fortex Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

Reviewer Comments:
These indications are identical to those of the Capless Pedicle Screw System (K052847).

Modifications:
The sponsor states that the modifications made as compared to the predicate Capless Pedicle Screw System is that the subject (b)(4). The sponsor states that the following are identical to the previous design: Material, Screw Diameter, Screw Shaft Sizing, Screw Threading, Cross-bar System, Rod Diameter, Sterility, Locking Vector, Rod Loading Direction, Set-Screw.

Reviewer Comments:
I will ask the sponsor to provide (b)(4)

Deficiency:
(b)(4)

Similarities:
The sponsor states that labeling has been changed to reflect the new name of the product. The Instructions for Use have been modified to address the addition of a threaded setscrew to the system.

The sponsor says that the following are the same for the subject device as compared to the predicate: Intended Use, Operating Principles, Basic Screw Design, Materials, Sterility Cycle.

Design Control Activities:

The sponsor has supplied a (b)(4) (b)(4). The sponsor states:

(b)(4)

Reviewer Comments:

(b)(4) (b)(4)

(b)(4)

Deficiency:

(b)(4)

End of Review (JHP)

7/29/09

Erica Takai PhD

Actng Branch Chief OSDB

Peck, Jonathan H

From: McGunagle, Daniel S.
Sent: Tuesday, July 28, 2009 2:49 PM
To: Peck, Jonathan H
Subject: FW: 24-Hour Alert for 51956 - X Spine Systems Inc

Daniel S. McGunagle

Orthopedic Devices Network Leader
(301)-796-5434, HFZ-4

From: EMMA.NESBIT@FDA.HHS.GOV [mailto:EMMA.NESBIT@FDA.HHS.GOV]
Sent: Wednesday, June 24, 2009 11:19 AM
To: ORA HQ CDRH Alerts
Subject: 24-Hour Alert for 51956 - X Spine Systems Inc

24-Hour Alert for 51956

Comments - 51956

Center Comments :
Email Comments :

Recall Date Information - 51956

Firm Awareness :	03/06/2009	**Classification :**	
Recall Initiation :	03/24/2009	**Recall Completed :**	
District Awareness :	03/25/2009	**Termination :**	
HHE Sent :		**State Press Issued :**	
Distribution Chain Notified :	03/24/2009	**Firm Press Issued :**	
Alert :	06/24/2009	**FDA Press Issued :**	
Recommendation :			

Recall Firm Information - 51956

Recalling Firm : X Spine Systems Inc
452 Alexandersville Rd
Miamisburg Ohio 45342-3658
United States

Manufacturing Firm 1: X Spine Systems Inc
452 Alexandersville Rd
Miamisburg Ohio 45342-3658
United States

Product 1 - 51956

Product Description : Capless Li Pedicle Screw System, Diameters - 4.75mm, 5.5mm, 6.5mm, 7.5mm, 8.25mm, Lengths 30mm-55mm,

Product Public Reason for Recall : A defect cause was discovered following a customer complaint pertaining to a post operative dissociation of the Capless Li Screw construct. The screw assembly is made up of three parts; a cup which locks onto a 5.5mm rod, a yoke that cradles the rod during fusion, and a screw that attached to the

vertebra. The screw ball on the screw was manufactured out of tolerance (undersized).

Code Information : Product numbers: 71088, 71692, 71708, 71750, 71761, 71781, 71807, 71849, 71881, 71090, 71693, 71709, 71751, 71762, 71787, 71808, 71850, 71882, 71092, 71694, 71710, 71752, 71763, 71789, 71809, 71851, 71885, 71682, 71695, 71711, 71753, 71764, 71791, 71810, 71857, 71886, 71686, 71696, 71712, 71755, 71765, 71793, 71811, 71858, 71889, 71687, 71698, 71716, 71756, 71766, 71795, 71813, 71859, 71893, 71688, 71700, 71746, 71757, 71767, 71797, 71814, 71873, 71894, 71689, 71701, 71747, 71758, 71768, 71799, 71815, 71874, 71896, 71690, 71705, 71748, 71759, 71769, 71801, 71816, 71877, 71897, 71691, 71707, 71749, 71760, 71780, 71806, 71817, 71878, 71899, 71900, 71937, 71957, 73417, 73427, 73440, 73453, 73470, 74073, 71903, 71939, 72184, 73418, 73428, 73441, 73454, 73471, 74097, 71904, 71940, 72419, 73419, 73429, 73445, 73455, 73472, 74098, 71907, 71943, 73409, 73420, 73430, 73446, 73456, 73760, 74099, 71908, 71944, 73411, 73421, 73431, 73447, 73464, 73761, 74100, 71911, 71947, 73412, 73422, 73433, 73448, 73465, 73762, 74101, 71912, 71948, 73413, 73423, 73435, 73449, 73466, 73763, 74102, 71915, 71952, 73414, 73424, 73437, 73450, 73467, 73886, 74103, 71916, 71953, 73415, 73425, 73438, 73451, 73468, 74047, 74104, 71936, 71956, 73416, 73426, 73439, 73452, 73469, 74072, 74105, 74107, 74125, 74143, 74293, 74305, 75280, 75297, 75307, 75317, 74108, 74127, 74144, 74294, 74306, 75282, 75299, 75308, 75318, 74109, 74129, 74285, 74295, 74307, 75283, 75300, 75309, 75319, 74110, 74131, 74286, 74296, 74432, 75284, 75301, 75310, 75320, 74111, 74132, 74287, 74299, 74987, 75285, 75302, 75311, 75321, 74112, 74134, 74288, 74300, 74991, 75287, 75303, 75312, 75322, 74116, 74135, 74289, 74301, 75248, 75289, 75304, 75313, 75323, 74119, 74137, 74290, 74302, 75273, 75291, 75305, 75314, 75324, 74121, 74139, 74291, 74303, 75276, 75293, 75305, 75315, 75333, 74123, 74141, 74292, 74304, 75278, 75295, 75306, 75316, 75334, 75335, 75355, 75376, 76369, 76536, 76593, 76602, 76613, 76639, 75336, 75358, 75377, 76370, 76537, 76593, 76603, 76614, 76640, 75337, 75360, 75379, 76372, 76538, 76594, 76605, 76615, 76642, 75338, 75362, 75382, 76374, 76540, 76595, 76606, 76616, 76737, 75344, 75364, 75384, 76375, 76542, 76596, 76607, 76618, 77253, 75346, 75365, 75386, 76376, 76588, 76597, 76608, 76619, 77260, 75346, 75367, 75588, 76377, 76589, 76598, 76609, 76621, 77261, 75350, 75370, 75798, 76406, 76590, 76599, 76610, 76629, 77262, 75351, 75372, 75802, 76407, 76591, 76600, 76611, 76630, 77263, 75353, 75375, 76139, 76534, 76592, 76601, 76612, 76638, 77264, 77265, 77811, 77852, 79382, 77266, 77815, 78174, 77267, 77817, 78175, 77270, 77820, 78176, 77322, 77823, 78518, 77647, 77851, & 79040

Industry-Product Code : 87-

(b)(4)

[redacted]

(b)(4)

(b)(4)

(b)
(4)

SPECIAL 510(k) MEMORANDUM

To:	K090224
From:	Jonathan H. Peck, Mechanical Engineer ODE/DGRND/Orthopedic Devices Branch
Date:	February 22, 2009
Subject:	Fortex Pedicle Screw System
Regulation:	888.3070 Product Code: MNH, MNI
Firm:	X-Spine Systems, Inc. 452 Alexandersville Rd. Miamisburg, OH 45342
Contact:	David Kirschman Phone: (937) 847-8400
Decision:	**Telephone Hold**

JP 2/23/09 PDG 2/23/09

Recommendation:

(b)(4) [redacted]

Summary:

This submission seeks clearance of a (b)(4) [redacted] (b)(4) [redacted]. All other components are identical. The sponsor has supplied a (b)(4) [redacted] (b)(4) [redacted]

Deficiencies:

(b)(4) [redacted]

Administrative Requirements:

This submission contains a Truthful and Accurate Statement, a 510(k) Summary and an Indications for Use page.

Internal Administrative Form:

		YES	NO
1.	Did the firm request expedited review?		X
2.	Did we grant expedited review?		N/A
3.	Have you verified that the Document is labeled Class III for GMP purposes?		N/A
4.	If, not, has POS been notified?		N/A
5.	Is the product a device?	X	

6.	Is the device exempt from 510(k) by regulation or policy?		X
7.	Is the device subject to review by CDRH?	X	
8.	Are you aware that this device has been the subject of a previous NSE decision?		X
9.	If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		N/A
10.	Are you aware of the submitter being the subject of an integrity investigation?		X
11.	If, yes, consult the ODE Integrity Officer.		N/A
12.	Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		N/A

Substantial Equivalence Decision Making Checklist:

		YES	NO	
1.	Is the product a device?	X		NO then Stop
2.	Is the device subject to 510(k)?			NO then Stop
3.	Is the indication statement the same?	X		YES then Go To 5
4.	Do differences in the indication statement raise new issues of safety and effectiveness?			YES then NSE
5.	Does the device have the same technological characteristics?	X		YES then Go To 7
6.	Could the new characteristics affect safety and effectiveness?			YES then Go To 8
7.	Are the descriptive characteristics precise enough?		X	NO then Go To 10 YES then SE
8.	Are there new types of safety and effectiveness questions?			YES then NSE
9.	Do accepted scientific methods exist to test the impact of the new characteristics?			NO then NSE
10.	Is performance data available?	X		NO then Request Data
11.	Does the performance data demonstrate substantial equivalence?			FINAL DECISION: **Telephone Hold**

Predicate Submissions:
The predicate submission referenced by the sponsor is the X-Spine – Capless Pedicle Screw System (K052847 and K072282).

Indications:
The Fortex Pedicle Screw System is indicated for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

In addition, the Fortex Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

Reviewer Comments:
These indications are identical to those of the Capless Pedicle Screw System (K052847).

Modifications:
The sponsor states that the modifications made as compared to the predicate Capless Pedicle Screw System is that the (b)(4) [redacted]. The sponsor states that the following are identical to the previous design: Material, Screw Diameter, Screw Shaft Sizing, Screw Threading, Cross-bar System, Rod Diameter, Sterility, Locking Vector, Rod Loading Direction, Set-Screw.

Reviewer Comments:
(b) [redacted]
b [redacted]

Deficiency:

(b)(4) [redacted]

Similarities:

The sponsor states that labeling has been changed to reflect the new name of the product. The Instructions for Use have been modified to address the addition of a threaded setscrew to the system.

The sponsor says that the following are the same for the subject device as compared to the predicate: Intended Use, Operating Principles, Basic Screw Design, Materials, Sterility Cycle.

(b)(4) [redacted]

Reviewer Comments:

(b)(4) [redacted]

Deficiency:

(b)(4) [redacted]

End of Review (JHP)

Peck, Jonathan H

From: Peck, Jonathan H
Sent: Monday, February 23, 2009 10:20 AM
To: 'dk@x-spine.com'
Subject: K090224 - Email Hold

Dear Dr. Kirschman,

I have reviewed your Special 510(k) (K090224) that proposes the addition of pedicle screws with set screws to the Capless Pedicle Screw System (K052847 and K072282). I am placing the

(b)(4)

[redacted]

Thank you,

Jonathan Peck

Jonathan Peck
Mechanical Engineer
FDA/CDRH/ODE/DGRND/Orthopedic Spinal Devices Branch
9200 Corporate Boulevard, HFZ-410
Rockville, MD 20850
Phone: (240) 276-3715
Fax: (240) 276-3761
Email: jonathan.peck@fda.hhs.gov

Telephone Hold

COVER SHEET MEMORANDUM

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

From: Reviewer Name Jonathan Peit

Subject: 510(k) Number K091224

To: The Record

Please list CTS decision code TH

☐ 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)

☒ Hold (Additional Information or Telephone Hold).

☐ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*		
510(k) Summary /510(k) Statement	*Attach Summary*		
Truthful and Accurate Statement.	*Must be present for a Final Decision*		
Is the device Class III?			
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
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			
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)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
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			

Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	*Contact OSB.*		
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		

Regulation Number **Class*** **Product Code**

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

Additional Product Codes: _____

Review: _____
(Branch Chief) (Branch Code) (Date)

Final Review: _____
(Division Director) (Date)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

June 30, 2009

X-SPINE SYSTEMS, INC.
452 ALEXANDERSVILLE RD.
MIAMISBURG, OHIO 45342
UNITED STATES
ATTN: DAVID KIRSCHMAN

510k Number: K090224

Product: FORTEX PEDICLE SCREW SYSTEM

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

K090224 / S1

X-spine Systems, Inc.
452 Alexandersville Rd.
Miamisburg, OH 45342
Phone: (800) 903-0640
Direct: (937) 847-8400
Fax: (937) 847-8410
www.x-spine.com

David Kirschman, M.D
Chief Medical Officer
(b)(4)

June 26, 2009

Jonathan H. Peck
Mechanical Engineer
Orthopedic Spinal Devices Branch
Food and Drug Administration/Office of Device Evaluation
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

Reference: K090224 – Supplement 1
Fortex Pedicle Screw System

Dear Mr. Peck:

Thank you for your review of our application. This letter should serve as a response to the deficiencies you noted in your email to us. We would like to respond to each deficiency in turn as follows:

(b)(4)
[redacted]
ol
(b)(4) [redacted]:

(b)(4)
[redacted]

15

Response (b)(4) [redacted]

(b)(4) [redacted]

(b)(4) [redacted]."

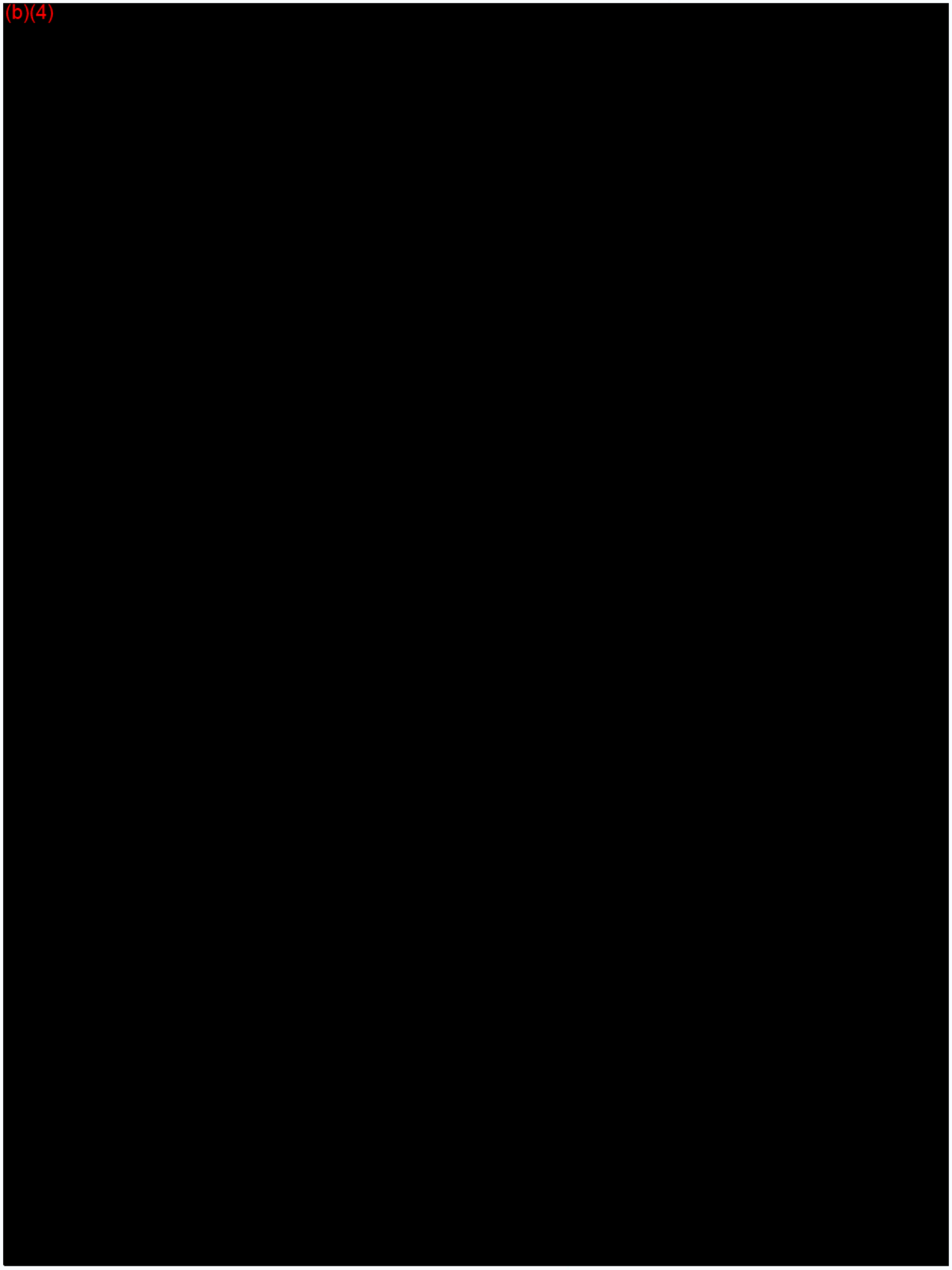
Response (b)(4) [redacted]:

(b)(4) [redacted]

(b)(4) [redacted]

16

(b)(4)



(b)(4)

[redacted]

Per your instructions, we will submit this response letter and all attachments to the Document Mail Center in a supplement entitled: "K090224 – Supplement 1". Thank you for your ongoing review of our application. If there are any questions, please feel free to contact me at 937-847-8400.

Sincerely,

David Kirschman, M.D.
Chief Medical Officer

Attachment A, Summary of Design Control Activities - Revision 1
Attachment B, X022 - Fortex Pedicle Screw System, Verification Testing Report
Attachment C, Appendix B, Engineering Drawings – Revision 1

Attachment A

Summary of Design Control Activities - Revision 1

Summary of Design Control Activities

The risk analysis method used to assess the impact of the modifications was a (b)(4) (b)(4) . The design verification tests that were performed as a result of this risk analysis assessment are listed in Table 2 below.

TABLE 2- Verification Tests

Modification	Possible Risks Associated with Modification	Verification Activities	Acceptance Criteria	Results
(b)(4)				

The (b)(4) used are the same as those submitted in the original submissions.

A declaration of conformity with design controls is included in the following section.

Attachment B

X022 - Fortex Pedicle Screw System, Verification Testing Report

TEST REPORT
for [redacted]

X-Spine Systems, Inc.

Fortex Pedicle Screw [redacted] Testing Per [redacted]

Requested by:
Dr. David Kirschman
X-Spine Systems, Inc.
452 Alexandersville Road
Miamisburg, OH 45342
(937) 847-8400

Prepared by:
[redacted]
Biomedical Engineer

Approved for Release:
6/23/2009

Abstract:

(b)(4) Testing

[redacted]

Background:

(b)(4) Testing

[redacted]

Purpose:

[redacted] (b)(4) [redacted].

Study Design:

[redacted] (b)(4) [redacted]

Methods:

(b)(4) Testing

[redacted]

Results:

(b)(4) Testing

Conclusions:

(b)(4) Testin

References:

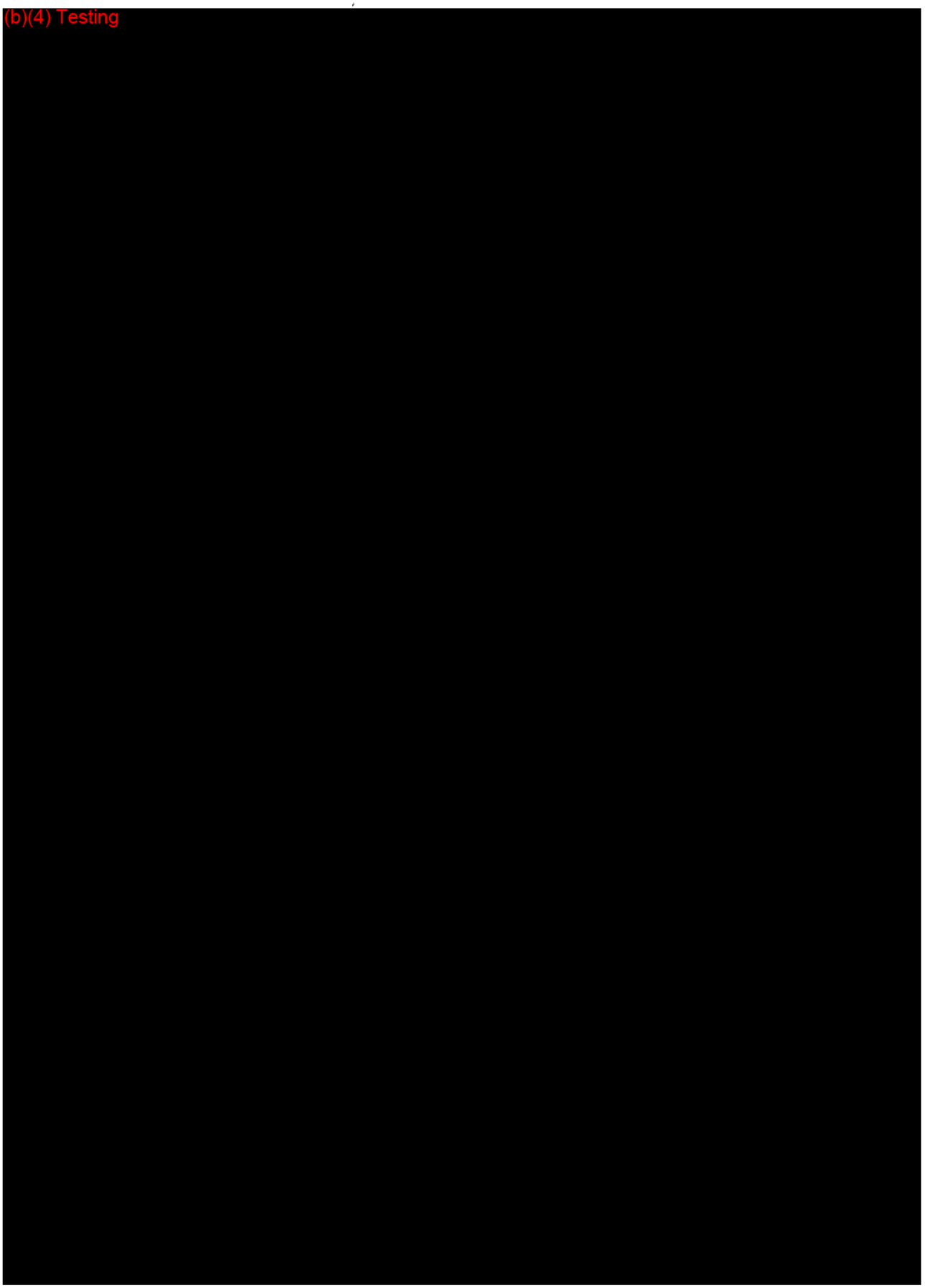
(b)(4) Testing

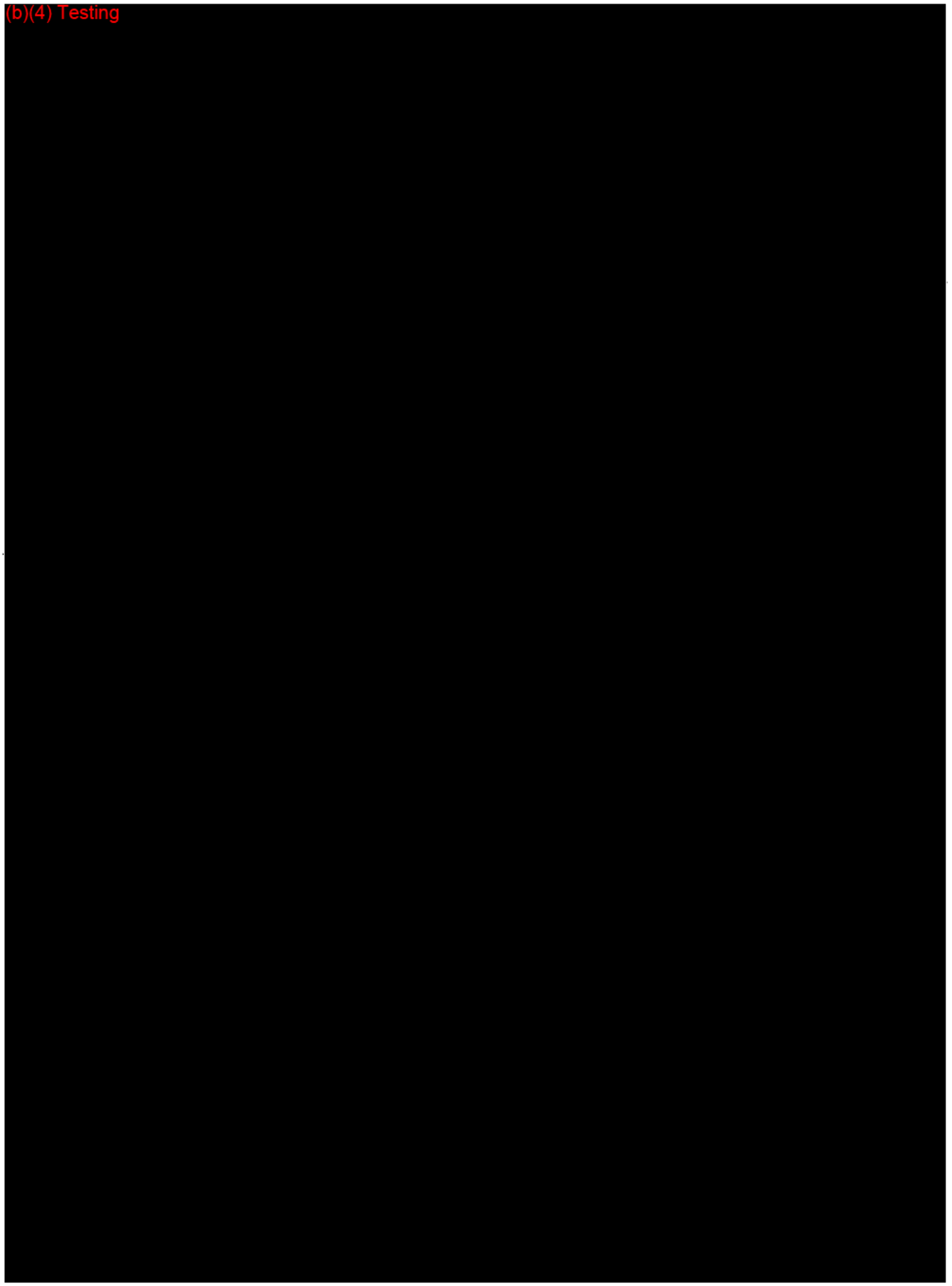
Appendix A:

(b)(4) Testing Protocol

(b)(4) Testing (b)(4) g Testing

(b)(4) Testing


(b)(4) Testing

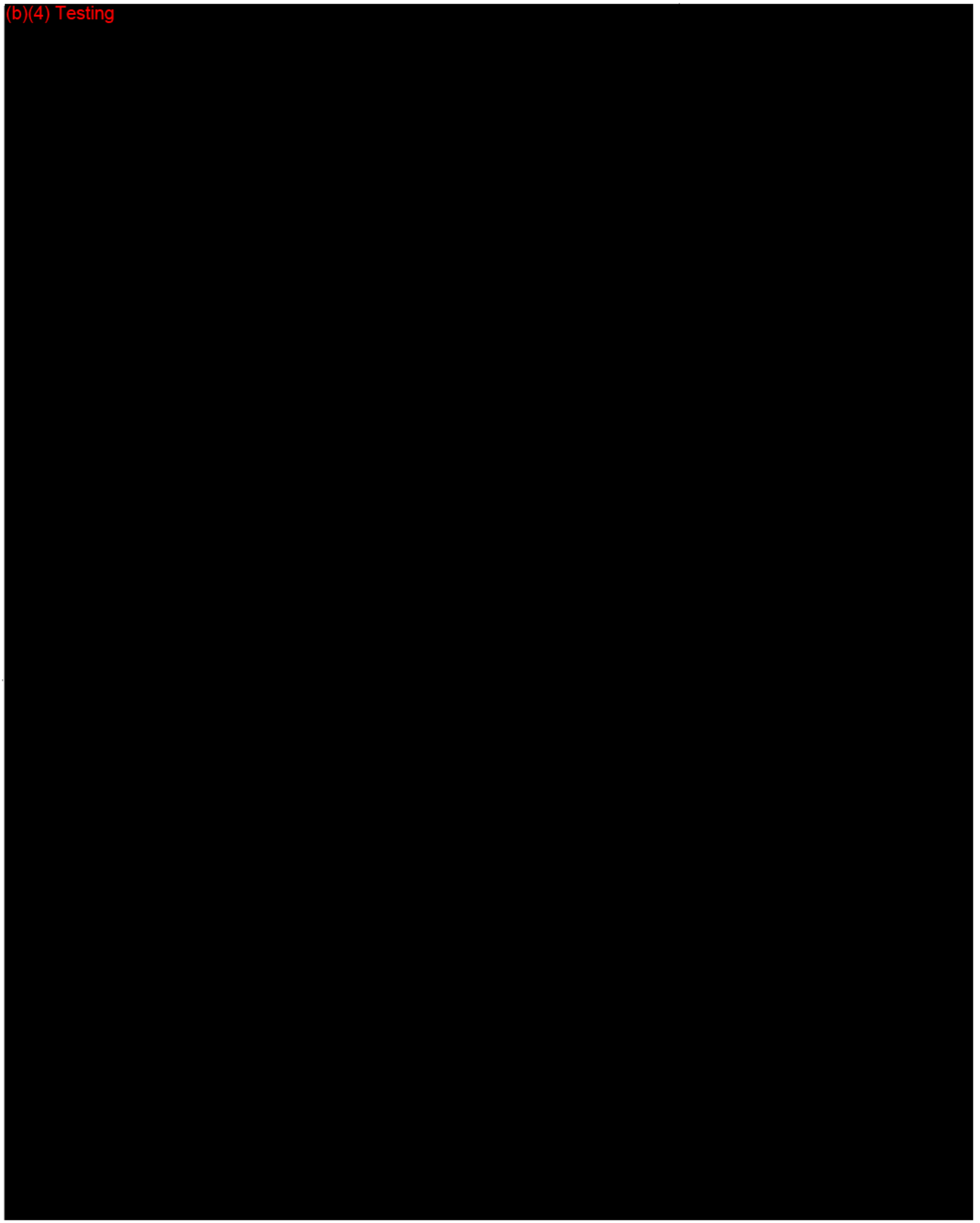

(b)(4) Testing

(b)(4) Testing

[redacted]

(b)(4) Testing

[redacted]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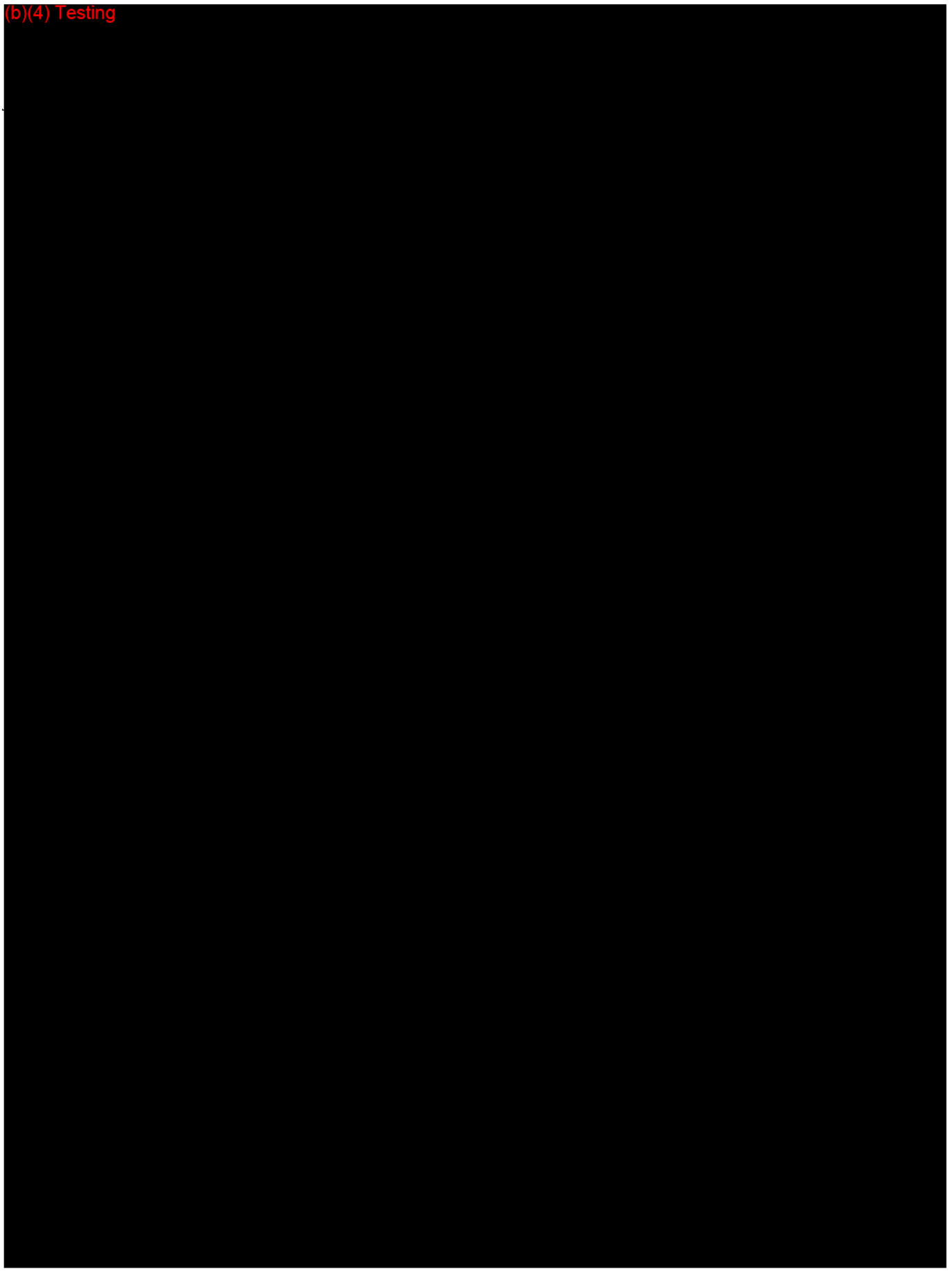
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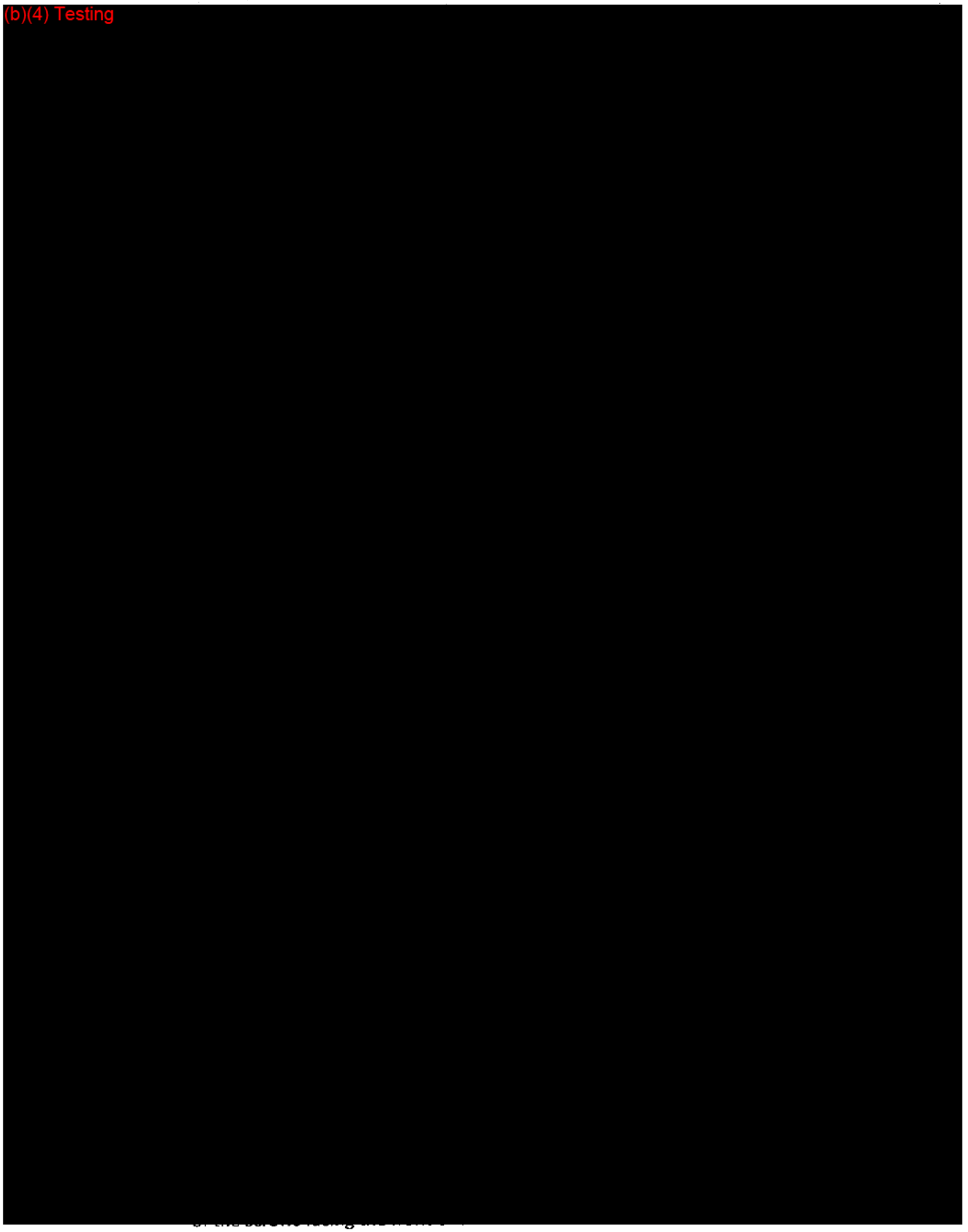
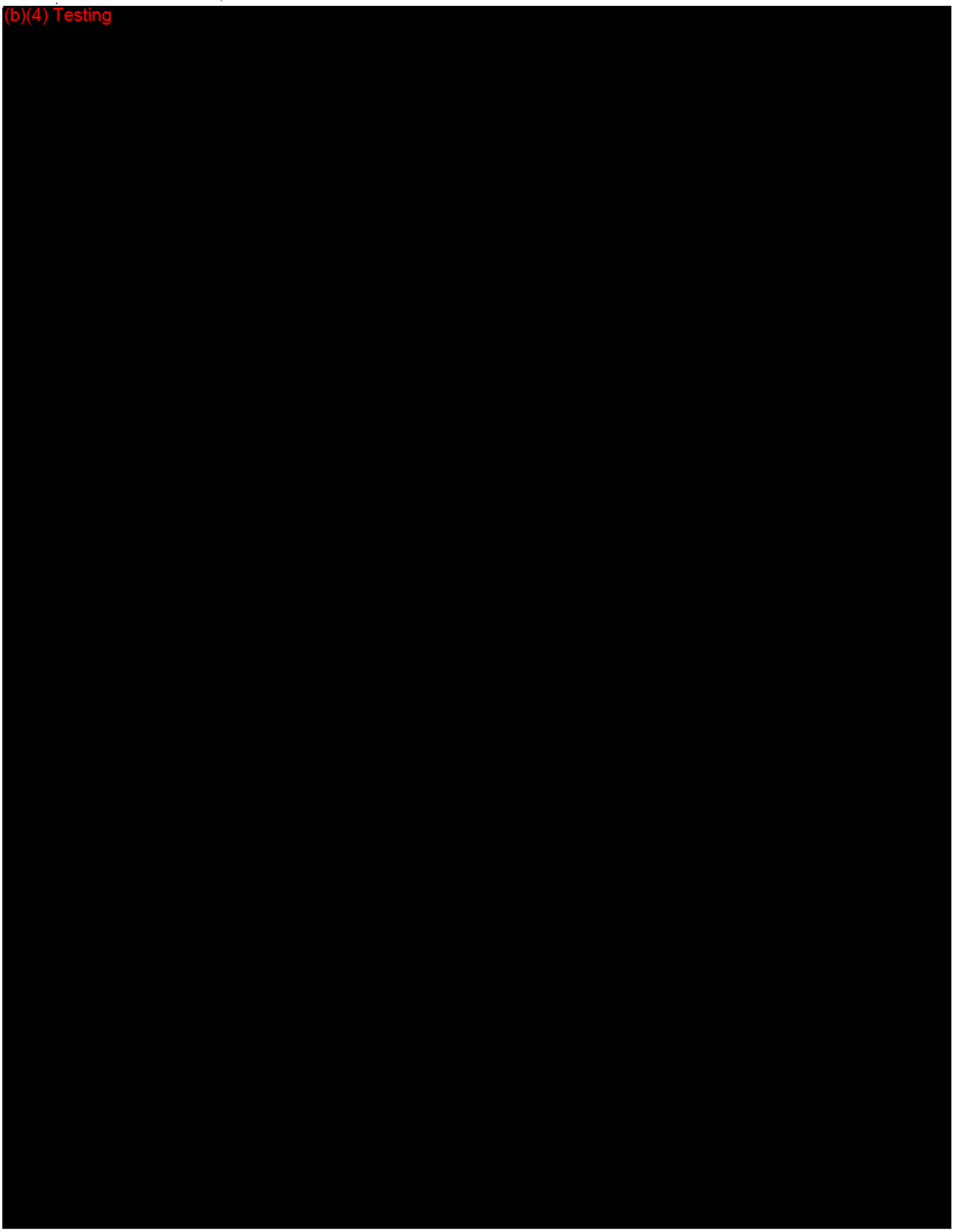
(b)(4) Testing

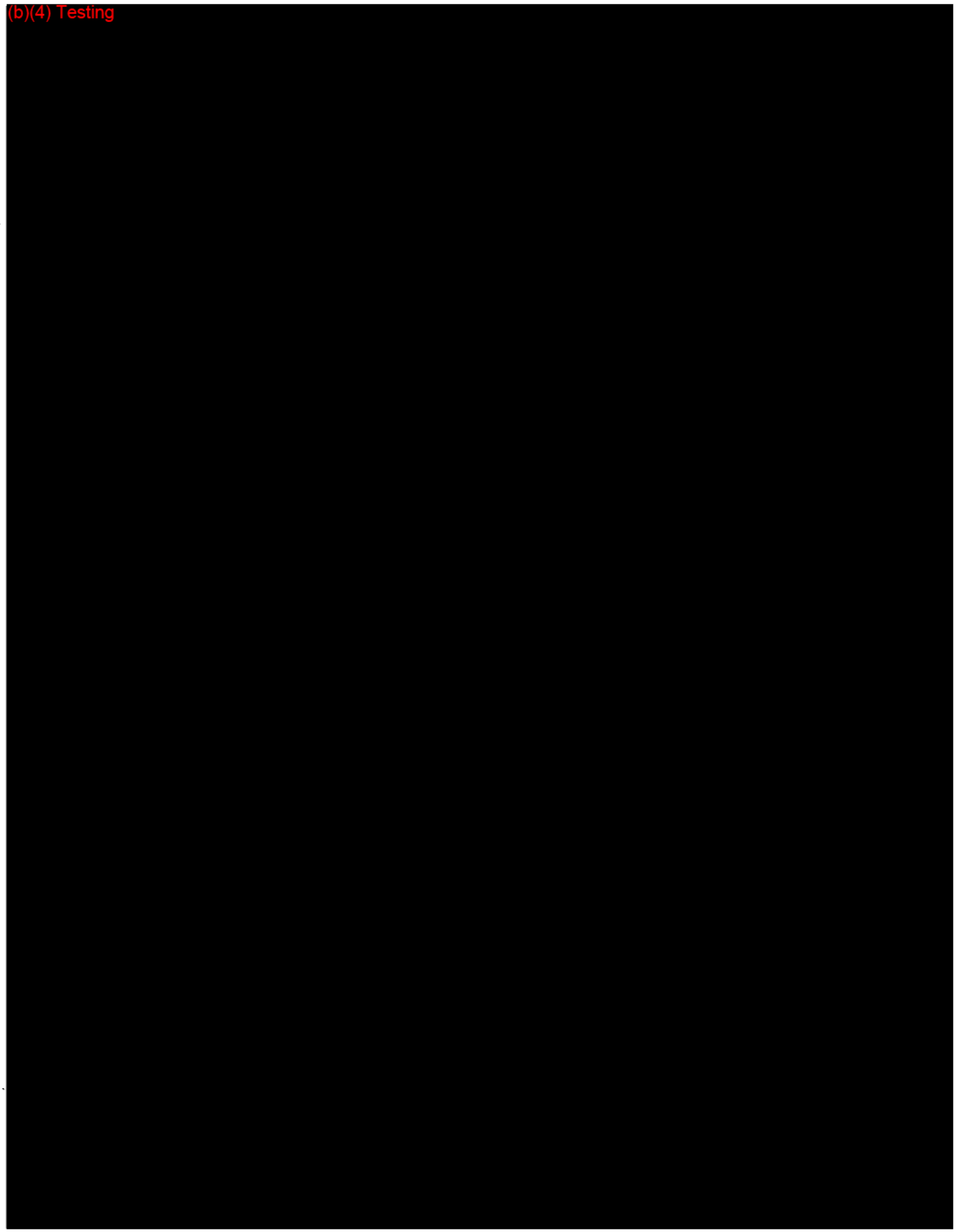


(b)(4) Testing

(b)(4) Testing


(b)(4) Testing

(b)(4) Testing



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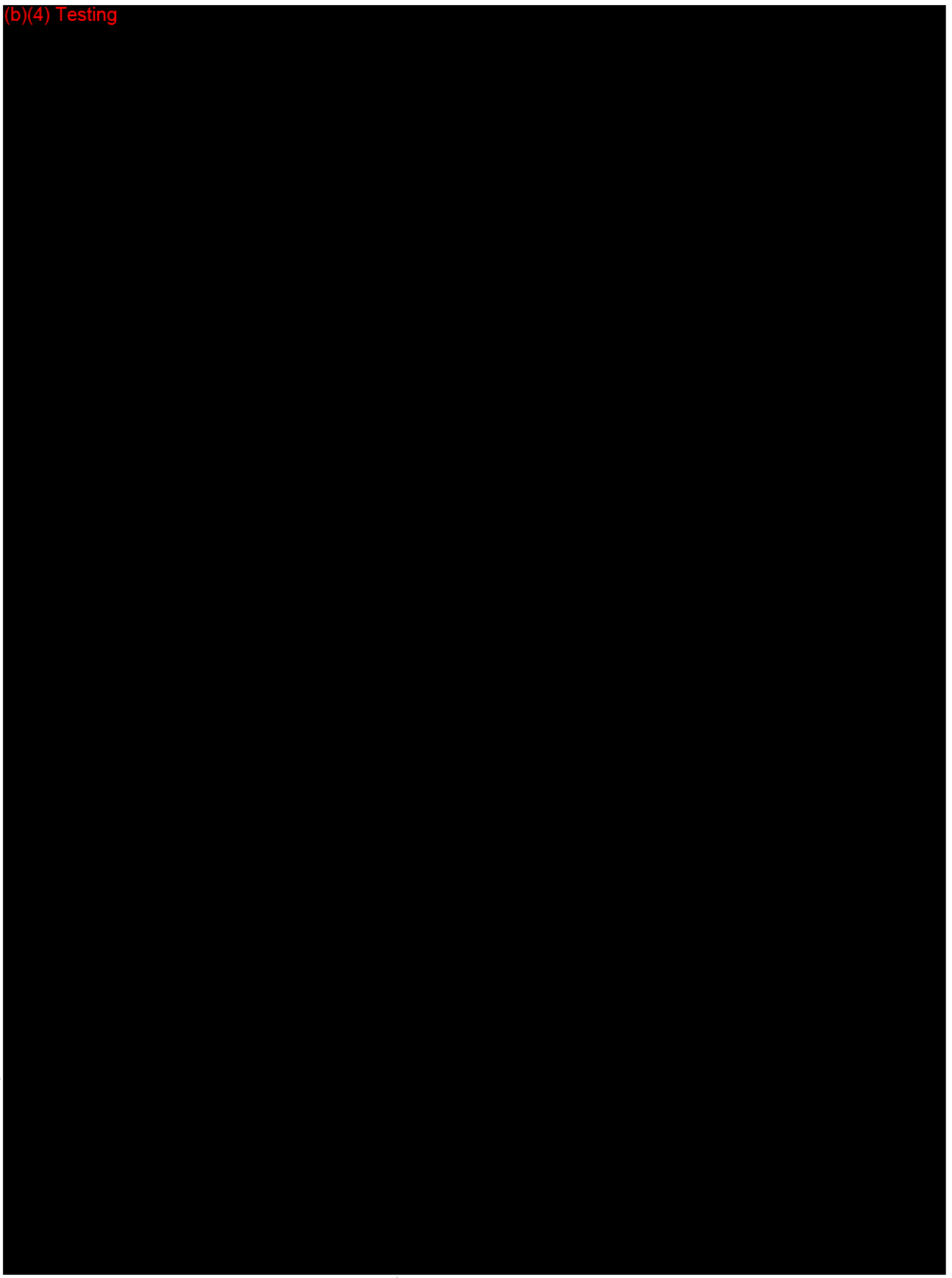


(b)(4) Testing


(b)(4) Testing

Appendix B:

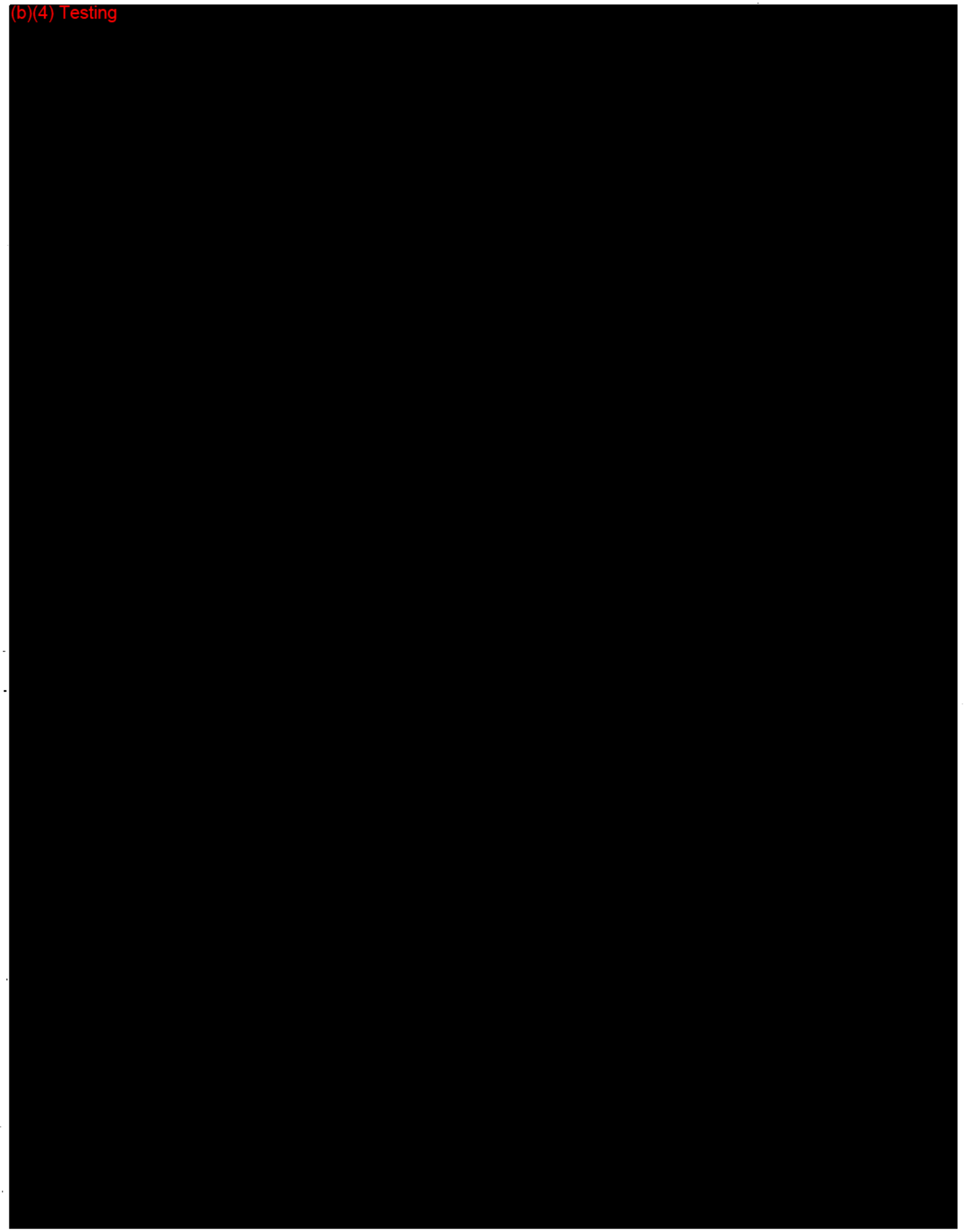
(b)(4) [redacted] Data Charts


(b)(4) Testing
(b)(4) Testing


(b)(4) Testing

Appendix C:

(b)(4) [redacted] Graphs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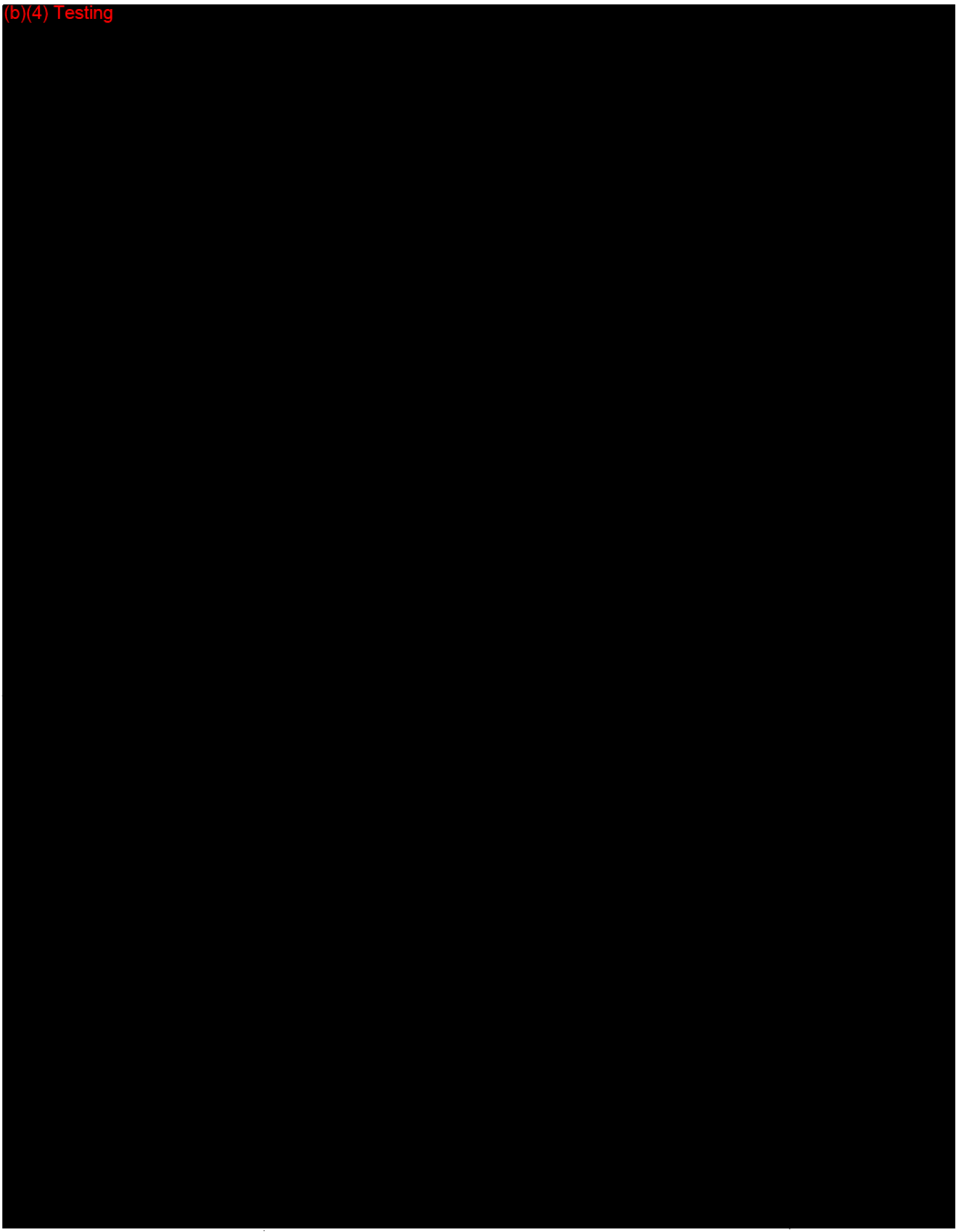
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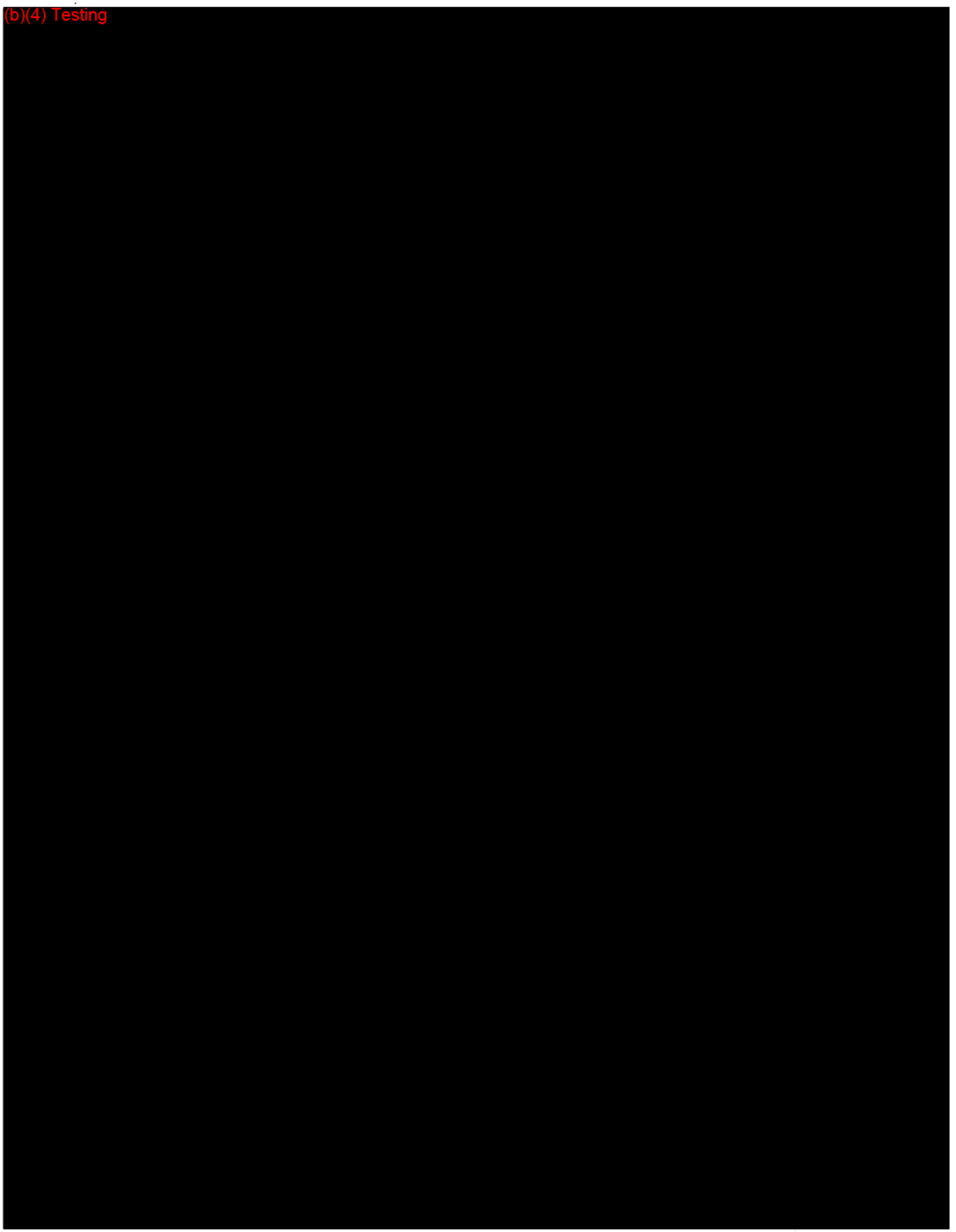
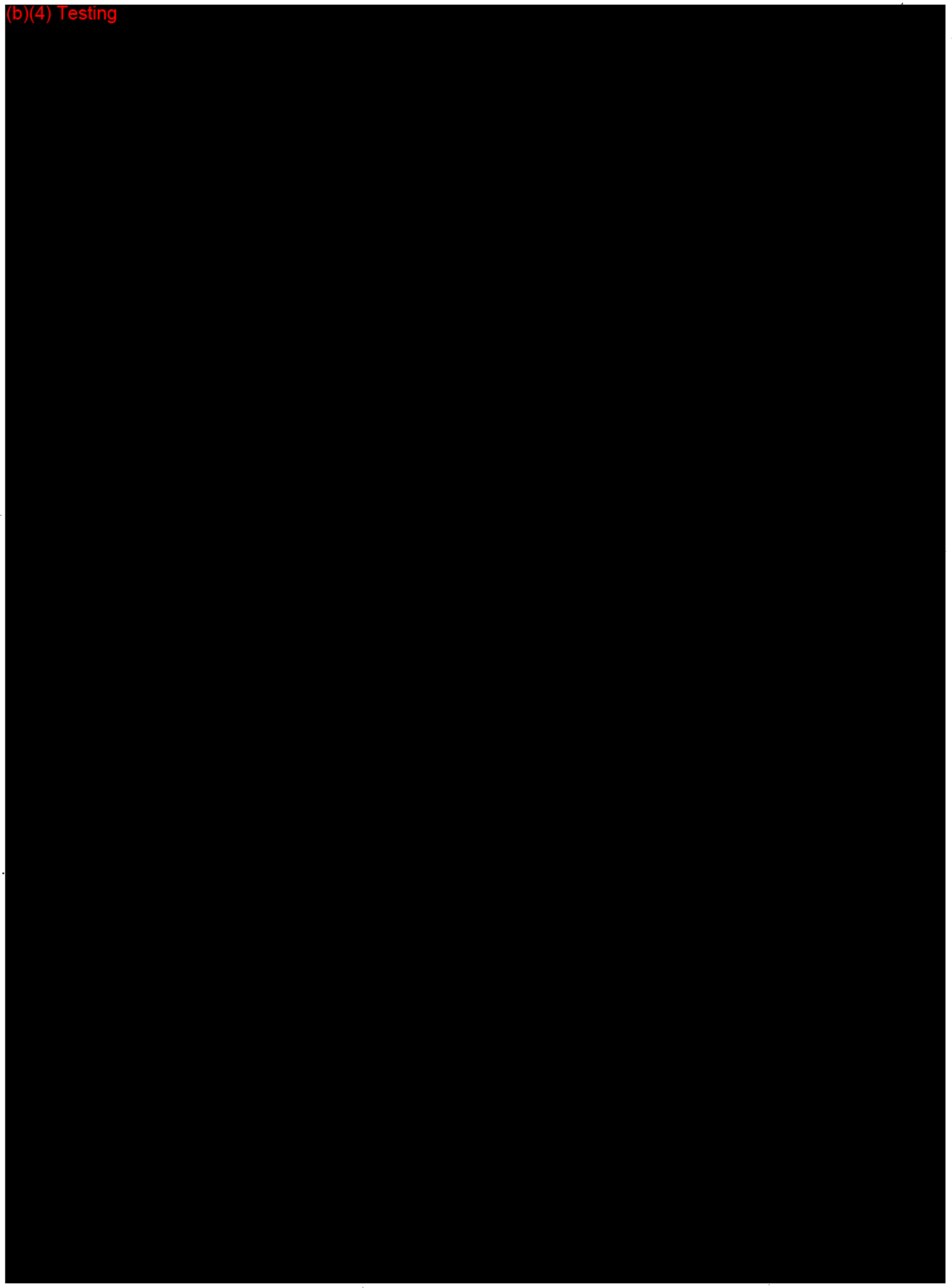
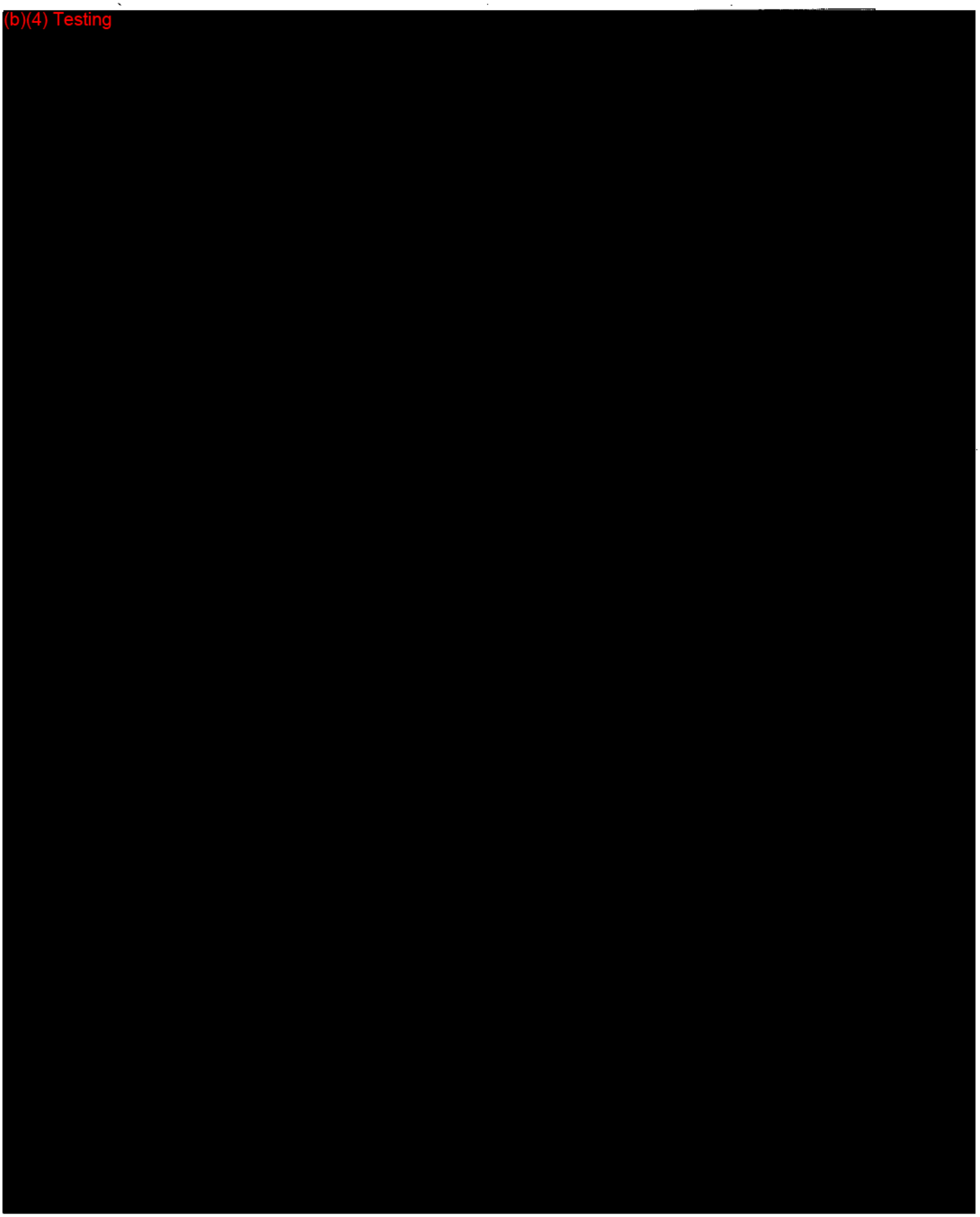

(b)(4) Testing

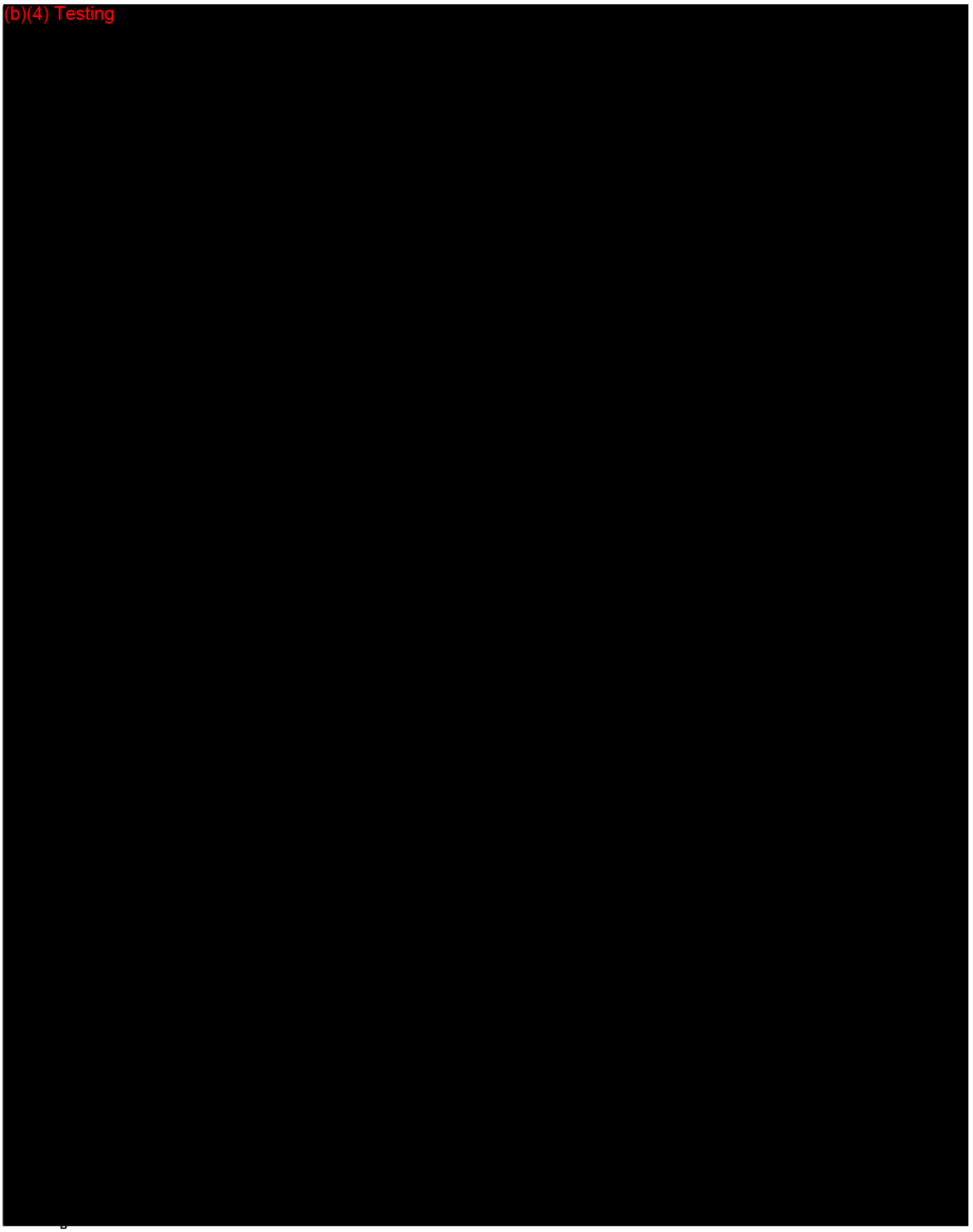
Appendix D:

(b)(4) Graphs


(b)(4) Testing

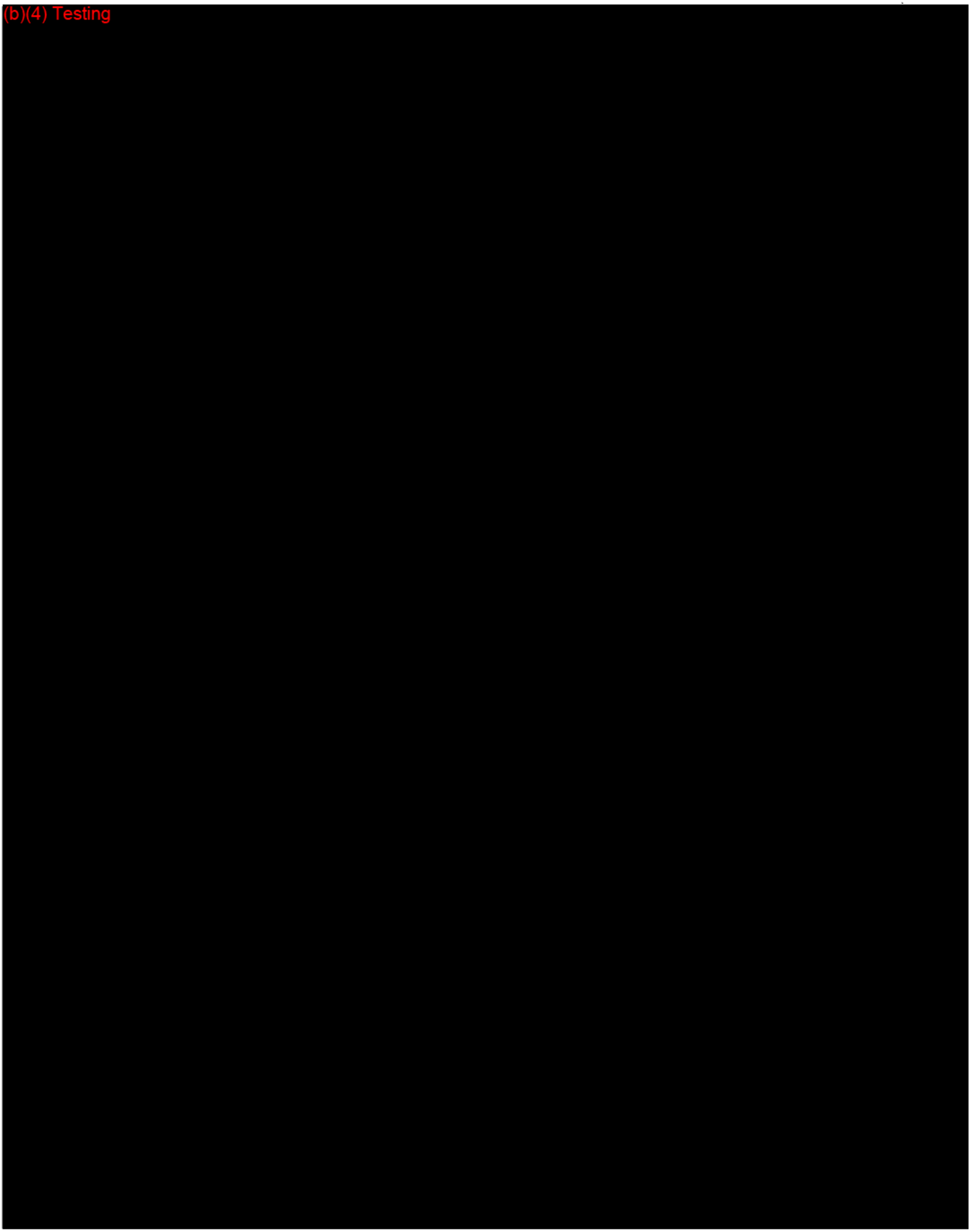
(b)(4) Testing




(b)(4) Testing

Appendix E:

(b)(4) [redacted] Graphs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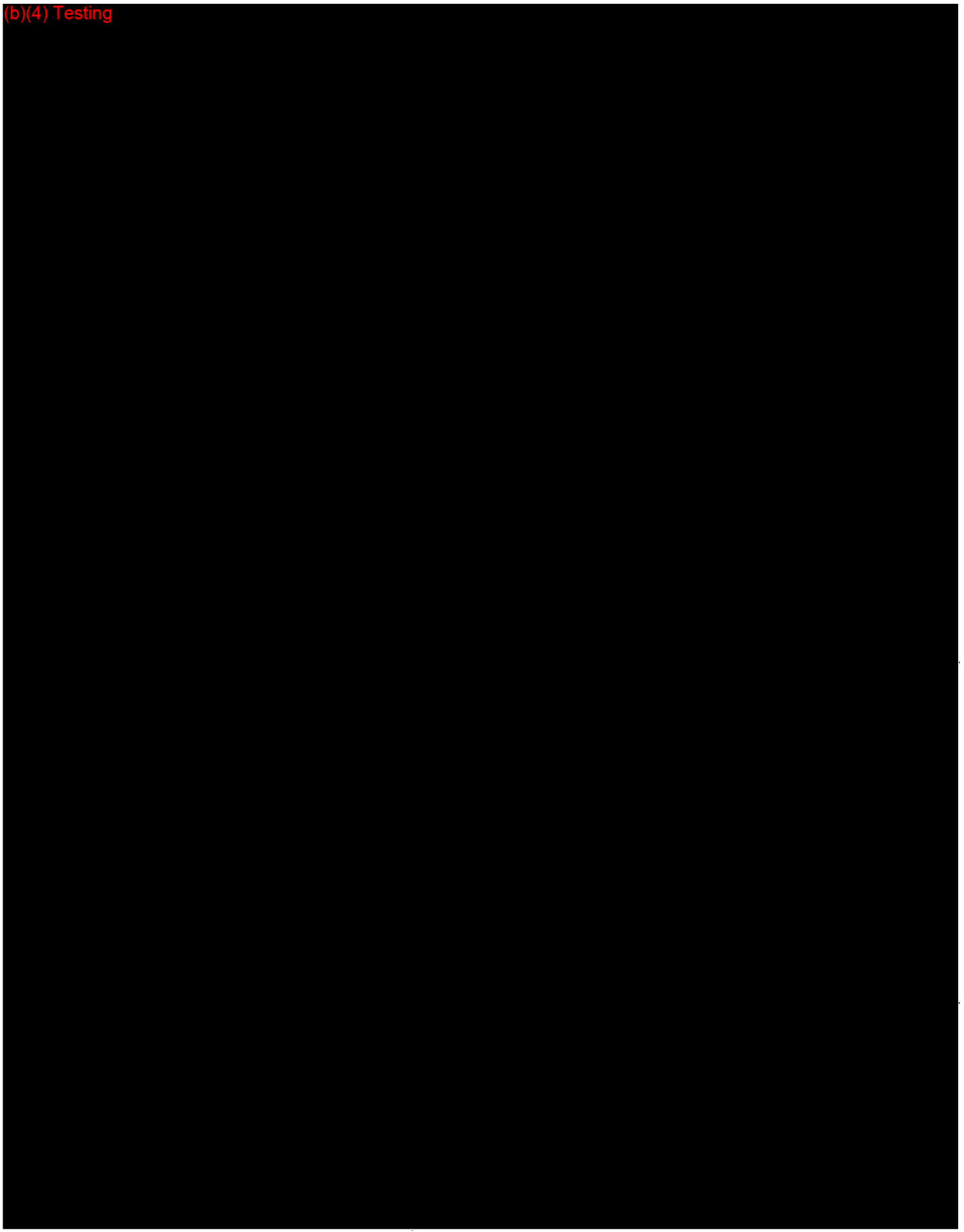

(b)(4) Testing

(b)(4) Testing

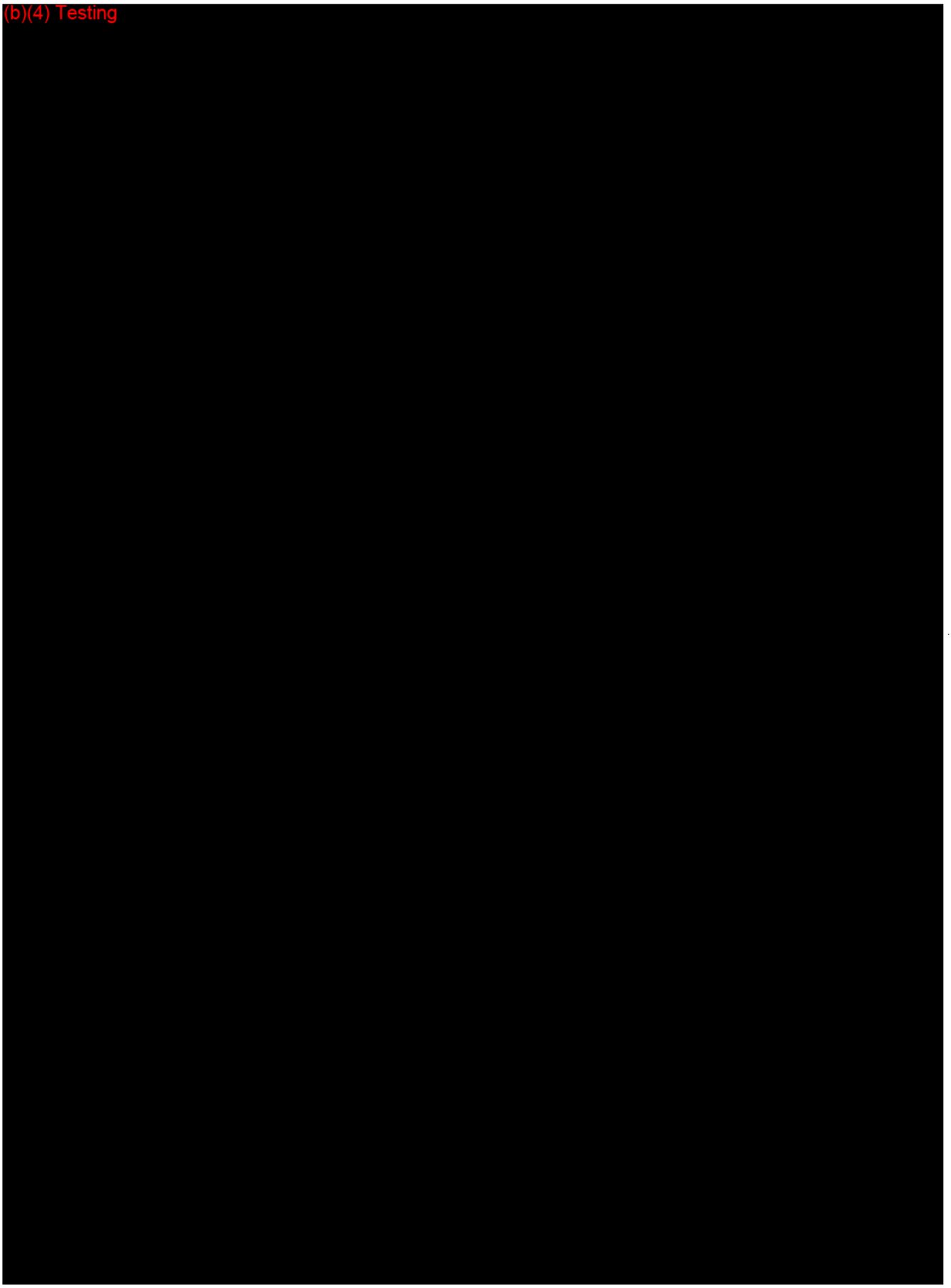
[redacted]

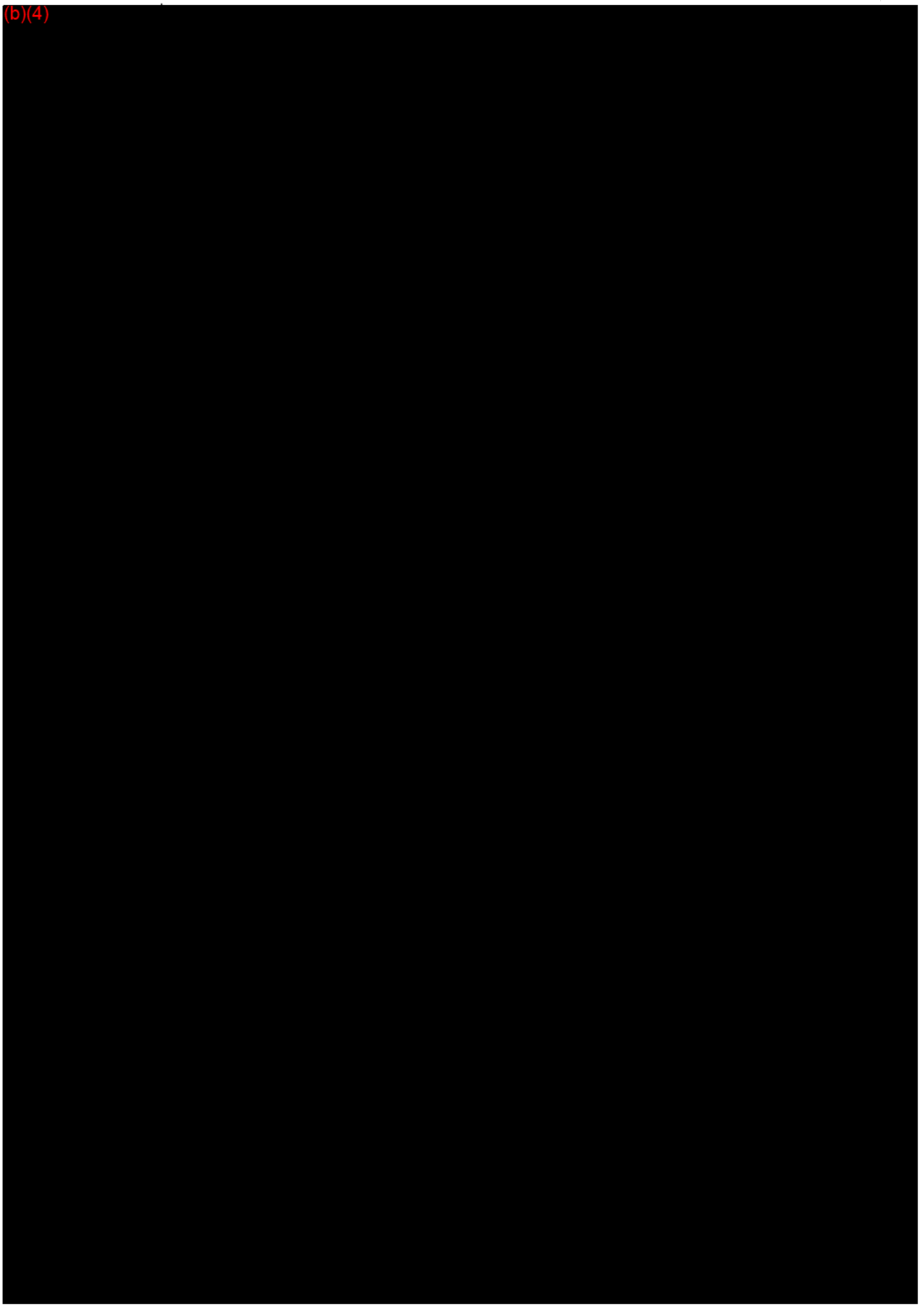
(b)(4) Testing

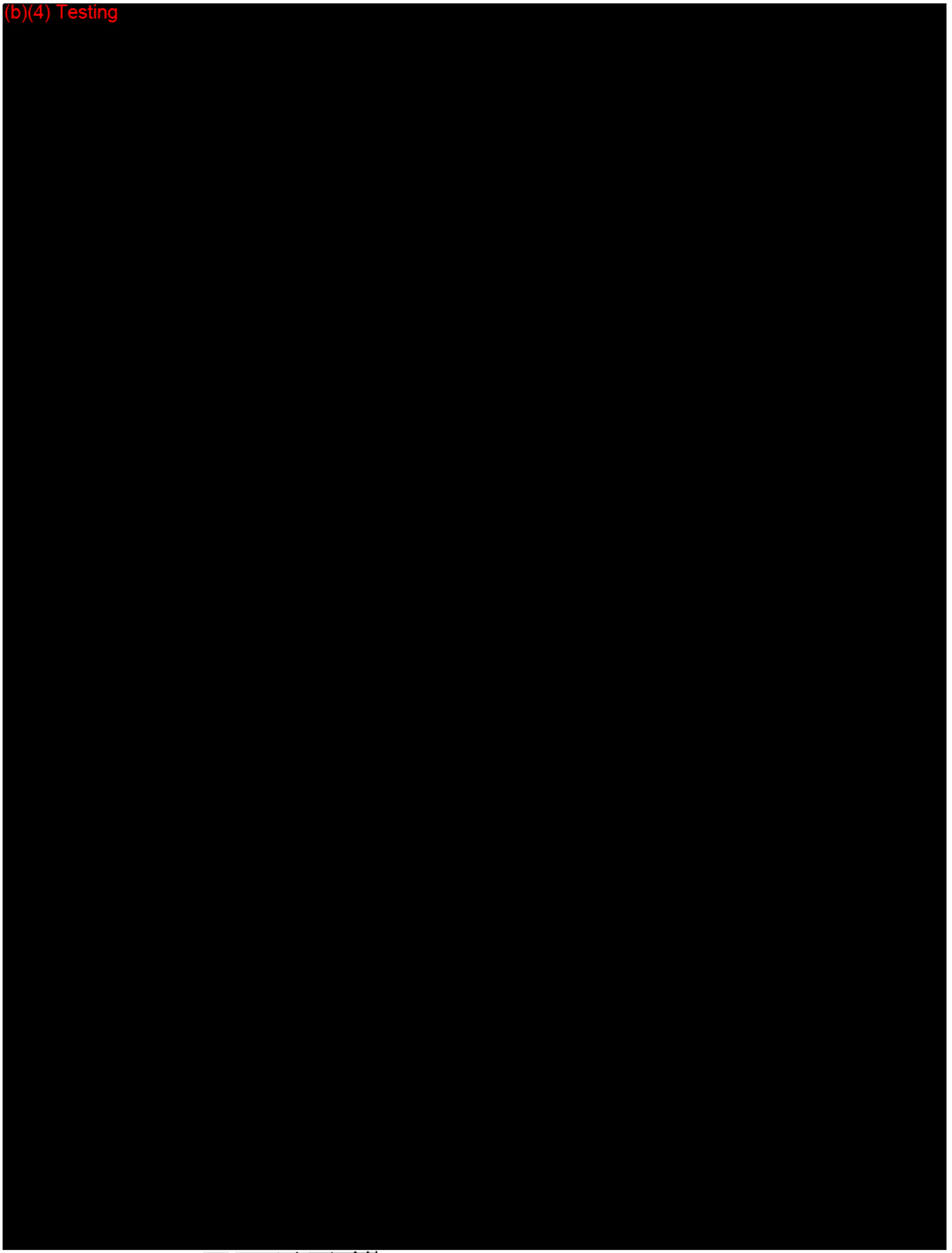
[redacted]

Appendix F:

(b)(4) Graphs


(b)(4) Testing

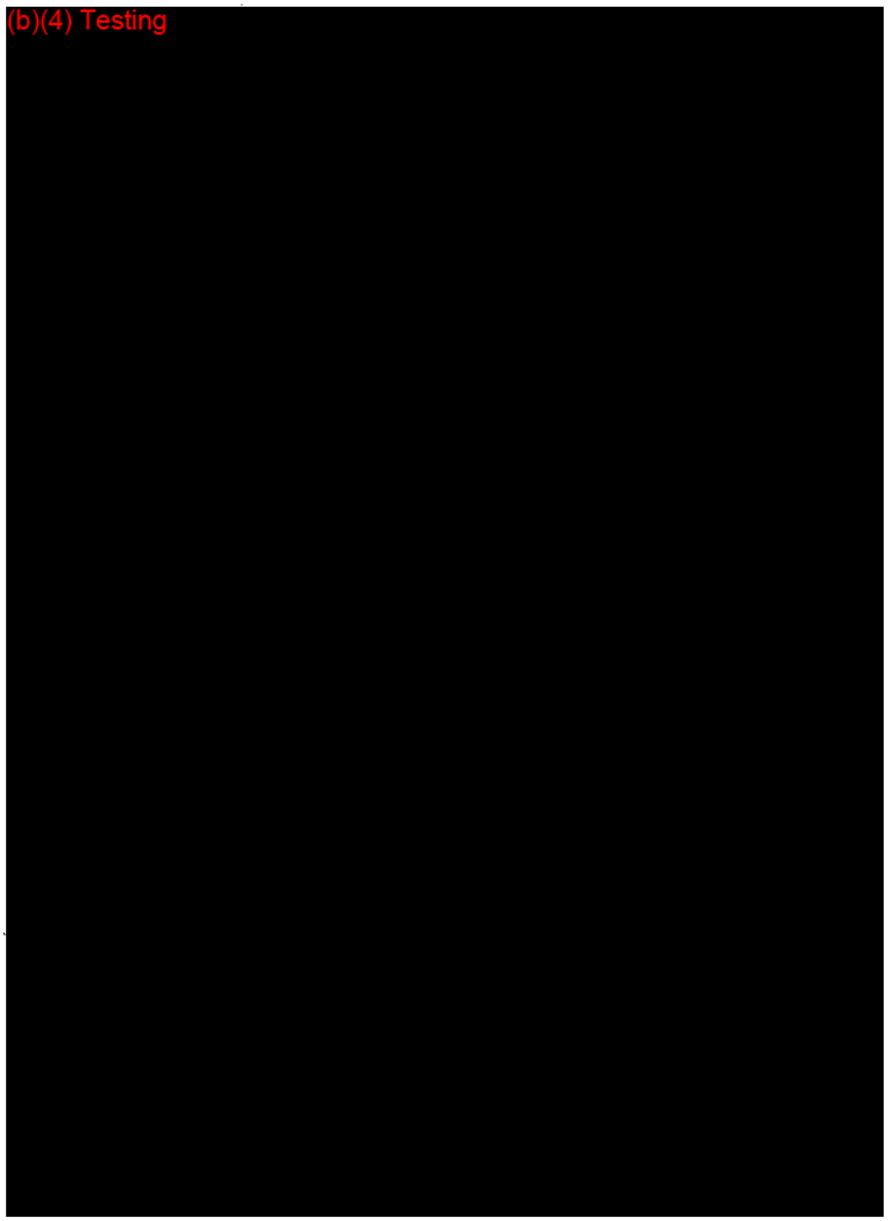

(b)(4)



[redacted] (b) [redacted]

Appendix G:

Lot Information


(b)(4) Testing

Attachment C

Appendix B
Engineering Drawings - Revision (b)

(b)(4) Engineering Drawings

(b)(4) Manufacturing Information

(b)(4) Engineering Drawings

(b)(4) Engineering Drawings

(b)(4) Engineering Drawings