

MAR 26 2014



RIVERPOINT
MEDICAL

K140415

Pg. 1 of 3

510(k) Summary

Submitter Information

Submitter's Name: Riverpoint Medical
Address: 825 NE 25th Ave.
Portland, OR 97232
Phone Number: (503) 517-8001 or 866 445-4923
Fax Number: (503) 517-8002
Registration Number: 3006981798
Contact Person: Douglas Rowley
(503) 517-8001
Date of Preparation: February 11th, 2014

Device Name

Trade Name: MonoTex
Common Name: PTFE Nonabsorbable Surgical Sutures
Classification Name: Suture, surgical, nonabsorbable, expanded
Polytetrafluoroethylene

Device Classification

FDA Class: 2
Product Classification: 878.5035: Nonabsorbable expanded polytetrafluoroethylene
surgical suture
Code: NBY
Classification Panel: Class II (special controls); General and Plastic Surgery

Predicate Devices (applicable 510(k) number listed):

K072076 (Cytoplast PTFE Suture, Osteogenics Biomedical, Inc.)

510(k) Summary - PTFE Suture



K140415

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Special Controls

FDA Guidance "Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA" was followed during the preparation of this submission.

Device Description

MonoTex Polytetrafluoroethylene (PTFE) nonabsorbable surgical sutures are medical devices used to secure tissues together or create wound closures during a surgical procedure or after an injury. MonoTex PTFE sutures are monofilament, and are composed of expanded polytetrafluoroethylene material attached to a standard medical grade suture needle as applicable (sutures can be provided without needles as well). Available Suture sizes will be standard according to USP requirements (6/0 through 5).

Intended Uses

Riverpoint MonoTex PTFE surgical suture is indicated for use in general soft tissue approximation and/or ligation, including cardiovascular, dental, general surgical procedures and repair of the dura mater. MonoTex PTFE sutures are not indicated for use in microsurgery, ophthalmic procedures, or peripheral neural tissues. MonoTex PTFE suture is provided sterile as a single use device.

Substantial Equivalence

MonoTex PTFE nonabsorbable sutures have been designed and manufactured to be substantially equivalent to the predicate device listed for safety and effectiveness. Materials used were selected based on known biocompatibility and established histories of use in the medical device industry for implantable devices, and are identical or substantially equivalent to the materials used in the predicate devices listed.

MonoTex PTFE sutures have been designed to meet the requirements for diameter, tensile strength, and needle attachment strength as specified per USP unless stated otherwise on labeling. Testing is performed on each lot of product to verify that requirements have been met prior to release.

Technological Characteristics

The MonoTex PTFE sutures within this submission have substantially equivalent technological characteristics as the predicate device listed. As with the predicate device, MonoTex PTFE sutures are monofilament, uncoated, synthetic nonabsorbable surgical sutures. MonoTex PTFE sutures are provided sterile for one-time use only, and meet USP requirements unless stated otherwise within labeling.



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K140415

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Performance Data

Per FDA's *Special Control Guidance Document: Surgical Sutures*, performance testing, including mechanical testing in accordance to USP for nonabsorbable suture and biocompatibility testing of the suture material in accordance to ISO 10993-1 has been performed to further ensure substantial equivalence with the predicate devices listed. All testing performed has demonstrated that MonoTex PTFE sutures are as safe and effective as the predicate, will meet current performance requirements for nonabsorbable surgical sutures unless stated otherwise in labeling, and that they are substantially equivalent to the applicable predicate devices.

Conclusion

Based on the information provided within this 510(k) submission, Riverpoint Medical concludes that the proposed MonoTex PTFE sutures are substantially equivalent to the predicate devices listed according to the requirements of the Federal Food, Drug, and Cosmetic Act.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

March 26, 2014

Riverpoint Medical
Mr. Douglas Rowley
825 Northeast 25th Avenue
Portland, Oregon 97232

Re: K140415

Trade/Device Name: MONOTEX PTFE Suture
Regulation Number: 21 CFR 878.5035
Regulation Name: Nonabsorbable expanded polytetrafluoroethylene surgical suture
Regulatory Class: Class II
Product Code: NBY
Dated: February 11, 2014
Received: February 18, 2014

Dear Mr. Rowley:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

Page 2 – Mr. Douglas Rowley

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (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 (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



RIVERPOINT
MEDICAL

K140415

Indications for Use Statement

510(k) Number: Unknown at this time
Device Name: Nonabsorbable expanded polytetrafluoroethylene (PTFE) surgical suture
Trade Name: MonoTex

Indications for Use:

MonoTex PTFE surgical suture is indicated for use in general soft tissue approximation and/or ligation, including cardiovascular, dental, general surgical procedures and repair of the dura mater. MonoTex PTFE sutures are not indicated for use in microsurgery, ophthalmic procedures, or peripheral neural tissues.

MonoTex PTFE suture is provided sterile as a single use device.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter L. Hudson -S
2014.03.20 09:36:18 -04'00'

Page 1 of 1

510(k) Indications for Use Statement – PTFE Suture



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WQ66-G609
Silver Spring, MD 20993-0002

March 26, 2014

Riverpoint Medical
Mr. Douglas Rowley
825 Northcast 25th Avenue
Portland, Oregon 97232

Re: K140415

Trade/Device Name: MONOTEX PTFE Suture
Regulation Number: 21 CFR 878.5035
Regulation Name: Nonabsorbable expanded polytetrafluoroethylene surgical suture
Regulatory Class: Class II
Product Code: NBY
Dated: February 11, 2014
Received: February 18, 2014

Dear Mr. Rowley:

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Page 2 – Mr. Douglas Rowley

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Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



Folder Type	PMN
Submission	K140415 - K10449
Document	Indications for Use
Description	Indications for Use
Document Date	26-Mar-2014
	002

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118



RIVERPOINT
MEDICAL

K140415

Indications for Use Statement

510(k) Number: Unknown at this time

Device Name: Nonabsorbable expanded polytetrafluoroethylene (PTFE) surgical suture

Trade Name: MonoTex

Indications for Use:

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MonoTex PTFE suture is provided sterile as a single use device.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter L. Hudson -S
2014.03.20 09:36:18 -04'00'

Collins, Virginia *

From: Collins, Virginia *
Sent: Thursday, March 27, 2014 11:22 AM
To: 'doug@prmed.com'
Cc: DCCLetters
Subject: K140415 SE Letter
Attachments: K140415.pdf

Tracking:	Recipient	Delivery
	'doug@prmed.com'	
	DCCLetters	Delivered: 3/27/2014 11:22 AM



RIVERPOINT
MEDICAL

K 140415
FDA CDRH DMC
FEB 18 2014
Received

510(k) Cover Sheet – PTFE Surgical Suture

510(k) Notification:

In accordance with the FDA Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this is to serve as a summary of Safety and Effectiveness for Riverpoint Medical PTFE Nonabsorbable Surgical Sutures.

The 510(k) Type (Abbreviated) was selected and prepared based on the FDA Guidance for Industry and Staff Document titled: *Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA (Dated June, 3, 2003)*.

Submitter Information

Submitter's Name:	Riverpoint Medical
Address:	825 NE 25 th Ave. Portland, OR 97232
Phone Number:	(503) 517-8001 or 866 445-4923
Fax Number:	(503) 517-8002
Registration Number:	3006981798
Contact Person:	Doug Rowley (503) 517-8001
Date of Preparation:	February 11 th , 2014

510(k) Type

Abbreviated

510(k) Cover Letter – PTFE Suture



Device Type (common name) **Trade Name**
 1. Nonabsorbable expanded polytetrafluoroethylene surgical suture MonoTex

Classification Recommendation
 1. 878.5035 Nonabsorbable expanded polytetrafluoroethelene surgical suture

Class; Panel

 Class II (special controls); General and Plastic Surgery

Product Codes
 1. NBY

Basis of Submission
 New device (substantially equivalent to currently marketed devices)

Design and Use of the Device

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
If yes, does this device type require reprocessed validation data?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?	X	

eCopy Statement

- The eCopy is an exact duplicate of the paper copy

Completed By / Date:

Dou Rowley 02/11/2014

Doug Rowley, 02/11/2014

510(k) Cover Letter – PTFE Suture



PTFE Suture 510(k) Table of Contents

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

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>

<p>1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)</p> <p>River Point LLC DBA Riverpoint Medical 825 NE 25th Avenue Portland OR 97232 US</p> <p>1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****8235</p>	<p>2. CONTACT NAME Patrick Ferguson</p> <p>2.1 E-MAIL ADDRESS patrick@rpped.com</p> <p>2.2 TELEPHONE NUMBER (include Area code) 503-5178001</p> <p>2.3 FACSIMILE (FAX) NUMBER (Include Area code) 503-5178002</p>
--	---

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

Select an application type:

- Premarket notification(510(k)); except for third party
- 513(g) Request for Information
- Biologics License Application (BLA)
- Premarket Approval Application (PMA)
- Modular PMA
- Product Development Protocol (PDP)
- Premarket Report (PMR)
- 30-Day Notice

3.1 Select a center

- CDRH
- CBER

3.2 Select one of the types below

- 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)

(b)(4) YES, I meet the small business criteria and have submitted the required qualifying documents to FDA (b)(4) I am not a small business

4.1 If Yes, please enter your Small Business Decision Number: SBD148374

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?

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/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm> 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

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

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

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 NO

PAPERWORK REDUCTION ACT STATEMENT

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

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850

[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4)

11-Feb-2014

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION CDRH PREMARKET REVIEW SUBMISSION COVER SHEET	Form Approval OMB No. 0910-0120 Expiration Date: December 31, 2013 See PRA Statement on page 5.
--	--

Date of Submission 02/11/2014	User Fee Payment ID Number (b)(4)	FDA Submission Document Number (if known) Unknown
----------------------------------	---	--

SECTION A TYPE OF SUBMISSION				
PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	PMA & HDE Supplement <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	510(k) <input checked="" type="checkbox"/> Original Submission: <input type="checkbox"/> Traditional <input type="checkbox"/> Special <input checked="" type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	Request for Feedback <input type="checkbox"/> Pre-Submission <input type="checkbox"/> Informational Meeting <input type="checkbox"/> Submission Issue Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Study Risk Determination <input type="checkbox"/> Other (specify):
IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Other Submission <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):

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 Riverpoint Medical	Establishment Registration Number (if known) 3006981798		
Division Name (if applicable) N/A	Phone Number (including area code) (503) 517-8001		
Street Address 825 NE 25th Avenue	FAX Number (including area code) (503) 517-8002		
City Portland	State / Province Oregon	ZIP/Postal Code 97232	Country USA
Contact Name Doug Rowley			
Contact Title QA/RA Director	Contact E-mail Address doug@rpmed.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)			
Company / Institution Name			
Division Name (if applicable)	Phone Number (including area code)		
Street Address	FAX Number (including area code)		
City	State / Province	ZIP Code	Country
Contact Name			
Contact Title	Contact E-mail Address		

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

<input type="checkbox"/> New Device <input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software/Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Packaging <input type="checkbox"/> Sterilization <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance Characteristics <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address

Other Reason (specify):

SECTION D2 REASON FOR APPLICATION - IDE

<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent/Applicant <input type="checkbox"/> Design/Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor	<input type="checkbox"/> Response to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing
<input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final		

Other Reason (specify):

SECTION D3 REASON FOR SUBMISSION - 510(k)

<input checked="" type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology
--	---	---

Other Reason (specify):

SECTION E								ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS			
Product codes of devices to which substantial equivalence is claimed								Summary of, or statement concerning, safety and effectiveness information <input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement			
1	NBY	2		3		4					
5		6		7		8					

Information on devices to which substantial equivalence is claimed (if known)					
	510(k) Number		Trade or Proprietary or Model Name		Manufacturer
1	K072076	1	Cytoplast PTFE Sutures	1	Osteogenics Biomedical, Inc.
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name
Nonabsorbable expanded polytetrafluoroethylene surgical suture

Trade or Proprietary or Model Name for This Device		Model Number	
1	MonoTex	1	Varies by size/needle combination
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions (regardless of outcome)					
1	K131147	2	K122626	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 NBY	C.F.R. Section (if applicable) 21CFR 878.5035	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel Class II		

Indications (from labeling)
 MonoTex PTFE surgical suture is indicated for use in general soft tissue approximation and/or ligation, including cardiovascular, dental, general surgical procedures and repair of the dura mater. MonoTex PTFE sutures are not indicated for use in microsurgery, ophthalmic procedures, or peripheral neural tissues. MonoTex PTFE suture is provided sterile as a single use device.

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

SECTION H	MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION
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<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name (if applicable)		Phone Number (including area code)	
Street Address		FAX Number (including area code)	
City	State / Province	ZIP Code	Country
Contact Name	Contact Title	Contact E-mail Address	

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

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
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Street Address		FAX Number (including area code)	
City	State / Province	ZIP Code	Country
Contact Name	Contact Title	Contact E-mail Address	

SECTION 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	14971	ISO	Risk Management	2007	2/11/2014
2	10993-1	ISO	Biological Evaluation of Medical Devices	2003	2/11/2014
3	(b)(4)	(b)(4)	(b)(4)	2007	2/11/2014
4	(b)(4)	(b)	(b)(4)	2008	2/11/2014
5	USP <861>, <871>, <881>.	USP	<861> Sutures - Diameter <871> Sutures - Needle Attachment <881> Sutures - Tensile Strength	USP 35	2/11/2014
6					
7					

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

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

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

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Department of Health and Human Services
 Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
 (To be filled in by applicant)

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TYPE OF 510(k) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ISO 14971: Medical Devices - Application of Risk Management to medical devices

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #5-40

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
 If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
 If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
 If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?
 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?
 If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?
 If yes, was the guidance document followed in preparation of this 510(k)?

Title of guidance: _____

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

² Authority [21 U.S.C. 380d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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

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

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
ISO 14971: Medical Devices - Application of Risk Management to medical devices

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER 6.5	SECTION TITLE Risk/Benefit Analysis	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A
-----------------------	--	--

TYPE OF DEVIATION OR OPTION SELECTED *
Section 6.5 was found not to be applicable to this product line.

DESCRIPTION
Risk/Benefit Analysis Guidance

JUSTIFICATION
The risk level found for this product line was found to be acceptable, making this section N/A.

SECTION NUMBER 6.2	SECTION TITLE Risk control option analysis	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
-----------------------	---	--

TYPE OF DEVIATION OR OPTION SELECTED *
Options given for risk reduction processes were selected.

DESCRIPTION
The selected options were: a) Inherent safety by design; b) Protective measures in the device itself...;c) Information for safety

JUSTIFICATION
Each option was used as applicable during the risk reduction phase for PTFE sutures.

SECTION NUMBER 3.4	SECTION TITLE Risk Management Plan	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
-----------------------	---------------------------------------	--

TYPE OF DEVIATION OR OPTION SELECTED *
Options were provided for various methods of criteria specification to be used when determining the acceptability of identified risks.

DESCRIPTION
The standard leaves the selection of the criteria to be used up to the device manufacturer.

JUSTIFICATION
Risk acceptability is identified within Riverpoint SOPs and followed during Risk Management activities. The criteria used is very similar to the matrix within section D.5 of the standard.

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

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

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TYPE OF 510(k) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE¹

(b)(4)

Please answer the following questions

Yes No

Is this standard recognized by FDA²?

FDA Recognition number³ # (b)(4)

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report⁴ describing the extent of conformance of the standard used included in the 510(k)?
 If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
 If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
 If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?
 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?
 If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance⁶ that is associated with this standard?
 If yes, was the guidance document followed in preparation of this 510(k)?

Title of guidance: _____

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

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

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

(b)(4)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
The standard includes multiple test options for validation.

DESCRIPTION
Required number of BIs for each half-cycle and/or full-cycle can vary.

JUSTIFICATION
Determined quantity of BIs (PCDs) based on load volume.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
The standard includes multiple test options for validation.

DESCRIPTION
Required number of temperature/humidity probes for temperature distribution study varies.

JUSTIFICATION
The number of probes used during PQ activities was selected based on applicable chamber size, and complied with requirements.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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

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

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TYPE OF 510(k) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ISO 10993: Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #2-98

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
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Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

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Were there any deviations or adaptations made in the use of the standard?
 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?
 If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?
 If yes, was the guidance document followed in preparation of this 510(k)?

Title of guidance: Use of standard ISO 10993, Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing

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

² Authority [21 U.S.C. 380e], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

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

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

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
ISO 10993: Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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JUSTIFICATION

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TYPE OF 510(k) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE¹

(b)(4)

Please answer the following questions

Yes No

Is this standard recognized by FDA²?

FDA Recognition number³ (b)(4)

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

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Were there any exclusions from the standard?
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance⁶ that is associated with this standard?
 If yes, was the guidance document followed in preparation of this 510(k)?

Title of guidance: TIR 19 and 19/A1: AAMI TIR 19/A1: 1999

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

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

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
(b)(4)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A
----------------	---------------	--

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A
----------------	---------------	--

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A
----------------	---------------	--

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

United States Pharmacopeia (USP) 35 (NF-30) - As it applies to Nonabsorbable surgical sutures only (sections <861><871><881>)

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #6-285 - 6-287

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

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If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?
If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA

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

² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or

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⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

United States Pharmacopeia (USP) 35 (NF-30) - As it applies to Nonabsorbable surgical sutures only (sections <861><871><881>)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
<861>, <871>, <881>	Surgical sutures, Diameter, Needle Attachment, Tensile Strength Testing	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

Diameter, Needle Attachment Strength, Tensile Strength, Physical specifications for surgical sutures per USP

DESCRIPTION

PTFE Sutures may not meet specified USP requirements for diameter, needle attachment, or tensile strength in all cases.

JUSTIFICATION

Per the FDA Guidance Document on Surgical Sutures, a deviation of this type is acceptable so long as labeling denotes this information. Riverpoint's labeling has been developed accordingly to accurately reflect and comply with applicable requirements.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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

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

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

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



Declaration of Conformity to a Recognized Standard – ISO 14971-1

Completed based on the "Declaration of Conformity" Content section of the FDA Guidance Document titled Guidance for Industry and FDA Staff – Recognition and Use of Consensus Standards

Standard Identification: ISO 14971-1: Medical devices – Application of risk management to medical devices

Statement: Riverpoint Medical hereby declares compliance with ISO 14971-1 for the Risk Management activities performed for its PTFE sutures.

Adaptations to the Standard: See Form 3654 within the 510(k) submission (number unknown)

Not Applicable requirements: See Form 3654 within the 510(k) submission (number unknown)

Deviations: See Form 3654 within the 510(k) submission (number unknown)

Deviations between samples tested and final product: No deviations

Testing Laboratory Information: N/A, applicable evaluation performed at Riverpoint.

Completed By:

A handwritten signature in blue ink, appearing to read 'D. Rowley', with the date '01/20/14' written below it.

Doug Rowley
QA Director

Declaration of Conformity to ISO 14971-1

510(k) Submission – PTFE Sutures

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118



Declaration of Conformity to a Recognized Standard – ISO 10993-1

Completed based on the “Declaration of Conformity” Content section of the FDA Guidance Document titled **Guidance for Industry and FDA Staff – Recognition and Use of Consensus Standards**

Standard Identification: ISO 10993-1: Biological evaluation of medical devices – Part 1: Evaluation and testing

Statement: Riverpoint Medical hereby declares compliance with ISO 10993-1 for the biological evaluation of its PTFE sutures.

Adaptations to the Standard: See Form 3654 within the 510(k) submission (number unknown)

Not Applicable requirements: See Form 3654 within the 510(k) submission (number unknown)

Deviations: See Form 3654 within the 510(k) submission (number unknown)

Deviations between samples tested and final product: N/A

Testing Laboratory Information: Testing performed by:

(b)(4) Third Party Information

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Completed By:

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Doug Rowley
QA Director

Declaration of Conformity to ISO 10993-1
510(k) Submission – PTFE Suture

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118



Declaration of Conformity to a Recognized Standard – ISO 11135-1

Completed based on the “Declaration of Conformity” Content section of the FDA Guidance Document titled **Guidance for Industry and FDA Staff – Recognition and Use of Consensus Standards**

Standard Identification: (b)(4)

Statement: Riverpoint Medical hereby declares compliance with (b)(4) validation of PTFE sutures.

Adaptations to the Standard: See Form 3654 within the 510(k) submission (number unknown)

Not Applicable requirements: See Form 3654 within the 510(k) submission (number unknown)

Deviations: See Form 3654 within the 510(k) submission (number unknown)

Deviations between samples tested and final product: No deviations present.

Testing Laboratory Information: Testing performed by:
(b)(4) Third Party Information

Completed By:

Doug Rowley
QA Director

Declaration of Conformity to ISO 11135-1

510(k) Submission – PTFE Sutures

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118



Declaration of Conformity to a Recognized Standard – ISO 10993-7

Completed based on the "Declaration of Conformity" Content section of the FDA Guidance Document titled **Guidance for Industry and FDA Staff – Recognition and Use of Consensus Standards**

Standard Identification:

(b)(4)

Statement:

Riverpoint Medical hereby declares compliance with (b)(4) (b)(4) applicable to PTFE sutures.

Adaptations to the Standard:

See Form 3654 within the 510(k) submission (number unknown)

Not Applicable requirements:

See Form 3654 within the 510(k) submission (number unknown)

Deviations:

See Form 3654 within the 510(k) submission (number unknown)

Deviations between samples tested and final product:

No deviations present.

Testing Laboratory Information:

Testing performed by:

(b)(4) Third Party Information

Completed By:

Doug Rowley
QA Director



Declaration of Conformity to a Recognized Standard – USP 35

Completed based on the “Declaration of Conformity” Content section of the FDA Guidance Document titled **Guidance for Industry and FDA Staff – Recognition and Use of Consensus Standards**

Standard Identification: United States Pharmacopeia: USP35-NF 30, sections: <861>, <871>, <881>.

Statement: Riverpoint Medical hereby declares that all applicable requirements for the physical testing of surgical sutures described within USP 35 have been met for Riverpoint’s PTFE sutures, unless otherwise stated on labeling. Applicable sections of this standard include: <861> Diameter; <871> Needle Attachment; <881> Tensile Strength; as well as specified Length requirements.

Adaptations to the Standard: See Form 3654 within the 510(k) submission (K131147)

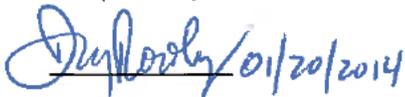
Not Applicable requirements: See Form 3654 within the 510(k) submission (K131147)

Deviations: See Form 3654 within the 510(k) submission (K131147)

Deviations between samples tested and final product: No deviations. Testing is performed on each lot of product.

Testing Laboratory Information: N/A, applicable evaluations performed at Riverpoint.

Completed By:

Handwritten signature of Doug Rowley in blue ink, dated 01/20/2014.

Doug Rowley
QA Director

Declaration of Conformity to USP 35

510(k) Submission – PTFE Sutures

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118



510(k) Cover Sheet – PTFE Surgical Suture

510(k) Notification:

In accordance with the FDA Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this is to serve as a summary of Safety and Effectiveness for Riverpoint Medical PTFE Nonabsorbable Surgical Sutures.

The 510(k) Type (Abbreviated) was selected and prepared based on the FDA Guidance for Industry and Staff Document titled: *Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA (Dated June, 3, 2003)*.

Submitter Information

Submitter's Name:	Riverpoint Medical
Address:	825 NE 25 th Ave. Portland, OR 97232
Phone Number:	(503) 517-8001 or 866 445-4923
Fax Number:	(503) 517-8002
Registration Number:	3006981798
Contact Person:	Doug Rowley (503) 517-8001
Date of Preparation:	February 11 th , 2014

510(k) Type

Abbreviated

510(k) Cover Letter – PTFE Suture



<u>Device Type (common name)</u>	<u>Trade Name</u>
1. Nonabsorbable expanded polytetrafluoroethylene surgical suture	MonoTex

Classification Recommendation
 1. 878.5035 Nonabsorbable expanded polytetrafluoroethelene surgical suture

Class; Panel

 Class II (special controls); General and Plastic Surgery

Product Codes
 1. NBY

Basis of Submission
 New device (substantially equivalent to currently marketed devices)

Design and Use of the Device

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
If yes, does this device type require reprocessed validation data?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?	X	

eCopy Statement

- The eCopy is an exact duplicate of the paper copy

Completed By / Date:

Doug Rowley 02/11/2014
 Doug Rowley, 02/11/2014

510(k) Cover Letter – PTFE Suture



Indications for Use Statement

510(k) Number: Unknown at this time

Device Name: Nonabsorbable expanded polytetrafluoroethylene (PTFE) surgical suture

Trade Name: MonoTex

Indications for Use:

MonoTex PTFE surgical suture is indicated for use in general soft tissue approximation and/or ligation, including cardiovascular, dental, general surgical procedures and repair of the dura mater. MonoTex PTFE sutures are not indicated for use in microsurgery, ophthalmic procedures, or peripheral neural tissues.

MonoTex PTFE suture is provided sterile as a single use device.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



510(k) Summary

Submitter Information

Submitter's Name: Riverpoint Medical
Address: 825 NE 25th Ave.
Portland, OR 97232
Phone Number: (503) 517-8001 or 866 445-4923
Fax Number: (503) 517-8002
Registration Number: 3006981798
Contact Person: Douglas Rowley
(503) 517-8001
Date of Preparation: February 11th, 2014

Device Name

Trade Name: MonoTex
Common Name: PTFE Nonabsorbable Surgical Sutures
Classification Name: Suture, surgical, nonabsorbable, expanded
Polytetrafluoroethylene

Device Classification

FDA Class: 2
Product Classification: 878.5035: Nonabsorbable expanded polytetrafluoroethylene
surgical suture
Code: NBY
Classification Panel: Class II (special controls); General and Plastic Surgery

Predicate Devices (applicable 510(k) number listed):

K072076 (Cytoplast PTFE Suture, Osteogenics Biomedical, Inc.)



Special Controls

FDA Guidance "Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA" was followed during the preparation of this submission.

Device Description

MonoTex Polytetrafluoroethylene (PTFE) nonabsorbable surgical sutures are medical devices used to secure tissues together or create wound closures during a surgical procedure or after an injury. MonoTex PTFE sutures are monofilament, and are composed of expanded polytetrafluoroethylene material attached to a standard medical grade suture needle as applicable (sutures can be provided without needles as well). Available Suture sizes will be standard according to USP requirements (6/0 through 5).

Intended Uses

Riverpoint MonoTex PTFE surgical suture is indicated for use in general soft tissue approximation and/or ligation, including cardiovascular, dental, general surgical procedures and repair of the dura mater. MonoTex PTFE sutures are not indicated for use in microsurgery, ophthalmic procedures, or peripheral neural tissues. MonoTex PTFE suture is provided sterile as a single use device.

Substantial Equivalence

MonoTex PTFE nonabsorbable sutures have been designed and manufactured to be substantially equivalent to the predicate device listed for safety and effectiveness. Materials used were selected based on known biocompatibility and established histories of use in the medical device industry for implantable devices, and are identical or substantially equivalent to the materials used in the predicate devices listed.

MonoTex PTFE sutures have been designed to meet the requirements for diameter, tensile strength, and needle attachment strength as specified per USP unless stated otherwise on labeling. Testing is performed on each lot of product to verify that requirements have been met prior to release.

Technological Characteristics

The MonoTex PTFE sutures within this submission have substantially equivalent technological characteristics as the predicate device listed. As with the predicate device, MonoTex PTFE sutures are monofilament, uncoated, synthetic nonabsorbable surgical sutures. MonoTex PTFE sutures are provided sterile for one-time use only, and meet USP requirements unless stated otherwise within labeling.



Performance Data

Per FDA's *Special Control Guidance Document: Surgical Sutures*, performance testing, including mechanical testing in accordance to USP for nonabsorbable suture and biocompatibility testing of the suture material in accordance to ISO 10993-1 has been performed to further ensure substantial equivalence with the predicate devices listed. All testing performed has demonstrated that MonoTex PTFE sutures are as safe and effective as the predicate, will meet current performance requirements for nonabsorbable surgical sutures unless stated otherwise in labeling, and that they are substantially equivalent to the applicable predicate devices.

Conclusion

Based on the information provided within this 510(k) submission, Riverpoint Medical concludes that the proposed MonoTex PTFE sutures are substantially equivalent to the predicate devices listed according to the requirements of the Federal Food, Drug, and Cosmetic Act.



Truthful and Accuracy Statement

I certify that, in my capacity as Quality Director of Riverpoint Medical, I believe to the best of my knowledge, that all data and information submitted in this premarket notification is truthful and accurate and that no material fact has been omitted.

A handwritten signature in blue ink, appearing to read 'Doug Rowley', written over a horizontal line.

(Signature)

Doug Rowley

(Typed Name)

02/11/2014

(Date)

510(k) Number: (unknown at this time)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0396
Expiration Date: December 31, 2015

CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

TO BE COMPLETED BY APPLICANT

With respect to all covered clinical studies (or specific clinical studies listed below (if appropriate)) submitted in support of this application, I certify to one of the statements below as appropriate. I understand that this certification is made in compliance with 21 CFR part 54 and that for the purposes of this statement, a clinical investigator includes the spouse and each dependent child of the investigator as defined in 21 CFR 54.2(d).

Please mark the applicable check box.

(1) As the sponsor of the submitted studies, I certify that I have not entered into any financial arrangement with the listed clinical investigators (enter names of clinical investigators below or attach list of names to this form) whereby the value of compensation to the investigator could be affected by the outcome of the study as defined in 21 CFR 54.2(a). I also certify that each listed clinical investigator required to disclose to the sponsor whether the investigator had a proprietary interest in this product or a significant equity in the sponsor as defined in 21 CFR 54.2(b) did not disclose any such interests. I further certify that no listed investigator was the recipient of significant payments of other sorts as defined in 21 CFR 54.2(f).

Clinical Investigators	(b)(4) Third Party Information
------------------------	--------------------------------

(2) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that based on information obtained from the sponsor or from participating clinical investigators, the listed clinical investigators (attach list of names to this form) did not participate in any financial arrangement with the sponsor of a covered study whereby the value of compensation to the investigator for conducting the study could be affected by the outcome of the study (as defined in 21 CFR 54.2(a)); had no proprietary interest in this product or significant equity interest in the sponsor of the covered study (as defined in 21 CFR 54.2(b)); and was not the recipient of significant payments of other sorts (as defined in 21 CFR 54.2(f)).

(3) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that I have acted with due diligence to obtain from the listed clinical investigators (attach list of names) or from the sponsor the information required under 54.4 and it was not possible to do so. The reason why this information could not be obtained is attached.

NAME <i>Doug Rowley</i>	TITLE <i>QA Director</i>
FIRM/ORGANIZATION <i>Riverpoint medical</i>	
SIGNATURE <i>D. Rowley</i>	DATE (mm/dd/yyyy) <i>01/21/2014</i>

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

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Public reporting burden for this collection of information is estimated to average 1 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary data, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information to the address to the right:

Do NOT send your completed form to the PRA Staff email address below.

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
PRASStaff@fda.hhs.gov

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

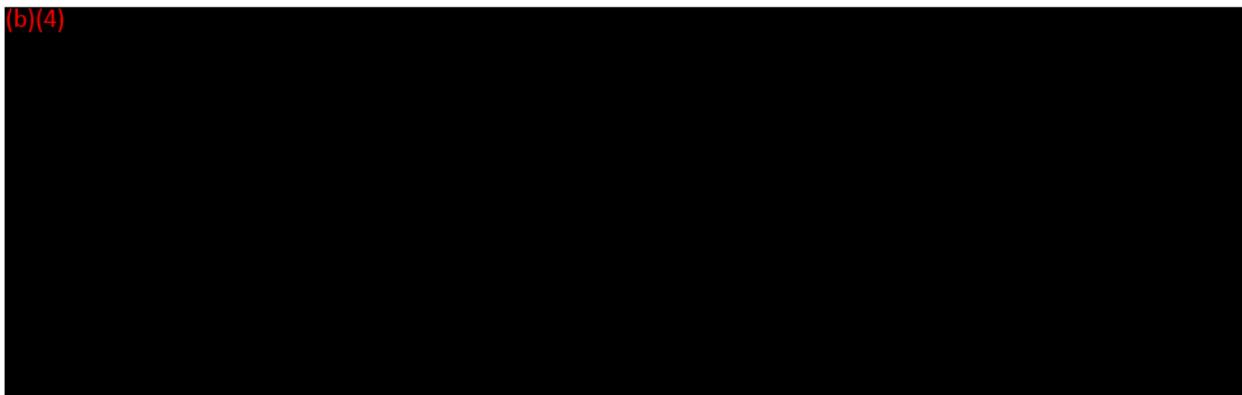


Predicate Device Comparison chart

Riverpoint Trade Name:	MonoTex	Predicate Device:	Osteogenics Biomedical, Inc: Cytoplast®	510(k) No(s):	K072076
Material:	Expanded polytetrafluoroethylene	Material:	Expanded polytetrafluoroethylene		
Intended Use:	MonoTex PTFE surgical suture is indicated for use in general soft tissue approximation and/or ligation, including cardiovascular, dental, general surgical procedures and repair of the dura mater. MonoTex PTFE sutures are not indicated for use in microsurgery, ophthalmic procedures, or peripheral neural tissues. MonoTex PTFE suture is provided sterile as a single use device.	Intended Use:	PTFE surgical suture is indicated for use in all types of soft tissue approximation and/or ligation, including cardiovascular, dental and general surgeries, as well as repair of the dura mater. The device is not indicated for use in ophthalmic surgery, microsurgery, and peripheral neural tissue.		
Needles:	Available with or without various standard suture needles attached.	Needles:	Available with or without standard suture needles attached		
Sizes Available:	Various diameters based on USP (unless stated in labeling), various lengths	Sizes Available:	Various per USP (unless stated in labeling)		
Colors Available:	White	Colors Available:	White		

Testing Summary

Riverpoint Medical nonabsorbable suture varieties have been selected based on substantial histories of use in the medical field. PTFE materials are widely used throughout the industry for implantable devices such as sutures, and have a substantial history of compatibility and safe use. MonoTex sutures within this submission were subjected to Biocompatibility testing per ISO 10993-1 and FDA requirements when in their final form. See the Safety and Effectiveness section of this submission for additional information.





(b)(4)

Sterilization Summary

(b)(4)

See the Sterilization section of this submission for additional information.



Safety and Effectiveness Summary – PTFE Suture

MonoTex PTFE sutures have been designed and manufactured to be substantially equivalent to the predicate device listed in this submission for all aspects of safety and effectiveness.

Materials

PTFE material was selected based on known biocompatibility and substantial history of use in the medical device industry for a wide variety of implantable devices and surgical sutures, and is identical or substantially equivalent to the material used in the predicate device.

Packaging

Riverpoint PTFE sutures are packaged into medical grade pouches composed of (b)(4)

(b)(4) These pouches provide excellent protection from microbial contamination, while allowing (b)(4) portion of the pouch during sterilization.

Patient Contact Materials

- Suture Material - PTFE
- Needle (when applicable): 300 or 400 series (b)(4) (industry standard)
- Tipping Additive

Additional material information has been included in the table below.

Design and Function / Device Description

MonoTex PTFE sutures have been designed to have the same general shape, size and method of function as the applicable predicate device, are available in the same industry standard sizes, and are intended to be used on the same anatomical sites and in the same manner as the predicate device listed.

Physical Description

MonoTex PTFE surgical sutures meet USP requirements as described in the USP 35 monograph for nonabsorbable surgical sutures unless otherwise noted in labeling. Applicable dimensions and functional characteristics include length, diameter, tensile strength and needle attachment strength.

PTFE Suture Device Description Table

Variety:	Regulation:	Product Code:	Material used:	Coating(s):	Additive(s):	Color Additive Information (21 CFR 70.5(c)):	Sizes (USP):
PTFE	878.5035	NBY	Expanded polytetrafluoroethylene	N/A	Medical grade (b)(4)	N/A	6/0 through 5



Risks to Health

The risks associated with MonoTex PTFE sutures have been evaluated per ISO 14971-1:2007 and Riverpoint requirements. As specified in the Risk Management Plan, a Failure Mode Effects Analysis (FMEA) was performed in order to identify and evaluate the risk levels and mitigating factors associated with each aspect of this device. A Risk Management Final Report was completed following the completion of the FMEA, which summarized the findings and conclusions of the overall Risk Analysis. Copies of associated Risk Management Documents have been included with this submission.

Biocompatibility

All Riverpoint Medical suture varieties were chosen based on substantial histories of use and acceptable biocompatibility of the suture materials involved.

Biocompatibility testing has been performed according to ISO 10993-1/FDA requirements on the MonoTex product within this submission. See the attached Biocompatibility testing summary (Memo for additional information). Full reports have been provided within this submission. The MonoTex PTFE sutures are considered to be a permanently implantable device type.

MonoTex PTFE sutures have been verified as being composed of fiber that is manufactured without the use of the known carcinogen Perfluorooctanoic acid (PFOA). Information provided by the material vendor, (b)(4) has been attached to this submission.

Outsourced (b)(4) testing was performed for additional verification of product safety and equivalence between the Riverpoint PTFE suture and the predicate device. This testing was performed by (b)(4) and resulted in findings of no differences between the Riverpoint PTFE sutures and the predicate device. See the report attached to the Predicate Device Equivalence Summary section of this submission for more information.

Sterilization

Riverpoint Medical PTFE sutures are sterilized via (b)(4). See the Sterilization Description section of this submission (section 6) for additional sterilization information.

Inspections / Performance Characteristics

USP Testing /In-Process Inspections

Inspections are performed throughout the manufacturing process to verify that all suture varieties meet Riverpoint requirements and specifications. The materials and assembled products undergo various inspections at incoming, throughout the assembly process, and prior to release to ensure that all requirements and specifications are met. The requirements for surgical suture specified in the United States Pharmacopeia (USP 35) have been incorporated into Riverpoint Medical's product specifications and

Safety and Effectiveness Summary – PTFE Suture

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118



inspection requirements, and are used as acceptance criteria whenever applicable. Finished goods inspections are performed according to USP for the following characteristics of each lot of product prior to release: length (+15%, -5%), diameter (<861>), needle attachment (<871>), and tensile strength (<881>).

As stated in applicable labeling, Riverpoint PTFE sutures are tested per USP requirements for nonabsorbable sutures, and are not released for distribution unless all applicable requirements are met. MonoTex PTFE sutures meet USP requirements unless stated otherwise on labeling.

(b)(4) Testing

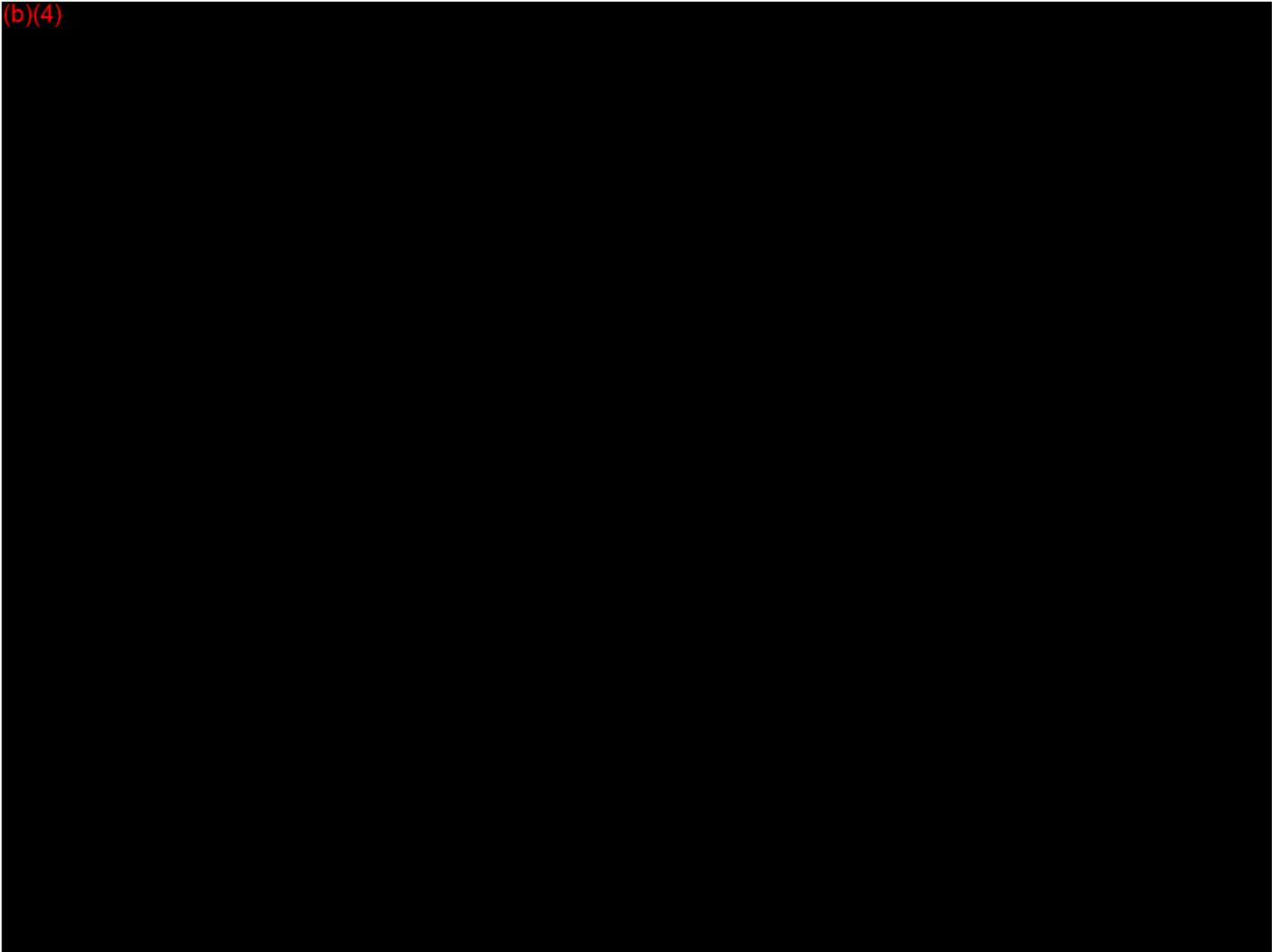
PTFE based materials have been used within the medical industry as permanently implantable devices for decades. While PTFE is able to boast several exceptional properties, its inherent stability is among the primary reasons for its widespread and continued use within the industry.

(b)(4)

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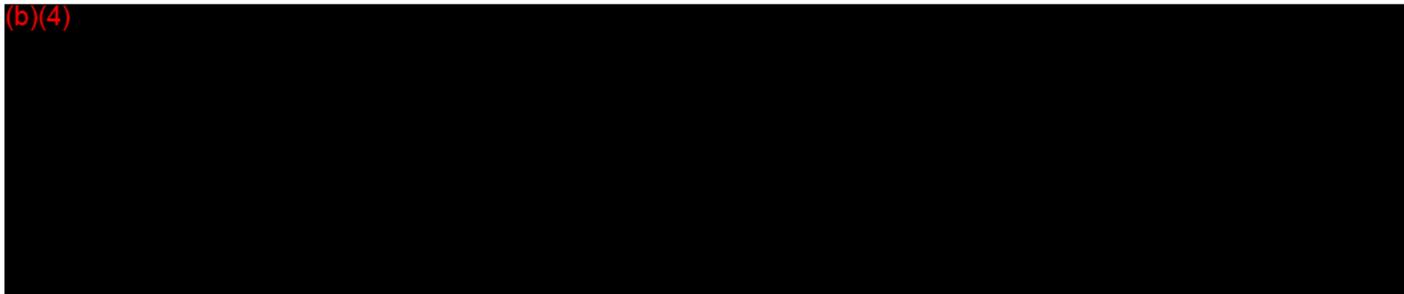
(b)(4)



Included documentation

- Study Summary Reports – Biocompatibility Testing of MonoTex Suture (b)(4)
- PFOA Information;
- Testing Records, Predicate and Competitors' product;
- Risk analysis Documents – Risk Management Plan, FMEA and Risk Analysis Final Reports (PTFE Sutures);

(b)(4)



Safety and Effectiveness Summary – PTFE Suture

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118



Date: 1/21/2014
To: PTFE Swaged Suture Files
By: Doug Rowley, RA/QA Director
RE: Biocompatibility Testing Performed – MonoTex PTFE Suture
Memo: 008-2014

Biocompatibility testing according to FDA and ISO 10993 requirements has been performed on the Riverpoint Medical surgical suture product MonoTex PTFE. All associated testing was based on ISO and FDA requirements for implantable devices. These sutures are nonabsorbable, may come into contact with blood, bone, or various patient tissues, and in some cases may be permanently implanted. PTFE suture was shown to be in compliance for the following tests, with applicable results on file at Riverpoint:

(b)(4)

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Conclusion: All testing performed found the Riverpoint PTFE sutures to meet applicable requirements, raising no additional concerns about the potential for issues associated with genotoxicity.



Based on the discussion with the experts at (b) (4) and our interpretation of the ISO 10993 standard, it is Riverpoint Medical's determination that the results of the array of in-vivo and in-vitro testing listed above show the PTFE suture product to meet the requirements of ISO 10993, and is therefore considered as safe as the predicate device as an implantable material with respect to biocompatibility.

 01/21/2014

Doug Rowley
RA/QA Director



FINAL (b)(4) REPORT: (b)(4)

(b)(4) TEST - ISO

Test Article

(b)(4)

*21 CFR Part 58 Compliance
GLP for Nonclinical Laboratory Studies*

Report Date

November 21, 2012

Study Director

(b)(6)

Sponsor

Riverpoint Medical
825 North East 25th Avenue
Portland, OR 97232



Date: 01/07/2014
To: PTFE Biocompatibility File
By: Doug Rowley, QA Director
RE: (b)(4) Testing of PTFE Sutures
CC: (b)(6) RA/QA Manager
Memo: 1/7/14

This memo has been written in order to document the (b)(4) assessment performed for Polytetrafluoroethylene (PTFE) surgical sutures manufactured by Riverpoint Medical.

PTFE materials are widely used throughout the medical industry today for a variety of applications, including permanent implantation at various locations throughout the body. This material is most commonly known by the brand-name Teflon®, and is a stable and inert material.

Riverpoint PTFE surgical sutures are composed of the suture material (PTFE) and a surgical steel suture needle (when applicable). These sutures are nonabsorbable, may come into contact with blood, bone, or various patient tissues, and in some cases may be permanently implanted. As such, biocompatibility testing requirements specified within ISO (b)(4) include an assessment of (b)(4) among other evaluations) for this product type.

As such, the following (b)(4) studies involving Riverpoint PTFE sutures were coordinated by Riverpoint and performed by a qualified independent laboratory:

(b)(4)
(4)

The (b)(4) study types listed above were selected based on discussions with multiple testing laboratories and input from FDA (the PTFE suture 510(k) reviewer in this case). In each study, the PTFE sutures were found to have met applicable requirements, resulting in the conclusion that this product is non-mutagenic.

(b)(4)

In addition to the (b)(4) testing described above, a substantial amount of additional biocompatibility testing has been performed on Riverpoint PTFE sutures in order to ensure compliance with ISO 10993 requirements for this device type. This testing has been summarized within Memo (b)(4) and the referenced documents are on file within the RA/QA Department. All testing performed found the Riverpoint PTFE sutures to meet applicable requirements, raising no additional concerns about the potential for issues associated with genotoxicity.

Created and Approved By:

A handwritten signature of Doug Rowley, dated 01/07/14.

Doug Rowley
QA Director



Date: 01/07/2014
To: PTFE Biocompatibility File
By: Doug Rowley, QA Director
RE: (b)(4) Testing of PTFE Sutures
CC: (b)(6) RA/QA Manager
Memo: (b)(4)

Attachment 1:

(b) (4)
(4) Test (Study Number (b)(4))



Date: 01/07/2014
To: PTFE Biocompatibility File
By: Doug Bradley, QA Director
RE: (b)(4) Testing of PTFE Sutures
CC: (b)(6) (b)(4), RA/QA Manager
Memo: (b)(4)

Attachment 2:

(b)(4) [Redacted] Test (Study Number (b)(4) [Redacted])



Date: 01/07/2014
To: PTFE Biocompatibility File
By: Doug Rowley, QA Director
RE: (b)(4) Testing of PTFE Sutures
CC: (b)(6) IA/QA Manager
Memo: (b)(4)

Attachment 3:

Opinion on (b)(4) of Riverpoint PTFE Sutures

(b)(4)



PTFE Suture 510(k) Submission:

PFOA Information (8 pages total)

(b)(4)



Doug Rowley <rowldoug@gmail.com>

Riverpoint Medical Question - PTFE Manufacturing

2 messages

Doug Rowley <rowldoug@gmail.com>

Mon, Nov 5, 2012 at 3:03 PM

To: (b)(4)

Hello M (b)(6)

I hope this email finds you well.

I have come across a question while preparing regulatory filings for PTFE sutures that I'm hoping you can assist with.

(b)(4) Manufacturing Information

Thank you very much for any assistance that you can provide with this. If you would prefer that I address these types of questions to one of your associates instead, please let me know.

Best regards,

Doug Rowley

Doug Rowley

RA/QA Director

Riverpoint Medical

doug@rmed.com

(b)(4) Manufacturing Information

Gmail - Riverpoint Medical Question - PTFE Manufacturing

<https://mail.google.com/> (b)(4)

Regards,

(b)(6)

(b)(4) Third Party Information

From: Doug Rowley [mailto:rowidoug@gmail.com]
Sent: Monday, November 05, 2012 6:03 PM
To: (b)(6) - FOY
Subject: Riverpoint Medical Question - PTFE Manufacturing

[Quoted text hidden]

Note:

This e-mail message is confidential and intended for the designated recipient(s) or their representative(s) only. If you are not the intended recipient or representative please note that you are not permitted to publish, copy or distribute this message.

In this case please contact us and delete this e-mail and any attachments. Thank you.

(b)(4) Third Party Information



PTFE Suture 510(k) Submission:

**Testing of Predicate and Competitor's Products for Stability Information
(62 pages total)**



CS0618PREM
 Contents: (12) sutures
 18 1/45 cm

CYTOPLAST PTFE
 WHITE MONOFILAMENT
 NON-ABSORBABLE SUTURE



Reverse Cutting
 3/8 Circle 13.1 mm

USP 4-0
EP 1.6
CE 0120



See Instructions For Use
 Do Not Reuse
 Made in USA

107 RCO0157
 8 2016-06
 Exp Date

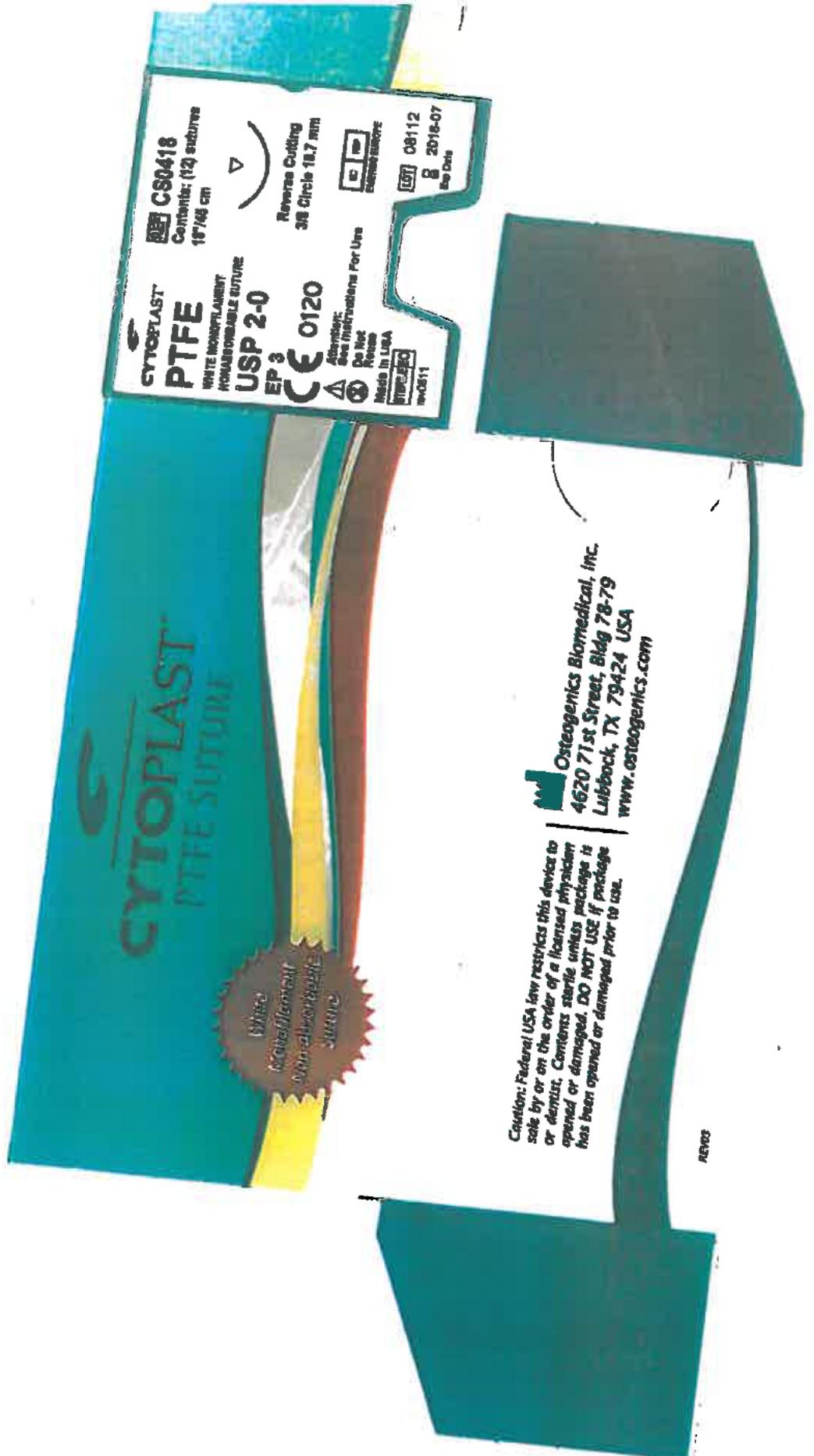
CYTOPLAST PTFE SUTURE

White Monofilament Non-absorbable Suture

Osteogenics Biomedical, Inc.
 4620 71st Street, Bldg 78-79
 Lubbock, TX 79424 USA
www.osteogenics.com

Caution: Federal USA law restricts this device to sale by or on the order of a licensed physician or dentist. Contents sterile unless package is opened or damaged. DO NOT USE if package has been opened or damaged prior to use.

45/03



CYTOPLAST
PTFE
 WHITE NONPLAQUEMANT
 NONABSORBABLE SUTURE
USP 2-0
EP 3
CE 0120
 Conformer:
 See Instructions For Use
 Do Not
 Reuse
 Made in USA
 1940811

CS0418
 Container: (12) sutures
 19"/48 cm

Reverse Cutting
 3/8 Circle 18.7 mm



LOT 08112
 Exp Date 2018-07

CYTOPLAST
PTFE SUTURE

White
 Nonabsorbable
 Suture

Caution: Federal USA law restricts this device to sale by or on the order of a licensed physician or dentist. Contents sterile unless package is opened or damaged. DO NOT USE if package has been opened or damaged prior to use.

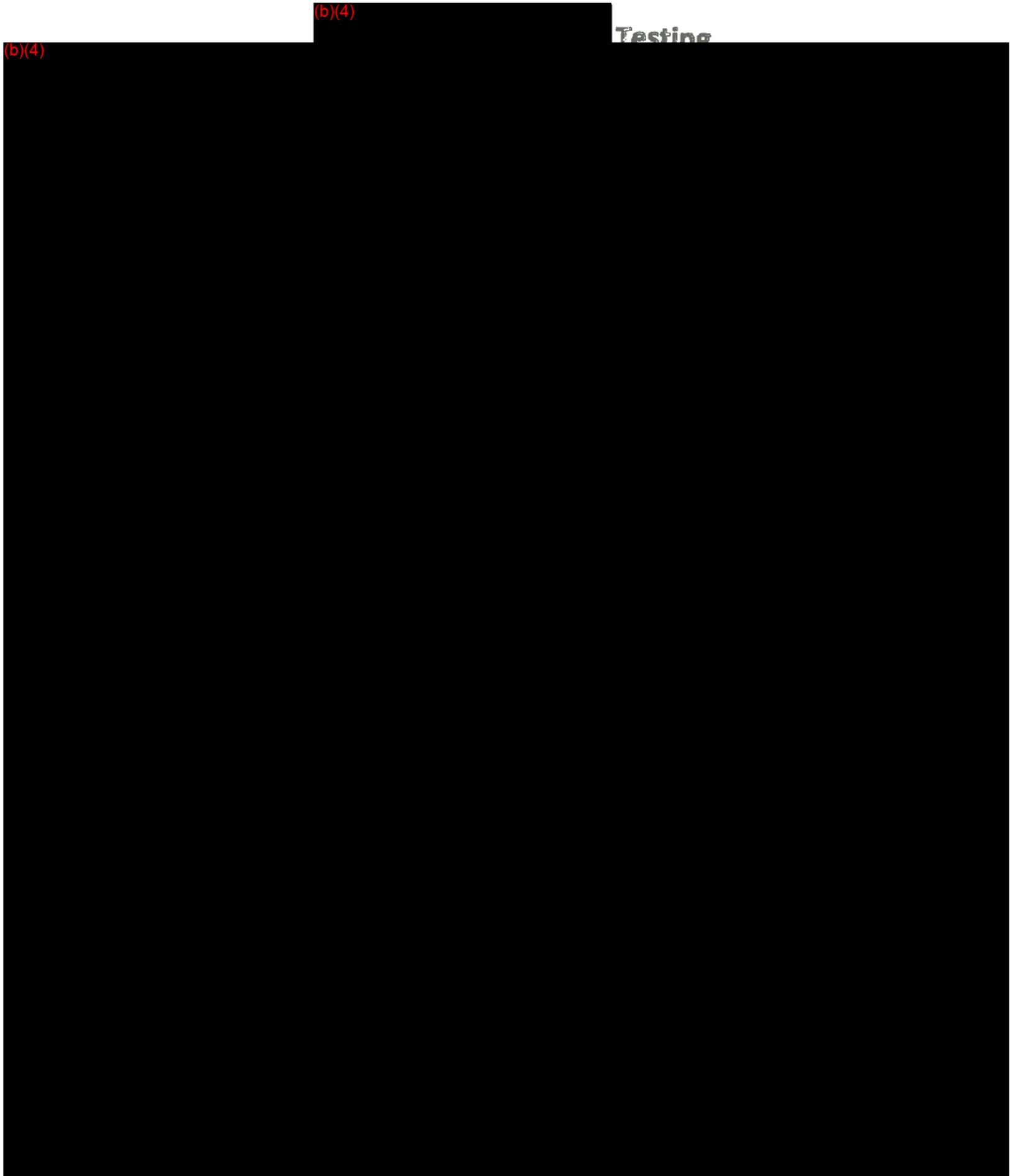
Osteogenics Biomedical, Inc.
 4620 71st Street, Bldg 78-79
 Lubbock, TX 79424 USA
www.osteogenics.com

REV03

(b)(4)

Testing

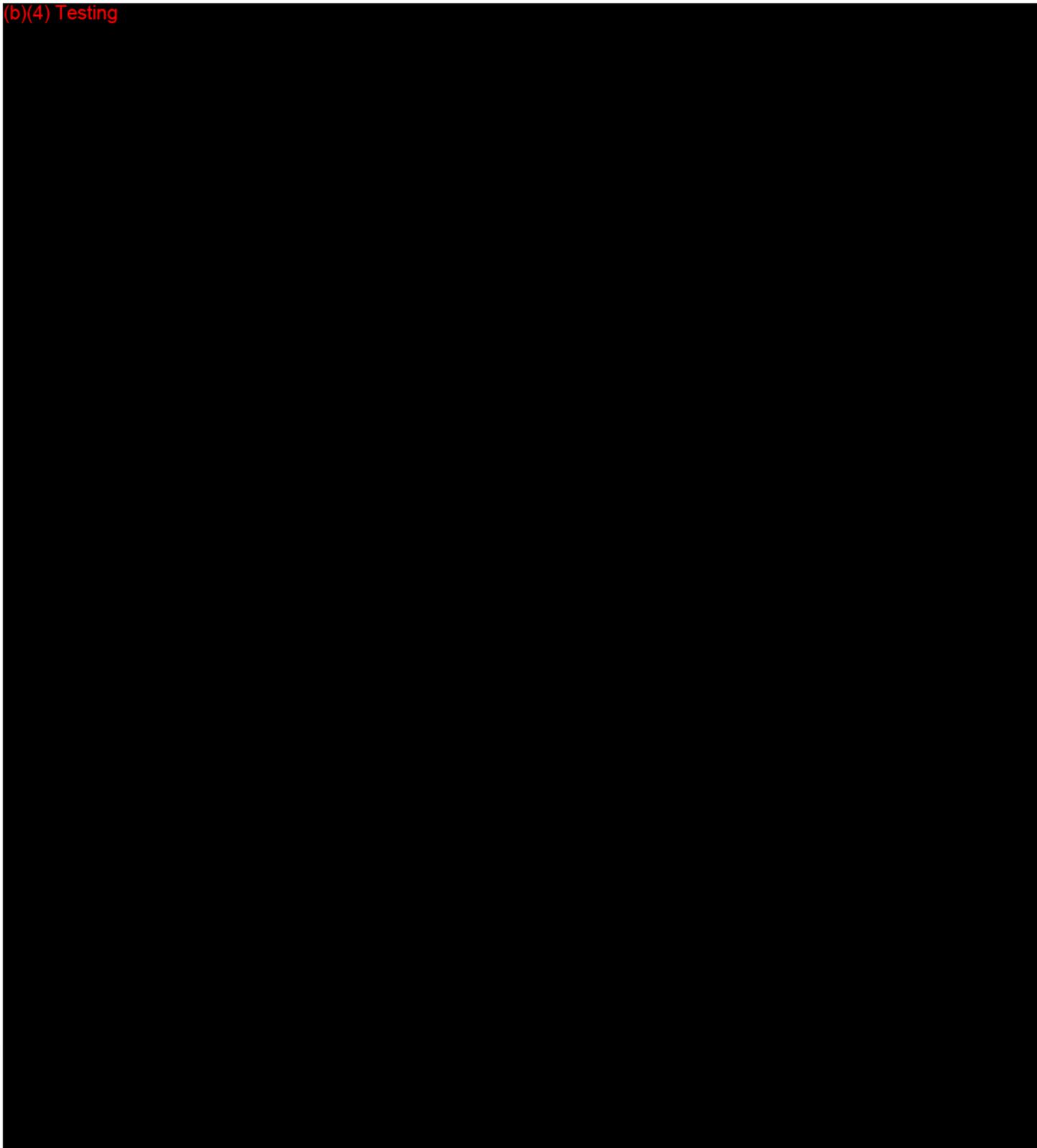
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Riverpoint Medical
825 NE 25th Avenue
Portland, Oregon 97232

Phone: 503.517.8001
www.rpmed.com

(b)(4) Testing

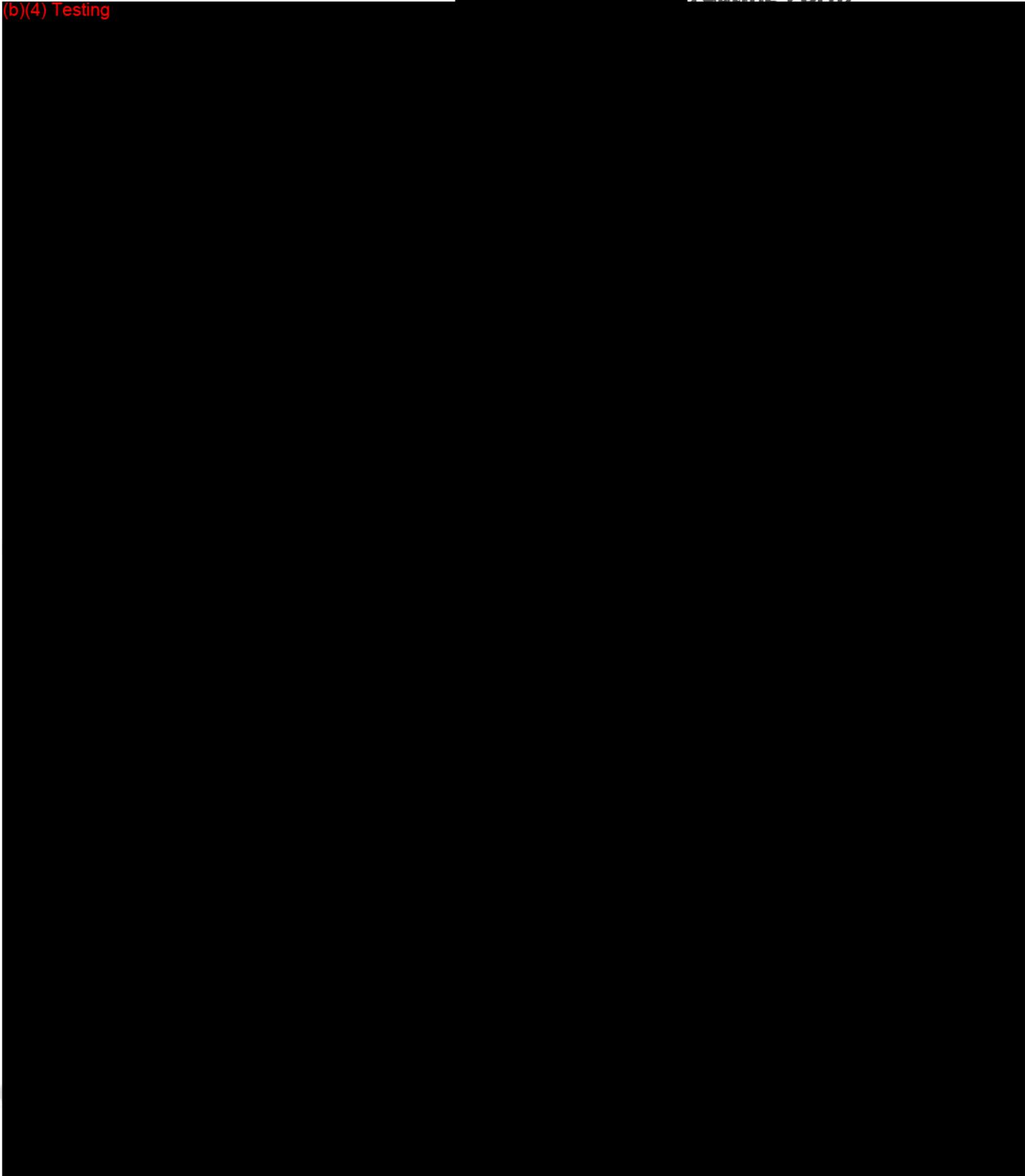


Riverpoint Medical

(b)(4) Testing

Testing Form

(b)(4) Testing

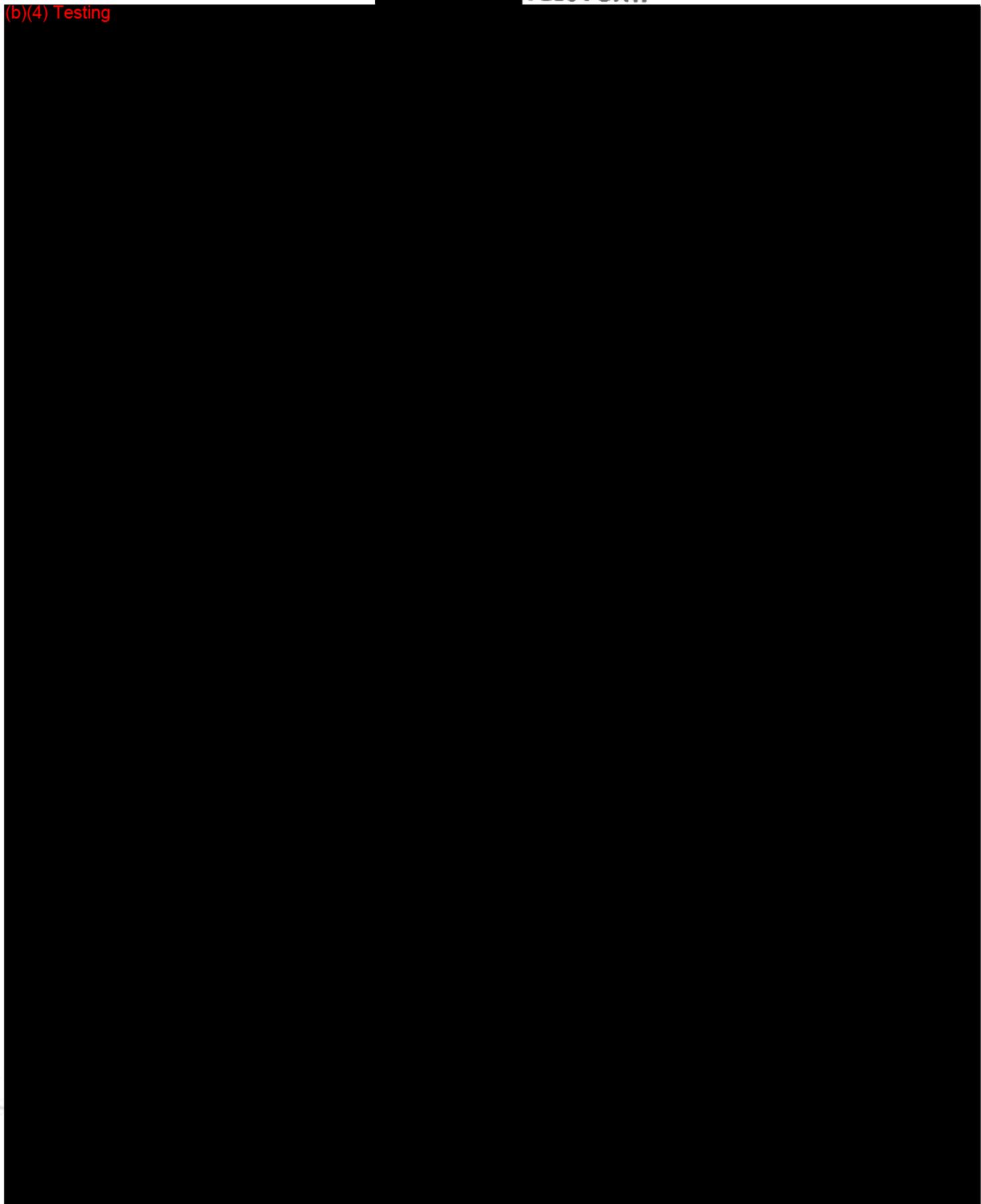


COORDINATOR

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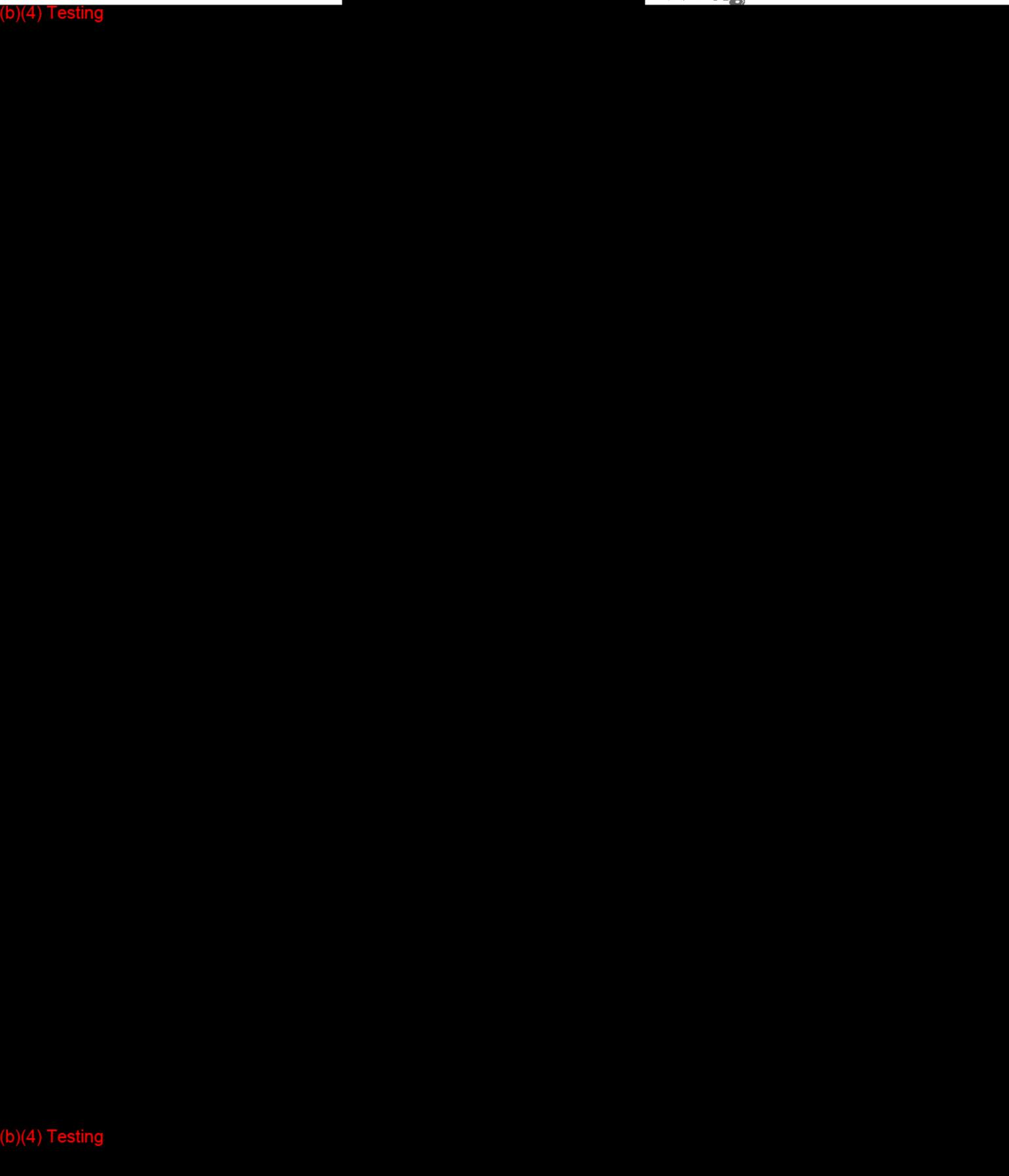
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(b)(4) Testing

Testing

(b)(4) Testing



(b)(4) Testing

COORDINATOR

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(b)(4) Testing



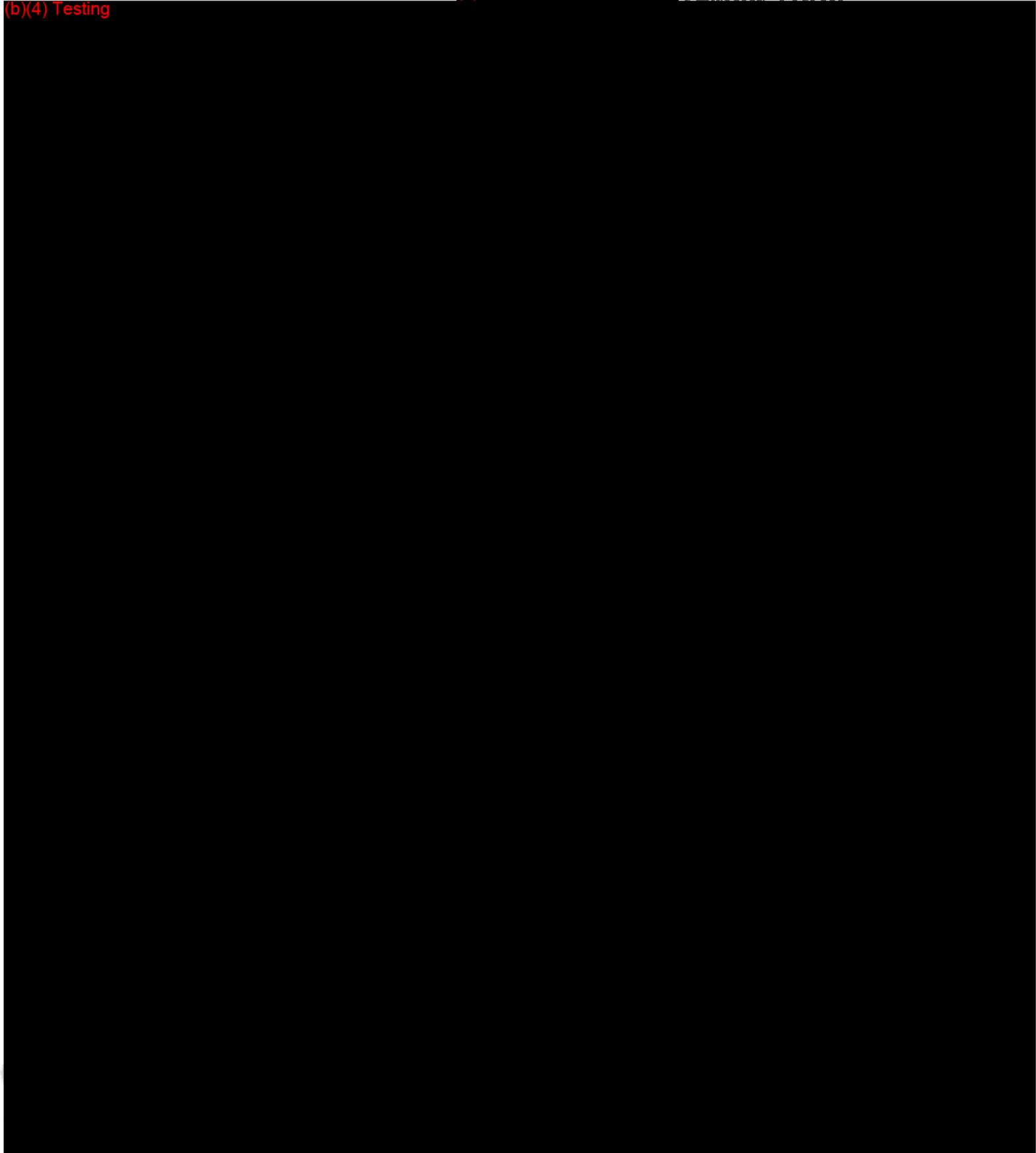
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Riverpoint Medical

(b) (4) Testing
(4)

Testing Form

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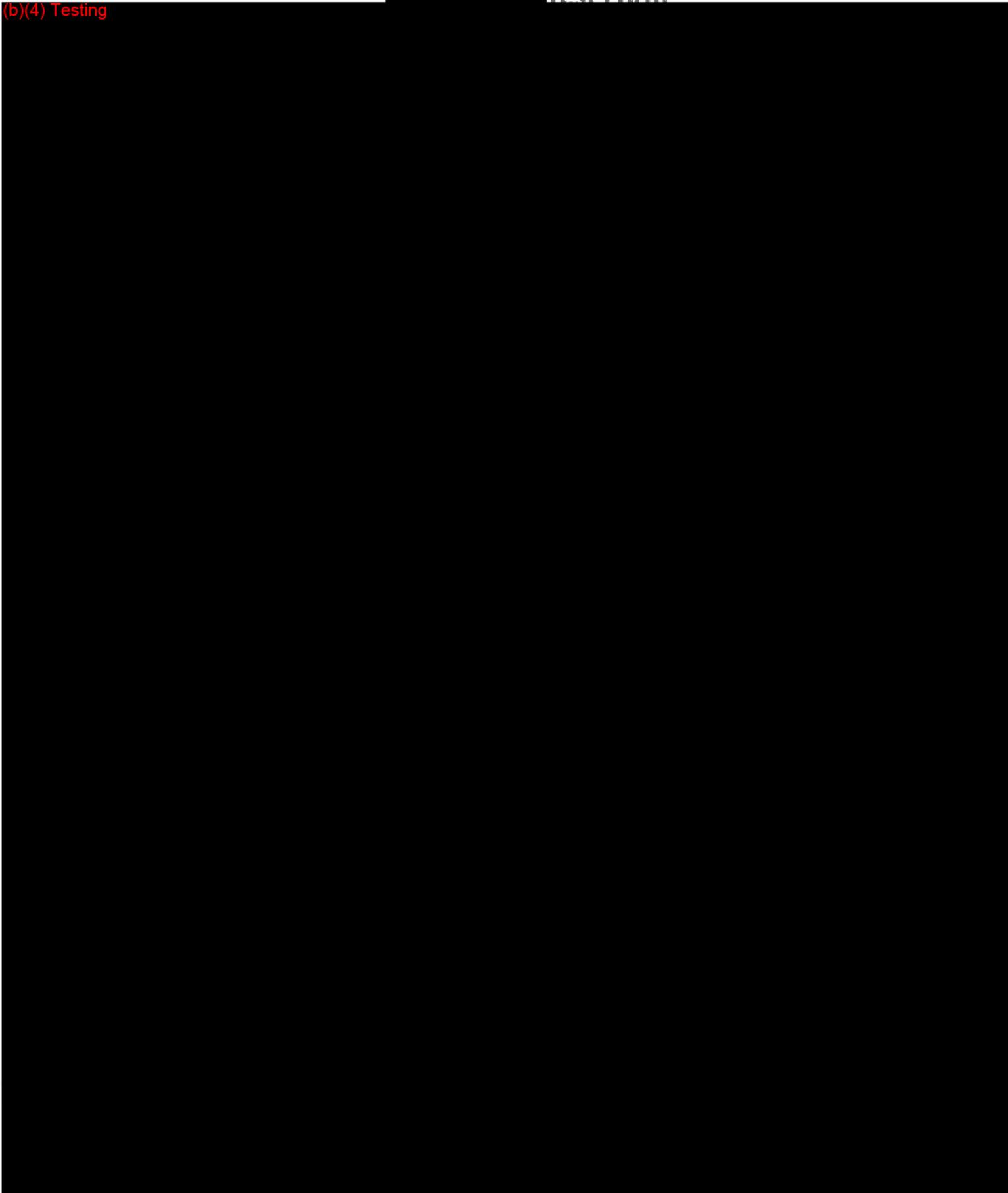


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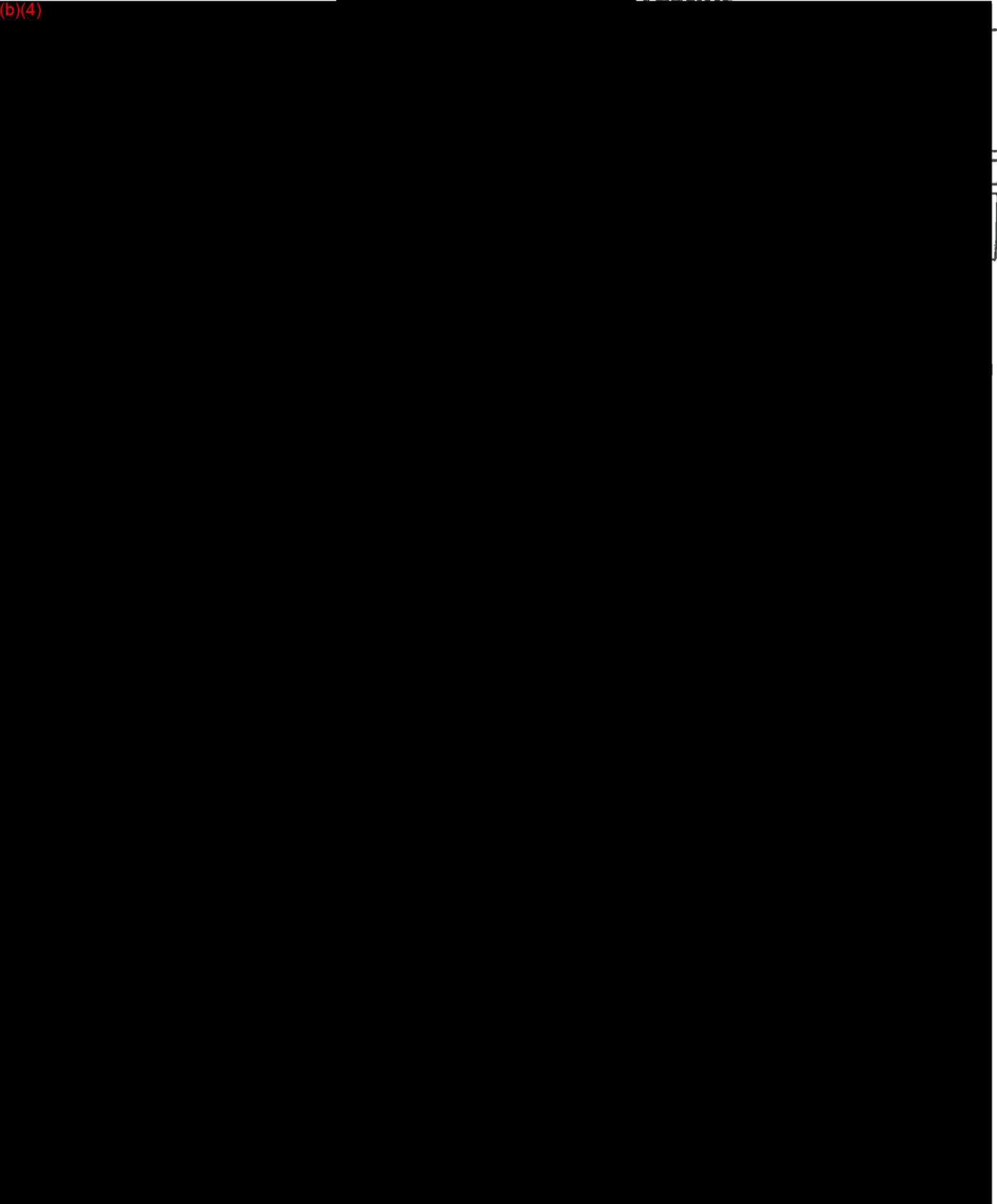
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(b)(4)

Testing

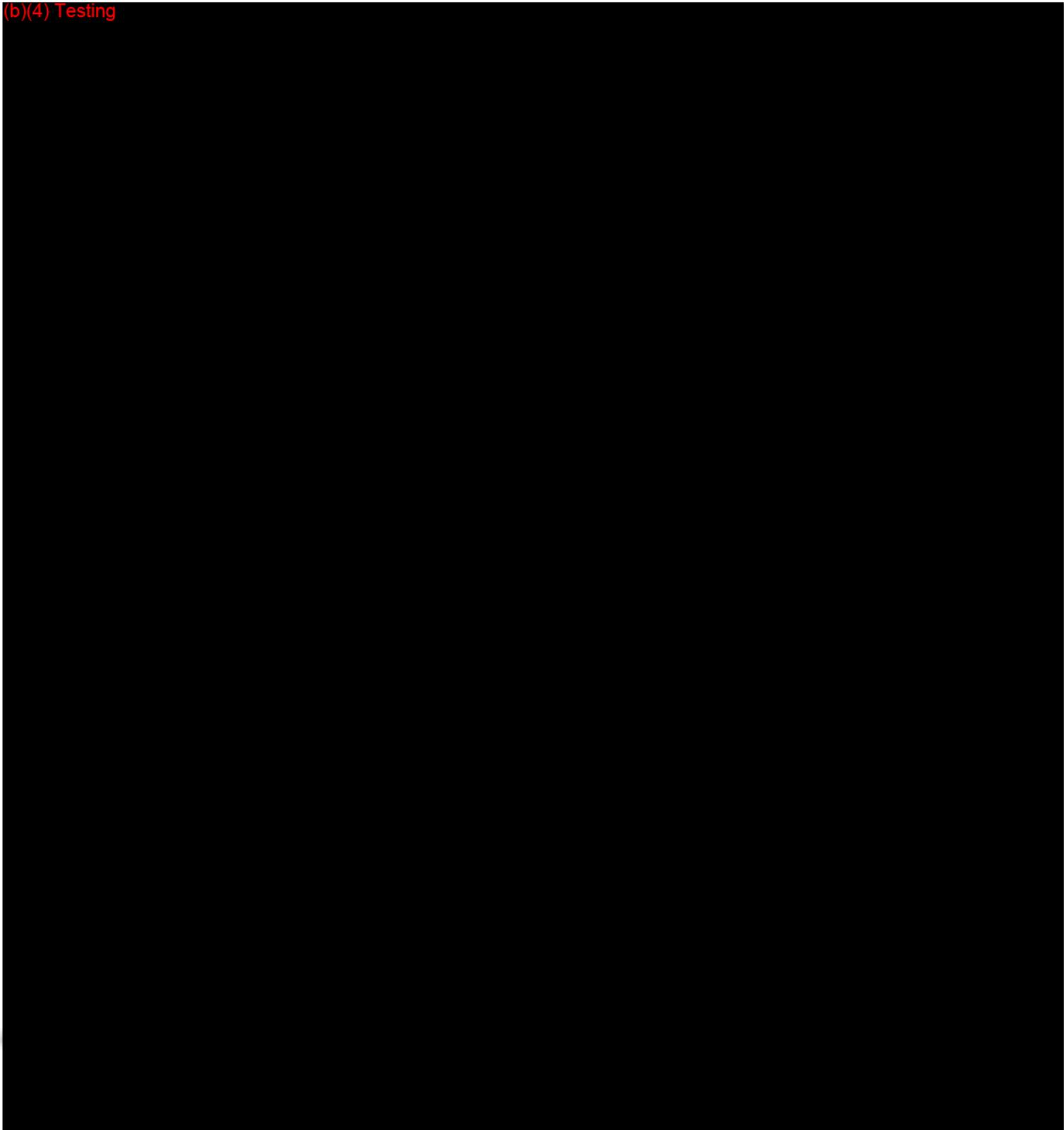
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Phone: 503.517.8001
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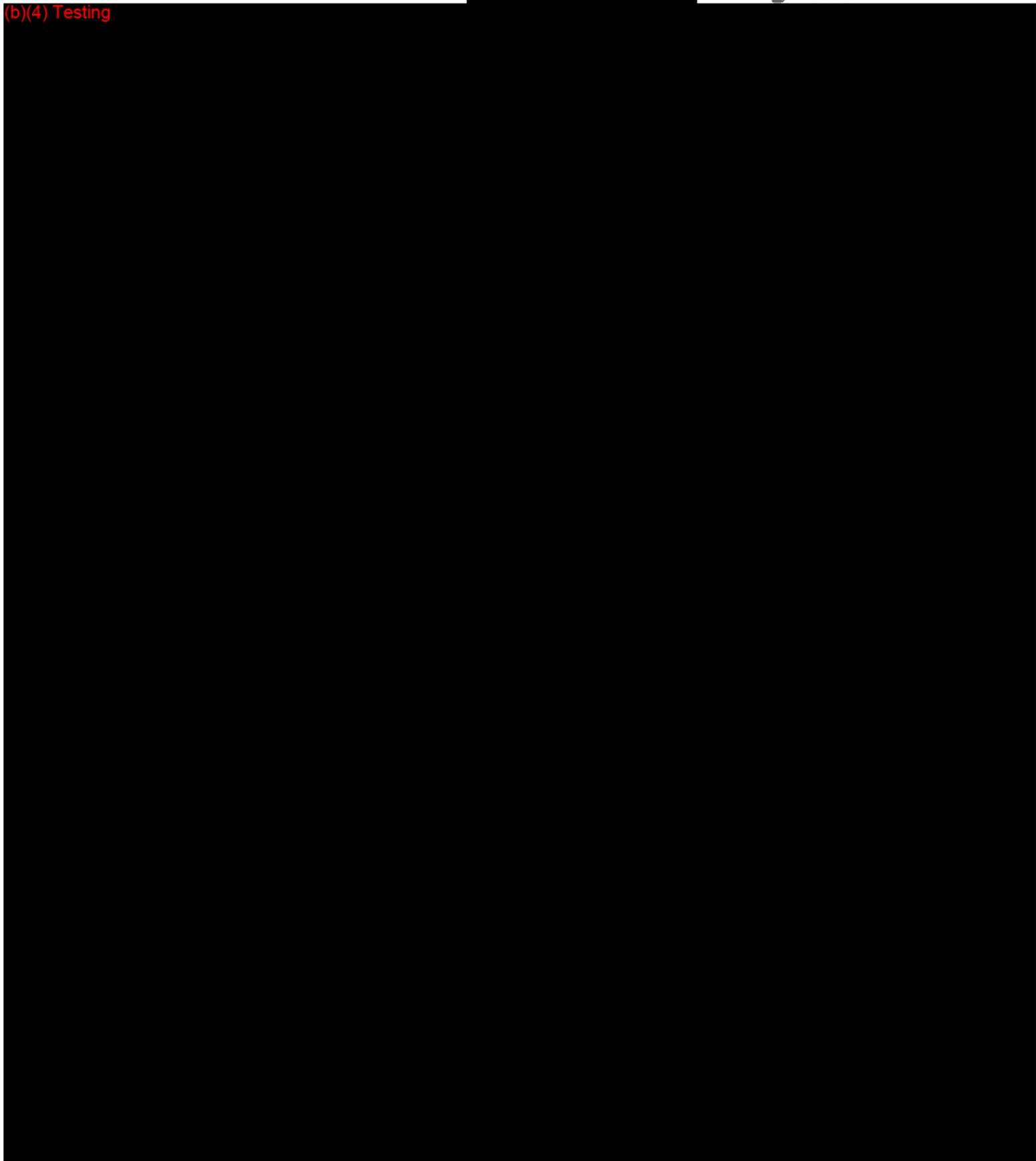
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Riverpoint Medical (b)(4) Testing

Testing Form

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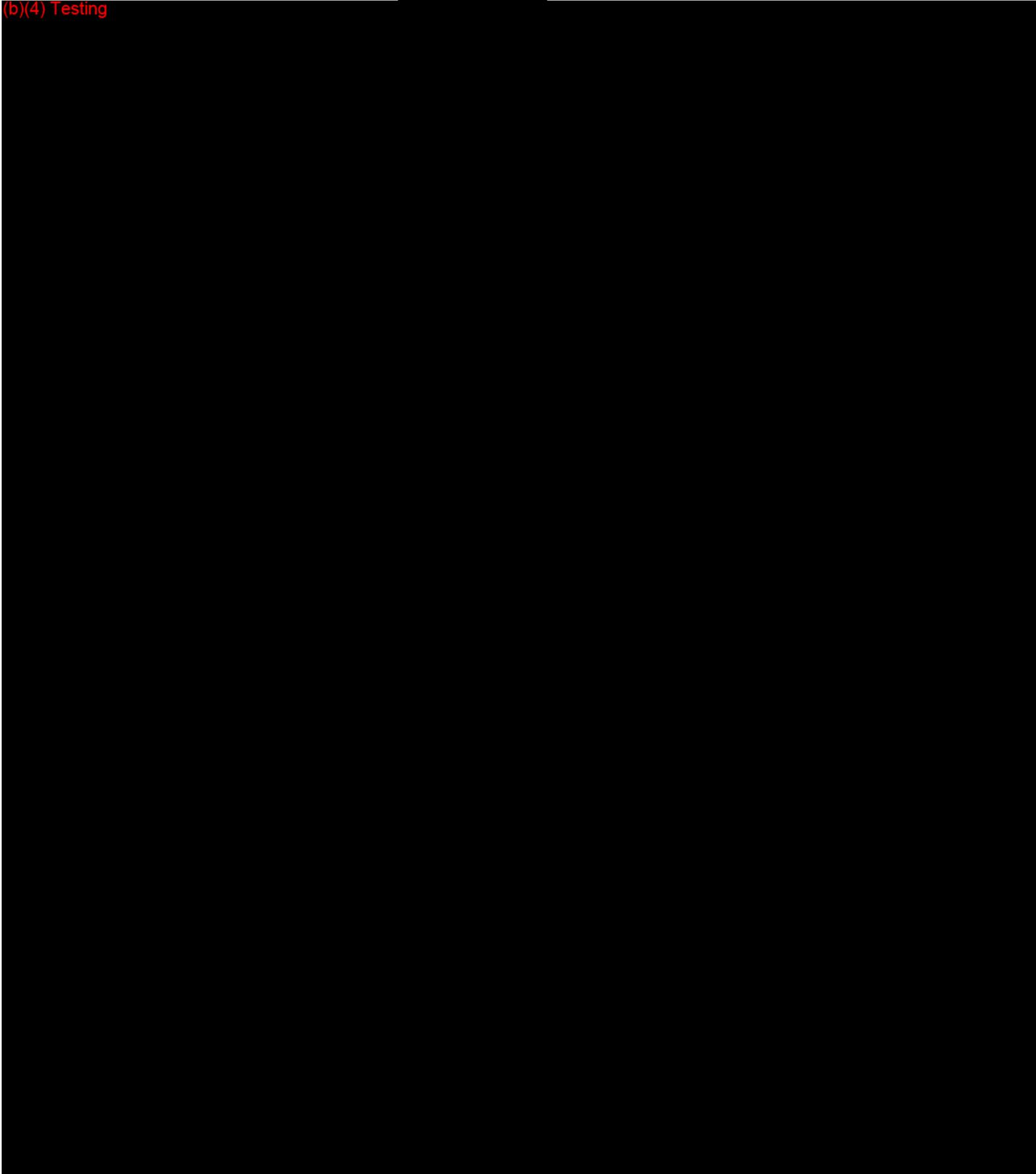


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Test Form

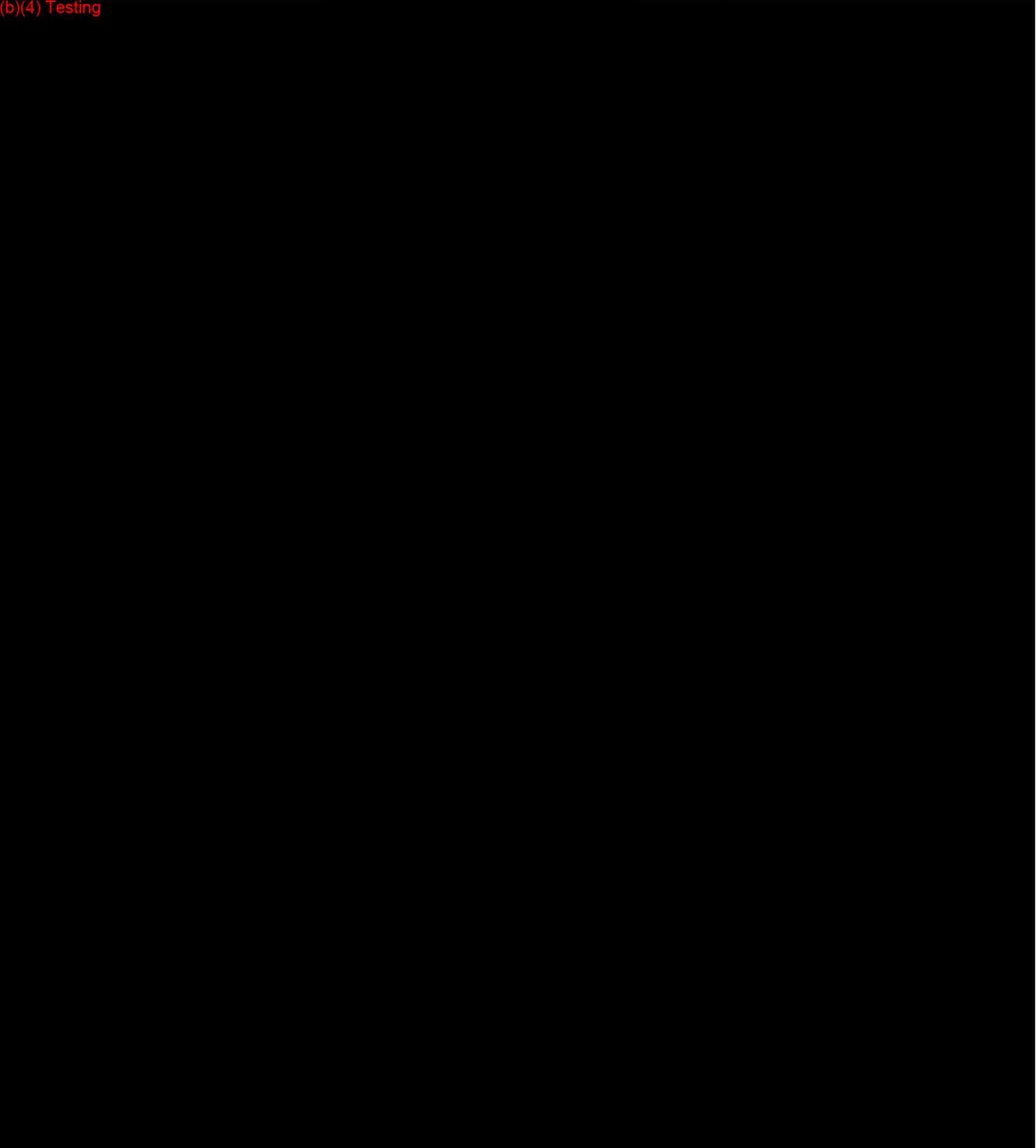
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(b)(4) Testing

Testing

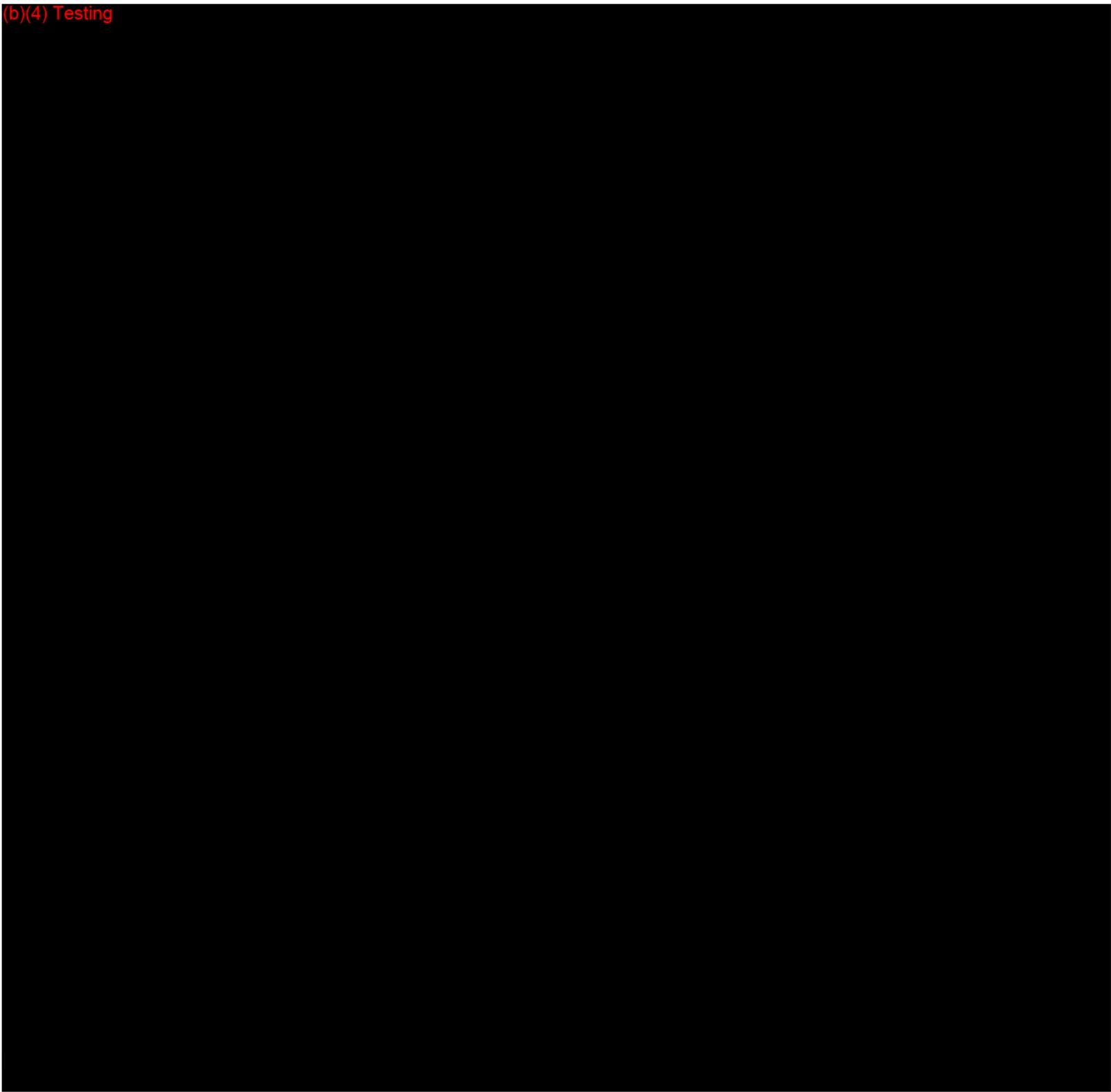
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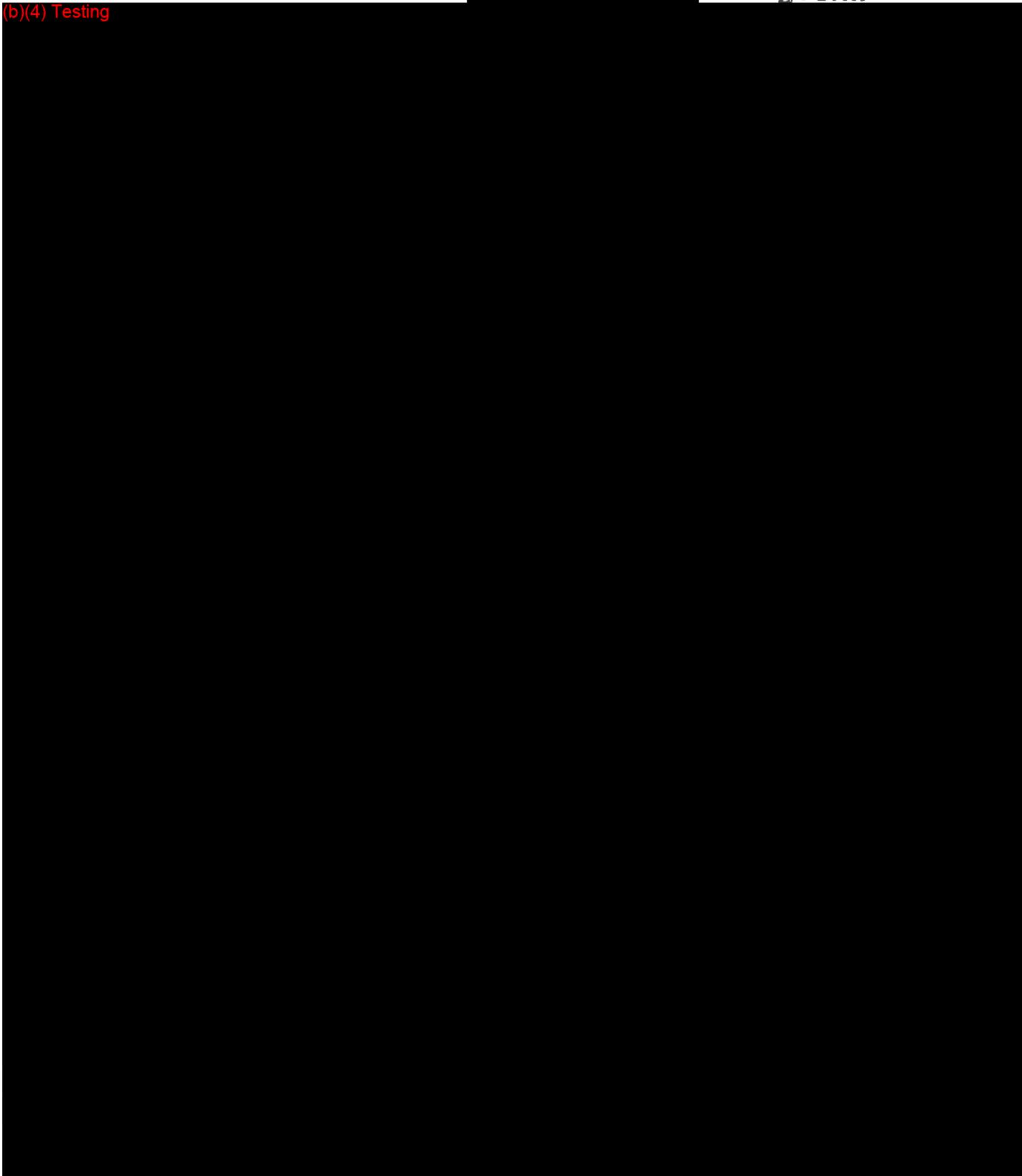
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Riverpoint Medical (b)(4) Testing

Testing Form

(b)(4) Testing

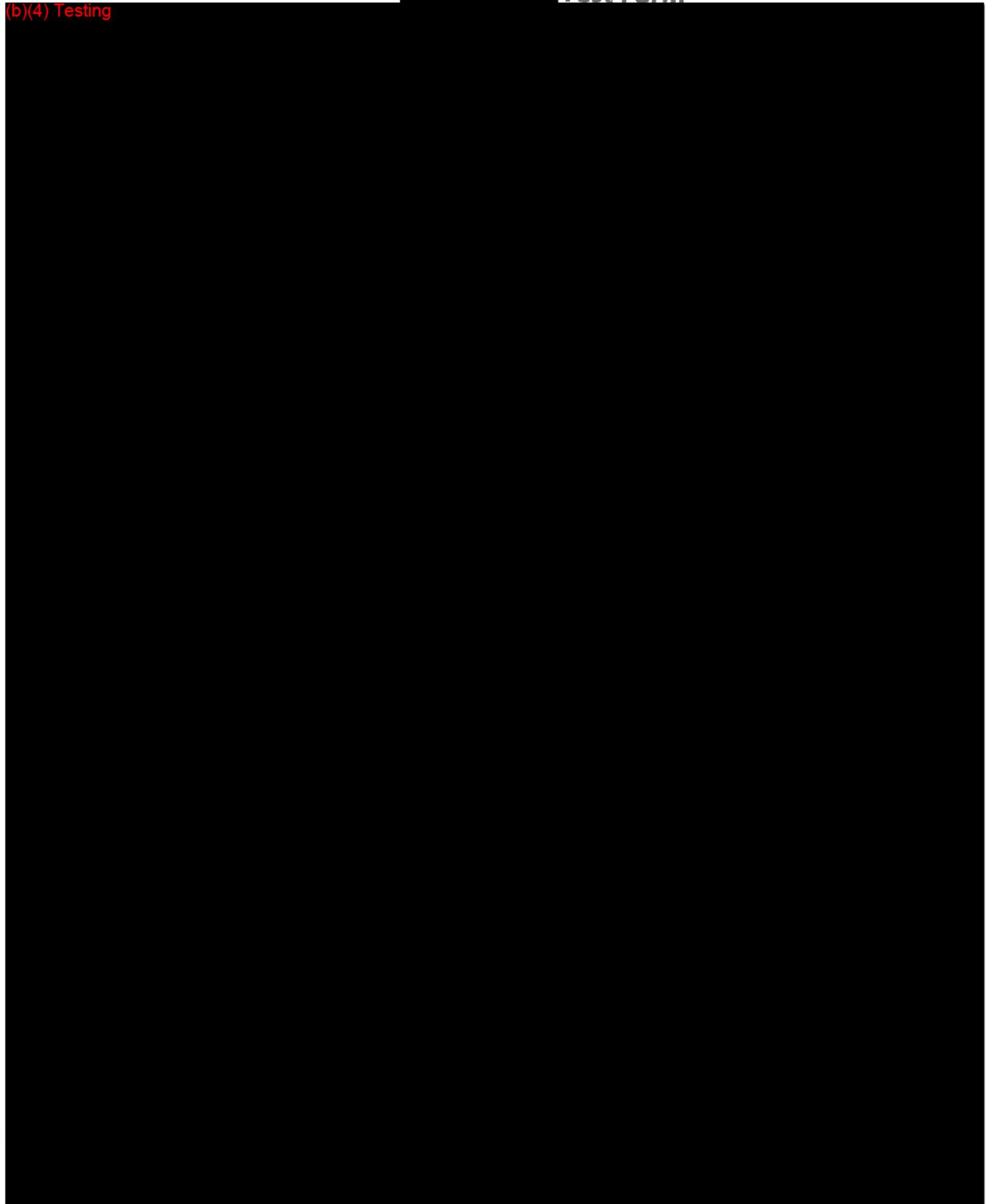


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Test Form

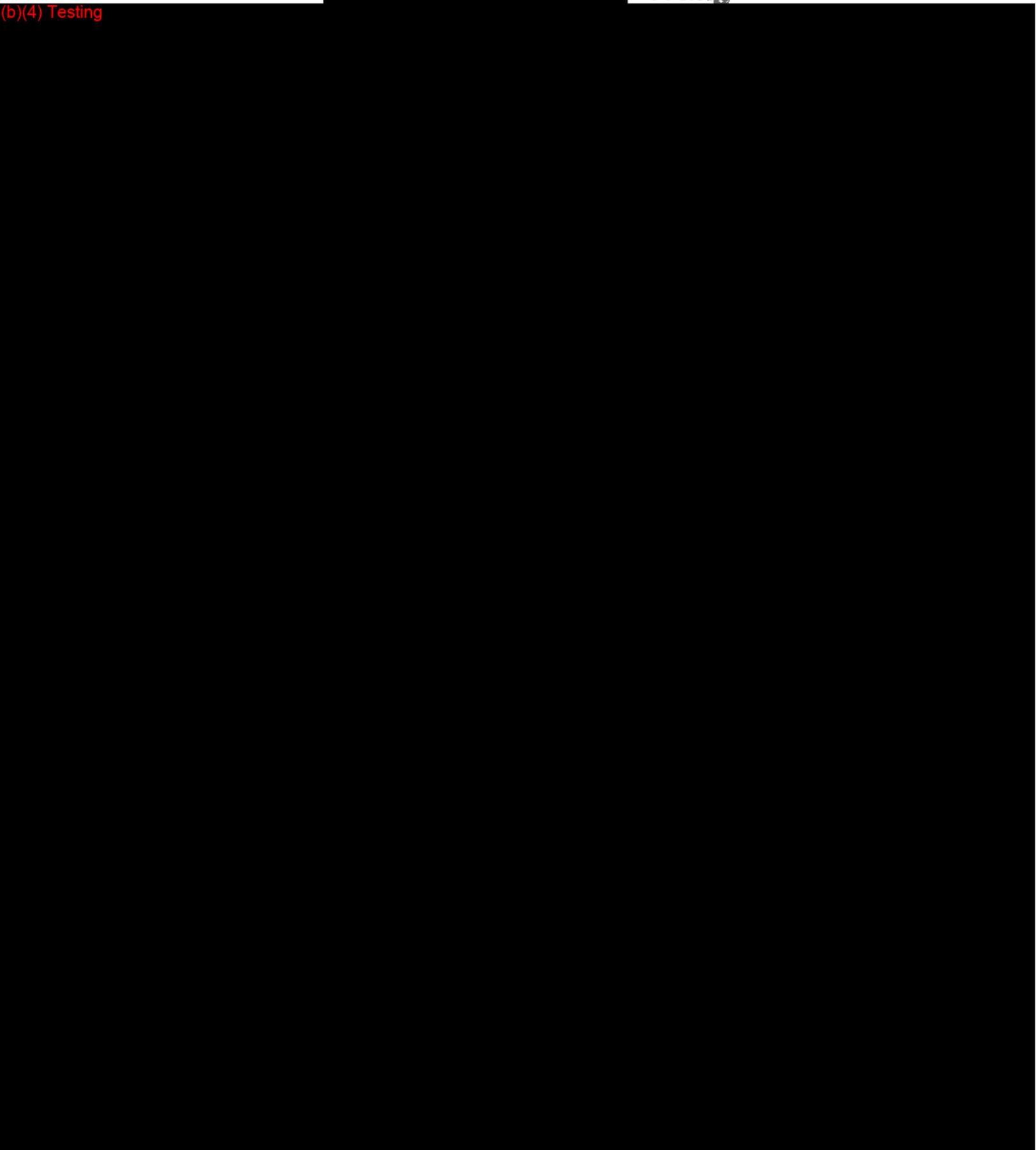
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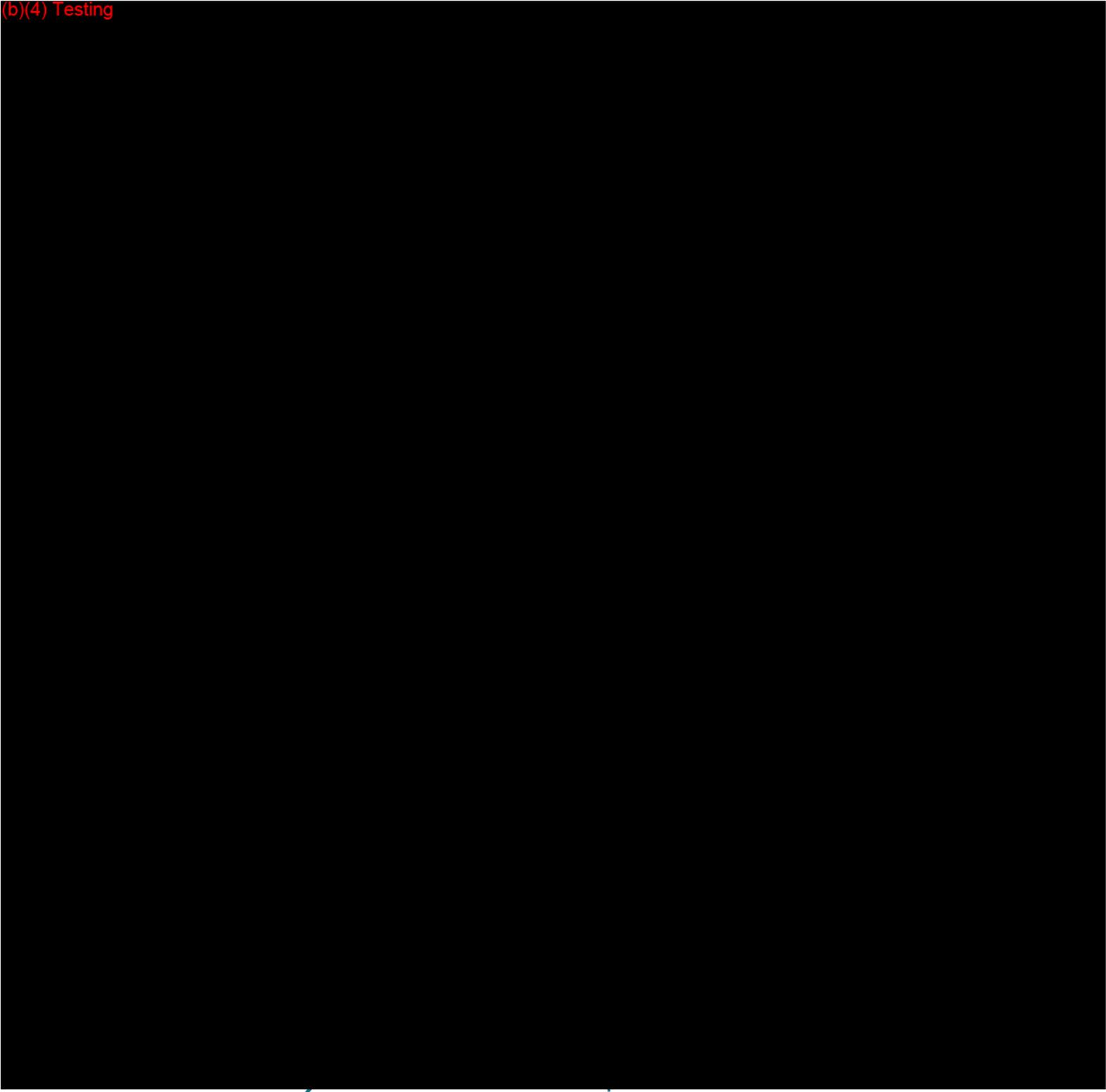
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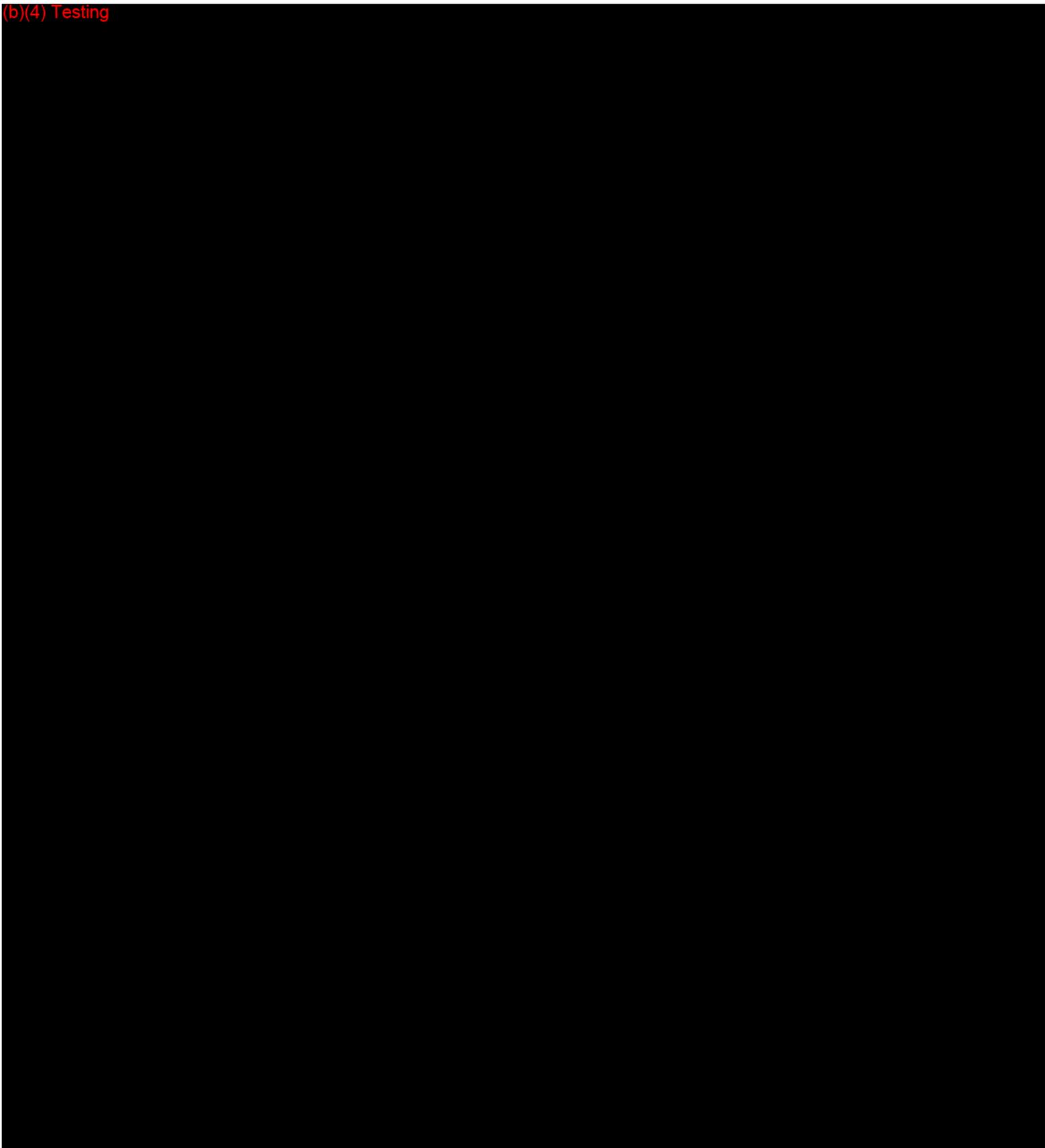
Phone: 503.517.8001
www.rpmed.com

(b)(4) Testing



Riverpoint Medical (b)(4) Testing **Testing Form**

(b)(4) Testing

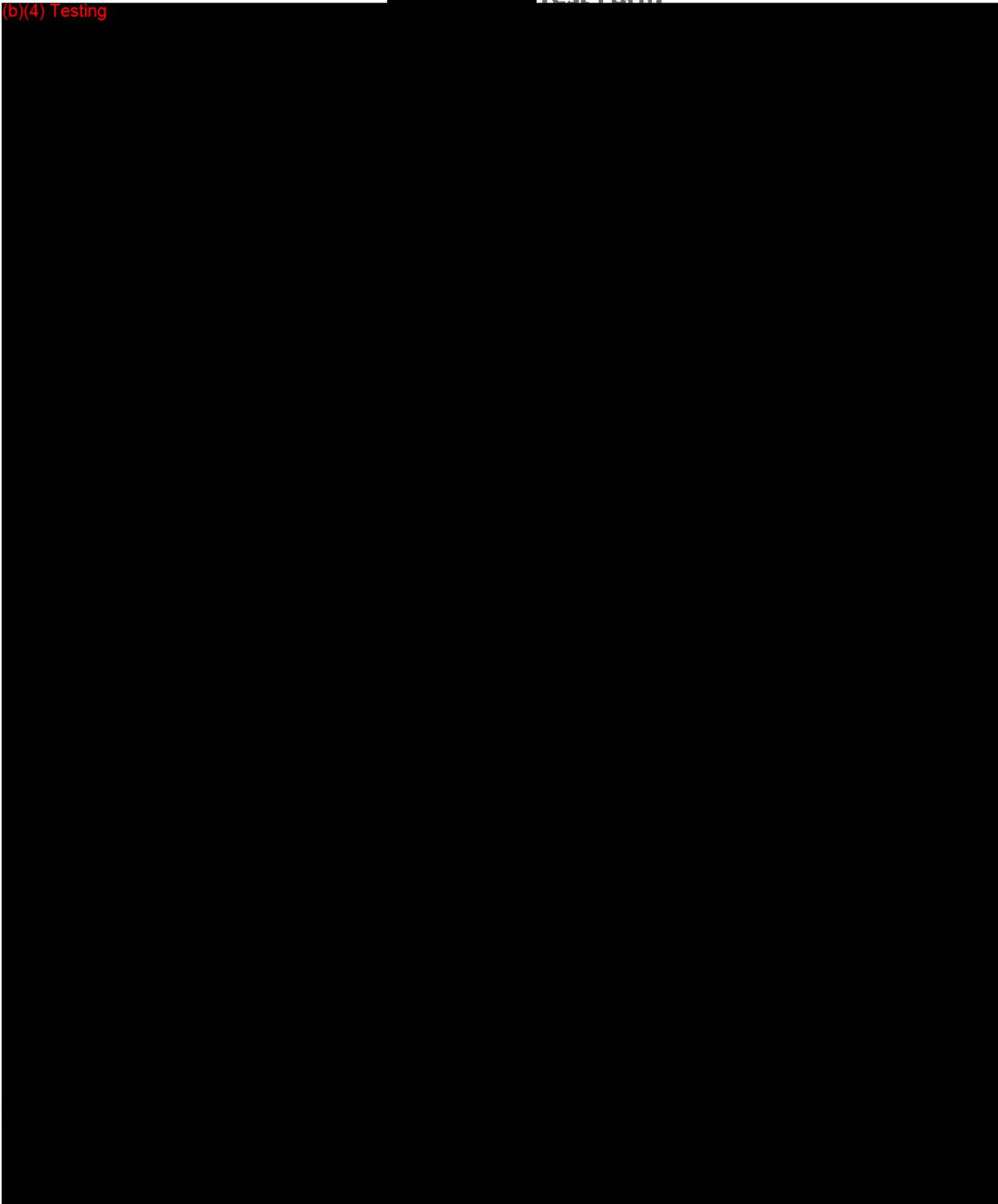


COORDINATOR

(b)(4) Testing

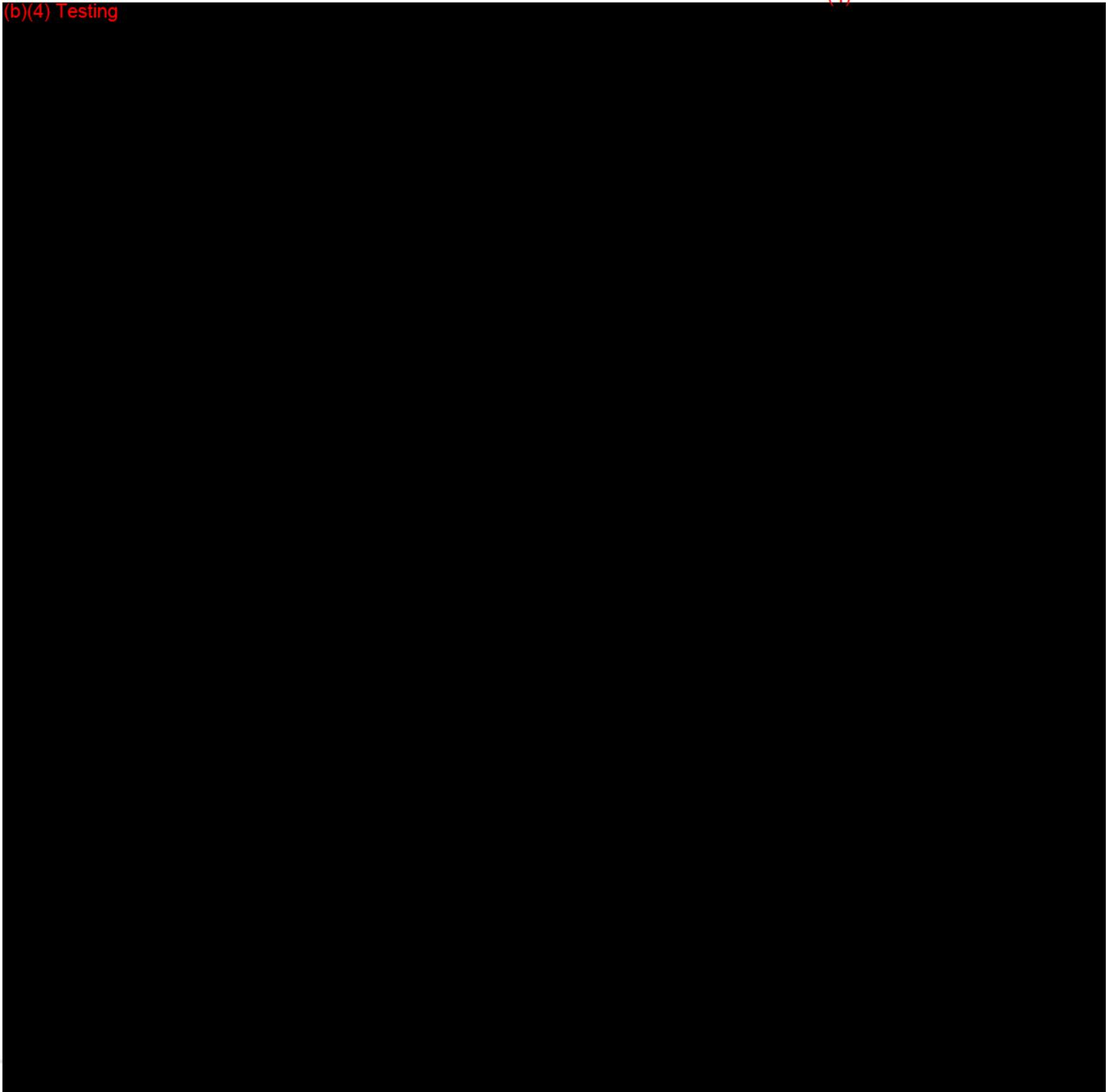
Test Form

(b)(4) Testing



	Test Report: (b)(4) Testing		
	TITLE: (b)(4) Testing		TESTING
	Issued by: Quality Assurance	Eff. Date: 06/14/13	Rev.: (b)(4) Pg. 1 of 4

(b)(4) Testing



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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

	Test Report: (b)(4) Testing		
	TITLE: (b)(4) Testing	TESTING	
	issued by: Quality Assurance	Eff. Date: 06/14/13	Rev: (b)

(b)(4) Testing



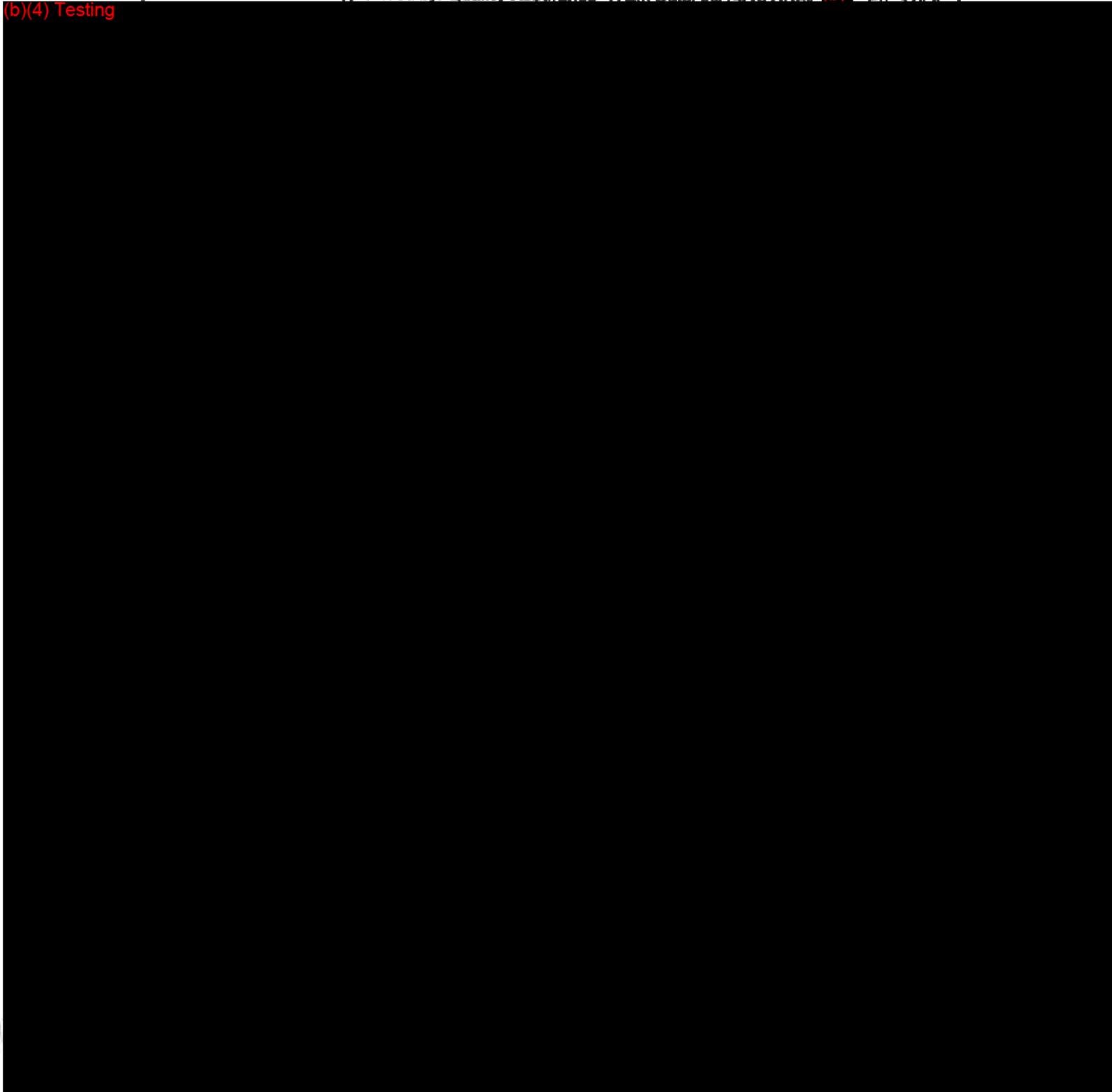
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DOCUMENT
COORDINATOR

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 RIVERPOINT MEDICAL	Test Report (b)(4) Testing		
	TITLE: (b)(4) Testing	TESTING	
	Issued by: Quality Assurance	Eff. Date: 06/14/13	Rev: (b)

(b)(4) Testing



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 RIVERPOINT MEDICAL	Test Report: (b)(4) Testing		
	TITLE: (b)(4) Testing		
	Issued by: Quality Assurance	Eff. Date: 06/14/13	Rev: (b)(4) Pg. 4 of 4

7.0 REVISION HISTORY

Revision	Details	Reviewers	Effective Date
(b)(4)	Initial Release	See (b)(4) Testing	06/14/2013
(4)			

COPY

**DOCUMENT
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Attachment 1: (b)(4) Testing [redacted] Test Data Sheet

((b)(4) Testing [redacted] Attachment)
(b)(6) [redacted] 18/13

COPY

RIVERPOINT MEDICAL	Work Instruction (b)(4)		
	TITLE: ATTACHMENT 1		
	Issued by: Quality Assurance	Eff. Date: 07/07/10	Rev. (b)(4) 4) Pg. 1 of 1

ATTACHMENT 1:

COPY

(b)(4)

Test Data Sheet



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Attachment 2:

(b)(4) [Redacted] Results and All Applicable Data

(b)(4) [Redacted] Attachment)
(b)(6) [Redacted] 06/18/13

COPY

(b)(4)

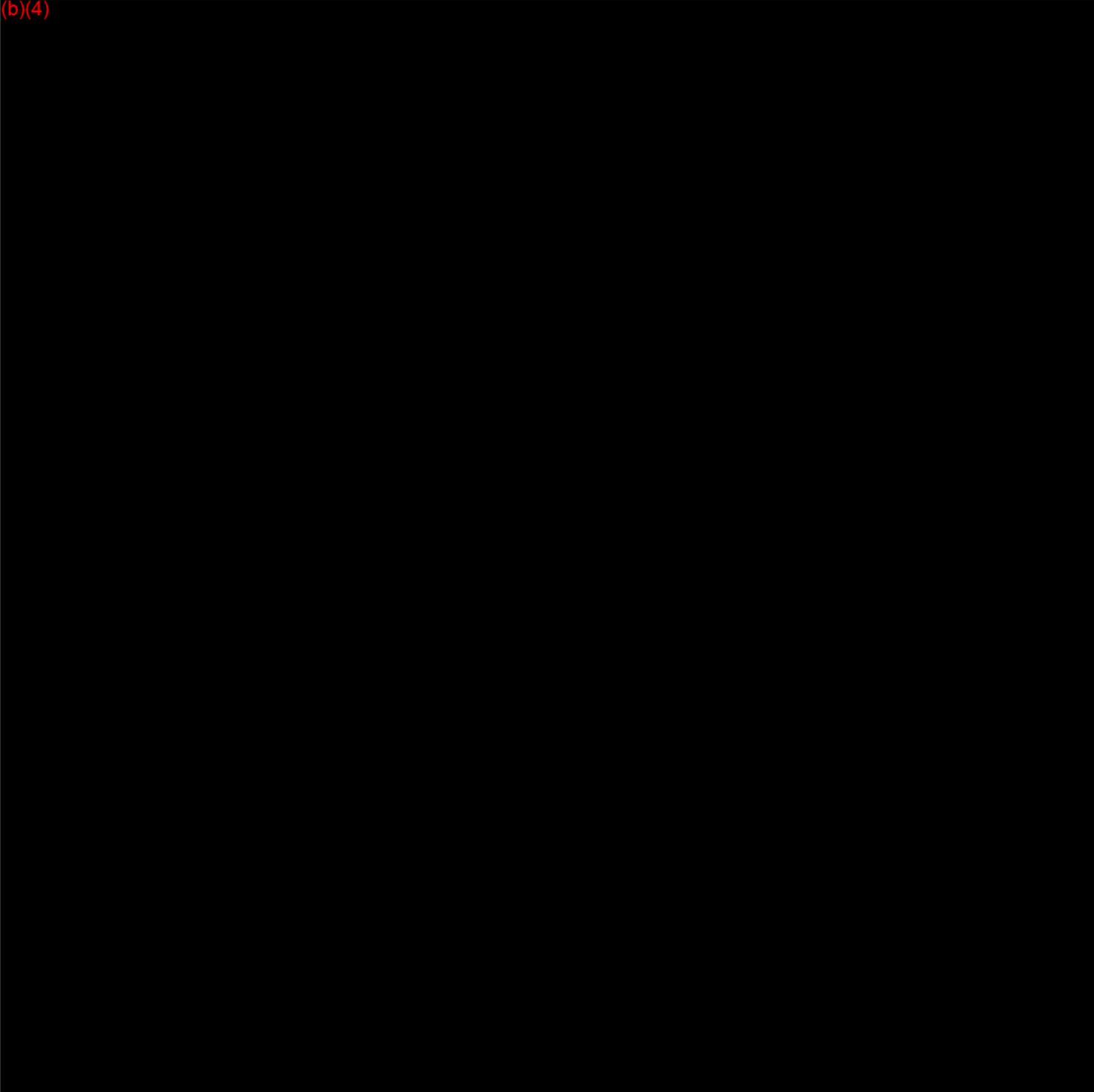
Testing

(b)(4)

Riverpoint Medical
825 NE 25th Avenue
Portland, Oregon 97232

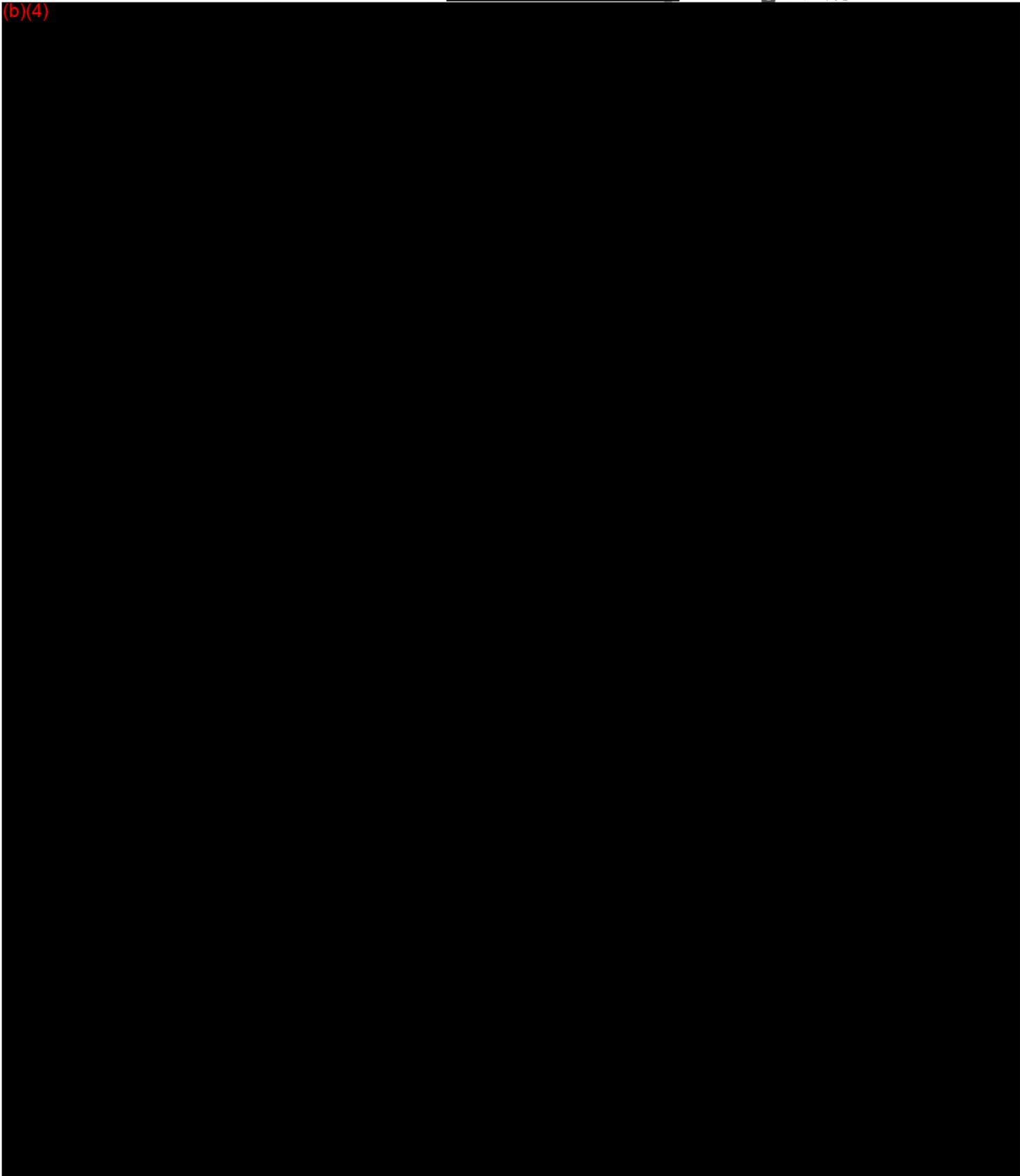
Phone: 503.517.8001
www.rpmed.com

(b)(4)



COPY

Riverpoint Medical (b)(4) Testing Form



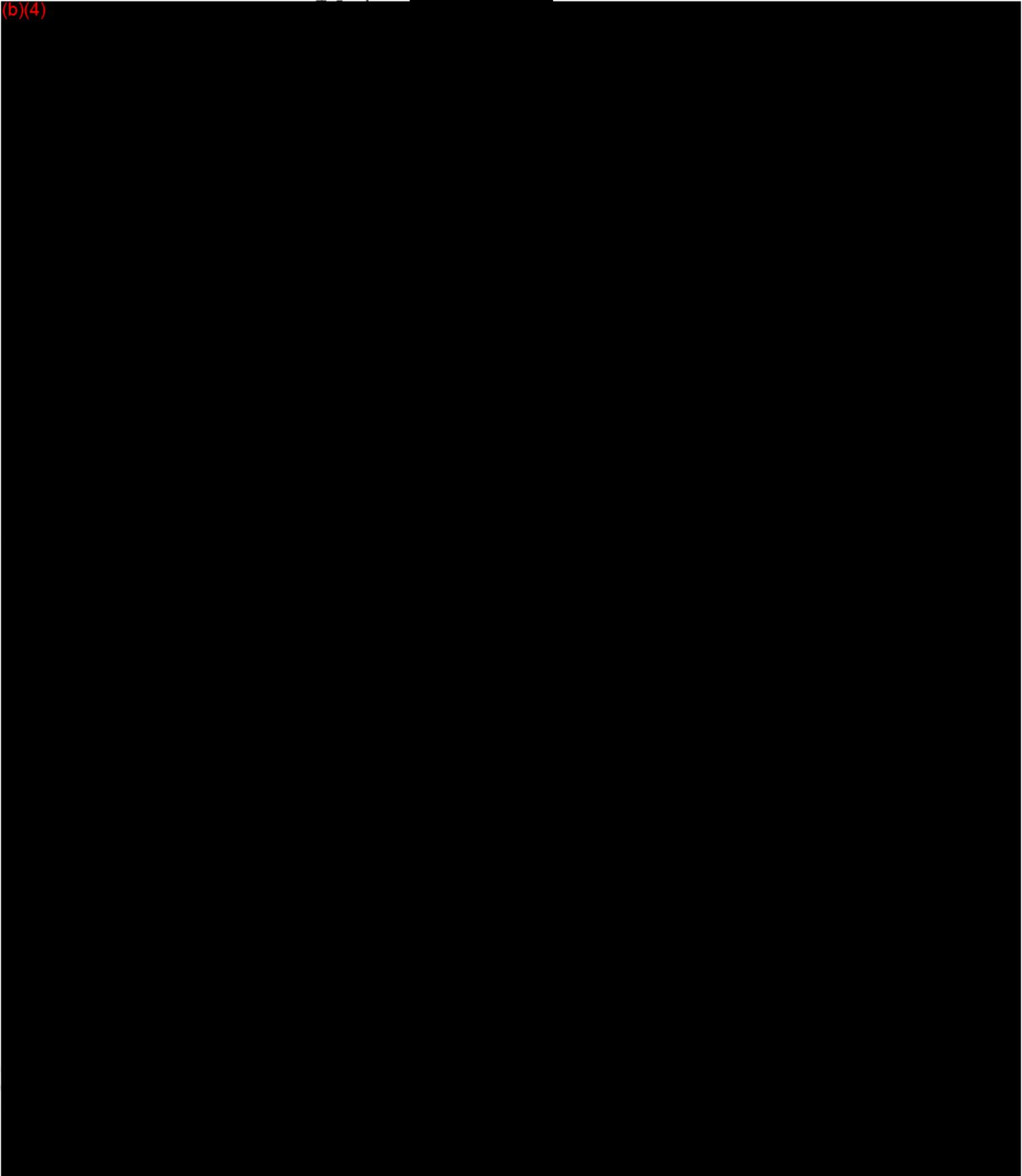
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DOCUMENT
COORDINATOR

(b)(4)

Test Form

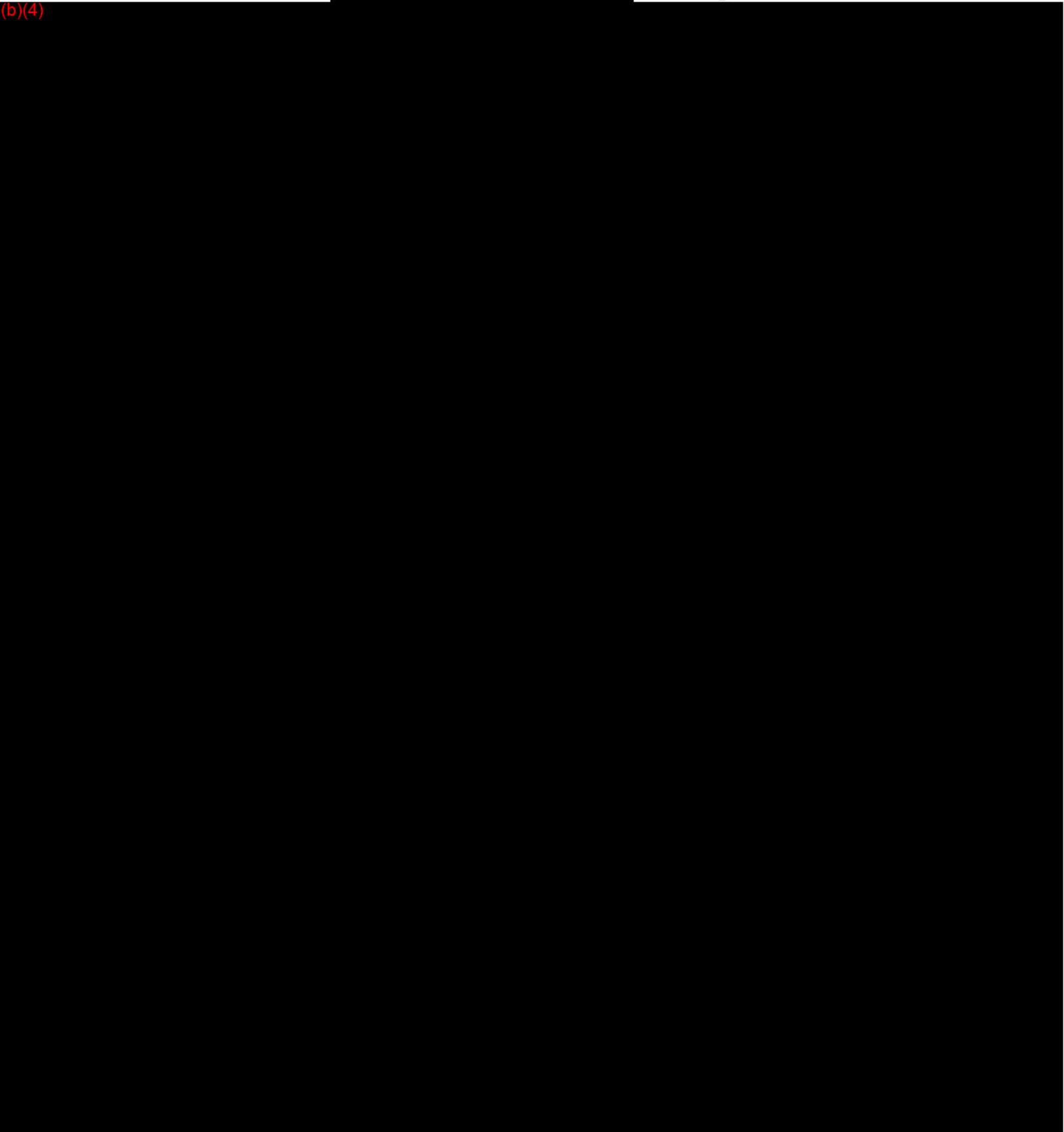
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(b)(4)

Testing

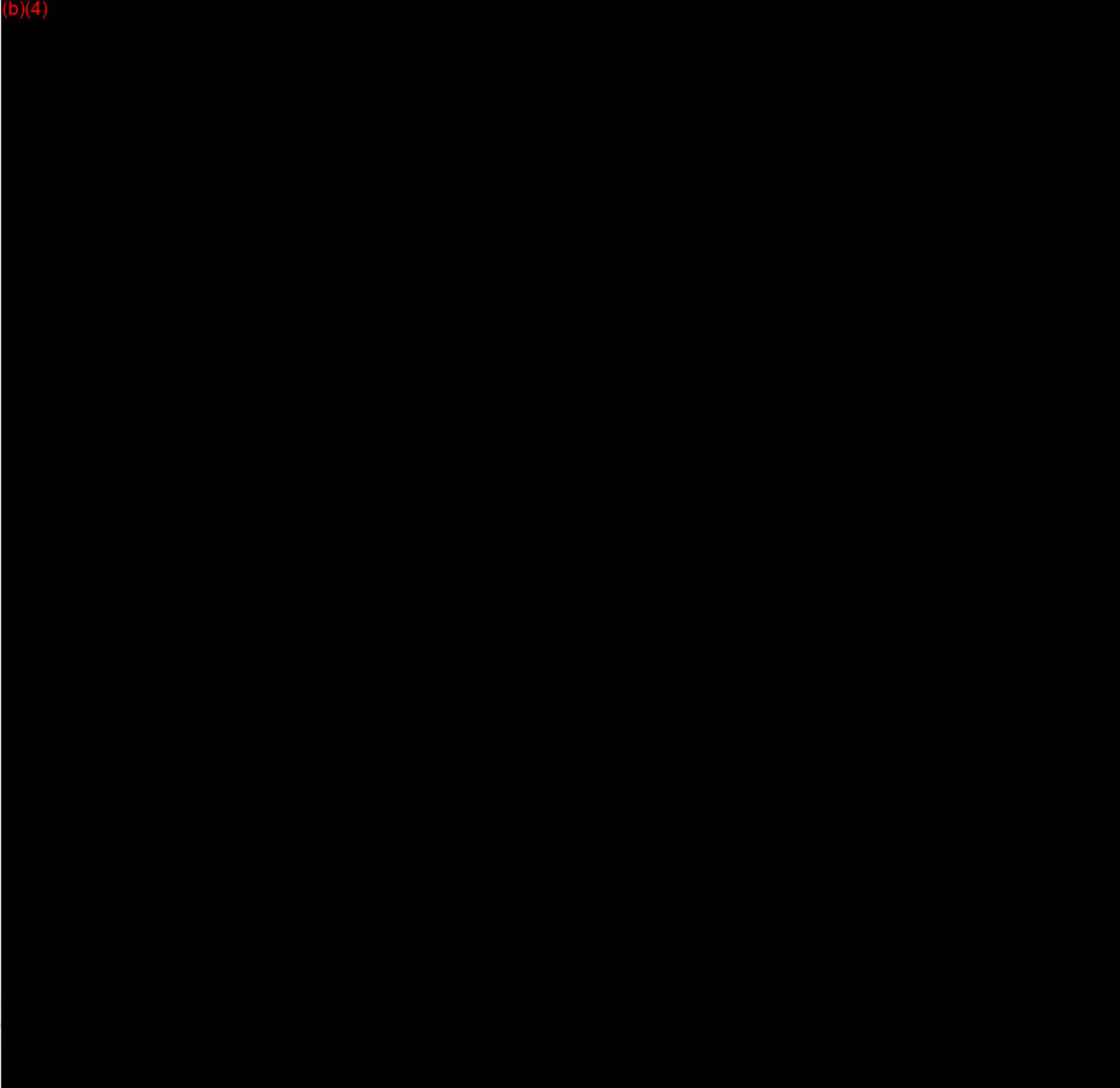
(b)(4)



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(b)(4)



Riverpoint Medical

(b)(4)

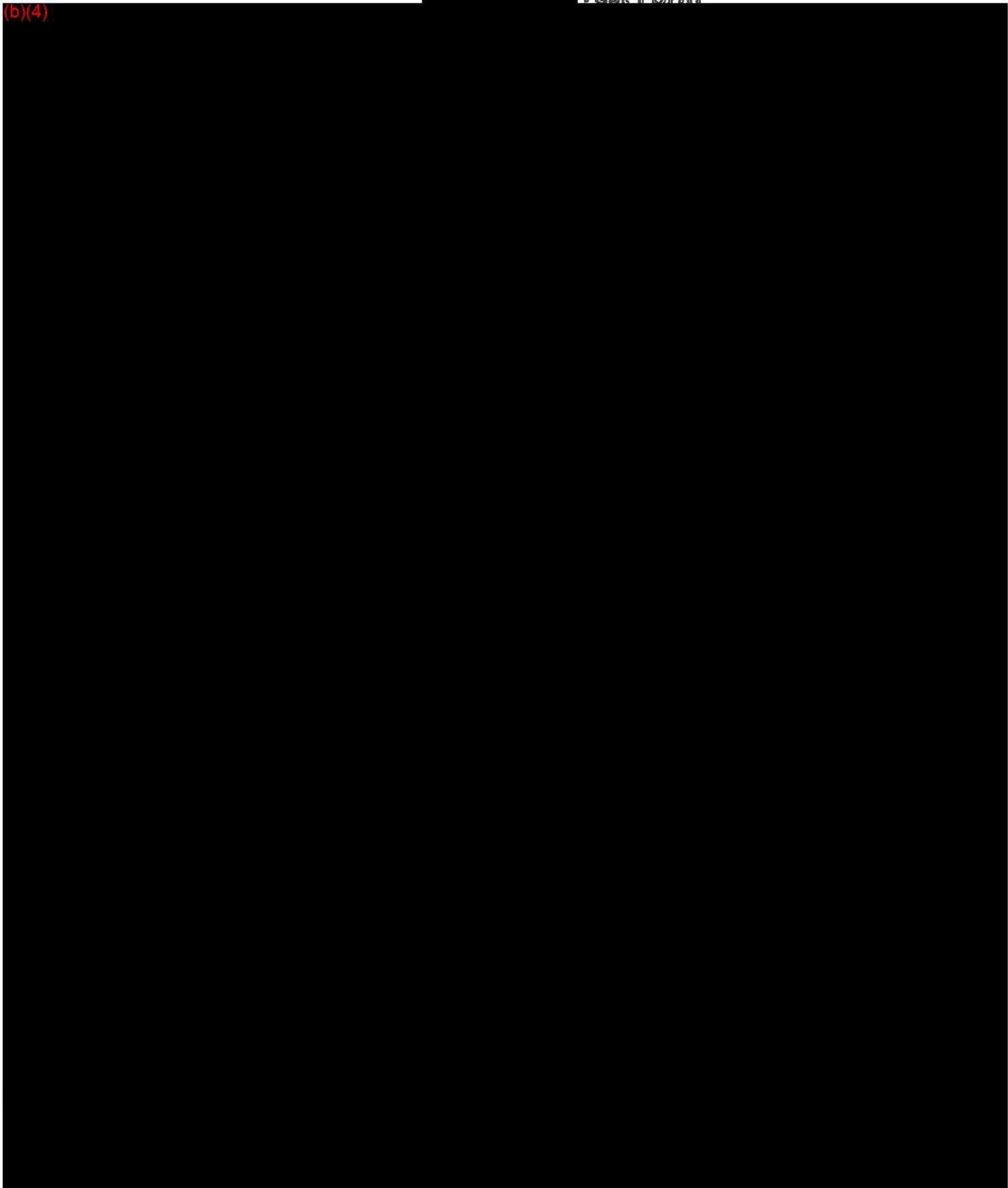
Testing Form

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Test Form

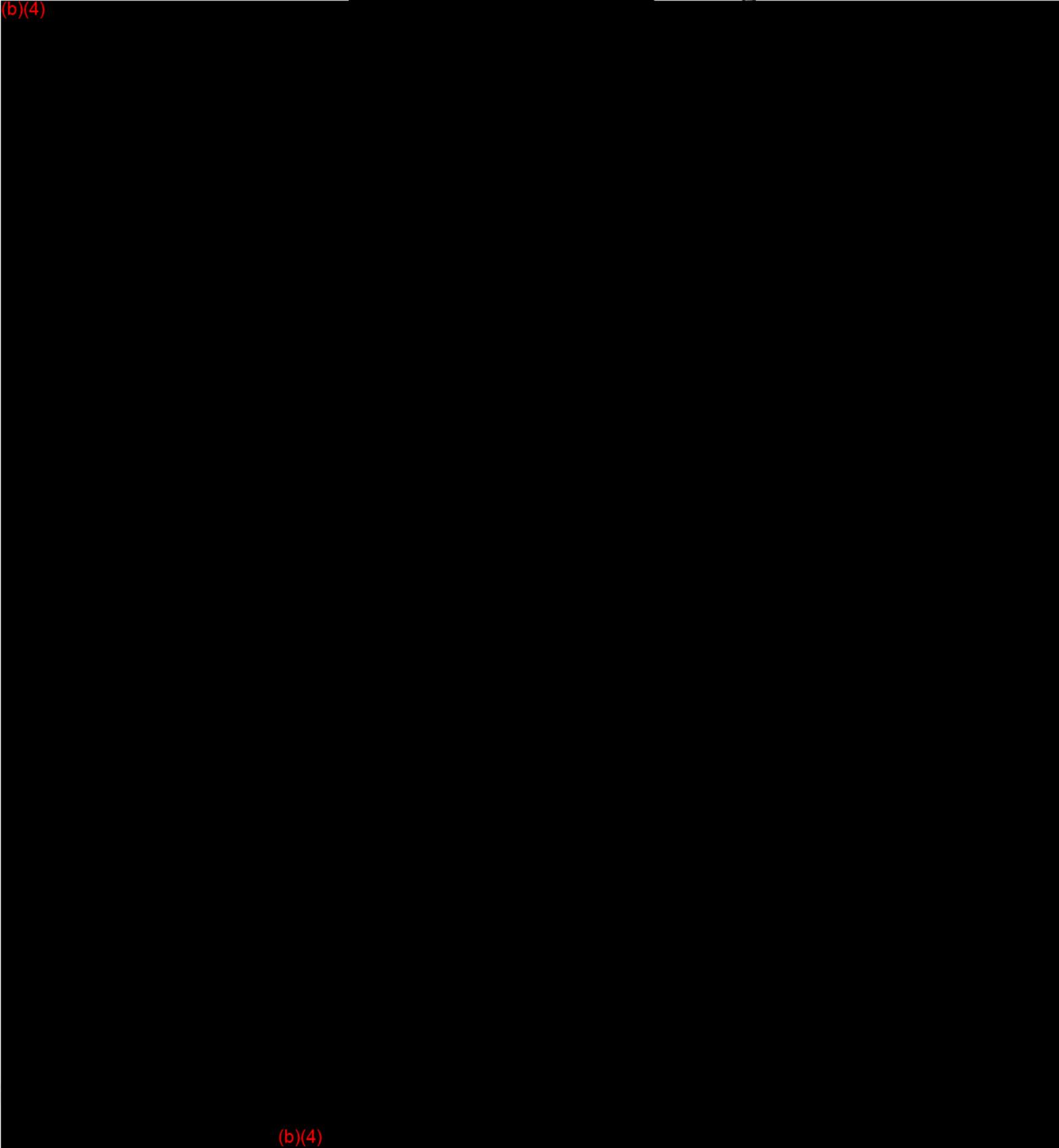
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(b)(4)

Testing

(b)(4)



(b)(4)

Page 1 of 1

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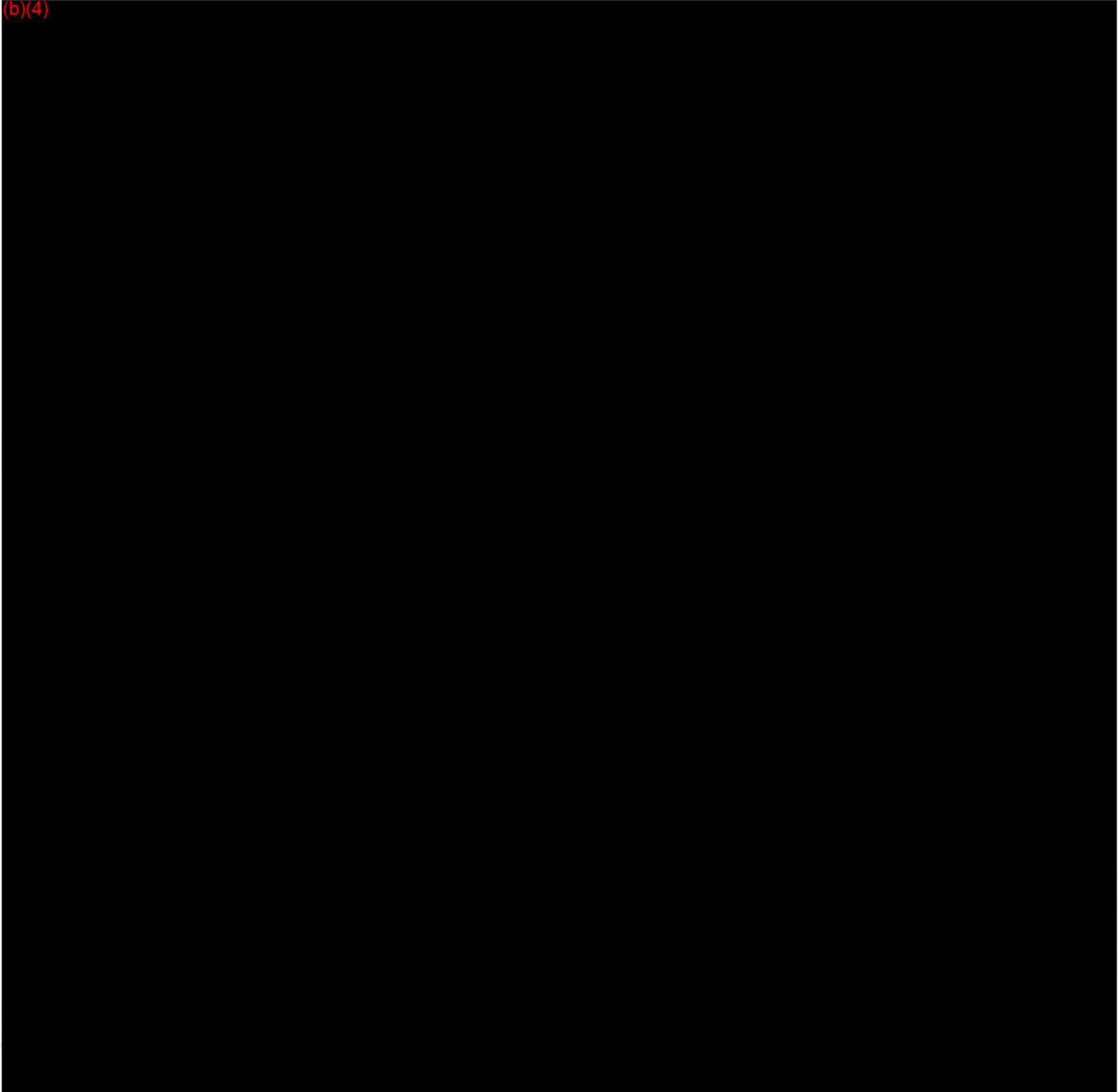
COORDINATOR

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Portland, Oregon 97232

Phone: 503.517.8001
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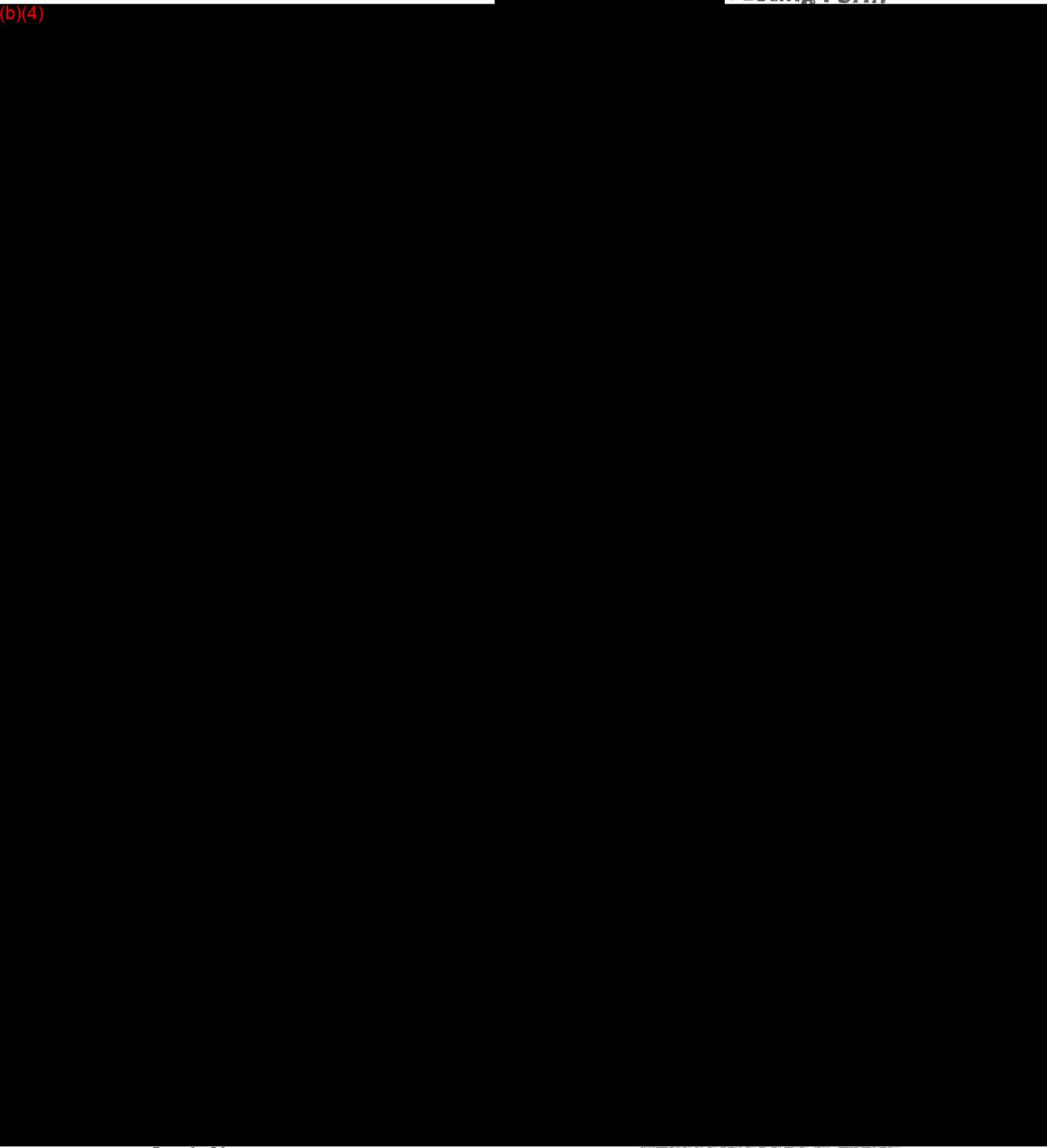
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Riverpoint Medical (b)(4)

Testing Form

(b)(4)



(b)(4)

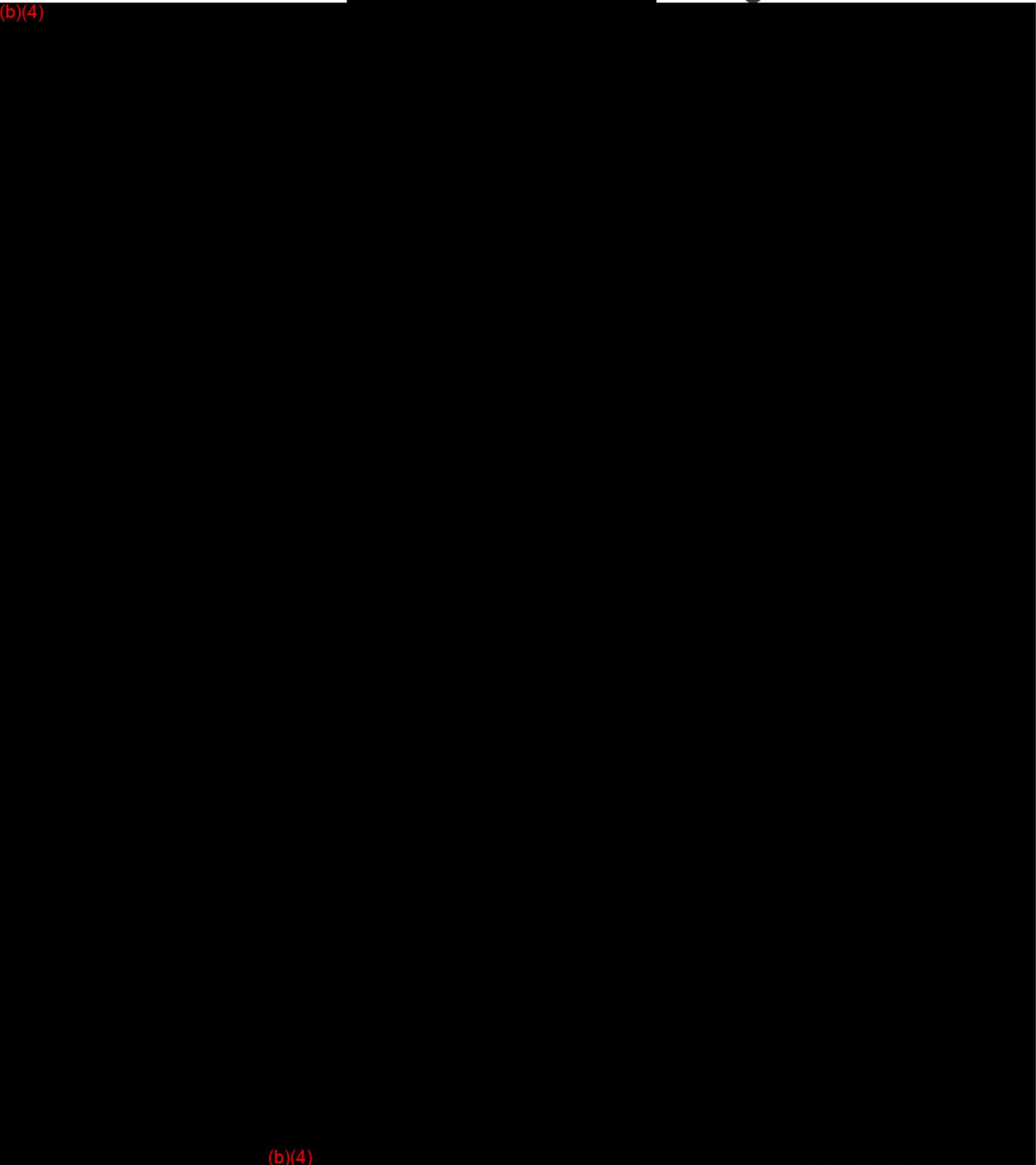
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(b)(4)

Testing

(b)(4)



(b)(4)

COORDINATOR

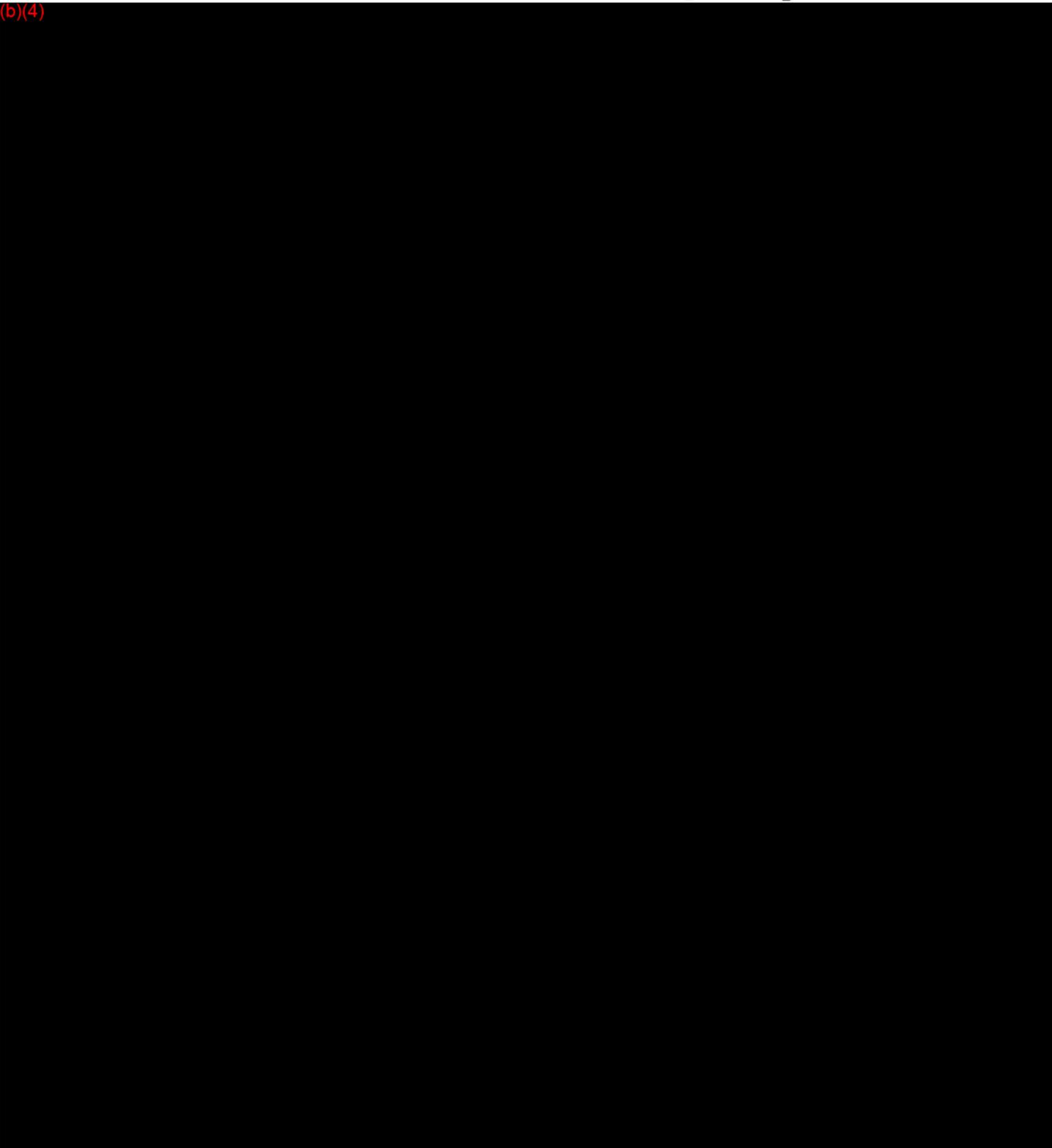
Riverpoint Medical
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Portland, Oregon 97232

Phone: 503.517.8001
www.rpmed.com

(b)(4)



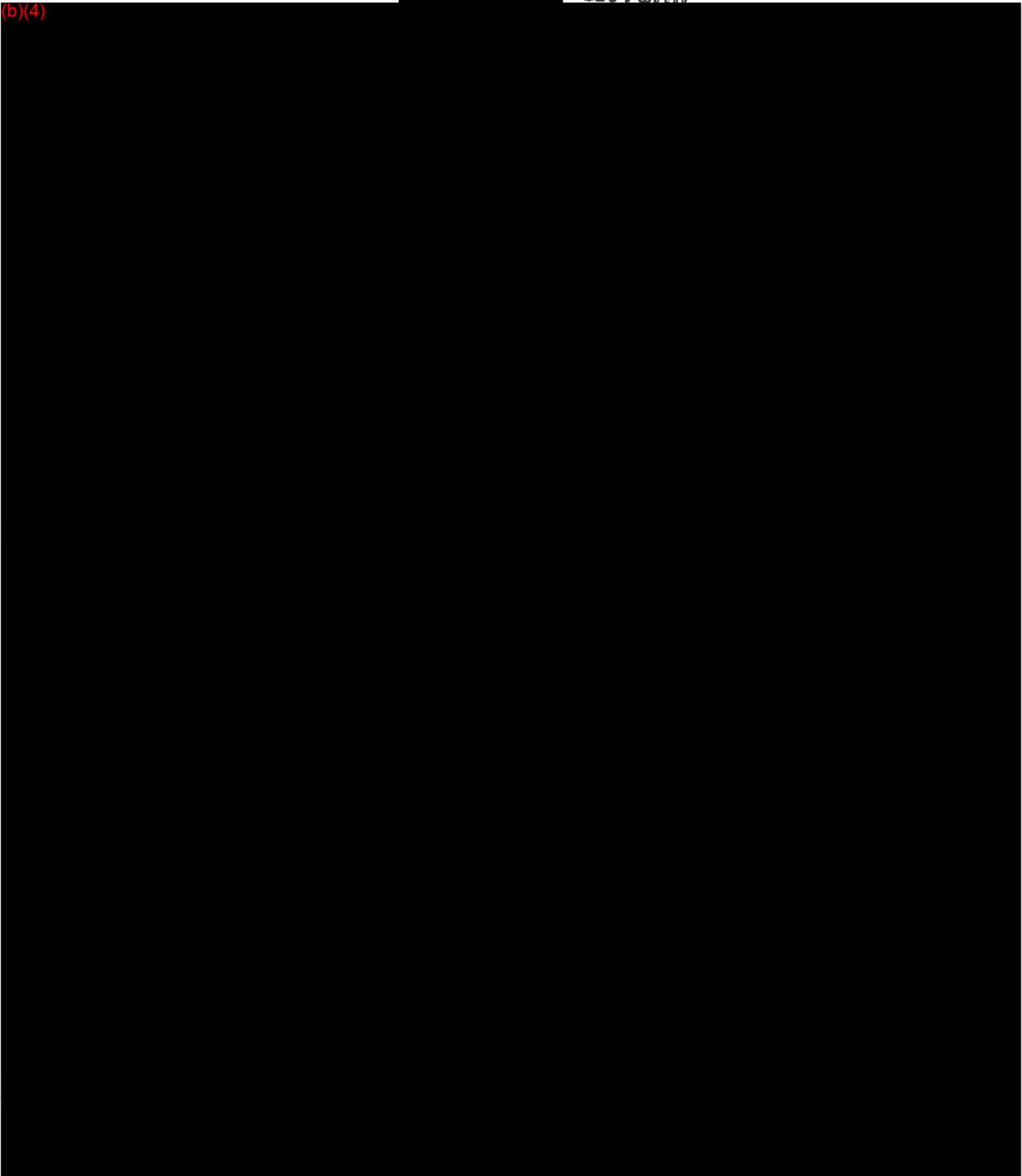
Riverpoint Medical (b)(4) Testing Form



(b)(4)

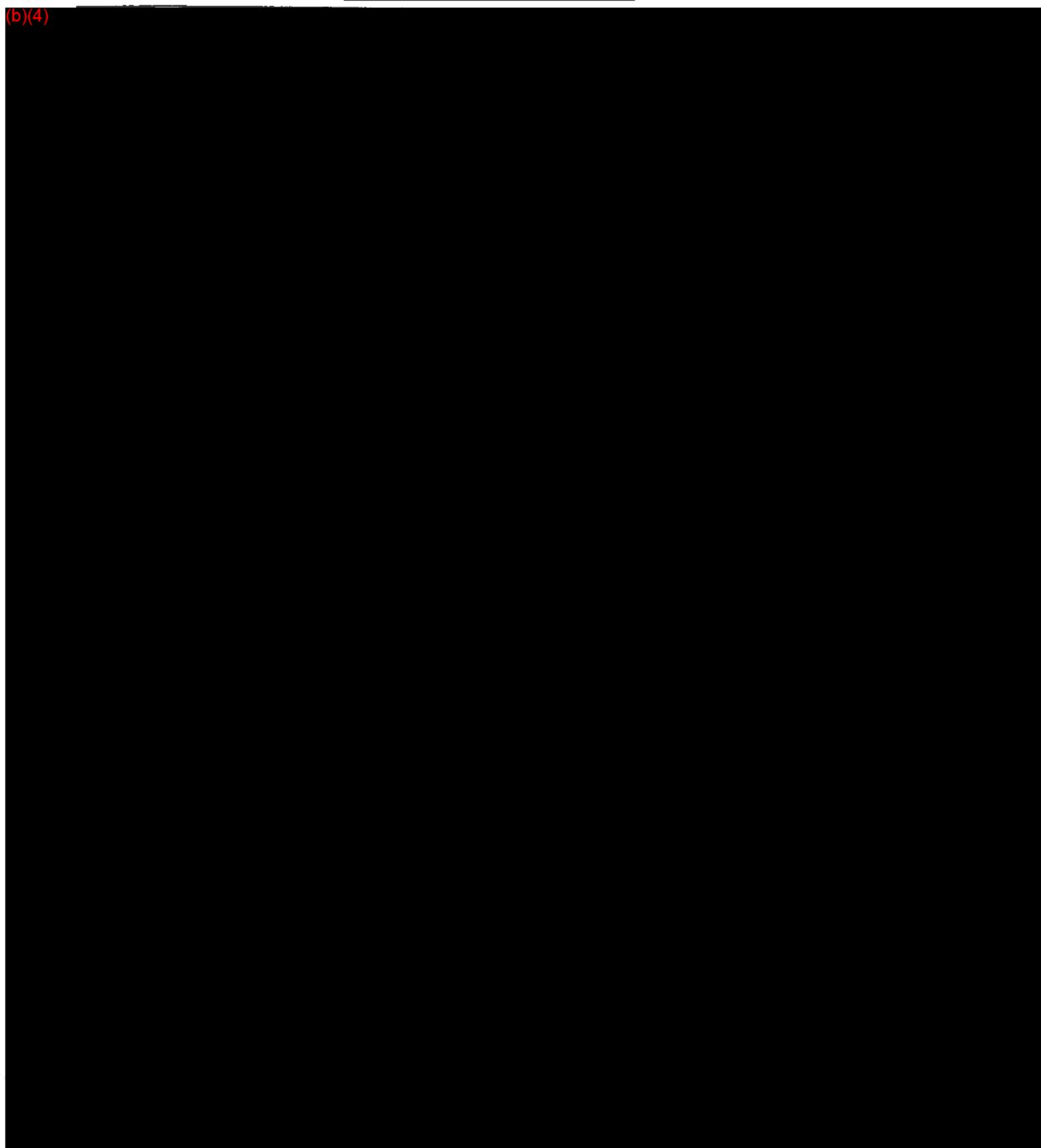
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(b)(4)



(b)(4)

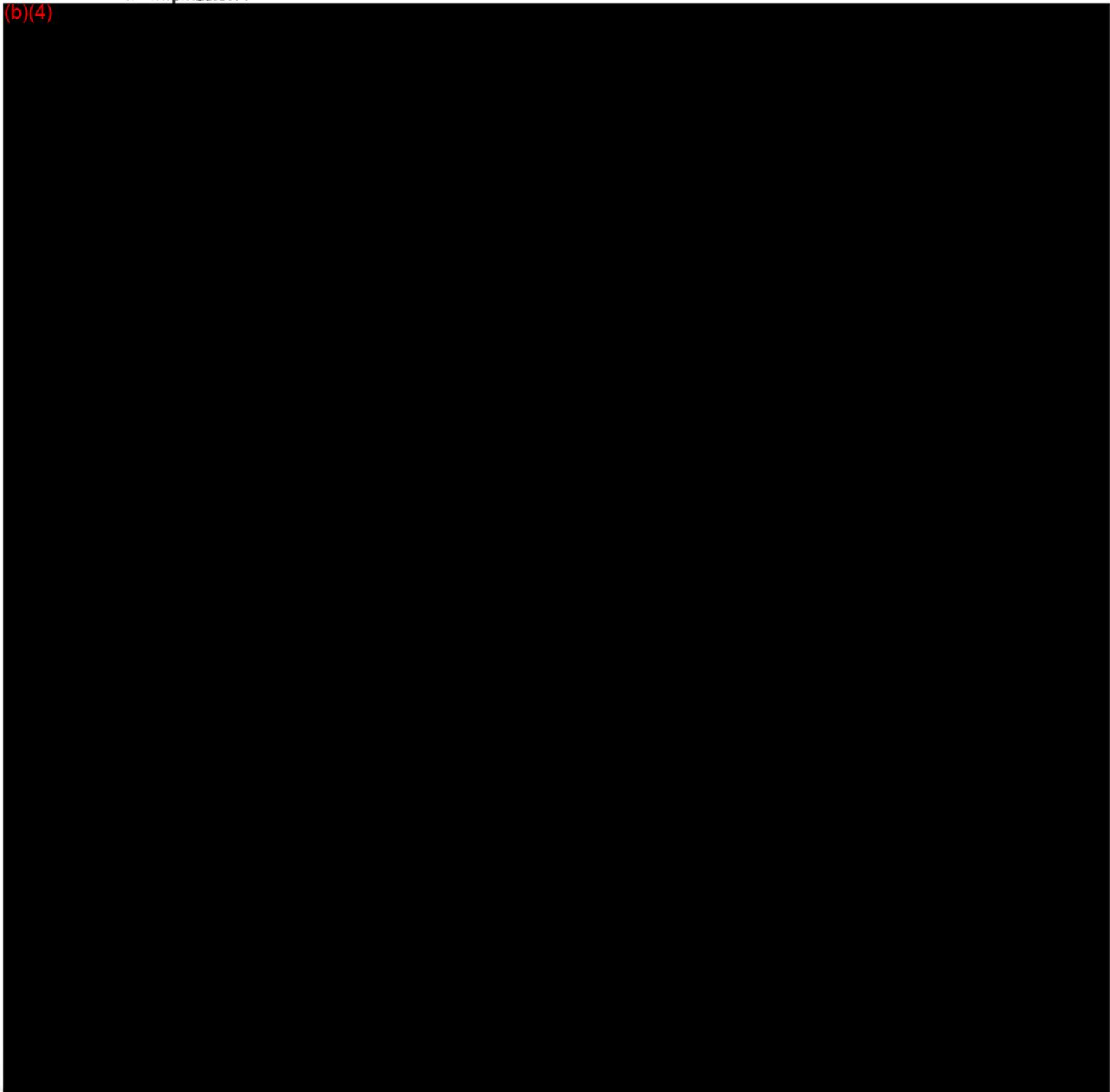
Testing



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Phone: 503.517.8001
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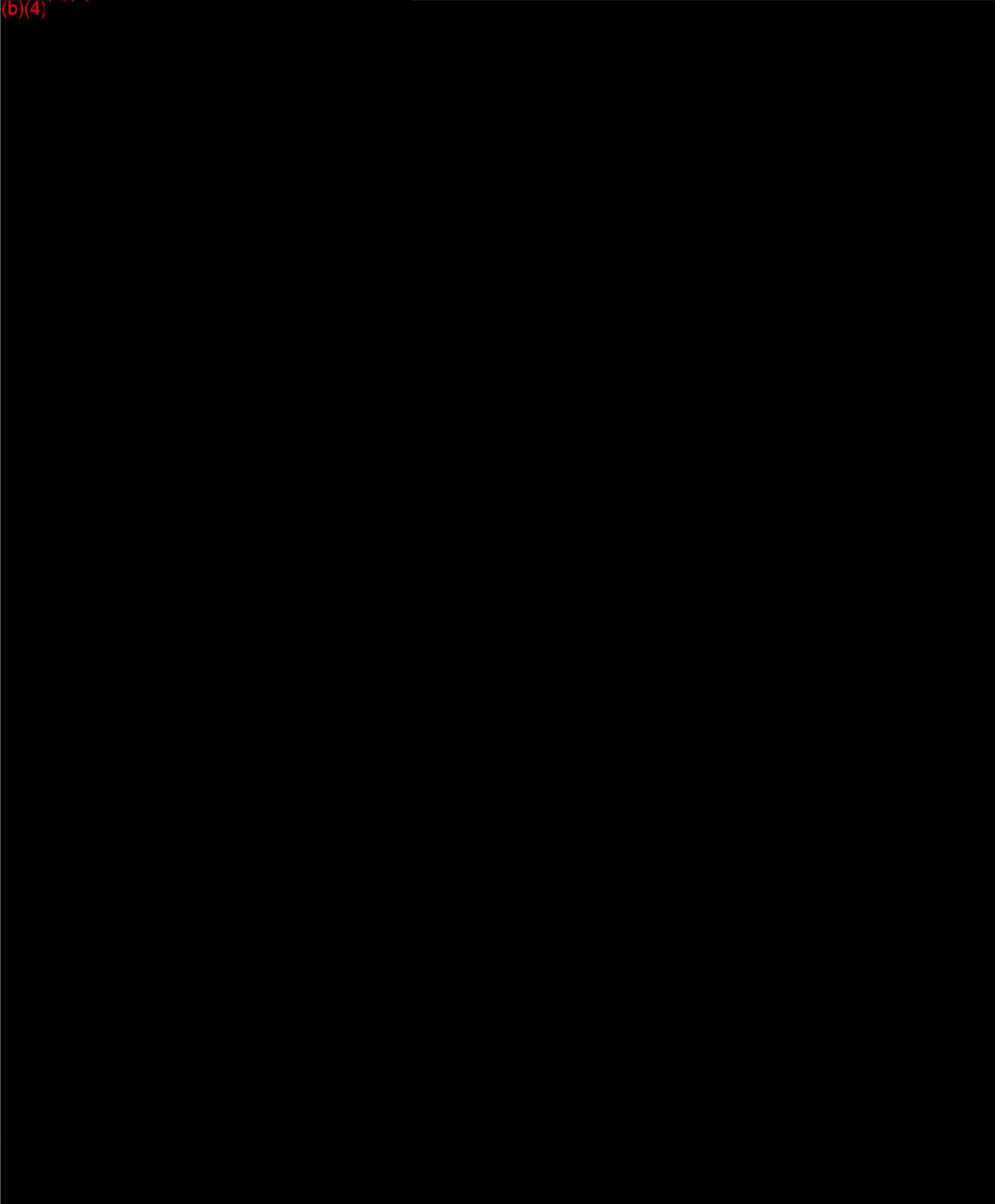
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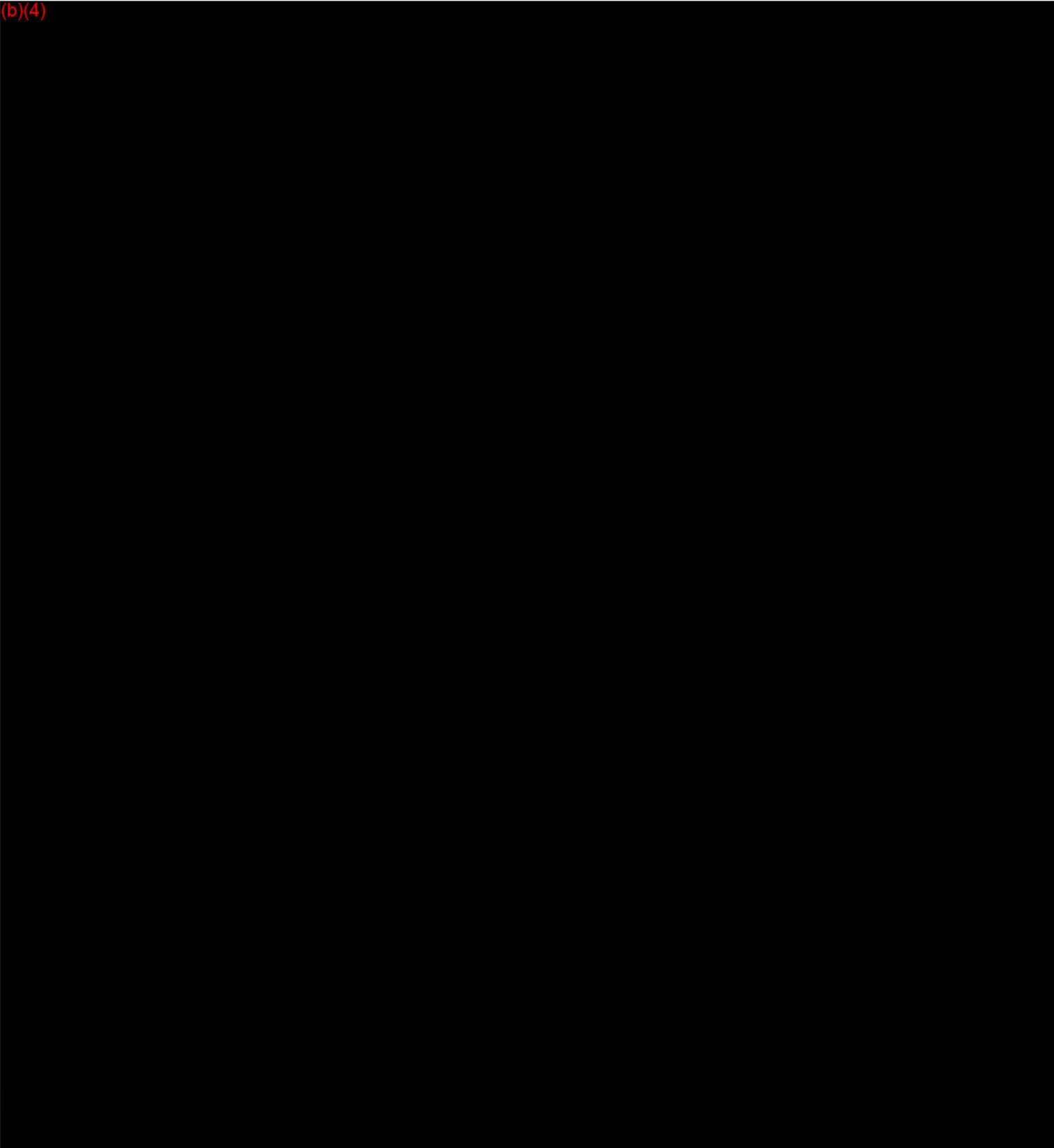
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Test Form

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Riverpoint Medical (b)(4) Testing Form



(b)(4)

DOCUMENT
COORDINATOR

(b)(4)

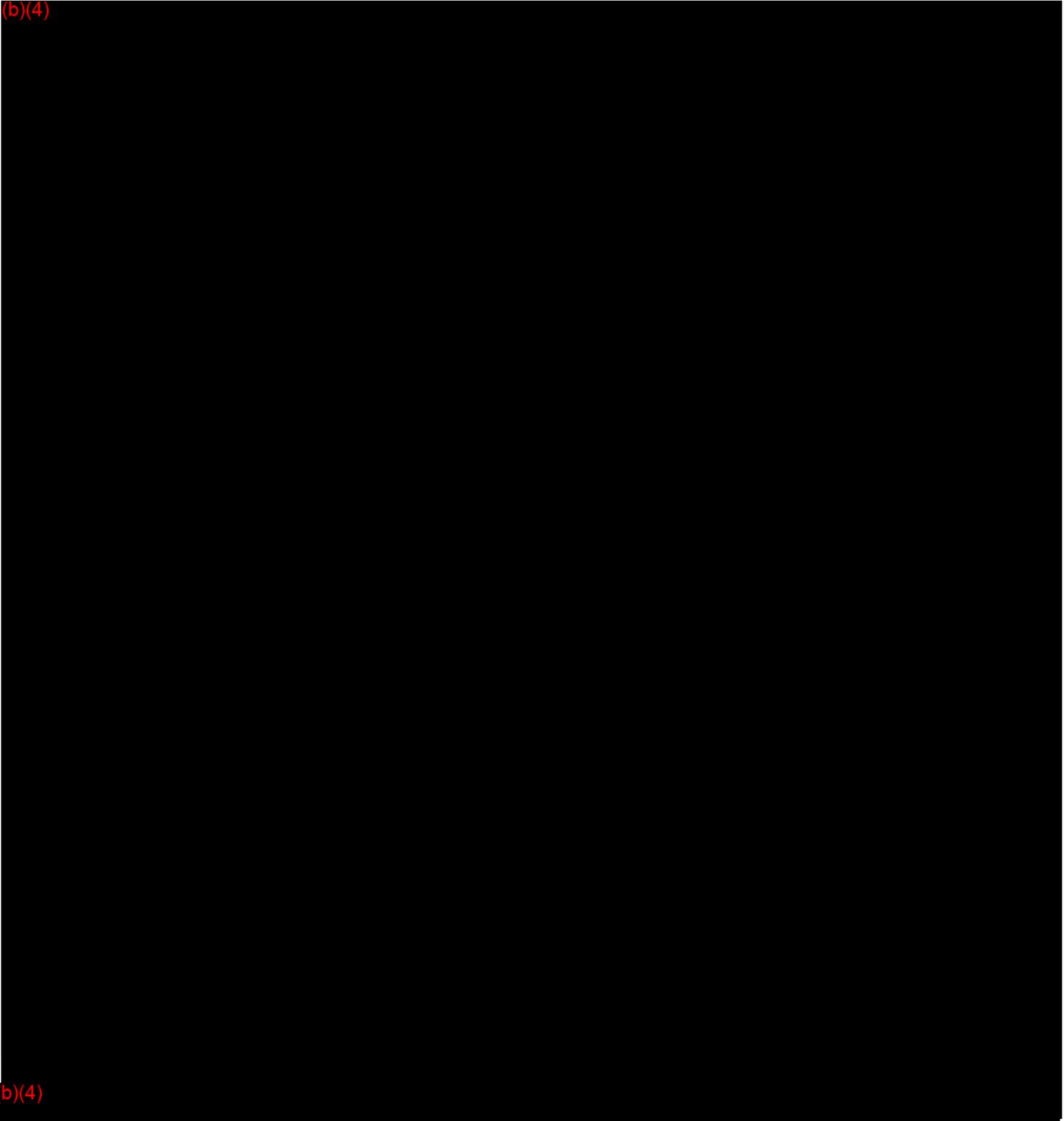
Testing

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Phone: 503.517.8001
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(b)(4)



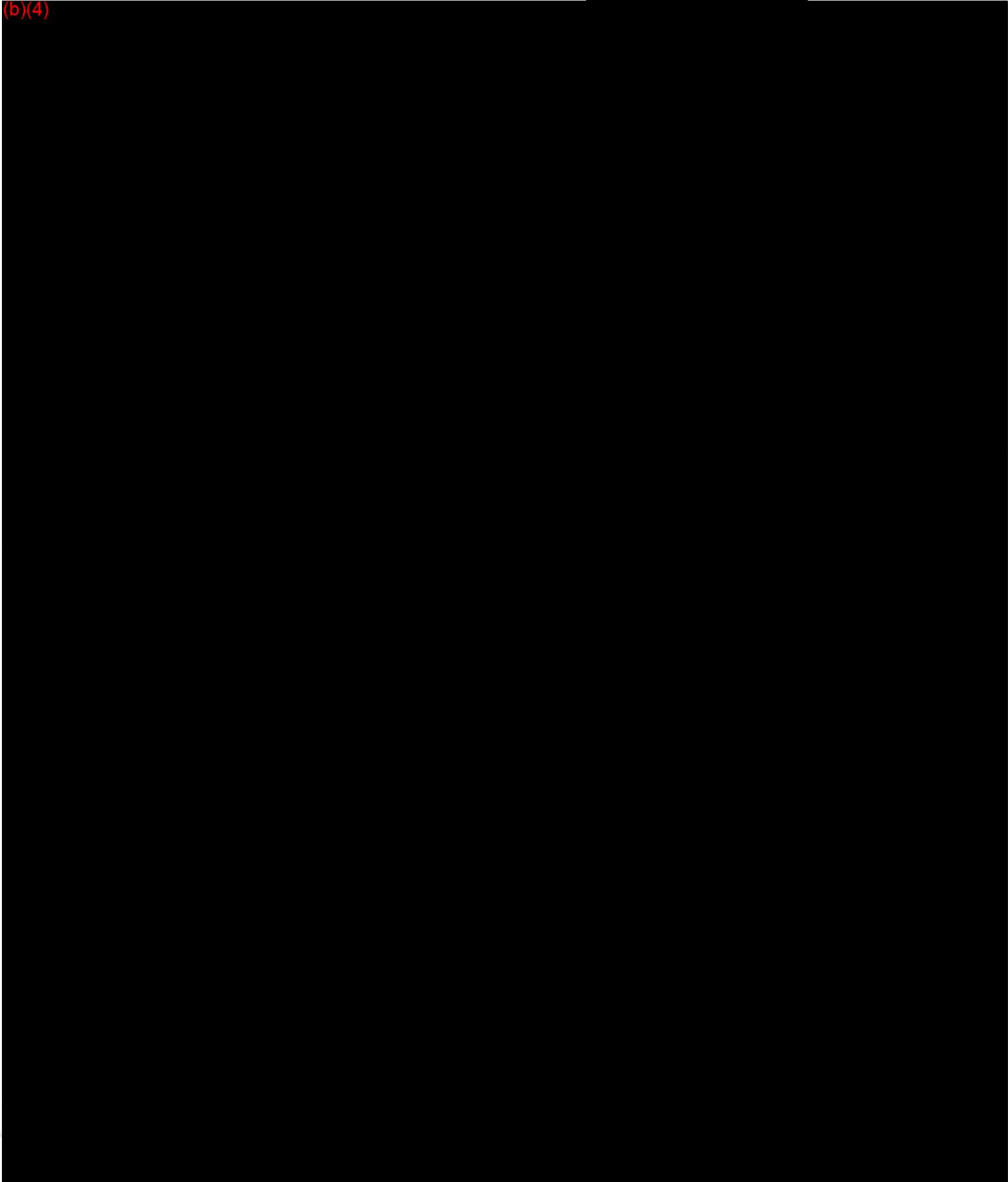
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Riverpoint Medical Needle

(b) (4)
(4)

Form

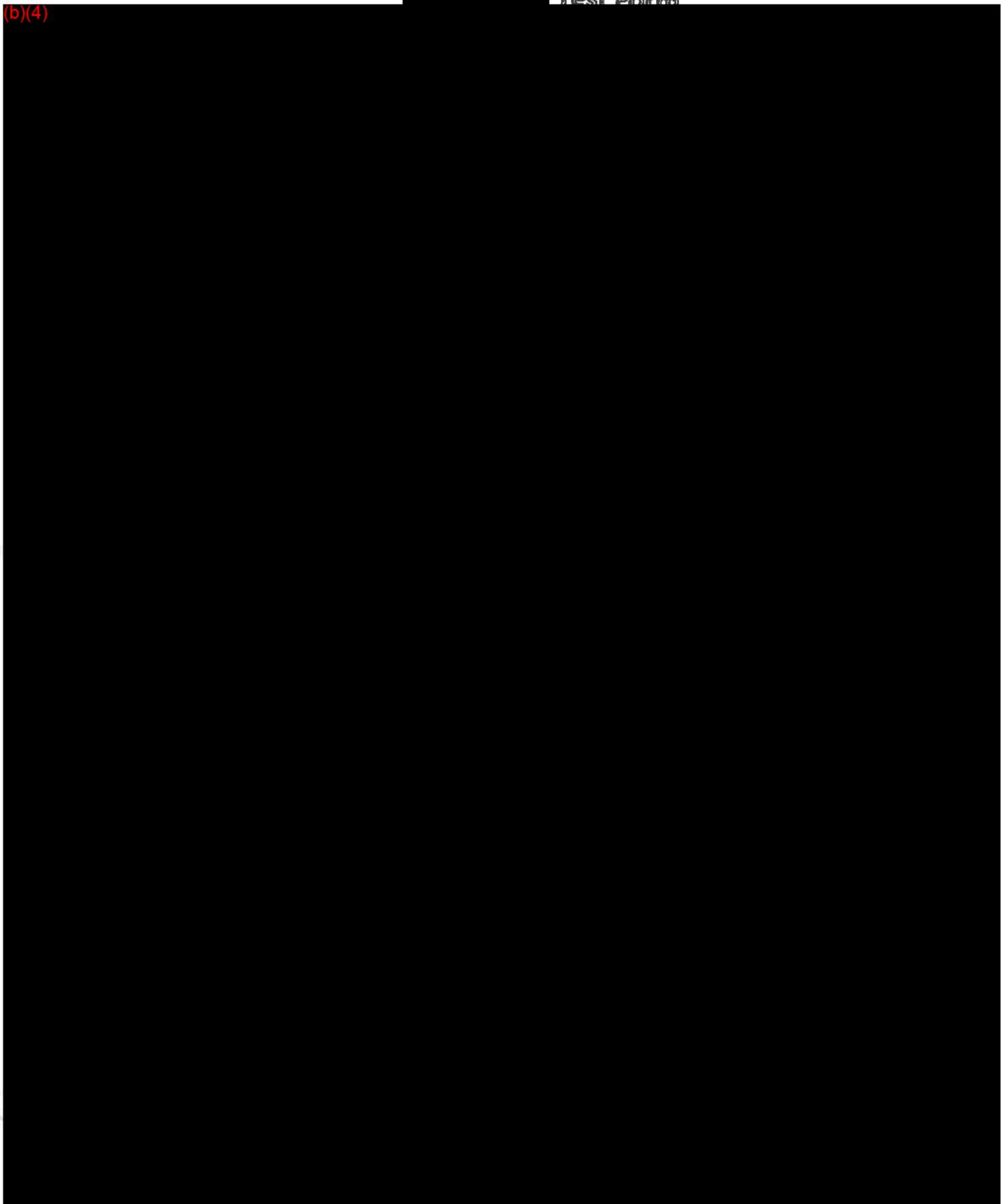
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(b)(4)

Test Form

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(b)(4)

Testing

(b)(4)

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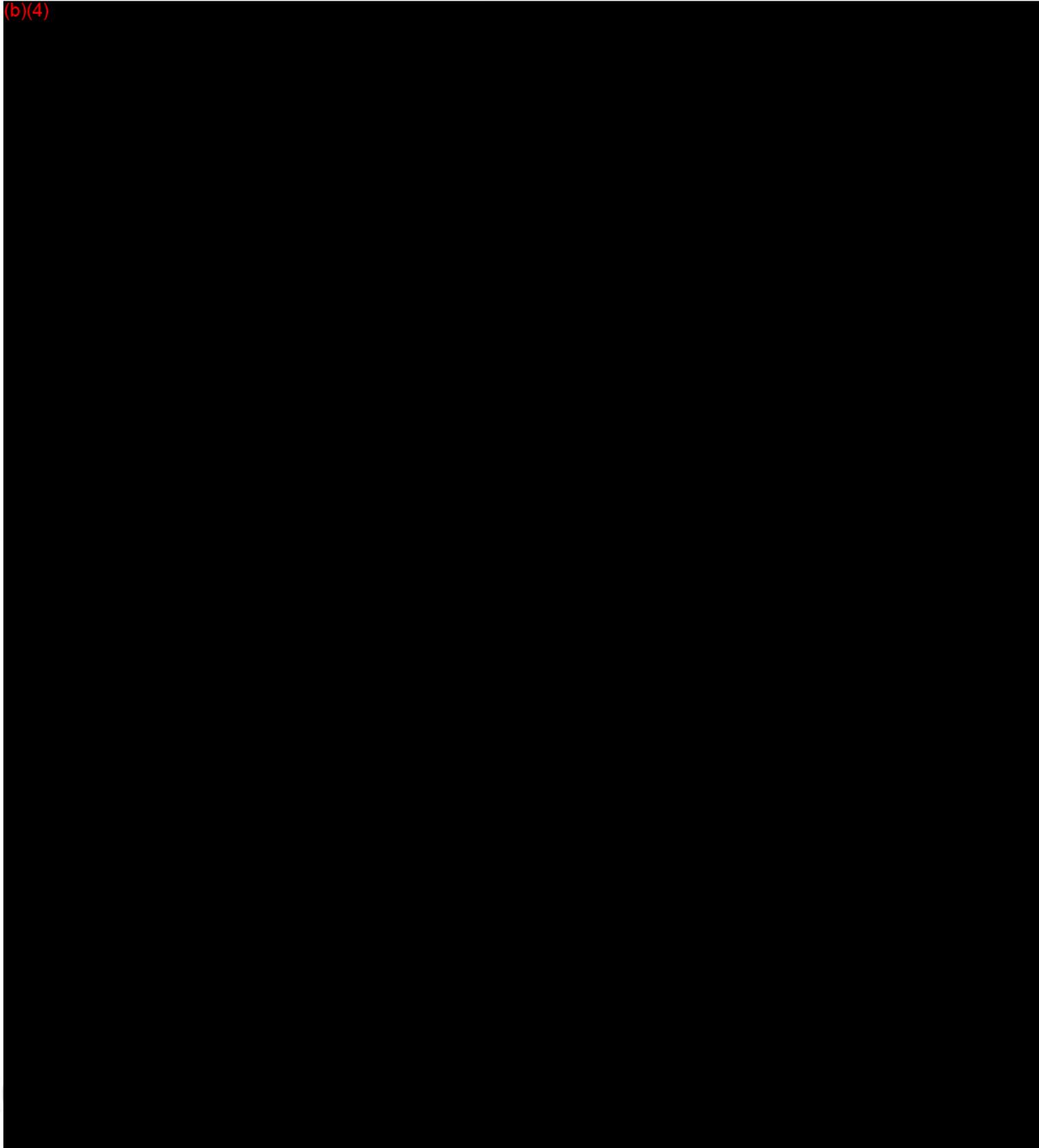
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Riverpoint Medical (b)(4) Testing Form

(b)(4)



(b)(4)

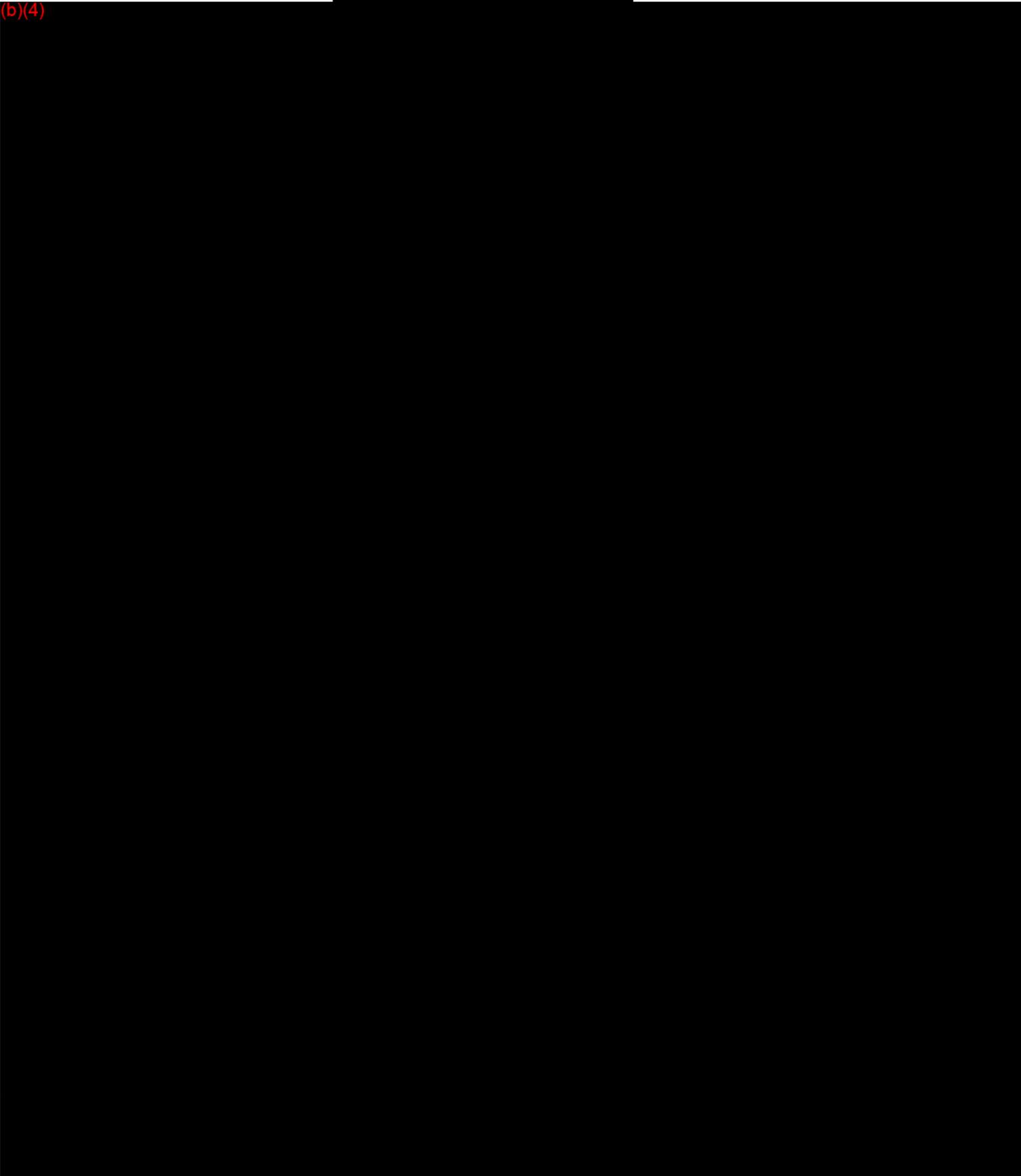
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(b)(4)

Testing

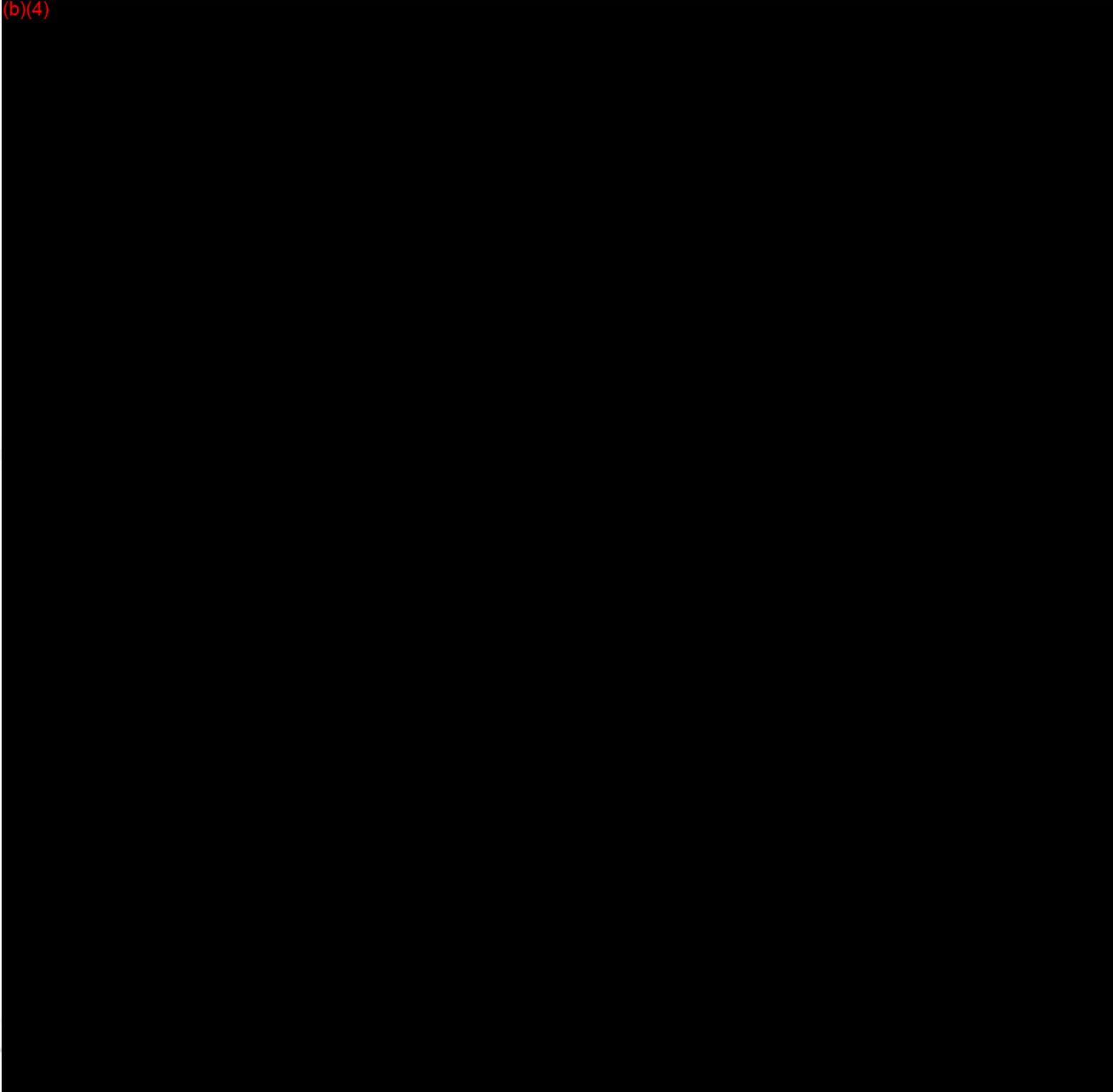
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(b)(4)



(b)(4)

Test Form

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Riverpoint Medical

(b)(4)

Testing Form

(b)(4)



PTFE Suture 510(k) Submission

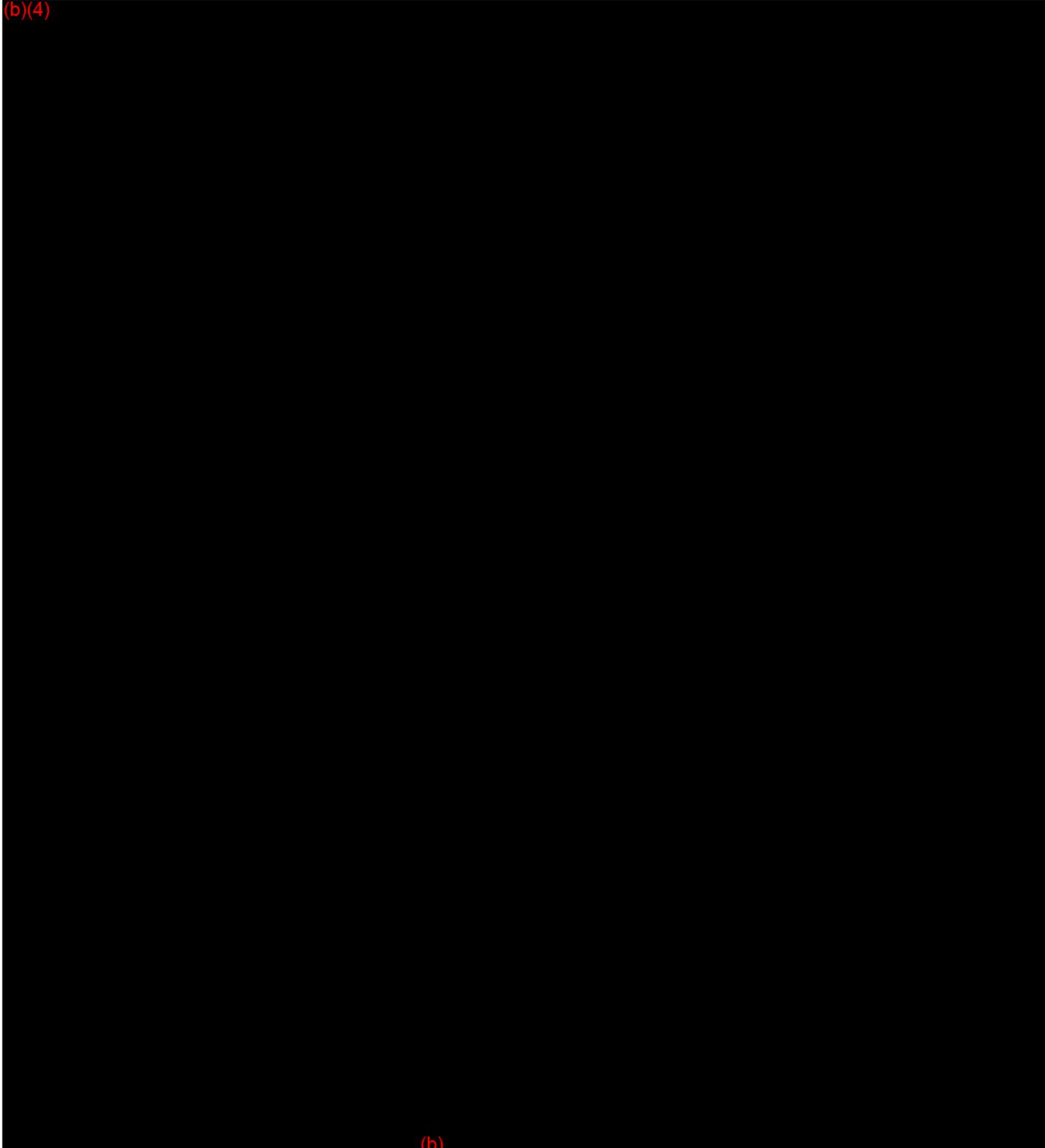
Risk Management

(12 pages)

Risk Management Plan

Product Name: *PTFE Sutures*

(b)(4)



(b)
(4)

**DOCUMENT
COORDINATOR**

Analysis

(b)(4)
Device to be evaluated: PTFE (b)(4)

Revision Level: (b)(4)

Description of Device: PTFE (Polytetrafluoroethylene) Suture will be a fluorocarbon-based suture material for use in the medical and veterinarian markets. It will be nonabsorbable and provided sterile for one time use only, and will be available in different sizes with various needles attached.

Intended use: PTFE Suture is indicated for use in all types of soft tissue approximation and/or ligation, including cardiovascular, dental and general surgeries, as well as repair of the dura mater. PTFE suture is not indicated for use in microsurgery, ophthalmic surgery, or peripheral neural tissue.

Designated Risk Management Team (RMT) for this device:

Department	Name
RA/QA	(b)(6)
Sales & Marketing / Exec. Management	
Production / Exec. Management	

Analysis

(b)(4)

(b)(4)

(b)(4) Risk Management

Analysis

(b)(4) Risk Management

Form **(b)(4)** - Rev **(b)(4)**
Risk Management Page 3 of 8

Analysis

(b)(4) Risk Management

(b)(4) Risk Management

Form **(b)(4)(5)** - Rev. **(4)**
Page 4 of 8

Analysis

(b)(4) Risk Management

(b)(4) Risk Management

Form **(b)**
Risk **(b)**
- Rev. **(b)**
Page 5 of 8 **(4)**

Analysis

(b)(4) Risk Management

(b)(4) Risk Management

Form **(b)**
K **(4)** - Rev. **(4)**
Ris **(b)**
Page 6 of 8

(b)(4) Risk Management

Analysis

(b)(4) Risk Management

Form **(b)(4)** - Rev. **(b)(4)**
Page 7 of 8

Analysis

(b)(4) Risk Management

(b)(4) Risk Management

(b)(4) Risk Management

(b)(4) Risk Management - Rev (4) -
Page 8 of 8

Risk Management Final Report

PTFE Suture
Document #: (b)(4) Risk Management

OBJECTIVE:

(b)(4) Risk Management

SCOPE:

(b)(4) Risk Management

RESULTS:

(b)(4) Risk Management

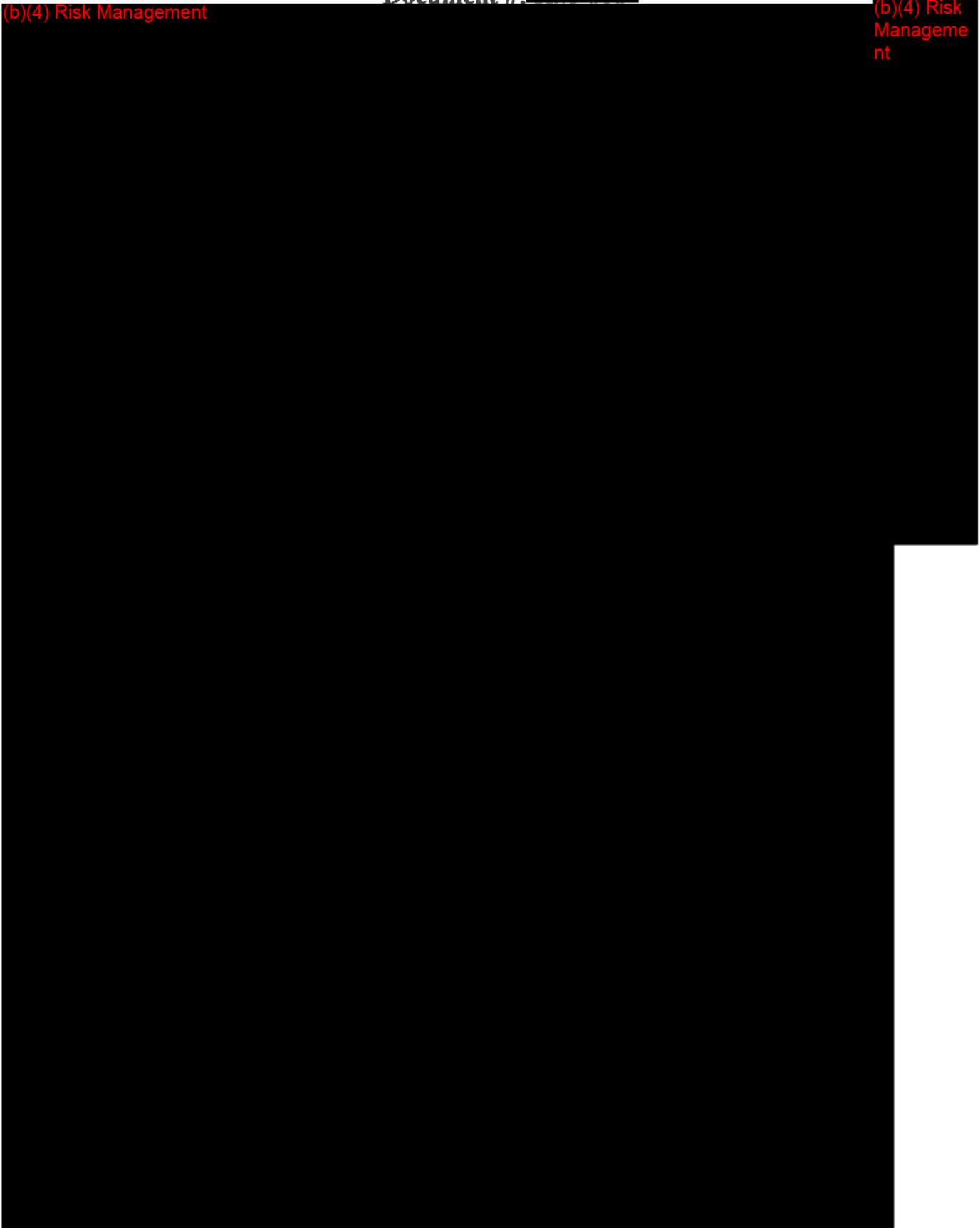
Risk Management Final Report

PTFE (b)(4) Risk Management Suture

Document #: (b)(4) Risk

(b)(4) Risk Management

(b)(4) Risk Management



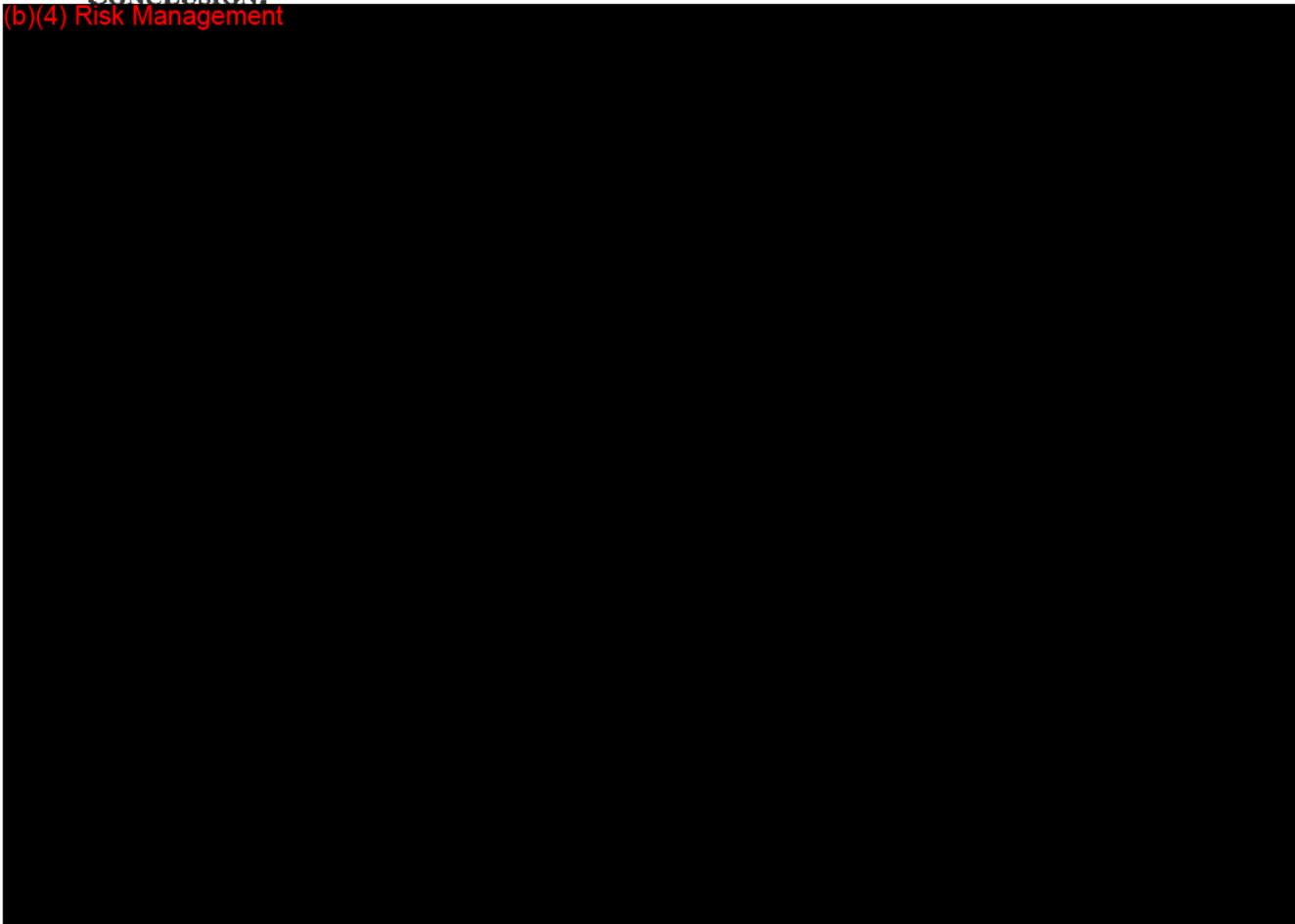
Risk Management Final Report

PTFE (b)(4) Risk Management Future

Document #: (b)(4) Risk Management

CONCLUSION:

(b)(4) Risk Management



(b)(4) Risk Management



PTFE Suture Proposed Labeling

Draft labeling has been created for MonoTex PTFE sutures to satisfy the requirements of CFR Part 801. All labeling will be formalized prior to marketing this product. A sample unit label, box label, and instructions for use (IFU) have been included in this submission. The included labels and IFU's contain the information that will be on the finished documents, but all are in Draft form at this time.

Included Documentation

- Sample Unit Labels
- Sample Box Labels
- Instructions for Use



PTFE Suture 510(k) Submission

Sample Label

(1 page)





PTFE Suture 510(k) Submission

Draft IFU's

(3 pages)

MONOTEX PTFE Surgical Suture Instructions for Use

CAUTION: Federal (FDA) law restricts this device to sale by or on the order of a physician.

DESCRIPTION: MONOTEX suture is nonabsorbable, monofilament surgical suture composed of polytetrafluoroethylene (PTFE) polymer that has been expanded under controlled conditions, resulting in microscopic pores in the structure of the material, while maintaining structural integrity and tensile strength. MONOTEX suture contains no coatings, dyes, or additives.

INDICATIONS: MONOTEX surgical suture is indicated for use in general soft tissue approximation and/or ligation, including cardiovascular, dental, general surgical procedures and repair of the dura mater. MONOTEX sutures are not indicated for use in microsurgery, ophthalmic procedures, or peripheral neural tissues. MONOTEX suture is provided sterile as a single use device.

PERFORMANCE: MONOTEX sutures have been shown to elicit a minimal tissue reaction. MONOTEX sutures, being nonabsorbable, are not absorbed by the body or subject to weakening caused by enzymes or the presence of infection.

MONOTEX PTFE sutures differ from USP requirements for nonabsorbable sutures only in diameter (oversized in diameter in some cases, see table below). This is stated on immediate product labeling whenever applicable.

Maximum MONOTEX Suture Oversize in Diameter (mm) from USP		
USP Size	USP Diameter (mm)	Maximum Overage (mm)
6/0	0.070 - 0.099	0.050
5/0	0.10 - 0.149	0.050
4/0	0.15 - 0.199	0.050
3/0	0.20 - 0.249	0.050
2/0	0.30 - 0.339	0.060
0	0.35 - 0.399	0.100
1	0.40-0.499	0.100
2	0.50 - 0.599	0.100
3&4	0.60 - 0.699	0.100
5	0.70 - 0.799	0.100

DRAFT

Public Use Only - Contact CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

CONTRAINDICATIONS: There are no known contraindications for MONOTEX sutures.

WARNINGS:

- Tissue ingrowth into the microscopic pores present on MONOTEX sutures can result in attachment of suture to the applicable tissue during long-term use. Removal of the suture may be difficult in these cases.
- MONOTEX sutures are not indicated for use during microsurgeries, ophthalmic procedures, or procedures involving peripheral neural tissues.,
- Do not resterilize. Discard open packages and unused sutures. Discard suture that is past the expiration date listed on the suture packaging.
- As with any foreign body, prolonged contact of any suture with salt solutions, such as those found in the urinary and biliary tracts, may result in calculus formation. Acceptable surgical practice should be followed for the management of contaminated or infected wounds.

PRECAUTIONS:

- Misuse of MONOTEX sutures (or any variety of suture) can result in serious patient injury or death. Medical professionals should familiarize themselves with this Instructions for Use prior to using MONOTEX sutures.
- Skin sutures which must remain in place longer than 7 days may cause localized irritation and should be snipped off or removed as indicated. Under some circumstances, notably orthopedic procedures, immobilization of joints by external support may be employed at the discretion of the surgeon.
- Avoid exposure to elevated temperatures.
- Conjunctival and vaginal mucosal sutures remaining in place for extended periods may be associated with localized irritation and should be removed as indicated. Subcuticular sutures should be placed as deeply as possible in order to minimize the erythema and induration normally associated with absorption.
- Care should be taken to avoid damage when handling this, or any other surgical suture. Avoid the crushing or crimping application of surgical instruments such as forceps and needle holders to the suture strand except when grasping the free end of the suture during an instrument tie.
- MONOTEX sutures require even tension applied to each strand when creating knots. Grasp each strand and apply equal force in opposite directions to apply this tension to the knot. The suture needle is not to be grasped when applying this

DRAFT

MONOTEX? - Bureau of Medical Devices/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

tension, and care should be taken to avoid the use of a jerking motion to avoid causing damage to the suture and/or suture needle. Improper or uneven tensioning of a square knot can result in an unsecure knot. Air present within the suture material will be forced out when tension is applied to the knot as described above. Accepted standard surgical knotting techniques of flat and square ties with additional throws as warranted by surgical circumstance and the experience of the surgeon will result in secure knots when the above steps are followed. Grasp the needle in an area one-third (1/3) to one-half (1/2) the distance from the swaged end to the point to avoid damage to the swage areas and needle points when forming knots. Reshaping the needle may cause the needle to lose strength and be less resistant to bending and breaking. Care should be taken when handling surgical needles to avoid accidental sticks with the needle. Discard used needles in "sharps" containers.

ADVERSE REACTIONS: Potential adverse events associated with the use of surgical sutures include wound dehiscence, infection, minimal acute inflammatory tissue reaction, irritation when skin sutures are left in place for greater than seven days, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, and transitory local irritation at the wound site. Broken needles may result in extended or additional surgeries or residual foreign bodies. Inadvertent needle sticks with contaminated surgical needles may result in the transmission of bloodborne pathogens

HOW SUPPLIED: MONOTEX surgical sutures are provided sterile for one time use only, and are provided in boxes of one, two, or three dozen pieces. MONOTEX sutures are available in USP sizes 6/0 - 5 with or without needles attached, and are available in precut lengths.

Manufactured by:

Riverpoint Medical
825 NE 25th Ave.
Portland, OR 97232
Ph. (503) 517-8001
Fax. (503) 517-8002

DRAFT

Public Use Only - Contact CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118



PTFE Suture Predicate Device Equivalence Summary

Riverpoint Medical PTFE sutures have been designed and manufactured to be substantially equivalent to the predicate device listed below. Charts have been included comparing the Riverpoint product to the predicate device. The 510(k) document control number believed to be associated with the predicate device is listed within the table. Predicate device 510(k) Summaries have been included in this submission for reference.

Components

All component materials used in the assembly of PTFE sutures are identical or substantially equivalent to the materials used in the predicate device listed in form and function. The component materials are described below.

Patient Contact component materials

- Needle: Standard 300 or 400 series suture needles
- Suture: Expanded Polytetrafluoroethylene (PTFE)

(b)(4)

Non-Patient Contact component materials

- Packaging: Pouches: (b)(4)
- Suture Cards: (b)(4)

Design and Function

Riverpoint Medical PTFE sutures have been designed to have the same general shape, sizes and method of function as the predicate device. The PTFE sutures included in this submission are indicated for the same intended use as the predicate device.

Inspections

Inspections are performed throughout the manufacturing process to verify that each lot of PTFE suture meets USP (unless specified otherwise on labeling) and Riverpoint requirements. These dimensional and functional verifications are performed according to USP 35 requirements for nonabsorbable surgical sutures according to the labeled USP size, and involve testing each lot of suture for length, diameter, tensile strength, and needle attachment prior to release. (b)(4) testing and visual inspections of the overall product are performed on each lot prior to release as well.



Predicate Device Comparison charts

Riverpoint Trade Name:	MonoTex	Predicate Device:	Osteogenics Biomedical, Inc: Cytoplast®	510(k) No(s):	K072076
Material:	Expanded Polytetrafluoroethylene	Material:	Expanded Polytetrafluoroethylene		
Intended Use:	MonoTex PTFE surgical suture is indicated for use in general soft tissue approximation and/or ligation, including cardiovascular, dental, general surgical procedures and repair of the dura mater. MonoTex PTFE sutures are not indicated for use in microsurgery, ophthalmic procedures, or peripheral neural tissues. MonoTex PTFE suture is provided sterile as a single use device.	Intended Use:	PTFE surgical suture is indicated for use in all types of soft tissue approximation and/or ligation, including cardiovascular, dental and general surgeries, as well as repair of the dura mater. The device is not indicated for use in ophthalmic surgery, microsurgery, and peripheral neural tissue.		
Needles:	Available with or without various standard suture needles attached.	Needles:	Available with or without standard suture needles attached		
Sizes Available:	Various diameters based on USP (unless stated in labeling), various lengths	Sizes Available:	Various per USP (unless stated in labeling)		
Colors Available:	White	Colors Available:	White		

Additional Information

Outsourced (b)(4) testing was performed for additional verification of product safety and equivalence between the Riverpoint PTFE suture and the predicate device. This testing was performed by (b)(4) and resulted in findings of no differences between the MonoTex PTFE sutures (Lot: (b)(4)) and the predicate device (Cytoplast® PTFE, Lot: (b)(4)). See attached (b)(4) report for more information.

Attached documentation

- Predicate device 510(k) summary

(b)(4) Analysis Report (b)(4) (Lab: (b)(4))



PTFE Suture 510(k) Submission

Predicate Device 510(k) Summary Copies

(3 pages)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Osteogenics Biomedical, Inc.
% Mr. Dustyn Webb
Regulatory/Quality Manager
4620 71st Street, Building 78-79
Lubbock, Texas 79424

OCT 31 2007

Re: K072076

Trade/Device Name: Cytoplast PTFE Suture
Regulation Number: 21 CFR 878.5035
Regulation Name: Nonabsorbable expanded polytetrafluoroethylene surgical suture
Regulatory Class: II
Product Code: NBY
Dated: October 9, 2007
Received: October 9, 2007

Dear Mr. Webb:

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 such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Dustyn Webb

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K072076
P. 1 of 1

Indications for Use

510(k) Number (if known): K072076

Device Name: Cytoplast PTFE Suture

Indications For Use:

The Cytoplast® PTFE Suture is indicated for use in all types of soft tissue approximation and/or ligation, including cardiovascular, dental and general surgeries, as well as repair of the dura mater. The device is not indicated for use in ophthalmic surgery, microsurgery and peripheral neural tissue.

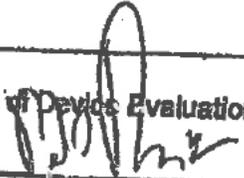
Prescription Use
(Part 21 CFR 801 Subpart D)

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)



(Division: Sign-Off)
Division of General, Restorative,
and Neurological Devices

Page 1 of 1

510(k) Number K072076



PTFE Suture 510(k) Submission

(b)(4)

Report

(5 pages)



PTFE Suture Physical Description

Riverpoint Medical PTFE surgical sutures meet USP requirements as described in the USP 35 monograph for nonabsorbable surgical sutures, unless otherwise noted in labeling. Applicable dimensions and functional characteristics include length, diameter, tensile strength and needle attachment strength.

PGLA Suture Device Description Table							
Variety:	Regulation:	Product Code:	Material used:	Coating(s):	Additive(s):	Color Additive Information (21 CFR 70.5(c)):	Sizes (USP):
PTFE	878.5035	NBY	expanded polytetrafluoroethylene	N/A	(b)(4)	N/A	6/0 through 5

NOTE: For this submission, “tipping” refers to the stiffening of the end of the suture material in order to attach a suture needle.

Resorption Profiles

PTFE Sutures, being nonabsorbable, are not resorbed by the patient.

Processing

(b)(4)

All suture varieties manufactured at Riverpoint Medical are inspected post-sterilization per USP requirements for the applicable suture type for diameter (<861>), needle attachment (<871>), and tensile strength (<881>). Records of all testing are retained within the Riverpoint Medical RA/QA Department, and compliance with USP requirements as applicable is verified prior to release.

Included documentation

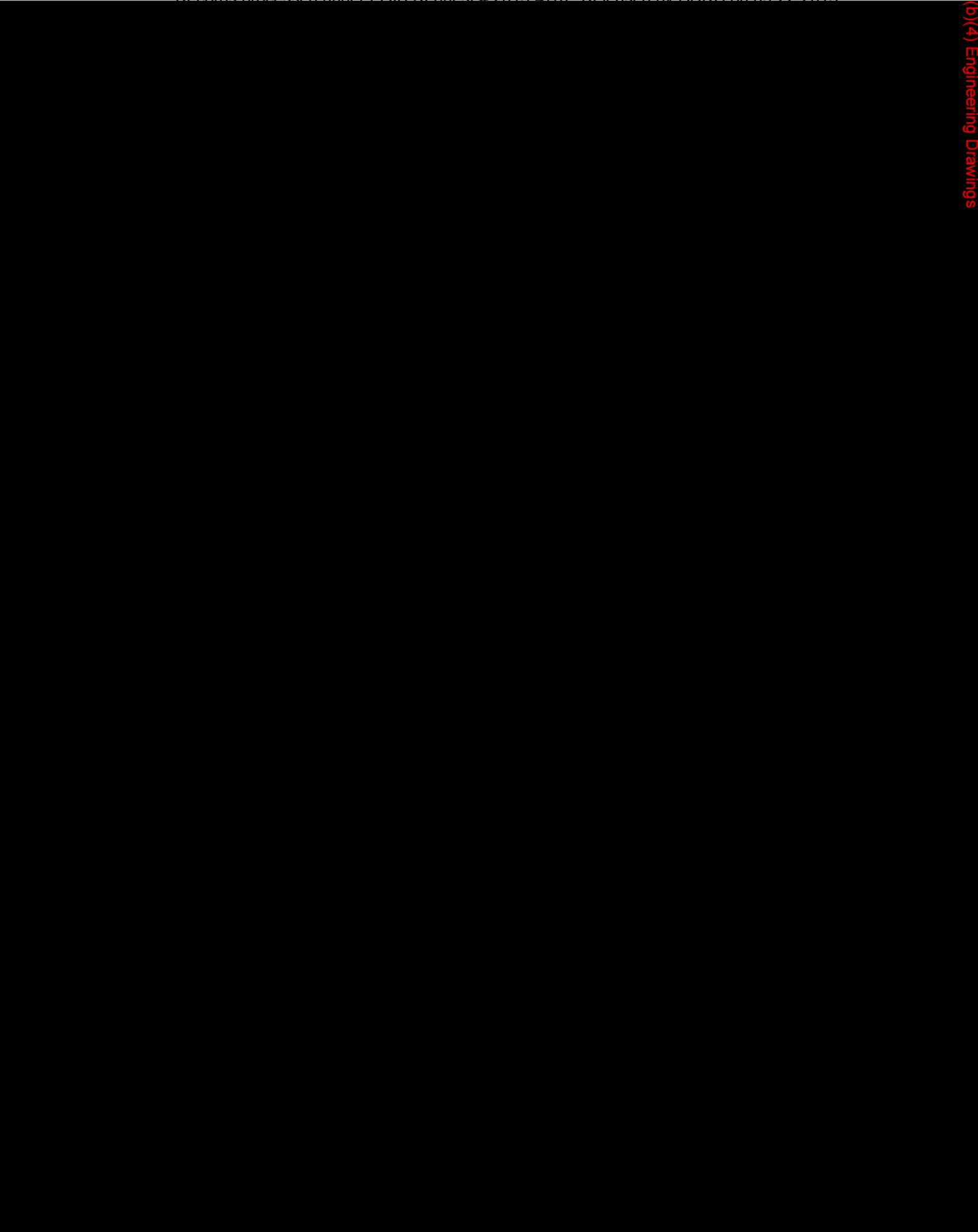
- Engineering Drawing (b)(4)
- Engineering Drawing (b)(4)
- Engineering Drawing (b)(4)
- Sample Product Specification Sheet (PTFE-2)
- Suture Needle Reference Charts



PTFE Suture 510(k) Submission

Engineering Drawings and Documents for Reference

(6 pages)

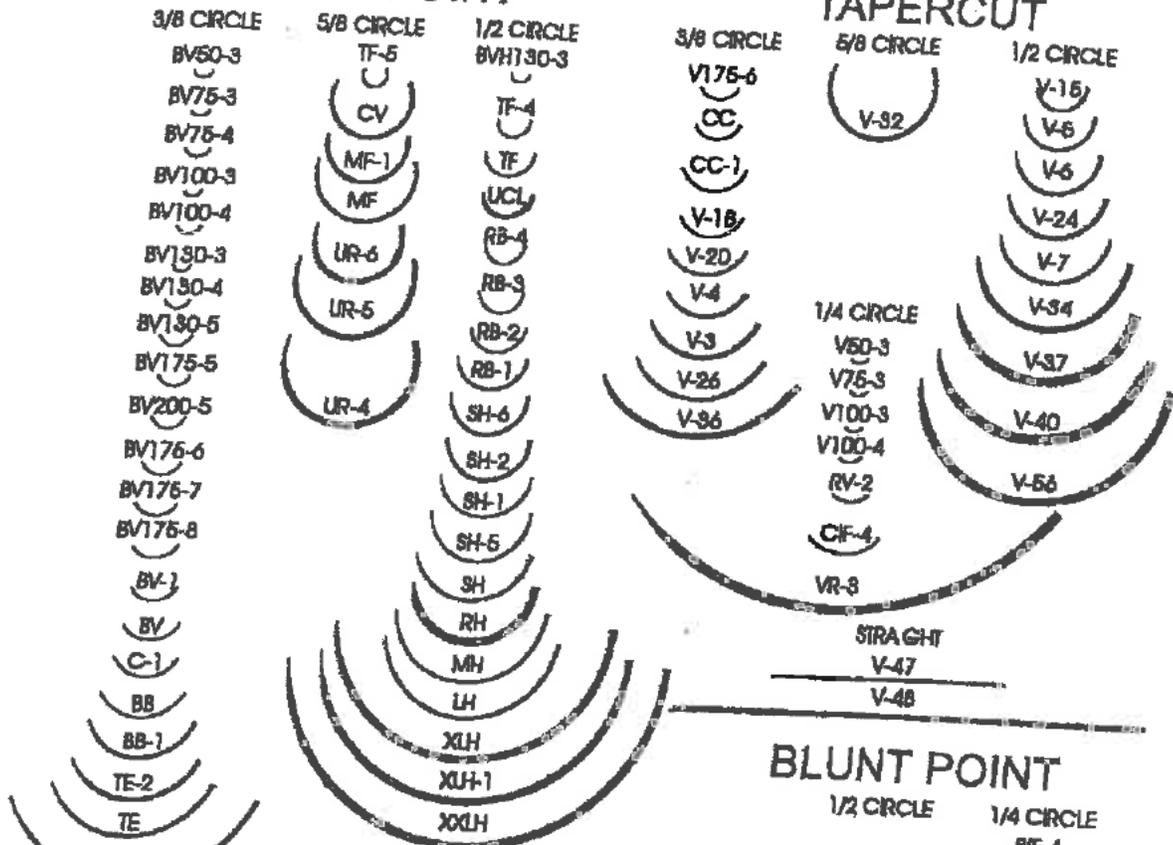


(b)(4) Engineering Drawings

SUTURE NEEDLE REFERENCE CHART

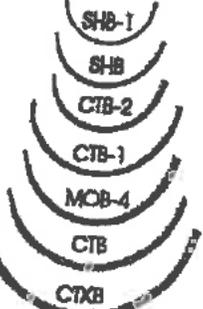
TAPER POINT

TAPERCUT



BLUNT POINT

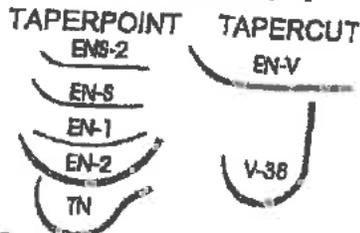
1/2 CIRCLE 1/4 CIRCLE
 Blunt Point Needle BF-4



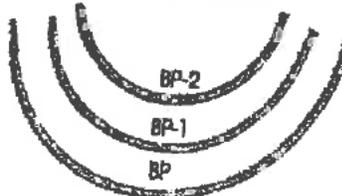
STRAIGHT

- ST30-2
- ST75-3
- ST100-3
- SIF-2
- ST-4
- ST-3
- ST-1
- ST

ENDOSCOPY

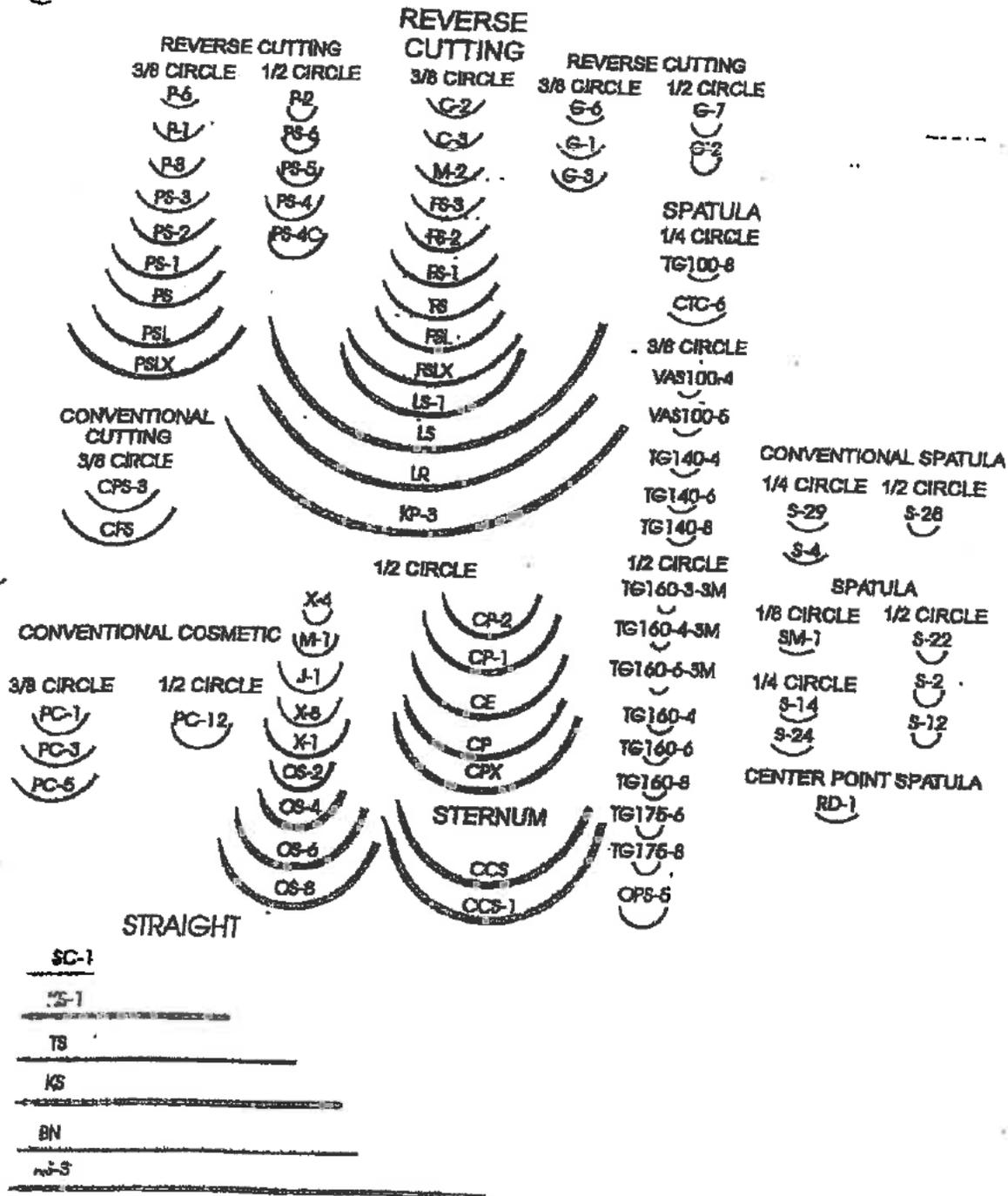


BLUNT POINT



SUTURE NEEDLE REFERENCE CHART

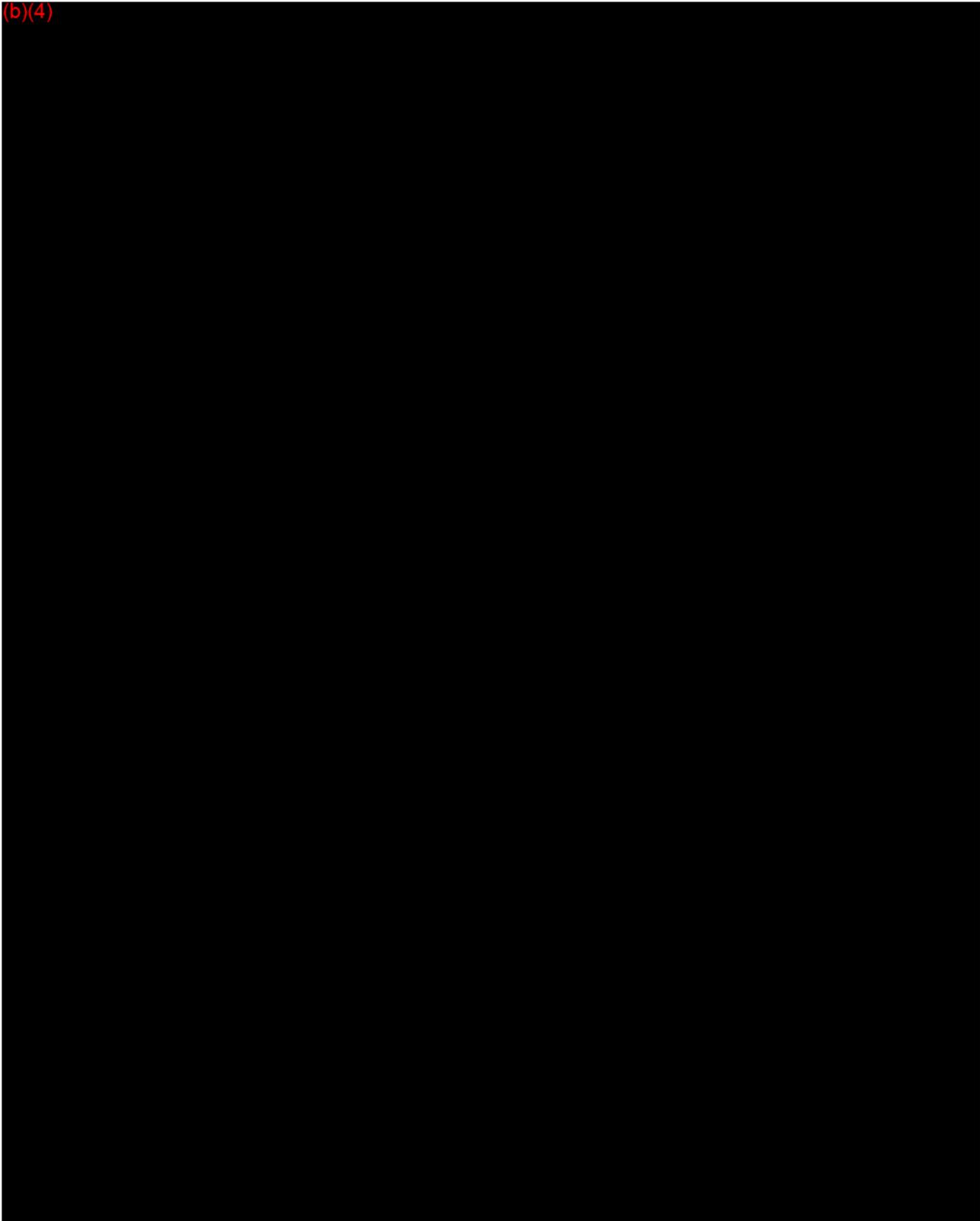
CUTTING EDGE





PTFE Suture Sterilization Information

(b)(4)



Sterilization information for 510(k) Submission – PTFE Suture

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118



Packaging

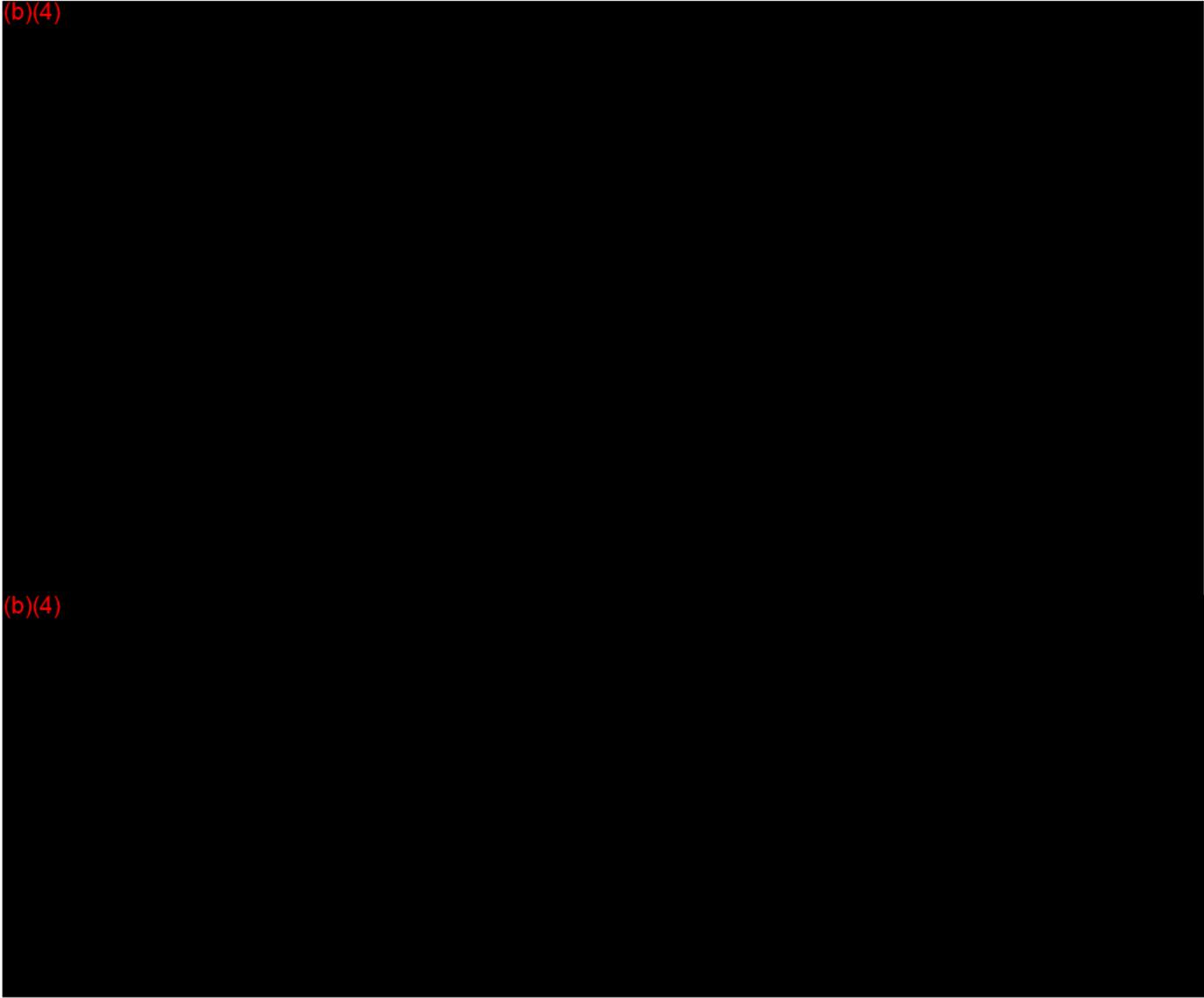
Prior to sterilization, PTFE sutures are packaged into (b)(4) pouches. These pouches are sealed using validated parameters on a band sealer (or equivalent) prior to sterilization to ensure sterility. The (b)(4) is able to penetrate through the (b)(4) portion of the pouches during the sterilization cycle.



Prior Communication Summary

In an effort to comply with the FDA guidance, *"Elements of a Complete Submission (RTA Items)(21 CFR 807.87 unless otherwise indicated) section 9*, Riverpoint Medical has included the following section to identify where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed.

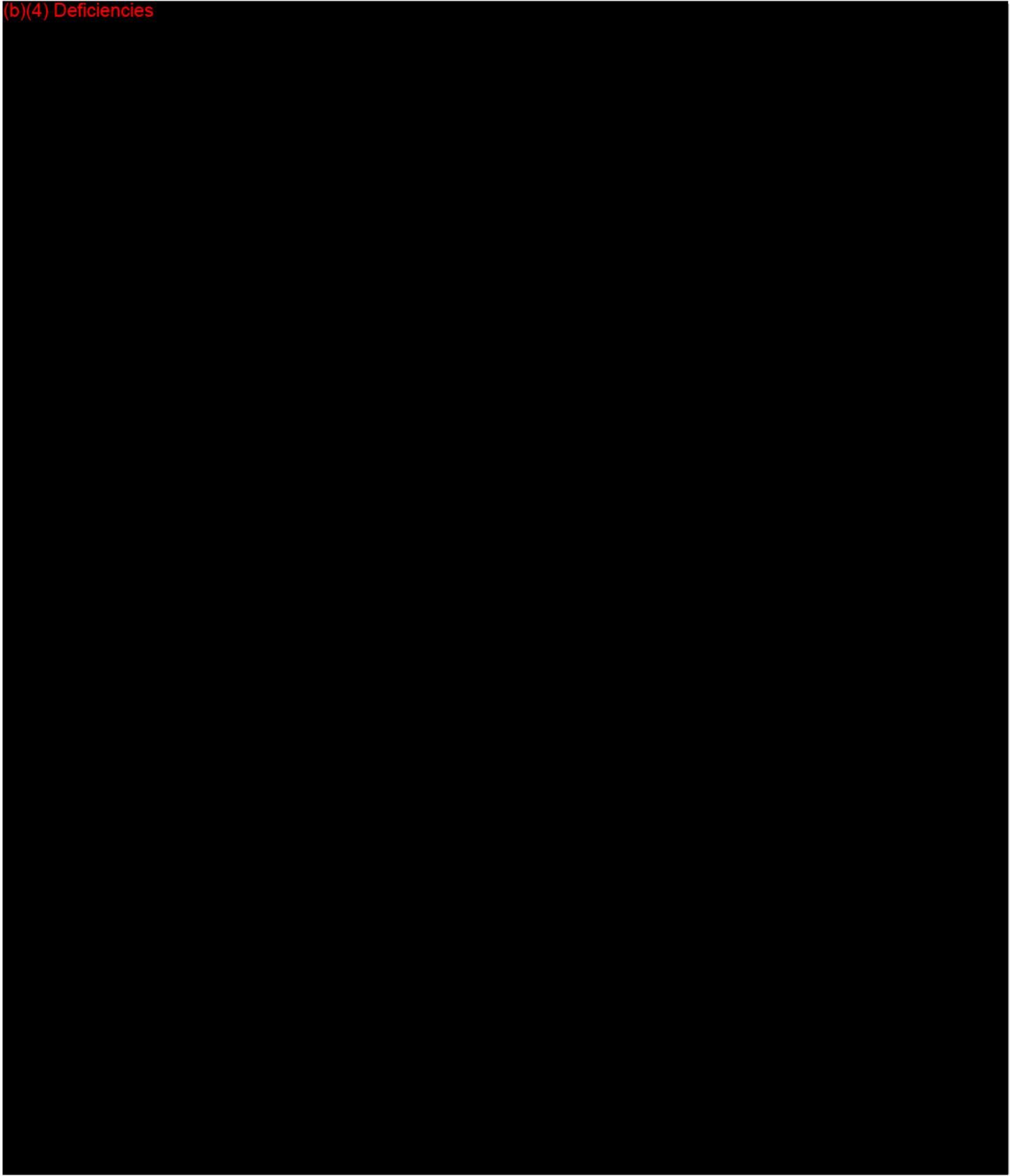
(b)(4)



(b)(4)

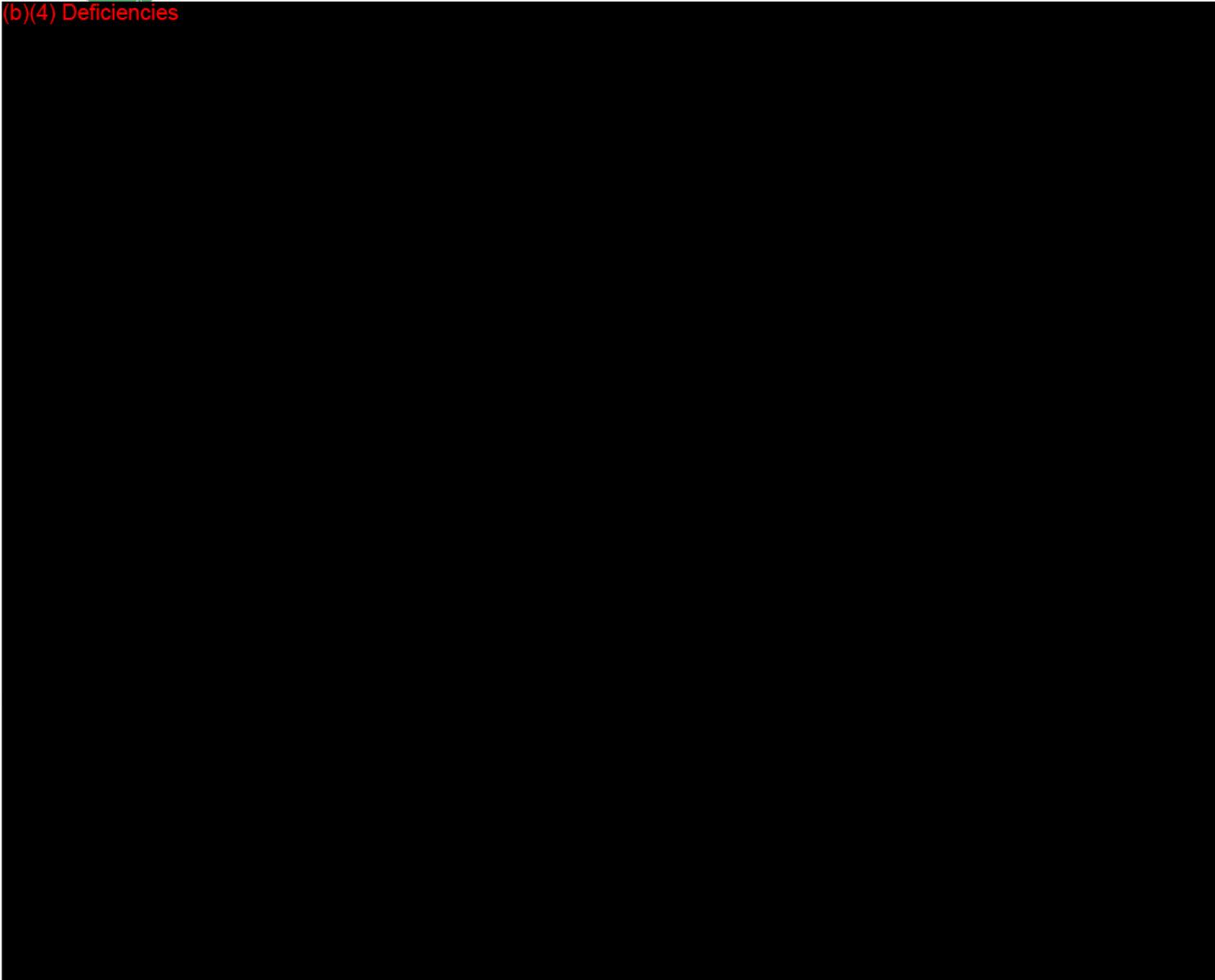


(b)(4) Deficiencies





(b)(4) Deficiencies



With the completion of the activities and documentation revisions described above, we consider the identified deficiencies associated with the (b)(4) [redacted] to have been addressed.

Completed By / Date:

(b)(6) [redacted]

1/27/14

QA/RA Manager, Riverpoint Medical, LLC.



PTFE Suture 510(k) Submission

Attachment 1: Prior FDA Communications (7 Pages)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 15, 2013

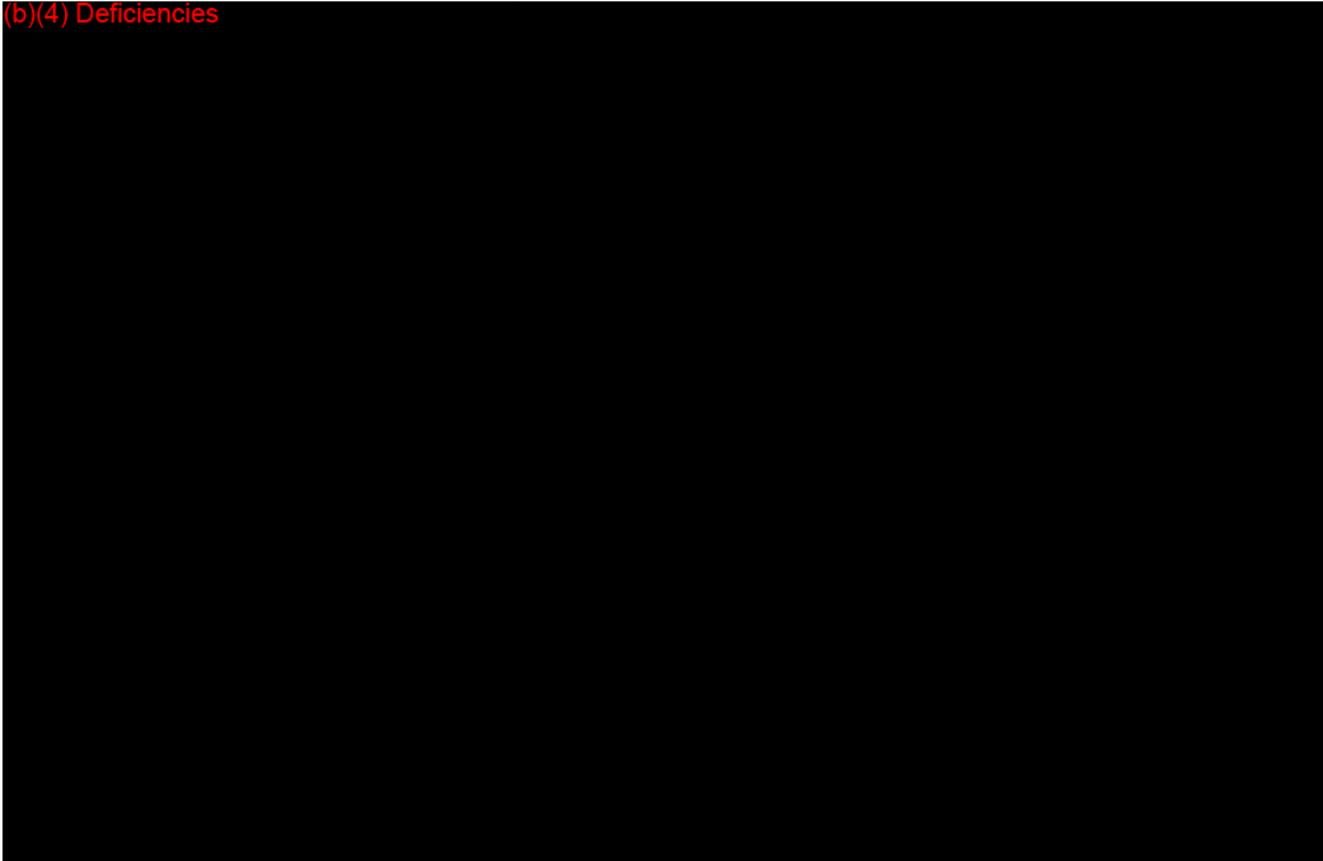
Riverpoint Medical
% Mr. Doug Rowley, RA/QA Director
825 NE 25th Avenue
Portland, Oregon 97232

Re: K131147
Trade Name: MonoTex PTFE Suture
Dated: June 20, 2013
Received: June 21, 2013

Dear Mr. Rowley:

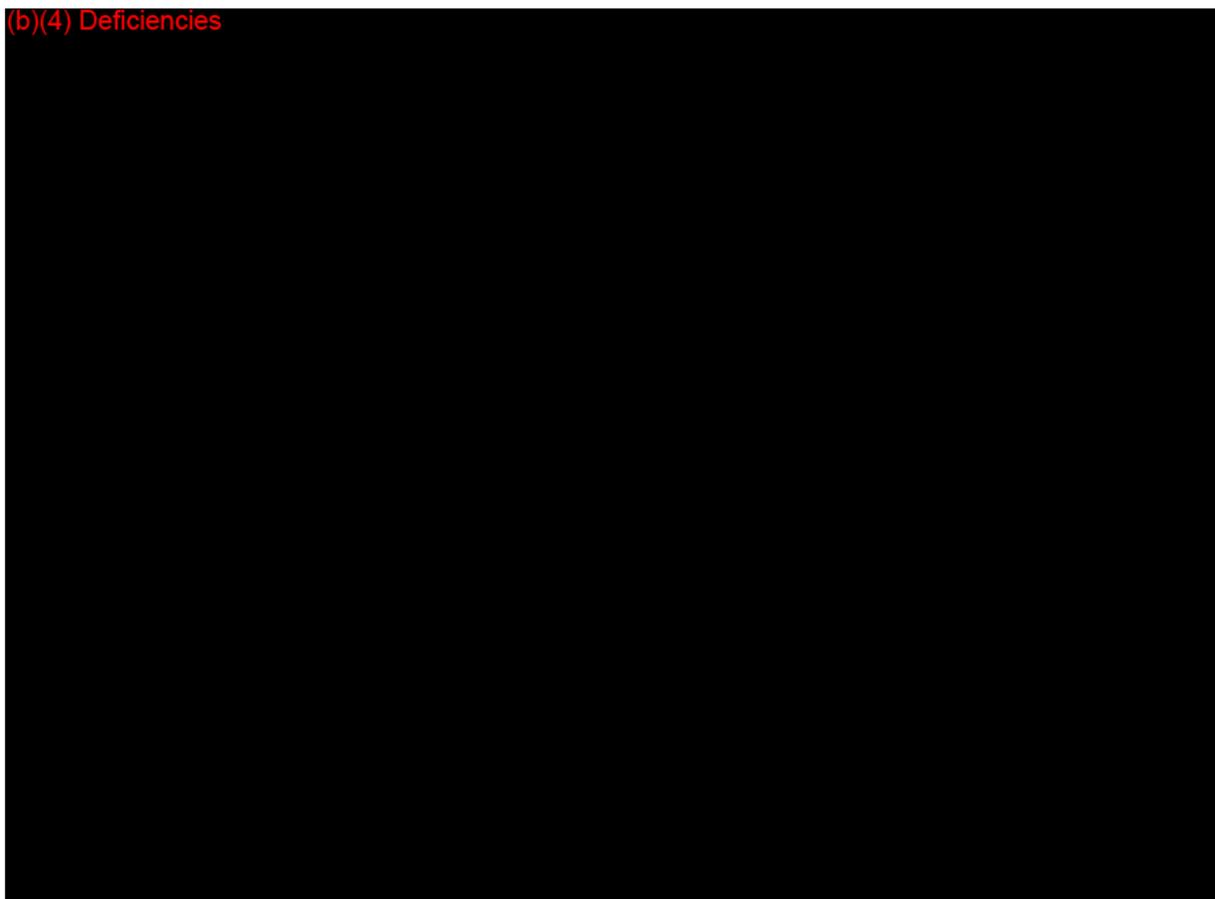
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require that you address the following deficiencies:

(b)(4) Deficiencies



Page 2 – Mr. Doug Rowley

(b)(4) Deficiencies



The deficiencies identified above 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 (Act) for determining substantial equivalence of your device.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(i), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Act. You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations (21 CFR 812).

In accordance with 21 CFR 807.87(i), FDA may consider a 510(k) to be withdrawn if the submitter fails to provide additional information within 30 days of an Additional Information (AI) request. FDA generally permits submitters additional time to respond to such requests. FDA intends to automatically grant a maximum of 180 calendar days from the date of the AI request, even if the submitter has not requested an extension. Therefore, submitters are no longer required to submit written requests for extension. However, you should be aware that

Page 3 – Mr. Doug Rowley

FDA intends to issue a notice of withdrawal under 21 CFR 807.87(l) if FDA does not receive, in a submission to the appropriate Document Control Center, a complete response to all of the deficiencies in this AI request within 180 calendar days of the date of this request. 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.

For further information regarding 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 Amendments of 2012 (MDUFA III), to the Federal Food, Drug, and Cosmetic Act, you may refer to our guidance document entitled "Guidance for Industry and Food and Drug Administration Staff FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals". You may review this document at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm>.

The requested information should reference your above 510(k) number and should be submitted in duplicate to:

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

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by section 1136 of the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to require an electronic copy (eCopy) for certain types of submissions. An eCopy is an exact duplicate of a paper submission, created and submitted on a CD, DVD, or other electronic media, accompanied by a signed cover letter and the complete original paper submission. This authorization applies to the original, amendments, supplements, and reports, as applicable, for your submission type.

For more information about FDA's new eCopy program, including the new technical standards for an eCopy, refer to the guidance document, "eCopy Program for Medical Device Submissions" at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf>. In addition, we strongly encourage you to visit FDA's eSubmitter website at <http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm221506.htm> in order to develop an eCopy in accordance with the new technical standards prior to sending it to FDA.

If you would like a meeting or teleconference with the review team and management to discuss your planned approach for responding to the deficiencies in this letter, please submit your request for feedback as a Submission Issue Q-Submission (Q-Sub). Please note, however, that a Submission Issue Q-Sub does not take the place of a formal response to this letter. As noted above, FDA will consider this 510(k) to be withdrawn if FDA does not receive, in a submission to the appropriate Document Control Center, a complete response to all of the deficiencies in this AI request within 180 calendar days of the date of this request.

Page 4 – Mr. Doug Rowley

If you have any minor clarification questions concerning the contents of the letter, please contact Maegen Colehour at (301) 796-6970. If you need information or assistance concerning the IDE regulations or 510(k) policy, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100, or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

David Krause -S

David Krause, Ph.D.
Chief, Plastic & Reconstructive
Surgery Branch I
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Riverpoint Medical
% Mr. Doug Rowley
RA/QA Director
825 NE 25th Avenue
Portland, Oregon 97232

Re: K122626

Trade Name: Riverpoint PTFE Suture

Dated: October 11, 2012

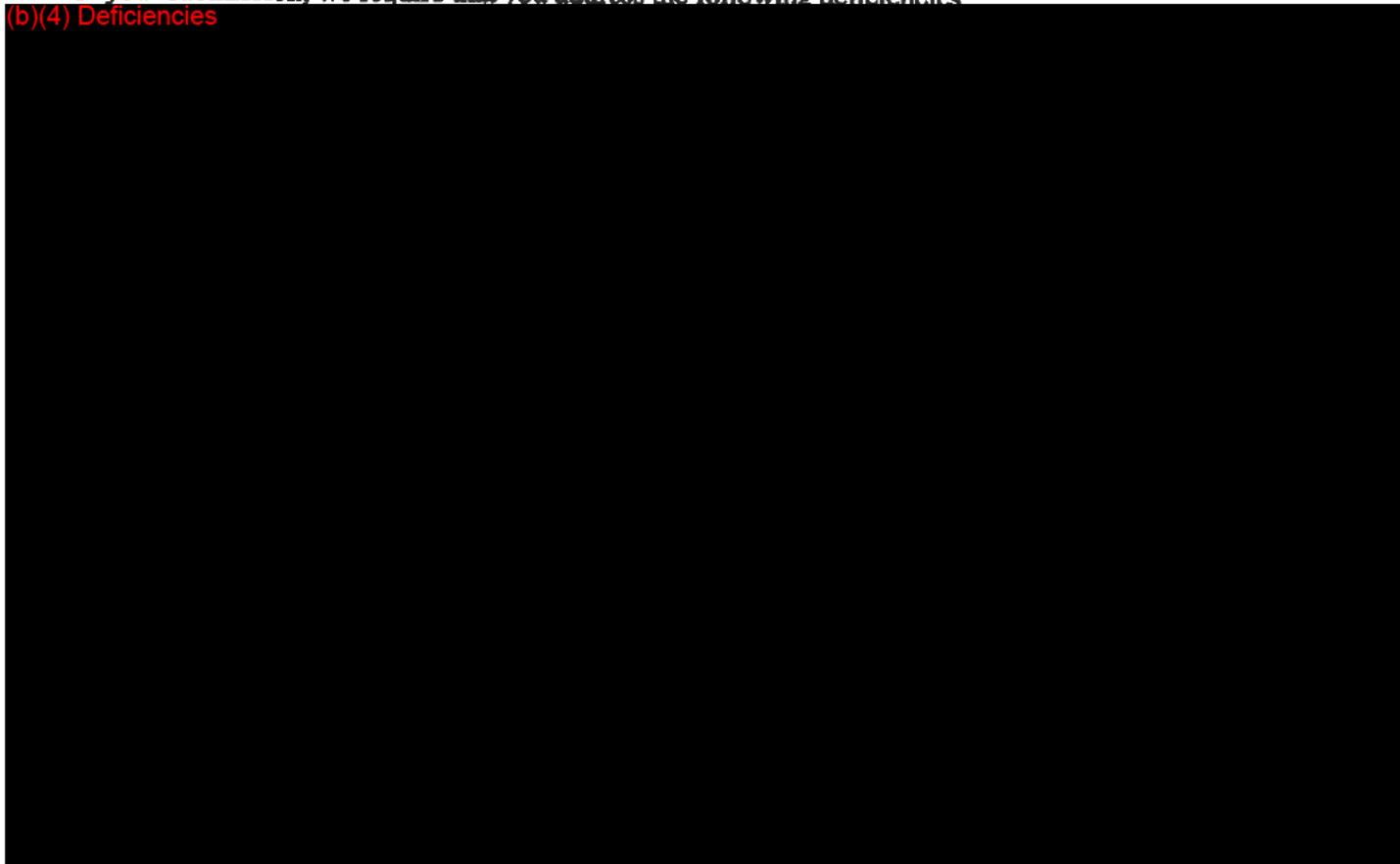
Received: October 12, 2012

OCT 19 2012

Dear Mr. Rowley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require that you address the following deficiencies:

(b)(4) Deficiencies



Page 2 – Mr. Doug Rowley

(b)(4) Deficiencies



The deficiencies identified above 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 (Act) for determining substantial equivalence of your device.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Act. You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations (21 CFR 812).

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k) (21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. For guidance on 510(k) actions, please see our guidance document entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment" at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM089738.pdf>. 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.

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 additional information request.

COPY

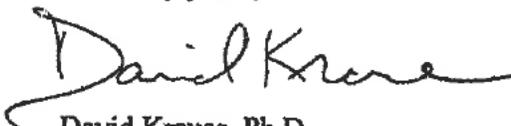
Page 3 – Mr. Doug Rowley

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

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

If you have any questions concerning the contents of the letter, please contact Maegen Colehour at (301) 796-6970 or Maegen.Colehour@fda.hhs.gov. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 796-7100, or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours, .



David Krause, Ph.D.
Chief
Plastic & Reconstructive Surgery Branch
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices
and Radiological Health

COPY



PTFE Suture 510(k) Submission:

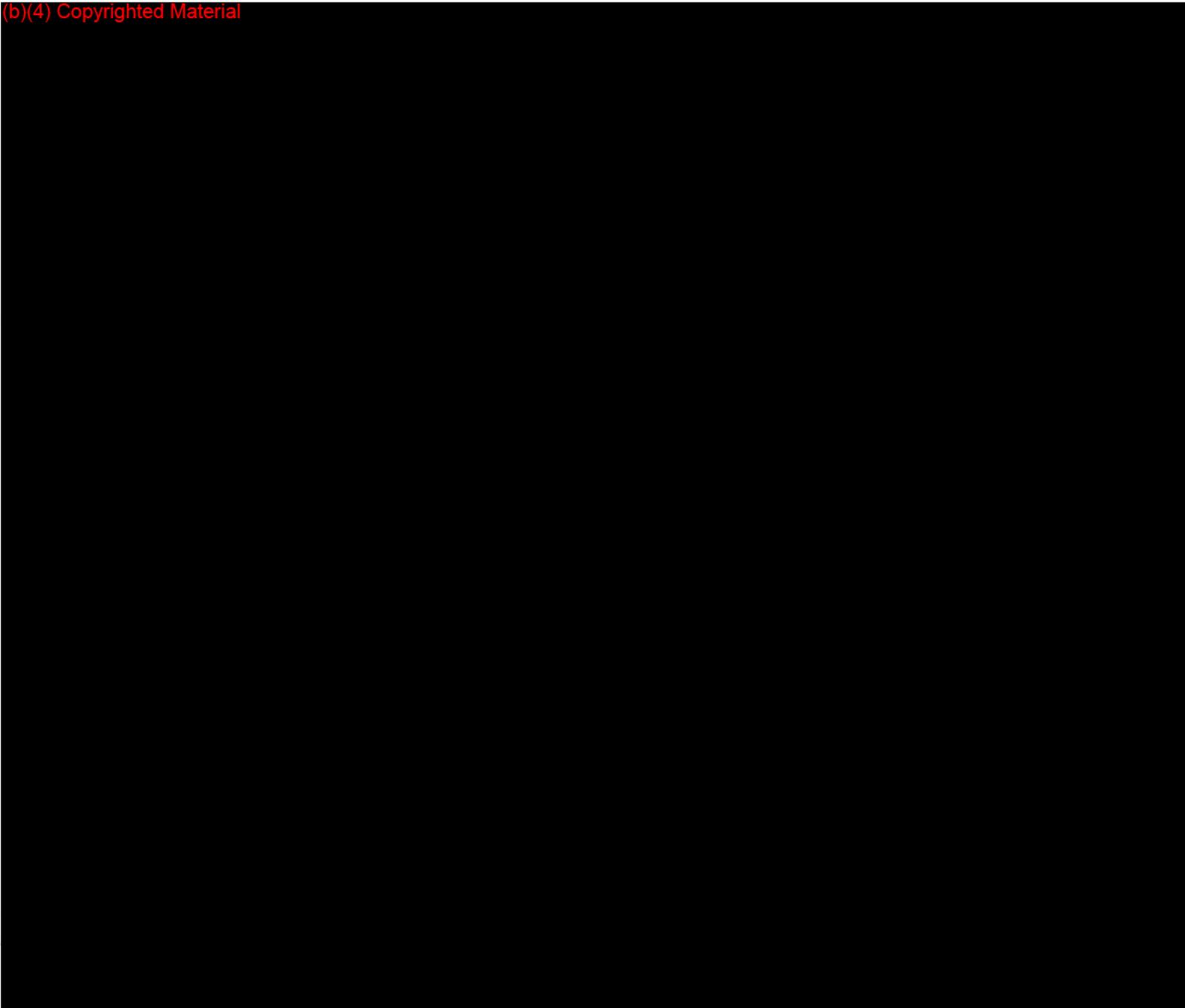
Attachment 2: Referenced Literature (12 pages)

Replacement of Chordae Tendineae with Polytetrafluoroethylene (PTFE) Sutures in Mitral Valve Repair: Early and Long-Term Results

Bruno Chiappini, Alvaro Sanchez, Philippe Noirhomme, Robert Verhelst, Jean Rubay, Alain Poncelet, Jean Christophe Funken, Gebrine El Khoury

Department of Cardiovascular and Thoracic Surgery, St. Luc Hospital, Catholic University of Leuven, Brussels, Belgium

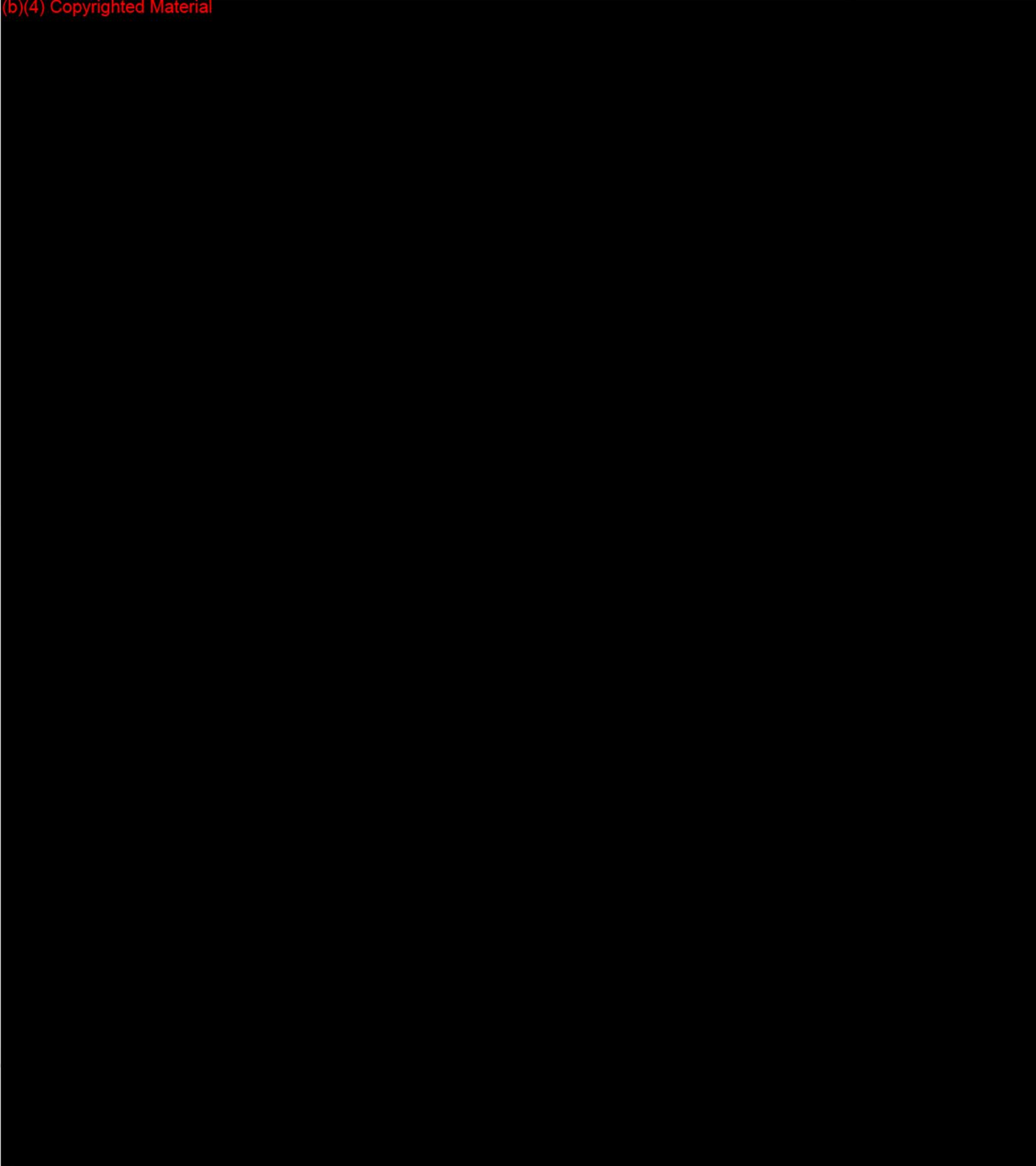
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658 *PTFE neochordae in mitral valve repair*
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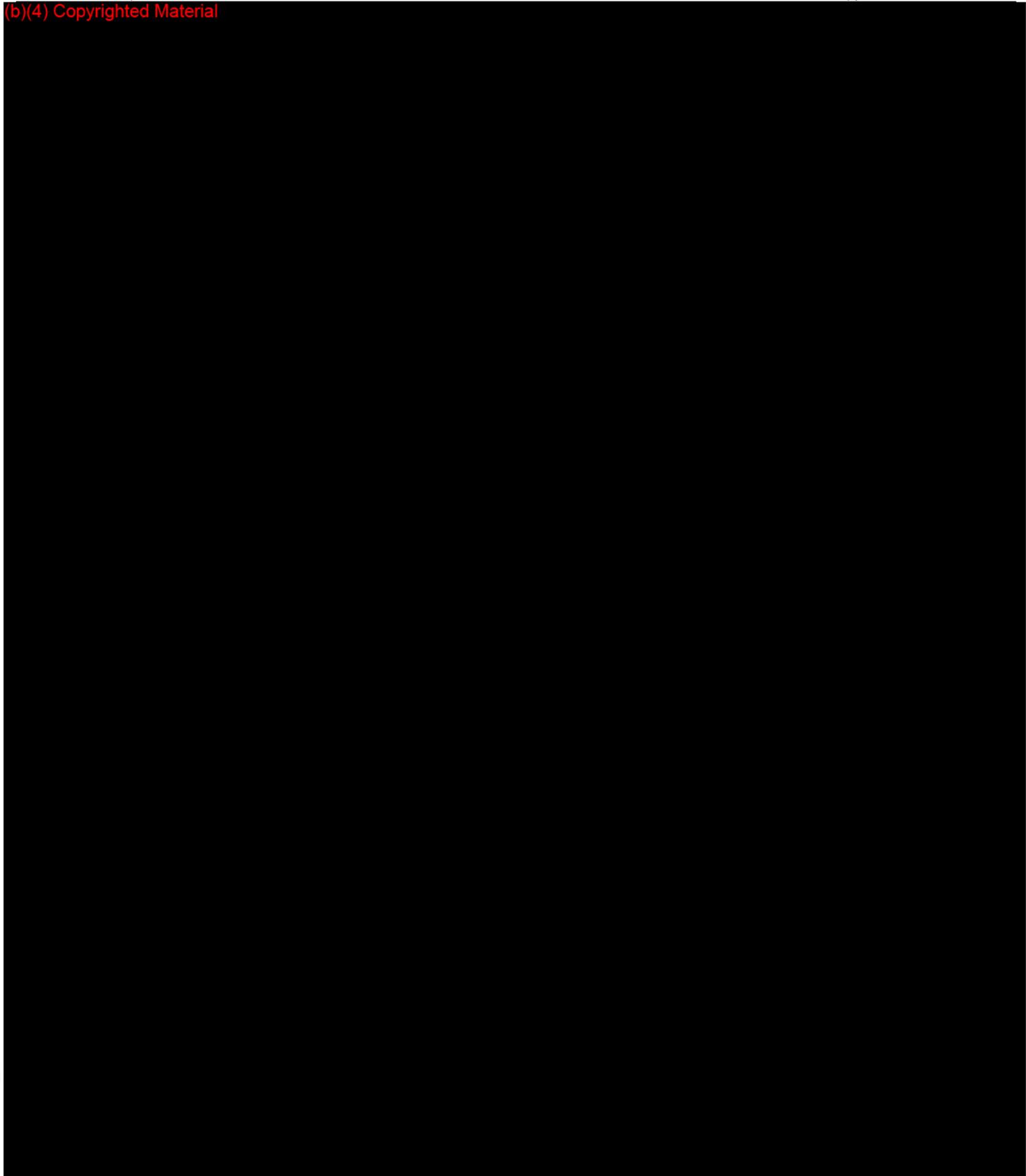
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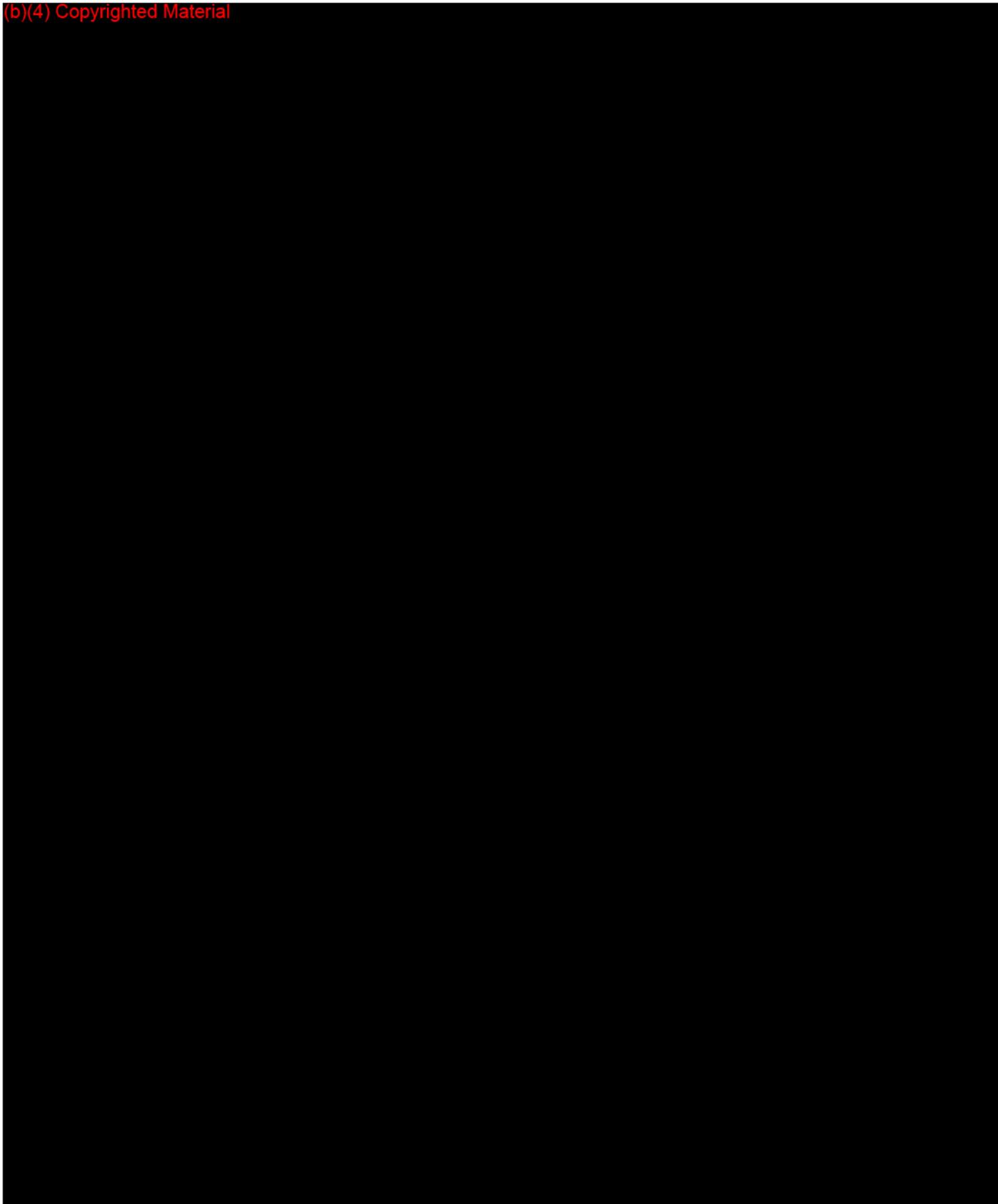
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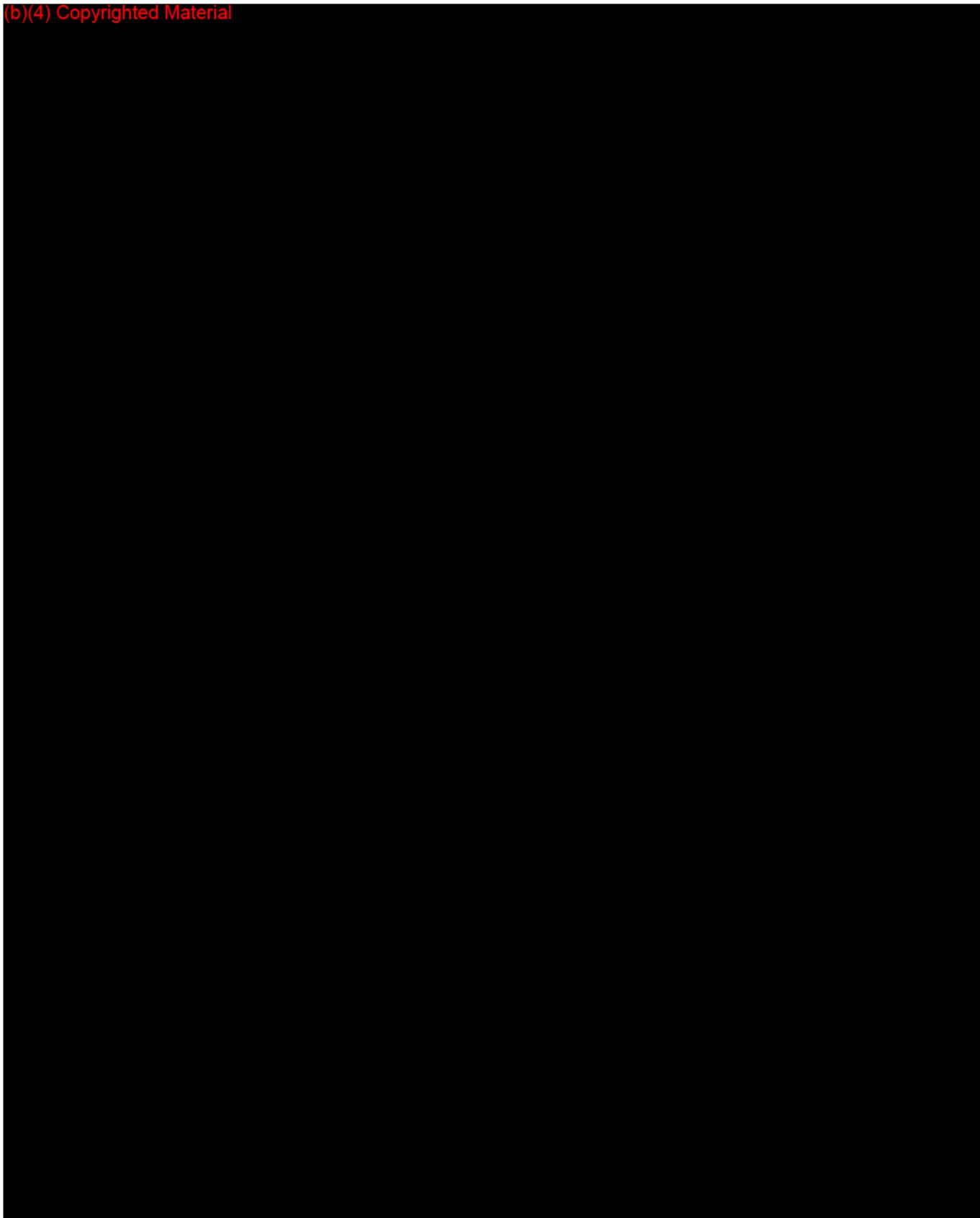
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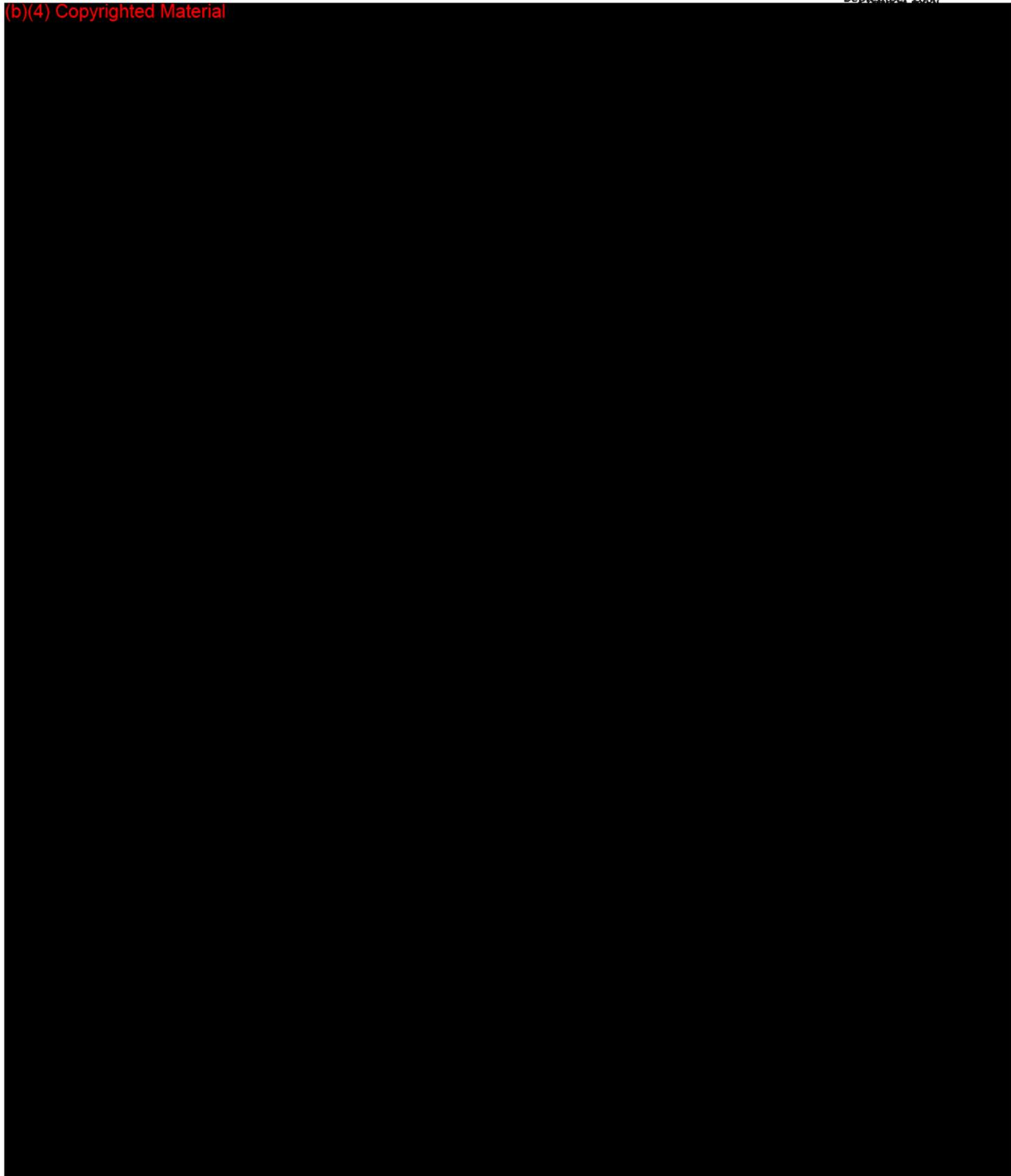
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662 *PTFE neochordae in mitral valve repair*
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Original
Article

Experimental Study on Stability of a High-porosity Expanded Polytetrafluoroethylene Graft in Dogs

Mitsuhiko Isaka, DVM, PhD,¹ Toshiya Nishibe, MD, PhD,¹ Yasuhiro Okuda, MS,³ Masaru Saito, DVM,² Takahiro Seno, DVM, PhD,² Kazuto Yamashita, DVM, PhD,² Yasuharu Izumisawa, DVM, PhD,² Tadao Kotani, DVM, PhD,² and Keishu Yasuda, MD, PhD¹

Purpose: The purpose of the present study was to evaluate the stability of a high-porosity expanded polytetrafluoroethylene (ePTFE) graft, which has been shown to possess excellent biocompatibility and tissue integration.

Methods: The graft used in the present study was a high-porosity ePTFE graft, which had an average internodal distance of approximately 60 μm and a random node architecture with tortuous path channels extending from the outer to the inner surface. Eleven beagle dogs (each group $n=3$ or 4) weighing 10-12 kg were used. The graft, with a 6 mm inside diameter and a 30-40 mm length, was implanted into the canine abdominal aorta and retrieved after 2-80 weeks. The deformation of the graft was evaluated by conventional computed tomography (CT). The radial tensile strength, longitudinal tensile strength, and suture retention strength of the graft were measured after 2-80 weeks.

Results: CT studies showed no anastomotic aneurysm or deformation of the graft. Physical tests demonstrated no significant deterioration in suture retention strength, radial tensile strength or longitudinal tensile strength for periods ranging from 2-80 weeks compared to pre-implantation grafts.

Conclusion: The graft possesses adequate stability that ensures safe and effective clinical use. (*Ann Thorac Cardiovasc Surg* 2006; 12: 37-41)

Key words: stability, high-porosity, expanded polytetrafluoroethylene

Introduction

Polytetrafluoroethylene (PTFE) is a fully fluorinated polymer with a chemical formula $(-\text{CF}_2-\text{CF}_2)$. Since a process to expanded PTFE (ePTFE) was discovered by Oga of Sumitomo Electric Industries while conducting experiments on wire coating,¹⁾ the technique was ultimately re-

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financed and applied to the development of a viable vascular prosthesis. In 1975, the first ePTFE graft was introduced to the market by two manufacturers, Impra and W.L. Gore and Associates. Early observation of aneurysmal change of ePTFE grafts led manufacturers to add a thin outer reinforcing wrap of porous fibrous PTFE or sinter on the outer surface.²⁾

The biological behavior of ePTFE grafts is largely influenced by their physical dimensions, which can be controlled by their manufacturing process. The physical structure of ePTFE grafts comprises a microporous framework of solid materials (nodes) connected by fine fibers (fibrils). Several investigators were able to demonstrate improved graft healing by making the graft more porous.³⁻⁷⁾ However, in such experiments, high-porosity ePTFE grafts lacked an outer wrap and were not clinically available

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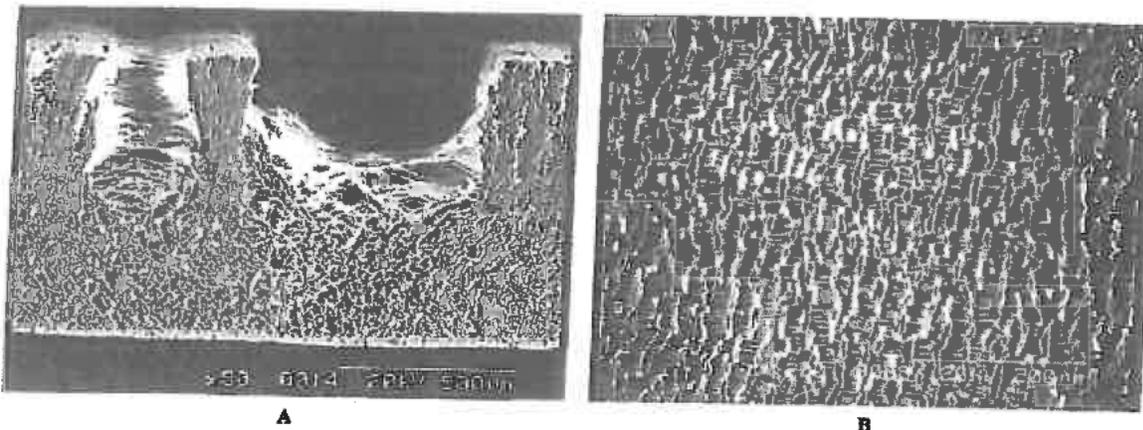


Fig. 1. Scanning electron micrographs of a high-porosity ePTFE graft with unique node-fibril morphology.
 A: Longitudinal section.
 B: Inner surface.

because of their physical fragility.

Recently, we developed a new high-porosity ePTFE graft with unique node-fibril morphology that possesses excellent biocompatibility and tissue integration.⁹ The purpose of the present study was to evaluate the stability of the graft using a canine abdominal aorta replacement model.

Material and Methods

Vascular grafts

The graft used in the present study was a high-porosity ePTFE graft with unique node-fibril morphology. The graft had an average internodal distance of approximately 60 μm and a random node architecture with tortuous path channels extending from the outer to the inner surface (Fig. 1).⁹ The graft had a 6 mm inside diameter and was 30-40 mm long. The graft was reinforced by a fluoropolyethylene filament.

Animal models

Eleven beagle dogs of either sex weighing 10-12 kg were used. The dog was chosen as a test animal because it has been reported to approximate the human in terms of vascular graft healing.⁹ All animals have received humane care in compliance with the "Principles of Laboratory Animal Care" formulated by the National Society for Medical Research and the "Guide for the Care and Use of Laboratory Animals" prepared by the Institute of Laboratory Animal Resources and published by the National

Institutes of Health (NIH Publication No. 86-23, revised 1985).

The animals were anesthetized with an intravenous injection of butorphanol (0.025 mg/kg), midazolam (0.3 mg/kg), and ketamine (5 mg/kg), and were endotracheally intubated. Anesthesia was then maintained with 1% to 2% sevoflurane mixed with nitrous oxide and oxygen. A midline abdominal incision was made, and the abdominal aorta below the renal artery was identified and isolated from the surrounding structures. Heparin (150 IU/kg) was given intravenously, proximal and distal control of the abdominal aorta was obtained, and a 1-2-cm section of the abdominal aorta was excised. The grafts were interposed between the edges of the abdominal aorta, using a continuous 5-0 monofilament polypropylene. After complete hemostasis was secured, the abdomen was closed layer to layer. Ampicillin (50 mg/kg) was given intravenously before the operation. No anticoagulant or antiplatelet drugs were given postoperatively. The grafts were harvested at intervals of 2 weeks ($n=4$), 4 weeks ($n=4$) and 80 weeks ($n=3$). The animals were anesthetized and computed tomography (CT) was performed. The abdomen was then reopened. The entire graft with a portion of the host artery was removed under systemic heparinization (150 IU/kg). The specimen was fixed with 10% buffered formalin for 2 weeks. Finally, the animals were sacrificed by a sufficient dose of potassium chloride.

Computed tomography (CT)

The deformation of the graft was evaluated by conven-

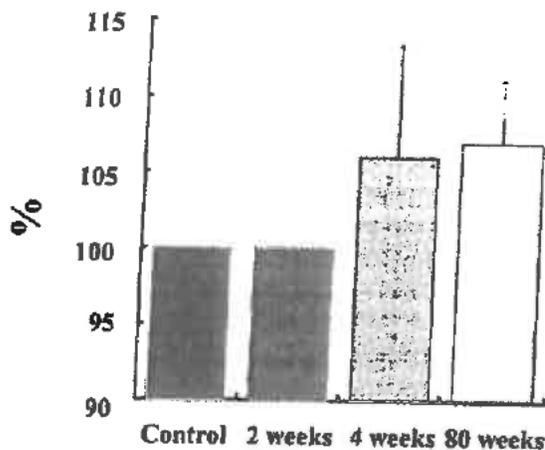
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Fig. 2. Deformity ratio measured by using CT. There was no significant difference in the deformity ratio over the time course.

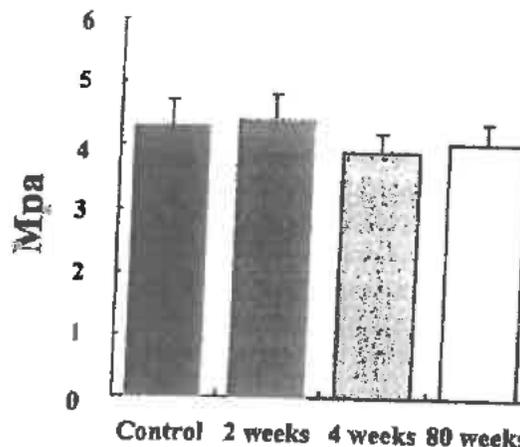


Fig. 3. Radial tensile strength. The strength did not change at all points as compared to pre-implantation.

tional CT. The CT was performed under the condition of 120 kV and 100 mA. The coronal sections were 1 mm thick. The maximum and minimum diameters of the graft were measured at the midpoint of the graft. The deformity ratio (%) was calculated as a percentage determined by dividing the maximum diameter into the minimum diameter.

Physical properties

The radial tensile strength, longitudinal tensile strength, and suture retention strength of the graft were evaluated according to test methods similar to those described by McClurken et al.¹⁰ The reinforced filament was stripped from the graft wall, and the graft was cut into a test strip. To measure radial tensile strength and longitudinal tensile strength for the graft wall, a test strip, 1 mm in width and 10 mm in length, was clamped between a pair of jaw grips and stretched at a constant rate of 20 mm/minutes. The resulting force required to maintain this constant crosshead speed was indicated on a recorder that was synchronized with an Instron tensile strength machine. The radial and longitudinal tensile strengths were defined as the force at break (unit: megapascal, Mpa).

To measure suture retention strength for the graft wall, a test strip, 10 mm in width and 10 mm in length, was mounted in an Instron tensile testing machine and a 5-0 monofilament suture with a tapered noncutting needle was passed through one wall. The test was performed in the longitudinal direction. A 3-mm bite was stressed at a con-

stant rate of 20 mm/minutes. The resulting force was recorded on a strip chart recorder with the peak force noted in g. The suture retention strength was defined as the peak force at the breaking point.

Statistics

Statistical analysis of distortion ratio, radial tensile strength, and longitudinal tensile strength was performed by analysis of variance (ANOVA), followed by the Bonferroni-Dunn test. The suture retention strength was analyzed by the Student's t test. P values <0.05 were considered significant. All data are expressed as mean \pm standard deviation.

Results

Deformity ratio

No grafts were found to be occluded when the CT was performed. There were no anastomotic aneurysms or other complications. The deformity ratio was 100 \pm 0% at 2 weeks, 106 \pm 7.3% at 4 weeks, and 107 \pm 4.1% at 80 weeks. There was no significant difference in the deformity ratio over the time course (Fig. 2).

Physical properties

The radial and longitudinal tensile strengths for the graft wall were 4.3 \pm 0.4 Mpa and 17.2 \pm 2.6 Mpa at pre-implantation, 4.4 \pm 0.4 Mpa and 15.0 \pm 1.5 Mpa at 2 weeks, 3.9 \pm 0.3 Mpa and 12.2 \pm 2.4 Mpa at 4 weeks, and 4.1 \pm 0.3 Mpa and 16.0 \pm 0.4 Mpa at 80 weeks, respectively. The strength did

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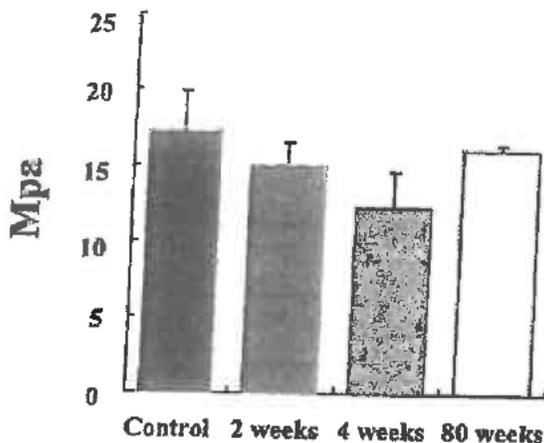


Fig. 4. Longitudinal tensile strength. The strength did not change at all points as compared to pre-implantation.

not change at all points as compared to pre-implantation (Figs. 3 and 4). The suture retention strength for the graft wall was measured at pre-implantation and 80 weeks. It was 479.3 ± 51.0 g at pre-implantation and 550.7 ± 81.6 g at 80 weeks. There was no significant difference in the suture retention strength between pre-implantation and 80 weeks (Fig. 5).

Comment

There is general agreement about the desirable characteristics of a vessel substitute that contribute to its function as an optimal vascular graft; it should be biocompatible with the host, resistant to infection, easy to sterilize and store, available in a variety of sizes, easy to implant, impervious to blood leakage, nonthrombogenic, compliant, low cost, easy to manufacture and physically durable.¹¹⁾ The graft should be free from deleterious dimensional instability over time, which would result in significant dilatation, aneurysm formation, rupture, or excessive elongation that could promote tortuosity, kinking, and eventual thrombosis. The graft should also be capable of being adequately sterilized without deterioration and conveniently stored in a sterilized condition for prolonged periods. Although a variety of synthetic materials were investigated as possible vascular grafts, including Vmynon-N, Nylon, PTFE, Ivalon, Orion, and polyethylene terephthalate (Dacron), the fabric materials, except PTFE and Dacron, lost significant tensile strength following implantation or exhibited other problems for

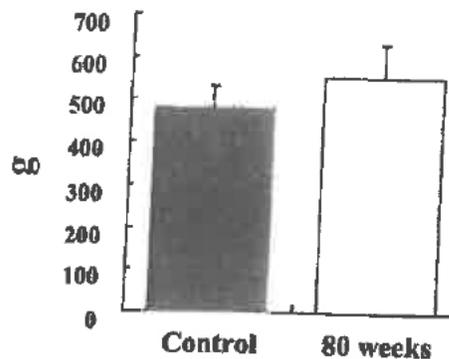


Fig. 5. Suture retention strength. There was no significant difference in the suture retention strength between pre-implantation and 80 weeks.

manufacturing or sterilization. Therefore, in Japan, only PTFE and Dacron grafts are commercially available as prosthetic grafts for peripheral vascular surgery.

It has been generally known that ePTFE grafts function well as vascular grafts. The internodal distance, which is defined as the average of the spacing between the nodes, has been widely used to describe the biological behavior of ePTFE grafts. In 1975, Campbell et al. performed extensive testing of ePTFE and concluded that an internodal distance of less than $22 \mu\text{m}$ was optimal.¹²⁾ They actually correlated increasing internodal distance with inferior patency in dogs, which appeared to be due to the development of a thicker pseudointima. Since then, the internodal distance in most commercially available grafts was set in the $17\text{-}20\text{-}\mu\text{m}$ range. However, in the 1980-1990s, several laboratories including ours revisited the relationship of internodal distance to graft healing.³⁻⁷⁾ ePTFE grafts with greater internodal distance, i.e., high-porosity ePTFE grafts, reportedly resulted in better graft healing as compared to standard ePTFE grafts. The large pore size allows rapid and unencumbered ingrowth of areolar tissue from the surrounding tissue through the interstices of the graft, thereby achieving a "healed" graft with an organized cellular, antithrombotic flow surface. However, high-porosity ePTFE grafts without an outer wrap were not clinically available because of their physical fragility.

Recently, we developed a new high-porosity ePTFE graft with unique node-fibril morphology.⁸⁾ The graft had a random node architecture with tortuous path channels extending from the outer to the inner surface. Our previ-

Experimental Study on Stability of a High-porosity Expanded Polytetrafluoroethylene Graft in Dogs

ous study demonstrated that, in the dog carotid interposition model, the graft exhibited satisfactory biocompatibility and tissue integration. The graft allowed adequate biologic communication to occur where cells and tissues could penetrate and vaginate, resulting in a faster rate of healing.

The graft exhibited a degree of physical properties similar to other ePTFE grafts on the market. Some data has been published indicating that the suture retention strength, radial tensile strength and longitudinal tensile strength were 700 g, 5.5 Mpa and 12.0 Mpa for an Impra graft, 600 g, 9.0 Mpa and 11.8 Mpa for a Gore-Tex graft, and 520 g, 3.6 Mpa and 12.4 Mpa for a Vitagraft,⁹ while 479.3 g, 4.3 Mpa and 17.2 Mpa for the graft, respectively. This result led us to test the stability of the graft, which is one of the desirable characteristics of an optimal vascular graft.

There have been several reports indicating that degeneration can occur in currently commercially available ePTFE grafts. Geiger suggested that, 12 months after implantation, the structure of ePTFE grafts was inhomogeneous with a widening of micropores, and both compressed and ruptured fibrils.¹³ Vanmaele et al. also reported loss of mechanical strength in ePTFE grafts within a week.¹⁴ However, the present study demonstrated that, in a canine abdominal aorta replacement model, the graft showed no significant deterioration in suture retention strength, radial tensile strength, or longitudinal tensile strength for periods ranging from 2-80 weeks. CT studies as well as macroscopic observation at sacrifice also demonstrated no anastomotic aneurysm or deformation of the graft.

In conclusion, the present study demonstrates that the graft possesses excellent stability. Taken together with our previous study, it is suggested that the graft be considered for evaluation in clinical trials.

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NOTE: This form is REQUIRED for holds and for final decisions.

Reviewer Name Maegen Colehour, MS

510(k) Number K140415

Please list CTS decision code: SE - Substantially Equivalent

Hold (Additional Information or Telephone Hold) Hold Date

Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.)

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Please complete the following for a final clearance decision (i.e, SE, SE with Limitations, etc.)	YES	NO
Indications for Use Page (Attach IFU)	X	
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Truthful and Accurate Statement (Must be present for a Final Decision)	X	
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Is this device intended for pediatric use only?		X
Is this a prescription device? (If both prescription & OTC, check both boxes.)	X	
Is clinical data necessary to support the review of this 510(k)?		X
For United States based clinical studies only, did the application include a completed Form FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If study was conducted in the United States and Form FDA 3674 was not included or was incomplete, then applicant must be contacted to obtain completed form.)		
Does this device include an Animal Tissue Source?		X
All Pediatric Patients age <= 21		X

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Neonate/Newborn (Birth to 28 days)		×
Infant (29 days to < 2 years)		×
Child (2 years to <12 years)		×
Adolescent (12 years to <18 years)		×
Transitional Adolescent A (18 years to <21 years); 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 years to <21 years); No special considerations compared to adults >= 21 years)		×
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance)		×

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David Krause -S
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