

FEB 01 2002

K013971

I. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

510(k) Summary Of Safety and Effectiveness

I. General Information

This Summary of Safety and Effectiveness information is being submitted in accordance with the requirements of the SMDA of 1990 and 21 § 807.92

Establishment:

- Address: Becton Dickinson VACUTAINER Systems
1 Becton Drive
Franklin Lakes, NJ 07417-1885
- Registration Number: 2243072
- Contact Person: Keith M. Smith
Director, Regulatory Affairs
Telephone No.:(201) 847-5837
Fax No. (201) 847-7040
- Date of Summary: September 28, 2001

Device

- Trade Name: BD Vacutainer™ Safety Coagulation tube
- Classification Name: Tubes, Vials, Systems, Serum Separators, Blood Collection
- Classification: Class II
- Performance Standards: None Established under 514 of the Food, Drug and Cosmetic Act

II. Safety and Effectiveness Information Supporting the Substantial Equivalence Determination

Substantial Equivalence Declaration:

The term "Substantial Equivalence" as used in this 510(k) Premarket Notification is limited to the definition of Substantial Equivalence found in the Federal Food, Drug, and Cosmetic Act, as amended and as applied under 21 CFR § 807, Subpart E, under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of, substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

- Device Description:

The BD Vacutainer™ Safety Coagulation tubes are sterile, plastic, evacuated blood collection tubes. The tubes contain 0.109M or 0.129M Sodium Citrate as an anticoagulant intended to prevent whole blood from clotting prior to analysis. The specimen is centrifuged and the plasma portion is analyzed for coagulation parameters to detect clotting time disorders and to monitor patients undergoing anticoagulation therapy. The benefits of a plastic tube decrease the occurrence of accidental breakage, increases the safety of laboratory personnel and reduces the necessity of repeat specimens.

- Intended Use:

The BD Vacutainer™ Safety Coagulation tube is an evacuated blood collection tube that provides a means of collecting, transporting and processing blood in a closed tube. The buffered sodium citrate additive provides an anticoagulated specimen that may be used for clinical laboratory coagulation assays. The benefits of a safety plastic coagulation tube with Hemogard Safety Closure Assembly are:

- reduced risk of specimen tube breakage
- reduced exposure to blood by laboratory personnel and to minimize blood splatter during stopper removal

These benefits lead to increased safety of laboratory personnel and reduced necessity of repeat specimen collection.

- Synopsis of Test Methods and Results

Clinical evaluations were performed to determine the safety and efficacy of the BD Vacutainer™ Safety Coagulation tube. The BD Vacutainer™ Safety Coagulation tube (plastic) was compared to the currently marketed VACUTAINER™ Brand Sodium Citrate Tube (glass). The results of the

clinical evaluation demonstrated that the BD Vacutainer™ Safety Coagulation tube provides clinically equivalent results when compared to the VACUTAINER™ Brand Sodium Citrate Tube for Normal, Warfarin, Heparin and other patient donors.

• Substantial Equivalence

Based on comparison of the device features, materials, and intended use, the BD Vacutainer™ Safety Coagulation tube can be shown to be substantially equivalent to the commercially available predicate device.

The predicate device, K number, and clearance date are identified below:

Manufacturer	Predicate Device	K-Number	Clearance Date
Becton Dickinson VACUTAINER™ Systems	VACUTAINER™ Brand Sodium Citrate Tube	N/A	Pre-Amendment Device and, therefore, exempt from premarket notification requirements according to the MDA of 1976



Keith M. Smith
Director, Regulatory Affairs

11/30/01
Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 01 2002

Mr. Keith M. Smith
Associate Director, Regulatory Affairs
BD Pharmaceutical Systems
Becton Dickinson and Company
1 Becton Drive
Mail Code 440
Franklin Lakes, New Jersey 07417-1880

Re: k013971
Trade/Device Name: BD Vacutainer™ Safety Coagulation Tube
Regulation Number: 21 CFR § 862.1675
Regulation Name: Tubes, Vials, Systems, Serum Separators, Blood Collection
Regulatory Class: II
Product Code: GIM
Dated: November 28, 2001
Received: December 3, 2001

Dear Mr. Smith:

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.

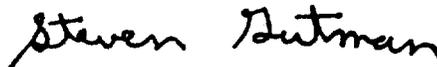
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

Page 2

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

B. INDICATIONS FOR USE

510(k) Number (if known): K013971

Device Name: BD Vacutainer™ Safety Coagulation tube

Indications for Use:

The BD Vacutainer™ Safety Coagulation tube is a plastic evacuated blood collection tube that provides a means of collecting, transporting and processing blood in a closed tube. The buffered sodium citrate additive provides an anticoagulated specimen that may be used for clinical laboratory coagulation assays. The benefits of a safety plastic coagulation tube with Hemogard Safety Closure Assembly are:

- reduced risk of specimen tube breakage
- reduced exposure to blood by laboratory personnel and to minimize blood splatter during stopper removal

These benefits lead to increased safety of laboratory personnel and reduced necessity of repeat specimen collection.

Stephane Bantada

 (Division Sign-Off)
 Division of Clinical Laboratory Devices

(Please do not Write below this line-continue on another page if needed)

510(k) Number K013971

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Or Over-the-Counter Use

(Per 21 CFR § 801.109)

(Optional format 1-2-96)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 01 2002

Mr. Keith M. Smith
Associate Director, Regulatory Affairs
BD Pharmaceutical Systems
Becton Dickinson and Company
1 Becton Drive
Mail Code 440
Franklin Lakes, New Jersey 07417-1880

Re: k013971
Trade/Device Name: BD Vacutainer™ Safety Coagulation Tube
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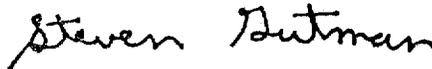
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Sincerely yours,



Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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B. INDICATIONS FOR USE

510(k) Number (if known): K013971

Device Name: BD Vacutainer™ Safety Coagulation tube

Indications for Use:

The BD Vacutainer™ Safety Coagulation tube is a plastic evacuated blood collection tube that provides a means of collecting, transporting and processing blood in a closed tube. The buffered sodium citrate additive provides an anticoagulated specimen that may be used for clinical laboratory coagulation assays. The benefits of a safety plastic coagulation tube with Hemogard Safety Closure Assembly are:

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These benefits lead to increased safety of laboratory personnel and reduced necessity of repeat specimen collection.

Stephene Boudreau
 (Division Sign-Off)
 Division of Clinical Laboratory Devices

(Please do not Write below this line-continue on another page if needed)
 510(k) Number K013971

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Or Over-the-Counter Use

(Per 21 CFR § 801.109)

(Optional format 1-2-96)

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

From: Reviewer(s) - Name(s) Valene R. Dada

Subject: 510(k) Number K013971

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices. (862-7750, 864.5400, 1-862-1675)
- NOT substantially equivalent to marketed devices.

De Novo Classification Candidate? YES NO

Other (e.g., exempt by regulation, not a device, duplicate, etc.)

- Is this device subject to Postmarket Surveillance? YES NO
- Is this device subject to the Tracking Regulation? YES NO
- Was clinical data necessary to support the review of this 510(k)? YES NO
- Is this a prescription device? YES NO
- Was this 510(k) reviewed by a Third Party? YES NO
- Special 510(k)? YES NO
- Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers YES NO

This 510(k) contains:

Truthful and Accurate Statement Requested Enclosed
(required for originals received 3-14-95 and after)

A 510(k) summary OR A 510(k) statement

The required certification and summary for class III devices N/A

The indication for use form (required for originals received 1-1-96 and after)

Material of Biological Origin YES NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

- No Confidentiality
- Confidentiality for 90 days
- Continued Confidentiality exceeding 90 days

Predicate Product Code with class:

Additional Product Code(s) with panel (optional):

GIM II 21CFR 862.1675 862-7750 864.5400

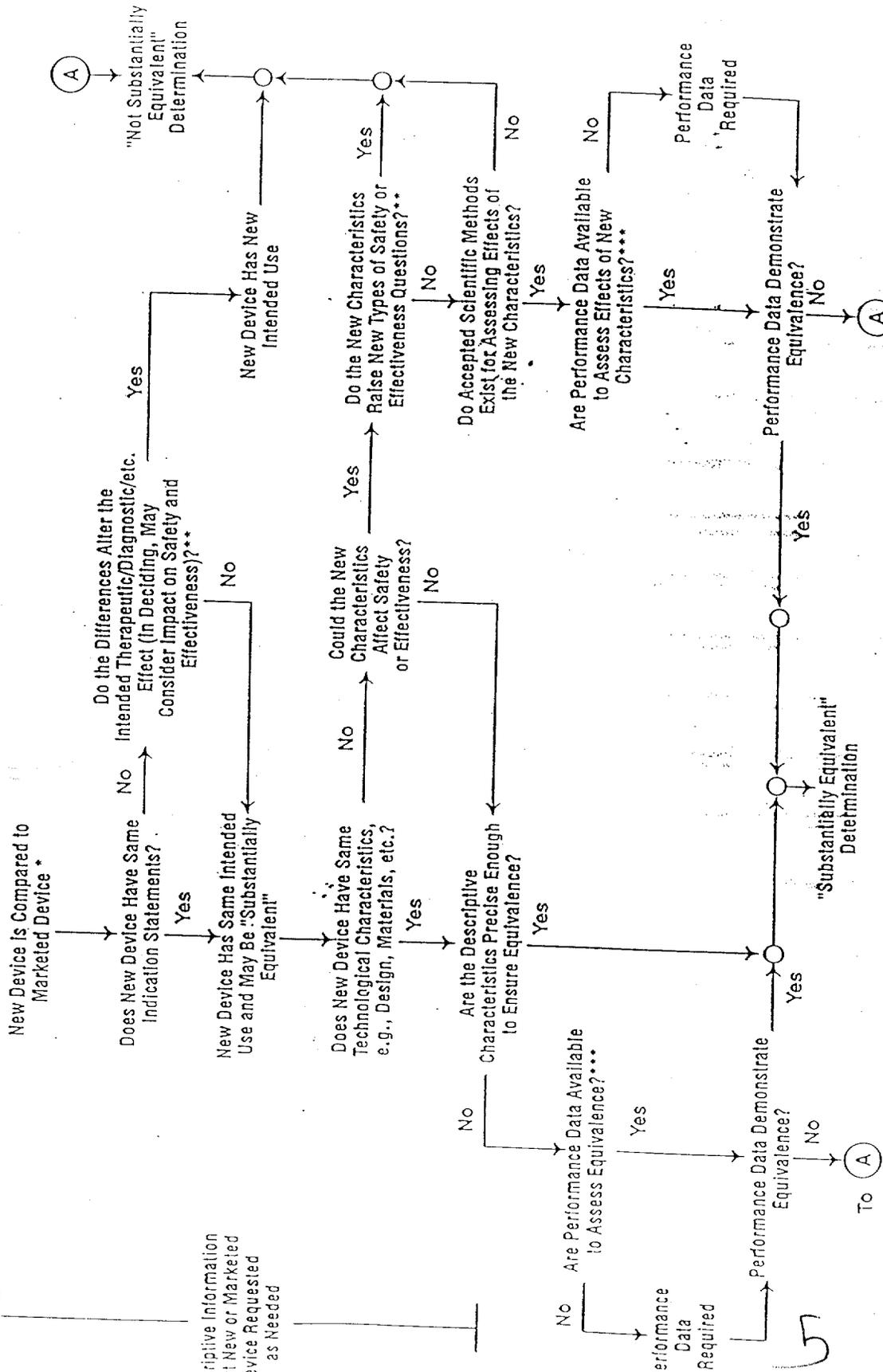
Review: Josephine Yantuck H9CB 1/31/02
(Branch Chief) (Branch Code) (Date)

Final Review: Robert J. Blue-Cutman
(Division Director) (Date)

Revised: 8/17/99

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510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



* 510(k) Submissions Compare New Devices to Marketed Devices. FDA Requests Additional Information if the Relationship Between Marketed and "Predicate" (Pre-Amendment, Classified Post-Amendment) Devices is Unclear.

** This Decision is Primarily Based on Descriptive Information Alone, But Limited Test Information is Sometimes Required.

*** Data May Be: 510(k), Other 510(k)s, The Center's Classification Files, or the Literature

**SCREENING CHECKLIST
FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS**

510(k) Number: K013971

The cover letter clearly identifies the type of 510(k) submission as (Check the appropriate box):

- Special 510(k) - Do Sections 1 and 2
- Abbreviated 510(k) - Do Sections 1, 3 and 4
- Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present	Inadequate or Missing
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510(k)] Manual.	✓	
Table of Contents.	✓	
Truthful and Accurate Statement.	✓	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	✓	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	✓	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510(k)] Manual.	✓	
Statement of Indications for Use that is on a separate page in the premarket submission.	✓	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510(k)] Manual.	✓	
<u>510(k) Summary</u> or 510(k) Statement.	✓	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	✓	
Identification of legally marketed predicate device. *	✓	
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]		
Class III Certification and Summary. **		
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]		
510(k) Kit Certification ***		

- * - May not be applicable for Special 510(k)s.
- ** - Required for Class III devices, only.
- *** - See pages 3-12 and 3-13 in the Premarket Notification [510(k)] Manual and the Convenience Kits Interim Regulatory Guidance.

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Section 2: Required Elements for a SPECIAL 510(k) submission:

	Present	Inadequate or Missing
Name and 510(k) number of the sponsor's own, unmodified predicate device.		
A description of the modified device and a comparison to the sponsor's predicate device.		
A statement that the intended use(s) and indications of the modified device, as described in its labeling, are the same as the intended uses and indications for the sponsor's unmodified predicate device.		
A statement that the modification has not altered the fundamental technology of the sponsor's predicate device.		
A Design Control Activities Summary that includes the following elements (a-e):		
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.		
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.		
c. A Declaration of Conformity with design controls that includes the following statements:		
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.		
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.		

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Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, SEE Required Elements for a Declaration of Conformity to a Recognized Standard, which is posted with the 510(k) boilers on the H drive.]		
For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has <u>not</u> been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device <u>and</u> any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

- * - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:		
b) Sterilization and expiration dating information:		
i) sterilization process		
ii) validation method of sterilization process		
iii) SAL		
iv) packaging		
v) specify pyrogen free		
vi) ETO residues		
vii) radiation dose		
c) Software Documentation:		

Items with checks in the "Present but Deficient" column require additional information from the sponsor. Items with checks in the "Missing" column must be submitted before substantive review of the document.

Passed Screening Yes No

Reviewer: Jisa King

Concurrence by Review Branch: _____

Date: _____

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 for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/cdrh/modact/leastburdensome.html>

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Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		✓
2. Did we grant expedited review?		✓
3. Have you verified that the Document is labeled Class III for GMP purposes? N/A		
4. If, not, has POS been notified?		
5. Is the product a device?	✓	
6. Is the device exempt from 510(k) by regulation or policy?		✓
7. Is the device subject to review by CDRH?	✓	
8. Are you aware that this device has been the subject of a previous NSE decision?		✓
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)? N/A		
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #191-2 and Federal Register 90N0332, September 10, 1991. N/A		

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HOO

REVISED:3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K _____

Reviewer: _____

Division/Branch: _____

Device Name: _____

Product To Which Compared (510(K) Number If Known): _____

	YES	NO	
1. Is Product A Device			If NO = Stop
2. Is Device Subject To 510(k)?			If NO = Stop
3. Same Indication Statement?			If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5. Same Technological Characteristics?			If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?			If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?			If NO = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

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1. Intended Use:
2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:
2. Explain why not subject to 510(k):
3. How does the new indication differ from the predicate device's indication:
4. Explain why there is or is not a new effect or safety or effectiveness issue:
5. Describe the new technological characteristics:
6. Explain how new characteristics could or could not affect safety or effectiveness:
7. Explain how descriptive characteristics are not precise enough:
8. Explain new types of safety or effectiveness questions raised or why the questions are not new:
9. Explain why existing scientific methods can not be used:
10. Explain what performance data is needed:
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

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"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K013971

Reviewer: Valerie R. Dada

Division/Branch: DCLD/HECB

Device Name: BD VACUTANINER SAFETY COAGULATION TUBE

Product To Which Compared (510(K) Number If Known): Vacutainer™ Sodium Citrate Tube (PRE-ADMENDMENT)

	YES	NO	
1. Is Product A Device	X		If NO = Stop
2. Is Device Subject To 510(k)?	X		If NO = Stop
3. Same Indication Statement?	X		If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5. Same Technological Characteristics?	X		If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?		X	If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?	X		If NO = Request Data
11. Data Demonstrate Equivalence?	X		Final Decision: SE

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

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1. **Intended Use:** Vacutainer® Tubes along with Vacutainer® needles and holders are used together as a system for the collection of venous blood. The BD Vacutainer® Safety Coagulation Tubes are used to transport and process blood for testing plasma or whole blood in the clinical laboratory for coagulation testing.
2. **Device Description:** Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

Summary: The Becton Dickinson Vacutainer™ Safety Coagulation Tube is a sterile, plastic, evacuated blood collection tube intended to be used in conjunction with Vacutainer™ holders and needles, as a system for the collection of venous blood. The Safety Coagulation Tube contains either 0.109M or 0.129M of buffered sodium citrate, that when mixed with venous blood, provides an anticoagulated specimen that may be used for clinical laboratory coagulation assays.

The Becton Dickinson Vacutainer™ Safety Coagulation Tube consists of an outer polyethylene terephthalate (PET) tube that serves to maintain vacuum, and an inner polypropylene (PP) tube that contains liquid sodium citrate into which the blood sample is collected. The Safety Coagulation Tube will be available in multiple draw volume configurations of 2.7 ml and 1.8 ml in both the 0.109M and 0.129M sodium citrate concentrations. The plastic tube will be 13mm x 75 mm for all draw volumes.

The Sponsor is claiming substantial equivalence to their pre-amendment Vacutainer™ Sodium Citrate Tube. The devices are regulated under 21 CFR 862.1675, as Class II devices. They are similar in intended use, and differ in design. The new device includes a HEMOGARD™ Closure Assembly (K945952), which reduces the risk of specimen tube breakage, and reduces exposure to blood by minimizing blood spatter during stopper removal.

This device was previously marketed by this company as 1.8 and 2.7ML Partial Draw Citrate Tube, available in citrate concentrations of 0.105M, and 0.129M. The tubes were voluntarily recalled due to sporadic testing results when performing aPTT tests on samples containing unfractionated heparin, aPTT in the normal population, and platelet counts in patients with EDTA-induced platelet clumping and pseudothrombocytopenia.

Since the recall, this is the second submission submitted for 510(k) clearance of the tube. The first submission (K003680) was severely deficient, and the Sponsor was issued a K9, Unable to Determine Letter. After several meetings and discussions with the FDA, the Sponsor submitted a pre-IDE to the FDA for review.

To support substantial equivalence, the Sponsor presented data to support tube draw volume, and a 4-site performance study.

All studies demonstrated acceptable results.

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EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

7. **Explain how descriptive characteristics are not precise enough:**
Descriptive characteristics are not precise enough because the device is intended for medical purposes to collect and to handles blood specimens prior to further testing. Data is needed to demonstrate that the device is safe and effect, as claimed by the Sponsor.
11. **Explain how the performance data demonstrates that the device is or is not substantially equivalent:** Data demonstrated that the device is substantially equivalent to a legally marketed device.

Samples were collected from normal donors; patients on warfarin anticoagulant therapy; patients on heparin anticoagulant therapy; and patients with other diagnoses', and compared to samples collected with predicated device. PT, aPTT, INR, Heparin Xa, platelet counts, F1.2, and p-selectin assays were performed. Data was presented using equivalence, regression and bias (Bland-Altman) statistics. Studies were performed using both tube sizes and both citrate concentrations.

All studies demonstrated acceptable results.

Valerie R. Dada

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
Center for Devices and Radiologic Health

Date: 28 JAN 02 **MEMORANDUM**

To: **FILE K013971**
BD VACUTAINER™ SAFETY COAGULATION TUBE
BECTON DICKINSON

Subject: Request for Additional Information

From: Valerie R. Dada, HEPB Reviewer *URD*

The Becton Dickinson Vacutainer™ Safety Coagulation Tube is a sterile, plastic, evacuated blood collection tube intended to be used in conjunction with Vacutainer™ holders and needles, as a system for the collection of venous blood. The Safety Coagulation Tube contains either 0.109M or 0.129M of buffered sodium citrate, that when mixed with venous blood, provides an anticoagulated specimen that may be used for clinical laboratory coagulation assays.

The Becton Dickinson Vacutainer™ Safety Coagulation Tube consists of an outer polyethylene terephthalate (PET) tube that serves to maintain vacuum, and an inner polypropylene (PP) tube that contains liquid sodium citrate into which the blood sample is collected. The Safety Coagulation Tube will be available in multiple draw volume configurations of 2.7 ml and 1.8 ml in both the 0.109M and 0.129M sodium citrate concentrations. The plastic tube will be 13mm x 75 mm for all draw volumes.

The Sponsor is claiming substantial equivalence to their pre-amendment Vacutainer™ Sodium Citrate Tube. The devices are regulated under 21 CFR 862.1675, as Class II devices. They are similar in intended use, and differ in design. The new device includes a HEMOGARD™ Closure Assembly (K945952), which reduces the risk of specimen tube breakage, and reduces exposure to blood by minimizing blood spatter during stopper removal.

This device was previously marketed by this company as 1.8 and 2.7ML Partial Draw Citrate Tube, available in citrate concentrations of 0.105M, and 0.129M. The tubes were voluntarily recalled due to sporadic testing results when performing aPTT tests on samples containing unfractionated heparin, aPTT in the normal population, and platelet counts in patients with EDTA-induced platelet clumping and pseudothrombocytopenia.

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H. TRUTHFUL AND ACCURATE STATEMENT

Premarket Notification

Truthful and Accurate Statement

[As Required by 21 CFR § 807.87 (j)]

I certify that in my capacity as Director, Regulatory Affairs of Becton Dickinson VACUTAINER Systems, I believe to the best of my knowledge, that all data and information submitted in this Premarket Notification are truthful and accurate and that no material fact has been omitted.



Keith M. Smith
Director, Regulatory Affairs
Becton Dickinson VACUTAINER Systems
Becton Dickinson and Company

11/30/01
Date

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B. INDICATIONS FOR USE

510(k) Number (if known): K013971

Device Name: BD Vacutainer™ Safety Coagulation tube

Indications for Use:

The BD Vacutainer™ Safety Coagulation tube is a plastic evacuated blood collection tube that provides a means of collecting, transporting and processing blood in a closed tube. The buffered sodium citrate additive provides an anticoagulated specimen that may be used for clinical laboratory coagulation assays. The benefits of a safety plastic coagulation tube with Hemogard Safety Closure Assembly are:

- reduced risk of specimen tube breakage
- reduced exposure to blood by laboratory personnel and to minimize blood splatter during stopper removal

These benefits lead to increased safety of laboratory personnel and reduced necessity of repeat specimen collection.

Josephine Banta

 (Division Sign-Off)
 Division of Clinical Laboratory Devices

(Please do not Write below this line-continue on another page if needed)
 510(k) Number K013971

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Or Over-the-Counter Use

(Per 21 CFR § 801.109)

(Optional format 1-2-96)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
 Center for Devices and
 Radiological Health
 Office of Device Evaluation
 Document Mail Center (HFZ-401)
 9200 Corporate Blvd.
 Rockville, Maryland 20850

December 03, 2001

BECTON DICKINSON & CO.
 1 BECTON DRIVE
 FRANKLIN LAKES, NJ 07417
 ATTN: KEITH SMITH

510(k) Number: K013971
 Received: 03-DEC-2001
 Product: BD VACUTAINER SAFETY
 COAGULATION TUBE

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

As a reminder, we would like to mention that FDA requires all 510(k) submitters to provide an indications for use statement on a separate page. If you have not included this indications for use statement in addition to your 510(k) summary (807.92), or a 510(k) statement (807.93), and your Truthful and Accurate statement, please do so as soon as possible. If the above mentioned requirements have been submitted, please do not submit them again. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturer International and Consumer Assistance (DSMICA) at the telephone or web site below for more information.

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) requires the categorization of commercially marketed test systems by level of complexity. If your device is a test system that requires categorization you will be notified of your complexity as an enclosure with any clearance letter.

Please remember that all correspondence concerning your submission MUST besent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the DMC will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the DMC (HFZ-401).

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from the DSMICA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact the DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsmamain.html> or me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
 Consumer Safety Officer
 Premarket Notification Staff

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1 Becton Drive
Mail Code 440
Franklin Lakes, NJ 07417-1880
Tel: 201.847.5837
Fax: 201.847.7040
keith_smith@bd.com

10013971



Indispensable to
human health

Office of Device Evaluation
510(k) Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
FOOD AND DRUG ADMINISTRATION
9200 Corporate Boulevard, Room Number 2N
Rockville, MD 20850

November 30, 2001

RE: 510(k) Premarket Notification
BD Vacutainer™ Safety Coagulation Blood Collection Tube

Document Control Clerk:

Pursuant to the requirements of Section 510(k) of the Federal Food, Drug and Cosmetic Act, notification is made of the intention of BD to introduce into interstate commerce the BD Vacutainer™ Safety Coagulation Blood Collection Tube.

The FDA Clinical Chemistry and Toxicology Panel considers these devices as Class II, Blood Specimen Collection Devices, 21 CFR 862.1675. This generic type of device may include blood collection tubes, vials, systems, serum separators, blood collection trays or vacuum sample tubes, and accessories.

If you have any comments or questions please call or fax me at Phone 201.847.5837, Fax 201.847.7040.

Sincerely,

Keith M. Smith
Associate Director, Regulatory Affairs
BD Pharmaceutical Systems
Becton Dickinson and Company

RECEIVED

DEC 3 12 07 PM '01

FDA/CDRH/REGISTRATION

SK38

RD

CH

510(k) Premarket Notification

BD Vacutainer™
Safety Coagulation tube

Becton Dickinson VACUTAINER Systems
1 Becton Drive
Franklin Lakes, NJ 07417-1885

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A. CDRH Premarket Submission Cover Sheet

Center for Devices and Radiological Health Premarket Submission Cover Sheet	
DATE OF SUBMISSION: November 28, 2001	FDA Document Number:
Section A Type of Submission	
<input checked="" type="checkbox"/> 510(k) <input type="checkbox"/> 510(k) Add'l information	<input type="checkbox"/> IDE <input type="checkbox"/> IDE Amendment <input type="checkbox"/> IDE Supplement <input type="checkbox"/> IDE Report
<input type="checkbox"/> PMA <input type="checkbox"/> PMA Amendment <input type="checkbox"/> PMA Report	<input type="checkbox"/> PMA Supplement - Regular <input type="checkbox"/> PMA Supplement - Special <input type="checkbox"/> PMA Supplement - 30 day
Section B1 Reason for Submission - 510(k)s Only	
<input checked="" type="checkbox"/> New device <input type="checkbox"/> Additional or expanded indications <input type="checkbox"/> Change in technology, design, materials or manufacturing process	
<input type="checkbox"/> Other reason (specify):	
Section B2 Reason for Submission - PMAs Only	
<input type="checkbox"/> New device <input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or expanded indications <input type="checkbox"/> Licensing agreement <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"/> Change in design, component or specification: <input type="checkbox"/> Software <input type="checkbox"/> Color Additive <input type="checkbox"/> Other (specify below): <input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager <input type="checkbox"/> Response to FDA correspondence (specify below) <input type="checkbox"/> Request for applicant hold <input type="checkbox"/> Request for removal of applicant hold <input type="checkbox"/> Request for extension
<input type="checkbox"/> Change in ownership <input type="checkbox"/> Change in correspondent <input type="checkbox"/> Other reason (specify):	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager <input type="checkbox"/> Distributor <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
Section B3 Reason for Submission - IDEs Only	
<input type="checkbox"/> New device <input type="checkbox"/> Addition of institution <input type="checkbox"/> Expansion / extension of study <input type="checkbox"/> IRB certification <input type="checkbox"/> Request hearing <input type="checkbox"/> Request waiver <input type="checkbox"/> Termination of study <input type="checkbox"/> Withdrawal of application <input type="checkbox"/> Emergency use: <input type="checkbox"/> Notification of emergency use <input type="checkbox"/> Additional information	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent <input type="checkbox"/> Design <input type="checkbox"/> Informed consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing <input type="checkbox"/> Protocol - feasibility <input type="checkbox"/> Protocol - other <input type="checkbox"/> Sponsor <input type="checkbox"/> Report submission: <input type="checkbox"/> Semi-annual progress <input type="checkbox"/> Annual progress <input type="checkbox"/> Unanticipated adverse effect <input type="checkbox"/> Waiver / site limit
<input type="checkbox"/> Other reason (specify):	<input type="checkbox"/> Response to FDA letter concerning: <input type="checkbox"/> Conditional approval <input type="checkbox"/> Deemed approval <input type="checkbox"/> Deficient final report <input type="checkbox"/> Deficient progress report <input type="checkbox"/> Deficient semi-annual report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request extension of time to respond to FDA <input type="checkbox"/> Request meeting <input type="checkbox"/> IOL submissions only: <input type="checkbox"/> Change in IOL style <input type="checkbox"/> Request for protocol waiver

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Section C				Product Classification			
Product Code: 75JKA		C.F.R. Section: 862.1675		Device class:			
				<input type="checkbox"/> Class I		<input checked="" type="checkbox"/> Class II	
				<input type="checkbox"/> Class III		<input type="checkbox"/> Unclassified	
Classification panel: Clinical Chemistry and Clinical Toxicology							
Section D Information on 510(k) Submissions							
Product codes of devices to which substantial equivalence is claimed:				Summary of, or statement concerning safety and effectiveness data: <input checked="" type="checkbox"/> 510(k) summary attached <input type="checkbox"/> 510(k) statement			
1. 75JKA	2.	3.	4.				
5.	6.	7.	8.				
Information on devices to which substantial equivalence is claimed:							
510(k) Number		Trade or proprietary or model name			Manufacturer		
1. Pre-amendment		1. VACUTAINER™ Brand Sodium Citrate Tube			1. Becton Dickinson VACUTAINER Systems		
2.		2.			2		
3		3			3		
Section E Product Information -- Applicable to All Applications							
Common or usual name or classification name: Blood Specimen Collection Device							
Trade or proprietary or model name				Model number			
1. BD Vacutainer™ Safety Coagulation tube				1. Multiple			
2				2			
3				3			
4				4			
FDA document numbers of all prior related submissions (regardless of outcome):							
1 K003680	2	3	4	5	6	7	8
7	8	9	10	11	12		
Intended use or indications for use:							
<p>The BD Vacutainer™ Safety Coagulation tube is a plastic evacuated blood collection tube that provides a means of collecting, transporting and processing blood in a closed tube. The buffered sodium citrate additive provides an anticoagulated specimen that may be used for clinical laboratory coagulation assays. The benefits of a safety plastic coagulation tube with Hemogard Safety Closure Assembly are:</p> <ul style="list-style-type: none"> • reduced risk of specimen tube breakage • reduced exposure to blood by laboratory personnel and to minimize blood splatter during stopper removal <p>These benefits lead to increased safety of laboratory personnel and reduced necessity of repeat specimen collections.</p>							

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Section F Manufacturing / Packaging / Sterilization Sites			
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA establishment registration number: 1917413	<input checked="" type="checkbox"/> Manufacturer & Sterilizer <input type="checkbox"/> Contract manufacturer	<input type="checkbox"/> Contract sterilizer <input type="checkbox"/> Repackager/relabeler
Company/Institution name: Becton Dickinson and Company			
Division name (if applicable): Becton Dickinson VACUTAINER Systems		Phone number (include area code): (308) 872 -6811	
Street address: 150 South 1 st Avenue		FAX number (include area code): (308) 872 - 5553	
City: Broken Bow	State/Province: NE	Country: U.S.A.	ZIP/Postal Code: 68822
Contact name: Dwayne Calek			
Contact title: Manager, Quality Assurance			
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA establishment registration number: 9617032	<input checked="" type="checkbox"/> Manufacturer & Sterilizer <input type="checkbox"/> Contract manufacturer	<input type="checkbox"/> Contract sterilizer <input type="checkbox"/> Repackager/relabeler
Company/Institution name: Becton Dickinson and Company			
Division name (if applicable): Division of U.K. Ltd.		Phone number (include area code): (011) 441-752-701281	
Street address: Belliver Industrial Estate		FAX number (include area code): (011) 441-752-788308	
City: Plymouth	State/Province:	Country: England	ZIP/Postal Code: PL6 7BP
Contact name: Keith Alderman			
Contact title: Manager, Quality Assurance			
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA establishment registration number:	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract manufacturer	<input type="checkbox"/> Contract sterilizer <input type="checkbox"/> Repackager/relabeler
Company/Institution name:			
Division name (if applicable):		Phone number (include area code):	
Street address:		FAX number (include area code):	
City:	State/Province:	Country:	ZIP/Postal Code:
Contact name:			
Contact title:			

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Section G Applicant or Sponsor			
Company / Institution name: Becton Dickinson and Company		FDA establishment registration number: 2243072	
Division name (if applicable): Becton Dickinson VACUTAINER Systems		Phone number (include area code): (201) 847 - 5837	
Street address: 1 Becton Drive		FAX number (include area code): (201) 847 - 7040	
City: Franklin Lakes	State / Province: NJ	Country: USA	ZIP / Postal Code: 07417-1885
Signature: 			
Name: Keith Smith			
Title: Director, Regulatory Affairs			
Section H Submission correspondent (if different from above)			
Company / Institution name:			
Division name (if applicable):		Phone number (include area code): ()	
Street address:		FAX number (include area code): ()	
City:	State / Province:	Country:	ZIP / Postal Code:
Signature:			
Contact Name:			
Contact Title:			

Your voluntary completion of this Premarket Submission Cover Sheet will not affect any FDA decision concerning your submission, but will help FDA's Center for Devices and Radiological Health process your submission more efficiently. The information you provide should apply *only* to a single accompanying submission. Please do not send cover sheets for any previous submissions. See the instructions for additional information on completing the cover sheet. If you have a question concerning completion of the cover sheet, please contact the Division of Small Manufacturers Assistance at (800) 638-2041 or (301) 443-6597.

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C. GENERAL SUMMARY

C.1 DEVICE NAME: BD Vacutainer™ Safety Coagulation tube

C.2 DEVICE CLASS: Class II, 21 CFR 862.1675

C.3 CLASSIFICATION: Tubes, Vials, Systems, Serum Separators, Blood Collection (75JKA)

C.4 REASON FOR SUBMISSION:

Becton Dickinson VACUTAINER Systems intends to introduce into commerce the BD Vacutainer™ Safety Coagulation tube.

The BD Vacutainer™ Safety Coagulation tube is a plastic evacuated blood collection tube that provides a means of collecting, transporting and processing blood in a closed tube. The buffered sodium citrate additive provides an anticoagulated specimen that may be used for clinical laboratory coagulation assays. The benefits of a safety plastic coagulation tube with Hemogard Safety Closure Assembly are:

- reduced risk of specimen tube breakage
- reduced exposure to blood by laboratory personnel and to minimize blood splatter during stopper removal

These benefits lead to increased safety of laboratory personnel and reduced necessity of repeat specimen collection.

C.5 SECTION 514, SPECIAL CONTROLS:

To the best of our knowledge, no performance standards (Section 514) or special controls [Section 513(B)] have been established for this device.

D. Principal Device Information

D.1 DEVICE DESCRIPTION

The BD Vacutainer™ Safety Coagulation tubes are sterile, plastic, evacuated blood collection tubes. The tubes contain 0.109M or 0.129M buffered Sodium Citrate as an anticoagulant intended to prevent whole blood from clotting prior to analysis. The specimen is centrifuged and the plasma portion is analyzed for coagulation parameters to detect clotting time disorders and to monitor patients undergoing anticoagulation therapy. The BD Vacutainer™ Safety Coagulation tube consists of a closure assembly, a buffered sodium citrate additive and a plastic tube.

The closure assembly is a HEMOGARD™ Closure Assembly, which consists of rubber stopper and a protective plastic shield to reduce user exposure to blood. The HEMOGARD™ Closure Assembly was described in 510(k) Premarket Notification K945952 which received FDA clearance on January 18, 1995. All closure assemblies are color coded to reflect additive type (see the chart VACUTAINER™ Tube/Stopper Closure Code Cross Reference located in the Product Insert, Section D.4 Device Labeling).

The BD Vacutainer™ Safety Coagulation tube will be offered in two draw volume configurations, 2.7ml and 1.8ml and in both the 0.109M and 0.129M sodium citrate concentrations.

The tube for the BD Vacutainer™ Safety Coagulation tube consists of one plastic tube designed to fit within another plastic tube of a different material. The principle of this design is that the two different plastic tubes perform separate and unique functions. The inner tube is made of polypropylene plastic, which functions to contain the liquid sodium citrate additive for the duration of the shelf life of the tube. Polypropylene has been historically proven to minimize and/or eliminate evaporation over prolonged periods of time under various conditions. The outer tube is made of polyethylene terephthalate (PET) plastic which functions to maintain vacuum within the tube for the duration of the shelf life of the tube. The dimensions of the PET tube will be 13 x 75mm. Evacuated (PET) plastic tubes have been marketed by Becton Dickinson for over ten years and were originally described in 510(k) Premarket Notification K901449/A, which received FDA clearance on June 19, 1990. The use of plastic instead of glass enhances user safety because of the reduced risk of tube breakage.

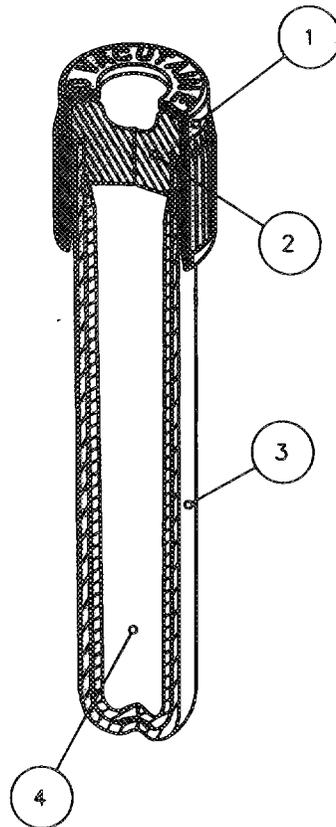
The tube is also designed to minimize the unfilled tube volume (headspace) after phlebotomy has been performed. Headspace is the unfilled tube volume above the sample. The headspace volume of both draw volumes is similar to the headspace volume of the predicate device, full draw glass tube. The BD Vacutainer™ Safety Coagulation tube achieves the similar headspace volume as the predicate device via the inner plastic tube's design. For each of the draw volumes, the inner tubes have been designed so that when phlebotomy is performed, the tube is a full draw, thus minimizing headspace and platelet activation. By design of the inner tube's dimensions, all blood draws can be obtained accurately without the preanalytical variable of headspace. The outer tube design allows for the tube configuration to remain 13x75mm and still retain a "full draw", for all draw volumes.

Tube inner surface area to specimen volume ratio

Tube type	Total Specimen Volume (Blood + additive) (mL)	Inner surface area to specimen volume ratio (1/cm)
Glass	5 (4.5 + 0.5mL)	4.7
Plastic	3 (2.7 + 0.3mL)	7.9
Plastic	2 (1.8 + 0.2mL)	11.8

The BD Vacutainer™ Safety Coagulation tube has been evaluated on four different patient populations: normal donors, patients on oral (warfarin) anticoagulant therapy, patients on intravenous (heparin) anticoagulant therapy and 'other' patients including Lupus Anticoagulant, Factor VIII and IX Deficiency, Liver Disease, Diabetes, Von Willebrand and Platelet Dysfunction. Clinical equivalency to the predicate device has been demonstrated within each patient population. Copies of the Clinical Evaluations have been provided as Attachments to this Premarket Notification.

The BD Vacutainer™ Safety Coagulation tubes will be offered in multiple tube configurations. The different tube configurations apply to draw volume, (2.7ml and 1.8mL) and to the Sodium Citrate additive concentration (0.109M or 0.129M). Data from each of the four configurations listed are in this 510(k) Premarket Notification.



1. HEMOGARD™ Safety Shield
2. Rubber Stopper Closure
3. Outer Tube (PET)
4. Inner Tube (Polypropylene)

D.2 INTENDED USE

The BD Vacutainer™ Safety Coagulation tube is a plastic evacuated blood collection tube that provides a means of collecting, transporting and processing blood in a closed tube. The buffered sodium citrate additive provides an anticoagulated specimen that may be used for clinical laboratory coagulation assays. The benefits of a safety plastic coagulation tube with Hemogard Safety Closure Assembly are:

- reduced risk of specimen tube breakage
- reduced exposure to blood by laboratory personnel and to minimize blood splatter during stopper removal

These benefits lead to increased safety of laboratory personnel and reduced necessity of repeat specimen collection.

D.3 MANUFACTURING AND STERILIZATION INFORMATION

Sterilization Method: Gamma Radiation Sterilization

Cycle Validation Method:

The sterilization cycle development and validation procedures followed are those recommended by the American National Standard, Association for the Advancement of Medical Instrumentation (AAMI), Guideline for Gamma Radiation Sterilization.

Sterility Assurance Level: The minimum sterility assurance level is 10^{-3} .

Radiation Dose Level: The minimum sterilization dose is determined by cycle validation and is approximately 8.0 kGy.

Manufacturing and Sterilization Sites:

The BD Vacutainer™ Safety Coagulation tube is manufactured and sterilized at the following two sites:

Manufacturing and Sterilization Site:

Becton Dickinson VACUTAINER Systems
150 South 1st Avenue
P.O. Box 686
Broken Bow, NE 68822
Establishment Registration Number: 1917413

Manufacturing and Sterilization Site:

Becton Dickinson VACUTAINER Systems
Division of UK Limited
Belliver Industrial Estate
Plymouth, England
Establishment Registration Number: 9617032

D.4 DEVICE LABELING

The BD Vacutainer™ Safety Coagulation tube is intended to be marketed as a sterile in-vitro diagnostic device. The tubes are packaged one hundred (100) labeled tubes per shelf carton and ten shelf cartons are placed in a labeled case carton. A product insert with instructions for use is included in each case. The draft BD Vacutainer™ Safety Coagulation tube device Labeling, included in this section, consists of the labeling items identified below:

- Product Insert
- Tube Label
- Shelf Carton Label
- EPS Tray Label
- Case Carton Label
- Preprinted Case Carton

Note:

The product inserts are the same for all VACUTAINER™ Brand Tubes with the exception of ACT (Activated Clotting Time) Tubes, which has a product specific insert. The principal device will have the same product insert as the currently marketed predicate device, the VACUTAINER™ Brand Sodium Citrate Tube with the additions as outlined.

The tube, shelf and case carton labels are specific to BD Vacutainer™ Safety Coagulation tube. The only difference in labeling between the different tube configurations is the draw volume and citrate molarity. Therefore, only examples of the 0.109M 2.7mL tube labels have been provided.

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Product Insert for Principal Device:

BD Vacutainer™

Safety Coagulation tube (On next two pages)

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VACUTAINER® Brand Evacuated Blood Collection System

For In Vitro Diagnostic Use.

INTENDED USE

VACUTAINER® Tubes, Needles and Holders are used together as a system for the collection of venous blood. VACUTAINER® Tubes are used to transport and process blood for testing serum, plasma or whole blood in the clinical laboratory.

PRODUCT DESCRIPTION

VACUTAINER® Tubes are evacuated tubes with color-coded (see table below) rubber stoppers or HEMOGARD® Closures. VACUTAINER® PLUS Tubes are plastic tubes with colored closures or stoppers. Both tube types contain additives in varying concentrations dependent upon the amount of vacuum and the required additive to blood ratio for the tube. See each shelf package or case label for specific additive quantity and approximate draw volume. Additive choice depends on the analytic test method. It is specified by the manufacturer of the test reagents and/or instrument on which the test is performed. Tube interiors are sterile.

VACUTAINER® TUBE STOPPER/CLOSURE	COLOR CODE	CROSS REFERENCE
ADDITIONAL GROUP/ADDITIVE	RUBBER	HEMOGARD®
Gel Separation Tubes SST® Tubes with Gel and Clot Activator PST™ Tubes with Gel and Heparin ¹	Red/Grey Green/Grey	Gold Light Green
Non-additive Tubes Silicone Coated Uncoated	Red ---	Red Pink
Serum Tubes with additives Thrombin ² PLUS Serum Thrombin ² , Soybean Trypsin Inhibitor	Yellow/Grey Red Light Blue	Orange Red Light Blue
Whole Blood/Plasma Tubes K ₂ EDTA or K ₃ EDTA Citrate/CTAD (Coagulation) Citrate (ESR) Sodium Fluoride/Sodium EDTA (Glucose) Sodium Fluoride/Potassium Oxalate (Glucose) Lithium Iodoacetate (Glucose) Heparin ¹ Acid Citrate Dextrose (ACD) Sodium Polyanethanesulfonate (SPS)	Lavender Light Blue Black Grey Grey Grey Green Yellow Yellow	Lavender Light Blue or Clear Black Grey Grey Grey Green Yellow Yellow
Trace Element Tubes Silicone Coated, or EDTA, or Heparin ¹	Royal Blue	Royal Blue
Lead Tubes Heparin ¹ K ₂ EDTA	Tan ---	Tan Tan

¹Heparin source is porcine. ²Thrombin source is bovine.

VACUTAINER® Serum Tubes

VACUTAINER® PLUS Serum Tubes are coated with silicone and micronized silica particles to accelerate clotting. Particles in the white film on the interior surface activate clotting when tubes are mixed 5 times by inversion. See Limitations of System and Clotting Instructions sections.

A silicone coating on the walls of most serum tubes reduces adherence of red cells to tube walls. Tube stoppers are lubricated with silicone or glycerine (see individual shelf package or case label) to facilitate stopper insertion.

VACUTAINER® Tubes for Lead and Trace Element Tests

Tubes for lead testing and other trace elements are labeled specifically for these purposes on the shelf package and case label. Use only appropriately labeled tubes for these tests. VACUTAINER® glass tubes with a tan closure for lead testing contain heparin and have been tested to a maximum of 10 µg/L of lead. VACUTAINER® PLUS tubes for lead testing have K₂EDTA anticoagulant. The PLUS tubes have a maximum of 2.5 µg/L of lead and are also suitable for routine hematology testing. The tubes for trace elements have been tested by water or acid extraction of the stoppered tube for 4 hours. Atomic absorption spectroscopy testing yielded results below these concentration limits:

VACUTAINER® TRACE ELEMENT TUBE'S CONTAMINATION UPPER LIMITS					
ANALYTE	µg/L	ANALYTE	µg/L	ANALYTE	µg/L
Antimony	0.8	Calcium	400*	Iron	60
Arsenic	1.0	Chromium	0.8	Lead	2.5
Cadmium	0.6	Copper	8.0	Magnesium	60*
				Manganese	1.5
				Zinc	40*

*Flame technique, all others flameless

SST® Brand Tubes and Transport Tubes

The interior of the tube wall is coated with micronized silica particles to accelerate clotting. A barrier polymer is present at the tube bottom. The density of this material causes it to move upward during centrifugation to the serum-clot interface, where it forms a barrier separating serum from fibrin and cells. Serum may be aspirated directly from the collection tube, eliminating the need for transfer to another container. SST® Brand Transport Tubes contain the same clot activator as SST® Tubes with approximately twice the quantity of barrier. This additional material produces a larger barrier between the serum and cells that is more stable when shipped from a phlebotomy site to a testing site. See Limitations of System.

VACUTAINER® PST™ Tubes

The interior of the tube wall is coated with lithium heparin to inhibit clotting. Heparin activates antithrombins, thus blocking the coagulation cascade and producing a whole blood/plasma sample instead of clotted blood plus serum. A barrier polymer is present at the tube bottom. The density of this material causes it to move upward during centrifugation to the plasma-cell interface, forming a separative barrier. Supernatant plasma may be aspirated directly from the collection tube, eliminating the need for manual transfer to another container. Plasma obtained in PST™ Tubes should be tested or removed from the tube within 2 hours of collection according to the NCCLS Guidelines. See Limitations of System.

VACUTAINER® Tubes for Immunohematology

The VACUTAINER® PLUS Tube (plastic) K₂EDTA as well as the VACUTAINER® Brand Tubes (glass) Serum and K₃EDTA may be used for routine immunohematology testing i.e. red cell grouping, Rh typing and antibody screens. Tubes must be filled to capacity (until vacuum is exhausted). Additive tubes (K₂ or K₃) must be inverted 8 to 10 times to assure complete mixing with blood, as erroneous results may occur.

VACUTAINER® CTAD Tubes

The CTAD tube is used for the collection and transport of specimens for hemostasis testing. The CTAD solution is a mixture of sodium citrate, theophylline, adenosine and dipyridole. The purpose of the additive is to anticoagulate the specimen and to minimize in vitro platelet aggregation.

VACUTAINER® Plus EDTA Tubes

The Plus EDTA tube is used for the collection and transport of specimens for hemostasis testing. The Plus EDTA solution is a mixture of sodium citrate, theophylline, adenosine and dipyridole. The purpose of the additive is to anticoagulate the specimen and to minimize in vitro platelet aggregation.

The general performance has been compared to the... (text is partially obscured and difficult to read)

VACUTAINER® BVACUTAINER® Blood Collection Needles

VACUTAINER® Blood Collection Needles are simple, double-ended, stainless steel needles. They have a threaded hub that fits into the threads of all VACUTAINER® Needle Holders. The venipuncture end of the needle has a point specially designed to enter the skin easily during venipuncture. The needle is lubricated with silicone. Multiple Sample Needles have a rubber sleeve covering the non-patient end of the needle that prevents leakage of blood into the holder during venipuncture. This product contains Dry Natural Rubber.

Single Sample Needles do not have a rubber sleeve covering the back end of the needle, and should be used to collect only one tube from a patient. Since blood will continue to flow through the needle, blood exposure will occur if more than one tube is collected during the venipuncture.

The tubes slide into the holder and are pushed onto the back end of the needle, allowing the vacuum in the tube to draw blood to a predetermined level. The needles are available in 1 and 1-1/2 inch lengths, in 18, 20, 21, and 22 gauge.

LIMITATIONS OF SYSTEM

The quantity of blood drawn varies with altitude, ambient temperature, barometric pressure, tube age, venous pressure, and filling technique. Tubes with draw volume smaller than the apparent dimensions indicated (partial draw tubes), may fill more slowly than tubes of the same size with greater draw volume.

For those tubes subjected to centrifugation to generate plasma or serum for testing, standard processing conditions do not completely sediment all cells, whether or not barrier gel is present. Accordingly, cell-based metabolism, as well as natural degradation *in vivo* affects serum/plasma analyte concentrations/activities beyond cellular changes. It is recommended that testing for glucose, uric acid, and lactate dehydrogenase (LD) be performed as soon after collection and separation as possible. Due to natural degradation, delay in separation of the serum or plasma from the cellular mass or in testing after separation will result in erroneous results for those analytes.

Prior to using CTAD tubes to collect specimens from warfarin patients for PT determinations with citrate sensitive reagents, please contact the BDV's Technical Services department at 1-800-631-0174.

Contact the BDV's Technical Service Department at 1-800-631-0174 before collecting samples in PLUS SST® and PLUS Serum Tubes for estradiol determinations on the Ciba Corning Diagnostics ACS-180 analyzer.

VACUTAINER® SST® Tubes, PST™ Tubes, and PLUS Tubes are not recommended for collection of samples for blood banking procedures. Glass EDTA and glass Serum Tubes are acceptable for blood banking procedures. VACUTAINER® SST® Tubes and PST™ Tubes are not recommended for collection of samples for therapeutic drug monitoring (TDM) assays.

Do not use PST™ Tubes for lithium measurement.

PRECAUTIONS

- Storage of glass tubes containing blood at or below 0°C may result in tube breakage.
- Do not remove conventional rubber stoppers by rolling with thumb. Remove stoppers with a twist and pull motion.
- Do not use tubes or needles if foreign matter is present.
- The paper label covering the connection of the needle shields will tear when the needle is opened. Do not use needle if label has been torn before venipuncture.
- Needle size and lot number are printed on each individual needle assembly.
- CTAD tubes must be protected from artificial and natural light during storage. Accumulated light exposure in excess of 12 hours can cause additive inactivation.

CAUTION:

- Practice Standard Precautions. Use gloves, gowns, eye protection, other personal protective equipment, and engineering controls to protect from blood splatter, blood leakage, and potential exposure to bloodborne pathogens.
- All glass has the potential for breakage. Examine all glass for potential damage in transit before use, and take precautionary measures during handling.
- Handle all biologic samples and blood collection "sharps" (lancets, needles, luer adapters, and blood collection sets) according to the policies and procedures of your facility. Obtain appropriate medical attention in the event of any exposure to biologic samples (for example, through a puncture injury), since they may transmit viral hepatitis, HIV (AIDS), or other infectious diseases. Utilize any built-in used needle protector, if the blood collection device provides one. Becton Dickinson does not recommend resheathing used needles. However, the policies and procedures of your facility may differ and must always be followed.
- Discard all blood collection "sharps" in biohazard containers approved for their disposal.
- Transferring a sample collected using syringe and needle to a tube is not recommended. Additional manipulation of sharps such as hollow bore needles increases the potential for needlestick injury.
- Transferring samples from syringe to an evacuated tube using a non-sharps device should be performed with caution for the reasons described below. • Depressing the syringe plunger during transfer can create a positive pressure, forcefully displacing the stopper and sample, causing splatters and potential blood exposure. • Using a syringe for blood transfer may also cause over or under filling of tubes, resulting in an incorrect blood-to-additive ratio and potentially incorrect analytic results. • Evacuated tubes are designed to draw the volume indicated. Filling is complete when vacuum no longer continues to draw, though some tubes may partially fill due to plunger resistance when filled from a syringe. The laboratory should be consulted regarding the use of these samples.
- If blood is collected through an intravenous (I.V.) line, ensure that line has been cleared of I.V. solution before beginning to fill blood collection tubes. This is critical to avoid erroneous laboratory data from I.V. fluid contamination.
- Overfilling or underfilling of tubes will result in an incorrect blood-to-additive ratio and may lead to incorrect analytic results or poor product performance.

STORAGE

Store tubes at 4-25°C (39-77°F), unless otherwise noted on the package label. Do not use tubes containing lithium iodoacetate if they become coated with a yellow film along the inner tube wall. All liquid preservatives and anticoagulants are clear and colorless, except CTAD which is yellow. Do not use if they are discolored or contain precipitates. Powdered and freeze-dried additives such as EDTA, heparin, and thrombin are white; fluoride and fluoride/oxalate may be pale pink. Do not use if color has changed. Do not use tubes after their expiration date.

SPECIMEN COLLECTION and HANDLING

READ THIS ENTIRE CIRCULAR BEFORE PERFORMING VENIPUNCTURE.

Required equipment not provided for specimen collection

- Practice Standard Precautions. Use gloves, eye protection, coats or gowns, and other appropriate apparel for protection from exposure to blood-borne pathogens or other potentially infectious materials.
- Any VACUTAINER® Needle Holders of the standard size may be used with 13 or 16 mm diameter tubes. Use the small (pediatric) needle holder with 10.25 mm diameter tubes. A pediatric tube adapter should be used to modify the standard holder to fit the small diameter tubes.
- Alcohol swabs for cleansing site. If additional tubes requiring sterile collections, such as blood cultures, are filled from the same venipuncture, use tincture of iodine or suitable alternative for cleansing. Follow the laboratory policy for sterile sample collection for site preparation and tube handling instructions. Do not use alcohol based cleansing materials when samples are to be used for blood alcohol testing.
- Dry sterile gauze
- Toasmqug.
- Needle disposal container for used needle or needle/holder combination.

Required equipment not provided for specimen processing

- Disposable transfer pipets if direct sampling from the instrument is not used or if specimen is stored separately.
- Centrifuge capable of generating 1100 G (RCF) at the tube bottom. A horizontal centrifuge head is preferred for barrier quality with SST® and PST™ Tubes.
- Gloves and other personal protective equipment as necessary for protection from exposure to bloodborne pathogens.

Preparation for Specimen Collection

Be sure the following materials are readily accessible before performing venipuncture:

- See required equipment above.
- All necessary tubes, identified for site, draw, and additive.
- Labels for positive patient identification of samples

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Recommended Order of Draw

1. Tubes for sterile samples
 2. Tubes without additives
 3. Tubes for coagulation studies (e.g., citrate)
 4. Tubes with other additives (e.g., heparin, EDTA)
- SST® Tubes and VACUTAINER® PLUS Serum tubes contain particulate clot activators and are considered additive tubes. These and VACUTAINER® PLUS Tubes are not to be used as discard tubes before drawing citrate tubes for coagulation studies. A glass discard tube must be used if only citrate tubes are drawn with a Blood Collection Set for venipuncture.

Prevention of Backflow

Since some evacuated blood collection tubes contain chemical additives, it is important to avoid possible backflow from the tube, with the possibility of adverse patient reactions. To guard against backflow, observe the following precautions:

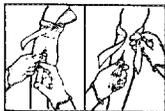
1. Place patient's arm in a downward position.
2. Hold tube with the stopper uppermost.
3. Release tourniquet as soon as blood starts to flow into tube.
4. Make sure tube additives do not touch stopper or end of the needle during venipuncture.

Venipuncture Technique and Specimen Collection

General Instructions

WEAR GLOVES DURING VENIPUNCTURE AND WHEN HANDLING BLOOD COLLECTION TUBES TO MINIMIZE EXPOSURE HAZARD.

1. Select tube or tubes appropriate for required specimen. For sterile collections, see the specific instructions noted in the collection device's instructions.
2. Assemble needle in holder. Be sure needle is firmly seated to ensure needle does not unthread during use. If drawing sterile specimen, use a sterile holder.
3. Gently tap tubes containing additives to dislodge any material that may be adhering to the stopper.
4. Place tube into holder. Note: Do not puncture stopper.
5. Select site for venipuncture.
6. Apply tourniquet. Prepare venipuncture site with an appropriate antiseptic. DO NOT PALPATE VENIPUNCTURE AREA AFTER CLEANSING.
7. Place patient's arm in a downward position.



8. Remove needle shield. Perform venipuncture WITH ARM DOWNWARD AND TUBE STOPPER UPPERMOST.
9. Push tube onto needle, puncturing stopper diaphragm. Center tubes in holder when penetrating the stopper to prevent sidewall penetration and resultant pressure vacuum loss.
10. REMOVE TOURNIQUET AS SOON AS BLOOD APPEARS IN TUBE. DO NOT ALLOW CONTENTS OF TUBE TO CONTACT THE STOPPER OR END OF THE NEEDLE DURING PROCEDURE.

Note: Blood may occasionally leak from the needle sleeve. Practice Standard Precautions to minimize exposure hazard. If no blood flows into tube or if blood ceases to flow before an adequate specimen is collected, the following steps are suggested to complete satisfactory collection:

- a. Push tube forward until tube stopper has been penetrated. If necessary, hold in place to ensure complete vacuum draw.
 - b. Confirm correct position of needle cannula in vein.
 - c. If the multiple sample device is used, remove tube and place new tube onto the holder.
 - d. If second tube does not draw, remove needle and discard. Repeat procedure from Step 1.
11. When first tube has filled to its stated volume and blood flow ceases, remove it from holder.
 12. Place succeeding tubes in holder, puncturing diaphragm to begin flow. See Recommended Order of Draw.
 13. While each successive tube is filling, turn the filled tube upside-down and return it to upright position. This is one complete inversion.
- For proper additive performance, invert SST® Tubes, and PLUS Serum Tubes 5 times. Invert Citrate or CTAD tubes 3-4 times. Invert all other filled additive tubes 8-10 times. Do not shake. Vigorous mixing may cause thrombosis. Insufficient mixing or delayed mixing in serum tubes may result in delayed clotting and incorrect test results. In tubes with anticoagulants, inadequate mixing may result in platelet clumping, clotting and/or incorrect test results.
14. As soon as blood stops flowing in the last tube, remove needle from vein, applying pressure to puncture site with dry sterile swab until bleeding stops.
 15. Once clotting has occurred, apply bandage if desired.
 16. After venipuncture, the top of the stopper may contain residual blood. Take proper precautions when handling tubes to avoid contact with this blood. Any needle holder that becomes contaminated with blood is considered hazardous and should be decontaminated with bleach or disposed of.
 17. Dispose of the used needle using an appropriate disposal device. DO NOT RESHIELD. Reshielding of needles increases the risk of needling injury and blood exposure.

Clotting Instructions

Allow blood to clot thoroughly before centrifugation. The following table gives the recommended minimum clotting times for specific tube types or additives:

MINIMUM CLOTTING TIME RECOMMENDATIONS	
PRODUCT	TIME (min)
Serum Tubes (Red Stoppers, Red or Pink Closures)	60
SST® Tubes	30
Thrombin Tubes	5

Recommended times are based upon an intact clotting process. Patients with abnormal clotting due to disease, or those receiving anticoagulant therapy require more time for complete clot formation. Separation of serum or plasma from cells should take place within 2 hours of collection to prevent erroneous test results.

Centrifugation

Caution: Do not centrifuge glass tubes at forces above 2200 RCF in a horizontal head (swinging bucket) centrifuge as breakage may occur. Glass tubes may break if centrifuged above 1300 RCF in fixed angle centrifuge heads. VACUTAINER® PLUS Tubes will withstand up to 10,000 RCF in a balanced centrifuge. Always use appropriate carriers or inserts. Use of tubes with cracks or chips or excessive centrifugation speed may cause tube breakage, with release of sample, droplets, and an aerosol into the centrifuge bowl. Release of these potentially hazardous materials can be avoided by using specially designed sealed containers in which tubes are held during centrifugation. Centrifuge carriers and inserts should be of the size specific to the tubes used. Use of carriers too large or too small for the tubes may result in breakage.

RCF is related to centrifuge speed setting (rpm) using either of the following equations:

$$rpm = \sqrt{\frac{RCF \times 10^5}{1.12 \times r}} \quad \text{or approximately} \quad rpm = \frac{10,000}{\sqrt{r}}$$

where "r", expressed in cm, is the radial distance from the center of the centrifuge head to the bottom of the tube. The following table gives recommended centrifuge speed and time.

PRODUCT	RCF (g)	TIME (min)
SST® and PST™ Tubes	1000 - 1300	10
PLUS SST® and PST™ Tubes - 13mm	1100 - 1300	10
PLUS SST® and PST™ Tubes - 16mm	1000 - 1300	10
All gel Transport Tubes	1100 - 1300	15
All non-gel tubes	≤1300	10
Citrate Tubes*	1500	15

*Citrate tubes should be centrifuged at a speed and time to force possible platelet-poor plasma (platelet count <10,000/ul) per NCCLS Guidelines.

Ensure that tubes are properly seated in the centrifuge carrier. Incomplete seating could result in separation of the HEMOGARD® Closure from the tube or extension of the tube above the carrier. Tubes extending above the carrier could catch on centrifuge head, resulting in breakage. Balance tubes to minimize the chance of glass breakage. Match tubes to tubes of the same fill level, glass tubes to glass, tubes with HEMOGARD® Closure to the carrier with the Closure, gel tubes to gel tubes, VACUTAINER® PLUS Tubes with PLUS Tubes, and tube size to tube size. The following table relates radius of centrifuge arm to required speed, in order to obtain the appropriate g-force.

CENTRIFUGE RADIUS / SPEED							
RADIUS (cm)	SPEED (rpm)	RADIUS (cm)	SPEED (rpm)	RADIUS (cm)	SPEED (rpm)	RADIUS (cm)	SPEED (rpm)
7	3750	12	2900	17	2400	22	2100
8	3500	13	2750	18	2350	23	2060
9	3300	14	2650	19	2280	24	2030
10	3150	15	2550	20	2200	25	2000
11	3000	16	2500	21	2160	26	1950

Always allow centrifuge to come to a complete stop before attempting to remove tubes. When centrifuge head has stopped, open the lid and examine for possible broken tubes. If breakage is indicated, use mechanical device such as forceps or hemostat to remove tubes. **Caution: Do not remove broken tubes by hand.** See centrifuge instruction manual for disinfection instructions.

The flow properties of the barrier material are temperature-related. Flow may be impeded if chilled before or during centrifugation. To optimize flow and prevent heating during centrifugation, seal refrigerated centrifuges to 25°C (77°F). Gel separation tubes should be centrifuged no later than 2 hours after collection.

Tubes should not be re-centrifuged once barrier has formed. Barriers are more stable when tubes are spun in centrifuges with horizontal (swinging bucket) heads than those with fixed angle heads. Plasma and serum from non-gel tubes should be removed from the cell layer within 2 hours of sample collection. Note: Some push-down filters may not be compatible with plastic tubes due to the tapered inner diameter of the tube.

Separated serum or plasma is ready for use. The tubes may be placed directly on the instrument carrier or serum/plasma may be pipetted into an analyzer cup. Some instruments can sample directly from a separator tube with the stopper in place. Follow the instrument manufacturer's instructions.

ANALYTIC EQUIVALENCY

Specifications of VACUTAINER® Tubes have been evaluated for an array of analyses over a variety of test methods and time periods. The Becton Dickinson Vacutainer Systems Technical Service Department is available to answer questions regarding these studies. Please contact them to obtain references and technical reports on these evaluations and any other information regarding the use of VACUTAINER® Tubes with your instrument/reagent system. Technical Service may be reached at 800-631-0174. You may write to Becton Dickinson Vacutainer Systems for information at:

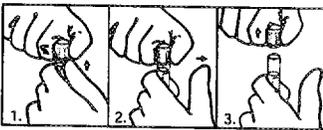
Technical Service
Becton Dickinson Vacutainer Systems
1 Becton Drive, Franklin Lakes, NJ 07417-1885

Whenever changing any manufacturer's blood collection tube type or size for a particular laboratory assay, the Laboratory Director should review the tube manufacturer's data and/or previous data generated to establish/verify your reference range data for your specific instrument and reagent system. Based on such information, the laboratory can then decide if changes are indicated.

REFERENCES

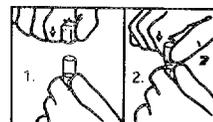
- National Committee for Clinical Laboratory Standards (NCCLS): *Evacuated Tubes and Additives for Blood Specimen Collection*. NCCLS Document H1-A4, NCCLS, Villanova, PA, 1996.
- National Committee for Clinical Laboratory Standards (NCCLS): *Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture*. NCCLS Document H3-A3, NCCLS, Villanova, PA, 1991.
- Landt M, Smith CH and Hortin GL. Evaluation of evacuated blood-collection tubes: Effects of three types of polymeric separators on therapeutic drug monitoring specimens. *Clin Chem* 1993; 39:1712-1717.
- Dasgupta A, Dean R, Saldana S, Kinneman G and McLawton RW. Absorption of therapeutic drugs by barriers in serum separator blood collection tubes. *Am J Clin Path* 1994; 101:456-461.
- Yawn BP, Loge C and Dale J. Prothrombin time, one tube or two? *Am J Clin Path* 1996; 105:794-97.
- Gottfried, EL and Adachi, MM. Prothrombin time (PT) and activated partial prothrombin time (APTT) can be performed on the first tube. *Am J Clin Path* 1997; 107:681-683.
- National Committee for Clinical Laboratory Standards (NCCLS): *Collection, Transport, and Processing of Blood Specimens for Coagulation Assays—Second Edition: Approved Guideline (December 1998)*. NCCLS Document H21-A2, Villanova, PA.

INSTRUCTIONS FOR REMOVAL OF HEMOGARD® CLOSURE



1. Grasp the VACUTAINER® Tube with one hand, placing the thumb under the HEMOGARD® Closure. (For added stability, place arm on solid surface.) With the other hand, twist the HEMOGARD® Closure while simultaneously pushing up with the thumb of the other hand ONLY UNTIL THE TUBE STOPPER IS LOOSENEED.
2. Move thumb away before lifting closure. DO NOT use thumb to push closure off tube. **Caution:** Any glass tube has the potential to crack or break. If the tube contains blood, an exposure hazard exists. To help prevent injury during closure removal, it is important that the thumb used to push upward on the closure be removed from contact with the tube as soon as the HEMOGARD® Closure is loosened.
3. Lift closure off tube. In the unlikely event of the plastic shield separating from the rubber stopper, DO NOT REASSEMBLE CLOSURE. Carefully remove rubber stopper from tube.

INSTRUCTIONS FOR REINSERTION OF HEMOGARD® CLOSURE



1. Replace closure over tube.
2. Twist and push down firmly until stopper is fully resealed. Complete reinsertion of the stopper is necessary for the closure to remain securely on the tube during handling.

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Becton Dickinson Vacutainer Systems Europe
Belvoir Industrial Estate
Plymouth, PL6 7BP, U.K.

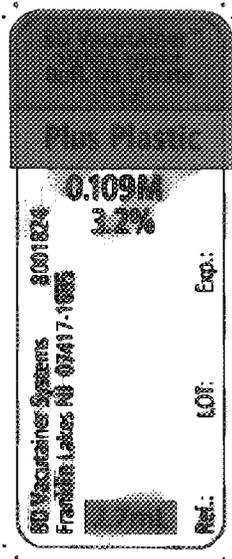
Becton Dickinson Vacutainer Systems
Franklin Lakes, NJ 07417-1885

U.S. Patent Nos. 4,741,446, 4,991,104, and foreign. Made in U.S.A. and England.

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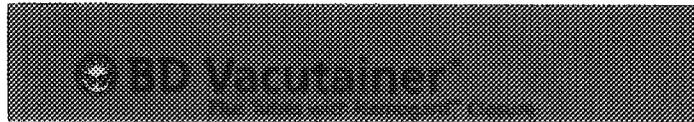
BD Vacutainer™ Safety Coagulation tube
Tube Label



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BD Vacutainer™ Safety Coagulation tube

Shelf Carton Label



BUFFERED SODIUM CITRATE:
0.3ml - 0.109M
TUBE INTERIOR COATING: NONE
STOPPER LUBRICATION: SILICONE

DE CITRATO DE SODIO: 0.3ml
TAMPONADO 0.109M
RECUBRIMIENTO INTERIOR: NONE
TAPON LUBRICADO CON SILICON

DE CITRATE DE SODIUM:
0.3ml TAMPONNE A 0.109M
TUBE: NONE
BOUCHON: SILICONE

CITRATO DE SODIO TAMPONADO
0.3ml - 0.109M
TUBO: NONE
ROLINA: SILICONIZAD

APPROX. DRAW • VOL. APPROX. • VACIO APROX • VOL. APROX.

EXP:

LOT:



(01)30382903630838

13 x 75 mm
REF 363083
8001158

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BD Vacutainer™ Safety Coagulation tube

EPS Tray Label



Blood Collection Tubes
Tube à Prélèvement de Sang Sous Vide
Tubo con Vacío para Extracción de Sangre
Coleta de Sangue a Vácuo
真空採血バキュテイナー集血管

• For In Vitro Diagnostic Use • Pour Diagnostic In Vitro • Para Uso En Diagnostico In Vitro • Para Diagnostico In Vitro •

※外箱裏面のみに記載下さい。

• Refer to package insert for instructions • Pour les recommandations d'utilisation, se reporter à la notice intérieure • Referirse al instructivo • Vide instruções no folheto interno •

※口蓋の上の面に記載の注意事項を必ずお読みください。

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100 Tubes

BD Vacutainer, Preanalytical Solutions, Franklin Lakes, NJ 07417
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BD Vacutainer™ Safety Coagulation tube

Case Carton Label



BUFFERED SODIUM CITRATE:
0.3ml - 0.109M
TUBE INTERIOR COATING: NONE
STOPPER LUBRICATION: SILICONE

DE CITRATO DE SÓDIO: 0.3ml
TAMPONADO 0.109M
RECUBRIMIENTO INTERIOR: NONE
TAPÓN LUBRICADO CON SILICON

DE CITRATE DE SODIUM:
0.3ml TAMPONNE A 0.109M
TUBE: NONE
BOUCHON: SILICONE

CITRATO DE SÓDIO TAMPONADO
0.3ml - 0.109M
TUBO: NONE
ROLHA: SILICONIZAD

APPROX. DRAW • VOL. APPROX. • VACIO APROX • VOL. APROX.



13 x 75 mm
REF 363083
8001159

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BD Vacutainer™ Safety Coagulation tube

Preprinted Case Carton



VACUTAINER®

Brand Blood Collection Tubes

Tube à Prélèvement de Sang Sous Vide
Tubo con Vacío para Extracción de Sangre
Coleta de Sangue a Vácuo
滅菌済みバキュテイナの採血管



DISCONTINUED

VDC30054

1000
(10 x 100)



ROYAL STOCK
ASSURES
ROYALTY STOCK
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ESTOQUE ROYALTY
先入れ先出し

EXP:

LOT:

LOT & EXP
IMPRINTING
AREA ZONE (A1)
(TOP OF IMPRINTING ZONE
IS 10MM (2 3/8")
FROM BOTTOM EDGE
OF CARTON

PANEL 2

VDC30054



VACUTAINER®

Brand Blood Collection Tubes

Tube à Prélèvement de Sang Sous Vide
Tubo con Vacío para Extracción de Sangre
Coleta de Sangue a Vácuo
滅菌済みバキュテイナの採血管



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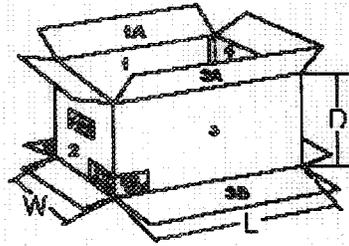
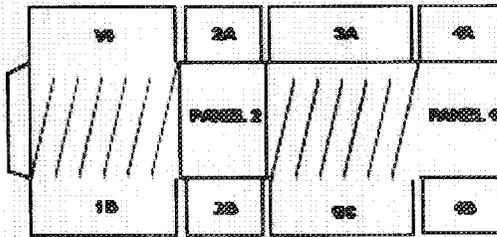
Becton Dickinson VACUTAINER Systems
Becton Dickinson and Company
Franklin Lakes, NJ 07417-1885
MADE IN U.S.A.

PANEL 4

40

BD Vacutainer™ Safety Coagulation tube

Preprinted Case Carton



<p>VACUTAINER® Brand Blood Collection Tubes</p> <p>Tube a Prelevamento de Sangue Sem Vácuo Tube con Vacío para Extracción de Sangre Coleta de Sangue a Vácuo 真空採血管 - サイナクサツパン</p> <p>UNUSUALLY QUALITY REQUIRES THE HANDLING</p>	<p>PANEL 1A</p>
<p>FOR USE WITH BLOOD COLLECTION TUBES POUR USAGE AVEC LES TUBES PARA USO CON TUBOS PARA COLETA DE SANGRE 使用時採血管にのみご利用下さい。</p>	<p>PANEL 3A</p>
<p>RECYCLE</p> <p>BOTTOM - OPEN OTHER SIDE FOND - OUVRIER DE L'AUTRE COTE FOND - ABREIR POR EL LADO CONTRARIO</p>	<p>PANEL 1B</p>
<p>3206</p> <p>Corrugated Recycle</p> <p>3015501 ()</p>	<p>PANEL 3B</p>

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E. PREDICATE DEVICE INFORMATION

E.1 IDENTIFICATION OF PREDICATE DEVICE

The Principal Device, the BD Vacutainer™ Safety Coagulation tube is substantially equivalent in materials (additive), function and intended use to the predicate device:

The VACUTAINER™ Brand Sodium Citrate Tube is a pre-amendment device, which is therefore exempt from premarket notification requirements.

The BD Vacutainer™ Safety Coagulation tube is designed to function like the VACUTAINER™ Brand Sodium Citrate Tube in that they both contain Sodium Citrate additive as an anticoagulant intended to prevent whole blood from clotting prior to analysis. The Sodium Citrate tubes are designed to have a 9:1 blood to additive ratio. The quantity of citrate additive is proportional to the draw volume, to maintain the required 9:1 blood to additive ratio. The dimension of the glass tube is 13mm x 75mm, the draw volume is 4.5ml.

The standard closure assembly is a basic rubber stopper. The tube is also available with the BD Vacutainer Brand™ HEMOGARD Closure Assembly that consists of a rubber stopper and a protective plastic shield to reduce exposure to blood. The Hemogard closure assembly was described in 510(k) Premarket Notification K945952 that received FDA clearance on January 18, 1995.

E.2 PREDICATE DEVICE LABELING

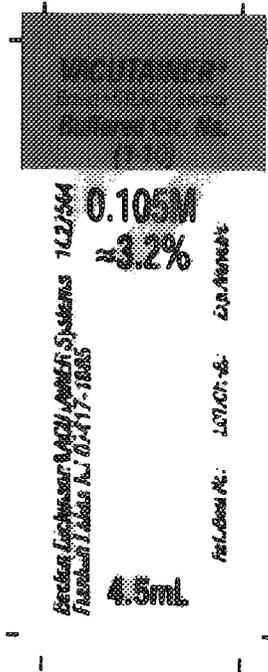
The predicate device, the VACUTAINER™ Brand Sodium Citrate Tube, is marketed as a sterile, in-vitro diagnostic device. The tubes are packaged one hundred (100) labeled tubes per shelf pack and ten shelf packs are placed in a labeled case carton. A product insert with instructions for use is included in each case. The Product Insert for the predicate device will be the same as the principal device with the added information specific to the principal device. A copy of the Product Insert has been provided in Section D.4 Device Labeling. The predicate device labeling included in this section consists of the labeling items identified below:

- Tube Label
- Preprinted Shelf Label
- EPS (Shelf package) Tray Label
- Case Carton Label
- Preprinted Case Carton

The tube, shelf and case carton labels are specific to the VACUTAINER™ Brand Sodium Citrate Tube.

VACUTAINER™ Brand Sodium Citrate Tube

Tube Label



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VACUTAINER™ Brand Sodium Citrate Tube

Shelf Package Tray Label

VACUTAINER® Brand
Tubes with HEMOGARD™ Closure

STERILE 13 x 75 mm

BUFFERED SODIUM CITRATE:
 0.5 mL - 0.105 M
 (EQUIVALENT TO 3.2%).
TUBE INTERIOR COATING:
 SILICONE
STOPPER LUBRICATION:
 SILICONE.

DE CITRATE DE SODIUM:
 0.5 mL TAMPONADO A 0.105 M
 (EQUIVALENT A 3.2%).
TUBE: SILICONE.
BOUCHON: SILICONE.

APPROX. DRAW VOL. APPROX.
VACIO APPROX. VOL. APPROX.

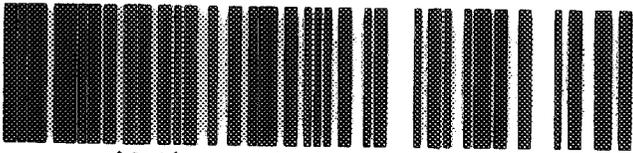
REORDER NUMBER
369714

FORMERLY 367714

DE CITRATO DE SODIO: 0.5 mL
TAMPONADO 0.105 M
(EQUIVALENTE A 3.2%).
RECUBRIMIENTO INTERIOR:
 SILICON
TAPÓN LUBRICADO CON SILICON.
CITRATO DE SÓDIO TAMPONADO
0.5 mL - 0.105 M
(EQUIVALENTE A 3.2%)
TUBO: SILICONIZADO.
ROLHA: SILICONIZADO.

EXP.:

LOT:



(01)30382903697145

L10131-00

44

VACUTAINER™ Brand Sodium Citrate Tube

EPS (Preprinted) Tray Label



Blood Collection Tubes
Tube à Prélèvement de Sang Sous Vide
Tubo con Vacío para Extracción de Sangre
Coleta de Sangue a Vácuo
真空採血管

• For In Vitro Diagnostic Use • Pour Diagnostic In Vitro • Para Uso En Diagnostico In Vitro • Para Diagnostico In Vitro •

※外箱裏面の事にご留意下さい。

• Refer to package insert for instructions • Pour les recommandations d'utilisation, se reporter à la notice intérieure • Referirse al instructivo • Vide instruções no folheto interno •

※口蓋の取り扱いに十分ご注意ください。

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100 Tubes

BD Vacutainer, Preanalytical Solutions, Franklin Lakes, NJ 07417
 Vacutainer is trademark of Becton, Dickinson and Company
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45

VACUTAINER™ Brand Sodium Citrate Tube

Case Carton Label

VACUTAINER® Brand Tubes with HEMOGARD™ Closure		REORDER NUMBER 369714
STERILE 13 x 75 mm		FORMERLY 367714
BUFFERED SODIUM CITRATE: 0.5 mL - 0.105 M (EQUIVALENT TO 3.2%). TUBE INTERIOR COATING: SILICONE STOPPER LUBRICATION: SILICONE.	APPROX. DRAW VOL. APPROX. VACIO APPROX. VOL. APROX.	DE CITRATO DE SODIO: 0.5 mL TAMPONADO 0.105 M (EQUIVALENTE A 3.2%). RECUBRIMIENTO INTERIOR: SILICON TAPÓN LUBRICADO CON SILICON. CITRATO DE SÓDIO TAMPONADO 0.5 mL - 0.105 M (EQUIVALENTE A 3.2%) TUBO: SILICONIZADO. ROLHA: SILICONIZADO.
DE CITRATO DE SODIUM: 0.5 mL TAMPONADO A 0.105 M (EQUIVALENT A 3.2%). TUBE: SILICONE. BOUCHON: SILICONE.		
L10132-00		

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VACUTAINER™ Brand Sodium Citrate Tube

Preprinted Case Carton



VACUTAINER®

Brand Blood Collection Tubes

Tube à Prélèvement de Sang Sous Vide
Tubo con Vacío para Extracción de Sangre
Coleta de Sangue a Vácuo
滅菌済みバキュテイナの採血管



BD
DICKINSON

VHC30054

VOC30054



1000
(10 x 100)

RODDE STOCK
ASAMER
ROBUSTION STOCK
ROVE EL STOCK
ESTOQUE ROUSTING
先入れ先出し

EXP:

LOT:

LOT & EXP.
MARKING
AREA: 20mm (3/4")
(TOP OF MARKING ZONE
IS 136mm (5-3/8")
FROM BOTTOM EDGE
OF CARTON.

PANEL 2



VACUTAINER®

Brand Blood Collection Tubes

Tube à Prélèvement de Sang Sous Vide
Tubo con Vacío para Extracción de Sangre
Coleta de Sangue a Vácuo
滅菌済みバキュテイナの採血管



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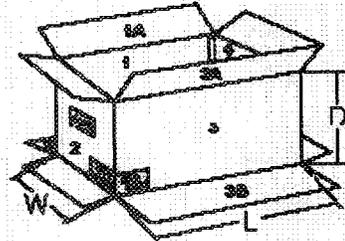
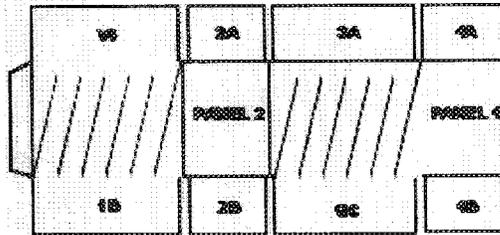
Becton Dickinson VACUTAINER Systems
Becton Dickinson and Company
Franklin Lakes, NJ 07417-1885
MADE IN U.S.A.

PANEL 4

47

VACUTAINER™ Brand Sodium Citrate Tube

Preprinted Case Carton



<p>VACUTAINER™ Brand Blood Collection Tubes</p> <p>Tubo à Prétraitement de Sang Sans Vite Tubo con Vite para Extracción de Sangre Cartera de Sangre a Vitecas 血液採集用 - サイナト管</p> <p>INSURETHERM QUALITY MAKES THE DIFFERENCE</p> 	<p>PANEL 1A</p>
<p>FOR AN EASY DIAGNOSTIC USE POUR UN DIAGNOSTIC EN VITE PARA USO DE EXTRACCIÓN DE SANGRE 血液採集用 (VITE) 管</p> 	<p>PANEL 3A</p>
<p></p> <p>BOTTOM - OPEN OPPOSITE END FOND - OUVRIRE DE L'AUTRE CÔTÉ FONDO - ABRIRE POR EL LADO CONTRARIO</p>	<p>PANEL 1B</p>
<p>3206</p> <p> Destroyed Recycle</p> <p>3015501 ()</p>	<p>PANEL 3B</p>

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F. 510(K) SUBSTANTIAL EQUIVALENCE JUSTIFICATION

The term "Substantial Equivalence" as used in this 510(k) Premarket Notification is limited to the definition of Substantial Equivalence found in the Federal Food, Drug, and Cosmetic Act, as amended and as applied under 21 CFR § 807, Subpart E, under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of, substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

F.1 SUBSTANTIAL EQUIVALENCE DECISION

The principal device presented in this submission, the BD Vacutainer™ Safety Coagulation tube, is substantially equivalent to the currently marketed predicate device, the VACUTAINER™ Brand Sodium Citrate Tube. The predicate and principal devices have similar materials (additive), function, and intended use.

The BD Vacutainer™ Safety Coagulation tube is designed to function like the VACUTAINER™ Brand Sodium Citrate Tube in that they both contain Sodium Citrate additive as an anticoagulant intended to prevent whole blood from clotting prior to analysis. In both devices, the tubes are designed to have a 9:1 blood to additive ratio. The quantity of citrate additive is proportional to the draw volume, to maintain the required 9:1 blood to additive ratio. The BD Vacutainer™ Safety Coagulation tube is for use in routine coagulation assays including, but not limited to, PT, APTT, Fibrinogen, Heparin Xa and platelet counts.

Table F.2 compares the device characteristics of the principal device, BD Vacutainer™ Safety Coagulation tube, and the predicate device, VACUTAINER™ Brand Sodium Citrate Tube. The manufacturing processes are compared in Table F.3.

F.2 COMPARISON OF DEVICE CHARACTERISTICS

	PRINCIPAL DEVICE	PREDICATE DEVICE
Product	BD Vacutainer™ Safety Coagulation tube	VACUTAINER™ Brand Sodium Citrate Tube
Intended use	Blood collection for coagulation assays	Blood collection for coagulation assays
Tube Material	Plastic: <ul style="list-style-type: none"> • Inner Tube is Polypropylene (liquid additive retention) • Outer Tube is PET (vacuum retention) 	Glass
Additive Type	Sodium Citrate	Sodium Citrate
Tube Coating	None	Silicone
Draw Volume	2.7ml or 1.8ml	4.5ml
Additive Concentrations (nominal)	0.109M buffered sodium citrate solution or 0.129M buffered sodium citrate solution	0.105M buffered Sodium citrate solution or 0.129M buffered sodium citrate solution
Tube Closure	HEMOGARD™ Safety Closure Assembly	HEMOGARD™ Safety Closure Assembly or Conventional Rubber Stopper

F.3 COMPARISON OF MANUFACTURING PROCESS

	PRINCIPAL DEVICE	PREDICATE DEVICE
Product	BD Vacutainer™ Safety Coagulation tube	VACUTAINER™ Brand Sodium Citrate Tube
Stopper Fabrication	Compression Molded Rubber	Compression Molded Rubber
Additive Dispense	Liquid	Liquid
Tube Evacuation	Vacuum Chamber	Vacuum Chamber
Unit Labeling	Printed Paper Label	Printed Paper Label or Imprinted on Tube
Sterilization method	Gamma Irradiation	Gamma Irradiation

G. PERFORMANCE VALIDATION

G.1 SUMMARY AND NEW PRODUCT CLAIMS

The BD Vacutainer™ Safety Coagulation tube is a plastic evacuated blood collection tube that provides a means of collecting, transporting and processing blood in a closed tube. The buffered sodium citrate additive provides an anticoagulated specimen that may be used for clinical laboratory coagulation assays. The benefits of a safety plastic coagulation tube with Hemogard Safety Closure Assembly are:

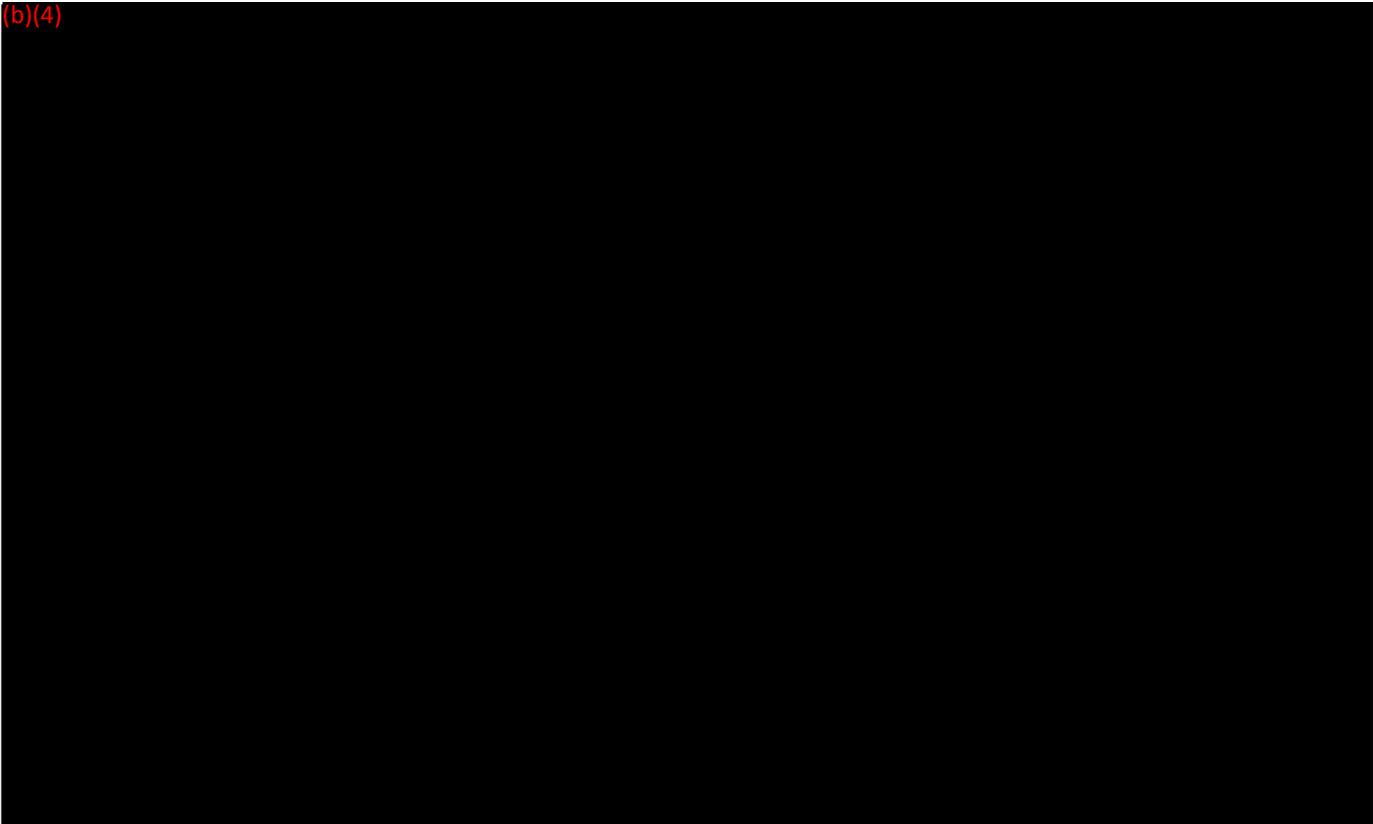
- reduced risk of specimen tube breakage
- reduced exposure to blood by laboratory personnel and to minimize blood splatter during stopper removal

These benefits lead to increased safety of laboratory personnel and reduced necessity of repeat specimen collection.

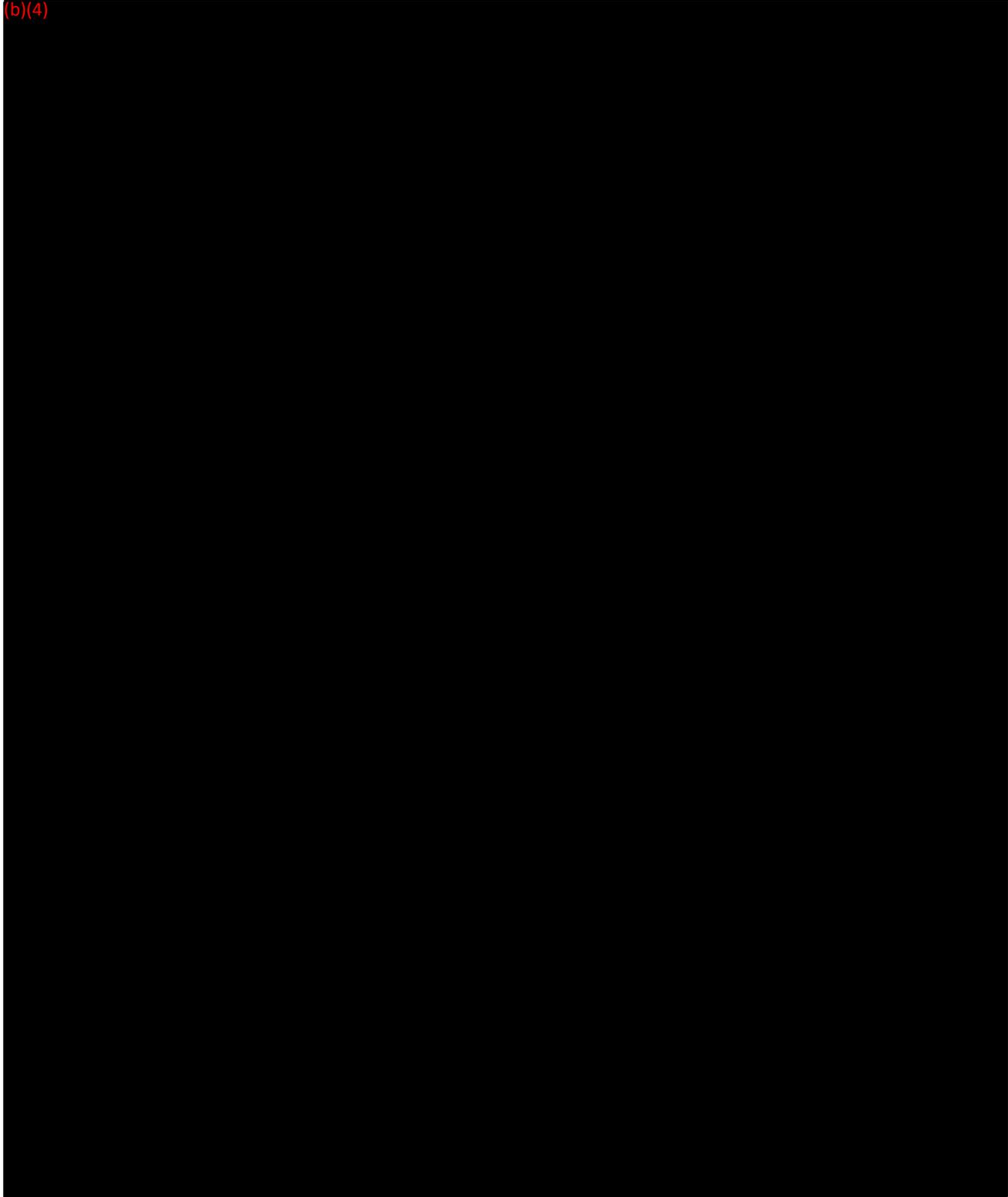
The predicate blood collection tube consists of a rubber stopper closure, a glass tube and liquid sodium citrate additive. The principal device and the predicate device have identical closure materials of composition. The Device performance has been demonstrated in clinical evaluations.

G.2 PERFORMANCE TESTING

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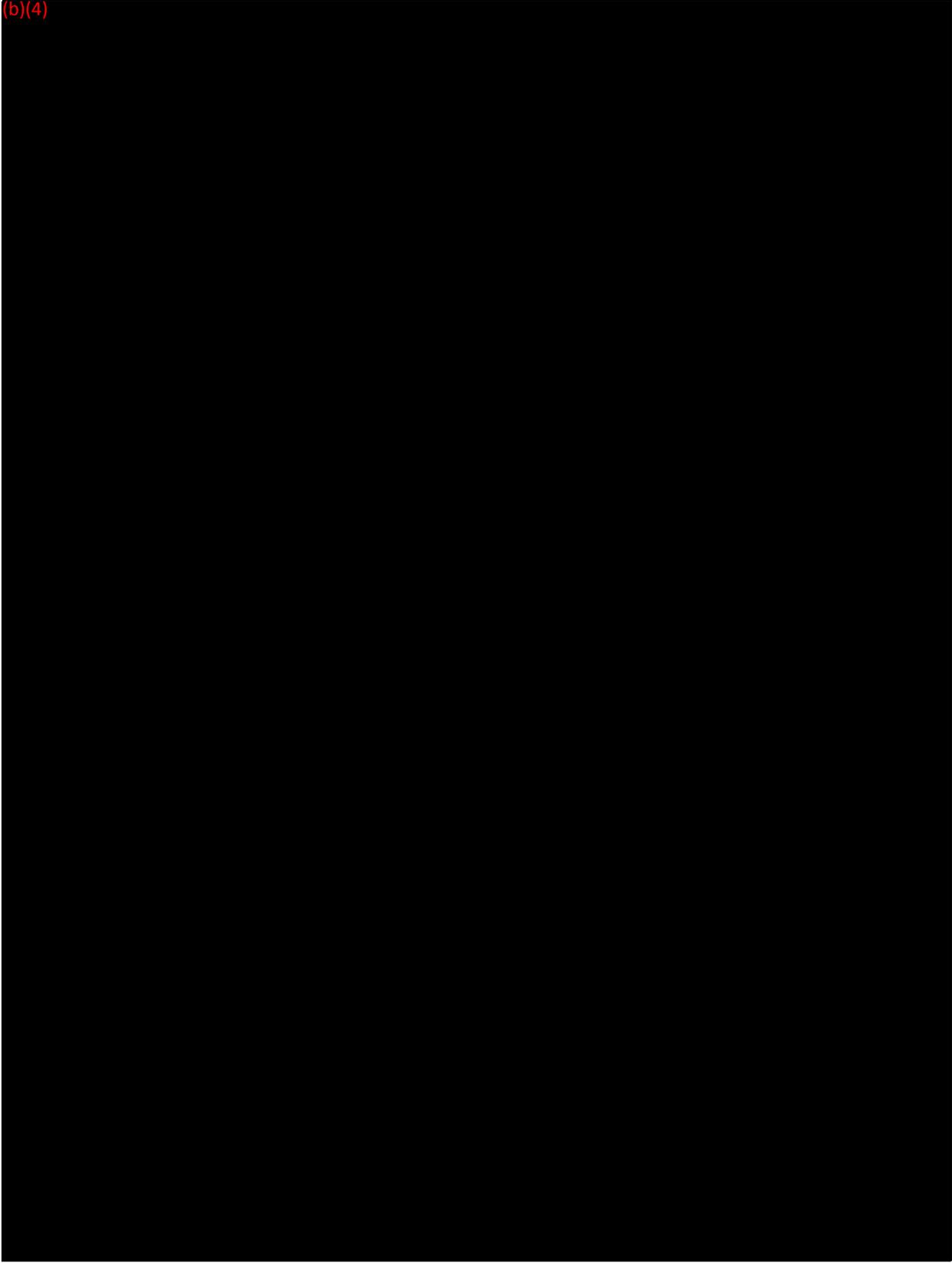


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52

(b)(4)



53

Clinical Performance

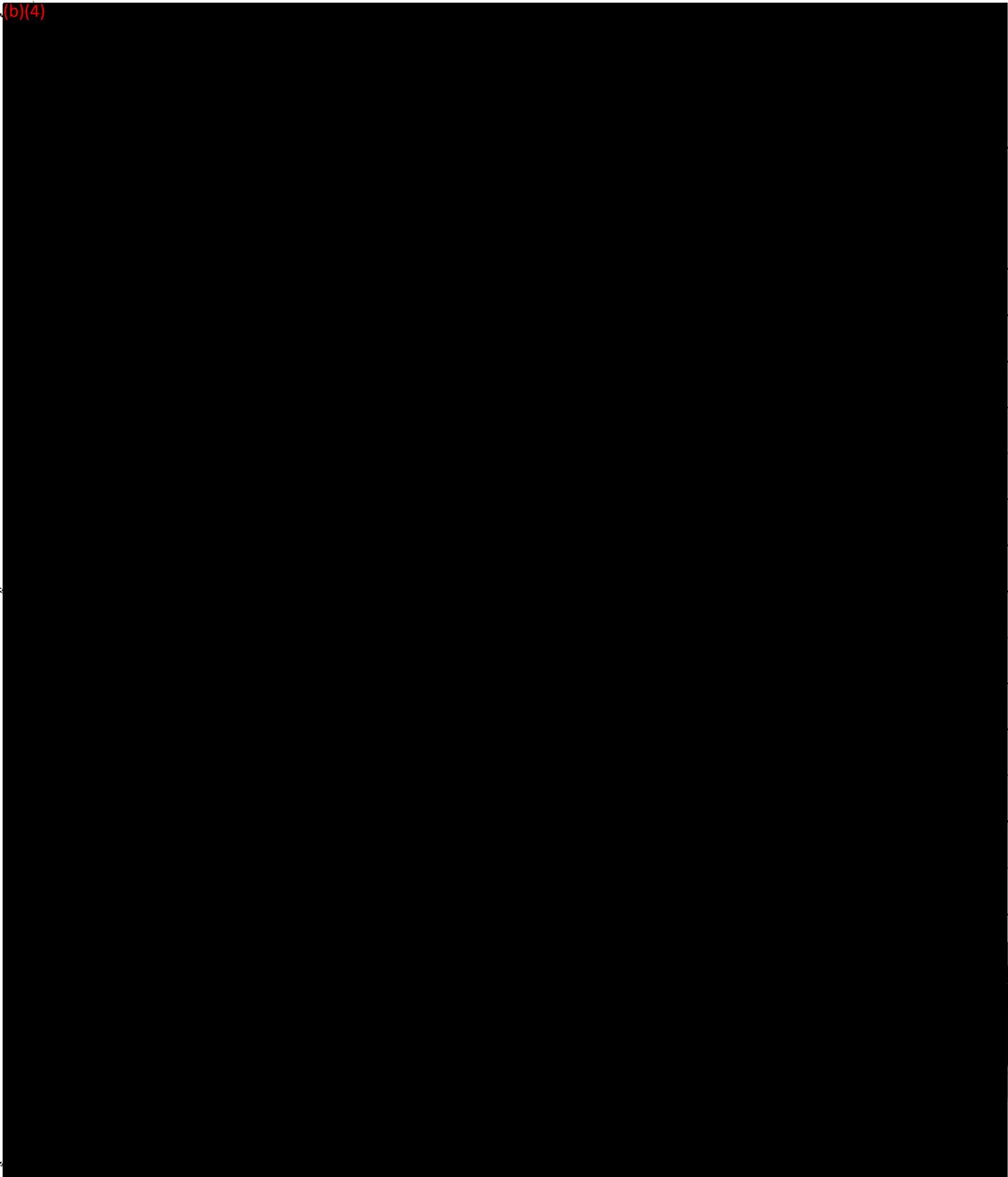
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54

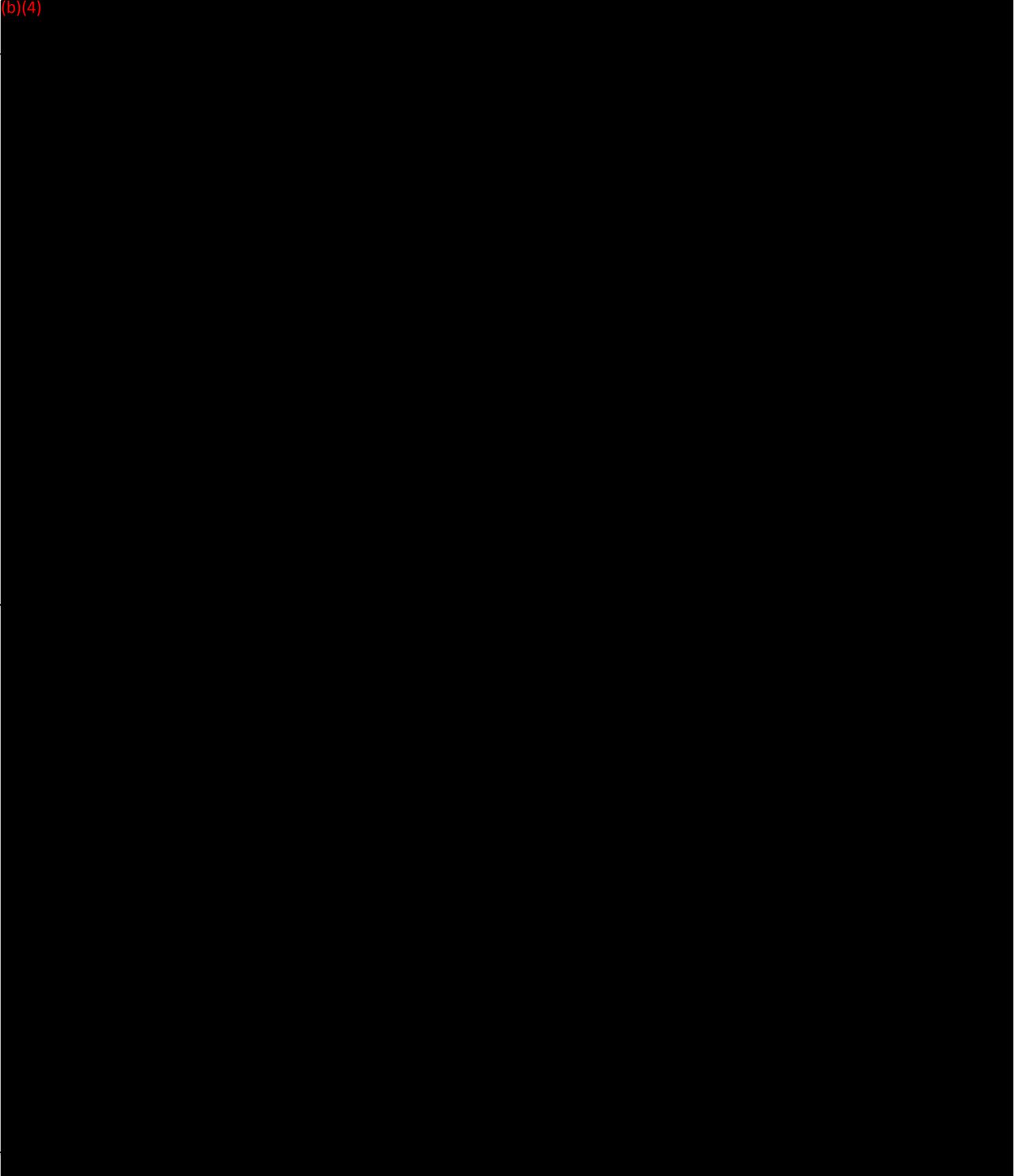
G.3 SUMMARY OF CLINICAL EVALUATIONS

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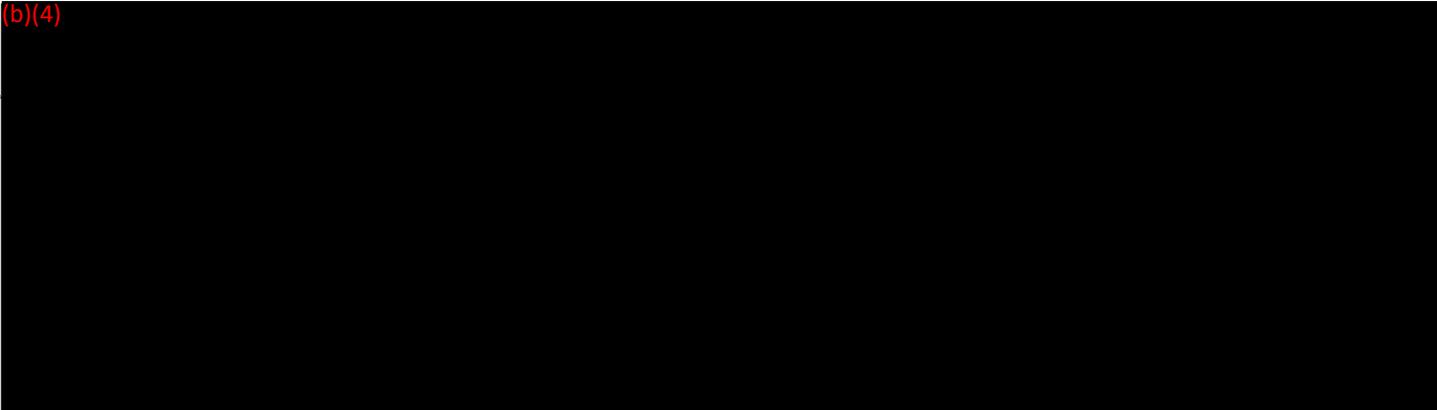
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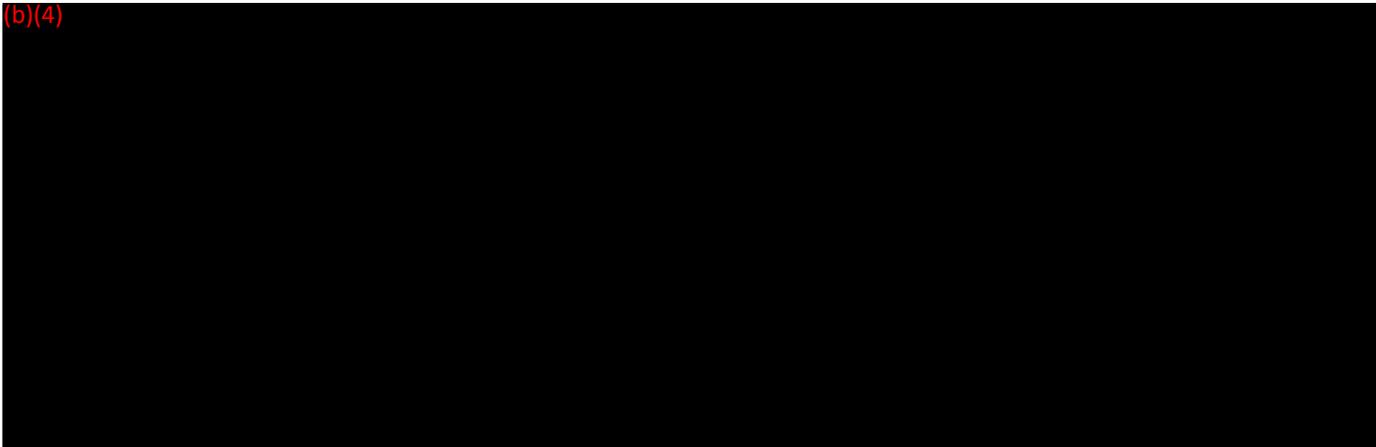
56

(b)(4)



Clinical Sites

(b)(4)



57

J. CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

J.1 STATEMENT OF COMPLIANCE WITH 21 CFR PART 54

In accordance with 21 CFR part 54, Financial Disclosure by Clinical Investigators, which requires any manufacturer conducting a clinical investigation with a medical device to provide documentation of financial interests and arrangements with the manufacturer, a completed FDA Form 3454 has been provided on the following page.

This disclosure will also be repeated one year after completion of the clinical investigation.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration

Form Approved: OMB No. 0910-0396
Expiration Date: 3/31/02

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 checkbox.

- (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) (6)

- (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	TITLE
Keith M. Smith	Director, Regulatory Affairs
FIRM/ORGANIZATION	
BD Vacutainer Systems	
SIGNATURE	DATE
	11/8/01

Paperwork Reduction Act Statement

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Food and Drug Administration
5600 Fishers Lane, Room 14C-03
Rockville, MD 20857

FORM FDA 3454 (3/99)

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**ATTACHMENTS: CLINICAL EVALUATIONS 1-10 ON
FOLLOWING PAGES**

60

**ATTACHMENT 1: CLINICAL EVALUATION- AT BD
VACUTAINER SYSTEMS (BDVS)**

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**BD CLINICAL STUDY: DETERMINATION OF NORMAL DONOR PT AND APTT USING 0.109 M
2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES**

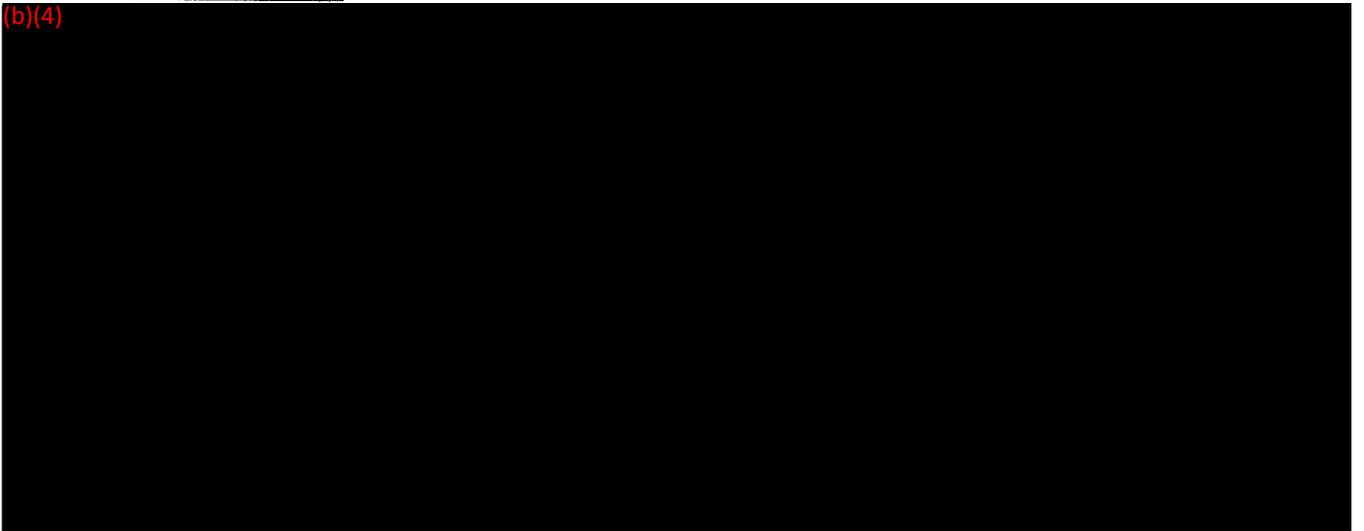
ABSTRACT

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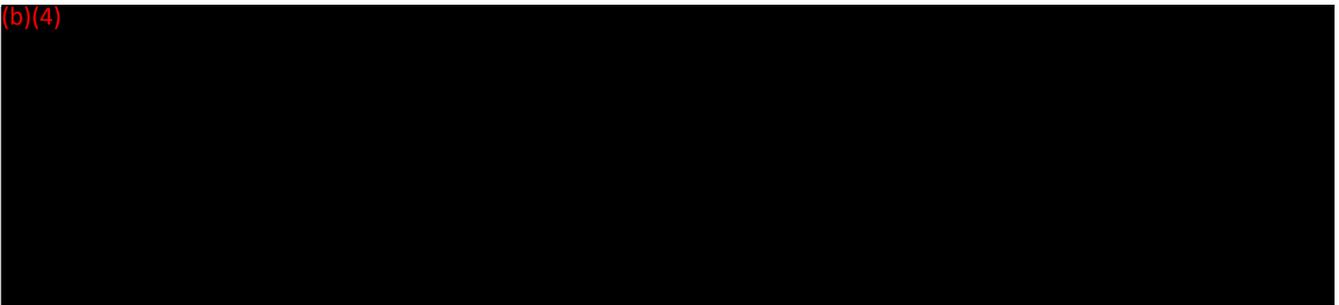
I. INTRODUCTION

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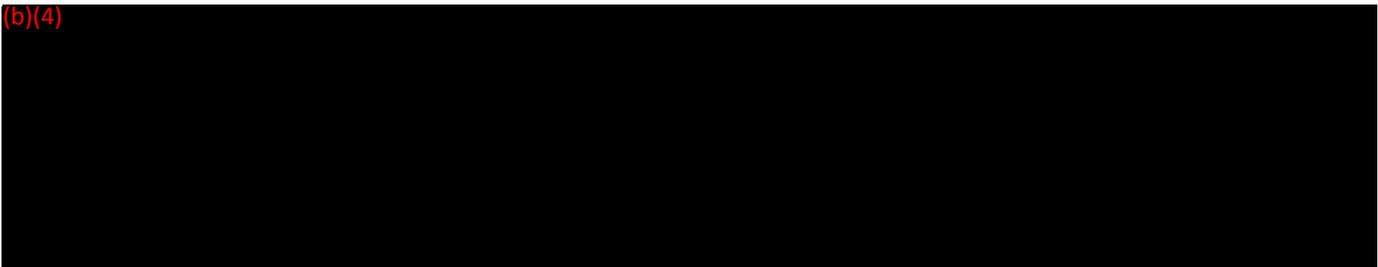
II. OBJECTIVE

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III. METHODS AND MATERIALS

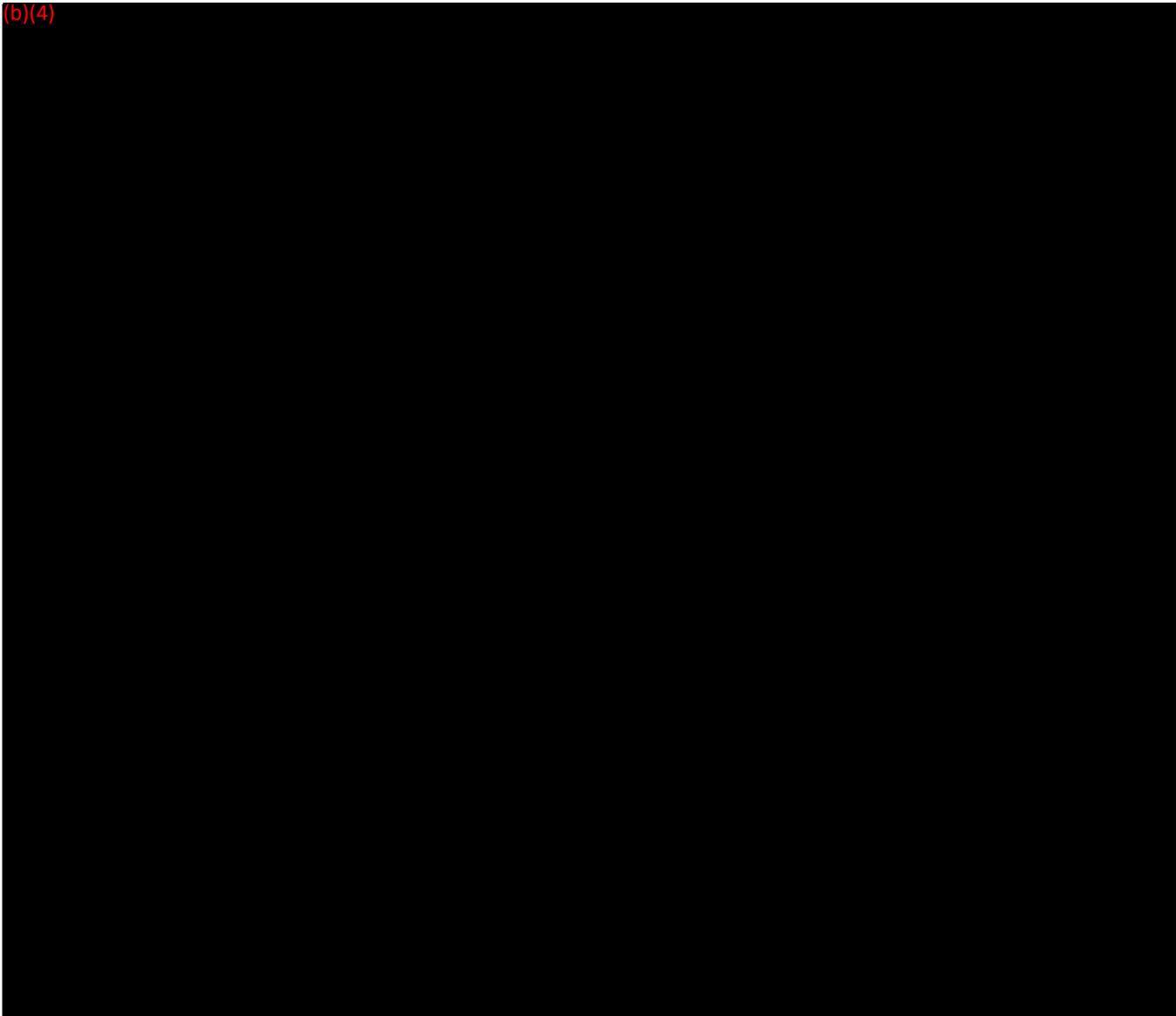
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62

**BD CLINICAL STUDY: DETERMINATION OF NORMAL DONOR PT AND APTT USING 0.109 M
2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES**

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IV. DATA ANALYSIS

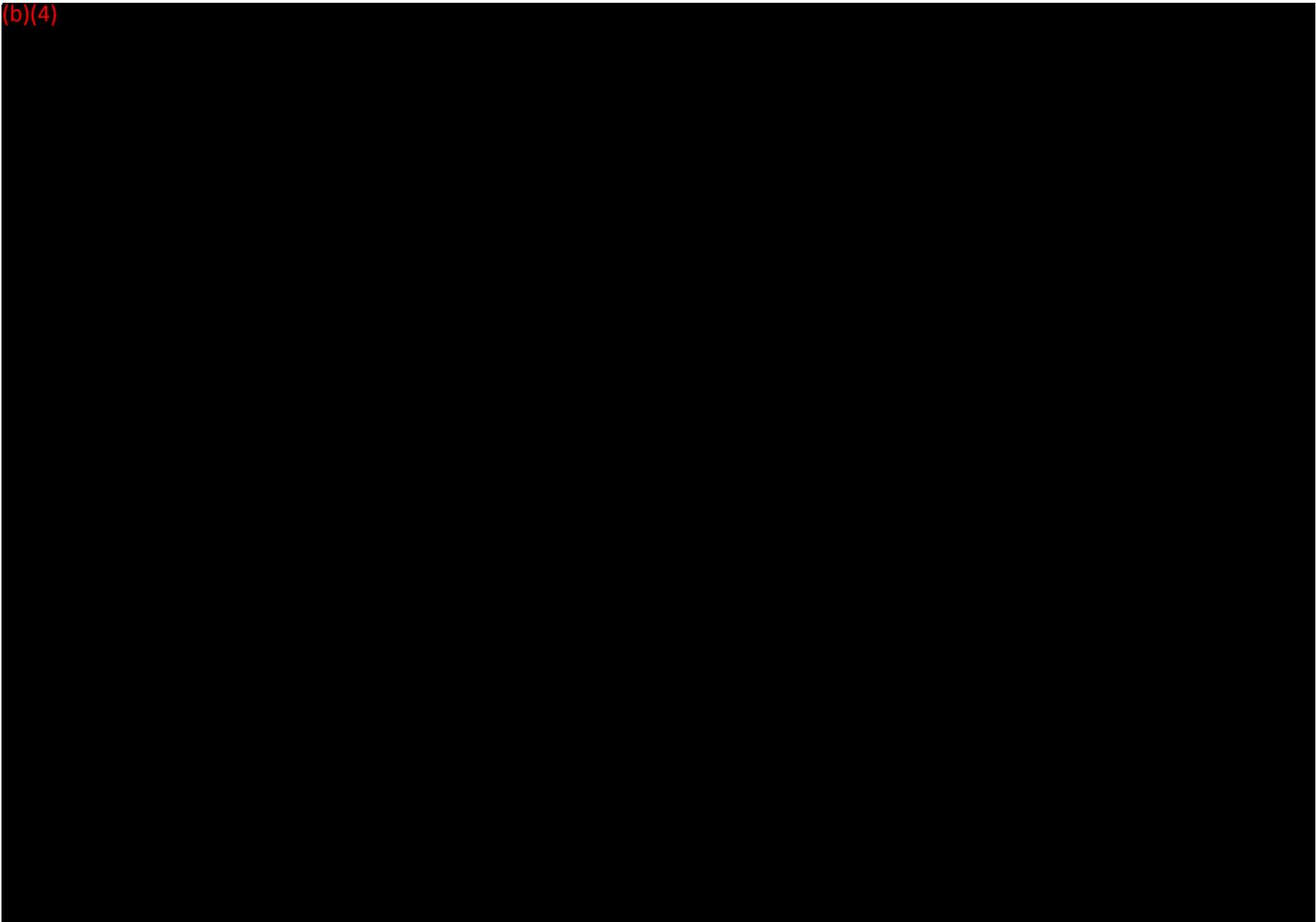
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63

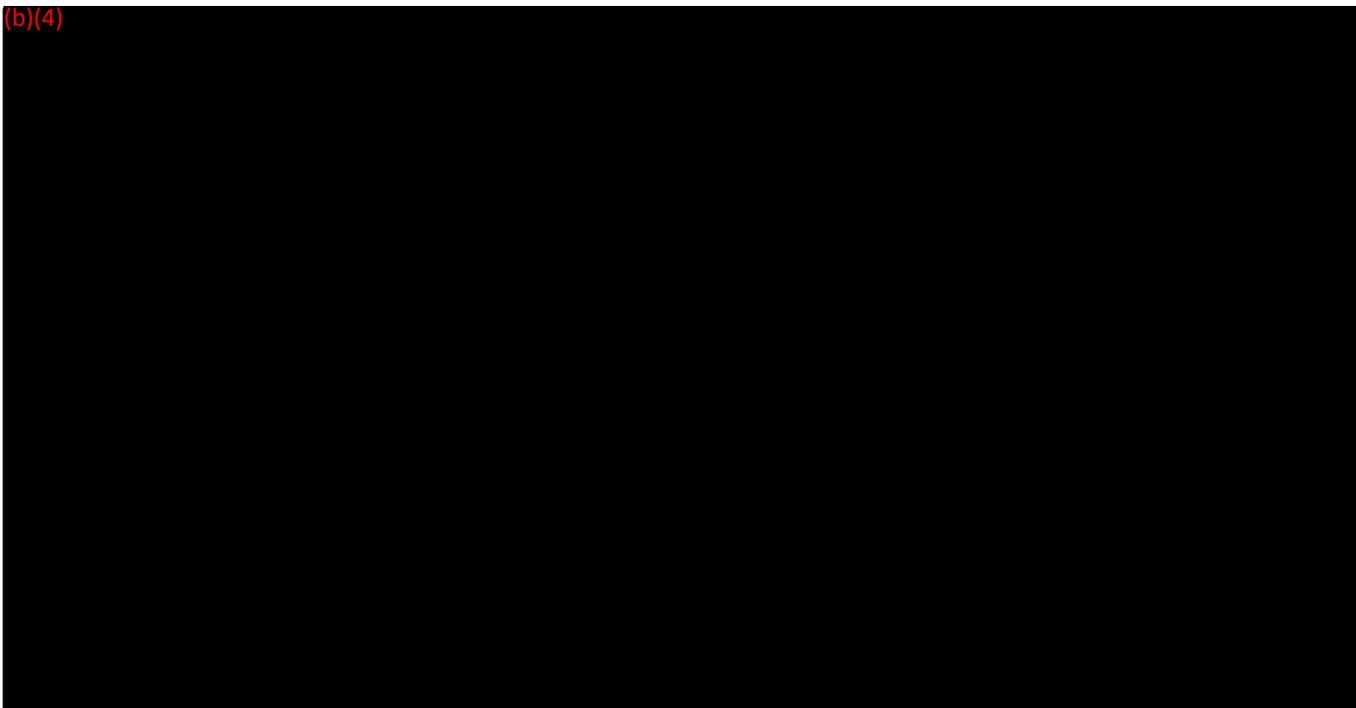
**BD CLINICAL STUDY: DETERMINATION OF NORMAL DONOR PT AND APTT USING 0.109 M
2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES**

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V. RESULTS AND DISCUSSION

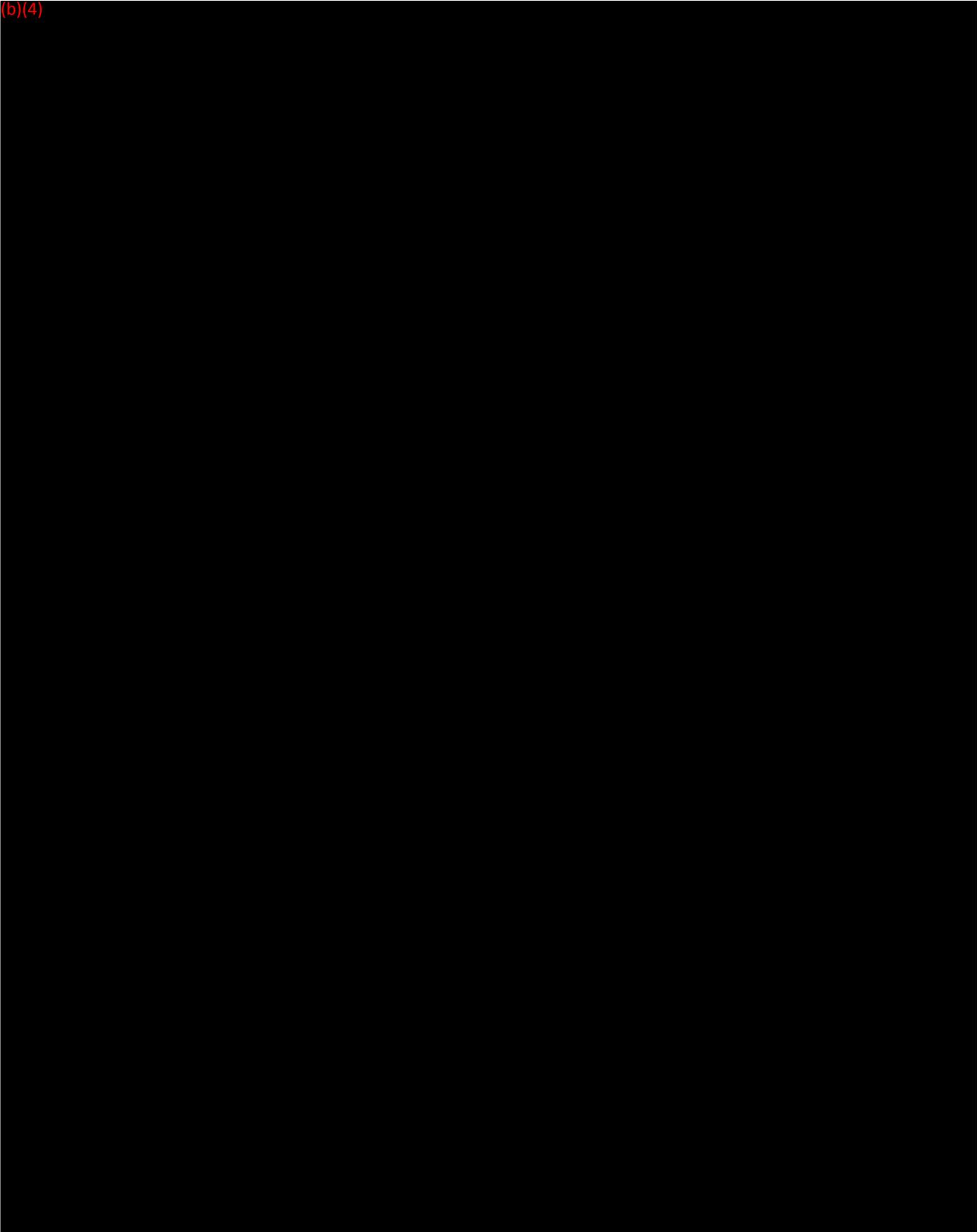
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64

**BD CLINICAL STUDY: DETERMINATION OF NORMAL DONOR PT AND APTT USING 0.109 M
2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES**

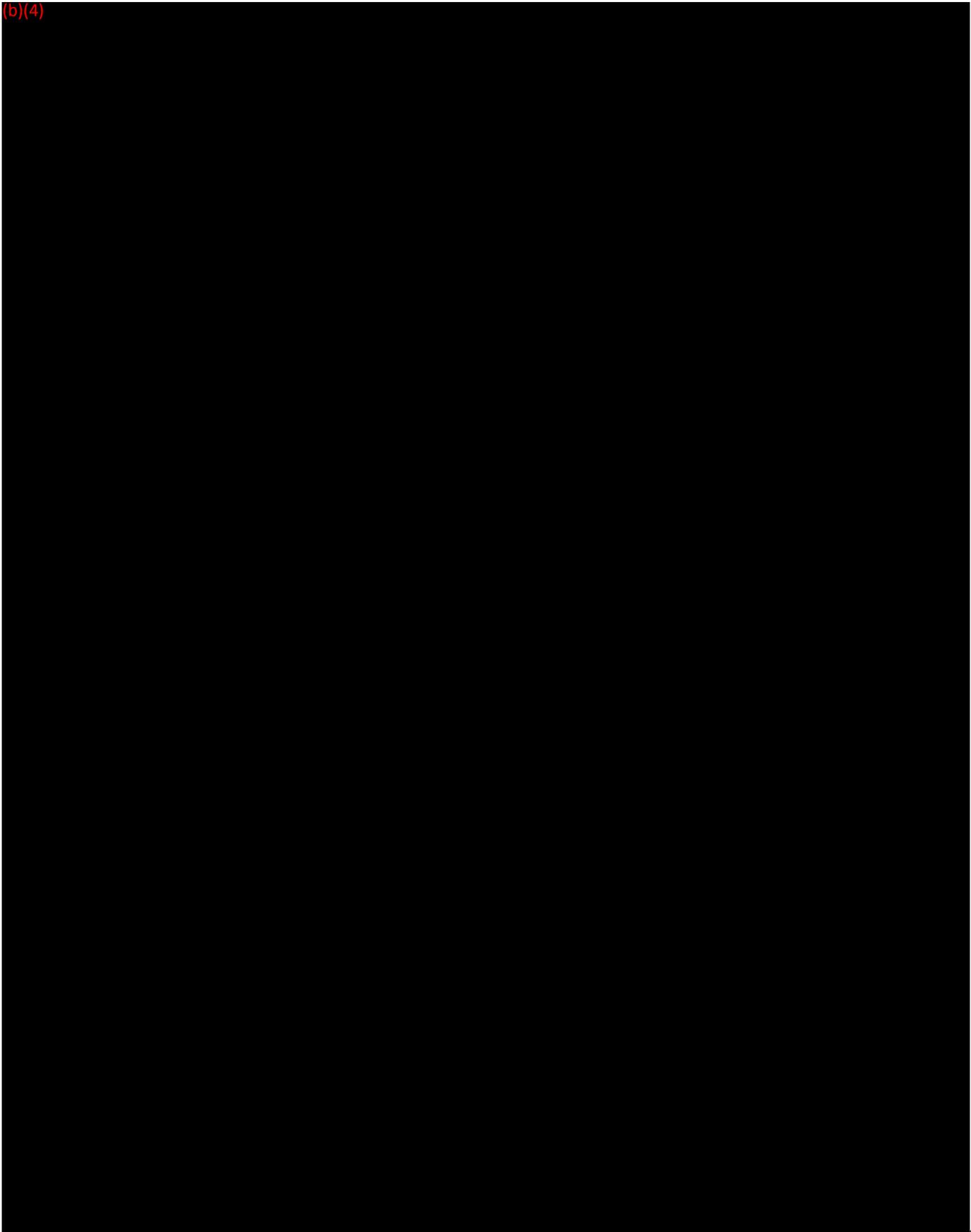
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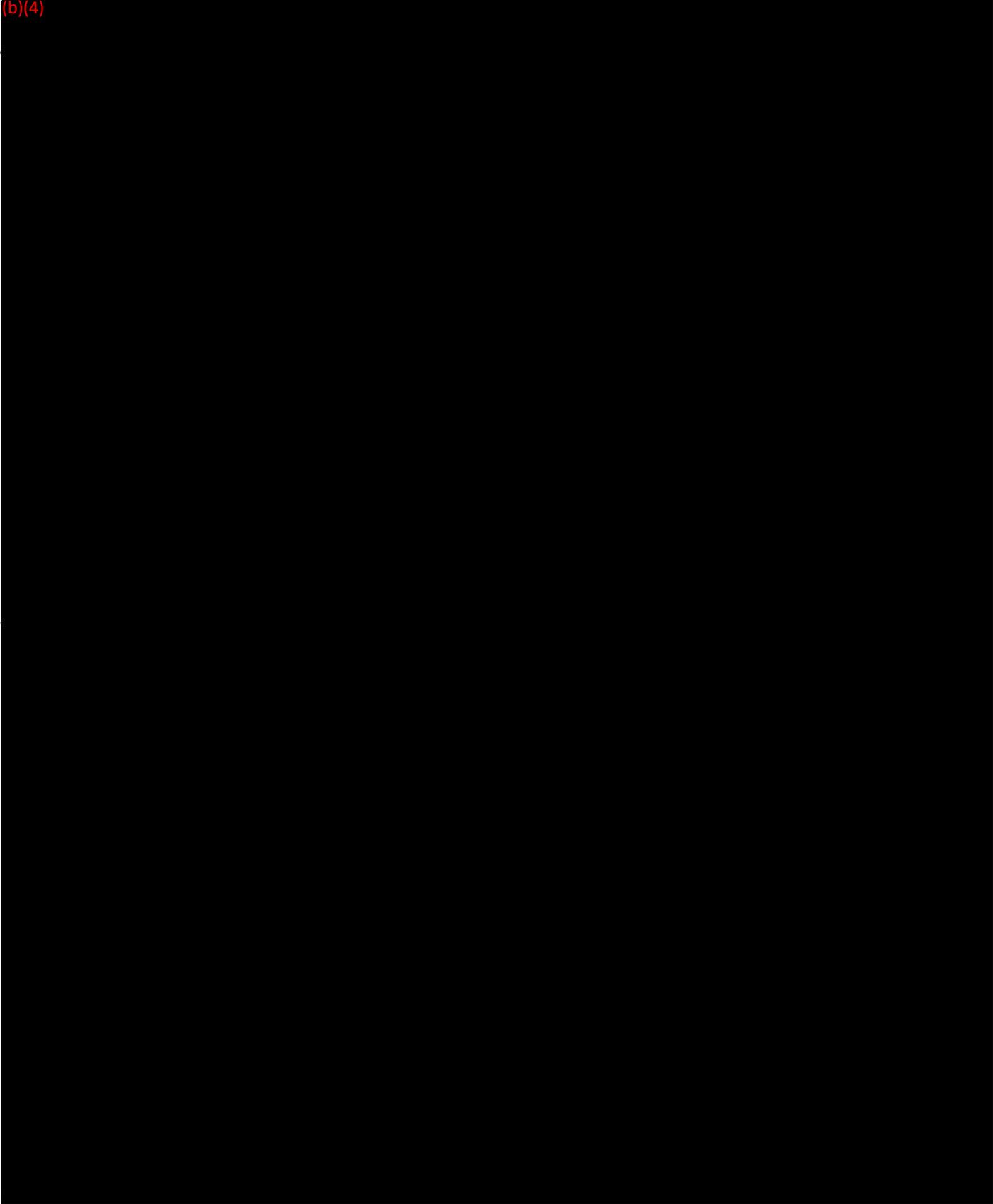
**BD CLINICAL STUDY: DETERMINATION OF NORMAL DONOR PT AND APTT USING 0.109 M
2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES**

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66

**BD CLINICAL STUDY: DETERMINATION OF NORMAL DONOR PT AND APTT USING 0.109 M
2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES**

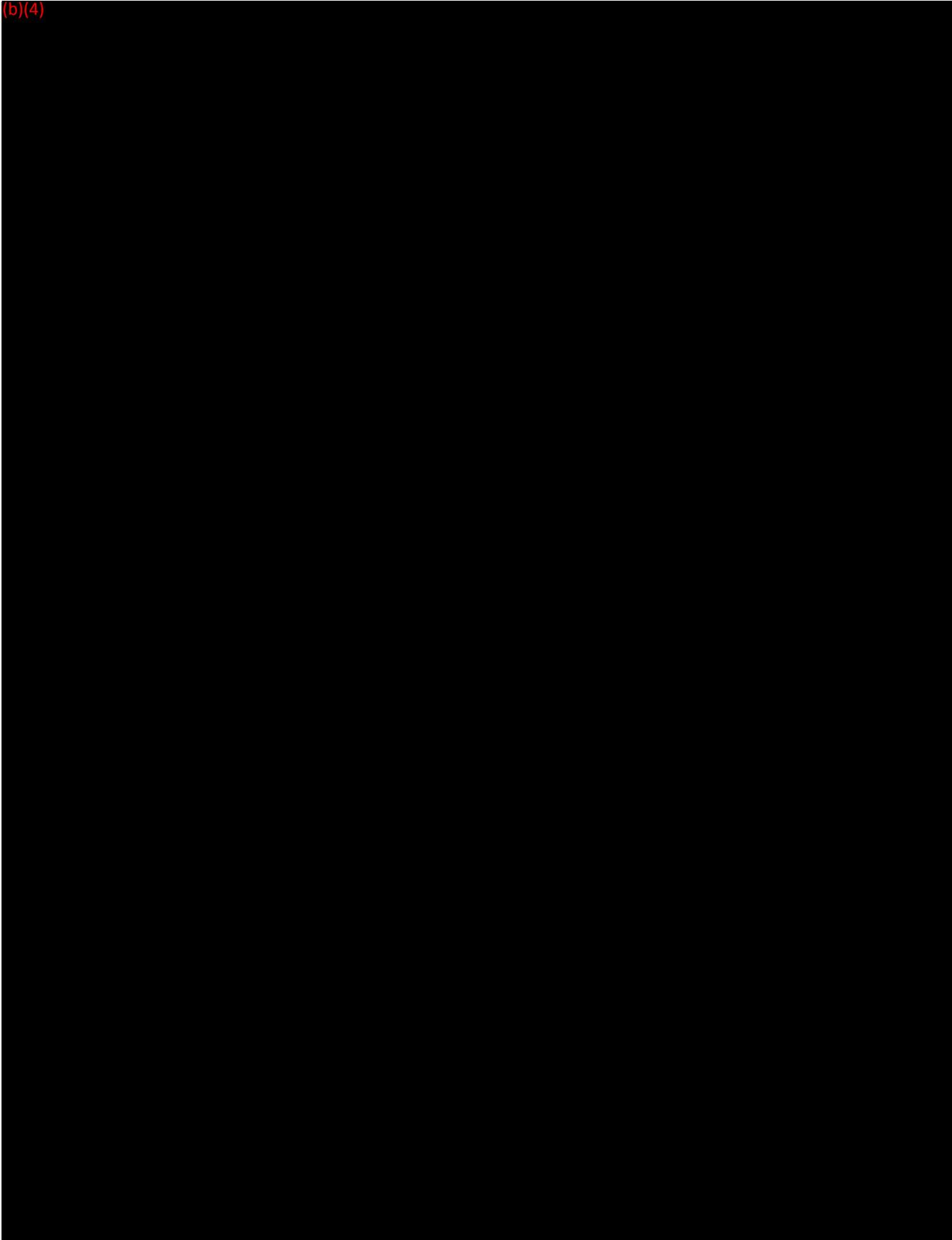


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67

**BD CLINICAL STUDY: DETERMINATION OF NORMAL DONOR PT AND APTT USING 0.109 M
2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES**

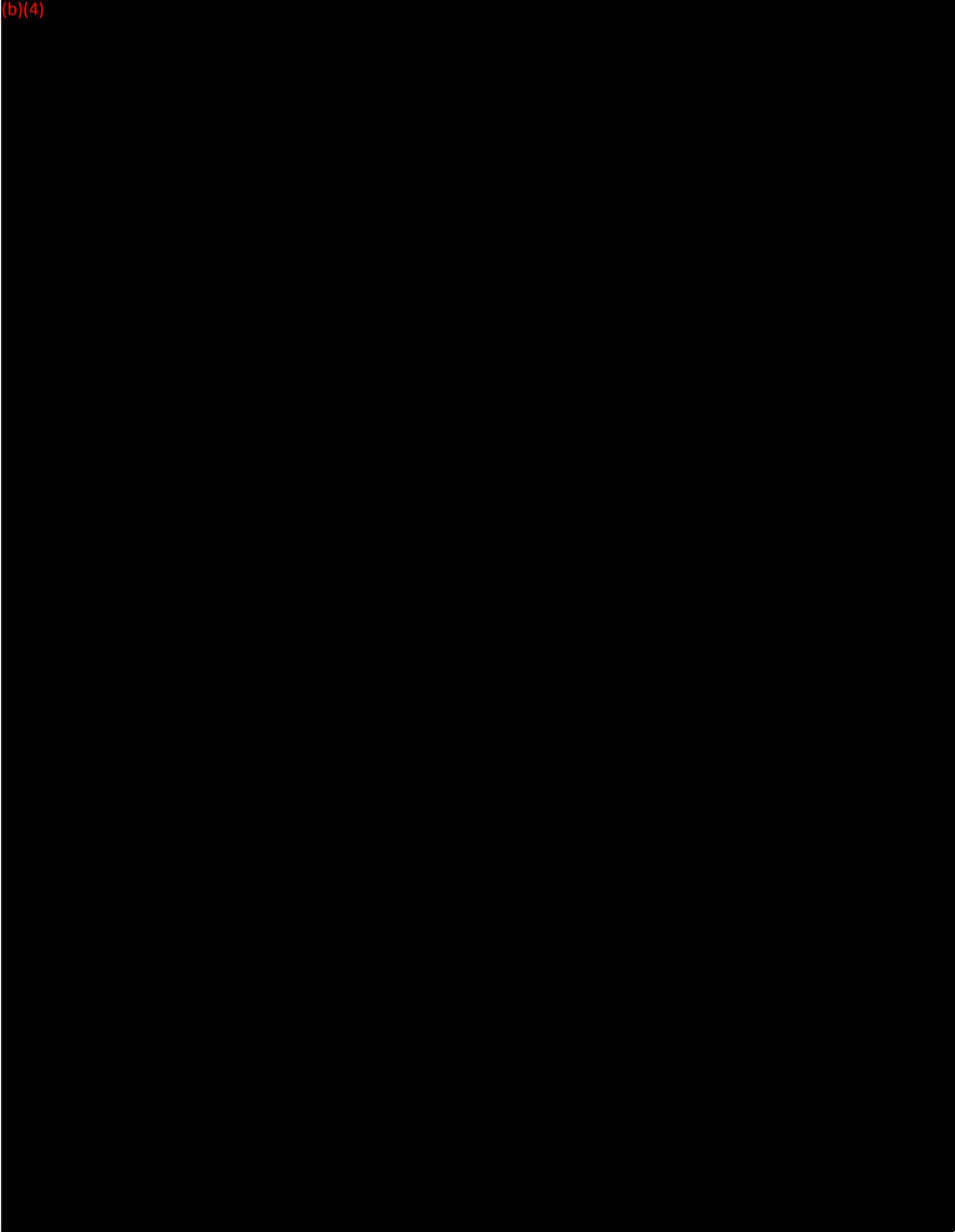
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68

**BD CLINICAL STUDY: DETERMINATION OF NORMAL DONOR PT AND APTT USING 0.109 M
2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES**

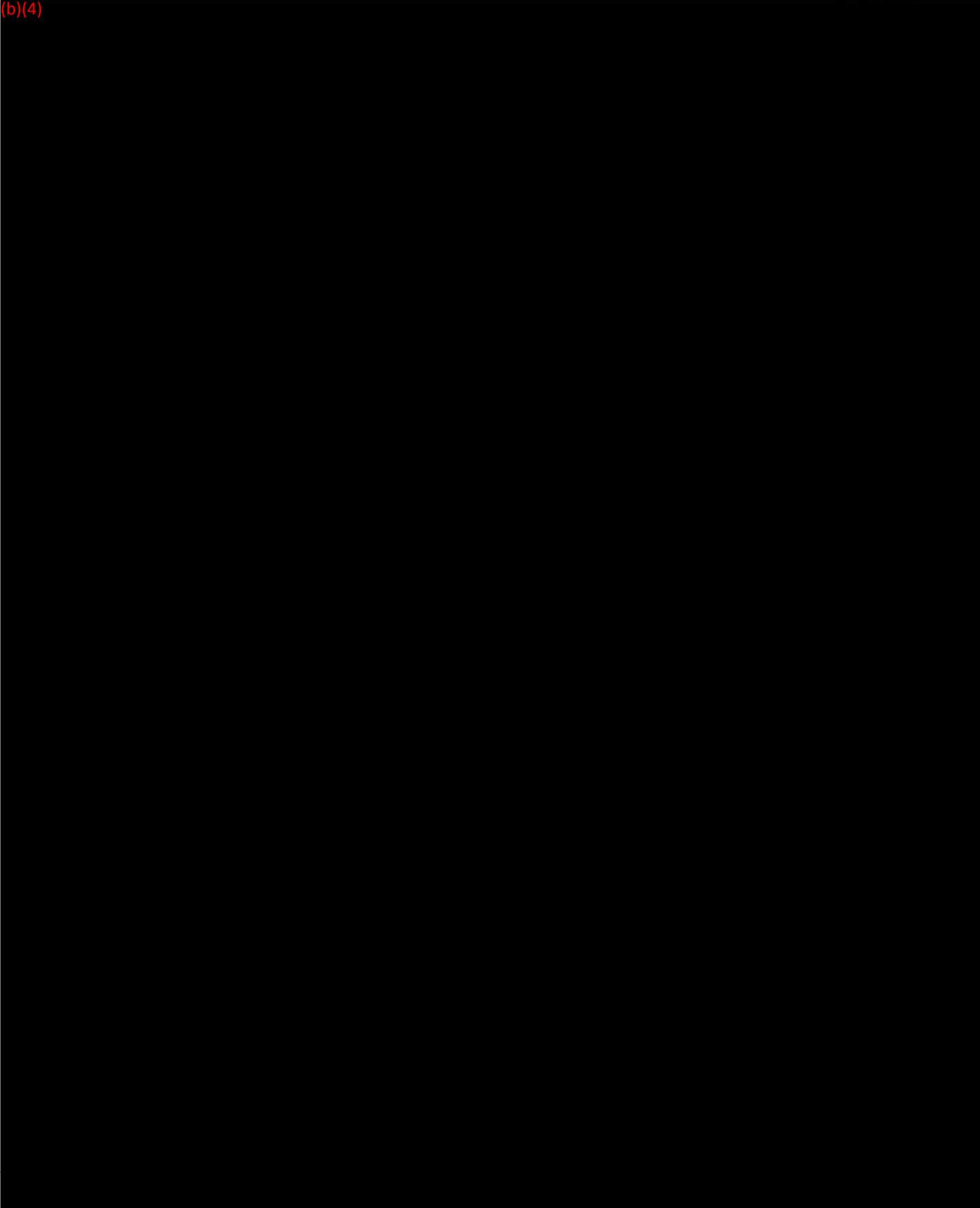
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69

**BD CLINICAL STUDY: DETERMINATION OF NORMAL DONOR PT AND APTT USING 0.109 M
2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES**

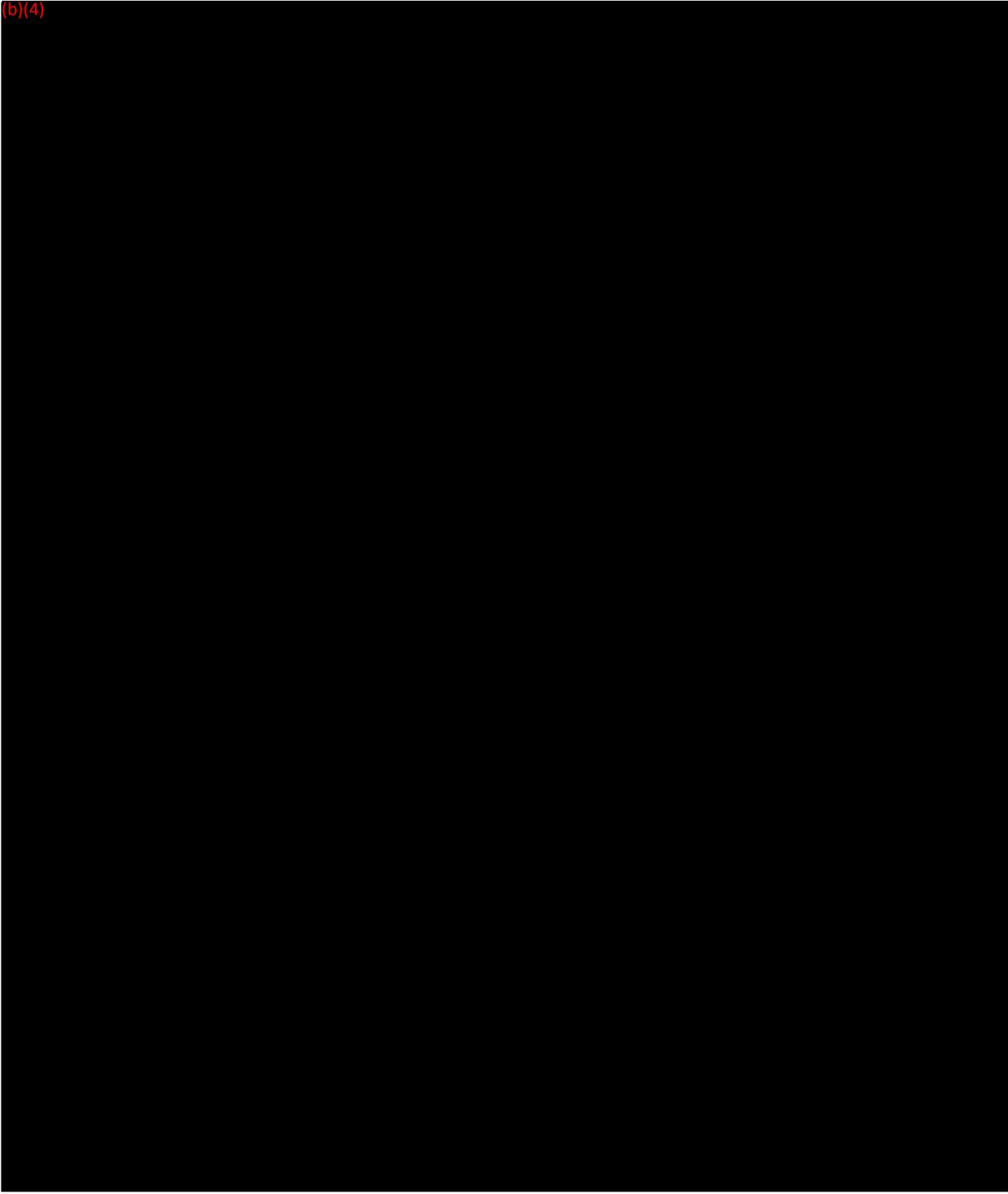
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**BD CLINICAL STUDY: DETERMINATION OF NORMAL DONOR PT AND APTT USING 0.109 M
2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES**

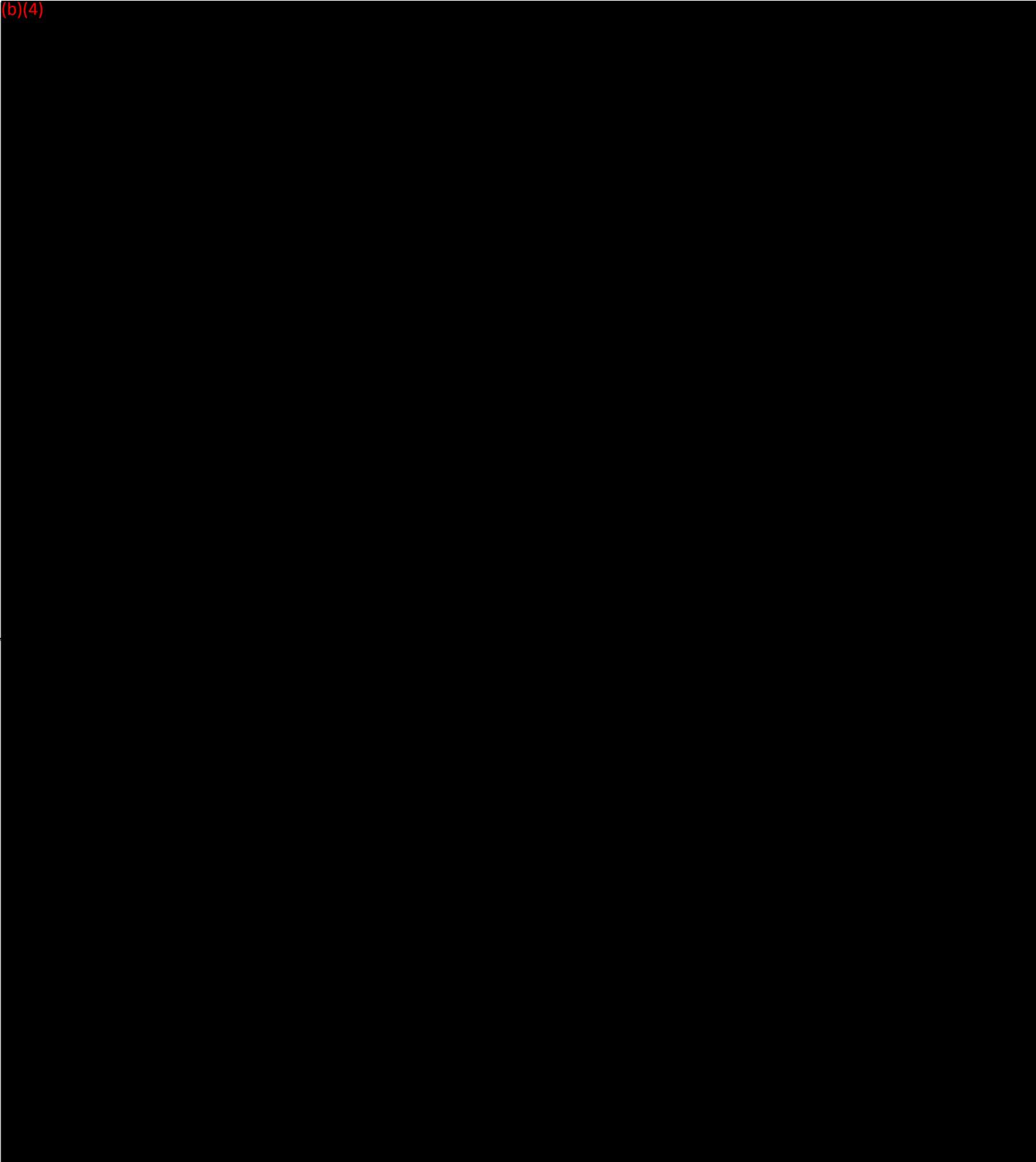
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71

**BD CLINICAL STUDY: DETERMINATION OF NORMAL DONOR PT AND APTT USING 0.109 M
2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES**

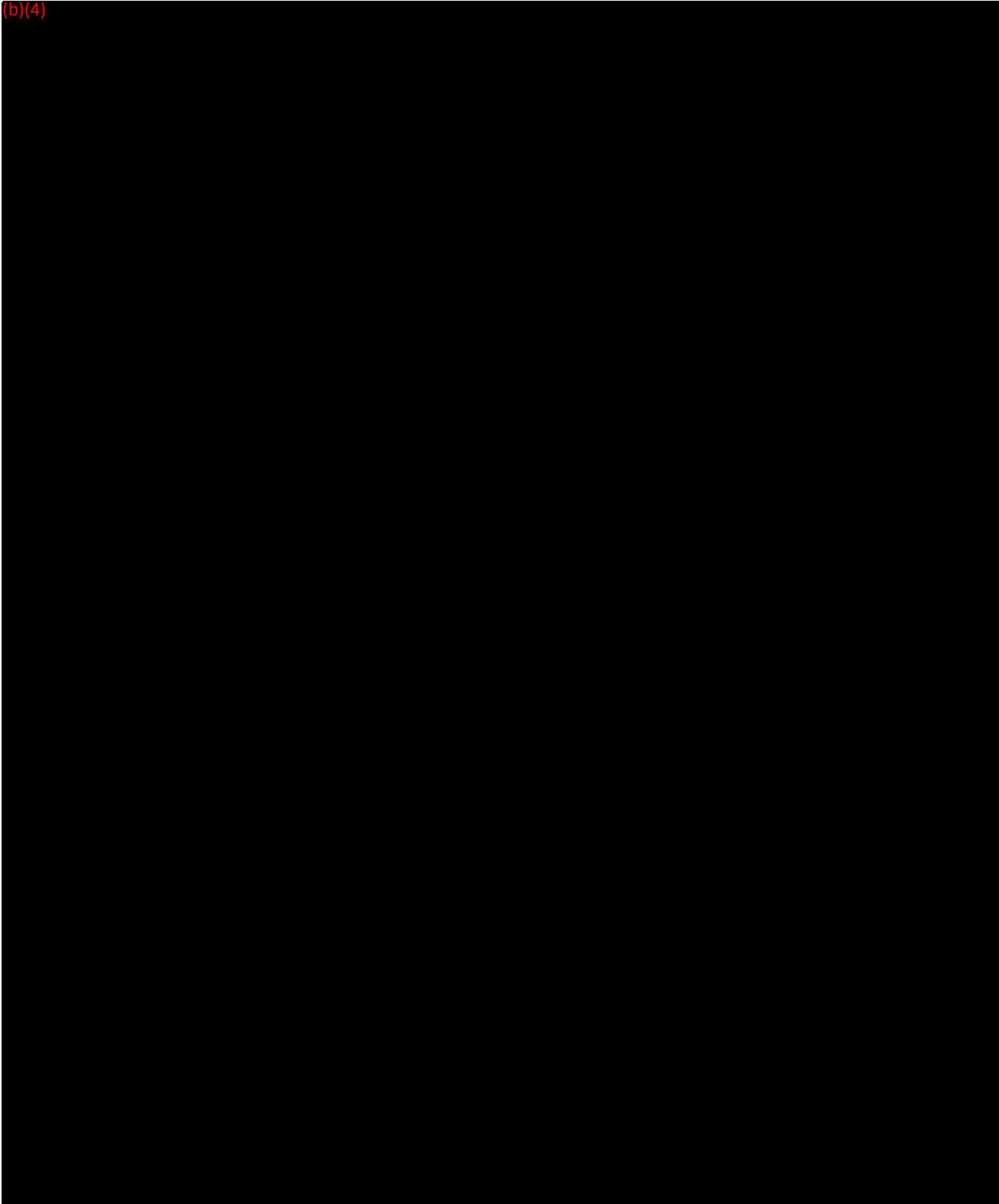
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**BD CLINICAL STUDY: DETERMINATION OF NORMAL DONOR PT AND APTT USING 0.109 M
2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES**

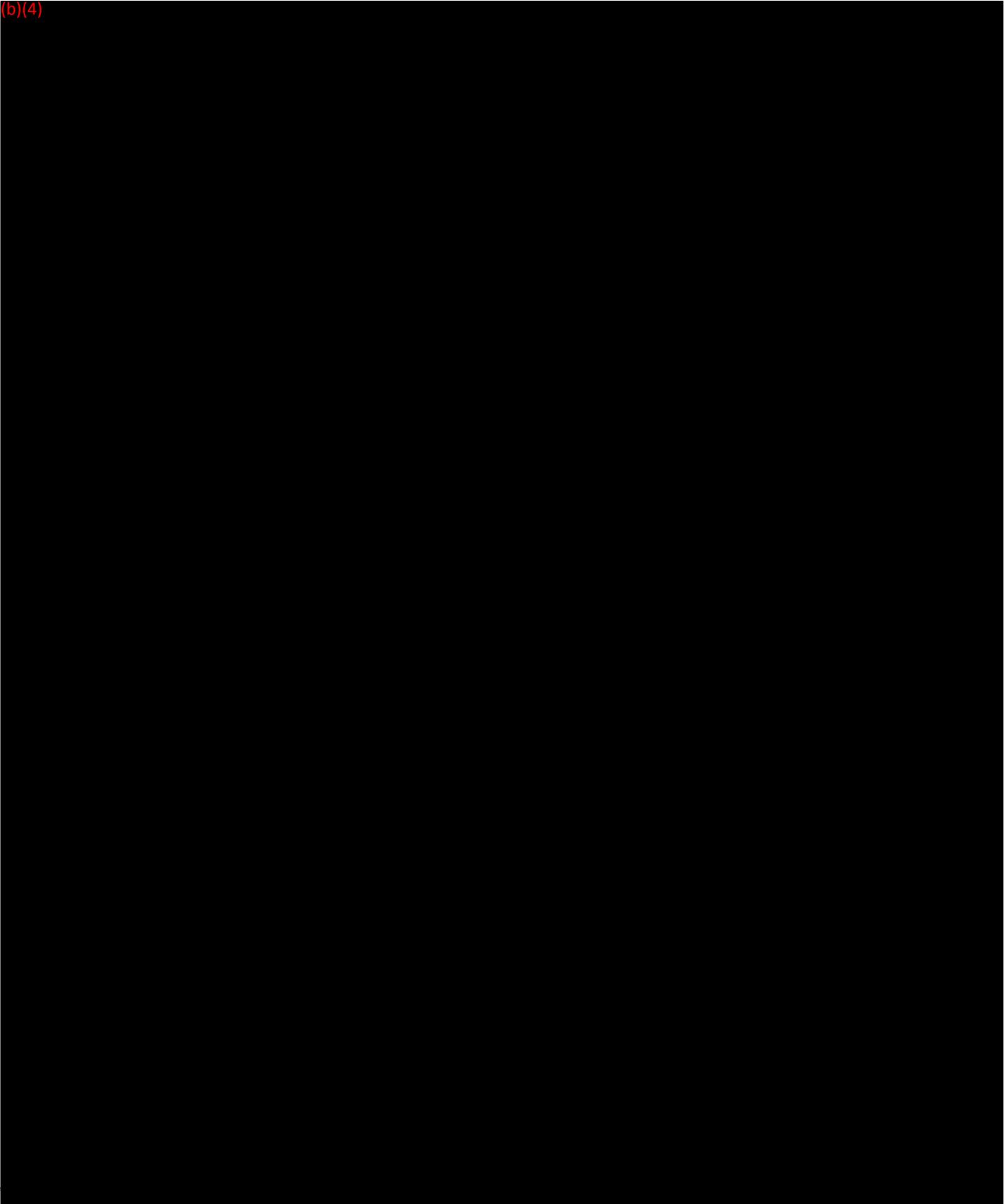
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**BD CLINICAL STUDY: DETERMINATION OF NORMAL DONOR PT AND APTT USING 0.109 M
2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES**

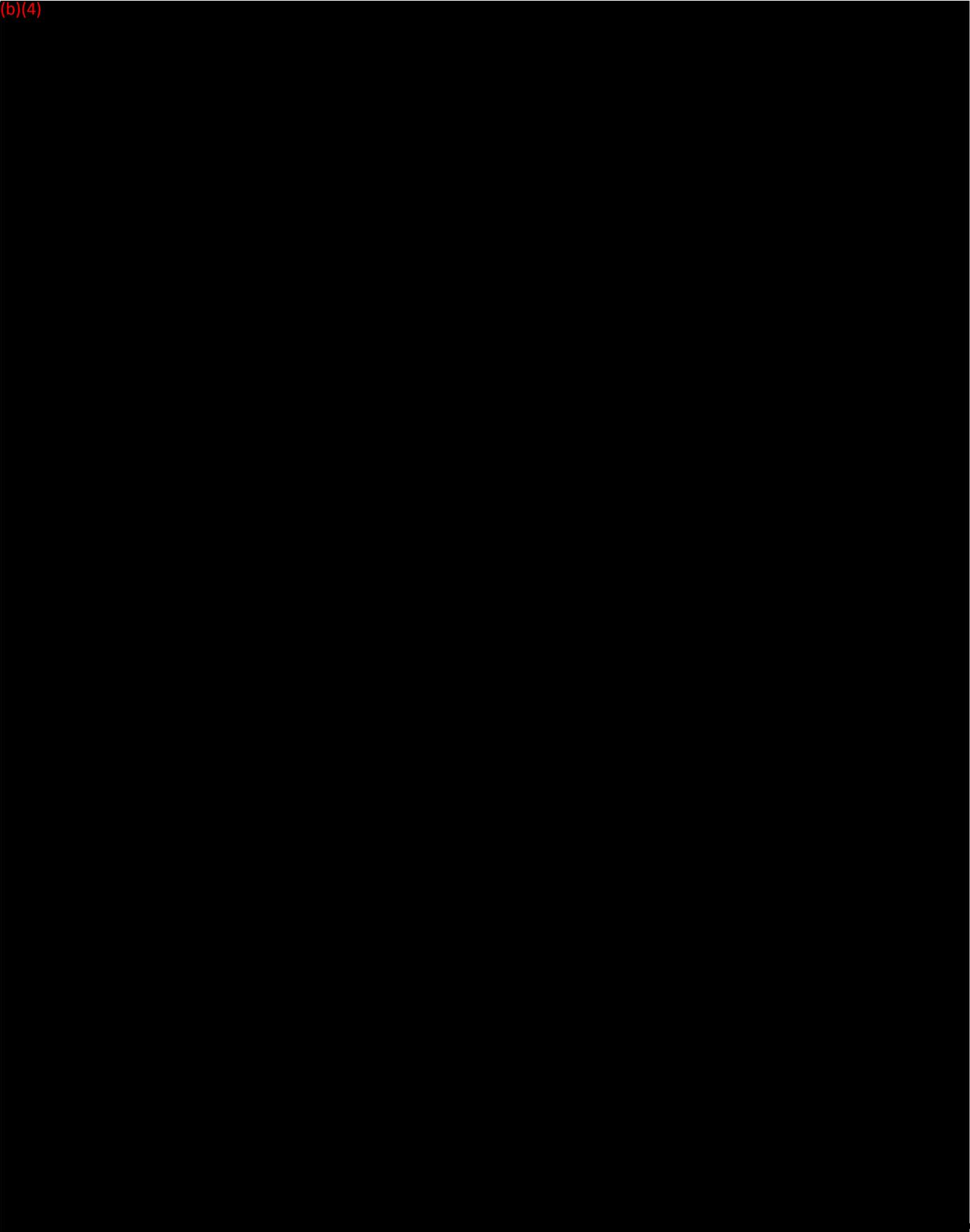
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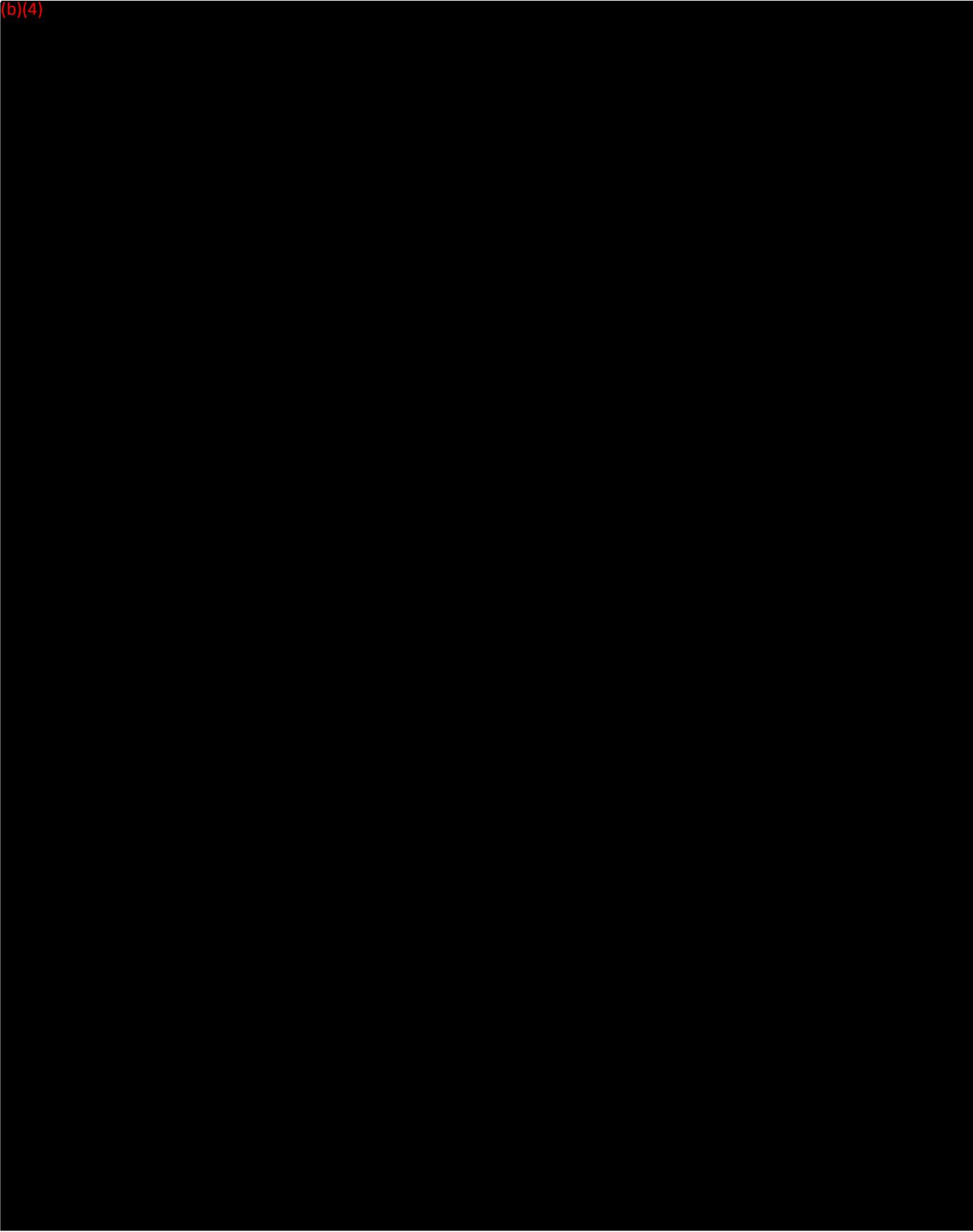
**BD CLINICAL STUDY: DETERMINATION OF NORMAL DONOR PT AND APTT USING 0.109 M
2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES**

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**BD CLINICAL STUDY: DETERMINATION OF NORMAL DONOR PT AND APTT USING 0.109 M
2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES**

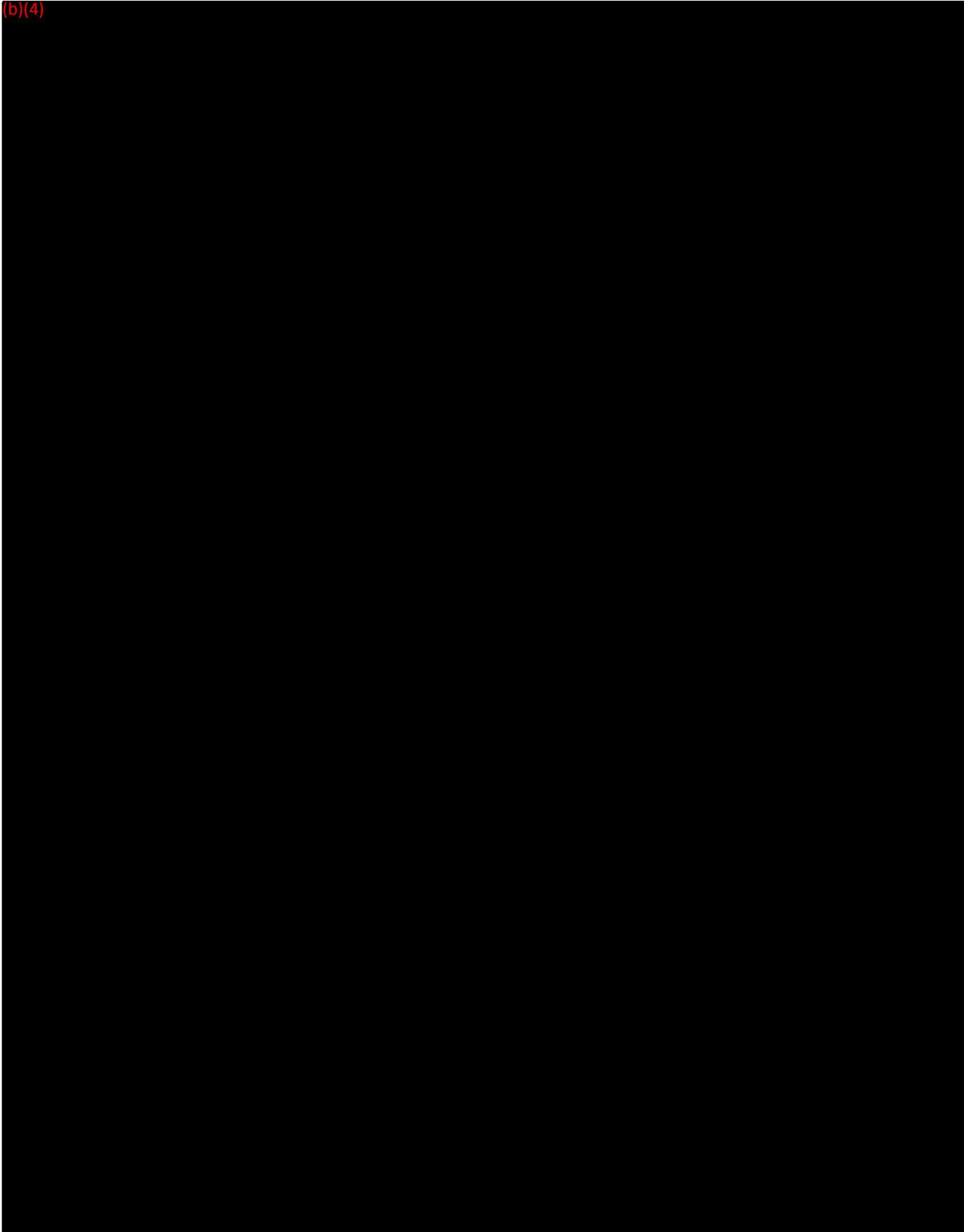
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**BD CLINICAL STUDY: DETERMINATION OF NORMAL DONOR PT AND APTT USING 0.109 M
2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES**

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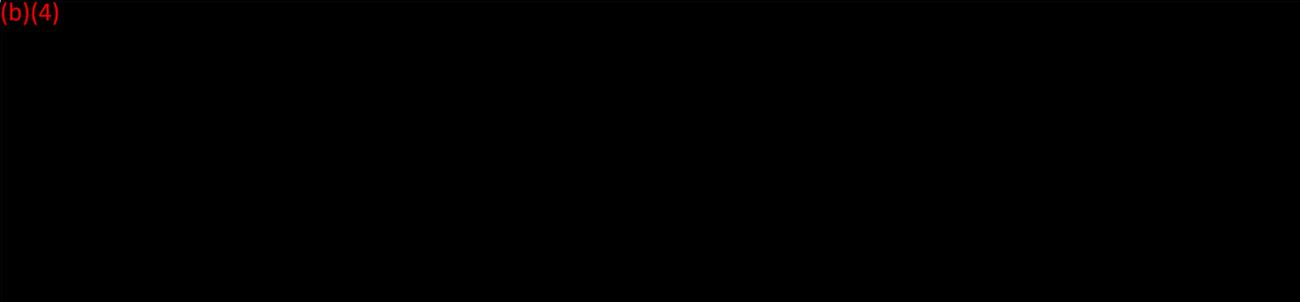


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**BD CLINICAL STUDY: DETERMINATION OF NORMAL DONOR PT AND APTT USING 0.109 M
2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES**

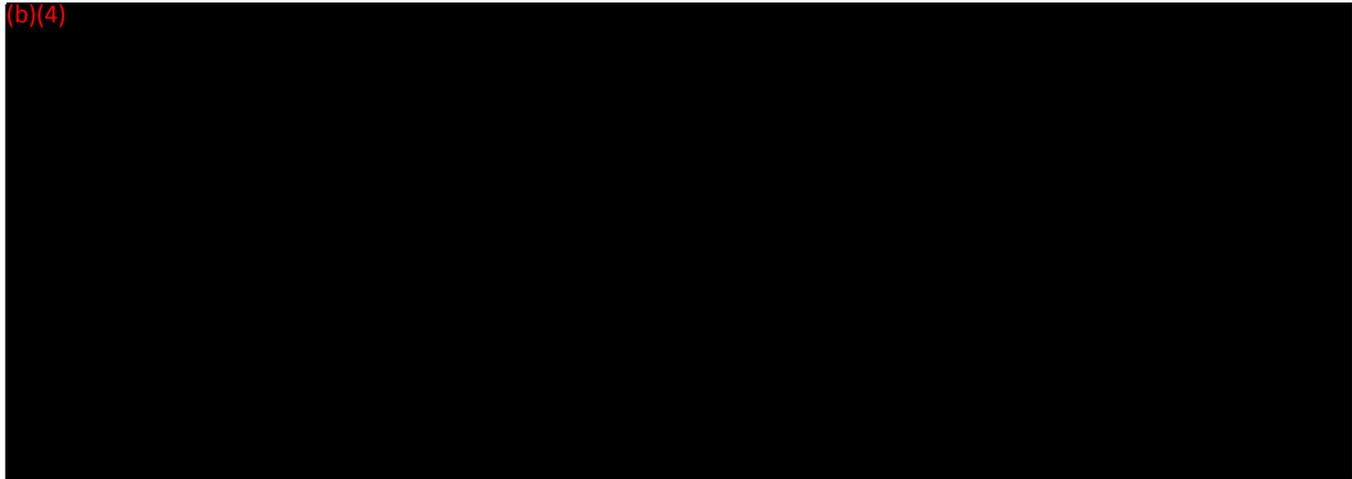
VI. CONCLUSIONS

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VII. REFERENCES

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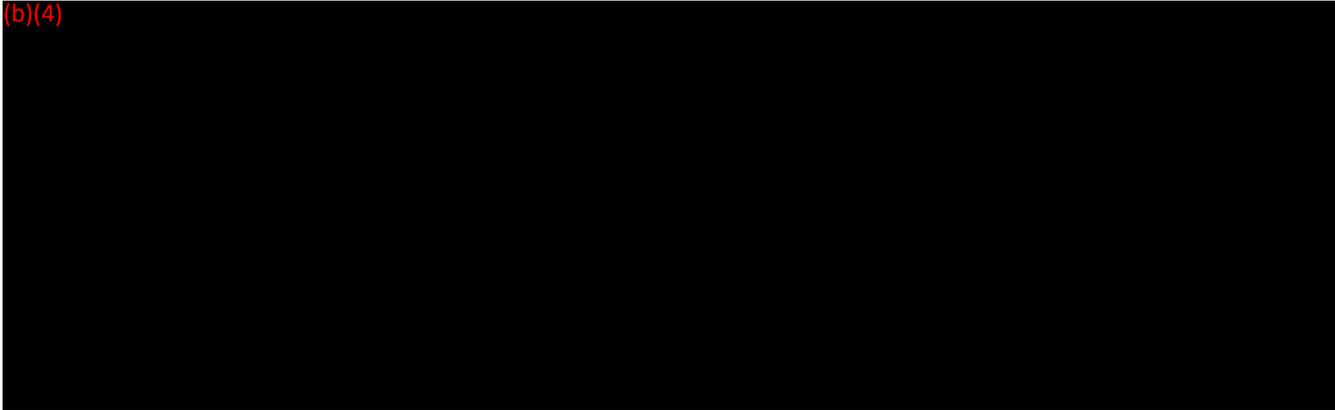
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**ATTACHMENT 2: CLINICAL EVALUATION- AT BD
VACUTAINER SYSTEMS (BDVS)**

**BD CLINICAL STUDY: DETERMINATION OF NORMAL DONOR PT AND APTT USING 0.129 M
2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES**

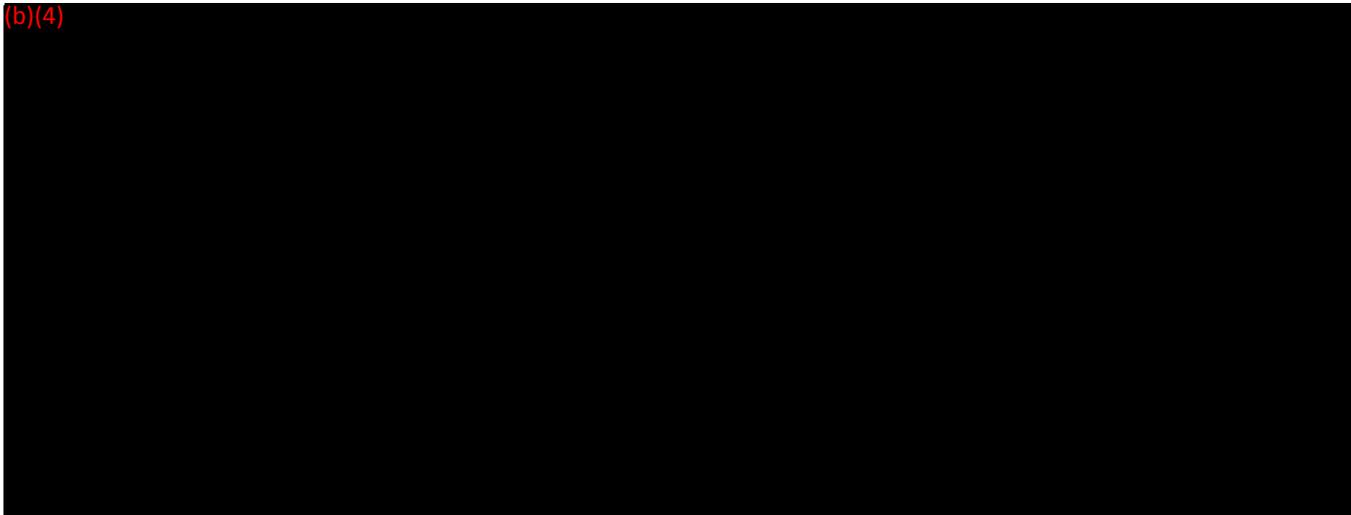
ABSTRACT

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I. INTRODUCTION

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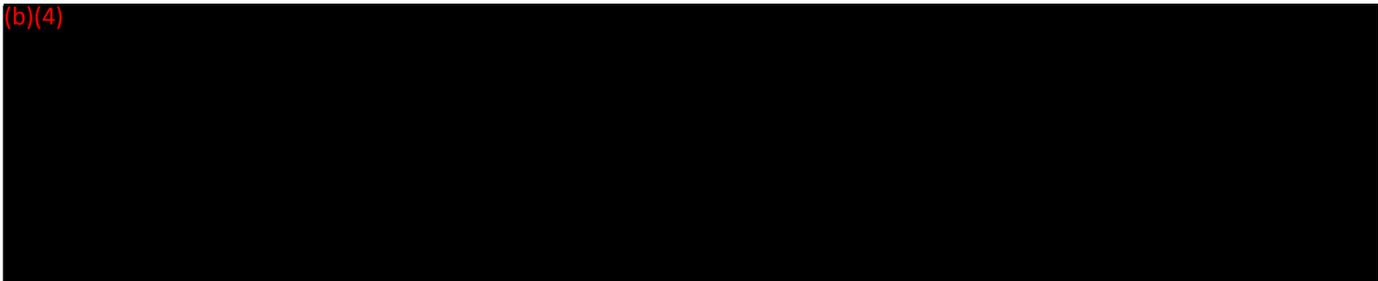
II. OBJECTIVE

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III. METHODS AND MATERIALS

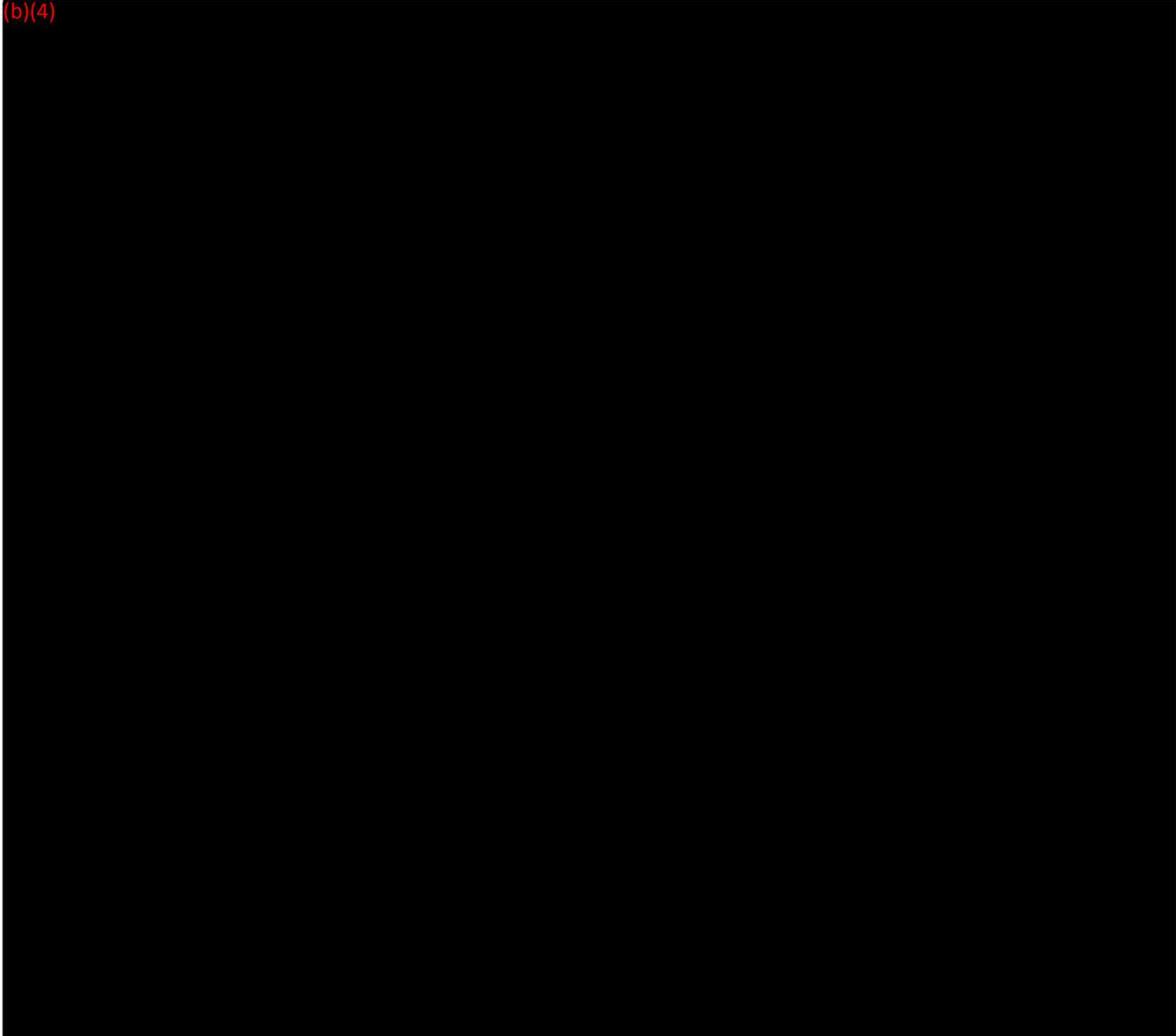
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80

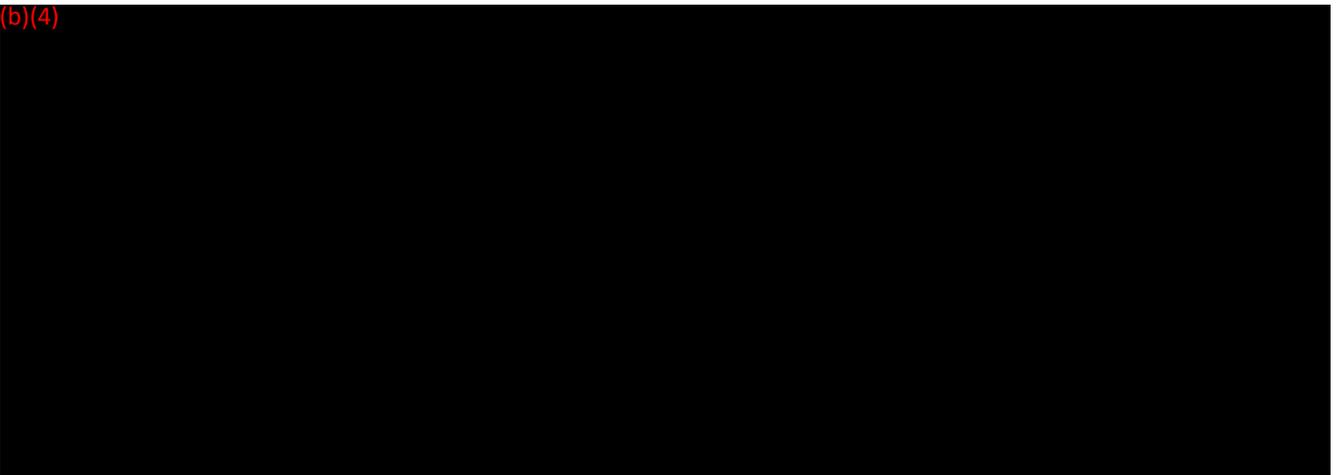
**BD CLINICAL STUDY: DETERMINATION OF NORMAL DONOR PT AND APTT USING 0.129 M
2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES**

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IV. DATA ANALYSIS

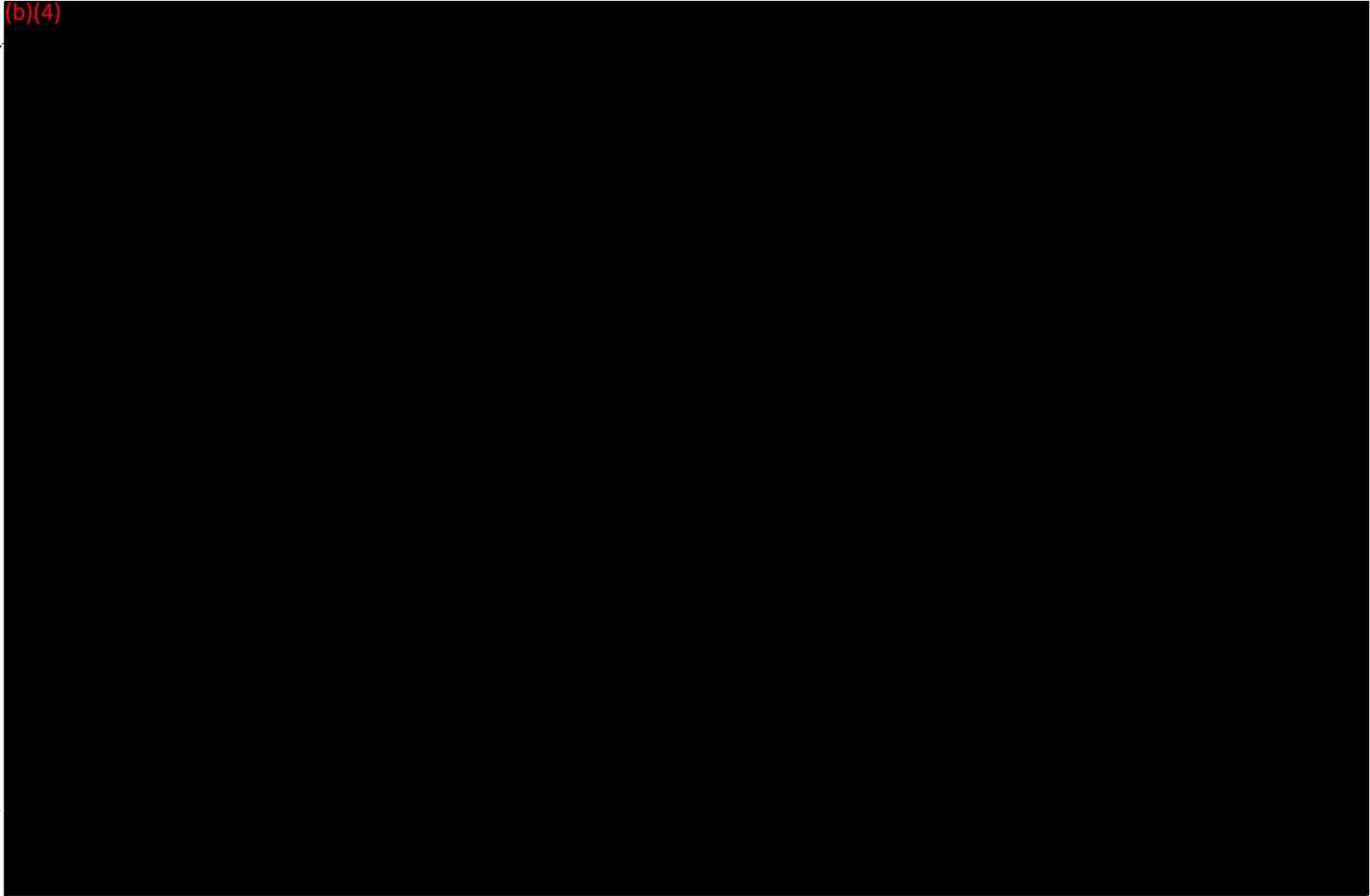
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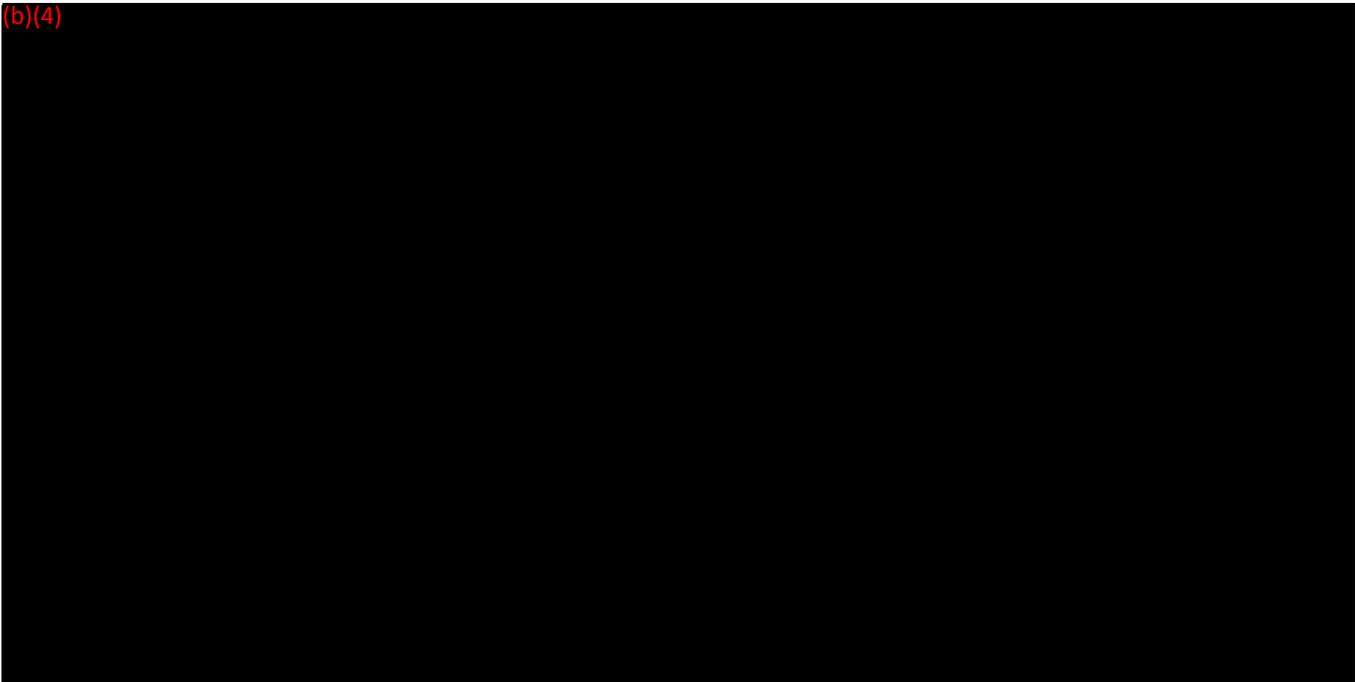
**BD CLINICAL STUDY: DETERMINATION OF NORMAL DONOR PT AND APTT USING 0.129 M
2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES**

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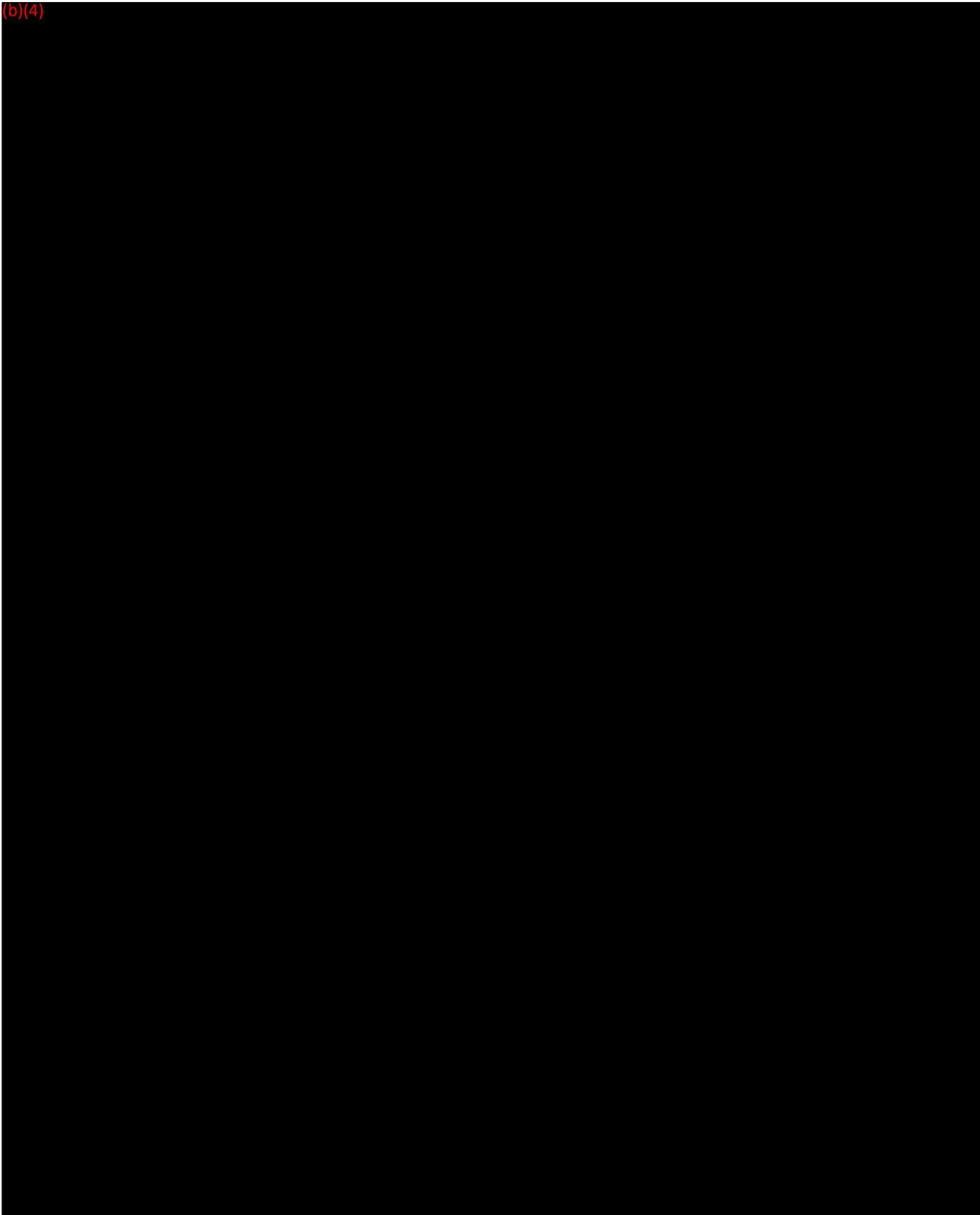
V. RESULTS AND DISCUSSION

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**BD CLINICAL STUDY: DETERMINATION OF NORMAL DONOR PT AND APTT USING 0.129 M
2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES**

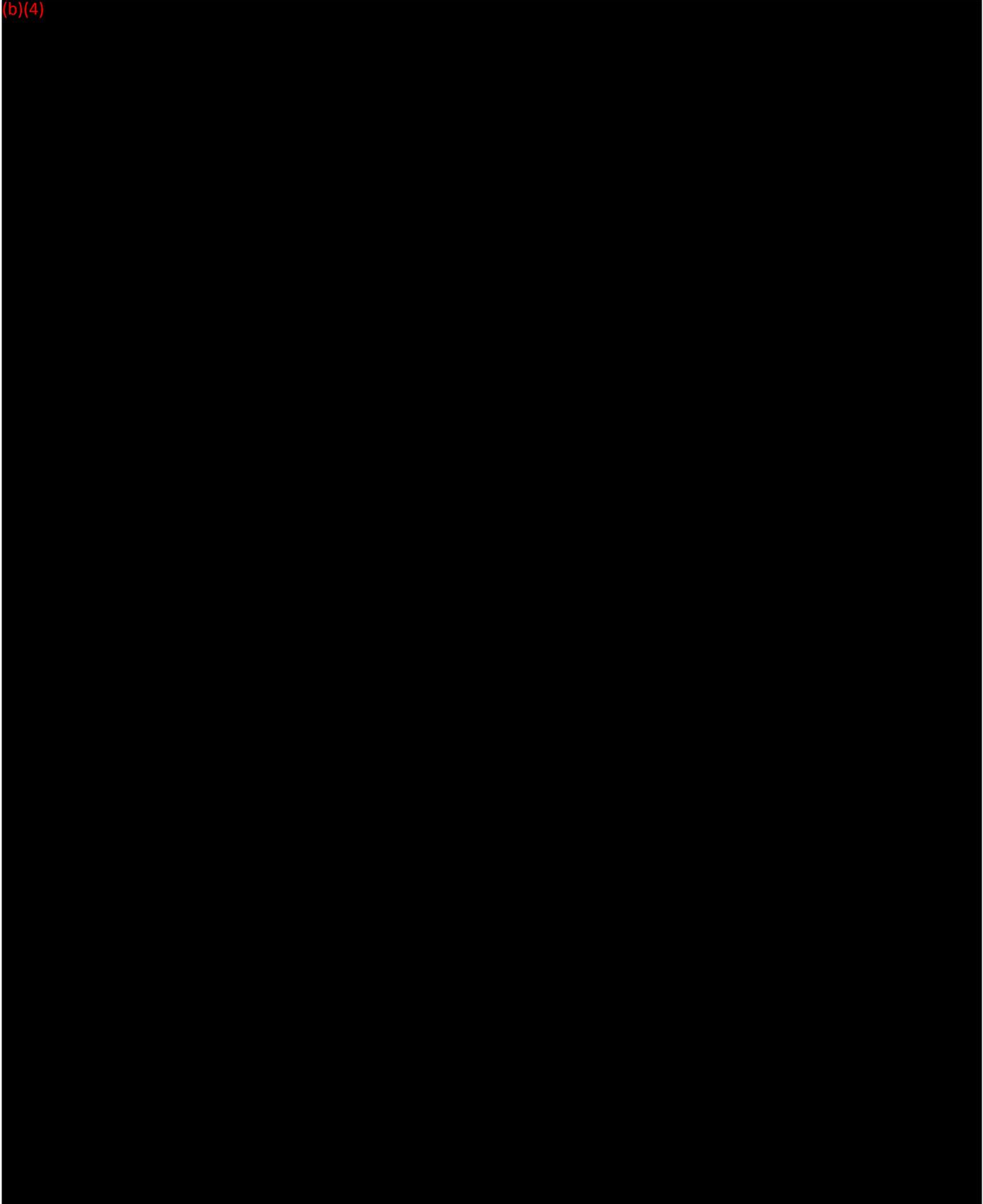
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**BD CLINICAL STUDY: DETERMINATION OF NORMAL DONOR PT AND APTT USING 0.129 M
2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES**

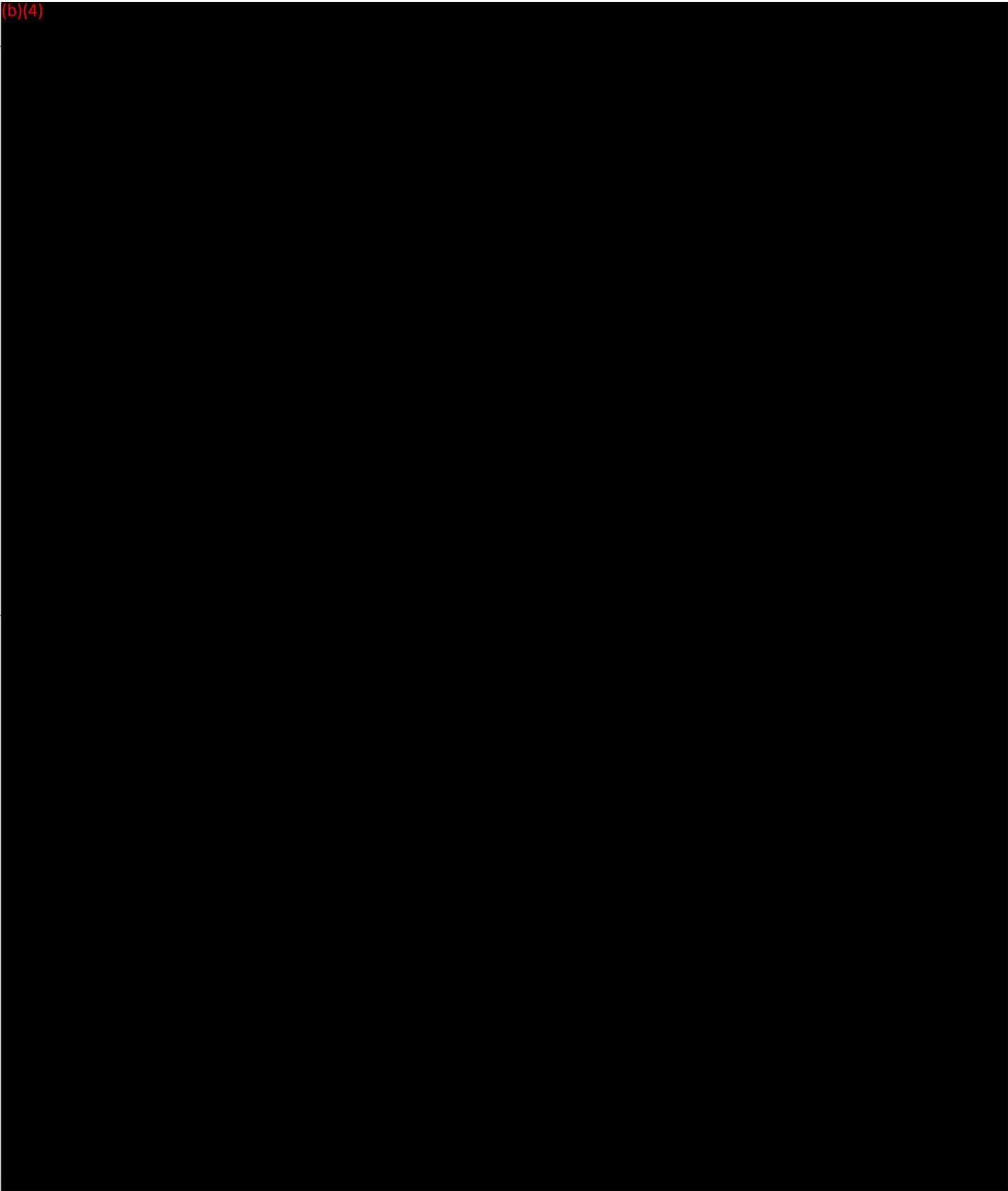
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**BD CLINICAL STUDY: DETERMINATION OF NORMAL DONOR PT AND APTT USING 0.129 M
2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES**

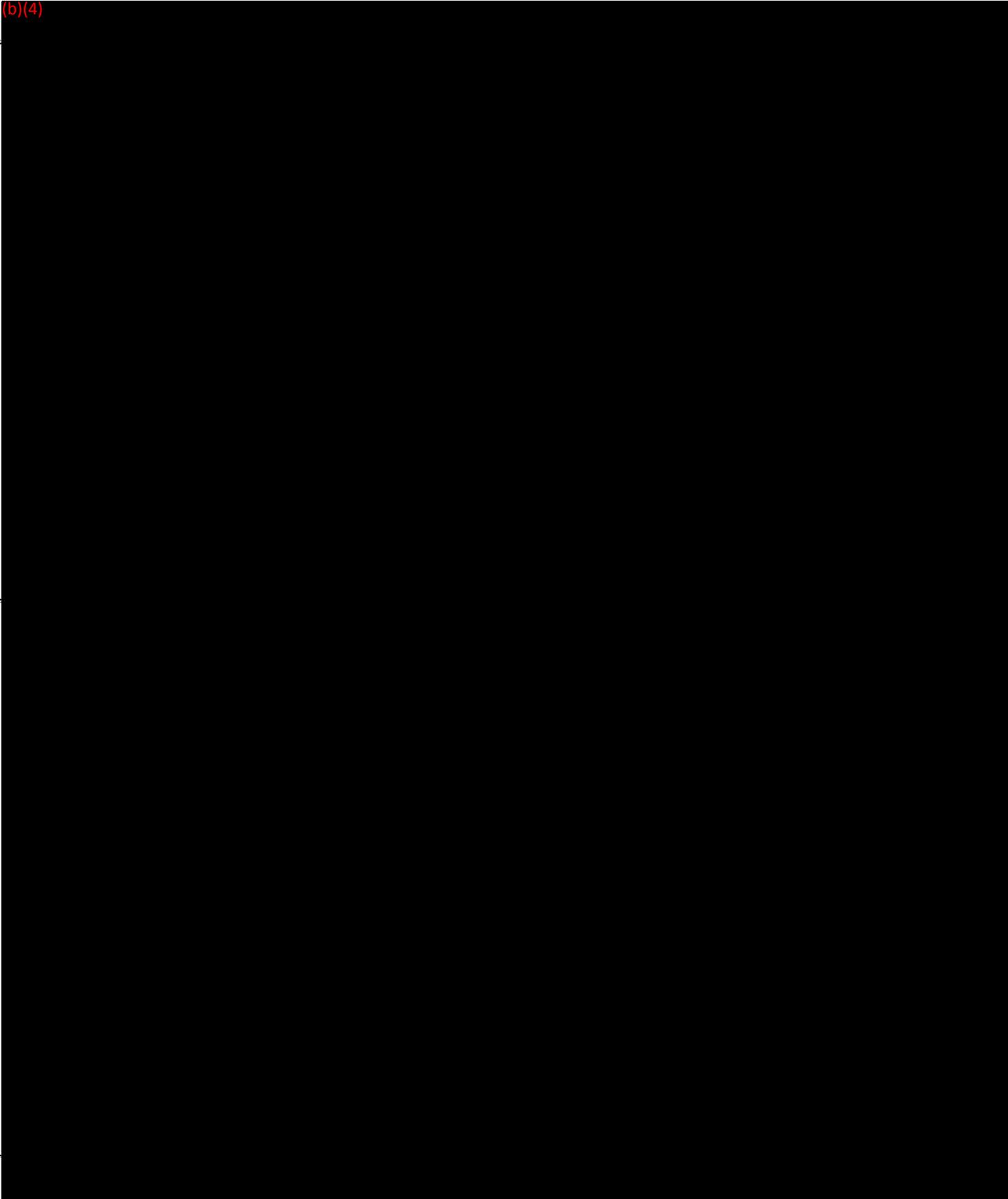
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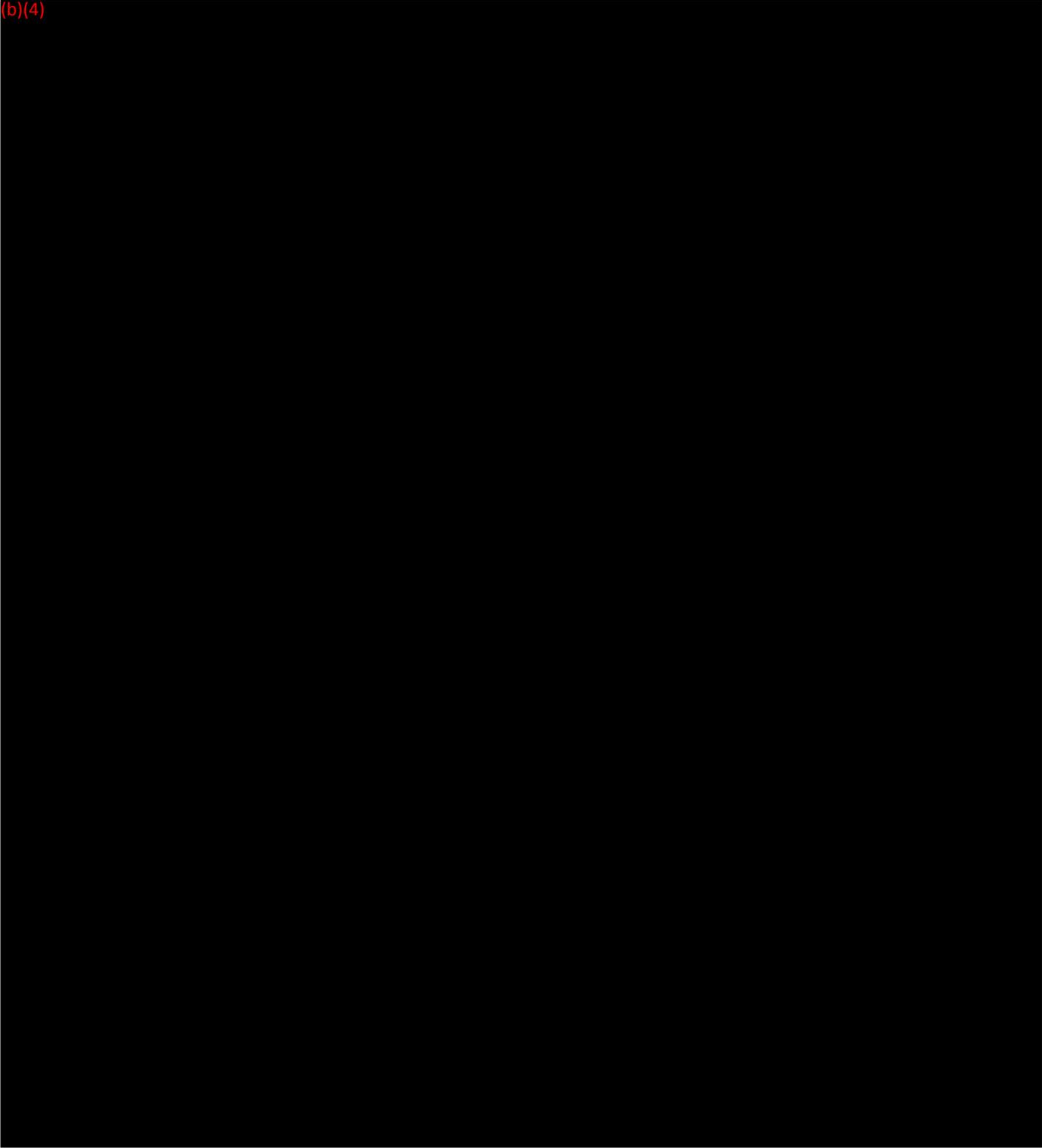
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2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES**

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**BD CLINICAL STUDY: DETERMINATION OF NORMAL DONOR PT AND APTT USING 0.129 M
2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES**

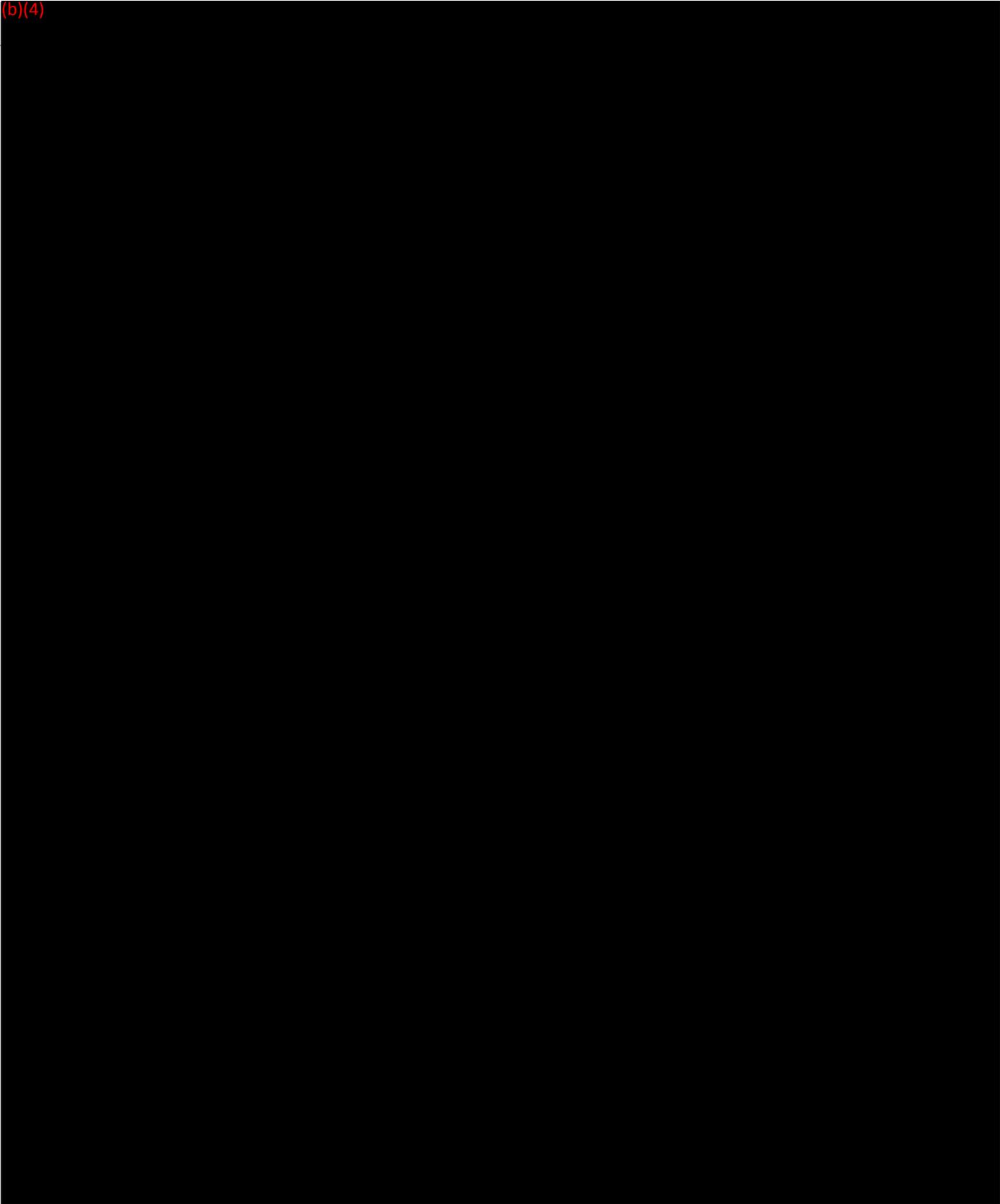
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2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES**

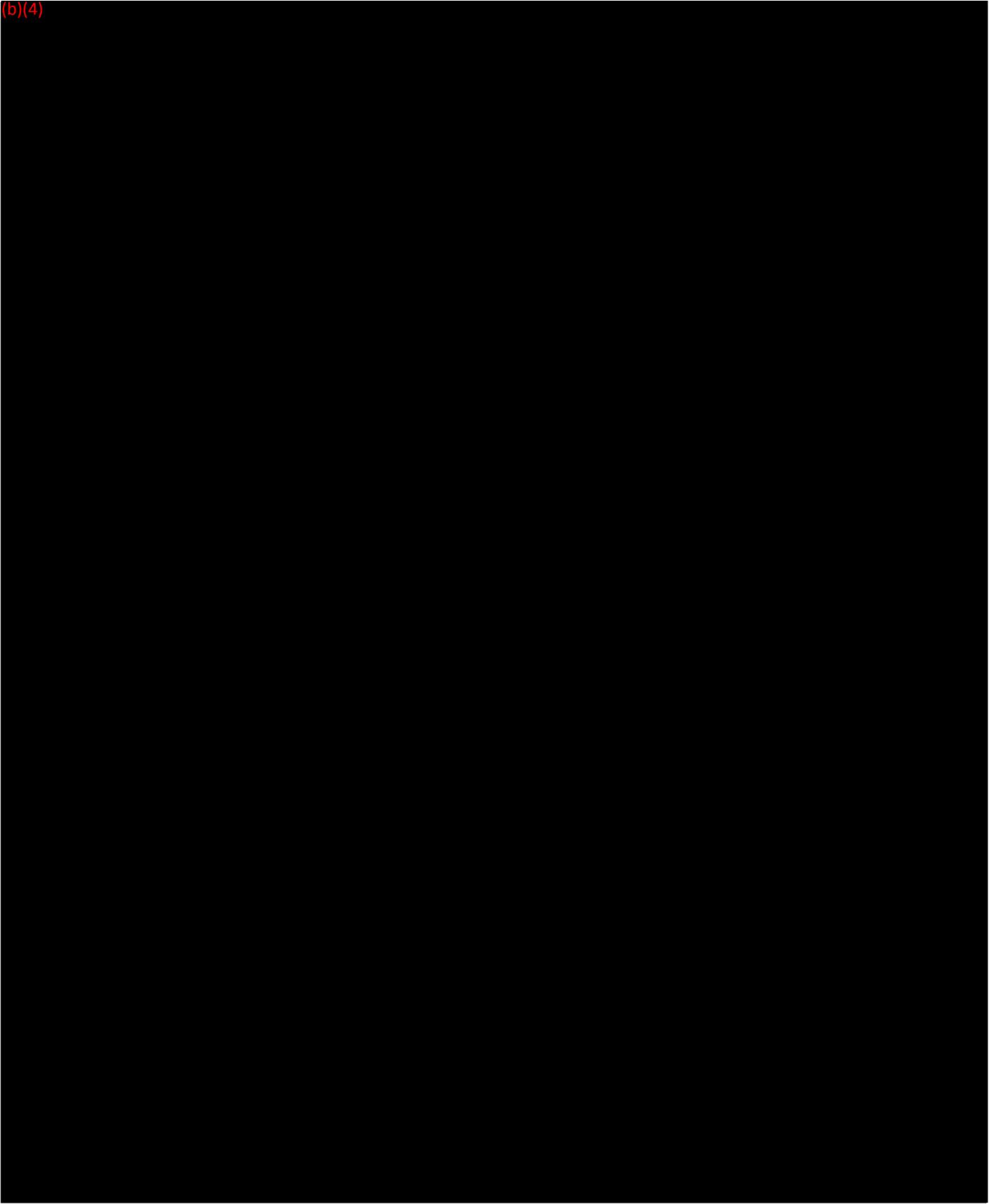
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2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES**

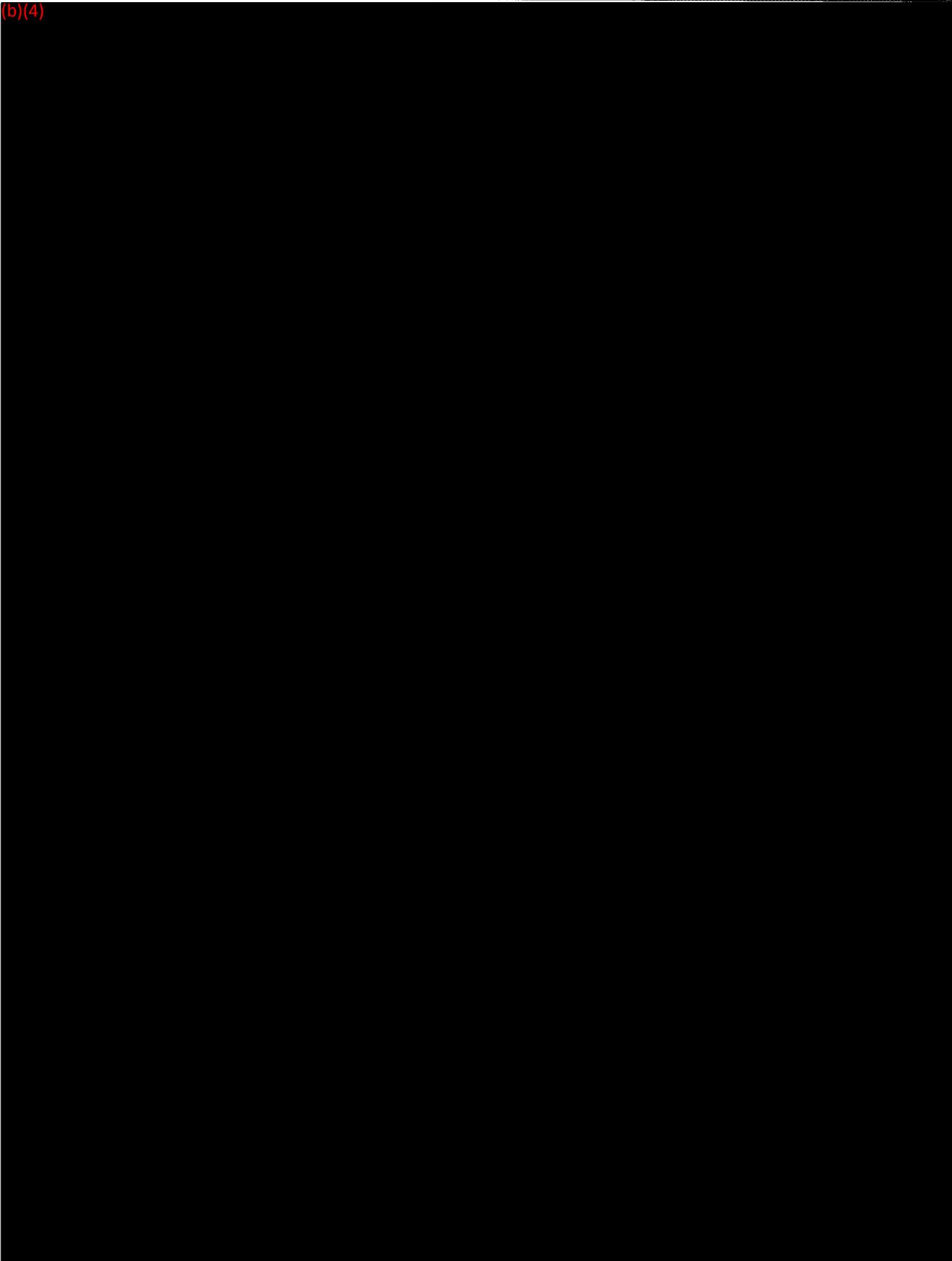
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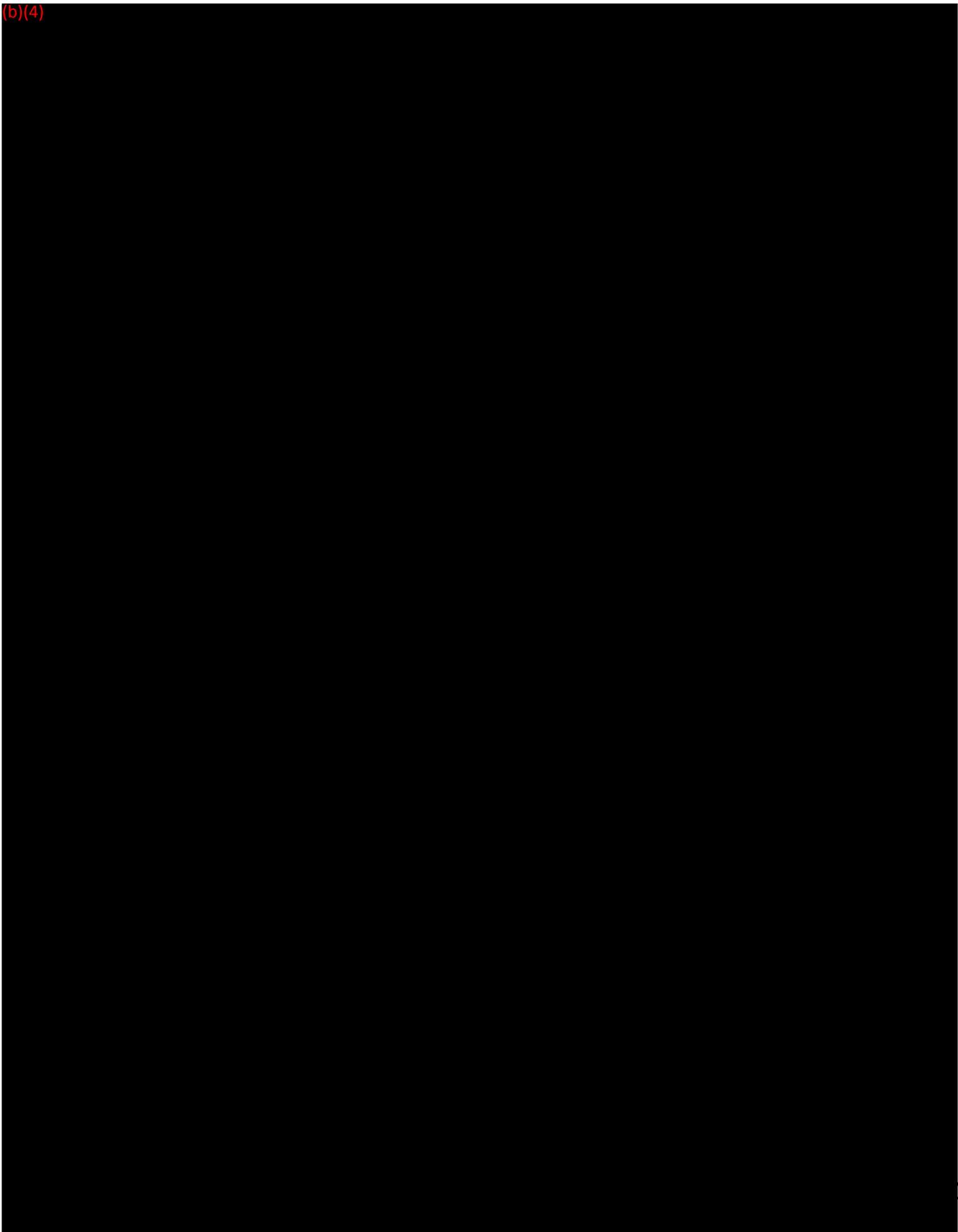
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2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES**

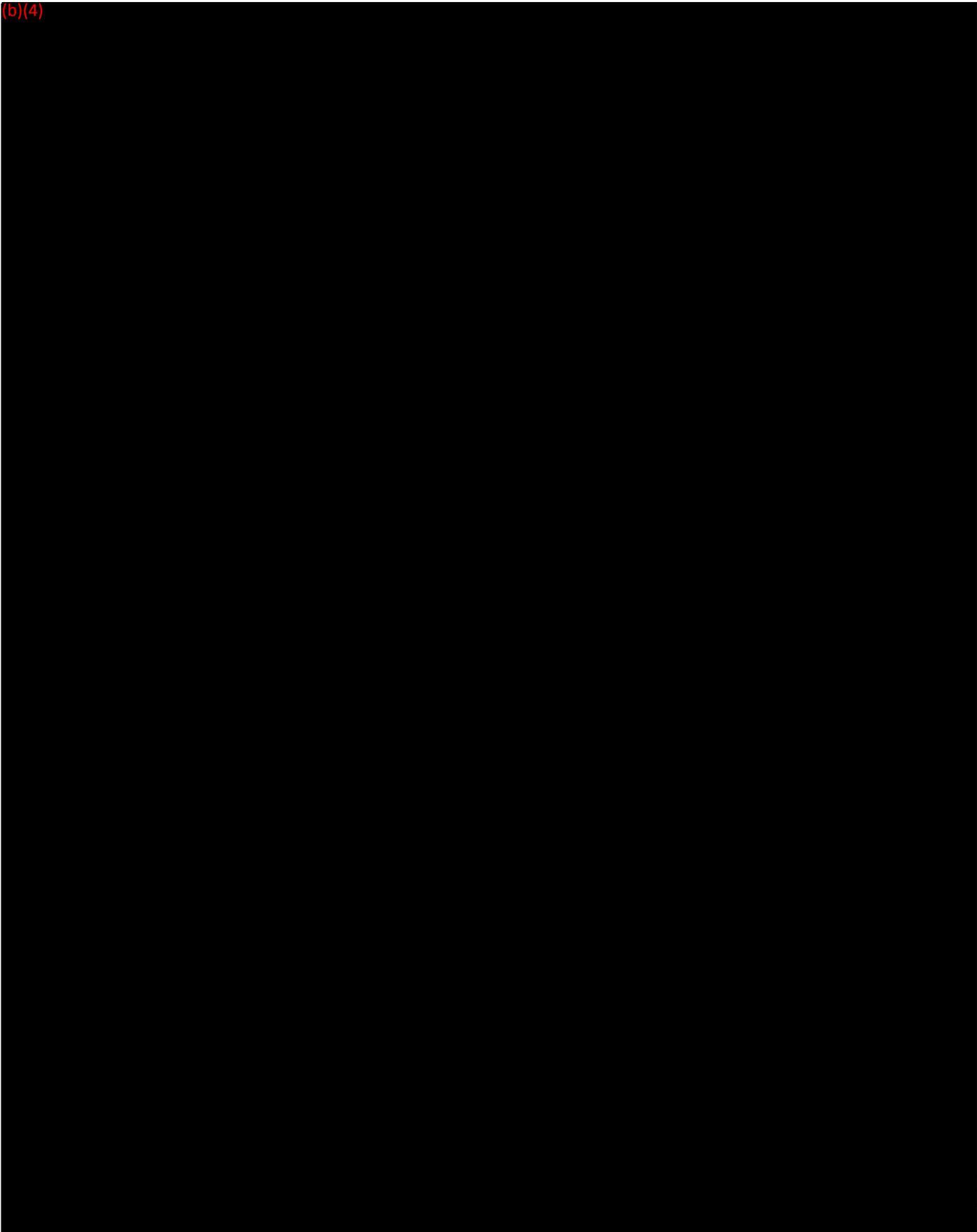
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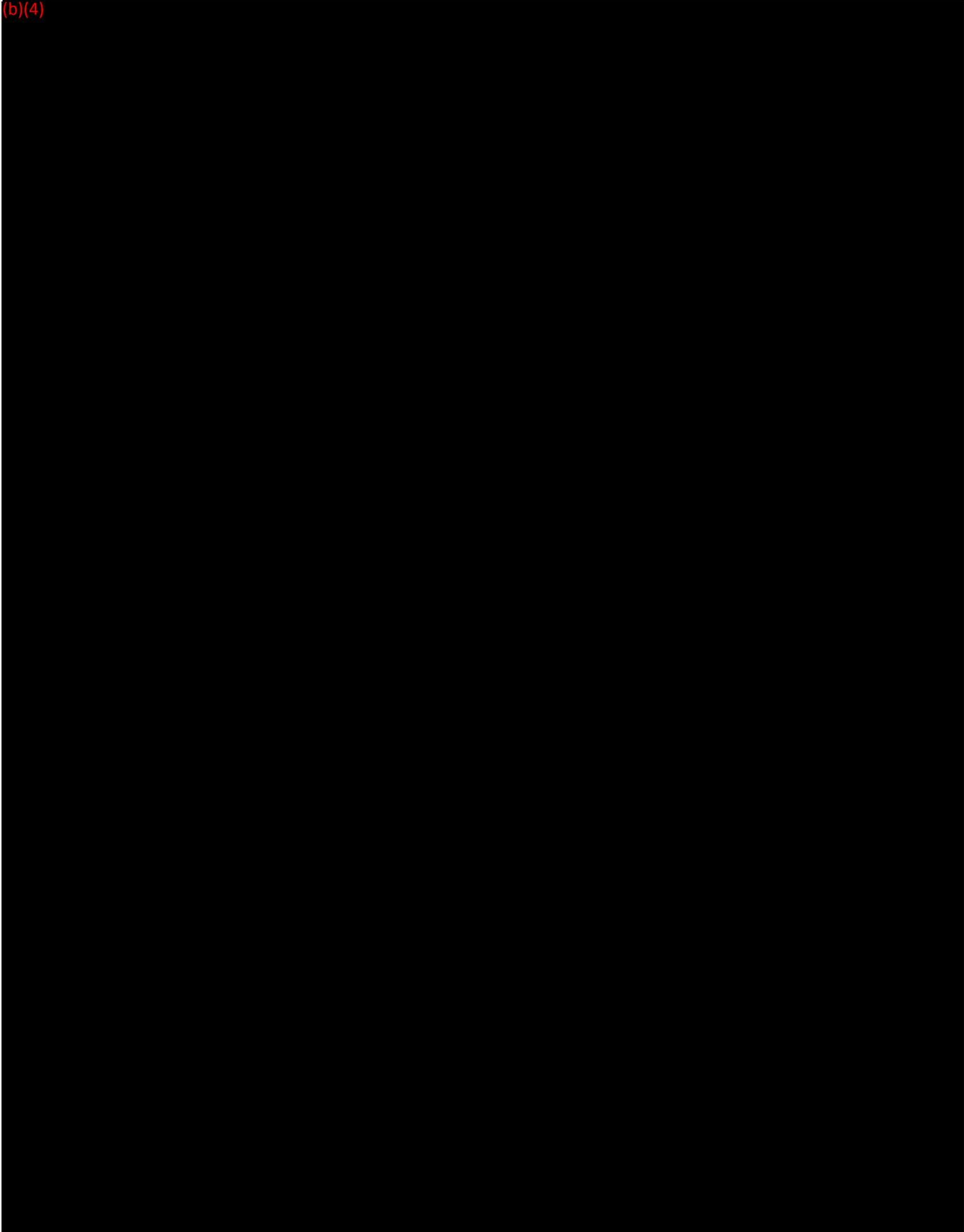
**BD CLINICAL STUDY: DETERMINATION OF NORMAL DONOR PT AND APTT USING 0.129 M
2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES**

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**BD CLINICAL STUDY: DETERMINATION OF NORMAL DONOR PT AND APTT USING 0.129 M
2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES**

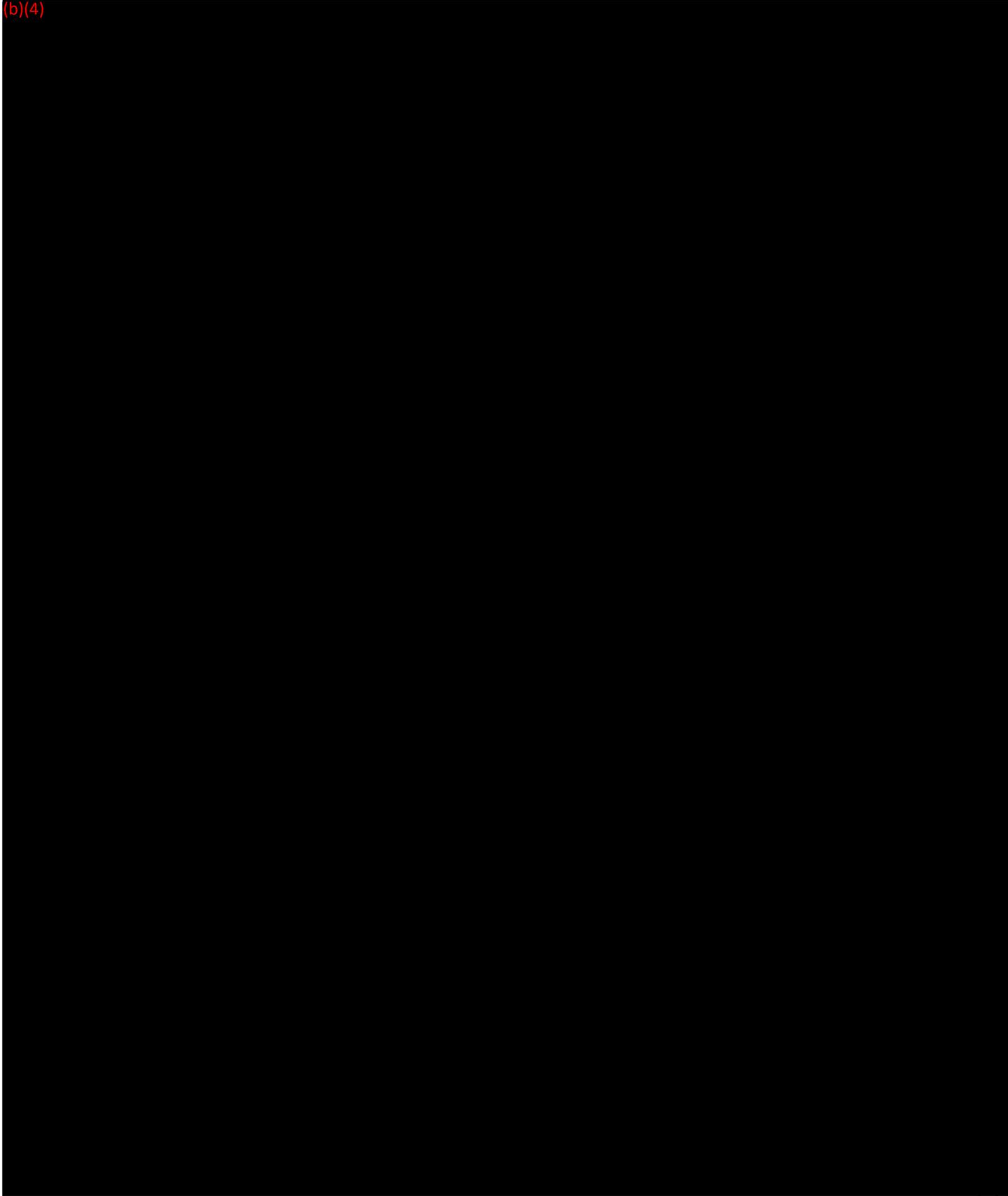
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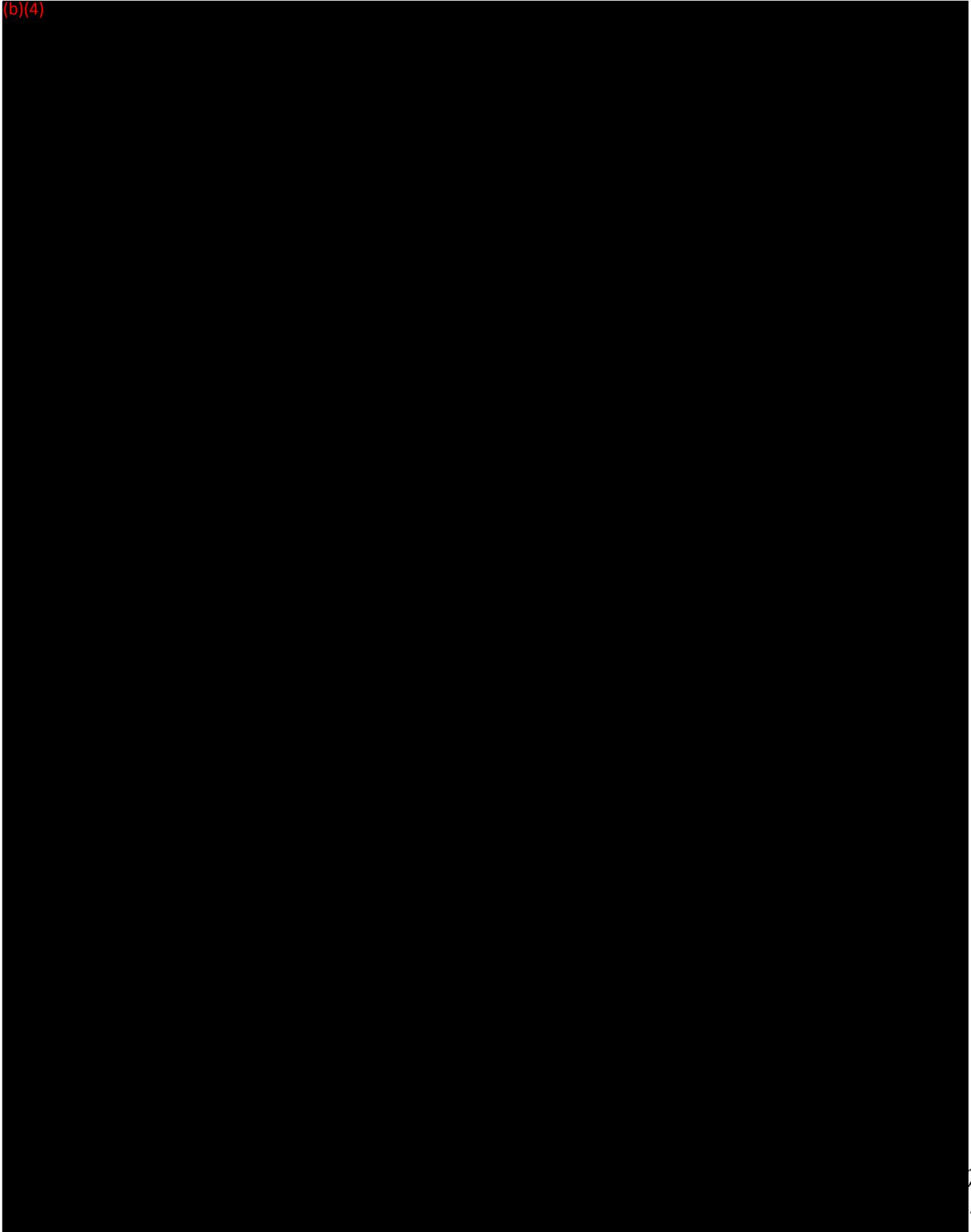
**BD CLINICAL STUDY: DETERMINATION OF NORMAL DONOR PT AND APTT USING 0.129 M
2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES**

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**BD CLINICAL STUDY: DETERMINATION OF NORMAL DONOR PT AND APTT USING 0.129 M
2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES**

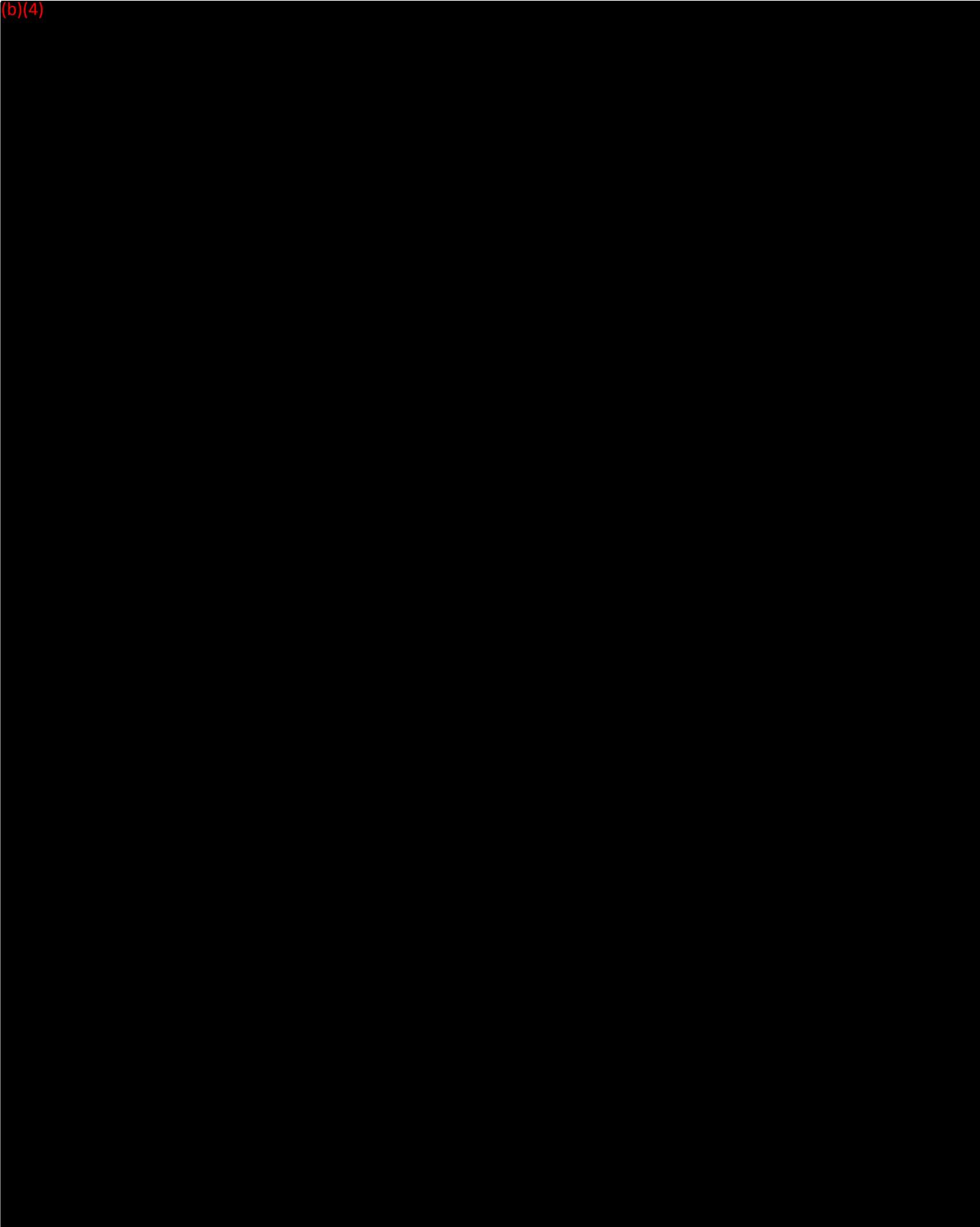
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**BD CLINICAL STUDY: DETERMINATION OF NORMAL DONOR PT AND APTT USING 0.129 M
2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES**

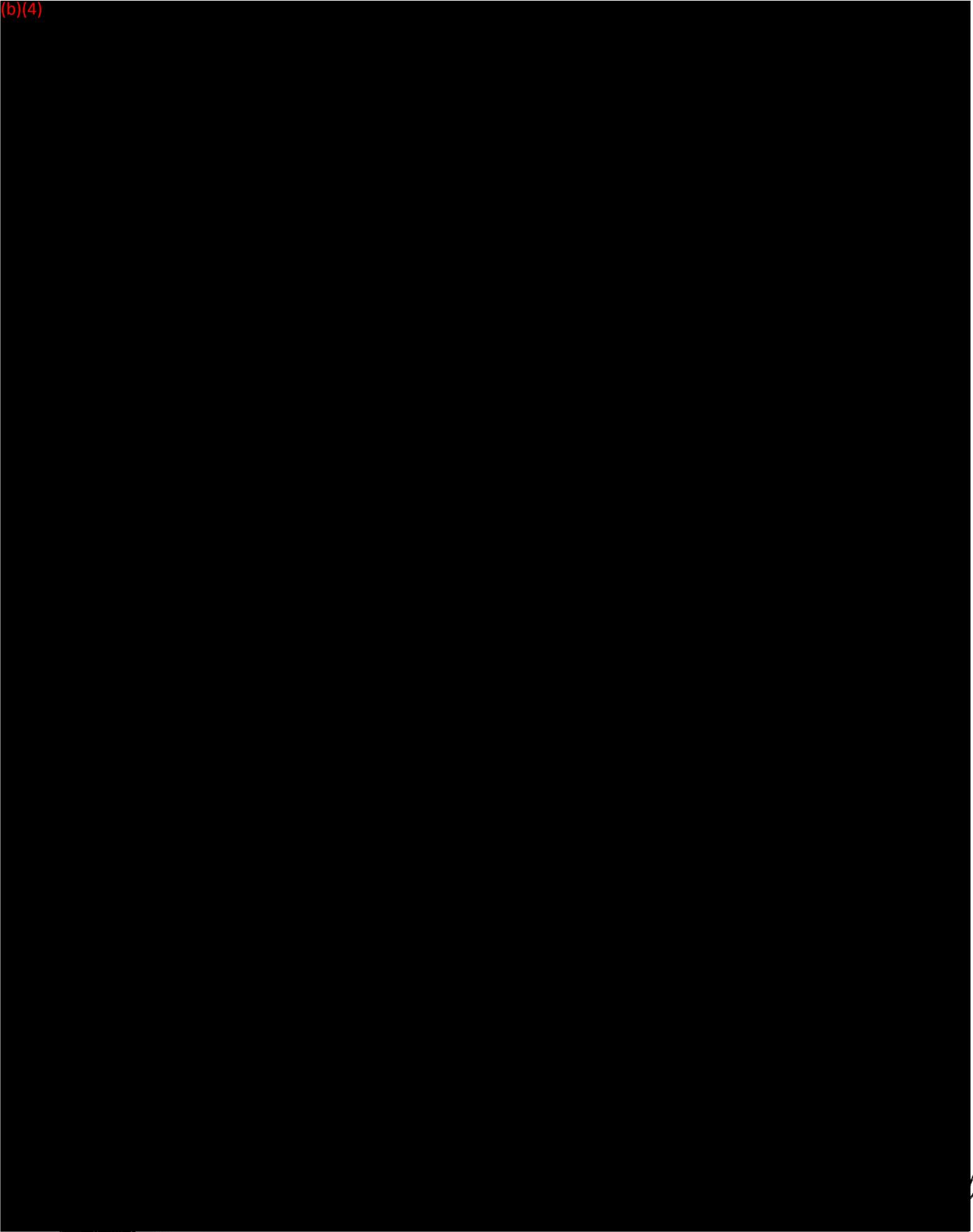
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**BD CLINICAL STUDY: DETERMINATION OF NORMAL DONOR PT AND APTT USING 0.129 M
2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES**

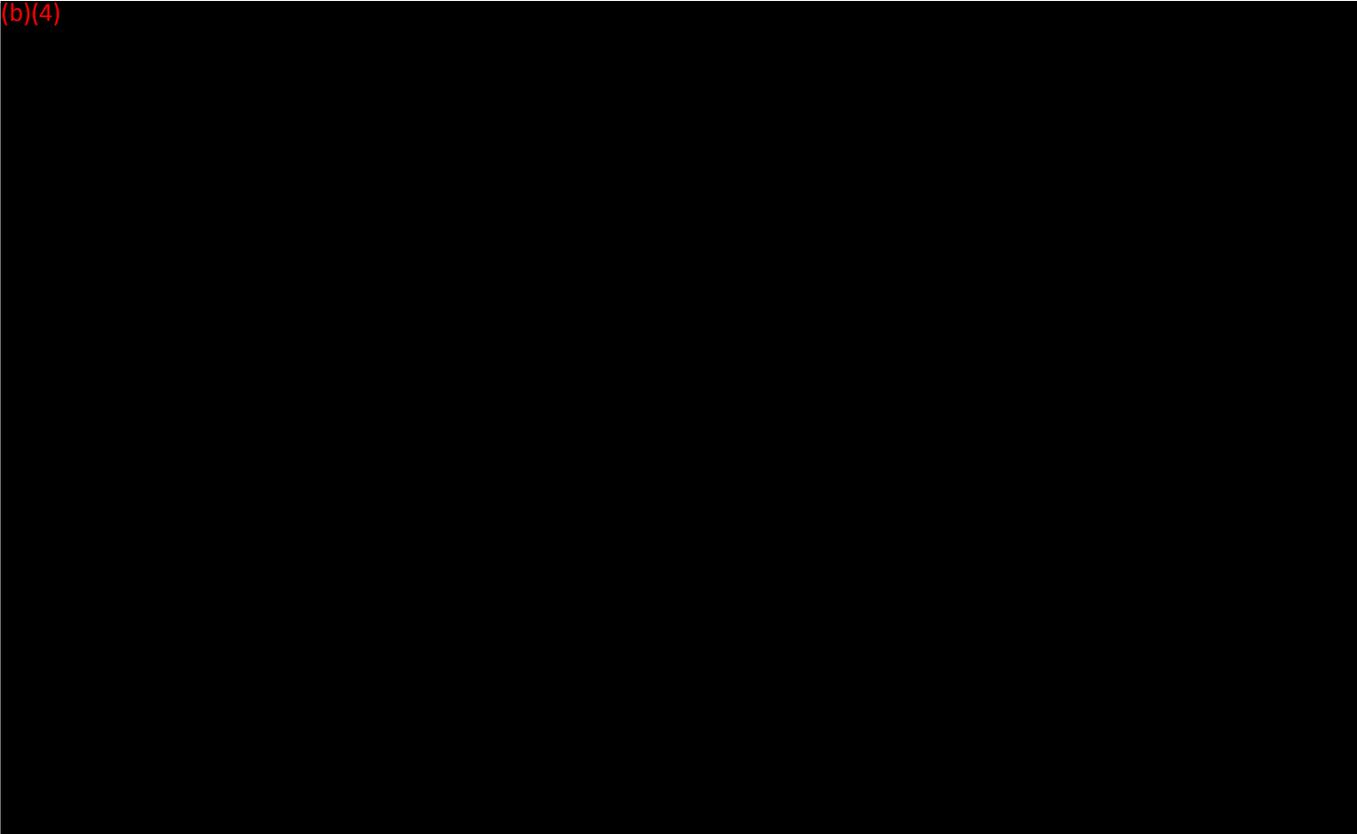
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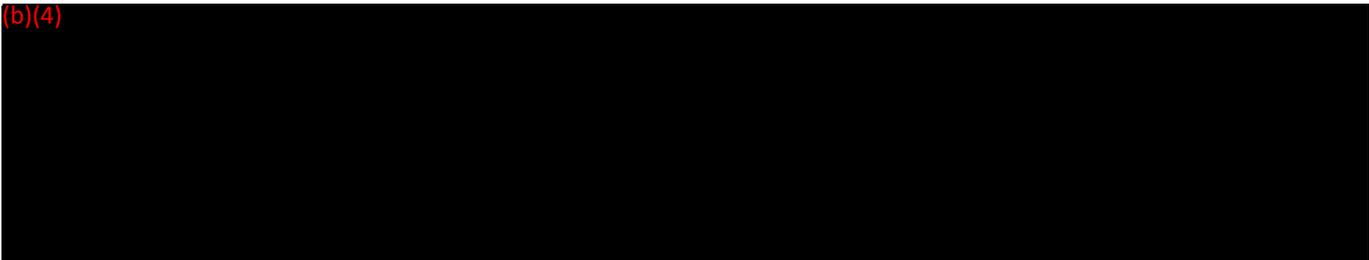
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2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES**

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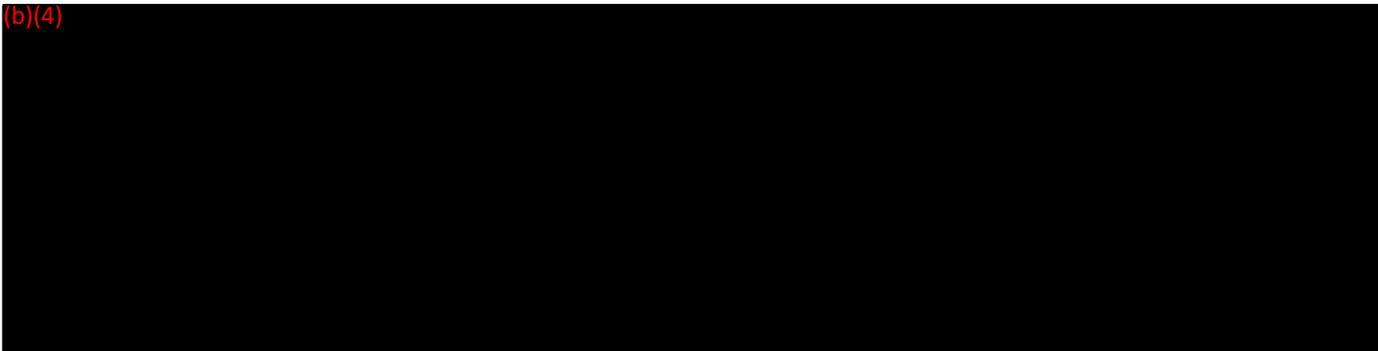
VI. CONCLUSIONS

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VII. REFERENCES

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ATTACHMENT 3: CLINICAL EVALUATION- AT (b)(4)

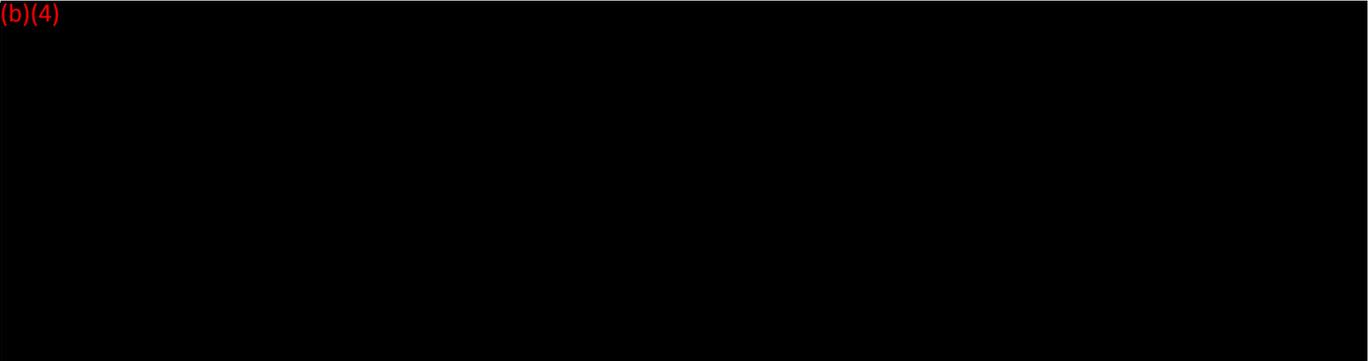
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BD CLINICAL STUDY: EVALUATION OF 0.129 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES USING THE ELECTRA 1400C™ ANALYZER

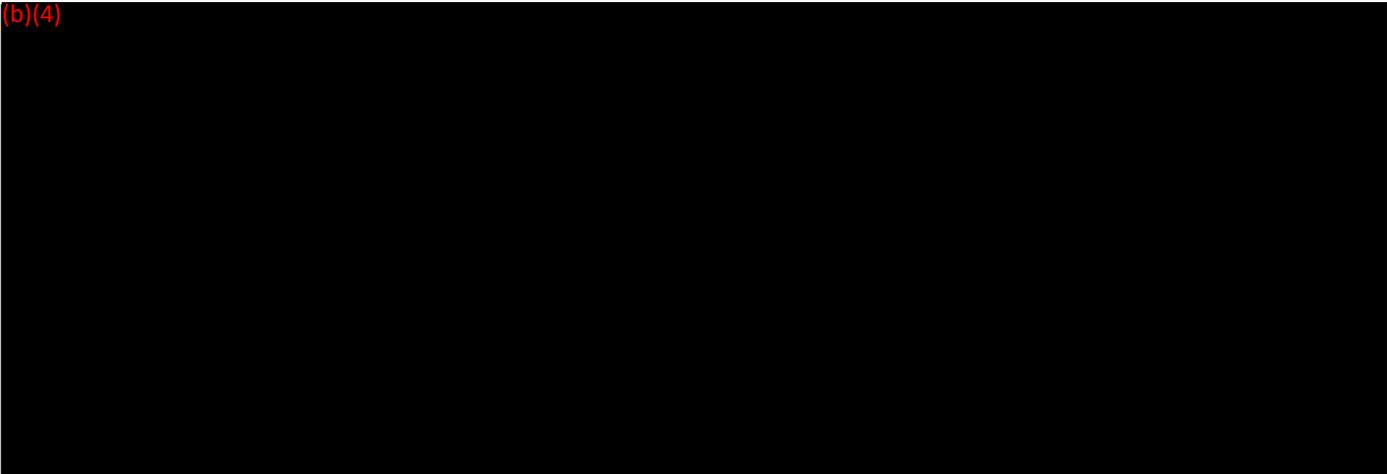
ABSTRACT

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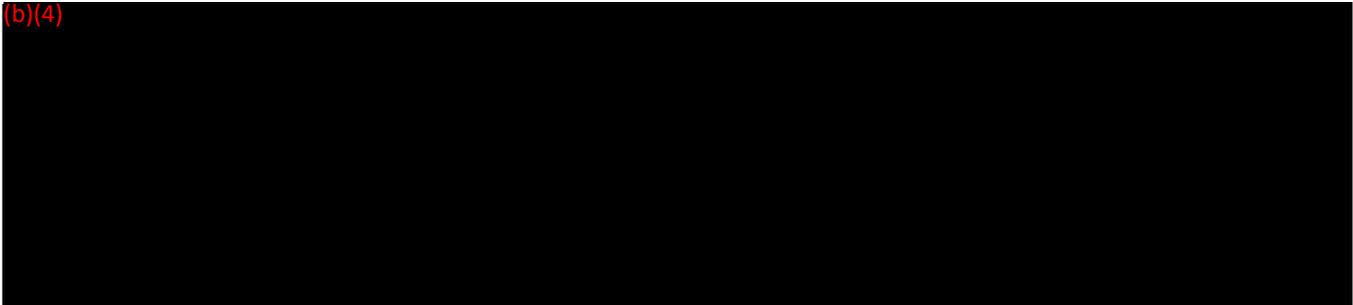
I. INTRODUCTION

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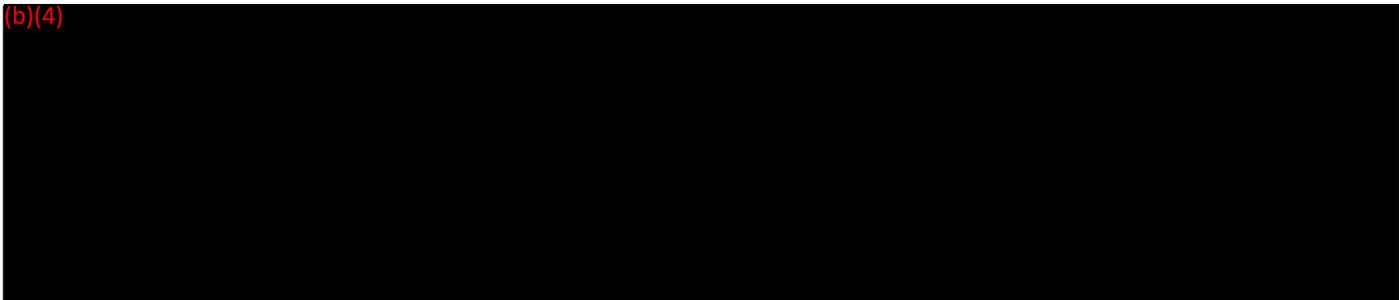
II. OBJECTIVE

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III. METHODS AND MATERIALS

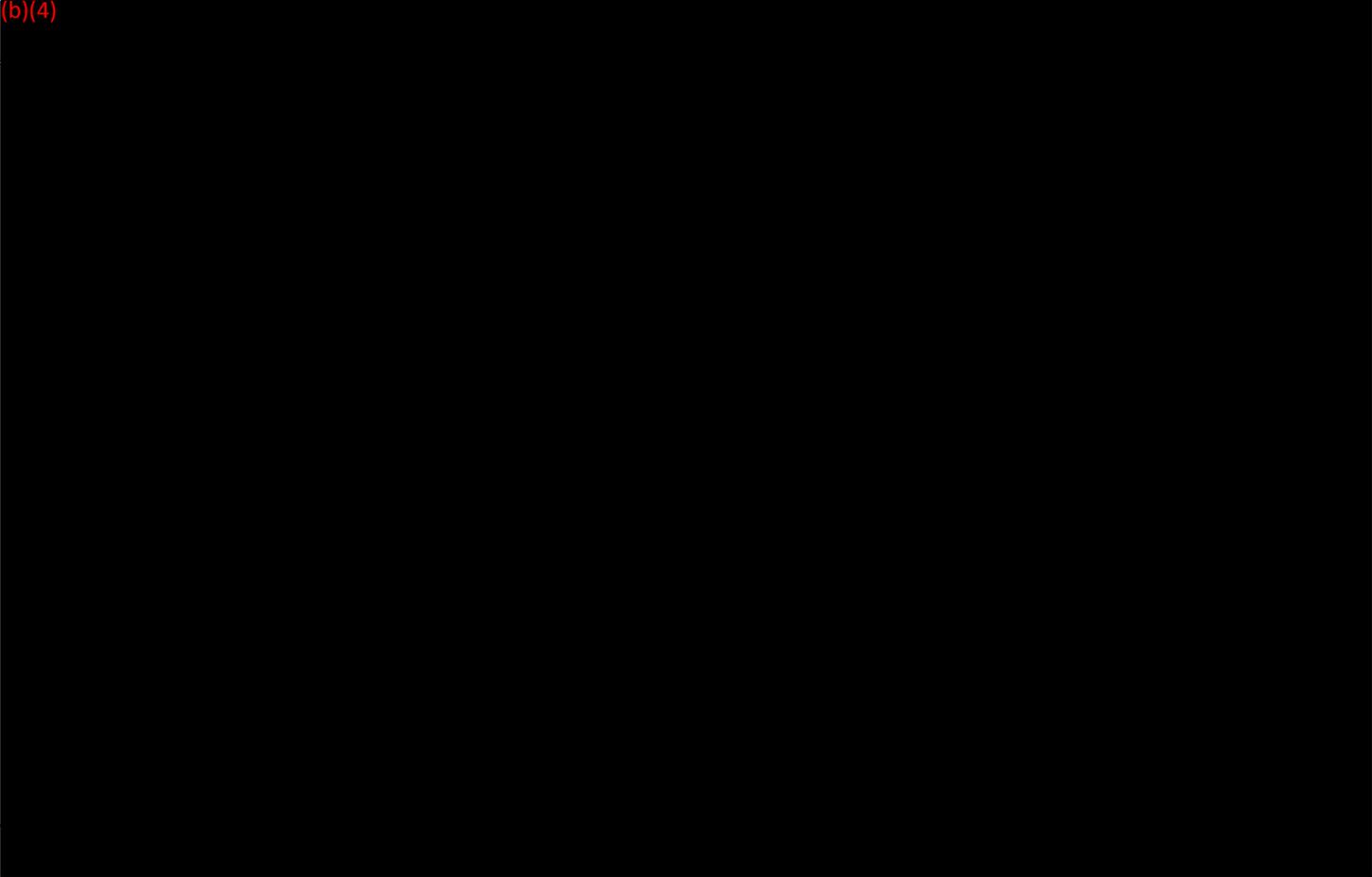
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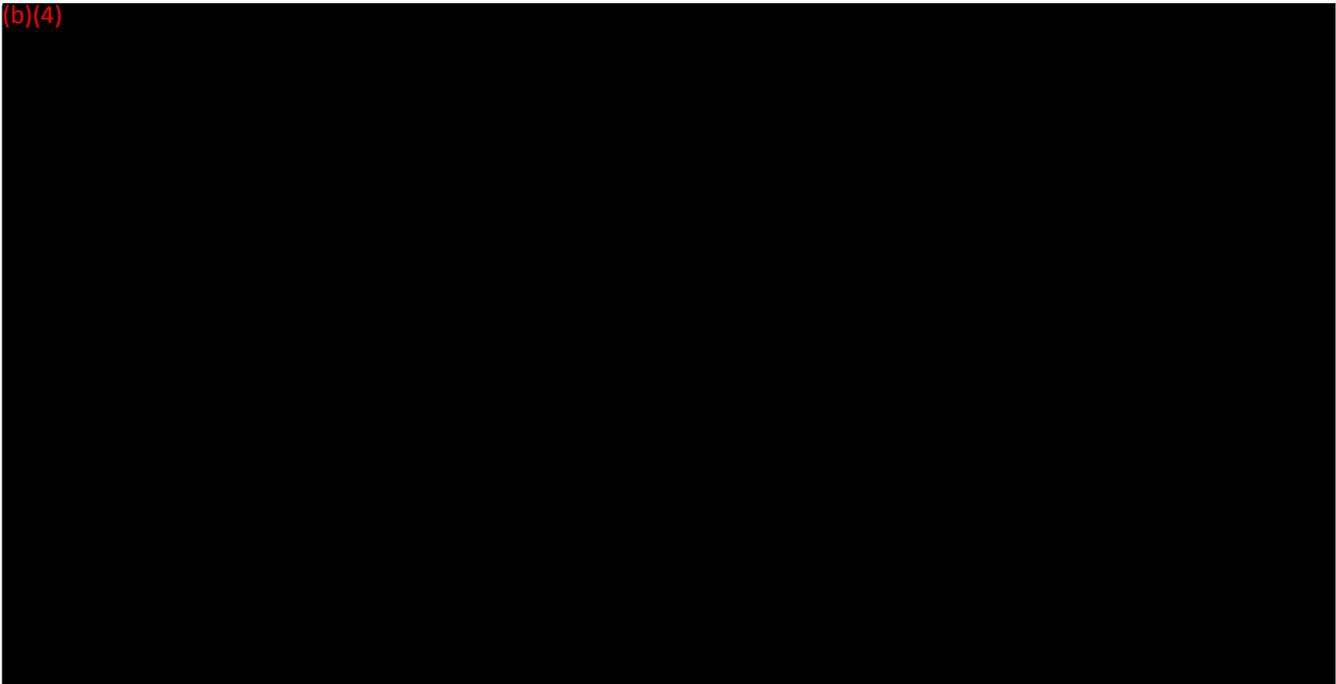
BD CLINICAL STUDY: EVALUATION OF 0.129 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES USING THE ELECTRA 1600C™ ANALYZER

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IV. DATA ANALYSIS

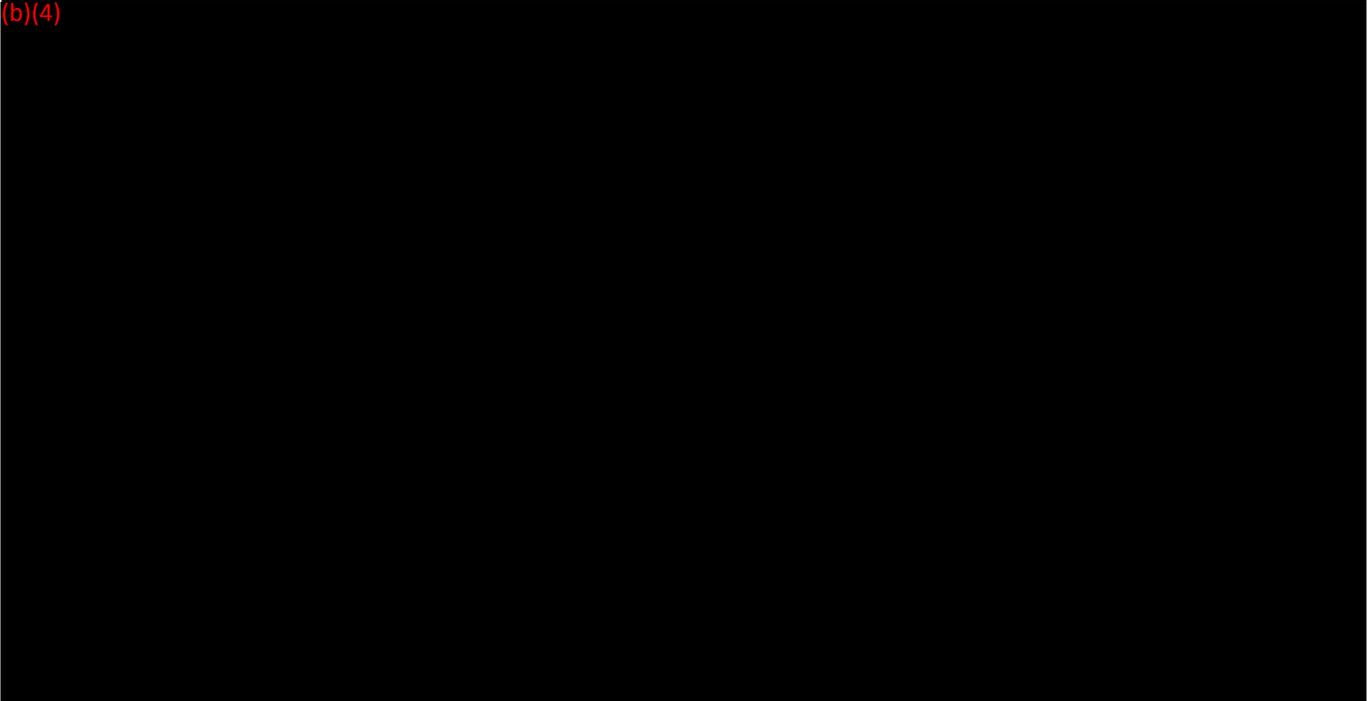
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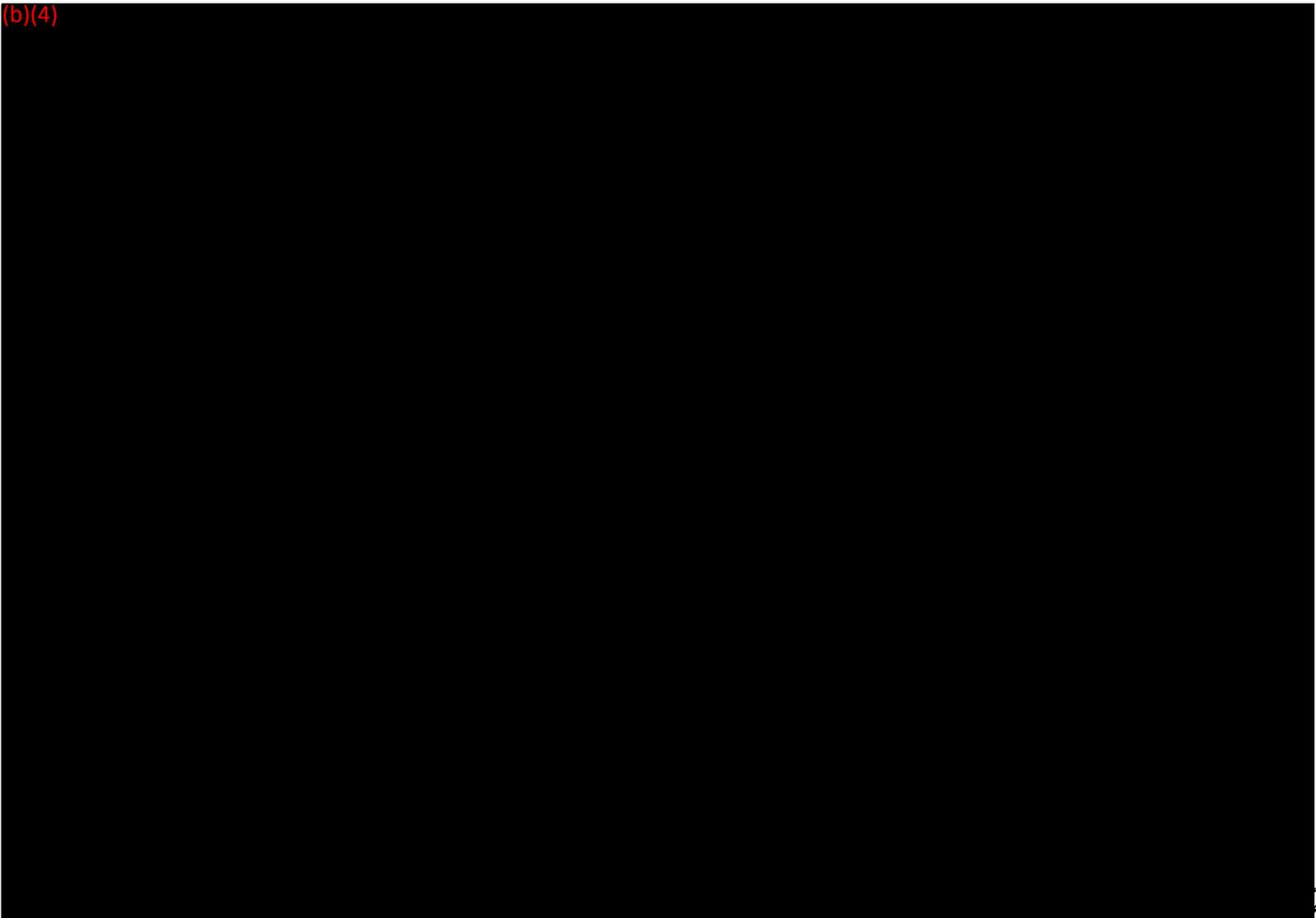
BD CLINICAL STUDY: EVALUATION OF 0.129 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES USING THE ELECTRA 1400C™ ANALYZER

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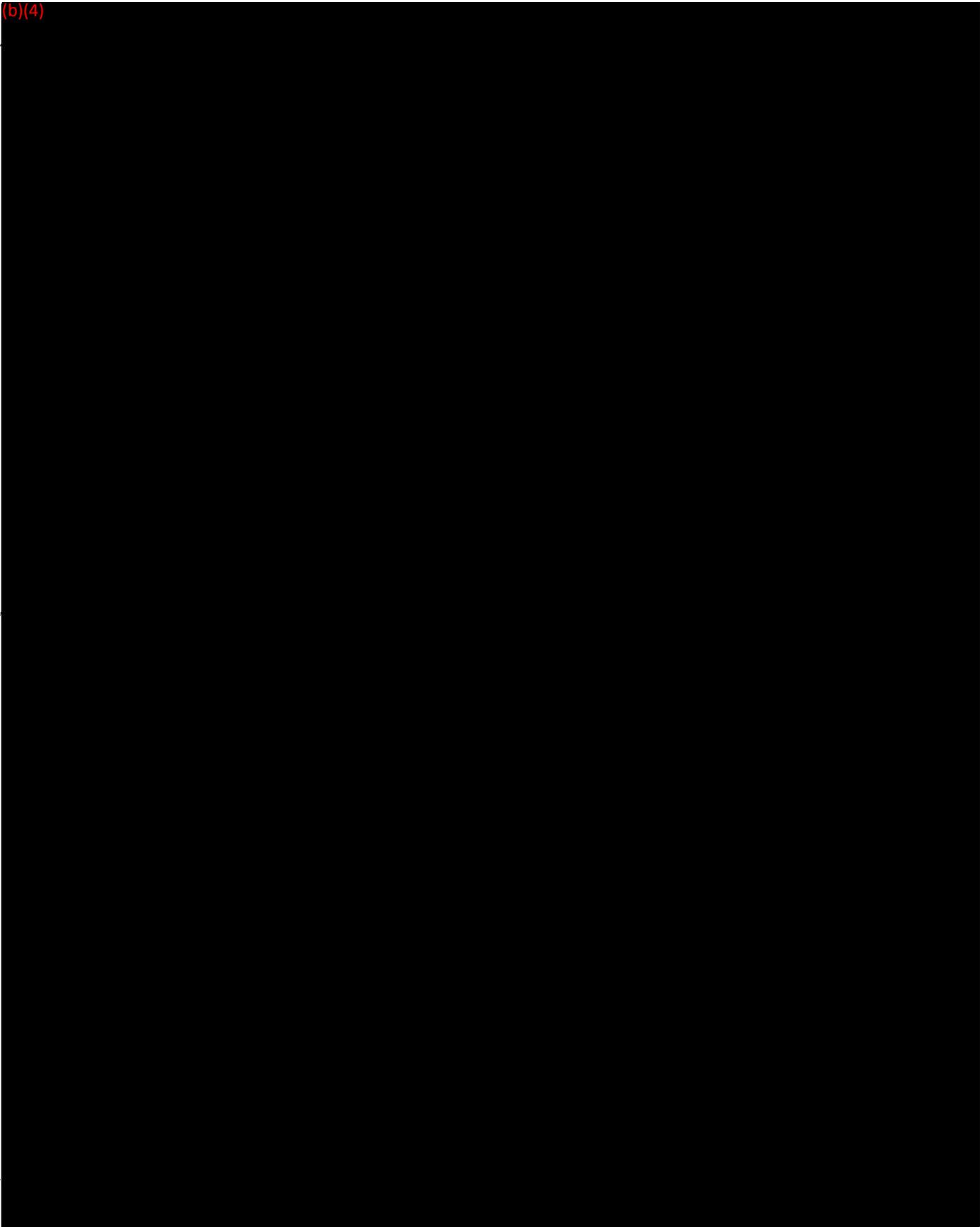
V. RESULTS AND DISCUSSION

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**BD CLINICAL STUDY: EVALUATION OF 0.129 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS
SODIUM CITRATE TUBES USING THE ELECTRA 1400C™ ANALYZER**

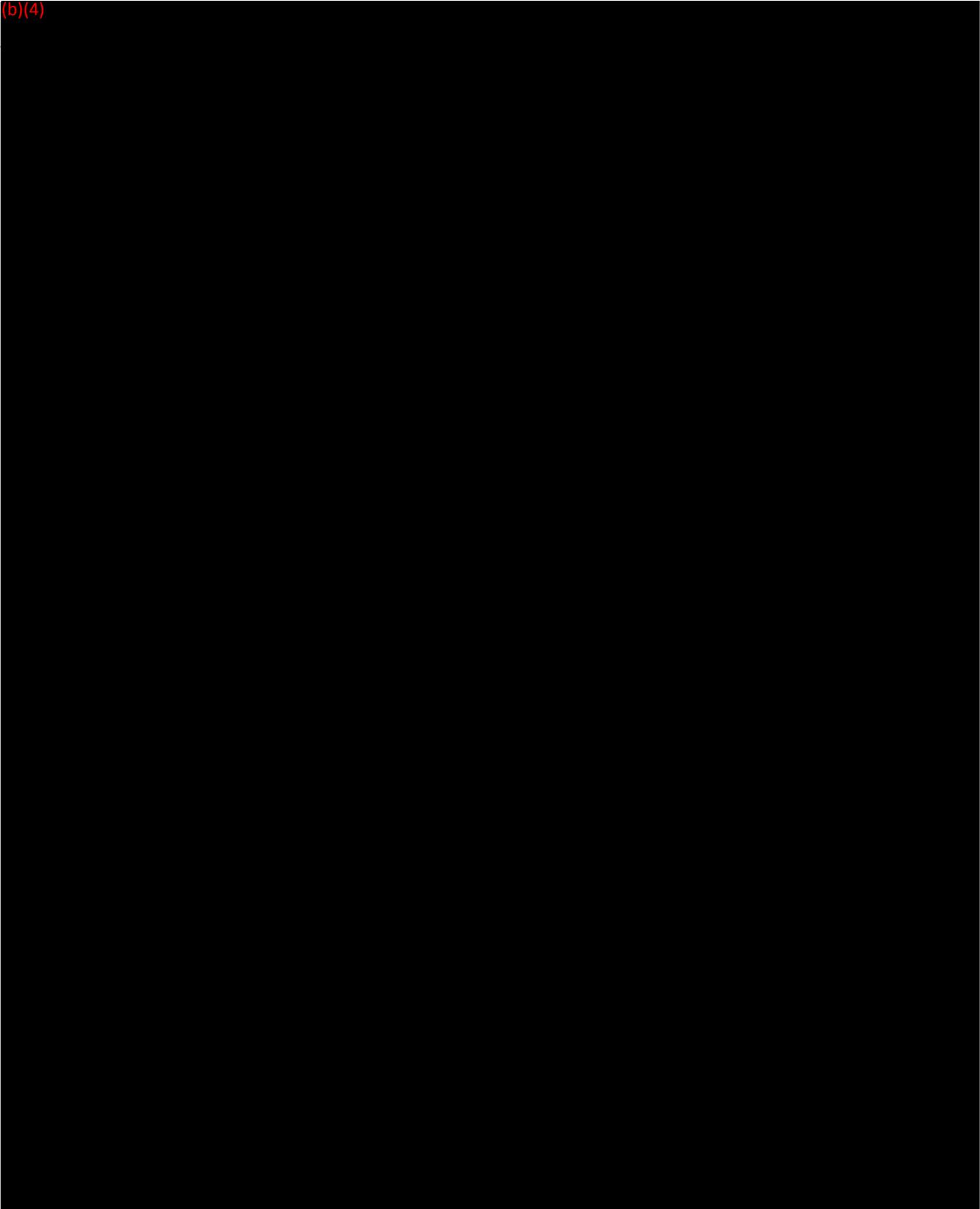
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BD CLINICAL STUDY: EVALUATION OF 0.129 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES USING THE ELECTRA 1400C™ ANALYZER

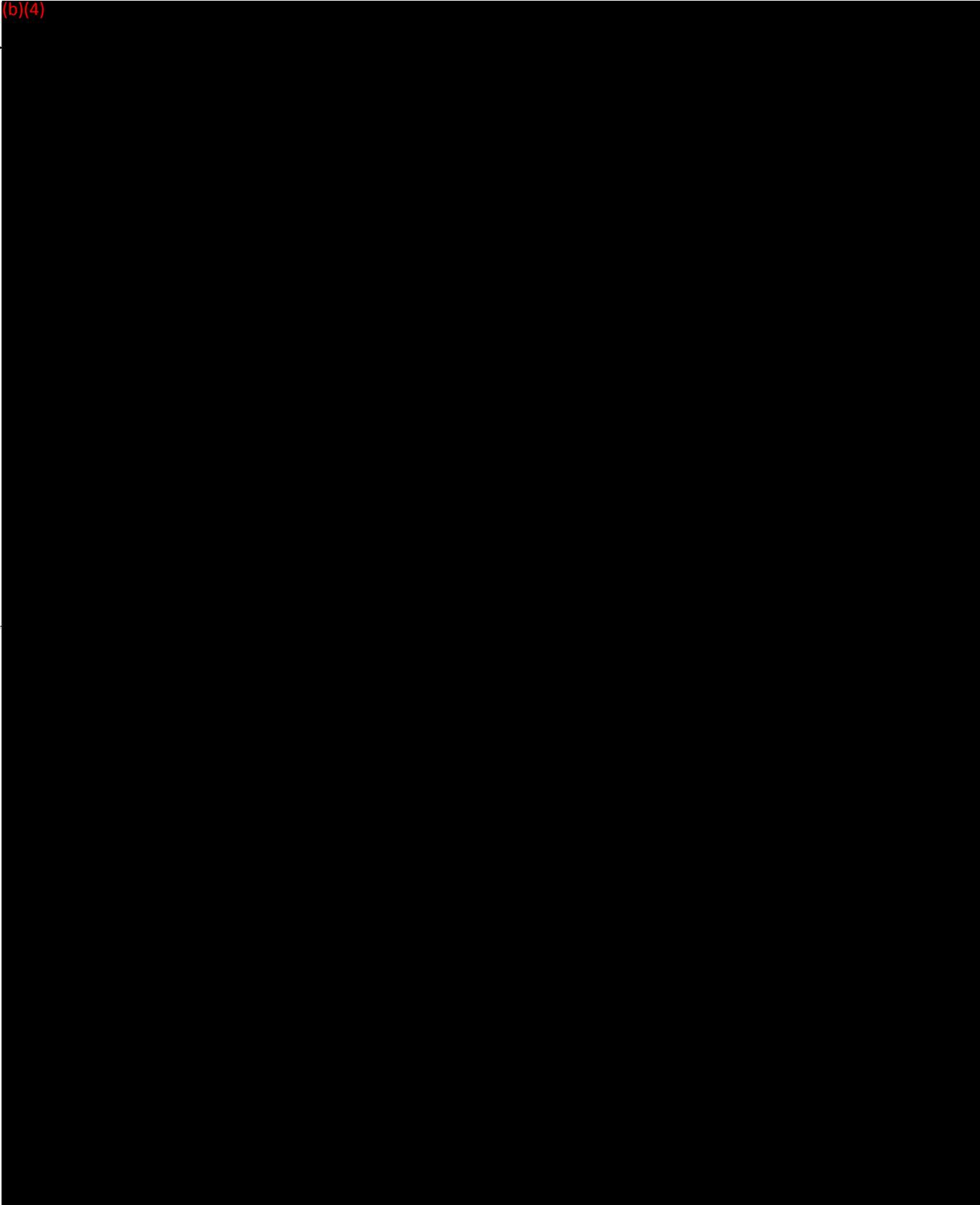
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BD CLINICAL STUDY: EVALUATION OF 0.129 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES USING THE ELECTRA 1400C™ ANALYZER

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BD CLINICAL STUDY: EVALUATION OF 0.129 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES USING THE ELECTRA 1400C™ ANALYZER

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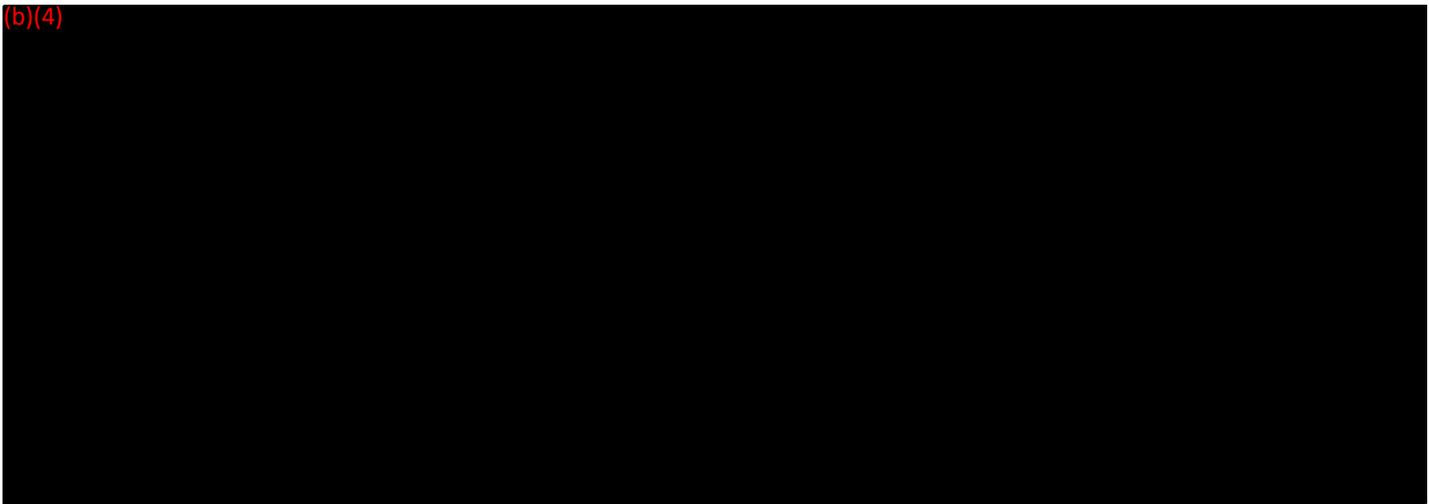
VI. CONCLUSIONS

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VII. REFERENCES

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ATTACHMENT 4: CLINICAL EVALUATION- AT S

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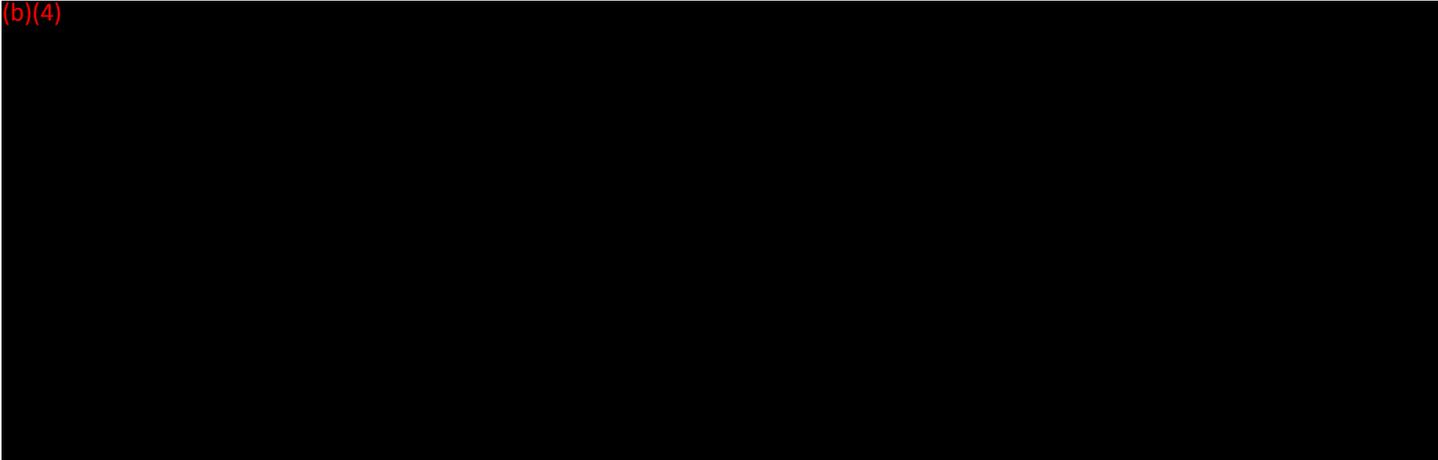
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BD CLINICAL STUDY: DETERMINATION OF NORMAL AND WARFARIN DONOR COAGULATION RESULTS USING 0.109 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES

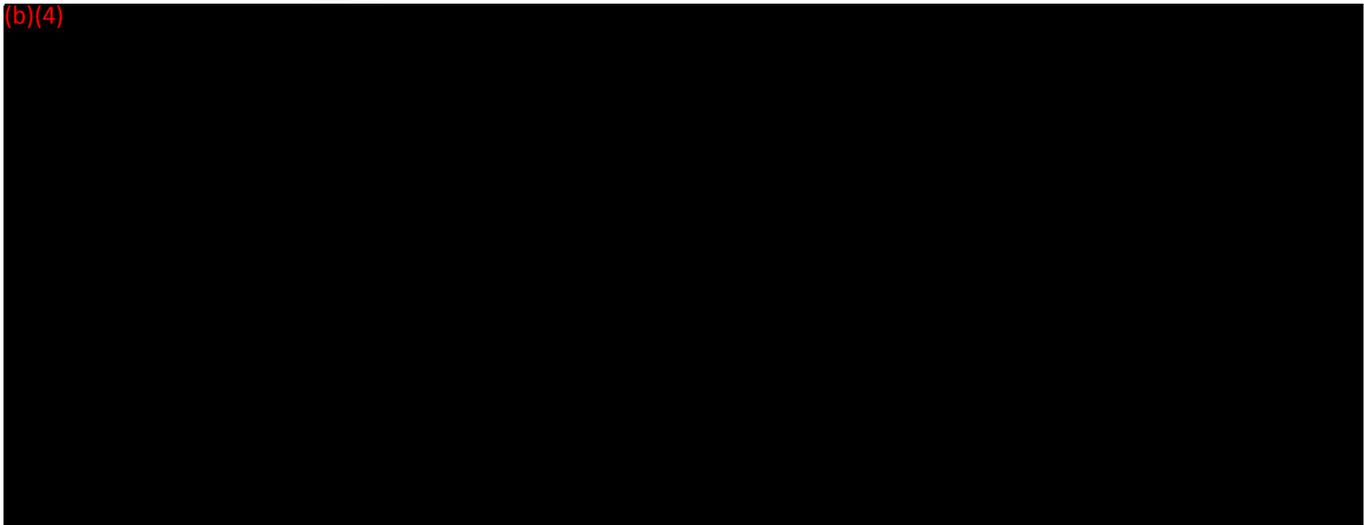
ABSTRACT

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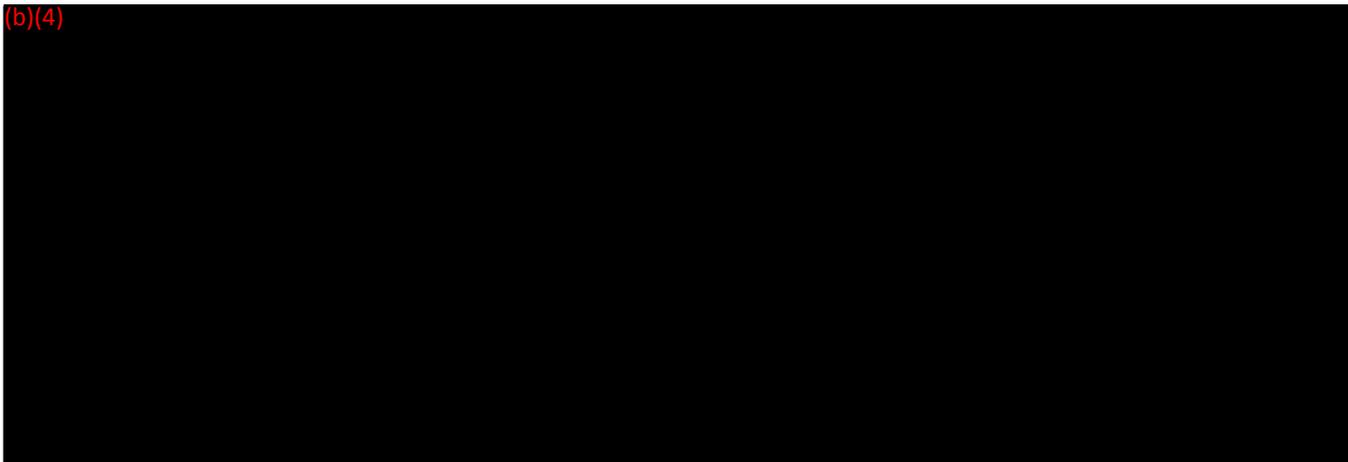
I. INTRODUCTION

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II. OBJECTIVE

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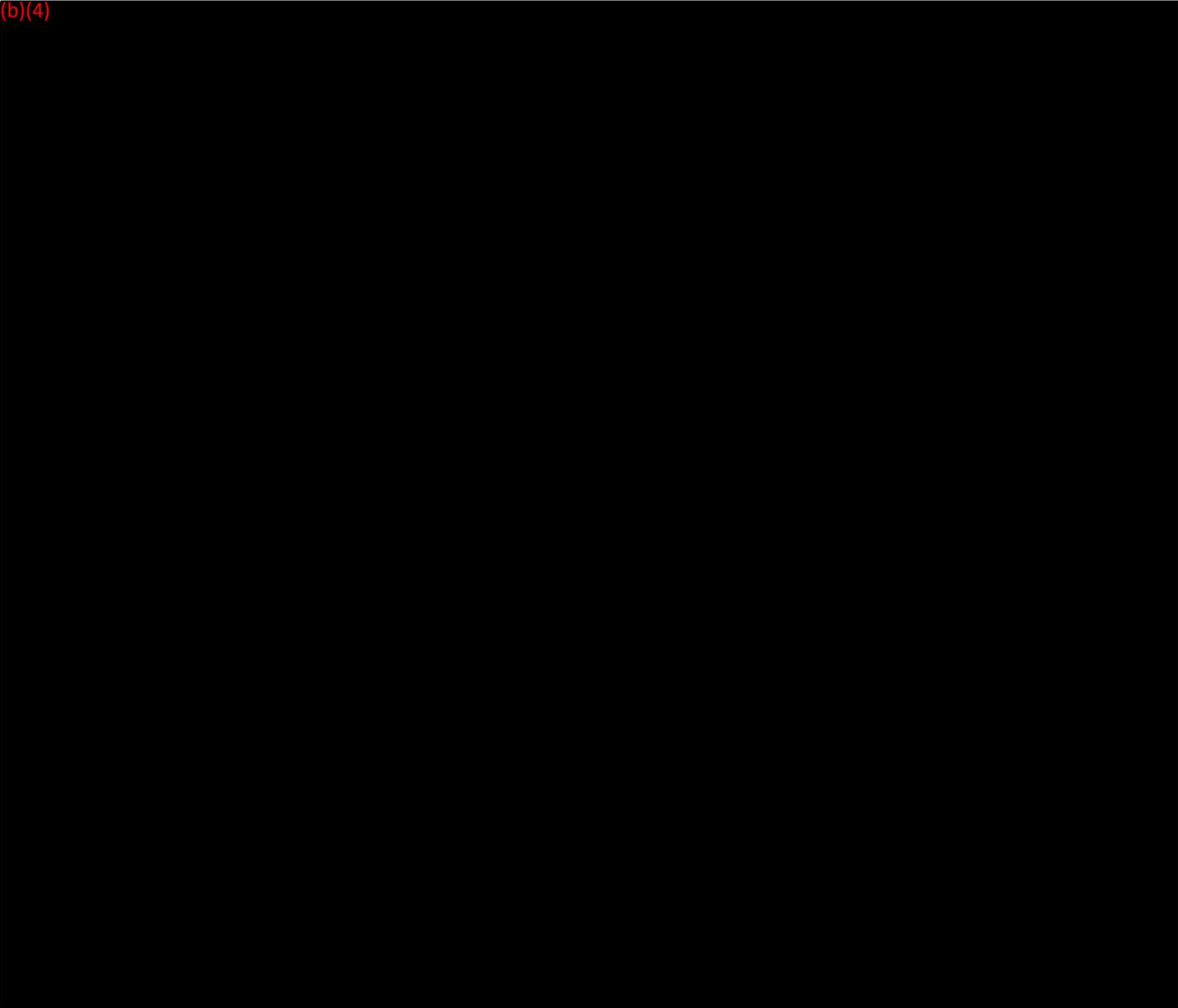


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BD CLINICAL STUDY: DETERMINATION OF NORMAL AND WARFARIN DONOR COAGULATION RESULTS USING 0.109 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES

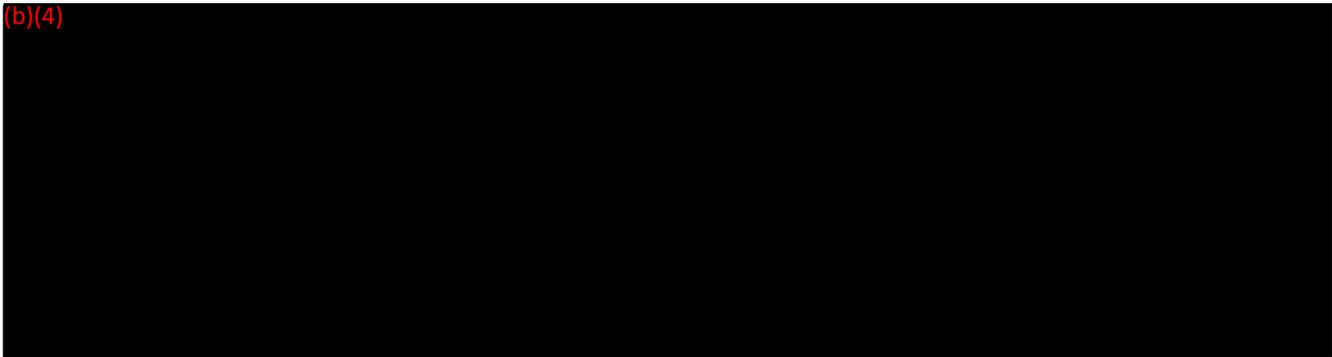
III. METHODS AND MATERIALS

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IV. DATA ANALYSIS

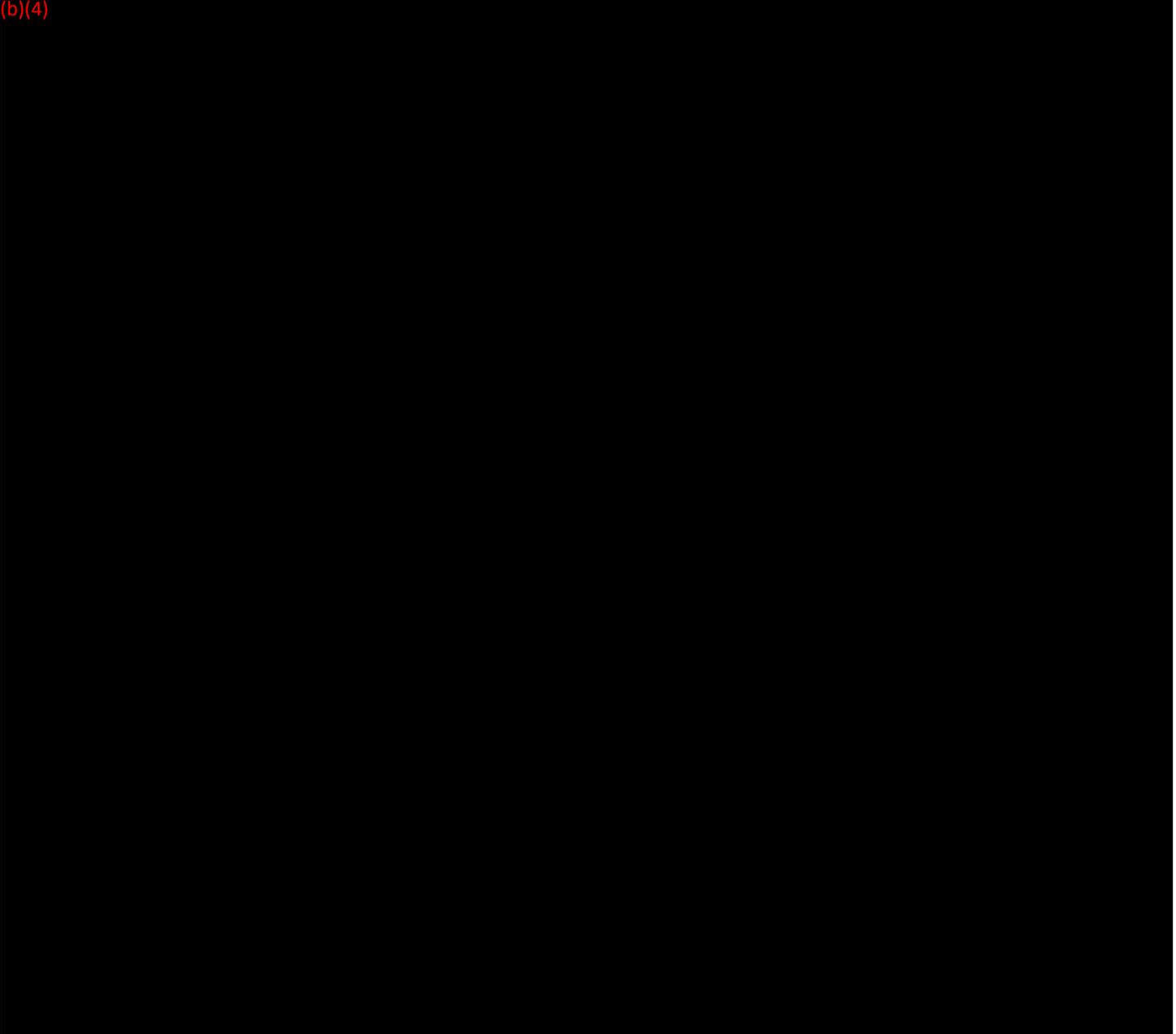
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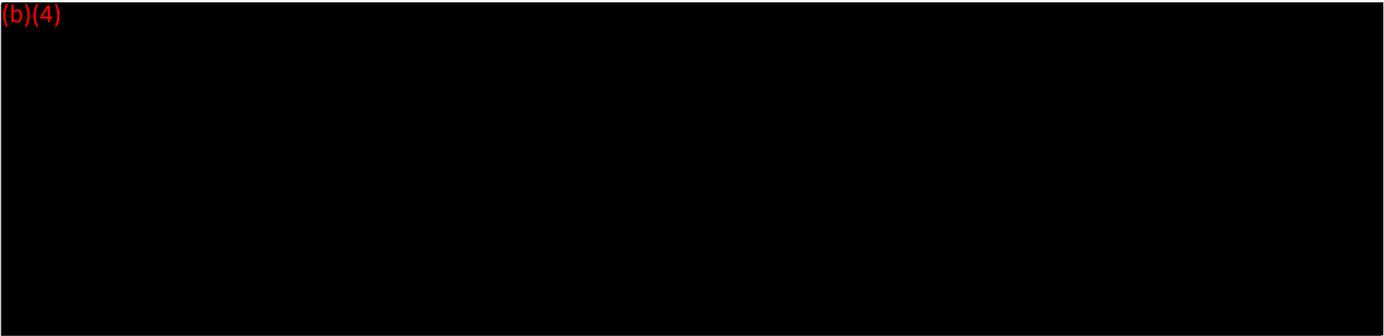
BD CLINICAL STUDY: DETERMINATION OF NORMAL AND WARFARIN DONOR COAGULATION RESULTS USING 0.109 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES

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V. RESULTS AND DISCUSSION

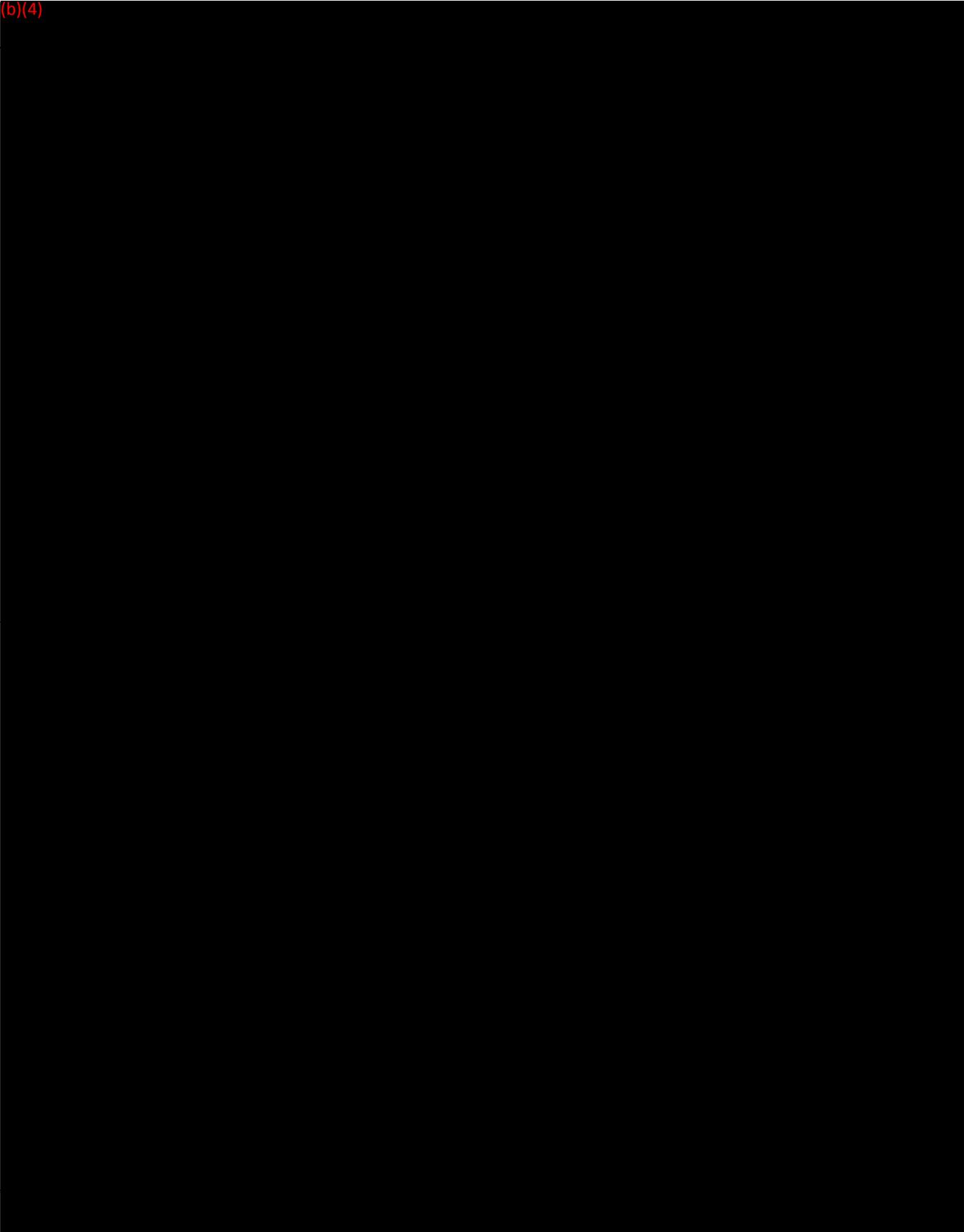
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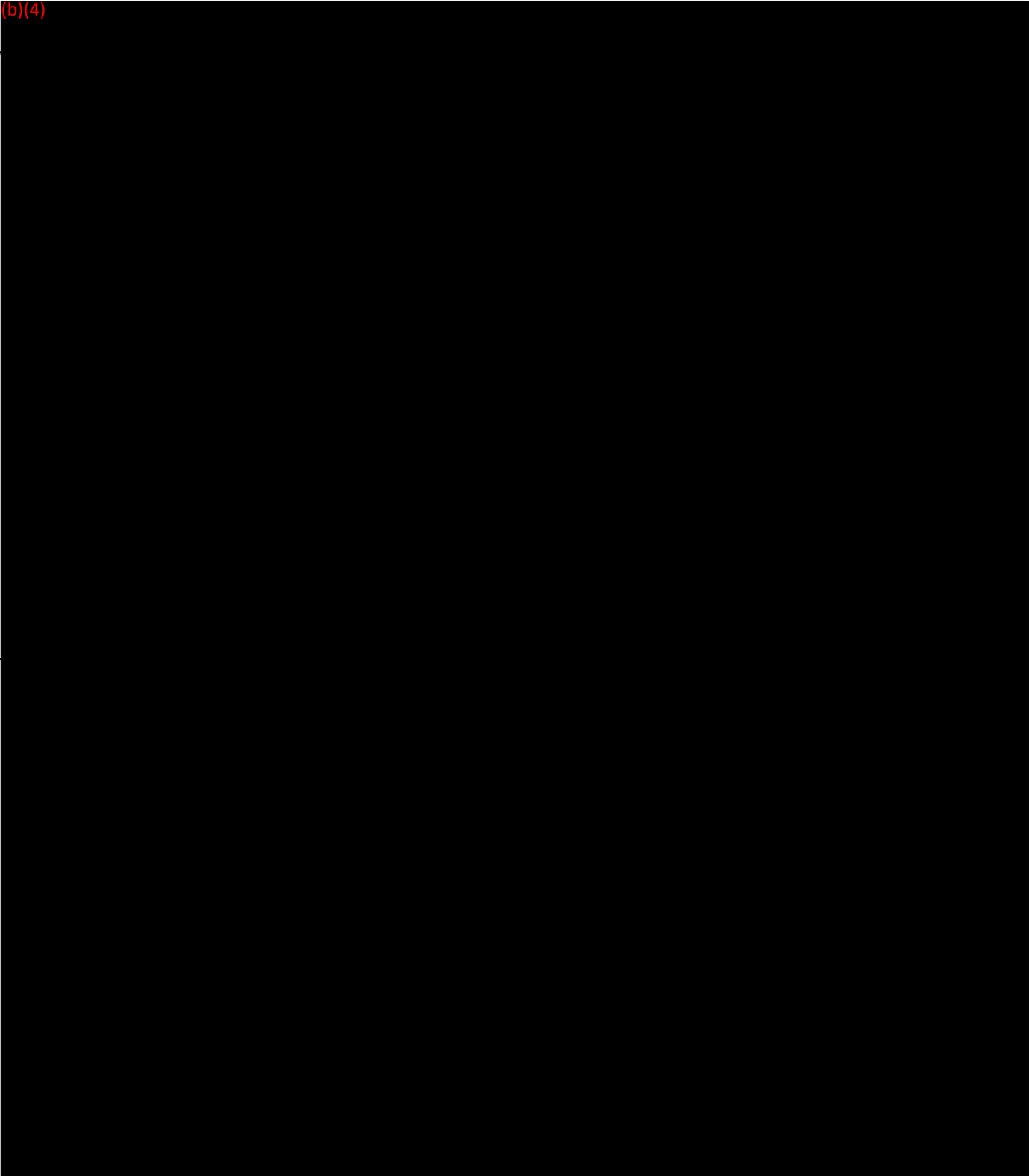
BD CLINICAL STUDY: DETERMINATION OF NORMAL AND WARFARIN DONOR COAGULATION RESULTS USING 0.109 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES

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BD CLINICAL STUDY: DETERMINATION OF NORMAL AND WARFARIN DONOR COAGULATION RESULTS USING 0.109 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES

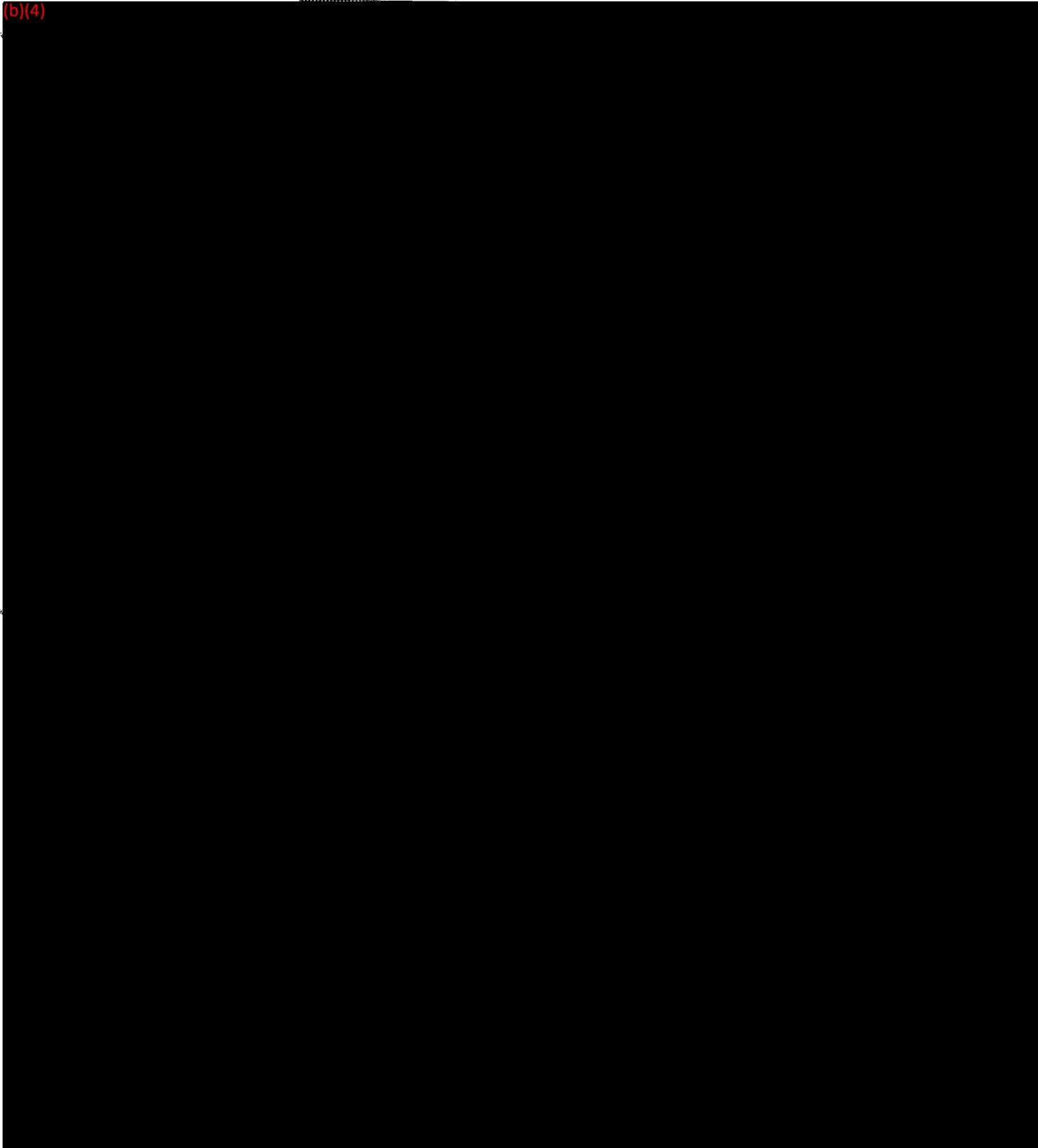
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BD CLINICAL STUDY: DETERMINATION OF NORMAL AND WARFARIN DONOR COAGULATION RESULTS USING 0.109 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES

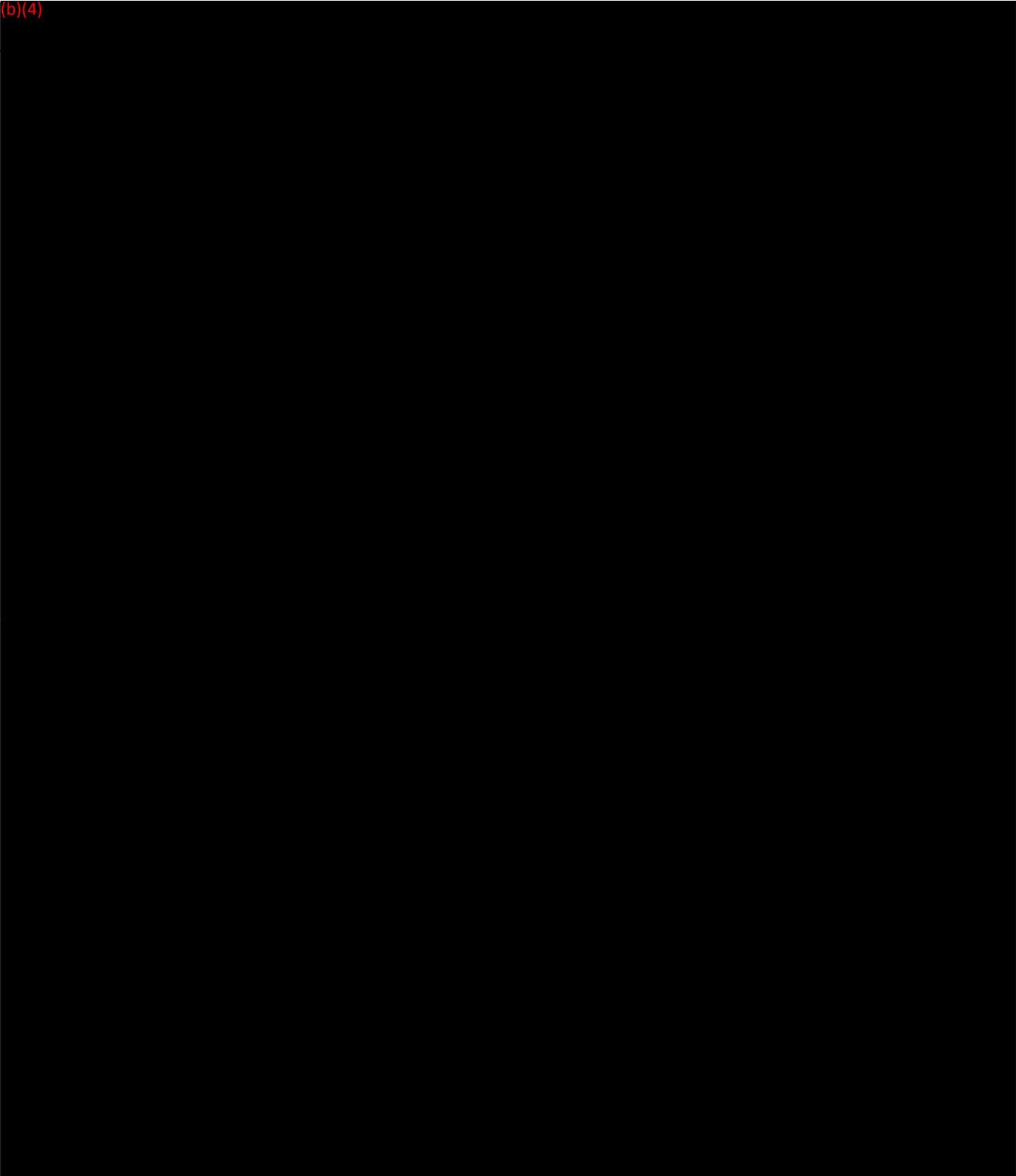
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BD CLINICAL STUDY: DETERMINATION OF NORMAL AND WARFARIN DONOR COAGULATION RESULTS USING 0.109 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES

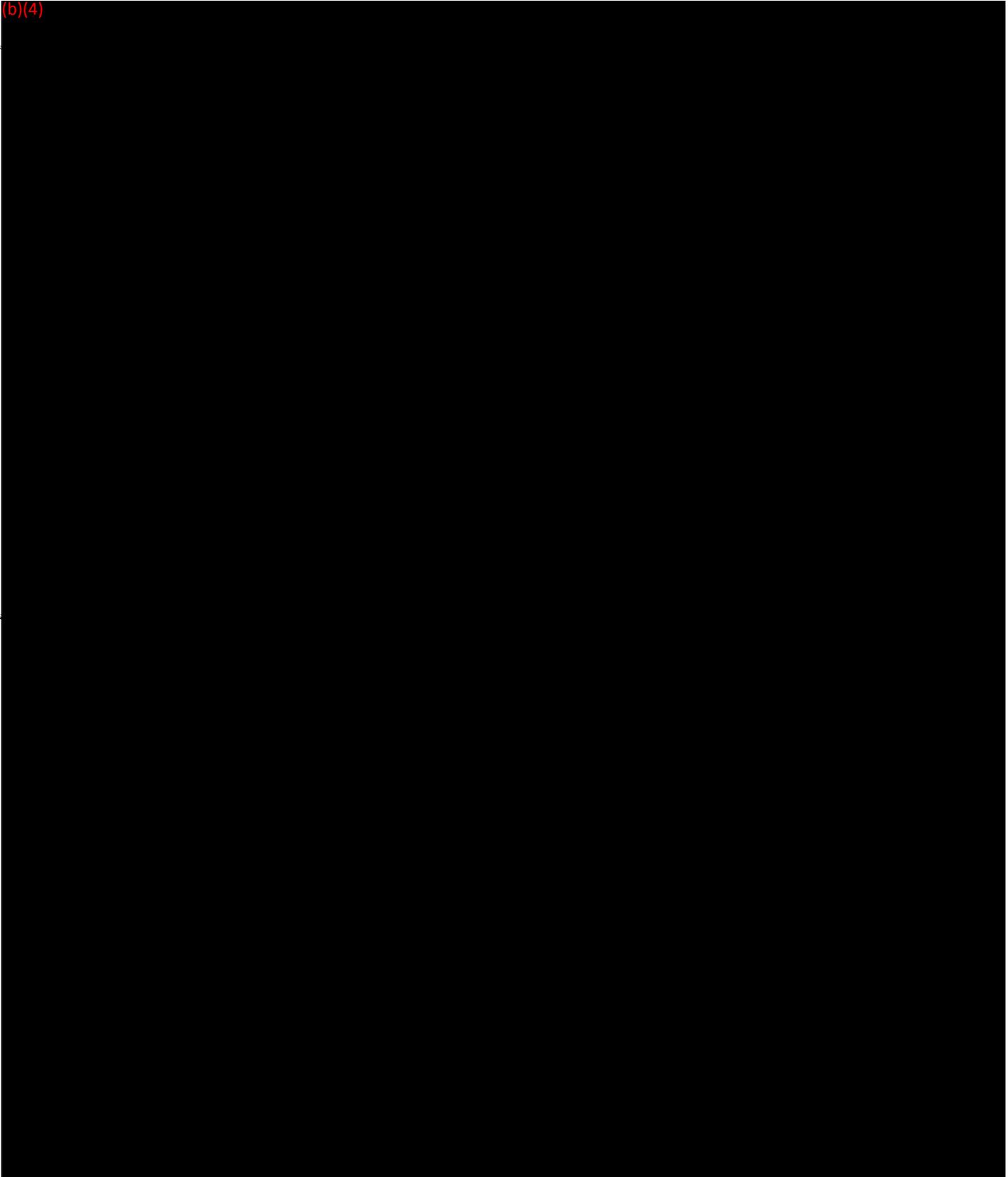
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BD CLINICAL STUDY: DETERMINATION OF NORMAL AND WARFARIN DONOR COAGULATION RESULTS USING 0.109 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES

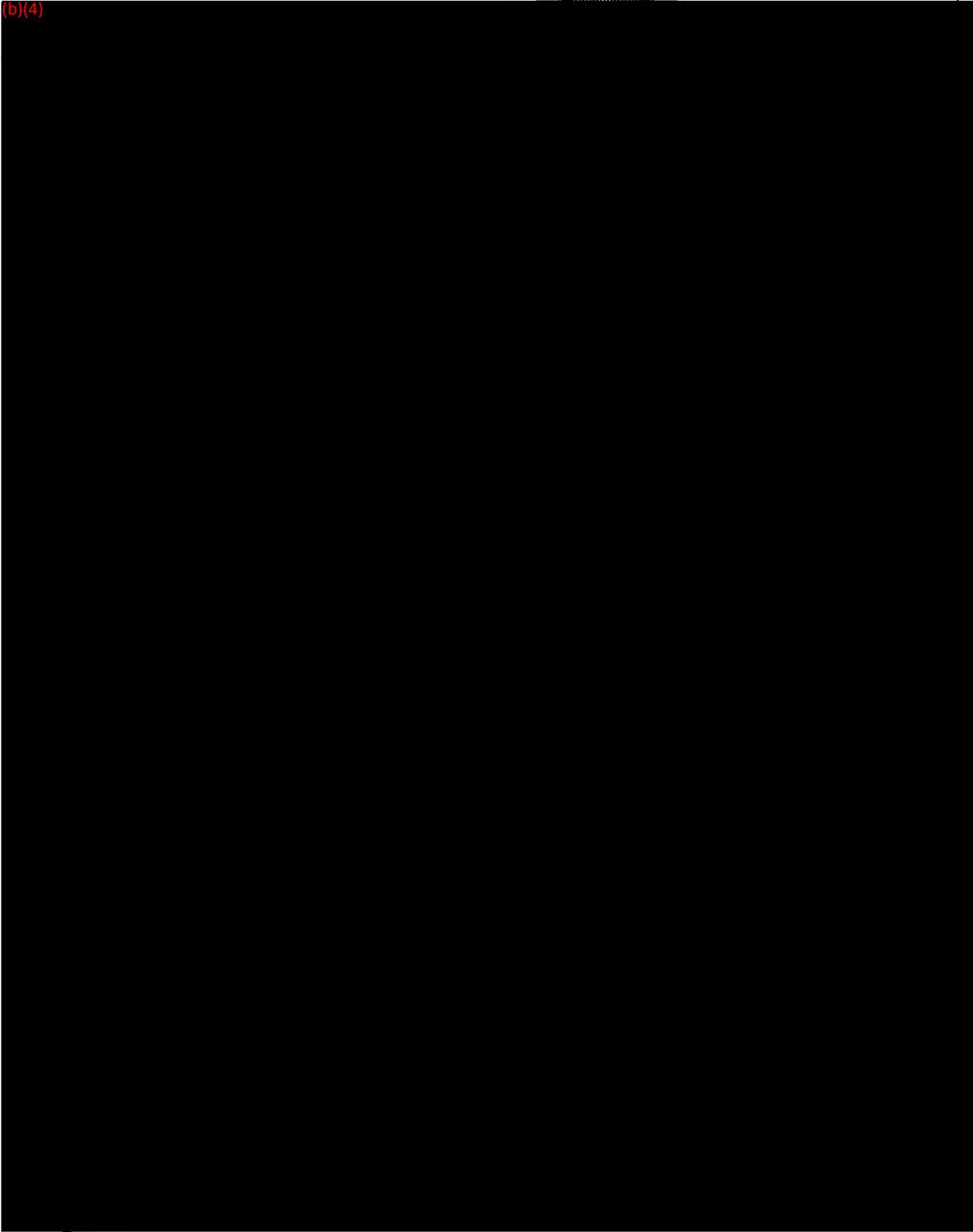
(b)(4)



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BD CLINICAL STUDY: DETERMINATION OF NORMAL AND WARFARIN DONOR COAGULATION RESULTS USING 0.109 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES

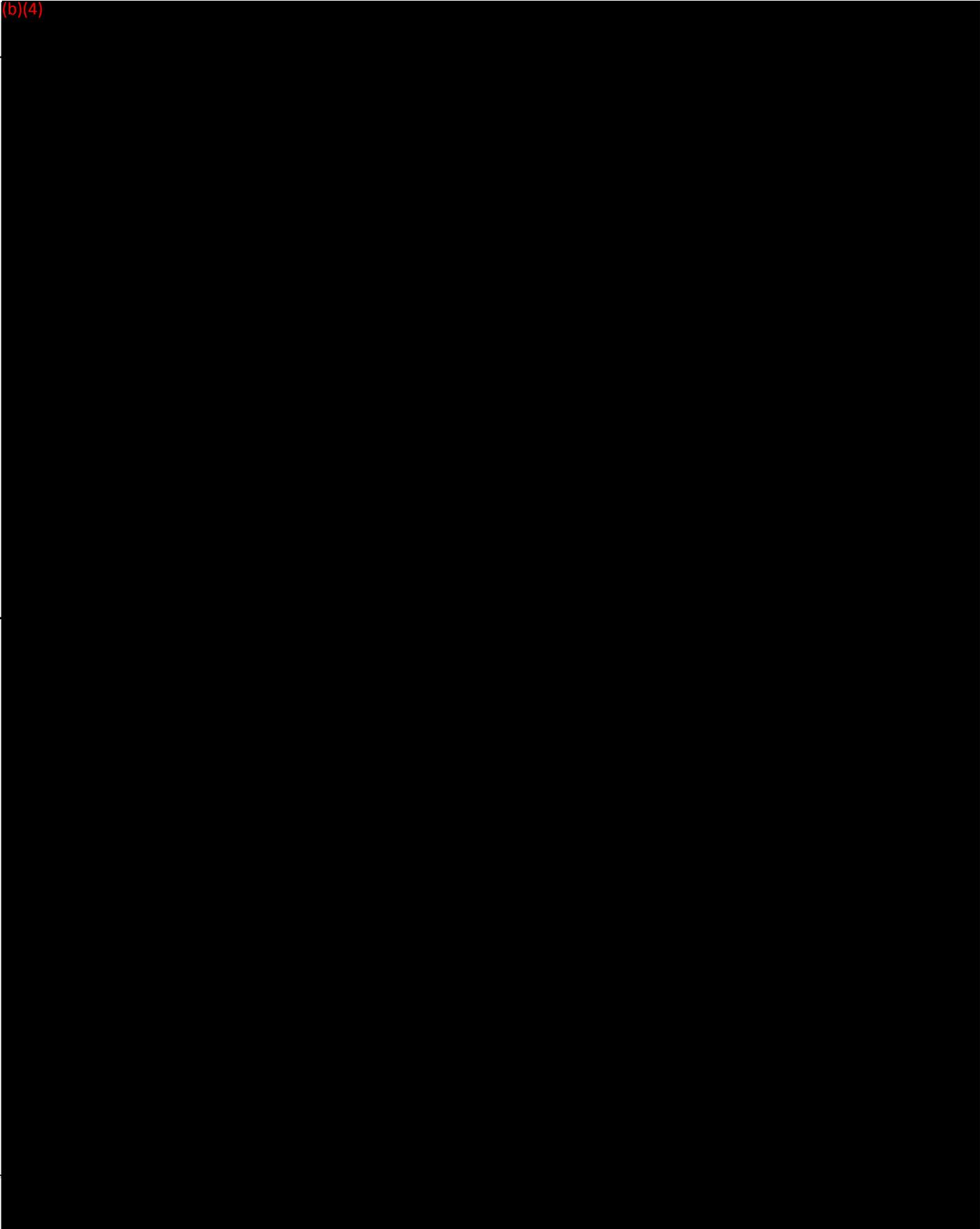
(b)(4)



116

BD CLINICAL STUDY: DETERMINATION OF NORMAL AND WARFARIN DONOR COAGULATION RESULTS USING 0.109 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES

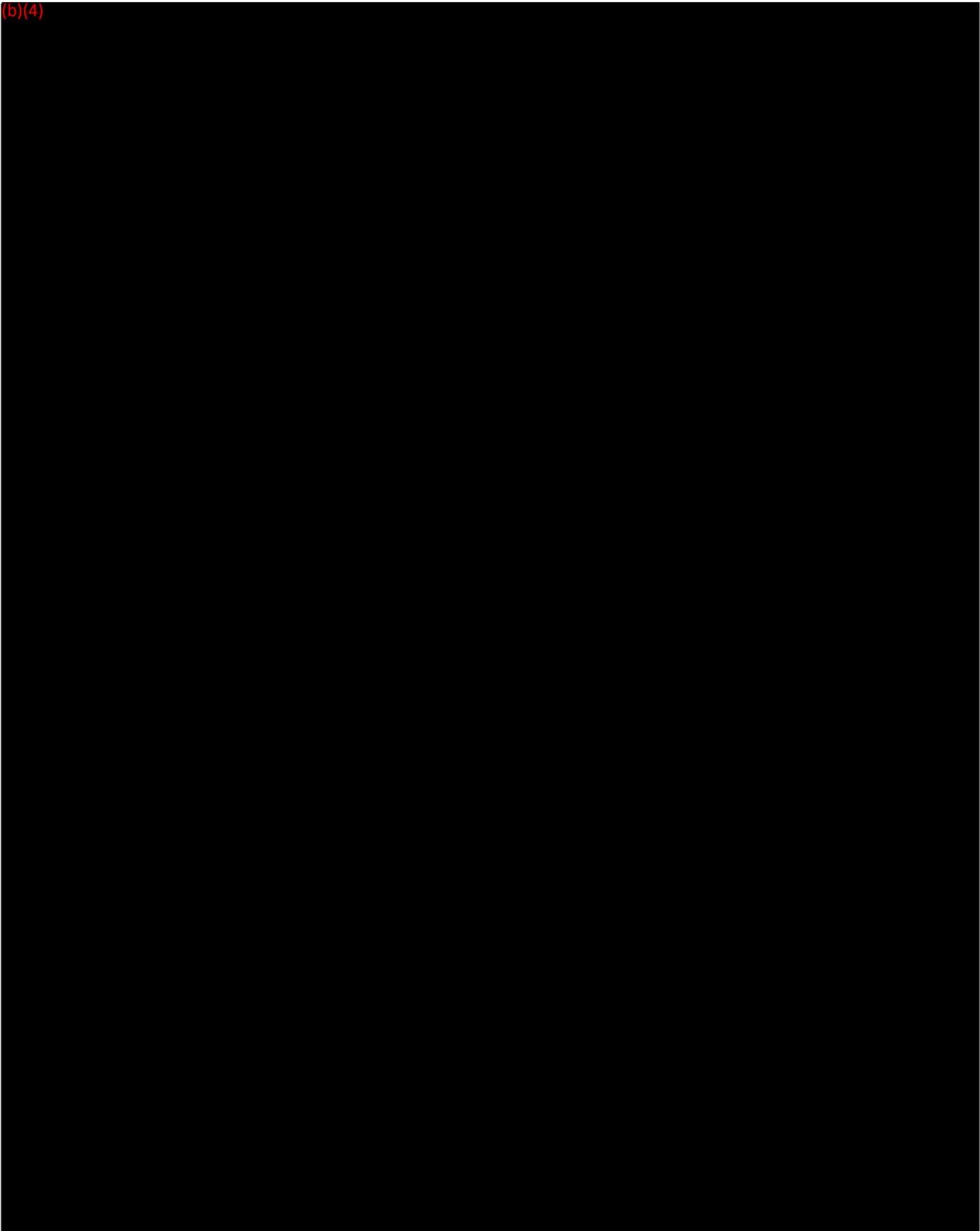
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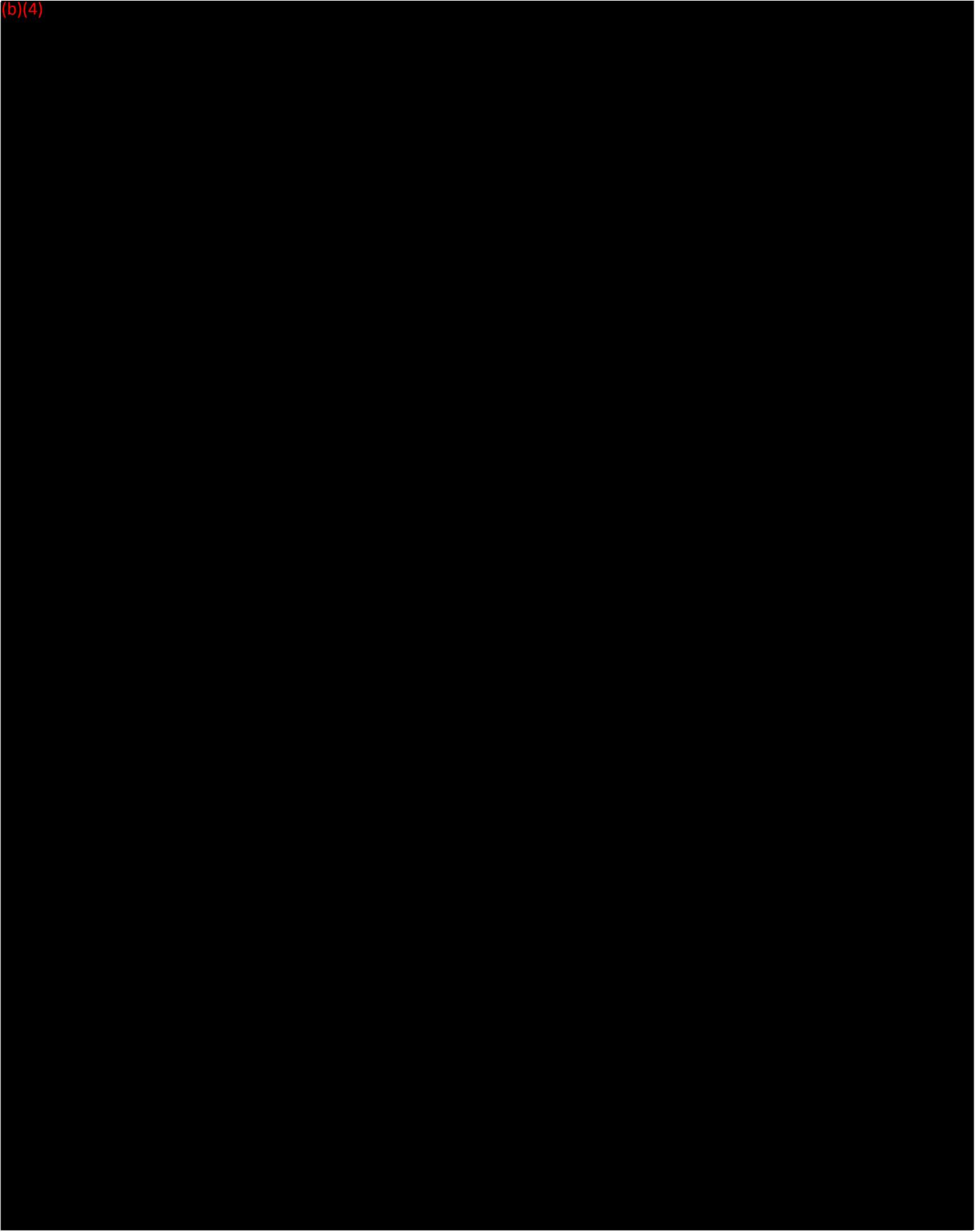
BD CLINICAL STUDY: DETERMINATION OF NORMAL AND WARFARIN DONOR COAGULATION RESULTS USING 0.109 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES

(b)(4)



BD CLINICAL STUDY: DETERMINATION OF NORMAL AND WARFARIN DONOR COAGULATION RESULTS USING 0.109 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES

(b)(4)



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BD CLINICAL STUDY: DETERMINATION OF NORMAL AND WARFARIN DONOR COAGULATION RESULTS USING 0.109 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES

(b)(4)



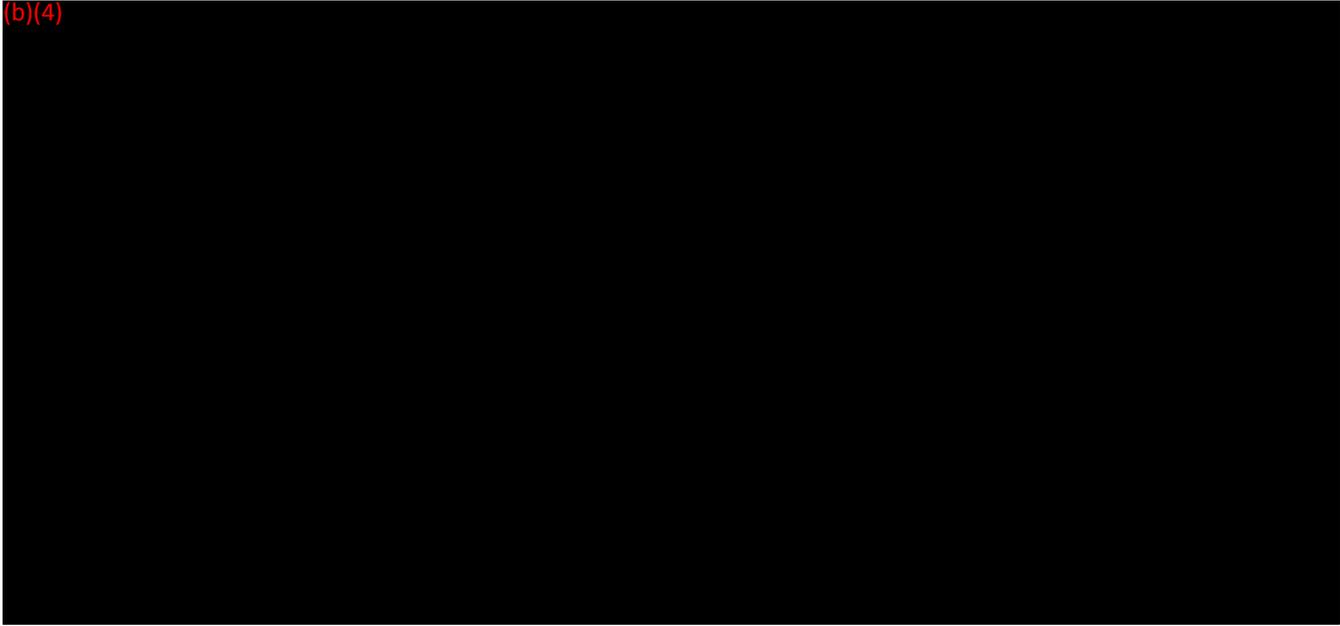
VI. CONCLUSIONS

(b)(4)



VII. REFERENCES

(b)(4)



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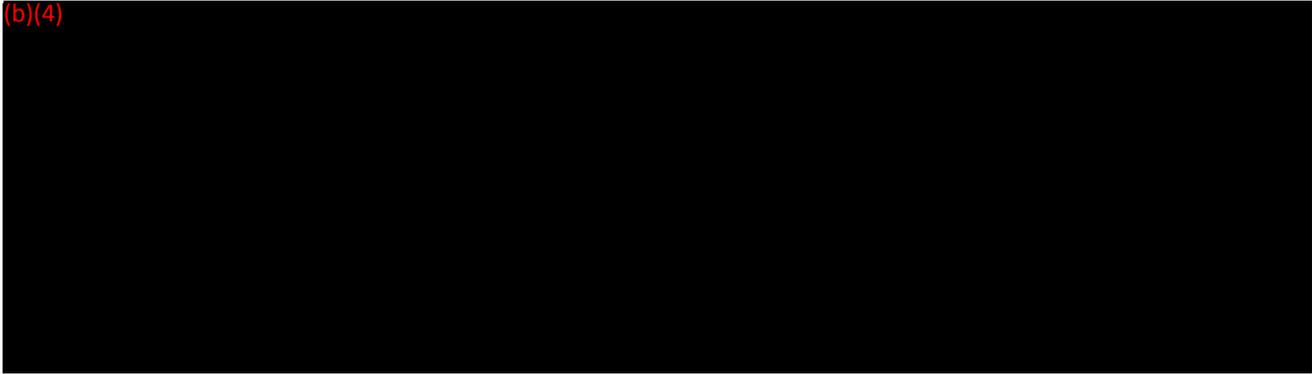
**ATTACHMENT 5: CLINICAL EVALUATION- AT BD
VACUTAINER SYSTEMS (BDVS) & (b)(4)**

(b)(4)

BD CLINICAL STUDY: EVALUATION OF BD 0.109 M AND 0.129 M VACUTAINER™ PLUS SODIUM CITRATE TUBES FOR PLATELET COUNTS ON NORMAL AND NON-NORMAL DONORS

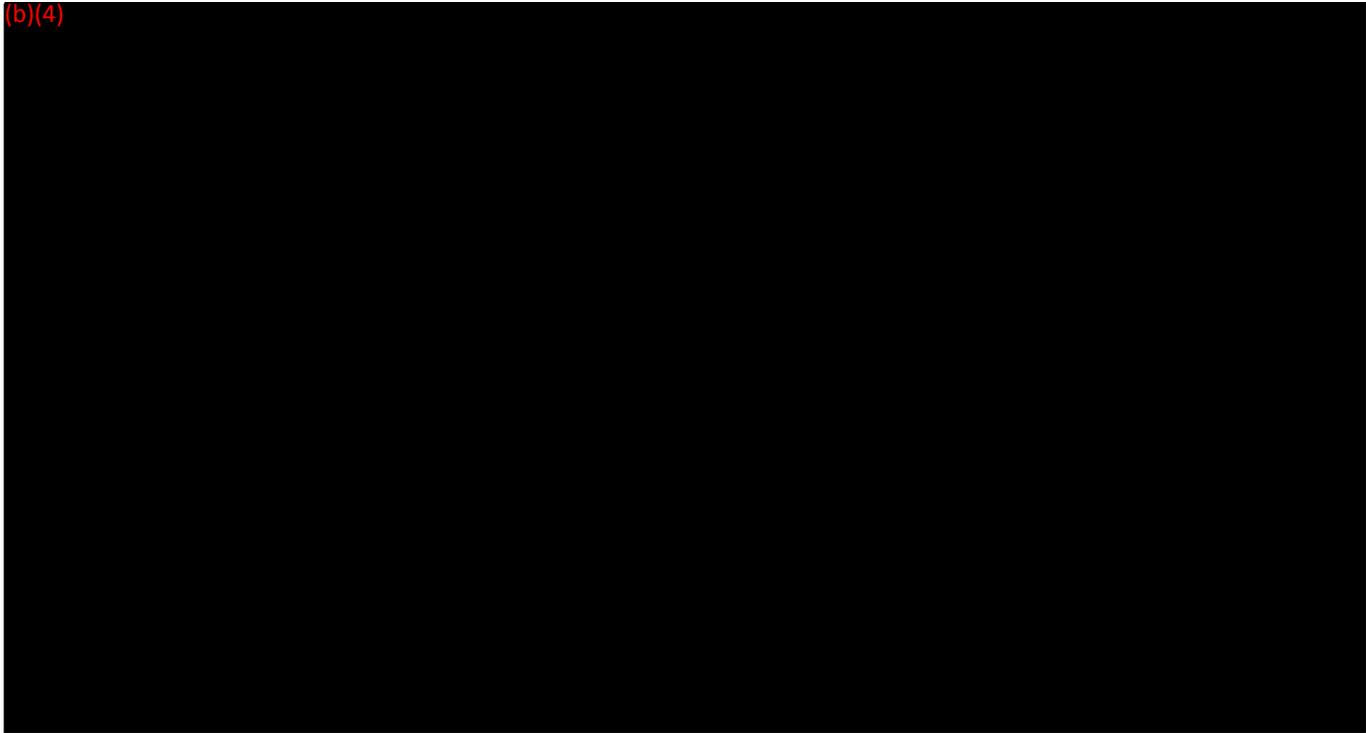
ABSTRACT

(b)(4)



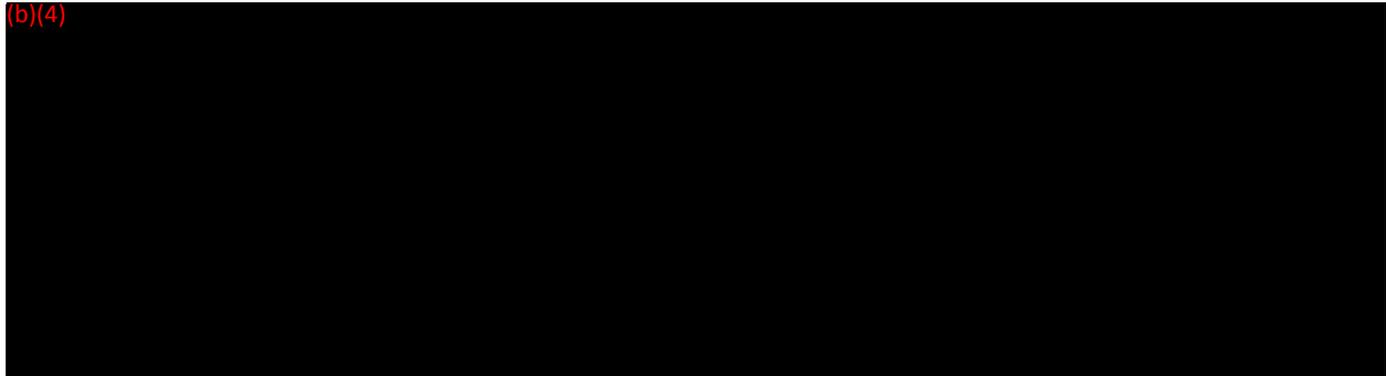
I. INTRODUCTION

(b)(4)



II. OBJECTIVES

(b)(4)

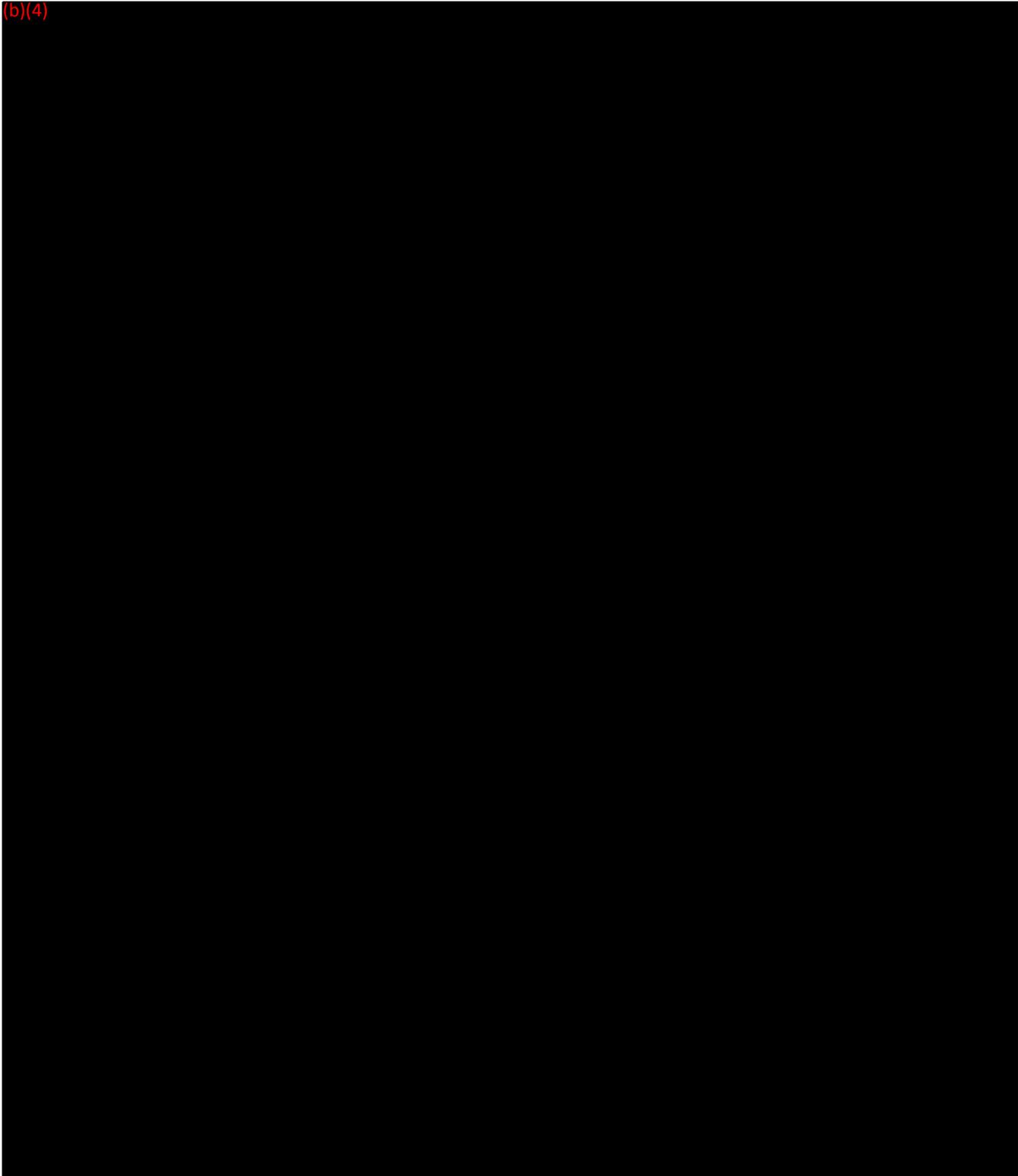


122

BD CLINICAL STUDY: EVALUATION OF BD 0.109 M AND 0.129 M VACUTAINER™ PLUS SODIUM CITRATE TUBES FOR PLATELET COUNTS ON NORMAL AND NON-NORMAL DONORS

III. METHODS AND MATERIALS

(b)(4)

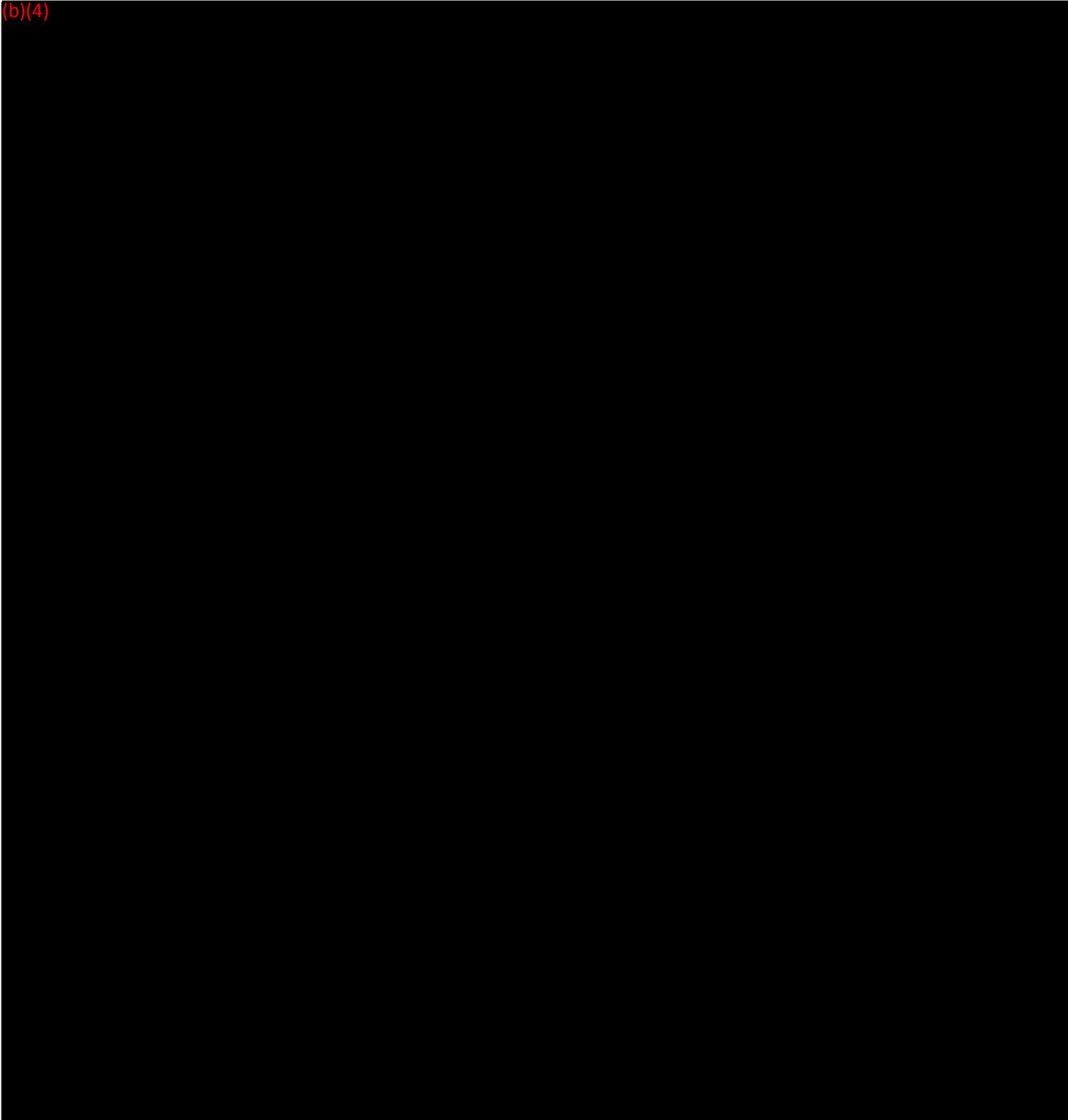


123

BD CLINICAL STUDY: EVALUATION OF BD 0.109 M AND 0.129 M VACUTAINER™ PLUS SODIUM CITRATE TUBES FOR PLATELET COUNTS ON NORMAL AND NON-NORMAL DONORS

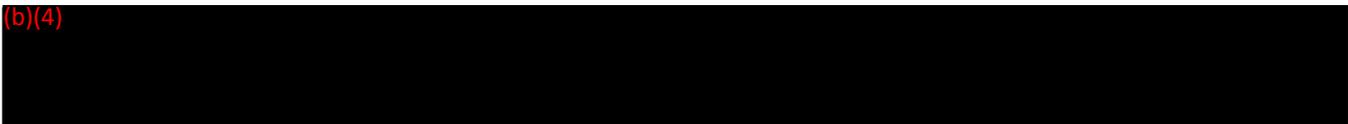
IV. DATA ANALYSIS

(b)(4)



V. DETAILS AND DEVIATIONS

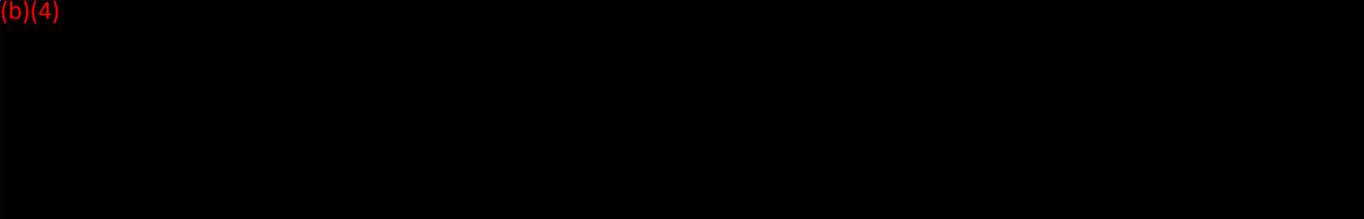
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124

BD CLINICAL STUDY: EVALUATION OF BD 0.109 M AND 0.129 M VACUTAINER™ PLUS SODIUM CITRATE TUBES FOR PLATELET COUNTS ON NORMAL AND NON-NORMAL DONORS

(b)(4)



VI. RESULTS AND DISCUSSION

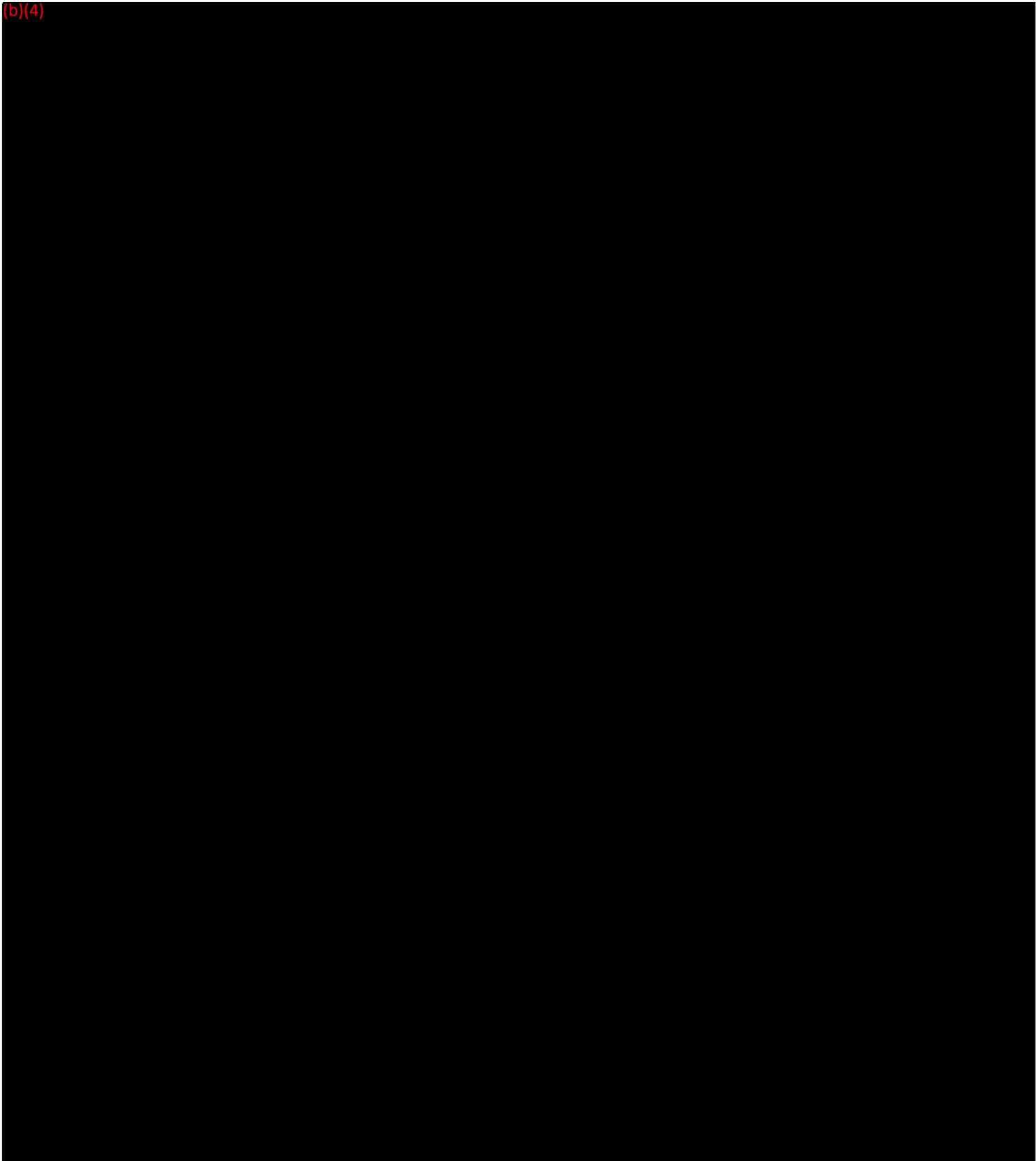
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125

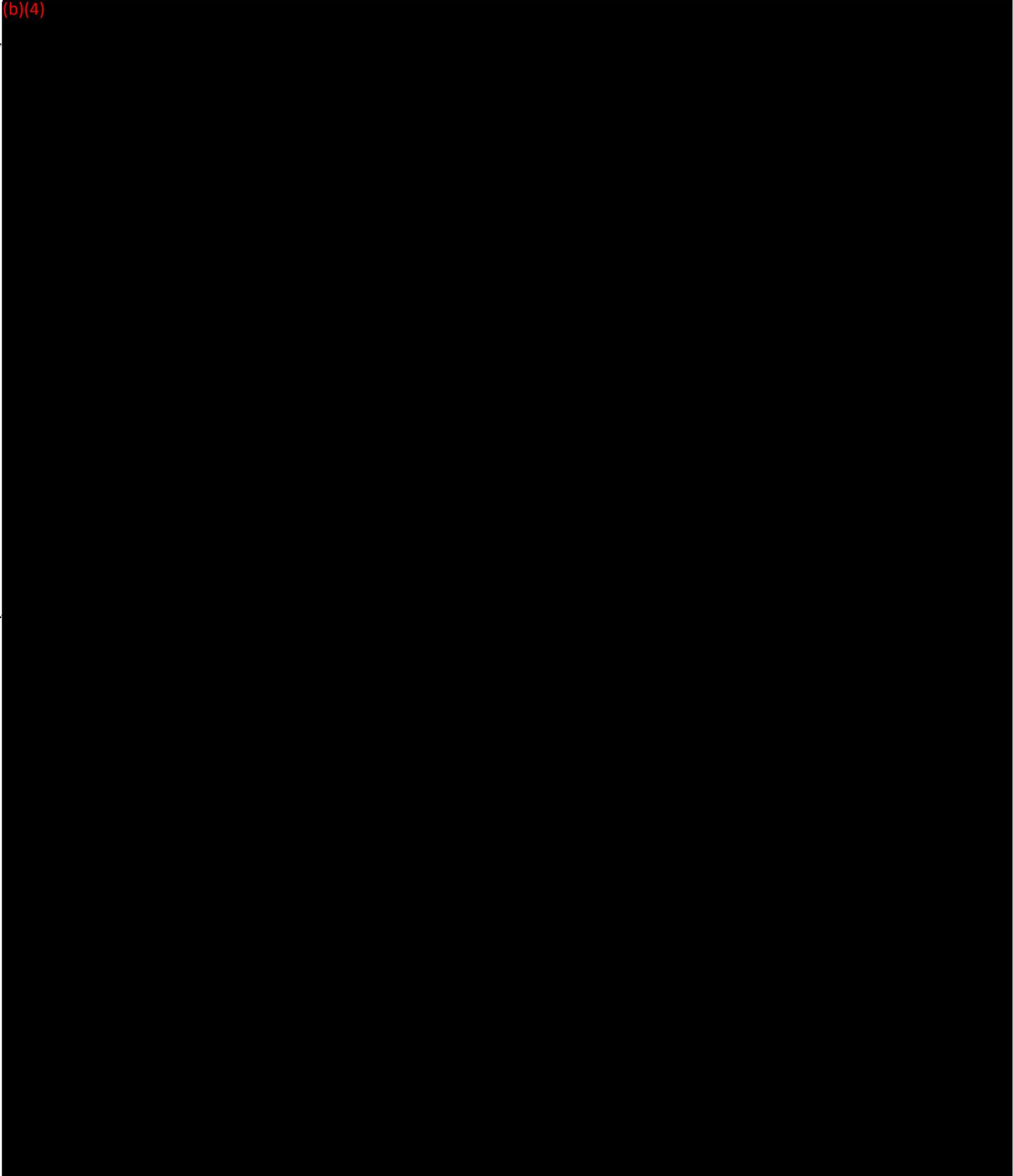
BD CLINICAL STUDY: EVALUATION OF BD 0.109 M AND 0.129 M VACUTAINER™ PLUS SODIUM CITRATE TUBES FOR PLATELET COUNTS ON NORMAL AND NON-NORMAL DONORS

(b)(4)



126

BD CLINICAL STUDY: EVALUATION OF BD 0.109 M AND 0.129 M VACUTAINER™ PLUS SODIUM CITRATE TUBES FOR PLATELET COUNTS ON NORMAL AND NON-NORMAL DONORS

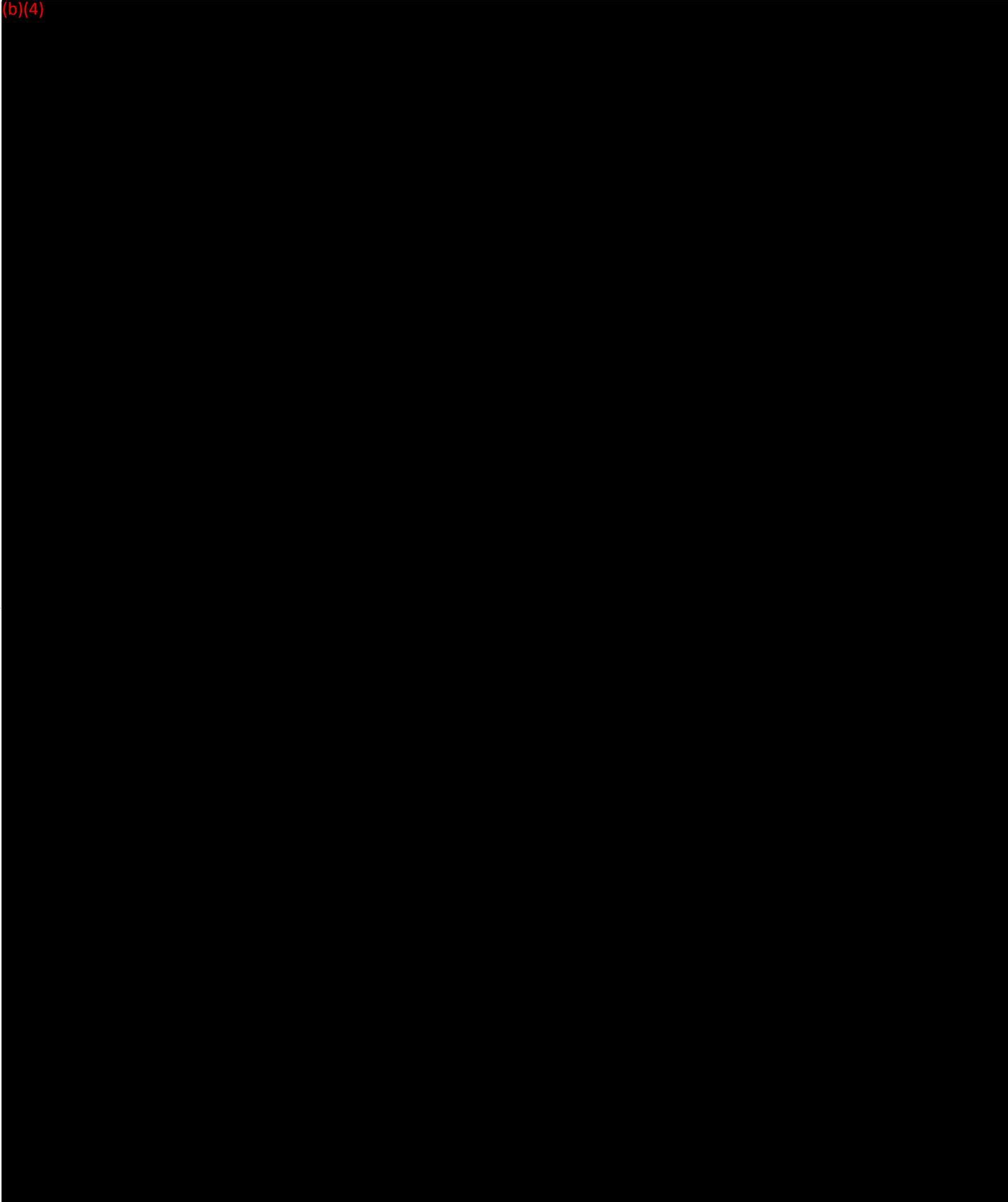


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127

BD CLINICAL STUDY: EVALUATION OF BD 0.109 M AND 0.129 M VACUTAINER™ PLUS SODIUM CITRATE TUBES FOR PLATELET COUNTS ON NORMAL AND NON-NORMAL DONORS

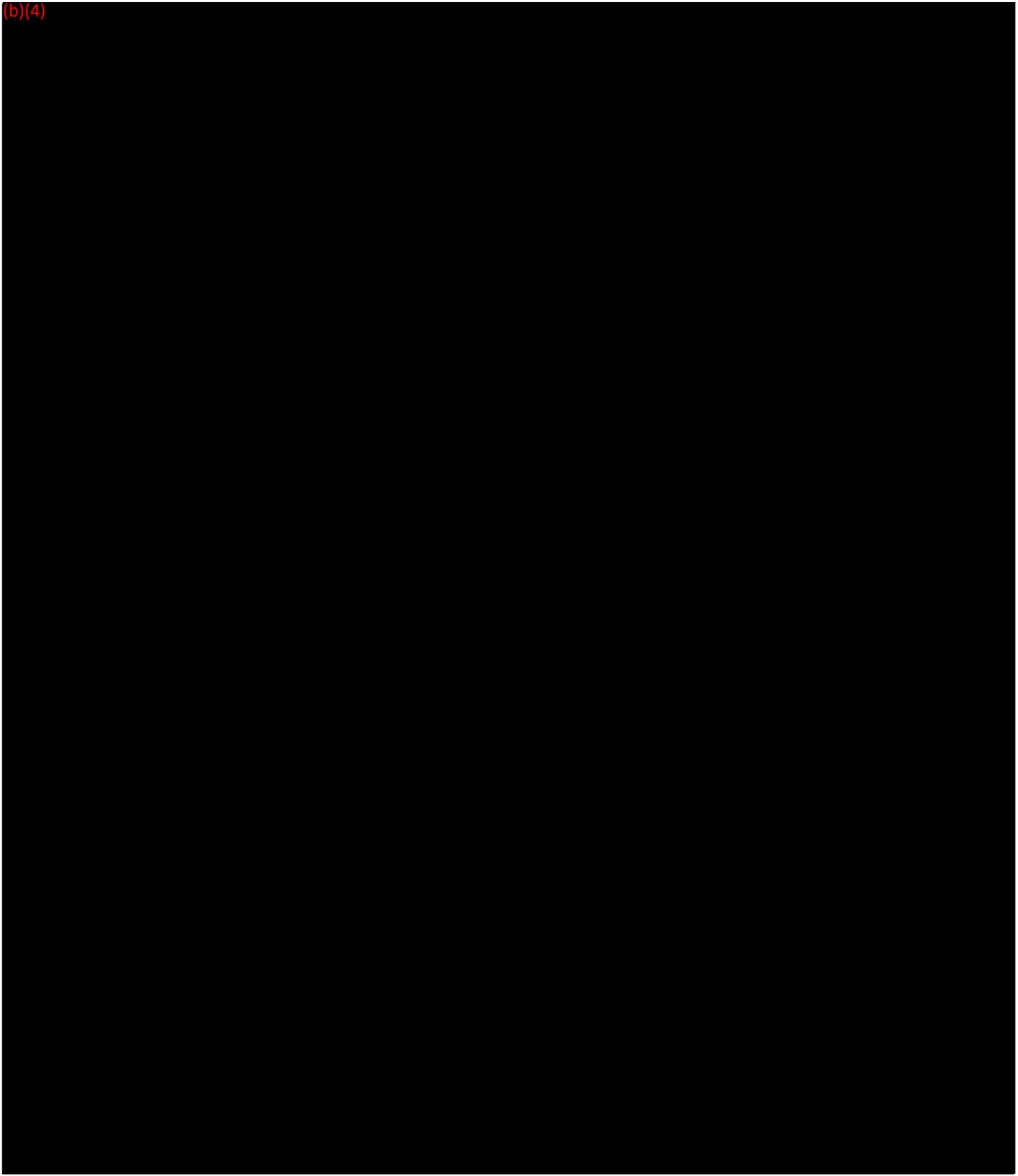
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128

BD CLINICAL STUDY: EVALUATION OF BD 0.109 M AND 0.129 M VACUTAINER™ PLUS SODIUM CITRATE TUBES FOR PLATELET COUNTS ON NORMAL AND NON-NORMAL DONORS

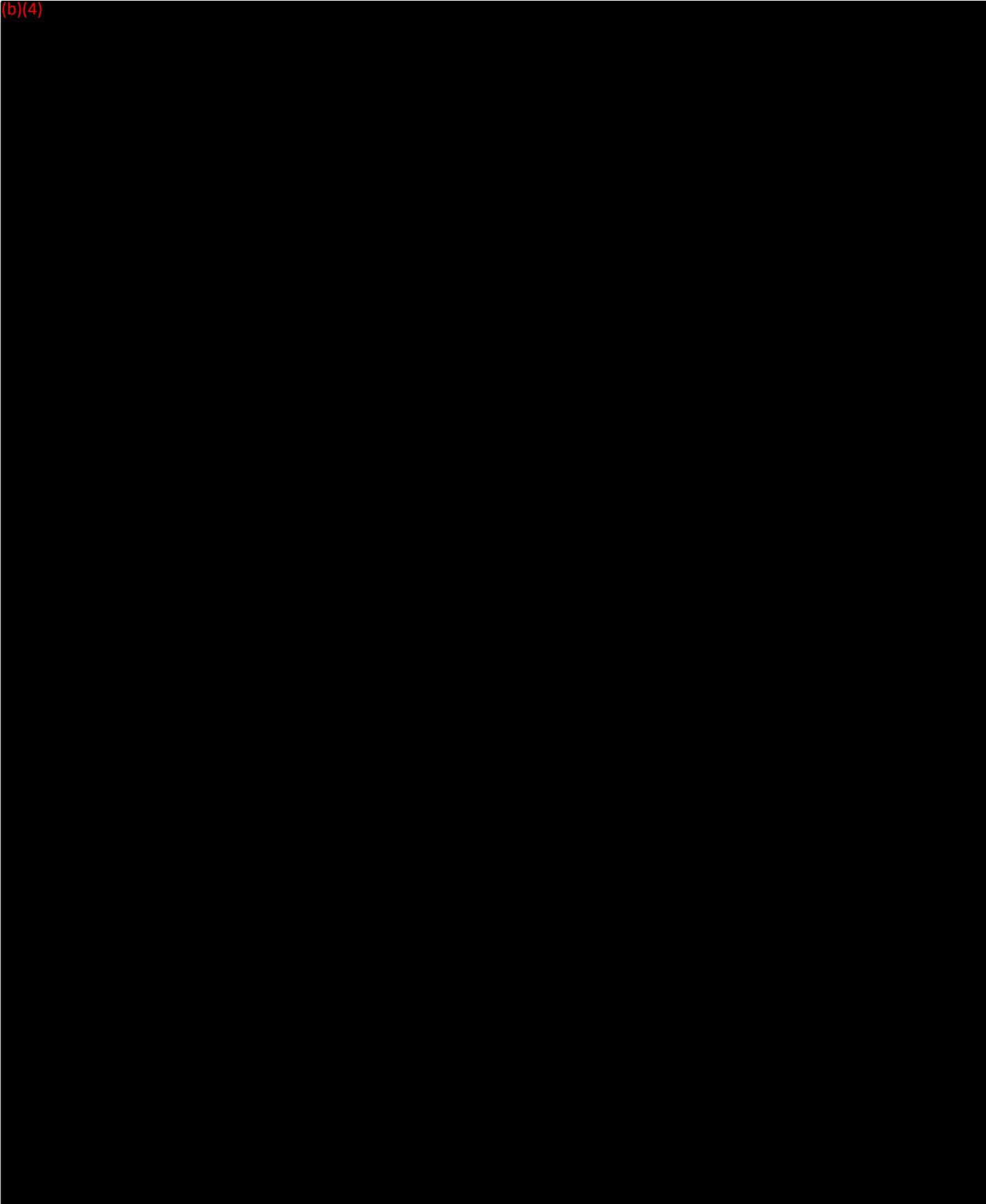
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129

BD CLINICAL STUDY: EVALUATION OF BD 0.109 M AND 0.129 M VACUTAINER™ PLUS SODIUM CITRATE TUBES FOR PLATELET COUNTS ON NORMAL AND NON-NORMAL DONORS

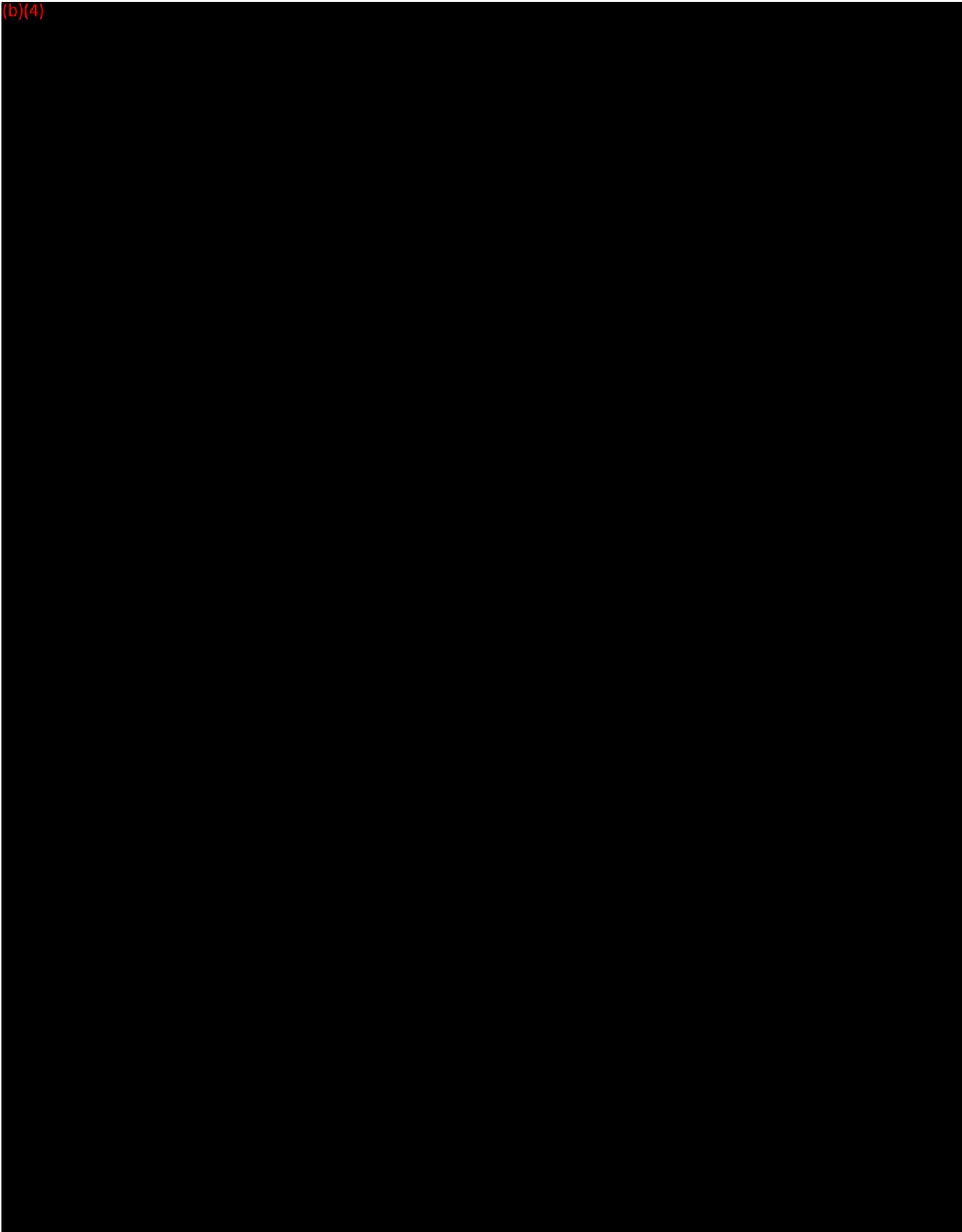
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130

BD CLINICAL STUDY: EVALUATION OF BD 0.109 M AND 0.129 M VACUTAINER™ PLUS SODIUM CITRATE TUBES FOR PLATELET COUNTS ON NORMAL AND NON-NORMAL DONORS

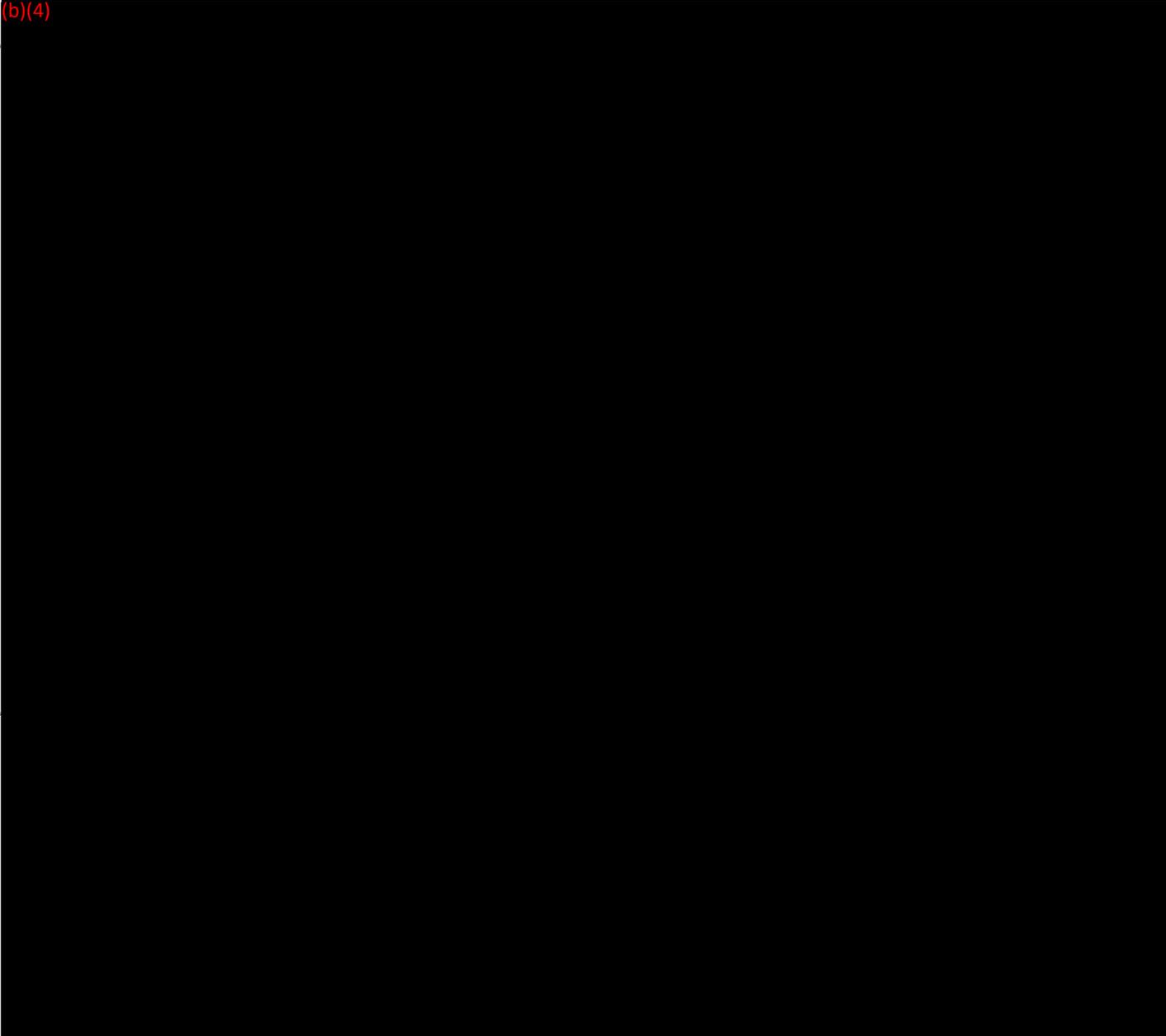
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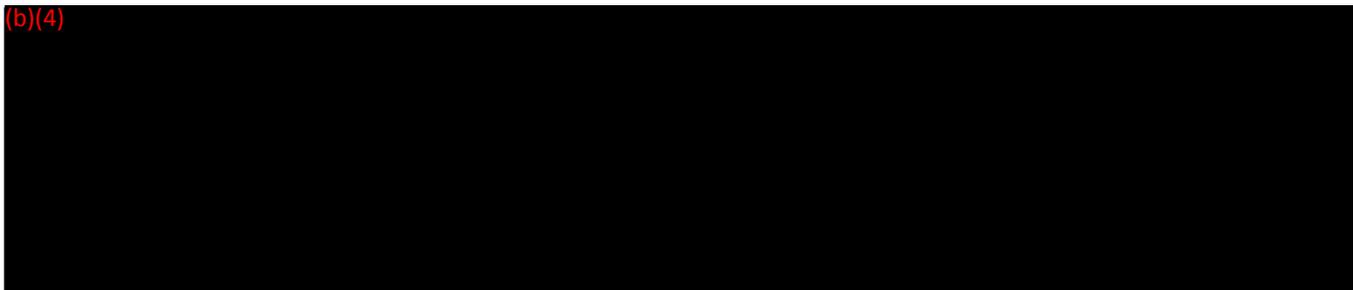
BD CLINICAL STUDY: EVALUATION OF BD 0.109 M AND 0.129 M VACUTAINER™ PLUS SODIUM CITRATE TUBES FOR PLATELET COUNTS ON NORMAL AND NON-NORMAL DONORS

(b)(4)



VI. CONCLUSIONS

(b)(4)

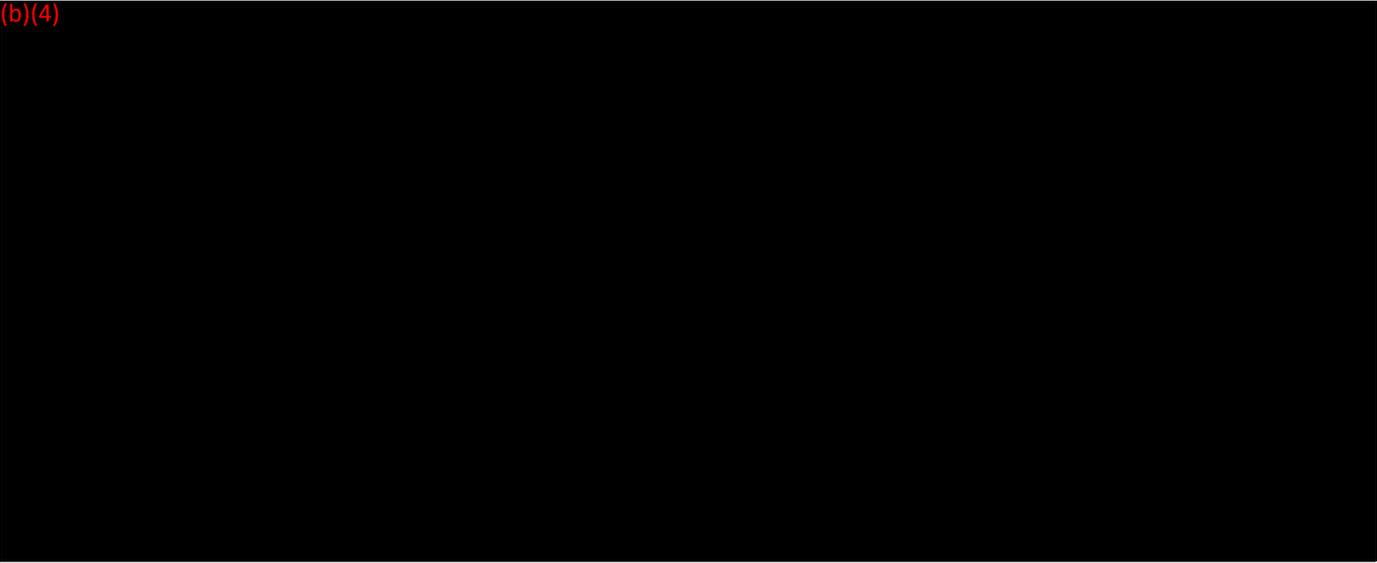


132

BD CLINICAL STUDY: EVALUATION OF BD 0.109 M AND 0.129 M VACUTAINER™ PLUS SODIUM CITRATE TUBES FOR PLATELET COUNTS ON NORMAL AND NON-NORMAL DONORS

VII. REFERENCES

(b)(4)



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ATTACHMENT 6: CLINICAL EVALUATION- AT

(b)(4)

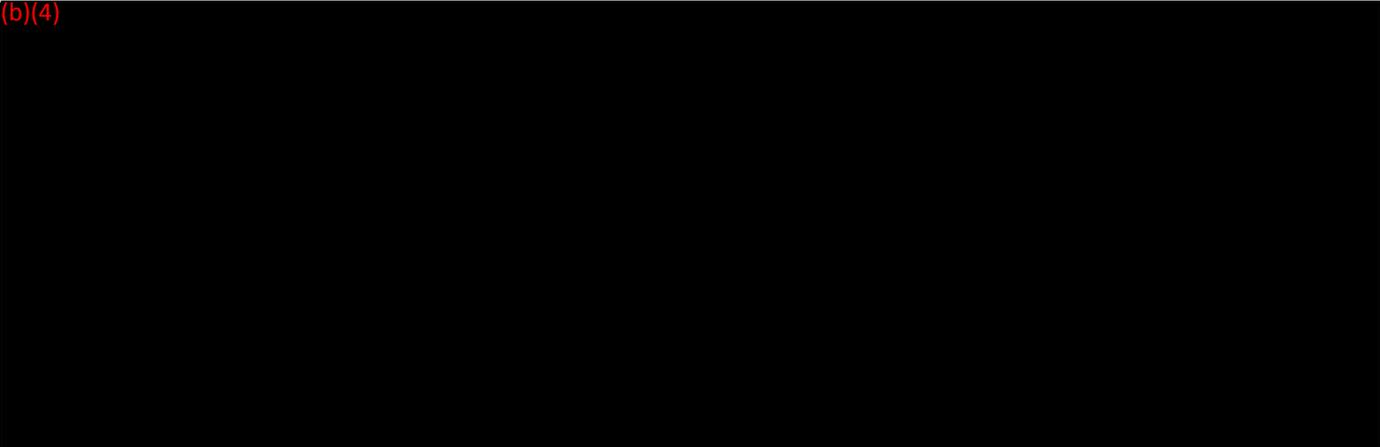
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134

BD CLINICAL STUDY: EVALUATION OF 0.109 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES USING THE ELECTRA 1409C™ ANALYZER

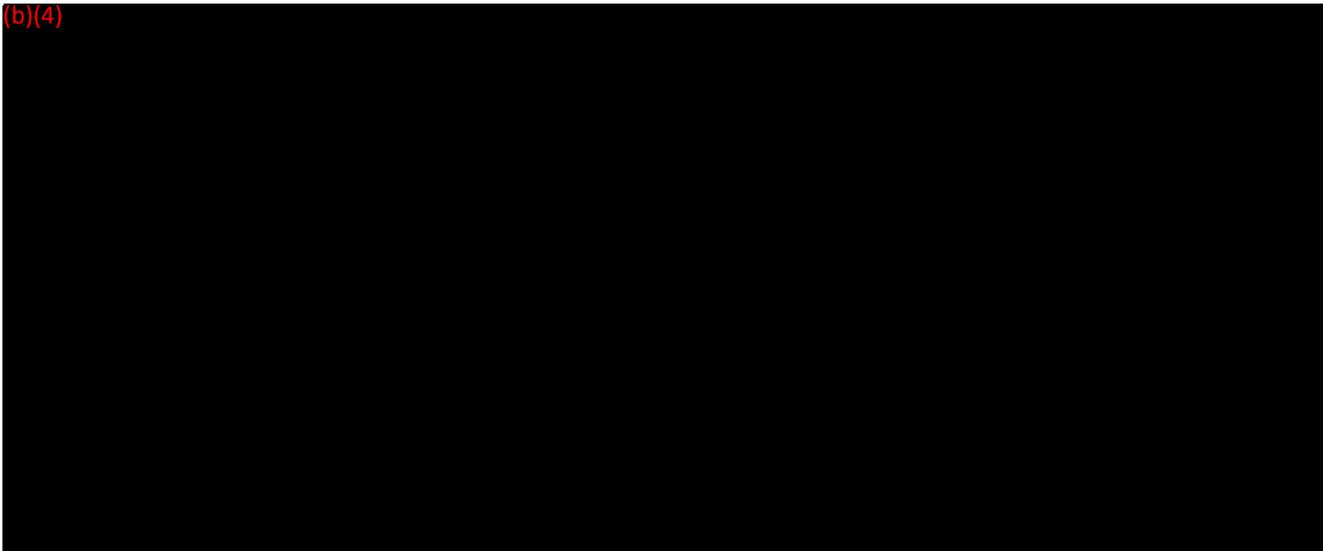
ABSTRACT

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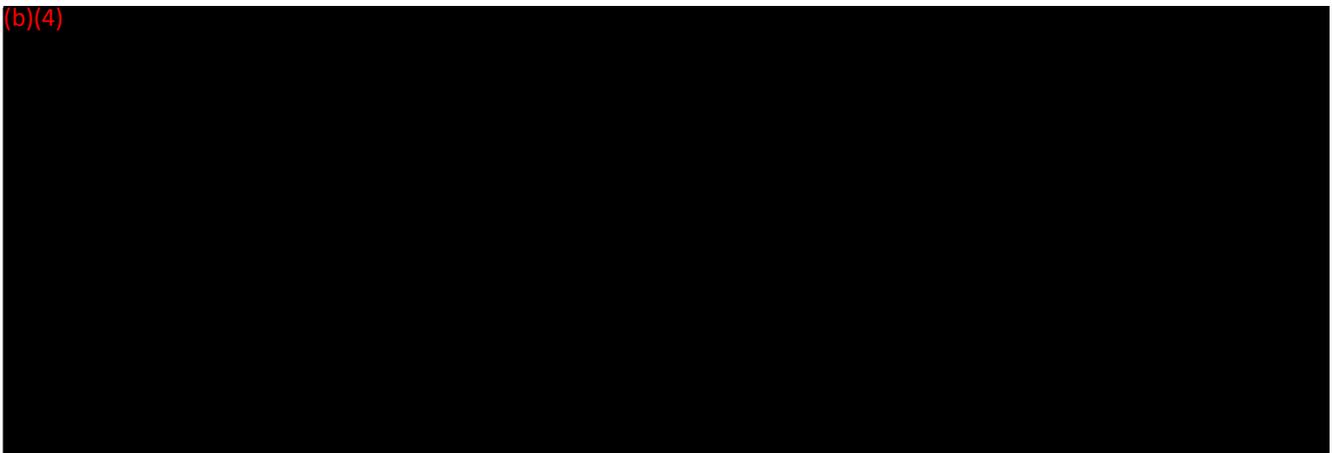
I. INTRODUCTION

(b)(4)



II. OBJECTIVE

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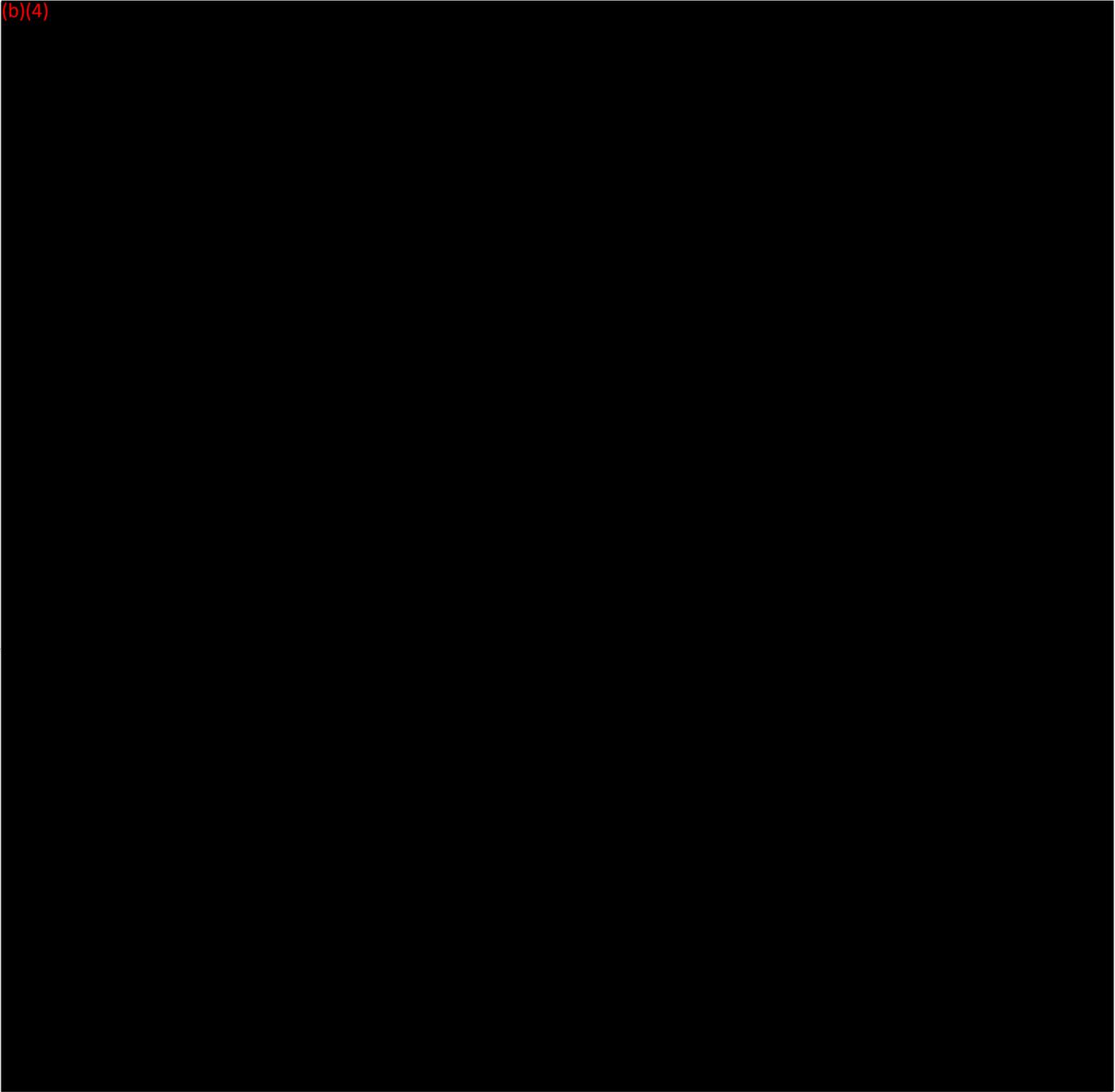


135

BD CLINICAL STUDY: EVALUATION OF 0.109 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES USING THE ELECTRA 1400C™ ANALYZER

III. METHODS AND MATERIALS

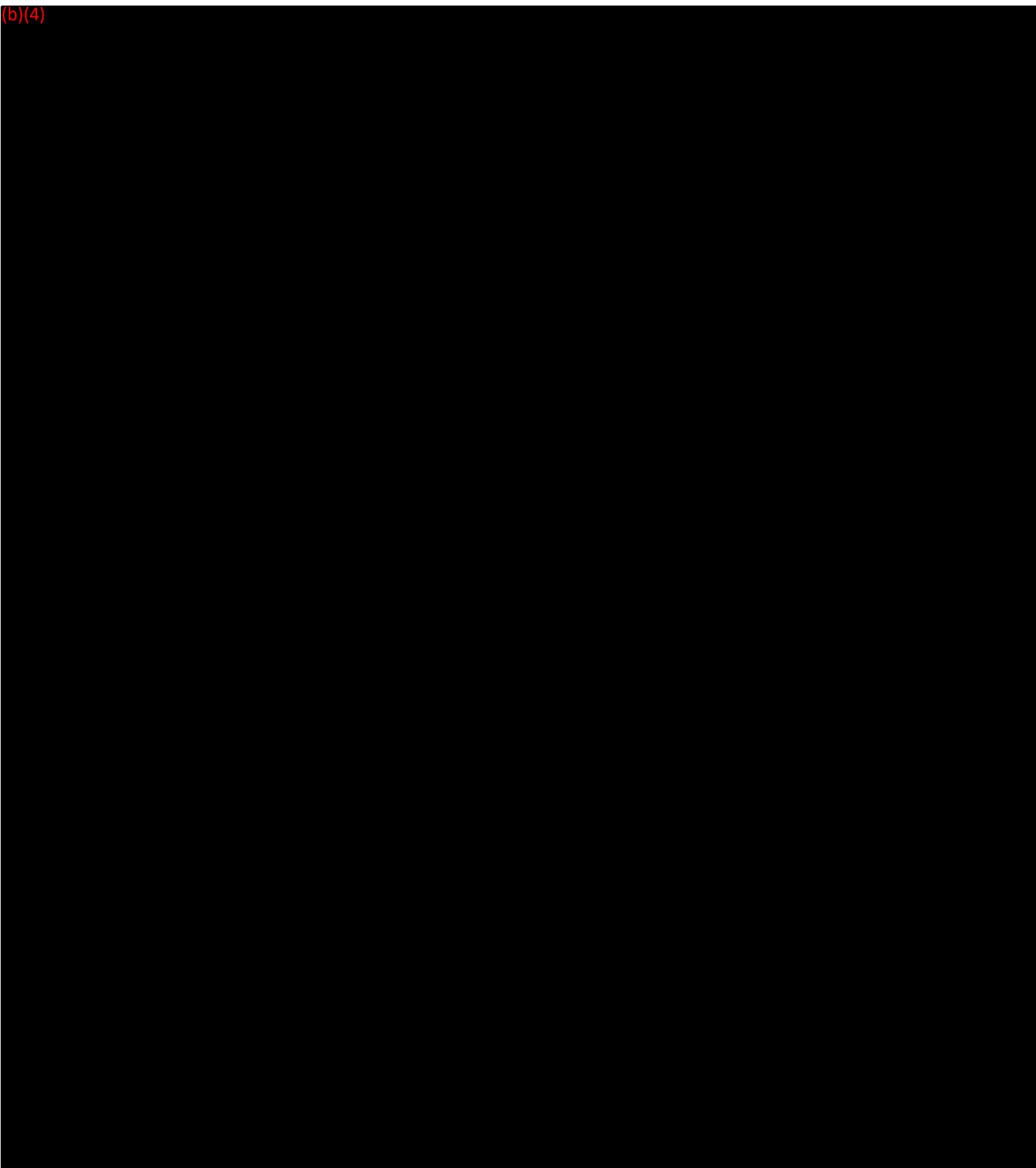
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**BD CLINICAL STUDY: EVALUATION OF 0.109 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS
SODIUM CITRATE TUBES USING THE ELECTRA 1400C™ ANALYZER**

IV. DATA ANALYSIS

(b)(4)

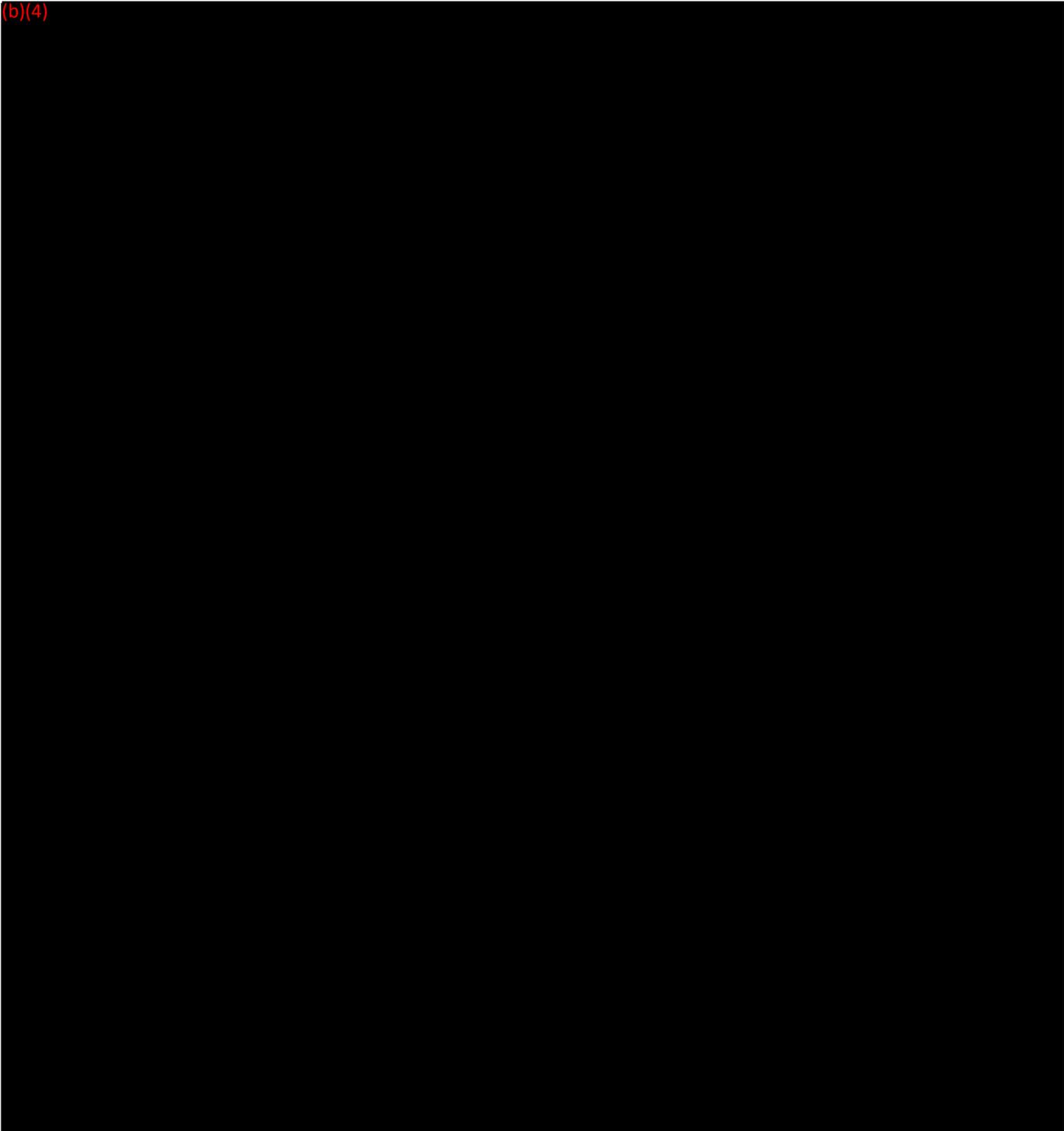


137

BD CLINICAL STUDY: EVALUATION OF 0.109 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES USING THE ELECTRA 1400C™ ANALYZER

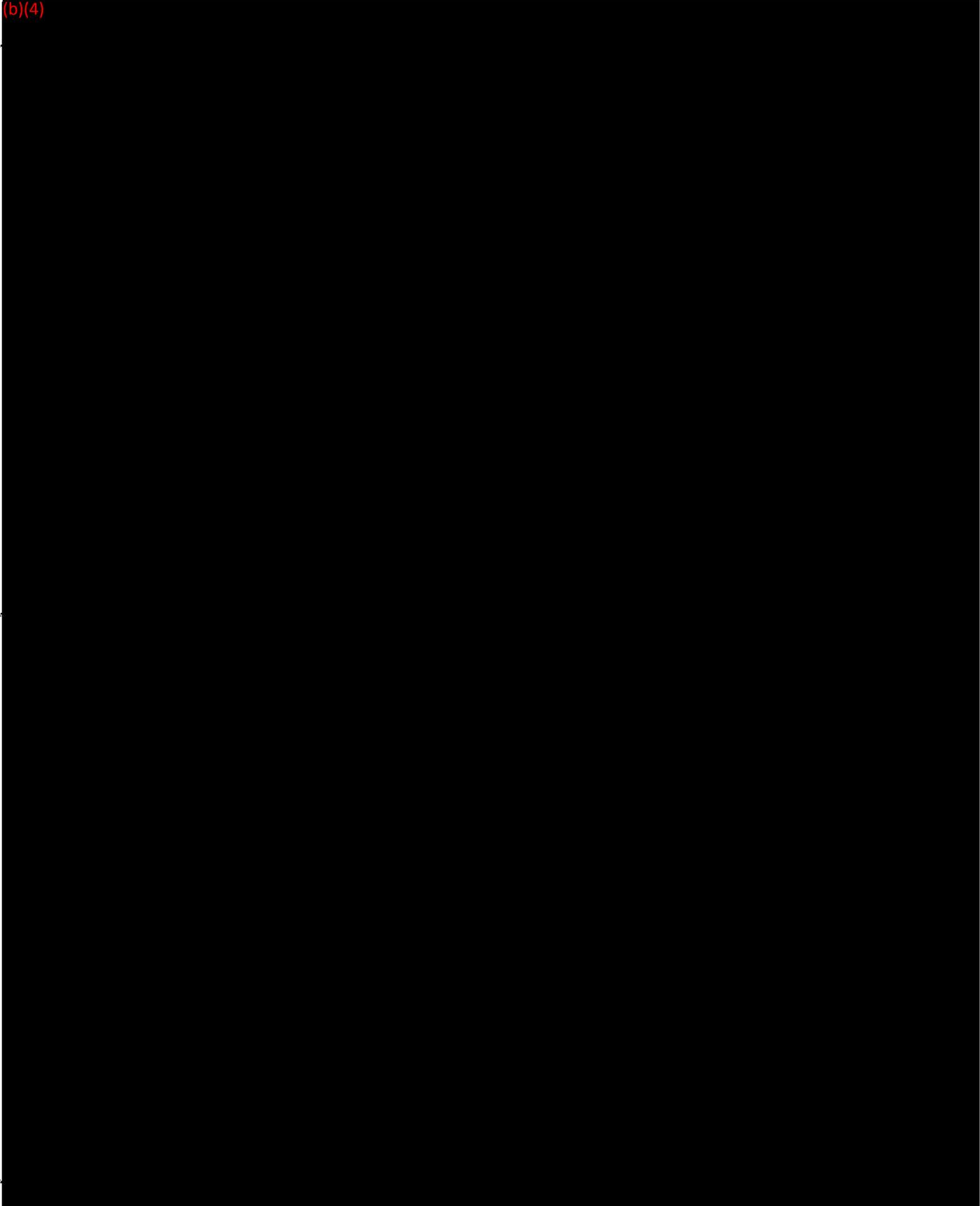
V. RESULTS AND DISCUSSION

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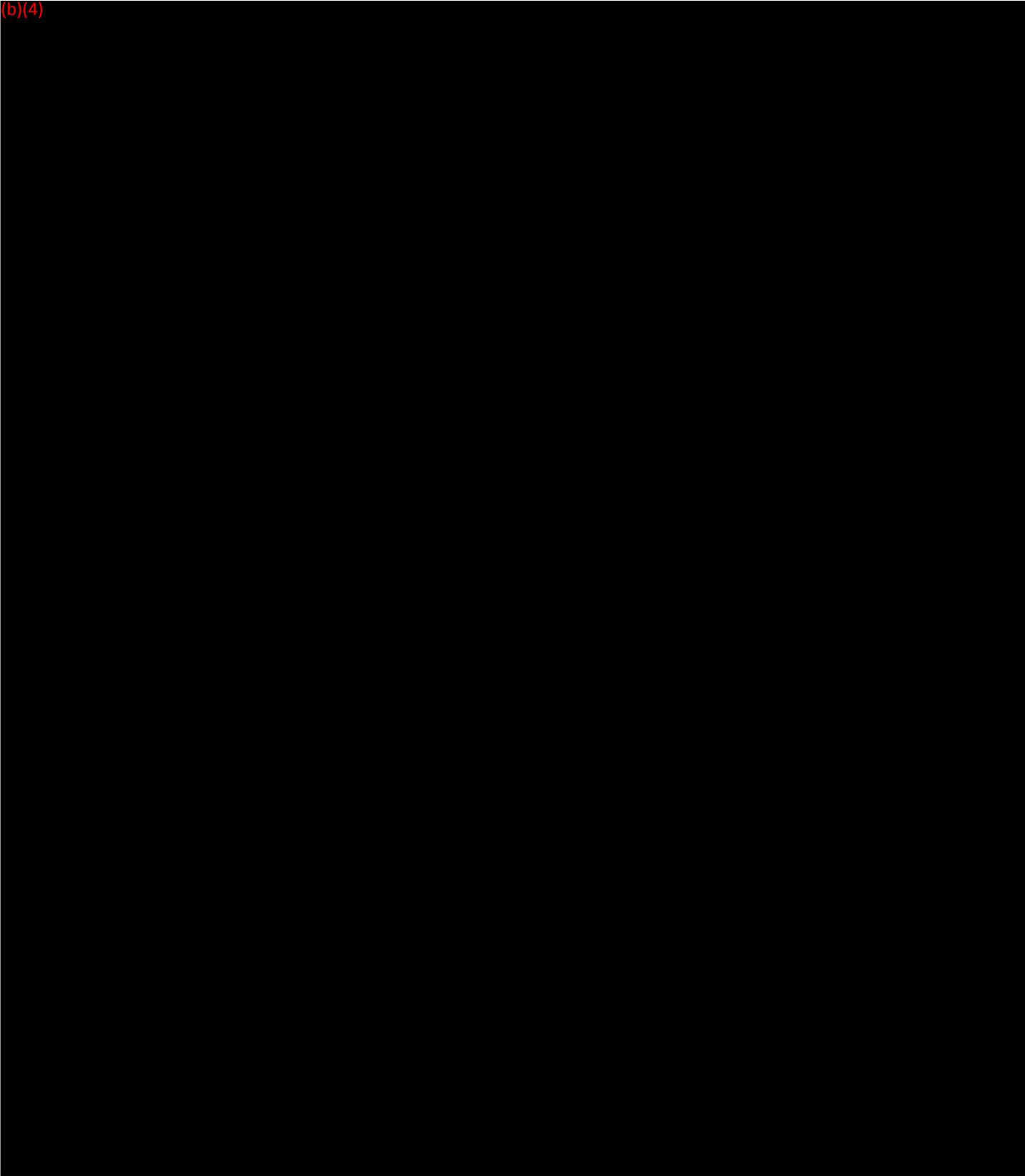
BD CLINICAL STUDY: EVALUATION OF 0.109 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES USING THE ELECTRA 1400C™ ANALYZER



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**BD CLINICAL STUDY: EVALUATION OF 0.109 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS
SODIUM CITRATE TUBES USING THE ELECTRA 1400C™ ANALYZER**

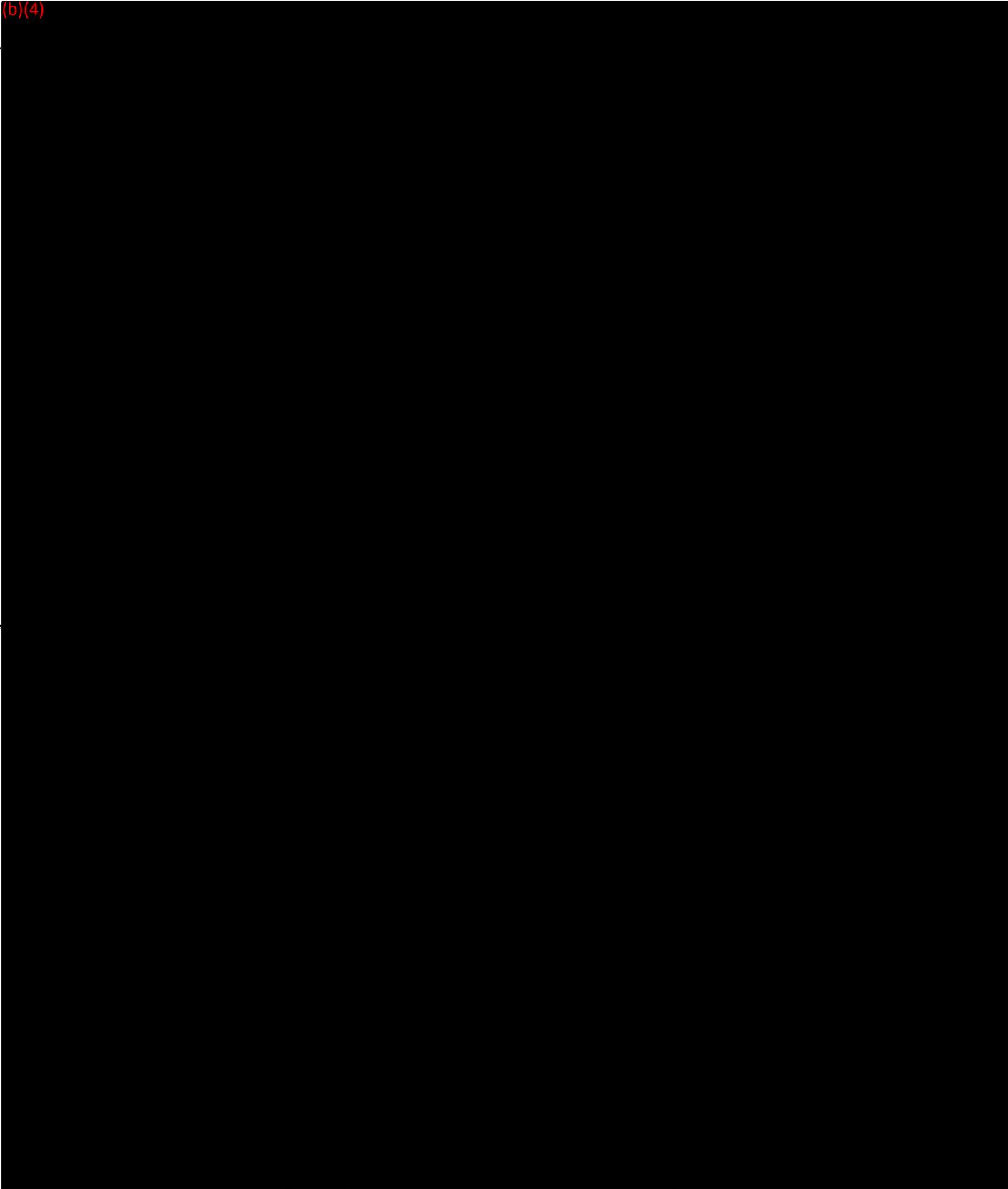
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140

**BD CLINICAL STUDY: EVALUATION OF 0.109 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS
SODIUM CITRATE TUBES USING THE ELECTRA 1400C™ ANALYZER**

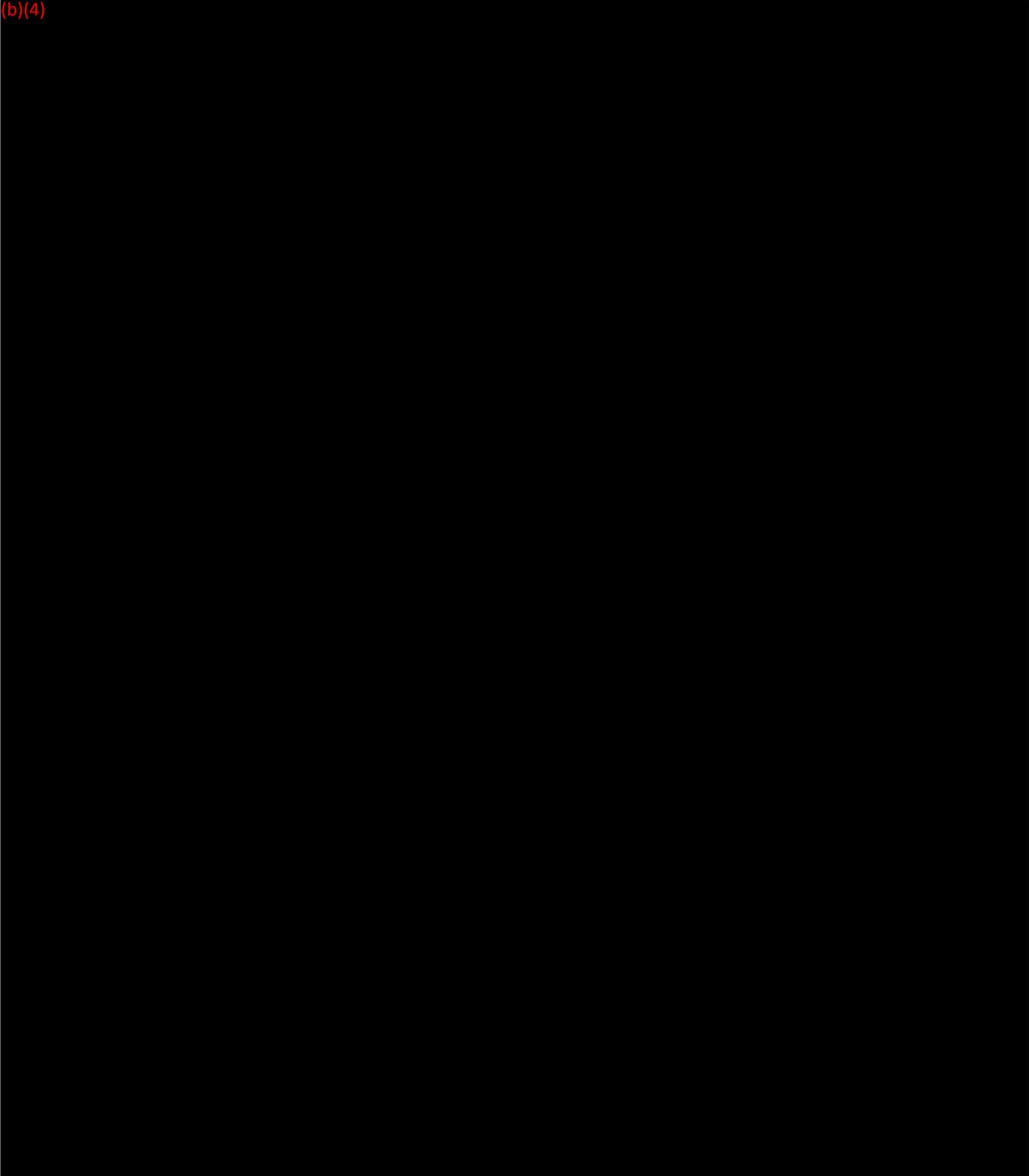
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141

**BD CLINICAL STUDY: EVALUATION OF 0.109 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS
SODIUM CITRATE TUBES USING THE ELECTRA 1400C™ ANALYZER**

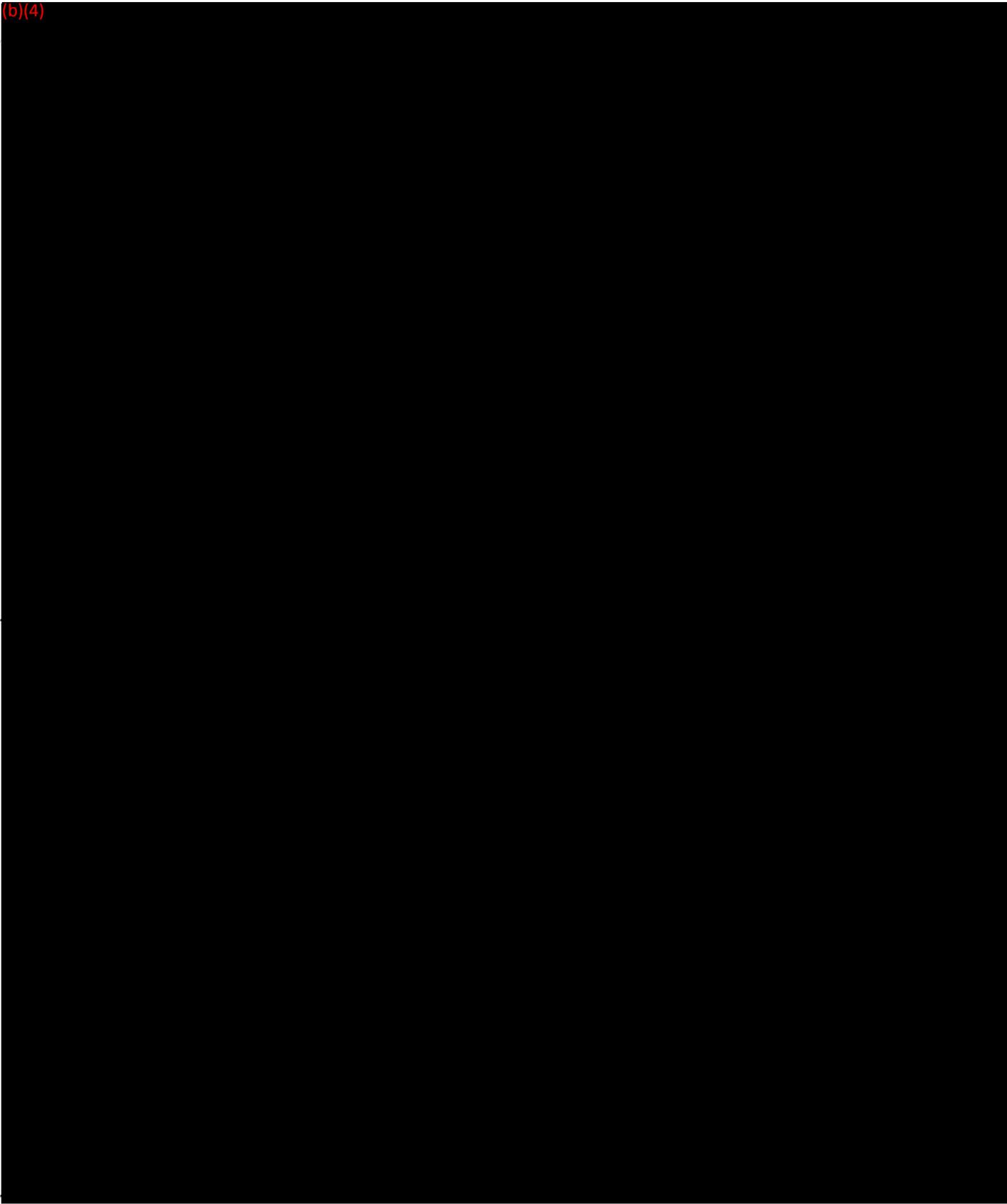
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142

**BD CLINICAL STUDY: EVALUATION OF 0.109 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS
SODIUM CITRATE TUBES USING THE ELECTRA 1400C™ ANALYZER**

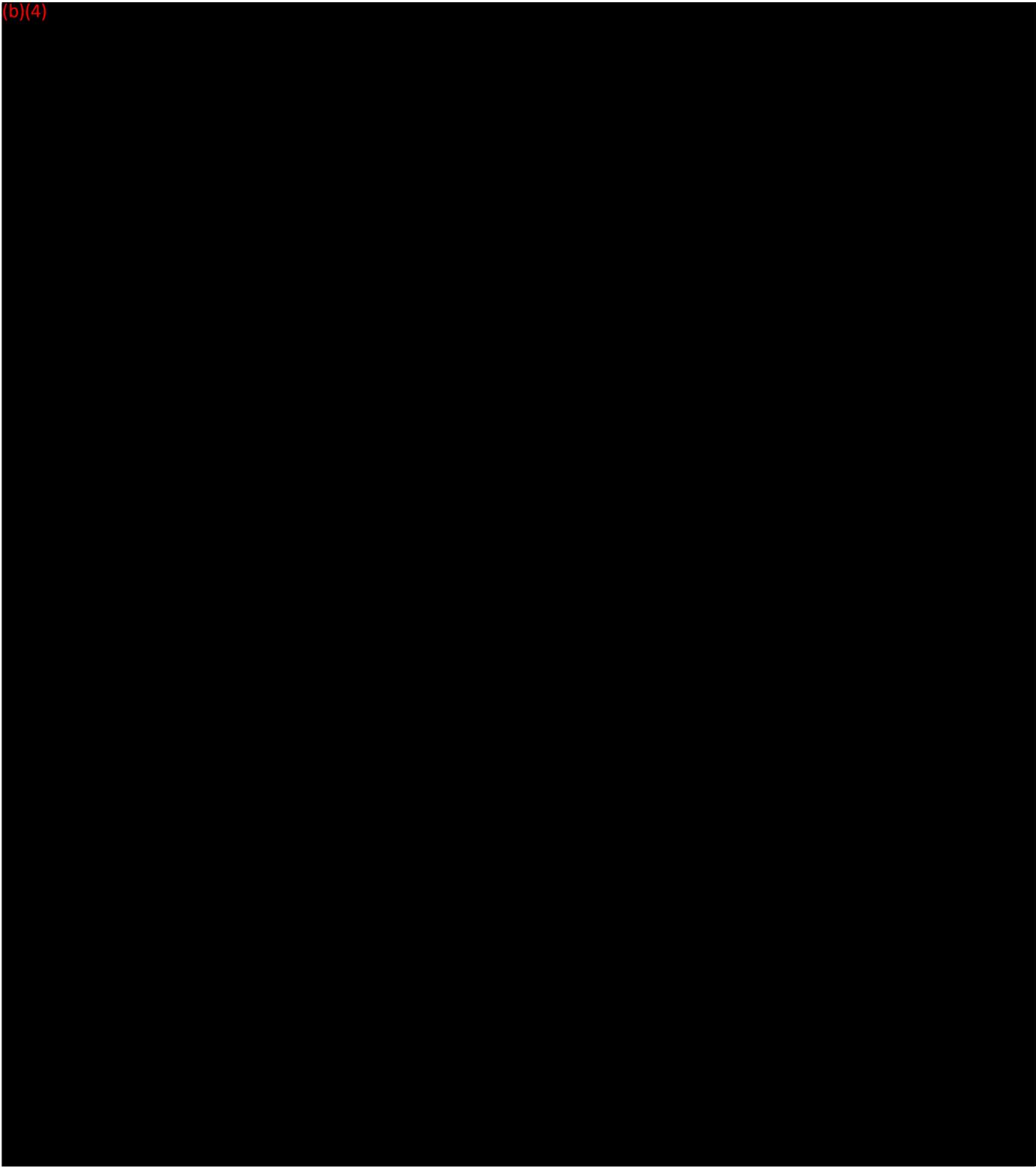
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143

**BD CLINICAL STUDY: EVALUATION OF 0.109 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS
SODIUM CITRATE TUBES USING THE ELECTRA 1400C™ ANALYZER**

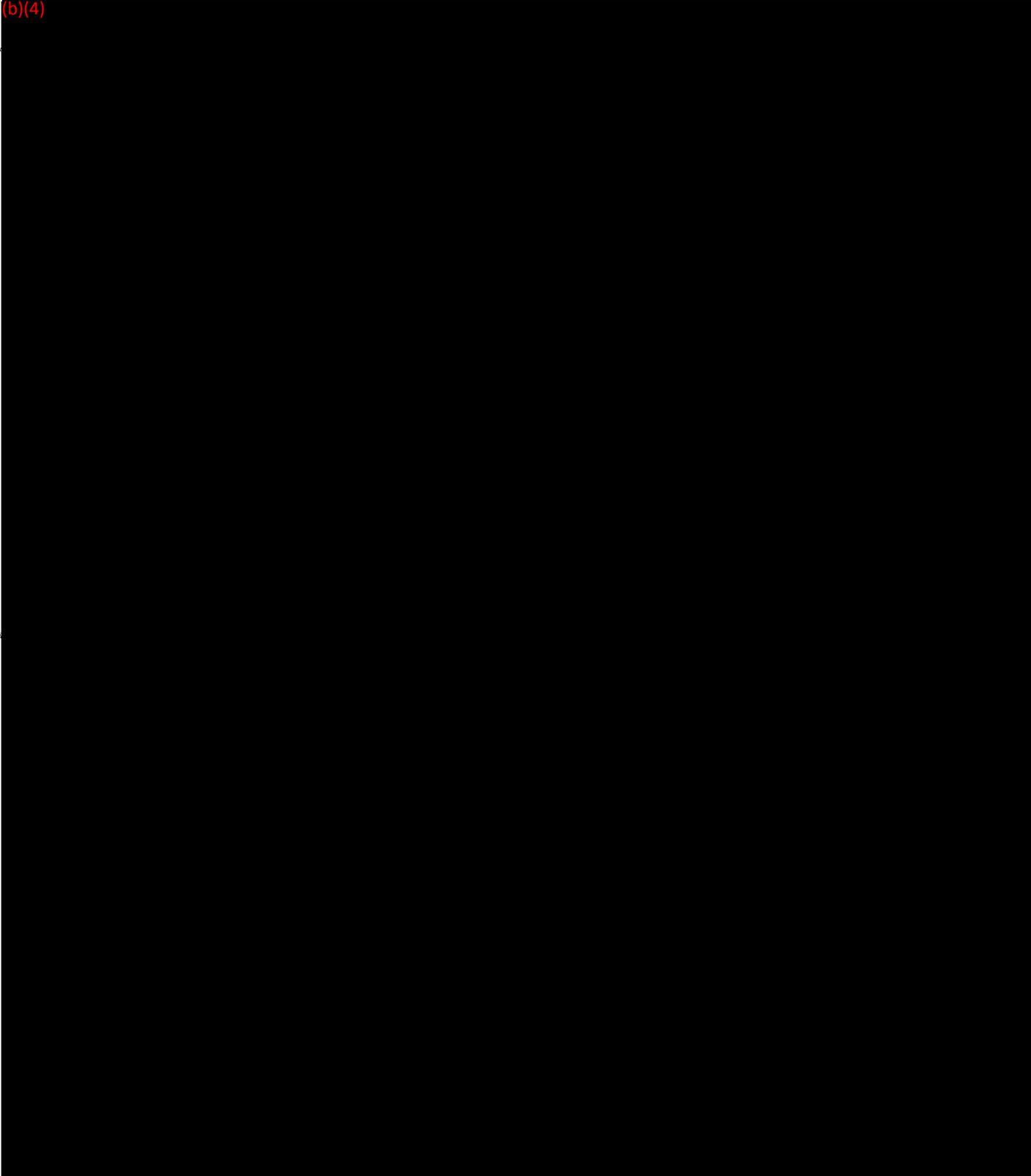
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144

**BD CLINICAL STUDY: EVALUATION OF 0.109 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS
SODIUM CITRATE TUBES USING THE ELECTRA 1400C™ ANALYZER**

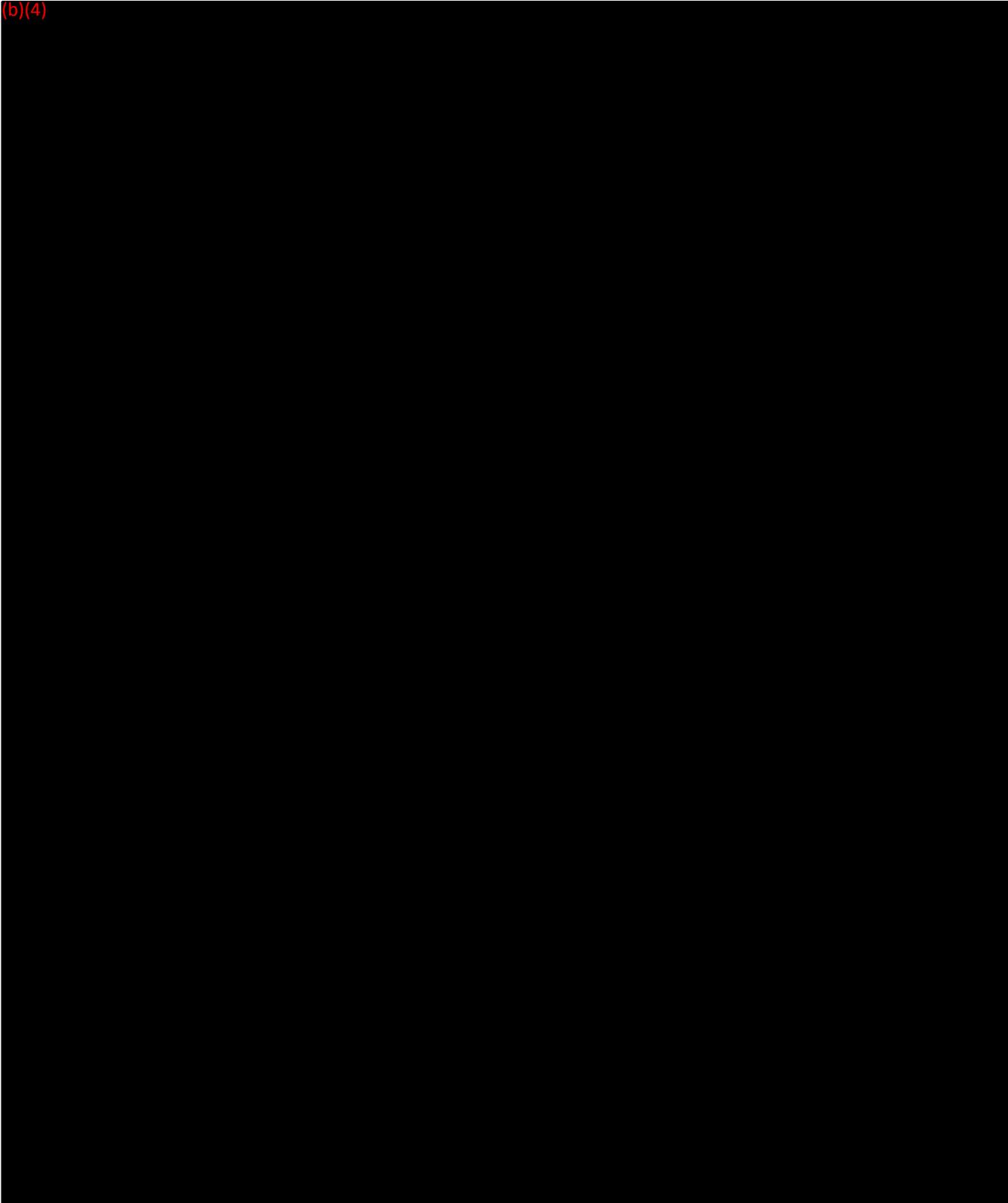
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145

**BD CLINICAL STUDY: EVALUATION OF 0.109 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS
SODIUM CITRATE TUBES USING THE ELECTRA 1400C™ ANALYZER**

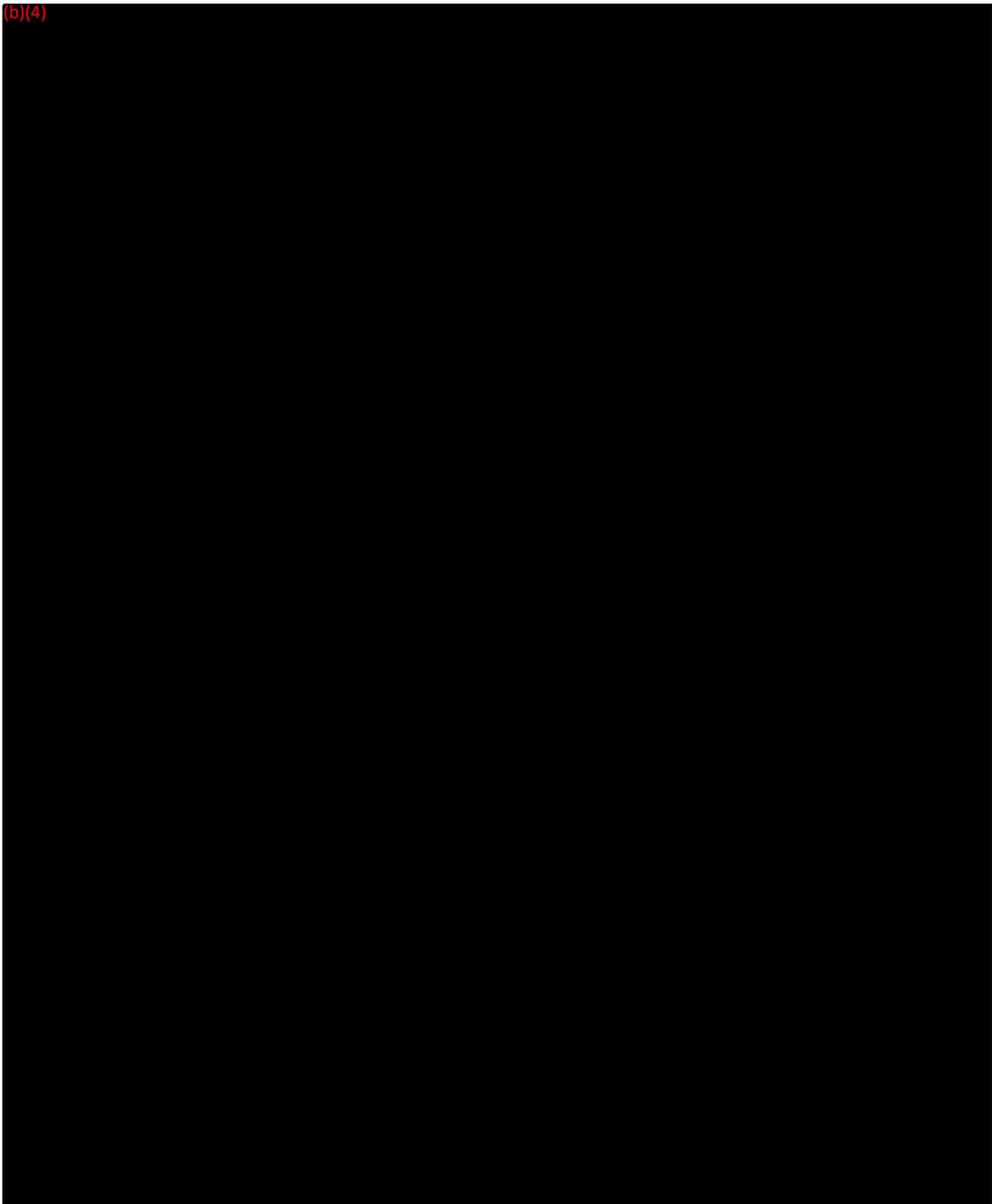
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146

**BD CLINICAL STUDY: EVALUATION OF 0.109 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS
SODIUM CITRATE TUBES USING THE ELECTRA 1400C™ ANALYZER**

(b)(4)

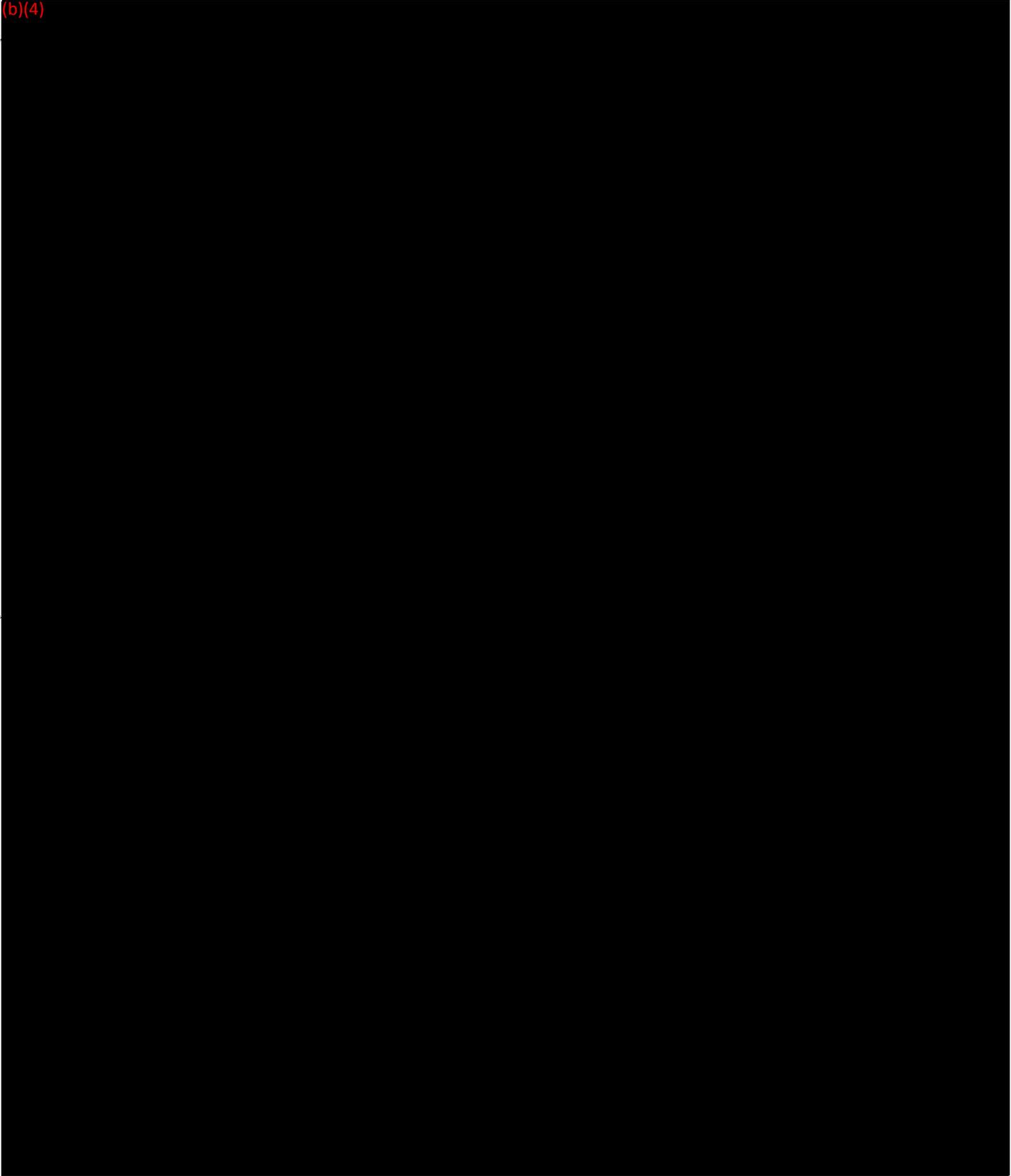


(Table VI).

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**BD CLINICAL STUDY: EVALUATION OF 0.109 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS
SODIUM CITRATE TUBES USING THE ELECTRA 1400C™ ANALYZER**

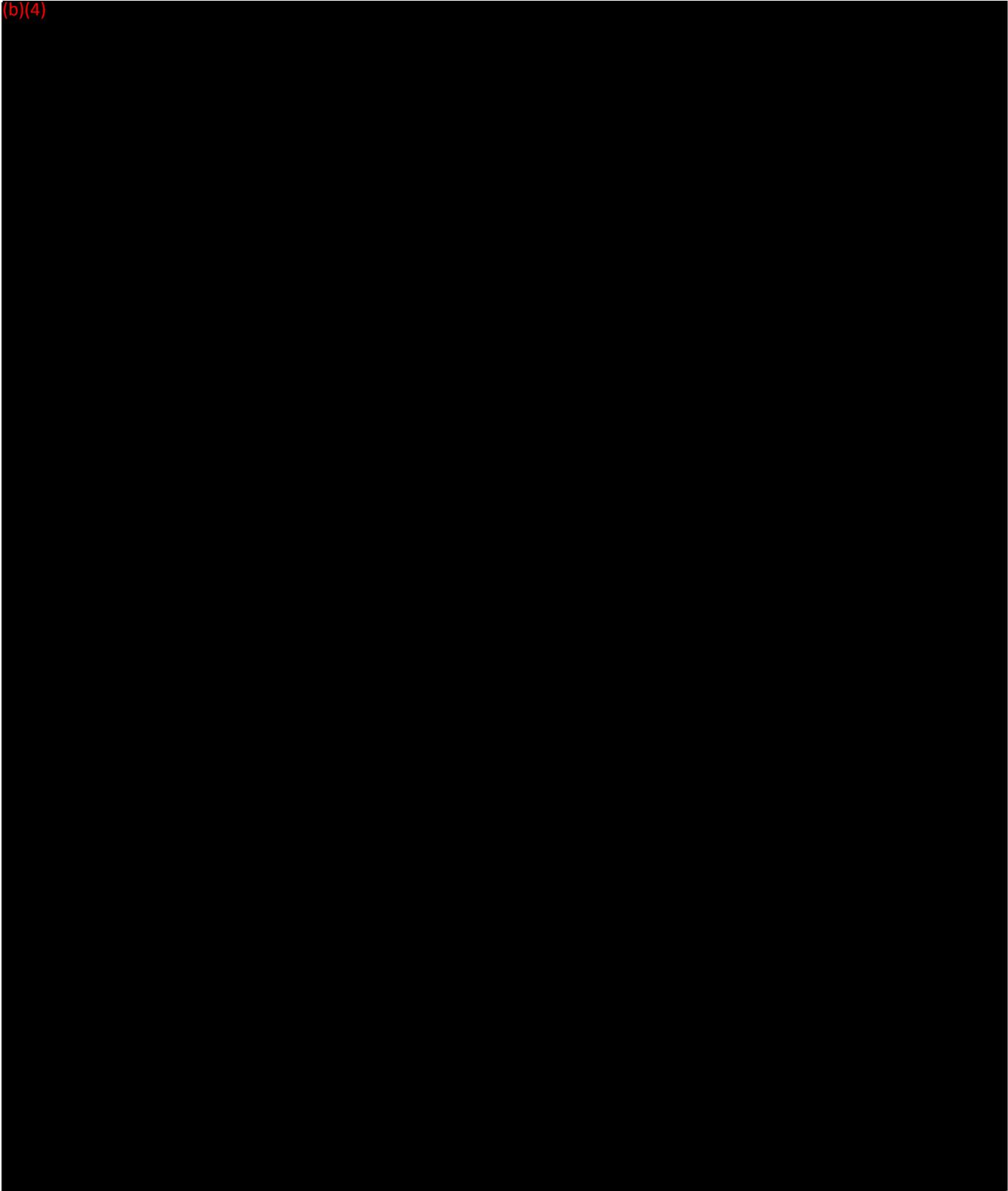
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148

**BD CLINICAL STUDY: EVALUATION OF 0.109 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS
SODIUM CITRATE TUBES USING THE ELECTRA 1400C™ ANALYZER**

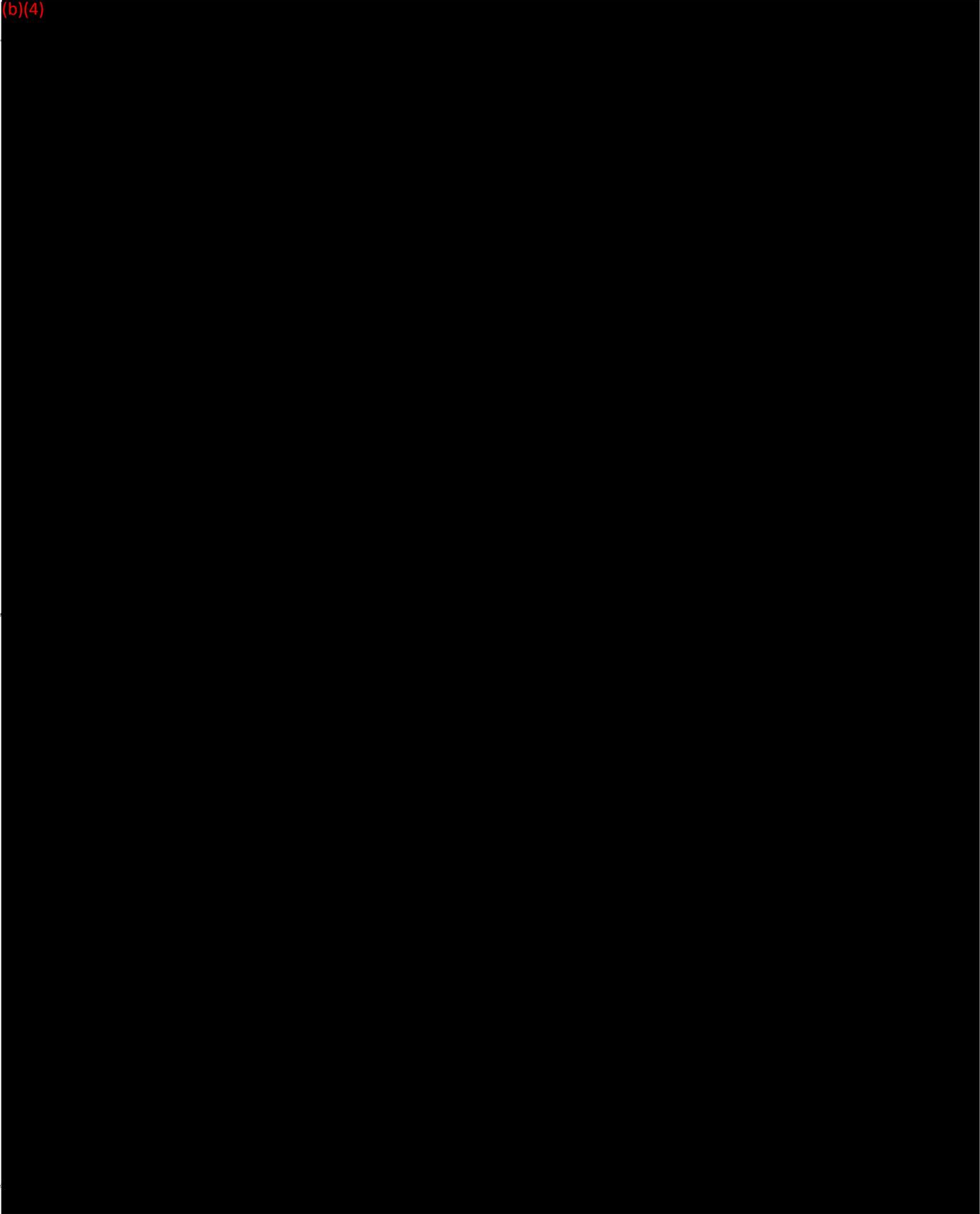
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149

**BD CLINICAL STUDY: EVALUATION OF 0.109 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS
SODIUM CITRATE TUBES USING THE ELECTRA 1400C™ ANALYZER**

(b)(4)



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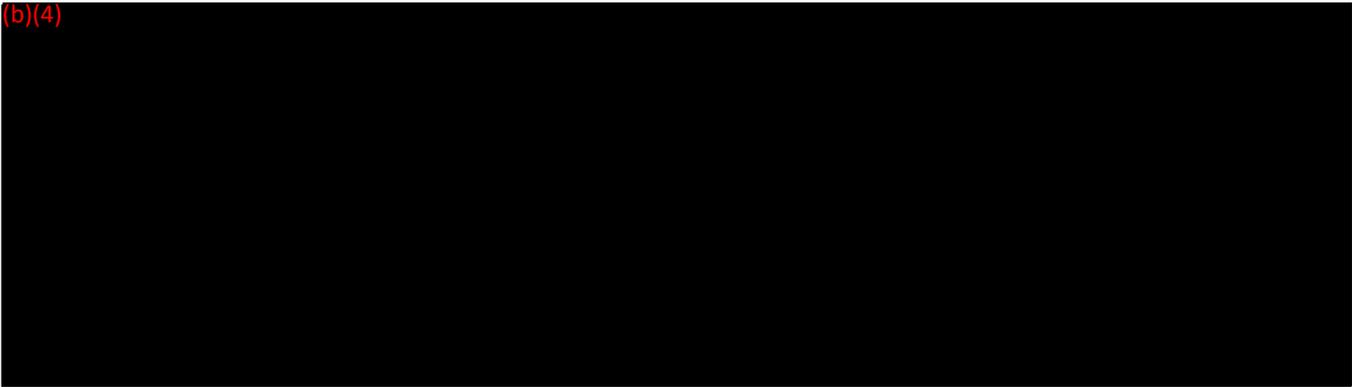
BD CLINICAL STUDY: EVALUATION OF 0.109 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES USING THE ELECTRA 1600C™ ANALYZER

(b)(4)



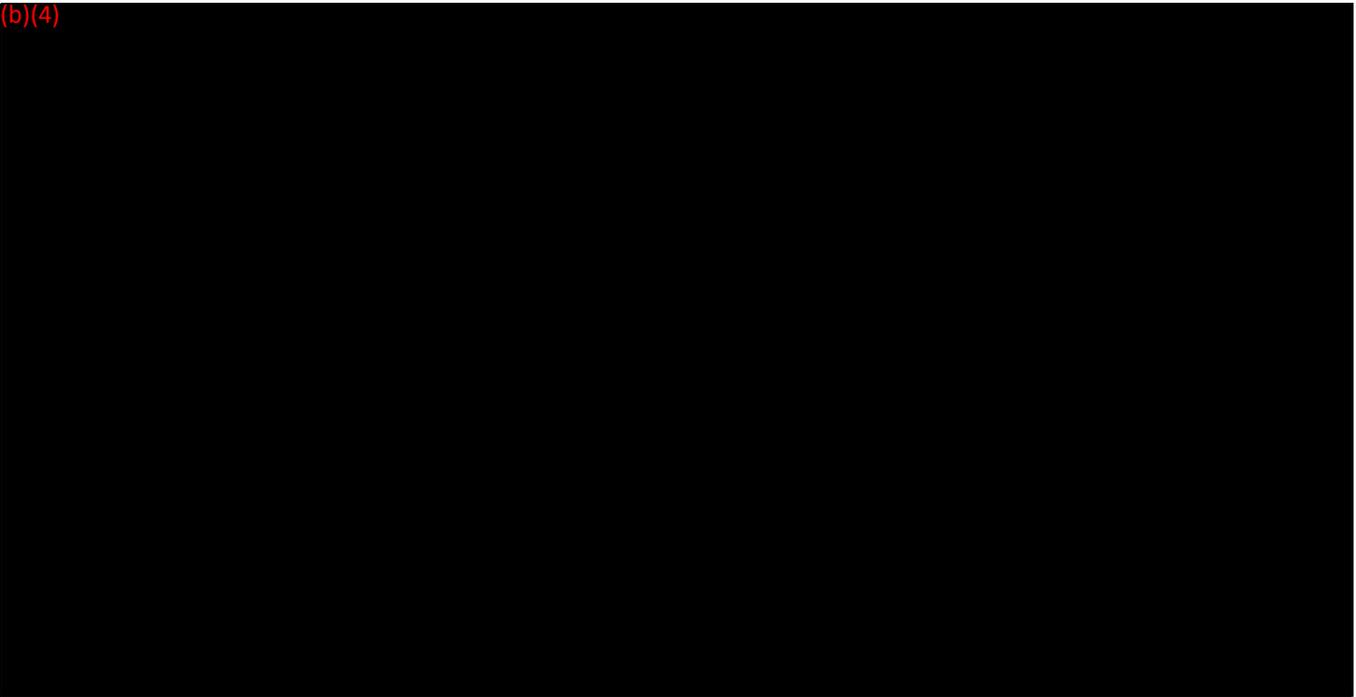
VI. CONCLUSIONS

(b)(4)



VII. REFERENCES

(b)(4)



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ATTACHMENT 7: CLINICAL EVALUATION- AT

(b)(4)

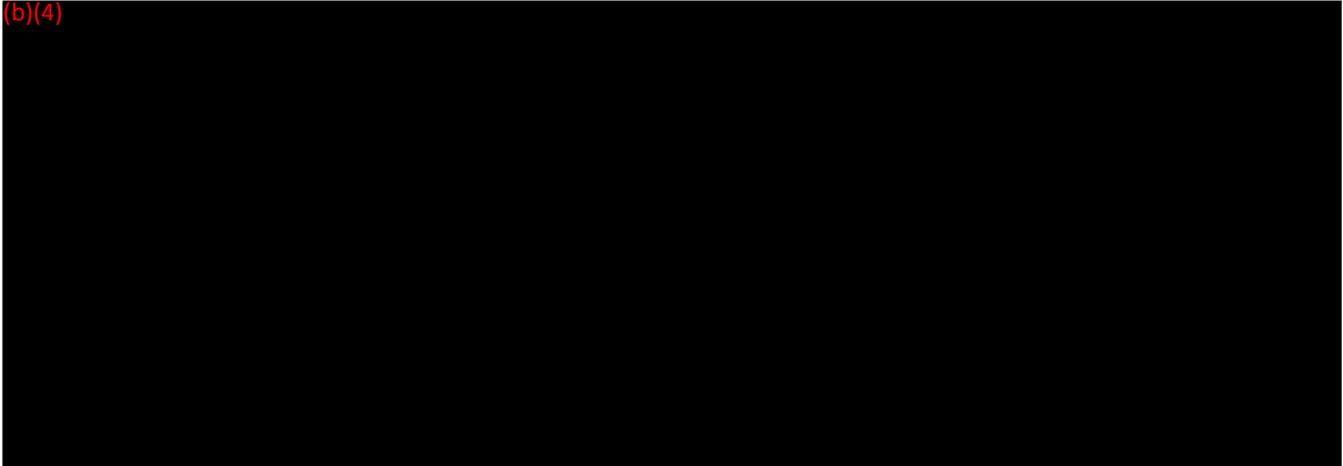
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152

**BD CLINICAL STUDY: EVALUATION OF 0.129 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS
SODIUM CITRATE TUBES USING THE ELECTRA 1400C™ ANALYZER**

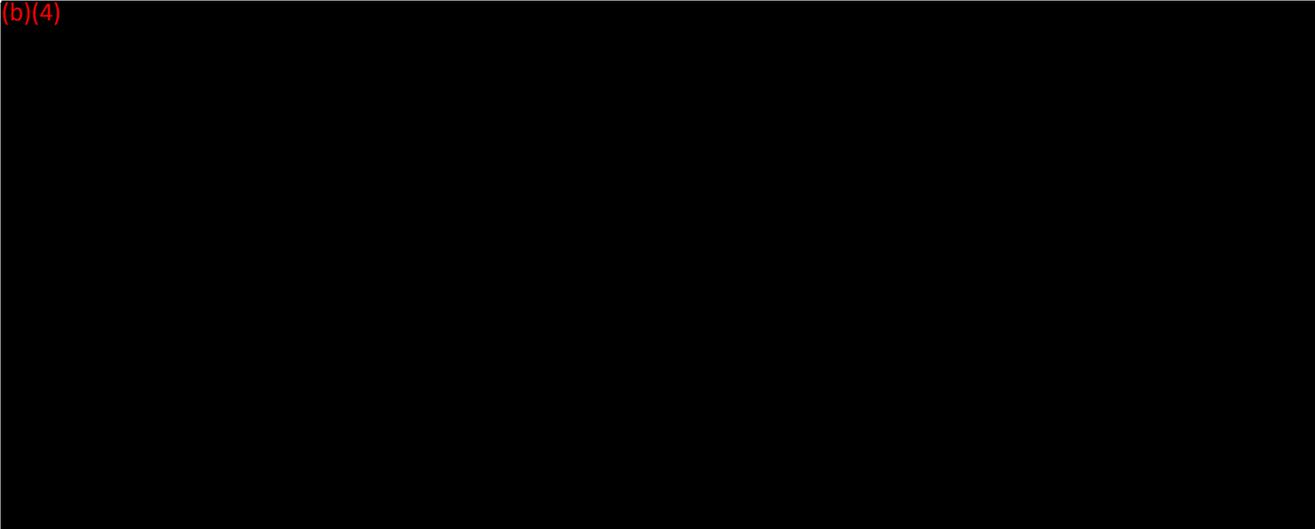
ABSTRACT

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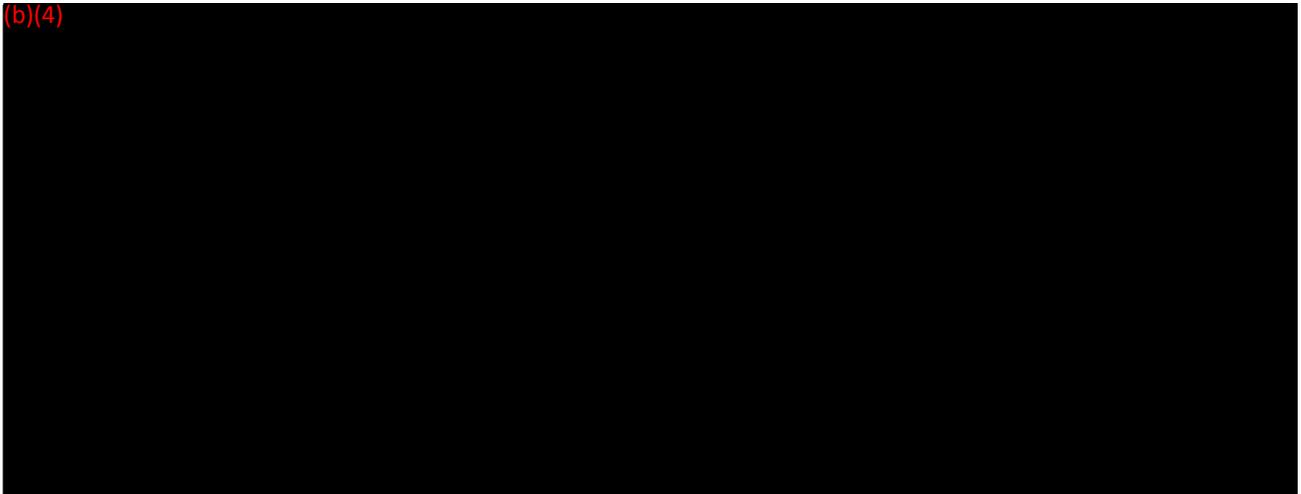
I. INTRODUCTION

(b)(4)



II. OBJECTIVE

(b)(4)

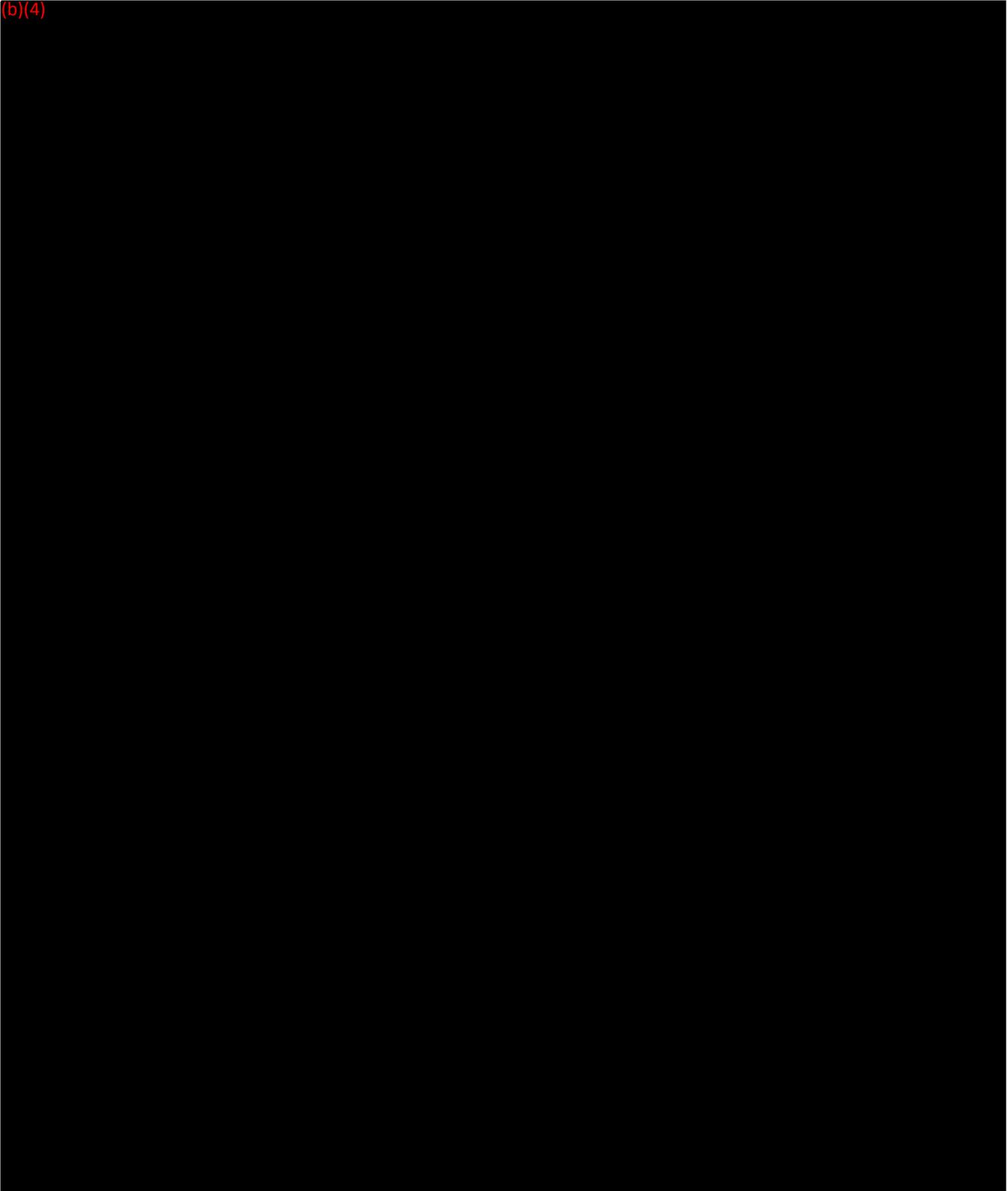


153

**BD CLINICAL STUDY: EVALUATION OF 0.129 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS
SODIUM CITRATE TUBES USING THE ELECTRA 1400C™ ANALYZER**

III. METHODS AND MATERIALS

(b)(4)

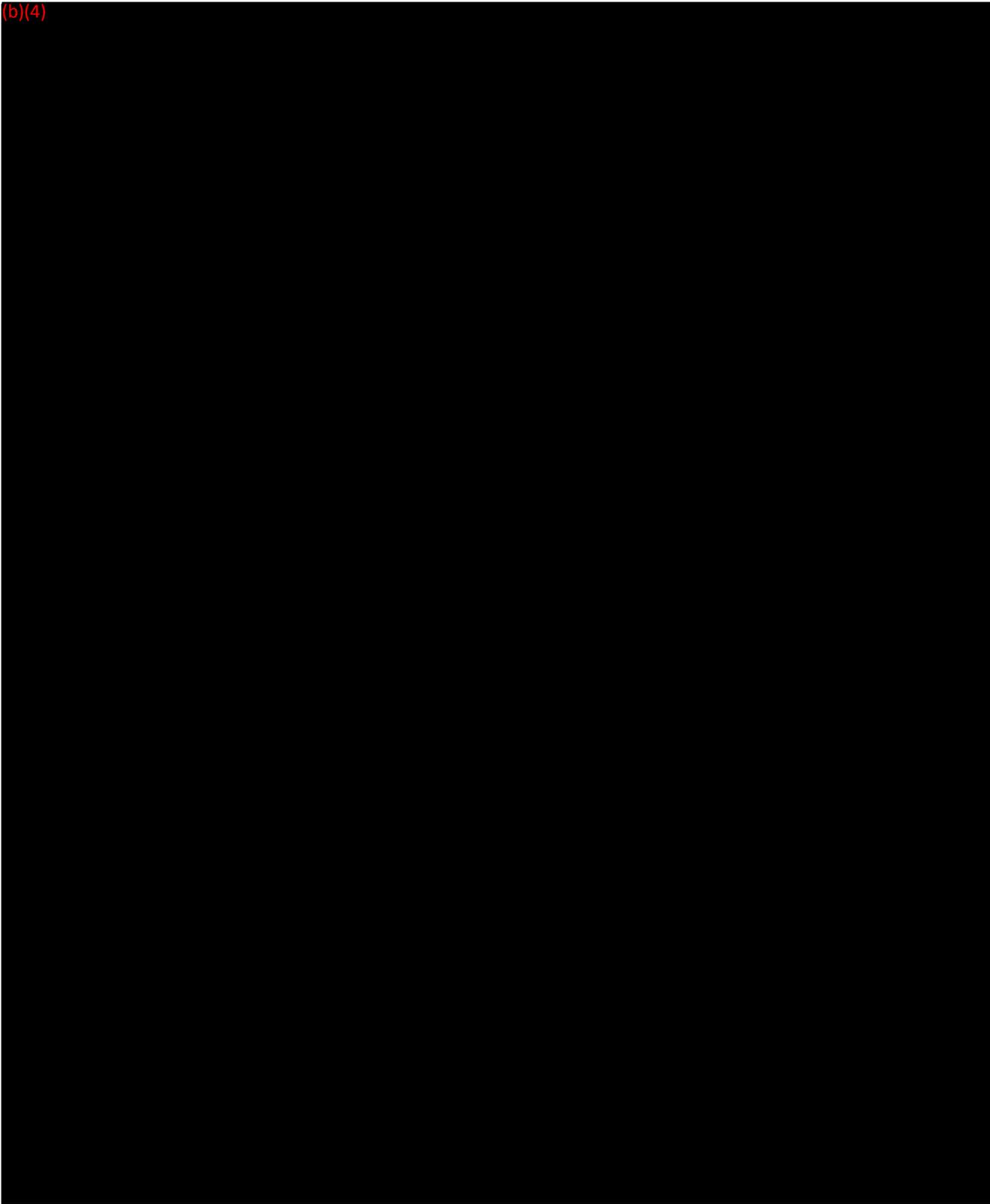


154

BD CLINICAL STUDY: EVALUATION OF 0.129 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES USING THE ELECTRA 1400C™ ANALYZER

IV. DATA ANALYSIS

(b)(4)

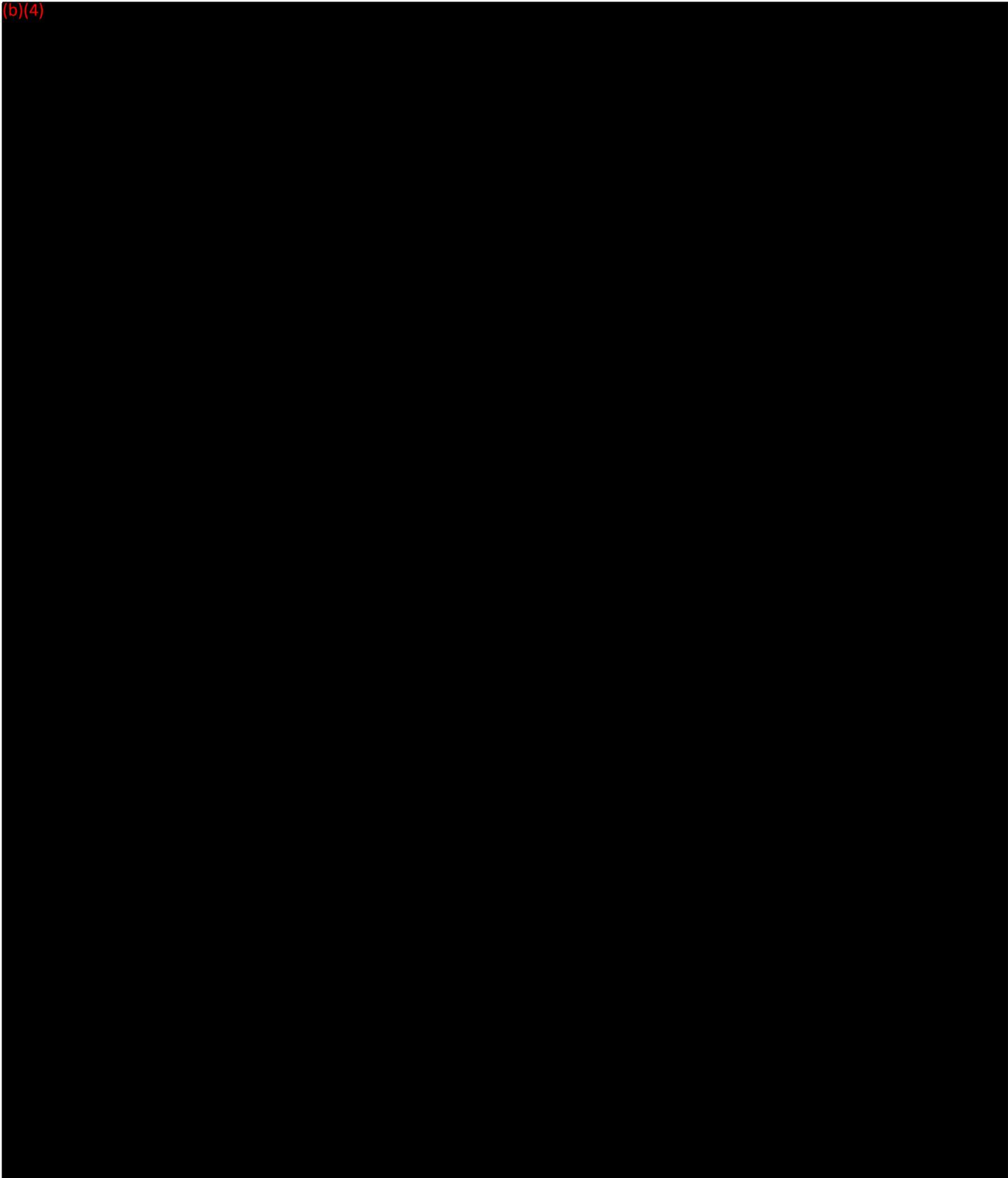


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BD CLINICAL STUDY: EVALUATION OF 0.129 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES USING THE ELECTRA 1400C™ ANALYZER

V. RESULTS AND DISCUSSION

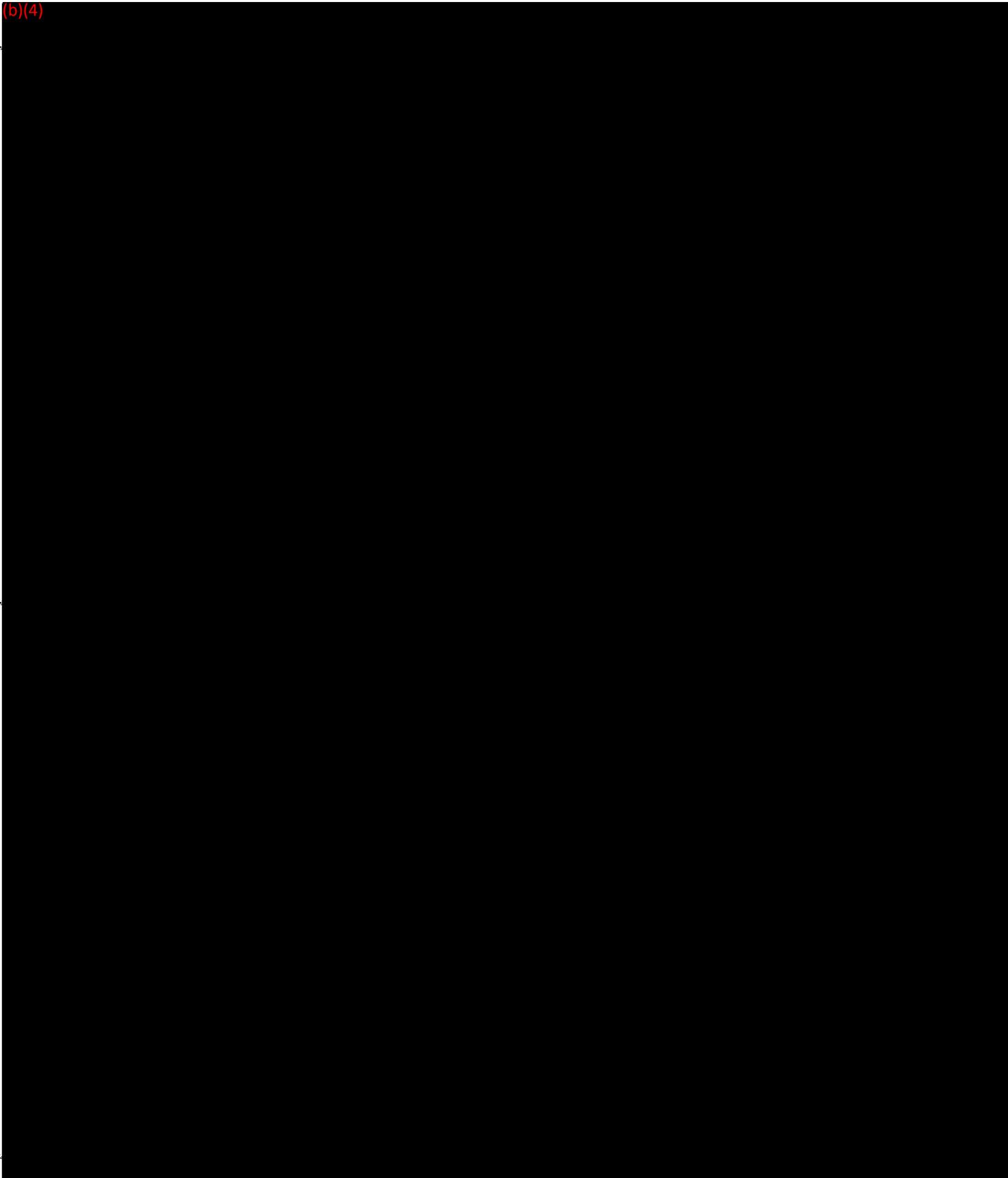
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156

**BD CLINICAL STUDY: EVALUATION OF 0.129 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS
SODIUM CITRATE TUBES USING THE ELECTRA 1400C™ ANALYZER**

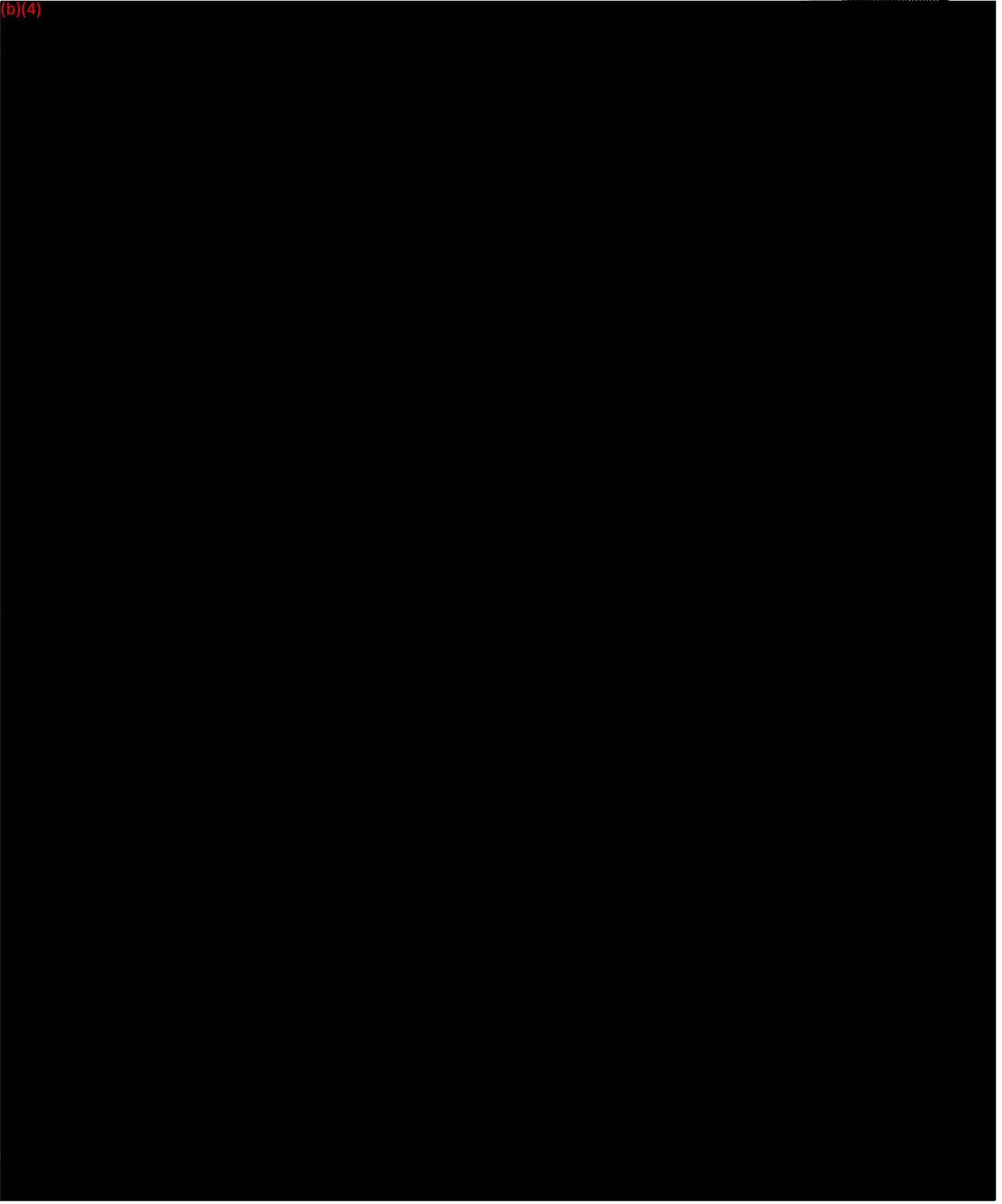
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157

**BD CLINICAL STUDY: EVALUATION OF 0.129 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS
SODIUM CITRATE TUBES USING THE ELECTRA 1400C™ ANALYZER**

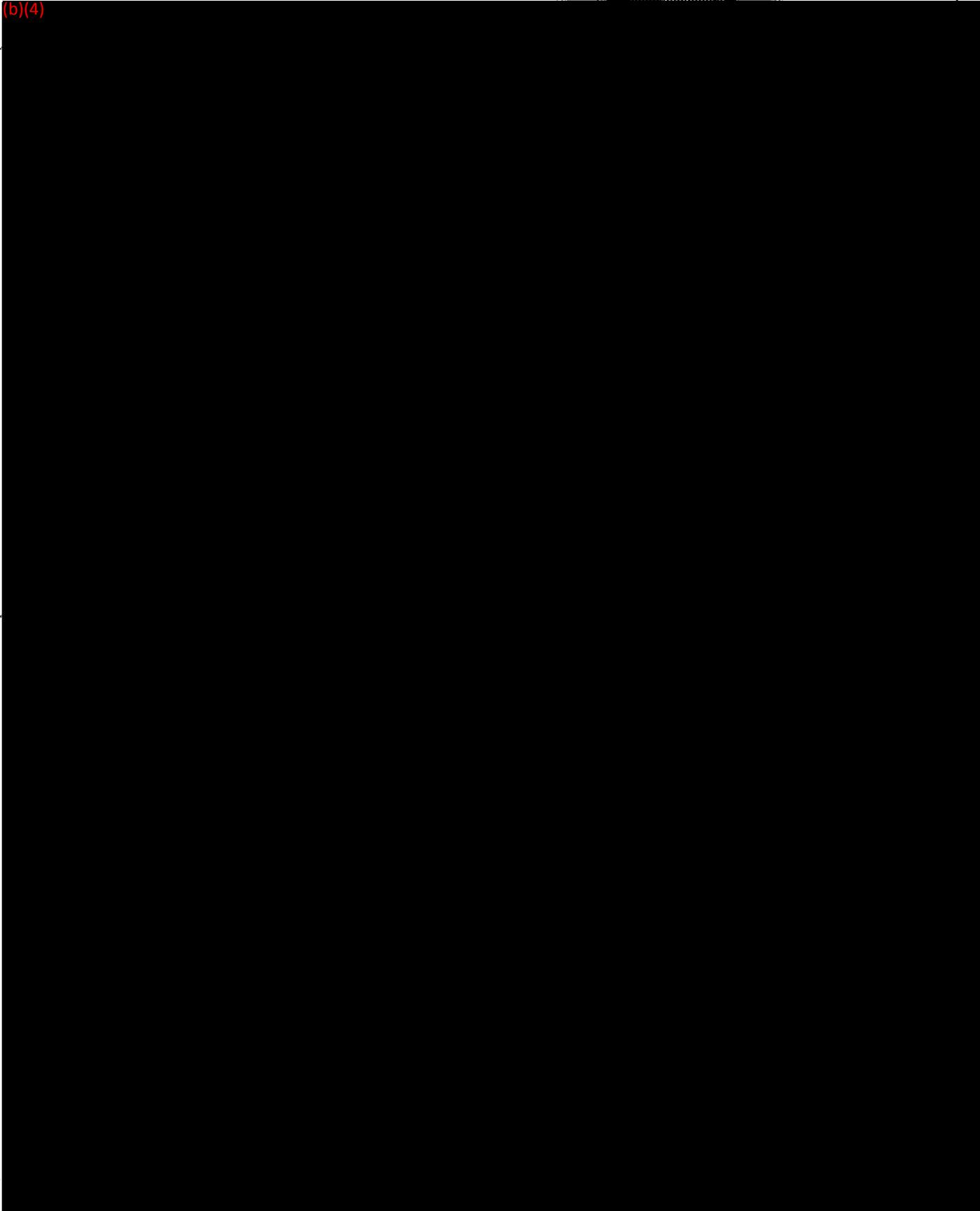
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158

BD CLINICAL STUDY: EVALUATION OF 0.129 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES USING THE ELECTRA 1400C™ ANALYZER

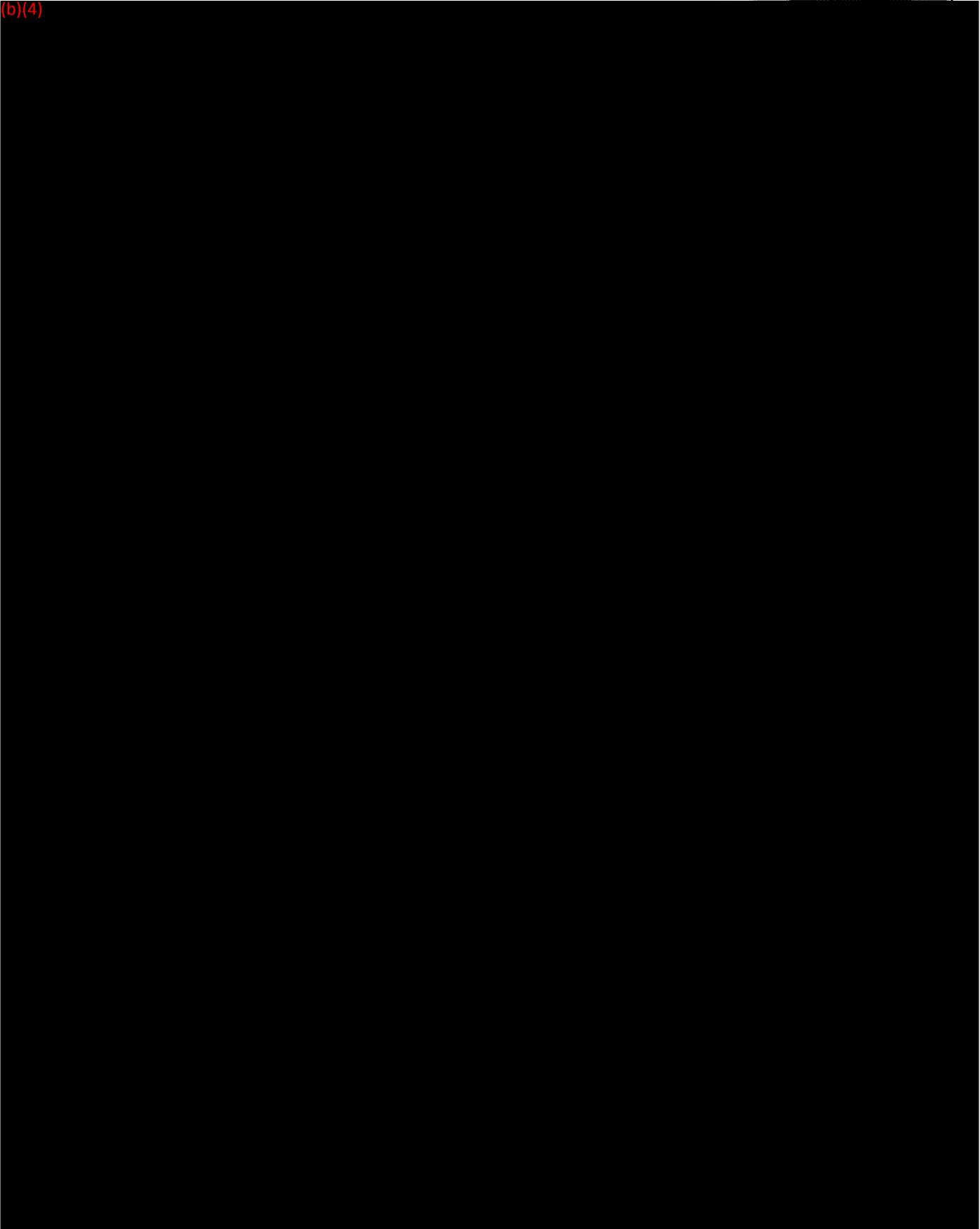
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159

BD CLINICAL STUDY: EVALUATION OF 0.129 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES USING THE ELECTRA 1400C™ ANALYZER

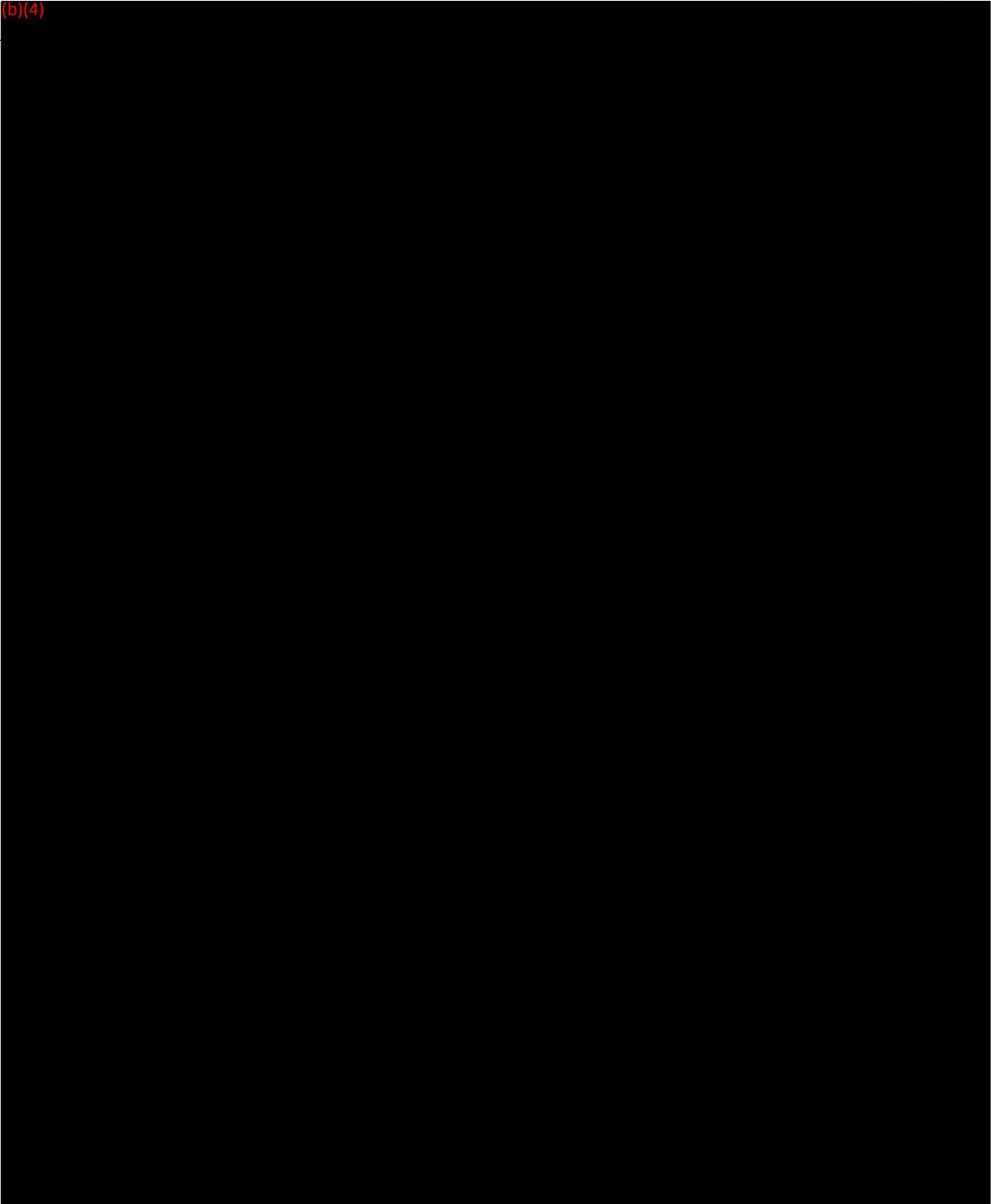
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160

**BD CLINICAL STUDY: EVALUATION OF 0.129 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS
SODIUM CITRATE TUBES USING THE ELECTRA 1400C™ ANALYZER**

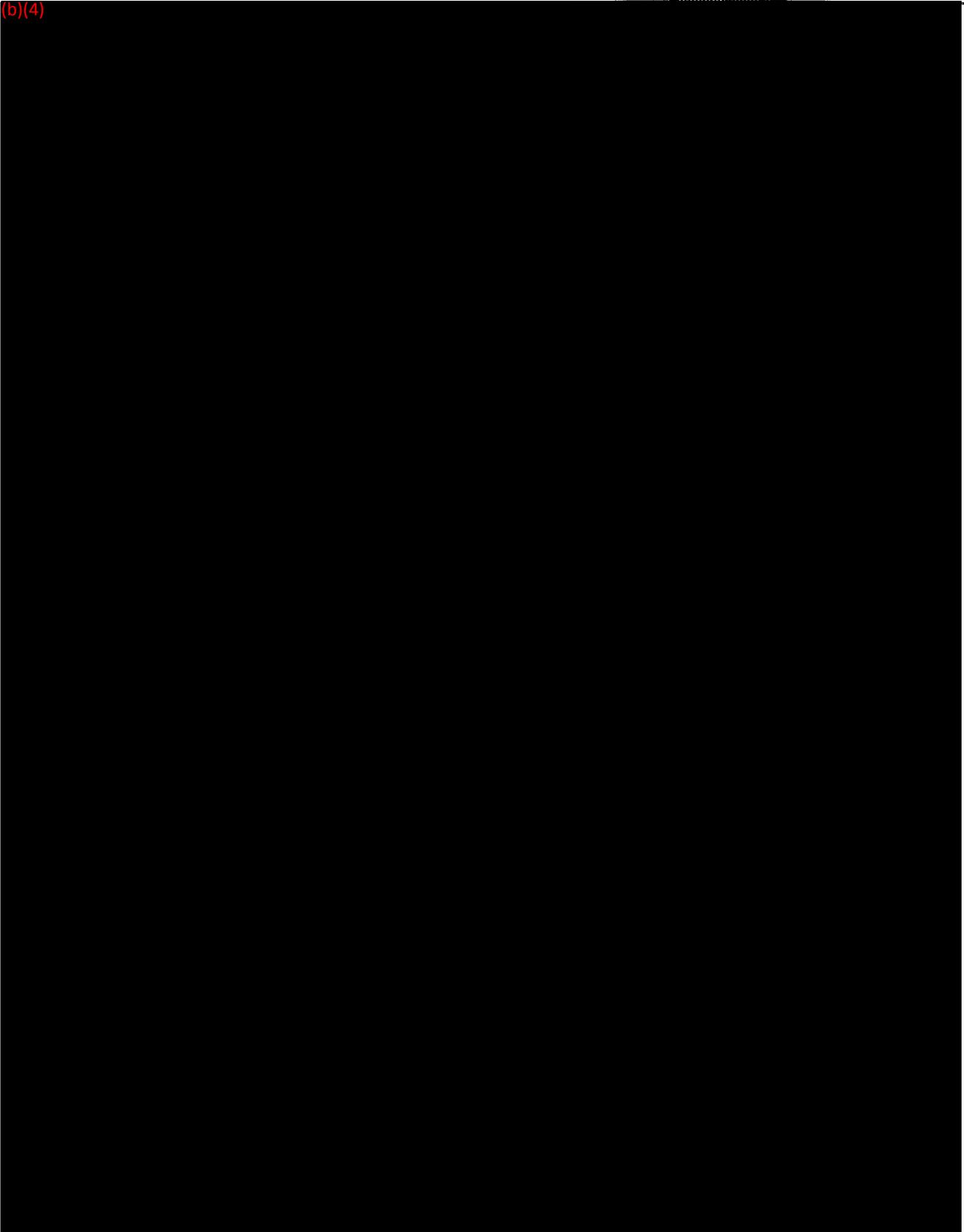
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161

BD CLINICAL STUDY: EVALUATION OF 0.129 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES USING THE ELECTRA 1400C™ ANALYZER

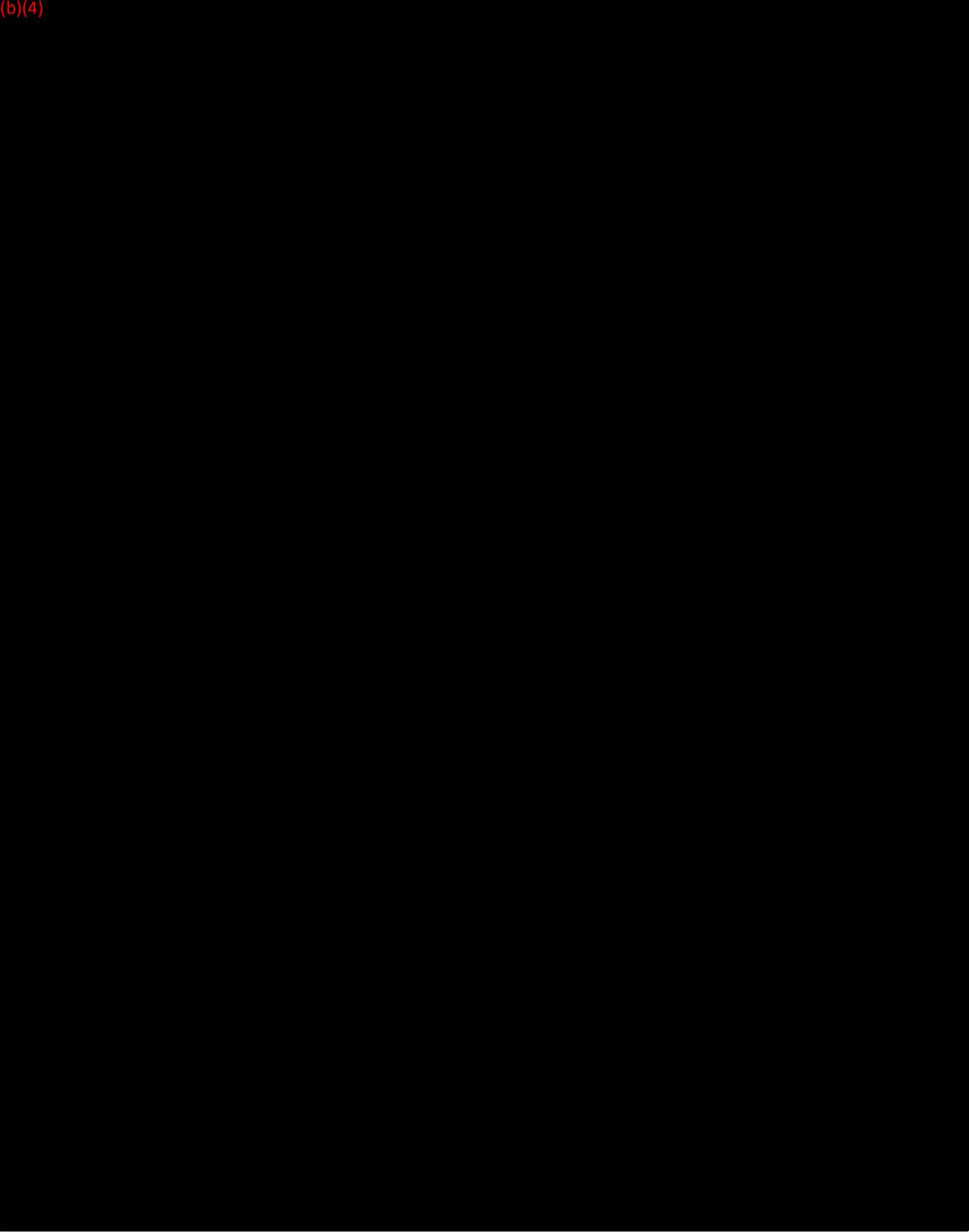
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162

BD CLINICAL STUDY: EVALUATION OF 0.129 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES USING THE ELECTRA 1400C™ ANALYZER

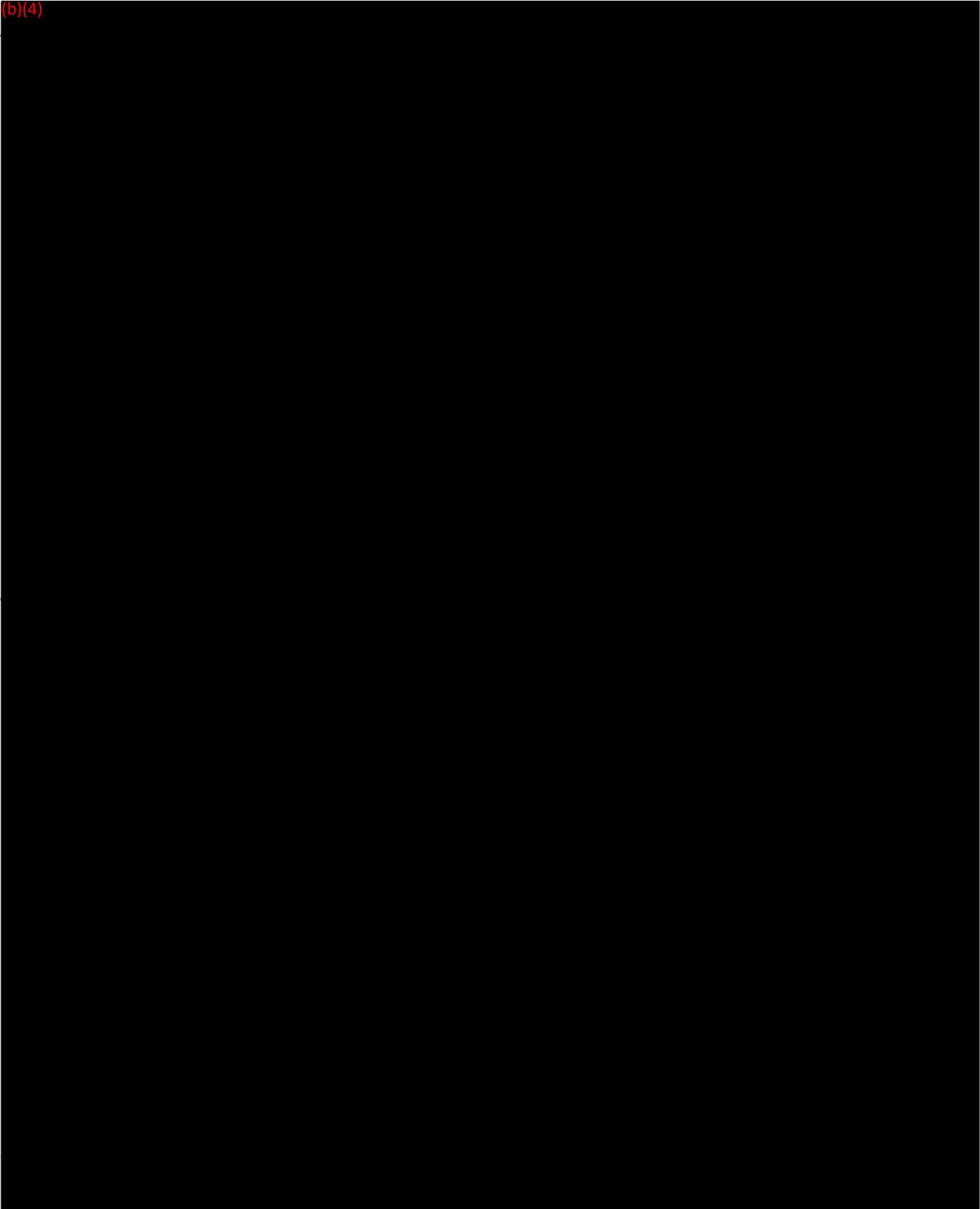
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**BD CLINICAL STUDY: EVALUATION OF 0.129 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS
SODIUM CITRATE TUBES USING THE ELECTRA 1400C™ ANALYZER**

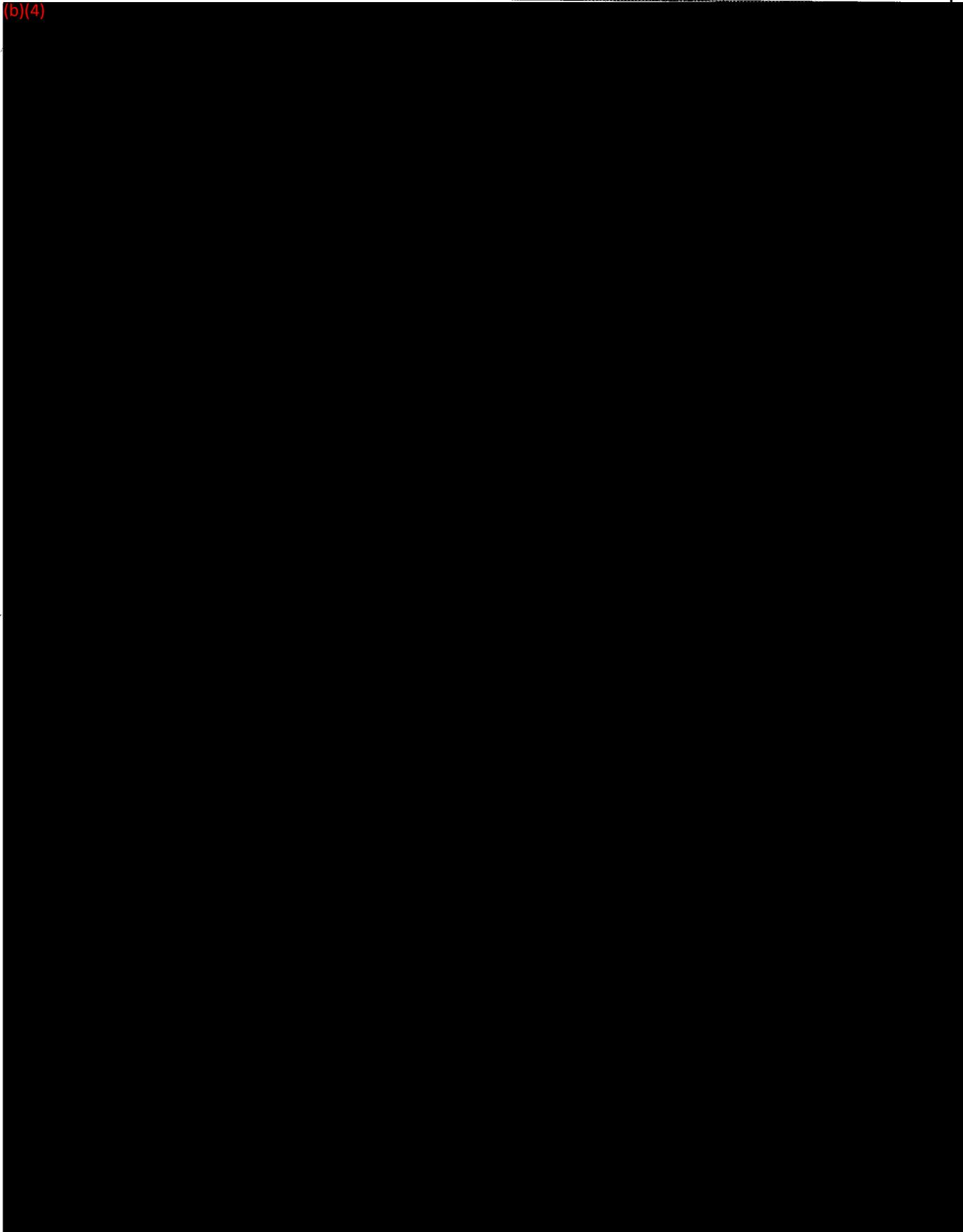
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164

BD CLINICAL STUDY: EVALUATION OF 0.129 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES USING THE ELECTRA 1400C™ ANALYZER

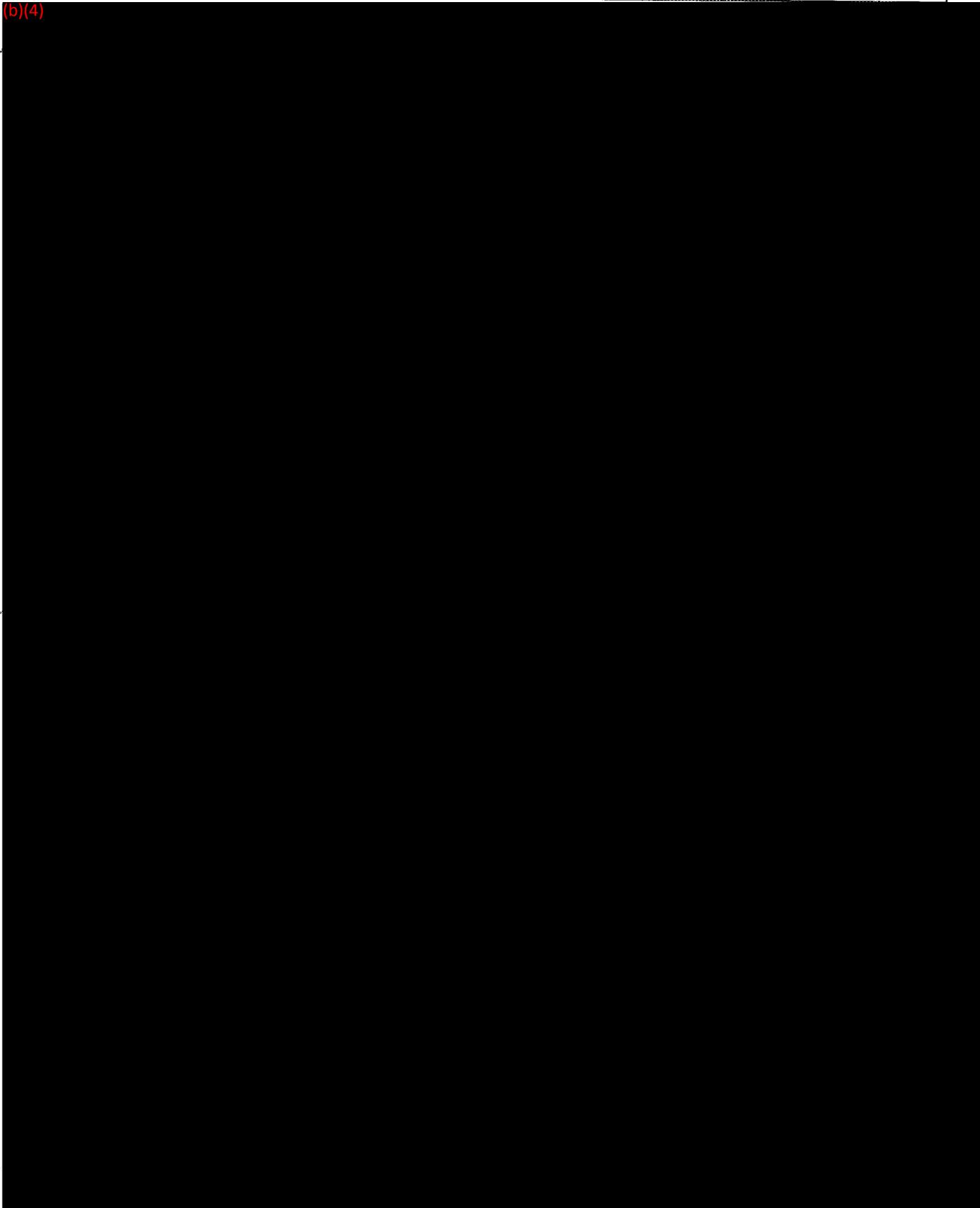
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165

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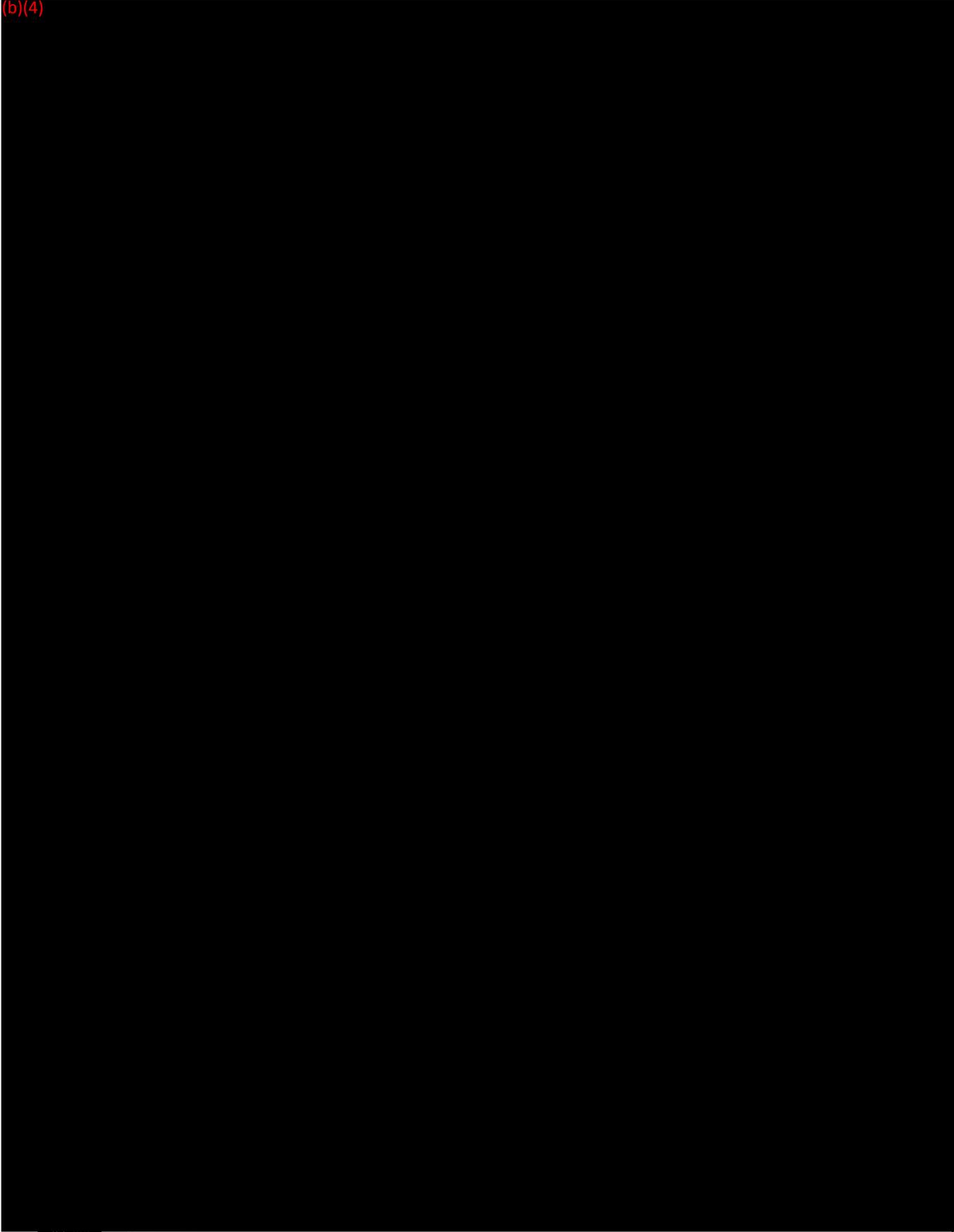
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166

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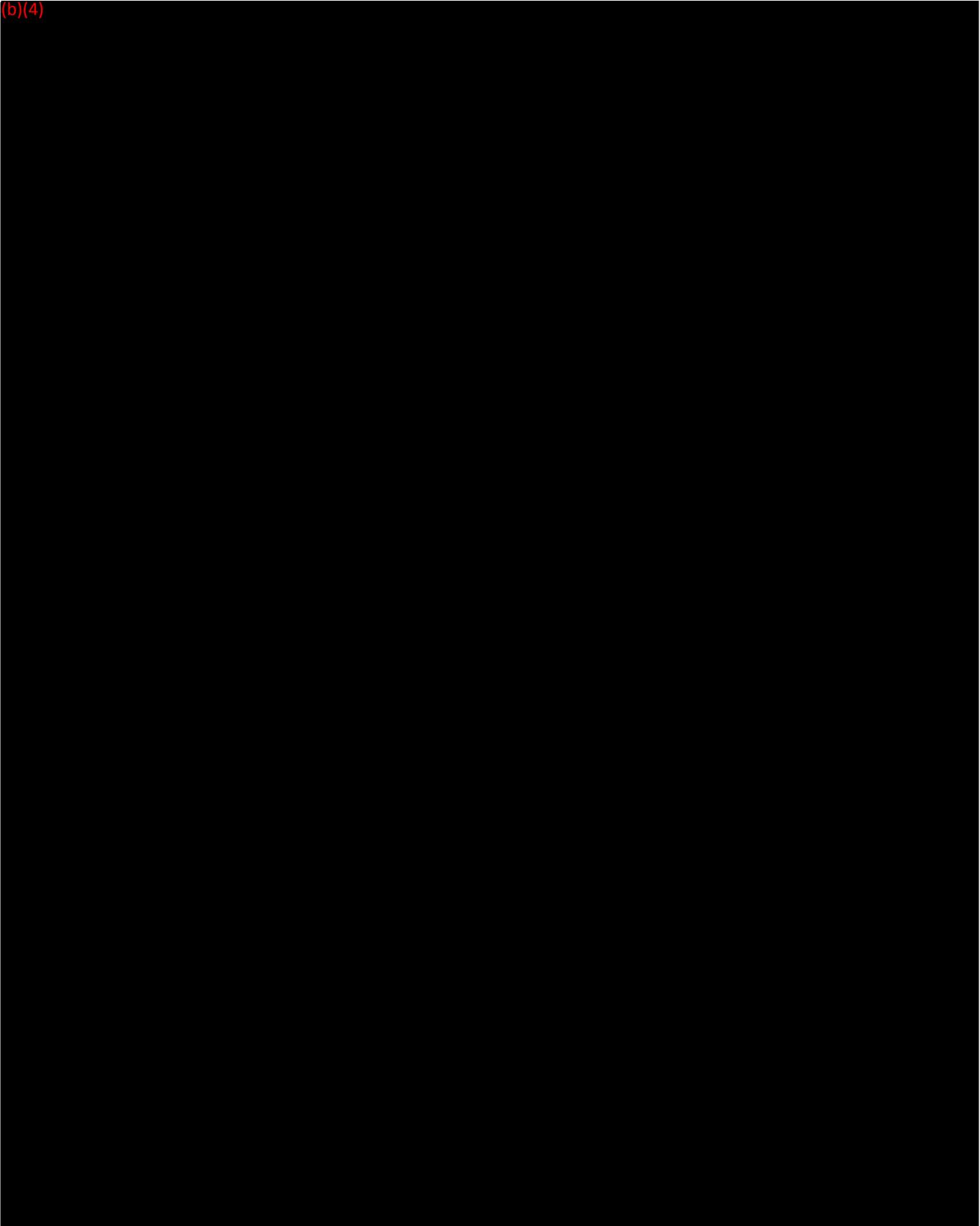
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167

BD CLINICAL STUDY: EVALUATION OF 0.129 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES USING THE ELECTRA 1400C™ ANALYZER

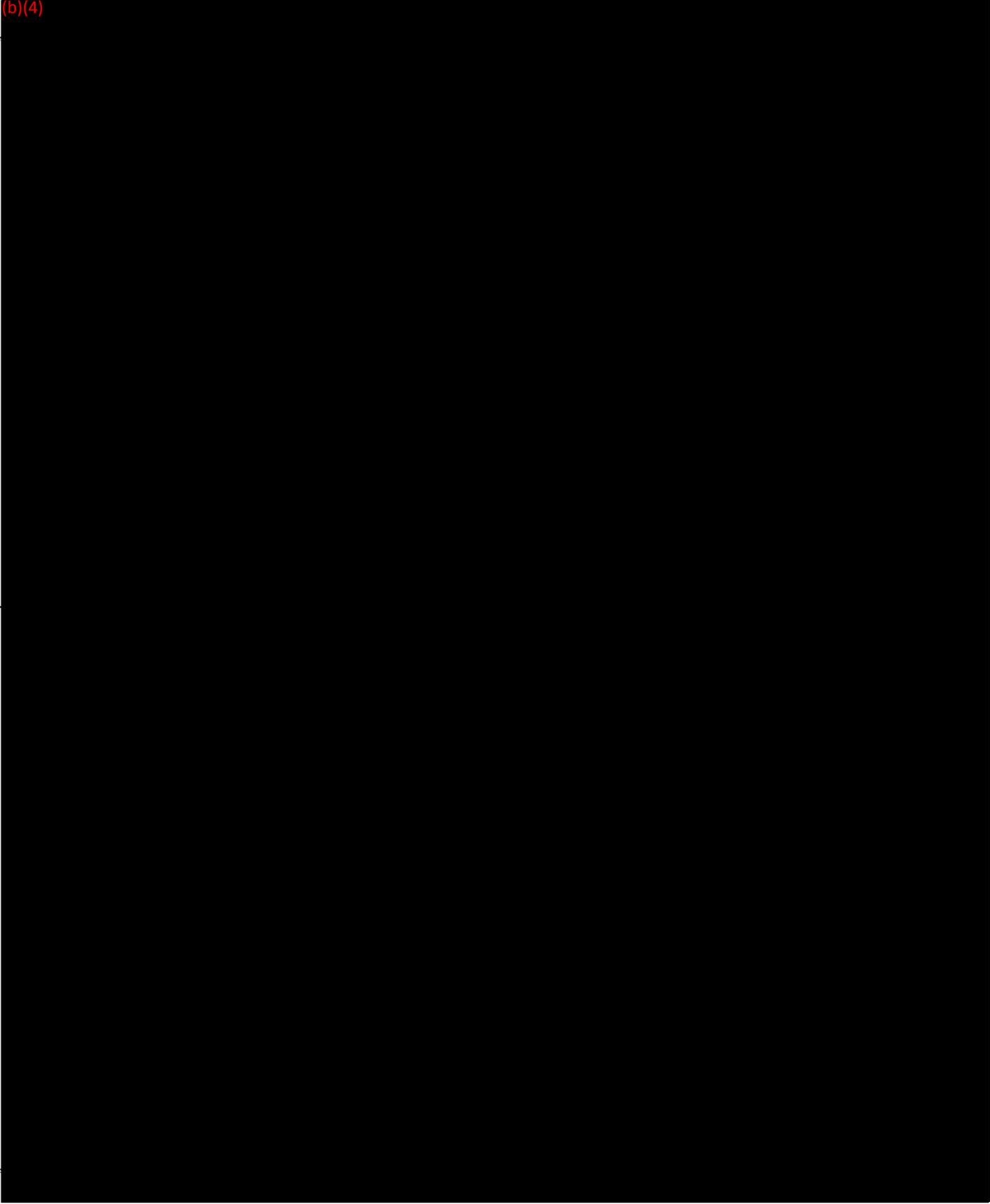
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**BD CLINICAL STUDY: EVALUATION OF 0.129 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS
SODIUM CITRATE TUBES USING THE ELECTRA 1400C™ ANALYZER**

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169

BD CLINICAL STUDY: EVALUATION OF 0.129 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES USING THE ELECTRA 1400C™ ANALYZER

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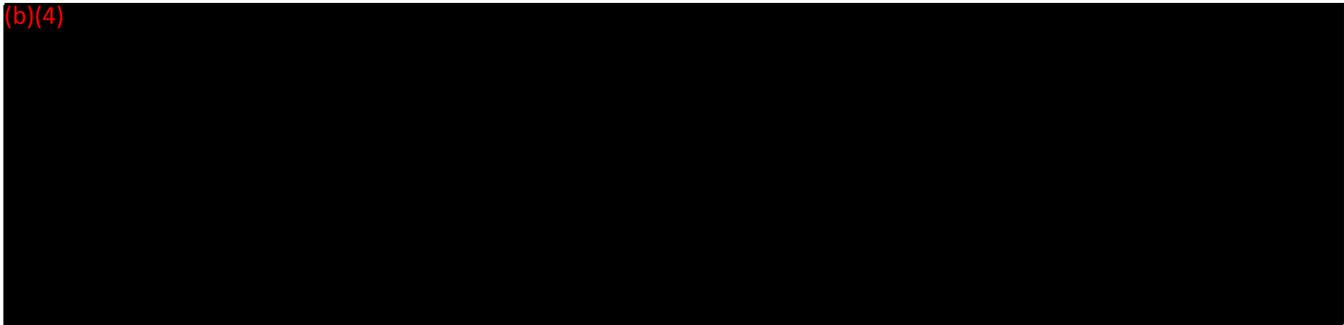
VI. CONCLUSIONS

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VII. REFERENCES

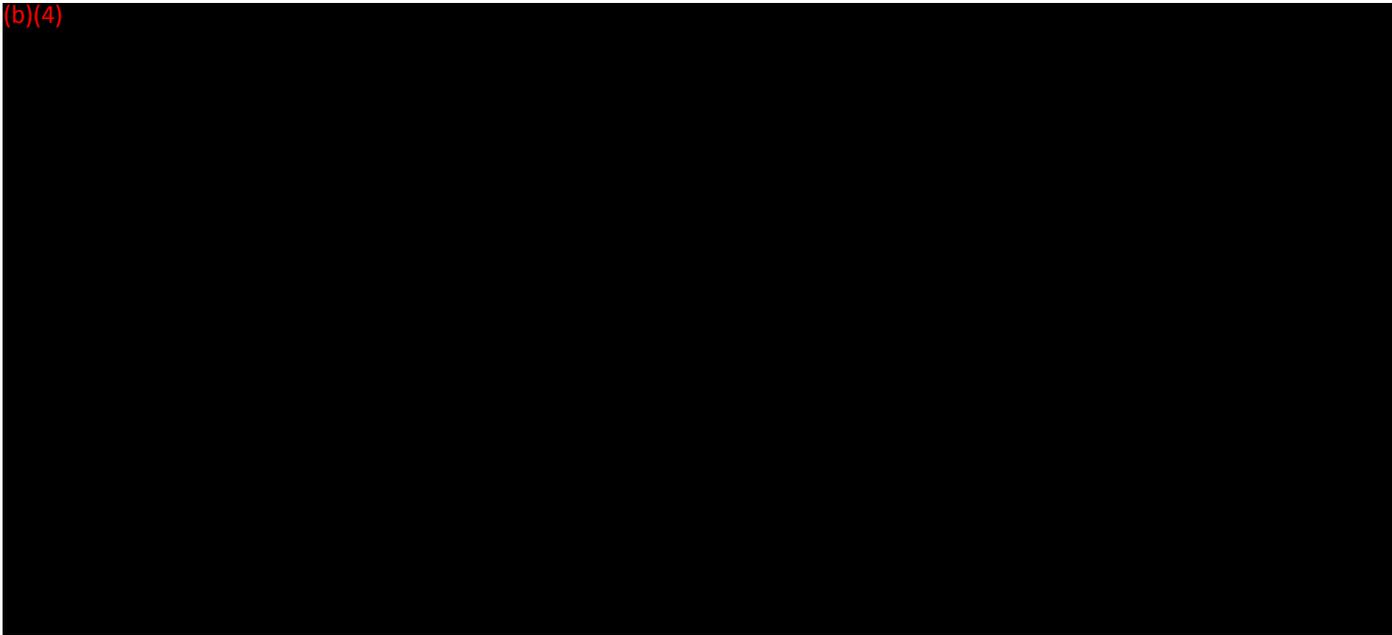
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170

BD CLINICAL STUDY: EVALUATION OF 0.129 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES USING THE ELECTRA 1400C™ ANALYZER

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**ATTACHMENT 8: CLINICAL EVALUATION- AT BD
VACUTAINER SYSTEMS (BDVS) &**

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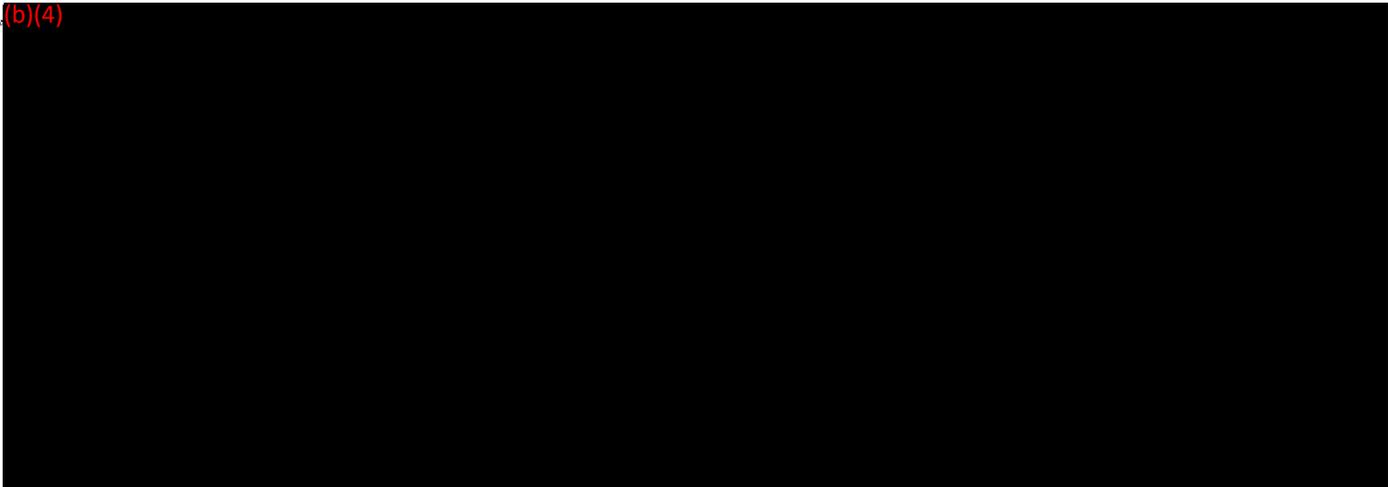
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172

BD CLINICAL STUDY: NORMAL AND NON-NORMAL DONOR PROTHROMBIN FRAGMENT 1+2 LEVELS USING 0.109 M AND 0.129 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES

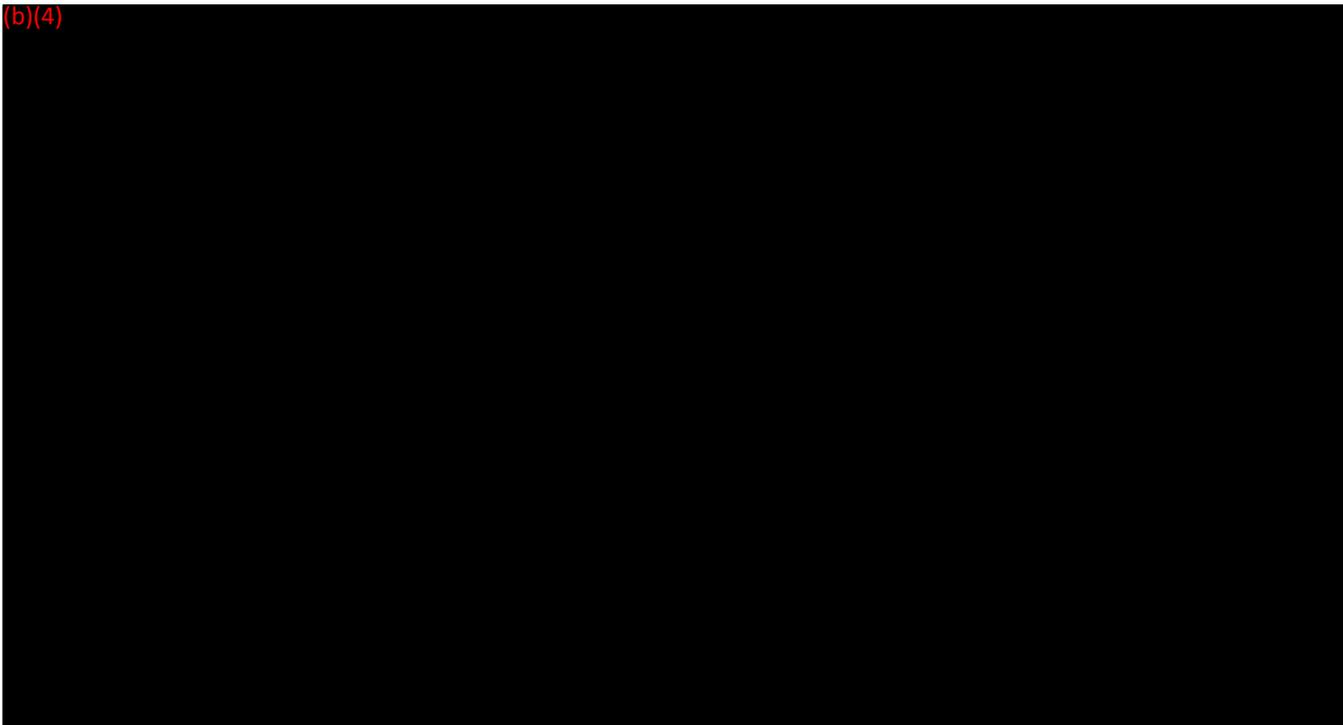
ABSTRACT

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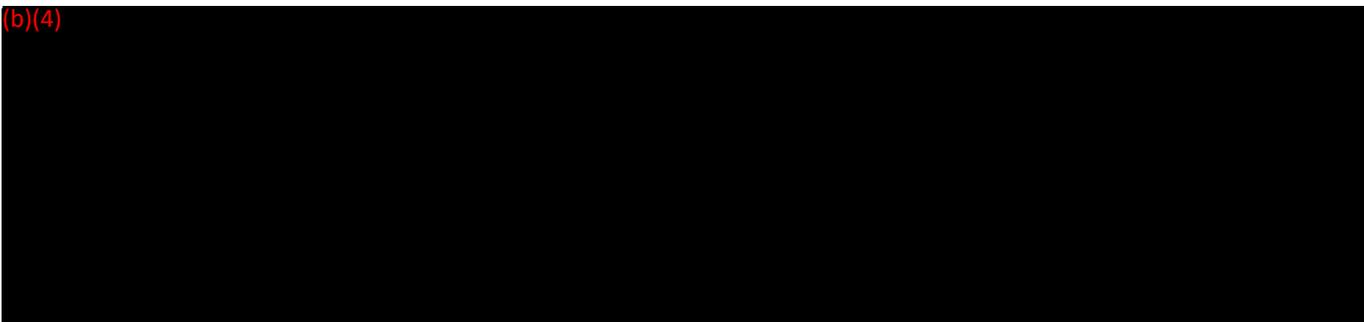
I. INTRODUCTION

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II. OBJECTIVE

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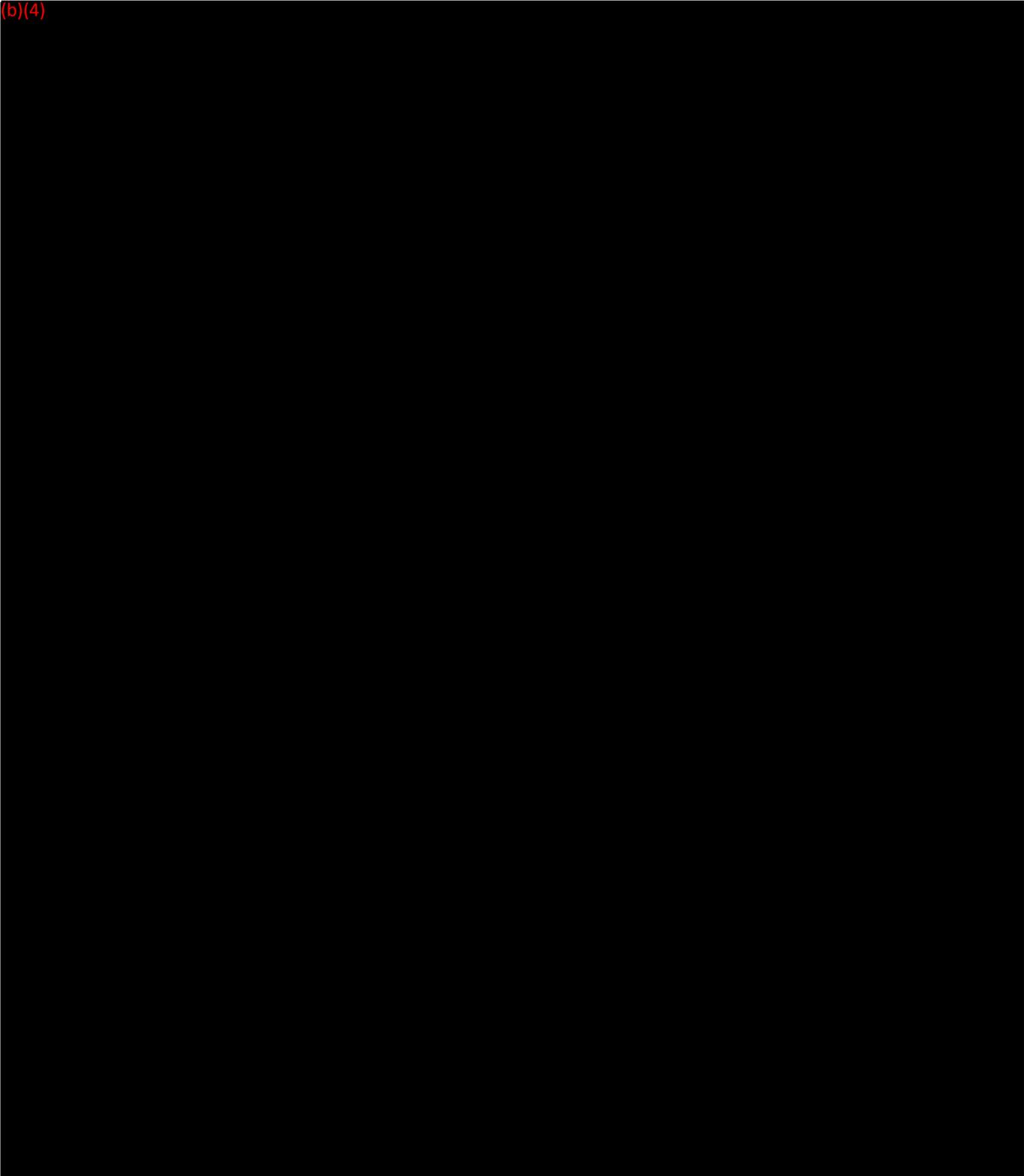


173

**BD CLINICAL STUDY: NORMAL AND NON-NORMAL DONOR PROTHROMBIN FRAGMENT 1+2
LEVELS USING 0.109 M AND 0.129 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES**

III. METHODS AND MATERIALS

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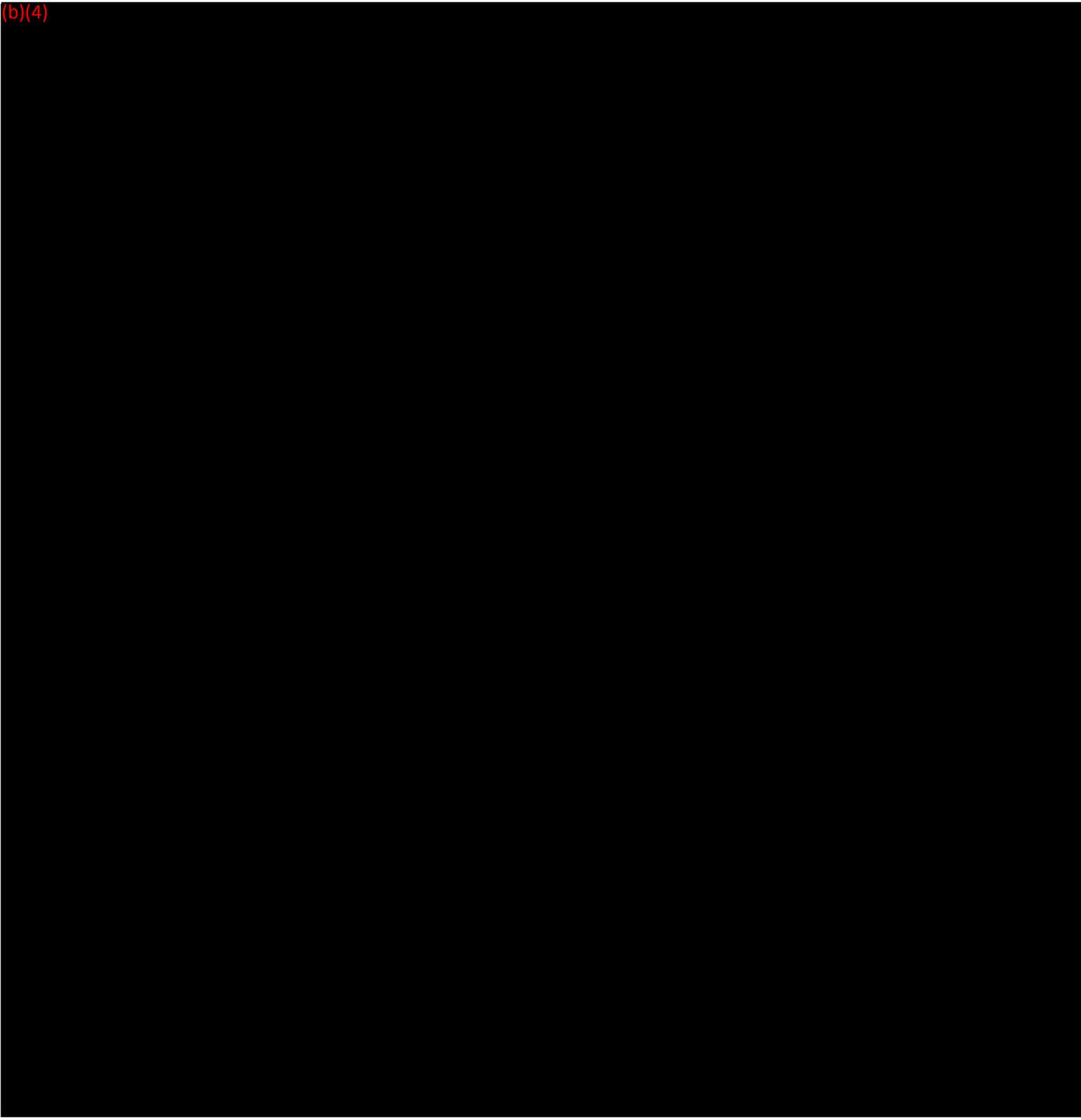


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BD CLINICAL STUDY: NORMAL AND NON-NORMAL DONOR PROTHROMBIN FRAGMENT 1+2 LEVELS USING 0.109 M AND 0.129 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES

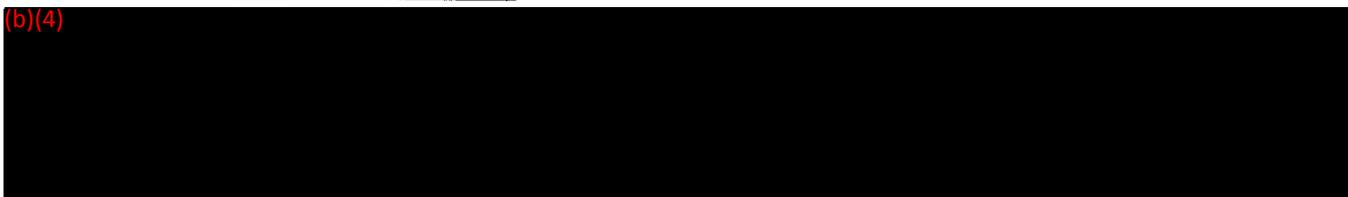
IV. DATA ANALYSIS

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VI. DETAILS AND DEVIATIONS

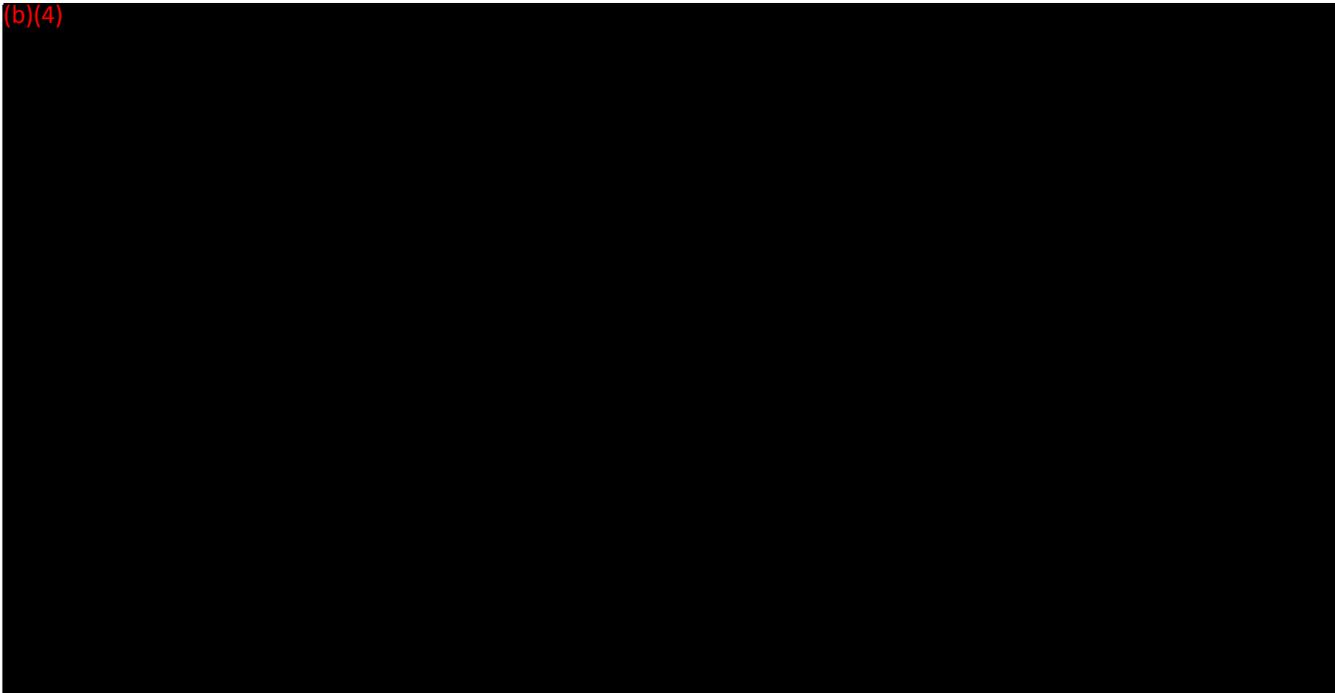
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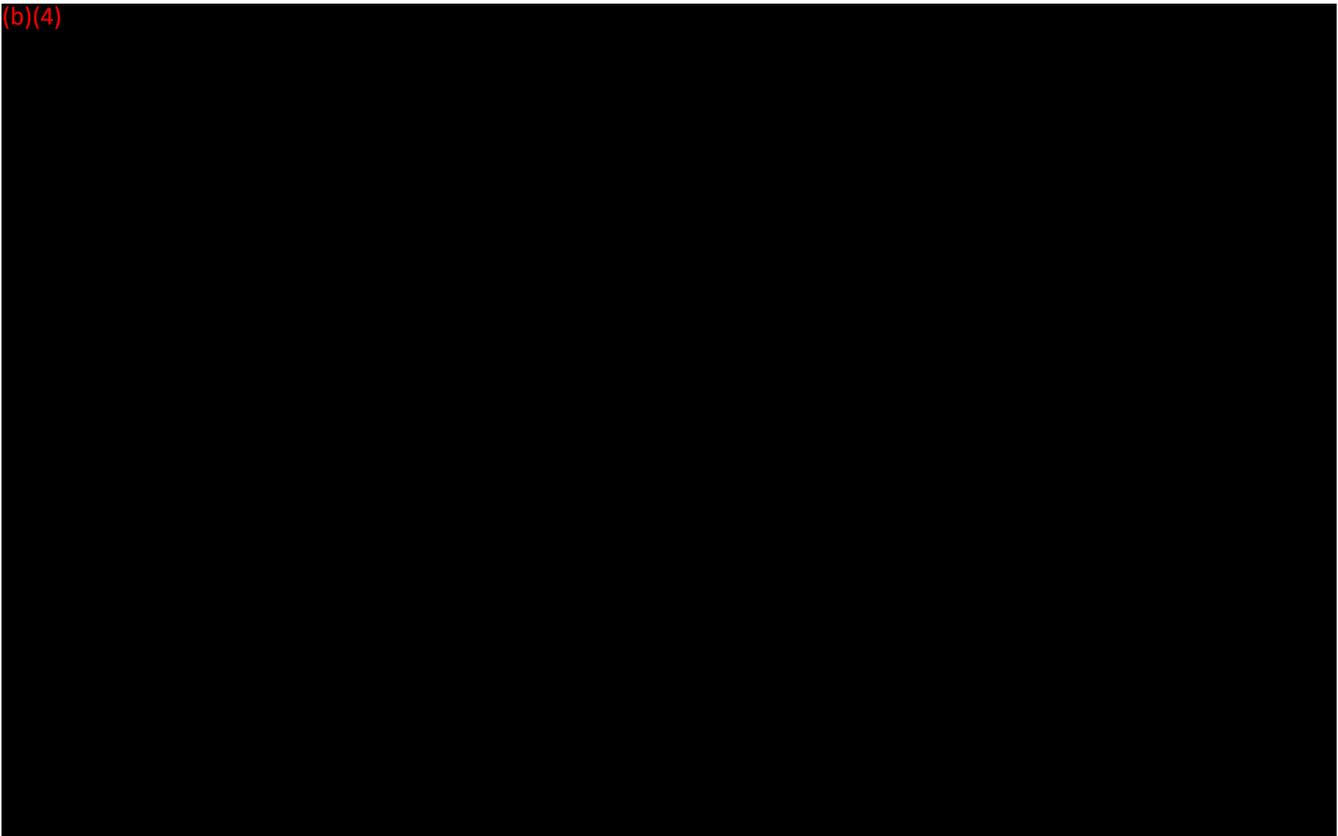
**BD CLINICAL STUDY: NORMAL AND NON-NORMAL DONOR PROTHROMBIN FRAGMENT 1+2
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VI. RESULTS AND DISCUSSION

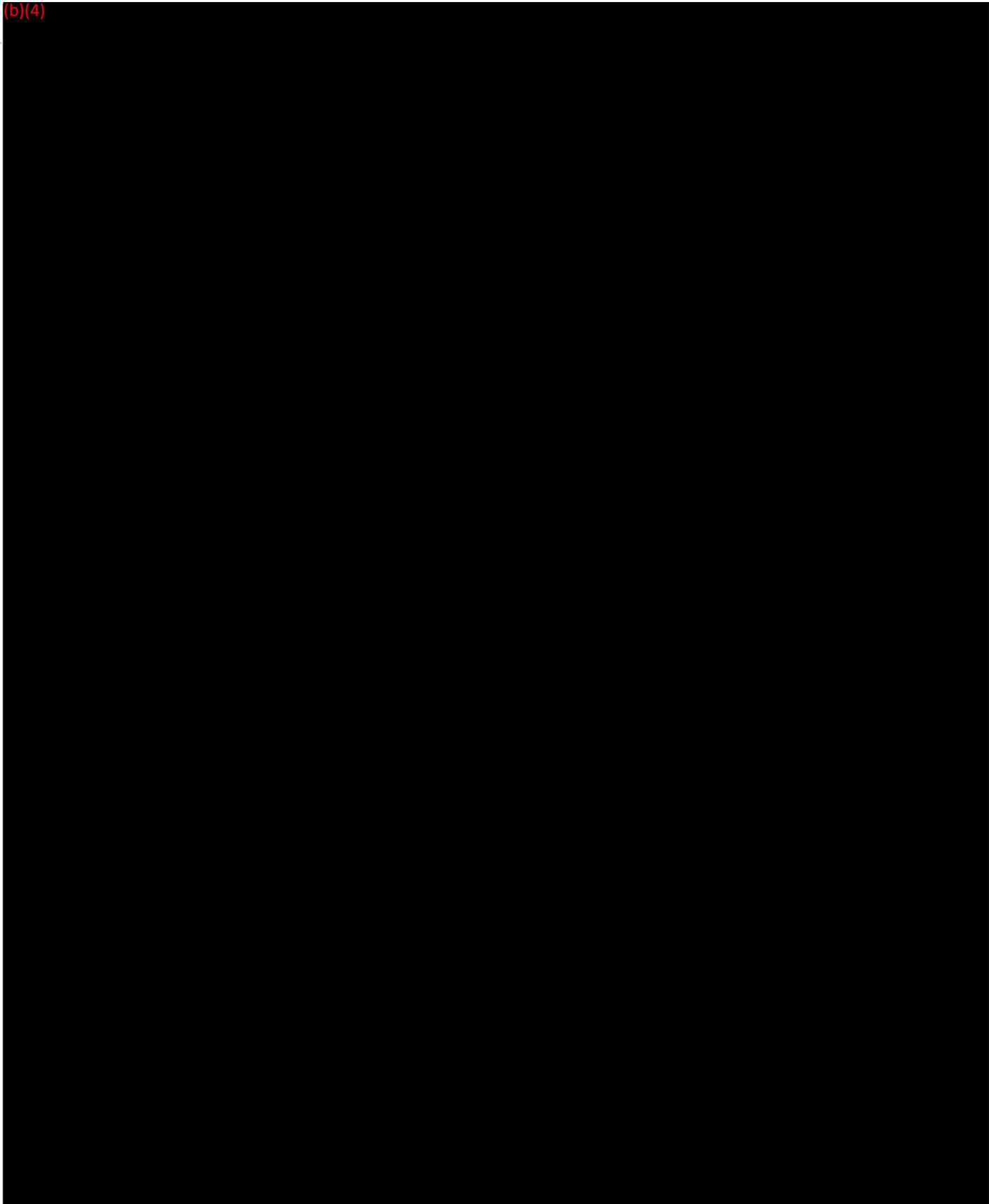
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**BD CLINICAL STUDY: NORMAL AND NON-NORMAL DONOR PROTHROMBIN FRAGMENT 1+2
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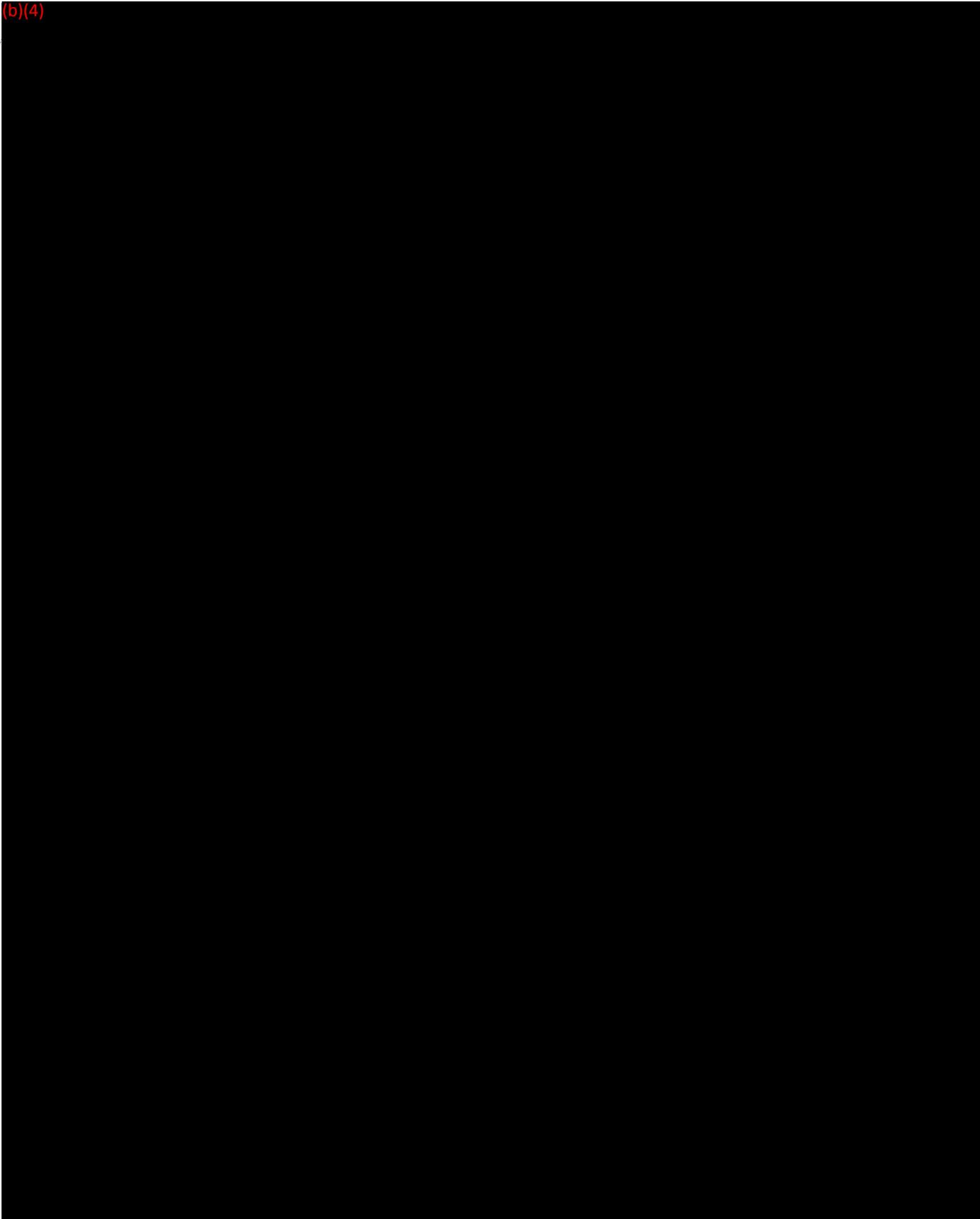
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177

**BD CLINICAL STUDY: NORMAL AND NON-NORMAL DONOR PROTHROMBIN FRAGMENT 1+2
LEVELS USING 0.109 M AND 0.129 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES**

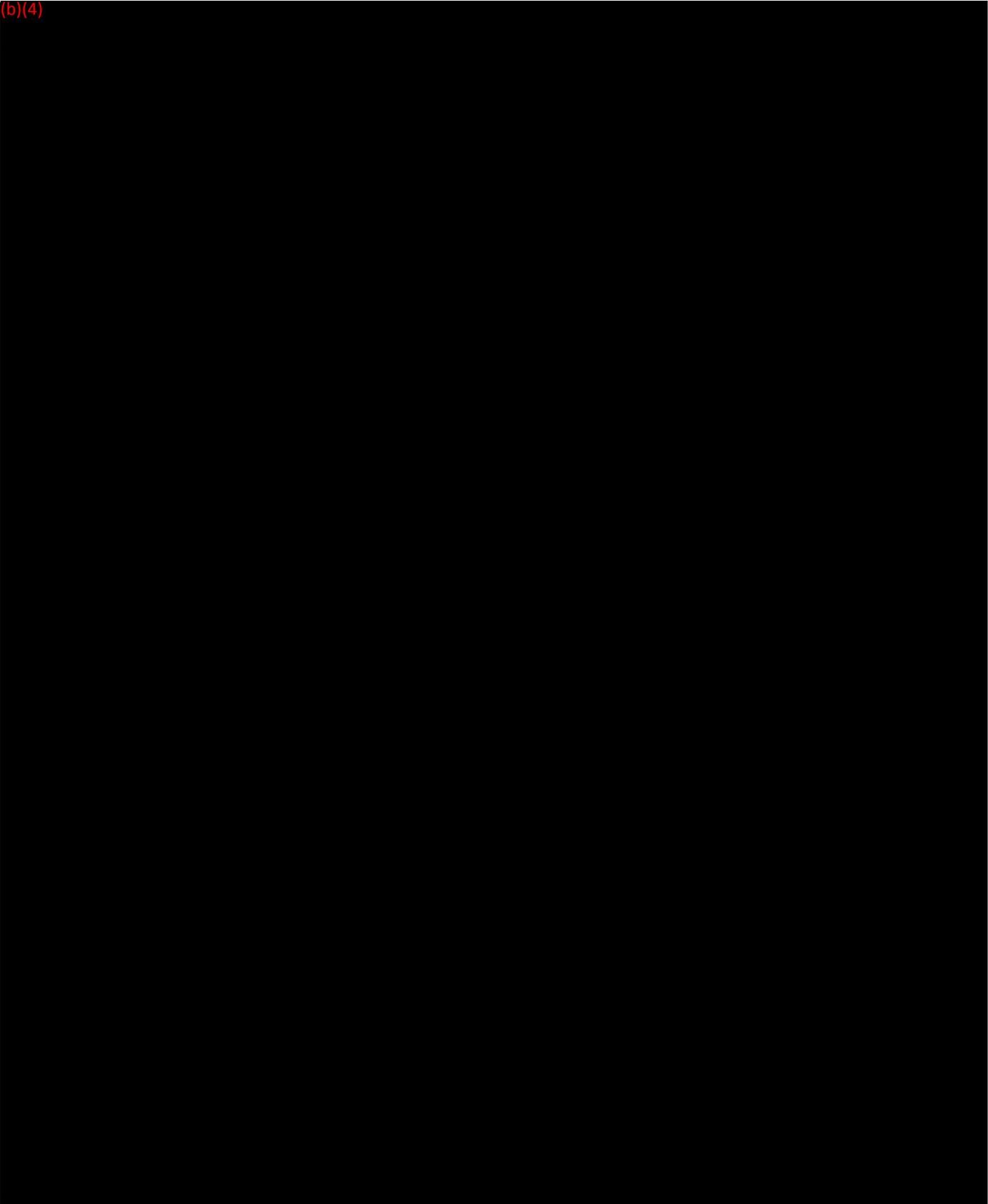
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178

**BD CLINICAL STUDY: NORMAL AND NON-NORMAL DONOR PROTHROMBIN FRAGMENT 1+2
LEVELS USING 0.109 M AND 0.129 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES**

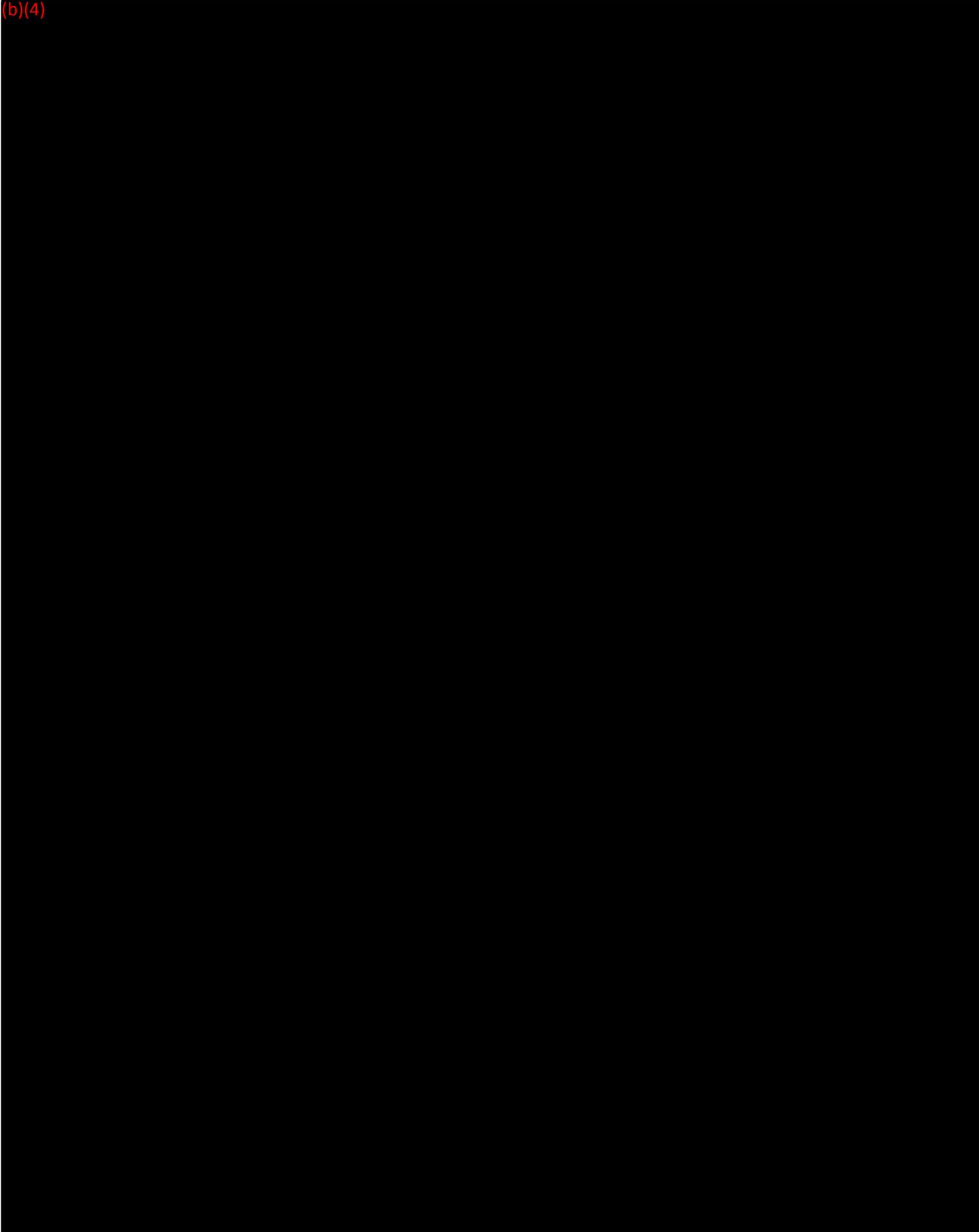
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179

**BD CLINICAL STUDY: NORMAL AND NON-NORMAL DONOR PROTHROMBIN FRAGMENT 1+2
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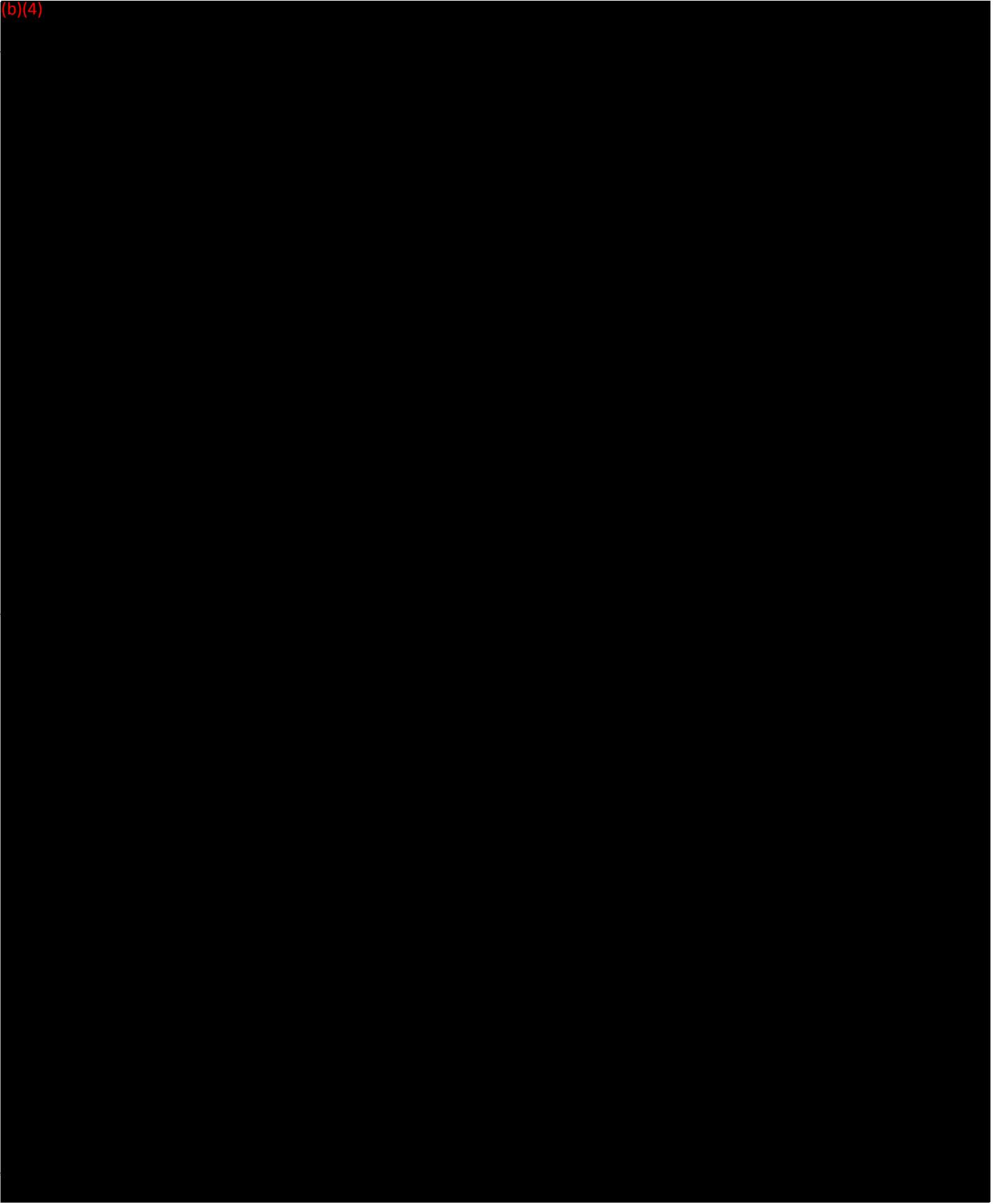
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**BD CLINICAL STUDY: NORMAL AND NON-NORMAL DONOR PROTHROMBIN FRAGMENT 1+2
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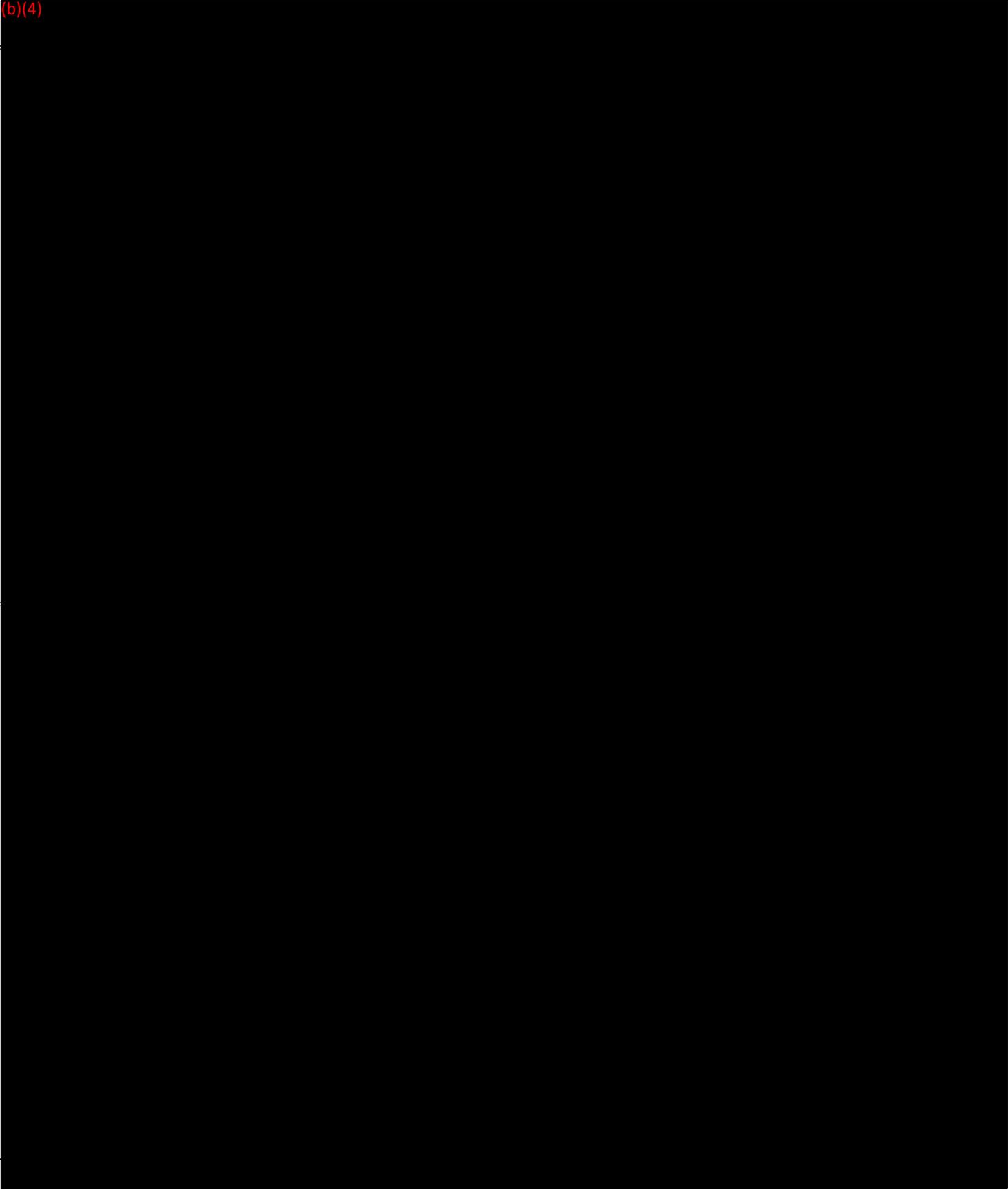
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**BD CLINICAL STUDY: NORMAL AND NON-NORMAL DONOR PROTHROMBIN FRAGMENT 1+2
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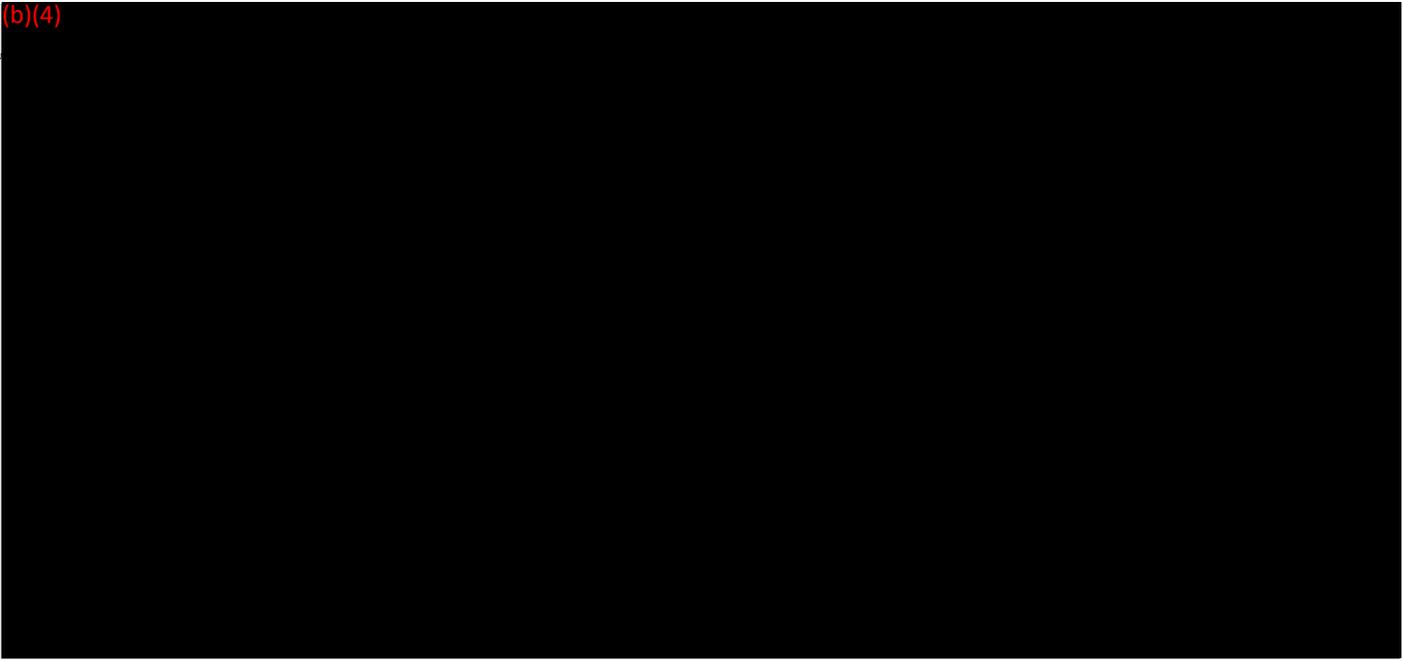
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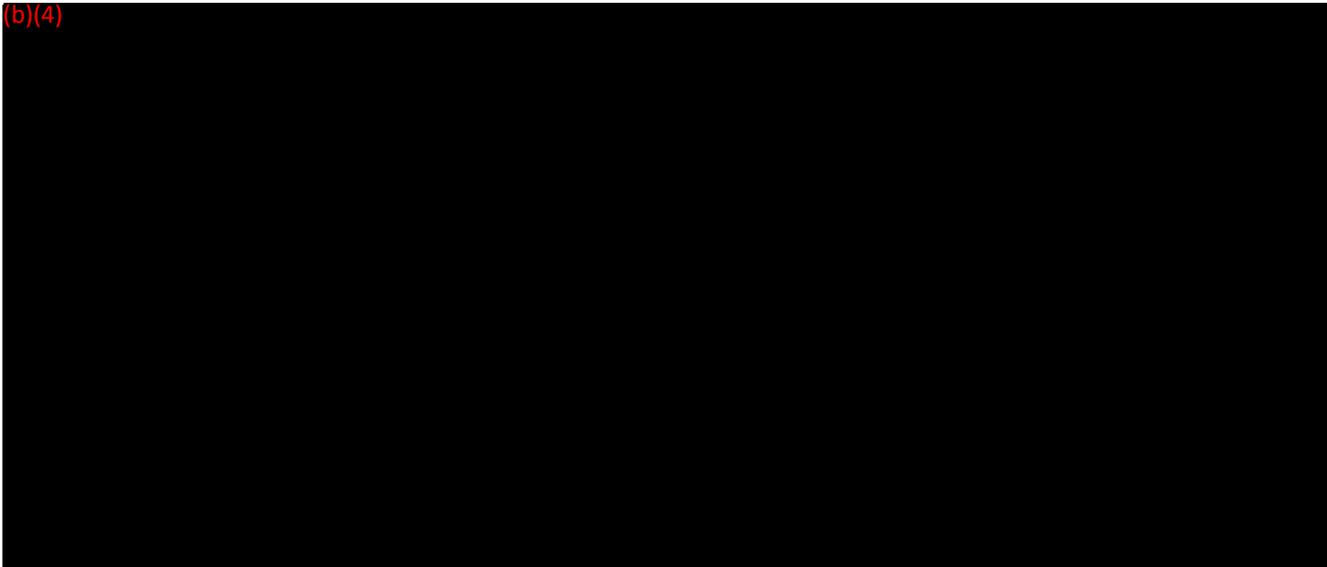
BD CLINICAL STUDY: NORMAL AND NON-NORMAL DONOR PROTHROMBIN FRAGMENT 1+2 LEVELS USING 0.109 M AND 0.129 M 2.7 and 1.8 ML BD VACUTAINER™ PLUS SODIUM CITRATE TUBES

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VII. CONCLUSIONS

(b)(4)



VIII. REFERENCES

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**ATTACHMENT 9: CLINICAL EVALUATION- AT BD
VACUTAINER SYSTEMS (BDVS) & (b)(4)**

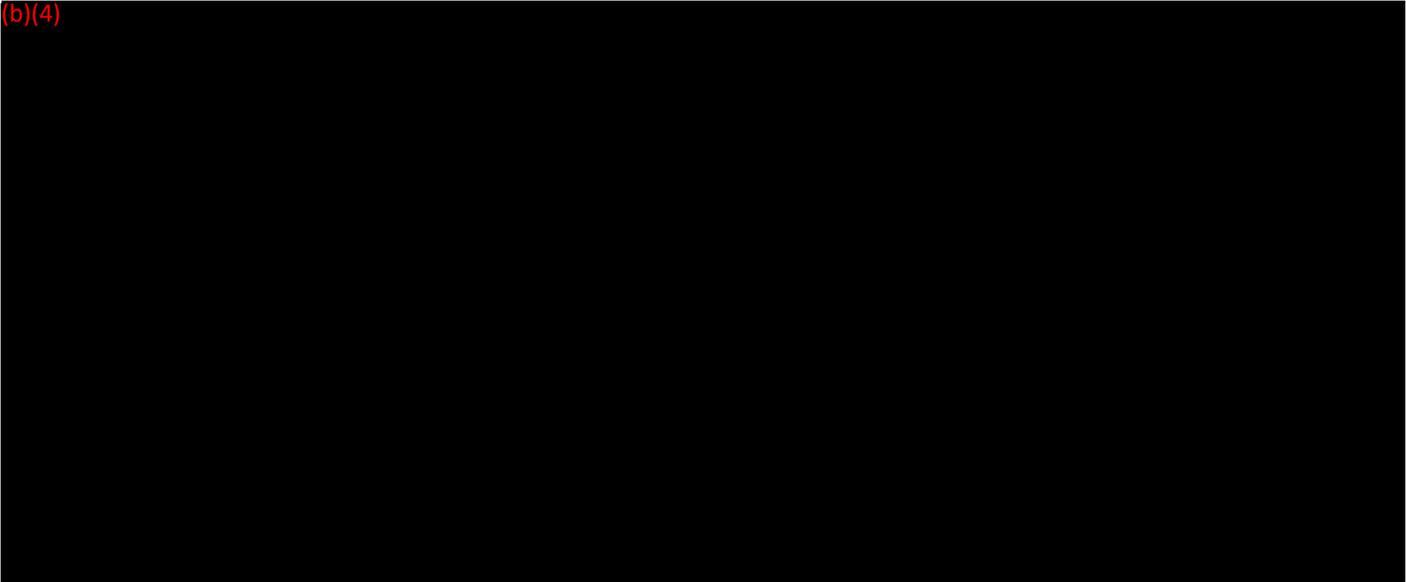
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BD CLINICAL STUDY: NORMAL AND NON-NORMAL DETERMINATION OF P SELECTIN, PT, APTT AND FIBRINOGEN USING 0.109 M BD VACUTAINER™ PLUS SODIUM CITRATE TUBES

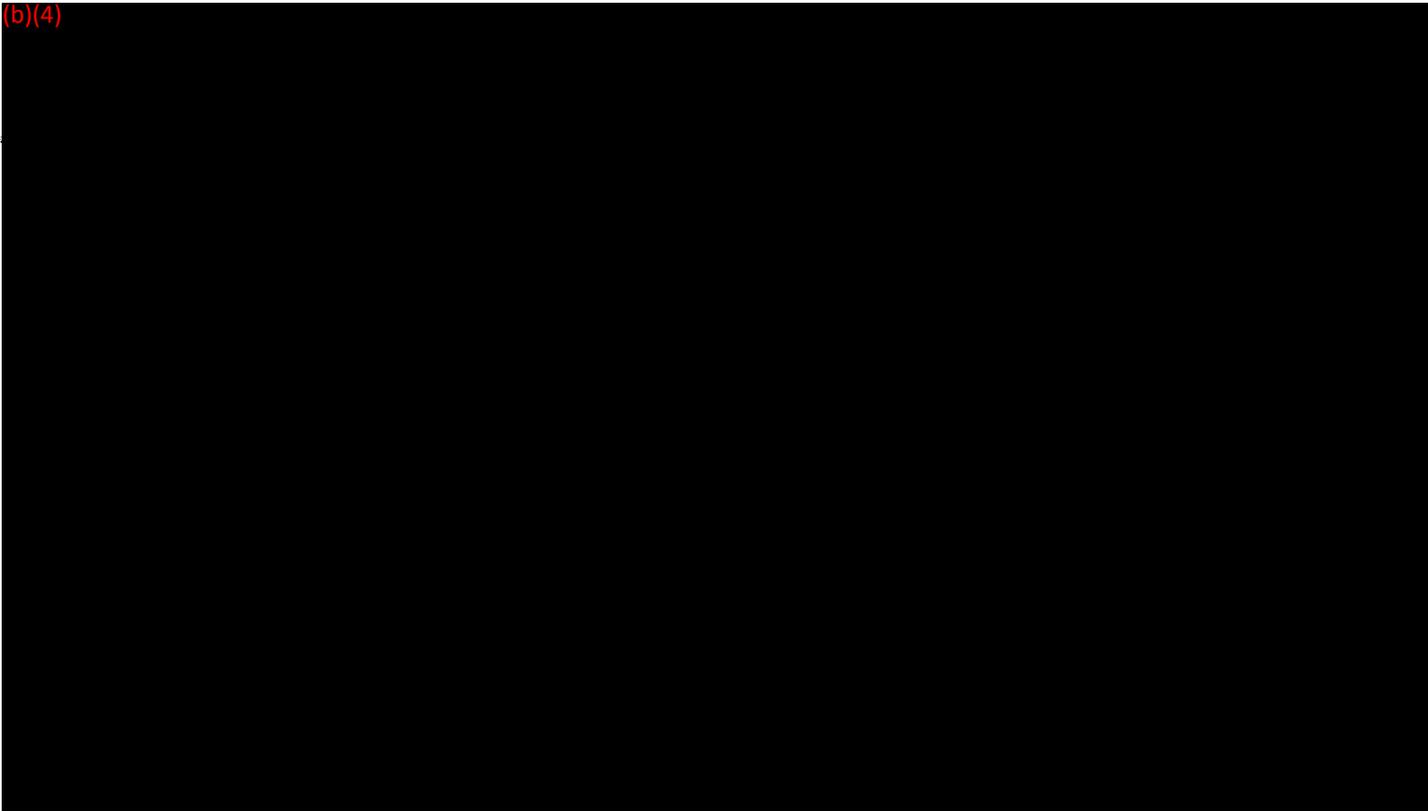
ABSTRACT

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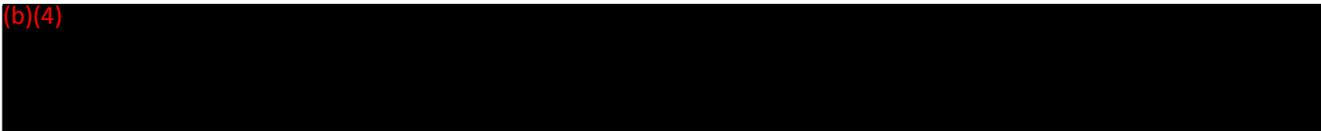
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II. OBJECTIVE

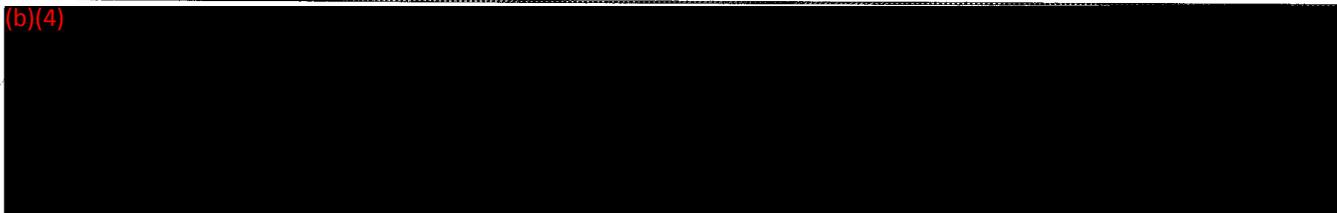
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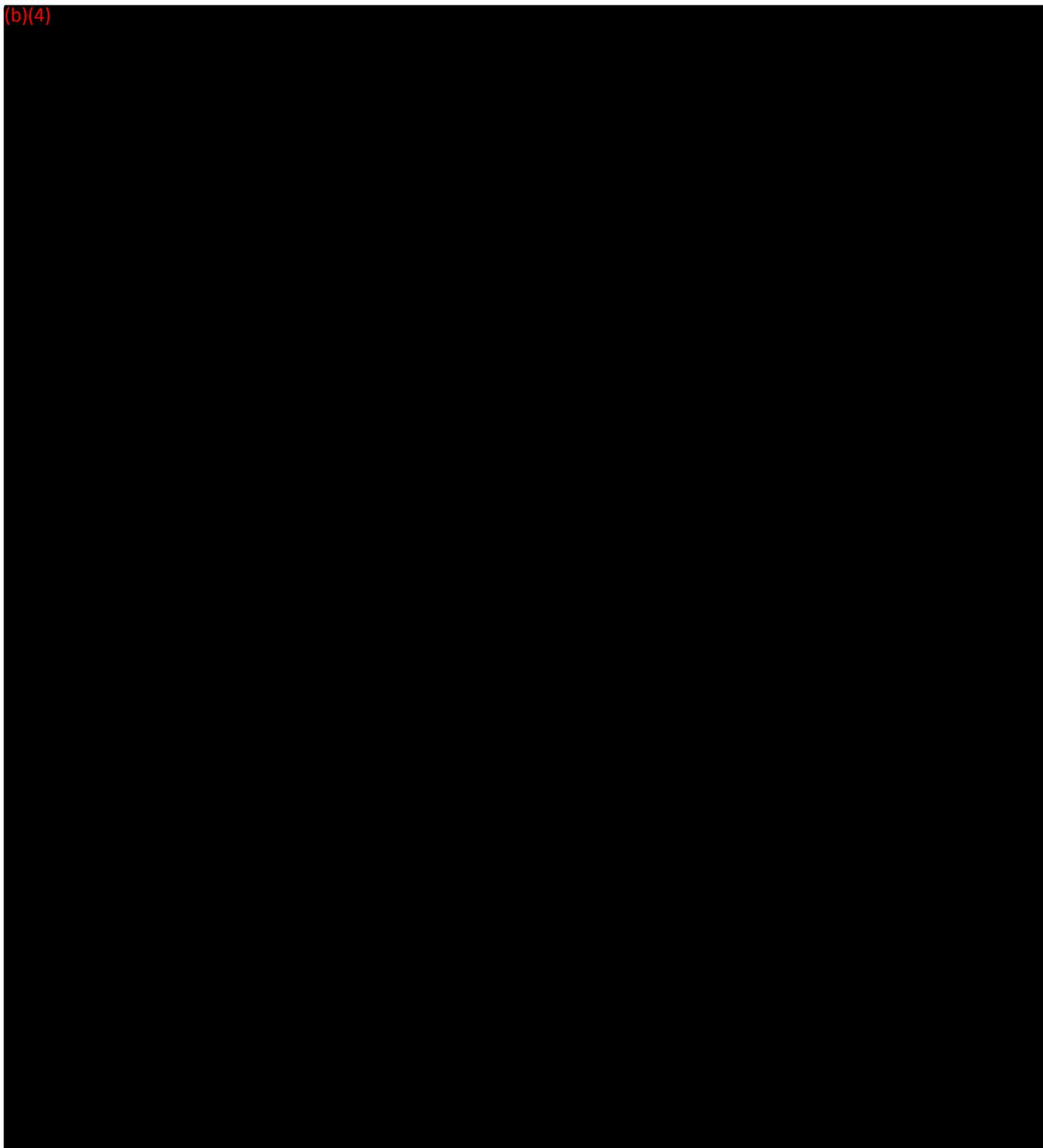
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III. METHODS AND MATERIALS

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BD CLINICAL STUDY: NORMAL AND NON-NORMAL DETERMINATION OF P SELECTIN, PT, APTT AND FIBRINOGEN USING 0.109 M BD VACUTAINER™ PLUS SODIUM CITRATE TUBES

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IV. DATA ANALYSIS

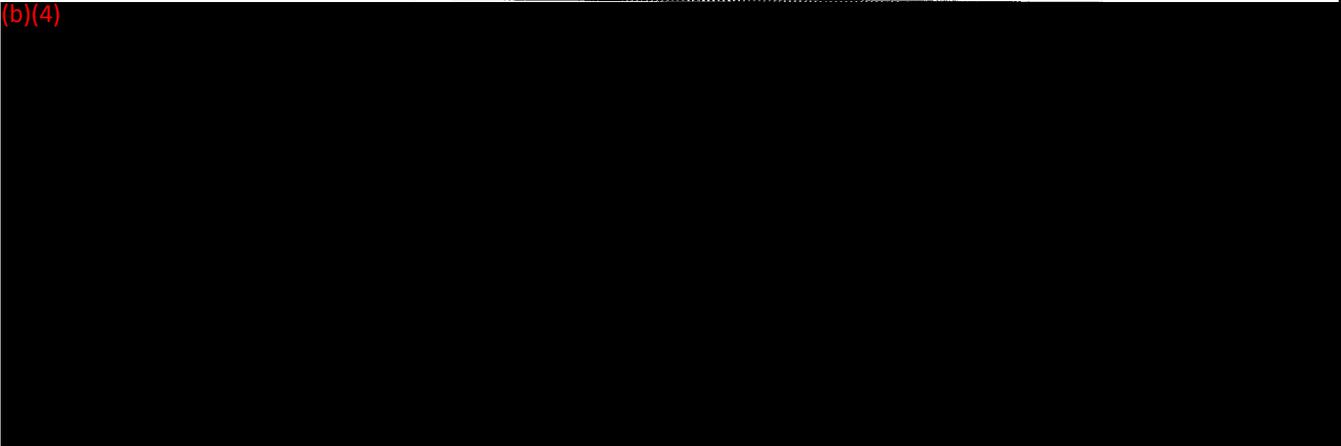
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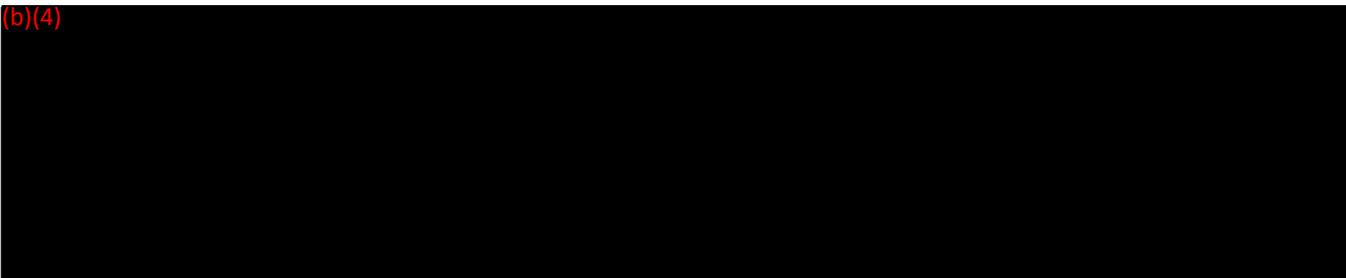
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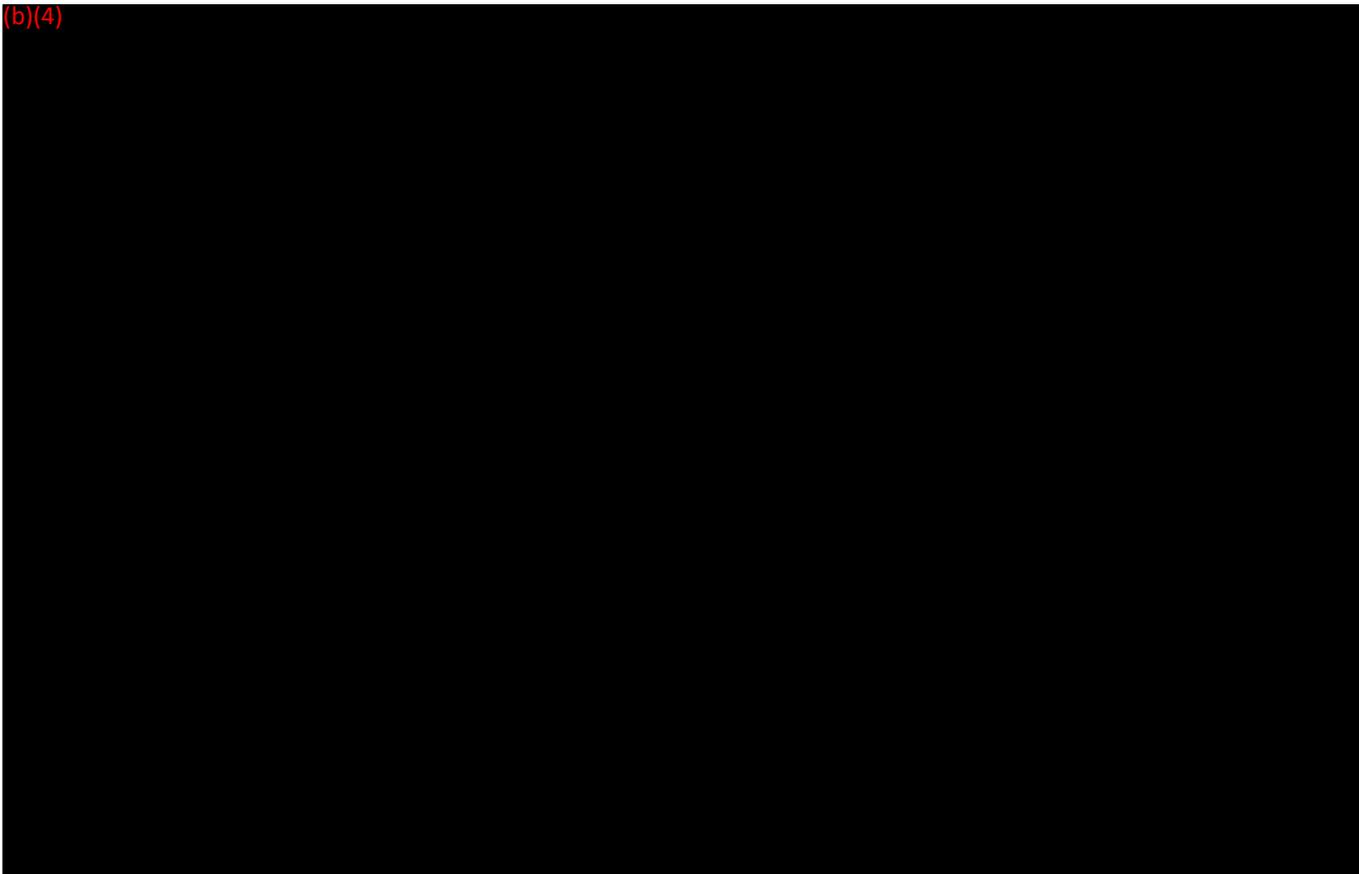
V. DETAILS AND DEVIATIONS

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VI. RESULTS AND DISCUSSION

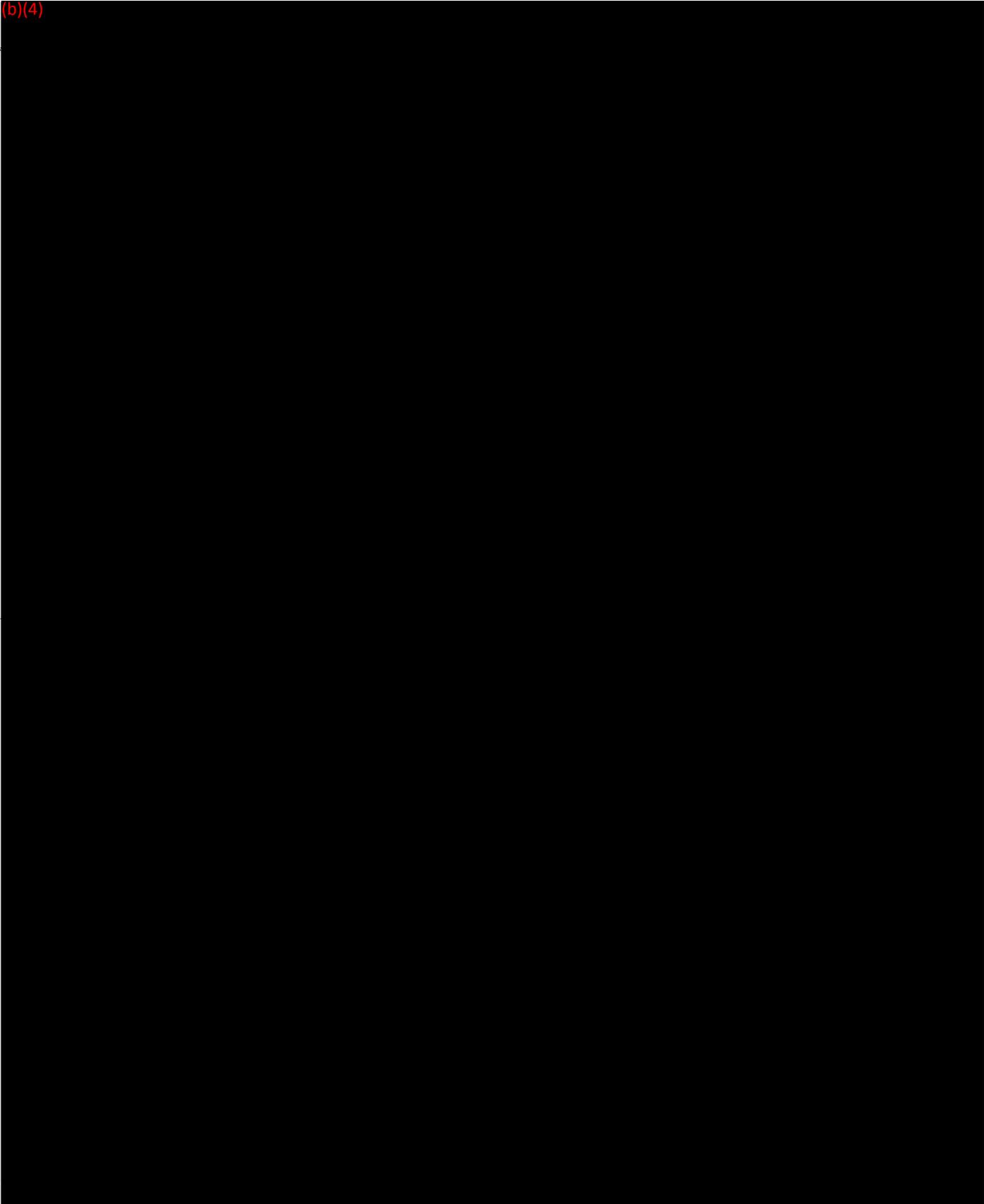
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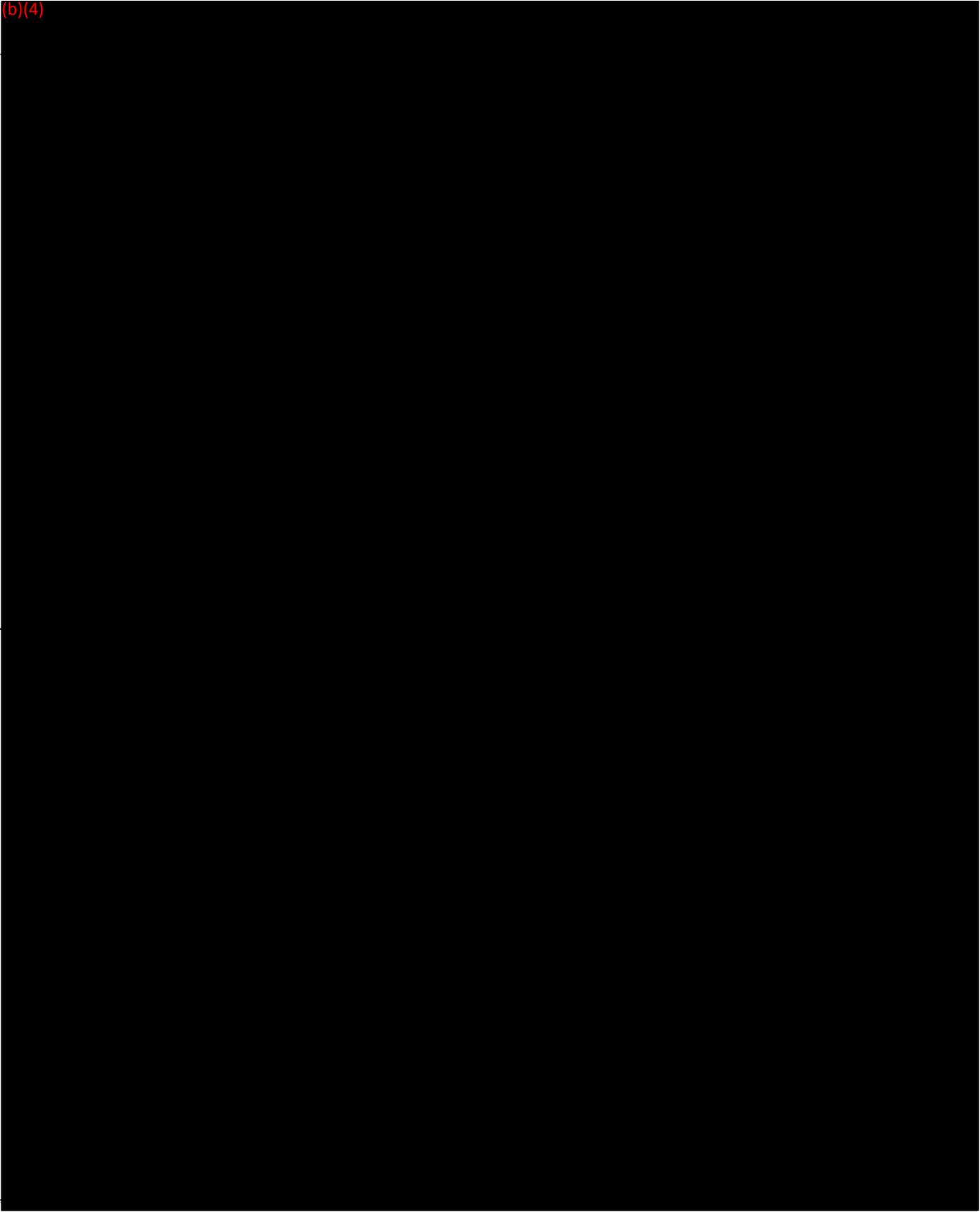
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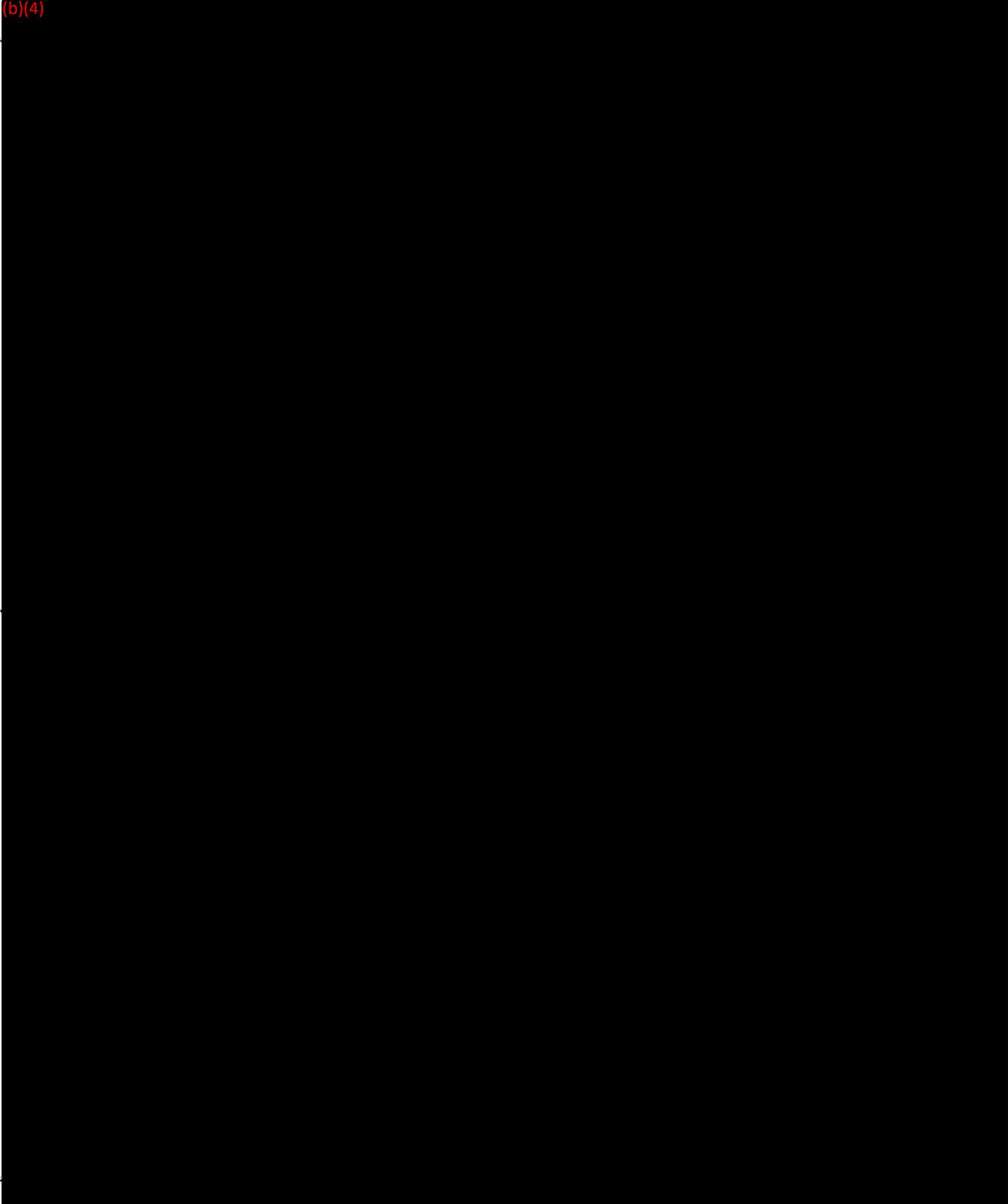
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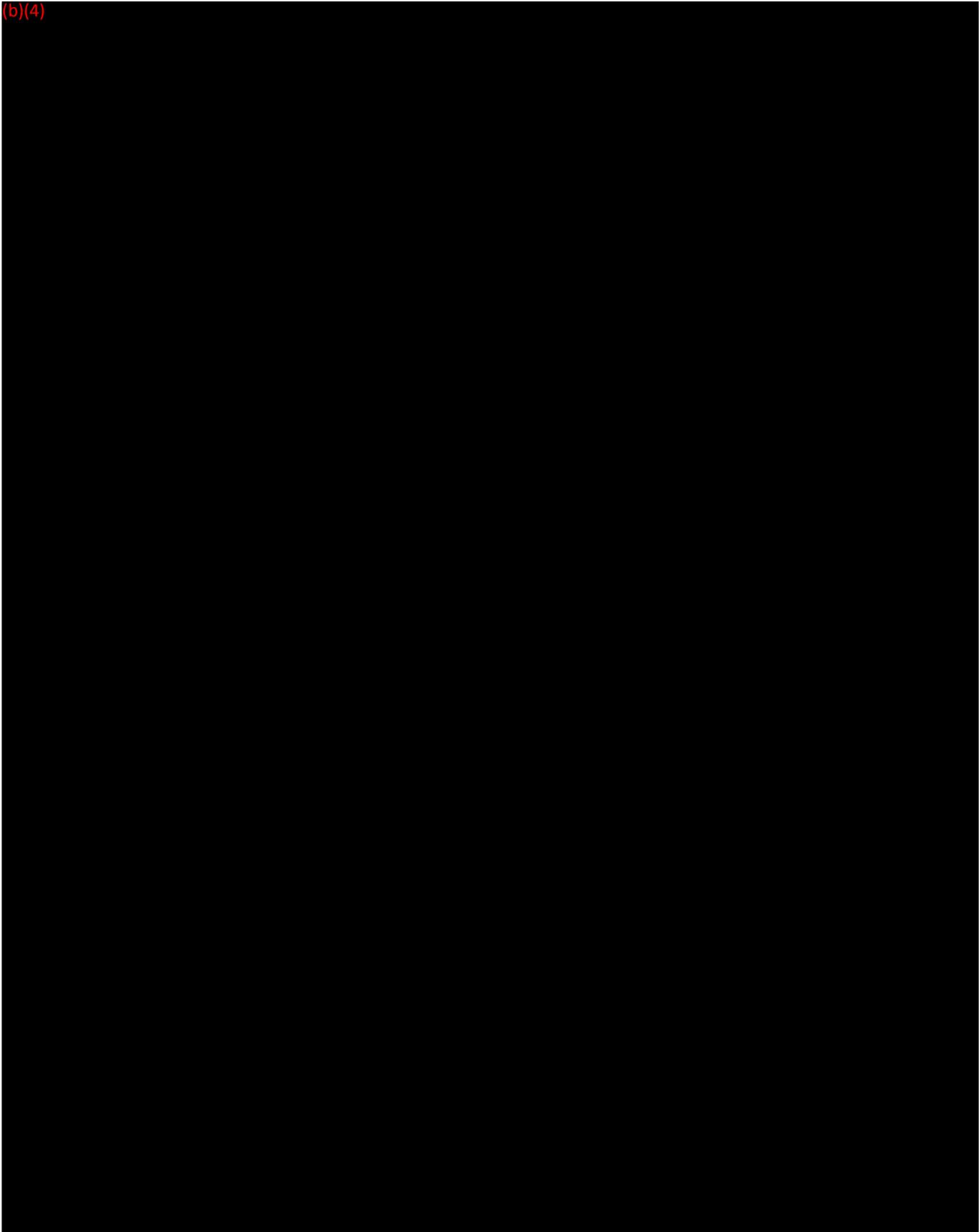
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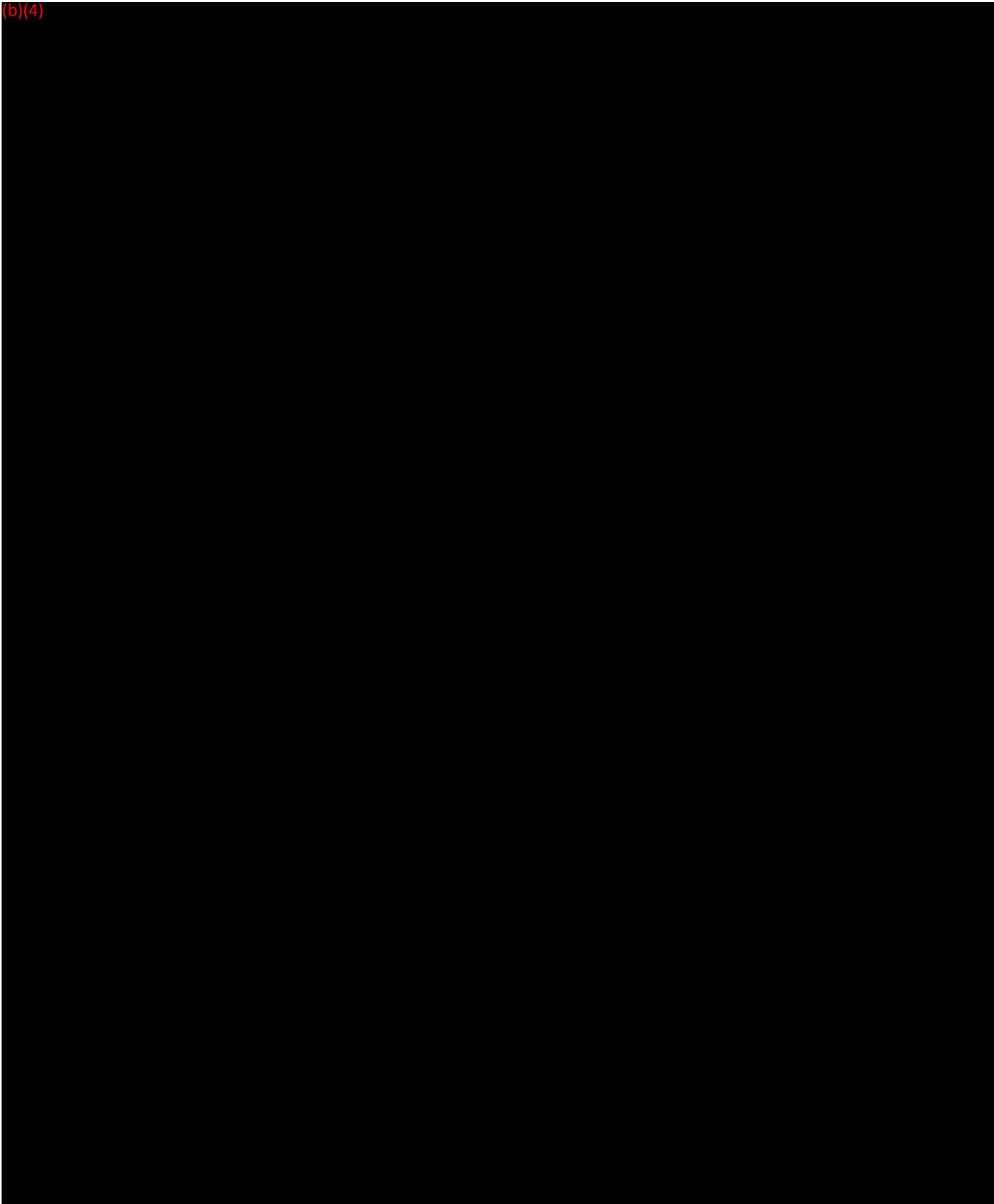
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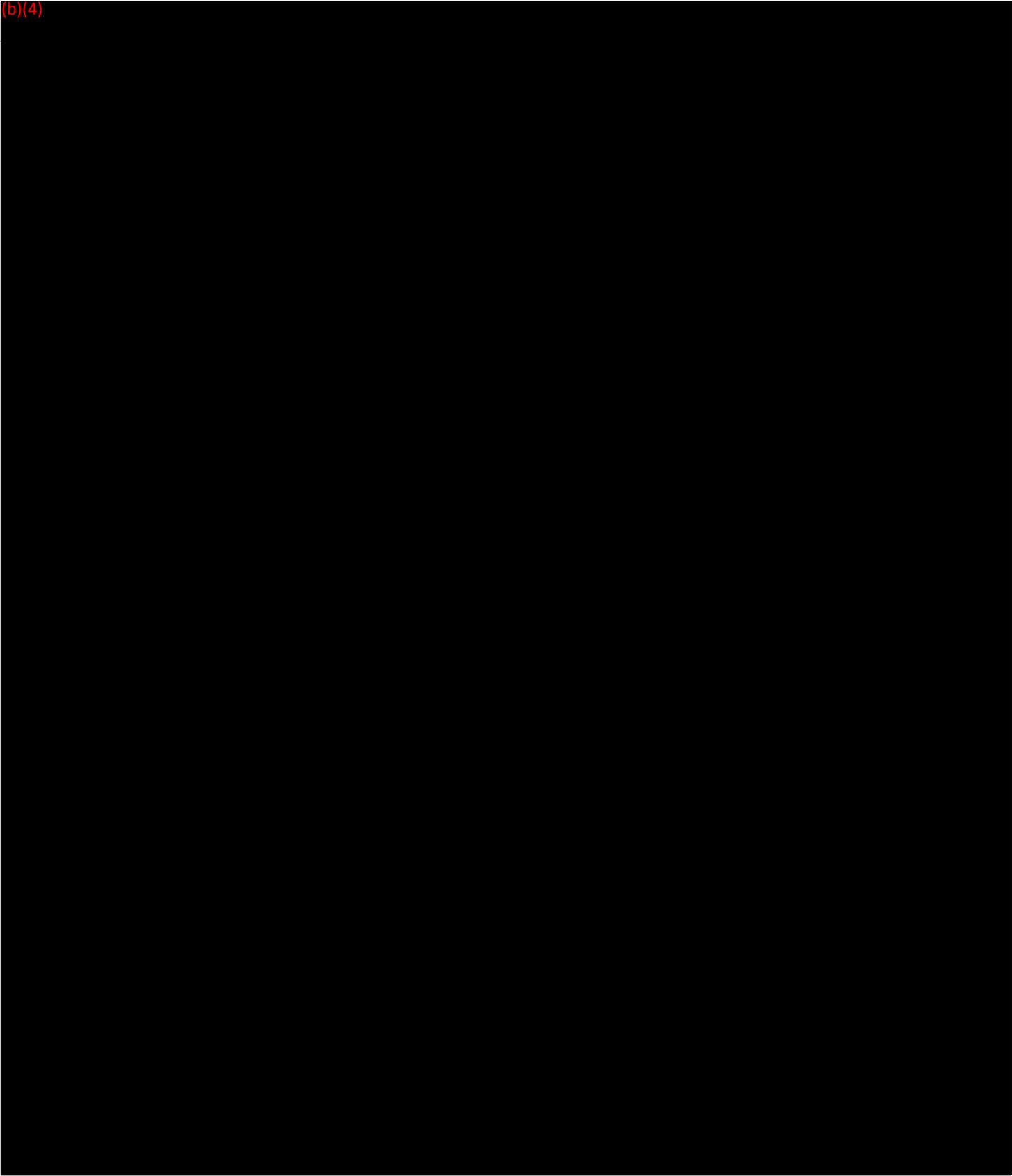
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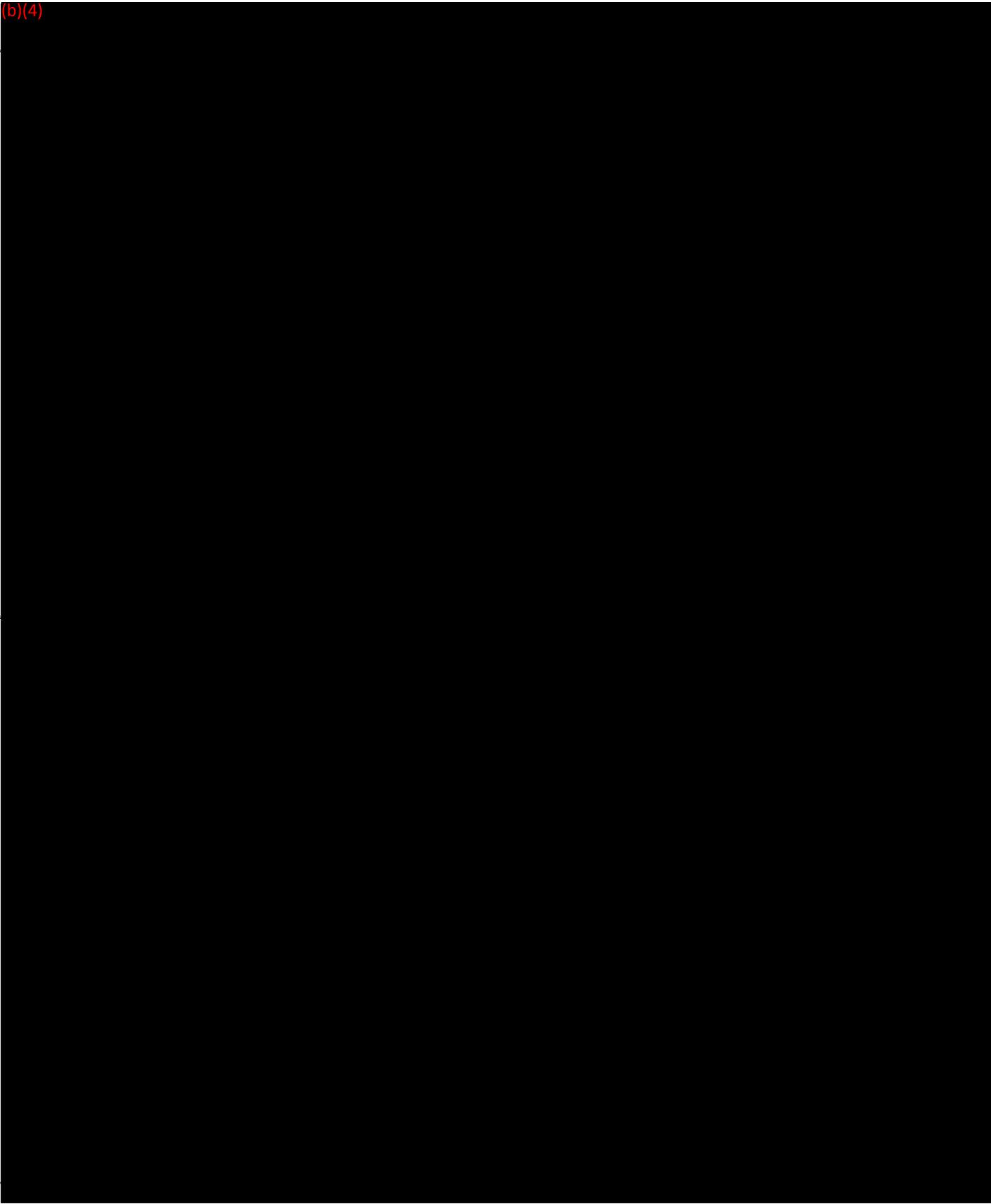
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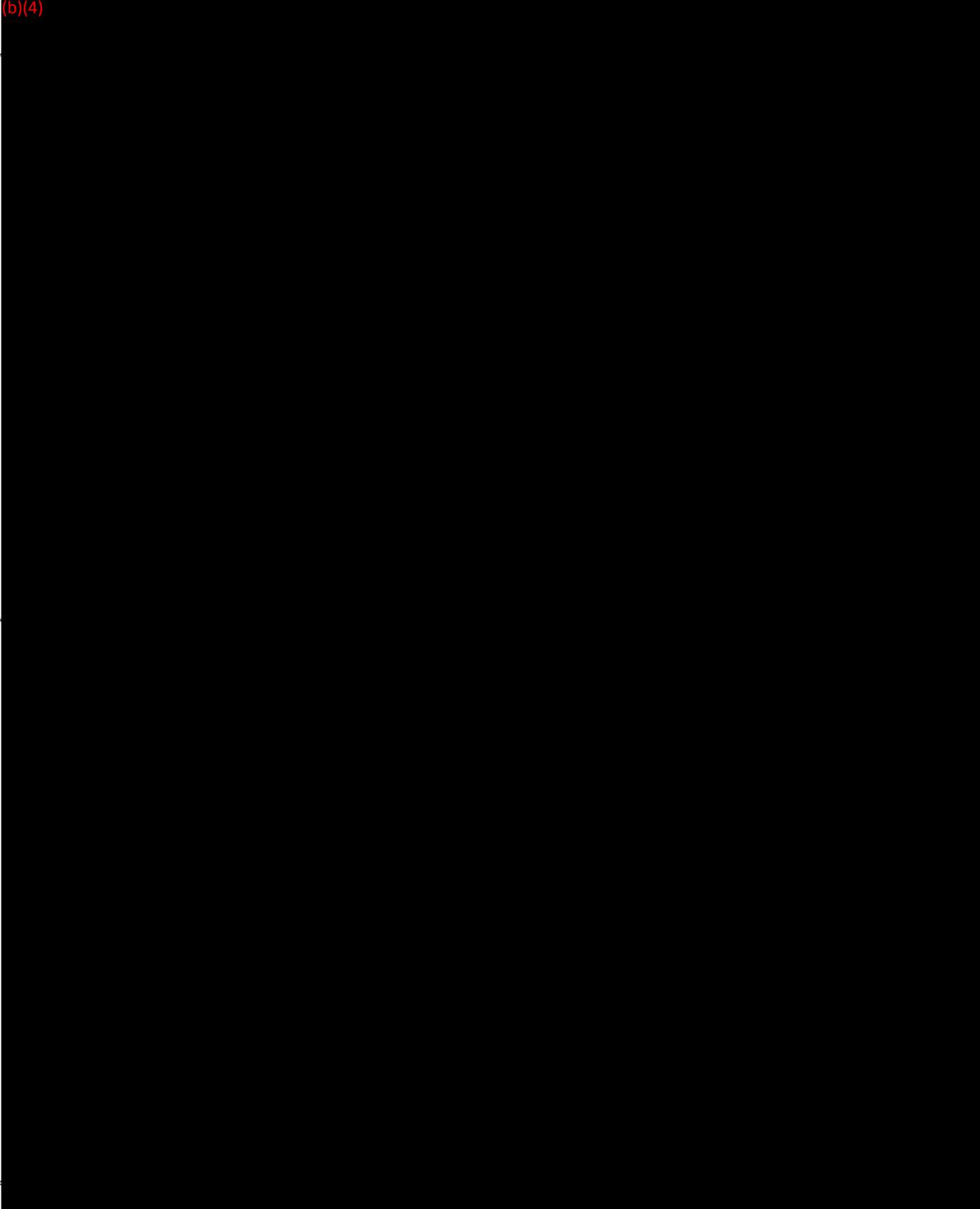
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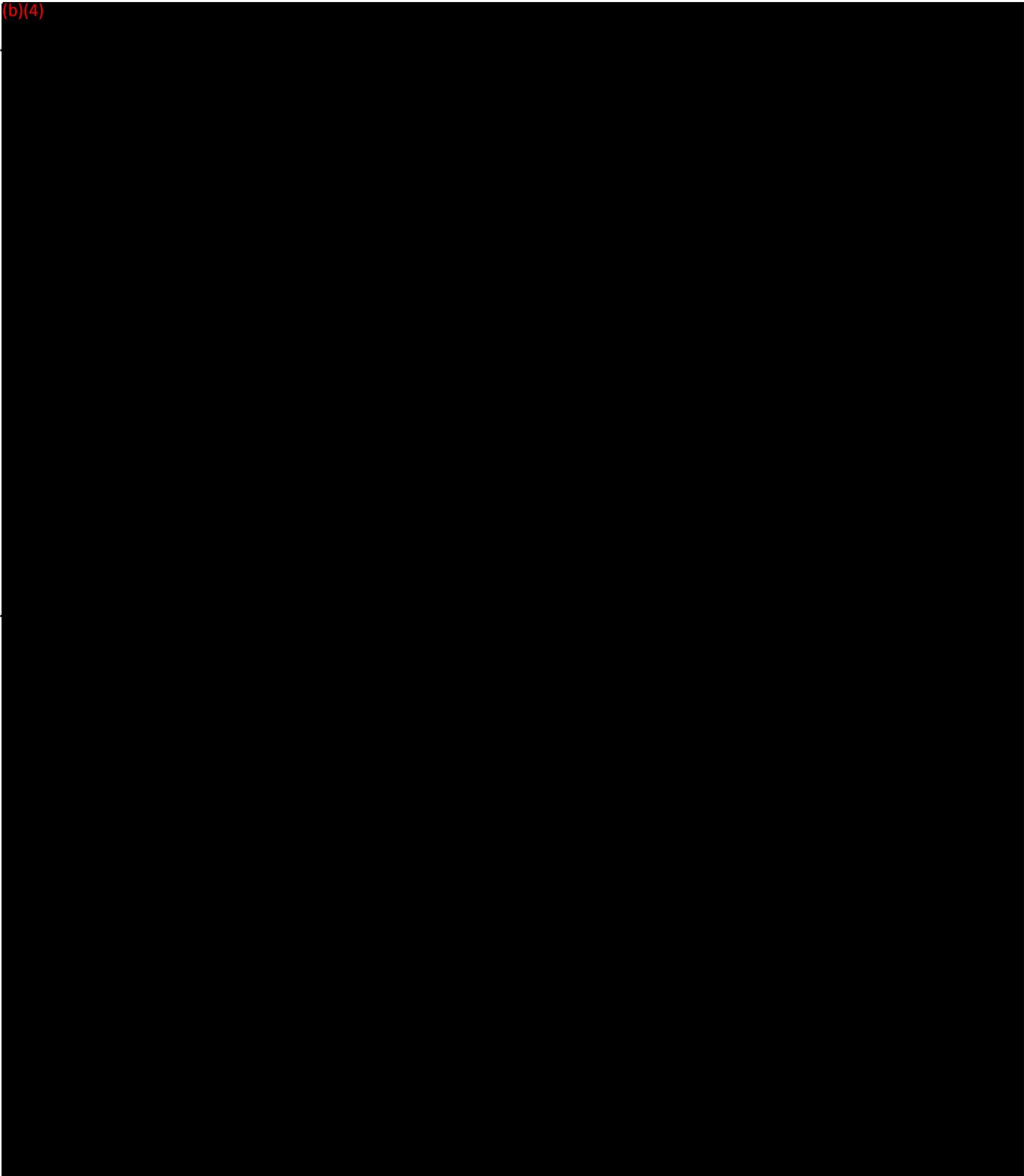
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BD CLINICAL STUDY: NORMAL AND NON-NORMAL DETERMINATION OF P SELECTIN, PT, APTT AND FIBRINOGEN USING 0.109 M BD VACUTAINER™ PLUS SODIUM CITRATE TUBES

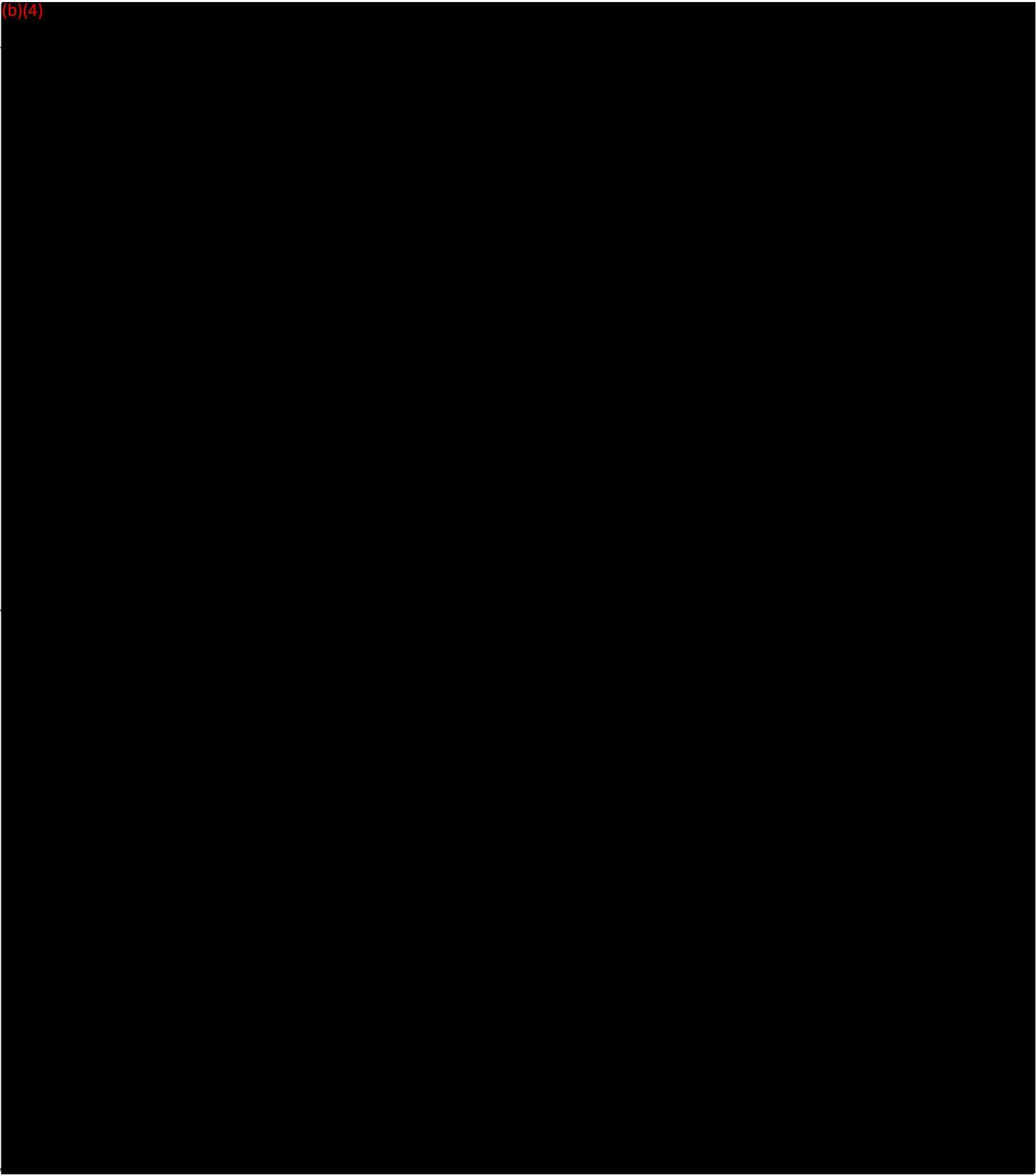
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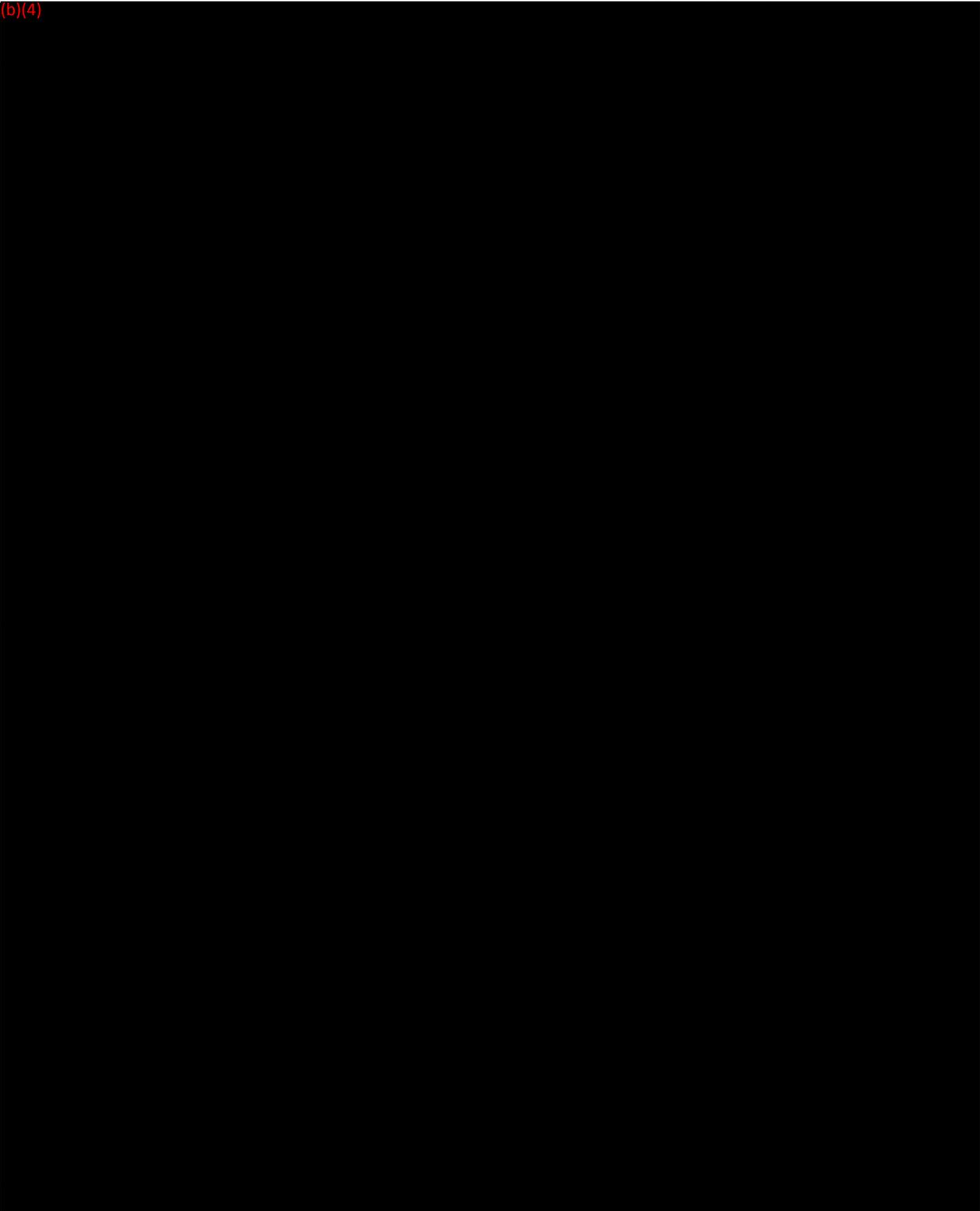
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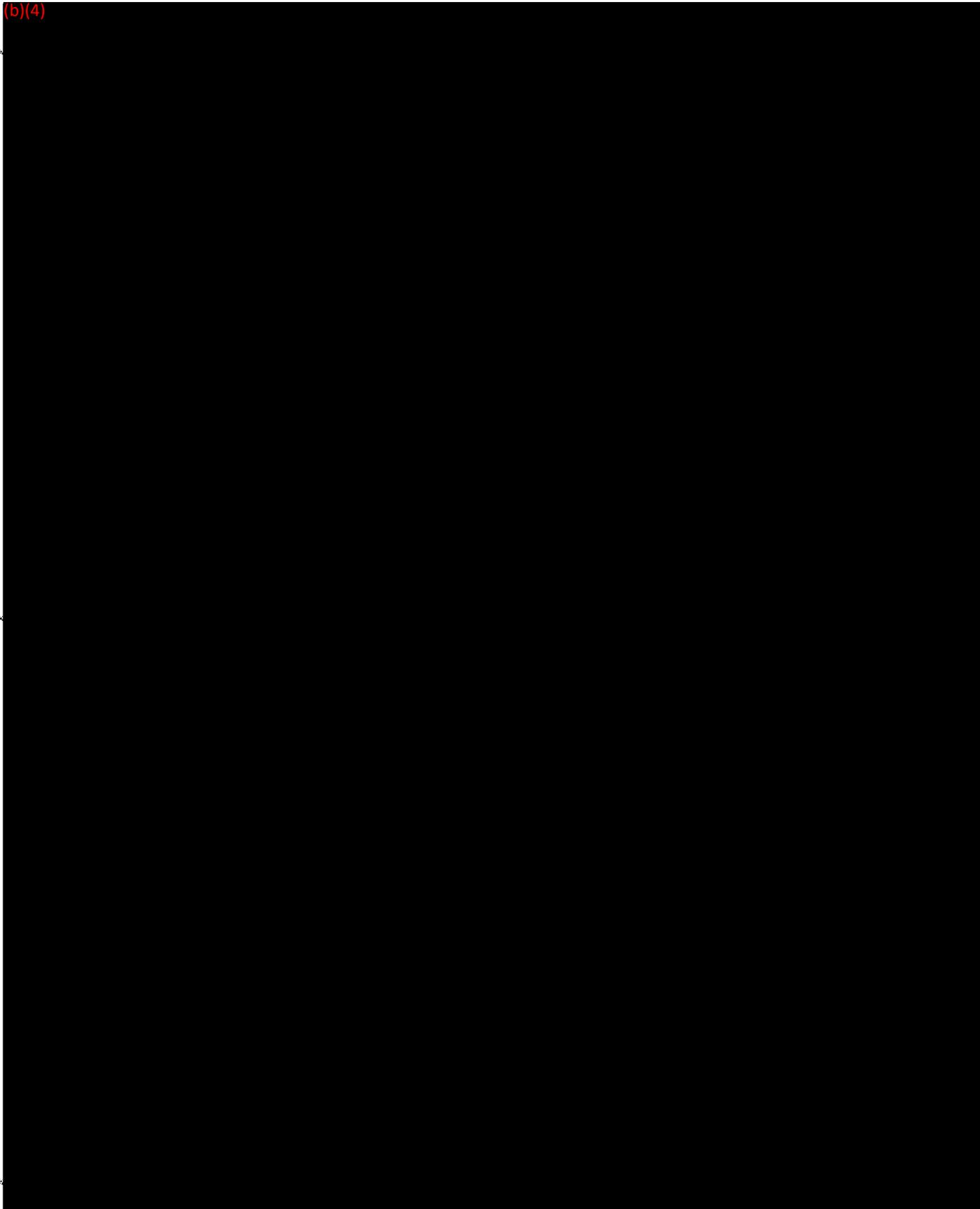
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BD CLINICAL STUDY: NORMAL AND NON-NORMAL DETERMINATION OF P SELECTIN, PT, APTT AND FIBRINOGEN USING 0.109 M BD VACUTAINER™ PLUS SODIUM CITRATE TUBES

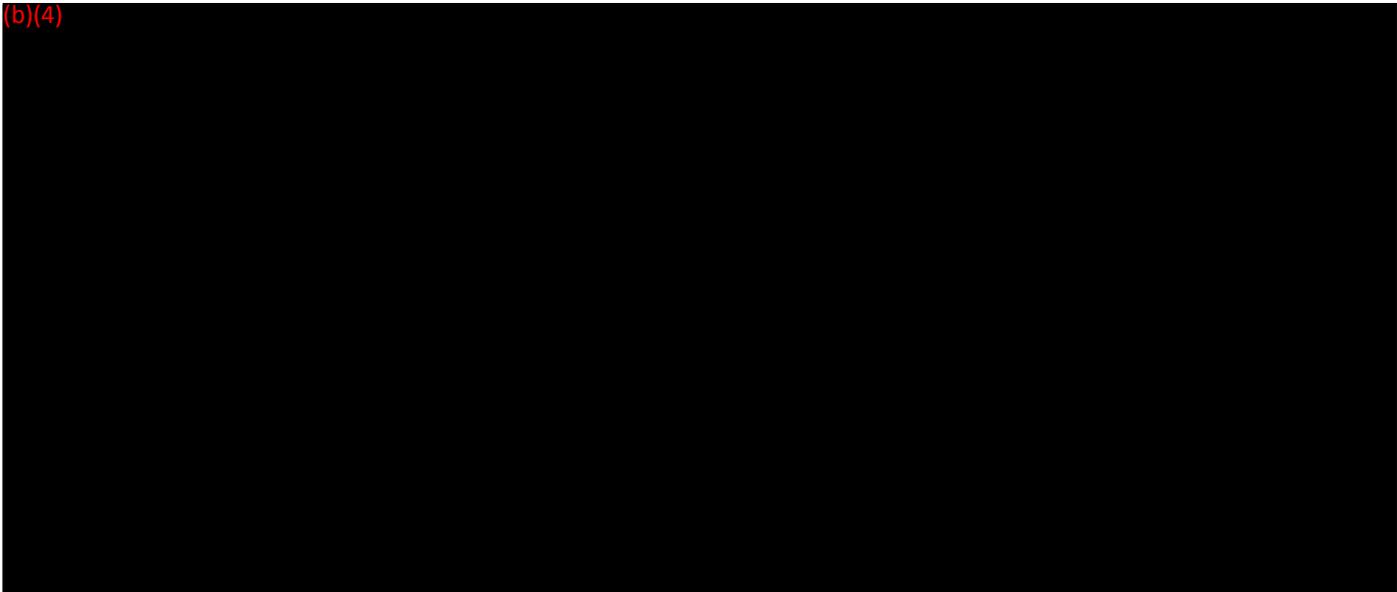
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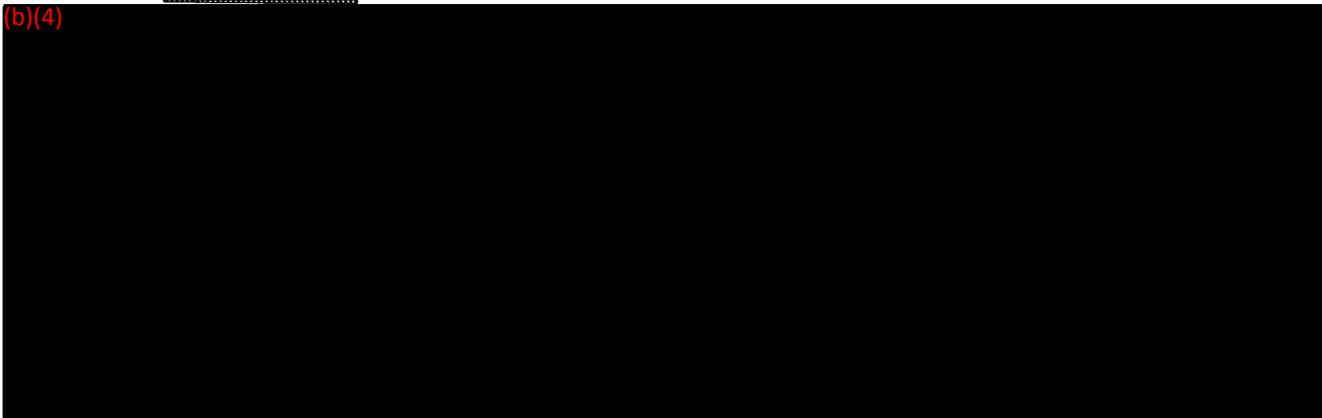
BD CLINICAL STUDY: NORMAL AND NON-NORMAL DETERMINATION OF P SELECTIN, PT, APTT AND FIBRINOGEN USING 0.109 M BD VACUTAINER™ PLUS SODIUM CITRATE TUBES

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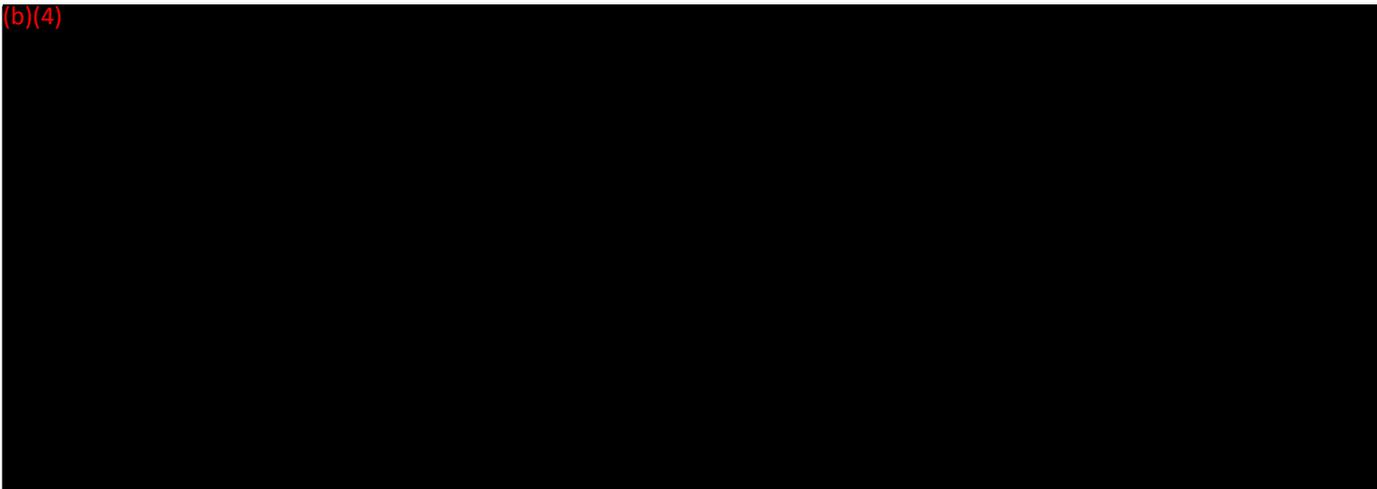
VII. CONCLUSIONS

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VIII. REFERENCES

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**ATTACHMENT 10: CLINICAL EVALUATION- AT BD
VACUTAINER SYSTEMS (BDVS) & (b)(4)**

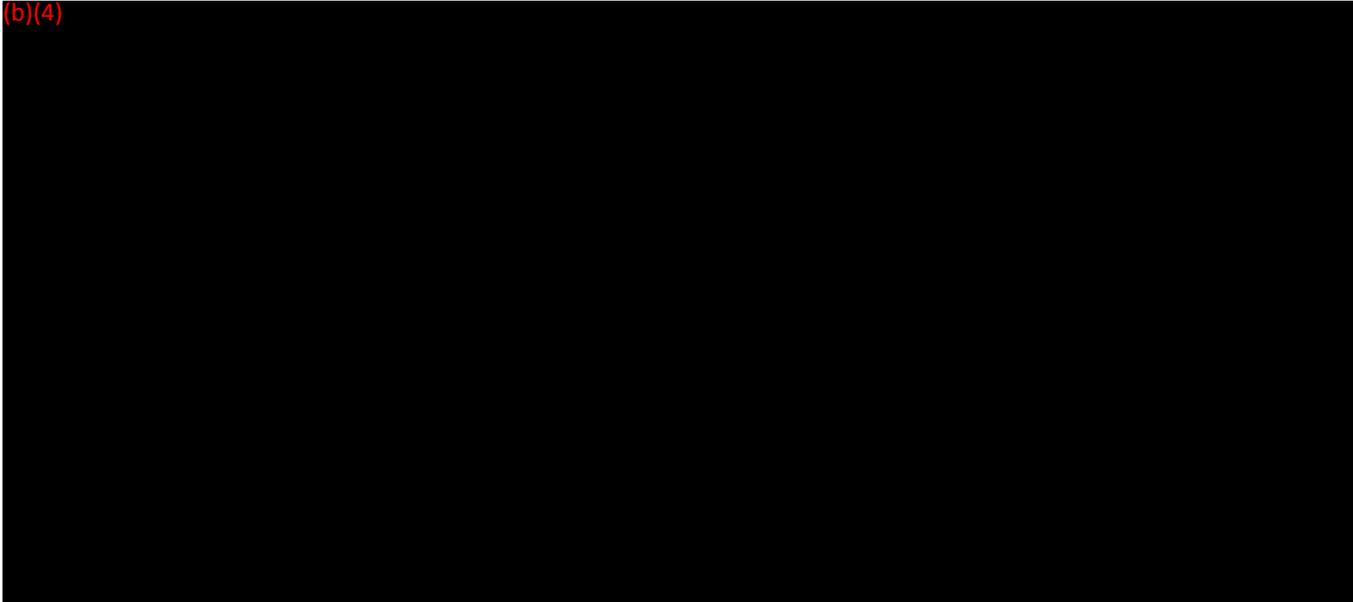
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BD CLINICAL STUDY: NORMAL AND NON-NORMAL DONOR - DETERMINATION OF P SELECTIN, PT, APTT AND FIBRINOGEN USING 0.129 M BD VACUTAINER™ PLUS SODIUM CITRATE TUBES

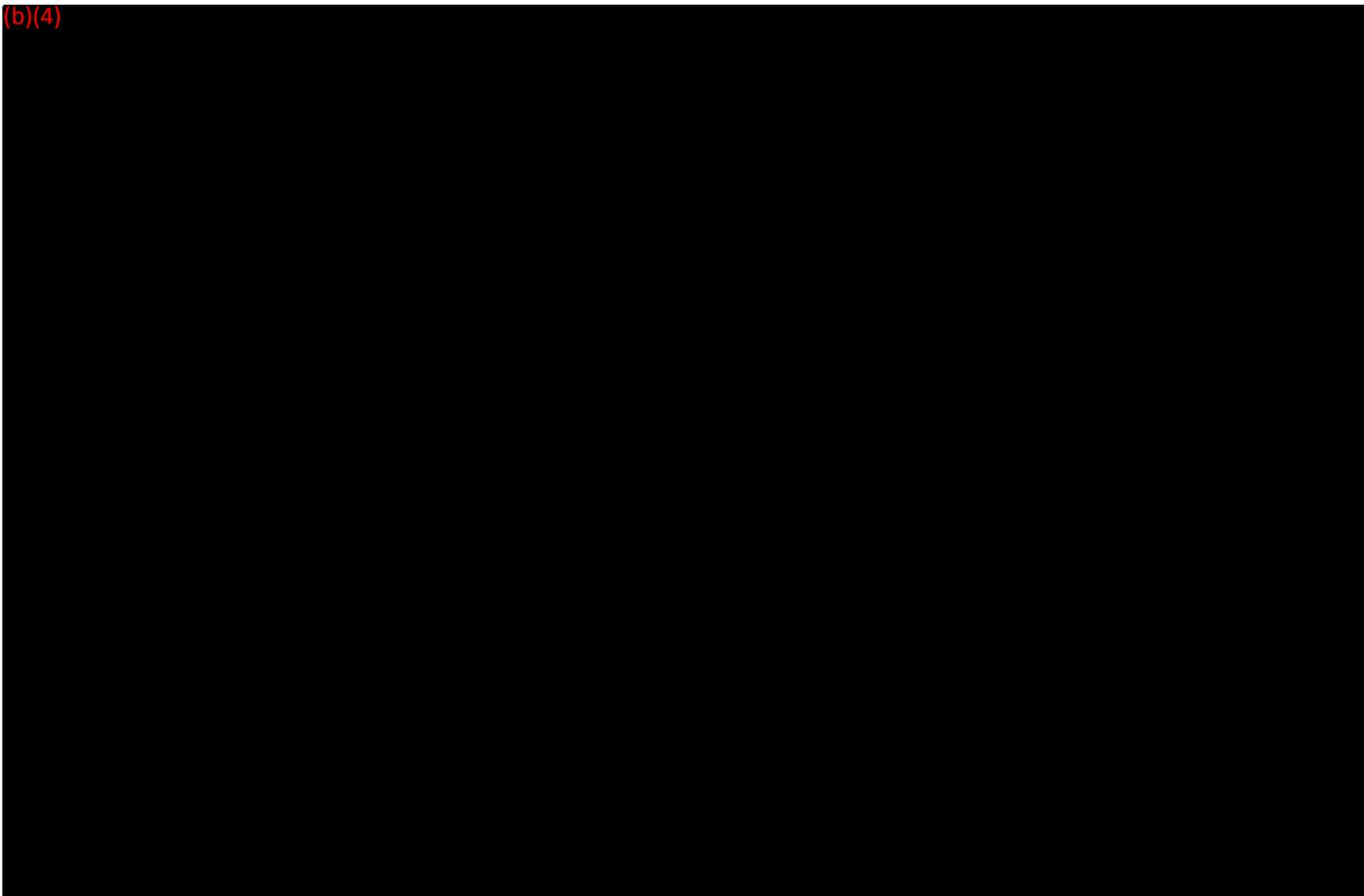
ABSTRACT

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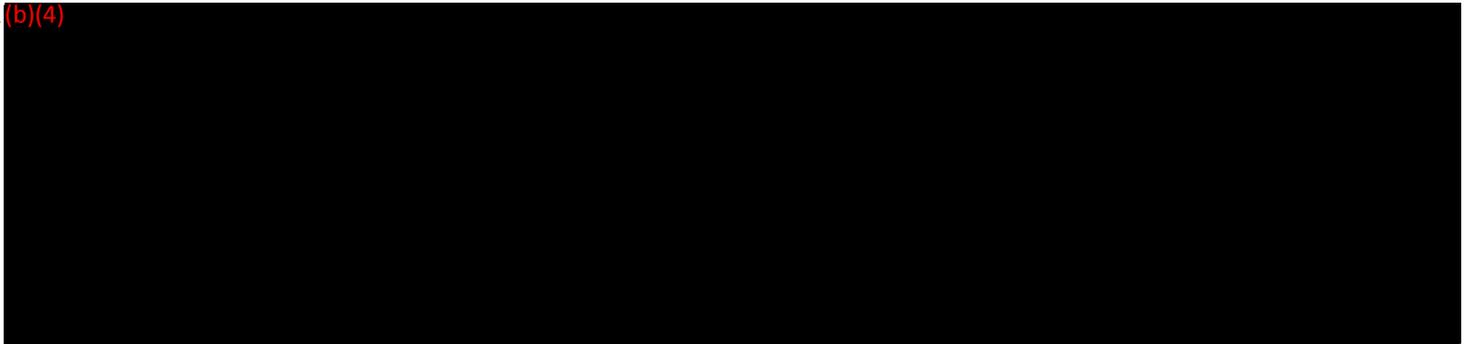


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BD CLINICAL STUDY: NORMAL AND NON-NORMAL DONOR - DETERMINATION OF P SELECTIN, PT, APTT AND FIBRINOGEN USING 0.129 M BD VACUTAINER™ PLUS SODIUM CITRATE TUBES

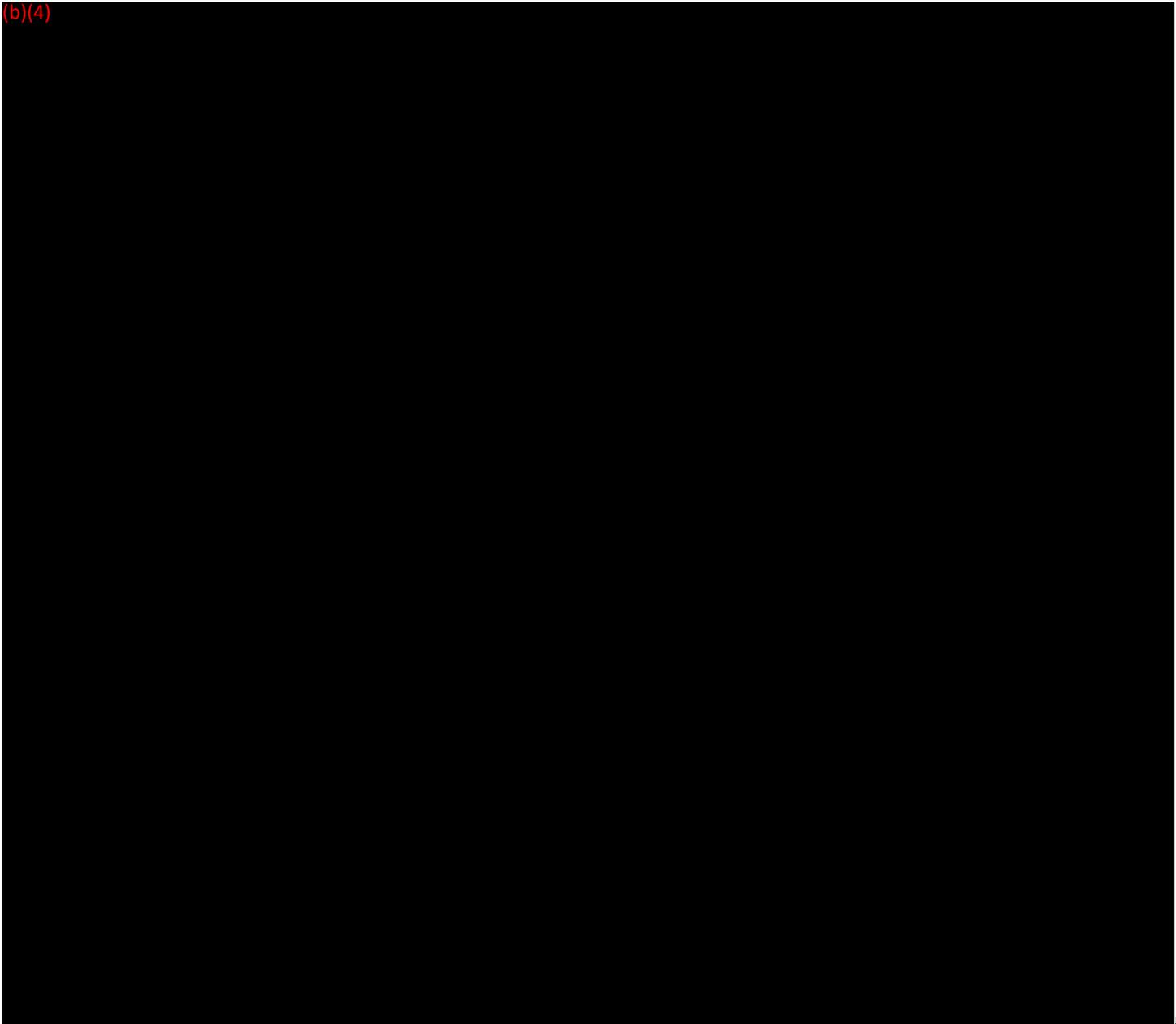
II. OBJECTIVE

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III. METHODS AND MATERIALS

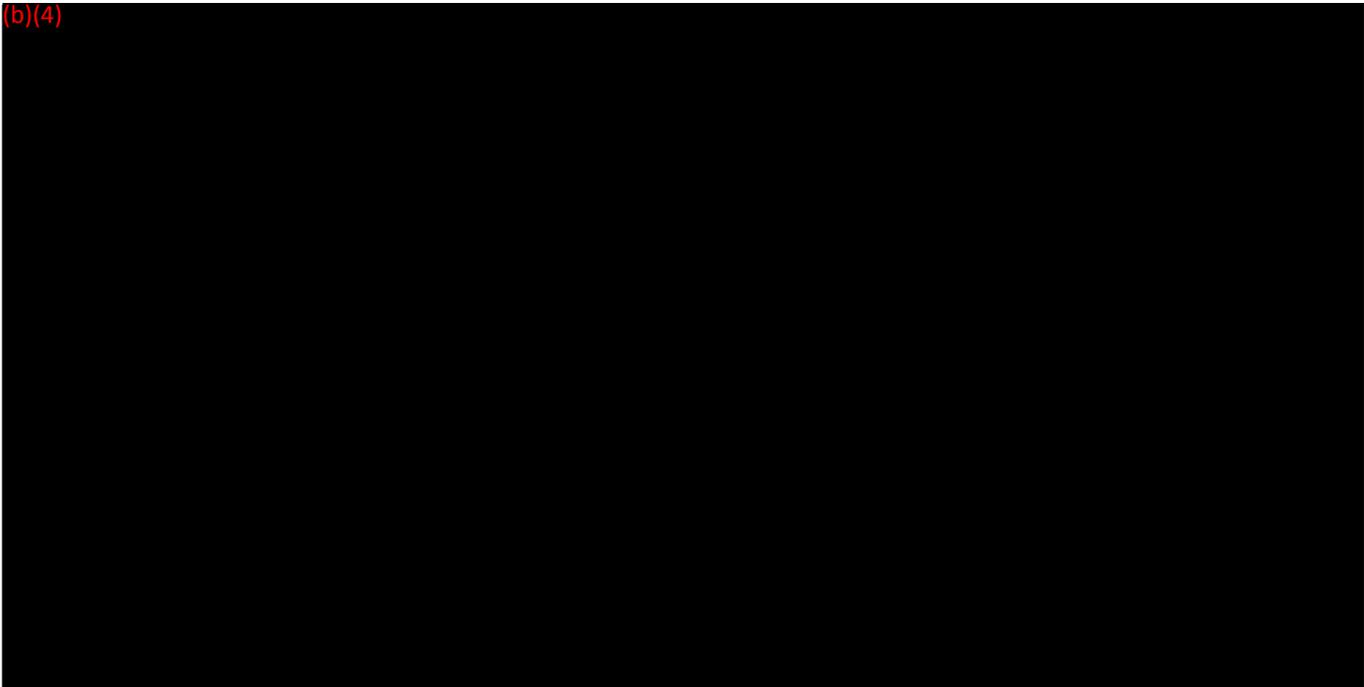
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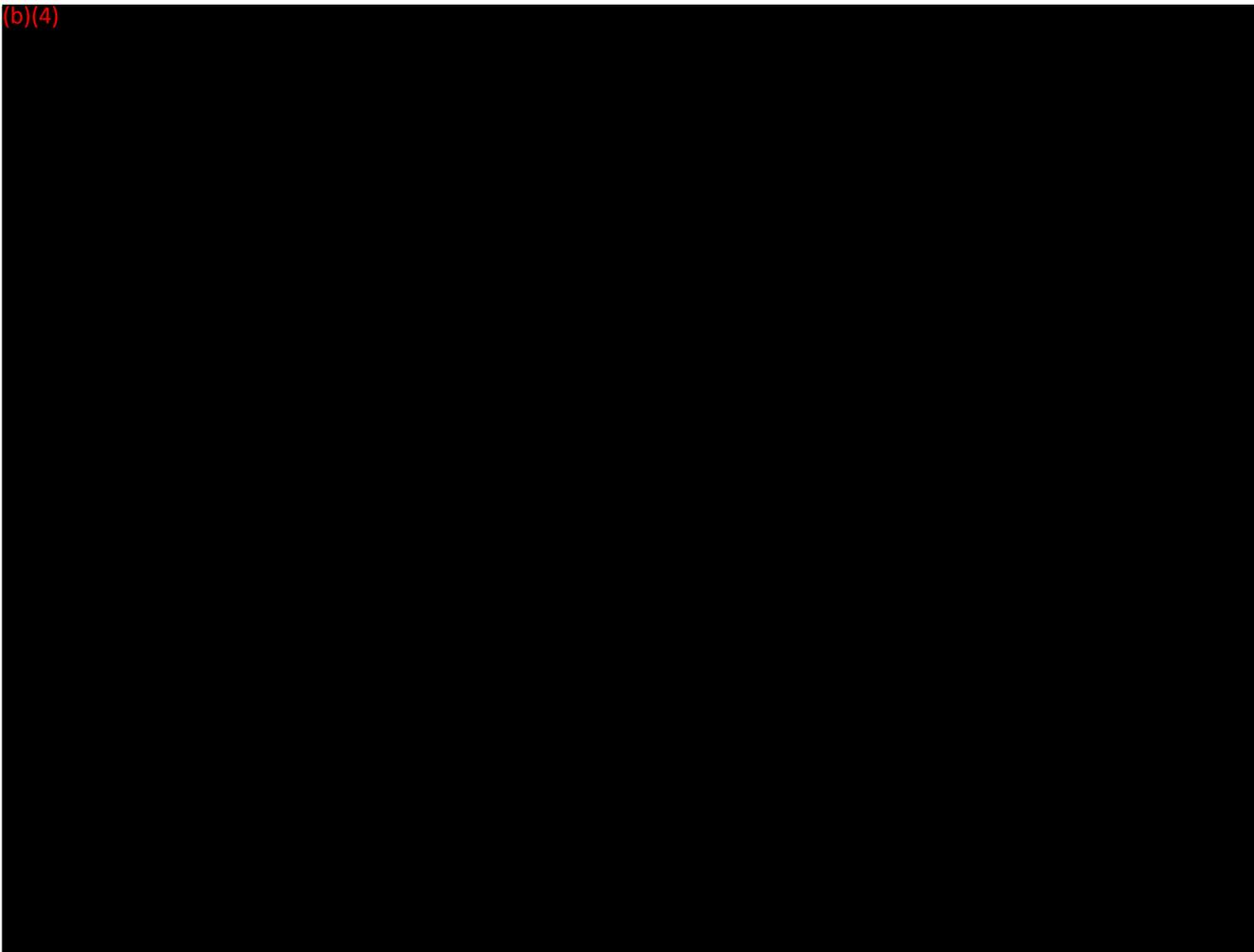
BD CLINICAL STUDY: NORMAL AND NON-NORMAL DONOR - DETERMINATION OF P SELECTIN, PT, APTT AND FIBRINOGEN USING 0.129 M BD VACUTAINER™ PLUS SODIUM CITRATE TUBES

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IV. DATA ANALYSIS

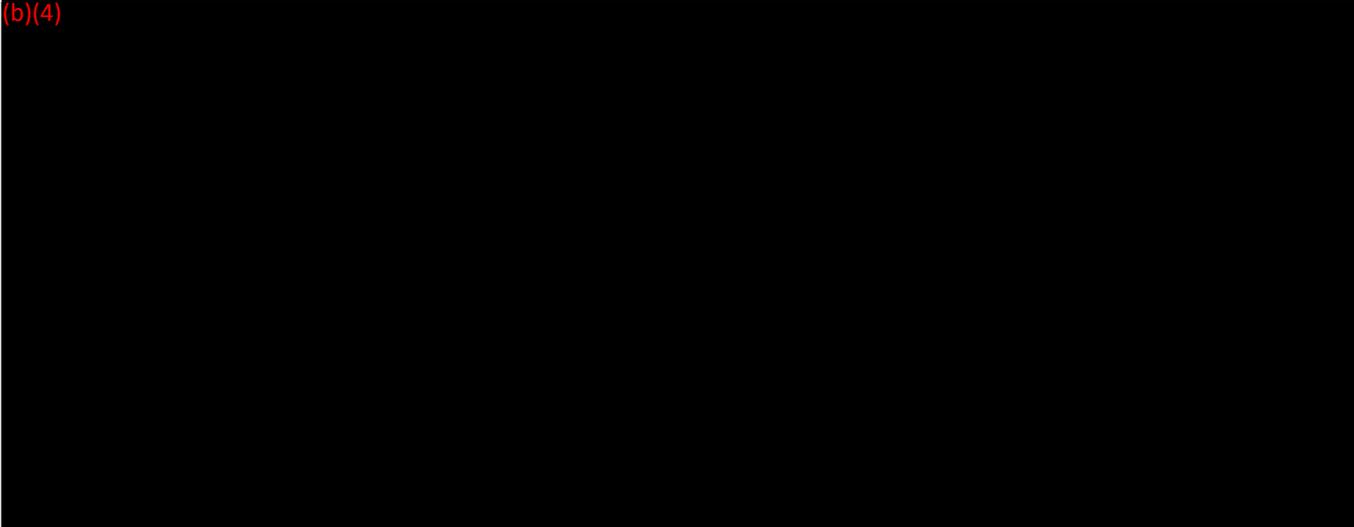
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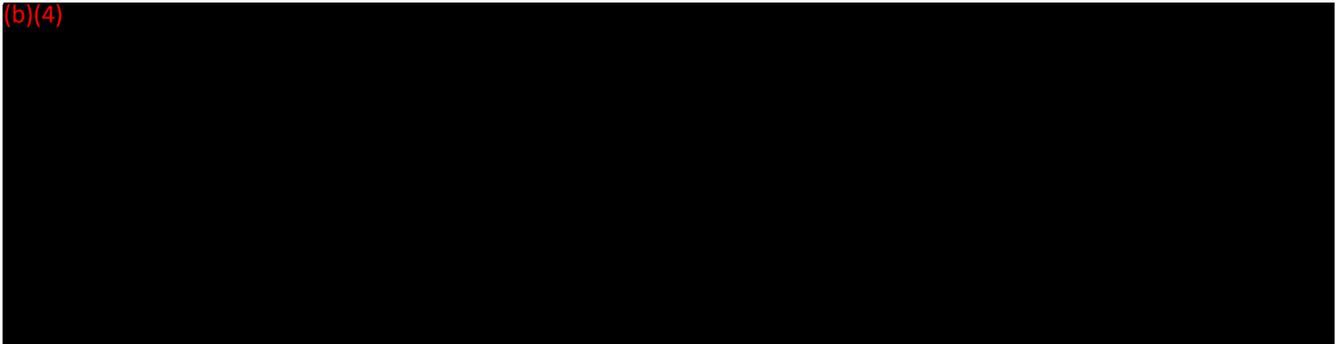
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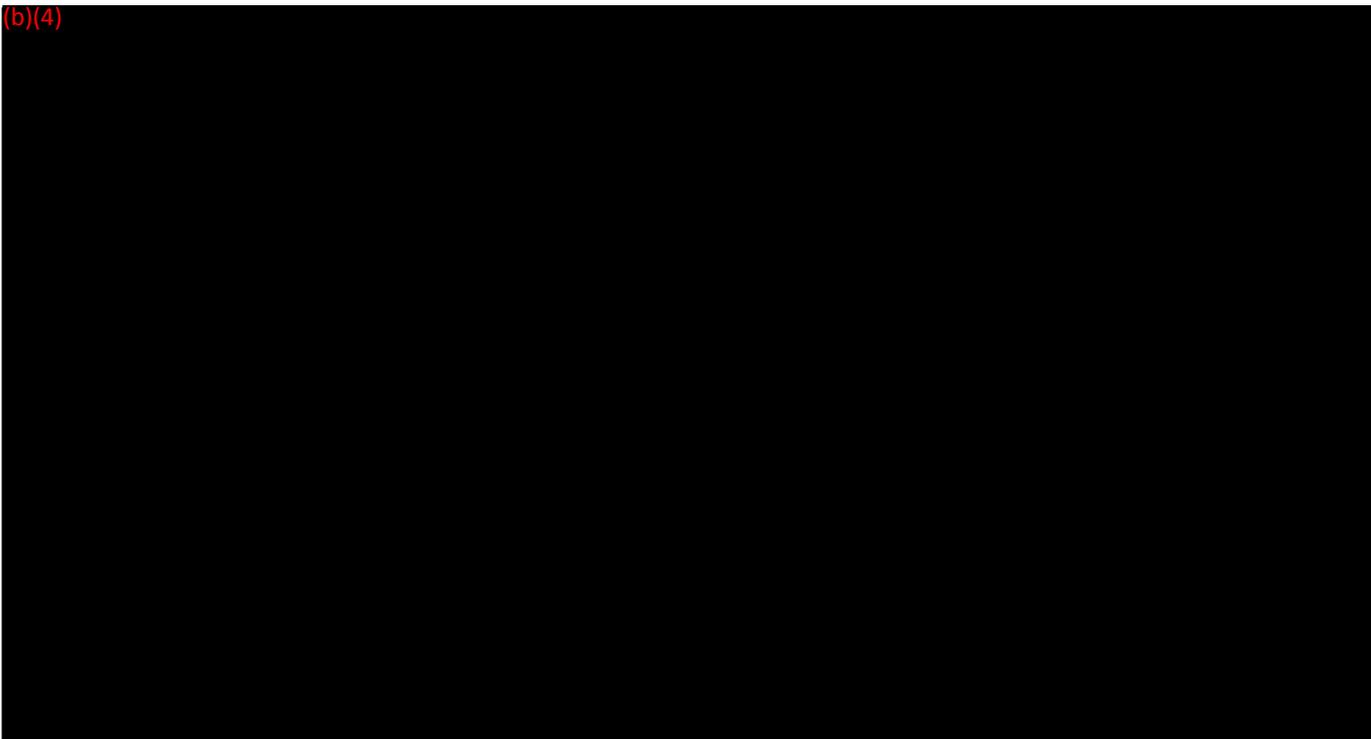
V. DETAILS AND DEVIATIONS

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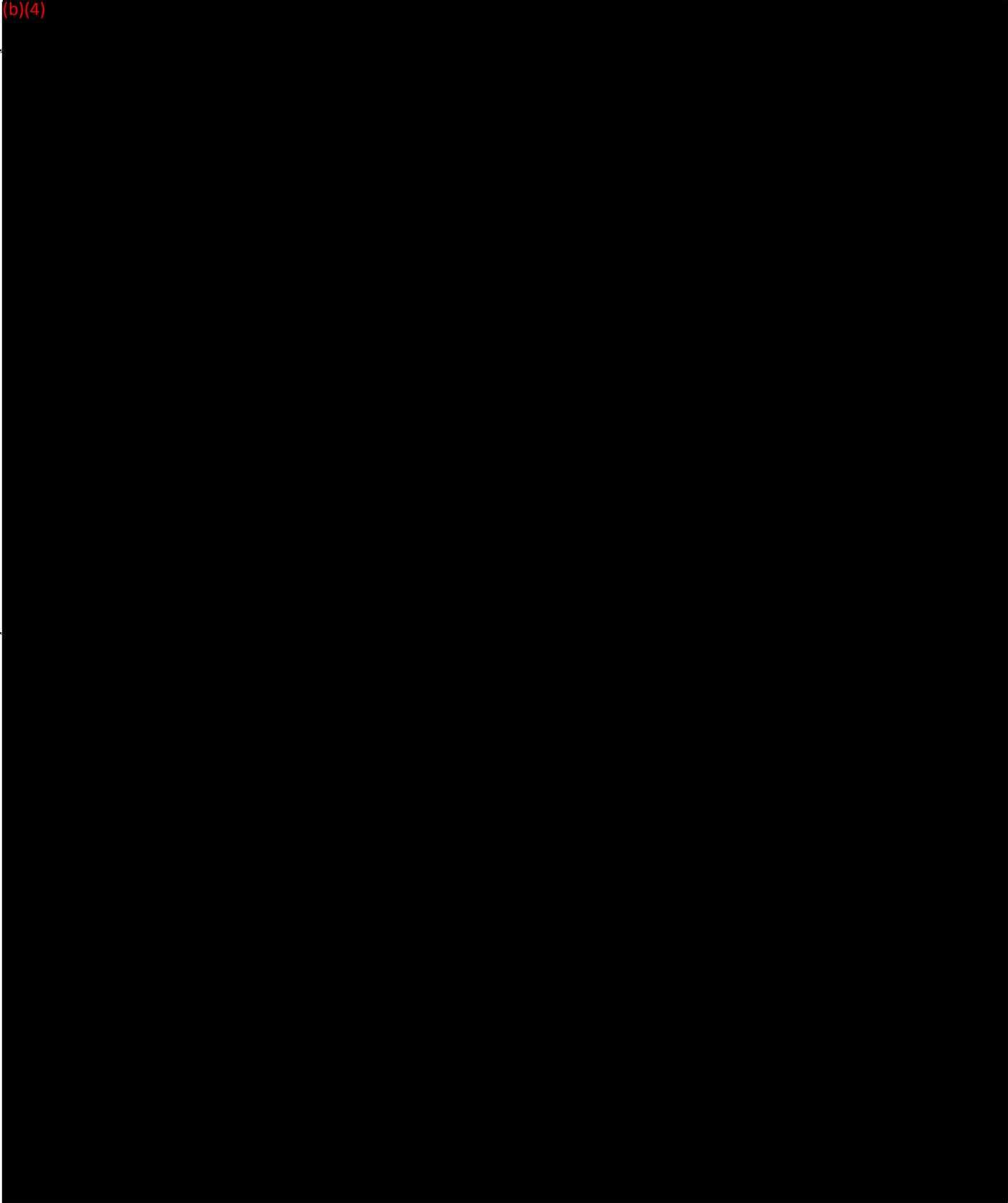
VI. RESULTS AND DISCUSSION

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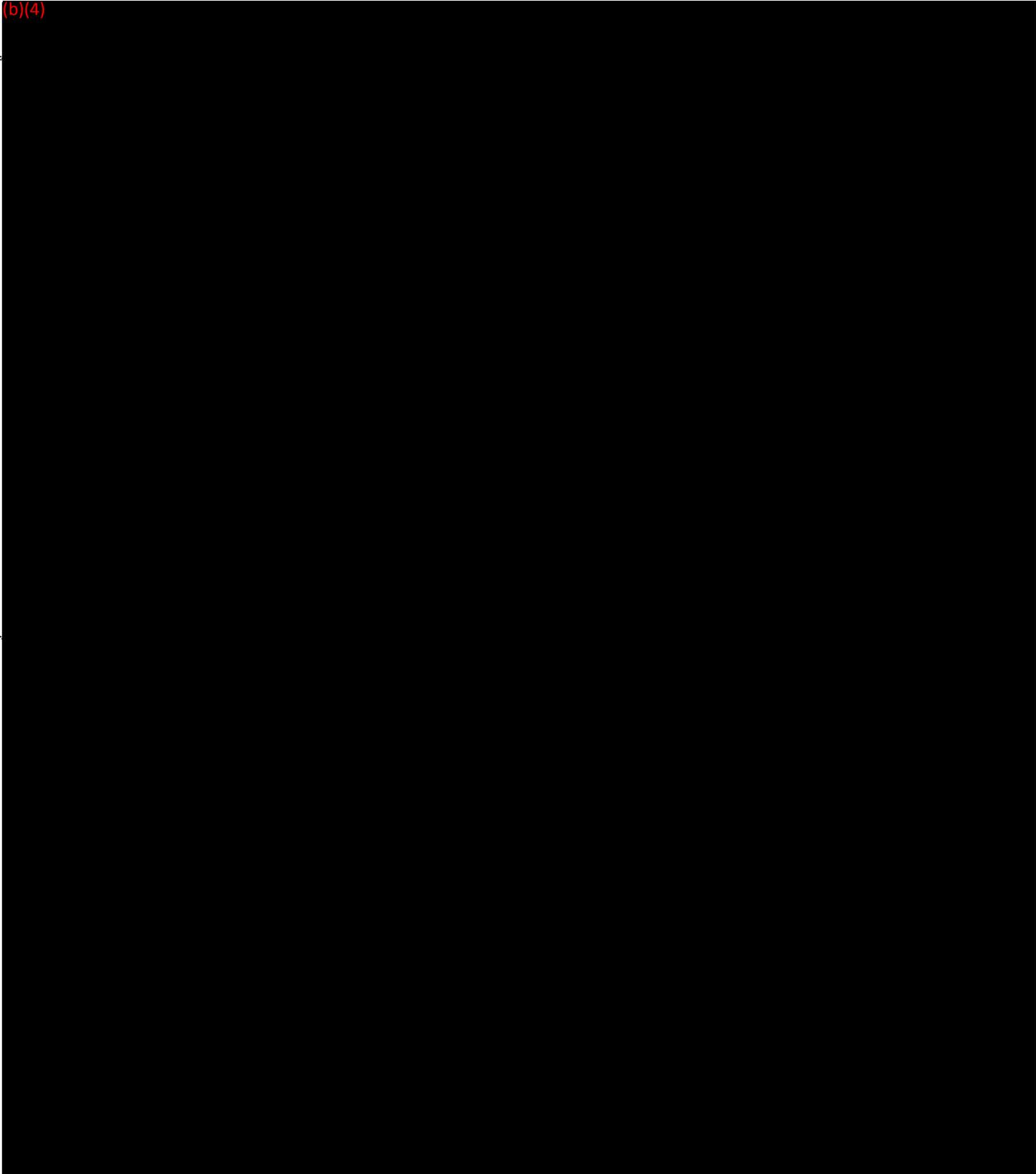
BD CLINICAL STUDY: NORMAL AND NON-NORMAL DONOR - DETERMINATION OF P SELECTIN, PT, APTT AND FIBRINOGEN USING 0.129 M BD VACUTAINER™ PLUS SODIUM CITRATE TUBES



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BD CLINICAL STUDY: NORMAL AND NON-NORMAL DONOR - DETERMINATION OF P SELECTIN, PT, APTT AND FIBRINOGEN USING 0.129 M BD VACUTAINER™ PLUS SODIUM CITRATE TUBES

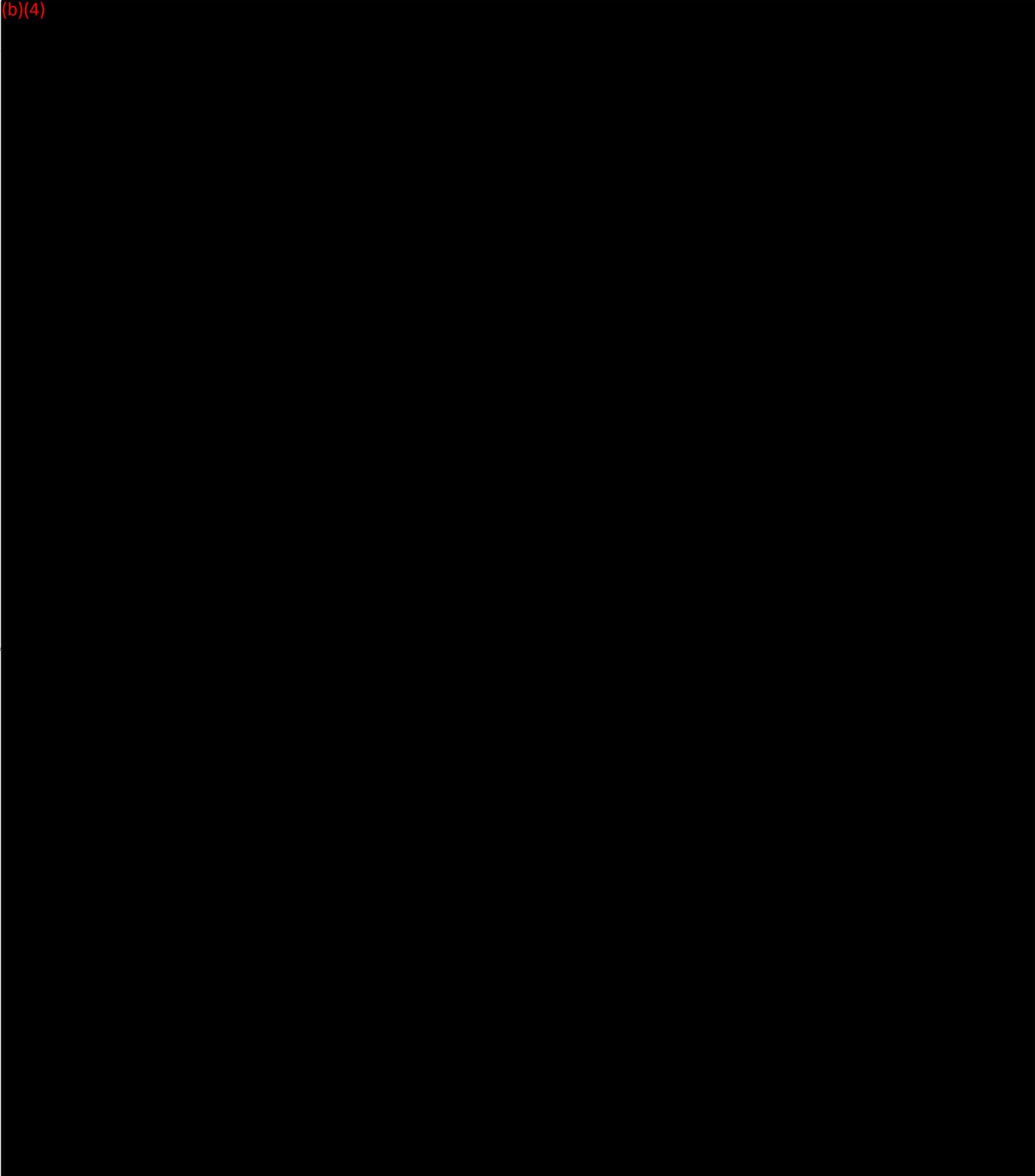
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BD CLINICAL STUDY: NORMAL AND NON-NORMAL DONOR - DETERMINATION OF P SELECTIN, PT, APTT AND FIBRINOGEN USING 0.129 M BD VACUTAINER™ PLUS SODIUM CITRATE TUBES

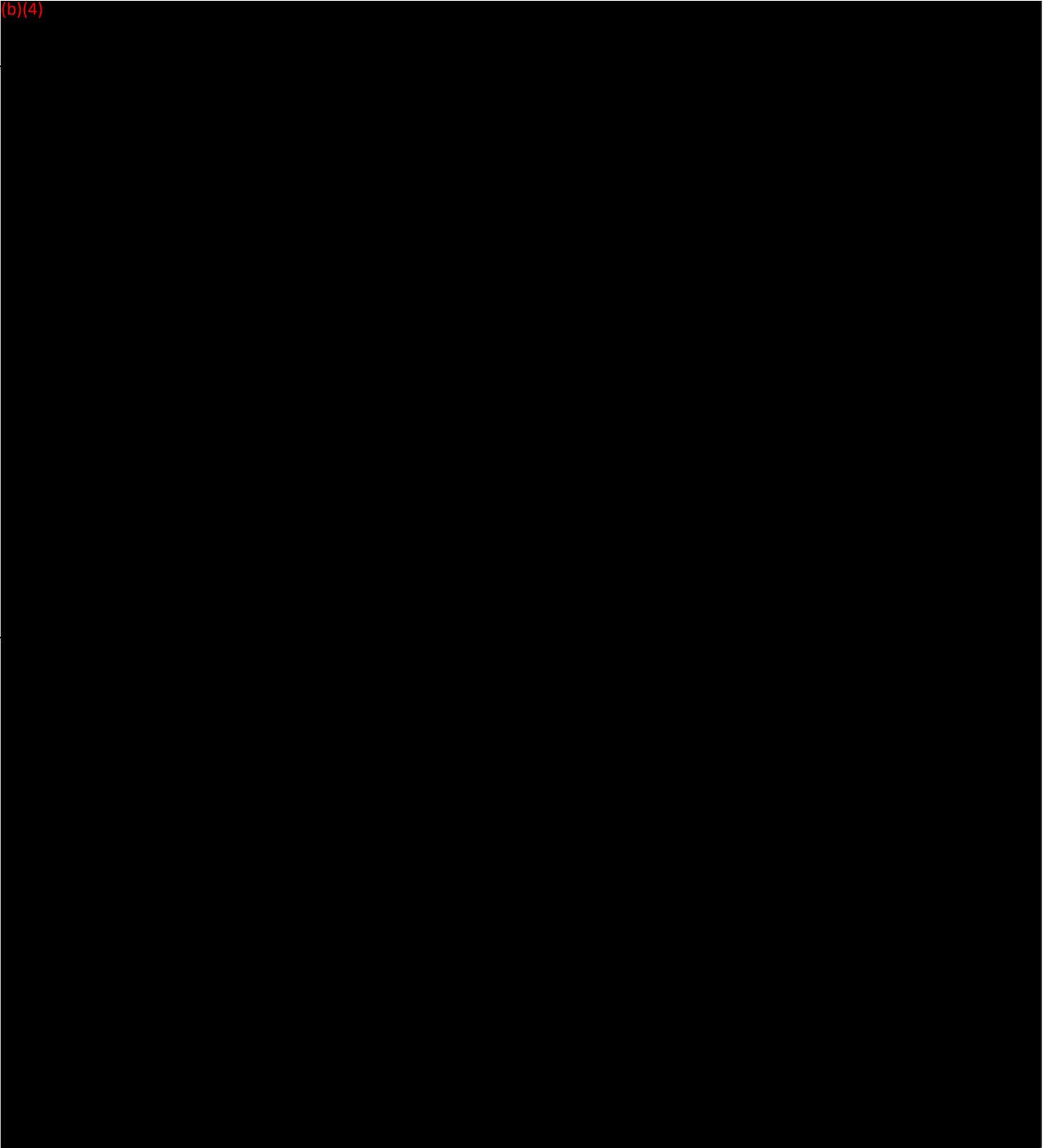
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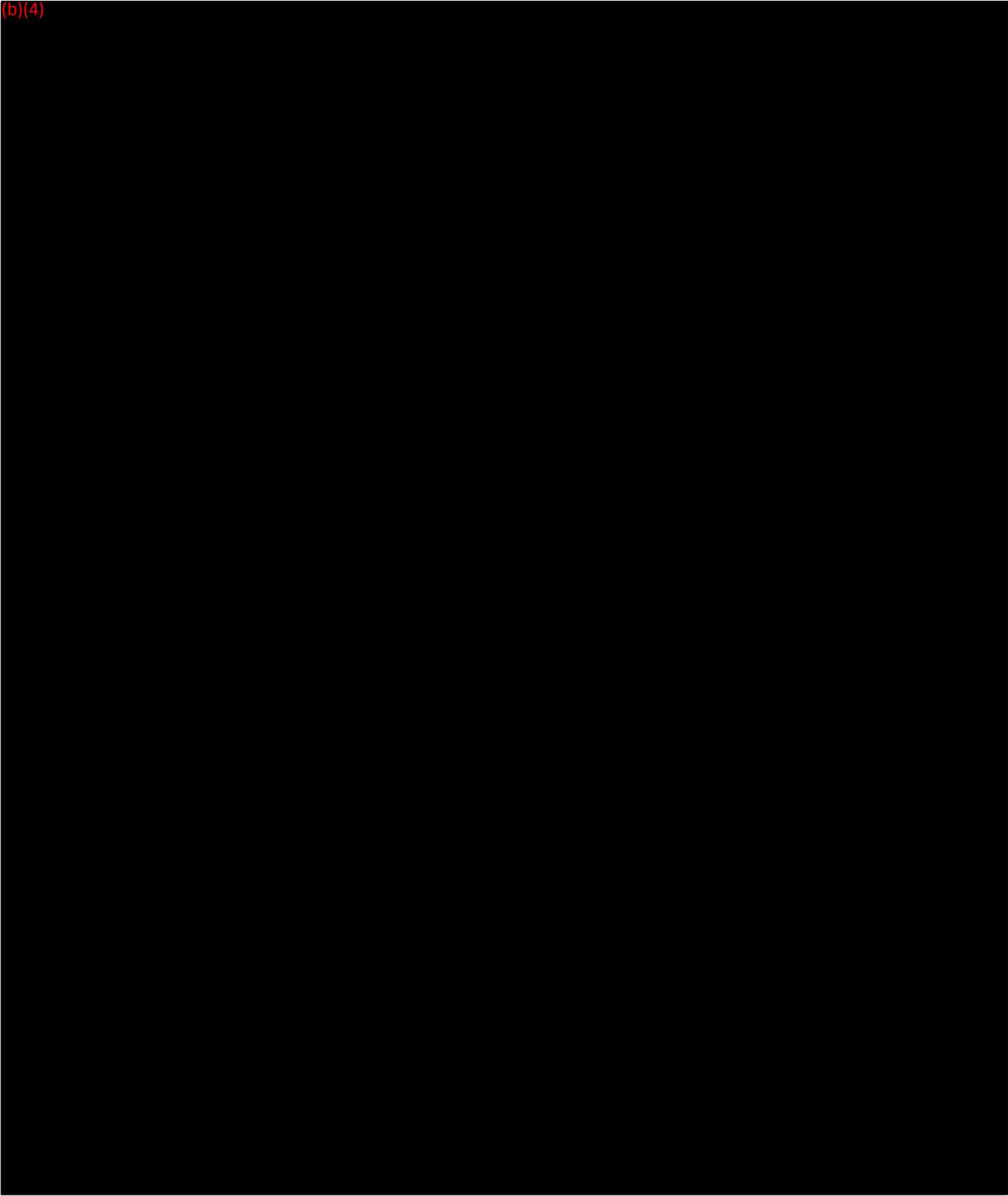
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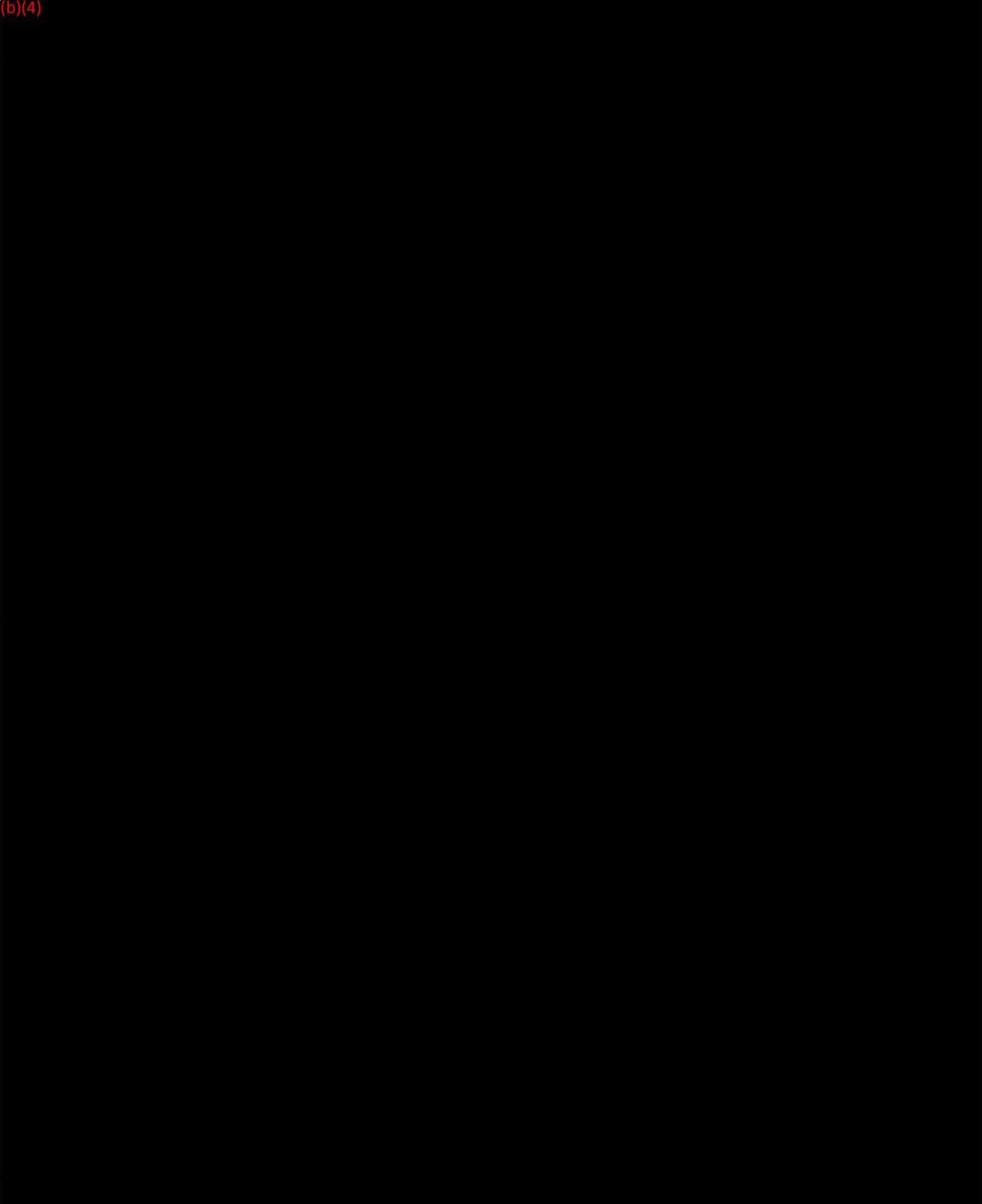
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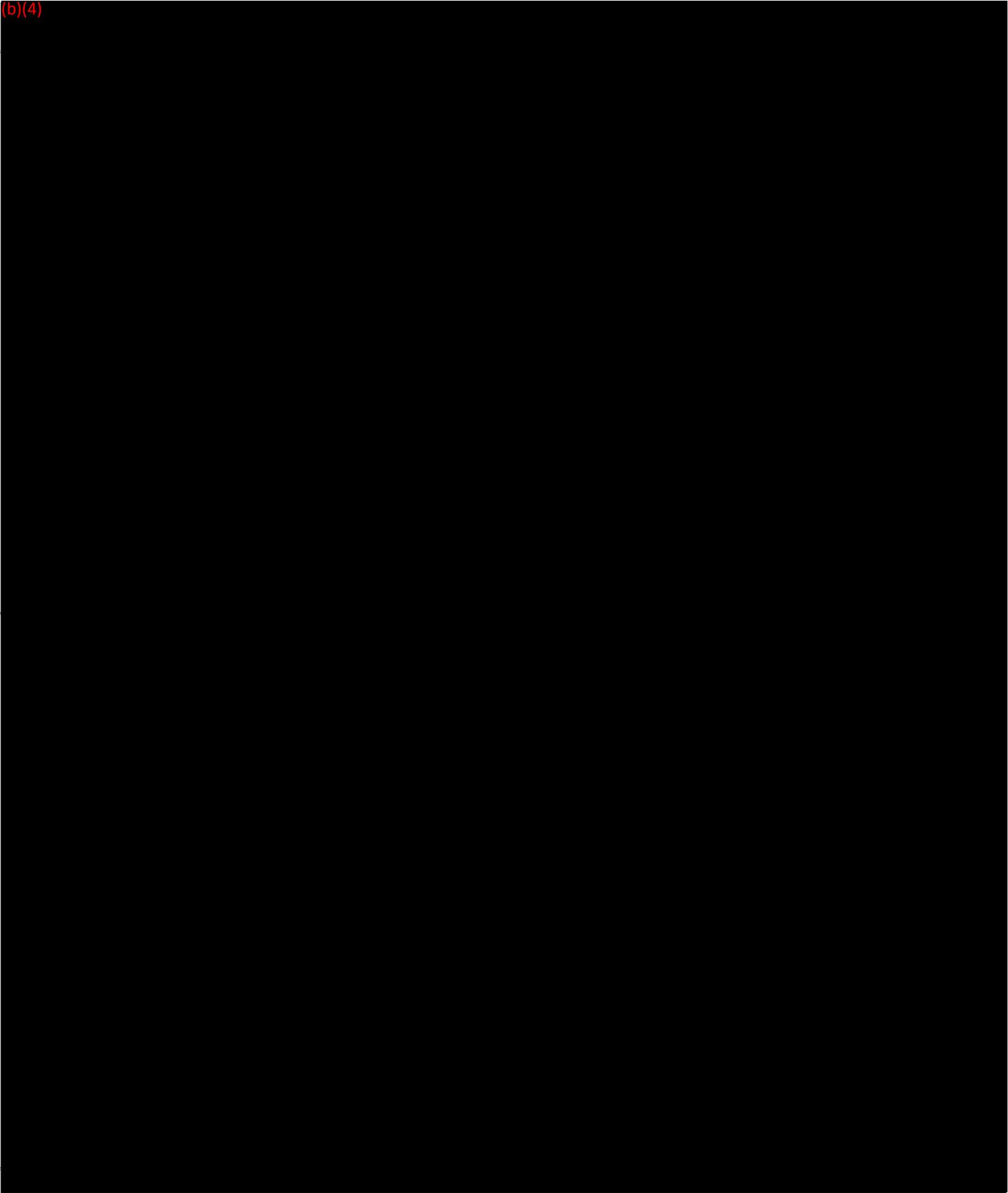


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BD CLINICAL STUDY: NORMAL AND NON-NORMAL DONOR - DETERMINATION OF P SELECTIN, PT, APTT AND FIBRINOGEN USING 0.129 M BD VACUTAINER™ PLUS SODIUM CITRATE TUBES

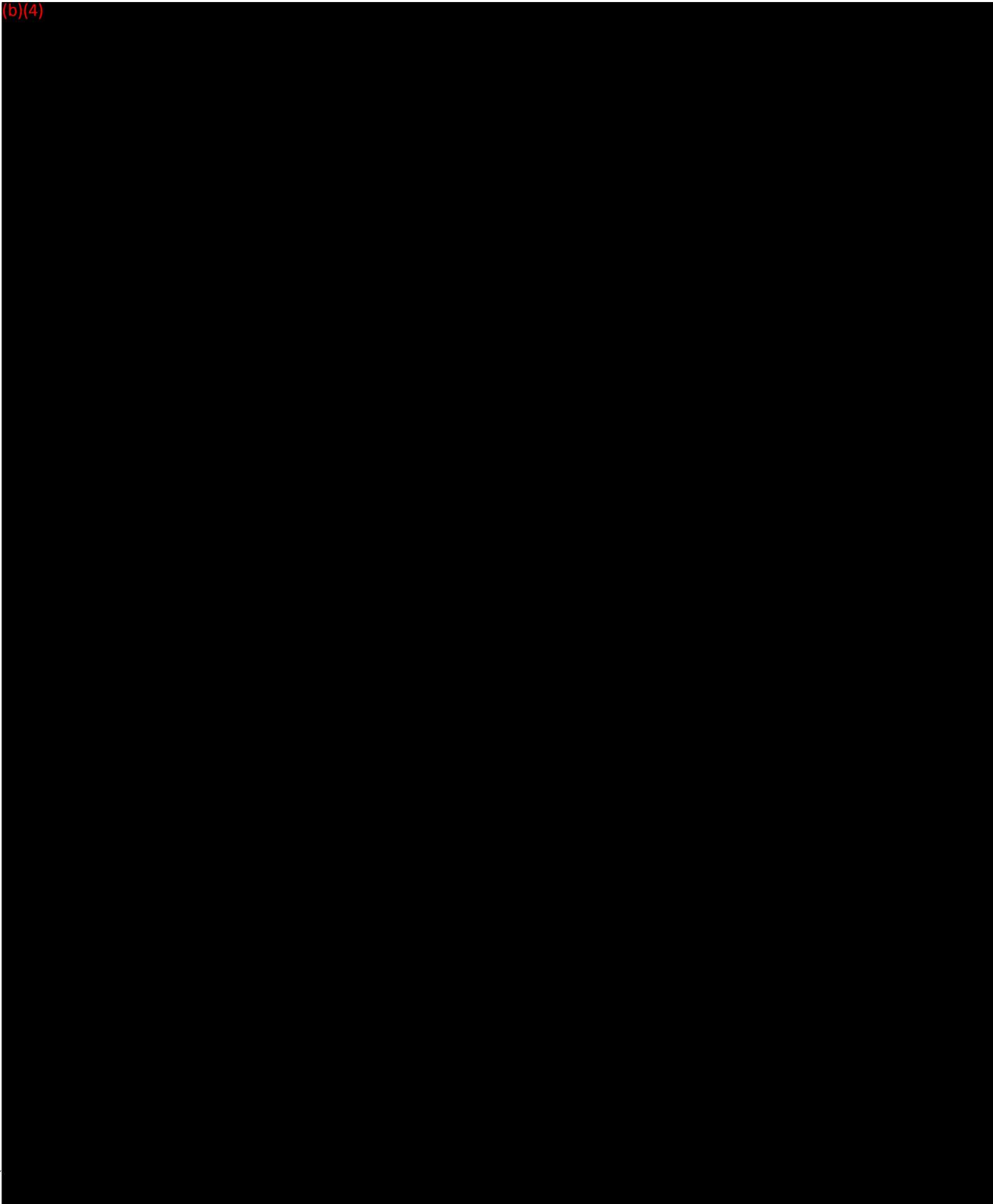
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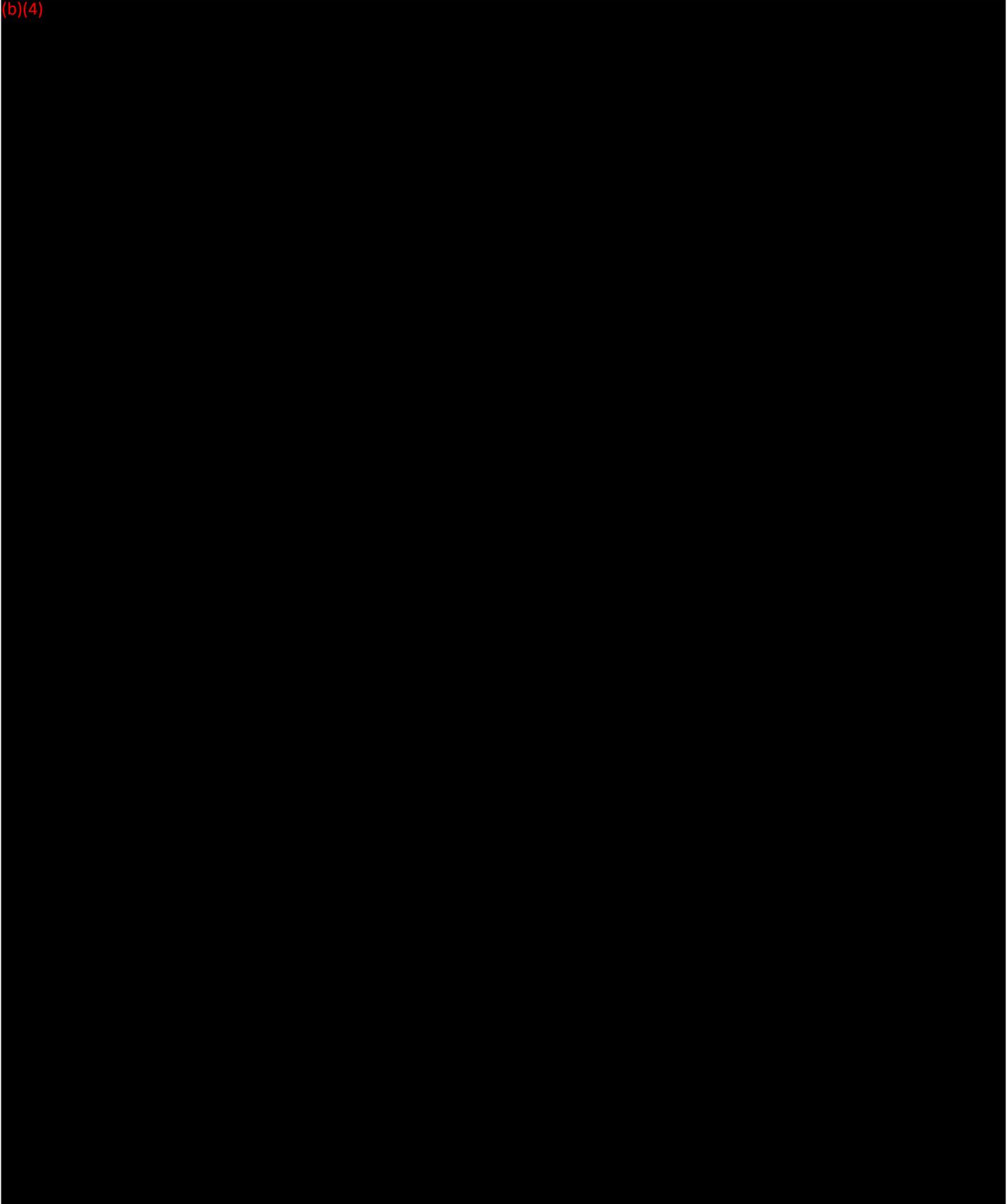
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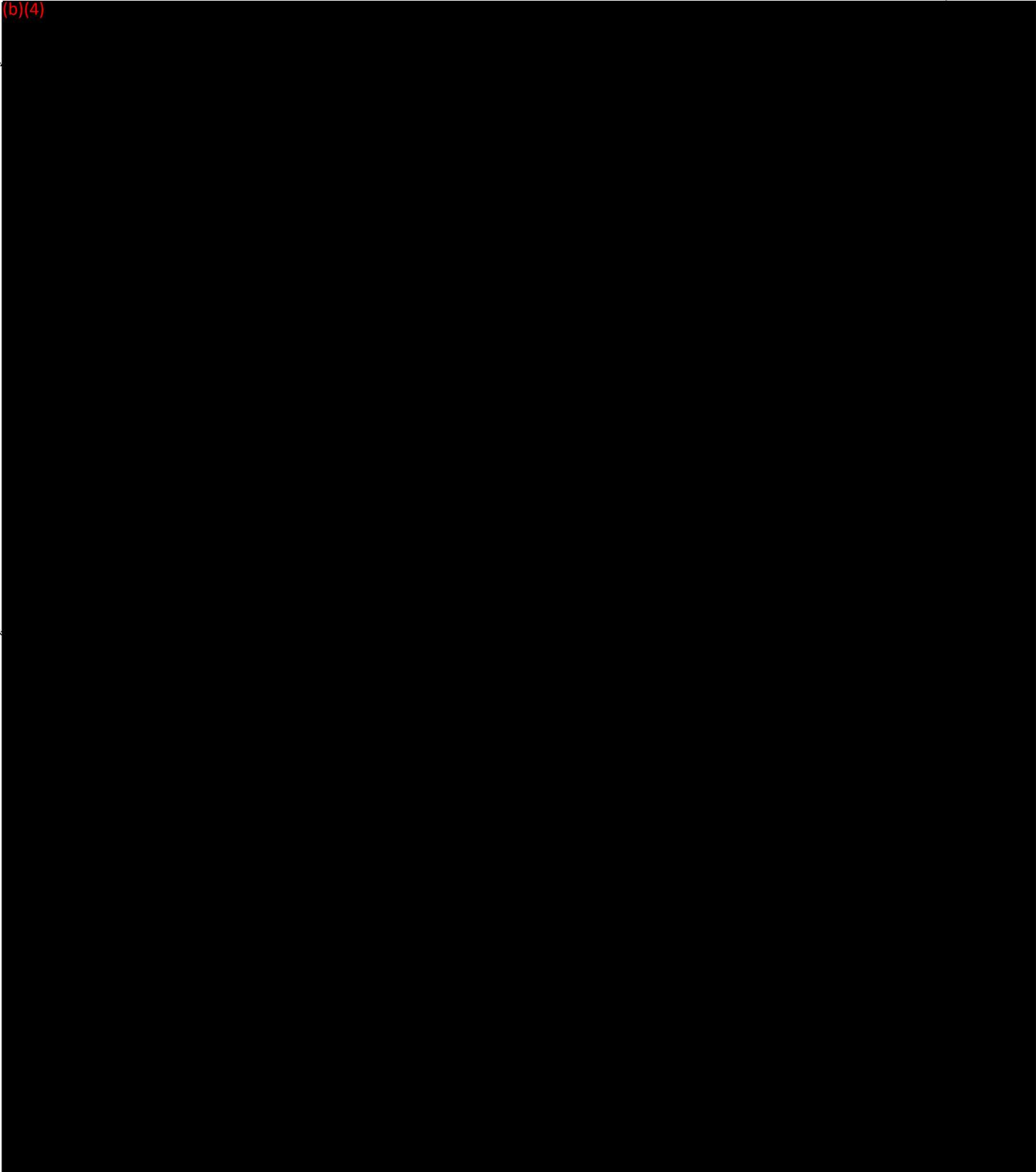
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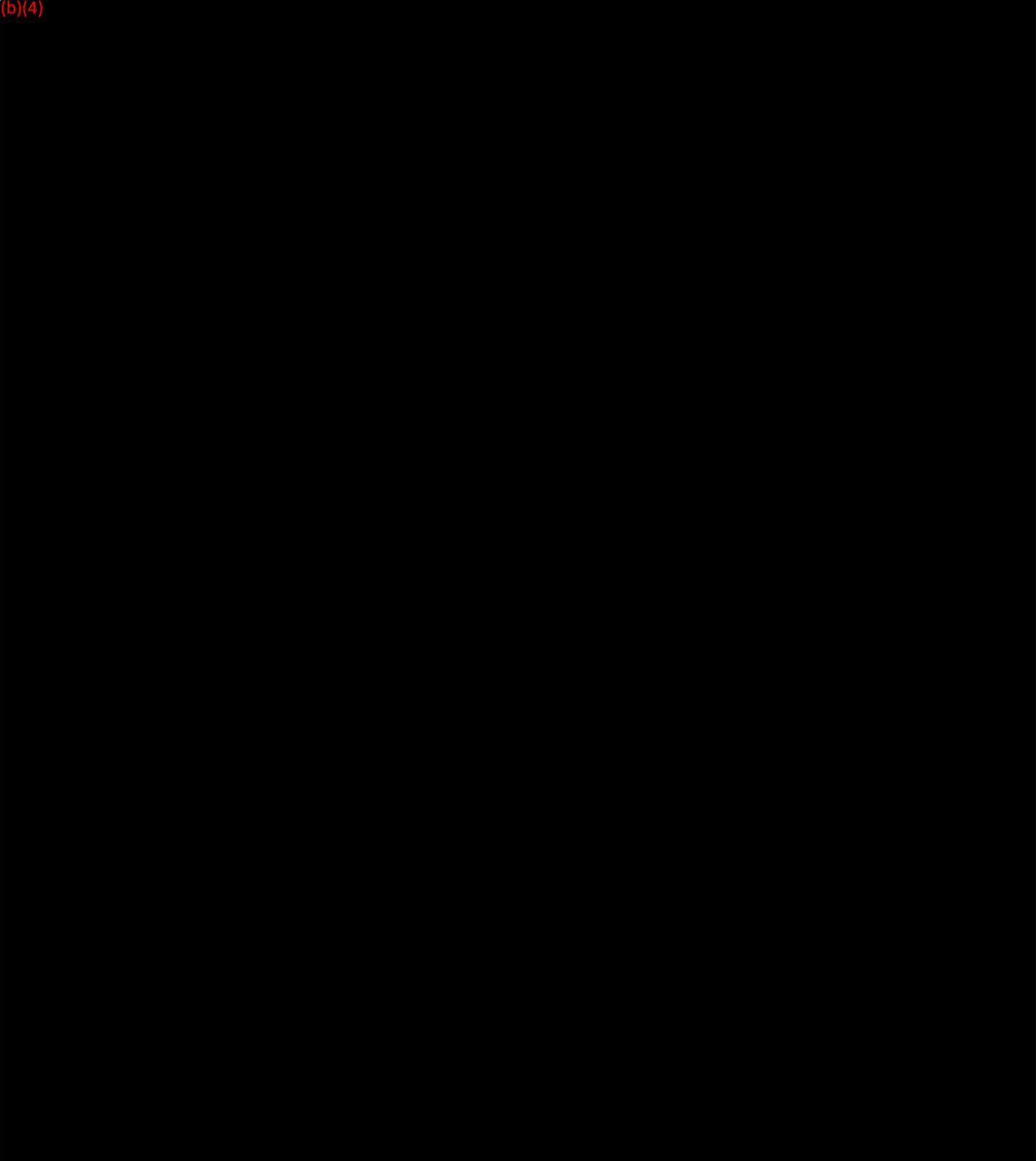
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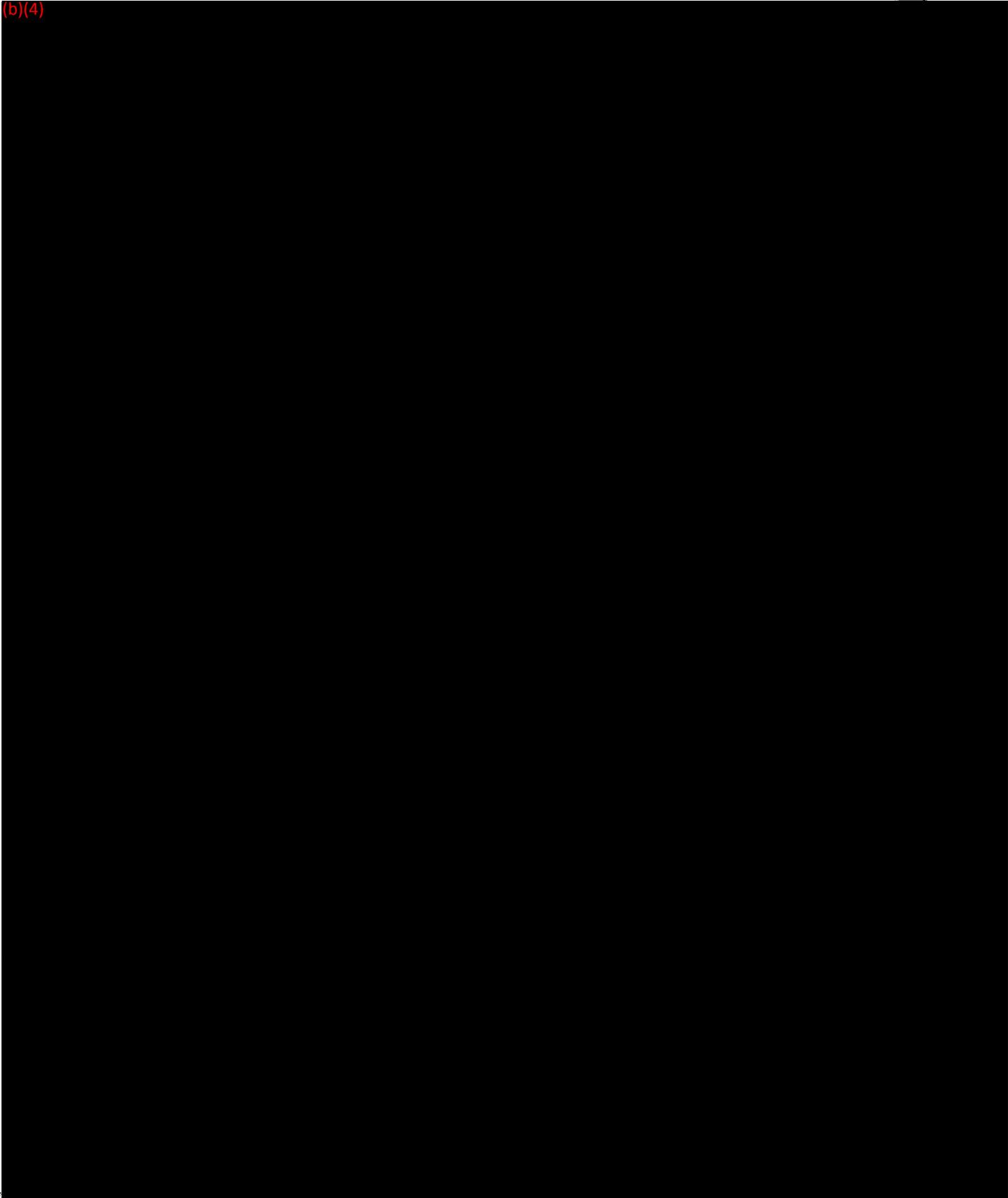
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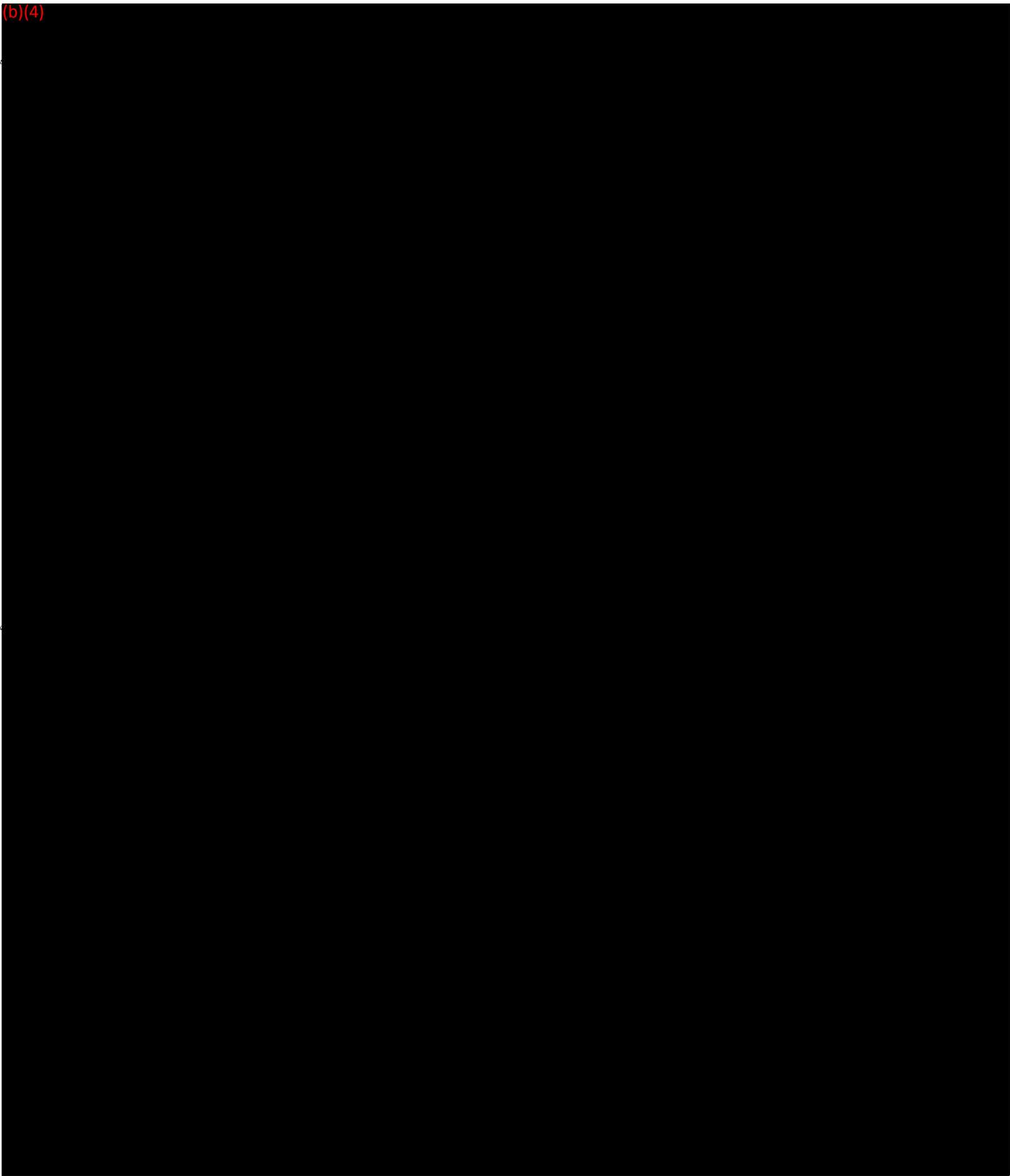
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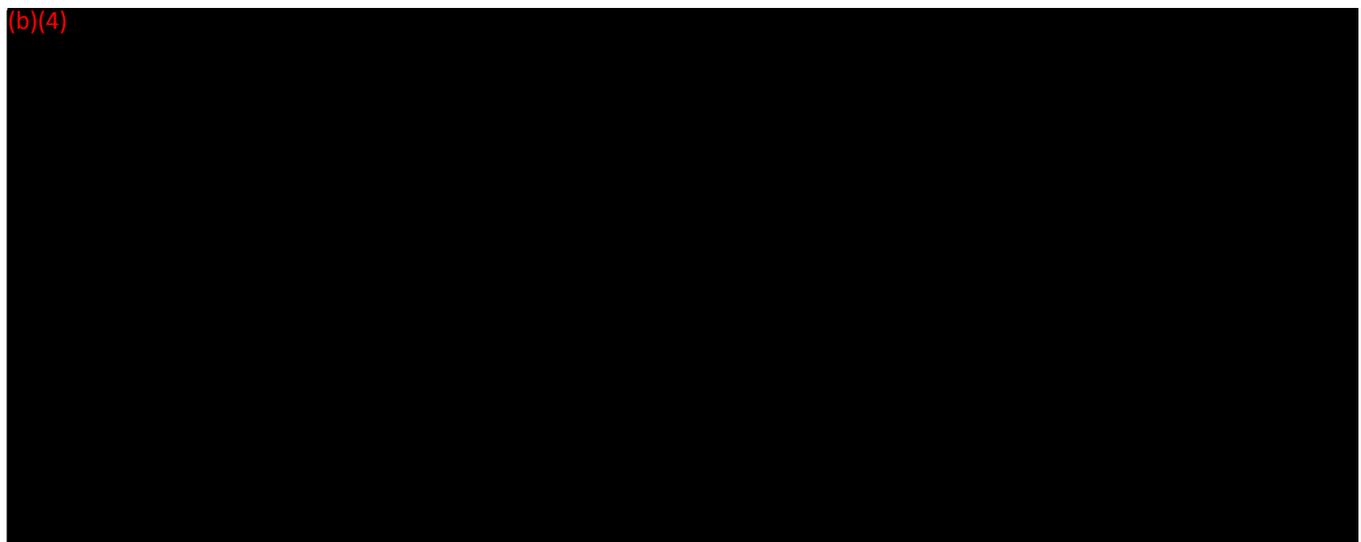
VII. CONCLUSIONS

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VIII. REFERENCES

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