510(K) Summary of Safety and Effectiveness

JAN 0 9 2013

Date Prepared: 12 October 2012

1. **Submitted By:**

John Roberts
Regulatory Affairs Specialist
BD Medical - Medical Surgical Systems
1 Becton Drive
Franklin Lakes, NJ 07417
Tel: 201 847 5473; Fax: 201 847 5307

2. **Device Name:**

Trade Name:	BD PhaSeal® Closed System Drug Transfer Device
Common Name:	Closed antineoplastic & hazardous drug reconstitution & transfer system
Classification Name:	Intravascular administration set
Classification:	Class II, 21 CFR 880.5440

3. **Predicate Device:**

BD PhaSeal® Connector, Injector, Protector – K120384

4. **Device Description:**

The PhaSeal® System is a sterile single-used closed system drug transfer device. The closed transfer of liquid takes place through a double membrane utilizing self-sealing elastomeric membranes, tightly fitted together through a bayonet fitting on all PhaSeal components. A single lumen cannula perforates the double membranes fro the transfer of liquid. When the cannula is retracted the membranes seal off the transfer of environmental contaminants into the system and/or escape of drug or vapor concentrations outside the system, thereby minimizing the individual and environmental exposure to drug vapor, aerosols and spills and also minimizing the risk of microbial contamination.

5. **Indications for Use**:

The PhaSeal system is an airtight and leakproof closed system drug transfer device (CSTD) that mechanically prohibits the transfer of environmental contaminants into the system and the escape of drug or vapor concentrations outside the system, thereby minimizing individual and environmental exposure to drug vapor, aerosols and spills. The PhaSeal system also prevents microbial ingress.

6. **Technological Characteristics:**

The technological characteristics of the subject device are identical to those of the predicate devices.

Characteristic	Subject Device: BD PhaSeal	Predicate Device: BD PhasSeal K120384	Equivalence
Transfer Mechanism	Elastomeric Double Membrane	Elastomeric Double Membrane	Identical to Predicate
Connection between PhaSeal Components	Bayonet Fitting with Elastomeric Double Membrane	Bayonet Fitting with Elastomeric Double Membrane	Identical to Predicate
Components	Protector, Injector, Connector	Protector, Injector, Connector	Identical to Predicate
Protector Spike	Stainless Steel or Plastic	Stainless Steel or Plastic	Identical to Predicate
Injector Cannula	Stainless Steel	Stainless Steel	Identical to Predicate
Fitting Connection to external standard syringe	Injector: Luer / Luer Lock Connection	Injector: Luer / Luer Lock Connection	Identical to Predicate
Fitting Connection to external standard IV line	Luer Lock or Spike Port	Luer Lock or Spike Port	Identical to Predicate
Fitting Connection to external standard IV bag	Spike	Spike	Identical to Predicate
Needle Safety Feature (Injector Only)	Safety sleeve	Safety sleeve	Identical to Predicate
Sterilization Method	EO	EO	Identical to Predicate

7. **Performance:**

The additional tests referenced in the table have been provided in order to substantiate the use of product code ONB - Closed antineoplastic and hazardous drug reconstitution and transfer system – for the BD PhaSeal® Closed System Drug Transfer Device. BD has included the additional airtight and leakproof requirement as both of these requirements are cited by the National Institute for Occupational Safety and Health (NIOSH) and the International Society of Oncology Pharmacy Practitioners (ISOPP) as essential requirements necessary to reduce health care workers from exposure to hazardous drugs. In addition, NIOSH also cites the need to prevent contaminates from entering the closed system during transfer. As such, BD proposes to extend the microbial ingress claim to the entire system; not just the PhaSeal Protector. As there is no change to the subject device in comparison to the predicate devices, the performance data provided represent the performance of both the predicate and subject device of this 510(k).

Item#	Performance Specification:	Status of BD PhaSeal® System
1	Leakproof Connections	No Leaks (Fluorescein Test)[1,2]
2	Airtight Connections	No Visable Smoke ($TiCl_4$ Test)[3]
3	Microbial Ingress	No Ingress at the Protector or Connector

8. **Conclusion:**

Based on comparison to the predicate device and the nonclinical tests provided, the modified BD PhaSeal® Closed System Drug Transfer Device is as safe, as effective, and performs as well as the legally marketed predicate device.

[1] Spivey S, Connor T. **Determining sources of workplace contamination with antineoplastic drugs and comparing conventional IV drug preparation with a closed system.** *Hosp Pharm.* 2003; 38(2): 135-139.
[2] Jorgenson J, Spivey S, Au C et al. **Contamination comparison of transfer devices intended for handling hazardous drugs.** *Hosp Pharm.* 2008; 43(9): 723-727
[3] *Ibid.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

January 9, 2013

Mr. John Roberts
Regulatory Affairs Specialist
Becton Dickinson & Company
1 Becton Drive
MC237
FRANKLIN LAKES NJ 07417

Re: K123213
Trade/Device Name: PhaSeal® - Closed System Transfer Device
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: ONB
Dated: October 12, 2012
Received: October 15, 2012

Dear Mr. Roberts:

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

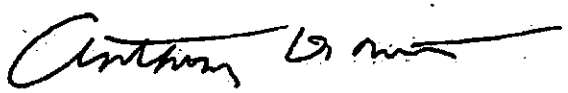
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K123213

Device Name: PhaSeal® – A Closed System Transfer Device

Indications for Use:

The PhaSeal system is an airtight and leakproof closed system drug transfer device (CSTD) that mechanically prohibits the transfer of environmental contaminants into the system and the escape of drug or vapor concentrations outside the system, thereby minimizing individual and environmental exposure to drug vapor, aerosols and spills. The PhaSeal system also prevents microbial ingress.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page __ of ___

Sajjad H. Syed

Digitally signed by Sajjad H. Syed
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Sajjad H. Syed, 0.9.2342.19200300.100.1.1=2000601742
Date: 2013.01.09 15:12:01 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K123213

K123213

V.1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 9, 2013

Mr. John Roberts
Regulatory Affairs Specialist
Becton Dickinson & Company
1 Becton Drive
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FRANKLIN LAKES NJ 07417

Re: K123213
Trade/Device Name: PhaSeal® - Closed System Transfer Device
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: ONB
Dated: October 12, 2012
Received: October 15, 2012

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Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Concurrence & Template History Page
[THIS PAGE IS INCLUDED IN IMAGE COPY ONLY]

Full Submission Number: K123213

For Office of Compliance Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=318

For Office of Surveillance and Biometrics Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=423

Digital Signature Concurrence Table	
Reviewer Sign-Off	Mary E. Brooks Digitally signed by Mary E. Brooks DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Mary E. Brooks, 0.9.2342.19200300.100.1.1=1300372349 Date: 2013.01.07 18:28:59 -05'00'
Branch Chief Sign-Off	Digitally signed by Richard C. Chapman Date: 2013.01.08 06:53:02 -05'00'
Division Sign-Off	Anthony D. Watson Anthony D. Watson 2013.01.08 14:27:58 -05'00'

Template Name: K1(A) – SE after 1996

Template History:

Date of Update	By	Description of Update
7/27/09	Brandi Stuart	Added Updates to Boiler Table
8/7/09	Brandi Stuart	Updated HFZ Table
1/11/10	Diane Garcia	Liability/Warranty sentence added at bottom of 1st page
10/4/11	M. McCabe Janicki	Removed IFU sheet and placed in Forms
9/25/12	Edwena Jones	Added digital signature format
12/12/12	M. McCabe Janicki	Added an extra line between letter signature block and the word "Enclosure". Also, added a missing digit in 4-digit extension on letterhead zip code: "002" should be "0002".

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(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K123213

* * * COMMUNICATION RESULT REPORT (JAN. 9. 2013 4:26PM) * * *

FAX HEADER 1:
FAX HEADER 2:

TRANSMITTED/STORED : JAN. 9. 2013 4:26PM E MODE	OPTION	ADDRESS	RESULT	PAGE
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REASON FOR ERROR
E-1) HANG UP OR LINE FAIL
E-2) BUSY
E-3) NO ANSWER
E-4) NO FACSIMILE CONNECTION

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

COVER SHEET MEMORANDUM

From: Reviewer Name Mary Brooks

Subject: 510(k) Number K123913

To: The Record

Please list CTS decision code SE

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☐ Hold (Additional Information or Telephone Hold).

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

Not Substantially Equivalent (NSE) Codes

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

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

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

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

§80.5440 Class II, Closed antineoplastic + hazardous drug reconstitution & transfer system — ONB

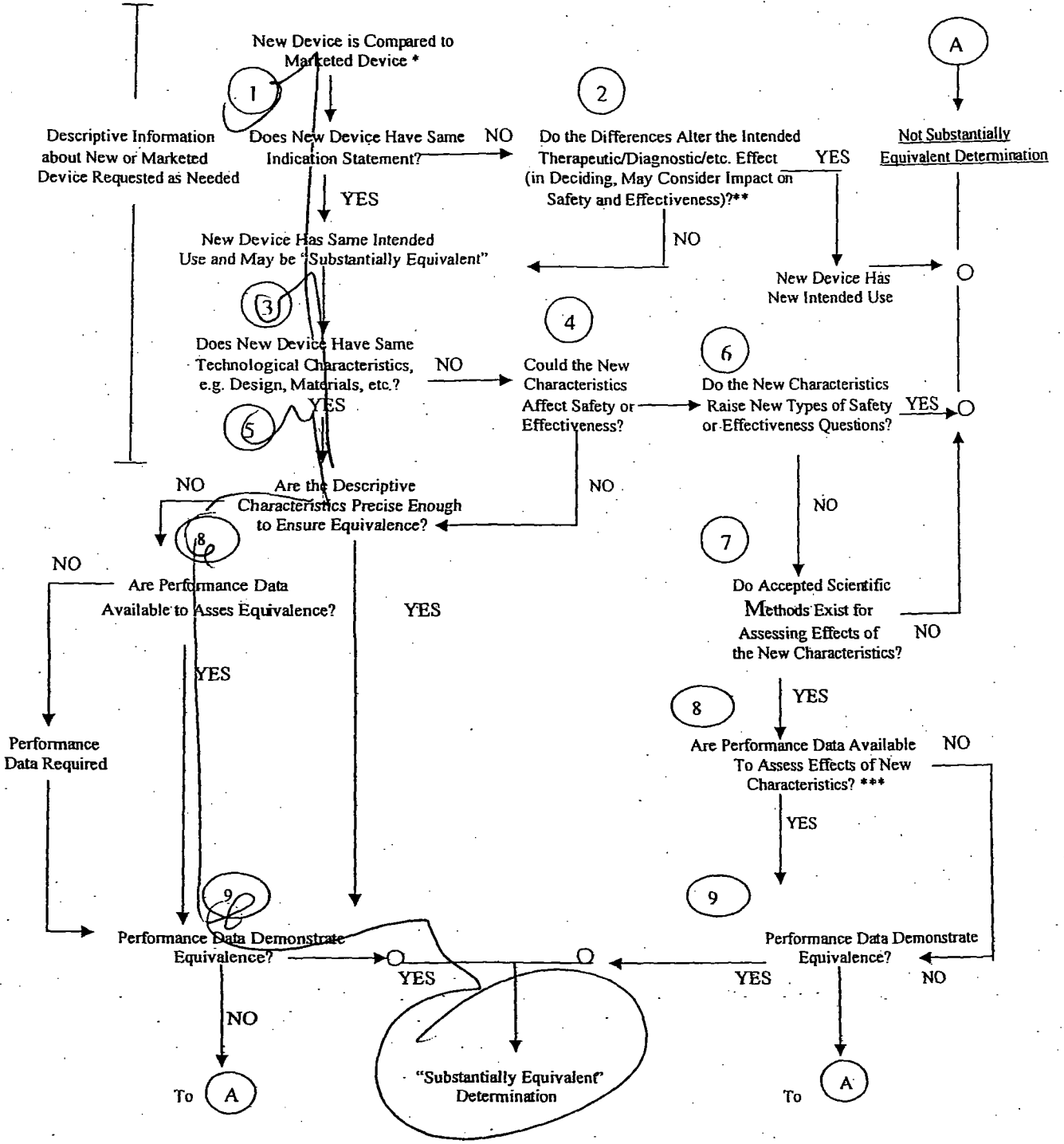
(*If unclassified, see 510(k) Staff)

Additional Product Codes: _____

Review: _____ 1/8/13 _____
(Branch Chief) (Branch Code) (Date)

Final Review: _____ 1/8/13
(Division Director) (Date)

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

DEPARTMENT OF HEALTH AND HUMAN SERVICES **M E M O R A N D U M**

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional

K123213

Date: January 7, 2013
To: The Record
From: Mary Brooks RN, BNS, MS

Office: ODE
Division: DAGRID

510(k) Holder: BD Surgical Systems
Device Name: BD PhaSeal Closed System Transfer Device
Contact: John Roberts
Phone: (201) 847-5473
Fax: (201) 847-5307
Email:john_w_roberts@bd.com

I. Purpose and Submission Summary

The 510(k) Becton, Dickinson and Company would like to re-classify the previously cleared PhaSeal Closed System Transfer Device under product code ONB(b) (4) [redacted] The wording in the indication for use statement has been modified to better reflect the definition of ONB product code. There is no design or performance change associated with this 510(k) submission. The subject device and predicate are identical. There are no changes in material or manufacturing process. The performance specifications, device design, models, accessories and components are identical to the predicate device

II. Administrative Requirements

	Yes	No	N/A
Indications for Use Section 3, page 11 Prescription	X		
Truthful and Accuracy Statement Section 5, page 16	X		
510(k) Summary Section 6, page 17	X		
Standards Data Report Form – Form 3654 1: No standard used - No Standards Form Required 2: Declaration of Conformity - Yes Standards Form Required 3: Standard but no declaration - Yes Standards Form Required	X		

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	

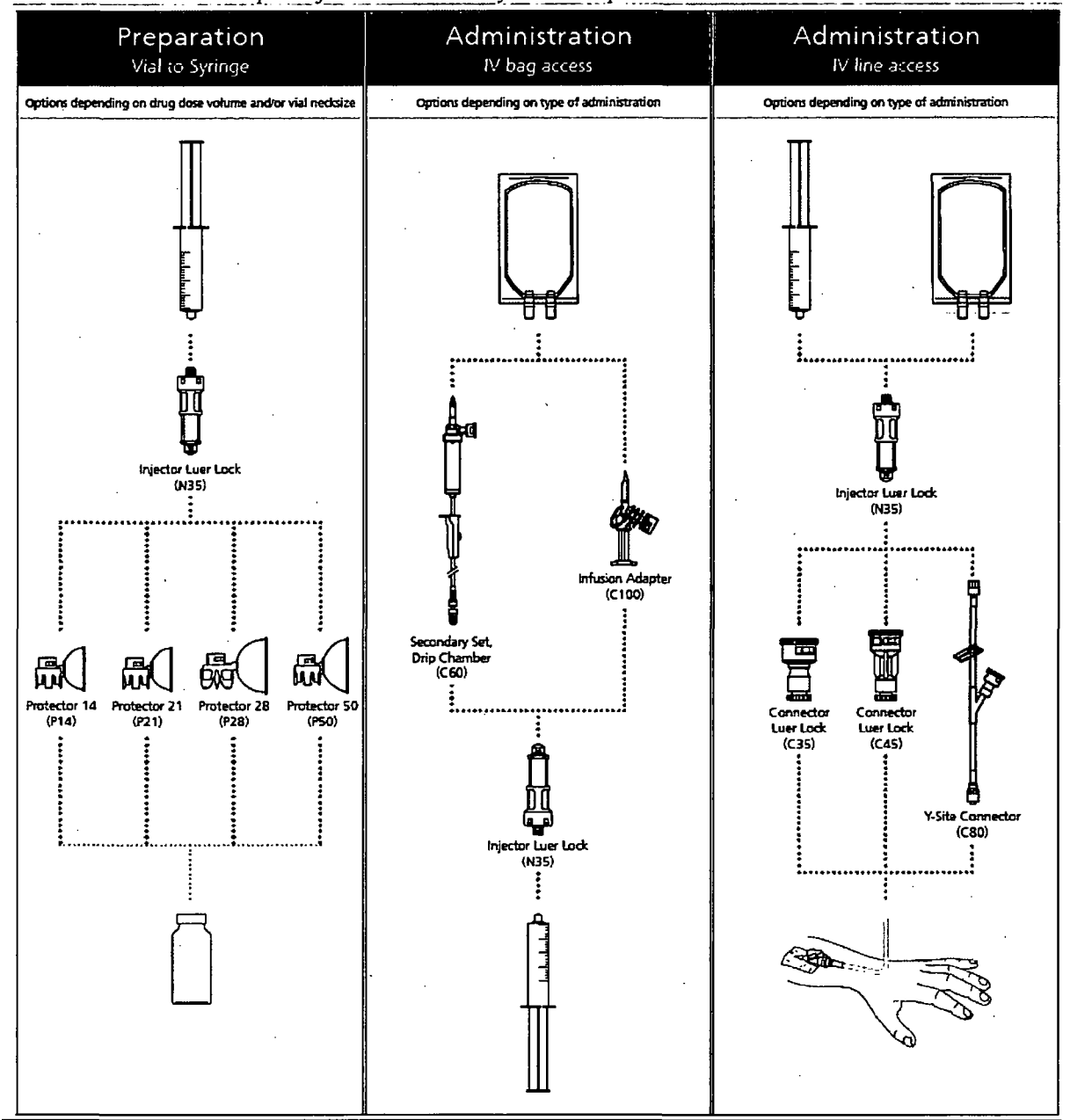
	Yes	No	N/A
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?		X	
Is the device sterile?	X		
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?		X	

The PhaSeal® System is a sterile single-used closed system drug transfer device. The closed transfer of liquid takes place through a double membrane utilizing self-sealing elastomeric membranes, tightly fitted together through a bayonet fitting on all PhaSeal components. A single lumen cannula perforates the double membranes fro the transfer of liquid. When the cannula is retracted the membranes seal off the transfer of environmental contaminants into the system and/or escape of drug or vapor concentrations outside the system, thereby minimizing the individual and environmental exposure to drug vapor, aerosols and spills and also minimizes the risk of microbial contamination. The PhaSeal® System is composed of the following components. Each of the components has been cleared via various 510(k)s. However, the entire system was once again cleared on 12 Sep 2012 for a modification to the indications for use.

Table 1. List of components of PhaSeal System and their respective 510(k) numbers.

PhaSeal Protector	P14	K120384
	P21	K120384
	P28	K120384
	P50	K120384
PhaSeal Injector	N30C	K120384
	N31	K120384
	N35	K120384
	N35C	K120384
PhaSeal Connector	C35	K120384
	C45	K120384
	C40	K120384
	C48	K120384
	C50	K120384
	C60	K120384
	C61	K120384
	C70	K120384
	C80	K120384
	C100	K120384

Picture 1: *Examples of BD PhaSeal® System and process*

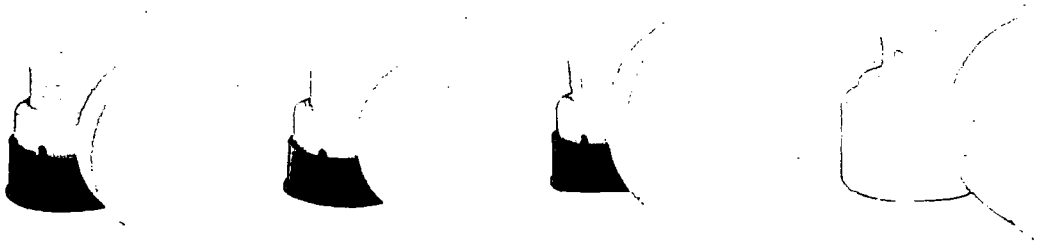


Description of Each Component of the PhaSeal System

- **PhaSeal Protector:**

The Protector is a drug vial adapter that is fitted to the drug vial and seals against the closure of the vial - see Picture 2. The Protector is used as a docking station between the drug vial and the Injector for injection of diluents into the drug vial and/or extraction of liquid drug from the vial. In addition the Protector equilibrates the pressure difference which occurs when fluid or air is added or removed to/from the drug vial. The Protector is provided in four different sizes which are intended to be compatible with various sizes of drug vials ranging from necks from Ø13mm to Ø28mm.

Picture 2: *PhaSeal Protector*

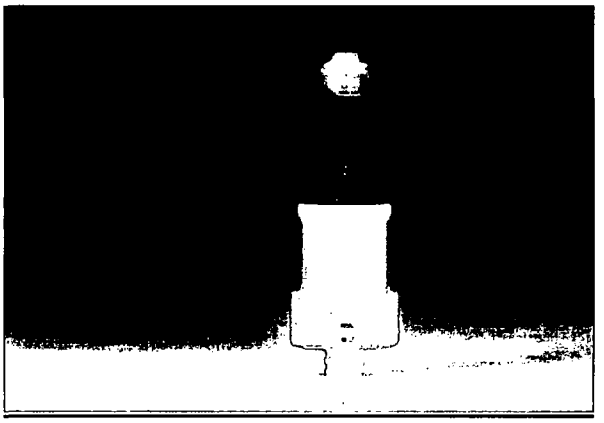


- **PhaSeal Injector:**

The Injector is designed with a single lumen cannula that is encapsulated in a plastic chamber- see Picture 3. One end of Injector locks onto an external device (i.e. syringe) equipped with Luer or Luer Lock fitting. The other end of Injector is sealed with a thermoplastic elastomeric membrane. The elastomeric membrane mates with the "docking station" of the PhaSeal Protector or PhaSeal Connector component equipped with the corresponding "docking station" (i.e. bayonet fitting). The bayonet fitting allows the two elastomeric membranes to be pressed together and a sealed transfer of drug to/from the Protector or to the Connector can be made.

The Injector has a safety feature that must be released to allow the cannula to penetrate the elastomeric membranes and the drug vial stopper. The safety feature is disengaged and re-engaged via the decisive push-turn-push ErgoMotion™ which is described in the BD PhaSeal Instructions for Use. While engaged, the cannula will remain in the safety sleeve – the blue color portion of the Injector. Once attached to a Protector or Connector, the Injector cannot be separated from the bayonet fitting until the needle has been fully retracted into the sealed chamber and the safety feature is re-engaged to ensure the cannula is in the sealed chamber. Thereafter the bayonet fitting can be opened and the Injector is released from the "docking station".

Picture 3: PhaSeal Injector



- **PhaSeal Connector:**

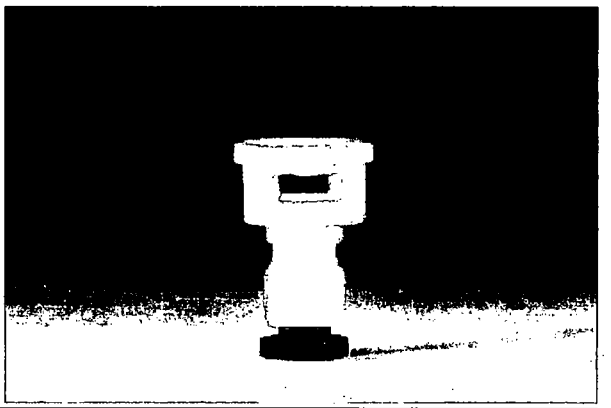
  The Connector is the interface for patient administration of the drug – see pictures 4-7. The bayonet fitting of the Connector mates with the Injector. The elastomeric membranes of the Connector and the Injector press together to create a seal that enables closed transfer of drug to the patient IV line or into an IV bag. After the drug transfer, the Injector cannula is pulled back via the decisive push-turn-push ErgoMotion™ into the safety sleeve and the Injector can be separated from the Connector. Connectors are provided with a variety of device mating features including a luer fitting, an IV spike (infusion adaptor), secondary set or Y-site connector

Picture 4: Connector – Infusion Adaptor

Picture 5: Connector – Y-Site

Picture 6: Connector - Secondary Set

Picture 7: Connector – Luer Lock



IV. Indications for Use

The PhaSeal system is an airtight and leakproof closed system drug transfer device (CSTD) that mechanically prohibits the transfer of environmental contaminants into the system and the escape of drug or vapor concentrations outside of the system, thereby minimizing individual and environmental exposure to drug vapor, aerosols and spills. The PhaSeal System also prevents microbial ingress

BD has included the additional descriptors "airtight" and "leakproof" to align with the definition of Closed System Transfer Devices provided by the National Institute for Occupational Safety and Health (NIOSH) and the International Society of Oncology Pharmacy Practitioners (ISOPP). These characteristics of Closed System Transfer Devices are essential requirements to reduce health care workers from exposure to hazardous drugs.

Potential routes of exposure to hazardous drugs include, but may not be limited to, dermal absorption, inhalation and ingestion. As none of the possible entry points can be eliminated as a potential risk, ISOPP specifies that only "Airtight" and "Leakproof" devices prevent chemical contamination:

- A product described as a closed-system must be "leakproof and airtight"—therefore vented, filtered devices are not closed. A product cannot be "semi-closed;"
- The vapor of cytotoxic products are not retained by filters with a diameter of 0.22μm and HEPA filters;

- To avoid confusion, it is strongly recommended that if a device claims to prevent chemical contamination it should be airtight and leakproof.[1]

In concurrence with these requirements proposed by ISOPP, NIOSH offers the following definition:

- Closed system drug-transfer device (CSTD): a drug transfer device that mechanically prohibits the transfer of environmental contaminants into the system and the escape of hazardous drug or vapor concentrations outside the system.[2]

It is also important to note that NIOSH stresses that a CSTD must also prohibit the transfer of environmental contaminants into the system. As such, BD has further modified the indication concerning microbial ingress to include the entire system as opposed to just the PhaSeal Protector.
To summarize, between the three definitions provided by FDA, NIOSH and ISOPP, BD has identified three critical characteristics of a CSTD.

- The system is airtight
- The system is leak proof
- The system prevents contaminates from entering the system

Reviewer Note: Acceptable
The modifications to the indication for use are within guidelines of FDA and NIOSH. The sponsor has provided supportive documentation in the submission to makes the claims above for the

V. Predicate Device Comparison

Characteristic	Subject Device: BD PhaSeal	Predicate Device: BD PhasSeal K120384	Equivalence
Transfer Mechanism	Elastomeric Double Membrane	Elastomeric Double Membrane	Identical to Predicate
Connection between PhaSeal Components	Bayonet Fitting with Elastomeric Double Membrane	Bayonet Fitting with Elastomeric Double Membrane	Identical to Predicate
Components	Protector, Injector, Connector	Protector, Injector, Connector	Identical to Predicate
Protector Spike	Stainless Steel or Plastic	Stainless Steel or Plastic	Identical to Predicate
Injector Cannula	Stainless Steel	Stainless Steel	Identical to Predicate
Fitting Connection to external standard syringe	Injector: Luer / Luer Lock Connection	Injector: Luer / Luer Lock Connection	Identical to Predicate
Fitting Connection to external standard IV line	Luer Lock or Spike Port	Luer Lock or Spike Port	Identical to Predicate
Fitting Connection to external standard IV bag	Spike	Spike	Identical to Predicate
Needle Safety Feature (Injector Only)	Safety sleeve	Safety sleeve	Identical to Predicate
Sterilization Method	EO	EO	Identical to Predicate

VI. **Labeling**

Reviewer Notes: Acceptable
The device name did not change from the identical predicate. The labeling is identical to their previous cleared device.

VII. **Sterilization/Shelf Life/Reuse**

Reviewer Notes: Acceptable
This device is identical to their recently cleared predicate. The changes were to the wording in the indication for use statement which has been modified to better reflect the definition of ONB product code.

VIII. **Biocompatibility**

Reviewer Notes: Acceptable
The device is identical to their recently cleared predicate The only changes was to the wording in the

indication for use statement which has been modified to better reflect the definition of ONB product code. There are no modifications or changes in materials.

IX. Software N/A

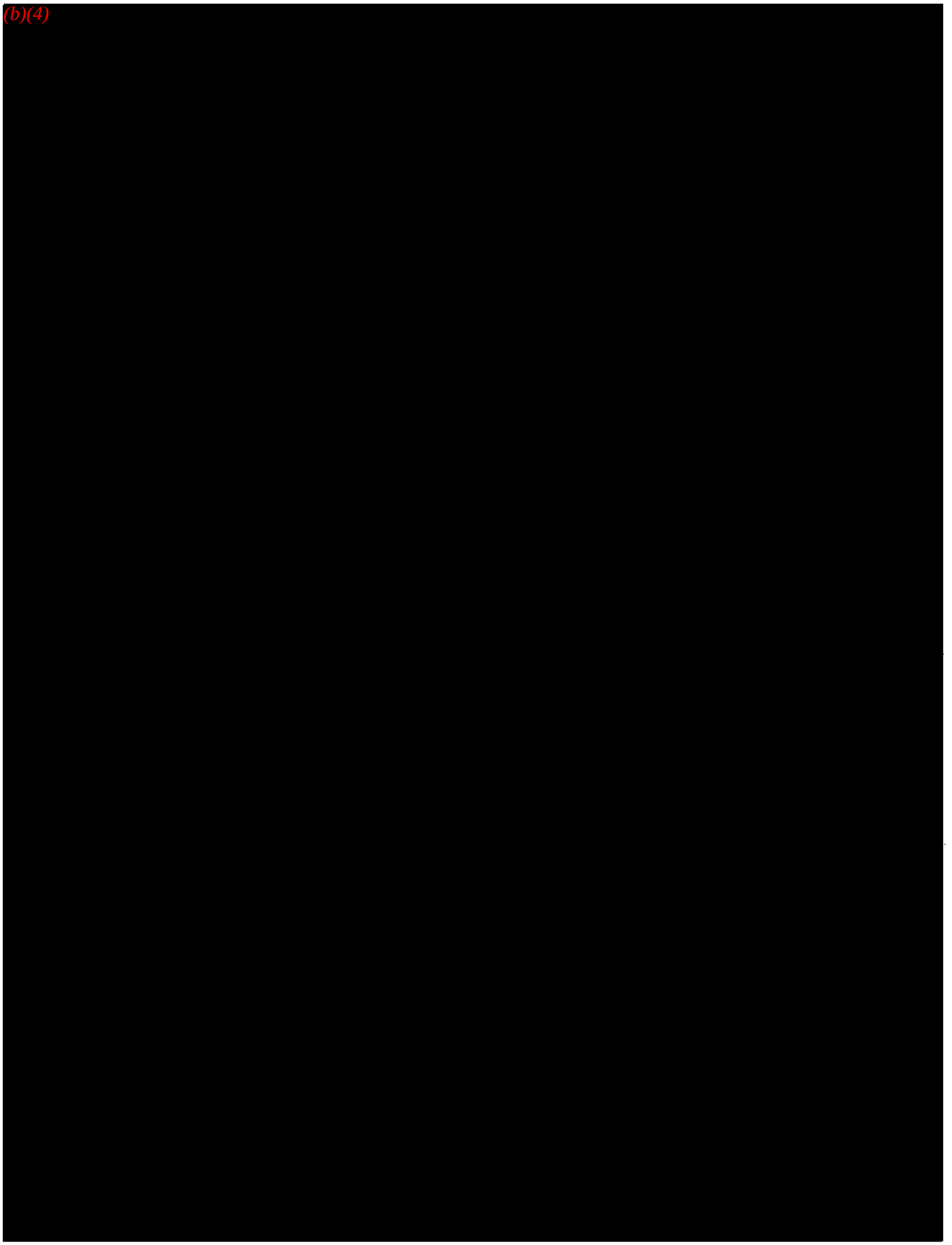
X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety N/A

XI. Performance Testing – Bench

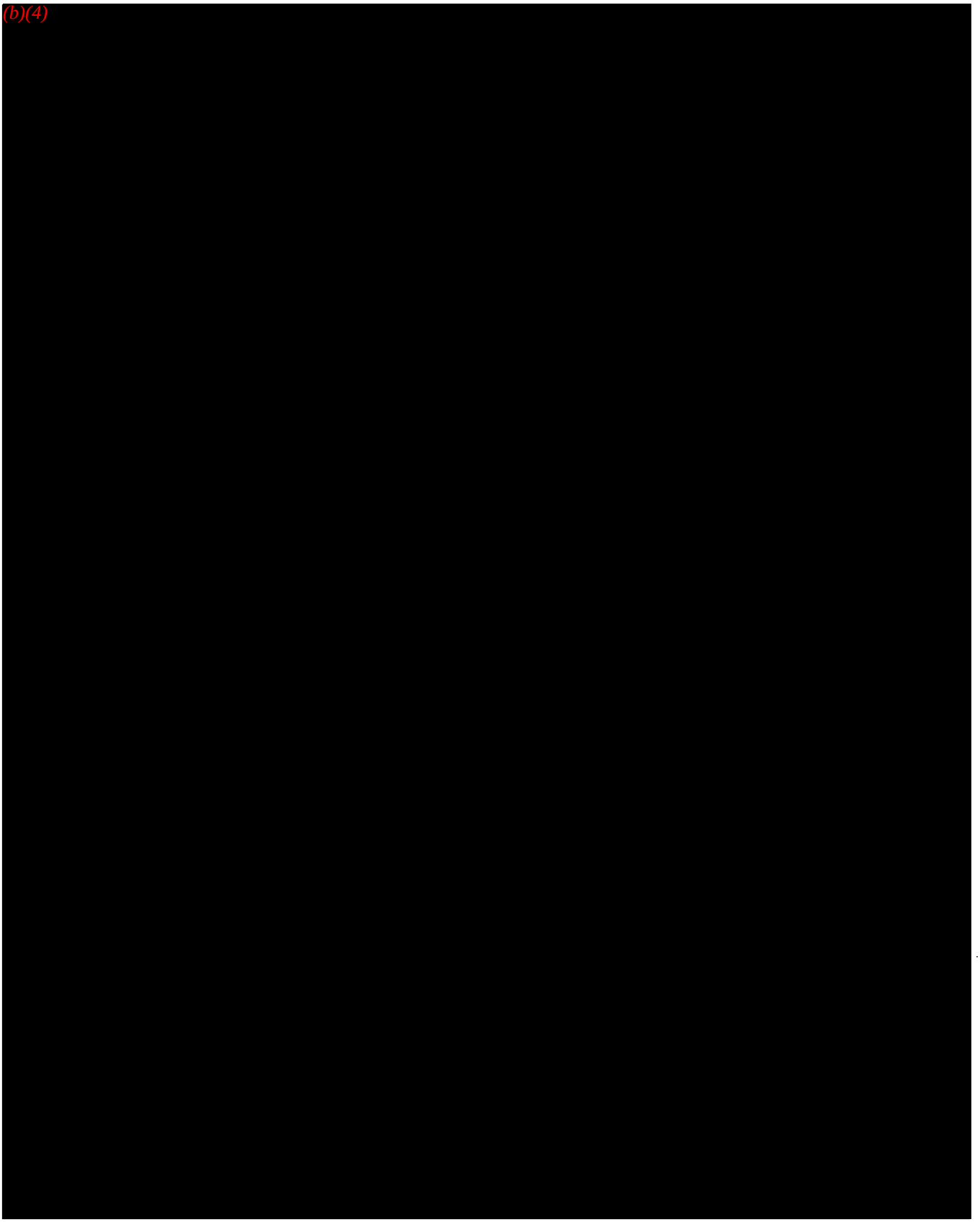
(b) (4)

[redacted]

(b)(4)



(b)(4)



(b)(4)

[redacted]

XII. **Performance Testing – Animal** N/A

XIII. **Performance Testing – Clinical**

XIV. **Substantial Equivalence Discussion**

	Yes	No	
1. Same Indication Statement?		X	If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?	X		If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?		X	If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
8. Performance Data Available?	X		If **NO** = Request Data
9. Data Demonstrate Equivalence?	X		Final Decision: SE

Note: See http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:

2. Explain why there is or is not a new effect or safety or effectiveness issue:

3. Describe the new technological characteristics:

4. Explain how new characteristics could or could not affect safety or effectiveness:

5. Explain how descriptive characteristics are not precise enough:
Modification to the indication for use and product code required justification and microbial ingress testing for the entire system.

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

7. Explain why existing scientific methods can not be used:

8. Explain what performance data is needed:
Review of the microbial ingress testing.
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:
The microbial ingress testing was needed to support the modifications to the Indications for use and for reclassification to product code, OBN.

XV. Deficiencies

The 510(K) Summary needed modification. The sponsor had listed all the previous predicate devices instead of the last predicate, which is identical device. The sponsor agreed to modify the Summary by listing the identical predicate device.

XVI. Contact History

December 12, 2012, Clarification to the predicates in the submission.
December 13, 2012, Received updated 510(k) Summary

XVII. Recommendation

Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: ONB

Digital Signature Concurrence Table	
Reviewer Sign-Off	Mary E. Brooks Digitally signed by Mary E. Brooks DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Mary E. Brooks, 0.9.2342.19200300.100.1.1=1300372349 Date: 2013.01.07 17:13:07 -05'00'
Branch Chief Sign-Off	Digitally signed by Richard C. Chapman Date: 2013.01.07 18:21:54 -05'00'
Division Sign-Off	Anthony D. Watson Anthony D. Watson 2013.01.08 14:24:31 -05'00'

Form Last Updated: Margaret McCabe Janicki 9/20/2012 – added Digital Signature concurrence table

Brooks, Mary E

From: Panguluri, Ramesh K
Sent: Friday, January 04, 2013 10:32 AM
To: Brooks, Mary E
Cc: Chapman, Richard
Subject: RE: Consult for K123213 PhaSeal Closed System

Dear Mary,
I have reviewed the Microbial ingress testing on the subject PhaSeal System and the testing is found to be adequate. In the predicate device they had only provided microbial ingress testing for the junction between the syringe and the injector. During the predicate review I asked them to provide microbial ingress testing for three junctions (vial/connector; connector/injector; and syringe/injector) and the testing was found to be adequate. Since the subject device is the same as the predicate I do not have any other concerns with the testing.

Thanks

Kapil

From: Brooks, Mary E
Sent: Thursday, January 03, 2013 7:55 PM
To: Panguluri, Ramesh K
Cc: Chapman, Richard
Subject: FW: Consult for K123213 PhaSeal Closed System

Hey Kapil,
Can you provide a quick turn around on this consult? It appears the testing was appropriate. I'm okay with an email response if that works for you. I'm on day 80 and ready to SE the submission but waiting your INCB's response.
Many thanks,
Mary

Mary E. Brooks RN, BSN, MS
Lieutenant Commander, United States Public Health Service
Nurse Consultant

Division of Anesthesiology, General Hospital,
Infection Control, & Dental Devices
Office of Device Evaluation
Center for Devices & Radiological Health
US Food & Drug Administration
WO66-G456
10903 New Hampshire Avenue
Silver Spring, MD, 20993-0002
(301) 796-6078
(301) 847-8109 (fax)
Mary.brooks@fda.hhs.gov

From: Brooks, Mary E
Sent: Wednesday, January 02, 2013 6:13 PM
To: Harry, Anya

Subject: FW: Consult for K123213 PhaSeal Closed System

Hey Anya,
Do you think you'll be able to complete this consult soon? I'm on day 79 and need to wrap it up…I'm happy with an email response if your bogged down.
Just let me know.
Thanks, M

From: Brooks, Mary E
Sent: Wednesday, December 12, 2012 6:52 PM
To: Claverie, Elizabeth F; Harry, Anya
Subject: Consult for K123213 PhaSeal Closed System

Hey Anya,
You just reviewed and approved microbial ingress testing K120384. The device is identical to the predicate, they are requesting to change the procode to ONB. They have provided additional microbial ingress testing to support their claim for connector. The full protocol starts on page 147 of the attached file.

<< File: PhaSeal 510(k) 12 Oct 2012.pdf >>
<< File: P21 4 IFU.pdf >>
<< File: C35 4 IFU.pdf >> << File: N35 4 IFU.pdf >>
<< File: C35 4 IFU.pdf >>
The intention of this submission is to modify the FDA-assigned product code of the previously cleared PhaSeal Closed System Transfer Device from LHI to product code ONB.

Current Product Code	LHI	Set, I.V. Fluid Transfer
Proposed Product Code	ONB	Closed Antineoplastic and Hazardous Drug Reconstitution and Transfer System

The ONB product code is defined by CDRH as follows:

Device: Closed Antineoplastic and Hazardous Drug Reconstitution and Transfer System

Regulation Description: Intravascular Administration Set

Definition: Reconstitute and transfer antineoplastic and other hazardous drugs in healthcare setting indicated to reduce exposure of healthcare personnel to chemotherapy agents in healthcare setting.

Physical State: Vial adaptor with piercing spikes, contain Luer-Lock connector fitted with elastomeric membrane to provide a sealed connection between syringe, I.V.
administration set or transfer bag. May contain side pressure-equalizing protector unit. May contain needle-free access port.

Technical Method: Placed over vial or container containing the chemotherapy drug. In order to meet this definition, the wording of the indication for use statement has been modified to better reflect the definition provided by the ONB product code. The additional text is **bolded** in the fully transposed

indications for use statement below. All other aspects of the indications for use statement are unchanged from the most recently cleared application K120384.

> The PhaSeal system is an **airtight and leakproof** closed system drug transfer device (CSTD) that mechanically prohibits the transfer of environmental contaminants into the system and the escape of drug or vapor concentrations outside the system, thereby minimizing individual and environmental exposure to drug vapor, aerosols and spills. The PhaSeal **system** also prevents microbial ingress.

BD has included the additional descriptors "airtight" and "leakproof" to align with the definition of Closed System Transfer Devices provided by the National Institute for Occupational Safety and Health (NIOSH) and the International Society of Oncology Pharmacy Practitioners (ISOPP). These characteristics of Closed System Transfer Devices are essential requirements to reduce health care workers from exposure to hazardous drugs. In addition, NIOSH also cites the need to prevent contaminates from entering the closed system during transfer. As such, in our most recent clearance, we added the following statement to the Indications for Use: "The PhaSeal protector also prevents microbial ingress." At the time of submission of K120384, we did not have microbial ingress data for the connector portion of the system. The current submission contains the microbial ingress data on the connector. As such, we propose to extend the microbial ingress claim to the entire system; not just the PhaSeal Protector.

Mary E. Brooks RN, BSN, MS
Lieutenant Commander, United States Public Health Service
Nurse Consultant

Division of Anesthesiology, General Hospital,
Infection Control, & Dental Devices
Office of Device Evaluation
Center for Devices & Radiological Health
US Food & Drug Administration
WO66-G456
10903 New Hampshire Avenue
Silver Spring, MD, 20993-0002
(301) 796-6078
(301) 847-8109 (fax)
Mary.brooks@fda.hhs.gov

Brooks, Mary E

From: John W Roberts [john_w_roberts@bd.com]
Sent: Friday, December 14, 2012 4:54 PM
To: Brooks, Mary E
Subject: FW: K123213 - BD PhaSeal Closed System Transfer Device
Attachments: Summary of Safety and Effectiveness - Revised.pdf

Good Afternoon Ms. Brooks,

My apologies, I sent this along yesterday, but mistyped the email address.

Thanks,
John

BD
John W Roberts
Regulatory Affairs

BD Medical – Medical Surgical Systems
1 Becton Drive, Franklin Lakes, NJ 07417 USA
Office: 201-847-5473 Mobile: 973-570-4645
Email: John_W_Roberts@bd.com Website: www.BD.com

From: John W Roberts
Sent: Thursday, December 13, 2012 4:20 PM
To: 'mary.brooks@hhs.fda.gov'
Subject: K123213 - BD PhaSeal Closed System Transfer Device

Good Afternoon Ms. Brooks,

As discussed this morning, I have attached the revised Summary of Safety and Effectiveness which incorporates the revised predicate identification as well as the inclusion of a summary conclusion statement. If there are any additional questions or concerns where I can provide assistance, please let me know.

Thanks,
John

BD
John W Roberts
Regulatory Affairs

BD Medical – Medical Surgical Systems
1 Becton Drive, Franklin Lakes, NJ 07417 USA
Office: 201-847-5473 Mobile: 973-570-4645
Email: John_W_Roberts@bd.com Website: www.BD.com

Please consider the environment before printing this email.

Contains Nonbinding Recommendations
Draft - Not for Implementation

Acceptance Checklist
for Traditional 510(k)s

(should be completed within 15 days of DCC receipt)

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

510(k) Number: _K123213 _____ Date Received: Oct 31, 2012

Lead Reviewer Name: Mary Brooks _ Branch: ___GHDB_____ Division: DAGRID Office: __ODE_

Preliminary Questions		
Answers in the shaded blocks indicate consultation with Center advisor is needed.	**Yes**	**No**
1. Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Office Jurisdiction Liaison to determine the appropriate action, and inform division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If the product does not appear to be a device or such a combination product, mark "No."	X	
Comments:		
2. Is the application with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the application is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Office Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If application should not be reviewed by your Center mark "No."	X	
Comments:		
3. Is a 510(k) the appropriate regulatory submission? If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."	X	

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

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

Organizational Elements

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

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

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

Submission should be designated RTA if not addressed

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

				Yes	N/A	No
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.					
A.	**Administrative**					
	1.	All content used to support the submission is written in English (including translations of test reports, literature articles, etc,)		X		☐
		Comments:				
	2.	510(k) cover letter that identifies:		X		☐
		a.	Device trade name or proprietary name	X		☐
		b.	Device common name	X		☐
		c.	Device class and panel	X		☐
		Comments:				
	3.	Submission contains Indications for Use Statement with Rx and/or OTC designated (see also 801.109) *Submitter should use format appropriate for the reviewing Center/Office (CDRH/ODE, CDRH/OIVD, CBER/OBRR, CBER/OCTGT). If not provided in correct format, request the correct format during substantive review.*		X		☐
		Comments: RX device				
	4.	Submission contains 510(k) Summary or 510(k) Statement *Either a) or b) must be answered "Yes" to be considered complete. Identify any missing element(s) as Comments.*		X		☐
		a.	Summary contains all elements per 21 CFR 807.92 *See also 510(k) Summary Checklist*	X	☐	☐
		b.	Statement contains all elements per 21 CFR 807.93	☐	X	☐
		Comments:				

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

Submission should be designated RTA if not addressed

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

			Yes	N/A	No
		• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			
	5.	Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended format*	X		☐
		Comments:			
	6.	Submission contains Class III Summary and Certification *See recommended content* *Form should be signed by a responsible person of the firm, not a consultant. CDRH is not currently able to accept a digital signature.* *"N/A" only if submission is not a Class III 510(k).*	X	☐	☐
		Comments:			
	7.	If submission relies upon a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (FDA Form 3654) or includes detailed information about how and the extent to which the standard has been followed *There should be a completed form for each referenced national or international standard.* *"N/A" only if submission does not reference any standards.*	☐	X	☐
		Comments:			
	8.	Does submission contain clinical data? *Select "N/A" for this item and 8.a. and 8.b. if the submission does not contain clinical data. If submission does contain clinical data, parts a. and b. must be answered "yes" for the 510(k) to be complete.*	☐	x	
		a. Submission includes Financial Certification/Disclosure Statement	☐	X	☐

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

Submission should be designated RTA if not addressed

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

				Yes	N/A	No
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.					
		b.	Submission includes Certification of Compliance with requirements of ClinicalTrials.gov Data Bank (FDA Form 3674) (42 U.S.C. 282(j)(5)(B))	☐	x	☐
		Comments:				
	9.	If this is a bundled submission, the submission has been appropriately bundled [i.e., the correct user fee(s) have been paid for the devices/indications (section 738 of the FD&C Act)] *See* Guidance for Industry and FDA Staff: Bundling Multiple Devices or Multiple Indications in a Single Submission. *"N/A" if not a bundled submission*		☐	X	☐
		Comments:				
	10.	The submission identifies prior submissions for the same device for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions.		☐		X
		a.	If there were prior submissions: within current submission, the sponsor has identified where in the current submission any issues related to substantial equivalence outlined in prior communications are addressed.	☐	X	☐
		Comments:				
B.	**Device Description**					
	11.	If there is a device-specific guidance document or special controls applicable to this submission, documentation has been provided to establish that the submitter has followed the recommendations in the applicable device-specific guidance document or special controls			X	☐

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

Submission should be designated RTA if not addressed

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

				Yes	N/A	No
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
		regarding the device description or otherwise met the applicable statutory or regulatory criteria through an alternative approach. *Select "No" if the submission does not include a rationale for any omitted information or any alternative approaches.* *Select "N/A" if there is no device-specific guidance document*				
		Comments:				
	12.	All descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:				
		a.	A description of the principle of operation and mechanism of action for achieving the intended therapeutic/diagnostic effect.	X		☐
		b.	A description of all conditions of use such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	X		☐
		c.	A list and description of each model for which clearance is requested. *Select "N/A" if there is only one model.*		X	☐
		Comments: The PhaSeal system is an airtight and leakproof closed system drug transfer device (CSTD) that mechanically prohibits the transfer of environmental contaminants into the system and the escape of drug or vapor concentrations outside of the system, thereby minimizing individual and environmental exposure to drug vapor, aerosols and spills. The PhaSeal System also prevents microbial ingress				
	13.	Where applicable, submission contains engineering drawing(s), schematics, illustrations and/or figures of the device that are clear and legible, and include dimensions		X	☐	☐
		a.	If engineering drawings, schematics, illustrations and/or figures are provided, one is provided for each model to be marketed	X	☐	☐

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

Submission should be designated RTA if not addressed

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

				Yes	N/A	No
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
		Comments:				
	14.	If device is intended to be marketed with multiple components, accessories, and/or as part of a system, *Select "N/A" if the device is not intended to be marketed with multiple components, accessories, and/or as part of a system.*		X		
		a.	A description (as detailed in item 12.a. and b. and 13 above) is provided for each component or accessory.	X		☐
		b.	A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance. *Select "N/A" if the submission states that the component(s)/ accessory(ies) do not have a prior 510(k) clearance.*		X	☐
		Comments:				
C.	**Substantial Equivalence Discussion**					
	15.	Submitter has identified a predicate(s) device		X		☐
		a.	Predicate's 510(k) number, trade name, and model number (if applicable) provided	X		☐
		b.	The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing	X		☐
		Comments:				
	16.	Submission includes a comparison of the following for the predicate(s) and subject device				
		a.	Indications for use	X		☐
		b.	Technology, including features, materials, and principles of	X		☐

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
			operation			
		Comments:				
	17.	Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., do not constitute a new intended use, affect safety or effectiveness, or raise different questions of safety and effectiveness) (see section 513(i)(1)(A) of the FD&C Act) *If there is no difference between the subject and predicate(s) with respect to indications for use or technology, this should be explicitly stated, in which case "N/A" should be selected. Select "No" only if the submission does not include an analysis of differences as described above or a statement that there are no differences. Note that due to potential differences in manufacturing that may not be known to the submitter, no identified differences does not necessarily mean that no performance testing is needed.*		X	☐	☐
		Comments:				
D.	**Proposed Labeling (see also 21 CFR part 801)**					
	18.	Submission includes proposed labels, labeling (e.g., instructions for use, package insert, operator's manual), and advertisements that describe the device, its intended use, and the directions for use				
		a.	Indications for use stated in labeling (21 CFR 801.61) and identical to IFU form and 510(k) Summary (if applicable)	X		☐
		b.	Directions for use included (including relevant hazards, warnings, precautions, contraindications), including directions for layperson (see 21 CFR 801.5) unless submission states that device qualifies for exemption per 21 CFR 801 Subpart D.	X		☐

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed					
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
		Comments:				
	19.	If indicated for prescription use, labeling includes the prescription use statement (see 21 CFR 801.109(b)(1)) or "Rx only" symbol [See also Alternative to Certain Prescription Device Labeling Requirements] *Select "N/A" if not indicated for prescription use.*		X	☐	☐
		Comments: RX device				
	20.	General labeling provisions				
		a.	Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1)	X		☐
		b.	Labeling includes device common or usual name (21 CFR 801.61)	X		☐
		Comments: Identical labeling				
	21.	If there is a device-specific guidance, special controls, or regulation, the provided labeling establishes that the submitter has followed the recommendations in the applicable guidance document, special controls, or regulation, or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. *Select "N/A" if there is no device-specific guidance or regulation.*		☐	X	☐
		Comments:				
	22.	If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10. *Select "N/A" if not an in vitro diagnostic device.*		☐	X	☐
E.	**Performance Data – General**					
	Submission: (*one of the below must be checked*) ☐ does ☐ does not					

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

Submission should be designated RTA if not addressed

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

			Yes	N/A	No
		• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			
	contain performance data. *If "does not" is selected, the performance data-related criteria below are omitted from the checklist.*				
	Comments:				
	23.	Full test report is provided for each completed test to explain how the data generated from the test supports a finding of substantial equivalence. (A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre-defined pass/fail criteria, results summary, and conclusions.)	X		☐
		Comments:			
	24.	Submission includes document to establish that the submitter has followed the recommendations for performance data outlined in the applicable device-specific guidance document or special controls, or otherwise met the applicable statutory or regulatory criteria through an alternative approach. *Select "N/A" if there is no device-specific guidance document.*	☐	X	☐
		Comments:			
	25.	If literature was used as performance data, submission includes reprints or a summary of each article, and a discussion as to how each article is applicable to support the substantial equivalence of the subject device to the predicate.	☐	X	☐
		Comments: This submission is identical to their own predicate. The submission was for reclassification of the product code and minor modifications to the Indications for Use. The identical articles were reviewed in the predicate device.			

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed					
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
	26.	If an animal study was conducted, *Select "N/A" if no animal study was conducted.*			X	
		a.	Submission includes a study protocol and final study report to explain how the data generated from the study supports a finding of substantial equivalence. (A final study report includes a contributing scientist report for each preclinical endpoint of evaluation within the protocol, such as performance/handling, in life, imaging, pathology, etc.)	☐		☐
		b.	Submission contains a statement that the study was conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58), or, if the study was not conducted in compliance with the GLP regulation, the submission explains why the noncompliance would not impact the validity of the study data provided to support a substantial equivalence determination.	☐		☐
		Comments:				
F.	**Sterilization**					
	Submission states that the device and/or accessories are: (*one of the below must be checked*) X sterile ☐ non-sterile but sterilized by the end user ☐ non-sterile when used This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "non-sterile when used" is selected, the sterility-related criteria below are omitted from the checklist.* *If information regarding the sterility status of the device is not provided, select "No."*					☐
	Comments: No modification in materials or sterilization process. The predicate and subject devices					

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

Submission should be designated RTA if not addressed

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

				Yes	N/A	No
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.					
	are identical.					
	27.	Assessment of the need for sterilization information				
		a.	Identification of device, and/or accessories, and/or components that are provided sterile.	☐	X	☐
		b.	Identification of device, and/or accessories, and/or components that are end user sterilized	☐	X	☐
		c.	Identification of device, and/or accessories, and/or components that are reusable and cleaning/disinfection instructions are provided.	☐	X	☐
		Comments:				
	28.	If the device, and/or accessory, and/or a component is provided sterile: *Select "N/A" if no part of the device, accessories, or components is provided sterile, otherwise complete a-f below.*			X	
		a.	Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.)	☐		☐
		b.	A description of method to validate the sterilization cycle (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided	☐		☐
		c.	For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits. *Select "N/A" if not sterilized using chemical sterilants.*	☐	X	☐
		d.	Submission includes description of packaging and packaging	☐		☐

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
			contents (e.g., if multiple devices are included within the same package)			
		e.	Sterility Assurance Level (SAL) stated	☐		☐
		f.	If device is blood-contacting, a permanent implant, or contacts cerebrospinal fluid, or device is labeled "non-pyrogenic," submission contains a description of the endotoxin method used to make a determination (e.g., LAL), endotoxin release specification (e.g., 20 EU/device), and a rationale for the specification. *Select "N/A" if device is not blood-contacting, not a permanent implant, does not contact cerebrospinal fluid, and is not labeled "non-pyrogenic." Select "N/A" if a rationale for omission is provided.*	☐	X	☐
		Comments:				
	29.	All sterility information provided as recommended in the following guidance documents or special controls, or information provided indicating the submitter has otherwise met the applicable statutory or regulatory criteria through an alternative approach: *Either "a" or "b" must be answered "Yes" to be considered complete.*				
		a.	Device-specific guidance document or special controls *Select "N/A" if no device-specific guidance document.*	☐	X	☐
		b.	Cross-cutting guidance document (for more information see "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile") *Select "N/A" if device-specific guidance followed instead.*	☐	X	☐
		Comments:				
G.	**Shelf Life**					

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

Submission should be designated RTA if not addressed

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

				Yes	N/A	No
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.					
	30.	If the device is provided sterile or the device is provided non-sterile and storage conditions (i.e., aging) could impact device safety or effectiveness, address the following: *Select "N/A" if the device is not provided sterile and the submitter states that storage conditions could not affect device safety or effectiveness.*			X	
		a.	Proposed shelf life/expiry date stated	☐		☐
		b.	Submission includes description of shelf life validation method(s) used to ensure device performance and sterility, as applicable, remain substantially equivalent to that of the predicate device throughout the stated shelf life.	☐		☐
		Comments:				
H.	**Biocompatibility**					
	Submission states that there: (*one of the below must be checked*) ☐ are X are not direct or indirect (e.g., through fluid infusion) patient-contacting components. This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "are not" is selected, the biocompatibility-related criteria below are omitted from the checklist. If information regarding whether the device is patient-contacting is not provided, select "No."*					☐
	Comments: No modification in materials or sterilization process. The predicate and subject devices are identical.					
	31.	Submission includes list of patient-contacting device components and associated materials of construction, including identification of color		☐		☐

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

Submission should be designated RTA if not addressed

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

			Yes	N/A	No
		• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			
		additives, if present			
		Comments:			
	32.	Submission identifies contact classification (e.g., surface-contacting, less than 24 hour duration)	☐		☐
		Comments:			
	33.	Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test, OR a statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).	☐		☐
I.	**Software**				
	Submission states that the device: (*one of the below must be checked*) ☐ does X does not contain software. This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not" is selected, the software-related criterion is omitted from the checklist. If information regarding whether the device contains software is not provided, select "No."*				☐
	Comments:				
	34.	All appropriate categories of software verification and validation	☐		☐

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

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
	36.	Submission includes evaluation of electromagnetic compatibility per IEC 60601-1-2 or equivalent FDA-recognized standard and if applicable, the device-specific standard OR submission includes electromagnetic compatibility evaluation using methods or standards that are not FDA-recognized and information indicating that these methods/standards otherwise meet applicable statutory and regulatory requirements.		☐		☐
		Comments:				
K.	**Performance Characteristics – In Vitro Diagnostic Devices Only (see also 21 CFR 809.10(b)(12))**					
	Submission indicates that device: (*one of the below must be checked*) ☐ is X is not an in vitro diagnostic device (IVD). *If "is not" is selected, the performance data-related criteria below are omitted from the checklist.*					
	Comments:					
	37.	Submission includes the following analytical studies, including associated protocols and line data:				
		a.	Precision/reproducibility (at least 3 sites generally necessary)	☐	☐	☐
		b.	Accuracy (includes linearity, assay cut-off, method comparison or comparison to clinical outcome, matrix comparison, reference range, and stability protocol and acceptance criteria)	☐	☐	☐
		c.	Sensitivity (detection limits (LoB, LoD, and LoQ))	☐	☐	☐

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

Decision: Accept ___ Refuse to Accept ___

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

Digital Signature Concurrence Table	
Reviewer Sign-Off	
Branch Chief Sign-Off	
Division Sign-Off	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

October 16, 2012

BECTON DICKINSON & CO.
1 BECTON DR.
MC237
FRANKLIN LAKES, NEW JERSEY 07417-1885
ATTN: JOHN ROBERTS

510k Number: K123213

Received: 10/15/2012

Product: BD PHASEAL CLOSED SYSTEM TRANS

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

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

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

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

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html. In addition, the 510(k) Program Video is now available for viewing on line at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm .

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041 , or at their internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

Mcdonald, Lisa *

om:	Microsoft Outlook
To:	john_w_roberts@bd.com
Sent:	Tuesday, October 16, 2012 9:30 AM
Subject:	Relayed: FW: K123213 ACK Letter

Delivery to these recipients or groups is complete, but no delivery notification was sent by the destination server:

john_w_roberts@bd.com (john_w_roberts@bd.com)

Subject: FW: K123213 ACK Letter

Form Approved: OMB No. 0910-511 Expiration Date: February 28, 2013. See Instructions for OMB Statement.

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

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

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)	2. CONTACT NAME
BD MEDICAL SURGICAL SYSTEMS 1 BECTON DRIVE FRANKLIN LAKE NJ 07417 US	John Roberts 2.1 E-MAIL ADDRESS john_w_roberts@bd.com 2.2 TELEPHONE NUMBER (include Area code) 201-8475473
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****0120	2.3 FACSIMILE (FAX) NUMBER (Include Area code)

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

Select an application type:	3.1 Select a center
[X] Premarket notification(510(k)); except for third party	[X] CDRH
[ ] 513(g) Request for Information	[ ] CBER
[ ] Biologics License Application (BLA)	3.2 Select one of the types below
[ ] Premarket Approval Application (PMA)	[X] Original Application
[ ] Modular PMA	Supplement Types:
[ ] Product Development Protocol (PDP)	[ ] Efficacy (BLA)
[ ] Premarket Report (PMR)	[ ] Panel Track (PMA, PMR, PDP)
[ ] Annual Fee for Periodic Reporting (APR)	[ ] Real-Time (PMA, PMR, PDP)
[ ] 30-Day Notice	[ ] 180-day (PMA, PMR, PDP)

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

[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA

[X] NO, I am not a small business

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

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

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

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

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

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

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

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

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

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

[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT

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

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

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

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4) 12-Oct-2012

Form FDA 3601 (01/2007)

"Close Window" Print Cover Sheet

Becton, Dickinson and Company
BD Medical – Medical Surgical Systems
510(k) Premarket Notification: Traditional

BD PhaSeal Closed System Transfer Device

K123213

1 Becton Drive
Franklin Lakes, New Jersey 07417
tel: 201.847.6800
www.bd.com

6

BD

Helping all people
live healthy lives

FDA CDRH DMC
OCT 15 2012
Received

12 October 2012

Office of Device Evaluation
Center for Devices and Radiological Health
Document Mail Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: 510(k) Premarket Notification: Traditional – PhaSeal Closed System Transfer Device

To Whom It May Concern:

BD hereby submits this **Traditional 510(k)** (original and copy) to re-classify the previously cleared PhaSeal Closed System Transfer Device under product code (b) (4) [redacted] In addition, the wording of the indication for use statement has been modified to better reflect the definition provided by the ONB product code. There is no design or performance change associated with this 510(k) submission.

We consider our intent to market this device as confidental information and request it be treated as such by FDA. We have taken precautions to protect the confidentiality of the intent to market these devices. We understand that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).
Thank you in advance for your consideration of our application. If there are any questions, please contact me at your earliest convenience.

Sincerely,

John Roberts
Regulatory Affair Specialist
BD Medical - Medical Surgical Systems
Tel: 201 847 5473
Fax: 201 847 5307
john_w_roberts@bd.com

1 Becton Drive
Franklin Lakes, New Jersey 07417
tel: 201.847.6800
www.bd.com

BD

Helping all people
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12 October 2012

Office of Device Evaluation
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10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: 510(k) Premarket Notification: Traditional – PhaSeal Closed System Transfer Device

To Whom It May Concern:

BD hereby submits this **Traditional 510(k)** (original and copy) to re-classify the previously cleared PhaSeal Closed System Transfer Device under product code (b) (4) [redacted] In addition, the wording of the indication for use statement has been modified to better reflect the definition provided by the ONB product code. There is no design or performance change associated with this 510(k) submission.

We consider our intent to market this device as confidental information and request it be treated as such by FDA. We have taken precautions to protect the confidentiality of the intent to market these devices. We understand that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).
Thank you in advance for your consideration of our application. If there are any questions, please contact me at your earliest convenience.

Sincerely,

John Roberts
Regulatory Affair Specialist
BD Medical - Medical Surgical Systems
Tel: 201 847 5473
Fax: 201 847 5307
john_w_roberts@bd.com

TABLE OF CONTENTS

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

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

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number (if known)
[redacted]15/2012		

SECTION A TYPE OF SUBMISSION

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

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

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

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
Becton, Dickinson and Company	2243072		
Division Name *(if applicable)*	Phone Number *(including area code)*		
[redacted]D Medical Surgical	(201) 847-5473		
[redacted]treet Address	FAX Number *(including area code)*		
1 Becton Drive MC237	(201) 847-5307		
City	State / Province	ZIP/Postal Code	Country
Franklin Lakes	NJ	07417	USA
Contact Name			
John Roberts			
Contact Title	Contact E-mail Address		
Regulatory Affairs Specialist	john_w_roberts@bd.com		

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

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

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

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

SECTION D2 REASON FOR APPLICATION - IDE

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

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☐ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology
- ☒ Other Reason *(specify)*:

To re-classify the previously cleared PhaSeal Closed System Transfer Device under product code ONB which was created in response to Citizens Petition Docket# FDA-2008-P-0196. In addition, the wording of the indication for use statement has been modified to better reflect the definition provided by the ONB product code.

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

[redacted]	LHI	2		3		4	
		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

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

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

	510(k) Number		Trade or Proprietary or Model Name		Manufacturer
1	K090634	1	PhaSeal Protector P14, P21, P28 AND P50	1	Carmel Pharma AB
2	K001368	2	P21, P50, P14, Injector Luer Lock, Infusion Adaptor	2	Carmel Pharma AB
3	K092782	3	Injector luer, Model N34, Injector Luer Lock, MODEL N35, Injector Luer Lock, N35C, Connector Luer Lock, Model C35,	3	Carmel Pharma AB
4	K972527	4	PhaSeal, System for sealed handling of Chemotherapeutic Agents	4	Carmel Pharma AB
5	K980381	5	PhaSeal, closed system for handling of patenteral drugs, additional administration devices. C80 Infusion Adapter, A10 PRO	5	Carmel Pharma AB
6	See 510(k) Cover Letter	6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Closed antineoplastic and hazardous drug reconstitution and transfer system

	Trade or Proprietary or Model Name for This Device		Model Number
1	BD PhaSeal Closed System Transfer Device	1	NA
2		2	
3		3	
4		4	
5		5	

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

1 K972527	2 K980381	3 K001368	4 K023747	5 K060866	6 K090634
7 K092782	8 K110023	9 K102711	10 K083540	11 K120384	12

Data Included in Submission

☒ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
ONB	880.5440	☐ Class I ☒ Class II ☐ Class III ☐ Unclassified

Classification Panel

876 Gastroenterology and Urology

Indications *(from labeling)*

The PhaSeal system is an airtight and leakproof closed system drug transfer device (CSTD) that mechanically prohibits the transfer of environmental contaminants into the system and the escape of drug or vapor concentrations outside of the system, thereby minimizing individual and environmental exposure to drug vapor, aerosols and spills. The PhaSeal System also prevents microbial ingress

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

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

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☒ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

(b) (4)

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☒ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

(b) (4)

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

SECTION I	UTILIZATION OF STANDARDS

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

	Standards No.	Standards Organization	Standards Title	Version	Date
1					
2	Standards No.	Standards Organization	Standards Title	Version	Date
3	Standards No.	Standards Organization	Standards Title	Version	Date
4	Standards No.	Standards Organization	Standards Title	Version	Date
5	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date

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

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

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

K123213

Becton Dickinson Medical Surgical
Franklin Lakes, New Jersey 07417

Becton, Dickinson and Company

510(k) Type: Traditional

Device Common Name: Closed antineoplastic and hazardous drug reconstitution and transfer system

Submitter: Becton, Dickinson and Company
1 Becton Drive
Franklin Lakes, NJ 07417 USA
Phone: 201 847 6800

Establishment Registration number: 2243072

Contact: John Roberts
Tel: 201 847 5473
Fax: 201 847 5307
Email: john_w_roberts@bd.com

Confidentiality: Confidentiality is claimed for those documents marked as such

Classification Regulation: 21 880.5440

Class: II

Panel: General Hospital

Product Code: ONB

Associated Documents:
1. 510(k) number K972527
2. 510(k) number K980381
3. 510(k) number K001368
4. 510(k) number K023747
5. 510(k) number K060866
6. 510(k) number K090634
7. 510(k) number K092782
8. 510(k) number K110023
9. 510(k) number K120384

Clearance letters associated with each of the referenced submissions are enclosed in Appendix I

Basis for Submission: Reclassification to Product Code ONB

III. Indications for Use Statement / Purpose of Submission

The intention of this submission is to modify the FDA-assigned product code of the previously cleared PhaSeal Closed System Transfer Device from LHI to product code ONB.

Current Product Code	LHI	Set, I.V. Fluid Transfer
Proposed Product Code	ONB	Closed Antineoplastic and Hazardous Drug Reconstitution and Transfer System

The ONB product code is defined by CDRH as follows:

> Device: Closed Antineoplastic and Hazardous Drug Reconstitution and Transfer System
>
> Regulation Description: Intravascular Administration Set
>
> Definition: Reconstitute and transfer antineoplastic and other hazardous drugs in healthcare setting indicated to reduce exposure of healthcare personnel to chemotherapy agents in healthcare setting.
>
> Physical State: Vial adaptor with piercing spikes, contain Luer-Lock connector fitted with elastomeric membrane to provide a sealed connection between syringe, I.V. administration set or transfer bag. May contain side pressure-equalizing protector unit. May contain needle-free access port.
>
> Technical Method: Placed over vial or container containing the chemotherapy drug.

In order to meet this definition, the wording of the indication for use statement has been modified to better reflect the definition provided by the ONB product code. The additional text is **bolded** in the fully transposed indications for use statement below. All other aspects of the indications for use statement are unchanged from the most recently cleared application K120384.

> The PhaSeal system is an **airtight and leakproof** closed system drug transfer device (CSTD) that mechanically prohibits the transfer of environmental contaminants into the system and the escape of drug or vapor concentrations outside the system, thereby minimizing individual and environmental exposure to drug vapor, aerosols and spills. The PhaSeal **system** also prevents microbial ingress.

BD has included the additional descriptors "airtight" and "leakproof" to align with the definition of Closed System Transfer Devices provided by the National Institute for Occupational Safety and Health (NIOSH) and the International Society of Oncology Pharmacy Practitioners (ISOPP). These characteristics of Closed System Transfer Devices are essential requirements to reduce health care workers from exposure to hazardous drugs. In addition, NIOSH also cites the need to prevent contaminates from entering the closed system during transfer. As such, in our most

recent clearance, we added the following statement to the Indications for Use: "The PhaSeal protector also prevents microbial ingress." At the time of submission of K120384, we did not have microbial ingress data for the connector portion of the system. The current submission contains the microbial ingress data on the connector. As such, we propose to extend the microbial ingress claim to the entire system; not just the PhaSeal Protector.

The amended indication for use statement, in the official format, is provided on the next page of this submission.

Indications for Use Statement

510(k) Number (if known): _____

Device Name: PhaSeal® – A Closed System Transfer Device

Indications for Use:

The PhaSeal system is an airtight and leakproof closed system drug transfer device (CSTD) that mechanically prohibits the transfer of environmental contaminants into the system and the escape of drug or vapor concentrations outside the system, thereby minimizing individual and environmental exposure to drug vapor, aerosols and spills. The PhaSeal system also prevents microbial ingress.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page __ of ___

510(K) Summary of Safety and Effectiveness

Date Prepared: 12 October 2012

1. **Submitted By:**

John Roberts
Regulatory Affairs Specialist
BD Medical - Medical Surgical Systems
1 Becton Drive
Franklin Lakes, NJ 07417
Tel: 201 847 5473; Fax: 201 847 5307

2. **Device Name:**

Trade Name:	BD PhaSeal® Closed System Drug Transfer Device
Common Name:	Closed antineoplastic & hazardous drug reconstitution & transfer system
Classification Name:	Intravascular administration set
Classification:	Class II, 21 CFR 880.5440

3. **Predicate Device:**

PhaSeal Protector:	K090634
PhaSeal Injector:	K001368, K092782
PhaSeal Connector:	K972527, K980381, K060866, K092782, K110023

4. **Device Description:**

The PhaSeal® System is a sterile single-used closed system drug transfer device. The closed transfer of liquid takes place through a double membrane utilizing self-sealing elastomeric membranes, tightly fitted together through a bayonet fitting on all PhaSeal components. A single lumen cannula perforates the double membranes fro the transfer of liquid. When the cannula is retracted the membranes seal off the transfer of environmental contaminants into the system and/or escape of drug or vapor concentrations outside the system, thereby minimizing the individual and environmental exposure to drug vapor, aerosols and spills and also minimizing the risk of microbial contamination.

5. **Indications for Use**:

The PhaSeal system is an airtight and leakproof closed system drug transfer device (CSTD) that mechanically prohibits the transfer of environmental contaminants into the system and the escape of drug or vapor concentrations outside the system, thereby minimizing individual and environmental exposure to drug vapor, aerosols and spills. The PhaSeal system also prevents microbial ingress.

6. **Technological Characteristics:**

The technological characteristics of the subject device are identical to those of the predicate devices.

7. **Performance:**

The additional tests referenced in the table have been provided in order to substantiate the use of product code ONB - Closed antineoplastic and hazardous drug reconstitution and transfer system – for the BD PhaSeal® Closed System Drug Transfer Device. BD has included the additional airtight and leakproof requirement as both of these requirements are cited by the National Institute for Occupational Safety and Health (NIOSH) and the International Society of Oncology Pharmacy Practitioners (ISOPP) as essential requirements necessary to reduce health care workers from exposure to hazardous drugs. In addition, NIOSH also cites the need to prevent contaminates from entering the closed system during transfer. As such, BD proposes to extend the microbial ingress claim to the entire system; not just the PhaSeal Protector. As there is no change to the subject device in comparison to the predicate devices, the performance data provided represent the performance of both the predicate and subject device of this 510(k).

Item#	Performance Specification:	Status of BD PhaSeal® System
1	Leakproof Connections	No Leaks (Fluorescein Test)[1,2]
2	Airtight Connections	No Visable Smoke ($TiCl_4$ Test)[3]
3	Microbial Ingress	No Ingress at the Protector or Connector

[1] Spivey S, Connor T. **Determining sources of workplace contamination with antineoplastic drugs and comparing conventional IV drug preparation with a closed system.** *Hosp Pharm.* 2003; 38(2): 135-139.
[2] Jorgenson J, Spivey S, Au C et al. **Contamination comparison of transfer devices intended for handling hazardous drugs.** *Hosp Pharm.* 2008; 43(9): 723-727
[3] *Ibid.*

Pre-Market Notification Truthful and Accurate Statement

I certify that, in my capacity as Regulatory Affairs Specialist at Becton, Dickinson and Company, I believe to the best of my knowledge that all data and information submitted in the Pre-Market Notification are truthful and accurate and that no material fact has been omitted.

(Signature)

12 Oct 2012
(Date)

John Roberts
Regulatory Affairs Specialist
BD Medical - Medical Surgical Systems

VI. Class III Summary and Certification

This Premarket Notification is written for a Class II Medical Device. The Class III Summary and Certification requirements do not apply.

VII. Financial Certification or Disclosure Statement

The Financial Certification and Disclosure requirements do not apply to this Premarket Notification since there were no clinical trials conducted or clinical investigators involved.

VIII. Declaration of Conformity and Summary Reports

This Premarket Notification is not an Abbreviated 510(k), therefore a Declaration of Conformity and Summary Report is not included.

IX. Executive Summary

1. Company Name and Address:

Becton, Dickinson and Company
1 Becton Drive
Franklin Lakes, NJ 07417

2. Contact Information:

John Roberts
Regulatory Affairs Specialist
Tel: 201 847 5473
Fax: 201 847 5307
E-mail: john_w_roberts@bd.com

3. Establishment Registration Information:

Manufacturing Sites: (b) (4) [redacted]

Parent Company: Becton, Dickinson and Company
1 Becton Drive
Franklin Lakes, NJ 07417
FDA Facility Registration Number: 2243072

Sterilization Sites: (b) (4) [redacted]

4. Identification of Subject Device

Trade Name:	BD PhaSeal® Closed System Drug Transfer Device
Common Name:	Closed antineoplastic & hazardous drug reconstitution & transfer system
Classification Name:	Intravascular administration set
Classification:	Class II, 21 CFR 880.5440

5. Identification of Predicate Device

PhaSeal Protector: K090634
PhaSeal Injector: K001368, K092782
PhaSeal Connector: K972527, K980381, K060866, K092782, K110023

6. Indications for Use

The PhaSeal system is an airtight and leak-proof closed system drug transfer device (CSTD) that mechanically prohibits the transfer of environmental contaminants into the system and the escape of drug or vapor concentrations outside the system, thereby minimizing individual and environmental exposure to drug vapor, aerosols and spills. The PhaSeal System also prevents microbial ingress.

7. Purpose of Submission

The intention of this submission is to modify the FDA-assigned product of the previously cleared PhaSeal Closed System Transfer Device from LHI to product code ONB.

Current Product Code	LHI	Set, I.V. Fluid Transfer
Proposed Product Code	ONB	Closed Antineoplastic and Hazardous Drug Reconstitution and Transfer System

The ONB product code is defined by CDRH as follows:

> Device: Closed Antineoplastic and Hazardous Drug Reconstitution and Transfer System
>
> Regulation Description: Intravascular Administration Set
>
> Definition: Reconstitute and transfer antineoplastic and other hazardous drugs in healthcare setting indicated to reduce exposure of healthcare personnel to chemotherapy agents in healthcare setting.
>
> Physical State: Vial adaptor with piercing spikes, contain Luer-Lock connector fitted with elastomeric membrane to provide a sealed connection between syringe, I.V. administration set or transfer bag. May contain side pressure-equalizing protector unit. May contain needle-free access port.
>
> Technical Method: Placed over vial or container containing the chemotherapy drug.

In order to meet this definition, the wording of the indication for use statement has been modified to better reflect the definition provided by the ONB product code. The additional text is **bolded** in the fully transposed indications for use statement below. All

other aspects of the indications for use statement are unchanged from the most recently cleared application K120384.

> The PhaSeal system is an **airtight and leakproof** closed system drug transfer device (CSTD) that mechanically prohibits the transfer of environmental contaminants into the system and the escape of drug or vapor concentrations outside the system, thereby minimizing individual and environmental exposure to drug vapor, aerosols and spills. The PhaSeal **System** also prevents microbial ingress.

BD has included the additional descriptors "airtight" and "leakproof" to align with the definition of Closed System Transfer Devices provided by the National Institute for Occupational Safety and Health (NIOSH) and the International Society of Oncology Pharmacy Practitioners (ISOPP). These characteristics of Closed System Transfer Devices are essential requirements to reduce health care workers from exposure to hazardous drugs.

Potential routes of exposure to hazardous drugs include, but may not be limited to, dermal absorption, inhalation and ingestion. As none of the possible entry points can be eliminated as a potential risk, ISOPP specifies that only "Airtight" and "Leakproof" devices prevent chemical contamination:

- A product described as a closed-system must be "leakproof and airtight"—therefore vented, filtered devices are not closed. A product cannot be "semi-closed;"
- The vapor of cytotoxic products are not retained by filters with a diameter of 0.22μm and HEPA filters;
- To avoid confusion, it is strongly recommended that if a device claims to prevent chemical contamination it should be airtight and leakproof.[1]

In concurrence with these requirements proposed by ISOPP, NIOSH offers the following definition:

- Closed system drug-transfer device (CSTD): a drug transfer device that mechanically prohibits the transfer of environmental contaminants into the system and the escape of hazardous drug or vapor concentrations outside the system.[2]

It is also important to note that NIOSH stresses that a CSTD must also prohibit the transfer of environmental contaminants into the system. As such, BD has further modified the indication concerning microbial ingress to include the entire system as opposed to just the PhaSeal Protector.

[1] ISOPP Standards of Practice. Journal of Oncology Pharmacy Practice. 2007; 13 Suppl: 1-81
[2] National Institute for Occupational Safety and Health (NIOSH) NIOSH alert 2004-165. Preventing occupational exposures to antineoplastic and other hazardous drugs in health care settings. Cincinnati, OH: NIOSH; 2004. Available at http://www.cdc.gov/niosh/docs/2004-165/pdfs/2004-165.pdf.

To summarize, between the three definitions provided by FDA, NIOSH and ISOPP, BD has identified three critical characteristics of a CSTD.

- The system is airtight
- The system is leak proof
- The system prevents contaminates from entering the system

Please find described in the Summary of Performance testing section outlined below 4 tests which demonstrate that the BD PhaSeal system meets these three requirements. Full study reports can be found in Appendix III

1. Spivey S, Connor T. "**Determining sources of workplace contamination with antineoplastic drugs and comparing conventional IV drug preparation with a closed system.**" *Hosp Pharm.* 2003; 38(2): 135-139.
2. Jorgenson J, Spivey S, Au C et al. "**Contamination comparison of transfer devices intended for handling hazardous drugs.**" *Hosp Pharm.* 2008; 43(9): 723-727

(b) (4) [redacted]

Device Description

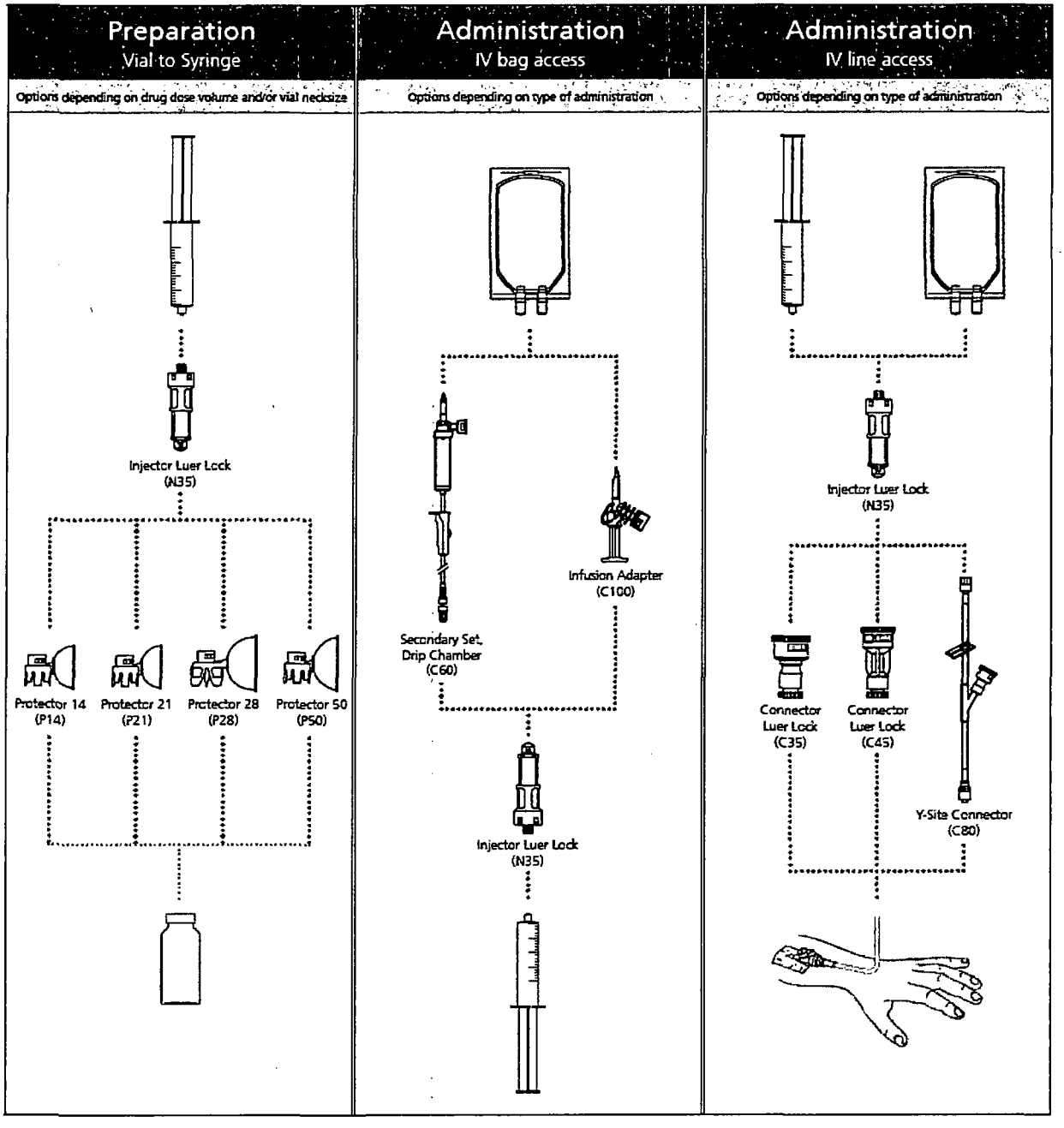
The PhaSeal® System is a sterile single-used closed system drug transfer device. The closed transfer of liquid takes place through a double membrane utilizing self-sealing elastomeric membranes, tightly fitted together through a bayonet fitting on all PhaSeal components. A single lumen cannula perforates the double membranes fro the transfer of liquid. When the cannula is retracted the membranes seal off the transfer of environmental contaminants into the system and/or escape of drug or vapor concentrations outside the system, thereby minimizing the individual and environmental exposure to drug vapor, aerosols and spills and also minimizes the risk of microbial contamination.

The PhaSeal® System is composed of the following components. Each of the components has been cleared via various 510(k)s. However, the entire system was once again cleared on 12 Sep 2012 for a modification to the indications for use. Specifically, the system was modified

Table 1. List of components of PhaSeal System and their respective 510(k) numbers.

PhaSeal Protector	P14	K120384
	P21	K120384
	P28	K120384
	P50	K120384
PhaSeal Injector	N30C	K120384
	N31	K120384
	N35	K120384
	N35C	K120384
PhaSeal Connector	C35	K120384
	C45	K120384
	C40	K120384
	C48	K120384
	C50	K120384
	C60	K120384
	C61	K120384
	C70	K120384
	C80	K120384
	C100	K120384

Picture 1: *Examples of BD PhaSeal® System and process*

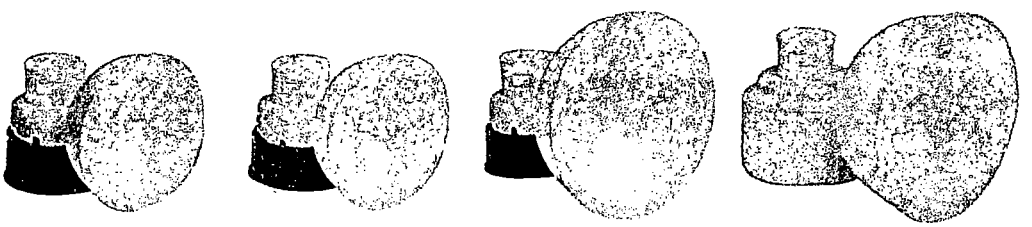


Description of Each Component of the PhaSeal System

- **PhaSeal Protector:**

The Protector is a drug vial adapter that is fitted to the drug vial and seals against the closure of the vial - see Picture 2. The Protector is used as a docking station between the drug vial and the Injector for injection of diluents into the drug vial and/or extraction of liquid drug from the vial. In addition the Protector equilibrates the pressure difference which occurs when fluid or air is added or removed to/from the drug vial. The Protector is provided in four different sizes which are intended to be compatible with various sizes of drug vials ranging from necks from Ø13mm to Ø28mm.

Picture 2: *PhaSeal Protector*

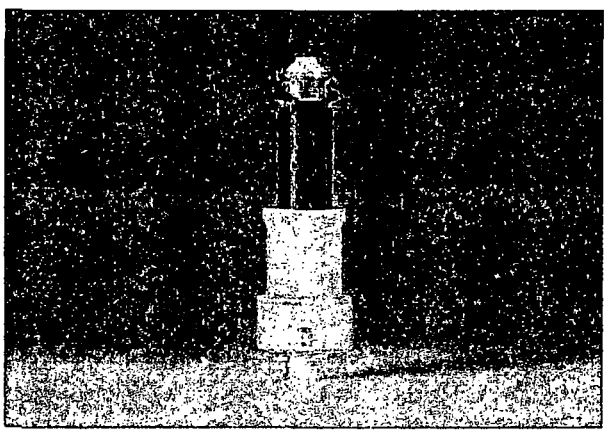


- **PhaSeal Injector:**

The Injector is designed with a single lumen cannula that is encapsulated in a plastic chamber- see Picture 3. One end of Injector locks onto an external device (i.e. syringe) equipped with Luer or Luer Lock fitting. The other end of Injector is sealed with a thermoplastic elastomeric membrane. The elastomeric membrane mates with the "docking station" of the PhaSeal Protector or PhaSeal Connector component equipped with the corresponding "docking station" (i.e. bayonet fitting). The bayonet fitting allows the two elastomeric membranes to be pressed together and a sealed transfer of drug to/from the Protector or to the Connector can be made.

The Injector has a safety feature that must be released to allow the cannula to penetrate the elastomeric membranes and the drug vial stopper. The safety feature is disengaged and re-engaged via the decisive push-turn-push ErgoMotion™ which is described in the BD PhaSeal Instructions for Use. While engaged, the cannula will remain in the safety sleeve – the blue color portion of the Injector. Once attached to a Protector or Connector, the Injector cannot be separated from the bayonet fitting until the needle has been fully retracted into the sealed chamber and the safety feature is re-engaged to ensure the cannula is in the sealed chamber. Thereafter the bayonet fitting can be opened and the Injector is released from the "docking station".

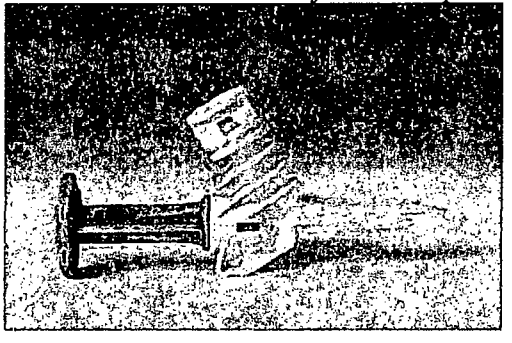
Picture 3: PhaSeal Injector



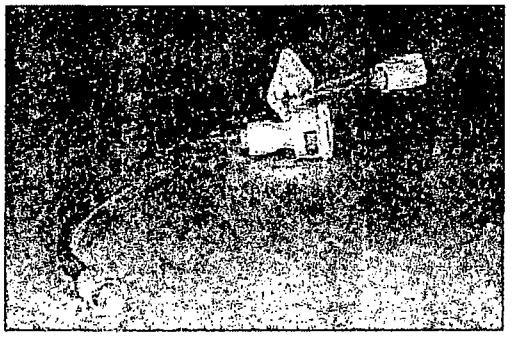
- **PhaSeal Connector:**

The Connector is the interface for patient administration of the drug – see pictures 4-7. The bayonet fitting of the Connector mates with the Injector. The elastomeric membranes of the Connector and the Injector press together to create a seal that enables closed transfer of drug to the patient IV line or into an IV bag. After the drug transfer, the Injector cannula is pulled back via the decisive push-turn-push ErgoMotion™ into the safety sleeve and the Injector can be separated from the Connector. Connectors are provided with a variety of device mating features including a luer fitting, an IV spike (infusion adaptor), secondary set or Y-site connector

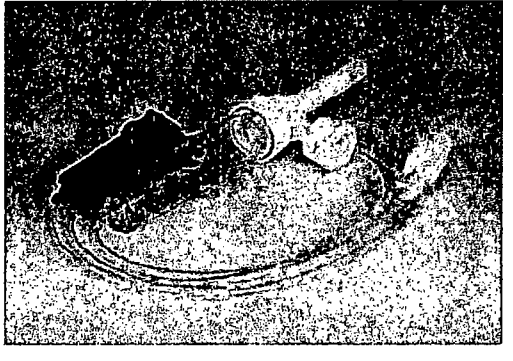
Picture 4: Connector – Infusion Adaptor



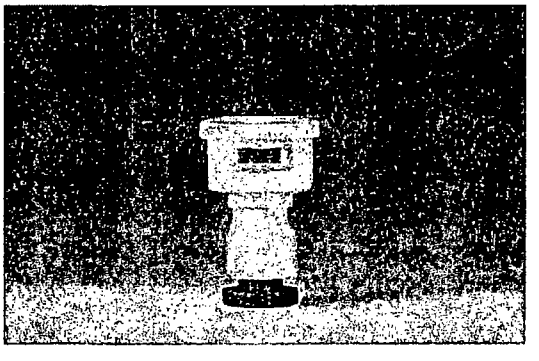
Picture 5: Connector – Y-Site



Picture 6: Connector - Secondary Set



Picture 7: Connector – Luer Lock



A. Summary of Performance Testing

In Appendix III, please find two peer-reviewed publications as well as two Microbial Ingress studies (per FDA guidance) to support the airtight, leak proof and contaminate free requirements that are essential to ensuring healthcare worker safety when preparing and administering hazardous drugs.

1. Spivey S, Connor T. "Determining sources of workplace contamination with antineoplastic drugs and comparing conventional IV drug preparation with a closed system." *Hosp Pharm.* 2003; 38(2): 135-139.
2. Jorgenson J, Spivey S, Au C et al. "Contamination comparison of transfer devices intended for handling hazardous drugs." *Hosp Pharm.* 2008; 43(9): 723-727

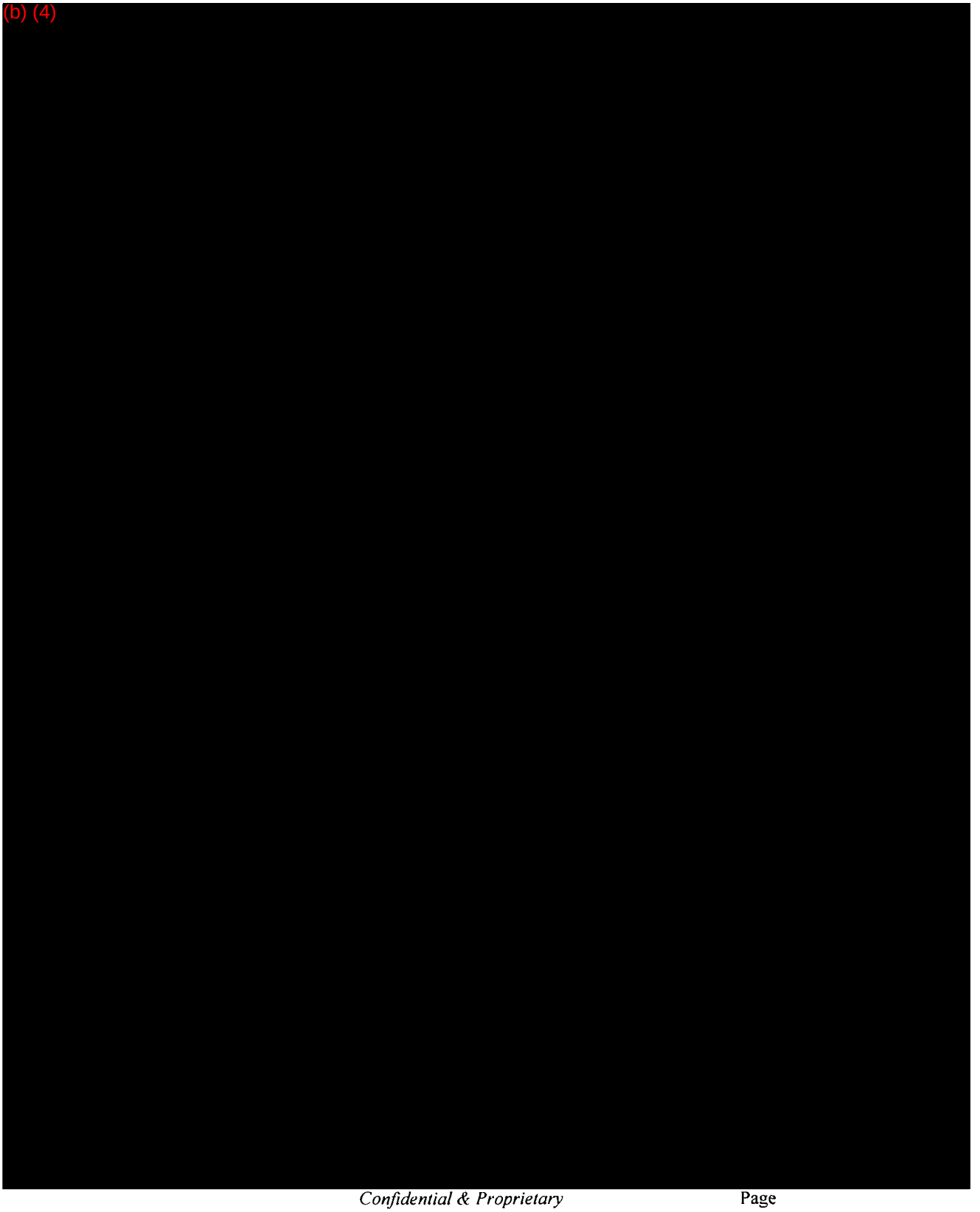
(b) (4)

(b) (4)

(b) (4)

[redacted]

(b) (4)



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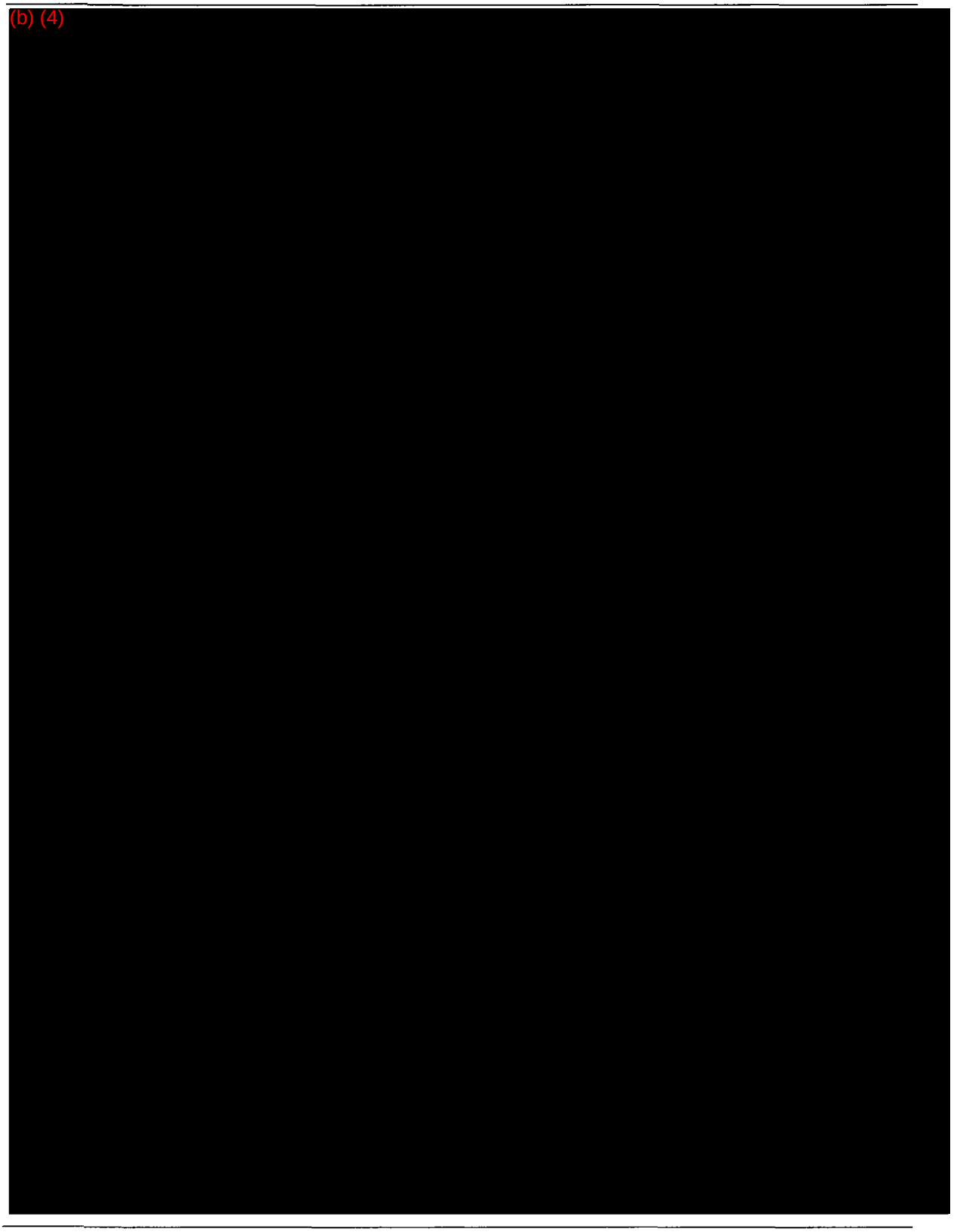

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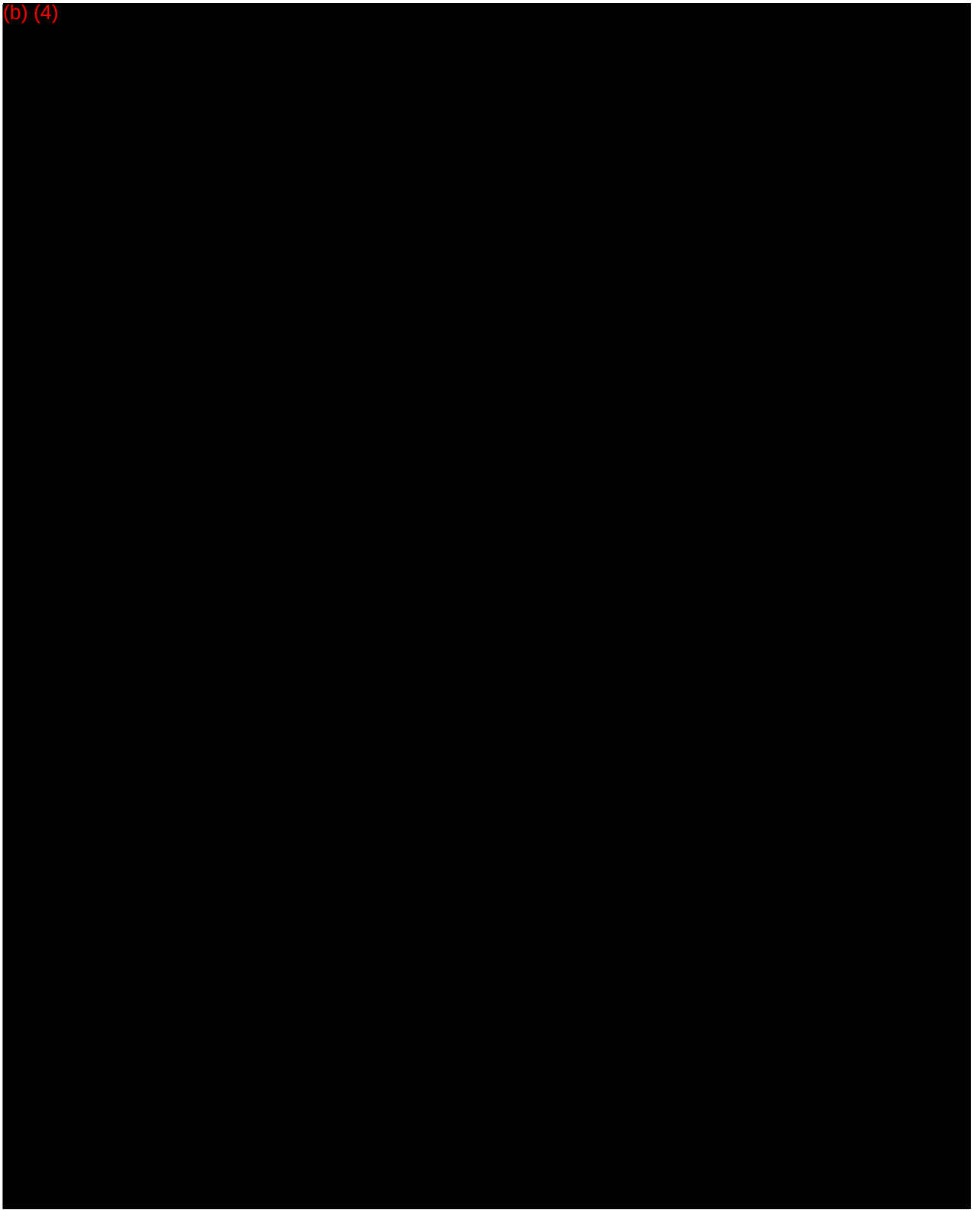

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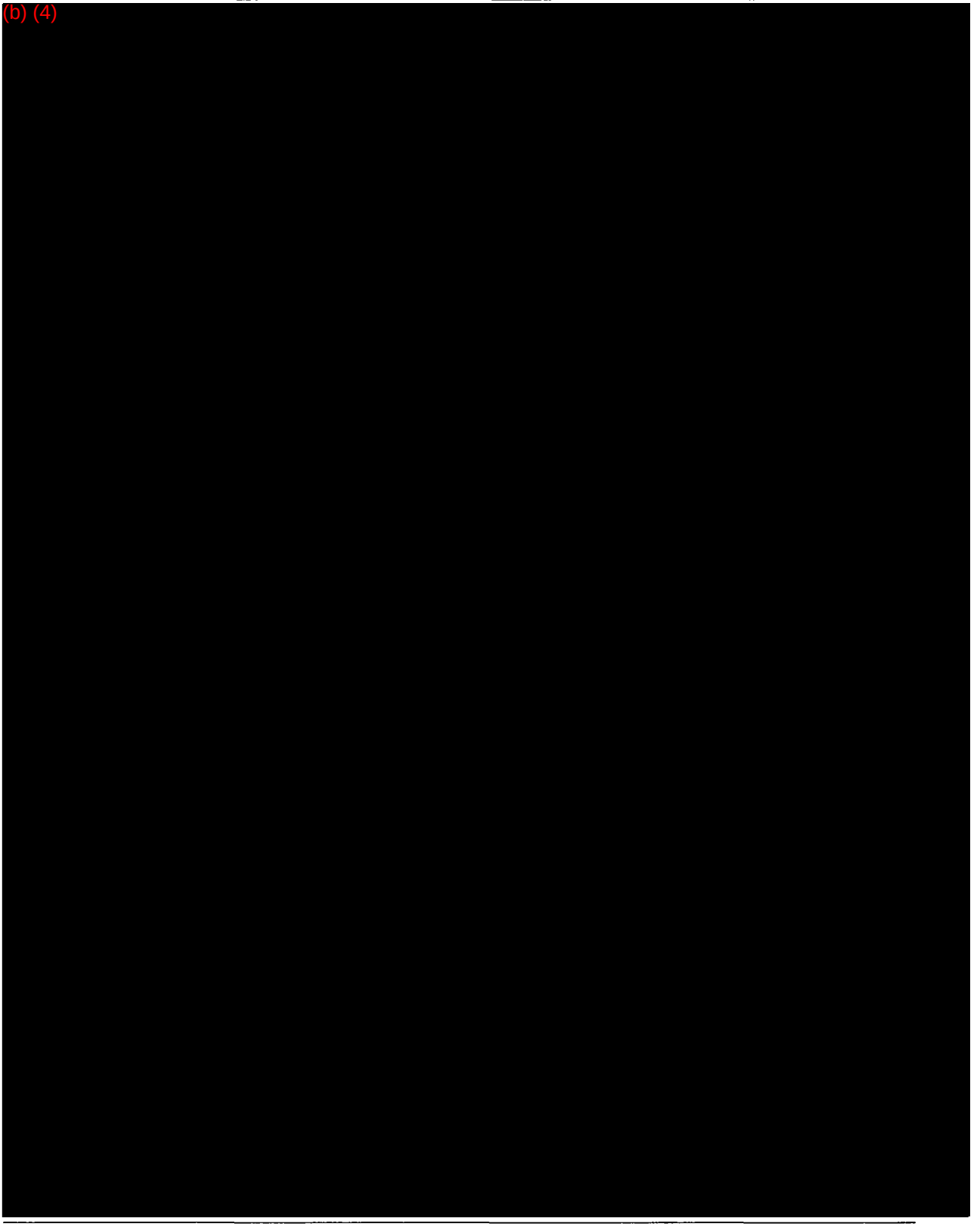

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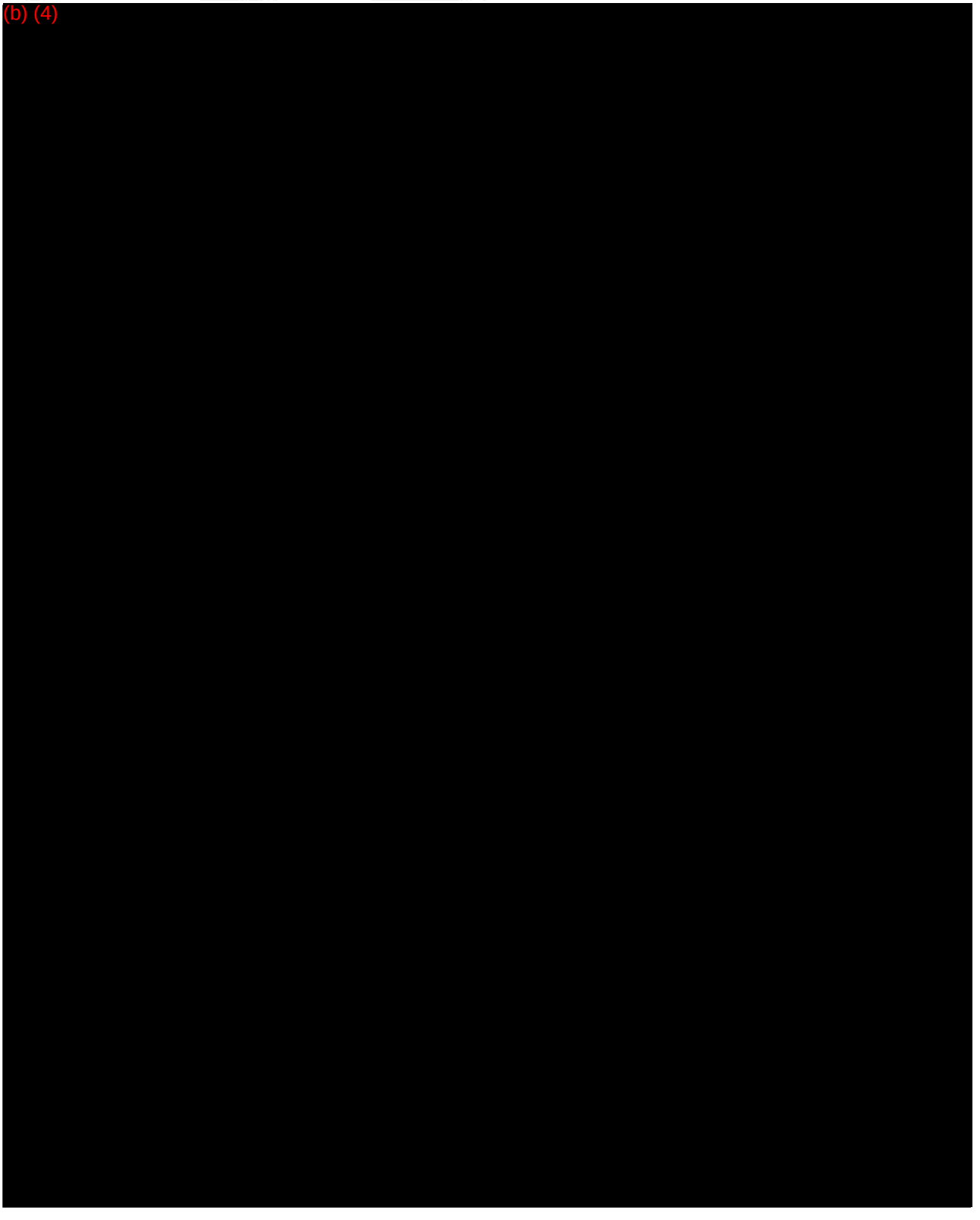

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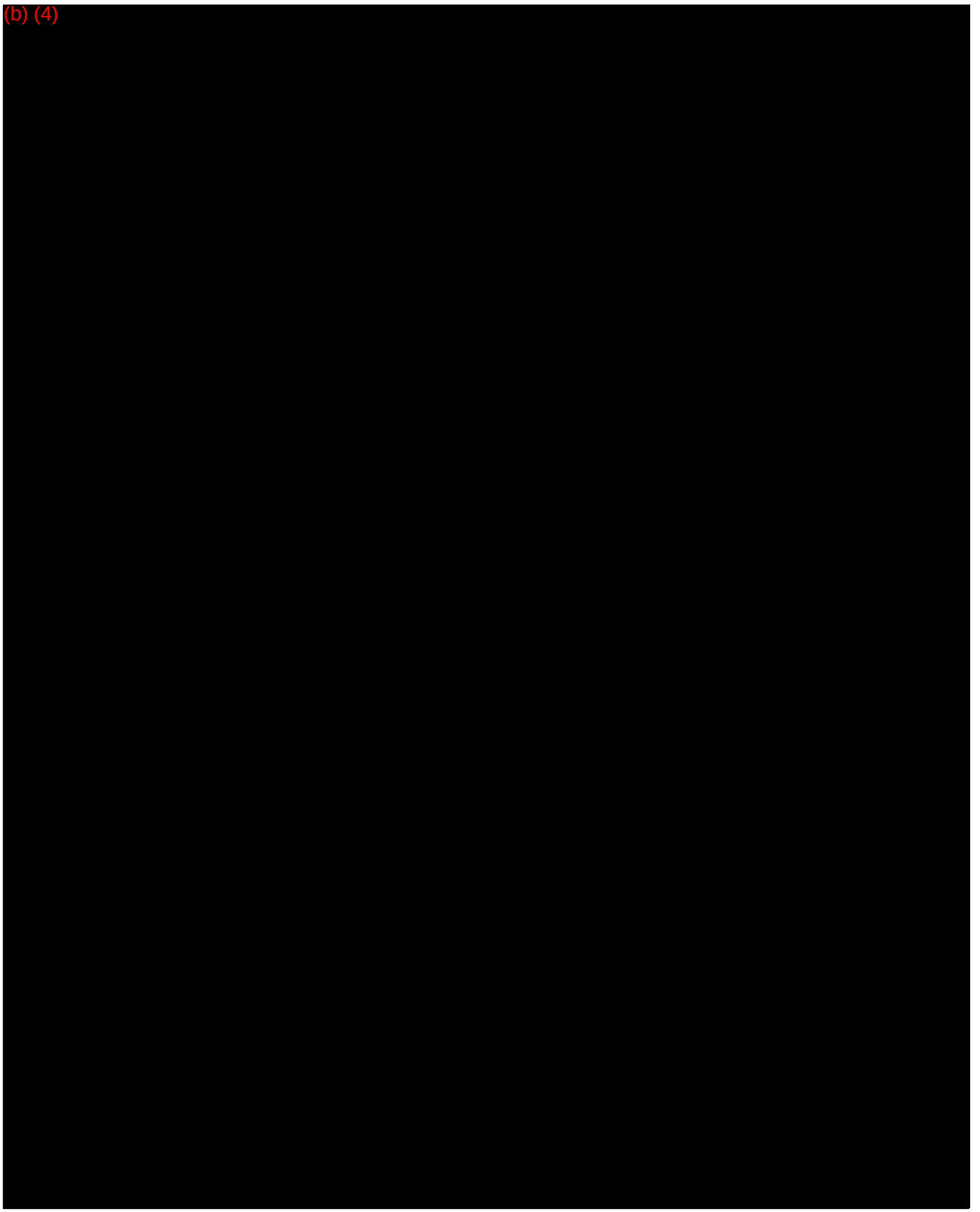

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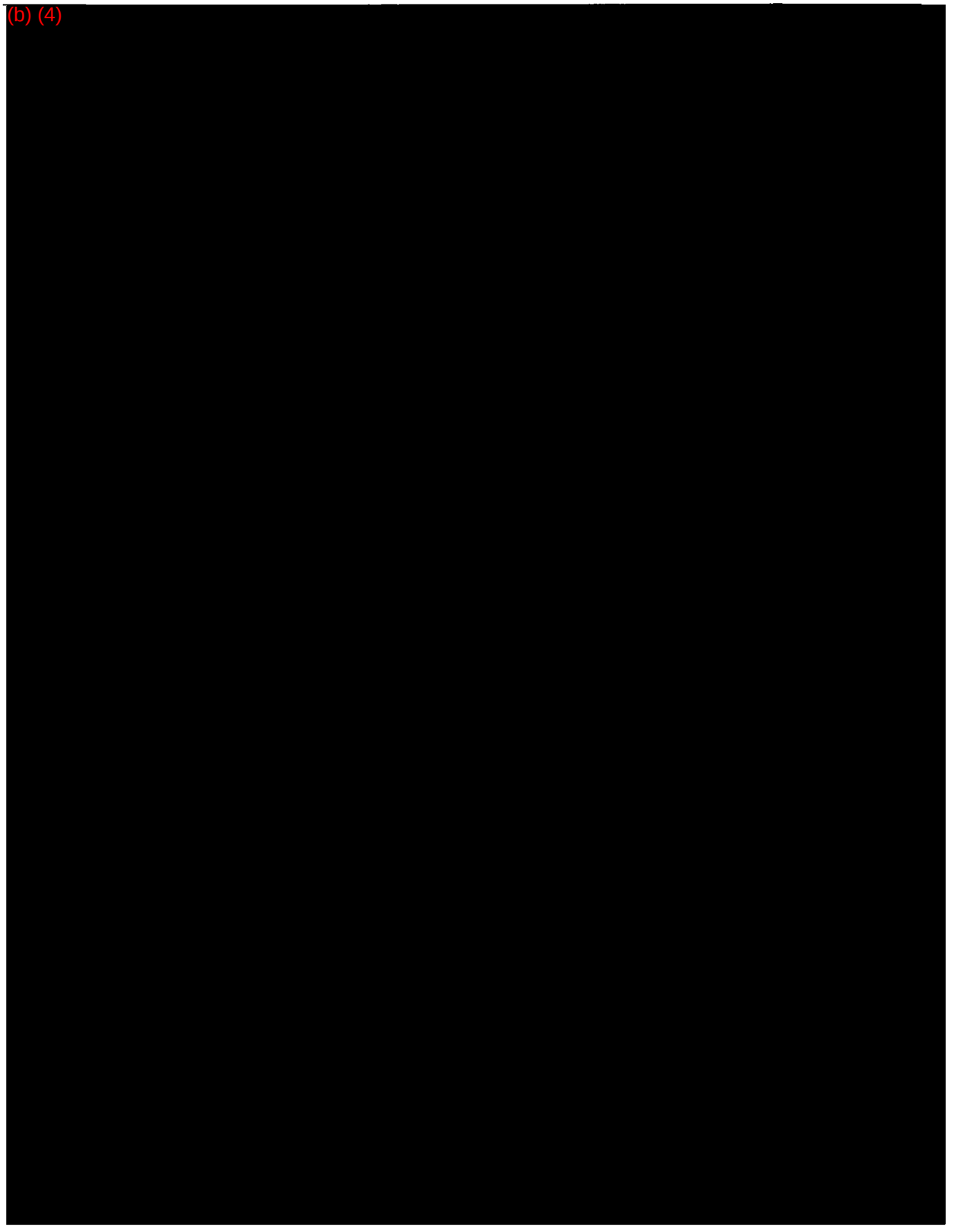


X. DEVICE DESCRIPTION

This section is not applicable, as change described in this 510(k0 relates only to the Reclassification of BD Phaseal to product code ONB, and the revision to the indications for use statement to better reflect the new product code. No other change has been made. The performance specifications, device design, models, accessories and components are identical to the predicate device

XI SUBSTANTIAL EQUIVALENCE RATIONALE

Characteristic	Subject Device: BD PhaSeal	Predicate Device: BD PhasSeal	Equivalence
Indications for Use	The PhaSeal system is an airtight and leak-proof closed system drug transfer device (CSTD) that mechanically prohibits the transfer of environmental contaminants into the system and the escape of drug or vapor concentrations outside the system, thereby minimizing individual and environmental exposure to drug vapor, aerosols and spills. The PhaSeal system also prevents microbial ingress	The PhaSeal system is a closed system drug transfer device (CSTD) that mechanically prohibits the transfer of environmental contaminants into the system and the escape of drug or vapor concentrations outside the system, thereby minimizing individual and environmental exposure to drug vapor, aerosols and spills. The PhaSeal Protector also prevents microbial ingress	Equivalent to Predicate
Description	Closed System Drug Transfer Device	Closed System Drug Transfer Device	Identical to Predicate
Transfer Mechanism	Elastomeric Double Membrane	Elastomeric Double Membrane	Identical to Predicate
Connection between PhaSeal Components	Bayonet Fitting with Elastomeric Double Membrane	Bayonet Fitting with Elastomeric Double Membrane	Identical to Predicate
Components	Protector, Injector, Connector	Protector, Injector, Connector	Identical to Predicate
Protector Spike	Stainless Steel or Plastic	Stainless Steel or Plastic	Identical to Predicate
Injector Cannula	Stainless Steel	Stainless Steel	Identical to Predicate
Fitting Connection to external standard syringe	Injector: Luer / Luer Lock Connection	Injector: Luer / Luer Lock Connection	Identical to Predicate
Fitting Connection to external standard IV line	Luer Lock or Spike Port	Luer Lock or Spike Port	Identical to Predicate
Fitting Connection to external standard IV bag	Spike	Spike	Identical to Predicate
Needle Safety Feature (Injector Only)	Safety sleeve - ErgoMotion™	Safety sleeve - ErgoMotion™	Identical to Predicate
Sterilization Method	EO	EO	Identical to Predicate

XII. Proposed Labeling

The following labeling has been provided as a representative sample of the BD PhaSeal Closed System Transfer Device labeling and instructions for use.

BD PhaSeal Connector

Proposed Labeled	Representative Sample	Page
Unit Label	C35 Labeling Provided	42
Shelf Label		43
Case Label		44
IFU		44

BD PhaSeal Injector

Proposed Labeled	Representative Sample	Page
Unit Label	N35 Labeling Provided	45
Shelf Label		46
Case Label		47
IFU		47

BD PhaSeal Protector

Proposed Labeled	Representative Sample	Page
Unit Label	P21 Labeling Provided	48
Shelf Label		49
Case Label		50
IFU		50

(b) (4)

VENDOR NOTES

EXPIRATION DATE,
MANUFACTURING DATE AND
LOT NUMBER AS SHOWN

The attached graphics have been set up in a non variable and variable format as depicted. The printing supplier and final manufacturing printer may print all or any portion of the graphic as long as the complete graphic is in place at the completion of production.
The following scenarios currently exist and are acceptable:
1. Outside printer to print entire label (variable and non variable).
2. Outside printer to print non variable and the Mfg site to print the balance.
3. Outside printer to print a given portion of the graphic and the Mfg site to print the balance.
4. Mfg site to print the entire label (variable and non variable).

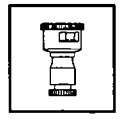
[redacted]
Process Black

(b) (4)

(b) (4)

BD PhaSeal™
Connector Luer Lock (C35)

50



REF 515200

LOT

QTY: 50

STERILE EO Rx Only CE 0413

Becton, Dickinson and Company Limited,
Pottery Road, Dun Laoghaire,
Co. Dublin, Ireland.
Made in Spain www.bd.com

DGL248301

VENDOR INFO

HOLDING LINES... DO NOT PRINT

PRINT BARCODE AS SHOWN

BD PhaSeal™
Connector Luer Lock (C35)

50

(17)123456(10)1234567(30)50

(01)50382905152001

REF 515200

LOT 1234567

20XX-XX

QTY: 50

STERILE EO Rx Only CE 0413

Becton, Dickinson and Company Limited,
Pottery Road, Dun Laoghaire,
Co. Dublin, Ireland.
Made in Spain www.bd.com

DGL248301

PRINT EXPIRATION DATE, MANUFACTURING DATE AND LOT NUMBER AS SHOWN

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2. *Outside printer to print non variable and the Mfg site to print the balance.*
3. *Outside printer to print a given portion of the graphic and the Mfg site to print the balance.*
4. *Mfg site to print the entire label (variable and non variable).*

[redacted]
Process Black

(b) (4)

(b) (4)

BD PhaSeal™
Connector Luer Lock (C35)

200

REF 515200

LOT

QTY: 200

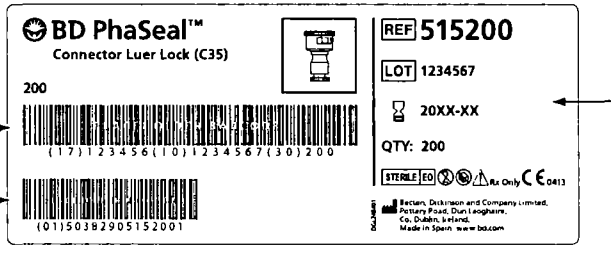
STERILE EO Rx Only CE 0413

Becton, Dickinson and Company Limited,
Pottery Road, Dun Laoghaire,
Co. Dublin, Ireland.
Made in Spain www.bd.com

DGL248401

VENDOR INFO

HOLDING LINES .. DO NOT PRINT



PRINT BARCODE AS SHOWN

PRINT EXPIRATION DATE, MANUFACTURING DATE AND LOT NUMBER AS SHOWN

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3. *Outside printer to print a given portion of the graphic and the Mfg site to print the balance.*
4. *Mfg site to print the entire label (variable and non variable).*

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Process Black

(b) (4)

(b) (4)

[redacted]

BD PhaSeal™
Injector Luer Lock
(N35)
REF 515003
LOT
STERILE EO
Rx Only CE 0413
Becton, Dickinson and
Company Limited,
Pottery Road,
Dun Laoghaire,
Co. Dublin, Ireland.
www.bd.com
DGW1132902

VENDOR NOTES

BD PhaSeal™
Injector Luer
Lock (N35)
REF 515003
LOT 1234567
20XX-XX
STERILE EO
Rx Only CE 0413
Becton, Dickinson and
Company Limited,
Pottery Road,
Dun Laoghaire,
Co. Dublin, Ireland.
www.bd.com
DGW1132902

EXPIRATION DATE,
MANUFACTURING DATE AND
LOT NUMBER AS SHOWN

The attached graphics have been set up in a
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4. Mfg site to print the entire label (variable and non variable).

[redacted]
Process Black

(b) (4)

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(b) (4)

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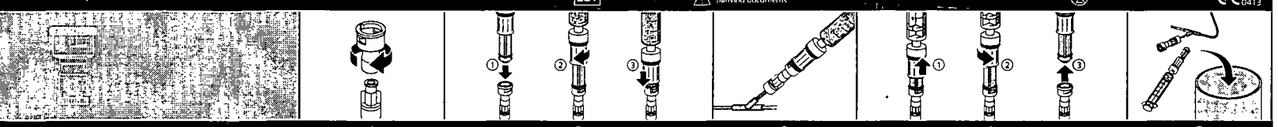
BD PhaSeal™

Manufacturer
Becton, Dickinson and Company Limited, Pottery Road, Dun Laoghaire, Co. Dublin, Ireland, www.bd.com

Connector Luer Lock (C35) | REF 515200

REF Catalogue number · LOT Batch code · Use by · Caution, consult accompanying documents · STERILE EO Sterilized using ethylene oxide · Do not use if package is damaged · Do not reuse · CE 0413

Material
PP
TPE



LANGUAGES	1	2	3	4	5
EN English – Instructions for use BD PhaSeal™ is a closed system for drug transfer from vial to patient. Needle-free closed Luer Lock connector intended for closed preparation and administration of drugs. To be connected to patient's IV-line. Compatible with drugs that are not contraindicated for polypropylene (PP). Use required and accepted IV practice. Sterile (ethylene oxide). Sterile unless package is damaged. Do not reuse to avoid contamination. Rx Only Precautions: Do not use if protective cass are loose or dislodged. Always grip white components when using the BD PhaSeal™ system. Do not grip blue part of the Injector. Do not use BD PhaSeal™ Connector Luer Lock (C35) as protection cap during transport or storage. The performance of the sealing membrane is reduced after multiple perforations and extended activation time.	Remove the grey protection cap from Connector. Attach the Connector to the patient's luer lock IV port or point of access.	① PUSH. Push the Injector into the connection interface. ② TURN. Hold onto the grip and turn. ③ PUSH. Push down to engage.	Perform drug transfer.	① PULL. Pull the Injector back. ② TURN. Hold onto the grip and turn. ③ PULL. Pull the Injector to separate from the connection interface.	Dispose without disconnecting the BD PhaSeal™ components.
CS Čeština – Návod k použití BD PhaSeal™ je uzavřený systém pro přenos léku z lékovky do pacienta. Uzavřený konektor Luer Lock bez jehly určený k uzavřené přípravě a podávání léků. Pro připojení na intravenózní linku pacienta, kompatibilní s léčivy která nejsou kontraindikována pro polypropylen (PP). Použijte požadovanou a uznávanou infuzní techniku. Sterilní (ethylenoxid). Sterilní, pokud není poškozen obal. Nepoužívejte znovu kvůli riziku kontaminace. Upozornění: Nepoužívejte pokud jsou ochranné kryty uvolněné nebo chybí. Při použití drže systém BD PhaSeal™ v bílé části. Nedržte modrý díl injektoru. Nepoužívejte konektor BD PhaSeal™ Luer Lock (C35) jako ochranný kryt během transportu nebo skladování. Po mnoha perforacích a delší době aktivace se výkonnost těsnicí membrány snižuje.	Sejměte ochranný šedý ochranný kryt. Připojte konektor k žilnímu katétru pacienta nebo místu přístupu	① ZATLAČIT. Zatlačte injektor do připojovacího rozhraní ② OTOČIT Uchopte držadlo a otočte. ③ ZATLAČIT. Zatlačením systém aktivujte.	Proveďte přenos léku.	① VYTÁHNOUT. Vytáhněte injektor ② OTOČIT. Uchopte držadlo a otočte. ③ VYTÁHNOUT. Vytáhněte injektor a odpojte ho od připojovacího rozhraní.	Likvidujte jednotlivě: aniž byste od sebe odpojili části systému BD PhaSeal™.
DA Dansk – Brugsanvisning BD PhaSeal™ er et lukket system for overførsel af lægemidler fra hætteglas til patient. Nålefri lukket Luer Lock Connector er beregnet til lukket forbered og administration af lægemidler. For tilslutning af patient-infusionsslange. Kompatibel med lægemidler, der ikke er kontraindiceret for polypropylen (PP). Anvend påkrævet og accepteret IV praksis. Steril (ethylen oxid). Steril hvis emballagen ikke er beskadiget. Må ikke genanvendes for at undgå kontaminations. Forbeholdsregler: Må ikke anvendes, hvis beskyttelsesholderne er løse eller helt fjernet. Tag altid fat i hvide komponenter ved brug af BD PhaSeal™-systemet. Tag ikke fat i blå del af Injector. Brug ikke BD PhaSeal™ Connector Luer Lock (C35) som beskyttelseshætte under transport eller opbevaring. Tætningsmembranens virkning reduceres efter adskillige perforeringer og længere aktiveringstid.	Fjern den grå beskyttelseshætte fra Connector. Tilslut Connector til patientens IV Luer Lock tilslutning eller anden tilslutning	① TRYK. Tryk Injector ind i fortandelsesfladeforen ② DREJ. Hold fast i greb og drej. ③ TRYK. Tryk nedad for at aktivere.	Udfør overførslen af lægemidlet.	① TRÆK. Træk Injector tilbage ② DREJ. Hold fast i greebet og drej. ③ TRÆK. Træk i Injector for at fjerne den fra forbindelsesfladeforen.	Bortskaffes uden at skille BD PhaSeal™-komponenterne fra hinanden.
DE Deutsch – Gebrauchsanweisung BD PhaSeal™ ist ein geschlossenes System für den Medikamententransfer von der Flasche zum Patienten. Nadelfreier geschlossener Luer Lock Connector für die gen. Nässene Zubereitung und Verabreichung von Arzneimitteln. Wird an das intravenose Infusionssystem des Patienten angeschlossen. Kompatibel mit allen Arzneimitteln auf die keine Kontraindikation für Polypropylen (PP) zutrifft. Verenden Sie die entsprechenden und anerkannten IV-Verfahren an. Steril (Ethylenoxid). Steril bei unbeschädigter Verpackung Zur Vermeidung von Kontaminationen nicht wiederverwenden. Sicherheitshinweise: Nicht verwenden, wenn die Schutzklappen lose oder entfernt sind. Bitte immer die weißen Bereiche anfassen, wenn Sie mit dem BD PhaSeal™ System arbeiten. Der blaue Teil des Injectors darf nicht benutzt werden. Verwenden Sie den BD PhaSeal™ Connector Luer Lock (C35) beim Transport oder während der Lagerung nicht als Schutzkappe. Die Leistung der Dichtmembran verringert sich nach mehrmaliger Perforation und längerer Aktivierungsdauer.	Nehmen Sie die graue Schutzkappe vom Connector ab. Befestigen Sie den Connector am Luer Lock des IV-Zugangs oder Zugangspunkt des Patienten	① DRÜCKEN. Drücken Sie den Injector in die Verbindungsschnittstelle. ② DREHEN. Halten Sie den Griff und drehen Sie. ③ DRÜCKEN. Drücken Sie zum Einrasten nach unten	Führen Sie den Medikamententransfer aus	① ZIEHEN. Ziehen Sie den Injector zurück. ② DREHEN. Halten Sie den Griff und drehen Sie. ③ ZIEHEN. Ziehen Sie den Injector aus der Verbindungsschnittstelle.	Entsorgen Sie das System, ohne die BD PhaSeal™-Komponenten voneinander zu trennen.
EL Ελληνικά – Οδηγίες χρήσης Το BD PhaSeal™ είναι ένα κλειστό σύστημα για μεταφορά φαρμάκων από το φιαλίδιο στον ασθενή. Το κλειστό συνδετικό Luer Lock χωρίς βελόνα προορίζεται για κλειστή προετοιμασία και χορήγηση φαρμάκων. Για σύνδεση σε ενδοφλέβιες (IV) γραμμές ασθενών. Συμβατό με φάρμακα που δεν αντενδείκνυνται για το πολυπροπυλένιο (PP). Χρησιμοποιήστε την απαιτούμενη και αποδεκτή πρακτική ενδοφλέβιας έγχυσης (IV). Αποστειρωμένο (με αιθυλενοξείδιο). Αποστειρωμένο εφόσον η συσκευασία δεν έχει υποστεί ζημιά. Να μην επαναχρησιμοποιείται προς αποφυγή μολυσματος. Προειδοποίηση: Μη χρήση εφόσον τα προστατευτικά παρεμβύσματα έχουν χαλαρώσει ή έχουν μετατοπιστεί. Κρατάτε πάντοτε στα λευκά εξαρτήματα όταν χρησιμοποιείτε το σωστημα BD PhaSeal™. Μην κρατάτε το εξάρτημα Injector από το μπλε τμήμα. Μην χρησιμοποιείτε το συνδετικό Luer Lock (C35) της BD PhaSeal™ ως προστατευτικό πώμα κατά τη μεταφορά ή αποθήκευση. Η απόδοση της μεμβράνης σφράγισης μειώνεται μετά από πολλαπλές διατρήσεις και παρατεταμένο χρόνο ενεργοποίησης.	Αφαιρέστε το γκρι προστατευτικό πώμα από τον Συνδετήρα. Συνδέστε τον Συνδετήρα στην θύρα IV ή τον σημείο πρόσβασης.	① ΩΘΗΣΤΕ. Ωθήστε το εξάρτημα Injector στο μέσο συνδεσης. ② ΣΤΡΕΨΤΕ. Κρατήστε τη λαβή και στρέψτε. ③ ΩΘΗΣΤΕ. Πιέστε προς τα κάτω για να ασφαλίσει.	Εκτελέστε την μεταφορά του φαρμάκου.	① ΤΡΑΒΗΣΤΕ. Τραβήξτε προς τα πίσω το εξάρτημα Injector. ② ΣΤΡΕΨΤΕ. Κρατήστε τη λαβή και στρέψτε. ③ ΤΡΑΒΗΣΤΕ. Τραβήξτε το εξάρτημα Injector για να διαχωρισετε από το μέσο συνδεσης.	Απορρίπτετε χωρίς να αποσυνδέσετε τα μέρη του συστήματος BD PhaSeal™.
ES Español – Instrucciones de uso BD PhaSeal™ es un sistema cerrado para la transferencia de medicamentos del vial al paciente. Conector Luer Lock cerrado sin aguja destinado a la preparación y administración cerrada de medicamentos. Para conectar a la línea intravenosa del paciente. Compatible con medicamentos que no estan contraindicados para el uso con polipropileno (PP). Siga el procedimiento intravenoso requerido y aceptado. Estéril (óxido de etileno). Estéril salvo que el envase este dañado. No reciclar para evitar la contaminación. Atención: No utilizar si los capuchones de los protectores estan sueltos o desplazados. Sostenga el sistema BD PhaSeal™ siempre por los componentes blancos. No sostenga el Injector por la parte azul. No utilice el Conector Luer Lock (C35) de BD PhaSeal™ como tapón de protección durante el transporte o almacenamiento. Tras varias perforaciones y un tiempo de activación prolongado se reduce el rendimiento de la membrana de cierre.	Quite el tapón de protección gris del Conector. Acople el conector al Luer Lock al puerto intravenoso o al punto de acceso del paciente.	① PRESIONE. Presione el Inyector en la interfaz de conexion. ② GIRE. Sostenga el asa y gire. ③ PRESIONE. Presione hacia abajo para acoplar	Realice la transferencia del medicamento	① TIRE. Tire el Inyector hacia atras. ② GIRE. Sostenga el asa y gire. ③ TIRE. Tire el Inyector para separarlo de la interfaz de conexión.	Desechelo sin desconectar los componentes de BD PhaSeal™
ET Eesti – Kasutusjuhend BD PhaSeal™ on suletud süsteem ravimi ülemineku viialist patsiendile. Nõelatsi suletud Luer Lock konnektor on mõeldud suletud ettevalmistamiseks ja manustamiseks. Ühendamiseks patsiendi IV-joonega. Sobib ravimitega, mis ei ole vastunäidustatud polüpropüleenile (PP). Kasutage nõutavat ja heakskiidetud IV-sisestamistava. Steriilne (etüleenoksiid). Steriilne juhul, kui pakend pole rikkumata. Taaskasutamine vältamiseks ärge kasutage uuesti. Ettevaatust: Ärge kasutage, kui kaitsekorgid on lahti või kõrvale läinud. Kui kasutate BD PhaSeal™ süsteemi, hoidke alati kinni valgetest osadest. Ärge hoidke blue'd Injektori osast. Ärge kasutage BD PhaSeal™ Konnektorit Luer Lock (C35) kaitsekorgina transpordi ega ladustamise ajal. Pärast mitmekordset läbistamist ja pikemaajalist kasutusaega väheneb tõkkemembraani efektiivsus.	Eemaldage konnektorilt hall kattekork. Ühendage konnektor patsiendi luer IV pordi luer lock ühendusega või juurdepääsukohaga.	① VAJUTAGE. Vajutage Injektor ühenduse liidesesse ② KEERAKE. Hoidke vastu ja keerake lahast kinni ja keerake. ③ VAJUTAGE. Ühendamiseks vajutage see alla.	Soovitage ravimi ülekanne	① TÕMMAKE. Tõmmake Injektor tagasi. ② KEERAKE. Hoidke vastu ja keerake lahast kinni ja keerake. ③ TÕMMAKE. Ühendilse lahtiseks eemaldamiseks tõmmake Injektorit.	Visake äraMeetle Ärge ärge BD PhaSeal™ üksikuid osi teisest lahti ühendamata.
FI Suomi – Käyttöohjeet BD PhaSeal™ on suljettu järjestelmä lääkeaineiden siirtämiseen lääkepullosta potilaaseen. Neulaton suljettu Luer Lock -yhteyskä lääkeaineiden sekoittelyyn ja lääkkeen suljetussa annostelemissä. Yhdistetään potilaan liikkeeseen. Soveltuu polypropeenille (PP) vasta-aiheisiksi todettujen aineiden sekoittamiseen. Käytettävä asianmukaisia ja hyväksyttyjä IV-käytäntöjen mukaisesti. Steriili (etyleenioksidi). Steriili ellei pakkaus ole rikki. Tuotetta ei saa käyttää uudelleen kontaminaatioriskin vuoksi. Varoitukset: Tuotetta ei saa käyttää, jos suojukset ovat vaan tai pois paikaltaan. Pidä aina kiinni valkoisista osista. Luo käyttäen BD PhaSeal™-järjestelmää. Älä pidä kiinni hevalemuksuksen tehnetä osista. Älä käytä BD PhaSeal™ Luer Lock (C35) -yhteyttä kuljetuksen tai säilytyksen aikana. Kalvosti alkon tiivistetä heikentyy, kun kalvo puhkaistaan useamman kerran ja kun sitä käytetään pitkäitty.	Poista harmaa suojakorkki Connector-liitännästä. Liitä Yhdistetä potilaan Luer Lock IV -liitäntään tai muuhun liitäntään.	① PAINA. Paina Neulattomuuden Yhdistäjään ② KÄÄNNÄ. Pidä kiinni valkoisesta osasta ja käännä. ③ PAINA. Liitä painamalla tiiviisti alaspäin.	Annostele lääke.	① VEDÄ. Vedä Neulattomuuden-irrotin ulospäin. ② KÄÄNNÄ. Pidä kiinni valkoisesta osasta ja käännä ③ VEDÄ. Irroita Neulattomuus-liitin Yhdistäjä-liitännästä vetämällä.	Hävitä kattavasti erottamatta BD PhaSeal™-järjestelmän osia lääkkeenmukaisella tai ruiskuista
FR Français – Mode d'emploi BD PhaSeal™ est un système clos pour le transfert de médicament du flacon au patient. Connecteur clos sans aiguille Luer Lock pour préparation et administration de médicaments en système clos. Se connecte à la ligne IV du patient. Compatible avec les médicaments qui ne sont pas contre-indiqués pour le polypropylène (PP). Utiliser les methodes IV requises et acceptées. Stérile à l'oxyde d'éthylène. Stérile sauf si le conditionnement est endommagé. Ne pas réutiliser pour éviter la contamination. Précautions : Ne pas utiliser si les capuchons de protection sont desserrés ou déplacés. Saisissez toujours les composants blancs lorsque vous utilisez le système BD PhaSeal™. Ne saisissez pas la partie bleue de l'injecteur. Ne pas utiliser le connecteur Luer Lock BD PhaSeal™ (C35) comme capuchon pendant le transport ou l'entreposage. La performance de la membrane est réduite après perforations multiples et une durée d'activation prolongée.	Enlevez le capuchon de protection gris du connecteur. Raccordez le connecteur au point d'accès Luer Lock	① POUSSEZ. Poussez l'injecteur dans l'interface de connexion. ② TOURNEZ. Maintenez la prise et tournez. ③ POUSSEZ. Poussez pour engager l'injecteur.	Effectuez le transfert du médicament.	① TIREZ. Retirez l'injecteur. ② TOURNEZ. Maintenez la prise et tournez. ③ TIREZ. Déconnectez l'injecteur pour le détacher de l'interface de connexion.	Eliminez sans déconnecter les composants BD PhaSeal™.
HE עברית – הוראות שימוש BD PhaSeal™ היא מערכת סגורה להעברת התרופה מהבקבוקון אל המטופל. מחבר Luer Lock סגור ללא מחט המיועד להכנה סגורה ומתן תרופות. לחיבור אל קווי עירוי תוך ורידי של המטופל. תואם לתרופות שאין להן התוויה נגד לפוליפרופילן (PP). יש לנקוט בכל שיטות העירוי התוך ורידי הנדרשות והמקובלות. סטרילי (תחמוצת אתילן). השתמש בשקית סטרילית אחת בלבד. אין להשתמש בה שוב כדי למנוע זיהום. אין להשתמש אם שקית האריזה ניזוקה. אין להשתמש אם מכסי המגן רופפים או חסרים. אחוז ההצלחה של ערבוב התרופות יורד לאחר מספר חדירות ומשך הפעלה ארוך. אין לתפוס את החלק הכחול של מזרק ההזרקה. אין להשתמש במחבר Luer Lock (C35) של BD PhaSeal™ כמכסה מגן במהלך הובלה או אחסון. ביצועי ממברנת האיטום יורדים לאחר מספר חדירות ומשך הפעלה ארוך.	הסר את מכסה המגן האפור ממחבר Luer Lock. חבר את המחבר אל אתר הזריקה או אל נקודת הגישה של המטופל.	① דחיפה: דחוף את מזרק ההזרקה (המזרק) אל תוך ממשק החיבור. ② סיבוב: תפוס במזרק וסובב. ③ דחיפה: דחוף כלפי מטה לחיבור.	בצע העברת של התרופה.	① משיכה: משוך את מזרק ההזרקה לאחור. ② סיבוב: תפוס במזרק וסובב. ③ משיכה: משוך את מזרק ההזרקה כדי להסיר את ממשק החיבור.	השלך את מערכת BD PhaSeal™ כמו לתוכן את הרכיבים זה מזה.
HR Hrvatski – Uputa za uporabu BD PhaSeal™ je zatvoreni sistem za prijenos lijeka iz bočice do bolesnika. Zatvoreni Luer Lock konektor bez igle je namijenjen za pripremu i primjenu lijekova u zatvorenom sustavu. Za spajanje na intravensku liniju bolesnika. Kompatibilno s lijekovima koji nisu kontraindicirani s polipropilenom (PP). Koristite potrebnu i prihvaćenu intravensku primjenu. Sterilno (etilenoksid). Sterilno je sve dok je pakiranje neoštećeno. Ne koristite ga ponovno kako biste izbjegli kontaminaciju. Mjere opreza: Ne koristite ga ako su zaštitne kapice labave ili uklonjene. Kad koristite BD PhaSeal™ sistem, uvijek prihvati za bijele dijelove sistema. Ne prihvati ni plavi dio injektora. Ne koristite BD PhaSeal™ konektor Luer Lock (C35) kao zaštitnu kapicu tijekom transporta ili skladištenja. Kvalitet brtvilnog membrane će smanjiti se nakon višestrukih perforacija i produljenog vremena aktiviranja.	Uklonite sivi zaštitni poklopac sa vrszrog dijela. Priključite konektor na luer stranu intravenskog ili prikljućka bolesnika ili na mjesto pristupa.	① GURNITE. Gurnite injektor u spojnu površinu. ② OKRENITE. Držite za držaj i okrenite. ③ GURNITE. Gurnite prema dolje dok se ne spoji.	Primjenite lijek.	① POVUCITE. Povucite injektor unatrag. ② OKRENITE. Držite za držaj i okrenite. ③ POVUCITE. Povucite injektor kako biste ga odvojili od sučelja površine.	Bacite cijelo bez rastavljanja komponenti BD PhaSeal™-a.
HU Magyar – Használati útmutató A BD PhaSeal™ zárt rendszerű gyógyszertranszferi biztosít az ampulla fejétől a betegig való beadásig. A tu nélkül, zárt Luer Lock csatlakozó cége a gyógyszerek zárt előkészítése és beadása. A beteg intravénás infúziós (kezelésének való csatlakoztatásra szolgál. Olyan gyógyszerrel el használható, melyet ne nem áll fenn polipropilénnel (PP) szemben adott ellenjavallat. Az előírt és elfogadott IV gyakorlatot alkalmazza. Steril (etilén-oxid). Sértetlen csomagolás esetén steril. Ne használja ujra a fertőzésveszély megelőzése érdekében. Vigyázat: Ne használja ha a védősapkák laza vagy hiányzik. A BD PhaSeal™ rendszer használata során mindig a fehér részek el tegye meg. Ne fogja meg az injektor kék részét. Szállítás vagy tárolás során ne használja a BD PhaSeal™ Connector Luer Lock (C35)-ot védőkupakként. Több perforáció és hosszú aktiválási idő után csökken a lezáró membrán tömítőképessége.	Távolítsa el a Connectorról a szürke védőkupakot. Csatlakoztassa a Connectort a páciens i.v. szerelékének Luer kapcsa végéhez.	① TOLJA. Tolja be az Injectort a csatlakozási felületbe. ② FORDÍTSA EL. Fogja meg a markolatot, és fordítsa el ③ TOLJA BE. Nyomja le a rögzítéshez.	Végezze el a gyógyszerbeadást.	① HÚZZA KI. Húzza vissza az Injectort. ② FORDÍTSA EL. Fogja meg a markolatot, és fordítsa el ③ HÚZZA KI. Húzza ki az Injectort a csatlakozófelületről történő eltávolításhoz elvégzett elvégzett.	A BD PhaSeal™ komponensek leválasztása nélkül dobja ki.

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DGP11701. PSA725

VENDOR NOTES

All text and graphics print process black

[redacted]
Process Black

(b) (4)

[redacted]

Status: Draft

(b) (4)

BD PhaSeal™

Manufacturer
Becton, Dickinson and Company Limited, Pottery Road, Dun Laoghaire, Co. Dublin, Ireland. www.bd.com

Connector Luer Lock (C35) | REF 515200

REF Catalogue number
LOT Batch code
Use by
Caution, consult accompanying documents
STERILE EO Sterilized using ethylene oxide
Do not use if package is damaged
Do not reuse
CE 0413

Material
PP
TPE

LANGUAGES	1	2	3	4	5
IT Italiano – Istruzioni per l'uso BD PhaSeal™ è un sistema chiuso per il trasferimento di farmaci dalla fiala al paziente. Connettore stagno senza ago progettato per la preparazione protetta e la somministrazione di farmaci. Da collegare al flessibile IV del paziente. Compatibile con farmaci non contenenti oli e polipropilene (PP). Seguire le procedure necessarie e approvate per la infusione endovenose. Sterile (assente di endotossine). Usa e getta. Non riutilizzare per evitare la contaminazione. Precauzioni: non utilizzare se i cappucci protettivi sono allentati o fuori posto. Alternare sempre i componenti bianchi durante l'uso del sistema BD PhaSeal™. Non afferrare la parte blu dell'iniettore. Non utilizzare BD PhaSeal™ Connector Luer Lock (C35) come tappo protettivo durante il trasporto o l'immagazzinaggio. Dopo ripetute perforazioni, e in seguito all'estensione del tempo di attivazione, la prestazione della membrana suddetta subisce una riduzione	Rimuovere il tappo grigio di protezione dal Connector. Collegare il Connector alla porta endovenosa luer lock o al punto di accesso del paziente.	① PREMERE. Premere l'iniettore nell'interfaccia di connessione. ② GIRARE. Attenere l'impugnatura e girare. ③ PREMERE. Premere verso il basso per invertire.	Iniziare il trasferimento del farmaco.	① TIRARE. Tirare l'iniettore all'indietro. ② GIRARE. Attenere l'impugnatura e girare. ③ TIRARE. Tirare l'iniettore per separarlo dall'interfaccia di connessione.	Smaltire senza scollegare i componenti BD PhaSeal™.
LT Lietuviškai – Naudojimo instrukcija BD PhaSeal™ yra uždara sistema, skirta vaistams iš buteliuko suleisti į pacientą. Užtikra Luer Lock jungtis yra skirta vaistams perkelti ir suleisti į pacientą uždarame sistemoje, jis nėra pilnai prie kitimo sistemos, projektuotos prie pacientų venos. Tinkama vartoti, kuriu gali kelti su polipropilenu (PP). Laikui vadovautis privalomos ir priimtinos medicininės praktikos nuostatomis. Sterili (nepatenkinta endotoksinų). Skirta vienkartiniam naudojimui. Atsargumo priemonės: nenaudokite jei apsaugos dangteliai atsilaisvinę arba nuimti. Keisdamas BD PhaSeal™ sistemą visada iš už šalių dalių. Nelaikykite mėlynių vaistinės dalių. Užkrėstumo ir sandėliuodamas BD PhaSeal™ jungties Luer Lock (C35) nenaudokite kaip apsauginio dangtelio. Atlikus daugiau nei kelių arba po tam tikro naudojimo laiko sandarinamos membranos efektyvumas sumažėja.	Nuimkite nuo jungties pilką apsauginį dangtelį. Prijunkite jungtį prie paciento antgalio „Luer" ir jungties arba kito patvirtinto prijungimo vietos.	① STUMPITE. Įstumkite injektorių į prijungimo sąsają. ② PASUKITE. Laikykite už pagamintuosius dalies ir sukite. ③ STUMKITE. Paspauskite. Lieti atsigręžimą.	Sukinti lizdo vaistu.	① TRAUKITE. Ištraukite injektorių. ② PASUKITE. Laikykite už pagamintuosius dalies ir sukite. ③ TRAUKITE. Patraukite injektorių. Lieti atskaitymą ir nuo prijungimo sąsajos.	Sąlaikite, nenaudokame „BD PhaSeal™" sudedamųjų dalių.
LV Latviešu – Lietošanas pamācība BD PhaSeal™ ir slēgta sistēma zāļu ārstniecīšanai no pudelītes uz pacientu. Slēgtu tvertnīšu Luera savienotājs ir paredzēts slēgtai zāļu sagatavošanai un ievadīšanai. Pievienojiet pacienta intravenozajai sistēmai. Saderīgs ar zālēm, kas nav kontrindicētas ar polipropilēnu (PP). Izmantojiet nepieciešamo un pieņemto ārstniecisko praksi. Sterilizēts ar etilēna oksīdu. Sterili, ja nav bojāts iepakojums. Nesatur pirogēnus. Tikai vienreizējai lietošanai. Uzmanību! Nelietojiet, ja aizsargvāciņi ir vaļīgi vai nenoņemti sākotnēji. Lietojot BD PhaSeal™ sistēmu, vienmēr savienot baltās daļas. Nesatveriet zilētajā daļu daļu. Nelietojiet BD PhaSeal™ savienotāja Luera savienojumu (C35) kā aizsargstāmeni pārvadāšanas vai uzglabāšanas laikā. Pēc vairākām perforācijām un pagarinātā aktivizēšanas perioda noteiktās membrānas veiktspēja samazinās.	Noņemiet pelēko aizsargvāciņu no savienotāja. Pievienojiet savienotāju pie pacienta IV porta vai Luera savienojuma vai piekļuves punkta	① STUMT. Iestumiet injektoru Gēro savienojošajā kontaktzonā. ② PAGRIEZT. Turot ķēro noskāšķiet vietā, pagrieziet to. ③ STUMT. Pastumiet tālāk uz leju, lai to fiksētu.	Ievadiet medikamentus.	① VILKT. Pavelciet injekcijas ķēro uzpakaļ. ② PAGRIEZT. Turot ķēro noskāšķiet vietā, pagrieziet to. ③ VILKT. Pavelciet injekcijas ķēro, lai to atdalītu no savienojošās kontaktvirsmas.	Izlietojiet pudeli. Nesatiemojiet BD PhaSeal™ komponentus.
NL Nederlands – Gebruiksaanwijzing BD PhaSeal™ is een gesloten systeem voor het overbrengen van geneesmiddelen van de flacon naar de patiënt. Naaldvrije, gesloten Luer Lock-aansluiting voor gesloten toediening en toediening van geneesmiddelen. Aan te sluiten op de intraveneuze lijn van een patiënt. Compatibel met geneesmiddelen die niet gecontra-indiceerd zijn voor polypropyleen (PP). Gebruik de vereiste en goedgekeurde medische praktijken voor IV-toediening. Steriel (vrij van endotoxinen). Niet hergebruiken om besmetting te voorkomen. Let op: Niet gebruiken indien beschermkappen los zitten of niet op de juiste plaats zitten. Pak altijd de witte onderdelen vast bij gebruik van het BD PhaSeal™-systeem. Houd het systeem met vast bij de blauwe onderdelen van de injector. Gebruik BD PhaSeal™ Connector Luer Lock (C35) niet als beschermkap tijdens transport of opslag. De prestaties van het afsluitingsmembraan nemen af na meerdere perforaties en langdurige activeringstijd.	Verwijder de grijze beschermkap van de Connector. Bevestig de Connector op de Luer Lock van de intraveneuze toegang of het toegangspunt van de patiënt.	① DUW. Duw de injector in de aansluiting. ② DRAAI. Houd goed vast en draai. ③ DUW. Duw naar beneden om aan te sluiten.	Breng het geneesmiddel over.	① TREF. Trek de injector terug ② DRAAI. Houd goed vast en draai. ③ TREF. Trek de injector uit de aansluiting	Goor weg zonder de BD PhaSeal™-onderdelen los te maken
NO Norsk – Bruksanvisning BD PhaSeal™ er et lukket system for overføring av legemiddel fra hetteglass til pasient. Nålefri, lukket Luer Lock-tilkobling beregnet på lukket tilførsel og administrasjon av legemidler. Skal kobles til pasientens IV-slange. Kompatibel med legemidler som ikke er kontraindisert for polypropylen (PP). Bruk i henhold til nødvendig og godkjent IV-praksis. Sterilt (virkemiddelfritt). Steril med metode basert på etylen. Må ikke gjenbrukes for å unngå forurensning. Forsiktig: Må ikke brukes hvis beskyttende hetter er løse eller feilplassert. Ta alltid tak på hvite komponenter når du bruker systemet BD PhaSeal™. Grip blått i den blå siden på injector. Bruk ikke BD PhaSeal™ Connector Luer Lock (C35) som beskyttende hette under transport eller lagring. Funksjonen på retningsmembranen blir redusert etter flere perforeringer og lengre aktiveringstid.	Fjern den grå vernehetten fra kontaktsten. Fest Connector til luerlåsens Neon eller ...	① TRYKK. Trykk inn i kontaktflaten. ② VRI. Hold fast i grepet og vri. ③ TRYKK. Trykk nedover for å aktivere.	Overfør legemiddel.	① DRA. Dra tilbake. ② VRI. Hold fast i grepet og vri. ③ DRA. Dra i for å skille den fra kontaktflaten.	Kasser uten å kvitte he BD PhaSeal™-komponentene.
PL Polski – Instrukcja obsługi BD PhaSeal™ to zamknięty system do przenoszenia leku z fiolki do pacjenta. Złącze bezigłowe typu Luer Lock przeznaczone jest do zamkniętego przygotowywania i podawania leków. Przeznaczony do kontaktu pacjenta. Zgodny z lekami, które nie są przeciwwskazanymi do polipropylenu (PP). Stosować wymagane i przyjęte praktyki infuzji. Sterylne (brak endotoksyn). Sterylne w nieuszkodzonym opakowaniu. Nie używać ponownie, aby uniknąć skażenia. Środki ostrożności: Nie używać w przypadku otwarcia lub utraty szczelności osłonowej. Podczas używania systemu BD PhaSeal™ zawsze trzymać za białe elementy. Nie trzymać za niebieski element środkowy. Nie używać złącza BD PhaSeal™ Luer Lock (C35) jako kapturka ochronnego podczas transportu lub przechowywania. Skuteczność membrany uszczelniającej ulega zmianom po wielokrotnym przebiciu i przedłużonym czasie aktywacji.	Zdejmij szary kapturek ochronny ze złącza. Podłącz złącze Connector do złącza Luer portu enfuzyjnego pacjenta lub punktu dostępu	① WCIŚNIJ. Wcisnij zwrotnik do interfejsu złącza. ② OBRÓĆ. Chwyć za uchwyty i obróć. ③ WCIŚNIJ. Wcisnij w dół do zaskoczenia.	Dokonaj przmieszenia leku.	① WYCIĄGNIJ. Wciągnij zwrotnik do góry ② OBRÓĆ. Chwyć za uchwyty i obróć. ③ WYCIĄGNIJ. Wciągnij zwrotnik do rozdzielenia z interfejsem złącza	Zużytzia bez odłączania elementów BD PhaSeal™
PT Português – Instruções para utilização O BD PhaSeal™ é um sistema fechado para transferência de produtos farmacêutico do frasco para o paciente. Conector Luer Lock fechado sem agulha destinado a preparação e administração fechada de produtos farmacêuticos. Para ser ligado a linha IV do paciente. Compatível com produtos farmacêuticos que não sejam contra-indicados para polipropileno (PP). Utilize a prática IV necessária e aceite. Estéril (isento de endotoxinas). Estéril, exceto se ocorrerem danos na embalagem. Não reutilize para evitar contaminação. Cuidados: Não utilizar se as tampas de protecção estiverem soltas ou tiverem sido retiradas. Ao utilizar o sistema BD PhaSeal™, aperte sempre os componentes brancos. Não aperte a parte azul do injector. Não utilize o BD PhaSeal™ Connector Luer Lock (C35) como tampa de protecção durante o transporte ou o armazenamento. O desempenho da membrana de isolamento fica reduzido após múltiplas perfurações e um tempo de activação prolongado.	Retire a tampa de protecção cinzenta do Conector. Fixe o Conector à porta IV com Luer Lock do paciente ou ao ponto de acesso.	① EMPURRE. Empurre o injector para a interface de ligação. ② RODE. Segure a pega e rode. ③ EMPURRE. Pressione para baixo para encaixar.	Efectue a transferência do produto farmacêutico.	① PUXE. Puxe o injector para trás. ② RODE. Segure a pega e rode. ③ PUXE. Puxe o injector para separá-lo da interface de ligação.	Deite fora sem arrebatar os componentes BD PhaSeal™
RU Русский – инструкция по применению BD PhaSeal™ — [illegible] для безопасного переноса лекарственных средств из одной емкости в другую, так же закрытая и при введении в вену пациента. Безыгольный коннектор Luer Lock предназначен для подключения к внутривенной системе. Совместим с лекарственными препаратами, которые не запрещены к применению с полипропиленом (ПП). Выполняйте внутривенные инъекции по общепринятой практике. Стерильно (не содержит пирогенных веществ). Стерильно при условии отсутствия повреждений упаковки. Не использовать повторно во избежание загрязнения. Не используйте, если защитные колпачки ослаблены или сняты. Всегда держите за белые детали. Не держите за синюю часть. Не используйте коннектор типа Luer Lock (C35) системы BD PhaSeal™ в качестве защитного колпачка при транспортировке или во время хранения. Функционирование мембраны ухудшается с увеличением количества проколов мембраны и увеличением времени активирования системы.	Снимите с коннектора серый защитный колпачок. Плотно подключите коннектор к внутривенной или периферической игле порта или точке доступа	① ЗАТЯНИТЕ. Затяните инъектор до упора. ② ПОВЕРНУТЬ. Возьмите инъектор за белую часть и поверните против часовой стрелки. ③ НАЖАТЬ. Надавите на инъектор до полного соединения с коннектором.	Введите все доступные препараты.	① ПОТЯНУТЬ. Оттяните инъектор. ② ПОВЕРНУТЬ. Возьмите инъектор за белую часть и поверните против часовой стрелки. ③ ПОТЯНУТЬ. Отсоедините за белые части для отделения от коннектора.	Выбросьте сразу, не отсоединяя от него компоненты системы BD PhaSeal™
SK Slovenčina – Návod na použitie BD PhaSeal™ je uzavretý systém na prenos liekov z fľaštičky pacientovi. Uzavretý konektor Luer Lock bez ihly určený na uzavretú prípravu a podávanie liekov. Na pripojenie na intravenóznu linku pacienta. Kompatibilný s liekmi, ktoré nie sú kontraindikované na polipropylén (PP). Používajte požadované a schválené postupy IV. Sterilné (vyšetrovací). Sterilné v prípade nepoškodenia obalu. Aby sa zabránilo kontaminácie, nepoužívajte opakovane. Upozornenie: Nepoužívajte, ak su ochranne časti v povolenie alebo poškodené. Pri použití systému BD PhaSeal™ chytajte vždy za biele časti. Nechytajte modrú časť injektora. Nepoužívajte konektor BD PhaSeal™ Luer Lock (C35) ako ochranný kryt počas prepravy alebo skladovania. Výkon tesniacej membrány je po viacerých perforáciách a predĺžený aktivačný dobe znížený.	Odstráňte z konektora šedú ochranný kryt. Pripojte konektor k luerovému uzáveru intravenózneho portu alebo k prístupovému bodu pacienta.	① ZATLAČTE. Zatlačte injektorové na pripojovacie rozhranie. ② OTOČTE. Uchopte za rukoväť a otočte. ③ ZATLAČTE. Zatlačte smerom nadol.	Vykonajte prenos lieku.	① POTIAHNITE. Potiahnite injektorové späť. ② OTOČTE. Uchopte za rukoväť a otočte. ③ POTIAHNITE. Potiahnite injektorové, aby ste ho oddelili. . od pripojovacieho rozhrania.	Zlikvidujte bez odpojenia komponentov BD PhaSeal™.
SL Slovenščina – Navodila za uporabo BD PhaSeal™ je zaprt sistem za prenos zdravila iz steklenička do bolnika. Zaprta konektor Luer Lock brez igle je namenjen zaprti pripravi in dajanju zdravil. Namenjen priključku na bolnik-ov venski kateter. Združljiv z zdravili, ki niso kontraindicirana za polipropilen (PP). Pri uporabi upoštevajte predpisane in sprejete postopke. Sterilno (polen uteži). Sterilno. Ce embalaža ni poškodovana. Ponovna uporaba ni zaradi tveganja okužbe priporočljiva. Varnostni ukrepi: Ne uporabljajte. Ce zaščitni pokrovčki niso dobro privit ali ali ni. Ko uporabljate sistem BD PhaSeal™, vedno delno primite bele komponente. Ne primetajte modrega dela injektora. Priključka BD PhaSeal™ Luer Lock (C35) ne uporabljajte kot zaščitni pokrov med prevozom ali shranjevanjem. Učinkovitost delovanja tesnilne opne se po več vbodih in večkratnem razteznju zmanjša.	Odstranite zeleni zaščitni pokrovčki z priključka. Konektor priključite na Luer Lock intravensa-ega kanala ali pa na vstopno točko	① POTISNITE. Potisnite injektor v priključek vrtnevski. ② OBRNITE. Držite za ulavke in obrnite ③ POTISNITE. Aktivacijo gas s potiskom navzdol.	Nadaljujte z prenosom zdravila.	① POVLECITE. Invertor zategnite iz vsekletke. ② OBRNITE. Držite za ulavke in obrnite ③ POVLECITE Povlecite vtvertor in ga tako ločite od priključnega vrtnevska.	Komponente BD PhaSeal™ pustite pri ljučene in zavrzite skrbleničko.
SV Svenska – Bruksanvisning BD PhaSeal™ är ett slutet system för överföring från flaska till patient. Nålfri, sluten Luer Lock-koppling avsedd för sluten beredning och administrering av läkemedel. För anslutning till patientens vensag. Kompatibel med läkemedel som inte är kontraindicerade för polypropylen (PP). Använd sedvanliga rutiner för intravenös hantering. Sterilt (värmekvalitet). Sterilt - oskadad förpackning. Återanvänd ej på grund av risk för kontaminering. Försiktighetsåtgärd: Använd inte om skyddslock är lösa eller felplacerade. Håll alltid i de vita komponenterna när du använder med BD PhaSeal™-systemet. Håll inte i den blå sidan vid användning av injektor. Använd inte BD PhaSeal™ Connector Luer Lock (C35) som skyddslock vid transport eller lagring. Membranets tätande egenskaper minskar med ökande antal perforeringar och längre aktiveringstid.	Ta bort det grå skyddslocket från Connector. Koppla Connector till luer lock porten eller annan luer lock-anslutning på patientens infusionsslang.	① TRYCK. Tryck Injector in i BD PhaSeal™-kopplingen. ② VRID. Håll i greppet och vrid. ③ TRYCK. Tryck för att aktivera Injector.	Utför läkemedelsöverföring.	① DRA. Dra tillbaka Injector. ② VRID. Håll i greppet och vrid. ③ DRA. Lossa Injector från BD PhaSeal™-kopplingen.	Avfallshanteras utan att koppla från BD PhaSeal™-komponenter.
TR Türkçe – Kullanım Talimatları BD PhaSeal™, ilaçın flakondan hastaya aktarılmasına yönelik kapalı bir sistemdir. Bağlantı kapalı hazırlanmaya ve uygulanmaya yönelik iğnesiz, kapalı Luer Lock, Hastanın IV hattına bağlanır. Polipropilen (PP) ile kontrendike olmayan ilaçlarla uyumludur. Gerekli ve kabul edilmiş olan IV uygulaması kullanın. Steril (ateşin olası). Ambalajı hasar görmedigi sürece sterildir. Kontaminasyonları kaçınmak için, tekrar kullanmayın. Önlemler: Koruyucu kapakların gevşemiş veya yerinden çıkmış olduğu durumda BD PhaSeal™ sistemini kullanmayın. BD PhaSeal™ sistemini kullanırken daima beyaz bileşenlerden tutun. Injector'ü mavi elemandan tutmayın. BD PhaSeal™ Connector Luer Lock (C35)'i taşıma veya saklama sırasında koruma kapağı gibi olarak kullanmayın. Birkaç kez delindikten ve uzatılmış bir etkinleşme süresinden sonra, sızdırmaz membranın performansı azalır.	Connector'dan gri koruma kapağını çıkarın. Connector'ı hastanın luer lock IV portuna veya erişim noktasına takın.	① TİTİN. Injector'ı başlantı ara yüzeyine itin. ② ÇEVİRİN. Sabtın tutun ve çevirin ③ TİTİN. İyice geçirmek için aşağı doğru itin	Kaç transferini gerçekleştirin.	① ÇEKİN. Injector'ı geri çekin ② ÇEVİRİN. Sabtın tutun ve çevirin ③ ÇEKİN. Bağlantı ara yüzeyinden ayırmak için Injector'ı çekin	BD PhaSeal™ parçalarını ayırmadan atın.

DGP11701 PSA729

VENDOR NOTES

[redacted]
Process Black

All text and graphics print process black

(b) (4)

Status: Draft

[redacted]

BD PhaSeal™

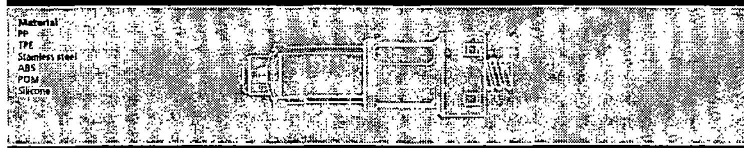
Manufacturer
Becton, Dickinson and Company Limited, Pottery Road, Dun Laoghaire, Co. Dublin, Ireland, www.bd.com

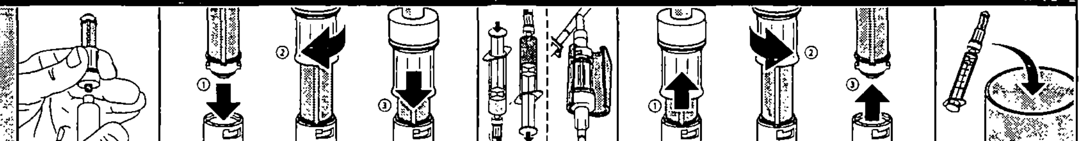
Injector Luer Lock

Injector Luer Lock (N35) | REF 515003
Injector Luer Lock (N35C) | REF 515004
Injector Luer Lock (N35CMulti) | REF 515005

REF Catalogue number
LOT Batch code
Use by
Caution, consult accompanying documents
STERILE EO Sterilized using ethylene oxide
Do not use if package is damaged
Do not reuse
CE 0413

N35C N35 N35C N35C N35 N35C N35 N35C N35C N35 N35C N35 N35C N35C





LANGUAGES	1	2	3	4	5
EN English – Instructions for use BD PhaSeal™ is a closed system for drug transfer from vial to patient. Injector Luer Lock intended for closed preparation and administration of drugs. Compatible with Luer Lock connections and with drugs that are not contraindicated for polypropylene (PP). Sterile (ethylene oxide). Sterile unless package is damaged. Use required and accepted IV practice. Do not reuse to avoid contamination. Rx Only. Precaution: When attaching Injector to drug vials with thick concave rubber stoppers, make sure the Injector is fully compressed and pressure equalization is working. Do not use if protective caps are loose or displaced. Always grip white components when using the BD PhaSeal™ system. Do not grip blue part of the Injector. Do not use BD PhaSeal™ Connector Luer Lock as protection cap together with Injector Luer Lock. The performance of the sealing membrane is reduced after multiple perforations and extended activation time. When Injector is connected to the distal end of an infusion line for long term infusion, total activation time of Injector in Connector should not exceed 24 hours. Clamp the lines before disengaging the Injector from the Connector.	Draw a volume of air equivalent to the dose or required volume of diluent into the syringe. Connect Injector to syringe or infusion line.	① PUSH. Push the Injector into the connection interface. ② TURN. Hold onto the grip and turn. ③ PUSH. Push down to engage.	Perform drug transfer.	① PULL. Pull the Injector back. ② TURN. Hold onto the grip and turn. ③ PULL. Pull the Injector to separate from the connection interface.	Dispose without disconnecting the BD PhaSeal™ components.
CS Čeština – Návod k použití [illegible]	Natáhněte do injekční stříkačky objem vzduchu, který odpovídá dávce, nebo požadovaný objem ředicího roztoku. Připojte injektor k injekční stříkačce nebo infuzní hadičce.	① ZATLAČIT. Zatlačte injektor do připojovacího rozhraní. ② OTOČIT. Uchopte drážkovanou část a otočte. ③ ZATLAČIT. Zatlačením systém aktivujte.	Proveďte přenos léku.	① VYTAHNOUT. Vytáhněte injektor. ② OTOČIT. Uchopte drážkovanou část a otočte. ③ VYTAHNOUT. Vytáhněte injektor a odpojte ho od připojovacího rozhraní.	Lahvičku zlikvidujte, aniž byste od ní odpojili části systému BD PhaSeal™.
DA Dansk – Brugsanvisning [illegible]	Træk en mængde luft ind i sprøjten, svarende til dosis eller påkrævet mængde fortyndingsmiddel. Tilslut Injector til sprøjte eller infusionsslange.	① TRYK. Tryk Injector ind i forbindelsesadapteren. ② DREJ. Hold fast i grebet og drej. ③ TRYK. Tryk nedad for at tilkoble.	Udfør overførsel af lægemidlet.	① TRÆK. Træk Injector tilbage. ② DREJ. Hold fast i grebet og drej. ③ TRÆK. Træk i Injector for at frigøre den fra forbindelsesadapteren.	Bortskaffes uden at skille BD PhaSeal™-komponenterne fra hinanden.
DE Deutsch – Gebrauchsanweisung [illegible]	Ziehen Sie entsprechend der Dosis bzw. des benötigten Volumens des Verdünnungsmittels Luft in die Spritze auf. Schließen Sie den Injector an die Spritze oder den Infusionsschlauch an.	① DRÜCKEN. Drücken Sie den Injector in die Verbindungsschnittstelle. ② DREHEN. Halten Sie den Griff und drehen Sie. ③ DRÜCKEN. Drücken Sie zum Einrasten nach unten.	Führen Sie den Medikamententransfer aus.	① ZIEHEN. Ziehen Sie den Injector zurück. ② DREHEN. Halten Sie den Griff und drehen Sie. ③ ZIEHEN. Ziehen Sie den Injector aus der Verbindungsschnittstelle.	Entsorgen Sie das System, ohne die BD PhaSeal™-Komponenten voneinander zu trennen.
EL Ελληνικά – Οδηγίες χρήσης [illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
ES Español – Instrucciones de uso [illegible]	Aspire un volumen de aire equivalente a la dosis o el volumen de diluyente necesario en la jeringa. Conecte el Injector a la jeringa o a la línea de infusión.	① PRESIONE. Presione el Injector en la interfaz de conexión. ② GIRE. Sostenga el asa y gire. ③ PRESIONE. Presione hacia abajo para acoplar.	Realice la transferencia del medicamento.	① TIRE. Tire el Injector hacia atrás. ② GIRE. Sostenga el asa y gire. ③ TIRE. Tire el Injector para separarlo de la interfaz de conexión.	Deséchelo sin desconectar los componentes de BD PhaSeal™.
ET Eesti – Kasutusjuhend [illegible]	Tõmmake süstlasse doosi või vajaliku koguse lahjendiga võrdne kogus õhku. Ühendage Injektor süstla või infusioonivoolikuga.	① VAJUTAGE. Vajutage Injektor ühenduse liidesesse. ② KEERAKE. Hoidke vastavast kohast kinni ja keerake. ③ VAJUTAGE. Ühendamiseks vajutage see alla.	Sooritage ravimi ülekanne.	① TÕMMAKE. Tõmmake Injektor tagasi. ② KEERAKE. Hoidke vastavast kohast kinni ja keerake. ③ TÕMMAKE. Ühenduse liidesest eemaldamiseks tõmmake Injektorit.	Visake ära ilma BD PhaSeal™ osasid üksteisest lahti ühendamata.
FI Suomi – Käyttöohje [illegible]	Vedä ruiskuun annosta vastaava määrä ilmaa tai tarvittava määrä laimenninta. Yhdistä neulansuojus lääkeruiskuun tai infuusioletkuun.	① PAINA. Paina Neulansuojus Yhdistäjään. ② KÄÄNNÄ. Pidä kiinni valkoisista osista ja käännä. ③ PAINA. Lukitse painamalla alaspäin.	Annostele lääke.	① VEDÄ. Vedä Neulansuojus-liitintä ulospäin. ② KÄÄNNÄ. Pidä kiinni valkoisista osista ja käännä. ③ VEDÄ. Irrota Neulansuojus-liitin Yhdistäjä-liittimestä vetämällä.	Hävitä laitteisto irrottamatta BD PhaSeal™-järjestelmän osia lääkelaimenuolasta tai ruiskusta.
FR Français – Mode d'emploi [illegible]	Aspirez dans la seringue un volume d'air équivalent à la dose ou au volume de diluant requis. Raccordez l'Injecteur à la seringue ou à la ligne de perfusion.	① POUSSEZ. Poussez l'Injecteur dans l'interface de connexion. ② TOURNEZ. Maintenez la prise et tournez. ③ POUSSEZ. Poussez pour engager l'injecteur.	Effectuez le transfert de médicament.	① TIREZ. Retirez l'Injecteur. ② TOURNEZ. Maintenez la prise et tournez. ③ TIREZ. Déconnectez l'Injecteur pour le détacher de l'interface de connexion.	Éliminez sans déconnecter les composants BD PhaSeal™.
HE עברית – הוראות שימוש [illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
HR Hrvatski – Uputa za uporabu [illegible]	U špricu uvucite volumen zraka jednak dozi ili potrebnom volumenu otopine za razrjeđivanje. Spojite injektor na špricu ili infuzijsku liniju.	① GURNITE. Gurnite injektor u spojnu površinu. ② OKRENITE. Držite za dršku i okrećite. ③ GURNITE. Gurnite prema dolje dok se ne spoji.	Prenijenite lijek.	① POVUCITE. Povucite injektor unatrag. ② OKRENITE. Držite za dršku i okrećite. ③ POVUCITE. Povucite injektor kako biste ga odvojili od spojne površine.	Bočicu bacite bez razdvajanja BD PhaSeal™ dijelova.
HU Magyar – Használati útmutató [illegible]	Szívjon fel a fecskendőbe a dózisnak vagy a szükséges hígító mennyiségnek megfelelő mennyiségű levegőt. Csatlakoztassa az Injectort a fecskendőhöz vagy az infúziós vezetékhez.	① TOLJA BE. Tolja be az Injectort a csatlakoztató felületbe. ② FORDÍTSA EL. Fogja meg a markolatot, és fordítsa el. ③ TOLJA BE. Nyomja le a rögzítéshez.	Végezze el a gyógyszerbeadást.	① HÚZZA KI. Húzza vissza az Injectort. ② FORDÍTSA EL. Fogja meg a markolatot, és fordítsa el. ③ HÚZZA KI. Húzza ki az Injectort a csatolófelülettől történő elválasztás érdekében.	A BD PhaSeal™ komponensek leválasztása nélkül dobja ki.

>>

DGP10002, PSA728.

VENDOR NOTES

All text and graphics print process black

Process Black

[redacted]

Status: Draft

(b) (4) [redacted]

BD PhaseSeal™

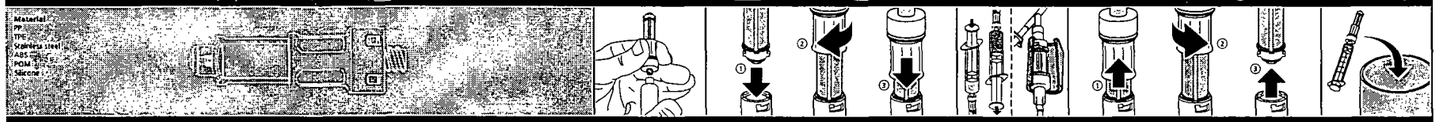
Manufacturer
Becton, Dickinson and Company Limited. Pottery Road, Dun Laoghaire, Co. Dublin, Ireland, www.bd.com

Injector Luer Lock

Injector Luer Lock (N35) | REF 515003
Injector Luer Lock (N35C) | REF 515004
Injector Luer Lock (N35CMulti) | REF 515005

REF Catalogue number | LOT Batch code | Use by | Caution, consult accompanying documents | STERILE EO Sterilized using ethylene oxide | Do not use if package is damaged | Do not re-use | CE 0413

Material
PP
TPE
Stainless steel
ABS
POM
Silicone



LANGUAGES	1	2	3	4	5
IT Italiano – Istruzioni per l'uso BD PhaseSeal™ è un sistema chiuso per il trasferimento di farmaci dalla fiala al paziente. Injector Luer Lock progettato per la preparazione protetta e la somministrazione di farmaci. Compatibile con connettori Luer Lock e con farmaci non contenenti/privi per il polipropilene (PP). Sterile (ossido di etilene). Sterile purché in confezione integra. Seguire le procedure necessarie e approvate per le infusioni endovenose. Non riutilizzare per evitare la contaminazione. Precauzioni: Se l'Injector viene fissato a fiale con tappi in gomma conicali è sempre accertarsi che sia premuto completamente e che l'equalizzazione della pressione funzioni. Non utilizzare se i cappucci protettivi sono allentati o fuori posto. Alternare sempre i componenti bianchi durante l'uso del sistema BD PhaseSeal™. Non afferrare la parte blu dell'Injector. Non utilizzare BD PhaseSeal™ Connector Luer Lock come tappo protettivo insieme a Injector Luer Lock. Dopo ripetute perforazioni, e in seguito all'estensione del tempo di attivazione le prestazioni della membrana potrebbero subirne una riduzione. Quando l'Injector è collegato all'estremità distale di una linea di infusione per infusioni di lunga durata, il tempo totale di attivazione dell'Injector all'interno del Connector non dovrà superare le 24 ore. Effettuare le linee di infusione prima di scollegare l'Injector dal Connector.	Aspirare nella siringa un volume di aria equivalente alla dose, oppure il volume di diluente necessario Collegare l'Injector alla siringa o alla linea di infusione.	① PREMERE. Premere l'Injector nell'interfaccia di connessione ② GIRARE. Afferrare l'impugnatura e girare. ③ PREMERE. Premere verso il basso per innestare.	Iniziare il trasferimento del farmaco.	① TIRARE. Tirare l'Injector all'indietro. ② GIRARE. Afferrare l'impugnatura e girare. ③ TIRARE. Tirare l'Injector per separarlo dall'interfaccia di connessione.	Smaltire senza scollegare i componenti BD PhaseSeal™
LT Lietuviškai – Naudojimo instrukcija BD PhaseSeal™ yra uždara sistema, skirta vaistams iš buteliuko suleisti tiesiai pacientui. Injector Luer Lock užrakto sistema pritaikyta paruošti ir saugiai atlikti vaistinius tirpalus ir vaistus, kurie gali kenkti su polipropilenu (PP). Sterili (etileno oksidu). Sterili, jei nepažeista pakuotė. Atlikti vaistavaisių privalomas ir patvirtintas veiksmų sekas prieš vaistų infuziją. Atsargumo priemonės: jungdami švirkštinį vožtuvą prie buteliukų ar kitokių užrakčių gumines tarpinės uždarykite. Jei švirkštinio prie vožtuvo prijungtos ir vaistai nepatenka į vieną pusę, Injector Luer Lock užrakto mechanizmas. Nenaudokite, jei atsuktos arba nuimtos apsauginės dangtelės. Naudodamiesi BD PhaseSeal™ sistema vienu iš jų kitu būdu. Nebeatlikti mišinių švirkštuose vėliau, BD PhaseSeal™ Injector Luer užrakto nenaudoti ne ilgiau apsauginę dangtelės karta su švirkštuose Luer užrakto. Atkreipkite dėmesį, kad ilgai infuzijai, kai vaistai ilgiau nei 24 valandas. Prieš atjungdami švirkštinį vožtuvą nuo jungties, užbaigiamas sistemos veiksmas.	Įsiurbti tiek oro kiek dozės pakeičiamo skysčio arba reikiamo skiedžiklio kiekį. Įvairiems poreikiams prie švirkštinio vožtuvo prijungti	① STUMKITE. Įstumkite švirkštinį prijungimo vožtuvą. ② PASUKITE. Laikykite už jungiamosios dalies ir sukite. ③ STUMKITE. Patraukite, kad susijungtų.	Subvirškite vaistą.	① TRAUKITE. Ištraukite švirkštinį. ② PASUKITE. Laikykite už jungiamosios dalies ir sukite ③ TRAUKITE. Patraukite švirkštinį, kad atskirtumėte jį nuo prijungimo sąsajos.	Sąlaikos nenuimkite BD PhaseSeal™ vaistelamosios sistemos
LV Latviešu – Lietošanas pamācība BD PhaseSeal™ ir slēgta sistēma šķīdumu pārnešanai no pudeles uz pacientu. Luera aizvēršas Sistēmas Injector Luer Lock ir paredzēta aizsargātai sagatavošanai un ievadīšanai. Saderīga ar Luera tipa savienojumiem un ar zālēm, kas nav kontrindicētas lietošanai ar polipropilēnu (PP). Sterilizēta (ar etilēna oksīdu). Sterila, ja nav bojāts iepakojums. Izmantojiet nepieciešamo un pieņemto intravenozas ievadīšanas praksi. Nelietojiet atkārtoti, lai nepieļautu infekcijas. Uzmanībai! Pirms ievilkt šķīdumu vai atkal ievilkt zāles caur pudeles aizbāznīti, nodrošiniet, lai pudeles iekšpusē nav spiediena. Nelietojiet, ja aizsargvāciņi ir atvērti vai nav pareizā vietā. Lietojot BD PhaseSeal™ sistēmu, vienmēr ievērojiet šādus soļus. Nevairākreiz ķīmiskus ar šļirci vai adatu. Nelietojiet BD PhaseSeal™ sterilizēšanas Luera savienotāju ilgāk par vienu piegādes laiku. Pēc vairākām punkcijām un saspiešanas elastīgā membrāna pakāpeniski zaudēs savu elastību. Kad pudeles šķērsi ir pievienota pie ārējās šķēles caurules galā ievietotie ārējais, pārliecinieties, ka ievietotie Luera Injektora aizbāznītiņas pareizi savienotāji nodrošina pārsegi 24 stundas. Saspiežot šķēles ar skavām pirms pudeles šķērsi pievienota caurule nav savienota.	Ievelciet šļircē gaisu līdz ekvivalentam gaisa vai ārstniecības daudzumam. Savienojiet ar pudeles šķērsi ar šļirces vai infūzijas šļirci.	① STUMT. Ievietojiet injektora šļirci savienotājā ar pudeles šķērsi. ② PAGRIEZT. Turot šļirci noķeršanā vietā, pagrieziet to. ③ STUMT. Pievienot šļirci uz leju, lai to fiksētu.	Ievadiet medikamentu.	① VILKT. Pavelciet injektora šļirci atpakaļ. ② PAGRIEZT. Turot šļirci noķeršanā vietā, pagrieziet to. ③ VILKT. Pavelciet injektora šļirci, lai to atdalītu no savienojošās horizontālvirsmas	Lai nodrošinātu pudeles, nostiprinošo BD PhaseSeal™ komponentus
NL Nederlands – Gebruiksaanwijzing BD PhaseSeal™ is een gesloten systeem voor het overbrengen van geneesmiddelen van de flacon naar de patiënt. Injector Luer Lock voor gesloten toedieningvan geneesmiddelen. Compatibel met Luer Lock-aansluitingen en met geneesmiddelen die niet geconcentreerd/oliehoudend zijn voor polypropeen (PP). Gesteriliseerd met ethyleenoxide. Steriel tenzij de verpakking beschadigd is. Gebruik de voorziene en geaccepteerde werkwijze voor (N)toediening. Niet hergebruiken om een besmetting te voorkomen. Let op: Als de Injector wordt aangesloten op geneesmiddelenflacons met dikke, conische rubberen stoppers, zorg er dan voor dat de Injector volledig is ingedrukt en er drukvereffening plaatsvindt. Niet gebruiken indien beschermkappen los zitten of niet op de juiste plaats zitten. Pas altijd de verschillende witte onderdelen van BD PhaseSeal™-systeem. Houd het systeem niet vast bij de blauwe onderdelen van de Injector. Gebruik BD PhaseSeal™ Connector Luer Lock niet als beschermkap op Injector Luer Lock. De drukzalen van het afsluitingsmembraan nemen af na meerdere perforaties en langdurige activeringstijd. Wanneer de Injector is aangesloten op het distale uiteinde van een infuuslijn voor langdurige infusie, mag de totale activeringstijd van de Injector en de Connector niet langer zijn dan 24 uur. Klem de lijnen af voordat u de Injector loskoppelt van de Connector	Trekt zoveel lucht in als overeenkomt met de vereiste hoeveelheid verdunner. Sluit de Injector aan op injectievocht of infusiglijn.	① DUW. Duw de Injector in de aansluiting ② DRAAI. Houd goed vast en draai. ③ DUW. Duw naar beneden om aan te sluiten.	Breng het geneesmiddel over	① TREK. Trek de Injector terug. ② DRAAI. Houd goed vast en draai. ③ TREK. Trek de Injector uit en aankoppeling.	Gooi weg zonder de BD PhaseSeal™-onderdelen los te maken.
NO Norsk – Bruksanvisning BD PhaseSeal™ er en lukket system for overføring av legemidler fra hetteglass til pasient. Injector Luer Lock er beregnet på lukket tilvirkning og administrasjon av legemidler. Kompatibel med Luer Lock-tilkoblinger og med legemidler som ikke er konsentrert for polypropylen (PP). Sterilisert (etylenoksid). Steril med mindre pakningen er skadet. Bruk fremgangsmåter for å unngå forurensning. Forsiktig: Under tilkobling av Injector til legemiddelhetteglass vær(t med tykk gummiproppe er det nødvendig å kontrollere at Injector er fullstendig presset sammen og at trykkutligning fungerer. Må ikke brukes hvis beskyttende hetter er løse eller forskjøvet. Til alltid bruk på hele komponentene når du bruk er systemet BD PhaseSeal™. Grip ikke i den hvite delen på Injector. Bruk ikke BD PhaseSeal™ Connector Luer Lock som beskyttende hette sammen med Injector Luer Lock. Funksjonen på tetningsmembranen blir redusert etter flere perforeringer og lengre aktiveringstid. Når Injector er koblet til den distale enden av en infusjonslange for langvarig infusjon, må den totale aktiveringstid van de Injector en de Connector net langer zijn dan 24 uur. Klem av linjene før frakopling av Injector fra Connector.	Trekk opp et luftrom som tilsvarer dosen eller det nødvendige volumet av fortynningsmiddel i sprøyten. Koble Injector til sprøyten eller infusjonslangen.	① TRYKK. Trykk inn i kontakthetten. ② VRI. Hold fast i grepet og vri. ③ TRYKK. Trykk sammen for å aktivere.	Overfør legemidler.	① DRA. Dra tilbake. ② VRI. Hold fast i grepet og vri. ③ DRA. Dra i for å skille den fra kontakthetten	Kaster uten å koble fra BD PhaseSeal™-komponentene.
PL Polski – Instrukcja obsługi BD PhaseSeal™ to zamknięty system do przenoszenia leku z fiolki do pacjenta. Injector Luer Lock przeznaczony jest do zamkniętego przygotowywania i podawania leków. Zgodny ze złączami typu Luer oraz z lekami które nie są przeznaczonymi do polipropylenu (PP). Sterylna (tlenek etylenu). Sterylna w innych przypadkach niż uszkodzone opakowanie. Nie używać ponownie. Aby uniknąć zakażenia. Środki ostrożności. Przy podłączaniu zaworu do fiolek z lekiem wypełnionych w głębi gumowe korki upewnić się, że zawór jest w pełni dociśnięty oraz że działa wyrównywanie ciśnienia. Nie używać w przypadku luźno ustawionej ochronnej. Podczas używania systemu BD PhaseSeal™ zawsze zmieniać ze białe elementy. Nie trzymać za niebieski element Injektora. Nie używać złącza BD PhaseSeal™ Luer Lock jako zatyczki ochronnej dla Injektora Luer Lock. Skuteczność membrany uszczelniającej ulega zmniejszeniu po wielu użyciu przebiciu i przedłużonym czasie aktywacji. Gdy zawór podłączony jest do dystalnego końca linii infuzyjnej do długotrwałej infuzji, całkowity czas aktywacji Injektora w złączu nie powinien przekraczać 24 godzin. Zaciskać linie przed odłączeniem Injektora od złącza.	Wybierz za pomocą strzykawki objętość powietrza równą objętości leku lub wymaganą objętość rozcieńczalnika. Podłącz Injektor do strzykawki lub linie infuzyjnej.	① WCIŚNIJ. Wciśnij Injektor do interfejsu złącza ② OBRÓĆ. Chwyć za uchwyt i obróć. ③ WCIŚNIJ. Wciśnij w dół do zaskoczenia.	Dokonaj przetoczenia leku.	① WYCIĄGNIJ. Wyciągnij Injektor do góry ② OBRÓĆ. Chwyć za uchwyt i obróć. ③ WYCIĄGNIJ. Wyciągnij Injektor do rozłączenia z interfejsem złącza.	Zużyte są bez odłączenia elementów BD PhaseSeal™.
PT Português – Instruções para utilização O BD PhaseSeal™ é um sistema fechado para transferência de produtos farmacêuticos de frasco para o paciente. Injector Luer Lock destinado à preparação e administração fechada de produtos farmacêuticos. Compatível com ligações Luer Lock e com produtos farmacêuticos que não entram contra-indicados para polipropileno (PP). Esterilizado de oxiletano. Estéril, excepto se ocorrerem danos na embalagem. Utilize a técnica IV necessária e aceite. Não reutilize para evitar contaminação. Cuidado: Ao ligar o Injector a frascos de produtos com tampas de borracha espessas e cónicas, certifique-se de que o Injector é totalmente comprimido e de que a equalização de pressão é efectiva. Não utilizar se as tampas de protecção estiverem soltas ou tiverem sido retiradas. Ao utilizar o sistema BD PhaseSeal™, aperte sempre os componentes brancos. Não aperte a parte azul do Injector. Não utilize o BD PhaseSeal™ Connector Luer Lock como tampa de protecção em conjunto com o Injector Luer Lock. O desempenho da membrana de vedamento fica reduzido após múltiplas perfurações e um tempo de activação prolongado. Quando o Injector é ligado à extremidade distal de uma linha de infusão para infusão a longo prazo, o tempo de activação total do Injector no Conector não deve ser superior a 24 horas. Fixe as linhas antes de desencadear o Injector do Conector.	Aspire um volume de ar equivalente à dose ou ao volume de diluente necessário para a seringa. Ligue o Injector à seringa ou à linha de infusão.	① EMPURRE. Empurre o Injector para a interface de ligação. ② RODE. Segure a aleta e rode. ③ EMPURRE. Pressione para baixo para encaixar.	Efectue a transferência do produto farmacêutico.	① PUXE. Puxe o Injector para trás. ② RODE. Segure a aleta e rode. ③ PUXE. Puxe o Injector para separá-lo da interface de ligação.	Deste fora sem desligar os componentes BD PhaseSeal™.
RU Русский – Инструкция по применению BD PhaseSeal™ — это система для асептического переноса препарата из флакона в шприц для инъекций. Injector Luer Lock предназначен для работы с лекарственными препаратами, которые не активны по взаимодействию с полипропиленом (ПП). Стерилизован этиленоксидом. Стерилен при условии сохранности герметичности упаковки. Выполняйте внутривенное вливание по общепринятой методике. Не используйте повторно во избежание контаминации. Меры предосторожности: При подсоединении системы к флакону с пробкой конической формы убедитесь, что воздух полностью поступил в систему и давление сравнялось. Не используйте, если защитные колпачки ослаблены или сняты. Используйте систему BD PhaseSeal™ каждый раз только белыми деталями. Не берите за синюю часть Injector. Не используйте соединитель BD PhaseSeal™ в качестве защитного колпачка для Luer-Lock системы BD PhaseSeal™. Герметичность мембраны снижается после нескольких проколов и длительного времени активации. При подключении Injector к дистальному концу линии для длительного внутривенного введения общее время активации Injector и соединителя не должно превышать 24 часа. Перед снятием Injector с соединителя перекройте систему для предотвращения попадания воздуха в организм.	Наберите в шприц соответствующий объем воздуха или необходимый объем растворителя Подсоедините Injector к шприцу или системе для введения	① НАЖАТЬ. Вставьте Injector в интерфейс ② ПОВЕРНУТЬ. Возьмите за крылья и поверните ③ НАЖАТЬ. Надавите до защелкивания	Выполните медикаментозное вливание	① ПОТЯНУТЬ. Отведите инжектор ② ПОВЕРНУТЬ. Возьмите за крылья и поверните против часовой стрелки. ③ ПОТЯНУТЬ. Потяните за инжектор для отсоединения интерфейса от соединителя.	выбросьте флакон, не отсоединяя от него присоедините систему BD PhaseSeal™.
SK Slovenčina – Návod na použitie BD PhaseSeal™ je uzatvorený systém na prenos liekov z liekovky pacientom. Injector Luer Lock určené na uzavretú prípravu a podávanie liekov na kompatibilnú s polypropylénom Luer Lock a s liekmi, ktoré nie sú kontraindikované na polypropylén (PP). Sterilné (etylénoxid). Sterilné v prípade neporušeného obalu. Používajte postupovanie a schválené postupy IV. Aby sa zabránilo kontaminácie nepoužívajte opätovne. Upozornenie: Pri potiahnutí injektora s liekom, ktoré majú silne vytiahnuť gumové tesnenie fliaš, sa uistite, že je injektor plne stlačený a je tiež vyrovnávanie tlaku. Nepoužívajte, ak sú ochranné kryty uvoľnené alebo posunuté. Pri použití systému BD PhaseSeal™ chyťajte vždy za biele časti. Nechystajte možnú časť miešania. Nepoužívajte konektor BD PhaseSeal™ Luer Lock ako ochranný kryt spolu s injektorom Luer Lock. Vplyv tesniaceho membránu je po viacerých perforáciách a dlhšej aktivačnej dobe znížený. Pred je injektor pripojený k distálnemu koncu infúznej línky v prípade infúzných infúzií, celková doba aktivácie injektora v konektore by nemala presahovať 24 hodín. Pred uvoľnením injektora z konektora stopka línky svorkou.	Vtiahnite objem vzduchu, rovnajúci sa objemu kvapaliny odobratej z fľaše alebo požadovanému objemu rozpúšťadla do injekčnej striekačky. Pripojte injektor k injekčnej striekačke alebo infúznej línke	① ZAŤAHNITE. Zatiahnite rotačnú časť na odpojenie ochranného rozhrania. ② OTOČTE. Uchopte za rukoväť a otočte. ③ ZAŤAHNITE. Zatiahnite smerom nadol.	Vykonajte prenos lieku.	① POTIAHNITE. Potiahnite rotačnú časť. ② OTOČTE. Uchopte za rukoväť a otočte. ③ POTIAHNITE. Potiahnite rotačnú časť, aby ste ho oddelili od prepojovacieho rozhrania.	Zlikvidujte bez odpojenia komponentov BD PhaseSeal™.
SL Slovenščina – Navodila za uporabo BD PhaseSeal™ je zaprt sistem za prenos zdravila iz viale/ampule do bolnika. Injektor Luer Lock je namenjen zaprti pripravi in odmerjanju zdravil. Združljiv z priključki Luer Lock in z zdravili, ki niso kontraindicirana za polipropilen (PP). Sterilno (etilen oksid). Sterilno, če embalaža ni poškodovana. Pri uporabi upoštevajte predpisane in sprejete postopke. Ponovna uporaba je lahek vir okužbe. Previdno! Pred vlečenjem zdravila v brizgo ali ponovnim polnjenjem brizge skozi gumijasti pokrovček preverite, da v viali ni podtlaka. Ne uporabljajte, če zaščitni pokrovčki niso dobro pritrjeni ali jih ni. Ko uporabljate sistem BD PhaseSeal™ vedno bodite pozorni na spremembe. Ne premaknite modrega dela injektorja. Sistema BD PhaseSeal™ Luer Lock ne uporabljajte kot zaščitni pokrov skupaj z injektorjem Luer Lock. Učinkovitost zaščitnega membrane se po več vbodih in večjem času aktivacije zmanjša. Kadar je injektor priključen na oddaljeni konec infuzijska za dolge ali ponavljajoče infuzije, skupni čas aktivacije injektorja in konektorja ne sme presegati 24 ur. Preden injektor odklopite od konektorja, najprej s sponko zaprite cevko za infuzijsko linijo.	V injekcijo potegnite toliko zraka, da ustreza odmerku ali potrebni količini redčila. Injektor priključite na brizgo ali infuzijsko linijo.	① POTISNITE. Potisnite injektor v priključni vmesnik. ② OBRNITE. Držite za ulomo in obrnite. ③ POTISNITE. Ali brizgo za potiskom navrtaki.	Nadaljujte s prenosom zdravila	① POVLECITE. Injektor potegnite za steklenico ② OBRNITE. Držite za ulomo in obrnite. ③ POVLECITE. Potegnite injektor in ga tako ločite od priključnega vmesnika	Komponente BD PhaseSeal™ pustite priključena in zavrzite steklenička
SV Svenska – Bruksanvisning BD PhaseSeal™ är ett slutet system för läkemedelsöverföring från flaska till patient. Injector Luer Lock avsedd för slutan beredning och administrering av läkemedel, i kompatibel med Luer Lock-anslutningar samt med läkemedel som inte är kontraindicerade för polypropylen (PP). Steril (etylenoxid). Steril i oskadad förpackad förpackning. Använd vedvanliga rutiner för intravenös administration. Återanvänd ej på grund av risk för kontaminationer. Försiktighetsåtgärder: Vid montering av Injector på läkemedelsflaskor med tjocka koniska gummiproppar – se till att Injector är helt intryckt och att tryckutjämningen fungerar. Använd inte om dryckslocken är lösa eller förskjutna. Håll alltid i de vita komponenterna när du använder med BD PhaseSeal™-systemet. Håll inte i den blå delen av Injector. Använd inte BD PhaseSeal™ Connector Luer Lock som skyddslock tillsammans med Injector Luer Lock. Membranets tätande egenskaper minskar med ökande antal perforeringar och längre aktiveringstid. När Injector används distalt på infusionsslang för långtidsinfusion, bör den totala tiden för sammankoppling av Injector och Connector ej överskrida 24 timmar. Stäng infusionsledningen stängklämmare innan borttagning av Injector från Connector.	Sprejgun komme dosa vsebuje ne manjša kot ustrezna količina zdravila ali potrebna količina redčila. Injektor s sprejgun vnesa infuzijsko hadlano.	① ITTIN. Injector v hadlano ena vzamnne rin. ② ČEVIRIN. Sajeni tutun ve cevrin. ③ ITTIN. Ione geçmnen için aşağı doğru run.	Bac transferine gerçekleştirin.	① ÇEKİN. Injector r oen cek in. ② ÇEVİRİN. Sabni tutun ve cevrin. ③ ÇEKİN. Bağlantı ayrıştırmak için Injector r cıkın.	BD PhaseSeal™ parçalarını ayırmadan atın.

VENDOR NOTES

All text and graphics print process black

Process Black

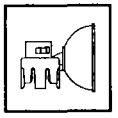
(b) (4) [redacted]

Status: Draft

(b) (4)

BD PhaSeal™
Protector (P21)

50



REF 515102

LOT

QTY: 50

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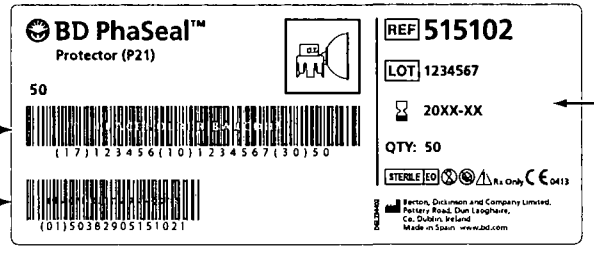
Co. Dublin, Ireland.
Made in Spain www.bd.com

REPRESENTATIVE GRAPHIC REV. 01
08/09/12
See the attached signature page

VENDOR INFO

HOLDING LINES DO NOT PRINT

PRINT BARCODE AS SHOWN



PRINT EXPIRATION DATE, MANUFACTURING DATE AND LOT NUMBER AS SHOWN

The attached graphics have been set up in a non variable and variable format as depicted. The printing supplier and final manufacturing printer may print all or any portion of the graphic as long as the complete graphic is in place at the completion of production. The following scenarios currently exist and are acceptable:

1. Outside printer to print entire label (variable and non variable).
2. Outside printer to print non variable and the Mfg site to print the balance.
3. Outside printer to print a given portion of the graphic and the Mfg site to print the balance.
4. Mfg site to print the entire label (variable and non variable).

[redacted]
Process Black

(b) (4)

(b) (4)

BD PhaSeal™
Protector (P21)

200

REF 515102

LOT

QTY: 200

STERILE EO Rx Only CE 0413

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Pottery Road, Dun Laoghaire,
Co. Dublin, Ireland.
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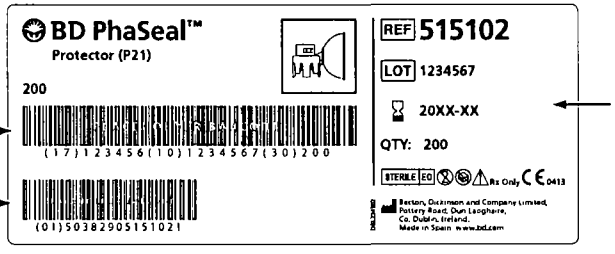
VENDOR INFO

HOLDING LINES.. DO NOT PRINT



PRINT BARCODE AS SHOWN

PRINT EXPIRATION DATE, MANUFACTURING DATE AND LOT NUMBER AS SHOWN

The attached graphics have been set up in a non variable and variable format as depicted. The printing supplier and final manufacturing printer may print all or any portion of the graphic as long as the complete graphic is in place at the completion of production. The following scenarios currently exist and are acceptable:

1. *Outside printer to print entire label (variable and non variable).*
2. *Outside printer to print non variable and the Mfg site to print the balance.*
3. *Outside printer to print a given portion of the graphic and the Mfg site to print the balance.*
4. *Mfg site to print the entire label (variable and non variable).*

[redacted]
Process Black

(b) (4)

(b) (4)

REPRESENTATIVE GRAPHIC REV.01
09/14/12
See the attached signature page

BD PhaSeal™

Manufacturer
Becton, Dickinson and Company Limited, Pottery Road, Dun Laoghaire, Co. Dublin, Ireland, www.bd.com

Protector

Protector (P14) | REF 515100
Protector (P21) | REF 515102
Protector (P21Multi)) | REF 515103
Protector (P28) | REF 515104
Protector (P50) | REF 515105
Protector (P50Multi)) | REF 515106

REF Catalogue number
LOT Batch code
Use by
Caution, consult accompanying documents
STERILE EO Sterilized using ethylene oxide
Do not use if package is damaged
Do not reuse
CE 0412

Material
PP
PE
Stainless steel
PA/PP
PTFE

	D1, H1	H2
P14	13 mm	ISO 8362 Part 1, 3 1.50+/-.06 mm
P21/ P28	20 mm	ISO 8362 Part 2 1.50+/-.06 mm
P50	28 mm	ISO 8362 Part 1, 3 1.50+/-.06 mm
P21/ P28	21 mm	ISO 8536 Part 1, 2, 3, 6 1.50+/-.06 mm

US only: P14, P21, P50

Protector will prevent microbial ingress for up to 168 hours when the system is used in an ISO Class V or greater environment, and when disinfected with 70% Isopropyl Alcohol or an alternate, validated disinfection method prior to attaching an Injector. (Excludes P28)

LANGUAGES	1	2	3	4	5	6	7
EN English – Instruction for use BD PhaSeal™ is a closed system for drug transfer from vial to patient. Protector intended for closed preparation of drugs. Compatible with standard vials with 13 mm, 20 mm and 28 mm neck, see D1 above and with drugs that are not contaminated for polypropylene (PP). Sterile (ethylene oxide). Sterile unless package is damaged. Use required and accessible IV Injector. Do not reuse to avoid contamination. Do not use if protective caps are loose or displaced. Always grip white components when using the BD PhaSeal™ system. Do not grip blue part of the Injector. When using drug vials with thick concave rubber stoppers make sure that the white parts of Protector and Injector are in contact and that the pressure equalization works. The performance of the sealing membrane is reduced after multiple perforations.	Remove the protection cap. Attach the Protector until it snaps on the vial	Draw a volume of air equivalent to the dose or required volume of diluent into the syringe. Connect the syringe to the Injector.	① PUSH. Push the Injector into the connection interface. ② TURN. Hold onto the grip and turn. ③ PUSH. Push down to engage.	Keeping the vial upright, push the air or the diluent into the vial. The expansion chamber will inflate.	Invert the system and withdraw the drug into the syringe. The expansion chamber will deflate.	① PULL. Pull the Injector back. ② TURN. Hold onto the grip and turn. ③ PULL. Pull the Injector to separate from the connection interface.	Dispose without disconnecting the BD PhaSeal™ components
CS Čeština – Návod k použití BD PhaSeal™ je uzavřený systém pro přenos léku z lékovky do pacienta. Protektor určený k uzavřené přípravě léků. Kompatibilní se standardními lékovými ams s hrdlem 13 mm, 20 mm a 28 mm, viz D1 výše, a s léčivy, která nejsou kontaminována pro polypropylen (PP). Sterilní (ethylenoxid). Sterilní, pokud není poškozen obal. Použijte požadovaný a schválený infuzní postup. Nepoužívejte opakovaně, aby se předešlo kontaminaci. Nepoužívejte, pokud jsou ochranné kryty uvolněné nebo chybí. Při používání dílčího systému BD PhaSeal™ vždy za bílé části. Nedotýkejte injektor za modrou část. Pokud používáte lékovky se silnou vydutou pryžovou zátkou, ujistěte se, že bílé části protektoru a injektoru jsou v kontaktu a vyrovnávání tlaku funguje. Po mnoha perforacích se vytvrdnutí těsnicí membrány sníží.	Sejměte ochranný kryt. Připojte protektor tak, aby zaklapl na lékovku.	Natáhněte do injekční stříkačky objem vzduchu, který odpovídá dávce, nebo požadovaný objem ředidla nebo rozpouštědla. Připojte stříkačku k injektoru.	① ZATLAČIT. Zatlačte injektor do připojovacího rozhraní. ② OTOČIT. Uchopte držadlo a otočte. ③ ZATLAČIT. Zatlačením systém aktivujte.	Držte lékovku ve svislé poloze a vtlačte vzduch nebo ředidlo do lékovky. Expanzní komora se nafoukne.	Systém převraťte a natáhněte lék do injekční stříkačky. Expanzní komora splasknе.	① VYTÁHNOUT. Vytáhněte injektor. ② OTOČIT. Uchopte držadlo a otočte. ③ VYTÁHNOUT. Vytáhněte injektor a odpojte ho od připojovacího rozhraní.	Lékovku zlikvidujte, aniž byste od ní odpojili části systému BD PhaSeal™
DA Dansk – Brugsanvisning BD PhaSeal™ er et lukket system for overførsel af lægemidler fra hætteglas til patient. Protector er beregnet til lukket administration af lægemidler. Kompatibel med standard hætteglas med 13mm, 20mm og 28mm hals, se D1 ovenfor, og med lægemidler, der ikke er kontamineret for polypropylen (PP). Steril (ætylen oxid). Steril, hvis indpakningen ikke er beskadiget. Anvend påkrævet og accepteret IV praksis. Må ikke genanvendes for at undgå kontaminering. Forholdsregel: Må ikke anvendes, hvis beskyttelseshætterne er løse eller forskudte. Tag altid fat i hvide komponenter ved brug af BD PhaSeal™-systemet. Tag ikke fat i blå del af Injector. Ved anvendelse af lægemiddelhætteglas med tykke, konkave gummiprapper skal man sikre sig, at de hvide dele på Protector og Injector er trykket sammen, og at tryksudligningen fungerer. Tætningsmembranens virkning reduceres efter adskillige perforeringer.	Fjern pæstyttelseshætten. Tryk Protector på, indtil den klikker fast på hætteglasset.	Træk en mængde luft ind i sprøjten, svarende til dosis eller påkrævet mængde fortyndingsmiddel. Tilslut sprøjten til Injector.	① TRYK. Tryk Injector ind i forbindelsesadapteren. ② DREJ. Hold fast i grebet og drej. ③ TRYK. Tryk nedad for at tilkoble.	Hætteglaset holdes opad, mens der trykkes luft eller fortyndingsmiddel ind i hætteglaset. Ekspansionskammeret fyldes med luft.	Vend systemet på hovedet og træk lægemidlet ind i sprøjten. Ekspansionskammeret tømmes for luft.	① TRÆK. Træk Injector tilbage. ② DREJ. Hold fast i grebet og drej. ③ TRÆK. Træk Injector for at fjerne den i fra forbindelsesadapteren.	Bortskaffes uden at skille BD PhaSeal™-komponenterne fra hinanden.
DE Deutsch – Gebrauchsanweisung BD PhaSeal™ ist ein geschlossenes System für den Medikamententransfer von der Flasche zum Patienten. Protector für die geschlossene Zubereitung von Arzneimitteln. Kompatibel mit allen standardmäßigen Arzneimittelflaschen mit einem 13 mm, 20 mm und 28 mm Halsdurchmesser siehe D1 oben) und mit Arzneimitteln, auf die keine Kontraindikationen für Polypropylen (PP) zutrifft. Steril (Ethylenoxid). Steril bei unbeschädigter Verpackung. Wenden Sie die erforderlichen und anerkannten IV-Verfahren an. Zur Vermeidung von Kontaminationen nicht wiederverwenden. Sicherheitshinweis: Nicht verwenden, wenn die Schutzkappen lose oder versetzt sind. Bitte immer die weißen Bereiche anfassen, wenn Sie mit dem BD PhaSeal™ System arbeiten. Der blaue Teil des Injectors darf nicht berührt werden. Bei Verwendung von Arzneimittelflaschen mit dicken konkaven Gummistopfen ist sicherzustellen, dass die weißen Teile vom Protector und Injector ineinander greifen und dass der Druckausgleich funktionieren. Die Leistung der Dispersionsmembran vermindert sich nach mehrmaligen Perforationen.	Nehmen Sie die Schutzkappe ab. Befestigen Sie den Protector, so dass er an der Flasche einrastet.	Ziehen Sie eine Luftmenge, die der Dosis oder der erforderlichen Menge Verdünnungsmittel entspricht, in die Spritze auf. Verbinden Sie die Spritze mit dem Injector.	① DRÜCKEN. Drücken Sie den Injector in die Verbindungsschnittstelle. ② DREHEN. Halten Sie den Griff und drehen Sie. ③ DRÜCKEN. Drücken Sie zum Einrasten nach unten.	Halten Sie die Flasche aufrecht und drücken Sie Luft oder Verdünnungsmittel in die Flasche. Die Druckkammer bläht sich auf.	Drehen Sie das System um und ziehen Sie das Medikament in die Spritze auf. Die Druckkammer wird entleert.	① ZIEHEN. Ziehen Sie den Injector zurück. ② DREHEN. Halten Sie den Griff und drehen Sie. ③ ZIEHEN. Ziehen Sie den Injector aus der Verbindungsschnittstelle.	Entsorgen Sie das System, ohne die BD PhaSeal™-Komponenten voneinander zu trennen.
EL Ελληνικά – Οδηγίες χρήσης Το BD PhaSeal™ είναι ένα κλειστό σύστημα για τη μεταφορά φαρμάκων από το φιαλίδιο στον ασθενή. Το εξάρτημα Protector προορίζεται για την κλειστή προετοιμασία φαρμάκων. Συμβατό με τυπικά φιαλίδια με λαιμό 13mm, 20mm και 28mm, δείτε το D1 παραπάνω και με φάρμακα που δεν αντενδείκνυνται για πολυπροπυλένιο (PP). Αποστειρωμένο (με αιθυλενοξείδιο). Αποστερεωμένο εφόσον η συσκευασία δεν έχει υποστεί ζημιά. Χρησιμοποιείτε την απαιτούμενη και αποδεκτή προσωπική ενδοφλέβια έγχυση (IV). Να μην επαναχρησιμοποιείται προς αποφυγή μόλυνσης. Παρεμβάλλεται: Να μην χρησιμοποιείται αν τα προστατευτικά πώματα είναι χαλαρά ή έχουν μετατοπιστεί. Κρατάτε πάντοτε τα λευκά τμήματα όταν χρησιμοποιείτε το σύστημα BD PhaSeal™. Μην κρατάτε το εξάρτημα Injector από το μπλε τμήμα. Όταν χρησιμοποιείτε φιαλίδια φαρμάκων με λαιμούς από παχύ καουτσούκ με κοίλο σχήμα, βεβαιωθείτε ότι τα λευκά τμήματα των εξαρτημάτων Protector και Injector είναι σε επαφή και ότι η εξισορρόπηση πίεσης λειτουργεί. Η απόδοση της μεμβράνης σφράγισης μειώνεται μετά από πολλαπλές διατρήσεις.	Αφαιρέστε το προστατευτικό πώμα. Προσαρμόστε το εξάρτημα Protector μέχρι να «κουμπώσει» στο φιαλίδιο.	Αντλήστε μια ποσότητα αέρα ανάλογου με τη δόση ή τον απαιτούμενο όγκο διαλυτικού. Συνδέστε τη σύριγγα στο εξάρτημα Injector.	① ΘΩΜΙΣΤΕ. Θώστε το εξάρτημα Injector στο μέσο διασύνδεσης. ② ΣΤΡΕΨΤΕ. Κρατήστε τη λαβή και στρέψτε. ③ ΘΩΜΙΣΤΕ. Πιέστε προς το κάτω για να ασφαλίσει.	Κρατώντας το φιαλίδιο σε όρθια θέση, πιέστε τον αέρα ή το διαλυτικό μέσα στο φιαλίδιο. Ο θάλαμος διαστολής θα διογκωθεί.	Αναστρέψτε το σύστημα και αποσύρετε το φάρμακο στη σύριγγα. Ο θάλαμος διαστολής θα ξεφουσκωθεί.	① ΤΡΑΒΗΞΤΕ. Τραβήξτε προς τα πίσω το εξάρτημα Injector. ② ΣΤΡΕΨΤΕ. Κρατήστε τη λαβή και στρέψτε. ③ ΤΡΑΒΗΞΤΕ. Τραβήξτε το εξάρτημα Injector για να διαχωριστεί από το μέσο σύνδεσης.	Απορρίπτετε χωρίς να αποσυνδέσετε τα μέρη του συστήματος BD PhaSeal™.
ES Español – Instrucciones de uso BD PhaSeal™ es un sistema cerrado para la transferencia de medicamentos del vial al paciente. El Protector está destinado a la preparación cerrada de medicamentos. Es compatible con viales estándar con cuello de 13 mm, 20 mm y 28 mm (véase D1 más arriba) y con medicamentos que no estén contraindicados para el uso con polipropileno (PP). Estéril (óxido de etileno). Estéril salvo que el envase esté dañado. Siga el procedimiento intravenoso requerido y aceptado. No reutilizar para evitar la contaminación. Atención: No utilizar si los capuchones de los protectores están sueltos o desplazados. Sostenga el sistema BD PhaSeal™ siempre por los componentes blancos. No sostenga el Injector por la parte azul. Al utilizar viales con tapón de goma cóncavo, asegúrese de que las partes blancas del Protector y el Injector estén en contacto y de que la ecualización de presiones funcione. Tras varias perforaciones, se reduce el rendimiento de la membrana de cierre.	Quite el tapón de protección. Conecte el Protector hasta que se acople al vial.	Aspire un volumen de aire equivalente a la dosis o el volumen de diluyente requerido en la jeringa. Conecte la jeringa al Injector.	① PRESIONE. Presione el Injector en la interfaz de conexión. ② GIRE. Sostenga el asa y gire. ③ PRESIONE. Presione hacia abajo para acoplar.	Con el vial en posición vertical, introduzca el aire o el diluyente en el vial. La cámara de expansión se inflará.	Invierta el sistema y cargue la jeringa con el medicamento. La cámara de expansión se desinflará.	① TIRE. Tire el Injector hacia atrás. ② GIRE. Sostenga el asa y gire. ③ TIRE. Tire el Injector para separarlo de la interfaz de conexión.	Deséchelo sin desconectar los componentes de BD PhaSeal™
ET Eesti – Kasutusjuhend BD PhaSeal™ on suletud süsteem ravimi ülekandmiseks viaalist patsiendile. Prootektor on ette nähtud ravimite lahustite ettevalmistamiseks. Sobib 13mm, 20mm ja 28mm kaelaga standardviaalidega, vt ülalpool D1, ja ravimitega, mis ei ole vastunäidustatud polüpropüleenile (PP). Steriilne (etüleenoksiid). Steriilne juhul, kui pakend pole vigastatud. Kasutage nõutavat ja heaks kiidetud IV sooritamisviisi. Saastumise vältimiseks ärge taaskasutage. Ettevaatust: Ärge kasutage, kui kaitsekorgid on lahti või kõrvale läinud. Kui kasutate BD PhaSeal™ süsteemi, hoidke alati lumn valgetest osadest. Ärge kunagi hoidke injektori sinist osa. Kui kasutate ravimviale koos paksuse nõgusate tumm-kummikorgiga, veenduge, et Prootektori ja Injektori valged osad on omavahel kontaktis ning et rõhuühtlustus töötab. Pärast mitmekordset läbistamist väheneb tulgevnimembraani efektiivsus.	Eemaldage kaitsekork. Ühendage Prootektor, kuni see naaldub ümbrealle pitskalsabb.	Tõmmake süstlasse vajalikku koguse lahjendaja või ravimi koguse ombu. Ühendage süstal Injektoriga.	① VAJUTAGE. Vajutage Injektor ühenduse liidesesse. ② KEERAKE. Hoidke vastavalt kohast lume ja keerake. ③ VAJUTAGE. Ühendamiseks vajutage see alla.	Suruge õhk või lahjendi viaali, hoides seda püstises asendis. Paisuamber täitub	Pöörake süsteem ümber ning tõmmake ravem tagasi süstlasse. Paisuamber tühjeneb.	① TÕMMAKE. Tõmmake Injektor tagasi. ② KEERAKE. Hoidke vastavalt kohast lume ja keerake. ③ TÕMMAKE. Ühendust lõdesest eemaldamiseks tõmmake Injektorit.	Visake jäätmete hulka ära BD PhaSeal™ osasid ülalnimetatud lahti ühendamata.
FI Suomi – Käyttöohje BD PhaSeal™ on suljettu järjestelmä lääkeaineiden siirtämiseen lääkepullosta potilaaseen. Paineentasaaja lääkkeineiden käsittelyyn suljetussa järjestelmässä. Soveltuu käytettäväksi normaalien 13 mm, 20 mm ja 28 mm x-mallisten lääkepullonsuiden kanssa, ks. D1 edellä, polypropyleenille (PP) vasta-aiheettomien lääkeaineiden suhteen. Steriili (etyleenioksidi). Steriili, mikäli pakkaus on ehjä. Käytettävä asianmukaisen ja hyväksytyn IV-käytännön mukaisesti. Tuotetta ei saa käyttää uudelleen kontaminaatioriskin vuoksi. Varoitustoimet: Tuotteita ei saa käyttää, jos suojukset ovat väljät tai pois paikaltaan. Pidä aina kiinni valkoisista osista, kun käsittelet BD PhaSeal™-järjestelmää. Älä pidä kiinni Neulansuojuksen sinisestä osasta. Jos lääkelaitevalossa on paksu kupeä kumituppa, varmista, että Paineentasaaja- ja Neulansuojuslaitteen valkoiset osat ovat kosketuksessa ja että paineentasaus toimii. Kalvosta alkaen toimenta heikentyy, kun kalvo puhkaistaan useamman kerran.	Poista suojus ontto. Liitä Paineentasaajaeliitin lukemuuksaan nan, että kuulet tunnen nastanhaluksen	Vedä ruiskuun annosta vastaava määrä ilmaa tai tarvittava määrä laimennnsta. Liitä ruisku Neulansuojus-laitteeseen.	① PAINA. Paina Neulansuojus Yhdistäjään. ② KIERRÄ. Pidä kiinni valkoisesta osasta ja kiierrä. ③ PAINA. Lukitse painamalla sitä alaspäin.	Pidä lääkelaitevalo pystyssä ja paina ilmaa tai laimennin lääkevialiin. Paineentasajan kammio täyttyy.	Käännä laitteisto ylösalaisin ja vedä lääkeaine ruiskuun. Paineentasajan kammio tyhjenyy	① VEDÄ. Vedä Neulansuojus-laitetta ulospäin ② KIERRÄ. Pidä kiinni valkoisesta osasta ja kiierrä ③ VEDÄ. Irrota Neulansuojus-kon Yhdistäjä-laitteesta vetamalla	Hävitä laitteesto irrottamatta BD PhaSeal™-järjestelmän osia lääkelaitevalosta tai ruiskusta.
FR Français – Mode d'emploi BD PhaSeal™ est un système clos pour le transfert de médicament du flacon au patient. Protecteur pour préparation de médicaments en système clos. Compatible avec les flacons standard dont le col a un diamètre de 13 mm, 20 mm et 28 mm, voir D1 ci-dessus, et avec les médicaments qui ne sont pas contre-indiqués pour le polypropylène (PP). Stérilisé à l'oxyde d'éthylène. Stérile sauf si le conditionnement est endommagé. Utilisez la méthode IV requise et acceptée. Ne pas réutiliser pour éviter la contamination. Précaution : Ne pas utiliser si les capuchons de protection sont desserrés ou déplacés. Saisissez toujours les composants blancs lorsque vous utilisez le système BD PhaSeal™. Ne saisissez pas la partie bleue de l'Injecteur. Lorsque vous utilisez des flacons de médicament avec des bouchons de caoutchouc épais et concaves, veillez à ce que les composants blancs du Protecteur et de l'Injecteur soient en contact et que l'égalisateur de pression fonctionne. La performance de la membrane est réduite après perforations multiples.	Enlevez le capuchon de protection. Enfoncez le Protecteur sur le flacon jusqu'au déclic.	Aspirez dans la seringue un volume d'air équivalent à la dose ou au volume de diluant requis. Raccordez la seringue à l'Injecteur.	① POUSSEZ. Poussez l'Injecteur dans l'interface de connexion. ② TOURNEZ. Maintenez la prise et tournez. ③ POUSSEZ. Poussez pour engager l'injecteur.	En maintenant le flacon verticalement, injectez le diluant ou l'air dans le flacon. La chambre d'expansion se gonfle.	Retournez le système et aspirez le médicament dans la seringue. La chambre d'expansion se dégonfle.	① TIREZ. Retirez l'injecteur. ② TOURNEZ. Maintenez la prise et tournez. ③ TIREZ. Déconnectez l'injecteur pour le détacher de l'interface de connexion.	Eliminez sans déconnecter les composants BD PhaSeal™.
HE עברית — הוראות שימוש BD PhaSeal™ הוא מערכת סגורה להעברת תרופה מהבקבוקון אל המטופל. מתאם להכנה סגורה של תרופות. תואם לבקבוקונים סטנדרטיים עם צוואר של 13 מ"מ, 20 מ"מ ו-28 מ"מ, ראה D1 לעיל, ולתרופות שאינן מוגבלות לשימוש עם פוליפרופילן (PP). סטרילי (באמצעות תחמוצת האתילן). סטרילי, אלא אם האריזה ניזוקה. יש להשתמש בשיטת IV הנדרשת והמקובלת. אין להשתמש שוב כדי למנוע זיהום. אזהרה: אין להשתמש אם מכסי המגן רופפים או הוסרו. יש לאחוז תמיד בחלקים הלבנים של המערכת BD PhaSeal™. אין לאחוז בחלק הכחול של המזרק (Injector). יש לוודא שחלקי המתאם (Protector) והמזרק הלבנים נמצאים במגע זה עם זה ושאיזון הלחצים פועל כראוי. יעילות קרום האיטום פוחתת לאחר מספר חדירות.	הסר את מכסה ההגנה. חבר את המתאם (Protector) עד שיינעל במקומו.	שאב אל תוך המזרק אוויר בנפח השווה לנפח המנה או לנפח הנדרש של חומר הדילול. חבר את המזרק למזרק (Injector).	① הזרקה. דחף את מזרק ההזרקה (Injector) אל ממשק החיבור. ② סיבוב. החזק במקום בעזרת הידית וסובב. ③ הזרקה. דחף כלפי מטה כדי להכניס.	השאר את הבקבוקון בתצוגה זקוף, דחף את האוויר או הדילול אל תוך הבקבוקון. הבקבוקון יתנפח.	חבר את המערכת והפוך את הבקבוקון. משוך את התרופה אל תוך המזרק.	① משוך. משוך את מזרק ההזרקה לאחור. ② סיבוב. החזק במקום בעזרת הידית וסובב. ③ משוך. משוך את מזרק ההזרקה כדי להפרידו ממשק החיבור.	השאר את מערכת BD PhaSeal™ מבלי לנתק את הרכיבים זה מזה.
HR Hrvatski – Uputa za uporabu BD PhaSeal™ je zatvoreni sustav za prijenos lijeka iz bočice do bolesnika. Prostetkor je namijenjen za pripremu lijekova u zatvorenom uvjetima. Kompatibilno sa standardnim bočicama s grlom promjera 13 mm, 20 mm i 28 mm, vidjeti D1 gore, te s lijekovima koji nisu kontraindicirani s polipropilen-hemom (PP). Sterilno (etilenov oksid). Sterilno ako nije oštećeno. Koristite potrebnu i prihvaćenu intravensku primjenu. Ne koristite ga ponovno i tako biste izbjegli kontaminaciju.. Mjere opreza: ne koristite ga ako su zaštitne kapice labave ili uklonjene. Kad koristite BD PhaSeal™ sistem, uvijek primite za bijele dijelove sistema. Ne primajte za plavi dio injektora. Kad koristite bočice s lijekom s debelim, konkavnim gumenim čepom, pobrinite se da se bijeli dijelovi prostetora i injektora dodiruju te da su tlakovi izjednačeni. Radna svojstva membrane za brtvljenje smanjuju se nakon višestrukih perforacija.	Uklonite zaštitni čep. Pričvrstite zaštitnu kapicu tako da klikne na bočici	U štrcaljku uvucite volumen zraka jednak dozi ili potrebnom volumenu otopine za razrjeđivanje. Povežite štrcaljku s injektor.	① GURNITE. Gurnite injektor u spojnu površinu. ② OKRENITE. Držite za držaj i okrenite. ③ GURNITE. Gurnite prema dolje dok se ne spoji.	Držite bocicu u uspravnom položaju i ubrizgajte zrak ili otopinu za razrjeđivanje u bočicu. Ekspanzijska komora će se napuhati.	Okrenite sustav i uvucite lijek u štrcaljku. Ekspanzijska komora će se ispuhati	① IZVUCITE. Povucite injektor unatrag. ② OKRENITE. Držite za držaj i okrenite. ③ POVUCITE. Povucite injektor kako biste ga odvojili od spojne površine.	Bocicu bacite bez razdvajanja komponenti BD PhaSeal™-a .
HU Magyar – Használati útmutató A BD PhaSeal™ zárt rendszerű gyógyszerátadási biztosít az ampulla felszívásától a betegbe való beadásig. A protektor célja a gyógyszerek zárt előkészítése. Szabványos, 13mm-es, 20mm-es és 28mm-es nyakú ampullákkal kompatibilis, lásd D1 fent, és olyan gyógyszerekkel használatos, melyekre nem áll fenn polipropilénre (PP) vonatkozó ellenjavallat. Steril (etilén-oxid). Sérülten csomagolás esetén steril. Az előírt és elfogadott IV gyakorlatot alkalmazza. Ne használja újra a kontaminációs megelőzése érdekében. Vigyázat: Ne használja, ha a védősapkak laza vagy hiányzik. A BD PhaSeal™ rendszer használata során mindig a fehér részeket fogja meg. Ne fogja meg az Injektor kék részét. Vattag, korkus gumiszoposval rendelkező gyógyszer ampullák használata esetén győződjön meg arról hogy a Protector és az Injector fehér részei érintkezznek, és a nyomás kiegyenlítés működik. Több perforáción keresztül a lezáró membrán teljesítménye romlik.	Távolítsa el a védőkupakot. Helyezze fel a Protectort úgy, hogy az a helyére pattanjon az ampullán.	Szívjon fel a adagnak vagy a szükséges hígításnak megfelelő mennyiségű levegőt a fecskendőbe. Csatlakoztassa a fecskendőt az Injectorhoz	① TOLJA BE. Tolja be az Injectort a csatlakorutató felületbe. ② FORDÍTSA EL. Fogja meg a markolatot, és fordítsa el ③ TOLJA BE. Nyomja le a rögzítéshez.	Az ampullát függőlegesen tartva nyomja be a levegőt vagy a hígítót az ampullába A táguló kamra feltöpdik.	Fordítsa át a rendszert és szívja fel a gyógyszert a fecskendőbe A táguló kamra leeresztődik.	① HUZZA KI. Húzza vissza az Injectort. ② FORDÍTSA EL. Fogja meg a markolatot, és fordítsa el ③ HUZZA KI. Húzza ki az Injectort a csatolófelületről történő elválasztás érdekében	A BD PhaSeal™ komponenset leválasztásuka nélkül dobja ki.

>>

VENDOR NOTES

All text and graphics print process black

Process Black

(b) (4)

(b) (4)

[redacted]

REPRESENTATIVE GRAPHIC REV.01
09/14/12
See the attached signature page

BD PhaseSeal™

Manufacturer
Becton, Dickinson and Company Limited, Pottery Road, Dun Laoghaire, Co. Dublin, Ireland, www.bd.com

Protector

Protector (P14) | REF 515100
Protector (P21) | REF 515102
Protector (P21Multi) | REF 515103
Protector (P28) | REF 515104
Protector (P50) | REF 515105
Protector (P50Multi) | REF 515106

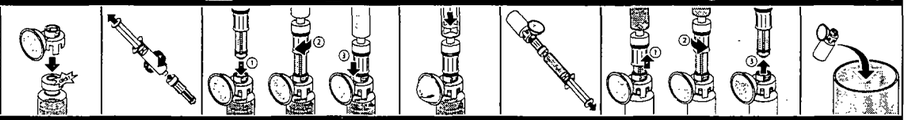
REF Catalogue number
LOT Batch code
Use-by
Caution, consult accompanying documents
STERILE EO Sterilized using ethylene oxide
Do not use if package is damaged
Do not reuse
CE 0413

Material
PP
PE
TPE
Stainless steel
PA/PP
PTFE

	D1	H1	H2
P14	13 mm	ISO 8362 Part 1.3	ISO 8362 Part 1.3 15~20 mm
P21/ P28	20 mm	ISO 8362 Part 2	ISO 8362 Part 1.3 30~40 mm
P28	28 mm	ISO 8362 Part 1.2.1a	ISO 8362 Part 1.2.1a 60~70 mm

US only: P14, P21, P50

Protector will prevent microbial ingress for up to 168 hours when the system is used in an ISO Class V or greater environment, and when disinfected with 70% Isopropyl Alcohol or an alternate, validated disinfection method prior to attaching an Injector. (Excludes P28)



LANGUAGES	1	2	3	4	5	6	7
IT Italiano – Istruzioni per l'uso	Rimuovere il tappo di protezione. Collegare il Protector finché non si [illegible] eliminare nella fiala con uno scatto	Aspirare nella siringa un volume di aria equivalente alla dose, oppure il volume di diluente necessario. Collegare la siringa all'Injector.	① PREMERE. Premere l'Injector nell'interfaccia di connessione. ② GIRARE. Afferrare l'impugnatura e girare. ③ PREMERE. Premere verso il basso per innestare	Mantenendo la fiala dritta, spingere l'aria o il diluente all'interno della fiala. La camera di espansione si gonfierà.	Capovolgere il sistema e aspirare il farmaco all'interno della siringa. La camera di espansione si sgonfierà.	① TIRARE. Tirare l'Injector all'indietro. ② GIRARE. Afferrare l'impugnatura e girare. ③ TIRARE. Tirare l'Injector per separarlo dall'interfaccia di connessione	Smaltire senza scollegare i componenti BD PhaseSeal™.
LT Lietuviškai – Naudojimo instrukcija	Nuimkite apsaugos dangtelį. Uždėkite prietaisą ir spauskite tol, kol jis užsifiksuos ant buteluko.	Įtraukite į švirkštą oro tiek, prilygstantį dozės kiekiui, arba reikiamą skiediklio kiekį. Prijunkite švirkštą prie injektoriaus.	① STUMKITĖ. Įstumkite injektorių į prijungimo sąsają ② PASUKITĖ. Laikykite už jungiamosios dalies ir sukite. ③ STUMKITĖ. Paspauskite, kad susijungtų.	Laikydami butelukų stačiai, įstumkite į jį orą arba skiediklį. Pietinos erme išsipūs.	Apverskite sistemą ir ištraukite vaistus į švirkštą. Pietinos erme susitrauks.	① TRAUKITĖ. Ištraukite injektorių. ② PASUKITĖ. Laikykite už jungiamosios dalies ir sukite. ③ TRAUKITĖ. Patraukite injektorių, kad atskirtumėte jį nuo prijungimo sąsajos.	Saliniste, neatjungdami BD PhaseSeal™ suvedamųjų dalių.
LV Latviešu – Lietošanas pamācība	Noņemiet aizsargvāciņu. Pieslēdziet antspiķa vai šļirces uzgali.	Ievelciet šļircē gaisu, kura daudzums ir ekvivalents devai vai atšķaidītāja nepieciešamajam daudzumam. Pievienojiet šļirci pie injektora.	① STUMT. Iestumiet injektora šļirci savienojošajā . ② PAGRIEZT. Turot šļirci horizontāli vertā, pagrieziet to. ③ STUMT. Pastumiet šļirci uz leju, lai to iskāztu.	Turot pudeliti taisni, iestumiet tajā gaisu vai atšķaidītāju. Izplešanās kamera paplešīsies	Apgrieziet sistēmu un ievelciet šļircē zāles. Izplešanās kamera saplaks.	① VILKT. Pavelciet injektora šļirci atpakaļ. ② PAGRIEZT. Turot šļirci horizontāli vertā, pagrieziet to. ③ VILKT. Pavelciet injektora šļirci, lai to atdalītu no savienojošās konstrukcijas	Likvidējiet pudeliti, neatvienojot BD PhaseSeal™ komponentus.
NL Nederlands – Gebruiksaanwijzing	Verwijder de beschermkap. Bevestig de Protector aan deze op de flacon klikt.	Trek een hoeveelheid lucht in de injectiespuit die overeenkomt met de dosis of de vereiste hoeveelheid verdunner. Sluit de injectiespuit aan op de Injector.	① DUW. Duw de Injector in de aansluiting ② DRAAI. Houd goed vast en draai. ③ DUW. Duw naar beneden om aan te sluiten.	Houd de flacon rechtop en duw de lucht of de verdunner in de flacon. De expansiekamer zal uitzetten	Keer het systeem om en trek het mengsel terug in de injectiespuit. De expansiekamer zal leeglopen	① TREK. Trek de Injector terug. ② DRAAI. Houd goed vast en draai. ③ TREK. Trek de Injector uit de aansluiting	Gooi weg zonder de BD PhaseSeal™-onderdelen los te maken
NO Norsk – Bruksanvisning	Fjern den beskyttende hetten	Trekk opp en luftmengde tilsvarende dosen eller det [illegible]	① TRYKK. Trykk inn i kontaktflaten: ② DRAI. Hold fast i grepet og vri. ③ TRYKK. Trykk nedover for å aktivere.	Hold hetteglasset oppreist, og trekk luften eller oppløsningsmidlet inn i hetteglasset. Ekspansjonskammeret tømmes.	Vend systemet opp ned og trekk opp legemidlet i sprøyten. Ekspansjonskammeret tømmes.	① DRA. Dra tilbake. [illegible] ② DRAI. Hold fast i grepet og vri. ③ DRA. Dra i for å skille den fra kontaktflaten.	Kaster uten å rokke fra BD PhaseSeal™-komponentene.
PL Polski – Instrukcja obsługi	Zdejmij osłonkę protektora. Wciśnij protektor na fiolkę do zatrzaśnięcia	Pobierz do strzykawki objętość powietrza równą dawce lub wymaganą objętość rozcieńczalnika. Podłącz strzykawkę do zestawu.	① WCIŚNIJ. Wcisnąć wkład do interfejsu złącza. ② OBRÓĆ. Chwyć za uchwyt i obróć. ③ WCIŚNIJ. Wcisnąć w dół do zaskoczenia	Trzymając fiolkę wyprostowaną wcisnąć rozcieńczalnik lub powietrze do fiolki. Komora rozszerzeniowa napełni się.	Odwróć system i pobierz lek do strzykawki. Komora rozszerzeniowa opróżni się.	① WYCIĄGNIJ. Wyciągnij inektor do góry. ② OBRÓĆ. Chwyć za uchwyt i obróć. ③ WYCIĄGNIJ. Wyciągnij inektor do rozdzielenia z interfejsem złącza	Zużytkuj bez odłączania elementów BD PhaseSeal™.
PT Português – Instruções para utilização	Retire a tampa de protecção. Fixe o Protector até encaixar no frasco.	Aspire um volume de ar equivalente à dose ou ao volume de diluente necessário para a seringa. Ligue a seringa ao injector	① EMPURRE. Empurre o injector para a interface de ligação. ② RODE. Segure a pega e rode. ③ EMPURRE. Pressione para baixo para encaixar.	Mantendo o frasco na vertical, empurre o ar ou o diluente para o interior do frasco. A câmara de expansão irá [illegible]se.	Inverta o sistema e retire o produto farmacêutico para o interior da seringa. A câmara de expansão irá esvaziar-se.	① PUXE. Puxe o injector para trás. ② RODE. Segure a pega e rode. ③ PUXE. Puxe o injector para separá-lo da interface de ligação.	Deite fora sem desligar os componentes BD PhaseSeal™.
RU Русский – Инструкция по применению	Снимите защитный колпачок. Наденьте предохранитель на флакон до [illegible]	Наберите в шприц соответствующую дозе препарата объем воздуха или необходимый объем растворителя. Подсоедините шприц к инжектору	① НАЖАТЬ. Вставьте инжектор в коннектор ② ПОВЕРНУТЬ. Возьмите инжектор за белую часть и поверните по часовой стрелке. ③ НАЖАТЬ. Надавите на инжектор до полного соединения с коннектором	Держа флакон с пробком вверх, впрыскните воздух в растворитель во флакон. Расширительная камера надуется.	Переверните флакон с двумя вверх и наберите препарат в шприц. Расширительная камера сдуется	① ПОТЯНИТЬ. Оттяните инжектор ② ПОВЕРНУТЬ. Возьмите инжектор за белую часть и поверните против часовой стрелки. ③ ПОТЯНИТЬ. Потяните за инжектор до полного отсоединения от коннектора	Выбросьте флакон, не отсоединяя от него компоненты BD PhaseSeal™.
SK Slovenčina – Návod na použitie	Odstráňte ochranný [illegible]. Pripojte chránič, pokým nezacvakne na fľaštičku s lekmi.	Vtiahnite do objem vzduchu rovnajúci sa dávke alebo požadovanému objemu riedidla do injekčnej striekačky. Pripojte injekčnú striekačku ku vstrekovaču.	① ZATLAČTE. Zatlačte vkladačku na pripojovacie rozhranie. ② OTOČTE. Uchopte za rukoväť a otočte. ③ ZATLAČTE. Zatlačte smerom nadol.	Fľaštičku s lekmi držte vzpriamene, vtlačte vzduch alebo riedidlo do fľaštičky s liekom. Expanzná komora sa nafúkne	Otočte systém a vtiahnite liek do injekčnej striekačky. Expanzná komora sa vypustí.	① POTIAHNITE. Potiahnite vstrekovač späť. ② OTOČTE. Uchopte za rukoväť a otočte. ③ POTIAHNITE. Potiahnite vstrekovač, aby ste ho oddelili od pripojovacieho rozhrania.	Zlikvidujte bez odpojenia komponentov BD PhaseSeal™.
SI Slovenščina – Navodila za uporabo	Odstranite zaščitni pokrov. Zaščitnik pritrdite na steklenico, da se zaskoči.	Vnesite toliko zraka, da ustreza odmerku ali potrebni količini redčila. Injekcijo pri tlačite na injektor.	① POTISNITE. Potisnite injektor v priključni vmesnik ② OBRNITE. Držite za ročaj in obrnite. ③ POTISNITE. Aktivirajte s potiskom navzdol.	Steklenička držite v pokončnem položaju, potisnite zrak ali redčilo v steklenička. Razširjena celica se bo napihnila	Sistem obrnite s steklenička navzgor in za seboj potegnite v injekcijo. Razširjena celica se bo splahnila.	① POVLECITE. Injektor potegnite iz steklenička ② OBRNITE. Držite za ročaje in obrnite. ③ POVLECITE. Povlecite injektor in ga tako ločite od priključnega vmesnika.	Komponente BD PhaseSeal™ pustite priklučene in zavrzite steklenička.
SV Svenska – Bruksanvisning	Ta bort dryddskyddet. Montera Protector tills den snappar på flaskan.	Fyll sprutan med en luftvolym motsvarande dosen eller med använd spädningsvätska enligt den koppla inop med Injector.	① TRYCK. Tryck injektor in i BD PhaseSeal™-kopplingen. ② VRID. Håll i greppet och vrid. ③ TRYCK. Tryck för att aktivera injektor.	Håll flaskan upprätt och spruta med spädningsvätska eller luft i flaskan. Expansionskammaren luftfylls.	Vänd systemet upp och ned och dra tillbaka läkemedlet i sprutan. Expansionskammaren töms på luft.	① DRA. Dra tillbaka injektor. ② VRID. Håll i greppet och vrid. ③ DRA. Lossa injektor från BD PhaseSeal™-kopplingen.	Avfallshanteras utan att koppla från BD PhaseSeal™-komponenter.
TR Türkçe – Kullanım Talimatları	Koruyucu kapağı çıkarın. Flakonun ağzına geçene kadar Protector'i kenek takın	Şırınganın içerisine doza eşdeğer bir miktarda hava veya gerekli miktarda seyreltici çekin. Şırıngayı Injector'a takın.	① İTİN. Injector'ı bağlantı ara yüzeyine itin. ② ÇEVİRİN. Sapını tutun ve çevirin. ③ İTİN. İğne geçmek için aşağı doğru itin.	Flakonu dik tutarak havayı veya seyreltiyi flakonun içine itin. Genleşme haznesi havayla dolacaktır	Sistemi ters çevirin ve ilacı şırınganın içine çekin. Genleşme haznesindeki hava boşalacaktır	① ÇEKİN. Injector'ı geri çekin. ② ÇEVİRİN. Sapını tutun ve çevirin. ③ ÇEKİN. Bağlantı ara yüzeyinden ayırmak için Injector'ı çekin.	BD PhaseSeal™ parçalarını ayırmadan atın

VENDOR NOTES

All text and graphics print process black

Process Black

(b) (4)

[redacted]

XII Sterilization and Shelf Life

This section is not applicable as the sterilization method and shelf life have not changed since the previous clearance of this device

XIV Biocompatibility

This section is not applicable as the materials of the device have not changed since the previous clearance of this device

XV. Software

This section is not applicable as there is no software associated with this device.

XVI. Electromagnetic Compatibility and Electrical Safety

This section is not applicable as there are no electrical components in this device.

XVII. Performance Testing - Bench

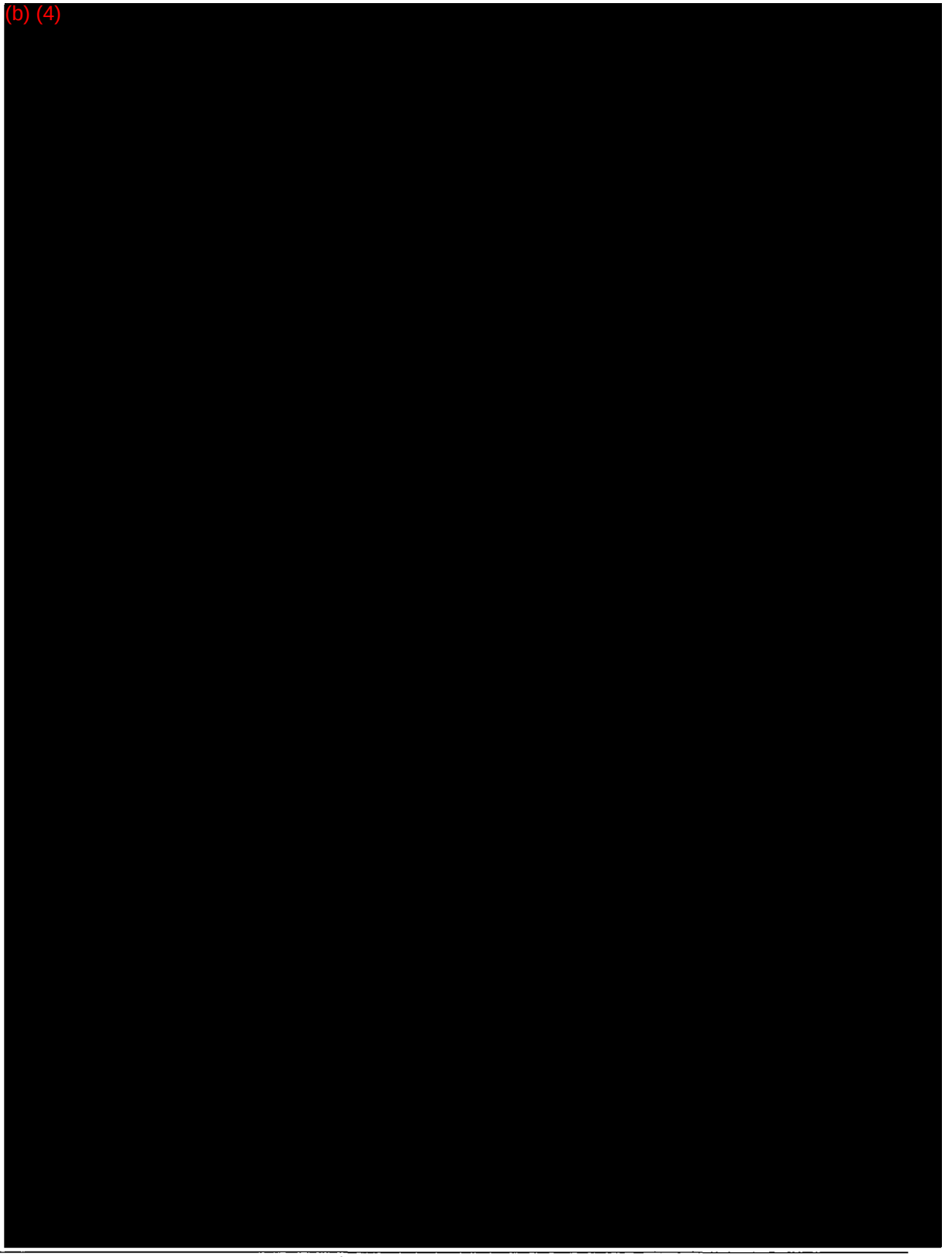
In Appendix III, please find two peer-reviewed publications as well as two Microbial Ingress studies (per FDA guidance) to support the airtight, leak proof and contaminate free requirements that are essential to ensuring healthcare worker safety when preparing and administering hazardous drugs.

1. Spivey S, Connor T. "Determining sources of workplace contamination with antineoplastic drugs and comparing conventional IV drug preparation with a closed system." *Hosp Pharm.* 2003; 38(2): 135-139.
2. Jorgenson J, Spivey S, Au C et al. "Contamination comparison of transfer devices intended for handling hazardous drugs." *Hosp Pharm.* 2008; 43(9): 723-727

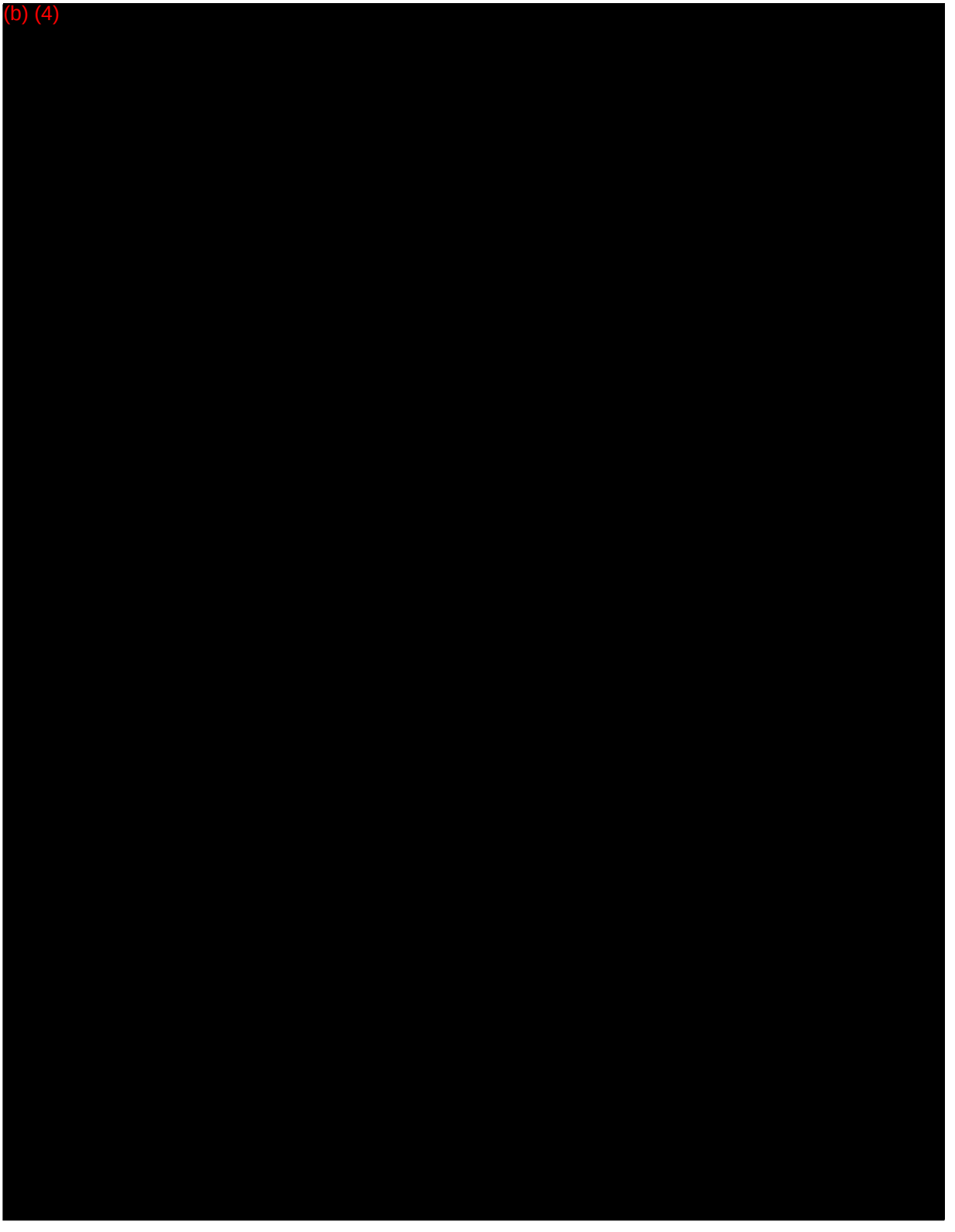
(b) (4) [redacted]

(b) (4) [redacted]

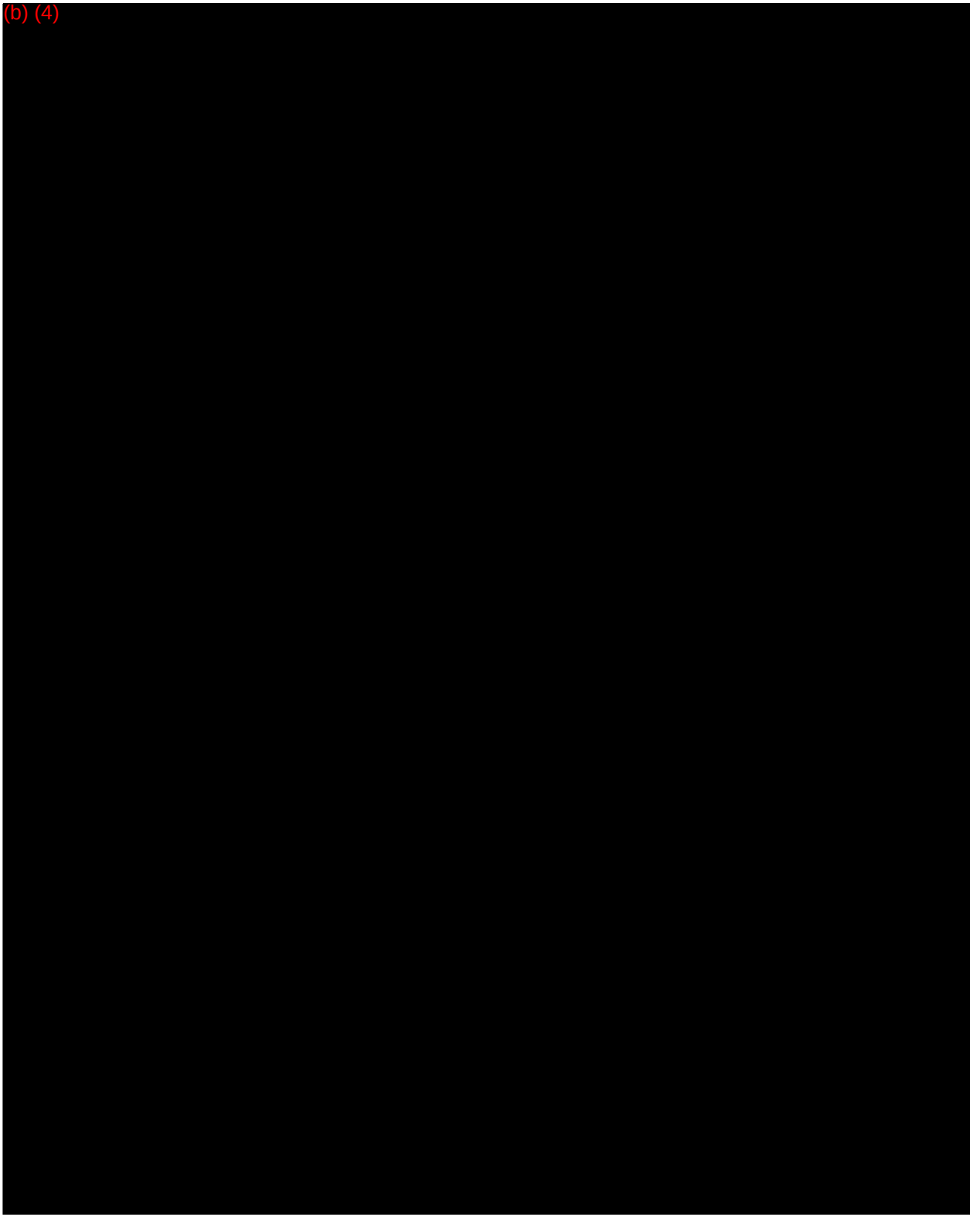
(b) (4)



(b) (4)



(b) (4)



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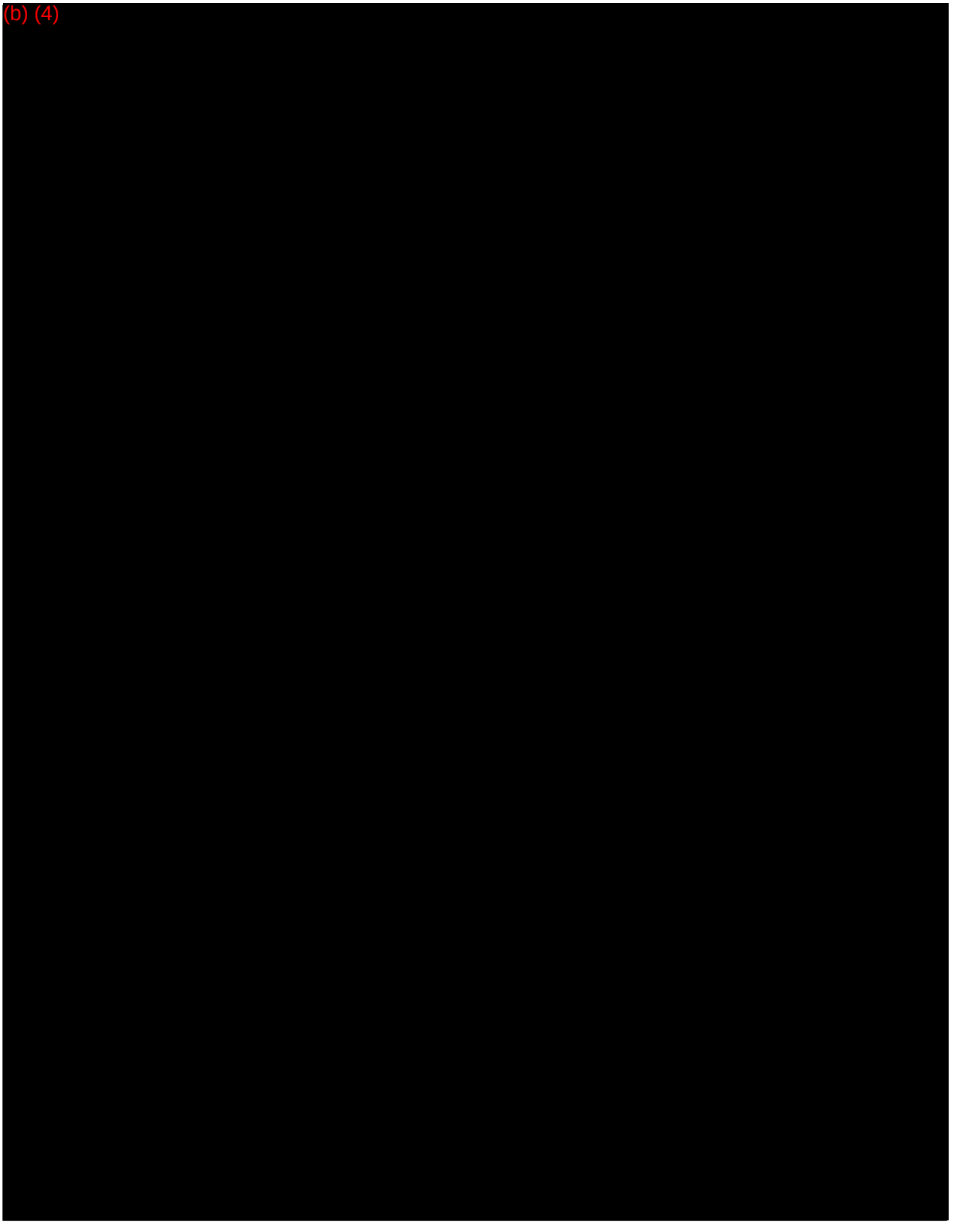

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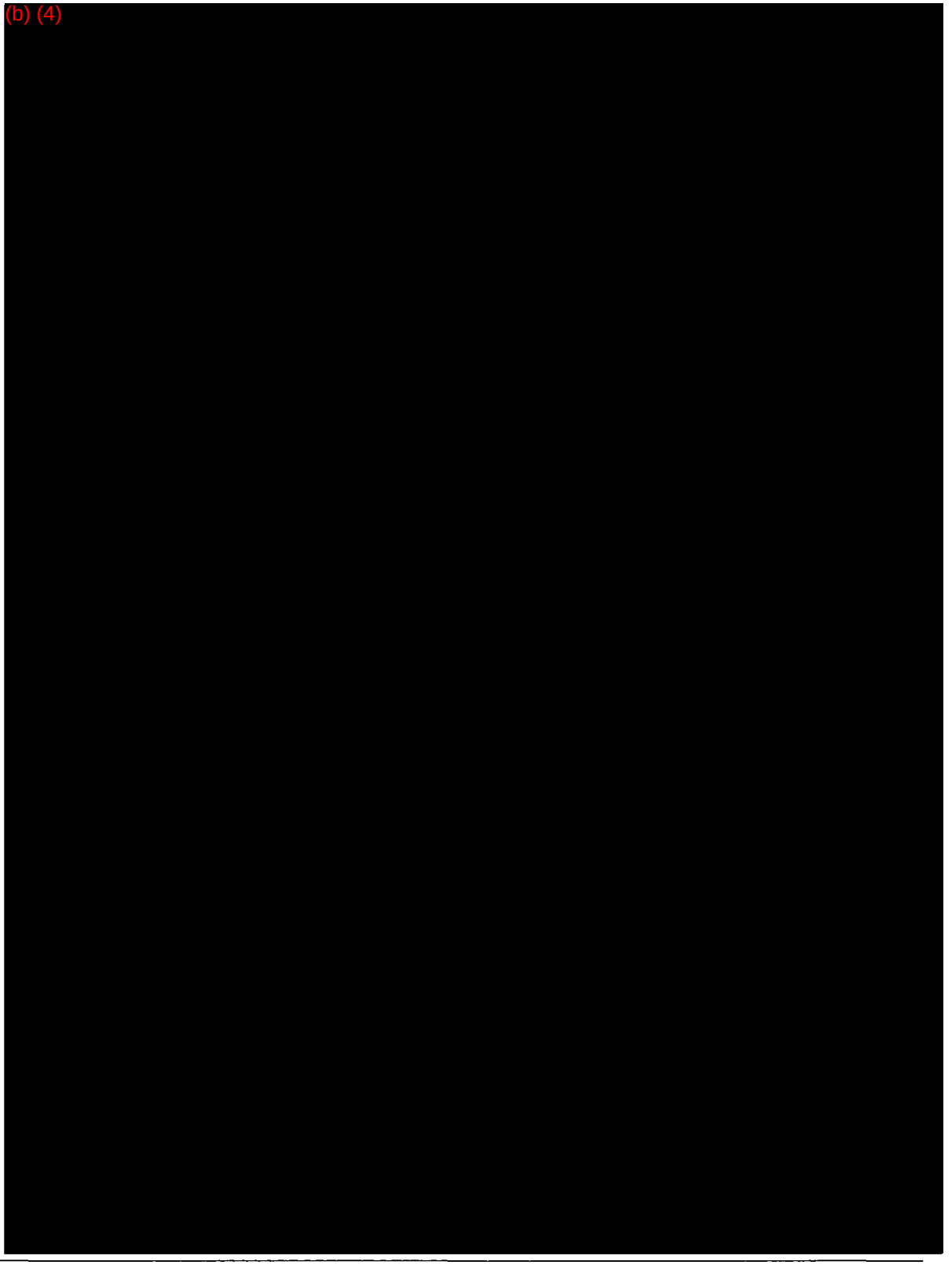

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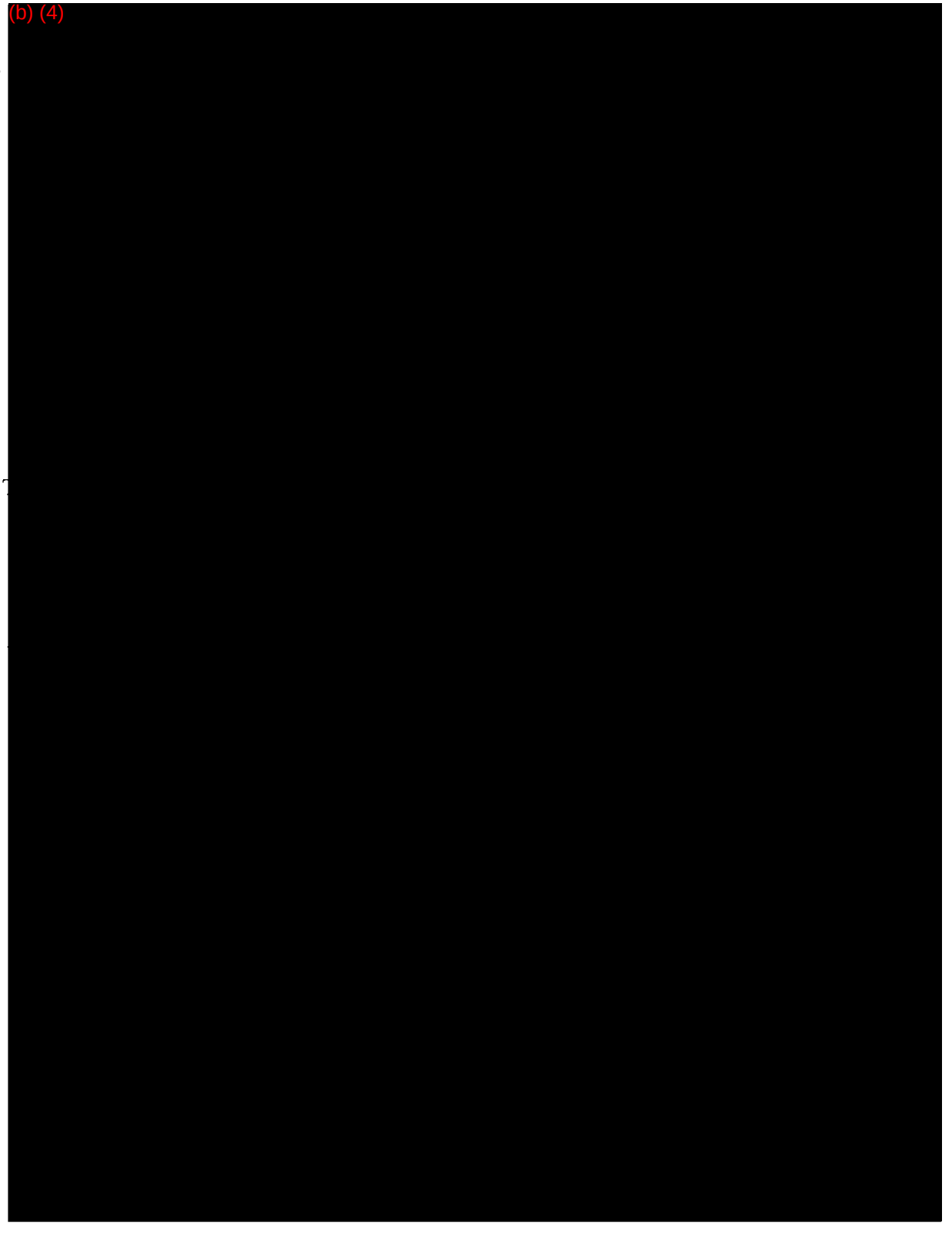

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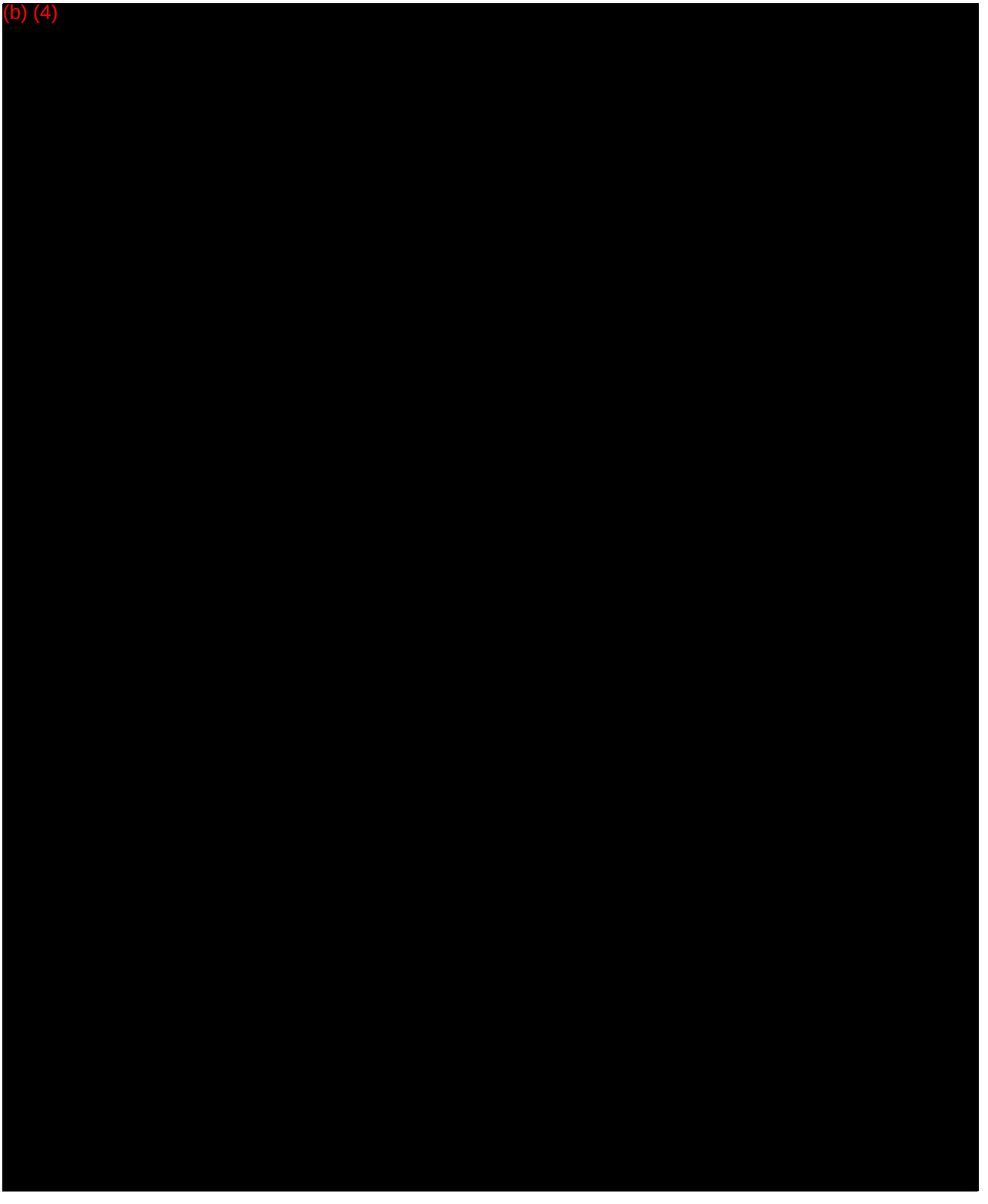

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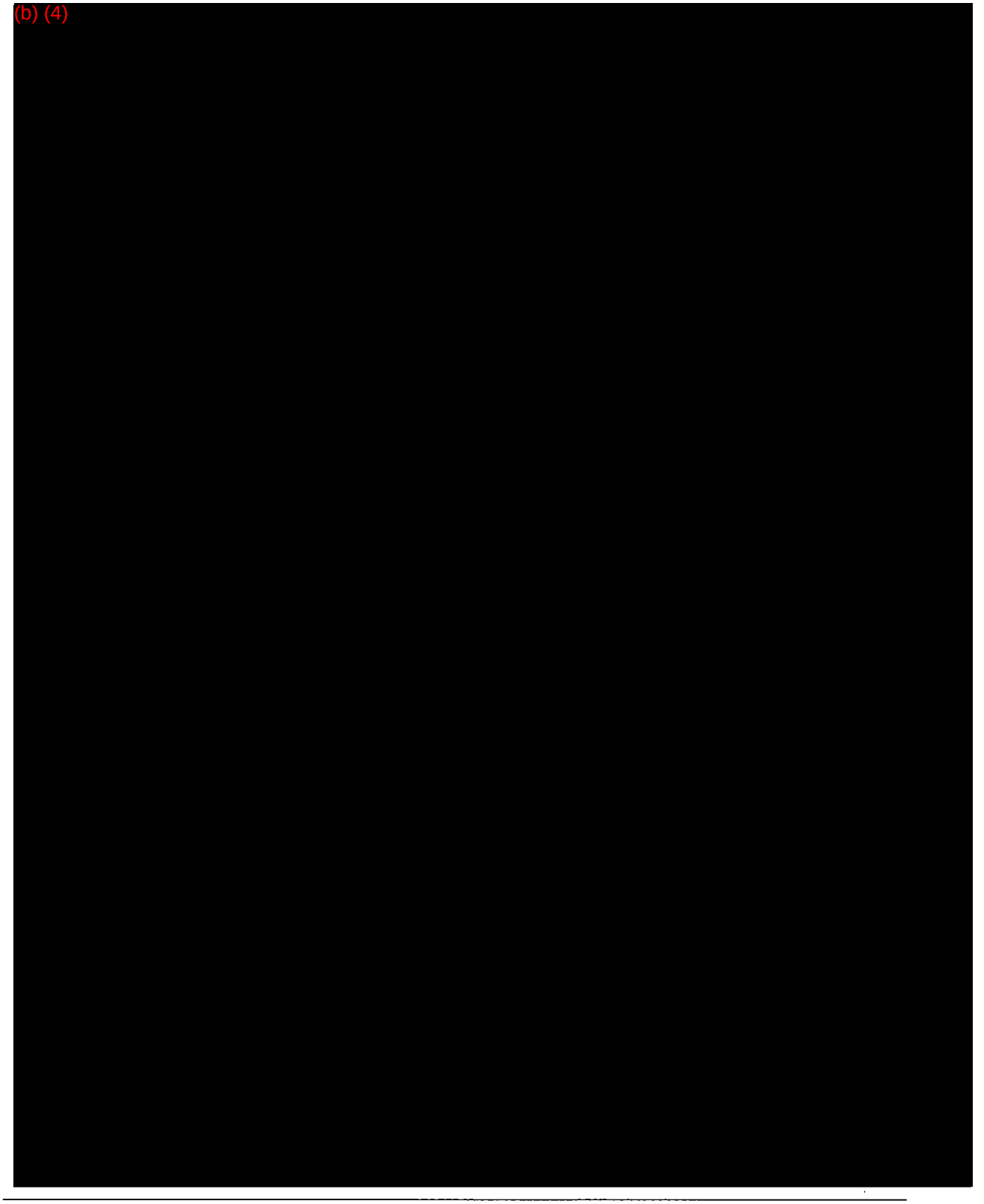


XVIII. Performance Testing - Animal

This section is not applicable as there are no animal studies associated with this submission.

XIX. Performance Testing - Clinical

This section is not applicable as there are no clinical studies associated with this submission.

Appendix I

1. 510(k) number K972527 Clearance Letter
2. 510(k) number K980381 Clearance Letter
3. 510(k) number K001368 Clearance Letter
4. 510(k) number K023747 Clearance Letter
5. 510(k) number K060866 Clearance Letter
6. 510(k) number K090634 Clearance Letter
7. 510(k) number K092782 Clearance Letter
8. 510(k) number K110023 Clearance Letter

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Fred Schlador
Consultant
Quality System Consulting
C/O Carmel Pharma AB
1425 Cressa Court
Carlsbad, California 92009

SEP 18 1997

Re: K972527
Trade Name: PhaSeal™ System For Sealed Handling Of Chemotherapeutic AG
Regulatory Class: II
Product Code: LHI
Dated: June 30, 1997
Received: July 7, 1997

Dear Mr. Schlador:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

27. Indications for Use Statement:

510(k) Number (if known): K972527

Device Name: **PhaSeal®** closed system for the preparation and administration of parenteral drugs

Indications for Use:

PhaSeal Protector 20 - Drug Vial Transfer Adapter
The Protector 20 is fitted to the drug vial and is used as a docking station between the drug vial for the parenteral drug and Injector Luer. In addition the Protector 20 equilibrates the pressure difference which occurs when fluid or air is added or removed from the drug vial. Liquid transfer takes place through tightly fitting elastomeric membranes to minimize exposure to potentially hazardous drug aerosols and spills that can occur during the reconstitution, administration and disposal processes.

PhaSeal Injector Luer – Drug Transfer Needle Device
The Injector Luer has an encapsulated cannula that is permanently locked onto a syringe using a Luer fitting. Sealed transfer of diluent, drug or air, between the single-use syringe and the various components in the system can be made via the Injector Luer in both the preparation and administration phases.

PhaSeal Connector Luer-Lock – Luer Lock Device
The Connector Luer Lock ensures a sealed connection between the single-use syringe and Injector Luer and the patient's IV line. With the help of the Connector Luer Lock, injections can be made without drug spillage.

PhaSeal Infusion Set - Intravascular Administration Set
The Infusion Set is a non-vented infusion device that has a built-in connector to be used as a way of making additions of parenteral drugs to infusion fluids in a closed system. The Infusion Set may be used to administer the infusion fluid.

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

Concurrence of CDRH, Office of Device Evaluation

Patricia Cascante

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K972527

Prescription Use ____ OR Over the Counter Use ✓
(Per 21 CFR 801.109)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Britt Novén
Manager, Regulatory Affairs
Carmel Pharma AB
Box 5352
S-402 28 Göteborg, Sweden

MAR - 3 1998

Re: K980381
Trade Name: PhaSeal® closed system for the preparation and administration of parenteral drugs
Regulatory Class: II
Product Code: LHI
Dated: January 30, 1998
Received: February 2, 1998

Dear Mr. Novén:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does

not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

27. Indications for Use Statement:

510(k) Number (if known): _____

Device Name: **PhaSeal®** *closed system for the preparation and administration of parenteral drugs*

Indications for Use:

PhaSeal Infusion Adapter - Intravascular Administration Set
The **Infusion Adapter** serves as the connecting part between the IV bag and an external IV line. (Example IV regulators.) The **Infusion Adapter** has a built in Connector which makes it possible to admix drugs into the infusion solution using the sealed double membrane technique.

PhaSeal Protection Cap – Special accessories
The **Protection Cap** is intended to be used as a mechanical cover for the membrane in the bayonet fitting of PhaSeal devices The Protection Cap mates with the other PhaSeal components equipped with the bayonet fitting. One end of the Protection Cap has a male bayonet fitting and in the other a female bayonet fitting.

PhaSeal Secondary Set – Intravascular Administration Set
The Secondary Set is a non-vented infusion set used when drug is handled as an admixture and is administered via Intravenous infusion. The Secondary Set has a built in Connector which makes it possible to admix drugs into the infusion solution using the sealed PhaSeal technique.

PhaSeal Extension Set - Intravascular Administration Set
The Extension Set serves as the port for bolus injection with PhaSeal if there is no Luer Lock fitting, for Connector Luer Lock in the patients IV line. The Extension Set has a built in Connector which makes it possible inject drugs into the IV line of the patient using the sealed double membrane technique.

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

_____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K980381

Prescription Use ✓ OR Over the Counter Use _____
(Per 21 CFR 801.109)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 12 2000

Kjel Andreasson
Head of Quality Assurance and
Regulatory Affairs Department
Carmel Pharma AB
Box 5352
SE-402 28 Göteborg, SWEDEN

Re: K001368
Trade Name: Protector 21, Protector 50, Protector 14, Injection Luer Lock, and Infusion Adapter
Regulatory Class: II
Product Code: LHI
Dated: April 25, 2000
Received: May 1, 2000

Dear Sir/Madam Andreasson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of

the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K001368

Exhibit 3 - Indications for Use Statement

Device Name: **PhaSeal®** - a System for Closed handling of Parenteral Drugs

PhaSeal Protector 21 - Drug Vial Transfer Adapter
The **Protector 21** is fitted to the drug vial and is used as a docking station between the drug vial for the parenteral drug and Injector. In addition the Protector equilibrates the pressure difference which occurs when fluid or air is added or removed from the drug vial. Liquid transfer takes place through tightly fitting elastomeric membranes to minimize exposure to potentially hazardous drug aerosols and spills that can occur during the reconstitution, administration and disposal processes.

PhaSeal Protector 50 - Drug Vial Transfer Adapter
The **Protector 50** is fitted to the drug vial and is used as a docking station between the drug vial for the parenteral drug and Injector. In addition the Protector equilibrates the pressure difference which occurs when fluid or air is added or removed from the drug vial. Liquid transfer takes place through tightly fitting elastomeric membranes to minimize exposure to potentially hazardous drug aerosols and spills that can occur during the reconstitution, administration and disposal processes.

PhaSeal Protector 14 - Drug Vial Transfer Adapter
The **Protector 14** is fitted to the drug vial and is used as a docking station between the drug vial for the parenteral drug and Injector. In addition the Protector equilibrates the pressure difference which occurs when fluid or air is added or removed from the drug vial. Liquid transfer takes place through tightly fitting elastomeric membranes to minimize exposure to potentially hazardous drug aerosols and spills that can occur during the reconstitution, administration and disposal processes.

PhaSeal Injector Luer Lock – Drug Transfer Needle Device
The **Injector Luer Lock** is designed with an encapsulated single lumen cannula which can be assembled to an external device equipped with Luer lock fitting, such as a disposable syringe or an IV administration set of the users choice. The other end of Injector Luer Lock is sealed with a thermoplastic elastomeric membrane. The bayonet fitting allows the two elastomeric membranes to be mated together. Sealed transfer between the various components of the system can be made via the Injector Luer Lock in the preparation phase as well as the administration phase.

PhaSeal Infusion Adapter – Intravascular Administration Set
The **Infusion Adapter** serves as the connecting part between the IV bag and an external IV line (example IV regulators). The **Infusion Adapter** has a built-in Connector which makes it possible to admix drugs into the infusion solution using the sealed double membrane technique.

Patricia Cusanti
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K001368

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 5 2002

Mr. Kjell Andreasson
Vice President, QA/RA
Carmel Pharma AB
Box 5352
SE-402 28 Göteborg,
SWEDEN

Re: K023747
Trade/Device Name: PhaSeal®
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: LHI
Dated: November 1, 2002
Received: November 8, 2002

Dear Mr. Andreasson:

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

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

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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K023747

Exhibit 3 - Indications for Use Statement

Device Name: **PhaSeal®** - a System for Closed handling of Parenteral Drugs

Infusion Adapter

The **Infusion Adapter** serves as a the connecting part between the IV bag and an external IV line (e.g. IV regulators). The **Infusion Adapter** has a built in Connector which makes it possible to admix drugs into the infusion solution using the sealed PhaSeal double membrane technique.

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K023747

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 28 2006

Mr. Kjell Andreasson
Vice President Quality Assurance and Regulatory Affairs
Carmel Pharma AB
Aminogatan 30, Molndal, Box 5352
Goteborg, Sweden SE 402 28

Re: K060866
Trade/Device Name: **PhaSeal Y-Site Line**-Intravascular Administration Set
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: LHI
Dated: March 27, 2006
Received: March 30, 2006

Dear Mr. Andreasson:

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

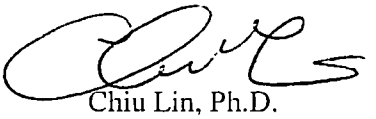
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit 3

Indications for Use

510(k) Number (if known): K060866

Device name: **PhaSeal Y-site Line** – Intravascular Administration Set

Indications for use:
The Y-site Line serves as the port for IV administration with PhaSeal if there is no Luer Lock fitting, for Connector Luer Lock in the patients IV line. The Y-site Line has a built in Connector which makes it possible to administer drugs into the IV line of the patient using the sealed double membrane technique.

Prescription Use: Yes (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use: No (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device evaluation (ODE)

Anthony D. [illegible]
[illegible], Hematology, General Hospital,
[illegible] Dental Devices
K060866

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 3 2009

Mr. Kjell Andreasson
President Quality Assurance and Regulatory Affairs
Carmel Pharma AB
Box 5352
SE 402 28 Goteborg
SWEDEN

Re: K090634
Trade/Device Name: Protector P14, P21, P28 and P50
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: LHI
Dated: February 20, 2009
Received: March 9, 2009

Dear Mr. Andreasson:

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

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

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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Ginette Y. Michaud, M.D.

Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 1

Indications for Use Statement

510(k) Number (if known)

Device Name Protector P14, P21, P28 and P50

Indications for Use The indication for use is reconstitution and transfer of drug solutions from one container to another while minimizing exposure to potentially hazardous drugs aerosols and spills that can occur during the reconstitution, administration and disposal process.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: Yes OR Over-The-Counter Use: No
(Per 21 CFR 801. 109)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K090634

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

Mr. Kjell Andreasson
President Quality Assurance and Regulatory Affairs
Carmel Pharma AB
Aminogatan 30
SE 431 53 Molndal
SWEDEN

DEC - 7 2009

Re: K092782
Trade/Device Name: Injector Luer N34
Injector Luer Lock N35
Injector Luer Lock N35C
Connector Luer Lock C35
Connector Luer Lock C45
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: LHI
Dated: September 4, 2009
Received: September 10, 2009

Dear Mr. Andreasson:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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

Sincerely yours,

For

Susan Runner, D.D.S., M.A.
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 1

Indications for Use Statement

510(k) Number (if known)

Device Name: Injector Luer N34
Injector Luer Lock N35
Injector Luer Lock N35C
Connector Luer Look C35
Connector Luer Lock C45

Indications for Use: The indication for use of the PhaSeal system and included components are reconstitution and transfer of drug solutions from one container to another while minimizing exposure to potentially hazardous drugs aerosols and spills that can occur during the reconstitution, administration and disposal process.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: Yes (Per 21 CFR 801.109) OR Over-The-Counter Use: No

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K092732

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Mr. Kjell Andreasson
Manager, Regulatory Affairs
Carmel Pharma AB
Aminogatan 30
Mölndal
SWEDEN S431 53

APR 12 2011

Re: K110023
Trade/Device Name: Infusion Adapter C100
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: LHI
Dated: March 1, 2011
Received: March 8, 2011

Dear Mr. Andreasson:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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

Sincerely yours,

for

Anthony Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 1

Indications for Use Statement

510(k) Number (if known)	K110023
Device Name	Infusion Adapter C100
Indications for Use	The indication for use is admixing of drug into an IV container and administration/transfer of drug from the container to an external IV line, while minimizing exposure to potentially hazardous drugs aerosols and spills that can occur during the admixing, administration and disposal process.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: Yes (Per 21 CFR 801. 109) OR Over-The-Counter Use: No

4/8/11

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
510(k) Number: K110023

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

SEP 12 2012

Mr. John Roberts
Regulatory Affairs Specialist
Becton, Dickinson and Company - Medical Surgical Systems
1 Becton Drive
Franklin Lakes, New Jersey 07417

Re: K120384
Trade/Device Name: PhaSeal® - A Closed System Transfer Device
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: LHI
Dated: August 23, 2012
Received: August 24, 2012

Dear Mr. Roberts:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to *premarket notification" (21CFR Part 807.97). For questions regarding the reporting of* adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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

Sincerely yours,

For

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use Statement

510(k) Number (if known): _____

Device Name: PhaSeal® – A Closed System Transfer Device

Indications for Use:

The PhaSeal system is a closed system drug transfer device (CSTD) that mechanically prohibits the transfer of environmental contaminants into the system and the escape of drug or vapor concentrations outside the system, thereby minimizing individual and environmental exposure to drug vapor, aerosols and spills. The PhaSeal Protector also prevents microbial ingress.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page __ of ___

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K120384

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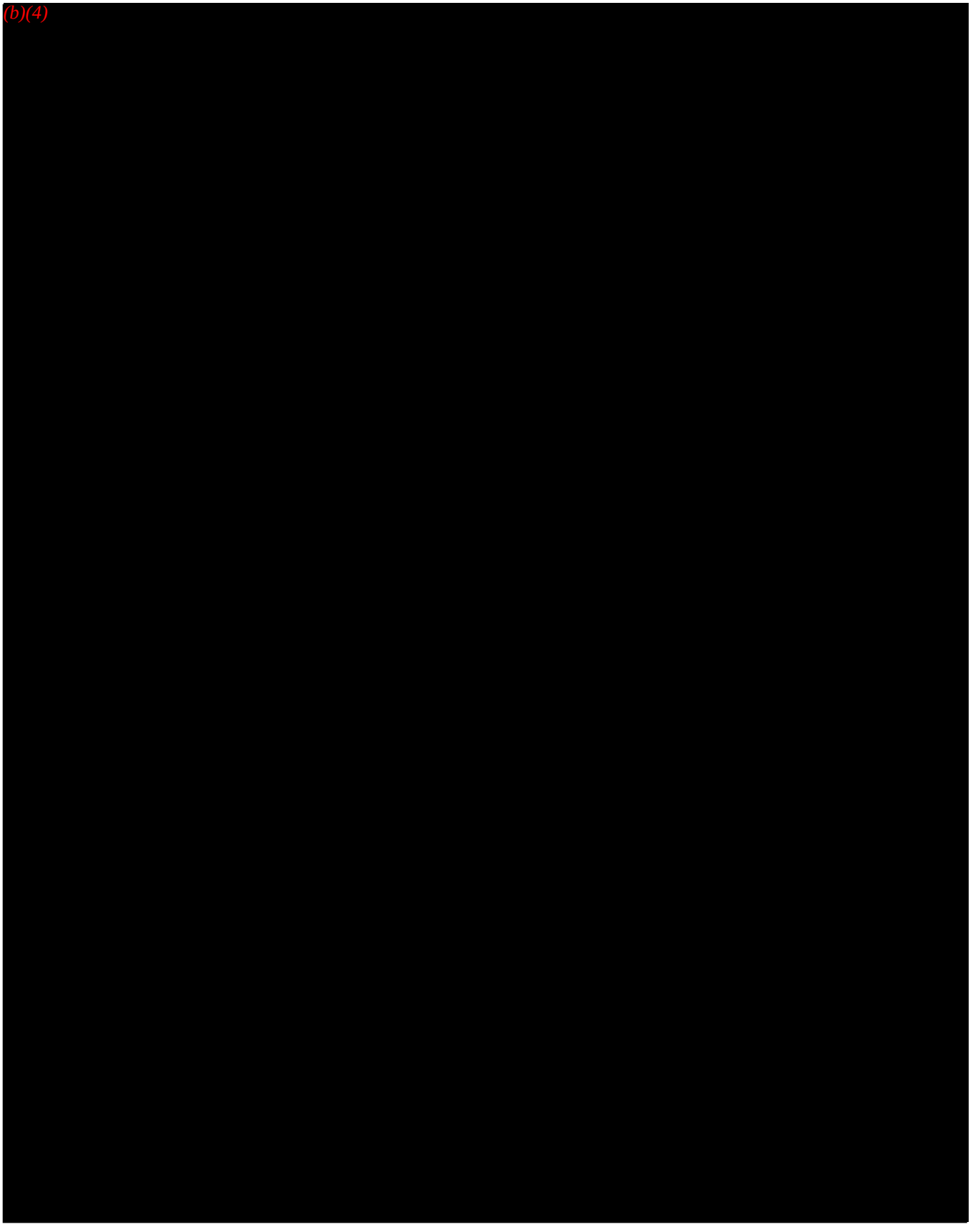

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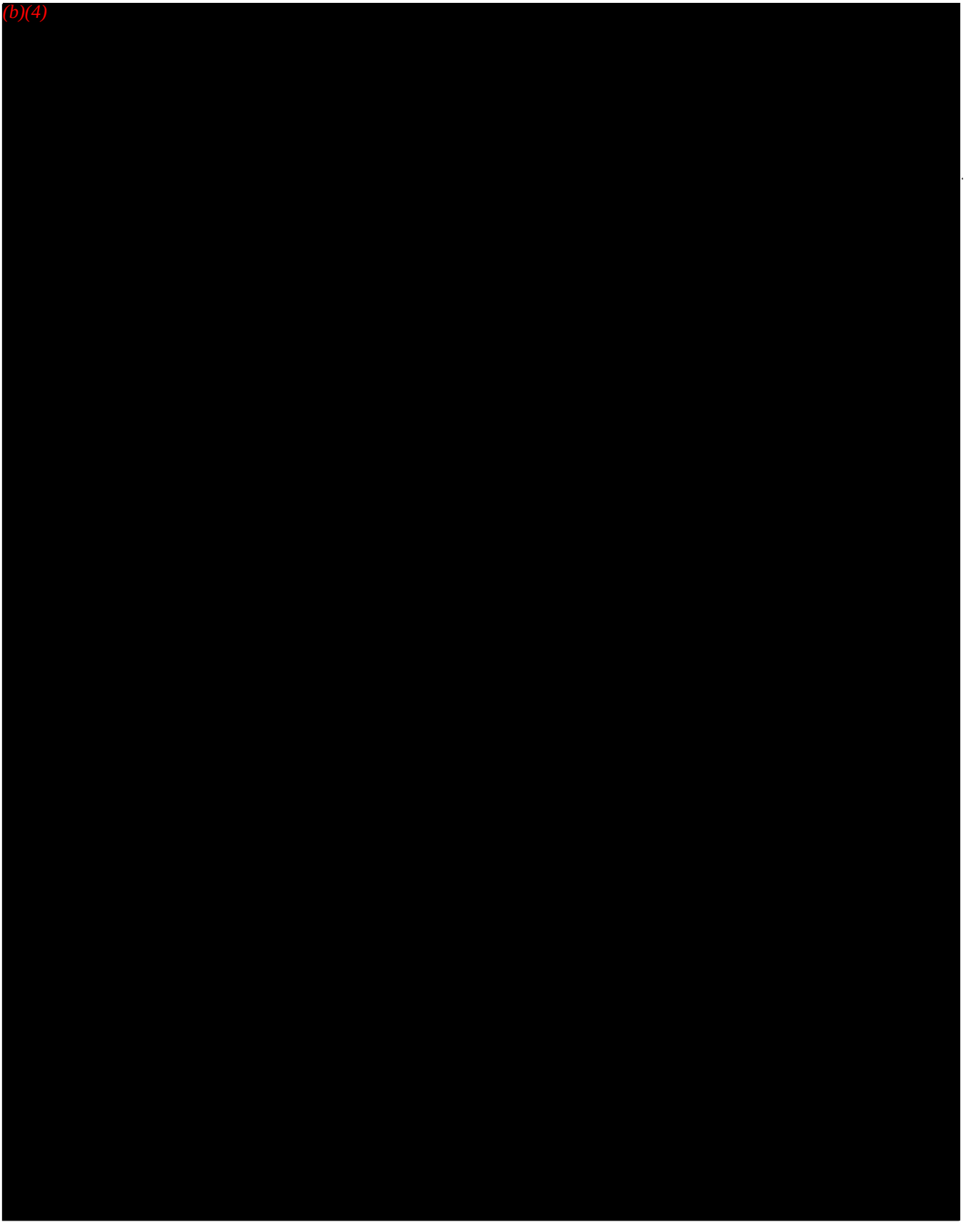

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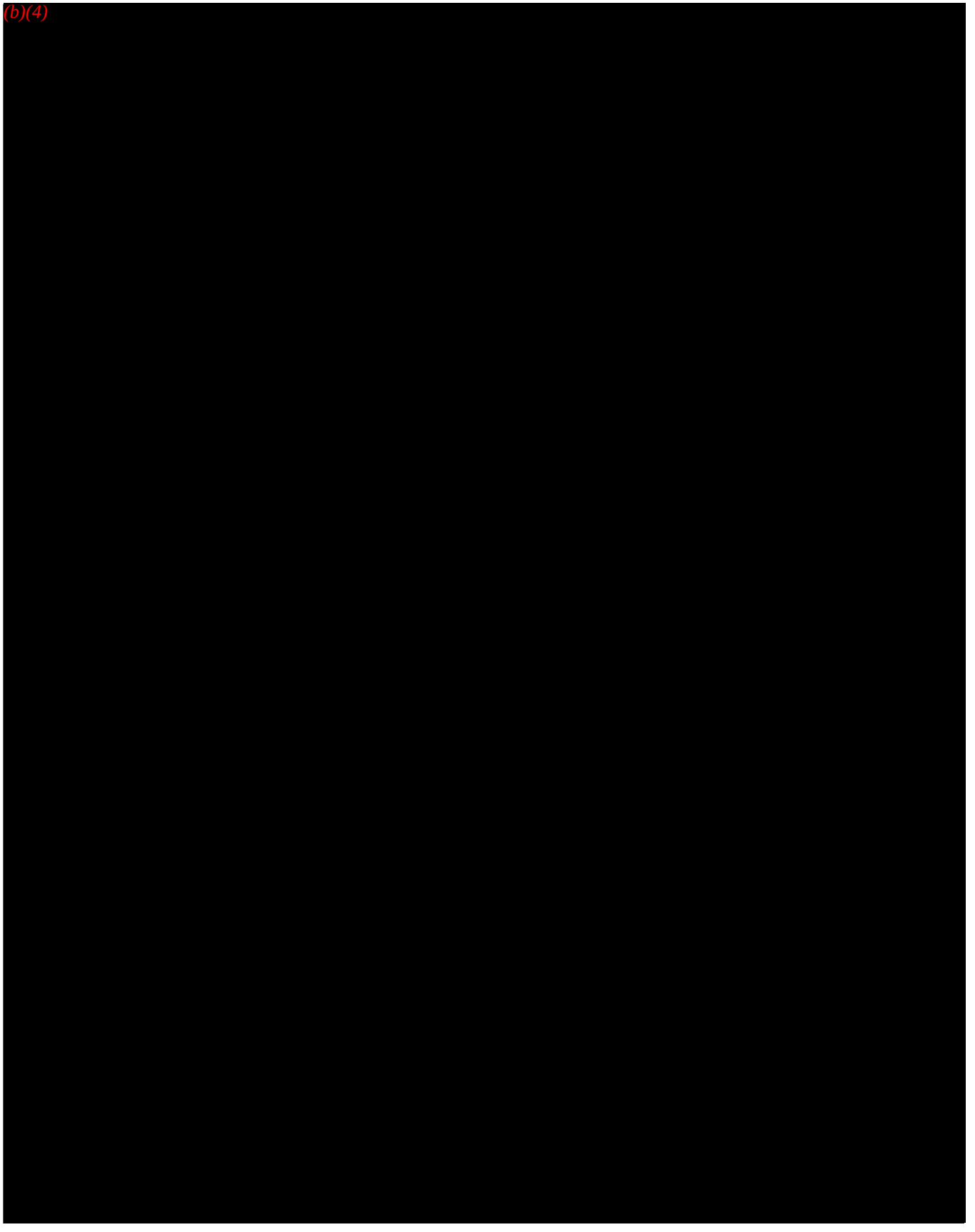

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Appendix III

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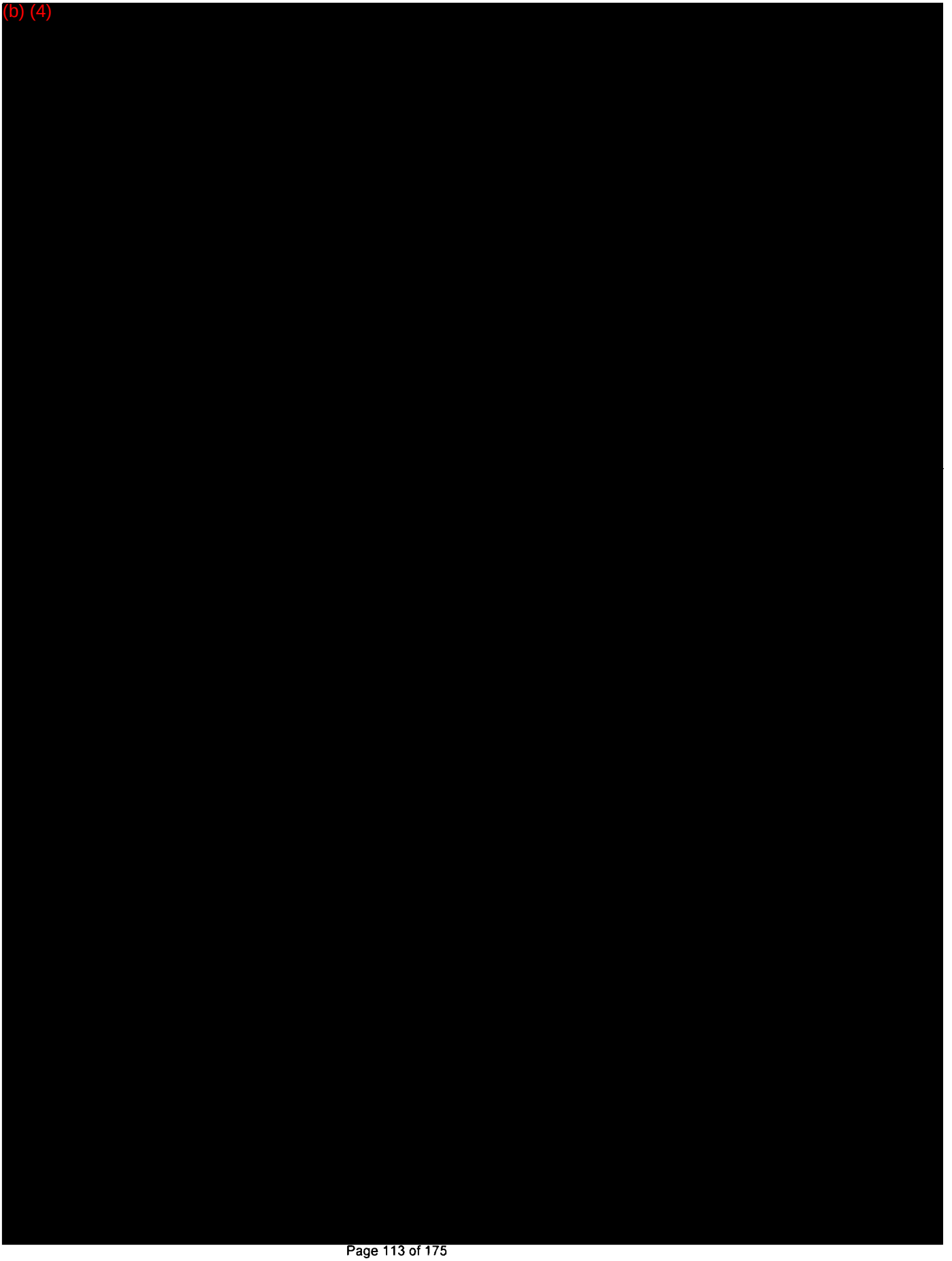

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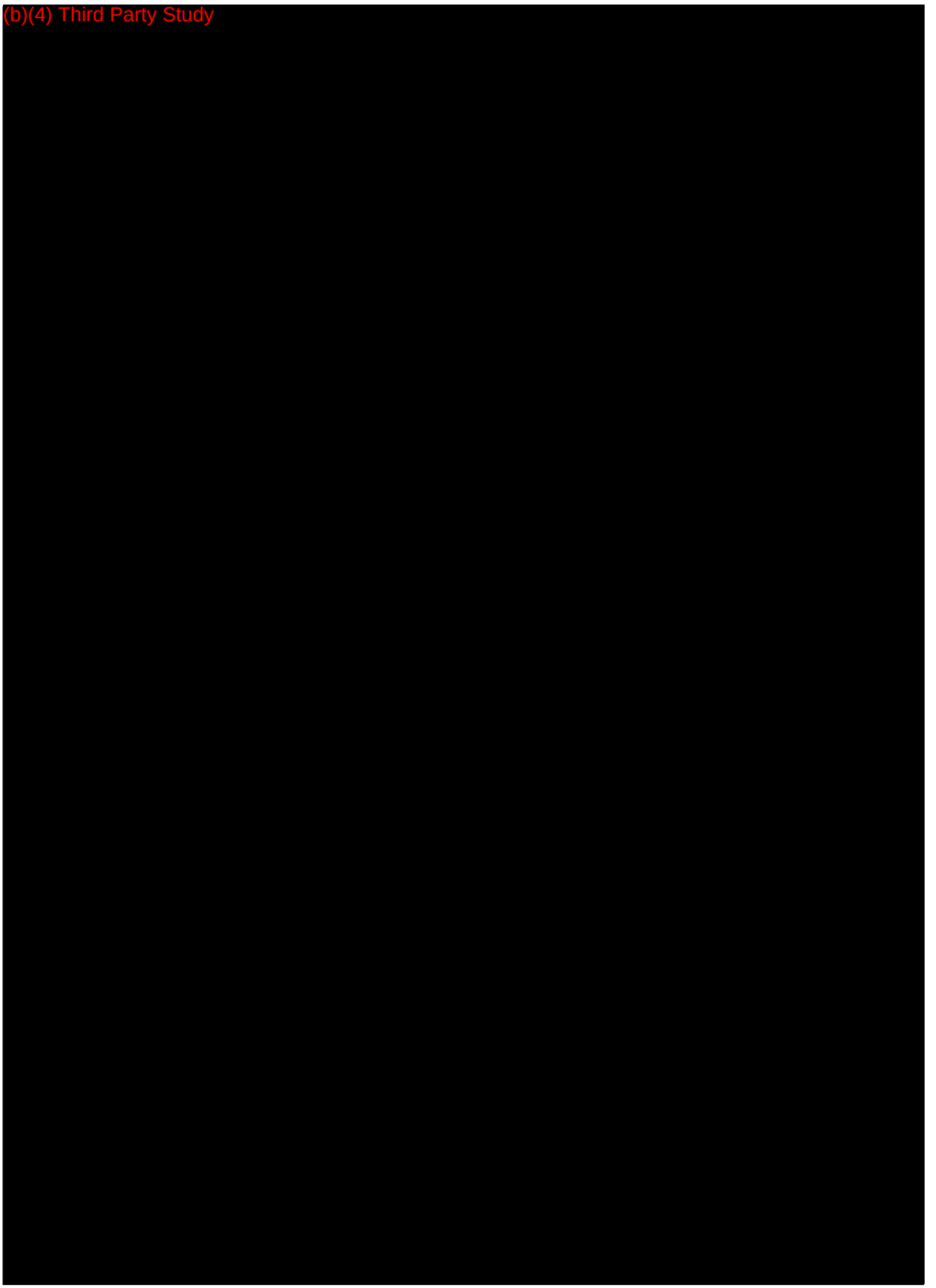

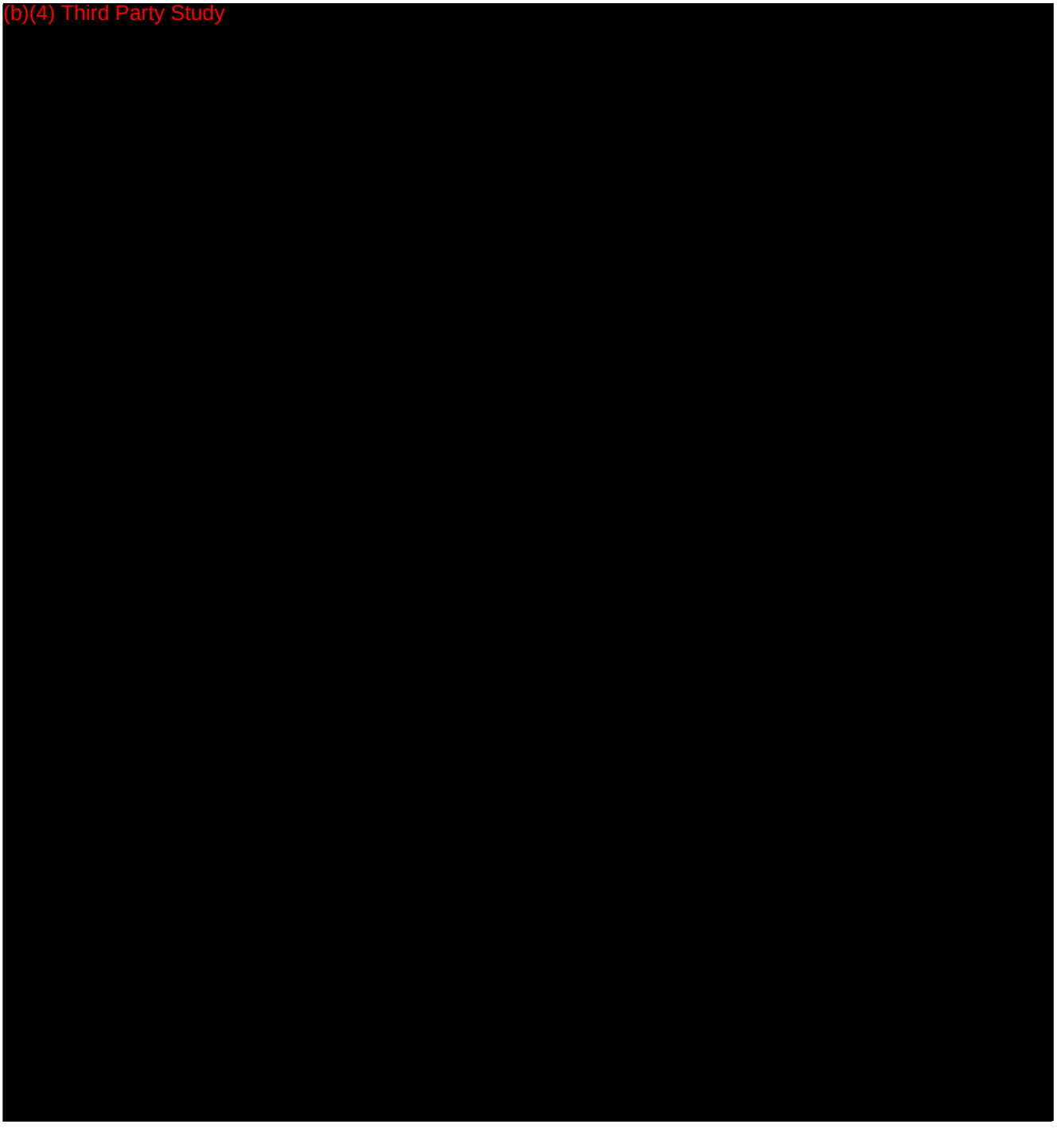

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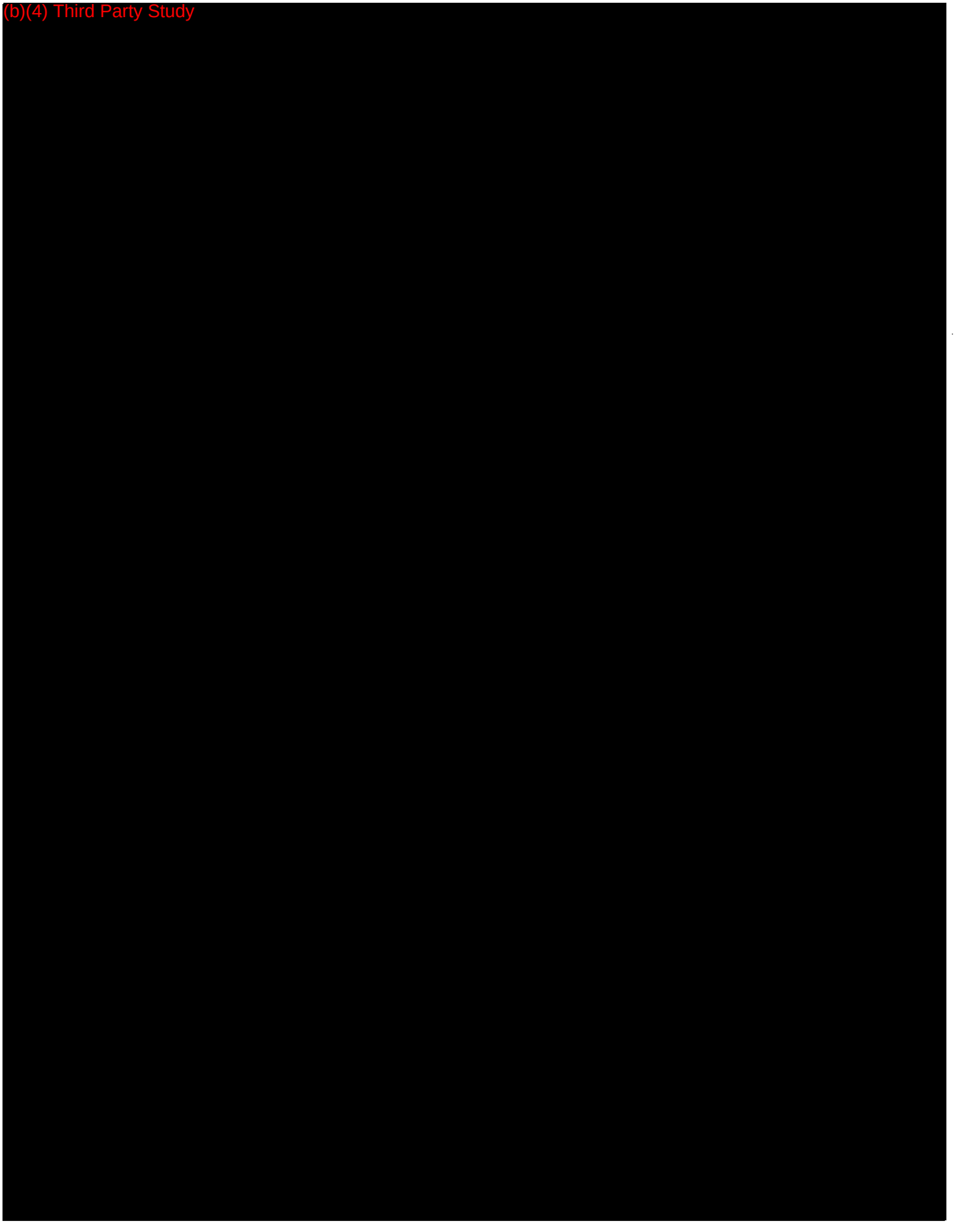

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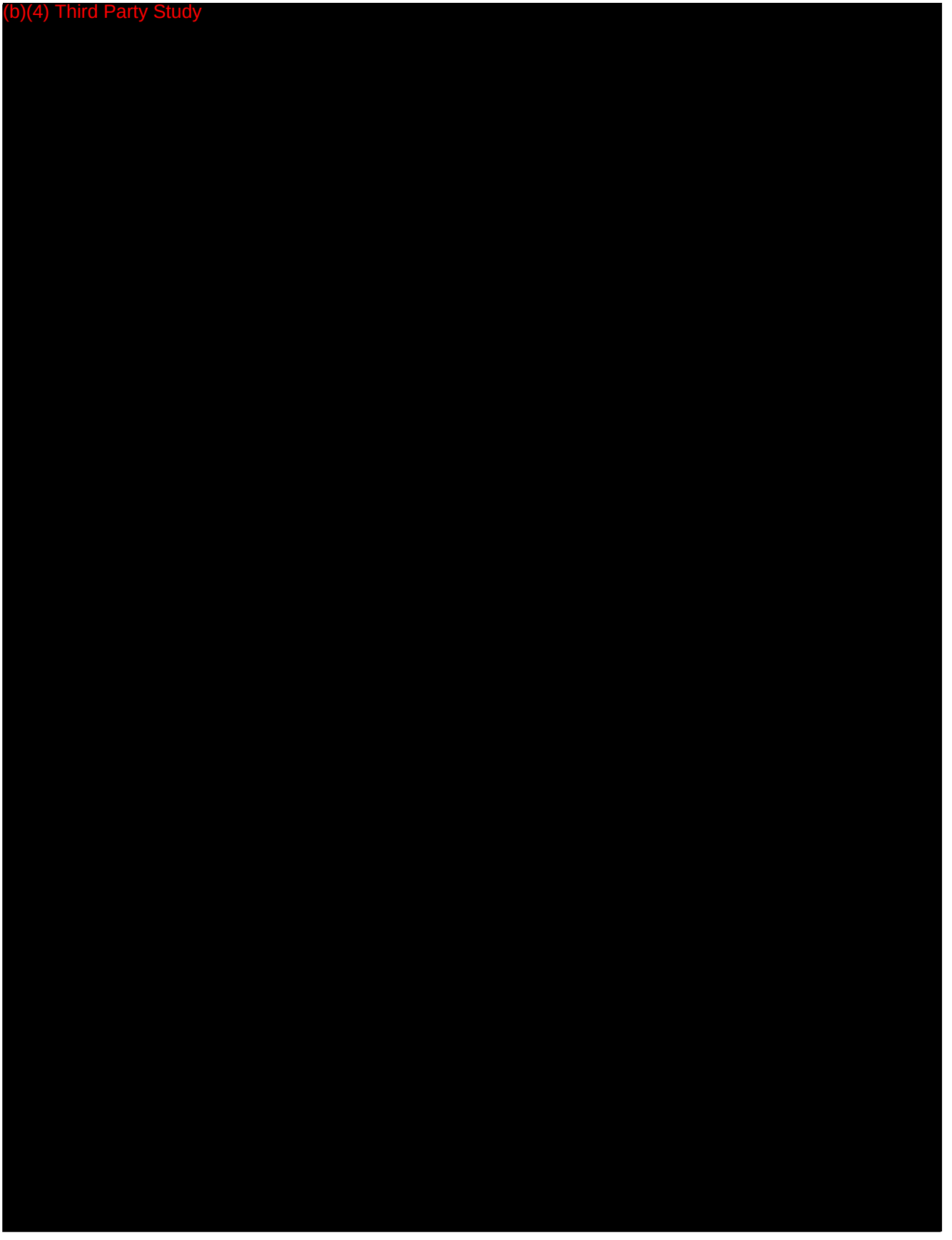

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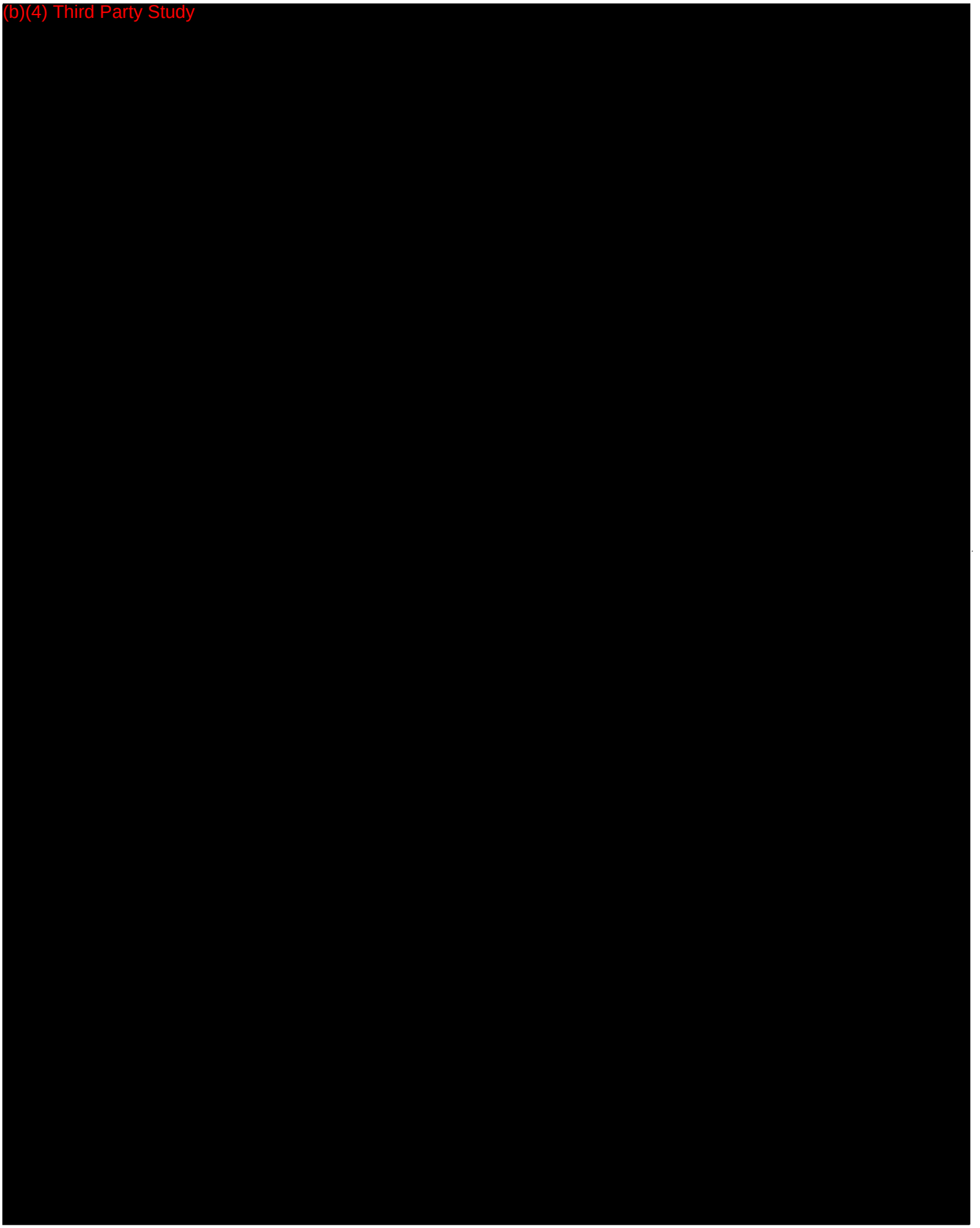

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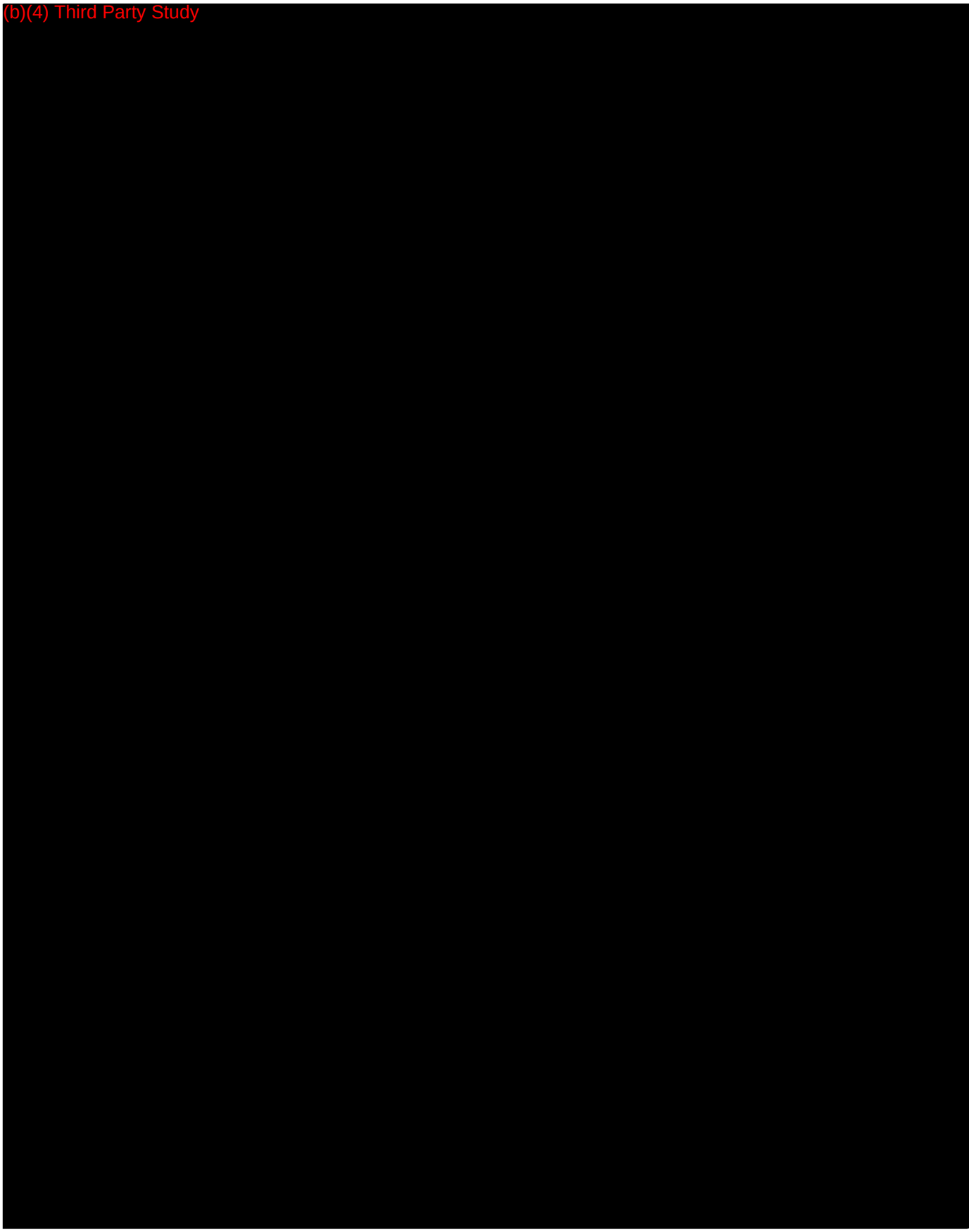

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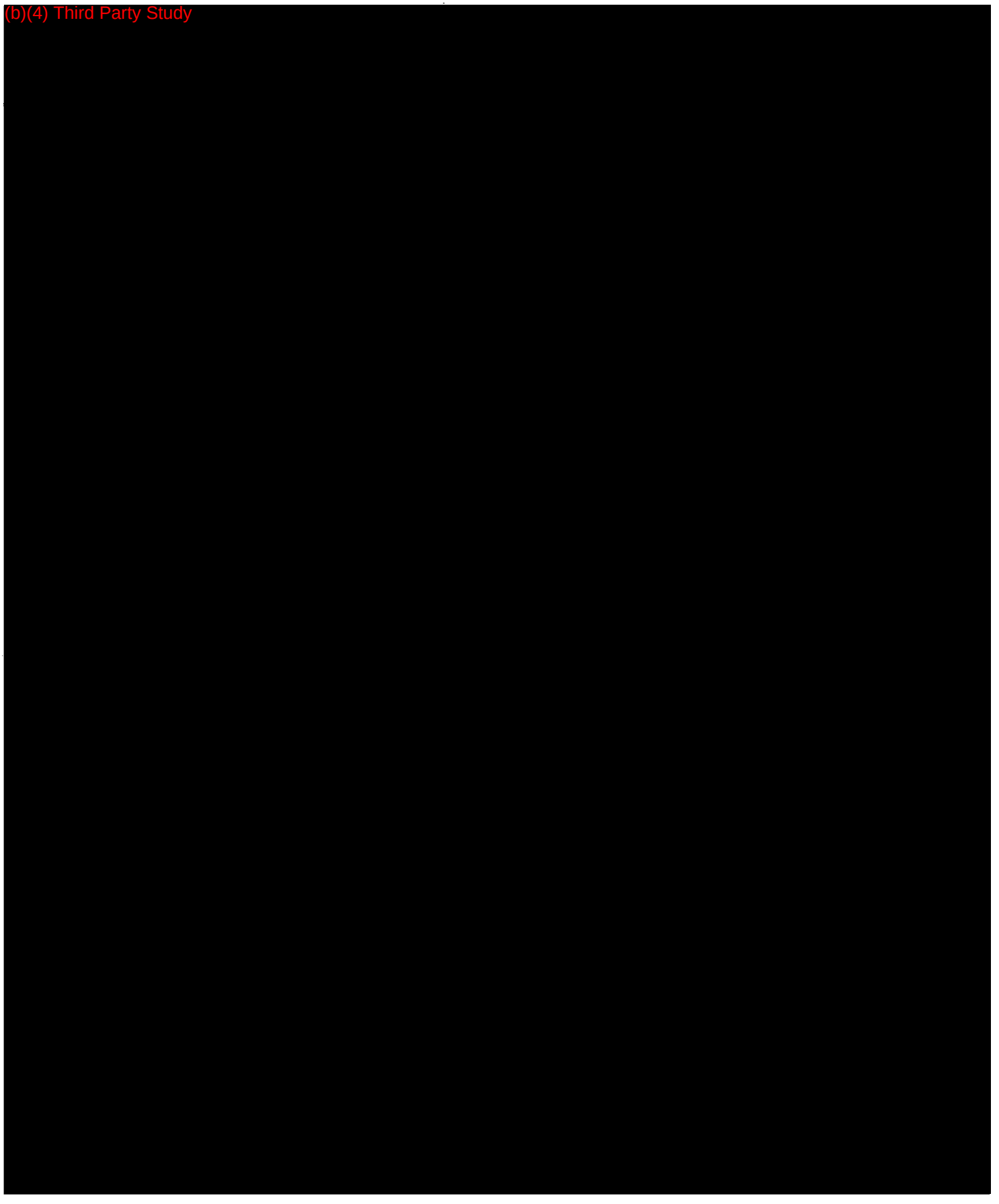

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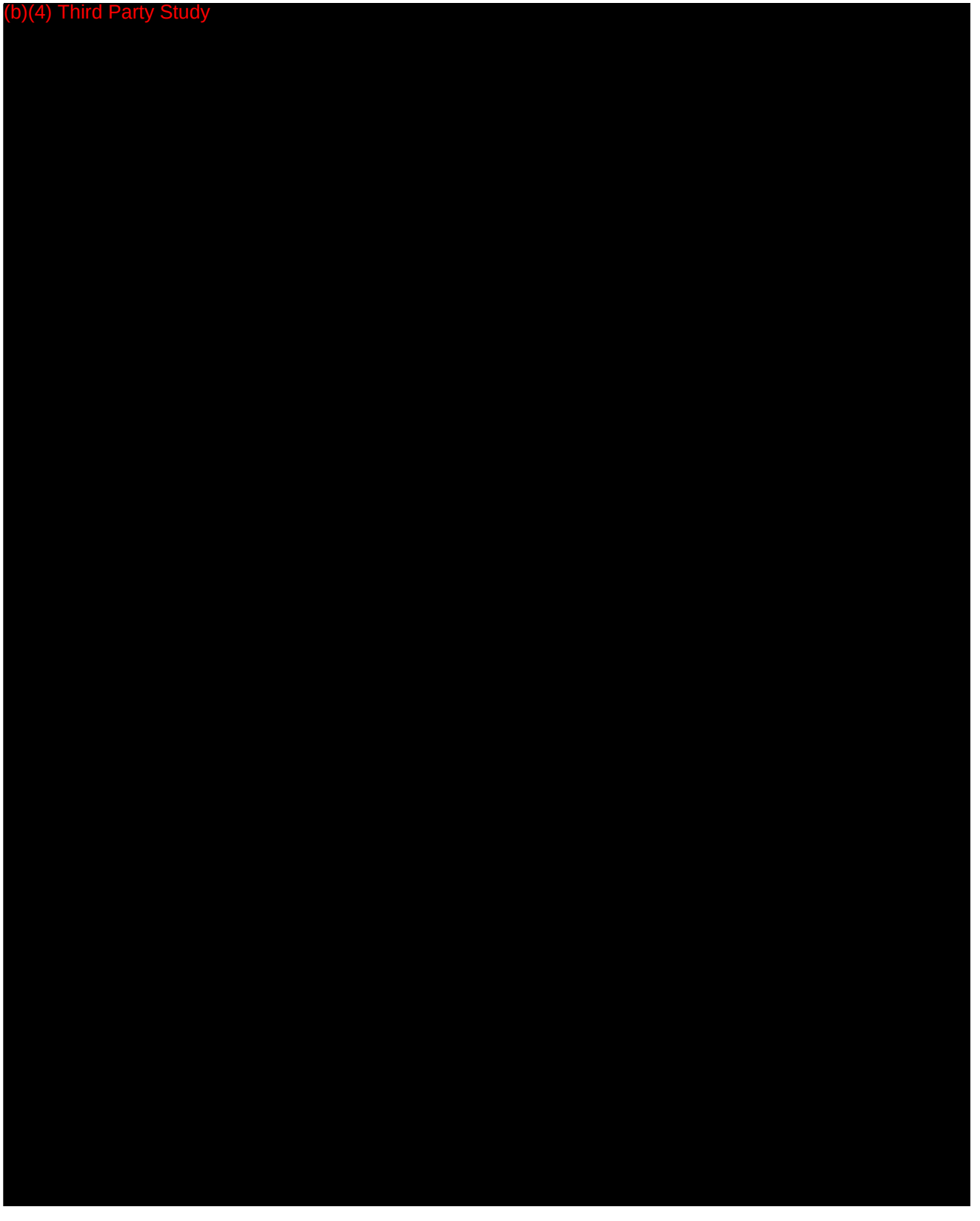

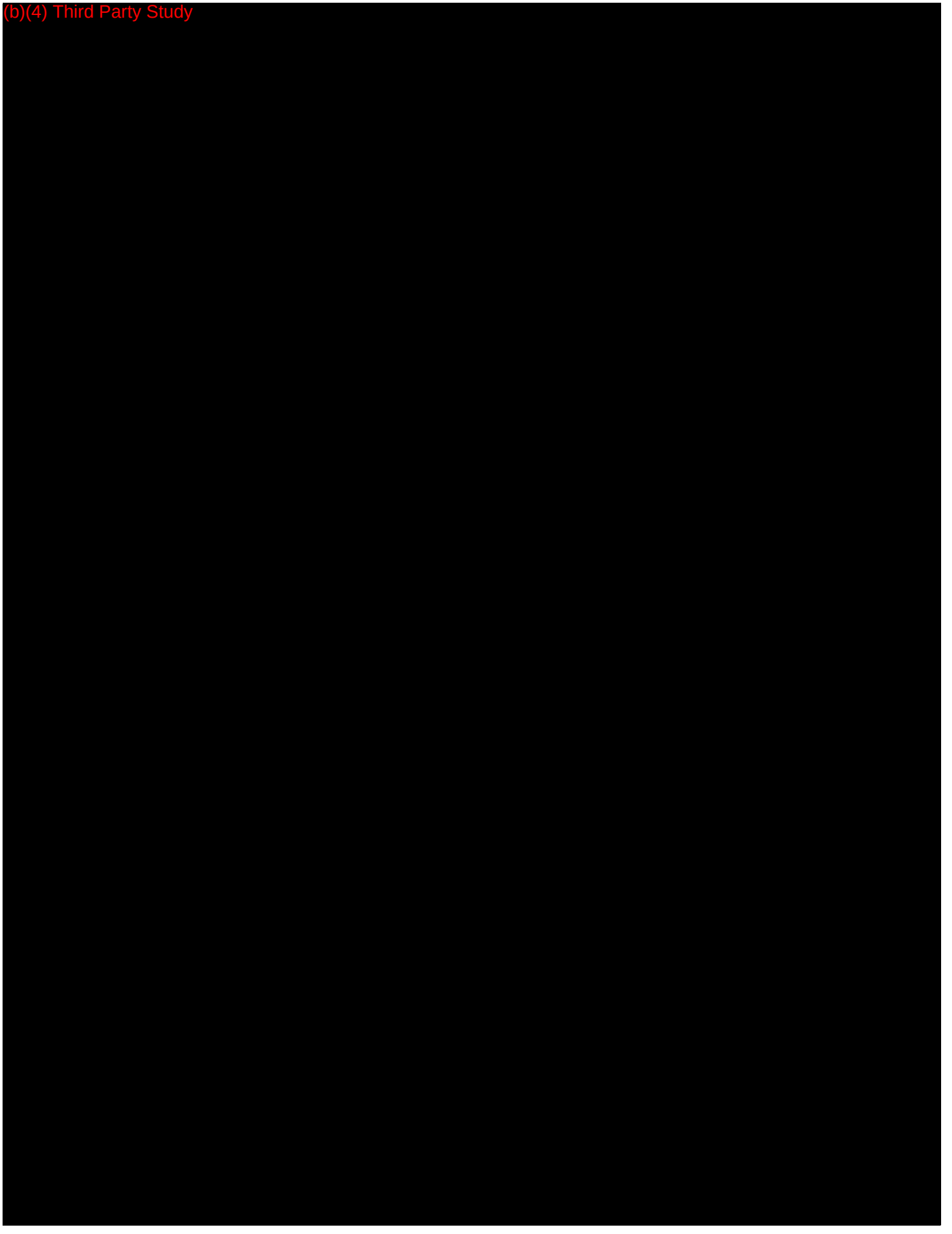

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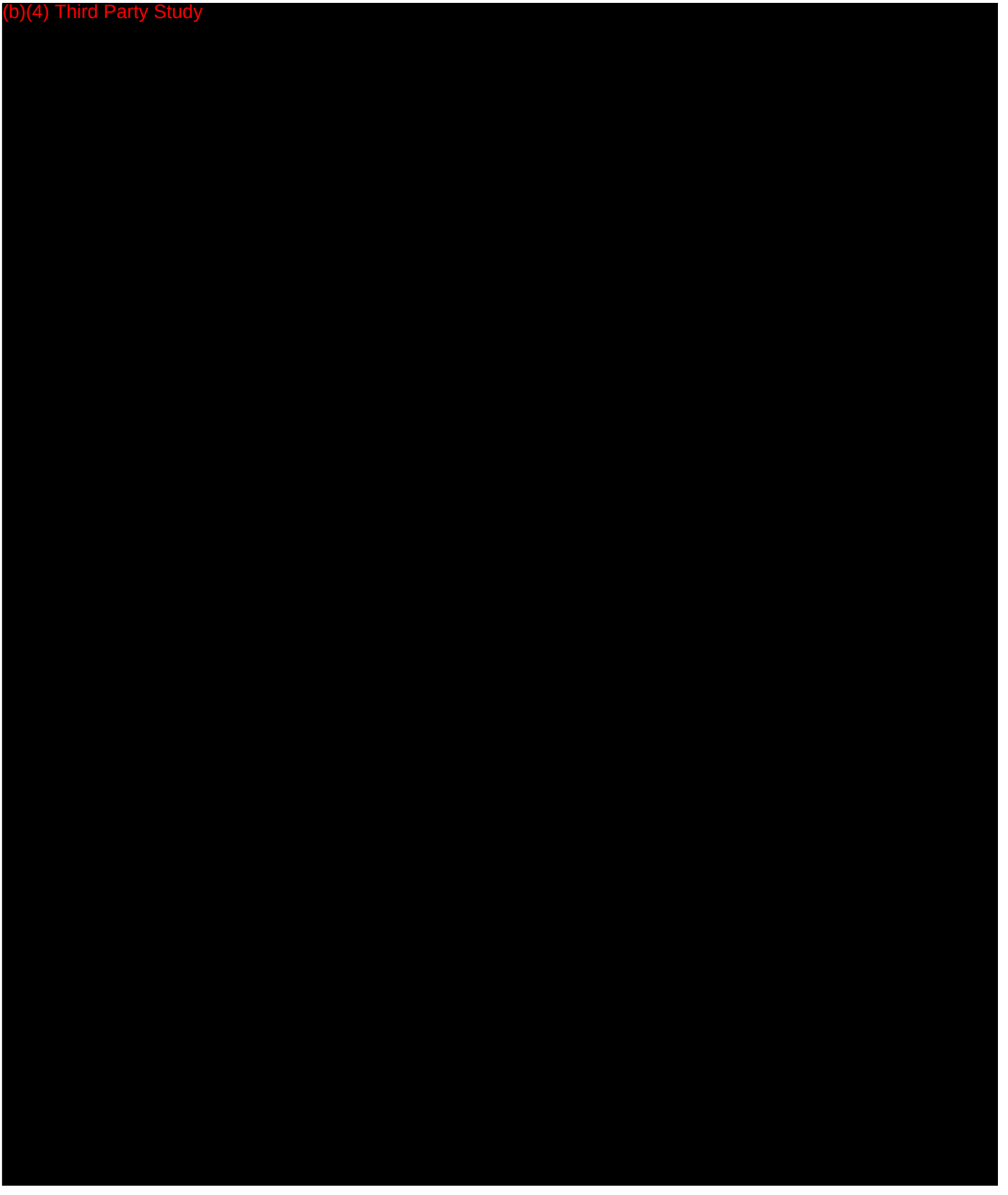

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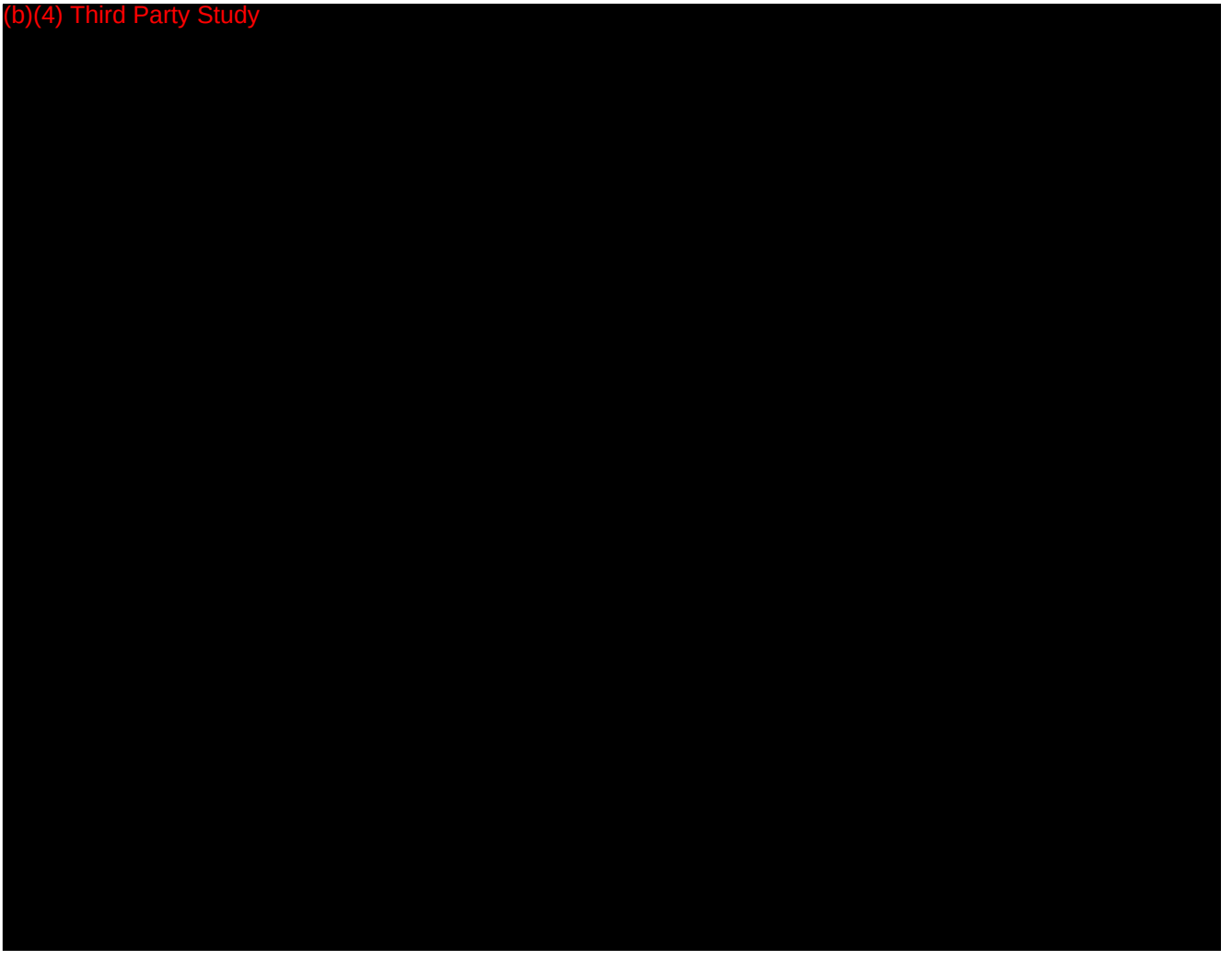

BY: _____ DATE: _____

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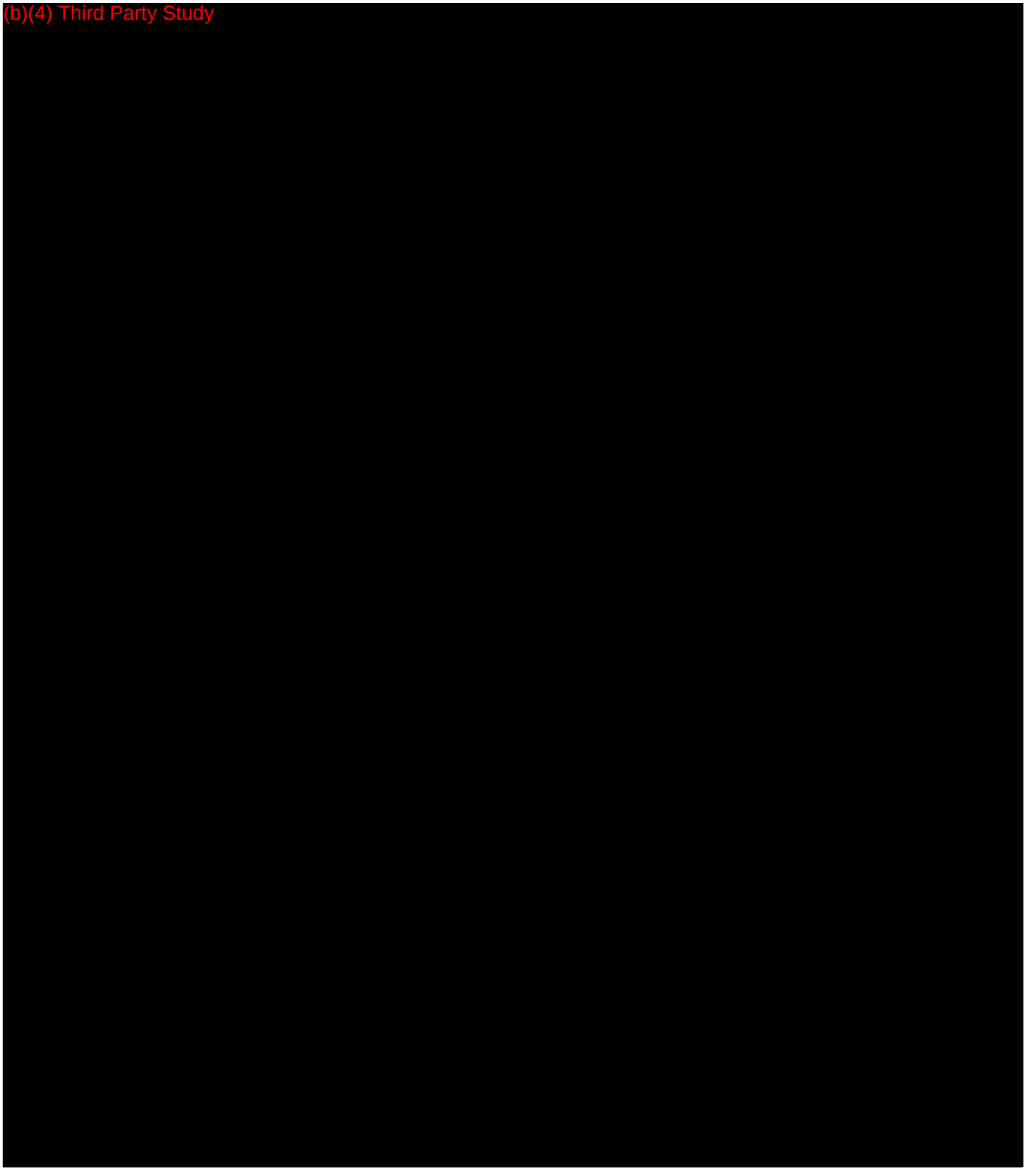

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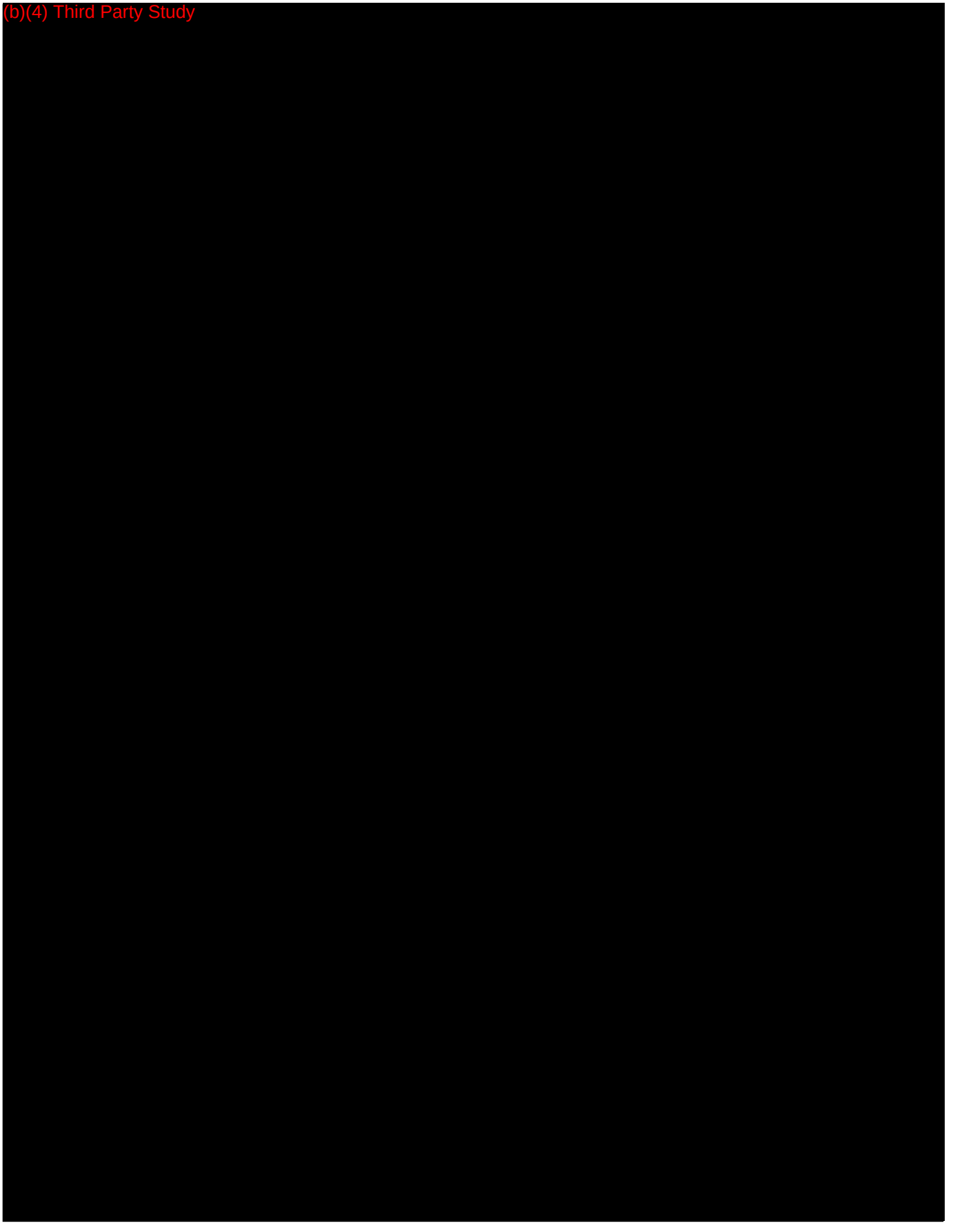

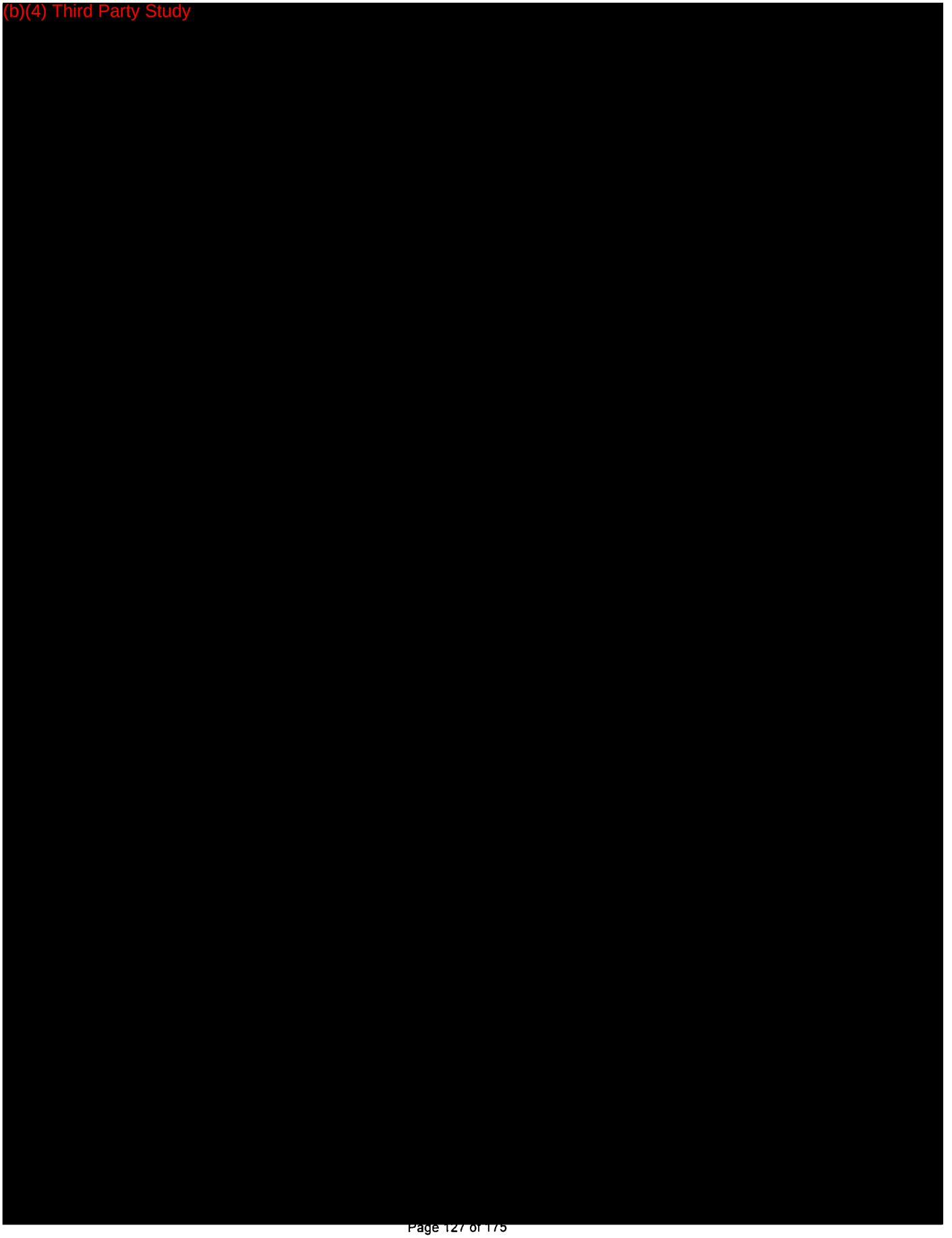

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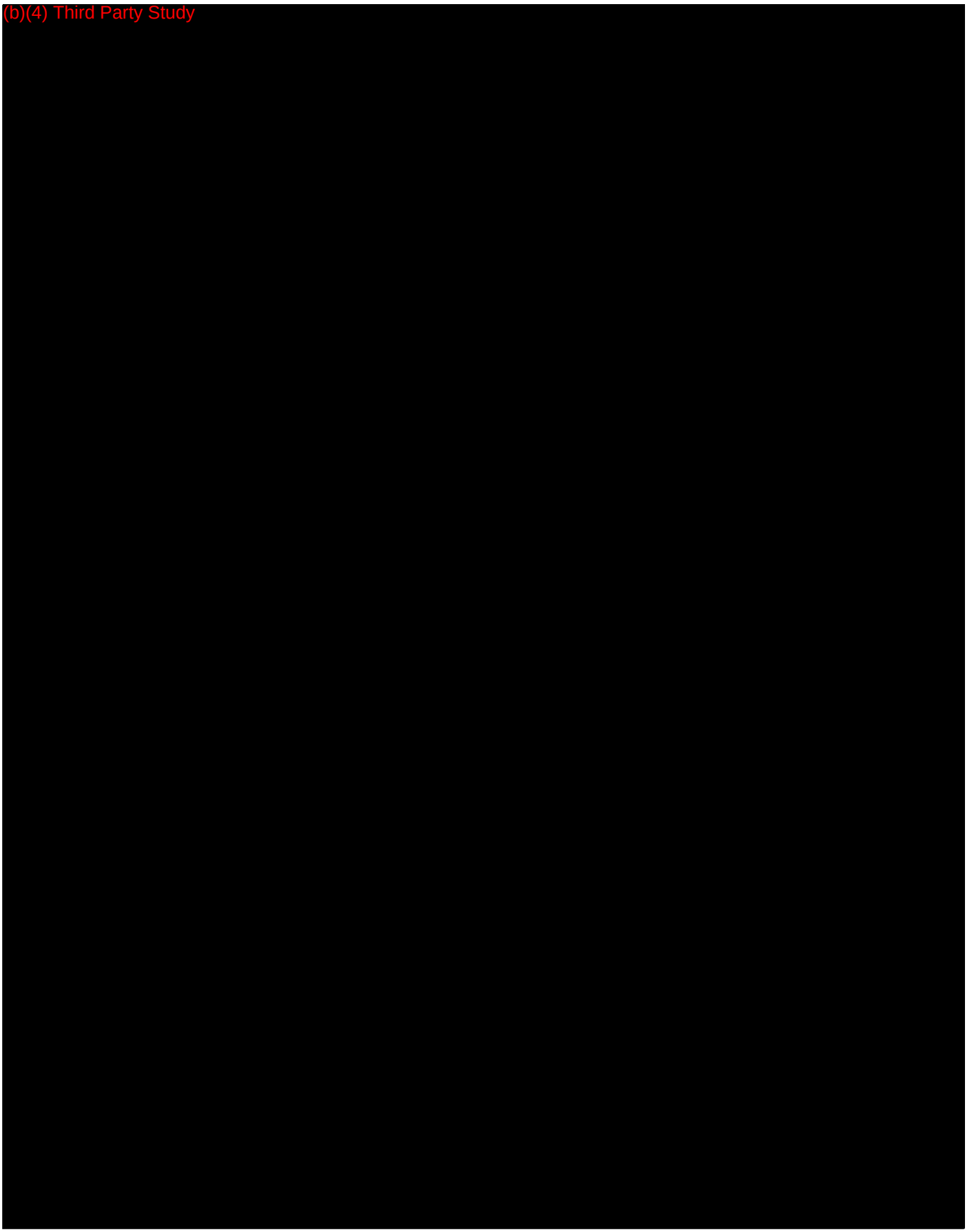

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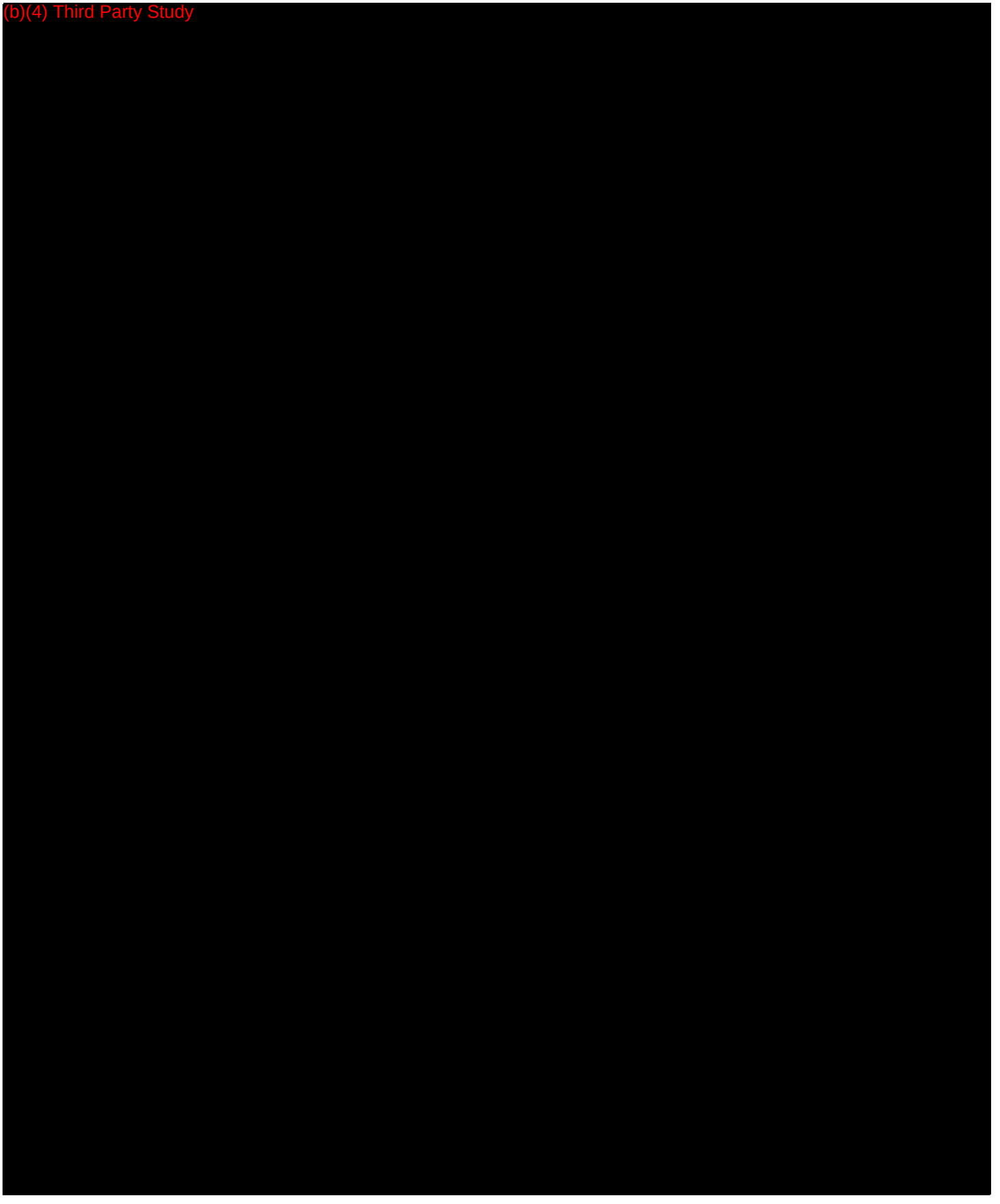

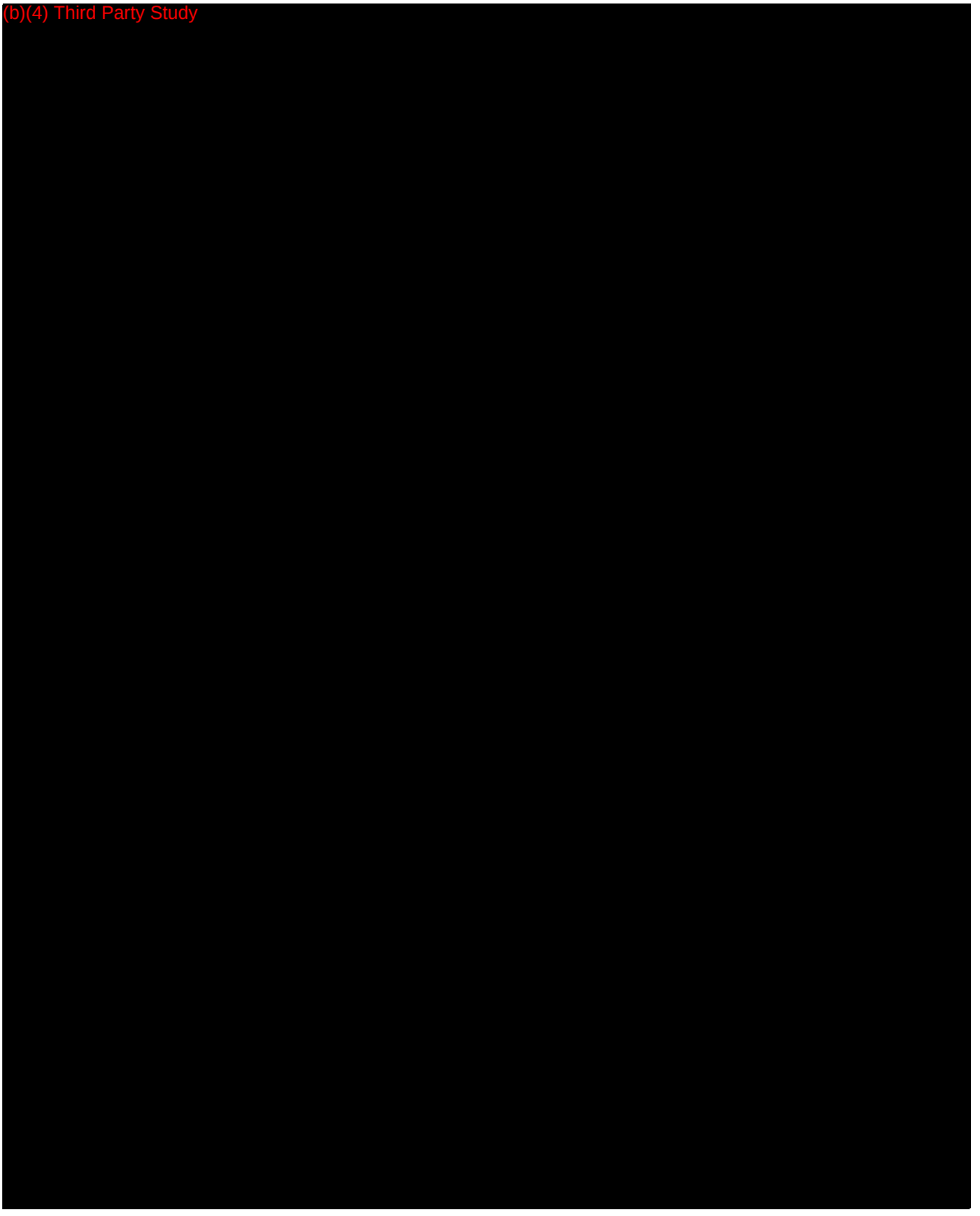

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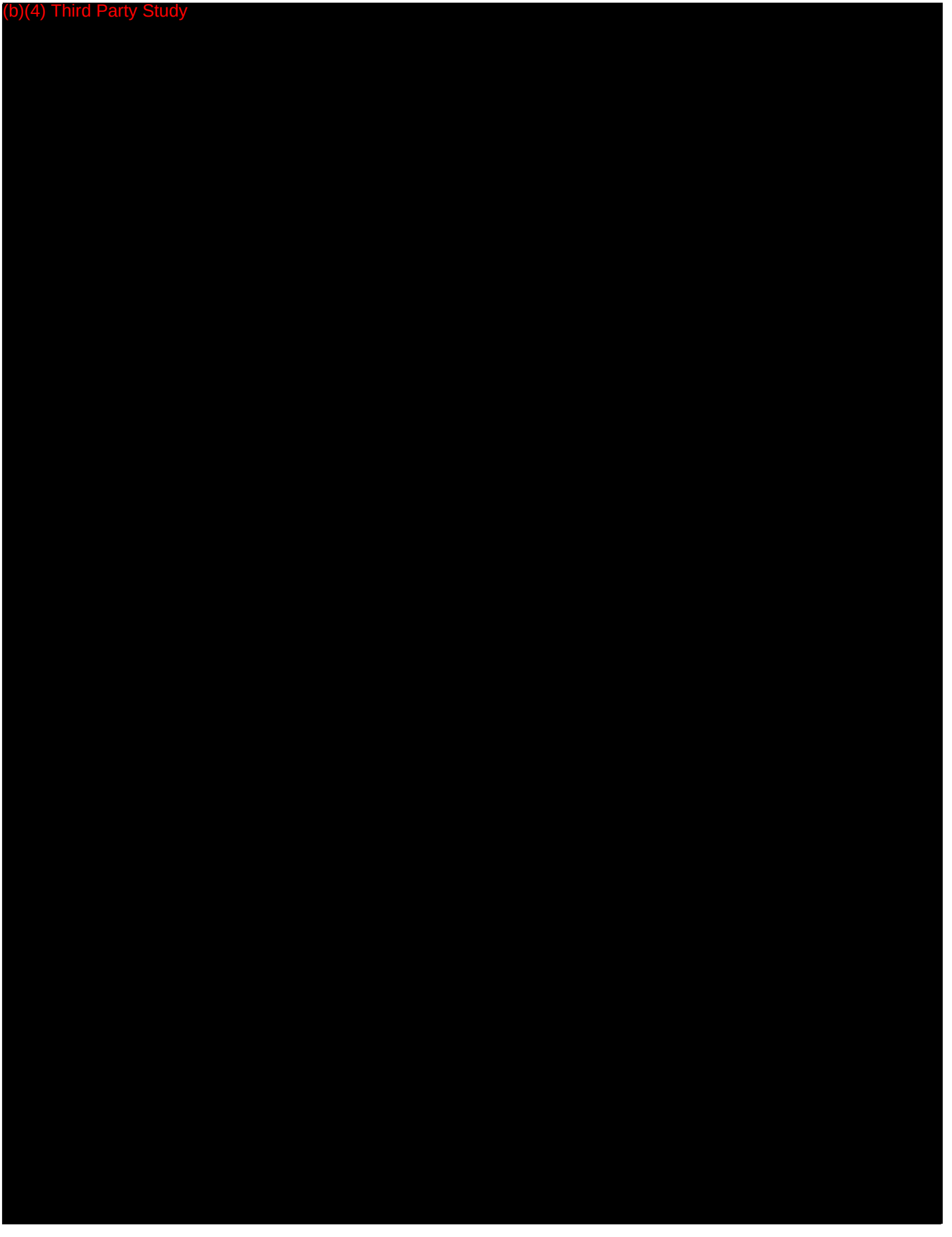

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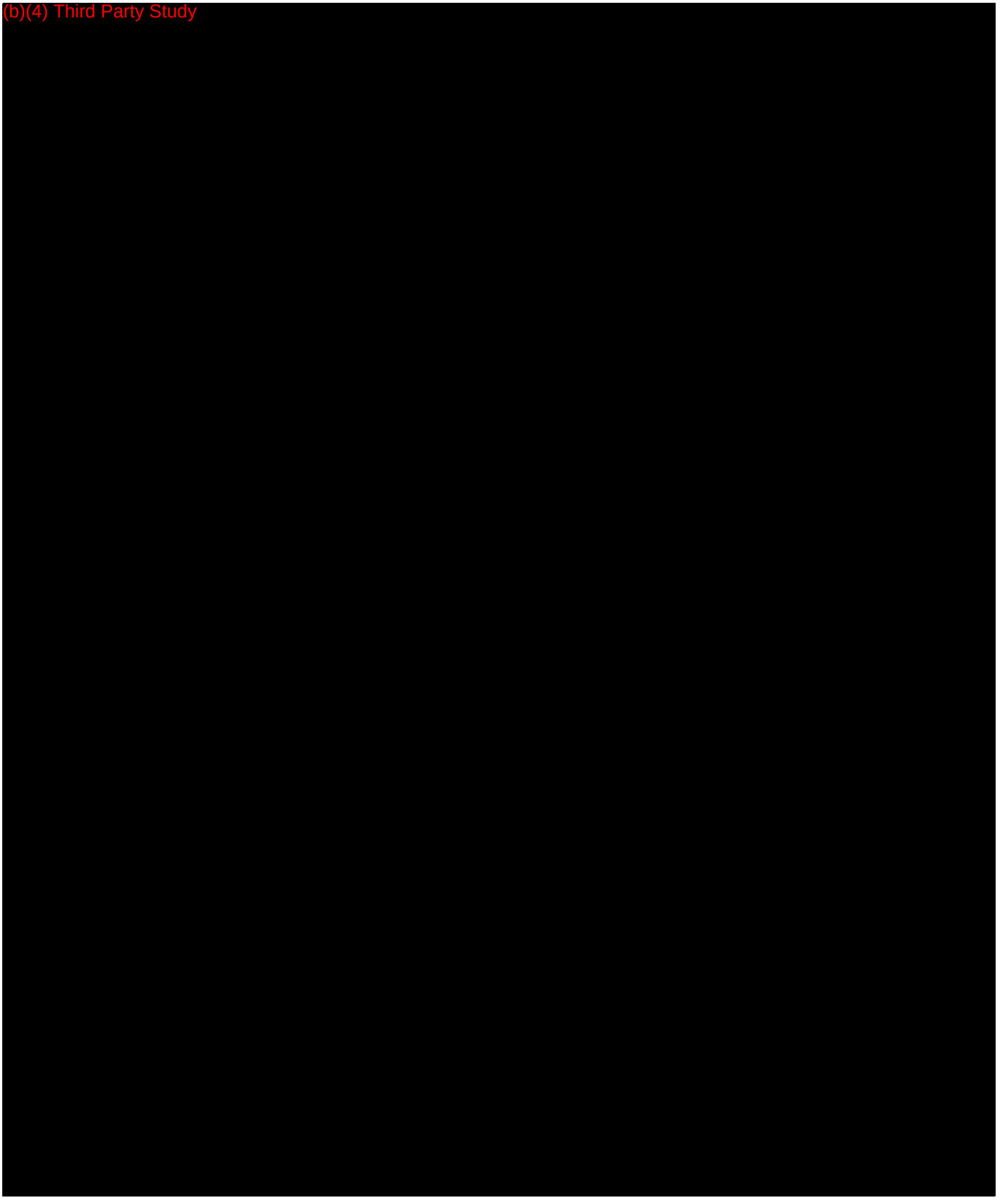

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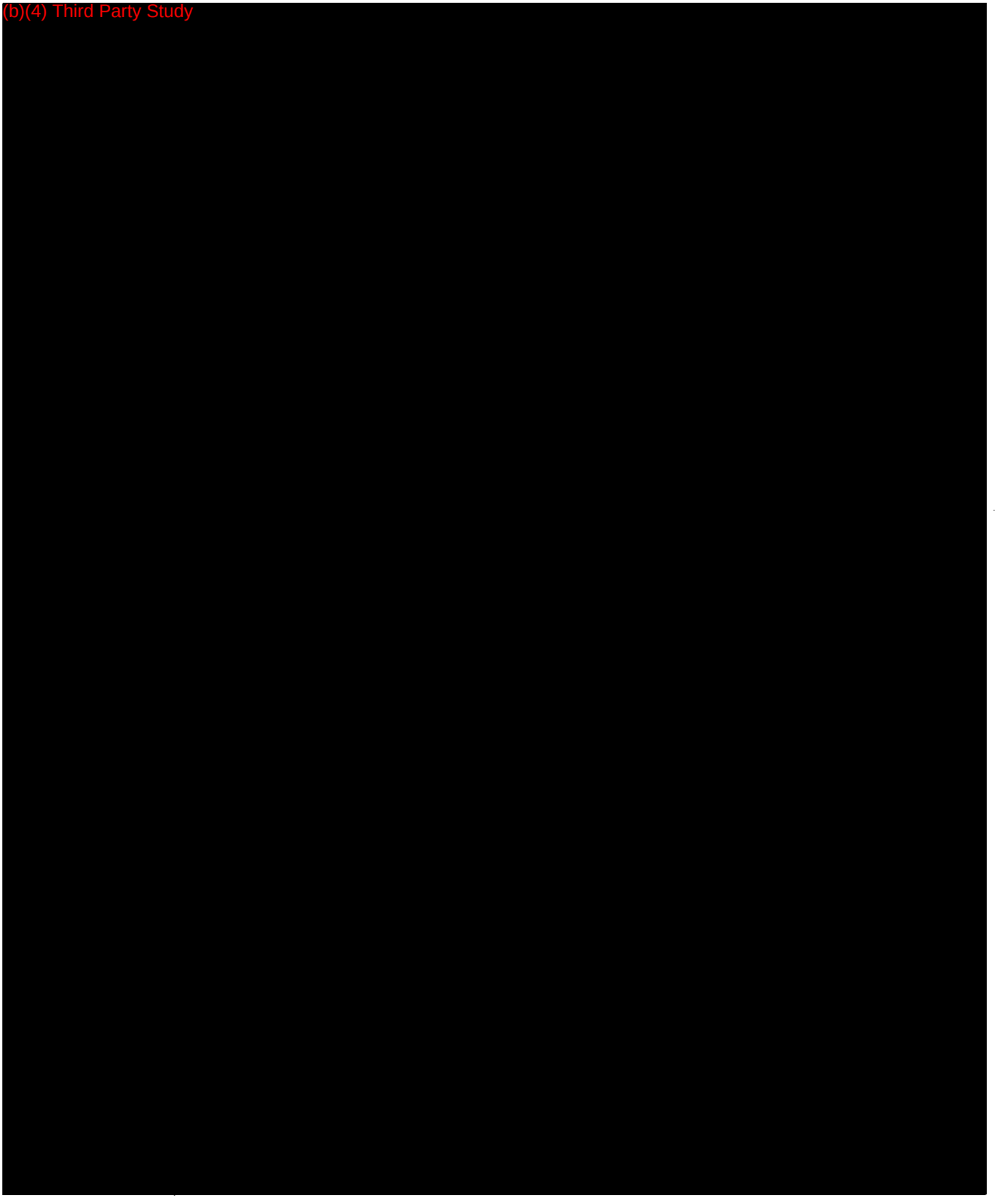

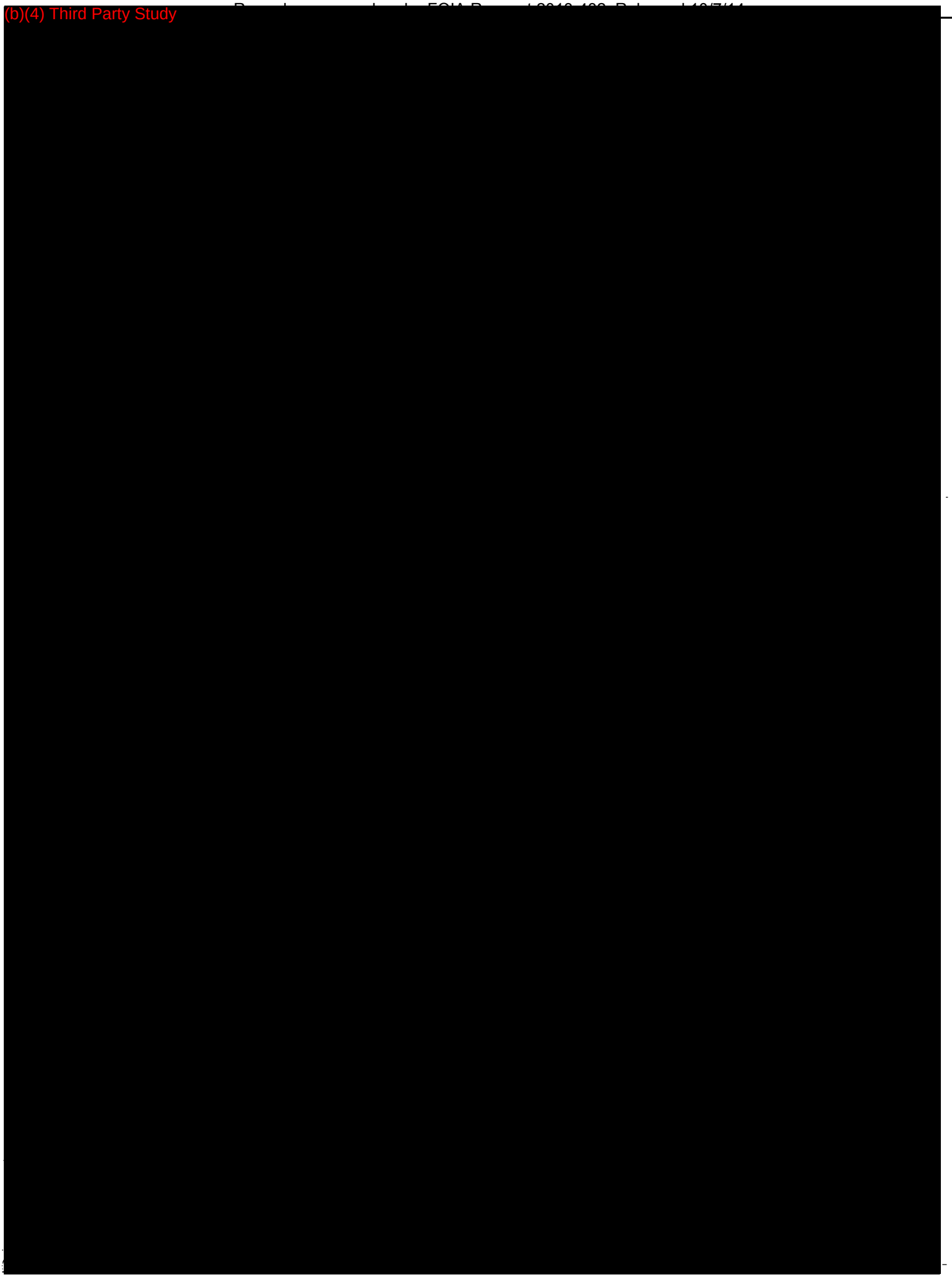

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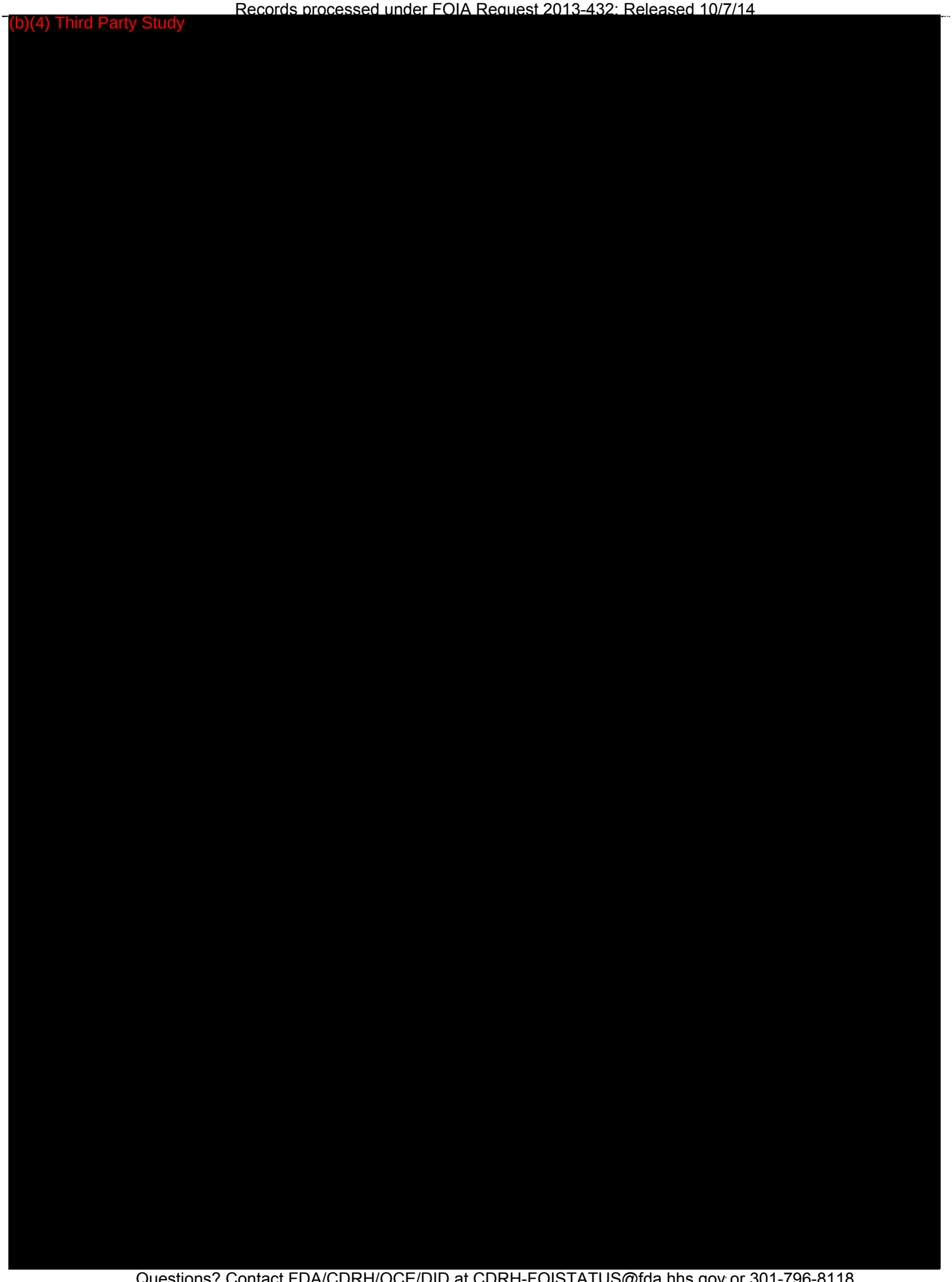

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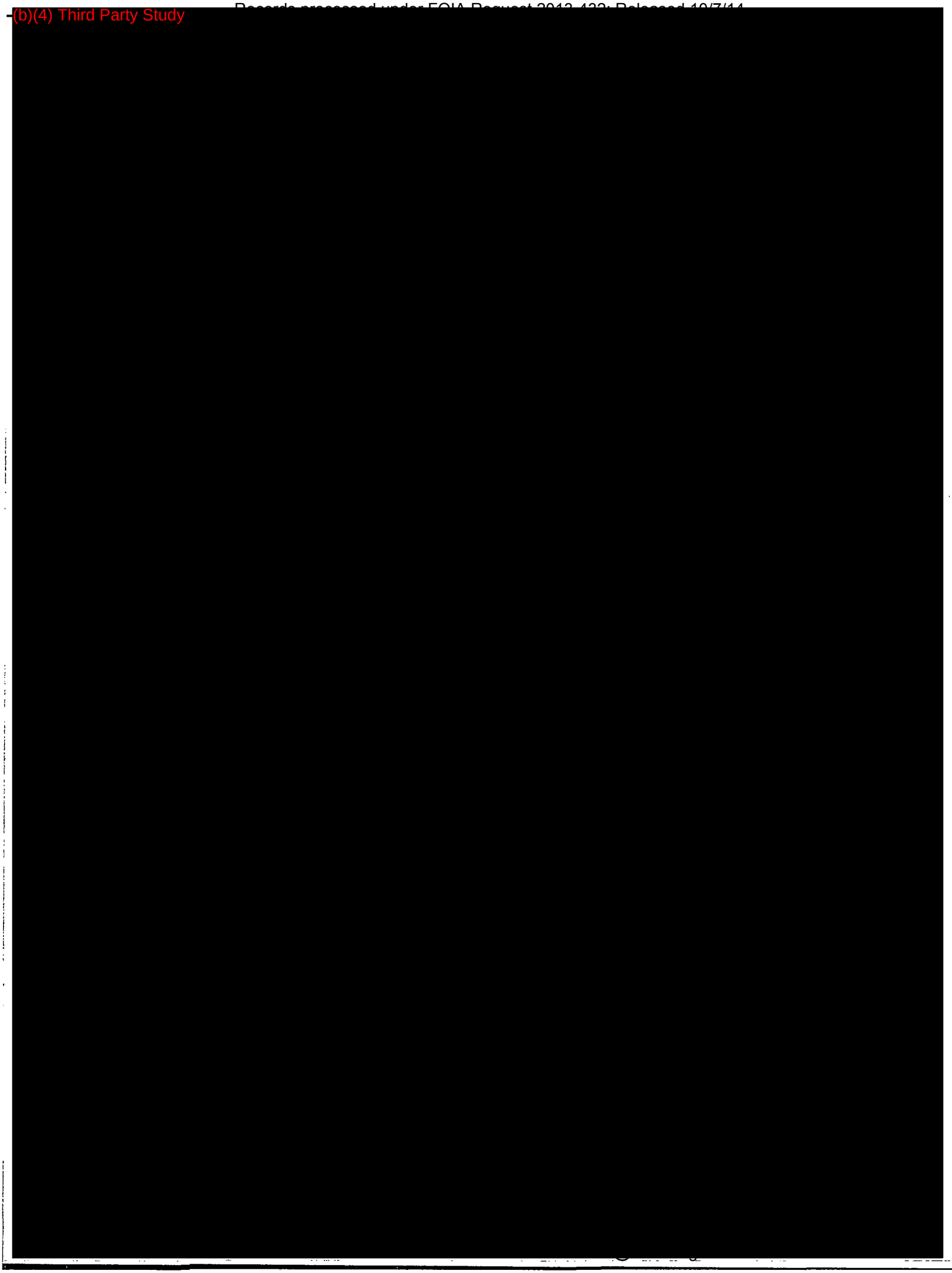

(b)(4) Third Party Study

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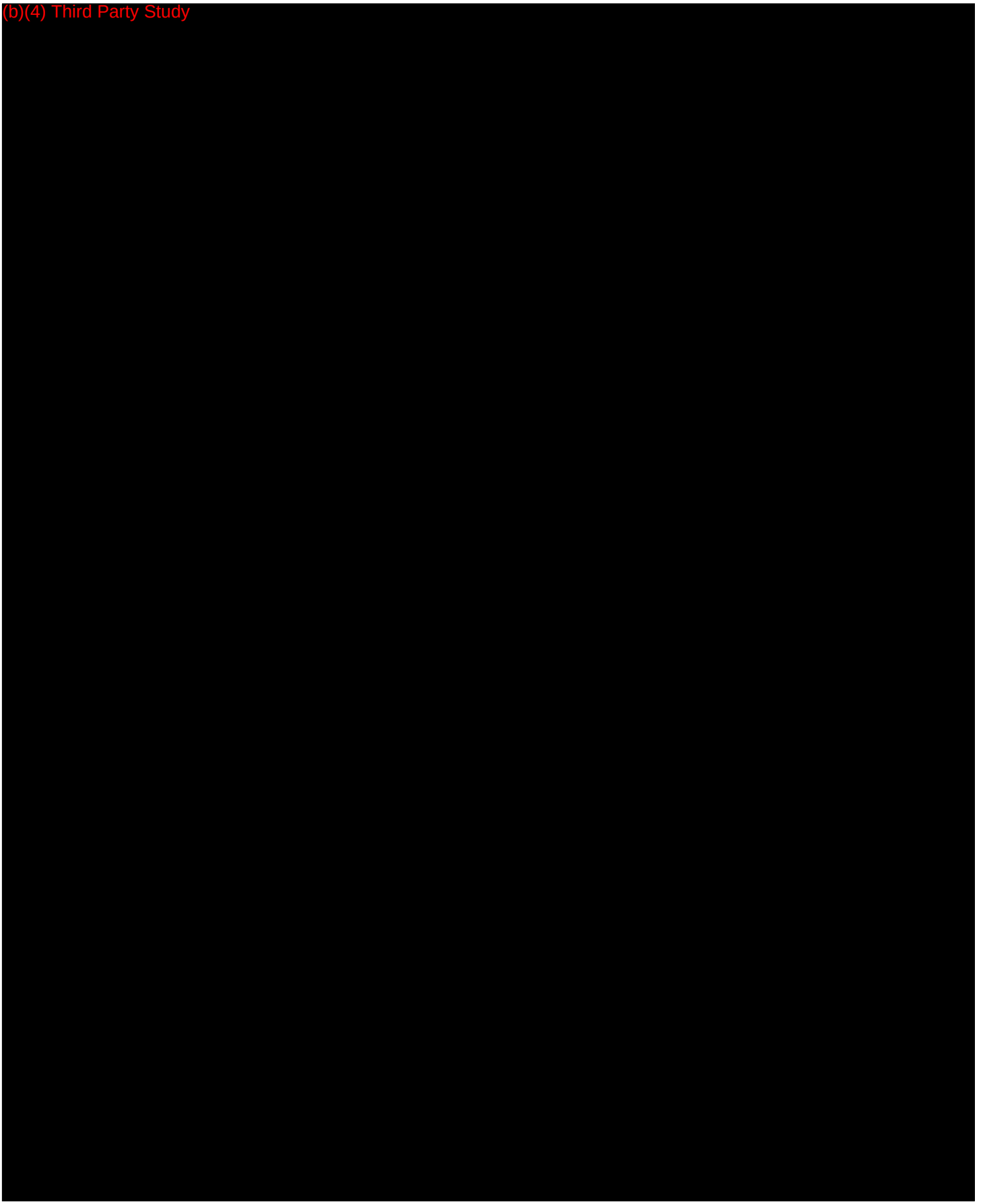

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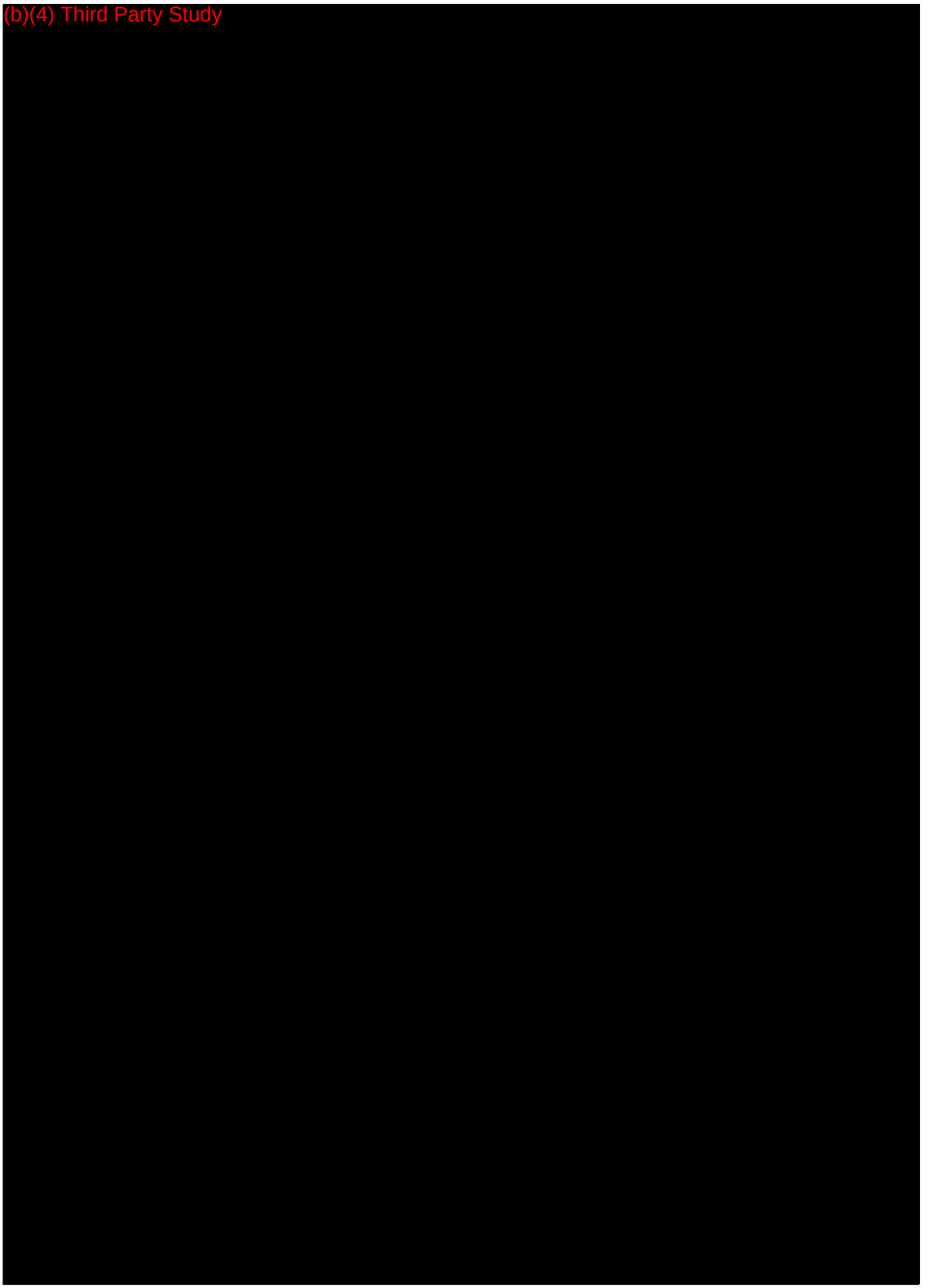

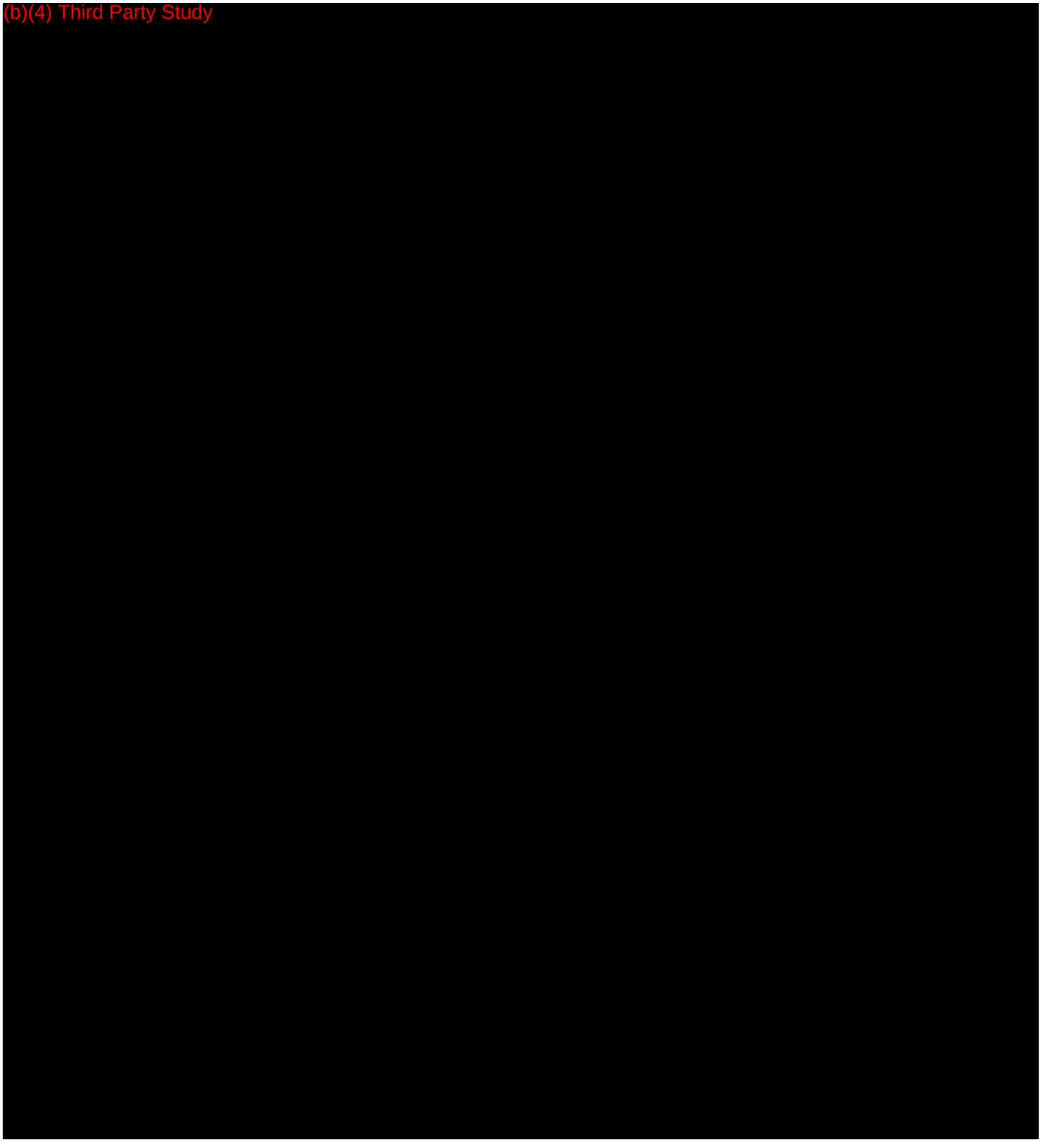

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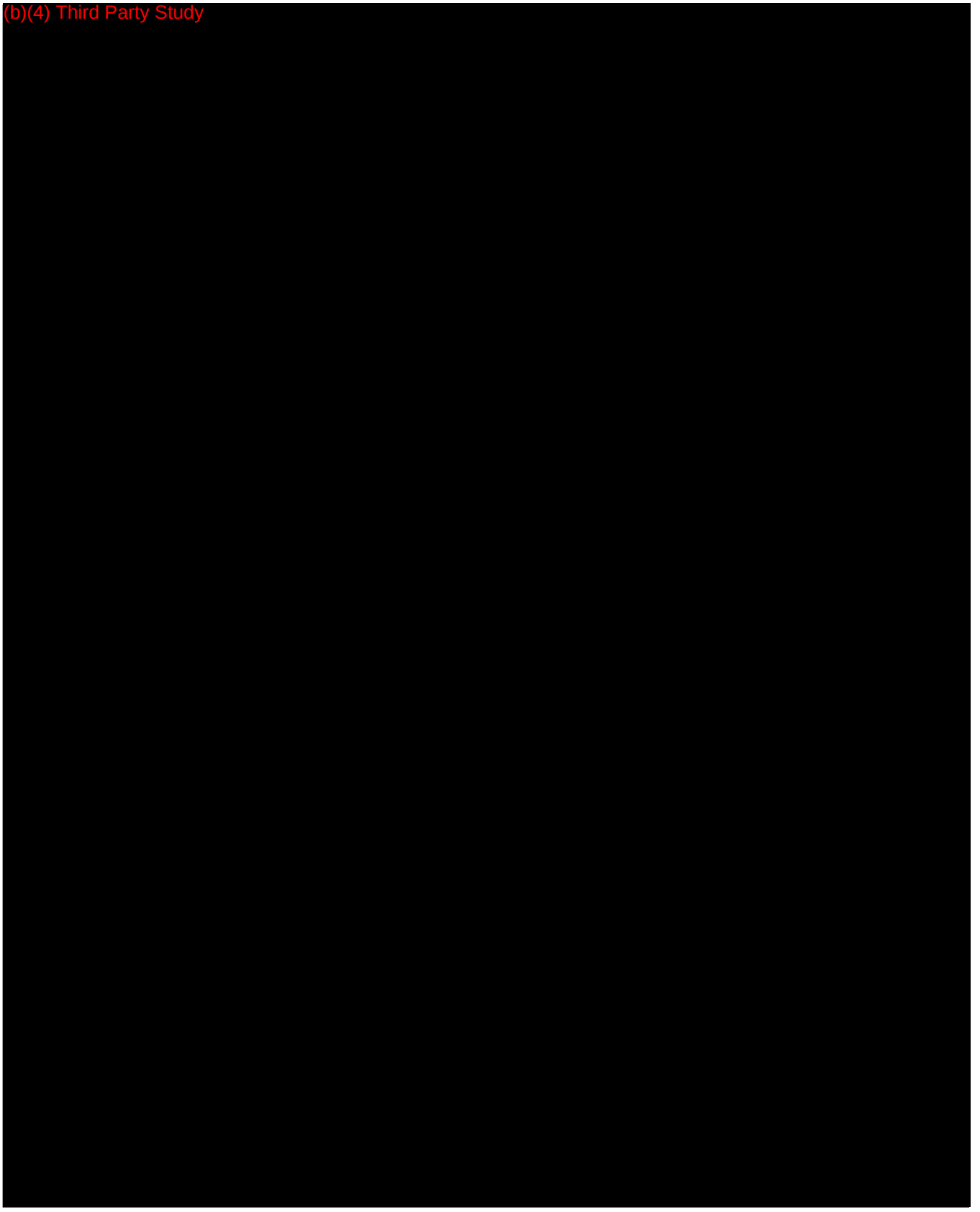

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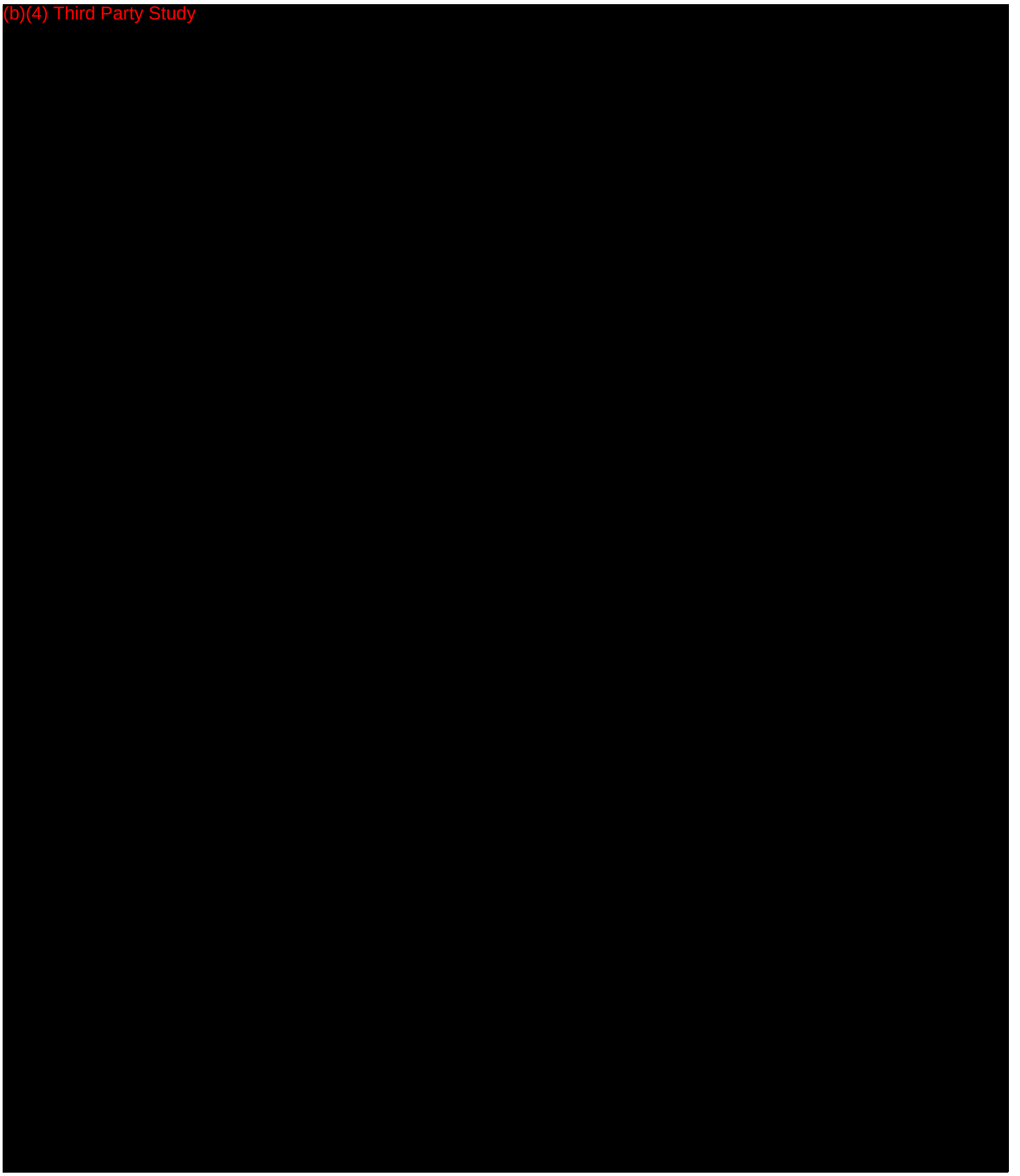

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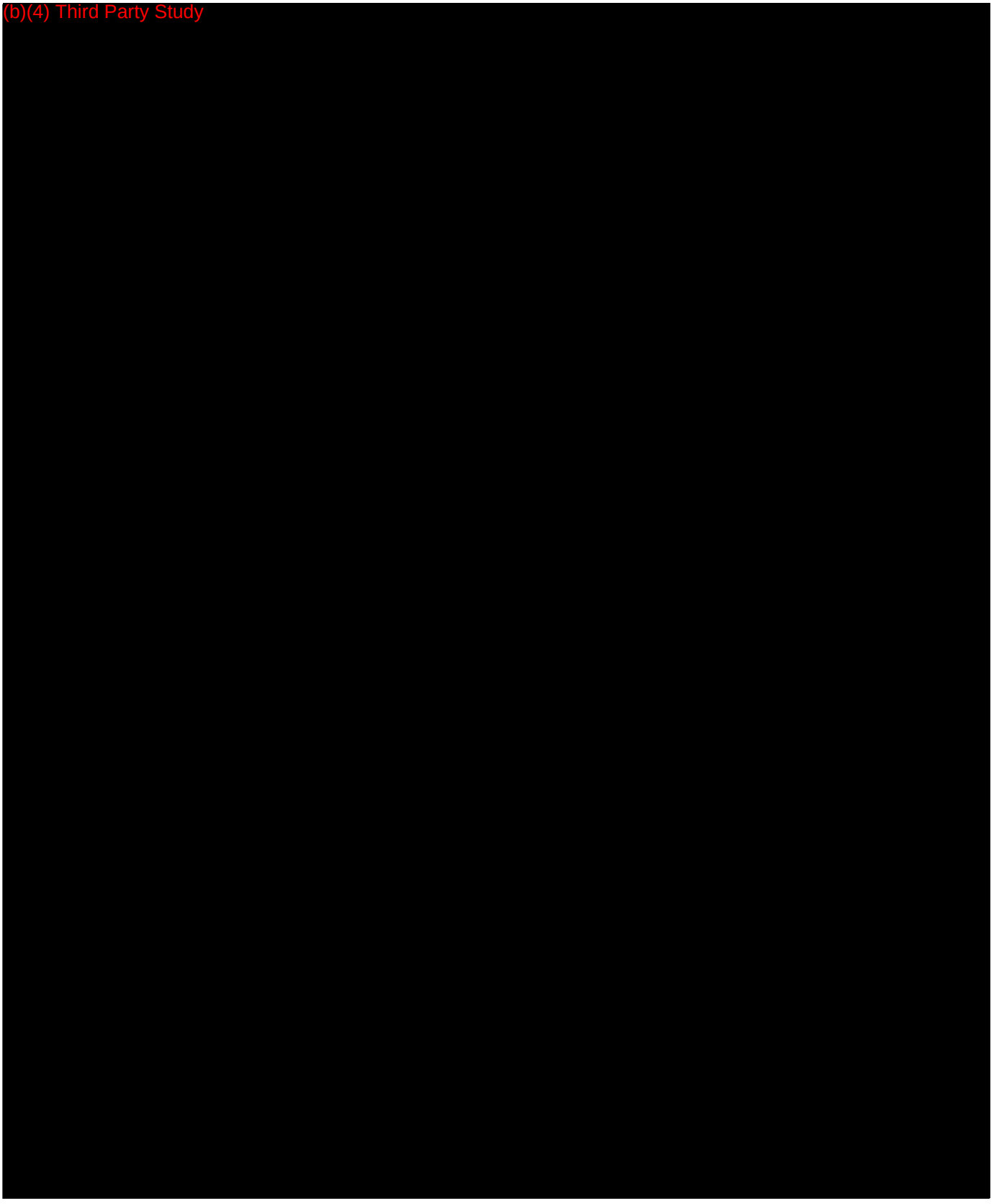

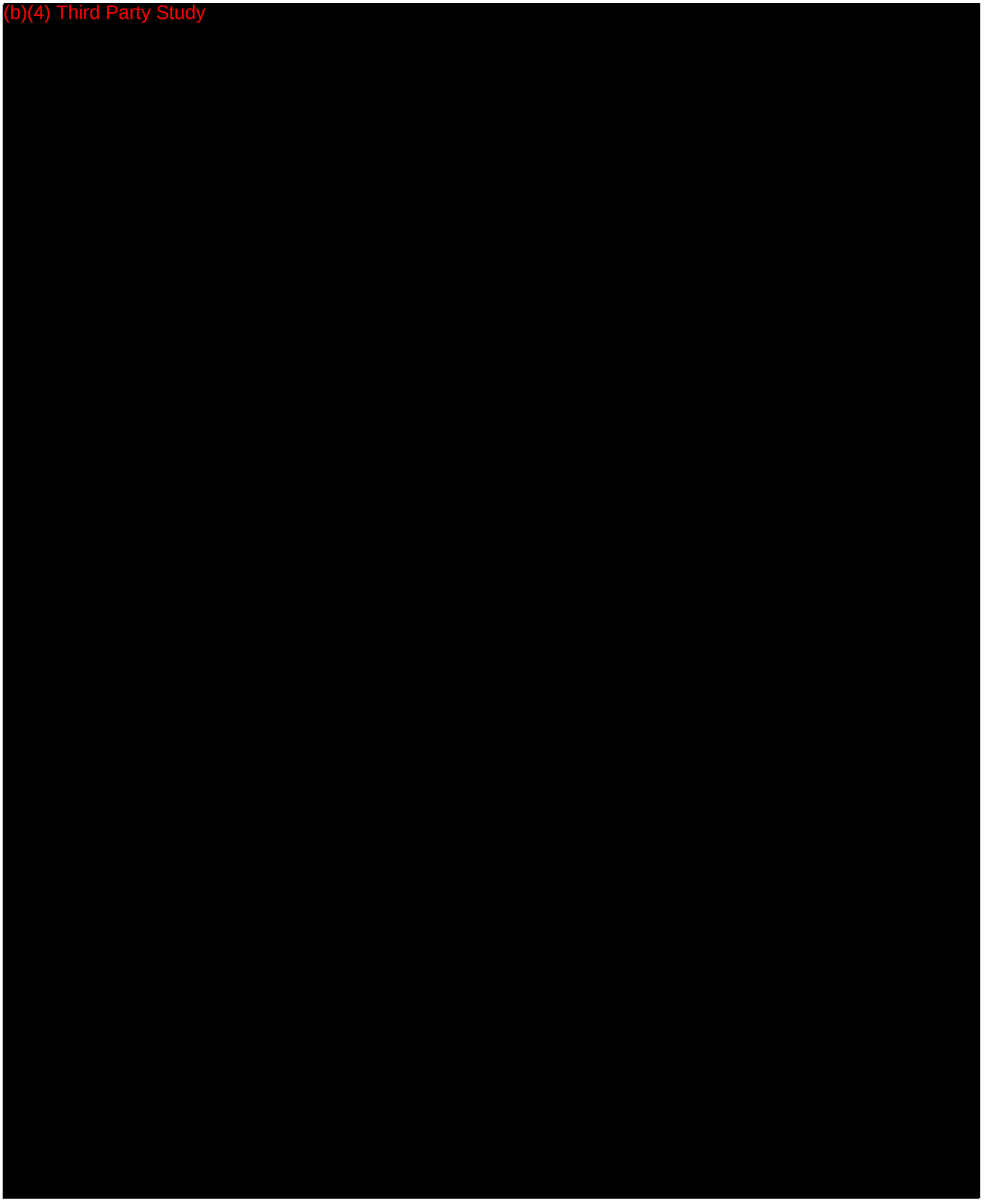

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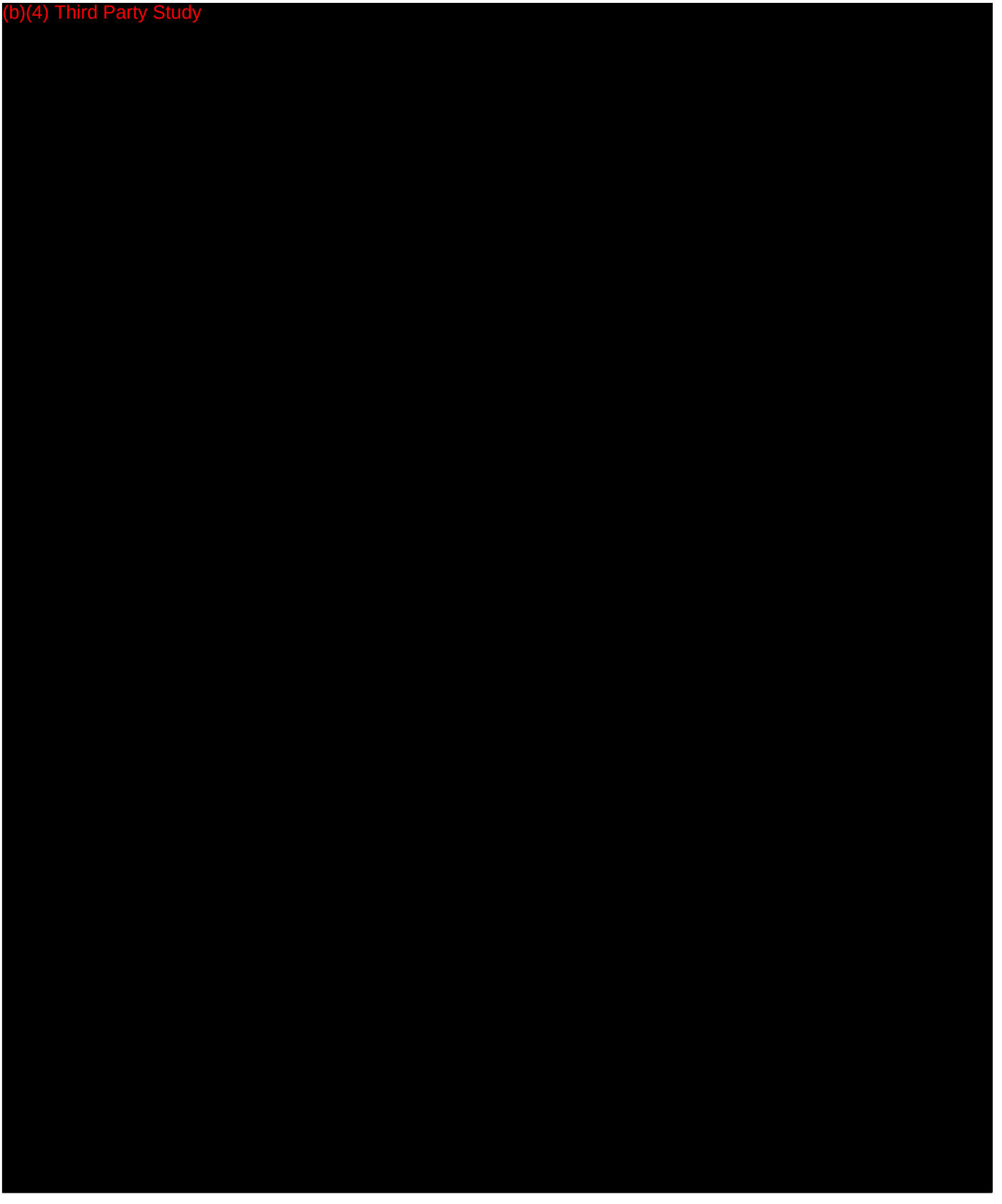

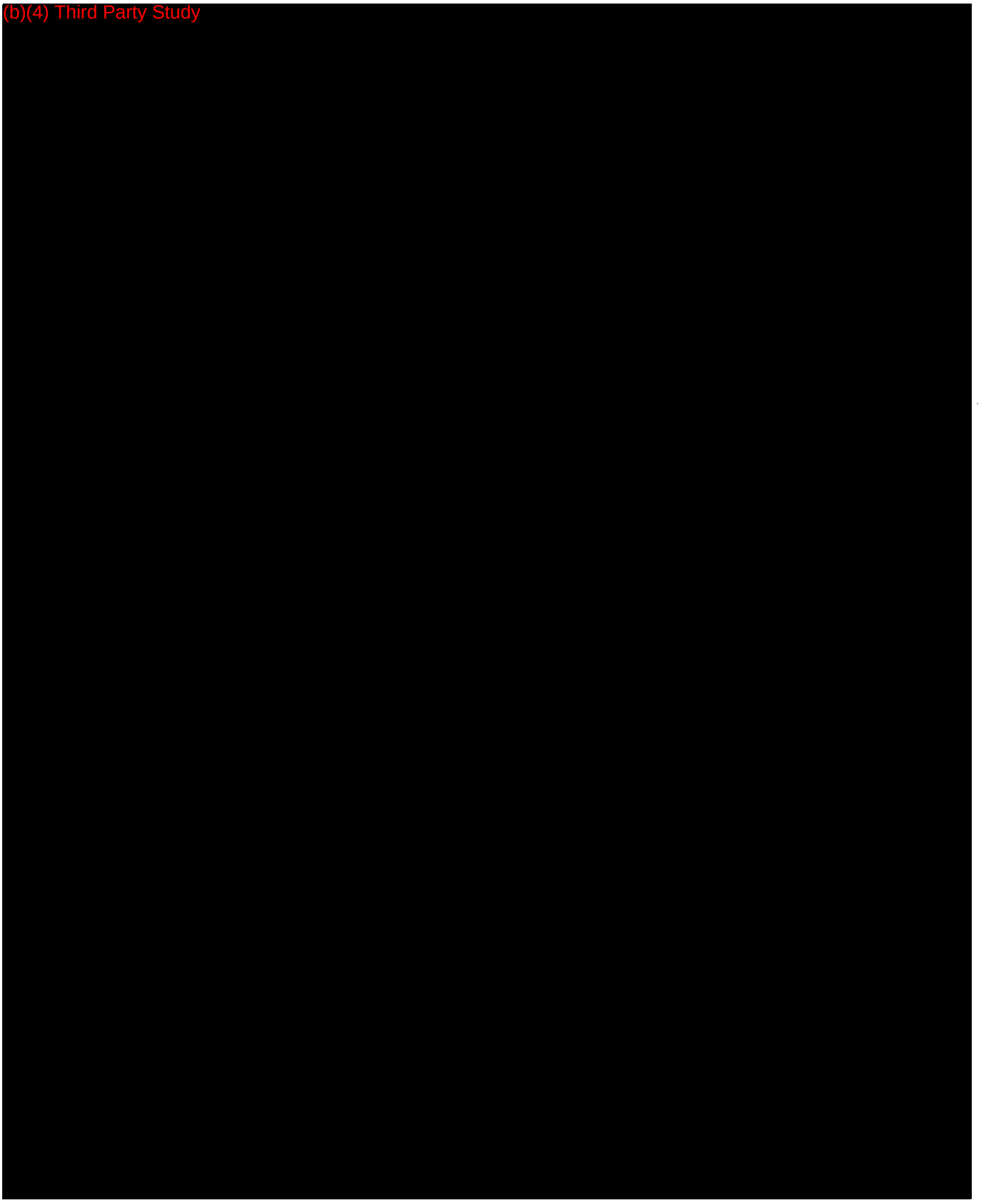

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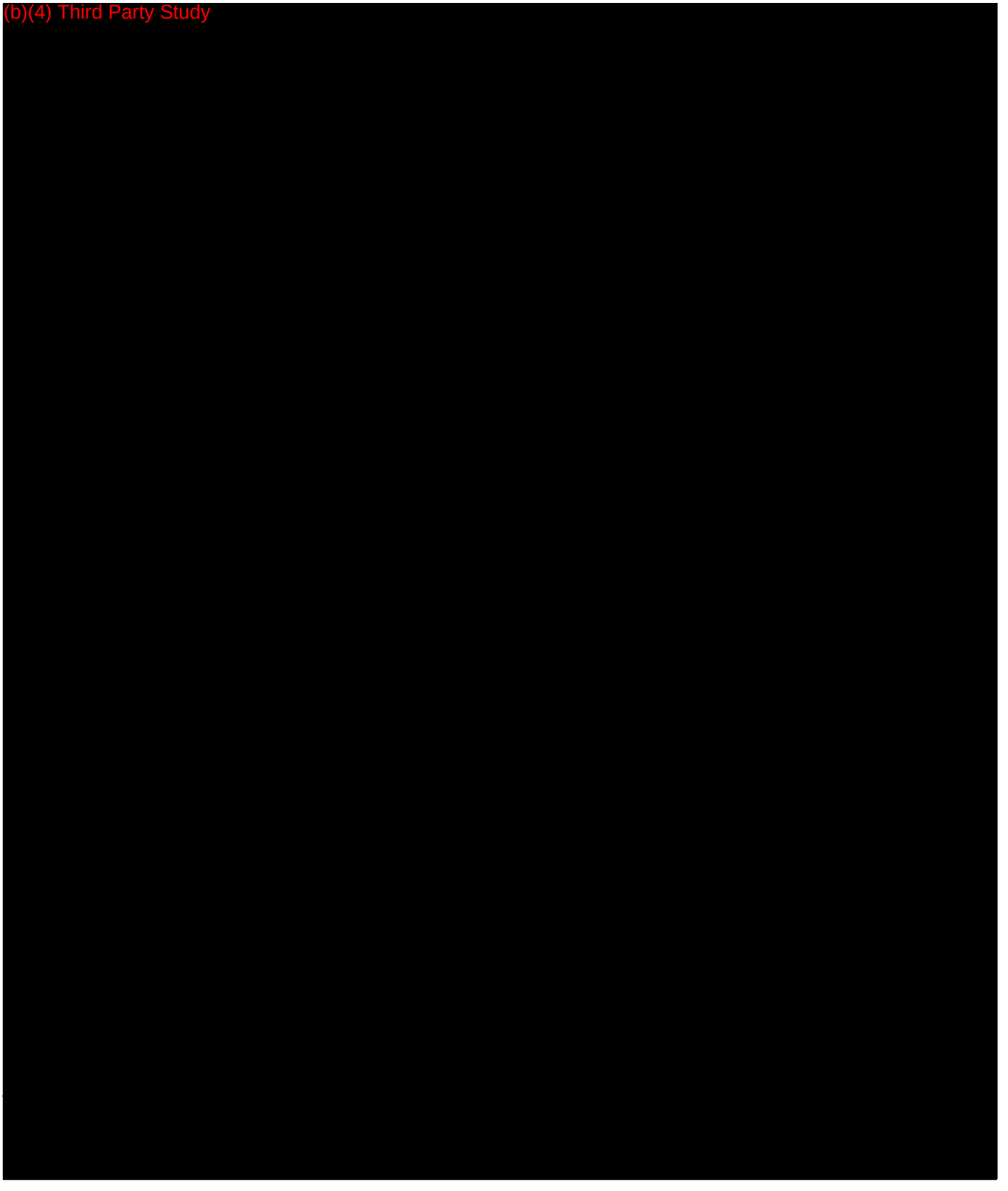

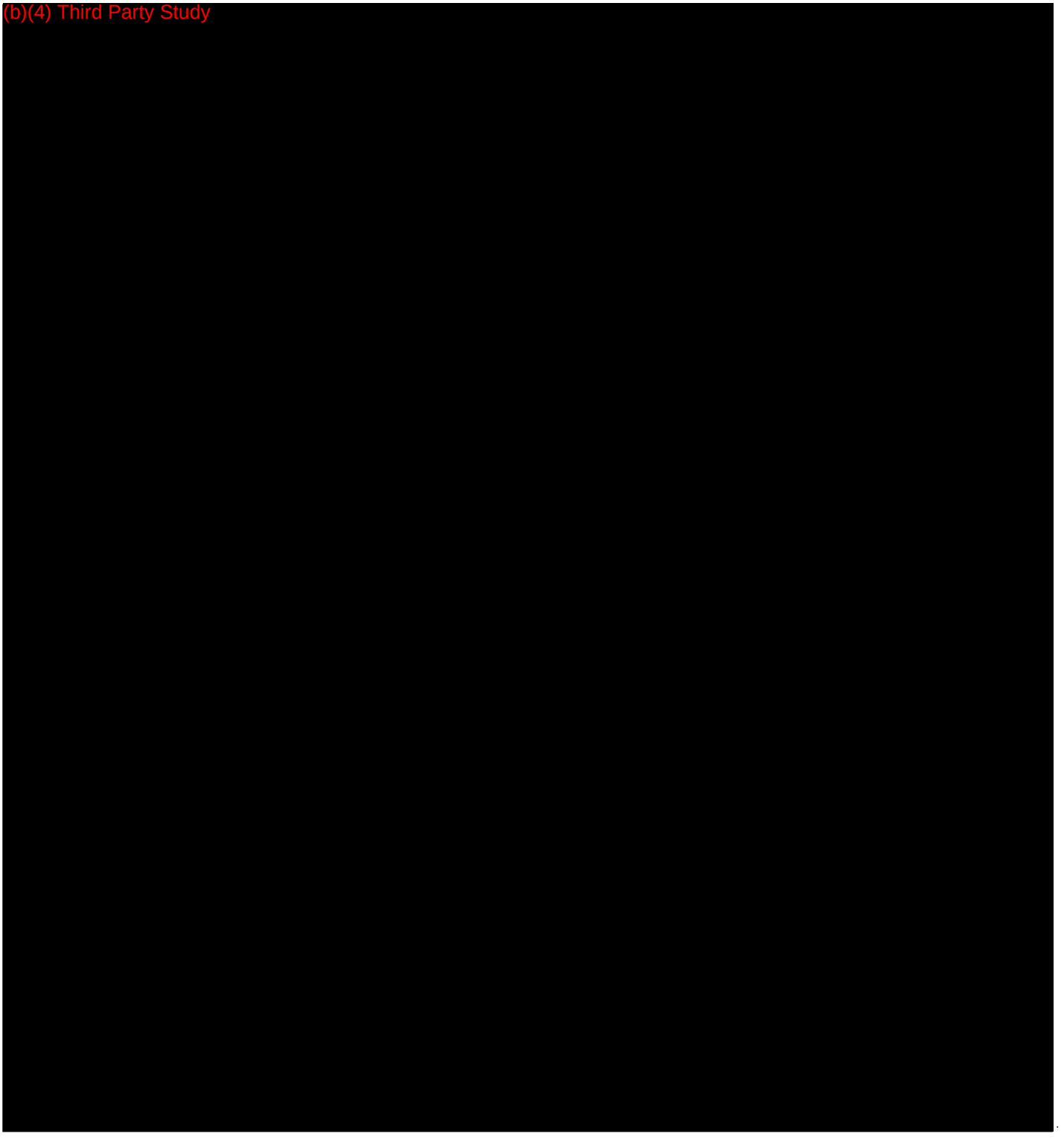

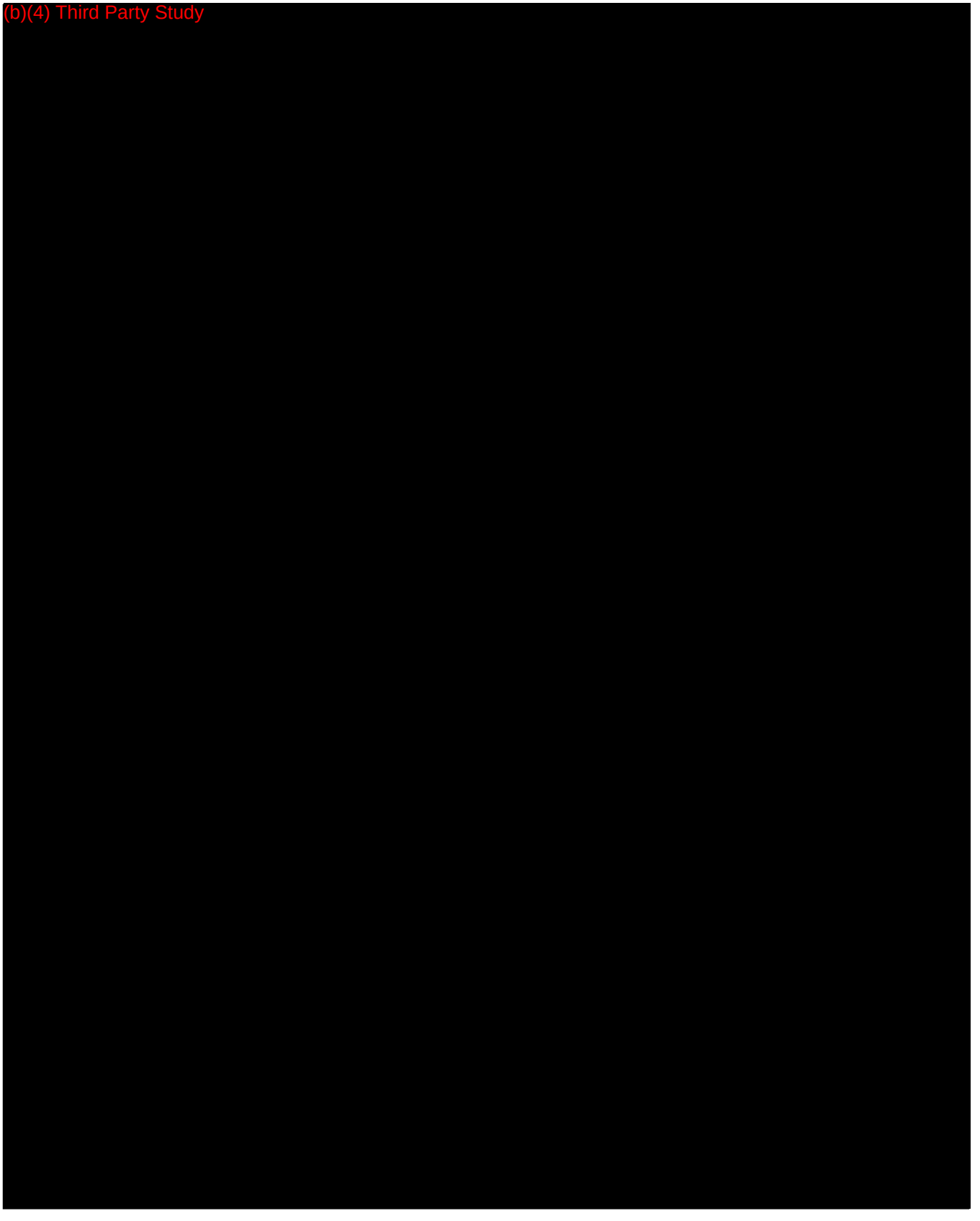

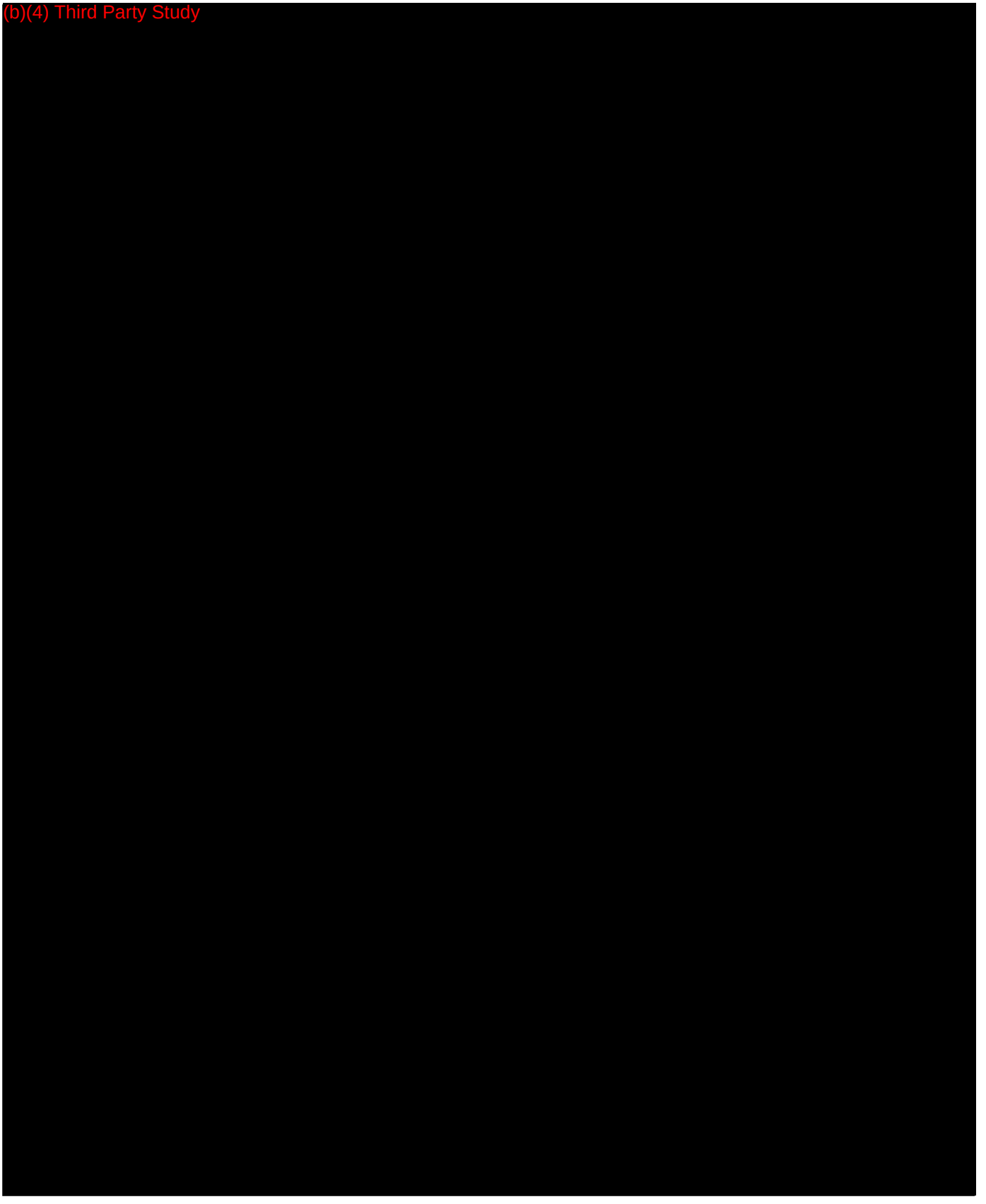

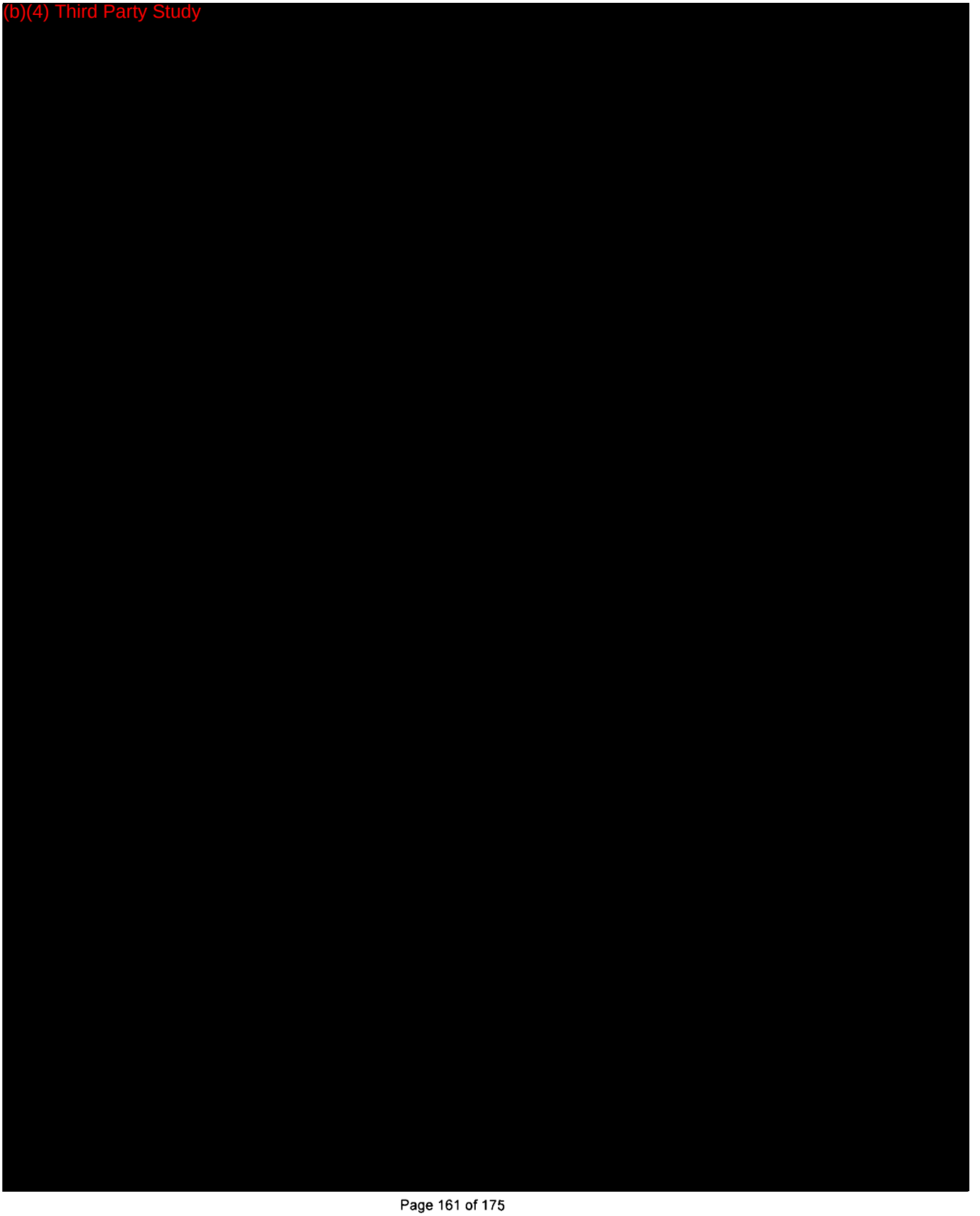

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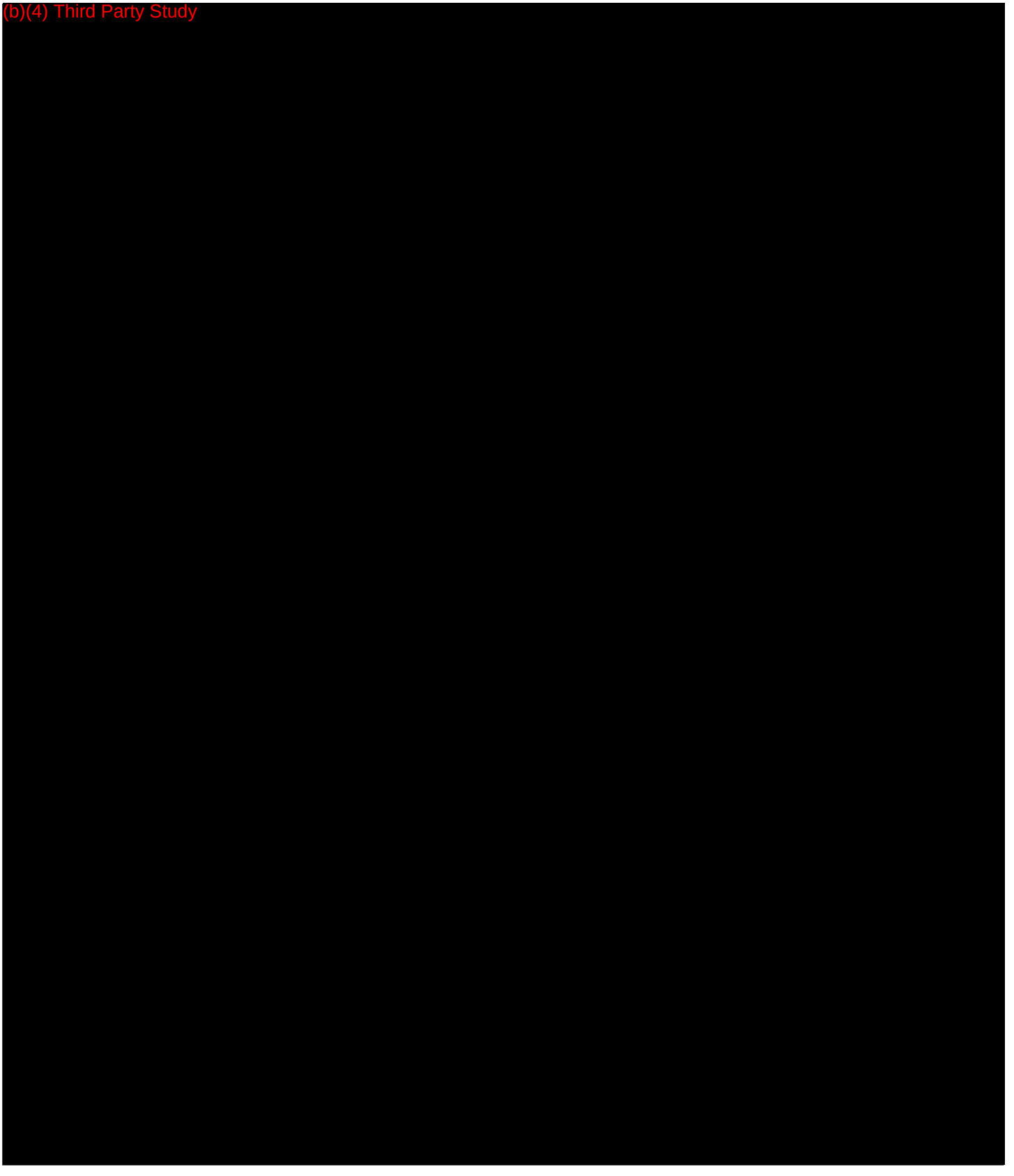

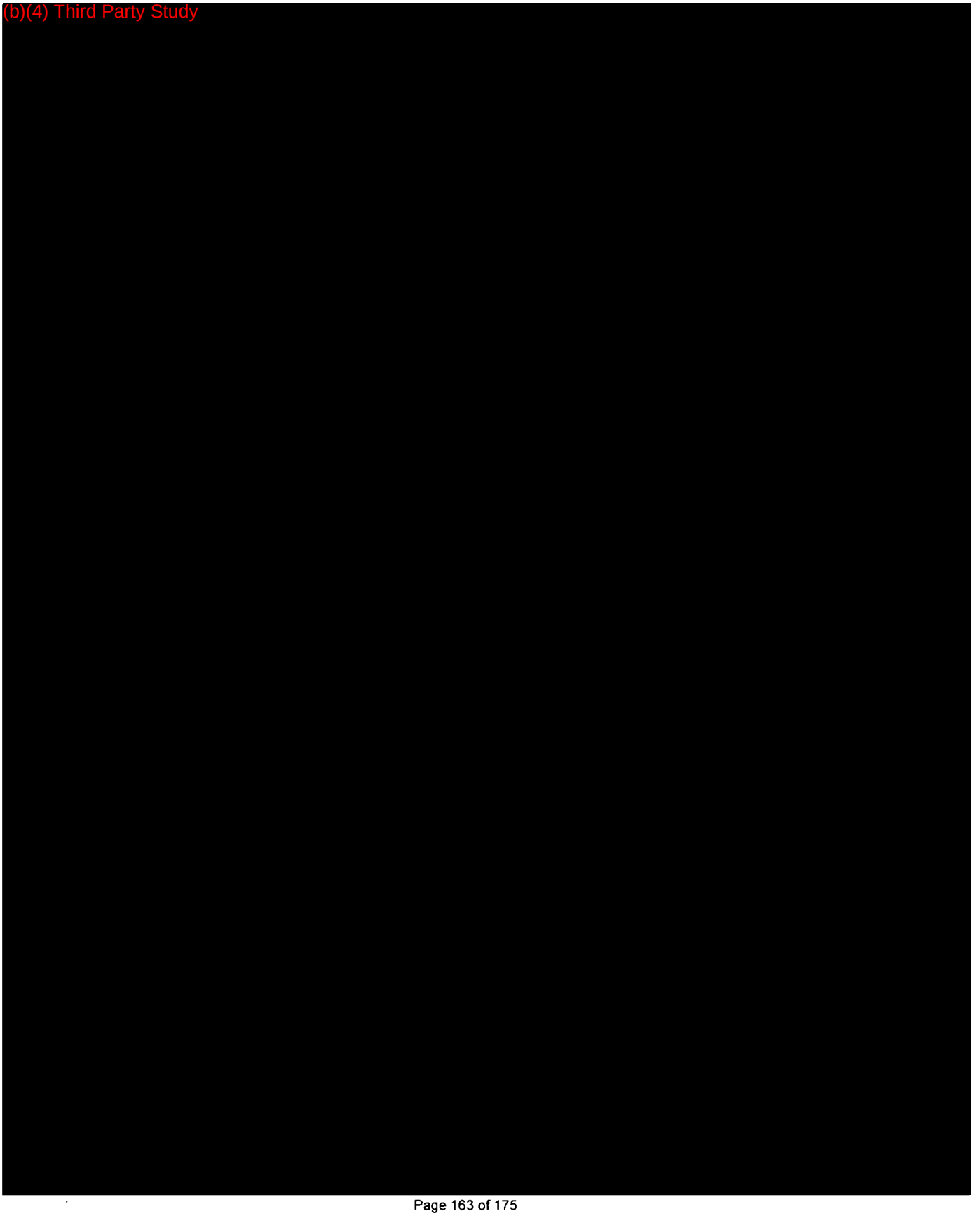

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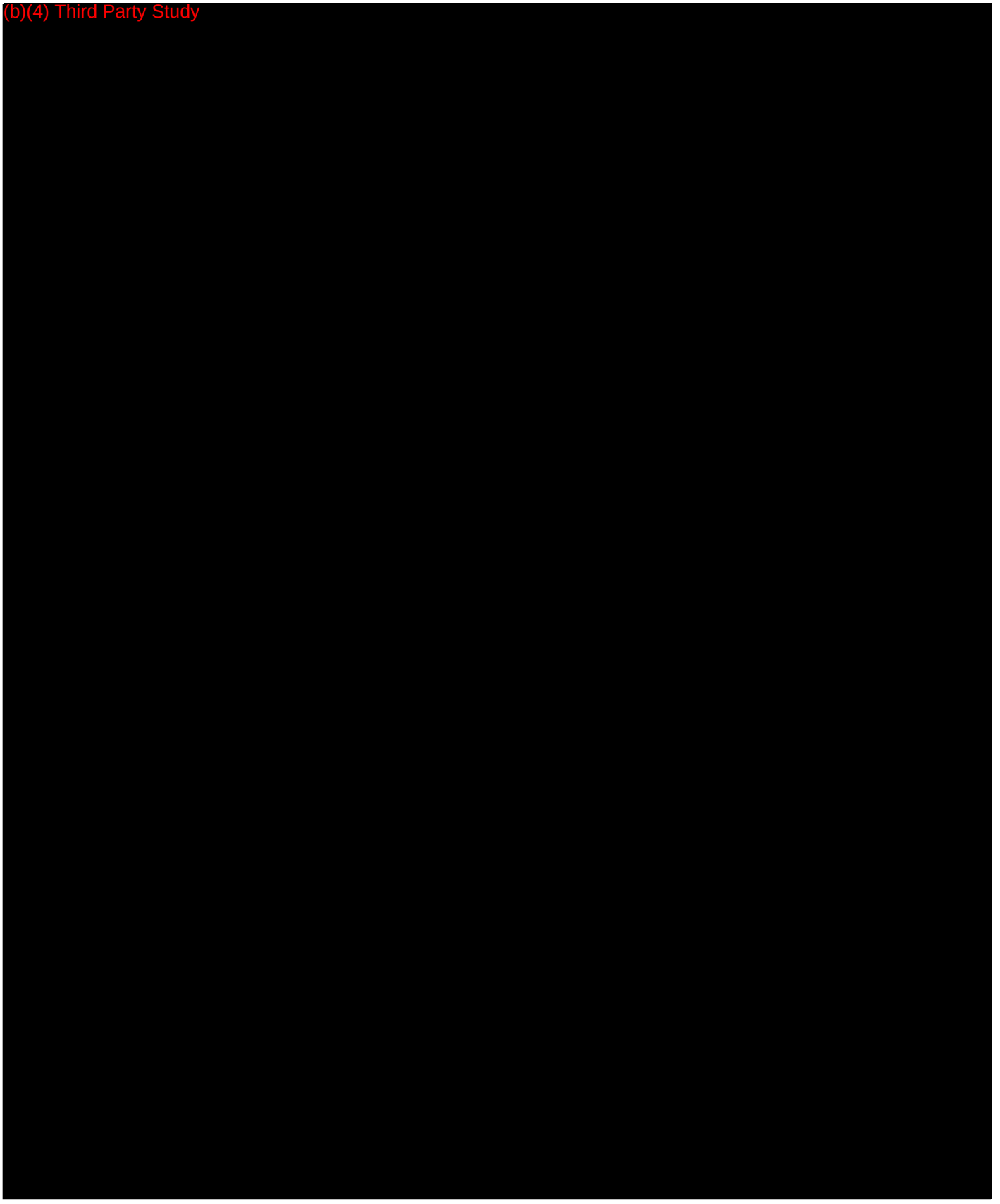

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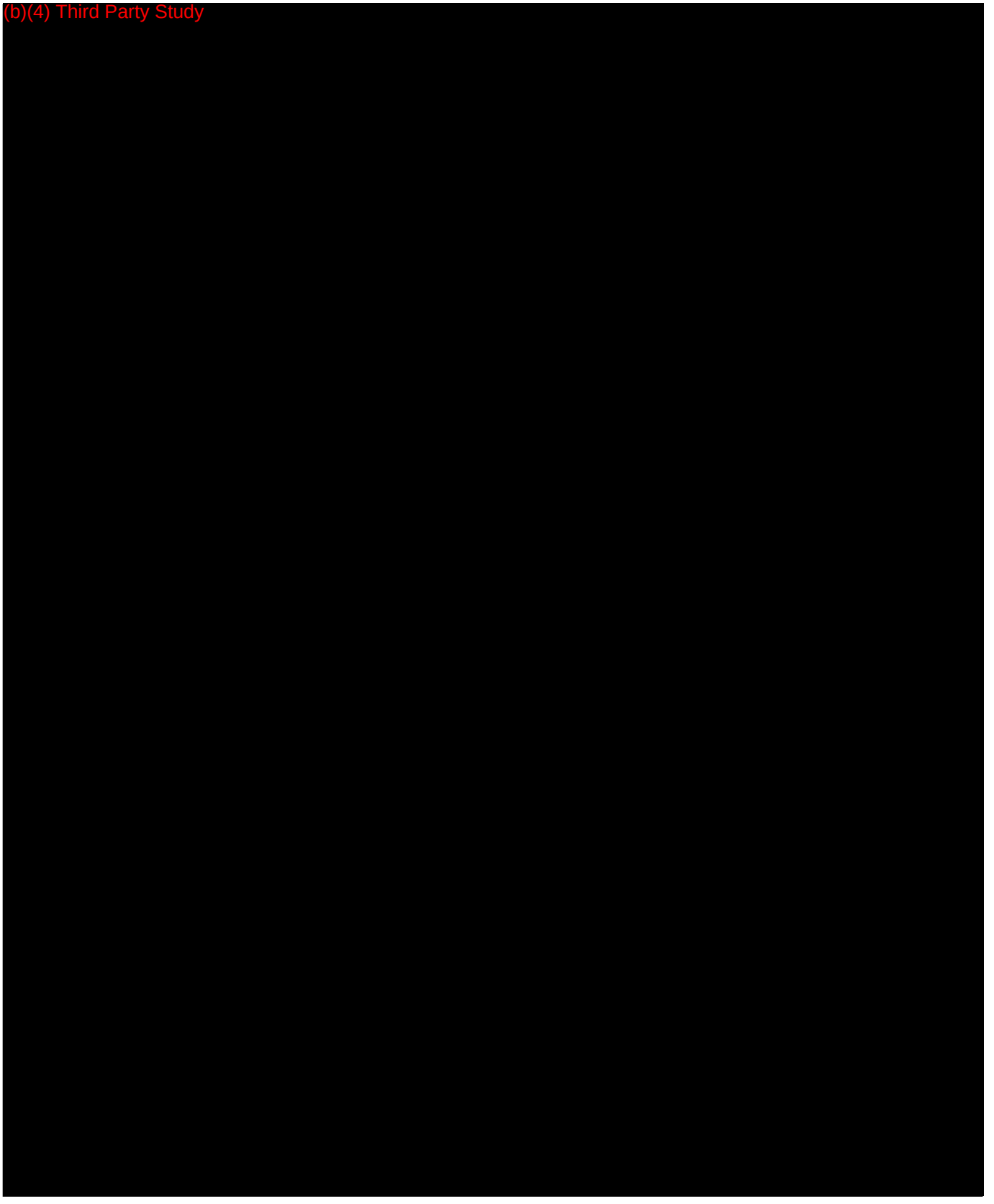

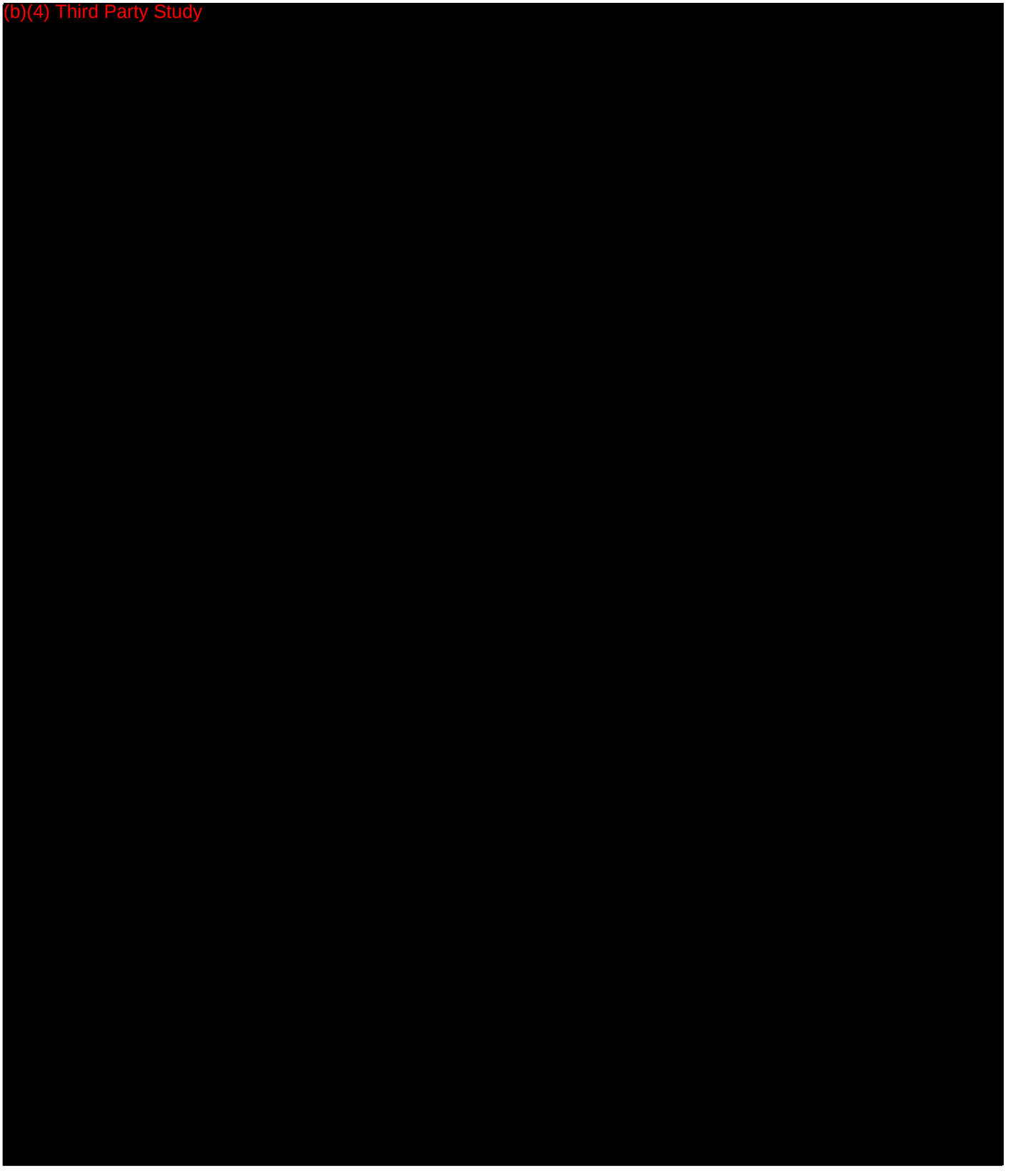

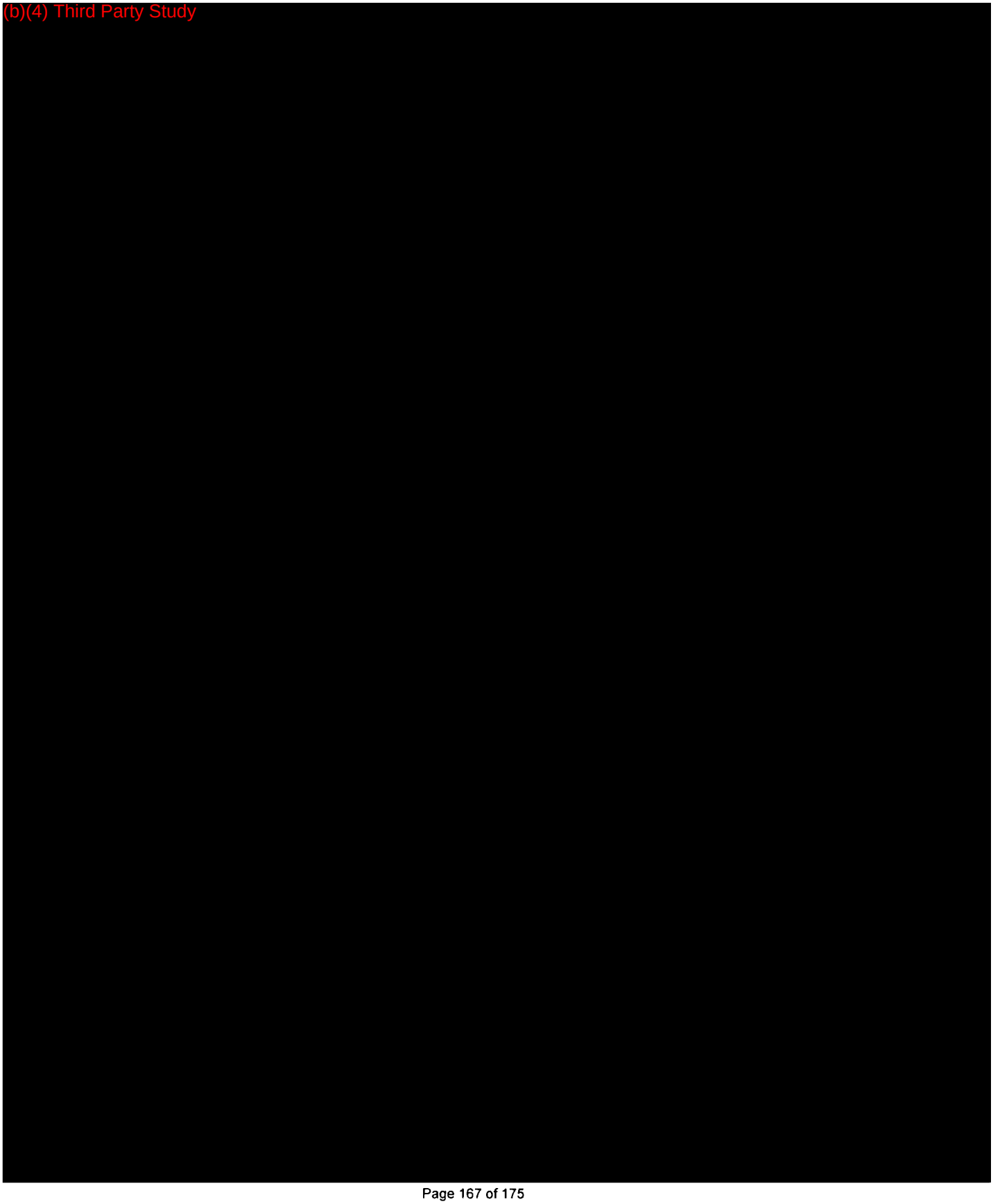

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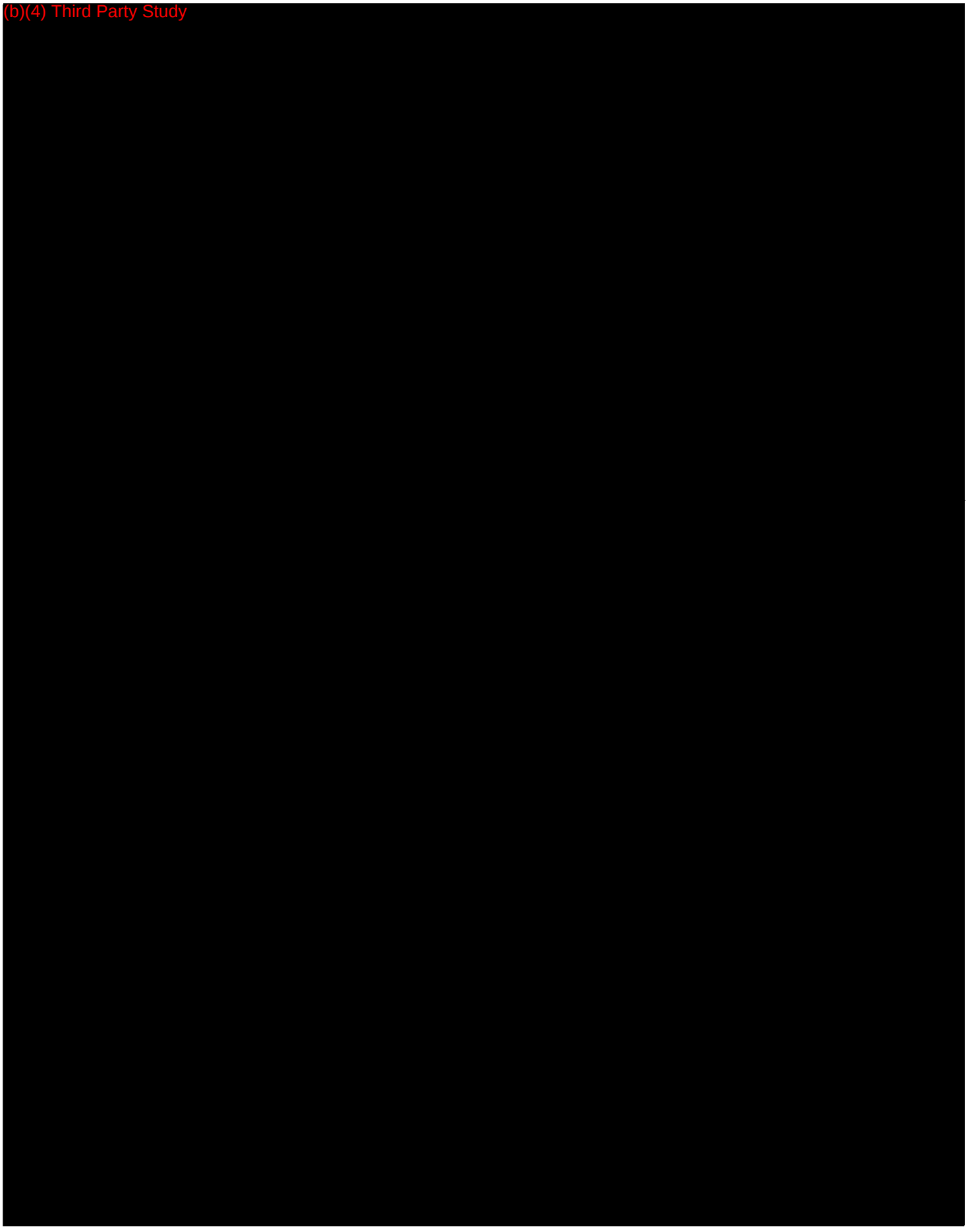

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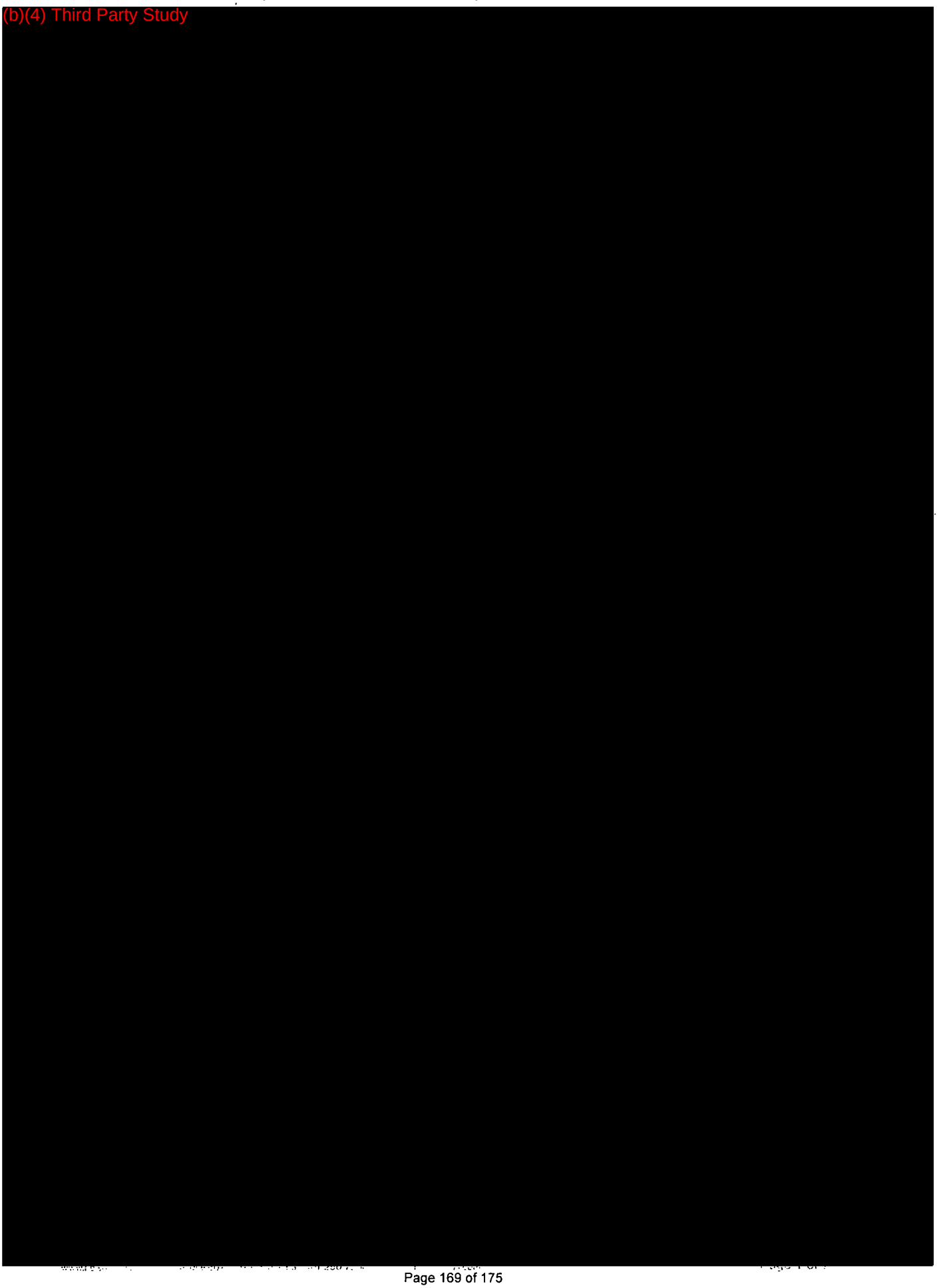

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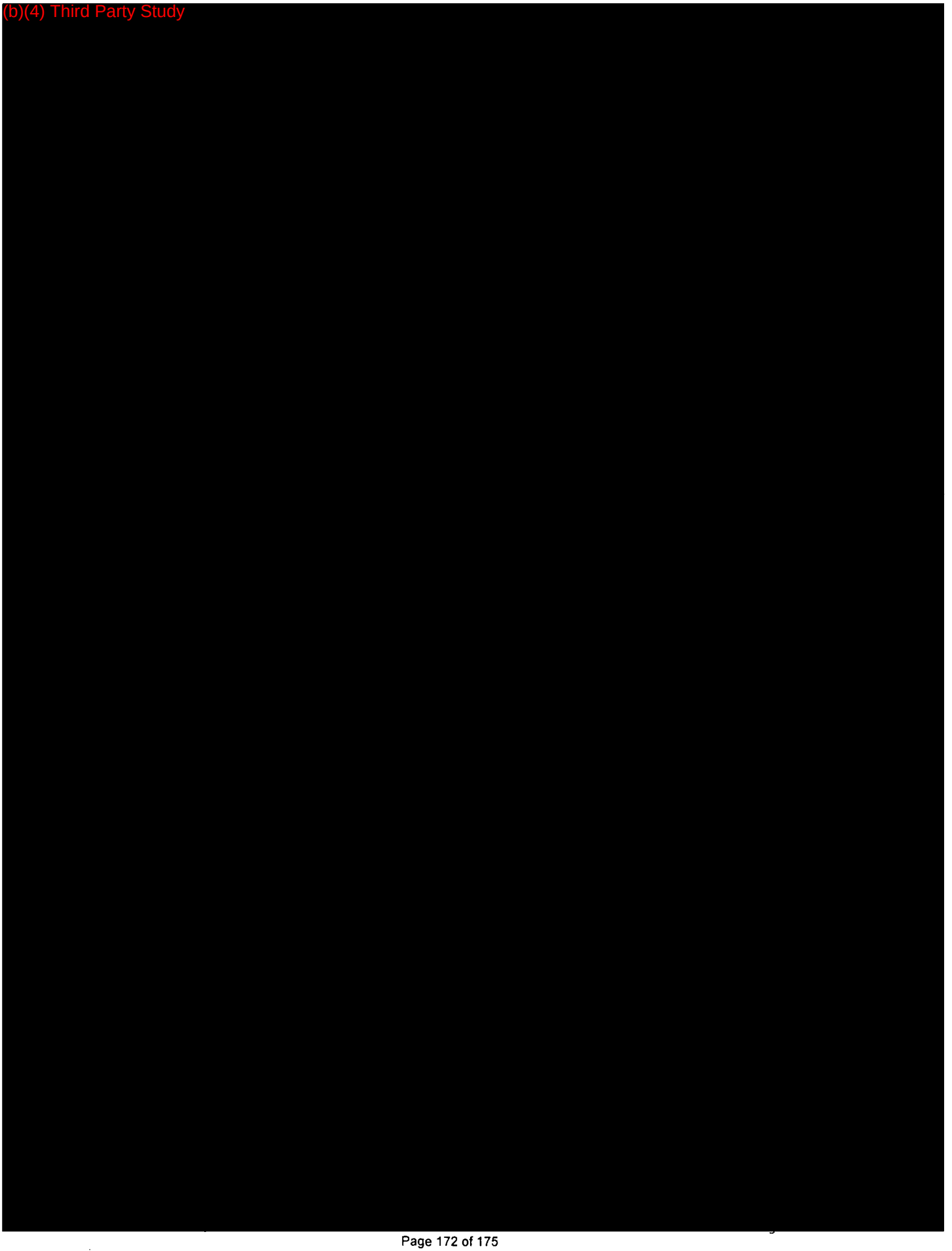

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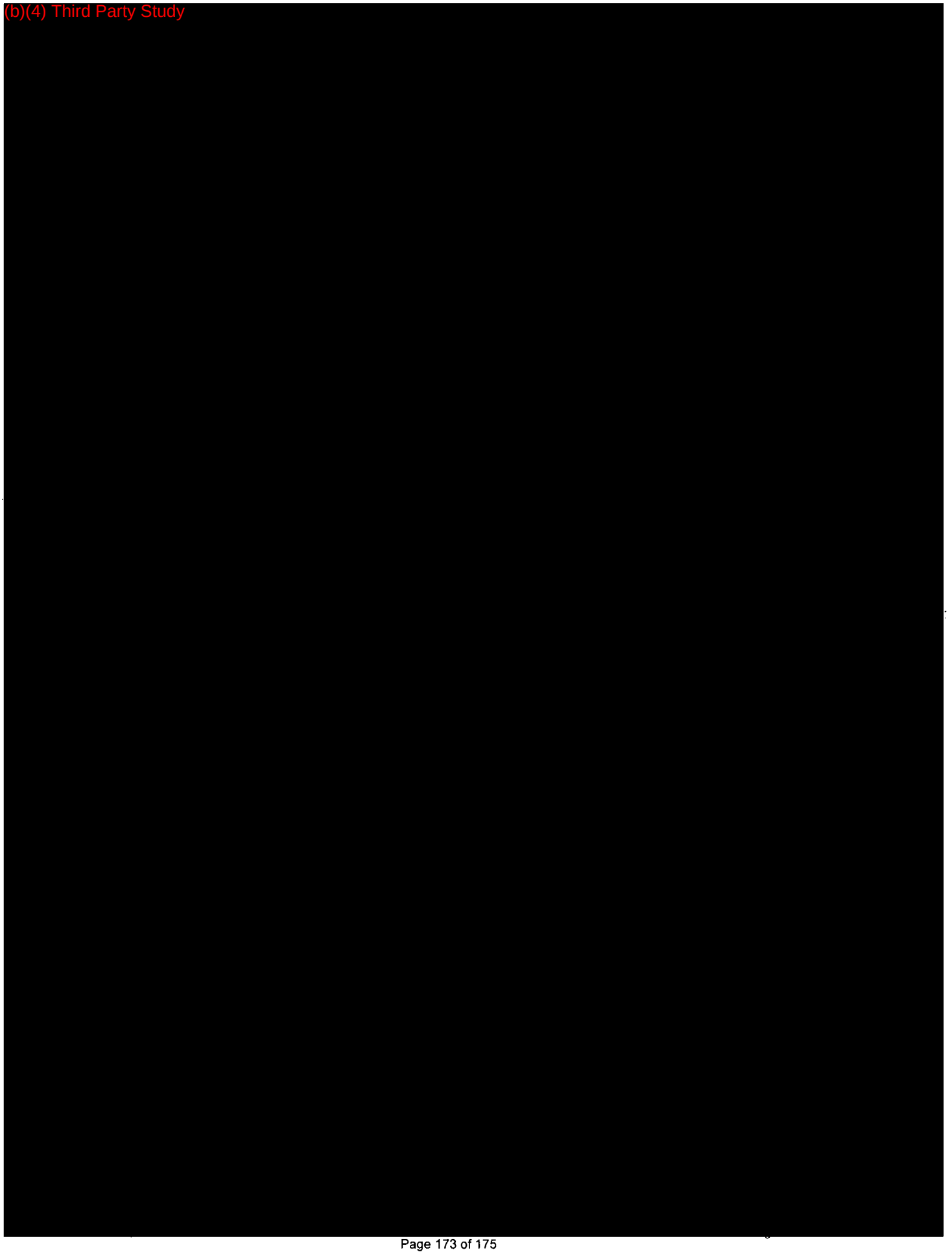

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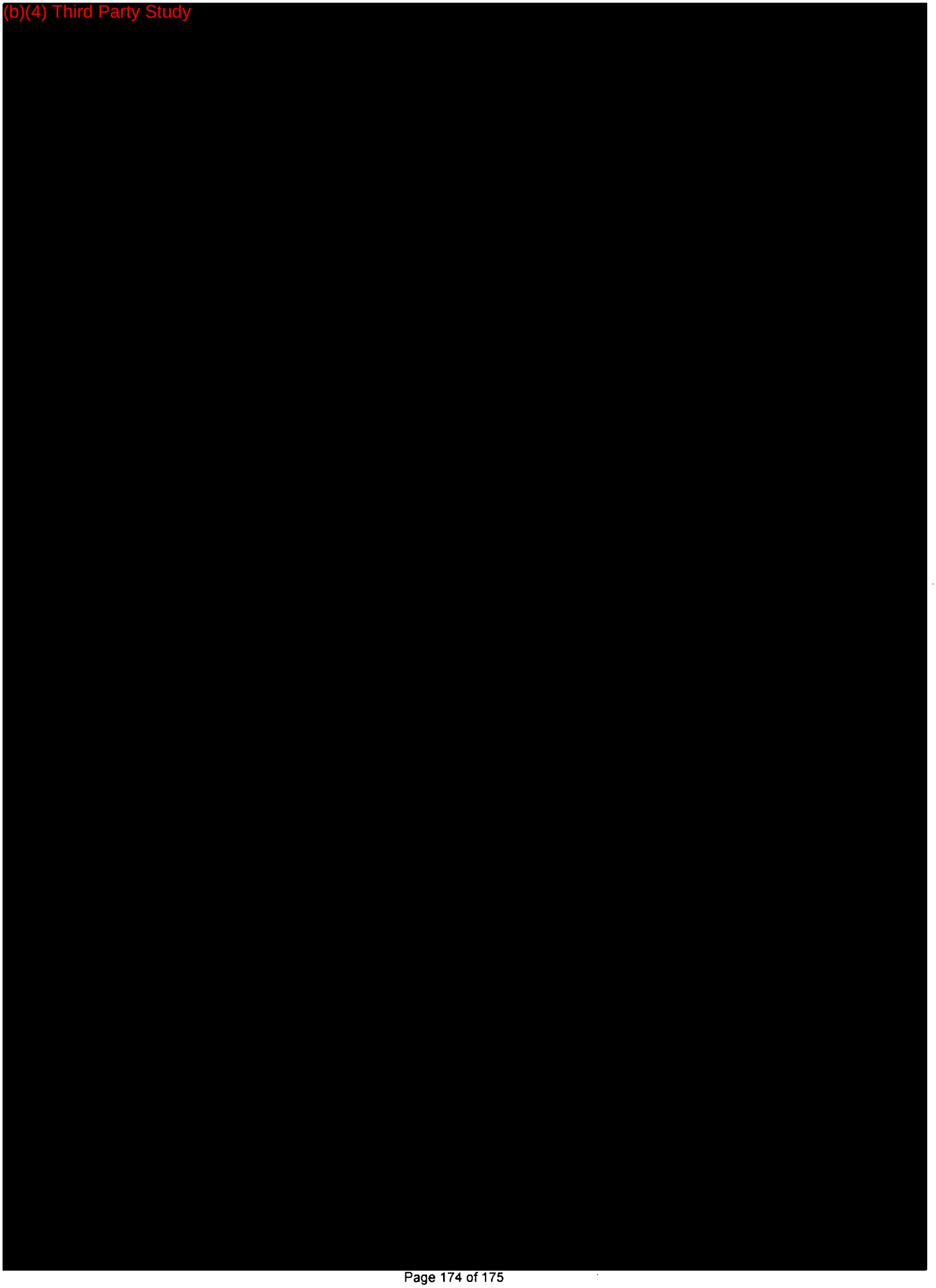

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