U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(cwf)
FOLDER:	K141681 - 1835 pages
COMPANY:	SYSMEX AMERICA, INC. (SYSMAMERA)
PRODUCT:	COUNTER, DIFFERENTIAL CELL (GKZ)
SUMMARY:	Product: SYSMEX XN SERIES
DATE REQUESTED:	Sep 29, 2015
DATE PRINTED:	Sep 29, 2015
Note:	Printed

1-CD

K141681 | A002

577 Aptakisic Road
Lincolnshire, IL 60069-4325
(800) 379-7639
(224)543-4699 Facsimile

June 30, 2014

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

RE: K141681- Revised Documents
510(k) Premarket Notification--Traditional
XN-Series (XN-11, XN-21) Automated Hematology Analyzers

Enclosed please find the 510(k) Premarket Notification submission for the Sysmex® XN series, Automated Hematology Analyzers (XN-11, XN-21). The XN-11 and XN-21 are the same analyzers as the recently cleared XN-Series (XN-10, XN-20) analyzers (K112605) with modifications to stabilize the HCT/MCV parameter to within +8% at room temperature (18°-26°C) for 24 hours and refrigerated temperature (2°-8°C) for 48 hours for commercial and reference laboratories. The XN series analyzers are Class II Automated cell counters reviewed under the Hematology panel and are being compared to the XE-5000 (K071967) which was cleared November 20, 2007. The product code is GKZ. The principal factors about the device are included in the table below.

Questions from Guidance for Industry/FDA Staff Format for Traditional /Abbreviated 510(k)s	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?		X
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data? NA		
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?	X	
Is the device implanted?		X

The Sysmex® XN series Automated Hematology Analyzers (XN-11, XN-21) are manufactured by Sysmex Corporation Japan (Owner/Operator No. 7010360) and imported and distributed into the USA by Sysmex America, Inc., Lincolnshire, IL (Registration No. 1422681). Sysmex considers the information appearing in Sections 8, 10-12, 16 and 20 to be confidential in nature and, therefore, not disclosable under the Freedom of Information Act. This protection to the manufacturer is provided under 21CFR 20.61 as well as 809.4.

Please contact me at 224-543-9618 or by fax at 224-543-4699 if there are questions.

Sincerely,

Sharita Brooks
Manager, Clinical Affairs
Sysmex America, Inc.

Enclosure: 1 complete paper copy of 510(k) Notification & 1 electronic copy that is an exact duplicate of paper copy.

(b)(4) Data Information

(b)(4) Data Information

4.3.2 Verification of XN-Series Body Fluid Performance when Connected to the SP-10

(b)(4) Data Information

(b)(4) Data Information

(b)(4) Data Information

(b)(4) Data Information

(b)(4) Data Information

[redacted]

Chapter 1 Introduction

Thank you for purchasing the XN series automated hematology analyzer.
Please read this manual carefully before operating this product.
Keep this manual in a safe place for future reference.

Note:
Operation of instruments and devices outside of recommended manufactures guidelines may result in inaccuracies.

US federal law restricts this device to sale by or on the order of a physician (or properly licensed medical practitioner).

Contact Address

Manufacturer

SYSMEX CORPORATION
1-5-1 Wakinohama-Kaigandori Chuo-ku, Kobe, Hyogo 651-0073 JAPAN

Authorized Representative

EC REP

European Representative
SYSMEX EUROPE GmbH
Bornbarch 1 D – 22848 Norderstedt, Germany
Phone: +49 40 5 27 26-0 / Fax: +49 40 5 27 26-100

Americas

SYSMEX AMERICA, Inc.
577 Aptakisic Road, Lincolnshire, IL 60069, U.S.A.
Phone: +1-224-543-9500 / Fax: +1-224-543-9505

Asia-Pacific

SYSMEX ASIA PACIFIC PTE LTD.
9 Tampines Grande, #06-18, Singapore 528735
Phone: +65-6221-3629 / Fax: +65-6221-3687

Ordering of Supplies and Replacement Parts

If you need to order supplies or replacement parts, please contact your local Sysmex representative.

Service and Maintenance

Please contact the Service Department of local Sysmex representative.

K141681

577 Aptakisic Road
Lincolnshire, IL 60069-4325
(800) 379-7639
(224)543-4699 Facsimile

June 24, 2014

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

RE: K141681
510(k) Premarket Notification--Traditional
XN-Series (XN-11, XN-21) Automated Hematology Analyzers

Enclosed please find the 510(k) Premarket Notification submission for the Sysmex® XN series, Automated Hematology Analyzers (XN-11, XN-21). The XN-11 and XN-21 are the same analyzers as the recently cleared XN-Series (XN-10, XN-20) analyzers (K112605) with modifications to stabilize the HCT/MCV parameter to within +8% at room temperature (18°-26°C) for 24 hours and refrigerated temperature (2°-8°C) for 48 hours for commercial and reference laboratories. The XN series analyzers are Class II Automated cell counters reviewed under the Hematology panel and are being compared to the XE-5000 (K071967) which was cleared November 20, 2007. The product code is GKZ. The principal factors about the device are included in the table below.

Questions from Guidance for Industry/FDA Staff Format for Traditional /Abbreviated 510(k)s	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?		X
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data? NA		
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?	X	
Is the device implanted?		X

The Sysmex® XN series Automated Hematology Analyzers (XN-11, XN-21) are manufactured by Sysmex Corporation Japan (Owner/Operator No. 7010360) and imported and distributed into the USA by Sysmex America, Inc., Lincolnshire, IL (Registration No. 1422681). Sysmex considers the information appearing in Sections 8, 10-12, 16 and 20 to be confidential in nature and, therefore, not disclosable under the Freedom of Information Act. This protection to the manufacturer is provided under 21CFR 20.61 as well as 809.4.

Please contact me at 224-543-9618 or by fax at 224-543-4699 if there are questions.

Sincerely,

Sharita Brooks
Manager, Clinical Affairs
Sysmex America, Inc.

Enclosure: 1 complete paper copy of 510(k) Notification & 1 electronic copy that is an exact duplicate of paper copy.

K141681

577 Aptakisic Road
Lincolnshire, IL 60069-4325
(800) 379-7639
(224)543-4699 Facsimile

June 23, 2014

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

RE: K141681
510(k) Premarket Notification--Traditional
XN-Series (XN-11, XN-21) Automated Hematology Analyzers

Enclosed please find the 510(k) Premarket Notification submission for the Sysmex® XN series, Automated Hematology Analyzers (XN-11, XN-21). The XN-11 and XN-21 are the same analyzers as the recently cleared XN-Series (XN-10, XN-20) analyzers (K112605) with modifications to stabilize the HCT/MCV parameter to within +8% at room temperature (18°-26°C) for 24 hours and refrigerated temperature (2°-8°C) for 48 hours for commercial and reference laboratories. The XN series analyzers are Class II Automated cell counters reviewed under the Hematology panel and are being compared to the XE-5000 (K071967) which was cleared November 20, 2007. The product code is GKZ. The principal factors about the device are included in the table below.

Questions from Guidance for Industry/FDA Staff Format for Traditional /Abbreviated 510(k)s	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?		X
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data? NA		
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?	X	
Is the device implanted?		X

The Sysmex® XN series Automated Hematology Analyzers (XN-11, XN-21) are manufactured by Sysmex Corporation Japan (Owner/Operator No. 7010360) and imported and distributed into the USA by Sysmex America, Inc., Lincolnshire, IL (Registration No. 1422681). Sysmex considers the information appearing in Sections 8, 10-12, 16 and 20 to be confidential in nature and, therefore, not disclosable under the Freedom of Information Act. This protection to the manufacturer is provided under 21CFR 20.61 as well as 809.4.

Please contact me at 224-543-9618 or by fax at 224-543-4699 if there are questions.

Sincerely,

Sharita Brooks

Sharita Brooks
Manager, Clinical Affairs
Sysmex America, Inc.

Enclosure: 1 complete paper copy of 510(k) Notification & 1 electronic copy that is an exact duplicate of paper copy.

577 Aptakisic Road
Lincolnshire, IL 60069-4222
(800) 779-7659
(224)543-1699 Facsimile

June 23, 2014

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

RE: K141851
Traditional Premarket Notification
XN-Series (XN-11, XN-21) Automated Hematology Analyzers

Enclosed please find the 510(k) Premarket Notification submission for the Sysmex® XN series Automated Hematology Analyzers (XN-11, XN-21). The XN-11 and XN-21 are the same analyzers as the recently cleared XN Series (XN-10, XN-20) analyzers (K112264) with modifications to stabilize the HGB/MCV parameter to within 2% at room temperature (18°-26°C) for 24 hours and refrigerated temperature (2°-8°C) for 48 hours for commercial and reference laboratories. The XN series analyzers are Class II Automated cell counters reviewed under the Hematology panel and are being compared to the XE-5000 (k071907) which was cleared November 20, 2007. The product code is GKZ. The principal factors about the devices are included in the table below.

Questions from Guidance for Industry/FDA Staff Format for Traditional (Abbreviated 510(k)s	YES	NO
Is the device intended for prescription use? (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?		X
Is the device a reprocessed single use device?		X
If yes, does this device have reprocessed validation data? N/A		
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission provide clinical information?	X	
Is the device implanted?		X

The Sysmex XN series Automated Hematology Analyzers (XN-11, XN-21) are manufactured by Sysmex Corporation Japan (Device Registration No. 9610060) and imported and distributed into the USA by Sysmex America, Inc., Lincolnshire, IL (Registration No. 1422084). Sysmex considers the information appearing in Sections 8, 10-12, to and [illegible] be considered confidential in nature and, therefore, not disclosable under the Freedom of Information Act. This protocol and the manufacturer is provided under 21CFR 20.61 as well as 807.4.

Please contact me at 224-678-2456 (fax at 224-563-1699 if there are questions

Sincerely,

Sonia Cooks
Manager, Clinical Affairs
Sysmex America, Inc

[illegible] Electronic paper copy of 510(k) Notification & 1 electronic copy that is an exact duplicate of paper copy

003 510k Cover Letter & Acceptance Checklist

K141681

577 Aptakisic Road
Lincolnshire, IL 60069-4325
(800) 379-7639
(224)543-4699 Facsimile

June 19, 2014

U.S. Food and Drug Administration
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
XN-Series (XN-11, XN-21) Automated Hematology Analyzers

Enclosed please find the 510(k) Premarket Notification submission for the Sysmex® XN series, Automated Hematology Analyzers (XN-11, XN-21). The XN-11 and XN-21 are the same analyzers as the recently cleared XN-Series (XN-10, XN-20) analyzers (K112605) with modifications to stabilize the HCT/MCV parameter to within +8% at room temperature (18°-26°C) for 24 hours and refrigerated temperature (2°-8°C) for 48 hours for commercial and reference laboratories. The XN series analyzers are Class II Automated cell counters reviewed under the Hematology panel and are being compared to the XE-5000 (K071967) which was cleared November 20, 2007. The product code is GKZ. The principal factors about the device are included in the table below.

Questions from Guidance for Industry/FDA Staff Format for Traditional /Abbreviated 510(k)s	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?		X
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data? NA		
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?	X	
Is the device implanted?		X

The Sysmex® XN series Automated Hematology Analyzers (XN-11, XN-21) are manufactured by Sysmex Corporation Japan (Owner/Operator No. 7010360) and imported and distributed into the USA by Sysmex America, Inc., Lincolnshire, IL (Registration No. 1422681). Sysmex considers the information appearing in Sections 8, 10-12, 16 and 20 to be confidential in nature and, therefore, not disclosable under the Freedom of Information Act. This protection to the manufacturer is provided under 21CFR 20.61 as well as 809.4.

Please contact me at 224-543-9618 or by fax at 224-543-4699 if there are questions.

Sincerely,

Sharita Brooks

Sharita Brooks
Manager, Clinical Affairs
Sysmex America, Inc.

Enclosure: 1 complete paper copy of 510(k) Notification & 1 electronic copy that is an exact duplicate of paper copy.

003 510k Cover Letter & Acceptance Checklist

DUPLICATE

sysmex

577 Aptakisic Road
Lincolnshire, IL 60069-4325
(800) 379-7639
(224)543-4699 Facsimile

June 19, 2014

U.S. Food and Drug Administration
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
XN-Series (XN-11, XN-21) Automated Hematology Analyzers

Enclosed please find the 510(k) Premarket Notification submission for the Sysmex® XN series, Automated Hematology Analyzers (XN-11, XN-21). The XN-11 and XN-21 are the same analyzers as the recently cleared XN-Series (XN-10, XN-20) analyzers (K112605) with modifications to stabilize the HCT/MCV parameter to within +8% at room temperature (18°-26°C) for 24 hours and refrigerated temperature (2°-8°C) for 48 hours for commercial and reference laboratories. The XN series analyzers are Class II Automated cell counters reviewed under the Hematology panel and are being compared to the XE-5000 (K071967) which was cleared November 20, 2007. The product code is GKZ. The principal factors about the device are included in the table below.

Questions from Guidance for Industry/FDA Staff Format for Traditional /Abbreviated 510(k)s	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?		X
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data? NA		
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?	X	
Is the device implanted?		X

The Sysmex® XN series Automated Hematology Analyzers (XN-11, XN-21) are manufactured by Sysmex Corporation Japan (Owner/Operator No. 7010360) and imported and distributed into the USA by Sysmex America, Inc., Lincolnshire, IL (Registration No. 1422681). Sysmex considers the information appearing in Sections 8, 10-12, 16 and 20 to be confidential in nature and, therefore, not disclosable under the Freedom of Information Act. This protection to the manufacturer is provided under 21CFR 20.61 as well as 809.4.

Please contact me at 224-543-9618 or by fax at 224-543-4699 if there are questions.

Sincerely,

Sharita Brooks

Sharita Brooks
Manager, Clinical Affairs
Sysmex America, Inc.

Enclosure: 1 complete paper copy of 510(k) Notification & 1 electronic copy that is an exact duplicate of paper copy.

55

001 Medical Device User Fee Cover Sheet (Form FDA 3601)

(b)(4)

(b)(4)

Floor Rockville
[Please do NC
8. USER FEE
(b)(4)
Form FDA 3601 (01/20

002 CDRH PREMARKET SUBMISSION COVER SHEET

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
06/19/2014	(b)(4)	

SECTION A — TYPE OF SUBMISSION

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

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

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

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
Sysmex America, Inc.	3009711478		
Division Name *(if applicable)*	**Phone Number *(including area code)***		
	(224) 543-9618		
Street Address	**FAX Number *(including area code)***		
577 Aptakisic Road	(224) 543-4699		
City	**State / Province**	**ZIP/Postal Code**	**Country**
Lincolnshire	IL	60069	USA

Contact Name: Sharita Brooks

Contact Title	Contact E-mail Address
Manager, Clinical Affairs	brooks@sysmex.com

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

Company / Institution Name			
Division Name *(if applicable)*	**Phone Number *(including area code)***		
Street Address	**FAX Number *(including area code)***		
City	**State / Province**	**ZIP Code**	**Country**

Contact Name

Contact Title	Contact E-mail Address

FORM FDA 3514 (1/13) Page 1 of 5 Pages

PSC Publishing Services (301) 443-6740 EF

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

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

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

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

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

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ 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

- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify)*:

SECTION D3 — REASON FOR SUBMISSION - 510(k)

- ☒ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☐ Other Reason *(specify)*:

FORM FDA 3514 (1/13) Page 2 of 5 Pages

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	GKZ	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- [x] 510 (k) summary attached
- [ ] 510 (k) statement

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

	510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1	K071967	Sysmex XE-5000	Sysmex Corporation
2	K112605	Sysmex XN-Series (XN-10, XN-20)	Sysmex Corporation
3			
4			
5			
6			

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

	Trade or Proprietary or Model Name for This Device	Model Number
1	Sysmex XN Series	XN-11 and XN-21
2		
3		
4		
5		

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

1	K0701967	2	K112605	3	K130898	4	Q131301	5		6	
7		8		9		10		11		12	

Data Included in Submission

- [x] Laboratory Testing
- [ ] Animal Trials
- [ ] Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
GKZ		[ ] Class I [x] Class II [ ] Class III [ ] Unclassified

Classification Panel

Hematology and Pathology Devices

Indications *(from labeling)*

The XN-Series modules (XN-11, XN-21) are quantitative multi-parameter automated hematology analyzers intended for in vitro diagnostic use in screening patient populations found in clinical and reference laboratories.

The XN-Series modules classify and enumerate the following parameters in whole blood: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, NEUT%/#, LYMPH %/#, MONO%/#, EO%/#, BASO%/#, IG%/#, RDW-CV, RDW-SD, MPV, NRBC#/%, RET%/#, IPF, IRF, RET-He and has a Body Fluid mode for body fluids. The Body Fluid mode enumerates the WBC-BF, RBC-BF, MN%/#, PMN%/#, and TC-BF parameters in body fluids (peritoneal, pleural and synovial). Whole blood should be collected in K_3 or K_3EDTA anticoagulant and peritoneal, pleural and synovial fluids in K_2EDTA anticoagulant to prevent clotting of fluid.

FORM FDA 3514 (1/13) Page 3 of 5 Pages

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.

FDA Document Number *(if known)*:

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

☒ Original ☐ Add ☐ Delete

Facility Establishment Identifier (FEI) Number:

☒ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

Company / Institution Name: Sysmex Corporation	Establishment Registration Number: 3010421384
Division Name *(if applicable)*:	Phone Number *(including area code)*: 224-543-9514
Street Address: 1-5-1 Wakinohama-Kaigandori Chuo-Ku	FAX Number *(including area code)*: 224-543-4699
City: Kobe	State / Province: Hyogo; ZIP Code: 651-0073; Country: Japan
Contact Name: Peter Shearstone	Contact Title: V.P. Regulatory Affairs; Contact E-mail Address: shearstonep@sysmex.com

☐ 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 Code: ; Country:
Contact Name:	Contact Title: ; Contact E-mail Address:

☐ 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 Code: ; Country:
Contact Name:	Contact Title: ; Contact E-mail Address:

FORM FDA 3514 (1/13) Add Continuation Page Page 4 of 5 Pages

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					
3					
4					
5					
6					
7					

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

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

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

The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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

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

FORM FDA 3514 (1/13) Page 5 of 5 Pages

003 510k Cover Letter & Acceptance Checklist

577 Aptakisic Road
Lincolnshire, IL 60069-4325
(800) 379-7639
(224)543-4699 Facsimile

June 19, 2014

U.S. Food and Drug Administration
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
XN-Series (XN-11, XN-21) Automated Hematology Analyzers

Enclosed please find the 510(k) Premarket Notification submission for the Sysmex® XN series, Automated Hematology Analyzers (XN-11, XN-21). The XN-11 and XN-21 are the same analyzers as the recently cleared XN-Series (XN-10, XN-20) analyzers (K112605) with modifications to stabilize the HCT/MCV parameter to within +8% at room temperature (18°-26°C) for 24 hours and refrigerated temperature (2°-8°C) for 48 hours for commercial and reference laboratories. The XN series analyzers are Class II Automated cell counters reviewed under the Hematology panel and are being compared to the XE-5000 (K071967) which was cleared November 20, 2007. The product code is GKZ. The principal factors about the device are included in the table below.

Questions from Guidance for Industry/FDA Staff Format for Traditional /Abbreviated 510(k)s	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?		X
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data? NA		
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?	X	
Is the device implanted?		X

The Sysmex® XN series Automated Hematology Analyzers (XN-11, XN-21) are manufactured by Sysmex Corporation Japan (Owner/Operator No. 7010360) and imported and distributed into the USA by Sysmex America, Inc., Lincolnshire, IL (Registration No. 1422681). Sysmex considers the information appearing in Sections 8, 10-12, 16 and 20 to be confidential in nature and, therefore, not disclosable under the Freedom of Information Act. This protection to the manufacturer is provided under 21CFR 20.61 as well as 809.4.

Please contact me at 224-543-9618 or by fax at 224-543-4699 if there are questions.

Sincerely,

Shanta Brooks

Shanta Brooks
Manager, Clinical Affairs
Sysmex America, Inc.

Enclosure: 1 complete paper copy of 510(k) Notification & 1 electronic copy that is an exact duplicate of paper copy.

Acceptance Checklist for Traditional 510(k)s

Device: XN-Series (XN-11, XN-21)

#	Preliminary Questions	Yes	N/A	No	Page
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)?	√			2
2	Is the application with the appropriate Center?	√			2
3	If a Request for Designation (RFD) was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD# and confirm the following: a. Is the device or combination product the same (e.g., design, formulation as that presented in the RFD submission? b. Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission?		√		
4	Is this device type eligible for a 510(k) submission?	√			2
5	Is there a pending PMA for the same device with the same indications for use?			√	
6	If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)?			√	
	Organizational Elements				
	a. Submission contains Table of Contents	√			1
	b. Each section is labeled	√			
	c. All pages of the submission are numbered	√			
	d. Type of 510(k) is identified—traditional, abbreviated, or special	√			8
	Elements of a Complete Submission (RTA Items) (21CFR 807.87 unless otherwise indicated				
A.	**Administrative**				
1.	All content used to support the submission is written in English	√			
2.	Submission identifies the following	√			
	a. Device trade name or proprietary name	√			15
	b. Device common name	√			15
	c. Device class and panel or Classification regulation	√			2
3.	Submission contains Indications for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109)	√			14
4.	Submission contains **510(k) Summary** (Either a. or b. must be answered "Yes" to be considered complete.)	√			15
	a. Summary contains all elements per 21 CFR 807.92	√			
	b. Statement contains all elements per 21 CFR 807.93		√		
5.	Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k)	√			20
6.	Submission contains Class III Summary and Certification		√		
7.	Submission contains clinical data	√			55
	a. Submission includes completed Financial Certification (FDA Form 3454) or Disclosure (FDA Form 3455) information for each covered clinical study included in the submission.	√			22

#	Elements of a Complete Submission (continued)	Yes	N/A	No	Page
	b. Submission includes completed Certification of Compliance with requirements of Clinical Trials.gov Data Bank (FDA Form 3674) (42 U.S.C. 282(j)(5)(B)) for each applicable device clinical trial included in the submission.	√			23
8.	If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains complete Standards Data Report for 510(k)s (FDA Form 3654).	√			302
9.	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 for the subject device.	√			2
	a. If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed.		√		
B.	**Device Description**				
10.	a. If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement.		√		
	b. If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.		√		
11.	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 effect.	√			30
	b. A description of proposed conditions for 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.	√			14
	c. A list and description of each device for which clearance is requested.		√		
12.	Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions.	√			34
13.	If device is intended to be marketed with multiple components, accessories, and/or as part of a system. a. Submission includes a list of all components, accessories and/or as part of a system.	√			15

#	Elements of a Complete Submission (continued)	Yes	N/A	No	Page
	b. Submission includes a description (as detailed in 11.a. and b. and 12 above) of each component or accessory.	√			
	c. A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance.		√		
C.	**Substantial Equivalence Discussion**				
14.	Submitter has identified a predicate(s) device	√			27
	a. Predicate's 510(k) number, trade name, and model number provided.	√			27
	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.	√			
15.	Submission includes a comparison of the following for the predicate(s) and subject device a. Indications for use	√			27
	b. Technology, including features, materials, and principles of operation	√			27
16.	Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any difference in technological characteristics are accompanied by information that demonstrates the device is safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate), affect safety or effectiveness, or raise different questions of safety and effectiveness.		√		
D.	**Proposed labeling (see also 21 CFR part 801)** *If in vitro diagnostic (IVD) device,* ***criteria 17, 18, and 19 may be omitted.***		√		
20.	a. If there are requirements regarding labeling, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes labeling to establish that the submitter has followed the device-specific requirement.		√		
	b. If there is a device specific guidance, other than a special controls guidance document, applicable to the device, the submission includes labeling to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.		√		
	c. If there is a special controls document applicable to the device, the submission includes labeling to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.		√		
21.	If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.	√			45

#	Elements of a Complete Submission (continued)	Yes	N/A	No	Page
E.	**Sterilization** *If in vitro diagnostic (IVD) device and sterilization is not applicable, select "N/A".* ***Questions 22 – 25 will be omitted.***		√		
F.	**Shelf Life**				
26.	Proposed shelf life/ expiration date stated.	√			49
27.	For sterile device, submission includes summary of methods used to establish that device sterility will remain substantially equivalent to that of the predicate through the proposed shelf life, or a rationale for why testing to establish shelf life is not applicable.		√		
28.	Submission includes summary of methods used to establish that device performance is not adversely affected by aging and therefore device performance will remain substantially equivalent to that of the predicate, or includes a rationale for why the storage conditions are not expected to affect device safety or effectiveness.	√			130 & 156
G.	**Biocompatibility** - *If in vitro diagnostic (IVD) device and sterilization is not applicable, select "N/A".* ***Questions 29 – 31 will be omitted.***		√		
H.	**Software-** Submission states that the device **does** contain software/ firmware.				
32.	Submission includes a statement of software level of concern and rationale for the software level of concern. √ **Does** contain software/firmware.	√			51
33.	All applicable software documentation provided based on level of concern identified by the submitter, as described in Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, or the submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through an alternative approach (i.e., the submitter has identified an alternative approach with a rationale).	√			51
I.	**EMC and Electrical Safety-** Submission states that the device **does** require EMC and Electrical Safety evaluation.				
34.	Submission includes evaluation of electrical safety (e.g., per IEC 60601-1, or equivalent FDA-recognized standard, and if applicable, the device-specific standard), OR Submission includes electrical evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternative methods or standards with a rationale).	√			52
35.	Submission includes evaluation of electromagnetic compatibility (e.g., 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 submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternative methods or standards with a rationale).	√			52

#	Elements of a Complete Submission (continued)	Yes	N/A	No	Page
J.	**Performance Data – General** --*If in vitro diagnostic (IVD) device, select "N/A".* ***Questions 36 – 39 will be omitted.***		√		
K.	**Performance Characteristics –In Vitro Diagnostic Devices Only (see also 21 CFR 809.10(b)(12))** Submission indicates that the device **is** an in vitro diagnostic device (IVD).				
40.	Submission includes the following studies, as appropriate for the device type, including associated protocol descriptions, study results and line data: a. Precision/reproducibility	√			92
	b. Accuracy (includes as appropriate linearity; calibrator or assay traceability; calibrator and/or assay stability protocol and acceptance criteria; assay cut-off; method comparison or comparison to clinical outcome; matrix comparison; and clinical reference range or cutoff.	√			58
	c. Sensitivity (detection limits, LoB, LoD, LoQ where relevant for the device type).	√			159
	d. Analytical specificity	√			161
41.	a. If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement.		√		
	b. If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.		√		
	c. If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.		√		

004 INDICATIONS FOR USE STATEMENT

510(k) Number (if known) _____

Device Name: XN-Series (XN-11, XN-21) Automated Hematology Analyzers

Indications for Use:

The XN-Series modules (XN-11, XN-21) are quantitative multi-parameter automated hematology analyzers intended for *in vitro* diagnostic use in screening patient populations found in clinical and reference laboratories.

The XN-Series modules classify and enumerate the following parameters in whole blood: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, NEUT%/#, LYMPH%/#, MONO%/#, EO%/#, BASO%/#, IG%/#, RDW-CV, RDW-SD, MPV, NRBC#/%, RET%/#, IPF, IRF, RET-He and has a Body Fluid mode for body fluids. The Body Fluid mode enumerates the WBC-BF, RBC-BF, MN%/#, PMN%/#, and TC-BF parameters in body fluids (peritoneal, pleural and synovial). Whole blood should be collected in K_2 or K_3EDTA anticoagulant and peritoneal, pleural and synovial fluids in K_2EDTA anticoagulant to prevent clotting of fluid.

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

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

005 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

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

1. Submitted by:	Sysmex America, Inc. 577 Aptakisic Road Lincolnshire, IL. 60069 Phone: (224) 543-9618; FAX: (224) 543-4699 Contact person: Sharita Brooks Date prepared: June 19, 2014
2. Name of Device:	Trade or proprietary name: Sysmex® XN-Series (XN-11, XN-21) Common name: Automated Hematology Analyzer Classification name: Automated Differential Cell Counter 21 CFR 864.5220 is a Class II device. Product Code: **GKZ** **Related Items:** **Product Code: 81 GIF** CELLPACK® DCL (Diluent) – K112605 CELLPACK™ DFL (Diluent) – K112065 CELLSHEATH(C)™ (Diluent) – K051459 **Product Code: 81 GGK** Lysercell™ WNR (Lyse) – K112605 Lysercell™ WDF (Lyse) – K112605 Lysercell™ WPC (Lyse) – K112605 **Product Code: 81 KJK** Fluorocell™ WNR (Stain) – K112605 Fluorocell™ WDF (Stain) – K112605 Fluorocell™ RET (Stain) – K112065 Fluorocell™ PLT (Stain) – K112605 Fluorocell™ WPC (Stain) – K112605 **Product Code: 81 KSA** XN CAL (Calibrator) – K120745 XN CAL PF (Calibrator) – K120747 **Product Code: 81 JPK** XN CHECK (Control) – K120742 XN CHECK BF (Control) – K120744 **Analyzer Components** SA-10 (Auto Sampler for single module) SA-20 (Auto Sampler for two modules) IPU (Information Processing Unit)
3. Predicate Device:	Sysmex® XE-5000Automated Hematology Analyzer

4. Device Description:	(b)(4) [redacted]
5. Intended Use:	The XN-Series modules (XN-11, XN-21) are quantitative multi-parameter automated hematology analyzers intended for *in vitro* diagnostic use in screening patient populations found in clinical and reference laboratories. The XN-Series modules classify and enumerate the following parameters in whole blood: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, NEUT%/#, LYMPH%/#, MONO%/#, EO%/#, BASO%/#, IG%/#, RDW-CV, RDW-SD, MPV, NRBC#/%, RET%/#, IPF, IRF, RET-He and has a Body Fluid mode for body fluids. The Body Fluid mode enumerates the WBC-BF, RBC-BF, MN%/#, PMN%/#, and TC-BF parameters in body fluids (peritoneal, pleural and synovial). Whole blood should be collected in K_2 or K_3EDTA anticoagulant and peritoneal, pleural and synovial fluids in K_2EDTA anticoagulant to prevent clotting of fluid.
6. Substantial equivalence-similarities and differences	The following table compares the XN-Series modules (XN-11, XN-21) Automated Hematology analyzers with the XE-5000 Automated Hematology analyzer.
7. Clinical Performance Data:	Studies were performed to evaluate the equivalency of the XN-Series Automated Hematology analyzers (Modules XN-11, XN-21) to the XE-5000 Automated Hematology analyzer. Results indicated equivalent performance.
8. Conclusions:	The performance data demonstrated substantial equivalence.

Table 1: Substantial Equivalence – Similarities and Differences to the XN-Series Automated Hematology analyzers (Modules XN-11, XN-21) and XE-5000 Automated Hematology analyzer.

Item	Predicate XE-5000 (K071967) 20-Nov-07	Device XN-Series (XN-11, XN-21)
Intended Use	(b)(4)	
Equivalency Data		
Similarities		
Specimen Type	(b)(4)	
Test Principle		
Parameters		

Reagents	(b)(4)	
Modes of Operation		
Measuring Channels		
Differences		
Item	**Predicate XE-5000 (K071967) 20-Nov-07**	**Device XN-Series (XN-11, XN-21)**
Specimen type	(b)(4)	
Test Principal		
Controls & Calibrators		
IPU		
Modes of Operation		
Parameters		
Sample Aspiration /Fluidic Pathway		
Software/Hardware		
Throughput		
Measuring Channels (see Section 11 for detailed information on these channels)		
Reagents		

Sample Aspiration Volume	(b)(4) [redacted]

006. TRUTHFUL AND ACCURACY STATEMENT

[As required by 21 CRF 807.87 J0]

I certify that, in my capacity as Manager of Clinical Affairs, I believe to the best of my knowledge that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

Sharita Brooks
Manager, Clinical Affairs
Sysmex America, Inc.

June 19, 2014
Date

Premarket Notification Number

007 Class III Summary and Certification

This section does not apply.

008 Financial Certification or Disclosure Statement & Certification of Compliance

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

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

TO BE COMPLETED BY APPLICANT

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

Please mark the applicable check box.

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

Clinical Investigators
(b)(4) [redacted]

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

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

NAME	TITLE
Sharita Brooks	Manager, Clinical Affairs
FIRM/ORGANIZATION: Sysmex America, Inc.	
SIGNATURE: Sharita Brooks	DATE *(mm/dd/yyyy)*: 06/19/2014

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

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

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

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

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

FORM FDA 3454 (4/13)

CERTIFICATION OF COMPLIANCE (FDA-3674)

Form Approved: OMB No. 0910-0616. Expiration Date: 2/28/2015. See PRA Statement on page 2.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance

Under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. Name of Sponsor/Applicant/Submitter
Sysmex America, Inc / Sharita Brooks

2. Date of the Application/Submission Which This Certification Accompanies
06/19/2014

3. Address
Address 1 *(Street address, P.O. box, company name c/o)*
577 Aptakisic Road
Address 2 *(Apartment, suite, unit, building, floor, etc.)*
City: Lincolnshire
State/Province/Region: IL
Country: USA
ZIP or Postal Code: 60069

4. Telephone and Fax Numbers *(Include country code if applicable and area code)*
(Tel): 224-543-9618
(Fax): 224-543-4699

PRODUCT INFORMATION

5. **For Drugs/Biologics:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s).
For Devices: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)

Sysmex XN-Series (XN-11, XN-21) Automated Hematology Analyzers

Continuation Page for #5

APPLICATION / SUBMISSION INFORMATION

6. Type of Application/Submission Which This Certification Accompanies

☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. Include IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/ Other Number *(If number previously assigned)*

If BLA was selected in item 6, provide Supplement Number

8. Serial Number Assigned to Application/Submission Which This Certification Accompanies

CERTIFICATION STATEMENT / INFORMATION

9. Check only one of the following boxes *(See instructions for additional information and explanation)*

☒ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

Certification Statement / Information section continued on page 2

CERTIFICATION STATEMENT / INFORMATION *(Continued)*

10. If you checked box C. in number 9, provide the National Clinical Trial (NCT) Number(s) for any "applicable clinical trial(s)," under 42 U.S.C. § 282(J)(1)(a)(i), section 402(j)(1)(a)(i) of the Public Health Service Act, referenced in the application/ submission which this Certification accompanies. *(Add continuation page as necessary.)*

NCT Number(s): ____

Continuation Page for #10

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.

Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. Name and Title of the Person who Signs Number 15

Name	Title
Sharata Brooks	Manager, Clinical Affairs

12. Address

Address 1 *(Street address, P.O. box, company name c/o)*	
577 Aptakisic Road	
Address 2 *(Apartment, suite, unit, building, floor, etc.)*	
City: Lincolnshire	State/Province/Region: IL
Country: USA	ZIP or Postal Code: 60069

13. Telephone and Fax Numbers *(Include country code if applicable and area code)*

(Tel): (224) 543-9618

(Fax): (224) 543-4699

14. Date of Certification

06/18/2014

15. Signature of Sponsor/Applicant/Submitter or an Authorized Representative *(Sign)*

Sign

Sharata Brooks

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

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

The burden time for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/ submission) per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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

009 Declarations of Conformity and Summary Reports

To date, no performance standards that affect this device have been finalized under Section 514 of the Food, Drug, and Cosmetic Act.

010 Executive Summary

Introduction

(b)(4)

[redacted]

Summary

The XN-Series modules (XN-11, XN-21) are quantitative multi-parameter automated hematology analyzers intended for *in vitro* diagnostic use in screening patient populations found in clinical and reference laboratories.

The XN-Series modules classify and enumerate the following parameters in whole blood: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, NEUT%/#, LYMPH%/#, MONO%/#, EO%/#, BASO%/#, IG%/#, RDW-CV, RDW-SD, MPV, NRBC#/%, RET%/#, IPF, IRF, RET-He and has a Body Fluid mode for body fluids. The Body Fluid mode enumerates the WBC-BF, RBC-BF, MN%/#, PMN%/#, and TC-BF parameters in body fluids (peritoneal, pleural and synovial). Whole blood should be collected in K_2 or K_3EDTA anticoagulant and peritoneal, pleural and synovial fluids in K_2EDTA anticoagulant to prevent clotting of fluid.

(b)(4)

[redacted]

Table 1: Substantial Equivalence – Similarities and Differences to the XN-Series Automated Hematology analyzers (Modules XN-11, XN-21) and XE-5000 Automated Hematology analyzer.

Item	Predicate XE-5000 (K071967) 20-Nov-07	Device XN-Series (XN-11, XN-21)
Intended Use	(b)(4)	
Equivalency Data		
Similarities		
Specimen Type	(b)(4)	
Test Principle		
Parameters		
Reagents		

Modes of Operation	(b)(4)
Measuring Channels	

Differences		
Item	**Predicate XE-5000 (K071967) 20-Nov-07**	**Device XN-Series (XN-11, XN-21)**
Specimen type	(b)(4)	
Test Principal		
Controls & Calibrators		
IPU		
Modes of Operation		
Parameters		
Sample Aspiration /Fluidic Pathway		
Software/Hardware		
Throughput		
Measuring Channels (see Section 11 for detailed information on these channels)		
Reagents		

	(b)(4)
Sample Aspiration Volume	[redacted]

011 Device Description

Introduction

The device description below is the same information submitted in the recently cleared XN-Series (XN-10, XN-20) hematology analyzers submission #K112605 (Cleared October 19, 2012). Additional information has been added (Section 11.1) to the device description to identify modifications made to the XN-series analyzers to (b)(4)

(b)(4)

Description

(b)(4)

- (b)(4)

XN-21 Module - same as recently cleared K112605 for XN-20 Module

(b)(4)

(b)(4)

11.1 Description of Device Modification

(b)(4)

[redacted]

Diagram 11a – Changes made to the recently cleared XN-Series (XN-10, XN-20) modules to develop the XN-11 and XN-21 modules

(b)(4)

[redacted]

Table 2: Performance/specifications of the XN-Series Analyzers (XN-11, XN-21)

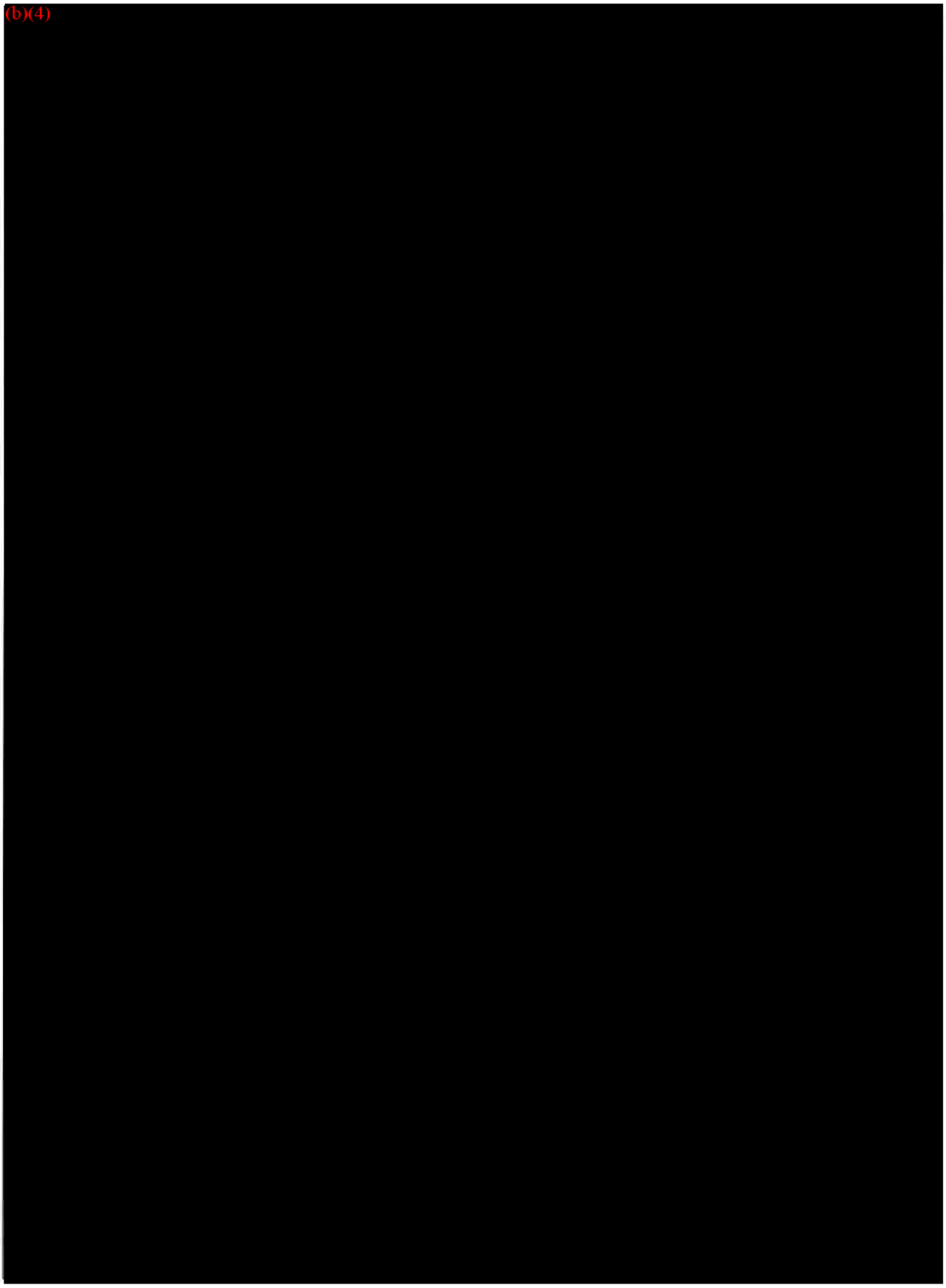
(b)(4)

[redacted]

	(b)(4) [redacted]
Acceptable background value	
Analysis range	
Throughput	
Accuracy Whole Blood Analysis Mode	

	(b)(4) [redacted]
Accuracy (Blood Cell Differential) Whole Blood Analysis Mode	
Reticulocyte Count	
Accuracy (Blood Cell Count) Body Fluid Analysis Mode	
Accuracy (Blood Cell Differentiation) Body Fluid Analysis Mode	

(b)(4)



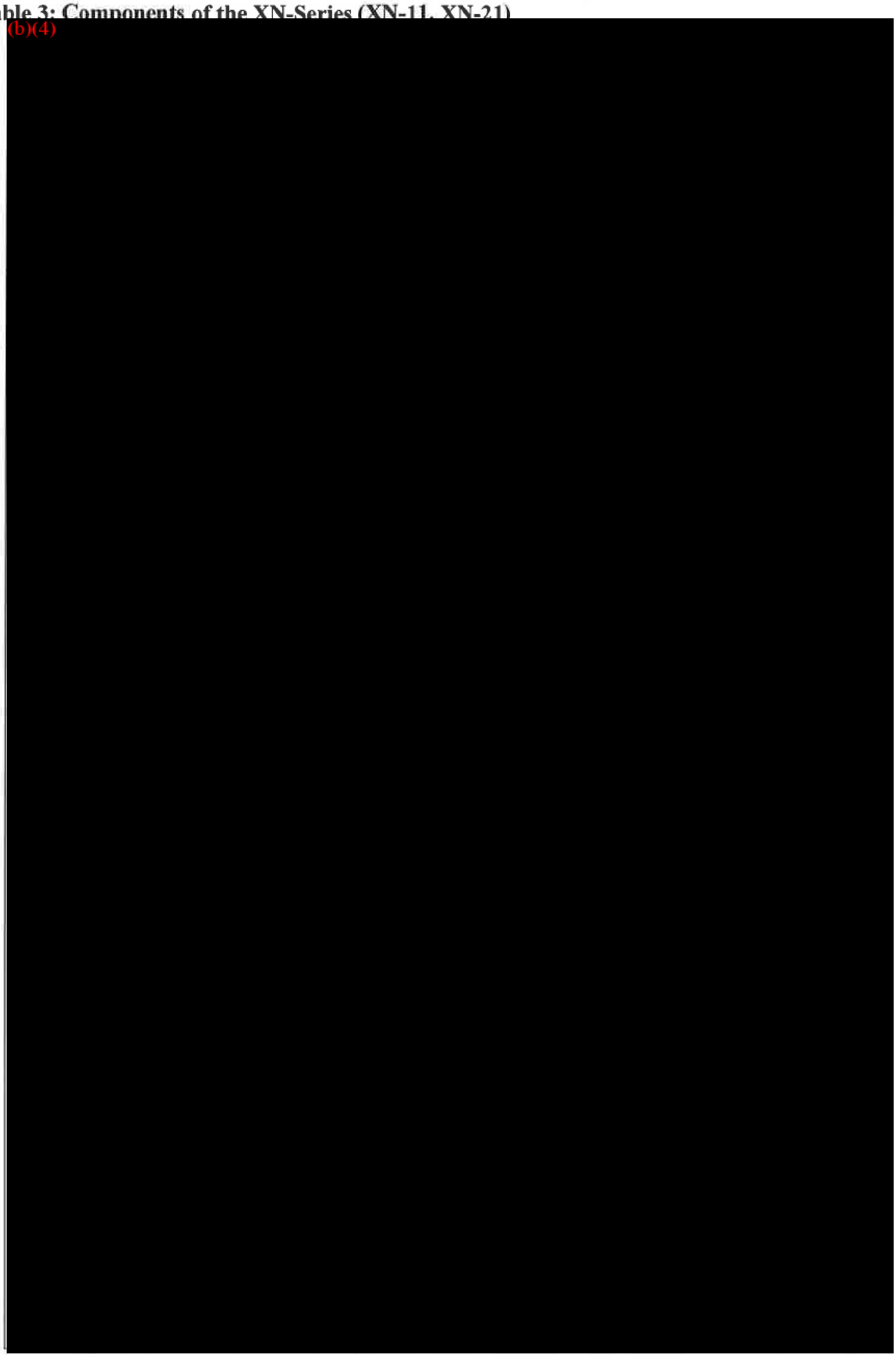
(b)(4)

[redacted]

(b)(4)

Table 3: Components of the XN-Series (XN-11, XN-21)

(b)(4)



012 Substantial Equivalence Discussion

The XN-Series module (XN-11, XN-21) analyzers were compared to the predicate XE-5000 automated hematology analyzer. The XN-Series modules use the same principles as the XE-5000 to perform whole blood and body fluid hematology analysis. The main differences between the XN-11 and XN-21 and the XE-5000 analyzers are the new reagents, controls, calibrators, heater and additional measuring channels.

Table 1: Substantial Equivalence – Similarities and Differences to the XN-Series Automated Hematology analyzers (Modules XN-11, XN-21) and XE-5000 Automated Hematology analyzer.

Item	Predicate XE-5000 (K071967) 20-Nov-07	Device XN-Series (XN-11, XN-21)
Intended Use	(b)(4)	
Equivalency Data		
Similarities		
Specimen Type	(b)(4)	
Test Principle		

Parameters	(b)(4) [redacted]
Reagents	
Modes of Operation	
Measuring Channels	

Differences

Item	Predicate XE-5000 (K071967) 20-Nov-07	Device XN-Series (XN-11, XN-21)
Specimen type	(b)(4) [redacted]	
Test Principal		
Controls & Calibrators		
IPU		
Modes of Operation		
Parameters		
Sample Aspiration /Fluidic Pathway		
Software/Hardware		
Throughput		
Measuring Channels (see Section 11 for detailed information on these channels)		

Reagents	(b)(4) [redacted]
Sample Aspiration Volume	

013 Proposed Labeling

Operator's Manuals.

1. **Box Labels:**
   The following were cleared in submission #K112605 and not included here.
   - CELLPACK DCL (Diluent)
   - CELLPACK DFL (Diluent)
   - Lysercell WNR (Lyse)
   - Lysercell WDF (Lyse)
   - Lysercell WPC (Lyse)
   - Fluorocell WNR (stain)
   - Fluorocell WDF (stain)
   - Fluorocell RET (stain)
   - Fluorocell PLT (stain)
   - Fluorocell WPC (stain)

   The following was cleared in submission #K992875 and not included here.
   - SULFOLYSER (Lyse)

   The following was cleared in submission #K051459 and not included here.
   - CELLSHEATH(C)™ (Diluent)

   The following were cleared by Streck and not included here.
   - XN CHECK (whole blood control) – K120742
   - XN CHECK BF (body fluid control) – K120744
   - XN CAL (calibrator) – K120745
   - XN CAL PF (calibrator for PLT-F) – K120747
   - RANGE CHECK X III (whole blood linearity) – K960557
   - Retic Chex (retic linearity) – K000115

2. **Material Safety Data Sheets (MSDS):**
   The following were cleared in submission #K112605 and not included here.
   - CELLPACK DCL (Diluent)
   - CELLPACK DFL (Diluent)
   - Lysercell WNR (Lyse)
   - Lysercell WDF (Lyse)
   - Lysercell WPC (Lyse)
   - Fluorocell WNR (stain)
   - Fluorocell WDF (stain)
   - Fluorocell RET (stain)
   - Fluorocell PLT (stain)
   - Fluorocell WPC (stain)

   The following was cleared in submission #K992875 and not included here.
   - SULFOLYSER (Lyse)

   The following were cleared in submission #K051459 and not included here.
   - CELLSHEATH(C)™ (Diluent)

The following were cleared by Streck and not included here.

- XN CHECK (whole blood control) – K120742
- XN CHECK BF (body fluid control) – K120744
- XN CAL (calibrator) – K120745
- XN CAL PF (calibrator for PLT-F) – K120747

3. Draft Sales Literature

This information is included in this section.

4. Operator's Manuals (OM)

- XN-1000 Instructions for Use (IFU) Manual – For use with single XN-11 and XN-21 module (Volume 2).

sysmex

XN-Series™
(XN-11/XN-21)
Automated Hematology Analyzers

Greater Possibilities by Design

XN-Series Automated Hematology Analyzer

For reference and commercial laboratories looking to advance, the XN-Series (XN-11/XN-21) is shaping hematology by bringing new possibilities to the laboratory.

Featuring a high performance design, accurate results on aged samples and modularity – the XN-Series enables any lab to create the perfect fit for its evolving needs.

The XN-Series (XN-11/XN-21) features:

Enhanced Walk Away Capabilities

- Automated Reflex and Rerun Testing
- User-definable Decision Rules
- Multi-system Shared Database

Workflow Efficiency

- Standardization of Consumables
- RFID for Reagent Management

About Sysmex

Sysmex is a global market leader in the development and implementation of clinical diagnostic and health IT products and services for laboratories, hospitals and healthcare organizations.

We deliver total solutions in the field of clinical laboratory testing and supply products and services to customers in more than 150 countries.

Specifications

Principles & Technologies	Fluorescent Flow Cytometry WBC-Diff, IG, NRBC, RET, IRF, PLT-F, IPF DC Sheath-Flow: PLT-I, RBC, HCT SLS Method: Hgb
Reportable Parameters	WBC, RBC, HGB, HGB,MCV, MCH, MCHC, PLT (PLT-I, PLT-F), NEUT%, LYMPH%, MON%, EO%, BASO%, NRBC%, NEUT#, LYMPH#, MONO#, EO#, BASO#, NRBC#, IG%, IG#, RDW-SD, RDW-CV, MPV, RET%, RET#, IRF, RET-He, IPF
Body Fluid Reportable Parameters	WBC-BF, MN#, MN%, PMN#, PMN%, TC-BF#, RBC-BF
Throughput	Whole Blood Mode: 100 Samples/ Hour (Max) per module Body Fluid Mode: 40 Samples/ Hour (Max) per module
Sample Volume	Whole Blood: 88 µL Dilution Mode: 70 µL Body Fluid Mode: 88 µL
Linearity	Whole Blood: WBC: within +/- 3% or +/- 0.20 x 10^3/µL (0.00 to 100.00 x 10^3/µL) within +/- 6% (100.01 to 310.00 x 10^3/µL) within +/- 11% (310.01 to 440.00 x 10^3/µL) RBC: within +/- 2% or +/- 0.03 x 10^6/µL (0.00 to 8.00 x 10^6/µL) within +/- 4% or +/- 0.06 x 10^6/µL (8.01 to 8.60 x 10^6/µL) PLT-I*: within +/- 5% or +/- 10 x 10^3/µL (0 to 1000 x 10^3/µL) within +/- 6% (1001 to 5000 x 10^3/µL) PLT-F**: within +/- 5% or +/- 10 x 10^3/µL (0 to 1000 x 10^3/µL) within +/- 6% (1001 to 5000 x 10^3/µL) Body Fluid Mode: WBC-BF: within +/- 0.010 x 10^3/µL) (0.000 to 0.050 x 10^3/µL, RBC< 1.000 x 10^6/µL) within +/- 20% (0.051 to 10.000 x 10^3/µL, RBC < 1.000 x 10^6/µL) RBC-BF: within +/- 2% or within +/- 0.010 x 10^6/µL (0.000 to 5.000 x 10^6/µL) within +/- 4% or +/- 0.06 x 10^6/µL (8.01 to 8.60 x 10^6/µL) TC-BF#: within 0.010 x 10^3/µL (0.000 to 0.050 x 10^3/µL, RBC< 1.000 x 10^6/µL) within +/- 20% (0.051 to 10.000 x 10^6/µL)
Data Storage Capacity	100,000 Samples per module

* PLT –I counted in the RBC/PLT channel (PLT particle size distribution)
** PLT –F counted on the PLT-F channel

Sysmex Addresses
1234 Rue de la Street
Anywhere, State Zip Code
Country
Tel. +12 345-6789
Fax +12 345-6789
www.url.ext

Sysmex Addresses
1234 Rue de la Street
Anywhere, State Zip Code
Country
Tel. +12 345-6789
Fax +12 345-6789
www.url.ext

Sysmex Addresses
1234 Rue de la Street
Anywhere, State Zip Code
Country
Tel. +12 345-6789
Fax +12 345-6789
www.url.ext

Sysmex Addresses
1234 Rue de la Street
Anywhere, State Zip Code
Country
Tel. +12 345-6789
Fax +12 345-6789
www.url.ext

014 Sterilization and Shelf Life

Sterilization is not applicable to this product.

The shelf lives for the reagents and quality control/calibrator materials are displayed in the table below. The manufacturer has performed bench testing and data is available upon request.

Table 4: Temperature and Shelf Life

Product	Temperature after first opening	Shelf Life after first opening
CELLPACK DCL	15-30°C	60 days
CELLPACK DFL	15-30°C	60 days
CELLSHEATH(C)	15-30°C	60 days
SULFOLYSER	15-30°C	60 days
Lysercell WNR	15-30°C	60 days
Lysercell WDF	15-30°C	90 days
Lysercell WPC	15-30°C	90 days
Fluorocell WNR	15-30°C	90 days
Fluorocell WDF	15-30°C	90 days
Fluorocell RET	15-30°C	90 days
Fluorocell PLT	15-30°C	90 days
Fluorocell WPC	15-30°C	90 days
XN CHECK	15-30°C	7 days
XN CHECK BF	15-30°C	30 days
XN CAL	15-30°C	4 hours
X CAL PF	15-30°C	4 hours

015 Biocompatibility - NA

This section does not apply.

016 Software

(b)(4)

017 Electromagnetic Compatibility and Electrical Safety

The XN-Series (XN-11, XN-21) complies with the following IEC (EN) standards:
EMC-

- IEC61326-2-6:2005 (EN61326-2-6:2006) Electrical equipment for analysis, control and laboratory use – EMC request.

Safety-

- IEC61010-1:01 Safety requirements for electrical equipment for measurement, control and laboratory use – Part 1: General requirements.
- IEC61010 – 2-101:02 Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-101: Particular requirements for *in vitro* diagnostic (IVD) medical equipment.
- IEC61010-2-081:01 Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes.

018 Performance Testing – Bench –NA

This section does not apply.

019 Performance Testing – Animal—NA

No animal testing was performed.

020 Performance Testing

Clinical Performance Data

(b)(4)

(b)(4)

Clinical Performance Data

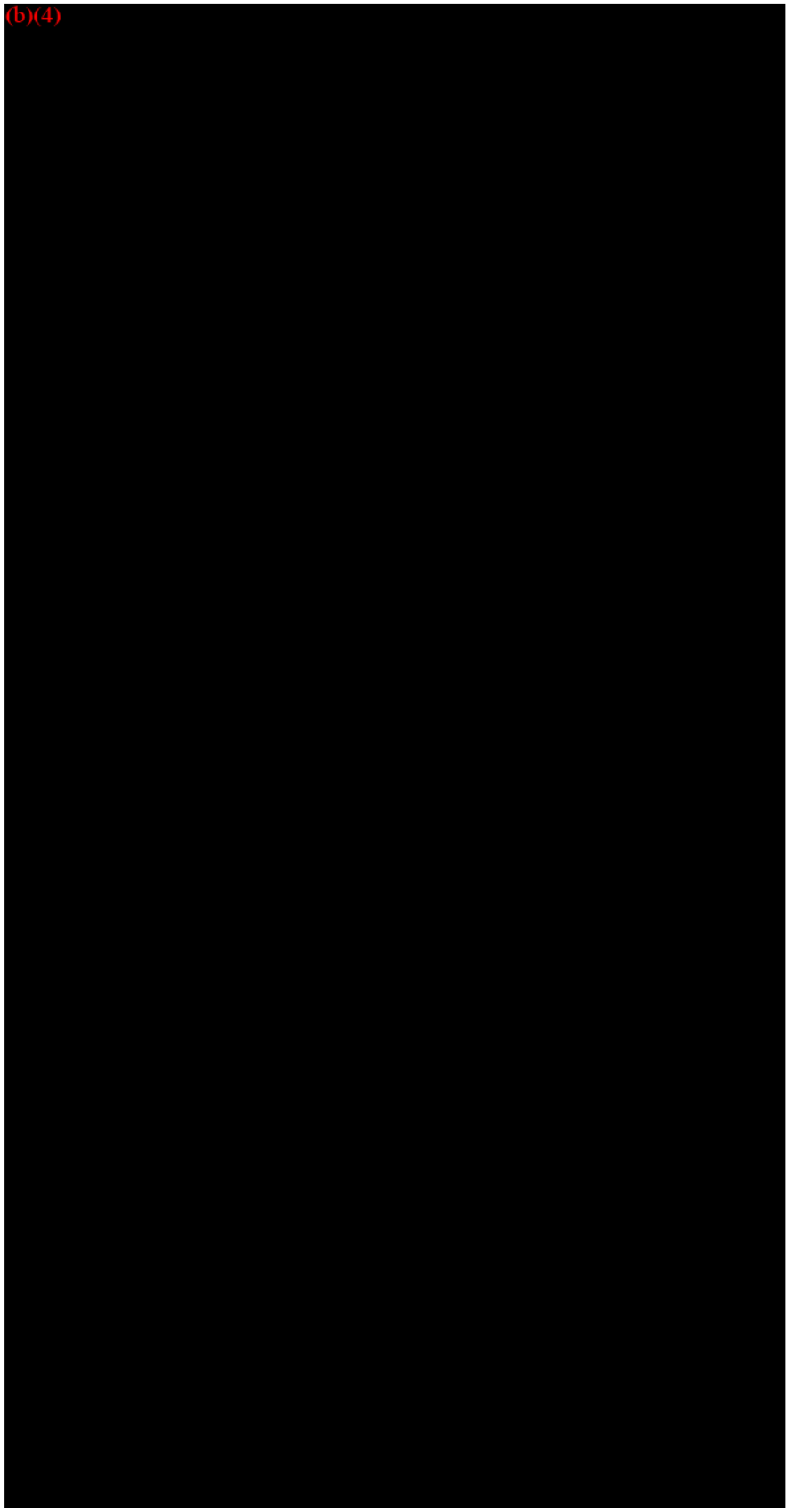
1.0 Whole Blood Studies

(b)(4)

Method Comparison (correlation) – Whole Blood

(b)(4)

(b)(4)



X Method: XE-5000 PLT-F Y Method: XN-11 PLT-F

(b)(4)

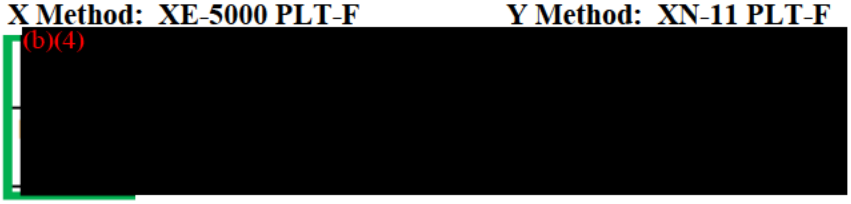
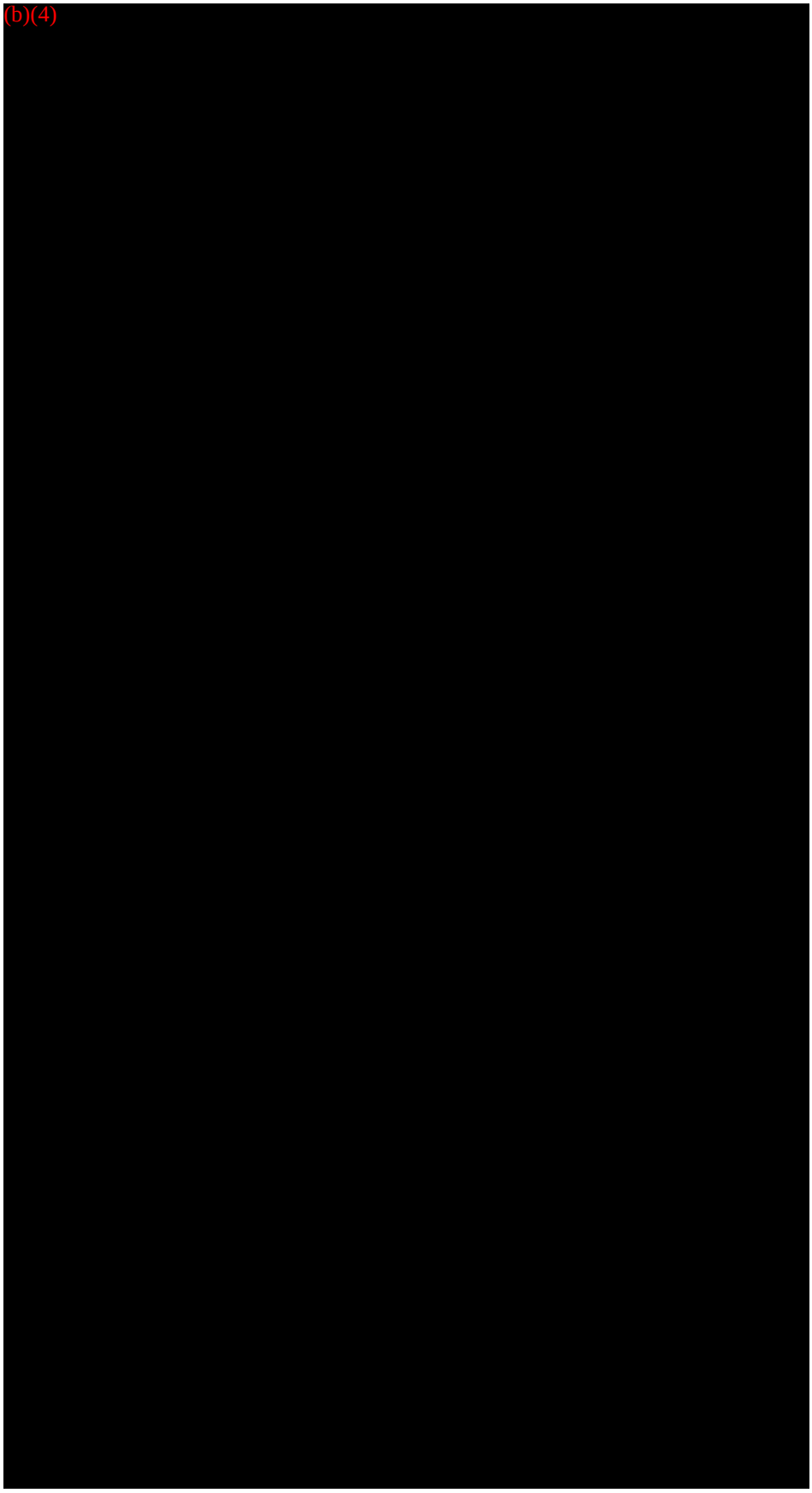


Table 5b: Statistical Summary – All Sites Combined

(b)(4)

(b)(4)

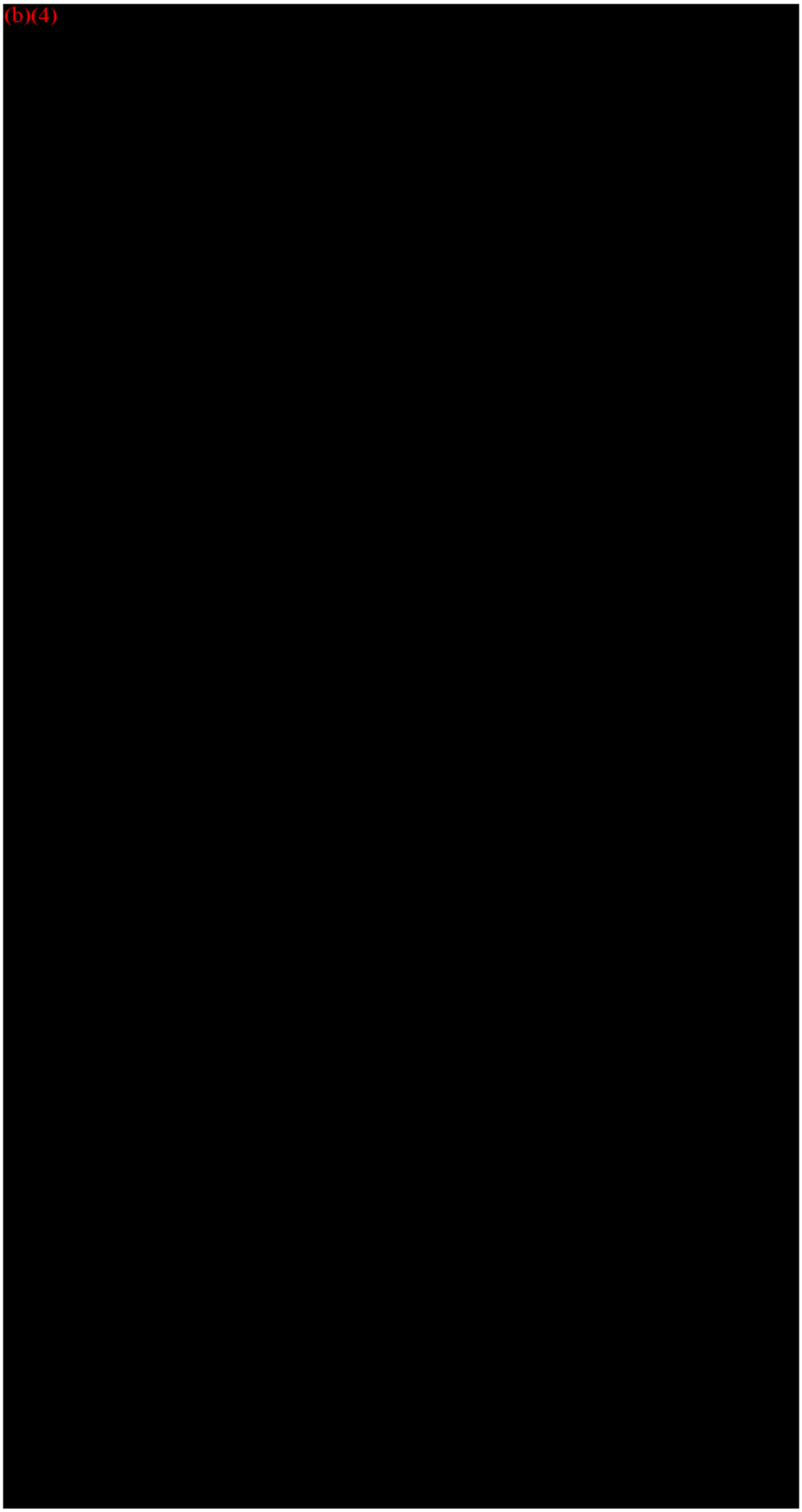


(b)(4)

Table 5c: Statistical Summary - Site 1

(b)(4)

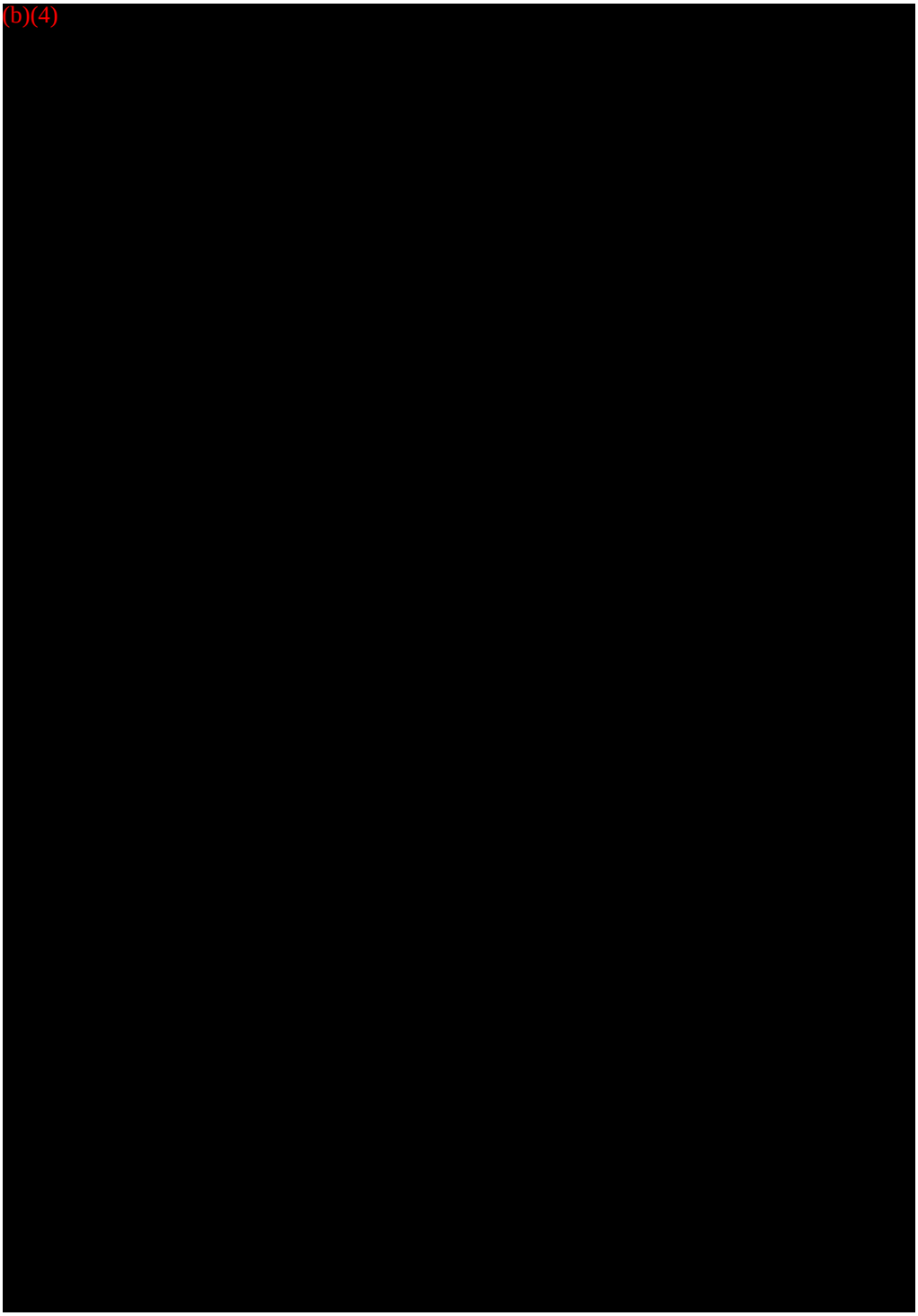
(b)(4)



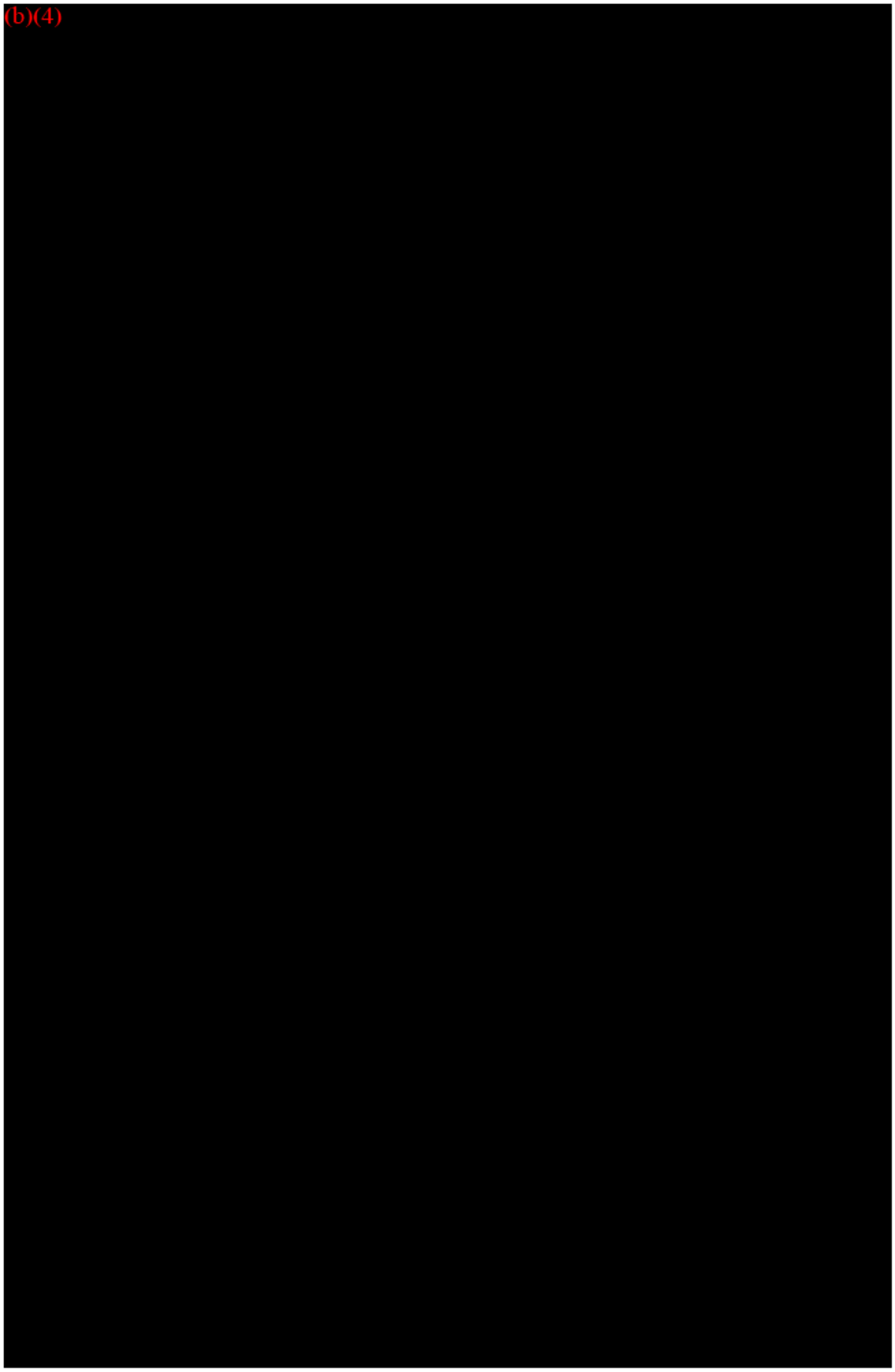
(b)(4)

Table 5d: Statistical Summary - Site 1

(b)(4)



(b)(4)

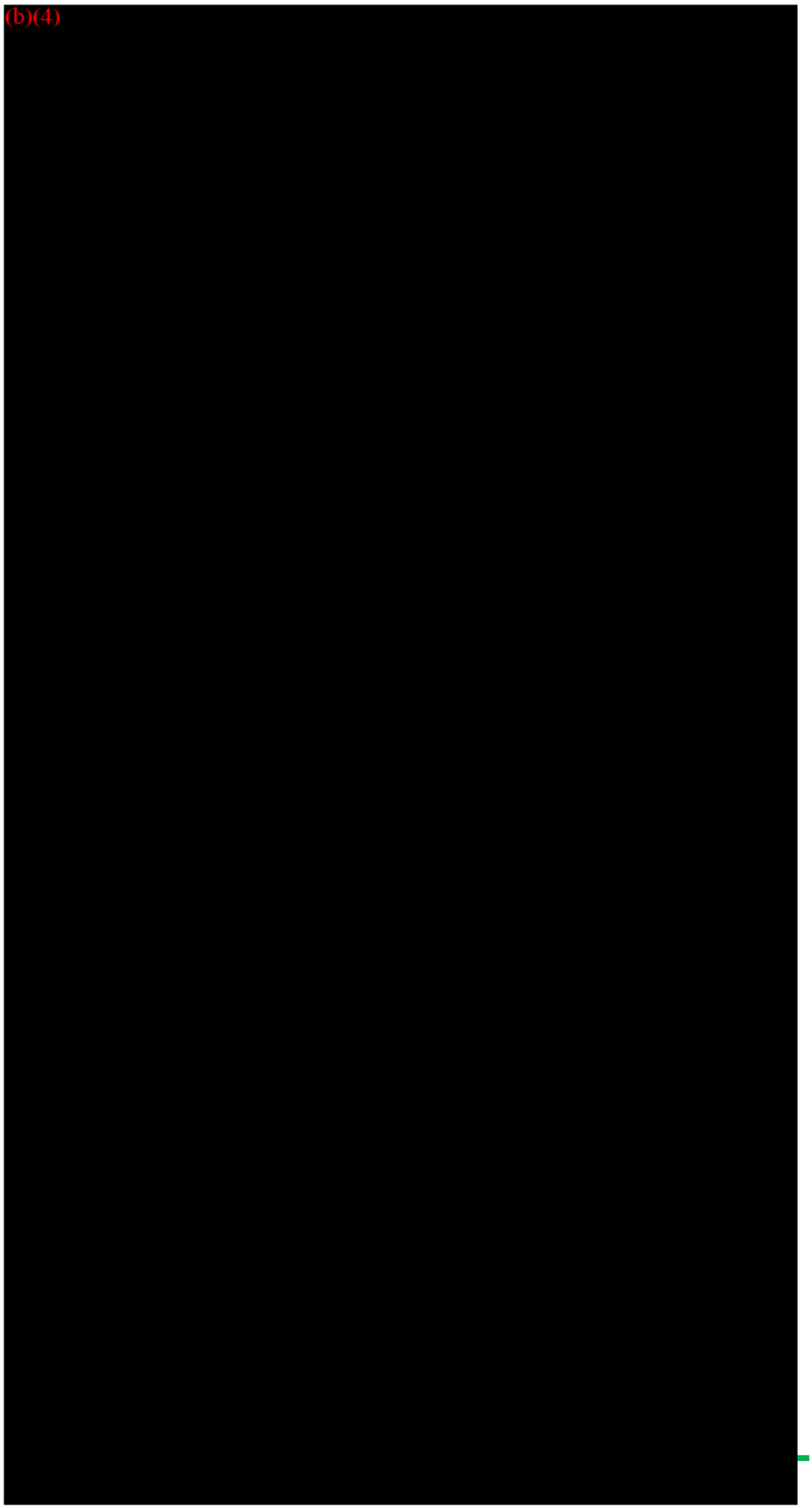


(b)(4)

Table 5e: Statistical Summary- Site 2

(b)(4)

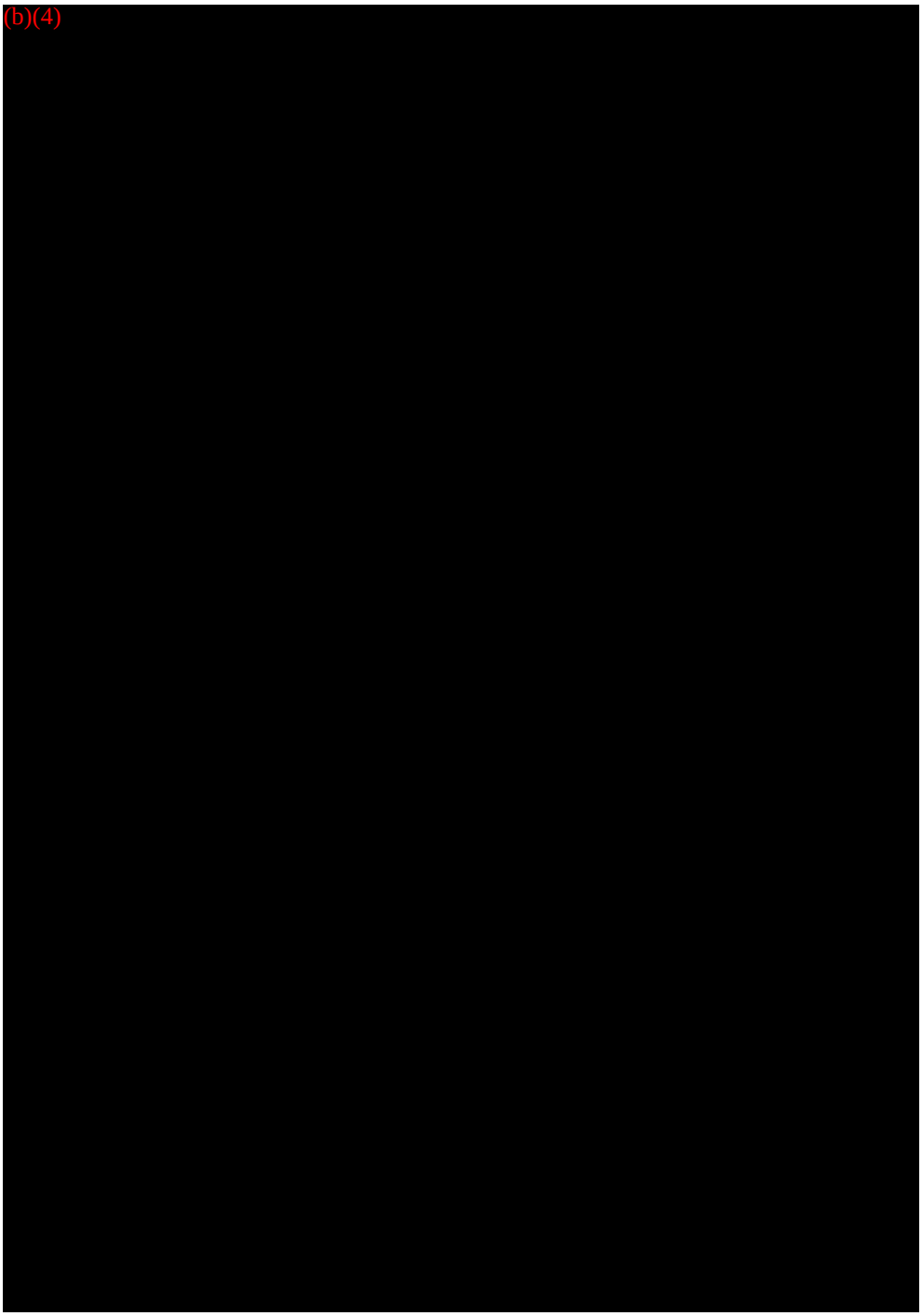
(b)(4)



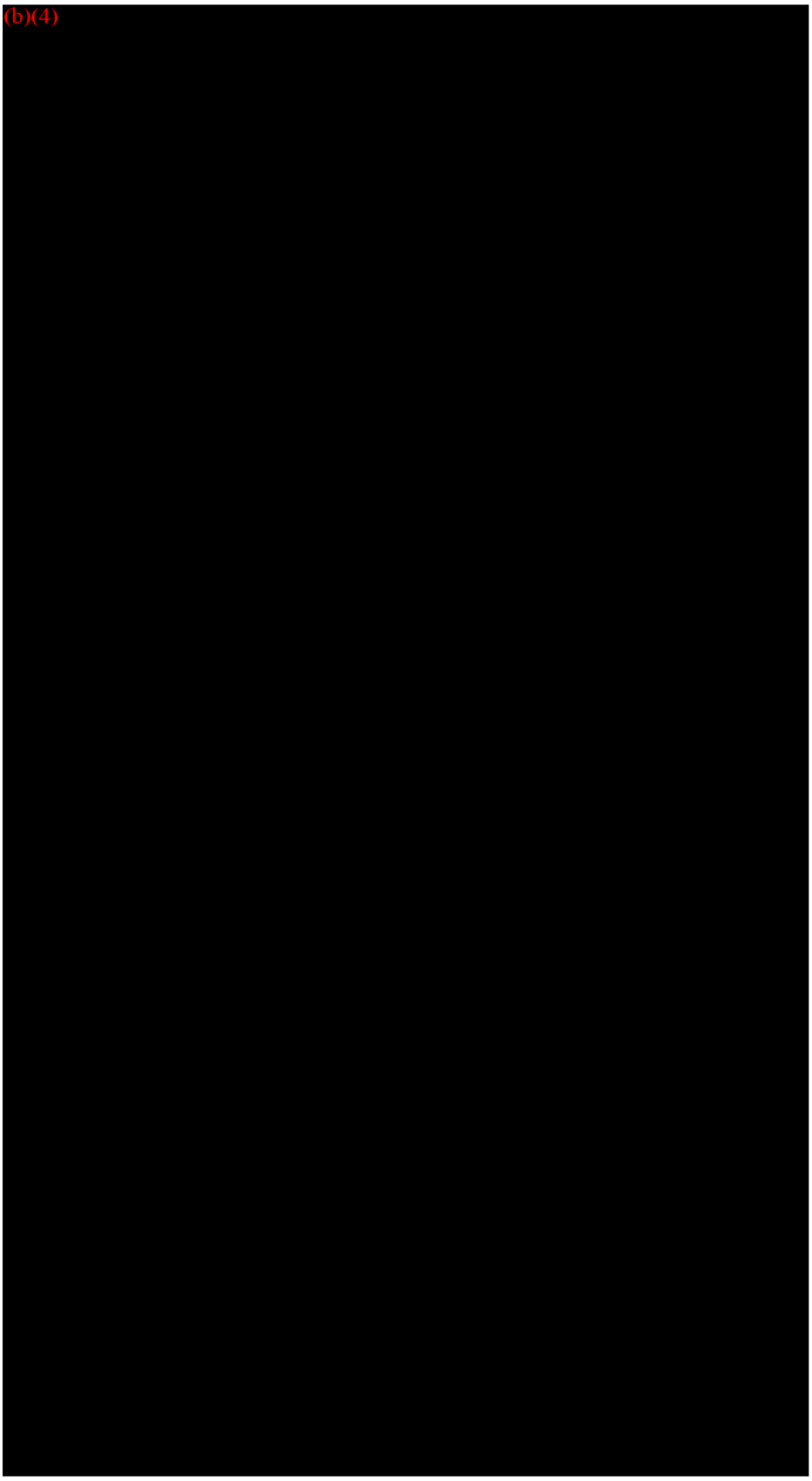
(b)(4)

Table 5f: Statistical Summary - Site 2

(b)(4)



(b)(4)

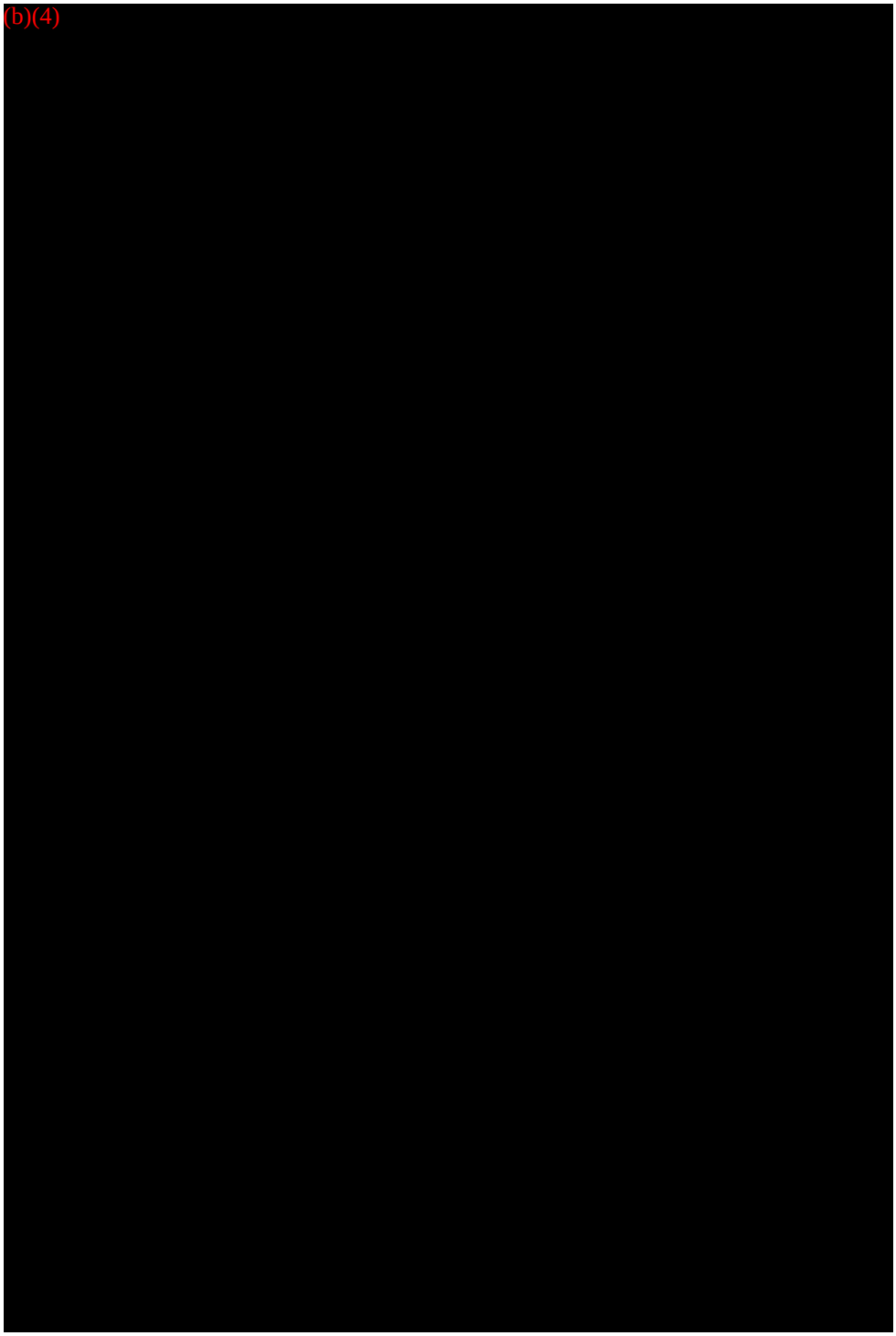


(b)(4)

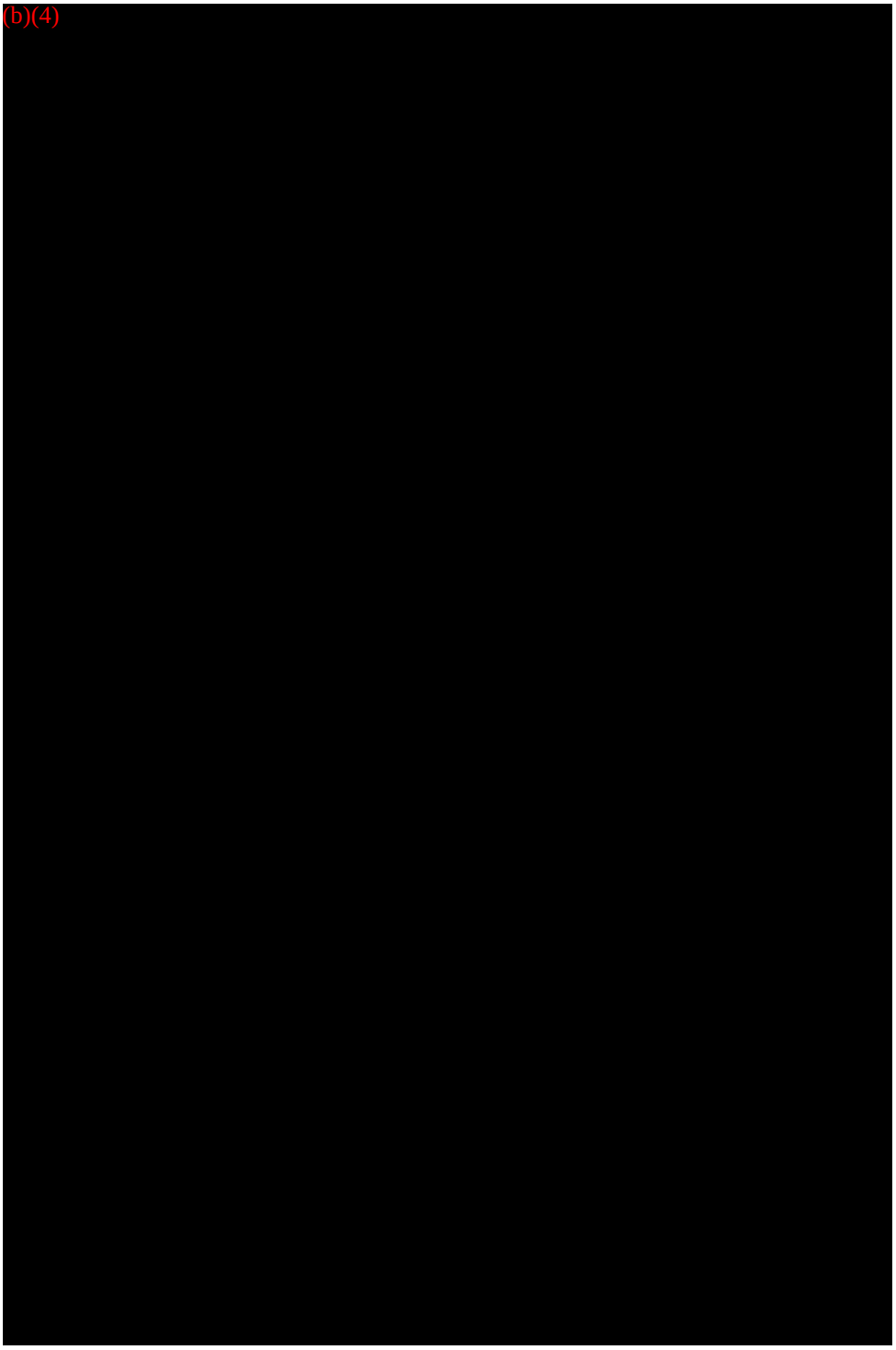
[redacted]

Table 5g: Statistical Summary - Site 3

(b)(4)



(b)(4)

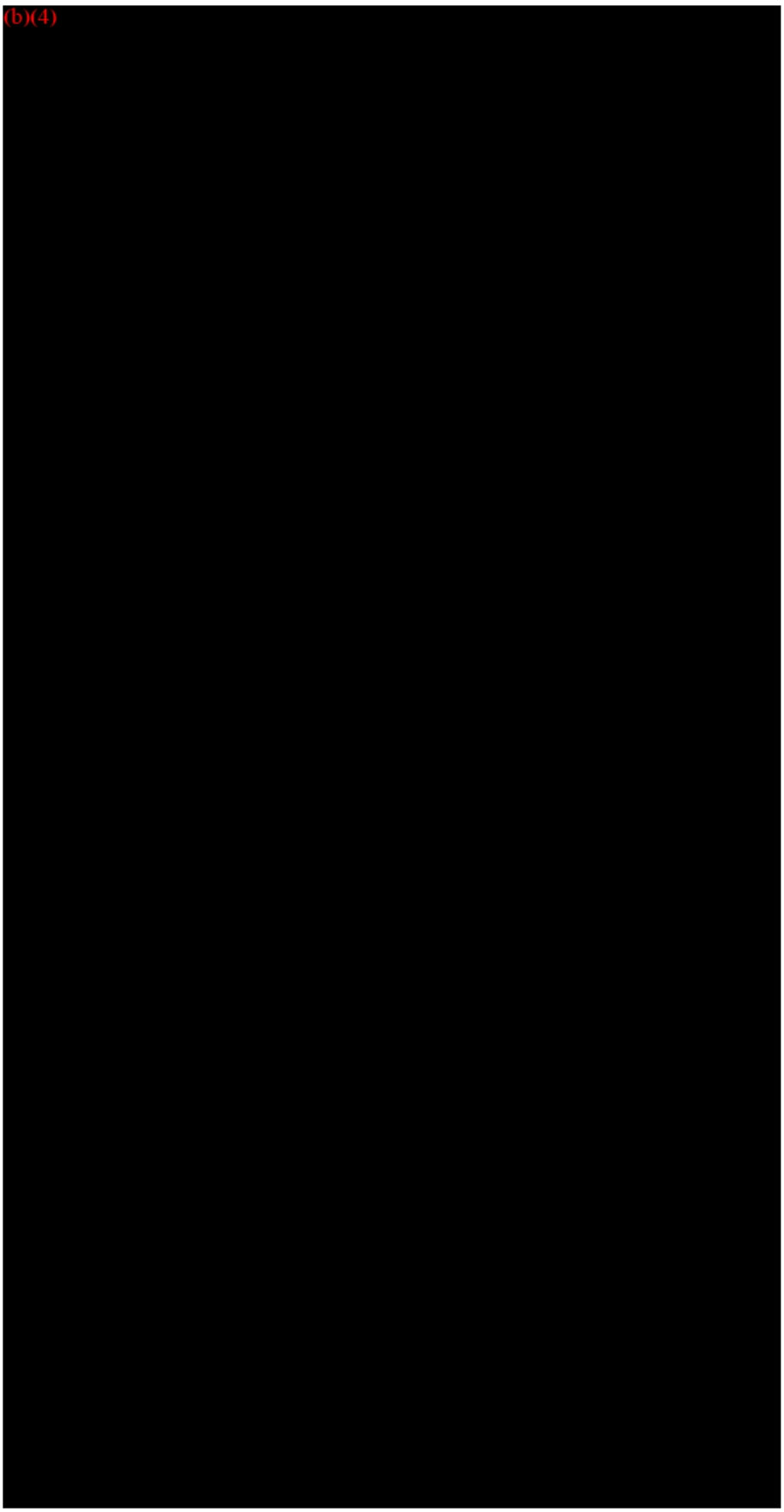


(b)(4)

Table 5h: Statistical Summary - Site 3

(b)(4)

(b)(4)



(b)(4)

[redacted]

Estimation of the Bias and Correlation Coefficient

(b)(4)

[redacted]

Table 6a: Estimation of Bias and Correlation Coefficient Limits – Whole Blood

(b)(4)

Table 6a: Estimation of Bias and Correlation Coefficient Limits – Whole Blood (continued)

(b)(4)

Table 6b: Estimation of Bias and Correlation Coefficient Limits – Whole Blood

(b)(4)

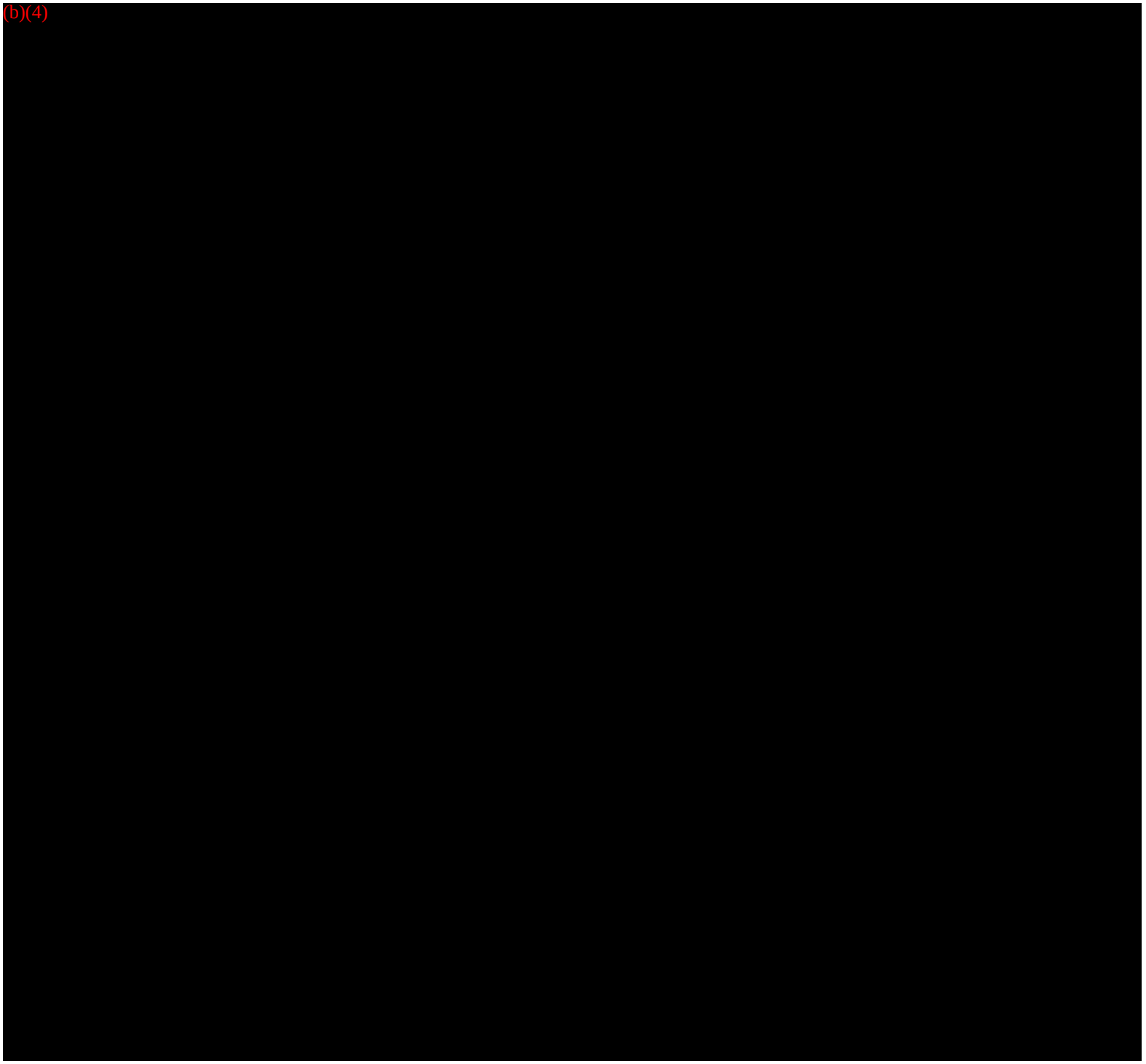


Table 6b: Estimation of Bias and Correlation Coefficient Limits – Whole Blood (continued)

(b)(4)

[redacted]

Discussion:

(b)(4)

Conclusion:

(b)(4)

Details of Data Analysis:

(b)(4)

TABLE 7: Demographics – (b)(4)

(b)(4)

**Gender and age were not recorded for all subjects

Flagging Comparison to the XE-5000 (Clinical Sensitivity) – Whole Blood

(b)(4)

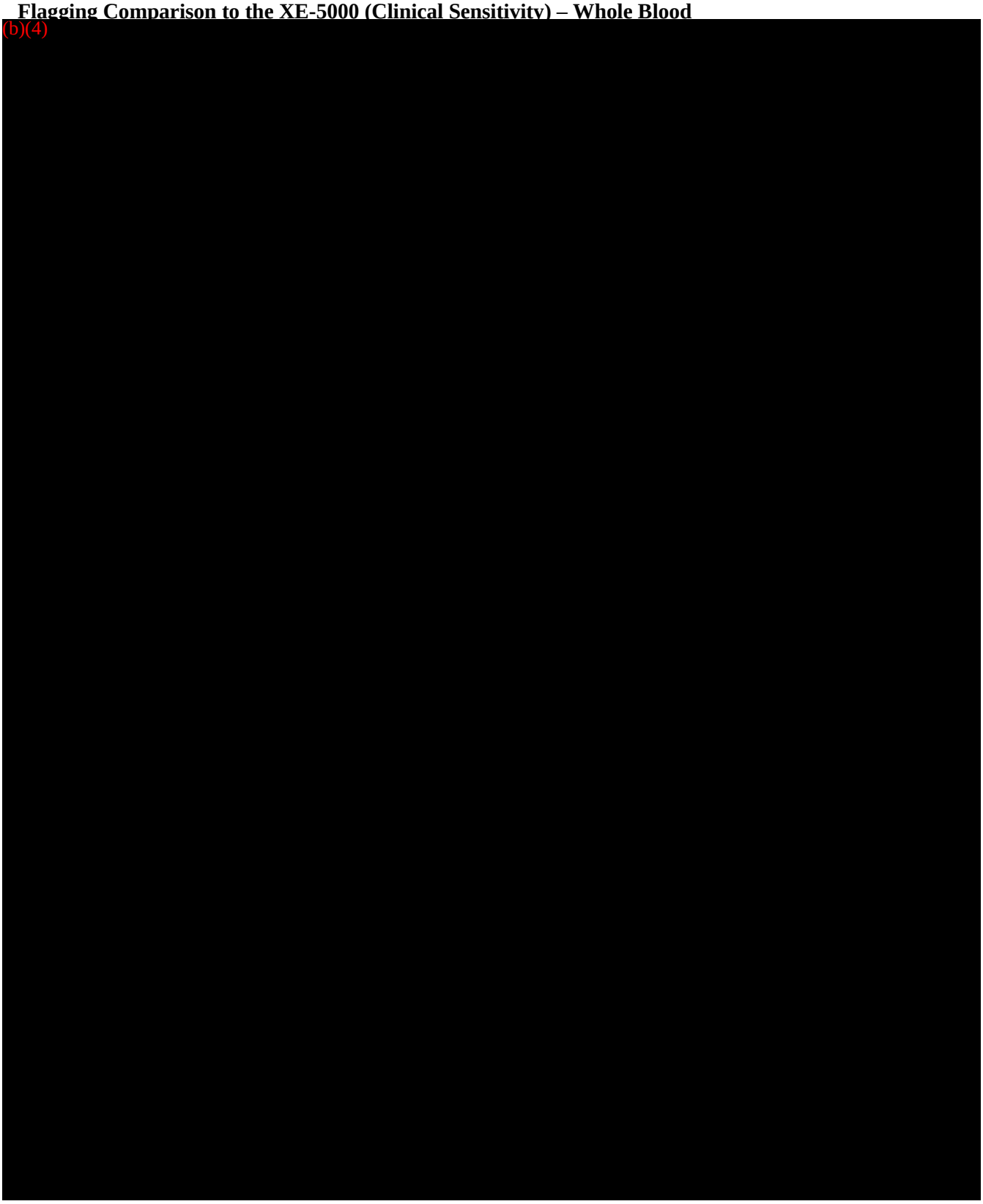


Table 8b: Overall Flagging Analysis – XE-5000 vs. XN-21 – All Sites Combined

(b)(4)

[redacted]

Statistical Summary

(b)(4)

Legend:

1	Negative (1)	Negativ
2	Positive (2)	Positive

Statistical Analysis

(Comparison of Test Method to a Gold St

Agreement	96.2%
Sensitivity	98.3%
	93.6%

calculated by the "S

	98.3%
t	93.6%
	55.7%
sitive	95.1%
gative	97.8%

m experimental resu

Date

e (1) N

(2) P

Table 8d: Overall Flagging Analysis – XE-5000 vs. XN-21 – Site 1

neg <-- Test --> pos

(b)(4)

Experiment Description

	Reference Method	Test Method
Analyst:	S. Brooks	S. Brooks
Date:	02 Jan 2013	02 Jan 2013
Comment:		

Accepted by:

Signature Date

Table 8e Overall Flagging Analysis – XE-5000 vs. XN-11 – Site 2

(b)(4)

[redacted]

Table 8f: Overall Flagging Analysis – XE-5000 vs. XN-21 – Site 2

(b)(4)

[redacted]

Statistical Summary

(b)(4)

Neg
Posi

Table 8g: Overall Flagging Analysis – XE-5000 vs. XN-11 – Site 3

(b)(4)

Experiment Description

Date

Table 8h: Overall Flagging Analysis – XE-5000 vs. XN-21 – Site 3

(b)(4)

[redacted]

(b)(4)

1.2.2 Reproducibility – Whole Blood

Introduction

(b)(4)

Procedure

(b)(4)

Expected Results:

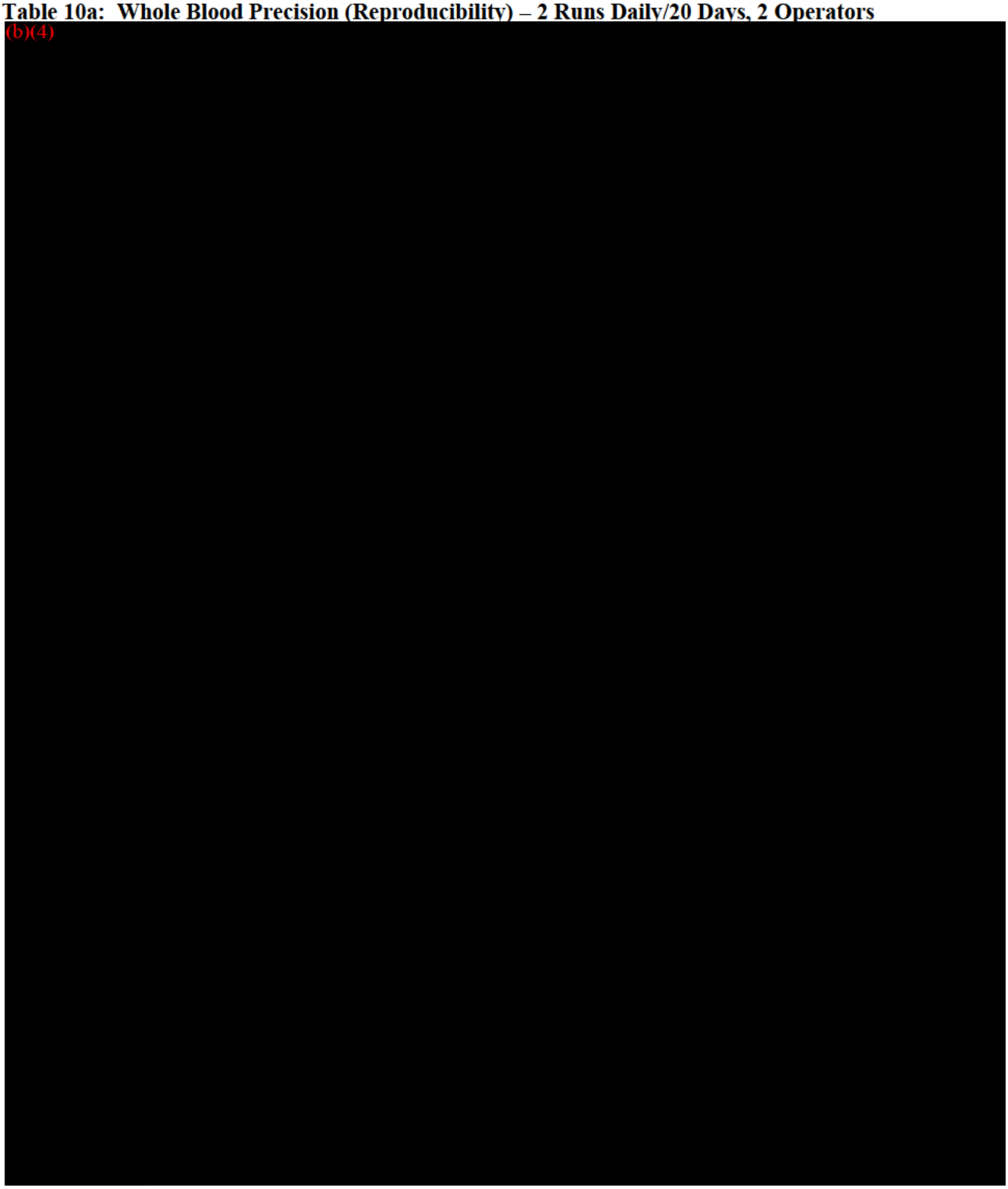
(b)(4)

Results:

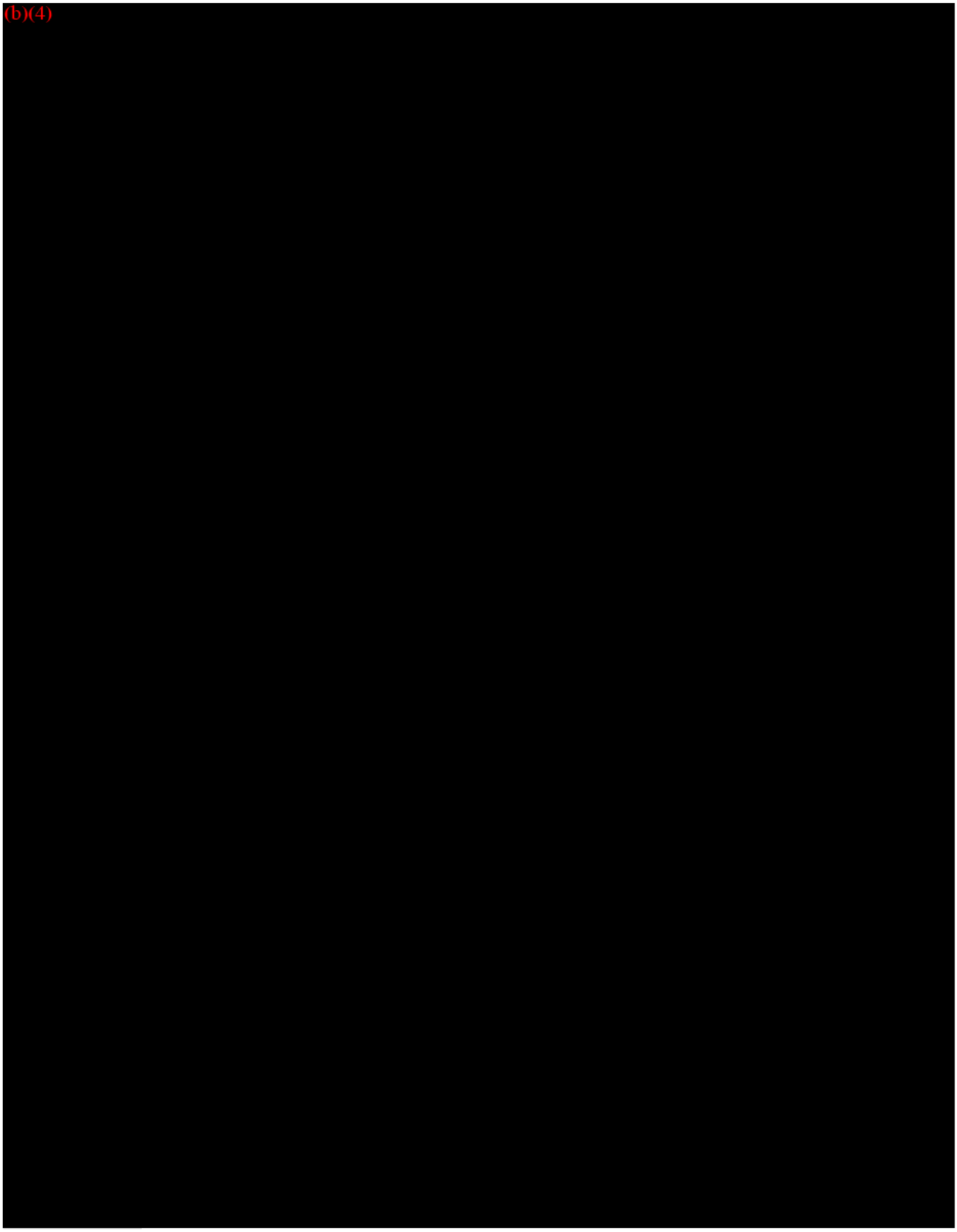
(b)(4)

Table 10a: Whole Blood Precision (Reproducibility) – 2 Runs Daily/20 Days, 2 Operators

(b)(4)



(b)(4)



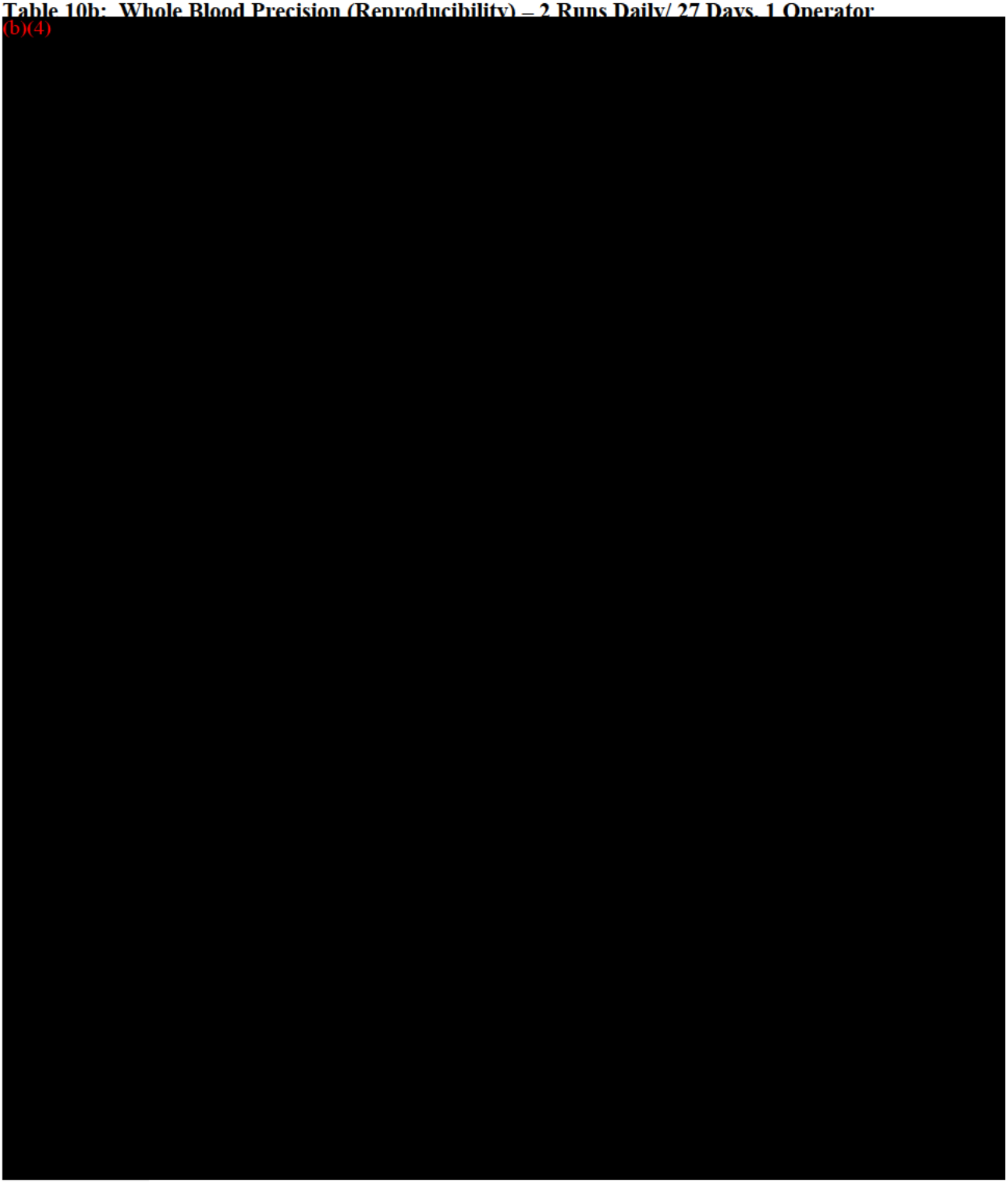
(b)(4)

[redacted]

(b)(4)

Table 10b: Whole Blood Precision (Reproducibility) – 2 Runs Daily/ 27 Days, 1 Operator

(b)(4)



(b)(4)

[redacted]

(b)(4)

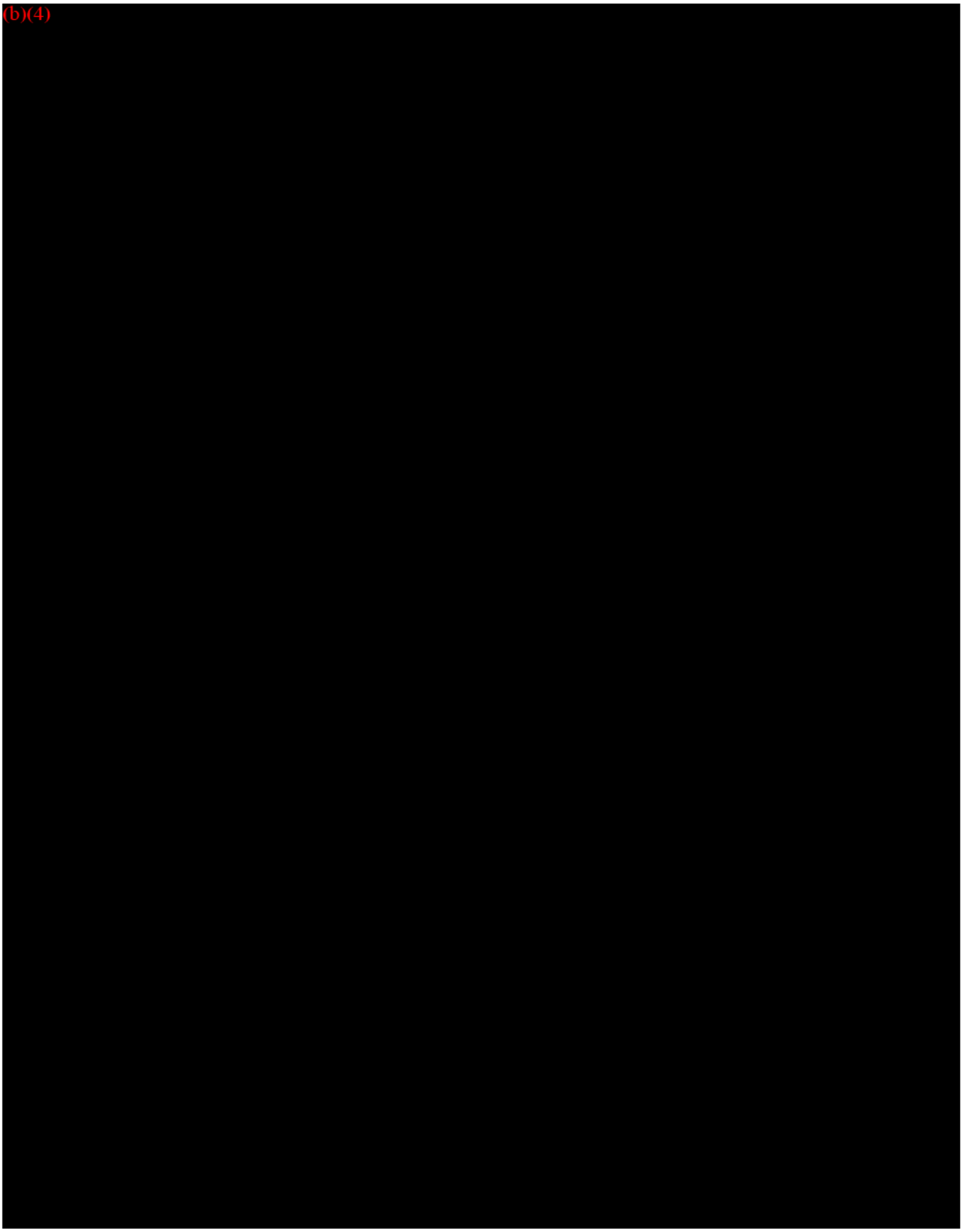
[redacted]

(b)(4)

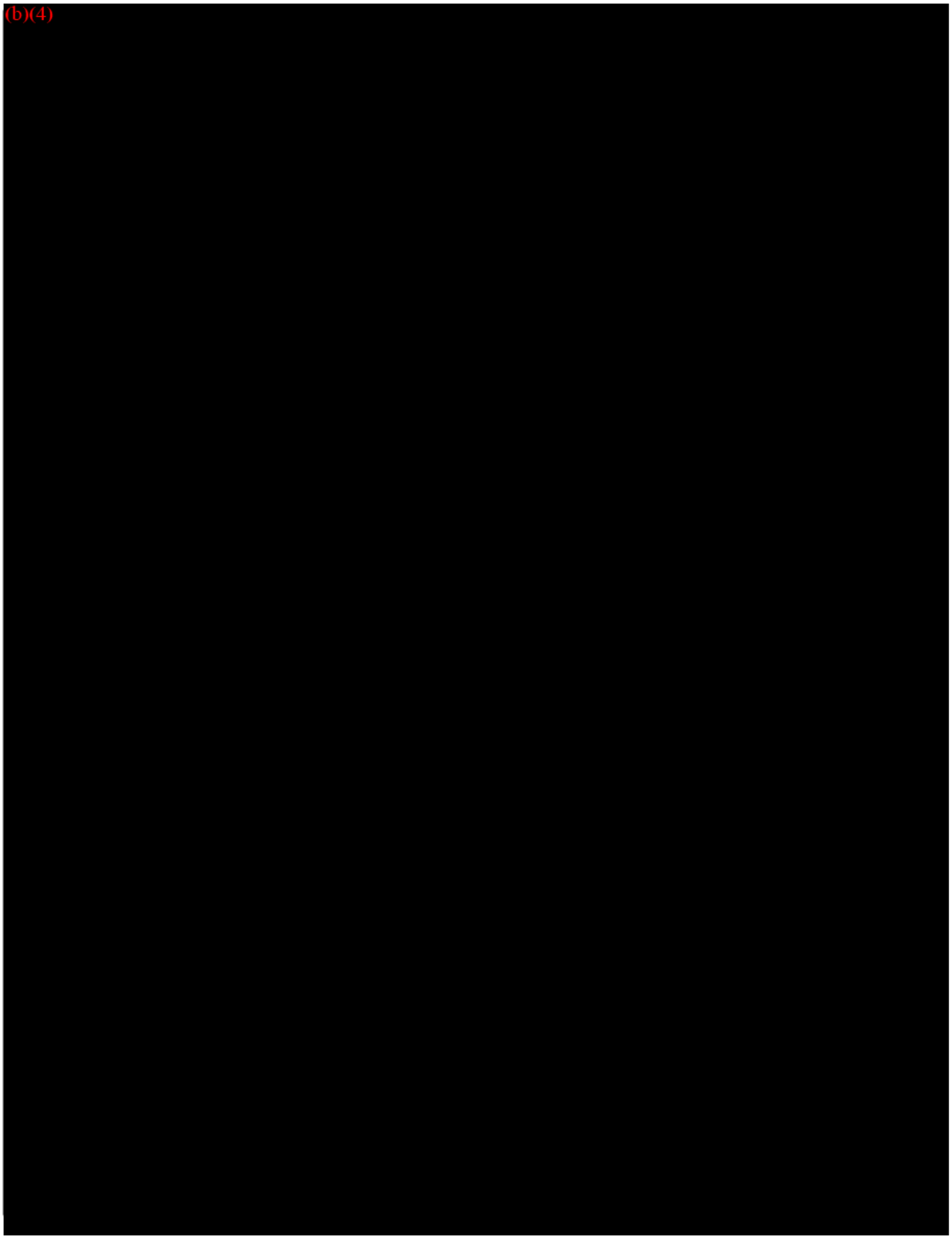
Table 10c: (b)(4)

(b)(4)

(b)(4)



(b)(4)

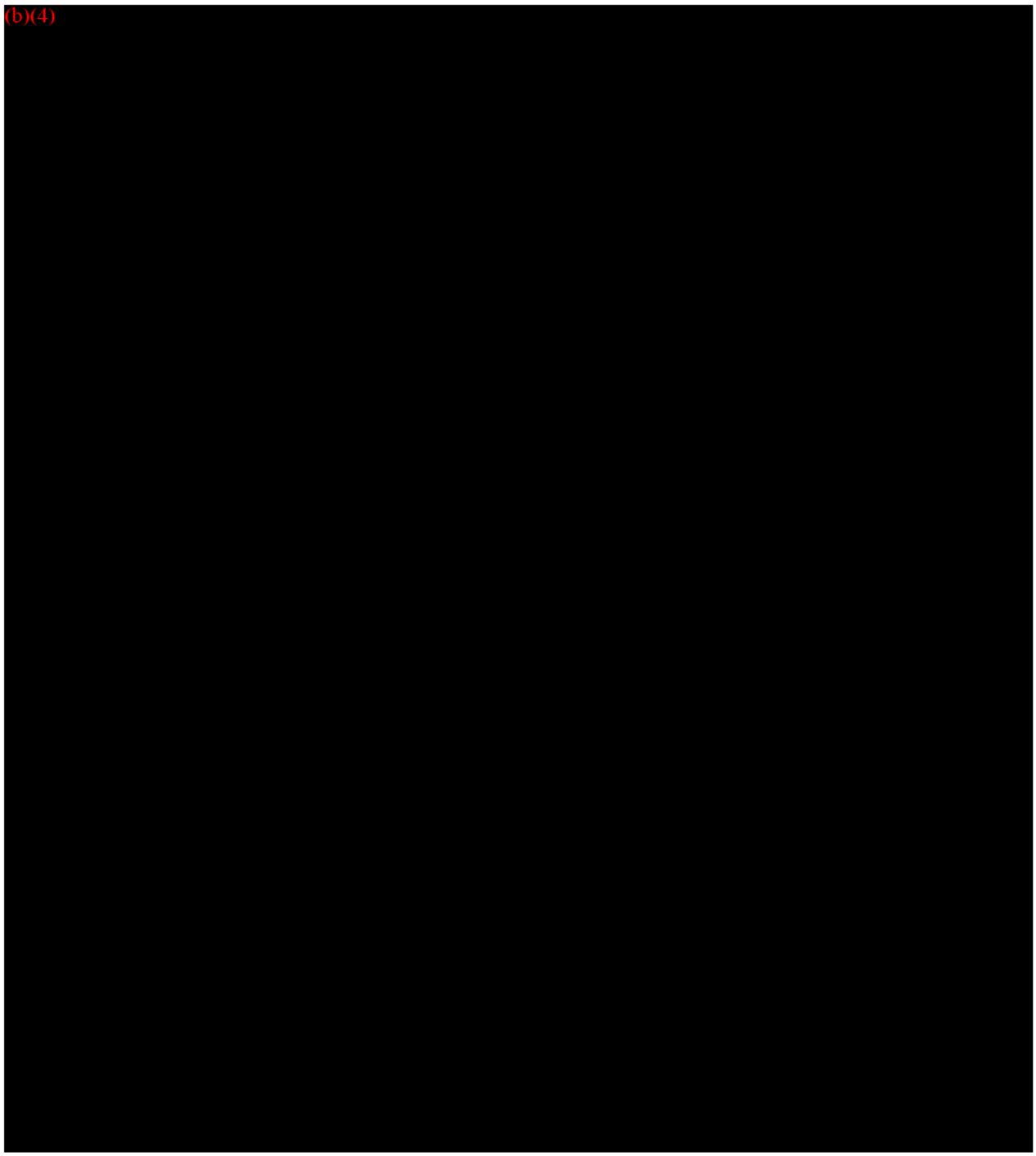


(b)(4)

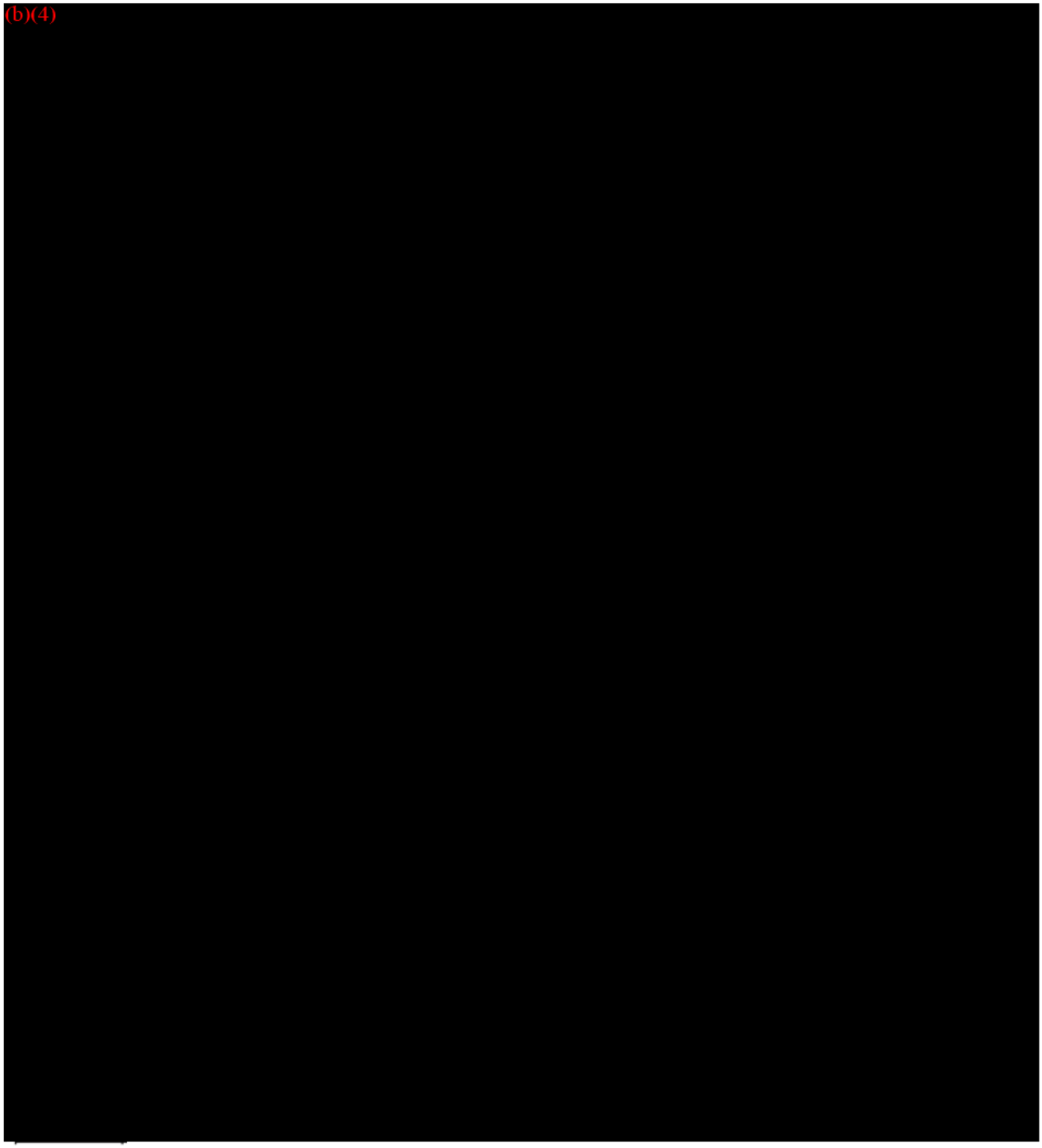
Table 10d: (b)(4)

(b)(4)

(b)(4)



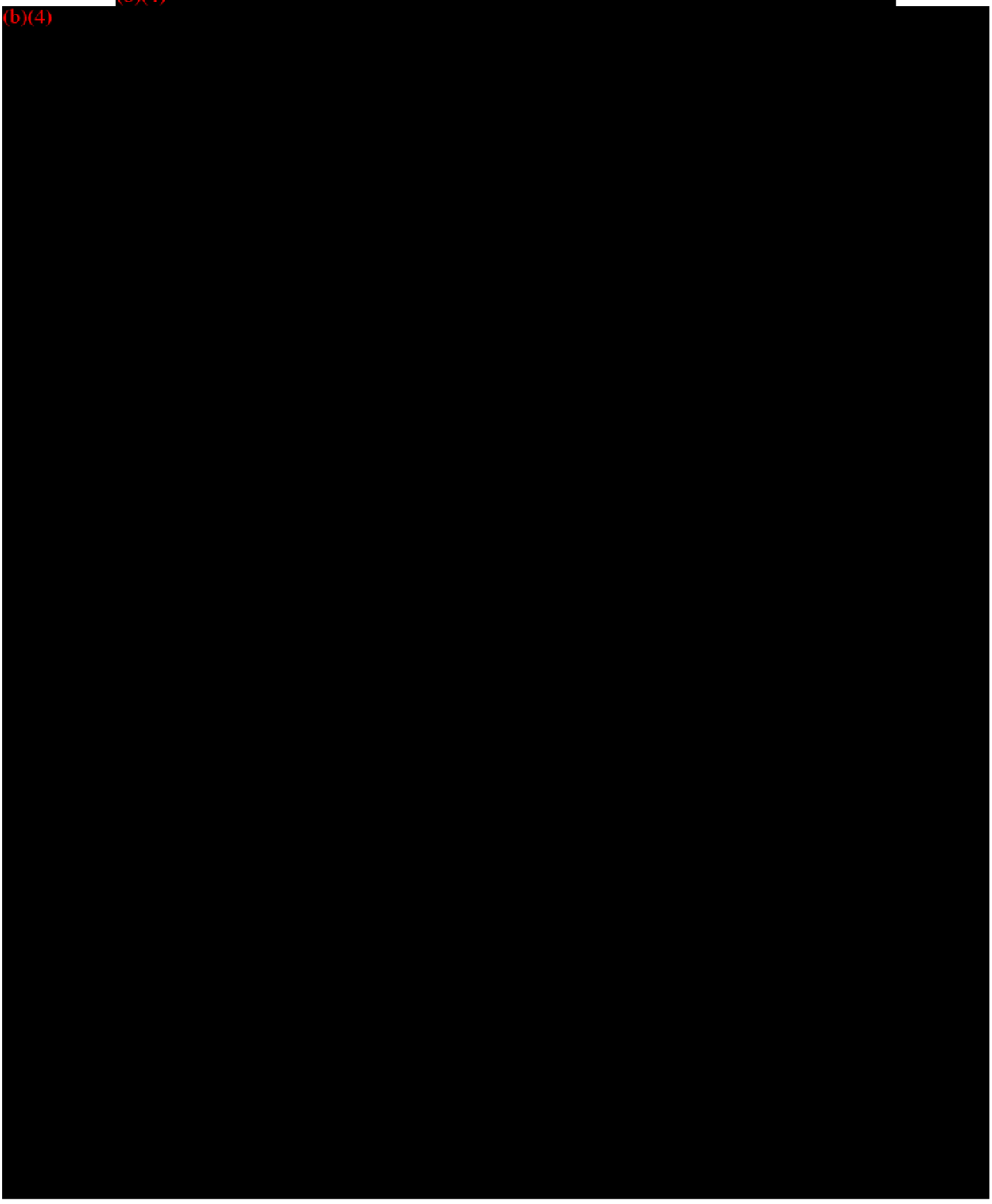
(b)(4)



(b)(4)

Table 10e: (b)(4)

(b)(4)



(b)(4)

[redacted]

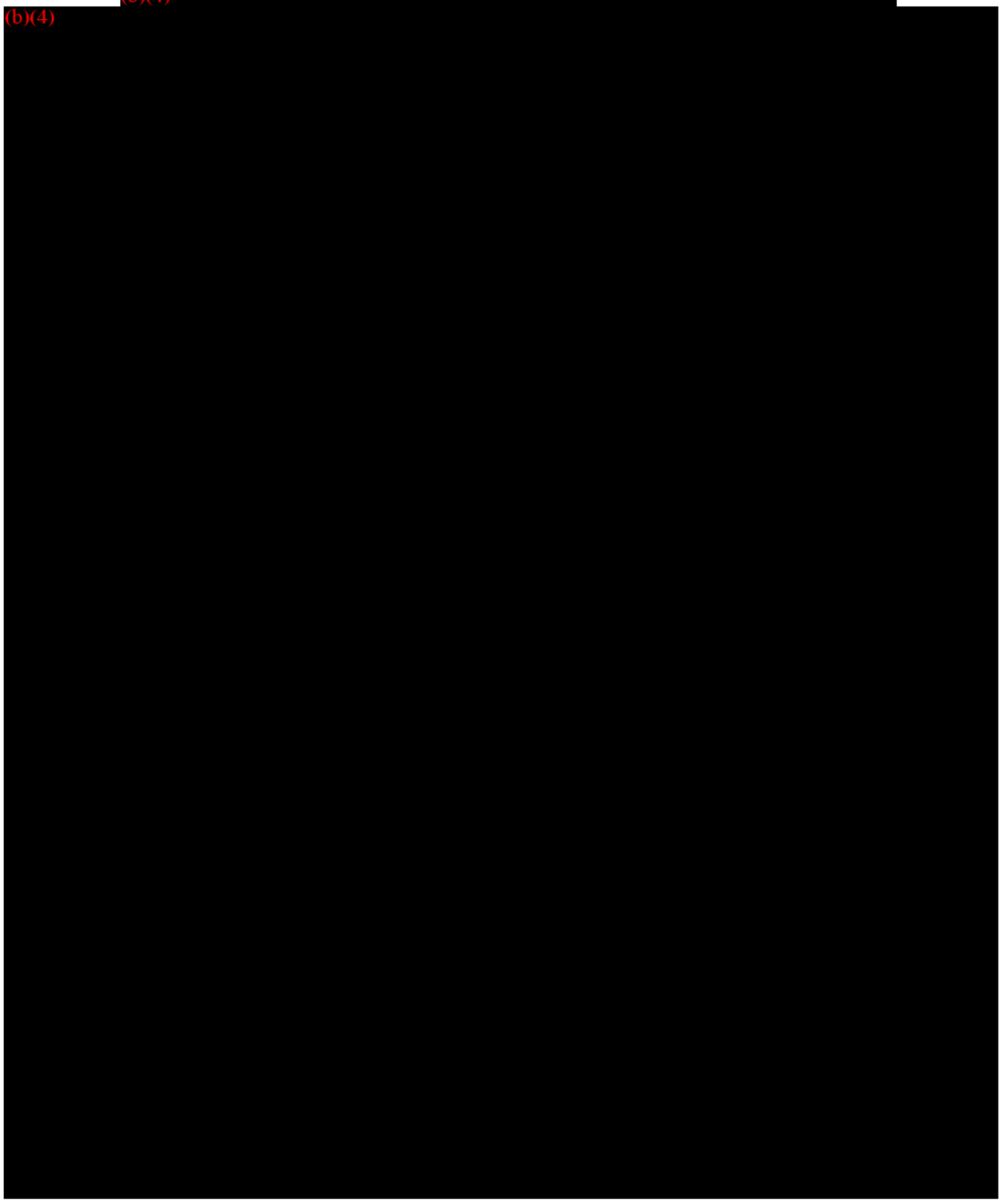
(b)(4)

[redacted]

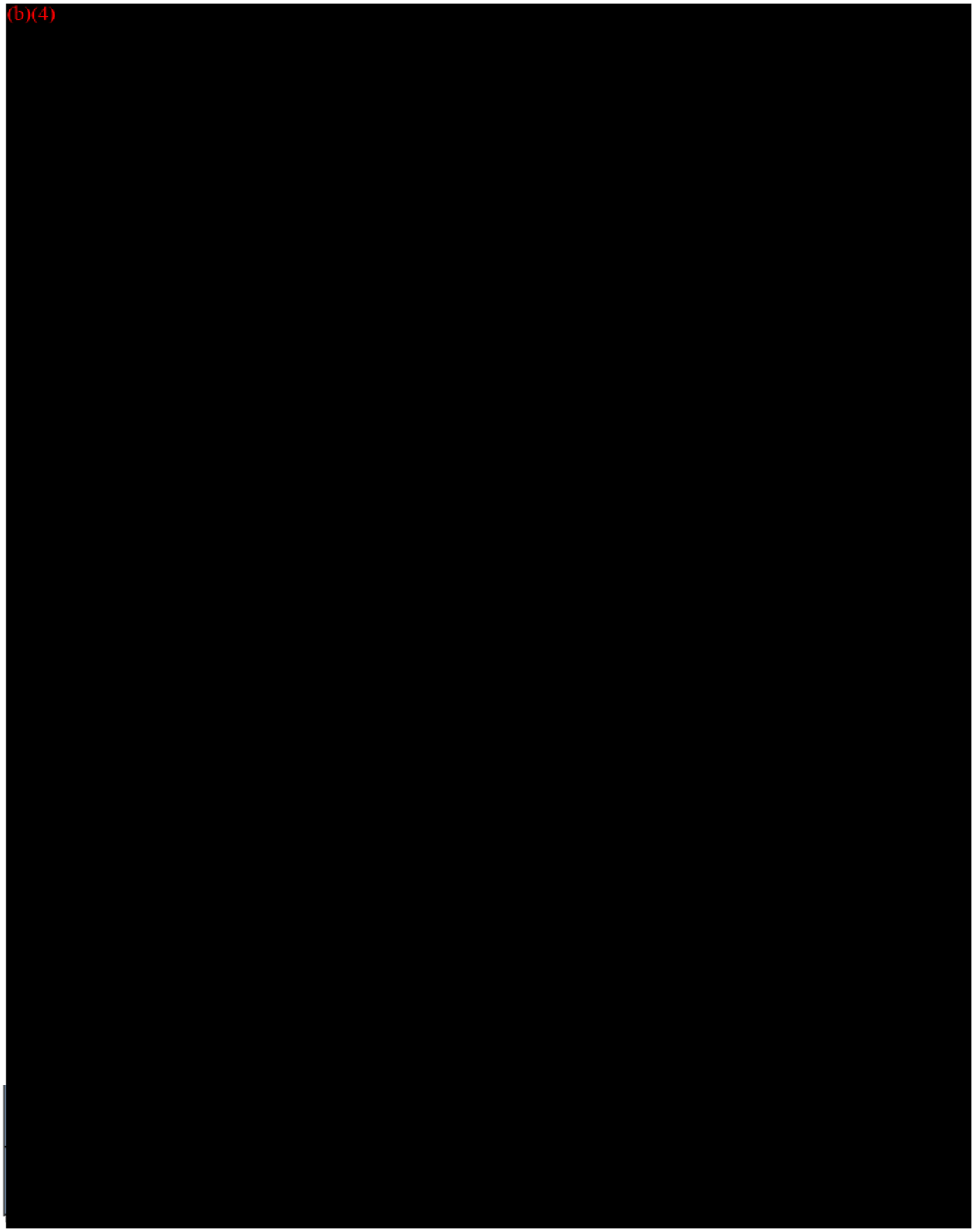
(b)(4)

Table 10f: (b)(4)

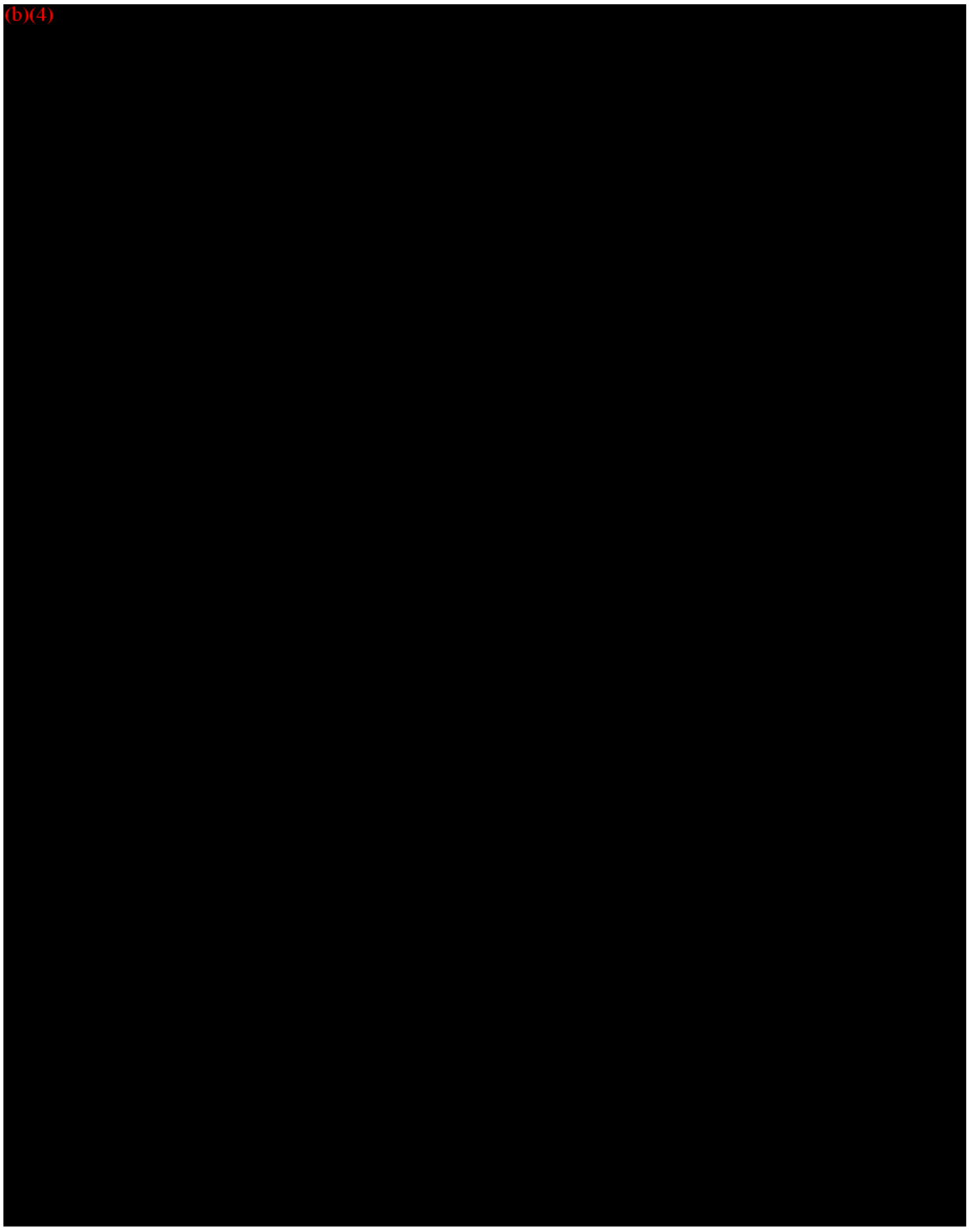
(b)(4)



(b)(4)



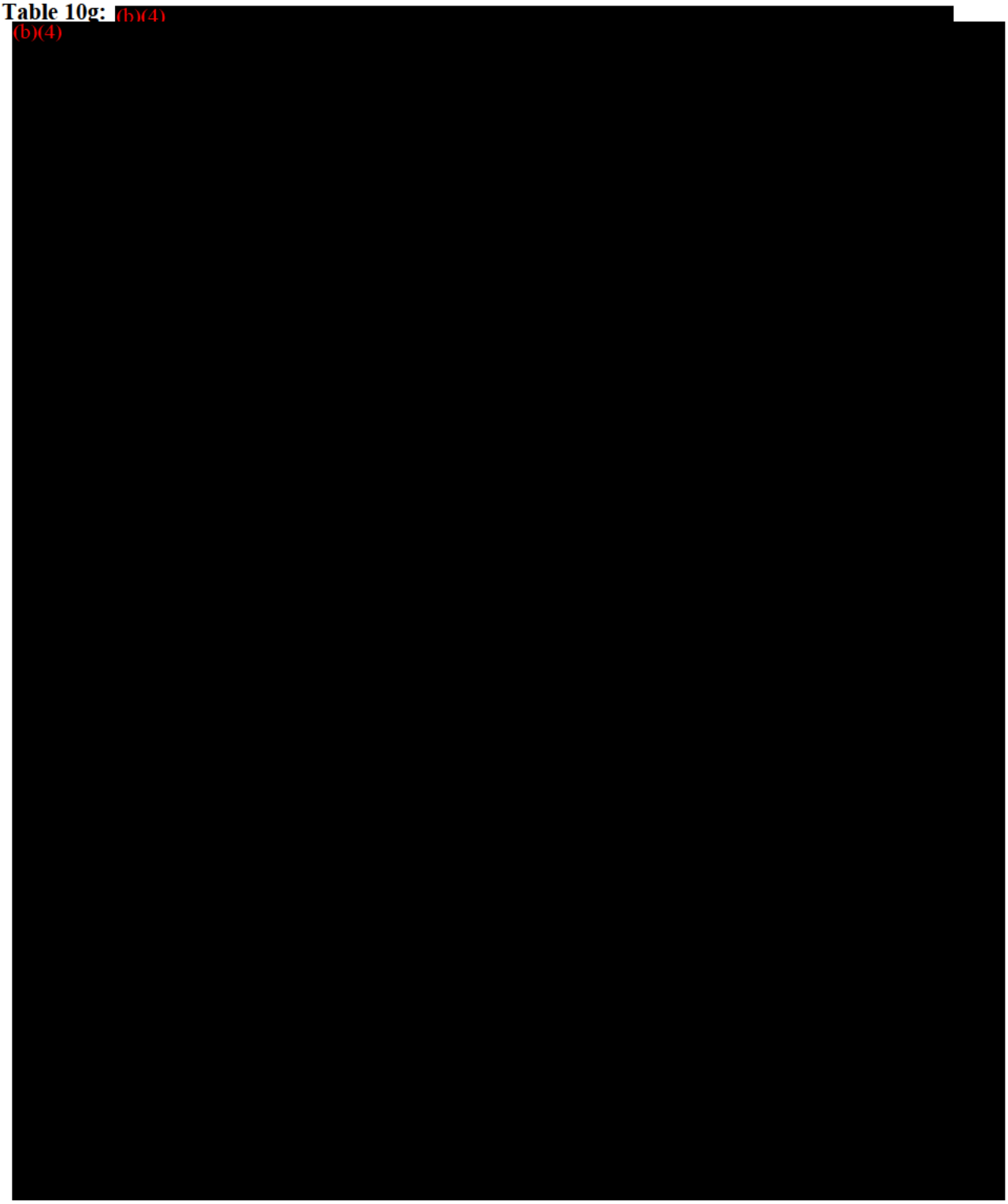
(b)(4)



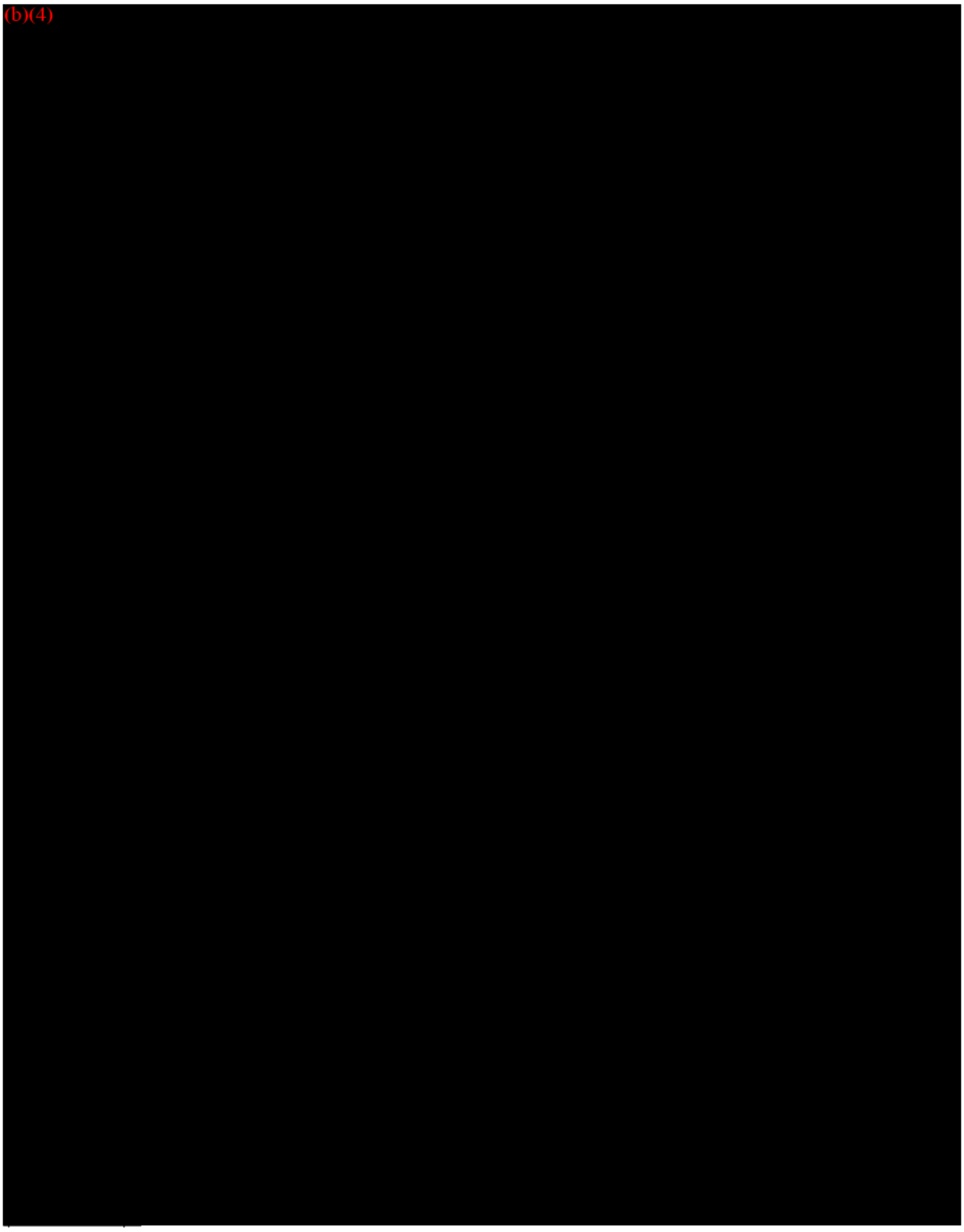
(b)(4)

Table 10g: (b)(4)

(b)(4)



(b)(4)



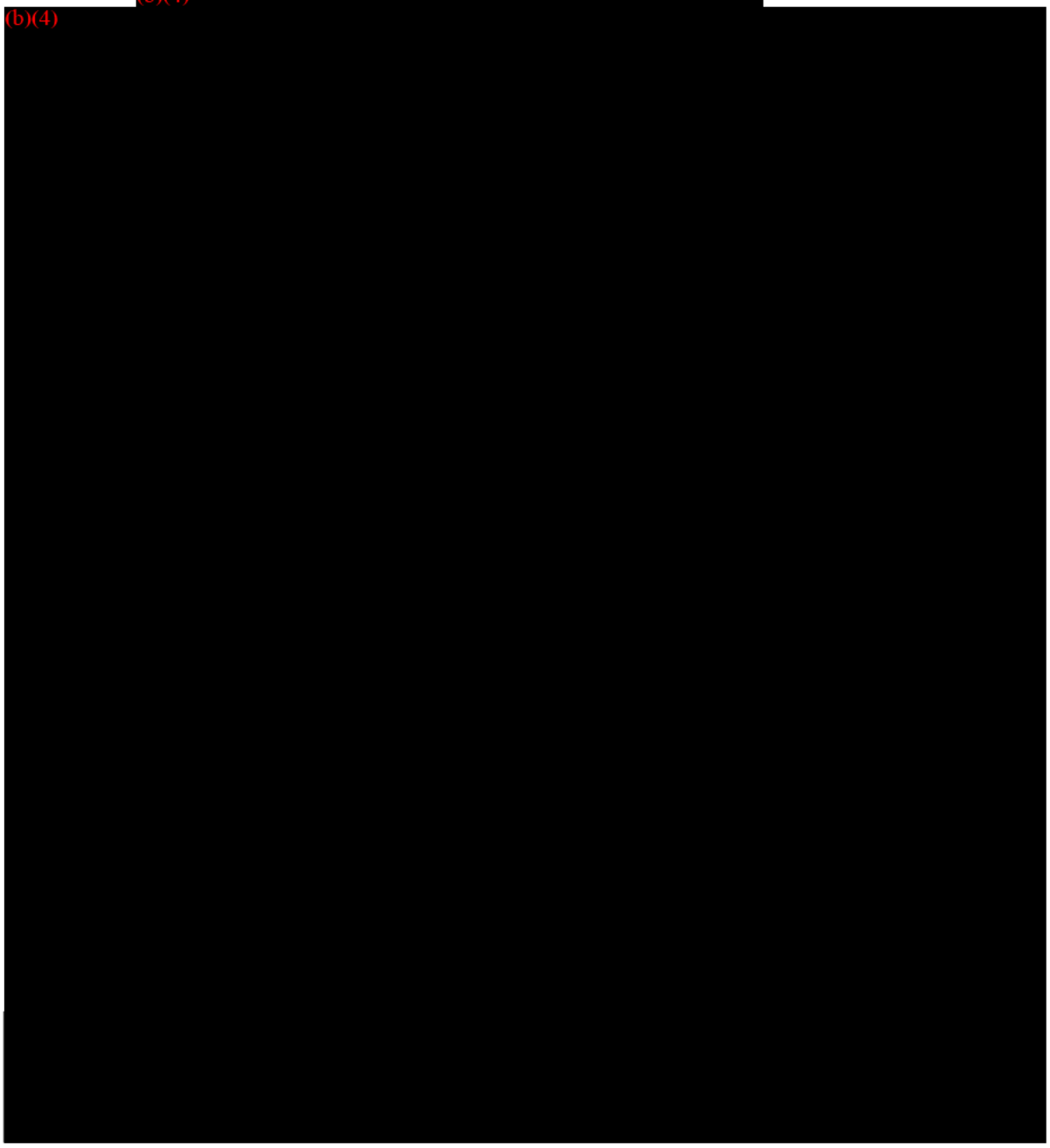
(b)(4)

[redacted]

(b)(4)

Table 10h: (b)(4)

(b)(4)



(b)(4)

[redacted]

(b)(4)

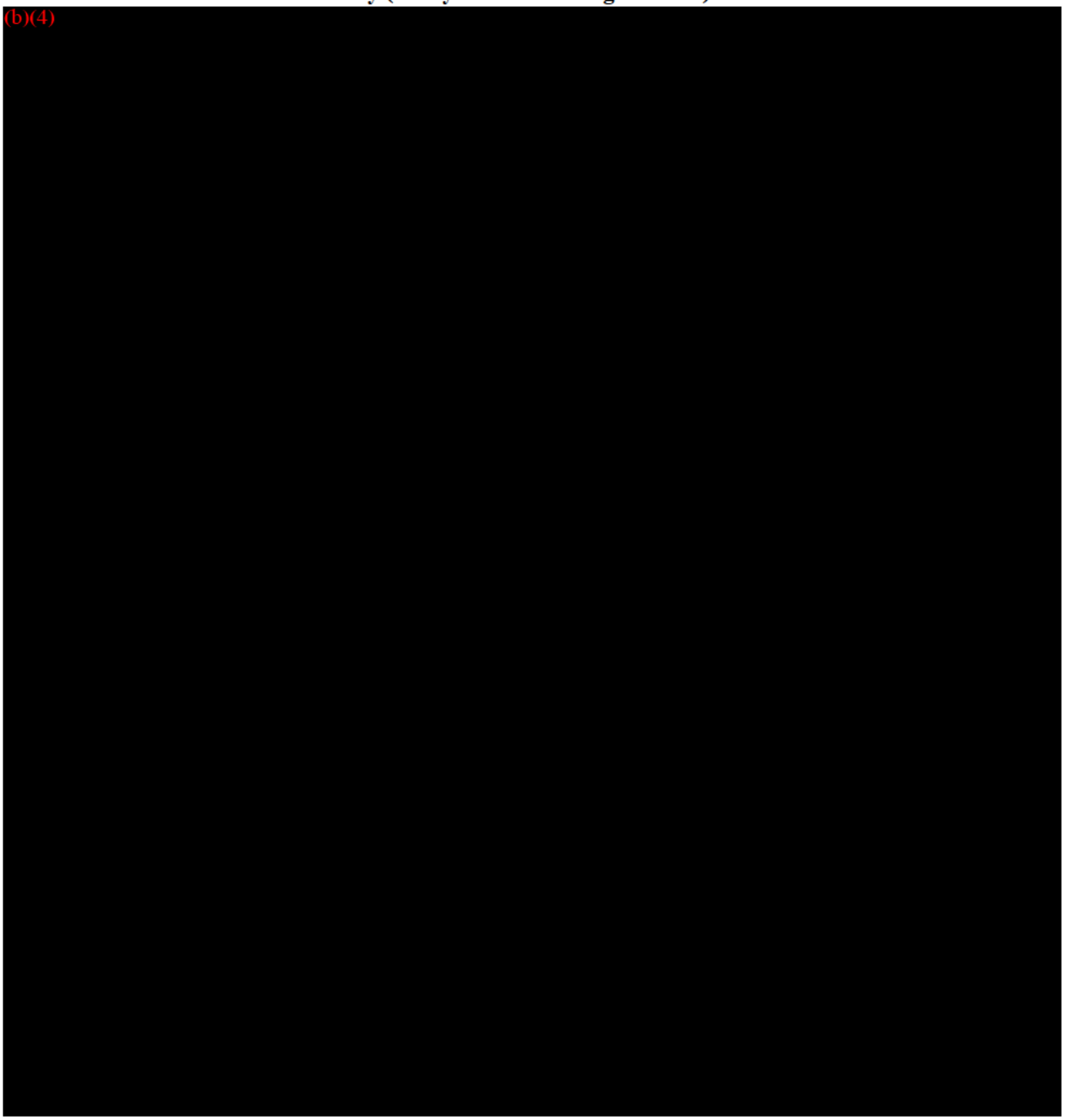
[redacted]

1.3 Linearity/Assay's Measuring (Reportable) Range – Whole Blood

(b)(4)

Table 11: Whole Blood Linearity (Analytical Measuring Interval) – XN-11 and XN-21

(b)(4)



(b)(4)

Table 12a: (b)(4)

(b)(4)

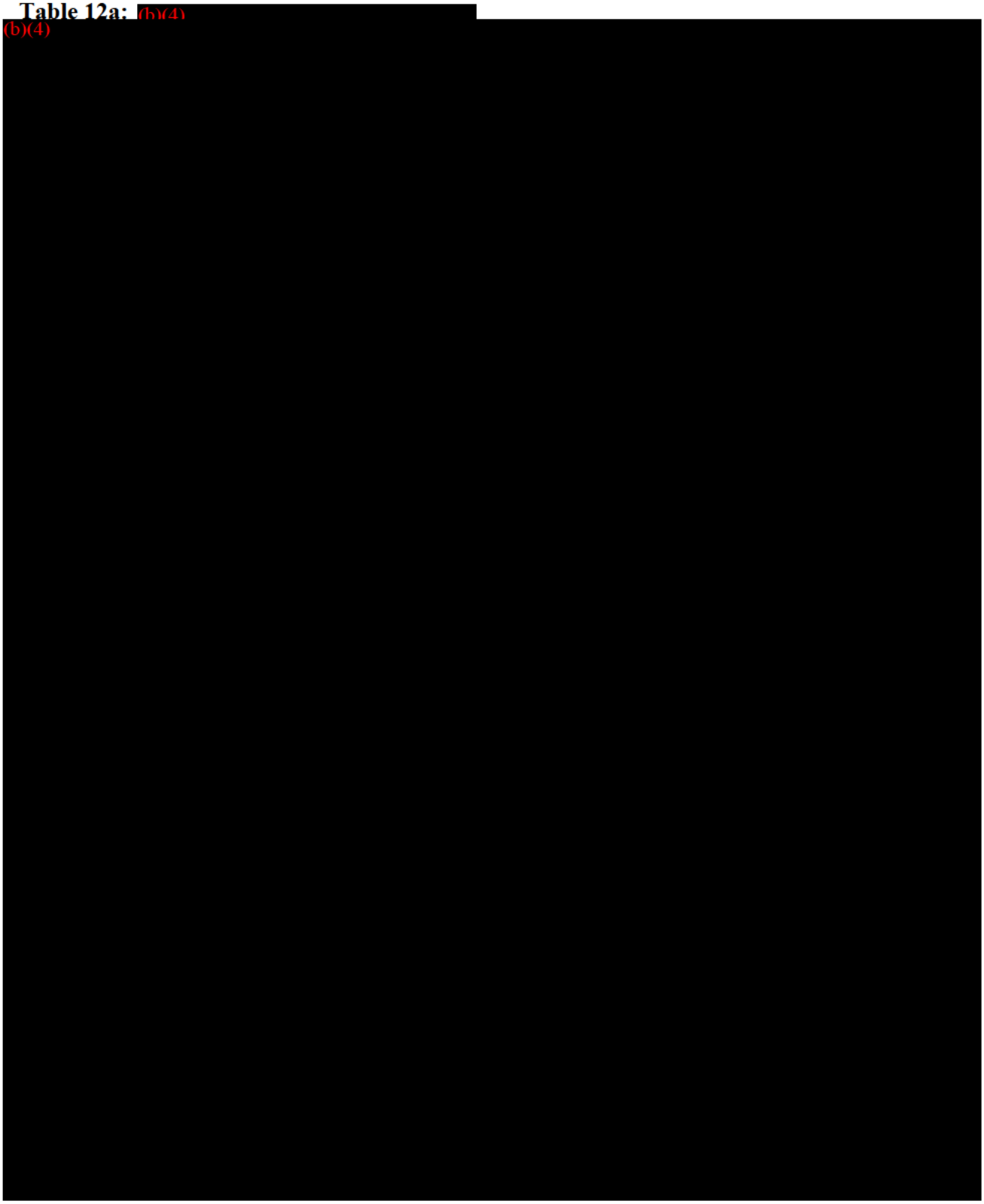


Table 12b (b)(4)

(b)(4)

[redacted]

1.5 Stability – Whole Blood

(b)(4)

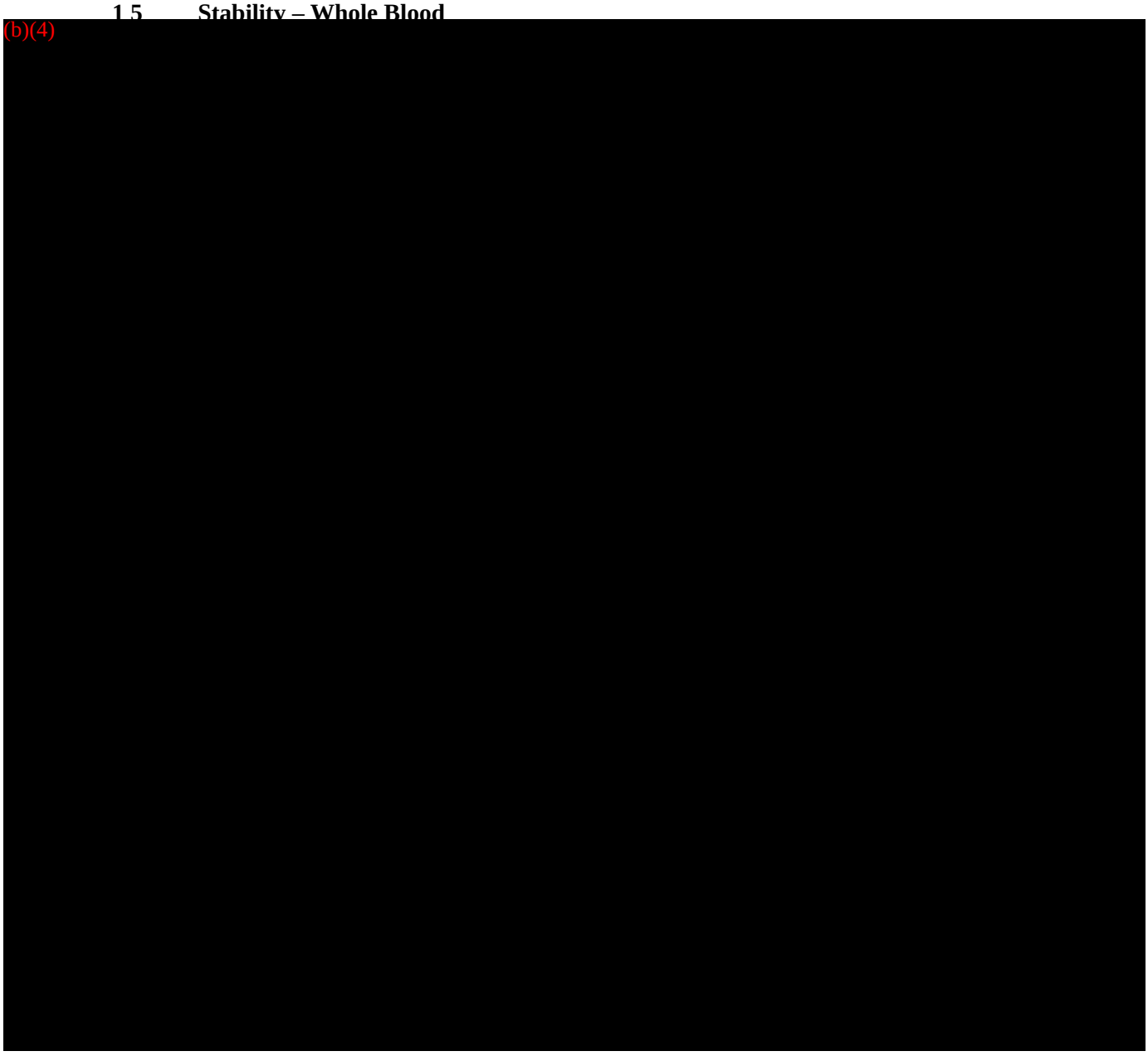
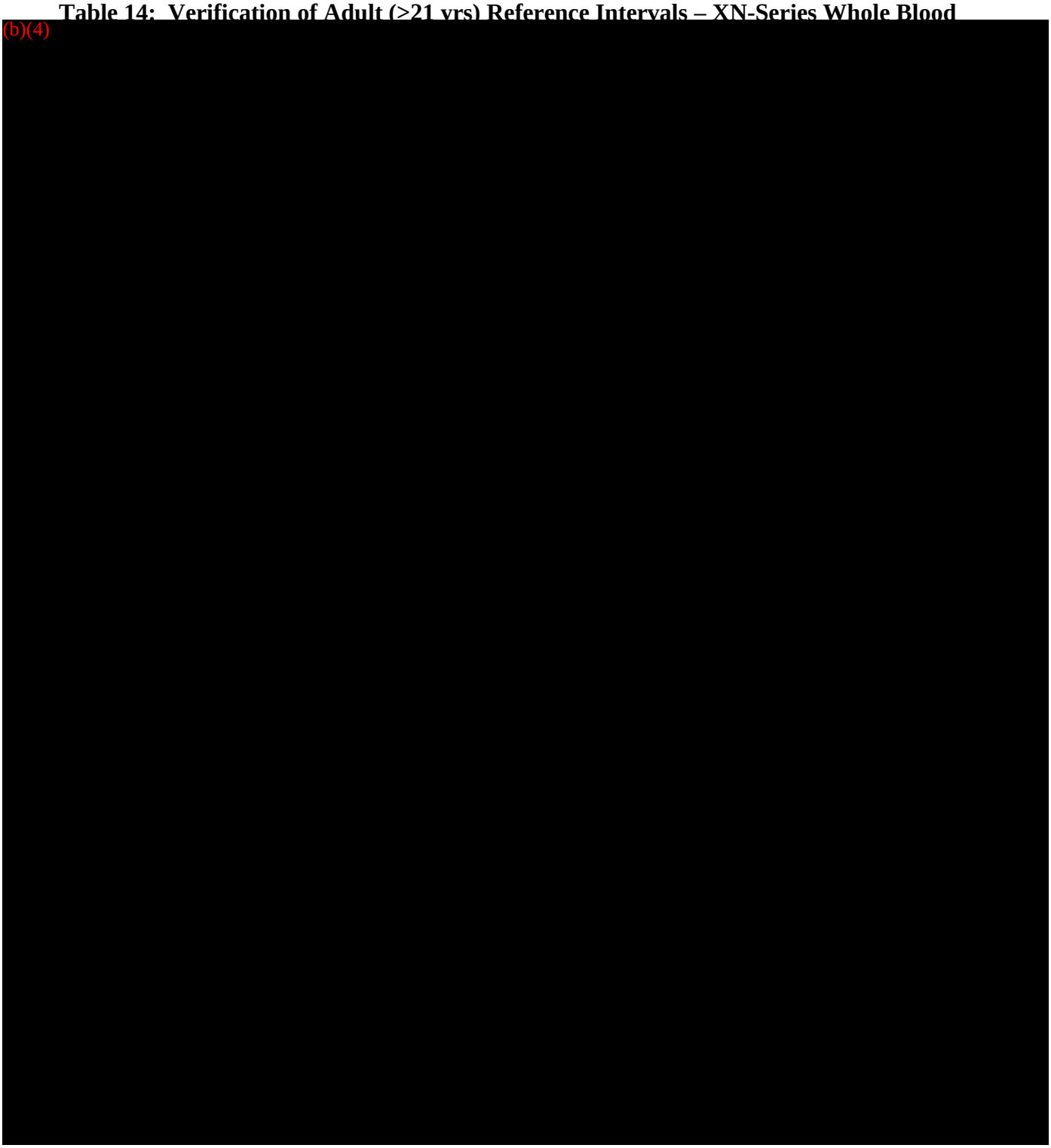


Table 13b: Whole Blood Stability – (b)(4)

(b)(4)

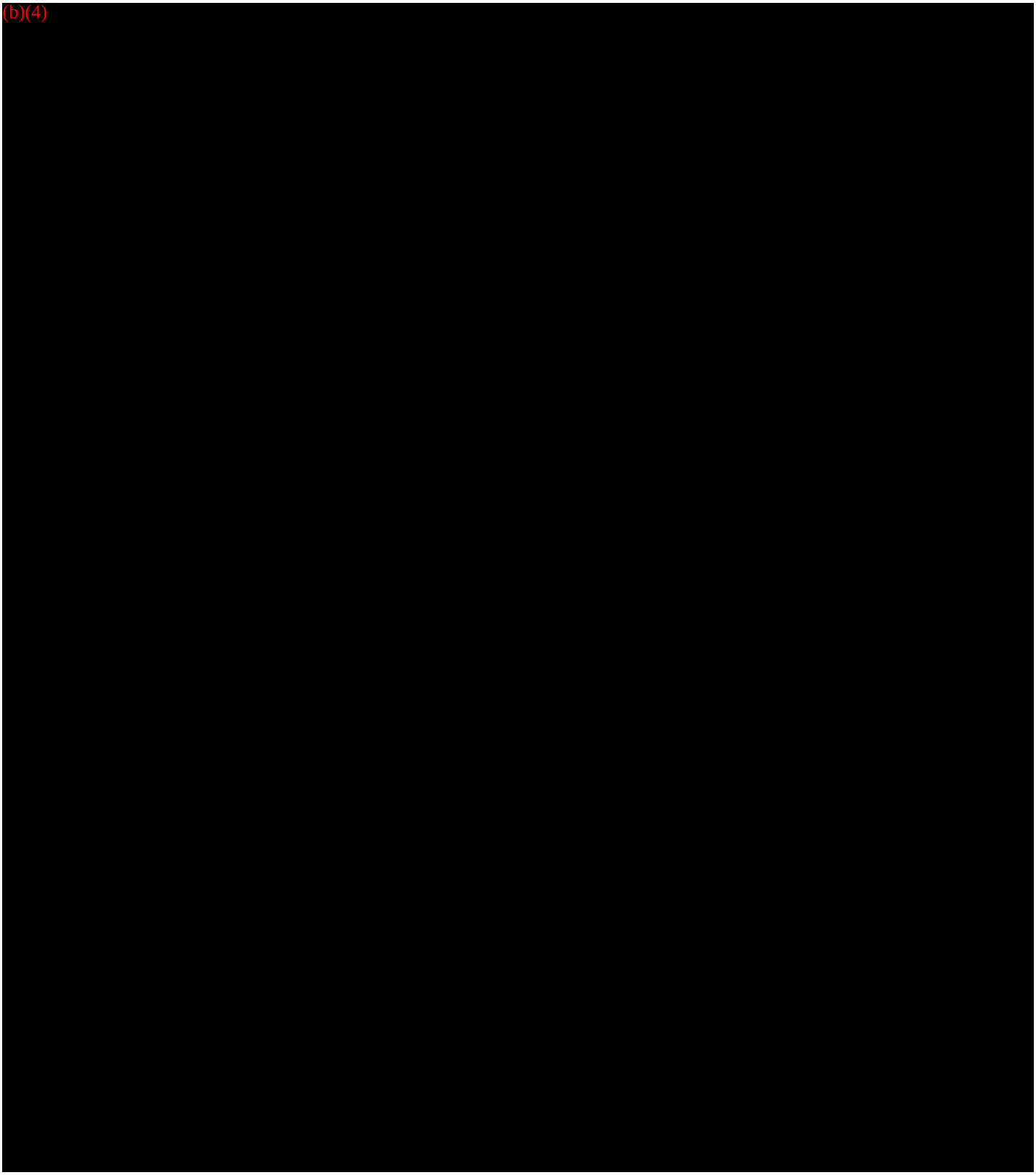
Table 14: Verification of Adult (>21 yrs) Reference Intervals – XN-Series Whole Blood

(b)(4)



2.0 Body Fluid Studies

(b)(4)



Results:

(b)(4)

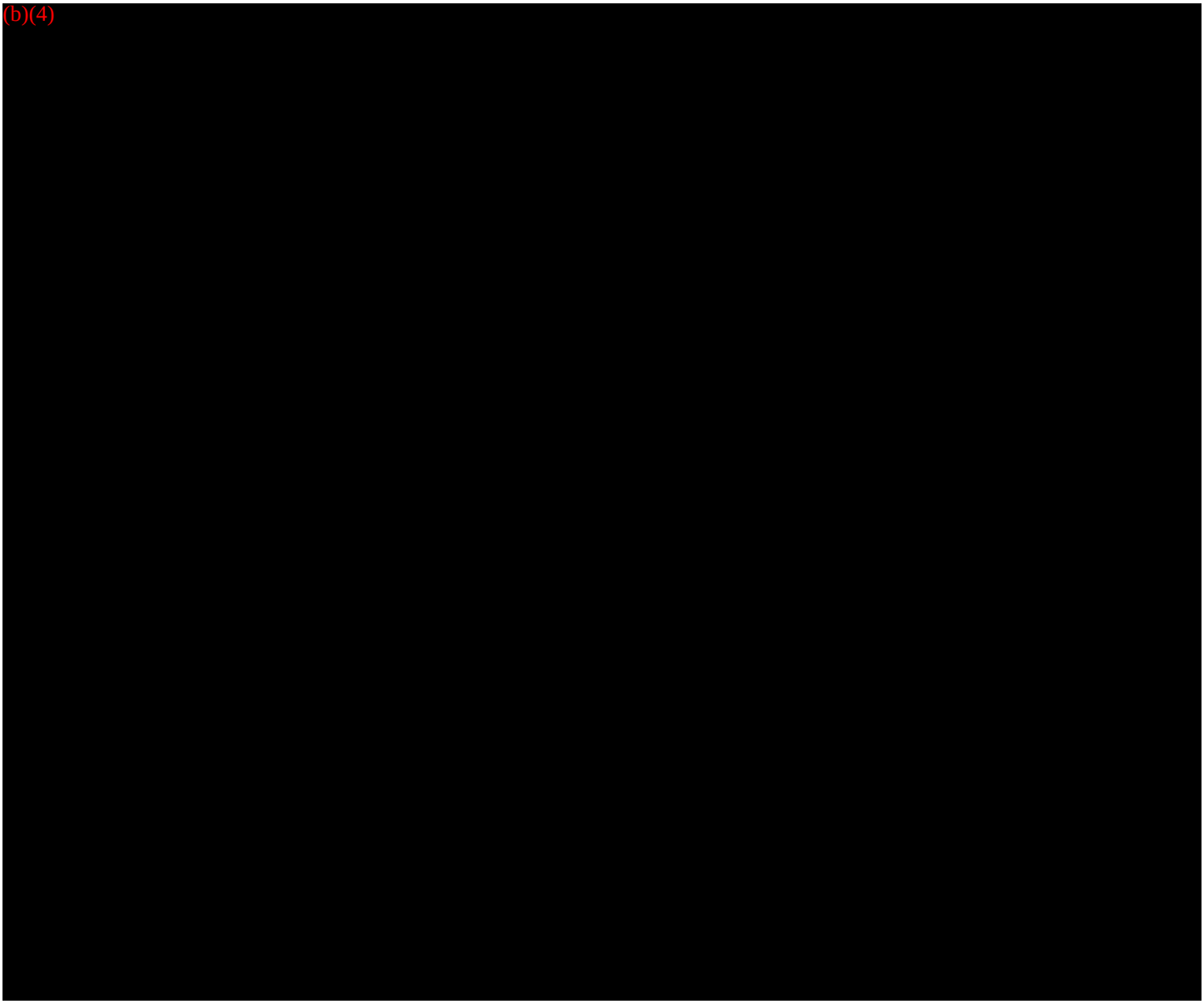


Table 15a: (b)(4)

(b)(4)

Table 15b: (b)(4)

(b)(4)

Table 16: (b)(4)

(b)(4)

Table 16b: Peritoneal Fluids (b)(4)

(b)(4)

Table 17a: Synovial Fluids (b)(4)

(b)(4)

[redacted]

(b)(4)

Table 18: (b)(4) **– Body Fluid**

(b)(4)

Table 18a: (b)(4) – Body Fluids – (b)(4)

(b)(4)

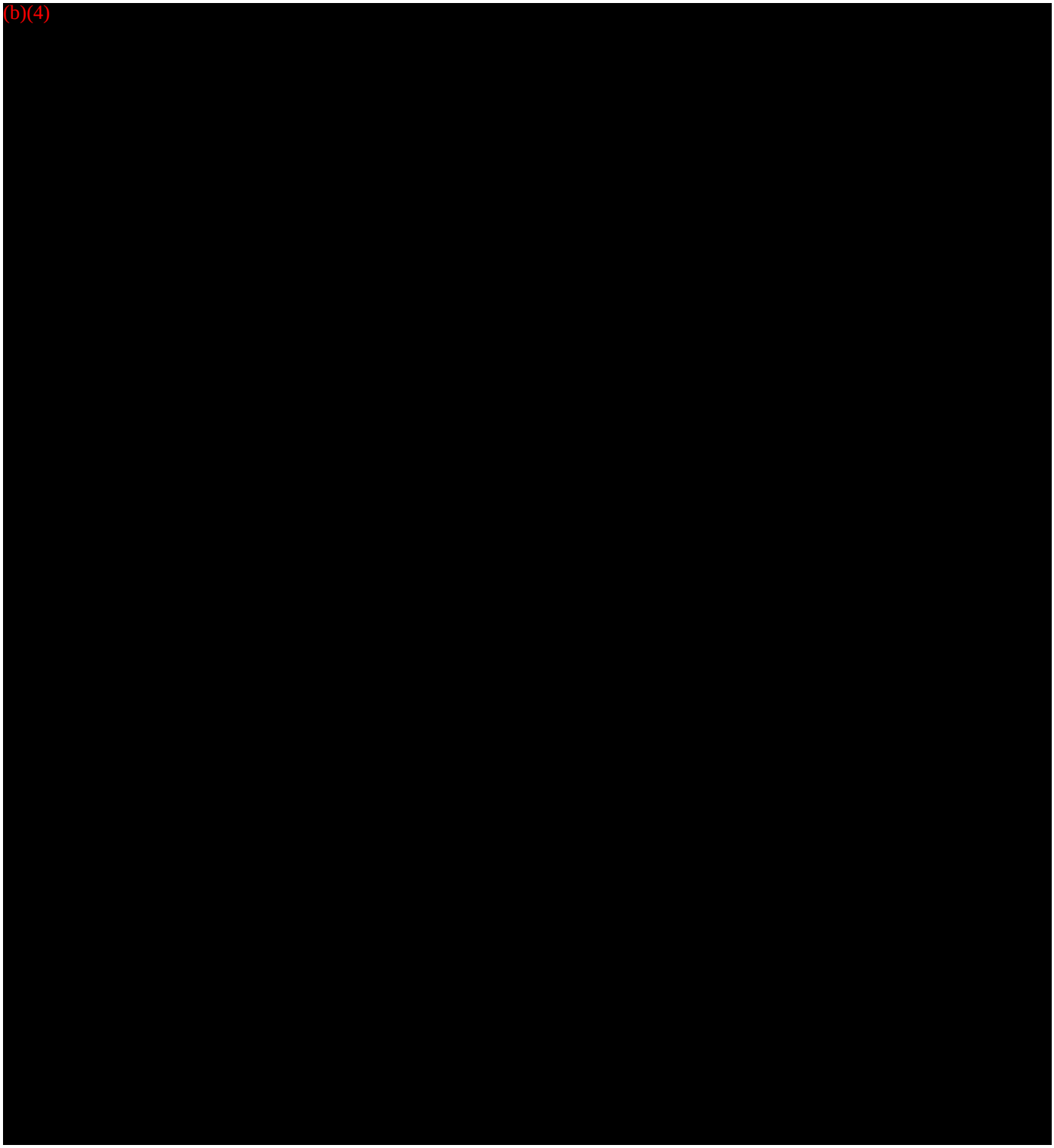


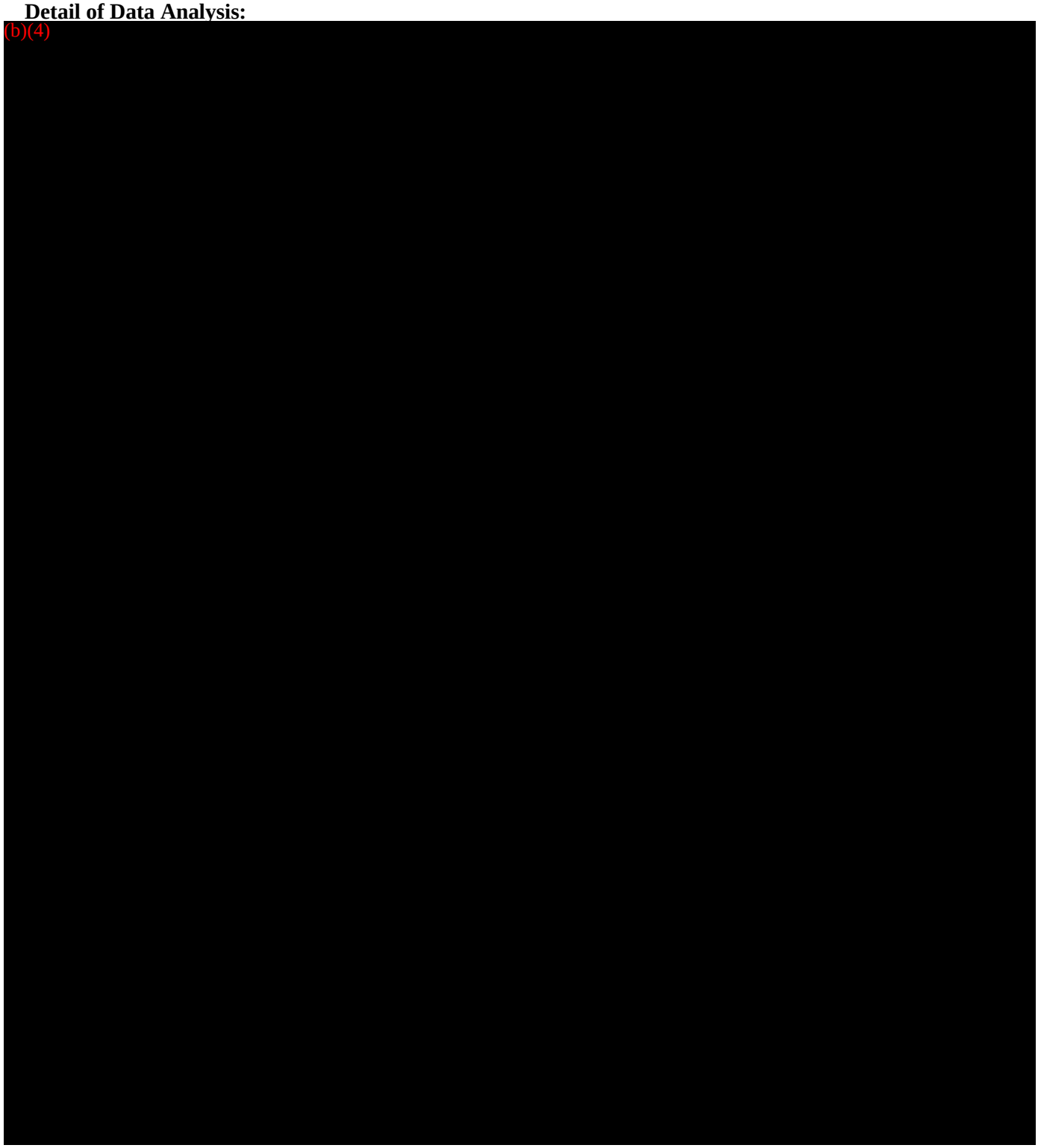
Table 18b: (b)(4) – Body Fluids – (b)(4)

Table 18c: (b)(4) – Body Fluids – (b)(4)

(b)(4)

Detail of Data Analysis:

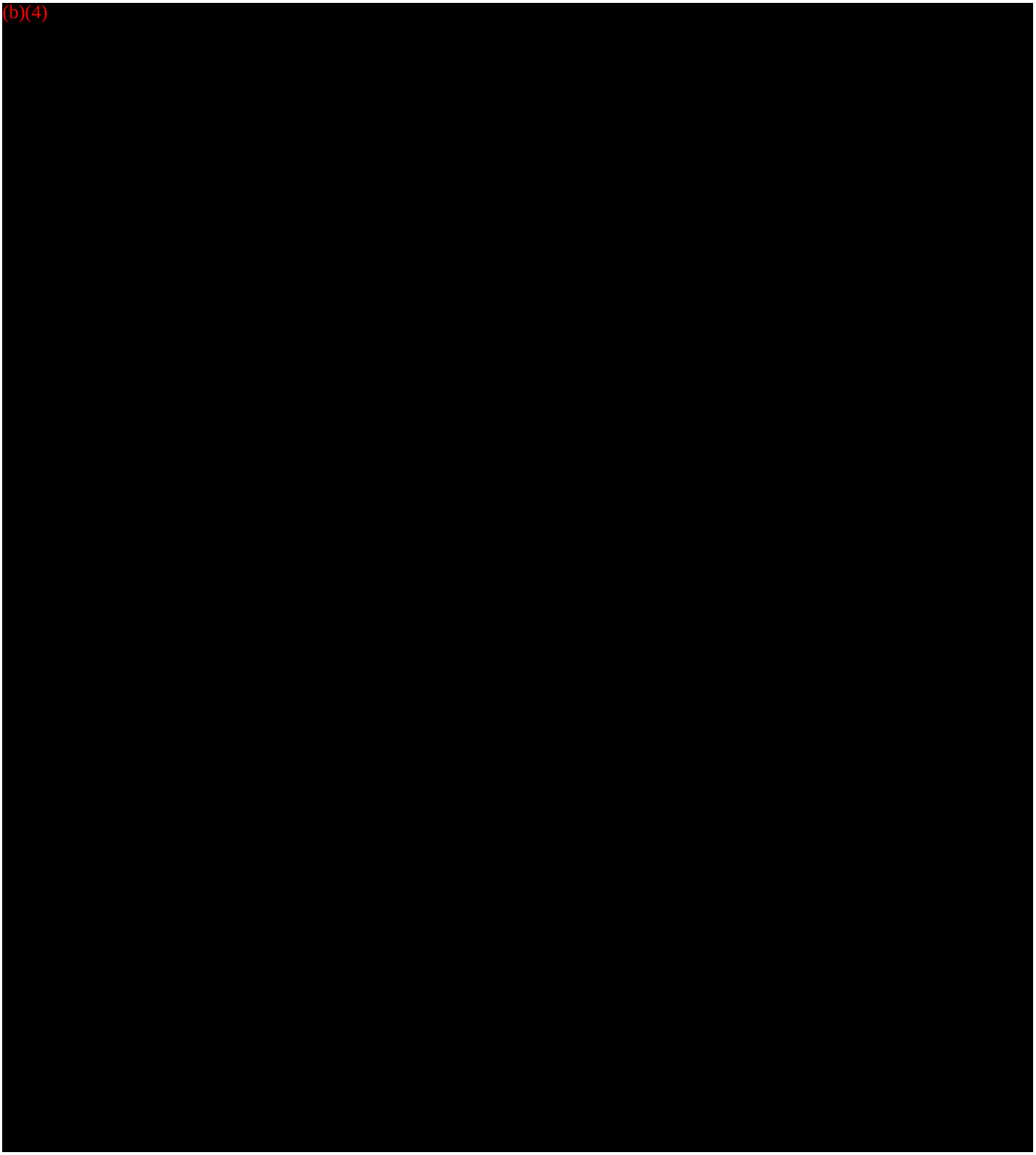
(b)(4)



2.2 Precision – Body Fluid

2.2.1 Repeatability – Body Fluid

(b)(4)



2.2.2 (b)(4) – Body Fluid

(b)(4)

Procedure:

(b)(4)

Expected Results:

(b)(4)

Results:

(b)(4)

Table 22a: Body Fluid (b)(4)

(b)(4)

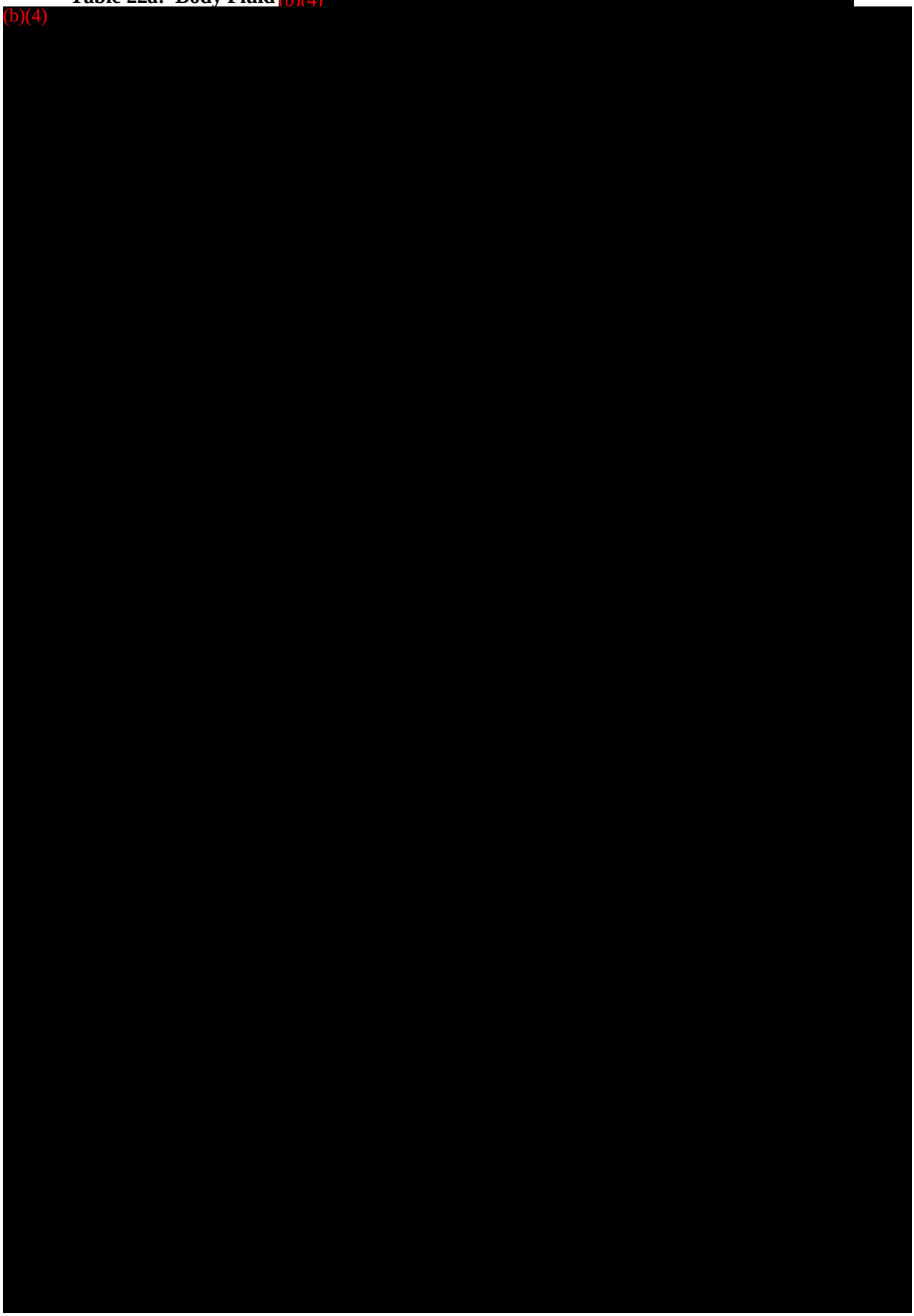


Table 22c: Body Fluid (b)(4)

(b)(4)

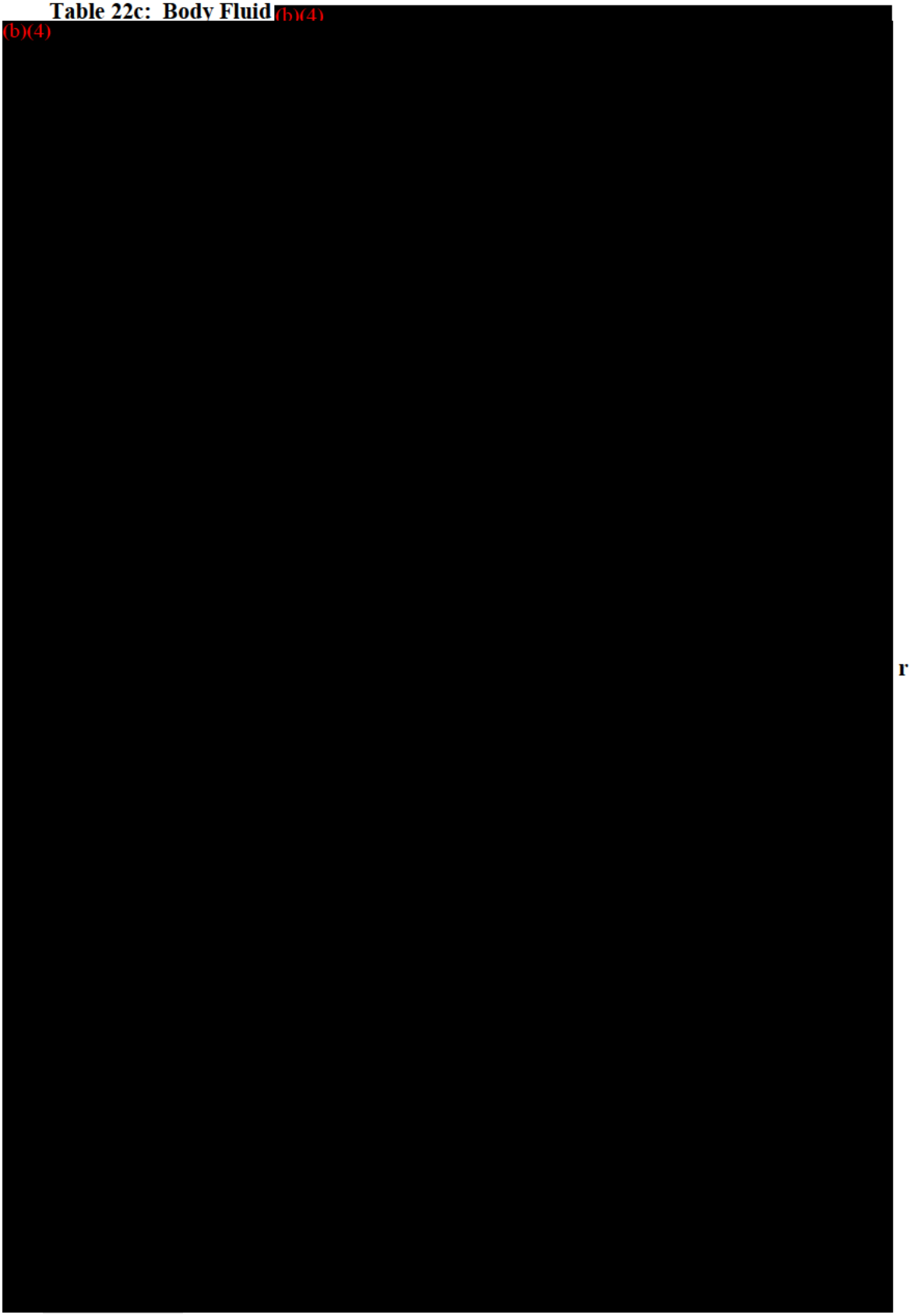


Table 22e: Body Fluid (b)(4)

(b)(4)

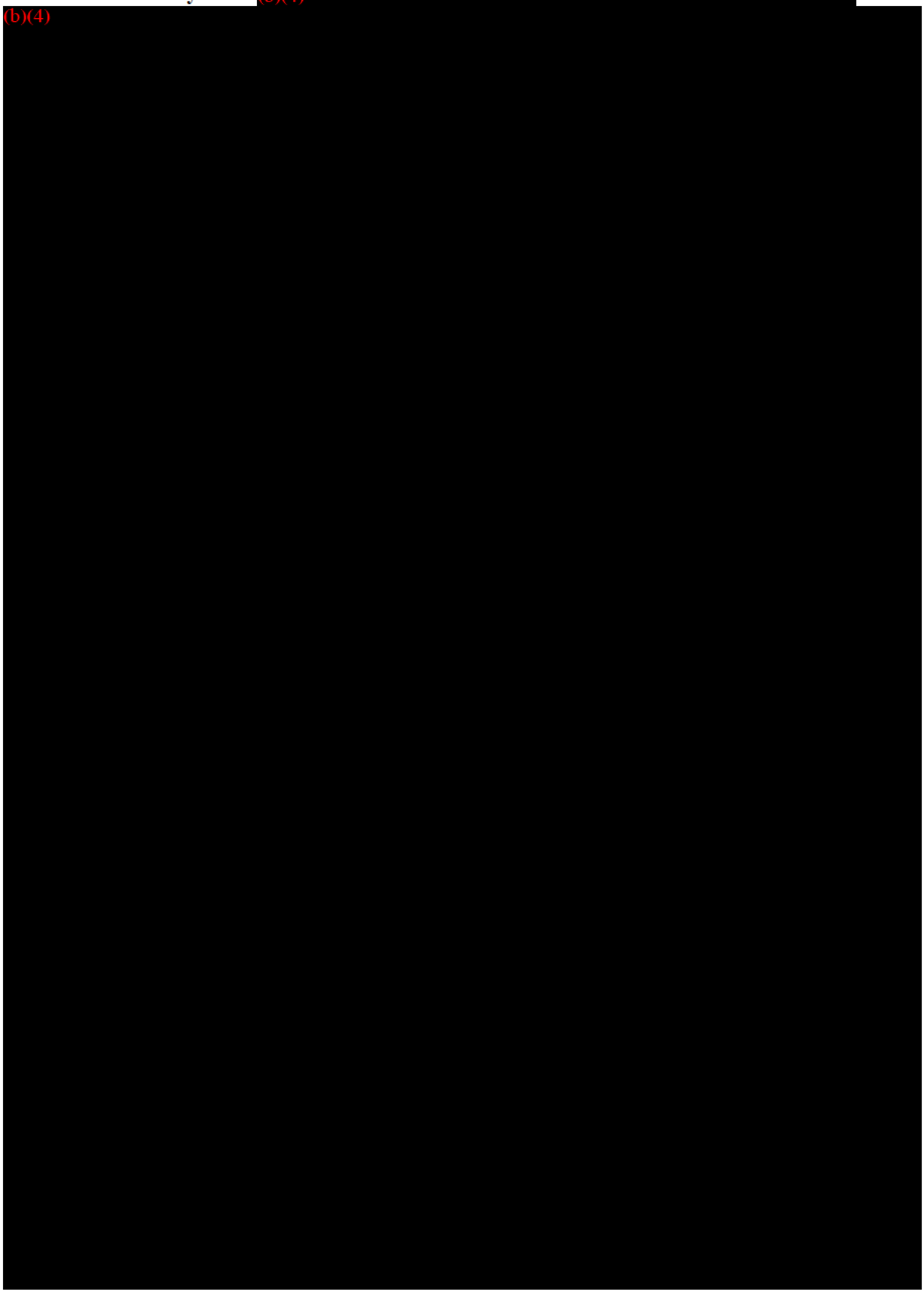
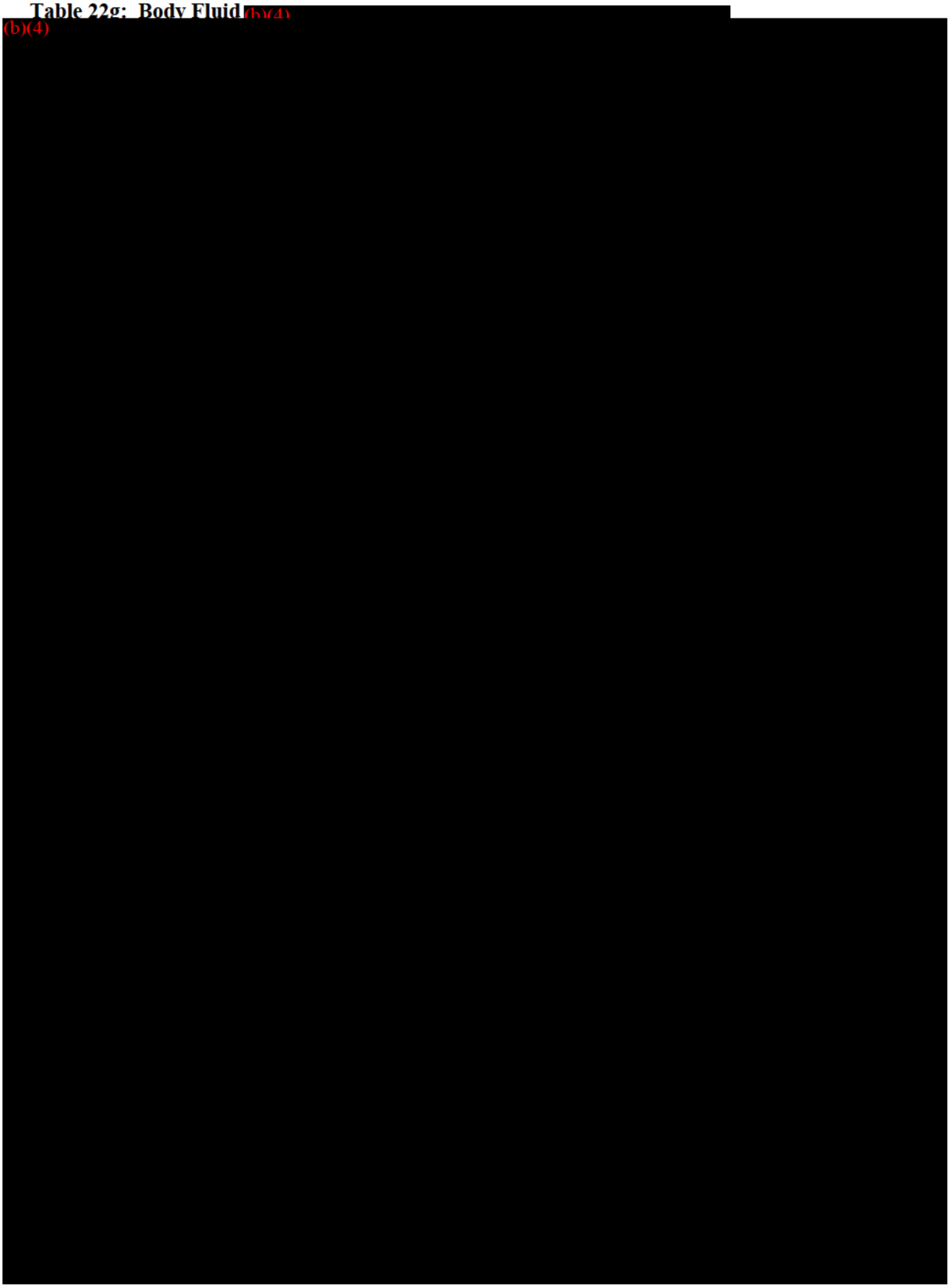


Table 22g: Body Fluid (b)(4)

(b)(4)

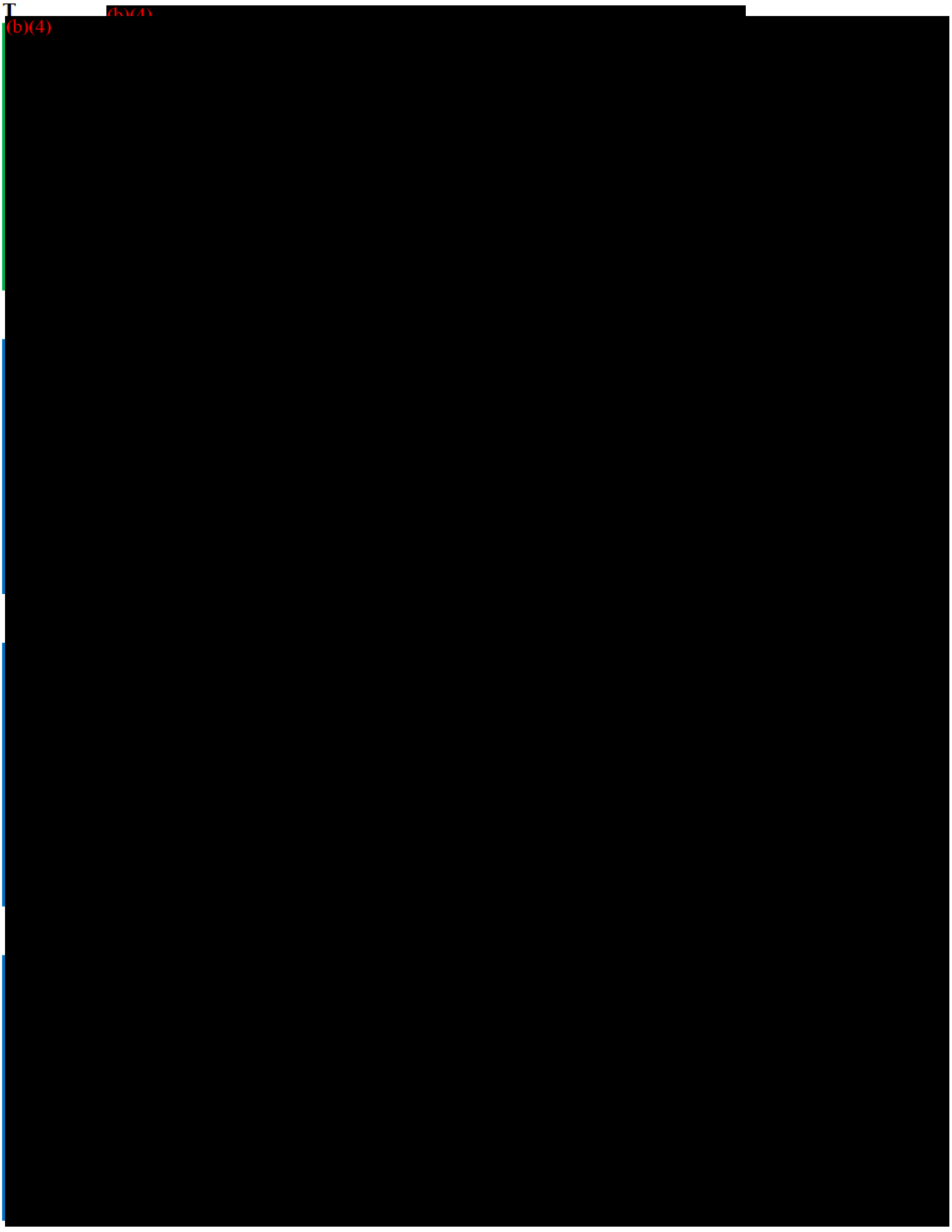


2.3 (b)(4) – Body Fluid

(b)(4)

T (b)(4)

(b)(4)



Conclusion: (b)(4)

2.4 (b)(4) – Body Fluid

(b)(4)

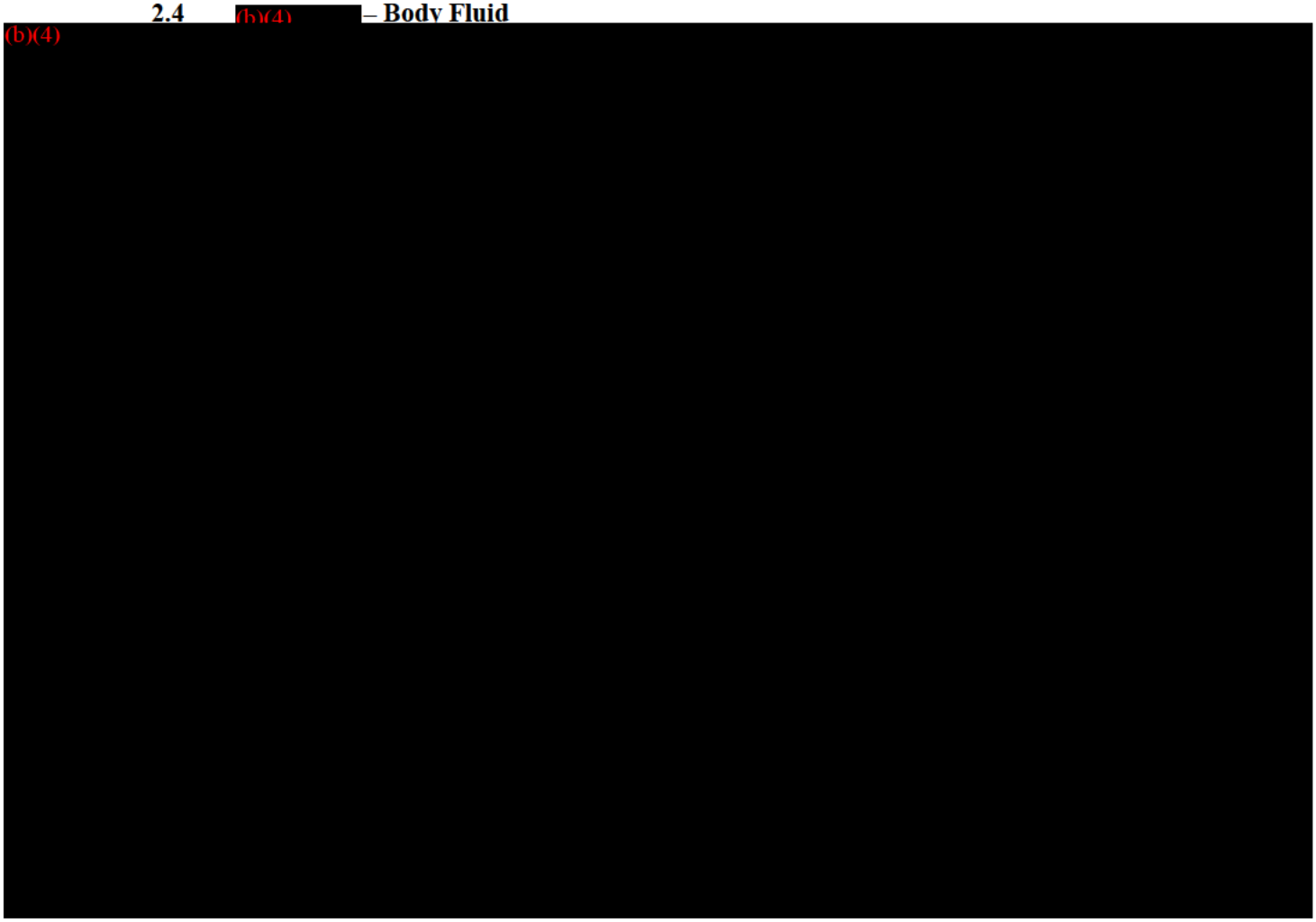


Table 24a: XN-11 Body Fluid (b)(4)

(b)(4)

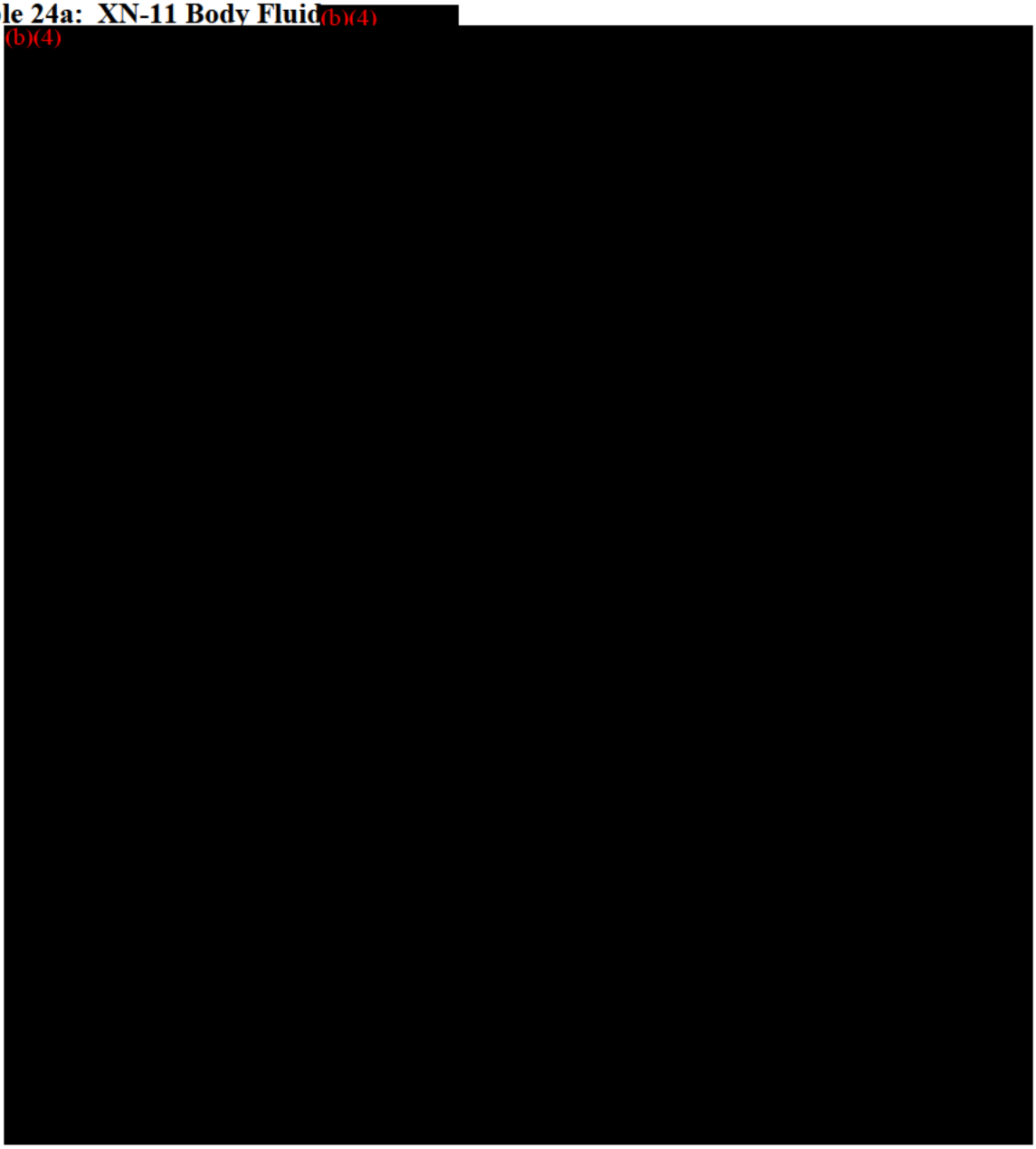
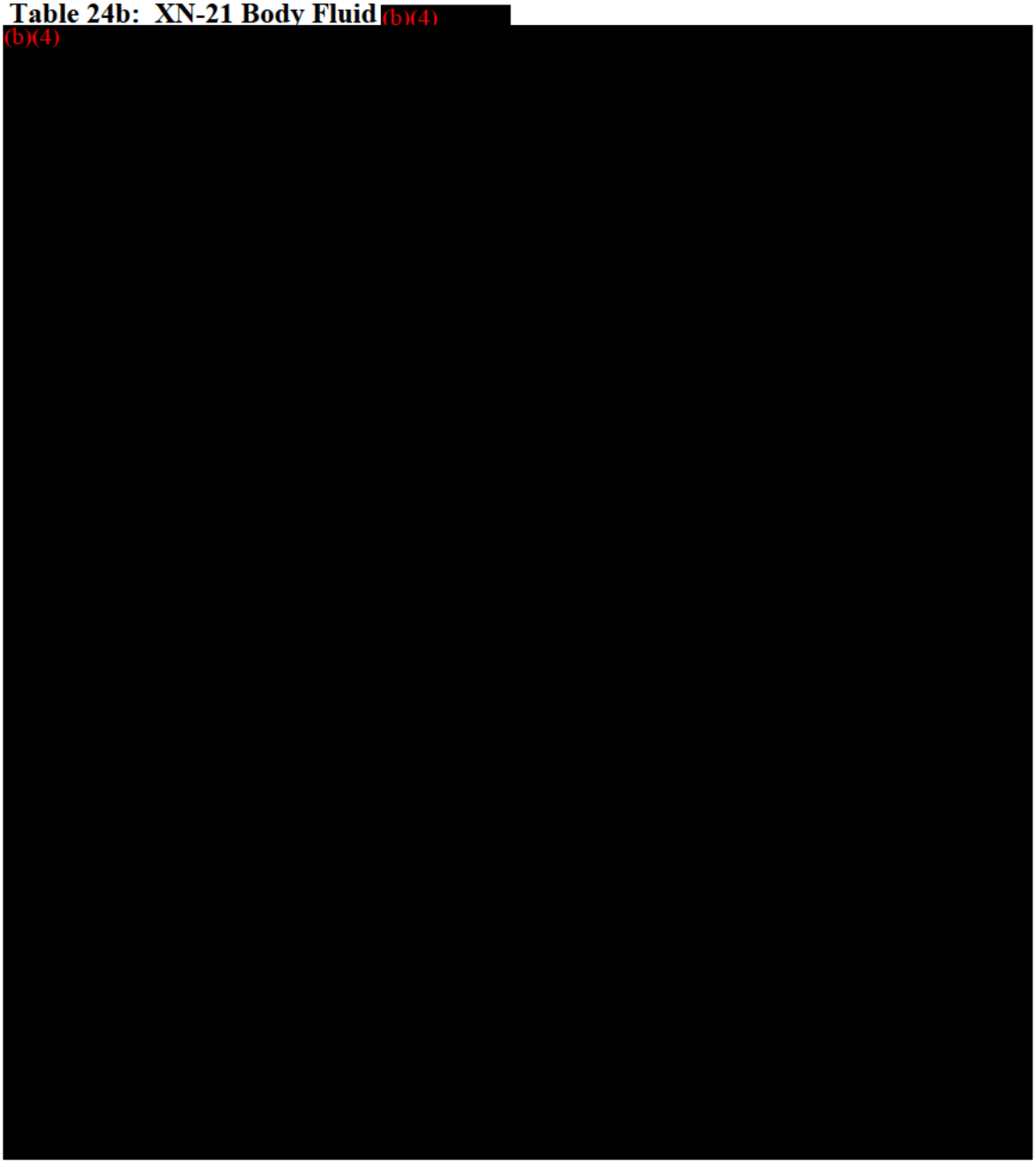


Table 24b: XN-21 Body Fluid (b)(4)

(b)(4)



Conclusion:

Carryover of the RBC-BF parameter on the XN-11 and XN-21 analyzers for Peritoneal, Pleural and Synovial fluids met the manufacturer specifications as stated in the tables above.

2.5 (b)(4) – Body Fluid

(b)(4)

2.6 (b)(4) – Body Fluid

(b)(4)

3.0 Other Studies

(b)(4)

Target Concentrations

(b)(4)

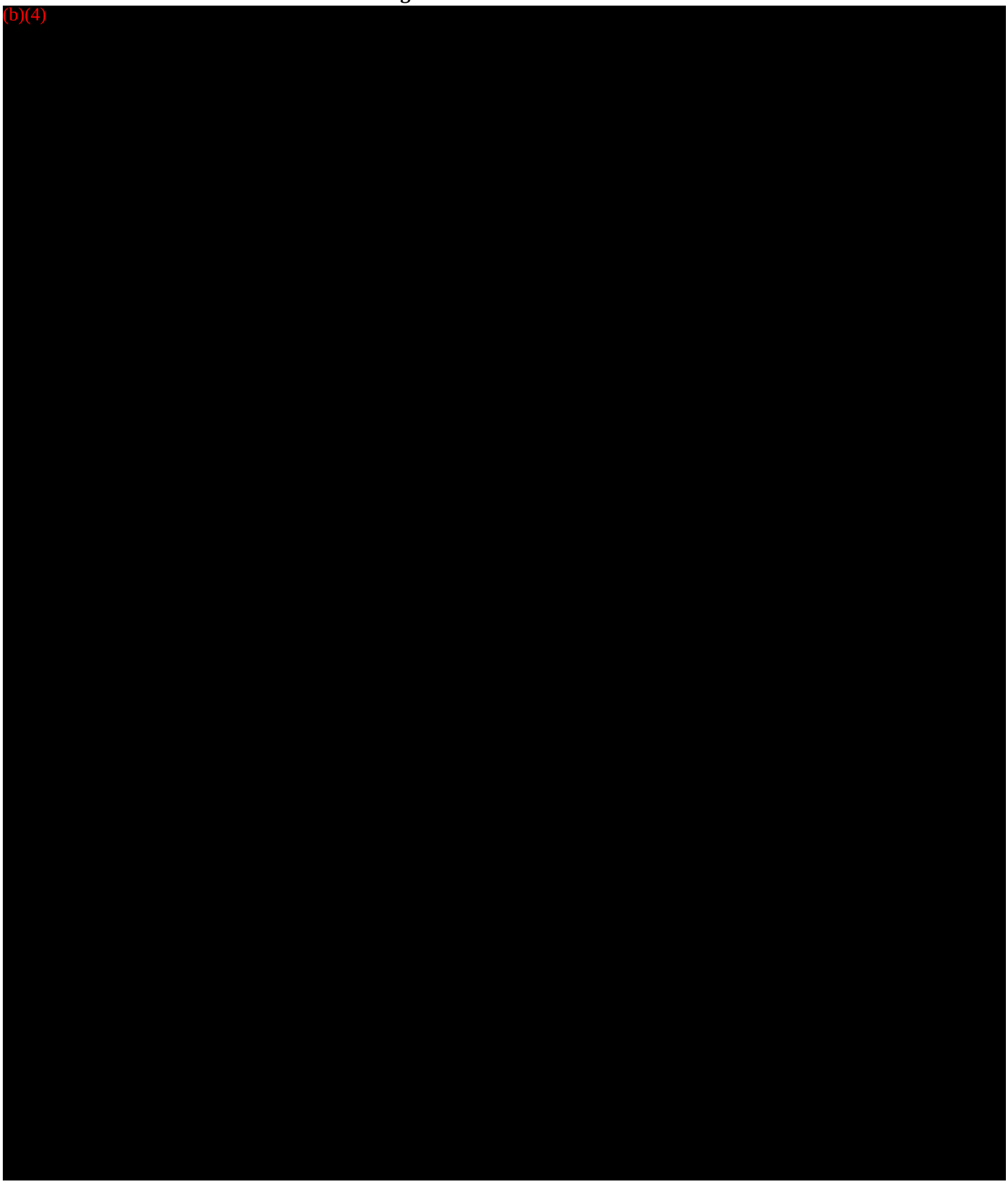


Table 31c: Whole Blood Mode (b)(4)

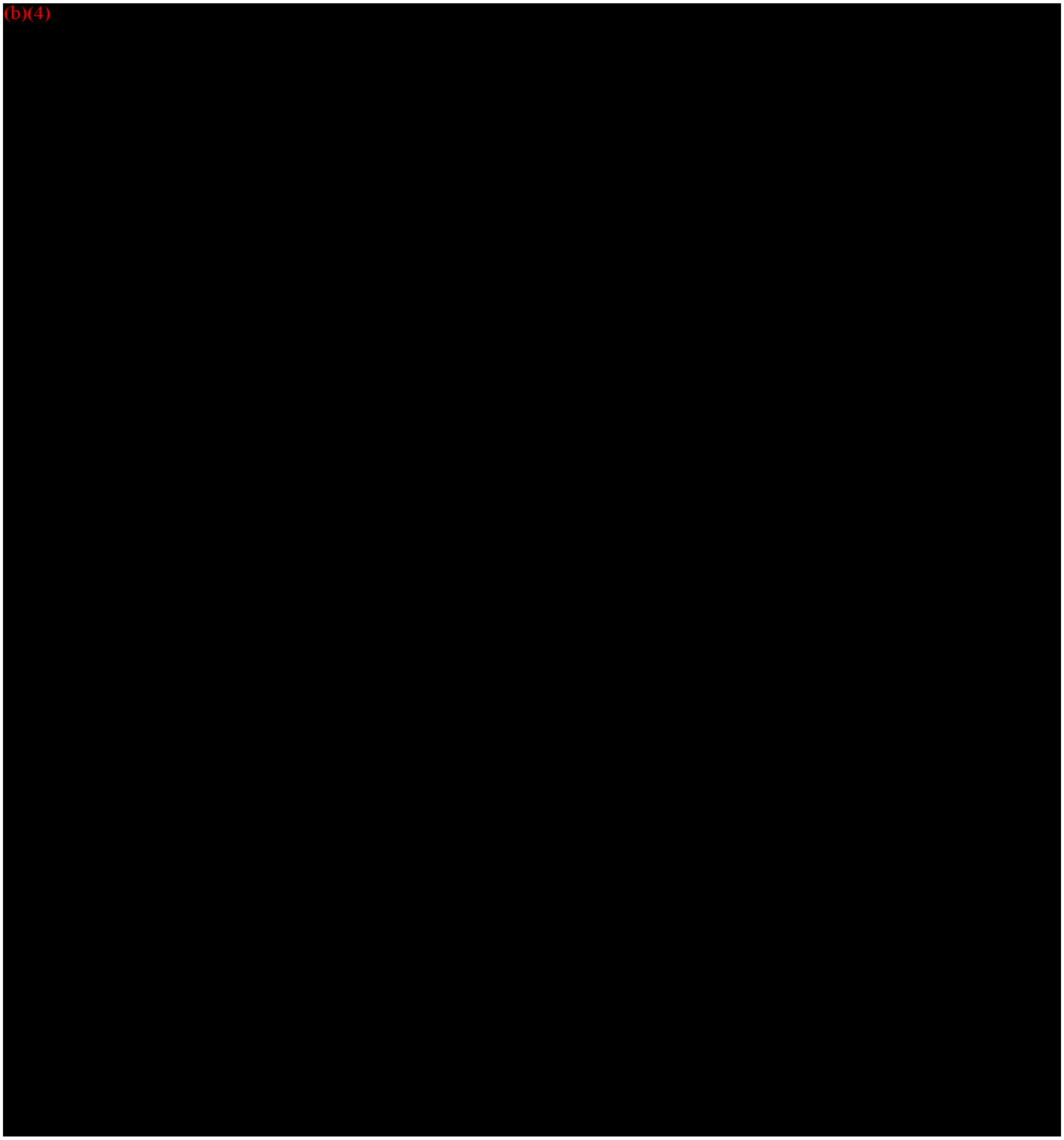
(b)(4)

3.3 Verification of Interfering substances

(b)(4)

Hemolysis

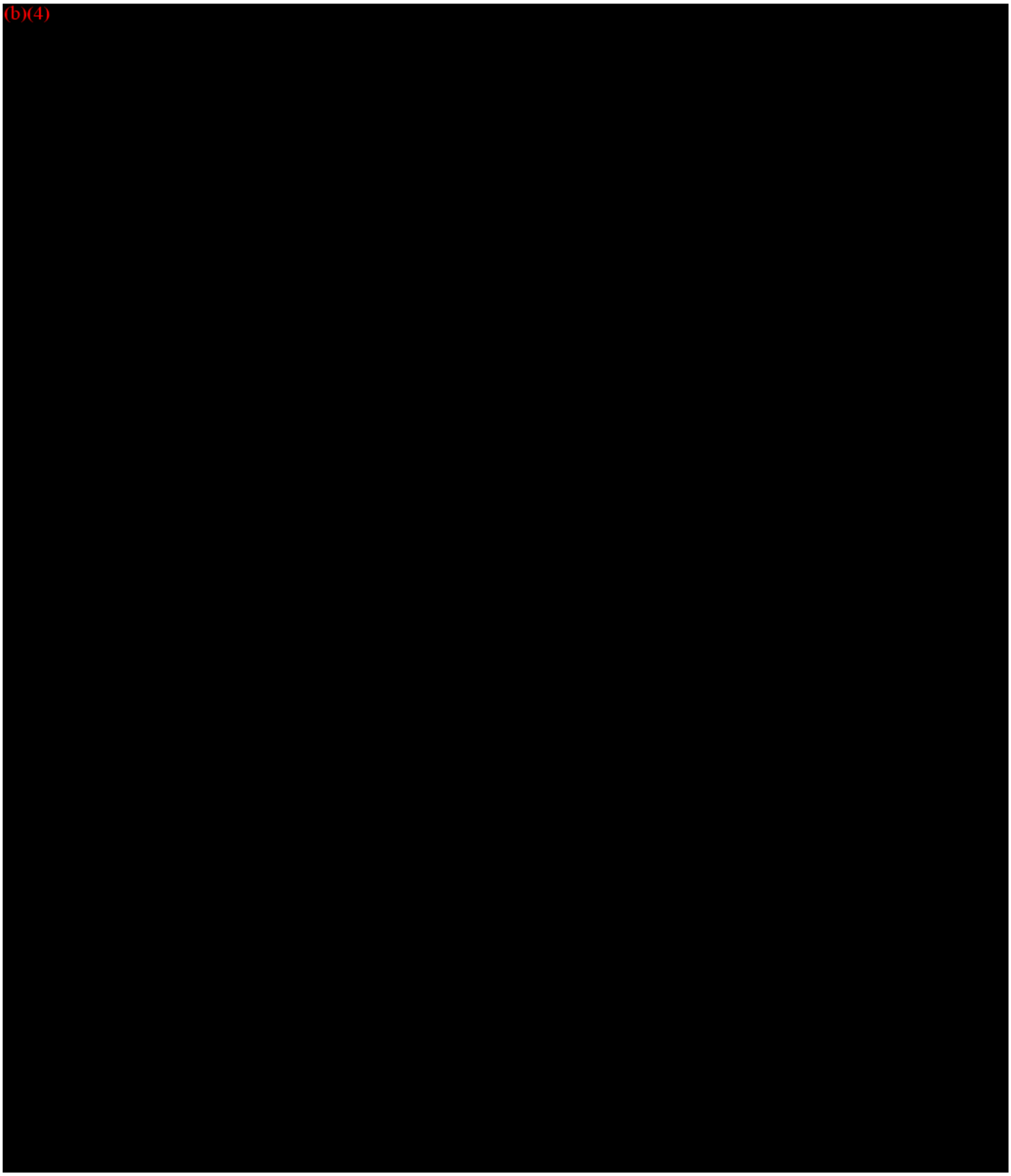
(b)(4)



(b)(4)

(b)(4)

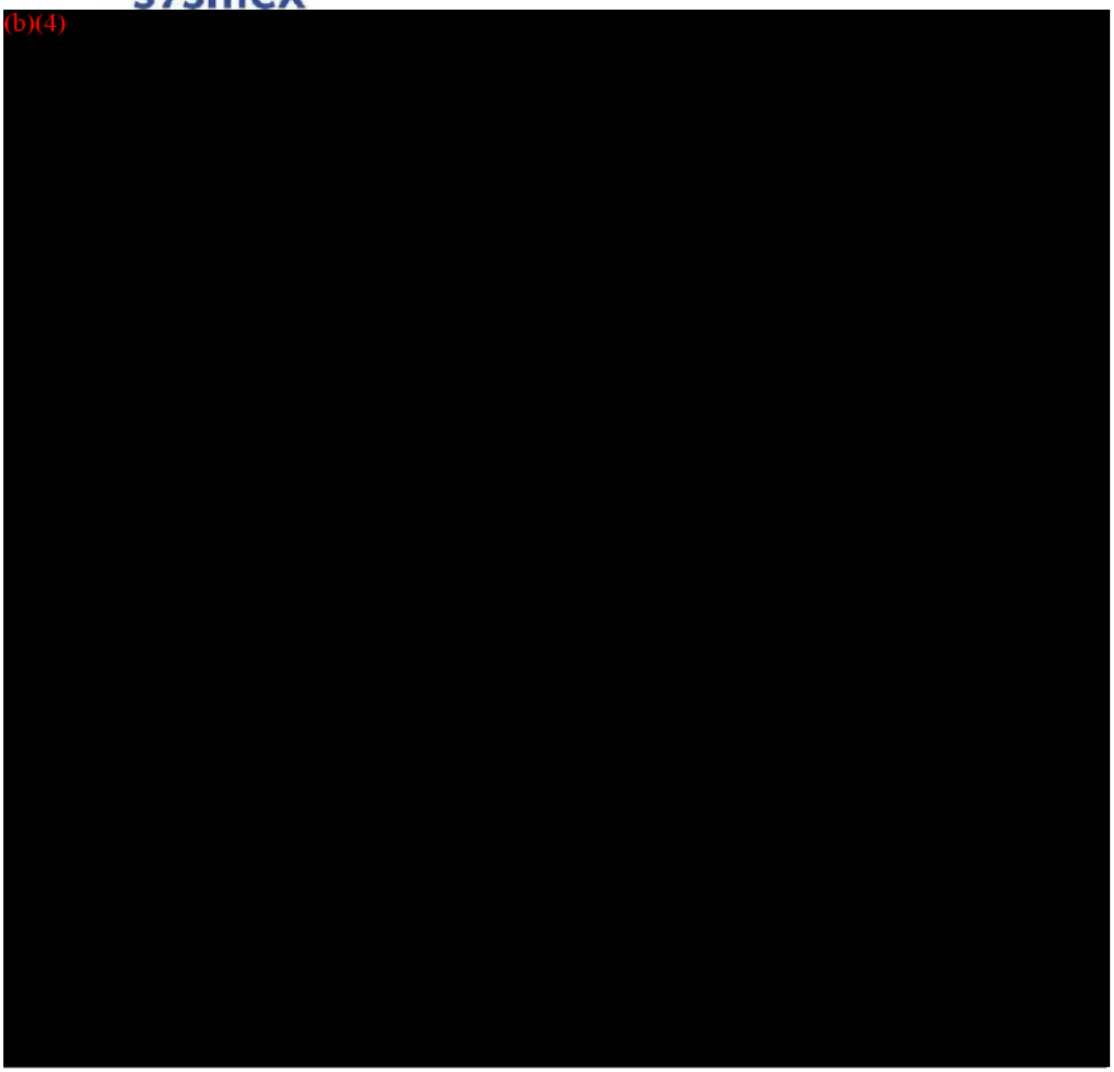
(b)(4)



(b)(4)

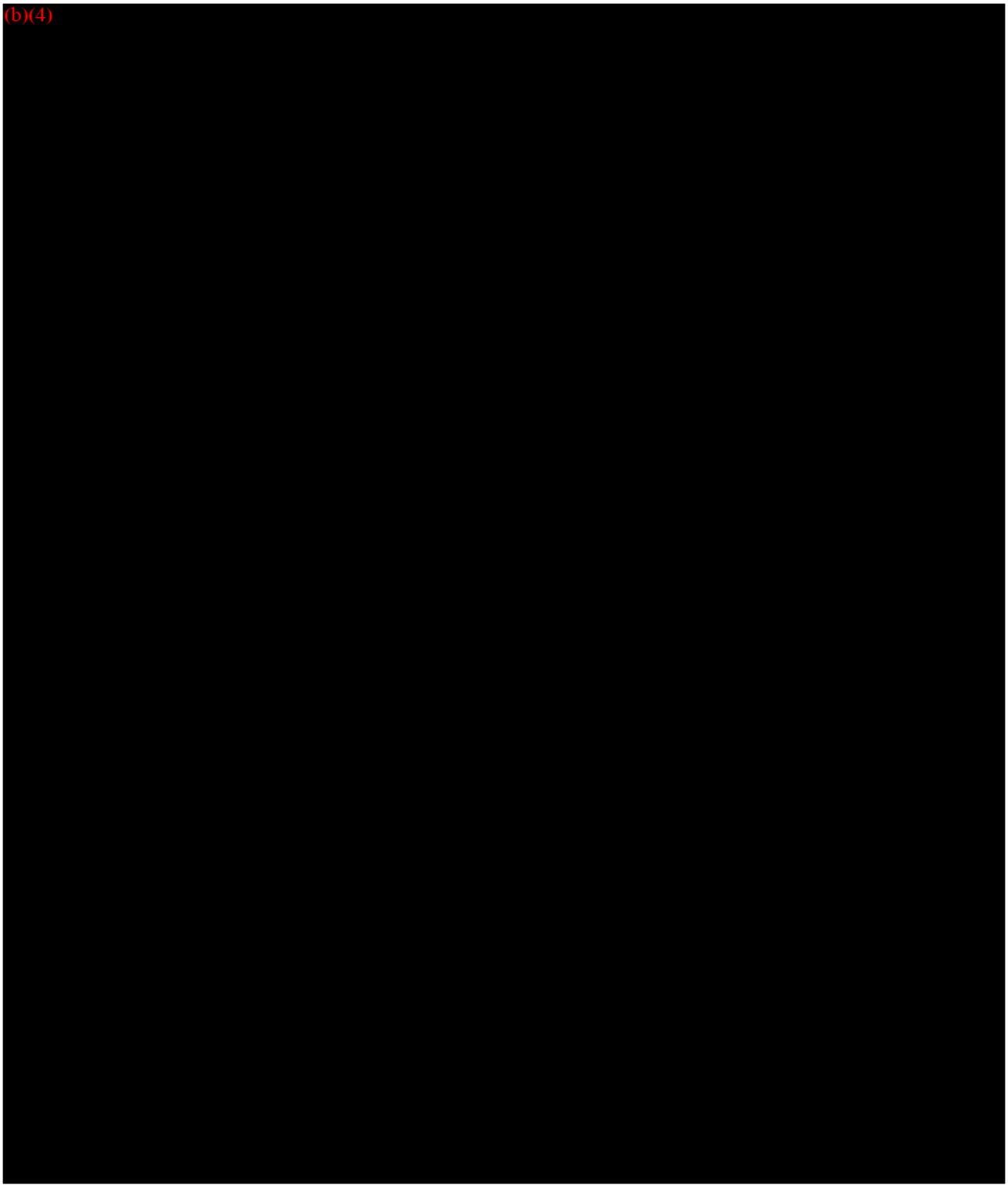
Bilirubin F

(b)(4)

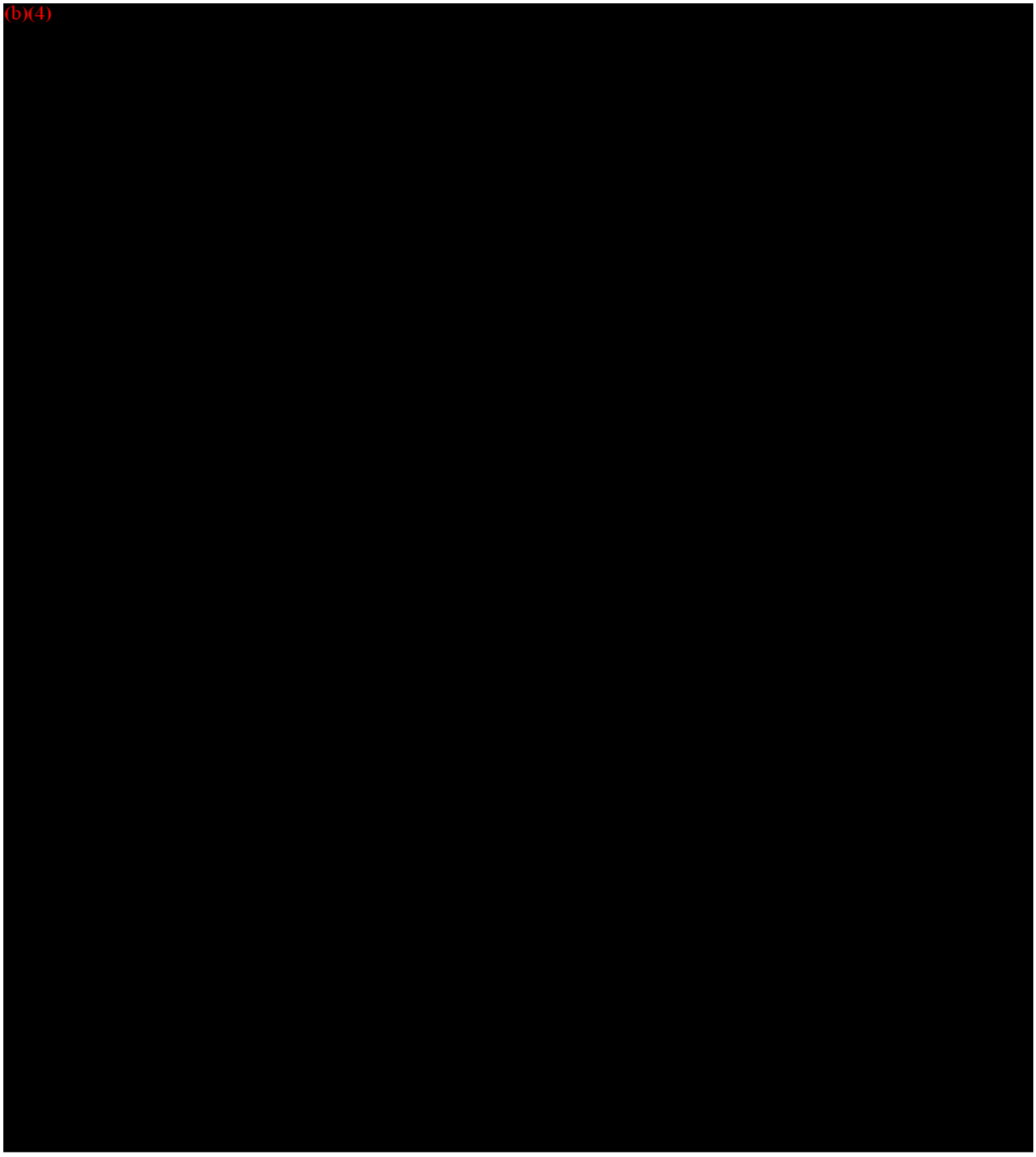


[1/4]

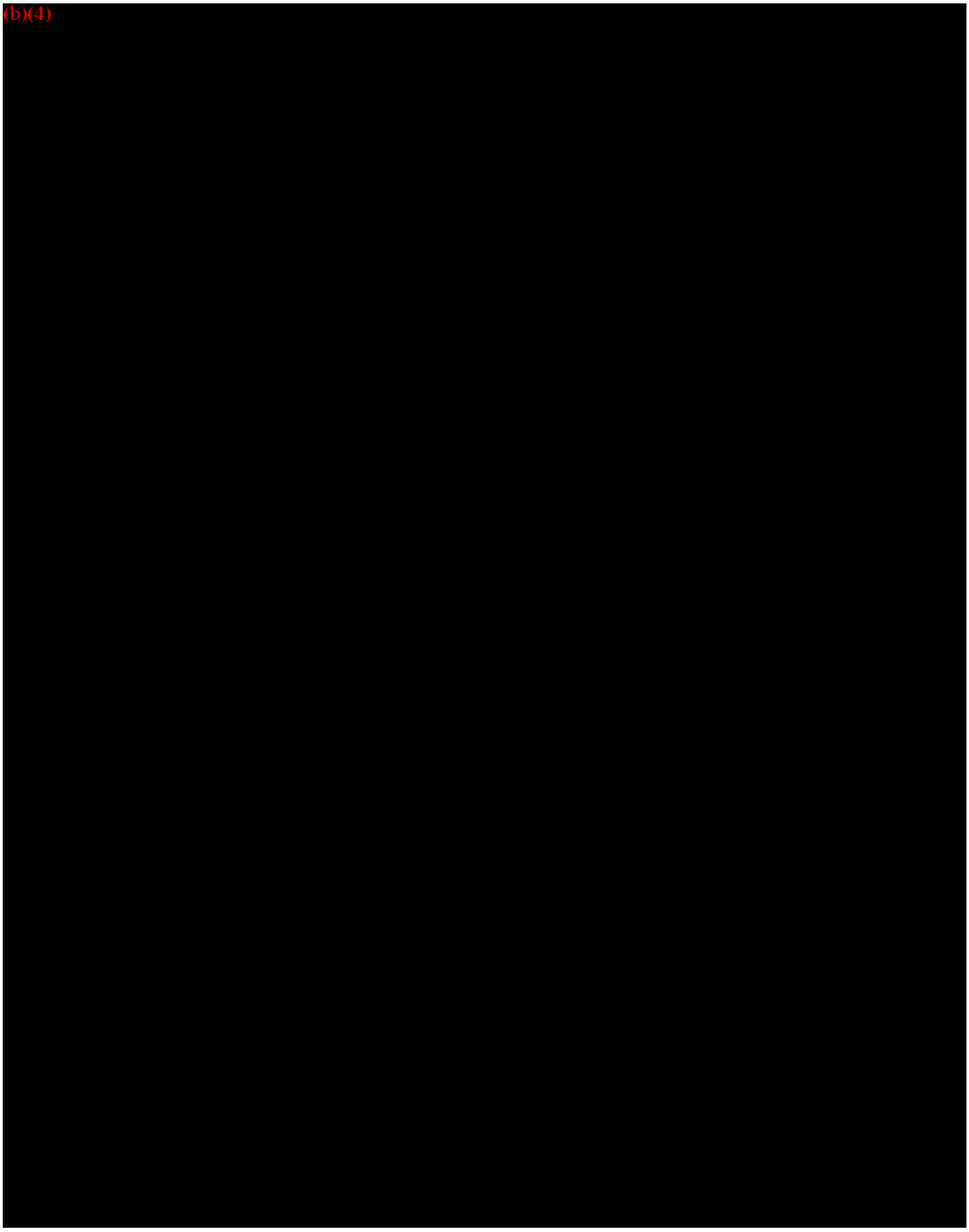
(b)(4)



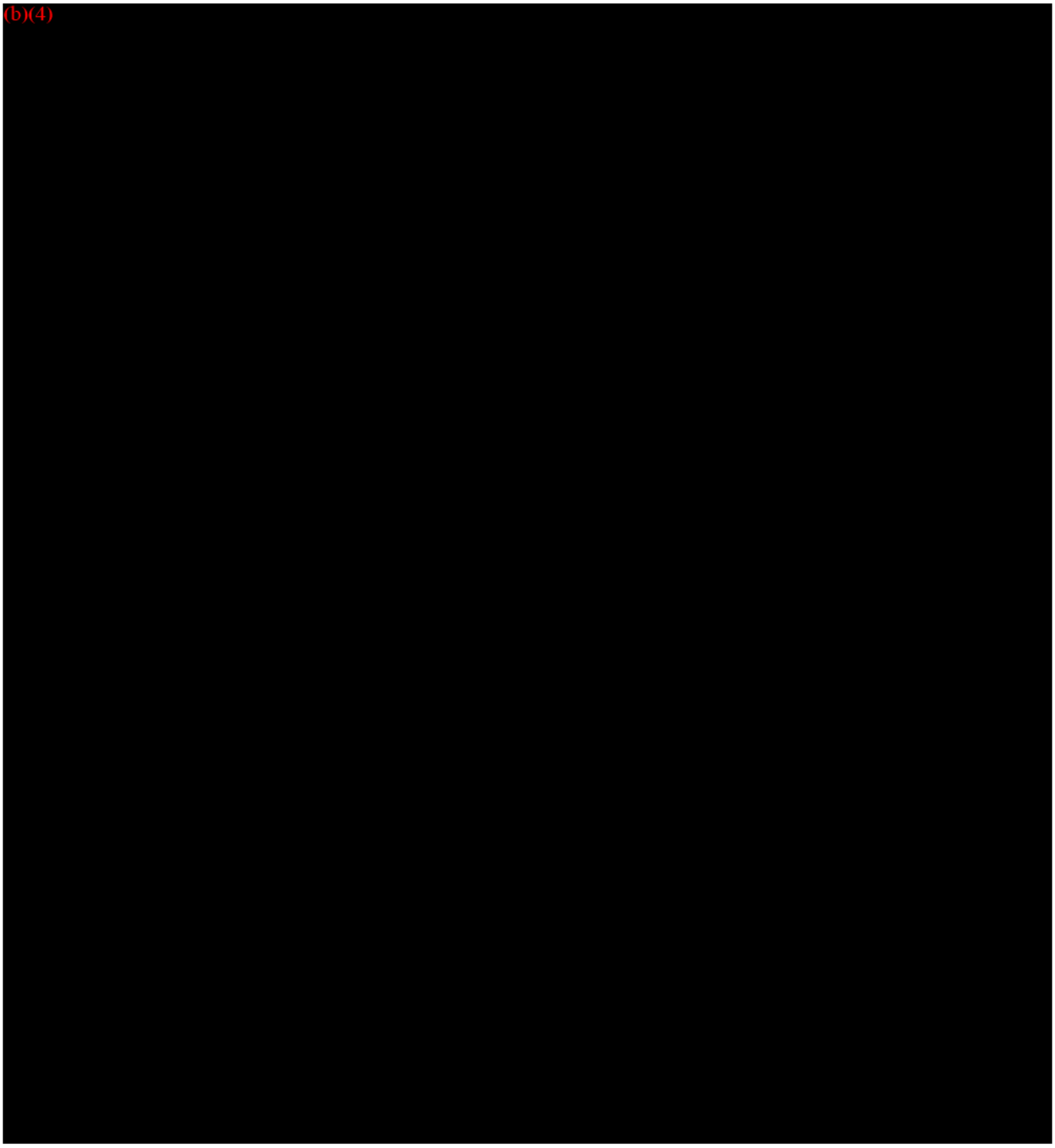
(b)(4)



(b)(4)

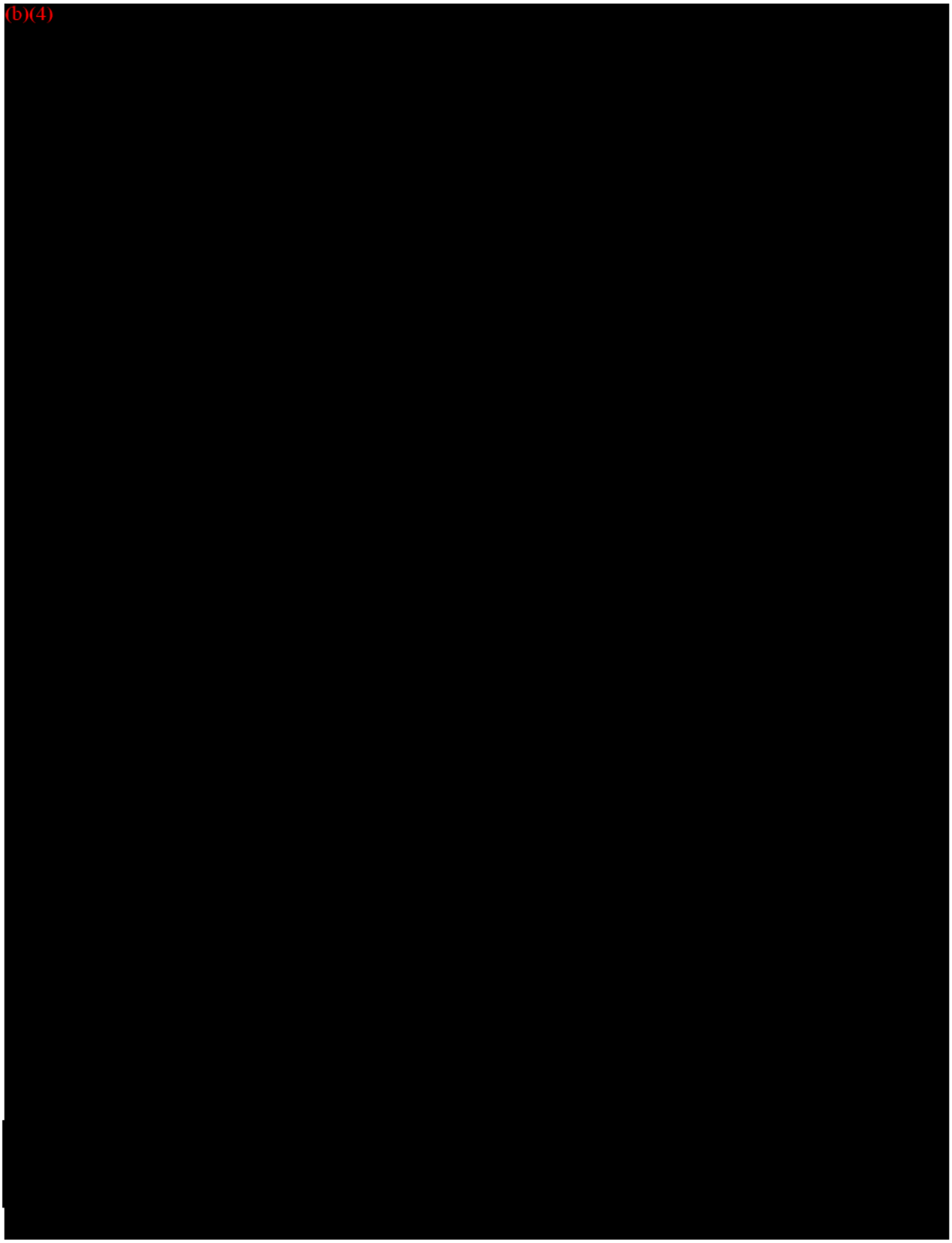


(b)(4)

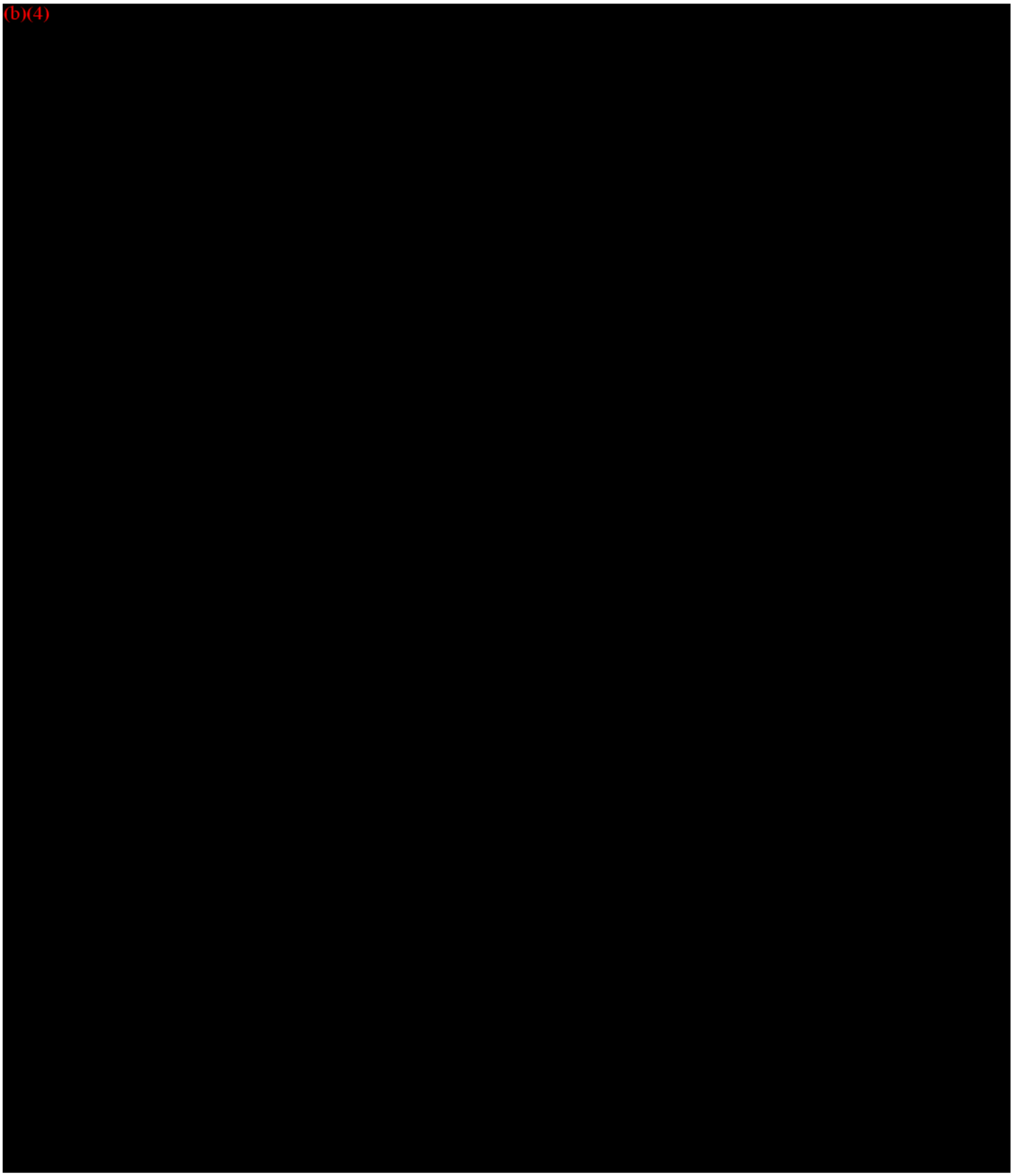


(b)(4)

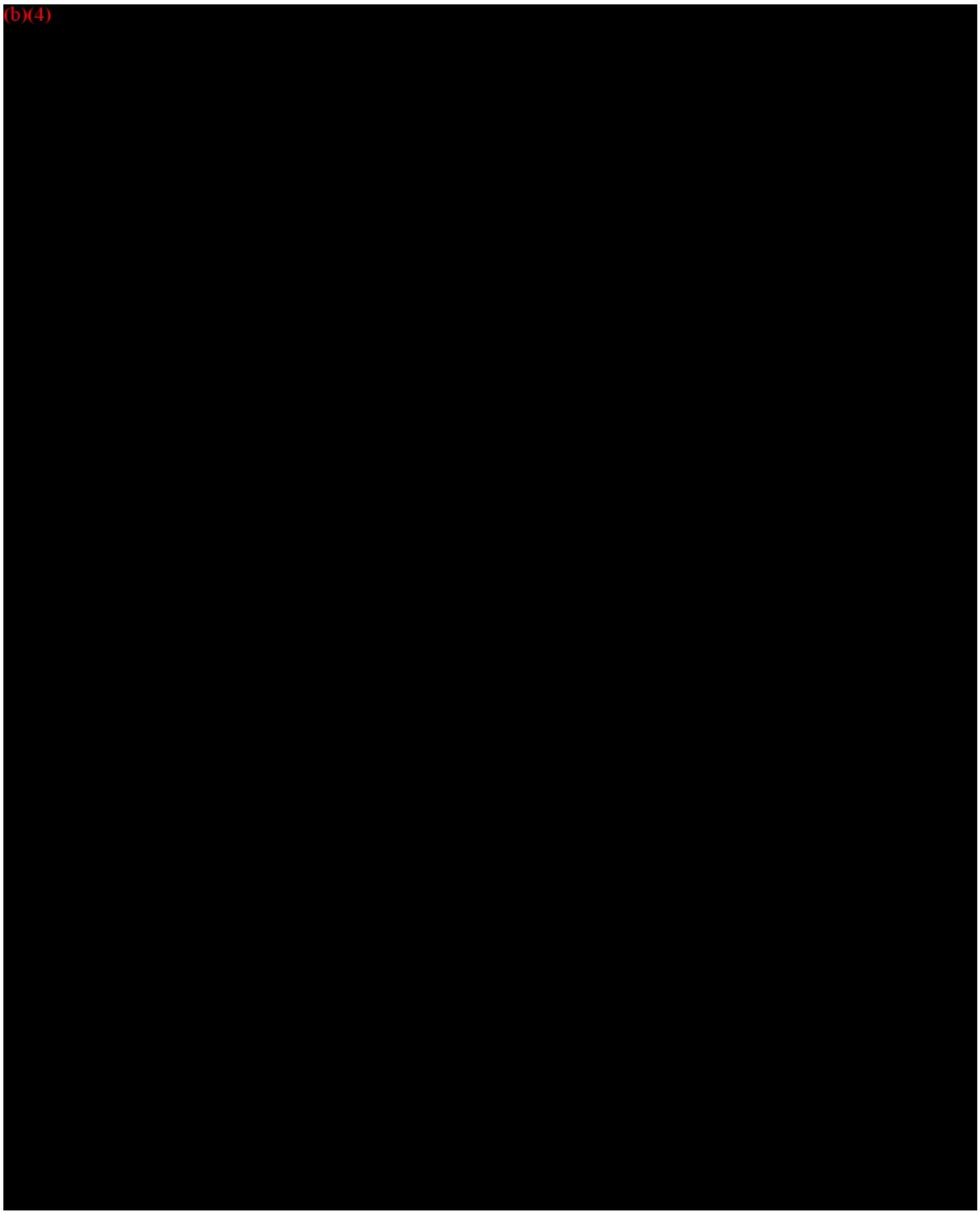
(b)(4)



(b)(4)

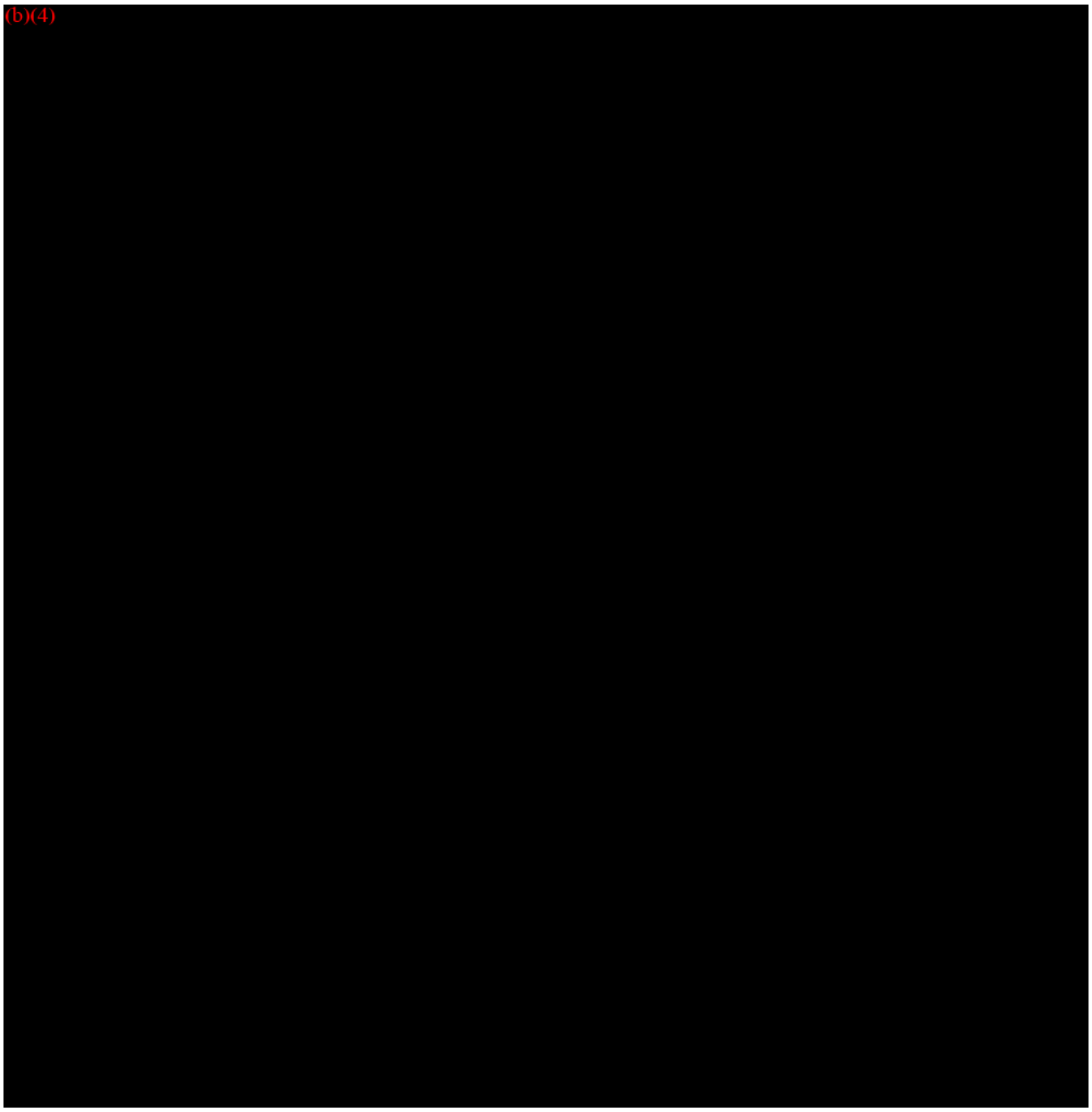


(b)(4)



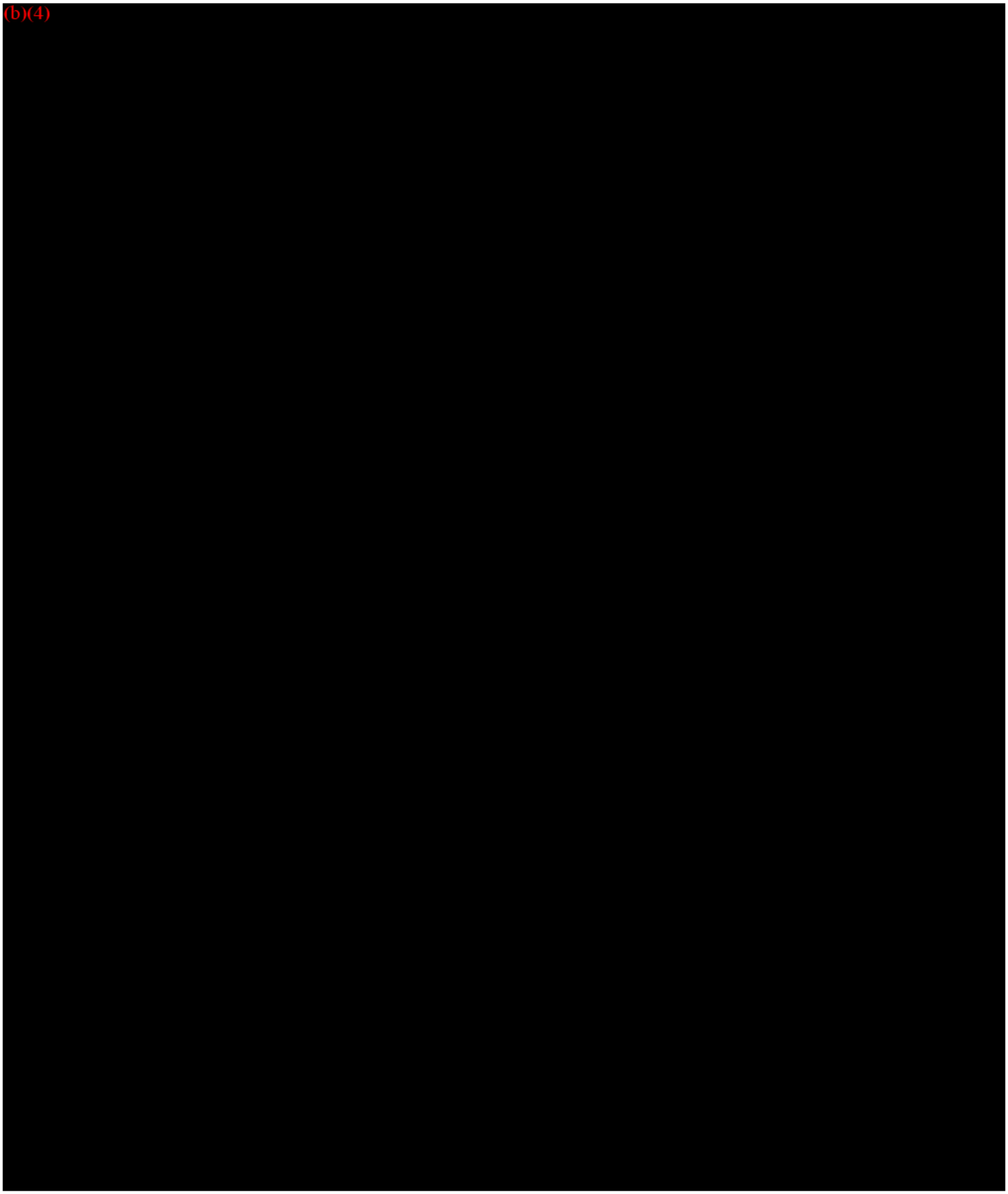
Lipemia

(b)(4)

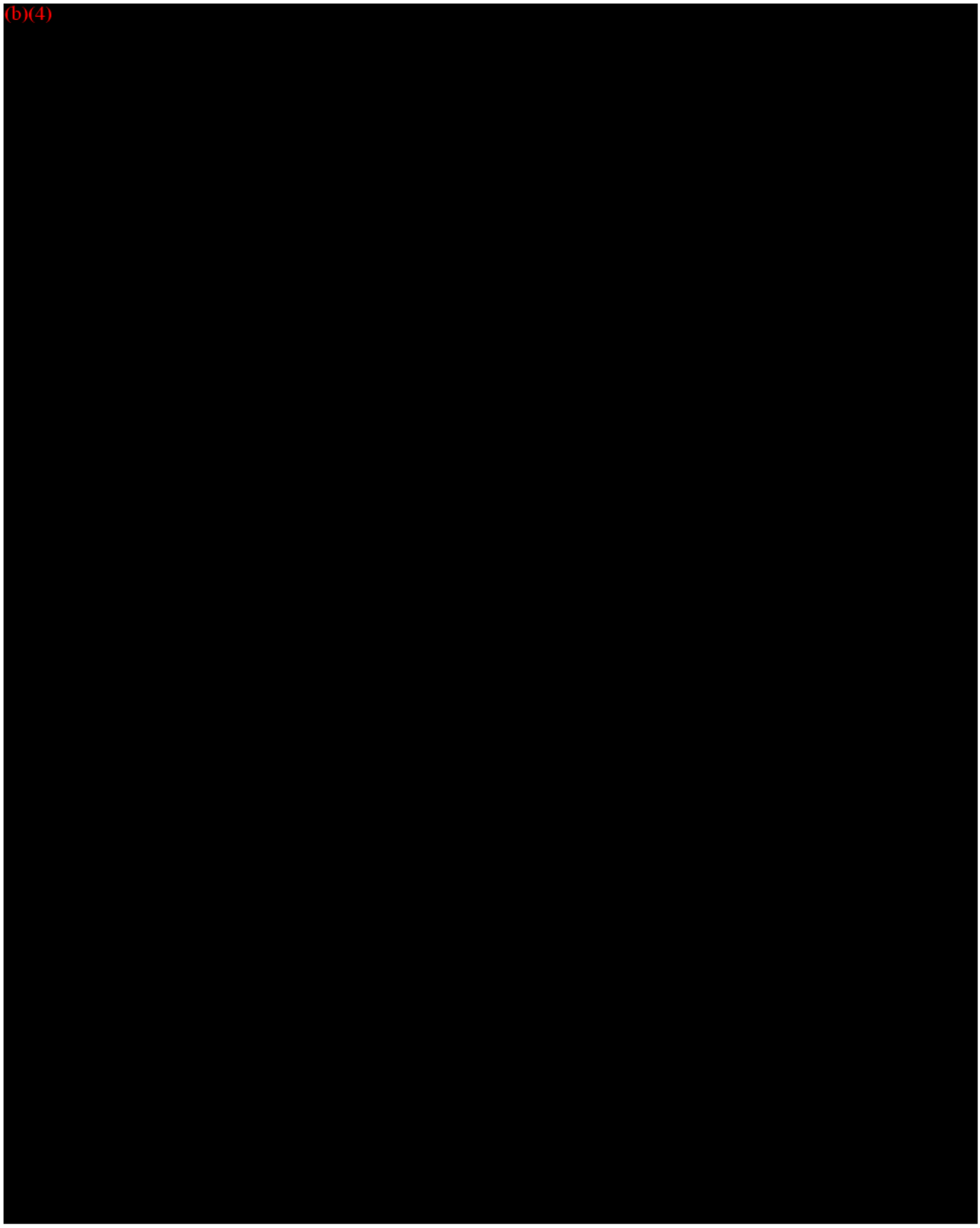


(b)(4)

(b)(4)



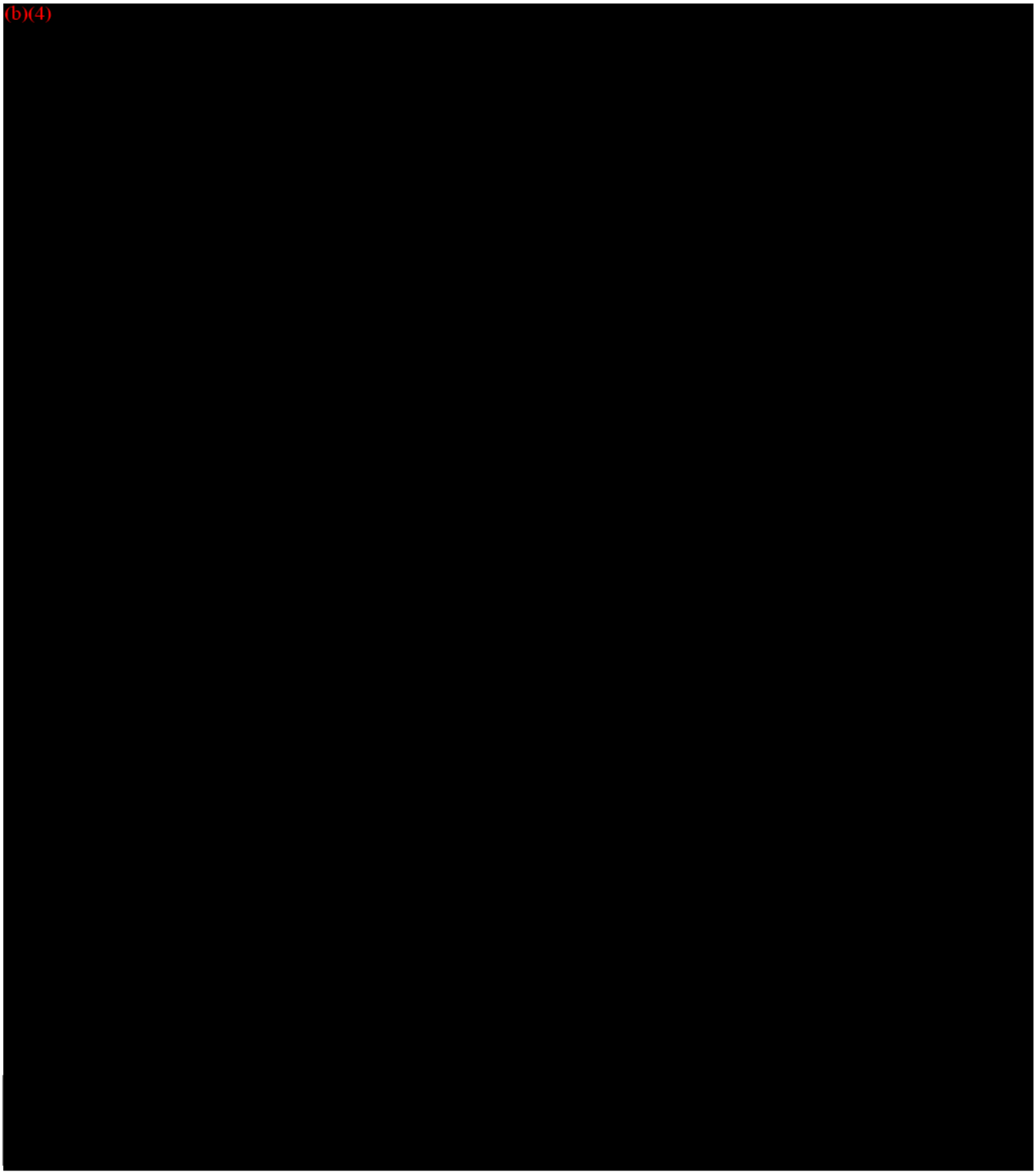
(b)(4)

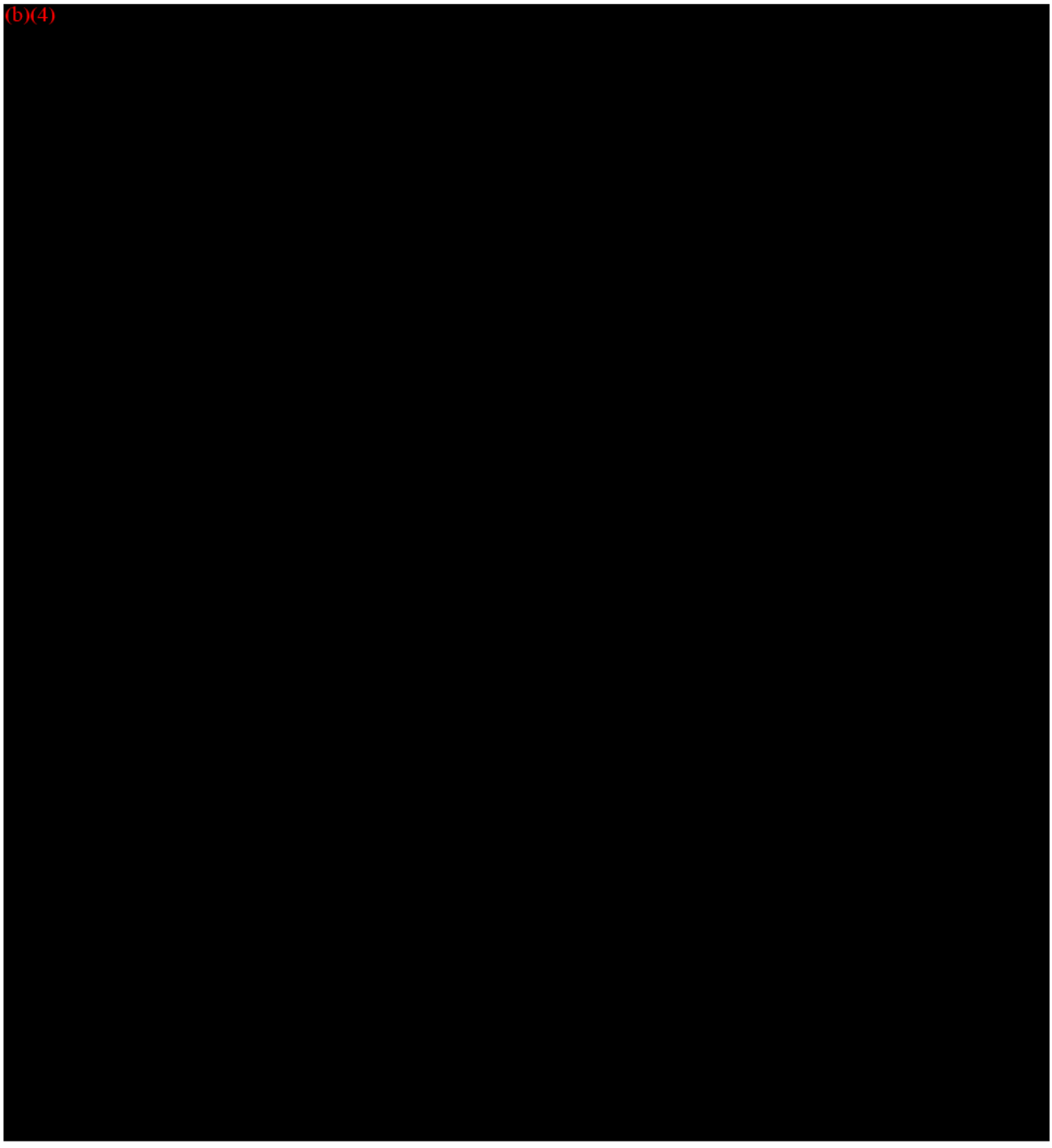


(b)(4)

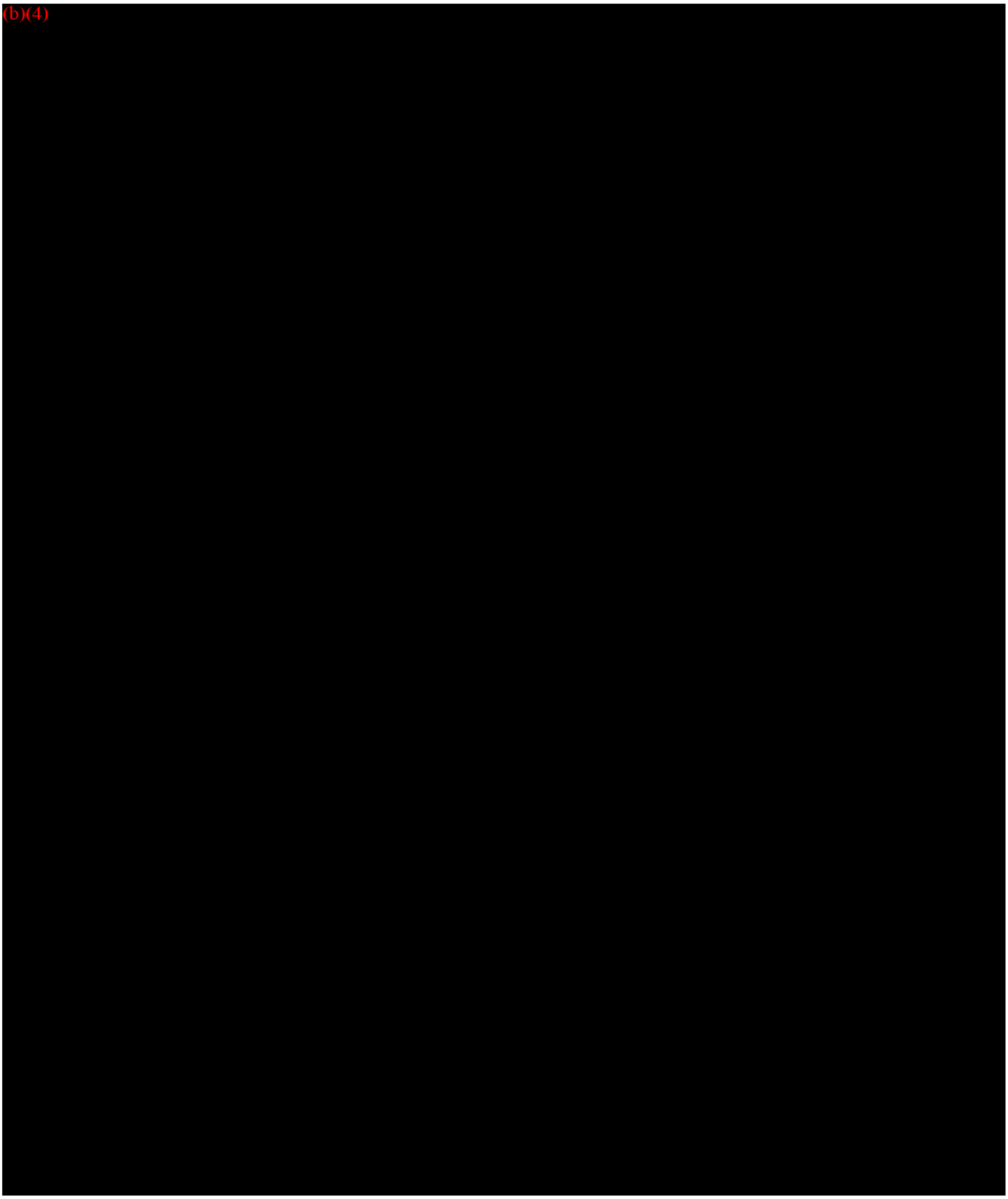
Turbidity

(b)(4)

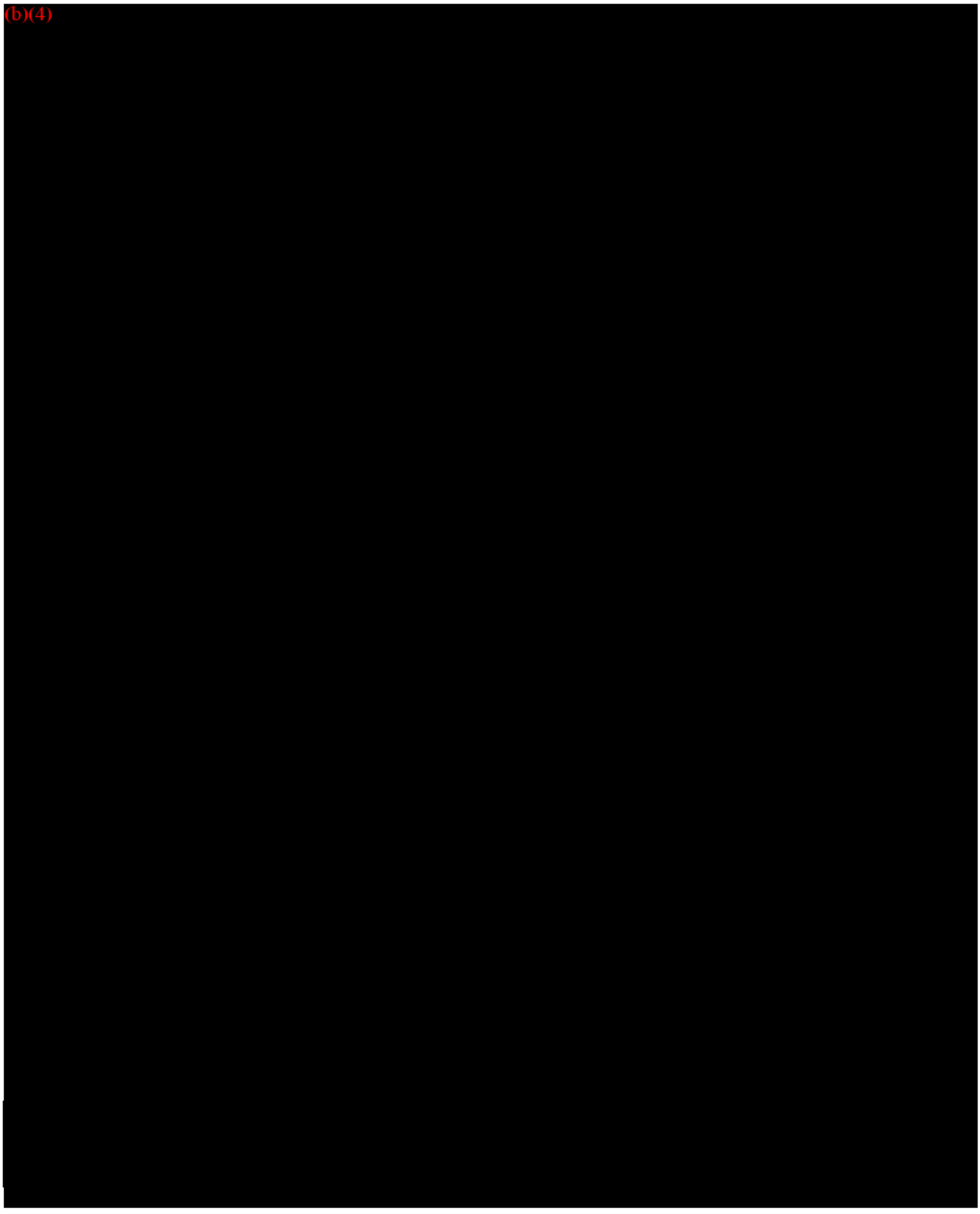




(b)(4)



(b)(4)



(b)(4)

3.4 Anticoagulant Comparison Study - (b)(4)

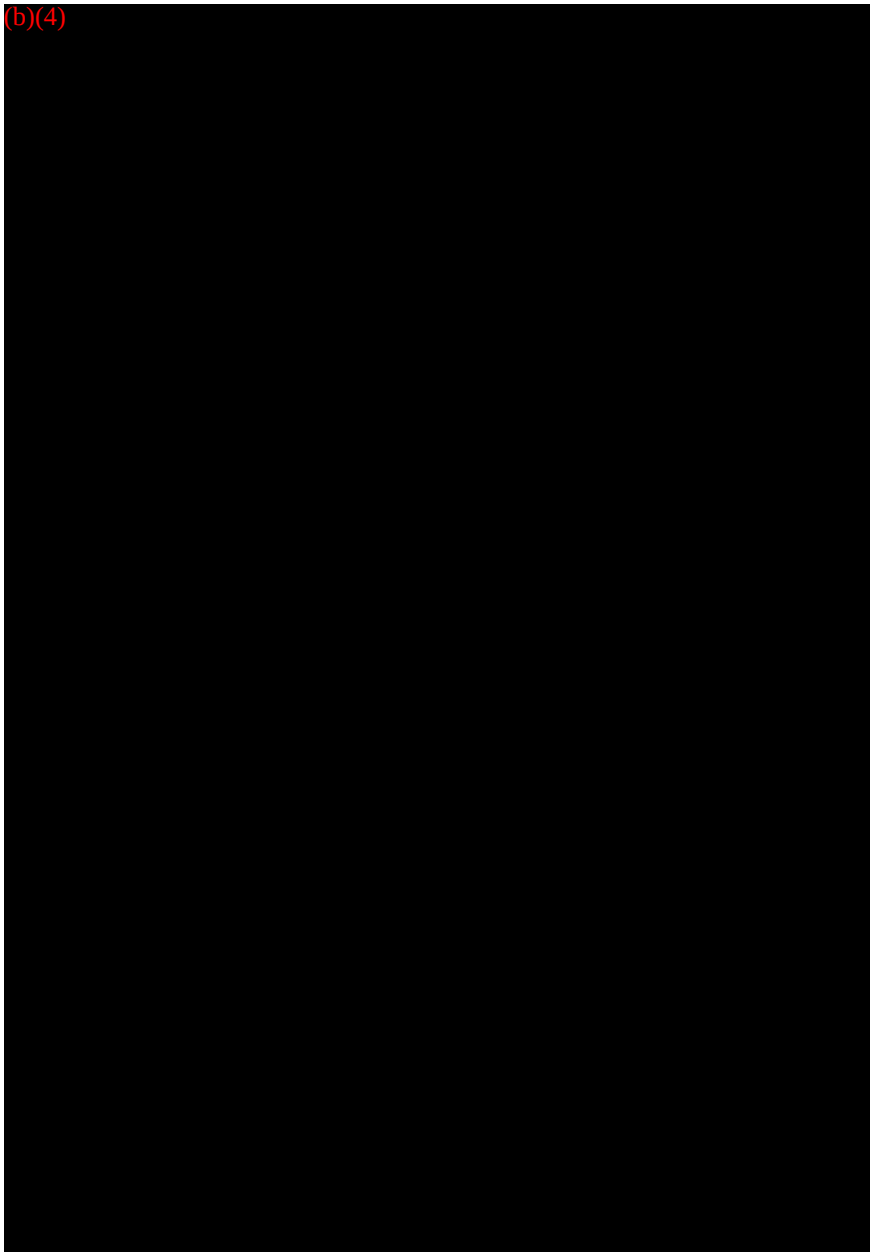
(b)(4)

Table 33: Estimation of Bias and Correlation Coefficient Limits – Whole Blood

(b)(4)

Table 4.1.1a: Statistical Summary – (b)(4)

(b)(4)



(b)(4)

[redacted]

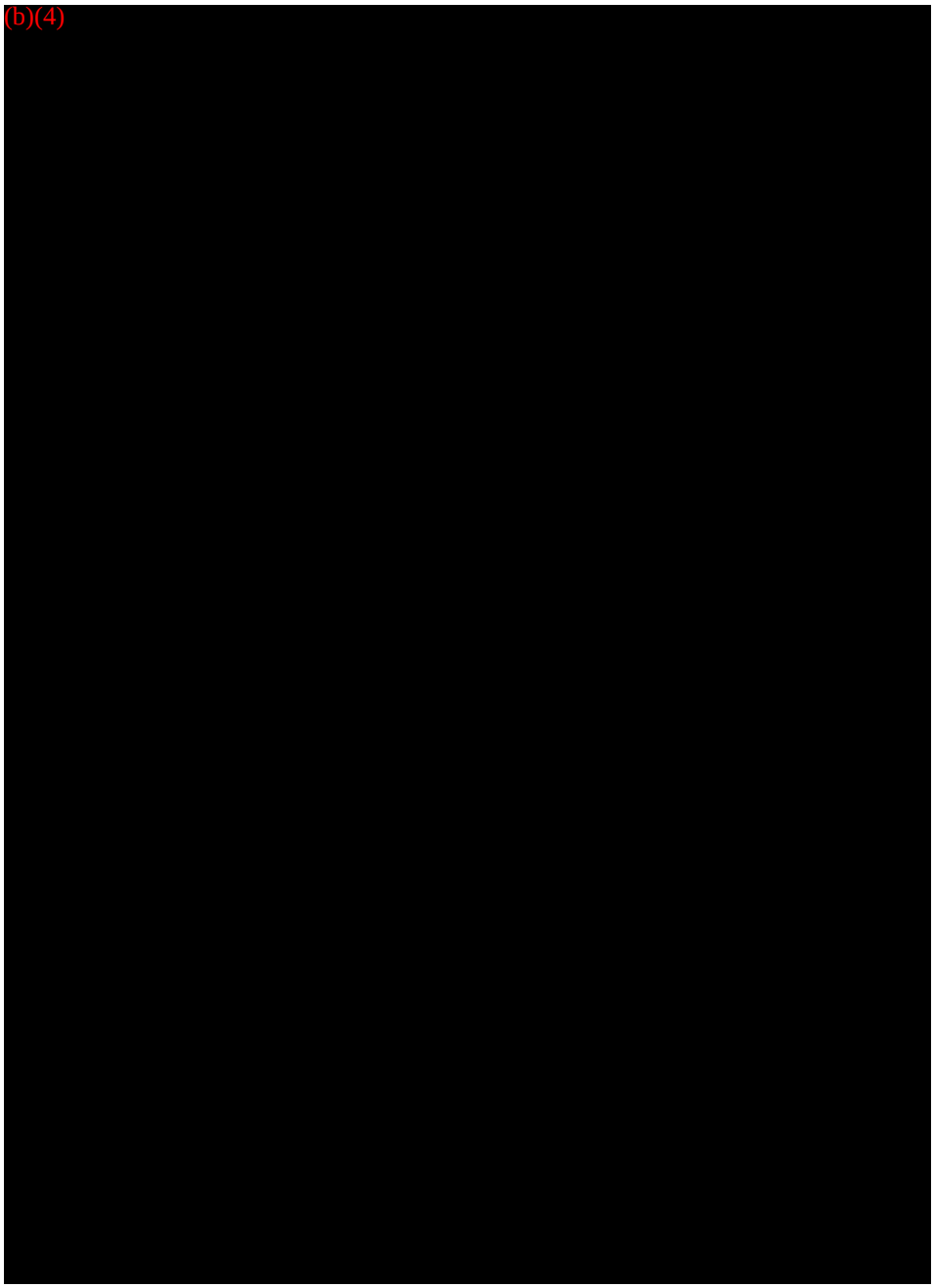
(b)(4)

Table 4.1.1b: Estimation of Bias – Whole Blood (continued)

(b)(4)

Table 4.1.1c: Statistical Summary – (b)(4)

(b)(4)



(b)(4)

[redacted]

(b)(4)

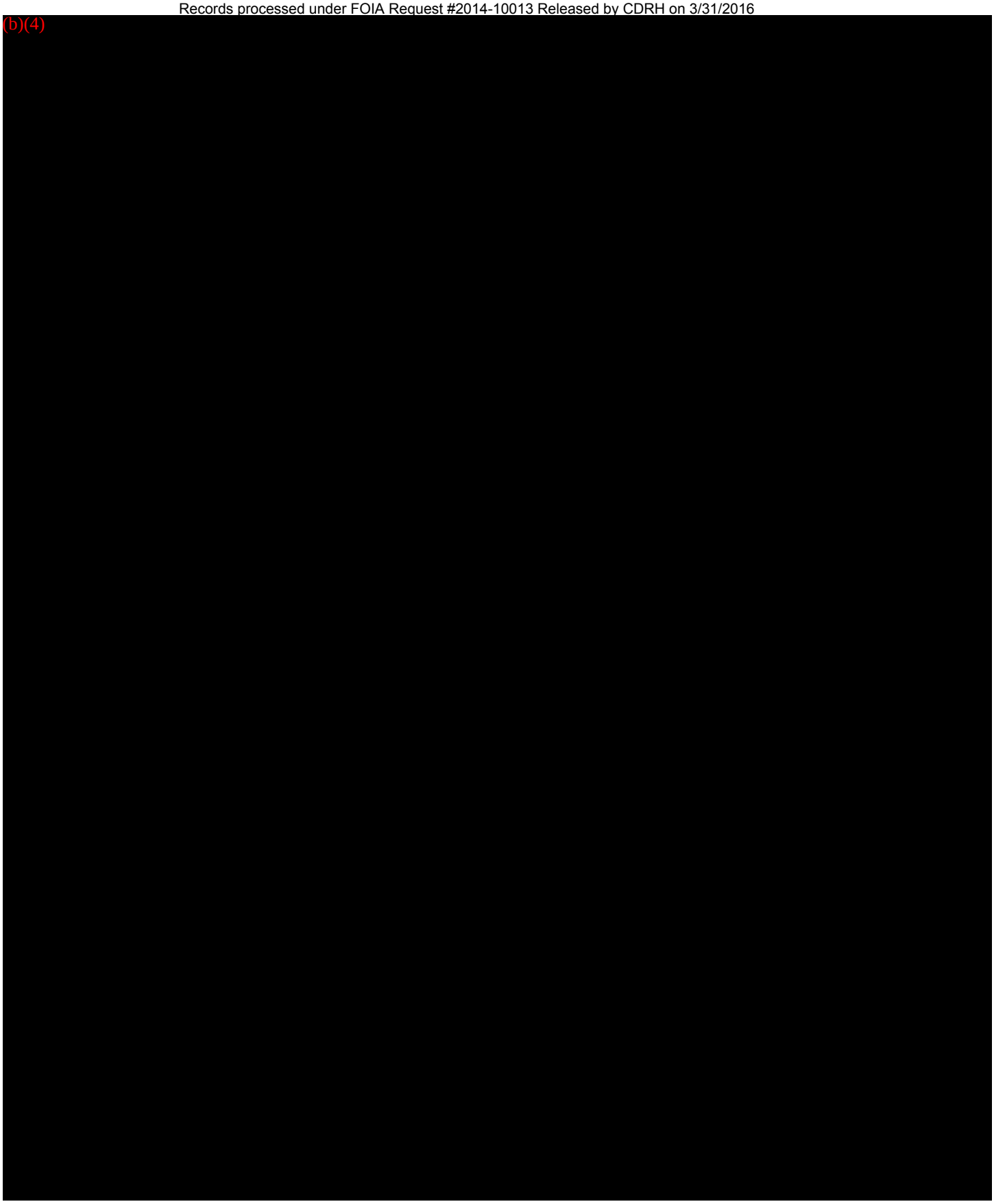
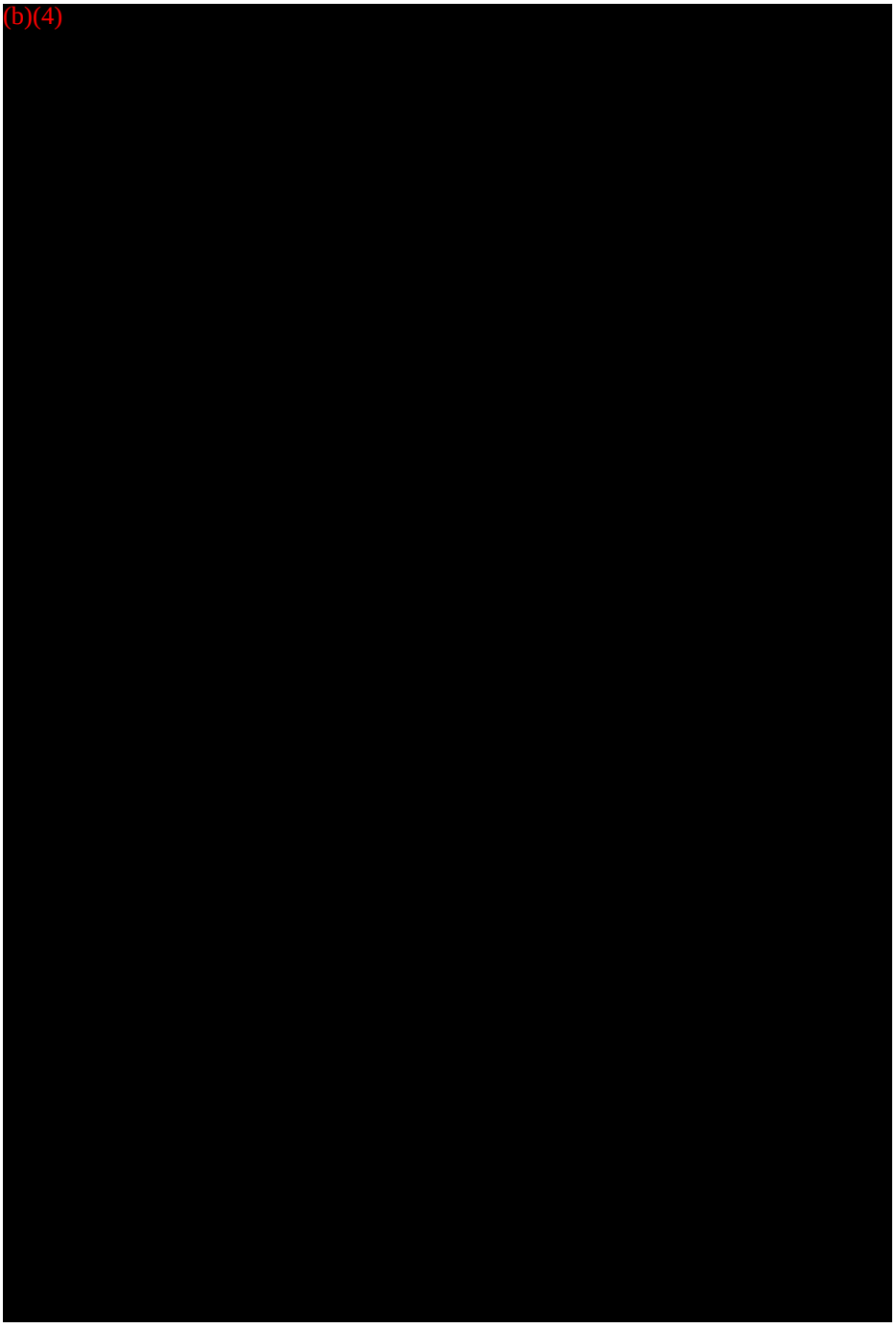


Table 4.1.1d: Estimation of Bias – Whole Blood (continued)

(b)(4)

Table 4.1.1e: Statistical Summary – (b)(4)

(b)(4)



(b)(4)

Discussion: (b)(4)

Conclusion: (b)(4)

Estimation of the Bias and Correlation Coefficient

(b)(4)

(b)(4)

(b)(4)

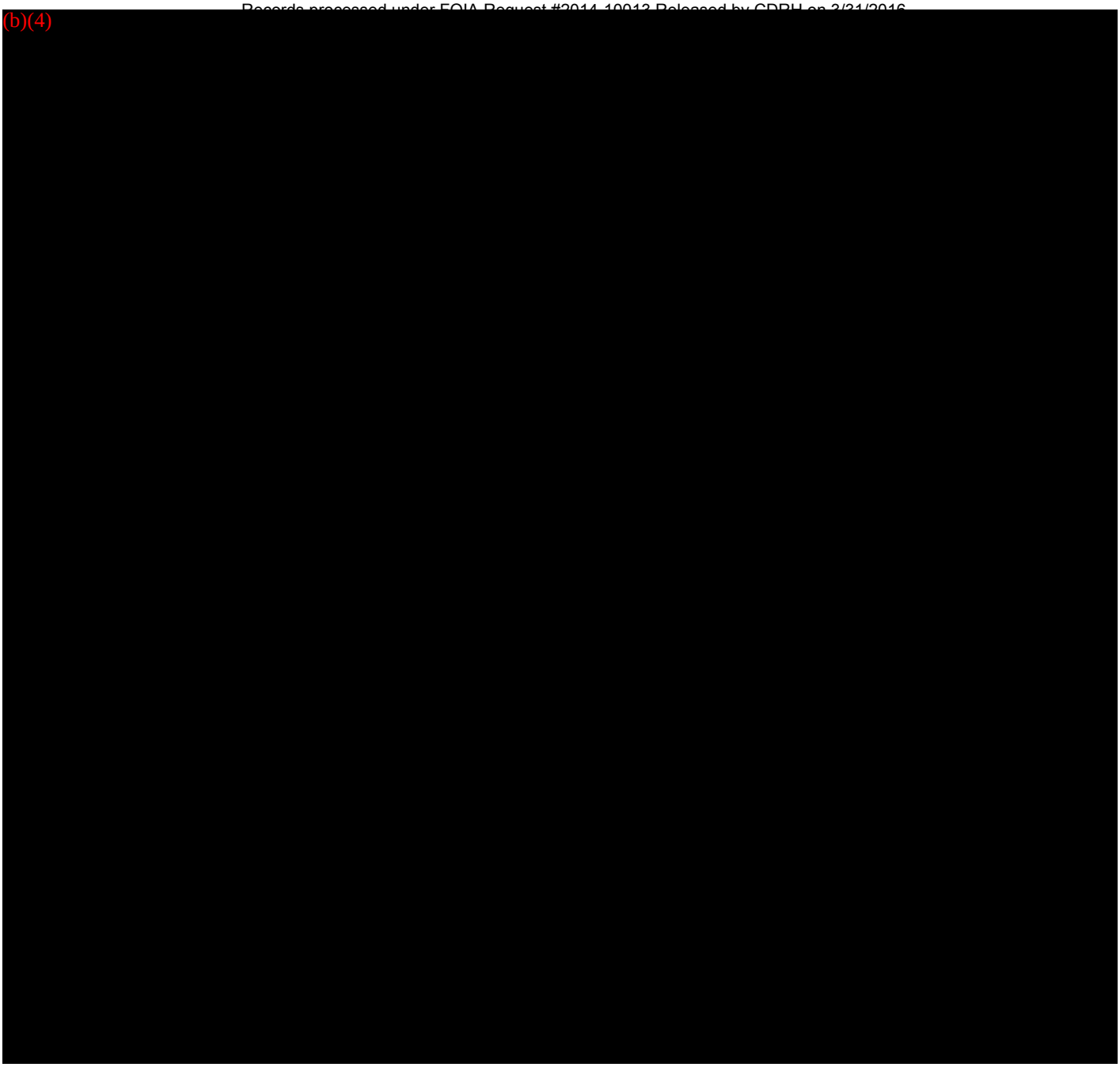


Table 4.1.1g: Statistical Summary – (b)(4)

(b)(4)

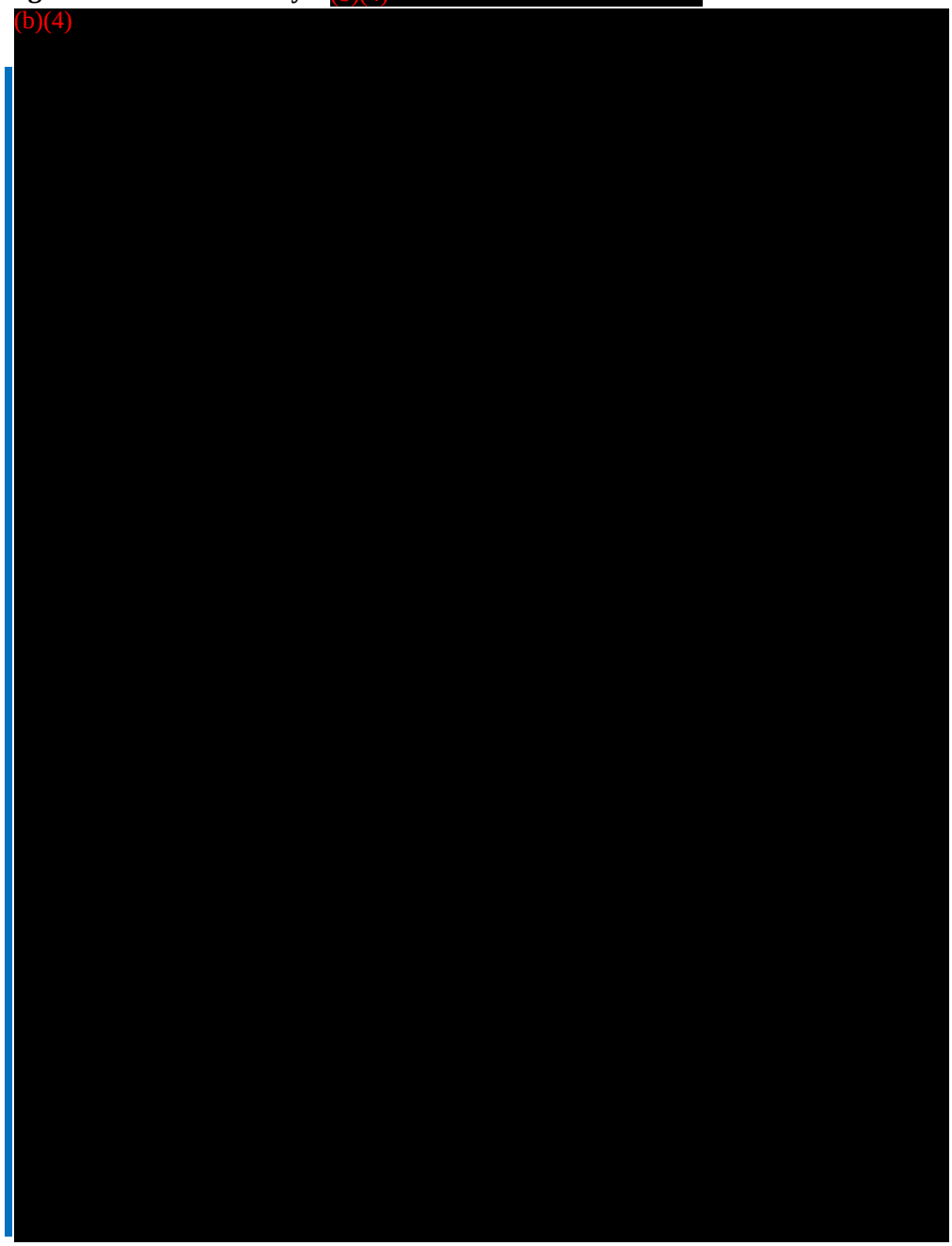


Table 4.1.1g: Statistical Summary – (b)(4)

(b)(4)

Conclusion: (b)(4) .

Estimation of the Bias and Correlation Coefficient

(b)(4)

(b)(4)

Table 4.1.1h: Estimation of Bias – Whole Blood

(b)(4)

Table 4.1.1h: (b)(4))

(b)(4)

Expected Results: (b)(4) .

Results: (b)(4)

Table 4.1.2a: Statistical Summary – Body Fluid Mode

(b)(4)

Table 4.1.2b: Statistical Summary – Body Fluid Mode

(b)(4)

Conclusion: (b)(4) .

(b)(4)

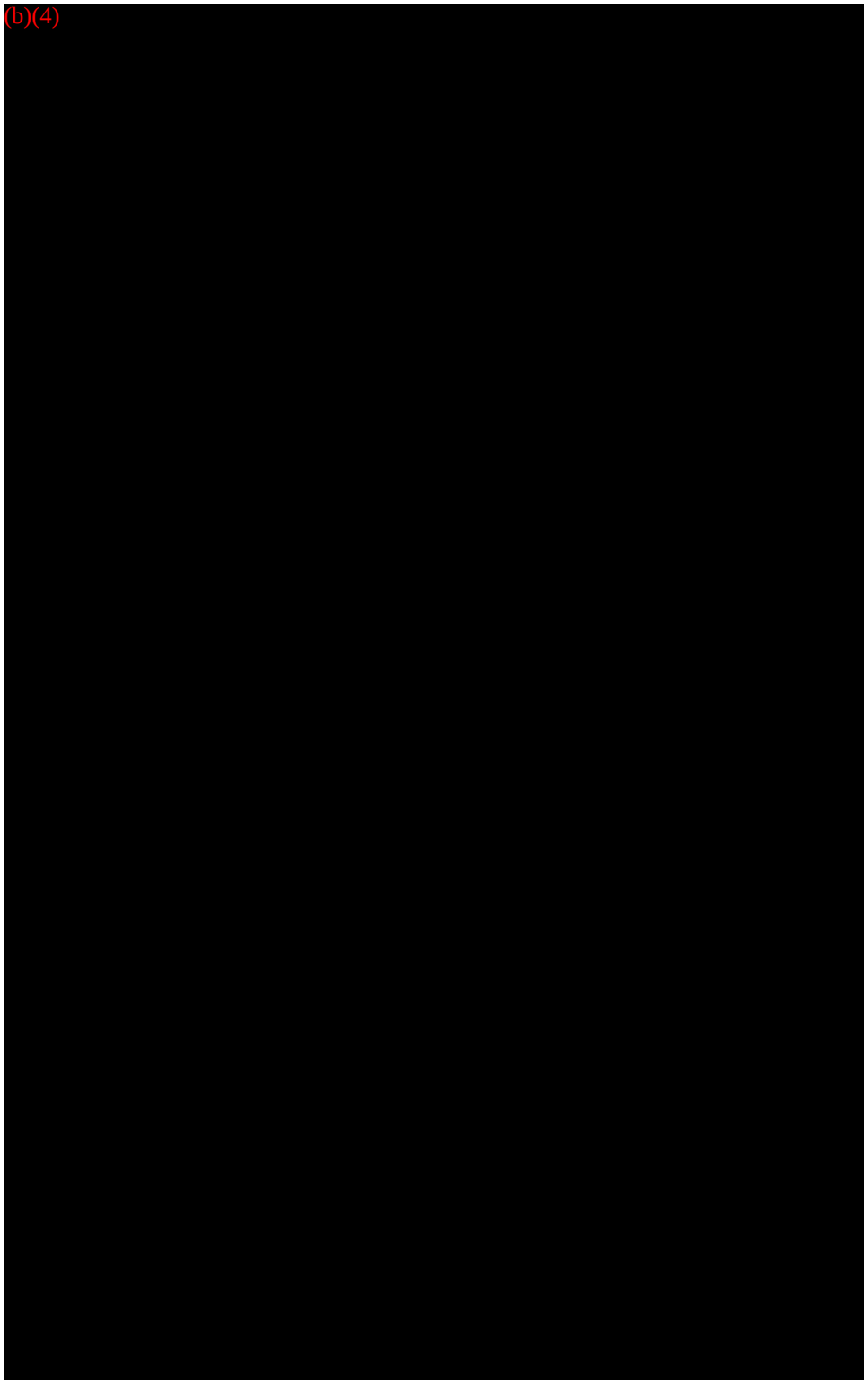
Table 4.1.2c: Estimation of Bias – Body Fluids – Site 1

(b)(4)

Table 4.2.1a: Statistical Summary – XN-21 Whole Blood Manual Mode

(b)(4)

(b)(4)



(b)(4)

Estimation of the Bias and Correlation Coefficient

(b)(4)

Table 4.2.1b: Estimation of Bias – XN-21 Manual Whole Blood Mode

(b)(4)

Table 4.2.1b: Estimation of Bias – XN-21 Manual Whole Blood Mode (continuation)

(b)(4)

Conclusion: (b)(4)

4.2.2 (b)(4)

(b)(4)

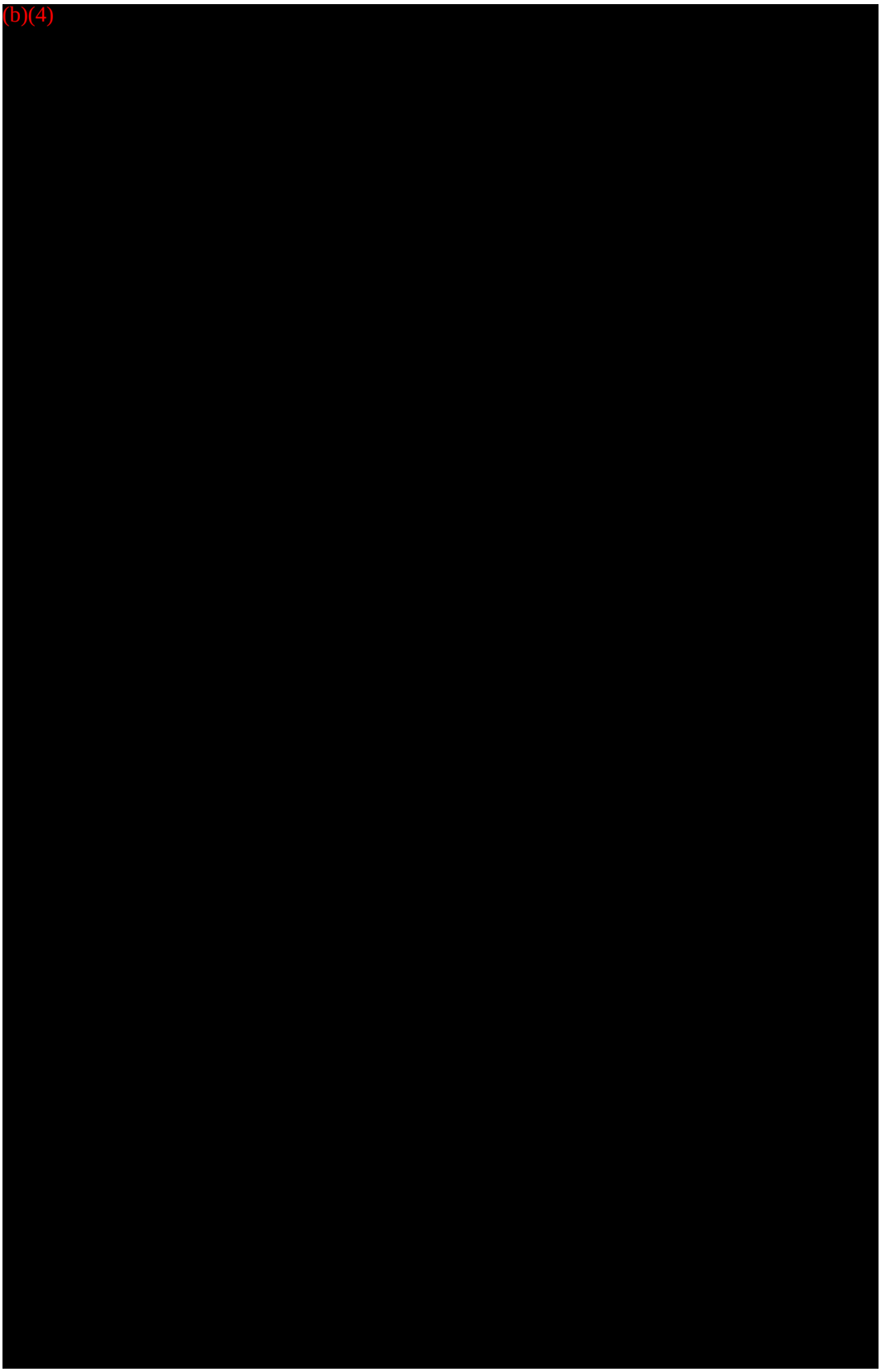
Expected Results: (b)(4)

Results: (b)(4) .

Table 4.2.2a: Statistical Summary – (b)(4)

(b)(4)

(b)(4)



(b)(4)

Conclusion: (b)(4) .

Estimation of the Bias and Correlation Coefficient

(b)(4)

Table 4.2.2b: Estimation of Bias – (b)(4)

(b)(4)

4.2.3 Pre-dilute Mode Normal Tube to Micro Tube Position Comparison

(b)(4)

Table 4.2.3a: Statistical Summary – (b)(4)

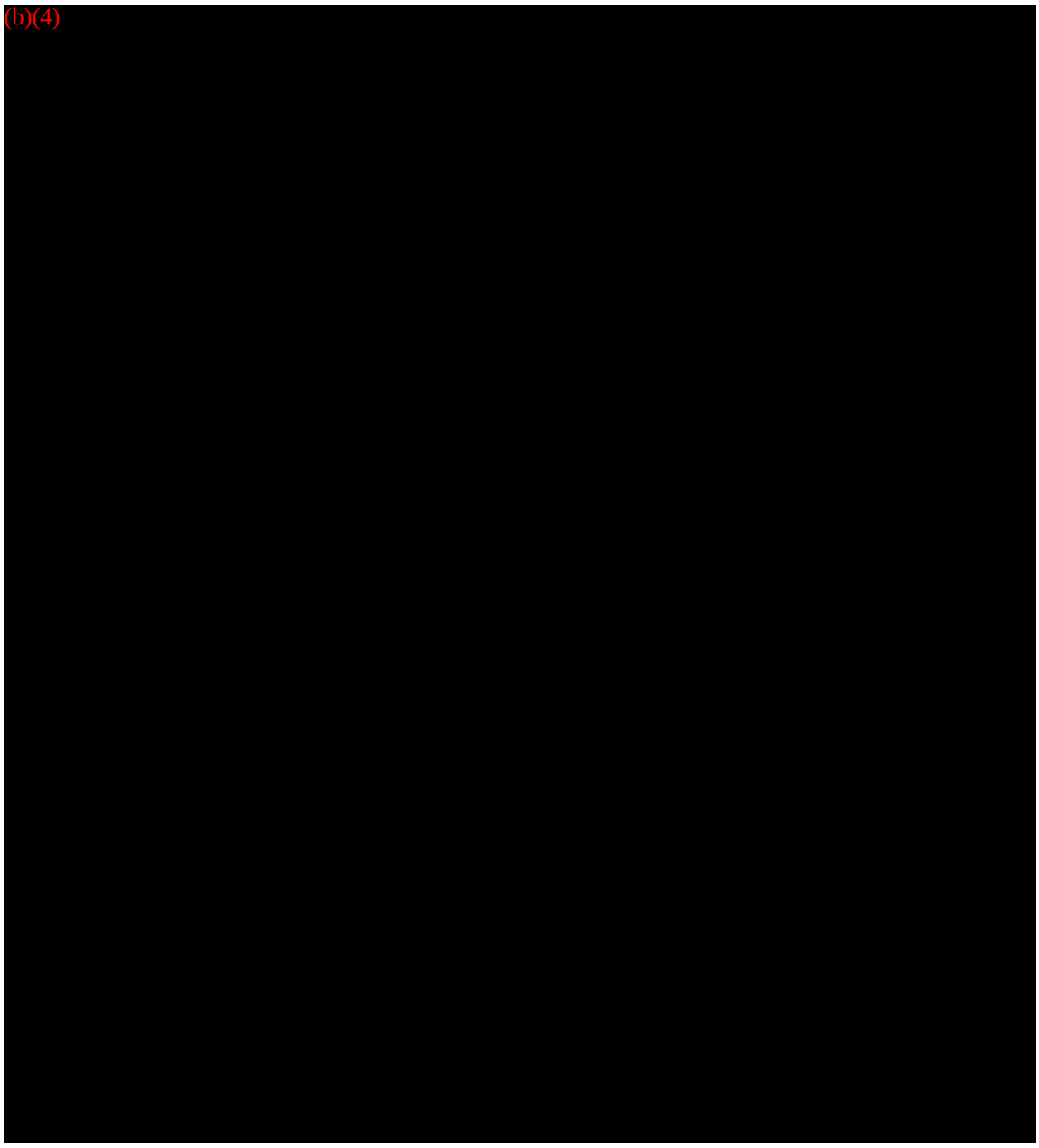


Table 4.2.3a: Statistical Summary – (b)(4))

(b)(4)

Table 4.2.3b: Correlation Coefficient and Estimation of Bias – (b)(4)

(b)(4)

4.2.4 Low WBC Mode Normal Tube to Micro Tube Position Comparison

(b)(4)

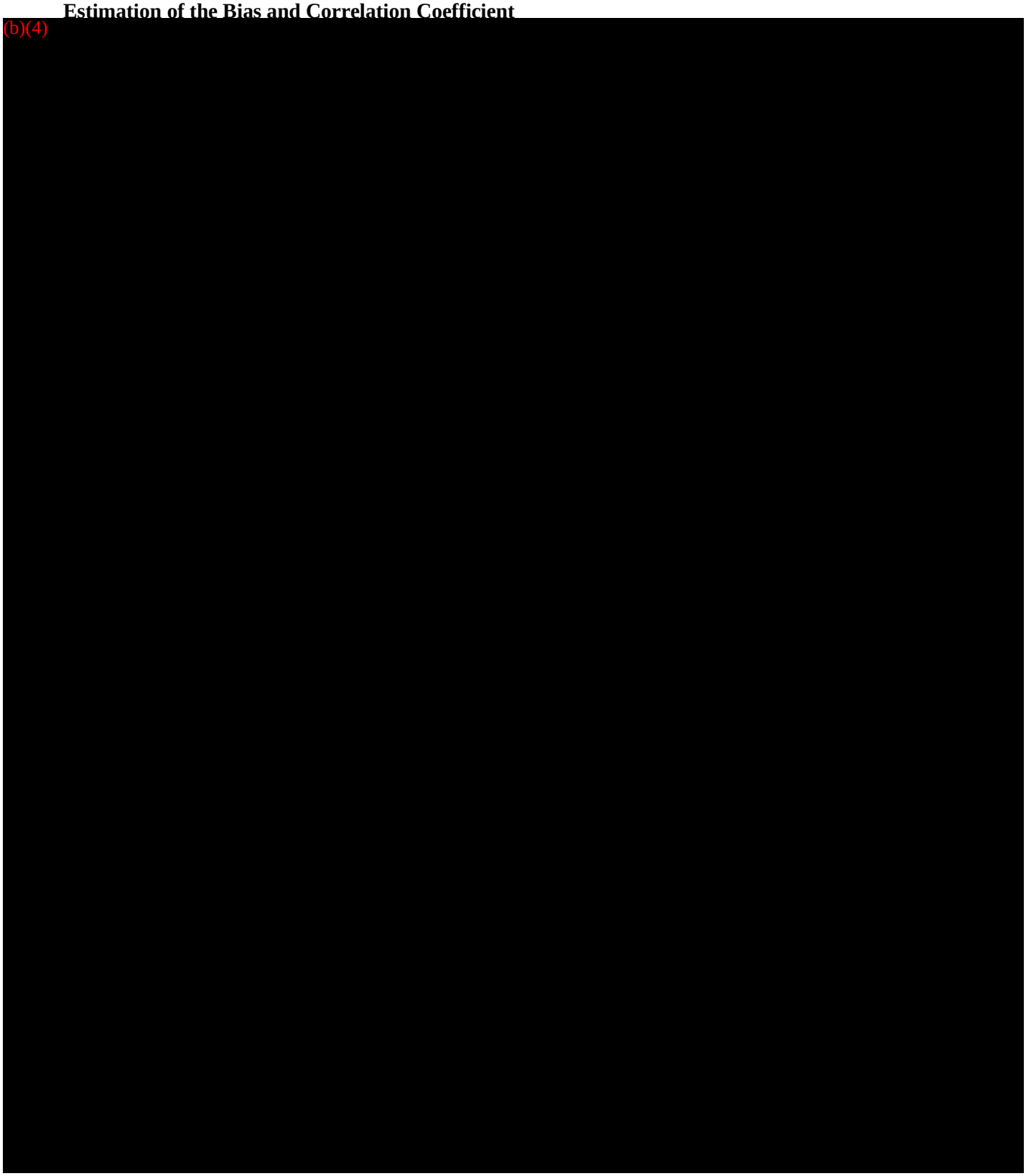
Table 4.2.4a: Statistical Summary – (b)(4)

(b)(4)

Conclusion: (b)(4)

Estimation of the Bias and Correlation Coefficient

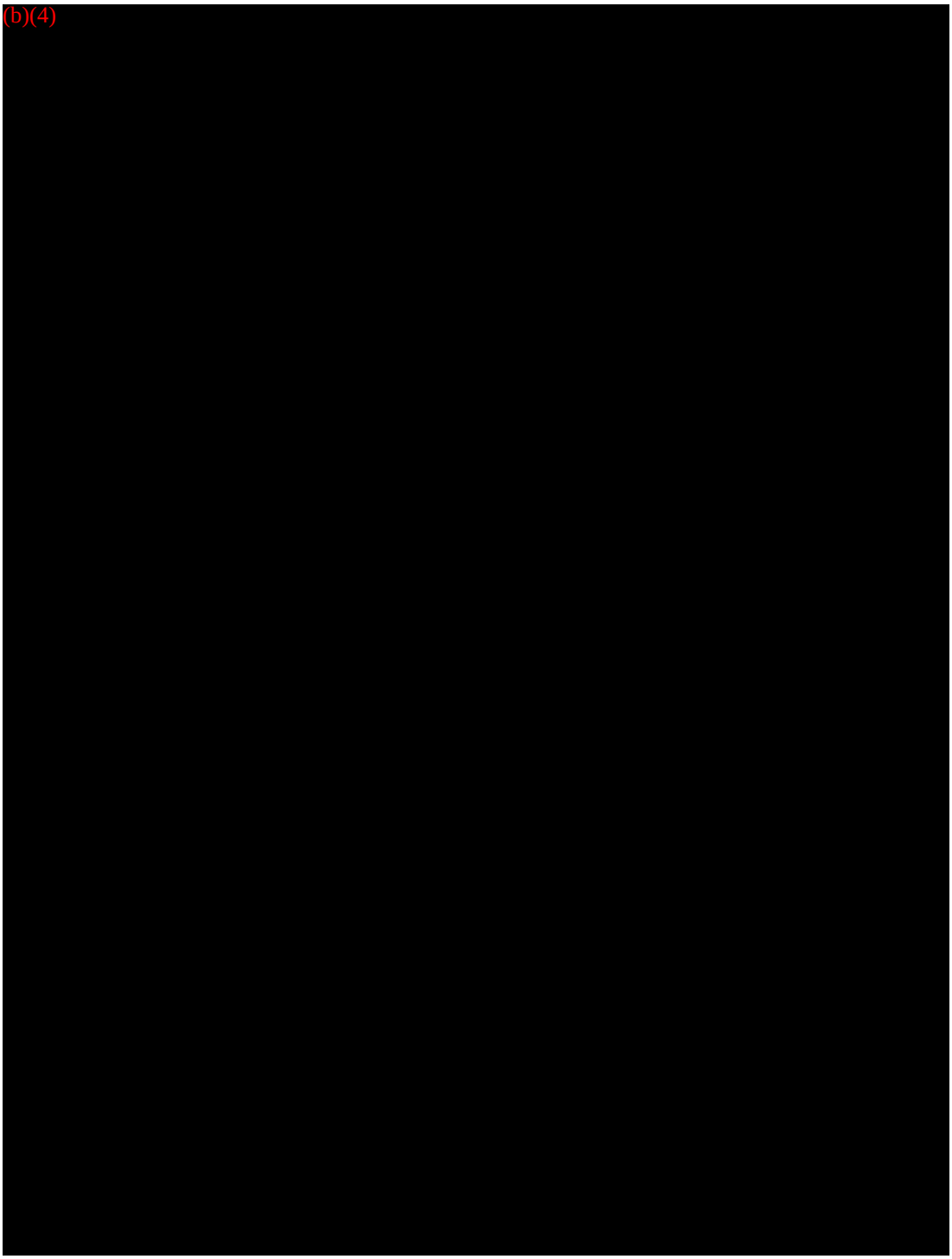
(b)(4)



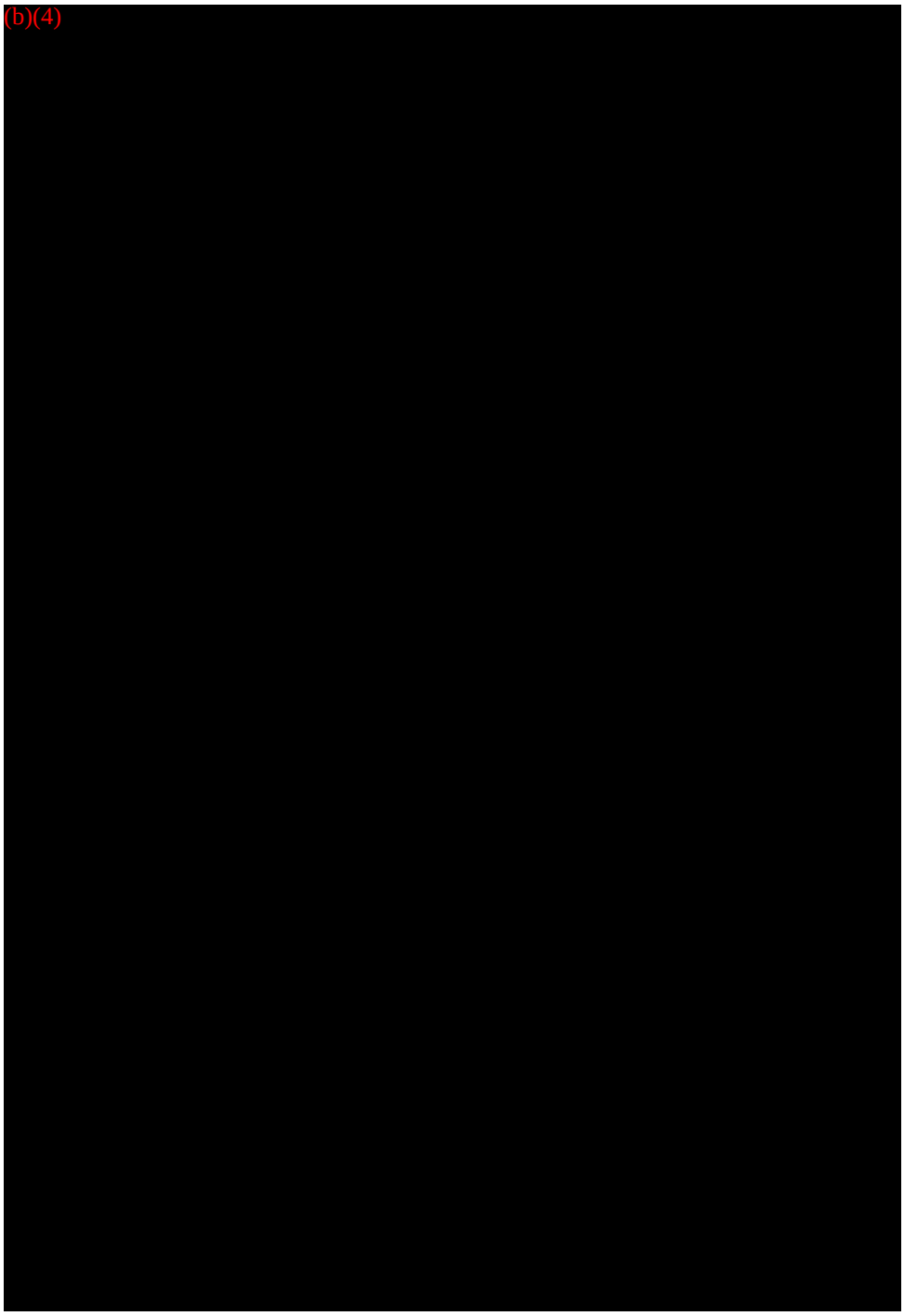
(b)(4)

Table 4.3.1.1a Statistical Summary

(b)(4)



(b)(4)



(b)(4)

Table 4.3.1.1b: Estimation of Bias and Correlation Coefficient Limits – Whole Blood

(b)(4)

(b)(4)

[redacted]

4.3.1.2 Whole Blood Precision – Devices Connected

(b)(4)

[redacted]

(b)(4)

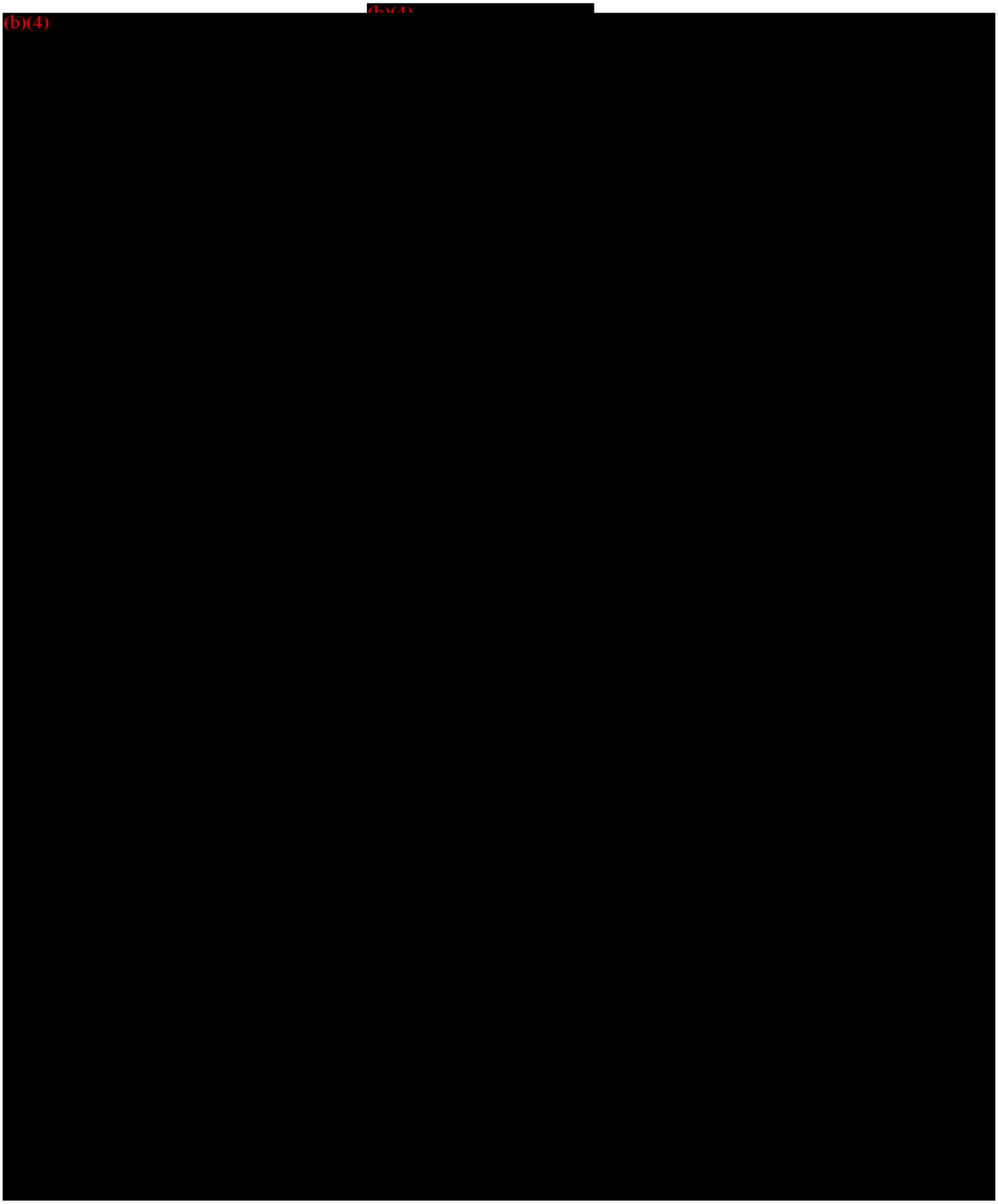


Table 4.3.1.3: Whole Blood Linearity (b)(4)

(b)(4)

Table 4.3.1.4: Whole Blood Carryover – XN-11

(b)(4)

[redacted]

(b)(4)

[redacted]

Target Concentrations – Whole Blood

(b)(4)

(b)(4)

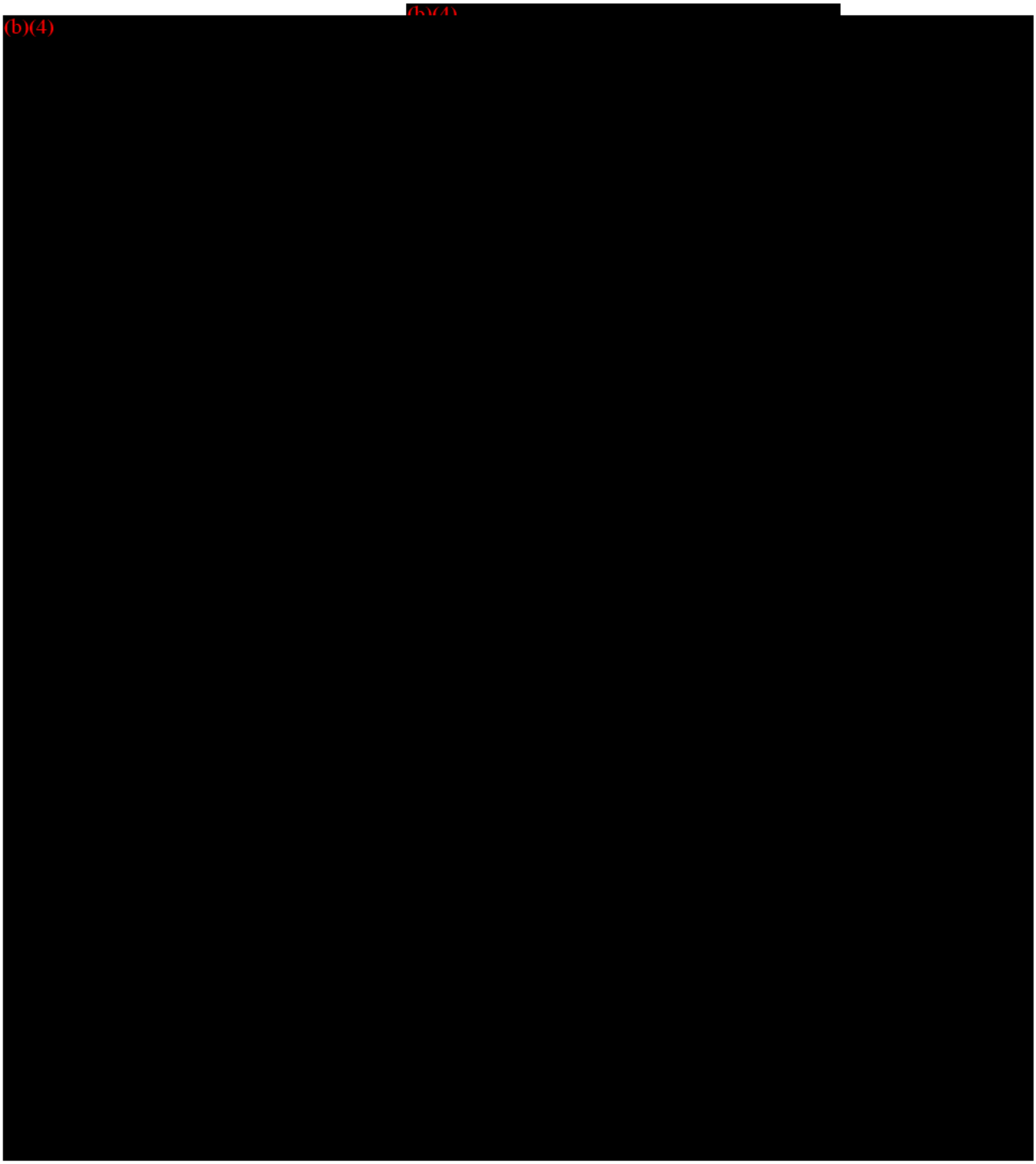


Table 4.3.2.1a: Body Fluids (b)(4)

(b)(4)

(b)(4)

Table 4.3.2.1b: Estimation of the Bias and Correlation Coefficient – Body Fluid

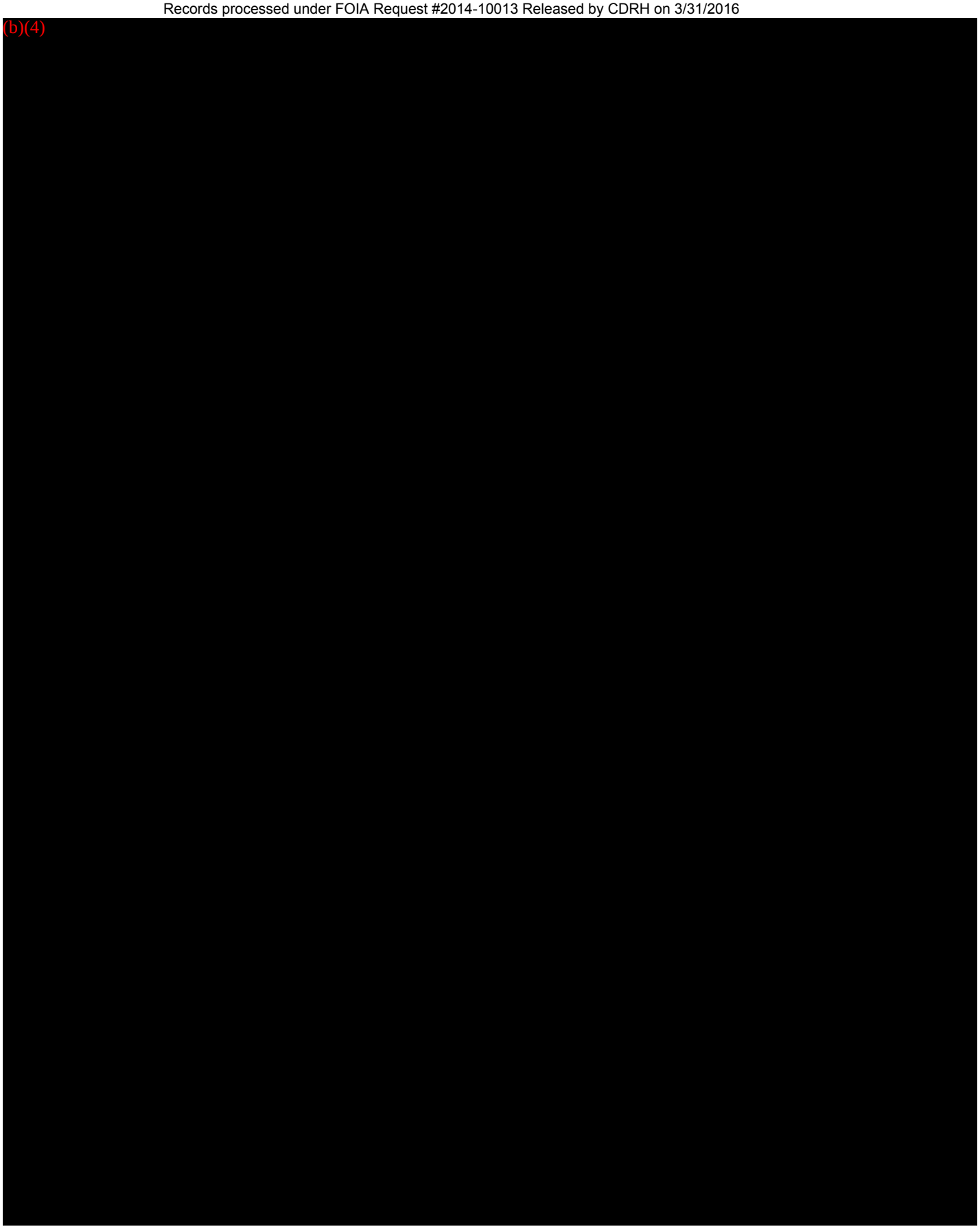
(b)(4)

Table 4.3.2.2: Body Fluid Precision (b)(4)

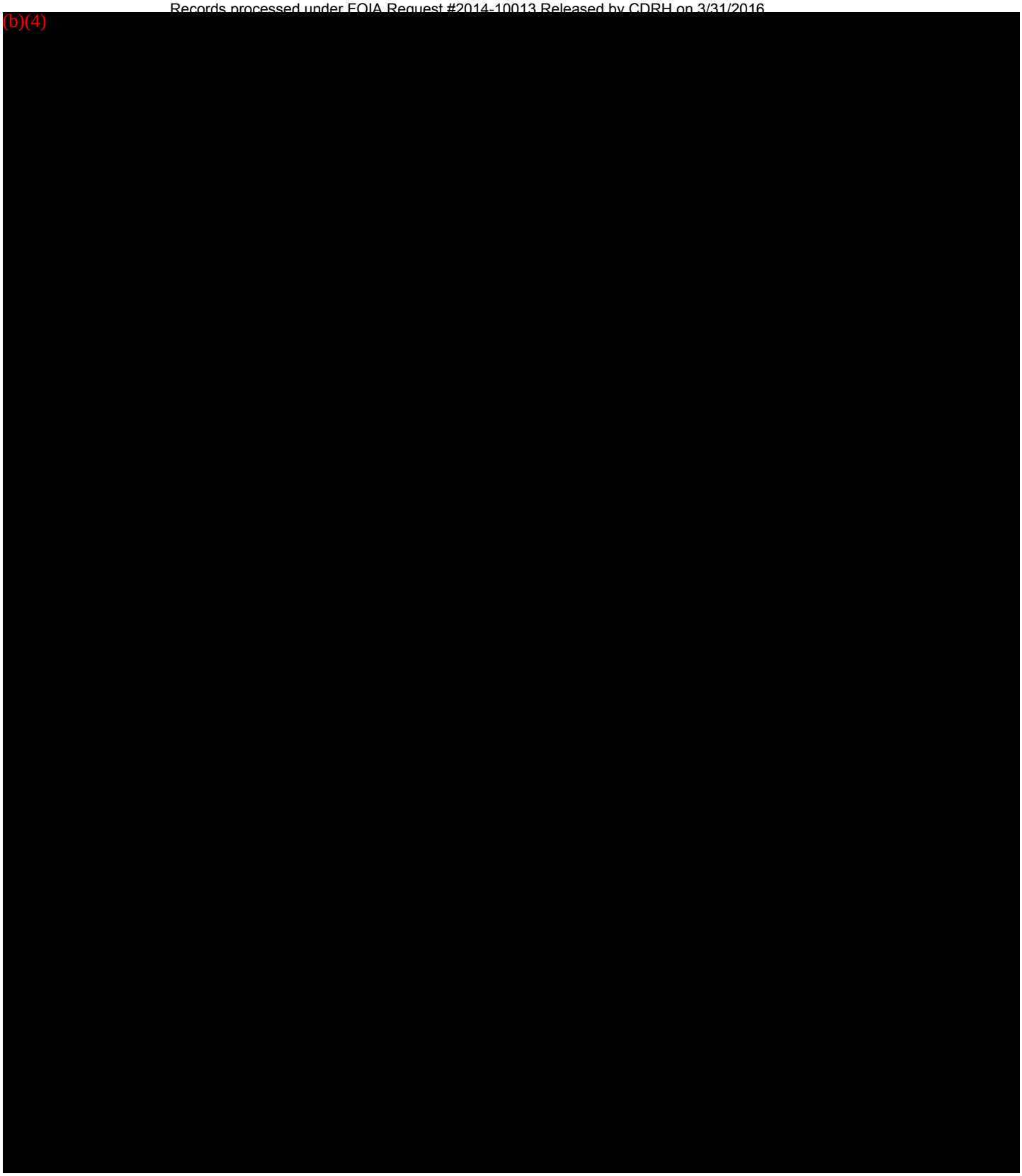
(b)(4)

(b)(4)

(b)(4)



(b)(4)



(b)(4)

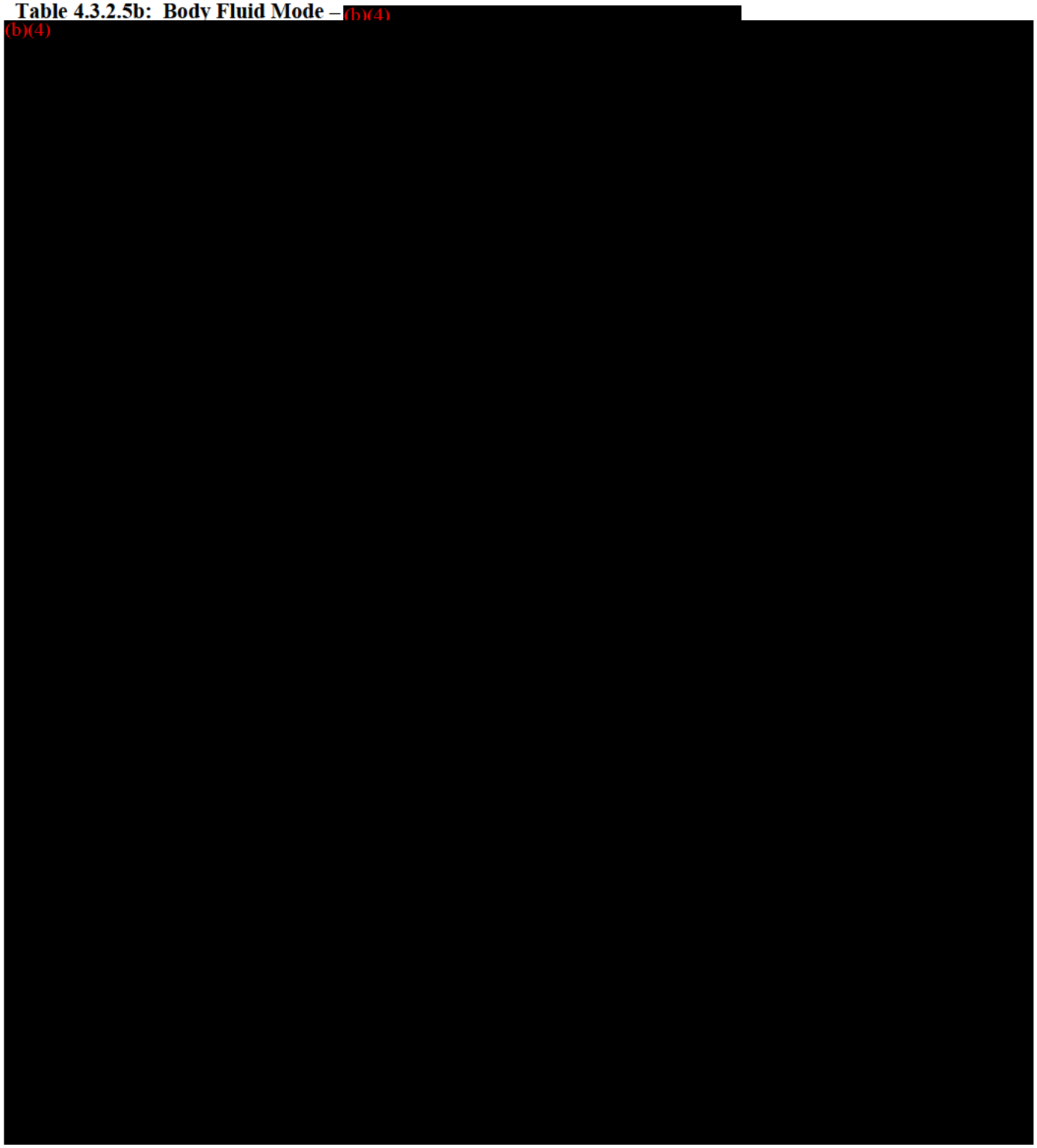
[redacted]

Target Concentrations – Body Fluid

(b)(4)

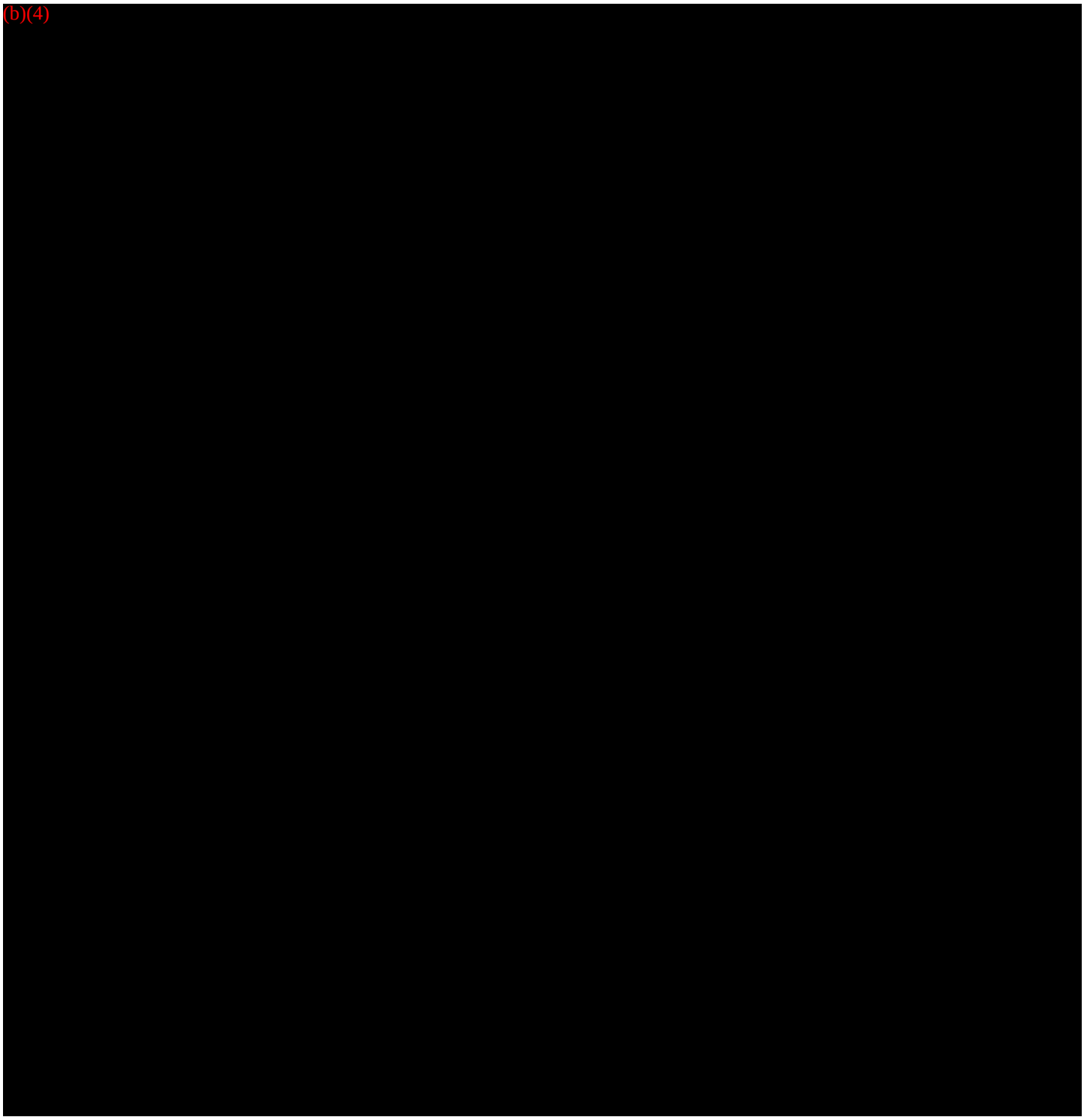
Table 4.3.2.5b: Body Fluid Mode – (b)(4)

(b)(4)



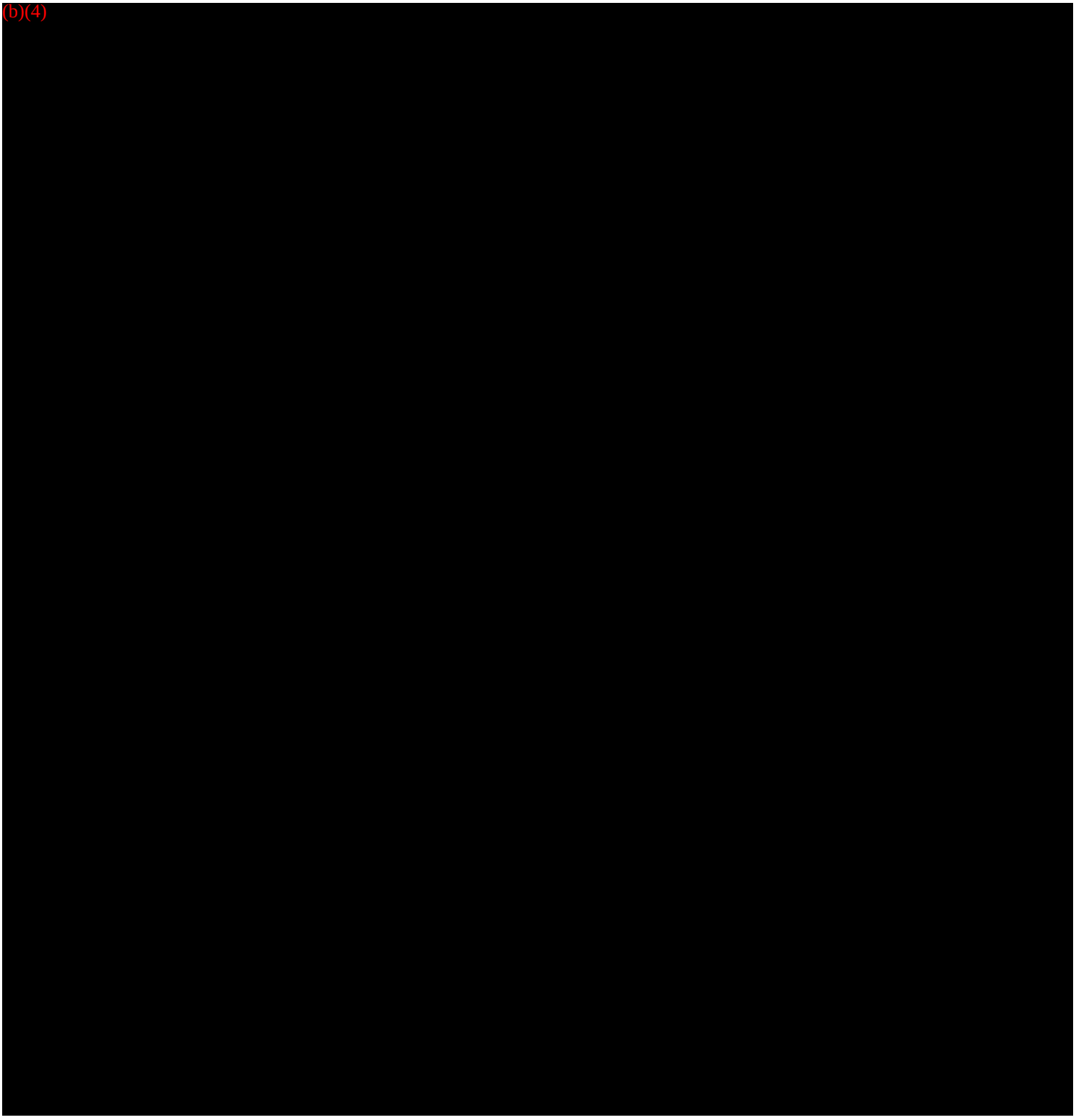
Calculations:

(b)(4)



Calculations:

(b)(4)



Calculations:

(b)(4)

Protocol for Evaluation of XN-Series (XN-11, XN-21) Automated Hematology Analyzers

September - December 2012

Principal Investigators: (b)(4)

Study Sponsor: Sysmex America, Inc.
577 Aptakisic Road
Lincolnshire, IL. 60069 USA
Phone: 847-996-4600
Fax: 847-996-4699

(b)(4)

Table of Contents

1.0 INTRODUCTION

(b)(4)

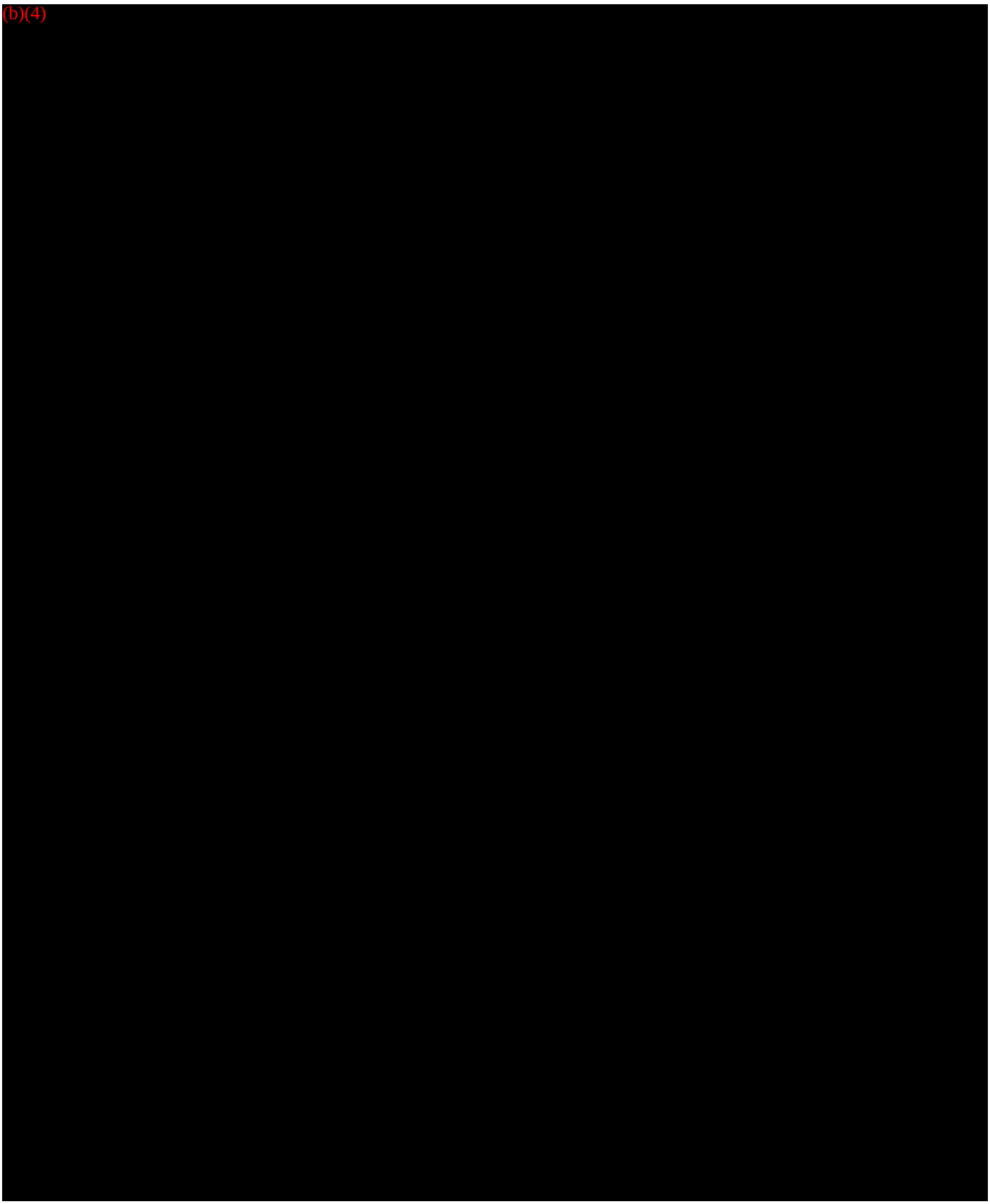
[redacted]

2.0 STUDY OBJECTIVE

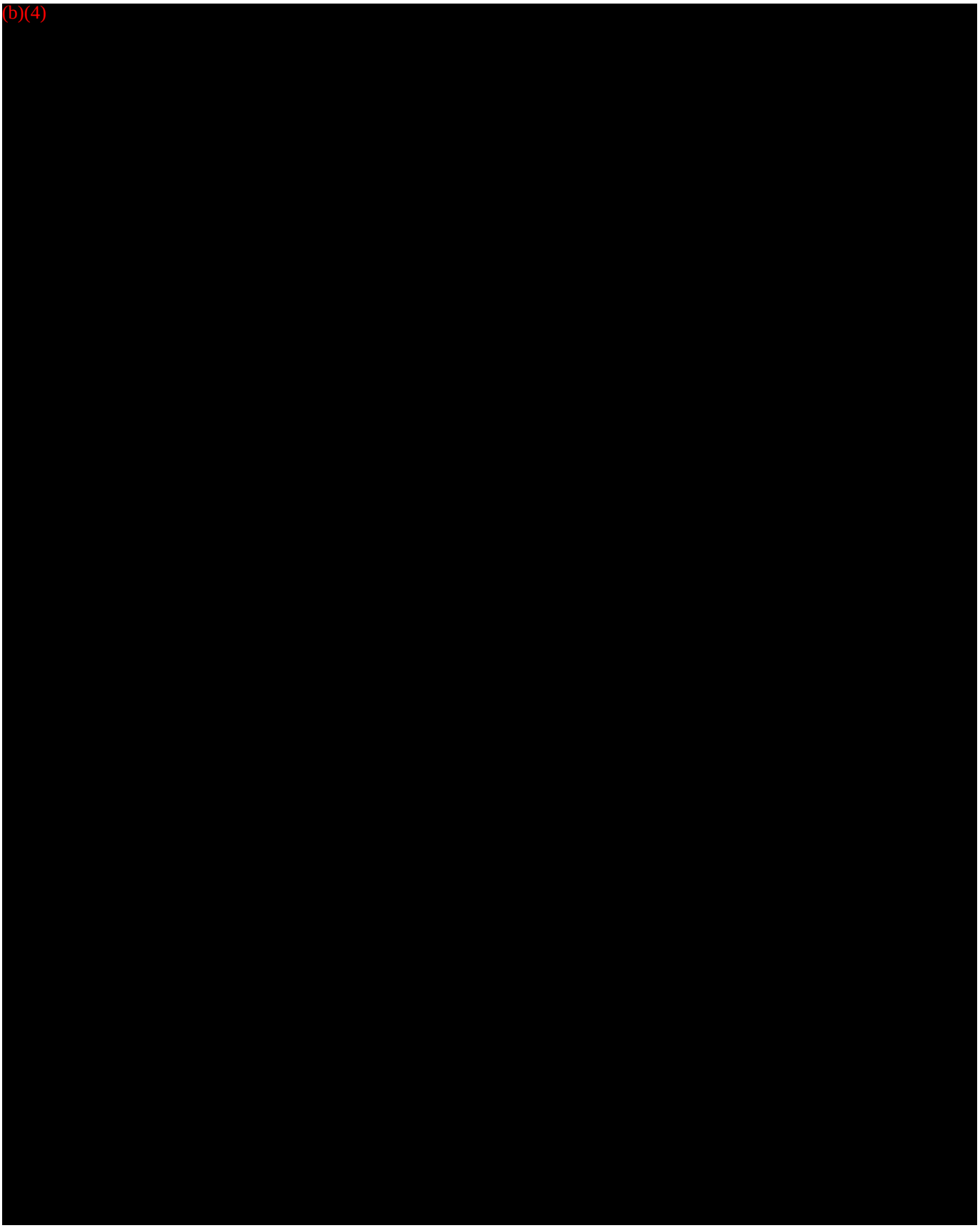
(b)(4)

[redacted]

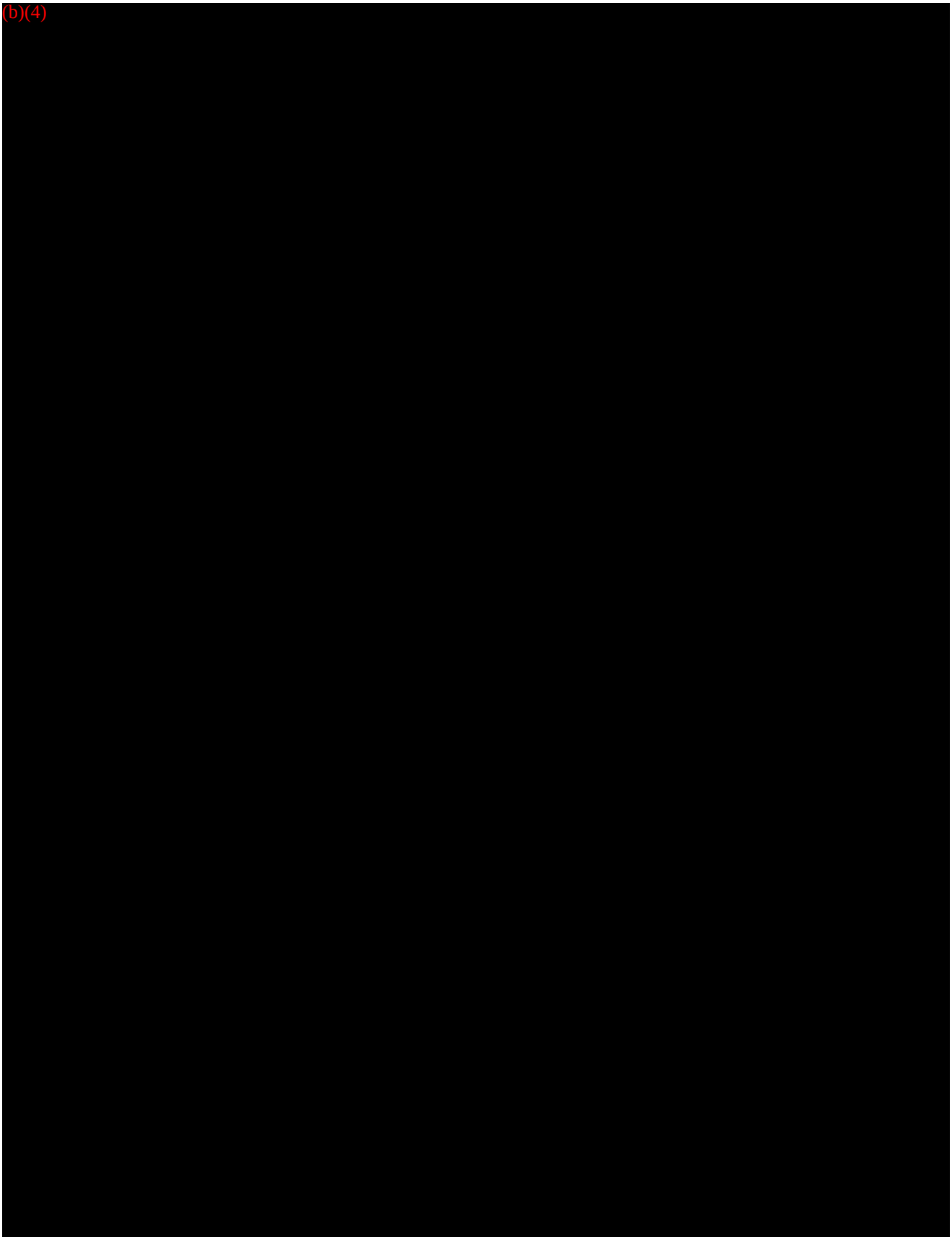
(b)(4)



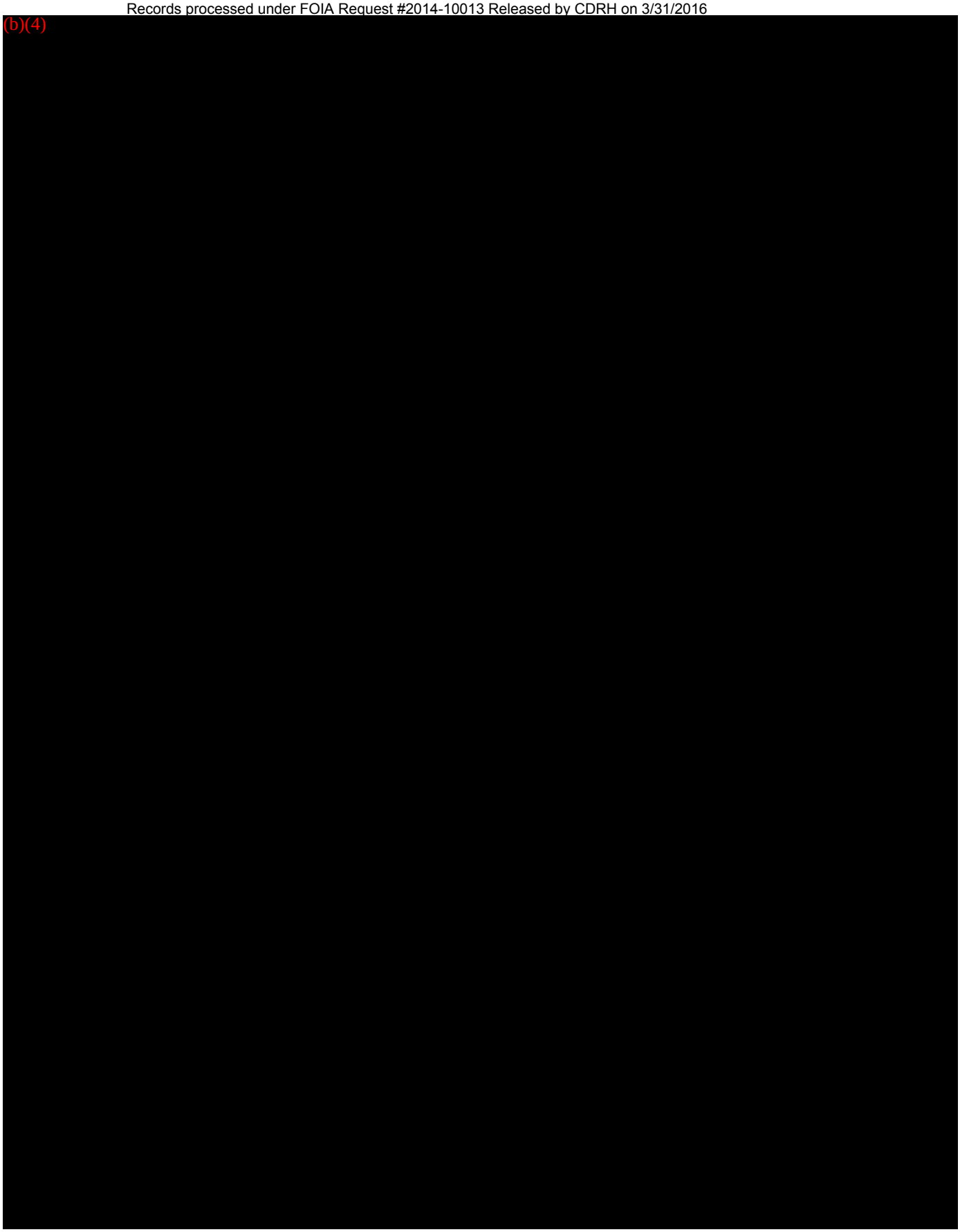
(b)(4)



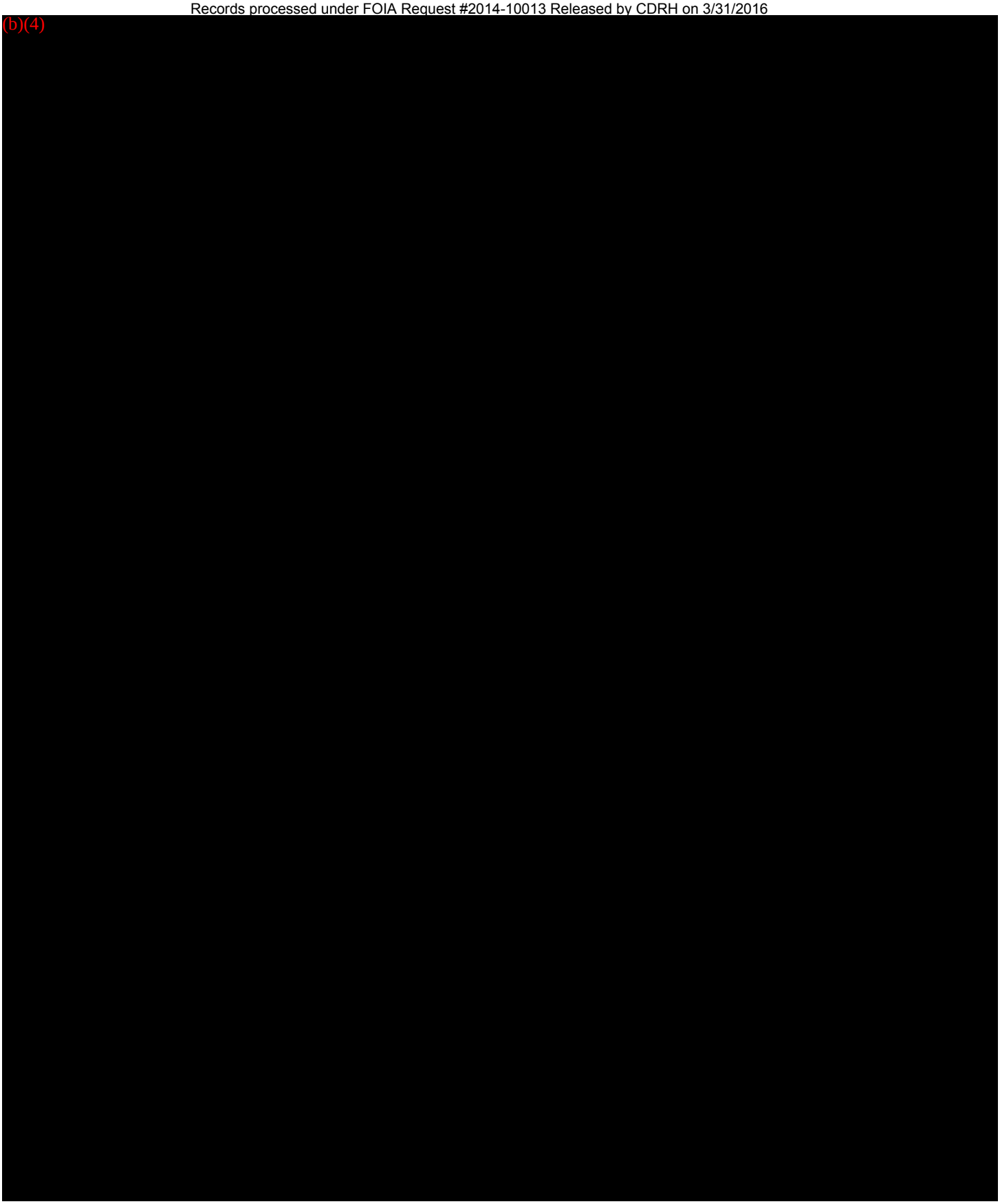
(b)(4)



(b)(4)



(b)(4)



Study Requirement: (b)(4)

.

Procedure:

(b)(4)

Table 2: Correlation Coefficient and Bias Acceptance Criteria – Body Fluid

(b)(4)

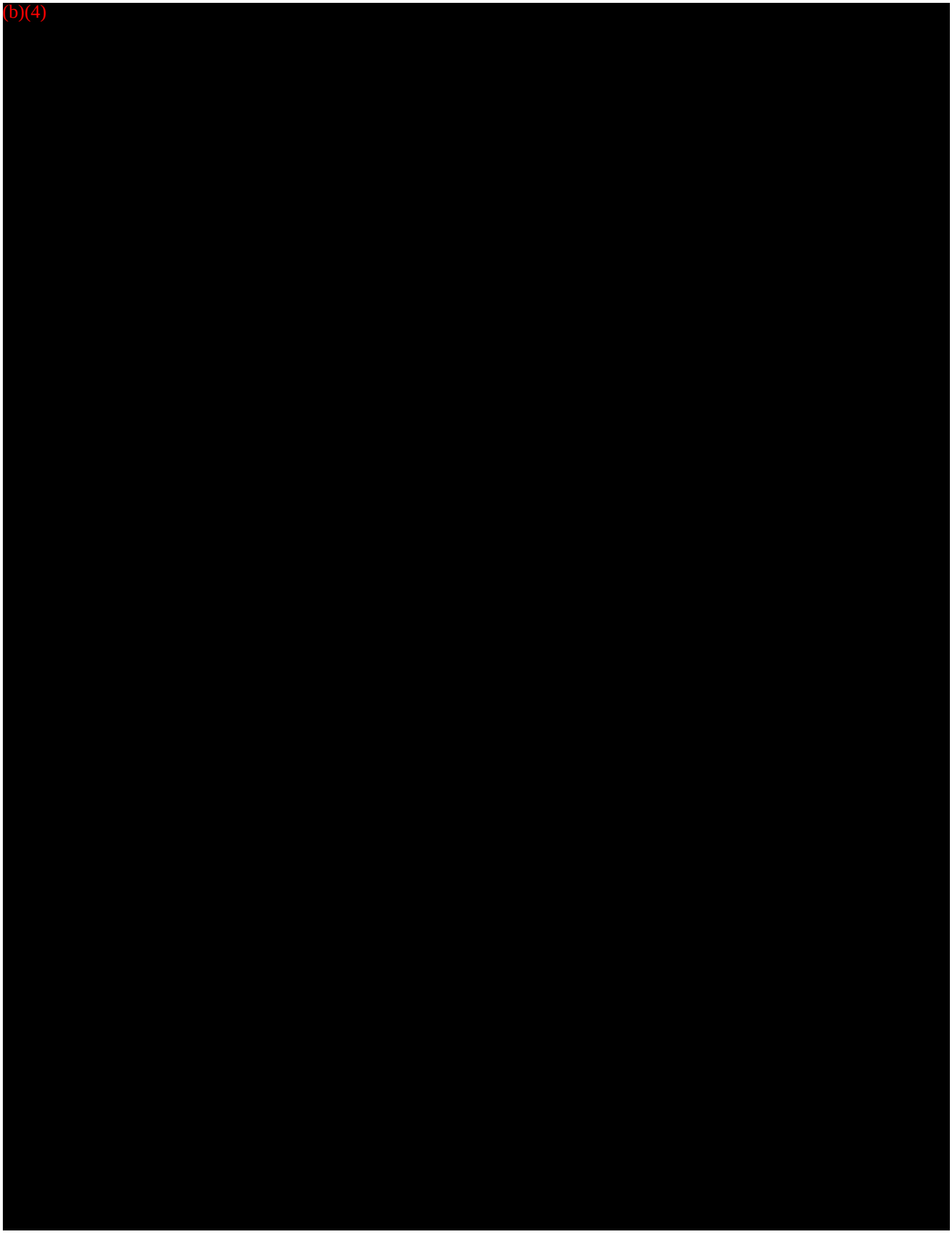
Expected Results: (b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)



Procedure:

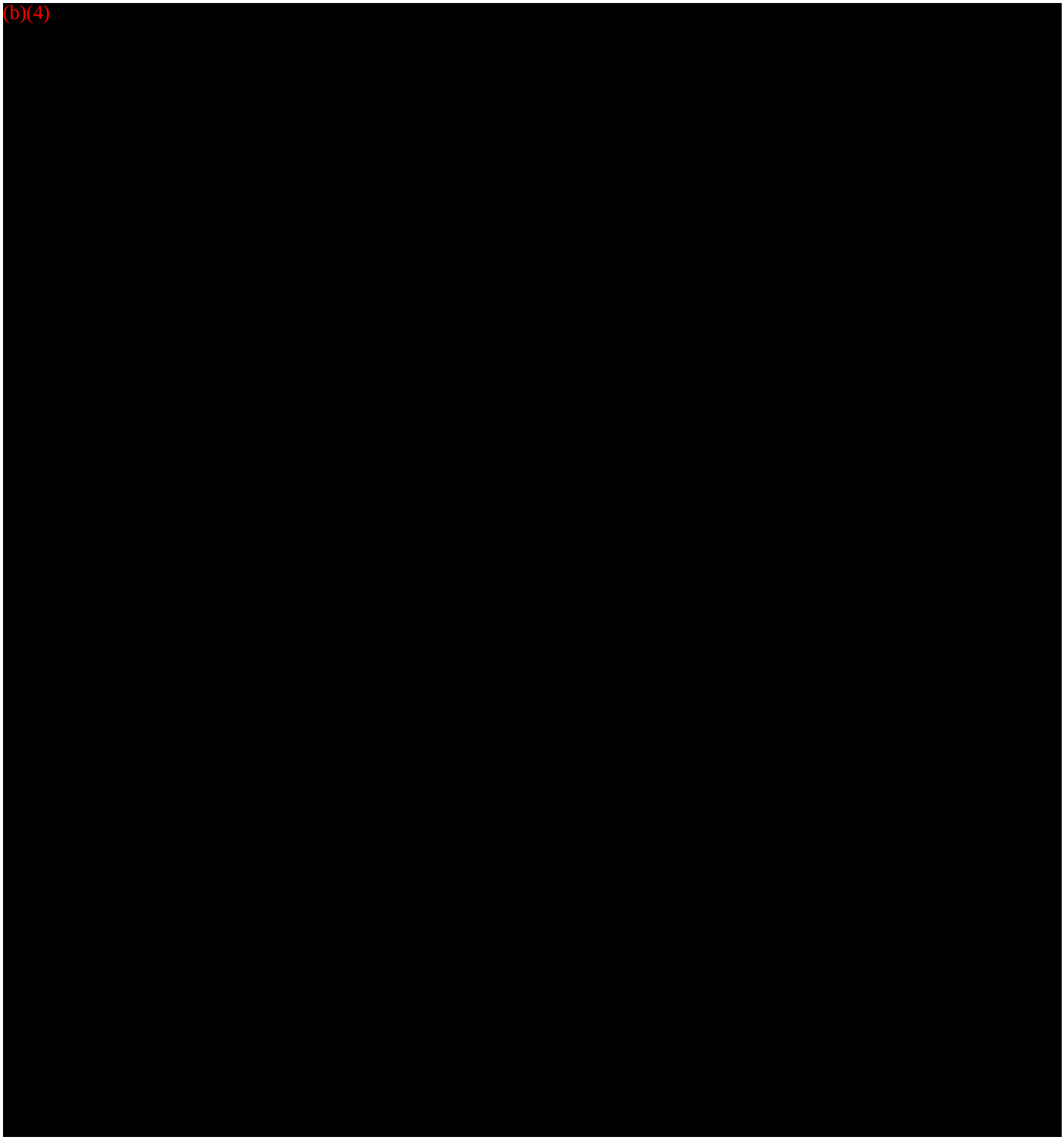
1. (b)(4)

2.

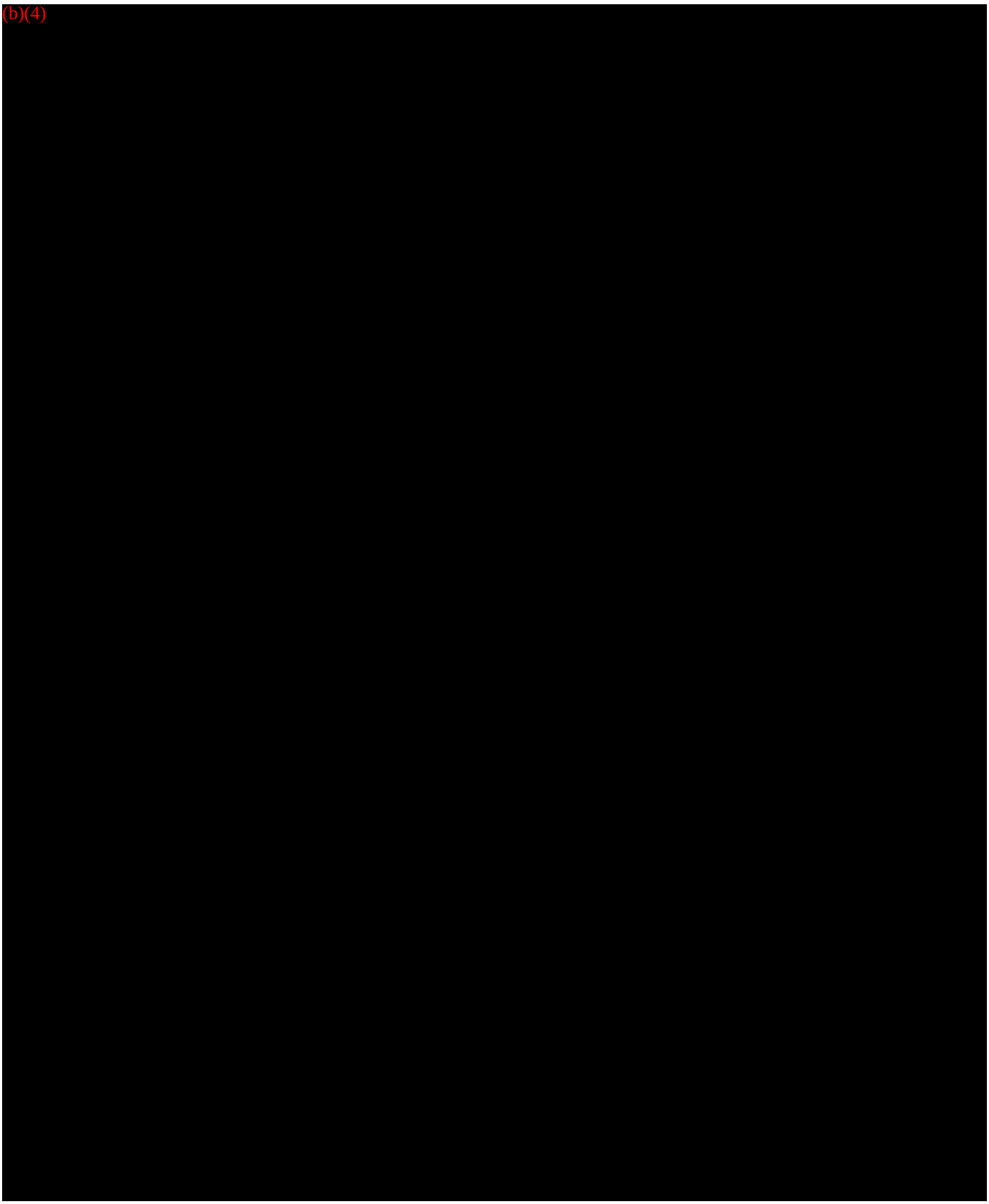
Target Range

(b)(4)

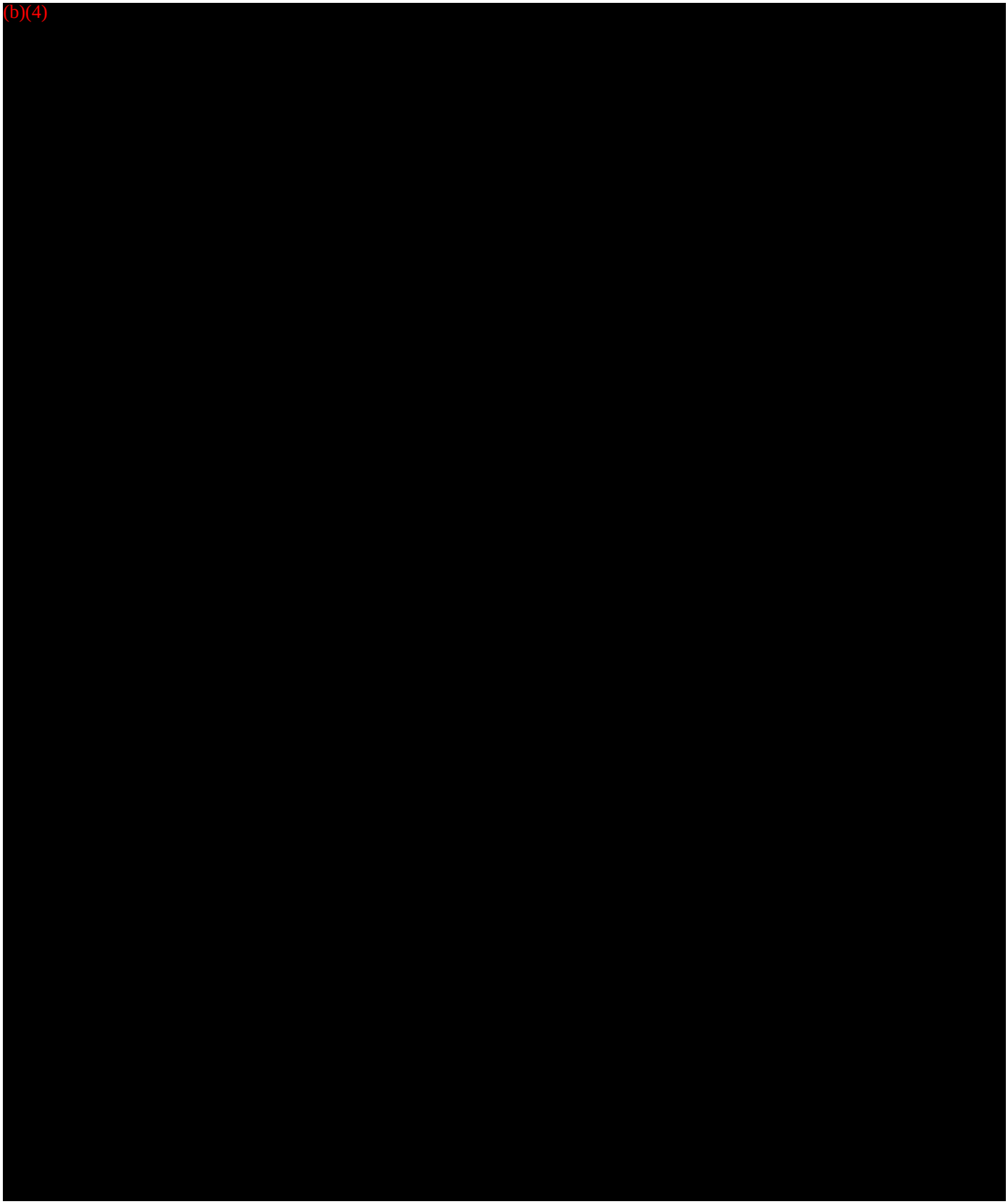
(b)(4)



(b)(4)



(b)(4)



(b)(4)

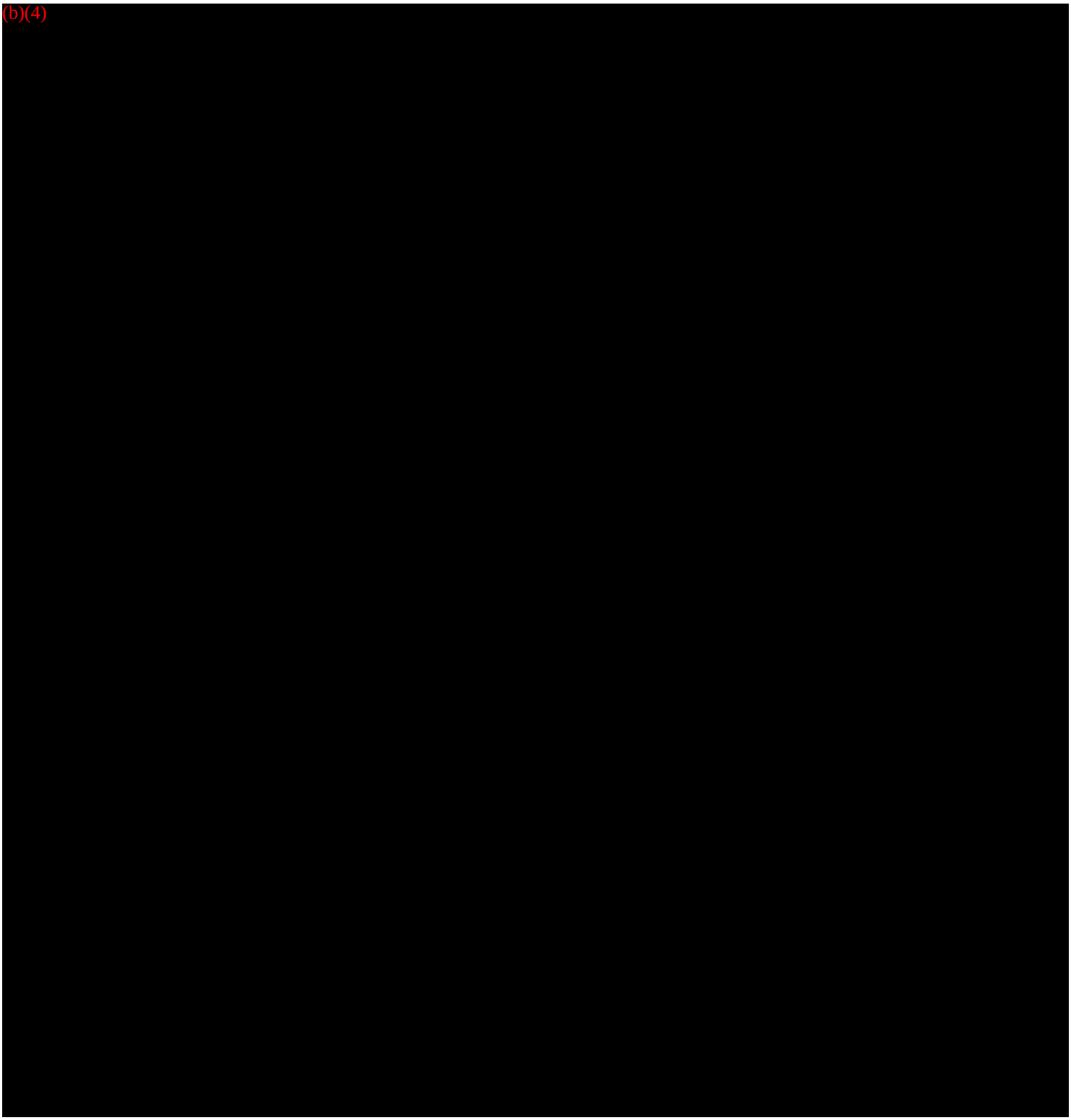
[redacted]

4.2.4.6 Verification of Reference Intervals

(b)(4)

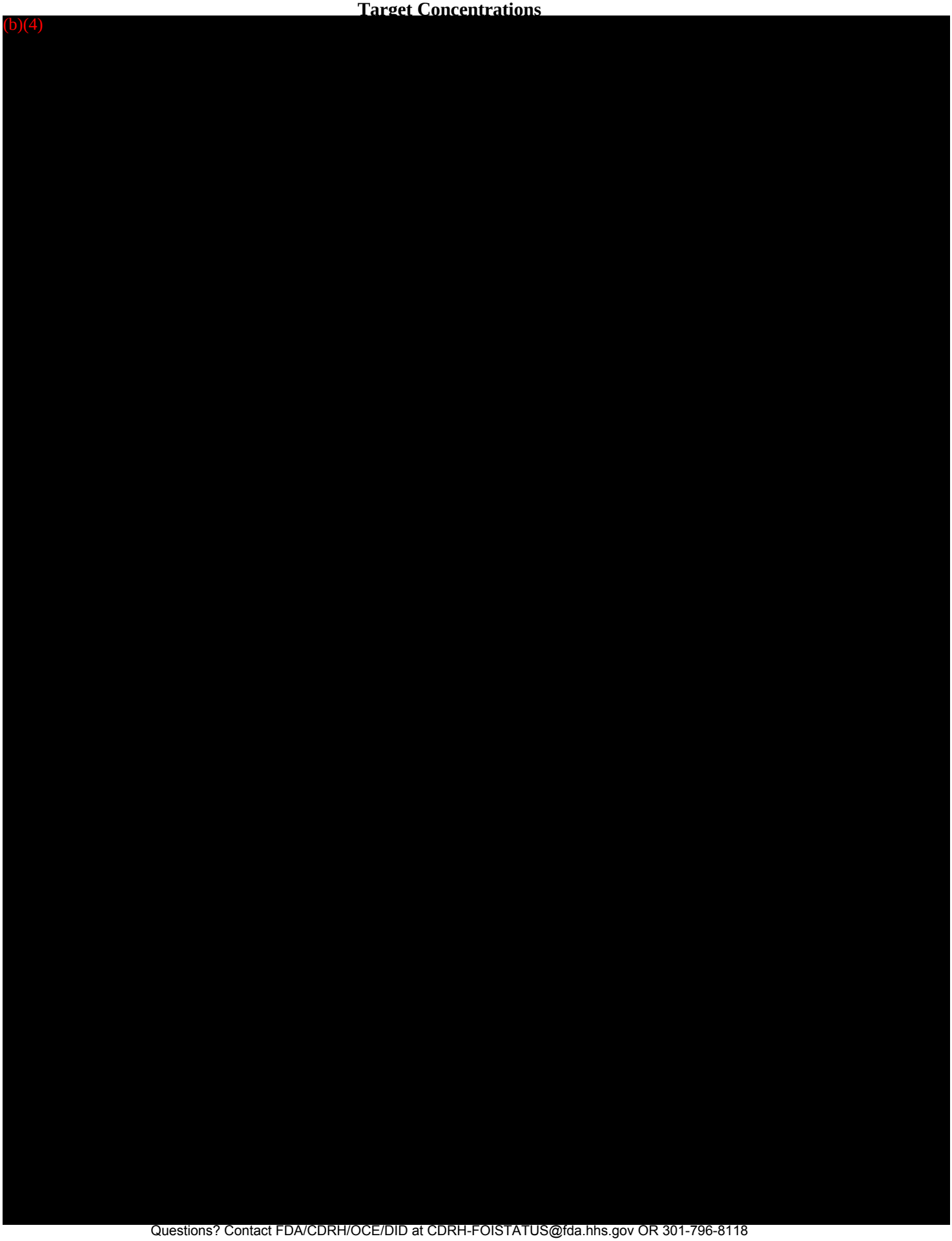
Calculation:

(b)(4)

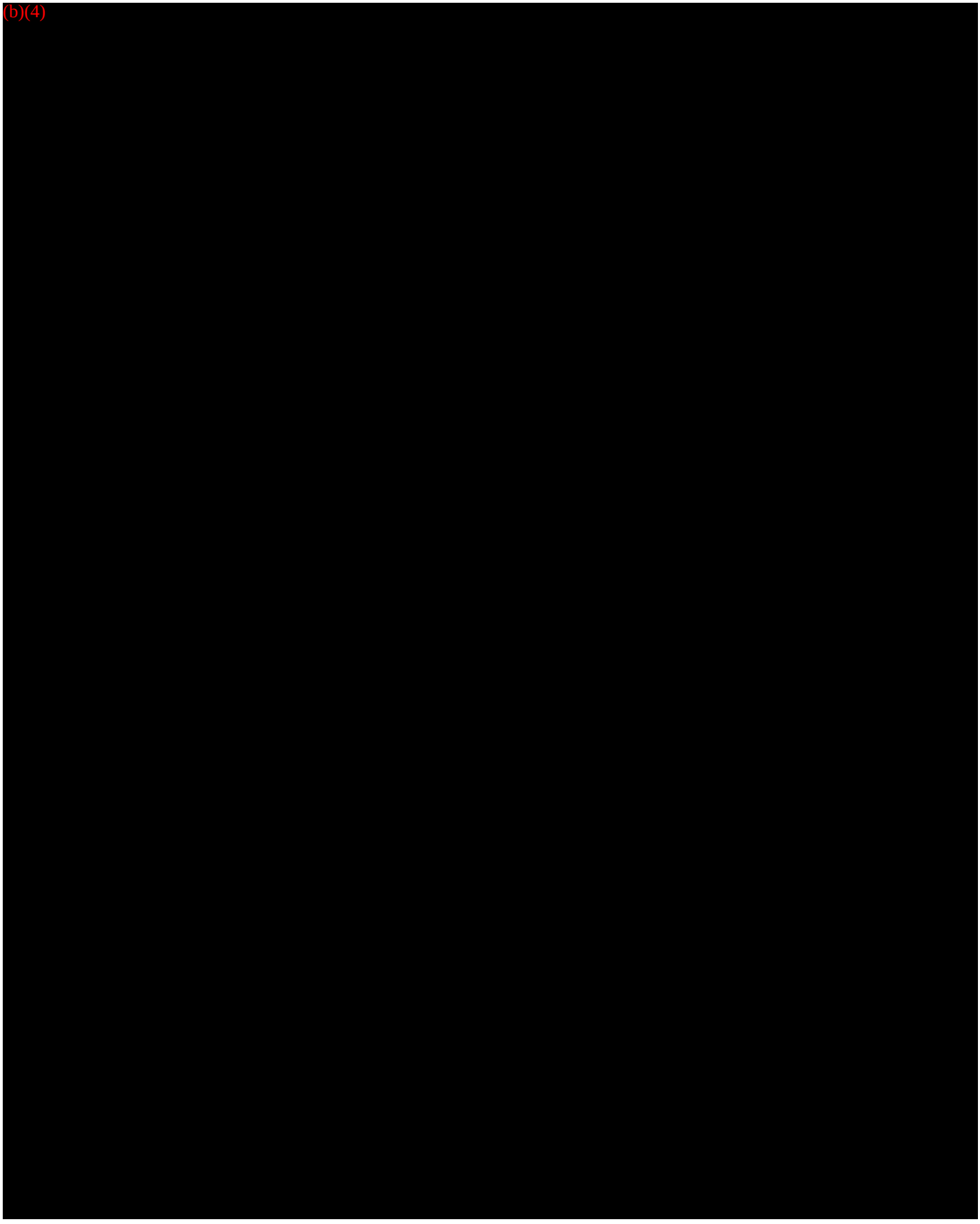


Target Concentrations

(b)(4)

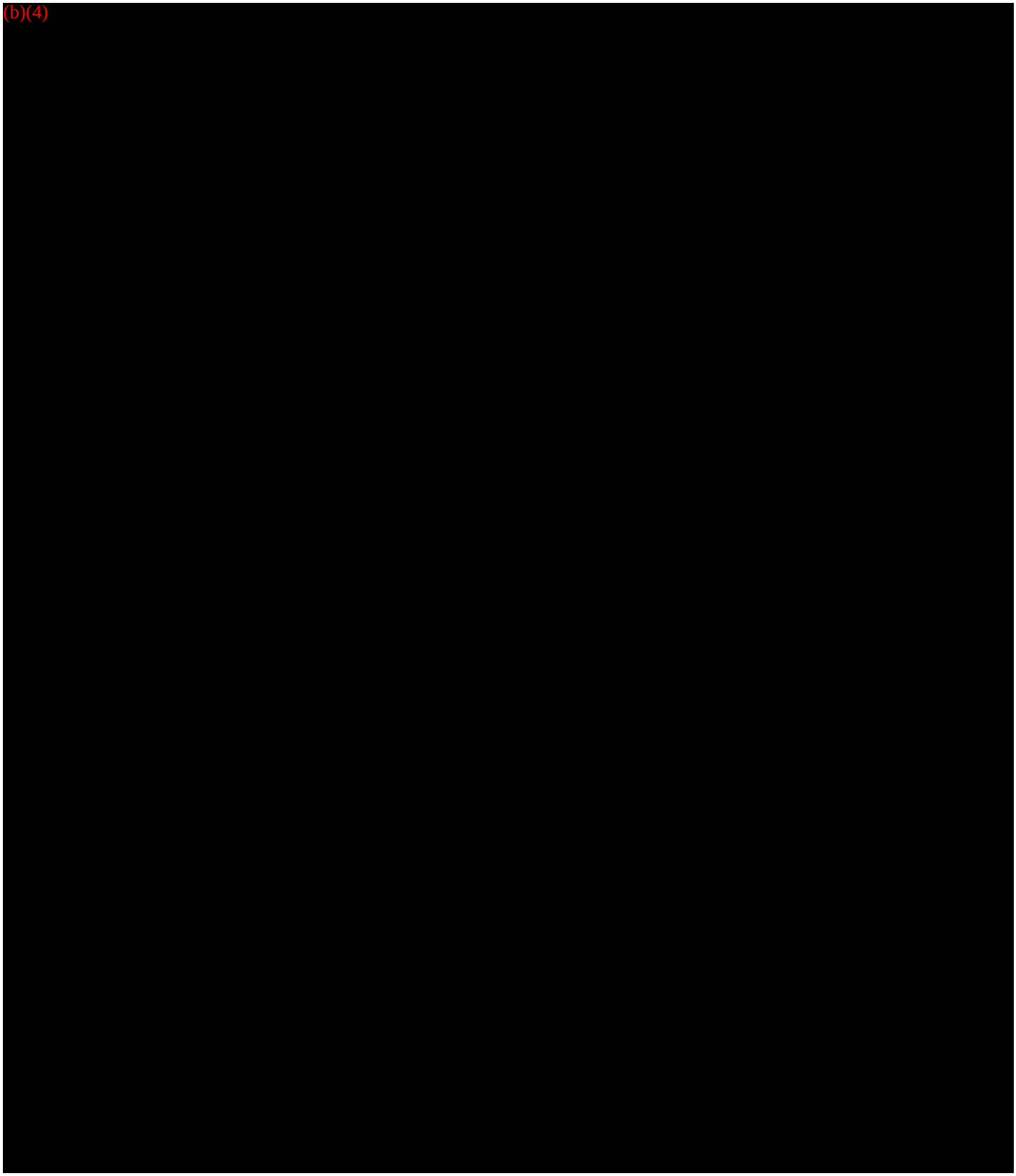


(b)(4)



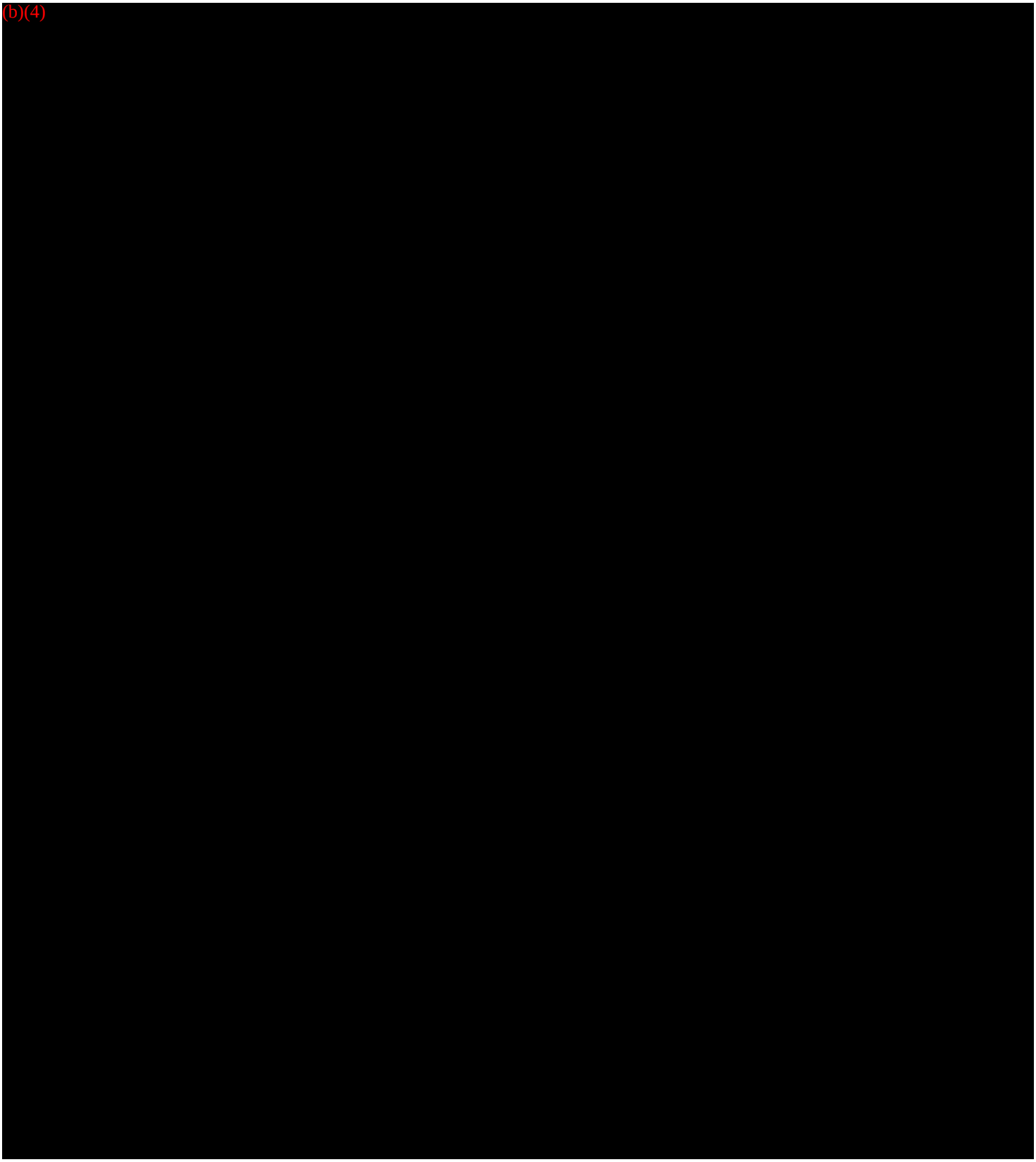
5.0 STATISTICAL PLAN

(b)(4)



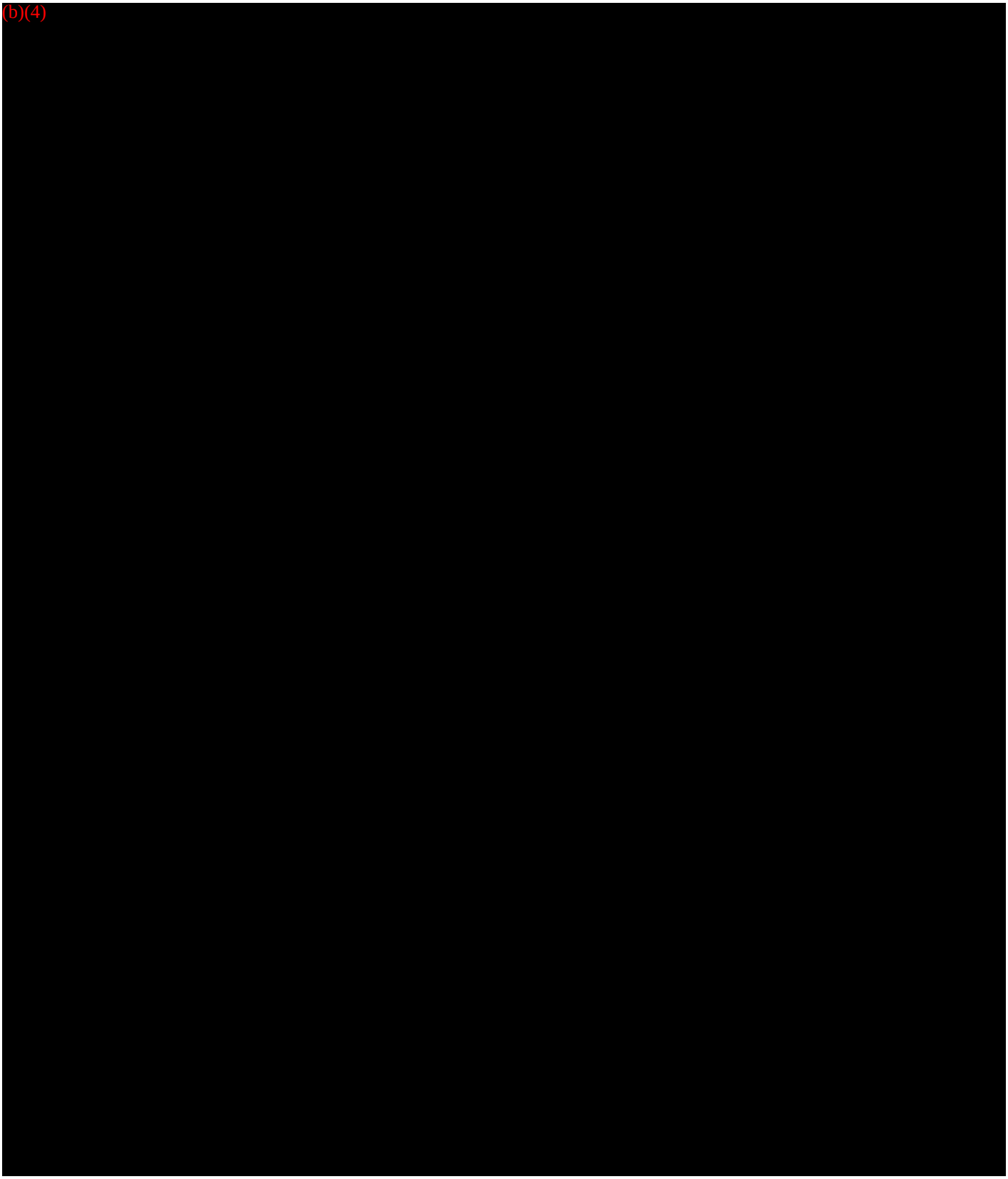
Appendix A:

(b)(4)



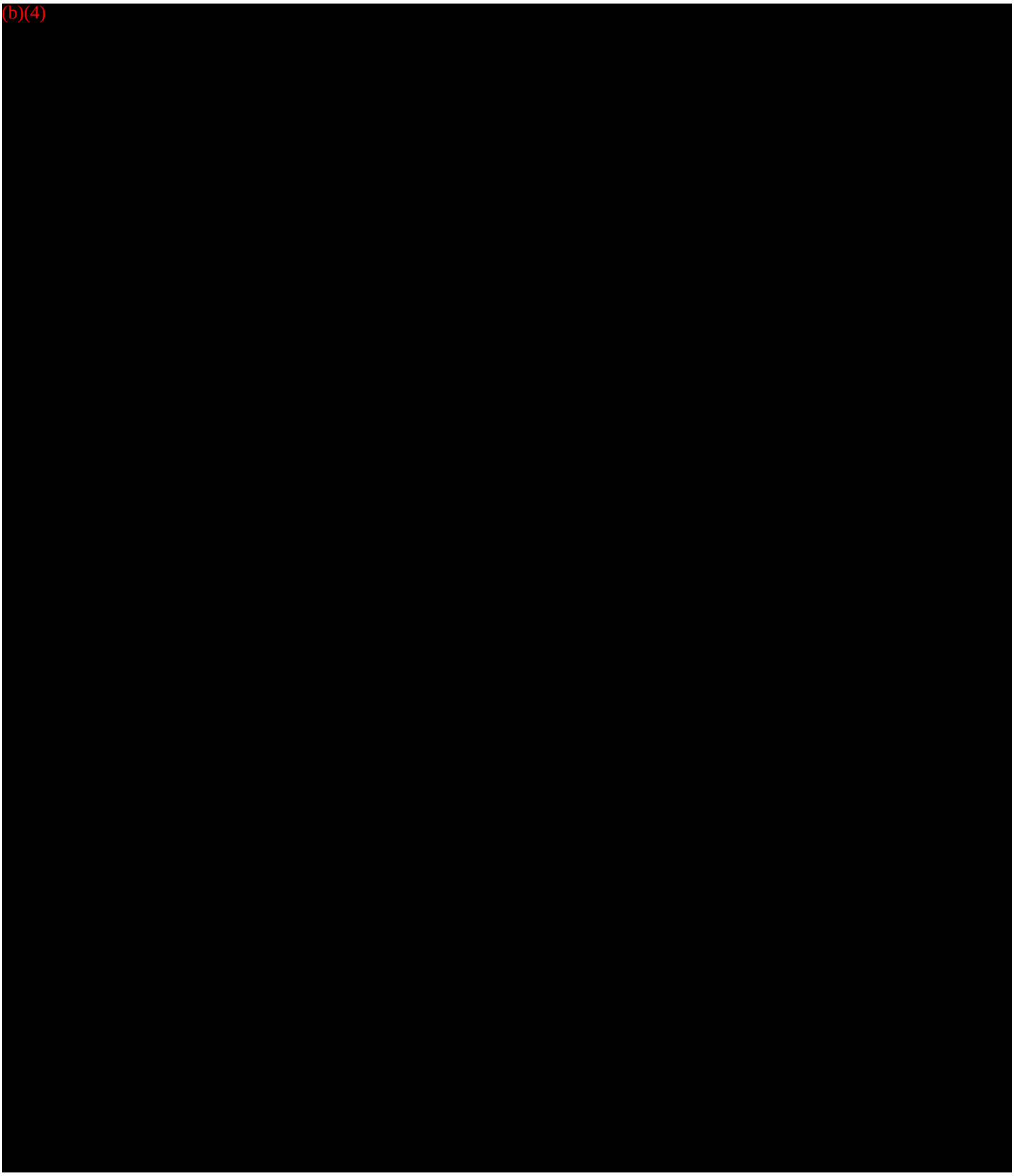
Appendix B:

(b)(4)



Appendix C:

(b)(4)



Appendix D:

(b)(4)

Protocol for Additional Studies on the XN-Series (XN-11, XN-21)
Automated Hematology Analyzers
June 2013 – June 2014

(b)(4)

Table of Contents

1.0 INTRODUCTION

(b)(4)

2.0 STUDY OBJECTIVE

(b)(4)

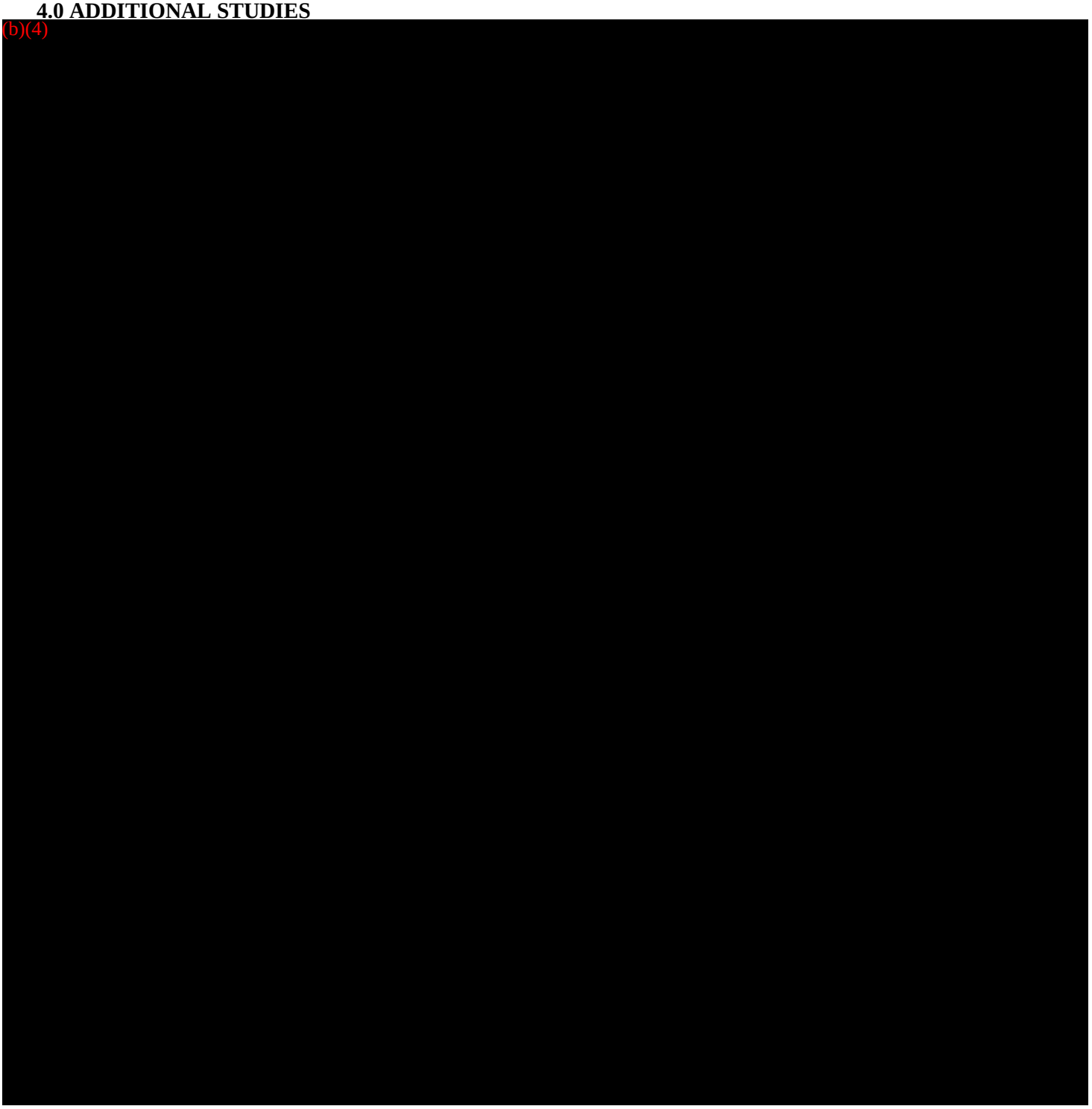
(b)(4)

3.0 INCLUSION/EXCLUSION CRITERIA

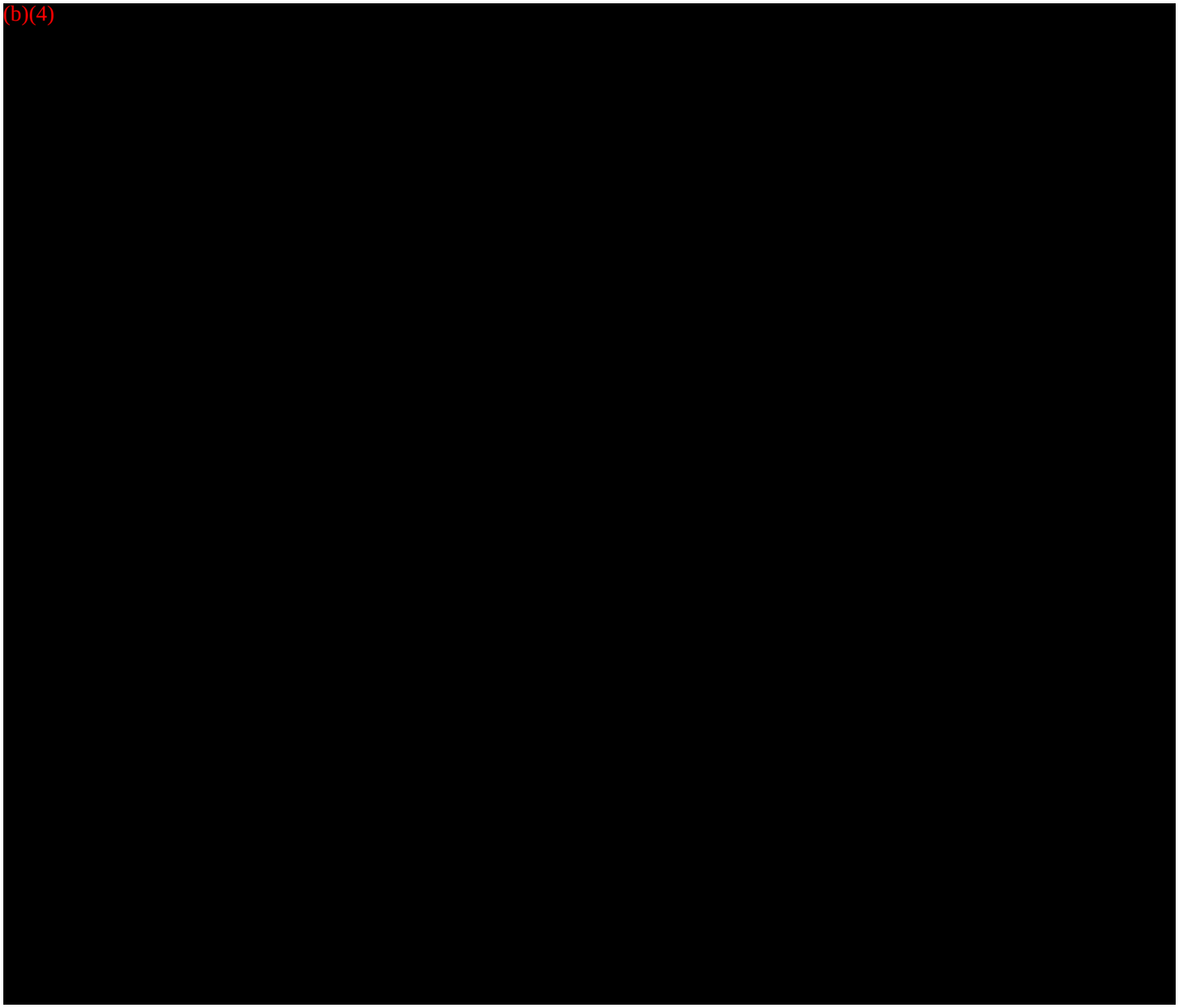
(b)(4)

4.0 ADDITIONAL STUDIES

(b)(4)



(b)(4)

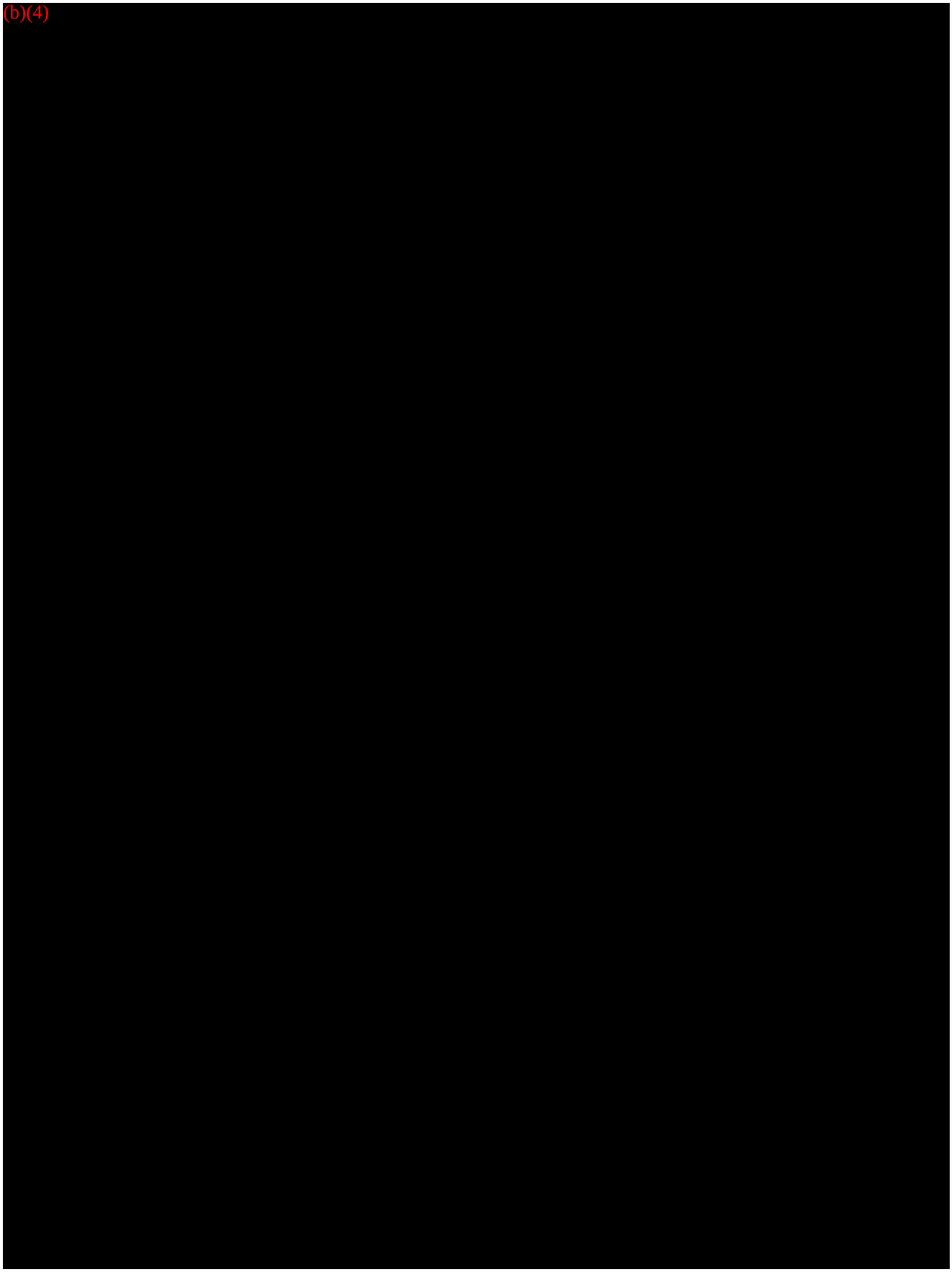


(b)(4)

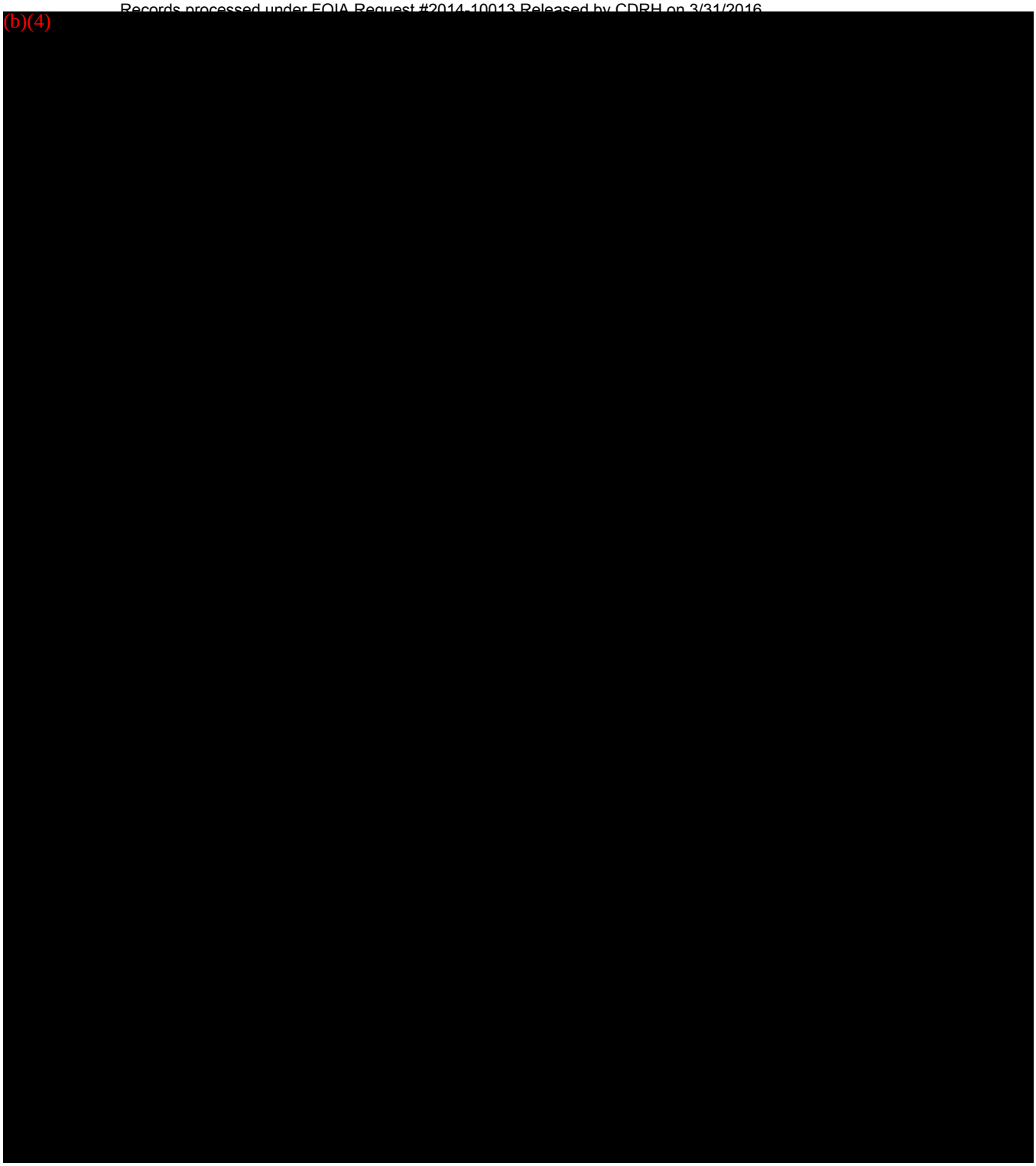
(b)(4)

(b)(4)

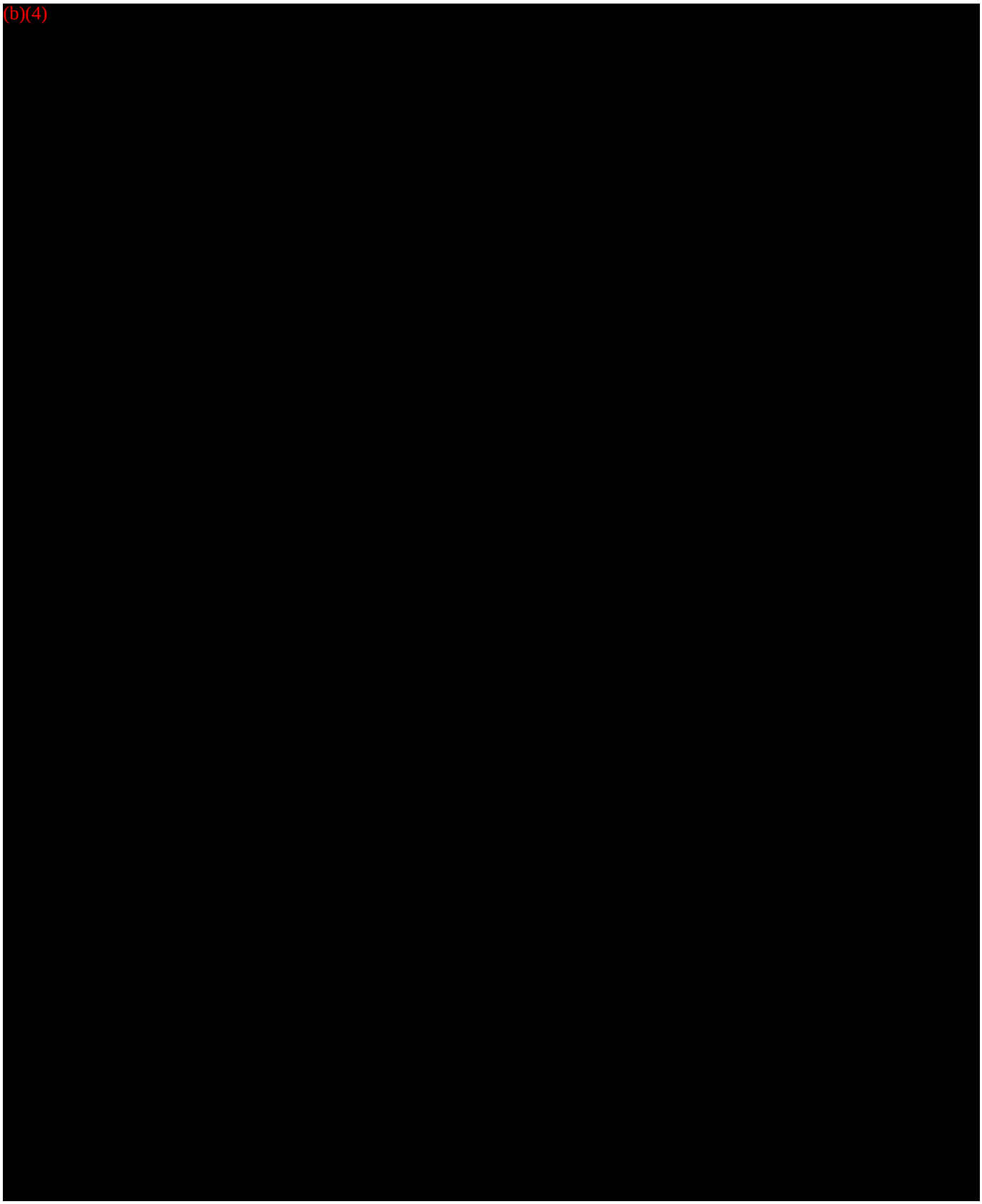
4.3 (b)(4)



(b)(4)

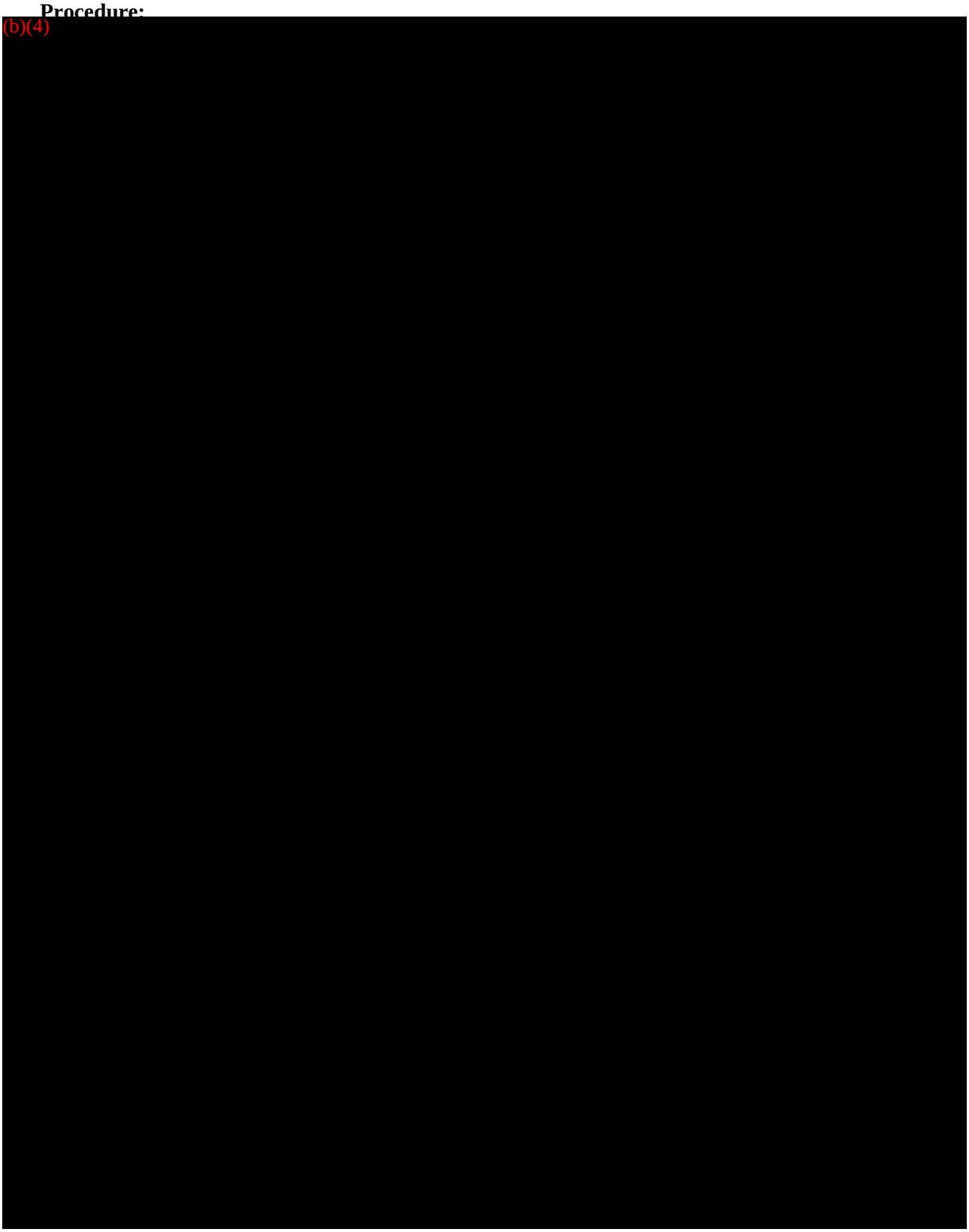


(b)(4)



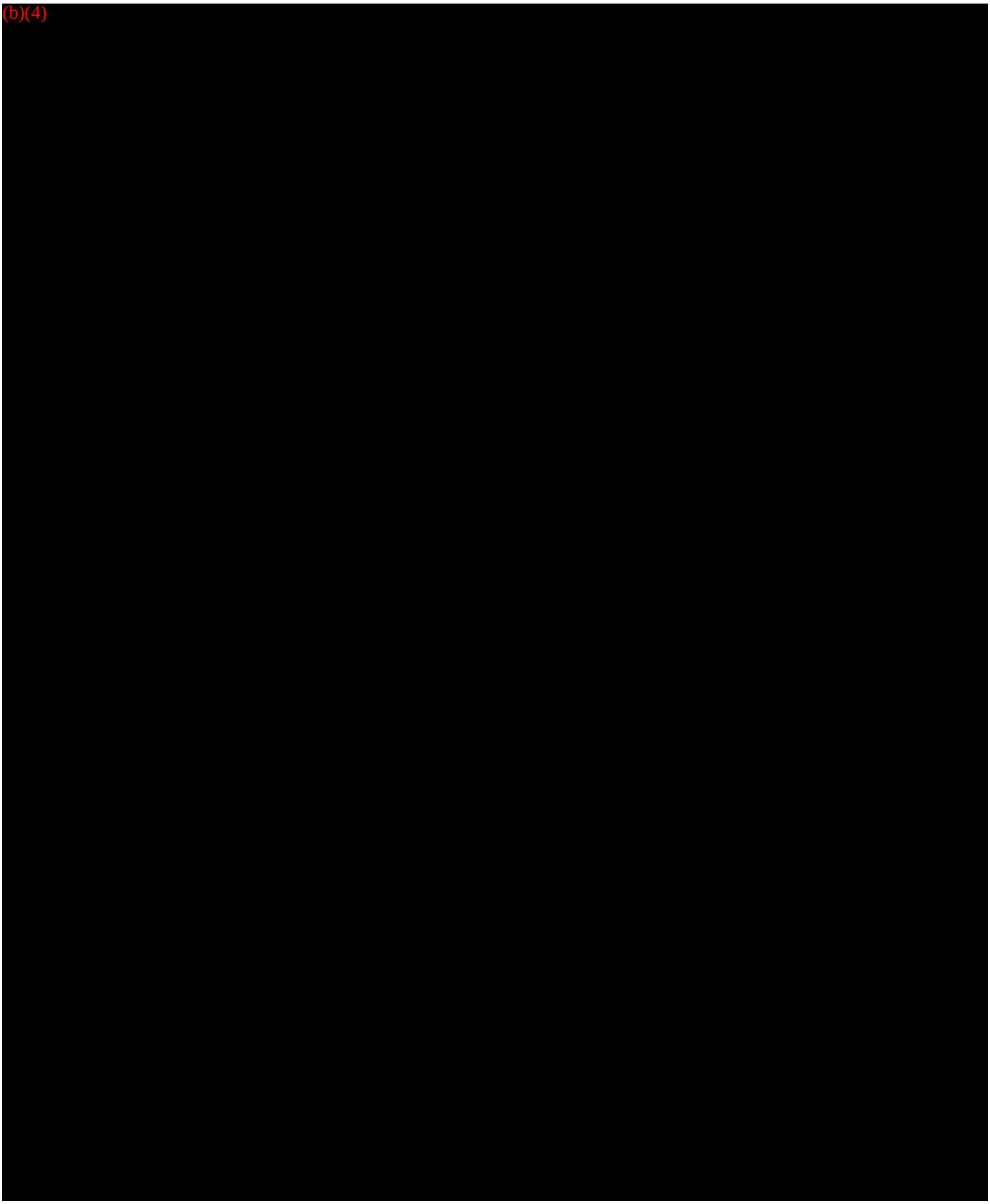
Procedure:

(b)(4)

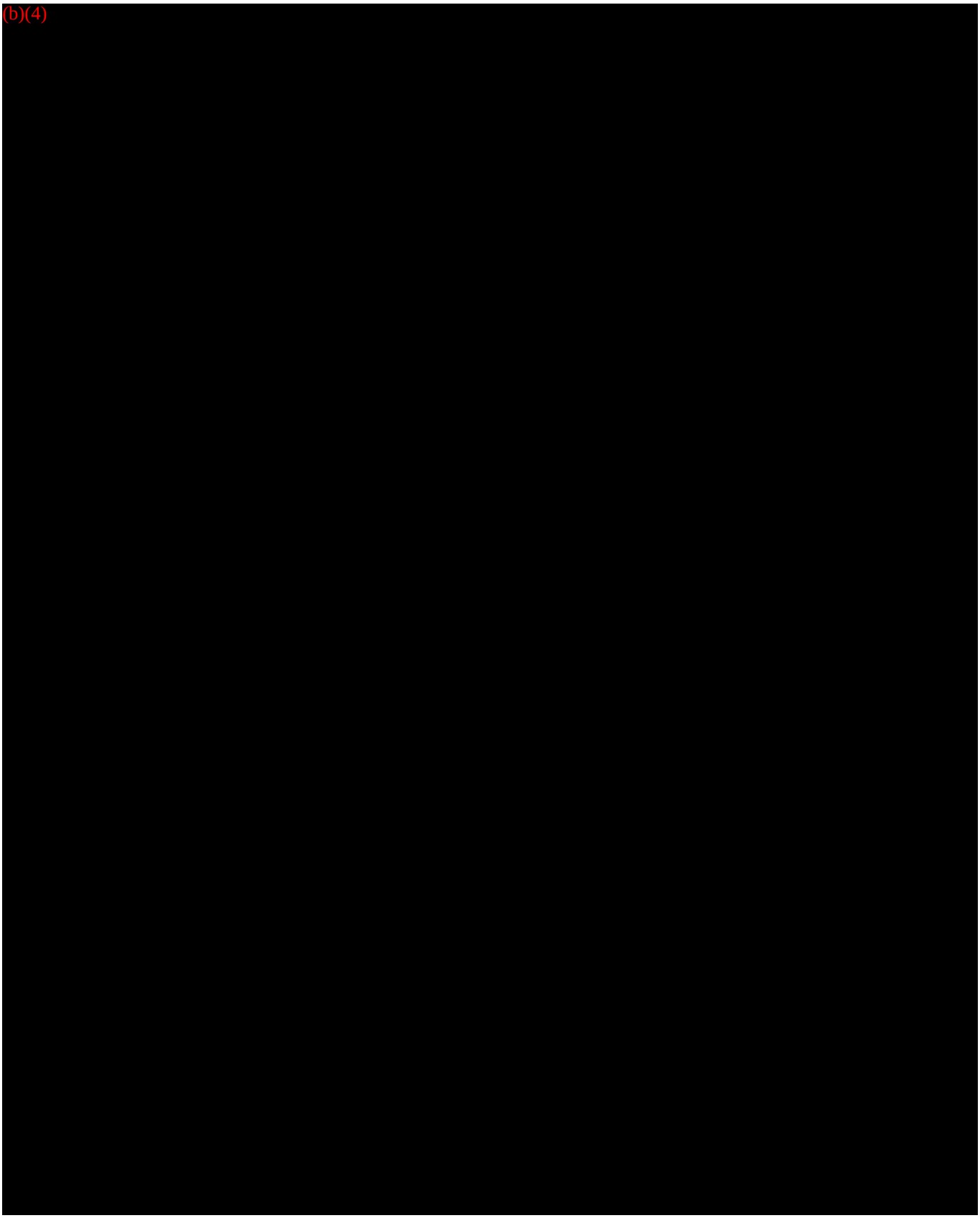


Procedures:

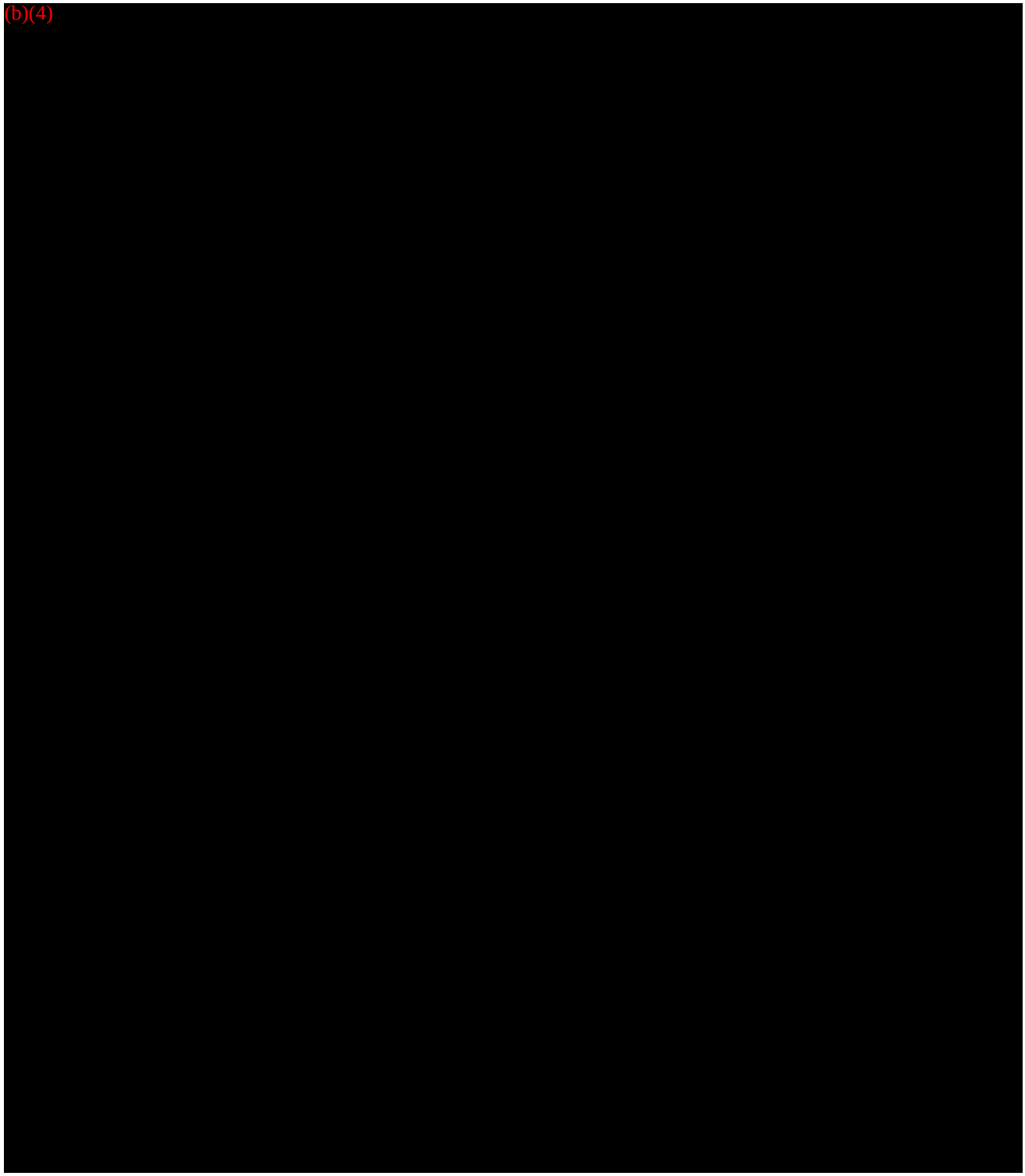
(b)(4)



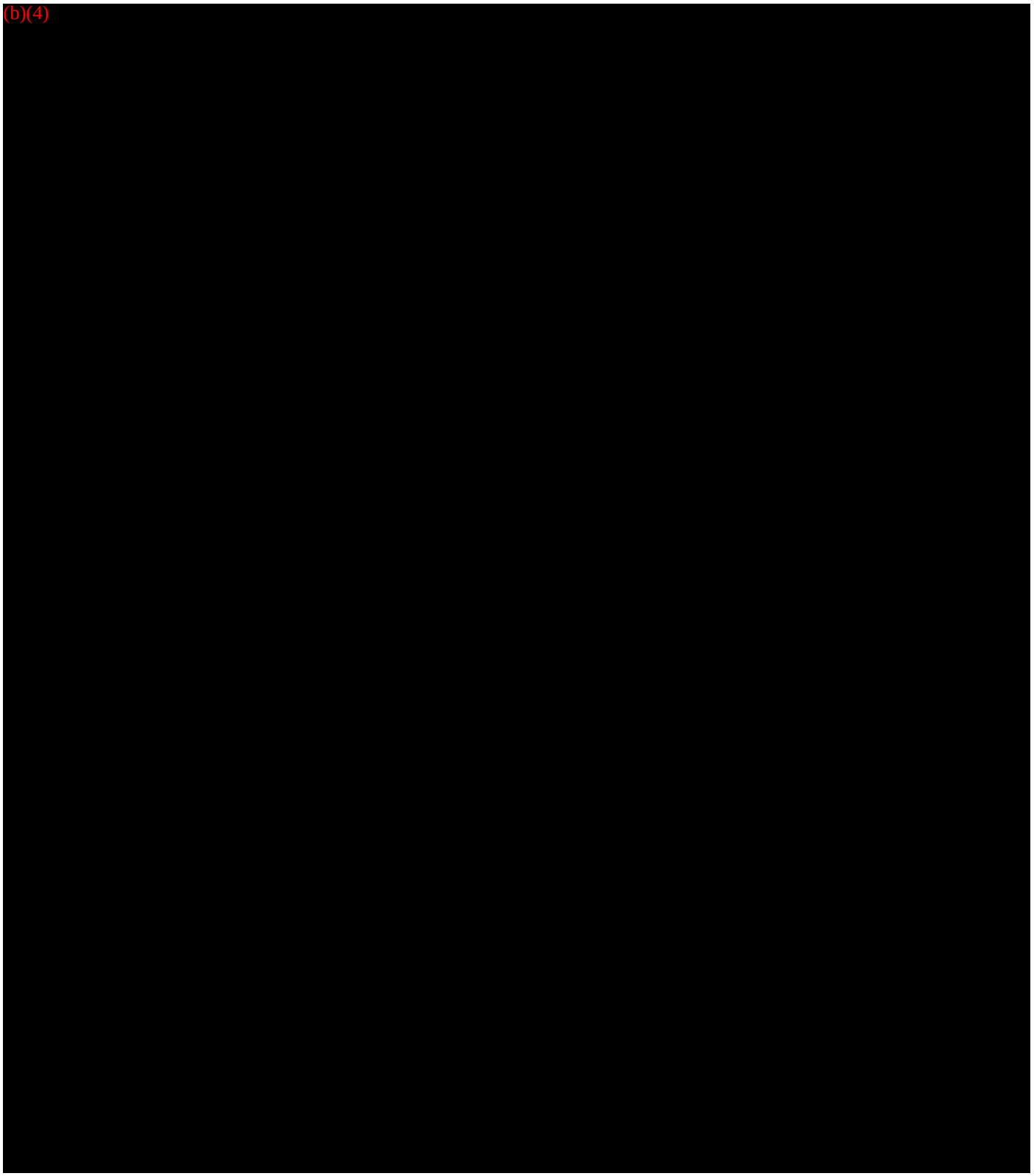
(b)(4)



(b)(4)



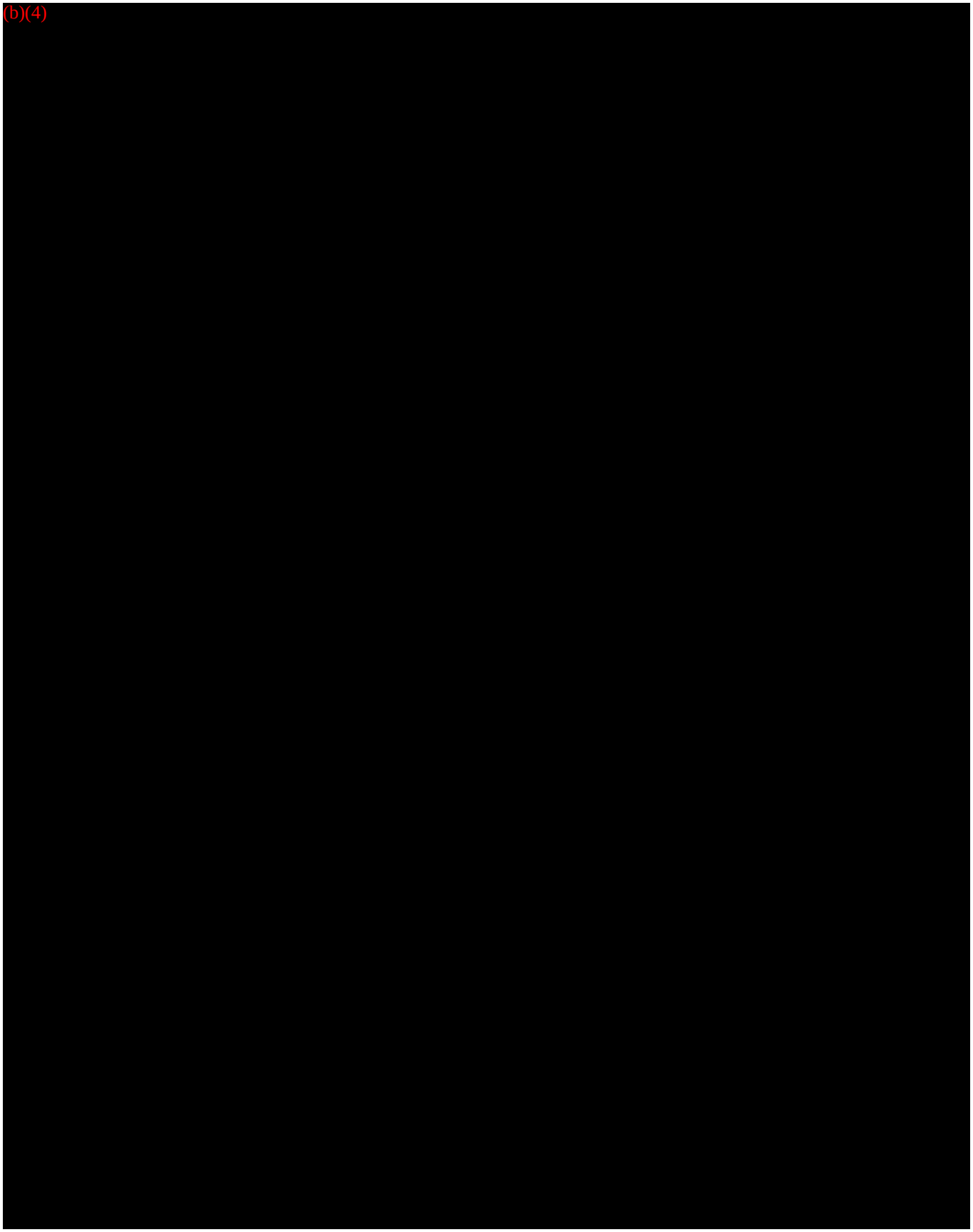
(b)(4)



4.3.2.4 Verification of Carryover Using Body Fluids

(b)(4)

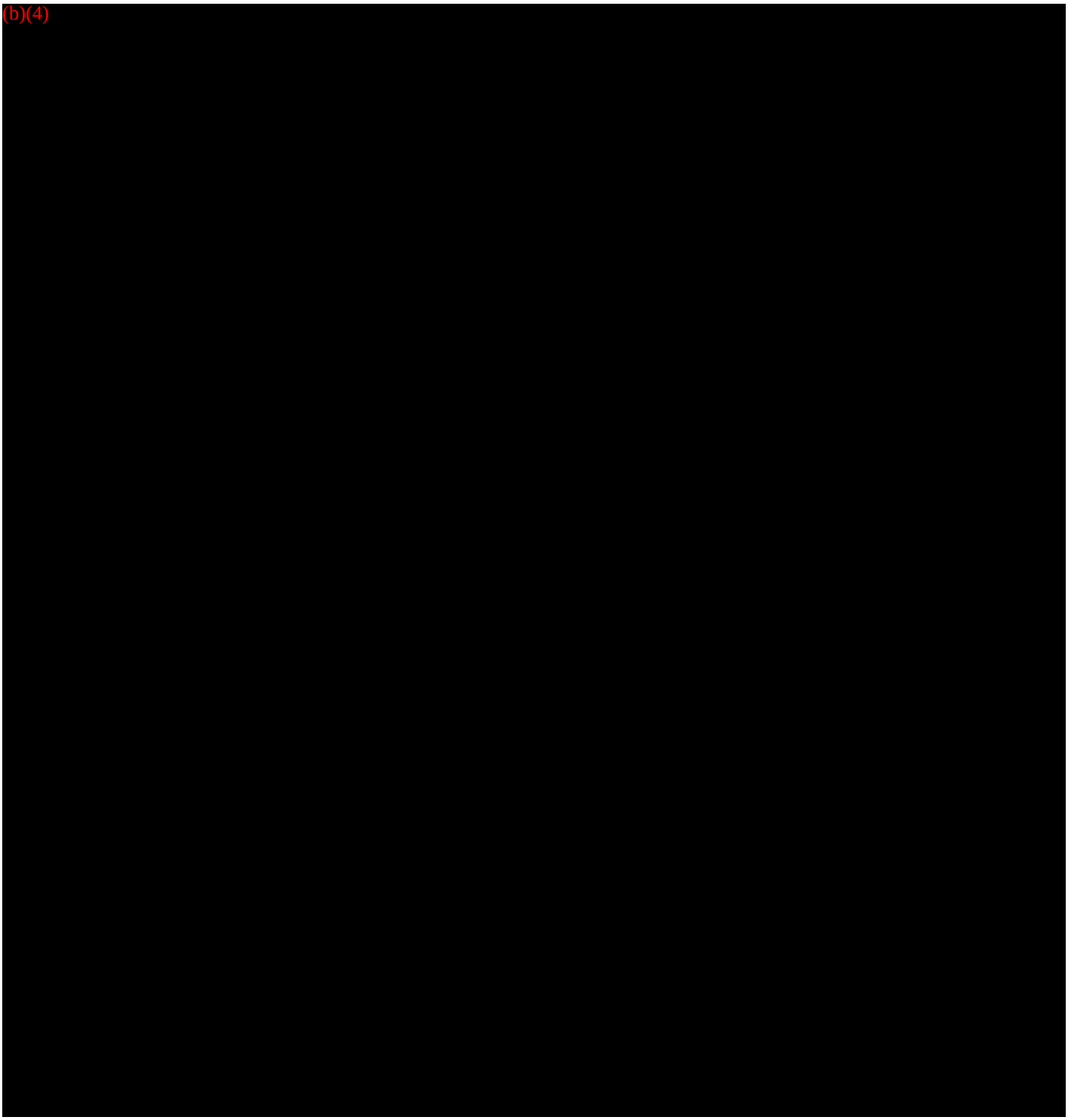
(b)(4)



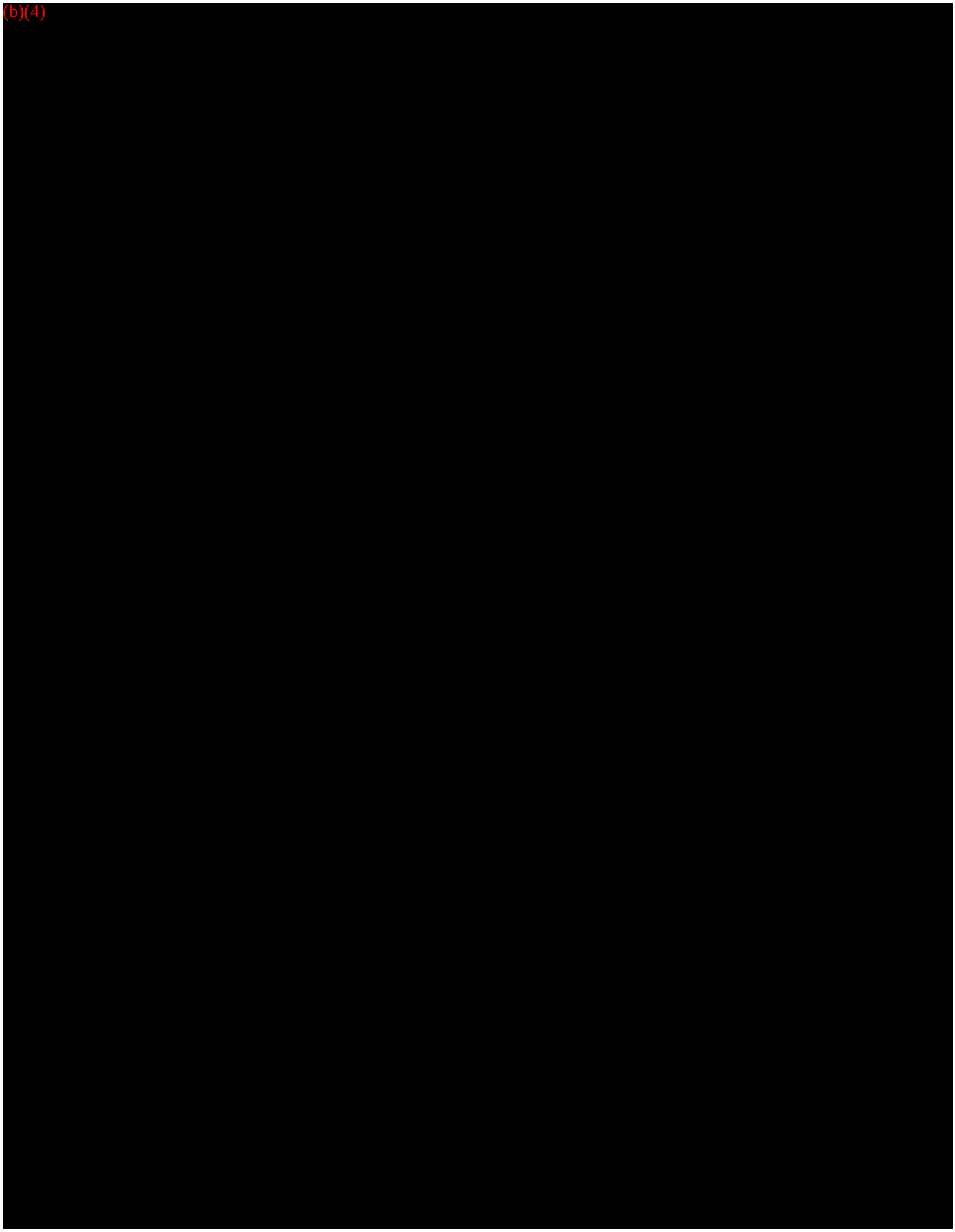
(b)(4)

Protocol for Evaluation of the XN-Series Analyzers
&
SP-10 Automated Slide Preparation /Staining Unit
When Connected

(b)(4)

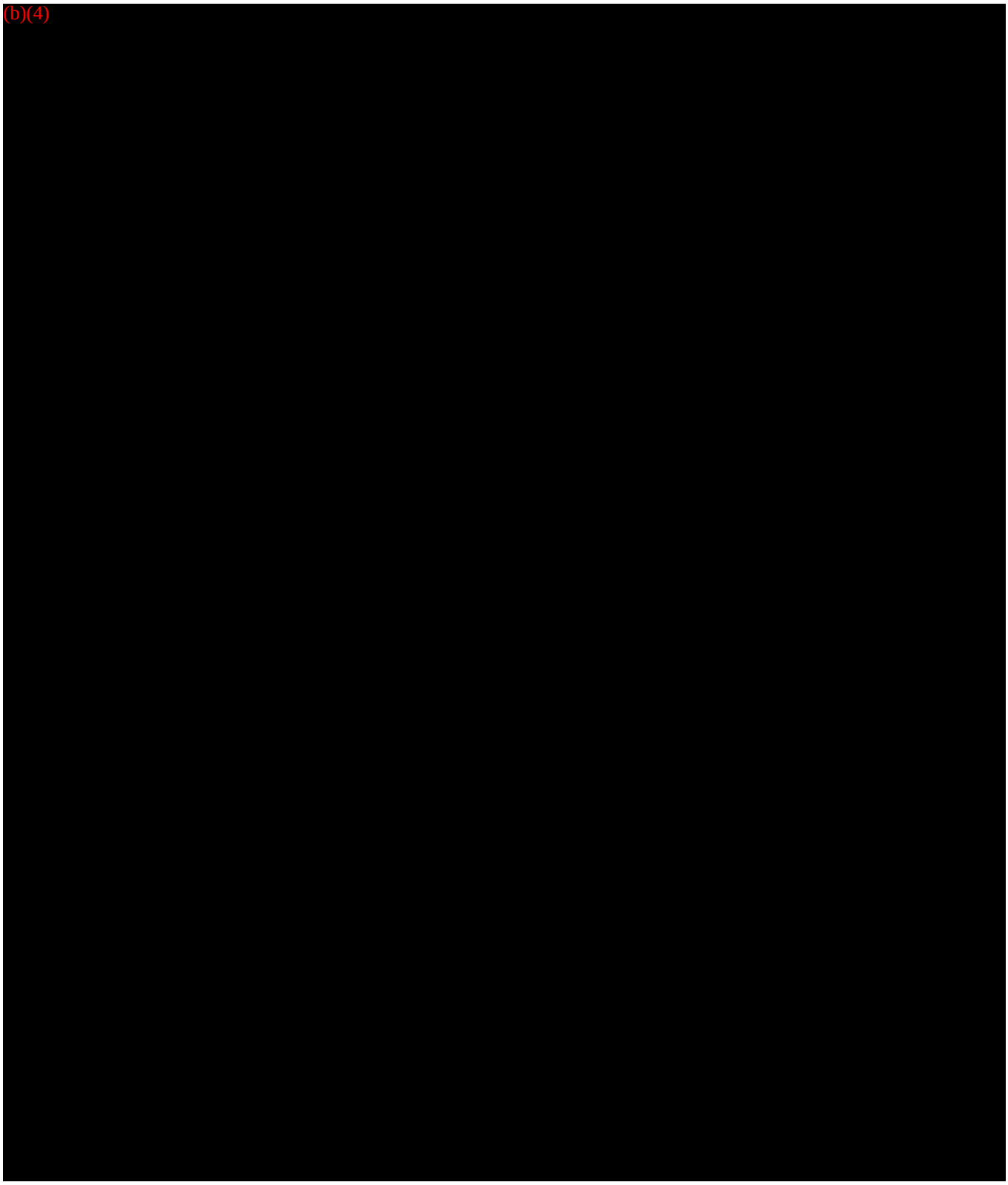


(b)(4)



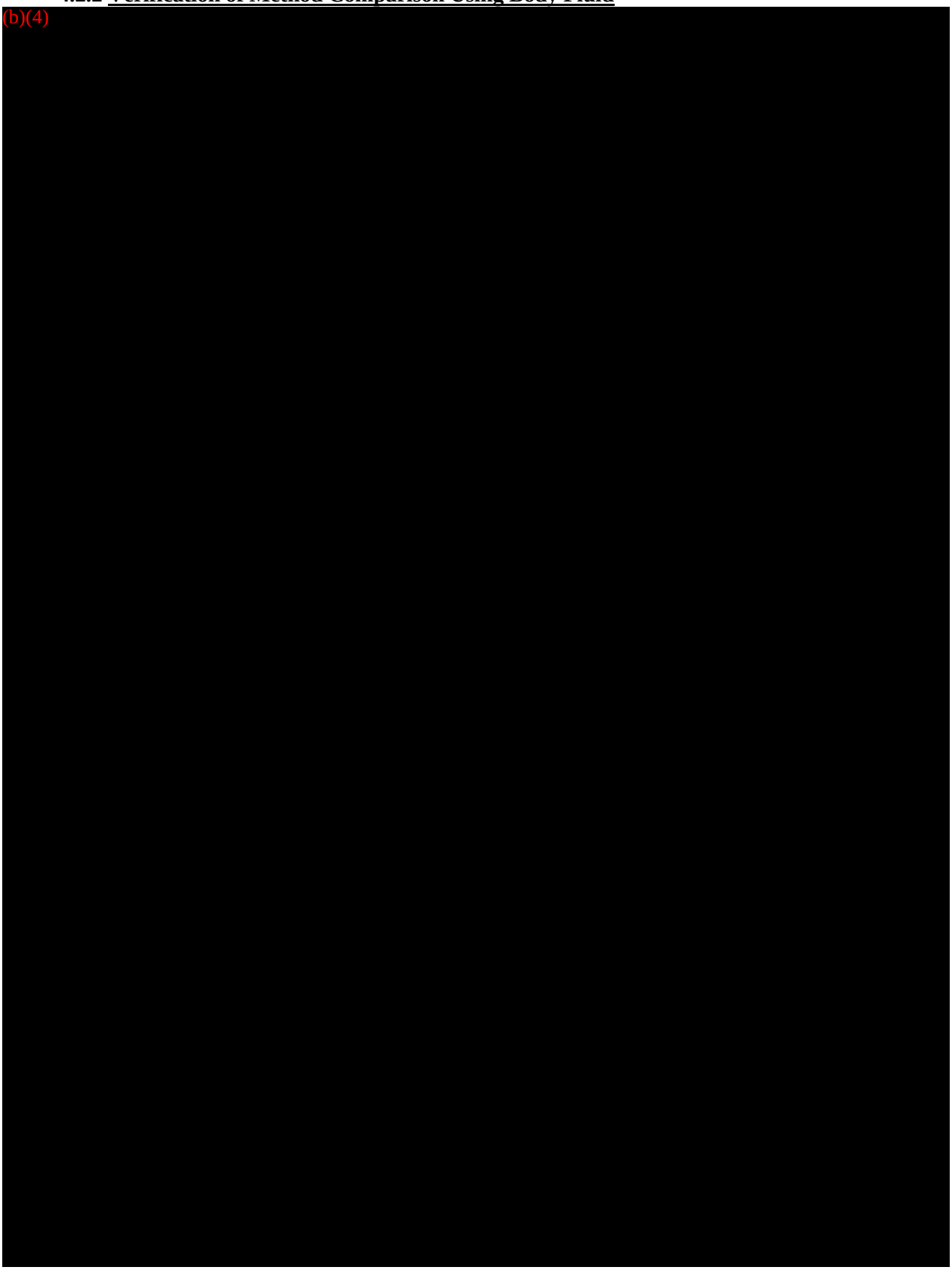
4.2 Performance Testing – XN-Series Analyzer

(b)(4)

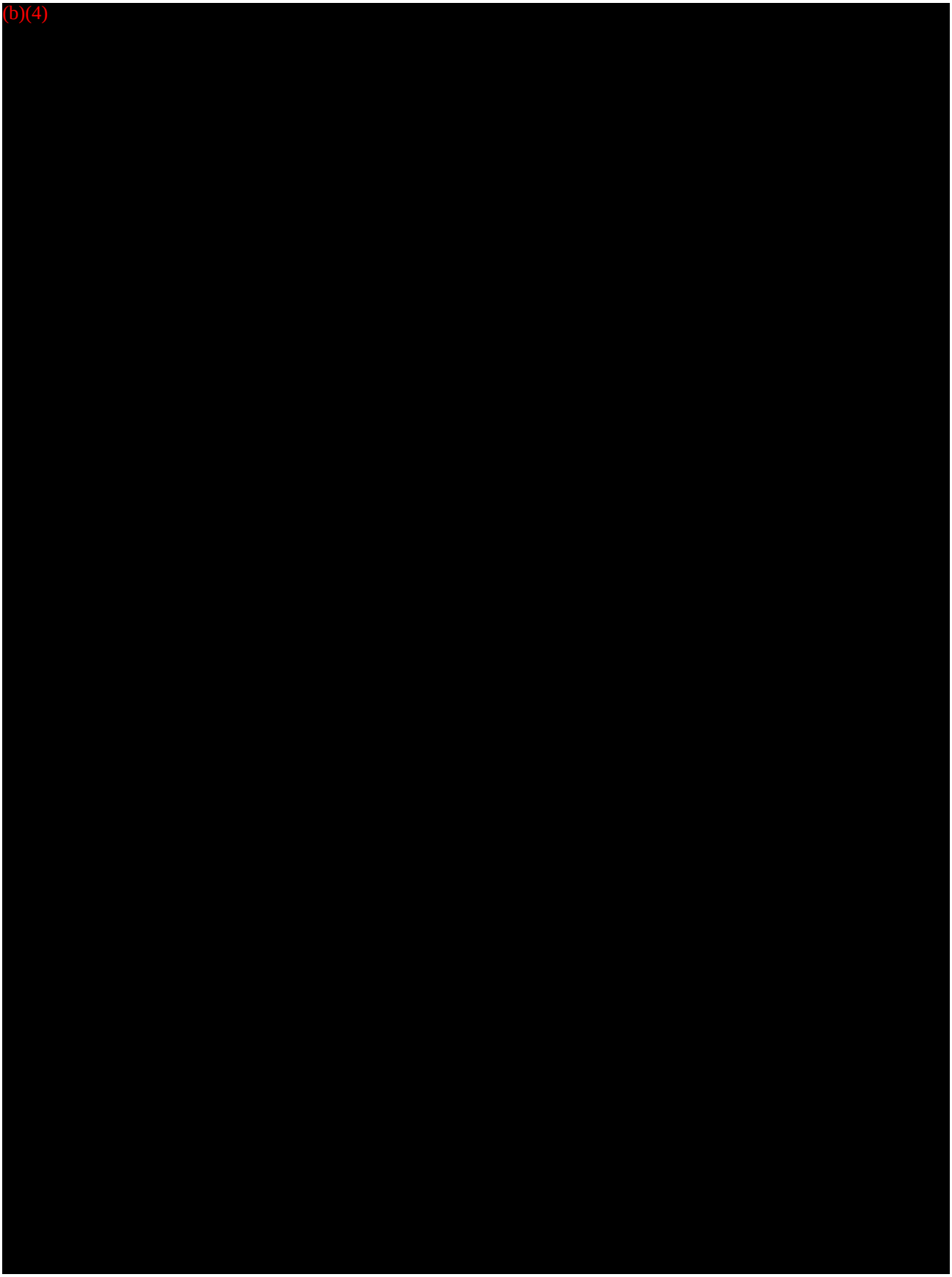


4.2.2 Verification of Method Comparison Using Body Fluid

(b)(4)

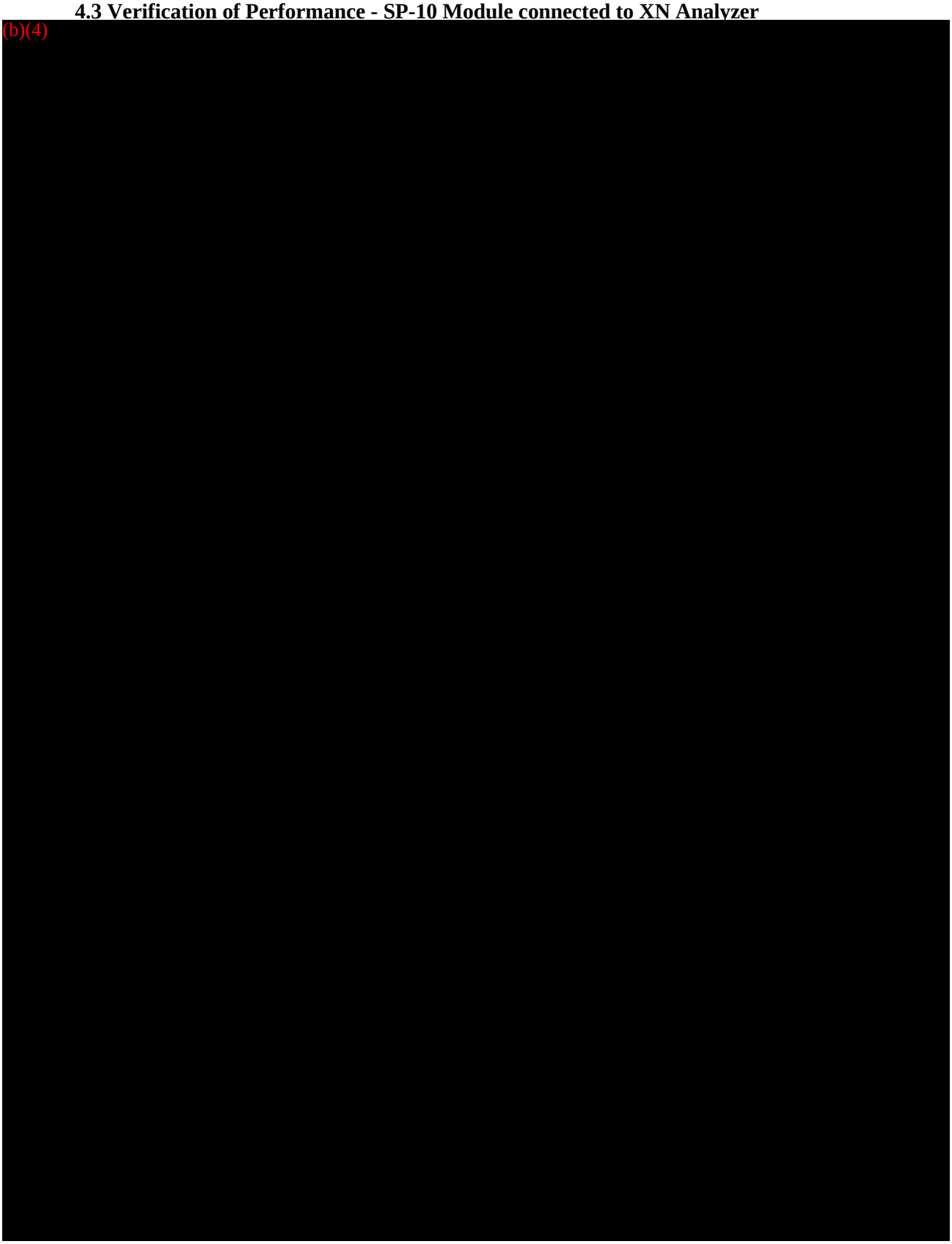


(b)(4)

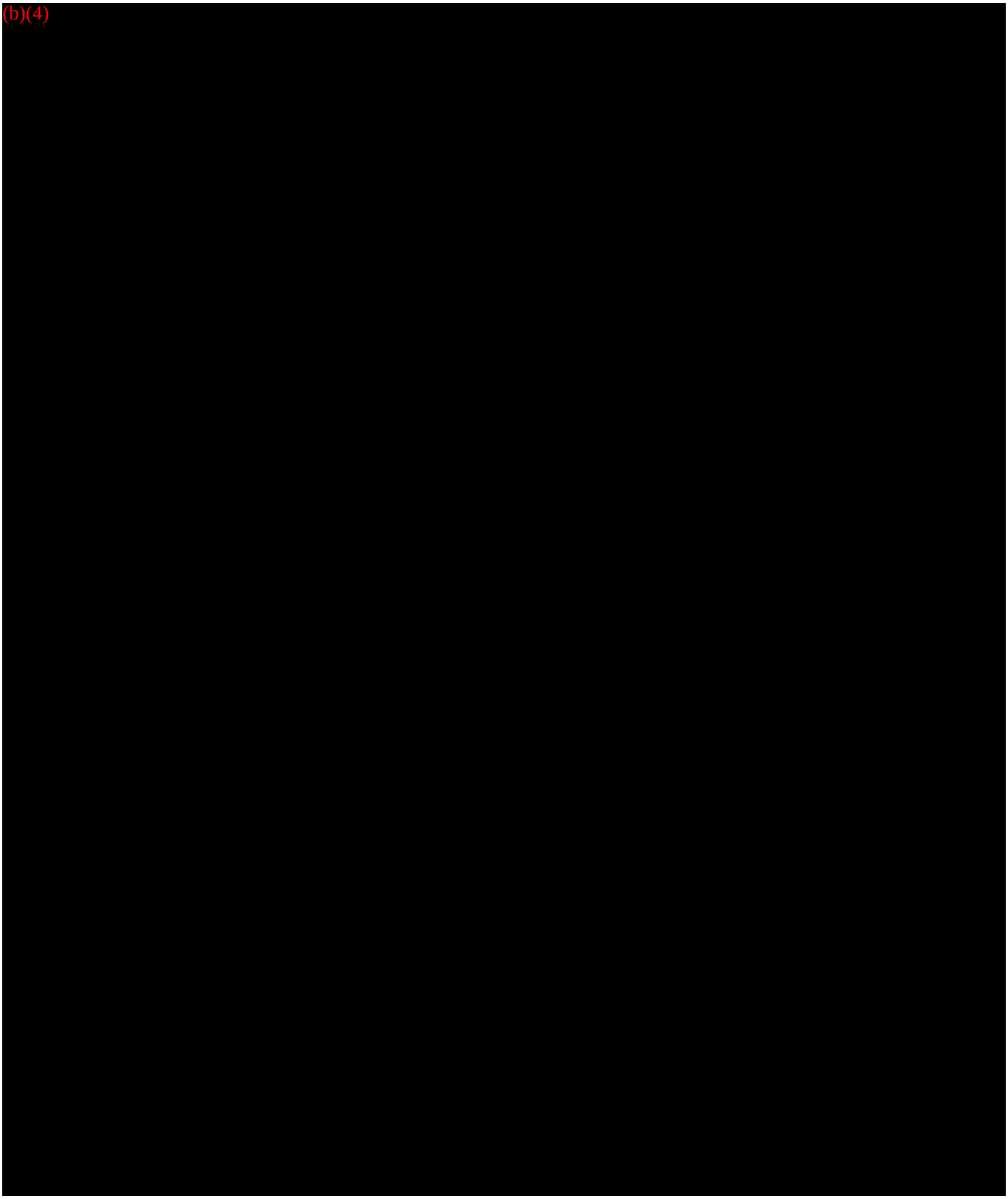


4.3 Verification of Performance - SP-10 Module connected to XN Analyzer

(b)(4)

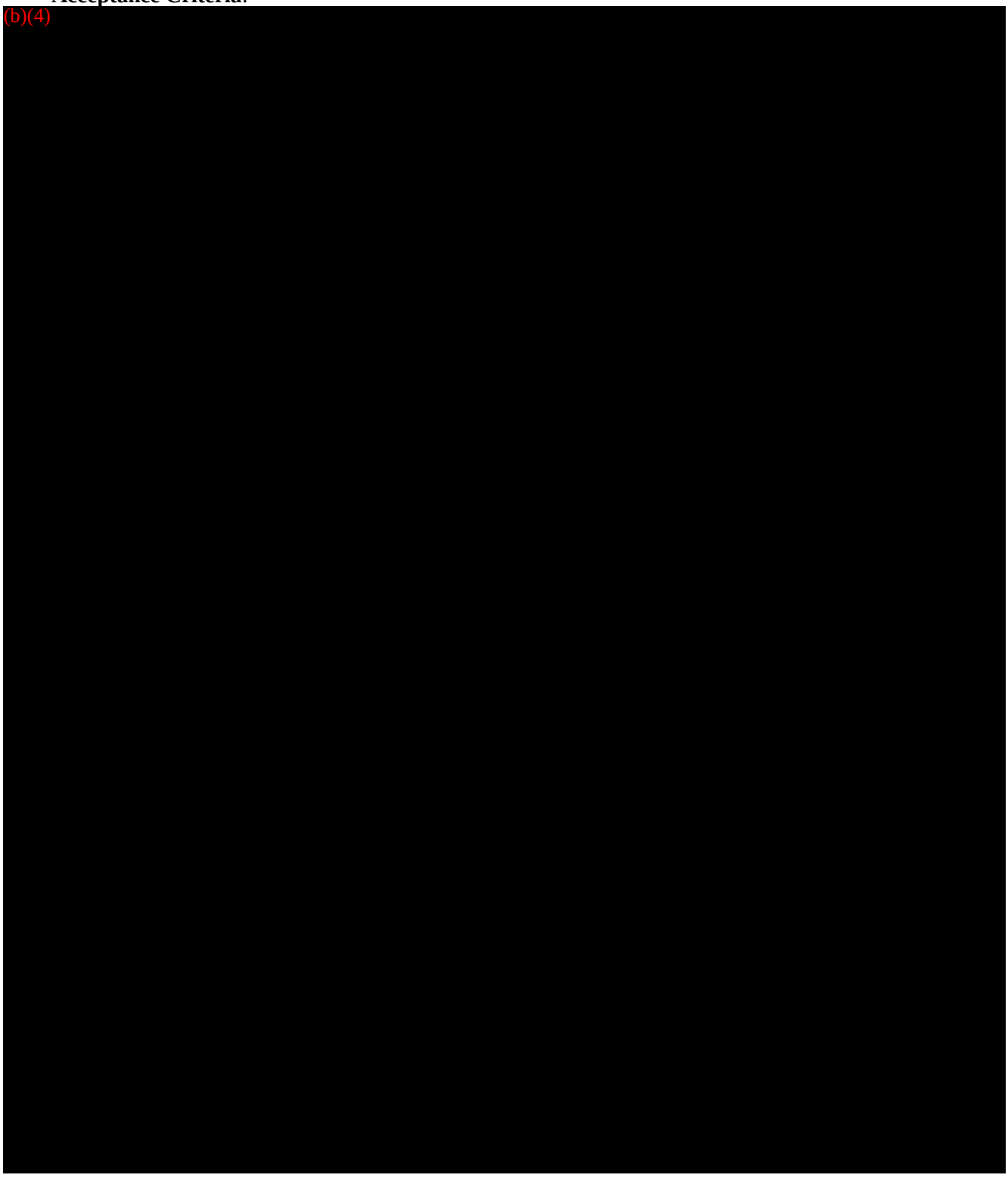


(b)(4)



Acceptance Criteria:

(b)(4)

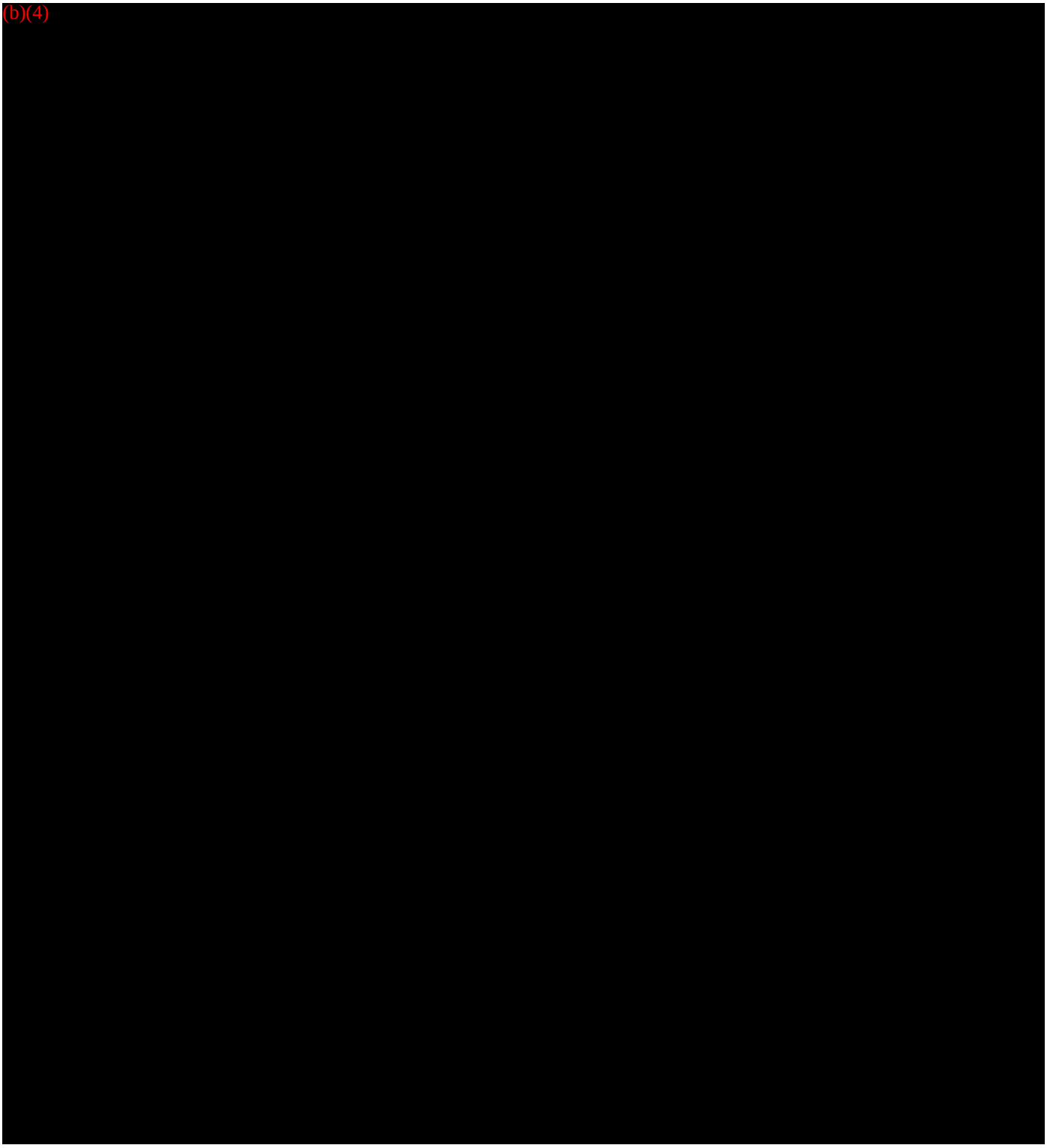


Appendix A

(b)(4)

Example B: Positive Sample

(b)(4)



21 Standards Data Report for 510(k) (Form FDA 3654)

FORM I

when c
standa

FORM FI

FORM FDA

FORM F

FORM FD

devi
wher
stanc

FORM F

FORM I

FORM F

FORM I

dev
whe
star

FORM

FORM F

FORM FI

FORM

FORM I

21 Standards Data Report for 510(k) (Form FDA 3654)

FORM I

when c
standa

FORM FI

FORM FDA

FORM F

FORM FD

devi
wher
stanc

FORM F

FORM I

FORM F

FORM I

dev
whe
star

FORM

FORM F

FORM FI

FORM

FORM I

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

(b)(4) Instructions for use manual with Instrument Drawings and Software Information

sysmex

Automated Hematology Analyzer

XN series

Administrator's Guide

(North American Edition)

Sysmex Corporation
KOBE, JAPAN

Code No. AR209147
PRINTED IN JAPAN
Date of Issue: October 2013
Software Version (IPU):
DVD1XNCD 00-11 onwards
Software Version (CT-90): 00-06 onwards

Table of Contents

Chapter 1 Introduction

Thank you for purchasing this automated hematology analyzer.

- This manual explains instrument settings and other routine operations of the hematology analyzer used in clinical laboratories.
- This manual is intended for Key administrators and operators to read, understand and use as reference for proper operations of the instrument.

> **Note:**
> Operation of instruments and devices outside of recommended manufactures guidelines may result in inaccuracies.

Contact Address

Manufacturer

SYSMEX CORPORATION
1-5-1 Wakinohama-Kaigandori Chuo-ku, Kobe, Hyogo 651-0073 JAPAN

Authorized Representative

EC REP

European Representative
SYSMEX EUROPE GmbH
Bornbarch 1 D – 22848 Norderstedt, Germany
Phone: +49 40 5 27 26-0 / Fax: +49 40 5 27 26-100

Americas

SYSMEX AMERICA, Inc.
577 Aptakisic Road, Lincolnshire, IL 60069, U.S.A.
Phone: +1-224-543-9500 / Fax: +1-224-543-9505

Asia-Pacific

SYSMEX ASIA PACIFIC PTE LTD.
9 Tampines Grande, #06-18, Singapore 528735
Phone: +65-6221-3629 / Fax: +65-6221-3687

1.1 Overview of the system

Analyzers

There are multiple types of analyzers with varying channels.

For details, see "Instruction For Use."
(➤Instruction For Use, "Chapter 1: 1.1 Intended use", "Chapter 1: 1.3 Reportable parameters.")

The analysis data appears on the screen of the IPU (Information Processing Unit)*.
* This manual refers to the Information Processing Unit as IPU.

Configuration description

System expansion is possible by combining components and options. The system name varies depending on the combination.

For details, see "Instruction For Use."
(➤Instruction For Use, "Chapter 1: 1.2.1 Configuration description.")

Note:
Please note that not all modules, configurations and parameters are available in all markets.

1.2 About the manuals

1.2.1 List of manuals

The following manuals are provided with this instrument.
Each manual is bound and included in the product; however, a manual with the same content is also built into the IPU. For procedures on viewing the manual, see "Instruction For Use."
(➤Instruction For Use, "Chapter 6: 6.8* On-line manuals")
* 6.9 in the XN-9000 manual.

- **Instructions for Use**
  This manual explains how to operate the instrument, focusing primarily on routine work.
- **Administrator's Guide (this manual)**
  This manual explains the operations, such as configuration of the instrument.
- **SP-10 Instructions for Use***
  This section explains how to operate the SP-10.
  * When using SP-10 Automated Hematology Slide Preparation Unit only.

1.2.2 Structure of this manual

This manual consists of the following chapters.

Chapter	Description
Chapter 1: Introduction	Explains this manual and precautions.
Chapter 2: Rules Setup	Explains an overview of rule and setting rules.
Chapter 3: Instrument Setup	Explains various function settings of analyzer and IPU, and system setting of transportation controller.
Chapter 4: Appendix	Explains IP message, principles of conveyor, barcode specifications, and default settings.

1.2.3 Points to note about this manual

- You may not reprint the contents of this manual in whole or in part without permission.
- The names of patients, doctors, etc., mentioned in this manual do not represent actual people in any way.
- Images and certain details related to product are for illustration purposes only and may not exactly match with what is indicated within this manuals.
- The screens used in this manual are for Windows 7.

1.3 Symbols used in this manual

Risk of infection
Indicates the presence of a biohazardous material or condition.

Warning!
High risk. Ignoring this warning could result in personal injury to the operator.

Caution!
Average risk. Ignoring this warning could result in property damage. To avoid damage and incorrect measuring results.

Information
Minor risk. Considerations that should be observed when operating this instrument.

Note:
Background information and practical tips.

Indicates that the operation supports the touchscreen.

1.4 Trademarks

- Sysmex is a registered trademark of SYSMEX CORPORATION, Japan.
- CELLPACK, CELLCLEAN, Fluorocell, SULFOLYSER, and Lysercell are trademarks of SYSMEX CORPORATION.
- ISBT128 (International Society of Blood Transfusion) is copyrighted by and is used under a license agreement with ICCBBA, Inc.
- Windows is a registered trademark of Microsoft Corporation in the U.S.A., Japan, and other countries.

Other company names and product names in this manual are the trademarks or registered trademarks of their respective owners. The fact that a trademark is not explicitly indicated in this manual does not authorize its use. TM and ® are not explicitly indicated in this manual.

1.5 Prohibited acts

- Modification, translation, reverse engineering, decompiling, and disassembly of this manual and the software is prohibited. The creation of derivative works based on this manual or the software is prohibited.
- Copying this manual or the software for purposes other than backup based on the license agreement is prohibited.

1.6 User permissions

The permissions of the logged on user may not allow that user to change settings.
Only the user permitted [All Administrators] or [Modify Settings] can change the setting of the various function.
For the details on user permissions, see Chapter 3.
(➤**P.3-30** "Chapter 3: Change settings and add users")

Chapter 2 Rules Setup

This chapter explains the procedures for setting rules to have the analyzer automatically perform a subsequent operation based on the results of the first analysis.

2.1 Types of rules

Rules

Rules can only be displayed and set for the [Built-in User] registered at the factory.
The analysis data are judged by setting rules. The results of judgment can be reviewed in the [Sample Explorer] and [Data Browser] screens. Up to 100 rules can be setup for each condition indicated below*.
A rule-based judgment is performed on the results of the first analysis. A rule-based judgment of the results of the first analysis is performed. Based on the result of the rule-based judgment, [Repeat] analysis, [Rerun] analysis, [Reflex] analysis, comment adding, smear preparation ([SP Rule] judgment), validation, or output is performed. [Repeat], [Rerun], and [Reflex] judgments will be performed for the second analysis results, but not for the third analysis results.

* Registering are possible for [Rerun/Reflex/Comment Rule], [SP Rule], [Validation Rule] or [Output Rule].

Analysis

[Repeat] analysis:	Repeats the first analysis.
[Rerun] analysis:	Repeats analysis of a sample while holding the results of the first analysis.
[Reflex] analysis:	Tests additional parameters due to the results of the first analysis.

Information

If you desire a rule change, registration, deletion or copy, contact Sysmex representative.

Note:

The rules are not applied to the results of analysis for maintenance (QC), analysis of sample number "0", and analysis that resulted in a barcode reader read error.

In the XN series, the following 5 types of rules can be set.

2.1.1 Repeat rule

[Repeat] means to do [Repeat] analysis if an error occurs in the first analysis*.
If an error occurs in the first analysis, a [Repeat] analysis is performed automatically. A [Repeat] rule is set for each error message. The settings can be checked in the rule setting area of the [Repeat Rule] screen.
(➤**P.2-7** "Repeat Rule")
[Repeat] judgment is only performed when the analyzer setting is ON. For the details, see Chapter 3.
(➤**P.3-12** "Chapter 3: Repeat setting")
* When the sampler (SA-01) is used, analysis is not performed. Only rule judgment is performed.

e.g.	Error message:	[0.25 MPa pressure error]
	Action:	[Repeat]
	Explanation:	If a [0.25 MPa pressure error] occurs, a [Repeat] analysis is automatically performed.

For a list of error messages, refer to the "Instruction For Use"*.
(➤Instruction For Use, "Chapter 14: 14.2 Error message list")
* The error messages below are [BlockRepeat (Fixed)], and are not displayed in the screen.
- [41°C reagent heater thermistor error]
- [34°C reagent heater thermistor error]
- [41°C FCM reaction chamber thermistor error]
- [34°C FCM reaction chamber thermistor error]
- [FCM detector thermistor error]
- [FCM sheath thermistor error]
- [Environment temperature thermistor error]
- [APD thermistor error]
- [Laser output error]

2.1.2 Rerun/Reflex/Comment rule

The result of the first analysis is judged, and a [Rerun] analysis, [Reflex] analysis, or addition of a comment is automatically performed. You can set the judgment conditions for [Rerun] analysis, [Reflex] analysis, and comments.[Rerun/Reflex/Comment Rule] do not function if an error occurs in the first analysis.
[Rerun] judgment and [Reflex] judgment are only performed when the analyzer setting is ON. For the details, see Chapter 3.
(➤**P.3-12** "Chapter 3: Rerun/Reflex setting")

Rerun

[Rerun] is used to judge the analysis result and automatically rerun the test*.
The result of the first analysis is judged, and a [Rerun] analysis is automatically performed. When there are multiple analyzers, you can specify which analyzer is used to perform [Rerun] analysis. However, if the specified analyzer does not have the [Rerun] analysis function, [Rerun] analysis is performed using the same analyzer as the initial analysis. You can set the judgment condition under which a [Rerun] analysis is performed.
* When the sampler (SA-01) is used, analysis is not performed. Only rule judgment is performed.

e.g.	Conditional Expression:	[IPMessage]([RBC Abn Distribution])[OR][IPMessage]([Dimorphic Population])
	Action:	[Rerun]([SameModule])
	Explanation:	If the judgment displays an IP message [RBC Abn Distribution] (RBC abnormal distribution) or [Dimorphic Population], [Rerun] analysis is performed automatically using the same analyzer as the initial analysis.

Reflex

[Reflex] is a setting that is used to judge analysis results and automatically perform analysis with additional discrete items not analyzed in the initial analysis*.
The result from the first analysis is judged, and a [Reflex] analysis is performed on the parameters that are different from the first test. Set the judgment conditions for performing a [Reflex] analysis of the initial analysis.
* When the sampler (SA-01) is used, analysis is not performed. Only rule judgment is performed.

e.g.	Conditional Expression:	[IPMessage]([PLT Abn Distribution])
	Action:	[Reflex]([DIFF+RET+PLT-F+WPC])
	Explanation:	If the judgment shows the IP message [PLT Abn Distribution](abnormal platelet distribution), a [Reflex] analysis is performed on discrete parameters [DIFF+RET+PLT-F+WPC].

Comment

A comment is a setting that judges the analysis result and automatically displays a comment.
If [None] is selected for the action, a conditional expression that only sets a comment can be set.

e.g.	Conditional Expression:	[ItemValue](HGB[***.* g/dL]) < 8.0
	Action:	[None]
	Comment:	Contact doctor
	Explanation:	When HGB is less than 8.0 g/dL, "Contact doctor" appears in the comment column.

2.1.3 SP Rule

[SP Rule] only appears when the XN-3000 (Standalone mode) is used.
[SP Rule] judgment is a setting that judges the analysis result and automatically registers a smear order in the [Work List] screen.
Analysis results that have been already judged using the [Repeat Rule] or the [Rerun/Reflex/Comment Rule] are judged, and smear orders are automatically registered in the [Work List] screen. The number of slides prepared and and the slide glass can be specified.
[SP Rule] judgment is only performed when the analyzer setting is ON. For details, see Chapter 3.
(➤**P.3-20** "Chapter 3: SP Settings")

e.g.	Conditional Expression:	[ResultFlag] ([Negative])
	Action:	[Smear] (2Slide)
	Slide glass specification (1st slide):	[Cassette1]
	Slide glass specification (2nd slide):	[Cassette2]
	Explanation:	When the flag judgment for analysis data is [Negative], 2 smears are prepared automatically. The slide glass of [Cassette 1] is used for the first slide, and the slide glass of [Cassette 2] is used for the second slide.

2.1.4 Validation rule

To validate means to approve the output of the analysis data for reporting. The [Validation Rule] sets the judgment condition under which validation is automatically performed.
The analysis result that have been already judged by the [Repeat Rule] or the [Rerun/Reflex/Comment Rule] is judged, and validation is automatically performed.

e.g.	Conditional Expression:	[ResultFlag]([Negative])
	Action:	[Validate]
	Explanation:	If an analysis data flag judgment result was Negative based on the [Rerun/Reflex/Comment Rule], validation is performed automatically.

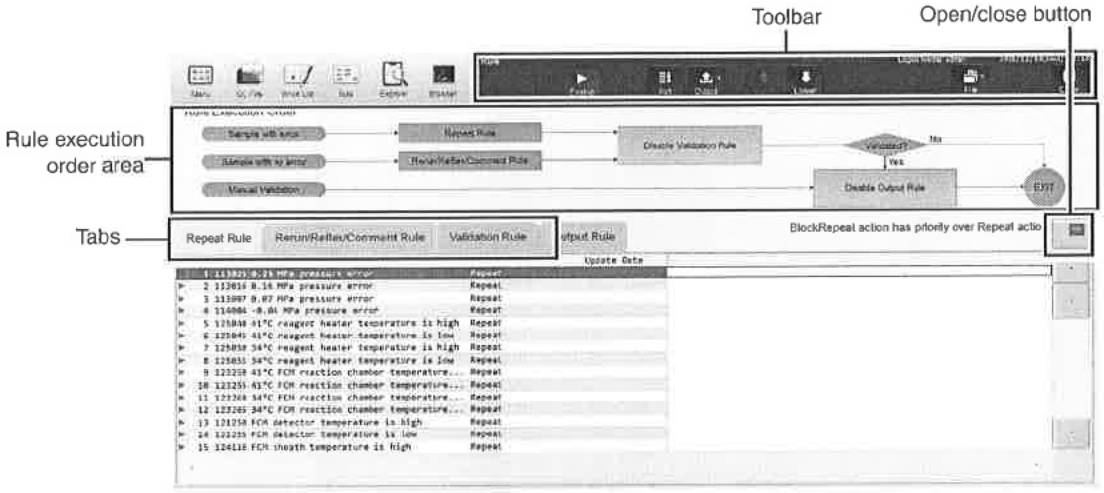
2.1.5 Output rule

The [Output Rule] sets the judgment condition for automatically outputting the analysis result.
Analysis result that has been already validated is judged and automatically output. You can also set the output destination.

e.g.	Conditional Expression:	[ResultFlag]([Negative])
	Action:	[ReportTo]([HC])
	Explanation:	If the Positive/Negative judgment is [Negative] the analysis data is automatically output to the host computer.

2.2 Rule screen

Click the [Rule] icon in the menu screen to display the following screen.



[Rule] screen

Toolbar

The button of the following functions are displayed.

[Enable]*1,2	Click to enable selected rule(s) in the [Rule] screen. If the rule was already enabled, clicking in the list disable the rule.
[Sort]	Click to display the dialog box for sorting rules in the [Rule] screen.
[Output]	Click to display the submenu for printing displayed rules in ledger format.
[Upper]	Click to move the selection up by 1 row.
[Lower]	Click to move the selection down by 1 row.
[File]	Click to display the submenu for saving, restoring or initializing the rules.
[Close]	Click to close the [Rule] screen.

*1 When [Repeat Rule] is [BlockRepeat(Fixed)], the settings cannot be changed.

*2 The setting of a rule that is valid only can be enabled.

Rule Execution Order

The order of execution of the rules is shown.

Click the open/close button to open/close the Rule Execution Order display area.

[Repeat Rule], [Rerun/Reflex/Comment Rule], [SP Rule]*

If the [Repeat] , [Rerun/Reflex] or [Perform Judgement of SP Rule] checkbox is not selected in the analyzer settings, the setting in the rule screen will not be valid.For the details, see Chapter 3.

(➤**P.3-12** "Chapter 3: Repeat setting",**P.3-12** "Chapter 3: Rerun/Reflex setting", **P.3-20** "Chapter 3: SP Settings")

* Only when using the XN-3000 sampler (Standalone mode).

[Validation Rule], [Output Rule]

The status of the rule appears below the rule name. If the rule in the rule screen is in effect, the status does not appear.

When a rule is set in the IPU settings, [Use Rule ####### Simple Setting] appears. If the rule is OFF, the background is gray and [Rule ####### Disabled] appears.

Tabs

Click a tab to change the displayed rule screen list. The [Repeat Rule], [Rerun/Reflex/Comment Rule], [SP Rule], [Validation Rule], and [Output Rule] tabs appear*.

* The tabs that appear vary depending on the instrument that is used.

> **Note:**
>
> You can select multiple data in the sample list as follows:
>
> - Drag multiple consecutive rows
> - While pressing Ctrl, click on the row that you want to select

Open/close button

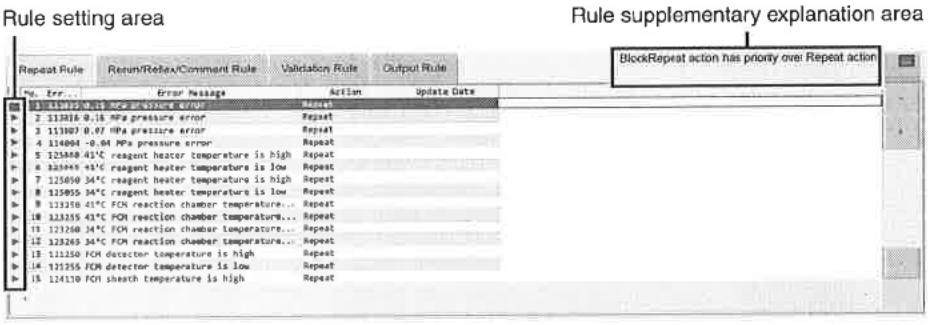
Click to open/close the rule execution order display area.

2.2.1 Rule screens

Repeat Rule

Click the [Repeat Rule] tab to display the following screen*.

* Errors that do not occur due to the instrument configuration are not displayed.
  For other errors that are not displayed, see below.
  (➤P.2-2 "2.1.1 Repeat rule")
  When the sampler (SA-01) is used, the screen below does not appear.



[Repeat Rule] screen

Rule setting area	Displays whether the rule is ON (▶), OFF (■) or invalid (✖).
[No.]	The unique number assigned to the error for which the [Repeat Rule] is applied is displayed.
[Error Code]	The error code is displayed.
[Error Message]	The error message is displayed.
[Action]	The following actions are displayed.
[None]	[Repeat] is not performed.
[BlockRepeat]	[Repeat] is not performed. Even if other errors occur that have [Repeat] set for the action, if an error occurs that has [BlockRepeat] set, [BlockRepeat] is given priority. [BlockRepeat] disables the [Repeat Rule]. It does not disable [Rerun] or [Reflex].
[Repeat]	[Repeat] is performed.
[BlockRepeat(Fixed)]	Displayed when the action is fixed at [BlockRepeat].
[Update Date]	The date and time the rule was registered or last modified is displayed.
Rule supplementary explanation area	A supplementary explanation of the rule is displayed.

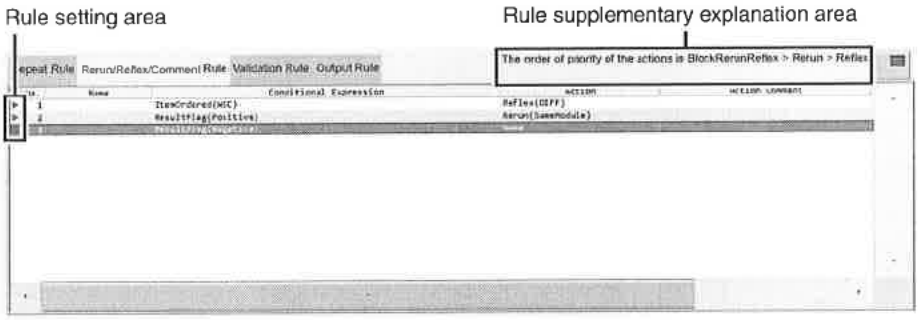
Note:

[Repeat Rule] is applied when an error occurs in the result of the first analysis and when an error occurs in the result of [Rerun], [Reflex]. [Repeat] analysis is not possible for some errors.

Rerun/Reflex/Comment Rule

Click the [Rerun/Reflex/Comment Rule] tab to display the following screen*.

* When the sampler (SA-01) is used, this is displayed as the [Comment Rule] screen.



[Rerun/Reflex/Comment Rule] screen

Rule setting area	Displays whether the rule is ON (▶), OFF (■) or invalid (✖).
[No.]	The rule number appears. If a number greater than "100" (the maximum number that can be registered) is entered, the number will be displayed in red.
[Name]	The name of the rule appears. If not entered, nothing appears.
[Conditional Expression]	Displays the conditional expression for whether [Rerun], [Reflex] is performed.
[Action]	The following actions are displayed.
[None]	[Rerun], [Reflex] is not performed.
[BlockRerunReflex]	[Rerun], [Reflex] is not performed. Even if there are other conditions with [Rerun] or [Reflex] set for the action that are satisfied, if a condition with [BlockRerunReflex] set is satisfied, [BlockRerunReflex] is given priority.
[Rerun]	[Rerun] analysis is performed. If multiple analyzers are used, the analyzer to be used for [Rerun] analysis can be specified.
[Reflex]	[Reflex] analysis is performed. The discrete item of the added channel appears in ( ). Even when the judgment is [Reflex], if the analysis items belonging to the discrete to be added and all channels were analyzed in the initial analysis, [Reflex] analysis will not be performed.
[QueryToHost]*	The host computer is queried if [Rerun], [Reflex] is necessary.
[Action Comment]	The comment to be added to the analysis data is displayed. Nothing appears if no comments have been entered. The display color varies depending on the importance of the comment.
[Low]	Displays in black characters on a white background.
[Medium]	Displays in black characters on an orange background.
[High]	Displays in white characters on a red background.
[Update Date]	The date and time the rule was registered or last modified is displayed.
[Description]	A description of the rule appears. If not entered, nothing appears.
Rule supplementary explanation area	A supplementary explanation of the rule is displayed.

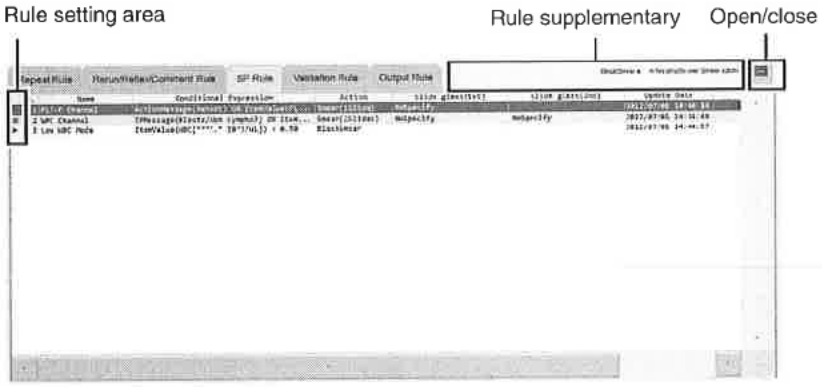
* Only when IPU service settings are being configured, this will appear.

> **Note:**
> The result of a [Rerun] or [Reflex] analysis cannot be consolidated with or compared to the result of the first analysis.

SP Rule

Click the [SP Rule] tab to display the following screen.

* Only when using the XN-3000 sampler (Standalone mode).

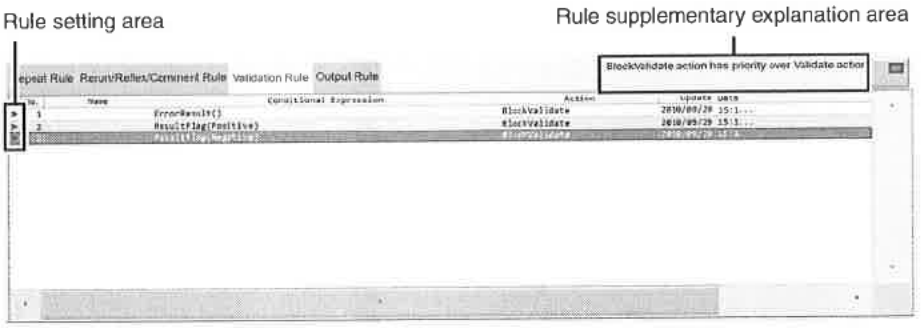


[SP Rule] screen

Rule setting area	Displays whether the rule is ON (▷), OFF (▩) or invalid (✖).
[No.]	The rule number appears. If a number greater than "100" (the maximum number that can be registered) is entered, the number will be displayed in red.
[Name]	The name of the rule appears. If not entered, nothing appears.
[Conditional Expression]	Displays the conditional expression for whether validation is performed.
[Action]	The following actions are displayed.
[BlockSmear]	Registration of smear orders (SP rule judgment) is not performed.
[Smear]	Registration of smear orders (SP rule judgment) is performed.
[slide glass (1st)], [slide glass (2nd)]	The slide glass used to prepare the smear can be specified. Select [NoSpecify], [Cassette1], or [Cassette2].
[Update Date]	The date and time the rule was registered or last modified is displayed.
[Description]	A description of the rule appears. If not entered, nothing appears.
Rule supplementary explanation area	A supplementary explanation of the rule is displayed.
Open/close button	Click to open/close the rule execution order display area.

Validation Rule

Click the [Validation Rule] tab to display the following screen.

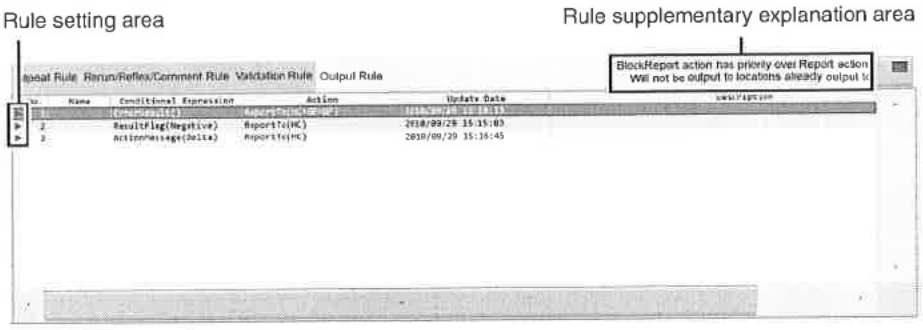


[Validation Rule] screen

Rule setting area	Displays whether the rule is ON (▶), OFF (■) or invalid (✖).
[No.]	The rule number appears. If a number greater than "100" (the maximum number that can be registered) is entered, the number will be displayed in red.
[Name]	The name of the rule appears. If not entered, nothing appears.
[Conditional Expression]	Displays the conditional expression for whether validation is performed.
[Action]	The following actions are displayed.
[BlockValidate]	Validation is not performed. Even if there are other conditions with [Validate] set for the action that are satisfied, if a condition with [BlockValidate] set is satisfied, [BlockValidate] is given priority.
[Validate]	Validation is performed.
[Update Date]	The date and time the rule was registered or last modified is displayed.
[Description]	A description of the rule appears. If not entered, nothing appears.
Rule supplementary explanation area	A supplementary explanation of the rule is displayed.

Output Rule

Click the [Output Rule] tab to display the following screen.



[Output Rule] screen

Rule setting area	Displays whether the rule is ON (▶), OFF (□) or invalid (✖).
[No.]	The rule number appears. If a number greater than "100" (the maximum number that can be registered) is entered, the number will be displayed in red.
[Name]	The name of the rule appears. If not entered, nothing appears.
[Conditional Expression]	Displays the conditional expression for output.
[Action]	The following actions are displayed.
[BlockReport]	Data is not output. Even if there are other conditions with [ReportTo] set for the action that are satisfied, if a condition with [BlockReport] set is satisfied, [BlockReport] is given priority.
[ReportTo]	Data that has been validated is output. The output destination appears in ( ).
[Update Date]	The date and time the rule was registered or last modified is displayed.
[Description]	A description of the rule appears. If not entered, nothing appears.
Rule supplementary explanation area	A supplementary explanation of the rule is displayed.

2.3 Enable/Disable rules

The enable/disable setting of each rule in the rule screen can be changed*.

* The setting of a rule that is valid only can be changed. The settings of a rule that is fixed to [BlockRepeat] cannot be changed.

Follow the steps below to enable/disable a rule.

1 Click the rule that you wish to enable or disable.

The rule is selected.
You can select multiple orders in the list.

2 Click the [Enable] button on the toolbar.

The rule is enabled/disabled.
When multiple lines of rules are selected, the enable/disable selection of the highlight-selected rule will apply to all selected rules.
For example, when the highlight-selected rule is enabled, all other selected rules are enabled.

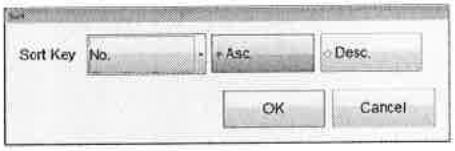
2.4 Sort rules

The rules can be sorted in the order of a specified keyword.
Sorting conditions can be set separately for each tab.
Follow the steps below to sort the rules.

1 Click the tab of the rules you wish to sort.

2 Click the [Sort] button on the toolbar.

The dialog box on the right appears.



3 Populate the displayed fields.

Sorting conditions can be set by clicking the sort key.
When a keyword is set, the numbers or letters can be sorted in [Asc.] order (0 to 9/A to Z) or [Desc.] order (9 to 0/Z to A).

[No.]	Sort by rule number.
[Name]*1	Sort by rule name.
[Error Code]*2	Sort by error code.
[Error Message]*2	Sort by error message.
[Update Date]	Sort by update date.

*1 [Rerun/Reflex/Comment Rule], [Validation Rule] or [Output Rule] only.
*2 [Repeat Rule] only.

4 Click [OK].

The dialog box will close and the rules will be sorted.

2.5 Print rules

Rules that have been registered can be printed as a list.
Follow the steps below to print rules.

1 Click the tab of the rules that you wish to print.

The rules appear.

2 Click the [Output] - [Ledger (LP)] button on the toolbar.

The displayed rules will be printed as a list.

2.6 Save rules

The various rules that have been registered can be saved to a single file.
Follow the steps below to save the rules.

> **Note:**
> - As part of good laboratory practices, rules should be saved during initial installation of instrument and any time there are updates or changes to rules.
> - Saved file should be stored in a location so it is readily accessible.

1 Click the [File] - [Backup] button on the toolbar.

The [Save As] dialog box appears.

2 Specify or create the folder to save the sample data into.

> **Note:**
> Even if the simple settings are used for the [Validation Rule] or [Output Rule], any content registered in the rule screen will be saved.

3 Check a file name.

The extension for a file is "rule".

> **Note:**
> The default file name is "[XN][Software version][Rule][Date of save_Time of save].rule".
> e.g.: [XXX][00-01][Rule][20100505_080808].rule

4 Click [Save].

All registered rules are saved.

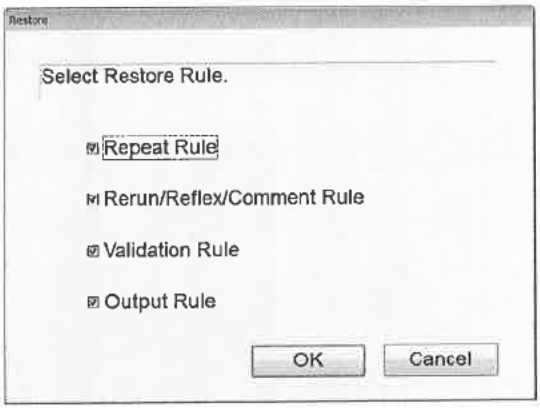
2.7 Restore saved rules

Saved rules can be restored.
Follow the steps below to restore saved rules.

1 Click the [File] - [Restore] button on the toolbar.

The dialog box on the right appears.

* The rules that appear vary depending on the instrument that is used.



2 Select the checkboxes of the rules that you wish to restore.

3 Click [OK].

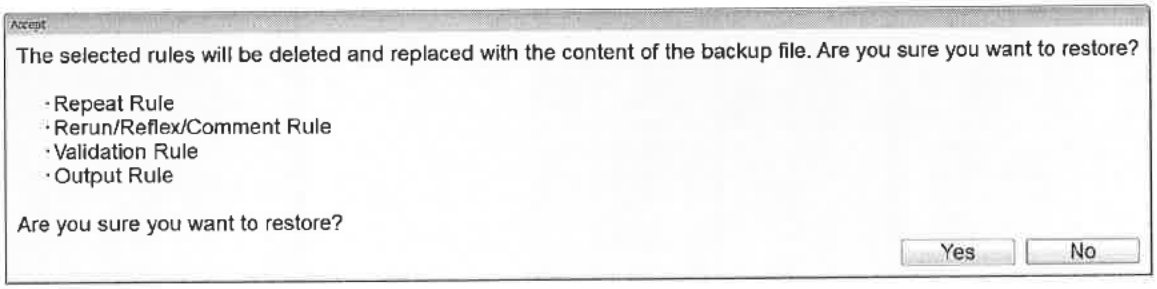
The [Open] dialog box appears.

4 Select the file that you wish to restore.

The extension for a file is "rule".

5 Click [Open].

The dialog box on the right appears.



6 Click [Yes].

The rules are restored.

> **Note:**
> Rule sorting settings and simple settings are retained even when rules are restored.

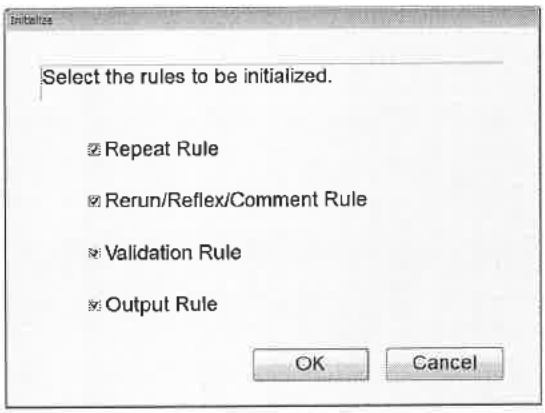
2.8 Initialize rules

Rules that have been set can be initialized.
Follow the steps below to initialize rules.

1 Click the [File] - [Initialize] button on the toolbar.

The dialog box on the right appears.

* The rules that appear vary depending on the instrument that is used.



2 Select the checkboxes of the rules that you wish to initialize.

3 Click [OK].

An initialization confirmation dialog box appears.

4 Click [Yes].

The rules are initialized.

> **Note:**
> Rule sorting settings and simple settings are retained even when the rules are initialized.

Chapter 3 Instrument Setup

This chapter explains how to configure analyzer and IPU settings.

Note:

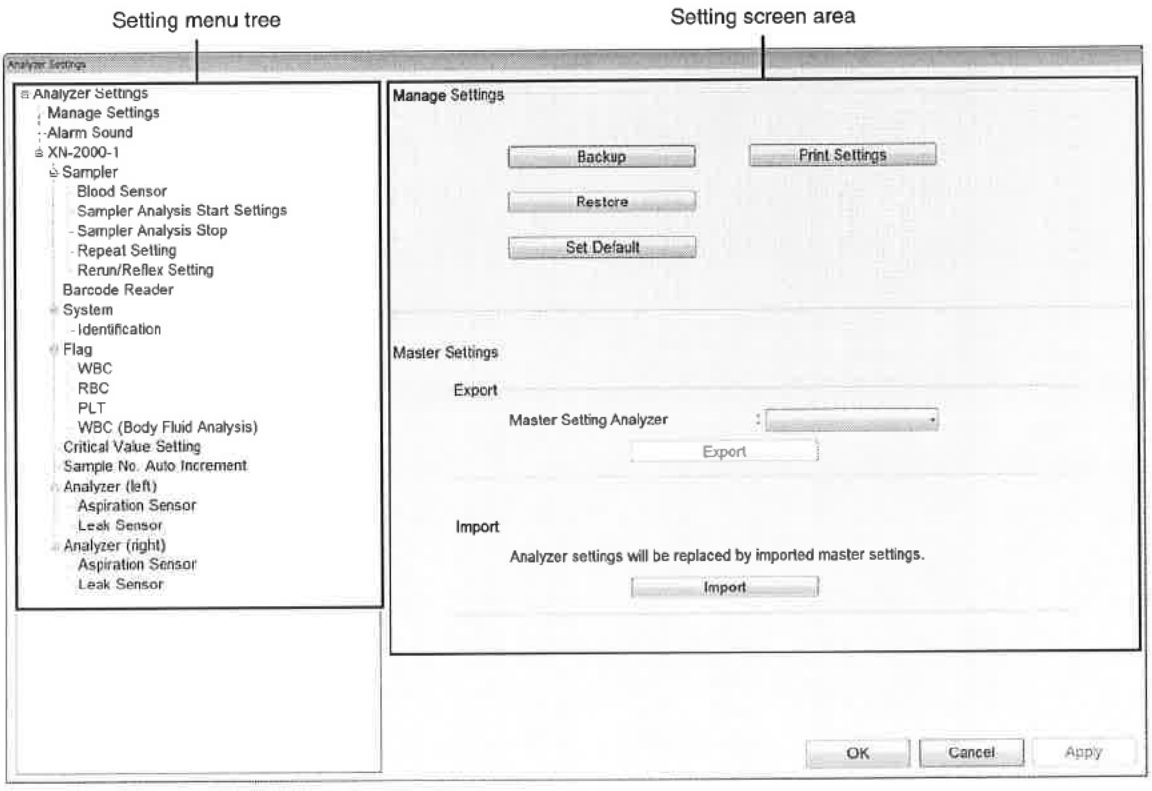
- If an analyzer is running, an alarm will sound on the IPU and the dialog box will not open.
- Sampler analysis cannot be started on the analyzers while the analyzer settings are being configured.

3.1 Open the settings

The instrument settings consist of [Analyzer Setting] for the specific analyzer type, and [IPU Setting] for configuring IPU application settings. The settings are configured from the [Analyzer Setting] and [IPU Setting] dialog boxes. For the details on the settings and their default values, see Chapter 4. (➤**P.4-12** "Chapter 4: 4.4 Default settings")

Open the analyzer settings

Click the [Analyzer Setting] icon to display the following dialog box.



Open the IPU settings

Click the [IPU Setting] icon to display the [IPU Setting] dialog box.

The configuration of the [IPU Setting] dialog box is similar to the [Analyzer Setting] dialog box.

Setting menu tree

This shows the settings. Click an item to open a setting screen for that item on the right.

Setting screen area

The setting screen for the item selected in the setting menu tree appears.

[OK]	Save changed settings and close the dialog box.
[Cancel]	Close the dialog box without saving changed settings.
[Apply]	Save and immediately apply changed settings. The dialog box does not close.

3.2 Analyzer settings

The analyzer settings are used to configure analyzer settings, sampler system settings, and flag settings. The items shown below, which appear in the setting menu tree of the [Analyzer Setting] dialog box, can be configured*.

* When system analysis mode is selected on the XN-9000 or the sampler (SA-01) is used, [Sampler Analysis Start Settings] does not appear.
  When the sampler (SA-01) is used, [Repeat Setting] and [Rerun/Reflex Setting] do not appear.

- Analyzer Settings
  - Manage Settings
  - Alarm Sound
  - XN-2000-1
    - Sampler
      - Blood Sensor
      - Sampler Analysis Start Settings
      - Sampler Analysis Stop
      - Repeat Setting
      - Rerun/Reflex Setting
    - Barcode Reader
    - System
      - Identification
    - Flag
      - WBC
      - RBC
      - PLT
      - WBC (Body Fluid Analysis)
    - Critical Value Setting
    - Sample No. Auto Increment
    - Analyzer (left)
      - Aspiration Sensor
      - Leak Sensor
    - Analyzer (right)
      - Aspiration Sensor
      - Leak Sensor

Note:

- When multiple analyzers are connected to the IPU, the name of each analyzer appears.
  e.g: [XN-2000-2] and [XN-2000-3].
- For XN-2000 or XN-3000, right and left is in indicated in [Analyzer].
  e.g: [Analyzer (right)] and [Analyzer (left)].
- For the XN-1000 or XN-9000, only [Analyzer] appears.
- [SP] settings only appear when the XN-3000 (Standalone mode) is used.

3.2.1 Manage settings

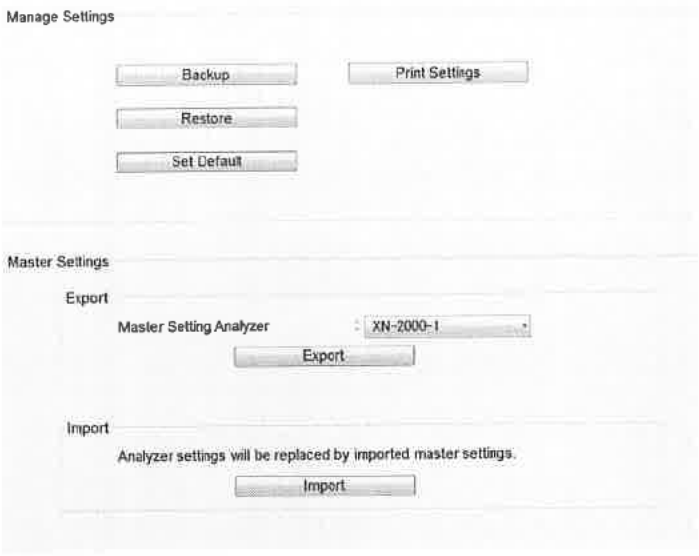
Settings can be managed.

[Backup]*1	The settings can be saved to a file. (➤**P.3-5** "Save settings")
[Restore]*2	Settings saved in a file can be restored (they will replace the current settings). (➤**P.3-6** "Restore settings")
[Set Default]*2	The settings can be returned to the default settings. (➤**P.3-6** "Initialize settings")
[Print Settings]*1	The settings in all analyzers and samplers connected to the IPU can be printed. (➤**P.3-7** "Print settings")
[Export]*1	Analyzer settings can be saved as a master file. (➤**P.3-7** "Save master settings")
[Import]*2	Analyzer settings can be imported from a master file. (➤**P.3-8** "Import master settings")

*1 Only displayed when setting changes have been applied. After changing a setting, click [Apply] to apply the setting.

*2 Only the [Built-in User] registered at the factory can be set.

Click [Manage Settings] in the [Analyzer Settings] tree to display the items below.



Save settings

The settings in all analyzers and samplers connected to the IPU can be saved to a file.
Follow the steps below to save the settings.

1 Click [Backup].

The [Save As] dialog box appears.

2 Specify or create the folder to save the sample data into.

3 Enter the file name.

The extension of a file is ".ini".

> **Note:**
> The default file name will be
> [XN][Software Version][AnalyzerSetting][Date of save_Time of save].ini.

4 Click [Save].

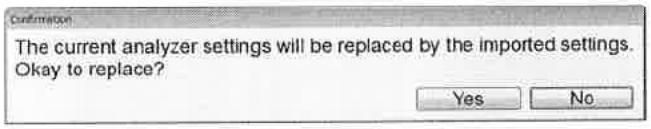
The settings are saved.

Restore settings

Settings can be imported from a saved file. These will replace the current settings.
Follow the steps below to restore settings.

1 Click [Restore].

The dialog box on the right appears.



2 Click [Yes].

The [Open] dialog box appears.

3 Select the file that you wish to restore.

The extension of a file is ".ini".

4 Click [Open].

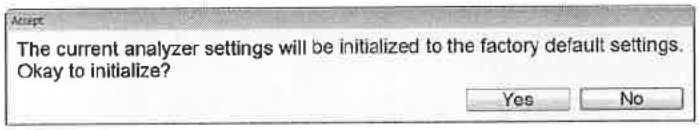
The settings are restored.

Initialize settings

The settings in all analyzers and samplers connected to the IPU can be returned to the default settings.
Follow the steps below to initialize the settings.

1 Click [Set Default].

The dialog box on the right appears.



2 Click [Yes].

The settings are initialized.

Print settings

Click [Print Settings]. The settings will be printed.
The print format is ledger format. The settings are printed in 2 columns, with the first column showing the setting name and the second column showing the setting.

Save master settings

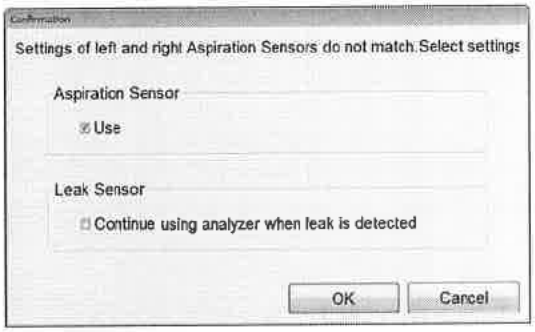
Analyzer settings can be exported as a master file. Note that identification settings will not be exported.
Follow the steps below to save the master settings.

1 Click [Export].

The [Save As] dialog box appears.

Note:

If the left and right analyzers of XN-2000, XN-3000 have different settings for [Aspiration Sensor] and [Leak Sensor] the dialog box on the right appears.
If the [Aspiration Sensor] is to be used in the master settings, select the checkbox.
To continue using [Leak Sensor] when a water leak is detected, select the checkbox.
Click [OK] to close the dialog box. The [Save As] dialog box appears.



2 Specify or create the folder to save the sample data into.

3 Enter the file name.

The extension of a file is ".smf".

Note:

The default file name is in the format
[XN][Software Version][AnalyzerSettingMaster][Date of save_Time of save].smf.

4 Click [Save].

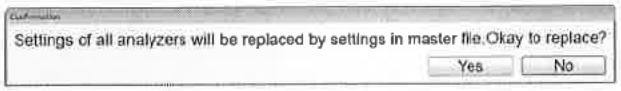
The master settings are saved.

Import master settings

When master settings are imported, the same settings are applied to all analyzers connected to the IPU. Follow the steps below to import master settings.

1 Click [Import].

The dialog box on the right appears.



2 Click [Yes].

The [Open] dialog box appears.

3 Select the file that you wish to open.

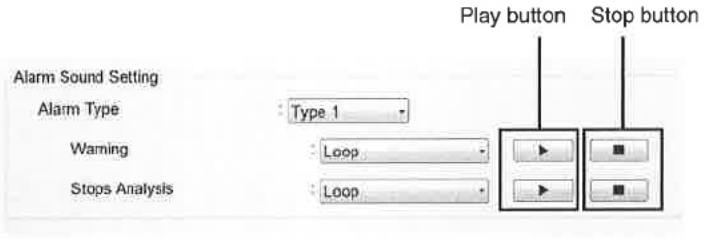
The extension of a file is ".smf".

4 Click [Open].

The settings are restored.

3.2.2 Alarm sound setting

Set the alarm sound that notifies the operator when an error has occurred. The alarm sound can be set separately for each analyzer.
Click [Alarm Sound] in the [Analyzer Settings] tree.



[Alarm Type]	Set the alarm type. Select from 3 types.
[Warning]	Set the alarm sound that notifies the operator when a warning error has occurred. [No Alarm], [Once], or [Loop] can be selected.
[Stops Analysis]	Set the alarm sound that notifies the operator when an analysis stop error has occurred. [No Alarm], [Once], or [Loop] can be selected.
Play button	Click to sound the selected alarm sound.
Stop button	Click to stop the alarm sound.

3.2.3 Sampler settings

Sampler settings can be configured.

[Blood Sensor]	Specify whether or not the [Blood Sensor] is used. When used, the sensor detects whether or not there is blood in the sample tube. (➤**P.3-10** "Blood Sensor setting")
[Sampler Analysis Start Settings]*1	Specify whether or not analysis is started automatically. (➤**P.3-11** "Analysis Start Setting")
[Sampler Analysis Stop]	Set the conditions for stopping analysis. (➤**P.3-11** "Analysis Stop setting")
[Repeat Setting]*2	Specify whether [Repeat] analysis is performed. (➤**P.3-12** "Repeat setting")
[Rerun/Reflex Setting]*2	Specify whether or not [Rerun] analysis / [Reflex] analysis is performed. (➤**P.3-12** "Rerun/Reflex setting")

*1 When system analysis mode is selected on the XN-9000 or the sampler (SA-01) is used, [Sampler Analysis Start Settings] does not appear.

*2 When the sampler (SA-01) is used, this does not appear.

Blood Sensor setting

Click [Sampler] - [Blood Sensor] in the [Analyzer Settings] tree.

[Use]	Select the checkbox to have blood volume monitored during sampler analysis.

Information

Not using the [Blood Sensor] may affect analysis results. For [Whole Blood] mode analysis, select [Use].

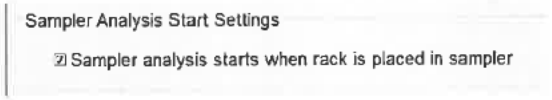
Note:

If you know in advance that a blood sample will be very thin (such as that of a dialysis patient), deactivate the [Blood Sensor].

Analysis Start Setting

Click [Sampler] - [Sampler Analysis Start Settings] in the [Analyzer Settings] tree*.

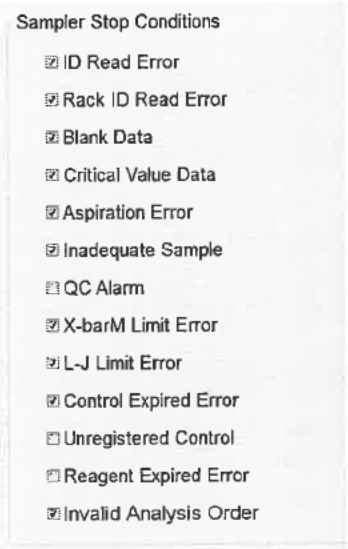
* When system analysis mode is selected on the XN-9000 or the sampler (SA-01) is used, [Sampler Analysis Start Settings] does not appear.



[Sampler analysis starts when rack is placed in sampler]	Select this checkbox to have sampler analysis automatically start when a rack is placed on the rack feed-in table.

Analysis Stop setting

Click [Sampler] - [Sampler Analysis Stop] in the [Analyzer Settings] tree.
Select the checkboxes of events that will stop sampler analysis.



[ID Read Error]	Unable to read the barcode label on the sample tube.
[Rack ID Read Error]*1	Unable to read the barcode label on the rack.
[Blank Data]	When the count is abnormally low.
[Critical Value Data]	When the value is outside the set range. (➤**P.3-17** "3.2.7 Critical Value Settings")
[Aspiration Error]	When aspiration does not take place or the amount is not sufficient. This can be set when the [Aspiration Sensor] is used. (➤**P.3-18** "Blood aspiration sensor settings")
[Inadequate Sample]	When there is no blood. This can be set when the [Blood Sensor] is used. (➤**P.3-10** "Blood Sensor setting")
[QC Alarm]	When the QC alarm sounds. This can be set when the QC alarm is used. (➤**P.3-49** "QC alarm settings")
[X-barM Limit Error]	When an X-barM control error occurs in QC.
[L-J Limit Error]	When an L-J control or X-bar control error occurs in QC.
[Control Expired Error]	When the registered control has expired.
[Unregistered Control]	When an unregistered control is used.
[Reagent Expired Error]	When an expired reagent is used.
[Invalid Analysis Order]*2	An order that cannot be analyzed was specified.

*1 When the transportation controller (CT-90) and the sampler (SA-01) is used, this does not appear.

*2 When the transportation controller (CT-90) is used, this does not appear.

Repeat setting

Click [Sampler] - [Repeat Setting] in the [Analyzer Settings] tree*.

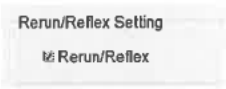
* When the sampler (SA-01) is used, this does not appear.

[Repeat]	Select this checkbox to perform [Repeat] analysis. When this function is off, [Repeat] analysis will not be performed even if a rule is set.

Rerun/Reflex setting

Click [Sampler] - [Rerun/Reflex Setting] in the [Analyzer Settings] tree*.

* When the sampler (SA-01) is used, this does not appear.

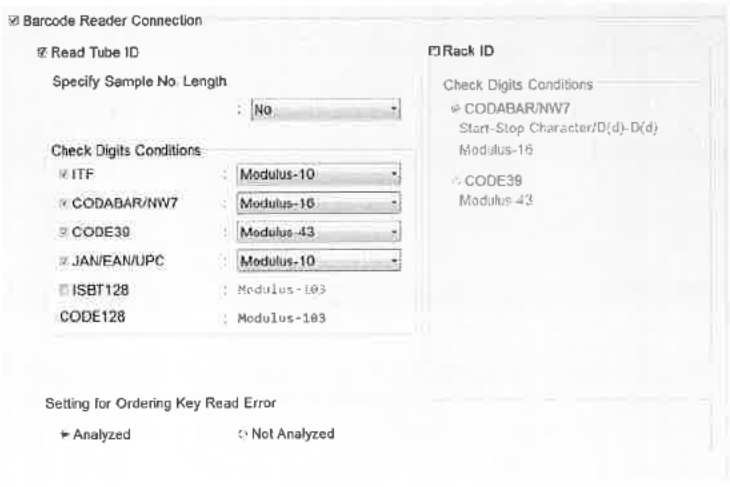


[Rerun/Reflex]	Select this checkbox to perform [Rerun]/[Reflex] analysis. When this function is off, [Rerun]/[Reflex] analysis will not be performed even if a rule is set.

3.2.4 Barcode reader setting

Specify whether or not a barcode reader is used. Advanced settings for barcode reading can be configured. This barcode read setting is a shared setting for the overall analyzer. The setting is applied to the barcode readers of both the analyzer and the sampler.

Click [Barcode Reader] in the [Analyzer Settings] tree.



[Barcode Reader Connection]*1	Select the checkbox to turn on the barcode reader function. When not selected, the items below are all grayed out and cannot be set.
[Read Tube ID]*1	Select this checkbox if sample tube barcode labels will be read. When the checkbox is selected, reading settings can be configured.

[Specify Sample No. Length]		Set whether or not the number of digits read are specified. If specified, enter the number of digits (1 to 22 digits). If a number of digits other than the specified number is read, a reading error will occur. However, quality control ([QC-]) and rinse ([RN-]) sample numbers reserved in the system are not subject to the digit number check.
[Check Digits Conditions]		Select the read code checkbox to set a code. A check digit can also be set.
	[ITF]	[Modulus-10]/[Through]
	[CODABAR/NW7]	[Modulus-11]/[W-Modulus-11]/[Modulus-16]/[Through]
	[CODE39]	[Modulus-43]/[Through]
	[JAN/EAN/UPC]	Select the check box to automatically the check digit be [Modulus-10].
	[ISBT128]	Select the check box to automatically the check digit be [Modulus-103].
	[CODE128]	Select the check box to automatically the check digit be [Modulus-103].
[Rack ID]*2		Select this checkbox if the rack barcode label will be read. When selected, reading settings can be configured.
[Check Digits Conditions]		Select the read code checkbox to set a code. A check digit can also be set.
	[CODABAR/NW7]	Select the check box to automatically the check digit be [Modulus-16]. The start/stop characters are [/D(d)-D(d)]. Use either "D" or "d" for the start/stop code.
	[CODE39]	Select the check box to automatically the check digit be [Modulus-43].
[Setting for Ordering Key Read Error]		This can be set when the sample tube label or rack label read function is on. Specify whether or not a sample for which an ordering key read error occurs is analyzed.

*1 When the transportation controller (CT-90) is used, this is always connected. The setting is grayed out and cannot be modified.

*2 When the transportation controller (CT-90) and the sampler (SA-01) is used, this does not appear..

⚠ Warning!

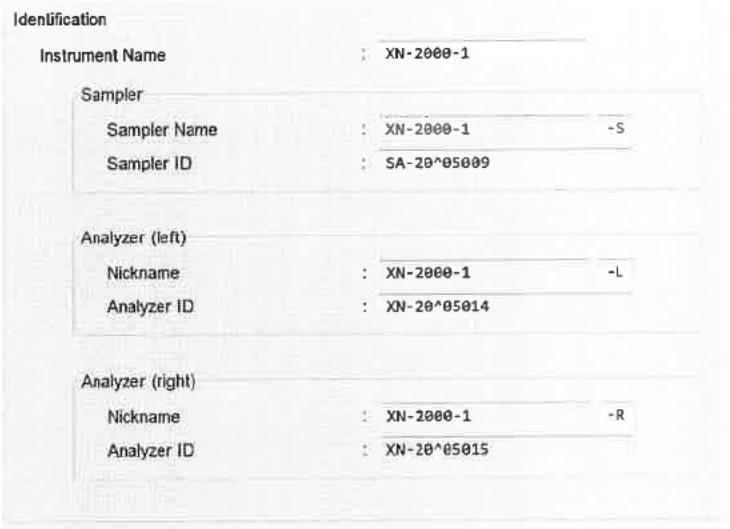
When using the hand-held barcode reader, use the barcode check digit function. There is a higher potential for read errors when a check digit is not used.

3.2.5 System settings

A system name and analyzer names can be set. The name and ID of the sampler and the analyzer can be checked.

Analyzer name settings

Click [System] - [Identification] in the [Analyzer Settings] tree.



[Instrument Name]	An instrument name can be entered. The instrument name set here will appear as an error location in the error log screen. You can enter up to 11 characters.
[Sampler Name]*	The name of the sampler appears. Detailed information is displayed to the right. The default value is as follows: [-S]: Indicates the sampler. The information can be changed. You can enter up to 2 characters.
[Sampler ID]*	The sampler ID number appears. The sampler ID appears in the format "Product Name^Serial Number". This cannot be changed.
[Analyzer (left)]/ [Analyzer (right)]	The analyzer name and analyzer ID appear. In the case of XN-1000 or XN-9000, this is [Analyzer] and only 1 field appears.
[Nickname]	The name of the analyzer appears. This is a number that is automatically assigned to devices connected to [Instrument Name] and the IPU. This cannot be changed. Detailed information is displayed to the right. The default values are as follows: [-L]: Indicates "left" on XN-2000, XN-3000. [-R]: Indicates "right" on XN-2000, XN-3000. [-A]: Indicates that the model is XN-1000 or XN-9000. The information can be changed. You can enter up to 2 characters.
[Analyzer ID]	The [Analyzer ID] of the analyzer appears. The Analyzer ID appears in the format "Instrument Product Name^Serial Number". This cannot be changed.

* When the sampler (SA-01) is used, this does not appear.

3.2.6 Flag settings

Flag settings can be configured. When the data meets specified conditions due to a specific abnormal blood conditions, an abnormal IP message will appear.
Settings can be configured for [WBC], [RBC], [PLT], and [WBC (Body Fluid Analysis)].
For the details on flags and the values* that can be entered, see "Instruction for Use."
(➤Instruction for Use, "Chapter 11: 11.6.1 IP message judgment conditions and judgment methods")

* The decimal point symbol set in Windows is displayed in the XN Series.
The only decimal point symbols displayed are "." (period) or "," (comma).

WBC flag settings

Set values that determine the display of WBC abnormal IP messages.

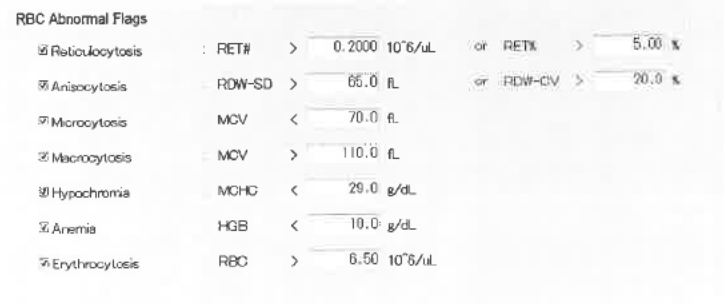
Click [Flag] - [WBC] in the [Analyzer Settings] tree.
Select the checkbox of a flag to have the judgment performed. The judgment values of the flag judgment items can also be set.

RBC flag settings

Set values that determine the display of RBC abnormal IP messages.

Click [Flag] - [RBC] in the [Analyzer Settings] tree.
Select the checkbox of a flag* to have the judgment performed.

* [Reticulocytosis] does not appear with all analyzer types.

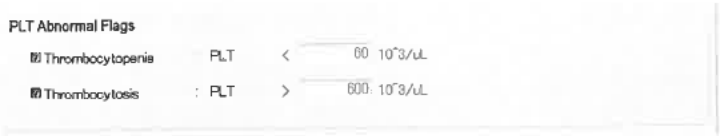


PLT flag settings

Set values that determine the display of PLT abnormal IP messages.

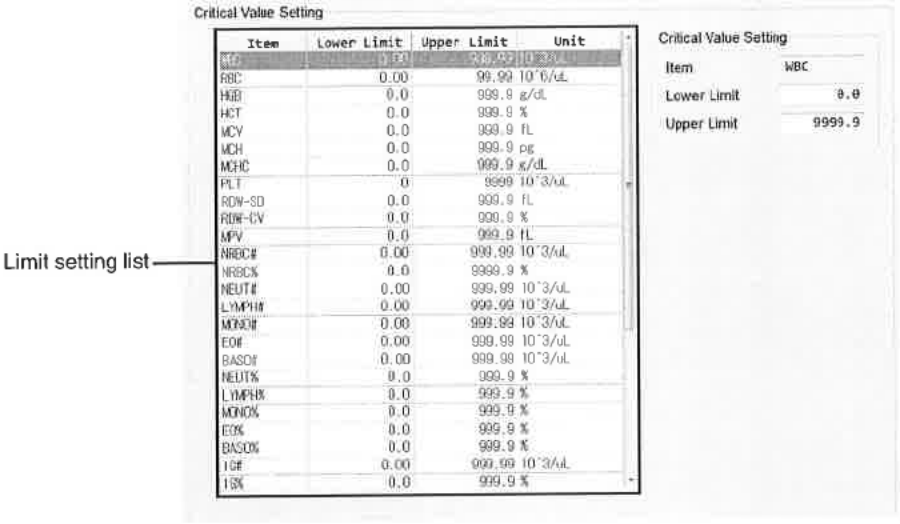
Click [Flag] - [PLT] in the [Analyzer Settings] tree.

Select the checkbox of a flag to have the judgment performed. The judgment values of the flag judgment items can also be set.



3.2.7 Critical Value Settings

Upper and lower limit values can be set for each item. The set upper and lower limit values are called "critical values". Analysis data that are outside the intervals set here are displayed with an exclamation mark "!". Sampler analysis can be set to stop when there is data with "!".
Click [Critical Value Setting] in the [Analyzer Settings] tree.

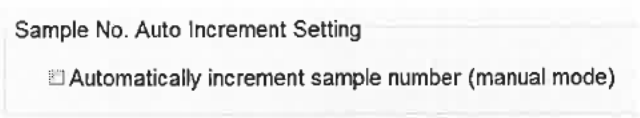


Limit setting list	Click to select an item.
[Critical Value Setting]	The settings for the item selected in the limit setting list appear.
[Item]	The item selected in the limit setting list appears. This cannot be entered.
[Lower Limit]*, [Upper Limit]*	An upper limit and a lower limit can be entered. If [Critical Value Setting] in the analyzer stop conditions is used, analysis will stop if a value is outside the set upper and lower limit range.

* The decimal point symbol set in Windows is displayed in the XN Series.
The only decimal point symbols displayed are "." (period) or "," (comma).

3.2.8 Sample number auto increment setting

Click [Sample No. Auto Increment] in the [Analyzer Settings] tree.



[Automatically increment sample number (manual mode)]	Select this checkbox to have the sample number automatically assigned as a sequential number when manual analysis is performed.

3.2.9 Analyzer settings

Analyzer settings can be configured.

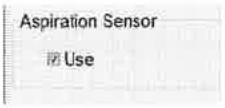
Blood aspiration sensor settings

Specify whether or not the [Aspiration Sensor] is used. When used, the sensor detects if the required sample was aspirated*.

* During [Pre-Dilution] / [Body Fluid] mode analysis, the blood aspiration sensor is always off, regardless of the setting.

Click [Analyzer] - [Aspiration Sensor] in the [Analyzer Settings] tree.

[Use]	Select the checkbox to use the [Aspiration Sensor].



Information

Not using the [Aspiration Sensor] may affect test results. For [Whole Blood] mode analysis, select [Use].

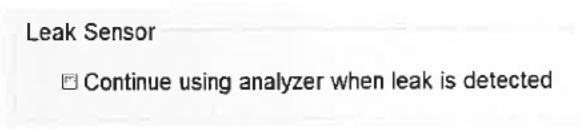
Note:

If you know in advance that a blood sample will be very thin (such as that of a dialysis patient), deactivate the [Aspiration Sensor].

Water leak sensor settings

Specify whether use of the analyzer is continued when a water leak is detected.

Click [Analyzer] - [Leak Sensor] in the [Analyzer Settings] tree.



[Continue using analyzer when leak is detected]	When the checkbox is selected, use of the analyzer can be continued when a water leak is detected.

Caution!

Unless otherwise directed by your local Sysmex representative, keep the setting set to OFF. If use is continued with the setting set to ON, the instrument and other devices may be damaged if leakage occurs.

3.2.10 SP-10 settings

Settings related to the SP-10 can be configured.

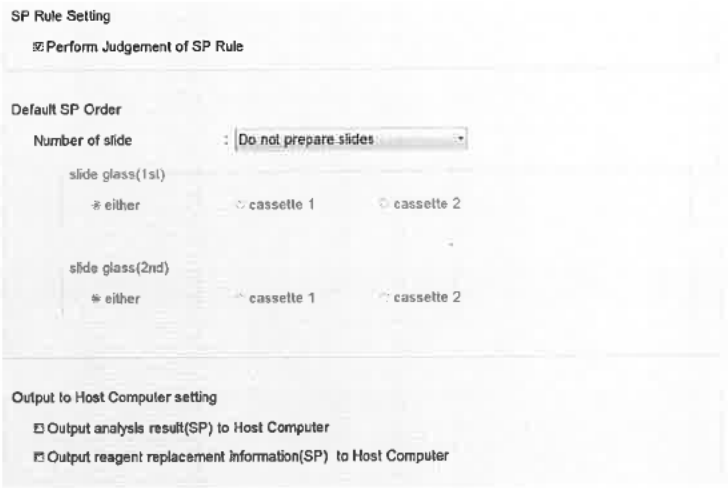
* Only when using the XN-3000 sampler (Standalone mode).

[SP Setting]	The following settings related to the SP-10 can be configured. • Whether [SP Rule] judgment is performed. • Number of samples prepared when an SP-10 order is not registered in the [Work List] screen. • Whether the SP-10 smear result and reagent replacement information are output to the host computer. (➤**P.3-20** "SP Settings")
[SP printer setting]	Set the information that is printed on the slide glass. (➤**P.3-21** "SP Printer Settings")

SP Settings

Click [XN-3000-1] - [SP] - [SP Setting] in the [Analyzer Setting] tree.

* Only when the XN-3000 (Standalone mode) is used.

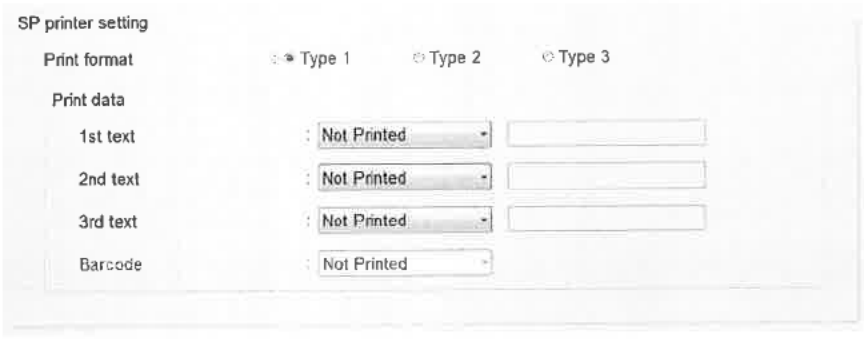


[SP Rule Setting]	Specify whether [SP Rule] judgment is performed.
[Perform Judgement of SP Rule]	Select the checkbox to perform [SP Rule] judgment. When this function is off, [SP Rule] judgment is not performed even if the rule is set.
[Default SP Order]	Set the number of samples prepared when an SP-10 order is not registered in the [Work List] screen. This order is also used when there is a smear preparation instruction from the host computer.
[Number of slide]	[Do not prepare slides], [1 slide], or [2 slides] can be selected.
[slide glass (1st)]	The 1st slide glass used to prepare a smear can be specified. Select [either], [cassette 1], or [cassette 2].
[slide glass (2nd)]	The 2nd slide glass used to prepare a smear can be specified. Select [either], [cassette 1], or [cassette 2].
[Output to Host Computer]	Specify whether the SP-10 smear result and reagent replacement information are output to the host computer.
[Output analysis result(SP) to Host Computer]	Select this checkbox to output the smear analysis result to the host computer.
[Output reagent replacement information(SP) to Host Computer]	When this checkbox is selected, reagent replacement information is output to the host computer.

SP Printer Settings

Click [XN-3000-1] - [SP] - [SP printer setting] in the [Analyzer Setting] tree.

* Only when the XN-3000 (Standalone mode) is used.



[SP printer setting]	Set the information that is printed on the slide glass.
[Print format]	The print format can be selected. For details on the print format, see the SP-10 "Instructions For Use". (➤SP-10 Instructions for Use, "Chapter 13: 13.2 Printer Print Format")
[Print data]	Set the information that is printed on the slide glass. For details on the printed information, see the SP-10 "Instructions For Use". (➤SP-10 Instructions for Use, "Chapter 13: 13.2 Printer Print Format")
[1st text] to [3rd text], [Barcode]	The settings below can be selected. [Not Printed], [Date], [Sample No.], [Patient ID], [Patient Name], [Last Name], [Sex], [Age], [Patient Comment], [Ward], [Doctor], [Sample Comment], [Fixed Text] If [Fixed Text] is selected, this can be entered at the left of the selection. Up to 15 characters can be entered. [3rd Text] cannot be entered when [Type 2] is set for [Print format]. [Barcode] cannot be entered when [Type 1] is set for [Print format].

3.3 IPU settings

The system settings of the IPU, external device connection settings, and automatic processing settings can be configured in the IPU settings.
The items shown below, which appear in the setting menu tree of the [IPU Setting] dialog box, can be configured.
(➤P.3-2 "Open the IPU settings")

- IPU Setting
  - Manage Settings
  - System
    - Facility Information
    - Basic System Language
    - IPU Shutdown
    - Date Format
    - User Administration
    - CSV Output
    - Security
    - Screen Keyboard
    - Patient ID Display
    - Notification of Program Updates
  - Displayed
    - Data Grid
    - Scattergram
  - Connect
    - Host Computer
    - Ticket Printer (DP)
    - Ticket Printer (DP) Print Format
    - Printer
  - Auto Process
    - Auto Validate
    - Auto Output
    - Analysis Ordering
    - Delta Check
  - Reference Interval
    - Catgory
    - Reference Interval
  - Unit
  - QC
    - QC Setting
    - QC Alarm
    - QC Chart Fixed Comment
    - QC Data Auto Output

3.3.1 Manage settings

Settings can be managed.

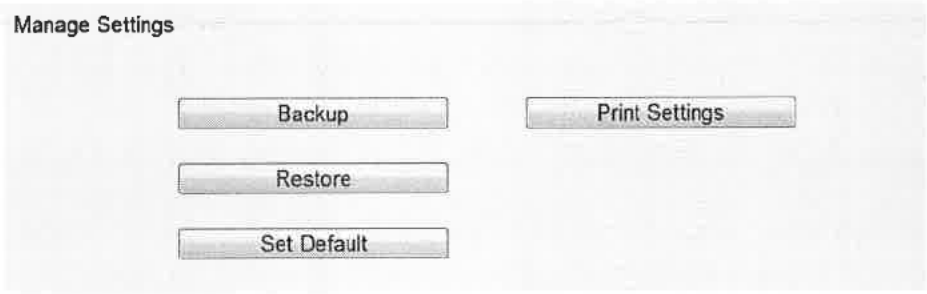
[Backup]*1	The current settings in the IPU can be saved to a file. (➤**P.3-23** "Save settings")
[Restore]*2	Settings saved in a file can be restored (they will replace the current settings). (➤**P.3-24** "Restore settings")
[Set Default]*2	The settings in the IPU can be returned to the default settings. (➤**P.3-25** "Initialize settings")
[Print Settings]*1	The settings in the IPU can be printed. (➤**P.3-25** "Print settings")

*1 Only displayed when setting changes have been applied. After changing a setting, click [Apply] to apply the setting.

*2 Only the [Built-in User] registered at the factory can be set.

Click [Manage Settings] in the [Analyzer Settings] tree to display the screen below*.

* When a user other than the [Built-in User] registered at the factory is logged on, [Restore] and [Set Default] are grayed out and cannot be selected.



Save settings

Follow the steps below to save the settings.

1 Click [Backup].

The [Save As] dialog box appears.

2 Specify or create the folder to save the sample data into.

3 Enter the file name.

The extension of a file is ".ini".

> **Note:**
> The default file name will be
> [XN][Software Version][IPUSetting][Date of save_Time of save].ini.

4 Click [Save].

The settings are saved.

Restore settings

Follow the steps below to restore settings to the IPU.

1 Click [Restore].

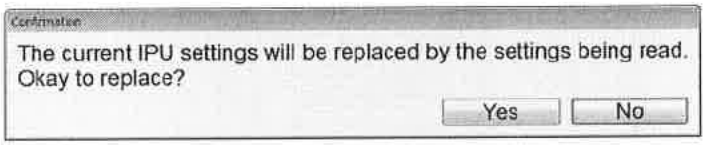
The [Open] dialog box appears.

2 Select the file that you wish to open.

The extension of a file is ".ini".

3 Click [Open].

The dialog box on the right appears.



4 Click [Yes].

The settings are replaced.

Information

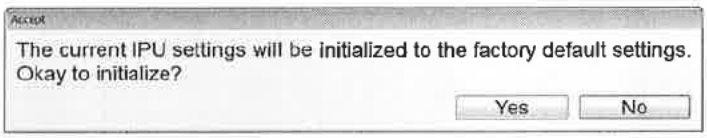
When settings are restored, the user information settings are also replaced by the restored data. Note that the [admin] (administrator) password is also replaced by the restored data.

Initialize settings

Follow the steps below to initialize the settings in the IPU.

1 Click [Set Default].

The dialog box on the right appears.



2 Click [Yes].

The settings are initialized.

Information

When the settings are initialized, the user information settings are also initialized. Note that the [admin] (administrator) password also returns to the default setting.

Print settings

Click [Print Settings]. The IPU settings will be printed.

The print format is ledger format. The settings are printed in 2 columns, with the first column showing the setting name and the second column showing the setting.

3.3.2 System settings

System settings can be configured.

[Facility Information]	Set the name of the facility that is using the system. The set facility name is used when analysis data is printed out. (➤**P.3-26** "Facility information setting")
[System Language]	Set the language that is used in the system and the language that is used in printing. (➤**P.3-27** "Change the display language (basic system language)")
[IPU Shutdown]	Specify whether or not the IPU is automatically shut down when all devices connected to the IPU are shut down. (➤**P.3-27** "IPU Shutdown setting")
[Date Format]	Set the format of the date that is printed and displayed on the IPU. (➤**P.3-27** "Date format setting")
[User Administration]	Register and delete users of the instrument. User permissions can also be set. (➤**P.3-28** "User information management (user administration)")
[CSV Output]	Specify whether image data is output when analysis data is output to CSV. If image data is output, select the output format ([BMP] or [PNG]) and the background color ([BLACK] or [WHITE]). In addition, specify whether the analysis data is divided into multiple files when the data exceeds 256 columns. (➤**P.3-32** "CSV output settings")
[Security]	Configure patient information and screen locking settings. (➤**P.3-33** "Security settings")
[Screen Keyboard]	Set whether or not the screen keyboard is used. (➤**P.3-34** "Screen keyboard setting")
[Patient ID Display]	Set the display position of the patient ID. (➤**P.3-34** "Patient ID display setting")

Facility information setting

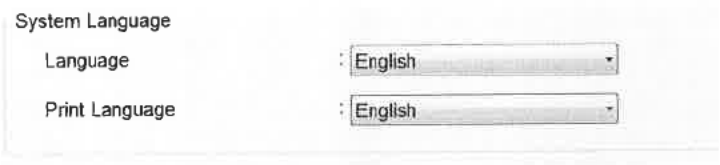
Click [System] - [Facility Information] in the [IPU Setting] tree.

[Facility Name]	The [Facility Name] can be entered. You can enter up to 32 characters.

Change the display language (basic system language)

Click [System] - [System Language] in the [IPU Setting] tree*.

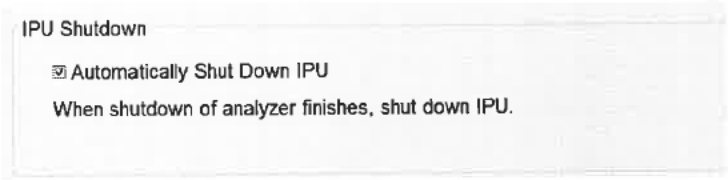
* Changed settings will be applied the next time startup or logon is performed.



[Language]	The language displayed in the system can be set. [English], [Spanish], [Portuguese], [French] can be selected.
[Print Language]	The language used for printing can be set. Languages that can be selected are the same as in [Language].

IPU Shutdown setting

Click [System] - [IPU Shutdown] in the [IPU Setting] tree.

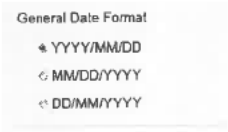


[Automatically Shut Down IPU]	Select the checkbox to have the IPU shut down automatically.

Date format setting

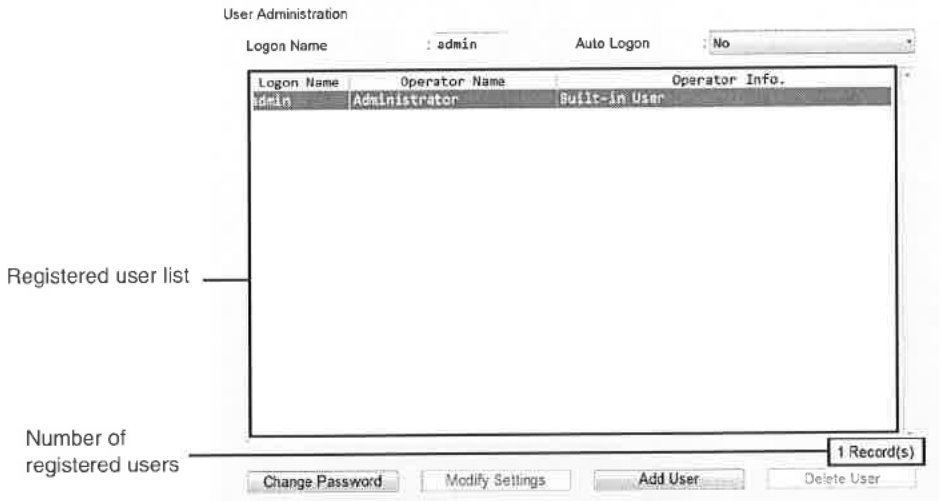
Click [System] - [Date Format] in the [IPU Setting] tree.

[General Date Format]	Select one of the following date formats.
[YYYY/MM/DD]	Year 4 digits/Month 2 digits/Day 2 digits
[MM/DD/YYYY]	Month 2 digits/Day 2 digits/Year 4 digits
[DD/MM/YYYY]	Day 2 digits/Month 2 digits/Year 4 digits



User information management (user administration)

Click [System] - [User Administration] in the [IPU Setting] tree.



[Logon Name]	The user name of the user logged onto the IPU appears.
[Auto Logon]	Select the user for auto logon. When [Same as OS Account Name] is selected, logon takes place using the same name as the OS account name when the IPU is started. If the same name cannot be found, auto logon does not take place.
Registered user list	The registered users are displayed. [Logon Name], [Operator Name], and [Operator Info.] appear. [Built-in User], which appears in [Operator Info.], indicates a factory registered user. A built-in user cannot be deleted or changed.
Number of registered users	The number of registered users is displayed.
[Change Password]	Click to display the dialog for changing the password. (➤**P.3-29** "Change the password")
[Modify Settings]	Click to display the dialog for changing user settings*. (➤**P.3-30** "Change settings and add users")
[Add User]	Click to display the dialog for adding a user. When the maximum number of users (101) have been registered, a user cannot be added. (➤**P.3-30** "Change settings and add users")
[Delete User]	Click to delete a user. [admin] (instrument administrator) cannot be deleted. (➤**P.3-32** "Delete a user")

* You can also double-click the user you want to change in the registered user display list to open a dialog box.

Information

The factory default password for [admin] (instrument administrator) is "m116m".
Change the password before using the instrument.

Change the password

Follow the steps below to change the password.

1 Click [Change Password].

The dialog box on the right appears.

> **Note:**
> - The logged on user can change his or her password.
> - Users with [All Administrators] authority can change the passwords of other users. For permission settings, see the following section:
> (➤P.3-30 "Change settings and add users")

2 Populate the displayed fields.

[Current Password]	Enter the current password. A user with [Built-in User] or [All Administrators] authority does not need to enter the password.
[New Password]	Enter the new password. You can enter up to 20 characters.
[Re-enter New Password]	Re-enter the new password for confirmation.

3 Click [OK].

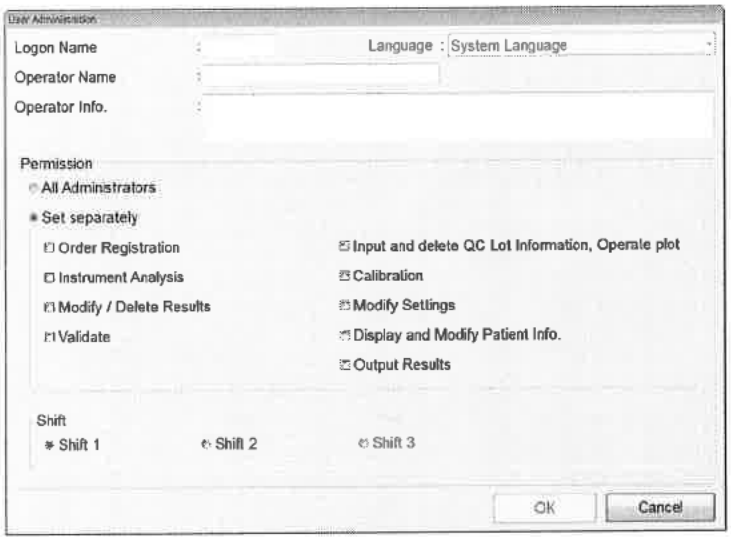
The password is changed.

Change settings and add users

Follow the steps below to change settings or add a user.

1 Click [Modify Settings] or [Add User].

The dialog box on the right appears.



Note:

The maximum number of users that can be registered is 20. This does not include factory registered users.

2 Populate the displayed fields.

- **Set basic user information.**

[Logon Name]	Enter the logon name of the user. You can enter up to 6 characters. If the dialog box is opened from [Modify Settings], this cannot be modified.
[Language]	Select the language that is displayed for the user. For the languages that are available, see the following. (➤**P.3-27** "Change the display language (basic system language)")
[Operator Name]	Enter the name of the logon user. You can enter up to 20 characters.
[Operator Info.]	Enter additional information related to the user. You can enter up to 100 characters.

● **Set user permissions.**

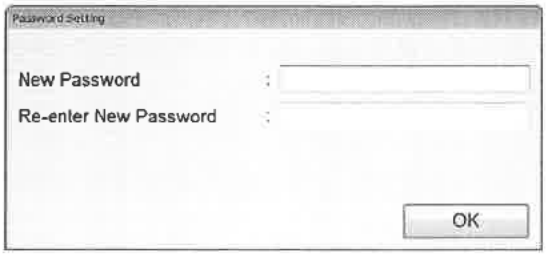
[All Administrators]	Select to give the user all permissions below.
[Set separately]	Select to separately specify the items below.
[Order Registration]	Select this check box to permit order registration. If not selected, the user cannot open the [Work List] screen.
[Instrument Analysis]	Select this check box to permit analysis of samples. If not selected, the user cannot perform analysis.
[Modify / Delete Results]	Select this check box to permit modification/deletion of analysis results.
[Validate]	Select this check box to permit validation of results.
[Input and delete QC Lot Information, Operate plot]	Select this check box to permit input and deletion of QC sample lot information, plot operation, and [Cursor Data Management].
[Calibration]	Select this check box to permit calibration.
[Modify Settings]	Select this check box to permit modification of settings.
[Display and Modify Patient Info.]	Select this check box to permit display and modification of patient information. [Patient Information] can be included in the saved data of Sample Explorer and in CSV file output. However, this must also be set in [Security]. (➤**P.3-33** "Security settings")
[Output Results]	Select this check box to permit external output.

● **Set shift.**

[Shift]	Select the shift. QC result plots can be viewed for each shift.

3 Enter the password.

Enter the new password (twice).
If settings are being modified, the dialog box on the right does not appear. Go to the next step.



4 Click [OK].

The dialog box closes, the settings are changed or the users are added.

Delete a user

Follow the steps below to delete a user.

1 **Click the user that you wish to delete in the list.**

The user is selected.

> **Note:**
> - Users with [All Administrators] authority can delete other users.
> - A [Built-in User] cannot be deleted.

2 **Click [Delete User].**

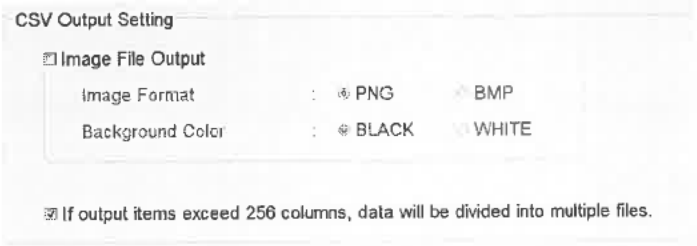
The dialog box on the right appears.

3 **Click [Yes].**

The selected user will be deleted.

CSV output settings

Click [System] - [CSV Output] in the [IPU Setting] tree.



[Image File Output]	Select the check box to have an image output when data is saved in CSV format. The image format ([PNG]/[BMP]) and background color ([BLACK]/[WHITE]) can be selected.
[If output items exceed 256 columns, data will be divided into multiple files.]	Select the check box to divide into multiple files if the output items exceed 256 columns.

Security settings

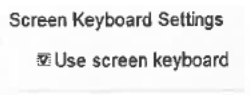
Click [System] - [Security] in the [IPU Setting] tree.

[Include patient information]	Select the check box to include [Patient Information] when saving analysis data.
[Output patient information]	Select the check box to include [Patient Information] when outputting analysis data to a CSV file.
[Use IPU screen lock timer]	Select the check box to turn on the IPU screen lock timer. When the IPU screen lock timer is used, the IPU screen will lock and operation will not be possible if the mouse or keyboard of the IPU is not used for the time set with the timer.
[Time until IPU screen lock]	The time until the screen is locked by the IPU screen lock timer can be set. The time can be set from 15 to 60 minutes in increments of 1 minute.

Screen keyboard setting

Click [System] - [Screen Keyboard] in the [IPU Setting] tree.

[Use screen keyboard]	Select the check box to enable use of the screen keyboard. Click an input box to display the screen keyboard. The screen keyboard is a Windows function.



Patient ID display setting

Click [System] - [Patient ID Display] in the [IPU Setting] tree.

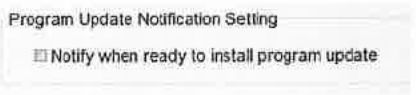
[Patient ID Display Settings]	Set patient ID display to [Right-justified] or [Left-justified]*.

* The patient ID displayed in the patient information area is always left-justified, regardless of the setting.

Program Update Notification Setting

Click [System] - [Notification of Program Updates] in the [IPU Setting] tree.

[Notify when ready to install program update]	Select to be notified when program updates are ready to be installed.



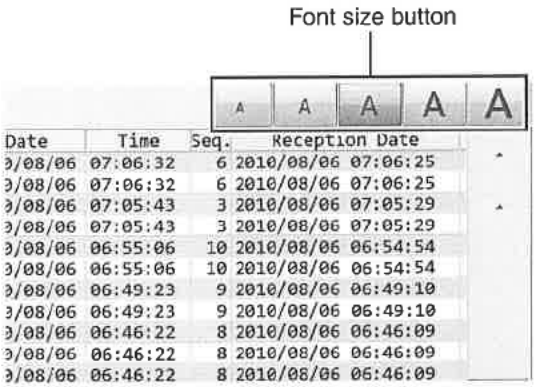
3.3.3 Display settings

Display settings can be configured.

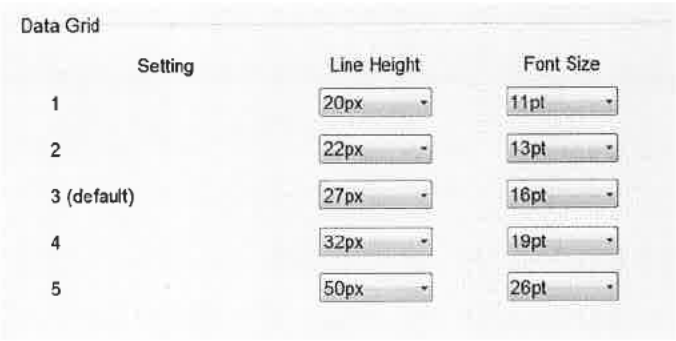
[Data Grid]	A data grid (line height and character size of lists) can be set. (➤**P.3-35** "Data grid setting")
[Scattergram]	The background color of a scattergram can be set. (➤**P.3-35** "Scattergram setting")

Data grid setting

Click a font size button on the list screen of each screen to change the data grid.



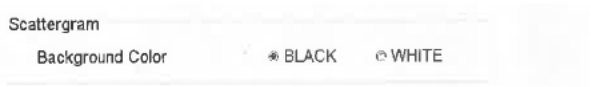
Click [Displayed] - [Data Grid] in the [IPU Setting] tree, and then set each item to change the data grid.



[Setting]	The numbers displayed on the font size button of the list screen of each screen appear.
[Line Height]	The line height can be set. Set to a height from 20 to 50 pixels in increments of 1 pixel.
[Font Size]	The size of characters displayed on the screen can be set. Set to a size from 11 to 30 points in increments of 1 point.

Scattergram setting

Click [Displayed] - [Scattergram] in the [IPU Setting] tree.



[Background Color]	The background color ([BLACK]/[WHITE]) of a scattergram can be selected.

3.3.4 Connection settings

Connection settings can be configured.

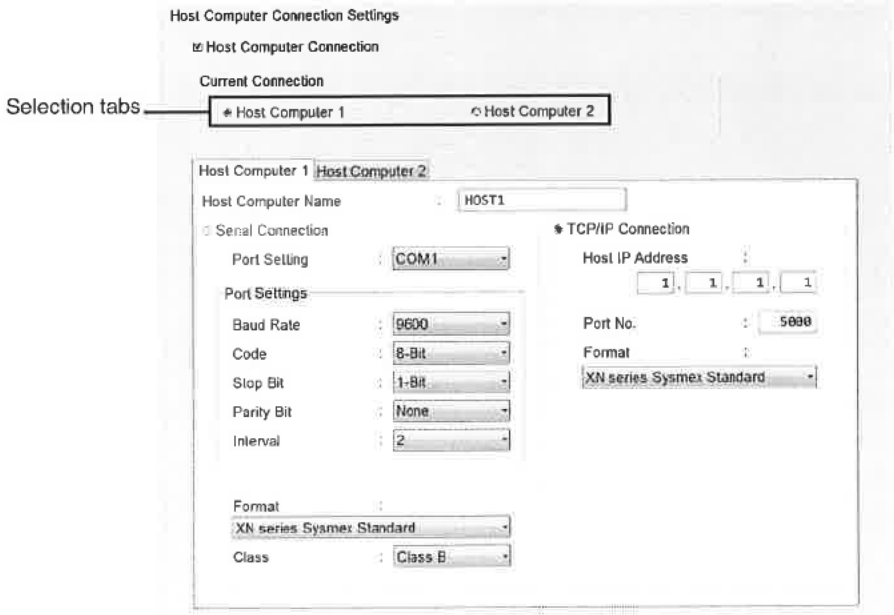
[Host Computer]	Configure host computer connection and communication settings. (➤**P.3-36** "Host computer connection")
[Ticket Printer (DP)]	Set the ticket printer connection and print display format. (➤**P.3-38** "Ticket printer (DP) connection")
[Ticket Printer (DP) Print Format]	Set the items printed by the ticket printer and the print positions. (➤**P.3-39** "Ticket (DP) print format settings")
[Printer]	Set connection of the graphic printer and list printer. (➤**P.3-40** "Graphic printer (GP)/List printer (LP) connection")

Note:

Only when a host computer and printers are connected, the output destinations of the [Output] button on the toolbar will be displayed.

Host computer connection

Click [Connect] - [Host Computer] in the [IPU Setting] tree.



[Host Computer Connection]	Select the checkbox to enable connection to a host computer. When this is not selected, interface settings cannot be configured.
[Current Connection]	Select [Host Computer 1] or [Host Computer 2]. Connection is only possible to 1 host computer. Up to 2 host computers can be registered.
Selection tabs	Click to display the connection settings of [Host Computer 1] or [Host Computer 2].

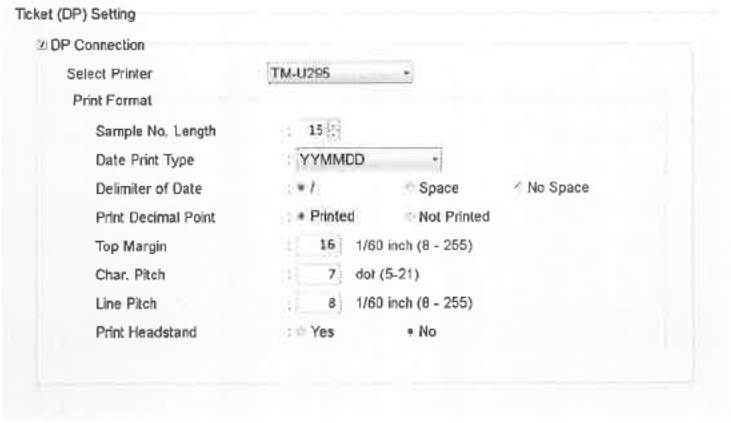
[Host Computer Name]	Enter the name of the host computer. The name entered here will appear in the host menu. You can enter up to 8 characters.
[Serial Connection]	Select to connect to the host computer by serial connection. Detailed parameters can be configured.
[Port Setting]	Select the port used for the host computer connection. A serial port can be selected.
[Port Settings]	The following settings are available.
[Baud Rate]	Select the transmission speed.
[Code]	Select the data bit length.
[Stop Bit]	Select the stop bit length.
[Parity Bit]	Select the parity check method.
[Interval]	Select the interval for transmission to the host computer.
[Format]	Select the serial communication format. [XN series Sysmex Standard] or [XN series ASTM] can be selected. When [XN series ASTM] is selected, the class cannot be selected.
[Class]	Select the transmission method.
[TCP/IP Connection]	Select to connect to the host computer by TCP/IP. Detailed parameters can be configured.
[Host IP Address]	Set the IP address of the host computer. Values from 0 to 256 can be entered.
[Port No.]	Set the port number of the host computer. A value from 0 to 65535 can be entered.
[Format]	Select the communication format for TCP/IP. [XN series Sysmex standard] or [XN series ASTM] can be selected.

Note:

The host computer to which the system connects can be changed in the host menu. Click [HOST] in the host computer area of the analyzer control menu to display the host menu.

Ticket printer (DP) connection

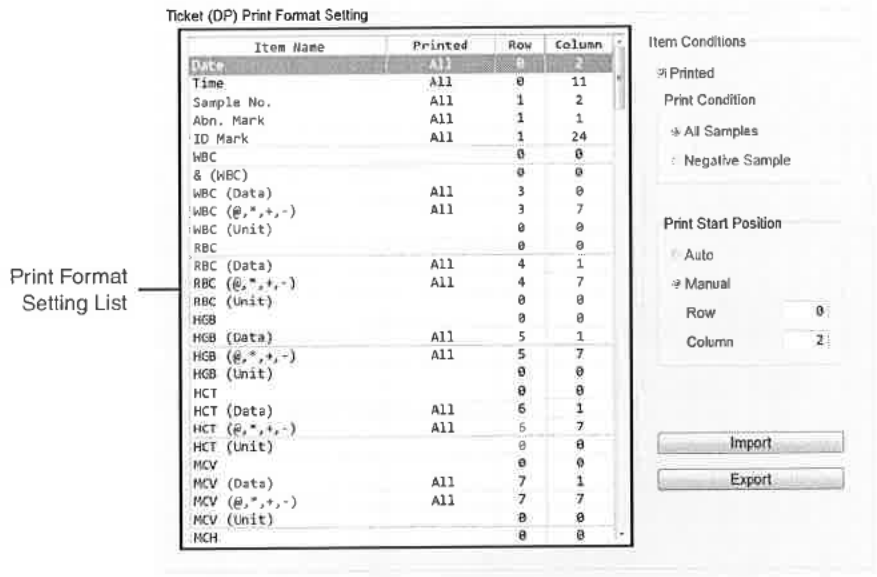
Click [Connect] - [Ticket Printer (DP)] in the [IPU Setting] tree.



[DP Connection]	Select to connect to the ticket printer (DP). When not selected, the items below are grayed out and cannot be set.
[Select Printer]	Select the printer to be connected. Only the [TM-U295] can be selected. Connect the printer to the IPU with a parallel cable. In some cases it is possible to connect to other than the above printer by means of a model change.
[Print Format]	The print format can be set.
[Sample No. Length]	Set the number of sample number digits that are printed. Any number from 1 to 22 can be selected.
[Date Print Type]	Set the format of the printed date. [YYMMDD], [MMDDYY], [DDMMYY], [DDMM], or [MMDD] can be selected. Y: Year (2 digits), M: Month (2 digits), D: Day (2 digits).
[Delimiter of Date]	Select the delimiter ([/], [Space], or [No Space]) used in the printed date. e.g: May 5, 2010 Slash: 10/05/05 Space: 10 05 05 No space: 100505
[Print Decimal Point]	Specify whether decimal points in data are printed.
[Top Margin]	Set the margin between the top of the ticket and the print start position in the indicated inch-based units. A value from 8 to 255 can be set.
[Char. Pitch]	Set the character pitch in dots. A value from 5 to 21 can be set.
[Line Pitch]	Set the line pitch in the indicated inch-based units. A value from 8 to 255 can be set.
[Print Headstand]	Specify whether headstand printing is performed.

Ticket (DP) print format settings

Click [Connect] - [Ticket Printer (DP) Print Format] in the [IPU Setting] tree.



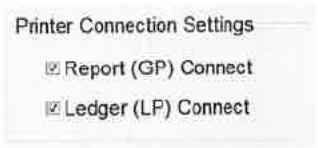
Print Format Setting List	Click the items that you wish to print. Displays only the reportable items. In date data, allowance must be made for any print spaces specified in Date Print Type and Delimiter of Date. In sample numbers, allowance must be made for any print spaces specified in Sample No. Length. Make sure the print spaces of items do not overlap.
[Printed]	Select the check box to have the item printed. Print details can be set.
[Print Condition]	Select the samples to be printed. For items with "&" after the item name, [All Samples] is always selected.
[Print Start Position]	[Auto] or [Manual] can be selected. When [Manual] is selected, set [Row] or [Column] for the print start position. A value from 0 to 255 can be entered. Set the column based on the print position of the most significant digit of each analysis item.
[Import]	A saved ticket (DP) print format can be imported. The extension of a file is ".dpf". The default file name is [XN][Software version][DPFormat].dpf. The procedure is the same as for importing master settings. (➤**P.3-8** "Import master settings")
[Export]	The current ticket (DP) print format settings can be saved to a file. The extension of a file is ".dpf". The procedure is the same as for exporting master settings. (➤**P.3-7** "Save master settings")

Information

If the row or column setting is incorrect, some analysis results may not be printed or printing will not be complete. Set the row and column to the correct position.
Depending on the state of adjustment of the printer and the length of the paper, printing may not take place correctly even if the content is within the possible layout range.

Graphic printer (GP)/List printer (LP) connection

Click [Connect] - [Printer] in the [IPU Setting] tree.



[Report (GP) Connect]	Select the check box to connect to a graphic printer.
[Ledger (LP) Connect]	Select the check box to connect to a list printer.

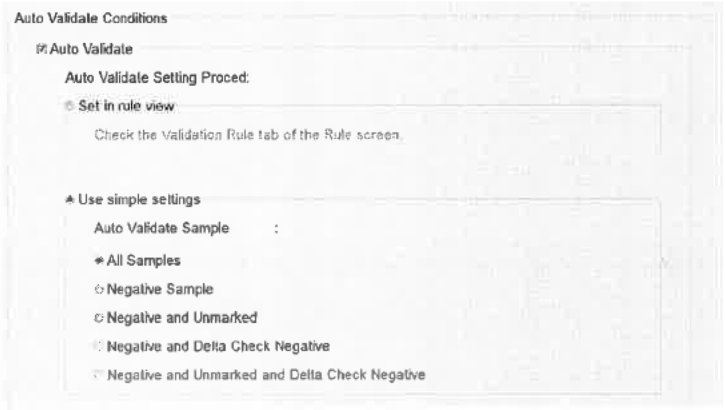
3.3.5 Automatic processing settings

Automatic processing settings can be configured.

[Auto Validate]	Specify whether validation takes place automatically. Set the samples to be validated. (➤**P.3-41** "Auto validate settings")
[Auto Output]	Specify whether output takes place automatically. Set the output destination. (➤**P.3-42** "Auto output settings")
[Analysis Ordering]	Set the keys and method used to query the host computer for analysis information. (➤**P.3-43** "Analysis ordering")
[Delta Check]	Specify whether delta check is performed. (➤**P.3-44** "Delta check settings")

Auto validate settings

Click [Auto Process] - [Auto Validate] in the [IPU Setting] tree.



[Auto Validate]	Select the check box to have samples automatically validated. Select whether validation conditions are set in the rule screen or using the simple settings.
[Set in rule view]	Select to enable the settings in [Validation Rule] in the rule screen.
[Use simple settings]*	Select to enable the simple settings. Select samples to be validated. When [Use simple settings] is selected, the settings in the rule screen are disabled.

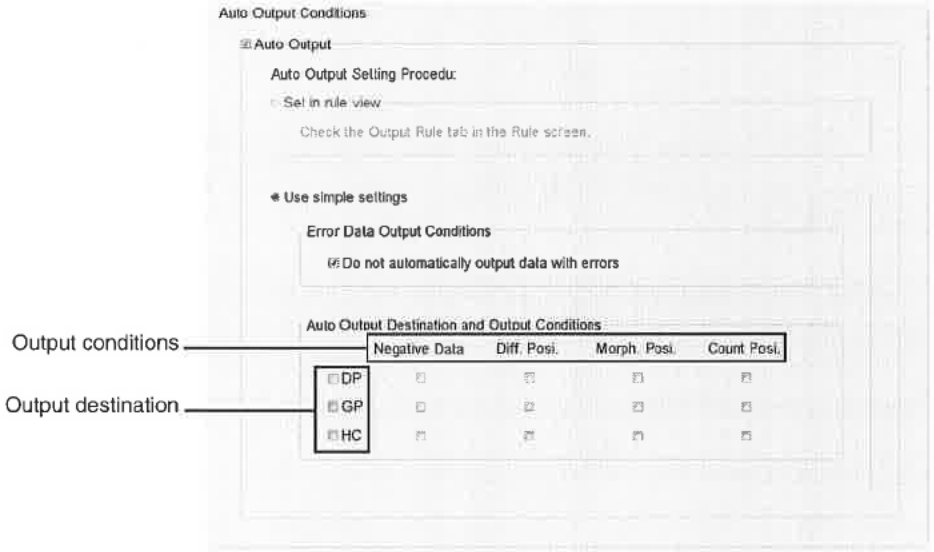
* Only when setting the delta check, the items including "Delta Check Negative" are displayed. (➤**P.3-44** "Delta check settings")
When auto validated samples are [All Samples], samples are validated regardless of the analysis mode.

> **Information**
>
> If you are using transportation controller (CT-90), an order is queried from the transportation controller to the host computer. Therefore, be sure to select the [Auto Validate] check box, and select [Use simple settings] - [All Samples].

> **Note:**
>
> An analysis result which has been validated only can be output.

Auto output settings

Click [Auto Process] - [Auto Output] in the [IPU Setting] tree.



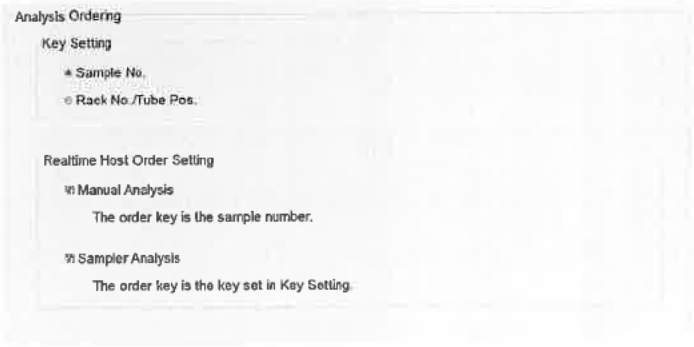
[Auto Output]	Select to have validated samples automatically output. The following settings are available.
[Set in rule view]	Select to enable the settings in the rule screen. Analysis data will be automatically output based on [Validation Rule] and [Output Rule].
[Use simple settings]	Select to set [Error Data Output Conditions] and [Auto Output Destination and Output Conditions]. When [Do not automatically output data with errors] is selected, data with errors are not output to any of the output destinations, regardless of the output conditions.
Output destination	Set the auto output destination.
[DP]	Select the check box to enable output from the ticket printer. Output conditions can be selected.

[GP]	Select the check box to enable output from the graphic printer. Output conditions can be selected.
[HC]	Select the check box to enable output from the host computer. Output conditions can be selected.
Output conditions	Set the output conditions. If both the conditions for output and no output are met, output does not take place.
[Negative Data]	When this is selected, data with neither any items judged abnormal nor any analysis errors are selected.
[Diff. Posi.]	When this is selected, sample data with abnormal blood cell differentiation are selected.
[Morph. Posi.]	When this is selected, sample data with abnormal blood cell morphology are selected.
[Count Posi.]	When this is selected, sample data with abnormal blood cell counts are selected.

Note:
Data that have already been transmitted are not output by auto output.

Analysis ordering

Click [Auto Process] - [Analysis Ordering] in the [IPU Setting] tree.



[Key Setting]*	Select [Sample No.] or [Rack No./Tube Pos.]. When there are pending orders in the [Work List] screen, the order key cannot be changed. When [Rack No./Tube Pos.] is selected, sample tube labels are not read.
[Realtime Host Order Setting]	Specify whether real-time queries are sent to the host computer when [Manual Analysis] or [Sampler Analysis] is performed.
[Manual Analysis]	Select to have host ordering performed during manual analysis. The order key is the sample number.
[Sampler Analysis]	Select to have host ordering performed during sampler analysis. The order key can be set.

* When the transportation controller (CT-90) is used, this is always [Sample No.]. This cannot be selected.

Delta check settings

Click [Auto Process] - [Delta Check] in the [IPU Setting] tree.

[Perform Delta Check] Select the check box to have delta check performed.

● Delta check

Purpose	Detects the possibility of the following errors: Possibility of sample mix-up. Possibility of a sample or instrument problem
Method	The difference between the data being judged and the previous analysis data is obtained using the [Patient ID] as a keyword.
Checked parameters	WBC, HGB, MCV, PLT. If the previous analysis was performed more than four days earlier, WBC judgment is not performed. * Analysis data from [Body Fluid] mode are not checked by delta check.
Display	[Check] is displayed in the [Action] column of the [Sample Explorer] screen and in the Action field of the [Data Browser] screen. The following Delta check details can be viewed in the [Data Browser] screen. • [The sample might be wrong. Check the sample.] • [Significant change in %s. Check the sample.]
Judgment method	The difference (Diff) between the judged data and the previous analysis data is obtained from the following equation: Diff = | a - b | / c × 100 a: Judged value b: Previous value c: The smaller of a and b
Supplementary information	The threshold (low level) for [Significant change in %s. Check the sample.] and the threshold (high level) for [The sample might be wrong. Check the sample.] are different. These thresholds are determined by proprietary Sysmex parameters and equations. The parameters and equations vary by analysis item. Normal: Diff value < Low level [Significant change in %. Check the sample.]: Low level < Diff value < High level [The sample might be wrong. Check the sample.]: High level < Diff value

Note:

Using the patient ID as a keyword, delta check compares the most recent analysis data with the previous analysis data and judges if the data is abnormal based on any changes in the data.

- If you are using multiple analyzers, you can compare data with a same patient ID across analyzers.
- When multiple IPUs are used with the transportation controller (CT-90), analysis data cannot be compared between IPUs.

3.3.6 Reference interval settings

The reference interval settings can be configured.

[Category]	Set the patient categories by age and gender. (➤**P.3-45** "Category settings")
[Reference Interval]	Set the values based on which abnormal judgments are made. (➤**P.3-46** "Reference interval settings")

Category settings

Click [Reference Interval] - [Category] in the [IPU Setting] tree.

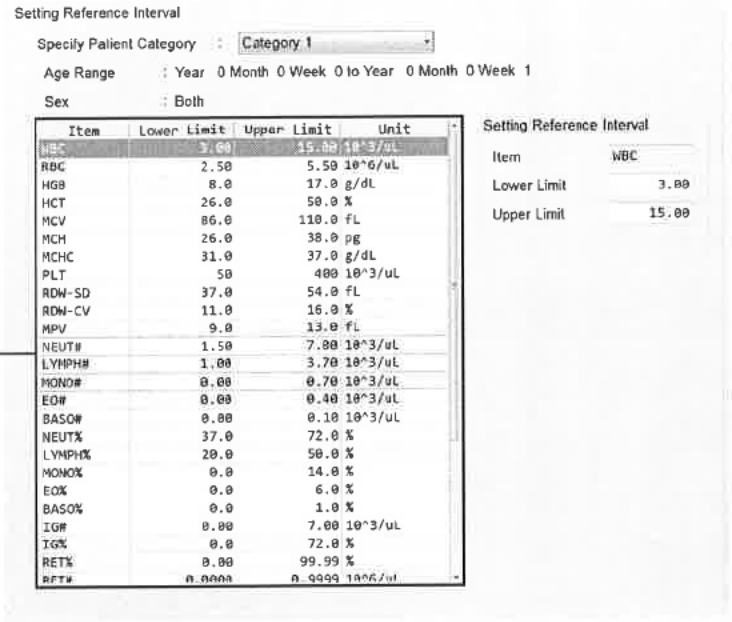
[Category 1] to [Category 7]	Select the category to be used.
[Lower Age Limit], [Upper Age Limit]	Enter values in [Year], [Month], and [Week]. [Year], [Month], and [Week] of [Lower Age Limit] and [Upper Age Limit] are the time elapsed after birth, not a date.
[Sex]	The gender can be specified.

Note:

If there is no information on the age or gender, or there is no applicable category, the limits of the universal category are automatically used.

Reference interval settings

Click [Reference Interval] - [Reference Interval] in the [IPU Setting] tree.



[Specify Patient Category]	Set the patient category. One of categories 1 to 7, or category 8 (the universal category), can be selected.
[Age Range]	The age range of the selected patient category appears.
[Sex]	The gender of the selected patient category appears.
List of reference interval values	Click an item to select it. Settings for the selected item can be configured in [Setting Reference Interval] at the right. All items cannot be displayed at once. Scroll the screen to display items that do not appear. [Unit] cannot be changed in this dialog box. To set the units, see the following section: (➤**P.3-47** "3.3.7 Unit settings (Unit)")
[Setting Reference Interval]	The current settings of the item selected in the list appear. An abnormal judgment of analysis data is made based on this reference interval.
[Item]	The selected item appears. This cannot be entered. When multiple analyzers are connected to the IPU, analyzable items can be set for any of the analyzers.
[Lower Limit]*, [Upper Limit]*	The lower limit and upper limit for judging abnormalities can be entered. You can enter up to 6 characters. If a reference interval is not needed, set the lower limit to [0] and the upper limit to a high value such as 999.9.

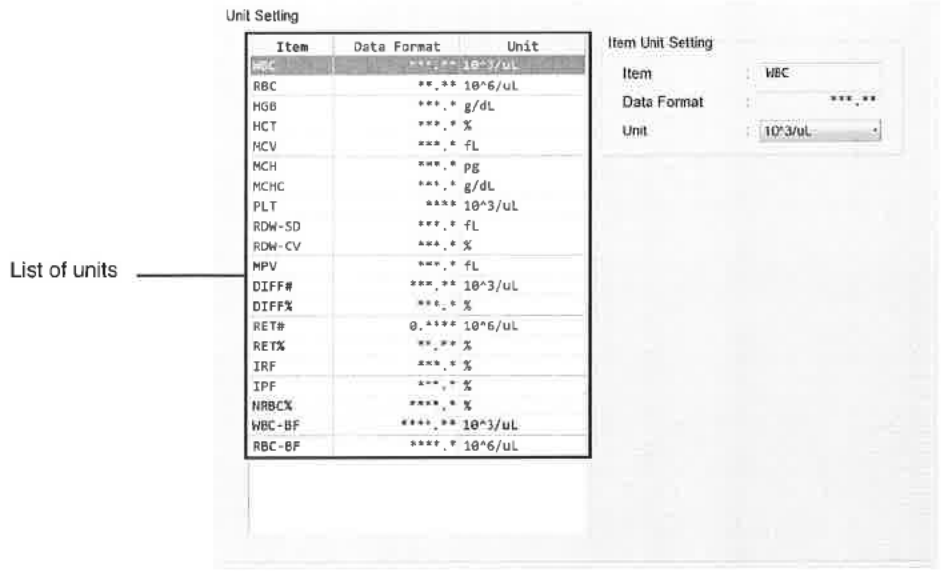
* The decimal point symbol set in Windows is displayed in the XN Series. The only decimal point symbols displayed are "." (period) or "," (comma).

Note:

When the analysis data of an item exceeds the upper or lower limit, "+" or "-" will appear to the right of the data.

3.3.7 Unit settings (Unit)

Click [Unit] in the [IPU Setting] tree.



List of units	Click an item to select it. Settings for the selected item can be configured in [Unit Setting] at the right.
[Item Unit Setting]	The current settings of the item selected in the list appear.
[Item]	The item selected in the list appears. This cannot be changed.
[Data Format]*	The data format of the item selected in the list is indicated using [*] and [.]. This cannot be changed. When multiple analyzers are connected to the IPU, analyzable items can be set for any of the analyzers.
[Unit]	Click to set the units. The units that can be selected vary depending on the item. When the units are changed, the displayed data format changes accordingly.

* The decimal point symbol set in Windows is displayed in the XN Series. The only decimal point symbols displayed are "." (period) or "," (comma).

3.3.8 QC settings

Quality control settings can be configured.

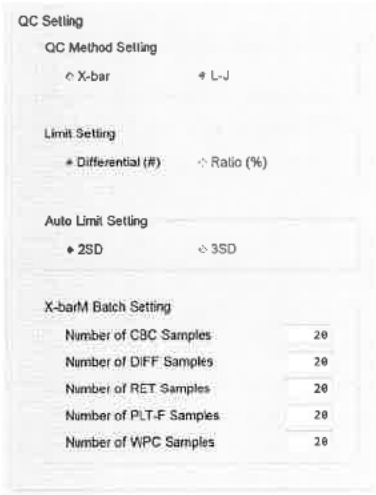
[QC Setting]	Set the quality control method and other basic settings. (➤**P.3-48** "QC settings")
[QC Alarm]	Configure settings for alarms that prompt you to perform QC. (➤**P.3-49** "QC alarm settings")
[QC Chart Fixed Comment]	Set fixed comments that can be added to plots in QC charts. (➤**P.3-50** "QC chart fixed comment settings")
[QC Data Auto Output]	Specify whether or not the plot data is output to a host computer when QC data is plotted on a QC chart. (➤**P.3-51** "QC data auto output settings")

QC settings

Click [QC] - [QC Setting] in the [IPU Setting] tree.

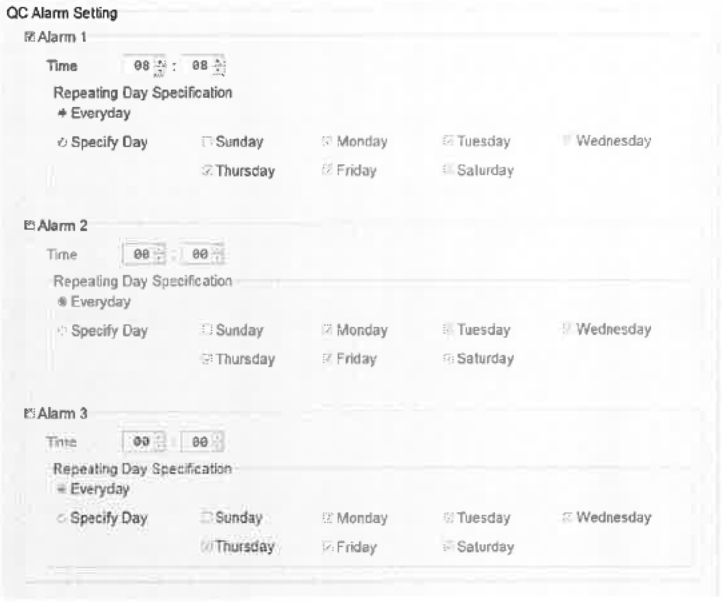
[QC Method Setting]	Select the QC method.
[Limit Setting]	Specify whether the QC limit value is calculated from the average (target) using the [Differential (#)] method ([SD]) or the [Ratio (%)] method ([CV]) .
[Auto Limit Setting]	Specify whether the limit used for auto limit is twice [SD] or [CV] ([2SD]) or 3 times [SD] or [CV] ([3SD]).
[X-barM Batch Setting]*	Set the number of samples (batches) per X-barM QC plot for each discrete item. Any number from 0 to 99 can be set.

* These discrete samples do not appear with all analyzer types.



QC alarm settings

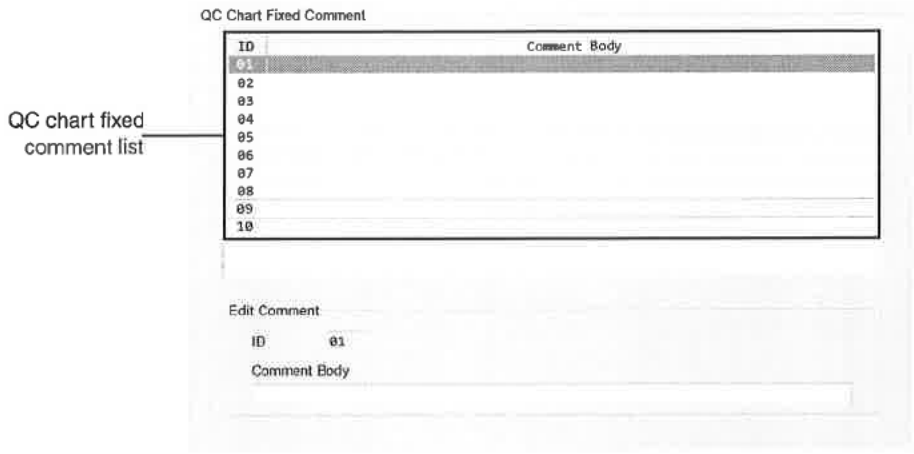
Click [QC] - [QC Alarm] in the [IPU Setting] tree.



[QC Alarm Setting]	Settings for alarms that prompt you to perform QC can be configured. 3 alarms can be registered.
[Alarm 1] to [Alarm 3]	When selected, the set alarm will sound. If the checkmark is removed, the time and day cannot be set. The settings will be grayed out and cannot be clicked.
[Time]	Set the time that the alarm will sound. Hour: A value from 00 to 23 can be set. Minute: A value from 00 to 59 can be set.
[Repeating Day Specification]	Set the day that the alarm will sound. [Everyday] or [Specify Day] can be selected.

QC chart fixed comment settings

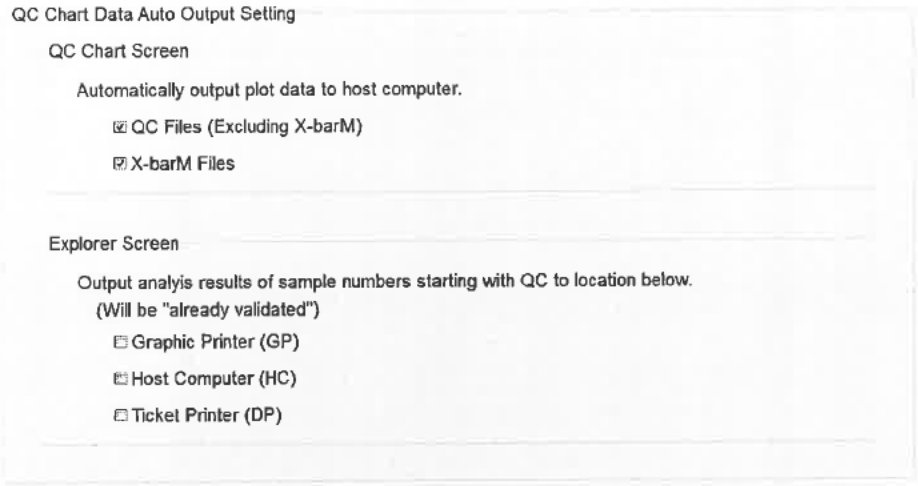
Click [QC] - [QC Chart Fixed Comment] in the [IPU Setting] tree.



QC chart fixed comment list	Displays the [ID] and [Comment Body] of each QC chart fixed comment.
[Edit Comment]	A comment selected in the list can be edited.
[ID]	ID numbers from 01 to 10 appear. An ID number cannot be changed.
[Comment Body]	A comment can be entered.If a comment cannot be fully displayed, [...] appears at the end. You can enter up to 100 characters.

QC data auto output settings

Click [QC] - [QC Data Auto Output] in the [IPU Setting] tree.



[QC Chart Screen]	Automatic output settings can be configured. When selected, [QC Files (Excluding X-barM)] and [X-barM Files] output can be set. To output QC chart data, a connection to a host computer is required. (➤**P.3-36** "Host computer connection") When the checkmark is removed, all items are grayed out and cannot be clicked.
[Explorer Screen]	The output destination for analysis results of sample numbers beginning with "QC-" that are received in the Explorer screen can be set. Select the check box to output from the [Graphic Printer (GP)], [Host Computer (HC)], or [Ticket Printer (DP)].

3.4 Graphic printer print settings (customize GP)

Analysis data, cumulative data, QC charts, and other data can be printed graphically from a graphic printer. The GP customize function can be used to configure the print settings of the graphic printer.

3.4.1 GP customize function

Setting the text to be printed and the image format

The following print settings can be configured.

- Text
- Line
- Image format (BMP)
- Table

Printing analysis data

The data below can be printed in a specified color at a specified location.

- Sample information
- Analysis data
- Reference intervals for abnormality judgments
- Scattergrams*
- Distributions*
- IP messages

* Colors cannot be specified.

Outputting print information

The print date and time, user name, software version, facility name, instrument name and other print-related information can be output.

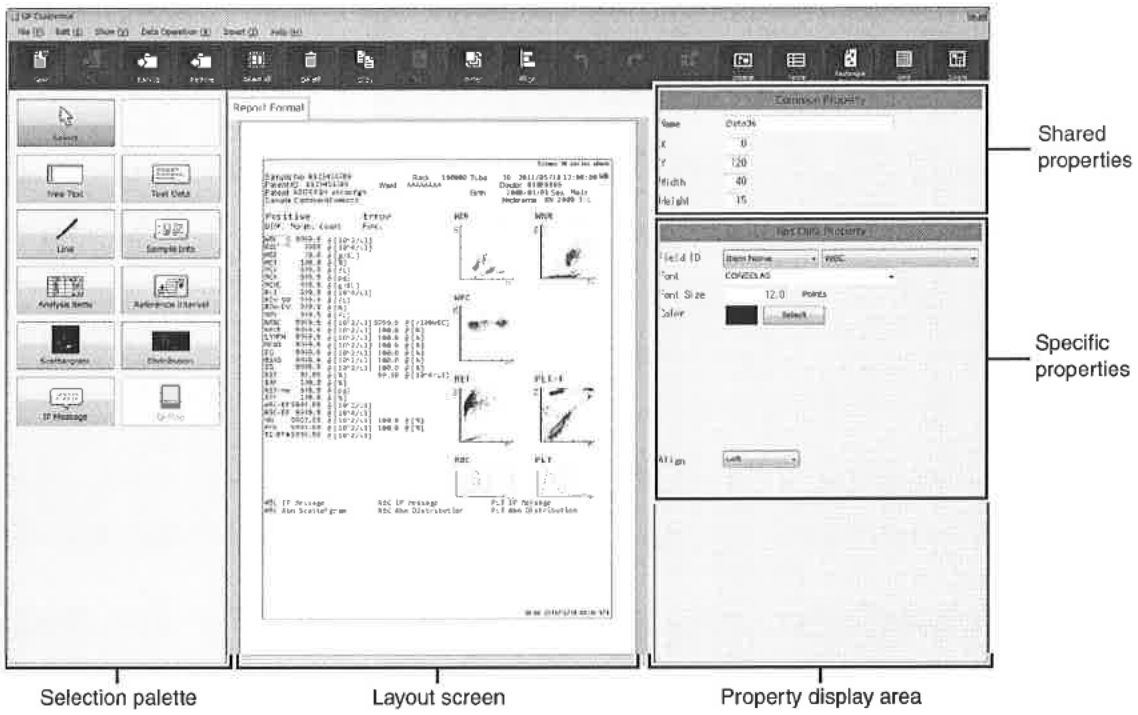
Printing from a graphic printer

Analysis data, scattergrams, QC charts, and other information can be printed from a graphic printer.

[Report Format]	Select the [Output] button on the toolbar and click [Report (GP)].

3.4.2 GP customize screen

The content printed by the graphic printer can be set in the GP customize screen.
Click the [GP Customize] icon in the menu screen to display the [GP Customize] screen.
To exit, click [File] - [EXIT] on the menu bar.
The screen consists of the following parts.



Toolbar

The button of the following functions are displayed.

[New]	Click to open a dialog for creating a new layout.
[Save]	This can be clicked when the layout has been changed. This temporarily saves the layout of the current layout screen.
[Select All]	Click to select all objects in the layout screen.
[Delete]	This can be clicked when an object is selected. Click to delete an object selected in the layout screen.
[Copy]	This can be clicked when an object is selected. Click to copy an object selected in the layout screen.
[Paste]	Click to paste a copied object on the layout screen.
[Order]	This can be clicked when an object is selected. Clicking this displays a list of sorting options. A sorting option can be selected to change the order of the objects. [Move Forward (F)], [Move Backward (B)], [Move to Front (I)], or [Move to Back (S)] can be selected.

[Align]	This can be clicked when an object is selected. Clicking this displays a list of alignment options. Select an alignment option to align the objects. [Left Aligned (L)], [Right Aligned (R)], [Top Aligned (O)], [Bottom Aligned (Q)], [Justify Vertically (H)], [Justify Horizontally (J)], [Center Vertically (K)], [Center Horizontally (M)], [Center Vertically in Rectangle (V)] or [Center Horizontally (T) in Rectangle],can be selected.
[Undo]	Click to undo the previous operation.
[Redo]	Click to cancel [Undo].
[Backup]	The print layout of the current layout screen can be saved. (➤**P.3-59** "3.4.3 Save layout")
[Restore]	Replaces the current layout screen with the layout of the file that is opened. (➤**P.3-60** "3.4.4 Restore saved layout")
[Cancel Template]	Click to clear an object in a template. Table edit items cannot be cleared.
[Image]	Any image can be added to the layout screen. A dialog box for selecting the image file appears. Image format is BMP.
[Table]	A table can be added to the layout screen. Click to open a dialog for setting the table.
[Rectangle Display]	Click to show edit frames around each item on the layout screen. Edit frames allow you to check for overlapping items.
[Grid]	Click to show/hide the grid on the layout screen. Showing the grid makes it easier to check the size and position of objects.
[Zoom]	Click to change the zoom of the layout image. 100%, 150%, or 200% can be selected.

Selection palette

Select the template and the items to be printed. (➤**P.3-54** "Selection palette")
The selected content appears in the layout screen.

Layout screen

Shows the print layout.
(➤**P.3-56** "Layout screen")

Property display area

This shows the items selected in the layout screen and the template properties. The properties can be set.
(➤**P.3-56** "Properties")

Selection palette

The following items are shown in the selection palette.

[Selection]	Click to change the layout screen to selection mode.

● Text and lines

Details for each edit item are displayed in the specific properties.
An item on the selection palette can also be clicked to display the item on the layout screen. A displayed item can be clicked to edit the item from the properties display area.

[Free Text]	Click to set the character size, color, and other settings. When the layout screen is clicked, a text frame appears. A text frame can also be displayed by dragging on the layout screen.
[Text Data]	The text data of a set item can be edited. When the layout screen is clicked, a text frame appears. A text frame can also be displayed by dragging on the layout screen.
[Line]	Click to configure line settings.

● Template

Sample information and analysis items are arranged in sets of names and values. Frequently used combinations of edit items are pre-grouped in a template.
Click the [New] button on the toolbar to open a dialog for selecting the template. A template can be selected from the list that appears in the dialog.
To cancel a template, click the [Cancel Template] icon on the toolbar. Table edit items cannot be canceled.
The size of a template cannot be changed.

[Sample Info]	Click to set the sample information template.
[Items]	Click to set the analysis items template.
[Scattergram]	Click to set the scattergram template.
[Distribution]	Click to set the distribution template.
[IP message]	Click to set the IP message template.
[Reference Interval]	Click to set the reference interval template.
[Q-Flag]	Click to set the Q-Flag template.

Note:

- Up to 15 edit items can be placed in the selection palette.
- If the layout screen is switched to a different format, the edit item palette changes to the state in which [Selection] is selected.

Layout screen

The layout screen shows the print image.
The selected edit items and template appear in the layout.
The layout area is 196 X 259 mm. The print size is A4 (210 x 297 mm).
Sample information and report items are printed. Only validated data can be printed.

Note:
A dummy image will appear in the layout screen.

Properties

The properties of the item that is selected in the layout screen are displayed. Details can be set for each item.
When an item is not selected on the layout screen, the properties do not appear.

● Shared properties

Detailed information common to all edit items is displayed.

[Name]	The name of the item. Immediately after an item is selected for editing, the default name ("Item" + "Serial number") appears. This name can be changed. You can enter up to 32 characters.
[X]	The X coordinate of the item on the layout screen. This can be entered within the range 0 to 555 pt.
[Y]	The Y coordinate of the item on the layout screen. This can be entered within the range 0 to 733 pt.
[Width]	The width of the item. This can be entered within a range up to 556 pt. The lower limit of the range varies depending on the object.
[Height]	The height of the item. This can be entered within a range up to 734 pt. The lower limit of the range varies depending on the object.

Note:
The position of the X and Y coordinates is displayed based on the point at the top left of the item.

● Specific properties

Specific details are shown for each edit item. The settings can be changed by selecting items and entering numerical values.

List of specific property edit items

Selection item/template in layout screen	Edit item	Description
Free text ([Free Text])	**[Text]**	Shows the text string. The text string can be entered and edited.
	[Font]	The text font can be selected.
	[FontSize]	The text size can be entered and edited.
	[Color]	Shows the current text color. [Selection] can be clicked to open the color selection dialog and change the text color.
	[Align]	The text alignment can be selected.
Item name, numerical value, mark, units ([Text Data])	**[Field ID]**	Type Selection: [Item], [Data], [Mark], or [Unit] can selected. Item Selection: Shows selection items based on the type.
	[Font]	The text font can be selected.
	[FontSize]	The text size can be entered and edited.
	[Color]	Shows the current text color. [Selection] can be clicked to open the color selection dialog and change the text color.
	[Align]	The text alignment can be selected.
Any image ([Image])	**[File Name]**	Shows the image file path. Click the button to select an image.
	[Fix Aspect Ratio]	Select to fix the aspect ratio of the image.
	[Width Ratio]	The image width can be set as a percentage. When [Fix Aspect Ratio] is ON, links with the [Height Ratio] value.
	[Height Ratio]	The image height can be set as a percentage. When [Fix Aspect Ratio] is ON, links with the [Width Ratio] value.
Scattergram, distribution image ("Image Field")	**[Field ID]**	Type Selection: [Scattergram] or [Distribution] can selected. Item Selection: Shows selection items based on the type.
	[Width Ratio]	The image width can be set as a percentage. Links with the [Height Ratio] value.
	[Height Ratio]	The image width can be set as a percentage. Links with the [Width Ratio] value.
Line ([Line])	**[LineStyle]**	The line style can be selected.
	[LineWidth]	The line width can be selected.

Selection item/template in layout screen	Edit item	Description
Table ([Table])	**[LineStyle]**	The table line style can be selected.
	[LineWidth]	The table line width can be selected.
	[Rows]	The number of rows in the table can be set.
	[Cols]	The number of columns can be entered.
	[MarginX]	The left and right margin of text in table cells can be set.
	[MarginY]	The margin above and below text in table cells can be set.
Table cell ("Table cell")	**[Text]**	Shows the text string in the cell. The text string can be entered and edited.
	[Font]	The text font can be selected.
	[FontSize]	The text size can be entered and edited.
	[Color]	Shows the current text color. [Selection] can be clicked to open the color selection dialog and change the text color.
	[Align]	The text alignment can be selected.
Sample information template	**[Item Name]**	Sample information can be selected.
Analysis item template	**[Item Name]**	An analysis item can be selected.
Scattergram template	**[Item Name]**	A scattergram can be selected.
Distribution template	**[Item Name]**	A distribution can be selected.
IP message template	**[Item Name]**	An IP message can be selected.
Reference interval template	**[Item Name]**	An analysis item that allows selection of a reference interval can be selected.
Q-flag template	**[Item Name]**	A suspect message can be selected.

3.4.3 Save layout

The print layout that currently appears in the layout screen can be saved.
Follow the steps below to save the layout.

1 Click the [Backup] button on the toolbar.

The [Save As] dialog box appears.

2 Specify or create the folder to save the sample data into.

3 Check a file name.

The extension for a file is ".gpf".

> **Note:**
> The default file name is in the following format:
> • Report Format: [XN][Software version][GPFormat(Report)].gpf

4 Click [Save].

The layout is saved.

3.4.4 Restore saved layout

Saved layout can be restored.
Follow the steps below to restore saved layout.

1 Click the [Restore] button on the toolbar.

The [Open] dialog box appears.

2 Select the file that you wish to restore.

The extension for a file is ".gpf".

3 Click [Open].

The layout selected for the layout screen is displayed.

3.4.5 Initialize layout

Layout that have been set can be initialized.
Follow the steps below to initialize layout.

1 Click the [File] - [Initialize] button on the menu bar.

An initialization confirmation dialog box appears.

2 Click [Yes].

The display of the layout screen is initialized.

3.5 Transportation controller settings (CT-90)

This section explains the procedure for configuring transportation controller settings.
Transportation controller settings are only necessary when the XN-9000 is used.
The transportation controller starts automatically when the Startup switch is touched in the barcode terminal. The transportation controller can also be started separately by turning on the power of its PC unit.
The transportation controller connects to the XN conveyor (CV-50), SP conveyor (CV-60), start yard/stock yard(ST40/41/42), and barcode terminal(BT-40). The transportation controller issues the command to send samples to the analyzers. The controller also manages analysis data and performs sample searches.
System configuration and analysis order settings can be changed from the setting screen of the transportation controller. The setting screen is displayed on the touch panel that is connected to the transportation controller.

3.5.1 Transportation controller system settings (CT-90)

System settings and host connection settings can be configured from the main screen in the transportation controller.

Syst. Setting

Follow the steps below to configure the system settings.

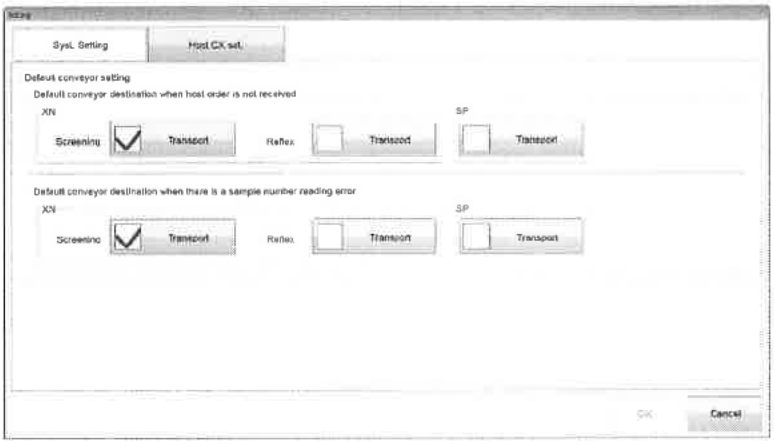
1 Touch the [Setting] button on the toolbar.

A dialog box appears.

2 Populate the displayed fields.

The following items appear.

- **Syst. settings**



[Default conveyor destination when host order is not received]	When host order is not received, specify the analyzer to which samples are sent.
[Default conveyor destination when there is a sample number reading error]	Set the analyzer to which samples are sent for which an ID read error occurred.

- **Host CX set.**

[Connect to host]	Select the check box to connect to the host.

3 Touch [OK].

The system settings are changed.

3.6 RU-20 Reagent Unit settings

This section explains how to configure the settings on the RU-20 Reagent Unit.
When the RU-20 is used, the settings can be changed from the RU area of the control menu.
When the power switch on the main unit is switched on, the RU-20 starts up.
The RU-20 dilutes concentrated reagent (CELLPACK DST) with purified water (RO water) and supplies the prepared reagent to a connected hematology analyzer or hematology slide preparation unit.
For details on the RU-20, see the RU-20 "Instructions For Use".
* The initial settings for the RU-20 are sent from the main unit.

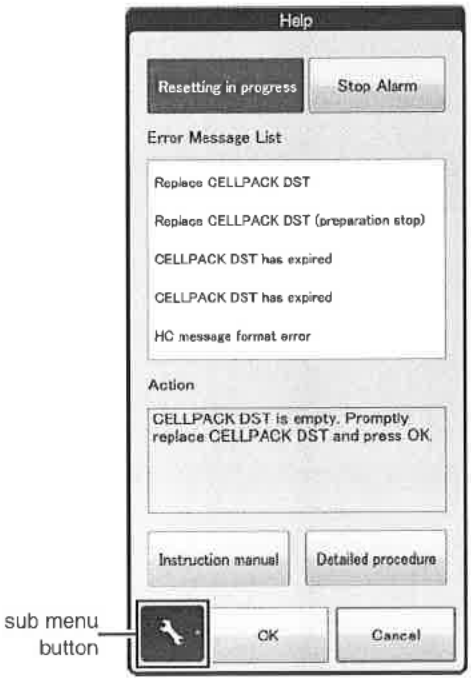
3.6.1 Reagent expiration stop and alarm settings

The RU-20 settings dialog can be used to configure reagent expiration stop and alarm settings.

Follow the steps below to configure the settings.

1 Click the RU menu button in the control menu.

The dialog box on the right appears.

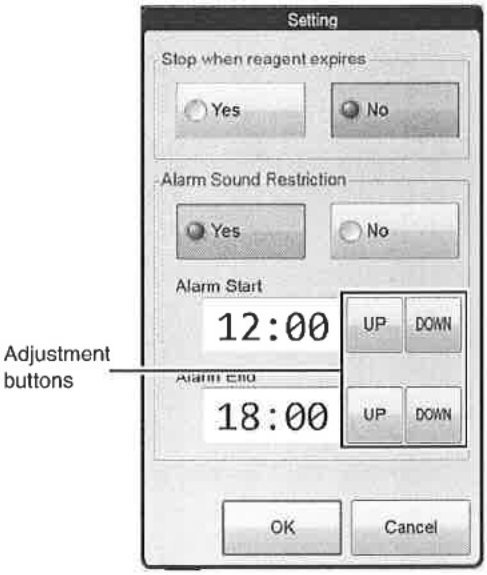


2 Click the submenu button.

The submenu on the right appears.

3 Click [Setting].

The dialog box on the right appears.



4 Configure the settings that appear.

The following settings appear.

[Stop when reagent expires]	Stops reagent preparation when the reagent expires. [Yes] or [No] can be selected.
[Alarm Sound Restriction]	Alarm activation can be restricted to a set time period. [Yes] or [No] can be selected. If you selected [Yes], set the [Alarm Start] time and [Alarm End] time. Alarms will only sound during the specified time period.

5 Touch [OK].

The settings are changed.

Chapter 4 Appendix

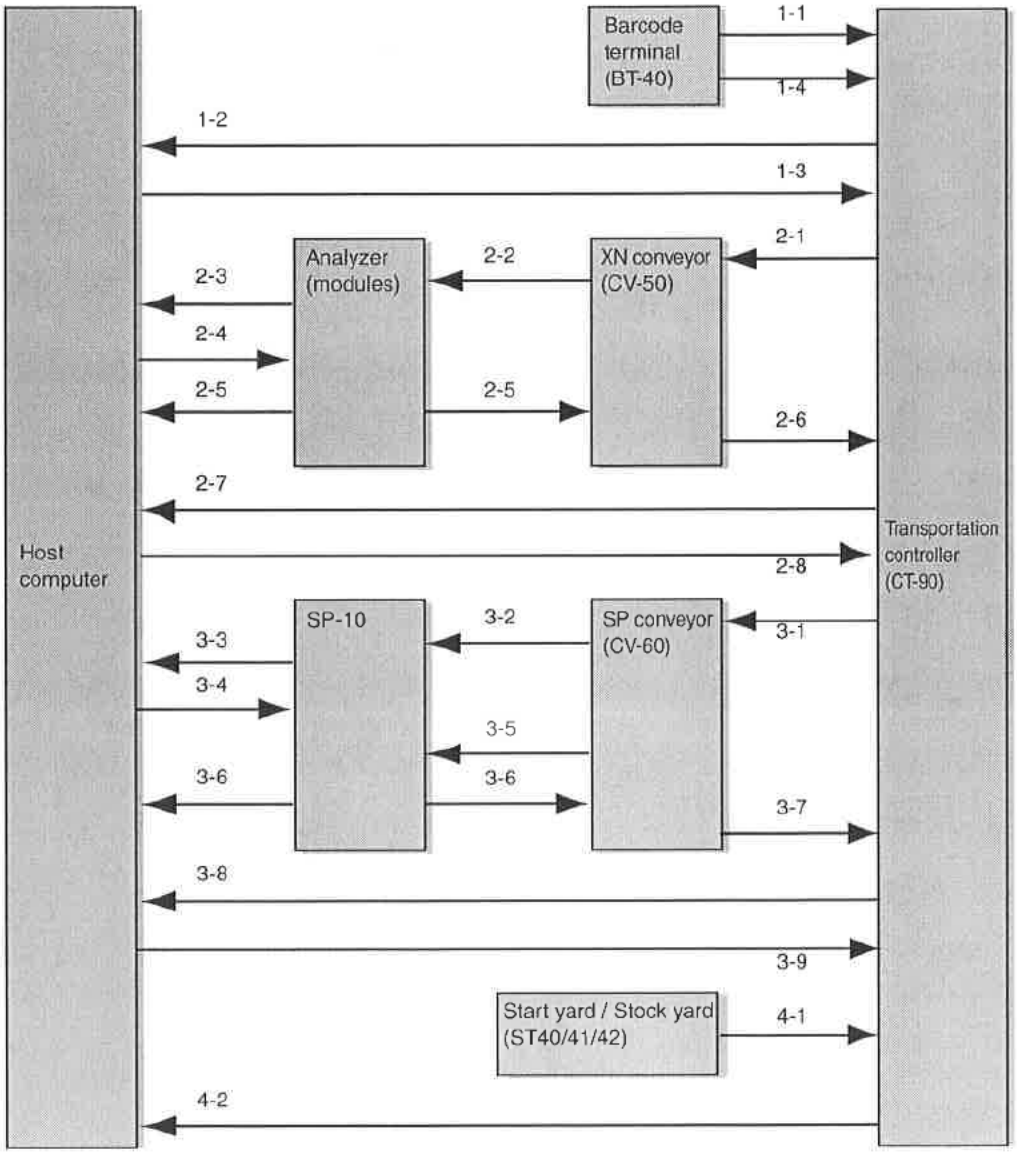
4.1 Interface protocol

Data can be output in various formats via the serial interface. For details, please contact the Sysmex Technical Assistance Center.

4.2 Transportation controller connections (CT-90)

4.2.1 Flow of data of the system

The flow of data in the system is as shown below when the XN-9000 is used.



1 Determining the conveying destination

1	**Barcode terminal (BT-40)**	Reads the sample/rack label and sends the sample position information to the transportation controller.
2	**Transportation controller (CT-90)**	Sends the sample position information to the host computer.
3	**Host computer**	Sends the sample analysis order by rack to the transportation controller.
4	**Barcode terminal (BT-40)**	Reads the barcode label at the carry-out position, and sends the rack number to the transportation controller.
5	**Transportation controller (CT-90)**	Identifies the rack and determines the conveying destination.

2 Analysis

1	**Transportation controller (CT-90)**	Sends an order to the XN conveyor (CV-50) for a rack to be conveyed.
2	**XN conveyor (CV-50)**	Sends the order for the rack to be conveyed to Analyzer.
3	**Analyzer**	The sample to be analyzed is identified from the order and the host computer is queried for the sample information.
4	**Host computer**	Sends the sample analysis order.
5	**Analyzer**	Performs analysis based on the received order. Sends the analysis data to the host computer. When analysis is finished, sends the analysis result to the XN conveyor (CV-50). Repeats the above until there are no more samples to be analyzed.
6	**XN conveyor (CV-50)**	Sends the analysis result to the transportation controller.
7	**Transportation controller (CT-90)**	Sends a query about an additional order.
8	**Host computer**	Whether or not an additional order exists and a description of the order are sent.

3 Smear analysis

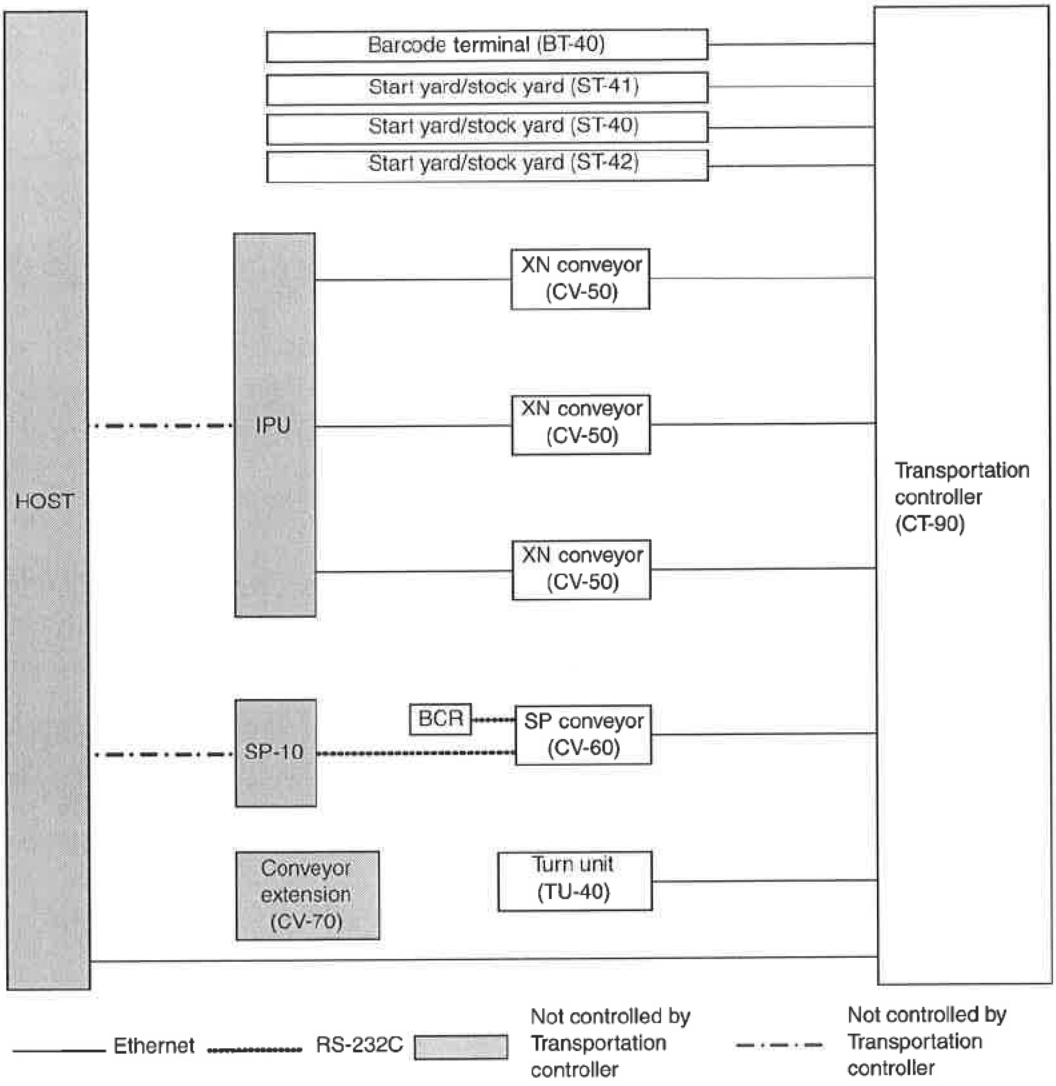
1	**Transportation controller (CT-90)**	Sends an order to the SP conveyor (CV-60) for a rack to be conveyed.
2	**SP conveyor (CV-60)**	Identifies the sample to be analyzed based on the order and reads the barcode label. Sends the sample number that was read to the SP-10.
3	**SP-10**	Queries the host computer for sample information.
4	**Host computer**	Sends the sample analysis order to the SP-10.
5	**SP conveyor (CV-60)**	Instructs the SP-10 to aspirate the sample to be analyzed.
6	**SP-10**	Performs analysis based on the received order. Sends the smear result and stain result to the host computer and SP conveyor (CV-60).
7	**SP conveyor (CV-60)**	Sends the smear result and stain result to the transportation controller.
8	**Transportation controller (CT-90)**	Sends a query about an additional order.
9	**Host computer**	Whether or not an additional order exists and a description of the order are sent.

4 Storage

1	**Start yard/Stock yard (ST40/41/42)**	Notifies the transportation controller that the rack has arrived.
2	**Transportation controller (CT-90)**	Creates rack storage information and sends it to the host computer.

4.2.2 Communication connection chart

Communication connections are as shown below when the XN-9000 is used.



4.3 ID Barcode specifications

Barcode labels can be affixed to sample tubes and racks to enable automatic reading of the ID by barcode reader. This section explains the specifications of barcode labels that can be read by the barcode reader of this machine.

4.3.1 Acceptable barcodes

The types of barcodes that can be used and check digit support are listed below.

Sample number

Barcode type	Check digit	Number of digits
ITF	Not used	Max. 22 digits (sample ID)
	Modulus 10	Max. 22 digits (sample ID) + 1 digit (check digit) = Max. 23 digits
CODABAR/ NW7	Not used	Max. 22 digits (sample ID)
	Modulus 11	Max. 22 digits (sample ID) + 1 digit (check digit) = Max. 23 digits
	Weighted Modulus 11	
	Modulus 16	
CODE 39	Not used	Max. 22 digits (sample ID)
	Modulus 43	Max. 22 digits (sample ID) + 1 digit (check digit) = Max. 23 digits
JAN/EAN/UPC	Modulus 10	12 digits (sample ID) + 1 digit (check digit)= 13 digits
ISBT 128	Modulus 103	Max. 22 digits (sample ID) + 1 digit (check digit) = Max. 23 digits
CODE 128	Modulus 103	Max. 22 digits (sample ID) + 1 digit (check digit) = Max. 23 digits

Information

- Do not use a rack ID barcode as a barcode for a sample ID.
- When using CODE 128, do not use function characters.

Note:

In CODE 128, any one of the characters "A", "B", "C", "a", "b" or "c" can be used for the start/ stop code.

Rack number

Barcode type	Check digit	Number of digits
CODABAR/NW7*	Modulus 16	6 digits (rack number) + 1 digit (check digit) = 7 digits
CODE 39	Modulus 43	6 digits (rack number) + 1 digit (check digit) = 7 digits

* When the transportation controller (CT-90) is used, this does not appear.

Information

Use either "D" or "d" for the start/stop code.

The reservation number of the special rack

This section explains the reservation numbers for special racks that are used when the XN-9000 is used.
The reservation numbers of the special racks are as follows:

SR****

- 00: The sample positions in the rack are associated with units in the system, and the samples are conveyed accordingly.
  The sample that is placed in rack position 10 is conveyed to conveyor "CV1".
  The sample that is placed in rack position 9 is conveyed to conveyor "CV2".
  Similarly, the samples in sample positions through position 1 are conveyed to the respectively associated units. However, QC samples are conveyed to all conveyers in sequential order.
- 01 to 10: The number on the rack label is associated with the unit configuration, and sample is transported.
  If the number of the rack label is "01", it is transported to conveyor "CV1". If the number of the rack label is "02", it is transported to conveyor "CV2". Similarly thereafter, all rack label numbers up to number "10" are associated with, and transported to, their respective units*.
  * CV1 is the conveyor (CV-40) connected to the rack discharge side of the barcode terminal (BT-40). From there on, the conveyors are enumerated in sequential order as CV2, CV3, and so on.
- H: The racks are transported for analyzer only.
- A: Conveying is possible for all analyzers connected to the conveyor controller, with the exception of the SP-10.
- S: Indicates the reservation number for Shutdown.
- R: Indicates the reservation number for Auto Rinse.
- Q: Indicates the reservation number for QC.
- SR: Indicates the reservation number for Special Rack.

CELLCLEAN AUTO placement methods and required time

When using the XN-3000/9000, the CELLCLEAN AUTO vials can be placed together in specified positions in 1 rack and automatically conveyed to all instruments. However, the overall rinsing operation will take longer because the instruments will be rinsed sequentially (approximate time: 15 minutes per instrument).

- XN-3000: The placement positions in the rack correspond to the instruments as follows:
  8th: SP-10, 9th: Analyzer (left), 10th: Analyzer (right)
- XN-9000: Special rack with reservation number ending with "00".

Quality control

Barcode type	Check digit	Number of digits
CODE 128	Modulus 103	3 digits (fixed character string "QC-") + 8 digits (lot number) + 1 digit (check digit) = 12 digits

Note:
The CODE 128 barcode for quality control is a special Sysmex code used for control blood.

Dimensions of barcode elements

Narrow Element ≥ 190 µm
Wide Element ≤ 1.2 mm
Narrow Element ≤ GAP between characters ≤ Wide Element

Narrow/Wide ratio

For each character, the narrow/wide ratios must be as follows:

Narrow (Max)	:	Wide (Min)	= 1 : 2.2 or more
Narrow (Min)	:	Narrow (Max)	= 1 : 1.3 or less
Wide (Min)	:	Wide (Max)	= 1 : 1.4 or less

PCS (Print Contrast Signal)

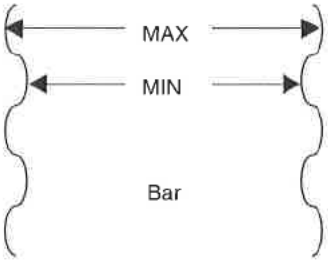
$$PCS = \frac{\text{Reflectivity of white - Reflectivity of black}}{\text{Reflectivity of white}}$$

The measurement method conforms to JIS (Japanese Industrial Standards) x0501, "5.3 Optical Characteristics of Bar Code Symbols".
Standard: PCS ≥ 0.45

Print quality of barcode label

Use barcode labels of Label Grade C or higher of the ANSI standards.
Reading of laminated labels may not be possible.

Irregularity and roughness of printing

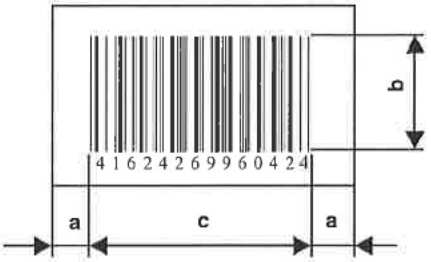


When a bar is magnified, it appears as shown at left.
Expressing the variation in the width of a bar as

$$S = \frac{MAX - MIN}{MAX} \times 100\%$$

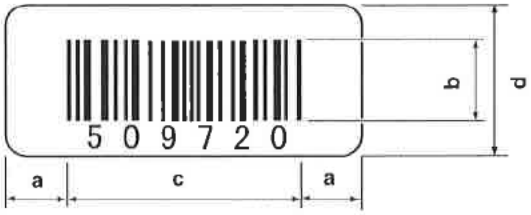
S must be ≤ 20%.

Dimensions of sample tube barcode label



Margin	**(Dimension a)**	5 mm or more
Bar height	**(Dimension b)**	10 mm or more
Effective barcode part	**(Dimension c)**	48 mm or less
Narrow width	-	0.19 mm or more

Dimensions of tube rack barcode label



Margin	**(Dimension a)**	3 mm or more
Bar height	**(Dimension b)**	8 mm or more
Effective barcode part	**(Dimension c)**	45 mm or less
Label height	**(Dimension d)**	15 mm or less
Narrow bar:Wide bar	-	1:2.5

4.3.2 Automatic assignment of sample ID and rack numbers

A sample ID number or rack number is automatically assigned to samples for which a barcode label read error occurred or for which analysis started while the analysis order was still being downloaded.
An automatically assigned sample number starts with a symbol that distinguishes it from other sample numbers.

● Sample ID number

Number starting with [ERR]	Assigned when a barcode label read error occurs. A barcode label read error also occurs when a number includes characters that cannot be used. When a serial number is assigned and the limit number is exceeded, the number returns to [00....01].
Number starting with [QC]	Assigned to a QC sample with a lot number or a QC file.
[BACKGROUNDCHECK]	Assigned to a background check sample.
Number starting with [PRE-CHK]	Assigned to a precision check sample.
Number starting with [CAL-CAL]	Assigned to samples calibrated by calibrator calibration (parameters other than PLT-F).
Number starting with [PF-CAL-CAL]*	Assigned to samples calibrated by calibrator calibration (PLT-F).

● Rack number

Automatically assigned rack numbers are 6 digits in length.

Number starting with [ERR]	Assigned when a rack label read error occurs. A barcode label read error also occurs when a number includes characters that cannot be used.

Information

Sample numbers starting with [QC] whose lower four digits are one of the following numbers are reserved.

- "1101", "1102", "1103": XN CHECK
- "1301", "1302": XN CHECK BF

4.3.3 Check digits

To improve the reliability of ID reading, a check digit can be added.
Using the sample ID "258416" as an example, the procedures for calculating the check digits for modulus 11 and weighted modulus 11 are explained below.

Modulus 11

1 Weight the value of each digit of "258416".

Digits and weightings are as follows.

Digit	22	21	20	19	18	17	16	15	14	13	12	11	10	9	8	7	6	5	4	3	2	1
Weighting	3	2	1	10	9	8	7	6	5	4	3	2	1	10	9	8	7	6	5	4	3	2

Calculate as follows.

Value of each digit	2	5	8	4	1	6
	x	x	x	x	x	x
Weighting	7	6	5	4	3	2
	14	30	40	16	3	12

e.g: The first digit of "258416" is "6", and thus "6" is multiplied by "2", the weighting of the first digit.

2 Add all the values that result from the multiplications.

Let the result be S.

S = 14 + 30 + 40 + 16 + 3 + 12 = 115

3 Calculate the remainder when S is divided by 11.

Calculate the complement of the remainder.
The complement of 11 will be the check digit.

115/11 = 10, remainder 5
11 - 5 = 6

The check digit is 6.

Note:
Symbols and characters other than the numeric characters "0" to "9" are treated as "0". When division of S by 11 results in a remainder of 0, or when calculation of the check digit results in 10, 0 is used for the check digit.

Weighted modulus 11

Weighted modulus 11 has 2 sets of weightings for each digit. The check digit is first calculated with the first set of weightings. If the resulting check digit is 10, the check digit is calculated again using the second set of weightings. The result will always be a value from 0 to 9. Aside from the different weightings, the calculation procedure is the same as for modulus 11.

1 Weight the value of each digit of "258416".

Digits and weightings are as follows.

Weighting	W12	W11	W10	W9	W8	W7	W6	W5	W4	W3	W2	W1
1st set	6	3	5	9	10	7	8	4	5	3	6	2
2nd set	5	8	6	2	10	4	3	7	6	8	5	9

Calculate as follows.

Value of each digit	2	5	8	4	1	6
	x	x	x	x	x	x
Weighting	8	4	5	3	6	2
	16	20	40	12	6	12

2 Add all the values that result from the multiplications.

Let the result be S.

S = 16 + 20 + 40 + 12 + 6 + 12 = 106

3 Calculate the remainder when S is divided by 11.

Calculate the complement of the remainder.
The complement of 11 will be the check digit.

106/11 = 9, remainder 7
11 - 7 = 4

The check digit is 4.

Note:

- Symbols and characters other than the numeric characters "0" to "9" are treated as "0". When division of S by 11 results in a remainder of 0, or when calculation of the check digit results in 10, 0 is used for the check digit.
- In weighted modulus 11, weightings for digits after the 12th digit (13th and higher digits) are 0. These are not included in the check digit calculation.

4.4 Default settings

4.4.1 Analyzer setting names and default settings

Sampler

Setting name		Default setting
Blood Sensor		Use
Sampler Analysis Start Settings*1		Sampler analysis starts when rack is placed in sampler
Sampler Stop Conditions	ID Read Error	Stop Sampler Analysis
	Rack ID Read Error*2	Stop Sampler Analysis
	Blank Data	Stop Sampler Analysis
	Critical Value Data	Stop Sampler Analysis
	Aspiration Error	Stop Sampler Analysis
	Inadequate Sample	Stop Sampler Analysis
	QC Alarm	Do Not Stop Sampler Analysis
	X-barM Limit Error	Stop Sampler Analysis
	L-J Limit Error	Stop Sampler Analysis
	Control Expired Error	Stop Sampler Analysis
	Unregistered Control	Do Not Stop Sampler Analysis
	Reagent Expired Error	Do Not Stop Sampler Analysis
	Invalid Analysis Order	Stop Sampler Analysis
Repeat Setting*3		Repeat
Rerun/Reflex Setting*3		Rerun/Reflex

*1 When system analysis mode is selected on the XN-9000 or the sampler (SA-01) is used, [Sampler Analysis Start Settings] does not appear.

*2 When the transportation controller (CT-90) and the sampler (SA-01) is used, this does not appear.

*3 When the sampler (SA-01) is used, this does not appear.

Barcode Reader

Setting name				Default setting
Barcode Reader Connection*1				Connect Barcode Reader
	Read Tube ID*1			Read Sample Tube ID
		Specify Sample No. Length		No
		Check Digits Conditions	ITF	Use ITF
			Check Digit	Modulus-10
			CODABAR/NW7	Use CODABAR/NW7
			Check Digit	Modulus-16
			CODE39	Use CODE39
			Check Digit	Modulus-43
			JAN/EAN/UPC	Use JAN/EAN/UPC
			Check Digit	Modulus-10
			ISBT128	Use ISBT128
			CODE128	Use CODE128
			Check Digit	Modulus-103
	Rack ID*2			Do Not Read Rack ID
		Check Digits Conditions (when read)		CODABAR/NW7 Start-Stop Character/D(d)-D(d) Modulus 16
Setting for Ordering Key Read Error				Analyzed

*1 When the transportation controller (CT-90) is used, this is always connected. The setting is grayed out and cannot be modified.

*2 When the transportation controller (CT-90) and the sampler (SA-01) is used, this does not appear.

Alarm

Setting name	Default setting
Warning	Loop
Stops Analysis	Loop

System

Setting name				Default setting
Identification	Instrument Name*	XN-1000		XN-1000-#
		XN-2000		XN-2000-#
		XN-3000		XN-3000-#
		XN-9000		XN-9000-#
		Sampler Name Suffix		-S
		Analyzer Name Suffix	XN-1000	-A
			XN-2000, XN-3000	Left Analyzer: -L Right Analyzer: -R
			XN-9000	-A

* "#" at the end of the instrument name and instrument abbreviation indicates a serial number appended to an instrument that connects to the IPU. Numbers 1 to 3 are assigned by the system.

Flags

Flag	Judgment	Judgment value setting*		
WBC Abnormal Flags				
Neutropenia	Judge	NEUT# < 1.00[x10^3/uL]	or	NEUT% < 0.0[%]
Neutrophilia	Judge	NEUT# > 11.00[x10^3/uL]	or	NEUT% > 100.0[%]
Lymphopenia	Judge	LYMPH# < 0.80[x10^3/uL]	or	LYMPH% < 0.0[%]
Lymphocytosis	Judge	LYMPH# > 4.00[x10^3/uL]	or	LYMPH% > 100.0[%]
Monocytosis	Judge	MONO# > 1.00[x10^3/uL]	or	MONO% > 100.0[%]
Eosinophilia	Judge	EO# > 0.70[x10^3/uL]	or	EO% > 100.0[%]
Basophilia	Judge	BASO# > 0.20[x10^3/uL]	or	BASO% > 100.0[%]
Leukocytopenia	Judge	WBC < 2.50[x10^3/uL]		
Leukocytosis	Judge	WBC > 18.00[x10^3/uL]		
NRBC Present	Judge	NRBC% > 2.0[%]		
IG Present	Judge	IG# > 0.10[x10^3/uL]	or	IG% > 100.0[%]
RBC Abnormal Flags				
Reticulocytosis	Judge	RET# > 0.2000[x10^6/uL]	or	RET% > 5.00[%]
Anisocytosis	Judge	RDW-SD > 65.0[fL]	or	RDW-CV > 20.0[%]
Microcytosis	Judge	MCV < 70.0[fL]		
Macrocytosis	Judge	MCV > 110.0[fL]		
Hypochromia	Judge	MCHC < 29.0[g/dL]		
Anemia	Judge	HGB < 10.0[g/dL]		
Erythrocytosis	Judge	RBC > 6.50[x10^6/uL]		
PLT Abnormal Flags				
Thrombocytopenia	Judge	PLT < 60[x10^3/uL]		
Thrombocytosis	Judge	PLT > 600[x10^3/uL]		

* The decimal point symbol set in Windows is displayed in the XN Series. The only decimal point symbols displayed are "." (period) or "," (comma).

Critical Value

Setting name		Default setting
Critical Value Settings	Item	WBC
	Lower Limit	WBC Lower Limit
	Upper Limit	WBC Upper Limit

Items	Lower Limit*	Upper Limit*	Unit
WBC	0.00	999.99	x10^3/uL
RBC	0.00	99.99	x10^6/uL
HGB	0.0	999.9	g/dL
HCT	0.0	999.9	%
MCV	0.0	999.9	fL
MCH	0.0	999.9	pg
MCHC	0.0	999.9	g/dL
PLT	0	9999	x10^3/uL
RDW-SD	0.0	999.9	fL
RDW-CV	0.0	999.9	%
MPV	0.0	999.9	fL
NRBC#	0.00	999.99	x10^3/uL
NRBC%	0.0	9999.9	%
NEUT#	0.00	999.99	x10^3/uL
LYMPH#	0.00	999.99	x10^3/uL
MONO#	0.00	999.99	x10^3/uL
EO#	0.00	999.99	x10^3/uL
BASO#	0.00	999.99	x10^3/uL
NEUT%	0.0	999.9	%
LYMPH%	0.0	999.9	%
MONO%	0.0	999.9	%
EO%	0.0	999.9	%
BASO%	0.0	999.9	%
IG#	0.00	999.99	x10^3/uL
IG%	0.0	999.9	%
RET%	0.00	99.99	%
RET#	0.0000	0.9999	x10^6/uL

Items	Lower Limit*	Upper Limit*	Unit
IRF	0.0	999.9	%
RET-He	0.0	999.9	pg
IPF	0.0	999.9	%

* The decimal point symbol set in Windows is displayed in the XN Series. The only decimal point symbols displayed are "." (period) or "," (comma).

Sample number auto increment

Setting name	Default setting
Sample No. Auto Increment Setting	Do not automatically increment (manual mode)

Analyzer

Setting name	Default setting
Aspiration Sensor	Use
Leak Sensor	When a water leak is detected, do not continue analysis.

SP Setting*

Setting name			Default setting
SP Rule Setting	Perform Judgement of SP Rule		ON
Default SP Order	Number of slide		Do not prepare slides
		slide glass(1st)/slide glass(2nd) (When prepared)	either
Output to Host Computer setting	Output analysis result(SP) to Host Computer		OFF
	Output reagent replacement information(SP) to Host Computer		OFF
SP printer setting	Print Format		Type 1
	Print data	[1st text] to [3rd text], [Barcode]	Not Printed

* Only when using the XN-3000 sampler (Standalone mode).

4.4.2 IPU setting names and default settings

System

Setting name			Default setting
Facility Information	Facility Name		None
System Language	Language		English
	Print Language		English
IPU Shutdown			Automatically Shut Down IPU
General Date Format			YYYY/MM/DD
User Administration	Auto Logon		No
CSV Output Setting	Image File Output		Do Not Output Image File
		Image Format (when output)	PNG
		Background Color (when output)	BLACK
		If output items exceed 256 columns, data will be divided into multiple files. (when output)	Divide Files
Security Setting	Analysis Data	Backup Data	Do not include patient information
		CSV File	Do not output patient information
	IPU Screen Lock		Do Not Use
Screen Keyboard Setting			Do Not Use
Patient ID Display Setting			Right-justified
Program Update Notification Setting			Do Not Use

Display

Setting name				Default setting
Data Grid	Line Height	Setting	1	20 px
			2	22 px
			3 (default)	27 px
			4	32 px
			5	50 px
	Font Size	Setting	1	11 pt
			2	13 pt
			3 (default)	16 pt
			4	19 pt
			5	26 pt
Scattergram				BLACK

Connection

Setting name			Default setting
Host Computer Connection			Do not connect to host
	Current Connection (when host computer connection is ON)		Host Computer 1
	Serial Connection (when host computer connection is ON)		OFF
	Port Settings		COM1
	Port Settings	Baud Rate	9600
		Code	8-bit
		Stop Bit	1-bit
		Parity Bit	None
		Interval	2
	Class		ClassB
	Format		XN series Sysmex Standard
	TCP/IP Connection (when host computer connection is ON)		ON
		HOST IP Address	1.1.1.1
		Port No.	5000
		Format	XN series Sysmex Standard
Ticket (DP) Setting	DP Connection		Do not connect to DP
	Select Printer (when DP connection is ON)		TM-U295
	Print Format	Sample No. Length	15
		Date Print Type	YYMMDD
		Delimiter of Date	/
		Print Decimal Point	Printed
		Top Margin	16 1/60 inch (8 - 255)
		Char. Pitch	7 dot (5 - 21)
		Line Pitch	8 1/60 inch (8 - 255)
		Print Headstand	No

Setting name				Default setting
Ticket (DP) Print Format Setting	Item Conditions	Printed		Varies by item.
			Print Condition	Varies by item. (All Samples/Negative)
		Print Start Position		Manual
Printer Connection Settings	Report (GP) Connect			Connect to GP
	Ledger (LP) Connect			Connect to LP

Automatic processing

Setting name			Default setting
Auto Validate			Do Not Auto Validate
	Auto Validate Setting Procedure (when auto validate is ON)		Use simple settings
		Auto Validate Sample (when simple settings are used)	All Samples
Auto Output			Do Not Auto Output
	Auto Output Setting Procedure (when auto output is ON)		Use simple settings
		Error Data Output Conditions	Do not automatically output data with errors
		Auto Output Destination and Output Conditions	Do Not Use
Analysis Ordering	Key Setting		Sample No.
	Realtime Host Order Setting		Realtime Request: No
Delta Check Setting			Do Not Use

Reference interval

Setting name	Default setting						
Patient Category Settings							Use Category
	Lower Age Limit			Upper Age Limit			
	Year	Month	Week	Year	Month	Week	Sex
Category 1	0	0	0	0	0	1	Both
Category 2	0	0	1	0	1	0	Both
Category 3	0	1	0	1	0	0	Both
Category 4	1	0	0	12	0	0	Both
Category 5	12	0	0	60	0	0	Male
Category 6	12	0	0	60	0	0	Female
Category 7	60	0	0	999	0	0	Both

Item	Lower limit*	Upper limit*	Units
WBC	3.00	15.00	x10^3/uL
RBC	2.50	5.50	x10^6/uL
HGB	8.0	17.0	g/dL
HCT	26.0	50.0	%
MCV	86.0	110.0	fL
MCH	26.0	38.0	pg
MCHC	31.0	37.0	g/dL
PLT	50	400	x10^3/uL
RDW-SD	37.0	54.0	fL
RDW-CV	11.0	16.0	%
MPV	9.0	13.0	fL
NEUT#	1.50	7.00	x10^3/uL
LYMPH#	1.00	3.70	x10^3/uL
MONO#	0.00	0.70	x10^3/uL
EO#	0.00	0.40	x10^3/uL
BASO#	0.00	0.10	x10^3/uL
NEUT%	37.0	72.0	%
LYMPH%	20.0	50.0	%

Item	Lower limit*	Upper limit*	Units
MONO%	0.0	14.0	%
EO%	0.0	6.0	%
BASO%	0.0	1.0	%
IG#	0.00	7.00	x10^3/uL
IG%	0.0	72.0	%
RET%	0.00	99.99	%
RET#	0.0000	0.9999	x10^6/uL
IRF	0.0	100.0	%
RET-He	0.0	99.9	pg
IPF	0.0	99.9	%

* The decimal point symbol set in Windows is displayed in the XN Series. The only decimal point symbols displayed are "." (period) or "," (comma).

Units

Item	Units	Format*1
WBC	10^3/uL	***.**
RBC	10^6/uL	**.**
HGB	g/dL	***.*
HCT	%	***.*
MCV	fL	***.*
MCH	pg	***.*
MCHC	g/dL	***.*
PLT	10^3/uL	****
RDW-SD	fL	***.*
RDW-CV	%	***.*
MPV	fL	***.*
DIFF#	10^3/uL	***.**
DIFF%	%	**.***
RET#*2	10^6/uL	0.****
RET%*2	%	**.**
IRF*2	%	***.*
IPF	%	***.*
NRBC%	%	****.*
WBC-BF	10^3/uL	***.***
RBC-BF	10^6/uL	**.***

*1 The decimal point symbol set in Windows is displayed in the XN Series.
The only decimal point symbols displayed are "." (period) or "," (comma).

*2 These items do not appear with all analyzer types.

Quality control

Setting name				Default setting
QC Setting	QC Method Setting			L-J
	Limit Setting			Differential (#)
	Auto Limit Setting			2SD
	X-barM Batch Setting	Number of CBC Samples		20
		Number of DIFF Samples		20
		Number of RET Samples*		20
		Number of PLT-F Samples*		20
		Number of WPC Samples*		20
QC Alarm Setting				Do Not Use Alarm
QC Chart Fixed Comment				Do Not Use
QC Chart Data Auto Output Setting	QC Chart Screen	Automatically output plot data to host computer.		QC Files (Excluding X-barM)
				X-barM Files
	Explorer Screen	Output analysis results of sample numbers starting with QC to location below.	Graphic Printer (GP)	Do not output
			Host Computer (HC)	Do not output
			Ticket Printer (DP)	Do not output

* These discrete samples do not appear with all analyzer types.

4.4.3 Transportation controller setting names and default settings (CT-90)

List of settings and default settings when the XN-9000 is used.

Setting name				Default setting
Syst. Setting	Default conveyor destination when host order is not received	XN	Initial	Transport
			Repeat	Do not transport
		SP		Do not transport
	Default conveyor destination when there is a sample number reading error	XN	Initial	Transport
			Repeat	Do not transport
		SP		Do not transport
Host CX set.				Connect to host

Index

Software Document for XN series (XN-11, XN-21)

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

(b)(4) Software Design

001_Whole Blood Method Comparison Graphs

All Sites Combined
Whole Blood Graphs
XE-5000 to XN-11

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

Graph 32

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

001_Whole Blood Method Comparison Graphs

Site 1

Whole Blood Accuracy Graphs

XE-5000 to XN-11

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

Site 1

Whole Blood Accuracy Graphs

XE-5000 to XN-21

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

Site 2

Whole Blood Accuracy Graphs

XE-5000 to XN-11

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

Site 2

Whole Blood Accuracy Graphs

XE-5000 to XN-21

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

Site 3
Whole Blood Accuracy Graphs
XE-5000 to XN-11

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

004_Body Fluid Method Comparison Graphs

All Sites Combined Pleural Fluid Method Comparison Graphs

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

All Sites Combined Peritoneal Fluid Method Comparison Graphs

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

All Sites Combined Synovial Fluid Method Comparison Graphs

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

005_All Body fluid Bland Altman Plots
All Sites Combined

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

006_Body Fluid Linearity Graphs

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

007_ WHOLE BLOOD
REFERENCE INTERVAL GRAPHS

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

Chapter 1 Introduction

Thank you for purchasing the XN series automated hematology analyzer.
Please read this manual carefully before operating this product.
Keep this manual in a safe place for future reference.

Note:
Operation of instruments and devices outside of recommended manufactures guidelines may result in inaccuracies.

US federal law restricts this device to sale by or on the order of a physician (or properly licensed medical practitioner).

Contact Address

Manufacturer

SYSMEX CORPORATION
1-5-1 Wakinohama-Kaigandori Chuo-ku, Kobe, Hyogo 651-0073 JAPAN

Authorized Representative

EC REP

European Representative
SYSMEX EUROPE GmbH
Bornbarch 1 D – 22848 Norderstedt, Germany
Phone: +49 40 5 27 26-0 / Fax: +49 40 5 27 26-100

Americas

SYSMEX AMERICA, Inc.
577 Aptakisic Road, Lincolnshire, IL 60069, U.S.A.
Phone: +1-224-543-9500 / Fax: +1-224-543-9505

Asia-Pacific

SYSMEX ASIA PACIFIC PTE LTD.
9 Tampines Grande, #06-18, Singapore 528735
Phone: +65-6221-3629 / Fax: +65-6221-3687

Ordering of Supplies and Replacement Parts

If you need to order supplies or replacement parts, please contact your local Sysmex representative.

Service and Maintenance

Please contact the Service Department of local Sysmex representative.

1-CP

K141681/A001

577 Aptakisic Road
Lincolnshire, IL 60069-4325
(800) 379-7639
(224)543-4699 Facsimile

June 30, 2014

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

RE: K141681- Revised Documents
510(k) Premarket Notification--Traditional
XN-Series (XN-11, XN-21) Automated Hematology Analyzers

Enclosed please find the 510(k) Premarket Notification submission for the Sysmex® XN series, Automated Hematology Analyzers (XN-11, XN-21). The XN-11 and XN-21 are the same analyzers as the recently cleared XN-Series (XN-10, XN-20) analyzers (K112605) with modifications to stabilize the HCT/MCV parameter to within +8% at room temperature (18°-26°C) for 24 hours and refrigerated temperature (2°-8°C) for 48 hours for commercial and reference laboratories. The XN series analyzers are Class II Automated cell counters reviewed under the Hematology panel and are being compared to the XE-5000 (K071967) which was cleared November 20, 2007. The product code is GKZ. The principal factors about the device are included in the table below.

Questions from Guidance for Industry/FDA Staff Format for Traditional /Abbreviated 510(k)s	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?		X
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data? NA		
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?	X	
Is the device implanted?		X

The Sysmex® XN series Automated Hematology Analyzers (XN-11, XN-21) are manufactured by Sysmex Corporation Japan (Owner/Operator No. 7010360) and imported and distributed into the USA by Sysmex America, Inc., Lincolnshire, IL (Registration No. 1422681). Sysmex considers the information appearing in Sections 8, 10-12, 16 and 20 to be confidential in nature and, therefore, not disclosable under the Freedom of Information Act. This protection to the manufacturer is provided under 21CFR 20.61 as well as 809.4.

Please contact me at 224-543-9618 or by fax at 224-543-4699 if there are questions.

Sincerely,

Sharita Brooks
Manager, Clinical Affairs
Sysmex America, Inc.

Enclosure: 1 complete paper copy of 510(k) Notification & 1 electronic copy that is an exact duplicate of paper copy.

K141681/S001

577 Aptakisic Road
Lincolnshire, IL 60069-4325
(800) 379-7639
(224)543-4699 Facsimile

September 16, 2014

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

RE: k141681
Responses to AI letter dated August 14, 2014
510(k) Premarket Notification--Traditional
XN-Series (XN-11, XN-21) Automated Hematology Analyzer

Dear Dr. Yvonne Doswell,

Enclosed please find both paper and electronic copy find our completed responses to your request for additional information dated August 14, 2014.

Please do not hesitate to contact me at 224-543-9618 or by fax at 224-543-4699 if you have questions.

Sincerely,

Sharita Brooks

Sharita Brooks
Manager, Clinical Affairs
Sysmex America, Inc.
brooks@sysmex.com
Office: 224-543-9618
Fax: 224-543-4699

Enclosure: 1 complete paper copy of 510(k) Notification & 1 electronic copy that is an exact duplicate of paper copy.

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

August 14, 2014

Sysmex America, Inc.
c/o Ms. Sharita Brooks
Manager, Clinical Affairs
577 Aptakisic Road
Lincolnshire, IL 60069-4325

Re: K141681
Trade/Device Name: Sysmex® XN-Series (XN-11, XN-21) Hematology Analyzers
Dated: June 24, 2014
Received: June 25, 2014

Dear Ms. Brooks:

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

1. Performance Testing:

(b)(4)

(b)(4)

b

(b)(4)

Sysmex Response:

c. (b)(4)

Sysmex Response:

d. (b)(4)

Sysmex Response:

(b)(4)

(b)(4)

e. (b)(4)

2. Precision/ Repeatability– Body Fluid

(b)(4)

Sysmex Response:

(b)(4)

[redacted]

3. Quality Controls/Calibrators

(b)(4)

[redacted]

Sysmex Response:

(b)(4)

[redacted]

Additional information

(b)(4)

[redacted]

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act (Act) for determining substantial equivalence of your device.

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

In accordance with 21 CFR 807.87(l), FDA may consider a 510(k) to be withdrawn if the submitter fails to provide additional information within 30 days of an Additional Information (AI) request. FDA generally permits submitters additional time to respond to such requests. FDA intends to automatically grant a maximum of 180 calendar days from the date of the AI request, even if the submitter has not requested an extension. Therefore, submitters are no longer required to submit written requests for extension. However, you should be aware that FDA intends to issue a notice of withdrawal under 21 CFR 807.87(l) if FDA does not receive, in a submission to the appropriate Document Control Center, a complete response to all of the deficiencies in this AI request within 180 calendar days of the date of this request. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

For further information regarding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee Amendments of 2012 (MDUFA III), to the Federal Food, Drug, and Cosmetic Act, you may refer to our guidance document entitled "Guidance for Industry and Food and Drug Administration Staff FDA and Industry Actions on Premarket Notification (510(k)) Submissions:

Effect on FDA Review Clock and Goals". You may review this document at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm.

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

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

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

For more information about FDA's new eCopy program, including the new technical standards for an eCopy, refer to the guidance document, “eCopy Program for Medical Device Submissions” at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocu

ments/UCM313794.pdf. In addition, we strongly encourage you to visit FDA's eSubmitter website at http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm221506 htm in order to develop an eCopy in accordance with the new technical standards prior to sending it to FDA.

If you have any minor clarification questions concerning the contents of this letter please contact Doswell, Yvonne directly at (240) 402-5025 or Yvonne.Doswell@fda.hhs.gov. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100, or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely Yours,

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostics and
Radiological Health
Center for Devices and Radiological Health

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

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

August 14, 2014

Sysmex America, Inc.
c/o Ms. Sharita Brooks
Manager, Clinical Affairs
577 Aptakisic Road
Lincolnshire, IL 60069-4325

Re: K141681
Trade/Device Name: Sysmex® XN-Series (XN-11, XN-21) Hematology Analyzers
Dated: June 24, 2014
Received: June 25, 2014

Dear Ms. Brooks:

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

1. Performance Testing:

a. (b)(4)

(b)(4)

b. (b)(4)

(b)(4)
.

Sysmex Response:

(b)(4)

c. (b)(4)

Sysmex Response:

(b)(4)

(b)(4)
.

d. (b)(4)

Sysmex Response:

(b)(4)

(b)(4)

e. (b)(4)

Sysmex Response:

(b)(4)

2. Precision/ Repeatability– Body Fluid

(b)(4)

Sysmex Response:

(b)(4)

3. Quality Controls/Calibrators

(b)(4)

Sysmex Response:

(b)(4)

(b)(4)

89735.htm.

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

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

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

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

If you have any minor clarification questions concerning the contents of this letter please contact Doswell, Yvonne directly at (240) 402-5025 or Yvonne.Doswell@fda.hhs.gov. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100, or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely Yours,

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostics and
Radiological Health
Center for Devices and Radiological Health

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

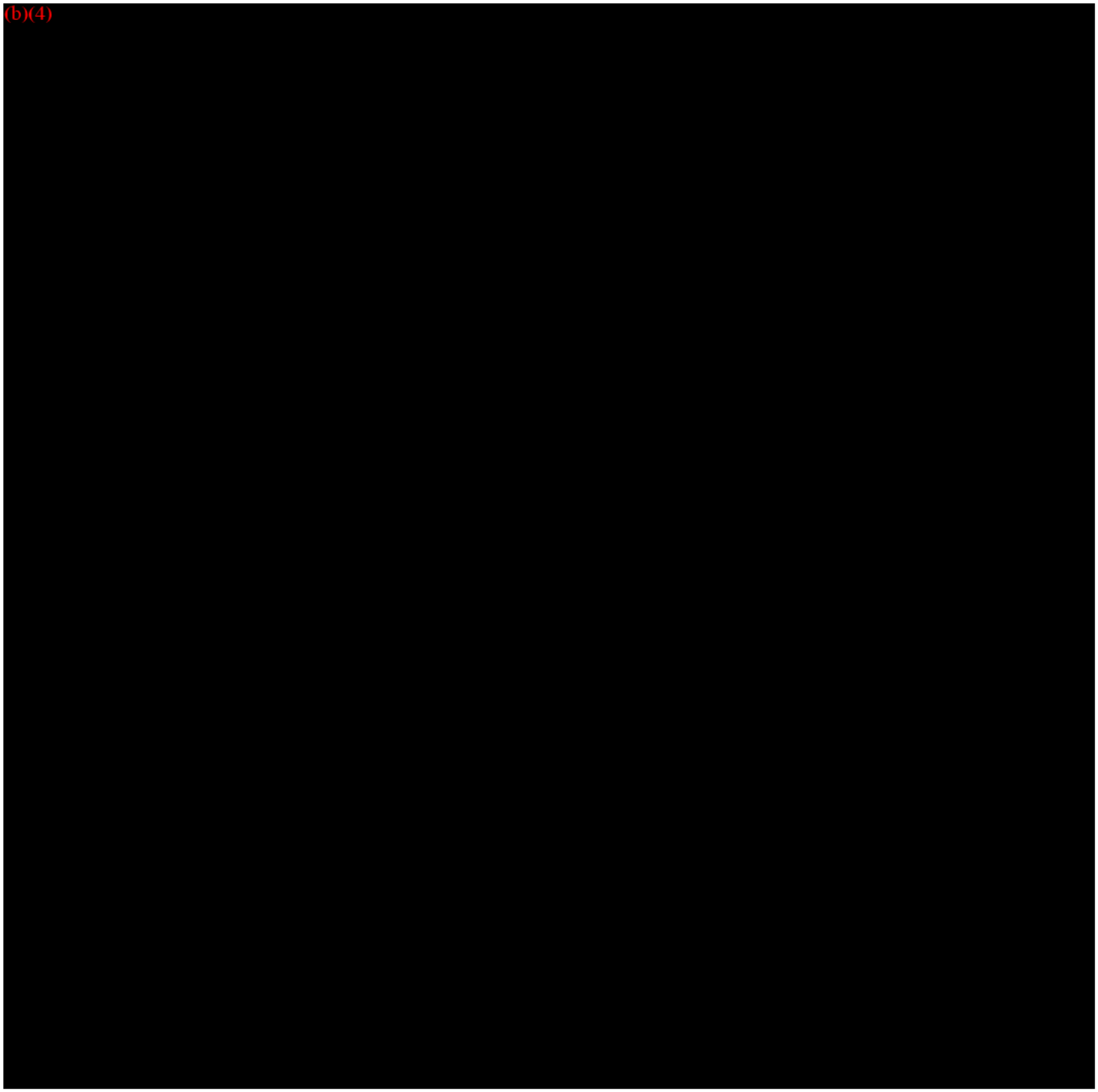
(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

RBC- Whole Blood Linearity Studies – XN-21

(b)(4)



(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data

(b)(4) Confidential Protocols and Data