

JUN 17 1998

K981013

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

I. General Information

This Summary of 510(k) Safety and Effectiveness information is being submitted in accordance with the requirements of the SMDA of 1990 and 21 CFR 807.92

Establishment:

- **Address:** Becton Dickinson VACUTAINER Systems
1 Becton Drive
Franklin Lakes, NJ 07417-1885
- **Registration Number:** 2243072
- **Contact Person:** Eileen Schweighardt
Regulatory Affairs Manager
Telephone no.: 201 - 847 - 4570
Facsimile no.: 201 - 847 - 4858
- **Date of Summary:** March, 1998

Device Name:

- **Trade Name:** VACUTAINER® Brand PLUS Tube
with EDTA Anticoagulant and
VACUTAINER® Brand PLUS Serum Tube
- **Classification Name :** Blood Specimen Collection Device
- **Classification:** Class II
- **Performance Standards:** None Established under 514 of
the Food, Drug and Cosmetic Act

II. Safety and Effectiveness Information Supporting the Substantial Equivalence Determination

Substantial Equivalence Declaration: The term "Substantial Equivalence" is used in this 510(k) Premarket Notification is limited to the definition of Substantial Equivalence as found in the Federal Food, Drug, and Cosmetic Act, as amended and as applied under 21 CFR § 807, Subpart E under which a device can be marketed without pre-market approval or reclassification.

- Device Description

The VACUTAINER® Brand PLUS Tube with EDTA and the VACUTAINER PLUS Serum Tube are evacuated plastic blood collection tubes for collecting, transporting and processing blood in a closed plastic tube. The VACUTAINER® Brand PLUS Tube with EDTA consists of closure assembly, a plastic tube and EDTA coating (dipotassium). The VACUTAINER PLUS Serum Tube consists of closure assembly, a plastic tube and silica clot activator.

The standard closure assembly is a basic rubber stopper. The tubes are also available with the VACUTAINER® Hemogard Closure Assembly, which consists of a rubber stopper and protective plastic shield to reduce user exposure to blood. The Hemogard closure assembly, intended to reduce user exposure to blood, was described in 510(k) Premarket Notification K945952 that received FDA clearance on January 18, 1995. All stopper/closures are color coded to reflect additive type (see the chart **VACUTAINER® Tube Stopper/Closure Color Code Cross Reference** located in the Product Insert, Attachment D)

- Intended Use

The VACUTAINER® Brand PLUS Tube with EDTA anticoagulant and the VACUTAINER Brand PLUS Serum Tube are evacuated blood collection tubes which provides a means collecting, transporting and processing blood in a closed plastic tube. Blood collected in a tube containing EDTA anticoagulant, VACUTAINER® Brand PLUS Tube with EDTA anticoagulant, is used primarily for clinical laboratory hematology studies. The VACUTAINER® Brand PLUS Serum Tube containing Silica activator is used primarily in clinical laboratory testing for chemistry assays.

In addition, the blood collected and processed in the VACUTAINER® Brand PLUS with EDTA anticoagulant and the VACUTAINER® Brand PLUS Serum Tube can be used immunohematology testing including ABO grouping, Rh typing and antibody screening which requires red cells and plasma or serum.

- Synopsis of Test Methods and Results

Clinical testing to evaluate the effectiveness of the tube for the additional Indications for Use described in premarket notification was performed. The results of the clinical evaluation demonstrate that the VACUTAINER® Brand PLUS (plastic) EDTA and PLUS Serum tubes provide equivalent results compared to the VACUTAINER® Brand (glass) Serum and EDTA tubes for immunohematology testing including ABO Grouping, Rh typing and antibody screening which requires red cells and plasma or serum.

- Substantial Equivalence

Becton Dickinson VACUTAINER Systems believes that the VACUTAINER® Brand PLUS Tube with EDTA and VACUTAINER® Brand PLUS Serum Tube with the expanded Indications for Use is substantially equivalent to a commercially available blood collection tube. Clinical testing, as described in this premarket notification, demonstrates equivalent performance and effectiveness and supports the determination of substantial equivalence. The predicate devices, manufacturer, K number and clearance date are identified below:

Manufacturer	Predicate Device	K-Number	Clearance Date
VACUTAINER Systems	VACUTAINER® Brand Serum Tube	Not Applicable	Pre-Amendment Device and, therefore, exempt from premarket notification requirements according to the MDA of 1976.
VACUTAINER Systems	VACUTAINER® Brand Tube with EDTA Anticoagulant	Not Applicable	Pre-Amendment Device and, therefore, exempt from premarket notification requirements according to the MDA of 1976.

Eileen Schweighardt
 Eileen Schweighardt
 Regulatory Affairs Manager
 Regulatory Affairs Department

March 16, 1998
 Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 17 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Eileen Schweighardt
Regulatory Affairs Manager
Becton Dickinson VACUTAINER Systems
1 Becton Drive
Franklin Lakes, New Jersey 07417

Re: K981013
VACUTAINER Brand (PLUS) Plastic Blood Collection Tube with
EDTA Anticoagulant and VACUTAINER Brand PLUS (Plastic)
Serum Tube
Regulatory Class: II
Product Code: JKA
Dated: March 17, 1998
Received: March 18, 1998

Dear Ms. Schweighardt:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use regulated by CDRH in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

In addition, we have determined that your indications for use which includes immunohematology testing for ABO grouping, Rh typing and antibody screening are subject to regulation by the Center for Biologics (CBER).

Our substantially equivalent determination does not apply to the indications for use regulated by CBER. CBER is reviewing BK980011 for the immunohematology claims. For information on applicable Agency requirements for marketing this product, we suggest you contact:

Mary Gustafson
HFM-370, Room 200 N. Woodmont
Center for Biologics Evaluation and Research
Food and Drug Administration, Rockville, MD 20852
(301) 827-3524

If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal

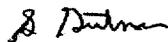
Page 2 - Ms. Schweighardt

Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action.

In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under section 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device indicated for uses regulated by CDRH in your 510(k) premarket notification although we recommend that you first contact Ms. Kochman from CBER at (301) 827-3524 before marketing your product with the immunohematology claims regulated by CBER. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice for your device on the labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), promotion, or advertising, please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-302) at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Steven I. Gutman, MD, MBA
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K981013

Device Name: VACUTAINER® Brand PLUS Tube with EDTA Anticoagulant and VACUTAINER® Brand PLUS Serum Tube

Indications for Use:

The VACUTAINER® Brand PLUS (plastic) Tube with EDTA and VACUTAINER® Brand Serum Tube are evacuated blood collection tubes which provide a means of collecting, transporting, separating and processing blood in a plastic tube. When the tube is used together with VACUTAINER® Brand Needles and Holders, it is a closed system for the collection of venous blood with the same indications as described herein.

Blood collected in PLUS EDTA and PLUS Serum tubes can be used for immunohematology testing including ABO Grouping, Rh typing and antibody screening which requires red cells and plasma or serum.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

Clara Sliv

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K981013



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 17 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Eileen Schweighardt
Regulatory Affairs Manager
• Becton Dickinson VACUTAINER Systems
1 Becton Drive
Franklin Lakes, New Jersey 07417

Re: K981013
VACUTAINER Brand (PLUS) Plastic Blood Collection Tube with
EDTA Anticoagulant and VACUTAINER Brand PLUS (Plastic)
Serum Tube
Regulatory Class: II
Product Code: JKA
Dated: March 17, 1998
Received: March 18, 1998

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In addition, we have determined that your indications for use which includes immunohematology testing for ABO grouping, Rh typing and antibody screening are subject to regulation by the Center for Biologics (CBER).

Our substantially equivalent determination does not apply to the indications for use regulated by CBER. CBER is reviewing BK980011 for the immunohematology claims. For information on applicable Agency requirements for marketing this product, we suggest you contact:

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Food and Drug Administration, Rockville, MD 20852
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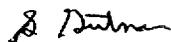
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Page 2 - Ms. Schweighardt

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Sincerely yours,



Steven I. Gutman, MD, MBA
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health



Enclosure

510(k) Number (if known): K981013

Device Name: VACUTAINER® Brand PLUS Tube with EDTA Anticoagulant and VACUTAINER® Brand PLUS Serum Tube

Indications for Use:

The VACUTAINER® Brand PLUS (plastic) Tube with EDTA and VACUTAINER® Brand Serum Tube are evacuated blood collection tubes which provide a means of collecting, transporting, separating and processing blood in a plastic tube. When the tube is used together with VACUTAINER® Brand Needles and Holders, it is a closed system for the collection of venous blood with the same indications as described herein.

Blood collected in PLUS EDTA and PLUS Serum tubes can be used for immunohematology testing including ABO Grouping, Rh typing and antibody screening which requires red cells and plasma or serum.

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

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(Optional Format 1-2-96)

Clara Sliv

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K981013

9

JUN 17 1998

Ms. Eileen Schweighardt
Regulatory Affairs Manager
Becton Dickinson VACUTAINER Systems
1 Becton Drive
Franklin Lakes, New Jersey 07417

Re: K981013
VACUTAINER Brand (PLUS) Plastic Blood Collection Tube with
EDTA Anticoagulant and VACUTAINER Brand PLUS (Plastic)
Serum Tube
Regulatory Class: II
Product Code: JKA
Dated: March 17, 1998
Received: March 18, 1998

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Page 2 - Ms. Schweighardt

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Sincerely yours,

Steven I. Gutman, MD, MBA
 Director
 Division of Clinical

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFZ 440 240	SLIVA Dut	6/16/98 6/18				Laboratory Devices Office of Device Evaluation Center for Devices and Radiological Health		

Enclosure

LE
 COPY

Memorandum

From: Reviewer(s) - Clara Slivi
Name(s)

Subject: 510(k) L98 10 13
Number

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

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Accepted for review 3/24/98.
- Is substantially equivalent to marketed devices. regulated by CDRH
- NOT substantially equivalent to marketed devices.

De Novo Classification Candidate? YES NO

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

- Is this device subject to Postmarket Surveillance? YES NO
- Is this device subject to the Tracking Regulation? YES NO
- Was clinical data necessary to support the review of this 510(k)? YES NO
- Is this a prescription device? YES NO
- Was this 510(k) reviewed by a Third Party? YES NO
- Special 510(k)? YES NO
- Abbreviated 510(k)? YES NO

This 510(k) contains:

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

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

The required certification and summary for class III devices

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

Animal Source Material Human Tissue Product Human Cell Product Human Extraction Product

(Please Check All That Apply)

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

No Confidentiality Confidentiality for 90 days Continued Confidentiality exceeding 90 days

Predicate Product Code with class:

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

ORA CLASS II

Review: → A Deter

CLCB

6/17/98

(Branch Chief)

(Branch Code)

17 (Date)

→ A Deter

6/18/98

6/17/98

Division Director

(DATE)

Division of Clinical
Laboratory Devices
Clara A. Sliva
Assistant Director for
Program Operations

To: The Record

From: Clara A. Sliva

Date: June 17, 1998

Re: K981013 Becton Dickinson VACUTAINER Systems SE documentation

The VACUTAINER Brand PLUS (plastic tube) with EDTA and VACUTAINER Serum tube are evacuated blood collection tubes which provide a means of collecting, transporting, separating and processing blood in a plastic tube. When the tube is used together with VACUTAINER Brand needles and holders it is a closed system for the collection of venous blood with the same indications for use. The VACUTAINER Brand PLUS tube consists of closure assembly, a plastic tube and silica clot activator.

The predicate device is the Becton Dickinson VACUTAINER Brand Plus PST Plasma Separation Tubes, K945952.

The device is classified as class II under the 862.1675 produce code = JKA TUBES, VIALS, SYSTEMS, SERUM SEPARATORS, BLOOD COLLECTION

The Labeling complies with 21 CFR 809.10 labeling regulations for in vitro diagnostic products. Sterilizing/Manufacturing information provided.

The immunohematology testing including ABO grouping, Rh typing and antibody screening is being reviewed by CBER as BK980011. Cheryl Kochman is the reviewer.

Based on the review of the above devices; K981013, I recommend the device is SUBSTANTIALLY EQUIVALENT to currently marketed serum and plasma collection tubes for use in the clinical laboratory. _____

Clara Sliva

Clara A. Sliva June 16, 1998

Memo to the Record:

On March 20, 1998 510k submitted to DCLD, assigned to Ann Hawthorne

On April 3, Ann sent an e-mail to Gene Berk indicating this device was reviewed by CBER

On April 13, the 510k was sent to Berk to review and transfer to CBER

On April 15, Gene sent the 510k back to Dr. Gutman indicating this was a joint review

On April 18, Dr. Gutman determined this was a joint review and re-assigned the 510k to Clara Sliva

It took from May 15-29 to determine who was reviewing the device in CBER

On June 3, it was determined the 510k was updated as a new 510k in CBER.

On June 12, 1998 the sponsor was informed that the indications for clinical use would be cleared by CDRH and the indications for CBER would be cleared by CBER. Sheryl Kochman was identified by the reviewer.

On June 12-16, we consulted with POS to determine which letter to send.

Clara Sliva

I N T E R O F F I C E M E M O R A N D U M

Date: 17-Jun-1998 10:05am EST
From: Shulman, Marjorie G.
 MYS@CDRH.FDA.GOV@SMTP@CVAX3
Dept:
Tel No:

TO: Sliva, Clara A.

(CAS@CDRH.FDA.GOV@SMTP@CVAX3)

Subject: K981013

Hi Clara,

Heather said that if you all want to send this letter you can (it is fine) or if you just want to send the straight SE with just our indication and note the telephone conversation in the file (that CBER is working on the other part) that is one way to go also. Thanks and please let me know if you have any other questions.

Marjie

CO

I N T E R O F F I C E M E M O R A N D U M

Date: 29-May-1998 12:22pm EST
From: Sliva, Clara A.
CAS
Dept: ODE_DCLD - HFZ-440
Tel No: 594-3084

TO: KOCHMAN (FDACB) (KOCHMAN@CBER.FDA.GOV @SMTP)
CC: Gutman, Steve (SIG)
CC: Aziz, Kaiser J. (KJA)
CC: WILSONL (FDACB) (WILSONL@CBER.FDA.GOV @SMTP)

Subject: FWD: status of 510k

Hi Sheryl

Thanks for review the parts relevant to CBER. Will you be able to provide a list of deficiencies by next week.

thanks

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I N T E R O F F I C E M E M O R A N D U M

Date: 27-May-1998 02:20pm EST
From: Sliva, Clara A.
CAS
Dept: ODE_DCLD - HFZ-440
Tel No: 594-3084

TO: Berk, Eugene (EMB)
CC: Hackett, Joseph L. (JLH)
CC: Aziz, Kaiser J. (KJA)
Subject: CBER consult

Hi Gene

re: K981013 Becton Dickinson Vacutainer PLUS Blood Collection Tube

Whom may I contact in CBER about the status of the above 510k.
Len Wilson & Jean Claggett in Paul Mied's do not have any knowledge of a 510k
being under joint review.

help! 510k submitted March 18, sent to CBER 4/28 90 days=JUNE 16

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I N T E R O F F I C E M E M O R A N D U M

Date: 27-May-1998 04:00pm EST
From: Sliva, Clara A.
CAS
Dept: ODE_DCLD - HFZ-440
Tel No: 594-3084

TO: PADGETT (FDACB) (PADGETT@CBER.FDA.GOV @SMTP)

CC: Gutman, Steve (SIG)
CC: Aziz, Kaiser J. (KJA)

Subject: FWD: CBER joint review

do you know who has the 510k.
could you ask the reviewer to send me an e-mail as soon as possible. If the reviewer has deficiencies, a letter will need to be prepared.
Is there a mechanism in place for identifying the reviewer and then notifying CDRH.

thanks for your help.

Clara sliva

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I N T E R O F F I C E M E M O R A N D U M

Date: 26-May-1998 08:37am EST
From: Sliva, Clara A.
CAS
Dept: ODE_DCLD - HFZ-440
Tel No: 594-3084

TO: WILSONL (FDACB) (WILSONL@CBER.FDA.GOV @SMTP)
CC: Gutman, Steve (SIG)
Subject: FWD: FW: status of 510k

Hi Len

No one has contacted me about the 510k. 90 days=June 25, 1998

thanks

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I N T E R O F F I C E M E M O R A N D U M

Date: 15-May-1998 11:35am EST
From: Wilson, Leonard
wilsonl@cber.fda.gov@SMTP@CVAX3
Dept:
Tel No:

TO: Nedjar, Sayah (nedjar@cbs5055530.cber.FDA.gov@SMTP@CVAX3)
CC: CLAGGETT, JANET (CLAGGETT@a1.CBER.FDA.GOV@SMTP@CVAX3)
CC: SLIVA, CLARA (CAS@CDRH.FDA.GOV@SMTP@CVAX3)

Subject: FW: status of 510k

Do we know if this is BK970024? If so, where are we in the review?

Len

> -----Original Message-----

> From: Sliva, Clara A. 594-3084 [SMTP:CAS@a1.cdrh.fda.gov]
> Sent: Friday, May 15, 1998 11:02 AM
> To: CLAGGETT, JANET
> Cc: Gutman, Steve
> Subject: status of 510k

>
>
> Hi

> joint review with CBER

> Has a reviewer been assigned to review K981013 Becton Dickinson Vacutainer
> plus
> EDTA. The file was sent to CBER in mid-April. If so, what is the status of
> the
> review.

> thanks for checking.

> clara sliva (CAS)

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I N T E R O F F I C E M E M O R A N D U M

Date: 15-May-1998 11:02am EST
From: Sliva, Clara A.
CAS
Dept: ODE_DCLD - HFZ-440
Tel No: 594-3084

TO: CLAGGETT (FDACB) (CLAGGETT@CBER.FDA.GOV @SMTP)
CC: Gutman, Steve (SIG)
Subject: status of 510k

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re: joint review with CBER
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clara sliva (CAS)

16

re: joint review with CBER

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thanks for checking.

clara sliva (CAS)

17

Jene

re: K981013 Becton Dickinson Vacutainer PLUS Blood Collection Tube

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Len Wilson & Jean Claggett in Paul Mied's do not have any knowledge of a 510k being under joint review.

help! 510k submitted March 18, sent to CBER 4/28 **90 days=JUNE 16**

clara

18

Jene

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help! 510k submitted March 18, sent to CBER 4/28 **90 days=JUNE 16**

clara

12

do you know who has the 510k.
could you ask the reviewer to send me an e-mail as soon as possible. If the reviewer has deficiencies, a letter will need to be prepared.
Is there a mechanism in place for identifying the reviewer and then notifying CDRH.

thanks for your help.

clara sliva

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Len

> -----Original Message-----

> From: Sliva, Clara A. 594-3084 [SMTP:CAS@a1.cdrh.fda.gov]

> Sent: Friday, May 15, 1998 11:02 AM

> To: CLAGGETT, JANET

> Cc: Gutman, Steve

> Subject: status of 510k

>

>

> Hi

>

> re: joint review with CBER

> Has a reviewer been assigned to review K981013 Becton Dickinson Vacutainer

> plus

> EDTA. The file was sent to CBER in mid-April. If so, what is the status of

> the

> review.

>

> thanks for checking.

>

> clara sliva (CAS)

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I N T E R O F F I C E M E M O R A N D U M

Date: 27-May-1998 02:20pm EST
From: Sliva, Clara A.
CAS
Dept: ODE_DCLD - HFZ-440
Tel No: 594-3084

TO: Berk, Eugene (EMB)

CC: Hackett, Joseph L. (JLH)

CC: Aziz, Kaiser J. (KJA)

Subject: CBER consult

Hi Gene

re: K981013 Becton Dickinson Vacutainer PLUS Blood Collection Tube

Whom may I contact in CBER about the status of the above 510k.
Len Wilson & Jean Claggett in Paul Mied's do not have any knowledge of a 510k
being under joint review.

help! 510k submitted March 18, sent to CBER 4/28 **90 days=JUNE 16**

c a

I N T E R O F F I C E M E M O R A N D U M

Date: 26-May-1998 08:37am EST
From: Sliva, Clara A.
CAS
Dept: ODE_DCLD - HFZ-440
Tel No: 594-3084

TO: WILSONL (FDACB) (WILSONL@CBER.FDA.GOV @SMTP)
CC: Gutman, Steve (SIG)
Subject: FWD: FW: status of 510k

Hi Len

No one has contacted me about the 510k. 90 days=June 25, 1998

thanks

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I N T E R O F F I C E M E M O R A N D U M

Date: 15-May-1998 11:35am EST
From: Wilson, Leonard
wilsonl@cber.fda.gov@SMTP@CVAX3
Dept:
Tel No:

TO: Nedjar, Sayah (nedjar@cbs5055530.cber.FDA.gov@SMTP@CVAX3)
CC: CLAGGETT, JANET (CLAGGETT@a1.CBER.FDA.GOV@SMTP@CVAX3)
CC: SLIVA, CLARA (CAS@CDRH.FDA.GOV@SMTP@CVAX3)

Subject: FW: status of 510k

Do we know if this is BK970024? If so, where are we in the review?

Len

> -----Original Message-----

> From: Sliva, Clara A. 594-3084 [SMTP:CAS@a1.cdrh.fda.gov]

> Sent: Friday, May 15, 1998 11:02 AM

> To: CLAGGETT, JANET

> Cc: Gutman, Steve

> Subject: status of 510k

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> a reviewer been assigned to review K981013 Becton Dickinson Vacutainer

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>

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> clara sliva (CAS)



I N T E R O F F I C E M E M O R A N D U M

Date: 15-May-1998 11:02am EST
From: Sliva, Clara A.
CAS
Dept: ODE_DCLD - HFZ-440
Tel No: 594-3084

TO: CLAGGETT (FDACB) (CLAGGETT@CBER.FDA.GOV @SMTP)

CC: Gutman, Steve (SIG)

Subject: status of 510k

Hi

re: joint review with CBER

Has a reviewer been assigned to review K981013 Becton Dickinson Vacutainer plus EDTA. The file was sent to CBER in mid-April. If so, what is the status of the review.

thanks for checking.

clara sliva (CAS)

21

I N T E R O F F I C E M E M O R A N D U M

Date: 15-May-1998 11:02am EST
From: Sliva, Clara A.
CAS
Dept: ODE_DCLD - HFZ-440
Tel No: 594-3084

TO: CLAGGETT (FDACB) (CLAGGETT@CBER.FDA.GOV @SMTP)
CC: Gutman, Steve (SIG)
Subject: status of 510k

Hi

re: joint review with CBER
Has a reviewer been assigned to review K981013 Becton Dickinson Vacutainer plus EDTA. The file was sent to CBER in mid-April. If so, what is the status of the review.

thanks for checking.

clara sliva (CAS)

I N T E R O F F I C E M E M O R A N D U M

Date: 15-May-1998 11:06am EST
From: Sliva, Clara A.
CAS
Dept: ODE_DCLD - HFZ-440
Tel No: 594-3084

TO: WILSONL (FDACB) (WILSONL@CBER.FDA.GOV @SMTP)

Subject: FWD: status of 510k

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Review Memorandum

Date: April 7, 1998
From: C. Ann Hawthorne, Chemist, Clinical Chemistry & Toxicology Branch,
DCLD, (HFZ-440)
Subject: TRANSFER TO CBER
To: The Record of K981013

Contact:
Eileen Schweighardt
Regulatory Affairs Manager
Becton Dickinson
(201) 847-4570

Background

The Becton Dickinson has submitted a new 510k for the currently legally marketed Vacutainer Brand PLUS (Plastic) Blood Collection Tube with EDTA Anticoagulant and Vacutainer Brand PLUS (Plastic) Serum Tube. The device is not modified, it was submitted to clear an added claim for blood typing/blood banking use. Since the device and device claims are not modified, there no issues relevant to CDRH.

Recommendation

Based on my discussion with POS (see e-mails included for the file), I recommend transferring this 510K to CBER (510k boilerplate SK-19), since the modified indications relate solely to issues under their purview.


C. Ann Hawthorne

W

I N T E R O F F I C E M E M O R A N D U M

Date: 03-Apr-1998 02:48pm EST
From: Hawthorne, C. Ann
CXH
Dept: ODE_DCLD - HFZ-440
Tel No: 594-1243 FAX 4-5940

TO: Berk, Eugene

(EMB)

CC: Montgomery, Alfred

(AWM)

Subject: CBER 510k responsibility

Gene:

I am reviewing a 510k for an expanded indications for use on a currently legally marketed blood collection tube. The device is **not** modified, it was submitted to clear an added claim for blood typing/blood banking use. I expect this to be a transfer to CBER (510k boilerplate SK-19), since there no issues relevant to CDRH. Please advise.

Also, if you know the URL of the InterCenter Agreement covering blood banking products, could you let me know, so that I may refer to it in my memo to the file.

Thanks

Ann



I N T E R O F F I C E M E M O R A N D U M

Date: 06-Apr-1998 09:54am EST
From: Berk, Eugene
EMB
Dept: ODE_POS - HFZ-404
Tel No: 594-1190

TO: Hawthorne, C. Ann (CXH)
CC: Montgomery, Alfred (AWM)
Subject: RE: CBER 510k responsibility

Yes this is a candidate for transfer to CBER as long as there are no device issues and the new indications for use don't contradict device use labeling.

What's a URL? If its something to do with a page on the Internet, as far as I know the Ombudsman's office has never put any of the InterCenter Agreements on the net, although I think they are working on it.

Eugene

PREMARKET NOTIFICATION (510(K)) CHECKLIST FOR ACCEPTANCE DECISION

K981013

Device Name VACUTAINER PLUS

Division/Branch CH

Administrative Reviewer Signature C. Olmi

Date 3/24/98

Supervisory Signature _____ Date _____

Did the firm request expedited review? Yes No

Did we grant expedited review? Yes _____ No NIA

Truthful and accurate statement enclosed? Yes _____ No

(If Not Enclosed, Must Be A Refuse To Accept Letter)

Required For Originals Received 3/14/95 And After

Is the Indication for Use Form enclosed? YES _____ No

(Required for Original 510(k)s received 1/1/96 and after -- must be submitted on a separate sheet of paper)

Without reviewing this 510(k), do you believe this device type may be a preamendments class III device? Yes No (IF YES, NOTIFY POS IMMEDIATELY IF THE OUTSIDE OF THE 510(k) HAS NOT BEEN STAMPED CLASS III SO THAT THE GMP INSPECTION CAN BE SCHEDULED AS SOON AS POSSIBLE). Class III devices can not receive a determination of substantial equivalence until the GMP inspection process has been completed.

Is this a file that was determined to be substantially equivalent by ODE, but placed on hold due to GMP violations and deleted after 12 months on hold? If so, a new ODE review is not required, please forward to POS.

_____ Yes No

Accepted

_____ Refuse To Accept

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I. CRITICAL ELEMENTS:	YES PRESENT OMISSION JUSTIFIED	NO INADEQUATE OMITTED
A. Is The Product A Device?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
B. Is The Device Exempt From 510(k) By Regulation Or Policy?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
C. Is Device Subject To Review By CDRH?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
D. (i) Are You Aware That This Device Has Been The Subject Of A Previous NSE Decision? (ii) If Yes, Does This New 510(k) Address The NSE Issue(s) (E.G., Performance Data)?	<input type="checkbox"/> <input type="checkbox"/>	<input checked="" type="checkbox"/> <input type="checkbox"/>
E. (i) Are You Aware Of The Submitter Being The Subject Of An Integrity Investigation? If Yes, Consult The ODE Integrity Officer. (ii) Has The ODE Integrity Officer Given Permission To Proceed With The Review? (Blue Book Memo #191-2 And Federal Register 90N-0332, September 10, 1991.)	<input type="checkbox"/> <input type="checkbox"/>	<input checked="" type="checkbox"/> <input type="checkbox"/>
F. Does The Submission Contain The Information Required Under Sections 510(k), 513(f), And 513(i) Of The Federal Food, Drug, and Cosmetic Act (Act) And Subpart E Of Part 807 In Title 21 Of The Code Of Federal Regulations?:	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1. Device Trade Or Proprietary Name	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2. Device Common Or Usual Name Or Classification Name	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3. Establishment Registration Number (Only Applies If Establishment Is Registered)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
4. Class Into Which The Device Is Classified Under (21 CFR Parts 862 to 892)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
5. Classification Panel	<input checked="" type="checkbox"/>	<input type="checkbox"/>
6. Action Taken To Comply With Section 514 Of The Act	N/A <input type="checkbox"/>	<input type="checkbox"/>
7. Proposed Labels, Labeling And Advertisements (If Available) That Describe The Device, Its Intended Use, And Directions For Use (Blue Book Memo #G91-1)	<input checked="" type="checkbox"/>	<input type="checkbox"/>

3

8. A 510(k) Summary Of Safety And Effectiveness Or A 510(k) Statement That Safety And Effectiveness Information Will Be Made Available To Any Person Upon Request	<input checked="" type="checkbox"/>	<input type="checkbox"/>
9. For Class III Devices Only, A Class III Certification And A Class III Summary	NIA <input type="checkbox"/>	<input type="checkbox"/>
10. Photographs Of The Device	<input type="checkbox"/>	<input type="checkbox"/>
11. Engineering Drawings For The Device With Dimensions And Tolerances	<input type="checkbox"/>	<input type="checkbox"/>
12. The Marketed Device(s) To Which Equivalence Is Claimed Including Labeling And Description Of The Device	<input checked="" type="checkbox"/>	<input type="checkbox"/>
13. Statement Of Similarities And/Or Differences With Marketed Device(s)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
14. Data To Show Consequences And Effects Of A Modified Device(s)	NIA <input type="checkbox"/>	<input type="checkbox"/>
15. Truthful And Accurate Statement	<input checked="" type="checkbox"/>	<input type="checkbox"/>
II. Additional Information That <u>Is</u> Necessary Under 21 CFR 807.87(h) :	<input checked="" type="checkbox"/>	<input type="checkbox"/>
A. Submitter's Name And Address	<input checked="" type="checkbox"/>	<input type="checkbox"/>
B. Contact Person, Telephone Number And Fax Number	<input checked="" type="checkbox"/>	<input type="checkbox"/>
C. Representative/Consultant If Applicable	<input checked="" type="checkbox"/>	<input type="checkbox"/>
D. Table Of Contents With Pagination	<input checked="" type="checkbox"/>	<input type="checkbox"/>
E. Address Of Manufacturing Facility/Facilities And, If Appropriate, Sterilization Site(s)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
III. Additional Information That <u>May Be</u> Necessary Under 21 CFR 807.87(h) :	<input checked="" type="checkbox"/>	<input type="checkbox"/>
A. Comparison Table Of The New Device To The Marketed Device(s)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
B. Action Taken To Comply With Voluntary Standards	NIA <input type="checkbox"/>	<input type="checkbox"/>
C. Performance Data	<input checked="" type="checkbox"/>	<input type="checkbox"/>
MARKETED DEVICE:	<input type="checkbox"/>	<input type="checkbox"/>
Bench Testing	<input type="checkbox"/>	<input type="checkbox"/>
Animal Testing	<input type="checkbox"/>	<input type="checkbox"/>
Clinical Data	<input type="checkbox"/>	<input type="checkbox"/>
NEW DEVICE:	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Bench Testing	<input type="checkbox"/>	<input type="checkbox"/>
Animal Testing	<input type="checkbox"/>	<input type="checkbox"/>

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Clinical Data	<input type="checkbox"/>	<input type="checkbox"/>
D. Sterilization Information	N/A <input type="checkbox"/>	<input type="checkbox"/>
E. Software Information	<input type="checkbox"/>	<input type="checkbox"/>
Hardware Information	<input type="checkbox"/>	<input type="checkbox"/>
G. If This 510(k) Is For A Kit, Has The Kit Certification Statement Been Provided?	<input type="checkbox"/>	<input type="checkbox"/>
H. Is This Device Subject To Issues That Have Been Addressed In Specific Guidance Document(s)?	<input type="checkbox"/>	<input type="checkbox"/>
If Yes, Continue Review With Checklist From Any Appropriate Guidance Documents.	<input type="checkbox"/>	<input type="checkbox"/>
If No, Is 510(k) Sufficiently Complete To Allow Substantive Review?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
I. Other (Specify)	<input type="checkbox"/>	<input type="checkbox"/>

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

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K _____

Reviewer: _____

Division/Branch: _____

Device Name: _____

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

YES NO

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

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

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

*

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

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

ATTACH ADDITIONAL SUPPORTING INFORMATION

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March 19, 1998

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

BECTON DICKINSON VACUTAINER SYSTEMS 510(k) Number: K981013
ONE BECTON DR Received: 18-MAR-1998
FRANKLIN LAKES, NJ 07417 Product: VACUTAINER PLUS TUBE
ATTN: EILEEN SCHWEIGHARDT WITH EDTA
ANTICOAGULANT ANDD
VACUTAINER PLUS

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

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522 (a) (1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers Assistance at the number below for more information.

With regard to the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88) which became effective September 1, 1992, the Center for Disease Control (CDC) and Prevention is currently handling complexity category/assignments concurrent with FDA's 510(k) review. To determine if your device requires a CLIA complexity categorization, contact CDC at (770)488-7655.

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

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

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Staff

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K981013

original



CELEBRATING THE FIRST ONE HUNDRED: 1897-1997

**BECTON
DICKINSON**

Becton Dickinson VACUTAINER Systems
1 Becton Drive
Franklin Lakes, New Jersey 07417
(201) 847-4500

March 17, 1998

Office of Device Evaluation
510(k) Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd. Room #2N
Rockville, MD 20850

RECEIVED

1998 03 11 46

FDA/CDRH/ODE/DMC

REF: 510(K) Premarket Notification
VACUTAINER® Brand PLUS (Plastic) Blood Collection Tube
with EDTA Anticoagulant
VACUTAINER® Brand PLUS (Plastic) Serum Tube

Document Control Clerk:
Pursuant to the requirements of Section 510(k) of the Federal Food, Drug and Cosmetic Act, notification is made of the intention of Becton Dickinson and Company to introduce into interstate commerce a modified VACUTAINER® Brand PLUS Blood Collection Tube with EDTA Anticoagulant and VACUTAINER® Brand PLUS Serum Tube.

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

In 1995 joint review authority was given to CDRH and CBER for devices with Blood Banking claims, therefore, I have attached four copies of the premarket notification, two copies for CBER review and two copies for CDRH review.

All information Becton Dickinson VACUTAINER® Systems considers confidential information or trade secrets has been marked "Confidential" and therefore, is considered to be exempt from disclosure according to 21 CFR 20.60 and 20.61.

If require additional information, please don't hesitate to contact me by telephone at 201 - 847 - 4570 or via telefax at 201 - 847 4858.

Sincerely,

Eileen Schweighardt

Eileen Schweighardt
Regulatory Affairs Manager

SK-19 CH class II
38

510(k) PREMARKET NOTIFICATION
VACUTAINER® BRAND PLUS TUBE
WITH EDTA ANTICOAGULANT
VACUTAINER® BRAND PLUS SERUM TUBE

BECTON DICKINSON & COMPANY
VACUTAINER SYSTEMS
1 BECTON DRIVE
FRANKLIN LAKES, NJ 07417

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ATTACHMENT A

CDRH PREMARKET SUBMISSION COVER SHEET

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
Premarket Submission Cover Sheet

Date of Submission:

FDA Document Number:

Section A**Type of Submission**

- | | | | |
|---|---|--|---|
| <input checked="" type="checkbox"/> 510(k) | <input type="checkbox"/> IDE | <input type="checkbox"/> PMA | <input type="checkbox"/> PMA Supplement - Regular |
| <input type="checkbox"/> 510(k) Add'l information | <input type="checkbox"/> IDE Amendment | <input type="checkbox"/> PMA Amendment | <input type="checkbox"/> PMA Supplement - Special |
| | <input type="checkbox"/> IDE Supplement | <input type="checkbox"/> PMA Report | <input type="checkbox"/> PMA Supplement - 30 day |
| | <input type="checkbox"/> IDE Report | | |

Section B1**Reason for Submission -- 510(k)s Only**

- | | | |
|--|--|---|
| <input type="checkbox"/> New device | <input checked="" type="checkbox"/> Additional or expanded indications | <input type="checkbox"/> Change in technology, design, materials or manufacturing process |
| <input type="checkbox"/> Other reason (specify): | | |

Section B2**Reason for Submission -- PMAs Only**

- | | | |
|---|---|--|
| <input type="checkbox"/> New device | <input type="checkbox"/> Change in design, component or specification: | <input type="checkbox"/> Location change: |
| <input type="checkbox"/> Withdrawal | <input type="checkbox"/> Software | <input type="checkbox"/> Manufacturer |
| <input type="checkbox"/> Additional or expanded indications | <input type="checkbox"/> Color Additive | <input type="checkbox"/> Sterilizer |
| <input type="checkbox"/> Licensing agreement | <input type="checkbox"/> Other (specify below): | <input type="checkbox"/> Packager |
| | | <input type="checkbox"/> Distributor |
| <input type="checkbox"/> Labeling change: | <input type="checkbox"/> Process change: | <input type="checkbox"/> Report submission |
| <input type="checkbox"/> Indications | <input type="checkbox"/> Manufacturer | <input type="checkbox"/> Annual or |
| <input type="checkbox"/> Instructions | <input type="checkbox"/> Sterilizer | <input type="checkbox"/> Post-approval |
| <input type="checkbox"/> Performance Characteristics | <input type="checkbox"/> Packager | <input type="checkbox"/> Adverse |
| <input type="checkbox"/> Shelf life | <input type="checkbox"/> Response to FDA correspondence (specify below) | <input type="checkbox"/> Device defect |
| <input type="checkbox"/> Trade name | <input type="checkbox"/> Request for applicant hold | <input type="checkbox"/> Amendment |
| <input type="checkbox"/> Other (specify below) | <input type="checkbox"/> Request for removal of applicant hold | |
| <input type="checkbox"/> Change in ownership | <input type="checkbox"/> Request for extension | |
| <input type="checkbox"/> Change in correspondent | | |
| <input type="checkbox"/> Other reason (specify): | | |

Section B3**Reason for Submission -- IDEs Only**

- | | | |
|---|---|---|
| <input type="checkbox"/> New device | <input type="checkbox"/> Change in: | <input type="checkbox"/> Response to FDA letter concerning: |
| <input type="checkbox"/> Addition of institution | <input type="checkbox"/> Correspondent | <input type="checkbox"/> Conditional approval |
| <input type="checkbox"/> Expansion / extension of study | <input type="checkbox"/> Design | <input type="checkbox"/> Deemed approval |
| <input type="checkbox"/> IRB certification | <input type="checkbox"/> Informed consent | <input type="checkbox"/> Deficient final report |
| <input type="checkbox"/> Request hearing | <input type="checkbox"/> Manufacturer | <input type="checkbox"/> Deficient progress report |
| <input type="checkbox"/> Request waiver | <input type="checkbox"/> Manufacturing | <input type="checkbox"/> Deficient semi-annual report |
| <input type="checkbox"/> Termination of study | <input type="checkbox"/> Protocol - feasibility | <input type="checkbox"/> Disapproval |
| <input type="checkbox"/> Withdrawal of application | <input type="checkbox"/> Protocol - other | <input type="checkbox"/> Request extension of time to |
| | <input type="checkbox"/> Sponsor | <input type="checkbox"/> Request meeting |
| <input type="checkbox"/> Emergency use: | <input type="checkbox"/> Report submission: | <input type="checkbox"/> IOL submissions only: |
| <input type="checkbox"/> Notification of emergency use | <input type="checkbox"/> Semi-annual progress | <input type="checkbox"/> Change in IOL style |
| <input type="checkbox"/> Additional information | <input type="checkbox"/> Annual progress | <input type="checkbox"/> Request for protocol waiver |
| | <input type="checkbox"/> Unanticipated verse | |
| <input type="checkbox"/> Other reason (specify): | <input type="checkbox"/> Waiver / site limit | |

Section C		Product Classification			
Product Code: 75JKA	C.F.R. Section: 862.1675	Device class: <input type="checkbox"/> Class I <input type="checkbox"/> Class III <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Unclassified			
Classification panel: Clinical Chemistry and Clinical Toxicology					
Section D		Information on 510(k) Submissions			
Product codes of devices to which substantial equivalence is claimed:		Summary of, or statement concerning safety and effectiveness data: <input checked="" type="checkbox"/> 510(k) summary attached <input type="checkbox"/> 510(k) statement			
1 75JKA	2			3	4
5	6			7	8
Information on devices to which substantial equivalence is claimed:					
510(k) Number	Trade or proprietary or model name	Manufacturer			
1 510(k) exempt	1 VACUTAINER® Brand Tube with EDTA Anticoagulant	1 Becton Dickinson VACUTAINER Systems			
2 510(k) exempt	2 VACUTAINER® Brand Serum Tube	2 Becton Dickinson VACUTAINER Systems			
3	3	3			
	4	4			
Section E		Product Information -- Applicable to All Applications			
Common or usual name or classification name: Blood Collection Tube					
Trade or proprietary or model name		Model number			
1 VACUTAINER® Brand PLUS Tube with EDTA Anticoagulant		1 Multiple			
2 VACUTAINER® Brand PLUS Serum Tube		2 Multiple			
FDA document numbers of all prior related submissions (regardless of outcome):					
1 K901449/A	2 K953463	3 K960250	4 K971449		
5					
6					
Intended use or indications for use: The VACUTAINER® Brand PLUS (plastic) Tube with EDTA and VACUTAINER Brand PLUS Serum Tube are evacuated blood collection tubes which provide a means of collecting, transporting, separating and processing blood in a plastic tube. When the tube is used together with VACUTAINER® Brand Needles and Holders, it is a closed system for the collection of venous blood with the same indications as described herein. Blood collected in an EDTA and Serum tubes can be used for immunohematology testing including ABO Grouping, RH typing and antibody screening which requires red cells and plasma or serum.					

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Section F Manufacturing / Packaging / Sterilization Sites			
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA establishment registration number: 1917413	<input checked="" type="checkbox"/> Manufacturer & Sterilizer <input type="checkbox"/> Contract manufacturer	<input type="checkbox"/> Contract sterilizer <input type="checkbox"/> Repackager/relabeler
Company/Institution name: Becton Dickinson VACUTAINER Systems			
Division name (if applicable):		Phone number (include area code): (308) 872 - 6811	
Street address: 150 South 1 st Avenue,		FAX number (include area code): (308) 872 - 5553	
City: Broken Bow	State/Province: NE	Country: U.S.A.	ZIP/Postal Code: 68822
Contact name: Dwayne Calek			
Contact title: QA Manager			
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA establishment registration number: 1024879	<input checked="" type="checkbox"/> Manufacturer & Sterilizer <input type="checkbox"/> Contract manufacturer	<input type="checkbox"/> Contract sterilizer <input type="checkbox"/> Repackager/relabeler
Company/Institution name: Becton Dickinson VACUTAINER Systems			
Division name (if applicable):		Phone number (include area code): (803) 469 - 8010	
Street address: Airport Rd		FAX number (include area code): (803) 469 - 1755	
City: Sumter	State/Province: SC	Country: USA	ZIP/Postal Code: 29151
Contact name: William Morrison			
Contact title: QA Manager			
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA establishment registration number:	<input checked="" type="checkbox"/> Manufacturer & Sterilizer <input type="checkbox"/> Contract manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager/relabeler
Company/Institution name: Becton Dickinson of U.K. Ltd			
Division name (if applicable):		Phone number (include area code): (011) 441 - 752- 701281	
Street address: Belliver Industrial Estate		FAX number (include area code): (011) 441-752- 788308	
City: Plymouth	State/Province: Devon	Country: England	ZIP/Postal Code: PL6 7BP
Contact name: K. Alderman			
Contact title: Manager, Quality Assurance			

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Section F (Continued)		Manufacturing / Packaging / Sterilization Sites			
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA establishment registration number:	<input type="checkbox"/> Manufacturer & Sterilizer <input type="checkbox"/> Contract manufacturer	<input type="checkbox"/> Contract sterilizer <input type="checkbox"/> Repackager/relabeler		
Company/Institution name: Becton Dickinson VACUTAINER Systems					
Division name (if applicable):			Phone number (include area code):		
Street address:			FAX number (include area code):		
City:	State/Province:	Country:	ZIP/Postal Code:		
Contact name:					
Contact title:					

Section G		Applicant or Sponsor			
Company / Institution name: Becton Dickinson VACUTAINER Systems		FDA establishment registration number: 2243072			
Division name (if applicable):		Phone number (include area code): (201) 847-4570			
Street address: 1 Becton Drive		FAX number (include area code): (201) 847-4858			
City: Franklin Lakes	State / Province: NJ	Country: US	ZIP / Postal Code: 07417-1885		
Signature: <i>Eileen Schweighardt</i> 3/13/1998					
Name: E. Schweighardt					
Title: Regulatory Affairs Manager					

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

ATTACHMENT B
GENERAL SUMMARY

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GENERAL SUMMARY

Trade Name: VACUTAINER® Brand PLUS Tube
with EDTA Anticoagulant and
VACUTAINER® Brand PLUS Serum Tube

Classification Name : Blood Specimen Collection Device

Classification: Class II

Device Description:

The VACUTAINER® Brand PLUS Tube with EDTA and the VACUTAINER PLUS Serum Tube are evacuated plastic blood collection tubes for collecting, transporting and processing blood in a closed plastic tube. The VACUTAINER® Brand PLUS Tube with EDTA consists of closure assembly, a plastic tube and EDTA coating (dipotassium). The VACUTAINER PLUS Serum Tube consists of closure assembly, a plastic tube and silica clot activator.

The standard closure assembly is a rubber stopper. The tubes are also available with the VACUTAINER® Hemogard Closure Assembly, which consists of a rubber stopper and protective plastic shield to reduce user exposure to blood. The Hemogard closure assembly, intended to reduce user exposure to blood, was described in 510(k) Premarket Notification K945952 that received FDA clearance on January 18, 1995. All stopper/closures are color coded to reflect additive type (see the chart VACUTAINER® Tube Stopper/Closure Color Code Cross Reference located in the Product Insert, Attachment D)

Reason for Submission:

Becton Dickinson VACUTAINER Systems intends to begin marketing the current VACUTAINER® Brand PLUS Tube with EDTA anticoagulant and the VACUTAINER® Brand PLUS Serum Tube with additional Indications for Use.

The VACUTAINER® Brand PLUS Tube with EDTA is a plastic blood collection tube intended for use in hematology studies and special chemistry studies to provide a means of collecting, transporting and processing venous blood in a closed system.

The VACUTAINER® Brand PLUS Serum Tube is a plastic blood collection tube intended for use in the clinical laboratory for analysis of serum to provide a means of collecting, transporting and processing venous blood in a closed system.

VACUTAINER Systems has expanded the Indications for Use on both plastic tubes to include immunohematology testing including ABO grouping, Rh typing and antibody screening which requires red cells and plasma or serum. 

VACUTAINER Systems believes that the VACUTAINER® Brand PLUS (Plastic) Tube with EDTA and the VACUTAINER® Brand PLUS Serum Tube with the additional Indications for Use are substantially equivalent to the VACUTAINER® Brand (glass) Serum Tube and the VACUTAINER® Brand (glass) Tube with EDTA.

Since 1970, glass EDTA and serum tubes have been the recognized blood collection tubes used by blood bank specialists for blood grouping typing and antibody screening. Under current routine blood bank procedures the blood sample is collected in the VACUTAINER® Brand (glass) Tube with EDTA anticoagulant and VACUTAINER® Brand (glass) Serum Tube. Both tubes are preamendment devices exempt from premarket notification regulations according to the Medical Device Amendments (MDA) of 1976. Further, the industry has utilized these tubes for immunohematology techniques prior to the MDA of 1976.

ATTACHMENT C
DEVICE DESCRIPTION

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C.1 Device Description

The VACUTAINER® Brand PLUS Tube with EDTA and the VACUTAINER® PLUS Serum Tube are evacuated plastic blood collection tubes for collecting, transporting and processing blood in a closed plastic tube. The VACUTAINER® Brand PLUS Tube with EDTA consists of closure assembly, a plastic tube and EDTA coating (dipotassium). The VACUTAINER PLUS Serum Tube consists of closure assembly, a plastic tube and silica clot activator coating.

The current commercially available VACUTAINER® Brand PLUS Tube with EDTA Anticoagulant was described in 510(k) Premarket Notification K971449 which received FDA clearance on June 17, 1997. The current VACUTAINER® Brand PLUS Serum Tube was described in premarket notification K960250 and received FDA clearance on March 29, 1996. The original VACUTAINER® Brand PLUS Tube with EDTA and VACUTAINER® Brand PLUS Serum Tube were described in 510(k) Premarket Notification K901449 which received FDA clearance on August 9, 1990. ←

The standard closure assembly is a basic rubber stopper. The tubes are also available with the VACUTAINER® HEMOGUARD Closure Assembly that consists of a rubber stopper and protective plastic shield to reduce user exposure to blood. The Hemogard closure assembly, intended to reduce user exposure to blood, was described in 510(k) Premarket Notification K945952 that received FDA clearance on January 18, 1995. All stopper/closures are color coded to reflect additive type (see the chart VACUTAINER® Tube Stopper/Closure Color Code Cross Reference located in the Product Insert, Attachment D)

The tubes are manufactured from PET (polyethylene terephthalate) plastic that enhances user safety and disposal because of the reduced risk of tube breakage and the use of incineration as a method of disposal. The EDTA anticoagulant coating of VACUTAINER® Brand PLUS Tube with EDTA is spray coated in the dipotassium (K₂) form. The EDTA additive is an anticoagulant, which provides a whole blood sample. The interior walls of the VACUTAINER® PLUS Serum Tube are spray-coated with silicone surfactant and silica clot activator. The silica clot activator promotes specimen clotting and provides a serum sample.

As described in the General Summary of this Premarket Notification, the Indications for Use for the VACUTAINER® Brand PLUS Tube with EDTA and the VACUTAINER® Brand PLUS Serum Tube have been expanded to include immunohematology testing including ABO grouping, Rh typing and antibody screening which requires red cells and plasma or serum.

C.2 Intended Use

The VACUTAINER® Brand PLUS Tubes with EDTA anticoagulant and the VACUTAINER® Brand PLUS Serum Tube are evacuated blood collection tubes which provide a means of collecting, transporting and processing blood in a closed plastic tube. Blood collected in a tube containing EDTA anticoagulant, VACUTAINER® Brand PLUS Tube with EDTA anticoagulant, is used primarily for clinical laboratory hematology studies. The VACUTAINER® Brand PLUS Serum Tube containing silica clot activator is used primarily in the clinical laboratory for chemistry assays. In addition, the blood collected and processed in the VACUTAINER® Brand PLUS with EDTA anticoagulant and the VACUTAINER® Brand PLUS Serum Tube can be used immunohematology testing including ABO grouping, Rh typing and antibody screening which requires red cells and plasma or serum.

C.3 Sterilization/Manufacturing Information:

Sterilization Method: Gamma Radiation Sterilization

Cycle Validation Method:

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

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

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

Manufacturing and Sterilization Sites:

The VACUTAINER® Brand PLUS tube with EDTA anticoagulant and VACUTAINER® Brand PLUS Serum Tubes are manufactured and sterilized at the following sites:

Manufacturing and Sterilization Site:

VACUTAINER® Brand PLUS EDTA Tube:

Becton Dickinson VACUTAINER Systems
150 South 1st Avenue
P.O. Box 686
Broken Bow, NE 68822

Establishment Registration Number: 1917413

Manufacturing Site and Sterilization Site, VACUTAINER® Brand PLUS Serum Tube:

Becton Dickinson VACUTAINER Systems
Airport Road
P.O. Box 2128
Sumter, SC 29151

Establishment Registration Number: 1024879

Alternate Manufacturing and Sterilization Site:

Becton Dickinson VACUTAINER Systems
Division of Becton Dickinson UK Limited
Belliver Industrial Estate
Plymouth, England

ATTACHMENT D
DEVICE LABELING

D.1 Device Packaging and Labeling

The VACUTAINER® Brand PLUS Tube with EDTA anticoagulant and the VACUTAINER® PLUS Serum Tube are intended to be marketed as a sterile in-vitro diagnostic device. The tubes are packaged one hundred (100) labeled tubes per shelf carton (EPS tray) and a labeled case carton consists of one-thousand (1000) tubes. The VACUTAINER® Brand PLUS Tube with EDTA and VACUTAINER® Brand PLUS Serum Tube device Labeling, included in this Attachment, consists of the labeling items identified below:

- Product Insert
- Unit Tube Label
- EPS (Shelf package) Tray Label
- Case Carton Label and Preprinted Case Carton

Note:

The product insert has been modified to include immunohematology testing including ABO grouping, RH typing and antibody screening which requires red cells and plasma or serum. Additional non-substantive changes are also included and have been highlighted as indicated.

The tube, shelf and case carton labels are specific to VACUTAINER® Brand PLUS Tube with EDTA anticoagulant and VACUTAINER® Brand PLUS Serum Tube.

This EPS tray is an alternative package that was described in Premarket Notification K971449, received clearance April 21, 1997.

This EPS tray package is an alternative to the preprinted shelf carton described in the predicate labeling, Section F Page 45. The equivalent preprinted shelf carton information appears as the second label placed on the EPS tray, identified on Page 22 of this section.

Insert
 Tube with EDTA Anticoagulant
 and PLUS Serum Tube

FRONT

ALL COPY PRINT PMS BLACK "C"

SIZE: 8.5" X 11"

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

VACUTAINER® PST Tubes

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

VACUTAINER® Tubes for Immunohematology
 VACUTAINER® PLUS Tubes (plastic) Serum and K₂EDTA as well as VACUTAINER® Brand Tubes (glass) Serum and K₃EDTA may be used for routine immunohematology testing i.e. red cell grouping, Rh typing and antibody screens.

VACUTAINER® Blood Collection Needles

VACUTAINER® Blood Collection Needles are single-use, double-ended, stainless steel needles. They have a threaded hub that fits into the threads of all VACUTAINER® Needle Holders. The venipuncture end of the needle has a point, specially designed to enter the skin easily during venipuncture. The needle is lubricated with silicone.

Multiple Sample Needles have a rubber sleeve covering the non-patient end of the needle that prevents leakage of blood into the holder during venipuncture. This rubber sleeve contains Dry Natural Rubber (DNR).

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

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

1. Appareil for protection from exposure to blood-borne pathogens or other potentially infectious materials.
2. Any VACUTAINER® Needle Holders of the standard size may be used with 13 or 16 mm diameter tubes. A pediatric tube may be used to modify the standard holder to fit the small diameter tubes.
3. Alcohol: cleansing site. If additional tubes requiring sterile collections, such as blood cultures, are filled at the same venipuncture, use tincture of iodine or suitable alternative for cleansing. Follow the laboratory policy for sterile sample collection for site preparation and tube handling instructions. Do not use alcohol based cleansing materials when samples are to be used for blood borne testing.
4. Dry sterile gauze.
5. Tourniquet.
6. Needle disposal container for used needle or needle/holder combination.

Required equipment not provided for specimen processing

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

Preparation for Specimen Collection

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

1. See required equipment above.
2. All necessary tubes, identified for size, draw, and additive.
3. Labels for positive patient identification of samples.

Recommended Order of Draw

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

VACUTAINER® Brand Evacuated Blood Collection System

For In Vitro Diagnostic Use.

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

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

VACUTAINER® TUBE STOPPER/CLOSURE COLOR CODE CROSS REFERENCE	
ADDITIVE GROUP/ADDITIVE	HEMOGARD™
Gel Separation Tubes	
SST® Tubes with Gel and Clot Activator	Gold
PST Tubes with Gel and Heparin ¹	Light Green
Non-additive Tubes	
Silicone Coated	Red
Uncoated	Pink
Serum Tubes with additives	
Thrombin ²	Yellow/Grey ³
Thrombin ² , Soybean Trypsin Inhibitor	Light Blue
Whole Blood/Plasma Tubes	
K ₂ EDTA ¹ or Heparin ¹	Lavender
Citrate (Coagulation)	Light Blue
Citrate (ESR)	Black
Sodium Fluoride/EDTA (Glucose)	Grey
Sodium Fluoride/Potassium Oxalate (Glucose)	Grey
Lithium Iodacetate (Glucose)	Green
Heparin ¹	Green ³
Add Citrate, Benzoin (C/D)	Yellow ³
Sodium Polyanthracene Sulfonate (SPS)	Yellow ³
Trace Element Tubes	
Silicone Coated, or EDTA, or Heparin ¹	Royal Blue
Lead Tubes	
Heparin ¹	Brown
K ₂ EDTA	Lavender

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

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

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

VACUTAINER® TRACE ELEMENT TUBES CONTAMINATION UPPER LIMITS			
ANA ¹	µg/L ANALYTE	µg/L ANALYTE	µg/L ANALYTE
Ant	0.8 Calcium	400.* Iron	60 Manganese
AlS	1.0 Chromium	0.9 Lead	2.5 Zinc
Cadm...	0.6 Copper	8.0 Magnesium	60*

*Flame technique, all others flameless

LIMITATIONS OF SYSTEM
The quantity of blood drawn varies with altitude, ambient temperature, barometric pressure, tube age, venous pressure, and filling technique. Tubes with draw volume smaller than the apparent dimensions indicated (partial draw tubes), may fill more slowly than tubes of the same size with greater draw volume. For those tubes subjected to centrifugation to generate plasma or serum for testing, standard processing conditions do not completely sediment all cells, whether or not barrier gel is present. Accordingly, cell-based metabolism, as well as natural degradation *ex vivo* affects serum/plasma analyte concentrations/activities beyond cellular changes. It is recommended that testing for glucose, uric acid, and lactate dehydrogenase (LD) be performed as soon after collection and separation as possible. Due to natural degradation, delay in separation of the serum or plasma from the cellular mass or in testing after separation will result in erroneous results for those analytes.

VACUTAINER® SST® Tubes and PST Tubes are not recommended for collection of samples for the therapeutic drug monitoring (TDM) assays and blood banking procedures. Do not use PST® Tubes for lithium measurement.

PRECAUTIONS

1. Storage of glass tubes containing blood at or below 0°C may result in tube breakage.
2. Do not remove conventional rubber stoppers by rolling with thumb. Remove stoppers with a twist and pull motion.
3. Do not use tubes or needles if foreign matter is present.
4. Lot number and needle size are printed on the paper label covering the connection of the needle shields. Do not use needle if label has been torn before venipuncture. This label will tear when the needle is opened.

CAUTION:

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

STORAGE

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

SPECI.

READ THIS ENTIRE CIRCULAR BEFORE PERFORMING VENIPUNCTURE.

Required equipment not provided for specimen collection

COLLECTION and HANDLING standard

Product
VACUTAINER® Brand PLUS
an
VACUTAINER® Bra

Prevention of Backflow

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

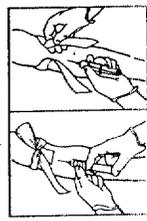
1. Place patient's arm in a downward position.
2. Hold tube with the stopper uppermost.
3. Release tourniquet as soon as blood starts to flow into tube.
4. Make sure tube additives do not touch stopper or end of the needle during venipuncture.

Venipuncture Technique and Specimen Collection

General Instructions

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

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



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

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

- a. Push tube forward until tube stopper has been penetrated. If necessary, hold in place to ensure complete vacuum draw.
- b. Confirm correct position of needle cannula in vein.
- c. If the multiple sample needle is used, remove tube and place new tube onto the holder.
- d. If second tube does not draw, remove needle and discard. Repeat procedure from Step 1.

11. When first tube has filled to its stated volume and blood flow ceases, remove it from holder.
12. Place succeeding tubes in holder, puncturing diaphragm to begin flow. See Recommended Order of Draw.
13. While each successive tube is filling, turn the filled tube upside-down and return it to upright position. This is one complete inversion.

For proper additive performance, invert SST® Tubes, and PLUS Serum Tubes 5 times. Invert all other filled additive tubes 8-10 times. Do not shake. Vigorous mixing may cause foaming or hemolysis. Insufficient mixing or delayed mixing in serum tubes may result in delayed clotting and incorrect test results. In tubes with anticoagulants, inadequate mixing may result in platelet clumping, clotting and/or incorrect test results.

14. As soon as blood stops flowing in the last tube, remove needle from vein, applying pressure to puncture site with dry sterile swab until bleeding stops.
15. Once clotting has occurred, apply bandage if desired.
16. After venipuncture, the top of the stopper may contain residual blood. Take proper precautions when handling tubes to avoid contact with this blood. Any needle holder that becomes contaminated with blood is considered hazardous and should be decontaminated with bleach or disposed of.
17. Dispose of the used needle using an appropriate disposal device. DO NOT RESHIELD. Reshielding of needles increases the risk of needlestick injury and blood exposure.

Clotting Instructions

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

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

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

In which tubes are held during centrifugation. Centrifuge carriers and inserts should be of the size specific to the tubes used. Use of carriers too large or too small for the tube may result in breakage. RCF is related to centrifuge speed setting (rpm) using either of the following equations:

$$rpm = \sqrt{\frac{RCF \times 105}{1.12 \times r}} \quad \text{or approximately} \quad rpm = \frac{10,000}{\sqrt{r}}$$

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

CENTRIFUGATION SPEED AND TIME		
PRODUCT	RCF (g)	TIME (min)
SST® and PST Tubes	1000 - 1300	10
PLUS SST® and PST Tubes - 13mm	1100 - 1300	10
PLUS SST® and PST Tubes - 16mm	1000 - 1300	10
All gel Transport tubes	1100 - 1300	15
All non-gel tubes	51300	10
Chitate Tubes®		

RCF = Relative Centrifugal Force, g's

Ensure that tubes are properly seated in the centrifuge carrier. Incomplete seating could result in separation of the HEMOGARD™ Closure from the tube or extension of the tube above the carrier. Tubes extending above the carrier could catch on centrifuge head, resulting in breakage. Balance tubes to minimize the chance of glass breakage. Match tubes to tubes of the same fill level, glass tubes to glass, tubes with HEMOGARD™ Closure to others with the Closure, gel tubes to gel tubes, and VACUTAINER® PLUS Tubes with PLUS Tubes.

The following table relates radius of centrifuge arm to required speed. In order to obtain the appropriate g-force.

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

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

The flow properties of the barrier material are temperature-related. Flow may be impeded if chilled before or during centrifugation. To optimize flow and prevent heating during centrifugation, set refrigerated centrifuges to 25°C (77°F). Gel separation tubes should be centrifuged no later than 2 hours after collection. Tubes should not be re-centrifuged once barrier has formed. Barriers are more stable when tubes are spun in centrifuges with horizontal (swinging bucket) heads than those with fixed angle heads. Plasma and serum from non-gel tubes should be removed from the cell layer within 2 hours of sample collection. Note: Some push-down filters may not be compatible with plastic tubes due to the tapered inner diameter of the tube.

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

ANALYTIC EQUIVALENCY

Verifications of analytical equivalence have been performed for an array of analytes over a variety of test methods and time periods. The Becton Dickinson VACUTAINER Systems Technical Service Department is available to answer questions regarding these studies. Please contact them to obtain references and technical reports on these evaluations and any other information regarding the use of VACUTAINER Tubes with your instrument/reagent system.

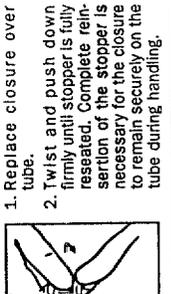
Technical Service may be reached at 800-631-0174. You may write to Becton Dickinson VACUTAINER Systems for information at:

- 1. Becton Drive, Franklin Lakes, NJ 07417-1895

When ever changing any manufacturer's blood separator tubes, please contact the Laboratory Director. The Laboratory Director should be notified of any change in the laboratory that may affect the data for your specific instrument. For Clinical Laboratory Standards (NCCLS): Evacuated Tubes and Additives for Blood Specimen Collection, Document H13-A, NCCLS, Villanova, PA, 19386. For Clinical Laboratory Standards (NCCLS): Procedures for the Collection of Diagnostic Blood Specimens from Patients, Document H13-B, NCCLS, Villanova, PA, 19386.

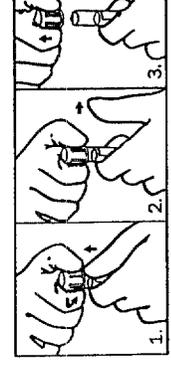
by the manufacturer. U.S. Government Patent, No. 4,741,446, 4,991,104, and foreign. Made in U.S.A. and England.
 Labels: Do not centrifuge glass tubes at forces above 2200 RCF in a horizontal head (swinging bucket) centrifuge as breakage may occur. Glass tubes may break if centrifuged above 3000 RCF in fixed angle centrifuge heads.
 VACUTAINER® PLUS Tubes will withstand up to 10,000 RCF in a balanced centrifuge. / appropriate carriers or inserts. Use of tubes with cracks or chips or excessive centrifugation may cause tube breakage, with release of sample, droplets, and an aerosol into the centrifuge. / Release of these potentially hazardous materials can be avoided by using specially designed sealed containers

INSTRUCTIONS FOR REMOVAL OF HEMOGARD™ CLOSURE



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

INSTRUCTIONS FOR REINSERTION OF HEMOGARD™ CLOSURE



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

VACUTAINER, ~~STOPPER~~ and HEMOGARD, are trademarks of Becton Dickinson and Company.
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 Becton Dickinson VACUTAINER Systems Europe
 38241 Mejian BP 37, France
 Becton Dickinson VACUTAINER Systems
 Franklin Lakes, NJ 07417-1885
 4003501 ()
 March 1998

BACK
 ALL COPY PRINT PMS BLACK "C"
 SIZE: 8.5" X 11"

Becton Dickinson VACUTAINER® Systems • Franklin Lakes, NJ 07417-1885		REFERENCE BLOCK		MICROFILM STAMP	
REV	ERCO #	DESCRIPTION	ART LAYOUT	DRAWN BY DATE	APPROVED BY DATE
00	R6-0950	TO RELEASE ARTWORK	R608-00	AYR 5/96	
01		REVISE COPY	R634-00	AYR 3/98	
			TRADE NAME VACUTAINER®	SCALE : FULL BOARD 1 OF 1	
			PACKAGING COMPONENT PRODUCT CIRCULAR	DRAWING NUMBER VDP40035-01	

Unit Label
VACUTAINER® Brand PLUS Tube with EDTA Anticoagulant

VACUTAINER®
PLUS*STERILE Interior
K₂ EDTA 10.5mg
Beckon Dickinson VACUTAINER Systems 1057200
Franklin Lakes, NJ 07417-1865
367863 7M933 MAY99
Refr./Best Air. Lot/Ch.-4: Exp./Hem. Use
6mL

60

Shelf Package Tray Label
VACUTAINER® Brand PLUS Tube with EDTA Anticoagulant

VACUTAINER PLUS 367863
Tubo con Tapón Lubricado

STERILE 13 x 100 mm

K ₂ EDTA 10.8 mg. STOPPER LUBRICATION: SILICONE.	APPROX. DRAW VOL. APPROX. VACIO APROX. VOL. APROX.	K ₂ EDTA 10.8 mg. TAPÓN LUBRICADO CON SILICON.
K ₂ EDTA 10.8 mg. BOUCHON: SILICONE.		K ₂ EDTA 10.8 mg. ROLHA: SILICONIZADA.

6 mL ←

EXP.:
LOT:


(01)30382903678632


4° - 25°C
1057000

61

Case Carton Label
VACUTAINER® Brand PLUS Tube with EDTA Anticoagulant

VACUTAINER® Brand PLUS 367863

STERILE 13 x 100 mm

K₂ EDTA 10.8 mg. STOPPER LUBRICATION: SILICONE.	APPROX. DRAW VOL. APPROX. VACIO APROX. VOL. APROX.	K₂ EDTA 10.8 mg. TAPÓN LUBRICADO CON SILICON.
K₂ EDTA 10.8 mg. BOUCHON: SILICONE.		K₂ EDTA 10.8 mg. ROLHA: SILICONIZADA.

6 mL ←


4° - 25°C
1057100

4 ✓

EPS (Preprinted) Tray Label
VACUTAINER® Brand PLUS Tube with EDTA Anticoagulant

VACUTAINER® 100 Tubes

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

VACUTAINER®
 QUALITY
 MAKES THE
 DIFFERENCE

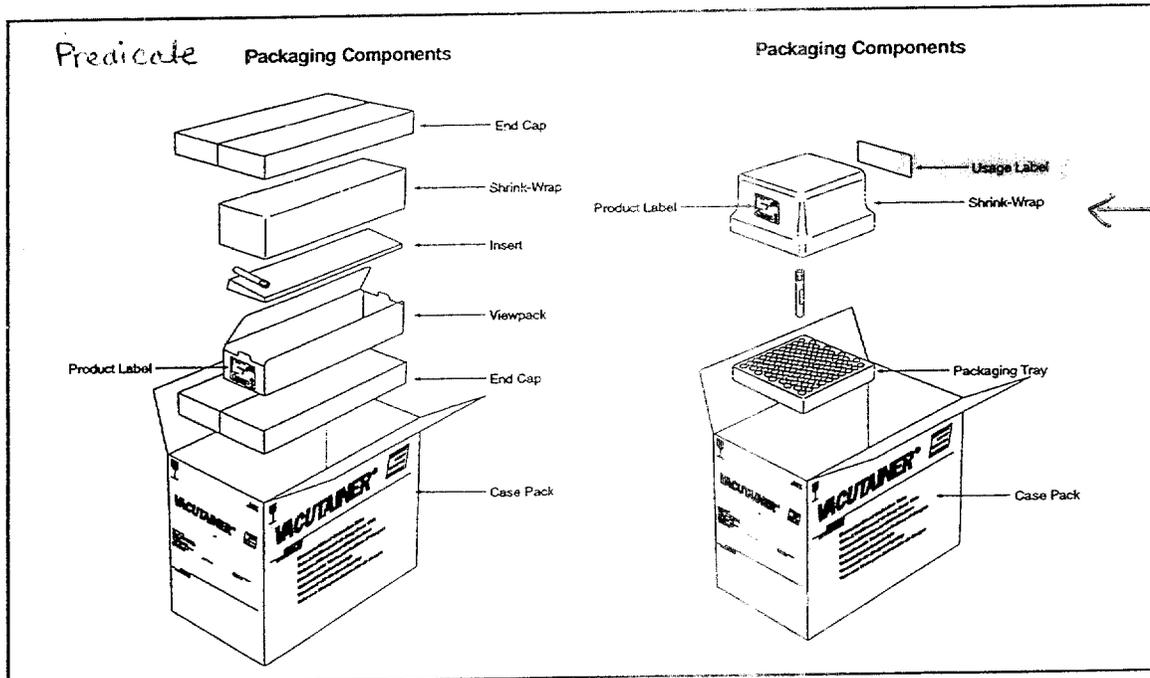
滅菌済みバキュテイナ®採血管

• FOR IN VITRO DIAGNOSTIC USE • Refer to package insert for instructions.
 • POUR DIAGNOSTIC IN VITRO • Pour les recommandations d'utilisation, se
 • PARA USO EN DIAGNOSTICO reporter à la notice intérieure.
 IN VITRO • Referir-se al instructivo.
 • PARA DIAGNÓSTICO IN VITRO • Vide instruções no folheto interno.

*体外診断用のみにご使用下さい。*使用方法は大箱内に在中の添付書参照の事。

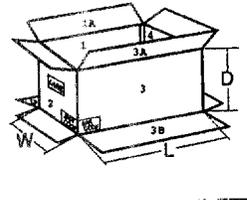
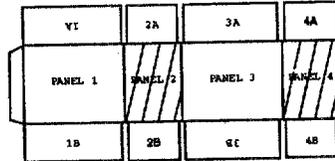
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 U.S. Patent Nos. 4,991,104, 4,741,446 and other corresponding foreign patents. Made in U.S.A.
1091101



63

Preprinted Case Carton
VACUTAINER® Brand PLUS Tube with EDTA Anticoagulant



<p>VACUTAINER® Tube à Prélèvement de Sang Sous Vide Tubo con Vacío para Extracción de Sangre Coleta de Sangue a Vácuo 減菌済みバキューイナ®採血管</p> <p style="text-align: right;">VACUTAINER® QUALITY MAKES THE DIFFERENCE</p>	PANEL 1A
<p>FOR IN VITRO DIAGNOSTIC USE POUR DIAGNOSTIC IN VITRO PARA USO EN DIAGNÓSTICO IN VITRO PARA DIAGNÓSTICO IN VITRO 体外診断用のみにご使用下さい。</p> <p>BECTON DICKINSON</p>	PANEL 3A
<p style="text-align: center;">↑ FUTURE PIN LABEL AREA ↓</p> <div style="display: flex; justify-content: space-between; align-items: center;"> <div style="text-align: center;"> <p>BOTTOM - OPEN OTHER END FOND - OUVRIR DE L'AUTRE CÔTÉ FONDO - ABRIR POR EL LADO CONTRARIO</p> </div> </div>	PANEL 1B
<p>3204</p> <div style="display: flex; justify-content: space-between; align-items: center;"> <div style="text-align: center;"> <p>ABRIR PELO OUTRO LADO 反対側を開けて下さい。</p> </div> <p>3005401 ()</p> </div> <p style="text-align: right;">↑ BOX CERT. AREA ↓</p>	PANEL 2B

64

Preprinted Case Carton
VACUTAINER® Brand PLUS Tube with EDTA Anticoagulant



VACUTAINER®
Brand Blood Collection Tubes

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



**BECTON
DICKINSON**

BAR CODE AREA

PANELS 1 & 3



1000
(10 x 100)

ROTATE STOCK
ASSURER
ROTATION STOCK
ROTE EL STOCK
ESTOQUE ROTATIVO
先入れ先出し

EXP:

LOT:

LOT & EXP.
IMPRINTING
AREA: 20mm (3/4")
(TOP OF IMPRINTING ZONE
IS 13mm (5/8")
FROM BOTTOM EDGE
OF CARTON.

PANEL 2



VACUTAINER®
Brand Blood Collection Tubes

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



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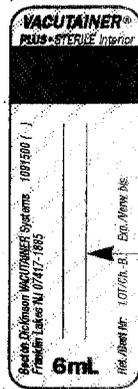
Becton Dickinson VACUTAINER Systems
Becton Dickinson and Company
Franklin Lakes, NJ 07417-1885

MADE IN U.S.A.

PANEL 4

65

Unit Tube Label
VACUTAINER® Brand PLUS Serum Tube



66

Shelf Package Tray Label
VACUTAINER® Brand PLUS Serum Tube

VACUTAINER PLUS **367815**
TUBES WITH ACTIVATOR

STERILE 13 x 100 mm	
CLOT ACTIVATOR.	ACTIVADOR DEL COAGULO.
TUBE INTERIOR COATING:	RECUBRIMIENTO INTERIOR:
SILICONE.	SILICON.
STOPPER LUBRICATION:	TAPÓN LUBRICADO
SILICONE.	CON SILICON.
ACTIVATEUR DE COAGULATION.	APPROX. DRAW VOL. APPROX.
TUBE: SILICONE.	VACIO APPROX. VOL. APROX.
BOUCHON: SILICONE.	6 mL
	ATIVADOR DE COÁGULO. TUBO: SILICONIZADO. ROLHA: SILICONIZADA.

EXP.:
LOT:


(01)30382903678151


4° - 25°C
L10031-00()

67

Case Carton Label
VACUTAINER® Brand PLUS Serum Tube

VACUTAINER® PLUS		367815
Tubo con HEMOLITICO - Citrato		
STERILE 13 x 100 mm		
CLOT ACTIVATOR.		ACTIVADOR DEL COAGULO.
TUBE INTERIOR COATING:		RECUBRIMIENTO INTERIOR:
SILICONE.		SILICON.
STOPPER LUBRICATION:	APPROX. DRAW	TAPÓN LUBRICADO
SILICONE.	VOL. APPROX.	CON SILICON.
ACTIVATEUR DE	VACIO APROX.	ATIVADOR DE COÁGULO.
COAGULATION.	VOL. APROX.	TUBO: SILICONIZADO.
TUBE: SILICONE.	6 mL ←	ROLHA: SILICONZADA.
BOUCHON: SILICONE.		
 4° - 25°C L10032-00()		

65

EPS (Preprinted) Tray Label
VACUTAINER® Brand PLUS Serum Tube

100 Tubes

VACUTAINER®

Brand Blood Collection Tubes

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

VACUTAINER®
 QUALITY
 MAKES THE
 DIFFERENCE

<ul style="list-style-type: none"> • FOR IN VITRO DIAGNOSTIC USE • POUR DIAGNOSTIC IN VITRO • PARA USO EN DIAGNOSTICO IN VITRO • PARA DIAGNÓSTICO IN VITRO 	<ul style="list-style-type: none"> • Refer to package insert for instructions. • Pour les recommandations d'utilisation, se reporter à la notice intérieure. • Referirse al instructivo. • Vide instruções no folheto interno.
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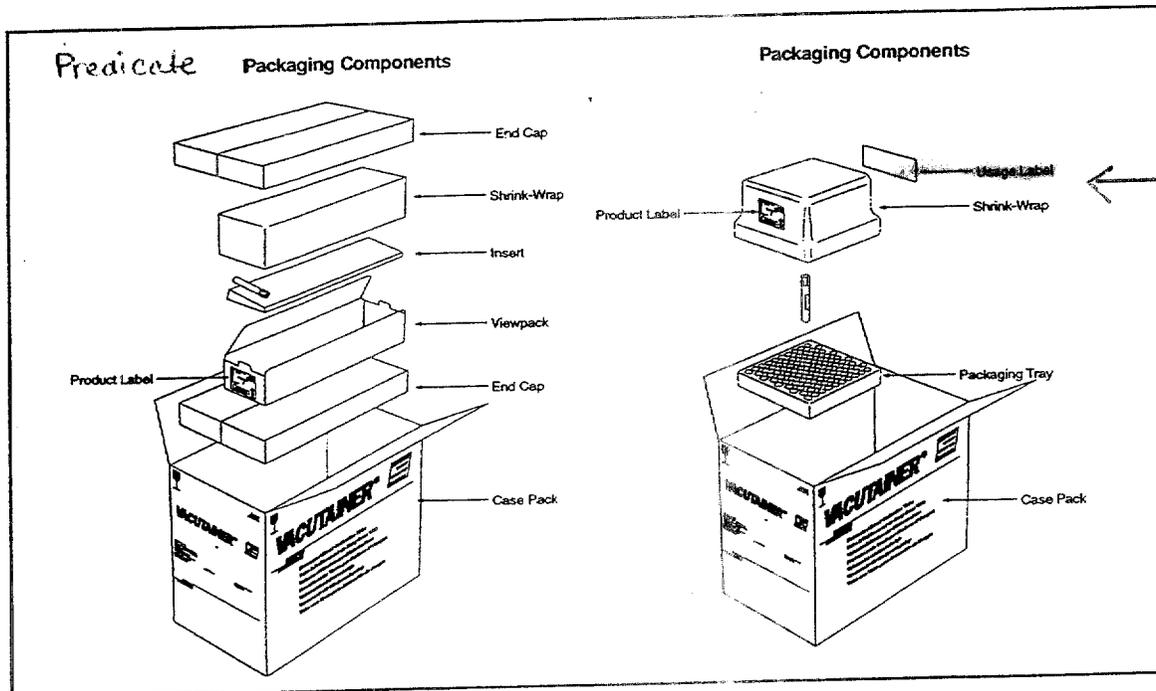
• 体外診断用のみにご使用下さい。• 使用法は大箱内に在中の説明書参照の事。

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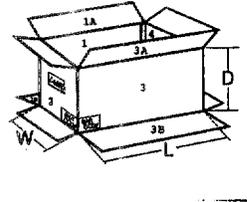
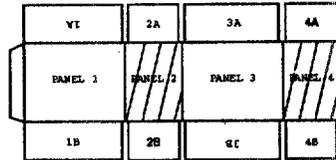
BECTON DICKINSON

Becton Dickinson VACUTAINER Systems
 Becton Dickinson and Company, Franklin Lakes, NJ 07417-1885
 U.S. Patent Nos. 4,991,104, 4,741,446 and other corresponding foreign patents. Made in U.S.A.
 1091101



65

Preprinted Case Carton
VACUTAINER® Brand PLUS Serum Tube



<p>VACUTAINER® Brand Blood Collection Tubes</p>	<p><i>Tube à Prélèvement de Sang Sous Vide</i> <i>Tubo con Vacío para Extracción de Sangre</i> <i>Coleta de Sangue a Vácuo</i> 減菌済みバキュテイナ®採血管</p>	<p>VACUTAINER® QUALITY MAKES THE DIFFERENCE</p>		PANEL 1A
<p>BECTON DICKINSON</p>				PANEL 3A
<p style="text-align: center;">↓ FUTURE PIN LABEL AREA ↓</p>				
	<p><i>TOP - OPEN OTHER END</i> <i>FOND - OUVRIRE DE L'AUTRE CÔTÉ</i> <i>FONDO - ABRIR POR EL LADO CONTRARIO</i></p>			PANEL 1B
3204	<p>Corrugated Recycles</p>	<p><i>ABRIR PELO OUTRO LADO</i> 反対側を開けて下さい。</p>		PANEL 3B
<p style="text-align: center;">↓ BOX CERT. AREA ↓</p>				
			3005401 ()	

70

Preprinted Case Carton
VACUTAINER® Brand PLUS Serum Tube



VACUTAINER®
Brand Blood Collection Tubes

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

VACUTAINER®
QUALITY
MAKES THE
DIFFERENCE

BECTON
DICKINSON

BAR CODE AREA

PANELS 1 & 3



1000
(10 x 100)

ROTATE STOCK
ASSURER
ROTATION STOCK
ROTE EL STOCK
ESTOQUE ROTATIVO
先入れ先出し

EXP.:

LOT:

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

PANEL 2



VACUTAINER®
Brand Blood Collection Tubes

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

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QUALITY
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DIFFERENCE

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

PANEL 4

ATTACHMENT E
EQUIVALENCY INFORMATION



E.1 Principal/Predicate Device Comparison

The current commercially available VACUTAINER® Brand PLUS Tube with EDTA Anticoagulant was described in 510(k) Premarket Notification K971449 which received FDA clearance on June 17, 1997. The current VACUTAINER® Brand PLUS Serum Tube was described in premarket notification K960250 and received FDA clearance on March 29, 1996.

This premarket notification describes additional Indications for Use for the VACUTAINER® Brand PLUS Tube with EDTA and the VACUTAINER® Brand PLUS Serum Tube. The VACUTAINER® Brand PLUS Tube with EDTA and the VACUTAINER® Brand PLUS Serum Tube Indications for Use now include immunohematology testing including ABO grouping, Rh typing and antibody screening which require red blood cells and plasma or serum.

Since 1970, glass EDTA and serum tubes have been the recognized blood collection tubes used by blood bank specialists for blood grouping, typing and antibody screening. Under current routine blood bank procedures the blood sample is collected in the VACUTAINER® Brand (glass) Tube with EDTA anticoagulant and VACUTAINER® Brand (glass) Serum Tube. The VACUTAINER® Brand Glass Tube with EDTA anticoagulant and VACUTAINER® Brand Glass Serum Tube are preamendment devices exempt from premarket notification regulations according to the Medical Device Amendments (MDA) of 1976. Further, the industry has utilized these tubes for immunohematology techniques prior to the MDA of 1976. The HEMOGARD® Closure Assembly was described in premarket notification K945952 that received FDA clearance on January 18, 1995.

VACUTAINER Systems believes that the VACUTAINER® Brand PLUS (Plastic) Tube with EDTA and the VACUTAINER® Brand PLUS Serum Tube with the additional Indications for Use are substantially equivalent to the VACUTAINER® Brand (glass) Tube with EDTA anticoagulant and VACUTAINER® Brand (glass) Serum Tube. Furthermore, this decision of substantial equivalence is supported by a clinical evaluation of the device performance for these additional Indications for Use. The results of the clinical evaluation support the use of these tubes for immunohematology (ABO, Rh and antibody screening), Attachment K.

Summarizing the minor differences between the principal and predicate device, the principal devices are manufactured from plastic and the predicate devices are manufactured from glass. Further, the VACUTAINER® PLUS Tubes with EDTA contain spray-dried K_2EDTA whereas the predicate device, VACUTAINER® Brand EDTA contains liquid K_3EDTA .

These are minor differences that do not significantly affect tube clinical performance or function, as demonstrated in the Attachment K Clinical Evaluation. Table 1 compares device characteristics of the principal device, VACUTAINER® Brand PLUS tube with EDTA, and the predicate device, VACUTAINER® Brand tube with EDTA. The manufacturing processes (Table 2) are compared on the following page.

Table 3 compare device characteristics of the principal device, VACUTAINER® Brand PLUS Serum tube, and the predicate device, VACUTAINER® Brand Serum tube. The manufacturing processes (Table 2) are compared on the following page.

TABLE 1: DEVICE CHARACTERISTICS

	Principle Device	Predicate Device
Product Type	VACUTAINER® Brand PLUS Tube with EDTA Anticoagulant	VACUTAINER® Brand Tube with EDTA Anticoagulant
Intended Use	Blood Collection for immunohematology	Blood Collection for immunohematology
Additive Type	K ₂ EDTA	K ₃ EDTA
Tube Coating	None	None
Additive Quantity (nominal)	1.8 mg/mL	0.081 mL 15% solution or 1.75 mg/mL
Draw Volume	6 mL	7 mL
Tube Material	Plastic	Glass
Tube Closure	Rubber Stopper or HEMOGARD™ Safety Closure Assembly	Rubber Stopper or HEMOGARD™ Safety Closure Assembly
Product Claim of Reduced Tube Breakage	Yes	No
Product Claim of Improved Method of Disposal (Incineration)	Yes	No

TABLE 2: COMPARISON OF MANUFACTURING PROCESS

	Principal Device	Predicate Device
Product Type	VACUTAINER® Brand PLUS Tube with EDTA Anticoagulant	VACUTAINER® Brand Tube with EDTA Anticoagulant
Tube Fabrication	Injection Molded	Glass
Stopper Fabrication	Compression Molded Rubber	Compression Molded Rubber
HEMOGARD™ Shield Fabrication	Injection Molded Plastic	Injection Molded Plastic
Additive Dispense	Spray Dry	Liquid
Tube Evacuation	Vacuum Chamber	Vacuum Chamber
Unit Labeling	Printed Paper Label or Imprinted on Tube	Printed Paper Label or Imprinted on Tube
Sterilization Method	Gamma Irradiation	Gamma Irradiation

28

TABLE 3: DEVICE CHARACTERISTICS

	Principle Device	Predicate Device
Product Type	VACUTAINER® Brand PLUS Serum Tube with Silica Clot Activator	VACUTAINER® Brand Serum Tube
Intended Use	Blood Collection for immunohematology	Blood Collection for immunohematology
Additive Type	Silica Clot activator	None
Tube Coating	Silicone	Silicone
Additive Quantity (nominal)	mg/mL	mg/mL
Draw Volume	6 mL	7 mL
Tube Material	Plastic	Glass
Tube Closure	Rubber Stopper or HEMOGARD™ Safety Assembly	Rubber Stopper or HEMOGARD™ Safety Closure Assembly
Product Claim of Reduced Tube Breakage	Yes	No
Product Claim of Improved Method of Disposal (Incineration)	Yes	No

3

TABLE 4: COMPARISON OF MANUFACTURING PROCESS

	Principal Device	Predicate Device
Product Type	VACUTAINER® Brand PLUS Serum Tube	VACUTAINER® Brand Serum Tube
Tube Fabrication	Injection Molded	Glass
Stopper Fabrication	Compression Molded Rubber	Compression Molded Rubber
HEMOGARD™ Shield Fabrication	Injection Molded Plastic	Injection Molded Plastic
Additive Dispense	Spray Dry	N/A
Tube Evacuation	Vacuum Chamber	Vacuum Chamber
Unit Labeling	Printed Paper Label or Imprinted on Tube	Printed Paper Label or Imprinted on Tube
Sterilization Method	Gamma Irradiation	Gamma Irradiation

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ATTACHMENT F
PREDICATE DEVICE INFORMATION

F. Predicate Device Information

As described in the General Summary of this premarket notification, VACUTAINER Systems intends to market the VACUTAINER® Brand PLUS Tube with EDTA (plastic) and VACUTAINER Brand PLUS Serum Tube (plastic) for additional indications for use. The VACUTAINER® Brand PLUS Tube with EDTA was originally described in premarket notification K901449 that received FDA clearance on August 9, 1990. The Indications for Use now includes immunohematology.

The predicate devices upon which substantial equivalence is based are the VACUTAINER® Brand Tube (glass) with EDTA anticoagulant and the VACUTAINER® Brand Serum Tube (glass). These tubes are preamendment devices and therefore, exempt from premarket notification according to the MDA of 1976. Further, the industry utilized the tubes for immunohematology techniques prior to the MDA of 1976. The HEMOGARD® Closure Assembly was described in premarket notification K945952 that received FDA clearance on January 18, 1995.

The VACUTAINER® Brand Tube with EDTA anticoagulant and VACUTAINER Brand Serum Tube are intended to be marketed a sterile in-vitro diagnostic device. The tubes are packaged one hundred (100) labeled tubes per shelf pack and a labeled case carton consists of (1000) tubes. The VACUTAINER® Brand Tube with EDTA anticoagulant and VACUTAINER Brand Serum Tube device labeling are included in this Attachment consists of the labeling items identified below:

- Predicate Device Product Insert
- Predicate Device Unit Label
- Predicate Device Shelf Pack Label and Preprinted Shelf Carton
- Predicate Device Case Carton Label and Preprinted Case Carton

VACUTAINER® Brand Evacuated Blood Collection System

For In Vitro Diagnostic Use.

INTENDED USE

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

PRODUCT DESCRIPTION

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

VACUTAINER® TUBE STOPPER/CLOSURE COLOR CODE CROSS REFERENCE

ADDITIVE GROUP/ADDITIVE	RUBBER STOPPER	HEMOGARD™ CLOSURE
Gelation Tubes SST® Tubes with Gel and Clot Activator SST® Tubes with Gel and Heparin†	Red/Grey Green/Grey	Gold Light Green
Non-additive Tubes Silicone coated Uncoated	Red	Red (Glass Tubes only) Pink
Serum Tubes with additives Thrombin* Particulate Clot Activator Thrombin*, Soybean Trypsin Inhibitor	Yellow/Grey Yellow/Red Light Blue	Orange Red (PLUS Tubes) Light Blue
Whole Blood/Plasma Tubes EDTA Citrate (Coagulation) Citrate (ESR) Sodium fluoride/EDTA/Potassium oxalate Lithium iodacetate/Heparin† (Glucose) Heparin† Heparin†, Glass Beads for L.E. Testing Acid Citrate Dextrose (ACD) Sodium polyanetholsulfonate (SPS)	Lavender Light Blue Black Grey Grey Green Green Yellow Yellow	Lavender Light Blue Black Grey Grey Green Green Yellow Yellow
Trace Element Tubes Silicone coated, or EDTA, or Heparin†	Royal Blue	Royal Blue
Lead Tubes Heparin†	Tan	Tan

†Heparin source is porcine. *Thrombin source is bovine.

VACUTAINER® Serum Tubes

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

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

VACUTAINER® Tubes for Lead and Trace Element Tests

ubes for lead testing and other trace elements are labelled specifically for these purposes on the shelf package and case label. Use only appropriately labelled tubes for these tests. VACUTAINER® Tubes with HEMOGARD™ Closure for lead testing are labelled to contain a maximum of 0.05 µg lead per tube. Tubes for trace elements have been tested by water or acid extraction of the stoppered tube for 4 hours. Atomic absorption spectroscopy testing yielded results below these concentration limits:

TRACE ELEMENT CONTAMINATION UPPER LIMITS

ANALYTE	µg/L	ANALYTE	µg/L
Antimony	0.8	Iron	60.0
Arsenic	1.0	Lead	2.5
Cadmium	0.6	Magnesium	60.0*
Calcium	400.0*	Manganese	1.5
Chromium	0.9	Zinc	40.0*
Copper	8.0		

*Flame technique, all others flameless

VACUTAINER® Brand Tubes and Transport Tubes

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

VACUTAINER® PST Tubes

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

VACUTAINER® Blood Collection Needles

VACUTAINER® Blood Collection Needles are single-use, double-ended, stainless steel needles. They feature a threaded hub that fits into the threads of all VACUTAINER® Needle Holders. The venipuncture point of the needle has a point specially designed to enter the skin easily during venipuncture. The needle is lubricated with silicone.

Multiple Sample Needles have a rubber sleeve covering the non-patient end of the needle that prevents leakage of blood into the holder during venipuncture.

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

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

LIMITATIONS OF SYSTEM

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

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

Contact the BDVS Technical Service Department at 1-800-631-0174 before collecting samples in PLUS SST® and PLUS Serum tubes for vitamin B₁₂, folate, and estradiol determinations on the Ciba Corning Diagnostics ACS:180 analyzer.

VACUTAINER® SST® Tubes and PST Tubes are not recommended for collection of samples for the therapeutic drug monitoring (TDM) assays and blood banking procedures. Do not use PST Tubes for lithium measurement.

PRECAUTIONS

- Storage of glass tubes containing blood at or below 0°C may result in tube breakage.
- Do not remove conventional rubber stoppers by rolling with thumb. Remove stoppers with a twist and pull motion.
- Do not use tubes or needles if foreign matter is present.
- Lot number and needle size are printed on the paper label covering the connection of the needle shields. Do not use needle if label has been torn before venipuncture. This label will tear when the needle is opened.

CAUTION:

- Practice Universal Precautions. Use gloves, gowns, eye protection, other personal protective equipment, and engineering controls to protect from blood splatter, blood leakage, and potential exposure to bloodborne pathogens.
- All glass has the potential for breakage. Examine all glass for potential damage in transit before use, and take precautionary measures during handling.
- Handle all biologic samples and blood collection "sharps" (lancets, needles, luer adapters, and blood collection sets) according to the policies and procedures of your facility. Obtain appropriate medical attention in the event of any exposure to biologic samples (for example, through a puncture injury) since they may transmit viral hepatitis, HIV (AIDS), or other infectious diseases. Utilize any built-in used needle protector, if the blood collection device provides one. Becton Dickinson does not recommend resheathing used needles. However, the policies and procedures of your facility may differ and must always be followed.
- Discard all blood collection "sharps" in biohazard containers approved for their disposal.
- Transferring a sample from a syringe to a tube is not recommended. Additional manipulation of sharps increases the potential for needlestick injury. In addition, depressing the syringe plunger during transfer can create a positive pressure, forcefully displacing the stopper and sample and causing a potential blood exposure. Using a syringe for blood transfer may also cause over or under-filling of tubes, resulting in an incorrect blood-to-additive ratio and potentially incorrect analytic results. Tubes, with draw volume smaller than apparent dimensions indicate, may not fill to their stated volume when filled from a syringe. The laboratory should be consulted regarding the use of these samples.
- If blood is collected through an intravenous (I.V.) line, ensure that line has been cleared of I.V. solution before beginning to fill blood collection tubes. This is critical to avoid erroneous laboratory data from I.V. fluid contamination.
- Underfilling of tubes will result in an incorrect blood-to-additive ratio and may lead to incorrect analytic results or poor product performance.

STORAGE

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

SPECIMEN COLLECTION and HANDLING

READ THIS ENTIRE CIRCULAR BEFORE PERFORMING VENIPUNCTURE.

Required equipment not provided for specimen collection

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

Required equipment not provided for specimen processing

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

Preparation for Specimen Collection

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

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

Recommended Order of Draw

- Tubes for sterile samples.
 - Tubes without additives.
 - Tubes for coagulation studies (e.g., citrate)
 - Tubes with other additives (e.g., heparin, EDTA).
- SST® Tubes, VACUTAINER® Clot Activator Tubes, and VACUTAINER® PLUS Tubes are considered additive tubes.

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**Predicate Device Product Insert
VACUTAINER® Brand Tube with EDTA Anticoagulant
and
VACUTAINER® Brand Serum Tube**



Prevention of Backflow

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

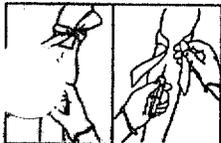
1. Place patient's arm in a downward position.
2. Hold tube with the stopper uppermost.
3. Release tourniquet as soon as blood starts to flow into tube.
4. Make sure tube additives do not touch stopper or end of the needle during venipuncture.

Venipuncture Technique and Specimen Collection

General Instructions

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

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



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

Note: Blood may occasionally leak from the needle sleeve. Practice Universal Precautions to minimize exposure hazard.

If no blood flows into tube or if blood ceases to flow before an adequate specimen is collected, the following steps are suggested to complete satisfactory collection:

- a. Push tube forward until tube stopper has been penetrated. If necessary, hold in place to ensure complete vacuum draw.
 - b. Confirm correct position of needle cannula in vein.
 - c. If the multiple sample needle is used, remove tube and place new tube onto the holder.
 - d. If second tube does not draw, remove needle and discard. Repeat procedure from Step 1.
11. When first tube has filled to its stated volume and blood flow ceases, remove it from holder.
 12. Place succeeding tubes in holder, puncturing diaphragm to begin flow. Draw tubes without additives before tubes with additives. See Recommended Order of Draw.
 13. While each successive tube is filling, turn the filled tube upside-down and return it to upright position. This is one complete inversion.
- For proper additive performance, invert SST® Tubes, Clot Activator Tubes, and PLUS Serum Tubes 5 times. Invert all other filled additive tubes 9-10 times. Do not shake. Vigorous mixing may cause foaming or hemolysis. Insufficient mixing or delayed mixing in serum tubes may result in delayed clotting and incorrect test results. In tubes with anticoagulants, inadequate mixing may result in platelet clumping, clotting and/or incorrect test results.
14. As soon as blood stops flowing in the last tube, remove needle from vein, applying pressure to puncture site with dry sterile swab until bleeding stops.
 15. Once clotting has occurred, apply bandage if desired.
 16. After venipuncture, the top of the stopper may contain residual blood. Take proper precautions when handling tubes to avoid contact with this blood. Any needle holder that becomes contaminated with blood is considered hazardous and should be decontaminated with bleach or disposed of.
 17. Dispose of the used needle using an appropriate disposal device. DO NOT RESHIELD. Reshielding of needles increases the risk of needlestick injury and blood exposure.

Clotting Instructions

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

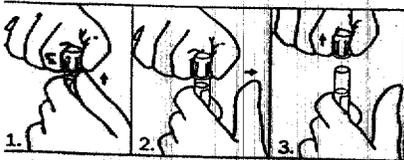
MINIMUM CLOTTING TIME RECOMMENDATIONS	
PRODUCT	CLOTTING TIME
SST® Tubes (Red Stoppers, Red Closures)	60 minutes
PLUS Tubes, CAT Tubes	30 minutes
Clot Activator Tubes	5 minutes

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

Centrifugation

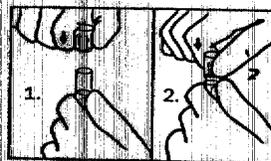
Do not centrifuge glass tubes at forces above 2200 RCF in a horizontal head (swinging bucket) centrifuge as breakage may occur. Glass tubes may break if centrifuged above 1300 RCF in a fixed angle centrifuge heads.

INSTRUCTIONS FOR REMOVAL OF HEMOGARD™ CLOSURE



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

INSTRUCTIONS FOR REINSERTION OF HEMOGARD™ CLOSURE



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

VACUTAINER® PLUS Tubes will withstand up to 10,000 RCF in a balanced centrifuge. Always use appropriate carriers or inserts. Use of tubes with cracks or chips or excessive centrifugation speed may cause tube breakage, with release of sample, droplets, and an aerosol into the centrifuge bowl. Release of these potentially hazardous materials can be avoided by using specially designed sealed containers in which tubes are held during centrifugation. Centrifuge carriers and inserts should be of the size specific to the tubes used. Use of carriers too large or too small for the tube may result in breakage.

Ensure that tubes are properly seated in the centrifuge carrier. Incomplete seating could result in separation of the HEMOGARD™ Closure from the tube or extension of the tube above the carrier. Tubes extending above the carrier could catch on centrifuge head, resulting in breakage. Balance tubes to minimize the chance of glass breakage. Match tubes to tubes of the same fill level, glass tubes to glass, tubes with HEMOGARD™ Closure to others with the Closure, gel tubes to gel tubes, and VACUTAINER® PLUS Tubes with PLUS Tubes.

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

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

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

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

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

RCF = Relative Centrifugal Force, g's

The following table relates radius of centrifuge arm to required speed, in order to obtain the appropriate g-force.

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

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

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

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

ANALYTIC EQUIVALENCY

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

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

It is the laboratory's ultimate responsibility to determine reference intervals for all analytes based upon the tubes used for sample collection by that laboratory. The clinical laboratory should establish/verify its reference ranges if changing specimen collection tube types and sizes, as this could potentially affect analytic results from patient samples.

VACUTAINER, SST, and HEMOGARD, are trademarks of Becton Dickinson and Company.

**BECTON
DICKINSON**

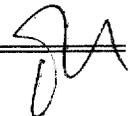
Becton Dickinson VACUTAINER Systems Europe
38241 Meylan BP 37, France

Becton Dickinson VACUTAINER Systems
Becton Dickinson and Company
Franklin Lakes, NJ 07417-1885

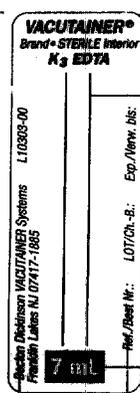
U.S. Patent Nos. 4,741,446, 4,991,104, and foreign. Made in U.S.A. and England.

4003500 ()
May 1996

**Predicate Device Product Insert
VACUTAINER® Brand Tube with EDTA Anticoagulant
and
VACUTAINER® Brand Serum Tube**



Predicate Device Unit Label
VACUTAINER® Brand Tube with EDTA Anticoagulant



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Predicate Device Shelf Carton Label
VACUTAINER® Brand Tube with EDTA Anticoagulant

VACUTAINER® Brand Tubes with HEMOGARD® Closure	REORDER NUMBER 367665
STERILE 13 x 100 mm	
K ₃ EDTA (15%). 0.081 mL, 0.34 M. TUBE: NO INTERIOR COATING. STOPPER LUBRICATION: SILICONE.	APPROX. DRAW VOL. APPROX. VACIO APROX. VOL. APROX.
K ₃ EDTA (15%). 0.081 mL, 0.34 M. TUBE: NON SILICONE. BOUCHON: SILICONE.	7 mL
EXP. LOT:	K ₃ EDTA (15%). 0.081 mL, 0.34 M. TUBO: SIN RECUBRIMIENTO INTERIOR TAPÓN LUBRICADO CON SILICON. K ₃ EDTA (15%). 0.081 mL, 0.34 M. TUBO: NÃO SILICONIZADO. ROLHA: SILICONIZADA.
	
(01)30362903676652	1008901



Preprinted Device Case Carton Label
VACUTAINER® Brand Tube with EDTA Anticoagulant

VACUTAINER® Brand
Tubes with HEMOGARD® Closure

STERILE 13 x 100 mm

K₃ EDTA (15%).
0.081 mL., 0.34 M.
TUBE: NO INTERIOR
COATING.
STOPPER LUBRICATION:
SILICONE.

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

7 mL

REORDER NUMBER
367665

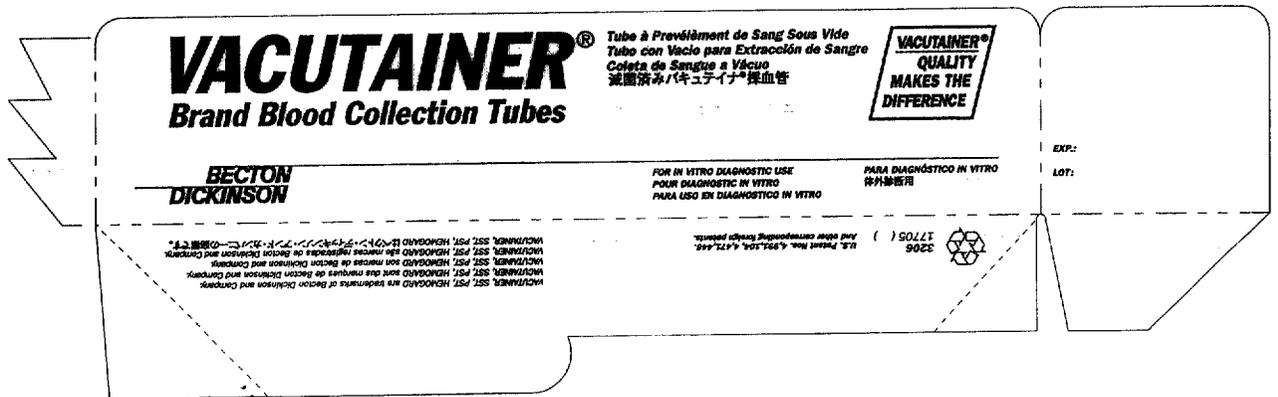
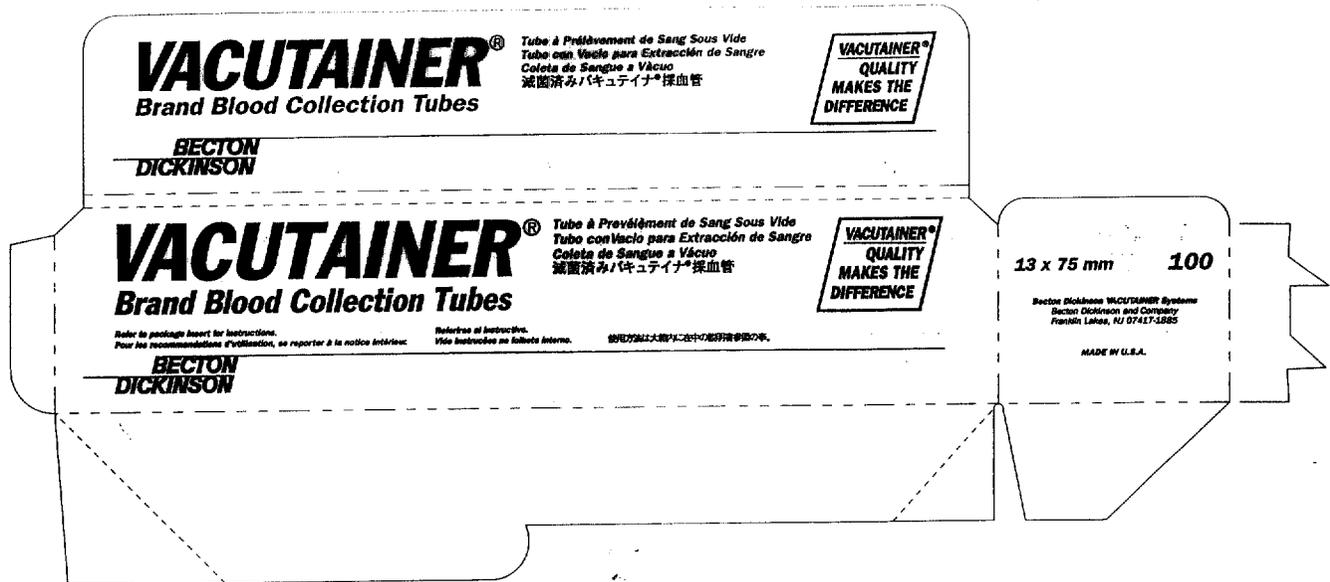
K₃ EDTA (15%).
0.081 mL., 0.34 M.
TUBO: SIN
RECUBRIMIENTO INTERIOR
TAPÓN LUBRICADO CON
SILICON.

K₃ EDTA (15%).
0.081 mL., 0.34 M.
TUBO: NÃO SILICONIZADO.
ROLHA: SILICONIZADA.

1009001

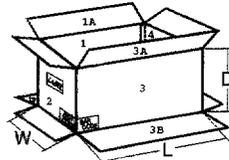
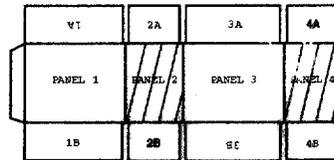
51

Predicate Device Shelf Carton
VACUTAINER® Brand Tube with EDTA Anticoagulant



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Predicate Device Preprinted Case Carton
VACUTAINER® Brand Tube with EDTA Anticoagulant



<p>VACUTAINER® <i>Brand Blood Collection Tubes</i></p>	<p><i>Tube à Prélèvement de Sang Sous Vide</i> <i>Tubo con Vácuo para Extracción de Sangre</i> <i>Coleta de Sangue a Vácuo</i> <i>減菌済みバキュテイン®採血管</i></p>	<p>VACUTAINER® QUALITY MAKES THE DIFFERENCE</p>		<p>PANEL 1A</p>	
<p>BECTON DICKINSON</p>				<p>FOR IN VITRO DIAGNOSTIC USE POUR DIAGNOSTIC IN VITRO PARA USO EN DIAGNOSTICO IN VITRO PARA DIAGNOSTICO IN VITRO 体外診断用のみにご使用下さい。</p>	<p>PANEL 3A</p>
<p>↑ FUTURE PIN LABEL AREA ↓</p>			<p>BOTTOM - OPEN OTHER END FOND - OUVRIER DE L'AUTRE COTE FONDO - ABRIR POR EL LADO CONTRARIO</p>	<p>PANEL 1B</p>	
<p>3204</p>		<p>ABRIR PELO OUTRO LADO 反対側を開けて下さい。</p>	<p>3005401 ()</p>	<p>PANEL 3B</p>	
<p>↑ BOX CERT. AREA ↓</p>					

109

Predicate Device Preprinted Case Carton
VACUTAINER® Brand Tube with EDTA Anticoagulant



VACUTAINER®
Brand Blood Collection Tubes

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



**BECTON
DICKINSON**

BAR CODE AREA

PANELS 1 & 3

1000
(10 x 100)



ROTATE STOCK
ASSURER
ROTATION STOCK
ROTE EL STOCK
ESTOQUE ROTATIVO
先入れ先出し

EXP:
LOT:

PANEL 2

LOT & EXP.
IMPRINTING
AREA: 20mm (3/4")
(TOP OF IMPRINTING ZONE
IS 13mm (5/8")
FROM BOTTOM EDGE
OF CARTON.



VACUTAINER®
Brand Blood Collection Tubes
Tube à Prélèvement de Sang Sous Vide
Tubo con Vacío para Extracción de Sangre
Coleta de Sangue a Vácuo
滅菌済みバキュテイナ®採血管



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

PANEL 4

90

Predicate Device Tube Label
VACUTAINER® Brand Serum Tube

VACUTAINER®
Brand • STERILE Interior
No Additive

7 ml

21

Predicate Device Shelf Carton Label
VACUTAINER® Brand Serum Tube

VACUTAINER® Brand
Tubes with HEMOGARD™ Closure

REORDER NUMBER
369615

STERILE 13 x 100 mm

FORMERLY 367615

NO ADDITIVE.
TUBE INTERIOR COATING:
SILICONE.
STOPPER LUBRICATION:
SILICONE.

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

TAPÓN LUBRICADO CON SILICÓN.
SEM ADITIVO.
TUBO: SEC0 (SIN ADITIVO).
RECUBRIMIENTO INTERIOR: SILICÓN.
TUBO: SILICONIZADO.
ROLHA: SILICONIZADA.

SEC (SANS ADITIF).
TUBE: SILICONE.
BOUCHON: SILICONE.

7 mL

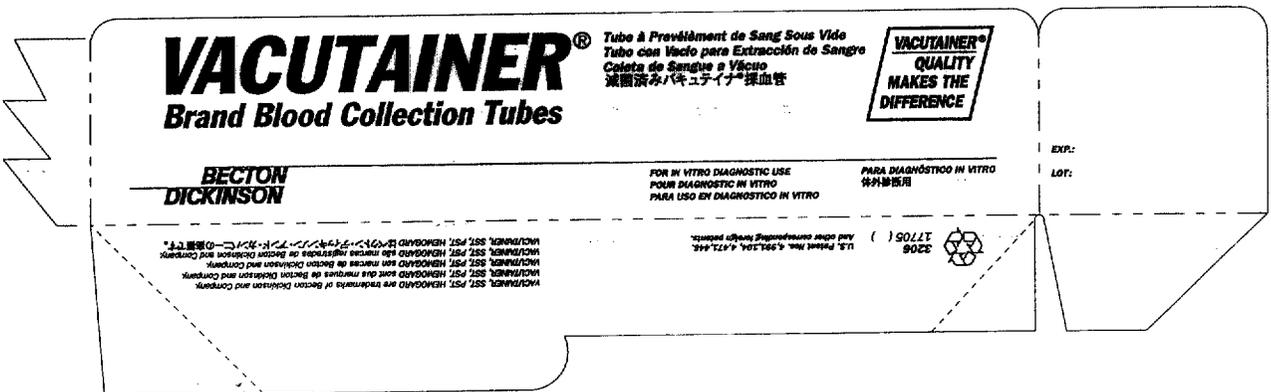
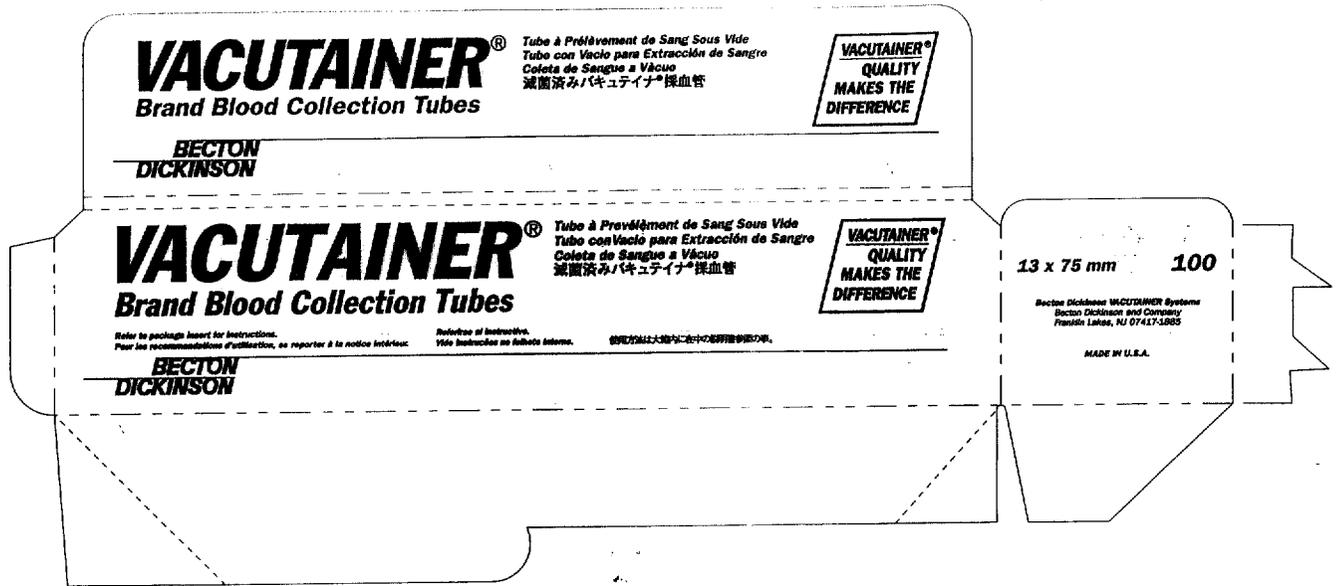
EXP.:
LOT:



(01)30382903696155 1000901()

92

Predicate Device Preprinted Shelf Carton
VACUTAINER® Brand Serum Tube



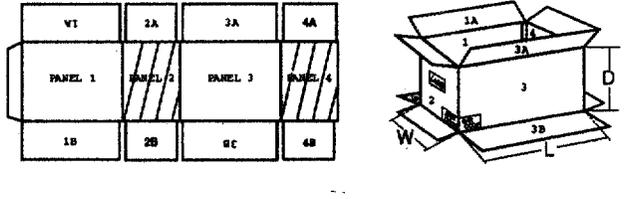
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Predicate Device Preprinted Shelf Carton Label
VACUTAINER® Brand Serum Tube

VACUTAINER® Brand Tubes with HEMOGARD™ Closure		REORDER NUMBER 369615
STERILE 13 x 100 mm		FORMERLY 367615
NO ADDITIVE.		TUBO: SECO (SIN ADITIVO).
TUBE INTERIOR COATING:		RECUBRIMIENTO INTERIOR:
SILICONE.		SILICON.
STOPPER LUBRICATION:	APPROX. DRAW	TAPÓN LUBRICADO
SILICONE.	VOL. APPROX.	CON SILICON.
	VACIO APPROX.	
	VOL. APROX.	SEM ADITIVO.
SEC (SANS ADITIF).		TUBO: SILICONIZADO.
TUBE: SILICONE.	7 mL	ROLHA: SILICONIZADA.
BOUCHON: SILICONE.		
1001001()		

gm

Predicate Device Preprinted Case Carton
VACUTAINER® Brand Serum Tube



<p>VACUTAINER® Brand Blood Collection Tubes</p>	<p><i>Tube à Prélèvement de Sang Sous Vide</i> <i>Tubo con Vacío para Extracción de Sangre</i> <i>Coleta de Sangue a Vácuo</i> 減菌済みバキューイナ®採血管</p>	<p>VACUTAINER® QUALITY MAKES THE DIFFERENCE</p>		PANEL 1A
<p>FOR IN VITRO DIAGNOSTIC USE POUR DIAGNOSTIC IN VITRO PARA USO EN DIAGNOSTICO IN VITRO PARA DIAGNOSTICO IN VITRO 体外診断用のみにご使用下さい。</p>				PANEL 2A
<p>BECTON DICKINSON</p>				
<p>↑ FUTURE PIN LABEL AREA ↓</p>				
				
<p>BOTTOM - OPEN OTHER END FOND - OUVRIRE DE L'AUTRE COTE FONDO - ABRIR POR EL LADO CONTRARIO</p>				PANEL 1B
3204	 <p>Corrugated Recycles</p>	<p>ABRIR PELO OUTRO LADO 反対側を開けて下さい。</p>	3005401 ()	PANEL 3A
<p>↑ BOX CENT. AREA ↓</p>				

g

Predicate Device Preprinted Case Carton
VACUTAINER® Brand Serum Tube



VACUTAINER®
Brand Blood Collection Tubes

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

VACUTAINER®
QUALITY
MAKES THE
DIFFERENCE

BECTON
DICKINSON

BAR CODE AREA

PANELS 1 & 3



1000
(10 x 100)

ROTATE STOCK
ASSEMBLER
ROTATION STOCK
ROTE EL STOCK
ENTORQUE ROTATIVO
先入れ先出し

EXP:

LOT:

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



VACUTAINER®
Brand Blood Collection Tubes

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

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Becton Dickinson and Company
Franklin Lakes, NJ 07417-1885
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PANEL 2

510(K) Premarket Notification
VACUTAINER® Brand PLUS Tube with EDTA
VACUTAINER® Brand PLUS Serum Tube

March 13, 1998

PANEL 4

Page 53

92

ATTACHMENT G
PERFORMANCE VALIDATION

97

G. Performance Validation

The VACUTAINER® Brand PLUS Tube with EDTA and the VACUTAINER PLUS Serum Tube are evacuated plastic blood collection tubes for collecting, transporting and processing blood in a closed plastic tube. The VACUTAINER® Brand PLUS Tube with EDTA consists of closure assembly, a plastic tube and EDTA coating (dipotassium). The VACUTAINER PLUS Serum Tube consists of closure assembly, a plastic tube and silica clot activator.

VACUTAINER® Brand PLUS Tubes offers the performance and effectiveness of a glass tube and the advantages of using a plastic tube. These advantages include reduced risk of breakage and enhanced ease of disposal. The principal device and the predicate devices have similar tube and closure design and closure materials of composition.

The standard closure assembly is a basic rubber stopper. The tube is also available with the VACUTAINER Systems Hemogard Closure assembly. The VACUTAINER Systems Hemogard Closure assembly consists of a rubber stopper and protective plastic shield to reduce user exposure to blood. The plastic tube enhances user safety and disposal because of the reduced risk of tube breakage and incineration as a method of disposal.

Becton Dickinson VACUTAINER® Systems believes that the additional Indications for Use do not significantly affect the safety or efficacy of device for its intended use. Clinical testing to evaluate the effectiveness of the tube for these additional indications for use was performed. The results of the clinical evaluation demonstrate that the VACUTAINER® Brand PLUS (plastic) EDTA and Serum tubes provide equivalent results compared to the VACUTAINER® Brand (glass) Serum and EDTA tubes for immunohematology testing including ABO Grouping, Rh typing and antibody screening which requires red cells and plasma or serum. The clinical report is included in Attachment K of this Premarket Notification.

ATTACHMENT H

PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT

Ja

PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT
[As Required By 21 CFR 807.87(j)]

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

Eileen Schweighardt 3/17/98
Eileen Schweighardt - Regulatory Affairs Manager Date
Becton Dickinson VACUTAINER Systems

I certify that, in my capacity as Project Engineer of Becton Dickinson VACUTAINER Systems, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Joan B. Wiseman 3/17/98
Joan B. Wiseman - Project Engineer Date
Becton Dickinson VACUTAINER Systems

Premarket Notification [510(k)] Number

100

ATTACHMENT I

**CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
INDICATIONS FOR USE FORM**

101

510(k) Number (if known): K981013

Device Name: VACUTAINER® Brand PLUS Tube with EDTA Anticoagulant and VACUTAINER® Brand PLUS Serum Tube

Indications for Use:

The VACUTAINER® Brand PLUS (plastic) Tube with EDTA and VACUTAINER® Brand Serum Tube are evacuated blood collection tubes which provide a means of collecting, transporting, separating and processing blood in a plastic tube. When the tube is used together with VACUTAINER® Brand Needles and Holders, it is a closed system for the collection of venous blood with the same indications as described herein.

Blood collected in PLUS EDTA and PLUS Serum tubes can be used for immunohematology testing including ABO Grouping, Rh typing and antibody screening which requires red cells and plasma or serum.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

Clara Sliv

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K981013

102

Attachment J
Summary of Safety and Effectiveness

103

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

I. General Information

This Summary of 510(k) Safety and Effectiveness information is being submitted in accordance with the requirements of the SMDA of 1990 and 21 CFR 807.92

Establishment:

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

- **Registration Number:** 2243072

- **Contact Person:** Eileen Schweighardt
Regulatory Affairs Manager
Telephone no.: 201 - 847 - 4570
Facsimile no.: 201 - 847 - 4858

- **Date of Summary:** March, 1998

Device Name:

- **Trade Name:** VACUTAINER® Brand PLUS Tube
with EDTA Anticoagulant and
VACUTAINER® Brand PLUS Serum Tube

- **Classification Name :** Blood Specimen Collection Device

- **Classification:** Class II

- **Performance Standards:** None Established under 514 of
the Food, Drug and Cosmetic Act

II. Safety and Effectiveness Information Supporting the Substantial Equivalence Determination

Substantial Equivalence Declaration: The term "Substantial Equivalence" is used in this 510(k) Premarket Notification is limited to the definition of Substantial Equivalence as found in the Federal Food, Drug, and Cosmetic Act, as amended and as applied under 21 CFR § 807, Subpart E under which a device can be marketed without pre-market approval or reclassification.

- Device Description

The VACUTAINER® Brand PLUS Tube with EDTA and the VACUTAINER PLUS Serum Tube are evacuated plastic blood collection tubes for collecting, transporting and processing blood in a closed plastic tube. The VACUTAINER® Brand PLUS Tube with EDTA consists of closure assembly, a plastic tube and EDTA coating (dipotassium). The VACUTAINER PLUS Serum Tube consists of closure assembly, a plastic tube and silica clot activator.

The standard closure assembly is a basic rubber stopper. The tubes are also available with the VACUTAINER® Hemogard Closure Assembly, which consists of a rubber stopper and protective plastic shield to reduce user exposure to blood. The Hemogard closure assembly, intended to reduce user exposure to blood, was described in 510(k) Premarket Notification K945952 that received FDA clearance on January 18, 1995. All stopper/closures are color coded to reflect additive type (see the chart **VACUTAINER® Tube Stopper/Closure Color Code Cross Reference** located in the Product Insert, Attachment D)

- Intended Use

The VACUTAINER® Brand PLUS Tube with EDTA anticoagulant and the VACUTAINER Brand PLUS Serum Tube are evacuated blood collection tubes which provides a means collecting, transporting and processing blood in a closed plastic tube. Blood collected in a tube containing EDTA anticoagulant, VACUTAINER® Brand PLUS Tube with EDTA anticoagulant, is used primarily for clinical laboratory hematology studies. The VACUTAINER® Brand PLUS Serum Tube containing Silica activator is used primarily in clinical laboratory testing for chemistry assays.

In addition, the blood collected and processed in the VACUTAINER® Brand PLUS with EDTA anticoagulant and the VACUTAINER® Brand PLUS Serum Tube can be used immunohematology testing including ABO grouping, Rh typing and antibody screening which requires red cells and plasma or serum.

- Synopsis of Test Methods and Results

Clinical testing to evaluate the effectiveness of the tube for the additional Indications for Use described in premarket notification was performed. The results of the clinical evaluation demonstrate that the VACUTAINER® Brand PLUS (plastic) EDTA and PLUS Serum tubes provide equivalent results compared to the VACUTAINER® Brand (glass) Serum and EDTA tubes for immunohematology testing including ABO Grouping, Rh typing and antibody screening which requires red cells and plasma or serum.

• Substantial Equivalence

Becton Dickinson VACUTAINER Systems believes that the VACUTAINER® Brand PLUS Tube with EDTA and VACUTAINER® Brand PLUS Serum Tube with the expanded Indications for Use is substantially equivalent to a commercially available blood collection tube. Clinical testing, as described in this premarket notification, demonstrates equivalent performance and effectiveness and supports the determination of substantial equivalence. The predicate devices, manufacturer, K number and clearance date are identified below:

Manufacturer	Predicate Device	K-Number	Clearance Date
VACUTAINER Systems	VACUTAINER® Brand Serum Tube	Not Applicable	Pre-Amendment Device and, therefore, exempt from premarket notification requirements according to the MDA of 1976.
VACUTAINER Systems	VACUTAINER® Brand Tube with EDTA Anticoagulant	Not Applicable	Pre-Amendment Device and, therefore, exempt from premarket notification requirements according to the MDA of 1976.

Eileen Schweighardt
 Eileen Schweighardt
 Regulatory Affairs Manager
 Regulatory Affairs Department

March 16, 1998
 Date

106

ATTACHMENT K

(2)

**EVALUATION OF VACUTAINER BRAND PLUS TUBES
FOR SPECIMEN COLLECTION FOR
IMMUNOHEMATOLOGY TESTING**

1. INTRODUCTION

Becton Dickinson VACUTAINER Systems (BDVS) has sold glass-evacuated tubes for blood collection for over thirty years. These VACUTAINER Brand Tubes are considered by many to be the reference blood collection container. In 1992 VACUTAINER Brand PLUS Tubes (plastic) with and without gel were introduced with documented equivalency for a limited array of routine chemistry analytes. PLUS Tubes with EDTA followed with documented equivalency for routine hematology tests.

This report addresses the requirement to document the performance characteristics of VACUTAINER PLUS Serum and K2EDTA Tubes versus VACUTAINER Brand Serum and K3EDTA Tubes for routine immunohematology tests as performed for donor grouping, typing and antibody screening. The information contained in this report is derived from two external clinical trials conducted at the Queen Elizabeth II Health Sciences Center (QEII), Halifax, NS, Canada and at the Glasgow and West of Scotland Blood Transfusion Service (SNBTS), Law, Lanarkshire, Scotland.

Tubes produced in Broken Bow, Nebraska and Sumter, South Carolina were evaluated at the QE II facility and product produced in Plymouth, England was tested at the Glasgow site.

2. OBJECTIVES

Determine if samples collected in VACUTAINER PLUS Tubes with K2EDTA and PLUS Serum Tubes yield results equivalent to those obtained from VACUTAINER Brand (glass) Serum control tubes and K3EDTA (glass) control tubes for routine immunohematology testing i.e. ABO, Rh and antibody screen.

Determine how long samples can be refrigerated and still maintain reproducible results from initial time testing to 28 days post collection.

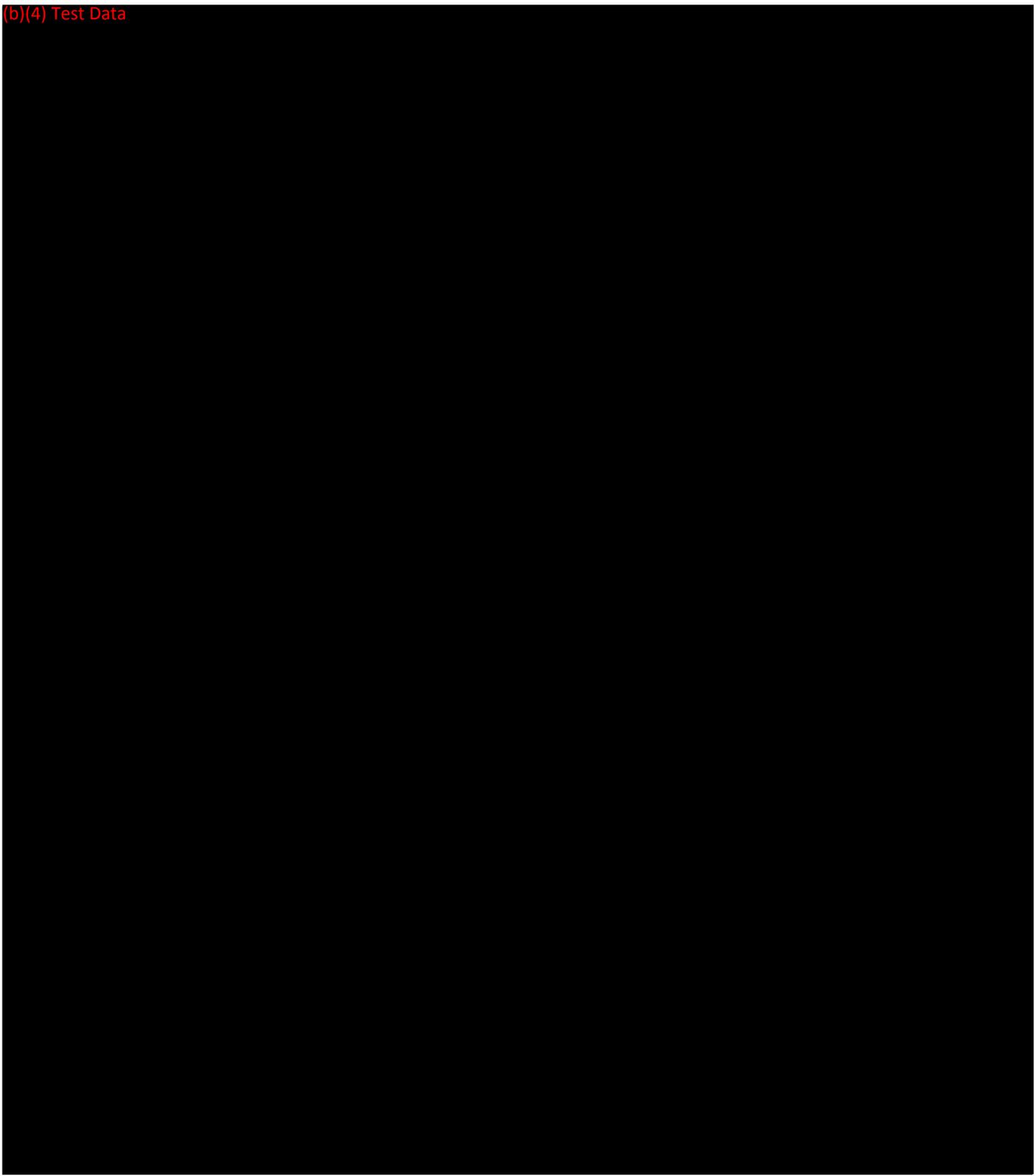
3. CLINICAL PROTOCOLS AND PROCEDURES

A total of (b)(4) donors, (b) from the QE II site and (b) from SNBTS were selected from their normal donor pools to provide a mix of ABO groups and Rh types. Included in the donor groups were individuals previously identified as having irregular red cell antibodies.

Samples for the trials were balanced and paired and the collection tube sequence was randomized for each phlebotomy.

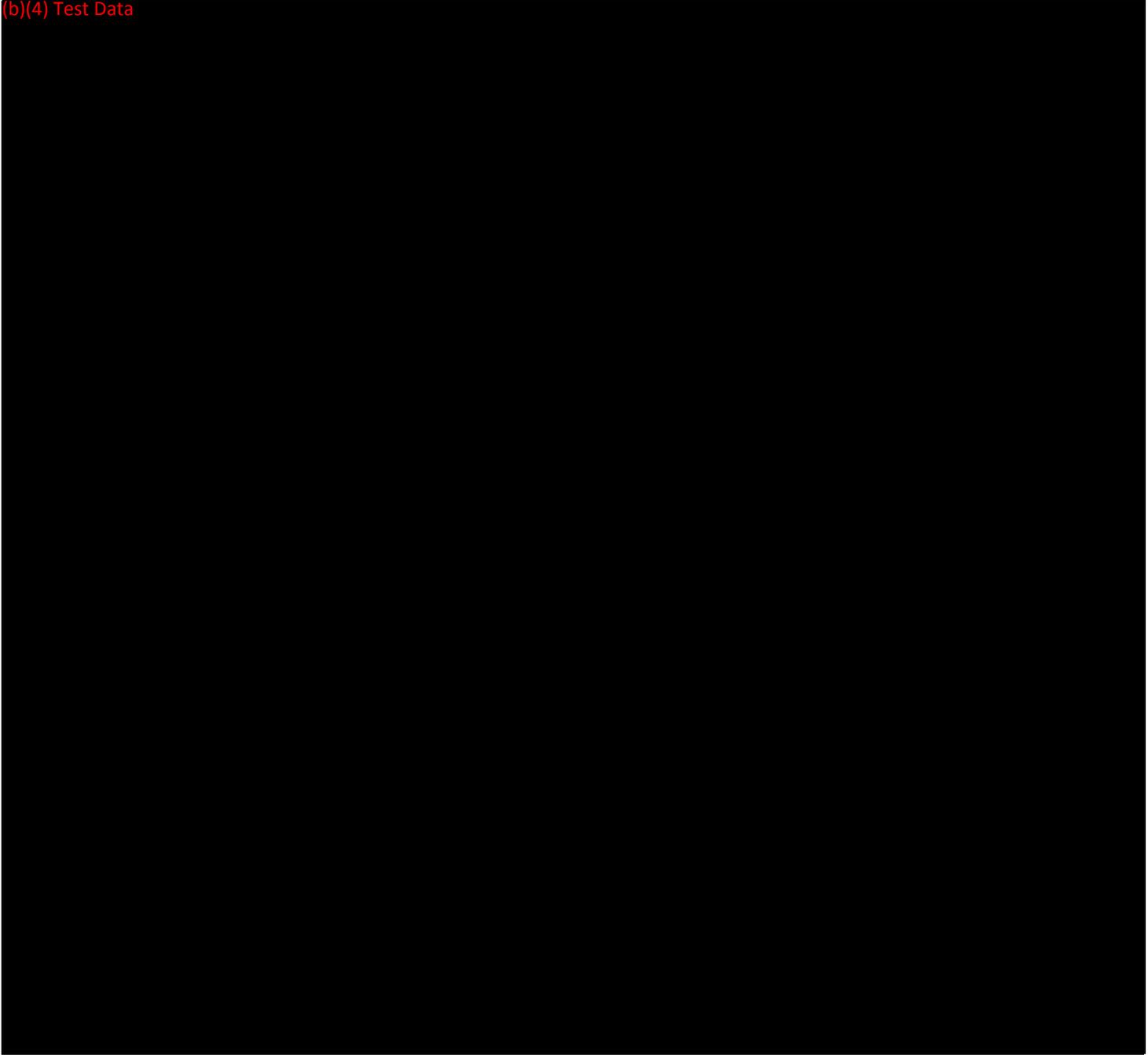
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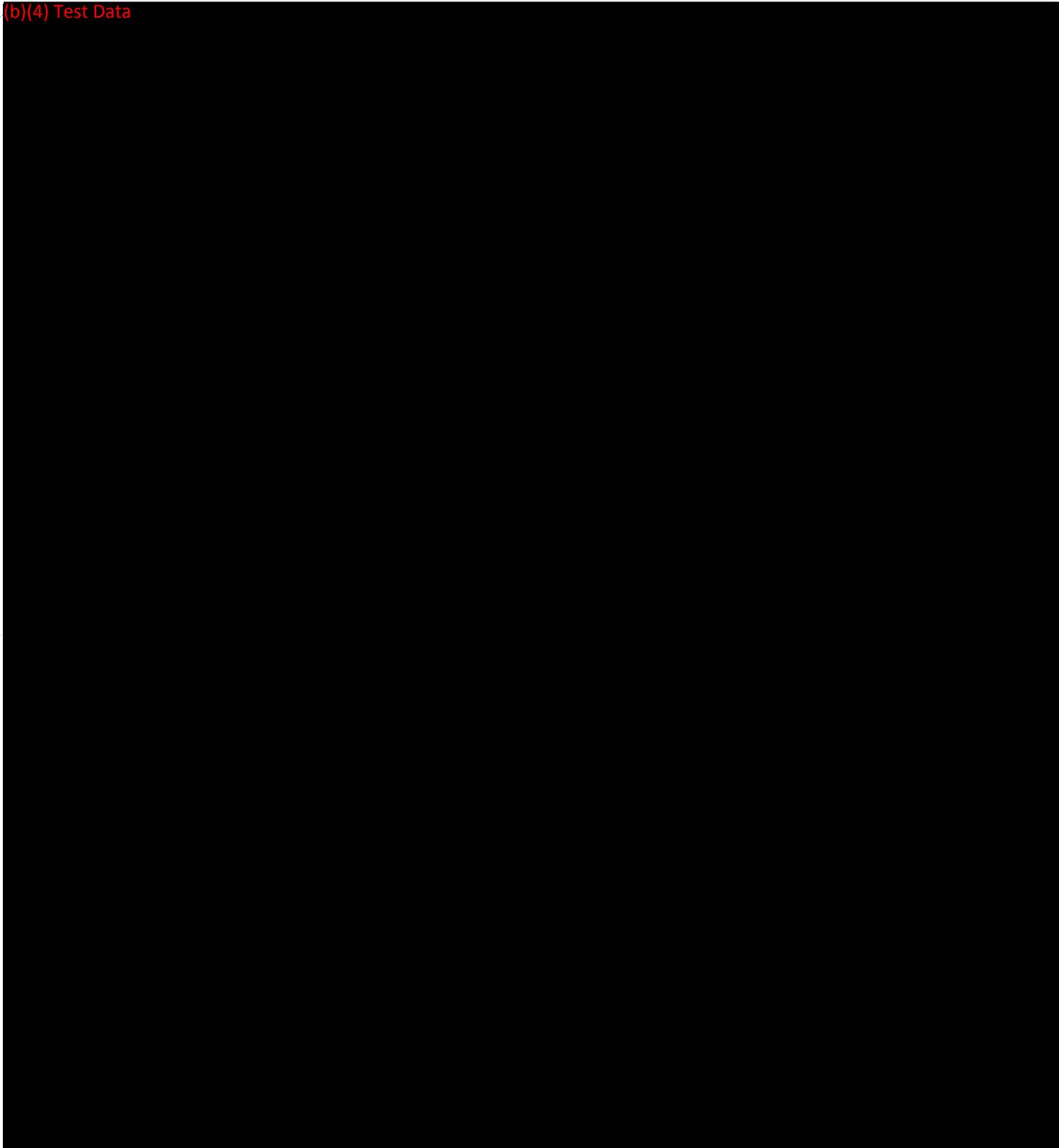
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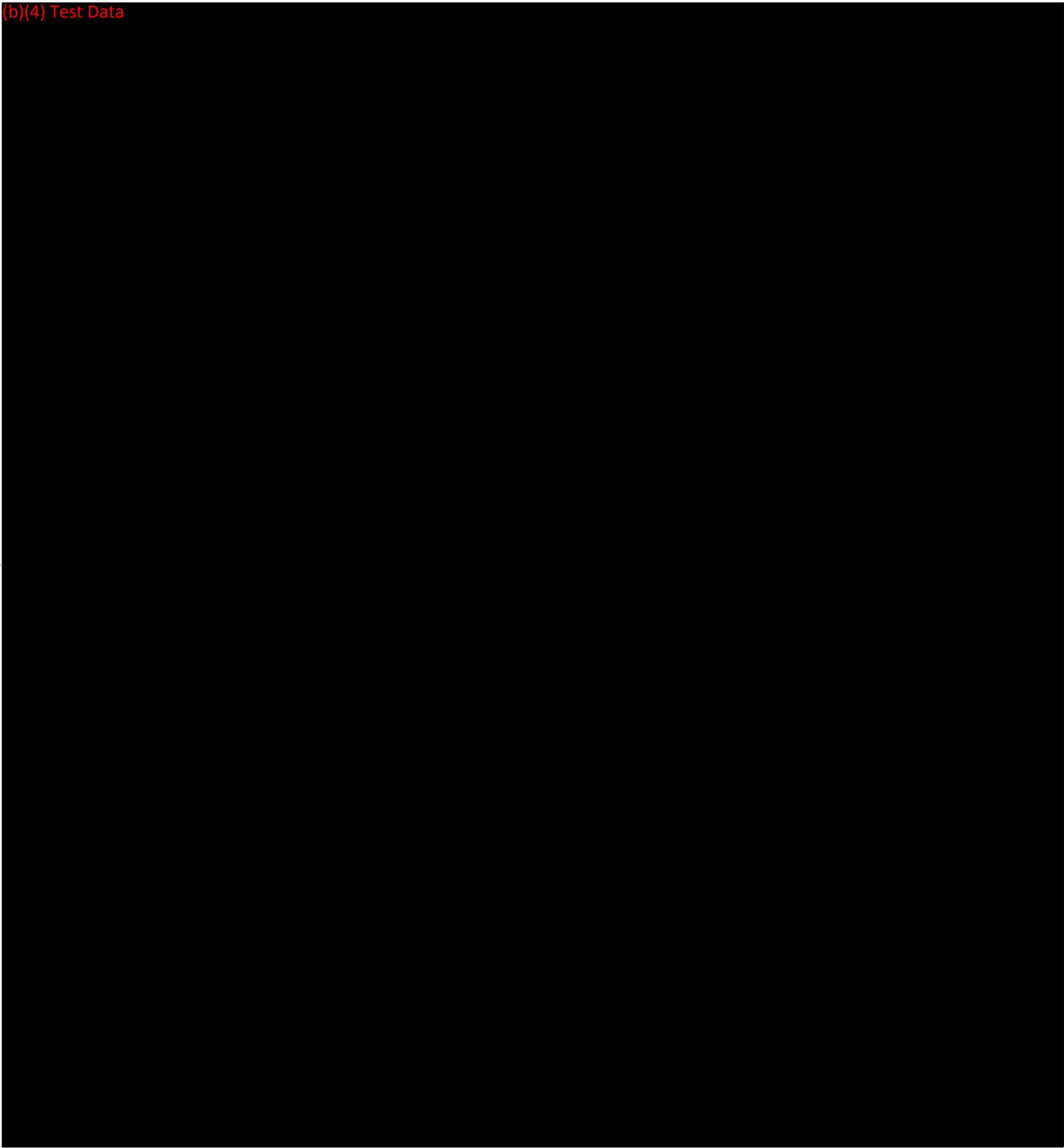
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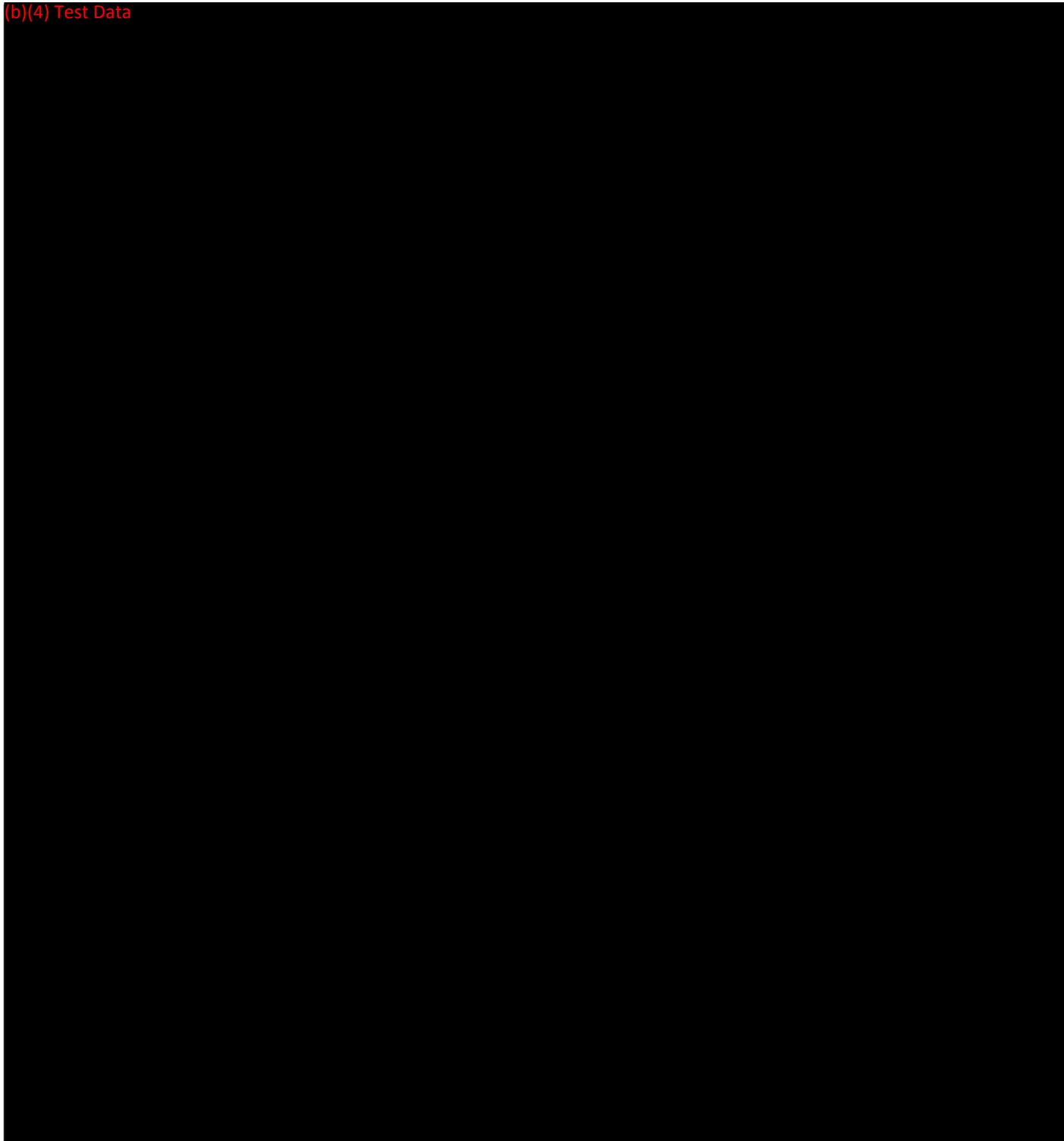
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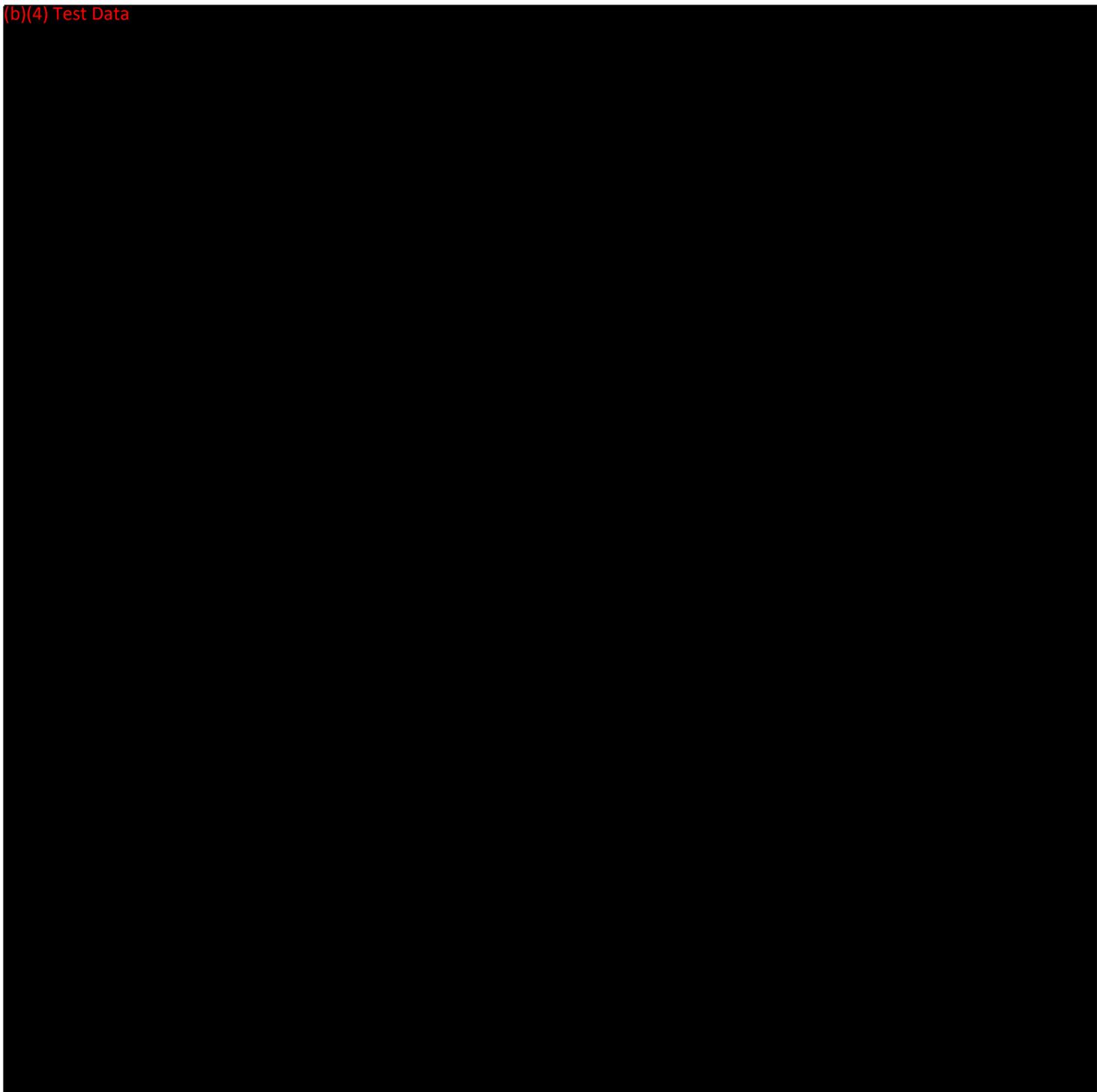
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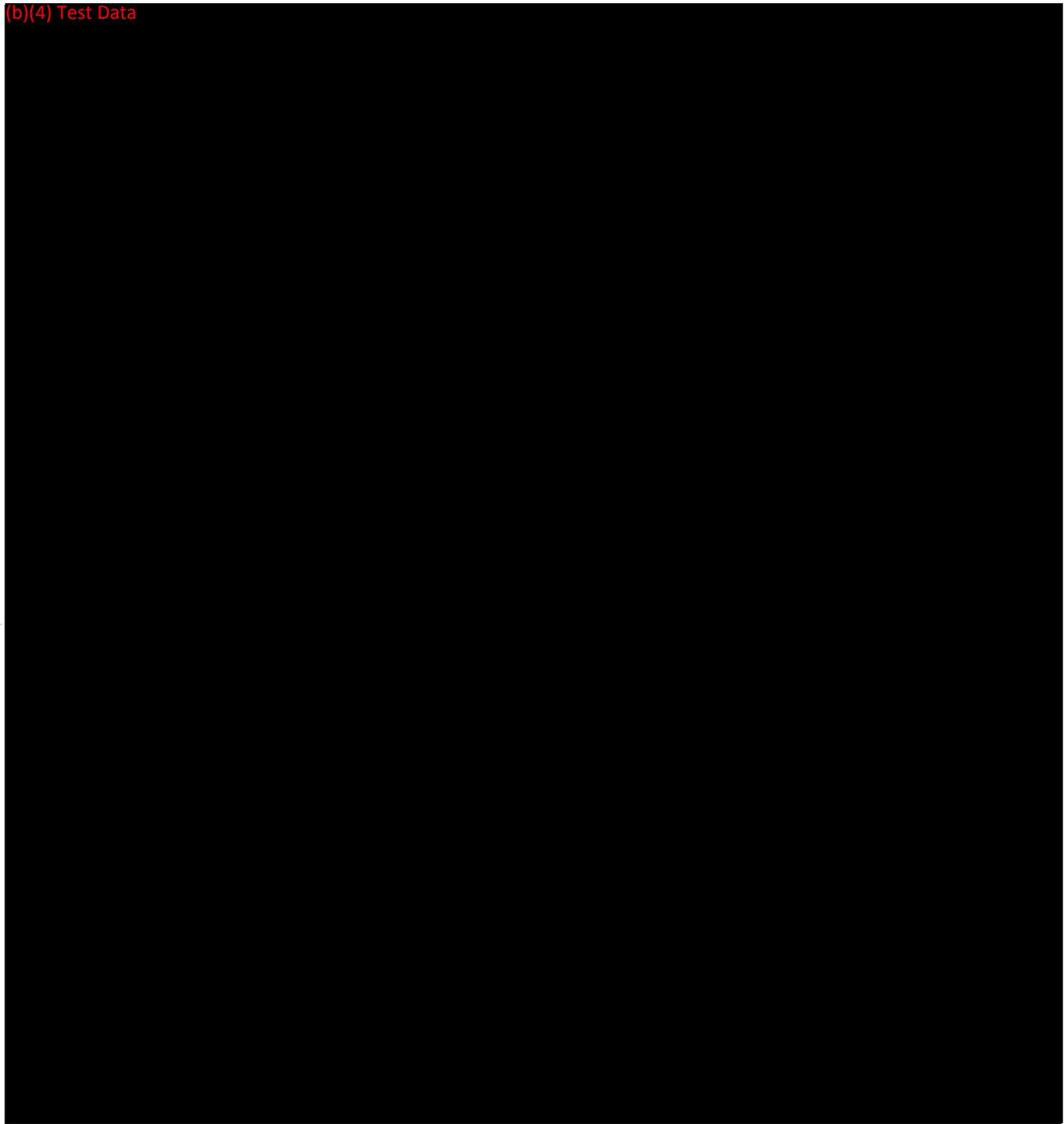
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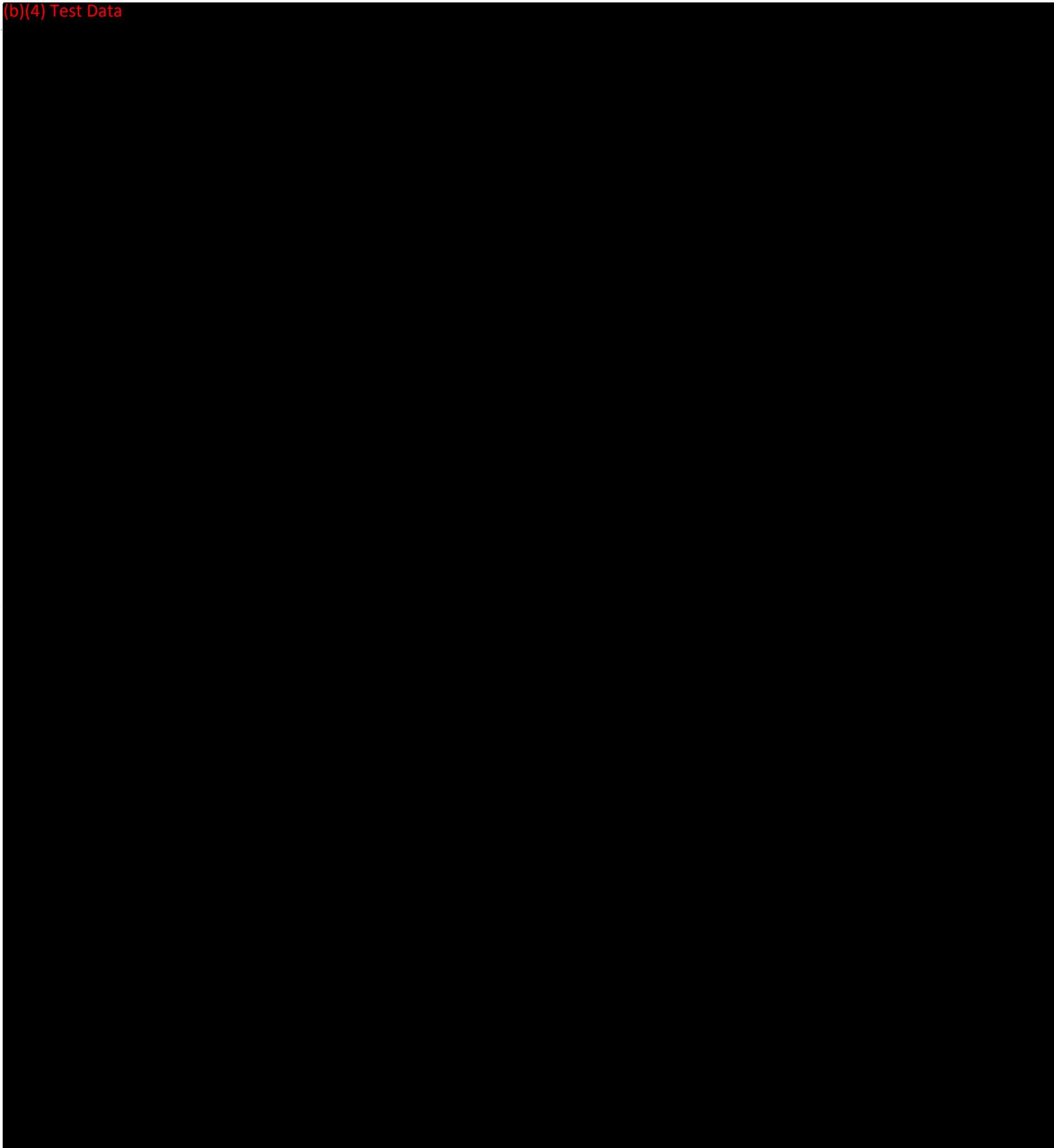
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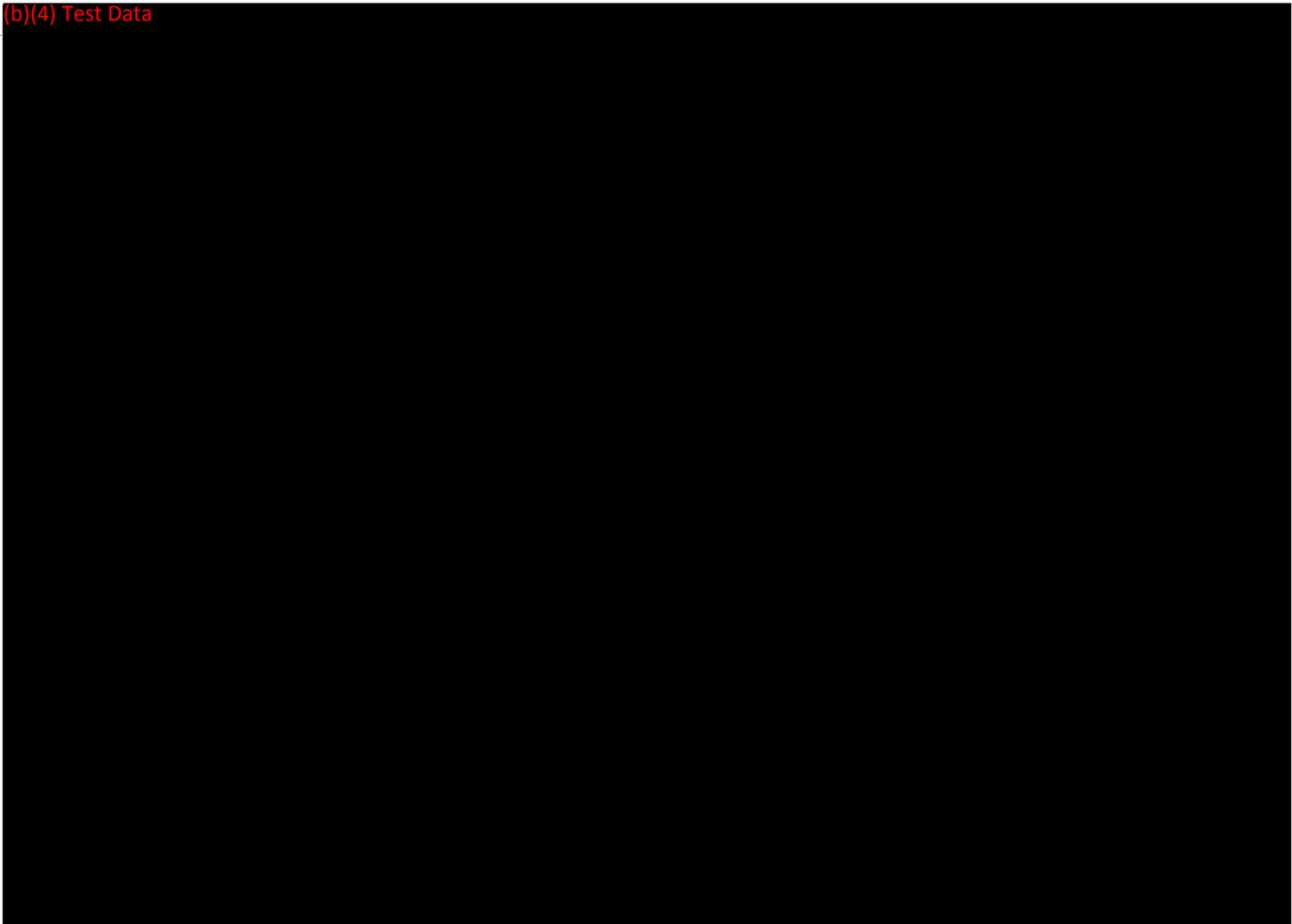
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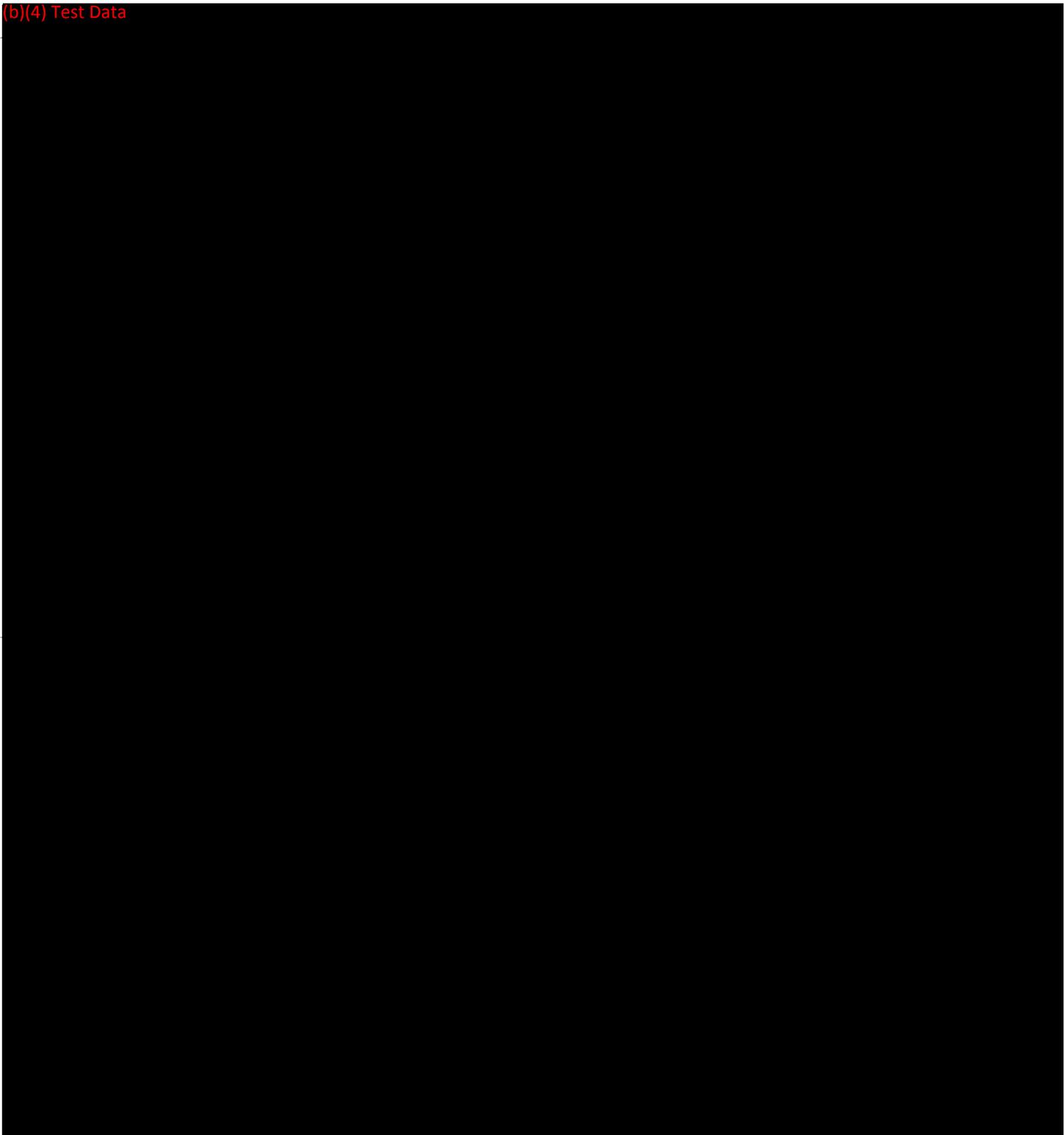
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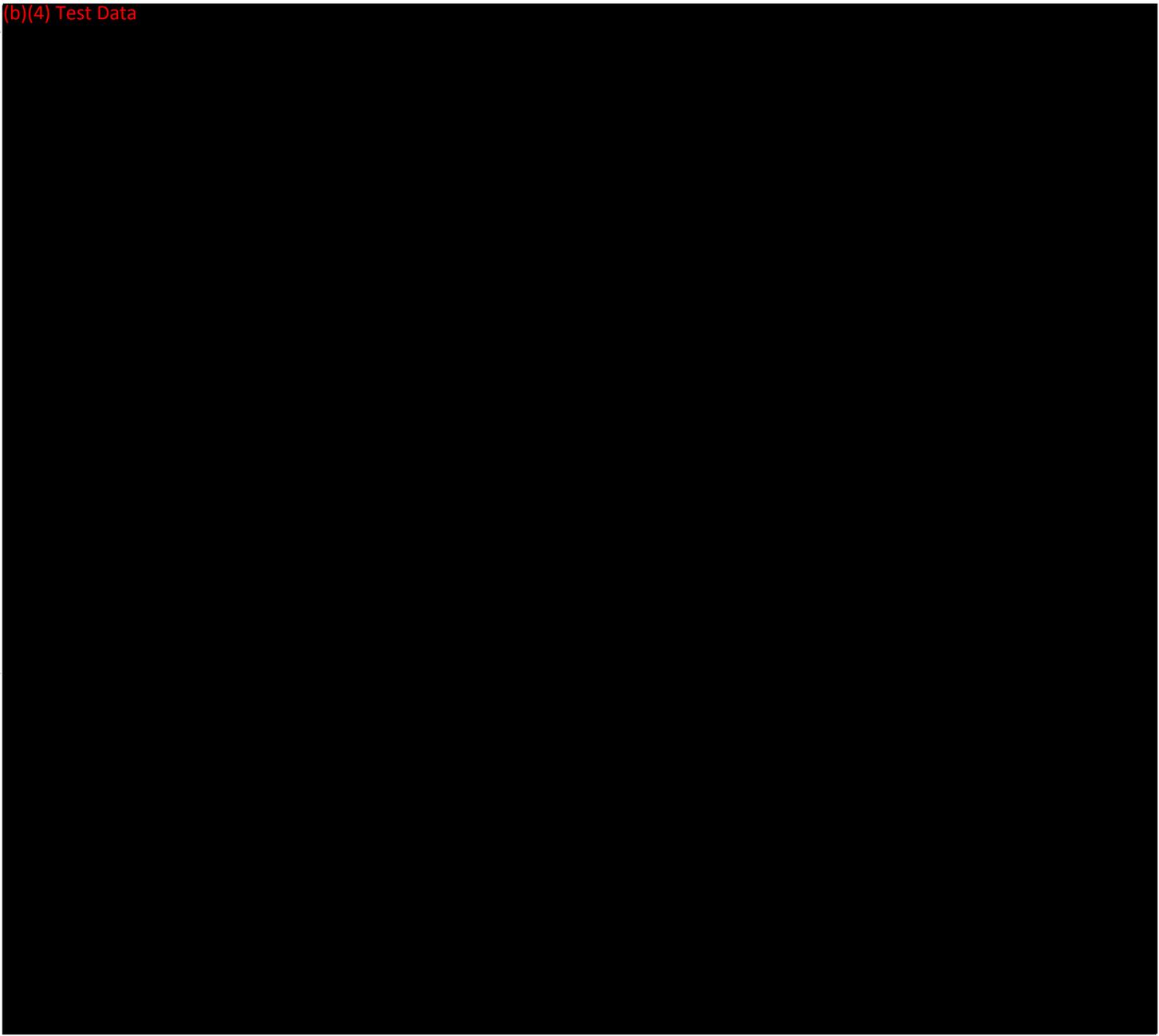
117

(b)(4) Test Data



115

(b)(4) Test Data



119