

# PAXgene® Blood DNA Tube

# For Research Use Only

Not for use in diagnostic procedures
To be used only in conjunction with the
PAXgene Blood DNA Kit (Cat. No. 761133)

**REF** 761115



#### I. Introduction

The PAXgene® Blood DNA Tube is a plastic, evacuated tube for the collection of whole blood and the subsequent isolation of genomic DNA. The tube contains an additive which anti-coagulates the blood and preserves genomic DNA. The PAXgene Blood DNA Tube is intended for use with the PAXgene Blood DNA Kit (Cat. No. 761133).

For Research Use Only. Not For Use In Diagnostic Procedures. The performance characteristics of this product have not been fully established. Its suggested use is for molecular test methods that require intact genomic DNA from whole blood. These test methods include, but are not limited to, PCR (polymerase chain reaction) based methods and Southern blot analysis.

#### **Product Features**

PAXgene Blood DNA Tube 8.5 mL • 16 x 100 mm 2.0 mL K<sub>3</sub>EDTA additive Sterile

BD Vacutainer® Plus plastic tube BD Hemogard™ closure 100 tubes/case 761115

#### I. Summary and Explanation

Research applications, including pharmacogenomic studies, gene sequencing, and SNP genotyping, yield important data. Therefore, the use of standardized methods for sample collection and nucleic acid isolation are of increasing importance. The PAXgene Blood DNA System, which is comprised of the PAXgene Blood DNA Tube and the PAXgene Blood DNA Kit, provides an efficient method for standardized blood collection, transport, and storage of whole blood specimens and isolation of genomic DNA. Purified DNA obtained using the PAXgene Blood DNA System performs well in a wide variety of downstream applications.

#### III. Principle of Procedure

The PAXgene Blood DNA Tube provides a means for the collection of 8.5 mL of whole blood in a closed, evacuated system. Blood is collected using standard venipuncture technique into an evacuated tube that contains 2.0 mL of DNA stabilization additive for a ratio of 0.24 mL of additive per mL of blood when the evacuated tube is filled correctly. Isolation of genomic DNA from the entire specimen is carried out using the PAXgene Blood DNA Kit (Cat. No. 761133).

# IV. Specimen Collection and Preparation for Analysis

#### A. Required Blood Collection Accessories (not included with PAXgene System)

- Blood collection devices such as the BD Vacutainer Blood Collection Needle or BD Vacutainer Blood Collection Set (see Section XII Ordering Information).
- A BD Vacutainer Tube Holder must be used to ensure proper function (see Section XII Ordering Information).
- 3. Labels for specimen identification, if required.
- 4. Alcohol swab for cleansing site.
- 5. Dry sterile gauze.
- 6. Tourniquet.
- 7 Riphazard container for used needle or needle/holder combination

#### B. Procedure for Specimen Collection

1. Ensure that the PAXgene Blood DNA Tube is at room temperature (18–25°C) prior to use and properly labeled with specimen identification.







- Collect blood into the PAXgene Blood DNA Tube using your institution's recommended procedure for standard venipuncture technique (see Section V Prevention of Backflow).
- Ensure that the blood has stopped flowing into the tube before removing the tube from the holder.



- After blood collection, gently invert the PAXgene Blood DNA Tube 8–10 times.
- 5. Store the PAXgene Blood DNA Tube upright at room temperature (18–25°C) up to 14 days, refrigerated (2–8°C) up to 28 days, or frozen at –20°C or –70°C.

# C. Guidelines for Freezing PAXgene Blood DNA Tubes Containing Blood Samples

- To freeze PAXgene Blood DNA Tubes, stand them upright in a metal or plastic wire rack. Do not freeze tubes upright in a Styrofoam™ tray as this may cause the tubes to crack.
- 2. If tubes are to be stored for less than 10 weeks, freeze the tubes in the wire rack at -20°C. For longer storage periods, freeze the tubes first at -20°C for 24 hours, and then transfer them to -70°C or -80°C.
- 3. To thaw PAXgene Blood DNA Tubes, place them in a wire rack in a water bath at 37°C for 15 minutes. After thawing, carefully invert the tubes 10 times.

Note: Frozen PAXgene Blood DNA Tubes are subject to breakage upon impact. To reduce the risk of breakage during shipment, frozen tubes should be treated in the same manner as glass tubes. Users must validate their own freezing and shipping protocol for PAXgene Blood DNA Tubes.

# D. Procedure for Specimen Preparation for Analysis

Blood samples should be processed in accordance with the instructions provided with the PAXgene Blood DNA Kit (Cat. No. 761133).

#### V. Prevention of Backflow

Since PAXgene Blood DNA Tubes contain a liquid additive, it is important to avoid possible backflow from the tube, with the possibility of adverse subject reactions. To guard against backflow, observe the following precautions:

- 1. Place subject'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 the tube additive does not touch stopper or non-patient end of the needle during venipuncture.

## VI. Limitations of System

- This tube is for research use only. Neither the clinical utility nor the performance characteristics of the PAXgene Blood DNA Tube and Kit as part of an in vitro diagnostic procedure have been established.
- 2. The quantity of blood drawn varies with altitude, ambient temperature, barometric pressure, tube age, venous pressure, and filling technique.
- Blood samples obtained with the PAXgene Blood DNA Tube should be prepared only with the PAXgene Blood DNA Kit (Cat. No. 761133).
- 4. Endotoxin not controlled. Blood and blood components collected and processed in the tube are not intended for infusion or introduction into the human body.

#### VII. Warnings and Precautions

- 1. Contents of this tube may cause irritation to eyes, digestive system and skin.
  - After skin contact, wash skin with soap and water. Get medical attention if irritation persists after washing.
  - · After eye contact, if irritation occurs, get medical assistance.
  - · After swallowing, rinse mouth. Get medical attention if any discomfort occurs.
- 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 blood borne pathogens.
- 3. Handle all blood samples and blood collection devices (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 blood exposure (for example, through a needlestick injury), since there is a risk of transmission of viral hepatitis, HIV, or other infectious diseases. Utilize any built-in needle protector after blood collection if the blood collection device provides one. PreAnalytiX does not recommend re-shielding used needles; however, the policies and procedures of your facility may differ and must always be followed.
- Discard all blood collection tubes and accessories in biohazard containers approved for their disposal.
- 5. Do not reuse PAXgene Blood DNA Tubes.
- 6. Do not use PAXgene Blood DNA Tubes after expiration date printed on tube label.
- Since this PAXgene Blood DNA Tube contains a chemical additive, precautions should be taken to prevent possible backflow from the tube during blood drawing (see Section V Prevention of Backflow).
- Transferring a blood sample collected with a syringe and needle into the PAXgene Blood DNA Tube is not recommended due to the increased potential for needlestick injury and creating incorrect blood to additive ratio.

#### VIII. Storage

Store the empty PAXgene Blood DNA Tubes at room temperature (18–25  $^{\circ}\text{C}).$ 

Do not use tubes after their expiration date.

#### IX. Instructions for Removal of BD Hemogard Closure

1. Grasp the PAXgene Blood DNA Tube with one hand, placing the thumb under the



BD Hemogard closure (for added stability, place arm on solid surface). With the other hand, twist the BD Hemogard closure while simultaneously pushing up with the thumb of the other hand ONLY UNTIL THE TUBE STOPPER IS LO

- Move thumb away before lifting closure. DO NOT use thumb to push closure off tube. Caution: 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 is removed from contact with the tube as soon as the BD Hemogard closure is loosened.
- 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.

### X. Instructions for Reinsertion of BD Hemogard Closure

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



### XI. Technical Assistance

If you have any questions regarding the PAXgene Blood DNA System, contact one of the QIAGEN Technical Services Departments listed on QIAGEN – Customer Service section.

# XII. Ordering Information

# **PAXgene Products**

#### PAXgene Blood DNA Tube / 761115

Content: 100 blood collection tubes.
Use with the PAXgene Blood DNA Kit (25).

#### PAXgene Blood DNA Kit (25) / 761133

Content: 25 Processing Tubes containing 25 mL Buffer BG1 (lysis buffer), Buffer BG2 (wash buffer), Buffer BG3 (digestion buffer), Buffer BG4 (resuspension buffer) and PreAnalvtiX Protease.

Use with the PAXgene Blood DNA Tube.

#### **BD Products\***

#### BD Vacutainer UltraTouch™ Push Button Blood Collection Set / 367365

Content: 21G 3/4 inch (0.8 x 19 mm) needle, 12 inch (305 mm) tubing with luer adapter. 50/box. 200/case

#### BD Vacutainer Safety-Lok™ Blood Collection Set / 367281 US / 367286 CE

Content: 21G 3/4 inch (0.8  $\times$  19 mm) needle, 12 inch (305 mm) tubing with luer adapter. 50/box, 200/case

# BD Vacutainer Eclipse™ Blood Collection Needle / 368609 CE

Content: 21G 11/4 inch (0.8 x 32 mm) needle, 48/box, 480/case

# BD Vacutainer Eclipse Blood Collection Needle with Pre-Attached Holder / 368650 Content: 21G 1¼ inch (0.8 × 32 mm) needle. 100/case

BD Vacutainer Eclipse Signal™ Blood Collection Needle / 368835 CE

Content: 21G 1¼ inch (0.8 × 32 mm) needle. 50/box. 400/case

#### BD Vacutainer One Use Holder / 364815

Content: Case only for 13 mm and 16 mm diameter. 1,000/case

\*These catalog numbers represent typical products that can be used with the PAXgene Blood DNA Tube.

#### To order BD Blood Collection Accessories:

Go to: http://www.bd.com/support/contact/international.asp

• Select country • Scroll down for BD Diagnostics - Preanalytical Systems • Dial number

#### OIAGEN - Customer Service

Argentina, Uruguay, and Paraguay Orders: 0800.444.5523

E-mail: crc\_argentina@bd.com

Australia

Orders: 1.800.656.100 Fax: 1.800.656.110 E-mail: bd\_anz@bd.com

Austria

Orders: 43.1.7063660 Fax: 43.1.706366011

E-mail: customercare.at@bd.com

Belgium

Orders: 32.53.720.556 Fax: 32.53.720.549 E-mail: orders.be@bd.com

Brazil

Orders: 0800.055.56.54

E-mail:

consultoria vacutainer@bd.com

Canada

Technical support: 1.800.631.0174

Orders: 1.866.979.9408 Fax: 1.800.565.0897

F-mail

customer.service.canada@bd.com

Central and Eastern Europe

Orders: 48.22.377.11.11 Fax: 48.22.377.11.02 Bulgaria orders:

info\_bulgaria@bd.com Czech Republic orders: info\_czech@bd.com

Croatia orders: info\_croatia@bd.com Hungary orders:

Hungary orders: info\_hungary@bd.com

Poland orders: info poland@bd.com

Romania orders: info\_romania@bd.com Southeast Europe orders:

info\_balkan@bd.com Serbia orders: info\_serbia@bd.com

Slovakia orders: info\_slovakia@bd.com Slovenia orders:

info\_slovenia@bd.com

Denmark

Orders: 45.43.43.45.66 Fax: 45.43.96.56.76 Orders: ordre.dk@bd.com Technical support:

hddenmark@hd.com

Finland

Orders: 358.9.88.70.780 Fax: 358.9.88.70.7816 Orders: tilaukset.fi@bd.com

France

Orders: 33.476.68.36.36 Fax: 33.476.68.36.93

E-mail: serviceclientbdf@bd.com Orders: commandesfr@bd.com

Technical support: vacutainerfr@bd.com

Germany

Orders: 49.6221.3050 Fax: 49.6221.305.216

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India

Orders: 91.124.3949390 Orders: bd\_india@bd.com

Ireland

(Aquilant Specialist Healthcare Services)

Customer support: 353.1.404.8350

Fax: 353.1.404.8352 F-mail:

contactus@aquilantscientific.ie

Israel (Lapidot Medical)

Customer support: 972.700.70.90.22

E-mail: cs@lapidot.com

Italy

Orders: 39.02.48240.500 Fax: 39.02.48240.775

Technical support: 39.3450655140

E-mail: ordini.it@bd.com

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Fax: 971.45.592.599
E-mail: EMA PAS@bd.com

The Netherlands

Orders: 31.20.582.94.20 Fax: 31.20.582.94.21 Orders: orders.nl@bd.com

New Zealand

Orders: 0800.572.468 Fax: 0800.572.469

E-mail: nz\_customerservice@bd.com

Norway

Customer support: 64.00.99.00 E-mail: bdnorge@bd.com Orders: ordre.no@bd.com Southeast Asia

Customer support: www.bd.com/en-sea/support Orders: 46.8.775.51.00

E-mail: bd sea@bd.com

Indonesia orders: 622.1577.1920 Malaysia orders: 603.2093.8788 Philippines orders: 63,2478,8881 Singapore orders: 65.6861.0633

Thailand orders: 662.646.1800 Vietnam orders: 848.3822.7409

South Korea

Orders: 080 340 3800 Fax: 02.3404.3785

Technical: 080.340.3800

Technical support: service korea@bd.com

Spain, Portugal, and Andorra Orders: 34.91.848.8174

Customer support: 34.902.27.17.27 Fax: 34.91.848.8115

E-mail: info.spain@bd.com

Sweden

Fax: 46.8.645.08.08

Orders: order.se@bd.com Technical support: bdsweden@bd.com

Switzerland

Orders: 41.61.485.22.24 Fax: 41.61.485.22.00 F-mail: infoch@bd.com

Orders: 0800.917.8776 E-mail:

bduk customerservice@bd.com

Customer support: 800.631.0174

or www.bd.com.

E-mail: productcomplaints@bd.com

## Change History

Revision	Date	Change Summary
01	2016-07	First issue (previous version: VD1750150[12]). Updated Research Use Only disclaimer in Section I. Updated blood collection drawings in Section IV. Added endotoxin limitation (4.) in Section VI.
02	2023-10	Updated PreAnalytiX GmbH street address. Added STERILE R, Single sterile barrier system symbol, Temperature limit symbol 4 to 25°C, Caution, Do not re-use, Do not use if package is damaged, Keep dry, Keep away from sunlight, Consult instructions for use symbol. Added REF symbol and catalog number to cover page. Updated customer service information. Updated formatting. Added Symbol Glossary. Updated trademark information.

# Symbol and Mark Key

Symbol	Meaning	
	Manufacturer	
REF	Catalogue number	
STERILE R	Sterilized using irradiation	
	Do not use if package is damaged and consult instructions for use	
紊	Keep away from sunlight	
<del>*</del>	Keep dry	
1	Temperature limit	
(2)	Do not re-use	
<u>i</u>	Consult instructions for use or consult electronic instructions for use	
<u></u>	Caution	
	Single sterile barrier system	



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The PAXgene Blood DNA Tube is made in the UK by BD for PreAnalytiX GmbH.

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2023-10 VDP40330(02) 500069295