



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)

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).

This tube is for research use only. The use of this product for diagnostic procedures and patient management is strictly prohibited. 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. 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) and Southern blot analysis.

Product Features

PAXgene Blood DNA Tube	8.5 ml • 16 x 100 mm	2.0 ml K ₃ EDTA additive	Sterile
761115	Plus • BD Hemogard™	100 tubes/case	RUO

For Research Use Only. Not For Use In Diagnostic Procedures. No claim or representation is intended to provide information for the diagnosis, prevention, or treatment of a disease. The performance characteristics of this product have not been fully established.

II. 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).

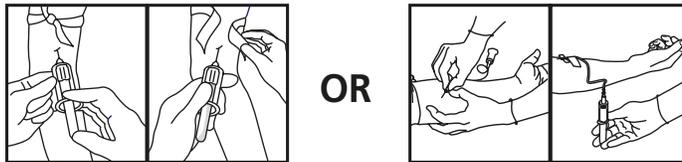
IV. Specimen Collection and Preparation for Analysis

- A. Required Blood Collection Accessories. (Not included with PAXgene System)**
1. Blood collection devices such as the BD Vacutainer® Blood Collection Needle or BD Vacutainer Blood Collection Set. See Ordering Information.

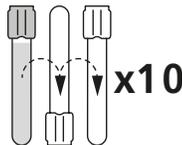
2. A BD Vacutainer Tube Holder must be used to ensure proper function. (See Ordering Information.)
3. Labels for specimen identification, if required.
4. Alcohol swab for cleansing site.
5. Dry sterile gauze.
6. Tourniquet.
7. Biohazard container for used needle or needle/holder combination.

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.



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



4. 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

1. 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 chemical 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 tube additives do not touch stopper or non-patient end of the needle during venipuncture.

VI. Limitations of System

1. This tube is for research use only, and therefore, the use of this product for diagnostic procedures and subject management is strictly prohibited. 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.
3. Blood samples obtained with the PAXgene Blood DNA Tube should be prepared only with the PAXgene Blood DNA Kit (Cat. No. 761133).

VII. Warnings and Precautions

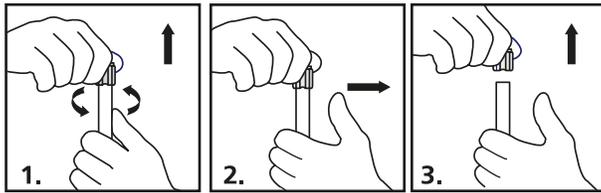
1. Contents of this tube may cause irritation to eyes, respiratory system and skin.
 - After inhalation, supply fresh air, and seek medical advice in case of complaints.
 - After skin contact, immediately wash with water and soap and rinse thoroughly.
 - After eye contact, rinse immediately with plenty of water for at least 15 minutes and seek medical advice.
 - After swallowing, immediately seek medical advice.
2. 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 biologic samples and blood collection devices (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, or other infectious diseases. Utilize any built-in used-needle protector 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.

4. Discard all blood collection tubes and accessories in biohazard containers approved for their disposal.
5. Do not re-use PAXgene Blood DNA Tubes.
6. Do not use PAXgene Blood DNA Tubes after expiration date printed on tube label.
7. 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 "Prevention of Backflow" section).
8. 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.

VIII. Storage

Store the empty PAXgene Blood DNA Tubes at room temperature (18–25°C). Do not use tubes after their expiration date.

IX. Instructions for Removal of BD Hemogard Closure

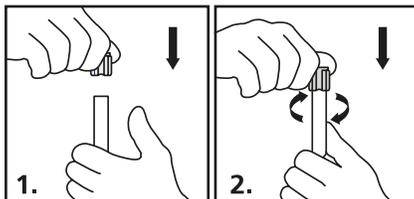


1. Grasp the PAXgene Blood DNA Tube with one hand, placing the thumb under the BD Hemogard Closure. (For added stability, place arm on solid surface). With the other

hand, twist the BD Hemogard Closure while simultaneously pushing up with the thumb of the other hand **ONLY UNTIL THE TUBE STOPPER IS LOOSENED**.

2. 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.
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.

X. Instructions for Reinsertion of BD Hemogard Closure



1. Replace closure over tube.
2. 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 PreAnalytiX Protease.
Use with the PAXgene Blood DNA Tube.

BD Products*

BD Vacutainer Push Button Blood Collection Set / 367344

Content: 21G 3/4 inch (0.8 × 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 × 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 1¼ inch (0.8 × 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. 1000/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

QIAGEN – Customer Service

Australia

Orders: 1.800.243.800
Technical: 1.800.243.066
Fax: 03.9840.9888

Austria

Orders: 0800.28.10.10
Technical: 0800.28.10.11
Fax: 0800.28.10.19

Belgium

Orders: 0800.79612
Technical: 0800.79556
Fax: 0800.79611

Brazil

Orders: 0800.557779
Technical: 0800.557779
Fax: 55.11.5079.4001

Canada

Orders: 800.572.9613
Technical: 800.DNA.PREP (800.362.7737)
Fax: 800.713.5951

China

Orders: 86.21.3865.3865
Technical: 800.988.0325
Fax: 86.21.3865.3965

Denmark

Orders: 80.885945
Technical: 80.885942
Fax: 80.885944

Finland

Orders: 0800.914416
Technical: 0800.914413
Fax: 0800.914415

France

Orders: 01.60.920.926
Technical: 01.60.920.930
Fax: 01.60.920.925

Germany

Orders: 02103.29.12000
Technical: 02103.29.12400
Fax: 02103.29.22000

Hong Kong

Orders: 800.933.965
Technical: 800.930.425
Fax: 800.930.439

Ireland

Orders: 1800.555.049
Technical: 1800.555.061
Fax: 1800.555.048

Italy

Orders: 800.789.544
Technical: 800.787.980
Fax: 02.334304.826

Japan

Orders: 03.6890.7300
Technical: 03.6890.7300
Fax: 03.5547.0818

Korea (South)

Orders: 080.000.7146
Technical: 080.000.7145
Fax: 02.2626.5703

Luxembourg

Orders: 8002.2076
Technical: 8002.2067
Fax: 8002.2073

Mexico

Orders: 01.800.7742.639
Technical: 01.800.7742.436
Fax: 01.800.1122.330

The Netherlands

Orders: 0800.0229592
Technical: 0800.0229602
Fax: 0800.0229593

Norway

Orders: 800.18859
Technical: 800.18712
Fax: 800.18817

Singapore

Orders: 1800.742.4362
Technical: 1800.742.4368
Fax: 65.6854.8184

Spain

Orders: 91.630.7050
Technical: 91.630.7050
Fax: 91.630.5145

Sweden

Orders: 020.790282
Technical: 020.798328
Fax: 020.790582

Switzerland

Orders: 055.254.22.11
Technical: 055.254.22.12
Fax: 055.254.22.13

UK

Orders: 01293.422.911
Technical: 01293.422.999
Fax: 01293.422.922

USA

Orders: 800.426.8157
Technical: 800.DNA.PREP (800.362.7737)
Fax: 800.718.2056

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E-mail: bd_anz@bd.com

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Orders: 43.1.706.36.60
Fax: 43.1.706.36.60-11
Email: customerservice.vac.ga@europe.bd.com

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Orders: 32.53.720.556
Fax: 32.53.720.549
Orders: orders.be@europe.bd.com

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Orders: 0800.055.56.54
E-mail: consultoria_vacutainer@bd.com

Canada

Orders: 800.268.5430
Fax: 800.565.0897
E-mail: custsvccan@bd.com

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Hungary: info_hungary@europe.bd.com
Poland: info_poland@europe.bd.com
Romania: info_romania@europe.bd.com
SEE: info_balkan@europe.bd.com
Serbia: info_serbia@europe.bd.com
Slovakia: info_slovakia@europe.bd.com
Slovenia: info_slovenia@europe.bd.com
Technical: bd_service_poland@bd.com

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Fax: 45.43.96.56.76
Orders: ordre.dk@europe.bd.com
Technical: bddenmark@europe.bd.com

Finland

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Fax: 358.9.88.70.7816
Orders: tilaukset.fi@europe.bd.com
Technical: bdsuomi@europe.bd.com

France

Orders: 33.476.68.94.96
Fax: 33.476.68.36.93
Orders: commandesfr@europe.bd.com
E-mail: serviceclientbdf@europe.bd.com
Technical: vacutainerfr@bd.com

Germany

Orders: 49.6221.305.553
Fax: 49.6221.305.379
Email: customerservice.vac.ga@europe.bd.com

Italy

Orders: 39.02.48.240.500
Technical: 39.335.424.388
Fax: 39.02.40.91.80.11
E-mail: ordini.it@europe.bd.com

Middle East & Africa (EMA)

Orders: 971.4.3379525
Fax: 971.4.03379551
E-mail: EMA_PAS@bd.com

The Netherlands

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

New Zealand

Orders: 0800.572.468
Fax: 0800.572.469
E-mail: nz_customerservice@bd.com

Norway (Puls Handicare)

Orders: 47.23.32.30.00
Fax: 47.23.32.30.99
E-mail: kundeservice@puls-norge.no

Spain, Portugal and Andorra

Orders: 34.91.848.8104
Technical: 34.902.27.17.27
Fax: 34.91.828.81.48
E-mail: info.spain@europe.bd.com

Sweden

Orders: 46.8.775.51.60
Fax: 46.8.775.51.95
Orders: order.se@europe.bd.com
Technical: bds sweden@europe.bd.com

Switzerland

Orders: 41.61.485.22.22
Fax: 41.61.485.22.00
E-mail: infoch@europe.bd.com

UK

Orders: 44.1.865.781.666
Fax: 44.1.865.717.313
E-mail: bduk_customerservice@europe.bd.com

USA

Orders: 888.237.2762
Technical: 800.631.0174
Fax: 800.847.2220
Technical: www.bd.com/vacutainer/contact

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