



A QIAGEN / BD Company



# PAXgene<sup>®</sup>

## *Blood ccfDNA Tube*

### **For Research Use Only**

Not for use in diagnostic procedures

To be used only in conjunction with the  
QIAGEN QIAamp<sup>®</sup> Circulating Nucleic Acid Kit (50) (Cat. No. 55114)  
or the QIASymphony<sup>®</sup> PAXgene Blood ccfDNA Kit (192) (Cat. No. 768536)

## I. Introduction

The PAXgene Blood ccfDNA System consists of a blood collection tube (PAXgene Blood ccfDNA Tube) and a ccfDNA purification kit (QIASymphony PAXgene Blood ccfDNA Kit) for the QIASymphony SP. It is intended for the collection, storage, and transport of blood and stabilization of ccfDNA in a closed tube and subsequent isolation and purification of ccfDNA from plasma for research applications.

The PAXgene Blood ccfDNA Tube is a plastic, closed, evacuated tube, for the collection, anticoagulation, transportation and storage of human whole blood specimens and the stabilization of ccfDNA. When the tube is used in conjunction with the QIASymphony PAXgene Blood ccfDNA Kit, or the QIAamp Circulating Nucleic Acid technology, high quality ccfDNA can be isolated for use in downstream analytical assays.

The system performance has been established in studies in which ccfDNA is purified from human plasma derived from PAXgene Blood ccfDNA Tubes. Users must validate the performance of the system in their laboratory for specific research applications.

For research use only. Not for use in diagnostic procedures. The performance characteristics of this product have not been fully established.

## Product Features

PAXgene Blood ccfDNA Tube	10.0 ml • 16 x 100 mm	1.5 ml additive	Sterile
BD Vacutainer® Plus plastic tube	BD Hemogard™ closure	100 tubes/case	768115

## II. Summary and Explanation

The PAXgene Blood ccfDNA System, which is comprised of the PAXgene Blood ccfDNA Tube and the QIAamp Circulating Nucleic Acid Kit or the QIASymphony PAXgene Blood ccfDNA Kit, provides an efficient method for standardized blood collection, transport, and storage of whole blood specimens, preservation of cells, and isolation of ccfDNA.

## III. Principle of Procedure

The PAXgene Blood ccfDNA Tube provides a means for the collection of 10.0 ml of whole blood in a closed, evacuated system. Blood is collected using standard venipuncture technique into an evacuated tube that contains 1.5 ml of cell stabilization additive for a ratio of 0.15 ml of additive per ml of blood when the evacuated tube is filled correctly. The tube contains an additive that anti-coagulates the blood and stabilizes blood cells via a non-cross-linking stabilization solution. This helps prevent the release of intracellular DNA into the plasma and stabilizes ccfDNA levels. Isolation of ccfDNA from plasma is carried out using the QIAamp Circulating Nucleic Acid Kit or the QIASymphony PAXgene Blood ccfDNA Kit.

## IV. Specimen Collection and Preparation for Analysis

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

1. Blood collection devices such as the BD Vacutainer UltraTouch™ Push Button Blood Collection Set (see Section XII Ordering Information).
2. 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. Biohazard container for used needle or needle/holder combination.

### B. Procedure for Specimen Collection



1. Ensure that the PAXgene Blood ccfDNA Tube is at room temperature (15–25°C) prior to use and properly labeled with specimen identification.
  2. Collect blood into the PAXgene Blood ccfDNA Tube using your institution's recommended procedure for standard venipuncture technique (see Section V Prevention of Backflow).
  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 ccfDNA Tube 8–10 times.
  5. Blood samples filled in PAXgene Blood ccfDNA Tubes are stable at room temperature (15–25°C) for up to 7 days or at higher temperatures (up to 35°C) for up to 1 day until centrifugation and plasma processing.
- ### C. Plasma Preparation for Analysis with the QIAamp Circulating Nucleic Acid Kit or with the QIASymphony Blood ccfDNA Kit
1. Centrifuge the PAXgene Blood ccfDNA Tube at room temperature (15–25°C) for 15 minutes at 1900 × g using a balanced centrifuge.  
Note: For optimal separation of plasma, use a swing-out rotor centrifuge.
  2. Optional: For research applications that require further purification of the plasma, perform a second centrifugation. Otherwise, continue with step 3.
    - a. Pipet the plasma into a 15 ml conical bottom centrifugation tube, making sure to not disturb the buffy coat and the cellular fraction.
    - b. Centrifuge for 10 minutes at room temperature (15–25°C) and 1900 × g using a balanced centrifuge.

Note: Do not exceed the tube manufacturer's maximum recommended centrifugation speed.

3. Process the plasma sample in accordance with the instructions provided with the QIAamp Circulating Nucleic Acid Kit or the QIASymphony PAXgene Blood ccfDNA Kit, or store the plasma in a suitable tube at  $-20^{\circ}\text{C}$  or  $-80^{\circ}\text{C}$ .

Note: For maximum ccfDNA yield, process the maximum volume of plasma available.

- a. For use with the QIAamp Circulating Nucleic Acid Kit:

Pipet the plasma into a 50 ml tube (not provided).

Note: Do not disturb the buffy coat or residual blood cell pellet at the bottom of the tube, if present.

- b. For use with the QIASymphony PAXgene Blood ccfDNA Kit:

Pipet the required plasma volume into a 14 ml,  $17 \times 100$  mm polystyrene, round-bottom tube.

Note: Do not disturb the buffy coat or residual blood cell pellet at the bottom of the tube, if present.

#### **D. Freezing and Thawing Plasma from Whole Blood Collected in the PAXgene Blood ccfDNA Tube**

1. For long-term storage, freezing plasma at  $-20^{\circ}\text{C}$  or  $-70^{\circ}\text{C}$  /  $-80^{\circ}\text{C}$  in cryogenic tubes is recommended.
2. Thaw the tubes at room temperature ( $15-25^{\circ}\text{C}$ ).

Note: Do not thaw at lower temperatures (e.g.,  $4^{\circ}\text{C}$ ).

3. If cryoprecipitates form in the plasma, vortex the tube for 30 seconds after thawing and continue according to the instructions provided with the QIAamp Circulating Nucleic Acid Kit or the QIASymphony PAXgene Blood ccfDNA Kit.

Note: Do not centrifuge the plasma to remove cryoprecipitates because they may contain ccfDNA.

Note: To avoid the formation of cryoprecipitates, tubes can be thawed for 30 minutes at  $30^{\circ}\text{C}$  instead of at room temperature.

#### **V. Prevention of Backflow**

Since PAXgene Blood ccfDNA 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. Neither the clinical utility nor the

performance characteristics of the PAXgene Blood ccfDNA 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. Plasma from blood samples obtained with the PAXgene Blood ccfDNA Tube should be prepared only with the QIAamp Circulating Nucleic Acid Kit or the QIASymphony PAXgene ccfDNA Kit.
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.

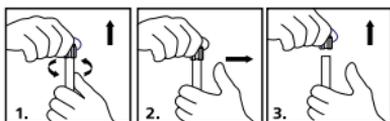
## VII. Warnings and Precautions

1. Contents of this tube may cause irritation to the eyes and skin.
  - After skin contact, wash skin with soap and water. Get medical attention if irritation persists after washing.
  - After eye contact, flush eyes with water as a precaution. If irritation occurs, get medical assistance.
  - After swallowing, rinse mouth. Get medical attention if any discomfort occurs.
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 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.
4. Discard all blood collection tubes and accessories in biohazard containers approved for their disposal.
5. Do not re-use PAXgene Blood ccfDNA Tubes.
6. Do not use PAXgene Blood ccfDNA Tubes after expiration date printed on tube label.
7. Since this PAXgene Blood ccfDNA Tube contains a liquid additive, precautions should be taken to prevent possible backflow from the tube during blood drawing (see Section V Prevention of Backflow).
8. Transferring a blood sample collected with a syringe and needle into the PAXgene Blood ccfDNA Tube is not recommended due to the increased potential for both needlestick injury and incorrect blood to additive ratio.

## VIII. Storage

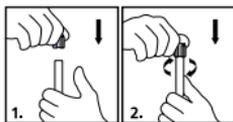
Store the unused PAXgene Blood ccfDNA Tubes at room temperature (15–25°C). Do not use tubes after their expiration date.

## IX. Instructions for Removal of BD Hemogard Closure



1. Grasp the PAXgene Blood ccfDNA 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. Reinsertion of BD 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.

## XI. Technical Assistance

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

## XII. Ordering Information

### PAXgene Products

#### PAXgene Blood ccfDNA Tube / 768115

Content: 100 blood collection tubes.

Use with the QIAamp Circulating Nucleic Acid Kit (50) (Cat. No. 55114) or the QIASymphony PAXgene Blood ccfDNA Kit (192) (Cat. No. 768536).

**QIASymphony PAXgene Blood ccfDNA Kit (192) / 768536**

For 192 preps of up to 2.4 or 4.8 ml human plasma each: Includes 2 reagent cartridges and enzyme racks and accessories. Use with the PAXgene Blood ccfDNA Tube.

**To order PAXgene Blood ccfDNA Tubes or Kits:**

Go to: <http://www.preanalytix.com/products/blood/ccfDNA>

**BD Products\*****BD Vacutainer UltraTouch Push Button Blood Collection Set / 367364**

Content: 23G 3/4 inch (0.6 × 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 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 ccfDNA 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 Products****QIAamp Circulating Nucleic Acid Kit (50) / 55114**

QIAamp Mini Columns, Tube Extenders (20 ml), QIAGEN Proteinase K, Carrier RNA, Buffers, VacConnectors, and Collection Tubes (1.5 ml and 2 ml).

**To order QIAGEN circulating DNA preparation kits:**

Go to: <http://www.qiagen.com/Products/Ordering-Information/>

## **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

### **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

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Orders: 0800.444.5523  
E-mail: crc\_argentina@bd.com

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

**Austria**

Orders: 43.1.706.36.60  
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**Belgium**

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

**Brazil**

Orders: 0800.055.56.54  
E-mail: consultoria\_vacutainer@bd.com

**Canada**

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Fax: 800.565.0897  
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Hungary orders: info\_hungary@europe.bd.com  
Poland orders: info\_poland@europe.bd.com  
Romania orders: info\_romania@europe.bd.com  
Southeast Europe orders: info\_balkan@europe.bd.com

**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

Serbia orders: info\_serbia@europe.bd.com  
Slovakia orders: info\_slovakia@europe.bd.com  
Slovenia orders: info\_slovenia@europe.bd.com

**Denmark**

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

**Finland**

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Fax: 358.9.88.70.7816  
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E-mail: bdsuomi@europe.bd.com

**France**

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

**Germany**

Orders: 49.6221305553  
Fax: 49.6221305379  
E-mail: customerservice.vac.ga@europe.bd.com

**Italy**

Orders: 39.02.48240.500  
Fax: 39.02.40.91.80.11  
Technical: 39.335.424388  
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 service: 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

Fax: 800.847.2220

Technical: 800.631.0174

E-mail: [www.bd.com/vacutainer/contact/](http://www.bd.com/vacutainer/contact/)

## Symbol and Mark Key

	Batch Code		Do Not Reuse
	Method of Sterilization Using Irradiation		Manufacturer
	Catalog Number		Recyclable
	Keep Away from Sunlight		Contains sufficient for <n> tests
	Temperature Limitation		Use By

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

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