



A QIAGEN / BD Company



PAXgene[®]

Blood ccfDNA Tube

For Research Use Only

Not for use in diagnostic procedures

REF 768115

STERILE R



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. In addition, genomic DNA (gDNA) can be isolated from the remaining buffy coat or nucleated cellular fraction after plasma removal.

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 and gDNA. It contains a stabilization additive without formaldehyde or formaldehyde releasing substances. High quality ccfDNA can be isolated from the plasma fraction for use in downstream analytical assays when the tube is used in conjunction with the QIASymphony PAXgene Blood ccfDNA Kit or QIAGEN ccfDNA isolation kits (QIAamp® Circulating Nucleic Acid Kit, QIAamp MinElute® ccfDNA Kits, EZ1® ccfDNA Kits).

Direct sampling of the plasma from the PAXgene Blood ccfDNA Tube on the QIASymphony SP is possible to reduce risk of sample mix up, processing time and material costs.

The remaining buffy coat, a leukocyte and platelet rich layer at the interface of plasma and red blood cell fractions, can be harvested and used to isolate gDNA using manual or automated methods that are based on magnetic bead or silica membrane technologies for DNA isolation.

This product was developed in accordance with the European Committee for Standardization Standard ISO 20186-3, *Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for venous whole blood — Part 3: Isolated circulating cell free DNA from plasma*.

The system performance has been established in studies in which ccfDNA and gDNA is purified from human plasma and cellular fraction 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 • 768115
10.0 mL draw volume
Safety-engineered BD Hemogard™ closure

RUO • Sterile • 100 tubes/case
16 x 100 mm tube • 1.5 mL liquid additive
Blue stopper • Pearlescent shield

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 collection, transport, and storage of whole blood specimens, preservation of cells, and isolation of ccfDNA from the plasma fraction. After plasma removal, gDNA can be isolated from the remaining buffy coat or nucleated cellular fraction.

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 without formaldehyde and formaldehyde releasing substances 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 QIASymphony PAXgene Blood ccfDNA Kit or QIAGEN ccfDNA isolation kits (QIAamp Circulating Nucleic Acid Kit, QIAamp MinElute ccfDNA Kits, EZ1 ccfDNA Kits).

IV. Specimen Collection and Processing

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. BD Vacutainer Tube Holder (see Section XII Ordering Information).
3. Labels for positive specimen identification.
4. Alcohol swab for cleansing site.
5. Dry sterile gauze.
6. Tourniquet.
7. Biohazard container for used needle or needle/holder combination.

B. Recommended Order of Draw

When using a single venipuncture to collect multiple tubes with different additives, follow the recommended tube order of draw per CLSI GP41, 7th ed. Collection of Diagnostic Venous Blood Specimens. PAXgene Blood ccfDNA Tubes should be collected last to avoid possible test result error due to additive carryover.

1. Tubes for sterile samples.
2. Tubes for coagulation studies (e.g., citrate).
3. Serum tubes with or without gel and clot activator.
4. Tubes with heparin additives.
5. Tubes with other additives (e.g., EDTA, fluoride).
6. PAXgene Blood ccfDNA Tube.

C. 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.



D. Procedure for Specimen Collection

1. Ensure that the PAXgene Blood ccfDNA Tube is at room temperature (15–25°C) prior to use.
2. Collect blood into the PAXgene Blood ccfDNA Tube using your institution's recommended procedure for standard venipuncture technique. In addition, follow instructions for Prevention of Backflow in Section IV.C.
3. Fill the tube to its maximum stated draw volume. Continue blood collection until vacuum is exhausted and 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 times to mix the blood with the additive. One complete inversion is defined as turning the filled tube upside-down, and then returning it to an upright position.
5. Store the filled PAXgene Blood ccfDNA Tube at room temperature (15–25°C).
See Performance Characteristics for ccfDNA stability and gDNA yield and purity in blood samples at room temperature (15–25°C), 30°C or 37°C.

E. Plasma Preparation Isolation of ccfDNA

1. Centrifuge the PAXgene Blood ccfDNA Tube at room temperature (15–25°C) for 15 minutes at 1600–3000 × g using a balanced swing out bucket centrifuge. If braking is preferred, it is recommended to use medium level braking, but should be validated for your specific workflow.
2. Pipet the plasma into a 15 mL conical bottom centrifugation tube, making sure to not disturb the buffy coat and the cellular fraction.
Optional second centrifugation: For applications that require further purification of the plasma, centrifuge for 10 minutes at room temperature (15–25°C) and 1600–3000 × g using a balanced centrifuge. Pipet the plasma into a 15 mL conical bottom centrifugation tube, making sure to not disturb the residual blood cell pellet, if present.
Note: Do not exceed the secondary tube manufacturer's maximum recommended centrifugation speed.
3. Process the plasma sample in accordance with the instructions provided with the ccfDNA sample preparation kit, or freeze the plasma (see Section IV.F. Freezing and Thawing Plasma).
Note: For maximum ccfDNA yield, process the maximum volume of plasma available.
Note: Do not disturb the buffy coat or residual blood cell pellet at the bottom of the tube, if present.
Note: When comparing ccfDNA yield to other blood collection tubes, take into account the dilution of the plasma by the PAXgene Blood ccfDNA Tube additive. If similar input volumes of blood are used, ccfDNA yields will be similar to plasma from a spray-dried K₂EDTA tube separated directly after blood draw. For more information, contact Technical Support.
 - a. For use with the QIAamp Circulating Nucleic Acid Kit:
Pipet the plasma into a 50 mL tube (not provided).
 - b. For use with the QIASymphony PAXgene Blood ccfDNA Kit:
Pipet the required plasma volume into a 14 mL, 17 × 100 mm polystyrene, round-bottom tube.
Note: For direct sampling of the plasma from the PAXgene Blood ccfDNA Tube on the QIASymphony SP, contact QIAGEN technical services to request a customized protocol.
 - c. For use with QIAamp MinElute ccfDNA Mini or Midi Kits or E21 ccfDNA Mini or Midi Kits:
Pipet the plasma into a 15 mL tube (not provided).

F. Freezing and Thawing Plasma

1. For long-term storage, aliquot and freeze plasma at –20°C or –70°C / –80°C in cryogenic tubes is recommended.
2. Thaw aliquot tubes at room temperature (15–25°C).
Note: Do not thaw at lower temperatures (e.g., 4°C).

- If cryoprecipitates form in the plasma, vortex the tube for 30 seconds after thawing and continue according to the instructions provided with the ccfDNA isolation kit.

Note: It is not recommended to 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°C instead of at room temperature.

G. Isolation of gDNA

After transferring plasma for ccfDNA isolation, the remaining buffy coat or nucleated cellular fraction can be used to isolate gDNA, if desired. Buffy coat samples can be aspirated and processed in accordance with the buffy coat processing instructions provided with the DNA sample preparation kit. Kit examples are provided in Section XII. Ordering Information.

H. Freezing and Thawing the Nucleated Cellular Fraction

- Stand the PAXgene Blood ccfDNA Tube upright in a wire rack. Do not freeze tubes upright in an expanded polystyrene (EPS) tray as this may cause the tubes to crack.
- The PAXgene Blood ccfDNA Tubes can be stored at -20°C and below. If tubes are to be kept at temperatures below -20°C, freeze them first at -20°C for 24 hours, then transfer them to -70°C or -80°C.
- Thaw the PAXgene Blood ccfDNA Tubes in a wire rack at room temperature (15–25°C).
- Carefully invert the thawed PAXgene Blood ccfDNA Tubes 10 times.

Note: The frozen PAXgene Blood ccfDNA 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 the PAXgene Blood ccfDNA Tubes.

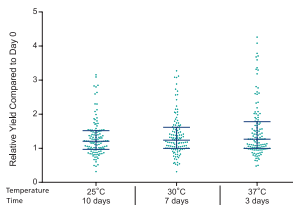
V. Performance Characteristics

A. ccfDNA Performance:

The performance characteristics of the PAXgene Blood ccfDNA Tube for ccfDNA stability were established using two validated qPCR assays (targeting 18S rDNA and DYS14 Y-chromosomal DNA sequences).

After blood is collected into the tube, the ccfDNA remains stable in whole blood for up to 10 days at temperatures up to 25°C. Based on ccfDNA stability studies, blood can be stored in the tube for up to 10 days at temperatures up to 25°C, 7 days at temperatures up to 30°C, or 3 days at temperatures up to 37°C (Figure 1).

Figure 1. ccfDNA Relative Yield for Blood Samples Stored in the PAXgene Blood ccfDNA Tube



Change in plasma ccfDNA yield after whole blood sample storage in comparison to plasma separated within 2 hours of blood collection (Day 0). Blood was drawn from a donor pool of approximately 200 consented, apparently healthy adult subjects and stored at various temperatures for the indicated number of days followed by tube centrifugation and ccfDNA purification from plasma using the QIAsymphony PAXgene Blood ccfDNA Kit on the QIAGEN QIAsymphony instrument. The relative ccfDNA yield was calculated as the ratio of the 18S rDNA CT value after sample storage compared to the CT value at Day 0. Medians and the 25th and 75th percentiles are denoted with box plots.

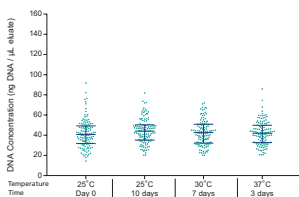
Table 1: Performance testing summary (automated, magnetic bead-based ccfDNA purification)

	Relative Yield Compared to EDTA Plasma at Day 0	Relative Yield (In Situ Stability) Compared to Day 0		
		Day 10, 25°C	Day 7, 30°C	Day 3, 37°C
n	120	120	120	120
Mean ± SD	0.92 ± 0.26	1.30 ± 0.54	1.37 ± 0.59	1.52 ± 0.81
Median	0.93	1.21	1.24	1.27
Interquartile range	0.74–1.05	0.97–1.52	1.00–1.62	1.00–1.78
Range	0.26–1.87	0.32–3.15	0.31–3.27	0.48–4.26
95% of samples	0.33–1.50	0.51–2.86	0.50–3.15	0.59–4.82

B. gDNA Performance

The performance characteristics of the PAXgene Blood ccfDNA Tube for gDNA were established measuring integrity, concentration, and purity.

After blood is collected into the tube, the gDNA remains stable in whole blood for up to 10 days at temperatures up to 25°C. Based on gDNA stability studies, blood can be stored in the tube for up to 10 days at temperatures up to 25°C, 7 days at temperatures up to 30°C, or 3 days at temperatures up to 37°C (Figure 2).

Figure 2. gDNA Concentration for Blood Samples Stored in the PAXgene Blood ccfDNA Tube

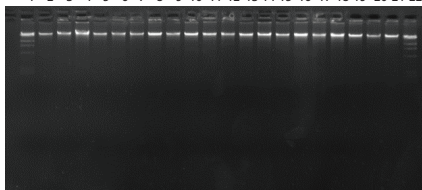
gDNA Concentration, Yield, and Purity using an Automated, Magnetic Bead-Based DNA Purification System: Blood was drawn from a donor pool of approximately 200 consented, apparently healthy adult subjects into PAXgene Blood ccfDNA Tubes. Tubes were centrifuged within 2 hours of blood collection, and an aliquot was extracted from 400 μ L of nucleated cellular fraction for processing. The remaining sample in each tube were stored at 25°C, 30°C, or 37°C for the indicated number of days. DNA was purified from 180 specimens using the QIAAsymphony DSP DNA Mini Kit (elution volume: 400 μ L) on the QIAGEN QIAAsymphony instrument. Medians and the 25th and 75th percentiles are denoted with box plots.

Table 2: Performance testing summary (automated, magnetic bead-based DNA purification)

	Yield (μg DNA / 400 μL input sample volume)				Purity (A_{260}/A_{280})			
	Day 0	Day 10, 25°C	Day 7, 30°C	Day 3, 37°C	Day 0	Day 10, 25°C	Day 7, 30°C	Day 3, 37°C
n	120	120	120	120	120	120	120	120
Mean \pm SD	16.61 \pm 5.54	17.80 \pm 4.95	17.03 \pm 4.95	16.80 \pm 4.76	1.83 \pm 0.07	1.84 \pm 0.06	1.84 \pm 0.07	1.85 \pm 0.06
Median	16.30	17.62	17.04	16.82	1.83	1.84	1.82	1.84
Interquartile range	12.73– 19.69	14.08– 20.12	12.93– 20.34	13.06– 19.95	1.79– 1.86	1.80– 1.88	1.79– 1.87	1.81– 1.88
Range	5.74–36.68	8.08–32.76	8.02–28.82	8.18–34.34	1.58–2.02	1.74–2.05	1.68–2.09	1.71–2.05
95% of samples	\geq 8.27	\geq 9.89	\geq 9.19	\geq 9.34	1.68–1.98	1.71–1.98	1.69–1.98	1.71–1.98

Figure 3. gDNA Integrity after Storage

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22



Blood was drawn from 20 consented, apparently healthy adult subjects into PAXgene Blood ccfDNA Tubes. Total gDNA was purified from 400 μL of nucleated cellular fraction using the QIAasympphony DSP DNA Mini Kit (elution volume: 400 μL) on the QIAGEN QIAasympphony instrument. For each subject, 400 ng gDNA was

separated by agarose gel electrophoresis (lanes 2–21). In lane 1 and 22, a Lambda x Hind III marker was loaded. The upper band of this marker represents a DNA fragment of 23 kb. The image shows gDNA isolation after storage at 30°C for 7 days. The data for all other time and temperature processing conditions are similar.

VI. Limitations

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 should be approximately 10.0 mL per PAXgene Blood ccfDNA Tube, but this volume may vary depending on various factors such as altitude, ambient temperature, barometric pressure, tube age, venous pressure, and filling technique.
3. The PAXgene Blood ccfDNA Tube is not designed for use with open blood collection systems (manual filling of tube with the BD Hemogard closure removed) due to the increased risk of blood exposure and risk of causing incorrect blood-to-additive ratio that may affect product performance. Blood should be collected directly into the tube, or a transfer device should be used if blood is collected and transferred from a syringe.
4. ccfDNA and gDNA yields depend on the patient, the quality of the specimen, and the method used for isolation.

VII. Warnings and Precautions

A. Precautions:

1. Examine tubes prior to use. Do not use tubes if foreign matter is present inside the tube.
2. Since this PAXgene Blood ccfDNA Tube contains a liquid additive, precautions should be taken to prevent possible backflow from the tube during blood draw (see Section IV.C. Prevention of Backflow).
3. Do not shake vigorously since this may cause hemolysis.
4. If tubes are not mixed 8 times immediately after collection, clotting of blood or fibrin formation may occur. This may also reduce effectiveness of blood stabilization that requires mixing with the additive immediately upon collection for best performance.
5. Remove BD Hemogard closures with a twist and pull motion. Removal by rolling with the thumb is not recommended (for detailed instructions see Section IX. Removal of BD Hemogard Closure).
6. After venipuncture, the top of the stopper may contain residual blood. Take proper precautions when handling tubes to avoid contact with this blood.
7. Under-filling of PAXgene Blood ccfDNA Tubes will result in an incorrect blood-to-additive ratio and may lead to incorrect analytical results or poor product performance.
8. Endotoxin is not controlled. Blood and blood components collected and processed in the tube are not intended for infusion or introduction into the human body.

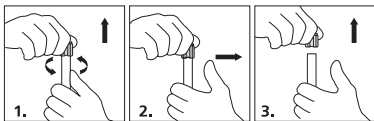
B. Warnings:

1. The liquid additive in this tube is a mild irritant and may cause irritation to the eyes and skin upon direct contact:
 - 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. A blood collection set must be used with the PAXgene Blood ccfDNA Tube (see Section XII. Ordering Information).
5. Excessive centrifugation speed (over 10,000 × g) may cause PAXgene Blood ccfDNA Tube breakage, exposure to blood and possible injury.
6. Transferring a blood sample from a syringe with a needle into the PAXgene Blood ccfDNA Tube is not recommended due to the increased risk for both needlestick injury and incorrect blood-to-additive ratio.
7. If blood is collected from 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 test results due to I.V. fluid contamination.
8. After use, discard all blood collection tubes and accessories in biohazard containers approved for their disposal.
9. Do not reuse the PAXgene Blood ccfDNA Tubes.
10. Do not use the PAXgene Blood ccfDNA Tubes after the expiration date printed on the tube label.

VIII. Storage

Store the unused PAXgene Blood ccfDNA Tubes at 4–25°C. Brief temperature excursions from –10°C to 50°C are permitted. The PAXgene Blood ccfDNA Tube additive may have a slightly yellow appearance; this does not affect the performance of the additive. Do not use tubes after their expiration date.

IX. Removal of BD Hemogard Closure

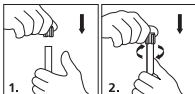


1. Grasp the PAXgene Blood ccfDNA Tube with one hand, placing the thumb under the BD Hemogard closure (for added stability, place arm on solid surface). With the other hand, twist the BD Hemogard closure while simultaneously pushing up with

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. If the tube contains blood, an exposure hazard exists.
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 Tube, go to: support.qiagen.com.

XII. Ordering Information

PAXgene Products

PAXgene Blood ccfDNA Tube / 768115

Content: 100 blood collection tubes.

10.0 mL • 16 × 100 mm

BD Hemogard closure

1.5 mL additive

100 tubes/case

Sterile

RUO

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: www.preanalytix.com

BD Products*

BD Vacutainer UltraTouch Push Button Blood Collection Set / 367364

Content: 21G 3/4 inch (0.6 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 x 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. 1,000/case

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

For more information on BD Blood Collection Accessories:

Go to: www.bd.com

QIAGEN Products*

For ccfDNA Isolation:

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).

QIAamp MinElute ccfDNA Kits (50) / 55204 Mini / 55284 Midi

QIAamp UCP MinElute Columns, QIAGEN Proteinase K, Magnetic Bead Suspension, buffers, bead elution tubes, collection tubes

EZ1 ccfDNA Kits (48) / 954134 Mini / 954154 Midi

Reagent cartridges, QIAGEN Proteinase K, Magnetic Bead Suspension, buffers, bead elution tubes, disposable tips

To order QIAGEN circulating DNA preparation kits:

Go to: www.qiagen.com/shop

For Genomic DNA Isolation:

QIASymphony DSP DNA Mini Kit (192) / 937236

2 reagent cartridges and enzyme racks and accessories.

** These catalog numbers represent typical sample preparation kits that can be used with the PAXgene Blood ccfDNA Tube.*

To order QIAGEN DNA preparation kits:

Go to: www.qiagen.com/shop

QIAGEN – Customer Service

Ordering www.qiagen.com/shop | Technical Support support.qiagen.com | www.qiagen.com

BD – Customer Service

Argentina, Uruguay, and Paraguay

Orders: 0800.444.5253

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

E-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:

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:

bddenmark@bd.com

Finland

Orders: 358.9.88.70.780

Fax: 358.9.88.70.7816

Orders: tilaukset.fi@bd.com

E-mail: bdsuomi@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

E-mail: customercare.de@bd.com

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

E-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

Middle East & Africa

Orders: 971.45.592.555

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

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

Orders: 46.8.775.51.00

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

E-mail: infoch@bd.com

UK

Orders: 0800.917.8776

E-mail:

bduk_customerservice@bd.com

USA

Customer support: 800.631.0174

or www.bd.com.

E-mail: productcomplaints@bd.com












Change History

Revision	Date	Change Summary
02	2016-07	<p>Updated to include compatibility with the QIAasympphony PAXgene Blood ccfDNA Kit.</p> <p>Updated Research Use Only disclaimer in Section I.</p> <p>Updated blood collection drawings, plasma preparation procedure, and freezing and thawing procedure in Section IV.</p> <p>Updated first aid measures (1.) and added expiration date precaution (6.) to Warnings and Precautions in Section VII.</p> <p>Added expiration date statement in Section VIII.</p> <p>Updated PAXgene and BD product lists in Section XII.</p>
03	2019-12	<p>Updated the Introduction, Summary and Explanation, and Principle of Procedure in Sections I. -III.</p> <p>Added Recommended Order of Draw, Isolation of gDNA, and Freezing and Thawing the Nucleated Cellular Fraction to Section IV.</p> <p>Updated the Procedure for Specimen Collection, Plasma Preparation Isolation of ccfDNA and Freezing and Thawing Plasma procedures in Section IV.</p> <p>Added Section V. Performance Characteristics.</p> <p>Updated Limitations, Warnings and Precautions and Storage in Sections VI. -VIII.</p> <p>Updated technical assistance contact information in Section XI.</p> <p>Updated QIAGEN product list in Section XII.</p> <p>Added PreAnalytiX patent website.</p>
04	2023-10	<p>Updated PreAnalytiX GmbH street address.</p> <p>Added ISO symbols: 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.</p> <p>Added REF symbol and catalog number to cover page.</p> <p>Updated customer service information.</p> <p>Updated formatting and Symbols Glossary.</p> <p>Updated trademark information.</p>

SYMBOLS GLOSSARY

Please refer to product labeling for applicable symbols.

Note: Text layout in symbols is determined by label design.

Symbol	Meaning
	Manufacturer
	Catalogue number
	Sterilized using irradiation
	Do not use if package is damaged and consult instructions for use
	Keep away from sunlight
	Keep dry
	Temperature limit
	Do not re-use
	Consult instructions for use or consult electronic instructions for use
	Caution
	Single sterile barrier system



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

Patent: www.preanalytix.com/patents

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