

Fresh Specimen Collection Tube 2 Pack

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PN-00107

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INTENDED USE

The Fresh Specimen Collection Tube 2 Pack consists of one (1) PAXgene Blood RNA Tube and one (1) EDTA Tube. The PAXgene Blood RNA Tube is intended for the collection, storage, and transportation of peripheral whole blood specimens, and for the stabilization of intracellular RNA in a closed tube and subsequent isolation and purification of intracellular RNA from whole blood in molecular testing. The EDTA Tube is intended for the collection, storage, and transportation of peripheral whole blood and bone marrow aspirate specimens for testing in the clinical laboratory.

PRINCIPLE OF OPERATION

The Fresh Specimen Collection Tube 2 Pack is a package of one (1) PAXgene Blood RNA Tube and one (1) EDTA Tube designed to be used to collect peripheral whole blood or bone marrow aspirate specimens.

The PAXgene Blood RNA Tube contains an additive that stabilizes the *in vivo* gene transcription profile by reducing post-collection RNA degradation and minimizing gene induction and repression.

The EDTA Tube (lavender top) contains spray-coated di-potassium EDTA (K₂EDTA), a common anticoagulant used in the preservation of whole blood and bone marrow aspirate specimens.

LIMITATIONS

- For *In vitro* diagnostic use.
- For Professional Use Only.
- Under-filling of the PAXgene Blood RNA Tubes will result in an incorrect blood-to-additive ratio and may lead to incorrect analytic results or poor product performance.
- The PAXgene Blood RNA Tube is not suitable for the collection and purification of viral RNA.
- The quantity of blood drawn should be 2.5 ml per PAXgene Blood RNA Tube, but this volume might vary with altitude, ambient temperature, barometric pressure, tube age, venous pressure, and filling technique.
- Endotoxin not controlled. Blood and blood components collected and processed in the tube are not intended for infusion or introduction into the human body.
- The quantity of blood or bone marrow aspirate drawn in the EDTA Tube 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.

MATERIALS AND METHODS

Materials Provided

The package contains:

Component	Description
PAXgene Blood RNA Tube (CE PreAnalytiX GmbH)	A plastic single-use blood collection tube with its vacuum designed to draw 2.5 mL of blood into the tube; designed to be used in conjunction with standard phlebotomy equipment to collect whole blood by venipuncture.
EDTA Tube (CE Becton, Dickinson and Company)	An evacuated plastic single-use fluid collection tube with color-coded (lavender top) BD Hemogard™ Closures and 10 mL liquid capacity; spray-coated with K ₂ EDTA; designed to be used in conjunction with standard phlebotomy equipment to collect whole blood by venipuncture.

Materials Required But Not Provided

- Disposable gloves and personal protective equipment
- Blood collection needles and multi-tube collection devices for 16 mm X 100 mm tubes
- Specimen collection needles and syringes for bone marrow aspiration
- Alcohol swab for cleansing site
- Tourniquet
- Gauze pads
- Bandage

- Sharps disposal container for disposal of used materials
- A "Discard Tube" if the PAXgene Blood RNA Tube is the only tube being drawn

Storage and Handling

- The Fresh Specimen Collection Tube 2 Pack should be stored between 4-25°C. Do not use tubes after their expiration date.
- The PAXgene Blood RNA Tube will maintain its performance characteristics after storage at temperatures of 4-25°C. Limited excursion temperatures up to 40°C are permitted.
- The EDTA Tube should be stored at 4-25°C, unless otherwise noted on the package label. EDTA spray coated additives may have a white to slightly yellow appearance; this does not affect the performance of the EDTA additive.

WARNINGS AND PRECAUTIONS OF PAXGENE BLOOD RNA TUBE

- Do not use products after their expiration date.
- Contents of this tube are irritating to skin.
 - After inhalation, supply fresh air: consult doctor in case of complaints.
 - After skin contact, immediately wash with water and soap, and rinse thoroughly.
 - After eye contact, rinse opened eye for fifteen minutes under running water, then consult a doctor.
 - After swallowing, immediately call a doctor.
- A blood collection set must be used with the PAXgene Blood RNA Tube.
- Handle all biologic samples and blood collection devices 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 needle stick injury), since they may transmit viral hepatitis, HIV (AIDS), or other infectious diseases. Utilize any built-in needle protector, if the blood collection set provides one. Reshielding used needles is not recommended. However, the policies and procedures of your facility may differ and must always be followed.
- Discard all blood collection tubes in accordance with the policies and procedures of your facility.
- Practice universal precautions. Use protective personal equipment and other engineering controls to protect from blood splatter, blood leakage, and potential exposure to blood borne pathogens.
- Do not re-use the tube.
- Since the PAXgene Blood RNA Tube contains a chemical additive, a blood collection set must be used for blood collection to prevent possible backflow from the tube.
- Excessive centrifugation speed (over 10,000 RCF) may cause PAXgene Blood RNA Tube breakage, exposure to blood and possible injury.
- Do not transfer a sample from a syringe to the PAXgene Blood RNA Tube.
- The tube contains: (+)-Tartaric acid (2%-4% by weight), Tetradecyltrimethylammonium oxalate (<10% by weight)

Hazard pictograms:



Singal word: Danger

Hazard Statements:

- H315 Causes skin irritation
- H318 Causes serious eye damage
- H317 May cause an allergic skin reaction
- H411 Toxic to aquatic life with long lasting effects

Precautionary statements:

- Prevention
 - P280 Wear protective gloves/eye protection/face protection
- Response
 - P302 + P352 IF ON SKIN: Wash with plenty of water
 - P333 + P313 If skin irritation or rash occurs: Get medical advice/attention
 - P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 - P310 Immediately call a POISON CENTER/doctor.

Storage

- Store away from incompatible materials.

Disposal

- P501 Dispose of contents/container in accordance with local/regional/national/international regulations

Fresh Specimen Collection Tube 2 Pack

- Safety Data Sheet (SDS) is available at: https://www.preanalytix.com/storage/download/PAXgene_Blood_RNA_Tube_IVD/SafetyDataSheets/902124-02_VS60342_SDS_Blood_RNA_TubeIVD_0415_EN_UK.pdf

WARNINGS AND PRECAUTIONS OF EDTA TUBE

- Do not use products after their expiration date.
- Do not remove conventional rubber stoppers by rolling with thumb. Remove stoppers with a twist and pull motion.
- Do not use tubes if foreign matter is present.
- 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.
- 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. Reshielding used needles is not recommended. However, the policies and procedures of your facility may differ and must always be followed.
- Overfilling or under filling of tubes will result in an incorrect blood-to-additive ratio and may lead to incorrect analytic results or poor product performance.
- Endotoxin not controlled. Blood and blood components collected and processed in the tube are not intended for infusion or introduction into the human body.

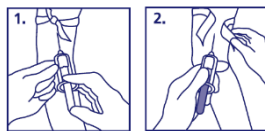
INSTRUCTIONS FOR USE

General guidelines for specimen collection can be found in Clinical and Laboratory Standards Institute (CLSI) H3-A6, Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture¹.

If the submitted specimen is Peripheral Whole Blood, fill the EDTA tube *before* the PAXgene Blood RNA tube.

If the submitted specimen is Bone Marrow Aspirate, fill *only* the EDTA tube with 2.5 mL of the Bone Marrow Aspirate. The PAXgene Blood RNA tube is not required.

Collecting Whole Blood Specimen in EDTA Tube



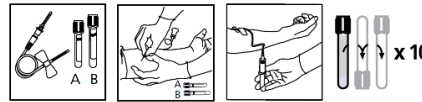
1. Assemble needle in holder. Be sure needle is firmly seated to ensure needle does not unthread during use.
2. Place tube into holder. Note: Do not puncture stopper.
3. Select site for venipuncture.
4. Apply tourniquet. Prepare venipuncture site with an appropriate antiseptic. **DO NOT PALPATE VENIPUNCTURE AREA AFTER CLEANSING.**
5. Place patient’s arm in a downward position.
6. Remove needle shield. Perform venipuncture **WITH ARM DOWNWARD AND TUBE STOPPER UPPER-MOST.**
7. Center tubes in holder when penetrating the stopper to prevent sidewall penetration and resultant premature vacuum loss. Push tube onto needle, puncturing stopper diaphragm.
8. **REMOVE TOURNIQUET AS SOON AS BLOOD APPEARS IN TUBE.**
9. When first tube has filled to its stated volume and blood flow ceases, remove it from holder.
10. Place succeeding tubes in holder, puncturing diaphragm to begin flow.
11. As soon as blood stops flowing in the last tube, remove tube from holder, remove needle from vein, applying pressure to puncture site with dry sterile swab until bleeding stops.
12. Once clotting has occurred, apply bandage if desired.

13. After venipuncture, the top of the stopper may contain residual blood. Take proper precautions when handling tubes to avoid contact with this blood.
14. Dispose of needle and holder per your facility’s policy and guidelines.
15. Store or transport specimens under recommended conditions.

Collecting Bone Marrow Aspirate Specimen in EDTA Tube

1. Follow your facility’s established procedures to collect bone marrow aspirate and transfer 2.5 mL in one EDTA tube.
2. Store or transport specimens under recommended conditions.

Collecting Specimen in PAXgene Blood RNA Tube

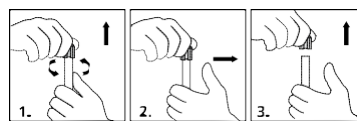


Draw Order:
Tube A - Discard Tube
Tube B - PAXgene Blood RNA Tube

1. Ensure that the PAXgene Blood RNA Tube is at 18–25°C prior to use and properly labeled with specimen identification.
2. The PAXgene Blood RNA Tube should be the last tube drawn in the phlebotomy procedure. If the PAXgene Blood RNA Tube is the only tube to be drawn, blood should be drawn into a “Discard Tube” prior to drawing blood into the PAXgene Blood RNA Tube so the interior volume of the blood collection set used during phlebotomy can be primed.
3. Using a blood collection set and a tube holder, collect blood into the PAXgene Blood RNA Tube using your institution’s recommended procedure for standard venipuncture technique. The following techniques shall be used to prevent possible backflow:
 - a. Place donor’s arm in a downward position.
 - b. Hold tube in a vertical position, below the donor’s arm during blood collection.
 - c. Release tourniquet as soon as blood starts to flow into tube.
 - d. Make sure tube additives do not touch stopper or end of the needle during venipuncture.
4. Allow at least 10 seconds for a complete blood draw to take place. Ensure that the blood has stopped flowing into the tube before removing the tube from the holder. The PAXgene Blood RNA Tube with its vacuum is designed to draw 2.5 ml of blood into the tube.
5. Immediately after blood collection, gently invert the PAXgene Blood RNA Tube 8–10 times.
6. Store the PAXgene Blood RNA Tube upright at room temperature (18–25°C) for a minimum of 2 hours before proceeding to shipment.

Instructions for Removal of BD Hemogard™ Closure

1. Grasp the PAXgene Blood RNA 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.



NAME AND ADDRESS OF THE LEGAL MANUFACTURER

The PAXgene Blood RNA Tube is manufactured and sterilized by:
PreAnalytiX GmbH
Feldbachstrasse

Fresh Specimen Collection Tube 2 Pack

8634 Hombrechtikon
Switzerland

The EDTA Tube is manufactured and sterilized by:

Becton, Dickinson and Company
Belliver Industrial Estate, Belliver Way
Roborough, Plymouth PL6 7BP
United Kingdom

ORDERING INFORMATION

Please contact Roche Foundation Medicine customer service.












REFERENCES


¹Clinical and Laboratory Standards Institute. H3-A6, Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard-Sixth Edition.

INTELLECTUAL PROPERTY


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GLOSSARY OF HARMONIZED SYMBOLS

	Temperature limit		Batch code (Lot)
	Use-by-date		Item number
	Do not reuse		Manufacturer
	<i>In-vitro</i> diagnostic medical device		Consult Instructions For Use
	Sterilized using radiation		Authorized representative in the European Community
	Contains sufficient for <n> tests		




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