

CTC Liquid Biopsy Blood Collection Kit

REF **FM-000107**



INDICATIONS AND USAGE

The CTC Liquid Biopsy Blood Collection Kit is intended for the collection and transportation of whole peripheral blood to be processed for Epic Sciences, Inc. laboratory testing. This product is intended for in-vitro use.

MATERIALS AND METHODS

Kit Contents

One 10mL Blood Tube	One Insulated Canister & Cap
One Conical Tube & Cap	One Phlebotomist Label Set
One Absorbent Sleeve	One Clinical Pack Mailer Bag

Materials Required but Not Provided

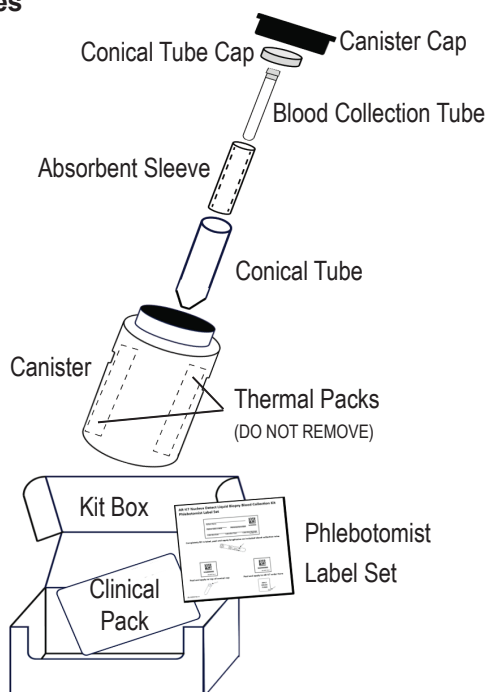
Material required for venipuncture whole blood collection (Sterile blood draw needle, tourniquet, alcohol wipes, and gauze.) A 21G or 22G needle is recommended by the blood tube manufacturer.

Storage and Handling

- When stored at room temperature (15°C to 30°C), the kit is stable through the labeled expiration dating on the bottom of the kit box (same expiration date as the blood collection tube).
- The kit with blood sample should be stored at room temperature (15°C-30°C) pending shipment pickup.
- Samples should be received by the lab within 72 hours of blood draw. Overnight shipping using the included Clinical Pack is recommended.
- The glass blood collection tube has the potential for breakage, precautionary measures should be taken during handling of the glass tube.
- The kit contains two thermal packs to maintain proper sample transportation temperatures. Do not remove the thermal packs from the canister.

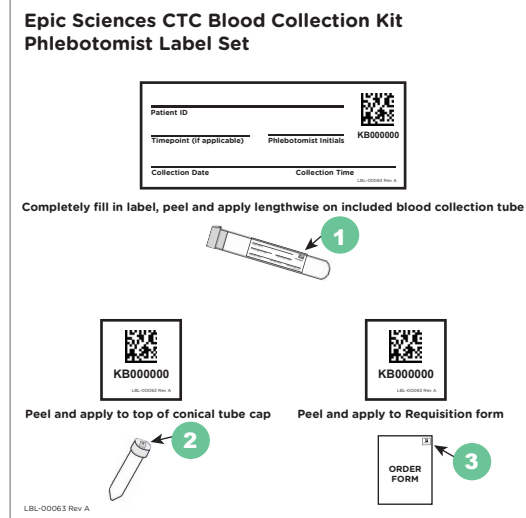
INSTRUCTIONS FOR USE

Kit Features



Preparing the Kit for Use

- Open the collection kit and inspect the blood collection tube for damage and verify the expiration dating.
 - Do not remove thermal packs or discard any items.
 - Do not mix components between kits.
- Complete the Sample Requisition form, fill out the blood tube label and apply all (3) phlebotomists labels as specified. Accuracy and completeness of the requisition form and tube label information including two patient identifiers is important and if missing may delay sample processing.

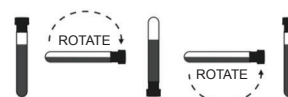


IMPORTANT:
Ensure all blank fields are completed and labels are applied as instructed. Unlabeled tubes may not be processed.

Collecting the Sample

Note: The first 5mL of blood collected from the fresh venipuncture cannot be used for collection into the provided blood tubes due to the possibility of contaminating epithelial cells during venipuncture. Ensure at least one blood tube of 5 mL or more is collected prior to the CTC sample to avoid adversely affecting the test results.

- The provided blood tube is designed to be a direct draw blood collection tube. Transferring a blood sample collected with a syringe and needle into the tube is not recommended due to the increased potential for hemolysis.
- It is recommended to collect specimen by venipuncture according to CLSI GP41-A6. The collection tube contains chemical additives, avoid possible backflow from the tube:
 - Keep patient's arm in the downward position during collection.
 - Hold tube with stopper in the upright position so that the tube contents do not touch the stopper or end of the needle during collection.
- Allow the tube to fill until the vacuum is exhausted and blood flow ceases. Total draw volume should be 8 – 10 ml.
- After sample collection, it is important to immediately mix the sample via gentle inversion 8 to 10 times. One inversion is a complete turn of the wrist, 180 degrees, and back per the figure below:



- Place filled blood tube into the absorbent sleeve and conical tube. Replace conical tube cap and ensure it is securely closed to prevent leakage. Place the sealed conical tube into the center of the canister between the thermal packs and replace the canister screw cap. Ensure canister screw cap is completely closed to prevent accidental leakage.

Shipping the Sample

1. Fold and place the completed sample requisition form into the kit box along with the canister.
2. Place the collection kit box directly in the Clinical Pack Mailer Bag provided. Seal the Pack and store at room temperature until shipment.
3. Sample processing is time sensitive, so ensure Courier pickup is scheduled for the same day the sample is collected.
4. All samples should be sent via Overnight service to:
Covance Central Laboratory Services SARL
Kit Receipt – CENTERLINX
Rue Moises-Marcinhes 7
Meyrin1217 Switzerland
LSN: 102520
5. Include applicable shipping documents and commercial invoices in the provided shipping sleeve on the Mailer Bag.

WARNINGS AND PRECAUTIONS

1. Do not use blood collection tube if cloudiness or precipitate is visible in the preservative reagent of the unused blood tube as this is a possible sign of product deterioration.
2. The preservative in the blood collection tube is subject to expiration which may impact test performance, do not use expired blood collection tubes.
3. Do not use any blood collection tube other than the tube provided with each collection kit.
4. Do not refrigerate or freeze kit or any of its contents.
5. Blood samples should be placed into the collection kit after blood draw and scheduled for same day shipping pickup. Do not refrigerate or freeze patient blood samples prior to shipment.
6. The kit contains components which are uniquely serialized, matched, and tracked. Please do not mix any components between kits.
7. Do not open or unpackage the kit until time of blood draw.

LIMITATIONS

The first 5mL of blood collected from the fresh venipuncture cannot be used for collection into the provided blood tubes due to the possibility of contaminating epithelial cells during venipuncture. Ensure at least one blood tube of 5 mL or more is collected prior to the CTC sample to avoid adversely affecting the test results.

CONTACT INFORMATION



Epic Sciences
9381 Judicial Drive, Suite 200
San Diego, CA 92121 U.S.A.
+1.858.356.6610
+1.800.941.0522 (USA)



Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands



www.epicsciences.com