



Multi-cancer  
early detection test

Standard Kit  
Specimen Collection Instructions



## Principles of the procedure

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The Galleri™ Specimen Collection Kit (containing the Streck Cell-Free DNA BCT®) is intended for whole blood collection and transport for further processing and testing of cell-free plasma DNA with the Galleri test. Accurate analysis of cell-free DNA (cfDNA) can be compromised by incorrect sample handling, shipping, and processing conditions.

The blood collection tube contains a preservative reagent that stabilizes nucleated blood cells (including circulating tumor cells), preventing the release of cellular genomic DNA, and inhibits nuclease mediated degradation of cfDNA, contributing to the overall stabilization of cfDNA.

## Blood collection tube reagent

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The specimen collection tube contains the anticoagulant K<sub>3</sub>EDTA and a cell preservative in a liquid medium.

## Precautions and limitations

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Collect specimens by venipuncture according to Clinical and Laboratory Standards Institute (CLSI) GP41.

### **PREVENTION OF BACKFLOW**

Streck Cell-Free DNA BCT® contains chemical additives, and it is important to avoid possible backflow from the tube by observing the following precautions:

- Keep the patient's arm in the downward position during the collection procedure.
- Hold the tube with the stopper in the uppermost position so that the tube contents do not touch the stopper or the end of the needle during sample collection.
- Release the tourniquet once blood starts to flow in the tube, or within 2 minutes of application.

# Materials

## GALLERI SPECIMEN COLLECTION KIT CONTENTS

- (1) Document Pouch Containing:  
Blood Tube Labels, Specimen Collection Instructions (SCI), Test Requisition Form (TRF)
- (2) 10 mL Streck Cell-Free DNA BCT®  
Blood Collection Tubes
- (1) Ambient Temperature Gel Pack
- (1) Foil Pouch
- (1) Custom Biohazard  
Bag and Absorbent  
Pad Combination
- (1) Cardboard Exterior Box
- (1) Pre-Printed Shipping Label Adhered  
to Bottom of Test Kit Box

## REQUIRED BUT NOT PROVIDED

Needle, tube adapter, alcohol swab, bandage, gloves, gauze, tourniquet

GRAIL

# Specimen collection instructions

## LABEL

1. Print on the primary barcode labels: Patient Name, Date of Birth, and Biological Sex (MRN if applicable).



2. Affix the primary barcode labels to the blood tubes by aligning:
  - The "top of tube" end of the label towards the stopper end of the tube.
  - The **red circle** directly over the **red owl** of the Streck logo, covering the entire Streck label and applying the label straight along the length of the tube.



- Affix the TRF label to the upper-right corner of the paper TRF or record the value in the GRAIL ID field on the electronic TRF.



## COLLECT

- Collect the specimen by venipuncture using a 21G or 22G needle according to your lab's procedures and/or CLSI GP41. Fill both tubes completely (~10mL).



- Gently mix with 10 complete inversions. **Do NOT refrigerate or freeze.**



- Complete the Specimen Information section on the paper or electronic TRF.



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## PACK

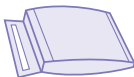
7. Place the two filled blood tubes into the biohazard bag; peel to expose the adhesive strip, fold, and press to seal.



8. Place the sealed biohazard bag with tubes in between the folded gel pack, which is inside the foil pouch. **Do NOT refrigerate or freeze the gel pack.**



9. Expose the adhesive strip on the foil pouch, fold, and press to seal.



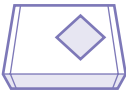
10. Place the sealed foil pouch into the box and the completed paper TRF on top if applicable.



11. Close and seal the box using the kit return seal from the label page.



**NOTE: If the blood specimen is known to be infectious, please add a “UN3373 Biological Substance, Category B” sticker to the top of the box and cross out the “Exempt Human Specimen” text on the bottom of the box.**



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## SHIP

12. The pre-paid return shipping label is pre-applied to the bottom of the box.



13. Ensure shipment of the specimen collection kit on the same day as sample collection. Be aware of your local pickup cutoff time to ensure next-day delivery to the GRAIL Laboratory.



14. Store the test kit at room temperature until it is shipped. **Do NOT refrigerate or freeze.**



## Storage and stability

When stored at 2–30° C (35.6–86° F), the unused specimen collection tube is stable through the expiration date. The shelf life is printed on each individual tube. If storage temperature conditions are exceeded, contact GRAIL Customer Service.

### **Do NOT freeze empty specimen collection tubes.**

Samples collected in the specimen collection tube for processing and testing with the Galleri kit are stable for up to 7 days at temperatures 1–40° C (33.8–104° F). Proper insulation may be required for shipment during extreme temperature conditions that would expose the samples to temperatures outside of this range.

Follow recommendations for order of draw outlined in CLSI GP41. Streck Cell-Free DNA BCT® should be drawn after the EDTA tube and before the fluoride oxalate (glycolytic inhibitor) tube. If a Streck Cell-Free DNA BCT® tube immediately follows a heparin tube in the draw order, Streck recommends collecting a nonadditive or EDTA tube as a waste tube prior to collection in the Streck Cell-Free DNA BCT®.

Inadequate or delayed mixing may result in poor product performance.

21G or 22G needle is advised for best results.

When using a winged (butterfly) collection set for venipuncture, a nonadditive or EDTA discard tube should be partially drawn first to eliminate air from the tubing.

Overfilling or underfilling a tube will result in an incorrect blood-to-additive ratio and may affect analytic results.

Broken or expired specimen collection tubes should be disposed of with infectious medical waste.

Glass has the potential for breakage; precautionary measures should be taken during handling of glass tubes.

All biological specimens and materials coming in contact with the tubes are considered biohazards and should be treated as if capable of transmitting infection. Dispose of in accordance with applicable regulations. Avoid contact with skin and mucous membranes.

Do not freeze specimens collected in the specimen collection tube, as cell lysis and tube breakage could result.

Check expiration date prior to using the tubes for collection. Do not use tubes after the expiration date.

Do not use tubes for collection of materials to be injected into patients.

Product is intended for use as supplied. Do not dilute or add other components to the specimen collection tube.

Do not use if cloudiness or precipitate visible in reagent of unused tube indicates product deterioration.

Single use only.

Do not transfer samples drawn into tubes containing other anticoagulants and/or preservatives into the Streck Cell-Free DNA BCT®.

Safety Data Sheet for the specimen collection tube can be obtained at [www.Streck.com](http://www.Streck.com) or by calling Streck Customer Service at 800-843-0912.

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Clinical and Laboratory Standards Institute. GP41, Procedures for the collection of diagnostic blood specimens by venipuncture. Approved Standard – Seventh Edition.

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