Follow recommendations for order of draw following your lab's procedures or as outlined in standard clinical guidelines such as CLSI GP41. Streck Cell-Free DNA BCT® CE should be drawn after the EDTA tube and before the fluoride oxalate (glycolytic inhibitor) tube. If a Streck Cell-Free DNA BCT® CE 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® CE.

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 biohazardous 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® CE.



## Glossary of Harmonized Symbols

| | |
|---|---|
| Manufacturer | Single Use Only |
| EC REP Authorized Representative in the European Community | Consult Instructions for Use |
| CE Marking of Conformity | REF Catalog (Part) Number |
| IVD In Vitro Diagnostic Medical Device | UKCA Marking of Conformity |

GRAIL, LLC
1525 O'Brien Drive
Menlo Park, CA 94025, USA

+1 833-694-2553
+1 650-999-9000 (Fax)
customerservice@grail.com
grail.com

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

QualRep Services BV
Utrechtseweg 310 Bldg 42
6812 AR Arnhem
The Netherlands
Globalreg@qservegroup.co
+(31) 207882630

UK Responsible Person:
GRAIL Bio UK Ltd.
New Penderel House, 4th Floor
283-288 High Holborn, London
WC1V 7HP

Revision History

Version 1 Initial Release (November 2021)

Version 2 Revised May 2022 to include: GRAIL, LLC; page numbers; revision number, date, and history; "For Professional Use Only"; updated Principles of the Procedure to reflect use in the GRAIL Clinical Laboratory; Serious Incident Reporting details; Glossary of Symbols; and other administrative changes.





GRAIL™

# Standard Kit
# Specimen Collection Instructions

## 2-Tube Profile

REF G0895

FOR PROFESSIONAL USE ONLY

## Principles of the procedure

The GRAIL Specimen Collection Kit, containing the CE Streck Cell-Free DNA Blood Collection Tube (BCT)®, is intended for whole blood collection and transport for further processing and testing at the GRAIL Clinical Laboratory. 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

The specimen collection tube contains the anticoagulant $K_3$EDTA and a cell preservative in a liquid medium.

## Precautions and limitations

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

### PREVENTION OF BACKFLOW

Streck Cell-Free DNA BCT® CE 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

## GRAIL SPECIMEN COLLECTION KIT CONTENTS

(1) Blood Tube Labels, Specimen Collection Instructions (SCI), Test Requisition Form (TRF), if applicable

(2) 10 mL Streck Cell-Free DNA BCT® CE Blood Collection Tubes

(1) Ambient Temperature Gel Pack

(1) Foil Pouch

(1) Custom Biohazard Bag and Absorbent Pad Combination

(1) Cardboard Exterior Box

## REQUIRED BUT NOT PROVIDED

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

GRAIL

# Specimen collection instructions

## LABEL

1. Print the patient information on the primary barcode labels.

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.

3. 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

4. Collect the specimen by venipuncture using a 21G or 22G needle according to your lab's procedures and/or CLSI GP41. Fill all 2 tubes completely (~10mL).

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

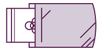
6. Complete the Specimen Information section on the paper or electronic TRF.



## 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.



## 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 Clinical 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 at the GRAIL Clinical Labratory 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.

# Serious incident reporting

Any serious incident in relation to the Galleri test in the EU shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

To report a serious incident to GRAIL, contact: customerservice@grail.com or contact GRAIL clinical support services at +1 833-694-2553.