

Precautions

- 1. Wear personal protective equipment (PPE) while handling specimens.
- 2. Do not freeze specimens collected in Cell-Free DNA BCT.
- 3. For single and professional use only.
- 4. Product is intended for use as supplied. Do not dilute or add other components to Cell-Free DNA BCT.
- 5. Specimen transport via pneumatic tube system is not advised.
- 6. This tube has been designed to fill with 10ml of blood. Underfilling of the Blood Collection Tubes (BCTs) with less than 10 mL of blood may impact the assay results

Caution

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 them are considered biohazards and should be treated as if capable of transmitting infection. Dispose of in accordance with federal, state and local regulations. Avoid contact with skin and mucous membranes.

Product should be disposed with infectious medical waste.

- 7. Safety Data Sheets can be obtained by emailing support@freenome.com.

Storage and stability

Store kits prior to blood draw at 2 °C to 25 °C until expiration date printed on label. Temporary excursions outside this range may occur during shipping and handling. Exposure to elevated temperatures consistent with distribution conditions has been evaluated; however, prolonged storage outside recommended conditions may adversely affect product performance.

Do not freeze empty Cell-Free DNA BCT.

After draw, whole blood containing Cell-Free DNA BCT should be stored at 16 °C to 25 °C for up to 7 days, including shipping.

Indications of product deterioration

Cloudiness or precipitate visible in reagent of empty tube. If indications of product deterioration occur, contact Freenome at support@freenome.com.

References

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

Glossary of symbols



Catalog Number



Batch Code



Serial Number



In Vitro Diagnostic Medical Device



By Prescription Only



Consult for Instructions For Use



Manufacturer



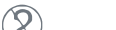
Use By



Temperature Limit



Biological Risk



Do Not Re-use



Manufactured for Freenome, LLC
3300 Marina Boulevard Brisbane, CA 94005
(833) 990-6185

support@freenome.com

For more information:
www.freenome.com/simplescreen



REF K00014

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INSTRUCTIONS FOR USE

Intended use

This blood collection kit is intended for whole blood collection for further processing and testing of cell-free plasma DNA with the SimpleScreen™ CRC screening blood test.

Principles of the procedure

Accurate analysis of cell-free DNA (cfDNA) can be compromised by sample handling, shipping and processing, causing lysis of nucleated blood cells and subsequent release of cellular genomic DNA. The preservative reagent contained in Cell-Free DNA BCT reduces the release of cellular genomic DNA. The blood collection tubes are intended for the preservation of cell-free DNA.

Blood collection tube reagents

Cell-Free DNA BCT contains the anticoagulant K3EDTA and a cell preservative in a liquid medium.

Limitations

Do not store outside of established conditions.

Do not transfer samples drawn into tubes containing other anti-coagulants and/or preservatives into Cell-Free DNA BCT.

Do not use past expiration date printed on label

Do not use for clinical chemistry assays.

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

Cell-Free DNA BCT is not intended for the stabilization of RNA nor is it intended for viral or microbial nucleic acids.

BLOOD COLLECTION KIT



Package contents:

- | | |
|---|--------------------------------------|
| 1 Patient insert | 6 Biohazard bag with document pocket |
| 2 Instructions for use | 7 Foil pouch |
| 3 Two (2) blood collection tube labels | 8 Ambient gel pack |
| 4 Absorbent sleeve | 9 Shipping envelope |
| 5 Two (2) 10.0ml blood collection tubes | 10 Outer box |

Materials that may be required but are not provided: Needle, tube adapter, alcohol swab, bandage, gloves, gauze, tourniquet

Before you begin

From the foil pouch, remove the biohazard bag containing the absorbent sleeve, blood collection tubes, and barcode labels. Leave the gel pack in the foil pouch.

Blood collection instructions

1. Collect specimen by venipuncture according to CLSI GP41.¹ Follow recommendations for order of draw outlined in CLSI GP41.²
For best results, a 21G or 22G needle is advised. Slower fill times may be observed when using a smaller gauge needle. **Fill tube completely.**

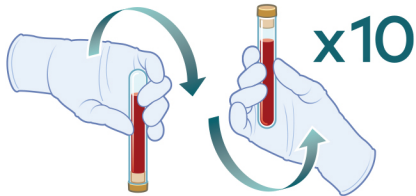
2. Remove tube from adapter and immediately mix by gentle inversion 10 times.

One inversion is a complete turn of the wrist, 180 degrees and back.

- ⚠ Inadequate, delayed, or over-mixing impacts assay performance and may result in incorrect results.

3. Repeat with second tube.

4. After collection, transport and store tubes within recommended temperature range.



Blood collection notes

¹ **Prevention of Backflow:** Since Cell-Free DNA BCT contains chemical additives, it is important to avoid possible backflow from the tube. To guard against backflow, observe the following precautions:

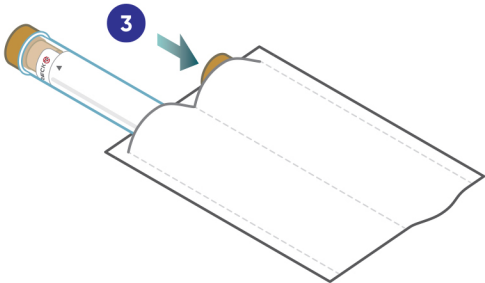
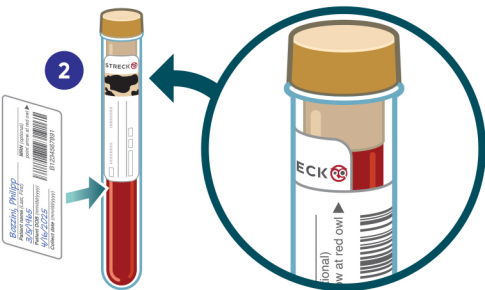
- Keep the patient's arm in the downward position during the collection procedure.
- Hold the tube with the stopper in the uppermost position so that the tube contents do not touch the stopper or the end of the needle.
- Release tourniquet once blood starts to flow in the tube, or within 2 minutes of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

When using a winged (butterfly) collection set for venipuncture and the Streck Cell-Free DNA BCT is the first tube drawn, a non-additive or EDTA discard tube should be partially drawn first in to eliminate air or "dead space" from the tubing.

Cell-Free DNA BCT does not dilute blood samples; therefore, no dilution factor correction is necessary.

² Cell-Free DNA BCT should be drawn after the EDTA tube and before the fluoride oxalate (glycolytic inhibitor) tube. If a Cell-Free DNA BCT immediately follows a heparin tube in the draw order, Streck recommends collecting a non-additive or EDTA tube as a waste tube prior to collection in the Cell-Free DNA BCT.

Shipping instructions



1. Fill out the blood collection tube labels:

- Patient name
- Medical record number (MRN - optional)
- Patient date of birth (DOB)
- Specimen collection date

2. Place a label on each filled blood collection tube with the black triangle pointing at the red owl symbol in Streck logo.

- ⚠ Do not cover expiration date.

3. Place the filled blood collection tubes into the absorbent sleeve.

4. Place the filled absorbent sleeve into the biohazard bag and close.

If applicable, complete the Test Requisition Form (TRF), then fold and insert the TRF into the outer document pocket of the biohazard bag.

5. Place the filled biohazard bag into the foil pouch and close.

- ⚠ Ensure the gel pack is in the foil pouch
- ⚠ Do not freeze or refrigerate the gel pack. Use gel pack at room temperature.

6. Place the filled foil pouch into the box and close.

7. Place the filled box into the provided shipping envelope and ship to Freenome.

⚠ Kit should be shipped on the same day that specimen is collected as it must be processed within 7 days of collection.

