

PRODUCT DESCRIPTION

The Guardant Shield™ Blood Collection Kit (BCK), designed for cancer screening, comprises all components used in the collection, packaging, and transportation of whole blood samples for the Shield Test.

PRINCIPLES OF THE PROCEDURE

Accurate analysis of cell-free DNA (cfDNA) can be compromised by sample handling and extreme shipping and processing conditions. The cfDNA blood collection tube (BCT) contains a formaldehyde-free preservative that stabilizes white blood cells, preventing the release of genomic DNA, allowing isolation of high-quality cell-free DNA.

BLOOD COLLECTION TUBE REAGENTS

The blood collection tube contains the anticoagulant K₃EDTA and a cell preservative in a liquid medium.

PRECAUTIONS

- For best results, a 21G or 22G needle is advised.
- Prevention of Backflow—Since cfDNA BCT contains chemical additives, it is important to avoid possible backflow from the tube. To guard against backflow, observe the following precautions:
 - a. Keep patient's arm in the downward position during the collection procedure.
 - b. 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.
 - c. Release tourniquet once blood starts to flow in the tube, or within 2 minutes of application.
- If the patient is having additional blood draws, the provided Guardant cfDNA BCT should be drawn after the EDTA tube and before the fluoride oxalate (glycolytic inhibitor) tube. If a blood collection tube immediately follows a heparin tube in the draw order, it is recommended that a non-additive or EDTA tube be collected as a waste tube prior to collection in the Guardant cfDNA BCT.
 - a. When using a winged (butterfly) collection set for venipuncture and the cfDNA BCT is the first tube drawn, a non-additive or EDTA discard tube should be partially drawn first in order to eliminate air or "dead space" from the tubing.
- Allow the tube to fill completely until blood stops flowing into the tube. Underfilling of tubes with less than 5ml of blood (bottom of the label indicates 5ml fill when tube is held vertically) may lead to incorrect analytical results or poor product performance. This tube has been designed to fill with 10ml of blood.
- Inadequate, delayed, or over mixing may result in incorrect analytical results or poor product performance.
- For single and for professional use only.
- Glass has the potential for breakage; precautionary measures should be taken during handling.
- Safety Data Sheet (SDS) for cfDNA BCT can be obtained by calling 855.722.7335.

LIMITATIONS

- Do not store outside of established conditions; do not freeze specimens collected in cfDNA BCT.
- Product is intended for use as supplied. Do not dilute or add other components to cfDNA BCT.
- Do not transfer samples drawn into tubes containing other anti-coagulants and preservatives into cfDNA BCT.
- Specimen transport via pneumatic tube system is not advised.
- Do not use past expiration date printed on label.
- Do not use for collection of materials to be injected into patients.
- Cloudiness or precipitate visible in reagent of unused tube indicates product deterioration. Do not use tube.

STORAGE AND STABILITY

1. Store tubes prior to blood draw at 2°C–30°C until expiration date printed on label.
2. Do not freeze cfDNA BCT.
3. After draw, ship immediately at room temperature. Specimen received after 7 days will be discarded.





MATERIALS THAT MAY BE REQUIRED BUT ARE NOT PROVIDED


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

REFERENCES

¹ Clinical and Laboratory Standards Institute. GP41, Procedures for the collection of diagnostic blood specimens by venipuncture. Approved Standard-Seventh Edition.

GLOSSARY OF SYMBOLS

 STERILE R Sterilized Using Irradiation	 LOT Batch Code	 REF Catalog Number	 Do Not Re-use	 Use By	 Biological Risks	 Contains Sufficient For $<math>N</math> Tests$
 IVD In Vitro Diagnostic Medical Device	 SN Serial Number	 Consult Instructions for Use	 Manufacturer	 Temperature Limit	 Rx Only By Prescription Only	

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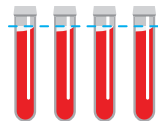
 **shield**TM

Instructions for Use

Blood Collection Kit | Cancer Screening

Blood Draw Instructions

- 1 Collect specimen by venipuncture according to CLSI GP41,¹ **filling provided tubes completely.**



- 2 Fill out the label placed on each of the four tubes and ensure patient identifiers are documented:

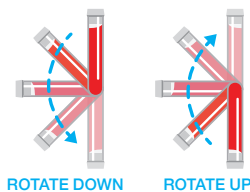
- Patient Name or MRN*
- DOB (Date of Birth)



DO NOT attach any other labels to the blood collection tube.

*Medical Record Number recorded in Test Requestion Form (TRF).

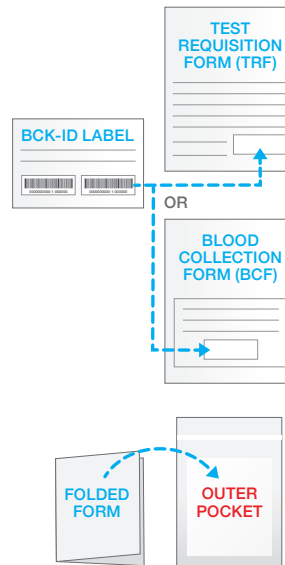
- 3 Mix by gentle inversion 8 to 10 times; one inversion is a complete turn of the wrist, 180 degrees, and back.



- 4 Complete Specimen Collection Information, including **Collection Date**, on the TRF. If the TRF is not available, complete the Blood Collection Form (BCF) included in the Blood Collection Kit (BCK).

Affix the Blood Collection Kit (BCK)-ID barcode from the label sheet to the designated area. The other BCK-ID label is a back-up should the first one be misplaced.

Fold and insert the form into outer pocket of specimen bag.



If using the portal, log into [GuardantGo.com](https://www.guardantgo.com) and follow the instructions to record Collection Date and BCK-ID electronically.

Do not refrigerate, freeze or centrifuge blood samples.

Shipping Instructions

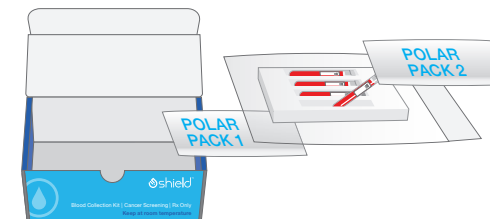
- 5 Place filled blood collection tubes into foam tray.



- 6 Place foam into specimen bag with absorbent sheet and close.



- 7 Place filled specimen bag into box on top of one polar pack.** Place second polar pack on top of specimen bag and close box.



- 8 Place kit into preprinted FedEx Clinical Pak and seal flap. Schedule a FedEx pick up online through [FedEx.com](https://www.fedex.com) or contact FedEx at 866-393-4585 for pick-up.

**Do not freeze polar packs. Use as is.