

Blood Collection Instructions

1. Collect specimen by venipuncture according to CLSI GP41¹.

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 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.

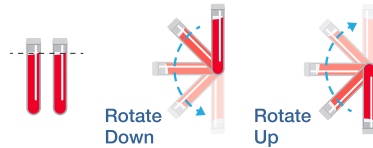
2. Follow recommendations for order of draw outlined in CLSI GP41¹.

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.

3. Fill tube completely. Remove tube from adapter and immediately mix by gentle inversion 10 times.

Inadequate, delayed, or over mixing may result in incorrect analytical results or poor product performance.

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



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

Note:

- For best results, a 21G or 22G needle is advised. Slower fill times may be observed when using a smaller gauge needle.
- 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 order 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.

PLASMA ISOLATION

- Centrifuge blood collection tubes containing whole blood for 10 minutes at 10 °C at 1,600 x g. Carefully unload the tubes

from the centrifuge without disturbing the buffy coat .

- Pipette maximum 5ml plasma from the specimen tube to a labeled 15ml centrifuge tube.
- Centrifuge plasma in 15ml centrifuge tube for 10 minutes at 10 °C at 3,220 x g. Note: Centrifuge speed may be adjusted down to 3,200 x g, if centrifuge does not support 3,220 x g.
- Pour contents of 15ml centrifuge tube for each specimen into an appropriately labeled 5ml conical screw cap tube.
- Isolate cell-free DNA using extraction kit manufacturer's instructions including any adaptations as required.

PLASMA Storage

Plasma may be stored at 2 °C to 8 °C for up to 24 hours or at -80 °C +/- 10 °C for up to 45 days. This has only been validated on the Guardant360 assay.

Shipping Instructions

1. Complete the Test Requisition Form (TRF)



2. Fill out barcode labels

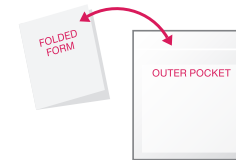
- Patient/ Subject ID
- DOB
- Collection Date



3. Place a barcode label on each tube with barcode in the vertical position



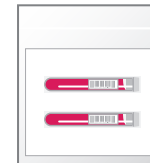
4. Place a barcode label on the TRF, then fold and insert the TRF into the outer pocket of the biohazard bag



5. Place filled blood tubes into foam tray

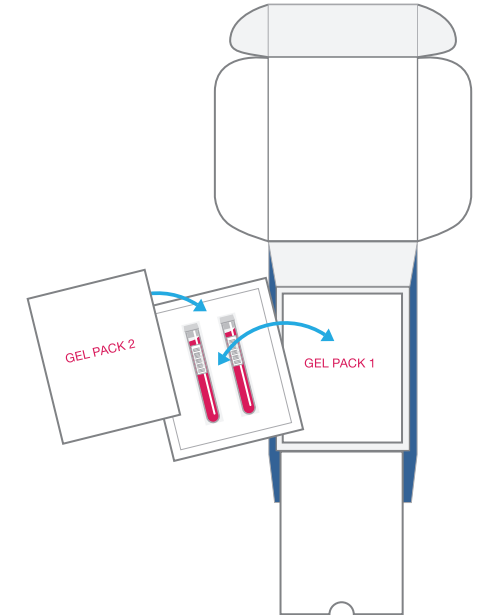


6. Place filled foam tray into the biohazard bag and close



7. Place filled biohazard bag into box on top of one of the gel packs.* Place the second gel pack on top of the specimen bag and close the box

8. Place the kit into the preprinted FedEx Clinical Pak, seal flap, and schedule a FedEx pick up



***DO NOT freeze Gel Packs. Use as is.**

INTENDED USE

The Guardant360 Blood Collection Kit is intended for whole blood collection for further processing and testing of cell-free plasma DNA with the Guardant360 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 tube is intended for the preservation of cell-free DNA.

BLOOD COLLECTION TUBE REAGENTS

Cell-Free DNA BCT contains the anticoagulant K₂EDTA and a cell preservative in a liquid medium.

LIMITATIONS

- Performance characteristics for this device have only been established on the Guardant360 assay.
- 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 or assays not intended for cell-free DNA analysis.
- 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.

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 for 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. 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.

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.
 - Remove and reinsert stopper by either gently rocking the stopper from side to side or by grasping with a simultaneous twisting and pulling action. A "thumb roll" procedure for stopper removal is NOT recommended as tube breakage and injury may result.
7. SDS(s) can be obtained by emailing sds@guardanthealth.com.

STORAGE AND STABILITY

1. Store tubes prior to blood draw at 2°C–30°C until expiration date printed on label
 - If stored consistently at 22 °C to 30 °C for longer than 8 months, reagent will acquire a yellow hue. This is normal and does not indicate product degradation.
2. Do not freeze empty Cell-Free DNA BCT.
3. After draw, whole blood containing Cell-Free DNA BCT should be stored at 18 °C to 25 °C for up to 7 days including shipping.

PACKAGE CONTENTS

Two (2) 10.0ml blood collection tubes, Two (2) Polar Bricks with pink labels, Foam Tray with two tube slots, Absorbent Sheet, 3" x 4", Biohazard Zip Style Bag with Document Pouch, 8" x 8", FedEx Clinical Pak Envelope, FedEx International Airbill Label, Barcode Labels and Instructions

INDICATIONS OF PRODUCT DETERIORATION

1. Cloudiness or precipitate visible in reagent of empty tube.
2. If indications of product deterioration occur, contact Guardant Health by emailing sds@guardanthealth.com.

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 HARMONIZED SYMBOLS

STERIL
Sterilized using irradiation

LOT
Batch Code

REF
Catalog Number

Do Not Re-use

Use By

Biological Risk

Content Sufficient for Number of Tests Specified

EC REP
Authorized Representative in the European Community

IVD
In Vitro Diagnostic Medical Device

Temperature Limitation

Consult Instructions For Use

Manufacturer

Date of Manufacture

Rx ONLY
By Prescription Only



MANUFACTURED FOR:

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EC REP

Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands

IVD CE

GH10000, GH10001
Assembled in USA

06/2021 REC-REG-000010 R7

Instructions for use

GUARDANT 360

BLOOD COLLECTION KIT

2 Tubes

Catalog No. GH10000

GH10001

GUARDANT HEALTH