Cell-Free DNA BCT® CE

CE

Streck

INSTRUCTIONS FOR USE

Cell-Free DNA BCT® CE is a direct draw whole blood collection tube intended for collection, transport and storage of blood samples. **This product is FOR EXPORT ONLY, not to be sold in the United States.**

SUMMARY AND PRINCIPLES

Cell-Free DNA BCT CE stabilizes cell-free plasma DNA as well as preserves cellular genomic DNA present in nucleated blood cells and circulating epithelial cells (tumor cells) found in whole blood.

Accurate analysis of cf-DNA can be compromised by sample handling, shipping and processing, causing lysis of nucleated blood cells and subsequent release of cellular genomic DNA. Additionally, degradation of cf-DNA due to nuclease activity can be problematic.

The preservative reagent contained in Cell-Free DNA BCT CE stabilizes nucleated blood cells, preventing the release of cellular genomic DNA, and inhibits nuclease mediated degradation of cf-DNA, contributing to the overall stabilization of cf-DNA. Samples collected in Cell-Free DNA BCT CE are stable for up to 14 days at temperatures between 6 °C to 37 °C, allowing convenient sample collection, transport and storage.

The preservative reagent contained in Cell-Free DNA BCT CE stabilizes circulating epithelial cells (tumor cells) in whole blood for up to 7 days at temperatures between 15 °C to 30 °C.

REAGENTS

Cell-Free DNA BCT CE contains the anticoagulant K_3EDTA and a cell preservative in a liquid medium.

PRECAUTIONS

1. For In Vitro Diagnostic Use.
2. Do not freeze specimens collected in glass Cell-Free DNA BCT CE. (Streck part numbers: 218996, 218997, 230244, 230250, 230251)
3. Do not use tubes after expiration date.
4. Do not use tubes for collection of materials to be injected into patients.
5. Product is intended for use as supplied. Do not dilute or add other components to Cell-Free DNA BCT CE.
6. Overfilling or underfilling of tubes will result in an incorrect blood-to-additive ratio and may lead to incorrect analytic results or poor product performance.
   CAUTION
   a. Glass has the potential for breakage; precautionary measures should be taken during handling of glass tubes (Streck part numbers: 218996, 218997, 230244, 230250, 230251).
   b. 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.
   c. Product should be disposed with infectious medical waste.
   d. Remove 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. Reinsert stopper by gently pushing stopper onto tube with a simultaneous twisting action.
   e. A pediatric tube adapter is strongly recommended to better fit the 10.25mm diameter 2.0ml Cell-Free DNA BCT CE.
7. SDS can be obtained at www.streck.com or by calling 800-843-0912.

STORAGE AND STABILITY

1. When stored at 2 °C to 30 °C, empty Cell-Free DNA BCT CE is stable through expiration date.
2. Short-term storage at 2 °C to 40 °C is acceptable for empty Cell-Free DNA BCT CE for up to 14 days.
3. Do not freeze empty Cell-Free DNA BCT CE. Proper insulation may be required for shipment during extreme temperature conditions.
4. Sample storage/stability:

	Sample Type		
	Cell-Free DNA	Cellular Genomic DNA	Epithelial Cells (Tumor Cells)
Sample Stability	14 days	14 days	7 days
Sample Storage Temperature	6 ºC to 37 ºC	6 ºC to 37 ºC	15 ºC to 30 ºC

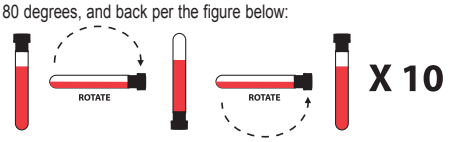
INDICATIONS OF PRODUCT DETERIORATION

1. Cloudiness or precipitate visible in reagent of empty tube.
2. If indications of product deterioration occur, contact Streck Technical Services at 402-691-7510 or technicalservices@streck.com.

INSTRUCTIONS FOR USE

For a video demonstration, visit www.streck.com/mixing.

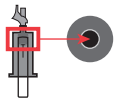
1. Collect specimen by venipuncture according to CLSI GP41-A6[1].
   Prevention of Backflow - Since Cell-Free DNA BCT CE contains chemical additives, it is important to avoid possible backflow from the tube.
   To guard against backflow, observe the following precautions:
   a. Keep patient's arm in 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 during sample collection.
   c. 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 GP41-A6[1]. Cell-Free DNA BCT CE should be drawn after the EDTA tube and before the fluoride oxalate (glycolytic inhibitor) tube. If a Cell-Free DNA BCT CE tube immediately follows a heparin tube in the draw order, Streck recommends collecting a non-additve or EDTA tube as a waste tube prior to collection in the Cell-Free DNA BCT CE.
3. Fill tube completely.
4. Remove tube from adapter and immediately mix by gentle inversion 8 to 10 times. Inadequate or delayed mixing may result in incorrect analytical results or poor product performance. One inversion is a complete turn of the wrist, 180 degrees, and back per the figure below:



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

Note:

1. For best results, a 21G or 22G needle is advised. Slower fill times may be observed when using a smaller gauge needle.
2. When using a winged (butterfly) collection set for venipuncture and the Streck Cell-Free DNA BCT CE 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.
3. For the 2.0ml Cell-Free DNA BCT CE, care must be taken to center the tube so the middle of the stopper is punctured per the figure below. To aid with proper insertion of the tube in standard holders and stabilize the tube during the draw, a pediatric tube adapter is strongly recommended to modify the standard holder to fit the 10.25mm diameter 2.0ml Cell-Free DNA BCT CE (Streck part number: 230250, 230251).



Correctly punctured stopper

4. Cell-Free DNA BCT CE does not dilute blood samples; therefore, no dilution factor correction is necessary.
5. As in the case with most clinical laboratory specimens, hemolysis, icterus and lipemia may affect the results obtained on blood samples preserved with Cell-Free DNA BCT CE.

DNA EXTRACTION

Extraction of cell-free plasma DNA and cellular genomic DNA can be accomplished using most commercially available kits that include a Proteinase K treatment step.

Cell-Free Plasma DNA

Streck has qualified two separate plasma separation spin protocols for your convenience.

Double Spin Protocol 1

Step 1. To separate plasma, centrifuge whole blood at 300 x g for 20 minutes at room temperature.
Step 2. Remove the upper plasma layer and transfer to a new conical tube (not provided).
Step 3. Centrifuge the plasma at 5000 x g for 10 minutes.
Step 4. Isolate cell-free DNA per kit manufacturer instructions.

Double Spin Protocol 2 (for maximum plasma recovery)

Step 1. To separate plasma, centrifuge whole blood at 1600 x g for 10 minutes at room temperature.
Step 2. Remove the upper plasma layer and transfer to a new conical tube (not provided).
Step 3. Centrifuge the plasma at 16000 x g for 10 minutes.
Step 4. Isolate cell-free DNA per kit manufacturer instructions.

For optimal results for all of the above protocols, include a Proteinase K treatment step (≥ 30 mAU/mL digest) at 60 °C in the presence of chaotropic salts for 1 hour when extracting cell-free DNA.

Cellular Genomic DNA

Step 1. To separate the white blood cells, either lyse the red blood cells and wash, or centrifuge whole blood and collect the buffy coat layer.
Step 2. Isolate genomic DNA per kit manufacturer instructions.

For optimal results, include a Proteinase K treatment step (≥ 30 mAU/ml digest) at 60 °C in the presence of chaotropic salts for 2 hours when extracting cellular genomic DNA.

FREEZING AND THAWING

PLASMA

1. To Freeze: For long-term storage, after spinning, collect and transfer the upper plasma layer to a cryogenic tube (not provided) and freeze at -20 ºC or -80 ºC.
2. To Thaw: Thaw cryogenic tubes at appropriate temperature as specified in your protocol.
   Note: If cryoprecipitates form in the plasma, vortex the tube for 30 seconds after thawing. Do not centrifuge the plasma.

CONCENTRATED CELLULAR COMPLEMENT

After spinning and the upper plasma layer is collected and transferred to a cryogenic tube, the remaining cellular material in the plastic Cell-Free DNA BCT CE (Streck part numbers: 230255, 230256, 230257) may be frozen for future use.

1. To Freeze: For long-term storage, freeze the remaining cellular material vertically directly in the plastic Cell-Free DNA BCT CE at -20 ºC or -80 ºC.
2. To Thaw: Thaw tubes at appropriate temperature as specified in your protocol.
   Note: A plastic Cell-Free DNA BCT CE, which has been completely filled with whole blood, should not be frozen; breakage may occur.

LIMITATIONS

1. For single use only.
2. Samples drawn in other anticoagulants or preservatives may cause coagulation in Cell-Free DNA BCT CE.
3. Specimen transport via pneumatic tube system is not advised.

REFERENCES

1. Clinical and Laboratory Standards Institute. GP41-A6, Procedures for the collection of diagnostic blood specimens by venipuncture. Approved Standard - Sixth Edition.

ORDERING INFORMATION

Please call our Customer Service Department at 800-228-6090 for assistance. Additional information can be found online at www.streck.com.

GLOSSARY OF SYMBOLS

See the Instructions (IFU) tab under Resources on the product page at www.streck.com.

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