

INSTRUCTIONS FOR USE

Cell-Free DNA BCT is a direct draw whole blood collection tube intended for collection, stabilization and transportation of cell-free plasma DNA. This product is for research use only and is not for use in diagnostic procedures.

SUMMARY AND PRINCIPLES

Nucleic acid detection in blood, including detection and analysis of cell-free DNA (cf-DNA) in plasma, is an emerging and promising field in disease diagnosis.

Analysis of cf-DNA has potential application in the diagnosis and monitoring of acute pathologies, as well as in prenatal diagnosis of fetal genetic diseases.

Although present in small amounts in the plasma of healthy individuals, increased levels of circulating cf-DNA in plasma appear to be associated with a number of clinical disorders. Studies indicate cf-DNA has potential application as a non-invasive, rapid and sensitive tool for molecular diagnosis and monitoring of acute pathologies as well as application in prenatal diagnosis of fetal genetic diseases.

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 Streck's Cell-Free DNA BCT stabilizes nucleated blood cells preventing the release of cellular genomic DNA and inhibits nuclease mediated degradation of cf-DNA contributing to the over-all stabilization of cf-DNA.

Cell-Free DNA BCT enhances purification, detection and analysis of cf-DNA while preserving cell surface antigenicity and maintaining cell morphology. Samples collected in Cell-Free DNA BCT are stable for up to 14 days at room temperature allowing convenient sample collection, transport and storage. Cell-Free DNA BCT is intended for clinical research, drug discovery, and diagnostic assay development.

For research use only. Not for use in diagnostic procedures.

REAGENTS

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

PRECAUTIONS

- Do not freeze specimens collected in Cell-Free DNA BCT as breakage could result.
- Do not use tubes after expiration date.
- Do not use tubes for collection of materials to be injected into patients.
- Overfilling or under-filling of tubes will result in an incorrect blood-to-additive ratio and may lead to incorrect analytic results or poor product performance.
- CAUTION**
 - Glass has the potential for breakage; precautionary measures should be taken during handling.
 - 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.

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 uppermost.
- Release tourniquet once blood starts to flow in the tube, or within 2 minutes of application.
- Tube contents should not touch stopper or the end of the needle during the collection procedure.

STORAGE AND STABILITY

- When stored at 18 to 30°C, unused Cell-Free DNA BCT is stable through expiration date.
- Do not freeze unfilled Cell-Free DNA BCT. Proper insulation may be required for shipment during extreme temperature conditions.
- Blood samples collected in Cell-Free DNA BCT are stable for 14 days at room temperature.

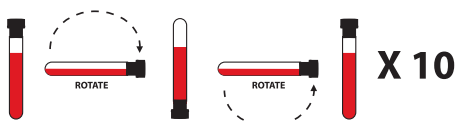
INDICATIONS OF PRODUCT DETERIORATION

- Cloudiness or precipitate visible.

INSTRUCTIONS FOR USE

Direct Draw Method

- Collect specimen by venipuncture according to CLSI H3-A6.
- Follow recommendations for order of draw outlined in CLSI H3-A6.
- Fill tube completely.
- Remove tube from adapter and immediately mix by gentle inversion 8 to 10 times. Inadequate or delayed mixing may result in inaccurate test results.



CELL-FREE PLASMA DNA EXTRACTION

- Extraction of cell-free plasma DNA can be accomplished using most commercially available kits.
- For optimal results, include a Proteinase K treatment step (≥ 30 mAU/ml digest) at 60°C for 1 hour in the presence of chaotropic salts.

PROCEDURES

- Cell-Free DNA BCT should be stored at room temperature (18-25°C).
- Collect blood into the tube according to CLSI document H3-A6.
- After sample collection, transport and store tubes within the recommended temperature range.

Note:

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

LIMITATIONS

- Do not expose to temperatures less than 0°C or greater than 50°C.
- Samples drawn in other anticoagulants or preservatives may cause coagulation in Cell-Free DNA BCT.

REFERENCES

- CLSI document H3-A6, Procedures for the Collection of Diagnostic Blood Specimens by enipuncture.

ORDERING INFORMATION

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

GLOSSARY OF HARMONIZED SYMBOLS

	Authorized Representative in the European Community		Catalog Number		Use By
	Batch Code		Manufacturer		Temperature Limitation
	In Vitro Diagnostic Medical Device		Consult Instructions for Use		Do not re-use
	Biological Risk	Glossary of symbols may contain symbols not used in the labeling of this product.			

Patent Pending

Streck
7002 S. 109 Street Omaha, NE 68128 USA

350547-1
2010-04