

## INSTRUCTIONS FOR USE

Cell-Free RNA BCT is a direct draw whole blood collection tube intended for collection, stabilization and transportation of cell-free plasma RNA. 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 RNA (cf-RNA) in plasma, is an emerging and promising field in disease diagnosis.

Analysis of cf-RNA 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-RNA in plasma appear to be associated with a number of clinical disorders. Studies indicate cf-RNA 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-RNA can be compromised by sample handling, shipping and processing, causing lysis of nucleated blood cells and subsequent release of cellular RNA. Additionally, degradation of cf-RNA due to nuclease activity can be problematic.

The preservative reagent contained in Streck's Cell-Free RNA BCT stabilizes nucleated blood cells preventing the release of cellular RNA and inhibits nuclease mediated degradation of cf-RNA contributing to the over-all stabilization of cf-RNA.

Cell-Free RNA BCT enhances purification, detection and analysis of cf-RNA while preserving cell surface antigenicity and maintaining cell morphology. Samples collected in Cell-Free RNA BCT are stable for up to 3 days at room temperature allowing convenient sample collection, transport and storage. Cell-Free RNA 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 RNA BCT contains the anticoagulant K<sub>3</sub>EDTA, nuclease inhibitors, metabolic inhibitors and a cell preservative in a liquid medium.

Note: It is normal for the reagent in Cell-Free RNA BCT to have a reddish appearance.

## PRECAUTIONS

1. Do not freeze specimens collected in Cell-Free RNA BCT as breakage could result.
2. Do not use tubes after expiration date.
3. Do not use tubes for collection of materials to be injected into patients.
4. 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

- a. Glass has the potential for breakage; precautionary measures should be taken during handling.
- 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 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 RNA BCT contains chemical additives, it is important to avoid possible backflow from the tube.

To guard against backflow, observe the following precautions:

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

## STORAGE AND STABILITY

1. When stored at 18 to 30°C, unused Cell-Free RNA BCT is stable through expiration date.
2. Do not freeze unfilled Cell-Free RNA BCT. Proper insulation may be required for shipment during extreme temperature conditions.
3. Blood samples collected in Cell-Free RNA BCT are stable for 3 days at room temperature.

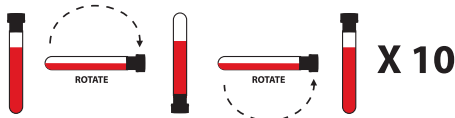
## INDICATIONS OF PRODUCT DETERIORATION

1. Cloudiness or precipitate visible.

## INSTRUCTIONS FOR USE

Direct Draw Method

- a. Collect specimen by venipuncture according to CLSI H3-A6.
- b. Follow recommendations for order of draw outlined in CLSI H3-A6.
- c. Fill tube completely.
- d. 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 RNA EXTRACTION

1. Extraction of cell-free plasma RNA can be accomplished using most commercially available kits.
2. 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

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

Note:

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

## LIMITATIONS

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

## REFERENCES

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

## 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](http://www.streck.com).

## GLOSSARY OF HARMONIZED SYMBOLS

EC REP	Authorized Representative in the European Community	REF	Catalog Number	Use By
LOT	Batch Code	Manufacturer		Temperature Limitation
IVD	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

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