

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. Cell-Free RNA BCT also stabilizes and preserves cellular RNA in white blood cells. **This product has not been cleared by the U.S. Food and Drug Administration for In Vitro Diagnostic Use. The product is For Research Use Only. Not for use in diagnostic procedures.**

SUMMARY AND PRINCIPLES

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 overall stabilization of both cfRNA^{1,2,3} and cellular RNA.⁴

Cell-Free RNA BCT enhances purification, detection and analysis of cf-RNA and cellular RNA. Samples collected in Cell-Free RNA BCT are stable for up to 7 days at temperatures between 18 °C to 25 °C, allowing convenient sample collection, transport and storage.

REAGENTS

Cell-Free RNA BCT contains the anticoagulant K₂EDTA, 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. **For Research Use Only. Not for use in diagnostic procedures.**
2. Do not freeze specimens in Cell-Free RNA BCT as breakage could result.
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 RNA BCT.
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.
 - 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.
7. SDS can be obtained at www.streck.com or by calling 800-843-0912.

STORAGE AND STABILITY

1. When stored at 18 °C to 30 °C, empty Cell-Free RNA BCT is stable through expiration date.
2. Short-term storage from 2 °C to 40 °C is acceptable for empty Cell-Free RNA BCT for up to 14 days.
3. Do not freeze unfilled Cell-Free RNA BCT. Proper insulation may be required for shipment during extreme temperature conditions.
4. Blood samples collected in Cell-Free RNA BCT are stable for up to 7 days when stored between 18 °C to 25 °C.

INDICATIONS OF PRODUCT DETERIORATION

1. Cloudiness or precipitate visible.
2. If indications of product deterioration occur, contact Streck Technical Services at 800-843-0912 or technicalservices@streck.com.

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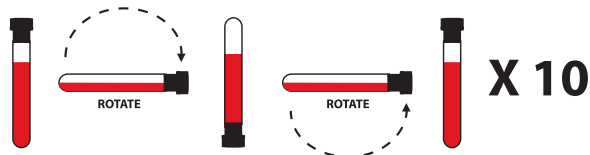
For a video demonstration, visit www.streck.com/mixing.

1. Collect specimen by venipuncture according to CLSI GP41-A6⁵.

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:

- 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-A6⁵. Cell-Free RNA BCT can be drawn after the EDTA tube and before the fluoride oxalate (glycolytic inhibitor) tube. If a Cell-Free RNA BCT tube 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 RNA BCT.
 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 RNA 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.

RNA EXTRACTION

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

Cell-free Plasma RNA

- 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 RNA 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 1 hour when extracting cell-free RNA.

Cellular RNA

- 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 RNA 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 RNA.

Note:

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

LIMITATIONS

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

REFERENCES

1. Fernando M.R., Norton S.E., Lechner J.M., Qin, J. Stabilization of cell-free RNA in blood samples using a new collection device. *Clinical Biochemistry* 2012; 45:1497-1502.
2. Qin J., Williams T., Fernando M.R. A novel blood collection device stabilizes cell-free RNA in blood during sample shipping & storage. *BioMed Central Research Notes* 2013;6:380.
3. Qin J., Fernando M.R., Bassett C. Preservation of circulating cell-free RNA in maternal blood using a blood collection device containing a stabilizing reagent. *Journal of Molecular & Genetic Medicine*, 2014, 8:1.
4. Das K., Norton S.E., Alt J.R., Williams T. L., Fernando M.R. Stabilization of cellular RNA in blood utilizing a specialized blood collection device. *Molecular Diagnostics & Therapy*, DOI 10.1007/s40291-014-0118.
5. Clinical and Laboratory Standards Institute, GP41-A6, Procedures for the collection and 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.

U.S. Patents 8,304,187; 8,586,306; Europe Patent EP2499259; Other Patents Pending.

See www.streck.com/patents for patents that may be applicable to this product.



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