RNA Complete BCT®

STRECK

INSTRUCTIONS FOR USE

RNA Complete BCT® is a direct draw whole blood collection tube intended for the stabilization of draw time concentrations of cell-free RNA and extracellular vesicles. **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 cell-free RNA or extracellular vesicle count can be compromised by stress from delayed sample processing, handling, and shipping, which could result in red and white blood cell lysis.

Samples collected in RNA Complete BCT are stable up to 7 days when stored within temperature ranges as listed in the Storage And Stability section, allowing convenient sample collection, transport and storage.

REAGENTS

RNA Complete BCT contains an anticoagulant and a proprietary preservative in a liquid medium

PRECAUTIONS

1. **For Research Use Only. Not for use in diagnostic procedures**.
2. Do not freeze specimens in glass RNA Complete 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. Hemolysis immediately after draw can be a sign of improper preanalytical technique and the tube should be discarded and redrawn.
6. Product is intended for use as supplied. Do not dilute or add other components to RNA Complete BCT.
7. 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. Unused tubes 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.
8. SDS can be obtained at streck.com or by calling 800-843-0912.

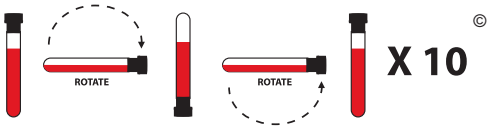
STORAGE AND STABILITY

1. When stored at 2 °C to 30 °C, empty RNA Complete BCT is stable through expiration date.
2. Blood samples collected in RNA Complete BCT are stable for up to 7 days when stored at room temperature.
3. Do not freeze unfilled RNA Complete BCT. Proper insulation may be required for shipment during extreme temperature conditions.
4. Ship tubes filled with blood in insulating coolers with room temperature thermal packs to limit exposure to temperature extremes.

INSTRUCTIONS FOR USE

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

1. Collect specimen by venipuncture according to CLSI GP41[1].
   Prevention of Backflow - Since RNA Complete 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[1]. RNA Complete BCT can be drawn after the EDTA tube and before the fluoride oxalate (glycolytic inhibitor) tube. If an RNA Complete 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 RNA Complete 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:
For best results, a 21G or 22G needle is advised. Slower fill times may be observed when using a smaller gauge needle.

CELL-FREE RNA EXTRACTION

Extraction of cell-free RNA can be accomplished using the following protocol and kits. Other protocols and kits require validation from the end user.

Step 1. To separate plasma, centrifuge whole blood at 1800 x g for 15 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 2800 x g for 15 minutes at room temperature.
Step 4. Isolate cell-free RNA per kit manufacturer instructions.

The RNA Complete BCT is compatible with the following commercially available nucleic acid isolation kits when used according to the manufacturer's instructions for use: QIAamp Circulating Nucleic Acid Kit (Qiagen), MagMAX Cell-Free Total Nucleic Acid Isolation Kit (ThermoFisher), and Plasma/Serum Circulating and Exosomal RNA Purification Kit (Slurry Format, Norgen). A DNase1 digest step is advised to deplete contaminating genomic or cell-free DNA.
Note: When using the QIAamp Circulating Nucleic Acid Kit, the provided plasma protocol was utilized with extension of the 60 °C incubation time from 30 to 60 minutes.

EXTRACELLULAR VESICLES/EXOSOME ISOLATION:

Isolation of extracellular vesicles can be accomplished using filter-based (Qiagen exoEasy), size-exclusion-based (Cell Guidance Systems exo-Spin), or precipitation-based (Thermo-Fisher Total Exosome Isolation Kit) methods.

LIMITATIONS

1. For single use only.
2. Tube is designed for direct draw with a standard needle holder and single use collection. Collection using other means, such as a syringe, or collection and transfer from other devices is not advised.
3. Specimen transport via pneumatic tube system is not advised.
4. Organic phase extraction methods, such as phenol-chloroform, will lead to low yields of RNA.
5. Exosomes isolated from RNA Complete may no longer be suitable for functional studies.

REFERENCES

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

ORDERING INFORMATION

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

TECHNICAL SUPPORT

Please call Streck Technical Services at 800-843-0912 for assistance. Additional information can be found online at streck.com.

GLOSSARY OF SYMBOLS

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

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

Streck
7002 S. 109 Street, La Vista, NE 68128 USA

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