Nucleic Acid Plus BCT™

INSTRUCTIONS FOR USE

Nucleic Acid Plus BCT™ is a direct draw whole blood collection tube intended for the stabilization of draw-time concentrations of cell-free DNA, cell-free RNA, extracellular vesicles, and select classes of plasma proteins.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 plasma analytes – including cell-free DNA, extracellular vesicles (EVs), cell-free RNA, and plasma proteins such as cytokines – can be compromised by delayed blood sample processing, handling, and shipping. Deterioration of blood components, including blood cell degradation, ex vivo hemolysis, and platelet activation, may alter plasma analyte concentrations and lead to inconsistent or misleading results.

The preservative reagent contained in Nucleic Acid Plus BCT stabilizes nucleated blood cells and erythrocytes while minimizing ex vivo hemolysis and platelet activation, thereby limiting the extraneous release of cellular materials such as genomic DNA from white blood cells, EVs, RNA, and proteins from all blood cells, especially immature red blood cells and activated platelets. This stabilization helps maintain draw-time plasma analyte concentrations during whole blood storage. Samples collected in Nucleic Acid Plus BCT are stable for up to 7 days for nucleic acid–based analytes and up to 5 days for plasma proteins and EVs, allowing convenient sample collection, transport, and storage. Protein stability duration is analyte dependent.

REAGENTS

Nucleic Acid Plus BCT contains ACD-A anticoagulant and proprietary preservatives in a liquid medium.

PRECAUTIONS

1. **For Research Use Only. Not for use in diagnostic procedures.**
2. Do not freeze specimens in glass Nucleic Acid Plus BCT as breakage could result.
3. Do not draw whole blood into Nucleic Acid Plus BCT past the expiration date printed on label. If sample collection occurs on or before the expiration date printed on the label, whole blood collected into Nucleic Acid Plus BCT should be stored at 18 °C to 25 °C for up to 7 days for cell-free DNA and cell-free RNA and 5 days for proteins and EVs prior to processing to plasma.
4. Do not use tubes for the collection of materials to be injected into patients.
5. The product is intended for use as supplied. Do not dilute or add other components to Nucleic Acid Plus 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.
7. Hemolysis immediately after draw can be a sign of improper collection technique and the tube should be discarded and redrawn.
   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 of with infectious medical waste.
   d. Remove and reinsert the 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.

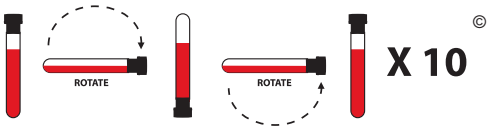
STORAGE AND STABILITY

1. When stored at 2 °C to 25 °C, unfilled Nucleic Acid Plus BCT is stable through expiration date. Do not freeze unfilled Nucleic Acid Plus BCT.
2. Blood samples collected in Nucleic Acid Plus BCT are stable for up to 7 days for cell-free DNA and cell-free RNA and up to 5 days for proteins when stored at 18 °C to 25 °C. For optimal performance, room temperature storage is recommended.
3. Ship tubes filled with blood in a protected ambient shipping package to limit exposure to temperature extremes.

INSTRUCTIONS FOR USE

For best practice in sample collection, refer to the BCT Phlebotomy Resource on the product page.
For a video demonstration, visit streck.com/mixing.

1. Collect specimens by venipuncture according to CLSI PRE02[1].
   Prevention of Backflow - Since Nucleic Acid Plus 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 PRE02[1]. Nucleic Acid Plus BCT can be drawn after the EDTA tube and before the fluoride oxalate (glycolytic inhibitor) tube. If a Nucleic Acid Plus 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 Nucleic Acid Plus BCT.
3. Fill the tube completely.
4. Remove the tube from the adapter and immediately mix by gentle inversion 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, ex vivo platelet activation and hemolysis may be observed when using a smaller gauge needle.
2. When using a winged (butterfly) collection set for venipuncture and the Nucleic Acid Plus 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.
3. As is the case with most clinical laboratory specimens, hemolysis, icterus, and lipemia may affect the results obtained on blood samples preserved with Nucleic Acid Plus BCT.
4. Mishandling of collected samples such as dropping or aggressive mixing may result in ex vivo platelet activation and hemolysis.

PLASMA ISOLATION

Note: Before isolating plasma, re-mix the blood sample by gentle inversion 10 times.
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.
Note: Nucleic Acid Plus BCT has been validated for a maximum centrifugation of 3,000 x g for 10 minutes. Exceeding these limits may result in breakage.

FREEZING AND THAWING PLASMA

1. To Freeze: For long-term storage, after the second spin, collect and transfer the plasma to a cryogenic tube (not provided) and freeze at -20 °C or -80 °C as specified in your protocol.
2. To Thaw: Thaw cryogenic tubes at an appropriate temperature as specified in your protocol.
3. As a general good practice for plasma protein analysis, it is recommended to aliquot plasma before freezing and avoid multiple freeze-thaw cycles.

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 DNA.

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, are not advised.
5. Exosomes isolated from Nucleic Acid Plus BCT may no longer be suitable for functional studies.
6. As the intrinsic stability of plasma proteins varies, and the analytical methods for protein analysis may differ, validating the compatibility of samples collected in Nucleic Acid Plus BCT and your protein analysis protocol is highly recommended. Refer to technical notes at streck.com for more details.

REFERENCES

1. Clinical and Laboratory Standards Institute, PRE02, Collection of diagnostic venous blood specimens. Approved Standard – Eighth Edition.
2. ISO 6710, Single-use containers for human venous blood specimen collection.

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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