



Alexius Biosciences
Decoding Life

Alexgen Cell-free DNA Tube

Cat No:1017



support@alexiusbio.com



www.alexiusbio.com

INSTRUCTIONS FOR USE

Alexgen Cell-free DNA Tube is a direct draw whole blood collection tube intended for collection, transport and storage of blood samples. The product is For Research Use Only. Not for use in diagnostic procedures.

SUMMARY AND PRINCIPLES

Alexgen Cell-free DNA Tube stabilizes cell-free plasma DNA as well as preserves cellular genomic DNA present in nucleated blood cells and circulating epithelial cells (tumor cells) found in whole blood.

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 Alexgen Cell-free DNA Tube stabilizes nucleated blood cells, preventing the release of cellular genomic DNA, and inhibits nuclease mediated degradation of cf-DNA, contributing to the overall stabilization of cf-DNA. Samples collected in Alexgen Cell-free DNA Tube are stable for up to 14 days at temperatures between 6 °C to 37 °C, allowing convenient sample collection, transport and storage.

The preservative reagent contained in Alexgen Cell-free DNA Tube stabilizes circulating epithelial cells (tumor cells) in whole blood for up to 7 days at temperatures between 15 °C to 30 °C.

REAGENTS

Alexgen Cell-free DNA Tube contains the anticoagulant K3EDTA and a cell preservative in a liquid medium.

PRECAUTIONS

1. **For Research Use Only. Not for use in diagnostic procedures.**
2. Do not freeze specimens collected in glass Alexgen Cell-free DNA Tube.
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 Alexgen Cell-free DNA Tube.
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

- Glass has the potential for breakage; precautionary measures should be taken during handling of glass tubes
- 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.

STORAGE AND STABILITY

1. When stored at 10 °C to 30 °C, empty Alexgen Cell-free DNA Tube is stable through expiration date.
2. Short-term storage at 2 °C to 40 °C is acceptable for empty Alexgen Cell-free DNA Tube for up to 14 days
3. Do not freeze empty Alexgen Cell-free DNA Tube. Proper insulation may be required for shipment during extreme temperature conditions.

4. Sample storage/stability:

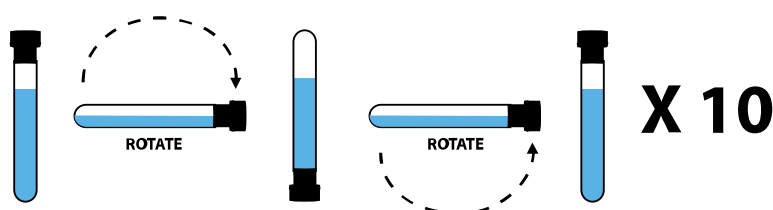
	Sample Type		
	Cell-Free DNA	Cellular Genomic DNA	Epithelial Cells (Tumor Cells)
Sample Stability	14 days	14 days	7 days
Sample Storage Temperature	6°C to 37°C	6°C to 37 °C	15 °C to 30 °C

INDICATIONS OF PRODUCT DETERIORATION

1. Cloudiness or precipitate visible in reagent of empty tube
2. If indications of product deterioration occur, contact Alexgen Technical Services at support@alexiusbio.com

INSTRUCTIONS FOR USE

1. Collect specimen by venipuncture according to CLSI guidelines
Prevention of Backflow - Since Alexgen Cell-free DNA Tube 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 in the uppermost position so that the tube contents do not touch the stopper or the end of the needle during sample collection.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 guidelines. Alexgen recommends collecting a EDTA tube as a waste tube prior to collection in the Alexgen Cell-free DNA Tube.
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 Alexgen Cell-free DNA Tube 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. Alexgen Cell-free DNA Tube does not dilute blood samples; therefore, no dilution factor correction is necessary.
4. As in the case with most clinical laboratory specimens, hemolysis, icterus and lipemia may affect the results obtained on blood samples preserved with Alexgen Cell-free DNA Tube.

LIMITATIONS

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

For enquiries email us at support@alexiusbio.com



Alexius Biosciences

A/619, Girivar Glean,

Near Palm Hotel, Odhav, Ahmedabad-382415

