Cell-Free DNA Blood Collection Tube (BCT)

INSTRUCTIONS

INTENDED USE

Cell-Free DNA Blood Collection Tube (in short name Cell-Free DNA BCT) is a direct draw whole blood collection tube intended for collection, stabilization and transportation of cell-free plasma or serum DNA and cellular genomic DNA present in nucleated cells. This product is for Research Use Only. Not for use in diagnostic procedures.

ORDER INFO

Name	Cat #	Size	Package
Cell-Free DNA Blood Collection Tube (BCT)	P8071(50)	10ml	50pcs/box
	P8071(100)	10ml	100pcs/box

SUMMARY AND PRINCIPLES

The implications of cfDNA in blood in clinical medicine were realized for about two decades. The cfDNA extracted from plasma or serum of cancer patients has shown characteristics typical of tumor DNA and may serve as noninvasive biomarkers for cancer detection and management. It was also demonstrated the presence of fetal cfDNA in maternal plasma. Clinical applications involving fetal cfDNA analysis include sex determination, single-gene disorders, aneuploidy detection and so on. Due to the low abundance of the cfDNA biomarkers of cancer or fetal origin, it is recommended that genomic DNA background levels be minimized to provide accurate measurements cfDNA levels.

The mixing cell protective reagent contained in Cell-Free DNA BCT can stabilize nucleated blood cells, preventing the release of cellular genomic DNA, inhibiting nuclease mediated degradation of cfDNA, and contribute to the overall stabilization of cfDNA. Blood samples collected in Cell-Free DNA BCT are stable for up to 14 days when stored at the recommended temperature range(6-37°C) or 72h when shipment.

REAGENTS

Cell-Free DNA BCT contains the anticoagulant K3 EDTA and a mixing cell protective reagent in a liquid medium.

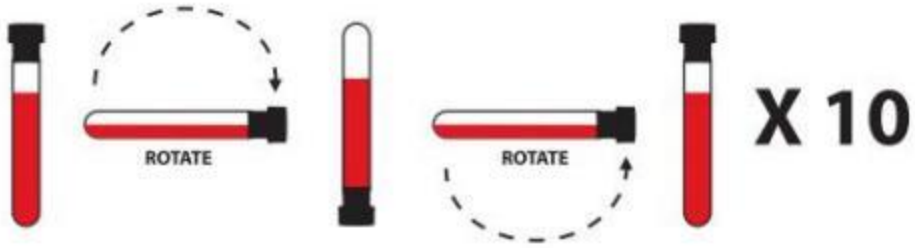
Cell-Free DNA Blood Collection Tube (BCT)

STORAGE AND STABILITY

1. When stored at 18-30°C, Cell-Free DNA BCT is stable through expiration date.
2. Blood samples collected in Cell-Free DNA BCT for cfDNA analysis are stable for 14 days when stored between 6-37°C.
3. Do not freeze unfilled Cell-Free DNA BCT.
4. During extreme temperature conditions, Cell-Free DNA BCT needs proper insulation for shipment.

INSTRUCTIONS FOR USE

1. Collect specimen by venipuncture according to WS/T225-2002.
2. Since Cell-Free DNA BCT contains chemical additives, it is very important to avoid possible backflow from the tube.
3. Fill tube completely.
4. Remove tube from adapter and immediately mix by gently inversion 8-10 times. 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 (6-37C).
6. Perform extraction in accordance with instrument manufacturer's instructions.

Cell free plasma or serum DNA and cellular genomic DNA extraction

1. Extraction of cell-free plasma DNA and cellular genomic DNA can be accomplished using most commercially available kits. (Magen IVD3182, IVD5432, ect)For optimal results, add 20μl of Proteinase K (20mg/μl) at 56C in the presence of chaotropic salts for 30 minutes.

Cell-Free DNA Blood Collection Tube (BCT)

NOTE

1. Reagents in Cell-Free DNA BCT do not dilute blood samples, and no dilution factor correction is necessary to obtain absolute count values.
2. Hemolysis, icterus and lipemia may affect the results obtained on blood samples preserved with Cell-Free DNA BCT.

LIMITATIONS

Blood samples drawn in other anticoagulants or preservatives may cause coagulation or hemolysis in Cell-Free DNA BCT.

PRECAUTIONS

1. For Research Use Only. Not for use in diagnostic procedures.
2. Do not freeze specimens collected in Cell-Free DNA 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. Do not dilute or add other components to Cell-Free DNA BCT.
6. 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

1. Glass has the potential for breakage, precautionary measures should be taken during handing.
2. All biological specimens and materials coming in contact with them are considered biohazards and should be disposed with infectious medical waste in according with federal, state and local regulations. Avoid contract with skin and mucous membranes.