

INTRODUCTION

Blood STASIS™ 21-ccfDNA tube is used for collecting whole blood and for isolating circulating, cell-free DNA (ccfDNA) from plasma. It is a plastic, evacuated tube. The tube has an additive inside that helps in the stabilization of blood cells and also helps in the anti-coagulation of blood cells. These 2 processes in turn prevent the release of intracellular DNA into plasma and stabilize ccfDNA levels.

INTENDED USE

Blood STASIS 21-ccfDNA tube is intended for collection, stabilization, transportation and storage of whole blood for subsequent isolation of circulating nucleic acids from plasma. Blood STASIS-21 Tube has to be used for research purposes only. Molecular testing methods that need ccfDNA are its suggested use.

Do not use Blood STASIS 21-ccfDNA tube for managing patients and diagnostic procedures. The clinical utility and the performance characteristics of this product have not been established for in vitro diagnostic procedure.

PRODUCT FEATURES	Blood STASIS 21-ccfDNA 9mL (BS21-CF10-100)	Blood STASIS 21-ccfDNA 6mL (BS21-CF6-100)	Blood STASIS 21-ccfDNA 3mL (BS21-CF3-200)
Tube Size	16 x 100mm	13 x 100mm	13 x 75mm
Blood draw volume	8 ml	5.4 ml	2.65 ml
Additive volume	1 ml	0.6 ml	0.35 ml
Sample stability	21 days	21 days	21 days
Sample Storage Temperature	15°C-30°C	15°C-30°C	15°C-30°C
Quantity of tubes	100	100	200

Blood STASIS™ 21-ccfDNA is for Research Use Only. Not for use in diagnostic procedures. No claim or representation is intended to provide information for the diagnosis, prevention, or treatment of a disease. The performance characteristics of this product have not been fully established.

SUMMARY

The Blood STASIS™ 21-ccfDNA product comprising of a single tube, delivers an effective method for standardization of blood collection, transport and storage of whole blood sample, preservation of ccfDNA.

PRINCIPLE OF PROCEDURE

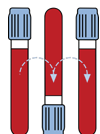
Blood STASIS 21-ccfDNA tube allows the collection from 2.65ml to 8ml (depending on he product) of whole blood in a closed, evacuated system. Blood is collected using standard venipuncture technique into an evacuated tube that contains either 0.35ml, 0.6ml or 1ml of cell stabilization additive. Isolation of ccfDNA from plasma is carried out using the MagBio cfKapture 21 Kit (Cat.No. CFK-D50-5ML) or any other method commercially available. However to ensure stability of separated plasma and high quality ccfDNA, we recommend the MagBio cfKapture 21 Kit for plasma separation and ccfDNA isolation.

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

- Required Blood Collection Accessories (not included with Blood STASIS 21-ccfDNA Tube).
- Collect specimen by venipuncture
- If required, use labels for sample identification.
- For the cleaning site, use alcohol swab.
- Dry Sterile Gauze
- Tourniquet is used.
- A biohazard container is used for used needle or needle/holder combination.

PROCEDURE FOR SPECIMEN COLLECTION

1. Blood STASIS 21-ccfDNA tube should be properly labeled with sample identification and be at room temperature before use.
 2. Collection of blood in the tube is done using the SOP for venipuncture technique used in customer's laboratory.
 3. Preventing back flow:
 - To guard against back flow, 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.
 - d. Make sure tube additives do not touch stopper or non-patient end of the needle during venipuncture.
 4. Before removing the tube from the holder it should be ensured that the blood flow into the tube has stopped.
 5. Fill Blood STASIS 21-ccfDNA tube to the indicated line on the tube.
 6. Invert the tube 8 to 10 times gently to allow efficient stabilization of specimen.
- Regardless of the additive type, all tubes should be gently inverted to ensure thorough mixing of the blood with the additive. Tubes must be mixed to ensure that the specimen does not clot.



7. Blood samples filled in Blood STASIS 21-ccfDNA tube are stable at room temperature (15–30°C) for up to 21 days until centrifugation and plasma processing.

PROCEDURE FOR PLASMA PREPARATION AND ccfDNA ISOLATION

TO AVOID IMMEDIATE FREEZING AND ANY COLD STORAGE OF SEPARATED PLASMA, WE RECOMMEND STABILIZATION OF PLASMA SAMPLE WITH **cfKapture 21 Kit** (CAT NO# CFK-D50-5ML).

A. Using cfKapture 21 Kit for plasma stabilization and ccfDNA isolation

Note: Using this procedure, stabilized plasma sample can be stored at room temperature for up to 21 days before proceeding with ccfDNA isolation.

1. Centrifuge the 10 mL blood tube at room temperature at 2000 x g for 15 minutes.
2. A second centrifugation step must be performed for further purification of plasma.
3. Pipette plasma into a 15 ml conical bottom centrifugation tube. Buffy coat and the cellular fraction must not be disturbed.
4. Centrifuge a second time the 15 ml conical tube for 10 minutes at 13000 x g at room temperature (15-25°C).
5. Pipette the clear plasma into a new 15 ml conical tube **containing 2mL of MagBio SE Buffer** to stabilize the plasma sample.
6. Cap the tube tightly and mix by gentle inversion 10 times.
7. Proceed with ccfDNA isolation using cfKapture 21 Kit or process at a later time. Stabilized plasma can be stored at room temperature for up to 21 days.

B. Preparing NON STABILIZED plasma sample for ccfDNA isolation

1. Centrifuge the blood tube at room temperature at 2000 x g for 20 minutes.
2. A second centrifugation step must be performed for further purification of plasma.
3. Pipette plasma into a 15 ml conical bottom centrifugation tube. Buffy coat and the cellular fraction must not be disturbed.
4. Centrifuge the 15ml conical tube for 10 minutes at 13000 x g at room temperature (15-25°C).
5. Pipette the clear plasma into a new 15 ml conical tube. The residual blood cell pellet at the bottom of the tube, if present, must not be disturbed.
6. Proceed with ccfDNA isolation using cfKapture 21 Kit (CAT NO# CFK-D50-5ML) or any other commercial kit that is used for processing the sample or store the plasma sample at -20°C to -80°C.

DNA EXTRACTION

Genomic DNA: Isolation of genomic DNA and circulating, cell-free DNA can be performed using the following kits:

- cfDNA: MagBio cfKapture 21 Kit - Circulating Cell-free Circulating DNA Isolation from stabilized plasma (Cat#CFK-D50-5ML)
- Genomic DNA: MagBio HighPrep Blood and Tissue DNA kit (Cat# HPBTS-D96)

STORAGE AND STABILITY

1. Store the unused Blood STASIS 21-ccfDNA tubes at room temperature (15–30°C) for 14 months.
2. Blood samples collected in Blood STASIS 21-ccfDNA tube for ccfDNA analysis are stable for 21 days when stored between (15–30°C).
3. Blood samples collected in Blood STASIS 21-ccfDNA for genomic DNA analysis are stable for 21 days when stored between (15–30°C).

Since Blood STASIS 21-ccfDNA tubes contain a chemical additive, it is important to avoid possible backflow from the tube, with the possibility of adverse subject reactions. To guard against backflow, observe the following precautions.

1. Place subject's arm in a downward position.
2. Hold tube with the stopper uppermost.
3. Release tourniquet as soon as blood starts to flow into tube.
4. Make sure tube additives do not touch stopper or non-patient end of the needle during venipuncture.

LIMITATIONS OF SYSTEM

1. This Blood STASIS 21-ccfDNA tube is for research use only, and therefore, the use of this product for diagnostic procedures and subject management is strictly prohibited. Neither the clinical utility nor the performance characteristics of Blood STASIS 21-ccfDNA tube and kits as part of an in vitro diagnostic procedure have been established.
2. The quantity of blood drawn varies with altitude, ambient temperature, barometric pressure, tube age, venous pressure, and filling technique.
3. Plasma from blood samples obtained with Blood STASIS 21-ccfDNA tube could be prepared with the MagBio cfKapture 21 Kit or any competitor's system commercially available. However to ensure higher quality of ccfDNA and subsequent downstream analysis we recommend the use of MagBio cfKapture 21 Kit.
4. Endotoxin not controlled. Blood and blood components collected and processed in the tube are not intended for infusion or introduction into the human body.

PRECAUTIONS

- Contents of this tube may cause irritation to eyes, respiratory system and skin.
- After inhalation, supply fresh air, and seek medical advice in case of complaints.
- After skin contact, immediately wash with water and soap and rinse thoroughly.
- After eye contact, rinse immediately with plenty of water for at least 15 minutes and seek medical advice.
- After swallowing, immediately seek medical advice.

- CONTINUE -

Blood STASIS™ 21-ccfDNA



- CONTINUE -

Practice Universal Precautions. Use gloves, gowns, eye protection, other personal protective equipment, and engineering controls to protect from blood splatter, blood leakage, and potential exposure to blood borne pathogens.

Handle all biologic samples and blood collection devices (lancets, needles, lue adapters, and blood collection sets) according to the policies and procedures of your facility. Obtain appropriate medical attention in the event of any exposure to biologic samples (for example, through a puncture injury), since they may transmit viral hepatitis, HIV, or other infectious diseases.

Discard all blood collection tubes and accessories in biohazard containers approved for their disposal. Since this Blood STASIS 21-ccfDNA tube contains a chemical additive, precautions should be taken to prevent possible back flow from the tube during drawing of blood (see Procedure for Specimen Collection).

Transferring a blood sample collected with a syringe and needle into the Blood STASIS 21-ccfDNA tubes is not recommended due to the increased potential for needle stick injury.

- Do not re-use Blood STASIS 21-ccfDNA tube. For single use only.
- Do not use Blood STASIS 21-ccfDNA tube after expiration date.
- Do not freeze blood sample collected in Blood STASIS 21-ccfDNA tube.
- Do not use injected contents of Blood STASIS 21-ccfDNA tube content on patients.
- Do not add any other component to Blood STASIS 21-ccfDNA tube.

ORDERING AND TECHNICAL ASSISTANCE

To place an ordering and technical assistance, call 301-302-0144 or visit our website at www.magbiogenomics.com.



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