Blood STASIS[™]-Omics

INTRODUCTION

Blood STASIS- Omics Tube is a plastic, evacuated tube; used for ambient stabilization of DNA, mRNA; proteins, and metabolites from a single blood sample. Blood STASIS- Omics Tube contains a non-fixative additive that helps maintain the integrity of DNA, mRNA; proteins, and metabolites and helps prevent the coagulation of whole blood.

INTENDED USE

Blood STASIS-Omics Tube is intended for ambient stabilization of DNA, mRNA; proteins, and metabolites from a single blood sample for their subsequent isolation from blood. Blood STASIS-Omics Tube has to be used for research purposes only.

Do not use Blood STASIS-Omics 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-Omics 9mL (BS-OM10-100)	Blood STASIS-Omics 6mL (BS-OM6-100)	Blood STASIS-Omics 3mL (BS-OM3-200)
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	upto 7 days	upto 7 days	upto 7 days
Sample Storage Temperature	15°C-30°C	15°C-30°C	15°C-30°C
Quantity of tubes	100	100	200

Blood STASIS™-Omics 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-Omics 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-Omics 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

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

- Required Blood Collection Accessories (not included with Blood STASIS-Omics 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-Omics 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-Omics 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-Omics tube are stable at room temperature (15-30°C) for up to 7 days until centrifugation and plasma processing

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-Omics 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-Omics tubes is not recommended due to the increased potential for needle stick injury.

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

ORDERING AND TECHNICAL ASSISTANCE

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

STORAGE AND STABILITY

1. Store the unused Blood STASIS-Omics tubes at room temperature (15–30°C) for 14 months.

2. Blood samples collected in Blood STASIS-Omics tube for ambient stabilization of DNA, mRNA; proteins, and metabolites analysis are stable for 7 days when stored between (15-30°C).

Since Blood STASIS-Omics 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-Omics 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-Omics 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. 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



Not all products are available in all countries. Please consult your local sales representative for details. For Blood STASIS will be trademark to Magbio Genomics, Inc. Specifications, terms and pricing are subject to change research use only Mol for use in diadmistic borcedures.



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