

DEVICE NAME

HemaSure-OMICs Direct Draw Blood Stabilization

INDICATION FOR USE

HemaSure-OMICs is a direct-draw venous whole blood collection device intended for the collection, storage, and transport of venous whole blood samples and stabilization of intracellular RNA, cell-free DNA (cfDNA) and genomic DNA, (gDNA). For molecular diagnostic and next-generation sequencing assays that require cfDNA, RNA, or gDNA from whole blood.

CONTENTS

HemaSure -OMICs Tube

STORAGE AND STABILITY

Pre-collection: 3 months from date of manufacture between 15-30° C. Transport and storage temperature tolerance 4-45°C

Sample stability and storage, post-collection: Separated plasma can be stored for 14 days at room temperature and several years when stored between 20° and -80°C.

Always separate the plasma before long term storage between -20° and -80°C.

Plasma can be thawed up to 3 times, so plan your storage aliquots accordingly.

If longer storage time is required, collected samples can be stored at -20 to -80° C.

Additional information available at www.mawidna.com.

WARNING AND PRECAUTIONS

For external use only. This product is a specimen collection device for biological samples. If the reagent inside the tube comes in contact with your eyes or your skin, it is recommended to immediately wash with water and soap. Device cap can be a choking hazard. Do not ingest.

DEVICES

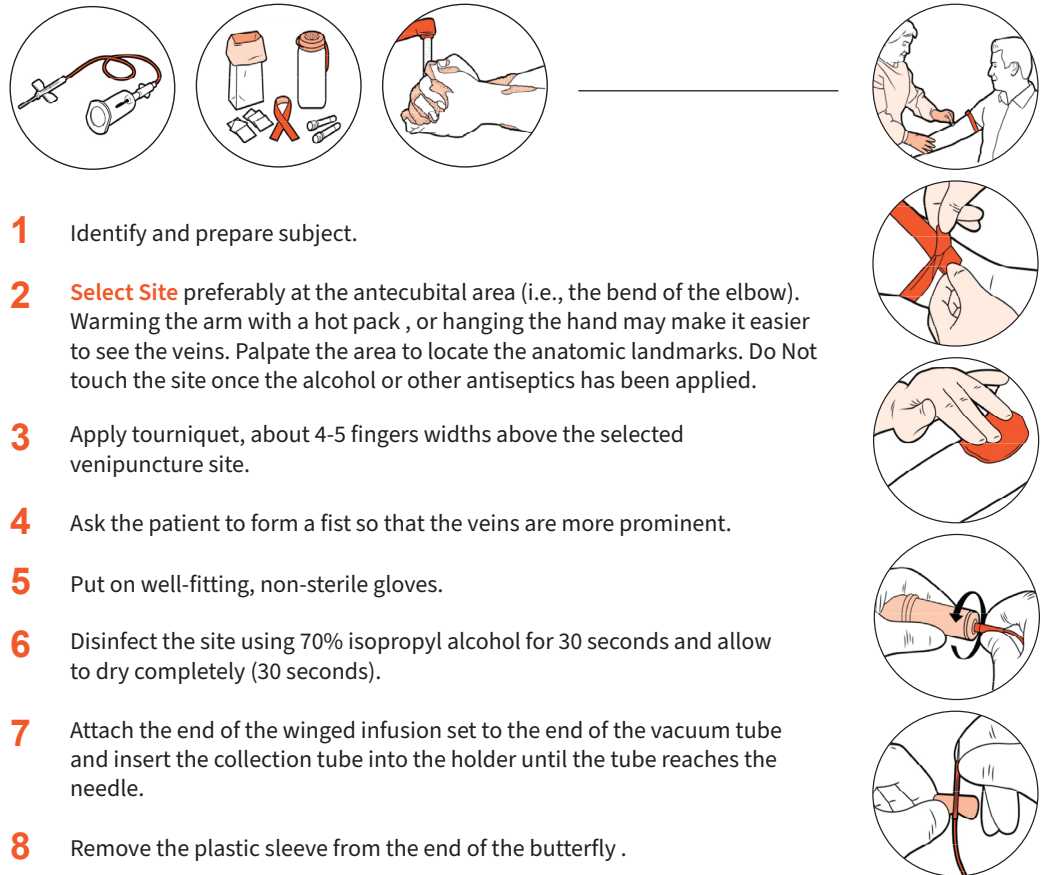
HemaSure-OMICs Blood tubes contain a pre-filled amount of stabilizing buffer. Consider this in any final yield.

REF /Catalog Number	Product Family Name	Stabilizing Buffer
HemaSure-OMICs-3	HemaSure-OMICs Blood Stabilization Direct Draw Device	3.0 mL x 50 Units
HemaSure-OMICs-6	HemaSure-OMICs Blood Stabilization Direct Draw Device	6.0 mL x 50 Units
HemaSure-OMICs-9	HemaSure-OMICs Blood Stabilization Direct Draw Device	9.0 mL x 50 Units

PREPARATION FOR USE

Before sample collection, verify preferred method of collection with your processing lab.

- Use a winged steel needle, usually 23 or 25 gauge with an extension tube (butterfly) or Safety-Lok blood collection set (BD, REF 367283). Keep the tube and needle separated until the needle is in the vein. (BD, REF 367283)
- Blood Collection supplies & equipment. Properly dispose of all contaminated supplies.
- Hemolysis, icterus, or lipemia might have limited effect on the stabilization capacity of HemaSure receiving the sample will further minimize the effects of hemolysis, icterus, and lipemia on the stability of cfDNA.



- 1 Identify and prepare subject.
- 2 **Select Site** preferably at the antecubital area (i.e., the bend of the elbow). Warming the arm with a hot pack, or hanging the hand may make it easier to see the veins. Palpate the area to locate the anatomic landmarks. Do Not touch the site once the alcohol or other antiseptics has been applied.
- 3 Apply tourniquet, about 4-5 fingers widths above the selected venipuncture site.
- 4 Ask the patient to form a fist so that the veins are more prominent.
- 5 Put on well-fitting, non-sterile gloves.
- 6 Disinfect the site using 70% isopropyl alcohol for 30 seconds and allow to dry completely (30 seconds).
- 7 Attach the end of the winged infusion set to the end of the vacuum tube and insert the collection tube into the holder until the tube reaches the needle.
- 8 Remove the plastic sleeve from the end of the butterfly.

HemaSure-OMICs Technology

mawi

INSTRUCTIONS FOR BLOOD COLLECTION – English

Caution: Read all steps before collecting samples.

DEVICE NAME

HemaSure-OMICs Direct Draw Blood Stabilization

INDICATION FOR USE

HemaSure-OMICs is a direct-draw venous whole blood collection device intended for the collection, storage, and transport of venous whole blood samples and stabilization of intracellular RNA, cell-free DNA (cfDNA) and genomic DNA, (gDNA). For molecular diagnostic and next-generation sequencing assays that require cfDNA, RNA, or gDNA from whole blood.

CONTENTS

HemaSure -OMICs Tube

STORAGE AND STABILITY

Pre-collection: 3 years from date of manufacture between 15-30° C. Transport and storage temperature tolerance 4-45° C

Sample stability and storage, post-collection: Separated plasma can be stored for 14 days at room temperature and several years when stored between 20° and -80° C.

Always separate the plasma before long term storage between -20° and -80° C.

Plasma can be thawed up to 3 times, so plan your storage aliquots accordingly.

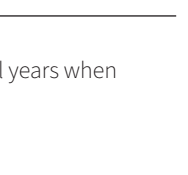
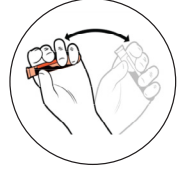
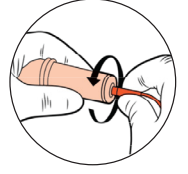
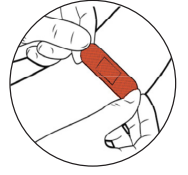
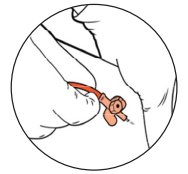
If longer storage time is required, collected samples can be stored at -20 to -80° C.

Additional information available at www.mawidna.com.

WARNING AND PRECAUTIONS

For external use only. This product is a specimen collection device for biological samples. If the reagent inside the tube comes in contact with your eyes or your skin, it is recommended to immediately wash with water and soap. Device cap can be a choking hazard. Do not ingest.

- 9 Use a thumb to draw the skin tight, about two fingers widths below the venipuncture site.
- 10 When the butterfly winged needle is inserted correctly the blood will flow through the tube, then push the vacuum tube completely onto the needle positioned in the blood tube adaptor.
- 11 Fill tube until it is full or until the vacuum is exhausted; if filling multiple tubes, carefully remove the full HemaSure Blood tube and replace with another tube, taking care not to move the needle in the vein.
- 12 After the required amount of blood has been collected, release the tourniquet.
- 13 Place dry gauze over the venipuncture site and slowly withdraw the needle.
- 14 Ask the parent or adult to continue applying mild pressure until there is no blood drops observed.
- 15 Put adhesive bandage on the patient if necessary.
- 16 Remove the butterfly from the vacuum tube holder.
- 17 Following laboratory instructions, invert the sample gently 10 times to mix the stabilizing additive with the blood before dispatch.
- 18 Dispose of the butterfly in a sharps container.
- 19 Properly dispose of all contaminated supplies in the appropriate biohazard waste in accordance with federal, state, and local regulations.
- 20 Label the blood tube with the patient identification number and date.



NOTES

- Separated plasma can be stored for several days at room temperature and several years when stored between 20° and -80° C.
- Always separate the plasma before long-term storage between -20° and -80° C.
- Plasma can be thawed up to 3 times, so plan your storage aliquots accordingly.

Attention. See instructions for use.

Storage temperature.

Use by date (collect sample by).

Consult package insert before use.

For one use only.

CE marking.

Do not use if package is damaged.

LOT Lot number.

REF Catalog Number.

Authorized representative.

Manufacturer.

In vitro diagnostic medical device.

Mawi DNA Technologies LLC
26203 Production Ave, Suite No.3 | Hayward, CA 94545
Tel: 510-256-5186 Toll Free (US & Canada): 855-DNA-SWAB
www.MawiDNA.com

EC REP CEpartner4U
Esdoornlaan 13 | 3951 DB
Maarn | The Netherlands
www.cepartner4u.com

