INFORMATION FOR USE (IFU)

MDXM0023

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Sodium Heparin Anticoagulant

Description: Sodium Heparin Anticoagulant solution is used for IRB-Approved research studies to support diagnostic claims for Sodium Heparin blood tubes.

Intended Use: Sodium Heparin Anticoagulant is added to a whole blood sample to prevent clotting. Add 1mL of the Sodium Heparin Anticoagulant solution per 100mL of whole blood and mix by rocking. This will mimic the same concentration of Sodium Heparin in a blood collection tube.

Product Specifications:

MRNDx Part Number	Volume	Storage Conditions	Stability
MDXM0023-10	10mL	15°C to 30°C	12 months
MDXM0023-50	50mL	15°C to 30°C	12 months
MDXM0023-250	250mL	15°C to 30°C	12 months

For Research Use Only – This product is intended for research and development use and should not be used for clinical diagnostic purposes.

IMPORTANT: Biosafety Level 1: The materials used to formulate this product contain no infectious material that pose hazard to laboratory personnel and the environment. These products are NOT intended for use in the manufacturing and/or processing of injectable products subject to licensure under section 351 of the Public Health Service Act or for any other product intended for administration to humans.

This product was manufactured in a facility under a Quality Management System certified by ISO 13485:2016 for the manufacturing of medical devices.

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