

INFORMATION FOR USE (IFU)

MDXM0021

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3.2% Sodium Citrate Anticoagulant

Description: 3.2% Sodium Citrate Anticoagulant solution is used for IRB-Approved research studies to support diagnostic claims for 3.2% Sodium Citrate blood tubes.

Intended Use: 3.2% Sodium Citrate Anticoagulant is added to a whole blood sample to prevent clotting. Add 12.5mL of the 3.2% Sodium Citrate Anticoagulant solution per 100mL of whole blood (1:9 Ratio) and mix by rocking. This will mimic the same concentration of 3.2% Sodium Citrate in a blood collection tube. Do not freeze material after adding 3.2% Sodium Citrate to whole blood.

Product Specifications:

MRNDx Part Number	Volume	Storage Conditions	Stability
MDXM0021-10	10mL	15°C to 30°C	12 months
MDXM0021-50	50mL	15°C to 30°C	12 months
MDXM0021-250	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.