



INFORMATION FOR USE (IFU)

MDXR0039

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Normal Serum Base Matrix

Description: Normal Serum Base Matrix is formulated with OTC “Off the Clot” serum derived from normal whole blood. Samples are collected from IRB-approved and consented healthy donors in an FDA-registered facility. All donors are screened negative for FDA transfusion markers using FDA-cleared test methods. Donor material is then pooled, sterile-filtered, and stored frozen to the volumes listed below.

Intended Use: Normal Serum Base Matrix is used to support your analytical studies. It may be used to titrate markers for determination of assay LOD and sample recovery, evaluation of assay precision, and other validation studies to support your regulatory submissions.

Product Specifications:

MRNDx Part Number	Volume	Storage Conditions	Stability
MDXR0039-100	100mL	-10 to -30 °C	24 months
MDXR0039-250	250mL	-10 to -30 °C	24 months
MDXR0039-500	500mL	-10 to -30 °C	24 months
MDXR0039-1000	1000mL	-10 to -30 °C	24 months

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

Caution Human Biological Material: Biosafety Level 2: Includes moderate-risk agents that are present in the community and associated with human. All donors are screened negative for FDA required viral markers using FDA-cleared test methods, however, all materials should be considered potentially infectious and handled with universal precautions.

IMPORTANT: 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.