INFORMATION FOR USE (IFU)

MDXR0039

Document #: MDX-SAL-IFU-015
Revision No: 002
Effective Date: Captured Electronically

Normal Clinical Matrix

Description: Normal Clinical Matrix is derived from anterior nasal swab samples diluted into either UTM, VTM, or Saline solution. 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 and stored frozen to the volumes listed below.

Intended Use: Normal Clinical 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
MDXR0039-5	5mL	-10 to -30 °C	24 months
MDXR0039-10	10mL	-10 to -30 °C	24 months
MDXR0039-50	50mL	-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 1: The materials used to formulate this product contain no infectious material that pose hazard to laboratory personnel and the environment. 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.