

INFORMATION FOR USE (IFU)

MDXB0008

Document #: MDX-SAL-IFU-013

Revision No: 002

Effective Date: Captured Electronically

Normal Pooled Human Serum

Description: OTC “Off the Clot” Normal Human Serum Pool is derived from whole blood collected from consented, healthy donors in an AABB–certified, IRB-approved, and FDA-licensed blood center. All units are screened negative for FDA required viral markers using FDA-cleared test methods. All whole blood units are allowed to clot naturally, after which the clot is removed by centrifugation, leaving behind OTC serum.

Intended Use: Normal Human Serum Pool may be used for research and development, analytical testing, and/or for *in vitro* manufacturing of your diagnostic test.

Product Specifications:

MRNDx Part Number	Volume	Storage Conditions	Stability
MDXB0008-10	10mL	-10 to -30 °C	24 months
MDXB0008-50	50mL	-10 to -30 °C	24 months
MDXB0008-100	100mL	-10 to -30 °C	24 months
MDXB0008-500	500mL	-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 units 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.