

INFORMATION FOR USE (IFU)

MRNHS-200

Document #: MDX-MM-PKI-014

Revision No: 000

Effective Date: Captured Electronically

MRNDx HIV ½ & Syphilis Verification Panel

Panel Description: The MRNDx HIV ½ & Syphilis Verification Panel is formulated using plasma from infected donors that were confirmed HIV ½ or Syphilis antibody positive, in addition to plasma donors found to be negative for HIV ½ & Syphilis antibodies. The panel also includes screening for markers on each of the individual donors. All samples have been heat inactivated to render them noninfectious and stabilized for storage at refrigerated temperatures and shipment at refrigerated or ambient temperatures.

Intended Use: The MRNDx HIV ½ & Syphilis Verification Panel is used to evaluate the performance of intended assays for the detection of HIV ½ & Syphilis antibodies in blood samples.

This panel should be run following your organization's quality system's requirements or the test manufacturer's recommendation for verification of diagnostic tests and platforms prior to reporting patient results.

Panel Configuration: The MRNDx HIV ½ & Syphilis Verification Panel contains 5 x HIV-1 reactive samples, 5 x HIV-2 reactive samples, 5 x Syphilis Reactive samples and 5 x HIV ½ & Syphilis Non-Reactive samples. All samples are prepared with preservatives and antimicrobials.

Panel Specifications:

MRNDx Part Number: MRNHS-200

Volume: 20 x 0.5mL

Storage Conditions: 2-8°C

Key to Panel Members

Member No.	Result	Member No.	Result
Member-01	HIV-1 Positive	Member-11	HIV-1 Positive
Member-02	HIV ½ & Syphilis Negative	Member-12	HIV-2 Positive
Member-03	HIV-2 Positive	Member-13	Syphilis Positive
Member-04	Syphilis Positive	Member-14	HIV-1 Positive
Member-05	Syphilis Positive	Member-15	HIV ½ & Syphilis Negative
Member-06	HIV ½ & Syphilis Negative	Member-16	HIV-2 Positive
Member-07	HIV-1 Positive	Member-17	Syphilis Positive
Member-08	HIV-2 Positive	Member-18	HIV ½ & Syphilis Negative
Member-09	HIV ½ & Syphilis Negative	Member-19	HIV-1 Positive
Member-10	Syphilis Positive	Member-20	HIV-2 Positive

Caution Human Biological Material: All materials are considered potentially infectious and should be handled with universal precautions. Positive and Negative Control material have been tested and have been found negative/non-reactive for at least; Anti-HCV, and HBsAg.

IMPORTANT: These products are NOT intended for use in the manufacturing 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.

For Research Use Only

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