

INFORMATION FOR USE (IFU)

MRNHS-100

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MRNDx HIV-Syphilis Verification Panel

Panel Description: The MRNDx HIV-Syphilis Verification Panel is formulated using plasma from normal and infected donors that were confirmed HIV or Syphilis antibody positive. All samples have been heat inactivated to render them noninfectious and stabilized for storage at refrigerated temperatures.

Intended Use: The MRNDx HIV-Syphilis Verification Panel is used to evaluate the performance of HIV & Syphilis antibodies in blood samples. This panel should be run according to your organization's quality system requirements, by following the recommendations of the test kit manufacturer, or by using the *CLSI EP23 Laboratory Quality Control Based on Risk Management* guidance document.

Panel Configuration: The MRNDx HIV-Syphilis Verification Panel contains 5 x HIV reactive samples, 5 x Syphilis reactive samples, 5 x HIV and Syphilis Reactive samples and 10 x Non-Reactive samples. All samples are prepared with preservatives and antimicrobials.

Panel Specifications:

MRNDx Part Number: MRNHS-100

Volume: 25 x 0.5mL

Storage Conditions: 2-8°C

Key to Panel Members

Member No.	Result	Lot No.	Member No.	Result	Lot No.
MRNHS-100-01	HIV Positive	2002100167	MRNHS-100-14	HIV/Syph Positive	2002100180
MRNHS-100-02	HIV Positive	2002100168	MRNHS-100-15	HIV/Syph Positive	2002100181
MRNHS-100-03	HIV Positive	2002100169	MRNHS-100-16	Negative	2002100182
MRNHS-100-04	HIV Positive	2002100170	MRNHS-100-17	Negative	2002100183
MRNHS-100-05	HIV Positive	2002100171	MRNHS-100-18	Negative	2002100184
MRNHS-100-06	Syph Positive	2002100172	MRNHS-100-19	Negative	2002100185
MRNHS-100-07	Syph Positive	2002100173	MRNHS-100-20	Negative	2002100186
MRNHS-100-08	Syph Positive	2002100174	MRNHS-100-21	Negative	2002100187
MRNHS-100-09	Syph Positive	2002100175	MRNHS-100-22	Negative	2002100188
MRNHS-100-10	Syph Positive	2002100176	MRNHS-100-23	Negative	2002100189
MRNHS-100-11	HIV/Syph Positive	2002100177	MRNHS-100-24	Negative	2002100190
MRNHS-100-12	HIV/Syph Positive	2002100178	MRNHS-100-25	Negative	2002100191
MRNHS-100-13	HIV/Syph Positive	2002100179			

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.