

INFORMATION FOR USE (IFU)

MRNCAG-301

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MRNDx Respiratory Verification Panel

Panel Description: The MRNDx Respiratory Verification Panel is formulated with organisms from clinical isolates purified from PCR confirmed individuals infected with SARS-CoV-2, Influenza A, and Influenza B. The panel also contains samples negative for SARS-CoV-2, Influenza A, and Influenza B. All samples have been chemically inactivated to render them noninfectious and stabilized in a Mock Nasal Fluid medium for storage and shipment at refrigerated temperatures.

Intended Use: The MRNDx Respiratory Verification Panel is used to evaluate the performance of respiratory virus assays for the detection of SARS-CoV-2, Influenza A, and Influenza B in nasal and nasopharyngeal 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 Respiratory Verification Panel contains 10 x SARS-CoV-2, Influenza A, and Influenza B Reactive Reference Materials (formulated with various combinations of clinical isolates at various concentrations) and 10 x Non-Reactive samples. All samples are prepared in Mock Nasal Fluid with preservatives and antimicrobials.

Panel Specifications:

MRNDx Part Number: MRNCAG-301

Volume: 20 x 0.5mL

Storage Conditions: 2-8°C

Key to Panel Members

Member No.	Result	Member No.	Result
Member-01	SARS-CoV-2, Flu A & Flu B Positive	Member-11	SARS-CoV-2, Flu A & Flu B Negative
Member-02	SARS-CoV-2, Flu A & Flu B Positive	Member-12	SARS-CoV-2, Flu A & Flu B Negative
Member-03	SARS-CoV-2, Flu A & Flu B Positive	Member-13	SARS-CoV-2, Flu A & Flu B Negative
Member-04	SARS-CoV-2, Flu A & Flu B Positive	Member-14	SARS-CoV-2, Flu A & Flu B Negative
Member-05	SARS-CoV-2, Flu A & Flu B Positive	Member-15	SARS-CoV-2, Flu A & Flu B Negative
Member-06	SARS-CoV-2, Flu A & Flu B Positive	Member-16	SARS-CoV-2, Flu A & Flu B Negative
Member-07	SARS-CoV-2, Flu A & Flu B Positive	Member-17	SARS-CoV-2, Flu A & Flu B Negative
Member-08	SARS-CoV-2, Flu A & Flu B Positive	Member-18	SARS-CoV-2, Flu A & Flu B Negative
Member-09	SARS-CoV-2, Flu A & Flu B Positive	Member-19	SARS-CoV-2, Flu A & Flu B Negative
Member-10	SARS-CoV-2, Flu A & Flu B Positive	Member-20	SARS-CoV-2, Flu A & Flu B Negative

Caution Human Biological Material: Positive panel members are treated chemically to inactivate the SARS-CoV-2, Influenza A, and Influenza B Viruses using a validated protocol. However, all materials are considered potentially infectious and should be handled with universal precautions.

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.