INFORMATION FOR USE (IFU)

MDXP0055

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Influenza A&B Molecular Validation Swabs

Description: Influenza A&B Molecular Swabs are formulated with inactivated whole Influenza A and Influenza B virus particles to mimic a positive clinical specimen. These controls may be used for all molecular testing formats. These swab controls are full-process and are designed to run with the same testing procedures as a patient sample so they can be used to monitor and QC all steps in molecular testing.

Intended Use: Influenza A&B Molecular Swabs are used to evaluate the performance of Influenza A and Influenza B molecular assays. It is recommended to run these swabs: for technician training, to monitor the effect of laboratory environmental conditions, to examine test kit lot-to-lot consistency, and to follow operator variation. The swabs should also be run according to your organization's quality system requirements for QC testing or by using the recommendations from the test kit manufacturer.

Panel Specifications:

- MRNDx Part Number: MDXP0055
- Volume: 5 x Influenza A and Influenza B Molecular Positive Swab Controls and 5 x Negative Swab Controls
- Storage Conditions: 2°C-30°C
- Stability: 12 months, room-temperature stable

Panel Key:

Member No.	Expected Result
MDXC0103	Positive
MDXC0104	Negative

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. Organisms used to coat swabs are treated chemically to inactivate the virus particles using a validated proprietary protocol. However, all materials should considered as potentially infectious and should be 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.