INFORMATION FOR USE (IFU)

MDXP0037

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Respiratory Triplex (SARS-CoV-2 & Influenza A/B) Swab Quality Control Kit

Description: The Respiratory Triplex (SARS-CoV-2 & Influenza A/B) swab controls are coated with recombinant proteins specific to SARS-CoV-2, Influenza A, and Influenza B. These proteins are formulated with stabilizers and preservatives, allowing for long-term storage of pouched swabs at room temperature. Swab controls should be tested with the same protocols as those used for a clinical swab specimen.

Intended Use: Respiratory Triplex (SARS-CoV-2 & Influenza A/B) Swab Quality Control Kit is used to evaluate the performance of SARS-CoV-2, Influenza A, and Influenza B in antigen-based assays. It is recommended to run this panel: for technician training, to monitor the effect of laboratory environmental conditions, to examine test kit lot-to-lot consistency, and to follow operator variation. These controls should also be run according to your organization's quality system requirements for external Q.C. testing or by using the recommendations of the test kit manufacturer.

Panel Specifications:

- MRNDx Part Number: MDXP0037
- Volume: 5 x Triplex (SARS-CoV-2, Influenza A, Influenza B) Positive Swab Controls and 5 x Negative Swab Controls
- Storage Conditions: 2-30 °C
- Stability: 1 year, room-temperature stable

Panel Key:

Member No.	Expected Result
MDXC0069	Positive
MDXC0070	Negative

For Research Use Only – This product is intended for research and development use and should not be used for clinical diagnostic purposes.

IMPORTANT: Biosafety Level 1: The materials used to formulate this product contain no infectious material that pose hazard to laboratory personnel and the environment. 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.