INFORMATION FOR USE (IFU)

MDXP0036

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Respiratory Triplex External Run Control Pack

Description: The Respiratory Triplex External Run Control Pack is formulated with inactivated, intact whole SARS-CoV-2, Flu A, and Flu B virus particles in a sample base matrix that mimics a true clinical specimen. These controls may be used for both antigen and molecular-based testing formats. Controls are designed to run with the same testing procedure as a patient sample.

Intended Use: The Respiratory Triplex External Run Control Pack is used to evaluate the performance of SARS-CoV-2, Flu A, and Flu B assays. It is recommended to run this panel: for technician training, to monitor effect of laboratory environmental conditions, to examine test kit lot-to-lot consistency, and to follow operator variation. These controls should also be run following your organization's quality system requirements for external Q.C. testing or using the recommendations of the test kit manufacturer.

Panel Specifications:

- MRNDx Part Number: MDXP0036
- Volume: 1 x 0.5mL Triplex (SARS-CoV-2, Flu A, Flu B) positive liquid control, 1 x 0.5mL negative liquid control
- Storage Conditions: 2-8 °C
- Stability: 12 months, refrigerated

Panel Key:

Member No.	Expected Result
MDXC0067	Positive
MDXC0068	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. Positive controls are treated chemically to inactivate the virus particles using a validated proprietary protocol. However, all materials should be 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.