

INFORMATION FOR USE (IFU)

MDXP0046

Document #: MDX-SAL-IFU-011

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Universal Negative External Run Control Pack

Description: The Universal Negative External Run Control Pack mimics a true, non-reactive clinical specimen. These controls may be used for both antigen and molecular testing formats. Controls are designed to run with the same testing procedure as a patient sample.

Intended Use: The Universal Negative External Run Control Pack is used to evaluate the performance of antigen and molecular testing formats. 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: MDXP0046
- Volume: 5x 0.5mL negative liquid controls
- Storage Conditions: 2-8 °C
- Stability: 12 months, refrigerated

Panel Key:

Member No.	Expected Result
MDXC0090	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.