REF 901200 NeuMoDx™ FluA/FluB/RSV/SARS-CoV-2 External Controls

CAUTION: For US Export Only

IVD For *in vitro* diagnostic use with the NeuMoDx 288 and NeuMoDx 96 Molecular System.

Electronic version is available at www.qiagen.com/neumodx-ifu
For detailed instructions, refer to the NeuMoDx 288 Molecular System Operator's Manual; p/n 40600108
For detailed instructions, refer to the NeuMoDx 96 Molecular System Operator's Manual; p/n 40600317
See also the NeuMoDx FluA/FluB/RSV/SARS-CoV-2 Test Strip Instructions for Use; p/n 40600555

INTENDED USE

The NeuMoDx FluA/FluB/RSV/SARS-CoV-2 External Controls are a component of the NeuMoDx FluA/FluB/RSV/SARS-CoV-2 Assay, an *in vitro* diagnostic nucleic acid amplification test intended for the simultaneous qualitative detection and differentiation of Influenza A virus (Flu A), Influenza B virus (Flu B), Respiratory Syncytial Virus (RSV), and SARS-CoV-2 RNA from nasopharyngeal (NP) swab specimens collected in transport medium by a healthcare provider (HCP) from individuals with signs and symptoms of Influenza like illness (ILI). As implemented on the fully automated NeuMoDx 288 Molecular System or NeuMoDx 96 Molecular System (NeuMoDx System(s)), the NeuMoDx FluA/FluB/RSV/SARS-CoV-2 External Controls serve as an aid in monitoring day-to-day system and reagent performance when running the NeuMoDx FluA/FluB/RSV/SARS-CoV-2 Assay. These qualitative controls must be run daily in order to process specimens with the NeuMoDx FluA/FluB/RSV/SARS-CoV-2 Assay.

SUMMARY AND EXPLANATION

The NeuMoDx FluA/FluB/RSV/SARS-CoV-2 External Controls are provided in a set of 15 paired positive and negative control vials. One set of external controls is processed every 24 hours to establish runtime validity of the NeuMoDx FluA/FluB/RSV/SARS-CoV-2 Assay. The target material in the positive control is a non-infectious, replication-defective mammalian recombinant virus containing Flu A, Flu B, RSV, and SARS-CoV-2 genome sequences and diluted in SeraCare transport medium (Seracare Life Sciences, Milford, MA, USA). The negative FluA/FluB/RSV/SARS-CoV-2 control consists of human RNase P gene in SeraCare transport medium.

The NeuMoDx FluA/FluB/RSV/SARS-CoV-2 Assay, as performed on the NeuMoDx 288 Molecular System and NeuMoDx 96 Molecular System, incorporates automated RNA extraction to isolate target nucleic acids from the specimen and real-time reverse transcription PCR targeting 2 conserved regions of the SARS-CoV-2 genome and Flu B genome and one conserved region for Flu A and RSV. The NeuMoDx FluA/FluB/RSV/SARS-CoV-2 Assay includes an exogenous RNA Sample Process Control (SPC2) to help monitor for the presence of potential inhibitory substances and for NeuMoDx System or reagent failures that may be encountered during the extraction and amplification processes.

Clinical laboratories typically require that external controls be incorporated into routine testing protocols to assess test performance and ensure that the test procedures meet established quality control requirements. The NeuMoDx FluA/FluB/RSV/SARS-CoV-2 External Controls are used to establish such routine run validity of the NeuMoDx FluA/FluB/RSV/SARS-CoV-2 Assay. Routine use of these controls enables laboratories to monitor day-to-day variation and lot-to-lot performance of the NeuMoDx FluA/FluB/RSV/SARS-CoV-2 Assay reagents and can assist the lab in identifying errors prior to reporting of test results.

PRINCIPLES OF THE PROCEDURE

The NeuMoDx FluA/FluB/RSV/SARS-CoV-2 External Controls are non-infectious materials formulated to mimic naturally occurring human nasopharyngeal (NP) swab specimens. The non-infectious, replication-defective mammalian recombinant virus used in the positive control allows for the verification of efficacious nucleic acid extraction procedure. One set of controls is processed every 24 hours. Such routine processing of the NeuMoDx External Controls enables the laboratories to ensure reliability of test results for human clinical specimens processed within the 24-hour validity period. The external controls are processed in a manner identical to the processing of the human clinical specimens intended for detection and differentiation of Flu A, Flu B, RSV, and SARS-CoV-2 RNA.

Expected results for the external controls are incorporated into the Control Validity algorithm included in the NeuMoDx System software. Upon successful processing of the external controls, the system software automatically establishes assay validity for a period of 24 hours. The system software will automatically alert the user to process the external controls when the control validity period has expired.

REAGENTS / CONSUMABLES

Material Provided

REF	Contents	Tests per unit	Total tests per kit
901200	**NeuMoDx FluA/FluB/RSV/SARS-CoV-2 External Controls** *Single use sets of FluA/FluB/RSV/SARS-CoV-2 Positive and Negative Controls to establish daily validity of NeuMoDx FluA/FluB/RSV/SARS-CoV-2 Assay (1 vial of each control = 1 set)*	1 set	15

Materials Required but Not Provided (Available Separately from NeuMoDx)

REF	Contents
300901	**NeuMoDx FluA/FluB/RSV/SARS-CoV-2 Test Strip** *Dried PCR reagents containing FluA/FluB/RSV/SARS-CoV-2 and SPC2 specific TaqMan® probes and primers*
100200	**NeuMoDx Extraction Plate** *Dried paramagnetic particles, lytic enzyme, and sample process controls*
400600	**NeuMoDx Lysis Buffer 3**
400100	**NeuMoDx Wash Reagent**
400200	**NeuMoDx Release Reagent**
100100	**NeuMoDx Cartridge**
235903	**Hamilton CO-RE / CO-RE II Tips (300 µL) with Filters**
235905	**Hamilton CO-RE / CO-RE II Tips (1000 µL) with Filters**

Instrumentation Required

NeuMoDx 288 Molecular System [REF 500100] or **NeuMoDx 96 Molecular System** [REF 500200]
NeuMoDx System Software version 1.9.2.6 or higher

WARNINGS AND PRECAUTIONS

- The NeuMoDx FluA/FluB/RSV/SARS-CoV-2 External Controls are use with only the NeuMoDx FluA/FluB/RSV/SARS-CoV-2 Assay as implemented on the NeuMoDx System.
- Do not use the NeuMoDx FluA/FluB/RSV/SARS-CoV-2 External Controls after the listed expiration date.
- Do not use the NeuMoDx FluA/FluB/RSV/SARS-CoV-2 External Controls if the packaging is damaged or the contents are not frozen upon arrival.
- Always handle specimens as if they are infectious and in accordance with safe laboratory procedures such as those described in *Biosafety in Microbiological and Biomedical Laboratories* [1] and in CLSI Document M29-A4.[2]
- Do not pipette by mouth. Do not smoke, drink, or eat in areas where specimens or reagents are being handled.
- Dispose of unused reagents and waste in accordance with country, federal, provincial, state, and local regulations.
- Clean, powder-free, nitrile gloves should be worn when handling all NeuMoDx reagents and consumables.
- Wash hands thoroughly after performing the test.
- Safety Data Sheets (SDS) are provided for each reagent (as applicable) at www.qiagen.com/neumodx-ifu

PRODUCT STORAGE, HANDLING, AND STABILITY

- The NeuMoDx FluA/FluB/RSV/SARS-CoV-2 External Controls are shipped with dry ice to maintain a frozen state; do not use if contents are not frozen upon receipt.
- It is recommended that the NeuMoDx FluA/FluB/RSV/SARS-CoV-2 External Controls be stored at -15 °C to -20 °C to ensure stability.
- Control vials are intended for single use only and should be tested once thawed.
- Refreezing after a first thaw is not recommended.
- Although the NeuMoDx FluA/FluB/RSV/SARS-CoV-2 External Controls are non-infectious, any unused material should be discarded after use as biohazard waste to reduce risk of contamination by the target nucleic acid contained in the vials.
- Discard any controls that appear cloudy or contain large precipitates after thawing.

INSTRUCTIONS FOR USE

1. One set of external controls must be processed every 24 hours throughout testing with the NeuMoDx FluA/FluB/RSV/SARS-CoV-2 Assay. If a set of valid test controls does not exist, the NeuMoDx System software will prompt the user for these controls to be processed before sample results can be reported.
2. If external controls are required, process the controls (1 positive control and 1 negative control):

NeuMoDx FluA/FluB/RSV/SARS-CoV-2 External Control	Label Color Scheme
NeuMoDx Flu A/FluB/RSV/SARS-CoV-2 Positive Control(s)	Red
NeuMoDx Flu A/FluB/RSV/SARS-CoV-2 Negative Control(s)	Black

3. Retrieve the set of NeuMoDx FluA/FluB/RSV/SARS-CoV-2 External Controls from freezer and allow the vials to thaw completely at room temperature (15-30 °C).
4. Vortex gently to ensure homogeneity.
5. Load the control vials into a standard 32-tube Specimen Tube Carrier, and ensure caps are removed from all tubes.
6. Place the Specimen Tube Carrier on the Autoloader shelf and use the touchscreen to load carrier into the NeuMoDx System.
7. The NeuMoDx System will recognize the barcode and start processing the controls unless reagents or consumables required for testing are not available.
8. Validity of the external controls will be assessed by the NeuMoDx System based on the expected results.

NeuMoDx FluA/FluB/RSV/SARS-CoV-2 External Control	NeuMoDx FluA/FluB/RSV/SARS-CoV-2 Result	SPC2 Result
NeuMoDx Flu A/FluB/RSV/SARS-CoV-2 Positive Control(s)	Flu A Detected Flu B Detected RSV Detected SARS-CoV-2 Detected	N/A
NeuMoDx Flu A/FluB/RSV/SARS-CoV-2 Negative Control(s)	Flu A Not Detected Flu B Not Detected RSV Not Detected SARS-CoV-2 Not Detected	SPC2 Valid

9. Discrepant result handling for external controls should be performed as follows:
   a) A Positive test result reported for a Negative Control sample indicates contamination in handling or on the system.
   b) A Negative (RNA Not Detected) result reported for a Positive Control may indicate there is a reagent or instrument related problem.
   c) In either of the above instances, or in the event of a No Result (NR), Unresolved (UNR), or Indeterminant (IND) result is reported for any target, repeat the failed control with freshly thawed vial(s) of the control(s) failing the validity test.
   d) If the Positive Control continues to report a negative result, contact QIAGEN technical support.
   e) If the Negative Control continues to report a positive result, attempt to eliminate all sources of potential contamination, including replacing all reagents and repeat the run before contacting QIAGEN technical support.

LIMITATIONS

1. The NeuMoDx FluA/FluB/RSV/SARS-CoV-2 External Controls can only be used in conjunction with NeuMoDx FluA/FluB/RSV/SARS-CoV-2 Test Strip on the NeuMoDx Systems**.**
2. Erroneous results could occur from improper handling, storage, or other technical error.
3. Operation of the NeuMoDx System is limited to use by personnel trained on the use of the NeuMoDx System.

REFERENCES

1. Biosafety in Microbiological and Biomedical Laboratories, 5th edition. HHS Publication No. (CDC) 21-1112, Revised December 2009.
2. Clinical and Laboratory Standards Institute (CLSI). Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline – Fourth Edition. CLSI document M29-A4; May 2014.

TRADEMARKS

NeuMoDx is a trademark of NeuMoDx Molecular, Inc.

All other product names, trademarks, and registered trademarks that may appear in this document are property of their respective owners.

SYMBOL KEY

	Manufacturer		Do not re-use
IVD	*In vitro* diagnostic medical device		Contains sufficient for <*n*> tests
EC REP	Authorized representative in the European Community		Consult instructions for use
REF	Catalog number	CE	CE Mark
LOT	Batch code	CONT	Contains
	Use-by date	BIO	Contains biological material of human origin
	Temperature limit		Caution

NeuMoDx Molecular, Inc.
1250 Eisenhower Place
Ann Arbor, MI 48108, USA

Technical support / Vigilance reporting: support@qiagen.com

Patent: www.neumodx.com/patents

EC REP
QIAGEN GmbH
QIAGEN Strasse 1
40724 Hilden
GERMANY
+49 2103 290

CE