REF 900301 NeuMoDx™ HIV-1 External Controls

℞ only

CAUTION: For US Export Only

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

For insert updates, go to: 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 HIV-1 Quant Test Strip Instructions for Use; P/N 40600412

INTENDED USE

The NeuMoDx HIV-1 External Controls are a component of the NeuMoDx HIV-1 Quant Assay, an *in vitro* diagnostic nucleic acid amplification test intended for the detection and quantitation of human immunodeficiency virus type 1 (HIV-1) RNA in human plasma. As implemented on the fully automated NeuMoDx 288 Molecular System or NeuMoDx 96 Molecular System (NeuMoDx System(s)), the NeuMoDx HIV-1 External Controls are used to establish runtime validity required to execute the NeuMoDx HIV Quant Assay for accurate quantitation of HIV-1 RNA in human plasma specimens.

SUMMARY AND EXPLANATION

The NeuMoDx HIV-1 External Controls are provided in 15 paired sets of positive and negative control vials. One set of external controls is processed every 24 hours to establish runtime validity of the NeuMoDx HIV-1 Quant Assay. The HIV-1 target in the positive control is a non-infectious, replication-defective mammalian recombinant virus containing HIV-1 genome sequences and diluted in Basematrix 53 Diluent (Basematrix) (Seracare Life Sciences, Milford, MA, USA). The negative HIV-1 control consists of Basematrix only.

The NeuMoDx HIV-1 Quant Assay combines automated RNA extraction, amplification, and detection by real-time reverse transcription PCR to enable the quantitative detection of HIV-1 RNA in human plasma specimens. The NeuMoDx HIV-1 Quant 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 HIV-1 External Controls are used to establish such routine run validity of the NeuMoDx HIV-1 Quant Assay. Routine use of these controls enables the laboratories to monitor day-to-day variation and lot-to-lot performance of the NeuMoDx HIV-1 Quant Assay reagents and can assist the lab in identifying errors prior to reporting of test results.

PRINCIPLES OF THE PROCEDURE

The NeuMoDx HIV-1 External Controls are non-infectious samples formulated to mimic naturally occurring human plasma specimens. The encapsulated target material 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 HIV-1 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 quantitative HIV-1 testing.

Expected results for both these 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 records the validity for a period of 24 hours. The system software automatically alerts the user to process the external controls when control validity period has expired.

REAGENTS / CONSUMABLES

Material Provided

REF	Contents	Tests per unit	Total tests per kit
900301	**NeuMoDx HIV-1 External Controls** *Single use sets of HIV-1 Positive and Negative Controls to establish daily validity of NeuMoDx HIV-1 Quant Assay (1 vial of each control = 1 set)*	1 set	15

Materials Required but Available Separately

REF	Contents
300500	**NeuMoDx HIV-1 Quant Test Strip** *Dried PCR reagents containing HIV-1-specific TaqMan® probes and primers, SPC2-specific TaqMan probe and primers.*
100200	**NeuMoDx Extraction Plate** *Dried paramagnetic particles, lytic enzyme, and sample process controls*
800304	**NeuMoDx HIV-1 Calibrators** *Single use sets of HIV-1 High and Low Calibrators to establish validity of standard curve*
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]

WARNINGS & PRECAUTIONS

- The NeuMoDx HIV-1 External Controls are for *in vitro* diagnostic use only with the NeuMoDx HIV-1 Quant Test Strip as implemented on the NeuMoDx System.
- Do not use the NeuMoDx HIV-1 External Controls after the listed expiration date.
- Do not use the NeuMoDx HIV-1 External Controls if the packaging is damaged or the contents are not frozen upon arrival.
- NeuMoDx HIV-1 External Controls contain defibrinated human plasma that is negative for HBV DNA, HCV RNA, HIV-1 RNA, Human Parvovirus B19 DNA, and HAV RNA using nucleic acid amplification methods, and non-reactive for HBsAg and antibodies to HIV-1 and HIV-2, HCV, HTLV I and HTLV II, HBs, and HBc using FDA licensed test methods. This does not ensure the absence of these or other human pathogens. Follow universal precautions when handling.
- 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-A3.[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 & STABILITY

- The NeuMoDx HIV-1 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 HIV-1 External Controls be stored at -15 °C to -20 °C to ensure stability.
- Control vials are intended for single use only. Thawed external controls may be stored at 4 °C for no longer than 24 hours.
- Refreezing after a first thaw is not recommended.
- Although the NeuMoDx HIV-1 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.
- Discard any controls that appear cloudy or contain large precipitates after thawing.

INSTRUCTIONS FOR USE

1. One set of external controls [REF 900301] needs to be processed every 24 hours throughout testing with the NeuMoDx HIV-1 Quant 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 HIV-1 External Control	Label Color Scheme
Positive Control (HIVPC)	Red
Negative Control (HIVNC)	Black

3. Retrieve the set of NeuMoDx HIV-1 External Controls from freezer and allow the vials to set at room temperature (15-30 °C) until completely thawed.
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 specimen tubes unless reagents or consumables required for testing are not available.
8. Validity of these external controls will be assessed by the NeuMoDx System based on the expected results.

NeuMoDx HIV-1 External Control	HIV-1 Result	SPC2 Result
Positive Control (HIVPC)	HIV-1 POSITIVE	N/A
Negative Control (HIVNC)	HIV-1 NEGATIVE	SPC2 Positive

9. Discrepant result handling for external controls should be performed as follows:
    a) A Positive test result reported for a negative control sample indicates a specimen contamination problem.
    b) A negative result reported for a positive control sample may indicate there is a reagent or instrument related problem.
    c) In either of the above instances, or in the event of an indeterminant (IND) result, repeat the failed control with freshly thawed vial(s) of the control(s) failing the validity test.
    d) If the Positive external control continues to report a Negative result, contact NeuMoDx technical support.
    e) If the Negative external 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 NeuMoDx customer service.

LIMITATIONS

1. The NeuMoDx HIV-1 External Controls can only be used in conjunction with NeuMoDx HIV-1 Quant Test Strip on the NeuMoDx Systems**.**
2. A valid calibration of the NeuMoDx HIV-1 Quant Test Strip using NeuMoDx HIV-1 External Calibrators [800304] is required *before* the NeuMoDx HIV-1 External Controls [REF 900301] can be processed.
3. Erroneous results could occur from improper handling, storage, or other technical error.
4. 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

SYMBOLS

SYMBOL	MEANING
℞ only	**Prescription use only**
	**Manufacturer**
IVD	***In vitro* diagnostic medical device**
EC REP	**Authorized representative in the European Community**
REF	**Catalog number**
LOT	**Batch code**
	**Use-by date**
	**Temperature limit**
	**Humidity limitation**
	**Do not re-use**
	**Contains sufficient for *<n>* tests**
	**Consult instructions for use**
	**Caution**
	**Biological risks**
CE	**CE Mark**

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Patent: www.neumodx.com/patents