REF 900401 NeuMoDx™ CMV External Controls

℞ only

CAUTION: For US Export Only

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

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 CMV Quant Test Strip Instructions For Use (package insert); P/N 40600165

INTENDED USE

The NeuMoDx CMV External Controls are intended for use with the NeuMoDx CMV Quant Test Strip to establish a runtime validity on the NeuMoDx 288 Molecular System and NeuMoDx 96 Molecular System (NeuMoDx System(s)) in order to process a quantitative *in vitro* diagnostic test to quantify cytomegalovirus (CMV) DNA from fresh and frozen human plasma specimens.

SUMMARY AND EXPLANATION

The NeuMoDx CMV External Controls are provided in a kit comprised of of 15 sets of positive and negative control vials. One set of external controls is processed every 24 hours to establish runtime validity of the NeuMoDx CMV Quant Assay. The NeuMoDx CMV positive control contains encapsulated CMV target nucleic acid formulated at 2.7 $\log_{10}$ IU/mL in Basematrix 53 Diluent (Basematrix) (Seracare Life Sciences, Milford, MA). The NeuMoDx CMV negative control consists of Basematrix only.

The NeuMoDx CMV Quant Assay combines automated DNA extraction, amplification, and detection by real-time PCR to enable the quantitative detection of CMV DNA in human plasma specimens. The NeuMoDx CMV Quant Assay includes an exogenous DNA Sample Process Control (SPC1) to help monitor for the presence of potential inhibitory substances as well as NeuMoDx System or reagent failures that may be encountered during the extraction and amplification processes.

However, 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 CMV External Controls are intended to be used to establish such *routine* run validity of the NeuMoDx CMV Quant Assay. Routine use of these controls enables the laboratories to monitor day-to-day variation, lot-to-lot performance of the NeuMoDx CMV Quant Assay reagents and can assist the lab in identifying errors prior to reporting of test results.

PRINCIPLES OF THE PROCEDURE

The NeuMoDx CMV External Controls have been formulated to mimic naturally occurring human plasma specimens. Additionally, the encapsulated material used in the positive control allows for the verification of efficacious nucleic acid extraction procedure. One set of controls – consisting of 1 positive and 1 negative control – should be processed every 24 hours. Such routine processing of the NeuMoDx CMV External Controls enables the laboratories to ensure efficacy of the 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 CMV 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
900401	**NeuMoDx CMV External Controls** *Single use sets of CMV Positive and Negative Controls to establish daily validity of NeuMoDx CMV Quant Assay* *(1 vial of positive control at 2.7 $\log_{10}$ IU/mL and 1 vial of negative control of Basematrix only = 1 set)*	1 set	15

Reagents and Consumables Required but Not Provided (Available Separately from NeuMoDx)

REF	Contents
201400	**NeuMoDx CMV Quant Test Strip** *Dried PCR reagents containing CMV- specific TaqMan® probes and primers, SPC1 specific TaqMan probe and primers.*
100200	**NeuMoDx Extraction Plate** *Dried paramagnetic particles, lytic enzyme, and sample process controls*
800400	**NeuMoDx CMV Calibrators** *Single use sets of CMV High and Low Calibrators to establish validity of standard curve*
400400	**NeuMoDx Lysis Buffer 1**
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 CMV External Controls are for *in vitro* diagnostic use only with the NeuMoDx CMV Quant Test Strip as implemented on the NeuMoDx Systems.
- Do not use the NeuMoDx CMV External Controls after the listed expiration date.
- Do not use the NeuMoDx CMV External Controls if the packaging is damaged or kit is not frozen upon arrival.
- Because the NeuMoDx CMV positive controls contain CMV target material, they should be handled carefully as cross-contamination with test samples could produce a false-positive result.
- 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 available upon request.

PRODUCT STORAGE, HANDLING & STABILITY

- The NeuMoDx CMV External Controls are shipped with dry ice to maintain a frozen state; do not use if kit contents are not frozen upon receipt.
- It is recommended that the NeuMoDx CMV External Controls be stored at ≤ -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 for 7 days.
- Refreezing after a first thaw is not recommended.
- Discard any unused material after use contains non-infectious target DNA and could cause a contamination risk.
- Discard any controls that appear cloudy or contain large precipitates after thawing.

INSTRUCTIONS FOR USE

1. One set of NeuMoDx CMV External Controls [REF 900401] needs to be processed once every 24 hours. If a set of valid test controls does not exist, the NeuMoDx 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 per System):

NeuMoDx CMV External Control	Label Color Scheme
Positive Control (PC)	Red
Negative Control (NC)	Black

3. Retrieve the set of NeuMoDx CMV External Controls from freezer and allow the vials to set at room temperature (15-30°C) until completely thawed. If using an already thawed set of controls, ensure that the thawed controls were stored at 4°C and are not more than 7 days old.
4. Vortex gently to ensure homogeneity.
5. Load the control vials into a standard 32-Tube Carrier, and ensure caps are removed from all tubes.
6. Place the 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 CMV External Control	CMV Result	SPC1 Result
Positive Control (PC)	CMV POSITIVE	N/A
Negative Control (NC)	CMV NEGATIVE	SPC1 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, repeat the *failed* control with a 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 customer service.
    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

- The NeuMoDx CMV External Controls can only be used in conjunction with NeuMoDx CMV Quant Test Strip on the NeuMoDx Systems**.**
- A valid calibration of the NeuMoDx CMV Quant Test Strip using NeuMoDx CMV Calibrators [800400] is required *before* the external controls can be processed.
- Erroneous results could occur from improper handling, storage, or other technical error.
- 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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