REF 900502 NeuMoDx™ EBV 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 EBV Quant Test Strip 2.0 Instructions For Use (package insert); P/N 40600562

INTENDED USE

The NeuMoDx EBV External Controls are a component of the NeuMoDx EBV Quant Assay 2.0, an *in vitro* diagnostic nucleic acid amplification test intended for the detection and quantitation of Epstein-Barr Virus (EBV) DNA in human plasma. As performed on the fully automated NeuMoDx 288 Molecular System or NeuMoDx 96 Molecular System (NeuMoDx System(s)), the NeuMoDx EBV External Controls are used to establish the runtime validity required to execute the NeuMoDx EBV Quant Assay 2.0 for accurate quantitation of EBV DNA in human plasma specimens.

SUMMARY AND EXPLANATION

The NeuMoDx EBV External Controls are provided in 10 sets of low positive, high positive, and negative control vials. One set of external controls is processed every 24 hours to establish runtime validity of the NeuMoDx EBV Quant Assay 2.0. The positive EBV External Controls contain a non-infectious, encapsulated EBV target diluted in Basematrix (Seracare® Life Sciences, Milford, MA, USA). The negative EBV External Controls consists of Basematrix only.

The NeuMoDx EBV Quant Assay 2.0 combines automated DNA extraction, amplification, and detection by real-time PCR to enable the quantitative detection of EBV DNA in human plasma specimens. The NeuMoDx EBV Quant Assay 2.0 includes an exogenous DNA Sample Process Control (SPC1) to help monitor for the presence of potential inhibitory substances in addition to any 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 EBV External Controls are used to establish such routine run validity of the NeuMoDx EBV Quant Assay 2.0. Routine use of these controls enables the laboratories to monitor day-to-day variation and lot-to-lot performance of the NeuMoDx EBV Quant Assay 2.0 reagents and can assist the lab in identifying errors prior to reporting of test results.

PRINCIPLES OF THE PROCEDURE

The NeuMoDx EBV 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 EBV External Controls enables 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 EBV testing.

Expected results for all 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

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REF	Contents	Tests per unit	Total Tests per kit
900502	**NeuMoDx EBV External Controls** *Single use sets of Quantitative EBV High Positive, EBV Low Positive, and Negative Controls to establish daily validity of NeuMoDx EBV Quant Assay 2.0 (1 vial of each control = 1 set)*	1 set	10

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

REF	Contents
201501	**NeuMoDx EBV Quant Test Strip 2.0** *Dried PCR reagents containing EBV specific TaqMan® probes and primers, SPC1 specific TaqMan probe and primers.*
100200	**NeuMoDx Extraction Plate** *Dried paramagnetic particles, Lytic enzyme, and sample process controls*
800501	**NeuMoDx EBV Calibrators** *Single use sets of EBV 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]
NeuMoDx System Software version 1.9.2.6 or higher

WARNINGS & PRECAUTIONS

- The NeuMoDx EBV External Controls are for *in vitro* diagnostic use only with the NeuMoDx EBV Quant Test Strip 2.0 as implemented on the NeuMoDx Systems.
- Do not use the NeuMoDx EBV External Controls after the listed expiration date.
- Do not use the NeuMoDx EBV External Controls if the packaging is damaged or contents are not frozen upon arrival.
- Because the NeuMoDx EBV positive controls contain EBV target material, they should be handled carefully as cross-contamination with clinical 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]
- When working with chemicals, always wear a suitable lab coat, disposable gloves, and protective goggles. For more information, please consult the appropriate safety data sheets (SDS).
- 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

Emergency information
CHEMTREC
Outside USA & Canada +1 703-527-3887

PRODUCT STORAGE, HANDLING & STABILITY

- The NeuMoDx EBV 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 EBV External Controls be stored at -20 to -15°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.
- Although the NeuMoDx EBV 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 NeuMoDx EBV External Controls [REF 900502] 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 high positive control, 1 low positive control, and 1 negative control):

NeuMoDx EBV External Control	Label Color Scheme
NeuMoDx EBV High Positive Control (C1EBV)	Red
NeuMoDx EBV Low Positive Control (C2EBV)	Grey
NeuMoDx EBV Negative Control (NCEBV)	Black

3. Remove a set of NeuMoDx EBV External Controls from freezer and thaw completely at room temperature (15-30 °C). The External Controls must be completely thawed and equilibrated to room temperature prior to use. 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 EBV External Control	EBV Result	SPC1 Result
NeuMoDx EBV High Positive Control (C1EBV)	EBV POSITIVE [Conc] 3.68 – 4.68 Log_{10} IU/mL	SPC1 Positive
NeuMoDx EBV Low Positive Control (C2EBV)	EBV POSITIVE [Conc] 1.58 – 2.78 Log_{10} IU/mL	SPC1 Positive
NeuMoDx EBV Negative Control (NCEBV)	EBV 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 may indicate contamination and the laboratory's quality control procedures need to be examined to find a root cause. Ensure to use separate areas for sample preparation, control handling and RT-PCR set up. Please refer to NeuMoDx 288 or 96 Molecular System Operator's Manual for additional troubleshooting tips.
    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 a No Result (NR), Unresolved (UNR), or 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 QIAGEN 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 QIAGEN technical support.

LIMITATIONS

- The NeuMoDx EBV External Controls can only be used in conjunction with NeuMoDx EBV Quant Test Strip 2.0 on the NeuMoDx Systems**.**
- A valid calibration of the NeuMoDx EBV Quant Test Strip 2.0 using NeuMoDx EBV Calibrators [800501] 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

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SYMBOL KEY

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

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 Emergo Europe B.V.
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

CE