REF 900102 NeuMoDx™ HBV 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 HBV Quant Test Strip Instructions for Use; p/n 40600136

INTENDED USE

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

SUMMARY AND EXPLANATION

The NeuMoDx HBV 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 HBV Quant Assay. The positive HBV external control contains a non-infectious, encapsulated HBV target diluted in Basematrix 53 Diluent (Basematrix) (Seracare Life Sciences, Milford, MA, USA). The negative HBV external control consists of Basematrix only.

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

PRINCIPLES OF THE PROCEDURE

The NeuMoDx HBV External Controls are non-infectious samples formulated to mimic naturally occurring human plasma and serum 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 HBV 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 HBV 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
900102	**NeuMoDx HBV External Controls** *Single use sets of HBV Positive and Negative Controls to establish daily validity of NeuMoDx HBV Quant Assay (1 vial of each control = 1 set)*	1 set	15

Materials Required but Not Provided (Available Separately from NeuMoDx)

REF	Contents
201300	**NeuMoDx HBV Quant Test Strip** *Dried PCR reagents containing HBV and SPC1 specific TaqMan® probes and primers*
100200	**NeuMoDx Extraction Plate** *Dried paramagnetic particles, lytic enzyme, and sample process controls*
800102	**NeuMoDx HBV Calibrators** *Single use sets of HBV 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 AND PRECAUTIONS

- The NeuMoDx HBV External Controls are for *in vitro* diagnostic use only with the NeuMoDx HBV Quant Test Strip as implemented on the NeuMoDx System.
- Do not use the NeuMoDx HBV External Controls after the listed expiration date.
- Do not use the NeuMoDx HBV 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
- Do not reuse.

PRODUCT STORAGE, HANDLING AND STABILITY

- The NeuMoDx HBV 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 HBV 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 HBV 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 needs to be processed every 24 hours throughout testing with the NeuMoDx HBV 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 HBV External Control	Label Color Scheme
Positive Control (HBVPC)	Red
Negative Control (HBVNC)	Black

3. Retrieve the set of NeuMoDx HBV 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 HBV External Control	HBV Result	SPC2 Result
Positive Control (HBVPC)	HBV POSITIVE	N/A
Negative Control (HBVNC)	HBV 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 HBV External Controls can only be used in conjunction with NeuMoDx HBV Quant Test Strip on the NeuMoDx Systems**.**
2. A valid calibration of the NeuMoDx HBV Quant Test Strip using NeuMoDx HBV External Calibrators is required *before* the NeuMoDx HBV External Controls 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

SYMBOL KEY

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

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

Sponsor (AUS):
QIAGEN Pty Ltd
Level 2 Chadstone Place
1341 Dandenong Rd
Chadstone VIC 3148
Australia

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

CE 2797

Technical support/Vigilance reporting: support@qiagen.com

Patent: www.neumodx.com/patents