REF 900601 NeuMoDx™ BKV External Control Kit

Rx Only

CAUTION: For US Export Only

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

*This package insert must be read carefully prior to product use. Package insert instructions must be followed accordingly. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.*
*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™ BKV Quant Test Strip Instructions For Use (package insert)*

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## INTENDED USE

The NeuMoDx™ BKV External Control Kit is intended for use with the NeuMoDx™ BKV 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 BK virus (BKV) DNA from human Plasma/Serum and Urine specimens.

## SUMMARY AND EXPLANATION

The NeuMoDx™ BKV External Control Kit is comprised of 15 sets of positive and negative control tubes, one NeuMoDx™ BKV Control Buffer and 30 empty secondary labelled tubes. One external control set is composed of one dried positive control tube sealed in a single aluminum pouch with a small orange desiccant sachet and NeuMoDx™ BKV Control Buffer used as negative control. One set of external controls is processed every 24 hours to establish runtime validity of the NeuMoDx™ BKV Quant Assay. The NeuMoDx™ BKV positive control contains a dried pellet of synthetic BKV target nucleic acid at 4 $\log_{10}$ IU/mL. The NeuMoDx™ BKV negative control consists of NeuMoDx™ BKV Control Buffer only.

The NeuMoDx™ BKV Quant Assay combines automated DNA extraction, amplification and detection by real-time PCR to enable the quantitative detection of BKV DNA in human in plasma/serum and urine specimens. The NeuMoDx™ BKV 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™ BKV External Control Kit are intended to be used to establish such routine run validity of the NeuMoDx™ BKV Quant Assay. Routine use of these controls enables the laboratories to monitor day-to-day variation, lot-to-lot performance of the NeuMoDx™ BKV Quant Assay reagents and can assist the lab in identifying errors prior to reporting of test results.

## PRINCIPLES OF THE PROCEDURE

The NeuMoDx™ BKV External Control Kit 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™ BKV External Control Kit 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 BKV 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 |
|---|---|---|---|
| 900601 | NeuMoDx™ BKV External Control Kit<br>*Single use sets of BKV Positive and Negative Controls to establish daily validity of NeuMoDx BKV Quant Assay*<br>*(1 vial of positive control at 4 $\log_{10}$ IU/mL and NeuMoDx™ BKV Control Buffer (negative control))* | 1 set | 15 |

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

| REF | Contents |
|---|---|
| 201800 | NeuMoDx™ BKV Quant Test Strip<br>*Dried PCR reagents containing BKV- specific TaqMan® probes and primers along with SPC1 specific TaqMan® probe and primers.* |
| 100200 | NeuMoDx™ Extraction Plate<br>*Dried paramagnetic particles, lytic enzyme, and sample process controls* |
| 800600 | NeuMoDx™ BKV Calibrator Kit<br>*Single use sets of BKV High and Low Calibrators to establish validity of standard curve* |
| 400500 | NeuMoDx™ Lysis Buffer 2 |
| 400100 | NeuMoDx™ Wash Reagent |
| 400200 | NeuMoDx™ Release Reagent |
| 100100 | NeuMoDx™ Cartridge |
| 235903 | Hamilton CO-RE Tips (300 µL) with Filters |
| 235905 | Hamilton CO-RE Tips (1000 µL) with Filters |

*Instrumentation Required*
NeuMoDx™ 288 Molecular System [REF 500100] or NeuMoDx™ 96 Molecular System [REF 500200]

## WARNINGS & PRECAUTIONS

- The NeuMoDx™ BKV External Control Kit is for *in vitro* diagnostic use only with the NeuMoDx™ BKV Quant Test Strip as implemented on the NeuMoDx™ Systems.
- Do not use the NeuMoDx™ BKV External Control Kit after the listed expiration date.
- Do not use the NeuMoDx™ BKV External Control Kit if the safety seal is broken or if the packaging is damaged upon arrival.
- Do not use consumables or reagents if the protective pouch is open or broken upon arrival.
- Do not mix up reagents for amplification from other commercial kits.
- Keep the NeuMoDx™ BKV External Control Kit protected from humidity in their aluminium envelopes with dedicated small orange desiccant sachet.
- Because the NeuMoDx™ BKV positive controls contain BKV 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 in accordance with the OSHA Standard on Bloodborne Pathogens[1], Biosafety Level 2[2] or other appropriate biosafety practices[3,4] should be used for materials that contain or are suspected of containing infectious agents.
- 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.neumodx.com/client-resources.
- A vertical bar in the text margin indicates changes in comparison to the previous I.F.U version.
- Do not reuse.

## PRODUCT STORAGE, HANDLING & STABILITY

- The NeuMoDx™ BKV External Control Kit is shipped at Room Temperature (+15 °C/+30 °C).
- It is recommended that the NeuMoDx™ BKV External Control Kit be stored at +15 °C/+30 °C to ensure stability.

- External Control vials (negative control, reconstituted positive control and/or empty tubes) are intended for single use only. After use, discard the residue of the reconstituted NeuMoDx™ BKV External Controls.
- Discard any unused material after use in biohazard waste as the material contains non-infectious target DNA and could cause a contamination risk.

## INSTRUCTIONS FOR USE

1. One set of the NeuMoDx™ BKV External Control Kit (REF 900601) 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 BKV External Control | Label Color Scheme |
|---|---|
| Positive Control (PC) | Red |
| Negative Control (NC) | Black |

3. If external controls are required, reconstitute the BKV Positive External Control and prepare the Negative Control following the steps below.
4. Cut the aluminum pouches of positive control at the point indicated by the lateral notches.
5. Remove the BKV positive control tube from the pouches immediately before use.
6. Prior to use, always ensure that the pouches are always well sealed and that the desiccant sachets are still inside. Use only undamaged packages.
7. Dispose of the aluminum pouches and their contents if the desiccant sachets turn from orange to green.
8. Centrifuge the BKV positive control tube prior to open it to ensure that DNA is at the bottom of the tube.
9. Vortex the NeuMoDx™ BKV Control Buffer and reconstitute BKV positive control tube with 800 µL of buffer. It is advisable to reconstitute the positive control immediately before use. The reconstituted positive control tubes are intended for single use only
10. Cap the reconstituted BKV positive control tube and vortex it for 30 seconds until the dried DNA is resuspended.
11. Centrifuge the BKV positive control tube for few seconds at medium speed to remove any residue from the cap and eliminate bubbles/foam.
12. Incubate the resuspended control at room temperature for 20 minutes prior to proceeding to the next step.
13. Vortex the BKV positive control tube for few seconds at medium speed and centrifuge it for few seconds at medium speed.
14. Transfer all contents of the reconstituted BKV positive control tube into a secondary empty labelled tube (NeuMoDx™ BKV Positive Control (PC) tube included in the kit). It is advisable to transfer each positive control into the secondary empty tube immediately before use. Both reconstituted positive control and secondary tubes are intended for single use only.
15. Transfer 800 µL of NeuMoDx™ BKV Control Buffer into a secondary empty labelled tube (NeuMoDx™ BKV Negative Control (NC) tube included in the kit). The filled secondary tubes are intended for single use only.
16. Load the control tubes into a standard 32-Tube Specimen Carrier.
17. Place the Specimen Tube Carrier on the Autoloader shelf and use the touchscreen to load carrier into the NeuMoDx™ System.
18. The NeuMoDxᴹ System will recognize the barcode and start processing the specimen tubes unless reagents or consumables required for testing are not available.
19. Validity of the external controls will be assessed by the NeuMoDx™ System based on the expected results.

| NeuMoDx BKV External Control | BKV Result | SPC1 Result |
|---|---|---|
| Positive Control (PC) | BKV Positive | N/A |
| Negative Control (NC) | BKV Not Detected | Valid |

20. 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 new 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™ BKV External Control Kit can only be used in conjunction with NeuMoDx™ BKV Quant Test Strip on the NeuMoDx™ Systems.
- A valid calibration of the NeuMoDx™ BKV Quant Test Strip using NeuMoDx™ BKV Calibrator Kit (REF 800600) 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. US Department of Labor, Occupational Safety and Health Administration. 29 CFR Part 1910.1030. Bloodborne Pathogens, https://www.osha.gov/lawsregs/regulations/standardnumber/1910/1910.1030.
2. US Department of Health and Human Services. Biosafety in Microbiological and Biomedical Laboratories, 5th Ed. Washington,DC: US Government Printing Office,December 2009.
3. World Health Organization. Laboratory Biosafety Manual, 3rd ed.Geneva: World Health Organization, 2004.
4. CLSI. Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline — Fourth Edition (M29-A4). Clinical and Laboratory Standards Institute, 2014.

## TRADEMARKS

## SYMBOLS

| SYMBOL | MEANING |
|---|---|
| Rx Only | Prescription use only |
|  | Manufacturer |
|  | Distributor |
| IVD | *In vitro* diagnostic medical device |
| REF | Catalog number |
| LOT | Batch code |
|  | Consult instruction for use |
|  | Caution, consult accompanying documents |
|  | Temperture limitation |
|  | Keep dry |
|  | Do not re-use |
|  | Do not expose to the light |
|  | Contains sufficient for <*n*> tests |
|  | Use by |

SENTINEL CH. S.p.A.
Via Robert Koch, 2
20152 Milano, Italy

www.sentineldiagnostics.com

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

+1 888 301 NMDX (6639)
techsupport@neumodx.com

Vigilance reporting: www.neumodx.com/contact-us

Patent: www.neumodx.com/patents