## REF 100100 NeuMoDx™ Cartridge

℞ 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*

### INTENDED USE

The NeuMoDx Cartridge is a proprietary consumable used for the efficacious extraction, purification, amplification, and detection of nucleic acids on the NeuMoDx 288 and NeuMoDx 96 Molecular Systems (NeuMoDx System(s)). The NeuMoDx Cartridge is universally used for all tests processed on NeuMoDx Systems.

### SUMMARY AND EXPLANATION

Each NeuMoDx Cartridge contains twelve microfluidic circuits that enable the processing of up to twelve samples once housed appropriately in the XPCR modules of the NeuMoDx System. The NeuMoDx Cartridge also incorporates a chamber to contain all the liquid waste generated while processing the samples.

### PRINCIPLES OF THE PROCEDURE

The NeuMoDx Systems use a combination of heat and proprietary extraction reagents to perform cell lysis, nucleic acid extraction and inactivation/reduction of inhibitors from unprocessed clinical specimens prior to presenting the extracted nucleic acid for detection by real-time polymerase chain reaction (PCR). An aliquot of the unprocessed specimen is mixed with the appropriate NeuMoDx Lysis Buffer and subjected to lysis at predetermined temperatures in the presence of lytic enzymes and paramagnetic particles.

The released nucleic acids are captured by paramagnetic particles and these particles (along with the bound nucleic acids) are then loaded into the NeuMoDx Cartridge where the unbound/non-specifically bound components are washed away using the NeuMoDx Wash Reagent and the bound nucleic acid is eluted using the NeuMoDx Release Reagent.

The NeuMoDx Systems mix the released nucleic acid with assay specific primers, probe(s), and the dried master mix contained in a NeuMoDx Test Strip. The System then dispenses the prepared, PCR-ready mixture into the NeuMoDx Cartridge where real-time PCR occurs.

### REAGENTS/CONSUMABLES

***Material Provided***

| REF | Contents | Tests per unit | Tests per package |
|---|---|---|---|
| 100100 | **NeuMoDx Cartridge** | 12 | 576 |

***Additional Materials Required but Not Provided (Available Separately from NeuMoDx)***

| REF | Contents |
|---|---|
| *various* | **NeuMoDx Lysis Buffer** *(as dictated by NeuMoDx Test Strip protocol)* |
| 100200 | **NeuMoDx Extraction Plate**<br>*Dried paramagnetic particles, lytic enzymes, and sample process controls* |
| 400100 | **NeuMoDx Wash Reagent** |
| 400200 | **NeuMoDx Release Reagent** |
| *various* | **NeuMoDx Test Strip** *(as applicable)* |
| 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

- This consumable is for *in vitro* diagnostic use with NeuMoDx Systems only.
- Do not use a NeuMoDx Cartridge after the listed expiration date.
- Do not use a NeuMoDx Cartridge if the product or packaging is visibly damaged upon arrival.
- Do not use a NeuMoDx Cartridge that has been dropped, as this may cause invalid results.
- Always handle the NeuMoDx Cartridge by the sides; do not touch the top surface.
- Do not place any labels on the NeuMoDx Cartridge.
- Do not reuse a NeuMoDx Cartridge.
- Do not open a NeuMoDx Cartridge before or after use.
- Always wear clean, powder free nitrile gloves when handling specimens or any NeuMoDx reagents or consumables.
- Wash hands thoroughly after performing a test.
- Do not pipette by mouth. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
- 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]
- Dispose of unused reagents and waste in accordance with country, federal, provincial, state and local regulations.

### PRODUCT STORAGE, HANDLING & STABILITY

- The NeuMoDx Cartridge is stable in the primary packaging at 18 to 28 °C through the stated expiration date on the immediate product label.
- Do not use consumables past the stated expiration date.
- A NeuMoDx Cartridge that remains only partially used will automatically be discarded three days.
- Do not use if the product or packaging has been visually compromised.
- Always handle cartridges by the sides and wear clean powder free, nitrile gloves during any handling.

### SPECIMEN COLLECTION, TRANSPORT & STORAGE

Validation of optimal specimen shipping conditions and specimen stability should be conducted by the user's laboratory for the sample matrix used and for each type of test performed.

### INSTRUCTIONS FOR USE

1. Open the plastic sleeve and remove a NeuMoDx Cartridge, taking care to only handle the cartridge by the sides and not touching the top surface of the cartridge.
2. Touch the arrow below the desired Cartridge Carrier icon on the NeuMoDx System touchscreen.
3. Place the NeuMoDx Cartridge into the Cartridge Carrier with barcode facing to the right to be read by the barcode scanner; Cartridges can be stacked in columns of five in the Cartridge Carrier.
4. Touch the arrow again on the touchscreen to load the Cartridge Carrier into the NeuMoDx System.
5. Once the barcode on the NeuMoDx Cartridge is read, the touchscreen will show a green section for Cartridges in the loaded Carrier. If this does not occur, unload the Carrier and ensure the barcode on the NeuMoDx Cartridge is facing to the right.

### LIMITATIONS

- The NeuMoDx Cartridge can only be used on NeuMoDx Systems and is not compatible with any other automated molecular diagnostic system.
- The performance characteristics of laboratory developed assays using this consumable must be validated by the user's laboratory before diagnostic claims can be made.
- Because detection of most pathogens is dependent on the number of organisms present in the sample, reliable results are dependent on proper specimen collection, handling, and storage.
- Erroneous test results could occur from improper specimen collection, handling, storage, technical error or sample mix-up. In addition, false negative results could occur because the number of organisms in the specimen is below the analytical sensitivity of the test.
- Use of this consumable is limited to personnel trained on the use of the NeuMoDx System.
- Good laboratory practices, including wearing gloves while loading all reagents and consumables into the system and changing gloves during specimen preparation is critical to reduce chance of contamination.

## REFERENCES

1. Centers for Disease Control and Prevention. 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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