July 2023

# NeuMoDx™ Cartridge Instructions for Use

576

Version 1

IVD

For In Vitro Diagnostic Use with the NeuMoDx 288 and NeuMoDx 96 Molecular Systems

℞ only

For prescription use only

CE

REF 100100

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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

# Contents

# 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. For in vitro diagnostic use.

# 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.

# Materials Provided

## Kit contents

| **NeuMoDx Cartridge REF 100100** | **Units per Package** | **Tests per Unit** | **Tests per Package** |
|---|---|---|---|
| NeuMoDx Cartridge | 48 | 12 | 576 |

# Materials Required but Not Provided

| REF | Contents |
|---|---|
| various | **NeuMoDx Lysis Buffer(s)** |
| 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** |

## Equipment*

- NeuMoDx 288 Molecular System [REF 500100] OR
  NeuMoDx 96 Molecular System [REF 500200]

* Prior to use, ensure that instruments have been checked and calibrated according to the manufacturer's recommendations.

# Warnings and Precautions

## Safety information

- 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.

## Emergency information

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

## Disposal

Dispose of as hazardous waste in compliance with local and national regulations. This also applies to unused products. Follow recommendations in the Safety Data Sheet (SDS).

# Product Storage, Handling, and 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 in-use will automatically be discarded after 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, and Storage

*Handle all specimens as if they are capable of transmitting infectious agents.*

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.
6. The N288 System will dispose of used cartridges and tips into the Biohazard Waste Container, which should be emptied as soon as possible when prompted by the NeuMoDx System Software.
7. The N96 System will place used cartridges in the Biohazard Waste Bin and tips in the Biohazard Tip Waste Bin; both waste bins should be emptied as soon as possible when prompted by the NeuMoDx System Software.

# Limitations

1. The NeuMoDx Cartridge can only be used on NeuMoDx Systems and is not compatible with any other automated molecular diagnostic system.
2. The performance characteristics of laboratory developed assays using this consumable must be validated by the user's laboratory before diagnostic claims can be made.
3. 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.
4. 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.
5. Use of this consumable is limited to personnel trained on the use of the NeuMoDx System.
6. 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.

# Quality Control

Local regulations typically specify that the laboratory is responsible for control procedures that monitor accuracy and precision of the complete analytical process, and must establish the number, type, and frequency of testing control materials. Depending on the assay used, control materials may not be provided by NeuMoDx Molecular, Inc.

Appropriate controls must be chosen and validated by the laboratory. In general, it is recommended that users process one set of positive and negative controls prior to processing patient samples, once every 24 hours of System operation. See specific IFU for assay being processed for more details.

# 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.

# Symbols

The following symbols may appear in the instructions for use or on the packaging and labeling:

| Symbol | Symbol definition |
|---|---|
|   | Contains reagents sufficient for <N> reactions |
|  | Use by |
|   | In vitro diagnostic medical device |
|   | Catalog number |
|   | Batch code |
|  | Manufacturer |
|  | Temperature limit |
|   | For prescription use only |
|   | Authorized representative in the European Community |
|  | Do not reuse |
|  | CE Mark |
|  | Consult instructions for use |
|   | Contains |

# Contact Information

For technical assistance and more information, please see our Technical Support Center at **support@qiagen.com**.

Technical support/Vigilance reporting: **support@qiagen.com**

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

# Ordering Information

| Product | Cat. no. |
|---|---|
| NeuMoDx Cartridge | 100100 |
| | |
| **Related Products** | |
| NeuMoDx Lysis Buffer 1 | 400400 |
| NeuMoDx Lysis Buffer 2 | 400500 |
| NeuMoDx Lysis Buffer3 | 400600 |
| NeuMoDx Lysis Buffer 4 | 400700 |
| NeuMoDx Lysis Buffer 5 | 400900 |
| NeuMoDx Lysis Buffer 6 | 401700 |
| NeuMoDx Extraction Plate | 100200 |
| NeuMoDx Wash Reagent | 400100 |
| NeuMoDx Release Reagent | 400200 |
| NeuMoDx Test Strip | various |
| Hamilton CO-RE / CO-RE II Tips (300 µl) with Filters | 235903 |
| Hamilton CO-RE / CO-RE II Tips (1000 µl) with Filters | 235905 |

For up-to-date licensing information and product-specific disclaimers, see the respective NeuMoDx kit handbook or operator manual. NeuMoDx kit handbooks are available at **www.neumodx.com** or can be requested from **support@qiagen.com** or your local distributor.

# Document Revision History

| Revision | Summary of Changes |
|---|---|
| A, 05/2022 | Initial Release<br>New Product Number (P/N 40600591) created for IVDR submission of General Reagents |
| B. 07/2023 | Updated Emergo Address to Westervoortsedijk 60; 6827 AT Arnhem The Netherlands.<br>Changed www.neumodx.com/client-resources to www.qiagen.com/neumodx-ifu. |

**Limited License Agreement for NeuMoDx Cartridge**

Use of this product signifies the agreement of any purchaser or user of the product to the following terms:

1. The product may be used solely in accordance with the protocols provided with the product and this handbook and for use with components contained in the panel only. NeuMoDx grants no license under any of its intellectual property to use or incorporate the enclosed components of this panel with any components not included within this panel except as described in the protocols provided with the product, this handbook, and additional protocols available at **www.neumodx.com**. Some of these additional protocols have been provided by NeuMoDx users for NeuMoDx users. These protocols have not been thoroughly tested or optimized by NeuMoDx. NeuMoDx neither guarantees them nor warrants that they do not infringe the rights of third-parties.
2. Other than expressly stated licenses, NeuMoDx makes no warranty that this panel and/or its use(s) do not infringe the rights of third-parties.
3. This panel and its components are licensed for one-time use and may not be reused, refurbished, or resold.
4. NeuMoDx specifically disclaims any other licenses, expressed or implied other than those expressly stated.
5. The purchaser and user of the panel agree not to take or permit anyone else to take any steps that could lead to or facilitate any acts prohibited above. NeuMoDx may enforce the prohibitions of this Limited License Agreement in any Court, and shall recover all its investigative and Court costs, including attorney fees, in any action to enforce this Limited License Agreement or any of its intellectual property rights relating to the panel and/or its components.

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