March 2024

NeuMoDx™ Extraction Plate Instructions for Use

Σ 384

Version 1

IVD

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

℞ only

For prescription use only

CE

REF 100200

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

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

40600590_C

NeuMoDx™ molecular
a QIAGEN company

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 [REF 500100]

For detailed instructions, refer to the *NeuMoDx 96 Molecular System Operator's Manual;* P/N 40600317 [REF 500200] or P/N 40600655 [REF 500201]

Contents

Intended Use

The NeuMoDx Extraction Plate contains a proprietary, dried reagent used for the efficient extraction of nucleic acids on the NeuMoDx 288 and NeuMoDx 96 Molecular Systems (NeuMoDx System(s)) in conjunction with other NeuMoDx reagents such as NeuMoDx Lysis Buffers, NeuMoDx Wash Reagent, and the NeuMoDx Release Reagent. The NeuMoDx Extraction Plate is universally used for all tests processed on the NeuMoDx Systems and is formulated to perform both RNA and DNA extraction.

Summary and Explanation

Each 24-well NeuMoDx Extraction Plate contains dried, room-temperature stable reagents including proprietary coated paramagnetic particles, a lytic enzyme, and RNA and DNA Sample Process Controls. Components within the Extraction Plate work in conjunction with the appropriate NeuMoDx Lysis Buffer to disrupt biological membranes in a temperature dependent manner and bind the nucleic acid while reducing activity of any nucleases present in clinical samples. The Sample Process Controls bind to the paramagnetic particles at the same time as the target nucleic acid, and are carried throughout the extraction procedure, serving as internal controls to monitor for any inefficiencies in the extraction process and presence of PCR inhibitors.

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 PCR. An aliquot of the unprocessed specimen is mixed with the appropriate Lysis

Buffer in the NeuMoDx Extraction Plate and is 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 NeuMoDx Release Reagent.

The NeuMoDx Systems mix the released nucleic acid with assay specific primers, probe(s), and 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 Extraction Plate 100200 Contents	**Units per package**	**Tests per unit**	**Tests per package**
NeuMoDx Extraction Plate *Dried paramagnetic particles, lytic enzymes, and sample process controls* *Contains 5-9% Proteinase K*	16	24	384

Materials Required but Not Provided

REF	Contents
100100	NeuMoDx Cartridge
various	NeuMoDx Lysis Buffer *(as dictated by NeuMoDx Test Strip protocol)*
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 or 500201]

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

Warnings and Precautions

Safety information

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 (SDSs). These are available online in convenient and compact PDF format at **www.qiagen.com/neumodx-ifu**, where you can find, view, and print the SDS for each NeuMoDx kit and kit component.

- The NeuMoDx Extraction Plate is for in vitro diagnostic use with NeuMoDx Systems only.
- Do not use reagents after the listed expiration date.
- Do not use if the product or packaging is damaged upon arrival or if foil seal is compromised.
- Ensure that the NeuMoDx Extraction Plate is at room temperature before use on the NeuMoDx System.
- Always handle NeuMoDx Extraction Plates by the sides; do not touch the top foil surface.
- Do not reuse any NeuMoDx consumables or reagents.
- Always wear clean, powder free nitrile gloves when handling specimens or any NeuMoDx reagents or consumables.
- Wash hands thoroughly after performing the 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).

- 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).
- Dispose of unused reagents and waste in accordance with country, federal, provincial, state, and local regulations.

Precautions

NeuMoDx Extraction Plate

DANGER

Contains: boric acid; proteinase K.

Causes skin irritation. Causes serious eye irritation. May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause respiratory irritation. May damage fertility or the unborn child.

Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Avoid breathing dust. Use only outdoors or in a well-ventilated area. Wear protective gloves/ protective clothing/ eye protection/ face protection. Wear respiratory protection. IF exposed or concerned: Call a POISON CENTER or doctor/ physician. Remove person to fresh air and keep comfortable for breathing. Take off contaminated clothing and wash before reuse. Store in a well-ventilated place. Keep container tightly closed. Store locked up. Dispose of contents/ container to an approved waste disposal plant.

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

- Do not use reagents past the stated expiration date.
- Do not use if the product or packaging has been visually compromised.
- Always wear clean, powder free nitrile gloves when handling specimens or any NeuMoDx reagents or consumables.
- Once loaded, the NeuMoDx Extraction Plate may remain onboard the NeuMoDx System for 28 days. Remaining shelf life of loaded Extraction Plates is tracked by the software and reported to the user in real time. Removal of an Extraction Plate that has been in use beyond its allowable period will be done automatically by the System.

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 for each type of test performed.

Instructions for Use

1. Open the foil pouch and remove the NeuMoDx Extraction Plate, taking care to only handle the plate by the sides and not touching the top surface of the plate.
2. Touch the arrow below the desired Extraction Plate Carrier icon on the NeuMoDx System touchscreen.
3. Place the NeuMoDx Extraction Plate into the Carrier with barcode facing to the right to be read by the barcode scanner.
4. Touch the arrow again on the NeuMoDx System touchscreen to load the Carrier into the NeuMoDx System.
5. Once the barcode on the NeuMoDx Extraction Plate is read, the touchscreen will show a green section for Extraction Plates in the loaded Carrier. If this does not occur, unload the Carrier and ensure the barcode on the NeuMoDx Extraction Plate is facing to the right.

Limitations

- The NeuMoDx Extraction Plate can only be used on the NeuMoDx System and is not compatible with any other automated molecular diagnostic system.
- The performance characteristics of lab-developed assays using this reagent are unknown and 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 reagent is limited to personnel trained on the use of the NeuMoDx System.
- Good laboratory practices, including wearing gloves while loading all reagents 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.

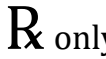
Appropriate controls must be chosen and validated by the laboratory. In general, it is recommended that users process one set of positive and negative controls prior to processing patient samples, once every 24 hours of System operation. See specific IFU for assay being processed for more details.

References

1. Centers for Disease Control and Prevention. *Biosafety in Microbiological and Biomedical Laboratories, 6th edition*. HHS Publication No. (CDC) 300859, Revised June 2020
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

Symbol	Symbol definition
	Warning
	Health Hazard
	Contains
	Contains biological material of animal origin
	Contains biological material of human origin
	Caution

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.

Patent: **www.neumodx.com/patents**

Ordering Information

Product	REF
NeuMoDx Extraction Plate	100200
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 Cartridge	100100
NeuMoDx Wash Reagent	400100
NeuMoDx Release Reagent	400200
NeuMoDx Test Strip (as applicable)	*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.qiagen.com/neumodx-ifu** or can be requested from **support.qiagen.com** or your local distributor.

Document Revision History

Revision	Summary of Changes
A, 05/2022	Initial Release New Product Number (P/N 40600590) created for IVDR submission of General Reagents.
B, 07/2023	Updated Emergo Address to Westervoortsedijk 60; 6827 AT Arnhem The Netherlands. Changed www.neumodx.com/client-resources to www.qiagen.com/neumodx-ifu.
C, 03/2024	Updated detailed instructions content to add [REF 500100] for NeuMoDx 288 Molecular System Operator's Manual, and [REF 500200 or P/N 40600655 [REF 500201] for NeuMoDx 96 Molecular System Operator's Manual. Added the patent URL in the Contact Information. Updated support@qiagen.com to support.qiagen.com

Limited License Agreement for NeuMoDx Extraction Plate

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.qiagen.com/neumodx-ifu. 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.

For updated license terms, see www.qiagen.com/neumodx-ifu.