July 2023

NeuMoDx™ Release Reagent Instructions for Use

Σ 2000

Version 1

IVD

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

℞ only

For prescription use only

CE

REF 400200

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

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

40600588_B

NeuMoDx™ molecular
a QIAGEN company

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 Release Reagent is a proprietary reagent used for the efficacious extraction of nucleic acids on the NeuMoDx 288 Molecular System and NeuMoDx 96 Molecular System (NeuMoDx System(s)) in conjunction with other NeuMoDx reagents, such as the NeuMoDx Extraction Plate, NeuMoDx Lysis Buffers, and NeuMoDx Wash Reagent.

Summary and Explanation

NeuMoDx Release Reagent is a proprietary reagent that releases captured nucleic acid from NeuMoDx proprietary paramagnetic particles, providing the eluate at the proper pH for mixing with dried reagents in a NeuMoDx Test Strip and subsequent real-time PCR.

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 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 NeuMoDx Release Reagent.

The NeuMoDx Systems mix the released nucleic acid with assay specific primers and 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 Release Reagent REF 400100	**Units per Package**	**Tests per Unit**	**Tests per Package**
NeuMoDx Release Reagent	2	~ 1,000*	~ 2,000*

Materials Required but Not Provided

REF	Contents
100100	**NeuMoDx Cartridge**
100200	**NeuMoDx Extraction Plate** ***Dried paramagnetic particles, lytic enzymes, and sample process controls***
various	**NeuMoDx Lysis Buffer(s)**
400100	**NeuMoDx Wash Reagent**
various	**NeuMoDx Test Strip**
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

- For in vitro diagnostic use with NeuMoDx Systems only.
- Do not use after the listed expiration date.
- Do not use if the safety seal is broken, if the packaging is damaged upon arrival, or if signs of leakage are present.
- Do not reuse any NeuMoDx consumable or reagent.
- Ensure that NeuMoDx Release Reagent is at room temperature before use on the NeuMoDx System.
- Safety Data Sheets (SDS) are provided for each reagent (as applicable) at **www.qiagen.com/neumodx-ifu**
- 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 Laboratories1 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

- NeuMoDx Release Reagent is stable in the primary packaging at 15 to 25 °C through the stated expiration date on the immediate product label.
- Do not use reagents past the stated expiration date.
- Do not use if the product or packaging has been visually compromised.
- Once loaded, the NeuMoDx Release Reagent may remain in use for 30 days. Remaining shelf life of loaded Release Reagent is tracked by the software and reported to the user in real time. Removal from the reagent drawer will be prompted by the System for Release Reagent that has been in use beyond its allowable period.

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. The NeuMoDx System will be preloaded with NeuMoDx Release Reagent when installed and qualified.
2. To change the NeuMoDx Release Reagent, touch the arrow below the Release Reagent icon on the NeuMoDx System touchscreen to unlock the appropriate Bulk Reagent Drawer (A or B) and follow the on-screen instructions.
    2a. Open Bulk Reagent Drawer (A or B).
    2b. Use the handheld barcode scanner to scan the barcode of the new NeuMoDx Release Reagent.
    2c. Remove and discard the temporary cap from the new NeuMoDx Release Reagent.
    2d. Without setting the tubing on any surface to avoid the risk of contamination, disconnect the cap with affixed black tubing from the current NeuMoDx Release Reagent.
    2e. Immediately place cap with affixed tubing into the new NeuMoDx Release Reagent. Turn cap to tighten.
    2f. Consult product SDS for proper disposal.

Limitations

- NeuMoDx Release Reagent can only be used on the NeuMoDx System and is not compatible with any other automated molecular diagnostic system.
- The performance characteristics of user assays using this reagent is unknown and must be validated by the user's laboratory before diagnostic claims can be made.
- Care must be taken when changing NeuMoDx Release Reagent on the NeuMoDx System to not contaminate the tubing.
- 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 changing gloves between handling patient specimens, are recommended to avoid contamination of specimens.

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

Symbol	Symbol definition
	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 LDT Release Reagent	400200
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 Extraction Plate	100200
NeuMoDx Wash Reagent	400100
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 New Product Number (P/N 40600588) 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.

Limited License Agreement for NeuMoDx Release Reagent

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.

For updated license terms, see **www.neumodx.com**.