REF 400200 NeuMoDx™ RELEASE Solution

Rx only

IVD For *In Vitro* Diagnostic Use on the **NeuMoDx™ 288** and **NeuMoDx™ 96 Molecular Systems**

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™ RELEASE Solution** is a proprietary reagent used for the efficacious extraction of nucleic acids on a **NeuMoDx™ 288** and **NeuMoDx™ 96 Molecular Systems** (**NeuMoDx™ System(s)**) in conjunction with other **NeuMoDx™** reagents, such as the **NeuMoDx™ Extraction Plate**, **NeuMoDx™** lysis buffers, and **NeuMoDx™ WASH Solution**.

SUMMARY AND EXPLANATION

NeuMoDx™ RELEASE Solution 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 pre-determined 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 Solution and the bound nucleic acid is eluted using NeuMoDx RELEASE Solution.

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 RT-PCR-ready mixture into the NeuMoDx Cartridge where Real-Time PCR occurs.

REAGENTS / CONSUMABLES

Material Provided

REF	Contents	Tests per unit	Tests per carton
400200	**NeuMoDx™ RELEASE Solution**	~ 1,000*	~ 2,000*

** tests per unit/carton may vary depending on actual use*

NeuMoDx™ Reagents and Consumables Required But Not Provided

REF	Contents
100200	**NeuMoDx™ Extraction Plate** *Dried paramagnetic particles, lytic enzymes, and sample process controls*
400400, 400500 400600, 400700	**NeuMoDx™ Lysis Buffer 1, 2, 3** and/or **4**
400100	**NeuMoDx™ WASH Solution**
100100	**NeuMoDx™ Cartridge**
various	**NeuMoDx™** test strip
235903	**Hamilton CO-RE Tips (300 µL) with Filters** (available from NeuMoDx or Hamilton)
235905	**Hamilton CO-RE Tips (1000 µL) with Filters** (available from NeuMoDx or Hamilton)

Other Equipment and Materials Required But Not Provided

NeuMoDx™ 288 Molecular System [REF 500100] OR **NeuMoDx™ 96 Molecular System** [REF 500200]

WARNINGS & PRECAUTIONS

- This reagent is for in vitro diagnostic use with NeuMoDx Systems only.
- Do not use the reagents 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.
- Ensure that NeuMoDx RELEASE Solution is at room temperature before use the NeuMoDx System.
- Do not reuse any NeuMoDx consumable or reagent.
- NeuMoDx RELEASE Solution is high in pH and should be handled with care, refer to SDS for more specific information.
- Safety Data Sheets (SDS) are provided for each reagent.
- Always wear clean powder free nitrile gloves when handling specimens or any NeuMoDx reagents and 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-A3 [2].
- Dispose of unused reagents and waste in accordance with country, federal, provincial, state and local regulations.

PRODUCT STORAGE, HANDLING & STABILITY

- NeuMoDx RELEASE Solution is stable in the primary packaging at 18 to 28 °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 primary or packaging has been visually compromised.
- NeuMoDx RELEASE Solution placed in the Reagent drawer of the NeuMoDx System is stable for 1 month when operating within the environmental conditions specified in the *NeuMoDx™ 288/96 Molecular System Operator's Manual(s)*. The NeuMoDx System software will prompt the removal of NeuMoDx RELEASE Solution that has been in-use for longer than 1 month.

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 for each type of test performed.

INSTRUCTIONS FOR USE

1. The NeuMoDx System will be pre-loaded with NeuMoDx RELEASE Solution when installed and qualified.
2. To change the NeuMoDx RELEASE Solution, touch the arrow below the release solution icon on the NeuMoDx System touchscreen to unlock the appropriate Bulk Reagent Drawer (A or B) and follow the on-screen instructions.
    a. Open Bulk Reagent Drawer (A or B).
    b. Use the handheld barcode scanner to scan the barcode of the new NeuMoDx RELEASE Solution.
    c. Remove and discard the temporary cap from the new NeuMoDx RELEASE Solution.
    d. 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 Solution.
    e. Immediately place cap with affixed tubing into the new NeuMoDx RELEASE Solution. Turn cap to tighten.
    f. Consult product SDS for proper disposal.

LIMITATIONS

1. NeuMoDx RELEASE Solution can only be used on the NeuMoDx System and is not compatible with any other automated molecular diagnostic system.
2. The performance characteristics of user assays using this reagent is unknown and must be validated by your laboratory before diagnostic claims can be made.
3. Care must be taken when changing NeuMoDx RELEASE Solution in the Reagent Drawer to not contaminate the tubing and to avoid prolonged exposure to air.
4. 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.
5. 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.
6. Use of this reagent is limited to personnel trained on the use of the NeuMoDx System.
7. Good laboratory practices, including changing gloves between handling patient specimens, are recommended to avoid contamination of specimens.

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
Rx only	Prescription Use Only
	Manufacturer
IVD	*In Vitro* Diagnostic Medical Device
EC REP	EC Representative
REF	Catalog Number
LOT	Batch Code
	Use By
	Temperature Limitation
	Humidity Limitation
	Do Not Reuse
CONTROL	Control
	Contains Sufficient for "n" Tests
	Consult Instructions for Use
	Caution
	Biological Risks (Potentially Biohazardous Material)
CE	CE Mark

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Patent: www.neumodx.com/patents

EC REP

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