March 2024

NeuMoDx™ Lysis Buffer 1 to 6 Instructions for Use

Σ 560

Version 1

IVD

CE

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

℞ only

For prescription use only

REF

400400 NeuMoDx Lysis Buffer 1
400500 NeuMoDx Lysis Buffer 2
400600 NeuMoDx Lysis Buffer 3
400700 NeuMoDx Lysis Buffer 4
400900 NeuMoDx Lysis Buffer 5
401700 NeuMoDx Lysis Buffer 6

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

EC REP

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

40600581_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

NeuMoDx Lysis Buffers 1, 2, 3, 4, 5, or 6 are proprietary buffers used for the efficacious extraction of nucleic acids from unprocessed clinical or biological specimens on the NeuMoDx 288 Molecular System and NeuMoDx 96 Molecular System (NeuMoDx System(s)) when used in conjunction with other NeuMoDx reagents, such as NeuMoDx Extraction Plate, NeuMoDx Wash Reagent**,** and the NeuMoDx Release Reagent, which are used for all tests processed on the NeuMoDx Systems. NeuMoDx Lysis Buffers can be used for extraction of nucleic acids from clinical or biological specimens when used in combination with specified NeuMoDx test strips.

Summary and Explanation

Each NeuMoDx Lysis Buffer is supplied in a disposable buffer container**,** which includes at least 80 ml of usable buffer. Each NeuMoDx Lysis Buffer contains a proprietary formulation of salts and detergent to provide efficient lysis of microorganisms in clinical or biological specimens.

Use of the NeuMoDx Lysis Buffer(s) to extract nucleic acids from clinical or biological specimens that are not indicated for use with the corresponding NeuMoDx Test strip has not been validated.

Refer to Table 1 for the corresponding NeuMoDx Test Strips indicated for use with NeuMoDx Lysis Buffer 1, 2, 3, 4, 5, or 6.

Table 1. NeuMoDx Lysis Buffer and its indicated NeuMoDx Test Strip

REF	Contents	NeuMoDx Test Strips
400400	NeuMoDx Lysis Buffer 1	NeuMoDx HBV Quant Assay [REF 201300] NeuMoDx CMV Quant Test Strip [REF 201400] NeuMoDx BKV Quant Test Strip [REF 201800] NeuMoDx HAdV Quant Test Strip [REF 200700] NeuMoDx EBV Quant Test Strip 2.0 [REF 201501] NeuMoDx HSV 1/2 Quant Test Strip [REF 202400] NeuMoDx HHV-6 Quant Test Strip [REF 202500]
400500	NeuMoDx Lysis Buffer 2	NeuMoDx CT/NG Assay [REF 200300] NeuMoDx TV/MG Assay [REF 201200] NeuMoDx HPV Test Strip [REF 617007] NeuMoDx SARS-CoV-2 Test Strip [REF 300800] NeuMoDx Flu A-B/RSV/SARS-CoV-2 Vantage Test [REF 300900] NeuMoDx HAdV Quant Test Strip [REF 200700] NeuMoDx BKV Quant Test Strip [REF 201800] NeuMoDx FluA/FluB/RSV/SARS-CoV-2 Test Strip [REF 300901]
400600	NeuMoDx Lysis Buffer 3	NeuMoDx HCV Quant Test Strip [REF 300300] NeuMoDx HIV-1 Quant Test Strip [REF 300500] NeuMoDx SARS-CoV-2 Test Strip [REF 300800] NeuMoDx FluA-B/RSV/SARS-CoV-2 Vantage Test [REF 300900] NeuMoDx FluA/FluB/RSV/SARS-CoV-2 Test Strip [REF 300901]
400700	NeuMoDx Lysis Buffer 4	NeuMoDx GBS Assay [REF 200400]
400900	NeuMoDx Lysis Buffer 5	NeuMoDx EBV Quant Test Strip [REF 201500]
401700	NeuMoDx Lysis Buffer 6	NeuMoDx Strep A/C/G Vantage Assay [REF 201902]

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/removal of inhibitors from unprocessed clinical or biological specimens prior to presenting the extracted nucleic acid for detection by real-time PCR. An aliquot of the unprocessed specimen is mixed with a NeuMoDx Lysis Buffer and subjected to lysis at predetermined temperatures in the presence of lytic enzymes and paramagnetic particles. Each NeuMoDx Lysis Buffer has been formulated and optimized for extraction of nucleic acids from clinical or biological specimens by providing an optimal environment for cell/particle lysis and binding of nucleic acids to occur. The stringent formulation of the buffers also inhibits the activity of any nucleases present in the sample, thereby protecting the nucleic acids from degradation.

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

REF	Contents	Units per package	Tests per unit	Tests per package
400400	NeuMoDx Lysis Buffer 1	4	~140*	~560*
400500	NeuMoDx Lysis Buffer 2	4	~140*	~560*
400600	NeuMoDx Lysis Buffer 3	4	~140*	~560*
400700	NeuMoDx Lysis Buffer 4	4	~80*	~320*
400900	NeuMoDx Lysis Buffer 5	4	~140*	~560*
401700	NeuMoDx Lysis Buffer 6	4	~80*	~320*

* Tests per unit/package may vary depending on actual use.

Materials Required but Not Provided

Additional reagents/consumables

REF	Contents
100100	NeuMoDx Cartridge
100200	NeuMoDx Extraction Plate *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 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.

- For in vitro diagnostic use with NeuMoDx Systems only.
- Do not refrigerate.
- Do not use any reagents after the listed expiration date.
- Do not use if the safety seal is broken or if the packaging is damaged upon arrival.
- Do not use if foil seal is damaged upon arrival or if signs of leakage are present.
- Be sure to remove the foil seal from the container prior to loading NeuMoDx Lysis Buffer 5 into the carrier for use.
- Ensure that each NeuMoDx Lysis Buffer is at room temperature before using on the NeuMoDx System.
- Do not reuse any NeuMoDx consumable or reagent.
- 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).

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

Precautions

NeuMoDx Lysis Buffer 1

WARNING

Contains: guanidine hydrochloride.

May be harmful if swallowed. Causes skin irritation. Causes serious eye irritation.

Wear protective gloves/ protective clothing/ eye protection/ face protection. Call a POISON CENTER/ doctor if you feel unwell. Take off contaminated clothing and wash before reuse.

NeuMoDx Lysis Buffer 2

WARNING

Contains: guanidine hydrochloride.

May be harmful if swallowed. Causes mild skin irritation

Wear protective gloves/ protective clothing/ eye protection/ face protection. Call a POISON CENTER/ doctor if you feel unwell. Take off contaminated clothing and wash before reuse.

NeuMoDx Lysis Buffer 3

WARNING

Contains: guanidine hydrochloride.

May be harmful if swallowed or if inhaled. Causes skin irritation. Causes serious eye irritation.

Wear protective gloves/ protective clothing/ eye protection/ face protection. IF exposed of concerned: Call a POISON CENTER/ doctor if you feel unwell. Take off contaminated clothing and wash before reuse

NeuMoDx Lysis Buffer 4

DANGER

Contains: sodium borate, decahydrate.

May damage fertility or the unborn child.

Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves/ protective clothing/ eye protection/ face protection. IF exposed or concerned: Get medical advice/ attention. Store locked up. Dispose of contents/ container to an approved waste disposal plant.

NeuMoDx Lysis Buffer 6

DANGER

Contains: alcohols, C12-14-secondary, ethoxylated; sodium borate, decahydrate.

Causes mild skin irritation. Causes serious eye 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. Wear protective gloves/ protective clothing/ eye protection/ face protection. IF exposed or concerned: If skin irritation occurs: Get medical advice/ attention. If eye irritation persists: 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

- NeuMoDx Lysis Buffers 1, 2, 3, 5, and 6 are stable in the primary packaging at 15– 28°C through the stated expiration date on the immediate product label.
- NeuMoDx Lysis Buffer 4 is stable in the primary packaging at 18–28°C through the stated expiration date on the immediate product label.
- Do not refrigerate.
- Do not use reagents past the stated expiration date.
- Do not use if product or packaging has been visually compromised. The presence of some minor precipitation after removal of the foil seal is normal; this will not prevent successful use of any of the NeuMoDx Lysis Buffers on the NeuMoDx System.
- Once loaded, NeuMoDx Lysis Buffers may remain on the system as stated in Table 2. below. Remaining shelf life of in use Lysis Buffers are tracked by the software and reported to the user in real time. Removal of any Lysis Buffer that has been in use beyond its allowable period will be prompted by the System.

Table 2. NeuMoDx Lysis Buffer and its corresponding on system days

REF	Contents	On system (days)
400400	NeuMoDx Lysis Buffer 1	62
400500	NeuMoDx Lysis Buffer 2	62
400600	NeuMoDx Lysis Buffer 3	28
400700	NeuMoDx Lysis Buffer 4	28
400900	NeuMoDx Lysis Buffer 5	14
401700	NeuMoDx Lysis Buffer 6	32

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. Ensure that the NeuMoDx Lysis Buffer is at room temperature before use on the NeuMoDx System. Invert the container several times to mix the buffer before removing the foil seal.
2. **IMPORTANT**: Prepare NeuMoDx Lysis Buffer container for use by pulling on the tab of the foil seal to remove it.
3. Some residual buffer on top of the septum cover is expected after removal of the foil seal; this will not impact performance.
   If buffer is noticeable on either side of the container, dab the sides gently using a low lint tissue such as a Kimwipe® prior to placing in the Buffer Carrier. Do not touch anything to the top surface of the septum cover.
4. To ensure proper orientation when positioning the container in the Buffer Carrier, the barcode should face to the right in order to be read by the barcode scanner.
5. Place the open container with foil seal removed in the Buffer Carrier until it "snaps" into place.
6. Load the Buffer Carrier by touching the arrow below the Buffer Container icon on the NeuMoDx System touchscreen.
7. Upon successful loading of the Buffer Carrier, the NeuMoDx System software should identify the type of buffer loaded and the Quantity as "80 mL".
   - 7a. If the Buffer Carrier is loaded correctly but the NeuMoDx System software recognizes it as an EMPTY POSITION, ensure that the NeuMoDx Lysis Buffer container is loaded in the proper orientation and the barcode is visible to the barcode scanner.
   - 7b. If the Buffer Carrier is loaded correctly but the NeuMoDx System software does not identify it by the correct buffer name, check to confirm the name of the Buffer indicated on the container.
   - 7c. If the Buffer Carrier is loaded correctly and the NeuMoDx System software recognizes it as the correct buffer, but the quantity is not reported as "80 mL", check to confirm that this is a NEW NeuMoDx Lysis Buffer container.

Limitations

- NeuMoDx Lysis Buffers can only be used on the NeuMoDx System and are not compatible with any other automated molecular diagnostic system.
- The performance of NeuMoDx Lysis Buffers have only been validated for use with the corresponding NeuMoDx Test strips as indicated in Table 1. The performance characteristics of user-developed assays using this reagent is unknown and must be validated by 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, or 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 with this buffer, control materials may not be provided by NeuMoDx Molecular, Inc.

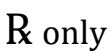
Appropriate controls must be chosen and validated by the laboratory. In general, it is recommended that users process one set of positive and negative controls prior to processing patient samples once every 24 hours of system operation. See specific IFUs for assay being processed for more details.

References

1. Centers for Disease Control and Prevention. *Biosafety in Microbiological and Biomedical Laboratories, 6th edition*. HHS Publication 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
	Caution

Symbol	Symbol definition
	Warning
	Health Hazard
	Contains
	Guanidine Hydrochloride

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	Contents	REF
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
Related Products		
NeuMoDx Cartridge		100100
NeuMoDx Extraction Plate		100200
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.

Notes.

Notes.

Notes.

Document Revision History

Revision	Description
A, May 2022	Initial Release (for IVDR submission). New Product Number (P/N 40600581) created for IVDR submission of General Reagents.
B, July 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, March 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 Lysis Buffer 1 to 6

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.