REF 400600 NeuMoDx™ Lysis Buffer 3

℞ only

IVD For *in vitro* diagnostic use with the NeuMoDx™ 288 and NeuMoDx™ 96 Molecular Systems

For insert updates, go to: www.neumodx.com/client-resources
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

NeuMoDx™ Lysis Buffer 3 is a proprietary buffer used for the efficacious extraction of nucleic acids from unprocessed clinical 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 Buffer 3 can be used for extraction of viral RNA from human plasma and serum samples.

SUMMARY AND EXPLANATION

NeuMoDx Lysis Buffer 3 is supplied in a disposable container**,** which includes at least 80 mL of usable buffer. NeuMoDx Lysis Buffer 3 contains a proprietary formulation of salts and chaotropic agents to provide efficient lysis of viral targets in human plasma and serum specimens.

Use of this buffer to extract nucleic acid from other specimens has not been validated.

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 specimens prior to presenting the extracted nucleic acid for detection by real-time PCR. An aliquot of unprocessed specimen is mixed with NeuMoDx Lysis Buffer 3 and subjected to lysis at predetermined temperatures in the presence of lytic enzymes and paramagnetic particles. NeuMoDx Lysis Buffer 3 is formulated and optimized for extraction of viral RNA from human plasma and serum samples by providing an optimal environment for cell/particle lysis and nucleic acid binding to occur. The stringent formulation of the buffer also inhibits or reduces any nuclease activity present in the sample, thereby protecting the viral RNA 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.

REAGENTS / CONSUMABLES

Material Provided

REF	Contents	Tests per unit	Tests per package
400600	**NeuMoDx™ Lysis Buffer 3** *Contains 33.5% Guanidine HCl*	~ 140*	~ 560*

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

Materials Required but Not Provided (Available Separately from NeuMoDx)

REF	Contents
100200	**NeuMoDx™ Extraction Plate** *Dried paramagnetic particles, lytic enzymes, and sample process controls*
400100	**NeuMoDx™ Wash Reagent**
400200	**NeuMoDx™ Release Reagent**
100100	**NeuMoDx™ Cartridge**
various	**NeuMoDx™ Test Strip** *(as applicable)*
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)

Instrumentation Required

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

WARNINGS AND PRECAUTIONS

- 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 3 into the carrier for use.
- Ensure that NeuMoDx Lysis Buffer 3 is at room temperature before use on the NeuMoDx System.
- Do not reuse any NeuMoDx consumable or reagent.
- Safety Data Sheets (SDS) are provided for each reagent (as applicable) at www.neumodx.com/client-resources.
- 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.

PRODUCT STORAGE, HANDLING AND STABILITY

- NeuMoDx Lysis Buffer 3 is stable in the primary packaging at 18 to 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 NeuMoDx Lysis Buffer 3 on the NeuMoDx System.
- Once loaded, NeuMoDx Lysis Buffer 3 may remain on the System for 28 days. Remaining shelf life of loaded Lysis Buffer 3 is tracked by the software and reported to the user in real time. Removal of Lysis Buffer 3 that has been in use beyond its allowable period will be prompted 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 and for each type of test performed.

INSTRUCTIONS FOR USE

1. Ensure that NeuMoDx Lysis Buffer 3 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 3 container for use by removing the foil seal using the tab.
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® to absorb 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 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 recognize the type of buffer as "Lysis Buffer 3" and the Quantity as "80 mL".

a. If the Buffer Carrier is loaded correctly, but the NeuMoDx System software recognizes it as an EMPTY POSITION, ensure that the NeuMoDx Lysis Buffer 3 container is loaded in the proper orientation and the barcode is visible to the barcode scanner.

b. If the Buffer Carrier is loaded correctly, but the NeuMoDx System software does not recognize it as "Lysis Buffer 3", check to confirm that this is a NeuMoDx Lysis Buffer 3 container.

c. If the Buffer Carrier is loaded correctly, and the NeuMoDx System software recognizes it as "Lysis Buffer 3", but the quantity is not reported as "80 mL", check to confirm that this is a NEW NeuMoDx Lysis Buffer 3 container.

LIMITATIONS

1. The NeuMoDx Lysis Buffer 3 container can only be used on the NeuMoDx System and is not compatible with any other automated molecular diagnostic system.
2. The performance of NeuMoDx Lysis Buffer 3 has ***only*** been validated using a NeuMoDx model viral RNA Assay in plasma. 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. 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 reagent is limited to personnel trained on the use of the NeuMoDx System.
6. 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 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

TRADEMARKS

SYMBOL KEY

℞ only	Prescription use only		Temperature limit
	Manufacturer		Do not re-use
IVD	*In vitro* diagnostic medical device		Contains sufficient for <*n*> tests
EC REP	Authorized representative in the European Community		Consult instructions for use
REF	Catalog number		Caution
LOT	Batch code		Biological risks
	Use-by date	CE	CE Mark

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