July 2023

NeuMoDx™ Viral Lysis Buffer and Vantage Viral Lysis Buffer Instructions for Use

Σ 2500

Version 1

IVD

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

℞ only

For prescription use only

CE

REF

401600
401500

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EC REP

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40600582_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 Viral Lysis Buffer is intended for the pretreatment of respiratory specimens suspected to be positive for SARS in UTM-RT® or equivalent prior to processing on the NeuMoDx 288 Molecular System or NeuMoDx 96 Molecular System (NeuMoDx System(s))

The NeuMoDx Vantage Viral Lysis Buffer is intended for the pretreatment of respiratory specimens suspected to be positive for Flu A, Flu B, RSV, or SARS in UVT-RT®, BD™ UVT, or Biologos Bio-VTM™ prior to processing on the NeuMoDx System(s).

The NeuMoDx Viral Lysis Buffer or NeuMoDx Vantage Viral Lysis Buffer is intended for use by trained clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and in vitro diagnostic procedures and/or NeuMoDx Molecular Systems. The NeuMoDx Viral Lysis Buffer or NeuMoDx Vantage Viral Lysis Buffer is not intended for self-testing or point-of-care use.

Summary and Explanation

Biological samples pretreated with NeuMoDx Viral Lysis Buffer or NeuMoDx Vantage Viral Lysis Buffer are suitable for subsequent processing on the NeuMoDx Systems for automated nucleic acid isolation and amplification. The lysis procedure described below has been designed as a generic protocol for offboard treatment of biological samples prior to loading on the NeuMoDx Systems. NeuMoDx has performed validation for a limited number of human specimen types with RNA viruses as the assay targets.

Principles of the Procedure

Biological specimen is added to NeuMoDx Viral Lysis Buffer or NeuMoDx Vantage Viral Lysis Buffer, which contains a proprietary formulation of chaotropic salt and surfactant in a 1:1 ratio and then placed on the NeuMoDx System for processing.

Materials Provided

Kit contents

NeuMoDx Viral Lysis Buffer	
401600	2 x 1000 ml

NeuMoDx Vantage Viral Lysis Buffer	
401500	2 x 1000 ml

Materials Required but Not Provided

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 *(available from NeuMoDx or Hamilton)*
235905	Hamilton CO-RE / CO-RE II Tips (1000 µL) with Filters *(available from NeuMoDx or Hamilton)*

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

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 Viral Lysis Buffer or NeuMoDx Vantage Viral Lysis Buffer is for *in vitro* diagnostic use with NeuMoDx Systems only.
- 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.
- Ensure that NeuMoDx Viral Lysis Buffer or NeuMoDx Vantage Viral Lysis Buffer is at room temperature before use.
- 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)
- Do not pipette by mouth. Do not smoke, drink, or eat in areas where specimens or reagents are being handled.
- Dispose of unused reagents and waste in accordance with country, federal, provincial, state and local regulations.
- Clean, powder-free, nitrile gloves should be worn when handling all NeuMoDx products.
- Wash hands thoroughly after performing the test.
- Safety Data Sheets (SDS) are provided for each reagent (as applicable) at **www.qiagen.com/neumodx-ifu**
- Do not reuse.

Precautions

NeuMoDx Viral Lysis Buffer

Contains: guanidine hydrochloride. Warning! May be harmful if swallowed or if inhaled. Causes skin irritation. Causes serious eye irritation. Wear protective gloves/ eye protection/ face protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. IF exposed or concerned: Call a POISON CENTER or doctor/ physician if you feel unwell. Specific treatment (see supplemental first aid instructions on this label). If skin irritation occurs: Get medical advice/ attention. If eye irritation persists: Take off contaminated clothing and wash before reuse.

NeuMoDx Vantage Viral Lysis Buffer

Contains: EDTA; guanidine hydrochloride; sodium borate, decahydrate. Danger! May be harmful if swallowed or if inhaled. Causes skin irritation. Causes serious eye irritation. May damage fertility or the unborn child. May cause damage to organs through prolonged or repeated exposure. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe mist or vapors. Wear protective gloves/ protective clothing/ eye protection/ face protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. IF exposed or concerned: Call a POISON CENTER or doctor/ physician if you feel unwell. Specific treatment (see supplemental first aid instructions on this label). If skin irritation occurs: Get medical advice/ attention. If eye irritation persists: Take off contaminated clothing and wash before reuse. 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

- The NeuMoDx Viral Lysis Buffer is stable in the primary packaging at 15°C to 28°C through the stated expiration date on the immediate product label.
- The NeuMoDx Vantage Viral Lysis Buffer is stable in the primary packaging at 4°C to 28°C through the stated expiration date on the immediate product label.
- Do not use reagents past the stated expiration date.
- Use a fresh pipette or pipette tip for each pipetting action.
- It is advisable to aliquot into smaller containers using aseptic technique to avoid contamination of the main bottle.
- Any buffer remaining after the shelf life has elapsed should be disposed in accordance with federal, provincial, state and/or local regulations.

Procedure

The NeuMoDx Viral Lysis Buffer or NeuMoDx Vantage Viral Lysis Buffer is intended for pretreatment of biological specimens before processing on the NeuMoDx Molecular Systems. Consult individual instructions for use for further details when using this reagent in conjunction with other NeuMoDx products.

Limitations

- The NeuMoDx Viral Lysis Buffer or NeuMoDx Vantage Viral Lysis Buffer should only be used in conjunction with NeuMoDx products to pretreat specimens before routine processing on NeuMoDx Systems.
- The performance of NeuMoDx Vantage Viral Lysis Buffer has only been validated using the NeuMoDx Flu A-B/RSV/SARS CoV-2 Assay in UTM–RT® and BD UVT universal transport medium when used at 1:1 ratio. The performance characteristics of laboratory developed tests using this reagent is unknown and must be validated by the laboratory before diagnostic claims can be made.
- The performance of NeuMoDx Viral Lysis Buffer has only been validated using a NeuMoDx model viral RNA assay in UTM-RT® universal transport medium. The performance characteristics of laboratory developed tests using this reagent is unknown and must be validated by the 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.
- 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.

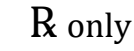
Appropriate controls must be chosen and validated by the laboratory. In general, it is recommended that users process one set of positive and negative controls prior to processing patient samples, once every 24 hours of System operation. See specific IFU for assay being processed for more details.

References

1. 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
	Do not reuse
	CE Mark
	Consult instructions for use
	Warning
	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.

Ordering Information

Product	Cat. no.
NeuMoDx Viral Lysis Buffer	401600
NeuMoDx Vantage Viral Lysis Buffer	401500
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.neumodx.com** or can be requested from **support@qiagen.com** or your local distributor.

Document Revision History

Revision	Description
A, May 2022	Initial Release (for IVDR submission). New Product Number (P/N 40600582) 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.

Limited License Agreement for NeuMoDx Viral Lysis Buffer and NeuMoDx Vantage Viral Lysis Buffer Kit

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.

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