July 2023

NeuMoDx™ Biohazard Waste Bag Instructions for Use

Version 1

IVD

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

℞ only

For prescription use only

CE

REF 600100

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EC REP

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40600587_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 Biohazard Waste Bag is an accessory product used to contain the biohazardous waste generated by the NeuMoDx 288 Molecular System and NeuMoDx 96 Molecular System (NeuMoDx System(s)). The NeuMoDx Biohazard Waste Bag is universally used for all tests run on the NeuMoDx Systems.

Summary and Explanation

The NeuMoDx Biohazard Waste Bag is used as an accessory to line the NeuMoDx Biohazard Waste Bin and collect biohazardous waste generated and automatically disposed of by the NeuMoDx 288 Molecular System. The Biohazard Waste Bag and associated container is used as a standalone accessory for disposing of biohazardous waste generated by the NeuMoDx 96 Molecular System. The NeuMoDx Biohazard Waste Bag consists of a clear liner inside a red biohazard waste bag, complete with absorbent material present in the bottom of the assembly.

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 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. Waste generated from processing tests is stored in the NeuMoDx Biohazard Waste Bag until properly disposed of by laboratory personnel.

Materials Provided

Kit contents

NeuMoDx Biohazard Waste Bag REF 600100	**Units per Package**	**Tests per Unit**	**Tests per Package**
NeuMoDx Biohazard Waste Bag	5	~ 500*	variable*

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

Materials Required but Not Provided

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 reuse.

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 or accessories.

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]

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 (SDS).

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

The NeuMoDx Biohazard Waste Bag should be stored at 18 to 28°C prior to use.

Do not use if product or packaging has been visually compromised.

Instructions for Use

NeuMoDx 288 Molecular System

The NeuMoDx 288 System software will prompt the user to empty the Biohazard Waste Bag after approximately 500 tests have been processed. Follow the steps prompted on the touchscreen display and consult the *NeuMoDx 288 Operator's Manual* for additional details.

NeuMoDx 96 Molecular System

The NeuMoDx Biohazard Waste Bag and Biohazard Waste Bin are provided as standalone accessories and may be used to dispose of biohazard waste generated from the NeuMoDx 96 Molecular System. See the *NeuMoDx 96 Operator's Manual* for additional details.

Limitations

1. The NeuMoDx Biohazardous Waste Bag can only be used with NeuMoDx Systems and is not compatible with any other automated molecular diagnostic system.
2. Use of this accessory is limited to personnel trained on the use of the NeuMoDx System.
3. Good Laboratory Practices, including changing gloves between handling patient specimens or biohazard waste 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

Symbols

The following symbols may appear in the instructions for use or on the packaging and labeling:

Symbol	Symbol definition
	In vitro diagnostic medical device
	Catalog number
	Batch code
	Manufacturer
	For prescription use only
	Authorized representative in the European Community
	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 Biohazard Bag	600100

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 40600587) 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 Biohazard Bag

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.
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