

REF 600100 NeuMoDx™ Biohazard Waste Bag

Rx only

IVD For *In Vitro* Diagnostic Use with 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™ Biohazard Waste Bag is a consumable product used to contain the biohazardous waste generated by the NeuMoDx™ 288 and NeuMoDx™ 96 Molecular Systems (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 a consumable to line the NeuMoDx™ Biohazard Waste Container and collect biohazardous waste generated and automatically disposed of from the NeuMoDx 288 Molecular System. The Biohazard Waste Bag and associated container is used as a stand-alone accessory for disposing of biohazardous waste generated from 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 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) as well as 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.



REAGENTS / CONSUMABLES

Material Provided

REF	Contents	Tests per unit (capacity)	Tests per carton
600100	NeuMoDx™ Biohazard Waste Bag	~ 500*	variable*

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

Other Equipment and Materials Required But Not Provided

1. NeuMoDx™ 288 Molecular System [REF 500100] OR NeuMoDx™ 96 Molecular System [REF 500200]
2. NeuMoDx™ Biohazard Waste Container [REF 600200]
3. Lab coat and disposable powder free, nitrile gloves



WARNINGS & PRECAUTIONS

- This waste container is for in vitro diagnostic use with NeuMoDx Systems only.
- Do not re-use.
- Safety Data Sheets (SDS) are provided for each 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-A3².
- Dispose of unused reagents and waste in accordance with country, federal, provincial, state and local regulations.





PRODUCT STORAGE, HANDLING & STABILITY

- The NeuMoDx Biohazard Waste Bag should be stored at 18 – 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 via a message on the touchscreen to empty the biohazard waste container 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 Container are provided as stand-alone 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 consumable 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

TRADEMARKS

NeuMoDx™ is a trademark of NeuMoDx Molecular, Inc.

SYMBOLS

SYMBOL	MEANING
Rx only	Prescription Use Only
	Manufacturer
IVD	<i>In Vitro</i> Diagnostic Medical Device
	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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