March 2024

NeuMoDx™ LDT Primer/Probe Strip Instructions for Use

Σ 96

Version 1

IVD

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

℞ only

For prescription use only

CE

REF 100400

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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

The NeuMoDx LDT Primer/Probe Strip is an empty, 16-well strip used for laboratory developed tests (LDTs) on the NeuMoDx 288 Molecular System and the NeuMoDx 96 Molecular System (NeuMoDx System(s)). NeuMoDx Systems, in conjunction with NeuMoDx reagents such as NeuMoDx Extraction Plate, NeuMoDx Lysis Buffers, NeuMoDx Wash Reagent and NeuMoDx Release Reagent make the development of LDTs streamlined and efficient, combining sample extraction with real-time PCR in one system. The NeuMoDx LDT Primer/Probe Strip is universally used for all LDTs processed on the NeuMoDx System.

Summary and Explanation

The NeuMoDx LDT Primer/Probe Strip is a foil-covered, empty, 16-well disposable plastic strip into which the user pipets assay-specific primers and probe(s) to process LDTs on a NeuMoDx System. It is used in parallel with NeuMoDx LDT Master Mix, DNA or NeuMoDx LDT Master Mix, RNA, which contain the required elements for real-time PCR, including Taq DNA polymerase, reverse transcriptase (if required), dNTPs, $MgCl_2$ and other buffer components.

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 the 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 the NeuMoDx Release Reagent. The NeuMoDx System mixes the released nucleic acid with the user provided LDT primers and probe(s) in the NeuMoDx LDT Primer/Probe Strip and then uses an aliquot of this solution to rehydrate the dried assay reagents in the appropriate NeuMoDx LDT Master Mix (DNA or RNA). Upon mixing with the user provided primers and probe(s) (LDT-specific reagents) and reconstitution of the dried PCR reagents, the NeuMoDx System will dispense the prepared, PCR-ready mixture into the NeuMoDx Cartridge where real-time PCR occurs.

Materials Provided

Kit contents

NeuMoDx LDT Primer Probe Strip REF 210100	Units per Package	Tests per Unit	Tests per Package
NeuMoDx LDT Primer/Probe Strip	6	16	96

Materials Required but Not Provided

REF	Contents
100100	NeuMoDx Cartridge
100200	NeuMoDx Extraction Plate *Dried paramagnetic particles, lytic enzymes, and sample process controls*
various	NeuMoDx Lysis Buffer(s) *As dictated by sample type and validation activities*
400100	NeuMoDx Wash Reagent
400200	NeuMoDx Release Reagent
100400	NeuMoDx LDT Master Mix, DNA or NeuMoDx LDT Master Mix, RNA *As dictated by assay target type*
235903	Hamilton CO-RE / CO-RE II Tips (300 µL) with Filters
235905	Hamilton CO-RE / CO-RE II Tips (1000 µL) with Filters

Reagents

- 10 mM Tris-HCl pH 8.0, RNase/DNase Free Water, or TE Low EDTA (0.1 mM)
- LDT primers and probe(s)

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 use the reagents after the listed expiration date.
- Do not use if the packaging is damaged upon arrival or if foil seal is damaged.
- 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.

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 LDT Primer/Probe Strip should be stored at 15–28°C.
- Stability of user provided LDT primer/probe mix in the NeuMoDx LDT Primer/Probe Strip must be validated by the user's laboratory.
- Do not use past the stated expiration date.
- Do not use if product or packaging has been visually compromised.

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. Remove a NeuMoDx LDT Primer/Probe Strip from the bag.
2. Using a pipet tip, pierce the foil covering the well for each sample to be loaded.
   2a. Prepare assay specific primers and probe(s): Dilute primers and probe(s) in water, 10mM Tris pH 8.0, or 1X TE with low EDTA (0.1mM). The final concentration of the primer/probe mix should be 1X after mixing with 18 µL of eluate in the NeuMoDx LDT Primer/Probe Strip.
   2b. *Example:* Add 4 µL of 6X primer/probe mix to a well. Once eluate is added to the well and mixed with the LDT primer/probe mix, there will be 24 µL at 1X primer/probe mix.
   2c. NeuMoDx recommends adding between 3 µL and 10 µL of the prepared primer/probe mix per well of the NeuMoDx LDT Primer/Probe Strip.
3. Carefully dispense the LDT primer/probe mix into the bottom of the wells to be used on the NeuMoDx LDT Primer/Probe Strip. There is no need to fill all wells, but loading must start from the bottom left well (see figure below). Place the NeuMoDx LDT Primer/Probe Strip in a Test Strip Carrier. Alternatively, snap the strip into place on the Carrier and then load with LDT primer/probe mix.

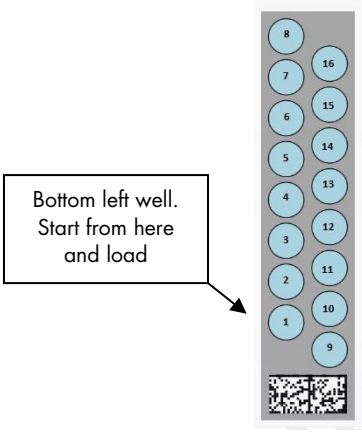


Figure 1. Order for filling LDT primer/probe mix wells

4. Touch the arrow below the desired Test Strip Carrier on the touchscreen to load the NeuMoDx LDT Primer/Probe Strip into the System. The wells will display as yellow. Touch the wells to define the assay type and map the locations on the NeuMoDx LDT Primer/Probe Strip that contain the LDT primer/probe mix.

Limitations

1. The NeuMoDx LDT Primer/Probe Strip can only be used on the NeuMoDx System and is not compatible with any other automated molecular diagnostic system.
2. The NeuMoDx LDT Primer/Probe Strip must be used in conjunction with NeuMoDx LDT Master Mix, DNA or NeuMoDx LDT Master Mix, RNA, which contain other required elements for PCR.
3. The performance characteristics of user assays are unknown and must be validated by the user's laboratory before diagnostic claims can be made.
4. The stability of user provided primers and probes in the NeuMoDx LDT Primer/Probe Strip must be validated by the user's laboratory.
5. When pipetting the user provided primers and probes into the NeuMoDx LDT Primer/Probe Strip, care must be taken not to contaminate the strip with specimen.
6. 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.
7. 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.
8. Use is limited to personnel trained on the use of the NeuMoDx System.
9. Good laboratory practices, including changing gloves between handling patient specimens, are recommended to avoid contamination of specimens.

Quality Control

Clinical Laboratory Improvement Amendments (CLIA) regulations specify that the laboratory is responsible for implementing control procedures that monitor accuracy and precision of the complete analytical process, and must establish the number, type, and frequency of testing control materials using verified performance specifications for an unmodified, FDA-cleared or approved test system (42 CFR Part 493.1256).

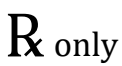
1. External control materials must be validated by the lab for each assay performed. This includes the composition of controls, timing/frequency of running, and decision criteria around whether to invalidate a set of results due to (in)validity of controls. External controls are not provided by NeuMoDx Molecular, Inc.
2. The primers and probe for the detection of Sample Process Control 1 (SPC1) are included in the NeuMoDx LDT Master Mix, DNA. Monitoring detection of SPC1 allows the NeuMoDx System to monitor the efficacy of the DNA extraction and PCR amplification processes and appropriately qualify the results.

References

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

Symbol	Symbol definition
	Do not reuse
	CE Mark
	Consult instructions for use
	Contains
	Caution

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	REF
NeuMoDx LDT Primer/Probe Strip	100400
Related Products	
NeuMoDx LDT Master Mix, DNA	100200
NeuMoDx LDT Master Mix, DNA	310100
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
NeuMoDx Cartridge	100100
NeuMoDx Extraction Plate	100200
NeuMoDx Wash Reagent	400100
NeuMoDx Release Reagent	400200
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.

Document Revision History

Revision	Summary of Changes
A, 05/2022	Initial Release New Product Number (P/N 40600592) 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.
C, 03/2024	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 LDT Primer/Probe Strip

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.

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