NeuMoDx™ SARS-CoV-2 Assay

Instructions For Use

For use under the Emergency Use Authorization (EUA) only

IVD *For in vitro diagnostic use*

℞ only

REF 300800 NeuMoDx™ SARS-CoV-2 Test Strip

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INTENDED USE

The NeuMoDx™ SARS-CoV-2 Assay performed on the NeuMoDx™ 288 Molecular System and NeuMoDx™ 96 Molecular System (NeuMoDx Molecular System(s)), is a real-time RT-PCR diagnostic test intended for the qualitative detection of SARS-CoV-2 coronavirus RNA from nasal, nasopharyngeal and oropharyngeal swabs in transport medium and bronchoalveolar lavage (BAL) specimens from individuals suspected of COVID-19 by their healthcare provider. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform moderate or high complexity tests.

Results are for the identification of 2019-nCoV RNA. The 2019-nCoV RNA is generally detectable in respiratory specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA. Clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative results do not preclude 2019-nCoV infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

The NeuMoDx™ SARS-CoV-2 Assay 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. The NeuMoDx™ SARS-CoV-2 Assay is only for use under the Food and Drug Administration's Emergency Use Authorization within the United States and territories.

SUMMARY AND EXPLANATION OF THE TEST

NeuMoDx SARS-CoV-2 Assay is a real-time reverse transcription PCR performed on the NeuMoDx Molecular systems. The NeuMoDx System automatically performs all the steps required to extract the target nucleic acid, prepare the isolated RNA for real-time reverse transcription polymerase chain reaction (RT-PCR) and, if present, amplify and detect target sequences of the non-structural protein 2 (Nsp2) gene and the N gene, both specific to the SARS-CoV-2 genome.

PRINCIPLES OF THE PROCEDURE

The NeuMoDx SARS-CoV-2 Assay combines automated RNA extraction and amplification/detection by real-time RT-PCR. Nasopharyngeal, oropharyngeal, or nasal swab samples are collected in the Copan UTM-RT® System or BD™ UVT System. There are two workflows available for specimen preparation with the NeuMoDx SARS-CoV-2 Assay. The direct workflow allows for the swab collection tube or an aliquot of the transport medium in a secondary tube to be loaded onto the NeuMoDx System for processing without further intervention. Alternatively, the swab sample medium is pretreated with NeuMoDx Viral Lysis Buffer before being placed on the NeuMoDx System for processing. The NeuMoDx System automatically begins processing by aspirating an aliquot of the swab medium and mixing it with NeuMoDx Lysis Buffer and the agents contained in the NeuMoDx™ Extraction Plate. The NeuMoDx System automates and integrates RNA extraction and concentration, reagent preparation, and nucleic acid amplification/detection of the target sequences using real-time RT-PCR. The included Sample Process Control (SPC2) helps monitor for the presence of inhibitory substances and for system, process, or reagent failures. No operator intervention is necessary once the specimen is loaded onto the NeuMoDx System.

The NeuMoDx™ System uses a combination of heat, lytic enzyme, and extraction reagents to automatically perform lysis, RNA extraction, and removal of inhibitors using the separately available NeuMoDx™ reagents. The released nucleic acids are captured by paramagnetic particles. The microspheres, with bound nucleic acid, are loaded into the NeuMoDx Cartridge where the unbound elements are washed away with NeuMoDx Wash Reagent. The bound RNA is then eluted using NeuMoDx Release Reagent. The NeuMoDx System uses the eluted RNA to rehydrate proprietary NeuDry™ amplification reagents containing all the elements necessary for amplification of the SARS-CoV-2 and SPC2 targets. This enables simultaneous amplification and detection of both target and control RNA sequences in one reaction. Upon reconstitution of the dried RT-PCR reagents, the NeuMoDx System dispenses the prepared RT-PCR-ready mixture into one PCR chamber (per specimen) of the NeuMoDx Cartridge. Reverse transcription, amplification, and

detection of the control and target sequences (if present) occur in the PCR chamber. The NeuMoDx Cartridge is designed to contain the amplicon following RT-PCR, virtually eliminating the risk of post-amplification contamination.

The amplified targets are detected in real time using hydrolysis probe chemistry (commonly referred to as TaqMan® chemistry) using fluorogenic oligonucleotide probe molecules specific to the amplicons of their respective targets. TaqMan probes consist of a fluorophore covalently attached to the 5'-end of the oligonucleotide probe and a quencher at the 3'-end. While the probe is intact, the fluorophore and the quencher are in proximity, allowing the quencher molecule to suppress the fluorescence emitted by the fluorophore via Förster Resonance Energy Transfer (FRET).

TaqMan probes are designed such that they anneal within a DNA region amplified by a specific set of primers. As the Taq DNA polymerase extends the primer and synthesizes the new strand, the 5' to 3' exonuclease activity of the Taq DNA polymerase degrades the probe that has annealed to the template. Degradation of the probe releases the fluorophore and breaks its proximity to the quencher, thereby overcoming the quenching effect due to FRET and allowing detection of the fluorophore. The resulting fluorescent signal detected in the NeuMoDx System quantitative RT-PCR thermal cycler is directly proportional to the fluorophore released and can be correlated to the amount of target present. A TaqMan probe labeled with a FAM fluorophore (470/510 nm) is used to detect the Nsp2 target and a TaqMan probe labeled with a HEX fluorophore (530/555 nm) is used to detect the N gene target. For detection of the SPC2, the TaqMan probe is labeled with a Far-Red fluorophore (680/715 nm). The NeuMoDx System software monitors the fluorescent signal emitted by the TaqMan probes at the end of each amplification cycle. When amplification is complete, the NeuMoDx System software analyzes the data and reports a result (POSITIVE/NEGATIVE/INDETERMINATE/UNRESOLVED).

REAGENTS AND MATERIALS

Material Provided

REF	Contents	Quantity Per Kit
300800	**NeuMoDx™ SARS-CoV-2 Test Strip** *Dried RT-PCR reagents containing SARS-CoV-2 and SPC2 specific TaqMan® probes and primers*	96 Tests

Additional Materials Required but Not Provided (Available Separately from NeuMoDx)

REF	Contents	Quantity Per Kit
100100	**NeuMoDx™ Cartridge**	576 Tests
100200	**NeuMoDx™ Extraction Plate**	384 Tests
400100	**NeuMoDx™ Wash Reagent**	2 x 2 L
400200	**NeuMoDx™ Release Reagent**	2 x 1 L
400500 (*Optional**)	**NeuMoDx™ Lysis Buffer 2**	4 x 80 mL
400600**	**NeuMoDx™ Lysis Buffer 3**	4 x 80 mL
401600 (*Optional**)	**NeuMoDx™ Viral Lysis Buffer**	2 x 1 L
235903	**Hamilton® CO-RE Tips (300 µL) with Filters**	480 Tips
235905	**Hamilton® CO-RE Tips (1000 µL) with Filters**	480 Tips

**Required only if a pretreatment step is desired for offboard lysis prior to loading of samples. See section "Instructions for Use" below.*

***Required only for direct processing of neat samples. See section "Instructions for Use" below.*

Swab and Transport Media (Not Provided)

Contents	Quantity Per Kit
3mL/1mL Universal Transport Medium (COPAN UTM) or Universal Viral Transport System (BD™ UVT)	96 Tests
Flexible Minitip Size Nylon® Flocked Swab (copan) **Flexible minitip flocked swab (BD)**	

Instrumentation Required (Not Provided)

NeuMoDx™ 288 Molecular System [REF 500100] or **NeuMoDx™ 96 Molecular System** [REF 500200]

WARNINGS & PRECAUTIONS

- The NeuMoDx™ SARS-CoV-2 Assay is for *in vitro* diagnostic use under Emergency Use Authorization only.
- For Prescription Use Only.
- Specimens should always be handled 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]
- Laboratories within the United States and its territories are required to report all positive results to the appropriate health authorities.
- Do not use the reagents or consumables after the listed expiration date.
- Do not use any reagents if the safety seal is broken or if the packaging is damaged upon arrival.
- Do not use consumables or reagents if the protective pouch is open or broken upon arrival.
- Minimum specimen volume of secondary aliquots is dependent on the tube size/specimen tube carrier as defined below. Volume below the specified minimum may result in a "Quantity Not Sufficient" error.
- The use of specimens stored at improper temperatures or beyond the specified storage times may produce invalid or erroneous results.
- Avoid microbial and ribonuclease (RNase) contamination of all reagents and consumables. The use of sterile RNase-free, disposable transferring pipettes with aerosol barriers is recommended when using secondary tubes. Use a new pipette for each specimen.
- To avoid contamination, do not handle or break apart any NeuMoDx Cartridge post-amplification. Do not retrieve NeuMoDx Cartridges from the Biohazard Waste Container (NeuMoDx 288 Molecular System) or Biohazard Waste Bin (NeuMoDx 96 Molecular System) under any circumstances. The NeuMoDx Cartridge is designed to prevent contamination.
- In cases where open-tube PCR tests are also conducted by the laboratory, care must be taken to ensure that the NeuMoDx SARS-CoV-2 Test Strip, the additional consumables and reagents required for testing, personal protective equipment such as gloves and lab coats, and the NeuMoDx System are not contaminated.
- Clean, powder-free, nitrile gloves should be worn when handling NeuMoDx reagents and consumables. Care should be taken not to touch the top surface of the NeuMoDx Cartridge, the foil seal surface of the NeuMoDx SARS-CoV-2 Test Strip and NeuMoDx Extraction Plate, or the top surface of the NeuMoDx Lysis Buffer containers; handling of the consumables and reagents should be done by touching side surfaces only.
- Safety Data Sheets (SDS) are available upon request
- Wash hands thoroughly after performing the test.
- 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.
- Use of the NeuMoDx SARS-CoV-2 is limited to personnel who have been trained in the procedures of a molecular diagnostic assay and the NeuMoDx Molecular Systems.
- The instruments and assay procedures reduce the risk of contamination by amplification product. However, nucleic acid contamination from the positive controls or specimens must be controlled by good laboratory practices.
- Good laboratory practices, including changing gloves between handling patient specimens, are recommended to avoid contamination.

PRODUCT STORAGE, HANDLING & STABILITY

- NeuMoDx SARS-CoV-2 Test Strips are stable in the primary packaging through the stated expiration date on the immediate product label when stored at 4 to 28 °C.
- Do not use consumables and reagents past the stated expiration date.
- Do not use any test product if the primary or secondary packaging has been visually compromised.
- Do not reload any test product that has previously been loaded onto another NeuMoDx System.
- Once loaded, the NeuMoDx SARS-CoV-2 Test Strip may remain onboard the NeuMoDx System for 10 days. Remaining shelf life of loaded test strips is tracked by the software and reported to the user in real time. Removal of a test strip that has been in use beyond its allowable period will be prompted by the System.

SPECIMEN COLLECTION, TRANSPORT, & STORAGE

Handle all specimens as if they are capable of transmitting infectious agents.

Samples should be collected using the Copan UTM-RT® System or BD™ UVT System using the validated nylon flocked swabs (see materials not provided). In addition, flocked swabs, polyester and rayon swabs are acceptable swab types. Follow manufacturer instructions for collection, transport, and storage provided in the Copan UTM-RT® System/BD™ UVT System instructions for use:

- After collection, the specimen should be stored at 2-25 °C and processed within 48 hours.
- If delivery and processing exceed 48 hours, specimens should be transported in dry ice and once in laboratory frozen at -70 °C or colder.

INSTRUCTIONS FOR USE

The NeuMoDx SARS-CoV-2 Assay accommodates two different workflows, depending on user/laboratory preference:

Workflow 1: DIRECT – swab samples are loaded directly onto the NeuMoDx System in primary collection tube or secondary specimen tubes

-or-

Workflow 2: PRETREATED – swab samples are pretreated with NeuMoDx Viral Lysis Buffer before loading onto the NeuMoDx System in primary collection tube or secondary specimen tubes

Test Preparation – DIRECT Workflow

Note: Bring all samples to room temperature (15 to 30 °C) before processing.

1. Apply specimen barcode label to a specimen tube compatible with the NeuMoDx System as described under 2. and 3 below.
2. If testing the specimen in the primary collection tube, place the barcoded tube into a Specimen Tube Carrier and ensure the cap and swab are removed prior to loading onto the NeuMoDx System. The primary swab collection tube may be labeled and placed directly into a 24-tube Specimen Tube Carrier with cap and swab removed
3. Alternatively, an aliquot of the transport medium may be transferred to a barcoded secondary tube and placed into a 32-tube Specimen Tube Carrier. If using a secondary tube, transfer an aliquot of the transport medium to the barcoded specimen tube compatible with the NeuMoDx System according to the volumes defined below:
    - Specimen Tuber Carrier (32-tube): 11 – 14 mm in diameter and 60 – 120 mm in height; minimum fill volume ≥ 550 µL
    - Specimen Tube Carrier (24-tube): 14.5 – 18 mm in diameter and 60 – 120 mm in height; minimum fill volume ≥ 1000 µL
    - Low Volume Specimen Tube Carrier (32-tube): 1.5 mL conical bottom microcentrifuge tube; minimum fill volume ≥ 500 µL

Test Preparation – PRETREATED Workflow

Note: Bring all samples to room temperature (15 to 30 °C) before processing.

WARNING: Pretreatment of swab samples with NeuMoDx Viral Lysis Buffer does not guarantee inactivation of any virus present. All samples should be handled as if they are capable of transmitting infectious agents.

1. Pretreat the sample transport medium with an equal volume of NeuMoDx Viral Lysis Buffer (i.e., 1+1). This can be done in the primary swab collection tube if the volume of transport medium is known. Alternatively, pretreatment can be done in a secondary tube by combining an aliquot of the transport medium with an equal volume of NeuMoDx Viral Lysis Buffer. The resulting mixture should meet the minimum volume requirements specified below.
2. Mix gently with pipette to ensure uniform distribution of NeuMoDx Viral Lysis Buffer.
3. If testing the specimen in the primary collection tube, place the barcoded tube into a Specimen Tube Carrier and ensure the cap and swab are removed prior to loading onto the NeuMoDx System.
4. If using a secondary tube, transfer an aliquot of the transport medium lysate to the barcoded specimen tube compatible with the NeuMoDx System according to the minimum volumes defined below:
    - Specimen Tuber Carrier (32-tube): 11 – 14 mm in diameter and 60 – 120 mm in height; minimum fill volume ≥ 550 µL
    - Specimen Tube Carrier (24-tube): 14.5 – 18 mm in diameter and 60 – 120 mm in height; minimum fill volume ≥ 1000 µL
    - Low Volume Specimen Tube Carrier (32-tube): 1.5 mL conical bottom microcentrifuge tube; minimum fill volume ≥ 500 µL

NeuMoDx System Operation

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

1. Populate the system carriers as necessary with the following consumables and use the touchscreen to load carrier(s) into the NeuMoDx System:
    - 1000 µL Pipette Tips
    - 300 µL Pipette Tips
    - NeuMoDx Cartridge
    - NeuMoDx Extraction Plate
    - NeuMoDx SARS-CoV-2 Test Strip
    - NeuMoDx Lysis Buffer 2 *(NOTE: remove foil seal from containers prior to loading)*
    - NeuMoDx Lysis Buffer 3 *(NOTE: remove foil seal from containers prior to loading)*
2. Replace NeuMoDx Wash and NeuMoDx Release Reagents, and empty Priming Waste as necessary.
3. Empty Biohazardous Waste Container as necessary or prompted by the NeuMoDx System software.
4. Load the specimen tube(s) into a standard 32-Tube carrier or 24-Tube Carrier, and ensure caps are removed from all specimen tubes.
5. Place the Specimen Tube carrier on the Autoloader shelf and use the touchscreen to load carrier into the system. This will initiate processing of test(s).
6. Load the test order onto the NeuMoDx System according to the workflow used for test preparation:
    - Untreated, neat swab samples prepared using the DIRECT workflow are tested by defining the sample as "**Transport Medium**"
    - Samples pretreated using the PRETREATED workflow are tested by defining the specimen as "**User-Specified 1**"
7. Populate one or more Test Strip Carrier(s) with NeuMoDx SARS-CoV-2 Test Strip(s) and use the touchscreen to load the Test Strip Carrier(s) into the NeuMoDx System.

8. If prompted by the NeuMoDx System software, add the necessary onboard consumables (NeuMoDx Cartridges, NeuMoDx Extraction Plates, NeuMoDx Lysis Buffer 2, NeuMoDx Lysis Buffer 3, CO-RE Tips) onto the NeuMoDx System consumable carriers and use the touchscreen to load carrier(s) into the NeuMoDx System, as appropriate.
9. If prompted by the NeuMoDx System software, replace NeuMoDx Wash Reagent and/or NeuMoDx Release Reagent, as appropriate.
10. If prompted by the NeuMoDx System software, empty the Priming Waste, Biohazard Waste Container (NeuMoDx 288 Molecular System only), Tip Waste Bin (NeuMoDx 96 Molecular System only), or Biohazard Waste Bin (NeuMoDx 96 Molecular System only), as appropriate.
11. Load the specimen(s) into a Specimen Tube Carrier and ensure caps are removed from all tubes.
12. Place the Specimen Tube Carrier(s) on the autoloader shelf and use the touchscreen to load the carrier(s) into the NeuMoDx System. This will initiate processing of the loaded specimens for the tests identified, given a valid test order is present in the system.

LIMITATIONS

- The NeuMoDx SARS-CoV-2 Assay has only been evaluated for use on NeuMoDx Molecular Systems.
- The NeuMoDx SARS-CoV-2 Assay has been designed for detection of SARS-CoV-2 RNA in nasopharyngeal or oropharyngeal swab samples collected with Copan UTM-RT System (UTM-RT®) or BD™ Universal Viral Transport System (UVT). Use of the NeuMoDx SARS-CoV-2 Assay with other sample types has not been assessed and performance characteristics are unknown.
- Nasal swabs and mid-turbinate nasal swabs are considered acceptable specimen types for use with the NeuMoDx SARS-CoV-2 but performance with these specimen types has not been established. Testing of nasal and mid-turbinate nasal swabs (self-collected under supervision of or collected by a healthcare provider) is limited to patients with symptoms of COVID-19. Please refer to FDA's FAQs on Diagnostic Testing for SARS-CoV-2 for additional information.
- Reliable results are dependent on proper specimen collection, handling, and storage.
- Erroneous results could occur from improper specimen collection, handling, storage, technical error, or specimen tube mix-up. In addition, false negative results could occur because the number of viral particles in the sample is below the limit of detection of the NeuMoDx SARS-CoV-2 Assay.
- If both the SARS-CoV-2 targets and the SPC2 target do not amplify, an invalid result (Indeterminate or Unresolved) will be reported and the test should be repeated.
- Deletions or mutations in the regions targeted by the NeuMoDx SARS-CoV-2 Assay may affect detection and could lead to an erroneous result.
- A positive result is indicative of the presence of SARS-CoV-2 RNA.
- A positive result does not necessarily indicate the presence of infectious SARS-CoV-2. However, a positive result for both targets is indicative of the presence of SARS-CoV-2 RNA.
- Negative results do not preclude infection with the SARS-CoV-2 virus and should not be the sole basis of a patient treatment/management or public health decision. Follow up testing should be performed according to the current CDC recommendations.
- Results from NeuMoDx SARS-CoV-2 Assay should be used as an adjunct to clinical observations and other information available to the physician.

CONDITIONS OF AUTHORIZATION FOR THE LABORATORY

The NeuMoDx™ SARS-CoV-2 Assay Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients and authorized labeling are available on the FDA website: https://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm

To assist clinical laboratories using the NeuMoDx SARS-CoV-2 Assay, the relevant Conditions of Authorization are listed below.

- Authorized laboratories[1] using the NeuMoDx SARS-CoV-2 Assay will include with result reports of the NeuMoDx SARS-CoV-2 Assay, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
- Authorized laboratories using the NeuMoDx SARS-CoV-2 Assay will perform the NeuMoDx SARS-CoV-2 Assay as outlined in the NeuMoDx SARS-CoV-2 Assay Instructions for Use. Deviations from the authorized procedures, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to perform the NeuMoDx SARS-CoV-2 Assay are not permitted.
- Authorized laboratories that receive the NeuMoDx SARS-CoV-2 Assay must notify the relevant public health authorities of their intent to run the test prior to initiating testing.
- Authorized laboratories using the NeuMoDx SARS-CoV-2 Assay will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- Authorized laboratories will collect information on the performance of the test and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and NeuMoDx Molecular Technical Support (techsupport@neumodx.com; 1-888-301-6639) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the test of which they become aware.
- All laboratory personnel using the test must be appropriately trained in RT-PCR techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use the test in accordance with the authorized labeling.
- NeuMoDx Molecular, its authorized distributor(s) and authorized laboratories using the NeuMoDx SARS-CoV-2 Assay will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

[1] For ease of reference, this letter will refer to, "United States (U. S.) laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests" as "authorized laboratories."

RESULTS

Available test results may be viewed or printed from the 'Results' tab in the Results window on the NeuMoDx System touchscreen. A test result is called Positive (POS), Negative (NEG), Indeterminate (IND), or Unresolved (UNR) based on the amplification status of the target and the Sample Process Control (SPC2).

Criteria for a positive or negative call are specified in the NeuMoDx SARS-CoV-2 Assay Definition File (ADF) as installed on the NeuMoDx System. Results are reported based on the ADF decision algorithm, summarized in *Table 1*, below.

All test controls should be examined prior to interpretation of patient results. If the controls are not valid, the patient results cannot be interpreted.

Table 1. NeuMoDx SARS-CoV-2 Assay Results Interpretation

OVERALL RESULT	TARGET 1 (Nsp2-gene) FAM	TARGET 2 (N-gene) HEX	PROCESS CONTROL (SPC2) Q-705	Interpretation
POSITIVE	**AMPLIFIED** [4 ≤ Ct < 12 AND EPR ≥ 1.2 AND EP ≥ 700] OR (12≤ Ct ≤40 AND EP ≥700)	N/A	N/A	SARS-CoV-2 RNA detected**
	N/A	**AMPLIFIED** (4 ≤ Ct < 12 AND EPR ≥1.5) AND EP ≥ 1000] OR (12 ≤ Ct ≤ 40 AND EP >1000)		
NEGATIVE	**NOT AMPLIFIED** N/A **OR** (4 < Ct < 12 AND EPR <1.2) **OR** (12 ≤ Ct ≤ 40 AND EP <700) **OR** (Ct > 40)	**NOT AMPLIFIED** N/A **OR** (4 < Ct < 12 AND EPR <1.5) **OR** (12 ≤ Ct ≤ 40 AND EP <1000) **OR** (Ct > 40)	**AMPLIFIED** (24≤ Ct ≤33 AND EP ≥1000)	SARS-CoV-2 RNA not detected
IND*	**NOT AMPLIFIED/System Errors Noted**			All target results were invalid; retest sample
UNR*	**NOT AMPLIFIED/No System Errors Noted**			All target results were invalid; retest sample

*The System is equipped with automatic Rerun/Repeat capability that the end user can choose to use to ensure that an IND/UNR result is automatically reprocessed to minimize delays in result reporting.

**A re-test may be performed if desired in the event of only one of the two SARS-CoV-2 targets being amplified.

A positive result may be reported for samples yielding a differential amplification status, such that only one of the targets—Target 1 (Nsp2 gene) or Target 2 (N gene)—amplifies. This may occur due to 1) a sample at concentrations near or below the limit of detection of the test, 2) a mutation in one of the target regions, or 3) other factors. In the case of a positive test where only one of the targets amplifies, repeat testing may be considered if the SPC2 control is negative. If the repeat result remains the same, additional confirmation testing should be conducted if clinically indicated.

Invalid Results

If a NeuMoDx SARS-CoV-2 Assay performed on the NeuMoDx System fails to produce a valid result, it will be reported as either Indeterminate or Unresolved based on the type of error that occurred, and the test should be repeated to obtain a valid result.

An Indeterminate result will be reported if a NeuMoDx System error is detected during sample processing. In the event of an Indeterminate result, a retest is recommended.

An Unresolved result will be reported if no target is detected and there is no amplification of the Sample Process Control, which indicates possible reagent failure or the presence of inhibitors. In the event of an Unresolved result, a retest is recommended as a first step. If the retest fails, a diluted specimen may be used to mitigate the effect of possible inhibition.

Quality Control

The Clinical Laboratory Improvement Amendments (CLIA) regulations specify that the laboratory is responsible for having 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 § 493.1256).

1. Control materials are not provided with the NeuMoDx Sars-CoV-2 Assay. However, the following control material were validated by NeuMoDx and are recommended. Controls must meet the same minimum volume specifications as clinical samples specified above based on the Specimen Tube Carrier size.
    - Positive Controls:
        - 5 µL of NATtrol™ SARS-CoV-2 (recombinant) Stock (ZeptoMetrix Catalog# 0831042) in 1 mL BD™ UVT medium.
    - Negative Control: Copan/BD™ UVT media or equivalent.
2. It is recommended that users process one set of positive and negative controls every 24 hours and prior to processing patient samples.
3. When processing controls, place the labeled controls in a specimen tube carrier and use the touchscreen to load the carrier into NeuMoDx System from the autoloader shelf. Once defined, the NeuMoDx System will recognize the barcodes and start processing controls.
4. The primers and probe specific for the Sample Process Control (SPC2) are included in each NeuMoDx SARS-CoV-2 Test Strip. This Sample Process Control allows the NeuMoDx System to monitor the efficacy of the RNA extraction and RT-PCR amplification processes.
5. Prior to RT-PCR, the NeuMoDx System automatically performs a 'FILL CHECK' to ensure that the PCR chamber is filled with solution and contains an adequate amount of fluorescent probe.
6. The NeuMoDx System software continuously monitors on-board sensors and actuators to ensure a safe and effective operation of the System.
7. Multiple fluidic error recovery modes are implemented by active monitoring of aspiration and dispense operations to ensure that the System can either complete processing of all samples in a safe and effective manner or provide an appropriate error code.
8. The NeuMoDx System is equipped with automatic Rerun/Repeat capability that the end user can choose to use to ensure that an INVALID result is automatically reprocessed to minimize delays in result reporting.
9. A positive test result reported for a negative control sample may indicate a specimen contamination problem. Please refer to NeuMoDx™ *288 or 96 Molecular System Operator's Manual* for troubleshooting tips.
10. A negative result reported for a positive control sample may indicate there is a reagent or NeuMoDx System related problem. Please refer to *NeuMoDx™ 288 or 96 Molecular System Operator's Manual* for troubleshooting tips.

PERFORMANCE CHARACTERISTICS

Analytical Sensitivity

The limit of detection (LoD) of the NeuMoDx SARS-CoV-2 Assay was determined by testing a dilution series of pooled negative clinical nasopharyngeal swab samples (Nylon Flocked Swab collected in UTM [Copan Diagnostic Inc, CA] or VTM [BD, NJ]) spiked with SARS-CoV-2 genomic RNA (BEI Resources NR-52285) and processed using the both DIRECT and PRETREATED workflows. At least twenty replicates of each dilution were evaluated across both NeuMoDx Systems for each workflow. The LoD was determined to be **150 copies/mL**.

Table 2. Detection Rate and Limit of Detection for SARS-CoV-2 on NeuMoDx 96 Molecular System: Pretreated Workflow

SARS-CoV-2 LoD: N96, Pretreated Workflow								
Target Level	**Valid results**	**Nsp2-gene Positive**		**Nsp2-gene Detection Rate**	**N-gene Positive**		**N-gene Detection Rate**	**Both Targets Amplified Rate**
		n	**Mean Ct**		**n**	**Mean Ct**		
250 cp/mL	22	22	31.7	100%	22	30.9	100%	100%
150 cp/mL	20	20	31.5	100%	20	31.0	100%	100%
50 cp/mL	24	0	n/a	0%	22	31.8	91.7%	0%
Negative	30	0	n/a	0.0%	0	n/a	0.0%	0.0%
N96 LoD: 150 cp/mL [lowest target level demonstrating >95% detection rate of both targets]								

Table 3. Detection Rate and Limit of Detection for SARS-CoV-2 on NeuMoDx 288 Molecular System: Pretreated Workflow

SARS-CoV-2 LoD: N288, Pretreated Workflow								
Target Level	**Valid results**	**Nsp2-gene Positive**		**Nsp2-gene Detection Rate**	**N-gene Positive**		**N-gene Detection Rate**	**Both Targets Amplified Rate**
		n	**Mean Ct**		**n**	**Mean Ct**		
250 cp/mL	21	21	32.1	100%	21	31.4	100%	100%
150 cp/mL	26	26	31.7	100%	26	31.2	100%	100%
50 cp/mL	21	11	32.2	52.4%	20	32.2	95.2%	52.4%
Negative	20	0	n/a	0%	0	n/a	0%	0%
N288 LoD: 150 cp/mL [lowest target level demonstrating >95% detection rate of both targets]								

Table 4. Detection Rate and Limit of Detection for SARS-CoV-2 on NeuMoDx 96 Molecular System: Direct Workflow

SARS-CoV-2 LoD: N96, Direct Workflow								
Target Level	**Valid results**	**Nsp2-gene Positive**		**Nsp2-gene Detection Rate**	**N-gene Positive**		**N-gene Detection Rate**	**Both Targets Amplified Rate**
		n	**Mean Ct**		**n**	**Mean Ct**		
400 cp/mL	24	23*	32.4	95.8%	24	31.1	100.0%	95.8%
250 cp/mL	24	24	33.0	100.0%	24	31.7	100.0%	100.0%
150 cp/mL	24	24	33.4	100.0%	24	32.4	100.0%	100.0%
50 cp/mL	24	12	32.6	50.0%	18	32.8	75.0%	41.7%**
Negative	22	0	n/a	0.0%	0	n/a	0.0%	0.0%
N96 LoD: 150 cp/mL [lowest target level demonstrating >95% detection rate of both targets]								

*This sample additionally displayed weak SPC2 amplification, and the lack of amplification was believed to be an artifact of system processing. This is supported by a 100% detection rate at the same target concentration in RPT-8505B (Clinical Evaluation). Additionally, for this study a 100% detection rate was achieved at the lower 250 cp/mL and 150 cp/mL concentrations.

** Ten of 24 samples had both targets detected at 50 cp/mL, for an overall positivity rate of 41.7%

Table 5. Detection Rate and Limit of Detection for SARS-CoV-2 on NeuMoDx 288 Molecular System: Direct Workflow

SARS-CoV-2 LoD: N288, Direct Workflow								
Target Level	**Valid results**	**Nsp2-gene Positive**		**Nsp2-gene Detection Rate**	**N-gene Positive**		**N-gene Detection Rate**	**Both Targets Amplified Rate**
		n	**Mean Ct**		**n**	**Mean Ct**		
400 cp/mL	24	24	32.8	100.0%	24	31.7	100.0%	100.0%
250 cp/mL	24	24	33.0	100.0%	24	32.0	100.0%	100.0%
150 cp/mL	22	21	33.5	95.5%	22	32.4	100.0%	95.5%
50 cp/mL	24	20	34.3	83.3%	24	33.4	100.0%	83.3%
Negative	24	0	n/a	0.0%	0	n/a	0.0%	0.0%
N288 LoD: 150 cp/mL [lowest target level demonstrating >95% detection rate of both targets]								

Inclusivity

The inclusivity of the NeuMoDx SARS-CoV-2 Assay was evaluated by *in silico* analysis mapping the assay primers and probes to all available SARS-CoV-2 sequences (n = 96) in the NCBI database as of 14 March 2020. The regions of the test's primers and probes were compared by *in silico* analysis to verify sequence homology with circulating SARS-CoV-2 strains. The NeuMoDx SARS-CoV-2 Assay had 100% homology to all but one sequence for the Nsp2 gene (Target 1). The one sequence was found to have a single nucleotide

mismatch in the forward primer with no predicted impact on performance of the assay. Homology between the N gene (Target 2) primers and probe was found to be 100% for all the available sequences.

Cross-reactivity/Microbial Interference

The NeuMoDx SARS-CoV-2 Assay was evaluated i*n silico* for possible cross-reactions with the microorganisms shown in *Table 6* by individually mapping the primers and probes of the NeuMoDx SARS-CoV-2 Assay to sequences in the NCBI database. None of the sequences analyzed showed homology for the primers or probe of the Nsp2 gene (Target 1). *Haemophilus influenzae* (CP000672.1) showed 80% homology to the forward primer of the N gene (Target 2) but had no significant homology to the reverse primer and probe. Similarly, SARS coronavirus (AY345986.1) showed homology for the forward primer and probe of the N gene but no significant homology for the reverse primer. *Pseudomonas aeruginosa* (CP000438.1) showed homology for the forward SPC2 primer but not for either of the SARS-CoV-2 targets. The *in silico* analysis therefore showed no probable cross-reactivity to any of the sequences evaluated. Further wet testing was done to confirm that *H. influenzae* and *P. aeruginosa* posed no risk of cross-reactivity or microbial interference with the primer and probe sets of the NeuMoDx SARS-CoV-2 Assay. Results are presented in *Tables 7* and *8*.

Table 6. *In Silico* Analysis for Cross-Reactive Organisms

Organism	NCBI GenBank Accession Number(s)	Organism	NCBI GenBank Accession Number(s)
Human coronavirus 229E	KF514433.1	Influenza B	MK969560.1
	KF514432.1	Enterovirus	JF896312.1
Human coronavirus OC43	KX344031.1	Respiratory syncytial virus	JN032120.1
	KF530099.1	Rhinovirus	NC_001490.1
Human coronavirus HKU1	KF430201.1	*Chlamydia pneumoniae*	NZ_LN847241.1
	MH940245.1	*Haemophilus influenzae*	CP000672.1
Human coronavirus NL63	KF530114.1	*Legionella pneumophila*	CP015928.1
	KF530113.1	*Mycobacterium tuberculosis*	AP018036.1
SARS coronavirus	AY686863.1	*Streptococcus pneumoniae*	CP027540.1
		Streptococcus pyogenes	AE009949.1
MERS coronavirus	MH013216.1	*Bordetella pertussis*	CP011448.1
Adenovirus	AC_000017.1	*Mycoplasma pneumoniae*	CP039772.1
Human Metapneumovirus (hMPV)	KJ627437.1	*Pneumocystis jirovecii* (PJP)	MH010446.1
Parainfluenza virus 1	KX639498.1	*Candida albicans*	NC_018046.1
Parainfluenza virus 2	KM190939.1	*Pseudomonas aeruginosa*	CP000438.1
Parainfluenza virus 3	KF530243.1	*Staphylococcus epidermis*	KY750253.1
Parainfluenza virus 4	KF483663.1	*Streptococcus salivarius*	CP020451.2
Influenza A	MH798556.1		

Table 7. Cross Reactivity and Interference Testing for *H. Influenzae*

SAMPLE		Valid results	N gene (HEX)			Nsp2 gene (FAM)			SPC2 (Q-705)
			Positive	% Positive	Avg Ct	Positive	% positive	Avg Ct	Avg Ct
Cross Reactivity	Neat UVT (Control Negative)	3	0	0%	N/A	0	0%	N/A	27.7
	UVT+H. Influenzae (7.2E6 CFU/mL)	3	0	0%	N/A	0	0%	N/A	28.3
Interference	Neat UVT + SARS-CoV-2 RNA (750 copies/mL) (Control Positive)	3	3	100%	32.03	3	100%	34.05	27.8
	UVT+H. Influenzae (7.2E6 CFU/mL) + SARS-CoV-2 RNA (750 copies/mL)	3	3	100%	32.45	3	100%	33.98	27.7

Table 8. Cross Reactivity and Interference Testing for *P. aeruginosa*

SAMPLE		Valid results	N gene (HEX)			Nsp2 gene (FAM)			SPC2 (Far Red)
			Positive	% Positive	Avg Ct	Positive	% positive	Avg Ct	Avg Ct
Cross-reactivity	UVT+P. aeruginosa (1^E6 CFU/mL)	3	0	0%	N/A	0	0%	N/A	27.5
Interference	Neat UVT Control Positive	3	3	100%	30.3	3	100%	32.0	26.9
	UVT + P. aeruginosa (1^E6 CFU/mL) + SARS-CoV-2 RNA (450 copies/mL)	3	3	100%	30.4	3	100%	32.0	27.0

Interfering Substances

The NeuMoDx SARS-CoV-2 Assay was evaluated for susceptibility to interference caused by substances potentially associated with the collection of nasopharyngeal swab specimens. Residual clinical negative nasopharyngeal swab specimens were spiked with SARS-CoV-2 genomic RNA (BEI Resources NR-52285) at 5X LoD and processed in the presence and absence of the agents shown below in *Table 9*. No substances included in the testing had an adverse effect on the assay performance.

Table 9. Substances Tested for Interference

	Substance	Concentration*
Endogenous	Mucin	0.5% (w/v)
	Blood (human)	2% (v/v)
Exogenous	Afrin® Original (oxymetazoline)	15% (v/v)
	Zicam® Cold Remedy Nasal Spray	5% (v/v)
	Flonase® Allergy Relief (fluticasone)	5% (v/v)
	Beclomethasone	10 mg/mL
	Mupirocin	11.4 mg/mL
	Relenza® (zanamivir)	5.25 mg/mL
	Tamiflu® (oseltamivir)	7.5 mg/mL
	Tobramycin	1.8 mg/mL

*Note: Concentrations shown are those used to saturate swabs before dosing contrived positive clinical samples with interfering substance. They are therefore representative of the level at the site of swab collection that can be tolerated.

Clinical Performance

a. Testing of Contrived Specimens

The performance of the NeuMoDx SARS-CoV-2 Assay with residual clinical nasopharyngeal swab samples (Nylon Flocked Swab collected in UTM [Copan Diagnostic Inc, CA] or VTM [BD, NJ]) was evaluated using a panel of 82 negative clinical samples and 87 contrived positive clinical samples previously submitted for influenza and/or respiratory syncytial virus testing from patients with signs and symptoms of upper respiratory infection. Positive contrived samples were prepared by spiking SARS-CoV-2 genomic RNA (BEI Resources NR-52285) into negative clinical samples. Of the 87 contrived positive samples, 57 were at concentrations 1-2X LoD and 30 were at concentrations 4-8X LoD. Processing of samples was done using both DIRECT and PRETREATED workflows across both NeuMoDx Systems.

All positive samples were reported positive and all negative samples were reported negative, as detailed in *Tables 10–13*, below.

Table 10. Pretreated Specimens on NeuMoDx 288 Molecular System Only

Pretreated Workflow: NeuMoDx 288 Molecular System					
Sample Concentration	**n**	**Target 1 (Nsp Gene)**		**Target 2 (N gene)**	
		% positive (two-sided 95% CI)	**Mean Ct**	**% positive (two-sided 95% CI)**	**Mean Ct**
225 c/mL ~1.5X LoD	12	100 (75.6 – 99.9)	32.5	100 (75.6 – 99.9)	32.2
400 c/mL ~2.7X LoD	11	100 (74.0 - 99.9)	31.4	100 (74.0 - 99.9)	30.2
500 c/mL ~3.3X LoD	10	100 (72.1 - 99.9)	31.2	100 (72.1 - 99.9)	30.2
1000 c/mL	5	100 (56.4 - 99.9)	30.5	100 (56.4 - 99.9)	29.4
2000 c/mL	6	100 (60.8 - 99.9)	30.2	100 (60.8 - 99.9)	28.8
Negative	29	0 (n/a)	n/a	0 (n/a)	n/a
Performance against the expected results are: **Positive Percent Agreement** **44/44 = 100% (95% CI: 91.9% - 100%)** **Negative Percent Agreement** **29/29 = 100% (95% CI: 88.2% - 100%)**					

Table 11. Pretreated Specimens on NeuMoDx 96 Molecular System Only

Pretreated Workflow: NeuMoDx 96 Molecular System					
Sample Concentration	**n**	**Target 1 (Nsp Gene)**		**Target 2 (N gene)**	
		% positive (two-sided 95% CI)	**Mean Ct**	**% positive (two-sided 95% CI)**	**Mean Ct**
225 c/mL ~1.5X LoD	12	100 (75.6 – 99.9)	32.0	100 (75.6 – 99.9)	31.5
400 c/mL ~2.7X LoD	3	100 (43.7 - 99.8)	31.2	100 (43.7 - 99.8)	30.4
500 c/mL ~3.3X LoD	3	100 (43.7 - 99.8)	31.5	100 (43.7 - 99.8)	30.6
1000 c/mL	2	100 (34.2 - 99.8)	30.2	100 (34.2 - 99.8)	29.2
2000 c/mL	2	100 (34.2 - 99.8)	30.1	100 (34.2 - 99.8)	28.9
Negative	20	0 (n/a)	n/a	0 (n/a)	n/a
Performance against the expected results are: **Positive Percent Agreement** **22/22 = 100% (95% CI: 85.0% - 100%)** **Negative Percent Agreement** **20/20 = 100% (95% CI: 83.8% - 100%)**					

Table 12. Direct Workflow Specimens on NeuMoDx 288 Molecular System Only

Direct Workflow: NeuMoDx 288 Molecular System					
Sample Concentration	**n**	**Target 1 (Nsp Gene)**		**Target 2 (N gene)**	
		% positive (two-sided 95% CI)	**Mean Ct**	**% positive (two-sided 95% CI)**	**Mean Ct**
225 c/mL ~1.5X LoD	12	100 (75.6 – 99.9)	33.8	100 (75.6 – 99.9)	32.7
400 c/mL ~2.7X LoD	11	100 (74.0 - 99.9)	32.4	100 (74.0 - 99.9)	31.1
500 c/mL ~3.3X LoD	11	100 (74.0 - 99.9)	32.5	100 (72.1 - 99.9)	31.3
1000 c/mL	6	100 (60.8 - 99.9)	31.9	100 (56.4 - 99.9)	30.5
2000 c/mL	6	100 (60.8 - 99.9)	31.1	100 (60.8 - 99.9)	29.7
Negative	33	0 (n/a)	n/a	0 (n/a)	n/a
Performance against the expected results are:					
Positive Percent Agreement	**46/46 = 100% (95% CI: 92.2% - 100%)**				
Negative Percent Agreement	**33/33 = 100% (95% CI: 89.5% - 100%)**				

Table 13. Direct Workflow Specimens on NeuMoDx 96 Molecular System Only

Direct Workflow: NeuMoDx 96 Molecular System					
Sample Concentration	**n**	**Target 1 (Nsp Gene)**		**Target 2 (N gene)**	
		% positive (two-sided 95% CI)	**Mean Ct**	**% positive (two-sided 95% CI)**	**Mean Ct**
225 c/mL ~1.5X LoD	12	100 (75.6 – 99.9)	33.4	100 (75.6 – 99.9)	32.3
400 c/mL ~2.7X LoD	4	100 (50.9 - 99.9)	32.7	100 (50.9 - 99.9)	31.7
500 c/mL ~3.3X LoD	4	100 (50.9 - 99.9)	32.6	100 (50.9 - 99.9)	31.5
1000 c/mL	1	100 (20.7 - 99.8)	31.9	100 (20.7 - 99.8)	30.2
2000 c/mL	2	100 (34.2 - 99.8)	31.5	100 (34.2 - 99.8)	29.7
Negative	0	0 (n/a)	N/A	0 (n/a)	N/A
Performance against the expected results are:					
Positive Percent Agreement	**23/23 = 100% (95% CI: 85.6% - 100%)**				
Negative Percent Agreement	**N/A**				

b. Testing of Clinical Specimens

The performance of the NeuMoDx SARS-CoV-2 Assay was also evaluated using clinical specimens. Leftover deidentified clinical nasopharyngeal (NP) swab specimens from symptomatic patients were collected with flocked minitip swabs into 3 mL BD Universal Viral Transport Medium (BD UVT). The specimens were submitted for SARS-CoV-2 testing to two external testing sites which performed the Comparator testing of these specimens with tests previously authorized by the U.S. FDA for emergency use. Testing with the NeuMoDx SARS-CoV-2 Assay was performed at one internal and one external testing site. A total of 40 samples were processed using the NeuMoDx SARS-CoV-2 Assay. Some samples were tested at both, the N288 and the N96 NeuMoDx Systems and employing both PRETREATED and DIRECT workflows. Results of the NeuMoDx SARS-CoV-2 Assay were in complete agreement with the comparator assay results for all clinical samples tested in this method comparison study (Tables 14 and 15).

Table 14. Qualitative Method Comparison Results for the NeuMoDx SARS-CoV-2 Assay on NeuMoDx Molecular Systems v. Reference Tests – PRETREATED Workflow

N96 and N288 Pretreated		Comparator Assay(s)		
		Pos	Neg	Total
NeuMoDx SARS-CoV-2 Assay	Pos	25	0	25
	Neg	0	15	15
	Total	25	15	40
Clinical sensitivity 100% (95% CI 86.6-100%)				
Clinical specificity 100% (95% CI 79.5-99.9%)				

Table 15. Qualitative Method Comparison Results for the NeuMoDx SARS-CoV-2 Assay v. Reference Tests – DIRECT Workflow (**a)** on the NeuMoDx 288 Molecular System (N288) and (**b)** on the NeuMoDx 96 Molecular System (N96)

(a)

N288 Direct		Comparator Assay(s)		
		Pos	Neg	Total
NeuMoDx SARS-CoV-2 Assay	Pos	10	0	10
	Neg	0	9	9
	Total	10	9	19
Clinical sensitivity 100% (95% CI 72.1-99.9%)				
Clinical specificity 100% (95% CI 69.9-99.9%)				

(b)

N96 Direct		Comparator Assay(s)		
		Pos	Neg	Total
NeuMoDx SARS-CoV-2 Assay	Pos	5	0	5
	Neg	0	6	6
	Total	5	6	11
Clinical sensitivity 100% (95% CI 56.4-99.9%)				
Clinical specificity 100% (95% CI 60.8-99.9%)				

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TRADEMARKS

SYMBOLS

SYMBOL	MEANING
℞ only	**Prescription use only**
	**Manufacturer**
	***In vitro* diagnostic medical device**
	**Catalog number**
	**Batch code**
	**Use-by date**
	**Temperature limit**
	**Humidity limitation**
	**Do not re-use**
	**Contains sufficient for *<n>* tests**
	**Consult instructions for use**
	**Caution**
	**Biological risks**

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