U.S. FOOD & DRUG ADMINISTRATION

January 22, 2021

Nahed Mohsen, Ph.D.
Vice President of Regulatory and Clinical Affairs
NeuMoDx Molecular, Inc.
1250 Eisenhower Place
Ann Arbor, MI 48108

Device:	NeuMoDx SARS-CoV-2 Assay
EUA Number:	EUA200073
Company:	NeuMoDx Molecular, Inc.
Indication:	This test is authorized for the following indications for use: Qualitative detection of SARS-CoV-2 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 (HCP). Qualitative detection of SARS-CoV-2 RNA from saliva specimens that are collected in a healthcare setting under the supervision of a HCP using the NeuMoDx Saliva Collection Kit from individuals suspected of COVID-19 as determined by a HCP due to symptoms. Emergency use of this test is limited to authorized laboratories.
Authorized Laboratories:	Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate or high complexity tests.

Dear Dr. Mohsen:

On March 30, 2020, based on your[1] request, the Food and Drug Administration (FDA) issued a letter authorizing emergency use of the NeuMoDx SARS-CoV-2 Assay, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3) for the qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal or oropharyngeal swabs, and nasal swabs from individuals suspected of COVID-19 by their healthcare provider. Testing was limited to laboratories certified under the Clinical Laboratory Improvement

[1] For ease of reference, this letter will use the term "you" and related terms to refer to NeuMoDx Molecular, Inc.

Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high and moderate complexity tests. Based on your request, FDA also granted updates to the authorized labeling on April 23, 2020.[2]

On September 23, 2020, you again requested to amend your Emergency Use Authorization (EUA). Based on that request, and having concluded that revising the March 30, 2020, EUA is appropriate to protect the public health or safety under section 564(g)(2)(C) of the Act (21 U.S.C. § 360bbb-3(g)(2)(C)), FDA is reissuing the March 30, 2020, letter in its entirety with the revisions incorporated.[3] Pursuant to section 564 of the Act and the Scope of Authorization (Section II) and Conditions of Authorization (Section IV) of this reissued letter, your product[4] is now intended for the indication described above.

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19. Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 subject to the terms of any authorization issued under Section 564(a) of the Act.[5]

FDA considered the totality of scientific information available in authorizing the emergency use of your product for the indication above. A summary of the performance information FDA relied upon is included in the "NeuMoDx SARS-CoV-2 Assay Instructions for Use" (identified below).

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of your product, described in the Scope of Authorization (Section II) of this letter, subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

[2] On April 23, 2020, your request was granted to update the Instructions for Use (IFU) of your product to: (1) add bronchoalveolar lavage (BAL) specimens to the intended use, (2) modify the intended use to incorporate: "*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,*" (3) update the Clinical Performance section with results from recent testing of clinical specimens, and (4) add minor edits for clarification. The Healthcare Provider Fact Sheet was also updated accordingly.

[3] The revisions to the March 30, 2020, letter and authorized labeling include: (1) revisions to the intended use to include the addition of qualitative detection of SARS-CoV-2 RNA in saliva specimens that are collected in a healthcare setting under the supervision of a HCP using the NeuMoDx Saliva Collection Kit from individuals suspected of COVID-19 as determined by a HCP due to symptoms, (2) modification of the IFU to reflect addition of saliva as a specimen type, (3) update the healthcare provider and patient fact sheets to include some additional warnings/precautions around the use of saliva specimens, and (4) update the intended use and fact sheets to reflect language used in more recent authorizations.

[4] For ease of reference, this letter will use the term "your product" to refer to the NeuMoDx SARS-CoV-2 Assay.

[5] U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*. 85 FR 7316 (February 7, 2020).

I have concluded that the emergency use of your product meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. The SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that your product may be effective in diagnosing COVID-19, and that the known and potential benefits of your product when used for diagnosing COVID-19, outweigh the known and potential risks of your product; and

3. There is no adequate, approved, and available alternative to the emergency use of your product.[6]

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited to the indication above.

Authorized Product Details

Your product is a qualitative test for use on the NeuMoDx 288 Molecular and NeuMoDx 96 Molecular Systems (includes the NeuMoDx 288 Molecular System Operator's Manual or NeuMoDx 96 Molecular System Operator's Manual) for the qualitative detection of SARS-CoV-2 RNA in nasal, nasopharyngeal and oropharyngeal swabs in transport medium and BAL specimens from individuals suspected of COVID-19 by their healthcare provider.

Your product is also for use with saliva specimens that are collected in a healthcare setting under the supervision of a HCP using the NeuMoDx Saliva Collection Kit from individuals suspected of COVID-19 as determined by a HCP due to symptoms.

Testing is limited to laboratories certified under CLIA that meet the requirements to perform moderate or high complexity tests.

The SARS-CoV-2 nucleic acid is generally detectable in respiratory and saliva specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 nucleic acid; 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. Negative results do not preclude SARS-CoV-2 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. Negative results for SARS-CoV-2 RNA from saliva should be confirmed by testing of an alternative specimen type if clinically indicated.

[6] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

The NeuMoDx Saliva Collection Kit consists of: one Saliva Collection Vial (empty vial), one Specimen Stabilization Tube prefilled with 1 ml Saliva Stabilization Buffer, one disposable transfer pipet, plastic bag, and the "NeuMoDx Saliva Collection Kit Instruction for Use."

The NeuMoDx SARS-CoV-2 Assay is based on fully automated sample preparation (nucleic acid extraction and purification) followed by reverse transcription. To use your product, SARS-CoV-2 nucleic acid is first extracted, isolated and purified from nasal, nasopharyngeal, and oropharyngeal swabs, BAL or saliva specimens. The purified nucleic acid is then reverse transcribed into cDNA followed by PCR amplification and detection using the reagents included in the NeuMoDx SARS-CoV-2 Test Strip and run on the NeuMoDx 288 Molecular and NeuMoDx 96 Molecular Systems, or other authorized instruments (as may be requested under Condition L below). Automated data management is performed by the software version 1.8.3.5, or otherwise authorized software, which assigns test results for all tests.

The NeuMoDx SARS-CoV-2 Assay includes the following materials or other authorized materials: NeuMoDx SARS-CoV-2 Test Strip, Cartridge, Extraction Plate, Wash Reagent, Release Reagent and Lysis Buffers.

Your product requires the following sample process control, or other authorized control materials (as may be requested under Condition L below), that are processed in the same way as the patient samples when tested with your product. The control listed below must generate expected results in order for a test to be considered valid, as outlined in the Instructions for Use:

- Sample Process Control (SPC2) – The SPC2 is a MS2 Phage genome included in each well. The MS2 primer and probe set is included in each specimen to test for the MS2 phage RNA genome, which controls for specimen quality and demonstrates that nucleic acid was generated by the extraction process.

You also recommend the use of external positive and negative controls (identified in the Instructions for Use), which are not included with the kit but are available commercially and are run as outlined in the Instructions for Use described below.

- Negative Control – to verify that no contamination of sample or reagents occurred. For saliva the recommended negative controls is molecular grade water added to Saliva Stabilization buffer; for swabs and BAL specimens the recommended negative control is transport media.

- Positive Control – to control for correct amplification and detection of all target sequences and controls adequate functioning of all reagents. The recommended positive control is a dilution of either purified SARS-CoV-2 genomic RNA, heat inactivated SARS-CoV-2 or recombinant SARS-CoV-2 in appropriate diluent for the specimen type.

Your product also requires the use of additional authorized materials and authorized ancillary reagents that are not included with your product and are described in the Instructions for Use.

Your product is authorized to be accompanied with the labeling entitled "NeuMoDx SARS-CoV-

2 Assay Instructions for Use" (available at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas) and the following fact sheets pertaining to the emergency use, which are required to be made available to healthcare provders and patients:

- Fact Sheet for Healthcare Providers: NeuMoDx Molecular, Inc. - NeuMoDx SARS-CoV-2 Assay
- Fact Sheet for Patients: NeuMoDx Molecular, Inc. - NeuMoDx SARS-CoV-2 Assay

The above described product, when accompanied by the "NeuMoDx SARS-CoV-2 Assay Instructions for Use," and two fact sheets, is authorized to be distributed to and used by authorized laboratories under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

The NeuMoDx Saliva Collection Kit with the "NeuMoDx Saliva Collection Kit Instructions for Use" is authorized to be distributed and used as part of the above described product as set forth in this EUA.

"Authorized labeling" refers to the "NeuMoDx SARS-CoV-2 Assay Instructions for Use," two fact sheets, and "NeuMoDx Saliva Collection Kit Instructions for Use."

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of your product, when used consistent with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of your product.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that your product may be effective in diagnosing COVID-19, when used consistent with the Scope of Authorization of this letter (Section II), pursuant to Section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that your product (as described in the Scope of Authorization of this letter (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of your product under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) of the Act described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1) of the Act, your product is authorized for the indication above.

III. Waiver of Certain Requirements

I am waiving the following requirements for your product during the duration of this EUA:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of your product, but excluding Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

IV. Conditions of Authorization

Pursuant to Section 564(e) of the Act, I am establishing the following conditions on this authorization:

NeuMoDx Molecular Inc. (You) and Authorized Distributor(s)[7]

A. Your product must comply with the following labeling requirements under FDA regulations: the intended use statement (21 CFR 809.10(a)(2), (b)(2)); adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5), (7), and (8)); appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4); and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

B. You and authorized distributor(s) must make your product available with the authorized labeling to authorized laboratories.

C. You and authorized distributor(s) must make available on your website(s) the authorized labeling.

D. You and authorized distributor(s) must make available all instructions related to the collection of saliva specimens using the NeuMoDx Saliva Collection Kit both in the shipped kit and on your website.

E. You and authorized distributor(s) must inform authorized laboratories and relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to your product and/or authorized labeling.

F. Through a process of inventory control, you and authorized distributor(s) must maintain records of the authorized laboratories to which they distribute your product and number they distribute.

G. Through a process of inventory control, you and authorized distributor(s) must maintain records of the numbers and locations to which the NeuMoDx Saliva Collection Kit is distributed.

[7] "Authorized Distributor(s)" are identified by you, NeuMoDx Molecular Inc., in your EUA submission as an entity allowed to distribute your product.

H. You and authorized distributor(s) must collect information on the performance of your product. You will report to FDA any suspected occurrence of false positive and false negative results and significant deviations from the established performance characteristics of the product of which you become aware.

I. You and authorized distributor(s) are authorized to make available additional information relating to the emergency use of your product that is consistent with, and does not exceed, the terms of this letter of authorization.

NeuMoDx Molecular, Inc. (You)

J. You must notify FDA of any authorized distributor(s) of your product, including the name, address, and phone number of any authorized distributor(s).

K. You must provide authorized distributor(s) with a copy of this EUA and communicate to authorized distributor(s) any subsequent amendments that might be made to this EUA and its authorized accompanying materials (e.g., Fact Sheets).

L. You may request changes to this EUA for your product, including to the Scope of Authorization (Section II in this letter) or to the authorized labeling, including requests to make available additional authorized labeling specific to an authorized distributor. Such additional labeling may use another name for the product but otherwise must be consistent with the authorized labeling, and not exceed the terms of authorization of this letter. Any request for changes to this EUA should be submitted to the Division of Microbiology (DMD)/Office of Health Technology 7 (OHT7) - Office of In Vitro Diagnostics and Radiological Health (OIR)/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH) and require appropriate authorization from FDA prior to implementation.

M. You must comply with the following requirements pursuant to FDA regulations: Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

N. You must have lot release procedures and the lot release procedures, including the study design and statistical power, must ensure that the tests released for distribution have the clinical and analytical performance claimed in the authorized labeling.

O. If requested by FDA, you must submit lot release procedures to FDA, including sampling protocols, testing protocols, and acceptance criteria, that you use to release lots of your product for distribution in the U.S. If such lot release procedures are requested by FDA, you must provide it within 48 hours of the request.

P. You must evaluate the analytical limit of detection and assess traceability[8] of your product with any FDA-recommended reference material(s). After submission to and concurrence with the data by FDA, you will update your labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require

[8] Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material.

concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

Q. You must have a process in place to track adverse events, including any occurrence of false results with your product, including with the NeuMoDx Saliva Collection Kit, and report any such events to FDA pursuant to 21 CFR Part 803. Serious adverse events, especially unexpected biosafety concerns, should immediately be reported to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov).

R. You must submit to FDA a summary report within 30 calendar days of the date of this letter summarizing the results of any testing performed using saliva specimens collected with the NeuMoDx Saliva Collection Kit during that timeframe, including the positivity rate for saliva specimens.

S. Upon request, you must conduct post-authorization studies and/or data analysis concerning the performance of saliva specimens with your authorized test. Such studies and/or data analysis will be agreed upon between you and FDA. After submission to FDA and DMD/OHT7-OIR/OPEQ/CDRH's review of the data, FDA will consider whether additional action is appropriate, such as revision or revocation of the EUA.

Authorized Laboratories

T. Authorized laboratories using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

U. Authorized laboratories using your product must use your product as outlined in the 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 use your product are not permitted.

V. Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.

W. Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

X. Authorized laboratories must collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and you (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 your product of which they become aware.

Y. All laboratory personnel using your product must be appropriately trained in RT-PCR techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.

NeuMoDx Molecular, Inc. (You), Authorized Distributor(s) and Authorized Laboratories

Z. You, authorized distributors, and authorized laboratories using your product must 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.

Conditions Related to Printed Materials, Advertising and Promotion

AA. All descriptive printed matter, advertising, and promotional materials relating to the use of your product shall be consistent with the authorized labeling, as well as the terms set forth in this EUA and the requirements set forth in section 502(a), (q)(1), and (r) of the Act and FDA implementing regulations.

BB. No descriptive printed matter, advertising, or promotional materials relating to the use of your product may represent or suggest that this test is safe or effective for the detection of SARS-CoV-2.

CC. All descriptive printed matter, advertising, and promotional materials relating to the use of your product shall clearly and conspicuously state that:

- This test has not been FDA cleared or approved but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories;
- This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and
- The emergency use of this test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

The emergency use of your product as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosure