March 10, 2020

Jill Taylor, Ph.D.
Director
Wadsworth Center, NYSDOH
Empire State Plaza, Coring Tower
Albany, NY 12237

Dear Dr. Taylor:

On February 29, 2020, based on a request by Wadsworth Center, New York State Department of Public Health ("Wadsworth Center NYSDOH"), the Food and Drug Administration (FDA) issued a letter authorizing emergency use of the New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel for the presumptive qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal/oropharyngeal swabs and sputa collected from individuals who meet Centers for Disease Control and Prevention (CDC) Coronavirus Disease 2019 (COVID-19) clinical and/or epidemiological criteria (for example, clinical signs and symptoms associated with COVID-19, contact with a probable or confirmed COVID-19 case, history of travel to a geographic locations where COVID-19 cases were detected, or other epidemiologic links for which COVID-19 testing may be indicated as part of a public health activity) pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3)[1]. The February 29, 2020 letter authorizing emergency use of this test limited testing to the Wadsworth Center NYSDOH, and the New York City Department of Health and Mental Hygiene, Public Health Laboratories, both of which are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests, and are also permitted under the New York State Clinical Laboratory Evaluation Program to perform clinical diagnostic molecular virology testing.

On March 7, 2020, FDA received a request from Wadsworth Center NYSDOH to amend the Emergency Use Authorization (EUA). In response to that request, and having concluded that revising the February 29, 2020 EUA is appropriate to protect the publich 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 February 29, 2020 letter in its entirety with amendments incorporated[2] to authorize, as amended, the emergency use of the New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR

[1] On February 11, 202, the virus tentatively named 2019-nCoV was formally designated as Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Also on February 11, 2020, the disease caused by SARS-CoV-2 was formally designated as Coronavirus Disease 2019 (COVID-19). This document uses the updated names.
[2] The amendments to the February 29, 2020 letter include: (1) additional authorized laboratories, (2) additional extraction methods, and (3) strike 'CDC" from the intended use when outlining the clinical and/or epidemiological criteria associated with COVID-19. The authorized Instructions for Use and authorized Fact Sheets have also been updated to incorporate these amendments, where applicable.

Diagnostic Panel. Accordingly, testing is now limited to qualified laboratories designated by Wadsworth Center, NYSDOH and, in the United States, certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests.[3]

On Feburary 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.[4]

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 the New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel (as described in the scope Section of this letter (Section II)) in individuals who meet COVID-19 clinical and/or epidemiological criteria for testing for the presumptive detection of SARS-CoV-2 by authorized laboratories, subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel in individuals who meet COVID-19 clinical and/or epidemiological criteria 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 the New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel may be effective in diagnosing COVID-19, and that the known and potential benefits of the New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel, when used for diagnosing COVID-19, outweigh the known and potential risks of such product; and

3. There is no adequate, approved, and available alternative to the emergency use of the New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel for diagnosing COVID-19.[5]

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

[4] 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. Feburary 4, 2020.

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

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 use of the authorized New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel by authorized laboratories for the presumptive detection of SARS-CoV-2 in individuals who meet COVID-19 clinical and/or epidemiological criteria for testing.

The Authorized New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel

The New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel is for the presumptive qualitative detection of SARS-CoV-2 RNA in nasopharyngeal/oropharyngeal swabs and sputa, and other specimens as authorized by FDA, collected from individuals who meet COVID-19 clinical and/or epidemiological criteria for testing. The testing procedure consists of nucleic acid extraction and purification from the human specimen using authorized extraction methods/instruments followed by real time RT-PCR, where the RNA is reverse transcribed into cDNA and then amplified using the primer sets and detected using specific probes. The real time reverse transcriptase (RT)-PCR is performed on the FDA cleared Applied Biosystems 7500 Fast Dx Real-Time PCR Instrument with SDS 1.4 software, or other authorized instruments or software.

The New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel uses all commercially sourced materials or other authorized materials and authorized ancillary reagents commonly used in clinical laboratories as described in the authorized procedures submitted as part of the EUA request.

The New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel requires the following control materials, or other authorized control materials; all controls listed below must generate expected results in order for a test to be considered valid, as outlined in the procedures submitted as part of the EUA request:

- Human Specimen Control (HSC): A human cell culture preparation used as an extraction control and positive control for the RNase P primer and probe set that is extracted and tested concurrently with each specimen extraction run.
- SARS-CoV-2 Positive Control (SARS-CoV-2 Pos): Run with each batch of specimens. Monitors improper assay setup, reagent failures of rRT-PCR reagents and reaction conditions.
- No Template Control (NTC): Nuclease-free water included in each run. Monitors for reagent and system contamination.
- RNase P (RP) control in clinical samples: The RP primer and probe set is included in each run to test for human RNase P, which controls for specimen quality and demonstrates that nucleic acid was generated by the extraction process.

The above described New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel, when labeled consistently with the labeling authorized by FDA, entitled "New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel Instructions for Use" (available at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-

authorizations), which may be revised by Wadsworth Center, NYSDOH in consultation with, and with concurrence of, the Division of Microbiology Devices (DMD)/Office of Health Technology 7 Office of In Vitro Diagnostics and Radiological Health (OHT7-OIR)/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH), 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 above-described New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel is authorized to be accompanied by the following information pertaining to the emergency use, which is required to be made available to healthcare providers and patients:

- Fact Sheet for Healthcare Providers: New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel

- Fact Sheet for Patients: New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel

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 the authorized New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel when used for the presumptive qualitative detection of SARS-CoV-2 and used consistently with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of such a 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 the authorized New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel may be effective in the presumptive detection of SARS-CoV-2, when used consistently 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 the authorized New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel, when used for detection of the SARS-CoV-2 in the specified population (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 the authorized New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel 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) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), the New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel described above is authorized to detect SARS-CoV-2 in individuals who meet COVID-19 clinical and/or epidemiological criteria.

This EUA will cease to be effective when the HHS declaration that circumstances exist to justify the EUA is terminated under Section 564(b)(2) of the Act or when the EUA is revoked under

Section 564(g) of the Act.

III. Waiver of Certain Requirements

I am waiving the following requirements for the New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel 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 the New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel

- Labeling requirements for cleared, approved, or investigational devices, including labeling requirements under 21 CFR 809.10 and 21 CFR 809.30, except for 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)), any 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)

IV. Conditions of Authorization

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

Wadsworth Center, New York State Department of Public Health (NYSDOH)

A. Wadsworth Center NYSDOH will make available the authorized New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel with the authorized labeling only to authorized laboratories. Wadsworth Center NYSDOH may request changes to the authorized labeling, and will promptly submit such requests. Such requests will be made by Wadsworth Center NYSDOH in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

B. Wadsworth Center NYSDOH will provide to authorized laboratories the authorized New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel Fact Sheet for Healthcare Providers and the authorized New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel Fact Sheet for Patients and any other New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel Fact Sheets that the Office of Counterterrorism and Emerging Threats (OCET)/Office of the Chief Scientist (OCS)/Office of the Commissioner (OC) and DMD/OHT7-OIR/OPEQ/CDRH may authorize. Wadsworth Center NYSDOH may request changes to the authorized New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel Fact Sheets. Such requests will be made by Wadsworth Center NYSDOH in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

C. Wadsworth Center NYSDOH will make available on its website the authorized New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel Fact Sheet for Healthcare Providers and the authorized New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel Fact Sheet for Patients and any other New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel Fact Sheets that OCET/OCS/OC and DMD/OHT7-OIR/OPEQ/CDRH may authorize.

D. Wadsworth Center NYSDOH will inform authorized laboratories and relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to the New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel, authorized labeling and authorized Fact Sheets.

E. Wadsworth Center NYSDOH will ensure that the authorized laboratories using the authorized New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

F. Wadsworth Center NYSDOH will maintain records of test usage.

G. Wadsworth Center NYSDOH will collect information on the performance of the test. Wadsworth Center NYSDOH will report to FDA any suspected occurrence of false positive and false negative results and significant deviations from the established performance characteristics of the test of which Wadsworth Center NYSDOH becomes aware.

H. Wadsworth Center NYSDOH is authorized to make available additional information relating to the emergency use of the authorized New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel that is consistent with, and does not exceed, the terms of this letter of authorization.

I. Wadsworth Center NYSDOH may request changes to the Scope of Authorization (Section II in this letter) of the authorized New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel. Such requests will be made by Wadsworth Center NYSDOH in consultation with, and require concurrence of, OCET/OCS/OC and DMD/OHT7-OIR/OPEQ/CDRH.

J. Wadsworth Center NYSDOH may request the addition of other instruments and associated software for use with the authorized New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel. Such requests will be made by Wadsworth Center NYSDOH in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

K. Wadsworth Center NYSDOH may request the addition of other extraction methods for use with the authorized New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel. Such requests will be made by Wadsworth Center NYSDOH in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

L. Wadsworth Center NYSDOH may request the addition of other specimen types for use

with the authorized New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel. Such requests will be made by Wadsworth Center NYSDOH in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

M. Wadsworth Center NYSDOH may request the addition and/or substitution of other control materials for use with the authorized New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel. Such requests will be made by Wadsworth Center NYSDOH in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

N. Wadsworth Center NYSDOH may request the addition and/or substitution of other materials and ancillary reagents for use with the authorized New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel. Such requests will be made by Wadsworth Center NYSDOH in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

O. Wadsworth Center NYSDOH may request the addition and/or substitution to the manufacturer of primer sets or specific probes. Such requests will be made by Wadsworth Center NYSDOH in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

P. Wadsworth Center NYSDOH will evaluate the analytical limit of detection and assess traceability[6] of the New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel with any FDA-recommended reference material(s). After submission to FDA and DMD/OHT7-OIR/OPEQ/CDRH's review of and concurrence with the data, Wadsworth Center NYSDOH will update its labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

Q. Wadsworth Center NYSDOH will track adverse events and report to FDA under 21 CFR Part 803.

Authorized Laboratories

R. Authorized laboratories will include with reports of the results of the New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

S. Authorized laboratories will perform the New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel as outlined in the New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel authorized procedures. Deviations from the authorized procedures, including the authorized RT-PCR instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to perform the New York SARS-

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

CoV-2 Real-time RT-PCR Diagnostic Panel are not permitted.

T. Authorized laboratories will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

U. Authorized laboratories will maintain records of test usage and 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 Wadsworth Center NYSDOH (via email: NYS.CoV2.test.event.report@health.ny.gov) 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.

V. 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.

W. Authorized laboratories 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.

Conditions Related to Advertising and Promotion

X. All advertising and promotional descriptive printed matter relating to the use of the authorized New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel shall be consistent with the Fact Sheets and authorized labeling, as well as the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.

Y. All advertising and promotional descriptive printed matter relating to the use of the authorized New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel shall clearly and conspicuously state that:

- This test has not been FDA cleared or approved;
- This test has been authorized 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
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests 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 authorization is terminated or revoked sooner.

No advertising or promotional descriptive printed matter relating to the use of the authorized New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel may represent or suggest that this test is safe or effective for the detection of SARS-CoV-2.

The emergency use of the authorized New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel 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 diagnostic tests for detection and/or diagnosis of the virus that causes 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,

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RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures