March 13, 2020

Faith Du, Regulatory Affairs Manager,
Thermo Fisher Scientific, Inc.
5781 Van Allen Way,
Carlsbad, CA 92008 US

Dear Mrs. Du:

This letter is in response to your request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of the Thermo Fisher Scientific, Inc. (Thermo Fisher) TaqPath COVID-19 Combo Kit for the qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal swab, nasopharyngeal aspirate, and bronchoalveolar lavage (BAL) specimens from individuals suspected of COVID-19 by their healthcare provider, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3). The TaqPath COVID-19 Combo Kit is for use only under EUA in the United States (U.S.) in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests.[1]

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.[2] 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.[3]

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 TaqPath COVID-19 Combo Kit (as described in the scope Section of this letter (Section II)) in individuals suspected of COVID-19

[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."
[2] On February 11, 2020, 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.
[3] 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*. February 4, 2020.

by their healthcare provider for the 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 TaqPath COVID-19 Combo Kit for testing individuals suspected of COVID-19 by their healthcare provider 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 TaqPath COVID-19 Combo Kit may be effective in diagnosing COVID-19, and that the known and potential benefits of the TaqPath COVID-19 Combo Kit, 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 TaqPath COVID-19 Combo Kit for diagnosing COVID-19.[4]

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 TaqPath COVID-19 Combo Kit by authorized laboratories for the qualitative detection of SARS-CoV-2 in individuals suspected of COVID-19 by their healthcare provider.

The Authorized TaqPath COVID-19 Combo Kit

The TaqPath COVID-19 Combo Kit is a qualitative test for the detection of nucleic acid from SARS-CoV-2 in nasopharyngeal swab, nasopharyngeal aspirate, and BAL specimens from individuals suspected of COVID-19 by their healthcare provider. The SARS-CoV-2 nucleic acid is generally detectable in nasopharyngeal swab, nasopharyngeal aspirate, and BAL 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.

To perform TaqPath COVID-19 Combo Kit testing, SARS-CoV-2 nucleic acid is first extracted, isolated and purified from nasopharyngeal swab, nasopharyngeal aspirate, or BAL specimens. The purified nucleic acid is then reverse transcribed into cDNA followed by PCR amplification and detection with the TaqPath COVID-19 Combo Kit on the Applied Biosystems 7500 Fast Dx Real-Time PCR instrument, or other authorized instruments. Data is analyzed and interpreted by the Applied Biosystems COVID-19 Interpretive Software, or other authorized software. The TaqPath COVID-19 Combo Kit includes the following primer/probe materials, or other authorized primer/probe materials and control materials, or other authorized control materials:

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

- TaqPath RT-PCR COVID-19 Kit - containing the TaqPath COVID-19 Assay Multiplex reagent, that include the three primer/probe sets specific to different SARS-CoV-2 genomic regions (Gene Orf-1ab, N Protein, S Protein) and primers/probes for bacteriophage MS2, and the MS2 Phage Control reagent.
- TaqPath COVID-19 Control Kit – containing the TaqPath COVID-19 Control - RNA positive control that contains the SARS-CoV-2 genomic regions targeted by the kit and the TaqPath COVID-19 Control Dilution Buffer.

The TaqPath COVID-19 Combo Kit requires the following control materials, or other authorized control materials, that are processed in the same way as the patient samples and are required to be included with each batch of specimens tested with the TaqPath COVID-19 Combo Kit . All controls listed below must generate expected results in order for a test to be considered valid, as outlined in the TaqPath COVID-19 Combo Kit Instructions for Use:

- Internal Positive Control (IPC) – MS2 phage control which is required as an extraction, reverse transcription and PCR amplification positive control.
- External positive control - TaqPath COVID-19 Control contains the SARS-CoV-2 RNA genomic regions targeted by the kit. The positive control is used to monitor for failures of rRT-PCR reagents and reaction conditions.
- Negative Control - molecular-grade, nuclease-free, non-DEPC-treated water used to monitor non-specific amplification, cross-contamination during experimental setup, and nucleic acid contamination of reagents.

The TaqPath COVID-19 Combo Kit also requires the use of additional authorized materials and authorized ancillary reagents that are not included with the test and are described in the authorized TaqPath COVID-19 Combo Kit Instructions for Use.

The above described TaqPath COVID-19 Combo Kit, when labeled consistently with the labeling authorized by FDA, entitled "TaqPath COVID-19 Combo Kit Instructions for Use" (available at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations), which may be revised by Thermo Fisher 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 TaqPath COVID-19 Combo Kit 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: TaqPath COVID-19 Combo Kit
- Fact Sheet for Patients: TaqPath COVID-19 Combo Kit

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 TaqPath COVID-19 Combo Kit, when used for the 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 TaqPath COVID-19 Combo Kit may be effective in the qualitative 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 TaqPath COVID-19 Combo Kit, when used for qualitative 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 TaqPath COVID-19 Combo Kit 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 TaqPath COVID-19 Combo Kit described above is authorized to detect SARS-CoV-2 in individuals suspected of COVID-19 by their healthcare provider.

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 TaqPath COVID-19 Combo Kit 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 TaqPath COVID-19 Combo Kit

IV. Conditions of Authorization

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

Thermo Fisher and Its Authorized Distributor(s)

A. This device 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)); 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).

B. Thermo Fisher and its authorized distributor(s) will make available the authorized TaqPath COVID-19 Combo Kit with the authorized labeling to authorized laboratories. Thermo Fisher may request changes to the authorized labeling. Such requests will be made by Thermo Fisher in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

C. Thermo Fisher and its authorized distributor(s) will provide to authorized laboratories the authorized TaqPath COVID-19 Combo Kit Fact Sheet for Healthcare Providers and the authorized TaqPath COVID-19 Combo Kit Fact Sheet for Patients.

D. Thermo Fisher and its authorized distributor(s) will make available on their website(s) the authorized TaqPath COVID-19 Combo Kit Fact Sheet for Healthcare Providers and the authorized TaqPath COVID-19 Combo Kit Fact Sheet for Patients.

E. Thermo Fisher and its authorized distributor(s) will inform authorized laboratories and relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to the TaqPath COVID-19 Combo Kit , authorized labeling and authorized Fact Sheets.

F. Through a process of inventory control, Thermo Fisher and its authorized distributor(s) will maintain records of the authorized laboratories to which they distribute the test and number of tests they distribute.

G. Thermo Fisher and its authorized distributor(s) will collect information on the performance of the test. Thermo Fisher 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 Thermo Fisher becomes aware.

H. Thermo Fisher and its authorized distributor(s) are authorized to make available additional information relating to the emergency use of the authorized TaqPath COVID-19 Combo Kit that is consistent with, and does not exceed, the terms of this letter of authorization.

I. Thermo Fisher and its authorized distributor(s) will send out a Customer Letter to authorized laboratories to inform them of acceptable material(s), other than clinical specimens, that will aid the authorized laboratories in verification of the authorized

TaqPath COVID-19 Combo Kit. Thermo Fisher will notify DMD/OHT7-OIR/OPEQ/CDRH when this condition has been completed.

Thermo Fisher

J. Thermo Fisher will notify FDA of any authorized distributor(s) of the TaqPath COVID-19 Combo Kit, including the name, address, and phone number of any authorized distributor(s).

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

L. Thermo Fisher may request changes to the authorized TaqPath COVID-19 Combo Kit Fact Sheet for Healthcare Providers and the authorized TaqPath COVID-19 Combo Kit Fact Sheet for Patients. Such requests will be made by Thermo Fisher in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

M. Thermo Fisher may request changes to the Scope of Authorization (Section II in this letter) of the authorized TaqPath COVID-19 Combo Kit. Such requests will be made by Thermo Fisher in consultation with DMD/OHT7-OIR/OPEQ/CDRH, and require concurrence of, Office of Counterterrorism and Emerging Threats (OCET)/Office of the Chief Scientist (OCS)/Office of the Commissioner (OC) and DMD/OHT7-OIR/OPEQ/CDRH.

N. Thermo Fisher may request the addition of other instruments and associated software for use with the authorized TaqPath COVID-19 Combo Kit. Such requests will be made by Thermo Fisher in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

O. Thermo Fisher may request the addition of other specimen types for use with the authorized TaqPath COVID-19 Combo Kit. Such requests will be made by Thermo Fisher in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

P. Thermo Fisher may request the addition and/or substitution of primers or probes for use with the authorized TaqPath COVID-19 Combo Kit. Such requests will be made by Thermo Fisher in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

Q. Thermo Fisher may request the addition and/or substitution of other ancillary reagents and materials for use with the authorized TaqPath COVID-19 Combo Kit. Such requests will be made by Thermo Fisher in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

R. Thermo Fisher will evaluate the analytical limit of detection and assess traceability[5] of the TaqPath COVID-19 Combo Kit with any FDA-recommended reference material(s). After submission to FDA and DMD/OHT7-OIR/CDRH's review of and concurrence with the data, Thermo Fisher 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.

S. Thermo Fisher will complete the agreed upon interference study. After submission to FDA and DMD/OHT7-OIR/CDRH's review of and concurrence with the data, Thermo Fisher 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.

T. Thermo Fisher will track adverse events, including any occurrence of false results and report to FDA under 21 CFR Part 803.

Authorized Laboratories

U. Authorized laboratories using the TaqPath COVID-19 Combo Kit will include with result reports of the TaqPath COVID-19 Combo Kit , all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

V. Authorized laboratories using the TaqPath COVID-19 Combo Kit will perform the TaqPath COVID-19 Combo Kit as outlined in the TaqPath COVID-19 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 TaqPath COVID-19 Combo Kit are not permitted.

W. Authorized laboratories that receive the TaqPath COVID-19 Combo Kit must notify the relevant public health authorities of their intent to run the test prior to initiating testing.

X. Authorized laboratories using the TaqPath COVID-19 Combo Kit will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

Y. 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 Thermo Fisher (1-800-955-6288, Option #2; or techservices@thermofisher.com) 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.

Z. All laboratory personnel using the test must be appropriately trained in RT-PCR

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

techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use the test in accordance with the authorized labeling.

Thermo Fisher, Its Authorized Distributor(s), and Authorized Laboratories

AA. Thermo Fisher, its authorized distributor(s) and authorized laboratories using the TaqPath COVID-19 Combo Kit 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

BB. All advertising and promotional descriptive printed matter relating to the use of the authorized TaqPath COVID-19 Combo Kit 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.

CC. All advertising and promotional descriptive printed matter relating to the use of the authorized TaqPath COVID-19 Combo Kit 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 TaqPath COVID-19 Combo Kit may represent or suggest that this test is safe or effective for the detection of SARS-CoV-2.

The emergency use of the authorized TaqPath COVID-19 Combo Kit 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 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