May 18, 2022

Ian McGill
Regulatory Affairs Manager
Thermo Fisher Scientific, Inc.
5791 Van Allen Way
Carlsbad, CA 94080

Device:	TaqPath COVID-19 Combo Kit
EUA Number:	EUA200010
Company:	Thermo Fisher Scientific, Inc. (Thermo Fisher)
Indication:	This test is authorized for the following indications for use: Qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal, oropharyngeal, anterior nasal, and mid-turbinate swabs, nasopharyngeal aspirate, and bronchoalveolar lavage (BAL) specimens from individuals suspected of COVID-19 by their healthcare provider. This test is also authorized for use with the Everlywell COVID-19 Test Home Collection Kit when used consistent with its authorization. Emergency use of this test is limited to authorized laboratories.
Authorized Laboratories:	Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.

Dear Ian McGill:

On March 13, 2020, based on your[1] request, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the emergency use of the TaqPath COVID-19 Combo Kit, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3) for the indications stated in the letter.[2] Based on your requests, FDA granted

[1] For ease of reference, this letter will use the term "you" and related terms to refer to Thermo Fisher Scientific, Inc. (Thermo Fisher).
[2] The March 13, 2020, letter authorized the 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. Emergency use of this test was

updates to the authorized labeling on March 24, 2020,[3] April 20, 2020,[4] May 9, 2020,[5] July 17, 2020,[6] November 20, 2020,[7] and February 23, 2021.[8] Also, FDA revised and reissued the letter on October 9, 2020[9] and October 12, 2021.[10] In addition, on September 23, 2021, FDA

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limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests.

[3] On March 24, 2020, your request was granted to update the Instructions for Use (IFU) of your product to: (1) add manual sample extraction procedures using the MagMAX Viral/Pathogen Nucleic Acid Isolation Kit, (2) add the Applied Biosystems 7500 Fast system that utilizes DCS versions 1.5.1 and 2.3, (3) add Applied Biosystems COVID-19 Interpretive Software v1.1, and (4) include some format changes and minor edits to the IFU for clarification.

[4] On April 20, 2020, your request was granted to update the IFU of your product to: (1) add three real-time PCR instruments: Applied Biosystems 7500 Real-Time instrument, QuantStudio 5 with 0.1ml Block, and Quant Studio 5 with 0.2 ml Block, (2) add four extraction procedure modifications: automated extraction with MagMAX Viral/Pathogen Nucleic Acid Isolation Kit and 200 µl sample input volume, automated extraction with MagMAX Viral/Pathogen II Nucleic Acid Isolation Kit and 200 or 400 µl sample input volume, manual extraction with MagMAX Viral/Pathogen II Nucleic Acid Isolation Kit and 200 µl sample input volume (3) update the Applied Biosystems COVID-19 Interpretive Software to v1.2 and v2.0, (4) add oropharyngeal, nasal, and mid-turbinate swab specimen types to the Intended Use, and the associated limitation regarding the nasal and mid-turbinate swabs, (5) add endogenous interfering substances study (6) add protocols for the new real-time PCR instruments and extraction methods, and (7) include minor edits in the IFU for clarification.

[5] On May 9, 2020, your request was granted to update the IFU of your product to: (1) add Applied Biosystems QuantStudio 7 Flex Real-Time PCR system, 384-well (RUO) and Applied Biosystems QuantStudio 5 Real-Time PCR system 384-well (ROU) instruments, (2) add Applied Biosystems COVID-19 Interpretive Software v2.2, (3) add extraction procedure for MagMAX Viral/Pathogen II Nucleic Acid Isolation Kit for manual extraction using 400µl specimen input, (4) add protocols for the new real-time PCR instruments and extraction methods and revise some of the existing procedures for clarification, (5) add additional products as an alternative to the KingFisher 96 KF microplate for automated RNA extraction, (6) update specimen storage recommendations, (7) update limitations section regarding nasal and mid-turbinate swabs, (8) include additional minor edits in the IFU for clarification.

[6] On July 17, 2020, your request was granted to update the IFU of your product to: (1) extend the expiration dating for reagents based on the results from an Accelerated Stability Study, (2) update the in silico analysis of inclusivity, (3) revise the TaqPath COVID-19 Combo Kit interpretive software to address the potential for false-negative results and Positive Control failures, (4) update the device labeling for clarity and consistency with the modifications authorized under this amendment, in addition to some minor updates requested by FDA.

[7] On November 20, 2020, your request was granted to update the IFU to (1) add use of additional PCR instrument systems with the TaqPath COVID-19 Combo Kit Advanced "high volume" workflows; (2) make updates to the Applied Biosystems COVID-19 Interpretive Software; and (3) update the device labeling for clarity and consistency with the requested modifications including some minor updates requested by FDA.

[8] On February 23, 2021, your request was granted to update to (1) add the MicroAmp EnduraPlate as an additional plastic reaction plate, and (2) add additional assay distributors.

[9] On October 9, 2020, the revisions to the March 13, 2020, letter and authorized labeling included: (1) revisions to the intended use and authorized labeling documents to authorize the use of this product with high volume workflows, (2) revisions to the intended use and authorized labeling documents to include testing of self-collected nasal swab samples using the Everlywell COVID-19 Test Home Collection Kit, including introduction of the TaqMan SARS-CoV-2 RNase P Assay to detect human RNase P nucleic acid as an endogenous control, and (3) revisions to the intended use, healthcare provider and patient fact sheets to reflect language more consistent with recent authorizations.

[10] On October 12, 2021, the revisions to the October 9, 2020, letter and authorized labeling included: (1) adding the MicroAmp Optical Film Compression Pad for use with the QuantStudio 5 Real-Time PCR System, (2) updating the in-use stability claims for the TaqPath COVID-19 Control Solution, (3) updating to add Conditions of Authorization (2) and (3) from the Viral Mutation Revision Letter – September 23, 2021 (R and S), (4) adding results from testing the FDA Reference Panel to the IFU, (5) updating the intended use to reflect language used in more recent authorizations, (6) updating the Conditions of Authorization to reflect language used in more recent authorizations, (7) adding Condition W. to limit testing of specimens collected with the Everlywell COVID-19 Test Home Collection Kit to laboratories designated by Everlywell, Inc. and instructing laboratories to follow the "Receiving

established additional Conditions of Authorization in response to the continued emergence of new variants of SARS-CoV-2.[11]

On July 30, 2021, you requested to further revise your EUA. Based on this request and having concluded that revising the October 12, 2021 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 October 12, 2021 letter in its entirety with the revisions incorporated.[12] 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[13] is now authorized for use consistent with 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.[14]

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 contained in the 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 (as described in the Scope of Authorization (Section II), subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

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:

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and Processing Everlywell Samples" standard operating procedure when accepting specimens, (8) removing of Condition P. (from the October 9, 2020 letter), and (9) making other minor labeling revisions including updating authorized labeling to fulfill Condition of Authorized (1) in the Viral Mutation Revision Letter – September 23, 2021.

[11] The Viral Mutation Revision Letter – September 23, 2021, can be accessed at: https://www.fda.gov/media/152406/download

[12] The revisions to the October 12, 2021, letter and authorized labeling include: (1) remove use of the TaqPath COVID-19 Combo Kit Advanced workflow product when distributed and used with reagent volumes that have been optimized for "high volume" workflows that use 14.0 µL or 17.5 µL of purified sample RNA, (2) update the threshold for detection of the MS2 Internal Control, (3) update the *in silico* analysis of inclusivity, (4) various minor clerical and software versioning updates, and (5) updates to the Letter of Authorization, Fact Sheet for Healthcare Providers and Fact Sheet for Patients to be consistent with language used in more recent authorizations.

[13] For ease of reference, this letter will use the term "your product" to refer to the "TaqPath COVID-19 Combo Kit."

[14] 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).

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 your product, 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 your product for diagnosing COVID-19.[15]

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.

The Authorized Product

Your product is authorized for the qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal, oropharyngeal, anterior nasal, and mid-turbinate swabs, nasopharyngeal aspirate, and bronchoalveolar lavage (BAL) specimens from individuals suspected of COVID-19 by their healthcare provider.

This test is also authorized for use with the Everlywell COVID-19 Test Home Collection Kit when used consistent with its authorization.

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

The SARS-CoV-2 nucleic acid is generally detectable in upper respiratory and BAL 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. The agent detected may not be the definite cause of disease. 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.

To use your product, SARS-CoV-2 nucleic acid is first extracted, isolated and purified from upper respiratory or BAL specimens. The purified nucleic acid is then reverse transcribed into cDNA followed by PCR amplification and detection using an authorized real-time PCR instrument and interpretive software as described in the authorized labeling (described below). Your product includes the materials (or other authorized materials as may be requested under Condition K. below) described in the Instructions for Use.

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

Your product requires control materials, or other authorized control materials, (as may be requested under Condition K. below) that are processed along with the patient samples when testing with your product as described in the Instructions for Use.

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, described below.

The labeling entitled "TaqPath COVID-19 Combo Kit Instructions for Use" and the "TaqPath COVID-19 Combo Kit Product Information Sheet" (available at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas), and the following fact sheets pertaining to the emergency use, which are required to be made available as set forth in the Conditions of Authorization (Section IV), are collectively referred to as "authorized labeling":

- Fact Sheet for Healthcare Providers: Thermo Fisher Scientific, Inc. - TaqPath COVID-19 Combo Kit
- Fact Sheet for Patients: Thermo Fisher Scientific, Inc. - TaqPath COVID-19 Combo Kit

The above described product, when accompanied by the authorized labeling provided as set forth in the Conditions of Authorization (Section IV), 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.

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 for the qualitative detection of SARS-CoV-2 and 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 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 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:

Thermo Fisher (You) and Authorized Distributor(s) [16]

A. Your products 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. 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 include a physical copy of the authorized Product Information Sheet with each shipped product to authorized laboratories and will make the authorized Instructions for Use electronically available. Authorized laboratories may request a copy of the Instructions for Use in paper form, and after such request, you must promptly provide the requested information without additional cost.

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 authorized labeling.

F. Through a process of inventory control, you and authorized distributor(s) must

[16] "Authorized Distributor(s)" are identified by you, Thermo Fisher, in your EUA submission as an entity allowed to distribute your product.

maintain records of the authorized laboratories to which they distribute your product and number of your product they distribute.

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

H. 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.

Thermo Fisher (You)

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

J. 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).

K. 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.

L. You must comply with the following requirements pursuant to FDA regulations: 21 CFR 820 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).

M. 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.

N. 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 products 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.

O. You must evaluate the analytical limit of detection and assess traceability[17] of your product with any FDA-recommended reference material(s). After submission to and concurrence with the date by FDA you will update your labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

P. You must have a process in place to track adverse events, including with the Everlywell COVID-19 Test Home Collection Kit, including any occurrence of false results with your product and report 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).

Q. You must evaluate the impact of SARS-CoV-2 viral mutations on your product's performance. Such evaluations must occur on an ongoing basis and must include any additional data analysis that is requested by FDA in response to any performance concerns you or FDA identify during routine evaluation. Additionally, if requested by FDA, you must submit records of these evaluations for FDA review within 48 hours of the request. If your evaluation identifies viral mutations that affect the stated expected performance of your device, you must notify FDA immediately (via email: CDRH-EUA-Reporting@fda.hhs.gov).

R. If requested by FDA, you must update your labeling within 7 calendar days to include any additional labeling risk mitigations identified by FDA regarding the impact of viral mutations on test performance. Such updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

Authorized Laboratories

S. 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.

T. Authorized laboratories using your product must use your product as outlined in the authorized labeling. 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.

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

V. 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.

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

W. Authorized laboratories testing anterior nasal swab specimens self-collected using the Everlywell COVID-19 Test Home Collection Kit must be laboratories designated by Everlywell, Inc. and follow the "Receiving and Processing Everlywell Samples" standard operating procedure when accepting specimens for testing.

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 (1-800-955-6288 or techservices@thermofisher.com) 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.

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

Z. You, authorized distributor(s) 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 material 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 meet the requirements set forth in section 502(a), (q)(1), and (r) of the Act, as applicable, and FDA implementing regulations.

BB. No descriptive printed matter, advertising or promotional material 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 material relating to the use of your product shall clearly and conspicuously state that:

- This product 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 product 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 product 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 Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-

3(b)(1), unless the declaration is terminated or the 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,

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Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration

Enclosure