December 14, 2021

Michael J. Wagner Esq.
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Quest Diagnostics Incorporated
33608 Ortega Highway
San Juan Capistrano, CA 92675

Device:	Quest Diagnostics RC COVID-19 +Flu RT-PCR
Laboratory:	Quest Diagnostics Nichols Institute ("Quest Diagnostics")
Indication:	Simultaneous qualitative detection and differentiation of nucleic acid from SARS-CoV-2, influenza A virus and/or influenza B virus in nasal swab specimens self-collected at home, using the Quest Diagnostics Self-Collection Kit for COVID-19 +Flu, by individuals suspected of respiratory viral infection consistent with COVID-19 when home collection is determined to be appropriate by a healthcare provider. Emergency use of this test is limited to authorized laboratories.
Authorized Laboratories:	Testing is limited to laboratories designated by Quest Diagnostics that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet the requirements to perform high complexity tests.

Dear Mr.Wagner:

On December 4, 2020, based on a request form Quest Diagnostics Infectious Disease, Inc., the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of the Quest Diagnostics RC COVID-19 +Flu RT-PCR, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3) for the indication stated in the letter.[1] On September 23, 2021, FDA established additional Conditions of Authorization in response to the continued emergence of new variants of SARS-CoV-2.[2]

[1] The Quest Diagnostics RC COVID-19 +Flu RT-PCR was authorized for the simultaneous qualitative detection and differentiation of nucleic acid from SARS-CoV-2, influenza A virus and/or influenza B virus in nasal swab specimens self-collected at home, using the Quest Diagnostics Self-Collection Kit for COVID-19 +Flu, by individuals suspected of respiratory viral infection consistent with COVID-19 when home collection is determined to be appropriate by a healthcare provider. Testing was limited to laboratories designated by Quest Diagnostics that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet the requirements to perform high complexity tests.

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

On November 8, 2021, FDA received a request to further amend the EUA. Based on that request, and having concluded that revising the December 4, 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, to you,[3] the December 4, 2020, letter in its entirety with the revisions incorporated.[4] 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[5] 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.[6]

There is an FDA-approved/cleared test for the qualitative detection and identification of SARS-CoV-2, influenza A virus and influenza B virus, along with some other organism types and subtypes not targeted by your product, but this is not an adequate and available alternative to your product. Respiratory viral infections caused by the influenza A and B viruses and SARS-CoV-2 can have similar clinical presentation and diagnostic considerations. Thus, to differentially detect SARS-CoV-2, information from a test that detects and differentiates the virus that causes COVID-19 and the common influenza viruses that cause seasonal epidemics of flu, influenza A and B (not influenza C), is needed during the flu season that coincides with the COVID-19 pandemic.

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 EUA Summary (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 of this letter (Section II), subject to the terms of this authorization.

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[3] For ease of reference, this letter will use the term "you" and related terms to refer to Quest Diagnostics Nichols Institute ("Quest Diagnostics"), a subsidiary of Quest Diagnostics Incorporated.

[4] The revisions to the December 4, 2020, letter and authorized labeling include: (1) update the EUA holder name from Quest Diagnostics Infectious Disease, Inc. to Quest Diagnostics Nichols Institute, (2) update the authorized labeling to fulfill Condition of Authorization (1) in the Viral Mutation Revision Letter – September 23, 2021, (3) update the Quest Diagnostics Self-Collection Kit for COVID-19 +Flu Quick Guide, Standard Operating Procedures (SOP) bundle, Fact Sheets for Healthcare Providers and Fact Sheet for Patients to reflect language used in more recent authorizations, (4) update the letter to add Conditions of Authorization (2) and (3) from the Viral Mutation Revision Letter – September 23, 2021 (conditions K. and L. below), and (5) delete Condition of Authorization N. from the December 4, 2020 letter, that was fulfilled.

[5] For ease of reference, this letter will use the term "your product" to refer to the Quest Diagnostics RC COVID-19 +Flu RT-PCR used for the indication identified above.

[6] 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. 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:

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 through the simultaneous detection and differentiation of SARS-CoV-2, influenza A virus, and/or influenza B virus nucleic acids, and that the known and potential benefits of your product when used for such a use, 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.[7]

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 for the simultaneous qualitative detection and differentiation of nucleic acid from SARS-CoV-2, influenza A virus and/or influenza B virus in nasal swab specimens self-collected at home, using the Quest Diagnostics Self-Collection Kit for COVID-19 +Flu by individuals suspected of respiratory viral infection consistent with COVID-19 when home collection is determined to be appropriate by a healthcare provider. Home self-collection is intended for individuals 18 years of age and older.

Results are for use as an aid in the differential diagnosis of SARS-CoV-2, influenza A, and influenza B in humans, and is not intended to detect influenza C. RNA from SARS-CoV-2, influenza A, and influenza B are generally detectable in nasal swabs during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2, influenza A virus, and/or influenza B virus 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. Negative results do not preclude SARS-CoV-2, influenza A, and/or influenza B 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. Specimens that are self-collected will not be tested with an internal control to confirm that the specimen was properly collected. Self-collected specimens from SARS-CoV-2, influenza A, and/or influenza B positive individuals may yield negative results if the specimen was not collected properly.

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

Your product uses an integrated nucleic acid testing system that fully automates all steps necessary to perform specimen processing through amplification, detection, and data interpretation. The assay incorporates an internal control, positive control and negative control, or other authorized control materials (as may be requested under Condition I. below), to monitor nucleic acid capture, amplification, and detection, as well as operator or instrument error. All controls must generate expected results in order for a test to be considered valid, as outlined in the authorized labeling (described below).

The product uses all commercially sourced materials or other authorized materials and authorized ancillary reagents commonly used in clinical laboratories as described in the authorized labeling.

When using the Quest Diagnostics Self-Collection Kit for COVID-19 +Flu, individuals must follow all specimen collection and mailing instructions provided with the home-collection kit, as described in the "Quest Diagnostics Self-Collection Kit for COVID-19 + Flu Quick Guide."

The above described product is authorized to be accompanied with laboratory procedures (described below), the "Quest Diagnostics Self-Collection Kit for COVID-19 +Flu Quick Guide" and the EUA Summary (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 information pertaining to the emergency use, which is required to be made available to healthcare providers and patients:

- Fact Sheet for Healthcare Providers: Quest Diagnostics - Quest Diagnostics RC COVID-19 +Flu RT-PCR
- Fact Sheet for Patients: Quest Diagnostics - Quest Diagnostics RC COVID-19 +Flu RT-PCR.

The above described product, when accompanied by the "Quest Diagnostics Self-Collection Kit for COVID-19 +Flu Quick Guide," the Standard Operating Procedures (SOP) bundle for the Quest Diagnostics RC COVID-19 +Flu assay, the EUA Summary (identified above) and the two Fact Sheets (collectively referenced as "authorized labeling") is authorized to be distributed and used 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 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, distribution and storage of your product.

IV. Conditions of Authorization

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

Quest Diagnostics (You)

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 will inform other 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.

C. You will make your product available with the authorized labeling to authorized laboratories.

D. You will require that entities[8] using your product acknowledge receipt of the following disclosure "*Specimens that are self-collected will not be tested with an internal control to confirm that the specimen was properly collected. Self-collected specimens from SARS-CoV-2, influenza A, and/or influenza B positive individuals may yield negative results if the specimen was not collected properly*" that authorized laboratories must also include in test reports as required by Condition S below.

[8] As used in this condition, "entities" refers to any organization that contracts with you to conduct testing (i.e., employers who are doing back-to-work testing, universities, hospitals, healthcare systems, etc.).

E. You will ensure that the authorized laboratories using your product have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

F. You will make available on your website(s), if applicable, the Fact Sheet for Healthcare Providers, the Fact Sheet for Patients, and the Quest Diagnostics Self-Collection Kit for COVID-19 +Flu Quick Guide.

G. You will maintain records of the authorized laboratories and test usage.

H. You 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.

I. 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. Such requests 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.

J. You will evaluate the analytical limit of detection and assess traceability of your product with any FDA-recommended reference material(s), if requested by FDA[9]. After submission to FDA and DMD/OHT7-OIR/OPEQ/CDRH's review of and concurrence with the data, FDA will update the EUA summary to reflect the additional testing. Such updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

K. 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).

L. 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.

[9] Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material. FDA may request, for example, that you perform this study in the event that we receive reports of adverse events concerning your product.

M. You will track adverse events, including any occurrence of false results with your product and report any such events to FDA pursuant to 21 CFR Part 803.

N. You will additionally track adverse events associated with the Quest Diagnostics Self-Collection Kit for COVID-19 +Flu, including occurrences of false results and report to FDA in accordance with 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).

O. You must include the Quest Diagnostics Self-Collection Kit for COVID-19 +Flu Quick Guide with the physical kit and make it available on your website.

Quest Diagnostics (You) and Other Authorized Laboratories

P. You and other authorized laboratories using your product will 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.

Q. You and other authorized laboratories using your product will 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 home specimen collection kits, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.

R. You and other authorized laboratories testing authorized specimens self-collected using the Quest Diagnostics Self-collection Kit for COVID-19 +Flu must follow any specimens accessioning protocol provided with the self-collection kit and/or outlined in the authorized labeling when accepting specimens for testing.

S. Authorized laboratories testing authorized self-collected specimens with your product must include in the test report the following limitation: "*Specimens that are self-collected will not be tested with an internal control to confirm that the specimen was properly collected. Self-collected specimens from SARS-CoV-2, influenza A, and/or influenza B positive individuals may yield negative results if the specimen was not collected properly.*"

T. You and other authorized laboratories using your product must include in the test report the following warning: "*Results (positive and negative) for influenza should be interpreted with caution. If an influenza result is inconsistent with clinical presentation and/or other clinical and epidemiological information, FDA-cleared Influenza NAATs are available for confirmation if clinically indicated*."

U. You and other authorized laboratories that receive your product will notify the relevant

public health authorities of their intent to run your product prior to initiating testing.

V. You and other authorized laboratories using your product will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

W. You and other authorized laboratories will collect information on the performance of your product. You will report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and you (michael.j.wagner@questdiagnostics.com) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which you become aware.

X. All laboratory personnel using your product must be appropriately trained in molecular techniques and use appropriate laboratory and personal protective equipment when handling this product and use your product in accordance with the authorized laboratory procedure.

Y. You and other 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 Printed Materials, Advertising and Promotion

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

AA. 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.

BB. All descriptive printed matter, advertising and promotional materials 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, influenza A virus, and influenza B virus, and 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 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