

March 21, 2022

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

Device: Quest COVID-19 PCR DTC

EUA Number: EUA220033

Company: Quest Diagnostics Nichols Institute (“Quest Diagnostics”)

Indication: A direct to consumer product intended for the qualitative detection of nucleic acids from SARS-CoV-2 in anterior nasal swab specimens collected using the Quest COVID-19 PCR Test Home Collection Kit when used consistent with its authorization by any individual, including individuals without symptoms or other reasons to suspect COVID-19.

This test is also intended for the qualitative detection of nucleic acids from SARS-CoV-2 in pooled samples containing up to four individual anterior nasal swab specimens collected using the Quest COVID-19 PCR Test Home Collection Kit when used consistent with its authorization by any individual, including individuals without symptoms or other reasons to suspect COVID-19.

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:

This letter is in response to your¹ request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of your product,² pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).

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

¹ 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.

² For ease of reference, this letter will use the term “your product” to refer to the Quest COVID-19 PCR DTC used for the indication identified above.

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.³

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 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.

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, and that the known and potential benefits of your product when used for diagnosing COVID-19, outweigh the known and potential risks of your product; and
3. There is no adequate, approved, and available alternative to the emergency use of your product.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 indication above.

Authorized Product Details

Your product is a direct to consumer product intended for the qualitative detection of nucleic acids from SARS-CoV-2 in anterior nasal swab specimens collected using the Quest COVID-19 PCR Test Home Collection Kit when used consistent with its authorization by any individual, including individuals without symptoms or other reasons to suspect COVID-19. Your product is

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. 85 FR 7316 (February 7, 2020).

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

also intended for the qualitative detection of nucleic acids from SARS-CoV-2 in pooled samples containing up to four individual anterior nasal swab specimens collected using the Quest COVID-19 PCR Test Home Collection Kit when used consistent with its authorization by any individual, including individuals without symptoms or other reasons to suspect COVID-19.

Testing of collected anterior nasal swab specimens 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.

Results are for the identification of SARS-CoV-2 viral RNA. SARS-CoV-2 RNA is generally detectable in anterior nasal swab 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.

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. Specimens collected at home from SARS-CoV-2 positive individuals may yield negative results if the specimen was not collected properly. Negative results from pooled testing should not be treated as definitive. If a patient’s clinical signs and symptoms are inconsistent with a negative result or if results are necessary for patient management, then the patient should be considered for individual testing. Specimens included in pools with a positive or invalid result must be tested individually prior to reporting a result. Specimens with low viral loads may not be detected in sample pools due to the decreased sensitivity of pooled testing.

Use of your product is not a substitute for visits to a healthcare provider. The information provided by this product should not be used to start, stop, or change any course of treatment unless advised by your healthcare provider.

To use your product, SARS-CoV-2 nucleic acid is first extracted, isolated and purified from anterior nasal swab specimens. The purified nucleic acid is then reverse transcribed into cDNA followed by PCR amplification and detection using an authorized real-time (RT) PCR instrument and authorized software. Your product includes the materials (or other authorized materials as may be requested under Condition H below) described in the authorized labeling (described below). Your product requires control materials (or other authorized control materials as may be requested under Condition H below) that are described in the authorized labeling (described below). 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 authorized labeling (described below).

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>), the “SARS-CoV-2 RNA, Qualitative Real-Time RT-PCR Package Insert”, and the following fact sheets pertaining to the emergency use, are required to be made available as set forth in the Conditions of Authorization (Section IV), and are collectively referred to as “authorized

labeling”:

- Fact Sheet for Healthcare Providers: Quest Diagnostics - Quest COVID-19 PCR DTC
- Fact Sheet for Individuals: Quest Diagnostics - Quest COVID-19 PCR DTC

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 consistent with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of your product.

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

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

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

III. Waiver of Certain Requirements

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

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

IV. Conditions of Authorization

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

authorization:

Quest Diagnostics (You)

- A. Your product must comply with the following labeling requirements pursuant to 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 must make your product available with the authorized labeling to authorized laboratories.
- C. You must make available on your website(s), the authorized fact sheets.
- D. You 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.
- E. You must 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. You must also ensure that authorized laboratories using your product have a process in place for providing test results via the agreed upon process as authorized by the Quest COVID-19 PCR Test Home Collection Kit.
- F. You must maintain records of the laboratories you designate as authorized laboratories and you must also maintain records of test usage by all such authorized laboratories.
- G. 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.
- H. 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. 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.
- I. You must collect information on the performance of your product. You must report to FDA 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.
- J. You must evaluate the analytical limit of detection and assess traceability of your

product with any FDA-recommended reference material(s), if requested by FDA.⁵ After submission to and review of and concurrence with the data, FDA will update the EUA Summary to reflect the additional testing.

- K. You must have a process in place to track adverse events, including any occurrence of false results with your product, including with the Quest COVID-19 PCR Test Home Collection Kit, 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-EUAREporting@fda.hhs.gov).
- L. 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).
- M. 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.
- N. You must evaluate the clinical performance of your product to support the screening claim in an FDA agreed upon post authorization clinical evaluation study within 6 months of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH). After submission to and concurrence with the data by FDA, you must update the authorized labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

Authorized Laboratories

- O. 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.
- P. 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.

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

- Q. Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product.
- R. 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.
- S. 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 (via email: 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 they become aware.
- T. All laboratory personnel using your product must be appropriately trained in PCR techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.
- U. Authorized laboratories testing authorized specimens collected using the Quest COVID-19 PCR Test Home Collection Kit must follow the “Unobserved Collected Sample Processing for COVID-19 Molecular Testing” standard operating procedure when accepting specimens for testing.
- V. Authorized laboratories testing authorized specimens collected using the Quest COVID-19 PCR Test Home Collection Kit must include in the test report for specific patients whose specimen(s) were collected without observation the following limitation:
“Specimens that are collected using the Quest COVID-19 PCR Test Home Collection Kit were not tested with an internal control to confirm that the specimen was properly collected. As such, unobserved collected specimens using the Quest COVID-19 PCR Test Home Collection Kit from SARS-CoV-2 positive individuals may yield negative results if the specimen was not collected properly.”
- W. Authorized laboratories using specimen pooling strategies when testing patient specimens with your product must include with negative test result reports for specific patients whose specimen(s) were the subject of pooling, a notice that pooling was used during testing and that *“Patient specimens with low viral loads may not be detected in sample pools due to the decreased sensitivity of pooled testing.”*
- X. Authorized laboratories implementing pooling strategies for testing patient specimens must use the “Protocol for Monitoring of Specimen Pooling Testing Strategies” recommendations available in the authorized labeling to evaluate the appropriateness of continuing to use such strategies based on the recommendations in the protocol.
- Y. Authorized laboratories must keep records of specimen pooling strategies implemented including type of strategy, date implemented, and quantities tested, and test result data generated as part of the “Protocol for Monitoring of Specimen Pooling Testing Strategies”. For the first 12 months from the date of their creation, such records must be

made available to FDA within 48 business hours for inspection upon request, and must be made available within a reasonable time after 12 months from the date of their creation.

Quest Diagnostics (You) and Authorized Laboratories

- Z. You and authorized laboratories using your product must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records must be made available to FDA for inspection upon request.

Conditions Related to Printed Materials, Advertising and Promotion

- AA. All descriptive printed matter, advertising and promotional materials relating to the use of your product shall be consistent with the authorized labeling, as well as the terms set forth in this EUA and 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 materials relating to the use of your product may represent or suggest that this test is safe or effective for the detection of SARS-CoV-2.
- CC. All descriptive printed matter, advertising and promotional materials relating to the use of your product shall clearly and conspicuously state that:
- This 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 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,

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

Enclosure⁶

⁶ Technical Correction on March 23, 2022, to add Condition N. to the letter.