



December 14, 2021

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

Device:	Quest Diagnostics PF SARS-CoV-2 Assay
EUA Number:	EUA201701
Company:	Quest Diagnostics Nichols Institute (“Quest Diagnostics”)
Indication:	Qualitative detection of nucleic acid from SARS-CoV-2 in anterior nasal swab specimens collected using the Quest Diagnostics Collection Kit for COVID-19 when used consistent with its authorization.
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 July 15, 2020, based on a request from Quest Diagnostics Infectious Disease, Inc., the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of the Quest Diagnostics PF SARS-CoV-2 Assay, 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

Based on subsequent requests, FDA reissued the letter in its entirety with revisions incorporated on August 21, 2020 and October 8, 2021.^{2,3} In addition, FDA established additional Conditions

¹ The Quest Diagnostics PF SARS-CoV-2 Assay was authorized for the qualitative detection of nucleic acid from SARS-CoV-2 in nasal swab specimens self-collected at home observed under healthcare provider (HCP) supervision via telemedicine, using the Quest Diagnostics Self-Collection Kit for COVID-19, or other authorized home-collection kit specified in this EUA’s authorized labeling, by individuals suspected of COVID-19 when home collection is determined to be appropriate by a healthcare provider, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3). Testing was limited to laboratories designated by Quest Diagnostics that were certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and met the requirements to perform high complexity tests.

² On August 21, 2020, the revisions to the July 15, 2020, letter and authorized labeling included: (1) removed the requirement for “*observed under healthcare provider (HCP) supervision via telemedicine*” for nasal swab specimens self-collected at home, (2) updated labeling documents to remove the requirement for observed collection of nasal

of Authorization in response to the continued emergence of new variants of SARS-CoV-2 on September 23, 2021.⁴

On November 8, 2021, FDA received a request to further amend the EUA. Based on that request, and having concluded that revising the October 8, 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, to you,⁵ the October 8, 2021, letter in its entirety with the revisions incorporated.⁶ 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 product⁷ is now intended for the indications 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.⁸

swab specimens self-collected at home, (3) added Conditions of Authorization specific to unobserved nasal swab specimens self-collected at home when used in combination with a authorized test that does not have a human specimen adequacy internal control, such as RNase P; and, (4) updated healthcare provider and patient fact sheets to include some additional warnings/precautions around the unobserved collection of nasal swab specimens self-collected at home when used in combination with the Quest Diagnostics PF SARS-CoV-2 Assay that does not have a human specimen adequacy internal control, such as RNase P. As described in the EUA Summary, information submitted included a study on nasal swab specimens (n = 37,084) that were self-collected using the Quest Diagnostics Self-Collection Kit for COVID-19 without observation demonstrating that, based on RNase P testing, nearly all participants were able to self-collect an adequate nasal swab specimen without observation.

³ On October 8, 2021, the revisions to the August 21, 2020, letter and authorized labeling included: (1) updating the intended use and authorized labeling with respect to anterior nasal swab specimens collected using the Quest Diagnostics Collection Kit for COVID-19 when used consistent with its authorization, (2) clarifying anterior nares as anterior nasal in the intended use and authorized labeling, (3) updating authorized labeling to fulfill Condition of Authorized (1) in the Viral Mutation Revision Letter – September 23, 2021, (4) updating the performance section of the EUA Summary to remove data from the Quest Diagnostics Collection Kit for COVID-19 which has a standalone EUA, (5) updating the Fact Sheets for Healthcare Providers and Patients to reflect language used in more recent authorizations, (6) updating to add Conditions of Authorization (2) and (3) from the Viral Mutation Revision Letter – September 23, 2021 (J and K below), and (7) updating the Conditions of Authorization, including consolidation of several conditions in H, updating based on the revised intended use and to reflect language used in more recent letters of authorization.

⁴ The Viral Mutation Revision Letter – September 23, 2021 can be accessed at:

<https://www.fda.gov/media/152406/download>.

⁵ 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.

⁶ The revisions to the October 8, 2021, letter and authorized labeling are to update the EUA holder name from Quest Diagnostics Infectious Disease, Inc. to Quest Diagnostics Nichols Institute and include some minor updates to the Fact Sheet for Healthcare Providers and Fact Sheet for Patients to reflect language used in more recent authorizations.

⁷ For ease of reference, this letter will use the term “your product” to refer to the Quest Diagnostics PF SARS-CoV-2 Assay used for the indications identified above.

⁸ 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*

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 Section 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.⁹

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 qualitative detection of nucleic acid from SARS-CoV-2 in anterior nasal swab specimens collected using the Quest Diagnostics Collection Kit for COVID-19 when used consistent with its authorization.

Use of this test is limited to laboratories designated by Quest Diagnostics that are certified under CLIA and meet the requirements to perform high complexity tests.

The SARS-CoV-2 nucleic acid 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 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. 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

Cosmetic Act, 21 U.S.C. § 360bbb-3. 85 FR 7316 (February 7, 2020).

⁹ No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

combined with clinical observations, patient history, and epidemiological information. Specimens that are collected will not be tested with an internal control to confirm that the specimen was properly collected. Collected specimens from SARS-CoV-2 positive individuals may yield negative results if the specimen was not collected properly.

Your product is used for detection of SARS-CoV-2 nucleic acid and 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 H. 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).

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.

The above described product is authorized to be accompanied with the labeling submitted as part of the EUA request (described below), and 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 product-specific 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 PF SARS-CoV-2 Assay
- Fact Sheet for Patients: Quest Diagnostics - Quest Diagnostics PF SARS-CoV-2 Assay

The above described product, when accompanied by the EUA Summary, Fact Sheet for Healthcare Providers, Fact Sheet for Patients and the Standard Operating Procedures (SOP) bundle for the Quest Diagnostics PF SARS-CoV-2 Assay (collectively referenced as “authorized labeling”) is authorized to be distributed to and used by authorized laboratories, 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.

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 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.
- C. You must make your product available with the authorized labeling to authorized laboratories.
- D. You must make available on your website(s) the authorized fact sheets.
- 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.
- 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 evaluate the analytical limit of detection and assess traceability of your product with any FDA-recommended reference material(s), if requested by FDA.¹⁰ After submission to and concurrence of the data by FDA, FDA will update the EUA summary to reflect the additional testing.
- J. 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).
- K. 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.
- L. You must have a process in place to track adverse events, including with the Quest Diagnostics Collection Kit for COVID-19 including any occurrences of false results with your product and report any such events to FDA under 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).

Authorized Laboratories

- M. 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.

¹⁰ 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.

- N. 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 home specimen collection kits, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.
- O. Authorized laboratories testing authorized specimens collected using the Quest Diagnostics Collection Kit for COVID-19 with your product must follow the Quest Diagnostics’ “Unobserved Collected Sample Processing for COVID-19 Molecular Testing” Non-Technical Standard Operating Procedure (SOP), when accepting specimens for testing.
- P. Authorized laboratories testing authorized specimens collected using the Quest Diagnostics Collection Kit for COVID-19 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 Diagnostics Collection Kit for COVID-19 were not tested with an internal control to confirm that the specimen was properly collected. As such, unobserved collected specimens using the Quest Diagnostics Collection Kit for COVID-19 from SARS-CoV-2 positive individuals may yield negative results if the specimen was not collected properly.”*
- Q. Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- 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 (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.

Quest Diagnostics (You) and Authorized Laboratories

- U. You and authorized laboratories must ensure that any records associated with this EUA, including test usage, 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

- V. 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.
- W. 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.
- X. 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 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 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

Enclosure