

August 21, 2020

Michael J. Wagner
Senior Corporate Counsel
Quest Diagnostics Infectious Disease, Inc.
33608 Ortega Highway Bldg B-West Wing
San Juan Capistrano, CA 92675

Device: Quest Diagnostics HA SARS-CoV-2 Assay

Company: Quest Diagnostics Infectious Disease, Inc. (“Quest Diagnostics”)

Indication: Qualitative detection of nucleic acid from SARS-CoV-2 in nasal swab specimens self-collected at home , 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.

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 your¹ request, the Food and Drug Administration (FDA) issued a letter authorizing the emergency use of your product² 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 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.

¹ For ease of reference, this letter will use the term “you” and related terms to refer to Quest Diagnostics Infectious Disease, Inc. (“Quest Diagnostics”).

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

On July 31, 2020, you requested to revise your Emergency Use Authorization (EUA). Based on that request, and having concluded that revising the July 15, 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 the July 15, 2020, letter in its entirety with the revisions incorporated.³ Pursuant to section 564 of the Act and the Scope of Authorization (Section II) and Conditions of Authorization (Section IV) of this reissued letter, this test 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.⁴

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 The revisions to the July 15, 2020, letter include: (1) removal of 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 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 HA 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.

⁴ 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).

3. There is no adequate, approved, and available alternative to the emergency use of your product.⁵

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 nasal swab specimens self-collected at home using the Quest Diagnostics Self-Collection Kit for COVID-19, or other authorized home-collection kit, by individuals suspected of COVID-19 when home collection is determined to be appropriate by a healthcare provider.

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 Quest Diagnostics Self-collection Kit for COVID-19, or other authorized home-collection kit, will provide specimen collection materials so that individuals can safely mail specimens to an authorized laboratory for testing using the Quest Diagnostics HA SARS-CoV-2 Assay.

The SARS-CoV-2 nucleic acid is generally detectable in 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 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 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 specified under Condition O 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 (described below).

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

⁵ No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

in the “Quest Diagnostics Observed Self-Collection Kit for COVID-19 Quick Guide.”

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/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 HA SARS-CoV-2 Assay
- Fact Sheet for Patients: Quest Diagnostics - Quest Diagnostics HA SARS-CoV-2 Assay

The above described product, when accompanied by the EUA Summary, Fact Sheet for Healthcare Providers, Fact Sheet for Patients, “Quest Diagnostics Self-Collection Kit for COVID-19 Quick Guide,” and the Standard Operating Procedures (SOP) bundle for the Quest Diagnostics HA SARS-CoV-2 Assay (collectively referenced as “authorized labeling”) is authorized to be distributed to and used by laboratories designated by Quest Diagnostics, 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 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 authorized labeling.
- C. You will make your product available with the authorized labeling to authorized laboratories.
- D. You will require that entities⁶ using the Quest Diagnostics Self-collection Kit for COVID-19, or any other authorized home specimen collection kit authorized for use with your product to test authorized specimens, 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. As such, unobserved self-collected specimens from SARS-CoV-2 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 Z below.
- E. You will make available on your website(s), if applicable, the Fact Sheet for Healthcare Providers, the Fact Sheet for Patients, the Quest Diagnostics Observed Self-Collection Kit for COVID-19 Quick Guide, and any other home specimen collection kit instructions authorized for use with your product (refer to Condition Q below).
- F. 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.

⁶ As used in this condition, "entities" refers to any organization that contract with you to conduct testing (i.e., employers who are doing back to work testing, universities, hospitals, healthcare systems, etc.).

- 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 the Scope of Authorization (Section II in this letter) of your authorized test. Such requests will be made in consultation with 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 concurrence of, Office of Counterterrorism and Emerging Threats (OCET)/Office of the Chief Scientist (OCS)/Office of the Commissioner (OC) and DMD/OHT7-OIR/OPEQ/CDRH.
- J. You may request changes to the authorized labeling. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- K. You may request the addition of other instruments and associated software for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- L. You may request the addition of other extraction methods for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- M. You may request the addition of other specimen types for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- N. You may request the addition and/or substitution of primers or probes for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- O. You may request the addition and/or substitution of control materials for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- P. You may request the addition and/or substitution of other ancillary reagents and materials for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- Q. You may request the addition and/or substitution of home specimen collection kits or kit components for use with the authorized Quest Diagnostics Self-Collection Kit for COVID-19. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

- R. 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.⁷ 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.
- S. 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.
- T. You will additionally track adverse events associated with the Quest Diagnostics Self-Collection Kit for COVID-19, or any other home specimen collection kit authorized for use with your product, including occurrences of false results and report 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).
- U. You will make available all instructions related to the self-collection of specimens using the Quest Diagnostics Self-Collection Kit for COVID-19, or any other home specimen collection kit authorized for use with your product, both in the distributed kit and on your website.
- V. You will submit to FDA a summary report within 30 calendar days of this letter summarizing the results of any testing performed using specimens collected with the Quest Diagnostics Self-Collection Kit for COVID-19 during that timeframe, including how many kits were requested and granted for home collection, how many kits were shipped and returned, how many specimens had to be rejected during accession and the main reasons for rejection, and the positivity rate of the Quest Diagnostics Self-Collection Kit for COVID-19 using your product.

Quest Diagnostics (You) and Other Authorized Laboratories

- W. 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.
- X. 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.

⁷ 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 authorized test.

- Y. You and other authorized laboratories when testing authorized specimens self-collected using home-collection kits authorized for use with your product you must follow any specimens accessioning protocol provided with the self-collection kit and/or outlined in the authorized labeling when accepting specimens for testing.
- Z. Authorized laboratories testing authorized specimens self-collected using the Quest Diagnostics Self-collection Kit for COVID-19, or any other authorized home specimen collection kit with your product, must include in the test report for specific patients whose specimen(s) were self-collected without observation the following limitation: *“Specimens that are self-collected were not tested with an internal control to confirm that the specimen was properly collected. As such, unobserved self-collected specimens from SARS-CoV-2 positive individuals may yield negative results if the specimen was not collected properly.”*
- AA. 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.
- BB. 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.
- CC. You and other authorized laboratories will 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.
- DD. 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.
- EE. You and other authorized laboratories will 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

- FF. All descriptive printed matter, including 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 the applicable requirements set forth in the Act and FDA regulations.
- GG. No descriptive printed matter, including 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.

HH. All descriptive printed matter, including advertising and promotional materials, relating to the use of your product shall clearly and conspicuously state that:

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an EUA for use by authorized laboratories;
- This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro 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 authorization is terminated or 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 is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosure