

March 10, 2023

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

Device: Quest COVID-19 Nucleic Acid Test Collection Kit

EUA Number: EUA220214

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

Indication: For the collection of anterior nares (nasal) swab specimens by any individual age 18 years or older (self-collected), 16 years and older (self-collected under adult supervision), or 2 years and older (collected with adult assistance), including individuals without symptoms or other reasons to suspect COVID-19 when determined to be appropriate by a healthcare provider, and is intended to be delivered as part of a testing program supported by an entity¹ designated by Quest Diagnostics.

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 requirements to perform high complexity tests and that test the specimens collected from the Quest COVID-19 Nucleic Acid Test Collection Kit with an in vitro diagnostic (IVD) molecular test that is indicated for use with the Quest COVID-19 Nucleic Acid Test Collection Kit when used consistent with its authorization.

Dear Mr. Wagner:

This letter is in response to your² request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of your product,³ pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).

¹ For the purposes of this EUA “entity” refers to any organization that contracts with Quest Diagnostics Incorporated (or a majority owned affiliate) to conduct testing (for example employers who are doing back to work testing, universities, hospitals, healthcare systems, government agencies etc.) that operates a testing program that includes collection kit supply pick-up locations and specimen drop-off locations overseen by a healthcare provider.

² 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.

³ For ease of reference, this letter will use the term “your product” to refer to the Quest COVID-19 Nucleic Acid

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-19.⁴ Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared on March 24, 2020, that circumstances exist justifying the authorization of emergency use of medical devices during the COVID-19 outbreak, subject to the terms of any authorization issued under Section 564(a) of the Act.⁵

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.

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 by serving as an appropriate means to collect and transport human specimens so that an authorized laboratory can detect SARS-CoV-2 RNA from the collected human specimen, and that the known and potential benefits of your product when used for such 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.⁶

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.

Test Collection Kit, used for the indication identified above.

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).

⁵ U.S. Department of Health and Human Services, *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 17335 (March 27, 2020).

⁶ No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

Authorized Product Details

Your product is a collection kit intended for for the collection of anterior nasal swab specimens by any individual age 18 years or older (self-collected), 16 years and older (self- collected under adult supervision), or 2 years and older (collected with adult assistance), including individuals without symptoms or other reasons to suspect COVID-19 when determined to be appropriate by a healthcare provider. The Quest COVID-19 Nucleic Acid Test Collection Kit is intended to be delivered as part of a testing program supported by an entity designated by Quest Diagnostics.

Your product is available via different workflows, outline in the authorized labeling below, through an entity that is designated by Quest Diagnostics and operates a testing program that includes collection kit supply pick-up locations and specimen drop-off locations overseen by a healthcare provider. Collection kit supplies for your product are sent to the designated entity by authorized distributors where they are assembled and distributed to patients/adult caregiver, when determined to be appropriate by a healthcare provider, at the pick-up location. Individuals using your product, then collect the specimen according to the provided authorized sample collection instructions (summarized in the authorized labeling below) and return the specimen to the drop-off location, according to the specimen return instructions. Once the specimens are accepted by the drop-off location, arrangements are made to have them transferred to a laboratory designated by Quest Diagnostics for testing.

Anterior nasal swab specimens collected using your product are transported at ambient temperature for testing at an authorized laboratory. The SARS-CoV-2 nucleic acid from the anterior nasal swabs is maintained in the specimen packaging. 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 that meet requirements to perform high complexity tests and that test the specimens collected using your product with an in vitro diagnostic (IVD) molecular test that is indicated for use with the Quest COVID-19 Nucleic Acid Test Collection Kit.

The Quest COVID-19 Nucleic Acid Test Collection Kit provides specimen collection and storage materials or other authorized materials (as may be requested under Condition S. below) as well as instructions for returning the specimen to the drop-off location, as described in the “COVID-19 Nucleic Acid Test Collection Kit (Concierge)” and the “COVID-19 Nucleic Acid Test Collection Kit (Locker)” instructions for use.

The labeling entitled “COVID-19 Nucleic Acid Test Collection Kit (Concierge),” “COVID-19 Nucleic Acid Test Collection Kit (Locker),” 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 following standard operating procedure (SOP): “Unobserved Collected Sample Processing for COVID-19 Molecular Testing” Non-Technical SOP, and the documents provided to authorized entities as part of the contract provisions⁷ is required to be made available as set forth in the Conditions of Authorization

⁷ Documents provided by Quest Diagnostics to authorized entities (described in footnote 1) they designate to use the Quest COVID-19 Nucleic Acid Test Collection Kit, included as part of the contract provisions, include: “Quest Self-Collection Kits for COVID-19 Testing Programs Instructions for Use For Front-line Staff,” “Information for Providing Collection Materials to Patients (Locker Workflow),” “Information for Accepting Specimens via

(Section IV), and are collectively referred to as “authorized labeling.”

The above described product, when accompanied by the authorized labeling as set forth in the Conditions of Authorization (Section IV) 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 by serving as an appropriate means to collect and transport human specimens so that an authorized laboratory can detect SARS-CoV-2 RNA from the collected human specimen 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

Specimen Drop-off Box (Locker Workflow),” “Information for Providing Collection Materials to Patients (Concierge Workflow),” and “Information for Accepting Specimens via Specimen Drop-off Box (Concierge Workflow).”

authorization:

Quest Diagnostics (You) and Authorized Distributor(s)⁸

- 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 and authorized distributor(s) must make available to authorized entities using the Quest COVID-19 Nucleic Acid Test Collection Kit all instructions related to the collection of anterior nasal swab specimens (i.e., the “COVID-19 Nucleic Acid Test Collection Kit (Concierge),” and/or the “COVID-19 Nucleic Acid Test Collection Kit (Locker)”) either electronically for bulk supplies or packaged within the convenience packs kit or the partially assembled packs, and make available all instructions on your website(s).
- C. You and authorized distributor(s) must inform authorized laboratories, authorized entities and relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to your product, or the authorized labeling.
- D. Through a process of inventory control, you and authorized distributor(s) must maintain records of the numbers and locations to which your product is distributed.
- E. You and authorized distributor(s) must maintain customer complaint files on record. You will report to FDA any significant complaints about usability or deviations from the established performance characteristics of the product of which you become aware.
- F. You and authorized distributor(s) are authorized to make available additional information relating to the emergency use of your product that is consistent with, and does not exceed, the terms of this letter of authorization.
- G. You and authorized distributors must have lot release procedures and the lot release procedures, including the study design and statistical power, must ensure that the tests released for distribution have the performance claimed in the authorized labeling.
- H. If requested by FDA, you and authorized distributors must submit lot release procedures to FDA, including sampling protocols, testing protocols, and acceptance criteria, that you use to release lots of the Quest COVID-19 Nucleic Acid Test Collection Kit for distribution in the U.S. If such lot release procedures are requested by FDA, you must provide it within 48 hours of the request.

⁸ “Authorized Distributor(s)” are identified by you, Quest Diagnostics, in your EUA submission as an entity allowed to distribute the Quest COVID-19 Nucleic Acid Test Collection Kit supplies to authorized entities (as described in Footnote 1) that are designated by Quest Diagnostics.

- I. You must comply with the following requirements pursuant to FDA regulations: 21 CFR 820 Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

Quest Diagnostics (You)

- J. You must notify FDA of any authorized distributor(s) of your product, including the name, address, and phone number of any authorized distributor(s).
- K. You must notify FDA of any authorized laboratories designated by Quest Diagnostics to use your product, including the name, address, and phone number of any authorized laboratories.
- L. You must keep records of any authorized entities designated by Quest Diagnostics to use your product and must make such records available to FDA within 5 business days for inspection upon request.
- M. You must have a process in place to designate authorized entities to use your product that ensures the use of your product by the authorized entity under this EUA is 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).
- N. You will require that entities using the Quest COVID-19 Nucleic Acid Test Collection Kit acknowledge receipt of the following disclosure *“Specimens that are collected using the Quest COVID-19 Nucleic Acid Test 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 Nucleic Acid Test Collection Kit 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 Y. below.
- O. You must provide authorized distributor(s), authorized entities and authorized laboratories with a copy of this EUA and communicate any subsequent revisions that might be made to this EUA and its authorized accompanying materials.
- P. You must provide authorized laboratories with a copy of the “Unobserved Collected Sample Processing for COVID-19 Molecular Testing” Non-Technical Standard Operating Procedure (SOP).
- Q. You must provide authorized entities using your product with copies of the authorized labeling (described in footnote 7) included as part of the contract provisions in the signed customer service agreement (described in footnote 1).

- R. 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 requests 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/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH) and require appropriate authorization from FDA prior to implementation.
- S. You must have a process in place to track adverse events associated with the Quest COVID-19 Nucleic Acid Test Collection Kit, including any occurrences of false results with your product, and report any such events to FDA pursuant to 21 CFR Part 803. Serious adverse events, especially unexpected biosafety concerns, should immediately be reported to DMD/OHT7/OPEQ/CDRH (via email: CDRH-EUAREporting@fda.hhs.gov).
- T. You must submit to FDA a summary report summarizing the results of testing performed using anterior nasal swab specimens collected with the Quest COVID-19 Nucleic Acid Test Collection Kit using the reporting parameters agreed upon by FDA to sufficiently assess updates made to the Quest COVID-19 Nucleic Acid Test Collection Kit. The summary report should be stratified by age group and kit option (Concierge or Locker) including how many kits were requested and sent for specimen collection to individuals, how many kits were distributed and returned according to the instructions, how many specimens had to be rejected during accession and the main reasons for rejection, and the positivity rate.

Authorized Entities

- U. Authorized entities using your product must have processes in place and oversee use of your product to ensure that your product is used as outlined in the authorized labeling and in the entity’s signed customer service agreement with Quest Diagnostics.
- V. Authorized entities must report significant customer complaints about the usability of your product of which they become aware to DMD/OHT7/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and you (michael.j.wagner@questdiagnostics.com).

Authorized Laboratories

- W. Authorized laboratories testing anterior nasal swab specimens collected using your product must follow the “Unobserved Collected Sample Processing for COVID-19 Molecular Testing” Non-Technical Standard Operating Procedure (SOP) when accepting specimens for testing.
- X. Authorized laboratories using your product must use it only in conjunction with COVID-19 in vitro diagnostic (IVD) molecular tests that are indicated for use with your product.

- Y. Authorized laboratories testing authorized specimens collected using your product must include in the test report the following limitation: *“Specimens that are collected using the Quest COVID-19 Nucleic Acid Test 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 Nucleic Acid Test Collection Kit from SARS-CoV-2 positive individuals may yield negative results if the specimen was not collected properly.”*
- Z. Authorized laboratories must collect information on the performance of your product and report to DMD/OHT7/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.

Quest Diagnostics (You), Authorized Distributor(s), Authorized Entities and Authorized Laboratories

- AA. You, authorized distributor(s), authorized entities and authorized laboratories using your product must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

Conditions Related to Printed Materials, Advertising and Promotion

- BB. 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 the requirements set forth in section 502(a), (q)(1), and (r) of the Act, as applicable, and FDA implementing regulations.
- CC. 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.
- DD. 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;
 - This product has been authorized only for the collection and maintenance of anterior nasal swab specimens as an aid in 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 medical devices 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 medical devices during the COVID-19 outbreak is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

Jeffrey E. Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health
Food and Drug Administration

Enclosure