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 Test Home Collection Kit
EUA Number:	EUA220010
Company:	Quest Diagnostics Nichols Institute ("Quest Diagnostics")
Indication:	A direct to consumer (DTC) product for collecting an anterior nasal swab (nasal) specimen at home (which includes in a community-based setting), from individuals age 18 years and older (self-collected), 16 years and older (self- collected under adult supervision), or 2 years and older (collected with adult assistance) that is sent for testing with an in vitro diagnostic (IVD) molecular test that is indicated for use with the Quest COVID-19 PCR Test Home Collection Kit, and the IVD is indicated for testing any individuals, including individuals without symptoms or other reasons to suspect COVID-19.
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 your[1] 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 emergency that has a significant potential to affect national security or the health and security of

[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 Test Home Collection Kit used for the indication identified above.

United States citizens living abroad, and that involves the virus that causes COVID-19.[3] 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 medical devices during the COVID-19 outbreak subject to the terms of any authorization issued under Section 564(a) of the Act.[4]

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, 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 home-collected human specimen, 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.[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 a direct to consumer (DTC) product for collecting an anterior nasal swab (nasal) specimen at home (which includes in a community-based setting), from individuals age 18 years

[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] 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)

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

and older (self-collected), 16 years and older (self- collected under adult supervision), or 2 years and older (collected with adult assistance) that is sent for testing with an in vitro diagnostic (IVD) molecular test that is indicated for use with the Quest COVID-19 PCR Test Home Collection Kit, and the IVD is indicated for testing any individuals, including individuals without symptoms or other reasons to suspect COVID-19.

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.

When using your product, individuals must follow all specimen collection and mailing instructions provided with the kit. The Quest COVID-19 PCR Test Home Collection Kit provides specimen collection and storage materials as well as materials for shipping the collected specimen to the testing laboratory, as described in the "Quest COVID-19 PCR Test Home Collection Kit" instructions for use.

All test results are delivered to the user via an online portal. Individuals with positive or inconclusive/invalid results will be contacted by a healthcare provider.[6] The DTC home collection system is intended to enable users to access information about their COVID-19 status that could aid with determining if isolation or quarantine is appropriate and to assist with healthcare decisions after discussion with a healthcare provider.

The Quest COVID-19 PCR Test Home Collection Kit is not a substitute for visits to a healthcare provider. The information provided by this kit when combined with an authorized test should not be used to start, stop, or change any course of treatment unless advised by a healthcare provider.

The labeling entitled "Quest COVID-19 PCR Test Home Collection Kit" instructions for use, the "Quest COVID-19 PCR Test Home Collection Kit" outer box labeling, 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 "Retail Collection Kit Workflow", the "Unobserved Collected Sample Processing for COVID-19 Molecular Testing" specimen accessioning SOP, and the following fact sheet 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 Individuals: Quest Diagnostics - Quest COVID-19 PCR Test Home Collection Kit

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 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

[6] For this EUA, a healthcare provider includes any health professional with prescribing abilities, including, but is not limited to, physicians, nurses, pharmacists, technologists, laboratory directors, and epidemiologists.

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 home 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 authorization:

Quest Diagnostics (You) and Authorized Distributor(s)[7]

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

[7] "Authorized Distributor(s)" are identified by you, Quest Diagnostics, in your EUA submission as an entity allowed to distribute your product.

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 all instructions related to the collection of anterior nasal swab specimens using Quest COVID-19 PCR Test Home Collection Kit both in the shipped kit, using the authorized outer box labeling, and on your website(s) and must make available the Fact Sheet for Individuals for the collection kit on your website.

C. You and authorized distributor(s) 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.

D. Through a process of inventory control, you and authorized distributor(s) must maintain records of the authorized laboratories to which they distribute your product and number of your product they distribute.

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.

Quest Diagnostics (You)

G. You must notify FDA of any authorized distributor(s) of your product, including the name, address, and phone number of any authorized distributor(s).

H. 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.

I. You must provide authorized distributor(s) and authorized laboratories with a copy of this EUA and communicate any subsequent amendments that might be made to this EUA and its authorized labeling.

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

K. You must maintain records of the authorized laboratories and test usage.

L. You must collect information on the performance of your product. You must report to FDA any suspected occurrence of false positive and false negative results and significant

deviations from the established performance characteristics of your product of which you become aware.

M. 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.

N. 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).

O. You must have lot release procedures and the lot release procedures, including the study design and statistical power, must ensure that your product released for distribution has the clinical and analytical performance claimed in the authorized labeling.

P. If requested by FDA, you must submit lot release procedures to FDA, including sampling protocols, testing protocols, and acceptance criteria, that you use to release lots of your product 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.

Q. You must provide additional specimen stability data from an FDA agreed upon post authorization study within 2 months of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH). After submitting the data to FDA and obtaining FDA concurrence regarding the conclusions of the study, you must update your 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.

R. You must submit to FDA a summary report within 30 calendar days of product launch summarizing the results of any testing performed using specimens collected with Quest COVID-19 PCR Test Home Collection Kit for use with your product during that timeframe, including how many specimens were received, how many specimens had to be rejected during accession and the main reasons for rejection, and the positivity rate for specimens collected with the authorized collection kit.

S. You must have a process in place to track adverse events associated with the Quest COVID-19 PCR Test Home Collection Kit, including any occurrence of false results with your product 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-EUA-Reporting@fda.hhs.gov).

T. You must have a process in place for reporting all test results to individuals who use the

Quest COVID-19 PCR Test Home Collection Kit. This process must include a requirement that all positive and invalid/indeterminate results must be reported to individuals who collected specimens using Quest COVID-19 PCR Test Home Collection Kit by a healthcare provider, defined in footnote 6. This process must ensure the Fact Sheet for Individuals for the authorized IVD molecular test used on the specimen is made available to individuals with the test result, for example via weblink.

U. You must have a healthcare provider available to provide information and counseling to individuals use the Quest COVID-19 PCR Test Home Collection Kit. You will ensure these healthcare providers have the Fact Sheet for Healthcare Providers that is relevant to the authorized IVD molecular test used on the specimen, for reference.

Authorized Laboratories

V. Authorized laboratories using your product will use it only in conjunction with COVID-19 IVD molecular tests that are indicated for use with the Quest COVID-19 PCR Test Home Collection Kit.

W. Authorized laboratories testing specimens collected using your product must follow the "Unobserved Collected Sample Processing for COVID-19 Molecular Testing" specimen accessioning protocol provided with your product when accepting specimens for testing.

X. Authorized laboratories using your product must have a process in place for reporting test results to relevant public health authorities, as appropriate. Authorized laboratories using your product must also have a process in place for reporting test results to you via the agreed upon process, as described in the EUA Summary for your product.

Y. 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.

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

Z. You, authorized distributor(s), 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;
- This product has been authorized only for the home collection and maintenance of anterior nasal swab specimens as an aid in detection of nucleic acid from SARS-CoV2, 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 is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

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

Enclosure