U.S. FOOD & DRUG ADMINISTRATION

May 27, 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:	SARS-CoV-2 RNA, Qualitative Real-Time RT-PCR
Company:	Quest Diagnostics Infectious Disease, Inc.
Indication:	Qualitative detection of nucleic acid from SARS-CoV-2 in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, tracheal aspirates, and bronchoalveolar lavage) collected from individuals suspected of COVID-19 by their healthcare provider. This test is also intended for use with nasal swab specimens that are self-collected at home or in a healthcare setting by individuals using an authorized home-collection kit, specified in this EUA's authorized labeling, when determined to be appropriate by a healthcare provider. Emergency use of this test is limited to authorized laboratories.
Authorized Laboratory:	Testing is limited to Quest Diagnostic Laboratories or other laboratories designated by Quest Diagnostics that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests.

Dear Mr. Wagner:

On March 17, 2020, based on your request, the Food and Drug Administration (FDA) issued a letter authorizing the emergency use of the Quest Diagnostics Infectious Disease, Inc. (Quest Diagnostics) SARS-CoV-2 RNA, Qualitative Real-Time RT-PCR ("Quest SARS-CoV-2 rRT-PCR") test for the qualitative detection of nucleic acid from SARS-CoV-2 in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate) from individuals suspected of COVID-19 by their healthcare provider, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3). The March 17, 2020, letter authorizing emergency use of this test, limited testing to Quest

Diagnostic Laboratories or other laboratories designated by Quest Diagnostics that are also certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests.[1]

On April 29, 2020, FDA received a request from Quest Diagnostics to amend their Emergency Use Authorization (EUA). In response to that request, and having concluded that revising the March 17, 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 March 17, 2020, letter in its entirety with the revisions incorporated[2] to additionally authorize the emergency use of the Quest SARS-CoV-2 rRT-PCR test to be used with an authorized home specimen collection method, including the Quest Diagnostics Self-collection Kit for COVID-19. 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 qualitative detection of nucleic acid from SARS-CoV-2 in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, tracheal aspirates, and bronchoalveolar lavage) collected from individuals suspected of COVID-19 by their healthcare provider. This test is now also intended for use with nasal swab specimens that are self-collected at home or in a healthcare setting by individuals using an authorized home-collection kit, specified in this EUA's authorized labeling, when determined to be appropriate by a healthcare provider.

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.[3]

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 Quest SARS-CoV-2 rRT-PCR test (as described in the scope Section of this letter (Section II)) in individuals suspected of COVID-19 by their healthcare provider for the detection of SARS-CoV-2 by authorized laboratories, subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

[1] For ease of reference, this letter will refer to, "Quest Diagnostic Laboratories or other laboratories designated by Quest Diagnostics that are also certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests" as "authorized laboratories."

[2] The revisions to the March 16, 2020 letter include: (1) revised intended use to include nasal swab specimens self-collected at home or in a healthcare setting by individuals using an authorized home-collection kit, specified in this EUA's authorized labeling, when determined appropriate by a healthcare provider, (2) addition of the Quest Diagnostics Self-collection Kit for COVID-19 as an authorized home-collection kit for use with the Quest SARS-CoV-2 rRT-PCR test, (3) additional labeling documents and conditions of authorization specific to home specimen collection; and, (4) updated healthcare provider and patient fact sheets to reflect more recent authorizations.

[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).

I have concluded that the emergency use of Quest SARS-CoV-2 rRT-PCR test for testing individuals suspected of COVID-19 by their healthcare provider 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 Quest SARS-CoV-2 rRT-PCR test may be effective in diagnosing COVID-19, and that the known and potential benefits of their Quest SARS-CoV-2 rRT-PCR test, when used for diagnosing COVID-19, outweigh the known and potential risks of such product; and

3. There is no adequate, approved, and available alternative to the emergency use of Quest SARS-CoV-2 rRT-PCR test for diagnosing COVID-19.[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 use of the authorized Quest SARS-CoV-2 rRT-PCR test by authorized laboratories for the qualitative detection of SARS-CoV-2 in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, tracheal aspirates, and bronchoalveolar lavage) collected from individuals suspected of COVID-19 by their healthcare provider and from nasal swab specimens that are self-collected at home or in a healthcare setting by individuals using an authorized home-collection kit, specified in this EUA's authorized labeling, when determined to be appropriate by a healthcare provider.

The Authorized Quest SARS-CoV-2 rRT-PCR Test

The Quest SARS-CoV-2 rRT-PCR test is a qualitative test for the detection of nucleic acid from the SARS-CoV-2 in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, tracheal aspirates, and bronchoalveolar lavage) collected from individuals suspected of COVID-19 by their healthcare provider.

Nasal specimens may also be self-collected at home or in a healthcare setting by individuals using an authorized self-collection kit, as specified in the authorized labeling, when determined to be appropriate by a healthcare provider.

Testing is limited to Quest Diagnostic Laboratories or other laboratories designated by Quest Diagnostics that are also certified under CLIA to perform high complexity tests. The authorized self-collection kit, including the Quest Diagnostics Self-collection Kit for COVID-19, will provide specimen collection materials to safely mail specimens to an authorized laboratory for testing using the Quest SARS-CoV-2 rRT-PCR test by Quest Diagnostics. Patients should follow all specimen collection and mailing instructions provided in the kit.

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

The SARS-CoV-2 RNA is generally detectable in respiratory 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.

To perform Quest SARS-CoV-2 rRT-PCR test, SARS-CoV-2 nucleic acid is first extracted, isolated and purified from upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, tracheal aspirates, and bronchoalveolar lavage). The purified nucleic acid is then reverse transcribed into cDNA followed by PCR amplification and detection with the Quest SARS-CoV-2 rRT-PCR test on with the Applied Biosystems 7500 Real Time PCR System (or ABI 7500 fast system run as a standard ABI 7500), or other authorized instruments and/or other authorized software. The Quest SARS-CoV-2 rRT-PCR test includes the following materials or other authorized materials: buffers, extraction reagents, 1-Step RT-qPCR Master Mix, Primer/Probe Master Mixes, exogenous RNA internal control reagents, Positive Control, and Negative Control.

This Quest SARS-CoV-2 rRT-PCR test requires the following control materials, or other authorized control materials, that are processed in the same way as the patient specimens and are required to be included with each batch of specimens tested with Quest SARS-CoV-2 rRT-PCR test. All controls listed below must generate expected results in order for a test to be considered valid, as outlined in the Quest SARS-CoV-2 rRT-PCR test Package Insert:

- Internal Process Control – Exogenous RNA control material which is required as an extraction, reverse transcription and PCR amplification positive control. This control should be added to each sample aliquot prior to extraction.
- Positive control - contains the SARS-CoV-2 synthetic RNA. The positive control is used to monitor for failures of rRT-PCR reagents and reaction conditions.
- Negative Control - used to monitor non-specific amplification, cross-contamination during experimental setup, and nucleic acid contamination of reagents.
- Internal Process Control for Self-collected Specimens: For each specimen submitted as part of the unsupervised self-collection program, a molecular assay for detecting the human specimen marker RNase P (RP) must also be performed. The specimen must be positive for the RP human specimen marker in order to be considered a valid specimen.

The Quest SARS-CoV-2 rRT-PCR test also requires the use of additional authorized materials and authorized ancillary reagents that are not included with the test and are described in the authorized Quest SARS-CoV-2 rRT-PCR test Package Insert.

The Quest SARS-CoV-2 rRT-PCR test described above, is authorized to be accompanied with the labeling submitted as part of the EUA request, and as described in the "SARS-CoV-2 RNA, Qualitative Real-Time RT-PCR (Test Code 39433) Package Insert" (available at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-useauthorizations), 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 SARS-CoV-2 rRT-PCR test
- Fact Sheet for Patients: Quest SARS-CoV-2 rRT-PCR test

The above described product, when accompanied by the "SARS-CoV-2 RNA, Qualitative Real-Time RT-PCR (Test Code 39433) Package Insert", Fact Sheet for Healthcare Providers, Fact Sheet for Patients, the "Self-Collected Sample Processing Non-Technical Standard Operating Procedure (SOP)" for sample accessioning, and the "Self-Collection Kit for COVID-19 Quick Guide" instructions for use for Quest Diagnostics Self-collection Kit for COVID-19 (collectively referenced as "authorized labeling") is authorized to be used by Quest Diagnostic Laboratories or other 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 the authorized Quest SARS-CoV-2 rRT-PCR test, when used for the qualitative detection of SARS-CoV-2 and used consistently with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of such a 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 the authorized Quest SARS-CoV-2 rRT-PCR test may be effective in diagnosing COVID-19, when used consistently 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 Quest SARS-CoV-2 rRT-PCR test, when used for qualitative detection of the SARS-CoV-2 in the specified population (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 Quest Diagnostics' authorized Quest SARS-CoV-2 rRT-PCR test 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) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), the Quest SARS-CoV-2 rRT-PCR test described above is authorized to detect SARS-CoV-2 in individuals suspected of COVID-19 by their healthcare provider.

III. Waiver of Certain Requirements

I am waiving the following requirements for Quest SARS-CoV-2 rRT-PCR test 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 the Quest SARS-CoV-2 rRT-PCR test.

IV. Conditions of Authorization

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

Quest Diagnostics

A. Quest SARS-CoV-2 rRT-PCR test 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. Quest Diagnostics will make available the authorized Quest SARS-CoV-2 rRT-PCR test with the following authorized labeling documents: "SARS-CoV-2 RNA, Qualitative Real-Time RT-PCR (Test Code 39433) Package Insert," Fact Sheet for Healthcare Providers, Fact Sheet for Patients, the "Self-Collected Sample Processing Non-Technical SOP," and self-collection instructions for use for the Quest Diagnostics Self-Collection Kit for COVID-19 to authorized laboratories.

C. Quest Diagnostics may request changes to the authorized labeling, including Fact Sheets. Such requests will be made by Quest Diagnostics in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

D. Quest Diagnostics will make available on their website(s) the authorized Fact Sheet for Healthcare Providers, Fact Sheet for Patients, and the Quest Diagnostics "Self-Collection Kit for COVID-19 Quick Guide" instructions.

E. Quest Diagnostics will inform authorized laboratories and relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to the Quest SARS-CoV-2 rRT-PCR test, authorized labeling, including authorized Fact Sheets.

F. Quest Diagnostics will ensure that the authorized laboratories using the authorized Quest SARS-CoV-2 rRT-PCR test have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

G. Quest Diagnostics will maintain records of the authorized laboratories and test usage.

H. Quest Diagnostics will collect information on the performance of the test. Quest Diagnostics will report to FDA any suspected occurrence of false positive and false negative results and significant deviations from the established performance

characteristics of the test of which Quest Diagnostics becomes aware.

I. Quest Diagnostics are authorized to make available additional information relating to the emergency use of the authorized Quest SARS-CoV-2 rRT-PCR test that is consistent with, and does not exceed, the terms of this letter of authorization.

J. Quest Diagnostics may request changes to the Scope of Authorization (Section II in this letter) of the authorized Quest SARS-CoV-2 rRT-PCR test. Such requests will be made by Quest Diagnostics in consultation with DMD/OHT7-OIR/OPEQ/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.

K. Quest Diagnostics may request the addition of other instruments and associated software for use with the authorized Quest SARS-CoV-2 rRT-PCR test. Such requests will be made by Quest Diagnostics in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

L. Quest Diagnostics may request the addition of other extraction methods for use with the authorized Quest SARS-CoV-2 rRT-PCR test. Such requests will be made by Quest Diagnostics in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

M. Quest Diagnostics may request the addition of other specimen types for use with the authorized Quest SARS-CoV-2 rRT-PCR test. Such requests will be made by Quest Diagnostics in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

N. Quest Diagnostics may request the addition and/or substitution of primers or probes for use with the authorized Quest SARS-CoV-2 rRT-PCR test. Such requests will be made by Quest Diagnostics in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

O. Quest Diagnostics may request the addition and/or substitution of control materials for use with the authorized Quest SARS-CoV-2 rRT-PCR test. Such requests will be made by Quest Diagnostics in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

P. Quest Diagnostics may request the addition and/or substitution of other ancillary reagents and materials for use with the authorized Quest SARS-CoV-2 rRT-PCR test. Such requests will be made by Quest Diagnostics in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

Q. Quest Diagnostics may request the addition and/or substitution of home specimen collection kits for use with the authorized Quest SARS-CoV-2 rRT-PCR test, that will be named in the authorized labeling. Such requests will be made by Quest Diagnostics

in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

R. Quest Diagnostics may request the addition and/or substitution of the components of the Quest Diagnostics Self-collection Kit for COVID-19, or any other home specimen collection kit authorized for use with the Quest SARS-CoV-2 rRT-PCR test. Such requests will be made by Quest Diagnostics in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

S. Quest Diagnostics will evaluate the analytical limit of detection and assess traceability[5] of this Quest SARS-CoV-2 rRT-PCR test with any FDA-recommended reference material(s). After submission to FDA and DMD/OHT7-OIR/CDRH's review of and concurrence with the data, Quest Diagnostics will update its labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

T. Quest Diagnostics will track adverse events, including any occurrence of false results and report to FDA under 21 CFR Part 803.

U. Quest Diagnostics 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 the Quest SARS-CoV-2 rRT-PCR test, 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).

V. Quest Diagnostics will make available all instructions related to the self-collection of nasal swab specimens using the Quest Diagnostics Self-Collection Kit for COVID-19, or any other home specimen collection kit authorized for use with the Quest SARS-CoV-2 rRT-PCR test, both in the shipped kit and on its website.

W. Quest Diagnostics will submit to FDA a summary report within 30 calendar days of this letter summarizing the results of any testing with the Quest SARS-CoV-2 rRT-PCR test performed using nasal 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 first Quest Diagnostics Self-Collection Kit for COVID-19 lot.

Authorized Laboratories

X. Authorized laboratories using the Quest SARS-CoV-2 rRT-PCR test will include with result reports of the Quest SARS-CoV-2 rRT-PCR test, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

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

Y. Authorized laboratories using the Quest SARS-CoV-2 rRT-PCR test will perform the Quest SARS-CoV-2 rRT-PCR test as outlined in the Quest SARS-CoV-2 rRT-PCR Package Insert. 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 perform the Quest SARS-CoV-2 rRT-PCR test are not permitted.

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 the Quest SARS-CoV-2 rRT-PCR test must follow any Specimens Accessioning protocols provided with the authorized self-collection kit and/or outlined in Quest Diagnostics' "Self-Collected Sample Processing Non-Technical SOP," when accepting specimens for testing.

AA. Authorized laboratories that receive the Quest SARS-CoV-2 rRT-PCR test must notify the relevant public health authorities of their intent to run the test prior to initiating testing.

BB. Authorized laboratories using Quest SARS-CoV-2 rRT-PCR test will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

CC. Authorized laboratories will collect information on the performance of the test and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and Quest Diagnostics (michael.j.wagner@questdiagnostics.com) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the test of which they become aware.

DD. All laboratory personnel using the test must be appropriately trained in RT-PCR techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use the test in accordance with the authorized labeling.

Quest Diagnostics and Authorized Laboratories

EE. Quest Diagnostics and authorized laboratories using the Quest SARS-CoV-2 rRT-PCRT test will 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

FF. All descriptive printed matter, including advertising and promotional materials, relating to the use of Quest Diagnostics' authorized Quest SARS-CoV-2 rRT-PCR test 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 Quest Diagnostics' authorized Quest SARS-CoV-2 rRT-PCR test 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 Quest Diagnostics' authorized Quest SARS-CoV-2 rRT-PCR test 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 diagnostic tests 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 Quest Diagnostics' authorized Quest SARS-CoV-2 rRT-PCR test 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 diagnostic tests 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,

_____
RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures