

August 7, 2020

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Device: SARS-CoV-2 RNA, Qualitative Real-Time RT-PCR

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

Indication: This test is authorized for the following indications for use in individuals suspected of COVID-19 by their healthcare provider:

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).

Qualitative detection of nucleic acid from SARS-CoV-2 in 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.

Qualitative detection of nucleic acid from SARS-CoV-2 in pooled samples containing up to four of the individual upper respiratory swab specimens (nasopharyngeal, mid-turbinate, anterior nares or oropharyngeal swabs) that were collected in individual vials containing transport media.

Emergency use of this test is limited to authorized laboratories.

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 March 17, 2020, based on your<sup>1</sup> request, the Food and Drug Administration (FDA) issued a letter authorizing the emergency use of your product<sup>2</sup> for the qualitative detection of nucleic

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<sup>1</sup> For ease of reference, this letter will use the term “you” and related terms to refer to Quest Diagnostics Infectious

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 test. Subsequently, on March 26, 2020, FDA granted your request to update the authorized labeling.<sup>3</sup>

On May 27, 2020, based on your request, FDA reissued the March 17, 2020, letter in its entirety with revisions incorporated.<sup>4</sup> On July 18, 2020, based on your request, FDA reissued the May 27, 2020, letter in its entirety with revisions incorporated.<sup>5</sup> Subsequently, on July 28, 2020, FDA granted your request to update the authorized labeling.<sup>6</sup>

On July 27, 2020, you requested to amend your Emergency Use Authorization (EUA). Based on that request, and having concluded that revising the July 18, 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 18, 2020, letter in its entirety with the revisions incorporated.<sup>7</sup> Pursuant to section 564 of the Act and the Scope of Authorization (Section II)

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Disease, Inc. (“Quest Diagnostics”).

<sup>2</sup> For ease of reference, this letter will use the term “your product” to refer to the SARS-CoV-2 RNA, Qualitative Real-Time RT-PCR (or Quest SARS-CoV-2 rRT-PCR test) used for the indications identified above.

<sup>3</sup> On March 26, 2020, your request was granted to update the Instructions for Use (IFU) of your product to; (1) change the SARS-CoV-2 primer-probes target combination from N1+N2 (separate wells) to N1+N3 (same well) in order to double testing capacity, and (2) temporarily allow use of a DNA-based internal process control in situations where supply chain issues limit the availability of the RNA-based internal process control.

<sup>4</sup> The revisions to the March 17, 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 your product, (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.

<sup>5</sup> The revisions to the May 27, 2020, letter include: (1) revised intended use to include use with pooled samples containing up to four individual upper respiratory swab specimens (nasopharyngeal, mid-turbinate, anterior nares or oropharyngeal swabs) collected under observation, in individual vials containing transport media, from individuals suspected of COVID-19 by their healthcare provider, (2) updated labeling documents to include the “Protocol for Monitoring of Specimen Pooling Testing Strategies,” (3) added conditions of authorization specific to sample pooling; and, (4) updated healthcare provider and patient fact sheets to reflect more recent authorizations.

<sup>6</sup> On July 28, 2020, your request was granted to update the Instructions for Use (IFU) of your product to add use of the Mag-Bind Viral RNA Xpress Kit (Omega Bio-Tek, Cat. M6219-2304) with the Hamilton MagEx STAR (“Omega Method”) as an additional extraction method, and the associated updated instructions and performance data.

<sup>7</sup> The revisions to the July 18, 2020, letter include: (1) removal of the RNaseP internal control requirement for unobserved self-collected samples, (2) updated labeling documents to remove the requirement to run the RNaseP internal control (3) added conditions of authorization specific to removal of the RNaseP internal control, (4) updated healthcare provider and patient fact sheets to include some additional warnings/precautions around the absence of an RNaseP internal control when unobserved self-collected specimens are tested, and (5) minor updates to the intended use to remove “individual” from the nasal swab specimens that are self-collected at home or in a healthcare setting to allow them to be considered for pooling and other minor clarifications in the pooling section to reflect more recent authorizations.

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.<sup>8</sup>

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 as described in the Scope of Authorization 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**

I have concluded that the emergency use of your product 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 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 such product; and
3. There is no adequate, approved, and available alternative to the emergency use of your product for diagnosing COVID-19.<sup>9</sup>

## **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.

## **The Authorized Product**

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<sup>8</sup> 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).

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

Your product 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.

Your test is also authorized for use with nasal swab specimens that are self-collected at home or in a healthcare setting by individuals using an authorized self-collection kit when determined to be appropriate by a healthcare provider.

Finally, your product is also authorized for use to detect nucleic acid from the SARS-CoV-2 in pooled samples containing up to four of the individual upper respiratory swab specimens (nasopharyngeal, mid-turbinate, anterior nares or oropharyngeal swabs) that were collected in individual vials containing transport media from individuals suspected of COVID-19 by their healthcare provider. Negative results from pooled testing should not be treated as definitive. If a patient's clinical signs and symptoms are inconsistent with a negative result or results are necessary for patient management, then the patient should be considered for individual testing. Specimens included in pools with a positive, inconclusive, or invalid result must be tested individually prior to reporting a result. Specimens with low viral loads may not be detected in sample pools due to the decreased sensitivity of pooled testing.

Testing is limited to laboratories designated by Quest Diagnostics that are certified under CLIA and meet the requirements 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 your product. Patients should follow all specimen collection and mailing instructions provided in the kit.

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. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information. Unobserved self-collected specimens 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 return negative results if the specimen was not collected properly.

To perform the SARS-CoV-2 RNA, Qualitative Real-Time RT-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 SARS-CoV-2 RNA, Qualitative Real-Time RT-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. Your product 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.

Your product 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. All controls listed below must generate expected results in order for a test to be considered valid, as outlined in the Package Insert (identified below):

- 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.

Your product 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 labeling.

Your product described above is authorized to be accompanied with the labeling entitled “SARS-CoV-2 RNA, Qualitative Real-Time RT-PCR (Test Code 39433) Package Insert” (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 SARS-CoV-2 rRT-PCR test
- Fact Sheet for Patients: Quest Diagnostics - 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” which includes the “Protocol for Monitoring of Specimen Pooling Testing Strategies,” and the 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 distributed and used by authorized laboratories, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of your product, when used for the qualitative detection of SARS-CoV-2 and used consistent 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 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, 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 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 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 your product for 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.

### **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 make your product available with the authorized labeling to authorized laboratories.

- C. You will require that entities<sup>10</sup> 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 AA below.
- D. You may request changes to the authorized labeling. Such requests will be made by you in consultation with, and require concurrence of, 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).
- E. You will make available on your 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.
- F. You will 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.
- G. 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.
- H. You will maintain records of the authorized laboratories and test usage.
- I. You will collect information on the performance of the test. You 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 you becomes aware.
- J. 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.
- K. You may request changes to the Scope of Authorization (Section II in this letter) of your product. Such requests will be made by you 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.

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<sup>10</sup> 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.).

- L. You may request the addition of other instruments and associated software for use with your product. Such requests will be made by you in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- M. You may request the addition of other extraction methods for use with your product. Such requests will be made by you in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- N. You may request the addition of other specimen types for use with your product. Such requests will be made by you in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- O. You may request the addition and/or substitution of primers or probes for use with your product. Such requests will be made by you in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- P. You may request the addition and/or substitution of control materials for use with your product. Such requests will be made by you in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- Q. You may request the addition and/or substitution of other ancillary reagents and materials for use with your product. Such requests will be made by you in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- R. You may request the addition and/or substitution of home specimen collection kits for use with your product, that will be named in the authorized labeling. Such requests will be made by you in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- S. You 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 your product. Such requests will be made by you in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- T. You will evaluate the analytical limit of detection and assess traceability<sup>11</sup> of your product with any FDA-recommended reference material(s). After submission to FDA and DMD/OHT7-OIR/OPEQ/CDRH's review of and concurrence with the data, you will update its 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.
- U. You will track adverse events, including any occurrence of false results and report to FDA pursuant to 21 CFR Part 803.

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<sup>11</sup> Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material.



- V. 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 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](mailto:CDRH-EUA-Reporting@fda.hhs.gov)).
- W. You 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 your product, both in the shipped kit and on your website.

### **Authorized Laboratories**

- X. 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.
- Y. Authorized laboratories using your product will perform the test as outlined in the 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 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 your product 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 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"*.
- BB. Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run the test prior to initiating testing.
- CC. 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.

- DD. 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](mailto:CDRH-EUA-Reporting@fda.hhs.gov)) and you ([michael.j.wagner@questdiagnostics.com](mailto: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.
- EE. Authorized laboratories using specimen pooling strategies when testing patient specimens with your product will include with test result reports for specific patients whose specimen(s) were the subject of pooling, a notice that pooling was used during testing and that “Patient specimens with low viral loads may not be detected in sample pools due to the decreased sensitivity of pooled testing.”
- FF. Authorized laboratories implementing pooling strategies for testing patient specimens must use the “Protocol for Monitoring of Specimen Pooling Testing Strategies” provided in the Package Insert to evaluate the appropriateness of continuing to use such strategies based on the recommendations in the protocol.
- GG. Authorized laboratories will keep records of specimen pooling strategies implemented including type of strategy, date implemented, and quantities tested, and test result data generated as part of the Protocol for Monitoring of Specimen Pooling Testing Strategies. For the first 12 months from the date of their creation, such records will be made available to FDA within 48 business hours for inspection upon request, and will be made available within a reasonable time after 12 months from the date of their creation.
- HH. 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**

- II. You and authorized laboratories using your product 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**

- JJ. 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.
- KK. 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.
- LL. 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 of the emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

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RADM Denise M. Hinton  
Chief Scientist  
Food and Drug Administration

Enclosure