

December 1, 2020

Robert R. Redfield, MD  
Director  
Centers for Disease Control and Prevention  
1600 Clifton Rd., MS D-14  
Atlanta, GA 30333

Device: CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel

Company: Centers for Disease Control and Prevention (CDC)

Indication: This test is authorized for the following indications for use:

Qualitative detection of nucleic acid from the 2019-nCoV in upper and lower respiratory specimens (such as nasopharyngeal (NP) or oropharyngeal (OP) swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate) collected from individuals suspected of COVID-19 by their healthcare provider.<sup>1</sup>

Qualitative detection of nucleic acid from SARS-CoV-2 in pooled samples containing up to four of the individual upper respiratory swab specimens (NP, OP, NP/OP combined, or nasal swabs) that were collected using individual vials containing transport media from individuals suspected of COVID-19 by their healthcare provider.

Emergency use of this test is limited to authorized laboratories.

Authorized Laboratories: Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.

Dear Dr. Redfield:

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<sup>1</sup> For this EUA, a healthcare provider includes, but is not limited to, physicians, nurses, pharmacists, technologists, laboratory directors, epidemiologists, or any other practitioners or allied health professionals.

On February 4, 2020, based on your<sup>2</sup> request, the Food and Drug Administration (FDA) issued a letter authorizing emergency use of the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel for the presumptive qualitative detection of nucleic acid from the 2019-nCoV<sup>3</sup> 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) collected from individuals who meet CDC criteria for 2019-nCoV testing, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3). The February 4, 2020, letter authorizing emergency use of this test limited testing to qualified laboratories designated by CDC and, in the United States, certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests.

On March 15, 2020, based on your request, FDA reissued the February 4, 2020, letter in its entirety with revisions incorporated.<sup>4</sup> Subsequently on March 30, 2020,<sup>5</sup> June 12, 2020,<sup>6</sup> and July 13, 2020,<sup>7</sup> FDA also granted updates to the authorized labeling.

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<sup>2</sup> For ease of reference, this letter will use the term “you” and related terms to refer to Centers for Disease Control and Prevention (CDC).

<sup>3</sup> On February 11, 2020, the virus tentatively named 2019-nCoV was formally designated as Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Also on February 11, 2020, the disease caused by SARS-CoV-2 was formally designated as Coronavirus Disease 2019 (COVID-19).

<sup>4</sup> The amendments to the February 4, 2020, letter include: (1) updated intended use to include specimens collected from individuals who meet “2019-nCoV clinical and/or epidemiological criteria (for example, clinical signs and symptoms associated with COVID-19, contact with a probable or confirmed COVID-19 case, history of travel to a geographic locations where COVID-19 cases were detected, or other epidemiologic links for which COVID-19 testing may be indicated as part of a public health investigation)” and “Testing in the United States is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests.”, (2) updated intended use to remove “presumptive”, (3) deletion of N3 vial of primer and probe, (4) use of an alternative fluorescent hydrolysis probe quencher chemistry (ZEN Double-Quenched Probe technology manufactured by Integrated DNA Technologies), (5) use of commercial manufactured and distributed lots of (i) primer and probe materials identified as acceptable on the CDC website and (ii) alternative positive control, RP control positive control and extraction control materials listed as acceptable on the CDC website, (6) use of a separately packaged standalone positive control, and (7) use of additional extraction methods, extraction reagents and associated instruments. The authorized Instructions for Use (IFU) and Fact Sheets were also updated to incorporate these amendments, where applicable.

<sup>5</sup> On March 30, 2020, your request was granted to update the Instructions for Use (IFU) of your product to; (1) add the acceptable RT-PCR master mix options - Quantabio qScript XLT One-Step RT-qPCR ToughMix, Quantabio UltraPlex 1-Step ToughMix (4X), and Promega GoTaq Probe 1- Step RT-qPCR System, and (2) add two minor clarifications.

<sup>6</sup> On June 12, 2020, your request was granted to update the Instructions for Use (IFU) of your product to; (1) add MagNA Pure 24 as an authorized extraction option for use with the test, (2) add alternative Roche external Lysis buffer product options, (3) add an alternative QIAGEN Buffer AVL product, (4) add a heat treatment method when used in combination with the Quantabio UltraPlex 1-Step ToughMix (4X) enzyme mix as an alternative to extraction in certain situations, (5) make minor clarifications and corrections to the Instructions For Use, and (6) updates to the Healthcare Provider and Patient Fact Sheets.

<sup>7</sup> On July 13, 2020, your request was granted to update the Instructions for Use (IFU) of your product to; (1) add the Promega Maxwell RSC 48 as an authorized extraction option for use with the test, and (2) update of in silico inclusivity analysis summary.

On August 26, 2020, you requested to amend your Emergency Use Authorization (EUA), to among other things add pooling of clinical specimens. Based on that request, and having concluded that revising the March 15, 2020, EUA is appropriate to protect the public health or safety under section 564(g)(2)(C) of the Act (21 U.S.C. § 360bbb-3(g)(2)(C)), FDA is reissuing the March 15, 2020, letter in its entirety with the revisions incorporated.<sup>8</sup> Accordingly, your product<sup>9</sup> is hereby authorized pursuant to section 564 of the Act when used pursuant to the Scope of Authorization (Section II) and Conditions of Authorization (Section IV) of this reissued letter.

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>10</sup>

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 Instructions for Use (identified below).

Having concluded that the criteria for issuance of this authorization under section 564(c) of the Act (21 U.S.C. § 360bbb-3(c)) are met, I am authorizing the emergency use of your product (as 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:

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<sup>8</sup> The revisions to the March 15, 2020, letter and authorized labeling include: (1) revisions to the intended use and authorized labeling documents to include pooling of up to four of the individual upper respiratory swab specimens (NP, OP, NP/OP combined, or nasal swabs) that were collected using individual vials containing transport media from individuals suspected of COVID-19 by their healthcare provider, (2) updates to the labeling documents to add the IVD version of the Promega Maxwell 48 instrument as acceptable for use, (3) add data for CDC testing of the FDA reference panel to the Instructions for Use (IFU), and (4) add new conditions of authorization concerning pooling.

<sup>9</sup> For ease of reference, this letter will use the term “your product” to refer to the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel (CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel) used for the indication identified above.

<sup>10</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).

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>11</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 Details**

Your product is authorized for the qualitative detection of SARS-CoV-2 RNA in upper and lower respiratory specimens (such as nasopharyngeal (NP) or oropharyngeal (OP) swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate) collected from individuals suspected of COVID-19 by their healthcare provider.

Your product is also authorized for the qualitative detection of nucleic acid from SARS-CoV-2 in pooled samples containing up to four of the individual upper respiratory swab specimens (NP, OP, NP/OP combined, or nasal swabs) that were collected using 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 certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high complexity tests.

SARS-CoV-2 RNA is generally detectable in upper and lower respiratory specimens during infection. Positive results are indicative of active infection with SARS-CoV-2 but 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

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<sup>11</sup> No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

The testing procedure consists of nucleic acid extraction and purification from the human specimen using authorized extraction methods/instruments followed by real time RT-PCR, where the RNA is reverse transcribed into cDNA and then amplified using the primer sets and detected using specific probes. The real time reverse transcriptase (RT)-PCR is performed on the FDA cleared Applied Biosystems 7500 Fast Dx Real-Time PCR Instrument with SDS 1.4 software, or other authorized instruments or software.

The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel includes the following materials or other authorized materials:

- 2019-nCoV\_N1 and 2019-nCoV\_N2 vials containing primers and probes that target the nucleocapsid (N) gene and are designed for specific detection of SARS-CoV-2 - either manufactured and/or distributed by CDC, CDC's International Reagent Resource (IRR), or by commercial manufacturers of primer and probe materials with lots identified as acceptable on the CDC website.<sup>12</sup>
- RP vial containing the internal control primers and probes that target the Human RNase P gene – either manufactured and/or distributed by CDC, CDC's IRR or by commercial manufacturers of lots of primer and probe materials identified as acceptable on the CDC website
- nCoVPC vial containing the SARS-CoV-2 positive control used in the assay – either included in the CDC and IRR distributed kit, provided as a separately packaged control or an alternative commercially manufactured and distributed positive control material listed as acceptable on the CDC website

The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel also requires the use of additional authorized materials and authorized ancillary reagents (as may be requested under Condition J. below) that are not included with the test but are commonly used in clinical laboratories and are described in the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Instructions for Use.

The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel requires the following control materials, or other authorized control materials (as may be requested under Condition J. below); all controls listed below must generate expected results in order for a test to be considered valid, as outlined in the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Instructions for Use:

- Human Specimen Control (HSC): A human cell culture preparation, negative human specimen material, or an alternative commercially manufactured and distributed extraction control identified as acceptable on the CDC website, used as an extraction control and positive control for the RNase P primer and probe set that is extracted and tested concurrently with each specimen extraction run.

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<sup>12</sup> A list of materials identified as acceptable for use with the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel is maintained on the following CDC webpage: <https://www.cdc.gov/coronavirus/2019-nCoV/lab/index.html>.

- Positive Control for 2019-nCoV (nCoVPC): Run with each batch of specimens. Monitors for failures of rRT-PCR reagents and reaction conditions.
- No Template Control (NTC): Nuclease-free water included in each run. Monitors for reagent and system contamination.
- RNase P (RP) control in clinical samples: The RP primer and probe set is included in each run to test for human RNase P, which controls for specimen quality and demonstrates that nucleic acid was generated by the extraction process.

The labeling entitled “CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel Instructions for Use,” (available at <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas>), the “CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Product Information Sheet,” the “CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel – Verification Requirements,” and the following fact sheets pertaining to the emergency use, which are required to be made available as set forth in the Conditions of Authorization (Section IV), are collectively referred to as “authorized labeling”:

- Fact Sheet for Healthcare Providers: Centers for Disease Control and Prevention (CDC) - CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel
- Fact Sheet for Patients: Centers for Disease Control and Prevention (CDC) - CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel

Your product, with the authorized labeling provided as set forth in the Conditions of Authorization (Section IV), is authorized to be distributed to and used by authorized laboratories under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

FDA does not have concerns with the use of remaining inventory of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel that was distributed under the original February 4, 2020, EUA when it is used in conjunction with the labeling and Instructions for Use associated with this re-issued EUA Letter of Authorization.

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 such 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 consistent with 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 the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel 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:

#### **Centers for Disease Control and Prevention (CDC) (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 maintain on your website electronic access to the current authorized labeling for your product.
- C. You will include a physical copy of the authorized Product Information Sheet with each shipped product to authorized laboratories, and will make the authorized Instructions for Use electronically available. Authorized laboratories may request a copy of the Instructions for Use in paper form, and after such request, you must promptly provide the requested information without additional cost.
- D. You will inform FDA of any authorized distributor(s) of your product, CDC qualified lots of commercially manufactured primer and probe sets, and list of alternative commercially manufactured and distributed positive control(s) and/or human specimen control material (extraction control) that are acceptable for use with your product.

- E. You will maintain on your website a list of commercial manufacturers' lots of primer and probe materials identified by you as acceptable alternatives to the CDC primer and probe set included in your product.
- F. You will maintain on your website a list of alternative commercially manufactured and distributed positive control(s) and/or human specimen control material (extraction control) that are acceptable for use with your product. Prior to posting the proposed alternative positive control and/or human specimen control (extraction control) on your website indicating that laboratories may use such controls in accordance with condition W of this letter, you must request in advance and receive concurrence from 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) for any proposed alternative positive control(s) and/or human specimen control.
- G. You will inform relevant public health authorities, IRR, and commercial manufacturers and distributors of CDC qualified acceptable materials of this EUA, including the terms and conditions herein, and any updates made to your product's authorized labeling.
- H. You will 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.
- I. 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.
- J. 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, including requests to make available additional authorized labeling specific to an authorized distributor. Such additional labeling may use another name for the product but otherwise must be consistent with the authorized labeling, and not exceed the terms of authorization of this letter. Any request for changes to this EUA should be submitted to the DMD/OHT7-OIR/OPEQ/CDRH and require appropriate authorization from FDA prior to implementation.
- K. You will comply with the following requirements pursuant to FDA regulations: 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).
- L. You 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 clinical and analytical performance claimed in the authorized labeling.



- M. 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.
- N. You will evaluate the analytical limit of detection and assess traceability<sup>13</sup> of your product with any FDA-recommended reference material(s). After submission to and concurrence with the data by FDA you will update your labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- O. You will have a process in place in accordance with 21 CFR Part 803 to track adverse events, including any occurrence of false results and report to FDA pursuant to 21 CFR Part 803.

**CDC (You) and International Reagent Resource (IRR)**

- P. You and IRR will inform authorized laboratories that receive your product of the terms and conditions herein, and any updates made to your product and/or authorized labeling.
- Q. Through a process of inventory control, you and IRR will maintain records of test usage, including a list of authorized laboratories supplied by you and IRR, for reagents you and they distribute.

**Manufacturers and/or Distributors of Commercial Materials Identified as Acceptable on the CDC Website**

- R. Commercial manufacturers and distributors of materials identified as acceptable on the CDC website for use with your product, will inform authorized laboratories that received the acceptable, CDC-qualified reagents distributed by them of the terms and conditions herein, and any updates made to your products or your authorized labeling made by you.
- S. Through a process of inventory control, commercial manufacturers and distributors of positive control(s) and/or human specimen control material (extraction) that are identified as acceptable on the CDC website for use with your product will maintain records of the authorized laboratories to which they distribute the test and number of tests they distribute. Such records will be made available to FDA and/or you upon request.
- T. Through a process of inventory control, manufacturers and distributors of commercially manufactured and available lots of primer and probe sets that are identified as acceptable on the CDC website for use with your product will maintain records of the authorized laboratories to which they distribute the test and number of tests they distribute. Such records will be made available to FDA and/or you upon request.

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<sup>13</sup> Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material.

## Authorized Laboratories

- U. Authorized laboratories using your product will include with test result reports, all authorized Fact Sheets available on the CDC website. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
- V. Authorized laboratories using your product will use your product as outlined in the authorized labeling available on the CDC website. Deviations from the authorized procedures, including the authorized RT-PCR instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted under this authorization.<sup>14</sup>
- W. Authorized laboratories that receive the commercially manufactured and distributed primer and probe sets identified as acceptable on the CDC website for use with your product, and are not able to obtain the authorized Human Specimen Control and authorized Positive Control for 2019-nCoV (NCoVPC) materials described in your product's authorized labeling, may use appropriate materials identified as acceptable materials on the CDC website for use with your product.
- X. Authorized laboratories that receive your product will notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- Y. 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.
- Z. 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 CDC ([respvirus@cdc.gov](mailto:respvirus@cdc.gov)) 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.
- AA. Authorized laboratories using specimen pooling strategies when testing patient specimens with your product will include with negative 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."

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<sup>14</sup> If an authorized laboratory is interested in implementing changes to the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel that are not in the scope (Section II) of this letter of authorization, FDA recommends you discuss with FDA after considering the policy outlined in [Immediately in Effect Guidance for Clinical Laboratories and Food and Drug Administration Staff: Policy for Diagnostics Testing in Laboratories Certified to Perform High Complexity Testing under CLIA prior to Emergency Use Authorization for Coronavirus Disease-2019 during the Public Health Emergency](https://www.fda.gov/media/135659/download), available at <https://www.fda.gov/media/135659/download>.

- BB. Authorized laboratories implementing pooling strategies for testing patient specimens must use the “Implementation and Monitoring of Pooled Specimen Testing” available in the authorized labeling to evaluate the appropriateness of continuing to use such strategies based on the recommendations in the protocol.
- CC. 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 (2 business days) for inspection upon request, and will be made available within a reasonable time after 12 months from the date of their creation.
- DD. Authorized laboratories will report adverse events, including problems with your products performance or results, to MedWatch by submitting the online FDA Form 3500 (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>) or by calling 1-800-FDA-1088
- EE. 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.

**CDC, International Reagent Resource (IRR), Manufacturers and/or Distributors of Commercial Materials Identified as Acceptable on the CDC Website and Authorized Laboratories**

- FF. CDC, IRR, manufacturers and distributors of commercial materials identified as acceptable on the CDC website, 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**

- GG. 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.
- HH. 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.
- II. No 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 2019-nCoV, 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 SARS-CoV-2 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic 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 2019-nCoV 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