

March 15, 2020

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

Dear Dr. Redfield:

On February 4, 2020, based on a request by the Centers for Disease Control and Prevention (CDC), 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-nCoV¹ 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 5, 2020, FDA received a request from CDC to amend the Emergency Use Authorization (EUA). In response to that request, and having concluded that revising the February 4, 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 February 4, 2020, letter in its entirety with the amendments incorporated² to authorize the emergency use of the

¹ 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 Identification 2019 (COVID-19).

² 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

CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel. Accordingly, testing is now intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in upper and lower respiratory specimens collected from individuals who meet COVID-19 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). In addition, 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.³

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of 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.⁴

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 the 2019-nCoV Real-Time RT-PCR Diagnostic Panel (as described in the Scope of Authorization section of this letter (Section II)) 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 COVID-19 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 location where COVID-19 cases were detected, or other epidemiologic links for which COVID-19 testing may be indicated as part of a public health activity) for the qualitative detection of nucleic acid from SARS-CoV-2 by authorized laboratories, subject to the terms of this authorization. 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.

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 and Fact Sheets also have been updated to incorporate these amendments, where applicable.

³ For ease of reference, this letter will refer to, “laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests” as “authorized laboratories.”

⁴ U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act*, 21 U.S.C. § 360bbb-3. February 4, 2020.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel in individuals who meet COVID-19 clinical and/or epidemiological criteria 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 the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel may be effective in diagnosing COVID-19, and that the known and potential benefits of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel, 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 the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel for diagnosing COVID-19.⁵

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel by authorized laboratories for the qualitative detection of SARS-CoV-2 in upper and lower respiratory specimens collected from individuals who meet COVID-19 clinical and/or epidemiological criteria for testing.

The Authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel

The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel is for the qualitative detection of SARS-CoV-2 RNA 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), and other authorized specimens collected from individuals who meet COVID-19 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 location where COVID-19 cases were detected, or other epidemiologic links for which COVID-19 testing may be indicated as part of a public health activity). 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

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

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 lots of primer and probe materials identified as acceptable on the CDC website ⁶
- 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 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; 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.
- 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

⁶ 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>.

demonstrates that nucleic acid was generated by the extraction process.

The above described CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel, when labeled consistently with the labeling authorized by FDA, entitled “CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel Instructions for Use” (available at <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>), which may be revised by CDC in consultation with, and with concurrence of, the Division of Microbiology Devices (DMD)/Office of Health Technology-7 Office of In Vitro Diagnostics and Radiological Health (OHT7-OIR)/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH), 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.

The above-described CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel is authorized to be accompanied by the following information pertaining to the emergency use, which is required to be made available to healthcare providers and patients:

- Fact Sheet for Healthcare Providers: CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel
- Fact Sheet for Patients: CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel

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 the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel 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 CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel may be effective in the qualitative detection of SARS-CoV-2, 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 the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel, 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 the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel

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 CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel described above is authorized to detect SARS-CoV-2 in individuals who meet COVID-19 clinical and/or epidemiological criteria.

This EUA will cease to be effective when the HHS declaration that circumstances exist to justify the EUA is terminated under Section 564(b)(2) of the Act or when the EUA is revoked under Section 564(g) of the Act.

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 the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel
- Labeling requirements for cleared, approved, or investigational devices, including labeling requirements under 21 CFR 809.10 and 21 CFR 809.30, except for 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)), any 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).

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)

- A. CDC will maintain on its website the current authorized labeling for the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel. CDC may request changes to the authorized labeling. Such requests will be made by CDC in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- B. CDC will maintain on its website the current authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Fact Sheet for Healthcare Providers and the current

authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Fact Sheet for Patients. CDC may request changes to the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Fact Sheet for Healthcare Providers and the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Fact Sheet for Patients. Such requests will be made by CDC in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

- C. CDC will inform FDA of any authorized distributor(s) of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel, 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 the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel.
- D. CDC will maintain on its website a list of commercial manufacturers lots of primer and probe materials identified by CDC as acceptable alternatives to the CDC primer and probe set included in the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel.
- E. CDC will maintain on its 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 the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel. CDC will notify DMD/OHT7-OIR/OPEQ/CDRH in advance of any proposed alternative positive control(s) and/or human specimen control (extraction control) material and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH, prior to posting the proposed alternative positive control and/or human specimen control (extraction control) on CDC's website indicating that laboratories may use such controls in accordance with condition X of this letter.
- F. CDC will inform relevant public health authorities, IRR, and commercial manufacturers and distributors of CDC acceptable materials of this EUA, including the terms and conditions herein, and any updates made to the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel, authorized labeling and authorized Fact Sheets.
- G. CDC 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 CDC becomes aware.
- H. CDC is authorized to make available additional information relating to the emergency use of the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel that is consistent with, and does not exceed, the terms of this letter of authorization.
- I. CDC may request changes to the Scope of Authorization (Section II in this letter) of the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel. Such requests will be made by CDC 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.

- J. CDC may request the addition of other instruments and associated software for use with the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel. Such requests will be made by CDC in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- K. CDC may request the addition of other extraction methods for use with the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel. Such requests will be made by CDC in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- L. CDC may request the addition of other specimen types for use with the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel. Such requests will be made by CDC in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- M. CDC may request the addition and/or substitution of other ancillary reagents and materials for use with the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel. Such requests will be made by CDC in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- N. CDC may request the addition and/or substitution of primers or probes for use with the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel. Such requests will be made by CDC in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- O. CDC will evaluate the analytical limit of detection and assess traceability⁷ of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel with any FDA-recommended reference material(s). After submission to FDA and DMD/OHT7-OIR/CDRH's review of and concurrence with the data, CDC 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.
- P. CDC will track adverse events and report to FDA under 21 CFR Part 803.

CDC and International Reagent Resource (IRR)

- Q. CDC and IRR will inform authorized laboratories that receive CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel reagents manufactured and/or distributed by them of the terms and conditions herein, and any updates made to the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel, authorized labeling and authorized Fact Sheets.

⁷ Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material.

- R. Through a process of inventory control, CDC and IRR will maintain records of test usage, including a list of authorized laboratories supplied by CDC and IRR, for reagents they distribute.

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

- S. Commercial manufacturers and distributors of materials identified as acceptable on the CDC website for use with the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel, will inform authorized laboratories that received CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel reagents distributed by them of the terms and conditions herein, and any updates made to the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel, authorized labeling and authorized Fact Sheets made by CDC.
- T. 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 the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel 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 CDC upon request.
- U. 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 the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel 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 CDC upon request.

Authorized Laboratories

- V. Authorized laboratories will include with reports of the results of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel, 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.
- W. Authorized laboratories will perform the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel as outlined in the current CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel Instructions for Use 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 perform the CDC 2019-nCoV Real-Time RT-PCR Diagnostic

Panel are not permitted.⁸

- X. Authorized laboratories that receive the commercially manufactured and distributed primer and probe sets identified as acceptable on the CDC website for use with the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel, and are not able to obtain the authorized Human Specimen Control and authorized Positive Control for 2019-nCoV (NCoVPC) materials described in the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Instructions for Use, may use appropriate materials identified as acceptable materials on the CDC website for use with the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel.
- Y. Authorized laboratories that receive the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel must notify the relevant public health authorities of their intent to run the test prior to initiating testing.
- Z. Authorized laboratories will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- AA. 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 CDC (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.
- BB. Authorized laboratories will report adverse events, including problems with test 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
- CC. 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

⁸ 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>.

DD. CDC, IRR, manufacturers and distributors of commercial materials identified as acceptable on the CDC website, and authorized laboratories 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 Advertising and Promotion

EE. All advertising and promotional descriptive printed matter relating to the use of the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel shall be consistent with the Fact Sheets and authorized labeling, as well as the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.

FF. All advertising and promotional descriptive printed matter relating to the use of the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel 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 diagnostic tests for detection and/or diagnosis of SARS-CoV-2 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

No advertising or promotional descriptive printed matter relating to the use of the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel may represent or suggest that this test is safe or effective for the detection of 2019-nCoV.

The emergency use of the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel 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 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,

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures