



July 24, 2020

Brian Krueger, PhD
Associate Vice President, Research and Development
Laboratory Corporation of America
1447 York Court
Burlington, NC 27215

Device: COVID-19 RT-PCR Test

Company: Laboratory Corporation of America (“LabCorp”)

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

Qualitative detection of nucleic acid from SARS-CoV-2 in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate) collected from individuals suspected of COVID 19 by their healthcare provider (HCP), as well as upper respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, nasal swabs, or mid-turbinate swabs) collected from any individual, including from individuals without symptoms or other reasons to suspect COVID-19 infection.

Qualitative detection of nucleic acid from SARS-CoV-2 in individual nasal swab specimens that are self-collected using the Pixel by LabCorp COVID-19 test home collection kit by individuals when determined by a HCP to be appropriate based on results of a COVID-19 questionnaire and the LabCorp At Home COVID-19 test home collection kit when directly ordered by a HCP.

Qualitative detection of nucleic acid from SARS-CoV-2 in pooled samples using a matrix pooling strategy (i.e., group pooling strategy), containing up to five individual upper respiratory swab specimens (nasopharyngeal, mid-turbinate, anterior nares or oropharyngeal swabs) per pool and 25 specimens per matrix, where each specimen is collected under observation or by a HCP using individual vials containing transport media.

Emergency use of this test is limited to authorized laboratories.

Authorized Laboratory: Testing is limited to laboratories designated by LabCorp that are also 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 Dr. Krueger:

On March 16, 2020, based on your¹ request, the Food and Drug Administration (FDA) issued a letter authorizing the emergency use of your product² for the qualitative detection of nucleic acid from SARS-CoV-2 in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate) from individuals suspected of COVID-19 by their healthcare provider, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3). The March 16, 2020, letter authorizing emergency use of this test limited testing to the Center of Esoteric Testing, Burlington, NC, or other laboratories designated by LabCorp that are also certified under CLIA, 42 U.S.C. §263a, to perform high complexity tests.³ Subsequently, on April 14, 2020, FDA granted your request to update the authorized labeling.⁴

On April 20, 2020, based on your request, FDA reissued the the March 16, 2020, letter in its entirety with revisions incorporated.⁵ Subsequently, on July 1, 2020, FDA granted your request to update the authorized labeling.⁶

On June 29, 2020, and subsequently on July 10, 2020, you again requested to amend your Emergency Use Authorization (EUA). Based on these requests, and having concluded that revising the April 20, 2020, EUA is appropriate to protect the public health or safety under

¹ For ease of reference, this letter will use the term “you” and related terms to refer to Laboratory Corporation of America (“LabCorp”).

² For ease of reference, this letter will use the term “your product” to refer to the COVID-19 RT-PCR Test used for the indications identified above.

³ For ease of reference, this letter will refer to, “the Center of Esoteric Testing, Burlington, North Carolina, or other laboratories designated by LabCorp that are also certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests” as “authorized laboratories.”

⁴ On April 14, 2020, your request was granted to update the Instructions for Use (IFU) of your product to; (1) add multiplex testing format using the N1, N2 and RP primer/probes to increase the throughput of the LabCorp EUA assay, (2) add an automated Hamilton Microlab Star liquid handler for the multiplex assay and, (3) add a second extraction method, the Thermo Fisher MagMAX Viral/Pathogen Nucleic Acid Isolation Kit on the Thermo Fisher KingFisher Flex Instrument to the multiplex assay.

⁵ On April 20, 2020, the amendments to the March 16, 2020, letter included: (1) amended intended use to include nasal swab specimens self-collected using Pixel by LabCorp COVID-19 Test Home Collection Kit, (2) additional conditions of authorization specific to home specimen collection; and, (3) revised the patient fact sheet to reflect the addition of at home specimen collection as an authorized collection method.

⁶ On July 1, 2020, your request was granted to update the authorized labeling of your product to; (1) add the LabCorp At Home COVID-19 Test Home Collection Kit as an authorized home collection kit for nasal specimens, that will not be administered through the Pixel platform, and associated authorized labeling, (2) update the intended use to include that the test is also for use with *“the LabCorp At Home COVID-19 test home collection kit to self-collect nasal swab specimens at home when directly ordered by a healthcare provider”*, (3) update the current home collection kit cotton swab to a foam swab going forward, (4) update the Pixel by LabCorp COVID-19 test home collection kit patient instructions, and (5) update the extraction protocol for the ThermoFisher MagMAX Viral/Pathogen Nucleic Acid Isolation Kit on the Thermo Fisher KingFisher Flex Instrument to reduce the sample and therefore reagent volumes to preserve extraction reagents due to current shortages.

section 564(g)(2)(C) of the Act (21 U.S.C. § 360bbb-3(g)(2)(C)), FDA is reissuing the April 20, 2020, letter in its entirety with the revisions incorporated.⁷ Pursuant to section 564 of the Act and the Scope of Authorization (Section II) and Conditions of Authorization (Section IV) of this reissued letter, this test is now authorized for use consistent with 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.⁸

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 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

⁷ The revisions to the April 20, 2020, letter include: (1) revised intended use to include use with upper respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, nasal swabs, or mid-turbinate swabs) collected from any individual, including from individuals without symptoms or other reasons to suspect COVID-19 infection, (2) revised intended use to include use with pooled samples using a matrix pooling strategy (group pooling strategy), containing up to five individual upper respiratory swab specimens (nasopharyngeal, mid-turbinate, anterior nares or oropharyngeal swabs) per pool and 25 specimens per matrix, where each specimen is collected under observation or by a HCP using individual vials containing transport media, (3) updates to the labeling documents to include the “Automated Aliquot and 4x4 Sample Pooling” standard operating procedure which includes the “Protocol for Monitoring of Specimen Pooling Testing Strategies,” (4) updates to the labeling documents to increase the sample stability for the Pixel by LabCorp COVID-19 test home collection kit to 6 days, (5) updates to the COVID-19 Questionnaire used with the Pixel by LabCorp COVID-19 test home collection kit to include updated risk based language, (6) added conditions of authorization specific to sample pooling; and, (7) revised the healthcare provider and patient fact sheets to reflect pooling and asymptomatic testing claims and also include language used in more recent authorizations.

⁸ 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).

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-19.⁹

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

Your product is authorized for the qualitative detection of nucleic acid from SARS-CoV-2 in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate) collected from individuals suspected of COVID 19 by their healthcare provider (HCP), as well as upper respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, nasal swabs, or mid-turbinate swabs) collected from any individual, including from individuals without symptoms or other reasons to suspect COVID-19 infection.

Your test is also authorized for use with individual nasal swab specimens that are self-collected using the Pixel by LabCorp COVID-19 test home collection kit by individuals when determined by a HCP to be appropriate based on results of a COVID-19 questionnaire and the LabCorp At Home COVID-19 test home collection kit when directly ordered by a HCP.

Finally, your product is also authorized for use to detect nucleic acid from the SARS-CoV-2 in pooled samples, using a matrix pooling strategy (group pooling strategy), containing up to five individual upper respiratory swab specimens (nasopharyngeal, mid-turbinate, anterior nares or oropharyngeal swabs) per pool and 25 specimens per matrix, where each specimen is collected under observation or by a HCP using individual vials containing transport media. 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 where the positive sample cannot be identified using the matrix 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 the Center for Esoteric Testing, Burlington, NC, or other laboratories designated by LabCorp that are also certified under the CLIA, 42 U.S.C. §263a, and meet the requirements to perform high complexity tests.

The SARS-CoV-2 nucleic acid is generally detectable in respiratory specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 nucleic acid; 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

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

not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

To perform the COVID-19 RT-PCR Test, SARS-CoV-2 nucleic acid is first extracted, isolated and purified from upper and lower respiratory specimens. The purified nucleic acid is then reverse transcribed into cDNA followed by PCR amplification and detection using an authorized real-time (RT) PCR instrument.

Your product uses all commercially sourced materials or other authorized materials and authorized ancillary reagents commonly used in clinical laboratories as described in the authorized labeling. The Pixel by LabCorp COVID-19 test home collection kit and the LabCorp At Home COVID-19 test home collection kit both provide specimen collection materials and materials to safely mail specimens to an authorized laboratory for testing using the COVID-19 RT-PCR test by LabCorp. Patients should follow all specimen collection and mailing instructions provided in the kit.

Your product requires the following control materials, or other authorized control materials (refer to Condition O), that are processed in the same way as the patient specimens and are required to be included with each batch of specimens tested with your product. All controls listed below must generate expected results in order for a test to be considered valid, as outlined in the in the authorized labeling:

- Internal Control - RNase P (RP) control in clinical samples: The RP primer and probe set is included in each run to test for human RP, which controls for specimen quality and demonstrates that nucleic acid was generated by the extraction process.
- Positive Template Control - contains *in vitro* transcribed SARS-CoV-2 RNA with genomic regions targeted by the kit. The positive control is used to monitor for failures of rRT-PCR reagents and reaction conditions.
- Negative Extraction Control (NEC) – Previously characterized negative patient sample. Used as an extraction control and positive control for the RP primer and probe set.
- No Template (Negative) Control - Nuclease-free, molecular-grade water 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 submitted as part of the EUA request (listed below), and as described in the EUA Summary (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: LabCorp - COVID-19 RT-PCR Test
- Fact Sheet for Patients: LabCorp - COVID-19 RT-PCR Test

The above described product, when accompanied by the EUA Summary, Fact Sheet for Healthcare Providers, Fact Sheet for Patients, COVID-19 questionnaire, “Pixel by LabCorp COVID-19 test home collection kit” patient instructions, “LabCorp At Home COVID-19 test home collection kit” patient instructions and the following standard operating procedures (SOPs): “Automated Aliquot and 4x4 Sample Pooling” which includes the “Protocol for Monitoring of Specimen Pooling Testing Strategies,” the “Accessioning of the LabCorp COVID-19 Home Test Kits,” “Accessioning of Pixel COVID-19 Test Specimens,” “Nucleic Acid Isolation for COVID-PCR Kingfisher Flex System,” “Nucleic Acid Isolation for COVID-PCR on the Hamilton MicroLab STAR,” and the “SARS-CoV-2 Detection by Nucleic Acid Amplification (LabCorp EUA – 384 Well Multiplex)” (collectively referenced as “authorized labeling”), is authorized to be distributed and used by the Center for Esoteric Testing, Burlington, NC, and other laboratories designated by LabCorp, 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 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 for the indication above.

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, distribution and storage of your product

IV. Conditions of Authorization

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

LabCorp (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 available your product all athorized labeling to authorized laboratories.
- C. 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).
- D. You will make available on your website(s) the authorized Fact Sheet for Healthcare Providers, Fact Sheet for Patients, “Pixel by LabCorp COVID-19 test home collection kit” patient insrtuctions, and the “LabCorp At Home COVID-19 test home collection kit” patient instructions.
- E. 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.
- F. 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.
- G. You will maintain records of the authorized laboratories and test usage.
- H. 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 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 the Scope of Authorization (Section II in this letter). 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.
- K. 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.
- L. 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.
- M. 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.
- N. 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.
- O. 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.
- P. 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.
- Q. You may request the addition and/or substitution of home specimen collection kits for use with your product. Such requests will be made by LabCorp in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- R. You may request the addition and/or substitution of the components of the Pixel by LabCorp COVID-19 Test Home Collection Kit, 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.
- S. You will evaluate the analytical limit of detection and assess traceability¹⁰ 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 the 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.

¹⁰ Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material.

- T. You will track adverse events, including any occurrence of false results and report to FDA pursuant to 21 CFR Part 803.
- U. You will additionally track adverse events associated with the Pixel by LabCorp COVID-19 Test Home Collection Kit, 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).
- V. You will make available all instructions related to the self-collection of specimens using the Pixel by LabCorp COVID-19 Test Home Collection Kit, the LabCorp At Home COVID-19 test home collection kit or any other home specimen collection kit authorized for use with your product, both in the shipped kit and on your website.
- W. You will notify FDA of any changes to the COVID-19 questionnaire used by a healthcare provider to determine eligibility of an individual to receive the Pixel by LabCorp COVID-19 Test Home Collection Kit, or any other home specimen collection kit authorized for use with your product.
- X. You will submit to FDA a summary report within 30 calendar days of authorization summarizing the results of any testing performed using specimens collected with any new home-collection kit authorized for use with your product during that timeframe, including how many specimens were received, how many specimens had to be rejected during accession and the main reasons for rejection, and the positivity rate for specimens collected with the authorized home-collection kit..

Authorized Laboratories

- Y. 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.
- Z. Authorized laboratories using you product will perform the test as outlined in the authorized labeling. Deviations from the authorized labeling, including the authorized 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.
- AA. Authorized laboratories testing specimens self-collected using the using the Pixel by LabCorp COVID-19 Test Home Collection Kit, 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 the Accessioning of the LabCorp COVID-19 Home Test Kits and Accessioning of Pixel

COVID-19 Test Specimens protocols when accepting specimens for testing.

- 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) and you (covid19requests@labcorp.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 authorized labeling 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.

LabCorp (You) 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 and 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,

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosure