



June 21, 2022

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531 S. Spring Street  
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Device: COVID-19 RT-PCR Test

EUA Number: EUA200011

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 (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 (nasopharyngeal or oropharyngeal swabs, anterior nasal swabs, or mid-turbinate swabs) collected from any individual, including individuals without symptoms or other reasons to suspect COVID-19.

Qualitative detection of nucleic acid from SARS-CoV-2 in individual anterior nasal swab specimens from individuals age 18 years and older (self-collected), 14 years and older (self-collected under adult supervision), or 2 years and older (collected with adult assistance) using the Labcorp At Home COVID-19 Test Home Collection Kit or Labcorp COVID-19 Test At 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 nasal or oropharyngeal swabs collected using individual vials containing transport media) per pool and 25 specimens per matrix. Anterior nasal swab specimens are collected in individual vials containing transport media either under observation by a HCP or self-collected using a home collection kit authorized for use with this test.

Emergency use of this test is limited to authorized laboratories.

Authorized Laboratories: Testing is limited to the Center for Esoteric Testing in Burlington, NC or other 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. Eisenberg:

On March 16, 2020, based on your<sup>1</sup> request, the Food and Drug Administration (FDA) issued a letter authorizing the emergency use of the COVID-19 RT-PCR Test for the qualitative detection of nucleic acid from SARS-CoV-2 in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate) from individuals suspected of COVID-19 by their healthcare provider, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3). The March 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. Based on your requests, the March 16, 2020, letter has been revised and reissued by FDA on April 20, 2020<sup>2</sup>, July 24, 2020<sup>3</sup>,

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

<sup>2</sup> The April 20, 2020, revisions to the March 16, 2020, letter included: (1) revised the 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.

<sup>3</sup> The July 24, 2020, revisions to the April 20, 2020, letter included: (1) revisions to the 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) revisions the 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) update 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) new conditions of authorization specific to sample pooling; and, (7) revisions to the healthcare provider and patient fact sheets to reflect pooling and asymptomatic testing claims and also include language used in more recent authorizations.

September 18, 2020<sup>4</sup>, December 9, 2020<sup>5</sup>, and April 28, 2021.<sup>6</sup> FDA has also granted updates to the authorized labeling at your request.<sup>7,8,9,10</sup>

In addition, FDA established additional Conditions of Authorization in response to the continued emergence of new variants of SARS-CoV-2 on September 23, 2021.

On April 28, 2022 and April 29, 2022, you again requested to amend your Emergency Use Authorization (EUA). Based on these requests, and having concluded that revising the April 28, 2021, 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 April 28, 2021, letter in its

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<sup>4</sup> The September 18, 2020, revisions to the July 24, 2020, letter included: (1) revisions to the intended use and authorized labeling documents to include pooling of self-collected samples collected either under observation by a HCP or self-collected using a home collection kit, (2) updates to the labeling documents to add the CERES Nanosciences Nanotrap Virus Capture Kit as a new extraction method, and (3) revisions to the fact sheets to reflect pooling of self-collected specimens.

<sup>5</sup> The December 9, 2020, revisions to the September 18, 2020, letter included: (1) revisions to the intended use and authorized labeling documents to remove use of the Pixel by LabCorp COVID-19 Test Home Collection Kit (due to issuance of a separate EUA) except as specified in footnote 11 (of the December 9, 2020, letter), along with associated updates to reflect this revision, (2) addition of conditions of authorization related to authorized distributor(s) for the LabCorp At Home COVID-19 test home collection kit and (3) updates to use language more consistent with recent authorizations.

<sup>6</sup> The April 28, 2021, revisions to the December 9, 2020, letter and authorized labeling included: (1) change of the name from “LabCorp” to “Labcorp,” (2) update the intended use to indicate testing of individual anterior nasal swab specimens from individuals age 18 years and older (self-collected), 14 years and older (self-collected under adult supervision), or 2 years and older (collected with adult assistance) using the Labcorp At Home COVID-19 Test Home Collection Kit when directly ordered by an HCP, specify nasal specimens as “anterior” nasal, delete “such as” before the list of authorized specimens (3) addition of limitation statements regarding performance with circulating variants and lack of evaluation with specimens collected from individuals 18 years and older by an adult in the home, (4) updates to the Healthcare Provider and Patient Fact Sheets to reflect language used in more recent authorizations, (5) addition of winter and summer sample stability data generated, (6) additional clinical data with real clinical positive samples, (7) update to the LoD study data presentation in the EUA Summary, (8) minor edits and formats to the EUA Summary, (9) addition of the ThermoFisher MagMAX Viral/Pathogen II (MVP II) Nucleic Acid Isolation Kit using the Hamilton MicroLab STAR and ThermoFisher KingFisher Flex instruments, (10) update to the LabCorp At Home COVID-19 Test Home Collection Kit IFU to include user warnings about the Sodium Chloride/0.9% (saline) in the collection tube, and (11) removal of Condition O. (from the December 9, 2020, letter) which was fulfilled.

<sup>7</sup> On April 14, 2020, your request was granted to update the Instructions for Use (IFU) of your product to: (1) add a multiplex testing format using the N1, N2 and RP primer/probes to increase the throughput of your test, (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.

<sup>8</sup> 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.

<sup>9</sup> On May 11, 2021, your request was granted to update the authorized labeling of your product to extend the shipping summer sample stability claim of anterior nasal swab specimens collected at home using the Labcorp At Home COVID-19 Test Home Collection Kit from 2 to 4 days.

<sup>10</sup> On April 6, 2022, your request was granted to update the Standard Operating Procedures (SOPs) of your product to: (1) add DC Health’s Test Yourself DC At-Home COVID-19 Collection Kit to the “Accessioning of the LabCorp COVID-19 Home Test Kits” SOP, and (2) clarify in the “SARS-CoV-2 Detection by Nucleic Acid Amplification (LabCorp EUA – 384 Well Multiplex)” SOP that an “Invalid” result is reported to patients and to DC Health as “Specimen Unsatisfactory for Evaluation”.

entirety with the revisions incorporated.<sup>11</sup> Pursuant to section 564 of the Act and the Scope of Authorization (Section II) and Conditions of Authorization (Section IV) of this reissued letter, your product<sup>12</sup> is now authorized for use consistent with the indication described above.

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19. Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 subject to the terms of any authorization issued under Section 564(a) of the Act.<sup>13</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 EUA Summary (identified below).

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 certain individuals 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;

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<sup>11</sup> The revisions to the April 28, 2021, letter and authorized labeling include: (1) extension of winter sample stability claim of anterior nasal swab specimens collected using the Labcorp At Home COVID-19 Test Home Collection Kit, (2) addition of the Labcorp COVID-19 Test At Home Collection Kit as an authorized home collection kit for nasal specimens, (3) update the intended use to indicate testing of individual anterior nasal swab specimens from individuals age 18 years and older (self-collected), 14 years and older (self-collected under adult supervision), or 2 years and older (collected with adult assistance) using the Labcorp At Home COVID-19 Test Home Collection Kit or the Labcorp COVID-19 Test At Home Collection Kit when directly ordered by an HCP, (4) revisions to all laboratory SOPs to include “For in vitro diagnostic use”, “Prescription use only”, and “For use under Emergency Use Authorization (EUA) only”, (5) revisions to the “Accessioning of Respiratory Specimens Collected with the LabCorp Home Collection Kits” SOP to include the Labcorp COVID-19 Test At Home Collection Kit, (6) revisions to the Healthcare Provider Fact Sheet to include the Labcorp COVID-19 Test At Home Collection Kit and to reflect language used in more recent authorizations, and (7) updates to the Patient Fact Sheet to reflect language used in more recent authorizations.

<sup>12</sup> For ease of reference, this letter will use the term “your product” to refer to the entire test system, i.e., COVID-19 RT-PCR Test, the Labcorp At Home COVID-19 Test Home Collection Kit, the Labcorp COVID-19 Test At Home Collection Kit, controls, ancillary reagents, and other materials, authorized under this EUA as outlined in the Scope of Authorization (Section II) and Conditions of Authorization (Section IV).

<sup>13</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).

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>14</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**

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

Your product is also authorized for use with individual nasal swab specimens from individuals age 18 years and older (self-collected), 14 years and older (self-collected under adult supervision), or 2 years and older (collected with adult assistance) using the Labcorp At Home COVID-19 Test Home Collection Kit or Labcorp COVID-19 Test At 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 (i.e., group pooling strategy), containing up to five individual upper respiratory swab specimens (nasopharyngeal, mid-turbinate, anterior nasal or oropharyngeal swabs collected using individual vials containing transport media) per pool and 25 specimens per matrix. Anterior nasal swab specimens are collected in individual vials containing transport media either under observation by an HCP or self-collected using a home collection kit authorized for use with this test.<sup>15</sup> 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.

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<sup>14</sup> No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

<sup>15</sup> Home collection kits currently authorized for use with this test include the Labcorp At Home COVID-19 Test Home Collection Kit, the Labcorp COVID-19 Test At Home Collection Kit and the Pixel by LabCorp COVID-19 Test Home Collection Kit. Please note that you, authorized laboratories, and authorized distributors must follow the terms and conditions set forth in EUA 203057 concerning specimens collected using the Pixel by LabCorp COVID-19 Test Home Collection Kit.

Testing of clinical specimens with the COVID-19 RT-PCR Test 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 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. The COVID-19 RT-PCR Test includes the materials (or other authorized materials as may be requested under Condition M. below) described in the EUA Summary.

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 Labcorp At Home COVID-19 Test Home Collection Kit and the Labcorp COVID-19 Test At Home Collection Kit 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 control materials (or other authorized control materials as may be requested under Condition M. below) that are described in the EUA Summary.

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.

The above described product is authorized to be accompanied with the standard operating procedures (SOPs) submitted as part of the EUA request (listed below), the EUA Summary (available at <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas>), 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):

- 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, the two fact sheets, 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 Respiratory Specimens Collected with the Labcorp Home Collection Kits,” “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)”, is authorized to be distributed and used under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

The Labcorp At Home COVID-19 Test Home Collection Kit with the “Labcorp At Home COVID-19 Test Home Collection Kit” patient instructions is authorized to be distributed and used as part of the above described product as set forth in this EUA.

The Labcorp COVID-19 Test At Home Collection Kit with the “Labcorp COVID-19 Test At Home Collection Kit” patient instructions and the Labcorp COVID-19 Test At Home Collection Kit registration card are authorized to be distributed and used as part of the above described product as set forth in this EUA.

“Authorized labeling” refers to the EUA Summary, the two fact sheets, the SOPs (described above), the “Labcorp At Home COVID-19 Test Home Collection Kit” patient instructions, the “Labcorp COVID-19 Test At Home Collection Kit” patient instructions, and the Labcorp COVID-19 Test At Home Collection Kit registration card.

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 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) and Authorized Distributor(s)<sup>16</sup>**

- A. You and authorized distributors must make available all instructions related to the collection of anterior nasal swab specimens using the Labcorp At Home COVID-19 Test Home Collection Kit or the Labcorp COVID-19 Test At Home Collection Kit, both in the shipped kit and on your website(s).
- B. You and authorized distributor(s) must make available on your website(s), if applicable, the authorized Fact Sheet for Healthcare Providers and Fact Sheet for Patients.
- C. Through a process of inventory control, you and authorized distributor(s) must maintain records of the numbers and locations to which the Labcorp At Home COVID-19 Test Home Collection kit and the Labcorp COVID-19 Test At Home Collection Kit are distributed.
- D. You and authorized distributor(s) must maintain customer complaint files on record. You must report to FDA any significant complaints about usability or deviations from the established performance characteristics of the product of which you become aware.
- E. You and authorized distributor(s) 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.
- F. You and authorized distributors must ensure that any records associated with this EUA, including test usage, are maintained until otherwise notified by FDA. Such records must be made available to FDA for inspection upon request.

##### **Labcorp (You)**

- G. Your product must comply with the following labeling requirements pursuant to 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).
- H. You must make your product available with the authorized labeling to authorized laboratories.

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<sup>16</sup> “Authorized Distributor(s)” are identified by you, Labcorp, in your EUA submission as an entity allowed to distribute the Labcorp At Home COVID-19 Test Home Collection Kit or the Labcorp COVID-19 Test At Home Collection Kit for use with your product.



- I. You must 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.
- J. You must 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.
- K. You must maintain records of the authorized laboratories and test usage.
- L. You must collect information on the performance of the test. You must 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.
- M. 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 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) and require appropriate authorization from FDA prior to implementation.
- N. You must evaluate the analytical limit of detection and assess traceability<sup>17</sup> of your product with any FDA-recommended reference material(s). After submission to and concurrence with the data by FDA, you must update your labeling to reflect the additional testing. Such labeling updates must be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- O. You must 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.
- P. You must additionally track adverse events associated with the Labcorp At Home COVID-19 Test Home Collection Kit and the Labcorp COVID-19 Test At Home Collection Kit, including occurrences of false results and report to FDA pursuant to 21 CFR Part 803. Serious adverse events, especially unexpected biosafety concerns, should immediately be reported to DMD/OHT7-OIR/OPEQ/CDRH (via email: [CDRH-EUA-Reporting@fda.hhs.gov](mailto:CDRH-EUA-Reporting@fda.hhs.gov)).
- Q. You must evaluate the impact of SARS-CoV-2 viral mutations on your product's performance. Such evaluations must occur on an ongoing basis and must include any additional data analysis that is requested by FDA in response to any performance concerns you or FDA identify during routine evaluation. Additionally, if requested by FDA, you must submit records of these evaluations for FDA review within 48 hours of the request. If your evaluation identifies viral

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<sup>17</sup> Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material.

mutations that affect the stated expected performance of your device, you must notify FDA immediately (via email: [CDRH-EUA-Reporting@fda.hhs.gov](mailto:CDRH-EUA-Reporting@fda.hhs.gov)).

- R. If requested by FDA, you must update your labeling within 7 calendar days to include any additional labeling risk mitigations identified by FDA regarding the impact of viral mutations on test performance. Such updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

### **Authorized Laboratories**

- S. Authorized laboratories using your product must 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.
- T. Authorized laboratories using your product must 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.
- U. Authorized laboratories testing specimens collected using the using the Labcorp At Home COVID-19 Test Home Collection Kit or the Labcorp COVID-19 Test At Home Collection Kit, must follow any Specimens Accessioning protocols provided with the authorized labeling when accepting specimens for testing.
- V. Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run the test prior to initiating testing.
- W. Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- X. Authorized laboratories must collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: [CDRH-EUA-Reporting@fda.hhs.gov](mailto:CDRH-EUA-Reporting@fda.hhs.gov)) and you ([covid19requests@labcorp.com](mailto: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.
- Y. Authorized laboratories using specimen pooling strategies when testing patient specimens with your product must 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.”*
- Z. 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.
- AA. Authorized laboratories must 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 must be made available to FDA within 48 business hours for inspection upon request and must be made available within a reasonable time after 12 months from the date of their creation.

BB. 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), Authorized Distributor(s) and Authorized Laboratories**

CC. You, authorized distributor(s), and authorized laboratories using your product must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records must be made available to FDA for inspection upon request.

### **Conditions Related to Printed Materials, Advertising and Promotion**

DD. All descriptive printed matter, 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 meet the requirements set forth in section 502(a), (q)(1), and (r) of the Act, as applicable, and FDA implementing regulations.

EE. No descriptive printed matter, 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.

FF. All descriptive printed matter, advertising and promotional materials relating to the use of your product shall clearly and conspicuously state that:

- This product has not been FDA cleared or approved but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories;
- This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and,
- The emergency use of this product 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 Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

The emergency use of your product as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

## **V. Duration of Authorization**

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

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Jacqueline A. O'Shaughnessy, Ph.D.  
Acting Chief Scientist  
Food and Drug Administration

Enclosure