April 20, 2020

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

Dear Dr. Krueger:

On March 16, 2020, based on your request, the Food and Drug Administration (FDA) issued a letter authorizing the emergency use of the Laboratory Corporation of America (LabCorp) 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, 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.[1]

On April 5, 2020, FDA received a request from LabCorp to amend the Emergency Use Authorization (EUA). In response to that request, and having concluded that revising the March 16, 2020, EUA is appropriate to protect the public health or safety under section 564(g)(2)(c) of the Act (21 U.S.C. § 360bbb-3(g)(2)(c)), FDA is reissuing the March 16, 2020, letter in its entirety with the amendments incorporated[2] to authorize the emergency use of the LabCorp COVID-19 RT-PCR Test to be used with a home specimen collection method. 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 intended for the qualitative detection of nucleic acid from SARS-CoV-2 in upper and lower respiratory specimens (such as nasal, nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate) collected from individuals suspected of COVID-19 by their healthcare provider. Nasal swab specimens may

[1] 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."
[2] The amendments to the March 16, 2020 letter include: (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.

also now be collected for use with this test using the Pixel by LabCorp COVID-19 test home collection kit to self-collect nasal swab specimens at home by individuals when determined by a healthcare provider to be appropriate based on results of a COVID-19 questionnaire.

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.[3] 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 are met, I am authorizing the emergency use of LabCorp's COVID-19 RT-PCR Test (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 LabCorp's COVID-19 RT-PCR Test for testing individuals suspected of COVID-19 by their healthcare provider meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. The SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that LabCorp's COVID-19 RT-PCR Test may be effective in diagnosing COVID-19, and that the known and potential benefits of the COVID-19 RT-PCR Test, 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 LabCorp's COVID-19 RT-PCR Test 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 LabCorp COVID-19 RT-PCR Test by authorized

[3] On February 11, 2020, the virus tentatively named 2019-nCoV was formally designated as Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Also on February 11, 2020, the disease caused by SARS-CoV-2 was formally designated as Coronavirus Disease 2019 (COVID-19). This document uses the updated names.
[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*. 85 FR 7316 (February 7, 2020).
[5] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

laboratories for the qualitative detection of SARS-CoV-2 in upper and lower respiratory specimens (such as nasal, nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate) collected from individuals suspected of COVID-19 by their healthcare provider and from nasal swab specimens collected for use with this test using the Pixel by LabCorp COVID-19 test home collection kit to self-collect nasal swab specimens at home by individuals when determined by a healthcare provider to be appropriate based on results of a COVID-19 questionnaire.

The Authorized LabCorp COVID-19 RT-PCR Test

LabCorp's COVID-19 RT-PCR Test is a qualitative test for the detection of nucleic acid from SARS-CoV-2 in upper and lower respiratory specimens (such as nasal, nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate) collected from individuals suspected of COVID-19 by their healthcare provider.

Nasal swab specimens may also now be collected for use with this test using the Pixel by LabCorp COVID-19 test home collection kit to self-collect nasal swab specimens at home by individuals when determined by a healthcare provider to be appropriate based on results of a COVID-19 questionnaire. The kit provides 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.

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.

To perform LabCorp's COVID-19 RT-PCR Test, SARS-CoV-2 nucleic acid is first extracted, isolated and purified from upper and lower respiratory specimens (such as nasal, nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate). The purified nucleic acid is then reverse transcribed into cDNA followed by PCR amplification and detection using an authorized real-time (RT) PCR instrument..

This COVID-19 RT-PCR Test uses all commercially sourced materials or other authorized materials and authorized ancillary reagents commonly used in clinical laboratories as described in the authorized procedures submitted as part of the EUA request.

This COVID-19 RT-PCR Test requires the following control materials, or other authorized control materials, that are processed in the same way as the patient samples and are required to be included with each batch of specimens tested with LabCorp's COVID-19 RT-PCR Test. All controls listed below must generate expected results in order for a test to be considered valid, as outlined in the COVID-19 RT-PCR Test Instructions for Use:

- 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.

LabCorp's COVID-19 RT-PCR Test 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 COVID-19 RT-PCR Test Instructions for Use.

The above described product, when labeled consistently with the authorized labeling available at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations, which may be revised by LabCorp 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. Authorized labeling includes the following documents: EUA Summary, Fact Sheet for Healthcare Providers, Fact Sheet for Patients, Standard Operating Procedures (SOP) for the COVID-19 RT-PCR Test (singleplex and multiplex versions), the Pixel by LabCorp COVID-19 Test Home Collection Kit Instructions and COVID-19 Questionnaire, SOP - Cotton Swab Quality Control, and the Procedure - Accessioning of Pixel COVID-19 Test Specimens.

The above-described COVID-19 RT-PCR Test 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: LabCorp's COVID-19 RT-PCR Test
- Fact Sheet for Patients: LabCorp's COVID-19 RT-PCR Test

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 LabCorp COVID-19 RT-PCR Test, 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 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 LabCorp COVID-19 RT-PCR Test 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 LabCorp's COVID-19 RT-PCR Test, 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 LabCorp's authorized COVID-19 RT-PCR Test 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 COVID-19 RT-PCR Test described above is authorized to detect SARS-CoV-2 in individuals suspected of COVID-19 by their healthcare provider.

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 LabCorp's COVID-19 RT-PCR Test 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 COVID-19 RT-PCR Test

IV. Conditions of Authorization

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

LabCorp

A. LabCorp's COVID-19 RT-PCR Test 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)); 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).

B. LabCorp will make available the authorized COVID-19 RT-PCR Test with the following authorized labeling documents: Fact Sheet for Healthcare Providers, Fact

Sheet for Patients, Standard Operating Procedures (SOP) for the COVID-19 RT-PCR Test (singleplex and multiplex versions), and the procedure for Accessioning of Pixel COVID-19 Test Specimens, to authorized laboratories.

C. LabCorp may request changes to the authorized labeling, including Fact Sheets. Such requests will be made by LabCorp in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

D. LabCorp will make available on their website(s) the authorized COVID-19 RT-PCR Test Fact Sheet for Healthcare Providers and the authorized COVID-19 RT-PCR Test Fact Sheet for Patients and the Pixel by LabCorp COVID-19 Test Home Collection Kit Instructions.

E. LabCorp will inform authorized laboratories and relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to the COVID-19 RT-PCR Test and authorized labeling, including authorized Fact Sheets.

F. LabCorp will ensure that the authorized laboratories using the authorized COVID-19 RT-PCR Test have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

G. LabCorp will maintain records of the authorized laboratories and test usage.

H. LabCorp will collect information on the performance of the test. LabCorp 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 LabCorp becomes aware.

I. LabCorp is authorized to make available additional information relating to the emergency use of the authorized COVID-19 RT-PCR Test that is consistent with, and does not exceed, the terms of this letter of authorization.

J. LabCorp may request changes to the Scope of Authorization (Section II in this letter) of the authorized COVID-19 RT-PCR Test. Such requests will be made by LabCorp 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. LabCorp may request the addition of other instruments and associated software for use with the authorized COVID-19 RT-PCR Test. Such requests will be made by LabCorp in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

L. LabCorp may request the addition of other extraction methods for use with the authorized COVID-19 RT-PCR Test. Such requests will be made by LabCorp in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

M. LabCorp may request the addition of other specimen types for use with the authorized COVID-19 RT-PCR Test. Such requests will be made by LabCorp in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

N. LabCorp may request the addition and/or substitution of primers or probes for use with the authorized COVID-19 RT-PCR Test. Such requests will be made by LabCorp in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

O. LabCorp may request the addition and/or substitution of control materials for use with the authorized COVID-19 RT-PCR Test. Such requests will be made by LabCorp in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

P. LabCorp may request the addition and/or substitution of other ancillary reagents and materials for use with the authorized COVID-19 RT-PCR Test. Such requests will be made by LabCorp in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

Q. LabCorp may request the addition and/or substitution of home specimen collection kits for use with the authorized COVID-19 RT-PCR Test. Such requests will be made by LabCorp in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

R. LabCorp 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 the COVID-19 RT-PCR Test. Such requests will be made by LabCorp in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

S. LabCorp will evaluate the analytical limit of detection and assess traceability[6] of this COVID-19 RT-PCR Test 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, LabCorp 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.

T. LabCorp will track adverse events associated with the authorized COVID-19 RT-PCR Test, including any occurrence of false results and report to FDA under 21 CFR Part 803.

U. LabCorp 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 the COVID-19 RT-PCR Test, including occurrences of false results and report to FDA under 21 CFR Part 803. Serious adverse events, especially unexpected biosafety concerns, should immediately be reported to DMD/OHT7-

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

OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov).

V. LabCorp will make available all instructions related to the self-collection of nasal swab specimens using the Pixel by LabCorp COVID-19 Test Home Collection Kit, or any other home specimen collection kit authorized for use with the COVID-19 RT-PCR Test, both in the shipped kit and on its website.

W. LabCorp will notfy FDA of any changes to the COVID-19 questionnaire used by a healthcare provider to determine eligbility 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 the COVID-19 RT-PCR Test.

X. LabCorp will conduct a brief costumer survey about the usability of the Pixel by LabCorp COVID-19 Test Home Collection Kit and include results in the summary report outlined in Condition Y.

Y. LabCorp will submit to FDA a summary report within 30 calendar days of this letter summarizing the results of any testing performed using nasal specimens collected with the Pixel by LabCorp COVID-19 Test Home Collection Kit during that timeframe, including how many kits were requested and granted for home collection, how many kits were shipped and returned, how many specimens had to be rejected during accession and the main reasons for rejection, and the positivity rate of the first Pixel by LabCorp COVID-19 Test Home Collection Kit lot.

Authorized Laboratories

Z. Authorized laboratories using LabCorp's COVID-19 RT-PCR Test 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.

AA. Authorized laboratories using LabCorp's COVID-19 RT-PCR Test will perform the COVID-19 RT-PCR Test as outlined in the COVID-19 RT-PCR Test procedures. Deviations from the authorized procedures, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to perform the COVID-19 RT-PCR Test are not permitted.

BB. Authorized laboratories testing nasal swab specimens self-collected using the using the Pixel by LabCorp COVID-19 Test Home Collection Kit with LabCorp's COVID-19 RT-PCR Test must follow the Accessioning of Pixel COVID-19 Test Specimens protocol when accepting specimens for testing.

CC. Authorized laboratories that receive LabCorp's COVID-19 RT-PCR Test must notify the relevant public health authorities of their intent to run the test prior to initiating testing.

DD. Authorized laboratories using LabCorp's COVID-19 RT-PCR Test will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

EE. 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 LabCorp (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.

FF. 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 and Authorized Laboratories

GG. LabCorp and authorized laboratories using LabCorp's COVID-19 RT-PCR Test 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

HH. All advertising and promotional descriptive printed matter relating to the use of LabCorp's authorized COVID-19 RT-PCR Test shall be consistent with the Fact Sheets and other authorized labeling, as well as the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.

II. All advertising and promotional descriptive printed matter relating to the use of LabCorp's authorized COVID-19 RT-PCR Test 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.

No advertising or promotional descriptive printed matter relating to the use of LabCorp's authorized COVID-19 RT-PCR Test may represent or suggest that this test is safe or effective for the detection of SARS-CoV-2.

The emergency use of LabCorp's authorized COVID-19 RT-PCR Test as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

V. Duration of Authorization

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

Sincerely,

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RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures