December 9, 2020

Brian Krueger, PhD
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Laboratory Corporation of America
1447 York Court
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Device:	Pixel by LabCorp COVID-19 Test Home Collection Kit
Company:	Laboratory Corporation of America (“LabCorp”)
Indication:	This product is authorized for the following indications for use: For direct to consumer self-collecting of an individual nasal swab specimen at home and sending that specimen for testing with LabCorp’s COVID-19 RT-PCR test, a real-time reverse transcription polymerase chain reaction (rRT-PCR) test, for the qualitative detection of nucleic acid from SARS-CoV-2. For use by adults 18 years and older, to self-collect individual nasal swab specimens, including for use by such individuals without symptoms or other reasons to suspect COVID-19 infection. Nasal swab specimens collected with LabCorp’s Pixel by LabCorp COVID-19 Test Home Collection Kit are also authorized to be tested with the COVID-19 RT-PCR test, for the 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, nasal or oropharyngeal swabs collected using individual vials containing transport media) per pool and 25 specimens per matrix. Emergency use of the COVID-19 RT-PCR test is limited to authorized laboratories.
Authorized Laboratories:	Testing of specimens collected using the Pixel by LabCorp COVID-19 Test Home Collection Kit using the COVID-19 RT-PCR test 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. Krueger:

This letter is in response to your[1] request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of your product,[2] pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19. Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 subject to the terms of any authorization issued under Section 564(a) of the Act.[3]

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;

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,

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[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 to refer to the entire direct to consumer product, i.e., the Pixel by LabCorp COVID-19 test home collection kit for self-collection of nasal swab specimens at home, the COVID-19 RT-PCR Test for testing the self-collected nasal swab specimens, and the associated 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).

[3] U.S. Department of Health and Human Services, D*etermination 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).

3. There is no adequate, approved, and available alternative to the emergency use of your product for diagnosing COVID-19.[4]

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 as a direct to consumer product for self-collecting an individual nasal swab specimen at home and sending that specimen for testing with LabCorp's COVID-19 RT-PCR test, a real-time reverse transcription polymerase chain reaction (rRT-PCR) test for the qualitative detection of nucleic acid from SARS-CoV-2. Nasal swab specimens collected with your Pixel by LabCorp COVID-19 Test Home Collection Kit are also authorized to be tested using your COVID-19 RT-PCR test 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, nasal or oropharyngeal swabs collected using individual vials containing transport media) per pool and 25 specimens per matrix. All test results are then delivered to the user via their Pixel by LabCorp account created during registration. Individuals with positive and invalid/indeterminate results additionally will receive a phone call from a healthcare provider.[5]

The direct to consumer home collection system is intended to enable users to access information about their COVID-19 infection status that could aid with determining if self-isolation (quarantine) is appropriate and to assist with healthcare decisions after discussion with a healthcare provider.

The Pixel by LabCorp COVID-19 Test Home Collection Kit is for use by adults 18 years and older, to self-collect individual nasal swab specimens, including for use by such individuals without symptoms or other reasons to suspect COVID-19 infection.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in respiratory specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with medical history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Negative results do not preclude SARS-CoV-2 infection.

Additionally, negative results from pooled testing should not be treated as definitive and may need follow up testing if inconsistent with an individual's signs and symptoms. 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.

Use of your product is not a substitute for visits to a healthcare provider. The information provided by this product should not be used to start, stop, or change any course of treatment

[4] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.
[5] For this EUA, a healthcare provider includes any health professional with prescribing abilities, including, but is not limited to, physicians, nurses, pharmacists, technologists, laboratory directors, and epidemiologists.

unless advised by your healthcare provider.

Testing of specimens collected using the Pixel by LabCorp COVID-19 Test Home Collection Kit is limited to the Center for Esoteric Testing, 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.

Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

To perform the COVID-19 RT-PCR Test, SARS-CoV-2 nucleic acid is first extracted, isolated and purified from nasal swab specimens, collected with your Pixel by LabCorp COVID-19 Test Home Collection Kit. 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 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. Individuals 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 M), that are processed in the same way as the 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 (optional): 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 individuals:

- Fact Sheet for Healthcare Providers: LabCorp - Pixel by LabCorp COVID-19 Test Home Collection Kit
- Fact Sheet for Individuals: LabCorp - Pixel by LabCorp COVID-19 Test Home Collection Kit

The above described product, when accompanied by the EUA Summary, Fact Sheet for Healthcare Providers, Fact Sheet for Individuals, "Pixel by LabCorp COVID-19 Test Home Collection Kit" instructions, "Pixel by LabCorp COVID-19 Test Home Collection Kit" box label, and the following standard operating procedures (SOPs): "Automated Aliquot and 4x4 Sample Pooling" which includes the "Protocol for Monitoring of Specimen Pooling Testing Strategies," "Accessioning of Pixel COVID-19 Asymptomatic Test Specimens," "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 authorized laboratories, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

The Pixel by LabCorp COVID-19 Test Home Collection Kit, with the "Pixel by LabCorp COVID-19 Test Home Collection Kit" instructions is authorized to be distributed and used as set forth in this EUA.

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 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) [6]

A. You and authorized distributors must make available all instructions related to the self-collection of nasal swab specimens using the Pixel by LabCorp COVID-19 Test Home Collection Kit both in the shipped kit and on your website.

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 Individuals.

C. You and authorized distributor(s) of the Pixel by LabCorp COVID-19 Test Home Collection Kit must include in the shipped kit the Fact Sheet for Individuals.

D. Through a process of inventory control, you and authorized distributor(s) must maintain records of the numbers and locations to which the Pixel by LabCorp COVID-19 Test Home Collection Kit is distributed.

E. You and authorized distributor(s) must maintain customer complaint files on record. You will report to FDA any significant complaints about usability or deviations from the established performance characteristics of the product of which you become aware.

F. 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.

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).

[6] "Authorized Distributor(s)" are identified by you, LabCorp, in your EUA submission as an entity allowed to distribute the Pixel by LabCorp COVID-19 Test Home Collection Kit.

H. You must make your product available with the authorized labeling to authorized laboratories.

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 individuals, 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 your product. You must report to FDA any suspected occurrence of false positive and false negative results and significant deviations from the established performance characteristics of your product of which you become aware.

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[7] of your product with any FDA-recommended reference material(s). After submission to and concurrence with the data by FDA, you will update your labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

O. You must have a process in place in accordance with 21 CFR Part 803 to track adverse events associated with your product, including any occurrence 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).

Authorized Laboratories

P. Authorized laboratories using your product must make available the Fact Sheet for Healthcare Providers to HCPs that communicate test results to individuals (refer to Condition U).

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

Q. 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.

R. Authorized laboratories testing specimens self-collected using the Pixel by LabCorp COVID-19 Test Home Collection Kit must follow any Specimens Accessioning protocols provided in the authorized labeling.

S. Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run the test prior to initiating testing.

T. Authorized laboratories using your product must have a process in place for reporting test results to relevant public health authorities, as appropriate. Authorized laboratories using your product must also have a process in place requiring that healthcare providers, defined in footnote 5, provide positive and invalid/indeterminate results to individuals whose specimens are tested.

U. Authorized laboratories testing specimens collected with the Pixel by LabCorp COVID-19 Test Home Collection Kit must have a process in place for reporting all test results to individuals who use the kit. This process must include a requirement that all positive and invalid/indeterminate results must be reported to individuals who self-collected specimens using the Pixel by LabCorp COVID-19 Test Home Collection Kit by a HCP via phone call.[8]

V. Authorized laboratories testing specimens collected with the Pixel by LabCorp COVID-19 Test Home Collection Kit must have a healthcare provider available to provide information and counseling to individuals.

W. 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) 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.

X. Authorized laboratories using specimen pooling strategies when testing individual's specimens with your product must include with test result reports for individuals whose specimen(s) were pooled, 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."*

Y. Authorized laboratories implementing pooling strategies for testing individual's 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.

[8] Please refer to footnote 5.

Z. 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 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.

AA. 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

BB. 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 will be made available to FDA for inspection upon request.

Conditions Related to Printed Materials, Advertising and Promotion

CC. 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 and FDA implementing regulations.

DD. 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.

EE. 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 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,
- 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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RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosure