U.S. FOOD & DRUG ADMINISTRATION

September 30, 2021

Jeff Albrecht
Associate Vice President
Laboratory Corporation of America
1447 York Court
Burlington, NC 27215

Device:	Labcorp SARS-CoV-2 & Influenza A/B Assay
EUA Number:	EUA210522
Company:	Laboratory Corporation of America (Labcorp)
Indication:	This test is authorized for the simultaneous qualitative detection and differentiation of SARS-CoV-2, influenza A virus, and/or influenza B virus RNA in anterior nasal swab specimens collected at home by individuals suspected of respiratory viral infection consistent with COVID-19 by a healthcare provider. This test is for use with anterior nasal swab specimens that are collected by 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 either the Labcorp COVID-19 + Flu Test Home Collection Kit or the Pixel by Labcorp COVID-19 + Flu Test Home Collection Kit when ordered directly by an HCP. Emergency use of this test is limited to authorized laboratories.
Authorized Laboratories:	Testing 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.

Dear Mr. Albrecht:

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).

[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 Labcorp SARS-CoV-2 & Influenza A/B Assay used for the indication identified 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.[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). There is an FDA-approved/cleared test for the qualitative detection and identification of SARS-CoV-2, influenza A virus and influenza B virus, along with some other organism types and subtypes not targeted by your product, but this is not an adequate and available alternative to your product. Respiratory viral infections caused by the influenza A and B viruses and SARS-CoV-2 can have similar clinical presentation and diagnostic considerations. Thus, to differentially detect SARS-CoV-2, information from a test that detects and differentiates the virus that causes COVID-19 and the common influenza viruses that cause seasonal epidemics of flu, influenza A and B (not influenza C) is needed during the flu season that coincides with the COVID-19 pandemic.

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, described in the Scope of Authorization of this letter (Section II), 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, through the simultaneous qualitative detection and differentiation of SARS-CoV-2, influenza A virus, and/or influenza B virus RNA, and that the known and potential benefits of your product when used for diagnosing COVID-19, outweigh the known and potential risks of your product; and

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

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[3] 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).

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

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.

Authorized Product Details
Your product is a qualitative test for the simultaneous qualitative detection and differentiation of SARS-CoV-2, influenza A virus, and/or influenza B virus RNA in anterior nasal swab specimens collected at home by individuals suspected of respiratory viral infection consistent with COVID-19 by a healthcare provider. The Labcorp SARS-CoV-2 & Influenza A/B Assay is intended for use as an aid in differential diagnosis of SARS-CoV-2, influenza A, and influenza B in human and is not intended to detect influenza C. Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar.

Your product is for use with anterior nasal swab specimens that are collected by 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 either the Labcorp COVID-19 + Flu Test Home Collection Kit or the Pixel by Labcorp COVID-19 + Flu Test Home Collection Kit when ordered directly by an HCP. Specimens collected using the Labcorp COVID-19 + Flu Test Home Collection Kit or the Pixel by Labcorp COVID-19 + Flu Test Home Collection Kit can be transported at ambient temperature for testing.

Testing 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.

RNA from SARS-CoV-2, influenza A, and influenza B is generally detectable in anterior nasal swab specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2, influenza A and/or influenza B RNA; 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 pathogens not detected by the test. Negative results do not preclude SARS-CoV-2, influenza A, and/or influenza B infection and should not be used as the sole basis for diagnosis, treatment, or other patient management decisions. Negative results must be combined with clinical observations, patient history, and/or epidemiological information.

The Labcorp COVID-19 + Flu Test Home Collection Kit includes the following items in the shipped kit: instructions for use, shipping box, return envelope, specimen biohazard bag, nasal swab, saline and tube, and a specimen confirmation form. The Pixel by Labcorp COVID-19 + Flu Test Home Collection Kit includes the following items in the shipped kit: instructions for use, shipping box, return envelope, specimen biohazard bag, nasal swab, saline and tube, and a registration card.

To use your product, SARS-CoV-2, influenza A, and/or influenza B nucleic acids are first

extracted, isolated and purified from anterior nasal swab 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 Labcorp SARS-CoV-2 & Influenza A/B Assay 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.

Your product requires the following control materials, or other authorized control materials (as may be requested under Condition K below), that are to be run as outlined in the procedures submitted as part of the EUA request. All controls listed below must generate expected results in order for a test to be considered valid, as outlined in the laboratory procedures submitted as part of the EUA request:

- cobas Buffer Negative Control – tris buffer used to monitor for reagent and system contamination that is run with each batch of specimens
- cobas SARS CoV-2 & Influenza A/B Positive Control – non-infectious plasmid DNA containing SARS-CoV-2, Sarbecovirus, Influenza A and Influenza B sequences; used to monitor for failures of RT-PCR reagents and reaction conditions
- RNA Internal Control- armored RNA of non-related sequence used with each sample to ensure correct processing of each sample and to monitor for potential inhibitors that may be present in the sample.

The above described product is authorized to be accompanied by 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), as well as the standard operating procedures (SOPs) submitted as part of the EUA request (listed below), and the following fact sheets pertaining to the emergency use, which are required to be made available to healthcare providers and patients:

- Fact Sheet for Healthcare Providers: Labcorp - Labcorp SARS-CoV-2 & Influenza A/B Assay
- Fact Sheet for Patients: Labcorp - Labcorp SARS-CoV-2 & Influenza A/B Assay

The above described product, when accompanied by the the EUA Summary, the "SARS-CoV-2 & Influenza A/B Assay SOP", the "Accessioning of the LabCorp COVID-19 + FluA/B Home Collection Kits" SOP, and the two fact sheets 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 COVID-19 + Flu Test Home Collection Kit with the "Labcorp COVID-19 + Flu Test Home Collection Kit" collection instructions and the Pixel by Labcorp COVID-19 + Flu Test Home Collection Kit with the "Pixel by Labcorp COVID-19 + Flu Test Home Collection Kit" collection instructions 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 "SARS-CoV-2 & Influenza A/B Assay

SOP", the "Accessioning of the LabCorp COVID-19 + FluA/B Home Collection Kits" SOP, the two Fact Sheets, the "Labcorp COVID-19 + Flu Test Home Collection Kit" collection instructions, and the "Pixel by Labcorp COVID-19 + Flu Test Home Collection Kit" collection instructions.

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 your 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, through the simultaneous qualitative detection and differentiation of SARS-CoV-2, influenza A virus, and/or influenza B virus RNA, 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 (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 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 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)[5]

A. 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

[5] "Authorized Distributor(s)" are identified by you, Labcorp, in your EUA submission as an entity allowed to distribute the Labcorp COVID-19 + Flu Test Home Collection Kit and/or the Pixel by Labcorp COVID-19 + Flu Test Home Collection Kit.

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 and authorized distributor(s) must make available on your website(s), if applicable, the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients.

C. You and authorized distributor(s) must make available all instructions related to the collection of anterior nasal swab specimens using the Labcorp COVID-19 + Flu Test Home Collection Kit and the Pixel by Labcorp COVID-19 + Flu Test Home Collection Kit, both in the shipped kit and on your website.

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

E. You and authorized distributor(s) must maintain customer complaint files concerning the Labcorp COVID-19 + Flu Test Home Collection Kit and the Pixel by Labcorp COVID-19 + Flu Test Home Collection Kit 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.

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

H. You must notify FDA of any authorized distributor(s) of the Labcorp COVID-19 + Flu Test Home Collection Kit and/or the Pixel by Labcorp COVID-19 + Flu Test Home Collection Kit, including the name, address, and phone number of any authorized distributor(s).

I. You must provide authorized distributor(s) with a copy of this EUA and communicate to authorized distributor(s) any subsequent amendments that might be made to this EUA and its authorized accompanying materials.

J. 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.

K. 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.

L. You must evaluate the analytical limit of detection and assess traceability of your product with any FDA-recommended reference material(s), if requested by FDA. [6] After submission to and concurrence with the data by FDA, DMD/OHT7-OIR/OPEQ/CDRH will update the EUA Summary to reflect the additional testing.

M. You must submit to FDA a summary report within 30 calendar days of product launch summarizing the results of any testing performed using anterior nasal swab specimens collected with the Labcorp COVID-19 + Flu Test Home Collection Kit and the Pixel by Labcorp COVID-19 + Flu Test Home Collection Kit during that timeframe, including how many specimens were received, how many specimens had to be rejected during accessioning and the reasons for rejection, and the positivity rate. In addition, for kits provided for specimen collection from very young children (2 to 4- year-olds), you must solicit post-collection usability feedback from parents/guardians performing collection to further assess the ease of use of the kit in this age group. Thereafter, monthly reporting must continue until FDA informs you that the cumulative data submitted within the monthly reports has sufficiently assessed your collection kit.

N. You must have a process in place to track adverse events, including any occurrence of false results with your product, including the Labcorp COVID-19 + Flu Test Home Collection Kit and the Pixel by Labcorp COVID-19 + Flu Test Home Collection Kit, and report to FDA in accordance with 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).

O. 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 mutations that affect the stated expected performance of your device, you must notify FDA immediately.

[6] Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material. FDA may request, for example, that you perform this study in the event that we receive reports of adverse events concerning your product.

P. If requested by FDA, you must update your labeling within 7 calendar days to include any additional labeling risk mitigations identified by FDA, such as those related to 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

Q. Authorized laboratories 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.

R. Authorized laboratories must use your product as outlined in the authorized labeling. 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 use your product are not permitted. When testing specimens using your product, you must have in place a suitable specimen receipt and accessioning SOP.

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 healthcare providers and relevant public health authorities, as appropriate.

U. 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.

V. 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

W. 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

X. 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.

Y. No descriptive printed matter, advertising or 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.

Z. 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, influenza A and/or influenza B, 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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RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosure
cc: Marcia Eisenberg, LabCorp