U.S. FOOD & DRUG ADMINISTRATION

May 17, 2022

Marcia Eisenberg, PhD
Chief Scientific Officer & Senior Vice President
Laboratory Corporation of America
1912 Alexander Dr.
Research Triangle Park, NC 27709

Device:	Labcorp Seasonal Respiratory Virus RT-PCR Test
EUA Number:	EUA210592
Company:	Laboratory Corporation of America (Labcorp)
Indication:	This test is authorized for the simultaneous qualitative detection and differentiation of RNA from SARS-CoV-2, Influenza A virus (Flu A), Influenza B virus (Flu B), and/or Respiratory Syncytial Virus (RSV) in nasopharyngeal (NP), mid-turbinate, and anterior nasal swab specimens from individuals suspected of respiratory viral infection consistent with COVID-19 by a healthcare provider. This test is also for use with individual anterior nasal swab specimens that are collected at home using the Labcorp COVID-19+Flu+RSV Test Home Collection Kit 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) when directly ordered 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 Dr. Eisenberg:

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 Seasonal Respiratory Virus RT-PCR Test 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, influenza B virus and Respiratory Syncytial 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, RSV 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 and RSV nucleic acids that cause seasonal epidemics of flu, influenza A and B (not influenza C), and RSV, 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, influenza B virus and/or RSV 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] 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).

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

Authorized Product Details

Your product is a multiplex real-time reverse transcription (RT) polymerase chain reaction (PCR) test intended for the simultaneous qualitative detection and differentiation of RNA from SARS-CoV-2, Influenza A virus (Flu A), Influenza B virus (Flu B), and/or Respiratory Syncytial Virus (RSV) in nasopharyngeal (NP), mid-turbinate, and anterior nasal swab specimens from individuals suspected of respiratory viral infection consistent with COVID-19 by a healthcare provider. Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2, influenza, or RSV can be similar.

This test is also for use with individual anterior nasal swab specimens that are collected at home using the Labcorp COVID-19+Flu+RSV Test Home Collection Kit 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) when directly ordered by an HCP.

Testing is limited to the Center for Esoteric Testing, Burlington, NC, or other laboratories designated by Labcorp that are also certified under CLIA 42 U.S.C. §263a, and meet the requirements to perform high complexity tests.

Results are for the identification and differentiation of RNA from SARS-CoV-2, Influenza A, Influenza B, and RSV. The Labcorp Seasonal Respiratory Virus RT-PCR Test is not intended to detect Influenza C. RNA from Influenza A, Influenza B, RSV, and SARS-CoV-2 is generally detectable in respiratory specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2, influenza A, influenza B, and/or RSV 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. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all SARS-CoV-2 results to the appropriate public health authorities.

Negative results do not preclude SARS-CoV-2, Influenza A, Influenza B, and/or RSV infection and should not be used as sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information. Specimens collected at home from SARS-CoV-2, Influenza A, Influenza B, and/or RSV positive individuals may yield negative results if the specimen was not collected properly.

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

The Labcorp COVID-19+Flu+RSV Test Home Collection Kit provides specimen collection and storage materials and materials for mailing specimens to authorized laboratories for testing using the Labcorp Seasonal Respiratory Virus RT-PCR Test, as described in the "Labcorp COVID-19+Flu+RSV Test Home Collection Kit Instructions for Use." Individuals should follow all specimen collection and mailing instructions when using the kit.

To use your product, SARS-CoV-2 nucleic acid is first extracted, isolated and purified from anterior nasal swab specimens collected using the Labcorp COVID-19+Flu+RSV 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 (described below).

Your product requires controls, as outlined in the authorized labeling (described below). Your product also requires the use of additional authorized materials and authorized ancillary reagents that are not included with your product and are described in the authorized labeling (described below).

The above described product, when accompanied (as set forth in the Conditions of Authorization (section IV)) 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), the "Labcorp Seasonal Respiratory Virus RT-PCR Test; Labcorp Seasonal Respiratory Virus RT-PCR DTC Test" SOP, the "Nucleic Acid Isolation for Labcorp Seasonal Respiratory Virus RT-PCR Test; Labcorp Seasonal Respiratory Virus RT-PCR DTC Test" SOP, the "Accessioning of Respiratory Specimens Collected with LabCorp Home Collection Kits" SOP, and the two fact sheets (listed below) which are required to be made available to healthcare providers and individuals, is authorized to be distributed and used under this EUA by authorized laboratories, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

- Fact Sheet for Healthcare Providers: Labcorp – Labcorp Seasonal Respiratory Virus RT-PCR Test
- Fact Sheet for Patient: Labcorp – Labcorp Seasonal Respiratory Virus RT-PCR Test

The Labcorp COVID-19+Flu+RSV Test Home Collection Kit with the "Labcorp COVID-19+Flu+RSV Test Home Collection Kit Instructions for Use" is 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 "Labcorp Seasonal Respiratory Virus RT-PCR Test; Labcorp Seasonal Respiratory Virus RT-PCR DTC Test" SOP, the "Nucleic Acid Isolation for Labcorp Seasonal Respiratory Virus RT-PCR Test; Labcorp Seasonal Respiratory Virus RT-PCR DTC Test" SOP, the "Accessioning of Respiratory Specimens Collected with LabCorp Home Collection Kits" SOP, and the "Labcorp COVID-

19+Flu+RSV Test Home Collection Kit Instructions for Use".

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, influenza B virus and/or RSV 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, but excluding Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

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+RSV 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), the authorized Fact Sheet for Healthcare Providers and Fact Sheet for Individuals.

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

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+RSV Test Home Collection Kit is distributed.

E. You and authorized distributor(s) must maintain customer complaint files concerning the Labcorp COVID-19+Flu+RSV 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+RSV Test Home Collection Kit, including the name, address, and phone number of any authorized distributor(s).

I. You must maintain records of the laboratories you designate as authorized laboratories and you must also maintain records of test usage by all such authorized laboratories.

J. 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.

K. You must have lot release procedures and the lot release procedures, including the study design and statistical power, must ensure that the Labcorp COVID-19+Flu+RSV Test Home Collection Kit released for distribution has the clinical and analytical performance claimed in the authorized labeling.

L. If requested by FDA, you must submit lot release procedures to FDA, including sampling protocols, testing protocols, and acceptance criteria, that you use to release lots of the Labcorp COVID-19+Flu+RSV Test Home Collection Kit for distribution in the U.S. If such lot release procedures are requested by FDA, you must provide them within 48 hours of the request.

M. You must comply with the following requirements pursuant to FDA regulations: 21 CFR 820 Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

N. You must inform authorized distributor(s), 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.

O. 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.

P. 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. 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.

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

R. 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 review of and concurrence with the data, FDA will update the EUA Summary to reflect the additional testing.

S. You must have a process in place to track adverse events, including any occurrence of false results with your product, including with the Labcorp COVID-19+Flu+RSV Test Home Collection Kit, 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-EUAReporting@fda.hhs.gov).

T. You must further evaluate the clinical performance of your product as authorized, using collected anterior nasal swab specimens in the intended use population for all claimed

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

analytes, in an FDA agreed upon post-authorization prospective clinical study within 6 months of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH). After submission to and concurrence with the data by FDA, you must update authorized labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

U. You must submit to FDA a summary report within 30 calendar days of product launch summarizing the results of any testing performed using specimens collected with the Labcorp COVID-19+Flu+RSV Test Home Collection Kit for use with your product during that timeframe, including how many specimens were received, how many specimens had to be rejected during accession and the main reasons for rejection, and the positivity rate for specimens collected with the authorized collection kit.

V. 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 (via email: CDRH-EUA-Reporting@fda.hhs.gov).

W. 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

X. 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.

Y. Authorized laboratories using your product 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.

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

AA. 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.

BB. Authorized laboratories using your product 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 (via email: covid19requests@labcorp.com) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.

CC. All laboratory personnel using your product must be appropriately trained in RT-PCR techniques and use appropriate laboratory and personal protective equipment when handling this kit and use your product in accordance with the authorized labeling.

DD. Authorized laboratories testing authorized specimens collected using the Labcorp COVID-19+Flu+RSV Test Home Collection Kit must follow the "Accessioning of Respiratory Specimens Collected with LabCorp Home Collection Kits" SOP when accepting specimens for testing.

Labcorp (You), Authorized Distributor(s) and Authorized Laboratories

EE. 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

FF. 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.

GG. 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.

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

- This product (collection kit in combination with the authorized test) 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 and differentiation of nucleic acid from SARS-CoV-2, influenza A, influenza B and/or Respiratory Syncytial Virus (RSV), 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,

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

Enclosure