

August 18, 2020

Dr. Nigel Lindner
Chief Innovation Officer & Head of Care Solutions
LumiraDx UK Ltd.
Dumyat Business Park, Bond Street
Alloa, GBR Fk10 2PB

Device: LumiraDx SARS-CoV-2 Ag Test

Company: LumiraDx UK Ltd.

Indication: Qualitative detection of the nucleocapsid protein antigen to SARS-CoV-2 directly from nasal swab specimens collected from individuals who are suspected of COVID-19 by their healthcare provider within the first twelve days of the onset of symptoms. Emergency use of this test is limited to authorized laboratories using the LumiraDx Platform.

Authorized Laboratories: Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C 263a, that meet the requirements to perform moderate, high or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Dear Dr. Lindner:

This letter is in response to your¹ 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

¹ For ease of reference, this letter will use the term “you” and related terms to refer to LumiraDx UK Ltd.

² For ease of reference, this letter will use the term “your product” to refer to the LumiraDx SARS-CoV-2 Ag Test used for the indication identified above.

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

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, 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

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 rapid microfluidic immunofluorescence assay that is used with the LumiraDx Platform intended for the qualitative detection of the nucleocapsid protein antigen to SARS-CoV-2 directly from nasal swab specimens collected from individuals suspected of COVID-19 by their healthcare provider within the first twelve days of the onset of symptoms. The SARS-CoV-2 nucleocapsid protein antigen is generally detectable in upper respiratory samples during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient 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. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and presence of clinical signs and symptoms consistent with COVID-19.

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.

Testing of nasal swab specimens using your product run on the LumiraDx Instrument as outlined in the “SARS-CoV-2 Ag Test Strip Product Insert - LumiraDx SARS-CoV-2 Ag Test” and the “LumiraDx Platform User Manual,” is limited to laboratories certified under CLIA that meet the requirements to perform high, moderate, or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

To use your product, the nasal swab specimen is eluted into a vial containing extraction buffer. A single drop of the specimen in extraction buffer is added to the Test Strip using the vial dropper cap provided. The LumiraDx Instrument is programmed to perform the test protocol using the dried reagents contained within the strip. The test result is determined from the amount of fluorescence the Instrument detects within the measurement zone of the Test Strip. The concentration of the analyte in the specimen is proportional to the fluorescence detected. The results are displayed on the Instrument touchscreen within 12 minutes from the addition of the sample.

The LumiraDx SARS-CoV-2 Ag Test includes the following materials or other authorized materials: LumiraDx Test Strips packed individually in sealed desiccant foil pouches, LumiraDx Test Product Insert, RFID (Radio frequency ID) Tag held inside the Test Strip carton, Extraction Buffer Vials, Dropper Lids, and LumiraDx SARS-CoV-2 Ag Test Quick Reference Instructions.

Your product also requires the use of the LumiraDx SARS-CoV-2 Ag Quality Controls or other authorized controls (refer to Condition S. below). Quality control standards are not included with the kit. However, quality controls are available separately with the “SARS-CoV-2 Antigen (Ag) Quality Controls Pack Insert - LumiraDx SARS-CoV-2 Ag Quality Controls.”

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 Instructions for Use.

The above described product, is authorized to be accompanied with labeling entitled “SARS-CoV-2 Ag Test Strip Product Insert - LumiraDx SARS-CoV-2 Ag Test,” the “LumiraDx Platform User Manual,” and the “LumiraDx SARS-CoV-2 Ag Test Quick Reference Instructions” (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 patients:

- Fact Sheet for Healthcare Providers: LumiraDx UK Ltd.- LumiraDx SARS-CoV-2 Ag Test
- Fact Sheet for Patients: LumiraDx UK Ltd.- LumiraDx SARS-CoV-2 Ag Test

The above described product, when accompanied by the labeling identified above and the two Fact Sheets (collectively referred to as “authorized labeling”) 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.

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 authorized 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, 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:

LumiraDx UK Ltd. (You) and Authorized Distributor(s)⁵

- A. Your product 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 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

⁵ “Authorized Distributor(s)” are identified by you, LumiraDx UK Ltd., in your EUA submission as an entity allowed to distribute your device.

available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

- B. You and authorized distributor(s) will make your product available with the authorized labeling to authorized laboratories. You may request changes to the authorized labeling. Such requests will be made in consultation with, and require concurrence of, 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).
- C. You and authorized distributor(s) will make available on your website(s) the authorized labeling.
- D. You and authorized distributor(s) will 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.
- E. Through a process of inventory control, you and authorized distributor(s) will maintain records of the authorized laboratories to which they distribute the test and number of tests they distribute.
- F. You and authorized distributor(s) will collect information on the performance of your product. You will report to FDA any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the product of which you become aware.
- G. 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.
- H. You and authorized distributor(s) will make available the LumiraDx SARS-CoV-2 Ag Quality Controls or other authorized control materials (refer to Condition S. below) at the same time as your product.

LumiraDx UK Ltd. (You)

- I. You will notify FDA of any authorized distributor(s) of your product, including the name, address, and phone number of any authorized distributor(s).
- J. You will provide authorized distributor(s) with a copy of this EUA and communicate to authorized distributor(s) any subsequent revisions that might be made to this EUA and its authorized accompanying materials (e.g., Fact Sheets).
- K. You may request 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. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

- L. You will comply with the following requirements pursuant to FDA regulations: 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).
- M. You must have lot release procedures and the lot release procedures, including the study design and statistical power, must ensure that the tests released for distribution have the clinical and analytical performance claimed in the authorized labeling.
- N. 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 your product for distribution in the U.S. If such lot release procedures are requested by FDA, you must provide it within 48 hours of the request.
- O. You may request changes to the Scope of Authorization (Section II in this letter) of your product. Such requests will be made 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.
- P. You may request the addition of other instruments and associated software for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- Q. You may request the addition of other specimen types for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- R. You may request the substitution for or changes to the authorized materials used in the detection process of SARS-CoV-2 for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- S. You may request the addition and/or substitution of control materials for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- T. You may request the addition and/or substitution of other ancillary reagents and materials for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- U. You will evaluate the analytical limit of detection and assess traceability⁶ of your

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

product 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, You will update labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

- V. You will complete the agreed upon real-time stability study for your product and notify DMD/OHT7-OIR/OPEQ/CDRH of the testing results as they become available until completion of the study. After submission to FDA of the study data and DMD/OHT7-OIR/OPEQ/CDRH's review of and concurrence with the data, you will update your product labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- W. You will complete the agreed upon flex studies for your product within 4 months of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH) and submit the study data for DMD/OHT7-OIR/OPEQ/CDRH's review and concurrence.
- X. You will track adverse events, including any occurrence of false results and report to FDA pursuant to 21 CFR Part 803.

Authorized Laboratories

- Y. Authorized laboratories using your product will include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating this labeling may be used, which may include mass media.
- Z. Authorized laboratories using your product will use your product as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized instruments, authorized clinical specimen types, authorized control materials, authorized ancillary reagents and authorized materials required to use your product are not permitted.
- AA. Authorized laboratories that receive your product will notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- BB. Authorized laboratories using your product will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- CC. Authorized laboratories will 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: customerservices.US@lumiradx.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.

DD. All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.

LumiraDx UK Ltd. (You), Authorized Distributors and Authorized Laboratories

EE. You, authorized distributors, and authorized laboratories using your product 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 Printed Materials, Advertising and Promotion

FF. All descriptive printed matter, including 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 the applicable requirements set forth in the Act and FDA regulations.

GG. No descriptive printed matter, including 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, including advertising and promotional materials, relating to the use of your product 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 proteins 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 Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or 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

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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,

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosure