



October 29, 2021

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
EUA Number: EUA202314
Company: LumiraDx UK Ltd.
Indication: Qualitative detection of the nucleocapsid protein antigen to SARS-CoV-2 directly from anterior nasal swab and nasopharyngeal swab specimens collected from individuals suspected of COVID-19 by their healthcare provider within the first twelve days of the onset of symptoms or from individuals without symptoms or other epidemiological reasons to suspect COVID-19. 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 product 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:

On August 18, 2020, based on your¹ request the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of the LumiraDx SARS-CoV-2 Ag Test, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3), for the indications stated in the letter.² On January 26, 2021, FDA granted your

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

² The August 18, 2020, letter authorized your product for the 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 was limited to authorized laboratories using the LumiraDx Platform. Testing was limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C 263a, that met the requirements to perform moderate, high or waived complexity tests. This test was authorized for use at the Point of

request to update the authorized labeling.³ Based on your request, the August 18, 2020, letter was revised and reissued by FDA on April 15, 2021.⁴ In addition, FDA established additional Conditions of Authorization in response to the continued emergence of new variants of SARS-CoV-2 on September 23, 2021.⁵

On April 26, 2021, June 3, 2021 and May 24, 2021, FDA received requests from you to amend the EUA. In response to those requests, and having concluded that revising the April 15, 2021, EUA is appropriate to protect the public health or safety under section 564(g)(2)(C) of the Act (21 U.S.C. § 360bbb-3(g)(2)(C)), FDA is reissuing the April 15, 2021, letter in its entirety with the amendments incorporated⁶ to authorize the emergency use of your product.⁷ Pursuant to section 564 of the Act, Scope of Authorization (Section II) and Conditions of Authorization (Section IV) of this reissued letter, your product is now intended for the indication 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.⁸

Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

³ On January 26, 2021, your request was granted to update the Instructions for Use (IFU) and/or Quick Reference Instructions (QRI) of the LumiraDx SARS-CoV-2 Ag Test to (1) add an additional alternative extraction buffer tube, (2) update the shelf-life, and (3) include minor updates and clarifications. FDA also concurred with the requested updates to the Test Strip Foil Label and the additional labeling for the authorized LumiraDx Platform instrument.

⁴ On April 15, 2021, the revisions to the August 18, 2020, letter and authorized labeling included: (1) revision to add nasopharyngeal swabs specimens as an authorized specimen type for use with the product, and specify nasal swabs as “anterior,” (2) revision to add a limitation about clinical performance of the product with respect to newly emerging variant strains of SARS-CoV-2, and (3) updates to the letter and fact sheets for consistency with language used in more recent authorizations.

⁵ The Viral Mutation Revision Letter – September 23, 2021, can be accessed at:

<https://www.fda.gov/media/152406/download>.

⁶ The revisions to the April 15, 2021, letter and authorized labeling include: (1) update the intended use to include use of your product with anterior nasal swab and nasopharyngeal swab specimens collected from individuals without symptoms or other epidemiological reasons to suspect COVID-19, (2) update authorized labeling to fulfill Condition of Authorization (1) in the Viral Mutation Revision Letter – September 23, 2021, (3) add Conditions of Authorization (2) and (3) from the Viral Mutation Revision Letter – September 23, 2021 (T. and U. below), (4) extend the shelf life to 7 months, (5) update the software to now assesses the optical signals from 3 assay channels measuring SARS-CoV-2 Ag (previously assessed 2 channels), (6) update the Cleaning and Disinfecting procedure for the LumiraDx Platform instrument and include the use of Alcohol as a disinfectant for respiratory samples, (7) update the LumiraDx SARS-CoV-2 Ag Quality Controls and LumiraDx SARS-CoV-2 Ag Test instructions for use to include 40 single bulb pipettes, instead of 24 pipettes, and (8) updates to the letter and fact sheets to reflect the updated intended use and for consistency with language used in more recent authorizations.

⁷ 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.

⁸ 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*

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 included in the “SARS-CoV-2 Ag Test Strip Product Insert - LumiraDx SARS-CoV-2 Ag Test” (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, 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.⁹

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 and intended for the qualitative detection of the nucleocapsid protein antigen to SARS-CoV-2 directly from anterior nasal swab and nasopharyngeal swab specimens collected from individuals suspected of COVID-19 by their healthcare provider within the first twelve days of the onset of symptoms or from individuals without symptoms or other epidemiological reasons to suspect COVID-19.

Your product does not differentiate between SARS-CoV and SARS-CoV-2. The SARS-CoV-2 nucleocapsid protein antigen is generally detectable in anterior nasal swab and nasopharyngeal swab 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-

Cosmetic Act, 21 U.S.C. § 360bbb-3. 85 FR 7316 (February 7, 2020).

⁹ No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

infection with other viruses. Additional confirmatory testing with a molecular test for positive results may be necessary if there is a low likelihood of SARS-CoV-2 infection, such as in individuals without known exposures to SARS-CoV-2 or residing in communities with low prevalence of infection. Negative results should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed. 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.

Testing of anterior nasal swab and nasopharyngeal 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. Your product is authorized for use at the 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 anterior nasal swab or nasopharyngeal 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 (as may be requested under Condition L. below), which are not included with your product but are available from you with the “SARS-CoV-2 Antigen (Ag) Quality Controls Pack Insert - LumiraDx SARS-CoV-2 Ag Quality Controls” instructions for use to be run as outlined in the “SARS-CoV-2 Ag Test Strip Product Insert - LumiraDx SARS-CoV-2 Ag Test.”

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,” the “LumiraDx SARS-CoV-2 Ag Test Quick Reference Instructions,” the “SARS-CoV-2 Antigen (Ag) Quality Controls Pack Insert - LumiraDx SARS-CoV-2 Ag Quality Controls” (available at <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-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)¹⁰

- 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 available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).
- B. You and authorized distributor(s) must make your product available with the authorized labeling to authorized laboratories.
- C. You and authorized distributor(s) must make available on your website(s) the authorized labeling.
- D. You and authorized distributor(s) must include a physical copy of the “SARS-CoV-2 Ag Test Strip Product Insert - LumiraDx SARS-CoV-2 Ag Test” and the “LumiraDx SARS-CoV-2 Ag Test Quick Reference Instructions” with each shipped product to authorized laboratories.
- E. You and authorized distributor(s) 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.
- F. Through a process of inventory control, you and authorized distributor(s) must maintain records of the authorized laboratories to which they distribute the test and number of tests they distribute.
- G. You and authorized distributor(s) 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 the product of which you become aware.
- H. 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.
- I. You and authorized distributor(s) will make available the “LumiraDx SARS-CoV-2 Ag Quality Controls” with the “SARS-CoV-2 Antigen (Ag) Quality Controls Pack Insert - LumiraDx SARS-CoV-2 Ag Quality Controls” instructions for use, or other

¹⁰ “Authorized Distributor(s)” are identified by you, LumiraDx UK Ltd., in your EUA submission as an entity allowed to distribute your product.

authorized control materials (refer to Condition L. below) at the same time as your product.

LumiraDx UK Ltd. (You)

- J. You must notify FDA of any authorized distributor(s) of your product, including the name, address, and phone number of any authorized distributor(s).
- K. You must 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).
- L. 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.
- 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 have lot release procedures and the lot release procedures, including the study design and statistical power, must ensure that your product released for distribution has the clinical and analytical performance claimed in the authorized labeling.
- O. 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.
- P. You must evaluate the analytical limit of detection and assess traceability¹¹ of your product with any FDA-recommended reference material(s). After submission to and concurrence with the data by FDA, you must 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.

¹¹ Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material.

- Q. 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.
- R. You will complete the agreed upon flex studies for your product within 2 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.
- S. You must track adverse events, including any occurrence of false results with your product and report to FDA pursuant in accordance with 21 CFR Part 803.
- T. 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).
- U. 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

- V. Authorized laboratories using your product must 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.
- W. 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 clinical specimen types, authorized control materials, authorized ancillary reagents and authorized materials required to use your product are not permitted.
- X. Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- Y. 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.

Z. 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 (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.

AA. 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 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, as applicable, and FDA implementing regulations.

DD. 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.

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 proteins from SARS-CoV-2, 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

Technical Correction October 29, 2021: shelf-life duration in footnote 6