June 10, 2025

Kelli Turner
Senior Program Manager, Regulatory Affairs
Roche Diagnostics Operations, Inc.
On behalf of
LumiraDx UK Ltd. Roche House Charles Avenue
Burgess Hill, England, RH15 9RY

Device:	LumiraDx SARS-CoV-2 Ag Test
EUA Number:	EUA202314
Company:	LumiraDx UK Ltd. (an indirect, wholly owned subsidiary of Roche)[1]
Indication:	Qualitative detection of the nucleocapsid protein antigen to SARS-CoV-2 in direct anterior nasal swab and nasopharyngeal swab specimens collected by a healthcare provider from individuals suspected of COVID-19 within the first twelve (12) days of symptom onset when tested at least twice over three days with at least 48 hours between tests and from individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested at least three times over five days with at least 48 hours between tests. 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 Kelli Turner:

On August 18, 2020, based on LumiraDx UK Ltd.'s 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

[1] On July 26, 2024, LumiraDx UK Ltd. and their US entity LumiraDx Inc. became indirect, wholly owned subsidiaries of Roche Holding AG and Roche Holdings, Inc., respectively (collectively referred to as "Roche" for ease of reference). Roche Diagnostics Operations, Inc., a wholly owned subsidiary of Roche Holdings, Inc., will act on behalf of LumiraDx UK Ltd. (an indirect, wholly owned subsidiary of Roche).

(the Act) (21 U.S.C. §360bbb-3), for the indications stated in the letter.[2] Based on LumiraDx UK Ltd.'s requests, updates to the authorized labeling were granted by FDA on January 26, 2021,[3] February 17, 2022,[4] and March 29, 2023[5] and acknowledged by FDA on August 15, 2023.[6] FDA also reissued the EUA on April 15, 2021,[7] October 29, 2021,[8,9] and July 21,

[2] The August 18, 2020, letter authorized the LumiraDx SARS-CoV-2 Ag Test 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 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, LumiraDx UK Ltd.'s 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 February 17, 2022, LumiraDx UK Ltd.'s request was granted to update the LumiraDx SARS-CoV-2 Ag Test to (1) extend the shelf-life expiration date of the LumiraDx SARS-CoV-2 Ag Test strips to 13 months, when stored at 2ºC – 30ºC, based on the results of LumiraDx UK Ltd.'s ongoing stability studies, (2) provide the additional temperature and humidity flex study data to fulfill Condition of Authorization R. of the Letter of Authorization re-issued on October 29, 2021, and (3) update the acceptable operating conditions in the Instructions For Use and QRI to reflect a maximum relative humidity of 75%, based on the results of the additional temperature and humidity flex study. FDA has also updated the Fact Sheet for Healthcare Providers and Fact Sheet for Patients to be consistent with more recent authorizations.

[5] On March 29, 2023, LumiraDx UK Ltd.'s request was granted to update the LumiraDx SARS-CoV-2 Ag Test to: (1) in response to Condition of Authorization (1) of the Repeat Testing Revision Letter dated November 1, 2022, revise the authorized use(s) as required and described in Appendix A, and make various updates to the authorized labeling as required and described in Appendix B of the letter, and (2) include results of additional reactivity studies. FDA has also updated the Fact Sheet for Healthcare Providers and Fact Sheet for Patients to be consistent with the November 1, 2022 Repeat Testing Revision Letter.

[6] On August 15, 2023, FDA acknowledged by email LumiraDx UK Ltd.'s request to update the LumiraDx SARS-CoV-2 Ag Test instructions for use with swab information in "Materials required but not provided with the Test Strip carton" section.

[7] 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.

[8] On October 29, 2021, the revisions to the April 15, 2021, letter and authorized labeling included: (1) updating 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) updating the authorized labeling to fulfill Condition of Authorization (1) in the Viral Mutation Revision Letter – September 23, 2021, (3) adding Conditions of Authorization (2) and (3) from the Viral Mutation Revision Letter – September 23, 2021 (T. and U.), (4) extending the shelf life to 7 months, (5) updating the software to now assesses the optical signals from 3 assay channels measuring SARS-CoV-2 Ag (previously assessed 2 channels), (6) updating the Cleaning and Disinfecting procedure for the LumiraDx Platform instrument and including the use of Alcohol as a disinfectant for respiratory samples, (7) updating 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) updating the letter and fact sheets to reflect the updated intended use and for consistency with language used in more recent authorizations.

[9] FDA issued a technical correction to the letter on October 29, 2021, to correct the shelf-life duration in footnote 6.

2022[10] with revisions incorporated. 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.[11] Further, FDA revised the authorized uses and established one additional Condition of Authorization requiring updates to product labeling regarding repeat, or serial, testing, for all currently authorized SARS-CoV-2 antigen tests on November 1, 2022.[12]

On March 1, 2022, FDA received requests from you[13] to amend the EUA. Based on these requests, having concluded that revising the July 21, 2022, 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 July 21, 2022, letter in its entirety with revisions incorporated[14] to authorize the emergency use of your product.[15] 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, as amended on March 15, 2023, 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, or a significant potential for a public health emergency, that affects, or 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.[16]

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[10] On July 21, 2022, the revisions to the October 29, 2021, letter and authorized labeling included: (1) revisions to the intended use to add "*when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests*" for individuals without symptoms or other epidemiological reasons to suspect COVID-19, (2) updates to the letter and authorized labeling, including the Fact Sheets, to reflect the revised intended use and also for consistency with language used in more recent authorizations, (3) addition of test kit options that include packaged nasal swabs and associated new catalog numbers, (4) updates to the cross-reactivity (analytical specificity) to include testing with *Staphylococcus aureus*, and (5) removal of Condition of Authorization R. from the October 29, 2021 letter (fulfilled).

[11] The Viral Mutation Revision Letter – September 23, 2021, can be accessed at: https://www.fda.gov/media/152406/download.

[12] The Repeat Testing Revision Letter - November 1, 2022, can be accessed at: https://www.fda.gov/media/162799/download.

[13] For ease of reference, this letter will use the term "you" and related terms to refer to LumiraDx UK Ltd. (an indirect, wholly owned subsidiary of Roche), see footnote 1 for additional details.

[14] The revisions to the July 21, 2022, letter and authorized labeling include: (1) transferring ownership of the EUA from LumiraDx UK Ltd. to LumiraDx UK Ltd. (an indirect, wholly owned subsidiary of Roche), (2) updating the Letter of Authorization to reflect revisions to the intended use that were granted by FDA on March 29, 2023 (see footnote 5), (2) removing anterior nasal swabs from the list of materials provided with kit, (3) transferring some of the manufacturing processes to Roche, and (4) updating the Fact Sheet for Healthcare Providers, Fact Sheet for Patients, and the Letter of Authorization, including some of the Conditions of Authorization, to reflect the updates made and for consistency with language used in more recent authorizations.

[15] 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.

[16] 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*. February 4, 2020. 85 FR 7316 (February 7, 2020). U.S. Department of Health

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). FDA has granted De Novo classification requests and cleared tests for the qualitative detection of SARS-CoV-2 protein antigens, but these are not an adequate and available alternative to your product.[17]

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.[18]

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

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and Human Services, *Amended Determination of a Public Health Emergency or Significant Potential for a Public Health Emergency Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b).* March 15, 2023. 88 FR 16644 (March 20, 2023) ("Amended Determination").

[17] To date, the FDA has granted De Novo classification requests for the following antigen tests; Sofia 2 SARS Antigen+ FIA, Sofia 2 SARS Antigen+ FIA Control Swab Set (Product Code: QVF; DEN220039) and the Healgen Rapid Check COVID-19/Flu A&B Antigen Test (Product Code: SCA; DEN240029), and in addition has cleared various tests (Search FDAs 510(k) Premarket Notification database; https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm; Product codes: QVF, QYT, SCA) for the qualitative detection of SARS-CoV-2 nucleocapsid protein antigens directly in anterior nasal swab specimens. For prescription use, available information indicates that there are not adequate and available alternatives to your product.

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

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 in direct anterior nasal swab and nasopharyngeal swab specimens collected by a healthcare provider from individuals suspected of COVID-19 within the first twelve (12) days of the onset of symptoms when tested at least twice over three days with at least 48 hours between tests and from individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested at least three times over five days with at least 48 hours between tests.

Your product does not differentiate between SARS-CoV and SARS-CoV-2. Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen, which is generally detectable in anterior nasal swab and nasopharyngeal swab specimens 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. The agent detected may not be the definitive cause of disease.

All negative results are 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 measures such as isolating from others and wearing masks. 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 moderate, high, or waived complexity tests. Your 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.

The anterior nasal swab or nasopharyngeal swab specimen is tested with your product according to the "SARS-CoV-2 Ag Test Strip Product Insert - LumiraDx SARS-CoV-2 Ag Test" and the "LumiraDx Platform User Manual."

The LumiraDx SARS-CoV-2 Ag Test includes the materials or other authorized materials (as may be requested under Condition L. below), necessary to collect (for some kits), process and test anterior nasal swab or nasopharyngeal swab specimens as described in the "SARS-CoV-2 Ag Test Strip Product Insert - LumiraDx SARS-CoV-2 Ag Test" and the "LumiraDx Platform User Manual."

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 labeling entitled "LumiraDx SARS-CoV-2 Ag Test" product insert, the "LumiraDx Platform User Manual," the "LumiraDx SARS-CoV-2 Ag Test Quick Reference Instructions," the "LumiraDx SARS-CoV-2 Ag Quality Controls" product insert (available at https://www.fda.gov/medical-devices/covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas), and the following product-specific information pertaining to the emergency use, are required to be made available as set forth in the Conditions of Authorization (Section IV), and are collectively referred to as "authorized labeling":

- Fact Sheet for Healthcare Providers: LumiraDx UK Ltd. (an indirect, wholly owned subsidiary of Roche)- LumiraDx SARS-CoV-2 Ag Test
- Fact Sheet for Patients: LumiraDx UK Ltd. (an indirect, wholly owned subsidiary of Roche)- LumiraDx SARS-CoV-2 Ag Test

The above described product, when accompanied by the authorized labeling provided as set forth in the Conditions of Authorization (Section IV), 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. (an indirect, wholly owned subsidiary of Roche) (You) and Authorized Distributor(s)[19]

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 "LumiraDx SARS-CoV-2 Ag Test" product insert and the "LumiraDx SARS-CoV-2 Ag Test Quick Reference Instructions" with each product shipped 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 your product is distributed and the number of your product distributed to each authorized laboratory

G. You and authorized distributor(s) must collect information on the performance of your product. You must report any significant deviations from the established performance characteristics of your product of which you become aware to the Division of Microbiology (DMD)/Office of Health Technology 7 (OHT7)/Office of Product

[19] "Authorized Distributor(s)" are identified by you, LumiraDx UK Ltd. (an indirect, wholly owned subsidiary of Roche), in your EUA submission as an entity allowed to distribute your product.

Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH) (via email: CDRH-EUA-Reporting@fda.hhs.gov).

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

LumiraDx UK Ltd. (an indirect, wholly owned subsidiary of Roche) (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 DMD/OHT7/OPEQ/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 the requested information within 48 hours of the request.

P. You must evaluate the analytical limit of detection and assess traceability[20] 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/OPEQ/CDRH.

Q. You will complete the agreed upon real-time stability study for your product and notify DMD/OHT7/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/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/OPEQ/CDRH.

R. 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.

S. 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).

T. 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/OPEQ/CDRH.

Authorized Laboratories

U. 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.

V. 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.

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

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

X. 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.

Y. Authorized laboratories must collect information on the performance of your product and must report any significant deviations from the established performance characteristic of your product of which they become aware to DMD/OHT7/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and you (via telephone: 1-800-800-5973).

Z. 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. (an indirect, wholly owned subsidiary of Roche) (You), Authorized Distributor(s) and Authorized Laboratories

AA. 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

BB. 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.

CC. 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.

DD. 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,

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Ellen J. Flannery, J.D.
Deputy Center Director for Policy
Director, Office of Policy
Center for Devices and Radiological Health
Food and Drug Administration

Enclosure