



November 30, 2021

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Device: LumiraDx SARS-CoV-2 RNA STAR Complete

EUA Number: EUA202584

Company: LumiraDx UK Ltd.

Indication: Qualitative detection of nucleic acid from SARS-CoV-2 in:
Anterior nasal, mid-turbinate nasal, nasopharyngeal and oropharyngeal swab specimens, collected dry or in transport media, from individuals suspected of COVID-19 by their healthcare provider (HCP).
Anterior nasal swab specimens collected dry or in transport media from any individual, including individuals without symptoms or other reasons to suspect COVID-19 when collected by a HCP or self-collected under the supervision of a HCP.
Anterior nasal swab specimens that are collected using a collection kit that conforms to HealthPulse@home when used consistent with its authorization.
Pooled samples containing up to five individual anterior nasal swab specimens, using specified workflows, collected in individual vials either dry or containing transport medium from any individual, including individuals without symptoms or other reasons to suspect COVID-19.
Emergency use of this test is limited to authorized laboratories.

Authorized Laboratories: Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.

Dear Dr. Blicharz:

On October 14, 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 RNA STAR Complete, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3) for the indication stated in the letter.² Based on your requests, the letter was revised and reissued by FDA on February 9, 2021,³ and March 29, 2021.⁴ FDA has also granted updates to the authorized labeling at your request.⁵ In addition, FDA established additional Conditions of Authorization in response to the continued emergence of new variants of SARS-CoV-2 on September 23, 2021.⁶

On July 23, 2021, you requested to amend your EUA. Based on that request, and having concluded that revising the March 29, 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 March 29, 2021, letter in its entirety with the revisions incorporated.⁷ Pursuant to section

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

² The October 14, 2020, letter authorized the LumiraDx SARS-CoV-2 RNA STAR Complete for the qualitative detection of nucleic acid from SARS-CoV-2 in upper respiratory specimens (such as nasal, mid-turbinate, nasopharyngeal, and oropharyngeal swabs) collected from individuals suspected of COVID-19 by their healthcare provider. Emergency use of this test was limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.

³ On February 9, 2021, the revisions to the October 14, 2020, letter and authorized labeling included: (1) updating the Instructions for Use to include new master mix and salt buffer formulations, a new positive control formulation and corresponding modification of the thermal profile for the LightCycler 480 II, additional transport media, an additional PCR instrument, a limitation regarding indicating that performance has not been established with all circulating variants, and other clarifying edits, (2) addition of a condition of authorization related to protocols for validation of instrumentation and other clarifying revisions to the conditions of authorization, and (3) addition of information indicating performance has not been established with all circulating variants to the healthcare provider fact sheet.

⁴ On March 29, 2021, the revisions to the February 9, 2021, letter and authorized labeling included: (1) updates to the Instructions for Use to include new master mix, salt mix and extraction buffer formulations, modification to reagents volumes and assay workflow, optimized sample preparation procedure, modification of the thermal profile for all validated PCR instruments, addition of two real-time PCR instruments, some additional ancillary reagents, and other clarifying edits, (2) updates to the result interpretation Ct cutoff thresholds, and (3) updates to the healthcare provider and patient fact sheets to reflect language used in more recent authorizations.

⁵ On March 22, 2021, your request was granted to update the Instructions for use for your product to include an RUO instrument qualification protocol and RUO label to fulfill Condition of Authorization P. in the February 9, 2021 Letter of Authorization.

⁶ The Viral Mutation Revision Letter – September 23, 2021, can be accessed at:

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

⁷ The revisions to the March 29, 2021, letter and authorized labeling include: (1) update to the company address, (2) updates to the intended use to include use of your product with “*anterior nasal, mid-turbinate nasal, nasopharyngeal and oropharyngeal swab specimens collected dry or in transport media from individuals suspected of COVID-19 by their healthcare provider (HCP),*” “*anterior nasal swab specimens collected dry or in transport media from any individual, including individuals without symptoms or other reasons to suspect COVID-19 when collected by a HCP or self-collected under the supervision of a HCP,*” “*anterior nasal swab specimens that are collected using a collection kit that conforms to HealthPulse@home when used consistent with its authorization*” and “*pooled samples containing up to five individual anterior nasal swab specimens, using specified workflows, collected in individual vials either dry or containing transport medium from any individual, including individuals without symptoms or other reasons to suspect COVID-19,*” (3) update authorized labeling to fulfill Condition of Authorization (1) in the Viral Mutation Revision Letter – September 23, 2021, (4) add Conditions of Authorization (2) and (3) from the Viral Mutation Revision Letter – September 23, 2021 (O. and P. below), (5) updates to the Instructions for Use (IFU) and product insert (PI) described below to reflect the updates to the intended use, (6) updates to the letter and fact sheets to reflect the updated intended use, including the addition of Conditions of

564 of the Act and the Scope of Authorization (Section II) and Conditions of Authorization (Section IV) of this reissued letter, your product⁸ is now authorized for use consistent with the indication described 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.⁹

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 “lumiraDx SARS-CoV-2 RNA STAR Complete Instructions for Use” (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

Authorization Q., T., W. and Z. related to specimen pooling, addition of Condition of Authorization V. and update to Condition of Authorization R. related to the use of the HealthPulse@home collection kit, (7) updates to current and the addition of new Quick Reference Instructions, that will be made available online for end users, (8) updates to the *in silico* inclusivity analysis in the performance section of the IFU and (9) updates to the letter and fact sheets for consistency with language used in more recent authorizations.

⁸ For ease of reference, this letter will use the term “your product” to refer to the LumiraDx SARS-CoV-2 RNA STAR Complete for the indication identified above.

⁹ 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.¹⁰

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, non-isothermal nucleic acid amplification qSTAR (Selective Temperature Amplification Reaction) method intended for the qualitative detection of nucleic acid from SARS-CoV-2 in anterior nasal, mid-turbinate nasal, nasopharyngeal and oropharyngeal swab specimens, collected dry or in transport media, from individuals suspected of COVID-19 by their healthcare provider (HCP).

Your product is also authorized for use with anterior nasal swab specimens collected dry or in transport media from any individual, including individuals without symptoms or other reasons to suspect COVID-19 when collected by a HCP or self-collected under the supervision of a HCP.

Your product is also authorized for use with anterior nasal swab specimens that are collected using a collection kit that conforms to HealthPulse@home when used consistent with its authorization.

Your product is also intended for the qualitative detection of nucleic acid from SARS-CoV-2 in pooled samples containing up to five individual anterior nasal swab specimens, using specified workflows, collected in individual vials either dry or containing transport medium from any individual, including individuals without symptoms or other reasons to suspect COVID-19.

Negative results from pooled samples should be treated as presumptive and, if inconsistent with clinical signs and symptoms or necessary for patient management, pooled samples should be tested individually. Specimens included in pools with a positive result must be tested individually prior to reporting a result. Specimens with low SARS-CoV-2 RNA concentrations may not be detected in sample pools due to the decreased sensitivity of pooled testing.

Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 USC. §263a that meet requirements to perform high complexity tests.

Specimens should only be pooled in areas with low SARS-CoV-2 prevalence, and when testing demand exceeds laboratory capacity or reagent availability. Pooled specimen testing is for use by authorized laboratories that will adhere to a protocol for ongoing monitoring of the pooling strategy or that limit testing to individuals who are subjected to a detailed infection prevention and control plan. Pooled samples with positive results must be tested individually prior to reporting results. Negative results from pooled samples should be reported as presumptive. If clinical signs and symptoms are inconsistent with a negative result or results are necessary for

¹⁰ No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

patient management, the patient should be considered for individual testing. Specimens with low viral genetic material may not be detected in pooled samples due to decreased sensitivity.

The SARS-CoV-2 nucleic acid is generally detectable in upper respiratory specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 nucleic acid; 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 viruses. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

To use your product, SARS-CoV-2 virions present in anterior nasal, mid-turbinate nasal, nasopharyngeal and oropharyngeal swab specimens are lysed by detergents in the extraction buffer and the nucleic acid is reverse transcribed into cDNA followed by non-isothermal nucleic acid qSTAR amplification (Selective Temperature Amplification Reaction) and detection with molecular beacons designed to anneal to the target amplicon measured using an authorized real-time (RT) PCR instrument. The LumiraDx SARS-CoV-2 RNA STAR Complete includes the following materials or other authorized materials: Master Mix, Internal Control & Primer Mix (IC/P Mix), Extraction Buffer, Salt Mix, Positive Control Media (Pos.Ctrl. Media) and Negative Control Media (Neg. Ctrl. Med).

Your product requires the following control materials, or other authorized control materials (as may be requested under Condition J. below), that are processed in the same way as the patient specimens and are required to be included with each batch of specimens tested with your product. All controls listed below must generate expected results in order for a test to be considered valid, as outlined in the Instructions for Use:

- Neg. Ctrl. Med –Molecular Biology Grade Water; used to control for cross-contamination and reagent contamination.
- Pos. Ctrl. Med – comprised of a quantified NATrol SARS-Related Coronavirus 2 (SARS-CoV-2) External Run Control; used to ensure test reagents are properly detecting SARS-CoV-2.
- Internal Control – comprised of a 40-bp synthetic RNA with a unique probe region for molecular beacon detection in the ROX channel; serves as a control for detection of inhibitors present in the specimen, assures that adequate amplification has taken place and that the enzymes and primers were not damaged during production, shipment and storage.
- RNaseP control (as applicable) - included for anterior nasal swab specimens that are collected using a collection kit that conforms to the HealthPulse@home EUA.

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 RNA STAR Complete Instructions for Use,” the

“lumiraDx SARS-CoV-2 RNA STAR Complete” product insert, the following Quick Reference Instructions: “lumiraDx SARS-CoV-2 RNA STAR Complete Quick Reference Instructions for Single Swab Format,” “lumiraDx SARS-CoV-2 RNA STAR Complete Quick Reference Instructions for Deepwell Format,” “lumiraDx SARS-CoV-2 RNA STAR Complete Quick Reference Instructions for 5 Pooled Swabs/96-Well Format,” “lumiraDx SARS-CoV-2 RNA STAR Complete Quick Reference Instructions for Single Swab Format Lightcycler 480 II - 384,” “lumiraDx SARS-CoV-2 RNA STAR Complete Quick Reference Instructions for Single Swab Format QS5 and QS7 Flex - 384,” and the following product-specific information pertaining to the emergency use, which is required to be made available as set forth in the Conditions of Authorization (Section IV), are collectively referred to as the “authorized labeling” (available at <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas>):

- Fact Sheet for Healthcare Providers: LumiraDx UK Ltd. – Lumira Dx SARS-CoV-2 RNA STAR Complete
- Fact Sheet for Patients: LumiraDx UK Ltd. – Lumira Dx SARS-CoV-2 RNA STAR Complete

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 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)¹¹

- 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 include a physical copy of the authorized “lumiraDx SARS-CoV-2 RNA STAR Complete” product insert with your product to authorized laboratories, and will make the authorized “lumiraDx SARS-CoV-2 RNA STAR Complete Instructions for Use” and the following Quick Reference Instructions: “lumiraDx SARS-CoV-2 RNA STAR Complete Quick Reference Instructions for Single Swab Format,” “lumiraDx SARS-CoV-2 RNA STAR Complete Quick Reference Instructions for Deepwell Format,” “lumiraDx SARS-CoV-2 RNA STAR Complete Quick Reference Instructions for 5 Pooled Swabs/96-Well Format,” “lumiraDx SARS-CoV-2 RNA STAR Complete Quick Reference Instructions for Single Swab Format Lightcycler 480 II - 384,” “lumiraDx SARS-CoV-2 RNA STAR Complete Quick Reference Instructions for Single Swab Format QS5 and QS7 Flex - 384,” electronically available with opportunity to request a copy in paper form, and after such request, promptly provide the requested information without additional cost.
- C. You and authorized distributor(s) must make available on your website(s) the authorized labeling.
- D. 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.

¹¹ “Authorized Distributor(s)” are identified by you, LumiraDx UK Ltd., in your EUA submission as an entity allowed to distribute your product.

- E. 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.
- F. You and authorized distributor(s) must 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.

LumiraDx UK Ltd. (You)

- H. You must notify FDA of any authorized distributor(s) of your product, including the name, address, and phone number of any authorized distributor(s).
- I. You must provide authorized distributor(s) with a copy of this EUA and communicate to authorized distributor(s) any subsequent amendments that might be made to this EUA and its authorized accompanying materials (e.g., Fact Sheets).
- J. 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.
- K. 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).
- L. 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.
- M. 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.

- N. You must evaluate the analytical limit of detection and assess traceability¹² of your product with any FDA-recommended reference material(s). After submission to and concurrence with the data by FDA, you will 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.
- O. You must evaluate the impact of SARS-CoV-2 viral mutations on your product's performance. Such evaluations must occur on an ongoing basis and must include any additional data analysis that is requested by FDA in response to any performance concerns you or FDA identify during routine evaluation. Additionally, if requested by FDA, you must submit records of these evaluations for FDA review within 48 hours of the request. If your evaluation identifies viral mutations that affect the stated expected performance of your device, you must notify FDA immediately (via email: CDRH-EUA-Reporting@fda.hhs.gov).
- P. If requested by FDA, you must update your labeling within 7 calendar days to include any additional labeling risk mitigations identified by FDA, such as those related to the impact of viral mutations on test performance. Such updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- Q. You will further evaluate the pooling performance of your product in an FDA agreed upon post authorization study within 4 months of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH). 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.
- R. You must have a process in place to track adverse events, including with a collection kit that conforms to the HealthPulse@home EUA, any occurrence of false results with your product and report any such events 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-EUARreporting@fda.hhs.gov).

Authorized Laboratories

- S. Authorized laboratories using your product 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.
- T. Authorized laboratories using specimen pooling strategies when testing patient specimens with your product will include with test result reports for specific patients whose specimen(s) were the subject of pooling, a notice that pooling was used during testing

¹² Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material.

and that “Patient specimens with low viral loads may not be detected in sample pools due to the decreased sensitivity of pooled testing.”

- U. 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.
- V. Authorized laboratories when testing anterior nasal swab specimens collected using a collection kit that conforms to the HealthPulse@home EUA authorized for use with your product must follow any specimen accessioning protocol provided with and/or developed for the collection kit when accepting specimens for testing.
- W. Authorized laboratories implementing pooling strategies for testing patient specimens must use the “Defining a sample pooling strategy” and “Monitoring the pooling strategy” procedures available in the authorized labeling to evaluate the appropriateness of continuing to use such strategies based on the recommendations in the protocols.
- 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 will keep records of specimen pooling strategies implemented including type of strategy, date implemented, and quantities tested, and test result data generated as part of the “Defining a sample pooling strategy” and “Monitoring the pooling strategy” procedures. For the first 12 months from the date of their creation, such records must be made available to FDA within 48 business hours for inspection upon request and must be made available within a reasonable time after 12 months from the date of their creation.
- AA. 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 (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.
- BB. All laboratory personnel using your product must be appropriately trained in nucleic acid amplification techniques and use appropriate laboratory and personal protective equipment when handling this test and use your product in accordance with the authorized labeling.

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

CC. 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

DD. 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 and FDA implementing regulations.

EE. 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.

FF. 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 for emergency use under an EUA for use by authorized laboratories;
- This product has been authorized only for the detection of nucleic acid 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