

November 15, 2021

To: Laboratories with tests listed in Appendix A.

Authorized Tests: Tests listed in Appendix A.¹

Indication: Qualitative detection of nucleic acid from SARS-CoV-2 in respiratory specimens collected from individuals suspected of COVID-19² by their healthcare provider. Use of the test is limited to the authorized laboratory.

Authorized Laboratories: Testing is limited to the single laboratory that developed the authorized test and that is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meets the requirements to perform tests of high complexity. The authorized laboratory for each authorized test is listed in Appendix A.

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the Act), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19. Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 subject to the terms of any authorization issued under Section 564(a) of the Act.³

On March 31, 2020, in response to this evolving public health emergency and continued concerns about the availability of sufficient in vitro diagnostic tests, FDA issued this EUA for certain molecular-based laboratory developed tests (LDTs) for use by the single developing laboratory (as described in the Scope of Authorization (Section II)) under Section 564 of the Act (21 U.S.C. § 360bbb-3). Under this EUA, authorized tests are authorized for use only in the single laboratory that developed the authorized test and that is certified under the Clinical

¹ For ease of reference, this letter will refer to the tests listed in Appendix A as the “authorized tests.” Appendix A is included on the FDA website at: <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2>

² On February 11, 2020, the virus tentatively named 2019-nCoV was formally designated as Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2). Also on February 11, 2020, the disease caused by SARS-CoV-2 was formally designated as Coronavirus Disease 2019 (COVID-19). This document uses the updated names.

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).

Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meets the requirements to perform tests of high complexity.

FDA has continued to periodically review the circumstances and the appropriateness of authorizing the emergency use of tests under this EUA as required by Section 564(g)(1) of the Act since it was issued on March 31, 2020. Based on this review and all available information, FDA has concluded that the criteria for issuance under Section 564(c) of the Act are met with respect to the authorized tests and has also determined that it is no longer appropriate to include any additional authorized tests under this EUA. As described below, FDA's decision to reissue this EUA pursuant to Section 564(c) of the Act is based in part on the changing circumstances of this pandemic. This includes a significant shift towards tests that can be used with pooled specimens that are collected as part of a serial testing program for screening. Such tests are outside the scope of this EUA. Given this, FDA is reissuing this EUA such that only tests that are listed in Appendix A are authorized for use as described in Section II of this letter when used consistent with the Conditions of Authorization (Section IV). FDA has updated the Conditions of Authorization and also updated the fact sheets to reflect the most up-to-date information as part of this reissuance.

FDA may authorize additional tests, as appropriate, either in individual EUAs or under a new umbrella EUA. At this stage of the pandemic, FDA intends to focus its review on the types of tests needed to meet the current public health needs, including tests intended for use as part of serial screening testing programs. Serial screening testing programs are expected to be a cornerstone of the current phase of the country's pandemic response as many schools, workplaces, communities, and other entities are setting up testing programs to rapidly screen for COVID-19, and FDA is providing streamlined approaches for authorization of tests intended for use in these programs. FDA will review individual EUA requests for tests based on a number of factors and may issue an EUA when the statutory criteria for issuance are met.

Having concluded that the criteria for issuance under Section 564(c) of the Act are met with respect to the tests listed in Appendix A of this letter, I am authorizing the emergency use of the tests listed in Appendix A as described in the Scope of Authorization (Section II) and pursuant to the Conditions of Authorization (Section IV) to detect SARS-CoV-2 in respiratory specimens from individuals suspected of COVID-19 by their healthcare provider for use in the single laboratory that developed the authorized test and that is certified under the CLIA, 42 U.S.C. § 263a, and meets the requirements to perform tests of high complexity.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the authorized tests listed in Appendix A of this reissued letter of authorization meet 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 the authorized tests may be effective in diagnosing COVID-19, and that the known

and potential benefits of the authorized tests when used for diagnosing COVID-19, outweigh the known and potential risks of the authorized tests; and

3. There is no adequate, approved, and available alternative to the emergency use of the authorized tests.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 authorized tests listed in Appendix A for the indication above.

Authorized Tests

Tests listed in Appendix A, when labeled consistent with the authorized test procedures and as described in the authorized test’s EUA summary (available at <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2>), are authorized to be used by the single laboratory that developed the authorized test, despite the fact that they do not meet certain requirements otherwise required by applicable federal law.

Authorized tests must be accompanied by the following product information pertaining to their emergency use, which is required to be made available to healthcare providers and patients:

- Fact Sheet for Healthcare Providers: Molecular LDT COVID-19 Authorized Test
- Fact Sheet for Patients: Molecular LDT COVID-19 Authorized Test

These facts sheets, the authorized test procedures, and the authorized test’s EUA summary are collectively referred to below as the “authorized labeling” for each authorized test.

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 the authorized tests outweigh the known and potential risks of such authorized tests.

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 the authorized tests listed in Appendix A may be effective for the indication above, when used consistently 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 the authorized tests (as described in the Scope of Authorization of this letter (Section II)) meet the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the authorized tests 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

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

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, the tests are authorized for the indication above.

This EUA will cease to be effective when the HHS declaration that circumstances exist to justify the EUA is terminated under Section 564(b)(2) of the Act or when the EUA is revoked under Section 564(g) of the Act.

III. Waiver of Certain Requirements

I am waiving the following requirements for the 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.

IV. Conditions of Authorization

Pursuant to Section 564(e) of the Act, I am establishing the following conditions on this authorization:

Authorized Laboratories (You)

- A. Your authorized 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 U.S.C. 352(f)), (21 CFR 809.10(b)(5), (7), and (8)); appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4); and any available information regarding performance of the product, including requirements under 21 CFR 809.10(b)(12).
- B. You must inform relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to your authorized product or authorized labeling.
- C. You must notify the relevant public health authorities of your intent to run your authorized product.
- D. You must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- E. You must include with test results, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
- F. You must make available on your website(s), if applicable, the Fact Sheet for

Healthcare Providers and the Fact Sheet for Patients.

- G. You are authorized to make available additional information relating to the emergency use of your authorized product that is consistent with, and does not exceed, the terms of this letter of authorization.
- H. You must use your authorized product as outlined in the authorized test procedures. Deviations from the authorized test procedures, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and/or authorized materials required to use your product are not permitted.
- I. You must collect information on the performance of your authorized product. You must report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your authorized product of which you become aware.
- J. You may request changes to the authorized labeling. Any request for changes to the authorized labeling must 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 evaluate the analytical limit of detection and assess traceability of your authorized product with any FDA-recommended reference material(s), if requested by FDA.⁵ After submission to FDA and DMD/OHT7-OIR/CDRH's review of and concurrence with the data, FDA will update the EUA summary to reflect the additional testing. Such updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- L. You must track adverse events, including any occurrence of false results with your authorized product and report any such events to FDA pursuant to 21 CFR Part 803.
- M. All laboratory personnel using your authorized product must be appropriately trained in molecular techniques and use appropriate laboratory and personal protective equipment when handling this product, and use your authorized product in accordance with the authorized test procedure.
- N. You 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.

⁵ Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material. FDA may request, for example, that you perform this study in the event that we receive reports of adverse events concerning your authorized test.

- 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 product, you must notify FDA immediately via email to 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 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.

Conditions Related to Printed Materials, Advertising and Promotion

- Q. All descriptive printed matter, advertising, and promotional materials, relating to the use of your authorized 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(q)(1) and (r) of the Act, as applicable, and FDA implementing regulations.
- R. No descriptive printed matter, advertising, or promotional materials relating to the use of your authorized product may represent or suggest that such test is safe or effective when used for detection SARS-CoV-2.
- S. All descriptive printed matter, advertising, and promotional material relating to the use of your authorized product shall clearly and conspicuously state that:
- This product has not been FDA cleared or approved by FDA, but has been authorized by FDA 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 Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or the 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