

April 9, 2021

Kelly Lewis Brezoczky
Executive Vice President
Lucira Health, Inc.
1412 62nd Street
Emeryville, CA 94608

Device:	Lucira CHECK-IT COVID-19 Test Kit
EUA Number	EUA210196
Company:	Lucira Health, Inc.
Indication:	Intended for the qualitative detection of nucleic acid from the novel coronavirus SARS-CoV-2 that causes COVID-19. This test is for nonprescription home use with self-collected anterior nasal (nasal) swab specimens in individuals aged 14 years and older (self-collected) or individuals ≥ 2 years (collected by an adult) with or without symptoms or other epidemiological reasons to suspect COVID-19.

Dear Ms. Brezoczky:

This letter is in response to your¹ request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of your product,² pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).

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

¹ For ease of reference, this letter will use the term “you” and related terms to refer to Lucira Health, Inc.

² For ease of reference, this letter will use the term “your product” to refer to the Lucira CHECK-IT COVID-19 Test Kit used for the indication identified above.

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).

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 “Lucira CHECK-IT COVID-19 Test Kit 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) in certain individuals for the detection of SARS-CoV-2 subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of your product meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. The SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;
2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that your product may be effective in diagnosing COVID-19, and that the known and potential benefits of your product when used for diagnosing COVID-19, outweigh the known and potential risks of your product; and
3. There is no adequate, approved, and available alternative to the emergency use of your product.⁴

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited to the indication above.

Authorized Product Details

Your product is a rapid, single-use test kit that utilizes a molecular amplification technology intended for the qualitative detection of nucleic acid from the novel coronavirus SARS-CoV-2 that causes COVID-19. This test is for nonprescription home use with self-collected anterior nasal (nasal) swab specimens in individuals aged 14 years and older (self-collected) or individuals ≥ 2 years (collected by an adult) with or without symptoms or other epidemiological reasons to suspect COVID-19.

SARS-CoV-2 viral RNA is generally detectable in anterior nasal swab 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. Individuals who test positive should self-isolate and seek additional care from their healthcare provider. Negative results are presumptive and confirmation

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

with a molecular assay performed in a laboratory certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, if necessary, for patient management may be performed, if necessary for patient management, may be performed. Negative results do not preclude SARS-CoV-2 infection. Individuals who test negative and continue to experience COVID-like symptoms should seek follow up care from their healthcare provider.

Your product contains all the components required to perform testing. To use your product, SARS-CoV-2 nucleic acid is first eluted and lysed from nasal swabs that are inserted into the Sample Vial. The eluant then enters into the Test Unit where the nucleic acid is then reverse transcribed (RT) into cDNA followed by loop-mediated isothermal amplification (LAMP) and detected by the Test Unit as a color change. Test results are displayed on the Test Unit via LED indicators. The Lucira COVID-19 All-In-One Test Kit includes the following materials or other authorized materials: 1 Sterile Nasal Swab, 1 Sample Vial, 1 Test Unit, Batteries, 1 Disposal Bag, and instructions.

Your product includes and is required to have the following control materials, or other authorized control materials (as may be requested under Condition M below), that are processed along with the specimen in the Test Unit. The Positive Internal Control (PIC) and Lysis Internal Control (LIC) contained within the Test Unit must generate expected signal/results in order for a test to be considered valid, as outlined in the specimen collection instructions, and the Instructions for Use.

Individuals can use the LUCI portal to report all results obtained with this product to relevant public health authorities in accordance with local, state, and federal requirements using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by the Centers for Disease Control and Prevention.

The labeling entitled “Lucira CHECK-IT COVID-19 Test Kit” Patient Instructions Pamphlet (QRI), the “Lucira CHECK-IT COVID-19 Test Kit Instructions for Use,” (available at <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas>), and the Lucira CHECK-IT COVID-19 Test Kit box label and the following fact sheet⁵ pertaining to the emergency use is 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: Lucira Health, Inc.- Lucira CHECK-IT COVID-19 Test Kit

Your product, when accompanied by the authorized labeling as set forth in the Conditions of Authorization (Section IV) is authorized to be distributed and used by individuals, as set forth in this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

⁵ Note that the information typically found in a Fact Sheet for Patients is contained in the “Lucira CHECK-IT COVID-19 Test Kit” Patient Instructions Pamphlet (QRI).

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:

Lucira Health, Inc. (You) and Authorized Distributor(s)⁶

- A. Your product must comply with the following labeling requirements pursuant to FDA regulations: the intended use statement in 21 CFR 809.10(a)(2), (b)(2); adequate directions for use in 21 U.S.C. 352(f) and 21 CFR 809.10(b)(5), (7), and (8); appropriate limitations on the use of the device including information required under 21 CFR

⁶ "Authorized Distributor(s)" are identified by you, Lucira Health, Inc., in your EUA submission as an entity allowed to distribute your product.

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 available the “Lucira CHECK-IT COVID-19 Test Kit” Patient Instructions Pamphlet (QRI), the “Lucira CHECK-IT COVID-19 Test Kit Instructions for Use” and the Fact Sheet for Healthcare Providers related to the use of your product on your website(s).
- C. You and authorized distributor(s) must include a physical copy of the “Lucira CHECK-IT COVID-19 Test Kit” Patient Instructions Pamphlet (QRI) and with each shipped kit (with Lucira CHECK-IT COVID-19 Test Kit box label) of your product.
- D. You and authorized distributor(s) must inform relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to your product and/or the authorized labeling.
- E. Through a process of inventory control, you and authorized distributor(s) must maintain records of the locations (e.g., pharmacies, doctor’s offices, etc.) to which your product is distributed and the number distributed to each location.
- F. You and authorized distributor(s) must maintain records of customer complaint files and report to FDA any significant complaints about usability or deviations from the established performance characteristics of which you and authorized distributor(s) become aware.
- G. You and authorized distributor(s) must collect information on the performance of your product and have a process in place to track adverse events, including any occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the product of which you become aware and report any such events to FDA in accordance with 21 CFR Part 803. Serious adverse events, especially unexpected biosafety concerns, should immediately be reported to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUAREporting@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) 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.

Lucira Health, Inc. (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, including the authorized labeling.
- L. You must make the “Lucira CHECK-IT COVID-19 Test Kit Instructions for Use,” and Fact Sheet for Healthcare Providers electronically available on your website(s). Additionally, you must provide the opportunity to request a copy of these authorized labeling documents in paper form, and after such request, promptly provide the requested labeling at no additional cost.
- M. 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 shall 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.
- N. You must comply with the following requirements pursuant to FDA regulations: Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).
- O. You must have lot release procedures and the lot release procedures, including the study design and statistical power, must ensure that the product released for distribution meet the clinical and analytical performance claimed in the authorized labeling.
- P. If requested by FDA, you must submit your 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 them within 48 hours of the request.
- Q. You must evaluate the analytical limit of detection and assess traceability⁷ 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.
- R. You must implement the agreed upon reporting-related software updates to the LUCI Portal within 3 months of this letter and notify DMD/OHT7-OIR/OPEQ/CDRH upon implementation. Upon implementation, you must ensure automatic test result reporting,

⁷ Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material.

using the LUCI Portal, to relevant public health authorities in accordance with local, state, and federal requirements.

- S. You must submit to FDA a summary report within 60 calendar days of product launch summarizing the results of any testing performed using your product during that timeframe, including how many products were distributed, the positivity rate for specimens tested with your product, and how many individuals reported results to their healthcare provider as encouraged by the “Lucira CHECK-IT COVID-19 Test Kit “ Patient Instructions Pamphlet (QRI).

Conditions Related to Printed Materials, Advertising and Promotion

- T. 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.
- U. 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.
- V. All descriptive printed matter, advertising, and promotional materials relating to the use of your product shall clearly and conspicuously state that:
- This OTC test kit (or product) has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA;
 - This OTC test kit (or product) has been authorized only for the testing of nasal swabs for detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and
 - The emergency use of this OTC test kit (or 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,

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosure