June 14, 2023

Elizabeth Mauro
Director, Global Regulatory Science
Pfizer Inc.
66 Hudson Boulevard East
New York, CA 10001

Device:	Lucira COVID-19 All-In-One Test Kit
EUA Number:	EUA202920
Company:	Pfizer Inc.
Indication:	Intended to detect the novel coronavirus SARS-CoV-2 that causes COVID-19. This test is for prescription home use with self-collected anterior nasal swab samples from individuals aged 14 years and older who are suspected of COVID-19 by their healthcare provider. This test is also authorized for use at the point of care (POC), in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation, with self-collected anterior nasal swab samples from individuals aged 14 years and older, and in individuals aged 13 years and under when the specimen is collected by a healthcare provider at the POC. This test utilizes a molecular amplification technology for the detection of SARS-CoV-2 RNA in individuals with known or suspected COVID-19.

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Dear Elizabeth Mauro:

On November 17, 2020, based on Lucira Health, Inc.'s request, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the Lucira COVID-19 All-In-One Test Kit, 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.[1] In addition, FDA

[1] The November 17, 2020, letter authorized the Lucira COVID-19 All-In-One Test Kit to detect the novel coronavirus SARS-CoV-2 that causes COVID-19. This test was authorized for prescription home use with self-collected nasal swab specimens in individuals aged 14 and older who are suspected of COVID-19 by their healthcare provider. This test was also authorized for use at the point of care (POC), in patient care settings operating under a

established additional Conditions of Authorization in response to the continued emergence of new variants of SARS-CoV-2 on September 23, 2021.[2] Subsequently, based on Lucira Health, Inc.'s requests, FDA also granted updates to the authorized labeling on July 28, 2022[3] and revised and reissued the letter on November 15, 2022.[4]

On April 19, 2023, and May 12, 2023, you[5] requested that FDA amend your EUA. Based on those requests, and having concluded that revising the November 15, 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 November 15, 2022, letter in its entirety with the revisions incorporated.[6] Pursuant to section 564 of the Act and the Scope of Authorization (Section II) and Conditions of Authorization (Section IV) of this reissued letter, your product[7] is now authorized for use consistent with the indication described 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

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CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation, with self-collected nasal swab specimens in individuals aged 14 and older, and in individuals aged 13 and under when the specimen is collected by a healthcare provider at the POC. This test utilizes a molecular amplification technology for the detection of SARS-CoV-2 RNA in individuals with known or suspected COVID-19.

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

[3] On July 28, 2022, Lucira Health, Inc.'s request was granted to update the device shelf-life stability claim from 12 months to 18 months when stored at 30±2°C. FDA also updated the Fact Sheet for Healthcare Providers to reflect language used in more recent authorizations.

[4] On November 15, 2022, the revisions to the November 17, 2020, letter and authorized labeling included: (1) addition of the following statement in the intended use "*Negative results are presumptive and confirmation with a molecular assay performed in a laboratory, if necessary for patient management, may be performed*," (2) incorporating language to address Condition of Authorization (1) in the Viral Mutation Revision Letter dated September 23, 2021, (3) updating the titles of some of the authorized labeling, (4) deleting Condition of Authorization P. from the November 17, 2020 letter (fulfilled), (5) deleting Condition of Authorization Q. from the November 17, 2020 letter (fulfilled), and (6) updates to the letter for consistency with language used in more recent authorizations, including incorporation of Conditions of Authorization (2) and (3) from the Viral Mutation Revision Letter – September 23, 2021 (Conditions of Authorization P and Q in the November 15, 2022 letter and also below).

[5] For ease of reference, this letter will use the term "you" and related terms to refer to Pfizer Inc.

[6] The revisions to the November 15, 2022, letter and authorized labeling include: (1) transfering ownership of the EUA for the Lucira COVID-19 All-In-One Test Kit from Lucira Health, Inc. to Pfizer Inc., (2) updating the intended use for consistency with language use in other home-use tests, (3) updating the list of authorized distributors, (4) removing the "Lucira Health, Inc. Healthcare Provider Guide to COVID-19 Data Reporting for Non-Lab-Based Testing" from the list of authorized labeling list, instead it will be offered as additional information under Condition of Authorization G. (below), and (5) updating the Fact Sheet for Healthcare Providers and the Letter of Authorization to reflect the updates made to the intended use and for consistency with language used in more recent authorizations.

[7] For ease of reference, this letter will use the term "your product" to refer to the Lucira COVID-19 All-In-One Test Kit for the indication identified above.

vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 subject to the terms of any authorization issued under Section 564(a) of the Act.[8]

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 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

3. There is no adequate, approved, and available alternative to the emergency use of your product.[9]

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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 single-use test kit intended to detect the novel coronavirus SARS-CoV-2 that causes COVID-19. This test is authorized for prescription home use with self-collected anterior nasal swab samples from individuals aged 14 years and older who are suspected of COVID-19 by their healthcare provider. This test is also authorized for use at the point of care (POC), in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or

[8] U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*. February 4, 2020. 85 FR 7316 (February 7, 2020). U.S. Department of Health 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").

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

Certificate of Accreditation, with self-collected anterior nasal swab samples from individuals aged 14 years and older, and in individuals aged 13 years and under when the specimen is collected by a healthcare provider at the POC. This test utilizes a molecular amplification technology for the detection of SARS-CoV-2 RNA in patients with known or suspected COVID-19.

SARS-CoV-2 viral RNA is generally detectable in anterior nasal swab samples during the acute phase of infection. Positive results indicate the presence of SARS-CoV-2 viral RNA, but clinical correlation with past medical 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. The agent detected may not be the definitive cause of disease. Individuals who test positive should self-isolate and seek additional care from their healthcare provider.

Negative results are presumptive and confirmation with a molecular assay performed in a laboratory, if necessary for patient management, may be performed. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment or management decisions for the individual, including infection control decisions. Negative results should be considered in the context of an individual's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19. Individuals who test negative and continue to experience COVID-19 like symptoms of fever, cough, and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care from their physician or healthcare provider.

All prescribing healthcare providers will report all test results they receive from individuals who use the authorized 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 (CDC).

Your product is performed using self-collected anterior nasal swab samples from individuals aged 14 years and older, and in individuals aged 13 years and under when the specimen is collected by a healthcare provider at the POC. When using your product, the individual performing the test must follow the instructions provided in the "Lucira COVID-19 All-In-One Test Kit" Package Insert when collecting the specimen, running the test procedure and interpreting the results.

The Lucira COVID-19 All-In-One Test Kit includes the materials or other authorized materials (as may be requested under Condition K. below) required to collect the anterior nasal swab sample and perform the test procedure, as described in the "Lucira COVID-19 All-In-One Test Kit" Package Insert and the "Lucira COVID-19 All-In-One Test Kit Instructions for Use."

Your product requires the following control materials, or other authorized control materials (as may be requested under Condition K. below), that are described in the Instructions for Use. 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 "Lucira Health COVID-19 All-In-One Test Kit" Package Insert, the "Lucira COVID-19 All-In-One Test Kit Instructions for Use"(available at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-

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authorizations-medical-devices/in-vitro-diagnostics-euas), and the following fact sheet pertaining to the emergency use, which are required to be made available as set forth in the Conditions of Authorization (Section IV), are collectively referred to as "authorized labeling:"

- Fact Sheet for Healthcare Providers[10]: Pfizer Inc.- Lucira COVID-19 All-In-One Test Kit

The above described product, when accompanied by the authorized labeling as set forth in the Conditions of Authorization (Section IV), is authorized to be distributed and used 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.

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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).

[10] Note that the information typically found in a Fact Sheet for Patients is contained in the "Lucira Health COVID-19 All-In-One Test Kit" Package Insert.

IV. Conditions of Authorization

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

Pfizer Inc. (You) and Authorized Distributor(s)[11]

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 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 on your website(s) all authorized labeling identified in Section II of this letter.

C. 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.

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 of your product distributed to each location.

F. 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 the Division of Microbiology (DMD)/Office of Health Technology 7 (OHT7) /Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH) (via email: CDRH-EUAReporting@fda.hhs.gov).

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

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[11] "Authorized Distributor(s)" are identified by you, Pfizer Inc., in your EUA submission as an entity allowed to distribute your product.

does not exceed, the terms of this letter of authorization.

Pfizer Inc. (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 revisions that might be made to this EUA and its authorized accompanying materials, including the authorized labeling.

J. You must include a physical copy of the "Lucira Health COVID-19 All-In-One Test Kit" Package Insert with each shipped kit of your product, and must make the authorized "Lucira COVID-19 All-In-One Test Kit Instructions for Use" electronically available for healthcare providers. Additionally, you must give healthcare providers the opportunity to request a copy of the "Lucira COVID-19 All-In-One Test Kit Instructions for Use" in paper form, and, after such request, promptly provide the requested labeling without additional cost.

K. 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 DMD/OHT7/OPEQ/CDRH and require appropriate authorization from FDA prior to implementation.

L. 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).

M. 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.

N. 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.

O. You must evaluate the analytical limit of detection and assess traceability[12] of your product with any FDA-recommended reference material(s) if requested by FDA. After

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

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submission to and concurrence with the data by FDA, you will update your labeling to reflect the additional testing if requested by FDA. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7/OPEQ/CDRH.

P. 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).

Q. 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.

Healthcare Providers

R. All prescribing healthcare providers must collect information on the performance of your product in the ordinary course of business and report to DMD/OHT7/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and to you (1-888-582-4724) 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.

S. All prescribing healthcare providers must report all test results they receive from individuals who use your 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 (available at: https://www.cdc.gov/csels/dls/sars-cov-2-livd-codes.html). Healthcare providers will also report to Lucira Health, Inc., when requested by Lucira Health, Inc., how many individuals reported test results compared to how many of your product they prescribed.

Point-of-Care Settings[13]

T. Point-of-care settings using your product must use your product without any deviations from the authorized labeling.

U. Point-of-care settings that receive your product must notify the relevant public health authorities of their intent to use your product prior to initiating testing.

[13] For purposes of this EUA, Point-of-Care (POC) settings are defined as patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

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V. Point-of-care settings using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

W. Point-of-care settings must collect information on the performance of your product and report to DMD/OHT7/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and to you (1-888-582-4724) 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.

Pfizer Inc. (You), Authorized Distributors, Healthcare Providers and Point-of- Care Settings

X. You, authorized distributors, healthcare providers and point-of-care settings 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

Y. 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.

Z. 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.

AA. 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;
- 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.

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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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Jeffrey E. Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health
Food and Drug Administration

Enclosure

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