February 16, 2023

Myriam Battistutta
Head of Regulatory
Ellume Limited
57 Didsbury Street
East Brisbane QLD, 4169 Australia

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| Device: | Ellume COVID-19 Home Test |
| EUA Number: | EUA203011 |
| Company: | Ellume Limited |
| Indication: | Non-prescription home use for the qualitative detection of nucleocapsid protein antigen from the SARS-CoV-2 virus with self-collected direct mid-turbinate nasal swab samples from individuals aged 16 years or older, or adult collected direct mid-turbinate nasal swab samples from individuals aged 2 years or older. This test is authorized for individuals with symptoms of COVID-19 within the first 4 days of symptom onset when tested at least twice over three days with at least 48 hours between tests, and for individuals without symptoms or other epidemiological reasons to suspect COVID-19, when tested at least three times over five days with at least 48 hours between tests. |

Dear Myriam Battistutta:

On December 15, 2020, based on your[1] request the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the Ellume COVID-19 Home Test 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, FDA granted updates to the authorized labeling on February 11, 2021[3] and also reissued the letter in its entirety with

[1] For ease of reference, this letter will use the term "you" and related terms to refer to Ellume Limited ("Ellume").
[2] The December 15, 2020, letter authorized the Ellume COVID-19 Home Test for the qualitative detection of SARS-CoV-2 nucleocapsid antigens from mid-turbinate nasal swabs that are self-collected by an individual age 16 years or older, or are collected by an adult from an individual 2 years of age and older for use in individuals with or without symptoms or other epidemiological reasons to suspect a COVID-19 infection.
The Ellume COVID-19 Home Test was authorized for non-prescription home use.
[3] On February 11, 2021, your request was granted via email to update the authorized labeling to address Condition of Authorization R and S. of the December 15, 2020, letter.

revisions incorporated on March 16, 2022.[4] 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.[5] Further, FDA revised the authorized uses and established one additional Condition of Authorization requiring updates to product labeling regarding repeat, or serial, testing, for all currently authorized SARS-CoV-2 antigen tests on November 1, 2022.[6]

On May 8, 2022, July 13, 2022, and November 15, 2022, you requested to amend your EUA. Based on these requests, and having concluded that revising the March 16, 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 revising and reissuing the March 16, 2022, letter in its entirety with the revisions incorporated.[7] 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[8] 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

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[4] On March 16, 2022, the revisions to the December 15, 2020, letter and authorized labeling included: (1) revisions to the intended use to: "*self-collected direct mid-turbinate nasal swab specimens from individuals aged 16 years or older with symptoms of COVID-19 within the first 7 days of symptom onset*," "*adult-collected mid-turbinate nasal swab specimens from individuals aged 2 years or older with symptoms of COVID-19 within the first 7 days of symptom onset*," and "*with self-collected mid-turbinate nasal swab specimens from individuals aged 16 years or older, or adult-collected mid-turbinate nasal swab specimens from individuals aged 2 years or older, with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over two to three days with at least 24 hours (and no more than 48 hours) between tests*," (2) updates to the Fact Sheet for Healthcare Providers and Fact Sheet for Patients to reflect the revised intended use and also for consistency with language used in more recent authorizations, (3) updates to the letter to reflect the revised intended use including the addition of Condition of Authorization S. (below), (4) updates to the other authorized labeling to reflect the revised intended use, (5) addition of Condition of Authorization R. (below) for additional clinical evaluation and inclusion of Conditions of Authorization (2) and (3) from the Viral Mutation Revision Letter – September 23, 2021 (T. and U. below), (6) removal of Condition of Authorization R. and S. from the December 15, 2020 letter (fulfilled) and Q. from the December 15, 2020 letter (due to revised intended use), (7) updates to the letter and authorized labeling for consistency with language used in more recent authorizations, and (8) updates to the Ellume COVID-19 Home Test software application user interface. A technical correction to the March 16, 2022, letter was issued March 18, 2022, to correct the description of the controls and control materials.

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

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

[7] The revisions to the March 16, 2022 letter and authorized labeling include: (1) incorporating your response to Condition of Authorization (1) of the Repeat Testing Revision Letter dated November 1, 2022 to revise the authorized use(s) as required and described in Appendix A, and make various updates to the authorized labeling as required and described in Appendix B of the letter, (2) revisions to the intended use to "*individuals with symptoms of COVID-19 within the first 4 days of symptom onset"* (previously within the first 7 days of symptom onset), (3) deleting Conditions of Authorization Q. and S. in the March 16, 2022, letter as fulfilled through data and information submitted to the Agency and associated updates to the authorized labeling, (4) deleting Condition of Authorization R. in the March 16, 2022, letter in accordance with the Repeat Testing Revision Letter dated November 1, 2022, (5) added Condition of Authorization S. (below) to be consistent with more recent over-the-counter authorizations, (7) updating the informational video's from mandatory to optional viewing prior to performing the test, and (8) updating the Letter of Authorization and Fact Sheet for Healthcare Professionals to reflect the revised intended use, and 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 Ellume COVID-19 Home Test used for the indication identified above.

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 "Ellume COVID-19 Home Test Product Overview for Healthcare Professionals" (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 (as 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 such product; and,

3. There is no adequate, approved, and available alternative to the emergency use of your product for diagnosing COVID-19.[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.

**The Authorized Product**

Your product is a rapid, lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from the SARS-CoV-2 virus. This test is authorized for non-prescription home use with self-collected direct mid-turbinate nasal swab samples from individuals aged 16 years or older or adult collected mid-turbinate swab samples from individuals aged 2 years or older. This test is authorized for individuals with symptoms of

[9] U.S. Department of Health and Human Services, D*etermination 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).

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

COVID-19 within the first 4 days of symptom onset when tested at least twice over three days with at least 48 hours between tests and for individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested at least three times over five days with at least 48 hours between tests. The Ellume COVID-19 Home Test does not differentiate between SARS-CoV and SARS-CoV-2.

The SARS-CoV-2 nucleocapsid protein antigen is generally detectable in mid-turbinate nasal swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but the clinical correlation with past medical history and other diagnostic information is necessary to determine infection status. Positive results do not rule out a bacterial infection or co-infection with other viruses and the agent detected may not be the definitive cause of disease. Individuals who test positive with the Ellume COVID-19 Home Test should self-isolate and seek follow up care with their physician or healthcare provider as additional testing may be necessary.

Negative results are presumptive and confirmation with a molecular assay, if necessary, for patient management may be performed. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control measures such as isolating from others and wearing masks. Negative results should be considered in the context of an individual's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

Test results will be reported 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). Automatic test result reporting occurs via the Ellume COVID-19 Home Test software application (app).

Your product is performed using mid-turbinate nasal swab specimens from individuals aged 2 years and older. When using your product, the individual performing the test must first read the "Ellume COVID-19 Home Test Product Information Leaflet" and the "Ellume COVID-19 Home Test Quick Start Guide" to download the Ellume COVID-19 Home Test App onto a compatible smartphone device,[11] and then connect the single use Analyzer to their smartphone. The individual performing the test has the option to view an informational video before they must follow the step-by-step instructions provided in the Ellume COVID-19 Home Test App when collecting the specimen, running the test procedure and interpreting the results provided from the Analyzer through the App.

The Ellume COVID-19 Home Test includes the materials or other authorized materials (as may be requested under Condition K. and L. below), required to collect the mid-turbinate nasal swab specimen and perform the test procedure and detect the result, as described in the "Ellume COVID-19 Home Test Product Overview for Healthcare Professionals," the "Ellume COVID-19 Home Test Product Information Leaflet" and the "Ellume COVID-19 Home Test Quick Start Guide".

Your product requires the following internal control materials, or other authorized control

[11] The Ellume COVID-19 Home Test must be run using a mobile software application, the Ellume COVID-19 Home Test App, on a compatible smartphone device. Compatible smartphone devices include an ARM64 Apple iPhone device with Bluetooth running iOS 12 or later versions of the OS, and Android Phones with Bluetooth 4.0 or later and XHDPI (720x1280px) resolution supporting Android API 23 (version 6.0) or later. Additional smartphone models as may be requested, and for which you receive appropriate authorization, in accordance with Condition K. below.

materials (as may be requested under Condition K below), that are processed along with the specimens. All internal controls must generate expected results in order for a test result to be considered valid, as outlined in the "Ellume COVID-19 Home Test Product Overview for Healthcare Professionals."

The following labeling is collectively referred to as "authorized labeling":

- "Ellume COVID-19 Home Test App" software application
- "COVID-19 Home Test Animated Instructions Video 2-12(Commercial)"
- "COVID-19 Home Test Animated Instructions Video 13+(Commercial)"
- "COVID19 Home Test Result Emails Specification" and,
- the "Ellume COVID-19 Home Test Product Information Leaflet", "Ellume COVID-19 Home Test" box label[12], "Ellume COVID-19 Home Test – Quick Start Guide", "Ellume COVID-19 Home Test Product Overview for Healthcare Professionals", "Ellume COVID-19 Home Test – Frequently Asked Questions," and the Fact Sheet for Healthcare Professionals[13], which are available at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas.

Your product, when accompanied by the authorized labeling, is authorized to be distributed to 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.

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 such 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 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, when used consistent with 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

[12] The "Ellume COVID-19 Home Test" box label include boxes for 1-test per box, and "Ellume COVID-19 Home Test" box labels for additional test kits numbers/options as may be requested, and for which you receive appropriate authorization, in accordance with Condition L. below. Ellume COVID-19 Home Test kits numbers/options are described in the "Ellume COVID-19 Home Test Product Overview for Healthcare Professionals" and the "Ellume COVID-19 Home Test Product Information Leaflet."

[13] Note that the information typically found in a Fact Sheet for Patients is contained in the authorized "Ellume COVID-19 Home Test - Frequently Asked Questions," that will be available to end users as set forth in the Conditions of Authorization (Section IV).

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 for 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:

**Ellume Limited (You) and Authorized Distributor(s) [14]**

A. Your product must comply with the following labeling requirements pursuant to 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 device, including requirements under 21 CFR 809.10(b)(12).

B. 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.

C. 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.

D. 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 the product of which you and authorized distributor(s) become aware.

E. 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

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

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 In Vitro Diagnostics/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH) (via email: CDRH-EUAReporting@fda.hhs.gov).

F. 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.

G. 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.

**Ellume Limited (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 make the authorized "Ellume COVID-19 Home Test Product Overview for Healthcare Professionals" (HCP IFU), "Ellume COVID-19 Home Test – Frequently Asked Questions," and the Fact Sheet for Healthcare Professionals electronically available on your website. Additionally, you must provide the opportunity to request a copy of the HCP IFU and Fact Sheet for Healthcare Professionals in paper form, and after such request, promptly provide the requested labeling at no 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 may request new box labels to allow additional test kits numbers/options for your product. Such additional labeling requests to this EUA should be submitted to and require concurrence of DMD/OHT7/OPEQ/CDRH prior to implementation.

M. You will comply with the following requirements pursuant to FDA regulations: 21 CFR Part 820 Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

N. You must have lot release procedures and the lot release procedures, including the study design and statistical power, must ensure that the tests released for distribution have the clinical and analytical performance claimed in the authorized labeling.

O. If requested by FDA, you must submit lot release procedures to FDA, including sampling protocols, testing protocols, and acceptance criteria, that you use to release lots of your product for distribution in the U.S. If such lot release procedures are requested by FDA, you must provide it within 48 hours of the request.

P. You must evaluate the analytical limit of detection and assess traceability[15] 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/OPEQ/CDRH.

Q. 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: CDRHEUA-Reporting@fda.hhs.gov).

R. 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/OPEQ/CDRH.

S. You must submit your product for any FDA-recommended independent evaluation to confirm the performance characteristics of your test, if requested by FDA. 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/OPEQ/CDRH.

**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, as applicable, 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.

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

V. All descriptive printed matter, advertising and promotional materials relating to the use of your product shall clearly and conspicuously state that:

- This product has not been FDA cleared or approved; but has been authorized by FDA under an EUA;
- This product has been authorized only for the detection of proteins from SARS- CoV-2, not for any other viruses or pathogens; and,
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

The emergency use of your product as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

**V. Duration of Authorization**

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

Jeffrey E. Shuren -S

Digitally signed by Jeffrey E. Shuren -S
Date: 2023.02.16 08:00:41 -05'00'

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