December 15, 2020

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

Device:	Ellume COVID-19 Home Test
Company:	Ellume Limited
Indication:	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. This test is intended for use in individuals with or without symptoms or other epidemiological reasons to suspect a COVID-19 infection. The Ellume COVID-19 Home Test is authorized for non-prescription home use.

Dear Myriam Battistutta:

This letter is in response to your[1] 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 Ellume Limited ("Ellume").
[2] 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.
[3] 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).

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 "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.[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.

The Authorized Product

Your product is a non-prescription home use test intended 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. This test is intended for use in individuals with or without symptoms or other epidemiological reasons to suspect a COVID-19 infection.

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 in an asymptomatic individual are presumptive and may need to be confirmed with a molecular assay. Positive results do not rule out a bacterial infection or co-infection with other viruses.

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

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 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.

Test results from your product will be automatically reported to relevant public health authorities, via your product's software application (app), 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 includes a single use Analyzer and a single use sampling and processing system that includes a sterile Nasal Swab with a child adapter, Processing Fluid, and a Dropper. To use your product the user must first download the Ellume COVID-19 Home Test App for iOS or Android phones. The user follows the instructions on the Quick Start Guide included in the kit box to connect the Analyzer to their phone. The user then views an informational video and follows the in-app self-paced, step-by-step instructions to complete the test.

Your product is a rapid, lateral flow immunoassay that involves the pre-mixing and binding of fluorophore specific to SARS-CoV-2 with viral nucleocapsid protein present in a patient specimen. First, the Processing Fluid is added into the Dropper to release the fluorophore. After collecting a mid-turbinate nasal specimen, the Nasal Swab is locked into the Dropper to release the viral antigens from the specimen, which are then bound by the fluorophore. An aliquot of the sample containing the fluorophore-labelled antigen complexes is dispensed into the Analyzer Sample Port. The deposited liquid wicks into the test strip by capillary action. The sample flows across a membrane and traverses a series of discrete capture zones, consisting of immobilized complementary antibodies to SARS-CoV-2 viral nucleoprotein. Fluorescence signals at the two test zones are detected using a single-use optoelectronics reader system, housed within the Analyzer. The tests and controls are interpreted according to thresholds set within the microprocessor contained in the Analyzer. The computed result is communicated to the app and displayed on the user's smartphone and if selected are also emailed to the user. The total time for the test is 20 min, 5 min for test set up and 15 min once the analyser is activated.

Your product requires the following internal control materials, or other authorized control materials (refer to Condition L), that are processed along with the specimens. All internal controls listed below must generate expected results in order for a test result to be considered valid, as outlined in the authorized labeling (listed in the next paragraph):

- Internal Control - immunoassay that detects the presence or absence of an endogenous human marker found ubiquitously in nasal samples. A 'Test Error' will be received by the user if no or too little sample is applied to the test.
- Internal Control - immunoassay whose biological reagents will fail and trigger a 'Test Error' result to the user if the product is exposed to extreme temperature and humidity that could be damaging to the test reagents.

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)"
- Ellume COVID-19 Home Test – "Product Information Leaflet"
- "COVID19 Home Test Result Emails Specification" and,
- the "Ellume COVID-19 Home Test" box label, "Ellume COVID-19 Home Test – Quick Start Guide", "Product Overview for Healthcare Professionals", "Ellume COVID-19 Home Test – Frequently Asked Questions," and the Fact Sheet for Healthcare Professionals,[5] which are available at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/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 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).

[5] 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).

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) [6]

A. You and authorized distributors must make available the Ellume COVID-19 Home Test – Quick Start Guide and the Ellume COVID-19 Home Test – Product Information Leaflet related to the use of your product both in the shipped kit and on your website.

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 numbers and locations (e.g., pharmacies, doctor's offices, etc.) to which your product is distributed and the number of test kits distributed to each location..

D. You and authorized distributor(s) must maintain customer complaint files on record. You must report to FDA any significant complaints about usability or deviations from the established performance characteristics of the product of which you 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 in accordance with 21 CFR Part 803. You must 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

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. 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

[6] "Authorized Distributor(s)" are identified by you, Ellume Limited, in your EUA submission as an entity allowed to distribute the Ellume COVID-19 Home Test.

regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

I. You must notify FDA of any authorized distributor(s) of your product, including the name, address, and phone number of any authorized distributor(s).

J. 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.

K. You must make the authorized "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.

L. 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.

M. You will 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).

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[7] 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.

Q. You must further evaluate the clinical performance of your product in asymptomatic individuals in an FDA agreed upon post authorization clinical evaluation study within 6 months of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH). After submission to and

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

review and concurrence with the data by FDA, you will update authorized 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 software updates (except for the reporting updates described in Condition S) to the Ellume COVID-19 Home Test App software application and other authorized labeling prior to distribution and provide written confirmation of completion to DMD/OHT7-OIR/OPEQ/CDRH.

S. You must implement the agreed upon reporting-related software updates to the Ellume COVID-19 Home Test software app within 2 months of this letter and submit to FDA and receive DMD/OHT7-OIR/OPEQ/CDRH's concurrence prior to implementation.

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 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,
- 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,

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosure
Technical correction: December 16, 2020