March 4, 2022

Bala Raja Ph.D.
President and CEO
Luminostics, Inc.
446 South Hillview Drive
Milpitas, CA 95035

Device:	Clip COVID Rapid Antigen Test
EUA Number:	EUA202907
Company:	Luminostics, Inc.
Indication:	Qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 directly from anterior nasal swab specimens collected from individuals who are suspected of COVID-19 by their healthcare provider within the first five days of onset of symptoms, or individuals without symptoms or other epidemiological reasons to suspect COVID-19, when tested twice over three days with at least 24 hours and no more than 48 hours between tests. Emergency use of this test is limited to authorized laboratories.
Authorized Laboratories:	Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high, moderate or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Dear Dr. Raja:

On December 7, 2020, based on your[1] request the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the Clip COVID Rapid Antigen 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] In addition, FDA established additional Conditions of

[1] For ease of reference, this letter will use the term "you" and related terms to refer to Luminostics, Inc.
[2] The December 7, 2020, letter authorized the Clip COVID Rapid Antigen Test for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 directly from anterior nasal swab specimens collected from individuals who are suspected of COVID-19 by their healthcare provider within the first five days of onset of symptoms. Testing was limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high, moderate, or waived complexity tests.

Authorization in response to the continued emergence of new variants of SARS-CoV-2 on September 23, 2021.[3]

On January 8, 2021, you requested to amend your EUA. Based on this request, and having concluded that revising the December 7, 2020, 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 December 7, 2020, letter in its entirety with the revisions incorporated.[4] 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[5] is now authorized for use consistent with the indications 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 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.[6]

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

This test was authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

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

[4] The revisions to the December 7, 2020 letter and authorized labeling include: (1) update the intended use to include use in individuals "*without symptoms or other epidemiological reasons to suspect COVID-19, when tested twice over 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 updated intended use and also for consistency with language used in more recent authorizations, (3) updates to the letter to reflect the updated intended use including the addition of Condition of Authorization Q. (below), (4) updates to the authorized labeling to reflect the updated intended use, (5) add Conditions of Authorization (2) and (3) from the Viral Mutation Revision Letter – September 23, 2021 (R. and S. below), (6) removal of Conditions of Authorization P., Q. and R. from December 7, 2020 letter (fulfilled), and (7) updates to the letter and authorized labeling for consistency with language used in more recent authorizations.

[5] For ease of reference, this letter will use the term "your product" to refer to the Clip COVID Rapid Antigen Test used for the indication identified above.

[6] 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).

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 such a use, 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.[7]

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 lateral flow immunoluminescent assay for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 directly from anterior nasal swab specimens collected from individuals who are suspected of COVID-19 by their healthcare provider within the first five days of onset of symptoms, or individuals without symptoms or other epidemiological reasons to suspect COVID-19, when tested twice over three days with at least 24 hours and no more than 48 hours between tests. Your product does not differentiate between SARS-CoV and SARS-CoV-2.

The SARS-CoV-2 nucleocapsid protein antigen is generally detectable in anterior nasal swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but the clinical correlation with patient 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.

Negative results should be treated as 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 decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19, and confirmed with a molecular assay, if necessary for patient management.

For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary, if there is a high likelihood of COVID-19, such as, an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with

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

high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

Testing of anterior nasal swab specimens using your product, as outlined in the "Clip COVID Rapid Antigen Test Package Insert Instructions for Use" is limited to laboratories certified under CLIA that meet the requirements to perform high, moderate, or waived complexity tests. This test is authorized for use at the POC, i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

When using your product, the individual performing the test must follow instructions provided in the "Clip COVID Rapid Antigen Test Package Insert Instructions for Use," the "Clip COVID Rapid Antigen Test Quick Reference Instructions" and the "Clip COVID Rapid Antigen Test Clip Analyzer Use Manual Instructions for Use" when collecting the specimen, running the test procedure and interpreting the results with the Clip Analyzer.

The Clip COVID Rapid Antigen Test includes the materials or other authorized materials (as may be requested under Condition K. below), required to collection the anterior nasal sample and perform the test procedure, as described in the "Clip COVID Rapid Antigen Test Package Insert Instructions for Use" and the "Clip COVID Rapid Antigen Test Quick Reference Instructions."

Your product requires various types of quality control, including the Procedural Control and the External Positive and Negative Control materials, or other authorized control materials (as may be requested under Condition K. below), that are included, and processed in the same way as the patient samples. All controls must generate expected results in order for a test to be considered valid, as outlined in the "Clip COVID Rapid Antigen Test Package Insert Instructions for Use."

Your product also requires the use of additional authorized materials and authorized ancillary reagents (as may be requested under Condition K. below) that are not included with your product and are described in the Instructions for Use, including the Clip Analyzer instrument which is not included with the kit but is available from you with the "Clip COVID Rapid Antigen Test Clip Analyzer Use Manual Instructions for Use", for result detection and interpretation.

The labeling entitled "Clip COVID Rapid Antigen Test Package Insert Instructions for Use" (available at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas), the "Clip COVID Rapid Antigen Test Quick Reference Instructions," and the following fact sheets 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: Luminostics, Inc.- Clip COVID Rapid Antigen Test
- Fact Sheet for Patients: Luminostics, Inc.- Clip COVID Rapid Antigen Test

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

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.

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:

Luminostics, Inc. (You) and Authorized Distributor(s)[8]

A. Your product must comply with the following labeling requirements under FDA regulations: the intended use statement (21 CFR 809.10(a)(2), (b)(2)); adequate

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

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 make your product available with the authorized labeling to authorized laboratories.

C. You and authorized distributor(s) must make available on your website(s) the authorized labeling.

D. You and authorized distributor(s) must include a physical copy of the authorized "Clip COVID Rapid Antigen Test Quick Reference Instructions," and the "Clip COVID Rapid Antigen Test Package Insert Instructions for Use" with each shipped kit of your product to authorized laboratories.

E. You and authorized distributor(s) must inform authorized laboratories and relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to your product and authorized labeling.

F. Through a process of inventory control, you and authorized distributor(s) must maintain records of the authorized laboratories to which they distribute the test and number of tests they distribute.

G. You and authorized distributor(s) must collect information on the performance of your product. You will report 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) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the product of which you become aware.

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.

Luminostics, Inc. (You)

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 changes that might be made to this EUA and its authorized accompanying materials (e.g., Fact Sheets).

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 not exceed the terms of authorization of this letter. Any request for changes to this EUA should be submitted to DMD/OHT7-OIR/OPEQ/CDRH and require appropriate authorization from FDA prior to implementation.

L. You must comply with the following requirements under 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).

M. 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.

N. 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.

O. You must evaluate the analytical limit of detection and assess traceability[9] of your product with any FDA-recommended reference material(s). After submission to FDA and DMD/OHT7-OIR/OPEQ/CDRH's review of and concurrence with the data, 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.

P. You must complete the agreed upon real-time stability study for your product and notify DMD/OHT7-OIR/OPEQ/CDRH of the testing results as they become available until completion of the study. After submission of the study data, and review and concurrence with the data by FDA, you must update your product labeling accordingly. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7- OIR/OPEQ/CDRH.

Q. You must evaluate the clinical performance of your product to support the serial screening claim 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 concurrence with the data by FDA, you must update the 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.

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

R. 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).

S. 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-OIR/OPEQ/CDRH.

T. You must have a process in place to track adverse events, including any occurrence of false results with your product, and report to FDA pursuant to 21 CFR Part 803.

Authorized Laboratories

U. Authorized laboratories using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

V. Authorized laboratories using your product must use your product as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.

W. Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.

X. Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

Y. Authorized laboratories must collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and you (via email: support@luminostics.com) 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.

Z. All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.

Luminostics, Inc. (You), Authorized Distributor(s) and Authorized Laboratories

AA. You, authorized distributor(s), and authorized laboratories 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

BB. 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.

CC. 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.

DD. 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 for use by authorized laboratories;
- 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,

_____
Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration

Enclosure