



October 23, 2020

Trisha Eustaquio, Ph.D.
Parexel International
Representing: Celltrion USA, Inc.
2520 Meridian Parkway Suite 200
Durham, NC 27713

Device: Sampinute COVID-19 Antigen MIA

Company: Celltrion USA, Inc.

Indication: Qualitative detection of receptor binding domains (RBDs) spike proteins from SARS-CoV-2 in nasopharyngeal swab specimens directly collected or collected in either BD Universal Viral Transport Media, Copan UTM-RT or CDC's formulation of VTM from individuals who are suspected of COVID-19 by their healthcare provider within the first five days of symptom onset.

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 or moderate complexity tests.

Dear Dr. Eustaquio:

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

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19. Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 subject to the terms of any authorization issued under Section 564(a) of the Act.³

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

² For ease of reference, this letter will use the term “your product” to refer to the Sampinute COVID-19 Antigen MIA, manufactured by BBB, Inc., used for the indication identified above.

³ U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and*

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 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 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.⁴

II. Scope of Authorization

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

Authorized Product Details

Your product is a visually read magnetic force-assisted electrochemical sandwich immunoassay (MESIA) intended for the qualitative detection of receptor binding domains (RBDs) spike proteins from SARS-CoV-2 in nasopharyngeal swab specimens directly collected or collected in either BD Universal Viral Transport Media, Copan UTM-RT or CDC's formulation of VTM⁵ from individuals who are suspected of COVID-19 by their healthcare provider within the first five days of symptom onset. The SARS-CoV-2 viral antigen is generally detectable in nasopharyngeal 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.

Cosmetic Act, 21 U.S.C. § 360bbb-3. 85 FR 7316 (February 7, 2020).

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

⁵ Refer to current Centers for Disease Control and Prevention (CDC) SOP# DSR-052-05 at <https://www.cdc.gov/coronavirus/2019-ncov/downloads/Viral-Transport-Medium.pdf>.

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 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.

Testing is limited to laboratories certified under CLIA that meet the requirements to perform high or moderate complexity tests.

To use your product, the patient sample is either added directly to the Reagent Solution Tube or placed in validated transport media. The sample is then added into the sample inlet of the Sampinute COVID-19 Antigen MIA test cartridge before the cartridge is inserted into the Sampinute Analyzer. The sample flows along the microfluidic channel, and if SARS-CoV-2 spike proteins are present in the sample, they form complexes with anti-SARS-CoV-2 spike protein antibodies conjugated to MNPs. These complexes then encounter and bind onto the working electrode of the electrochemical sensor, that is coated with anti-SARS-CoV-2 spike protein antibodies. The presence of SARS-CoV-2 spike proteins is measured via introduction of a detection buffer followed by the electrochemical measurement step.

The Sampinute COVID-19 Antigen MIA includes the following materials or other authorized materials: Sampinute COVID-19 Antigen MIA test cartridges, Reagent Tubes, Sterile nasal swabs, Negative control solution, Positive control solution, and Package insert.

Your product requires various types of quality control, including use of the External Control materials, or other authorized control materials (as may be requested under Condition L. below), that are processed in the same way as the patient samples. All controls listed below must generate expected results in order for a test to be considered valid, as outlined in the Instructions for Use:

- Positive Control Solution: salt solution with non-infectious SARS-CoV-2 antigen and less than 0.1% sodium azide
- Negative Control Solution: salt solution with less than 0.1% sodium azide

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 “Sampinute COVID-19 Antigen MIA” Instructions for Use, “Sampinute COVID-19 Antigen MIA Quick Reference Guide” Package Insert, and the “Sampinute Analyzer User Manual” (available at <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas>), 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: Celltrion USA, Inc.- Sampinute COVID-19 Antigen MIA
- Fact Sheet for Patients: Celltrion USA, Inc.- Sampinute COVID-19 Antigen MIA

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:

Celltrion USA, Inc. (You)⁶ and BBB, Inc.

⁶ The sole distributor is Celltrion USA, Inc.

- 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 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 BBB, Inc. will comply with the following requirements under 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).
- C. You and BBB, Inc. 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.
- D. If requested by FDA, you and BBB, Inc. 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 and BBB, Inc. must provide it within 48 hours of the request.

Celltrion USA, Inc. (You)

- E. You will make your product available with the authorized labeling to authorized laboratories.
- F. You will make available on your website(s) the authorized labeling.
- G. You will include a physical copy of the authorized Quick Reference Guide with each shipped kit of your product to authorized laboratories, and will make the authorized Instructions for Use electronically available with the opportunity to request a copy in paper form, and after such request, promptly provide the requested information without additional cost.
- H. You will inform authorized laboratories and relevant public health authorities of this EUA, including the terms and conditions herein, and any authorized updates made to your product and authorized labeling.
- I. Through a process of inventory control, you will maintain records of the authorized laboratories to which you distribute the test and number of tests you distribute.
- J. You will collect information on the performance of your product. You will report to FDA 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.

- K. You 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.
- 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. 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 evaluate the analytical limit of detection and assess traceability⁷ of your product with any FDA-recommended reference material(s). After submission to and concurrence with the data by FDA, you will update your labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- N. You will further evaluate the clinical performance of your product in an FDA agreed upon post authorization clinical evaluation study within 4 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 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.
- O. You will further evaluate additional EMC testing in compliance with IEC60601 of your product in an FDA agreed upon post authorization evaluation study for a period of 6 months from of the date of this letter (unless otherwise agreed to with DMD/OHT7- OIR/OPEQ/CDRH). You will report to FDA any suspected occurrence of EMC-related incidents or adverse events to FDA within 7 days of their occurrence. After submission to 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.
- P. You will 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

- Q. Authorized laboratories using your product will 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.
- R. Authorized laboratories using your product will use your product as outlined in the

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

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.

- S. Authorized laboratories that receive your product will notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- T. Authorized laboratories using your product will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- U. Authorized laboratories will collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov), BBB, Inc (via website: www.bbbtech.com) and you (Celltrion USA, Inc. (via email: Sampinute@celltrion.com or via phone: (201) 988-4615)) 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.
- V. 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.

Celltrion USA, Inc. (You), BBB, Inc. and Authorized Laboratories

- W. You, BBB, Inc., and authorized laboratories using your product will 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

- X. All descriptive printed matter, including 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 the applicable requirements set forth in the Act and FDA regulations.
- Y. No descriptive printed matter, including 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.
- Z. All descriptive printed matter, including advertising and promotional materials, relating to the use of your product shall clearly and conspicuously state that:
 - This test has not been FDA cleared or approved;
 - This test has been authorized by FDA under an EUA for use by authorized laboratories;

- This test has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens; and
- This test 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 authorization is terminated or 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