May 20, 2022

Ally Danta
Senior Associate
Parexel International
Representing: Celltrion USA, Inc.
One Evertrust Plaza, Suite 1207
Jersey City, NJ 07302

Device:	Celltrion DiaTrust COVID-19 Ag Home Test
EUA Number:	EUA210501
Company:	Celltrion USA, Inc.
Indication:	Non-prescription home use for the qualitative detection of SARS-CoV-2 nucleocapsid and receptor binding domain (RBD) antigens with: Self-collected and adult-collected direct mid-turbinate nasal swab specimens from individuals aged 14 years or older with symptoms of COVID-19 within the first seven days of symptom onset. Self-collected and adult-collected mid-turbinate nasal swab specimens from individuals aged 14 years or older, with or 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.

Dear Ally Danta:

On October 21, 2021, based on your[1] request the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use for the Celltrion DiaTrust COVID-19 Ag Home Test, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3) for the indications stated in the letter. On December 17, 2021, February 14, 2022, and April 27, 2022, FDA acknowledged your notices of minor changes to manufacturing processes and additional distributors. On March 23, 2022, FDA acknowledged updates to the labeling to address conformance with Section 508 of the Rehabilitation Act and posted the updated labeling.

On November 9, 2021, December 13, 2021, and January 31, 2022, FDA received requests from you to amend your EUA. In response to those requests, and having concluded that revising the October 21, 2021 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 October 21,

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

2021, letter in its entirety with the revisions incorporated[2] to authorize the emergency use of your product.[3] Pursuant to section 564 of the Act, Scope of Authorization (Section II) and Conditions of Authorization (Section III) of this reissued letter, your product is now intended for the indication 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.[4]

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 "Celltrion DiaTrust COVID-19 Ag Home Test Healthcare Provider 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:

[2] The revisions to the October 21, 2021 letter and authorized labeling include: (1) updates to the intended use to incorporate minor changes in wording to align with recent authorizations; (2) use of an additional packaging material for the test card (3) updates to the software application to clarify the specimen collection process and the test steps and to increase the usability of the mobile app (4) updates to expand the unopened shelf-life stability from 12 to 18 months when stored at 2°C - 30°C; (5) addition of a Condition of Authorization for further evaluation of clinical performance of your test for detection of the SARS-CoV-2 omicron variant; (6) addition of Conditions of Authorization related to meeting the requirements of either ISO 13485 or 21 CFR 820 and removal of Conditions of Authorization related to meeting subparts of 21 CFR 820; (7) removal of Condition of Authorization related to updating the software application as this Condition of Authorization has been fulfilled (8) minor updates to the Fact Sheet for Healthcare Providers to align wording with recent authorizations, match the date of reissuance of the letter, and update the webpage links; (9) updates to the IFU to align wording of the specimen collection steps and the test steps with the updates to the software application, and match the date of re-issuance of the letter; (10) update the Conditions of Authorization Section to add Condition L, (11) remove HUMASIS Co., Ltd. from the Conditions of Authorization section, and remove Waiver of Certain Requirements section (due to addition of Condition L), and (12) minor updates to the Celltrion DiaTrust COVID-19 Ag Home Test Instructions for Use for clarity and to match the date of re-issuance of the letter.

[3] For ease of reference, this EUA will use the term "your product" to refer to the Celltrion DiaTrust COVID-19 Ag Home Test used for the indication identified above.

[4] 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).

1. The SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that your product may be effective in diagnosing COVID-19, and that the known and potential benefits of your product when used for diagnosing COVID-19, outweigh the known and potential risks of your product; and

3. There is no adequate, approved, and available alternative to the emergency use of your product.[5]

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 immunoassay intended for the qualitative detection of SARS-CoV-2 nucleocapsid protein and receptor binding domain (RBD) antigens. This test is authorized for non-prescription home use with self-collected and adult-collected direct mid-turbinate nasal swab samples from individuals aged 14 years or older with symptoms of COVID-19 within the first seven days of symptom onset.

This test is also authorized for non-prescription home use with self-collected mid-turbinate nasal swab specimens from individuals aged 14 years or older with or 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.

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

Negative results are presumptive, 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 an individual'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

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

results may be necessary, if there is a high likelihood of SARS-CoV-2 infection, such as an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with 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 SARS-CoV-2 infection, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

Individuals who test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care with their physician or healthcare provider.

Individuals should provide all results obtained with this product to their healthcare provider for public health reporting. All healthcare providers will report all test results they receive from individuals who use the authorized product to relevant public health authorities in accordance with local, state, and federal requirements using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by the Centers for Disease Control and Prevention (CDC).

Your product is performed using mid-turbinate swab samples from individuals aged 14 years or older. The individual using your product is instructed to download, open and follow the step-by-step mobile- or Web-application based instructions on the Celltrion DiaTrust COVID-19 Ag Home Test Application (Celltrion SafeKey) onto a computer or compatible smartphone[6] when collecting the specimen, running the test procedure and interpreting the results, as also described in the "Celltrion DiaTrust COVID-19 Ag Home Test Instructions for Use" and the "Celltrion DiaTrust COVID-19 Ag Home Test Healthcare Provider Instructions for Use."

The Celltrion DiaTrust COVID-19 Ag Home Test includes the materials or other authorized materials (as may be requested), required to collect the anterior nasal (nares) swab sample and perform the test procedure, as described in the "Celltrion DiaTrust COVID-19 Ag Home Test Instructions for Use" and the "Celltrion DiaTrust COVID-19 Ag Home Test Healthcare Provider Instructions for Use."

Your product includes an internal control test line ("C") that must generate the expected result for a test to be considered valid, as outlined in the "Celltrion DiaTrust COVID-19 Ag Home Test Instructions for Use" and the "Celltrion DiaTrust COVID-19 Ag Home Test Healthcare Provider Instructions for Use."

The labeling entitled "Celltrion DiaTrust COVID-19 Ag Home Test Healthcare Provider Instructions for Use," the "Celltrion DiaTrust COVID-19 Ag Home Test Instructions for Use," and the "Celltrion DiaTrust COVID-19 Ag Home Test" box labels (available at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas), the "Celltrion DiaTrust COVID-19 Ag Home Test Application (Celltrion SafeKey)" software application and the following fact sheet pertaining to the emergency use, is required to be made available as set forth in the

[6] Compatible smart phone includes Apple iPhone running Operation System (iOS) 14.2 or later versions of the iOS, and Android Phones running Android 10 or later versions. Additional smart phone models as may be requested, and for which you receive appropriate authorization, in accordance with Condition S. below.

Conditions of Authorization (Section IV), and are collectively referred to as "authorized labeling":

- Fact Sheet for Healthcare Professionals[7]: Celltrion USA, Inc. - Celltrion DiaTrust COVID-19 Ag Home Test

The above described product, when accompanied by the authorized labeling as set forth in the Conditions of Authorization (Section IV) is authorized to be distributed and used under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of your product, when used consistent with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of your product.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that your product may be effective in diagnosing COVID-19, when used consistent with the Scope of Authorization of this letter (Section II), pursuant to Section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that your product (as described in the Scope of Authorization of this letter (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of your product under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) of the Act described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1) of the Act, your product is authorized for the indication above.

III. Conditions of Authorization

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

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

A. Your product must comply with the following labeling requirements: the intended use statement in 21 CFR 809.10(a)(2), (b)(2); adequate directions for use in 21 U.S.C. 352(f)

[7] Note that the information typically found in a Fact Sheet for Individuals is contained in the authorized "Celltrion DiaTrust COVID-19 Ag Home Test Instructions for Use " that will be available to end users as set forth in the Conditions of Authorization (Section IV).

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

and 21 CFR 809.10(b)(5), (7), and (8); appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4); and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

B. You and authorized distributor(s) must make available the "Celltrion DiaTrust COVID-19 Ag Home Test Instructions for Use" for use in the shipped kit using the "Celltrion DiaTrust COVID-19 Ag Home Test" box labels and make these two documents electronically available on your website.

C. 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.

D. 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 tests distributed to each location.

E. You and authorized distributor(s) must maintain records of customer complaint files and report to FDA any significant complaints about usability or deviations from the established performance characteristics of which you and authorized distributor(s) become aware.

F. You and authorized distributor(s) must collect information on the performance of your product and have a process in place to track adverse events, including any occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the product of which you become aware and report any such events to FDA in accordance with 21 CFR Part 803. Serious adverse events, especially unexpected biosafety concerns, should immediately be reported to the Division of Microbiology (DMD)/Office of Health Technology 7 (OHT7)-Office of In Vitro Diagnostics and Radiological Health (OIR)/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH) (via email: CDRH-EUAReporting@fda.hhs.gov).

G. You and authorized distributor(s) are authorized to make available additional information relating to the emergency use of your product that is consistent with, and does not exceed, the terms of this letter of authorization.

H. You and authorized distributor(s) 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.

Celltrion USA, 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 revisions that might be made to this EUA and its authorized accompanying materials, including the authorized labeling.

K. You must make the authorized "Celltrion DiaTrust COVID-19 Ag Home Test Healthcare Provider Instructions for Use" and the "Fact Sheet for Healthcare Professionals" electronically available on your website. Additionally, you must provide the opportunity to request a copy of the "Celltrion DiaTrust COVID-19 Ag Home Test Healthcare Provider Instructions for Use" and "Fact Sheet for Healthcare Professionals" in paper form, and after such request, promptly provide the requested labeling at no additional cost.

L. Within three months of the date of this letter, you must establish and maintain a quality system that is appropriate for your product's design and manufacture, and that meets the requirements of either the 2016 edition of ISO 13485 or 21 CFR Part 820. You must submit to DMD/OHT7-OIR/OPEQ/CDRH a notification of compliance on such date.

M. If requested by FDA, you must submit associated documents or records related to your quality system for FDA review within 48 hours of the request.

N. You must have a signed agreement with each authorized distributor that ensures the distribution of the authorized product is consistent with this Letter of Authorization.

O. You must develop and implement a physical sampling procedure and final acceptance activities procedure within 2 weeks of the date of this letter. These procedures must be agreed to by DMD/OHT7-OIR/OPEQ/CDRH and include a process for sampling after importation and prior to distribution in the US.

P. 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.

Q. 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.

R. You must collect information on the performance of your product. You will report to DMD/OHT7-OIR/OPEQ/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.

S. 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-OIR/OPEQ/CDRH and require appropriate authorization from FDA prior to implementation.

T. 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 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.

U. 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.

V. You must further evaluate the clinical performance of your product for the detection of the SARS-CoV-2 omicron variant, in accordance with the 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 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.

W. You and must evaluate the impact of SARS-CoV-2 viral mutations on your product's performance. Such evaluations must occur on an ongoing basis and must include any additional data analysis that is requested by FDA in response to any performance concerns you or FDA identify during routine evaluation. Additionally, if requested by FDA, you must submit records of these evaluations for FDA review within 48 hours of the request. If your evaluation identifies viral mutations that affect the stated expected performance of your device, you must notify FDA immediately (via email: CDRH-EUA-Reporting@fda.hhs.gov).

X. 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.

Y. You must evaluate the clinical performance of your product in children 13 years of age and younger 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

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

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.

Z. 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 must be made in consultation with, and require concurrence of, DMD/OHT7- OIR/OPEQ/CDRH.

AA. 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-OIR/OPEQ/CDRH.

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;
- 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.

IV. 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
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