Medek
Health Systems

COVID-19 Antigen

Rapid Diagnostic Test

The Celltrion DiaTrust™ COVID-19 Antigen test is a lateral flow immunochromatographic assay intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2.

- **Identify acute infection with 93% sensitivity and 99% specificity**
- **Rapid 15 Minute Result**
- **Point of Care Use**
- **Nasopharyngeal Nasal Swab Collection**

EACH KIT CONTAINS

Test Device	Nasal Swab
Extraction Vial	Control Swab

MEDEKTESTKITS.COM

131 Waterman Ave
Mount Dora - FL 32757
888-996-3335

The MEDEK supplied test kit is FDA authorized for use without a separate reading machine at the Point of Care.

Product Information and Limitations of Sale:

- Results in 15 minutes w/ rapid testing
- Each set (box) has 25 individual tests
- For use as an aid in identifying SARS-CoV-2, nucleocapsid protein antigen
- Verification of use case prior to shipping is mandatory

Governance

A. Celltrion DiaTrustTM COVID-19 Ag Rapid Test is a rapid test based on lateral flow immunoassay intended for the qualitative detection of nucleocapsid proteins and receptor binding domains (RBDs) from the SARS-CoV-2 spike proteins in human nasopharyngeal swab specimens directly collected from individuals who are suspected of COVID-19 by their healthcare provider within the first seven days of symptom onset, or from individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over two or three days with at least 24 hours and no more than 48 hours between tests. Testing is 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 complexity, moderate complexity, or waived 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.

B. Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency issued on the web on March 16, 2020 by U.S. Food and Drug Administration (FDA") which may be found here:

https://www.fda.gov/media/135659/download

C. The Celltrion DiaTrustTM COVID-19 Antigen test is authorized for use using nasopharyngeal swab specimen collected from individuals who are suspected of COVID-19 by their healthcare provider within the first seven days of symptom onset.

Compliance

A. All sales of Products are subject to the purchaser's compliance with the Policy and that the Products shall only be used by health professionals as defined in subsection (g) at:
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=810.2

B. The Products shall not be made available, offered, distributed or marketed, directly or indirectly, to the general public, or made available, sold, distributed or marketed to anyone who the Representative or the Approved Account knows or has any reason to know will make available, offer, distribute or market, directly or indirectly, the Products to the general public.

C. The Products are only for preliminary screening purposes and shall only be used to determine if additional testing is required.

Buyer Requirements

A. Qualified parties who agree to follow the guidance in the Policy including, but not limited to, validation, FDA notification, reporting of results, Emergency Use Authorization, clinical testing and distribution.

B. Payment must be made prior to shipment.

C. Payments accepted: Wire transfer or Credit Card (AMEX Preferred).

D. Order questions: Medek Health Systems, LLC - (352) 516-3072.

E. Wire transfer questions: (352) 383-2111

F.

BANK:	First National Bank of Mount Dora
ABA:	063104312
BENEFICIARY:	Medek Health Systems, LLC 131 Waterman Avenue Mount Dora, FL 32757
ACCOUNT NO:	30112085

Misc.

A. FDA guidelines for the product are attached below.

B. COVID-19 Antigen Rapid Diagnostic package insert is attached below.

C. Fact sheet for healthcare providers is attached below.

D. Fact sheet for patients is attached below.

U.S. FOOD & DRUG ADMINISTRATION

September 1, 2021

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

Device:	Celltrion DiaTrust COVID-19 Ag Rapid Test
EUA Number:	EUA210190
Company:	Celltrion USA, Inc.
Indication:	Qualitative detection of nucleocapsid and receptor binding domains (RBDs) from the SARS-CoV-2 in human nasopharyngeal swab specimens directly collected from individuals who are suspected of COVID-19 by their healthcare provider within the first seven days of symptom onset, or from individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over two or 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 complexity, moderate complexity, or waived 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. Eustaquio:

On April 16, 2021, based on your[1] request the Food and Drug Administration (FDA) issued a letter authorizing use of the Celltrion DiaTrust COVID-19 Ag Rapid Test for the qualitative detection of nucleocapsid and receptor binding domains (RBDs) from the SARS-CoV-2 in human nasopharyngeal swab specimens directly collected from individuals who are suspected

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

of COVID-19 by their healthcare provider within the first seven days of symptom onset, or from individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over two or three days with at least 24 hours and no more than 48 hours between tests, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3). Testing was limited to laboratories certified under CLIA, 42 U.S.C. §263a, that meet the requirements to perform high complexity, moderate complexity, or waived tests. 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. Based on your requests, FDA granted updates to the authorized labeling on May 11, 2021.[2]

On June 10, 2021, you requested to revise your Emergency Use Authorization (EUA). Based on that request, and having concluded that revising the April 16, 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 April 16, 2021, letter in its entirety with the revisions incorporated.[3] Accordingly, your product[4] is hereby authorized pursuant to section 564 of the Act when used pursuant to the Scope of Authorization (Section II) and Conditions of Authorization (Section IV) of this reissued letter.

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.[5]

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 Rapid Test" 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.

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[2] On May 11, 2021, your request was granted via email to update the Instructions for Use (IFU) of the Celltrion DiaTrust COVID-19 Ag Rapid Test to fix some minor errors.

[3] The revisions to the April 16, 2021, letter and authorized labeling include: (1) updates to expand the unopened shelf-life stability from 10 to 12 months when stored at 2-30°C; (2) updates to the Conditions of Authorization to add new conditions related to circulating SARS-CoV-2 variants (Conditions G. and H. below) as well as E and F.; and (3) updates to the webpage links in the Fact Sheets for Healthcare Providers, and the date on the Fact Sheet for Patients was updated to match the date of re-issuance of the letter.

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

[5] 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. 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 your product; and

3. There is no adequate, approved, and available alternative to the emergency use of your product.[6]

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 rapid test based on lateral flow immunoassay intended for the qualitative detection of nucleocapsid and receptor binding domains (RBDs) from the SARS-CoV-2 in human nasopharyngeal swab specimens directly collected from individuals who are suspected of COVID-19 by their healthcare provider within the first seven days of symptom onset, or from individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over two or 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 and RBD protein antigen is generally detectable in human nasopharyngeal swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient 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.

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. For serial testing programs, additional confirmatory testing with a

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

molecular test for negative results may be necessary, if there is a high likelihood of SARS-CoV-2 infection, such as in 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 SARS-CoV-2 or residing in communities with low prevalence of infection.

Testing of nasopharyngeal swab specimens using your product, as outlined in the "Celltrion DiaTrust COVID-19 Ag Rapid Test" Instructions for Use is limited to laboratories certified under CLIA that meet the requirements to perform high complexity, moderate complexity, or waived 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.

To use your product, the patient nasopharyngeal swab specimen (the direct swab) is transferred to the extraction buffer test tube, during which time the virus particles in the sample are disrupted, exposing internal viral nucleoproteins. After removing the swab from the test tube the filter cap is attached and the swab specimen is immediately dispensed into the sample well of the test device to initiate the test. The specimen migrates towards the conjugate pad, which contains conjugated antibodies with colloidal gold directed against the SARS-CoV-2 antigen. When the sample contains SARS-CoV-2 antigens, an antigen-antibody-conjugate complex is formed. The sample-conjugate complex then passes over the membrane until it reaches the capture zone (test line – coated with anti-mouse monoclonal antibody to SARS-CoV-2) where the complex binds forming a visible colored band in the test line. The specimen continues to migrate across the membrane along the strip until it reaches the control line (coated with goat anti-mouse IgG) where excess conjugate binds and produces a second visible line on the membrane. Test results are interpreted at 10 minutes.

The Celltrion DiaTrust COVID-19 Ag Rapid Test includes the following materials or other authorized materials: test devices packaged individually in aluminum pouch, disposable test tube with 0.3 mL of extraction buffer, filter cap, sterilized swabs for specimen collection, positive control swab and negative control swab.

Your product requires various types of quality control, including the procedural internal control that is built in the 'control line (c)' of the test device and the external positive and negative controls, or other authorized control materials (as may be requested under Condition P. 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 swab –contains non-infectious recombinant SARS-CoV-2 RBD antigen and non-infectious recombinant SARS-CoV-2 nucleoprotein antigen dried onto the swab
- Negative control swab – sterile swab

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 "Celltrion DiaTrust COVID-19 Ag Rapid Test" Instructions for Use and "Quick Reference Instruction Celltrion DiaTrust COVID-19 Ag Rapid Test" (available at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas), and the following fact sheets pertaining to the emergency use, is required to be made available as set forth in the Conditions of Authorization (Section IV), and are collectively referred to as "authorized labeling":

- Fact Sheet for Healthcare Providers: Celltrion USA, Inc. - Celltrion DiaTrust COVID-19 Ag Rapid Test
- Fact Sheet for Patients: Celltrion USA, Inc. - Celltrion DiaTrust COVID-19 Ag Rapid Test

The above described product, when accompanied by the authorized labeling provided 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) [7] and HUMASIS Co., Ltd.

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 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 HUMASIS Co., Ltd. must comply with the following requirements pursuant to FDA regulations: 21 CFR 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).

C. You and HUMASIS Co., Ltd. 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 HUMASIS Co., Ltd. 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.

E. You and HUMASIS Co., Ltd. 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.

F. You and HUMASIS Co., Ltd. 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

[7] The sole distributor of the product is Celltrion USA, Inc.

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 HUMASIS Co., Ltd. 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.

H. If requested by FDA, you and HUMASIS Co., Ltd. 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.

Celltrion USA, Inc. (You)

I. You must make your product available with the authorized labeling to authorized laboratories.

J. You must make available on your website(s) the authorized labeling.

K. You will include a physical copy of the "Quick Reference Instruction Celltrion DiaTrust COVID-19 Ag Rapid Test" with with each shipped product to authorized laboratories and will make the "Celltrion DiaTrust COVID-19 Ag Rapid Test" 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.

L. You 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.

M. Through a process of inventory control, you must maintain records of the authorized laboratories to which you distribute your product and number distributed.

N. You 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.

O. 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.

P. 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.

Q. You must evaluate the analytical limit of detection and assess traceability[8] of your product with any FDA-recommended reference material(s). After submission to and review and concurrence with the data by FDA, you must update labeling to reflect the additional testing. Such labeling updates must be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

R. 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.

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

Authorized Laboratories

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

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

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

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

W. 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.

X. 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), HUMASIS Co., Ltd. (via email: info@humasis.com or via phone: +82-31-8085-6284) and Celltrion USA, Inc. (via email: Diatrust@celltrion.com or via phone: (201) 499-1844) 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.

Y. 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), HUMASIS Co., Ltd. and Authorized Laboratories

Z. You, HUMASIS Co., Ltd., 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

AA. 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.

BB. 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.

CC. 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,

_____
RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosure
cc: Vicky Lee
HUMASIS Co., Ltd
37, Gunpocheomdansaneop 2-ro
Gunpo-si, Gyeonggi-do
KOREA, REPUBLIC OF

FACT SHEET FOR HEALTHCARE PROVIDERS

Celltrion USA, Inc. **Updated: September 1, 2021**

Celltrion DiaTrust™ COVID-19 Ag Rapid Test

Coronavirus Disease 2019 (COVID-19)

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the Celltrion DiaTrust™ COVID-19 Ag Rapid Test.

The Celltrion DiaTrust™ COVID-19 Ag Rapid Test is authorized for use using human nasopharyngeal swab specimens collected from individuals who are suspected of COVID-19 by their healthcare provider within the first seven days of the onset of symptoms, or from individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over two or three days with at least 24 hours and no more than 48 hours between tests.

All patients whose specimens are tested with this assay will receive the Fact Sheet for Patients: Celltrion DiaTrust™ COVID-19 Ag Rapid Test.

What are the symptoms of COVID-19?
Many patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, dyspnea). The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that symptoms may include cough, shortness of breath or dyspnea, fever, chills, fatigue, myalgias, headache, sore throat, new loss of taste or smell, congestion or runny nose, nausea or vomiting or diarrhea. COVID-19 can present with a mild to severe illness, although some people infected with COVID-19 may have no symptoms at all. Based on what is known about the virus that causes COVID-19, signs and symptoms may appear any time from 2 to 14 days after exposure to the virus. Based on preliminary data, the median incubation period is approximately 5 days, but may range 2-14 days. For further information on the symptoms of COVID-19 please see the link provided in "*Where can I go for updates and more information?*" section.

Public health officials have identified cases of COVID-19 infection throughout the world, including the United States, which may pose risks for public health. Please check the CDC COVID-19 webpage for the most up to date information (see link provided in "*Where can I go for updates and more information?*" section at the end of this document) or your local jurisdictions website for the most up to date information.

This test is to be performed only using direct human nasopharyngeal swab specimens collected from individuals who are suspected of COVID-19 by their healthcare provider within the first seven days of the onset of symptoms or in individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over two (or three) days with at least 24 hours (and no more than 48 hours) between tests.

What do I need to know about COVID-19 testing?
Current information on COVID-19 for healthcare providers is available at CDC's webpage, *Information for Healthcare Professionals* (see links provided in "*Where can I go for updates and more information?*" section).

- The Celltrion DiaTrust™ COVID-19 Ag Rapid Test can be used to test nasopharyngeal swab specimens directly collected.
- The Celltrion DiaTrust™ COVID-19 Ag Rapid Test should be ordered for the detection of COVID-19 in individuals who are suspected of COVID-19 by their healthcare provider and who are within the first seven days of onset of symptoms, or from individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over two or three days with at least 24 hours and no more than 48 hours between tests.
- The Celltrion DiaTrust™ COVID-19 Ag Rapid Test is authorized for use in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity, moderate complexity, or waived tests. This test is authorized

for use at the Point of Care (POC), i.e., patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.
- Please refer to the Celltrion DiaTrust™ COVID-19 Ag Rapid Test instructions for use for additional information.

Specimens should be collected with appropriate infection control precautions. Current guidance for COVID-19 infection control precautions are available at the CDC's website (see links provided in "*Where can I go for updates and more information?*" section).

Use appropriate personal protective equipment when collecting and handling specimens from individuals suspected of having COVID-19 as outlined in the CDC *Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)*. For additional information, refer to CDC *Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons Under Investigation (PUIs) for Coronavirus Disease 2019 (COVID-19) (*see links provided in "*Where can I go for updates and more information?*" section).

What does it mean if the specimen tests positive for the virus that causes COVID-19?
A positive test result for COVID-19 indicates that antigens from SARS-CoV-2 was detected, and the patient is infected with the virus and presumed to be contagious. Laboratory test results should always be considered in the context of clinical observations and epidemiological data in making a final diagnosis and patient management decisions. Patient management should follow current CDC guidelines.

The Celltrion DiaTrust™ COVID-19 Ag Rapid Test has been designed to minimize the likelihood of false positive test results. However, in the event of a false positive result, risks to patients could include the following: a recommendation for isolation of the patient, monitoring of household or other close contacts for symptoms, patient isolation that might limit contact with family or friends and may increase contact with other potentially COVID-19 patients, limits in the ability to work, delayed diagnosis and treatment for the true infection causing the symptoms, unnecessary prescription of a treatment or therapy, or other unintended adverse effects.

All laboratories using this test must follow the standard testing and reporting guidelines according to their appropriate public health authorities.

What does it mean if the specimen tests negative for the virus that causes COVID-19?
A negative test result for this test means that SARS-CoV-2 antigens were not present in the specimen above the limit of detection. However, a negative result does not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Antigen tests are known to be less sensitive than molecular tests that detect viral nucleic acids.

The amount of antigen in a sample may decrease as the duration of illness increases. In symptomatic patients, specimens collected after day 7 of illness may be more likely to be negative compared to a RT-PCR assay. Therefore, negative results should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management. When a diagnostic test's result is negative, the possibility of a false negative result should be considered in the context of a patient's recent exposures and the presence of clinical signs and symptoms consistent with COVID-19. The possibility of a false negative result should especially be considered if the patient's recent exposures or clinical presentation indicate that COVID-19 is likely, and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative. If COVID-19 is still suspected based on exposure history together with other clinical findings, re-testing or testing with molecular methods should be considered by healthcare providers in consultation with public health authorities.

Risks to a patient of a false negative test result include: delay or lack of supportive treatment, lack of monitoring of infected individuals and their household or other close contacts for symptoms resulting in increased risk of spread of COVID-19 within the community, or other unintended adverse events.

A negative antigen test should not be the sole basis used to determine if a patient can end isolation precautions. For additional recommendations regarding infection control, refer to CDC's *Discontinuation of Isolation for Persons with COVID-19 Not in Healthcare Settings* (Interim Guidance) (see links provided in "Where can I go for updates and more information" section).

The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between 5th Feb, 2021 and 25th Feb 2021. The clinical performance has not been established in all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.

What do I need to know about Serial Testing in Asymptomatic Individuals?
In asymptomatic patients, serial testing may assist in identifying infected individuals and facilitate timely infection control practices. A negative test result does not rule out infection but repeat testing over two or three days may decrease the risks of false negative results. Additional clinical studies are underway to assess the performance of rapid antigen tests when used with serial testing. An initial negative test result should be the first of a minimum of two tests. An asymptomatic individual undergoing serial testing with two or more negative results may require ongoing serial testing or confirmatory testing, depending on patient history and potential exposures. An asymptomatic individual undergoing serial testing with one or more positive results indicates that SARS-CoV-2 antigen is present but does not rule out coinfection with other pathogens.

Additional confirmatory testing with a molecular test for negative 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 SARS-CoV-2 or residing in communities with low prevalence of infection. For additional recommendations regarding confirmation of antigen test results, please refer to the CDC's Interim Guidance for Antigen Testing for SARS-CoV-2 (see links provided in " Where can I go for updates and more information" section).

What is an EUA?
The United States FDA has made this test available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of in vitro diagnostics (IVDs) for the detection and/or diagnosis of the virus that causes COVID-19.

An IVD made available under an EUA has not undergone the same type of review as an FDA-approved or cleared IVD. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives, and based on the totality of scientific evidence available, it is reasonable to believe that this IVD may be effective in diagnosing COVID-19.

The EUA for this test is in effect for the duration of the COVID-19 declaration justifying emergency use of IVDs, unless terminated or revoked (after which the test may no longer be used).

What are the approved available alternatives?
There are no approved available alternative antigen tests. Any tests that have received full marketing status (e.g., cleared, approved), as opposed to an EUA, by FDA can be found by searching the medical device databases here: https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases. A cleared or approved test should be used instead of a test made available under an EUA, when appropriate and available. FDA has issued EUAs for other tests that can be found at: https://www.fda.gov/emergency-

preparedness-and- response/mcm-legal-regulatory-and-policy- framework/emergency-use-authorization.

Where can I go for updates and more information?
CDC webpages:
General:
https://www.cdc.gov/coronavirus/2019-ncov/index.html
Symptoms:
https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html
Healthcare Professionals:
https://www.cdc.gov/coronavirus/2019-nCoV/hcp/index.html
Information for Laboratories:
https://www.cdc.gov/coronavirus/2019-nCoV/lab/index.html
Laboratory Biosafety:
https://www.cdc.gov/coronavirus/2019-nCoV/lab-biosafety-guidelines.html
Isolation Precautions in Healthcare Settings:
https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html
Specimen Collection:
https://www.cdc.gov/coronavirus/2019-nCoV/guidelines-clinical-specimens.html
Infection Control:
https://www.cdc.gov/coronavirus/2019-ncov/php/infection-control.html
Discontinuation of Isolation:
https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in-home-patients.html
Influenza: https://www.cdc.gov/flu/index.htm
Interim Guidance for Antigen Testing for SARS-CoV-2:
https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html

FDA webpages:
General: www.fda.gov/novelcoronavirus
EUAs: (includes links to patient fact sheet and manufacturer's instructions) https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas

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Report Adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) or by calling **1-800-FDA-1088**

FACT SHEET FOR PATIENTS

Celltrion USA, Inc. **April 16, 2021**

Celltrion DiaTrust™ COVID-19 Ag Rapid Test

Coronavirus Disease 2019 (COVID-19)

You are being given this Fact Sheet because your sample(s) was tested for the Coronavirus Disease 2019 (COVID-19) using the Celltrion DiaTrust™ COVID-19 Ag Rapid Test.

This Fact Sheet contains information to help you understand the risks and benefits of using this test for the diagnosis of COVID-19. After reading this Fact Sheet, if you have questions or would like to discuss the information provided, please talk to your healthcare provider.

For the most up to date information on COVID-19 please visit the CDC Coronavirus Disease 2019 (COVID-19) webpage:
https://www.cdc.gov/COVID19

What is COVID-19?
COVID-19 is caused by the SARS-CoV-2 virus which is a new virus in humans causing a contagious respiratory illness. COVID-19 can present with a mild to severe illness, although some people infected with COVID-19 may have no symptoms at all. Older adults and people of any age who have underlying medical conditions have a higher risk of severe illness from COVID-19. Serious outcomes of COVID-19 include hospitalization and death. The SARS-CoV-2 virus can be spread to others not just while one is sick, but even before a person shows signs or symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc.). A full list of symptoms of COVID-19 can be found at the following link: https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.

What is the Celltrion DiaTrust™ COVID-19 Ag Rapid Test?
The Celltrion DiaTrust™ COVID-19 Ag Rapid Test is a type of test called an antigen test. Antigen tests are designed to detect proteins from the virus that causes COVID-19 in nasopharyngeal swabs. The presence of viral proteins indicate you may have been infected with the virus and are likely to be contagious.

Why was my sample tested?
You were tested because your healthcare provider believes you may have been exposed to the virus that causes COVID-19 based on your signs and symptoms (e.g., fever, cough, difficulty breathing), and/or other risk factors and you are within the first seven days of the onset of symptoms, or ii) you are undergoing serial testing even though you do not have symptoms or other risk factors for COVID-19 infection,

What are the known and potential risks and benefits of the test?

Potential risks include:
- Possible discomfort or other complications that can happen during sample collection.
- Possible incorrect test result (see below for more information).

Potential benefits include:
- The results, along with other information, can help your healthcare provider make informed recommendations about your care.
- The results of this test may help limit the spread of COVID-19 to your family and those you come in close contact with.

What does it mean if I have a positive test result?
If you have a positive test result, it is very likely that you have COVID-19 because proteins from the virus that causes COVID-19 were found in your sample. Therefore, it is also likely that you may be placed in isolation to avoid spreading the virus to others. There is a very small chance that this test can give a positive result that is wrong (a false positive result). Your healthcare provider will work with you to determine how best to care for you based on the test results along with medical history, and your symptoms.

What does it mean if I have a negative test result?
A negative test result means that proteins from the virus that causes COVID-19 were not found in your sample. It is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. This means that you could possibly still have COVID-19 even though the test is negative. If your test result is

- **Where can I go for updates and more information?** The most up-to-date information on COVID-19 is available at the CDC General webpage: **https://www.cdc.gov/COVID19**. In addition, please also contact your healthcare provider with any questions/concerns.

negative, your healthcare provider will consider the test result together with all other aspects of your medical history (such as symptoms, possible exposures, and geographical location of places you have recently traveled) in deciding how to care for you. The amount of antigen in a sample may decrease the longer you have symptoms of infection. In symptomatic people, specimens collected after you have had symptoms for more than seven days may be more likely to be negative compared to a molecular assay.

It is important that you work with your healthcare provider to help you understand the next steps you should take.

What is serial testing?
Serial testing is when a single person is tested for COVID-19 more than once using the same test. Because the amount of antigen in your sample may change over time and false results may occur, repeated testing may identify more individuals with COVID-19 infection than testing a single time. By repeating testing, it may be possible to more quickly identify cases of COVID-19 infection and reduce spread of infection. Additional testing with a molecular COVID-19 test may be necessary, depending on your individual risk factors and test results.

What are the differences between antigen tests and other COVID-19 tests?
There are different kinds of tests for diagnosing COVID-19. Molecular tests (also known as PCR tests) detect genetic material from the virus. Antigen tests detect proteins from the virus. Antigen tests are very specific for the virus, but are not as sensitive as molecular tests. This means that a positive result is highly accurate, but a negative result does not rule out infection.

If your test result is negative, you should discuss with your healthcare provider whether an additional molecular test would help with your care, and when you should discontinue home isolation. If you do not have an additional test to determine if you are infected and may spread the infection to others, the CDC currently recommends that you should stay home until three things have happened:

- You have had no fever for at least 24 hours (that is one full day of no fever without the use of medicine that reduces fevers).

AND

- Other symptoms have improved (for example, when your cough or shortness of breath has improved but, loss of taste and smell may persist for weeks or months after recovery and need not delay the end of isolation).

AND

- At least 10 days have passed since your symptoms first appeared.

For more information, the CDC has provided guidelines on how to prevent the spread of COVID-19 if you are sick: https://www.cdc.gov/coronavirus/2019-ncov/downloads/sick-with-2019-nCoV-fact-sheet.pdf.

Is this test FDA-approved or cleared?
No. This test is not yet approved or cleared by the United States FDA. FDA may issue an Emergency Use Authorization (EUA) when certain criteria are met, which includes that there are no adequate, approved, available alternatives. The EUA for this test is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of in vitro diagnostics for the detection and/or diagnosis of the virus that causes COVID-19. This EUA will remain in effect (meaning this test can be used) for the duration of the COVID-19 declaration justifying emergency of IVDs, unless it is terminated or revoked by FDA (after which the test may no longer be used).

What are the approved alternatives?
There are no approved available alternative antigen tests. Any tests that have received full marketing status (e.g., cleared, approved), as opposed to an EUA, by FDA can be found by searching the medical device databases here:https://www.fda.gov/medical-devices/device- advice-comprehensive-regulatory-assistance/medical- device-databases. A cleared or

- **Where can I go for updates and more information?** The most up-to-date information on COVID-19 is available at the CDC General webpage: **https://www.cdc.gov/COVID19**. In addition, please also contact your healthcare provider with any questions/concerns.

approved test should be used instead of a test made available under an EUA, when appropriate and available. FDA has issued EUAs for other tests that can be found at: https://www.fda.gov/emergency-preparedness-and- response/mcm-legal-regulatory-and-policy- framework/emergency-use-authorization.

- **Where can I go for updates and more information?** The most up-to-date information on COVID-19 is available at the CDC General webpage: **https://www.cdc.gov/COVID19**. In addition, please also contact your healthcare provider with any questions/concerns.

CELLTRION USA

QUICK REFERENCE INSTRUCTION

Celltrion DiaTrust™

COVID-19 Ag Rapid Test

- For use under the Emergency Use Authorization (EUA) only
- For *in vitro* diagnostic use
- For Prescription Use only
- Please refer to the package insert for detailed assay instructions, cautions, limitations and warnings

INTENDED USE

Celltrion DiaTrust™ COVID-19 Ag Rapid Test is a rapid test based on lateral flow immunoassay intended for the qualitative detection of nucleocapsid proteins and receptor binding domains (RBDs) from the SARS-CoV-2 spike proteins in human nasopharyngeal swab specimens directly collected from individuals who are suspected of COVID-19 by their healthcare provider within the first seven days of symptom onset, or from individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over two or three days with at least 24 hours and no more than 48 hours between tests. Testing is 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 complexity, moderate complexity, or waived 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.

The Celltrion DiaTrust™ COVID-19 Ag Rapid Test does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid and RBD protein antigen. Antigen is generally detectable in human nasopharyngeal swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with the patient 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. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

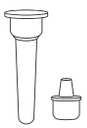
Negative results should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management may be performed. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection 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.

For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary, if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with 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 SARS-CoV-2 or residing in communities with low prevalence of infection.

The Celltrion DiaTrust™ COVID-19 Ag Rapid Test is intended for use by medical professionals or trained operators who are proficient in performing tests, trained clinical laboratory personnel, or individuals trained in POC settings. In the United States, the Celltrion DiaTrust™ COVID-19 Ag Rapid Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

MATERIAL PROVIDED

1. Test device (25 ea)



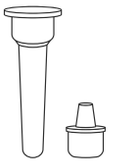
2. Test tube filled with extraction buffer and filter cap (25 ea)

3. NPS swab (25 ea)

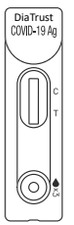
4. Quick reference instruction (1 ea)
5. Positive control swab (1 ea)
6. Negative control swab (1 ea)

TESTING PROCEDURE

1) Prepare an aluminum pouch containing the test device and place it on the testing surface along with the test tube filled with the extraction buffer and filter cap. In case the tests were refrigerated, keep them ambient for 30 minutes to let it reach the room temperature.

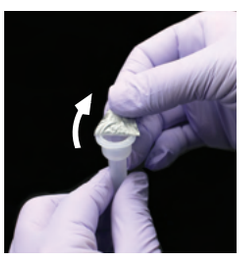


2) Release the test device from the aluminum pouch and place it on a flat surface just prior to starting test.

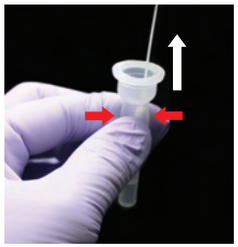


3) Collect the specimen by following CDC guidelines. After swabbing, immediately insert the swab into extraction buffer tube. Do not leave the sampled swab dry in open air as it may affect the test's performance. If specimens are not tested before 4 hours when stored in extraction buffer, a new specimen should be collected and retested.

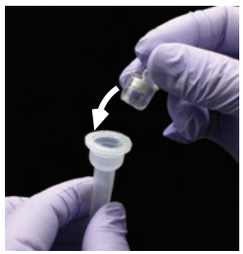
4) Collect the buffer fluid at the bottom of the test tube by shaking it and then peel off the seal of the test tube. Insert the tip of the swab with the patient specimen and move the swab up and down more than 10 times to ensure sufficient sample extraction.

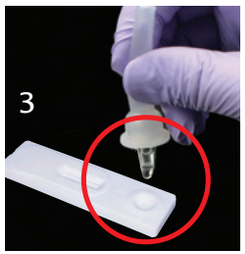


5) Remove the swab while pressing against the sides of the tube to ensure maximum amount of liquid has been squeezed from the swab.



6) Equip the filter cap on the test tube and immediately dispense three drops of sample extracts (100 µL) into the sample well of the device. (If you have dropped the test device after sample application, please discard the device and restart the test using a new device.)





7) Read results 15 minutes after applying the sample. Do not read results after 20 minutes.

RESULT INTERPRETATION

Read results 15 minutes after applying the sample. Do not read results after 20 minutes.

NEGATIVE
If no colored line appears in the test line (T) and a colored line is present in the control region (C), then the result is negative.

POSITIVE
If colored line is visible in the test line (T) and control line (C), the result is positive.

INVALID
If there is no colored line in the control region (C), the result is invalid. If invalid results are obtained, please discard the device and re-do the testing from the specimen collection using a new device.

Note: A negative result is presumptive and confirmation with a molecular assay, if necessary, for patient management may be performed.

Note: For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary after second negative result for asymptomatic patients, if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with 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 SARS-CoV-2 or residing in communities with low prevalence of infection.

STORAGE AND STABILITY

An unopened test device should be stored at 2 - 30°C (36 - 86°F). The shelf-life of the test device is 10 months and it is stable until the expiration date marked on the label. An opened test device is stable up to 1 hour after released from the aluminum pouch.

EXTERNAL QUALITY CONTROL

It is recommended that positive and negative external control swabs are run once with every new lot, shipment, and each new user. External positive and negative control swabs are provided in the kit. The external control should be tested using the nasopharyngeal swab test procedure provided in the instructions for use or the quick reference instruction.

ASSISTANCE

If you have any questions regarding the use of this product or if you want to report a test system problem, please contact Humasis Co., Ltd. (via email: info@humasis.com, via phone: +82-31-8085-6284) or Celltrion USA, Inc. (via email: Diatrust@celltrion.com, or via phone: (201) 499-1844).

The full Instructions for use can be found at the following website: <www.DiaTrustCOVID.com>

A paper copy of the instructions for use can be requested without additional cost. Please contact Celltrion USA, Inc. at <(201) 499-1844> or <Diatrust@celltrion.com> to obtain a copy free of charge.

In the USA, this product has not been FDA cleared or approved; but has been authorized by FDA under an EUA for use by authorized laboratories; use by laboratories certified under the CLIA, 42 U.S.C. §263a, that meet requirements to perform moderate, high or waived complexity tests. This product 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.

This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens; and in the USA, - 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 the virus that causes COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless declaration is terminated or the authorization is revoked sooner.

Humasis Co., Ltd.
Rm. 114, 502, 504, 604, 604-1, B03-1, B03-2, 88, Jeonpa-ro, Dongan-gu, Anyang-si, Gyeonggi-do, 14042, Republic of Korea

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