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 Instructions for Use for detailed assay instructions, cautions, limitations and warnings.

INTENDED USE

Celltrion DiaTrust™ COVID-19 Ag Rapid Test is a lateral flow immunoassay intended for the qualitative detection of SARS-CoV-2 nucleocapsid and receptor binding domain (RBD) antigens in direct mid-turbinate nasal swab specimens from individuals who are suspected of COVID-19 by their healthcare provider within the first 7 days of symptom onset, or from individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours, and no more than 48 hours, between tests. 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 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.

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 antigens. Antigen is generally detectable in mid-turbinate nasal swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine patient 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.

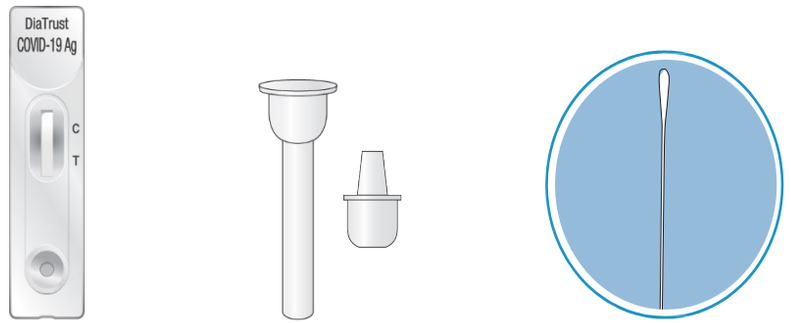
Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

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 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.

The Celltrion DiaTrust™ COVID-19 Ag Rapid Test is intended for use by healthcare professionals or operators who are proficient in performing tests 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

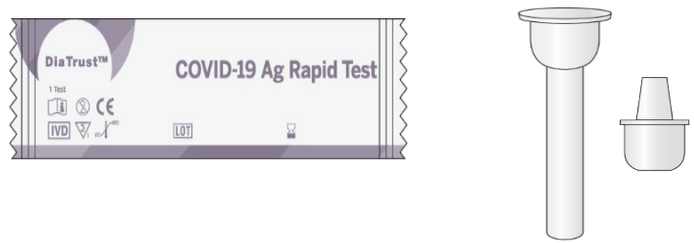


1. Test device (25ea) **2. Test tube filled with extraction buffer and filter cap (25 ea.)** **3. Swab (25ea)**

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

TESTING PROCEDURE

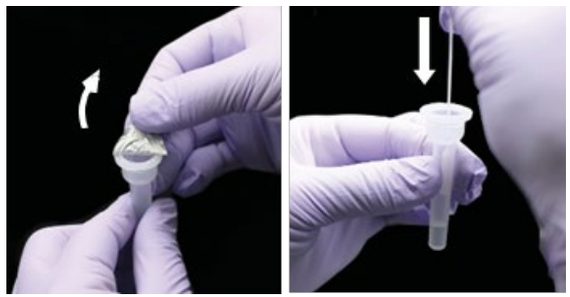
1) Prepare an aluminum pouch containing the test device and place it on the testing surface along with the test tube filled with the extraction buffer and filter cap. In case the tests were refrigerated, keep them ambient for 30 minutes to let it reach the room temperature.



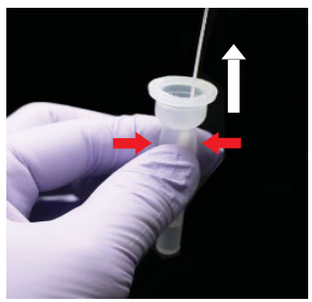
2) Release the test device from the aluminum pouch and place it on a flat surface just prior to starting test.

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.

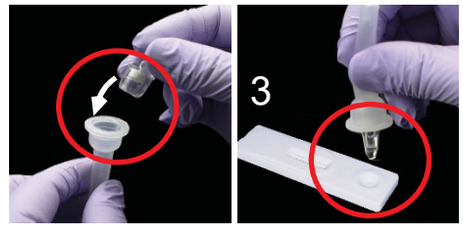
4) Collect the buffer fluid at the bottom of the test tube by shaking it and then peel off the seal of the test tube. Insert the tip of the swab with the patient specimen and move the swab up and down more than 10 times to ensure sufficient sample extraction.



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

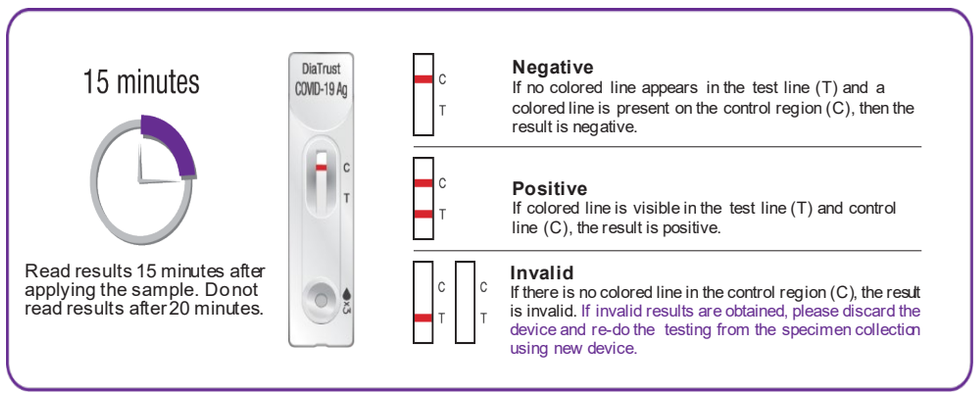


6) Equip the filter cap on the test tube and immediately dispense three drops of sample extracts (100 μL) into the sample well of the device.
(If you have dropped the test device after sample application, please discard the device and restart the test using new device.)



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

RESULT INTERPRETAION



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 in an individual with as a close contract 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 18 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 swab test procedure provided in the instructions for use or the quick reference instruction.

ASSISSTANCE

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 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.
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