

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. Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.

INTENDED USE

Celltrion DiaTrust™ COVID-19 Ag Rapid Test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein and receptor binding domain (RBD) protein antigens in direct mid-turbinate nasal swab specimens from individuals who are suspected of COVID-19 by their healthcare provider within the first seven (7) days of symptom onset when tested at least twice over three days with at least 48 hours between tests, or from individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested at least three times over five days with at least 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.

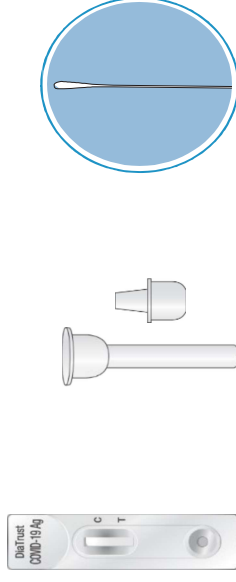
The Celltrion DiaTrust™ COVID-19 Ag Rapid Test does not differentiate between SARS-CoV and SARS-CoV-2. Results are for the identification of SARS-CoV-2 nucleocapsid and RBD protein antigens which are generally detectable in mid-turbinate nasal swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with 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 and 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.

All negative results are presumptive and confirmation with a molecular assay, if necessary for patient management may be performed. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions such as isolating from others and wearing masks. 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.

The Celltrion DiaTrust™ COVID-19 Ag Rapid Test is intended for use by healthcare professionals or operators who are proficient in performing tests in point of care settings. The Celltrion DiaTrust™ COVID-19 Ag Rapid Test is only for *in vitro* diagnostic use under the Food and Drug Administration's Emergency Use Authorization. This product has not been FDA cleared or approved.

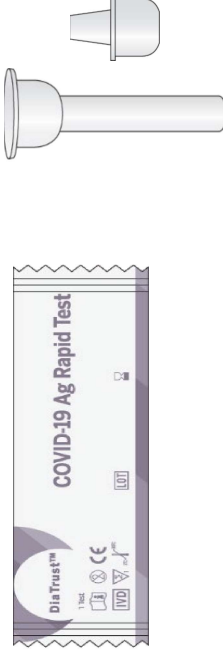
MATERIAL PROVIDED



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 extraction buffer and filter cap. In case the tests were refrigerated, keep them ambient for 30 minutes to let it reach the room temperature.

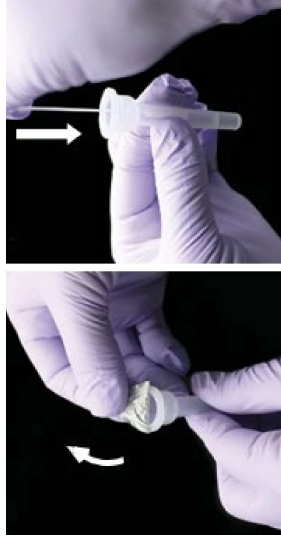


2) Release the test device from the aluminum pouch and place it on a flat surface just prior to starting test.

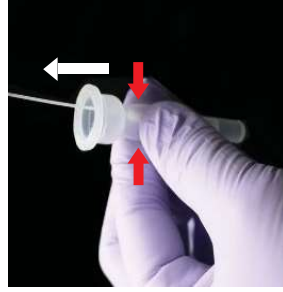


3) Collect the specimen by following CDC guidelines. After swabbing, immediately insert the swab into extraction buffer tube. Do not leave the sampled swab dry in open air as it may affect the test's performance. If specimens are not tested before 4 hours when stored in extraction buffer, a new specimen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

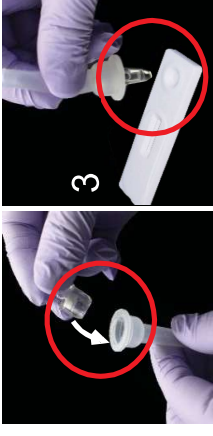
4) Collect the buffer fluid at the bottom of the test tube by shaking it and then peel off the seal of the test tube. Insert the tip of the swab with the patient specimen and move the swab up and down more than 10 times to ensure sufficient sample extraction.



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.

15 minutes



RESULT INTERPRETAION

15 minutes



Read results 15 minutes after applying the sample. Do not read test results before 15 minutes or after 20 minutes. Results read before 15 minutes or after 20 minutes may lead to false positive, ...



COVID-19 Negative (-)

If the Control (C) line is visible, but the Test (T) line is not visible, the test is negative.

To increase the chance that the negative result for COVID-19 is accurate, you should:

- Test again in 48 hours if the individual has symptoms on the first day of testing.
- Test 2 more times at least 48 hours apart if the individual does not have symptoms on the first day of testing.



COVID-19 Positive (+)

If the Control (C) line and the Test (T) line are visible, the test is positive. Any faint visible red test (T) line with the control line (C) should be read as positive.

Repeat testing does not need to be performed if patients have a positive result at any time.



Invalid

If the Control (C) line is not visible, the test is invalid. Retest with a new swab and new test device.



Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results.

Status on first day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	Negative	Negative for COVID-19

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

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 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.

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 Emergency Use Authorization. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. 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 declaration is terminated or the authorization is revoked sooner.

This product has been authorized 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.

Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals and three times over five days (with at least 48 hours between tests) for asymptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.

If the individual has had symptoms longer than 7 days you should consider testing them at least three times over five days with at least 48 hours between tests.



Humasis Co., Ltd.

Site 1: Rm. 114, 502, 504, 604, 604-1, 803-1, 803-2,
88, Jeonpa-ro, Dongan-gu, Anyang-si, Gyeonggi-do, 14042, Republic of Korea
Site 2: 37, Gunpocheomdansaneop 2-ro, Gunpo-si, Gyeonggi-do, 15880, Republic of Korea

Distributed by Celltrion USA, Inc.

One Evertrust Plaza Suite 1207, Jersey City, New Jersey, 07302, USA

Tel: (201) 499-1844

Fax: (201) 603-6767

Email: Diatrust@celltrion.com

www.DiaTrustCOVID.com

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