Celltrion DiaTrust™
COVID-19 Ag Home Test

INSTRUCTIONS FOR USE

For use under the Emergency Use Authorization (EUA) only. 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 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 the declaration is terminated, or authorization is revoked sooner.

STORAGE & STABILITY

An unopened test device should be stored at 2-30°C (68-86°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. If the tests were refrigerated, keep them at room temperature for 30 minutes prior to use.

TEST PROCEDURES

I. Swab Holding Position

Ensure all packaging is intact. Do not use the test if there is visible damage to the packaging or test pouch.

DOWNLOAD & OPEN APP

Scan the QR code through your smartphone (Android 10 or newer, iOS 14.2 or newer) camera to download the free Celltrion DiaTrust™ COVID-19 Ag Home Test App (CELLTRION SAFKEY). Follow the instructions as described in the mobile app.

Elderly population can acquire help from others to download & guide through the app.

Celltrion DiaTrust™ COVID-19 Ag Home Test App can also be accessed through https://celltriontrial.safekey.tools via a computer if any error occurs with QR code.

Please follow the step-by-step instructions available on the mobile app.

WHAT IS INCLUDED IN THIS BOX?

*The actual size of the test device may differ from the image.

PRECAUTIONS BEFORE THE TEST

- Please carefully read the precautions outlined in the Instructions for Use manual prior to starting your test. Then please refer to the mobile app and follow the detailed instructions required to collect your sample. Failure to follow the instructions can result in inaccurate results.
- Wash or sanitize your hands and dry them thoroughly before starting the test. Make sure they are completely dry.
- This test involves taking a sample from deep inside your nose. When performing the test, pay particular attention to the instructions on how to swab your nose.
- Testing should be completed within 30-60 minutes of opening the test pouch.

How to Read the Results

A Positive Result indicates that viral antigens from COVID-19 were present in the specimen, and it is very likely that you have COVID-19 and should self-isolate. It is important to be under the care of your healthcare provider. Please make sure to compare your red colored line to the Line Level chart.

A Negative Result indicates that viral antigens from COVID-19 were not present in the specimen.

An Invalid Result indicates that the test was not completed properly or the mobile app encountered an error. Please discard the test and try again.

HOW TO READ THE RESULTS

A Positive Result

- If no red colored line appears in the test line (T Line Level 1 - 11) and a red colored line is present in the control region (C Line Level 1 - 11), then the result is positive.

A Negative Result

- If no red colored line appears in the control region (C Line Level 0), the result is negative.

An Invalid Result

- If there is no red colored line in the control region (C Line Level 0), the result is invalid.

These are photos of actual positive results. Please note that the test line can show up faintly. This faint line still indicates a positive result.

PRECAUTIONS BEFORE THE TEST

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- If no red colored line appears in the test line (T Line Level 1 - 11) and a red colored line is present in the control region (C Line Level 1 - 11), then the result is positive.

A Negative Result

- If no red colored line appears in the control region (C Line Level 0), the result is negative.

An Invalid Result

- If there is no red colored line in the control region (C Line Level 0), the result is invalid.

These are photos of actual positive results. Please note that the test line can show up faintly. This faint line still indicates a positive result.

PRECAUTIONS BEFORE THE TEST

- Please carefully read the precautions outlined in the instructions for use manual prior to starting your test. Then please refer to the mobile app and follow the detailed instructions required to collect your sample. Failure to follow the instructions can result in inaccurate results.
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COVID-19 Ag Home Test

INSTRUCTIONS FOR USE

INTENDED USE

Celltrion DiaTrust™ COVID-19 Ag Home Test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein and receptor binding domain (RBD) antigens from SARS-CoV-2. This test is authorized for non-prescription home use 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 7 days of symptom onset. This test is also authorized for non-prescription home use with self-collected and adult-collected direct 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 Celltrion DiaTrust™ COVID-19 Ag Home Test does not differentiate between SARS-CoV-1 and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid and RBD protein antigens. Antigens are generally detectable in mid-turbinate swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with past exposure 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 with a positive result with the Celltrion DiaTrust™ COVID-19 Ag Home Test 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 and isolation 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 results may be necessary. If there is a high likelihood of SARS-CoV-2 infection, such as with 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.

Individuals who test negative and continue to experience COVID-19 like symptoms of fever, cough, or shortness of breath within 3 to 7 days of testing should also be tested using a molecular test. 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.

FREQUENTLY ASKED QUESTIONS

WILL THIS TEST HURT?

No, the mid-turbinate nasal swab is not sharp, and it should not hurt. Sometimes the swab can feel slightly uncomfortable. If you feel pain, please stop the test and seek advice from your healthcare provider.

WHAT ARE THE KNOWN POTENTIAL RISKS AND BENEFITS OF THIS TEST?

Possible risks include:
- Possible incorrect test results (see HOW TO READ THE RESULTS section)

Potential benefits include:
- The results, along with information, can help you and your healthcare provider make informed decisions about your care.

The results of this test may help limit the spread of COVID-19 to your family and others in your community.

For more information on EUAs go here: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

WHAT IS SERIAL TESTING?

Serial testing is when a single person is tested for COVID-19 more than once. Because antigen tests are less sensitive than other COVID-19 tests and false results may occur, repeated testing may identify more individuals with COVID-19 infection than a single test. By repeating testing, it may be possible to more quickly identify cases of COVID-19 infection and reduce spread of infection. Additional testing with molecular COVID-19 testing may be necessary, depending on your individual risk factors and test results. It is important that you work with your healthcare provider to help you understand the next steps you should take. Serial testing (i.e., testing every day or every other day) is more likely to detect COVID-19, especially when you do not have any symptoms.

WHAT IS THE DIFFERENCE BETWEEN AN ANTIGEN AND MOLECULAR TEST?

There are different kinds of tests for COVID-19. Molecular tests (also known as PCR tests) detect genetic material or viral RNA of the virus. Antigen tests, on the other hand, detect specific proteins from the virus that causes COVID-19. Antigen tests are very specific for the COVID-19 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 is necessary and if you should continue to follow the same treatment and protective measures. Celltrion DiaTrust™ COVID-19 Ag Home Test is compared to a laboratory-based molecular tests. This means that there is a higher chance this test will give you a negative result when you have COVID-19.

HOW ACCURATE IS THIS TEST?

The clinical evaluation of the Celltrion DiaTrust™ COVID-19 Ag Home Test was evaluated by testing a total of 452 prospectively collected direct mid-turbinate nasal swab samples, consisted of 45 positive and 447 negative samples from suspected COVID-19 patients in United States that were within seven days of symptom onset or asymptomatic individuals aged 14 years and older. The Celltrion DiaTrust™ COVID-19 Ag Home Test was compared to an FDA authorized molecular SARS-CoV-2 test. The Celltrion DiaTrust™ COVID-19 Ag Home Test correctly identified 86.7% of positive specimens and 99.8% of negative specimens in that clinical study.

WHAT IF YOU TEST POSITIVE?

A positive result means that antigens from COVID-19 were detected and it is likely that you currently have COVID-19 disease. There is a very small chance that this test can give a positive result that is wrong (a false positive result). If you test positive you should self-isolate at home per CDC recommendations to stop spreading the virus to others. Please consult the CDC recommendations regarding self-isolation at www.cdc.gov/coronavirus. Seek follow-up care with your healthcare provider immediately. Your healthcare provider will work with you to determine how best to care for you based on your test result(s) along with your medical health, and your symptoms.

WHAT IF YOU TEST NEGATIVE?

A negative result indicates no antigens for COVID-19 were detected. However, it is possible for this test to give a negative result that is incorrect (false negative) in some people. People with COVID-19 and negative test results are presumptive and may still have COVID-19. This means that you could possibly still have COVID-19 even though the test is negative. If you receive a negative result, you should test again in 24-48 hours. If you test negative and continue to experience symptoms of fever, cough and/or shortness of breath you should seek further testing with your healthcare provider immediately. Your healthcare provider may suggest you need another test to determine if you have contracted the virus causing COVID-19. If you are concerned about your COVID-19 infection status after testing or think you may need follow up testing, please contact your healthcare provider.

HAZARDOUS INGREDIENT FOR REAGENT

Chemical Name (CAS) GHS Code for each ingredient Conc.
Sodium Azide 0.09% Acute Toxic 2 (oral), H300 0.09%
Acute Toxic 1 (dermal), H310

The extraction buffer solution in the extraction buffer tube contains a hazardous ingredient shown in above table. If the extraction buffer solution contacts the skin or eye, immediately wash with plenty of running water. If the irritation persists, please seek medical advice at:https://www.poison.org/contact-us or 1-800-222-1222.

If you have any questions, please contact Humasis Co., Ltd. (via email: info@humasis.com, via phone: +82-31-8085-6284) or Celltrion USA, Inc. (via email: covidusa@celltrion.com, via phone: 1 (949) 498-1844).

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CONTENT

1 TEST

EASY Sample Collection

15 mins

Results in 15 Minutes

Hotel to your smartphone (Android 10 or newer, iOS 14.2 or newer) to download the free Celltrion DiaTrust™ COVID-19 Ag Home Test App. Once downloaded, the app will guide you through the test procedure. The app also provides a result interpretation of your test result.

PRECAUTIONS BEFORE THE TEST

1. Open the aluminum pouch when you are ready to do the test.
2. Scramble the liquid in the extraction buffer with a swab.
3. Insert the swab into the nose and collect a sample.
4. Insert the swab into the extraction buffer and mix the contents.
5. Place the contents into the sample cap and mix.
6. Insert the cap onto the test device.

INTERPRETATION OF RESULT

NEGATIVE

POSITIVE

INVALID

If you have symptoms of COVID-19, you can use a single test.
If you do not have symptoms of COVID-19, you will need at least two tests per person.
You may need to purchase additional tests to perform serial (repeat) testing.
This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test.

Scan the QR code through your smartphone (Android 10 or newer, iOS 14.2 or newer) to download the free Celltrion DiaTrust™ COVID-19 Ag Home Test App. If any error occurs with QR code, Celltrion DiaTrust™ COVID-19 Ag Home Test App can also be accessed through https://celltrion.safekey.tools.

Please follow the step-by-step instructions available on the mobile app.
Celltrion DiaTrust™
COVID-19 Ag
Home Test

EASY Sample Collection

Results in 15 Minutes

CONTENTS

- Test Device (2 ea.)
- Test Tube (Extraction Buffer) (1 ea.)
- Filter Cap (2 ea.)
- Swab (2 ea.)
- Instructions for Use (1 ea.)

PRECAUTIONS BEFORE THE TEST

- Only open the aluminum pouch when you are ready to do the test.

INTERPRETATION OF RESULT

- NEGATIVE
- POSITIVE
- INVALID

INSTRUCTIONS FOR USE

- If you have symptoms of COVID-19, you can use a single test.
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INSTRUCTIONS FOR USE

Only open the aluminum pouch when you are ready to do the test.

INTERPRETATION OF RESULT

Please carefully read the precautions outlined in the Quick Reference Instruction manual prior to starting your test. Then please refer to the mobile app and follow the detailed instructions required to collect your sample.

PRECAUTIONS BEFORE THE TEST

This test involves taking a sample from deep inside your nose. When performing the test, pay particular attention to the instructions on how to swab your nose.

CONTENTS

Test Device (25 ea.)
Test Tube (Extraction Buffer) (25 ea.)
Filter Cap (25 ea.)
Swab (25 ea.)
Instructions for Use (1 ea.)

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