**COVID-19 Ag Home Test**

**INSTRUCTIONS FOR USE**
For use under the Emergency Use Authorization (EUA) only. This test is intended to be used as an aid in the diagnosis of a current infection with the virus that causes COVID-19. This test is intended for individuals aged 14 years and older only. Do not use on children under 14 years of age.

**STORAGE & 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. If the tests were refrigerated, keep them at room temperature for 30 minutes prior to use.

**WHAT IS INCLUDED IN THIS BOX?**
- *: The actual size of the test device may differ from the image.

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

**FOR INSTRUCTIONS AVAILABLE ON THE MOBILE APP**
Celltrion DiaTrust™ COVID-19 Ag Home Test App can also be accessed through https://celltrion.safekey.tools via a computer if any error occurs with the QR code.

**PRECAUTIONS BEFORE THE TEST**
- **Elderly population can acquire help from others to download a guide through the app.**
- Celltrion DiaTrust™ COVID-19 Ag Home Test App can also be accessed through https://celltrion.safekey.tools via a computer if any error occurs with the QR code.

Please Follow the Step-by-Step Instructions Available on the Mobile App.

**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.

<table>
<thead>
<tr>
<th>Line Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-1</td>
<td>Negative</td>
</tr>
<tr>
<td>2-9</td>
<td>Positive</td>
</tr>
<tr>
<td>10-11</td>
<td>Invalid</td>
</tr>
</tbody>
</table>

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.

**TEST PROCEDURES**

**I. Swab Holding Position**

1. Peel open the swab package and take the swab out.
2. Hold the swab near the middle where it is thin (at the second notch; refer to the image above).
   - **Note:** Do not touch the soft tip or lay it down on any surfaces.

**II. Collecting Your Nasal (mid-turbinate) Swab Sample**

*Incorrect swabbing may lead to an inaccurate test result. This is particularly important if you do not have symptoms.*

1. Insert the entire soft end of the swab straight back into your nostril less than one inch (about 2 cm) or until resistance is felt.
2. Gently remove the swab.
3. Using the same swab, repeat steps 1-3 in your other nostril.
   - **Note:** The swab included in the kit is designed for collection of samples from adults. Do not collect swabs from children under 14 years of age.

**III. After Sample Collection**

**COLLECTION OF BUFFER FLUID**

1. Place the filter cap on the test tube.
2. Squeeze the tube while removing the swab to squeeze out as much liquid from the swab as possible.
3. Place the filter cap on the test tube.

**DISPENSATION OF THREE DROPS INTO SAMPLE WELL**

1. Put the tip of the swab into the test tube. Move the swab up and down at least 10 times to properly mix the fluid.
2. Squeeze the tube while removing the swab to squeeze out as much liquid from the swab as possible.
3. Place the filter cap on the test tube.
4. Immediately dispense three drops of the sample extract into the well at the bottom of the test device. On the mobile application, tap the “Completed” button to start a 15-minute timer.
   - **Note:** Adding only one drop of solution or the entire vial may result in false negative results.
4. Read results at 15 minutes after applying the sample. Do not read results after 20 minutes. On the mobile application, images of four potential results will be displayed. Click the image that best represents your result for the presence of red colored lines in the device window next to each of the two letters, C (Control) and T (Test).
   - **Note:** False negative or false positive results can occur if results are read before 15 minutes or after 20 minutes.

- **Negative results do not rule out COVID-19.**
- **If your first test result is negative, you should test again in 24 to 48 hours.**
- **Note:** A negative result is presumptive and additional testing with a molecular assay, may be needed.

The Celltrion DiaTrust™ COVID-19 Ag Home Test is for use under 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 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)(3) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(3), unless the declaration is terminated, or authorization is revoked sooner.
Celltrion DiaTrust™ 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 and 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 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 medical history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Individuals who test positive with 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 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 an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of SARS-CoV-2 infection, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

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

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

The Celltrion DiaTrust™ COVID-19 Ag Home Test is authorized for non-prescription self-use or a lay user testing another person 14 years or older in a non-laboratory setting. The Celltrion DiaTrust™ COVID-19 Ag Home Test is only for use under the Food and Drug Administration’s Emergency Use Authorization.

WARNINGS & PRECAUTIONS

• Do not use this test for individuals under 14 years of age. The swab included in the kit is designed for collection of samples from adults and additional safety measures are needed for safe collection in children under 14 years of age.

• Testing for asymptomatic individuals should be performed at least twice over three days, with at least twenty-four hours and no more than 48 hours between tests. You may need to purchase additional tests to perform this serial (repeat) testing.

• Do not use the test device if the pouch is damaged or open.

• Keep sealed until usage, and once opened use immediately.

• Test samples immediately after collection.

• Do not use the test device if the pouch is damaged or open.

• Do not re-use the device.

• If you have dropped the test device after sample application, please discard the test device and restart the test using a new test device.

• This test is intended for diagnosis of coronavirus infection by detecting COVID-19 antigen, but should not be used as a sole criterion for the determination of SARS-CoV-2 infection. Other laboratory tests and clinical information (signs and symptoms) should be used and considered for diagnosis.

• Inadequate or inappropriate nasal swab sample collection may yield false test results.

• To obtain accurate results, the test must be performed as indicated in the application (Celltrion SafeKey) and/or Instructions for Use.

• Do not touch the swab head when handling the swab.

• Do not ingest the extraction bu∂er or any of the test components.

• Keep out of reach of children.

• Avoid contact with skin and eyes.

• If contact with the body occurs, rinse with water. If irritation persists, seek medical advice.

• Discard Celltrion DiaTrust™ COVID-19 Ag Home Test in accordance with local, state and federal regulations or accreditation requirements.

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?

Potential risks include:

• Possible discomfort during sample collection.

• Possible incorrect test results (see HOW TO READ THE RESULTS section).

Potential benefits include:

• The results, along with other information, can help you and your healthcare provider make informed decisions about your health.

• 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 test 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 differences in how tests of COVID-19. Molecular tests (also known as PCR tests) detect genetic material from the virus. Antigen tests, such as the Celltrion DiaTrust™ COVID-19 Ag Home Test detect 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 testing. If you test positive, the Celltrion DiaTrust™ COVID-19 Ag Home Test was evaluated by testing a total of 492 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 or out of 14 days of symptom onset. 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 test result means that antigens from COVID-19 were detected and it is very likely you currently have COVID-19 disease. There is a very small chance that a test may 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 history, and your symptoms.

WHAT IF YOU TEST NEGATIVE?

A negative result test indicates no antigens from COVID-19 were detected. It is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19 and negative results are presumptive and may need to be confirmed with a molecular test. This means that you could 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 care 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

The extraction buffer solution in the extraction buffer tube contains a hazardous ingredient as shown in above table. If the extraction buffer solution contacts the skin or eye, immediately wash with plenty of running water. If 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. Israel email: info@humasis.com, via phone: +972-3-8085-6284 or Celltrion USA, Inc. Israel email: celltrionusa.CS@celltrion.com, or via phone: (201) 499-1844

P60-05/IFU/V03-R02/202205

CONC.

Sodium Acetate (0.0682-23-8)

Acute T-2 (oral), H300

0.098%

Acute T-1 (oral), H310

Hazardous chemical information provided by Chemical Safety Data Services (CSDS), 3544 Meridian Avenue, Suite 100, Santa Monica, CA 90404, 1-310-453-6643.
Humasis Co., Ltd.

Distributed by Celltrion USA, Inc.

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

PRECAUTIONS BEFORE THE TEST

Follow the Step-by-Step Instructions available on the Mobile App.

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) camera to download the free Celltrion DiaTrust™ COVID-19 Ag Home Test App (CELLTRION SAFEKEY).
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DIAGNOSTIC RESULTS

If you are positive, seek medical advice immediately.
If you are negative, you do not have COVID-19.
If you are invalid, try again as per the instructions.
Celltrion DiaTrust™ COVID-19 Ag Home Test

Results in 15 Minutes

Sample Collection

2 TESTS

CONTENT

- 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: C
- POSITIVE: C
- INVALID: C

INSTRUCTIONS FOR USE

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