Celltrion DiaTrust™ COVID-19 Ag Home Test

INSTRUCTIONS FOR USE

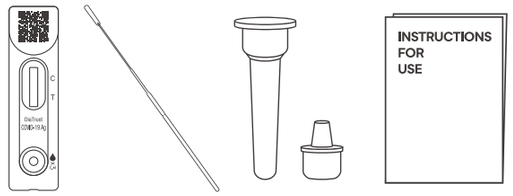
For use under the Emergency Use Authorization (EUA) only.
For *in vitro* diagnostic use.
This test is intended to be used as an aid in the diagnosis of a current infection with the virus that causes COVID-19.
This test is intended for individuals aged 14 years and older only.
Do not use on children under 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 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.
For the most current expiration dates of this test, please refer to: http://www.fda.gov/covid-tests.

WHAT IS INCLUDED IN THIS BOX?

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



√ 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 SAFEKEY). 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://celltrion.safekey.tools** via a computer if any error occurs with the QR code.

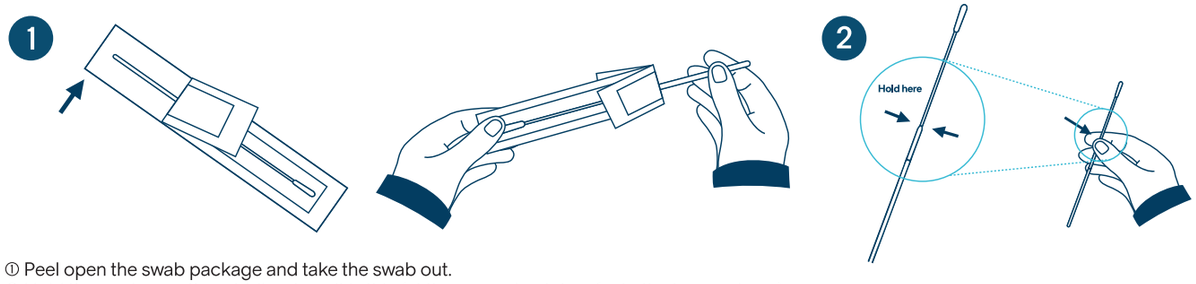
Please Follow the Step-by-Step Instructions Available on the Mobile App.

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.

TEST PROCEDURES

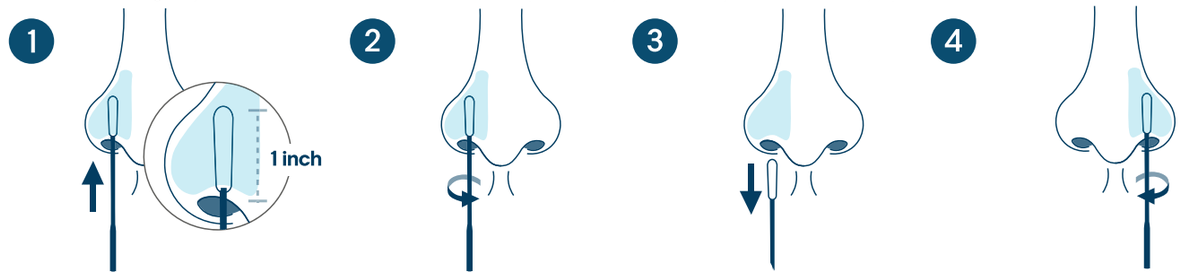
I. Swab Holding Position



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

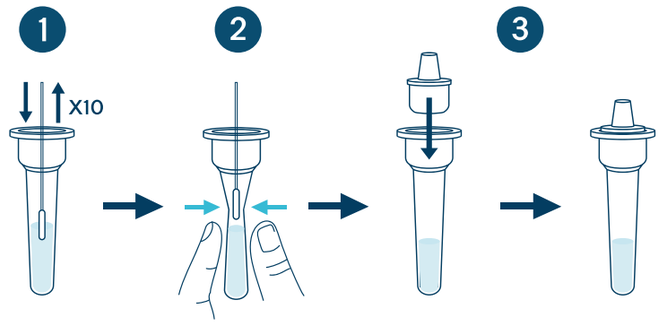
*Incorrect swabbing may lead to an inaccurate test result. This is particularly important if you do not have symptoms.



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 Slowly swirl the swab, gently rubbing it along the insides of your nasal passage several times.
③ Gently remove the swab.
④ 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

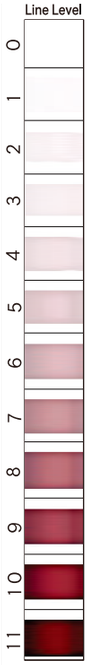


DISPENSATION OF THREE DROPS INTO SAMPLE WELL

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.
Note: False negative results can occur if the specimen is not properly mixed or too vigorously mixed.
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.
√ 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). Follow the instructions based on your test result.
Note: Do not read test results before 15 minutes or after 20 minutes. Results read before 15 minutes or after 20 minutes may lead to a false positive, false negative, or invalid result.

HOW TO READ THE RESULTS

Please make sure to compare your red colored line to the Line Level chart



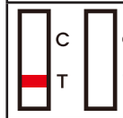
COVID-19 NEGATIVE (-)

If no red colored line appears in the test line (T Line Level 0) and a red colored line is present on the control region (C Line Level 1 - 11), then the result is negative.
To increase the chance that the negative result for COVID-19 is accurate, you should:
- **Test again in 48 hours if you have symptoms on the first day of testing.**
- **Test 2 more times at least 48 hours apart if you do not have symptoms on the first day of testing.**

A negative test result indicates that the virus that causes COVID-19 was not detected in your sample. A negative result is presumptive, meaning it is not certain that you do not have COVID-19. You may still have COVID-19 and you may still be contagious. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR. If you test negative and continue to experience COVID-19-like symptoms, (e.g., fever, cough, and/or shortness of breath) you should seek follow up care with your health care provider.

COVID-19 POSITIVE (+)

If a red colored line is visible in the test line (T Line Level 1 - 11) and control line (C Line Level 1 - 11), the result is positive.
You do not need to perform repeat testing if you have a positive result at any time.
A positive test result means that the virus that causes COVID-19 was detected in your sample and it is very likely you have COVID-19 and are contagious. Please contact your doctor/primary care physician or your local health authority immediately and adhere to the local guidelines regarding self-isolation. There is a very small chance that this test can give a positive result that is incorrect (a false positive).



INVALID

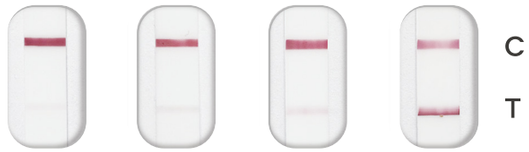
If there is no red colored line in the control region (C Line Level 0), the result is invalid. Re-test with a new swab and new test device.

√ Dispose the test in general waste.

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	Positive	Positive for COVID-19
	Negative	Negative	Negative	Negative for COVID-19

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.
These are photos of actual positive results. Please note that the test line can show up faintly. Any faint visible red test (T) line with the control line (C) should be read as positive.



The Celltrion DiaTrust™ COVID-19 Ag Home Test is for use under Emergency Use Authorization (EUA) only. In the USA, 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)(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.

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 mid-turbinate nasal swab samples from individuals aged 14 years or older. This test is authorized for individuals with symptoms of COVID-19 within the first seven (7) days of symptom onset when tested at least twice over three days with at least 48 hours between tests, and for 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.

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 which 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 and 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 may be necessary.

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 measures such as isolating from others and wearing masks. 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.

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 authorized product to 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 intended for non-prescription self-use or an adult testing another person 14 years or older in a non-laboratory setting. The Celltrion DiaTrust™ COVID-19 Ag Home 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.

HOW TO USE THIS TEST

- Serial testing should be performed in all individuals with negative results; individuals with symptoms of COVID-19 and initial negative results should be tested again after 48 hours. Individuals without symptoms of COVID-19, and with initial negative results, should be tested again after 48 hours and, if the 2nd test is also negative, a 3rd time after an additional 48 hours. You may need to purchase additional tests to perform this serial (repeat) testing.
- If you test negative but continue to have symptoms of COVID-19, and both your first and second tests are negative, you may not have COVID-19, however you should follow-up with your healthcare provider.
- If your test is positive, then proteins from the virus that causes COVID-19 have been found in your sample and you likely have COVID-19.

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.
- A nasal swab sample can be self-collected by an individual age 14 years and older.
- Wear a safety mask or other face-covering when collecting a specimen from a child or another individual.
- Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
- 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 the declaration is terminated or authorization is revoked sooner.
- If you have had symptoms longer than 7 days you should consider testing at least three times over five days with at least 48 hours between tests.
- Do not read test results before 15 minutes or after 20 minutes. Results read before 15 minutes or after 20 minutes may lead to a false positive, false negative, or invalid result.
- **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.**
- Do not use the test device beyond the expiration date.
- Keep sealed until usage, and once opened use immediately.
- Test samples immediately after collection.
- Do not use if any of the test kit contents or packaging is damaged.
- Test components are single-use. 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 buffer or any of the test components.
- Keep testing kit and kit components away from children and pets before and after use. Avoid contact with skin and eyes. Do not ingest any kit components. The reagent solution contains harmful chemicals (see table below). If the solution contacts your body, flush with large amounts of water. **If irritation persists, seek medical advice: http://www.poisonhelp.org or 1-800-222-1222.**

Chemical Name (CAS)	GHS Code for each ingredient	Conc.
Sodium Azide (26628-22-8)	Acute Tox.2 (oral), H300 Acute Tox.1 (dermal), H310	0.09%

- Discard Celltrion DiaTrust™ COVID-19 Ag Home Test in accordance with local, state and federal regulations or accreditation requirements.
- For more information on EUAs please visit: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization
- For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19

LIMITATIONS

- There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to the sensitivity of the test technology. This means that there is a higher chance this test will give a false negative result in an individual with COVID-19 as compared to a molecular test, especially in samples with low viral load.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between March, 2021 and July, 2021. The clinical performance has not been established for 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.
- All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary. If you continue to have symptoms of COVID-19, and both your first and second tests are negative, you may not have COVID-19, however you should follow-up with a healthcare provider.
- If the test is positive, then proteins from the virus that causes COVID-19 have been found in the sample and you likely have COVID-19.
- This test is read visually and has not been validated for use by those with impaired vision or color-impaired vision.
- Incorrect test results may occur if a specimen is incorrectly collected or handled.

FREQUENTLY ASKED QUESTIONS

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 recommendations 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 THE DIFFERENCE BETWEEN AN ANTIGEN AND MOLECULAR TEST?

There are different kinds of tests for the SARS-CoV-2 virus that causes COVID-19. Molecular tests detect genetic material from the virus. Antigen tests, such as the Celltrion DiaTrust™ COVID-19 Ag Home Test, detect proteins from the virus. Due to the lower sensitivity of antigen tests, there is a higher chance this test will give you a false negative result when you have COVID-19 than a molecular test would.

HOW ACCURATE IS THIS TEST?

Clinical studies have shown that antigen tests more accurately determine whether you are infected with the virus that causes COVID-19 when taken multiple times across several days. Repeat testing improves test accuracy. This serial testing approach is recommended to minimize the risk of incorrect results. For more information on the performance of the test and how the performance may apply to you, please refer to the performance data in the Healthcare Provider Instructions for Use (IFU), available at www.diatrustcovid.com.

WHAT IF I HAVE A POSITIVE TEST RESULT?

A positive result means that it is very likely you have COVID-19 because proteins from the virus that causes COVID-19 were found in your sample. You should self-isolate from others and contact a healthcare provider for medical advice about your positive results.

WHAT IF I HAVE A NEGATIVE TEST RESULT?

A negative test result indicates that antigens from the virus that causes COVID-19 were not detected in your sample. However, if you have symptoms of COVID-19, and your first test is negative, you should test again in 48 hours since antigen tests are not as sensitive as molecular tests. If you do not have symptoms and received a negative result, you should test at least two more times with 48 hours in between tests for a total of three tests. If you have a negative result, it does not rule out SARS-CoV-2 infection; you may still be infected and you may still infect others. It is important that you work with your healthcare provider to help you understand the next steps you should take.

WHAT DOES AN INVALID TEST RESULT MEAN?

An invalid result means the test was not able to tell if you have COVID-19 or not. If the test is invalid, a new swab should be used to collect a new nasal specimen and you should test again with a new test.

IMPORTANT

Do not use this test as the only guide to manage your illness. Consult your healthcare provider if your symptoms persist or become more severe.

Individuals should provide all results obtained with this product to their healthcare provider.

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: celltrionusa.CS@celltrion.com, or via phone: (201) 499-1844)

Humasis Co., Ltd.

Site 1: Rm. 114, 502, 504, 604, 604-1, B03-01, B03-02, 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

P60-05/IFU/V04-R02/202303