Celltrion DiaTrust™
COVID-19 Ag Home Test

INSTRUCTIONS FOR USE

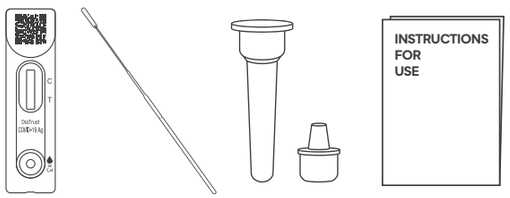
For use under the Emergency Use Authorization (EUA) only.
For *in vitro* diagnostic use.
This test is intended to be used as an aid in the diagnosis of a current infection with the virus that causes COVID-19.
This test is intended for individuals aged 14 years and older only.
Do not use on children under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

STORAGE & STABILITY

Only open the aluminum pouch when you are ready to do the test. Immediately perform the test after opening the pouch. An unopened test device should be stored at **2 - 30°C (36 - 86°F)**. If the tests were refrigerated, keep them at room temperature for 30 minutes prior to use.
It is stable until the expiration date marked on the label.

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 QR code.

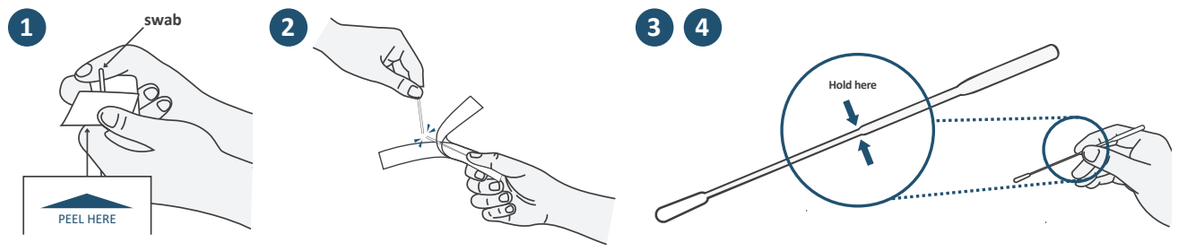
Please Follow the Step-by-Step Instructions Available on the Mobile App.

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

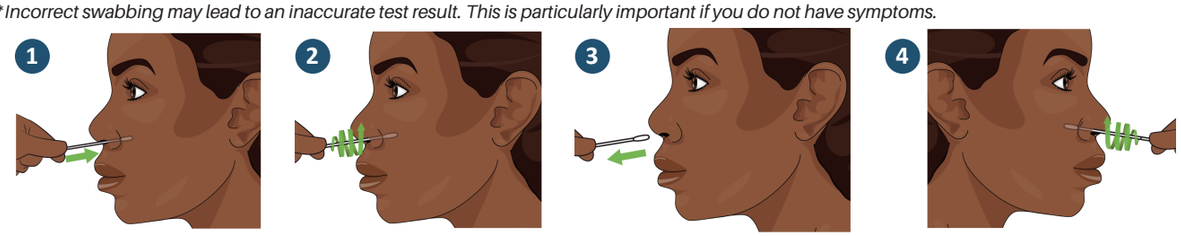
I. Swab Breakpoint and Holding Position



① Look for the “PEEL HERE” sign to peel open the swab package halfway. Make sure the soft tip is still covered with the packaging.
② Identify the breakpoint on the swab and break off the handle.
③ Remove the swab from the package. Do not touch the soft tip or lay it down on any surfaces.
④ You will see two notches on the handle. Make sure to hold the swab at the second notch, as pictured.

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 rotate 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 this process in your other nostril with the same end of the swab.

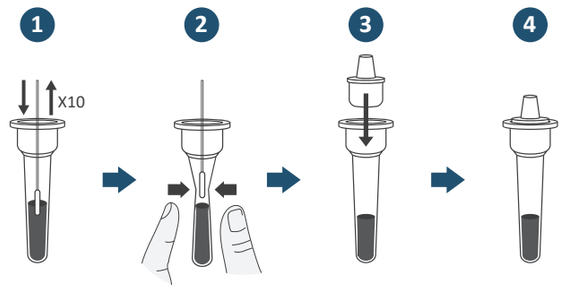
Note: The swab included in the kit is designed for collection of samples from adults. Do not collect swabs from children under 14 years of age.

AFTER SAMPLE COLLECTION

- ✓ Put the tip of the swab into the test tube. Move the swab up and down at least 10 times to ensure sufficient sample extraction is extracted.
- ✓ Remove the swab while pressing against the sides of the tube to ensure maximum amount of liquid has been squeezed from the swab.
  Note: False negative results can occur if the specimen is not properly mixed or too vigorously mixed.
- ✓ Put the filter cap on the opening of the test tube and immediately dispense three drops of sample extract into the sample well of device. Click the “Completed” button and the 15 minute timer will start on the mobile application.
  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. Click the “YES” or “NO” button on the application 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: False negative or false positive can occur if results are read before 15 minutes or after 20 minutes.

Please refer to figure below for AFTER SAMPLE COLLECTION

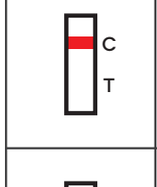
– Collection of buffer fluid –



– Dispensation of three drops into sample well –

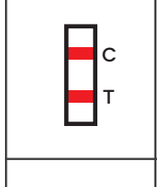
HOW TO READ THE RESULTS

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.



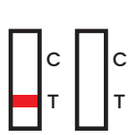
NEGATIVE

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.



POSITIVE

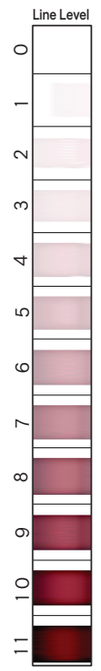
If a red colored line is visible in the test line (T Line Level 1 - 11) and control line (C Line Level 1 - 11), the result is positive.



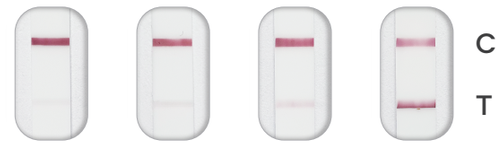
INVALID

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

- ✓ If invalid results are obtained, please discard the device and repeat the testing using a **new** device.
- ✓ Dispose the test in general waste.



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.



- Negative results do not rule out COVID-19.
- In case of negative test result: Continue to follow all social distancing, recommendations and take protective measures. If suspicions of infection persist, repeat the test after 1 - 2 days and consult your doctor or local COVID-19 center.
- 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)(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) of the SARS-CoV-2 spike proteins in mid-turbinate swabs from the SARS-CoV-2 virus. This test is authorized for non-prescription home use with self-collected and adult-collected direct mid-turbinate swab samples from individuals aged 14 years or older with symptoms of COVID-19 within the first seven days of symptom onset.

This test is also authorized for non-prescription home use with self-collected and adult-collected mid-turbinate swab samples from individual 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 and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen and/or receptor binding domain (RBD). These antigens are generally detectable in mid-turbinate swabs 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 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 (LIVD) 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 an adult lay user testing another person 14 years or older.
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 beyond the expiration date.
- Keep sealed until usage, and once opened use immediately.
- Test samples immediately after collection.
- Do not use the test device if the test pouch is damaged or open.
- Do not re-use the 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 extraction liquid.
- 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 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 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 different kinds of tests for 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 isolating at home. There is a higher chance of false negative results with antigen tests than with 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 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, 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 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 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 history, and your symptoms.

WHAT IF YOU TEST NEGATIVE?
A negative test result indicates no antigens for 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 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 follow up 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

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%

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

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