Celltrion DiaTrust™ COVID-19 Ag Home Test

Celltrion DiaTrust™ COVID-19 Ag Home Test is a lateral flow immuno assay 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.

- Direct Mid-Turbinate Swab Samples
- Non-prescription Home Use (OTC)
- Result in 15 minutes

Product **Specifications**

Sample Type	DIRECT MID-TURBINATE SWAB SAMPLES
Storage Temperature	2 - 30°C (36 - 86°F)
Sample-to-answer time	15 mins

Contents

- 2 test cassettes with test
- strip 2 extraction buffers
- 2 filter caps
- 2 swabs
- 1 Instruction For Use

*** This content is applicable for 2 Tests Kit packaging.**
*** 1 pack and 5 pack kits also available**

Clinical Performance

All subjects

- Positive Percentage Agreement: 86.7 % (95% CI: 73.8%-93.7%)
- Negative Percentage Agreement: 99.8 % (95% CI: 98.7%-100.0%)

Symptomatic subjects

- Positive Percentage Agreement: 86.1% (95% CI: 71.3% - 93.9%)
- Negative Percentage Agreement: 99.4% (95% CI: 96.8% - 99.9%)

Asymptomatic subjects

- Positive Percentage Agreement: 88.9 % (95% CI: 56.8%-98.0%)
- Negative Percentage Agreemtn: 100.0% (95% CI: 98.6%-100.0%)

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203.930.2154 hello@liloclean.com

Celltrion DiaTrust™ COVID-19 Ag Home Test

Precautions and Warnings

- For in vitro diagnostic use only
- This product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization (EUA).
- 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.
- All the results within the United States and its territories are required to be reported to the appropriate public health authorities.
- This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
- 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 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 sample collection may yield false test results.
- To obtain accurate results, the test must be performed as indicated in the Instructions for Use
- Results should be read within 15 minutes. If the test is read before 15 minutes or after 20 minutes, false negative or false positive results may occur.
- Inadequate or improper nasal swab sample collection may result in false negative test results.
- Do not touch the swab head when handling the swab.
- Do not ingest.
- 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.

Limitations

- 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.
- 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 a COVID-19.
- 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
- This test detects both viable (live) and non-viable SARS-CoV-2. Test performance depends on the amount of virus (antigens) in the sample and may or may not correlate with viral culture results performed on the same sample.
- A negative test result may occur if the level of antigens in a sample is below the detection limit of the test or if the sample was collected or transported improperly.
- Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result.
- Test results must be evaluated in conjunction with other clinical data available to the physician.
- Positive test results do not rule out co-infections with other pathogens.
- Negative test results are not intended to rule in other non-SARS-CoV-2 viral or bacterial infections.
- Negative results should be treated as presumptive and confirmed with an FDA-authorized molecular assay, if necessary, for clinical management.
- Performance of nasal swabs collected from patients without symptoms or other epidemiological reasons to suspect COVID-19 infection or for serial screening, when tested twice over two to three days with at least 24 but not more than 48 hours between tests has not yet been determined; a study to support use will be completed.
- If the differentiation of specific coronaviruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.
- The amount of antigen in a sample may decrease as the duration of illness increases. Specimens collected after seven days are more likely to be negative compared to RT-PCR. The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between March and July of 2021. The clinical performance has not been established in 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.
- The Celltrion DiaTrust™ COVID-19 Ag Home Test does not differentiate between SARS-CoV and SARS-CoV-2.

*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 SARSCoV-2, not for any other viruses or pathogens; and, 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.

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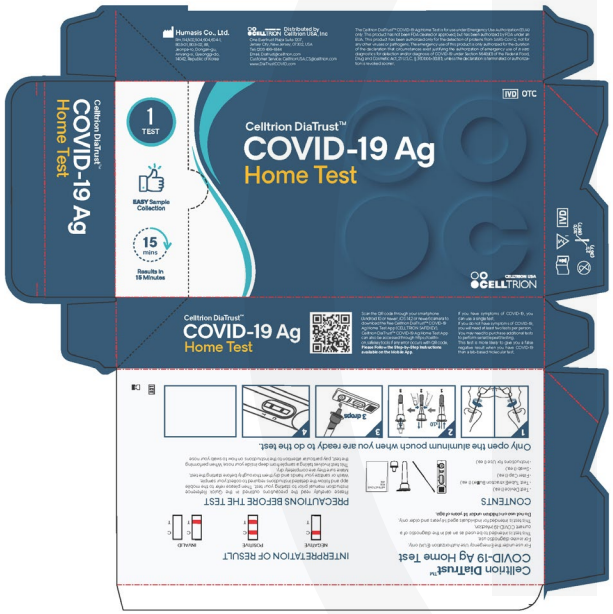
Humasis Co., Ltd.
Distributed by
Celltrion USA, Inc
Celltrion DiaTrust™
COVID-19 Ag
Home Test
1
TEST
EASY Sample Collection
15
mins
Results in 15 Minutes
IVD
OTC
CELLTRION USA
CELLTRION
Scan the QR code through your smartphone.
If you have symptoms of COVID-19, you can use a single test.
If you do not have symptoms of COVID-19, you will need at least two tests per person.
Please Follow the Step-by-Step Instructions available on the Inside Ap
This test is more likely to give you a false negative result when you have COVID-19 than a test does from our nos
Only open the aluminum pouch when you are ready to do the test.
1
2
3 drops
3
4
CONTENTS
PRECAUTIONS BEFORE THE TEST
INTERPRETATION OF RESULT
NEGATIVE
POSITIVE
INVALID


Humasis Co., Ltd.
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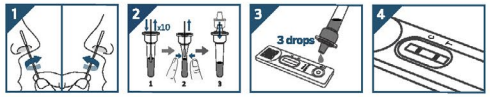

INTERPRETATION OF RESULT

PRECAUTIONS BEFORE THE TEST

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.
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.

CELLTRION USA
CELLTRION

Celltrion DiaTrust™
COVID-19 Ag
Home Test

Results in 15 Minutes
EASY Sample Collection

For in vitro diagnostic use.
This test is intended to be used as an aid in the diagnosis of a current COVID-19 infection.
This test is intended for individuals aged 14 years and older only.
Do not use on children under 14 years of age

LOT

25 TESTS/KIT

For use under the Emergency Use Authorization (EUA) only.

IVD OTC

CELLTRION USA
CELLTRION

Celltrion DiaTrust™
COVID-19 Ag
Home Test

Results in 15 Minutes
EASY Sample Collection

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

CELLTRION USA
CELLTRION

Celltrion DiaTrust™
COVID-19 Ag
Home Test

15 mins
Results in 15 Minutes
EASY Sample Collection

CELLTRION USA
CELLTRION

Celltrion DiaTrust™
COVID-19 Ag
Home Test

Humasis Co., Ltd
Rm.114,502,504,604,604-1, B03-01, B03-02,
88, Jeongja-ro, Bongdan-gu, Anyang-si,
Gyeonggi-do, 14042, Republic of Korea

Distributed by Celltrion USA, Inc.
One Evertrust Plaza Suite 1207,
Jersey City, New Jersey, 07302, USA
Tel: (201) 499-1944
Email: DiaTrust@celltrion.com
Customer Service: CelltrionUSA.CS@celltrion.com
www.DiaTrustCOVID.com

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REF CT-P60 D-2 05

Celltrion DiaTrust™
COVID-19 Ag
Home Test

25 TESTS/KIT

CELLTRION USA
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Celltrion DiaTrust™
COVID-19 Ag
Home Test

Scan the QR code through your smartphone (Android 6 or Newer, iOS 10.0 or newer) camera to download the Celltrion DiaTrust™ COVID-19 Ag Home Test App. (CELLTRION DiaTrust, Celltrion DiaTrust™ COVID-19 Ag Home Test App can also be accessed through https://celltrion.us/diatrust if anyone occurs with QR recognition.)
Please 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 repeat testing.
To ensure reliable test results, a false negative result when you have COVID-19 than a lab-based molecular test.

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.

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Celltrion DiaTrust™
COVID-19 Ag Home Test

INSTRUCTIONS FOR USE

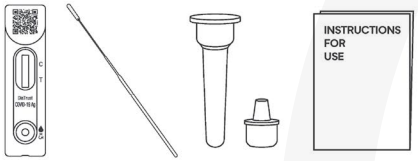
For use under the Emergency Use Authorization (EUA) only.
For *in vitro* diagnostic use.
This test is intended to be used as an aid in the diagnosis of a current infection with the virus that causes COVID-19.
This test is intended for individuals aged 14 years and older only.
Do not use on children under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

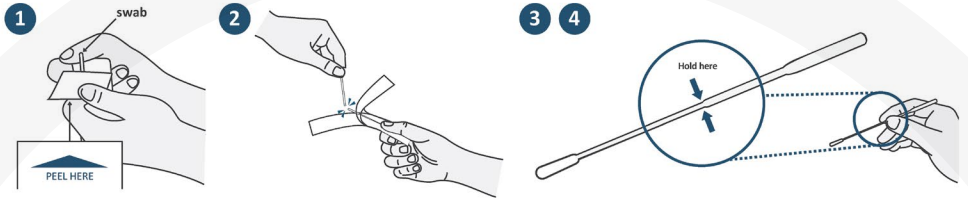
Please Follow the Step-by-Step Instructions Available on the Mobile App.

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

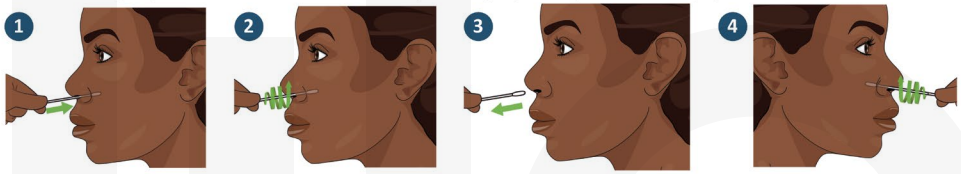
I. Swab Breakpoint and Holding Position



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.*



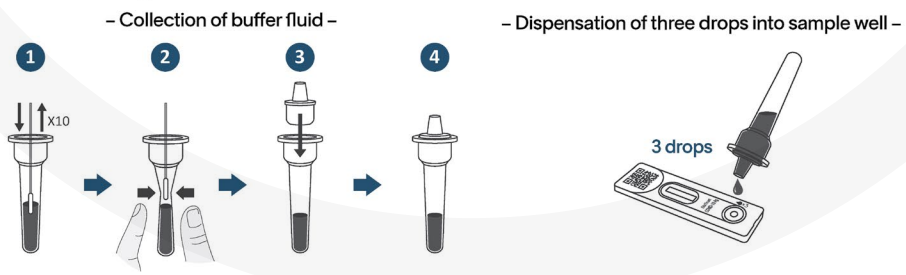
① Insert the entire soft end of the swab straight back into your nostril less than one inch (about 2 cm) or until resistance is felt.
② Slowly rotate the swab, gently rubbing it along the insides of your nasal passage several times.
③ Gently remove the swab.
④ Using the **same** swab, repeat this process 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

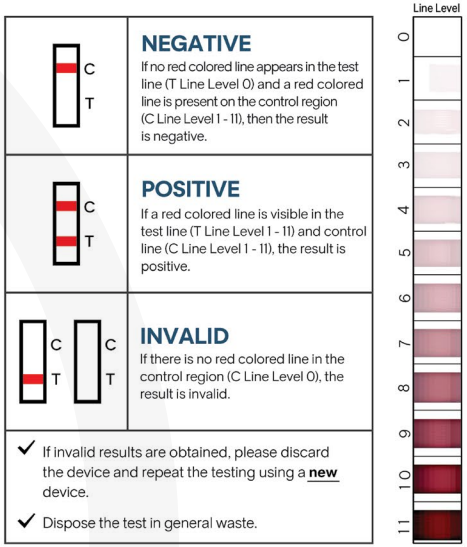
- ✓ Put the tip of the swab into the test tube. Move the swab up and down at least 10 times to ensure sufficient sample extraction is extracted.
- ✓ Remove the swab while pressing against the sides of the tube to ensure maximum amount of liquid has been squeezed from the swab.
  Note: False negative 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



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.



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 (26628-228)	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)

Humasis Co., Ltd.
Rm. 114, 502, 504, 604, 604-1, B03-01, B03-02,
88, Jeongja-ro, Bundang-gu, Anyang-si,
Gyeonggi-do, 14042, Republic of Korea
Fax: (201) 803-6767

Celltrion DiaTrust™ COVID-19 Ag Home Test

Healthcare Provider Instructions for Use

For use under the Emergency Use Authorization (EUA) only

For in vitro diagnostic 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. 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 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 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 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.

[SUMMARY AND EXPLANATION]

Coronavirus is a group of viruses that belongs to the Family Coronaviridae; a type of RNA virus of 27 - 32 kb commonly found in birds and mammals including human. Coronavirus is divided into four genera: alpha, beta, gamma and delta. The virus causes illness ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS-CoV) and Severe Acute Respiratory Syndrome (SARS-CoV).

Coronavirus disease 2019 (COVID-19) is a new strain caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The disease originated from Wuhan city of China in December 2019. The World Health Organization (WHO) publicly named this virus 'COVID-19' and declared it a pandemic and a Public Health Emergency of International Concern. The infection is typically spread from one person to another via direct contact or respiratory droplets from cough or sneeze. Latent period from exposure to onset of symptoms is between one to fourteen days (four to seven days on average). Common symptoms and signs of infection include fever, cough, shortness of breath and breathing difficulties. In severe cases, infections can cause pneumonia, severe acute respiratory syndrome, kidney failure and even death.

Due to the wide variety of symptoms, it is difficult to differentiate COVID-19 from other existing respiratory viruses or bacteria. Diagnosing COVID-19 through isolating the virus or detecting specific genes from the collected respiratory droplet specimens is a challenge in terms of time and accessibility as it requires long hours, well-equipped laboratory and advanced technology which are often not available to many public. The test is designed to detect antigen to SARS-CoV-2, and it will help assess if an individual has COVID-19 antigen within 15 minutes r.

[TEST PRINCIPLE]

The Celltrion DiaTrust™ COVID-19 Ag Home Test is a lateral flow immunoassay test. The Celltrion DiaTrust™ COVID-19 Ag Home Test is designed to detect antigens from the SARS-CoV-2 from direct mid-turbinate swab samples from individuals with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over two or three days with at least 24 hours but not more than 48 hours between tests. This test is also authorized to detect antigens from the SARS-CoV-2 from 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 authorized for non-prescription home use with mid-turbinate nasal swab specimens from individuals aged 14 years and older. The Celltrion DiaTrust™ COVID-19 Ag Home Test is validated for use from direct specimens testing without transport media.

A nitrocellulose membrane strip in the device having a test line and a control line, wherein the test line is pre-coated with anti-mouse monoclonal antibody to SARS-CoV-2 to detect SARS-CoV-2 nucleocapsid and RBDs from the SARS-CoV-2 spike proteins, and the control line is coated with goat anti-mouse IgG. When the extracted swab specimen is dispensed into to the sample well, the specimen migrates towards the conjugate pad, which contains conjugated antibodies with colloidal gold directed against the SARS-CoV-2 antigen. When the sample contains SARS-CoV-2 antigens, an antigen-antibody-conjugate complex is formed. The sample-conjugate complex then passes over the membrane until it reaches the capture zone (test line). Here, the complex is bound to immobilized antibodies and form

visible colored band in the test line. The sample then migrates across the membrane along the strip until it reaches the control line where excess conjugate binds and produces a second visible line on the membrane. This control line indicates that the sample has migrated across the membrane as intended and indicates that the test was correctly performed. This test does not use biotin-Streptavidin/avidin chemistry in any of the steps for coupling reagents.

[MATERIALS SUPPLIED]

Kit components	Quantity			
	1 Test Kit	2 Tests Kit	5 Tests Kit	25 Tests Kit
Test cassette with test strip	1 ea/box	2 ea/box	5 ea/box	25 ea/box
Extraction buffer (0.3 mL / test tube)[1]	1 ea/box	2 ea/box	5 ea/box	25 ea/box
Filter cap	1 ea/box	2 ea/box	5 ea/box	25 ea/box
Swab	1 ea/box	2 ea/box	5 ea/box	25 ea/box
Instructions for Use	1 ea/box	1 ea/box	1 ea/box	1 ea/box

[1] Extraction buffer is provided in the sealed test tube.

[MATERIALS REQUIRED BUT NOT PROVIDED]

- Celltrion DiaTrust™ COVID-19 Ag Home Test Application (Celltrion SafeKey)
- Smartphone for using App, Celltrion SafeKey (Android 10 or newer, iOS 14.2 or newer)
- Compatible computer for web-based App (https://celltrion.safekey.tools)

[PRECAUTIONS AND WARNINGS]

- For in vitro diagnostic use only
- This product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization (EUA).
- 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.
- All the results within the United States and its territories are required to be reported to the appropriate public health authorities.
- This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
- 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 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 sample collection may yield false test results.

- To obtain accurate results, the test must be performed as indicated in this Instructions for Use
- Results should be read within 15 minutes. If the test is read before 15 minutes or after 20 minutes, false negative or false positive results may occur.
- Inadequate or improper nasal swab sample collection may result in false negative test results.
- Do not touch the swab head when handling the swab.
- Do not ingest
- 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.

[LIMITATIONS]

- 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.
- 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 a COVID-19.
- 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
- This test detects both viable (live) and non-viable SARS-CoV-2. Test performance depends on the amount of virus (antigens) in the sample and may or may not correlate with viral culture results performed on the same sample.
- A negative test result may occur if the level of antigens in a sample is below the detection limit of the test or if the sample was collected or transported improperly.
- Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result.
- Test results must be evaluated in conjunction with other clinical data available to the physician.
- Positive test results do not rule out co-infections with other pathogens.
- Negative test results are not intended to rule in other non-SARS-CoV-2 viral or bacterial infections.
- Negative results should be treated as presumptive and confirmed with an FDA-authorized molecular assay, if necessary, for clinical management.
- Performance of nasal swabs collected from patients without symptoms or other epidemiological reasons to suspect COVID-19 infection or for serial screening, when tested twice over two to three days with at least 24 but not more than 48 hours between tests has not yet been determined; a study to support use will be completed.
- If the differentiation of specific coronaviruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.
- The amount of antigen in a sample may decrease as the duration of illness increases. Specimens collected after seven days are more likely to be negative compared to RT-PCR.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between March and July of 2021. The clinical performance has not been established in 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.

- The Celltrion DiaTrust™ COVID-19 Ag Home Test does not differentiate between SARS-CoV and SARS-CoV-2.

CHEMICAL HAZARD AND SAFETY INFORMATION

Hazardous ingredients for the extraction buffer

Chemical Name (CAS)	Material Safety Data Sheet	GHS Code for each ingredient	Conc.
Sodium Azide (26628-22-8)	Material Safety Data Sheet	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.

[STORAGE AND STABILITY]

An unopened test device should be stored at 2 - 30°C (36 - 86°F). It is stable until the expiration date marked on the label. Do not open the aluminum pouch until you are ready to use the test device. Use the test device immediately after opening the aluminum pouch. If the tests were refrigerated, keep them at room temperature for 30 minutes prior to use.

[QUALITY CONTROL]

A procedural internal control is built in the 'control line (c)' of the device and is used to ensure that the applied specimen has migrated well into the device. It is coated with goat anti-mouse IgG and a red colored line will always appear when the test is performed properly.

External run controls are not required to use the Celltrion DiaTrust™ COVID-19 Ag Home Test.

[TEST PROCEDURE]

When opening the test device, download the mobile application (Celltrion SafeKey) using QR code from Instructions for Use provided with the test kit and follow the instructions as described in the mobile application.

1. Test Preparation

   Following the instruction in the mobile application, when you are ready to proceed with the test, tear open the two aluminum pouches.

   1) Prepare the aluminum pouch containing the test device and place it on the testing surface along with the reagents from the second aluminum pouch - test tube filled 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.

      ** Testing should be completed within 30-60 minutes of opening the pouch.*

2) Remove the test device, test tube and filter cap from the aluminum pouches and place it on a flat surface just prior to starting test.

3) Scan the QR code on the test device through your mobile phone camera. If you are having difficulty scanning the QR on the test device, you may type the serial number into the input box below. The serial number is printed on the test device.

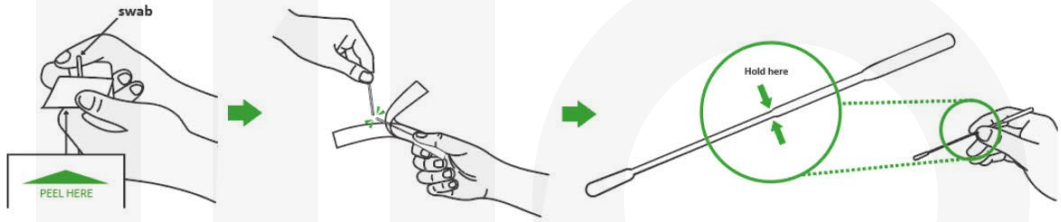
4) Fill out the requested personal information and symptoms about the person who will be tested.

2. Specimen collection (CDC guideline):

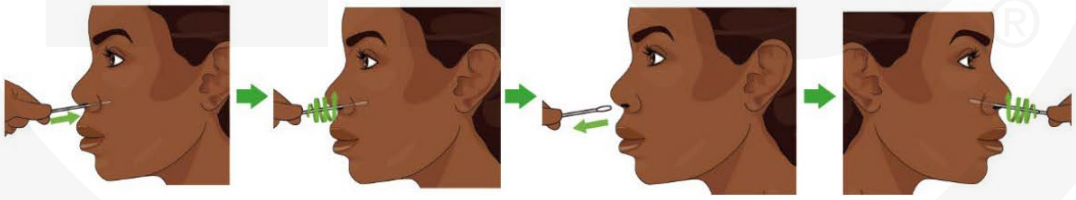
Use only the swabs provided with the test kit (FA/FANAB01 and Miraclean Technology, Item No. 96000) for specimen collection following the instruction on the mobile application.

1) Make sure extraction buffer tube and filter cap are also readily available before starting sample collection, as the collected swab sample must be immediately inserted into the extraction buffer tube for sample extraction. After swabbing, immediately insert the swab into extraction buffer tube. Do not leave the sampled swab dry in open air as it may result in incorrect test results.

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



3) Insert the entire soft end of the swab straight back into your nostril less than one inch (about 2cm) or until resistance is felt. Slowly rotate the swab, gently rubbing it along the insides of your nasal passage several times. Gently remove the swab. 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.

3. Test method

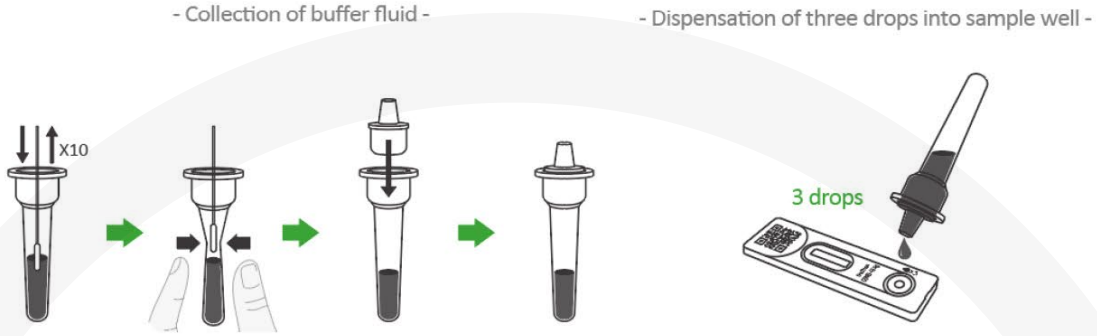
1) Put the tip of the swab into the test tube. Move the swab up and down at least 10 times to ensure sufficient sample is extracted.

2) Remove the swab while pressing against the sides of the tube to ensure maximum amount of liquid has been squeezed from the swab.

** Avoid swabbing and inserting excessive amount of mid-turbinate nasal specimen into the test tube, as it may block the filter cap when dispensing sample extracts.*

***Note:** False negative results can occur if the specimen is not properly mixed or too vigorously mixed.*

3) Put the filter cap on the opening of 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 test device and restart the test using a new test device.*

***Note:** Adding only one drop of solution or the entire vial may result in false negative results.*

4) Click the "Completed" button and the 15 minute timer will start on the mobile application.

5) Read results 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 results can occur if results are read before 15 minutes or after 20 minutes.

** You will be instructed to take a picture of the test device. Please note that the photos are not processed and have no effect on reported results. They are collected for future reference only.*

6) Dispose the remainder of the test in general waste.

[INTERPRETATION OF RESULTS]

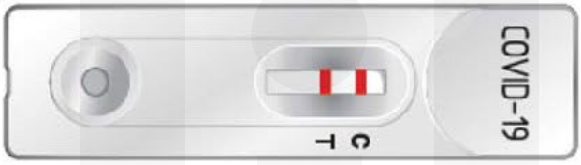
- Negative result: If no red colored line appears in the test line (T) and a red colored line is present on the control region (C), then the result is negative. A negative result indicates viral antigens were not detected in the specimen and the individual is presumed negative for COVID-19.
  - Negative 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 and/or your first test is negative, repeat the test after 1 - 2 days and consult your healthcare provider or local COVID-19 center.
  - Note: A negative result is presumptive and confirmation with a molecular assay, if necessary, for patient management may be performed.

    For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary after second negative result for asymptomatic patients, if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with as 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 SARS-CoV-2 or residing in communities with low prevalence of

infection.

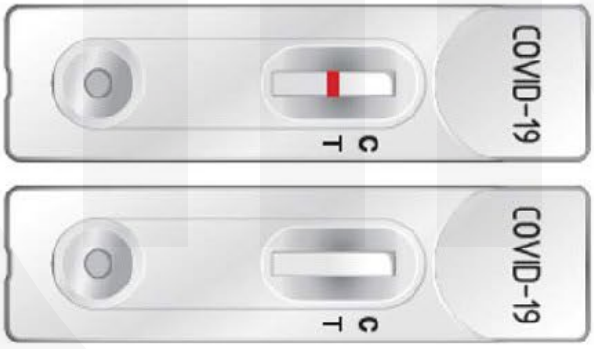
- Positive result: If red colored line is visible in the test line (T) and control line (C), the result is positive. A positive result indicates that viral antigens from COVID-19 were present in the specimen and the individual is positive for COVID-19.

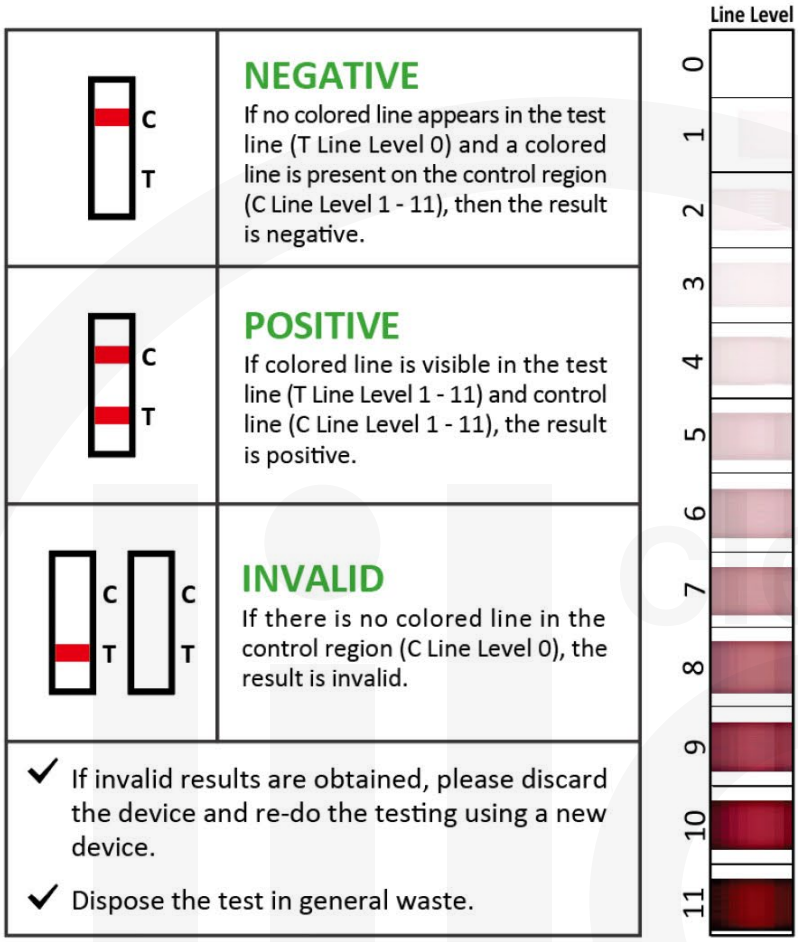
  - Persons who test positive with the Celltrion DiaTrust™ COVID-19 Ag Home Test should self-isolate and seek follow up care with their physician or healthcare provider as additional testing and public health reporting may be necessary.



- Invalid result: If there is no red colored line in the control region (C), the result is invalid.

  - In case of an invalid test result: Repeat the test using new test kit. If the test result is still invalid, contact your doctor or local COVID-19 center. An invalid results does not indicate if the individual did or did not have COVID-19 and should be repeated.





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.

[PERFORMANCE CHARACTERISTICS]

Analytical testing is conducted with the nasopharyngeal swab specimen, and the matrix equivalency study is conducted to support mid-turbinate nasal swab as the specimen type.

1) Limit of detection (LoD)

LoD studies determine the lowest detectable concentration of SARS-CoV-2. The LoD was determined by limiting dilution studies using SARS-CoV-2 virus inactivated by beta-Propiolactone (BPL).

Negative sample was prepared by collecting nasopharyngeal swab samples from healthy donors (negative clinical matrix) eluted in PBS.

The positive standard materials are prepared with the six different concentrations of SARS-CoV-2 inactivated virus (Conc. 6.3×10^5 $TCID_{50}$/mL, NMC-nCoV02 #24) that is serially diluted in PBS and negative clinical matrix.

The diluted positive standard materials are applied to the swab tip with 100 µL of approximate absorption volume. The extraction buffer tubes are prepared and each swab samples are inserted into each extraction buffer tubes. The swab was moved up and down inside the tube 10 times and taken out by pressing to remove the extracted liquid. The filter cap was equipped onto the test tube, then three drops of extracts (100 µL) was dispensed into the sample inlet. The result was read 15 minutes after applying the sample.

Serial dilutions of the inactivated SARS-CoV-2 were tested in 5 replicates. The lowest concentration at which all 5 replicates were positive was treated as the tentative LoD for each test. Based on this testing, the tentative LoD was 3.2×10^1 $TCID_{50}$/mL.

The LoD of each test was then confirmed by testing 20 replicates with concentrations near the tentative limit of detection. The final LoD of Celltrion DiaTrust™ COVID-19 Ag Home Test was determined to be the lowest concentration resulting in positive detection more than 95% of the time, which is at least 19 out of 20 replicates.

In conclusion, the limit of detection (LoD) of Celltrion DiaTrust™ COVID-19 Ag Home Test for NP swab is 3.2×10^1 $TCID_{50}$/mL.

3) Cross-reactivity (Analytical specificity) and Microbial Interference Studies

Wet-testing:

The study was performed to evaluate the cross-reactivity of the Celltrion DiaTrust™ COVID-19 Ag Home Test.

Nasopharyngeal swab sample from healthy donors (negative clinical matrix) were collected and eluted in extraction buffer to be used as a negative standard material. For each test, the diluted sample was added to a sterile nasal swab before conducting the test according to the instruction for use. Positive standard materials (NMC-nCoV02 #24, 6.3×10^5 $TCID_{50}$/mL) were spiked into negative sample and were diluted to make low concentration level (6.3×10^1 $TCID_{50}$/mL, approx. 2xLoD) for testing.

Potential cross-reactive organisms listed in the below table were prepared at the concentration of 10^5 PFU/mL or higher for viruses and 10^6 CFU/mL or higher for bacteria. They were spiked into the negative and low positive samples and were tested in 3 replicates. A total of 31 pathogens listed in the below table showed no cross-reactivity with the Celltrion DiaTrust™ COVID-19 Ag Home Test.

List of organisms		Testing conc.	Test result	
			Negative (No. of negative/ No. of replicates)	**Low Positive** (No. of positive/ No. of replicates)
Other high priority pathogens from the same virus family	Coronavirus OC43	4.4×10^7 PFU/mL	3/3	3/3
	Coronavirus 229E	3×10^6 PFU/mL	3/3	3/3
	Coronavirus NL63	1×10^5 $TCID_{50}$/mL	3/3	3/3
	MERS-coronavirus	1.183×10^5 $TCID_{50}$/mL	3/3	3/3
Other high priority organisms	Human adenovirus 1	7×10^7 PFU/mL	3/3	3/3
	Human adenovirus 3	2.4×10^6 PFU/mL	3/3	3/3
	Human adenovirus 5	4.0×10^7 PFU/mL	3/3	3/3
	Human adenovirus 7	2.0×10^8 PFU/mL	3/3	3/3
	Respiratory syncytial virus A	8.0×10^5 PFU/mL	3/3	3/3
	Respiratory syncytial virus B	2.4×10^6 PFU/mL	3/3	3/3
	Parainfluenza 1	2.8×10^5 PFU/mL	3/3	3/3
	Parainfluenza 2	2×10^7 PFU/mL	3/3	3/3
	Parainfluenza 3	8×10^5 PFU/mL	3/3	3/3
	Parainfluenza 4a	1.3×10^8 PFU/mL	3/3	3/3
	Rhinovirus 1	1.4×10^5 PFU/mL	3/3	3/3
	Metapneumovirus	6×10^5 PFU/mL	3/3	3/3
	Human enterovirus	1×10^5 PFU/mL	3/3	3/3
	Influenza A H1N1	2×10^5 PFU/mL	3/3	3/3
	Influenza A H3N2	4.9×10^6 PFU/mL	3/3	3/3
	Influenza B	1×10^6 PFU/mL	3/3	3/3
	Mycoplasma pneumonia (whole organism)	1×10^7 CFU/mL	3/3	3/3
	Streptococcus pyogenes	1×10^6 CFU/mL	3/3	3/3
	Bordetella pertussis	1×10^6 CFU/mL	3/3	3/3
	Streptococcus pneumoniae	1×10^6 CFU/mL	3/3	3/3
	Legionella pneumophila	1×10^6 CFU/mL	3/3	3/3
	Haemophilus influenzae	1×10^6 CFU/mL	3/3	3/3
	Candida albicans	1×10^6 CFU/mL	3/3	3/3
	Chlamydia pnuemoniae	2.0×10^7 $TCID_{50}$/mL	3/3	3/3
	Pooled human nasal wash	100%	3/3	3/3
	Staphylococcus epidermidis	1×10^6 CFU/mL	3/3	3/3
	Staphylococcus aureus	1×10^6 CFU/mL	3/3	3/3

Human coronavirus HKU1 spike protein at the concentration of 10 µg/mL was spiked into negative and positive samples. It was tested in 3 replicates using the Celltrion DiaTrust™ COVID-19 Ag Home Test, and no cross-reactivity was observed.

In-silico:

To estimate the likelihood of cross-reactivity with SARS-CoV-2 virus in the presence of organisms that were not available for wet testing, *in silico* analysis was used to assess the degree of protein sequence homology.

- Human coronavirus HKU1: 25% homology was found between SARS-CoV-2 Receptor Binding Domain spike proteins and HKU1 spike protein, and 44% homology was found between SARS-CoV-2 Nucleocapsid protein and HKU1 Nucleocapsid protein. Therefore, cross-reactivity cannot be ruled out.
- *Pneumocystis jirovecii*: No significant similarity was found between SARS-CoV-2 RBD spike protein / nucleocapsid protein and *P. jirovecii*. But minor similarity was found between some partial proteins of P. jirovecii RU 7and SARS-CoV-2 RBD spike protein / nucleocapsid protein. Therefore, cross-reactivity cannot be ruled out.
- *Mycobacterium tuberculosis*: No significant similarity was found between *M. tuberculosis* and SARS-CoV-2 RBD spike protein / nucleocapsid protein despite of increasing expect threshold.
- SARS-CoV: 72% homology was found between SARS-CoV-2 Receptor Binding Domain spike proteins and SARS-CoV spike protein, and 96% homology was found between SARS-CoV-2 Nucleocapsid protein and SARS-CoV Nucleocapsid protein. Therefore, cross-reactivity is highly likely.
- The Celltrion DiaTrust™ COVID-19 Ag Home Test does not differentiate between SARS-CoV and SARS-CoV-2.

Endogenous interference substances study:

Test to evaluate interference of the Celltrion DiaTrust™ COVID-19 Ag Home Test was performed.

Extraction buffer was used as negative sample. Positive standard materials were spiked into negative sample and were diluted to make low concentration level (6.3×10^1 $TCID_{50}$/mL, approx. 2xLoD) for testing.

Potential interfering substances were added to the negative and positive samples and were tested using the Celltrion DiaTrust™ COVID-19 Ag Home Test in 3 replicates. The test results demonstrated that 48 interfering substances did not affect the performance of Celltrion DiaTrust™ COVID-19 Ag Home Test.

No.	Interfering substances	Testing conc.	Negative	Negative + Interfering substances	Low positive	Low pos. + Interfering substances
1	Whole blood	4%	3/3*	3/3*	3/3**	3/3**
2	Mucin	0.5%	3/3*	3/3*	3/3**	3/3**
3	Chloraseptic	1.5 mg/mL	3/3*	3/3*	3/3**	3/3**
4	NeilMed NasoGel	5% v/v	3/3*	3/3*	3/3**	3/3**
5	CVS Nasal drops	15% v/v	3/3*	3/3*	3/3**	3/3**
6	Afrin (Oxymetazoline)	15% v/v	3/3*	3/3*	3/3**	3/3**
7	Sodium cromoglycate	15% v/v	3/3*	3/3*	3/3**	3/3**

No.	Interfering substances	Testing conc.	Negative	Negative + Interfering substances	Low positive	Low pos. + Interfering substances
	(CVS nasal spray, Cromolyn)					
8	Zicam	15% v/v	3/3*	3/3*	3/3**	3/3**
9	Homeopathic (Alkalol)	1:10 dilution	3/3*	3/3*	3/3**	3/3**
10	Sore throat Phenol Spray	15% v/v	3/3*	3/3*	3/3**	3/3**
11	Tobramycin	5 µg/mL	3/3*	3/3*	3/3**	3/3**
12	Mupirocin	10 mg/mL	3/3*	3/3*	3/3**	3/3**
13	Fluticasone Propionate	5% v/v	3/3*	3/3*	3/3**	3/3**
14	Tamiflu (Oseltamivir Phosphate)	5 mg/mL	3/3*	3/3*	3/3**	3/3**
15	Albumin, human	3000 mg/dL	3/3*	3/3*	3/3**	3/3**
16	Bilirubin	500 µmol/L	3/3*	3/3*	3/3**	3/3**
17	Hemoglobin	500 mg/dL	3/3*	3/3*	3/3**	3/3**
18	Cholesterol	20 µmol/L	3/3*	3/3*	3/3**	3/3**
19	Triglyceride	1000 mg/dL	3/3*	3/3*	3/3**	3/3**
20	Biotin	0.75 mg/mL	3/3*	3/3*	3/3**	3/3**
21	Sodium citrate	25 mg/mL	3/3*	3/3*	3/3**	3/3**
22	Heparin	100 U/mL	3/3*	3/3*	3/3**	3/3**
23	EDTA	5 µmol/L	3/3*	3/3*	3/3**	3/3**
24	K3-EDTA	20 mg/mL	3/3*	3/3*	3/3**	3/3**
25	Diphenhydramine hydrochloride	5 mg/mL	3/3*	3/3*	3/3**	3/3**
26	Acetaminophen	199 µmol/L	3/3*	3/3*	3/3**	3/3**
27	Acetylsalicylic acid	3.62 mmol/L	3/3*	3/3*	3/3**	3/3**
28	Ibuprofen	2.425 mmol/L	3/3*	3/3*	3/3**	3/3**
29	Olopatadine hydrochloride	5 mg/mL	3/3*	3/3*	3/3**	3/3**
30	Hanmi Ko-and-Cool Nasal Spray (Chlorpheniramine Maleate 250 mg/ 100 mL, Xylometazoline Hydrochloride 0.1 g/100 mL)	10%(v/v)	3/3*	3/3*	3/3**	3/3**
31	Samchundang Narista-S Nasal Spray (Chlorpheniramine Maleate 2.5 mg/mL, Dipotassium Glycyrrhizinate 3 mg/mL, Naphazoline Hydrochloride 0.5 mg/mL)	10%(v/v)	3/3*	3/3*	3/3**	3/3**
32	Sodium chloride	20 mg/mL	3/3*	3/3*	3/3**	3/3**
33	Zanamivir	5 mg/mL	3/3*	3/3*	3/3**	3/3**

No.	Interfering substances	Testing conc.	Negative	Negative + Interfering substances	Low positive	Low pos. + Interfering substances
34	Oseltamivir	10 mg/mL	3/3*	3/3*	3/3**	3/3**
35	Artemether-lumefantrine	50 µmol/L	3/3*	3/3*	3/3**	3/3**
36	Doxycycline hyclate	70 µmol/L	3/3*	3/3*	3/3**	3/3**
37	Quinine	150 µmol/L	3/3*	3/3*	3/3**	3/3**
38	Lamivudine	1 mg/mL	3/3*	3/3*	3/3**	3/3**
39	Erythromycin	81.6 µmol/L	3/3*	3/3*	3/3**	3/3**
40	Ciprofloxacin	30.2 µmol/L	3/3*	3/3*	3/3**	3/3**
41	Rheumatoid factor positive plasma	10%(v/v)	3/3*	3/3*	3/3**	3/3**
42	Neutrogena lotion (glycerin)	1% (v/v)	3/3*	3/3*	3/3**	3/3**
43	Hand sanitizer (ethyl alcohol)	1% (v/v)	3/3*	3/3*	3/3**	3/3**
44	Hand soap (benzalkonium chloride)	1% (v/v)	3/3*	3/3*	3/3**	3/3**
45	Laundry detergent (C12-15 pareth-7 and sodium laureth-12 sulfate)	1% (v/v)	3/3*	3/3*	3/3**	3/3**
46	Bleach (sodium hypochlorite)	1% (v/v)	3/3*	3/3*	3/3**	3/3**
47	Surface sanitizer (citric acid)	1% (v/v)	3/3*	3/3*	3/3**	3/3**
48	Dish-washing liquid (sodium lauryl sulfate)	1% (v/v)	3/3*	3/3*	3/3**	3/3**

*: Negative / **: Positive

4) High-dose Hook effect

Pooled nasopharyngeal specimens were used as clinical matrix, and SARS-CoV-2 virus inactivated by beta-Propiolactone (BPL) was spiked to make various high concentration levels of SARS-CoV-2 antigens. Prepared samples of each concentration levels were tested using Celltrion DiaTrust™ COVID-19 Ag Home Test in 3 replicates following instructions.

No high-dose hook effect was observed up to 6.3×10^5 $TCID_{50}$/mL, approx. 20,000xLoD.

SARS-CoV-2 inactivated virus (6.3×10^5 $TCID_{50}$/mL)		
$TCID_{50}$/mL (concentration)	Test results (No. of positives/ No. of replicates)	
	Lot 1	Lot 2
3.2×10^1 [1xLoD]	3/3	3/3
1.3×10^2 [4xLoD]	3/3	3/3
1.5×10^4 [500xLoD]	3/3	3/3
6.3×10^5 [20,000xLoD]	3/3	3/3

5) Flex study

The robust use of Celltrion DiaTrust™ COVID-19 Ag Home Test was demonstrated by ten (10) Flex studies: temperature and humidity, delay in sample testing, delay in result reading, extraction buffer volume variability, swab mixing expression variability, disturbance during testing, testing on non-level surface, impact of light sources, test device held at 90° angle and disturbance during analysis - receiving a phone call while the mobile app is running.

6) Clinical performance

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, aged 14 years and older at four clinical sites. Mid-turbinate nasal swabs were collected and tested by each study participant, eluted in the extraction buffer and tested with the device immediately, using only the QRI and App. Results of each samples were confirmed by FDA EUA RT-PCR.

According to the test results, clinical performance results of the Celltrion DiaTrust™ COVID-19 Ag Home Test was as follows:

Table 1. Demographic and Clinical Characteristics

Characteristic		Total number	Total Positive by RT-PCR	% Positive
Age Range	14-24	88	12	12/88 (13.6%)
	25-64	381	31	31/381 (8.1%)
	≥65	23	2	2/23 (8.7%)
Sex				
Female		266	18	18/266 (6.8%)
Male		226	27	27/226 (11.9%)
Total		492	45	45/492 (9.1%)

Table 2. Observations of All subjects

All Data		Reference PCR Results		
		Positive	Negative	Total
DiaTrust™ COVID-19 Ag Home Test	Positive	39	1	40
	Negative	6	446	452
	Total	45	447	492

PPA:86.7 % (95% CI: 73.8%-93.7%)

NPA: 99.8 % (95% CI: 98.7%-100.0%)

Table 3. Observations of Symptomatic subjects

Symptomatic Data		Reference PCR Results		
		Positive	Negative	Total
DiaTrust™ COVID-19 Ag Home Test	Positive	31	1	32
	Negative	5	174	179
	Total	36	175	211

PPA: 86.1% (95% CI: 71.3% - 93.9%)

NPA: 99.4% (95% CI: 96.8% - 99.9%)

Table 4. Observations of Asymptomatic subjects

Asymptomatic Data		Reference PCR Results		
		Positive	Negative	Total
DiaTrust™ COVID-19 Ag Home Test	Positive	8	0	8
	Negative	1	272	273
	Total	9	272	281

PPA: 88.9 % (95% CI: 56.8%-98.0%)

NPA: 100.0% (95% CI: 98.6%-100.0%)

Table 5. PPA and NPA by days since onset of symptoms

Days since symptom onset	PPA (95% CI)	NPA (95% CI)
Asymptomatic	88.9% (8/9) (95% CI: 56.5% - 98.0%)	100% (272/272) (95% CI: 98.6% - 100.0%)
1	75.0% (3/4) (95% CI: 30.1% - 95.4%)	95.8% (23/24) (95% CI: 79.8% - 99.3%)
2	100.0% (8/8) (95% CI: 67.6% - 100.0%)	100.0% (40/40) (95% CI: 91.2% - 100.0%)
3	100.0% (9/9) (95% CI: 70.1% - 100.0%)	100.0% (38/38) (95% CI: 90.8% - 100.0%)
4	85.7% (6/7) (95% CI: 48.7% - 97.4%)	100.0% (30/30) (95% CI: 88.6% - 100.0%)
5	66.7% (2/3) (95% CI: 20.8% - 93.9%)	100.0% (24/24) (95% CI: 86.2% - 100.0%)
6	100.0% (2/2) (95% CI: 34.2% - 100.0%)	100.0% (12/12) (95% CI: 75.8%-100.0%)
7	33.3% (1/3) (95% CI: 6.1%-79.2%)	100.0% (7/7) (95% CI: 64.6%-100.0%)

[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: celltrionusa.CS@celltrion.com, or via phone: (201) 499-1844). Test system problems may also be reported to the FDA through the MedWatch medical products reporting program (phone: 800.FDA.1088; fax: 800.FDA.0178; http://www.fda.gov/medwatch).

[REFERENCES]

[1] Zhu N, Zhang D, Wang W, et al. A Novel Coronavirus from Patients with Pneumonia in China, 2019. N Engl J Med 2020.

[2] Huang C, Wang Y, Li X, et al. Clinical features of patients infected with 2019 novel coronavirus in Wuhan, China. Lancet 2020.

[3] Kang CK, Song KH, Choe PG, et al. Clinical and Epidemiologic Characteristics of Spreaders of Middle East Respiratory Syndrome Coronavirus during the 2015 Outbreak in Korea. J Korean Med Sci 2017; 32:744-9.

[4] WHO, Novel Coronavirus (2019-nCoV) situation reports. Available at: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/situationreports/ (Accessed at 2 Feb, 2020).

FACT SHEET FOR HEALTHCARE PROVIDERS

Celltrion USA, Inc. **October 21, 2021**

Celltrion DiaTrust™ COVID-19 Ag Home Test

Coronavirus Disease 2019 (COVID-19)

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the Celltrion DiaTrust™ COVID-19 Ag Home Test.

The Celltrion DiaTrust™ COVID-19 Ag Home Test is authorized for non-prescription home use using mid-turbinate swab samples self-collected or adult-collected from individuals aged 14 years and older with symptoms of COVID-19 within the first seven days of symptom onset and from individuals aged 14 years and older with or without symptoms or other epidemiological reasons to suspect COVID-19 infection when tested twice over three days with at least 24 hours but not more than 48 hours between tests.

This test is authorized for non-prescription home use using mid-turbinate swab samples self-collected or adult-collected from individuals aged 14 years and older, with symptoms of COVID-19 within the first seven days of symptom onset and from individuals aged 14 years and older with or without symptoms or other epidemiological reasons to suspect COVID-19 infection, when tested twice over three days with at least 24 hours but not more than 48 hours between tests.

All individuals who use this assay are required to receive and should carefully review the Celltrion DiaTrust™ COVID-19 Ag Home Test Instructions for Use before they use the test.

What are the symptoms of COVID-19?
Many patients with COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, dyspnea), although some individuals experience only mild symptoms or no symptoms at all. The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that, when present, symptoms include cough, shortness of breath or dyspnea, fever, chills, myalgias, headache, sore throat, new loss of taste or smell, nausea or vomiting or diarrhea. Signs and symptoms may appear any time from 2 to 14 days after exposure to the virus, and the median time to symptom onset is approximately 5 days. For further information on the symptoms of COVID-19 please see the link provided in "*Where can I go for updates and more information?*" section.

Public health officials have identified cases of COVID-19 infection throughout the world, including the United States. Please check the CDC COVID-19 webpage (see link provided in "*Where can I go for updates and more information?*" section at the end of this document) or your local jurisdictions website for the most up to date information.

What do I need to know about COVID-19 testing?
Current information on COVID-19 for healthcare providers is available at CDC's webpage, *Information for Healthcare Professionals* (see links provided in "*Where can I go for updates and more information?*" section).

- The Celltrion DiaTrust™ COVID-19 Ag Home Test is for non-prescription home use with self-collected mid-turbinate swab samples from individuals aged 14 years or older with symptoms of COVID-19 within the first seven days of symptom onset.
- The Celltrion DiaTrust™ COVID-19 Ag Home Test is for non-prescription home use with adult-collected mid-turbinate swab samples from individuals aged 14 years or older with symptoms of COVID-19 within the first seven days of symptom onset.
- The Celltrion DiaTrust™ COVID-19 Ag Home Test is for non-prescription home use with self-collected and adult-collected mid-turbinate swab samples from individuals aged 14 years or older with or without symptoms or other epidemiological reasons to suspect COVID-19 infection when tested twice over three days with at least 24 hours but not more than 48 hours between tests.

Report Adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) or by calling **1-800-FDA-1088**

What does it mean if the specimen tests positive for the virus that causes COVID-19?
A positive test result for COVID-19 indicates that antigens from SARS-CoV-2 were detected, and therefore the patient is infected with the virus and presumed to be contagious. COVID-19 test results should always be considered in the context of clinical observations and epidemiological data (such as local prevalence rates and current outbreak/epicenter locations) in making a final diagnosis and patient management decisions. Patient management should be made by a healthcare provider and follow current CDC guidelines.

The Celltrion DiaTrust™ COVID-19 Ag Home Test has been designed to minimize the likelihood of false positive test results. However, in the event of a false positive result, risks to patients could include the following: a recommendation for isolation of the patient, monitoring of household or other close contacts for symptoms, patient isolation that might limit contact with family or friends and may increase contact with other potentially COVID-19 patients, limits in the ability to work, delayed diagnosis and treatment for the true infection causing the symptoms, unnecessary prescription of a treatment or therapy, or other unintended adverse effects.

Test results are automatically reported through the Celltrion DiaTrust™ COVID-19 Ag Home Test App (Celltrion SafeKey) to relevant public health authorities in accordance with local, state, and federal requirements.

All healthcare providers must follow the standard testing and reporting guidelines according to their appropriate public health authorities.

What does it mean if the specimen tests negative for the virus that causes COVID-19?
A negative test result for this test means that SARS-CoV-2 antigens were not present in the specimen above the limit of detection. However, a negative result does not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Antigen tests are known to be less sensitive than molecular tests that detect viral nucleic acids. The amount of antigen in a sample may decrease as the duration of illness increases. Specimen collected after day 7 of illness may be more likely to be negative compared to a RT-PCR assay. Therefore, negative results should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management.

When diagnostic testing is negative, the possibility of a false negative result should be considered in the context of a patient's recent exposures and the presence of clinical signs and symptoms consistent with COVID-19. The possibility of a false negative result should especially be considered if the patient's recent exposures or clinical presentation indicate that COVID-19 is likely, and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative. If COVID-19 is still suspected based on exposure history together with other clinical findings, re-testing or testing with molecular methods should be considered by healthcare providers in consultation with public health authorities.

Risks to a patient of a false negative test result include: delayed or lack of supportive treatment, lack of monitoring of infected individuals and their household or other close contacts for symptoms resulting in increased risk of spread of COVID-19 within the community, or other unintended adverse events.

A negative antigen test should not be the sole basis used to determine if a patient can end isolation precautions. For additional recommendations regarding infection control, refer to CDC's *Discontinuation of Isolation for Persons with COVID-19 Not in Healthcare Settings* (Interim Guidance) (see links provided in *"Where can I go for updates and more information?"* section).

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 in 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

What do I need to know about Serial Testing in Asymptomatic Individuals?

In asymptomatic individuals, serial testing may assist in identifying infected individuals and facilitate timely infection control practices. A negative test result does not rule out infection but repeat testing over two or three days may decrease the risk of false negative results. Additional clinical studies are underway to assess the performance of rapid antigen tests when used with serial testing. An initial negative test result should be the first of a minimum of two tests. An asymptomatic individual undergoing serial testing with two or more negative results may require ongoing serial testing or confirmatory testing, depending on patient history and potential exposures. An asymptomatic individual undergoing serial testing with one or more positive results indicates that SARS-CoV-2 antigen is present, but does not rule out coinfection with other pathogens.

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 SARS-CoV-2 or residing in communities with low prevalence of infection. For additional recommendations regarding confirmation of antigen test results, please refer to the CDC's Interim Guidance for Antigen Testing for SARS-CoV-2 (see links provided in *"Where can I go for updates and more information?"* section).

What is an EUA?

The United States FDA has made this test available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of in vitro diagnostics (IVDs) for the detection and/or diagnosis of the virus that causes COVID-19.

An IVD made available under an EUA has not undergone the same type of review as an FDA-approved or cleared IVD. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives, and based on the totality of scientific evidence available, it is reasonable to believe that this IVD may be effective in diagnosing COVID-19.

The EUA for this test is in effect for the duration of the COVID-19 declaration justifying emergency use of IVDs, unless terminated or revoked (after which the test may no longer be used).

What are the approved available alternatives?

There are no approved available alternative tests. Any tests that have received full marketing status (e.g., cleared, approved), as opposed to an EUA, by FDA can be found by searching the medical device databases here: https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases.

A cleared or approved test should be used instead of a test made available under an EUA, when appropriate and available. FDA has issued EUAs for other tests that can be found at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

Report Adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) or by calling **1-800-FDA-1088**

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hello@liloclean.com

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