

OHC COVID-19 Antigen Self Test

User Instructions

For Emergency Use Authorization (EUA) Only.
In vitro diagnostic use only.

- For more information on EUAs visit: <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>
- For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19

In the USA, this product has not been FDA cleared or approved; but has been authorized by FDA under an Emergency Use Authorization. This product has been authorized only for the detection of



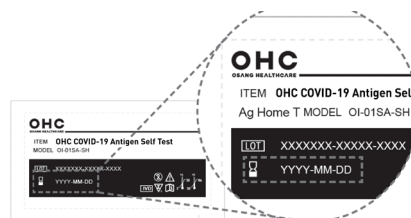
Prepare to Perform the Test

1. Bring test kit to room temperature (15-30°C / 59-86°F).
****Before washing your hands, please prepare by blowing your nose.****

2. Wash your hands with soap and water, or use hand sanitizer before performing the test. Make sure you rinse thoroughly and your hands are dry before starting.

3. Check test expiration date on the back of the foil. Do not use if the expiry date has passed

NOTE: Testing should commence immediately after opening the sealed pouches.



4. Open the pouch and remove the test device from the foil pouch.



5. Place the test device on a flat surface.

01.

Open the pouch that contains the extraction buffer tube & filter cap.

Open the seal of the tube carefully without spilling the liquid inside the tube.

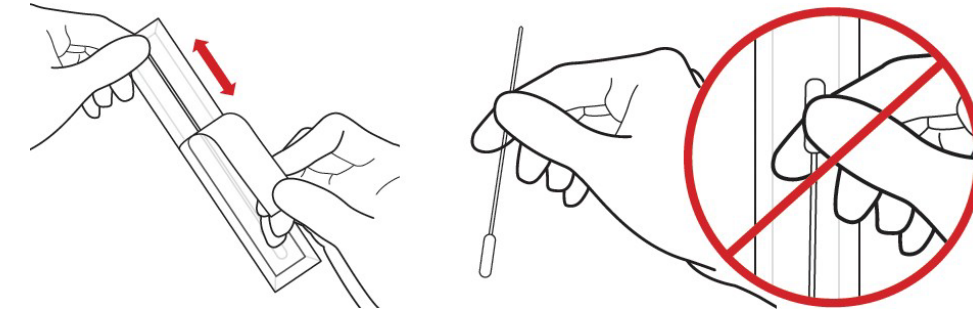
Punch a hole in the box to hold the tube.

If any liquid spills, do not use the tube.

02.

Remove the swab from the packaging.

Ensure that you only touch the handle of the swab and NOT the soft pad on the tip.



03.

Holding the stick end of the swab, gently insert the foam end of the swab into the nostril approximately 1/2 to 3/4 of an inch.

Do not insert the swab any further if you feel resistance.
****Swab both nostrils****

04.

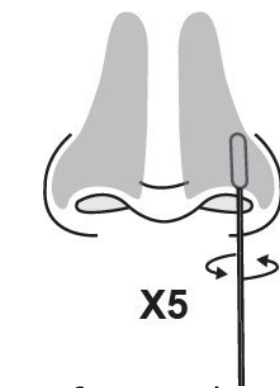
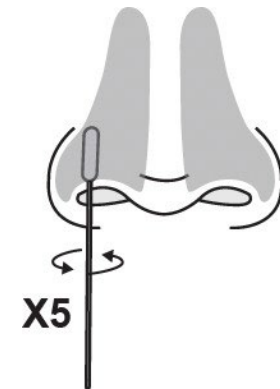
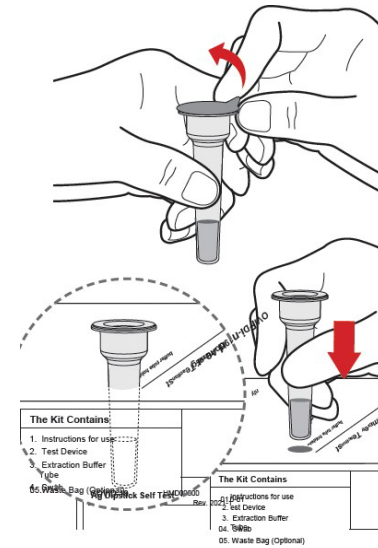
Firmly and slowly rotate the swab at least 5 times, brushing against the inside walls of the nostril at least 5 times for a total of 15 seconds.

****Do not just spin the swab.****

Gently remove the swab, and using the same swab, repeat in the second nostril with the same end of the swab.

NOTE: When swabbing others, please wear a face mask. With children, the maximum depth of insertion into the nostril may be less than 3/4 of an inch, and you may need to have a second person to hold the child's head while swabbing.

WARNING! Inaccurate test results may occur if the nasal swab specimen is not properly collected.

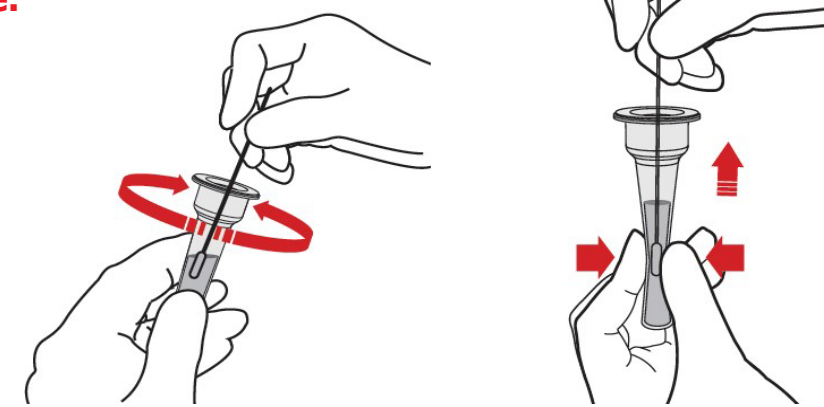


05.

Directly insert the sterile swab taken from the nostril into the extraction buffer tube and stir in more than 10 times. Take out the swab from the extraction buffer tube by squeezing and applying pressure on both sides of the tube.

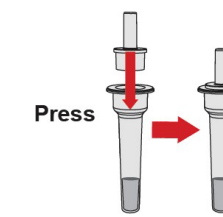
WARNING! Failure to squeeze the tube can lead to incorrect results due to excess buffer in the swab.

WARNING! The sample should be mixed into the buffer immediately, but no more than an 1 hour after collecting the sample.



06.

Dispose of the swab and seal the tube securely with the nozzle cap.

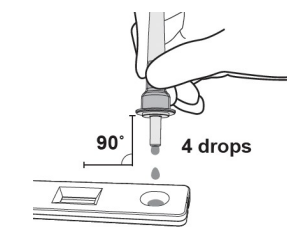


07.

Hold the tube uprights above the sample well. **Drop 4 drops** onto the sample well.

****Do not apply the liquid in the rectangular result window.****

WARNING! Adding more or less than 4 drops of solution into the sample well may result in incorrect results.



08.

Set the timer and read the test result at 15 minutes. Do not read the result after 20 minutes.

Read test result at 15 minutes
DO NOT read after 20 minutes
WARNING! Do not move or lift the test device during this time.

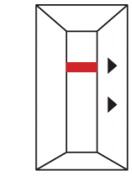


After the test is completed, dispose of used materials in household trash. Do not flush or pour test liquids down a drain.

WARNING! Inaccurate test interpretations may occur if results are read before 15 minutes or after 20 minutes.

Look at the result window and locate the letters C and T on the side of the window. A pink/purple line should always appear at the C position; this is a control line and signals that the test is working properly.

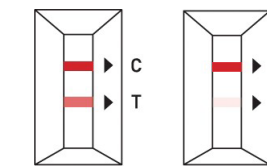
Negative Result



If the Control (C) line is visible, but the Test (T) line is not visible, the test is negative.

A negative test result indicates that antigens from the virus that causes COVID-19 were not detected from the specimen. A negative result does not rule out COVID-19. 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. If you test negative and continue to experience COVID-19 like symptoms of fever, cough, and/or shortness of breath you should seek follow up care with your health care provider. You should test again in 24 hours (but no more than 48 hours), regardless of whether or not you have symptoms.

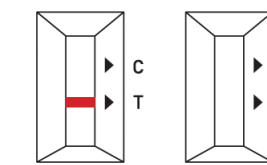
Positive Result



If a Control (C) line and the Test (T) line are visible, the test is positive. Any faint visible pink/purple test (T) line with the control line (C) should be read as positive.

A positive test result means that the virus that causes COVID-19 was detected in your sample and it is very likely you have COVID-19 and are contagious. Please contact your doctor/primary care physician or your local health authority immediately and adhere to the local guidelines regarding self-isolation. There is a very small chance that this test can give a positive result that is incorrect (a false positive). Your healthcare provider will work with you to determine how best to care for you based on your test results along with medical history and your symptoms.

Invalid Result



If a control (C) line is not visible, the test is invalid. Re-test with a new swab and new test device.

Intended Use

The OHC COVID-19 Antigen Self Test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2. The test is authorized for non-prescription home use with self-collected anterior nasal (nares) swabs from individuals aged 14 years and older when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests. The test is authorized for individuals with symptoms of COVID-19 within the first 7 days of symptom onset, or individuals without symptoms or other epidemiological reasons to suspect COVID-19.

This test is also intended for non-prescription home use with adult-collected anterior nasal (nares) swab specimens from individuals aged 2 years and older when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests. The test is authorized for individuals aged 2 years and older with symptoms of COVID-19 within the first 7 days of symptom onset, or individuals without symptoms or other epidemiological reasons to suspect COVID-19.

The OHC COVID-19 Antigen Self Test does not differentiate between SARS-CoV or SARS-CoV-2 viruses.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in anterior nasal (nares) swabs during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient 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 OHC COVID-19 Antigen Self Test should self-isolate and seek follow up care with their physician or healthcare provider as additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

All negative results should be treated as presumptive and confirmation with a molecular assay may be necessary if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control 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.

Individuals who test negative and continue to experience COVID-like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care from their 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 OHC COVID-19 Antigen Self Test is intended for non-prescription self-use and/or as applicable, for an adult lay user testing another aged 2 years or older. The OHC COVID-19 Antigen Self Test is only for use under the Food and Drug Administration’s Emergency Use Authorization.

Warnings and Precautions

Read instructions carefully before performing a test. Failure to follow directions may produce inaccurate test results.

- All test materials must be at room temperature before use.
- Wear a safety mask or other face-covering when collecting a specimen from a child or another individual.
- Inadequate or improper specimen collection and handling may yield false negative results. Collect specimen and immediately perform test according to instructions.
- This test is read visually. Individuals with impaired vision or color-impaired vision may not be able to adequately interpret test results.
- Wash hands thoroughly or use hand sanitizer after handling.
- Dispose of kit contents and patient samples in household trash.
- This is a qualitative test, therefore quantitative values of SARS-CoV-2 antigen concentration cannot be determined.

-The immune response cannot be evaluated using this test. Other test methods are required for that purpose.

-The test does not differentiate between SARS-CoV and SARS-CoV-2.
-Children 2 to 13 years of age should not swab themselves and should instead be swabbed by an adult.
-Use the test kit once only. Do not reuse. Do not use with multiple specimens.

-The test is intended to aid in the diagnosis of a current SARS-CoV-2 infection. Please consult a healthcare professional to discuss your results and if any additional testing is required.
-Keep testing kit and kit components away from children and pets before and after use. If ingested, seek medical advice.
-Do not use on anyone under two years of age.
-Do not open the kit contents until ready for use. If the test cassette is open for an hour or longer, invalid test results may occur.
-Do not use the test after the expiration date shown on the test cassette pouch.
-Do not use the test if the pouch is damaged or open.
-Make sure there is sufficient light when testing.
-Do not use nasal sprays for at least 30 minutes before collecting a nasal sample.
-In the event of a spillage, ensure that it is cleaned thoroughly using a suitable disinfectant.
-Use only the component of this test kit.
-If you suspect the presence of blood on the swab, discard the swab and repeat the test with a fresh one.
-Remove any piercings from the nose before starting the test.
-Do not use on anyone who is prone to nosebleeds or has had facial injuries or head injuries/surgery in the past six months.
-Inadequate or improper nasal swab sample collection may yield false negative test results.
-Do not touch the swab head when handling the swab.
- Avoid contact with your skin, eyes, nose, or mouth. Do not ingest any kit components. The Reagent Solution contains a harmful chemical (see table below). If contact the body occurs, flush with copious amounts of water. If irritation persists, seek medical advice: https://www.poisonhelp.org or 1-800-222-1222.

Hazard Category (mixture)	GHS Hazard Class for mixture	Labeling of Harm(s)	Hazardous Ingredients (%)	Recommended PPE Statement
Category 2	Eye Irritation	Causes eye irritation (H320)	Sodium azide / 26628-22-8 / (0.05%) <p>Triton X-100 / 9002-93-1 / (1%)</p> <p>BIS (trimethylsilyl acetamide) / 25561-30-2 / (1.0%)</p> <p>Tris (hydroxymethyl) aminoethane / 77-86-1 / (1.2%)</p>	NA
Category 2	Skin Irritation	Causes skin irritation (H315)	Sodium azide / 26628-22-8 / (0.05%) <p>Triton X-100 / 9002-93-1 / (1%)</p> <p>BIS (trimethylsilyl acetamide) / 25561-30-2 / (1.0%)</p> <p>Tris (hydroxymethyl) aminoethane / 77-86-1 / (1.2%)</p>	NA

SERIAL TESTING INFORMATION AND LIMITATIONS

- Testing for all individuals should be performed at least twice over three days, with at least 24 hours and no more than 48 hours between tests. You may need to purchase additional tests to perform this serial (repeat) testing.

- For serial testing, if your first test result is negative, you should test again with a new test in 24 to 48 hours.

- Serial testing (i.e., testing every day or every other day) is more likely to detect COVID-19.

- If your first or second test is positive, then proteins from the virus that causes COVID-19 have been found in your sample and you likely have COVID-19.

- If both your first and second tests are negative, you may not have COVID-19, however you should follow-up with your healthcare provider if you are at high risk for COVID-19.

Frequently Asked Questions

Q: WHAT IS COVID-19?

A: COVID-19 is caused by the SARS-CoV-2 virus which is a new virus in humans causing a contagious respiratory illness. COVID-19 can present with mild to severe illness, although some people infected with COVID-19 may have no symptoms at all. Older adults and people of any age who have underlying medical conditions have a higher risk of severe illness from COVID-19. Serious outcomes of COVID-19 include hospitalization and death. The SARS-CoV-2 virus can be spread to others even before a person shows signs or symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc.). A full list of symptoms of COVID-19 can be found at the following link: https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.

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

A: Potential risks include:

- Possible discomfort during sample collection.
- Possible incorrect test results (see Result Interpretation 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.

Q: WILL THIS TEST HURT?

A: No, the 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.

Q: WHAT IS THE DIFFERENCE BETWEEN AN ANTIGEN AND MOLECULAR TEST?

A: 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 OHC COVID-19 Antigen Self Test detect proteins from the virus. 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. 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. 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.

Q: HOW ACCURATE IS THIS TEST?

A: The performance of the OHC COVID-19 Antigen Self-Test was established in a prospective clinical study of symptomatic individuals using an EUA molecular test as a comparator method. The data from this study were analyzed using the minimum recommended number of low positives demonstrating that the test correctly identified 82.9% of positive samples and correctly identified 98.6% of negative samples. For more detailed information on test performance please see Section 13 of the Health Care Provider Instructions for Use. A negative result in individuals with or without symptoms does not rule out COVID-19. You can still infect others if you have a negative result. COVID-19 antigen tests are less sensitive than molecular (PCR) tests. The performance of antigen tests can vary with the amount of virus in your sample. Therefore, you should contact your healthcare provider to determine if additional testing with a highly sensitive COVID-19 molecular test is needed. Additional information is available in the Healthcare Provider Instructions for Use at http://www.osanghc.com/en/ifu/hometest.

Q: IS THERE OTHER INFORMATION AVAILABLE DESCRIBING THE PERFORMANCE OF THIS TEST?

A: Yes. Please see the Healthcare Provider Instructions for Use available at http://www.osanghc.com/en/ifu/hometest/ for additional information. The performance of this test is still being studied in patients without signs and symptoms of respiratory infection and for serial screening. Performance may differ in these populations.

Q: WHAT IS SERIAL TESTING?

A: Serial testing is when one person tests themselves multiple times for COVID-19 on a routine basis, such as every day or every other day. By testing more frequently, you may detect COVID-19 more quickly and reduce spread of infection. Serial testing (i.e. testing every day or every other day) is more likely to detect COVID-19. Testing should be performed at least twice over three days, with at least 24 hours and no more than 48 hours between tests. You may need to purchase additional tests to perform this serial (repeat) testing.

Q: WHAT IF YOU TEST POSITIVE?

A: A positive result means that it is very likely you have COVID-19 because proteins from the virus that causes COVID-19 were found in your sample. You should self-isolate from others and contact a healthcare provider for medical advice about your positive result. Your healthcare provider will work with you to determine how best to care for you based on your test result, medical history, and symptoms.

Q: WHAT IF YOU TEST NEGATIVE?

A: A negative test result indicates that antigens from the virus that causes COVID-19 were not found in your sample. You should test again in 24 to 48 hours. If you receive a second negative result 24 to 48 hours after your first negative result, then you are likely not infected with COVID-19. However, negative results do not rule out SARS-CoV-2 infection.

It is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. This means that you could possibly still have COVID-19 even though the test is negative. For example, you may get a false negative result if you did not perform the test correctly or if the level of antigen from the virus causing COVID-19 was below the test limits. The amount of antigen in a sample may decrease the longer you have symptoms of infection. 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. Your healthcare provider will consider the test result together with all other aspects of your medical history (such as symptoms, possible exposures, and geographical location of places you have recently traveled) in deciding how to care for you. Your healthcare provider may suggest you need another test to determine if you have contracted the virus causing COVID-19.

It is important that you work with your healthcare provider to help you understand the next steps you should take.

Q: WHAT DOES AN INVALID TEST MEAN?

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

Storage and Stability

Store the OHC COVID-19 Antigen Self Test at 4-30°C / 39.2-86°F and protect from direct sunlight.Ensure all kit contents are at room temperature before use. Kit contents are stable until the expiration date printed on the outer packaging. Do not use beyond the expiration date. Do not freeze the kit.




Important

This test is intended to be used as an aid in the clinical diagnosis of a current COVID-19 infection. Do not use this test as the only guide to manage your illness. Please consult your healthcare provider if your symptoms persist or become more severe, or if you are concerned at anytime.

Individuals should provide all results obtained with this product to their healthcare provider for public health reporting.

Symbols

Please refer to Healthcare Provider (HCP) IFU online for specifics regarding the Symbols glossary.

	OSANG Healthcare co., Ltd. 132, Anyangcheondong-ro, Dongan-gu, Anyang-si, Gyeonggi-do, South Korea 14040 www.osanghc.com
	FA INC. 10-5 Myeonghaksandanseo-ro, Yeondong-myeon, Sejong-si, 30068, South Korea www.facompany.co.kr
	MT Promedt Consulting GmbH Altenhofstrasse 80, 66386 St, Ingbert, Germany www.mt-procons.com

Manufacturer and Authorized representative information for sterile swabs is as below.

Sterile swab manufacturer

 **FA INC.** 10-5 Myeonghaksandanseo-ro, Yeondong-myeon, Sejong-si, 30068, South Korea www.facompany.co.kr

 **MT Promedt Consulting GmbH** Altenhofstrasse 80, 66386 St, Ingbert, Germany www.mt-procons.com