OSOM®
COVID-19 Antigen Home Test

FOR OVER-THE-COUNTER AT HOME USE

Quick Reference Instructions

For Emergency Use Authorization (EUA) only.

For *in vitro* diagnostics use.

In the USA, this product has not been FDA cleared or approved; but has been authorized by FDA under an Emergency Use Authorization. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

Read the instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.

For more information on EUAs please visit: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19

An anterior nasal swab sample can be self-collected by an individual aged 14 years and older. Children aged 2 to 13 years should be tested by an adult.

INSTRUCTIONS FOR USE

For the Healthcare Provider Instructions for Use (IFU), please visit: osomhometests.com

KIT CONTENTS

Single-use test device in a foil pouch (2)

Collection tube with buffer liquid (2)

Nasal swab package (2)

Quick Reference Instructions (1)

STORAGE AND STABILITY

Store the test kit at 15-30°C (59-86°F) until use. Ensure all test components are at room temperature before use. The OSOM COVID-19 Antigen Home Test is stable until the expiration date marked on the outer packaging and container. Do not use beyond the expiration date.

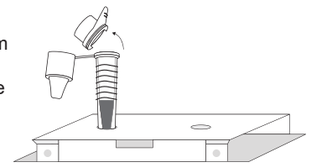
PREPARATION

1. Read all of the instructions entirely before testing.
2. Check the test's expiration date. Do not use an expired test.
3. Make sure you have all the test kit components.
4. Wash your hands with soap and water for 30 seconds or use hand sanitizer. **Hands must be rinsed thoroughly before testing. Make sure hands are dry before starting.**

5. **Remove the test device from the foil pouch** by tearing along the indexed tear-line. Lay the test device on a flat, level surface (table or countertop).
6. Instruct the individual to **blow his/her nose to remove excess mucus**.
7. Open the nasal swab package. **Do not touch the swab tip or lay it down on any surface**.

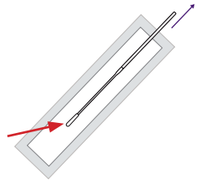
TEST PROCEDURE

1. Remove the white cap from the collection tube and place the tube into the hole within the box insert.



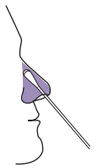
WARNING: If any liquid spills, discard test kit and re-start test using a new test kit.

2. Remove the swab from the packaging and be careful not to touch the swab tip or lay the swab down on the table.



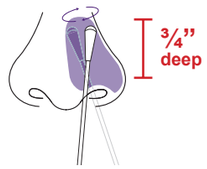
Do not touch the swab tip!

3. Swab both nostrils of the individual carefully as shown. Insert the entire soft tip of the swab into the individual's first nostril about ½ to ¾ of an inch.

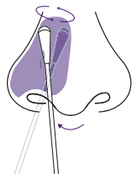


Firmly brush against the entire inner walls of the nostril in a complete circle at least 4 times. Do not just spin the swab. Remove the swab.

WARNING: Hands must be rinsed thoroughly before testing. Do not enter the swab any farther if you feel any resistance.



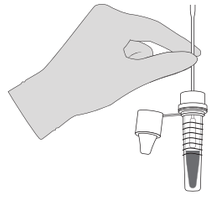
Using the SAME SWAB, repeat the step above in the OTHER nostril.



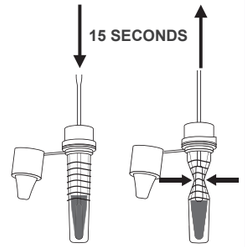
Note: If you are swabbing others, please wear a face mask. With children, the maximum depth of insertion into the nostril may be less than ½ to ¾ of an inch, and you may require another adult to hold the child's head while swabbing.

WARNING: False negative results may occur if the nasal swab is not properly collected.

4. Remove the collection tube from the box insert and insert the swab into the collection tube containing buffer liquid.



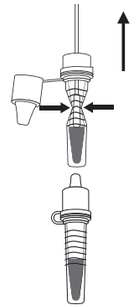
5. Plunge the swab up and down while squeezing the swab tip repeatedly from the outside of the tube for 15 seconds. Be careful not to contaminate the swab. Avoid spilling or splashing of the collection tube contents.



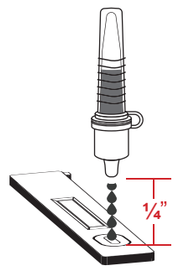
6. Remove the swab while squeezing the sides of the tube to extract the liquid.

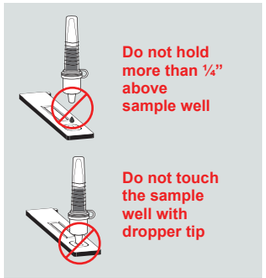
WARNING: Failure to squeeze the tube can lead to incorrect results due to excess buffer in the swab tip.

Firmly cap the collection tube with the attached dropper tip.



7. Invert the collection tube and tap the side of the tube to remove any air bubbles from the dropper tip.





Hold the dropper tip about ¼ of an inch vertically above the test device sample well (use both of your hands if needed) and slowly squeeze the tube until all of the liquid (**at least 5 drops**) is dispensed into the sample well.

DO NOT dispense the liquid into the rectangular result viewing window.

8. Wait 15 minutes, then read your test results.

WARNING: Reading before 15 minutes or after 30 minutes can lead to false results

DO NOT disturb the test device during this time. Inaccurate results can occur if the test is disturbed.

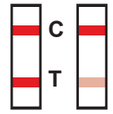
VIDEO INSTRUCTIONS

FPO

Scan this QR code to view video instructions.

READ AND INTERPRET THE RESULTS

Table 1: Results Interpretation



COVID-19 Positive (+):
Any visible pink/purple colored Test line indicates a positive result.

If the Control (C) line and the Test (T) line are visible, the test is positive. Any faint visible [color] Test (T) line with the Control line (C) should be read as positive. You do not need to perform repeat testing if you have a positive result at any time.

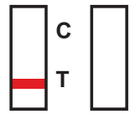
A positive test result means that the virus that causes COVID-19 was detected in your sample and it is very likely you have COVID-19 and are contagious. Please contact your doctor/primary care physician or your local health authority immediately and adhere to the local guidelines regarding self-isolation. There is a very small chance that this test can give a positive result that is incorrect (a false positive).

COVID-19 Negative (-)
If the Control (C) line is visible, but the Test (T) line is not visible, the test is negative.

To increase the chance that the negative result for COVID-19 is accurate, you should:

- Test again in 48 hours if you have symptoms on the first day of testing.
- Test 2 more times at least 48 hours apart if you do not have symptoms on the first day of testing.

A negative test result indicates that the virus that causes COVID-19 was not detected in the sample. A negative result does not rule out COVID-19. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR tests. If the test is negative but COVID-19-like symptoms (e.g., fever, cough, and/or shortness of breath) continue, follow up testing for SARS-CoV-2 with a molecular test or testing for other respiratory disease should be considered. If applicable, seek follow up care with the primary health care provider.



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

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results for COVID-19.

Table 2: Test Result Interpretation When Repeat Testing is Performed

Status on First Day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	Positive	Positive for COVID-19
	Negative	Negative	Negative	Negative for COVID-19

Results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

Report your test result(s) at MakeMyTestCount.Org – this voluntary and anonymous reporting helps public health teams understand COVID-19 spread in your area and across the country and informs public health decisions.

INTENDED USE

The OSOM COVID-19 Antigen Home Test is a lateral flow immunoassay device intended for the qualitative detection of nucleocapsid protein antigen from the SARS-CoV-2 virus.

This test is authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older or adult collected anterior nasal (nares) swab samples from individuals aged 2 years or older. This test is authorized for individuals with symptoms of COVID-19 within the first 5 days of symptom onset when tested at least twice over three days with at least 48 hours between tests, and for individuals without symptoms or other epidemiological reasons to suspect COVID-19, when tested at least three times over five days with at least 48 hours between tests.

The OSOM COVID-19 Antigen Home Test does not differentiate between SARS-CoV or SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen, which is generally detectable in anterior nasal (nares) samples 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 and the agent detected may not be the definitive cause of disease. Individuals who test positive with the OSOM COVID-19 Antigen Home Test should self-isolate and seek follow up care with their physician or healthcare provider as additional testing may be necessary.

All negative results are presumptive and confirmation with a molecular assay, if necessary for patient management, may be performed. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control measures such as isolating from others and wearing masks. Negative results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

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

Individuals should provide all results obtained with this product to their healthcare provider for public health reporting and to receive appropriate medical care. 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 OSOM COVID-19 Antigen Home Test is intended for non-prescription self-use and/or as applicable, for an adult lay user testing another aged 2 years or older in a non-laboratory setting. The OSOM COVID-19 Antigen Home Test is only for in vitro diagnostic use under the Food and Drug Administration's Emergency Use Authorization. This product has not been FDA cleared or approved.

HOW TO USE THIS TEST

Serial testing should be performed in all individuals with negative results; individuals with symptoms of COVID-19 and initial negative results should be tested again after 48 hours. Individuals without symptoms of COVID-19, and with initial negative results, should be tested again after 48 hours and, if the 2nd test is also negative, a 3rd time after an additional 48 hours. You may need to purchase additional tests to perform this serial (repeat) testing.

- If you test negative but continue to have symptoms of COVID-19, and both your first and second tests are negative, you may not have COVID-19, however you should follow-up with your healthcare provider.
- If your test is positive, then proteins from the virus that causes COVID-19 have been found in your sample and you likely have COVID-19.

WARNINGS, PRECAUTIONS, AND SAFETY INFORMATION

Read the OSOM COVID-19 Antigen Home Test Package Insert carefully before performing a test. Failure to follow directions may produce inaccurate test results.

- In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
- **Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals and three times over five days (with at least 48 hours between tests) for asymptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.**

  If you have had symptoms longer than 5 days you should consider testing at least three times over five days with at least 48 hours between tests.
- An anterior nasal swab sample can be self-collected by an individual age 14 years and older. Children ages 2 to 13 years should be tested by an adult.
- If you have had symptoms longer than 5 days you should consider testing at least three times over five days with at least 48 hours between tests.
- Do not use on anyone under 2 years of age.
- Wear a safety mask or other face-covering when collecting a specimen from a child or another individual.
- Do not use if any of the test kit contents or packaging is damaged.
- Test components are single-use. Do not re-use.
- Do not use kit past its expiration date.
- Do not touch the swab tip.
- Once opened, the test device should be used within 30 minutes.
- Do not read test results before 15 minutes or after 30 minutes. Results read before 15 minutes or after 30 minutes may lead to a false positive, false negative, or invalid result.
- Keep testing kit and kit components away from children and pets before and after use. Avoid contact with your skin, eyes, nose, or mouth. Do not ingest any kit components. The reagent solution contains harmful chemicals (see table below). If the solution contacts your skin, eyes, nose, or mouth, flush with large amounts of water.
- **If irritation persists, seek medical advice: https://www.poisonhelp.org or 1-800-222-1222**.

Chemical Name	Hazards (GHS Code) for each ingredient	Concentrations
Triton X-100/9002-93-1	H302, Harmful if swallowed H315, Skin irritation H318, Serious eye damage	0.1%
Lauryldimethylamine oxide (LDAO)/1643-20-5	H302, Harmful if swallowed H315, Skin irritation H318, Serious eye damage H319, Serious eye irratation	0.5%

LIMITATIONS

- There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to the sensitivity of the test technology. This means that there is a higher chance this test will give a false negative result in an individual with COVID-19 as compared to a molecular test, especially in samples with low viral load.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between June 2022 and July 2022. The clinical performance has not been established for all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
- All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary. If you continue to have symptoms of COVID-19, and both your first and second tests are negative, you may not have COVID-19, however you should follow-up with a healthcare provider.
- If the test is positive, then proteins from the virus that causes COVID-19 have been found in the sample and you likely have COVID-19.
- These test results are shown as lines of color. Because these lines can be very faint, users with conditions affecting their vision such as far sightedness, glaucoma, or color blindness are encouraged to seek assistance to interpret results accurately (e.g., reading glasses, additional light source, or another person).
- Incorrect test results may occur if a specimen is incorrectly collected or handled.
- Hand soap liquid gel may produce false positive results.

FREQUENTLY ASKED QUESTIONS

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 Warnings and Read and Interpret the Results sections for more information).

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

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

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

Q: HOW ACCURATE IS THIS TEST?

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

Q: WHAT IF I HAVE A POSITIVE TEST RESULT?

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.

Q: WHAT IF I HAVE A NEGATIVE TEST RESULT?

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

Q: WHAT DOES AN INVALID TEST RESULT 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 you should test again with a new test.

IMPORTANT

Do not use this test as the only guide to manage your illness. Consult your healthcare provider if your symptoms persist or become more severe. Individuals should provide all results obtained with this product to their healthcare provider.

Index of Symbols

Σ	Contains sufficient for <n> tests	%	Humidity limitation		Use-by date
	Consult instructions for use	REF	Catalog number	IVD	*In vitro* diagnostic medical device
	Temperature limit	LOT	Batch code		Do not reuse

SUPPORT

If you have questions regarding the use of this product, or if you want to report a problem with the test, please contact SEKISUI Diagnostics Technical Services at (800) 491-6220 or techservices@sekisuidiagnostics.com.

Additional information is also available for you and your healthcare provider at osomhometests.com. The Quick Reference Instructions, Fact Sheet for Health Care Providers and Health Care Provider Instructions for Use are also available at osomhometests.com. The OSOM COVID-19 Antigen Home Test Letter of Authorization, authorized Fact Sheet, and authorized labeling are available on the FDA website.

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