OSOM®
COVID-19 Antigen Home Test
FOR OVER-THE-COUNTER AT HOME USE
Quick Reference Instructions
For Healthcare Provider Instructions for Use (IFU), please visit: osomhometests.com

INSTRUCTIONS FOR USE

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

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 inner seal 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 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 wall 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 swabs 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.

Keep 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

Scan this QR code to view video instructions.

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.

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)

READ AND INTERPRET THE RESULTS

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

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

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

Table 1: Results Interpretation

<table>
<thead>
<tr>
<th>Positive pink/purple colored Test line</th>
</tr>
</thead>
<tbody>
<tr>
<td>T Indicates a positive result.</td>
</tr>
</tbody>
</table>

Table 2: Test Result Interpretation When Repeat Testing is Performed

<table>
<thead>
<tr>
<th>Status on First Day of Testing</th>
<th>With Symptoms</th>
<th>Without Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st Result Day 1</td>
<td>2nd Result Day 5</td>
<td>3rd Result Day 5</td>
</tr>
<tr>
<td>Positive</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Negative</td>
<td>Positive</td>
<td>N/A</td>
</tr>
<tr>
<td>Negative</td>
<td>Negative</td>
<td>N/A</td>
</tr>
<tr>
<td>Positive</td>
<td>N/A</td>
<td>Positive</td>
</tr>
<tr>
<td>Negative</td>
<td>Negative</td>
<td>Positive</td>
</tr>
<tr>
<td>Positive</td>
<td>N/A</td>
<td>Negative</td>
</tr>
<tr>
<td>Negative</td>
<td>Negative</td>
<td>Negative</td>
</tr>
</tbody>
</table>

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

Report your test result(s) at UnidadTestCount.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.
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 (nasal) swab samples from individuals aged 14 years or older to detect proteins from the virus that causes COVID-19. It is not intended to be used as the sole basis for treatment or patient management decisions, including infection control measures or isolation and seeking follow-up care with their physician or healthcare provider as additional testing may be necessary.

The OSOM COVID-19 Antigen Test does not differentiate between SARS-CoV-2 or SARS-CoV-2. Results are for the identification of SARS-CoV-2 nucleoprotein antigen, which is generally detectable in anterior nasal (nasal) swab 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 establish the diagnosis of COVID-19. False negative results may occur justifying the authorization of emergency use of in vitro diagnostics for detection and/or quantitation of antigens from SARS-CoV-2, not for any other viruses or pathogens. The emergency use 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 at the time of collection and the 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 test will give you a false negative result when you have COVID-19 than a molecular test would. 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. If your test is positive, then proteins from the virus that causes COVID-19 have been found in the sample and you have COVID-19. If irritation persists, seek medical advice: https://www.poisonhelp.org or 1-800-222-1222.

CONTENTS OF THE TEST KIT
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 test is also negative, at least two more times in the next 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 do not test positive on any additional tests you should follow-up with your healthcare provider.
- If the test is positive, then proteins from the virus that causes COVID-19 have been found in your sample and you likely have COVID-19.

WANTING, 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 US, this product has not been 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. There is currently no guarantee that the authorization will be renewed after the declaration expires.

- 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.

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 of a negative test result with an antigen test will give a false negative diagnosis than a negative test result with a laboratory-based molecular test.
- 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.

FREQUENTLY ASKED QUESTIONS
Q: WHAT ARE THE KNOWN POTENTIAL RISKS AND BENEFITS OF THIS TEST?
A: Potential risks include:
- Potential 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 the COVID-19 virus to your family and others in your community.

For more information on EUAs go here: https://www.fda.gov/emergency-preparedness-and-disaster/emergency-legal-regulatory-and-political-framework/emergency-use-authorization

Q: WHERE CAN I ORDER OR PURCHASE THIS PRODUCT?
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 repeatedly over 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 performance may apply to you, please refer to the performance data in the Healthcare Provider Instructions for Use (IFU), available at https://www.osomhometests.com or 1-800-491-6220.

Q: WHAT IS 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 IS A NEGATIVE TEST RESULT?
A: A negative test result indicates that there is no evidence that the virus that causes COVID-19 was 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 have been infected and not tested positive.

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.

Q: IF I HAVE A POSITIVE TEST RESULT?
A: If your test is positive, then proteins from the virus that causes COVID-19 have been found in your sample.

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 Providers 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.

Manufactured by:
ANP Technologies, Inc. 824 Interchange Blvd. Newark, DE 19711, USA

Distributed by:
SEKISUI Diagnostics, LLC 6659 Top Gun Street San Diego, CA 92121 USA

CONTACT & TECHNICAL SUPPORT
US +1 800-491-6220 (Monday to Friday – 8:00 AM to 5:00 PM ET) techservices@sekisuidiagnostics.com (24/7)

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TIN 3456-6-df 06/2023
COVID-19 Antigen Home Test

For use under Emergency Use Authorization (EUA) only.

The OSOM COVID-19 Antigen Home Test is intended for the qualitative detection of SARS-CoV-2 nucleocapsid protein antigen in anterior nasal (nares) swab samples. This test does NOT determine if you had COVID-19 in the past or if you have immunity. Determining a negative result requires multiple tests. You may need to purchase additional tests to perform serial (repeat) testing. This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test.

If you test positive for COVID-19 please contact your doctor/primary care physician or your local health authority immediately and adhere to the local guidelines regarding self-isolation.

For home testing (ages 2 and up).

Manufactured by:
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824 Interchange Blvd.
Newark, DE 19711, USA

Distributed by:
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In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under Emergency Use Authorization (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.

The OSOM COVID-19 Antigen Home Test is a lateral flow immunoassay that uses antibodies to detect nucleocapsid protein antigen from SARS-CoV-2 in anterior nasal swabs. The test is authorized for individuals with symptoms of COVID-19 within the first five (5) days of symptom onset, when tested twice over three days with at least 48 hours between tests or individuals without symptoms or other epidemiological reasons to suspect COVID-19, when tested at least three (3) times over five (5) days and at least 48 hours between tests.

For more information on expiration dating for COVID-19 antigen tests, please refer to http://www.fda.gov/covid-tests

Scan QR Code to view video instructions.

Use within 30 minutes after opening the foil pouch.

Avoid contact of the extraction liquid in Tube with skin and eyes.

Item necessary to use the test but not provided in the test kit is a timer.
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