OSOM® COVID-19 Antigen Rapid Test

QUICK REFERENCE GUIDE

For use under Emergency Use Authorization (EUA) only.

REF **1066-40**

IVD ℞ONLY

Directly Collected Mid-Turbinate Nasal Swab

The OSOM® COVID-19 Antigen Rapid Test is a lateral flow chromatographic immunoassay intended for the qualitative detection of the SARS-CoV-2 nucleocapsid protein antigen in direct mid-turbinate (MT) nasal swab specimens collected by a healthcare provider from individuals suspected of COVID-19 within the first 7 days of symptom onset when tested at least twice over three days with at least 48 hours between tests and from 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. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, that meet the requirements to perform moderate, high or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

The OSOM COVID-19 Antigen Rapid Test does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen, which is generally detectable in MT nasal swab specimens 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 patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definitive cause of disease. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

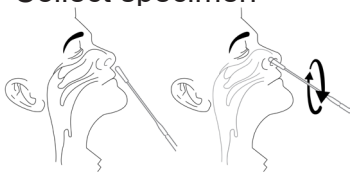
All negative results are presumptive and confirmation with a molecular assay, if necessary for patient management, may be performed. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control 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.

The OSOM COVID-19 Antigen Rapid Test is intended for use by medical professionals or operators who are proficient in performing tests in point of care settings. The OSOM COVID-19 Antigen Rapid 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.

See Instructions for Use for complete use instructions, warnings, precautions, and limitations.

- **Read all instructions carefully before performing the test. Failure to follow the instructions may result in 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 for use by authorized laboratories. 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 7 days, you should consider testing at least three times over five days with at least 48 hours between tests. This product is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.**

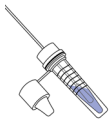
1 Collect specimen



Prior to collecting the nasal swab, the patient should be instructed to blow their nose.

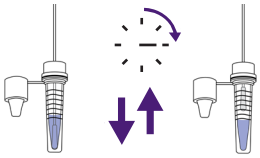
Tilt head back 70 degrees. Carefully insert swab into the nostril, parallel with the bridge of the nose, no more than 1" deep, or until you feel resistance at the turbinates. Rotate the swab in a circular path at least 4 times around the entire inside nostril's wall for approximately 15 seconds. Repeat with the **same swab** in the other nostril.

2 Remove white cap and immerse swab in buffer



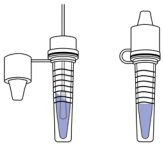
Remove white cap of collection tube and **insert** test swab into buffer.

3 Plunge swab up and down for 15 seconds



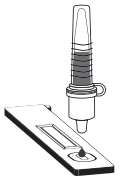
Carefully **plunge** swab up and down for 15 seconds.
DO NOT SPILL CONTENTS OR CONTAMINATE THE SWAB.

4 Remove swab and cap tube with affixed clear dropper



Remove the test swab while pressing and rotating the tip against the inside wall of the tube to extract the liquid. Discard the swab and cap tube with affixed clear dropper tip.

5 Invert tube and dispense 5 drops into sample well



Remove test device from foil pouch and lay it flat. Invert the capped collection tube and tap the side to remove air bubbles from the dropper tip. Hold the tube vertically, 1/4 inch above the device.
Squeezing gently, dispense five (5) drops of sample solution to the sample well.
Test Device should be on a flat surface to avoid spillage and inaccurate results. Adding less drops may produce invalid or inaccurate results.

6 Read results at 15 minutes

Read results in test window at 15 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.**

Notes:

- Testing must be performed within 30 minutes of specimen collection.
- Do not use visually bloody or overly viscous specimen.
- Inadequate specimen collection or improper sample handling/storage may yield erroneous results.
- Use only the swab provided in the test kit.

OSOM® COVID-19 Antigen Rapid Test

QUICK REFERENCE GUIDE

For use under Emergency Use Authorization (EUA) only.

RESULTS INTERPRETATION

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

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

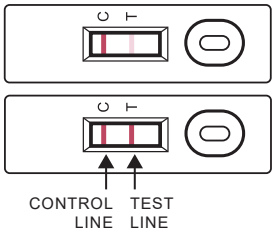
Results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

COVID-19 Positive (+)

If the 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.

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).



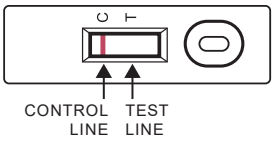
Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Individuals who test positive with the OSOM COVID-19 Antigen Rapid Test should self-isolate and seek follow up care with their physician or healthcare 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.

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.**

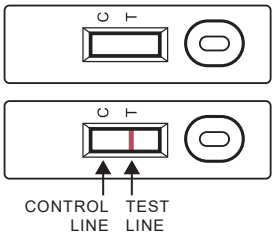


A negative test result indicates that the virus that causes COVID-19 was not detected in the sample. A negative result does not rule out COVID-19. There is a higher chance of false negative results with antigen tests compared to laboratory based tests such as PCR tests. If the test is negative but COVID-19-like 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.

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. The negative test result interpretation is shown by the figure above.

Invalid

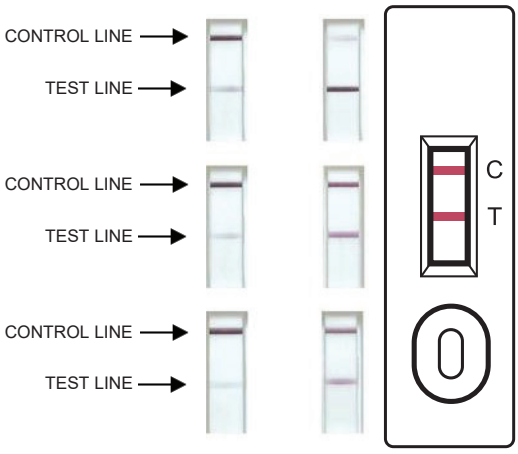
If the control (C) line is not visible, the test is invalid. Re-test with a new swab and new test device. The Invalid test result interpretation is shown by the figure to the right:



TEST DEVICE

Positive Specimen Indication

Any visible pink/purple colored test line is positive. All six examples below are positive.



IMPORTANT

Negative Procedural Control

The clearing of the test strip's background color in the results viewing window is a built-in negative control, indicating that the test has been performed correctly. The test area's color in the window should turn from dark red to light pink or white within 15 minutes and allow for clear interpretation of the test result. If the background color remains dark red and interferes with the reading of the test result, then the test is invalid. Should this occur, review the procedure, and repeat the test with a new patient sample using a new test device. Do not reuse patient samples and swabs.

Assistance:

If you have questions regarding the use of this product, or if you want to report a problem with the OSOM COVID-19 Antigen Rapid Test, please contact SEKISUI Diagnostics Technical Services at (800) 332-1042 or techservices@sekisuidiagnostics.com.

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

SEKISUI DIAGNOSTICS
Tel: 800-332-1042
sekisuidiagnostics.com

3452-4
06/2023