osom®

COVID-19 Antigen Rapid Test

INSTRUCTIONS FOR USE

REF 1066-40 IVD $\mathbb{R}_x$ ONLY

FOR USE UNDER EMERGENCY USE AUTHORIZATION (EUA) ONLY

For *in vitro* diagnostic use | For prescription use only

FOR DIRECTLY COLLECTED MID-TURBINATE NASAL SWAB SPECIMENS

CONTENTS

INTENDED USE

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 healthcare 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.

SUMMARY AND EXPLANATION OF THE TEST

Coronaviruses are a large family of viruses which may cause illness in animals or humans. SARS-CoV-2 is an enveloped, single-stranded RNA virus of the β genus. The virus, which causes COVID-19, can trigger mild to severe respiratory illness and has spread rapidly worldwide.

The OSOM COVID-19 Antigen Rapid Test is a lateral flow immunochromatographic assay for the detection of nucleocapsid protein antigen specific to SARS-CoV-2 in MT nasal swab specimens directly collected and extracted using OSOM buffer. The OSOM COVID-19 Antigen Rapid Test contains all components required to carry out a test for SARS-CoV-2.

PRINCIPLE OF THE PROCEDURE

The OSOM COVID-19 Antigen Rapid Test is an immunochromatographic lateral flow membrane assay that uses antibodies to detect SARS-CoV-2 nucleocapsid protein in MT nasal swabs. The MT nasal swab specimen requires a sample preparation step in which the sample is eluted into the extraction buffer solution. Extracted swab sample is then added to the sample well of the test device to initiate the test. When the swab sample migrates on the test strip, SARS-CoV-2 viral antigens bind to anti-SARS-CoV-2 nucleocapsid protein monoclonal antibody conjugated to an indicator and detector particles on the test strip forming an immune complex. The immune complex is then migrated to and captured at the Test line, which contains another monoclonal antibody against SARS-CoV-2, anchored to the nitrocellulose membrane which captures any formed immune complex with the SARS-CoV-2 antigen. Test results are interpreted at 15 minutes. The presence of a colored line in the Control line region “C” and the Test line region “T” indicates COVID-19 positive. The presence of one colored line in the Control line region “C” indicates COVID-19 negative.

No appearance of a colored line in the Control region “C” indicates an invalid test regardless if a colored Test line is present or not at the Test line region “T”. Results should not be read after 30 minutes.

REAGENTS AND MATERIALS

Materials Provided in Each Test Kit

	Description	Quantity
OSOM COVID-19 Antigen Test Devices	Test devices containing LFI test strip in a plastic housing	40
OSOM Antigen Buffer Tubes	Nasal swab specimen collection & dispensing tube containing OSOM Antigen Buffer	2 x 20
Sterile, Nasal Swabs		40
Instructions For Use (IFU)		1
Quick Reference Guide	For Direct Nasal Swab Samples	1

Materials Required but Not Provided

	Description
Clock, timer, or stopwatch	
Gloves	
Disinfection agent	
OSOM COVID-19 Antigen Control Kit Catalog #1068	Kit contains the following components: 5 Positive Control Swabs 5 Sterile Nasal Swabs (Negative Control) 1 Instructions for Use (IFU)

WARNINGS, PRECAUTIONS AND SAFETY INFORMATION

1 For *in vitro* diagnostic use.

2 For prescription use only.

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

4 In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an EUA for use by authorized laboratories; use by certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform moderate, high or waived complexity tests and 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.

5 **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.**

6 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.

7 This product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests 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.

8 Federal Law restricts this device to sale by or on the order of a licensed practitioner (U.S. only).

9 This product has been authorized only for the detection of SARS-CoV-2 antigen, not for any other viruses or pathogens.

10 Laboratories within the United States and its territories are required to report all results to the appropriate public health laboratories.

11 Treat all specimens as potentially infectious. Follow universal precautions when handling samples, the test kit and its contents.

12 Leave test device sealed in its foil pouch until just before use. Do not use if pouch is damaged or open. Do not use if any of the test kits or packaging is damaged.

13 Do not touch the swab tip.

14 Do not use the test kit past its expiration date.

15 Do not mix components from different test kit lots.

16 Test devices are single use only and should be discarded after use. Do not reuse test device.

17 Do not store specimens in viral transport media for specimen storage.

18 Inadequate or inappropriate sample collection, storage, and transport may yield false test results.

19 To obtain accurate results, the test must be performed as indicated in this Instructions for Use.

20 All components of this test kit should be discarded as biohazard waste according to federal, state and local regulatory requirements.

21 Solutions used to prepare the positive control swab are non-infectious. However, patient samples, controls and test devices should be handled as though they contain infectious agents. Observe established precautions against microbial hazards during use and disposal.

22 Wear appropriate personal protection equipment when handling patient specimens and running each test. Change gloves between processing of specimens from persons suspected or confirmed to be infected with COVID-19.

23 **INVALID RESULTS**, indicated by no Control Line, can occur when an insufficient volume of sample solution is added to the test device. To ensure delivery of an adequate volume, hold the sample tube vertically, ~¼ inch above the sample well of the test device and dispense five (5) free drops quickly by squeezing the sides of the dropper tube into the sample well of the test device.

24 False negative results can occur if the sample swab is not extracted properly in the buffer solution.

25 Swabs in the kit are approved for use with OSOM COVID-19 Antigen Rapid Test. **DO NOT USE OTHER SWABS.**

26 The antigen buffer solution packaged in the collection tube of this test kit contains buffer validated for use with this test. **DO NOT USE OTHER BUFFER SOLUTIONS.**

27 **Do not use the original packaging to store the swabs after specimen collection. Dispose of the swab as biohazard waste in accordance with state and federal laws**.

CHEMICAL AND SAFETY INFORMATION

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	GHS CODE FOR EACH INGREDIENT	CONCENTRATION
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 irritation	0.5%

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

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

STORAGE AND STABILITY

The OSOM COVID-19 Antigen Rapid Test and components should be stored between 15-30°C (59-86°F).

Ensure all kit components are at room temperature before use.

Kit components in the OSOM COVID-19 Antigen Rapid Test are stable until the expiration date printed on the outer packaging. Do not use beyond the expiration date.

The Test Device must remain in the sealed foil pouch until use. Once the pouch has been opened, the test device should be used within 60 minutes. Use beyond one hour may not produce accurate results.

For best performance, specimens should be tested immediately after collection. Swabs should be placed in extraction buffer within 60 minutes of collection. Inoculated buffer should be added to the device within 120 minutes after placement in extraction buffer, if kept at ambient (room) temperature.

CONTROLS

OSOM COVID-19 Antigen Rapid Test contains a built-in procedural as well as external controls.

Procedural Control Description
The built-in “Control” region serves as an internal procedural control when a colored line appears in the Control line region (“C line”). It confirms sufficient specimen volume and correct procedural technique.

External Control Description
OSOM COVID-19 Antigen Control Kit (Catalog #1068) - sold separately

SEKISUI Diagnostics provides an external positive and negative assayed quality control kit, the OSOM COVID-19 Antigen Control Kit, to monitor the performance of the OSOM COVID-19 Antigen Rapid Test. Good laboratory practice recommends running positive and negative external controls regularly. Evaluation of external controls is recommended prior to using a new shipment or new lot of OSOM COVID-19 Antigen Rapid Tests. Evaluation of external controls is also recommended when there is a new operator. External controls may also be used in initial laboratory validations of the OSOM COVID-19 Antigen Rapid Test in accordance with appropriate federal, state, and local guidelines or accreditation requirements, as applicable. The OSOM COVID-19 Antigen Control Kit is to be used with

the OSOM COVID-19 Antigen Rapid Test. The procedure for running the external controls is provided separately by OSOM COVID-19 Antigen Control Kit IFU. The Positive and Negative Controls can be used in the same fashion as patient samples for the purpose of verification of the test performance or to evaluate new operators or new lots of test kits. The user may also utilize additional control kits as required by laboratory specific requirements.

- **Positive Control Swab**: The external positive control swab consists of non-infectious recombinant SARS-CoV-2 nucleocapsid antigen spiked onto a sterile nasal swab. It is labeled specifically as the Positive Control swab.
- **Negative Control Swab**: The negative control swab consists of a sterile swab without non-infectious SARS-CoV-2 nucleocapsid recombinant antigen.

If the correct control results are not obtained, do not report patient results or perform further patient testing. Please contact SEKISUI Diagnostics Technical Services at (800) 332-1042 or techservices@sekisuidiagnostics.com.

SPECIMEN COLLECTION AND HANDLING

Test specimens immediately after collection for optimal test performance. Inadequate specimen collection or improper sample handling/storage/transport may yield erroneous results. Refer to the CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19) https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html

To collect a specimen:

1 Prior to collecting the mid-turbinate nasal swab, the patient should be instructed to blow their nose. Open the sterile packaging and remove the swab. Do NOT touch any part of the swab other than the shaft. Tilt head back 70 degrees. Carefully insert swab into the nostril, parallel with the bridge of the nose, no more than 1 inch deep, or until you feel resistance at the turbinate. 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 *(Figure 1)*.

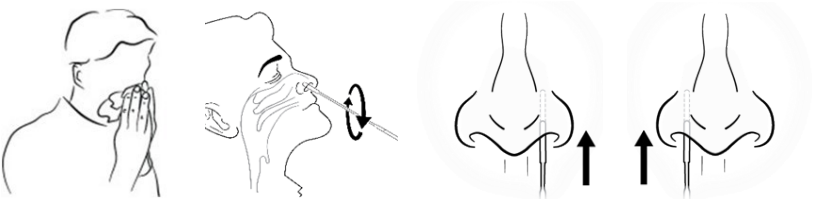


Figure 1: Mid-turbinate Nasal Swab Collection

- Do not use visually bloody or overly viscous specimens.
- Do not return the nasal swab to the original paper packaging.
- The swabs provided are authorized for use with the OSOM COVID-19 Antigen Rapid Test — **do not use other swabs**.

Directly collected nasal swabs should be tested immediately after collection.

SPECIMEN TRANSPORT AND STORAGE

For best performance, specimens should be tested immediately after collection. Swabs should be placed in extraction buffer within 60 minutes of collection. Inoculated buffer should be added to the device within 120 minutes after placement in extraction buffer, if kept at ambient (room) temperature.

TEST PROCEDURE

Sample Preparation and Testing

The OSOM COVID-19 Antigen Rapid Test and components can be used immediately upon opening and should be stored at room temperature (15-30°C). Opened or in-use test components should be used promptly (within 60 minutes). Use beyond one hour may not produce accurate results.

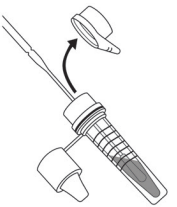


Figure 2:
Transfer Sample Swab into Buffer Tube

1 After specimen collection (see instructions above), remove the white cap from the collection tube and insert the test swab into the buffer, *(see Figure 2 to the left)*.

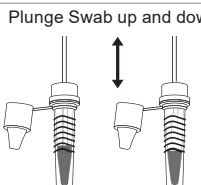


Figure 3:
Illustration of Sample Extraction

2 Carefully plunge the test swab up and down for 15 seconds, *(see Figure 3 to the left)*. Make sure to hold the tube in an upright position to prevent spillage or splashing of the contents.

Figure 4:
Close the Buffer Tube

3 Remove the test swab while pressing and rotating the tip against the inside wall of the tube to extract the liquid. Discard the swab safely. Firmly cap the collection tube with the affixed clear dropper tip, *(see Figure 4 to the left)*.

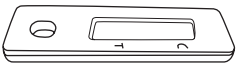


Figure 5:
Test Position During Testing

4 Remove the test device from the sealed foil pouch and lay flat on a clean surface, *(see Figure 5 to the left)*.
Test Device should be on a flat surface to avoid spillage and inaccurate results.

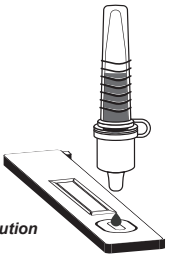


Figure 6:
Dispensing Sample Solution into the Sample Well

5 Invert the capped sample extraction tube and tap the side to remove any 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 into the sample well. Do **NOT** touch the sample pad with the dropper tip, *(see Figure 6 to the left)*. **Adding fewer drops may produce invalid or inaccurate results**.

6 Wait for the colored line(s) to appear. Read results in test window 15 minutes after dispensing. **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.**

RESULTS INTERPRETATION

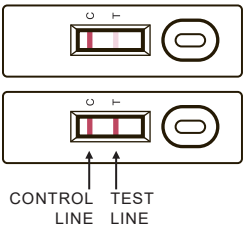
Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results for COVID-19.

Table 1: Results Interpretation

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 (+)



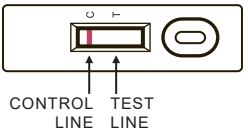
If the Control (C) line and the Test (T) line are visible, the test is positive. Any faint visible pink/purple Test (T) line with the control (C) should be read as positive.

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. The positive test result interpretation is shown by the figure on the left.

COVID-19 Negative (-)



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

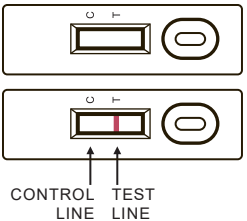
To increase the chance that the negative result for COVID-19 is accurate, you should:

- **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 on the left.

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 on the left.

LIMITATIONS

- This test detects both viable (live) and non-viable SARS-CoV-1, and SARS-CoV-2. Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.
- 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.
- If the patient continues to have symptoms of COVID-19, and both the patient's first and second tests are negative, the patient may not have COVID-19, however additional follow-up may be needed.
- If the test is positive, then proteins from the virus that causes COVID-19 have been found in the sample and the individual likely has 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)
- This test is only used for testing direct human mid-turbinate nasal swab specimens.
- Viral transport media (VTM) should not be used with this test.
- This test is not for use in at-home testing settings.
- Do not use the test on children under 5 years of age. The test has only been tested in children aged 5 and above.
- A negative test result may occur if the level of antigen in a sample is below the detection limit of the test.
- The performance of the OSOM COVID-19 Antigen Rapid Test was evaluated using the procedures provided in this product insert only. Modifications to these procedures may alter the performance of the test.
- Performance has not been established for use with specimens other than mid-turbinate nasal swabs. Other specimen types have not been evaluated and should not be used with this assay.
- Incorrect test results may occur if a specimen is improperly collected, transported, or handled.
- False results may occur if a specimen is tested more than 30 minutes after collection. Specimen should be tested as quickly as possible after specimen collection.

- False negative results may occur if an inadequate volume of extraction buffer is used (e.g., less than 5 drops).
- False negative results may occur if the test kit is not used within 60 minutes after opening in environmental conditions of 40ºC/95%RH.
- False negative results may occur if testing is performed at unleveled surfaces of 45° angle up or 45° angle down.
- False negative results may occur if testing is performed under disturbances equal to or greater than shaking at 500 rpm.
- False negative results may occur if swabs are stored in their original paper packaging following specimen collection.
- Positive test results do not rule out co-infections with other pathogens.
- Positive test results do not differentiate between SARS-CoV-1 and SARS-CoV-2.
- Negative test results are not intended to rule in other non-SARS viral or bacterial infections.
- All COVID-19 antigen negative test results are presumptive and confirmation with a molecular assay may be necessary. If the differentiation of specific SARS viruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.
- The results obtained with this test should only be interpreted in conjunction with clinical findings, and the results from other laboratory tests and evaluations. This is especially important if the patient has had recent exposure to COVID-19, or clinical presentation indicates that COVID-19 is likely and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative. In this case, direct testing for the SARS-CoV-2 virus (e.g., PCR testing) should be considered.
- All operators using the product must be appropriately trained in performing and interpreting the results of the product, use appropriate personal protective equipment when handling this test kit, and use the product in accordance with the authorized labeling.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between 04/09/2021 and 05/25/2021. 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 performance of this device has not been assessed in a population vaccinated against COVID-19.

CONDITIONS OF AUTHORIZATION FOR LABORATORY

The OSOM COVID-19 Antigen Rapid Test Letter of Authorization*, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for patients, and authorized labeling are available on the FDA website: (https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2)

However, to assist clinical laboratories using the OSOM COVID-19 Antigen Rapid Test ("your product" in the conditions below), the relevant Conditions of Authorization are listed below:

A Authorized laboratories using your product must include, with test result reports, all Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

B Authorized laboratories using your product must use your product as outlined in the "authorized labeling". Deviations from the authorized procedures, including the authorized instruments, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.

C Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating tests.

D Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

E Authorized laboratories must collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and SEKISUI Diagnostics Inc. (via email: techservices@sekisuidiagnostics.com) for any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.

F All operators using your product must be appropriately trained in performing and interpreting the results of your product. Use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.

G SEKISUI Diagnostics and authorized laboratories using your product must ensure

that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

*The letter of authorization refers to, “Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high, moderate or waived complexity tests. This test is authorized for use at the Point of Care (POC) i.e., in patient care settings operating under CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation” as “authorized laboratories.”

PERFORMANCE CHARACTERISTICS

ANALYTICAL PERFORMANCE

The following studies have been performed to validate the performance of the OSOM COVID-19 Antigen Rapid Test:

1. Limit of Detection (LoD) - Analytical Sensitivity

The Limit of Detection (LoD) of the OSOM COVID-19 Antigen Rapid Test was determined using serial dilutions of gamma-irradiated, inactivated virus from the USA-WA1/2020 SARS-CoV-2 strain. Contrived samples were prepared by spiking the strain into pooled human anterior nares/nasal swab matrix obtained from healthy volunteers confirmed negative by RT-PCR. 50 µL of the spiked sample preparation was pipetted onto a swab and subsequently transferred to a pre-filled OSOM COVID-19 Antigen Buffer Tube and tested as per the IFU. The preliminary LoD initially determined by testing two-fold dilution series of 3 replicates per concentration was confirmed by testing in 20 replicates. The confirmed LoD was 3.11×10^2 $TCID_{50}$/mL. Based upon the testing procedure for this study the LoD of 3.11×10^2 $TCID_{50}$/mL equates to 15.55 $TCID_{50}$/swab. The preliminary LoD was 311 $TCID_{50}$/mL, which was further confirmed by an additional 20 replicates. **Table 2** below summarizes LoD testing results.

Table 2: Results of LoD Confirmation

Concentration ($TCID_{50}$/mL)	Negative Results	Positive Results
311	0/20	20/20

2. NIH/RADx Variant Testing

The performance of this device in the detection of the Omicron variant of SARS-CoV-2 was evaluated in a dilution series of clinical specimens which were positive for the Omicron variant as shown in **Table 3**. This testing was conducted by the National Institutes of Health (NIH) as a component of the Rapid Acceleration of Diagnostics (RADx®) initiative. The clinical specimens used to prepare this dilution series were not identical to the previous specimen pools prepared and tested by RADx to assess performance with the omicron variant. Results from this dilution series cannot be compared to other specimen pools and do not indicate that a test will have different clinical performance

compared to other EUA authorized tests. Compared to an EUA authorized RT-PCR method, this test detected 100% of live virus Omicron samples at a Ct-value of 22.7. Testing was also compared to two additional EUA-authorized OTC antigen tests (Assay #1 and Assay #2). Omicron dilutions at lower viral concentrations (Ct-values greater than 23.6) were not detected by this test in this study.

Table 3: Performance Summary of Testing Dilutions of Clinical Specimens

Omicron Pool 2 - Live Omicron Clinical Samples	Average N2 Ct (n=9)	Assay #1 Percent Positive (n = 5)	Assay #2 Percent Positive (n = 5)	OSOM COVID-19 Antigen Test Percent Positive (n=5)
Dilution 1	**19.8**	100	100	100
Dilution 2	**20.8**	100	100	100
Dilution 3	**21.5**	100	100	100
Dilution 4	**22.7**	100	100	100
Dilution 5	**23.6**	100	0	60
Dilution 6	**24.0**	60	0	0
Dilution 7	**24.8**	0	0	0
Dilution 8	**25.8**	0	0	0
Dilution 9	**27.4**	0	0	0
Dilution 10	**28.1**	0	0	0
Dilution 11	**29.1**	0	0	0

3. Cross-reactivity (Analytical Specificity) & Interference

To establish that the OSOM COVID-19 Antigen Rapid Test does not cross-react with or suffer from interference with other human coronaviruses, microbes, or other high prevalence disease agents/ normal or pathogenic flora likely to be encountered in the clinical specimen, cross-reactivity studies were conducted.

The results are presented in **Table 4** below. Other than the SARS-CoV-1 Urbani strain, no other cross-reactivity was observed with any of the tested organisms. Moreover, no interference was found with any of the tested organisms spiked with low positive SARS-CoV-2.

Table 4: Cross-Reactivity & Microbial Interference Testing of the OSOM COVID-19 Antigen Rapid Test

Virus/Bacteria/Fungi	Cross-Reactivity Results	Interference Results
PNM collected in VTM	No Cross-Reactivity	No Interference
SARS virus	Cross-Reactive	Interference
MERS Coronavirus	No Cross-Reactivity	No Interference
Coronavirus 229E	No Cross-Reactivity	No Interference
Coronavirus OC43	No Cross-Reactivity	No Interference
Coronavirus NL63	No Cross-Reactivity	No Interference
Coronavirus HKU1[1]	In-Silico Analysis	In-Silico Analysis
Adenovirus	No Cross-Reactivity	No Interference
Human metapneumovirus	No Cross-Reactivity	No Interference
Parainfluenza virus 1	No Cross-Reactivity	No Interference
Parainfluenza virus 2	No Cross-Reactivity	No Interference
Parainfluenza virus 3	No Cross-Reactivity	No Interference

Table 4: Cross-Reactivity & Microbial Interference Testing of the OSOM COVID-19 Antigen Rapid Test (Continued)

Virus/Bacteria/Fungi	Cross-Reactivity Results	Interference Results
Parainfluenza virus 4b	No Cross-Reactivity	No Interference
Influenza A	No Cross-Reactivity	No Interference
Influenza B	No Cross-Reactivity	No Interference
Enterovirus 68	No Cross-Reactivity	No Interference
Respiratory syncytial virus	No Cross-Reactivity	No Interference
Human Rhinovirus 75	No Cross-Reactivity	No Interference
Haemophilus influenzae	No Cross-Reactivity	No Interference
Streptococcus pneumoniae	No Cross-Reactivity	No Interference
Streptococcus pyogenes	No Cross-Reactivity	No Interference
Candida albicans	No Cross-Reactivity	No Interference
Bordetella pertussis	No Cross-Reactivity	No Interference
Mycoplasma pneumoniae	No Cross-Reactivity	No Interference
Chlamydia pneumoniae	No Cross-Reactivity	No Interference
Legionella pneumophila	No Cross-Reactivity	No Interference
Mycobacterium tuberculosis	No Cross-Reactivity	No Interference
P. jiroveci-S. cerevisiae[2]	In-Silico Analysis	In-Silico Analysis
Staphylococcus aureus subsp. *Aureus*	No Cross-Reactivity	No Interference

Table 4: Cross-Reactivity & Microbial Interference Testing of the OSOM COVID-19 Antigen Rapid Test (Continued)

Virus/Bacteria/Fungi	Cross-Reactivity Results	Interference Results
Staphylococcus epidermidis	No Cross-Reactivity	No Interference

[1] In-Silico analysis of HKU1 revealed two experimentally derived linear B-cell epitopes specific for SARS- CoV-2. However, upon review of the overlap in both SARS-CoV-1, SARS-CoV-2 and HKU1, it was observed that regions of high homology are not associated with B-cell epitopes. While we cannot rule out cross- reactivity, we conclude there is low probability of cross reactivity with HKU1 nucleocapsid.

[2] In-Silico analysis of Pneumocystis jirovecii was carried out using 11,975 Pneumocystis jirovecii protein sequences available from GenBank and aligned with the SARS-CoV-2 nucleocapsid protein sequences using BLASTP with parameters set to find significant homologous sequences. No significant homology was observed with regard to the SARS-CoV-2 nucleocapsid protein. Therefore, we conclude that there is very low chance of cross-reactivity with Pneumocystis jirovecii.

4. Endogenous and Exogenous Interference Substances Studies

Interfering substances testing was carried out using a panel of fourteen (14) endogenous and exogenous substances tested at concentrations recommended by FDA in the EUA template guidance for Antigen Tests. No interference (false negative or false positive) was observed for any of the tested substances (**Table 5**).

Table 5: Potential Interfering Substances Testing of the OSOM COVID-19 Antigen Rapid Test

Substance	Concentration	Cross-Reactivity Results	Interference Results
Human Blood	4% v/v	No Cross-Reactivity	No Interference
Mucin	0.5%	No Cross-Reactivity	No Interference
Chloraseptic® CH23902	1.5 mg/mL	No Cross-Reactivity	No Interference
NeilMed Naso GEL	5% v/v	No Cross-Reactivity	No Interference

Table 5: Potential Interfering Substances Testing of the OSOM COVID-19 Antigen Rapid Test (Continued)

Substance	Concentration	Cross-Reactivity Results	Interference Results
Nasal Drops	15% v/v	No Cross-Reactivity	No Interference
Nasal Spray	15% v/v	No Cross-Reactivity	No Interference
Zicam®	5% v/v	No Cross-Reactivity	No Interference
Homeopathic	10% v/v	No Cross-Reactivity	No Interference
Sore Throat Chloraseptic® spray	15% v/v	No Cross-Reactivity	No Interference
Tobramycin	4 µg/mL	No Cross-Reactivity	No Interference
Mupirocin	10 mg/mL	No Cross-Reactivity	No Interference
Tamiflu®	5 mg/mL	No Cross-Reactivity	No Interference
Walgreens Fluticasone Propionate	5% v/v	No Cross-Reactivity	No Interference

5. High-dose Hook Effect

High-dose hook effect was evaluated by testing the gamma-irradiated, inactivated stock virus at 2.8E+05 $TCID_{50}$/mL in triplicate to verify that false negative results do not occur when tested with extremely high concentrations of SARS-CoV-2 virus. None of the assays tested produced a false negative at the concentration tested (**Table 6**).

Table 6: Hook Effect Study Results

Test Concentration ($TCID_{50}$/mL)	Replicates	Positive Results
2.80E+05	3	3/3

CLINICAL PERFORMANCE

To evaluate the clinical performance of the OSOM COVID-19 Antigen Rapid Test, individuals aged ≥ 5 years who were identified by their clinicians as being symptomatic for COVID-19 (e.g., any symptom such as fever, dry cough, tiredness, aches and pains, sore throat, diarrhea, conjunctivitis, headache, loss of taste or smell, a rash on skin, or discoloration of fingers or toes) within the previous 7 days, were enrolled prospectively into an IRB-approved study. The study was conducted between April and May 2021 at four (4) point-of-care (POC) sites by 9 test operators who were blinded to the patient diagnosis. Mid-turbinate specimens were tested immediately after collection, and no transport media was used for shipping the samples to a different location for testing. All clinical specimens were tested and evaluated in accordance with the proposed diagnostic algorithm, including retesting when appropriate. Test results were compared to the results from the same samples using a highly sensitive EUA approved COVID-19 RT-PCR test.

Results

A total of 304 evaluable specimens were tested at three POC sites (one of the original 4 sites was removed due to all subjects being unevaluable). The agreement between the RT-PCR comparator and the OSOM COVID-19 Antigen Rapid Test was calculated as indicated below by **Table 7**.

Table 7: Clinical Study Performance Analysis

	Method	RT-PCR Test		Total
		Positive	Negative	
OSOM COVID-19 ANTIGEN RAPID TEST	Positive	39	8	47
	Negative	2	255	257
	Total	41	263	304

Positive Percent Agreement = (39/41) x 100% = **95.1% (95% CI = 83.5 to 99.4%)**
Negative Percent Agreement = (255/263) x 100% = **97.0% (95% CI = 94.1 to 98.7%)**
Positive Predictive Value (PPV) = (39/47) x 100% = **83.0% (95% Confidence Interval = 69.8 to 92.5%)**
Negative Predictive Value (NPV) = (255/257) x 100% = **99.2% (95% Confidence Interval = 97.2 to 99.9%)**

Patient Demographics

Demographics data is provided by **Table 8** below.

Table 8: OSOM COVID-19 Antigen Rapid Test Positive Results by Age Group

Age Group (years)	Positive	Sum	% Positivity Rate
5 to 21	9	54	16.7%
22 to 59	32	205	15.6%
≥ 60	6	45	13.3%
Sum	47	304	15.5%

Performance Analysis — Per Days of Symptoms

Breakdown by days post-symptom onset is provided by **Table 9** below.

Table 9: Clinical Performance Breakdown by Days Post-Symptom Onset

Days Post-Symptom Onset	Number of the Specimens Tested	OSOM COVID-19 Antigen Rapid Test Positive	RT-PCR Positives	PPA (95% CI)
Less than 2 days	75	5	3	100.0%
2-3 days	130	19	19	94.7%
4-5 days	65	19	15	100.0%
6-7 days	34	4	4	75.0%
Total	304	47	41	

SERIAL TESTING

A prospective clinical study was conducted between January 2021 and May 2022 as a component of the Rapid Acceleration of Diagnostics (RADx) initiative from the National Institutes of Health (NIH). A total of 7,361 individuals were enrolled via a decentralized clinical study design, with a broad geographical representation of the United States. Per inclusion criteria, all individuals were asymptomatic upon enrollment in the study and at least 14 days prior to it and did not have a SARS-CoV-2 infection in the three months prior to enrollment. Participants were assigned to one of three EUA authorized SARS-CoV-2 OTC rapid antigen tests to conduct serial testing (every 48 hours) for 15 days. If an antigen test was positive, the serial-antigen testing result is considered positive.

At each rapid antigen testing time point, study subjects also collected a nasal swab for comparator testing using a home collection kit (using a 15-minute normalization window between swabs). SARS-CoV-2 infection status was determined by a composite comparator method on the day of the first antigen test, using at least two highly sensitive EUA RT-PCRs. If results of the first two molecular tests were discordant, a third highly sensitive EUA RT-PCR test was performed, and the final test result was based upon the majority rule.

Study participants reported symptom status throughout the study using the MyDataHelps app. Two-day serial antigen testing is defined as performing two antigen tests 36 – 48 hours apart. Three-day serial antigen testing is defined as performing three antigen tests over five days with at least 48 hours between each test.

Out of the 7,361 participants enrolled in the study, 5,609 were eligible for analysis. Among eligible participants, 154 tested positive for SARS-CoV-2 infection based on RT-PCR, of which 97 (62%) were asymptomatic on the first day of their infection, whereas 57 (39%) reported symptoms on the first day of infection. Pre-symptomatic subjects were included in the positive percent agreement (PPA) of asymptomatic individuals, if they were asymptomatic on the first day of antigen testing, regardless of whether they developed symptoms at any time after the first day of testing. Performance of the antigen test with serial testing in individuals is described in **Table 10**.

Table 10: Data establishing PPA of COVID-19 antigen serial testing compared to the molecular comparator single day testing throughout the course of infection with serial testing. Data is from all antigen tests in study combined.

DAYS AFTER FIRST PCR POSITIVE TEST RESULT	ASYMPTOMATIC ON FIRST DAY OF TESTING			SYMPTOMATIC ON FIRST DAY OF TESTING		
	Ag Positive / PCR Positive (Antigen Test Performance % PPA)					
	1 Test	2 Test	3 Test	1 Test	2 Test	3 Test
0	9/97 (9.3%)	35/89 (39.3%)	44/78 (56.4%)	34/57 (59.6%)	47/51 (92.2%)	44/47 (93.6%)
2	17/34 (50.0%)	23/34 (67.6%)	25/32 (78.1%)	58/62 (93.5%)	59/60 (98.3%)	43/43 (100.0%)
4	16/21 (76.2%)	15/20 (75.0%)	13/15 (86.7%)	55/58 (94.8%)	53/54 (98.1%)	39/40 (97.5%)
6	20/28 (71.4%)	21/27 (77.8%)	16/18 (88.9%)	27/34 (79.4%)	26/33 (78.8%)	22/27 (81.5%)
8	13/23 (56.5%)	13/22 (59.1%)	4/11 (36.4%)	12/17 (70.6%)	12/17 (70.6%)	7/11 (63.6%)
10	5/9 (55.6%)	5/8 (62.5%)		4/9 (44.4%)	3/7 (42.9%)	

1 Test = one (1) test performance on the noted days after first PCR positive test result. Day 0 is the first day of documented infection with SARS-CoV-2.

2 Tests = two (2) tests performance an average of 48 hours apart. The first test performed on the indicated day and the second test performed 48 hours later.

3 Tests = three (3) tests performance an average of 48 hours apart. The first test performed on the indicated day, the second test performed 48 hours later, and a final test performed 48 hours after the second test.

SYMBOLS

	Consult instructions for use	IVD	*In vitro* diagnostic use only
REF	Catalog number	LOT	Batch code
	Contains sufficient for <n> tests		Temperature limit
	Use-by date		Do not Re-use
	Humidity limitation	$\mathbb{R}_{x}$ONLY	Caution: Federal law restricts this device to sale by or on the order of a physician

ORDERING AND CONTACT INFORMATION

Reorder Numbers:
OSOM COVID-19 Antigen Rapid Test (Includes testing components for conducting up to 40 Tests). (Catalog Number 1066-40)

OSOM COVID-19 Antigen Control Kit (Catalog Number 1068)

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.

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