OSOM®
COVID-19 Test

For *In Vitro* Diagnostic Use
For Prescription Use Only
For Use with Kit Provided Swabs
CLIA Complexity-WAIVED

INSTRUCTIONS FOR USE

IVD $\mathbb{R}_{ONLY}$ REF 1092

- A Certificate of Waiver is required to perform this test in a CLIA Waived environment. To obtain CLIA waiver information and a Certificate of Waiver, contact your state health department. Additional information is available at www.cms.hhs.gov/CLIA.
- Laboratories with a Certificate of Waiver must follow the manufacturer's instructions for performing the test.
- Failure to follow the instructions or any modification to the manufacturer's instructions will result in the test being classified as high complexity.

INTENDED USE

The OSOM® COVID-19 Test is a lateral flow immunochromatographic assay for the rapid, qualitative detection of SARS-CoV-2 nucleoprotein protein antigens directly in anterior nasal swab specimens from individuals with signs and symptoms of upper respiratory infection (i.e., symptomatic) when testing is started within 4 days of symptom onset. The test is intended for use as an aid in the diagnosis of SARS-CoV-2 infections (COVID-19) in symptomatic individuals when either: tested at least twice over three days with at least 48 hours between tests; or when tested once, and negative by the OSOM COVID-19 Test and followed up with a molecular test.

The test does not differentiate between SARS-CoV or SARS-CoV-2.

A negative test result is presumptive, and it is recommended these results be confirmed by a molecular SARS-CoV-2 assay. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for diagnosis, treatment, or other patient management decisions.

Performance characteristics for SARS-CoV-2 were established during the January 2022 to February 2024 SARS-CoV-2 pandemic when SARS-CoV-2 Omicron was the predominant SARS-CoV-2 variant in circulation. When other SARS-CoV-2 virus variants are emerging, performance characteristics may vary.

SUMMARY AND EXPLANATION OF THE TEST

The first case of the coronavirus disease 19 (COVID-19) was reported when an outbreak of unknown respiratory illnesses occurred in Wuhan, China on December 31, 2019. COVID-19 Caused by Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) is a respiratory illness, like influenza, with symptoms such as a cough, fever, fatigue, and in more severe cases, difficulty breathing or shortness of breath. The WHO officially declared COVID-19 a pandemic on March 11, 2020.[1]

OSOM COVID-19 Test is a lateral flow immunochromatographic assay intended for the direct detection of the presence or absence SARS-CoV-2 antigen in 15 minutes using respiratory specimens collected from individuals suspected of COVID-19 by their healthcare provider within four days of symptom onset.

PRINCIPLE

The OSOM COVID-19 Test is designed to detect the extracted nucleocapsid protein antigen specific to SARS-CoV-2 in anterior nasal swab specimens directly collected from individuals who are suspected of COVID-19 by their healthcare provider within the first four days of symptom onset.[2-3]

When specimens are extracted and added to the sample well of test device, SARS-CoV-2 viral antigens present in the specimen bind to antibodies against SARS-CoV-2 nucleocapsid conjugated to gold colloidal particles and biotin in the test strip. The antigen-conjugate immunocomplexes migrate across the test strip and are captured at the test line of nitrocellulose membrane.

Test results are interpreted at 15-30 minutes visually. The presence of two pinkish-red colored lines in the control line "C" and test line "Ag" indicates COVID-19 positive. The presence of one colored line in the control line "C" indicates COVID-19 negative. The control line (C) must be present in the test window for self-procedure validation control. This colored control band always appears at the control line position (C) in valid test results. Any test result is not valid without appearance of the control line in the test window.

REAGENTS AND MATERIALS

Provided

27* - Test devices in sealed aluminum foil pouch with desiccant
27* - Reagent tubes with extraction buffer (0.3 mL)
25 - Sample collection swabs
1 - Positive control swab
1 - Negative control swab
1 - Instructions for Use (IFU)
1 - Quick Reference Guide (QRG)

***NOTE:** Two extra test devices have been included for external QC testing.

Required but not provided

- Timer
- Tube rack for specimens
- Any necessary personal protective equipment

STORAGE AND STABILITY

- The test kit should be stored at 2-30°C in the original sealed pouch. Do not freeze.
- Bring all test components to room temperature at least 30 minutes prior to use.
- The freshly collected anterior nasal swab specimen should be processed no later than one hour after specimen collection at room temperature (15-30°C) or before 48 hours when stored at 2-8°C in a sterile container.
- The test is stable until the expiration date printed on the outside of the box. Do not use after the expiration date.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use.
- For prescription use only.
- Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
- Serial testing should be performed in symptomatic individuals with negative results at least twice over three days (with 48 hours between tests). You may need to purchase additional tests to perform this serial (repeat) testing or follow up testing with a molecular test.
- For use with kit provided swabs. Use only swabs provided with the kit.
- Do not use if any of the test kit contents or packaging is damaged.
- Do not use any test component after the expiration date which is printed on the outer packaging.
- Do not interchange kit contents from different lots.
- Test components are single-use. Do not re-use.
- Do not touch the swab tip.
- Once opened, the test device should be used within 90 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.
- Ensure that there is sufficient lighting for testing and interpretation.
- Do not use the kit to evaluate patient specimens if either the positive control swab or negative control swab fails to give the expected results.

- As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
- Use appropriate precautions in the collection, handling, storage, and disposal of patient samples and used kit contents.
- Nitrile or latex gloves should be worn when performing this test.
- Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- Handle all specimens as though they contain infectious agents.
- Do not eat, drink, or smoke in the area where the specimens and kit contents are handled.
- Dispose of used contents as biohazardous wastes in accordance with federal, state, and local requirements.
- The Extraction Reagent contains potentially harmful chemicals (see table below). If the test solution contacts the skin or eye, flush with copious amounts of water.

If irritation persists, seek medical advice:
visit https://www.poison.org/contact-us Or call 1-800-222-1222.

Chemical Name	Harms (GHS Code) for each ingredient	Concentration
Sodium Azide	Acute Tox. 2 (Oral), H300 Acute Tox. 1 (Dermal), H310	0.09%
Gentamicin	Skin sensitization (H317)	0.004%

REAGENT PREPARATION

Conduct all testing on a level surface.

After opening the package, retrieve the COVID-19 Test Device in the foil pouch and the Reagent Tube pre-filled with extraction buffer. Remove the test device from the sealed pouch immediately before use. Label the device with patient or control identification and please proceed directly to sample collection.

Remove the cap from the Reagent Tube.

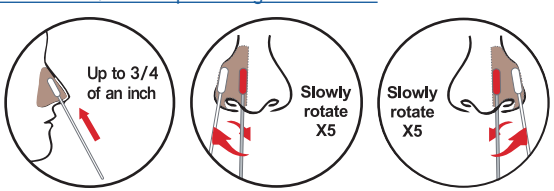
Proceed to Sample Collection.

SAMPLE COLLECTION

Acceptable sample type for testing with the OSOM COVID-19 Test is direct anterior nasal swab specimen. It is essential that correct sample collection must be followed. Inadequate sample collection, improper specimen handling and/or transport may yield false results; therefore, sample collection requires specific training and guidance due to the importance of specimen quality to obtain accurate test results.

Freshly collected sample should be processed as soon as possible, but no later than one hour at room temperature or up to 48 hours at 2-8°C when stored in a sterile container after sample collection. Samples in extraction buffer can be processed up to thirty minutes after collection when kept at room temperature.

To collect the anterior nasal swab sample, tilt the patient's head back 70 degrees and insert the soft end of the swab into patient's nostril no more than ¾ of an inch into the nose. Slowly rotate the swab, gently pressing against the inside of patient's nostril at least 5 times for a total of 15 seconds. Get as much nasal discharge as possible on the soft end of the swab. Gently remove the swab. Use the same end of the swab and repeat the same steps on the other nostril. Refer to: Interim Guidelines for Collecting and Handling of Clinical Specimens for COVID-19 Testing at https://www.cdc.gov/covid/hcp/clinical-care/clinical-specimen-guidelines.html.



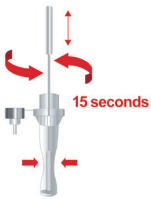
TEST PROCEDURE AND PROTOCOL

Collect sample according to instructions in “Sample Collection”. Test device and sample should be brought to room temperature (15-30°C) prior to testing.

1

Insert the collected swab into the Reagent Tube.

2

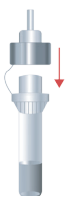


Swirl and plunge the swab up and down in the extraction buffer while squeezing the sides of the tube for 15 seconds.

3

Remove the swab while squeezing the sides of the tube to the swab head for extracting the maximum amount of liquid from the swab. Properly discard the swab.

4



Firmly close the dropper tip onto the Reagent Tube containing the sample.

5

With the processed Reagent Tube hold vertically, squeeze gently to dispense 2 drops of the sample into the sample well of the test device.

NOTE: Too few drops can result in invalid results, and too many drops could produce incorrect results.

Read the results at 15 minutes visually. Do not read result more than 30 minutes after the sample application.

NOTE: False negative or false positive results can occur if read before 15 or after 30 minutes.

RESULTS INTERPRETATION

Positive

If the Control (C) line and the Test (Ag) line are visible, the test is positive. Any visible faint red or pink Test (Ag) line with a visible Control (C) line should be read as positive. Repeat testing is not needed for individuals with a positive result.

Negative

If the Control (C) line is visible, but the Test (Ag) line is not visible, the test is negative. A negative test result indicates that the virus that causes COVID-19 was not detected in the sample.

NOTE: Negative results are presumptive and may be confirmed with a molecular assay, if necessary, for patient management.

Individuals with symptoms of COVID-19 and initial negative results should be tested again after 48 hours or followed up with a molecular test.

Invalid

If a Control (C) line is not visible, the test is not valid.
Re-test with a new swab and a new test cassette.
If the problem persists, please call +1-800-332-1042.

QUALITY CONTROL

Internal Quality Control: The presence of a pinkish red colored band in the Control area of the window acts as an internal control to ensure adequate migration has occurred, but does not determine if an adequate sample has been added. In the absence of this Control line, the test is invalid and must be repeated. If the control line does not develop in 15 minutes, the test result is considered invalid and retesting with a new device is recommended.

If the internal procedural Control line is still absent on the retest, please contact SEKISUI Diagnostics Technical Services at +1-800-332-1042 or techservices@sekisuidiagnostics.com.

External Control: Positive and negative control swabs are supplied with each kit. These controls provide additional quality control material to assess that the test kit reagents perform as expected. Process the controls in the same manner as clinical sample swab, and conduct the assay as described in Test Procedure and Protocol section. Controls should minimally be run before using each new lot or shipment of OSOM COVID-19 Test, at regular intervals afterwards or any time when the validity of the test results are questioned. All users should follow local, state and federal regulations regarding quality control procedures.

If the controls do not perform as expected, do not report patient results. Please contact SEKISUI Diagnostics Technical Services at +1-800-332-1042 or techservices@sekisuidiagnostics.com.

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.
- This test is not for use in at-home testing settings.
- Viral transport media (VTM) should not be used with this test.
- Negative test results are not intended to rule out other non-SARS viral or bacterial infections.
- Positive test results do not rule out co-infections with other bacterial or viral pathogens.
- False positive test results are more likely when prevalence of upper respiratory infection is low in the community.
- This test is read visually and has not been validated for use by those with impaired vision or color-impaired vision.
- Accurate results are dependent on adequate specimen collection, transport, storage, and processing. Failure to observe proper procedures in any one of these steps can lead to incorrect results.
- Results from this antigen test should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to determine infection status.
- This test detects both viable (live) and non-viable SARS-CoV-2 virus. Test performance depends on the amount of virus (antigens) in the sample and may or may not correlate with viral culture results performed on the same sample. A false-negative test result may occur if the level of viral antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly.
- The test results should be interpreted in conjunction with other clinical and laboratory data available to the healthcare provider.
- This device is a qualitative test and does not provide information on the viral concentration present in the specimen.
- There is a risk of erroneous results (i.e., false negatives) due to the presence of novel, emerging respiratory viral variants (e.g., specific strains or isolates).
- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between January 2022 and February 2024. 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.

CLINICAL PERFORMANCE

The clinical performance of the OSOM COVID-19 Test was established with 824 anterior nasal samples prospectively collected from subjects between January 2022 and February 2024 at four clinical point-of-care sites in the U.S. Samples were collected by untrained non-laboratory personal from sequentially enrolled subjects who presented with symptoms of COVID-19 and within 4 days of onset of symptoms. Samples were tested with OSOM COVID-19 Test. All subjects were confirmed as positive or negative by the FDA Cleared RT-PCR method, used as the comparator method for the study. OSOM COVID-19 Test was performed by operators who had no prior experience in the laboratory and were representative of the intended users. Operators used only the QRI to conduct without comprehensive training provided. All testing was conducted by operators in a blinded fashion.

Out of the 184 samples that tested positive with the comparator RT-PCR test, 156 were positive and 28 were negative using OSOM COVID-19 Test. Additionally, 638 out of 640 samples that were negative on RT-PCR were also negative on OSOM COVID-19 Test. The agreement between the OSOM COVID-19 Test and RT-PCR are presented below.

Table 1. Comparison Result with Comparator RT-PCR method

OSOM COVID-19 Test	Comparator RT-PCR		Total
	Positive	Negative	
Positive	156	2	158
Negative	28	638	666
Total	184	640	824
Positive Percent Agreement (PPA) = (156/184) x 100% = 84.78% (95% CI: 78.89%-89.26%)			
Negative Percent Agreement (NPA) = (638/640) x 100% = 99.69% (95% CI: 98.87%-99.91%)			

Table 2. Positive Results by Age Group

Age Group	Comparator RT-PCR method		
	# of Specimen Tested	# of Positive Specimen	Prevalence (%)
≤5 years	46	5	10.87
6 to 21 years	194	21	10.82
22 to 60 years	464	120	25.86
≥61 years	120	38	31.67
Total	824	184*	22.33
** OSOM COVID-19 Test yielded positive results for 4 samples in the age group below 5 years old, 16 samples in the age group of 6 to 21 years, 103 samples in the age group of 22 to 60 years, and 33 samples in the age group over 61 years.*			

Table 3. Positive Results Stratified by Days Post-Symptom Onset

Days Post Onset	RT-PCR Positive	OSOM COVID-19 Test Positive	Positive Rate (%)	95% CI
1	30	22	73.33	55.55 - 85.82
2	56	46	82.14	70.16 - 90.00
3	53	45	84.91	72.95 - 92.15
4	45	43	95.56	85.17 - 98.77
Total	184	156	84.78	78.89 - 89.26

ASSAY SENSITIVITY: LIMIT OF DETECTION (LOD)

To verify analytical sensitivity of OSOM COVID-19 Test, Limit of Detection (LoD) was established using serial dilutions of Gamma-irradiated SARS-CoV-2 Virus, isolate 2019-nCoV/USA-WA1/2020 was selected as a wild-type strain and heat-inactivated SARS-CoV-2 Omicron variant strain, isolate hCoV-19/USA/MD-HP20874/2021 (Lineage B.1.1.529) and UV inactivated SARS-CoV-2 Delta variant strain, isolate USA/PHC658/2021 (Lineage B.1.617.2) were selected as the current dominant variant strain in circulation. Contrived samples were prepared by spiking the strain into pooled negative clinical matrix. A preliminary LoD was determined by spiking 50 µL of serially diluted sample onto swab heads and tested using the OSOM COVID-19 Test. A preliminary LoD test was performed by spiking 50 µL of each diluted sample onto the sample collection swab head. The confirmatory LoD test was performed at the selected preliminary LoD concentration and at concentrations above and below the preliminary LoD with an additional 20 replicates. Based on the testing procedure for this study, the results of LoD are presented below table.

Table 4. LoD Study Summary

SARS-CoV-2 Variant	Strain	LoD	% Positive
Wild	2019-nCoV/USA-WA1/2020, Gamma-irradiated	7.0×10^2 $TCID_{50}$/mL (3.5×10^1 $TCID_{50}$/swab)	95%
Omicron	hCoV-19/USA/MD-HP20874/2021, Heat Inactivated	1.95×10^2 $TCID_{50}$/mL (9.8×10^0 $TCID_{50}$/swab)	95%
Delta	USA/PHC658/2021, UV Inactivated	5.21×10^2 $TCID_{50}$/mL (2.6×10^1 $TCID_{50}$/swab)	95%

Furthermore, the LoD was established using the 1st WHO International Standard for SARS-CoV-2 Antigen (NIBSC 21/368) in real clinical matrix of nasal fluid. Initially, a preliminary LoD test was performed by spiking 50 µL of each diluted sample onto the sample collection swab head in three replicates. Following this, a confirmatory LoD test with 17 additional replicates was conducted at the preliminary LoD concentration, a total of 20 replications. To determine LoD concentration, additional dilutions were investigated bracketing the confirmed LoD concentration, with each dilution level undergoing 20 replications. It was determined that the LoD of the 1st WHO International Standard for SARS-CoV-2 Antigen (NIBSC 21/368) in nasal matrix was confirmed to be 889 IU/mL (44 IU/swab).

ANALYTICAL REACTIVITY (INCLUSIVITY)

The analytical reactivity test was conducted with the currently available 15 clinical isolates and/or inactivated viral stock strains of SARS-CoV-2 which included most representing variants of Alpha, Beta, Gamma, Delta, Kappa, and Omicron (See table below).

Table 5. Inclusivity Study Results

Lineage/ Variant	Strain	Concentration
Wild	USA-WA1/2020	4.79×10^4 $TCID_{50}$/mL
B.1.1.7 (Alpha)	USA/CA_CDC_5574/2020	6.77×10^6 genome equivalency/mL
	England/204820464/2020	7.19×10^3 $TCID_{50}$/mL
	USA/CA_CDC_5574/2020	2.39×10^4 $TCID_{50}$/mL

Table 5. Inclusivity Study Results

Lineage/ Variant	Strain	Concentration
B.1.351 (Beta)	hCoV-19/USA/MD-HP01542/2021	7.20 × 10^4 genome equivalency/mL
	USA/MD-HP01542/2021	3.80 × 10^6 genome equivalency/mL
	South Africa/KRISP-K005325/2020	1.90 × 10^4 $TCID_{50}$/mL
P.1 (Gamma)	Japan/TY7-503/2021	1.58 × 10^4 $TCID_{50}$/mL
	USA/NY-Wadsworth-21033899-01/2021	7.85 × 10^3 $TCID_{50}$/mL
B.1.617.2 (Delta)	hCoV-19/USA/MD-HP05285/2021	7.20 × 10^7 genome equivalency/mL
	USA/PHC658/2021	5.21 × 10^2 $TCID_{50}$/mL
	USA/MD-HP05285/2021	5.00 × 10^3 genome copies/mL
B.1.617.1 (Kappa)	USA/CA-Stanford15_S02 /2021	8.48 × 10^4 $TCID_{50}$/mL
B.1.1.529 (Omicron)	hCoV-19/USA/MD-HP20874/2021	1.95 × 10^2 $TCID_{50}$/mL
	USA/GA-EHC-2811C/2021	2.11 × 10^4 genome copies/mL

ASSAY CROSS-REACTIVITY AND MICROBIAL INTERFERENCE

Cross-reactivity of the OSOM COVID-19 Test was evaluated by 43 potential pathogens of bacteria (10), fungi (1), virus (31), and negative matrix (1) that could potentially cross-react with the OSOM COVID-19 Test. The final concentration of each organism is described in the table below. The microbial interference was also performed with the same panel of microorganisms at the same concentrations in the samples that were spiked with SARS-CoV-2 at 3x LoD. The samples were tested in triplicates for both cross-reactivity and interference studies. No cross-reactivity and no microbial interference were observed. The results for cross-reactivity and microbial interference are presented in the table below.

Table 6. Cross Reactivity and Microbial Interference Results

Pathogen	Concentration Tested	Cross-Reactivity/ Microbial Interference
Human Coronavirus, 229E	1.0×10^5 $TCID_{50}$/mL	No
Human Coronavirus, OC43	4.5×10^4 $TCID_{50}$/mL	No
Coronavirus, NL63	1.0×10^5 $TCID_{50}$/mL	No
MERS-CoV, EMC/2012	1.0×10^5 $TCID_{50}$/mL	No
SARS-CoV, Urbani	1.0×10^5 PFU/mL	No
Adenovirus Type 2, C	1.0×10^5 $TCID_{50}$/mL	No
Human Adenovirus 1	1.0×10^5 $TCID_{50}$/mL	No
Human Mastadenovirus B, Type 7	1.0×10^5 $TCID_{50}$/mL	No
Human Metapneumovirus, TN/83-1211	1.0×10^5 $TCID_{50}$/mL	No
Coronavirus HKU1 was not tested for cross-reactivity due to a lack of availability. 20 clinical samples containing Coronavirus HKU1 were tested and all resulted as negative.		

Table 6. Cross Reactivity and Microbial Interference Results

Pathogen	Concentration Tested	Cross-Reactivity/ Microbial Interference
Human Parainfluenza Virus 1, HPIV1/ FRA/29221106/2009	1.0×10^5 $TCID_{50}$/mL	No
Human Parainfluenza Virus 2, Greer	1.0×10^5 $TCID_{50}$/mL	No
Human Parainfluenza Virus 3, NIH 47885	1.0×10^5 $TCID_{50}$/mL	No
Human Parainfluenza Virus 4B, 19503	1.0×10^5 $TCID_{50}$/mL	No
Influenza A Virus/A/New Caledonia/20/1999 (H1N1)	1.0×10^5 $CEID_{50}$/mL	No
Influenza A Virus/A/San Diego/1/2009 (H1N1) pdm09	1.0×10^5 $TCID_{50}$/mL	No
Influenza A Virus/A/Victoria/361/2011 (H3N2)	1.0×10^5 $CEID_{50}$/mL	No
Influenza A Virus/A/Wisconsin/67/2005 (H3N2)	1.0×10^5 $CEID_{50}$/mL	No
Influenza B Virus/B/Brisbane/60/2008 (Victoria Lineage)	1.0×10^5 $CEID_{50}$/mL	No
Influenza B Virus/B/Texas/06/2011 (Yamagata Lineage)	1.0×10^5 $CEID_{50}$/mL	No
Influenza B Virus/B/GL/1739/54	1.0×10^5 $CEID_{50}$/mL	No
Enterovirus 71 (EV-71), MP4	1.0×10^5 $TCID_{50}$/mL	No
Enterovirus Species D Type 68, USA/2018-23087	1.0×10^5 $TCID_{50}$/mL	No
Human Respiratory Syncytial Virus A/Long	1.0×10^5 PFU/mL	No
Human Respiratory Syncytial Virus A/2001/2-20	1.0×10^5 $TCID_{50}$/mL	No
Human Respiratory Syncytial Virus B/PR-348-00 MISC082	1.0×10^5 $TCID_{50}$/mL	No
Human Respiratory Syncytial Virus A/1998/12-21	1.0×10^5 $TCID_{50}$/mL	No
Rhinovirus 20, 15-CV19	1.0×10^5 $TCID_{50}$/mL	No
Measles Virus, Edmonston	1.7×10^4 $TCID_{50}$/mL	No
Mumps Virus, MuV/Iowa.US/2006	1.0×10^5 $TCID_{50}$/mL	No
Coxsackie Virus B4	1×10^5 U/mL $TCID_{50}$	No
Epstein-Barr (Strain: B95-8)	1.0×10^5 cp/mL	No
Haemophilus influenzae, (Type b; Eagan)	1.0×10^6 CFU/mL	No
Streptococcus pneumoniae, (Z022, 19F)	1.0×10^6 CFU/mL	No
Streptococcus pyogenes, Bruno	1.0×10^6 CFU/mL	No
Streptococcus salivarius	1.0×10^6 CFU/mL	No
Candida albicans, Z006	1.0×10^6 CFU /mL	No
Bordetella pertussis	1.0×10^6 CFU /mL	No
Mycoplasma pneumoniae	1.0×10^6 CFU /mL	No
Coronavirus HKU1 was not tested for cross-reactivity due to a lack of availability. 20 clinical samples containing Coronavirus HKU1 were tested and all resulted as negative.		

Table 6. Cross Reactivity and Microbial Interference Results

Pathogen	Concentration Tested	Cross-Reactivity/ Microbial Interference
Chlamydophila pneumoniae	1.0×10^6 IFU/mL	No
Legionella pneumophila subsp. *pneumophila*	1.0×10^6 CFU /mL	No
Staphylococcus aureus, (MRSA; COL)	1.0×10^6 CFU/mL	No
Staphylococcus epidermidis, (MRSE; RP62A)	1.0×10^6 CFU/mL	No
Pooled human nasal wash	N/A	No
Coronavirus HKU1 was not tested for cross-reactivity due to a lack of availability. 20 clinical samples containing Coronavirus HKU1 were tested and all resulted as negative.		

ENDOGENOUS INTERFERENCE

To assess endogenous interference with the performance of the OSOM COVID-19 Test, positive and negative samples were tested with potentially interfering substances that may be found in the upper respiratory tract. This study was performed to demonstrate that thirty (30) potentially interfering substances do not cross-react nor interfere with the detection of SARS-CoV-2 in OSOM COVID-19 Test.

Table 7. Interfering Substances Testing Results

Interfering Substances	Active Ingredients	Concentration Tested	Interference (Yes/No)
Beclomethasone dipropionate	Beclomethasone dipropionate	5.04×10^0 µg/mL	No
Budesonide Nasal Spray	Budesonide	15% v/v	No
Dexamethasone	Dexamethasone	1.20×10^1 µg/mL	No
Flunisolide	Flunisolide	8.70×10^1 µg/mL	No
Hand Sanitizer Gel	Ethyl alcohol 70%	1% v/v	No
Hand Soap Fresh Breeze Scent	N/A	10% v/v	No
Histaminum 30C	Histaminum hydrochloricum, HPUS	5% w/v	No
Homeopathic Allergy Nasal Spray	N/A	15% v/v	No
Molnupiravir	Molnupiravir	4.20×10^4 µg/mL	No
Mucin (Bovine submaxillary Glands, Type I-S)	Mucin protein	2.5 mg/mL	No
Mupirocin	Mupirocin	1.50×10^0 µg/mL	No
Nasacort Allergy 24HR	Triamcinolone acetonide	15% v/v	No
Nasal Allergy Relief	Cardiospermun Galphimia glauca Luffa operculate Sabadilla	15% v/v	No
Nasal Drops	Xylometazoline	15% v/v	No
Nasal Spray 1	Oxymetazoline	15% v/v	No
Nasal Spray 2	Cromolyn sodium	15% v/v	No

Table 7. Interfering Substances Testing Results

Interfering Substances	Active Ingredients	Concentration Tested	Interference (Yes/No)
Nasal Spray 3	Fluticasone propionate	15% v/v	No
Nasal Spray 4	Phenylephrine HCl	15% v/v	No
NasoGEL (Gel Spray)	Sodium Hyaluronate, Allantoin, Sodium chloride, Methylparaben, Propylparaben	15% v/v	No
Nasonex 24hr Allergy	Mometasone furoate monohydrate	15% v/v	No
Oseltamivir Phosphate	Oseltamivir Phosphate	3.99×10^{-1} µg/mL	No
Human Neutrophils	N/A	5×10^{6} cells/mL	No
Remdesivir	Remdesivir	2.40×10^{3} µg/mL	No
Sore Throat (Oral Pain Reliever spray)	Phenol, Menthol	15% v/v	No
Sore throat Lozenges	Benzocaine, Menthol	15% w/v	No
Tobramycin	Tobramycin	3.30×10^{1} µg/mL	No
Whole Blood	N/A	2.5%	No
ZICAM® Oral mist	Zincum aceticum, Zincum gluconicum	15% v/v	No
Zinc Lozenges	Zincum gluconicum	5% w/v	No
Biotin	N/A	3500 ng/mL	No

HIGH-DOSE HOOK EFFECT

The OSOM COVID-19 Test was tested up to 2.8×10^{6} $TCID_{50}$/mL of gamma-irradiated SARS-CoV-2 and no high-dose hook effect was observed.

REPRODUCIBILITY

A reproducibility study was conducted to determine the performance of the OSOM COVID-19 Test using a contrived sample panel consisting of a true negative (TN), a high negative sample (HN, 0.1x LoD), a low positive (LP, 1.0x LoD) and a medium positive (MP, 3.0x LoD), tested over 5 non-consecutive days, by untrained operators, in intended use settings. Contrived samples were prepared using negative clinical matrix pooled nasal wash solution, confirmed COVID-19 negative by a SARS-CoV-2 RT-PCR system, by spiking with gamma irradiation inactivated SARS-CoV-2 whole virus (isolate 2019-nCoV/USA-WA1/2020). The inactivated SARS-CoV-2 was diluted to 3.0x LoD, 1.0x LoD or 0.1x LoD concentrations, and 50 µL of each diluted test sample was applied directly onto sample collection swab head. True negative swab samples were prepared by applying 50 µL of negative pooled nasal wash directly to sample collection swab head.

The prepared contrived swabs were randomized and blindly distributed to each operator at 3 discrete Point-of-Care sites (POC) and an internal site, and then tested with 3 lots of OSOM COVID-19 Test per operator. A total of 7 assigned operators at 3 POC sites and 3 operators in the internal site each tested using 60 coded samples (TN: 15, HN: 15, LP: 15, and MP: 15 samples, respectively). The results of this study showed that percent agreement from all 10 operators was 100% for True Negative, High Negative, and Medium Positive samples, and 98% for Low Positive samples.

Table 8. Reproducibility Study Results

Sample	No of Positive Result/No of Total Tested (% Positive Rate)				Total	
	Site 1 (3 operators)	Site 2 (2 operators)	Site 3 (2 operators)	Site 4 (3 operators)	Agreement	95% CI
True Negative	0/45 (0%)	0/30 (0%)	0/30 (0%)	0/45 (0%)	150/150 (100%)	97.5-100.0
High Negative	0/45 (0%)	0/30 (0%)	0/30 (0%)	0/45 (0%)	150/150 (100%)	97.5-100.0
Low Positive	42/45 (93.3%)	30/30 (100%)	30/30 (100%)	45/45 (100%)	147/150 (98%)	94.3-99.3
Medium Positive	45/45 (100%)	30/30 (100%)	30/30 (100%)	45/45 (100%)	150/150 (100%)	97.5-100.0

REFERENCES

1. Neeraja R, et al. Diagnostics for SARS-CoV-2 detection: A comprehensive review of the FDA-EUA COVID-19 testing landscape. Biosensors and Bioelectronics 165 (2020) 112454.
2. IFCC Information Guide on COVID-19 (https://ifcc.org/resources-downloads/ifcc-information-guide-on-covid-19-introduction/).
3. Diao B, et al. Diagnosis of Acute Respiratory Syndrome Coronavirus 2 Infection by Detection of Nucleocapsid Protein. medRxiv doi:https://doi.org/10.1101/2020.03.07.20032524.

GLOSSARY

	Caution: Federal law restricts this device to sale by or on the order of a physician
	Catalog number
	Batch code
	Use-by date
	Consult instructions for use
	*In Vitro* Diagnostic Medical Device
	Temperature limit
	Positive control
	Negative control
	Do not re-use
	Manufacturer
	Contains sufficient for <n> tests
	Attention, see instructions for use

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