OHC COVID-19 Antigen Self Test
Health Care Provider Instructions for Use (IFU)

For *In vitro* diagnostic use only
For use under an Emergency Use Authorization (EUA) Only.
For use with anterior nasal swabs specimens

ISC03106 Rev. February-2023

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1. INTENDED USE

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

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

The OHC COVID-19 Antigen Self 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 anterior nasal (nares) 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 infection status. 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 OHC COVID-19 Antigen Self Test should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary.

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

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

Individuals should provide all results obtained with this product to their healthcare provider for public health reporting and to receive appropriate medical care. All healthcare providers will report all test results they receive from individuals who use the authorized product to relevant public health authorities in accordance with local, state, and federal requirements using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by CDC.

The OHC COVID-19 Antigen Self Test is intended for non-prescription self-use and/or as applicable an adult lay user testing another person 2 years of age or older in a non-laboratory setting. The OHC COVID-19 Antigen Self Test is only for use under the Food and Drug Administration's Emergency Use Authorization. This product has not been FDA cleared or approved.

2. EXPLANATION OF THE TEST

COVID-19 (short for 'Coronavirus Disease 2019') is a disease first recognized in 2019 that is caused by a type of novel coronavirus called SARS-CoV-2. Due to its rapid spread, the World Health Organization (WHO) recognized the disease as a global pandemic on March 11, 2020. Individuals infected with SARS-CoV-2 may have a range of symptoms from asymptomatic infection to severe respiratory illness and even death. The virus is spread primarily from person to person through respiratory particles, even by individuals without symptoms.

The OHC COVID-19 Antigen Self Test is a rapid, qualitative immunochromatographic assay for the determination of the presence of SARS-CoV-2 antigens in self-collected anterior nasal swab specimens. The test strip is composed of the following parts: sample pad, reagent pad, reaction membrane, and absorbing pad. The reagent pad contains the colloidal-gold conjugated with the monoclonal antibodies against the nucleocapsid protein of SARS-CoV-2; the reaction membrane contains the secondary antibodies for nucleocapsid protein of SARS-CoV-2. The whole strip is fixed inside a plastic device. When the sample is added into the sample well, conjugates dried in the reagent pad are dissolved and migrate along with the sample. If SARS-CoV-2 nucleocapsid antigen is present in the sample, a complex forms between the anti-SARS-2 conjugate and the virus will be captured by the specific anti-SARS-CoV-2 monoclonal antibodies coated on the test line region (T).

The results of the test are interpreted at 15 minutes. Refer to the Interpretation of Results section.

3. MATERIALS AND REAGENTS PROVIDED

The OHC COVID-19 Antigen Self Test is offered in a 1, 2, 4, 5, and 25 test/kit sizes. The kit configurations are provided below:

Number of Test/Kit	1 Test/Kit	2 Tests/Kit	4 Tests/Kit	5 Tests/Kit	25 Tests/Kit
Test Cassette	1	2	4	5	25
Sterile Swab	1	2	4	5	25
Extraction Buffer Tube & Filter Cap	1	2	4	5	25
Instructions for Use	1	1	1	1	1

4. MATERIALS REQUIRED BUT NOT PROVIDED

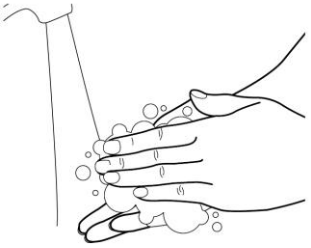
- Timer

5. QUALITY CONTROL

Each OHC COVID-19 Antigen Self Test has a built-in internal procedural control. The pink/purple line appearing at the “C” position is an internal procedural control. This procedural control line indicates that sufficient flow has occurred, and the functional integrity of the test cassette has been maintained. A distinct pink/purple Control line should always appear if the test has been performed correctly. If the Control line does not appear, the test result is invalid, and a new test should be performed.

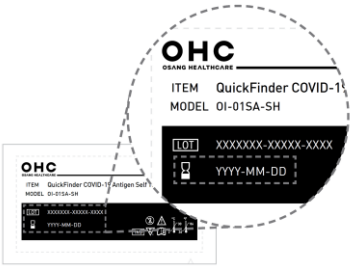
6. PREPARE TO PERFORM THE TEST

1. Bring test kit to room temperature (59-86 °F /15-30°C).
****Before washing your hands, please prepare by blowing your nose****

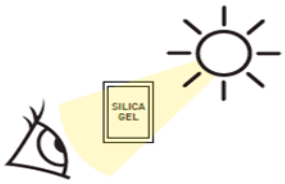


2. Wash your hands with soap and water, or use hand sanitizer before performing the test. Make sure you rinse thoroughly and your hands are dry before starting.

3. Check test expiration date on the back of the foil. Do not use if the expiry date has passed.

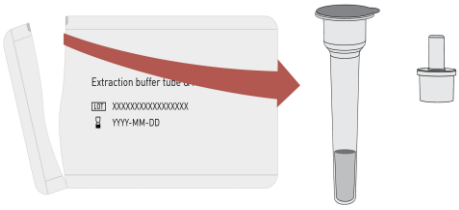


NOTE: Testing should commence immediately
after opening the sealed pouches.



4.Open the pouch and remove the test device from the foil pouch. Ensure the desiccant contains only white and yellow beads.
NOTE: If green beads are present use a new test device.

5. Place the test device on a flat surface.

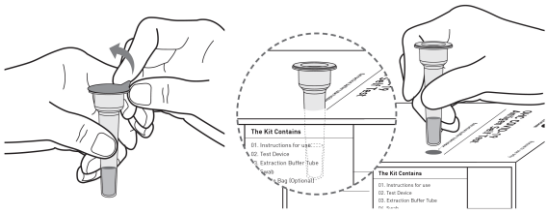


7. TEST PROCEDURES

1. Open the pouch that contains the extraction buffe tube & filter cap.

Open the seal of the tube carefully without spilling the liquid inside the tube.

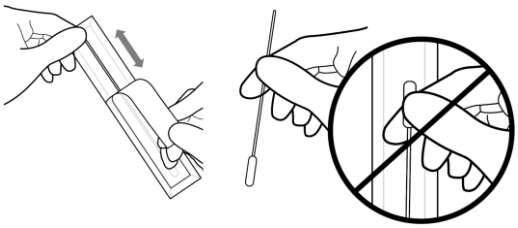
Punch a hole in the box to hold the tube.



If any liquid spills, do not use the tube.

2. Remove the swab from the packaging.

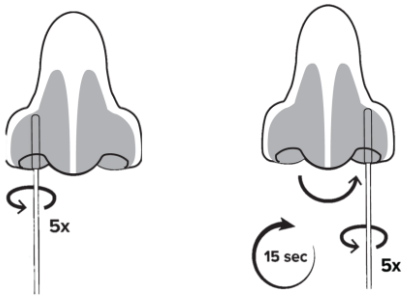
Ensure that you only touch the handle of the swab
and NOT the soft pad on the tip.



3. Holding the stick end of the swab, gently insert
the foam end of the swab into the nostril approximately ½ to ¾ of an inch.

Do not insert the swab any farther if you feel resistance
**** Swab Both Nostrils****

4. Firmly and slowly rotate the swab at least 5 times, brushing against the inside walls of the nostril at least 5 times for a total of 15 seconds.
****Do not just spin the swab****

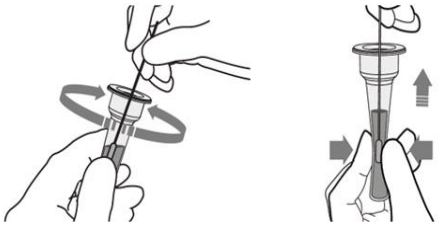


Gently remove the swab, and using the same swab,
repeat in the second nostril with the same end of the swab.

NOTE: When swabbing others, please wear a face mask.
With children, the maximum depth of insertion into the nostril may be less than ¾ of an inch, and you may need to have a second person to hold the child's head while swabbing.

WARNING! Inaccurate test results may occur if the nasal specimen is not properly collected.

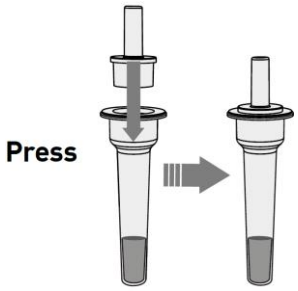
5. Directly insert the swab taken from the nostril into the extraction buffer tube and stir in more than 10 times.
Take out the swab from the extraction buffer tube
by squeezing and applying pressure on both sides of the tube.



WARNING! Failure to squeeze the tube can

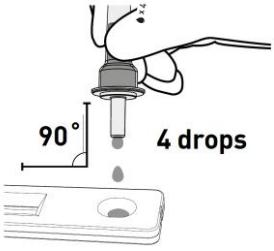
lead to incorrect results due to excess buffer in the swab.

WARNING! The sample should be mixed into the buffer immediately, but no more than 1 hour after collecting the sample.



6. Dispose of the swab and seal the tube securely with the filter cap.

7. Hold the tube upright above the sample well.
Drop 4 drops onto the sample well.



****Do not apply the liquid in the rectangle result window****

WARNING! Adding more or less than 4 drops of solution into the sample well may result in incorrect results.

8. Set the timer and read the result at 15 minutes.
Do not read the result after 20 minutes.

Read test result at 15 minutes.
DO NOT read after 20 minutes.
WARNING! Do not move or lift the test device during this time.

After the test is completed, dispose of used materials in household trash.
Do not flush or pour test liquids down the drain.

WARNING! Inaccurate test interpretation may occur if results are read before 15 minutes or after 20 minutes.
Look at the result window and locate the letters C and T on the side of the window.
A pink/purple line should always appear at the C position; this is a control line and signal that the test is working properly

8. TEST INTERPRETATION

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

Status on first day of Testing	First Result Day 1	First Result Day 3	First 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.

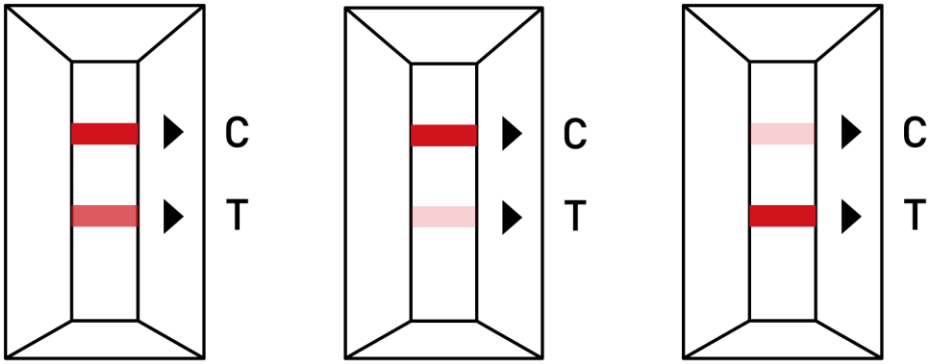
COVID-19 POSITIVE(+)

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

Repeat testing does not need to be performed if patients have a positive result at any time.

If the test cassette looks like the examples below, then protein from the virus that causes COVID-19 was detected in the sample. The test is positive if there are two pink/purple lines present, one at the Control "C" line and one at the Test "T" line. Look very closely for line next to "T". This line can be very faint. Any visible pink/purple "T" line is a positive result when the "C" line is also present.

The Test line (pink/purple line) may vary in shade and intensity (light or dark, weak, or strong) depending on the concentration of antigen present in the sample. The intensity of the Control line should not be compared to that of the Test line for the interpretation of the test result. Any faint visible pink/purple Test line should be interpreted as positive, when the control line (C) line is also present.



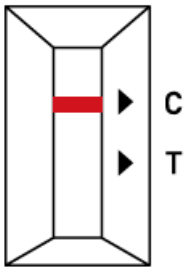
IF THE TEST IS POSITIVE

A positive test result means that the virus that causes COVID-19 was detected in the sample, and it is very likely the individual has COVID-19 and is contagious. Please contact the patient's doctor/primary care physician (if applicable) and the local health authority immediately and instruct your patient to 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 (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 OHC COVID-19 Antigen Self 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 the individual has symptoms on the first day of testing.**
- **Test 2 more times at least 48 hours apart if the individual does not have symptoms on the first day of testing.**

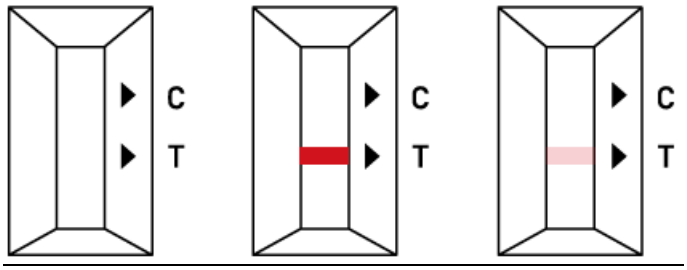
IF THE TEST IS NEGATIVE

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.

INVALID

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



If the test cassette looks like the examples below then the test **was not able to give a result** and you must **repeat the test with a new swab, a new tube, and a new test cassette.** The test is INVALID if there is no line next to "C".

IF THE TEST IS INVALID

If a line does not appear on the control line position (C) in **15 minutes,** the **test result is invalid.** Retest with a new OHC COVID-19 Antigen Self Test.

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

9. STORAGE AND STABILITY

- OHC COVID-19 Antigen Self Test should be stored between 2 to 30 °C (35.6 to 86 °F).
- Kit components in the OHC COVID-19 Antigen Self Test are stable until the expiration date printed on the label.
- The Test Cassette must remain in the sealed pouch until use.
- Ensure all kit components are at room temperature before use.

10. WARNINGS, PRECAUTIONS, AND SAFETY INFORMATION

- 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. This product has been authorized only for the detection of proteins from SARS-Co-V-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 if 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 symptoms longer than 7 days you should consider testing at least three times over five days with at least 48 hours between tests.**
- An anterior nasal swab sample can be self-collected by an individual age 14 years and older. Children age 2 to 13 years should be tested by an adult.
- Do not use on anyone under 2 years of age.
- Wear a safety mask or other face-covering when collecting a specimen from a child or another individual.
- Do not use if any of the test contents or packaging is damaged.
- Test components are single-use. Do not re-use.
- Do not use kit past its expiration date. For information about current expiration dates for at-home OTC COVID-19 diagnostic tests, visit http://www.fda.gov/covid-tests.
- Do not touch the swab tip.
- Once opened, the test card should be used within 60 minutes.
- **Do *not* read test results before 15 minutes or after 20 minutes. Results read before 15 minutes or after 20 minutes may lead to a false positive, false negative, or invalid result.**
- **Keep testing kit and kit components away from children and pets before and after use. Avoid contact with your skin, eyes, nose, or mouth, 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	Concentrations
Sodium azide	H320, eye irritation H315, skin irritation	0.05%
Triton-X-100	H320, eye irritation H315, skin irritation	1.0%
BIS (trimethylsilyl acetamide)	H320, eye irritation H315, skin irritation	1.0%

Chemical Name	GHS Code for each ingredient	Concentrations
Tris (hydroxymethyl) aminomethane	H320, eye irritation H315, skin irritation	1.2%

- For more information on EUAs, please visit: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization
- For most up to date information on COVID-19, please visit: www.cdc.gov/COVID19
- Use of personal protection materials such as gloves is recommended.
- Do not use nasal sprays for at least 30 minutes before collecting a nasal sample.
- Remove any piercings from nose before starting the test.
- Do not use on anyone who is prone to nosebleeds or has had facial injuries or head injuries/surgery in the past six months.
- Make sure there is sufficient light for testing. For best results, read test in a well-lit area.
- The test should be performed at ambient temperature (i.e., 15-30^{o}C).
- Use only components of this test kit.
- In the event of spillage, ensure that it is cleaned thoroughly using suitable disinfectant.
- The control line may show up within a few minutes of starting the test. It may take up 15 minutes for the test line to show up.

11. LIMITATIONS

- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between January-February 2022. The clinical performance has not been established for all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, with change over time.
- 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.
- All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary.
- 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.
- This test is read visually and has not been validated for use by those with impaired vision or color-impaired vision.
- Incorrect test results may occur if a specimen is incorrectly collected or handled.
- This test detects both viable (live) and nonviable SARS-CoV-2. 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.

12. PERFORMANCE CHARACTERISTICS

a. Analytical Sensitivity: Limit of Detection (LoD)

The Limit of Detection (LoD) of the OHC COVID-19 Antigen Self Test was determined using serial dilutions of heat inactivated SARS-CoV-2 (USA-WA1/202). Contrived samples were prepared by spiking the strain into pooled human nasopharyngeal swab matrix obtained from healthy volunteers confirmed negative by RT-PCR.

The preliminary LoD initially determined by testing two-fold serial dilution series of 3 replicates was confirmed by testing in 20 replicates. The confirmed LoD for the OHC COVID-19 Antigen Self Test was 1.40 x 10^4 $TCID_{50}$/mL which equates to 7.00 x 10^2 $TCID_{50}$/swab.

b. NIH RADx Variant Testing

The performance of this test 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. 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, the OHC COVID-19 Antigen Self Test detected 100% of live virus Omicron samples at a Ct-value of 23.6 (n=5). 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 24.0) were not detected by the OHC COVID-19 Antigen Self Test in this study.

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

c. High-dose hook effect

The OHC COVID-19 Antigen Self Test was tested up to 2.86 x 10^6 $TCID_{50}$/mL heat inactivated SARS-CoV-2 (USA-WA1/2020) and no high-does hook effect was observed.

d. Endogenous Interfering Substances

The OHC COVID-19 Antigen Self Test was evaluated for performance in the presence of potentially interfering substances that might be present in a respiratory specimen. The positive (3X LoD SARS-CoV-2) and negative specimens were tested with the addition of potentially interfering substances. The performance of the OHC COVID-19 Antigen Self Test was not affected by any of the potentially interfering substances listed in the table below at the concentrations tested.

Substance	Concentration
Whole blood	4% v/v
NasoGEL (NeilMed)	5% v/v
Phenylephrine (Nasal Drop)	15% v/v
Mucin (porcine stomach type II)	0.5%
Oxymetazoline (Nasal Spray)	15% v/v
Tobramycin	4 µg/ml
Body & Hand Lotion	0.5% w/v
Hand Lotion	5% w/v
Hand Sanitizer with Aloe, 62% ethyl alcohol	5% v/v
Hand Sanitizer 80% ethanol, fast drying	15% v/v
Body Lotion with 1.2% dimethicone	0.5% w/v

Substance	Concentration
Homeopathic (Alkalol)	10% v/v
Oseltamivir phosphate (Tamiflu)	5 mg/mL
Cromolyn (Nasal Spray)	15% v/v
Chloraseptic (Menthol/Benzocaine)	1.5 mg/mL
Zicam	5% v/v
Sore Throat Phenol Spray	15% v/v
Mupirocin	10 mg/mL
Fluticasone Propionate	5% v/v
Hand soap liquid gel	10% w/v
Hand Sanitizer cream lotion	15% v/v

e. Analytical Specificity: Cross-reactivity and Microbial interference

Cross reactivity and interference studies were performed for related pathogens, high prevalence disease agents, and normal or pathogenic flora that are reasonably likely to be encountered in the clinical specimens of the nasal cavity. Each organism was and virus (13 bacteria and 16 viruses) were tested in both absence and presence of inactivated SARS-CoV-2 (SARS-CoV-2 isolate USA-WA1/2020) at the 3X LoD. All testing samples were prepared in the negative clinical nasal wash. No cross reactivity or interference was observed for any of the organisms tested, except for SARS-coronavirus which exhibited cross-reactivity when tested as 7.90×10^3 $TCID_{50}$/mL. A titration of SARS-CoV was performed to find the concentration at which cross-reactivity was no longer observed. Cross reactivity was no longer observed for SARS-CoV at 7.90×10^0 $TCID_{50}$/mL. These results are not unexpected in that the OHC COVID-19 Antigen Self Test targets the nucleocapsid protein which is present on both SARS-CoV and SARS-CoV-2 viruses.

ID	Organism	Concentration Tested for Cross Reactivity	Concentration Tested for Microbial Interference
229E	Human coronavirus 229E	1.43×10^5 $TCID_{50}$/mL	1.43×10^5 $TCID_{50}$/mL
OC43	Human coronavirus OC43	1.43×10^5 $TCID_{50}$/mL	1.43×10^5 $TCID_{50}$/mL
NL63	Human coronavirus NL63	1.43×10^5 $TCID_{50}$/mL	1.43×10^5 $TCID_{50}$/mL
SARS	SARS-coronavirus		
MERS	MERS-coronavirus	1.0×10^6 $TCID_{50}$/mL	1.0×10^6 $TCID_{50}$/mL
AV1	Adenovirus (e.g. C1 Ad. 71)	1.43×10^5 $TCID_{50}$/mL	1.43×10^5 $TCID_{50}$/mL
hMPV	Human metapneumovirus (hMPV)	1.43×10^5 $TCID_{50}$/mL	1.43×10^5 $TCID_{50}$/mL
P1	Parainfluenza virus 1	1.43×10^5 $TCID_{50}$/mL	1.43×10^5 $TCID_{50}$/mL
P2	Parainfluenza virus 2	1.43×10^5 $TCID_{50}$/mL	1.43×10^5 $TCID_{50}$/mL
P3	Parainfluenza virus 3	1.43×10^5 $TCID_{50}$/mL	1.43×10^5 $TCID_{50}$/mL

ID	Organism	Concentration Tested for Cross Reactivity	Concentration Tested for Microbial Interference
P4	Parainfluenza virus 4b	1.43 x 10^5 $TCID_{50}$/mL	1.43 x 10^5 $TCID_{50}$/mL
FluA	Influenza A	1.43 x 10^5 $CEID_{50}$/mL	1.43 × 10^5 $CEID_{50}$/mL
FluB	Influenza B	1.43 x 10^5 $CEID_{50}$/mL	1.43 × 10^5 $TCID_{50}$/mL
EV68	Enterovirus 68	1.43 x 10^5 $TCID_{50}$/mL	1.43 × 10^5 $TCID_{50}$/mL
RSV	Respiratory syncytial virus	1.0 x 10^5 PFU/mL	1.0 × 10^5 pfu/mL
RV	Rhinovirus	1.43 x 10^5 $TCID_{50}$/mL	1.43 × 10^5 $TCID_{50}$/mL
HI	*Haemophilus influenzae*	1.0 x 10^6 cfu/vial	1.00 ×10^6 cfu/mL
SPN	*Streptococcus pneumonia*	1.0 X 10^6 cfu/mL	1.0 x 10^6 cfu/mL
SPY	*Streptococcus pyogenes*	1.0 x 10^6 cfu/vial	1.0 × 10^6 cfu/mL
CA	*Candida albicans*	1.0 x 10^6 cfu/vial	1.0 × 10^6 cfu/mL
BP	*Bordetella pertussis*	1.0 x 10^6 cfu/vial	1.0 × 10^6 cfu/mL
MP	*Mycoplasma pneumonia*	1.0 x 10^6 cfu/vial	1.0 × 10^6 cfu/mL
CP	*Chlamydia pneumoniae*	1.0 x 10^6 IFU/mL	1 × 10^6 IFU/mL
LP	*Legionella pneumophila*	1.0 x 10^6 cfu/mL	1.0 × 10^6 cfu/mL
MT	*Mycobacterium tuberculosis*	1.0 X 10^6 cfu/mL	1.0 × 10^6 cfu/mL
PC	*Pneumocystis carinii*	1.00 x 10^6 cfu/mL	1.0 × 10^6 cfu/mL
PJ	*Pneumocystis jiroveci-S. cerevisiae* (recombinant)	1.0 x 10^6 cfu/mL	1.0 × 10^6 cfu/mL
SA	*Staphylococcus aureus* subsp. *aureus*	1.0 x 10^6 cfu/vial	1 × 10^6 cfu/mL
SE	*Staphylococcus epidermidis*	2.33 x 10^5 cfu/vial	2.33 × 10^5 cfu/mL
PNW	Pooled Negative Nasal Wash	N/A	N/A

To estimate the likelihood of cross reactivity with SARS-CoV-2 of organisms that were not available for wet testing, *in-silico* analysis using the Basic Local Alignment Search Tool (BLAST) managed by the National Center for Biotechnology Information (NCBI) was used to assess the degree of protein sequence homology. HKU1 nucleocapsid phosphoproteins was analyzed and the results are below.

- The homology between SARS-CoV-2 nucleocapsid protein and human coronavirus HKU1 nucleocapsid phosphoproteins is relatively low, 36.7% across 82% of sequences, but cross-reactivity cannot be ruled out.

f. Flex Study

A robust use of OHC COVID-19 Antigen Self Test was demonstrated by seven (7) flex studies as follows:

1) Delay in reading results study
2) Disturbance while testing study
3) Mixing study
4) Non-level surface testing study
5) Sample volume variability study
6) Lighting
7) Temperature and Humidity

13. CLINICAL EVALUATION

Clinical Performance: Prospective Serial Testing Study at National Institutes of Health:

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 test 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 A.

Table A: 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 Per 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 Tests	3 Tests	1 Test	2 Tests	3 Tests
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%)
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	12/23 (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 performed on the noted days after the first PCR positive test results. Day 0 is the first day of documented infection with SARS-CoV-2.
2 Tests = two (2) tests performed 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 performed 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.

Clinical Performance: OSANG Clinical Evaluation:

An OSANG prospective study was completed at six (6) sites in the United States for clinical validation of the OHC COVID-19 Antigen Self Test for the detection of the SARS-CoV-2 in subject-collected anterior nasal (AN) swab samples. The study evaluated the investigational test's performance in symptomatic individuals (those suspected of COVID-19). A total of 259 symptomatic subjects were enrolled and each were currently experiencing symptoms associated with COVID-19, **within 7 days of symptom onset**. Each enrolled subject either self-collected one sample from their anterior nasal passages (from both nostrils), or had one sample collected from him/her by another individual. Each subject then had a mid-turbinate sample (from both nostrils) collected from him/her by one of the study personnel. Test results from the OHC COVID-19 Antigen Self Test (candidate test) were compared to highly sensitive molecular FDA EUA Authorized SARS-CoV-2 assays to determine test performance. An analysis was performed which identified that 41/120 (34%) of study subjects had low viral loads based on the Ct values from a comparator method RT-PCR test. This may be associated with the Omicron variant since the low positive percentage in this study is higher than that observed in prior clinical studies for previously authorized COVID-19 rapid antigen tests. Antigen test performance decreases as the percent of low positives increases since the comparator method is significantly more sensitive than the candidate test. Therefore, to be consistent with previous studies, the analysis for the primary performance calculation was conducted to reflect a study population with 10-20% low positives. Multiple Percent Positive Agreement (PPA) calculations are presented below for the positive sample cohort when a range of low positive samples was included (10% to 20%). At 10% low positives the PPA was 82.9% and the negative percent agreement (NPA) was 98.6% with 95% confidence interval bounds of 73.8% to 89.4% PPA and 94.9% to 99.6% for NPA, respectively. This was the basis of the authorization. At 20% low positives, the PPA was 73.7% with 95% confidence interval bounds of 64.3% to 81.4%.

Primary Analysis					
	10% Low Positives	12.5% Low Positives	15% Low Positives	17.5% Low Positives	20% Low Positives
High Positive Samples	79	79	79	79	79
Low Positive Samples	9	12	14	17	20
Total Comparator Positives for PPA Calculation	88	91	93	96	99
Total Device Positives for PPA Calculation	73	73	73	73	73
PPA (%)	82.9 (73/88)	80.2 (73/91)	78.5 (73/93)	76.0 (73/96)	73.7 (73/99)
95% CI (XX% - XX%)	73.8-89.4	70.9-87.1	69.1-85.6	66.6-83.5	64.3-81.4
NPA (%)	98.6 (137/139)				
95% CI (XX% - XX%)	94.4-99.6				

When all study participants are included, the PPA is 64.2% and the negative percent agreement is 98.6% with the 95% confidence interval bounds of 55.3% to 72.2% for the PPA and 94.9% to 99.6% for the NPA, respectively.

Age and Gender Distribution and positive Rate of Symptomatic Subjects Within First 7 Days of Symptom Onset				
Subject Age	**Female**	**Male**	**Positives**	**% Positivity Rate**
<14 years of age	20	21	11	26.8%
14-24 years of age	18	10	10	35.7%
>24-64 years of age	100	71	88	51.5%
=>65 years of age	13	6	11	57.9%
Total	**151**	**108**	**120**	**46.3%**

Positive Results Broken Down by Days Since Symptom Onset				
Days Post Symptom Onset	**Number of Samples tested**	**OHC COVID-19 Antigen Self Test Positives**	**RT-PCR Positives**	**PPA**
0	15	6	8	75.0%
1	63	13	27	48.1%
2	84	25	38	63.2%
3	57	19	26	73.1%
4	17	8	10	70.0%
5	11	4	5	80.0%
6	9	4	5	80.0%
7	3	0	1	0.0%
Total	**259**	**79**	**120**	**64.2%**

14. TECHNICAL SUPPORT

For questions, or to report a problem, please call Technical Support at 844-760-0556 (Available Hours: Mon. to Fri.: 9 a.m. – 5 p.m. PST) or covidhometest@osangllc.com .

Test system problems may also be reported to the FDA using the MedWatch reporting system (phone: 1-800 FDA-1088; fax: 1-800 FDA-1078: or http://www.fda.gov/medwatch).

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15. INTERNATIONAL SYMBOL USAGE

You may see one or more of these symbols on the labelling/packaging of this product:

	Use-by date		Batch Code		*In vitro* diagnostic device
	Reference number		Consult instructions for use		Manufacturer
	Contains sufficient for <n> test		Temperature limit		Do not reuse
	Caution		Do not use if the packaging is damaged		Date of manufacture