OSANG HEALTHCARE

QuickFinder™ COVID-19/Flu Antigen Self Test Healthcare Provider Instructions for Use (IFU)

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

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1. INTENDED USE

The QuickFinder™ COVID-19/Flu Antigen Self Test is a lateral flow immunoassay intended for the qualitative detection and differentiation of SARS-CoV-2, influenza A, and influenza B protein antigens.

This test is authorized for non-prescription home use with self-collected anterior nares nasal swab specimens from individuals aged 14 years or older, or with adult-collected anterior nasal swab specimens from individuals two (2) years or older. This test is only authorized for individuals with signs and symptoms of respiratory infection consistent with COVID-19 within the first four (4) days of symptom onset when tested at least twice over three days with at least 48 hours between tests.

Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar.

Results are for the simultaneous identification of SARS-CoV-2, influenza A, and influenza B virus protein antigens but do not differentiate between SARS-CoV and SARS-CoV-2 viruses and are not intended to detect influenza C antigens.

The viral antigens targeted by this test are generally detectable from specimens collected using nasal swabs during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine 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. Individuals who test positive with the QuickFinder™ COVID-19/Flu 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, Influenza A and Influenza B infection and should be used for the sole basis for treatment or patient management decisions, including infection control decisions 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 SARS-CoV-2, influenza A and influenza B infection.

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

The QuickFinder™ COVID-19/Flu Antigen Self Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

2. SUMMARY AND EXPLANATION OF THE TEST

The ongoing COVID-19 pandemic, along with other seasonally prevalent illnesses such as influenza (Flu), continue to be among the world's most pressing healthcare issues. While contagious respiratory illnesses such as COVID-19 and influenza share similar symptoms and means of transmission, they are caused by different viruses. The Centers for Disease Control and Prevention (CDC) has also raised concerns about the potential co-infection with two or more of the respiratory viruses. There is an urgent need for rapid COVID-19 and Influenza A/B diagnostic over-the-counter tests so that patients can seek appropriate treatment with their healthcare provider before their symptoms worsen.

The QuickFinder™ COVID-19/Flu Antigen Self Test is a rapid lateral flow test for the qualitative detection of the SARS-CoV-2, Influenza A and Influenza B using anterior nares nasal swab samples from those who are suspected of COVID-19, Influenza A and Influenza B. The QuickFinder™ COVID-19/Flu Antigen Self Test is validated for testing direct samples

without transport media.

The cassette contains membranes which are pre-coated with anti-SARS-CoV-2 nucleocapsid protein monoclonal antibodies, anti-influenza A nucleoprotein monoclonal antibodies and anti-influenza B nucleoprotein monoclonal antibodies on the test lines. Another anti-SARS-CoV-2 nucleocapsid protein monoclonal antibodies, anti-influenza A nucleoprotein monoclonal antibodies and anti-influenza B nucleoprotein monoclonal antibodies are each bound to the beads. When the sample is put into the sample well, the antibodies bound to the beads and the antigen in the sample bind to form complexes and migrate to the membrane. The complexes will be captured by coated antibodies on the membrane, and then the line will form a visible line. The presence of SARS-CoV-2, influenza A and influenza B antigens are indicated by lines visible in the S-marked position, A-marked position, and B-marked position in the results window, respectively.

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

3. MATERIALS AND REAGENTS PROVIDED

The QuickFinder™ COVID-19/Flu 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
Quick Reference Instructions (QRI)	1	1	1	1	1

4. MATERIALS REQUIRED BUT NOT INCLUDED

- Materials required but not provided: A clock or timer
- Recommended materials: Disposable gloves and mask, if swabbing others.

5. WARNINGS, PRECAUTIONS, AND SAFETY INFORMATION

- Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
- For in vitro diagnostic use.
- 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-CoV-2, influenza A and influenza B, 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 Section564(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 COVID-19 negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals. You may need to purchase additional tests to perform this serial testing.**
- **Consistent with serial testing recommendations for SARS-CoV-2, for multi-analyte tests, symptomatic individuals who test positive for influenza A or B on the initial test but test negative for SARS-CoV-2 should be tested again in 48 hours to evaluate for co-infection with SARS-CoV-2 infection.**
- 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 kit contents or packaging is damaged.
- Do not use the test after the expiration date shown on the external packaging.
- Use only components of this test kit.
- Ensure all kit components are at room temperature before use.
- Test components are single-use. Do not re-use.
- Do not touch the swab tip.
- Once opened, the test cassette should be used immediately.
- 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.
- Faint lines may appear on the test strip prior to running the test when tests are stored at hot or humid conditions. Do not read or interpret test results until after the sample has been added to the test cassette and the test has been allowed to run for 15 minutes.
- Faint blue lines can occur near the "A" position of the test strip with some Flu B samples at high viral loads. Only test lines that appear at both the correct position and in the correct color should be read and interpreted.
- Make sure there is sufficient light for testing. For best results, read test in a well-lit area.
- In the event of spillage, ensure that it is cleaned thoroughly using suitable disinfectant.
- Do not use any nasal sprays, gels or creams at least 30 minutes before you collect a nasal sample.
- The test sample must be collected from both nostrils with the same swab.
- Do not use on anyone who is prone to nosebleeds or has had facial injuries or head injuries/surgery in the past six months.
- Remove any piercings from nose before starting the test.
- To ensure accurate test results for Influenza B, avoid contamination with hand soap liquid gel.
- Dispose of unused contents and containers after use.

- 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 in the next column). If the solution contacts your skin, eyes, nose, or mouth, flush with large amounts of water. If irritation persists, seek medical advice: https://www.poison-help.org or 1-800- 222-1222.

Hazard Category (Mixture)	GHS Hazard Statement for Mixture	Labeling of Harm(s)	Hazardous Ingredients (%)
3	Mild skin irritation	Causes mild skin irritation (H316)	• Triton X-100 / 1% • Proclin 300 / 0.05%
2	Serious eye irritation	Causes serious eye irritation (H319)	• Triton X-100 / 1% • Proclin 300 / 0.05%

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

6. QUALITY CONTROL

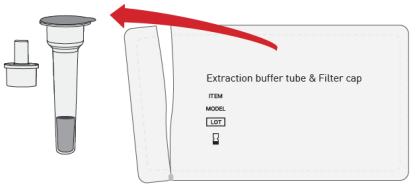
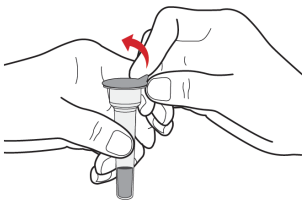
Internal Quality Control

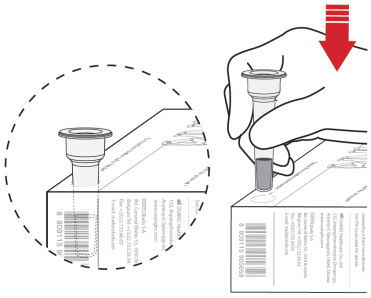
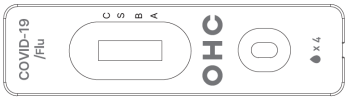
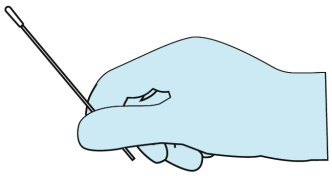
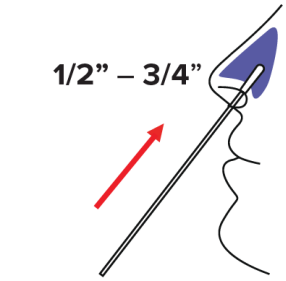
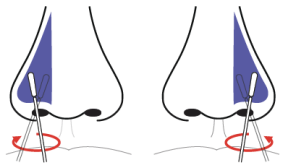
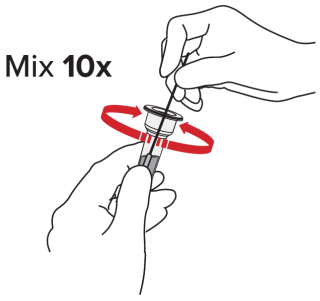
Each QuickFinder™ COVID-19/Flu Antigen Self Test has a built-in internal procedural control. The red line appearing at the "C" position is an internal procedural control. This procedural control line indicates that sufficient flow has occurred, and the functional integrity of the test cassette has been maintained. A distinct red Control line should

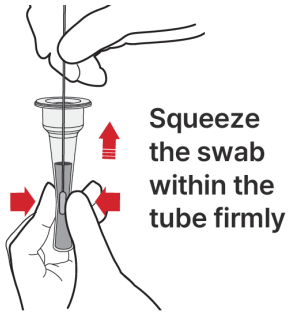
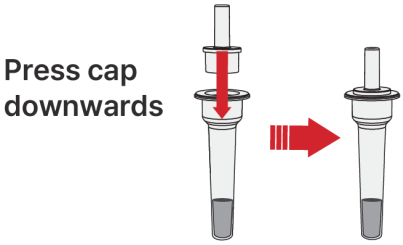
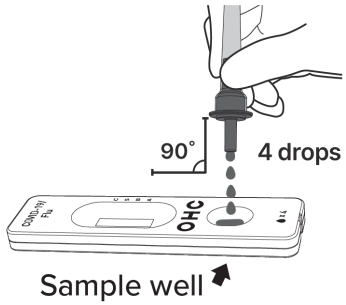
always appear if the test has been performed correctly. If the Control line does not appear, the test result is invalid, and a new test should be performed.

External Quality Control
External run controls are not required to use the QuickFinder™ COVID-19/Flu Antigen Self Test in a home setting.

7. TEST PROCEDURE

BEFORE GETTING STARTED	
1. Check expiration date on the outside of the box. Do not use beyond the expiration date. For the most current expiration dates of this test, please refer to: https://www.fda.gov/covid-tests.	
2. Wash hands thoroughly for at least 20 seconds before and after handling nasal swab samples.	
3. Before testing, read the Quick Reference Instructions carefully. Bring the test kit to room temperature (59-86°F) when you are ready to begin the test.	
PREPARE THE MATERIALS	
4. Arrange the materials on a clean, dry, flat surface. Your box may contain one or more test kits. Use only one individually packaged kit for each test. DO NOT open the individual pouches until you are ready to begin the test.	
5. Open the foil pouch that contains the extraction buffer tube and filter cap.	
6. Pick up the extraction buffer tube and remove the sealing foil of the tube without spilling the buffer solution inside the tube.	

7. Push the extraction buffer tube into the perforated tube holder located at the front of the box, labeled "Insert Tube Here."	
8. Remove the test cassette from its foil pouch. DO NOT remove the test cassette until you are ready to begin the test.	
PERFORMING THE TEST	
9. Open swab package from the stick end and remove the swab by the stick side. DO NOT touch the swab head. DO NOT contaminate the swab head with any liquid gel soap as this can lead to false results.	
10. Gently insert the swab head ½ to ¾ inch into individual's nostril. For young children, swab should not be inserted more than 1/2 inch. DO NOT insert the swab any farther if you feel any resistance. Using medium pressure, rub and rotate the swab against the inside of the individual's nostril, making at least 5 circles. **REPEAT IN THE OTHER NOSTRIL USING THE SAME SWAB.** **NOTE:** When swabbing others, wear a face mask. With children, you may not need to insert the swab as far into the nostril. For very young children, you may need another person to steady the child's head while swabbing. **STOP: Did you swab BOTH nostrils? Inaccurate test results may occur if the nasal sample is not properly collected.**	 
11. Place the swab into the extraction buffer tube and completely immerse the swab head in the solution. Vigorously mix the solution by rotating the swab forcefully against the side of the tube **at least 10 times,** keeping the swab tip submerged in the buffer solution the entire time.	

12. Remove the swab while squeezing the tube with your fingers to ensure that the sample on the swab is fully mixed into the buffer solution.	
13. Attach the filter cap onto the test tube.	
14. Squeeze only 4 DROPS of the buffer solution into the sample well. DO NOT squeeze more than 4 drops from the tube into the sample well.	
15. Set a timer and read the test result after 15 minutes. DO NOT disturb the cassette during this time. Inaccurate results can occur if the cassette is disturbed. DO NOT interpret test result before 15 minutes or after 30 minutes.	

8. INTERPRETATION OF RESULTS

Test results are read and interpreted visually. Read result at 15-30 minutes with good lighting. Test results should not be read until after the sample has been added and the test has been allowed to run for 15 minutes, and only test lines that appear at the correct position and in the correct color should be read and interpreted.

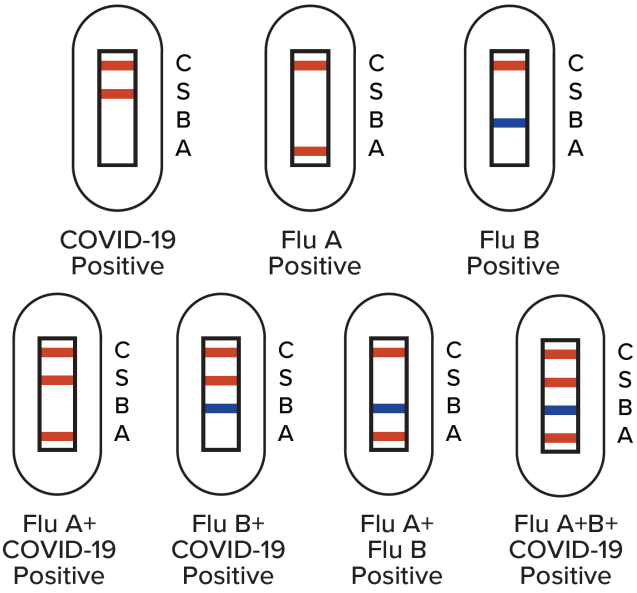
Look at the result window and locate the letters C and S, B, A on the side of the window.
A red line should always appear at the C position; this is a control line and signal that the test is working properly. The information for each line is as follows:

C = Control (red line)
S = COVID-19 (SARS-CoV-2) (red line)
B = Influenza B (blue line)
A = Influenza A (red line)

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results. 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, Flu A and Flu B.

POSITIVE (+)

If the control line at **C** is visible, and any other line or multiple lines on **S, B** and/or **A** appear, the test is positive.



IF THE TEST IS POSITIVE

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

A positive test result means that the COVID-19, Flu A and/or Flu B virus(es) were detected in the sample, and tt is very likely the individual has the respective infection(s) and are 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 small chance that this test can give you 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 QuickFinder™ COVID-19/Flu 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.

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.

Note: The Test line may vary in shade and intensity (light or dark, weak, or strong). The intensity of the Control line should not be compared to that of the Test line for the interpretation of the test result.

NEGATIVE (-)

If the control line at "C" is visible and you do not see a line at 'A', 'B' or 'S', the test is negative.

Negative

To increase the chance that the negative result for COVID-19, Flu A and Flu B is accurate, you should test again in 48 hours if this is your first test and you have symptoms on the first day of testing.

IF THE TEST IS NEGATIVE

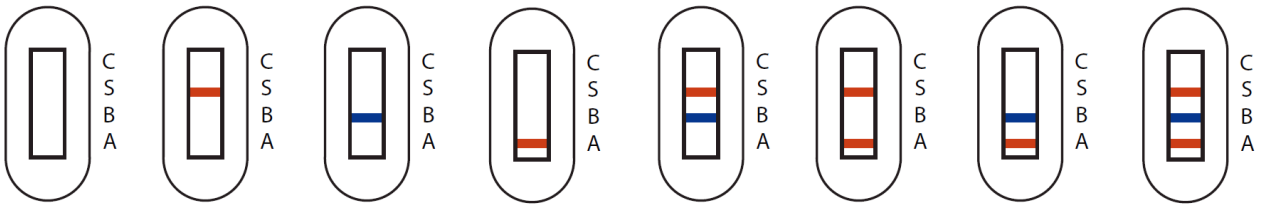
The virus that causes COVID-19, Flu A, and/or Flu B were not detected in the sample. A negative result does not rule out COVID-19, Flu A and/or Flu B. There is a higher chance of false negative results with antigen tests compared to laboratory-based molecular tests. If you tested negative and continue to experience COVID-19, Flu A and/or Flu B-like symptoms, you should seek follow-up care with your healthcare 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 a control line is not visible at "C" after 15 minutes, even if any other line is visible in the results window, THE TEST HAS FAILED and is considered invalid.

If the test cassette looks like the examples below then the test **result is invalid** and you must **repeat the test with a new swab sample, a new tube, and a new test cassette.**



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

Status on First Day of Testing	**Day 0 (Test 1)**	**Day 2 (Test 2)**
With Symptoms	COVID-19 (-) Serial testing recommended for COVID-19 Flu A or B (-) Flu A or B result is Negative	COVID-19 (-) COVID-19 result is Negative **COVID-19 (+)** **COVID-19 result is Positive** Flu A or B (-) Flu result is Negative **Flu A or B (+)** **Flu result is Positive**
	COVID-19 (-) Serial testing recommended for COVID-19 Flu (+) Flu A or B result is Positive	COVID-19 (-) COVID-19 result is Negative **COVID-19 (+)** **COVID-19 result is Positive** Flu A or B (-) **Maintain Flu Positive interpretation** **Flu A or B (+)** **Flu A or B result is Positive**
	COVID-19 (+) **COVID-19 Positive** Flu A or B (-) Flu A or B Negative	No serial testing recommended
	COVID-19 (+) **COVID-19 Positive** **Flu A or B (+)** **Flu A or B Positive**	No serial testing recommended

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.

9. STORAGE AND STABILITY

- QuickFinder™ COVID-19/Flu Antigen Self Test should be stored between 36 °F (2°C) to 86°F (30 °C).

10. LIMITATIONS

- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between October, 2023 to January, 2024, when omicron was the predominant SARS-CoV-2 strain. 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 COVID-19 and influenza and their prevalence, which 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 and influenza as compared to a molecular test, especially in samples with low viral load.
- All COVID-19 and influenza antigen test negative results are presumptive and confirmation with a molecular assay may be necessary.
- If you continue to have symptoms consistent with COVID-19 and influenza, and both your first and second tests are negative, you may not have COVID-19 or influenza; however, you should follow-up with a healthcare provider.
- Based on sequence analysis, a potential for cross-reactivity between the SARSCoV-2 test and HKU1 exists. Wet testing for HKU1 coronavirus was not conducted and therefore, cross-reactivity between SARS-CoV-2 and HKU1 coronavirus cannot be ruled out.
- Liquid gel hand soap may cause false negative results with this test. Please ensure that hands are dry after washing prior to performing the test.
- If the test is positive, then proteins from the virus that causes COVID-19, Flu A and/or Flu B have been found in the sample and the individual likely has COVID-19, Flu A and/or Flu B.
- 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.

11. PERFORMANCE CHARACTERISTICS

A. Analytical Performance

- **Limit of Detection (LoD) (Analytical Sensitivity)**

The Limit of Detection (LoD) of the QuickFinder™ COVID-19/Flu Antigen Self Test was determined using serial dilutions of one strain of UV inactivated SARS-CoV-2 (USA-WA1/202) and two live strains of Influenza A and Influenza B. Contrived samples were prepared by spiking the strain into pooled human negative swab matrix (PNSM) obtained from healthy volunteers confirmed negative by RT-PCR. The preliminary LoD initially determined by testing ten-fold serial dilution series of three (3) replicates was confirmed by testing twenty (20) replicates. The confirmed LoD for the QuickFinder™ COVID-19/Flu Antigen Self Test is shown in the table below.

Virus Strains	Stock Concentration ($TCID_{50}$/mL)	LoD Concentration ($TCID_{50}$/mL)	$TCID_{50}$/Swab	# Positive/ #Total Tested	Percent Detected (%)
SARS-CoV-2 (USA-WA1/2020)	3.16×10^6	1.58×10^3	7.90×10^1	20/20	100%
Influenza A H1N1pdm09: A/Victoria/4897/2022	2.02×10^5	2.02×10^2	1.01×10^1	20/20	100%
Influenza A H3N2: A/Darwin/6/2021	4.17×10^5	2.09×10^2	1.04×10^1	20/20	100%
Influenza B Victoria: B/Washington/02/2019	3.16×10^6	3.16×10^3	1.58×10^2	20/20	100%
Influenza B Yamagata: B/Florida/4/2006	1.17×10^5	2.93×10^1	1.46	20/20	100%

- **Analytical Reactivity**

The QuickFinder™ COVID-19/Flu Antigen Self Test had wet testing (analytical reactivity) performed by establishing the LoD for Influenza A strains, Influenza B strains and SARS-CoV-2 strains on the QuickFinder™ COVID-19/Flu Antigen Self Test to determine if the device can detect target analytes across a variety of strains. A selection of temporal, geographic and genetically diverse Influenza strains were tested on the QuickFinder™ COVID-19/Flu

Antigen Self Test for inclusivity. Individual virus strains were diluted in pooled negative swab matrix (PNSM) at 10-fold dilutions and tested in triplicate. PNSM, un-spiked, was tested in triplicate. After a 10-fold break point was established testing two-fold dilution points of the lowest positive ten-fold dilution was completed. The lowest 10-fold or 2-fold dilution that demonstrated three (3) positives replicates for each was identified.

Analyte	Strain	Lineage	Concentration
SARS-CoV-2	USA-WA1/2020	Wild-type	1.58 x 10^3 $TCID_{50}$/mL
	XBB.1.5	Omicron Variant	400 $TCID_{50}$/mL
Influenza A (H1N1)	A/California/04/2009	H1N1pdm09	2.8 x 10^3 $TCID_{50}$/mL
	A/Brisbane/02/2018	H1N1pdm09	1.9 X 10^2 $TCID_{50}$/mL
	A/Michigan/45/2015	H1N1pdm09	1.9 X 10^1 $TCID_{50}$/mL
	A/Guangdong-Maonan/SWL1536/2019	H1N1pdm09	1.0 x 10^3 $TCID_{50}$/mL
	A/NY/03/2009	H1N1pdm09	4.6 X 10^4 $TCID_{50}$/mL
	A/Indiana/02/2020	H1N1pdm09	9.7 x 10^6 $CEID_{50}$/mL
	A/Wisconsin/588/2019	H1N1pdm09	2.8 x 10^4 FFU/mL
	A/Sydney/5/2021	H1N1pdm09	6.0 x 10^3 $TCID_{50}$/mL
	A/Hawaii/66/2019	H1N1pdm09	7.4 x 10^7 $CEID_{50}$/mL
	A/Wisconsin/67/2022	H1N1pdm09	4.2 x 10^2 $TCID_{50}$/mL
	A/Ohio/09/2015	(H1N1)v	1.4 x 10^6 $CEID_{50}$/mL
Influenza A (H1N2)	A/Minnesota/19/2011	(H1N2)v	8.00 x 10^6 $CEID_{50}$/mL
Influenza A (H3N2)	A/Tasmania/503/2020	H3N2	1.3 x 10^5 FFU/mL
	A/New York/21/2020	H3N2	3.3 x 10^5 FFU/mL
	A/Alaska/01/2021	H3N2	3.8 x 10^4 FFU/mL
	A/Hong Kong/45/2019	H3N2	3.8 x 10^4 FFU/mL
	A/Hong Kong/2671/2019	H3N2	1.1 x 10^3 $TCID_{50}$/mL
	A/Indiana/08/2011	(H3N2)v	8.1 x 10^2 $TCID_{50}$/mL
Influenza A (H5N1)	A/mallard/Wisconsin/2576/2009	H5N1	4.00 x 10^6 $CEID_{50}$/mL
Influenza A (H7N3)	A/northern pintail/Illinois/10OS3959/2010	H7N3	2.80 x 10^6 $CEID_{50}$/mL
Influenza B non-Victoria, non-Yamagata	B/Maryland/1/1959	Non-Victoria, non-Yamagata	3.4 x 10^3 $CEID_{50}$/mL
Influenza B Victoria lineage	B/Brisbane/60/2008	Victoria	1.6 x10^0 $TCID_{50}$/mL
	B/Colorado/06/2017	Victoria	2.9 x 10^1 $TCID_{50}$/mL
	B/Texas/02/2013	Victoria	2.5 x 10^1 $TCID_{50}$/mL
	B/Michigan/01/2021	Victoria	1.4 x 10^4 $TCID_{50}$/mL
Influenza B Yamagata lineage	B/Texas/06/2011	Yamagata	1.5 x 10^3 $TCID_{50}$/mL
	B/Utah/09/2014	Yamagata	1.26 x 10^3 $TCID_{50}$/mL
	B/Wisconsin/01/2010	Yamagata	1.78 x 10^2 $TCID_{50}$/mL

- **Competitive Interference**

Competitive interference testing (i.e., evaluation of potential for a high concentration of one targe virus to interfere with detection of a low concentration of another target virus) for the QuickFinder™ COVID-19/Flu Antigen Self Test was completed and no competitive interference across analytes was observed. The testing was performed with different combinations of low (3x LoD) and high concentrations (either 1000x LoD or the highest concentration achievable exceeding 10^5 PFU/mL, $CEID_{50}$/mL or $TCID_{50}$/mL) of live Influenza A, live Influenza B and UV inactivated SARS-CoV-2 on the QuickFinder™ COVID-19/Flu Antigen Self Test device to determine if the candidate device can detect target analytes across a variety of analyte concentrations.

Combination	Viral Target in Sample			
	Influenza A (H1N1pdm09/A/ Victoria/4897/2022)	**Influenza B (Yamagata/B/ Florida/4/2006)**	**SARS-CoV-2 (USA-WA1/2020)**	**Results**
1	High	3X LoD	Negative	Pass. No competitive interference.
2	High	Negative	3X LoD	Pass. No competitive interference.
3	High	3X LoD	3X LoD	Pass. No competitive interference.
4	3X LoD	High	Negative	Pass. No competitive interference.
5	Negative	High	3X LoD	Pass. No competitive interference.
6	3X LoD	High	3X LoD	Pass. No competitive interference.
7	3X LoD	Negative	High	Pass. No competitive interference.
8	Negative	3X LoD	High	Pass. No competitive interference.
9	3X LoD	3X LoD	High	Pass. No competitive interference.

- **High-dose hook effect**

No high dose hook effect was observed when tested with up to a concentration below with the QuickFinder™ COVID-19/Flu Antigen Self Test.

Analyte	Strain	Lineage	Concentration
SARS-CoV-2	USA-WA1/2020	SARS-CoV-2	3.16×10^6 $TCID_{50}$/mL
Influenza A (H1N1)	A/Wisconsin/67/22	H1N1pdm09	2.02×10^5 $TCID_{50}$/mL
Influenza A (H3N2)	A/Darwin/6/21	H3N2	4.17×10^5 $TCID_{50}$/mL
Influenza B Victoria lineage	B/Washington/02/19	Victoria	3.16×10^6 $TCID_{50}$/mL
Influenza B Yamagata lineage	B/Florida/04/2006	Yamagata	1.17×10^5 $TCID_{50}$/mL

B. Analytical Specificity:

- **Cross-reactivity and microbial interference**

Cross-reactivity and microbial interference studies were performed with 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 tested with and without the presence of UV inactivated SARS-CoV-2, live Influenza A, and Influenza B viruses at 3X co-spike equivalency LoD.

Cross reactivity:

For cross reactivity, each organism was tested in replicate of three (3) at the concentrations listed in the following table of results. All testing samples were prepared in the pooled nasal wash (PNW). No cross reactivity or interference was observed for any of the organisms tested.

IDI	Organism	Concentration	Influenza A Test Results (Positive/ Total)	Influenza B Test Results (Positive/ Total)	SARS-CoV-2 Test Results (Positive/ Total)
229E	Human coronavirus 229E	1.58E+05 $TCID_{50}$/mL	0/3	0/3	0/3
OC43	Human coronavirus OC43	7.00E+05 $TCID_{50}$/mL	0/3	0/3	0/3
NL63	Human coronavirus NL63	7.05E+04 $TCID_{50}$/mL	0/3	0/3	0/3
SARS	SARS-coronavirus	1.25E+05 PFU/mL	0/3	0/3	0/3
MERS	MERS-coronavirus	1.47E+05 $TCID_{50}$/mL	0/3	0/3	0/3
AV1	Adenovirus Type 1	2.23E+05 $TCID_{50}$/mL	0/3	0/3	0/3
AV7	Adenovirus Type 7	1.58E+05 $TCID_{50}$/mL	0/3	0/3	0/3
hMPV	Human metapneumovirus 4 Type B2	3.50E+05 $TCID_{50}$/mL	0/3	0/3	0/3
P1	Parainfluenza virus 1	2.00E+05 $TCID_{50}$/mL	0/3	0/3	0/3
P2	Parainfluenza virus 2	1.75E+05 $TCID_{50}$/mL	0/3	0/3	0/3
P3	Parainfluenza virus 3	7.00E+05 $TCID_{50}$/mL	0/3	0/3	0/3
P4	Parainfluenza virus 4b	2.39E+05 $TCID_{50}$/mL	0/3	0/3	0/3
EV68	Enterovirus 68	2.23E+05 $TCID_{50}$/mL	0/3	0/3	0/3
RSVA	Respiratory syncytial virus A	3.50E+05 $TCID_{50}$/mL	0/3	0/3	0/3
RSVB	Respiratory syncytial virus B	2.29E+05 $TCID_{50}$/mL	0/3	0/3	0/3
RV	Rhinovirus	7.05E+04 $TCID_{50}$/mL	0/3	0/3	0/3
HI	*Haemophilus influenzae*	9.68E+06 CFU/mL	0/3	0/3	0/3
SPN	*Streptococcus pneumonia*	1.81E+07 CFU/mL	0/3	0/3	0/3
SPY	*Streptococcus pyogenes*	7.50E+07 CFU/mL	0/3	0/3	0/3
CA	*Candida albicans*	1.21E+07 CFU/mL	0/3	0/3	0/3
BP	*Bordetella pertussis*	2.90E+08 CFU/mL	0/3	0/3	0/3
MP	*Mycoplasma pneumonia*	2.50E+07 CFU/mL	0/3	0/3	0/3
CP	*Chlamydia pneumoniae*	4.33E+06 IFU/mL	0/3	0/3	0/3
LP	*Legionella pneumophila*	6.50E+06 CFU/mL	0/3	0/3	0/3
MT	*Mycobacterium tuberculosis*	3.03E+06 CFU/mL	0/3	0/3	0/3
PJ	*P. jiroveci-S. cerevisiae*	1.30E+07 CFU/mL	0/3	0/3	0/3
SA	*Staphylococcus aureus* subsp. *aureus*	2.60E+08 CFU/mL	0/3	0/3	0/3
SE	*Staphylococcus epidermidis*	9.00E+07 CFU/mL	0/3	0/3	0/3
CX	*Corynebacterium xerosis*	2.30E+07 CFU/mL	0/3	0/3	0/3
EC	*Escherichia coli*	1.79E+08 CFU/mL	0/3	0/3	0/3
LA	*Lactobacillus Acidophilus*	1.21E+07 CFU/mL	0/3	0/3	0/3
MC	*Moraxella catarrhalis*	2.50E+08 CFU/mL	0/3	0/3	0/3
NM	*Neisseria meningitidis*	3.43E+06 CFU/mL	0/3	0/3	0/3
NE	*Neisseria Elongata*	2.68E+08 CFU/mL	0/3	0/3	0/3
PA	*Pseudomonas aeruginosa*	3.45E+08 CFU/mL	0/3	0/3	0/3
SS	*Streptococcus salivarius*	1.01E+06 CFU/mL	0/3	0/3	0/3
ME	Measles	8.48E+05 $TCID_{50}$/mL	0/3	0/3	0/3
MU	Mumps	8.48E+05 $TCID_{50}$/mL	0/3	0/3	0/3

IDI	Organism	Concentration	Influenza A Test Results (Positive/ Total)	Influenza B Test Results (Positive/ Total)	SARS-CoV-2 Test Results (Positive/ Total)
EBV	Epstein Barr Virus	1.83E+06 CP/mL	0/3	0/3	0/3
CMV	Cytomegalovirus	7.05E+04 $TCID_{50}$/mL	0/3	0/3	0/3

Microbial interference:
For evaluating microbial interference against the SARS-CoV-2, Influenza A (H1N1pdm09), Influenza B (Yamagata) test lines, the organisms were tested with SARS-CoV-2 UV-inactivated SARS-CoV-2: USA-WA1/2020 (ZeptoMetrix # 0810587UV), Live Flu A: H1N1pdm09/A/Victoria/4897/2022 (ZeptoMetrix# 0810684CF), Live Flu B: Yamagata/B/Florida/4/2006 (ZeptoMetrix # 0810255CF) diluted to 3x LoD concentration in negative pooled nasal wash (PNW). No microbial interference was seen with the organisms tested at the concentrations shown below.

IDI	Organism	Concentration	Influenza A Test Results (Positive/ Total)	Influenza B Test Results (Positive/ Total)	SARS-CoV-2 Test Results (Positive/ Total)
229E	Human coronavirus 229E	1.58E+05 $TCID_{50}$/mL	3/3	3/3	3/3
OC43	Human coronavirus OC43	7.00E+05 $TCID_{50}$/mL	3/3	3/3	3/3
NL63	Human coronavirus NL63	7.05E+04 $TCID_{50}$/mL	3/3	3/3	3/3
SARS	SARS-coronavirus	1.25E+05 PFU/mL	3/3	3/3	3/3
MERS	MERS-coronavirus	1.47E+05 $TCID_{50}$/mL	3/3	3/3	3/3
AV1	Adenovirus Type 1	2.23E+05 $TCID_{50}$/mL	3/3	3/3	3/3
AV7	Adenovirus Type 7	1.58E+05 $TCID_{50}$/mL	3/3	3/3	3/3
hMPV	Human metapneumovirus 4 Type B2	3.50E+05 $TCID_{50}$/mL	3/3	3/3	3/3
P1	Parainfluenza virus 1	2.00E+05 $TCID_{50}$/mL	3/3	3/3	3/3
P2	Parainfluenza virus 2	1.75E+05 $TCID_{50}$/mL	3/3	3/3	3/3
P3	Parainfluenza virus 3	7.00E+05 $TCID_{50}$/mL	3/3	3/3	3/3
P4	Parainfluenza virus 4b	2.39E+05 $TCID_{50}$/mL	3/3	3/3	3/3
EV68	Enterovirus 68	2.23E+05 $TCID_{50}$/mL	3/3	3/3	3/3
RSVA	Respiratory syncytial virus A	3.50E+05 $TCID_{50}$/mL	3/3	3/3	3/3
RSVB	Respiratory syncytial virus B	2.29E+05 $TCID_{50}$/mL	3/3	3/3	3/3
RV	Rhinovirus 1A	7.05E+04 $TCID_{50}$/mL	3/3	3/3	3/3
HI	*Haemophilus influenzae*	9.68E+06 CFU/mL	3/3	3/3	3/3
SPN	*Streptococcus pneumonia*	1.81E+07 CFU/mL	3/3	3/3	3/3
SPY	*Streptococcus pyogenes*	7.50E+07 CFU/mL	3/3	3/3	3/3
CA	*Candida albicans*	1.21E+07 CFU/mL	3/3	3/3	3/3
BP	*Bordetella pertussis*	2.90E+08 CFU/mL	3/3	3/3	3/3
MP	*Mycoplasma pneumonia*	2.50E+07 CFU/mL	3/3	3/3	3/3
CP	*Chlamydia pneumoniae*	4.33E+06 IFU/mL	3/3	3/3	3/3

IDI	Organism	Concentration	Influenza A Test Results (Positive/ Total)	Influenza B Test Results (Positive/ Total)	SARS-CoV-2 Test Results (Positive/ Total)
LP	*Legionella pneumophila*	6.50E+06 CFU/mL	3/3	3/3	3/3
MT	*Mycobacterium tuberculosis*	3.03E+06 CFU/mL	3/3	3/3	3/3
PJ	*P. jiroveci-S. cerevisiae*	1.30E+07 CFU/mL	3/3	3/3	3/3
SA	*Staphylococcus aureus* subsp. *aureus*	2.60E+08 CFU/mL	3/3	3/3	3/3
SE	*Staphylococcus epidermidis*	9.00E+07 CFU/mL	3/3	3/3	3/3
CX	*Corynebacterium xerosis*	2.30E+07 CFU/mL	3/3	3/3	3/3
EC	*Escherichia coli*	1.79E+08 CFU/mL	3/3	3/3	3/3
LA	*Lactobacillus acidophilus*	1.21E+07 CFU/mL	3/3	3/3	3/3
MC	*Moraxella catarrhalis*	2.50E+08 CFU/mL	3/3	3/3	3/3
NM	*Neisseria meningitidis*	3.43E+06 CFU/mL	3/3	3/3	3/3
NE	*Neisseria elongata*	2.68E+08 CFU/mL	3/3	3/3	3/3
PA	*Pseudomonas aeruginosa*	3.45E+08 CFU/mL	3/3	3/3	3/3
SS	*Streptococcus salivarius*	1.01E+06 CFU/mL	3/3	3/3	3/3
ME	Measles	8.48E+05 $TCID_{50}$/mL	3/3	3/3	3/3
MU	Mumps	8.48E+05 $TCID_{50}$/mL	3/3	3/3	3/3
EBV	Epstein Barr Virus	1.83E+06 CP/mL	3/3	3/3	3/3
CMV	Cytomegalovirus	7.05E+04 $TCID_{50}$/mL	3/3	3/3	3/3
PNW	Pooled Negative Nasal Wash	N/A	3/3	3/3	3/3

- **Endogenous/Exogenous Interfering Substances**

The QuickFinder™ COVID-19/Flu 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 co-spike PNW with UV inactivated SARS-CoV-2, and live Influenza A and B) and negative specimens were tested with the addition of the potentially interfering substances. Each substance was tested in replicates of three (3). The performance of the QuickFinder™ COVID-19/Flu Antigen Self Test was not affected by any of the potentially interfering substances listed in the table below at the concentrations noted.

Substance	Concentration	Interference (Yes/No)
Human Whole Blood (EDTA tube)	4% v/v	No
Mucin (porcine stomach, type II)	0.5%	No
Chloraseptic (Menthol/Benzocaine)	1.5 mg/mL	No
Naso GEL (NeilMed)	5% v/v	No
Nasal Drops (Phenylephrine)	15% v/v	No
Nasal Spray (Oxymetazoline)	15% v/v	No
Nasal Spray (Cromolyn)	15% v/v	No
Zicam	5% v/v	No

Substance	Concentration	Interference (Yes/No)
Homeopathic (Alkalol)	10% v/v	No
Sore Throat Phenol Spray	15% v/v	No
Tobramycin	4 µg/mL	No
Mupirocin	10 mg/mL	No
Fluticasone Propionate	5% v/v	No
Tamiflu (Oseltamivir Phosphate)	5 mg/mL	No
FluMist/FluMist Quadrivalent Live intranasal influenza virus vaccine	15% v/v	No
Zanamivir	282 ng/mL	No
Biotin	3,500 ng/mL	No
Body and Hand Lotion	0.5% w/v	No
Body Lotion with 1.2% dimethicone	0.5% w/v	No
Hand Lotion	5% w/v	No
Hand Sanitizer with Aloe, 62% ethyl alcohol	5% v/v	No
Hand Sanitizer with cream lotion	15% v/v	No
Hand Sanitizer, 80% ethanol, fast drying	15% v/v	No
Hand soap liquid gel*	0.05% w/v	No

*** Interference was observed with ≥ 0.1% (w/v) for hand soap liquid gel and influenza B results.**

12. CLINICAL EVALUATION

A prospective clinical study was completed at six (6) sites in the United States for clinical validation of the QuickFinder™ COVID-19/Flu Antigen Self Test for the detection of SARS-CoV-2, Influenza A and/or Influenza B in subject-collected anterior nasal swab (ANS) samples. The study evaluated the QuickFinder™ COVID-19/Flu Antigen Self Test performance in symptomatic individuals (those suspected of COVID-19, Influenza A and/or Influenza B). A total of 608 symptomatic subjects were enrolled who were currently experiencing symptoms associated with COVID-19, Influenza A and/or Influenza B. 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 of the subjects also had an ANS sample (from both nostrils) collected from him/her by one of the study personnel. Test results from the QuickFinder™ COVID-19/Flu Antigen Self Test were compared to highly sensitive molecular FDA cleared SARS-CoV-2, Influenza A, and Influenza B RT-PCR assays. Out of 608 enrolled subjects, there were 577 evaluable subjects. Of the 577 evaluable subjects for SARS-CoV-2, the analysis resulted in a positive percent agreement (PPA) of 88.7% (95% CI: 81.2%-93.4%) and negative percent agreement (NPA) of 99.6% (95% CI: 98.5%-99.9%). There were 577 evaluable subjects for Influenza A, the analysis resulted in a PPA of 88.5% (95% CI: 77.0% – 94.6%) and a NPA of 98.9% (95% CI: 97.5% -99.5%). There were 577 evaluable subjects for Influenza B, the analysis resulted in a PPA of 85.4% (95% CI: 71.6% – 93.1%) and a NPA of 99.6% (95% CI: 98.6% to 99.9%).

SARS-CoV-2 Primary Analysis

SARS-CoV-2	Comparator Positives	Comparator Negatives	Total
QuickFinder™ COVID-19/Flu Antigen Self Test Positives	94	2	96
QuickFinder™ COVID-19/Flu Antigen Self Test Negatives	12	469	481
Total	**106**	**471**	**577**

Positive Percent Agreement (94/106) = 88.7% (95% CI: 81.2%-93.4%) Negative Percent Agreement (469/471) = 99.6% (95% CI: 98.5% - 99.9%)

Positive Results Broken Down by Days Since Symptom Onset for SARS-CoV-2

Days post COVID-19 Symptoms Onset	Number of Subject samples tested	QuickFinder™ COVID-19/Flu Antigen Self Test Positives	Comparator Positives	% Positive Rate (by Comparator)	PPA
0	11	0	0	0.0%	NA
1	137	23	27	19.7%	85.2%
2	224	35	41	18.3%	85.4%
3	126	26	27	21.4%	96.3%
4	79	10	11	13.9%	90.9%
Total	**577**	**94***	**106**	**18.4%**	**88.7% (95% CI: 81.2% -93.4%)**

*NOTE: Two false positive subjects were excluded from the QuickFinder™ COVID-19/Flu Antigen Self Test Positives count for the purposes of this table.

Influenza A Primary Analysis

Influenza A	Comparator Positives	Comparator Negatives	Total
QuickFinder™ COVID-19/Flu Antigen Self Test Positives	46	6	52
QuickFinder™ COVID-19/Flu Antigen Self Test Negatives	6	519	525
Total	**52**	**525**	**577**
Positive Percent Agreement (46/52) = 88.5% (95% CI: 77.0%-94.6%) Negative Percent Agreement (519/525) = 98.9% (95% CI: 97.5% - 99.5%)			

Influenza B Primary Analysis

Influenza B	Comparator Positives	Comparator Negatives	Total
QuickFinder™ COVID-19/Flu Antigen Self Test Positives	35	2	37
QuickFinder™ COVID-19/Flu Antigen Self Test Negatives	6	534	540
Total	**41**	**536**	**577**
Positive Percent Agreement (35/41) = 85.4% (95% CI: 71.6%-93.1%) Negative Percent Agreement (534/536) = 99.6% (95% CI: 98.6% - 99.9%)			

Subjects Demographics

	Subjects (by lay-user collection and testing (N=86)	Self-collecting and testing (N=491)	Overall (N=577)
Mean (SD)	12.0 (13.5)	36.7 (15.8)	33 (17.8)
Median [Min, Max]	10 [2, 74]	33 [14, 80]	29 [2, 80]
Age Group			
≥2-<14 years of age	79 (91.9%)	0 (0.0%)	79 (13.7%)
14-24 years of age	2 (2.3%)	145 (29.5%)	147 (25.5%)
>24-64 years of age	1 (1.2%)	313 (63.7%)	314 (54.4%)
≥65 years of age	4 (4.7%)	33 (6.7%)	37 (6.4%)
Sex at Birth			
Female	34 (39.5%)	300 (61.1%)	334 (57.9%)
Male	52 (60.5%)	191 (38.9%)	243 (42.1%)
Ethnicity			
Hispanic/Latino	4 (4.7%)	87 (17.7%)	91 (15.8%)
Not Hispanic/Latino	82 (95.3%)	404 (82.3%)	486 (84.2%)
Race			
American Indian or Alaskan Native	0 (0.0%)	0 (0.0%)	0 (0.0%)
Asian	0 (0.0%)	11 (2.2%)	11 (1.9%)
Black or African American	4 (4.7%)	38 (7.7%)	42 (7.3%)
Native Hawaiian/Pacific Islander	0 (0.0%)	5 (1.0%)	5 (0.9%)
White	77 (89.5%)	428 (87.2%)	505 (87.5%)
Unknown/Prefer not to answer	0 (0.0%)	2 (0.4%)	2 (0.3%)
Other (Mixed race/biracial)	5 (5.8%)	7 (1.4%)	12 (2.1%)

**Total up to 99.9 or 100.1 due to rounding*

13. 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 A total of 7,361 individuals were enrolled via a decentralized clinical study design, with a broad geographical - 13 - 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.
Performance of the antigen test with serial testing in symptomatic individuals is described in the table below. Data establishing PPA of COVID-19 antigen serial testing compared to molecular comparator single day testing throughout the course of infection with serial testing. Data is from all antigen tests in the study combined.

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

Days After First PCF Positive Test Result	Symptomatic on First Day of Testing		
	Antigen Positive/PCR Positive (Antigen Test Performance % PPA)		
	1 Test	2 Test	3 Test
0	34/57 (59.6%)	47/51 (92.2%)	44/47 (93.6%)
2	58/62 (93.5%)	59/60 (98.1%)	43/43 (100.0%)
4	55/58 (94.8%)	53/54 (98.1%)	39/40 (97.5%)
6	27/34 (79.4%)	26/33 (78.8%)	22/27 (81.5%)
8	12/17 (70.6%)	12/17 (70.6%)	7/11 (63.6%)
10	4/9 (44.4%)	3/7 (42.9%)	N/A

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

14. CUSTOMER 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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NEXUS DX, INC.
6759 Mesa Ridge Road San Diego, CA 92121

15. SYMBOLS USED ON THE PRODUCT LABELS

The table below describes the symbols on the QuickFinder™ COVID-19 Antigen Self Test package.

SYMBOL	DESCRIPTION
	Use by Date
	Reference number
	Contains sufficient for <n> test
	Caution
	Batch Code
	Consult instructions for use
	Storage temperature range
	Do not use if seal or packaging is broken or damaged
	*In vitro* diagnostic
	Manufacturer
	Do not reuse
	Date of manufacture

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