OSOM®

Flu SARS-CoV-2 Combo Home Test

For use under Emergency Use Authorization (EUA) only.

For *in vitro* diagnostic use

For use with anterior nasal swab specimens.

HEALTHCARE PROVIDER INSTRUCTIONS FOR USE

IVD REF **1074**

INTENDED USE

The OSOM® Flu SARS-CoV-2 Combo Home 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 *in vitro* detection of SARS-CoV-2, influenza A virus, 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 OSOM Flu SARS-CoV-2 Combo Home 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 not be used as 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 OSOM Flu SARS-CoV-2 Combo Home Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

SUMMARY AND 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. 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. Along with the common cold, influenza is one of the most common acute respiratory infections, producing symptoms such as headache, chills, dry cough, body aches, and fever. The influenza A virus is typically more prevalent and is associated with the most serious influenza epidemics, while influenza B infections usually present with milder symptoms.

PRINCIPLE OF THE PROCEDURE

The OSOM Flu SARS-CoV-2 Combo Home Test consists of a Test Strip that separately detects influenza A, influenza B, and SARS-CoV-2 antigens. The test procedure requires the solubilization of the nucleoproteins from a nasal swab sample by mixing the swab in buffer liquid. The Test Strip is then placed in the sample mixture, which migrates along the membrane surface. If influenza A, influenza B, and/or SARS-CoV-2 viral antigens are present in the sample, it will form a complex with antibodies to influenza A, influenza B and/or SARS-CoV-2 conjugated to colloidal gold. The complex will then be bound by another anti-influenza A, anti-influenza B and/or anti SARS-CoV-2 antibody coated on the nitrocellulose membrane. A pink to purple control line must appear in the control region of the Test Strip for results to be valid. The appearance of a second and possibly third or fourth light pink to purple line in the test line region indicates a influenza A, influenza B, and/or SARS-CoV-2 positive result. A visible control line with no test line is a negative result.

KIT CONTENTS

2 x Sterile Nasal Swabs

2 x Individually pouched Test Strips

2 x Tubes containing 250 µl of buffer liquid

2 x Result Interpretation Cards

1 x User Instructions

1 x Tube holder (backside of carton)

MATERIALS REQUIRED BUT NOT PROVIDED

- Clock or timer.

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-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 Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated, or authorization is revoked sooner.
- **Serial testing should be performed in individuals with SARS-CoV-2 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 (repeat) 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 aged 14 years and older. Children aged 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 or open.
- Test components are single-use. Do not re-use the test strip, buffer liquid, or swab.
- If any liquid spills from the buffer tube, discard test components and re-start test using new test components.
- Do not use the test kit after its expiration date.
- Only use the nasal swabs provided in the kit. Do not touch the swab tip prior to testing.
- Once opened, the test device should be used within 30 minutes.
- **Do not read test results before 10 minutes or after 30 minutes. Results read before 10 minutes or after 30 minutes may lead to a false positive, false negative, or invalid result.**
- Eyewear protection is recommended.
- **Keep testing kit and kit components away from children and pets before and after use. Avoid contact with your skin, eyes, nose, or mouth. Do not ingest any kit components. The reagent solution contains harmful chemicals (see table below). If the solution contacts your skin, eyes, nose, or mouth, flush with large amounts of water. If irritation persists, seek medical advice: https://www.poisonhelp.org or 1-800-222-1222.**

Chemical Name CAS	GHS Code for each Ingredient	Concentration (%)
Sodium Azide 26628-22-8	Acute Tox. 2 (Oral), H300 Acute Tox. 1 (Dermal), H310 Aquatic Acute 1, H400 Aquatic Chronic 1, H410	0.09%
Dodecan-1-ol, ethoxylated 9002-92-0	Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Dam. 1, H318 Aquatic Acute 2, H401	0.6%

- 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

STORAGE AND STABILITY

Store the test kit between 59-86°F (15-30°C) in a place out of direct sunlight

- Reagents and devices must be used at room temperature (59-86°F/15-30°C).
- The unsealed test strip is valid for 30 minutes. It is recommended to use the test kit immediately after opening.
- The expiration date is on the package.

QUALITY CONTROL

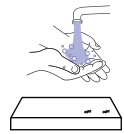
Each OSOM Flu SARS-CoV-2 Combo Home Test has a built-in internal procedural control. The pink/purple line appearing at the “CONT” position verifies proper assembly and capillary flow of the test strip. A distinct pink/purple Control Line should always appear if the test has been performed correctly. If the Control Line does not appear, the test result is invalid, and a new test should be performed using a new swab and new test kit.

TEST PROCEDURE

PREPARING FOR THE TEST

NOTE: Do not open the test contents until ready for use. If the test strip is open for 30 minutes or longer, invalid test results may occur.

1. **Check the test's expiration date printed on the outer test packaging.** For information about current expiration dates for at-home OTC COVID-19 diagnostic tests, visit http://www.fda.gov/covid-tests.

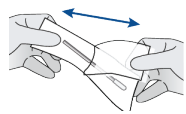


2. **Wash** your hands with soap and water for 20 seconds and dry them thoroughly, or use hand sanitizer.

3. **Turn over** the test kit box to locate the holes on the backside of the carton.

4. **Remove** the cap from one tube gently to avoid spilling the liquid and place it in the tube holder.

SAMPLE COLLECTION



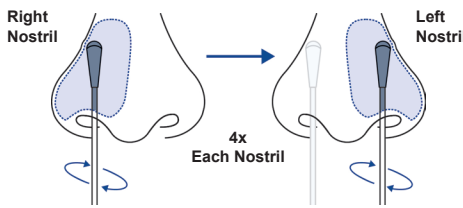
1. **Remove** swab from the pouch by the stick end.

⚠ **DO NOT touch the swab tip (soft end).**

2. **GENTLY INSERT** the swab no more than ¾ of an inch into the nostril.

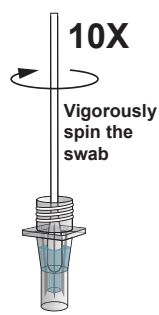
⚠ **DO NOT insert the swab any farther if you feel any resistance.**

3. **SLOWLY ROTATE** the swab at least 4 times against the nostril wall. **REMOVE** the swab and repeat in the other nostril using the same swab.



Note: If you are swabbing others, please wear a face mask. With children, the maximum depth of insertion into the nostril may be less than ½ to ¾ of an inch, and you may require another adult to hold the child's head while swabbing.

RUNNING THE TEST



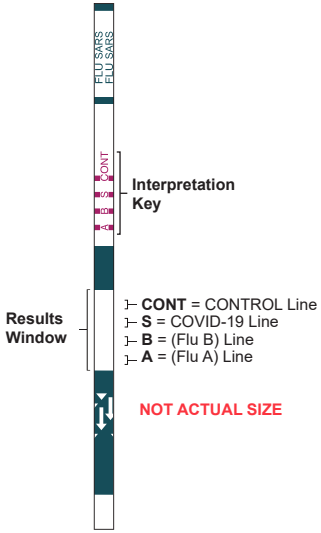
4. With cap removed, **INSERT** swab through the ridges of the tube into the liquid. **MIX** thoroughly by spinning the swab **at least 10 times** in the liquid.

NOTE: Make sure the swab tip is in the liquid when mixing. The swab may not reach the bottom of the tube.

Best results are obtained when the swab is vigorously mixed in the liquid.

⚠ **Sample must be mixed in the extraction buffer within 30 minutes of sample collection.**

INTERPRETING THE RESULTS



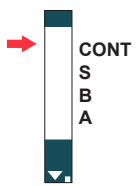
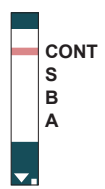
• **PLACE** test strip, arrows pointing down, within dashed area of a **Result Interpretation Card** included in the kit. Ensure arrows on the test strip are pointing in the same direction as the arrows on the **Interpretation Card** and that the **Results Window** is aligned.

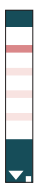
• Look for lines next to '**CONT**' (Control), '**S**', '**B**' and '**A**' in the **Results Window**.

• Look closely! Any faint line at a test line is a positive.

• Make sure there is a visible line next to **CONT**. If the **CONT** line is missing, your result is INVALID. Repeat with a new test and sample.

The Invalid, Negative, and Positive test results are explained in the table below:

Result	Device Image
Invalid Test Result **CHECK to see if a line is visible at the Control line "CONT". If a Control line is not visible at "CONT" after 10 minutes, even if any of the other lines are visible in the results window, THE TEST HAS FAILED and is considered invalid.** STOP If you do not see a "**CONT**" line, **DO NOT CONTINUE** reading the results. It means your test is invalid. Repeat the test with a new sample and new test kit materials. **Note: The image displayed above is one example only; additional invalid outcomes are possible. For a complete set of invalid results, go to: osomhometests.com/invalidresults.**	 **Invalid**
Negative Test Result If the Control line at "**CONT**" is visible and you do not see a line at "**S**", "**B**" or "**A**", it means you may not have COVID-19, Flu B, or Flu A virus. To increase the chance that the negative result for COVID-19 is accurate, you should test again in 48 hours. If you still have COVID-19, Flu B, Flu A, or symptoms, you should seek follow up care with your healthcare provider.	 **Negative**

Result	Device Image
Positive Test Result If the Control line at "**CONT**" is visible and any other line or multiple lines at "**S**", "**B**" and/or "**A**" appear, the test is **positive**. **NOTE:** Any pink/red line, no matter how faint, should be considered an indication of a positive result. 	 **COVID-19 Positive**  **Flu B Positive**  **Flu A Positive**  **COVID-19 + Flu B Positive**  **COVID-19 + Flu A Positive**  **Flu B + Flu A Positive**  **COVID-19 + Flu B + Flu A Positive**

INVALID RESULTS

If the Control (**CONT**) line is not visible, the test is invalid. The test could not tell whether or not COVID-19, influenza A (Flu A), or influenza B (Flu B) are in the sample. Re-test with a new swab and new test device.

NEGATIVE (-) RESULTS

If the Control (**CONT**) line is visible, and you do not see a line at "**S**", "**B**", or "**A**", the test is negative.

NOTE:

COVID-19 Negative (-) Result

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.

The virus from COVID-19, Flu A, and/or Flu B were not detected in the sample. A negative result does not mean it is certain that you do not have COVID-19, Flu A and/or Flu B infection. 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.

POSITIVE (+) RESULTS

If the Control (**CONT**) line is visible and any other line or multiple lines on "**S**", "**B**" and/or "**A**" appear, the test is positive.

COVID-19 Positive (+) Result

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

A positive test result means that the virus that causes COVID-19, Flu A and/or Flu B virus(es) was detected in the sample, and it 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 very small chance that this test can give a positive result that is incorrect (a false positive).

Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Individuals who test positive with the OSOM Flu SARS-CoV-2 Combo Home 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.

Repeat testing is needed to improve test accuracy for SARS-CoV-2. Please follow the table below when interpreting test results. Serial (repeat) SARS-CoV-2 testing does not need to be performed if patients have a positive SARS-CoV-2 result.

Status on First Day of Testing	Day 0 (First Test)	Serial Testing?	Day 2 (Second Test)	Final Interpretation
With Symptoms	SARS-CoV-2 (+) Influenza A and B (-)	NO	Not needed	Positive for COVID-19 Presumptive negative for Influenza
	SARS-CoV-2 (+) Influenza A and/or B (+)	NO	Not needed	Positive for COVID-19 Positive for Influenza A and/or B
	SARS-CoV-2 (-) Influenza A and/or B (-)	YES	SARS-CoV-2 (+) Influenza A and/or B (-)	Positive for COVID-19 Presumptive Negative for Influenza
	SARS-CoV-2 (-) Influenza A and/or B (+)	YES	SARS-CoV-2 (+) Influenza A and/or B (+)	Positive for COVID-19 Positive for Influenza A and/or B
	SARS-CoV-2 (-) Influenza A and/or B (-)	YES	SARS-CoV-2 (-) Influenza A and/or B (+)	Presumptive Negative for COVID-19 Positive for Influenza A and/or B
	SARS-CoV-2 (-) Influenza A and/or B (-)	YES	SARS-CoV-2 (-) Influenza A and/or B (-)	Presumptive Negative for COVID-19 Presumptive Negative for Influenza
	SARS-CoV-2 (-) Influenza A and/or B (-)	YES	SARS-CoV-2 (+) Influenza A and/or B (+)	Positive for COVID-19 Positive for Influenza A and/or B
	SARS-CoV-2 (-) Influenza A and/or B (+)	YES	SARS-CoV-2 (-) Influenza A and/or B (-)	Presumptive Negative for COVID-19 Positive for Influenza A and/or B
	SARS-CoV-2 (-) Influenza A and/or B (+)	YES	SARS-CoV-2 (-) Influenza A and/or B (+)	Presumptive Negative for COVID-19 Positive for Influenza A and/or B
	SARS-CoV-2 (-) Influenza A and/or B (+)	YES	SARS-CoV-2 (+) Influenza A and/or B (+)	Positive for COVID-19 Positive for Influenza A and/or B

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.

LIMITATIONS

- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between October 2023 and January 2024. 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, 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 SARS- CoV-2COVID-19 as compared to a molecular test, especially in samples with low viral load.

- All antigen test negative results, for SARS- CoV-2 or influenza, 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 SARS- CoV-2 infectionCOVID-19, however additional follow-up may be needed.
- If the test is positive, then proteins from the viruses that causes COVID-19 or influenza infection have been found in the sample and the individual likely has a respiratory infection with SARS- CoV-2COVID-19 or influenza.
- 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.
- Based on sequence analysis, a potential for cross-reactivity between the SARS-CoV-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.
- This device is a qualitative test and does not provide information on the viral load present in the specimen.

PERFORMANCE CHARACTERISTICS

ANALYTICAL PERFORMANCE

Limit of Detection (Analytical Sensitivity)

The limit of detection (LoD) for the OSOM Flu SARS-CoV-2 Combo Home Test was established using dilutions of one SARS-Related Coronavirus 2 (SARS-CoV-2) Lineage BA.5 Omicron Variant strain (Zeptometrix Catalog number 0810658CFHI), two influenza A strains (Influenza A H1N1: Influenza A/Michigan/45/15, Influenza A H3N2: Influenza A/Singapore/INFIMH-16-0019/2016) and four influenza B strains (Influenza B/Colorado/6/2017, Influenza B/Phuket/3073/13, Influenza B/Brisbane/35/18, Influenza B/Florida/02/06) in negative clinical matrix. The isolate dilutions were tested by adding fifty (50) µL to the head of the nasal swab and extracting the swab per the OSOM Flu SARS-CoV-2 Combo Home Test Instructions for Use.

In this study, range finding testing was followed by final dilution testing to determine the LoD of the assay. Range finding involved testing a series of 10-fold dilutions in replicates of three (3) to determine the starting point for the dilution series to determine LoD. The dilution of each virus which resulted in the lowest concentration that generated 100% positive detection rate was set as the target for the next dilution series, which involved testing three (3) replicates of two (2)-fold dilutions. In the final dilution testing, the lowest concentration that generated ≥95% positive detection rate was set as the LoD concentration. Confirmatory testing was done on 3 different days, totaling forty (40) replicates per lot of test sticks.

Virus Strains	Stock Concentration ($TCID_{50}$/mL)	LoD concentration ($TCID_{50}$/mL)	$TCID_{50}$/ Swab	# Positive/ # Total Tested	Percent Detected (%)
SARS-CoV-2 BA.5 Omicron Variant	6.15×10^6	3.08×10^4	1540	80/80	100%
Influenza A/ Michigan/45/15 (H1N1)	1.41×10^5	3.53×10^2	17.7	78/80	97.5%
Influenza A/ Singapore/ INFIMH-16-0019/16 (H3N2)	3.6×10^6	1.58×10^4	790	79/80	98.8%
Influenza B/ Phuket/3073/13 (Yamagata)	1.86×10^4	9.3×10^1	4.7	80/80	100%

Virus Strains	Stock Concentration ($TCID_{50}$/mL)	LoD concentration ($TCID_{50}$/mL)	$TCID_{50}$/ Swab	# Positive/ # Total Tested	Percent Detected (%)
Influenza B/ Colorado/06/17 (Victoria)	1.41×10^5	2.82×10^2	14.1	80/80	100%
Influenza B/ Brisbane/35/18 (Victoria)	1.15×10^7	2.30×10^4	1150	80/80	100%
Influenza B/ Florida/02/06 (Victoria)	1.15×10^7	2.30×10^4	1150	80/80	100%

Analytical Reactivity

The analytical reactivity of the monoclonal antibodies targeting SARS-CoV-2 in the OSOM Flu SARS-CoV-2 Combo Home Test were evaluated with the currently available SARS-CoV-2 strains and influenza strains using a dilution series. Concentrations listed in the table below indicate the lowest detectable concentrations for which all replicates were positive.

Strain	Concentration	Concentration Units
A/St.Petersburg/61/2015	2.3E+06	$CEID_{50}$/mL
A/Massachusetts/15/2013	8.0E+06	$CEID_{50}$/mL
A/Bangladesh/3002/2015	3.3E+05	$CEID_{50}$/mL
A/Hawaii/66/2019	3.7E+07	$CEID_{50}$/mL
A/Wisconsin/588/2019	2.8E+04	FFU/mL
A/Indiana/02/2020	9.7E+06	$CEID_{50}$/mL
A/Dominican Republic/7293/2013	5.0E+03	$TCID_{50}$/mL
A/Iowa/53/2015	2.9E+05	$CEID_{50}$/mL
A/Idaho/07/2018	3.2E+02	$TCID_{50}$/mL
A/California/04/2009	3.5E+03	$TCID_{50}$/mL
A/Brisbane/10/2007	8.0E+05	$CEID_{50}$/mL
A/Perth/16/2009	5.5E+05	$CEID_{50}$/mL
A/Victoria/361/2011	6E+05	$CEID_{50}$/mL
A/Texas/50/2012	1.8E+04	$TCID_{50}$/mL
A/Tasmania/503/2020	3.3E+05	FFU/mL
A/Indiana/08/2011	4.1E+03	$TCID_{50}$/mL
A/Ohio/09/2015	3.5E+06	$CEID_{50}$/mL
A/Minnesota/19/2011	1.6E+07	$CEID_{50}$/mL
A/northern pintail/Illinois/10OS3959/2010	1.4E+06	$CEID_{50}$/mL
A/mallard/Wisconsin/2576/2009	1.6E+06	$CEID_{50}$/mL
B/Brisbane/60/2008	1E+05	$CEID_{50}$/mL
B/Colorado/6/2017	4.0E+05	$CEID_{50}$/mL
B/Texas/06/2011	4.0E+06	$CEID_{50}$/mL
B/Wisconsin/1/10	1.41E+02	$TCID_{50}$/mL
B/Lee/1940	4.5E+04	$CEID_{50}$/mL
B/Malaysia/2506/2004	3.0E+03	$CEID_{50}$/mL

Strain	Concentration	Concentration Units
Isolate hCoV-19/USA/ MD-HP05285/2021 (Delta variant)	6.65E+05	GC/mL
hCoV-19/USA/MD-HP40900/2022, (Lineage XBB.1.5; Omicron Variant)	8E+01	$TCID_{50}$/mL

Analytical Specificity: Cross-Reactivity and Microbial Interference

Cross-reactivity and microbial interference with related pathogens, high prevalence disease agents, and normal or pathogenic flora that are reasonably likely to be encountered in the clinical specimen were evaluated with OSOM Flu SARS-CoV-2 Combo Home Test. Each organism was tested in replicates of five (5) at the concentration listed in the following table of test results.

For cross reactivity, the organisms listed below were tested in negative samples. Testing showed no evidence of cross-reactivity at the concentrations tested.

In silico analysis using the Basic Local Alignment Search Tool (BLAST) managed by the National Center for Biotechnology Information (NCBI) was conducted to assess the degree of protein sequence homology for the following: *Pneumocystis jirovecii, Mycobacterium tuberculosis,* Human coronavirus HKU1 N protein, and human SARS coronavirus N protein.

- No significant protein homology was found between the nucleocapsid protein sequences of Human coronavirus HKU1 compared to Influenza A or Influenza B nucleocapsid proteins.
- No significant protein homology was found between the nucleocapsid protein sequences of SARS Coronavirus compared to Influenza A or Influenza B nucleocapsid proteins.
- The comparison between the SARS-CoV-2 N protein and Human coronavirus HKU1 N protein revealed low homology of 30.2% identity across 100% of the full sequences, but cross-reactivity cannot be ruled out.
- The comparison between the SARS-CoV-2 N protein and human SARS coronavirus N protein revealed significant homology of 90.5% identity across 100% of the full sequences, but cross-reactivity cannot be ruled out.
- No significant protein homology was found between the nucleocapsid protein sequences of Human coronavirus HKU1 compared to Influenza A or Influenza B nucleocapsid proteins.
- No significant protein homology was found between the nucleocapsid protein sequences of SARS Coronavirus compared to Influenza A or Influenza B nucleocapsid proteins.

Microorganism Introduced	Concentration	**Influenza A** Test Results (positive/total)	**Influenza B** Test Results (positive/total)	**SARS-CoV-2** Test Results (positive/total)
NCM in Saline Only	N/A	0/5	0/5	0/5
Human coronavirus 229E	1.43×10^5 $TCID_{50}$/mL	0/5	0/5	0/5
Human coronavirus OC43	1.43×10^5 $TCID_{50}$/mL	0/5	0/5	0/5
Human coronavirus NL63	1.43×10^5 $TCID_{50}$/mL	0/5	0/5	0/5
MERS-coronavirus	1.43×10^5 $TCID_{50}$/mL	0/5	0/5	0/5

** Recommended testing concentrations were not achievable due to the low vial concentrations. The samples were tested undiluted.*

Microorganism Introduced	**Concentration**	**Influenza A** Test Results (positive/total)	**Influenza B** Test Results (positive/total)	**SARS-CoV-2** Test Results (positive/total)
Rhinovirus Type 1A	1.43×10^5 $TCID_{50}$/mL	0/5	0/5	0/5
Influenza A (H1N1)*	7.05×10^4 $TCID_{50}$/mL	N/A	0/5	0/5
Influenza A (H3N2)	1.43×10^5 $TCID_{50}$/mL	N/A	0/5	0/5
Influenza B (Victoria)	1.43×10^5 $TCID_{50}$/mL	0/5	N/A	0/5
Influenza B (Yamagata)*	9.30×10^3 $TCID_{50}$/mL	0/5	N/A	0/5
Parainfluenza virus 1	1.00×10^5 U/mL	0/5	0/5	0/5
Parainfluenza virus 2	1.43×10^5 $TCID_{50}$/mL	0/5	0/5	0/5
Parainfluenza virus 3	1.43×10^5 $TCID_{50}$/mL	0/5	0/5	0/5
Parainfluenza virus 4A	1.00×10^5 U/mL	0/5	0/5	0/5
Staphylococcus aureus (Protein A producer)	1.00×10^6 CFU/mL	0/5	0/5	0/5
Cytomegalovirus*	7.05×10^4 $TCID_{50}$/mL	0/5	0/5	0/5
Coxsackievirus	1.00×10^5 U/mL	0/5	0/5	0/5
Measles	1.43×10^5 $TCID_{50}$/mL	0/5	0/5	0/5
Corynebacterium diphtheriae	1.00×10^6 CFU/mL	0/5	0/5	0/5
Lactobacillus acidophilus	1.00×10^6 CFU/mL	0/5	0/5	0/5
Mycobacterium tuberculosis (avirulent)	1.00×10^6 CFU/mL	0/5	0/5	0/5
Neisseria gonorrhoeae	1.00×10^6 CFU/mL	0/5	0/5	0/5
Streptococcus pneumoniae	1.00×10^6 CFU/mL	0/5	0/5	0/5
Streptococcus salivarius	1.00×10^6 CFU/mL	0/5	0/5	0/5
Adenovirus Type 1	1.00×10^5 U/mL	0/5	0/5	0/5
Adenovirus Type 7	1.00×10^5 U/mL	0/5	0/5	0/5
Human Metapneumovirus (hMPV)	1.43×10^5 $TCID_{50}$/mL	0/5	0/5	0/5
*Enterovirus**	8.5×10^4 $TCID_{50}$/mL	0/5	0/5	0/5

** Recommended testing concentrations were not achievable due to the low vial concentrations. The samples were tested undiluted.*

Microorganism Introduced	**Concentration**	**Influenza A** Test Results (positive/total)	**Influenza B** Test Results (positive/total)	**SARS-CoV-2** Test Results (positive/total)
Respiratory syncytial virus Type B	1.43×10^5 $TCID_{50}$/mL	0/5	0/5	0/5
Haemophilus influenzae	1.00×10^6 CFU/mL	0/5	0/5	0/5
Streptococcus pyogenes	1.00×10^6 CFU/mL	0/5	0/5	0/5
Candida albicans	1.00×10^6 CFU/mL	0/5	0/5	0/5
Pooled human nasal wash – representative of normal respiratory microbial flora	N/A – Pooled Human Nasal Wash was added directly to swabs without dilution.	0/5	0/5	0/5
Bordetella pertussis	1.00×10^6 CFU/mL	0/5	0/5	0/5
Mycoplasma pneumoniae	1.00×10^6 CCU/mL	0/5	0/5	0/5
Chlamydophila pneumoniae	1.00×10^6 IFU/mL	0/5	0/5	0/5
Legionella pneumophila	1.00×10^6 CFU/mL	0/5	0/5	0/5
Staphylococcus epidermidis	1.00×10^6 CFU/mL	0/5	0/5	0/5
Epstein Barr Virus	1.00×10^5 cp/mL	0/5	0/5	0/5
Human herpes virus	1.43×10^5 $TCID_{50}$/mL	0/5	0/5	0/5
Mumps virus	1.43×10^5 $TCID_{50}$/mL	0/5	0/5	0/5
Escherichia coli	1.00×10^6 CFU/mL	0/5	0/5	0/5
Moraxella catarrhalis	1.00×10^6 CFU/mL	0/5	0/5	0/5
Neisseria meningitidis	1.00×10^6 CFU/mL	0/5	0/5	0/5
Pseudomonas aeruginosa	1.00×10^6 CFU/mL	0/5	0/5	0/5
Klebsiella pneumoniae	1.00×10^6 CFU/mL	0/5	0/5	0/5

** Recommended testing concentrations were not achievable due to the low vial concentrations. The samples were tested undiluted.*

Microbial interference

For evaluating microbial interference against the SARS-CoV-2, Influenza A (H1N1), Influenza B (Victoria) test lines, the organisms were tested with SARS-CoV-2 heat-inactivated isolate BA.5 Omicron Variant (Zeptometrix Catalog number 0810658CFHI), Influenza A/Michigan/45/2015 (ZeptoMetrix PN 0810538CF) or Influenza B/Florida/02/06 (ZeptoMetrix PN 0810037CF) diluted to 2x LoD concentration in negative clinical matrix and tested in replicates of five (5). No cross reactivity was seen with the organisms tested at the concentrations shown below.

Microorganism Introduced	**Microorganism Concentration**	**Influenza A** Test Results (positive/total)	**Influenza B** Test Results (positive/total)	**SARS-CoV-2** Test Results (positive/total)
NCM in Saline Only	N/A	5/5	5/5	5/5
Human coronavirus 229E	1.43×10^5 $TCID_{50}$/mL	5/5	5/5	5/5
Human coronavirus OC43	1.43×10^5 $TCID_{50}$/mL	5/5	5/5	5/5
Human coronavirus NL63	1.43×10^5 $TCID_{50}$/mL	5/5	5/5	5/5
MERS-coronavirus	1.43×10^5 $TCID_{50}$/mL	5/5	5/5	5/5
Rhinovirus Type 1A	1.43×10^5 $TCID_{50}$/mL	5/5	5/5	5/5
Influenza A (H1N1)*	7.05×10^4 $TCID_{50}$/mL	5/5	5/5	5/5
Influenza A (H3N2)	1.43×10^5 $TCID_{50}$/mL	5/5	5/5	5/5
Influenza B (Victoria)	1.43×10^5 $TCID_{50}$/mL	5/5	5/5	5/5
Influenza B (Yamagata)*	9.30×10^3 $TCID_{50}$/mL	5/5	5/5	5/5
Parainfluenza virus 1	1.00×10^5 U/mL	5/5	5/5	5/5
Parainfluenza virus 2	1.43×10^5 $TCID_{50}$/mL	5/5	5/5	5/5
Parainfluenza virus 3	1.43×10^5 $TCID_{50}$/mL	5/5	5/5	5/5
Parainfluenza virus 4A	1.00×10^5 U/mL	5/5	5/5	5/5
Staphylococcus aureus (Protein A producer)	1.00×10^6 CFU/mL	5/5	5/5	5/5
Cytomegalovirus*	7.05×10^4 $TCID_{50}$/mL	5/5	5/5	5/5
Coxsackievirus	1.00×10^5 U/mL	5/5	5/5	5/5
Measles	1.43×10^5 $TCID_{50}$/mL	5/5	5/5	5/5
Corynebacterium diphtheraie	1.00×10^6 CFU/mL	5/5	5/5	5/5
Lactobacillus acidophilus	1.00×10^6 CFU/mL	5/5	5/5	5/5

** Recommended testing concentrations were not achievable due to the low vial concentrations. The samples were tested undiluted.*

Microorganism Introduced	**Microorganism Concentration**	**Influenza A** Test Results (positive/total)	**Influenza B** Test Results (positive/total)	**SARS-CoV-2** Test Results (positive/total)
Mycobacterium tuberculosis (avirulent)	1.00×10^6 CFU/mL	5/5	5/5	5/5
Neisseria gonorrhoeae	1.00×10^6 CFU/mL	5/5	5/5	5/5
Streptococcus pneumoniae	1.00×10^6 CFU/mL	5/5	5/5	5/5
Streptococcus salivarius	1.00×10^6 CFU/mL	5/5	5/5	5/5
Adenovirus Type 1	1.00×10^5 U/mL	5/5	5/5	5/5
Adenovirus Type 7	1.00×10^5 U/mL	5/5	5/5	5/5
Human Metapneumovirus (hMPV)	1.43×10^5 $TCID_{50}$/mL	5/5	5/5	5/5
Enterovirus*	8.5×10^4 $TCID_{50}$/mL	5/5	5/5	5/5
Respiratory syncytial virus Type B	1.43×10^5 $TCID_{50}$/mL	5/5	5/5	5/5
Haemophilus influenzae	1.00×10^6 CFU/mL	5/5	5/5	5/5
Streptococcus pyogenes	1.00×10^6 CFU/mL	5/5	5/5	5/5
Candida albicans	1.00×10^6 CFU/mL	5/5	5/5	5/5
Pooled human nasal wash – representative of normal respiratory microbial flora	N/A – Pooled Human Nasal Wash was added directly to swabs without dilution.	5/5	5/5	5/5
Bordetella pertussis	1.00×10^6 CFU/mL	5/5	5/5	5/5
Mycoplasma pneumoniae	1.00×10^6 CCU/mL	5/5	5/5	5/5
Chlamydophila pneumoniae	1.00×10^6 IFU/mL	5/5	5/5	5/5
Legionella pneumophila	1.00×10^6 CFU/mL	5/5	5/5	5/5
Staphylococcus epidermidis	1.00×10^6 CFU/mL	5/5	5/5	5/5
Epstein Barr Virus	1.00×10^5 cp/mL	5/5	5/5	5/5
Human herpes virus	1.43×10^5 $TCID_{50}$/mL	5/5	5/5	5/5
Mumps virus	1.43×10^5 $TCID_{50}$/mL	5/5	5/5	5/5
Escherichia coli	1.00×10^6 CFU/mL	5/5	5/5	5/5
Moraxella catarrhalis	1.00×10^6 CFU/mL	5/5	5/5	5/5

** Recommended testing concentrations were not achievable due to the low vial concentrations. The samples were tested undiluted.*

Microorganism Introduced	Microorganism Concentration	Influenza A Test Results (positive/total)	Influenza B Test Results (positive/total)	SARS-CoV-2 Test Results (positive/total)
Neisseria meningitidis	1.00 x 10^6 CFU/mL	5/5	5/5	5/5
Pseudomonas aeruginosa	1.00 x 10^6 CFU/mL	5/5	5/5	5/5
Klebsiella pneumoniae	1.00 x 10^6 CFU/mL	5/5	5/5	5/5

** Recommended testing concentrations were not achievable due to the low vial concentrations. The samples were tested undiluted.*

Endogenous Interfering Substances

A total of twenty-nine (29) potentially interfering substances, either naturally present in respiratory specimens or artificially introduced into the nasal cavity or nasopharynx, were tested to evaluate the susceptibility of the OSOM Flu SARS-CoV-2 Combo Home Test to interference when elevated levels of these substances were added to the nasal swab head in the absence (negative) and presence (positive) of SARS-CoV-2, two different strains of influenza A, or two different strains of influenza B. Each substance was tested in replicates of five (5). No interference was observed for any of the substances at the concentration listed below, that is all 5 replicates were negative for each tested substance.

Interfering Substance Introduced	Concentration	Interference (Yes/No)
Control (NCM in Saline only)	N/A	No
Chloraseptic (Menthol/ Benzocaine) Throat Lozenge	3 mg/mL	No
Sore Throat Spray (Phenol Oral Anesthetic)	5% w/v	No
Mucin	2.5 mg/mL	No
Whole Blood	5%	No
Leukocytes	5 x 10^6 cells/mL	No
Nasal drops (Phenylephrine)	15% v/v	No
NasalCrom (Cromolyn)	15% v/v	No
Afrin (Oxymetazoline)	15% v/v	No
Saline Nasal Spray	15% v/v	No
Beclomethasone	15% v/v	No
Dexamethasone	15% v/v	No
Flunisolide	15% v/v	No
Triamcinolone	15% v/v	No
Budesonide	15% v/v	No
Mometasone	15% v/v	No
Nasal spray (Fluticasone Propionate)	15% v/v	No
NasoGEL	5% v/v	No
Nasal spray (Zicam)	15% v/v	No
Nasal wash (Alkalol)	15% v/v	No
Tamiflu (Oseltamivir Phosphate)	5 mg/mL	No
Remdesivir	5 mg/mL	No
Molnupiravir	5 mg/mL	No
Zanamivir	5.5 mg/mL	No
Mupirocin Ointment	7.5 mg/mL	No
Mupirocin powder	10 mg/mL	No

Interfering Substance Introduced	Concentration	Interference (Yes/No)
Tobramycin	1.25 mg/mL	No
Hand Sanitizer with Aloe	5%	No
Hand Sanitizer Lotion (Vaseline)	10%	No
Liquid Hand Sanitizer (NatureWell)	15%	No
Hand Soap Liquid Gel (Softsoap)	10%	No

High Dose Hook Effect

No high-dose hook effect was observed with the OSOM Flu SARS-CoV-2 Combo Home Test when testing high concentrations of SARS-CoV-2, Influenza A or Influenza B strains.

Viral Strain Tested	Concentration ($TCID_{50}$/mL)
Influenza A/Michigan/45/15 (H1N1)	1.41×10^5 $TCID_{50}$/mL
Influenza B/Colorado/6/2017 (Victoria)	1.41×10^5 $TCID_{50}$/mL
SARS-CoV-2 BA.5 Omicron Variant	6.15×10^6 $TCID_{50}$/mL

Competitive Interference

For co-infection, SARS-CoV-2 at levels near LoD was tested in the presence of high levels of influenza A or influenza B and near LoD influenza A and influenza B in the presence of high levels of SARS-CoV-2. Additionally, the performance of the OSOM ULTRA PLUS FLU A&B Test was evaluated in the presence of high levels of influenza A and influenza B. Contrived high and low titer influenza A (H1N1 and H3N2) and B positive samples were. No competitive interference was observed between SARS-CoV-2 and influenza A and B as listed in the table below.

Sample	High titer target		Low titer target		Low titer target Percent Positivity
	Virus Name	Concentration ($TCID_{50}$/mL)	Virus Name	Concentration ($TCID_{50}$/mL)	
1	Flu A (H1N1)	1.13×10^5	inactivated SARS-Cov-2	6.16×10^4	100%
2	Flu A (H1N1)	1.13×10^5	Flu B (Victoria)	5.64×10^2	100%
3	Flu A (H1N1)	1.13×10^5	Flu B (Yamagata)	1.86×10^2	100%
4	Flu A (H3N2)	1.58×10^6	inactivated SARS-CoV-2	6.16×10^4	100%
5	Flu A (H3N2)	1.58×10^6	Flu B (Victoria)	5.64×10^2	100%
6	Flu A (H3N2)	1.58×10^6	Flu B (Yamagata)	1.86×10^2	100%
7	Flu B (Victoria)	1.13×10^5	inactivated SARS-CoV-2	6.16×10^4	100%
8	Flu B (Victoria)	1.13×10^5	Flu A (H1N1)	7.06×10^2	100%
9	Flu B (Victoria)	1.13×10^5	Flu A (H3N2)	3.16×10^4	100%
10	Flu B (Yamagata)	1.49×10^4	inactivated SARS-CoV-2	6.16×10^4	100%

Sample	High titer target		Low titer target		Low titer target Percent Positivity
	Virus Name	Concentration ($TCID_{50}$/mL)	Virus Name	Concentration ($TCID_{50}$/mL)	
11	Flu B (Yamagata)	1.49×10^4	Flu A (H1N1)	7.06×10^2	100%
12	Flu B (Yamagata)	1.49×10^4	Flu A (H3N2)	3.16×10^4	100%
13	inactivated SARS-CoV-2	3.08×10^6	Flu A(H1N1)	7.06×10^2	100%
14	inactivated SARS-CoV-2	3.08×10^6	Flu A (H3N2)	3.16×10^4	100%
15	inactivated SARS-CoV-2	3.08×10^6	Flu B (Victoria)	5.64×10^2	100%
16	inactivated SARS-CoV-2	3.08×10^6	Flu B (Yamagata)	1.86×10^2	100%
17	Flu A (H1N1)	1.13×10^5	Flu B (Yamagata) &	Flu B (Yamagata): 1.86×10^2	100%
			inactivated SARS-CoV-2	SARS-CoV-2: 6.16×10^4	100%
18	Flu A (H3N2)	1.58×10^6	Flu B (Victoria) &	Flu B (Victoria): 5.64×10^2	100%
			inactivated SARS-CoV-2	SARS-CoV-2: 6.16×10^4	100%
19	Flu A (H3N2)	1.58×10^6	Flu B (Yamagata) &	Flu B (Yamagata): 1.86×10^2	100%
			inactivated SARS-CoV-2	SARS-CoV-2: 6.16×10^4	100%
20	Flu B (Victoria)	1.13×10^5	Flu A (H1N1) &	Flu A (H1N1): 7.06×10^2	100%
			inactivated SARS-CoV-2	SARS-CoV-2: 6.16×10^4	100%
21	Flu B (Victoria)	1.13×10^5	Flu A (H3N2) &	Flu A (H3N2): 3.16×10^4	100%
			inactivated SARS-CoV-2	SARS-CoV-2: 6.16×10^4 $TCID_{50}$/mL	100%
22	Flu B (Yamagata)	1.49×10^4	Flu A (H1N1) &	Flu A (H1N1): 7.06×10^2	100%
			Inactivated SARS-CoV-2	SARS-CoV-2: 6.16×10^4	100%
23	Flu B (Yamagata)	1.49×10^4	Flu A (H3N2) &	Flu A (H3N2): 3.16×10^4	100%
			Inactivated SARS-CoV-2	SARS-CoV-2: 6.16×10^4	100%

Sample	High titer target		Low titer target		Low titer target Percent Positivity
	Virus Name	Concentration ($TCID_{50}$/mL)	Virus Name	Concentration ($TCID_{50}$/mL)	
24	Inactivated SARS-CoV-2	3.08×10^6	Flu A (H1N1) &	Flu A (H1N1): 7.06×10^2	100%
			Flu B (Victoria)	Flu B (Victoria): 5.64×10^2	100%
25	Inactivated SARS-CoV-2	3.08×10^6	Flu A (H1N1) &	Flu A (H1N1): 7.06×10^2	100%
			Flu B (Yamagata)	Flu B (Yamagata): 1.86×10^2	100%
26	Inactivated SARS-CoV-2	3.08×10^6	Flu A (H3N2) &	Flu A (H3N2): 3.16×10^4	100%
			Flu B (Victoria)	Flu B (Victoria): 5.64×10^2	100%
27	Inactivated SARS-CoV-2	3.08×10^6	Flu A (H3N2) &	Flu A (H3N2): 3.16×10^4	100%
			Flu B (Yamagata)	Flu B (Yamagata): 1.86×10^2	100%

CLINICAL PERFORMANCE

A prospective clinical study to establish the performance characteristics of the OSOM Flu SARS-CoV-2 Combo Home Test was conducted with specimens prospectively collected from October 2023 to January 2024 at seven (7) sites across the United States. Subjects performed testing on self-collected swab samples in age groups 14 and older, and adult collected samples for age groups 2-13, in a simulated at-home environment, with the exception of 2 cases.

Samples were collected from individuals with associated symptoms of respiratory infection, who provided informed consent. Two (2) nasal swabs were collected from each subject according to standard collection methods. One (1) nasal swab was self-collected and used for immediate testing with the OSOM Flu SARS-CoV-2 Combo Home Test per the test procedure. The other nasal swab sample was collected by a healthcare professional in VTM, at least 15 minutes after each subject/tester completed sample collection and testing on the investigational test. The HCP collected specimens were sent for testing by the reference methods, FDA-cleared molecular comparator tests, within the allowable time frames of specimen collection per the product instructions.

Nasal swab specimens were collected from 726 subjects enrolled in the prospective clinical study. Of those, 23 swab samples were unevaluable due to eligibility criteria, candidate device invalid, or reference sample handling issues, leaving a total of 703 evaluable samples for the SARS-CoV-2 performance evaluation. In addition, 4 swab samples were not evaluable due to reference results not being available, leaving a total of 699 evaluable samples for the Flu A/B performance evaluation.

Subject Demographics

	Subjects (by lay-user collection and testing (N=61)	Self-collecting and testing (N=642)	Overall (N=703)
Age			
Mean (SD)	8.9 (2.7)	38.7 (14.7)	36.1 (16.4)
Median [Min, Max]	9 [3, 14]	37 [14, 85]	35 [3, 85]
Age Group			
≥2-<14 years of age	59 (96.7%)	0 (0.0%)	59 (8.4%)
14-21 years of age	2 (3.3%)	65 (10.1%)	67 (9.5%)
22-64 years of age	0 (0.0%)	548 (85.4%)	548 (78.0%)
≥65 years of age	0 (0.0%)	29 (4.5%)	29 (4.1%)
Sex at Birth			
Female	31 (50.8%)	410 (63.9%)	441 (62.7%)
Male	30 (49.2%)	232 (36.1%)	262 (37.3%)
Ethnicity			
Hispanic/Latino	38 (62.3%)	241 (37.5%)	279 (39.7%)
Not Hispanic/Latino	23 (37.7%)	401 (62.5%)	424 (60.3%)
Race			
American Indian or Alaskan Native	0 (0.0%)	3 (0.5%)	3 (0.4%)
Asian	0 (0.0%)	13 (2.0%)	13 (1.8%)
Black or African American	6 (9.8%)	64 (10.0%)	70 (10.0%)
Native Hawaiian/Pacific Islander	0 (0.0%)	1 (0.2%)	1 (0.1%)
White	51 (83.6%)	538 (83.8%)	589 (83.8%)
Unknown/Prefer not to answer	0 (0.0%)	10 (1.6%)	10 (1.4%)
Other (Mixed race/biracial)	4 (6.6%)	13 (2.0%)	17 (2.4%)

SARS-COV-2 PERFORMANCE

Investigational Test results for SARS-CoV-2 vs. FDA-cleared molecular test

SARS-CoV-2	Comparators Positives	Comparators Negatives	Sum
Investigational Positives	86	5	91
Investigational Negatives	58	554	612
Sum	**144**	**559**	**703**

Positive Percent Agreement = (86/144) = 59.7% (95% CI: 51.6%-67.4%)
Negative Percent Agreement = (554/559) = 99.1% (95% CI: 97.9%-99.6%)

Controlled Analysis

Controlled Analysis for SARS-CoV-2

	All Study Cohort	10% Low Positives	12.5% Low Positives	15% Low Positives	17.5% Low Positives	20% Low Positives
High Positive Samples	82	82	82	82	82	82
Low Positive Samples	62	10	12	15	18	21
Total Comparator Positive for PPA Calculation	144	92	94	97	100	103
Total Test Positives for PPA Calculation	86	80	80	80	81	81
PPA	**59.7**	**87.0**	**85.1**	**82.5**	**81.0**	**78.6**

Controlled Analysis for SARS-CoV-2

	All Study Cohort	10% Low Positives	12.5% Low Positives	15% Low Positives	17.5% Low Positives	20% Low Positives
95% CI (XX% - XX%)	51.5-67.4	78.6-92.4	76.5-90.9	73.7-88.8	72.2-87.5	69.8-85.5
NPA (%)	99.1%					
95% CI (XX% - XX%)	98.0%-99.6%					

SARS-CoV-2 Clinical Performance in Subjects on Days Post Symptoms Onset

Days of COVID-19 Symptoms	Number of Subject samples tested	Investigational Positives	Comparator Positives	% Positive Rate (by Comparator)	PPA (95% CI)
Day 0	19	2	5	26.3%	**40.0% (11.8%-76.9%)**
Day 1	130	24	38	29.2%	**63.2% (47.3%-76.6%)**
Day 2	239	24	46	19.2%	**52.2% (38.1%-65.9%)**
Day 3	195	24	33	16.9%	**72.7% (55.8%-84.9%)**
Day 4	120	12	22	18.3%	**54.5% (34.7%-73.1%)**
Total	**703**	**86**	**144**	**20.5%**	**59.7% (51.6%-67.4%)**

Note: The five false positive subjects were excluded from the Investigational Positives count for the purpose of this table (i.e., DPSO stratified PPA).

INFLUENZA A PERFORMANCE

Investigational Test results for FLU A vs. FDA-cleared molecular test

FLU A	Comparators Positives	Comparators Negatives	Sum
Investigational Positives	67	3	**70**
Investigational Negatives	5	624	**629**
Sum	**72**	**627**	**699**

Positive Percent Agreement = (67/72) = 93.1% (95% CI: 84.8%-97%)

Negative Percent Agreement = (624/627) = 99.5% (95% CI: 98.6%-99.8%)

INFLUENZA B PERFORMANCE

Investigational Test results for FLU B vs. FDA-cleared molecular test

FLU B	Comparators Positives	Comparators Negatives	Sum
Investigational Positives	41	2	**43**
Investigational Negatives	5	651	**656**
Sum	**46**	**653**	**699**

Positive Percent Agreement = (41/46) = 89.1% (95% CI: 77%-95.3%)

Negative Percent Agreement = (651/653) = 99.7% (95% CI: 98.9%-99.9%)

SERIAL TESTING

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

At each rapid antigen testing time point, study subjects also collected a nasal swab for comparator testing using a home collection kit (using a 15-minute normalization window between swabs). SARS-CoV-2 infection status was determined by a composite comparator method on the day of the first antigen test, using at least two highly sensitive EUA RT-PCRs. If results of the first two molecular 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 RTPCR, 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 the molecular comparator single day testing throughout the course of infection with serial testing. Data is from all antigen tests in study combined.

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

DAYS AFTER FIRST PCR POSITIVE TEST RESULT	SYMPTOMATIC ON FIRST DAY OF TESTING		
	Ag 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 (98.3%)	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%)	

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

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

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

SYMBOLS

	Manufacturer
	Consult instructions for use
	Catalog number
	Contains sufficient for <n> tests
	Use-by date
	*In vitro* diagnostic use only
	Batch code
	Temperature limit
	Do not re-use
OTC	Over-the-Counter

ORDERING AND CONTACT INFORMATION

Reorder Numbers:
OSOM Flu SARS-CoV-2 Combo Home Test (Catalog Number 1074)

Technical Support:
If you have questions regarding the use of this product, or if you want to report a problem with the OSOM Flu SARS-CoV-2 Combo Home Test, please contact SEKISUI Diagnostics Technical Services at (800) 491-6220 or techservices@sekisuidiagnostics.com.

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