OSOM®

Flu SARS-CoV-2 Combo Test

For use under Emergency Use Authorization (EUA) only

For *in vitro* diagnostic use

For use with anterior nasal swab specimens.

INSTRUCTIONS FOR USE

IVD Rx ONLY REF 1080

INTENDED USE

The OSOM® Flu SARS-CoV-2 Combo Test is a lateral flow immunochromatographic assay intended for *in vitro* rapid, simultaneous qualitative detection and differentiation of influenza A and influenza B nucleoprotein antigens and SARS-CoV-2 nucleocapsid antigen directly from anterior nasal swab specimens of individuals with signs and symptoms of respiratory infection consistent with COVID-19 by their healthcare provider within the first four (4) days of symptom onset when tested at least twice over three (3) 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. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, that meet the requirements to perform moderate, high or waived complexity tests.

This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Results are for the simultaneous *in vitro* detection and differentiation of SARS-CoV-2, influenza A virus, and influenza B virus protein antigen, but does not differentiate, between SARS-CoV and SARS-CoV-2 viruses and is not intended to detect influenza C antigens.

These viral antigens are generally detectable in anterior nasal swab specimens 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.

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

The OSOM Flu SARS CoV-2 Combo Test is only for *in vitro* diagnostic use under the Food and Drug Administration's Emergency Use Authorization. This product has not been FDA cleared or approved.

SUMMARY AND EXPLANATION

Along with the common cold, influenza is one (1) of the most common acute respiratory infections, producing symptoms such as headache, chills, dry cough, body aches, and fever. It affects 5%-20% of the United States population annually, resulting in more than 200,000 hospitalizations and 36,000 deaths.[1] 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. Diagnosis is difficult because the initial symptoms can be similar to those caused by other infectious agents. Considering that the influenza virus is highly contagious, accurate diagnosis and prompt treatment of patients can have a positive effect on public health. Accurate diagnosis and the ability to distinguish between A or B antigens can also help reduce the inappropriate use of antibiotics and gives the physician the opportunity to prescribe an antiviral therapy. Initiation of antiviral therapy should begin as soon as possible after onset, ideally within 48 hours of the appearance of symptoms, as treatment may reduce the duration of symptoms.[2]

Coronaviruses are enveloped RNA viruses that are found broadly among humans, other mammals, and birds. The viruses are known to cause mild symptoms, but sometimes severe respiratory, enteric, hepatic, and neurological diseases can occur. Seven (7) coronavirus species are known to cause human disease, four (4) of which (229E, OC43, NL63 and HKU-1) are quite prevalent and can cause mild cold symptoms, especially in immunocompetent people.[3] There are three (3) other strains that are known to cause severe acute respiratory disease. These strains include severe acute respiratory syndrome coronavirus (SARS-CoV), Middle East respiratory syndrome coronavirus (MERS-CoV), and the 2019 Novel Coronavirus (COVID-19). These strains are all zoonotic in origin and have been linked to sometimes fatal respiratory illness. The prevalence of SARS and MERS has been quite low in recent years; the Novel Coronavirus (COVID-19) was recently identified in December 2019. The main manifestations of illness include fever, fatigue, and dry cough. Nasal congestion, runny nose, sore throat, myalgia, and diarrhea are found in a few cases. Most epidemiological studies suggest a 1-14 day incubation period. The median incubation period is estimated at 5.1 days, with most developing symptoms before 11.5 days.[4] Infected but asymptomatic people can also be an infectious source. The OSOM Flu SARS-CoV-2 Combo Test can provide rapid detection of influenza A, influenza B, and/or SARS-CoV-2 viral antigens from symptomatic patients.

PRINCIPLE OF THE PROCEDURE

The OSOM Flu SARS-CoV-2 Combo Test consists of a Test Stick 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 an Extraction Buffer vial. The Test Stick 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 mouse monoclonal IgG antibodies to influenza A, influenza B and/or SARS-CoV-2 conjugated to colloidal gold. The complex will then be bound by another rat anti-influenza A, mouse anti-influenza B and/or mouse 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 Stick 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 an 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

25 - Sterile Nasal Swabs
27* - Test Sticks
27* - Extraction Buffer vials each containing 0.25 mL phosphate buffered salt solution (with 0.09% sodium azide as a preservative)
1 - Flu A / Flu B / SARS-CoV-2 Positive Control Swab (packaged with a desiccant tablet) coated with non-infectious recombinant influenza A, influenza B, and SARS-CoV-2 containing 0.05% sodium azide
1 - Flu A / Flu B / SARS-CoV-2 Negative Control Swab (packaged with a desiccant tablet) coated with nonviable Group C Streptococci containing 0.09% sodium azide
2 - Result Interpretation Cards
1 - Instructions for Use (IFU)
1 - Quick Reference Guide (QRG)
1 - Workstation

***NOTE:** Two (2) extra Test Sticks and Extraction Buffer vials have been included in the kit for External Quality Control (QC) testing.

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer or clock
- OSOM Flu SARS-CoV-2 Combo Control Kit for additional quality control (Catalog Number 1079)

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use.
- 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.
- The test has been authorized for emergency use by FDA under an Emergency Use Authorization (EUA) for use by authorized laboratories certified under the CLIA that meet the requirements to perform moderate, high or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.
- **Serial (repeat) testing should be performed in individuals with SARS-CoV-2 negative results at least twice over three (3) 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.**
- Do not use the kit contents beyond the expiration date printed on the outside of the box.
- Swabs, Extraction Buffer Vials, and Test Sticks are for single use only (do not reuse).
- If any liquid spills from the buffer tube, discard test components and re-start test using new test components.
- The Extraction Buffer vial contains only enough liquid for one (1) test. Do not add a second Test Stick to the same Extraction Buffer vial as invalid or incorrect results may occur.
- Do not interchange or mix components from different kit lots.

- Follow your clinical and/or laboratory safety guidelines and use appropriate precautions in the collection, handling, storage, and disposal of patient samples, all used kit contents, and all items exposed to patient samples.[5]
- Use of nitrile or latex (or other equivalent) gloves and other personal protective equipment are recommended when handling patient samples.[5]
- Inadequate or inappropriate sample collection, storage, and transport may yield false test results.
- Only use the nasal swabs provided in the kit. Do not touch the swab tip prior to testing.
- Once removed from the canister, the Test Stick 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 results.**
- Dispose of unused contents and containers in accordance with federal, state, and local regulations.
- The Result Interpretation Card should be cleaned after each use by spraying the laminated card with 70% ethanol alcohol or alternately by wiping with a clean towel moistened with 70% ethanol alcohol. The Result Interpretation Card should be wiped dry with a clean towel.
- Wearing eye 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

KIT STORAGE AND STABILITY

Store the OSOM Flu SARS-CoV-2 Combo Test at room temperature (15-30°C/59-86°F) in the original packaging, away from direct sunlight. Kit contents are stable in the unopened canister until the expiration date printed on the kit box.

- Do not freeze any of the test kit components.
- Do not use Test Sticks or Extraction Buffer after expiration date.
- Recap the desiccated Test Stick canister immediately after removing a Test Stick.
- Test Sticks that have been outside of the desiccated container for more than 30 minutes should be discarded.

SAMPLE HANDLING, TRANSPORT AND STORAGE

- The test performance depends on the quality of the sample obtained as well as the handling and transport of the sample. Negative results can occur from inadequate sample collection and/or handling. Training in specimen collection is highly recommended because of the importance of specimen quality.
- To obtain accurate results, do not use visually bloody or overly viscous samples.
- If a culture result is desired for influenza, a separate swab must be collected for the culture.
- Freshly collected patient samples should be processed in the Extraction Buffer vial as soon as possible after collection. If the sample cannot be processed immediately, the patient swab may be stored at room temperature (15-30ºC/59-86ºF) for up to 30 minutes or refrigerated (2-8ºC/36-46ºF) for up to 30 minutes prior to testing in a clean dry container. Refrigerated samples should come to room temperature before testing.
- To transport patient samples, place swab in a clean, dry container such as a plastic or glass tube.
- Once the swab has been mixed in the Extraction Buffer vial, the extracted sample must be used within 30 minutes when stored at room temperature (15-30ºC/59-86ºF) or refrigerated (2-8ºC/36-46ºF).

QUALITY CONTROL

The OSOM Flu SARS-CoV-2 Combo Test provides two (2) types of controls: internal procedural controls to aid in determining test validity, and two (2) external controls, a positive and negative control swab.

Internal Procedural Controls

Several controls are incorporated into each Test Stick as routine quality checks for the test system and operator.

1. The appearance of the control line in the results window is an internal procedural control. It also verifies proper assembly of the Test Stick. If the control line does not appear at the read time, the test is invalid.

2. The clearing of the background in the results area is another internal procedural control. It also serves as an additional capillary flow control. At the read time, the background should appear white to light pink and not interfere with the reading of the test. If the background color does not clear and interferes with the test result, the test is invalid.

Contact SEKISUI Diagnostics Technical Services at (800) 332-1042 or techservices@sekisuidiagnostics.com if you experience a problem.

External Quality Control Testing

The OSOM Flu SARS-CoV-2 Combo Test kit includes one (1) combined positive control swab that contains recombinant antigen for influenza A, influenza B, and SARS-CoV-2 and one (1) negative control swab that contains non-viable Group C Streptococci.

Use the controls to help ensure that the Test Sticks are functioning properly and to demonstrate proper performance by the test operator. It is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure was run correctly and to verify the test is working properly.

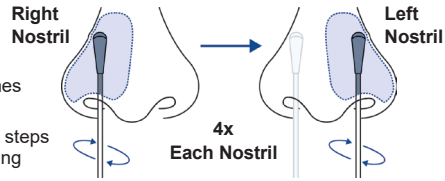
External quality control requirements should be established in accordance with your local, state, and federal regulations or accreditation requirements. To perform a positive or negative control test, complete the steps in the Test Procedure section, treating the control swab in the same manner as a patient swab. Minimally, SEKISUI Diagnostics recommends that Positive and Negative external controls be run with each new lot, shipment received, and with each new untrained operator.

SPECIMEN COLLECTION AND PREPARATION

Only nasal swabs can be used with this test. Use of nasal washes, nasal aspirates or nasopharyngeal swabs has not been validated.

Nasal Swab Sample

1. Gently insert the sterile swab no more than ¾ of an inch into the nostril.
2. Rotate the swab at least 4 times against the nasal wall.
3. Remove the swab and repeat steps 1 and 2 in the other nostril using the same swab.



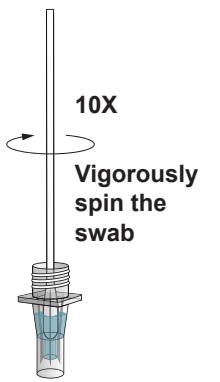
4. Sample should be processed in the Extraction Buffer as soon as possible after collection. Sample must be mixed in the extraction buffer within 30 minutes of sample collection.

TEST PROCEDURE

1 **Twist** cap off Buffer vial.
Insert the swab through the ridges into the liquid.

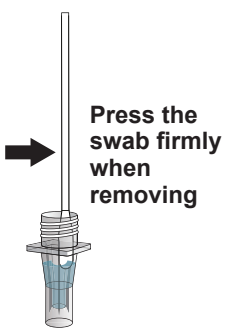
Mix thoroughly by spinning the swab **at least 10 times** in the liquid.

NOTE: Nasal swabs may not reach the bottom of the vial. Ensure that the swab is fully immersed in the liquid when mixing.



2 **Press** the swab against the side of the vial to remove any excess sample in the swab.

Remove and **Discard** the swab.

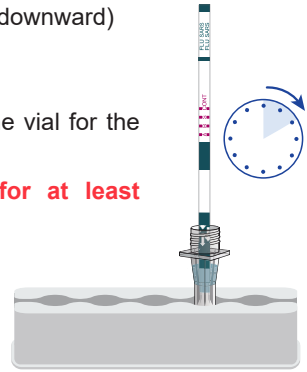


3 **Insert** Test Stick (arrows pointing downward) into the vial.

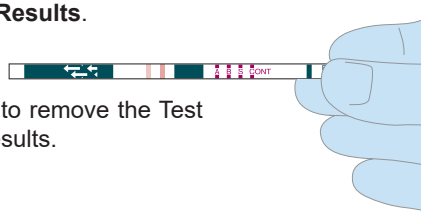
Set a timer for **10 minutes.**

NOTE: Leave the Test Stick in the vial for the full 10 minutes.

⚠ **DO NOT handle or remove for at least 10 minutes.**



4 **Read** test at 10 minutes. Do not read test before 10 minutes or after 30 minutes.
See **Interpretation of Results**.



NOTE: You may need to remove the Test Stick to read the test results.

INTERPRETATION OF RESULTS

Interpretation Key

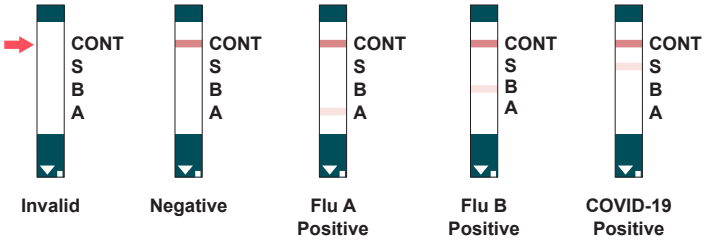
Results Window

- **CONT** = CONTROL Line
- **S** = COVID-19 Line
- **B** = (Flu B) Line
- **A** = (Flu A) Line

NOT ACTUAL SIZE

Place Test Stick, arrows pointing down, within dashed area of the **Result Interpretation Card** included in the kit. Ensure arrows on the Test Stick are pointing in the same direction as the arrows on the **Result Interpretation Card** and that the **Results Window** is aligned.

INTERPRETATION OF RESULTS



+LOOK CLOSELY WHEN INTERPRETING THE RESULTS!

The Control Line must be present for the result to be valid.

The appearance of **ANY** shade of a very light or faint pink to purple line at the Influenza "A" Test Line, Influenza "B" Test Line, or SARS-CoV-2 "S" Test Line along with a "CONT" Control Line indicates a positive result for the respective target according to the examples above.

Even if you see a very light or faint pink to purple Test Line, as long as the Control Line is present, it is a positive test result.

It is possible to have **more than one (1) positive Test Line,** which could indicate a co-infection with influenza A, B, and/or SARS-CoV-2.

If more than one (1) positive Test Line is observed, retest with a new patient sample, Extraction Buffer vial, and Test Stick. A differing result should be followed by confirmatory testing with another test method, such as PCR.

INVALID RESULT

If the pink to purple Control Line does not appear, even if **ANY** shade of a very light or faint pink to purple line appears at any of the Test Lines, the result is considered invalid. If at 10 minutes the background color does not clear, and it interferes with the reading of the test, the result is considered invalid. If the test is invalid, a new test should be performed with a new patient sample, Extraction Buffer vial, and Test Stick.

NEGATIVE RESULT

At 10 minutes, the appearance of **ONLY** the pink to purple Control Line indicates that influenza A, influenza B, or SARS-CoV-2 has **NOT** been detected. A negative result should be reported as a presumptive negative for the presence of influenza and/or SARS-CoV-2 antigen.

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.**

A negative test result indicates that the virus that causes COVID-19 was not detected in the sample. A negative result does not rule out COVID-19. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR tests. If the test is negative but COVID-19-like symptoms, e.g., fever, cough, and/or shortness of breath continue, follow up testing for SARS-CoV-2 with a molecular test or testing for other respiratory disease should be considered. If applicable, seek follow-up care with the primary 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 RESULT

The appearance of **ANY** shade of a very light or faint pink to purple line at the Influenza "A" Test Line, Influenza "B" Test Line, and/or SARS-CoV-2 "S" Test Line along with a "CONT" Control Line indicates a positive result for the presence of influenza A, influenza B, and/or SARS-CoV-2 viral antigen. A positive result does not rule out co-infections with other pathogens or identify any specific influenza A subtype, influenza B lineage, or SARS-CoV-2 variant.

NOTE: Positive test lines are usually very prominent but at times may vary in shade and intensity. A pink to purple line of any intensity or thickness in the A, B, or S region is considered a positive result. The intensity of the Control Line should not be compared to that of the Test Line for the interpretation of the test result.

Take time to look at test lines very carefully. If you see a very light or faint pink to purple Test Line, this is considered a POSITIVE result.

NOTE: It is possible to have more than one (1) positive Test Line, which could indicate a co-infection with influenza A, B, and/or SARS-CoV-2. If more than one (1) positive Test Line is observed, retest with a new patient sample, Extraction Buffer vial, and Test Stick. Repeatable influenza A and B "dual positive" results should be confirmed by viral culture or an FDA-cleared influenza A and B molecular assay before reporting results.

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 was detected in the sample, and it is very likely the individual has COVID-19 and is contagious. Please contact the patient's doctor/primary care physician (if applicable) and the local health authority immediately and instruct your patient to adhere to the local guidelines regarding self- isolation. There is a very small chance that this test can give a positive result that is incorrect (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 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 negative SARS-CoV-2 results. Please follow the table below when interpreting test results with symptoms. 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

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-2 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 infection, however additional follow up may be needed.
- If the test is positive, then proteins from the viruses that cause COVID-19 or influenza infection have been found in the sample and the individual likely has a respiratory infection with SARS-CoV-2 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.
- Use of OSOM Flu SARS-CoV-2 Combo Test is limited to laboratory personnel and CLIA waived users. Not for home use.
- The contents of this kit are to be used for the qualitative detection of influenza type A and B antigens as well as SARS-CoV-2 antigen from direct anterior nasal swab samples only.
- This test detects viable (live) and non-viable influenza A, influenza B, and SARS-CoV-2. Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture or molecular results performed on the same sample.
- A negative test result may occur if the level of antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly.
- Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result.
- Test results must be evaluated in conjunction with other clinical data available to the physician.
- Positive test results do not rule out co-infections with other pathogens.
- Positive test results do not identify specific influenza A subtypes, influenza B lineages, or SARS-CoV-2 variants.
- Negative test results cannot rule out diseases caused by other bacterial or viral pathogens.
- Positive and negative predictive values are highly dependent on prevalence. False negative test results are more likely during peak activity when prevalence of disease is high. False positive test results are more likely during periods of low viral activity when prevalence is moderate to low.
- Individuals who received nasally administered influenza vaccine may have positive test results for up to three (3) days after vaccination.
- Monoclonal antibodies may fail to detect, or detect with less sensitivity, influenza viruses that have undergone minor amino acid changes in the target epitope region.
- If the differentiation of specific influenza A, influenza B, or SARS subtypes or variants is needed, additional testing, in consultation with state or local public health departments, is required.

CONDITIONS OF AUTHORIZATION FOR THE LABORATORY AND PATIENT CARE SETTINGS

The OSOM Flu SARS-CoV-2 Combo Test Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

However, to assist in using the OSOM Flu SARS-CoV-2 Combo Test ("your product" in the conditions below). the relevant Conditions of Authorization are listed below:

- Authorized laboratories* using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating this labeling may be used, which may include mass media.
- Authorized laboratories using your product must use your product as outlined in OSOM Flu SARS-CoV-2 Combo Test Instructions for Use and Quick Reference Guide. Deviations from the authorized procedures, including authorized instruments, authorized clinical specimen types, authorized control materials, authorized ancillary reagents and authorized materials required to use your product are not permitted.
- Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- Authorized laboratories must collect information on the performance of your product and report any significant deviations from the established performance characteristics of your product of which they become aware to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and SEKISUI Diagnostics by contacting Technical Services (via email at techservices@sekisuidiagnostics.com or via phone at (800) 332-1042).
- All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.
- SEKISUI Diagnostics, authorized distributors, and authorized laboratories using your product must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

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

PERFORMANCE CHARACTERISTICS

ANALYTICAL PERFORMANCE

Limit of Detection (Analytical Sensitivity)

The limit of detection (LoD) for the OSOM Flu SARS-CoV-2 Combo Test was established using dilutions of one (1) SARS-Related Coronavirus 2 (SARS-CoV-2) Lineage BA.5 Omicron Variant strain (Zeptometrix Catalog number 0810658CFHI), two (2) influenza A strains (Influenza A H1N1: Influenza A/Michigan/45/15, Influenza A H3N2: Influenza A/Singapore/INFIMH-16-0019/2016) and four (4) 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 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 each of 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 three (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%
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 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.

Type	Strain	Concentration	Concentration Units
Influenza H1N1 (pdm 2009)	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

Type	Strain	Concentration	Concentration Units
Influenza H3N2	A/Brisbane/10/2007	8.0E+05	$CEID_{50}$/mL
	A/Perth/16/2009	5.5E+05	$CEID_{50}$/mL
	A/Victoria/361/2011	6.0E+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
Influenza H1N1 (Swine variant)	A/Ohio/09/2015	3.5E+06	$CEID_{50}$/mL
Influenza H1N2v	A/Minnesota/19/2011	1.6E+07	$CEID_{50}$/mL
Influenza H7N3 (Avian variant)	A/northern pintail/ Illinois/10OS3959/2010	1.4E+06	$CEID_{50}$/mL
Influenza H5N1 (Avian variant)	A/mallard/ Wisconsin/2576/2009	1.6E+06	$CEID_{50}$/mL
Influenza B (Victoria Lineage)	B/Brisbane/60/2008	1.0E+05	$CEID_{50}$/mL
	B/Colorado/6/2017	4.0E+05	$CEID_{50}$/mL
	B/Malaysia/2506/2004	3.0E+03	$CEID_{50}$/mL
Influenza B (Yamagata Lineage)	B/Texas/06/2011	4.0E+06	$CEID_{50}$/mL
	B/Wisconsin/1/10	1.41E+02	$TCID_{50}$/mL
Influenza B (non-Victoria/Yamagata)	B/Lee/1940	4.5E+04	$CEID_{50}$/mL
SARS CoV-2	Isolate hCoV-19/USA/ MD-HP05285/2021 (Delta variant)	6.65E+05	GC/mL
SARS CoV-2	hCoV-19/USA/MD-HP40900/2022, (Lineage XBB.1.5; Omicron Variant)	8.0E+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 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
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

** 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)
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
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

** 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)
Chlamydophila pneumoniae	1.00 x 10^6 IFU/mL	0/5	0/5	0/5
Legionella pneumophila	1.00 x 10^6 CFU/mL	0/5	0/5	0/5
Staphylococcus epidermidis	1.00 x 10^6 CFU/mL	0/5	0/5	0/5
Epstein Barr Virus	1.00 x 10^5 cp/mL	0/5	0/5	0/5
Human herpes virus	1.43 x 10^5 $TCID_{50}$/mL	0/5	0/5	0/5
Mumps virus	1.43 x 10^5 $TCID_{50}$/mL	0/5	0/5	0/5
Escherichia coli	1.00 x 10^6 CFU/mL	0/5	0/5	0/5
Moraxella catarrhalis	1.00 x 10^6 CFU/mL	0/5	0/5	0/5
Neisseria meningitidis	1.00 x 10^6 CFU/mL	0/5	0/5	0/5
Pseudomonas aeruginosa	1.00 x 10^6 CFU/mL	0/5	0/5	0/5
Klebsiella pneumoniae	1.00 x 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. 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 x 10^5 $TCID_{50}$/mL	5/5	5/5	5/5
Human coronavirus OC43	1.43 x 10^5 $TCID_{50}$/mL	5/5	5/5	5/5
Human coronavirus NL63	1.43 x 10^5 $TCID_{50}$/mL	5/5	5/5	5/5
MERS-coronavirus	1.43 x 10^5 $TCID_{50}$/mL	5/5	5/5	5/5
Rhinovirus Type 1A	1.43 x 10^5 $TCID_{50}$/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)
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
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

** 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)
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
Neisseria meningitidis	1.00×10^6 CFU/mL	5/5	5/5	5/5
Pseudomonas aeruginosa	1.00×10^6 CFU/mL	5/5	5/5	5/5
Klebsiella pneumoniae	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.*

Endogenous Interfering Substances

A total of thirty (30) 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 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 (2) different strains of influenza A, or two (2) 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 five (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
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 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 x 10^5 $TCID_{50}$/mL
Influenza B/Colorado/6/2017 (Victoria)	1.41 x 10^5 $TCID_{50}$/mL
SARS-CoV-2 BA.5 Omicron Variant	6.15 x 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 and/or influenza B and near LoD influenza A and/or influenza B in the presence of high levels of SARS-CoV-2. No competitive interference was observed between SARS-CoV-2 and influenza A/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 x 10^5	inactivated SARS-Cov-2	6.16 x 10^4	100%
2	Flu A (H1N1)	1.13 x 10^5	Flu B (Victoria)	5.64 x 10^2	100%
3	Flu A (H1N1)	1.13 x 10^5	Flu B (Yamagata)	1.86 x 10^2	100%
4	Flu A (H3N2)	1.58 x 10^6	inactivated SARS-CoV-2	6.16 x 10^4	100%
5	Flu A (H3N2)	1.58 x 10^6	Flu B (Victoria)	5.64 x 10^2	100%
6	Flu A (H3N2)	1.58 x 10^6	Flu B (Yamagata)	1.86 x 10^2	100%
7	Flu B (Victoria)	1.13 x 10^5	inactivated SARS-CoV-2	6.16 x 10^4	100%
8	Flu B (Victoria)	1.13 x 10^5	Flu A (H1N1)	7.06 x 10^2	100%
9	Flu B (Victoria)	1.13 x 10^5	Flu A (H3N2)	3.16 x 10^4	100%
10	Flu B (Yamagata)	1.49 x 10^4	inactivated SARS-CoV-2	6.16 x 10^4	100%
11	Flu B (Yamagata)	1.49 x 10^4	Flu A (H1N1)	7.06 x 10^2	100%
12	Flu B (Yamagata)	1.49 x 10^4	Flu A (H3N2)	3.16 x 10^4	100%
13	inactivated SARS-CoV-2	3.08 x 10^6	Flu A(H1N1)	7.06 x 10^2	100%
14	inactivated SARS-CoV-2	3.08 x 10^6	Flu A (H3N2)	3.16 x 10^4	100%
15	inactivated SARS-CoV-2	3.08 x 10^6	Flu B (Victoria)	5.64 x 10^2	100%
16	inactivated SARS-CoV-2	3.08 x 10^6	Flu B (Yamagata)	1.86 x 10^2	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)	
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%
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%

Sample	High titer target		Low titer target		Low titer target Percent Positivity
	Virus Name	Concentration ($TCID_{50}$/mL)	Virus Name	Concentration ($TCID_{50}$/mL)	
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 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 two (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 Test per the test procedure. The other nasal swab sample was collected by a healthcare professional (HCP) in viral transport media, at least 15 minutes before or 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, four (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.

SUBJECTS DEMOGRAPHICS

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%)

Subject demographics

	Subjects (by lay-user collection and testing (N=61)	Self-collecting and testing (N=642)	Overall (N=703)
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 (5) 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 (3) months prior to enrollment. Participants were assigned to one (1) of three (3) 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 (2) highly sensitive EUA RT-PCRs. If results of the first two (2) molecular tests were discordant, a third highly sensitive EUA RT-PCR test was performed, and the final test result was based upon the majority rule.

Study participants reported symptom status throughout the study using the MyDataHelps app. Two-day serial antigen testing is defined as performing two (2) antigen tests 36-48 hours apart. Three-day serial antigen testing is defined as performing three (3) antigen tests over five (5) 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.

ASSISTANCE

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 Test, please contact SEKISUI Diagnostics Technical Services at (800) 332-1042 or techservices@sekisuidiagnostics.com.

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1. US Department of Health and Human Services. National Institutes of Health. Influenza [Fact Sheet]. January 2011.
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REORDER

OSOM Flu SARS-CoV-2 Combo Test Kit (Catalog Number 1080)

OSOM Flu SARS-CoV-2 Combo Control Kit (Catalog Number 1079)

SYMBOLS

LOT	Batch code
REF	Catalog number
℞ ONLY	Caution: Federal law restricts this device to sale by or on the order of a physician
	Consult instructions for use
	Contains sufficient for <n> tests
	Device for near-patient testing
	Device not for self-testing
	Do not re-use
IVD	In Vitro Diagnostic Medical Device
QTY	Quantity
	Manufacturer
CONTROL −	Negative control
CONTROL +	Positive control
	Temperature limit
	Uncontaminated recycled content-packaging, kit box, Instructions for Use is recyclable if it can be collected, separated, or otherwise recovered from the waste stream through an established recycling program.
	Use-by date

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