osom®

Flu SARS-CoV-2 Combo Home Test

QUICK REFERENCE INSTRUCTIONS

For use under Emergency Use Authorization (EUA) only

For *in vitro* diagnostic use.
For use with anterior nasal swab specimens.

Carefully read all instructions before performing the test. Failure to follow the instructions may result in inaccurate test results. Refer to the Instructions for Use (IFU) for more complete information.

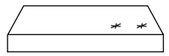
An anterior nasal swab sample can be self-collected by an individual aged 14 years or older. Children aged 2-13 years should be tested by an adult.

MATERIALS PROVIDED

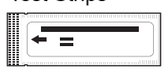
2x Tubes with buffer liquid

2x Sterile Nasal Swabs

1x Tube Holder (backside of carton)



2x Sealed Test Strips



2x Result Interpretation Cards

Required but not provided: Timer or clock

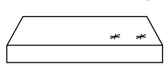
PREPARING FOR THE TEST

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.

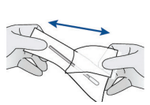


4. **Remove** the cap from one (1) tube gently to avoid spilling the liquid and place it in the tube holder.

SAMPLE COLLECTION

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

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

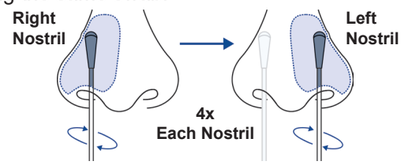


SAMPLE COLLECTION (CONTINUED)

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.**

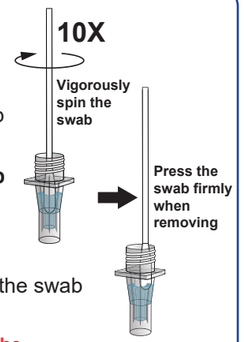
3 **SLOWLY ROTATE** the swab **at least 4 times** against the nostril wall.
REMOVE the swab and repeat in the other nostril using the same swab.



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.



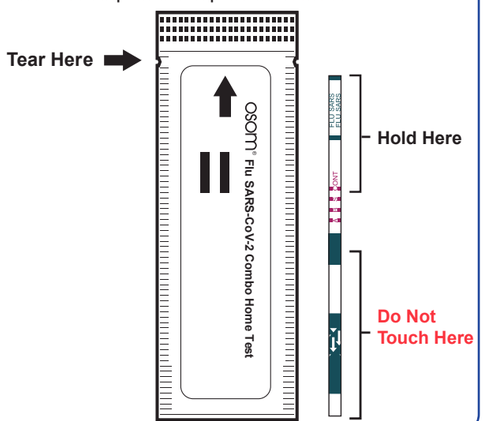
NOTE: Make sure the swab tip is in the liquid when mixing. The swab may not reach the bottom of the tube.

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

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

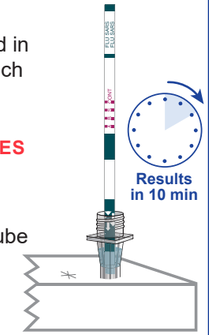
5 **PRESS** the swab against the side of the tube to remove any excess sample in the swab.
REMOVE and **DISCARD** the swab.

6 **OPEN** the test strip pouch carefully at the notch.
HOLD the test strip at the top as indicated.



RUNNING THE TEST (CONTINUED)

7 With the arrows pointing down, **INSERT** the test strip into the liquid in the tube. The test strip may not reach the bottom of the tube.



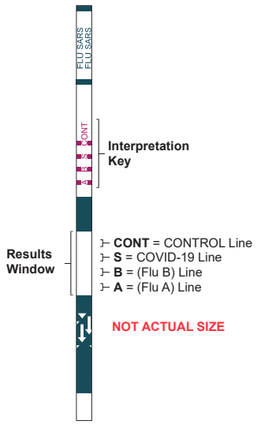
⚠ **TEST STRIP MUST BE INSERTED INTO THE TUBE WITHIN 30 MINUTES OF COMPLETING STEP 5.**

8 **SET** a timer for **10 minutes**
NOTE: Leave the test strip in the tube for the **full 10 minutes**.

⚠ **DO NOT** handle or remove.

⚠ **DO NOT** interpret results before **10 minutes** or after **30 minutes**. Inaccurate test interpretations may occur.

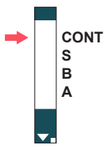
INTERPRETING THE RESULTS



- **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 result.
- 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.

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.



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.

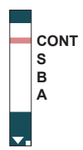
NOTE: The image displayed above is one (1) example only; additional invalid outcomes are possible. For a complete set of invalid results, go to: osomhometests.com/invalidresults.

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 from the first day of testing.

If you still have COVID-19, Flu B, Flu A, or symptoms, you should seek follow-up care with your healthcare provider.

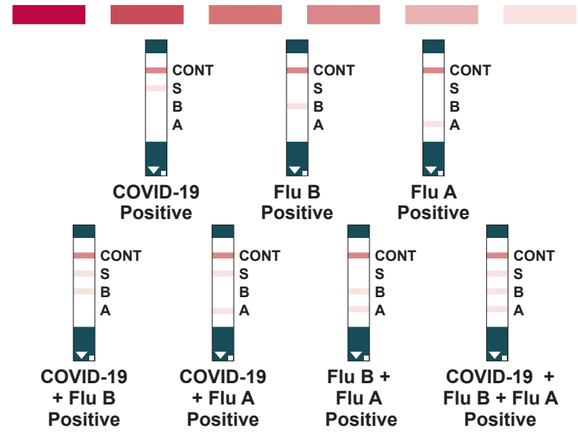


Negative

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.



Serial (repeat) testing is needed for **all samples that are negative for SARS-CoV-2 on the first day of testing**, even if they are positive for influenza A and/or B. Repeat testing is needed to improve test accuracy for SARS-CoV-2. Please follow the table below when interpreting test results. Serial (repeat) testing does not need to be performed if patients have a positive SARS-CoV-2 result on the first day of testing.

Status on First Day of Testing: With Symptoms			
Day 0 (First Test)	**Serial Testing?**	**Day 2 (Second Test)**	**Interpretation**
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

AFTER TEST IS COMPLETED, DISPOSE OF USED MATERIALS IN HOUSEHOLD TRASH.

UNDERSTANDING YOUR RESULTS

INVALID RESULT: The test could not tell whether or not you have COVID-19, influenza A (Flu A), or influenza B (Flu B). The test needs to be repeated with a new kit and sample.

NEGATIVE RESULT: 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.

POSITIVE RESULT: The COVID-19, Flu A and/or Flu B virus(es) were detected in your sample. It is very likely that you have the respective infection(s) and are contagious. Please contact your healthcare provider or your local health authorities and follow local guidelines for self-isolation. There is a small chance that this test can give you a positive result that is incorrect (a false positive).

RESULTS REPORTING

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

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 (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.

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.

HOW TO USE THIS TEST

Serial testing should be performed in all individuals with SARS-CoV-2 negative results; individuals with symptoms of COVID-19 and initial negative results should be tested again after 48 hours. You may need to purchase additional tests to perform this serial (repeat) testing.

If you test SARS-CoV-2 negative but continue to have symptoms of COVID-19, and both your first and second tests are negative, you may not have COVID-19, however you should follow-up with your healthcare provider.

If your test is SARS-CoV-2 positive, then proteins from the virus that causes COVID-19 have been found in your sample and you likely have COVID-19.

WARNINGS, PRECAUTIONS, AND SAFETY INFORMATION

- For *in vitro* diagnostic use.
- Read the instructions fully and carefully before performing the procedure.
- 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 (3) days (with 48 hours between tests) for symptomatic individuals.**
- **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.**
- If uncertain how to proceed, contact SEKISUI Diagnostics Technical Services at (800) 491-6220 or techservices@sekisuidiagnostics.com.
- This test may only be used in symptomatic individuals.
- Wear safety mask or other face covering when collecting a specimen from another person.
- The OSOM Flu SARS-CoV-2 Combo Home Test is only intended for use with direct anterior nasal specimens and is not for use with viral transport media (VTM).
- An anterior nasal swab sample can be self-collected by an individual age 14 years and older. Children age 2 to 13 years should be tested by an adult.
- Do not use on anyone under two (2) years of age.
- Test components are single use. Do not reuse the test strip, buffer liquid, or swab.
- If any liquid spills from the buffer tube, discard test components and restart test using new test components.
- Do not use if any of the test kit contents or packaging is damaged or open.
- 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.
- Do not touch swab tip when handling the swab.
- When collecting a sample, only use the swab provided in the kit.
- Inadequate or inappropriate sample collection, storage or transport may yield false test results.
- 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.
- Testing should be performed in an area with good lighting.
- **This test is read visually. Individuals with impaired vision or color-impaired vision should ensure help in interpretation of their test results.**
- Dispose of all used materials in accordance with federal, state, and local regulatory requirements.
- Do not use the test kit after its expiration date.
- Positive results do not rule out co-infections with other pathogens.
- Negative results do not rule out Flu A, Flu B, or SARS-CoV-2, particularly in those who have been in contact with the virus.
- 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: http://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.

LIMITATIONS

- This device is a qualitative test and does not provide information on the viral load present in the specimen.
- All negative results are presumptive and confirmation with a molecular assay may be necessary. If you continue to have symptoms of COVID-19 or influenza and both your first and second tests are negative, you may not have COVID-19 or influenza, however you should follow up with a healthcare provider.
- This device is only for use with human specimens.
- If the test is positive, then proteins from the virus that causes COVID-19 have been found in the sample and you likely have COVID-19.
- A negative test result may occur if the level of antigen in the sample is below the detection limit of the test or if the sample is collected, handled or transported improperly.
- 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.
- There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to the sensitivity of the test technology. This means that there is a higher chance this test will give a false negative result in an individual with COVID-19 as compared to a molecular test, especially in samples with low viral load.
- 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.

FREQUENTLY ASKED QUESTIONS

Q: WHAT ARE THE KNOWN POTENTIAL RISKS AND BENEFITS OF THIS TEST?

A: Potential risks include:
- Possible discomfort during sample collection.
- Possible incorrect test results (see "Warnings, Precautions and Safety Information" and "Interpreting The Results" sections for more information).

Potential benefits include:
- The results, along with other information, can help you and your healthcare provider make informed recommendations about your care.
- The results of this test may help limit the spread of COVID-19 and flu to the family of the tested individual and others in your community.

Q: WHAT IS THE DIFFERENCE BETWEEN AN ANTIGEN AND MOLECULAR TEST?

A: There are different kinds of tests for the viruses that cause COVID-19 and the flu. Molecular tests detect genetic material from the virus. Antigen tests, such as the OSOM Flu SARS-CoV-2 Combo Home Test, detect proteins from the virus. Due to the lower sensitivity of antigen tests, there is a higher chance this test will give you a false negative result when you have COVID-19 than a molecular test would.

Q: WHAT IF I HAVE A COVID-19 POSITIVE TEST RESULT?

A: A positive result means that it is very likely you have COVID-19 because proteins from the virus that causes COVID-19 were found in your sample. You should self-isolate from others and contact a healthcare provider for medical advice about your positive result.

Q: WHAT IF I HAVE A COVID-19 NEGATIVE TEST RESULT?

A: A negative test result indicates that antigens from the virus that causes COVID-19 were not detected in your sample. However, if you have symptoms of COVID-19, and your first test is negative, you should test again in 48 hours since antigen tests are not as sensitive as molecular tests. If you do not have symptoms and received a negative result, you should test at least two (2) more times with 48 hours in between tests for a total of three (3) tests. If you have a negative result, it does not rule out SARS-CoV-2 infection; you may still be infected and you may still infect others. It is important that you work with your healthcare provider to help you understand the next steps you should take.

Q: HOW ACCURATE IS THIS TEST?

A: Clinical studies have shown that antigen tests more accurately determine whether you are infected with the virus that causes COVID-19 when taken multiple times across several days. Repeat testing improves test accuracy. This serial-testing approach is recommended to minimize the risk of incorrect results. For more information on the performance of the test and how the performance may apply to you, please refer to the performance data in the Healthcare Provider Instructions for Use (IFU), available at osomhometests.com.

Q: WHAT DOES AN INVALID TEST RESULT MEAN?

A: An invalid result means the test was not able to tell if you have COVID-19 and influenza infection or not. If the test is invalid, a new swab should be used to collect a new nasal specimen and you should test again with a new test.

IMPORTANT: Do not use this test as the only guide to manage your illness. Consult your healthcare provider if your symptoms persist or become more severe. Individuals should provide all results obtained with this product to their healthcare provider.

SYMBOLS

Manufacturer		IVD	*In vitro* diagnostic medical device		Use by Date
Consult instructions for use		REF	Catalog number		Do not reuse
Temperature limit		LOT	Batch code	OTC	Over-the-Counter

SUPPORT

If you have questions regarding the use of this product, or if you want to report a problem with the test, please contact SEKISUI Diagnostics Technical Services at (800) 491-6220 or techservices@sekisuidiagnostics.com.

SEKISUI DIAGNOSTICS
Tel: 800-491-6220
sekisuidiagnostics.com

SEKISUI Diagnostics, LLC
6659 Top Gun Street
San Diego, CA 92121 USA

FOR SUBMISSION ONLY

3506-5-df
09/2024

ARTWORK SPECIFICATION

1 Supplier will use the information:

1.1	ARTWORK:	3505-5-df
1.2	DIMENSIONS:	4.375” x 1.250” x 6.000”
1.3	CAD:	288
1.4	COLOR(s):	Cyan Magenta Yellow Black

DEVELOPMENT LABEL

07/15/2024