# osom®

## Flu SARS-CoV-2 Combo Test

## QUICK REFERENCE GUIDE

REF 1080

IVD $\mathbb{R}_{x}$ONLY

**For use under an Emergency Use Authorization (EUA) only**

For *in vitro* diagnostic use

For use with anterior nasal swab specimens.

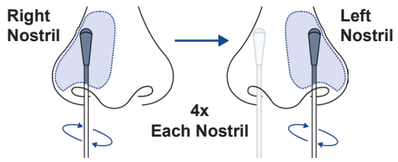
Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results. **Refer to the Instructions for Use (IFU) for more complete information.**

## SAMPLE COLLECTION

1. **GENTLY INSERT** the swab no more than ¾ of an inch into the nostril. For young children, swab should not be inserted more than 1/2 inch.

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

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

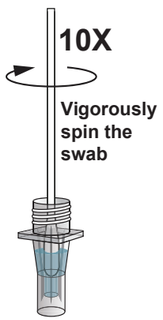



4. Sample must be mixed in the extraction buffer within 30 minutes of sample collection. Sample should be processed in the Extraction Buffer as soon as possible after collection.

## RUNNING THE TEST

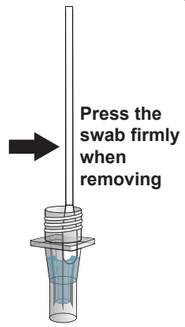
1. **TWIST** cap off Buffer vial.
**INSERT** the swab through the ridges into the liquid.
**MIX** thoroughly by spinning the swab **at least 10 times** in the liquid.

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




## RUNNING THE TEST (CONTINUED)

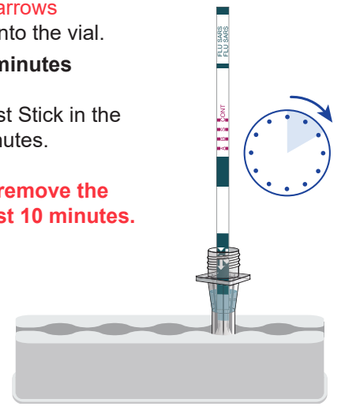
2. **PRESS** the swab against the side of the vial to remove any excess sample in the swab.
**REMOVE** and **DISCARD** the swab.



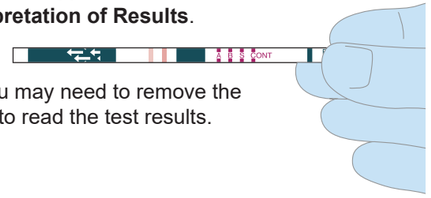

3. **INSERT** Test Stick (arrows pointing downward) into the vial.
**SET a timer for 10 minutes**

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

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

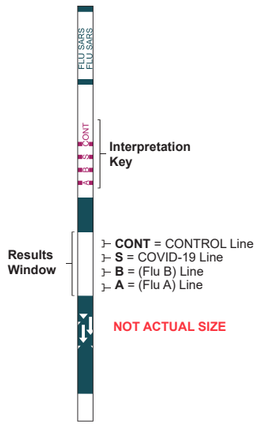


4. **READ** test at 10 minutes. Do not read test before 10 minutes or after 30 minutes.
See **Interpretation of Results**.



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

## INTERPRETATION OF RESULTS



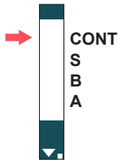

**PLACE** Test Stick, arrows pointing down, within dashed area of the **Result Interpretation Card** included in the kit. Ensure arrows on the Test Stick are pointing in the same direction as the arrows on the **Result Interpretation Card** and that the **Results Window** is aligned.

**LOOK CLOSELY WHEN INTERPRETING THE RESULTS!**

## 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.**

If the test is invalid, a new test should be performed with a new patient sample. Extraction Buffer vial, and Test Stick.

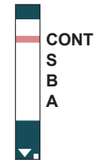



**Invalid**

## 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 COVID-19, Flu B, or Flu A virus have not been detected.

Negative results should be reported as a presumptive negative for the presence of influenza and/or SARS-CoV-2 antigen.

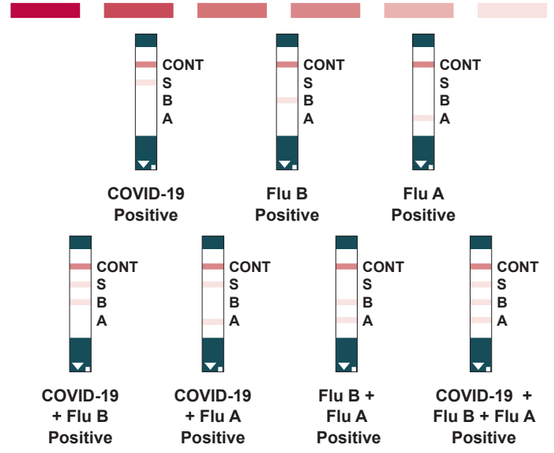



**Negative**

## 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.




It is possible to have more than one positive Test Line, which could indicate a co-infection with influenza A, B, and/or SARS-CoV-2, the virus that causes COVID-19. If more than one 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.

Laboratories within the United States and its territories are required to report all SARS-CoV-2 results to the appropriate public health authorities.

## SERIAL TESTING

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 (+)<br>Influenza A and B (-) | NO | Not needed | Positive for COVID-19<br>Presumptive negative for Influenza |
| SARS-CoV-2 (+)<br>Influenza A and/or B (+) | NO | Not needed | Positive for COVID-19<br>Positive for Influenza A and/or B |
| SARS-CoV-2 (-)<br>Influenza A and/or B (-) | YES | SARS-CoV-2 (+)<br>Influenza A and/or B (-) | Positive for COVID-19<br>Presumptive Negative for Influenza |
| SARS-CoV-2 (-)<br>Influenza A and/or B (+) | YES | SARS-CoV-2 (+)<br>Influenza A and/or B (+) | Positive for COVID-19<br>Positive for Influenza A and/or B |
| SARS-CoV-2 (-)<br>Influenza A and/or B (-) | YES | SARS-CoV-2 (-)<br>Influenza A and/or B (+) | Presumptive Negative for COVID-19<br>Positive for Influenza A and/or B |
| SARS-CoV-2 (-)<br>Influenza A and/or B (-) | YES | SARS-CoV-2 (-)<br>Influenza A and/or B (-) | Presumptive Negative for COVID-19<br>Presumptive Negative for Influenza |
| SARS-CoV-2 (-)<br>Influenza A and/or B (-) | YES | SARS-CoV-2 (+)<br>Influenza A and/or B (+) | Positive for COVID-19<br>Positive for Influenza A and/or B |
| SARS-CoV-2 (-)<br>Influenza A and/or B (+) | YES | SARS-CoV-2 (-)<br>Influenza A and/or B (+) | Presumptive Negative for COVID-19<br>Positive for Influenza A and/or B |
| SARS-CoV-2 (-)<br>Influenza A and/or B (+) | YES | SARS-CoV-2 (+)<br>Influenza A and/or B (+) | Positive for COVID-19<br>Positive for Influenza A and/or B |

## EXTERNAL QUALITY CONTROL PROCEDURE

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.

## WARNINGS AND PRECAUTIONS

1. Do not use the kit contents beyond the expiration date printed on the outside of the box.
2. Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result.
3. 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.
4. **Serial testing should be performed in individuals with 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.**
5. This test may only be used in symptomatic individuals.

## EUA - WARNINGS AND PRECAUTIONS

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, and influenza A and 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.

## INTENDED USE

**Please see the Instructions for Use for the full 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 days with at least 48 hours between tests. 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. It is intended to aid in the rapid differential diagnosis of influenza A, influenza B, and COVID-19 viral infections.

## 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) 332-1042 or techservices@sekisuidiagnostics.com.



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

SEKISUI DIAGNOSTICS

3520-1
03/2024