osom COVID-19/Flu A&B Combo Test

CLIA waived for use with anterior nasal swab samples

QUICK REFERENCE GUIDE

REF 1099 | Rx ONLY | IVD

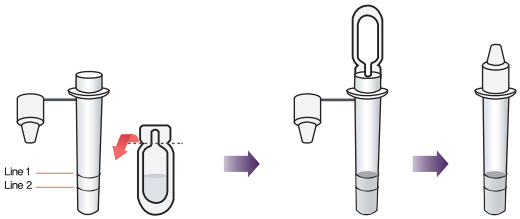
For *In Vitro* Diagnostic Use
For Prescription Use Only
For Use with Kit Provided Swabs

- CLIA waived for use with anterior nasal swabs.
- Laboratories with Certificate of Waiver must follow the manufacturer's instructions for performing the test.
- Certificate of Waiver is required to perform the test in a waived setting.
- Failure to follow the instructions or any modification to the manufacturer's instructions will result in the test being classified as high complexity.

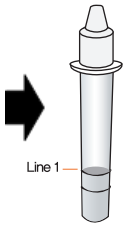
For more information, refer to the Product Instructions for Use, test procedure, warnings, precautions, limitations, and the QC section.

Sample Collection and Preparation

Fill the empty reagent tube with ampule solution



- Please look carefully, there are two lines on the empty tube.
- Flip over the TOP part of the ampule cap, then squeeze the ampule completely into the empty tube.
- Close the tube tightly with the dropper tip.

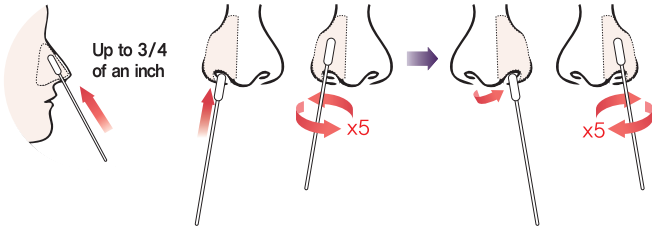


Please confirm that the liquid level is at or above Line 1, then go to Collect Sample.

NOTE:
It is acceptable if the liquid level is above the Line 1. However, please do not proceed with this test, if the liquid level is below the Line1, as this may result in false or invalid results.

NOTE: The reagent tube may be placed in a Tube Holder during sample preparation for convenience. Use of the Tube Holder is optional.

Collect sample



NOTE: Be careful not to touch the swab tip (soft end) with hand.

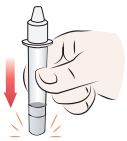
- To collect the anterior nasal swab sample, tilt the patient's head back 70 degrees and insert the soft end of the swab into the patient's nostril no more than ¾ of an inch.
- Slowly brush the swab 5 times for a total of 15 seconds, gently pressing against the inside of the patient's nostril.
- Remove the swab and repeat the same steps on the other nostril with the same swab.

NOTE:

- With children, the maximum depth of insertion into the nostril may be less than ¾ of an inch, and you may need to have a second person hold the child's head while swabbing.
- Failure to swab properly may cause false negative results.
- The freshly collected specimens should be processed as soon as possible, but no later than one hour after specimen collection when stored in a sterile container at room temperature (15-30°C) or within 24 hours when stored in a sterile container at 2-8°C.
- Do not freeze swab specimens before testing.

Test Procedure

1



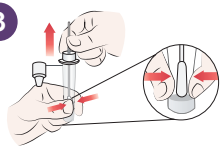
Tap the tube vertically on the table and remove the dropper tip to open the tube

2



Insert the swab into the tube until the swab head touches the bottom of the tube. Hold the swab head at the bottom of the tube tightly by squeezing the tube. Then stir the swab at least 15 times.

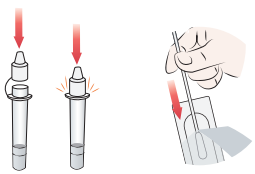
3



Squeeze the sides of the tube to express as much liquid as possible from the swab head and then remove the swab.

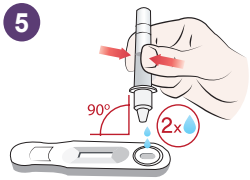
NOTE: If you don't squeeze the swab head, there may not be sufficient sample material to perform the test properly (i.e., potentially resulting in a false negative result).

4



Firmly close the dropper tip, put the swab back into the package. Safely dispose of the swab and the package.

5



NOTE: Invalid results can occur if less than 2 drops are added to the sample well.

Hold the tube vertically to dispense the sample. Add 2 drops of sample to the Sample loading well of the test device.

NOTE: Sample must be applied to the test cassette within 30 minutes of completing Step 2.

6



Wait 15 minutes after adding sample to the Sample loading well and read the results at 15 minutes visually.

NOTE: False results can occur if the test is read before 15 minutes or after 20 minutes.

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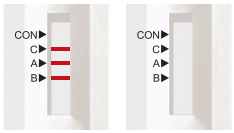
Interpretation of Results



CON = Control line
C = COVID-19 line
A = Influenza A line
B = Influenza B line

Look for lines next to CON, C, A, and B.

Invalid Result



A pinkish-red colored line should always appear at the Control line (CON) position. If a line does not form at the Control line position in 15 minutes, the test result is invalid and the test should be repeated with a new swab and a new test device. If the problem persists, please call SEKISUI Diagnostics Technical Services at +1-800-332-1042 or techservices@sekisuidiagnostics.com.

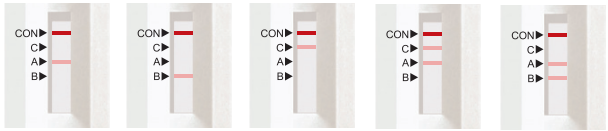
Negative Result



If the Control line (CON) is visible, but no other lines appear the test is negative.

NOTE: Negative results are presumptive and may be confirmed with a molecular assay, if necessary, for patient management.

Positive Result



Flu A Positive | Flu B Positive | COVID-19 Positive | COVID-19 & Flu A Positive | Flu A & Flu B Positive

If the Control line (CON) is visible and one or more lines appear(s) for any of the viruses, the test is positive for that or those viruses.

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 line of any intensity or thickness that appears in the Flu A (A), Flu B (B), or COVID-19 (C) 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 test line appear, this is considered a POSITIVE result.

NOTE: 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. If more than one positive test line is observed, retest with a new patient sample and new test kit. Repeatable "dual positive" results should be confirmed by an FDA-cleared molecular assay before reporting results.

External Quality Control (QC) Test Step Instructions

External positive and negative control swabs are supplied with each kit. These controls provide additional quality control material to assess that the test kit reagents perform as expected. Process the provided control swabs in the same manner as clinical sample swab and follow the steps in the "Sample Testing Procedure" section. The positive and negative external control swabs must be run once for each new kit lot; each new shipment of the test kits; each new operator; or as required by internal quality control procedures and in accordance with local, state, and federal regulations or accreditation requirements.

Intended Use

The OSOM COVID-19/Flu A&B Combo Test is a lateral flow immunochromatographic assay intended for the qualitative detection and differentiation of influenza A, and influenza B nucleoprotein antigens and SARS-CoV-2 nucleocapsid antigen directly in anterior nasal swab (ANS) samples from individuals with signs and symptoms of respiratory tract infection. Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar.

All negative results are presumptive and should be confirmed with a molecular assay, if necessary, for patient management. Negative results do not rule out infection with influenza or SARS-CoV-2 and should not be used as the sole basis for treatment or patient management decisions.

Positive results do not rule out bacterial infection or co-infection with other viruses.

Assistance

For questions or technical support, please contact SEKISUI Diagnostics Technical Services at +1-800-332-1042 or techservices@sekisuidiagnostics.com.

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SEKISUI DIAGNOSTICS

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