For use under Emergency Use Authorization (EUA) only

For individuals aged 14 years or older. Children aged 2-13 years should be supervised. Carefully read all instructions before performing the test. Failure to follow the instructions may result in inaccurate testing results. For use with anterior nasal swab specimens.

NOTE: Do not open the test contents until ready for use.

MATERIALS PROVIDED
- 2x 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 tube gently to avoid spilling the liquid and place it in the tube holder.

SAMPLE COLLECTION

1. REMOVE swab from the pouch by the stick end. DO NOT touch the swab tip (soft end).

2. GENTLY INSERT the swab no more than ½ 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.

SAMPLE COLLECTION (CONTINUED)

4. Turn over the test kit box to locate the test strip pouch carefully at the notch.

5. TEAR HERE

6. Fold back the test strip pouch carefully at the notch.

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

   • Look for lines next to 'CONT' (Control), 'S', 'B' and 'A' in the Results Window.
   • Look closely! Any faint line at a test line is a positive.
   • Make sure there is a visible line next to CONT. If the CONT line is missing, your result is INVALID. Repeat with a new test and sample.

RUNNING THE TEST

1. WITH LEFT HAND, rotate swab through the ridges of the tube into the liquid. MIX thoroughly by spinning the swab at least 10 times in the liquid.

2. Remove any excess sample in the swab. Place the swab against the side of the tube to hold the swab firmly.

3. GENTLY INSERT the swab into the nostril. You may need to insert the swab at least 10 to 15 mm into the nostril (nostril wall). For 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.

4. SLOWLY ROTATE the swab at least 4 times against the nostril wall. GENTLY INSERT the swab into the nostril.

5. WITH RIGHT HAND, hold the test strip pouch firmly (Repeat the process as many times as needed).

6. TEAR HERE

7. WITH LEFT HAND, rotate swab through the ridges of the tube into the liquid. MIX thoroughly by spinning the swab at least 10 times in the liquid.

8. Press the swab firmly when removing.

9. SLOWLY ROTATE the swab at least 4 times against the nostril wall. GENTLY INSERT the swab into the nostril.

10. SLOWLY ROTATE the swab at least 4 times against the nostril wall. GENTLY INSERT the swab into the nostril.

11. SLOWLY ROTATE the swab at least 4 times against the nostril wall. GENTLY INSERT the swab into the nostril.

12. SLOWLY ROTATE the swab at least 4 times against the nostril wall. GENTLY INSERT the swab into the nostril.

13. SLOWLY ROTATE the swab at least 4 times against the nostril wall. GENTLY INSERT the swab into the nostril.

RUNNING THE TEST (CONTINUED)

1. 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.

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

3. SET a timer for 10 minutes. NOTE: Leave the test strip in the tube for the full 10 minutes. DO NOT handle or remove.

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

INTERPRETING THE RESULTS

Place the test strip in the extraction buffer within 30 minutes of sample collection.

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.

PRESS the swab against the side of the tube to remove any excess sample in the swab.

REMOVE and DISCARD the swab.

OPEN the test strip pouch carefully at the notch.

HOLD the test strip at the top as indicated.

Tear Here

Hold Here

CONSULT the Table below to interpret test results. Repeat testing does not need to be performed if patients have a positive SARS-CoV-2 result on the first day of testing.

<table>
<thead>
<tr>
<th>Interpretation</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>CONT</td>
<td>Positivity for COVID-19</td>
</tr>
<tr>
<td>A</td>
<td>Positive for Influenza A and/or B</td>
</tr>
<tr>
<td>S</td>
<td>Positive for COVID-19</td>
</tr>
<tr>
<td>B</td>
<td>Positive for Influenza A and/or B</td>
</tr>
<tr>
<td>A and B</td>
<td>Positive for COVID-19 and Influenza A and/or B</td>
</tr>
</tbody>
</table>

A negative test result for COVID-19 does not need to be performed if patients have a positive SARS-CoV-2 result on the first day of testing.

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 pinked line, no matter how faint, should be considered an indication of a positive result.

RESULT INTERPRETATION

1. If the line at "A" is visible, and any other lines at "B" and/or "S" are missing, your result is positive for Influenza A and/or B. Please refer to the table below when interpreting test results. Serial (repeat) testing does not need to be performed.

2. If the line at "S" is visible, and any other lines at "B" and/or "A" are missing, your result is positive for COVID-19. Please refer to 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.

3. If the line at "B" is visible, and any other lines at "S" and/or "A" are missing, your result is positive for Influenza A and/or B. Please refer to 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.

4. If the line at "A" and "B" is visible, and any other line or lines at "S" are missing, your result is positive for COVID-19 and Influenza A and/or B. Please refer to 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.

AFTER TEST IS COMPLETED, DISPOSE OF USED MATERIALS IN HOUSEHOLD TRASH.
SARS-CoV-2 infection. If uncertain how to interpret, contact SEKISUI Diagnostics Technical Services at (800) 491-6220 or techservices@sekisuidiagnostics.com.

• This test may only be used with individuals with SARS-CoV-2 symptoms.

• 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 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 a period of at least 24-48 hours.

Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar. Results are for the simultaneous identification provider.

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.

Your test result 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.

FREQUENTLY ASKED QUESTIONS

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

A: Possible false results (see Warnings and Reagent Interpretation sections for more information).

Possible benefit includes:

• 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 or others in your community.

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

A: Different kinds of tests for the viruses that cause COVID-19 and the flu. Molecular tests detect viral 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 positive result.

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 result indicates that 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 receive a negative result, you should test at least two more times with 48 hours between tests for a total of three tests. If you have a negative result, it does not rule out SARS-CoV-2 infection; you may still be infected with another virus. It is important that you work with your healthcare provider to help understand the next steps you should take.

Q: DOES THE test have an IN VITRO PERFORMANCE DATA?

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 results for infectious diseases. The manufacturer is required to minimize the risk of incorrect results. For more information on the performance of the test and the performance how the test may perform 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 or influenza infection or not. If the test result is invalid, a new swab should be used to collect a new nasal specimen and you should test again with the new swab.

SEKISUI Diagnostics, LLC

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Tel: 800-491-6220

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