Prepare to Perform the Test

2. Wash your hands with soap and water, or use hand sanitizer before performing the test. Make sure your rinse thoroughly and your hands are dry before starting.
3. Check test expiration date on the back of the foil. Do not use if the expiry date has passed

NOTE: Testing should commence immediately after opening the sealed pouches.
4. Open the pouch and remove the test device from the foil pouch. Ensure the desiccant contains only white and yellow beads.
NOTE: If green beads are present use a new test device.
5. Place the test device on a flat surface.

Test Procedure

01. Open the pouch that contains the extraction buffer tube & filter cap.
Open the seal of the tube carefully without spilling the liquid inside the tube.
Punch a hole in the box to hold the tube.

If any liquid spills, do not use the tube.

02. Remove the swab from the packaging.
Ensure that you only touch the handle of the swab and NOT the soft pad on the tip.

03. Holding the stick end of the swab, gently insert the foam end of the swab into the nostril approximately 1/2 to 3/4 of an inch.

Do not insert the swab any further if you feel resistance.

**Swab Both Nostrils**

04. Firmly and slowly rotate the swab at least 5 times, brushing against the inside walls of the nostril at least 5 times for a total of 15 seconds.

**Do not just spin the swab.**

Gently remove the swab, and using the same swab, repeat in the second nostril with the same end of the swab.

NOTE: When swabbing others, please wear a face mask. With children, the maximum depth of insertion into the nostril may be less than 3/4 of an inch, and you may need to have a second person to hold the child’s head while swabbing.

WARNING! Inaccurate test results may occur if the nasal swab specimen is not properly collected.

05. Directly insert the swab taken from the nostril into the extraction buffer tube and stir in more than 10 times. Take out the swab from the extraction buffer tube by squeezing and applying pressure on both sides of the tube.

WARNING! Failure to squeeze the tube can lead to incorrect results due to excess buffer in the swab.

WARNING! The sample should be mixed into the buffer immediately, but no more than an hour after collecting the sample.

06. Dispose of the swab and seal the tube securely with the nozzle cap.

07. Hold the tube upright above the sample well. Drop 4 drops onto the sample well.

**Do not apply the liquid in the rectangular result window.**

WARNING! Adding more or less than 4 drops of solution into the sample well may result in incorrect results.

08. Set the timer and read the test result at 15 minutes. Do not read the result after 20 minutes.

Read test result at 15 minutes.

DO NOT read after 20 minutes.

WARNING! Do not move or lift the test device during this time.

After the test is completed, dispose of used materials in household trash. Do not flush or pour test liquids down a drain.

Read and Interpret the Results

WARNING! Inaccurate test interpretations may occur if results are read before 15 minutes or after 20 minutes.

Look at the result window and locate the letters C and T on the side of the window. A pink/purple line should always appear at the C position; this is a control line and signals that the test is working properly.
Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results for COVID-19

<table>
<thead>
<tr>
<th>Status on</th>
<th>First Result</th>
<th>Second Result</th>
<th>Third Result</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 0</td>
<td>Negative</td>
<td>Negative</td>
<td>Negative</td>
<td>Negative for COVID-19</td>
</tr>
<tr>
<td>Day 1</td>
<td>Negative</td>
<td>Negative</td>
<td>Negative</td>
<td>Negative for COVID-19</td>
</tr>
<tr>
<td>Day 2</td>
<td>Negative</td>
<td>Negative</td>
<td>Negative</td>
<td>Negative for COVID-19</td>
</tr>
<tr>
<td>Day 3</td>
<td>Positive</td>
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<td>Positive</td>
<td>Positive for COVID-19</td>
</tr>
<tr>
<td>Day 4</td>
<td>Positive</td>
<td>Positive</td>
<td>Positive</td>
<td>Positive for COVID-19</td>
</tr>
<tr>
<td>Day 5</td>
<td>Positive</td>
<td>Positive</td>
<td>Positive</td>
<td>Positive for COVID-19</td>
</tr>
</tbody>
</table>

Results should be considered in the context of an individual’s recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

Negative result

If the Control (C) line is visible, but the Test (T) line is not visible, the test is negative.

To increase the chance that the negative result for COVID-19 is accurate, you should:
- Test again in 48 hours if you have symptoms on the first day of testing.
- Test 2 more times at least 48 hours apart if you do not have symptoms on the first day of testing.

A negative test result indicates that the virus that causes COVID-19 was not detected in your sample. A negative result is presumptive, meaning it is not certain that you do not have COVID-19. You may still have COVID-19 and you may still be contagious. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests, such as PCR. If you test negative and continue to experience COVID-19 like symptoms (e.g., fever, cough, and/or shortness of breath) you should seek follow up care with your healthcare provider.

Positive result

If a Control (C) line and the Test (T) line are visible, the test is positive. Any faint visible pink/purple test (T) line with the control line (C) should be read as positive.

You do not need to perform repeat testing if you have a positive result at any time.

A positive test result means that the virus that causes COVID-19 was detected in your sample and it is likely you have COVID-19 and are contagious. Please contact your doctor or primary care physician or your local health authority immediately and 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).

Invalid result

If a control (C) line is not visible, the test is invalid. Re-test with a new swab and new test device.

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.
Important
The OHC COVID-19 Antigen Self Test is a lateral flow immunoassay device intended for the qualitative detection of nucleocapsid protein antigen from the SARS-CoV-2 virus.

This test is authorized for non-prescription home use with self-collected anterior nasal (nasal) swab samples from individuals aged 14 years and older or adult collected anterior nasal (nasal) swab samples from individuals aged two years or older. Individuals with symptoms of COVID-19 within the first 7 days of symptom onset when tested twice over three days with at least 48 hours between tests, and for individuals without symptoms or other epidemiological reasons to suspect COVID-19, when tested at least three times over five days with at least 48 hours between tests.

The OHC COVID-19 Antigen Self Test does not differentiate between SARS-CoV-1 and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen, which is generally detectable in anterior nasal (nasal) swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with past medical 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 test is designed to detect the presence of disease. Individuals who test positive with the OHC COVID-19 Antigen Self 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 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 COVID-19.

Individuals who test negative and continue to experience COVID-19-like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow-up care with their physician or healthcare provider.

Individuals should provide all test results obtained with this product to their healthcare provider for public health reporting and to receive appropriate healthcare. All healthcare providers will report all test results they receive from individuals who use the authorized product to relevant public health authorities in accordance with local, state, and federal requirements using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by CDC.

The OHC COVID-19 Antigen Self Test is intended for non-prescription self-use and/or as an adulterer test for anyone testing another person 2 years of age or older in a non-laboratory setting. The OHC COVID-19 Antigen Self Test is only for use under the Food and Drug Administration’s Emergency Use Authorization. This product has not been FDA cleared or approved.

Warnings, Precautions, and Safety Information

Read instructions carefully before performing a test. Failure to follow may produce inaccurate test results.

In the US, 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, not for any other viruses or pathogens. The emergency use of this product is only authorized for the duration of the declaration of emergency that circumstances exist justifying the authorization of emergency use of such test. The declaration of emergency has not been extended beyond the period of declaration.

The OHC COVID-19 Antigen Self Test is intended for non-prescription self-use and/or as an adulterer test for anyone testing another person 2 years of age or older in a non-laboratory setting. The OHC COVID-19 Antigen Self Test is only for use under the Food and Drug Administration’s Emergency Use Authorization. This product has not been FDA cleared or approved.

HOW TO USE THIS TEST

- Serial testing should be performed in all individuals with negative results, individuals with symptoms of COVID-19 and initial negative results should be tested again after 48 hours. Individuals with symptoms of COVID-19, and with initial negative results, should be tested again after 48 hours. If the 2nd test is negative, a 3rd test after an additional 48 hours. You may need to purchase additional tests to perform this serial (repeat) testing.

- If this test fails but continues to have symptoms of COVID-19, and both your first and second tests are negative, you may not have COVID-19, tested at least twice over three days with should be 48 hours between tests, and for individuals without symptoms or other epidemiological reasons to suspect COVID-19, when tested at least three times over five days with at least 48 hours between tests.

- 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 hazardous 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.

Q: WHAT ARE THE KNOWN AND POTENTIAL RISKS AND BENEFITS OF THE TEST?
A: Possible risks include:
- Possible discomfort during sample collection.
- Possible incorrect result (see Warnings and Result Interpretation section 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 potential spread of COVID-19 to your family and others in your community.

For more information on EUAs go here:

Q: WHAT IS THE DIFFERENCE BETWEEN AN ANTIGEN AND MOLECULAR TEST?
A: There are different kinds of tests for the SARS-CoV-2 virus that causes COVID-19. Molecular tests detect genetic material from the virus. Antigen tests, such as the OHC COVID-19 Antigen Self 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: 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 several days after testing. 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, how frequently you should test refer to your provider for testing data available at http://www.osanghc.com/en/infectious-disease-

Q: WHAT IF I HAVE A 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 NEGATIVE TEST RESULT?
A: A negative test result indicates that the virus from the SARS-CoV-2 virus was 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 more times with 48 hours in 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 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: 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 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.
**OHC COVID-19 Antigen Self Test**

- This test can be used at home on people aged 2 years old and up.
- Determining a negative result requires multiple tests.
- You may need to purchase additional tests to perform serial (repeat) testing.
- This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test.
- The OHC COVID-19 Antigen Self Test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in anterior nasal (nares) swabs from individuals within the first 7 days of symptom onset when tested twice over three days with at least 48 hours between tests. The test is authorized for individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested three times over five days with at least 48 hours between tests. Negative results are presumptive.

* In the USA, this product has not been FDA cleared or approved; but has been authorized by FDA under an Emergency Use Authorization. The product has been authorized only for the detection of proteins from SARS-CoV-2, 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. § 360bb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

* This test does NOT determine if you had COVID-19 in the past or if you have immunity.

**For Symbol Glossary, refer to Instructions for Use.**

**The Kit Contains:**
- 1 Test Cassette
- 1 Sterile Swab
- 1 Extraction Buffer Tube & Filter cap
- 1 Instructions for use

Needed but not provided: Timer

**For Emergency Use Authorization (EUA) only.**
For in vitro diagnostic use.
For Ages 2 and Up.

**FAST EASY RESULTS IN 15 MINUTES**

**15 mins**

**SWAB MIX TEST READ**

**X5**

**OHC COVID-19**

Ⓒ OSANG Healthcare Co., Ltd.

For the most current expiration dates of this test, please refer to:
www.fda.gov/covid-tests.
OHC COVID-19 Antigen Self Test

- This test can be used at home on people aged 2 years old and up.
- Determining a negative result may require multiple tests.
- You may need to purchase additional tests to perform serial testing.
- This test is not likely to give you a false negative result when you have COVID-19 than a lab-based molecular test.
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For Emergency Use Authorization (EUA) only.
For in vitro diagnostic use.
For Ages 2 and Up.

For the most current expiration dates of this test, please refer to:
www.fda.gov/covid-tests.

Scan this QR Code for more information.

For Symbol Glossary, refer to Instructions for Use.
For Symbol Glossary, refer to Instructions for Use.

OHC COVID-19 Antigen Self Test
4 Tests
ISC02942  Rev. 2023-05-03

For Emergency Use Authorization (EUA) only.
For in vitro diagnostic use.
For Ages 2 and Up.

Insert tube here
Inserte el tubo aquí

Authorization. This product has been authorized only for the detection of proteins from SARS-CoV-2, 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.

* This test does NOT determine if you had COVID-19 in the past or if you have immunity.

- This test can be used at home on people aged 2 years old and up.
- Determining a negative result requires multiple tests.
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- This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test.

The OHC COVID-19 Antigen Self Test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in anterior nasal (nares) swabs from individuals when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests. The test is authorized for individuals with symptoms of COVID-19 within the first 7 days of symptom onset, or individuals without symptoms or other epidemiological reasons to suspect COVID-19.

* 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 is produced outside the USA and is imported and distributed in the USA by OSANG Healthcare Co., Ltd.

The Box Contains
4 Test Cassettes
4 Sterile Swabs
4 Extraction Buffer Tubes & Filter caps
1 Instructions for use
Needed but not provided: Timer

For the most current expiration dates of this test, please refer to: www.fda.gov/covid-tests.

Scan this QR Code for more information.

70 × 100 × 130 (mm)
5.118×3.937×2.755(in)

Ⓒ OSANG Healthcare Co., Ltd.
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* In the USA, this product has not been FDA cleared or approved; but has been authorized by FDA under an Emergency Use Authorization (EUA) only.

For in vitro diagnostic use.
For Ages 2 and Up.

5 Tests

For Symbol Glossary, refer to Instructions for Use.

Scan this QR Code for more information.

For the most current expiration dates of this test, please refer to: www.fda.gov/covid-tests.

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Pasadena, CA 91101
Tel: +1-844-760-0556
Technical Support: covidhometest@osangllc.com

FAST EASY RESULTS IN 15 MINUTES
detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. The emergency use of this product is only authorized for the diagnosis of the disease 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.

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- 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:
  - Detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
  - The emergency use of this product is only authorized for the diagnosis of the disease 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.

For the most current expiration dates of this test, please refer to: www.fda.gov/covid-tests.