**User Instructions**

**For Emergency Use Authorization (EUA) Only. For In Vitro Diagnostic use.**

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, 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-b(3)(B), unless the declaration is terminated or authorization is revoked sooner.

Carefully read the instructions before performing the test. Failure to follow the instructions may result in inaccurate test results.

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.

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

Please refer to the Healthcare Provider (HCP) IFU online for specifics about materials provided in the kit: http://www.osanghc.com/en/ifu/hometest/

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.
4. Open the pouch and remove the test device from the foil pouch. Ensure the desiccant contains only white and yellow beads.
5. Place the test device on a flat surface.

Test Procedure

1. Open the pouch that contains the extraction buffer tube & filter cap.
   
2. Open the seal of the tube carefully without spilling the liquid inside the tube.
   
3. Punch a hole in the box to hold the tube.
   
4. Remove the swab from the packaging.
   
5. 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 1 hour after collecting the sample.

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

7. Hold the tube upright above the sample well.
   
8. Drop 4 drops onto the sample well.
   
9. **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.

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

9. 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.

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

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 First Day of Testing</th>
<th>First Result</th>
<th>Second Result</th>
<th>Third Result</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>With Symptoms</td>
<td>Positive</td>
<td>N/A</td>
<td>N/A</td>
<td>Positive for COVID-19</td>
</tr>
<tr>
<td>Without Symptoms</td>
<td>Positive</td>
<td>N/A</td>
<td>N/A</td>
<td>Positive for COVID-19</td>
</tr>
</tbody>
</table>

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

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 4 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 (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/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
Do not use this test as the only guide to manage your health. Consult your healthcare provider if your symptoms persist or become more severe.

Individuals should provide all test results obtained with this product to their healthcare provider.

Storage and Stability
Store the OHC COVID-19 Antigen Self Test at 2-30°C / 36-86°F and protect from direct sunlight. Ensure all kit contents are at room temperature before use. Kit contents are stable until the expiration date printed on the outer packaging. Do not use beyond the expiration date. Do not freeze the kit.

Symbols
Please refer to Healthcare Provider (HP) file online for specifics regarding the Symbols glossary.

If you have any questions about using the test or reading the results, please call our customer care hotline.
Telephone: 844-760-0555
Email: covidhometest@osangllc.com

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 and, 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 your test is positive but you have symptoms of COVID-19, and both your first and second tests are negative, you may not have COVID-19, however you should stay isolated from others.
- If your test is 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 (FAQ)

Q: WHAT IS THE KNOWLEDGE AND POTENTIAL RISKS AND BENEFITS OF THE TEST?
A: Potential 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 EULAs go here: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

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 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 http://www.osanghc.com/en/efs_homestest/

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 which COVID-19 was not detected in your sample. However, you may 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 between tests for a total of 3 additional 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: A 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.

Unintended Use
The OHC COVID-19 Antigen Self Test is a lateral flow immunodiagnostic assay 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 2 years 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 2 years of age or older in a non-laboratory setting. 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 nucleocapsid antigen, which is generally detectable in anterior nasal (nasal) swab specimens during the acute phase of infection. 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 for at least 3 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.

Read instructions carefully before performing a test. Failure to follow may produce inaccurate test results.
- 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, 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)(3) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-2(b)(3), unless the declaration is terminated or authorization is revoked.

- Serial testing should be performed in individuals with negative results at least twice over three days with at least 48 hours between tests) for symptomatic individuals and three times over five days (with at least 48 hours between tests) for asymptomatic individuals. You may need to purchase additional tests (if not validated for use by those with impaired vision or color-impaired vision. Inconclusive test results may occur if a specimen is incorrectly collected or handled.

Antigen test negative results are presumptive and confirmation with a molecular assay may be necessary. If you 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 to help you understand the next steps you should take.

Optical Nemesis
- Test components are single-use. Do not re-use.
- Do not read test results before 15 minutes or after 20 minutes. Results may show up within minutes of starting the test. It may take up to 15 minutes for the test line to show up.
- Do not touch the touch tip.
- Once opened, the test card should be used within 60 minutes.
- Do not use test results before 15 minutes or after 20 minutes. Results read before 15 minutes or after 20 minutes may lead to a false positive, false negative or invalid result.

- 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.poisongroup.org/ or 1-800-222-1222.

- For more information on EULAs please visit: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization
- For most up to date information on COVID-19, please visit: www.cdc.gov/covid19
- Use of personal protection materials such as gloves is recommended.
- Do not use nasal swabs for at least 30 minutes before collecting a nasal sample.
- Remove any piercings from nose before starting the test.
- Do not use on anyone who is prone to nosebleeds or has had facial injuries or head injuries/surgery in the past six months.
- Make sure there is sufficient light for testing. For best results, read test results with good lighting.
- The test should be performed at ambient temperature (i.e., 15-30°C).
- Use only components of this test kit.
- In the event of spillage, ensure that it is cleaned thoroughly using suitable disinfectant.
- The control line may show up within a few minutes of starting the test. The control line will be a single purple line and will be similar in appearance to the test line. If the control line is not present, the test is considered invalid.

Limitations
- 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 may indicate 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 January-February 2020 from individuals with laboratory-confirmed COVID-19, 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. Perturbations in the time of testing, the specific variants circulating, including newly emerging strains of SARS-CoV-2 and their variant(s) may affect test performance.
- All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary. If you 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 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.
- This test is usually and not validated for use by those with impaired vision or color-impaired vision. Inconclusive test results may occur if a specimen is incorrectly collected or handled.

- 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.

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- - 2 -
**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.

**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.

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* 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.
- 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 not 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 nucleoprotein antigens 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.

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For Symbol Glossary, refer to Instructions for Use.
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For Emergency Use Authorization (EUA) only.

For in vitro diagnostic use.

For Ages 2 and Up.

Insert tube here

Inserte el tubo aquí

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The Box Contains

- 4 Test Cassettes
- 4 Sterile Swabs
- 4 Extraction Buffer Tubes & Filter caps
- 1 Instructions for use

Needed but not provided: Timer

Scan this QR Code for more information.

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

70 × 100 × 130 (mm)

5.118×3.937×2.755(in)

Ⓒ OSANG Healthcare Co., Ltd.

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FAST EASY RESULTS IN 15 MINUTES

15 mins
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