OHC OSANG HEALTHCARE

OHC
COVID-19 Antigen Self Test

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 § 360bbb-3(b)(1), 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

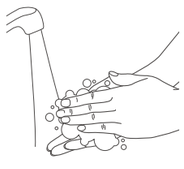
Please refer to the Healthcare Provider (HCP) IFU online for specifics about materials provided in the kit: http://www.osanghc.com/en/ifu/hometest/

Prepare to Perform the Test

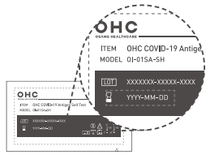
1. Bring test kit to room temperature (15-30°C / 59-86°F).

****Before washing your hands, please prepare by blowing your nose.****

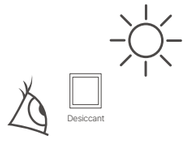
2. Wash your hands with soap and water, or use hand sanitizer before performing the test. Make sure your rinse thoroughly and your hands are dry before starting.



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.



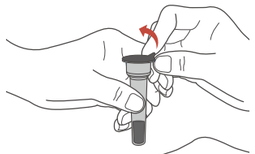
5. Place the test device on a flat surface.

Test Procedure

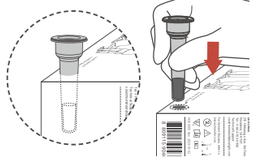
01.

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.

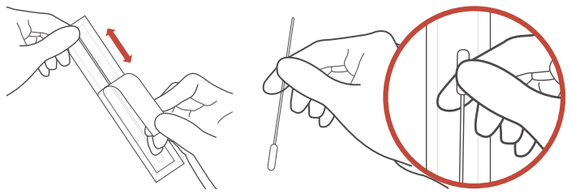


If any liquid spills, do not use the tube.

02.

Remove the swab from the packaging.

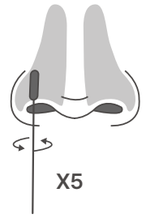
Ensure that you only touch the handle of the swab and NOT the soft pad on the tip.



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.

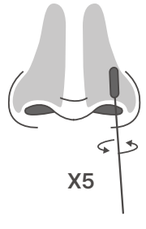
Do not insert the swab any further if you feel resistance.
****Swab Both Nostrils****



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.

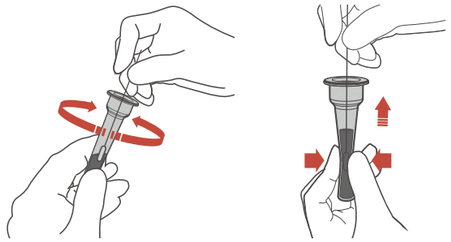
WARNING! Inaccurate test results may occur if the nasal swab specimen is not properly collected.

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.

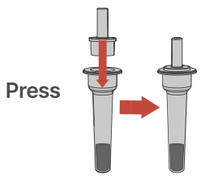
WARNING! Failure to squeeze the tube can lead to incorrect results due to excess buffer in the swab.

WARNING! The sample should be mixed into the buffer immediately, but no more than an 1 hour after collecting the sample.



06.

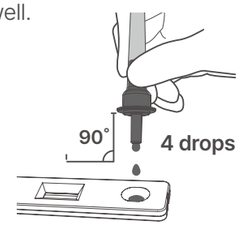
Dispose of the swab and seal the tube securely with the nozzle cap.



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.

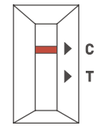
Look at the result window and locate the letters C and T on the side of the window. A pink/purple line should always appear at the C position; this is a control line and signals that the test is working properly.

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results for COVID-19

Status on First Day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	Positive	Positive for COVID-19
	Negative	Negative	Negative	Negative for COVID-19

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

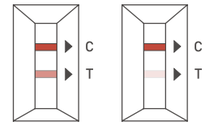


If the Control (C) line is visible, but the Test (T) line is not visible, the test is negative.

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

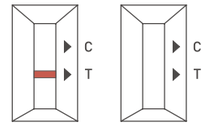


If a Control (C) line and the Test (T) line are visible, the test is positive. Any faint visible pink/purple test (T) line with the control line (C) should be read as positive.

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/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.

Intended Use

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 (nares) swab samples from individuals aged 14 years or older or adult collected anterior nasal (nares) swab samples from individuals aged two years or older. This test is authorized for individuals with symptoms of COVID-19 within the first 7 days of symptom onset when tested at least 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 and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen, which is generally detectable in anterior nasal (nares) 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 agent detected may not be the definite cause 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 results obtained with this product to their healthcare provider for public health reporting and to receive appropriate medical care. 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 applicable an adult lay user 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 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. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
- **Serial testing should be performed in individuals with negative results at least twice over three days (with 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 to perform this serial (repeat) testing. If you have had symptoms longer than 7 days you should consider testing at least three times over five days with at least 48 hours between tests.**
- An anterior nasal swab sample can be self-collected by an individual age 14 years and older. Children age 2 to 13 years should be tested by an adult.
- Do not use on anyone under 2 years of age.
- Wear a safety mask or other face-covering when collecting a specimen from a child or another individual.
- Do not use if any of the test kit contents or packaging is damaged.
- Test components are single-use. Do not re-use.
- Do not use kit past its expiration date.
- Do not touch the swab tip.
- Once opened, the test card should be used within 60 minutes.
- **Do not read 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.poisonhelp.org or 1-800-222-1222.**

Chemical Name	GHS Code for each ingredient	Concentrations
Sodium azide	H320, eye irritation H315, skin irritation	0.05%
Triton-X-100	H320, eye irritation H315, skin irritation	1.0%
BIS (trimethylsilyl acetamide)	H320, eye irritation H315, skin irritation	1.0%
Tris (hydroxymethyl) aminomethane	H320, eye irritation H315, skin irritation	1.2%

- For more information on EUAs please visit: https://www.fda.gov/emergency-preparedness-and-response/mcmlegal-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 sprays 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 in a well-lit area.
- 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. It may take up to 15 minutes for the test line to show up.

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 will give 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 2022. The clinical performance has not been established 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. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
- 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 a 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 read visually and has not been validated for use by those with impaired vision or color-impaired vision.
- Incorrect test results may occur if a specimen is incorrectly collected or handled.

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 without symptoms of COVID-19, and with initial negative results, should be tested again after 48 hours and, if the 2nd test is also negative, a 3rd test after an additional 48 hours. You may need to purchase additional tests to perform this serial (repeat) testing.
- If you test 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.
- 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 ARE THE KNOWN AND POTENTIAL RISKS AND BENEFITS OF THE TEST?

A: Potential risks include:
- Possible discomfort during sample collection.
- Possible incorrect test result (see Warnings and Result Interpretation sections 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: https://www.fda.gov/emergency-preparedness-and-response/mcm-legalregulatory-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/ifu/hometest/

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 antigens from 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 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.

Important

Do not use this test as the only guide to manage your illness. 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 (HCP) IFU 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: 844-760-0556
Email: covidhometest@osangllc.com

Manufactured for OSANG LLC.
215 N Marengo Ave. 3rd Fl.
Pasadena CA 91101

OSANG Healthcare Co., Ltd.

132, Anyangcheondong-ro, Dongan-gu, Anyang-si, Gyeonggi-do, Korea (14040) www.osanghc.com

ISC02945 Rev.2023-05-03

85 × 30 × 130 (mm)
3.346×1.181×5.118(in)

85 × 40 × 130 (mm)
3.346×1.574×5.118(in)

OHC COVID-19
Antigen Self Test

2 Tests

OHC COVID-19 Antigen Self Test

2 Tests

- 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 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. 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.

FAST EASY RESULTS IN 15 MINUTES

OHC COVID-19 Antigen Self Test

Scan this QR Code for more information.

LOT REF

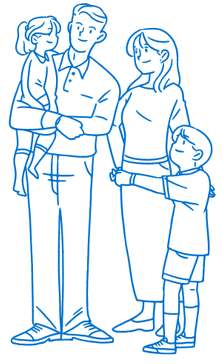
For the most current expiration dates of this test, please refer to: www.fda.gov/covid-tests.

OHC OSANG HEALTHCARE

OHC COVID-19 Antigen Self Test

2 Tests

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



Insert tube here
Inserte el tubo aquí

OHC COVID-19 Antigen Self Test

© OSANG Healthcare Co., Ltd.

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

OSANG Healthcare Co., Ltd.
132, Anyangcheondong-ro,
Dongan-gu, Anyang-si, Gyeonggi-do,
14040, South Korea
Tel: +82-31-460-0369
Website: www.osanghc.com

USA Office
215 N Marengo Ave. 3rd Floor.
Pasadena, CA 91101
Tel: +1-844-760-0556
Technical Support:
covidhometest@osangllc.com

For Symbol Glossary, refer to Instructions for Use.

ISC02941 Rev. 2023-05-03

8 809115 904621

70 × 100 × 130 (mm)

5.118×3.937×2.755(in)

70 × 120 × 130 (mm)
5.118×4.724×2.755(in)

OHC OSANG HEALTHCARE

Insert tube here
Inserte el tubo aquí

OHC COVID-19 Antigen Self Test

5 Tests

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

- 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 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 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.

FAST EASY RESULTS IN 15 MINUTES

OHC COVID-19 Antigen Self Test

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

Scan this QR Code for more information.

REF

LOT

ISC02943 Rev. 2023-05-03

8 809115 904607

OHC COVID-19 Antigen Self Test

5 Tests

OHC OSANG HEALTHCARE

For Symbol Glossary, refer to Instructions for Use.

The Box Contains

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

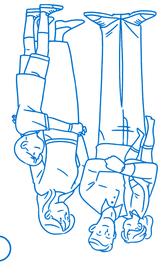
OHC

OSANG Healthcare Co., Ltd.
132, Anyangcheondong-ro,
Dongan-gu, Anyang-si,
Gyeonggi-do, 14040, South Korea
Tel: +82-31-460-0369
Website: www.osanghc.com

USA Office
215 N Marengo Ave. 3rd Floor.
Pasadena, CA 91101
Tel: +1-844-760-0556
Technical Support:
covidhometest@osangllc.com

135 × 130 × 260 (mm)
10.236×5.118×5.314(in)

OHC OSANG HEALTHCARE



Insert Tube Here
Inserte el tubo aquí

OHC COVID-19 Antigen Self Test

25 Tests

- 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 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 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.

SWAB MIX TEST READ

FAST EASY RESULTS IN 15 MINUTES

OHC COVID-19 Antigen Self Test

25 Tests

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

Scan this QR Code for more information.

REF

LOT

ISO22944 Rev. 2023-05-03

8 809115 904591

OHC COVID-19 Antigen Self Test

25 Tests

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

OHC OSANG HEALTHCARE

OHC

The Kit Contains

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

OSANG Healthcare Co., Ltd.
132, Anyangcheondong-ro, Dongan-gu,
Anyang-si, Gyeonggi-do, 14040,
South Korea
Tel: +82-31-460-0369
Website: www.osanghc.com

USA Office
215 N Marengo Ave. 3rd Floor.
Pasadena, CA 91101
Tel: +1-844-760-0556
Technical Support:
covidhometest@osangllc.com

For Symbol Glossary, refer to Instructions for Use.