**OHC COVID-19 Antigen Self Test**

**User Instructions**

**For Emergency Use Authorization (EUA) Only.**

*In vitro diagnostic use only.*


*For the use of EUA only.*

*COVID-19 Antigen Self Test*

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*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)(5) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 360bb-5(b)(5). The declaration is terminated or 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 to 13 years should be tested by an adult. Please refer to the Healthcare Provider (HCP) IFU online for specifics about materials provided in the kit: [http://www.osanghc.com/en/ifu/homeTest/](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.

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.

**05.**

Posteriorly 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.

**06.**

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

07.

Hold the tube uprights 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.

**Negative Result**

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

A negative test result indicates that antigens from the virus that causes COVID-19 were not detected from the specimen. A negative result does not rule out COVID-19. There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests. This means that there is a higher chance this test will give you a negative result when you have COVID-19. If you test negative and continue to experience COVID-19 like symptoms of fever, cough, and/or shortness of breath you should seek follow up care with your health care provider. You should test again in 24 hours (but no more than 48 hours), regardless of whether or not you have symptoms.

**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.

A positive test result means that the virus that causes COVID-19 was detected in your sample and it is very 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).

Your healthcare provider will work with you to determine how best to care for you based on your test results along with medical history and your symptoms.

**Invalid Result**

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

**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.

**Read and Interpret the Results**

- 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).
- **Your healthcare provider will work with you to determine how best to care for you based on your test results along with medical history and your symptoms.**

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Intended Use

The OHC COVID-19 Antigen Self Test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigens from SARS-CoV-2. The test is authorized for non-prescription home use with self-collected anterior nasal (nasal) swabs from individuals aged 2 years and older 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.

This test is also intended for non-prescription home use with adult-collected anterior nasal (nasal) swabs from individuals aged 2 years and older when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests. It 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.

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. Antigen is generally detectable in anterior nasal (nares) swabs during the acute phase of infection. Positive results indicate the presence of clinical signs and symptoms consistent with COVID-19. The test is generally intended for use in individuals with symptoms of COVID-19 or with suspected exposure to SARS-CoV-2. The test is not intended for use in individuals without symptoms or other epidemiological reasons to suspect COVID-19.

Warnings and Precautions

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

- All test materials must be at room temperature before use.
- Wash a safety mask or other face covering when collecting a specimen from a child or another individual.
- Use a new, unused swab for each person. Do not use a swab to collect a specimen from a child and another individual.
- Handle the combination of specimen matrix and stabilizer may not be able to adequately interpret test results.
- Disperse of kit contents and patient sample in household trash.
- This is a qualitative test, therefore quantitative values of SARS-CoV-2 antigen concentration cannot be determined.

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For in vitro diagnostic use

For Emergency Use Authorization (EUA) only.

This test can be used at home on people aged 2 years old and up.

Items necessary to use the kit, but not provided:
- Timer
- You will need at least two tests per person.
- You may need to purchase additional tests to perform serial (repeat) testing.
- This test is more likely to give you a false negative result than a lab-based molecular test.
- This 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.

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For Symbol Glossary, refer to Instructions for Use.
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The Box Contains
- 4 Test Cassettes
- 4 Sterile Swabs
- 4 Extraction Buffer Tubes & Filter caps
- 1 Instructions for use

For Symbol Glossary, Refer to Instructions for Use

OHC COVID-19
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ISC02942  Rev. 2022-06

Scan this QR Code
for more information.
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