COVID-19 Antigen Self Test

User Instructions

For Emergency Use Authorization (EUA) Only.

In vitro diagnostic use only.

- For more information on EUAs visit: https://www.fda.gov/emergency-preparedness-and-response/emergency-use-authorization
- For the most up to date information on COVID-19, please visit: https://www.cdc.gov/covid19

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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 regarding use of this product.

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 the tube if the expiry date has passed.
4. Open the pouch and remove the test device from the sealed pouches.
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 spills 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 sterile 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.

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

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.

07. 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 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.

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

WARNING! DO NOT read after 20 minutes

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

Analysis

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.

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! In 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.
Intended Use

The OHC COVID-19 Antigen Self Test is a lateral flow immunoassay intended for the qualitative detection of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in anterior nasal (nasal) swabs during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or coinfection 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 advice from their healthcare provider.

Storage and Stability

Store the OHC COVID-19 Antigen Self Test at 4°C to 30°C / 30.2 to 86.8°F and protect from direct sunlight. Ensure all kit contents are at room temperature before use. All kit components should be used before the expiration date printed on the outer packaging. Do not use after the expiration date. Do not freeze the kit.

Important

This test is intended to be used as an aid in the clinical diagnosis of a current COVID-19 infection. Do not use this test as the only guide to management for COVID. Results from this test should not be used alone to determine how best to care for you based on your test result, medical history, and symptoms. Please consult a healthcare provider to discuss your results.

Individuals should provide all results obtained with this product to their healthcare provider for public health reporting. 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 local, state, and federal, and national guidelines.
For in vitro diagnostic use
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This test can be used at home on people aged 2 years 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 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.
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For Symbol Glossary, refer to Instructions for Use.
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OHC COVID-19 Antigen Self Test
25 Tests
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