COVID-19 Antigen Home Test

Quick Reference Instructions

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

Test Procedure

1. Open the test packaging. Remove the swab from the stem. Be careful not to touch the soft, fabric tip of the swab.
2. Insert the swab about ½ to ¾ inch into the nostril. (Collect the anterior nasal swab specimen.)
3. Circle the swab against the nasal wall 5 times. Do not just spin the swab.
4. Pull the swab out of the nose while rubbing it against the walls and repeat the process with the same swab in the other nostril.

WARNING: Inaccurate test results may occur if the nasal swab specimen is not properly collected. Collect specimen and immediately perform test according to instructions.

Note: With children, the maximum depth of insertion into the nostril may be less than ¼ of an inch, and you may need to have a second person to hold the child’s head while swabbing.

5. Place swab into the tube that you previously placed in the tube holder.
6. Remove the tube from the tube holder. Rotate the swab while squeezing the lower part of the tube 10-15 times so that a slight pressure is exerted on the tip of the swab.

WARNING: Failure to rotate the swab 10-15 times may lead to incorrect results.

7. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.
8. Secure the dropper cap onto the buffer tube.

WARNING: Do not add test sample to the test device.

9. Invert the tube and add 3 drops of the solution to the sample well by gently squeezing the tube.
10. Do not add test sample to the rectangular results window. Do not touch the sample well with dropper tip.

WARNING: Do not hold the dropper tube more than 1” above sample well.

WARNING: Adding other than the recommended number of drops may result in inaccurate results.

11. Set a timer and read the results at 15 minutes.

WARNING: Do not read the result before 15 minutes or after 30 minutes.

After test is completed, dispose of used materials in trash.

Read and Interpret Your Results

- Negative result
  If the Control (C) line is visible, but the Test (T) line is not visible, the test is negative. Any faint visible 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 very likely you have COVID-19 and are contagious. Please contact your doctor/pimary 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).

- Positive result
  If the Control (C) line and the Test (T) line are visible, the test is positive. An faint visible 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 very likely you have COVID-19 and are contagious. Please contact your doctor/pimary 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 the Control (C) line is not visible, the test is invalid. Re-test with a new swab and new test device.

WARNING: 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.

- 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.

WARNING: Do not read the result before 15 minutes or after 30 minutes. Inaccurate test interpretations may occur.

Look at the result window and locate the letters C and T on the side of the window: A red 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:

- 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 health care provider.

- All test materials must be at room temperature before use
- Exposure to humidity may decrease the stability of the test.
- Store the kit at 2-8°C / 36-68°F until use and protect from direct sunlight. The expiration date of the materials is indicated on the external packaging. Do not freeze the kit.

Storage and Stability

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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 time 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.
The Fastep COVID-19 Antigen Home Test is intended for non-prescription home use with self-collected anterior nasal (nasal) swab samples from individuals aged 14 years or older and collected anterior nasal (nasal) swab samples from individuals aged 2 years or older. This test is authorized for individuals with symptoms of COVID-19 within the first 5-10 days of symptom onset. It is intended to be used twice daily 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 Fastep COVID-19 Antigen Home Test does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleoprotein antigen, which is generally detectable in anterior nasal (nasal) swab specimens during the acute stage 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 the infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definitive cause of disease. Individuals who test positive with the Fastep COVID-19 Antigen Home Test should self-isolate and seek follow-up care with their healthcare provider 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 should still seek medical attention. Unused test kits should be disposed of according to facility guidelines. Individuals who are tested and found to be negative are encouraged to follow safety and health measures, including vaccination and public health recommendations.

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 EUA.
- 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-2(b)(2)), unless the declaration is terminated or authorization is revoked sooner.
- 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.
- For information about current expiration dates for at-home OTC COVID-19 diagnostic tests, visit "At-Home OTC COVID-19 Diagnostic Tests"
Antigen Home Test
COVID-19

Quick results in 15 minutes
Easy to use

For use under the FDA Emergency Use Authorization (EUA) only.

Insert tube here

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For symbol glossary, refer to Instructions for Use

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Items necessary to use the test but not provided in the test kit:

* Timer

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