Frequently Asked Questions

Flowflex COVID-19 Antigen Home Test

1. What is the Flowflex COVID-19 Antigen Home Test?

The Flowflex COVID-19 Antigen Home Test is a rapid test for the detection of SARS-CoV-2 antigens in anterior nasal specimens. It is intended for self-testing use. For use under an Emergency Use Authorization (EUA) only.

2. How does this test work?

This test uses a nasal swab sample to determine the presence or absence of COVID-19 antigens in nasal samples. For a demonstration on how this test works, watch the instructional video.

3. Where can I buy this product?

Click here to view our growing list of retailers.

4. What is serial testing? Do I have to serial test with the Flowflex COVID-19 Antigen Home Test?

Serial testing is a process in which a user must test themselves twice within a two-to-three-day period. The Flowflex COVID-19 Antigen Home Test has been authorized for use as a single test by individuals with or without symptoms.

5. What is the age range for this test?

This test is authorized for nonprescription home use with self-collected (unobserved) direct anterior nasal (NS) swab specimens from individuals aged 14 years and older or with adult-collected anterior NS samples from individuals aged 2 years or older.

6. Will this test work if I do not have COVID-19 symptoms?

This test is intended for individuals with or without symptoms or other epidemiological reasons to suspect COVID-19.

7. How many tests come with the test package?

This test is available in 1-test, 2-test, 5-test and 25-test packages.

8. Can I swab my throat/ear instead of my nose?

Please do not swab your throat / ear. Please only swab your nose to collect sample and follow instructions on the package insert.

9. I lost my swab, can I use a Q-tip instead of the swab?

Please only use the swab that is provided with the test. Contact customer service at (800) 838-9502 for assistance.

10. How deep should I insert the swab into my nose?

Insert the swab ½ to ¾ inches inside your nostril. With children, the maximum depth of insertion into the nostril may be less than ¾ of an inch, and you may need to have a second person hold the child's head while swabbing.
Note: A false-negative result may occur if the nasal swab specimen is not properly collected.

11. Should I swab my left or right nostril?

Please use the swab to collect specimen from both of your nostrils to ensure sufficient sample collection to generate an accurate result.

12. For how long do I have to swab my nostril?

Firmly rub the swab in a circular motion around the inside wall of the nostril 5 times. Take approximately 15 seconds to collect the specimen. Be sure to collect any nasal drainage that may be present onto the swab. Repeat this in the other nostril.

13. The test cassette, extraction buffer tube, nasal swab, or tube holder is missing from the test package. What should I do?

Please contact customer service at (800) 838-9502.

14. I spilled some of the extraction buffer. What should I do now?

Do not use the test and contact customer service at (800) 838-9502.

15. After nasal specimen collection, how long do I need to swirl the nasal swab in the buffer tube?

Place the swab into the buffer tube and swirl for 30 seconds. Rotate the swab 5 times while squeezing the tube. Remove the swab while squeezing the tube to extract as much liquid as possible. Attach the dropper tip firmly onto the tube. Mix thoroughly by swirling or flicking the bottom of the tube. Then gently squeeze the tube and dispense 4 drops of solution into the Sample Well.

16. How many drops should I put in the cassette well? Can I put in all the buffer solution?

You should dispense 4 drops of solution into the cassette sample well. Please do not overuse the buffer solution.

17. Where should I dispense the solution on the cassette?

You should dispense 4 drops of solution into the cassette Sample Well marked with an “S”.

18. How long does it take to obtain results?

Results are available in 15 minutes.

19. Will this test cause any pain?

No, the nasal swab is not sharp, and it should not hurt. Sometimes the swab can feel slightly uncomfortable. If you feel pain, please stop the test and seek advice from your healthcare provider.

20. Are there any limitations as to who can use this test?

Do not use this test on children under two years of age. Do not use this test on anyone who is prone to nosebleeds or has had facial injuries or head injuries/surgery in the past six months.

21. What are the known and potential risks and benefits of this test?

Potential risks include:
- Possible discomfort during sample collection.
- Possible incorrect test results (see Result Interpretation section).

Potential benefits include:
- The results, along with other information, can help you and your healthcare provider make informed decisions about your care.
- The results of this test may help limit the spread of COVID-19 to your family and others in your community.

22. Is the test result still valid if I see a pinkish color on the test strip after applying the sample to the test cassette sample well?

A pinkish background color on the test strip will not affect the result of your test.

23. What is the difference between Antigen, Molecular, and Antibody tests?

There are different kinds of tests for COVID-19. Molecular tests (also known as PCR tests) detect genetic material from the virus. Antigen tests, such as the Flowflex COVID-19 Antigen Home Test detect proteins from the virus. Antigen tests are very specific for the COVID-19 virus but are not as sensitive as molecular tests. This means that a positive result is highly accurate, but a negative result does not rule out infection. If your test result is negative, you should discuss with your healthcare provider whether an additional molecular test is necessary and if you should continue isolating at home.

Another type of test is an antibody test. A COVID-19 antibody test detects antibodies that have been produced by your immune system in response to a previous COVID-19 infection or vaccination. Antibody tests are not suitable for diagnosing an active COVID-19 infection.

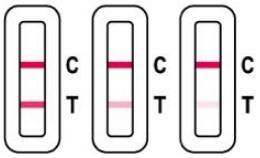
For more information on the different kinds of COVID-19 tests, please visit: https://www.fda.gov/consumers/consumer-updates/coronavirus-disease-2019-testing-basics

24. What do the two red lines on the cassette mean after I complete the test?

If both the control line (C) and test line (T) appear, even if the line on the test line (T) is very faint, this means that you have a positive test result, because antigens from COVID-19 were detected, and it is very likely you currently have COVID-19. Please refer to the package insert for more information.

25. What does it mean if I have a positive test result?

A positive test result means that antigens from COVID-19 were detected and it is very likely you currently have COVID-19. There is a very small chance that this test can give a positive result that is wrong (a false-positive result).



If you test positive you should self-isolate at home per CDC recommendations to stop spreading the virus to others. Please consult the CDC recommendations regarding self-isolation at www.cdc.gov/coronavirus. Seek follow-up care with your healthcare provider immediately. Your healthcare provider will work with you to determine how best to care for you based on your test result(s), medical history and symptoms.

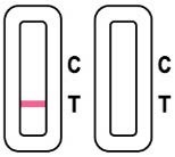
26. What does it mean if I have a negative test result?

A negative test result indicates no antigens for COVID-19 were detected. It is possible for this test to give a negative result that is incorrect (a false-negative result) in some people with COVID-19. Negative results are presumptive and may need to be confirmed with a molecular test. This means that you could possibly still have COVID-19 even though the test is negative.

If you test negative and continue to experience symptoms of fever, cough and/or shortness of breath you should seek follow-up care with your healthcare provider immediately. Your healthcare provider may suggest you need another test to determine if you have contracted the virus causing COVID-19. If you are concerned about your COVID-19 infection status after testing or think you may need follow-up testing, please contact your healthcare provider.

27. What if I have an invalid result?

An invalid test result indicates that not enough specimen volume was collected or incorrect test operation are the likely reasons for an invalid result. Please review the instructions again and repeat the test with a new cassette. If the problem persists, call (800) 838-9502 for assistance.



28. What is a false-positive and a false-negative test result?

A false positive is a test result that indicates a person has a specific disease or condition when the person actually does not have the disease or condition. A false-negative test result indicates a person does not have a specific disease or condition when the person actually does have the disease or condition. Incorrect specimen collection and sample preparation can result in false-negative and false-positive test results. Therefore, before you begin the test, it is very important to read the package insert provided in the test package and follow the instructions.

29. How accurate is this test?

The performance of the Flowflex COVID-19 Antigen Home Test was established in an all-comers clinical study conducted between March 2021 and May 2021 with 172 nasal swabs self-collected or pair-collected by another study participant from 108 individual symptomatic patients (within 7 days of onset) suspected of COVID-19 and 64 asymptomatic patients. All subjects were screened for the presence or absence of COVID-19 symptoms within two weeks of study enrollment. The Flowflex COVID-19 Antigen Home Test was compared to an FDA authorized molecular SARS-CoV-2 test. The Flowflex COVID-19 Antigen Home Test correctly identified 93% of positive specimens and 100% of negative specimens.

30. What is EUA? How does that affect this test?

The United States FDA has made this test available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of diagnostics (IVDs) for the detection and/or diagnosis of the virus that causes COVID-19. An IVD made available under an EUA has not undergone the same type of review as an FDA-approved or cleared IVD. The FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives, and based on the totality of scientific evidence available, it is reasonable

to believe that this IVD may be effective in diagnosing COVID-19. The EUA for this test is in effect for the duration of the COVID-19 declaration justifying emergency use of IVDs, unless terminated or revoked (after which the test may no longer be used).

31. Do I need insurance to perform this test?

No, you do not need insurance to use this test. The Flowflex COVID-19 Antigen Home Test is for over-the-counter (OTC) use.

32. Do I need a prescription to use this test?

No, you do not need a prescription to use this test. The Flowflex COVID-19 Antigen Home Test is for over-the-counter (OTC) use.

33. Is this test acceptable for travel? Can it be used for proof of a negative COVID-19 test result?

The type of testing and documentation required for international/air travel may be different based on the travel destination, airline, and state requirements. Therefore, we recommend that you contact your airline carrier, visit the CDC/TSA website, and your local health department's website for the latest requirements on the type of acceptable testing and documentation for your travel destination.

34. Can people who are vaccinated use this test?

Yes, individuals with or without symptoms can use this test regardless of vaccination status.

35. Is this test reusable?

No, the Flowflex COVID-19 Antigen Home Test is a single-use test and cannot be reused.

36. If your question is not listed above, please contact us.

Customer Support: (800) 838-9502