COVID-19 Antigen Home Test
Package Insert

A rapid test for the detection of SARS-CoV-2 antigens in anterior nasal specimens. For self-testing use. For use under an Emergency Use Authorization (EUA) only. Carefully read the instructions before performing the test. Failure to follow the instructions may result in inaccurate test results.

PREPARATION

1. Wash or sanitize your hands. Make sure they are dry before starting the test.
2. Read the instructions.
3. Check your kit contents and make sure you have everything. Check the expiration date printed on the cassette foil pouch. Do not use if the pouch is damaged or open.

TEST PROCEDURE

1. Remove the foil from the top of the extraction buffer tube.
2. Punch through the perforated circle on the kit box to form a tube holder. Place the tube in the tube holder. For 25 test quantity kit box the tube holder is provided.
3. Open the swab packaging at the stick end, not the swab tip. Do not touch the swab tip.
4. Gently insert the entire absorbent tip of the swab into 1 nostril (½ to ⅙ of an inch). 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 to hold the child’s head while swabbing.
   - Note: A false negative result may occur if the nasal swab specimen is not properly collected.
5. 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.
6. Remove the swab from the nostril and immediately place into the extraction buffer tube. Note: Test samples immediately after collection, and no more than one hour after the swab is added to the reagent solution, if stored at room temperature.

RESULT INTERPRETATION

Only the control line (C) and no test line (T) appears. This means that no SARS-CoV-2 antigen was detected.

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 healthcare provider. If you do not have symptoms, you should test again in 24 hours (but not more than 48 hours).

Both the control line (C) and test line (T) appear. This means that SARS-CoV-2 antigen was detected. NOTE: Any faint red or pink line in the test line region (T) should be considered 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.

Control line (C) fails to appear. If a control (C) line is not visible, the test is invalid. Re-test with a new swab and new test cassette. If the problem persists, call (800) 838-9502 for assistance.
Q: WHAT IS THE DIFFERENCE BETWEEN AN ANTIGEN AND MOLECULAR TEST?
A: There are different kinds of tests for the virus that causes COVID-19. Molecular 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, meaning they 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.

Q: HOW ACCURATE IS THIS TEST?
A: The performance of Flowflex COVID-19 Antigen Home Test was established in an all-comers clinical study conducted between March 30 and May 2, 2021 with 172 nasalswabs self-collected or pair-collected by another study participant from 108 individual symptomatic patients (within 7 days of onset) suspected of COVID-19. The Flowflex COVID-19 Antigen Home Test was compared to a 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 in that study.

Q: WHAT IF YOU TEST POSITIVE?
A: A positive test 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. Your healthcare provider will consult with others and contact your healthcare provider for medical advice about your positive result. Your healthcare provider will work with you to determine how best to care for your COVID-19 diagnosis, medical history, and symptoms.

Q: WHAT IF YOU TEST NEGATIVE?
A: A negative test result means that antigens from the virus that causes COVID-19 were not found in your sample. If you do not have symptoms and you receive a second negative result 24 to 48 hours after your first negative result, then you are very unlikely to have COVID-19. However, there is a small chance that you could still have COVID-19. It is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. This means that you could possibly still have COVID-19 even though the test is negative. For example, you may get a false negative result if you did not perform the test correctly or if the level of antigen is very low in your sample. The amount of antigen in a sample may decrease the longer you have symptoms of infection. If you test negative and continue to experience COVID-19 like symptoms, please contact your healthcare provider. Your healthcare provider may suggest you need another test to determine if you have contracted the virus causing COVID-19. Your healthcare provider can help you understand the steps you should take.

Q: WHAT IF THE TEST IS INVALID?
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 the test should be run again, using a new test cassette and extraction buffer tube.

Q: WHAT IS SERIAL TESTING?
A: Serial testing is repeated testing with at least twenty-four hours between tests. This means that there is a higher chance this test will give you a negative result when you have a COVID-19.

Q: HOW OFTEN SHOULD I BE TESTING?
A: For COVID-19, clinicians and other healthcare workers should test individuals without symptoms as a way to track outbreaks. The U.S. Department of Health and Human Services recommends testing for COVID-19 on a routine basis for individuals who are at increased risk for exposure (e.g., healthcare personnel, essential workers). This is because the virus that causes COVID-19 can be spread to others even if a person shows signs or symptoms of being sick (e.g., fever, cough, difficulty breathing, etc.). All tests should be performed for suspected COVID-19 according to the following guidelines: [link to testing guidelines].