Flowflex COVID-19 Antigen Home Test

Package Insert

The Flowflex Web App allows you to track and report your COVID-19 test results.
- The Web App is optional and not required to run a COVID-19 test. It will assist you in interpreting your visual test result and report your result to local health authorities.
- Ensure you have an internet connection and scan the Flowflex QR code or go to www.flowflexcovid.com prior to starting the test.
- Ensure you are using a compatible web browser (Chrome, Firefox, Edge, or Safari) and your electronic device has a camera.
- Click on "Report Your Test Result.”
- Create an account.

To perform a COVID-19 test:
1. Log in to the Flowflex Web App - Ensure you are connected to the internet during your test.
4. Read result.

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 ¾ 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.
7. Immediately place the swab into the tube and swirl for 30 seconds. Note: A false negative result may occur if the swab is not swirled at least 30 seconds.
8. Rotate the swab 5 times while squeezing the tube. Note: A false negative result may occur if the swab is not rotated five times.
9. Remove the swab while squeezing the tube. Dispose of the swab in the trash.
10. Gently squeeze the tube and dispense 4 drops of solution into the Sample Well. Dispose the tube in the trash. Note: A false negative or invalid result may occur if less than 4 drops of fluid are added to the Sample Well.
11. Set the timer for 15 minutes. Result should be read at 15 minutes. Do not read after 30 minutes. Dispose the test cassette in the trash. Note: A false negative or false positive result may occur if the test result is read before 15 minutes or after 30 minutes.

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 follow up care with your healthcare provider. If you do not have symptoms, you should test again in 24 hours (but no 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.

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.

KIT CONTENTS

Test Cassette Buffer Tube Disposable Nasal Swab Tube Holder (only for 25 test quantity) Package Insert Timer (Not included)

SPECIMEN COLLECTION

SELF COLLECTION COLLECTION BY AN ADULT

Dry, clean, flat surface. Locate the Result Window and Sample Well on the cassette.

A nasal swab sample can be self-collected by an individual aged 14 years and older. Children aged 2 to 13 years should be tested by an adult.
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 mean you are definitely negative. You should talk to your healthcare provider whether an additional test is necessary and if you should continue isolating at home. There is a higher likelihood of false negative results with antigen-based molecular tests. This means that there is a higher chance this test will give you a negative result when you have COVID-19.

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 8 and May 15, 2021 with 172 nasal swabs self-collected and 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 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 in that study.

WHAT IF YOU TEST NEGATIVE?

A: A negative test result means that it is very likely you have COVID-19 because proteins from the virus that causes COVID-19 were not found in your sample. If you have symptoms, you likely do not have COVID-19. 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.

WHAT IF YOU TEST POSITIVE?

A: A positive test result means that it is likely you have COVID-19 because proteins from the virus that causes COVID-19 were found in your sample. If you have symptoms, you likely do not have COVID-19. If you do not have symptoms and you receive a second positive result 24 to 48 hours after your first positive result, then you are very likely to have COVID-19.

WHAT IF I NEED TO SELF-CONFIRM MY RESULTS?

A: You can perform serial testing to help confirm your results. Serial testing (i.e., testing every other day) is more likely to detect COVID-19, especially for individuals who have underlying medical conditions and are more likely to be infected with 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 the virus in your body was below the limit of detection. The amount of antigen in a sample may decrease the longer you have symptoms of infection. If you test negative and continue to have symptoms, contact your healthcare provider.

WHO SHOULD SEEK MEDICAL CARE IF THEY TEST POSITIVE?

A: Your healthcare provider will need you to test again if you test positive. Your healthcare provider may need to determine if you should seek medical care.

WHAT IF I TEST POSITIVE AND I HAVE UNDERLYING MEDICAL CONDITIONS?

A: If you test positive and you have underlying medical conditions, contact your healthcare provider. Your healthcare provider may need to determine if you should seek medical care.

WHAT IF I TEST POSITIVE AND I AM NOT SICK?

A: If you test positive and you are not sick, call your healthcare provider. Your healthcare provider may need to determine if you should seek medical care.

WHAT IF I TEST NEGATIVE AND I AM NOT SICK?

A: If you test negative and you are not sick, call your healthcare provider. Your healthcare provider may need to determine if you should seek medical care.

WHAT IF I TEST POSITIVE AND I AM SICK?

A: If you test positive and you are sick, call your healthcare provider. Your healthcare provider may need to determine if you should seek medical care.

WHAT IF I TEST NEGATIVE AND I AM SICK?

A: If you test negative and you are sick, call your healthcare provider. Your healthcare provider may need to determine if you should seek medical care.

WHAT IF I TEST POSITIVE AND I HAVE UNDERLYING MEDICAL CONDITIONS?

A: If you test positive and you have underlying medical conditions, your healthcare provider may need to determine if you should seek medical care.

WHAT IF I TEST NEGATIVE AND I HAVE UNDERLYING MEDICAL CONDITIONS?

A: If you test negative and you have underlying medical conditions, your healthcare provider may need to determine if you should seek medical care.

WHAT IF I TEST POSITIVE AND I AM NOT SICK?

A: If you test positive and you are not sick, call your healthcare provider. Your healthcare provider may need to determine if you should seek medical care.

WHAT IF I TEST NEGATIVE AND I AM NOT SICK?

A: If you test negative and you are not sick, call your healthcare provider. Your healthcare provider may need to determine if you should seek medical care.

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A: If you test negative and you have underlying medical conditions, your healthcare provider may need to determine if you should seek medical care.

WHAT IF I TEST POSITIVE AND I AM SICK?

A: If you test positive and you are sick, call your healthcare provider. Your healthcare provider may need to determine if you should seek medical care.

WHAT IF I TEST NEGATIVE AND I AM SICK?

A: If you test negative and you are sick, call your healthcare provider. Your healthcare provider may need to determine if you should seek medical care.

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A: If you test positive and you are not sick, call your healthcare provider. Your healthcare provider may need to determine if you should seek medical care.

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WHAT IF I TEST NEGATIVE AND I HAVE UNDERLYING MEDICAL CONDITIONS?

A: If you test negative and you have underlying medical conditions, your healthcare provider may need to determine if you should seek medical care.

WHAT IF I TEST POSITIVE AND I AM SICK?

A: If you test positive and you are sick, call your healthcare provider. Your healthcare provider may need to determine if you should seek medical care.