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.
2. Answer a few questions on the Web App.
4. Read result.

TEST PROCEDURE

1. 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.

2. Completely insert the swab into the nostril to at least 15 mm (⅙ to ⅜ of an inch). With children, the maximum depth of insertion into the nostril may be less than ⅜ of an inch, and you may need to have a second person to hold the child’s head while swabbing.

3. Once the swab is inserted, rotate the swab 5 times.

4. Gently insert the entire absorbent tip of the swab into 1 nostril (⅙ to ⅜ of an inch). With children, the maximum depth of insertion into the nostril may be less than ⅜ of an inch, and you may need to have a second person to hold the child’s head while swabbing.

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

If the Control (C) line is visible, but the Test (T) line is not visible, the test is negative. To increase the chance that the negative result for COVID-19 is accurate, you should:
- 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 antigens from 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 healthcare provider.

If the Control (C) line and the Test (T) line are visible, the test is positive. Any faint visible red or pink 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/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).

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) 838-5502 for assistance.

If the Control (C) line and the Test (T) line are visible, the test is positive.
Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals and three times over five days for asymptomatic individuals. If the reagent solution contacts the skin, eyes, nose, or mouth, flush with large amounts of water.

Clinical studies have shown that antigen tests more accurately detect genetic material from the virus, Antigen tests, such as the Flowflex COVID-19 Antigen Home Test, detect proteins from the virus. Due to the lower sensitivity of antigen tests compared to nucleic acid tests, there is a higher chance this test will give you a negative result when you have COVID-19 than a molecular test would.

Q: WHAT IS THE DIFFERENCE BETWEEN AN ANTIGEN AND MOLECULAR TEST?
A: There are different kinds of tests for the SARS-CoV-2 virus that causes COVID-19, which can be grouped into two main types: antigen tests and molecular tests.

Individuals should report the test result through the Flowflex Web App or provide all results obtained with this product to their healthcare provider for public health reporting.

HCare PROVIDERS

You may need to contact or consult your healthcare provider's instructions for data submission.

If the result is invalid, it is invalid as a result of errors in test technique and not due to the product being used as the sole basis for treatment or patient management decisions, including infection control measures.

Q: WHAT IS AN INVALID TEST RESULT MEAN?
A: If the result is invalid, the test should not be used. People should check the test result through the Flowflex Web App or all results obtained with this product to their healthcare provider for public health reporting.

Healthcare providers will report these results to the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by CDC.

Negative results are presumptive and are confirmed with a molecular assay. If necessary, for patient management actions, laboratory confirmation of a negative test result is particularly important. The Flowflex COVID-19 Antigen Test Home Kit is intended for the qualitative detection of the SARS-CoV-2 nucleocapsid protein antigen in nasal (naso) samples in adults and children aged 14 years and older.

This test is intended to be used as an aid to clinical diagnosis and does not exclude the need for additional testing. False-negative results may occur if the antigen is not present or is present at a concentration below the detection limit for the test. The performance of this test was established based on the evaluation of a limited number of clinical specimens using the Clinical and Laboratory Improvement Amendments Act (CLIA) waived method. The test is used as the sole basis for treatment of patient management decisions, including infection control measures such as isolation. The test is intended for use in adults and children aged 14 years and older. The test is intended for use in adults and children aged 14 years and older.

Possible discomfort during sample collection.

You should report any side effects you experience to your healthcare provider.

Q: WHERE CAN I FIND THE RESULTS?
A: You can find your test result through the Flowflex Web App. The results may also be shared with your healthcare provider. If additional testing is needed, your healthcare provider will contact you.

It is important that you continue to follow public health guidelines and stay informed about the latest developments in your area. For more information, you can visit the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 360b; 30-l), unless the declaration is terminated, or authorization is revoked sooner.

Immunological tests are not necessary to confirm infection status. Negative results do not rule out bacterial infection. False-negative results may occur if the antigen is not present or is present at a concentration below the detection limit for the test. In the event of an invalid result, the test should be repeated using a new test kit.

People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection. The incubation period of infectious disease varies. The epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever and cough, sputum, sore throat, myalgia and fatigue are found in a few cases.

Positive results indicate that the test kit detects SARS-CoV-2 and the patient may be infected. Patient education and counseling may be necessary. The test kit detects the SARS-CoV-2 virus, which is a new virus in humans causing a respiratory illness. The illness may be termed COVID-19 and can vary from asymptomatic to severe respiratory illness with pneumonia.

It is important to understand the potential risks and benefits of this test.

The results of this test may help limit the spread of COVID-19 to your family and others in your community.

If you are positive, then proteins from the virus that causes COVID-19 have been found in your body. Antigen tests, such as the Flowflex COVID-19 Antigen Home Test, detect proteins from the virus. To confirm the infection, additional testing may be necessary.

Q: WHAT IS THE RISK OF FALSE-NEGATIVE RESULTS?
A: False-negative results may occur if the antigen is not present or is present at a concentration below the detection limit for the test. In the event of an invalid result, the test should be repeated using a new test kit.

The laboratory results from this test may be used as the sole basis for treatment or patient management decisions, including infection control measures. Store test kits and materials in a cool, dry place away from temperatures exceeding 100°F (38°C) and physical damage. Do not re-use. Do not use with multiple specimens.

A: COVID-19 is caused by the SARS-CoV-2 virus which is a new virus in humans causing a respiratory illness. The illness may be termed COVID-19 and can vary from asymptomatic to severe respiratory illness with pneumonia.

The results of the test may help limit the spread of COVID-19 to your family and others in your community.

The test is intended to be used as an aid to clinical diagnosis and does not exclude the need for additional testing. False-negative results may occur if the antigen is not present or is present at a concentration below the detection limit for the test.