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.

**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. 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.
4. Open the pouch and lay the cassette on a clean, flat surface. Locate the Result Window and Sample Well on the cassette.
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 reagent solution, if more than one hour after the swab was collected. If the problem persists, call (800) 838-9502 for assistance.
8. Gently insert the entire absorbent tip of the swab into 1 nostril (1/2 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.
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 seek follow up care with your healthcare provider.

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.

A false negative result may occur if the nasal swab specimen is not properly collected.

A positive test result indicates that antigens from the virus that causes COVID-19 were 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 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.

A false positive result may occur if the test result is read before 15 minutes or after 30 minutes.

A neutral result does not rule out COVID-19. 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.

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, 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 into 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.
FREQUENTLY ASKED QUESTIONS

Q: WHAT IS COVID-19?
A: COVID-19 is a respiratory virus that causes COVID-19 disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be a source of infection. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be a source of infection.

Q: WHAT IS THE KNOWN POTENTIAL RISKS AND BENEFITS OF THIS TEST?
A: Potential risks include:
- Possible discomfort during sample collection.
- Possible incorrect test results (see Warnings and Result Interpretation section).

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

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 for the SARS-CoV-2 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 your status with your healthcare provider whether an additional test is necessary and if you should continue isolating at home. There is a higher chance of false negative results with antigen tests than with molecular tests. If you have a positive antigen test result, there is a higher chance this test will give you a negative result when you have COVID-19 than a molecular test would.

Q: HOW ACCURATE IS THIS TEST?
A: The performance of Flowflex COVID-19 Antigen Home Test was established in an all-comers population, 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 had undergone urine and/or throat sample collection in the presence of COVID-19 home testing. 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.

Q: WHAT IF YOU TEST POSITIVE?
A: A positive 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. You should self-isolate from others and contact a healthcare provider for medical advice about your positive result. Your healthcare provider will work with you to determine how best to care for you based on your test result, medical history, and symptoms.

Q: WHAT IF YOU TEST NEGATIVE?
A: A negative test result indicates that antigens from the virus that causes COVID-19 were not found in your sample. If you have symptoms, you likely do not have COVID-19. However, negative results do not rule out SARS-CoV-2 infection. 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 from the virus causing COVID-19 was below the test limits. The amount of antigen in a sample may decrease the longer you have symptoms of infection. 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. Your healthcare provider will consider the test result together with all other aspects of your medical history (such as symptoms, possible exposures, and geographical location of places you have recently traveled) in deciding how to care for you. Your healthcare provider may suggest you need another test to determine if you have contracted the virus causing COVID-19. It is important that you work with your healthcare provider to help you understand the next steps you should take.

Q: WHAT DOES AN INVALID TEST RESULT MEAN?
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 collected and another test should be run again, using a new test cassette and extraction buffer tube.

INDEX OF SYMBOLES

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<th>Symbol</th>
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<tr>
<td>M</td>
<td>Medical device Use-by date</td>
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<tr>
<td>D</td>
<td>Date of manufacture</td>
</tr>
<tr>
<td>LOT</td>
<td>Batch code</td>
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ACON Laboratories, Inc. 
San Diego, CA 92121, USA  
flowflexcovid.com  
Customer Support: 1-800-838-9502  
Effective Date: 2022-XX-XX  
Number: 1151297703
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-3 (b)(1), unless the declaration is terminated or authorization is revoked sooner.
Flowflex™
COVID-19 Antigen Home Test

Contents:
- 25 Test Cassettes
- 25 Extraction Buffer Tubes
- 25 Disposable Nasal Swabs (Sterile Nasal Swabs)
- 1 Tube Holder
- 1 Package Insert (En/Es)

Items necessary to use the kit, but not provided:
- Timer

The Flowflex COVID-19 Antigen Home Test is a lateral flow chromatographic immunosorbent assay (IFA) for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in anterior nasal swab specimens from individuals who have complained of COVID-19 symptoms within 7 days of symptom onset or without symptoms or other epidemiological reasons to suspect COVID-19 infection.
COVID-19 Antigen Home Test

The Flowflex COVID-19 Antigen Home Test is a lateral flow immunoassay test kit for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in anterior nasal swab specimens directly from individuals within 7 days of symptom onset or without symptoms or other epidemiological reasons to suspect COVID-19.

Contents:
- 5 Test Cassette
- 5 Extraction Buffer Tubes
- 5 Disposable Nasal Swabs
- 1 Package Insert (En/Es)
- 1 Timer

Items necessary to use the kit, but not provided:
- Nasal Swab

Easy to Use
Quick Results

COVID-19 Antigen Home Test

Scan to learn more about the test

COVID-19 Test
A rapid test for the detection of COVID-19 antigens in nasal swab specimens. For in vitro diagnostic use. For use under an Emergency Use Authorization (EUA) only.
This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test. For ages 2 to 13, an adult must collect and test the anterior nares specimen.