

### 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 when you test yourself multiple times for COVID-19 on a routine basis, such as every day or every other day. By testing more frequently, you may detect COVID-19 more quickly and reduce spread of infection. Serial testing (i.e. testing every day or every other day) is more likely to detect COVID-19, especially when you do not have any symptoms but feel you may have been exposed to the virus. Individuals with symptoms of COVID-19 and initial negative results should be tested again after 48 hours. Individuals without symptoms of COVID-19, and with initial negative results, should be tested again after 48 hours and, if the 2nd test is also negative, a 3rd time after an additional 48 hours. You may need to purchase additional tests to perform this serial (repeat) testing.

### 5. Does the Flowflex COVID test work for new variants?

We are continuously monitoring the arrival of new COVID-19 variants, and we promptly evaluate our test's performance against any new variants, as clinical samples containing the new variants become available to us.

This process takes time, but as soon as the results are in, we issue a Press Release on our website to keep consumers informed in a timely manner.

Please check the website for updates at [www.flowflexcovid.com](http://www.flowflexcovid.com) in the news section towards the bottom of the page.

Alternatively, [www.aconlabs.com](http://www.aconlabs.com) in the News/Tradeshow section.

### 6. 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.

### 7. 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.

### 8. How many tests come with the test package?

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

### 9. 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.

### **10. 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. Customer Service hours are 5 a.m. – 5 p.m. (PST), 7 days a week.

### **11. How deep should I insert the swab into my nose?**

Insert the swab  $\frac{1}{2}$  to  $\frac{3}{4}$  inches inside your nostril. With children, the maximum depth of insertion into the nostril may be less than  $\frac{3}{4}$  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.

### **12. 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.

### **13. 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.

### **14. My Flowflex test did not include any English instructions, what should I do?**

Please fill out the Contact Us form ([Contact Us - Flowflexcovid.com](https://www.flowflexcovid.com/contact-us)) and provide the Lot number and location where the product was purchased. Customer Service hours are 5 a.m. – 5 p.m. (PST), 7 days a week.

### **15. 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. Customer Service hours are 5 a.m. – 5 p.m. (PST), 7 days a week.

### **16. What color should the solution be inside the extraction buffer tube?**

The solution should be clear and colorless. If you receive a solution that has a yellow color, do not use this test kit. Please contact customer service at (800) 838-9502 for assistance. Customer Service hours are 8 a.m. – 8 p.m. (EST), 7 days a week.

### **17. 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. Customer Service hours are 5 a.m. – 5 p.m. (PST), 7 days a week.

### **18. 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.

### **19. 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.

## 20. 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”.

## 21. The liquid in the little tube seems low, how can I tell if I have enough liquid to perform the test?

If the little tube contains approximately 1/4 inch (0.24 inch or 6 mm) of buffer solution or more, there is enough buffer solution to perform the test.

## 22. I just put my swab into the little tube, but I am concerned because the liquid does not cover the entire swab tip. Is this okay?

If the little tube contains approximately 1/4 inch (0.24 inch or 6 mm) of buffer solution or more, there is enough buffer solution to perform the test, even if the entire swab tip is not covered.

## 23. I ran my test and applied 4 drops of the liquid to the test cassette, but I am concerned because the liquid did not cover the entire swab tip when I prepared the sample. Is this okay?

If you were able to apply 4 drops of liquid unto the test cassette sample well marked “S”, and you followed all the instructions on the product insert, then it is fine. The entire swab tip does not need to be covered.

## 24. I performed the test according to the instructions, but when I tried to squeeze 4 drops out of the little liquid bottle, there was just enough liquid for 3 drops. Is my test result valid?

For the test to provide an accurate result, you must apply 4 drops of liquid unto the test cassette sample well, the one marked with an “S”. If your tube contained only enough liquid for 3 drops, you must repeat the test with a new cassette and a newly collected specimen sample.

## 25. How long does it take to obtain results?

Results are available in 15 minutes.

## 26. 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.

## 27. 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.

## 28. 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.

### 29. 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.

### 30. 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.

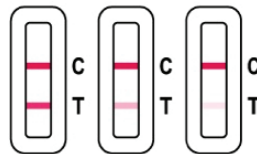
Another type of test is an antibody test. A COVID-19 antibody test detects antibodies that have been produced by your immune system in response to a previous COVID-19 infection or vaccination. Antibody tests are not suitable for diagnosing an active COVID-19 infection.

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>

### 31. 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.

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



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.

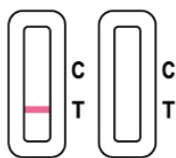
### 33. What does it mean if I have a negative test result?



A negative test result indicates that antigens from the virus that causes COVID-19 were not detected in your sample. However, if you have symptoms of COVID-19, and your first test is negative, you should test again in 48 hours since antigen tests are not as sensitive as molecular tests. If you do not have symptoms and received a negative result, you should test at least two more times with 48 hours in between tests for a total of three tests. If you have a negative result, it does not rule out SARS-CoV-2 infection; you may still be infected and you may still infect others. It is important that you work with your healthcare provider to help you understand the next steps you should take.

### 34. What if I have an invalid result?

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. If the problem persists, call (800) 838-9502 for assistance. Customer Service hours are 5a.m. – 5 p.m. (PST), 7 days a week.



### 35. 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.

### 36. 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.

### 37. 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).

### 38. 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.

### 39. 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.

### 40. Is this test eligible for Flexible Spending Accounts (FSAs)?

Yes, this test is an eligible expense that can be reimbursed under FSAs.

#### 41. 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 view your local health department's website for the latest requirements on the type of acceptable testing and documentation for your travel destination.

#### 42. Do you offer proctoring services with this test to travel/to travel abroad/for international travel/to travel back to the US?

AZOVA is authorized to offer proctoring services for travel purposes in conjunction with ACON's Flowflex Antigen Home test.

For more details, go to [www.azova.com/flowflexvideo](http://www.azova.com/flowflexvideo) before performing your test, or call (844) 692-9682. There is an additional cost associated with the proctoring services provided by AZOVA.

We also recommend you visit the CDC, the TSA, and your airline carrier websites, to view the latest documentation and accepted testing requirements for your destination.

#### 43. Do you offer proctoring services and results with this test that I could provide my work?

We do not currently offer proctoring services that would allow you to provide a test result to your employer.

#### 44. Can people who are vaccinated use this test?

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

#### 45. Is this test reusable?

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

#### 46. Why did my Flowflex test come in a blue box instead of a white box?

Flowflex tests in a blue box are intended only for distribution and use outside the USA, and they do not have FDA Emergency Use Authorization. Please fill out the Contact Us form ([Contact Us - Flowflexcovid.com](http://Contact Us - Flowflexcovid.com)) and provide the Lot number and location where the product was purchased.

#### 47. What is the Flowflex CPT code to bill insurance?

The CPT Code is 87426

- **Short Descriptor:** SARSCOV CORONAVIRUS AG IA
- **Medium Descriptor:** IAAD IA SEVERE AQT RESPIR SYND CORONAVIRUS
- **Long Descriptor:** Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative; severe acute respiratory syndrome coronavirus (eg, SARS-CoV, SARS-CoV-2 [COVID-19])

#### 48. What is the Flowflex NDC code?

The NDC code for the 1-Test configuration is 82607-0660-26.

#### 49. What is the Flowflex LOINC code?

The LOINC code is 97097-0

- **Description :** SARS-CoV-2 (COVID-19) Ag [Presence] in Upper respiratory specimen by Rapid immunoassay

## 50. Where is the Flowflex COVID-19 Antigen Home Test manufactured?

The test is manufactured by ACON's **FDA registered**, state-of-the-art manufacturing facility in China. The manufacturing facility is ISO13485: 2016 certified and inspected by the FDA. For over 25 years, ACON has continued to supply billions of IVD tests per year Worldwide.

## 51. The Flowflex COVID-19 Antigen Home Test is manufactured in China, is it safe to use?

Yes, it is safe to use. The test is manufactured by ACON's **FDA registered**, state-of-the-art manufacturing facility in China. The manufacturing facility is ISO13485: 2016 certified and inspected by the FDA. For over 25 years, ACON has continued to supply billions of IVD tests per year Worldwide.

## 52. What is the nasal swab made of, is it sterile, how is it sterilized, are chemical residues on the swab?

The tip of the nasal swab is made of polyurethane foam and, is sterile and safe to use. The swab is sterilized using Ethylene Oxide before aeration to remove any residual components. After the aeration process, no chemicals should be left on the swabs.

## 53. Is the yellowish color on the tip of my nasal swab normal?

Yes, discoloration of the swab tip is normal and due to UV exposure. The swab is safe to use and will have no impact on test performance.

## 54. The package containing my Flowflex tests was left outside in freezing temperatures for a few hours – below the storage temperature listed on the kit box. Will it affect the tests performance, and should I throw the tests away?

Our R&D Dept. has checked and confirmed that the Flowflex kits that were frozen are still working. Make sure the entire kit is back to room temperature and that the extraction buffer is thawed and back to liquid solution form before the kit is used for the testing.

## 55. The package containing my Flowflex tests was left outside in very high temperatures for a few hours – above the storage temperature listed on the kit box. Will it affect the tests performance, and should I throw the tests away?

Our R&D Dept. has checked and confirmed that the Flowflex kits that were exposed to temperatures above average (up to 65 °C / 150 °F) for a few hours are still working. Make sure the entire kit is cooled back to room temperature and there is still a least 1/3 of an inch of buffer in the tube before the kit is used for the testing.

## 56. What is the new shelf life of the Flowflex COVID-19 Antigen Home Test?

On March 15, 2023 the [FDA granted ACON Laboratories, Inc.](#) a shelf life extension from 12 months to 24 months, for its Flowflex COVID-19 Antigen Home Test, when stored at 36-86°F (2-30°C). Refer to the table for the new expiration date using the lot number printed on the test kit box.

Lot Number Range	New Expiration Dates
COV1100041 to COV1100088	October 2023
COV1110071 to COV1110266	November 2023
COV1120041 to COV1125011	December 2023
COV2010001 to COV2010100	January 2024
COV2020003 to COV2030010	February 2024
COV2030011 to COV2030023	March 2024

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

Customer Service hours are 5 a.m. – 5 p.m. (PST), 7 days a week.