**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 before performing the test.

### 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 ⅛ of an inch).** With children, the maximum depth of insertion into the nostril may be less than ⅛ 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.**
7. **Immediately place the swab into the tube and swirl for at least 30 seconds.**
8. **30 sec.**
9. **5x**
10. **Remove the swab while squeezing the tube. Dispose the swab in the trash.**
11. **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.
12. **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.**

### RESULT INTERPRETATION

**Negative**

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

**Positive**

- 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.

**Invalid**

- 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.
Do not use if any of the test kit contents or packaging is damaged or open.

FOR FDA EMERGENCY USE AUTHORIZATION (EUA) ONLY

Test components are single use. Do not re-use. Do not use with multiple specimens.

Make sure there is sufficient light when testing.

Do not use on anyone who is prone to nosebleeds or has had facial injuries or head trauma in the last 6 months.

False negative test results may occur if a specimen is incorrectly collected or handled.

Do not touch the swab tip when handling the swab.

The test is intended to be read at 15 minutes. If the test is read before 15 minutes or after 30 minutes, false negative or false positive results may occur, and the test should be repeated with a new test card.

Do not ingest any kit components.

Avoid exposure of your skin, eyes, nose, or mouth to the solution in the extraction tube. The Reagent Solution contains a high pH solution (see table below).

Hazard Category (mixture) Hazard Statement for mixture Labeling of Harm(s)
Not classified Acute eye/ocular toxicity May cause eye irritation
Category 2 Eye irritation May cause eye irritation
Category 3 Skin irritation Causes mild skin irritation

If the reagent solution contacts the skin or eyes, flush with plenty of water. If irritation persists, seek medical advice. https://www.pothotelp.org or 1-800-222-1222

What is COVID-19?
COVID-19 is caused by the SARS-CoV-2 virus which is a new virus in humans causing a contagious respiratory illness. COVID-19 can present with mild to severe illness, although some people infected with COVID-19 may have no symptoms at all. Older adults and people of any age who have underlying medical conditions are at higher risk of severe illness when infected with COVID-19. COVID-19 serious outcomes of COVID-19 include hospitalization and death. The SARS-CoV-2 virus can cause serious illness even in people who do not have obvious signs of being sick (e.g., fever, coughing, difficulty breathing, etc.). A full list of symptoms of COVID-19 can be found at the following link: https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html

Will this test result mean?
A: 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 immediately.

What are the known potential risks and benefits of this test?
Potential risks include:
• Possible discomfort during sample collection.
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.

What is the difference between an antigen and molecular test?
There are different kinds of tests for the virus that causes COVID-19. Molecular tests detect viral RNA from the virus, 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 SARS-CoV-2 infection. If you test positive 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. This means that there is a higher chance this test will give you a negative result when you have COVID-19 than a molecular test would.

How accurate is this test?
A: 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 for infection with SARS-CoV-2 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 test should be used within 60 minutes. The performance of 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 (who had symptoms within six days of symptom 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 test should be used within 60 minutes. The Flowflex COVID-19 Antigen Home Test correctly identified 93% of positive specimens and 100% of negative specimens. The results of this test may help limit the spread of COVID-19 to your family and others in your community.

What happens 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.

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 was negative. For example, you may find 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.

What if an invalid test result means?
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.

What does an invalid test result mean?
A: This test is intended to be used as an aid in the clinical diagnosis of active COVID-19. Do not use this test as the only guide to manage your illness. Please consult your healthcare provider if your symptoms persist or become more severe, or if you are concerned at any time.

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.

© ACON Laboratories, Inc. San Diego, CA 92121, USA
flowflexcovid.com
Customer Support: 1-800-838-9502

SERIAL NUMBER: 03-001-0010-999955

Effective Date: 2022-03-08

Index of Symbols

Manufacturer Date of manufacture

Contains sufficient for ☑️ tests Catalogue number

In vitro diagnostic medical device Batch code

Consult instructions for use

Temperature limit

Do not reuse

A: The Flowflex COVID-19 Antigen Home Test Package Insert carefully before performing a test. Failure to follow directions may produce inaccurate test results.

The Test is intended to aid in the diagnosis of active COVID-19. Please consult your healthcare professional to discuss your results and if any additional testing is required.

Take the test cassette out of the pouch before use. Once opened, the test cassette should be used within 60 minutes.

The Flowflex COVID-19 Antigen Home Test is only for use under the Food and Drug Administration’s Emergency Use Authorization.

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious 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 an important source of infection. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, myalgia, and diarrhea are found in a few cases.

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

© ACON Laboratories, Inc. San Diego, CA 92121, USA
flowflexcovid.com
Customer Support: 1-800-838-9502

Effective Date: 2022-03-08

Index of Symbols

Manufacturer Date of manufacture

Contains sufficient for ☑️ tests Catalogue number

In vitro diagnostic medical device Use-by date

Consult instructions for use Batch code

Temperature limit Do not reuse

© ACON Laboratories, Inc. San Diego, CA 92121, USA
flowflexcovid.com
Customer Support: 1-800-838-9502

Effective Date: 2022-03-08