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.
3. Check your kit contents and make sure you have everything. Check the expiration date printed on the cassette foil pouch.
4. Open the pouch and locate the Result Window and Sample Well on the cassette.

**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 end. Do not touch the swab head.
4. Gently insert the entire absorbent tip of the swab head 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 around the inside wall of the nostril immediately place into the extraction buffer tube. Note: Test samples may occur if the nasal swab 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.
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. Gently insert the entire absorbent tip of the swab head 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 around the inside wall of the nostril immediately place into the extraction buffer tube. Note: A false negative result may occur if the nasal swab specimen is not properly collected.
10. Attach the dropper tip firmly onto the tube. Mix thoroughly by swirling or flicking the bottom of the tube.
11. Gently squeeze the tube and dispense 4 drops of solution into the Sample Well. Gently squeeze the tube and dispense 4 drops of fluid are added to the Sample Well. 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. 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 no antigens for COVID-19 were detected. It is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19 and negative results are presumptive and may need to be confirmed with a molecular test. This means that you could possibly still have COVID-19 even though the test is negative. If you test negative and continue to experience symptoms or symptoms become more severe, please consult your healthcare provider. It is important that you work with your healthcare provider to help you understand the next steps you should take.

Both the control line (C) and test line (T) appear. This means that SARS-CoV-2 antigen was detected. A positive test result means that antigens from COVID-19 were detected and it is very likely you currently have COVID-19 disease.

Self-isolate to avoid spreading the virus to other people and consult your healthcare provider as soon as possible. Your healthcare provider will work with you to determine how best to care for you.

Neither the control line (C) nor the test line (T) appears. This means that the assay failed. This means that COVID-19 was not detected. Review the instructions again and repeat the test with a new cassette. If the problem persists, call (800) 839-9502 for assistance.

Control line (C) fails to appear. No test line (T) appears. This means that COVID-19 was not detected. Review the instructions again and repeat the test with a new cassette. If the problem persists, call (800) 839-9502 for assistance.
The Flowflex COVID-19 Antigen Home Test is a lateral flow chromatographic immunoassay intended 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 other epidemiological reasons to suspect COVID-19 infection. This test is authorized for non-prescription home use with self-collected anterior nasal swab specimens directly from individuals aged 14 years and older. The Flowflex COVID-19 Antigen Home Test does not differentiate between SARS-CoV and SARS-CoV-2.

Q: WHAT IS THE INTENDED USE OF THIS PRODUCT?
A: The Flowflex COVID-19 Antigen Home Test is intended to aid in the diagnosis of a current COVID-19 infection. Please consult a healthcare professional to discuss your results and any additional testing is required.

Q: WILL THIS TEST HURT?
A: No. The swab is soft, 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.

Q: WHAT ARE THE KNOWN POTENTIAL RISKS AND BENEFITS OF THIS TEST?
A: 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.

Q: WHAT IS THE DIFFERENCE BETWEEN AN ANTIGEN AND MOLECULAR TEST?
A: 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 SARS-CoV-2 virus but are not as sensitive as molecular tests. The assays 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 you should continue isolating at home.

Q: 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 2021 and May 2021 with 172 nasal swabs self-collected or paired-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 the Flowflex COVID-19 SARS-CoV-2 test. The Flowflex COVID-19 Antigen Home Test correctly identified 93% of positive specimens and 100% of negative specimens.

FOR FDA EMERGENCY USE AUTHORIZATION (EUA) ONLY
- This product has not been FDA cleared or approved but has been authorized by FDA for emergency use.
- This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
- The use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of IVDs 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. § 360bb-3(b)(1)), unless the declaration is terminated, or authorization is revoked sooner.
- For more information on EUAs please visit: https://www.fda.gov/emergency-preparedness-and-response/emergency-use-authorization.
- For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19
- For detailed instructions, please visit: www.aconlabs.com

INTENDED USE
The Flowflex COVID-19 Antigen Home Test is a lateral flow chromatographic immunoassay intended 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 other epidemiological reasons to suspect COVID-19 infection. This test is authorized for non-prescription home use with self-collected anterior nasal swab specimens directly from individuals aged 14 years and older. The Flowflex COVID-19 Antigen Home Test does not differentiate between SARS-CoV and SARS-CoV-2.

RESULTS
The Flowflex COVID-19 Antigen Home Test correctly identified 93% of positive specimens and 100% of negative specimens.

WARNINGs, PREcautions, and SAFETY INFORMATION
- Read the Flowflex COVID-19 Antigen Home Test Package Insert carefully before performing a test. Failure to follow directions may produce inaccurate test results.