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.
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.

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. 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 ½ 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.
4. Immediately place the swab 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.
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

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. NOTE: Any faint line in the test line region (T) should be considered positive.

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.

Control line (C) fails to appear. Not enough specimen volume or incorrect operation are the likely reasons for an invalid result. Review the instructions again and repeat the test with a new cassette. If the problem persists, call (800) 838-9502 for assistance.
The new coronaviruses belong to the beta genus. COVID-19 is an acute respiratory infectious disease. Currently, patients infected by the new coronavirus are the main source of infection; symptoms consistent with COVID-19.

defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2. Individuals who use the authorized product to relevant public health authorities in accordance public health reporting. Healthcare providers will report all test results they received from individuals aged 14 years and older or with adult-collected anterior nasal samples directly from individuals aged 2 years or older. The Flowflex COVID-19 Antigen Home Test does not differentiate between SARS-CoV-2 and SARS-CoV. Results are for the identification of SARS-CoV-2 nucleo-capid protein antigen. This antigen is generally found in anterior nasal swabs during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected generally found in anterior nasal swabs during the acute phase of infection. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected

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

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

FREQUENTLY ASKED QUESTIONS

Q: WILL THIS TEST HURT?

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.

Q: HOW ACCURATE IS THIS TEST?

A: The performance of Flowflex COVID-19 Antigen Home Test was compared to an FDA authorized device

Q: WHAT IF YOU TEST NEGATIVE?

A: A negative test result indicates no antigens for COVID-19 were detected. It is possible for the test to give a negative result that is incorrect (false negative) in some people with COVID-19. If you are concerned about your COVID-19 infection status after testing or think you may need follow up testing, please consult your healthcare provider.

This test is intended to be used as an aid in the clinical diagnosis of a current COVID-19 infection. 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 provide all results obtained with this product to their healthcare provider for public health reporting.

Please visit www.aconlabs.com to obtain the complete instructions for use and fact sheet for healthcare providers.

HEALTHCARE PROVIDERS

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<th>Manufacturer</th>
<th>SD Code</th>
<th>Date of Manufacture</th>
<th>Catalog Number</th>
<th>Contains sufficient for &lt;= tests</th>
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<th>Use-by date</th>
<th>Consult instructions for use</th>
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