

COVID-19 Antigen Test

Instruction for COVID19 antigen test

This test is authorized by EUA as a rapid test for the detection of SARS-CoV-2 antigens in anterior nasal specimens. A negative test result may occur if the level of antigen in a sample is below the detection limit of the test. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.

SPECIMEN COLLECTION

SELF COLLECTION	COLLECTION BY AN ADULT	
		A nasal swab sample can be self-collected by an individual aged 14 years and older. Children aged 2 to 13 years should be tested by an adult.

TEST PROCEDURE

<p>1. </p> <p>Remove the foil from the top of the extraction buffer tube.</p>	<p>2. </p> <p>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.</p>	<p>3. </p> <p>Open the swab packaging at the stick end, not the swab end. Do not touch the swab head.</p>	<p>4. </p> <p>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 ¼ 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.</p>	<p>5. </p> <p>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.</p>	<p>6. </p> <p>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.</p>
<p>7. </p> <p>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.</p>	<p>8. </p> <p>Rotate the swab 5 times while squeezing the tube. Note: A false negative result may occur if the swab is not rotated five times.</p>	<p>9. </p> <p>Remove the swab while squeezing the tube. Dispose the swab in the trash.</p>	<p>10. </p> <p>Attach the dropper tip firmly onto the tube. Mix thoroughly by swirling or flicking the bottom of the tube.</p>	<p>11. </p> <p>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.</p>	<p>12. </p> <p>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.</p>

1. Interpretation of Result

RESULT INTERPRETATION

<p></p> <p>Negative</p> <p>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.</p>	<p></p> <p>Positive</p> <p>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.</p>	<p></p> <p>Invalid</p> <p>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.</p>
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