COVID-19 Rapid Antigen Testing

Updated October 27, 2020

What is an antigen or rapid test?

Rapid antigen tests are commonly used to test for respiratory viruses, such as RSV in children and influenza. The U.S. Food and Drug Administration (FDA) has granted emergency use authorization for antigen tests that look for the virus that causes COVID-19^{1,2}.

Antigen tests look for proteins found on or within the virus that causes COVID-19. They tell you if you have COVID-19 right now and could spread it to other people. An antigen test is like a PCR test, where a sample is collected with a nasal or nasopharyngeal swab, but you are able to get the results much quicker. Results take about 15 minutes.



Are COVID-19 rapid antigen tests accurate?

The most accurate COVID-19 test is a PCR test. Antigen tests are usually accurate but you may be asked to also get a PCR test if the test result was not what was expected. For example, if you have symptoms of COVID-19 but your test result was negative, you should get a PCR test.

A PCR test tells you if you have COVID-19 right now and could spread it to other people. It almost always detects if a person is infected with the virus (this is called specificity). This test is done with a nasal or nasopharyngeal swab or with saliva. A lab must process the test and give you the results. PCR test results are not available immediately. It may take a few days to get your test result. After you get tested, you should isolate until you get your test result.

Rapid antigen tests can detect only high amounts of virus and are less sensitive than PCR tests. They work best when someone has symptoms of COVID-19 (this is called symptomatic). Antigen tests are most accurate during the first 5-7 days of your illness when your viral load is highest³. If you had symptoms of COVID-19 but your test result was negative, it may be a false negative test result. This means the antigen test did not identify the virus, but you do actually have COVID-19.

When antigen testing is used to test people who don't have symptoms (called asymptomatic) there is a higher chance of having a false positive result. This means your test result was positive but you don't actually have COVID-19.

³ https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html





¹ https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas#individual-anti

² https://www.fda.gov/media/135659/download

You may need to get a PCR test to confirm the results of your antigen test. You should get a PCR test within 24-28 hours after you got your rapid antigen test if:

- You have symptoms of COVID-19 but your rapid antigen test result was negative.
- You do not have symptoms of COVID-19 and were not in close contact with someone who has COVID-19 but your rapid antigen test result was positive.



Who should get a COVID-19 rapid antigen test?

Antigen tests work best when someone has symptoms of COVID-19 or had a known exposure to COVID-19. This means you came into close contact with a person who tested positive while he or she was infectious.

Antigen tests may be useful in certain situations for people who do not have symptoms. People who work or live in congregate care settings, like a nursing home or correctional facility, may need to get tested more often because there is such a high chance of COVID-19 spreading in these environments. Repeated use of antigen testing may be a more time and cost effective strategy to control the spread of the virus in these settings rather than waiting for the results of a PCR test.

Right now, there is not enough data to know if using antigen tests is effective for people with COVID-19 who do not have symptoms. The CDC has guidance for using antigen tests as screening tests for people who do not have symptoms of COVID-19 or who do not have a known exposure to COVID-19⁴. It is important for medical professionals and organizations who provide rapid antigen testing to understand the factors that can affect the accuracy of test results. Screening tests are often done in places like nursing homes and long-term care facilities⁵; correctional facilities⁶; workplaces⁷ that test employees; or schools⁸ that offer testing to students, faculty, and staff.

If your agency or organization provides rapid antigen testing, you should be aware of the <u>FDA EUA</u> for antigen <u>tests</u> and any potential implications for the <u>Clinical Laboratory Improvement Amendments (CLIA)</u> certificate of waiver.



What do my rapid antigen test results mean?

When you interpret the results of a rapid antigen test, you should consider how likely it is that you have COVID-19.

- Do you have symptoms of COVID-19?
- Were you in close contact (within 6 feet for a total of 15 minutes or longer) to someone who tested positive for COVID-19?
- Do you live or work in an environment where there are many cases of COVID-19?

⁸ https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/k-12-testing.html





⁴ https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html

⁵ https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-antigen-testing.html

⁶ https://www.cdc.gov/coronavirus/2019-ncov/community/correction-detention/guidance-correctional-detention.html

⁷ https://www.cdc.gov/coronavirus/2019-ncov/community/organizations/testing-non-healthcare-workplaces.html

How to interpret and respond to test results

Rapid antigen test result	If you:	If you:
	Have symptoms of COVID-19	Do not have symptoms of COVID-19
	OR	AND
	Had close contact* with someone who tested positive for COVID-19	Did not have close contact* with someone who tested positive for COVID-19
Positive	 Positive case of COVID-19 (this means you are positive and have COVID-19). You do not need a PCR test to confirm your rapid antigen test result. You should isolate right away. The health department will call you about your test result and ask who you may have been in close contact with. You should tell anyone who came into close contact* with you to quarantine for 14 days. 	 Presumptive positive (this means we assume you have COVID-19). You will be considered a confirmed case unless a PCR test is negative. You should isolate right away. Get a PCR test to confirm the positive antigen result. You need to get a PCR test within 2 days after your rapid antigen test. The test should be sent to a CLIA certified laboratory. The PCR result will be your official test result. The health department may call you about your test result and ask who you may have been in close contact with.
Negative	 Presumptive negative (this means we assume you do not have COVID-19). If you have symptoms: You should isolate until your negative test result is confirmed. Get a PCR test to confirm the negative antigen result. You need to get a PCR test within 2 days after your rapid antigen test. The test should be sent to a CLIA certified laboratory. The PCR result will be your official test result. If you test negative but had a close contact or known exposure to someone who tested positive for COVID-19, you must still complete your quarantine period. 	 Negative, not a COVID-19 case (this means you do not have COVID-19). You do not need to get a PCR test to confirm your rapid antigen test result. Once you have your test result, public health and medical providers will not need to follow-up about your test.

*A close contact or a known exposure means that you were within 6 feet of someone known to have COVID-19 for a total of 15 minutes or longer while the person was infectious. A person is infectious up to 2 days before his or her symptoms begin. If the person did not have symptoms, he or she is infectious up to 2 days before he or she was tested.

An antigen test will be considered a false positive and will not be counted as a positive COVID-19 case if:

- The sample specimen was taken correctly within the proper time frame
- The confirmatory PCR test result is negative
- You did not get symptoms of COVID-19

An antigen test will be considered a false negative if:

- The sample specimen was taken correctly within the proper time frame
- The confirmatory PCR test result is positive





Healthcare providers and public health workers should provide the same recommendations for a positive antigen test that they would a positive PCR test; most importantly, making sure the person knows to isolate right away. Case investigation and contact tracing for a positive antigen test will follow the same public health protocols as other positive test results.

How are rapid antigen test results reported to the Utah Department of Health?

All COVID-19 test results, including positive and negative rapid antigen results, must be reported electronically as required by federal law and the Utah <u>Communicable Disease Rule</u>. More information on COVID-19 reporting requirements, including the manner, timing, frequency, and required data elements, is available under the "Information for Laboratories and Testing Facilities" section of the <u>Recommendations for</u> <u>Providers</u> section of the coronavirus.utah.gov website. Any questions about reporting can be sent to <u>edx@utah.gov</u>.





