

Idaho Interim Guidance on Use of Rapid Antigen Tests for COVID-19

Revised March 2021

The U.S. Food and Drug Administration (FDA) has issued emergency use authorizations (EUAs) for several rapid antigen tests, which greatly increase point-of-care testing options for COVID-19.

Rapid antigen tests are less complex than most molecular tests and provide results in 30 minutes or less. As point of care diagnostics, they can be used in doctors' offices and other facilities with a valid Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver. Reverse transcription polymerase chain reaction (RT-PCR) testing, the gold-standard for COVID-19 diagnosis, is both highly sensitive and specific but requires more complex laboratory expertise and equipment and is not available as a point of care test. Rapid antigen tests are less sensitive than the RT-PCR test, which means that more viral particles must be present in the nose (or other approved sampling site) to generate the positive result. Lower sensitivity means that false negatives may occur more frequently, particularly very early or very late in the course of infection. All authorized rapid antigen tests have specificity similar to RT-PCR, which means that false positive results are expected to occur about as frequently as with an RT-PCR test. False positive results can occur and are most likely to occur in populations where the prevalence of SARS-CoV-2 infection is low.

People with COVID-19 disease tend to shed greater amounts of virus within the first five days of symptom onset. After viral shedding peaks, it steadily declines over 10 to 20 days depending on the patient's immune response and the severity of disease. Given this progression, rapid antigen tests are most likely to detect SARS-CoV-2 infections early in an illness and may be less useful for those who have been ill for over a week (see Figure 1). Since rapid antigen tests are most likely to yield a positive result during peak infectivity, they may be useful in asymptomatic serial screening, as a means of rapidly identifying infected and potentially infectious individuals. As part of a community mitigation strategy, serial screening programs can provide point of care testing with fast, actionable results to identify cases that might otherwise not be detected and limit silent spread.

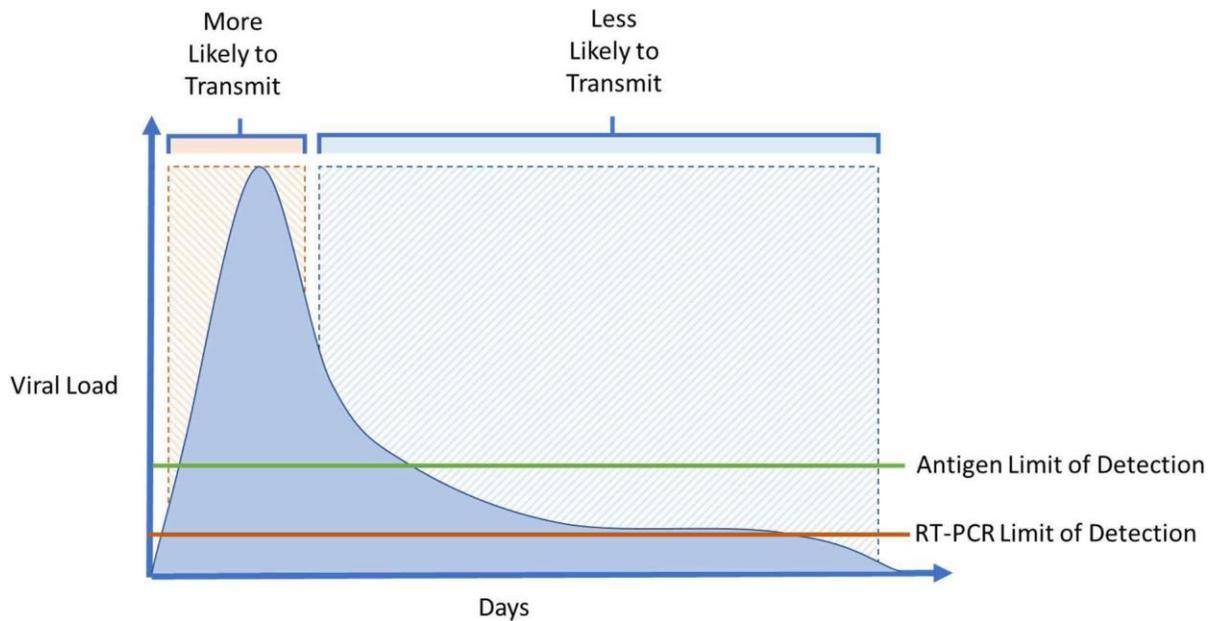


Figure 1 Illustration of timing of viral load (aka amount of detectable virus) relative to symptom onset, and relative sensitivity of antigen tests vs RT-PCR tests in detecting SARS-CoV-2.

Providers can have confidence in positive rapid test results for clinically compatible patients in locations with moderate to high disease prevalence. Confirmatory RT-PCR testing is not needed to confirm a clinically compatible positive rapid antigen test.

Negative antigen test results should be confirmed with RT-PCR testing if there is a high degree of suspicion or a known exposure to COVID-19.

See CDC guidelines on interpretation of antigen test results for further detail on when to perform confirmatory RT-PCR testing and mitigation protocols (<https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html>).

Please contact the Idaho Bureau of Laboratories at statelab@dhw.idaho.gov if you need support identifying an appropriate lab to implement confirmatory RT-PCR testing.

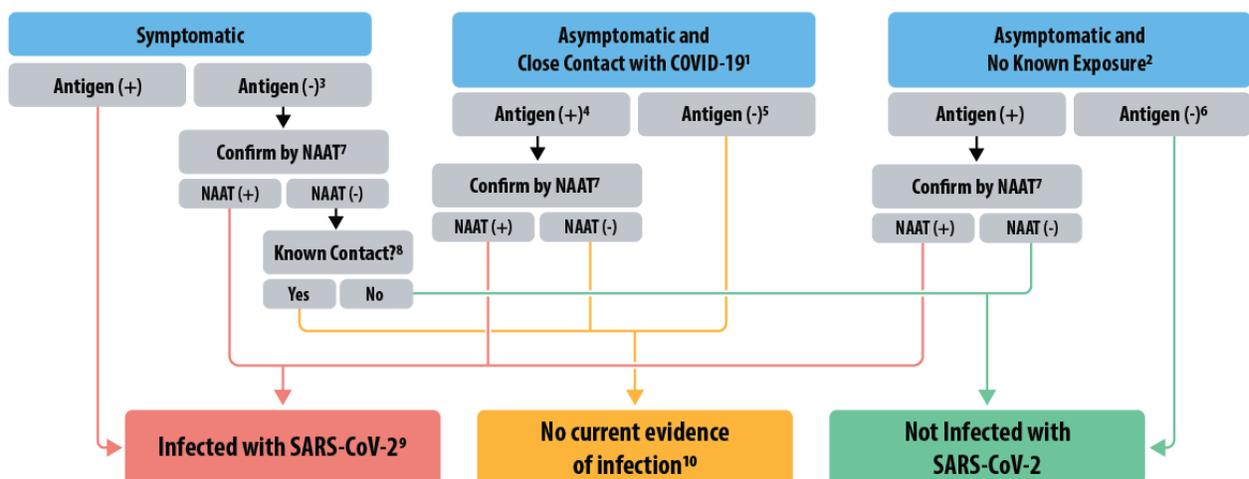


Figure 2 CDC guidance on confirmatory NAAT testing protocol for rapid antigen testing.

Recommendations:

- Rapid antigen tests have the best performance in individuals with COVID-19-compatible symptoms who seek medical care within the first 5-7 days after illness onset. Given the high specificity of rapid antigen tests, positive test results in this situation can be accepted without further confirmatory testing.
- Rapid antigen tests may be useful in settings where multiple people have COVID-19-like symptoms and need to be tested with a rapid turn-around time for infection control decision making (e.g. symptomatic staff and/or residents in group settings like long term care facilities, workplaces, schools, and correctional facilities).
- As part of a community testing strategy, rapid antigen testing may be useful for serial screening, including for asymptomatic persons at risk of exposure to SARS-CoV-2 but without a known exposure to an individual with confirmed SARS-CoV-2 infection. Although rapid antigen tests typically have lower sensitivity than RT-PCR tests, given their high specificity and rapid turnaround time, when used as part of a serial testing strategy, they can help limit viral transmission by identifying infectious individuals quickly. Examples may include workplace settings, students living in dormitories on college campuses, emergency medical services (EMS) providers, K-12 teachers in high-prevalence communities, or student-athletes engaged in higher risk sports (wrestling, basketball, etc). Providers should follow-up negative rapid antigen test results with RT-PCR testing in settings where the index of suspicion for COVID-19 is high.
- A negative rapid antigen test result should be considered a “presumptive negative” and should never be used as the sole criteria to permit the tested individual to engage in unprotected interaction with others, particularly in high-risk group settings such as congregate living facilities (e.g., long-term care facilities, correctional facilities, etc.), congregate employment settings, contact sports, schools, etc. It is essential that usual infection control mitigation measures remain in place (e.g., mask wearing, physical distancing, and hand hygiene).
- Results of all positive and negative rapid antigen tests should be reported to local public health districts or the Idaho Division of Public Health, Bureau of Communicable Disease Prevention, Epidemiology Section.
- RT-PCR remains the gold standard for clinical diagnostic detection of SARS-CoV-2. Any rapid antigen test result that is inconsistent with the clinical context (i.e., the pre-test probability) should be confirmed with a RT-PCR test. Please contact the Idaho Bureau of Laboratories at statelab@dhw.idaho.gov if you need support identifying an appropriate lab to implement confirmatory RT-PCR testing.
- RT-PCR testing is preferred for patients being tested who are: asymptomatic, later in the course of illness, hospitalized, in high risk settings (e.g., LTCFs), have severe illness, or patients whose clinical care requires the most sensitive testing available for clinical decision making.

References

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