IDAHO DEPARTMENT OF HEALTH & WELFARE
DIVISION OF PUBLIC HEALTH

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

Revised September 28, 2020

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).

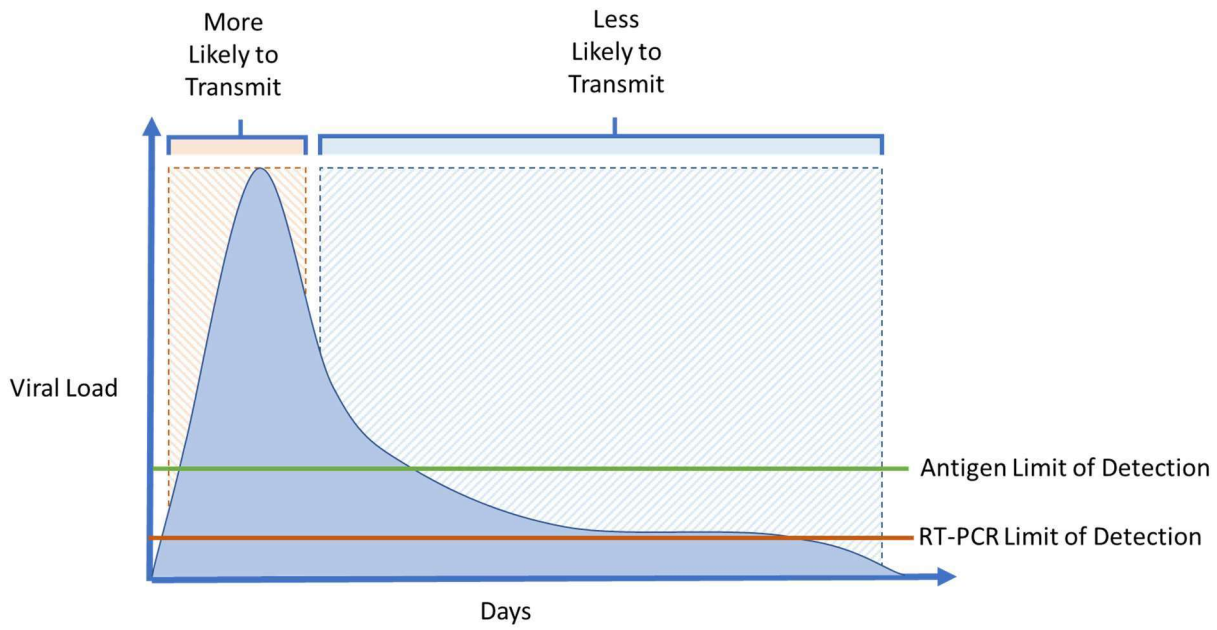

Figure 1 Illustration of timing of viral load (aka amount of detectable virus) relative to symptom onset, and relative sensitivity of antigen tests vs RT-PCR tests in detecting SARS-CoV-2.

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.

Recommendations:

- 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.
- RT-PCR testing is preferred for patients being tested who are: asymptomatic, later in the course of illness, hospitalized, have severe illness, or patients whose clinical care requires the most sensitive testing available for clinical decision making. RT-PCR testing is also preferred for healthcare workers.
- Rapid antigen tests are best used for 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).

- Rapid antigen testing may be considered for serial testing of individuals who are participating in group events in lower risk settings (such as outdoor group activities), although data to guide the use of rapid antigen tests as a screening test in asymptomatic individuals are limited.
- 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.
- 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.

References

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