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

August 10, 2020

The U.S. Food and Drug Administration (FDA) has issued emergency use authorizations (EUAs) for two rapid antigen tests which provide point-of-care testing options for COVID-19: Becton-Dickinson and Company's BD Veritor System for Rapid Detection of SARS-CoV-2 and Quidel Corporation's Sofia SARS Antigen FIA. Both rapid antigen tests detect the presence of the SARS-CoV-2 virus nucleocapsid (N) protein.

These rapid antigen tests are less complex to use than most molecular tests, provide results in 30 minutes or less, and can be done in doctors' offices and other locations with CLIA certificate of waiver. Polymerase chain reaction (PCR) testing, the gold-standard for COVID-19 diagnosis, requires more complex laboratory expertise and equipment, and is performed only in CLIA certified laboratories. The rapid antigen test is less sensitive than the PCR test, which means the patient respiratory samples will need to have about 100 times more virus in the sample to be positive compared to PCR testing. Although the sensitivity of rapid antigen tests is lower than most nucleic acid tests, the rapid antigen tests have comparably high specificity (99% per FDA-EUA package inserts). Despite high specificity, false positive results can occur and are most likely in populations where the prevalence of SARS-CoV-2 infection is low.

People with COVID-19 disease tend to shed greater amounts of virus in the first several days of symptoms and shedding is generally higher among symptomatic compared to asymptomatic persons. After viral shedding peaks, it steadily declines over 10 to 20 days depending on the patient's immune response and 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 people with asymptomatic infections or those who have been ill for several days (see Figure 1).

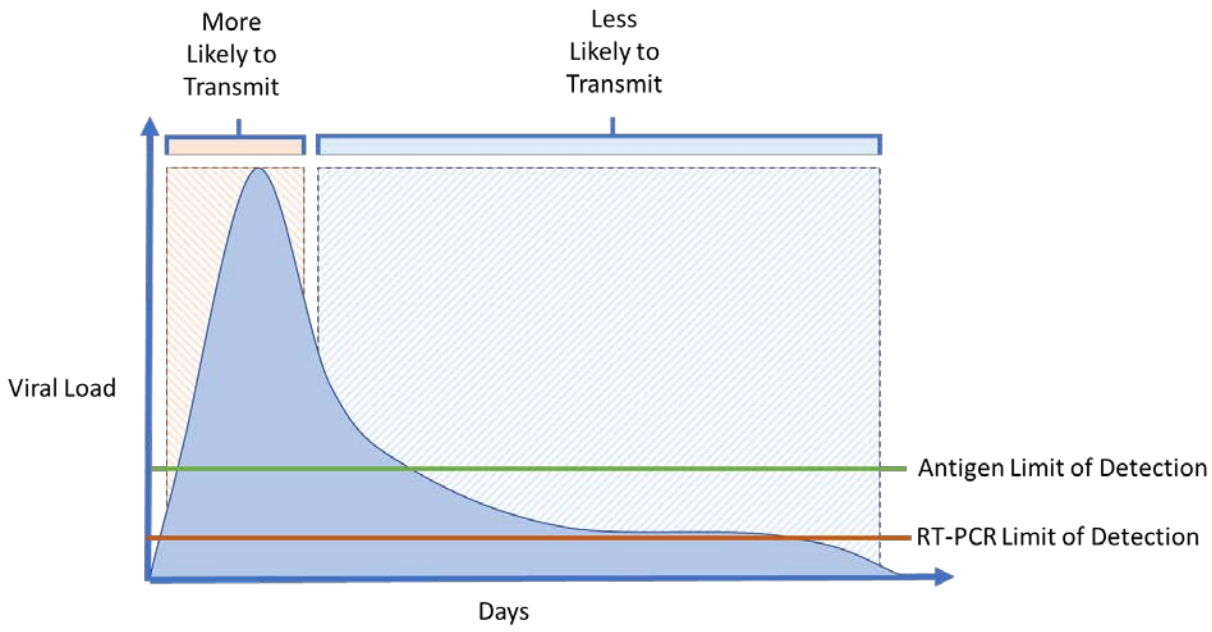

Figure 1 Illustration of timing of viral load (aka amount of detectable virus) relative to symptom onset, and relative sensitivity of antigen tests vs RT-PCR tests in detecting SARS-CoV-2.

Although providers can have confidence in positive rapid test results from specimens collected early in the course of illness, negative antigen test results should be followed with PCR testing if there is a high degree of suspicion for COVID-19.

Positive rapid antigen test results are adequate to diagnose a patient with COVID-19 when the patient has clinically compatible illness. No PCR testing is needed to confirm a positive rapid antigen test.

Recommendations:

- Rapid antigen tests are best used for individuals **with COVID-19-compatible symptoms who present for medical care within the first 5 days after illness onset**, or who may be seen in other 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.
- Because of lower sensitivity, providers should follow-up negative rapid antigen test results with PCR testing in settings where the index of suspicion for COVID-19 is high. Because of the possibility of a false negative results, a negative rapid antigen test result should never be used 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.
- 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. PCR testing is also preferred for healthcare workers.
- 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:

APHL. American Public Health Laboratories. Considerations for Implementation of SARS-CoV-2 Rapid Antigen Testing. Version 2, July 6, 2020. https://www.aphl.org/programs/preparedness/Crisis-Management/Documents/APHL-SARSCov2-Antigen-Testing-Considerations.pdf

CDC. Rapid influenza diagnostic tests. www.cdc.gov/flu/professionals/diagnosis/clinician_guidance_ridt.htm.

CDC. CDC Decision Memo Regarding Duration of Isolation and Precautions for Adults with COVID-19. https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html.

Kawasuji H, et al. Viral load dynamics in transmissible symptomatic patients with COVID-19. medRxiv preprint at doi.org/10.1101/2020.06.02.20120014.

FDA. FDA Emergency Use Authorizations. www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covidinvitrodev.