COLLEGE of AMERICAN PATHOLOGISTS

The ABCs of Rapid Antigen Testing for Consumers
October 16, 2020

1. **Is this considered a point-of-care test and what is that? Where do you get it (schools, doctors' offices, hospital, pharmacies)?**
   Antigen tests are immunoassays that detect the presence of a specific viral antigen, which implies current viral infection. Antigen tests are relatively inexpensive and can be used at the point of care. The currently authorized devices return results in approximately 15 minutes. Antigen tests for SARS-CoV-2 are generally less sensitive than molecular viral tests. Proper interpretation of antigen test results is important for accurate clinical management of patients with suspected COVID-19, or for identification of potentially infected persons when used for screening.

   Laboratory and testing professionals who conduct **diagnostic or screening testing** for SARS-CoV-2 with rapid antigen tests, even in a point-of-care environment, must also comply with Clinical Laboratory Improvement Amendments (CLIA) regulations and any state or local requirements. Any laboratory or testing site that intends to report patient-specific test results must first obtain a CLIA certificate and meet all requirements to perform that testing.

2. **Who can administer these tests? Teachers, parents?**
   Laboratory and testing professionals who conduct **diagnostic or screening testing** for SARS-CoV-2 with rapid antigen tests, even in a point-of-care environment, must also comply with Clinical Laboratory Improvement Amendments (CLIA) regulations. Any laboratory or testing site that intends to report patient-specific test results must first obtain a CLIA certificate and meet all requirements to perform that testing.

   Testing can only be performed in a laboratory with a CLIA certificate by personnel qualified to work in that laboratory.

3. **What does rapid antigen testing mean and how does it work?**
   Antigen tests are relatively inexpensive and can be used at the point of care. The currently authorized devices return results in approximately 15 minutes.
   These diagnostic tests quickly detect fragments of proteins found on or within the virus by testing samples collected from the nasal cavity using swabs. There are currently four SARS-CoV-2 antigen tests that have received emergency use authorization (EUA) from the Food and Drug Administration (FDA). All these tests are approved for point-of-care-testing by facilities operating under a CLIA Certificate of Waiver. The antigen test can provide results at the testing site and in minutes; however, antigen tests may not detect all active infections, based on their mechanism of action. These tests are very specific for the virus but are not as sensitive as molecular polymerase chain reaction (PCR) tests. Therefore, positive results from antigen tests are highly accurate, but there is a higher chance of false negatives, so negative results do not rule out infection. Negative results from an antigen test may need to be confirmed with a PCR (molecular) test prior to making treatment decisions or to prevent the possible spread of the virus due to a false negative.

4. **What are the concerns over false/negative/positive tests? If that happens what's the next step for the consumer or the next test they need to take? If negative but a person still has symptoms, does that then require a need for a PCR test?**
   The sensitivity of current FDA-authorized antigen tests varies, and thus negative diagnostic testing results should be handled differently depending on the testing device and its stated performance characteristics. In most cases, negative antigen diagnostic test results are considered presumptive. CDC recommends confirming negative antigen test results with an RT-PCR test when the pretest probability is relatively high, especially

if the patient is symptomatic or has a known exposure to a person confirmed to have COVID-19. Ideally, confirmatory RT-PCR testing should take place within two days of the initial antigen testing.

Antigen tests are very specific for the virus but are not as sensitive as molecular tests. This means that a positive result is highly accurate, but a negative result does not rule out infection. If a test result is negative, you should discuss with your health care provider whether an additional molecular test would help with care, and when home isolation should be discontinued. If an individual does not have an additional test to determine if they are infected and may spread the infection to others, the Centers for Disease Control and Prevention (CDC) currently recommends staying home until three things have happened:

- No fever for at least 72 hours (that is three full days of no fever without the use of medicine that reduces fevers) AND
- Other symptoms have improved (for example, when cough or shortness of breath has improved) AND
- At least 10 days have passed since onset of symptoms.

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5. **How important is specimen collection and timing of specimen collection with the rapid antigen tests since the specimen is not going to a laboratory?**
   All testing for SARS-CoV-2, including rapid antigen testing, is directly impacted by the integrity of the specimen, which depends on specimen collection and handling. Improper specimen collection may cause some swabs to have limited amounts of viral genetic or antigenic material for detection. Inadequate quality assurance procedures could result in cross contamination of the specimen, which could cause inaccurate test results. Delays from sample collection to testing should be minimized.

6. **Once you get the result is there a benefit to follow up testing and if so what is it?**
   If less sensitive tests, such as some rapid point-of-care tests, are used, health care providers should be aware of the performance of the tests and may want to consider different testing approaches, such as serial testing. "Negative" results should be considered as "presumptive negative," and health care providers should consider them in the context of clinical observations, patient history, and epidemiological information. Thus, if there is a significant new outbreak in a congregate care facility (nursing home) or high clinical suspicion of an infection in an individual resident, a negative point-of-care test should be confirmed with a highly sensitive molecular test (refer to CDC guidelines).

7. **If the test is positive, what should you do next?**
   What does it mean an individual has a positive test result? It is very likely that the individual has COVID-19 because proteins from the virus that causes COVID-19 were found in that sample. Therefore, it is also likely that an individual's health care provider may require isolation to avoid spreading the virus to others. There is a very small chance that this test can give a positive result that is wrong (a false-positive result). A health care provider will work with an individual to determine how best to care for the individual based on the test result(s) along with medical history, and current symptoms.

8. **If the test is negative, what should you do next?**
   A negative test result means that proteins from the virus that causes COVID-19 were not found in the sample. It is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. This means that an individual could possibly still have COVID-19 even though the test is negative. If a test result is negative, your health care provider will consider the test result together with all other aspects of the individuals medical history (such as symptoms, possible exposures, and geographical location of places you have recently traveled) in deciding further care. The amount of antigen in a sample may decrease the longer symptoms of infection have been present. Specimens collected after symptoms for more than seven days may be more likely to be negative compared to testing performed with a molecular assay. It is important that individuals work with their health care provider to help understand the next steps to take.

Reference: *CDC Coronavirus Disease 2019 (COVID-19): Interim Guidance for Rapid Antigen Testing for SARS-CoV-2.* Accessed Oct 10, 2020.