Patients are asking about antibody blood tests for COVID-19 as they are being discussed in the news and in social media. The nasal swab polymerase chain reaction (PCR) test is the only test meant to diagnose COVID-19.

**Why are antibody tests for COVID-19 problematic?**

Antibody blood tests alone are not meant to diagnose COVID-19 or to identify if a person has been previously infected. The FDA allowed these antibody tests to be quickly released under an Emergency Usage Authorization (EUA). Since the tests were released under the EUA, they were only authorized for use by a limited number of labs with special clinical and technical expertise. An Emergency Usage Authorization (EUA) does not mean that the test is FDA cleared or approved. There is limited data about the accuracy and reliability of these tests in patients. The FDA also notes that “We unfortunately see unscrupulous actors marketing fraudulent test kits and using the pandemic as an opportunity to take advantage of Americans’ anxiety. Some test developers have falsely claimed their serological tests are FDA approved or authorized. Others have falsely claimed that their tests can diagnose COVID-19 or that they are for at-home testing, which would fall outside of the policies outlined in our March 16 guidance, as well as the updated guidance. Also, since that time, the FDA has become aware that a concerning number of commercial serology tests are being promoted inappropriately, including for diagnostic use, or are performing poorly based on an independent evaluation by the NIH.”

**What are the recommendations for using antibody tests?**

While the CDC and the FDA discuss the antibody tests, some states specifically note that antibody tests are not recommended to reliably determine whether or not someone has experienced a past infection with COVID-19. Clinicians should follow the recommendations of the state where they practice. Clinicians should also familiarize themselves with which specific serology tests have been EUA authorized and the performance measures (sensitivity, specificity, positive predictive value (PPV) at a determined prevalence of disease, and negative predictive value (NPV) at a determined prevalence of disease) of the test they are ordering.
How should a healthcare provider interpret an antibody test?

Antibody tests for COVID-19 are still new, and these early tests need to be interpreted with caution. Negative antibody tests do not rule out COVID-19 infection. Patients may not have had time to develop an immune response or may not mount an immune response if they are immunocompromised. Positive antibody tests may be due to past or present COVID-19 or from some other coronavirus. There may be cross-reactivity with other common non-COVID-19 coronaviruses. Results from antibody testing need to be interpreted together with the presence of COVID-19 symptoms and nasal PCR test results. At this time, it is unclear if the antibodies measured can provide protection (immunity) against getting infected again or how long that protection may last. Antibody tests should not be used as the sole basis to diagnose or exclude COVID-10 infection or immunity for any reason.

What are COVID-19 antibody tests useful for?

While antibody tests are problematic when used to test for past infection in individual patients, they are useful to answer population-level questions about COVID-19 infections such as whether the prevalence of antibodies conveys immunity and if so, for how long and what is the prevalence of COVID-19 in different communities.

References