CommonSpirit

CommonSpirit Health
COVID-19 Antibody Testing Guidelines
May 1, 2020

Fundamentally there are two testing types for COVID-19. Molecular tests utilize polymerase chain reaction (PCR) techniques to detect the genetic material of the COVID-19 virus. These tests are useful for diagnosing active infection (when positive) and the resolution of the infection (when negative). In contrast, antibody (AB) tests use different techniques to detect the presence of antibodies that the immune system has developed in response to the infection and persist after the infection has cleared. This type of test is often used to determine the extent or spread of a disease in a community.

Numerous clinical laboratories across the country now offer and promote COVID-19 AB tests. The appropriate role of AB testing is controversial. Some companies and media reports suggest AB testing could be used for a variety of clinical and workplace purposes. However, experts in the fields of infectious diseases and clinical laboratory medicine believe COVID-19 AB testing currently has a very limited role.

These specialists note the accuracy and reliability of AB tests vary by different companies. Furthermore, there is as yet, an undiscovered understanding of whether or not the presence of antibodies confer immunity and protect from re-infection. The timing of when antibodies form (if at all) in people also varies and the duration of the presence of antibodies is unknown.

These issues raise important questions—what is the appropriate role of COVID-19 AB testing, and should CommonSpirit provide in-house testing?

Recently, an esteemed panel of infectious diseases and laboratory medicine physicians from across CommonSpirit Health discussed these issues and reached consensus. In brief, they concluded that because of the potential for testing inaccuracies and the unknown level of protection of antibodies, COVID-19 AB tests should not be used to make decisions regarding diagnosis, return-to-work following infection or use of personal protective equipment (PPE). Moreover, COVID-19 AB tests should not be used to stratify and deploy employees to specific COVID-19 (cohort) units. These positions are congruent with recommendations from the Infectious Diseases Society of America (IDSA).[1]

The attached Frequently Asked Questions (FAQs) provides additional, specific information.

Prepared by:
Robert Wiebe, MD, Chief Medical Officer
Heather Miller, MBA, Director, Physician Engagement
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[1] https://www.idsociety.org/globalassets/idsa/public-health/covid-19/idsa-covid-19-antibody-testing-primer.pdf

Are COVID-19 antibody (AB) tests FDA-approved?

The Food and Drug Administration (FDA) has used its Emergency Use Authorization (EUA) process to make several AB tests available to the public. Through this pathway, the FDA holds that the test is reliable and accurate, however, the traditional vigorous FDA approval process has not been enforced. AB tests by Ortho, Cellex, Chembio, Mount Sinai, Autobio and DiaSorin are now available. FDA publishes a current list at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd.

How accurate are the AB tests?

To be accurate, the test must recognize antibodies specific to the virus responsible for COVID-19, without reacting to similar antibodies that people may carry if they have been infected by related coronaviruses. Scientists assess the accuracy of diagnostic tests in two ways. Sensitivity is the ability of a test to correctly identify those with the disease (true positive rate), whereas specificity is the ability of the test to correctly identify those without the disease (true negative rate). There are varying degrees of specificity and sensitivity among the tests. Although reputable manufactures may claim their own product accuracy, none of these tests, even those with EUAs, have had their accuracy evaluated by the FDA.

Should AB tests be used to diagnose/detect active infection?

No. Because antibodies may not be produced in early infection, and some patients may not develop a detectable response due to underlying immune conditions, the presence of antibodies should not be used to indicate active infection. Molecular/polymerase chain reaction (PCR) testing is the preferred method of testing for COVID-19 as it measures presence of viral genetic material (i.e., antigen) rather than the body's immune response (i.e., antibodies).

Does the presence of ABs indicate immunity to COVID-19?

It is not clear. Based on studies of other viruses, the presence of antibodies suggests some level of immunity exists, but definitive studies for COVID-19 are pending. Also unknown is the level of antibody (titer) required for any immunity, and how long the suspected immunity lasts.

Should we use the AB test to make return-to-work decisions?

No. Since the degree and duration of immunity conferred by antibodies are unknown, AB tests should not be used for return-to-work decisions. There are suggestions that people might still shed virus and be contagious despite the presence of antibodies. Likewise, there are false positive and false negative results associated with the AB tests that limit their usefulness.

What should the AB test be used for?

Currently, the major role of AB testing is for epidemiologic studies to determine the prevalence or spread of the disease in a community. AB testing can also be used to screen convalescent plasma for possible therapeutic transfusions. Due to the uncertainties surrounding accuracy and unknown level of protection of immunity, AB tests should not be used to make decisions regarding use of PPE or return-to-work. People should continue to avoid risk of exposure to COVID-19 regardless of AB test results.

Should we have in-house AB testing capability at CommonSpirit Health?

Yes. In-house testing will allow us to support epidemiologic and other research studies. Second, it will be beneficial to have this capability in anticipation of new knowledge regarding the COVID-19 antibodies

and possible future national guidelines. As the tests improve we may be able to use for retrospective diagnosis and immunity status.