

June 4, 2020

Early on in the COVID-19 pandemic, the [FDA](#) changed its regulations to make it easier for companies to sell novel coronavirus antibody tests. Because of this, any company that notified FDA could distribute novel coronavirus antibody tests according to Section IV.D of the FDA's *Policy for Diagnostic Testing for Coronavirus Disease*. This was problematic for the quality of laboratory testing, however, as notification did not mean that the test has been reviewed or approved by the FDA.

Because of these issues, the FDA recently revised its position, and now requires EUA submission of coronavirus antibody tests for these tests to be marketed or distributed. This increases the scrutiny by which these coronavirus antibody tests are marketed, ensuring that the people of Indiana have access to good, quality, testing devices.

A complete listing of serology tests with Emergency Use Authorization can be found on the [FDA's website](#).

**Q. We are getting many offers for rapid COVID-19 tests that give results in minutes. Are these tests accurate and reliable?**

**A.** Not necessarily. Only tests with [Emergency Use Authorization](#) have met the FDA criteria.

**Q. Will ISDH Laboratory offer antibody tests for COVID-19?**

**A.** Our laboratory is in the process of bringing serology testing in-house.

**Q. How will ISDH use COVID-19 serology results?**

**A.** Indiana will focus on serology for prevalence testing, expanding use clinically only once more is known about the role of serology in assessing immunity to COVID-19.

**Q. If a COVID-19 antibody (IgM, IgG, or total antibody) test with proven performance is used, what clinical information does it provide?**

**A.** A positive result indicates that the person was likely infected with SARS-COV-2. This may not have clinical relevance for that individual. Patients with positive antibody tests can be classified as *presumptive* COVID-19 cases.

**Q. Does the presence of antibodies to COVID-19 mean the patient is infected?**

**A.** Not necessarily. It may indicate a past infection that has been cleared or a current infection which began within the past week or two.

**Q. Does the presence of antibodies to COVID-19 mean the patient is no longer contagious?**

**A.** No, patients can still be shedding infectious virus even though they have an antibody response. It also doesn't mean that they are immune because we don't know if this antibody response is enough to protect someone from re-infection or for how long.

**Q. Does the presence of antibodies to COVID-19 mean the patient is immune to reinfection?**

**A.** We don't know that yet. The antibody tests do not indicate whether the antibodies are neutralizing and protective or not.

**Q. Are there any disadvantages or concerns with using the antibody tests, even the authorized tests?**

**A.** Patients who are told their antibody test is negative may decrease social distancing efforts, thinking they are not infectious. This could be dangerous, as a patient can be infected and shedding virus to other people but not have developed antibodies yet. Anyone who is told their antibody test is positive may also decrease social distancing efforts, thinking that they are not at risk for infection any longer. This could be dangerous, as even the approved tests may produce false-positive results; a person can also carry the virus without showing symptoms, which can increase spread to vulnerable individuals.

**Q. So even the authorized tests can produce false-positive results?**

**A.** Yes. Serology tests can produce false-positive results. This has to do with the positive predictive value of the test, or the likelihood that a positive test result represents a true positive. There are two things that impact the positive predictive value of a test, first, the specificity of the test. Most of the tests that have received authorization have demonstrated that they have specificity for COVID-19. The second thing, however that helps determine the positive predictive value of a test, is how common a disease is in the community. The more common a disease is, the less false positives are observed by serology testing. Because COVID-19 is still relatively rare in the population (ex. 1-5%), the likelihood that a positive serology result is a true positive, and not a false positive, is higher than if COVID-19 were more prevalent in our communities (ex. 40-50%).

**Q. Can we use antibody test to make decisions about grouping persons residing in congregate settings (e.g. school dormitories, long-term care facilities, correctional facilities)?**

**A.** No, because the antibody test does not give information on the infectious status, it is not useful for this purpose.

**Q. Can we use antibody test to determine if an employee can go back to work?**

**A.** Because the antibody test does not give information on the infectious status, it is not useful for this purpose. Refer to the CDC [guidance](#) for when infected employees may return to work.