Providence St. Joseph Health

Infectious Disease Clinical Decision Team and Laboratory Services Joint Statement on Serologic Testing for SARS-CoV-2 Antibodies (COVID-19) for Healthcare Providers
April 28, 2020

Situation: Many reference labs and test vendors now offer antibody testing against SARS-CoV-2 (COVID-19). The state of science on antibodies produced during SARS-CoV-2 infection is unclear.

Background:

- There is no gold standard for testing. Different tests show varying sensitivities and specificities in detecting antibodies.
  - The prevalence of seroconversion has been reported as low as 67% and as high as 100% in the literature using various antibody tests.
  - FDA Emergency Use Authorization has been granted to a few tests only. There are many more tests on the market that have not been vetted by the FDA in any way. Even if Emergency Use Authority is given to a serology test, the validation is <u>not</u> equivalent to the exhaustive evaluation normally required, particularly in regards to cross-reactivity to endemic coronaviruses that cause the 'common cold'.
- People may or may not produce antibodies to SARS-CoV-2 after exposure. Those who do seroconvert generally do so by day 10 after symptom onset. Antibodies are not yet present when patients are acutely infected, whether or not they are symptomatic.
  - Immunocompromised people and people with very mild symptoms/low viral loads may not seroconvert.
  - IgM seroconversion is not seen in a significant subset of people and may be delayed.
  - IgG seroconversion is seen more often and is seen at highest peak 14 days or more after symptom onset.
- People who are producing antibodies may still test positive for SARS-CoV-2 by nucleic acid amplification test (NAAT) testing, raising the possibility that they are still contagious.
- The antibodies have not yet been shown to be immunoprotective. The duration of antibody production is also unknown.

Assessment and Recommendation:

1. Serologic testing cannot be used as a sole method to diagnose COVID-19.
2. A positive test may indicate the patient has been exposed to the virus, especially in the context of a compatible clinical history (i.e COVID-19-like illness, close contact with known positive individual, etc).
   a. In a population with low disease prevalence or in asymptomatic individuals, the false positive rate could be higher than true positive rate.
3. A negative test does not rule out the patient has been exposed to the virus or cannot infect others. Repeat testing in 5 to 7 days may be warranted.
4. A positive test does not imply immunity or that the patient is not currently contagious.
   a. <u>These tests cannot be used to inform return to work decisions, staffing decisions or use of personal protective equipment.</u>
5. It is unclear if Medicare/Medicaid or private insurance will pay for this testing. The patient may be liable for payment.

Below is the excerpt from the Infectious Disease Society of America IDSA COVID-19 Antibody Testing Primer, April 22, 2020*:
"As serological testing for SARS-CoV-2 advances, there are multiple issues that need to be addressed, from test quality to interpretation. Unlike molecular tests for COVID-19 (e.g., PCR), antibody tests may be better suited for public health surveillance and vaccine development than for diagnosis. The current antibody testing landscape is varied and clinically unverified, and these tests should not be used as the sole test for diagnostic decisions. Further, until more evidence about protective immunity is available, serology results should not be used to make staffing decisions or decisions regarding the need for personal protective equipment."

https://www.idsociety.org/news--publications-new/articles/2020/emphasizing-need-for-more-information-idsa-releases-antibody-testing-primer2/
https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-serological-test-validation-and-education-efforts
"Immunity passports" in the context of COVID-19" Scientific Brief, 24 April 2020 World Health Organization