COVID-19 Serology (Antibody) Testing – May 29, 2020 1600

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What is COVID-19 Serology Testing?
- Serology testing measures the body's immune response to COVID-19 infection in the form of antibody production against the SARS-CoV-2 virus.
- There is a single COVID-19 serology order available in Epic, however, the Spectrum Health laboratory performs a two-step antibody test to increase specificity and avoid reporting false positive results. An initial screen will be used to measure total antibody (IgA, IgM, and IgG), and positives will be confirmed by a second method that is specific to IgG. The positive predictive value of a positive result for IgG by out test methodology is approximately 100% regardless of the prevalence of SARS-COV-2 in the community.
- Specificity is critical when the expected prevalence in a community is low. This serology testing is not expected to cross-react with other circulating coronaviruses that cause the common cold.

What does a positive COVID-19 Serology test indicate?
- ***A positive IgG result indicates previous infection with COVID-19, but at this time it is unknown if presence of IGG antibodies indicates immunity or protection against future infection with SARS CoV-2.***
- This test should not be used to detect acute COVID-19 disease. Symptomatic patients suspected to have acute COVID-19 infection should be tested using a nasopharyngeal molecular assay.
- Whether positive or negative for the presence of COVID-19 antibodies, serology testing results do not support easing of behaviors such as employee restrictions, social distancing, wearing masks, or hand hygiene.

Does a positive COVID-19 Serology test indicate a need for isolation?
- Because a positive IgG result indicates previous infection, there is no need to initiate isolation based upon a positive serology test.
- Per routine care, isolation should be initiated based upon a patient's symptoms, travel screen, and/or positive molecular assay for COVID-19.

Who can be tested?
- Serology testing is recommended only for individuals at least 10-14 days either post-symptom onset or following an exposure to individuals with confirmed COVID-19 infection. Patients tested prior to this time may be falsely negative for IgG antibodies.
- Immunocompromised patients may have a delayed antibody response or may not have detectable levels of antibodies with exposure.
- Serology testing should NOT be utilized in place of routine pre-operative or pre-admission screening.

Inpatient indications for SARS CoV-2 antibody testing include:
- *Adults*:
  - Assessing for presence of IgG antibodies to evaluate for potential convalescent sera donation in a patient without a history of previous positive COVID-19 molecular test
- *Pediatrics:*
  - Incomplete or complete Kawasaki Disease

- Pediatric multisystem inflammatory syndrome in children (MIS-C)

It is strongly discouraged that SARS CoV-2 antibody testing be done on inpatients unless any of the above indications are met.

Ambulatory indications for SARS CoV-2 antibody include determination of previous exposure in patients who have had:
- COVID-19 compatible symptoms > 10 days prior
- Known or possible exposure > 10 day prior
- No previous history of positive COVID-19 molecular test

Do all potential candidates for convalescent sera donation need a COVID-19 antibody test?
- Patients with a previous history of confirmed COVID-19 by molecular testing DO NOT antibody testing to be considered for potential convalescent plasma donation.
- IgG antibody testing for potential convalescent plasma donation is warranted in patients with a recent history of an illness suspicious for COVID-19 that was not confirmed by molecular testing or had exposure to a known case of COVID-19

How does testing occur?
- Testing requires an order from a provider,but is not restricted to certain patient groups based on symptoms or risk factors for severe disease.
- Testing specifics:
  - Epic Order: "COVID-19 IgG Antibody"
  - A serum specimen (gold top tube) is required for testing by immunoassay methodology.
  - Turnaround time from collection to result is expected to be less than 24 hours.
  - The list price for serology testing is $45 per test, but it is anticipated that most insurance plans will support COVID-19 serology testing.
  - Spectrum Health draw sites for specimen collection: https://www.spectrumhealth.org/locations

When will testing be available?
- COVID-19 serology testing is expected to go-live May 21 with an initial availability of approximately 1,000 tests per day.