
Summary statement: As of 4/21/2020 the CT DPH, CDC, WHO, and Infectious Disease Society of America recommend against serologic testing for clinical decision-making, staff distribution, or to adjust measures aimed at reducing infectious exposure.

Situation: There is high interest in the potential role for SARS-CoV-2 serologic testing to identify immune protection from Covid-19. The concept of an “immune passport” has been suggested to inform decisions about social distancing measures, staff distribution, and return to work. Use of serology has been proposed for documenting past Covid-19 exposure. Guidance on test indications and interpretation is urgently needed.

Background: High sensitivity and specificity for detection of SARS CoV-2 exposure by serology has been reported in hospitalized patients 14 days after symptom onset. Sensitivity and specificity for determination of immunity or viral exposure in non-hospitalized patients is unknown. As a result:

1. Positive serologic testing may indicate prior infection and may help document infection in those who were not tested for virus or tested negative for viral RNA.
2. False negative results may occur if tested <11d post symptom onset, prior to IgG rise.
3. It is unknown if a detectable antibody response is required for immune protection.
4. It is unknown if positive serologic testing indicates short term or long-term immunity.
5. Serologic testing does not currently provide any information on risk of infecting others.
6. High false negative and false positive rates may occur with unproven assays, such as due to cross reactivity with other coronaviruses, which could dangerously lead to a false sense of security.

Assessment: Uncertainty in serologic test performance is mainly a result of limited understanding of this new disease and lack of test experience in non-hospitalized individuals.

Until more data is available, serologic testing has limited utility. Inappropriate use may create risks to those who presume they are protected and to those with whom they interact. Ongoing studies will clarify the role of serologic testing at both the individual and public health level.

Recommendations

- Routine serological testing is not currently recommended in any patient population although positive result may indicate prior infection
- Serology should not be used to diagnose acute Covid-19; use RNA test (e.g. PCR) instead
- If ordered, serologic testing should be
  o performed a minimum of 11 days after onset of symptoms
  o limited to IgG at this time
- Clinical decision making should not be influenced by serologic status. Importantly, adjustment of infection precaution measures should not be based on serologic testing results
- Beware of testing scams including direct-to-consumer labs and fraudulent test kits

Connecticut Department of Public Health (4/21/20): "The FDA states that it is not aware of any antibody test that can prove a current COVID-19 diagnosis. Until further studies are conducted, these tests cannot reliably determine who might have had COVID-19 and who might be immune to COVID-19. It is important to note that most of the antibody test kits have not been reviewed or approved by the FDA, and negative results to do not rule out SARS-CoV-2 infection."

Infectious Disease Society of America (4/20/20): "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...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."