

USET Tribal Epidemiology Center Recommendations for Tribal Consideration

USET TEC COVID-19 Guidance 2020-007:

Recommendations for Antibody Testing

(Issued 5/13/2020, updated 8/24/2020)



Background

Covid-19, the disease caused by the novel coronavirus SARS-CoV-2, first appeared in China in late December 2019. Due to rapid spread, it was declared a pandemic by the World Health Organization on March 11, 2020. The virus was identified quickly and its genome was sequenced by scientists in China, who shared the genetic sequence with the world on January 12, 2020. This genetic sequencing led to the rapid development of polymerase chain reaction (PCR) tests to diagnose acute cases. This also has assisted in developing serological tests (tests for antibodies to SARS-CoV-2). The following updated recommendations are based on current information from the World Health Organization (WHO), the Centers for Disease Control and Prevention (CDC), and the US Food and Drug Administration (FDA) and replaces our previously issued *Recommendations for Tribal Consideration: Recommendations for Antibody Testing*.

Potential Uses for Antibody Testing

Testing for antibodies for SARS-CoV-2 has the following potential uses:

- To determine if a patient has been infected in the past with the virus (antibodies take at least 1 to 3 weeks to develop after a person is infected).
- To do seroprevalence studies to determine the rate of infection in a given population, as well as to determine a truer mortality rate for the disease.
- To identify potential donors for convalescent plasma for treatment of severe cases.

Cautions Regarding Antibody Testing

There are several things to be aware of regarding antibody testing:

- Not all people who are infected develop detectable antibodies to SARS-CoV-19
- Currently, the degree to which antibody production confers immunity is unknown
- Early infection, antibodies may not be present at detectable levels
- The actual sensitivity and specificity in the clinical setting of some of the various tests available are currently either unknown or only imperfectly known
- Some antibody tests may cross-react with other antibodies to organisms other than SARS-CoV-2, such as other common human coronaviruses
- A false-positive test could lead to complacency on the part of the patient and increase their risk of becoming infected
- Even a true positive test does not mean that standard precautions, such as social distancing, mask wearing, hand washing, and the use of Personal Protective Equipment (PPE) by healthcare workers may be discontinued

Recommendations

Until more is known, particularly about whether antibody production confers immunity, antibody testing for SARS-CoV-2 has limited usefulness in the clinical setting. This is a rapidly evolving field so recommendations may change. Results of any antibody testing must be considered in light of other evidence, such as patient symptoms, known exposure history, and the statistical performance of the test. An antibody test may be useful in certain cases:

- A patient who has symptoms and ancillary test findings (lab, imaging) suspicious for Covid-19 who tests negative on a molecular (PCR) test.

The USET Tribal Epidemiology Center (TEC) is charged under the Indian Health Care Improvement Act with providing epidemiologic and public health support to federally recognized Tribal Nations in the Nashville Area. The USET TEC is a designated public health authority.

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- A patient presenting late in the course of illness (more than a week after onset of symptoms), when a molecular test is more likely to be negative, and an antibody test is more likely to be positive (the molecular testing should still be done).
- A young patient presenting with symptoms of Multisystem Inflammatory Syndrome in Children (MIS-C), which is thought to be a late sequela of COVID-19 infection, at a time when a molecular test is likely to be negative.
- A patient who had symptoms of COVID-19, but was never tested, and there is an important reason to know whether the patient actually had COVID-19 (but remember, it is unknown whether antibodies confer immunity).

Specific Antibody Tests

There are now many commercially available antibody tests. More than 20 tests now have Emergency Use Authorization (EUA) from the FDA, and only tests with EUA should be used. If there is a good reason to perform an antibody test, the clinician responsible for ordering the test and interpreting the results should be familiar with the specific test and its performance characteristics. The Positive Predictive Value (PPV) of a test is the probability that individuals with positive test results are truly positive. The PPV of an antibody test is affected by a test's sensitivity, specificity, and the percentage of truly antibody positive individuals in the population (the local prevalence of the disease). In a low prevalence situation, the specificity of a test must be very high to achieve a good PPV. There are several currently available antibody tests with a specificity of >99.5% (this is the level of test specificity needed in a low prevalence situation to achieve a reasonably high PPV). These may be found on the [FDA website](#).

Seroprevalence Surveys

A seroprevalence survey consists of sampling a representative number of persons in a defined population for antibodies. This type of study can yield valuable information about the spread of a disease. However, for the study to be accurate and meaningful, it must be well-planned and well-executed. The CDC is currently conducting several seroprevalence surveys in the US. For more information, see the [CDC website](#).

Summary

Until more is known about immunity to COVID-19, antibody testing has limited clinical application (see above under Recommendations). Current recommendations from WHO and CDC state that a positive antibody test in an individual does not mean that the individual is definitely protected from infection, and does not remove the need for the use of PPE and other standard precautions, such as social distancing. Community seroprevalence surveys should only be done with expert consultation and advice in order to have meaningful and accurate results.

Additional Resources

- The CDC has an excellent overview of antibody testing: [Interim Guidelines for COVID-19 Antibody Testing](#).
- The FDA has several good resources:
 - [A summary of antibody test characteristics and performance](#).
 - [All antibody tests with current Emergency Use Authorization](#).
 - A number of antibody tests have been listed as [Should No Longer be Used and/or Distributed for COVID-19](#).
- The World Health Organization has useful [technical advice](#).
- The Association of Public Health Laboratories (APHL) and the Council of State and Territorial Epidemiologists have put out a joint document entitled [Public Health Considerations: Serologic Testing for COVID-19](#).