



Statement on Serologic Testing for SARS-CoV-2

May 6, 2020

AUDIENCE: Healthcare providers and interested members of the public.

BACKGROUND:

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) which first appeared in Wuhan, China in December 2019 and has since spread worldwide. Coronavirus is a single-stranded RNA virus. It has a viral envelope consisting of a lipid bilayer where several structural proteins are anchored, including the spike (S) protein. Inside the envelope there is the nucleocapsid, which is formed from the nucleocapsid protein (N) bound to the single-stranded RNA genome. Both the S and N proteins are highly immunogenic and represent targets for production of neutralizing antibodies in the human host. The immune response against the virus plays a role in determining the course of COVID-19 disease but has yet to be fully understood.

Diagnostic testing for SARS-CoV-2 is currently conducted via detection of viral RNA via real-time reverse-transcription polymerase chain reaction (RT-PCR) from nasal and pharyngeal swabs, bronchoalveolar lavage, and blood plasma.

Serologic testing for SARS-CoV-2 by means of detecting IgM or IgG antibodies to the virus is the subject of this Statement.

WHAT IS THE ROLE OF SEROLOGIC TESTING FOR SARS-CoV-2?

Serologic (antibody) tests for SARS-CoV-2 can be used to track the spread of disease as part of surveillance efforts. These tests can help us understand the extent of current and past COVID-19 infections in the community, and how far the pandemic has progressed.

SFDPH does not currently recommend the use of serologic tests to diagnose or exclude SARS-CoV-2 infection, and results from these tests should not be used as the sole basis for treatment or patient management decisions. While there are over 150 laboratories and manufacturers marketing COVID-19 serologic tests, none have been validated for the diagnosis of SARS-CoV-2 infection. Additionally, only a few serologic tests have been reviewed by the US Food and Drug Administration (FDA) and issued an Emergency Use Authorization. Most serologic tests have not been reviewed or authorized by the FDA. **As serologic tests currently on the market might not be reliable, test results must be interpreted with caution:**

- Antibodies may not be detected during early days of infection. It can take 1-3 weeks after symptoms occur to develop antibodies to SARS-CoV-2. Therefore, a negative serologic test result does not rule out infection.
- False positive results are possible due to past or present infection with other coronavirus strains.
- There is limited information on whether the presence of SARS-CoV-2 specific antibodies can reliably determine if someone is no longer infectious or whether that person is immune to reinfection or how long any immunity may last.



- Information to help patients understand their serologic test results can be found here: <https://www.cdc.gov/coronavirus/2019-ncov/testing/serology-overview.html>
- A list of commercial manufacturers and laboratories that have notified the FDA that they have validated tests and are offering serologies tests is available in the FDA [What Laboratories and Manufacturers are Offering Tests for COVID-19](https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2#offeringtests) FAQs (posted at www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2#offeringtests, under “*What serology tests are being offered under the policy outlined in Section IV.D. of the Policy for Diagnostic Tests for COVID-19*”).

Because all existing serologic tests are currently classified as moderate or high complexity, they can only be performed by a laboratory with a CLIA certificate of compliance or certificate of accreditation and California clinical laboratory license. Results from antibody/serologic tests for SARS-CoV-2 should be reported through the [CalREDIE Electronic Laboratory system](https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/CalREDIE-ELR.aspx) (at www.cdph.ca.gov/Programs/CID/DCDC/Pages/CalREDIE-ELR.aspx).

This statement is current as of the posted date.