Antibody/Serology Tests for SARS-CoV-2

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Antibody tests alone cannot be used to detect SARS-CoV-2, the virus that causes COVID-19.

There is great interest in using serology tests to determine past or present SARS CoV-2 infection and immunity in patients. At this point in time, however, there are no antibody tests that have been validated for the diagnosis of SARS-CoV-2 infection, and the utility of the currently available serologic assays has not been established. Due to concerns about both false negatives and false positives, health care providers should use caution when interpreting the results of serologic tests for SARS-CoV-2 until there is additional data on their best use.

Serology tests for SARS CoV-2 should not be used to definitively diagnose or exclude SARS-CoV-2 infection, and results should be interpreted with caution. As antibodies may not be detected during early days of infection, a negative result does not rule out infection. False positive results are also possible due to past or present infection with other coronavirus strains. In addition, there is limited information about whether the presence of SARS-CoV-2 specific antibodies can reliably determine if someone is no longer infectious, whether that person is immune to reinfection, or how long any immunity may last (http://publichealth.lacounty.gov/eprp/lahan/alerts/LAHANCOVID041620.pdf).

The U.S. Food and Drug Administration (FDA) states that is not aware of an antibody test that has been validated for the diagnosis of COVID-19 infection. While the FDA remains open to submissions of these tests for such uses, based on the underlying scientific principles of antibody tests, they state that they do not expect that an antibody test can be shown to definitively diagnose or exclude COVID-19 infection (www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2#serology).

Antibody tests may indicate whether someone has been exposed to SARS-CoV-2.

Using this type of test for many patients may help the medical community to better understand how the immune response against the SARS-CoV-2 virus develops in patients over time and how many people may have been infected. While there is a lot of uncertainty with this new virus, it is also possible that, over time, broad use of antibody tests and clinical follow-up will provide the medical community with more information about whether and how long a person who has recovered from the virus is at lower risk of infection if exposed to the virus again. (www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2#serology).

As of April 15, 2020, four antibody tests have been approved by the FDA for emergency use authorization: Cellex, Ortho Clinical Diagnostics, Chembio Diagnostic Systems, and the Mount Sinai Laboratory.