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Provider Alert: SARS-CoV-2 Serology Testing Information
April 27, 2020

Key Messages

- Results from serologic tests should not be used as the basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
- Some serology tests are being falsely marketed as "FDA authorized" or "FDA approved" and as CLIA-waived point of care (POC) tests. No serology tests are currently approved for use in the POC setting.
- At the current time, healthcare providers should report any serology tests results (positive and negative) to Santa Barbara County Public Health Department via CalREDIE.
- Laboratories should report only the results from serologic tests that have an FDA Emergency Use Authorization (EUA).

Situation

There is great interest in using serology tests to determine past or present SARS CoV-2 infection and immunity in patients. The clinical value of serologic antibody testing has not been clearly demonstrated. Serologic testing should not be used routinely to assess patients for acute infection or long-term immunity.

- Serologic testing should not be used to diagnose acute infection.
- False negative results can occur, particularly early in infection.
- False positive results are also possible due to potential cross-reactivity with routine coronaviruses that cause mild respiratory infection (e.g. HKU1, NL63, OC43, 229E).
- At this point, serologic testing for the presence of SARS-CoV-2 specific antibodies has not been determined to provide reliable evidence of immunity.
- Providers should use caution when interpreting the results of serologic tests for SARS CoV-2.

On March 16, in order to accelerate the availability of COVID-19 diagnostic tests, the FDA published a revised Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency which allows developers to market their tests without prior FDA review if certain conditions are met. This policy has led to some confusion and created the opportunity for false claims by some companies that their serological tests are FDA approved or authorized, or that they can diagnose COVID-19, see the FDA COVID-19 April 7 update: Serological Tests.

As of 4/22/20 the FDA has granted to two cassette-based serologic tests and two high throughput enzyme immunoassays. All four assays must be performed at either a moderate

or high complexity CLIA-certified laboratory and **are not for point-of-care or at home use**. A complete list of tests that have FDA EUAs can be found here**.**

Use of Serologic Tests
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 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.

While antibody tests by themselves are of limited value in the immediate diagnosis or screening of individual patients, serology can help us understand the current and past prevalence in the community, how far the pandemic has progressed, and, in the future, may potentially inform strategies for return to work, along with other clinical data.

For more information, see FDA Serology/Antibody Test FAQs, "*If antibody tests are not used for diagnosis or exclusion of SARS-CoV-2 infection, what is their purpose?*"

Serology Tests without an EUA
These tests have not been reviewed by the FDA, have not been FDA authorized, and have not received a CLIA categorization. Without an EUA, the tests are considered high complexity and may not be performed as moderate or waived complexity tests.

Under the current policy during this public health emergency, the FDA is allowing the use of SARS-CoV-2 antibody test kits without an EUA if the test has been validated, the FDA has been notified, and the following information is included in the test reports:

- This test has not been reviewed by the FDA.
- Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
- Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
- Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.

*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 FAQs, see "*What serology tests are being offered under the policy outlined in Section IV.D. of the Policy for Diagnostic Tests for COVID-19*".