LAHAN
Los Angeles County Health Alert Network

LAC DPH Health Advisory:

SARS-CoV-2 Serology

April 16, 2020

County of Los Angeles
Public Health

This message is intended for all healthcare providers in Los Angeles County.
Please distribute as appropriate.

Key Messages

- Results from serologic tests should not be used as the sole 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 not report any serology tests results to LAC DPH. Laboratories should report only the results from serologic tests that have an FDA Emergency Use Authorization (EUA). Labs should report both positive and negative results through Electronic Laboratory Reporting (ELR) or fax (see Reporting for more information).

Situation

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. Providers should use caution when interpreting the results of serologic tests for SARS CoV-2 until there is additional data on their best use because of concerns of both false negative and false positive results.

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**.** The FDA has been notified of over 70 serologic assays for COVID-19 but has only authorized four EUAs for clinical laboratories as of April 15, 2020. 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

There are currently over 70 commercial manufacturers and laboratories* marketing serologic assays for COVID-19 antibody testing without an EUA under the new FDA policy. 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, see FDA General FAQs "*When tests are offered prior to or without an EUA…what is their CLIA categorization*?"

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.

See FDA Serology/Antibody Test FAQs, "*Can I offer my SARS-CoV-2 antibody test kit without and EUA*?"

*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*".

Visit the LAC DPH COVID-19 Provider website for up-to-date resources and guidance.

Refresh your browser to view the latest versions

http://publichealth.lacounty.gov/acd/ncorona2019/

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