April 21, 2020

CDPHE COVID-19 Serological Testing Guidance for Labs and LPHA

During the ongoing COVID pandemic, many companies are distributing rapid serological test kits to detect IgM and/or IgG antibodies in COVID-19 patients. Some of these tests are being marketed as rapid, point-of-care tests (POC) for use outside the laboratory setting. As of April 21, 2020, none of these tests have been evaluated or approved for this type of use. CDPHE discourages the use of any serological assay that has not been approved by the FDA or at the state level, for any purpose other than research. Furthermore, until better information about test accuracy and immunity following infection is available, CDPHE recommends against using unapproved antibody testing for purposes other than epidemiological studies, convalescent plasma donation and research.

As of April 21, 2020, no COVID-19 serological tests have been reviewed by or received Emergency Use Authorization for use outside the moderate or high complexity CLIA laboratory setting.

As of April 21, 2020 there are four serological tests that have been granted Emergency Use Authorization (EUA) by the FDA for COVID-19 testing. FDA EUA's COVID-19 tests are listed here https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations
These serology tests have been approved to test blood products from patients suspected of COVID-19 infection, and testing must be performed inside CLIA high and moderate complexity laboratories.

There is no CDC guidance for public health action or interpretation of results from serological testing. The Infectious Disease Society of America has released a COVID-19 Antibody Testing Primer (https://www.idsociety.org/globalassets/idsa/public-health/covid-19/idsa-covid-19-antibody-testing-primer.pdf) that provides context on the background and interpretation of antibody tests for COVID-19. Results from all COVID-19 testing, including serological testing, must be reported to CDPHE.

Use of serological tests may give a false sense of safety to patients. While results from these tests may indicate that a patient has been exposed to COVID-19, they cannot reliably determine if the patient is currently infected. Due to open questions related to antibodies and immunity, serological tests can not definitively predict whether a patient will be immune to infection with the virus in the future, or if they can currently spread the virus to others. Negative antibody test results can be the result of testing early in the infection, prior to the development of a strong immunological response. Additionally, antibody tests may cross react with other seasonal respiratory viruses resulting in false positive results. If and when any of these issues is meaningfully resolved, CDPHE will update guidance accordingly.

The most accurate, FDA-approved testing available at this time is molecular based testing, or PCR testing. This type of testing detects the presence of the COVID-19 virus in patient samples, but is not useful in determining past exposure in fully recovered patients.