

April 4, 2020 **PUBLIC HEALTH ADVISORY** 

## **COVID-19 Testing Guidance**

Testing for Coronavirus Disease 2019 (COVID-19) is now available in a number of public health, hospital and commercial laboratories in California. However, broad-scale testing is not yet available. In Imperial County, the Public Health Department continues to work with hospitals to ensure testing for high-risk individuals through a regional Public Health laboratory. Local health-care providers now have access to commercial laboratories that are performing diagnostic tests authorized by the U.S. Food and Drug Administration (FDA) under an Emergency Use Authorization (EUA).

As companies market test kits and new laboratories begin offering COVID-19 testing, it is difficult to know if a given lab or assay has been certified or approved.

- Any laboratory performing COVID-19 testing must be a CLIA-certified laboratory. If there are any concerns about a testing laboratory, the California Department of Public Health (CDPH) Laboratory Field Services can be contacted at LFSCOVID@cdph.ca.gov
- The FDA has not authorized any test that is available to purchase for testing at home for COVID-19.
- At this time, the FDA list does not include serologic tests to identify antibodies to SARS-CoV-2. FDA does not intend to object to the development and distribution by commercial manufacturers or the development and use by laboratories of serologic tests, provided the test has been validated, notification has been provided to the FDA, and appropriate disclaimers are included in the test report. The FDA states that antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.

Anyone who tests positive using an antibody test should receive confirmatory testing using a validated PCR test. Until then, patients who test positive should remain isolated per the CDC guidance at: <a href="https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in-home-patients.html">https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in-home-patients.html</a>

Reporting confirmed cases of COVID-19 cases and SARS-CoV-2 virus by health-care providers and laboratories respectively, is now mandatory. Only results from confirmatory tests – not antibody rapid tests — are required to be reported to the Public Health Department and are included in the tally of positive cases in the countywide case count.

Providers can report confirmed cases using the <u>Confidential Morbidity Report</u> and faxing to the Epidemiology section at (442) 265-1477 or via CalREDIE, the statewide electronic disease reporting system.

For the most up-to-date information, health-care providers should monitor the <u>CDC</u> <u>Coronavirus Disease 2019 website</u>. For local information, visit the Public Health Department's website at <u>www.icphd.org.</u>

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