Technical Bulletin

Serology Tests for SARS-CoV-2 (COVID-19) Now Available

TO: Medical Staff and Clients

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SUBJECT: FDA EUA-approved serology tests for SARS-CoV-2 (COVID-19) are available at DLS

DLS is now providing an FDA Emergency Use Authorization (EUA) approved test for SARS-CoV-2 (COVID-19) immunoglobulin G (IgG) - **DLS order code Q7202**. In the near future we plan to add a total immunoglobulin test that is expected to be a more sensitive indicator of mature antibody response with a design that preserves specificity.

In an April 18, 2020 FDA Letter to Health Care Providers, serology should be used for evidence of **past infection** and NOT for diagnosis – especially IgM because "IgM antibodies may not develop early, or at all, in infected patients." A possible exception to this is seroconversion from negative to positive in acute and convalescent serum, respectively.

- Testing for active infection should be with a molecular diagnostic assay. A single serum negative result does not rule out the possibility of SARS-CoV-2 infection.
- Results from an antibody test should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection, or to assess infection or immune status.
- Positive results suggest past exposure to SARS-COV-2; however, all conditions that may result in a false positive have not been evaluated.
- Most data suggests detectable antibody forms in many people around 8-10 days after onset of symptoms, and that most people are positive by day 14 post-onset.
- It is not yet known how long antibody detected by these tests lasts.
- It is not yet known if detected antibody signifies immunity - partial or complete. Consequently, results should NOT be used to make decisions such as return to work/school, to discontinue personal protective equipment, or to discontinue social distancing measures.

This is a new disease. Rather than delaying the availability of tests until more is known, FDA has approved these tests for EUA because manufacturers have shown performance characteristics and have disclosed the uncertainties. There are still unanswered questions that will take time to resolve as we gather more evidence. Performance of all EUA serology tests is posted on the FDA website: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/eua-authorized-serology-test-performance.

To diagnose active SARS-CoV-2 infection, order the molecular diagnostic test:**DLS order code 7179**.

DLS encourages providers to follow Department of Health (DOH) guidelines, (https://health.hawaii.gov/docd/for-healthcare-providers/news-updates/), as well as those of **their respective institutions**.

Please address questions to Susan Krause at 589-5126, Dr. Wes Kim at 589-5131, Dr. Chris Whelen at 589-5242, or DLS Client Services at 589-5101.

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