Technical Bulletin

Serology Test Update for SARS-CoV-2 (COVID-19)

TO: Medical Staff and Clients

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SUBJECT: Serology tests for SARS-CoV-2 (COVID-19) should be used with caution, and NOT for diagnosis

Several manufacturers have received FDA Emergency Use Authorization (EUA) approval of serology assays for SARS-CoV-2 (COVID-19). On April 18, 2020 FDA posted "Important Information on the Use of Serological (Antibody) Tests for COVID-19 - Letter to Health Care Providers " to their website. They encourage use, but NOT for diagnosis – especially IgM because "IgM antibodies may not develop early, or at all, in infected patients."

As of this writing, these tests must be performed in a licensed diagnostic laboratory. There are many unanswered questions about them at this early stage. They all have disclaimers similar to those from non-EUA products. These include (in general):

- Negative results do not rule out SARS-CoV-2 infection. Test for active infection with a molecular diagnostic assay.
- Results from antibody testing 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, most tests have not been evaluated for cross-reactivity to with non-SARS-CoV-2 coronavirus strains or other conditions.
- It is unknown how early after exposure (or symptoms develop) that antibody can be detected by these tests.
- It is unknown how long it antibody detected by these tests lasts.
- It is unknown if detected antibody signifies immunity - partial or complete.

This is a new disease. Rather than delaying the availability of tests until more is known, FDA appears to be approving them for EUA as long as they show performance characteristics (often with low numbers and wide confidence intervals) and disclose the uncertainties. Requiring a licensed laboratory to perform testing is one way to ensure limitations are reported along with results.

DLS is actively reviewing the progress reputable companies are making toward providing tests that have more data to support their use. When DLS begins this testing service, there will likely still be unanswered questions that may need to resolve themselves with time and experience.

Because tests cannot be used as the sole basis to diagnose or exclude SARS-CoV-2 infection, providers should consider validated molecular diagnostic testing (**DLS order code 7179**) performed at DLS when patients meet established criteria.

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 refer any questions to DLS Client Services at 589-5101.