Technical Bulletin

Limitations of Rapid Serology Tests for SARS-CoV-2 (COVID-19)

TO: Medical Staff and Clients

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SUBJECT: Rapid antigen or IgM/IgG test for SARS-CoV-2 (COVID-19) are unproven in the United States

Numerous manufacturers have notified the FDA of their intent to sell rapid antigen or IgM/IgG test for SARS-CoV-2 (COVID-19). They have the option to pursue FDA EUA approval **or** not pursue FDA EUA approval and report results with the following disclaimers:

- 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.

These disclosures mean the performance of these test has not been verified independently, they may lack sensitivity (false negatives), they cannot be used alone, and there is cross-reactivity (false positives). As of this writing, all of the manufacturers are using this option and **none** of them are pursuing FDA EUA approval.

State and federal law requires diagnostic laboratories to verify/validate the performance characteristics of any test they perform on human specimens. In other words, labs must conduct validation testing that manufacturers are unwilling to do if they are going to offer testing. This is unrealistic.

So that puts these assay in the "provider performed" testing category, which would need to be **outside** a hospital lab's point-of-care (POC) program because of the laboratory's oversight of POC under their College of American Pathologists accreditation.

Providers who choose to perform this testing should carefully review manufacturers' claims and any data used to support those claims. 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 **symptomatic** 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 Dr, Amy Woron, Manager - DLS Microbiology Lab at 441-5436, or DLS Client Services at 589-5101.