



To: Speaker Scott K. Saiki, Co-chair, House of Representatives
Mr. Peter Ho, Co-chair, President & CEO, Bank of Hawaii
Mr. James Koshiba, Co-chair, Organizer, Hui Aloha

From: Mark Wasielewski, President, Diagnostic Laboratory Services, Inc.
Andrew Whelen, MD, Vice President and Technical Director of Microbiology,
Diagnostic Laboratory Services, Inc.

Date: April 13, 2020

Hrg: House Select Committee on COVID-19 Economic and Financial Preparedness; Monday,
April 13, 2020

Re: Comments on COVID-19 Testing for Diagnostic Laboratory Services, Inc.

Diagnostic Laboratory Services, Inc. (DLS) is Hawaii's largest locally owned and operated medical and clinical testing laboratory and an affiliate of The Queen's Health Systems. DLS has over 50 locations and provides quality services to communities throughout Hawaii, Guam and Saipan.

As it relates to DLS operations, the following are status updates for each of the questions posed by the committee:

- *What is DLS's current and projected COVID testing need and capacity?*

DLS's current demand for testing varies daily, but surges significantly due to drive-through sampling. The normal daily demand without major drive-through activity ranges between 200-500 COVID test requests. When drive-through samplings are performed, DLS has seen in excess of 1000 COVID test requests.

DLS currently performs between 180-280 tests per day on island. On island testing is primarily limited to extraction and/or detection (kits) supplies. The rest of the tests are sent to one of two mainland laboratories: Quest Diagnostics Laboratory or Laboratory Corporation of America (better known as LabCorp). These two laboratories were initially not able to meet their target turnaround time of 3-5 days due to the national surge in COVID test requests; however, the turnaround time more recently has been within their stated timeframe.

- *What is DLS's current and projected processing capacity for rapid and in-state results?*

DLS's current COVID testing capacities are as follows:

- Supplies limit the capacity, which is 188 tests most days. This consists of two daily batches of 94 tests each run at the main DLS Halawa facility. Each batch of 94 takes 5 hours to complete; however, subsequent runs can be started before the

first on is complete. Consequently, instrument/run time is not a present constraint.

- A rapid 45 minute test is available at the DLS laboratory within the Queen's Medical Center Punchbowl location; however, there are currently only 100 tests available. We have requested more test kits but additional supply is not guaranteed at this time.
- DLS continues to attempt to increase our capacity by working with our current testing vendors to obtain either additional equipment and/or additional testing consumables.

- *What is DLS's current and projected need for antibody testing and processing?*

We are getting many inquiries about the availability of antibody testing, so the need is there. If/when credible products are available, assays that would indicate early antibody in acute cases can be helpful as PCR tests become negative; usually 7-10 days after symptoms develop. There is the potential for needing to test a large percentage of the state's population and tourists once FDA Emergency Use Authorization (EUA) approved laboratory tests that are Clinical Laboratory Improvement Amendments (CLIA) compliant are available. DLS is working with several large and experienced laboratory testing vendors to prepare for the surge of requests once these tests are available. Currently, only one of these vendors, Abbott Laboratories, has given DLS a projected availability date of May 17, 2020.

There are many companies offering antibody tests that are not FDA approved, but are available with FDA notification. CLIA licensed laboratories such as DLS, would need to perform extensive validation studies that the companies are unwilling or unable to perform in order to offer these tests. These studies require known infected and non-infected individuals to be tested and monitored over time with human use protocols approved by an Institutional Review Board in order to establish the role and efficacy of the test at various stages of disease.

These non-FDA approved tests; however, may be "provider performed" meaning physicians may perform the test outside of a CLIA licensed laboratory. Physicians that choose to use these methods should carefully review the manufacturer's claims and critique the power and the results of these studies. Providers are also required by law to document mandatory disclaimers. As recently reported by CNN, there are many tests that appear to be of very poor quality. While DLS cannot perform these tests due to CLIA requirements, DLS can provide technical consultation for those considering using one of these testing methods.

There is one company that has obtained FDA approval for antibody testing: Cellex. Upon review of the manufacturer specifications, it is stated that "Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. IgM antibodies may not be detected in the first few days of infection; the sensitivity of the qSARS-Cov-2 IgG/IgM Rapid Test early after infection is unknown. False positive results for IgM and IgG antibodies may occur due to cross-

reactivity from pre-existing antibodies or other possible causes.” These are similar disclaimers required for non-approved tests, so users should exercise extreme caution and understanding of their limitations.

- *Do we need more laboratory facilities in Hawaii?*

No, additional facilities are not needed. The limitation is supplies. Increased allocation of collection and testing supplies would expand capacity. Another facility would just be fighting for the same short supplies. DLS has expanded the acceptability of specimen, swab, and transport fluid types in order to ease the shortage. We just need more supplies, and as yet, swabs and transport media are just not available in these quantities. Once acceptable serological blood tests are available, DLS will have the capacity to test a much larger percentage of the population.

Thank you for the opportunity to provide comments on DLS efforts related to COVID-19 testing for our state.