



Technical Bulletin

Expanded Capacity for SARS-CoV-2 (COVID-19) Testing at DLS Central Facility

TO: Medical Staff and Clients

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SUBJECT: Significant expansion of SARS-CoV-2 (COVID-19) testing available with ThermoFisher platforms

Manufacturing limitations of testing supplies has been the main constraint of COVID-19 testing capacity. One of the exceptions has been ThermoFisher, who increased production from 10,000 tests per week initially to 18 million tests per week today, with a future target of 30 million tests per week. On **August 20, 2020**, DLS began performing real-time reverse transcriptase PCR testing using ThermoFisher products and instruments. DLS and ThermoFisher have established a multimillion dollar supply agreement that will assure DLS can increase capacity to 1000 tests per day immediately with significant ramp up over the coming weeks and months.

The test performance according to package insert is as follows:

Sensitivity: 100% (95% CI - 88.43% to 100.00%)
Specificity: 100% (95% CI - 88.43% to 100.00%)
Limit of Detection: 10 genomic copy equivalents (GCE).

DLS suffered a sudden and unexpected reduction in supply allocation for our main high-throughput instrument 7 weeks ago. We deeply appreciate the testing support of the Hawaii Department of Health State Laboratories and Sonic Clinical Laboratories of Hawaii during this time to ensure our patient's specimens remained on-island in order to avoid long delays in test results.

Test code is the same for the "24-hour" test at Central.

Test:	SARS-CoV-2 (COVID-19) Real-Time PCR
DLS Order code:	7179
Specimen:	Nasopharyngeal swab, oropharyngeal swab, nasal swab
Transport Media:	UTM, Sterile saline, E-swab, Zymo (various lid colors based on supplier)
Transport/Stability:	Refrigerated for 48 HOURS or Frozen at -70°F
Turnaround time:	1-3 days (may be impacted due to high volume) Not available STAT Clients will be notified of a "Detected" result

Please refer any questions to DLS Client Services at 589-5101 or Dr. Amy Woron, Manager - DLS Microbiology Lab at 441-5436
<https://www.cdc.gov/coronavirus/2019-ncov/index.html> <https://health.hawaii.gov/docd/advisories/novel-coronavirus-2019/>

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