



Technical Bulletin

Molecular Testing for SARS-CoV-2 (COVID-19) at DLS-Guam

TO: Medical Staff and Clients

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SUBJECT: Molecular test for SARS-CoV-2 (COVID-19) is now available on Guam

On April 23, 2020, DLS-Guam began performing a real-time reverse transcriptase PCR test using the BD Max platform. The test is currently under expedited review by the Food and Drug Administration (FDA) for Emergency Use Authorization (EUA), and is available for clinical purposes.

These are **provider collected specimens**. Do not send suspected COVID-19 infected patients to patient service centers.

The assay has 2 target sequences, with an internal fluorescent probe for real time detection. The primers and probes are designed to be specific. In silico analysis shows that sequences of all probes and primers have no cross reactivity to other respiratory flora or pathogen sequences, and match SARS-COV-2 (COVID-19) sequences. Thirty (30) specimens that did not contain SARS-COV-2 (COVID-19) all tested negative.

The analytical sensitivity is demonstrated by detecting 95% of replicates at the limit of detection (LOD), which was 40 genome equivalents/microliter. The package insert reports it detected 100% of 50 samples at 1-5 times the LOD.

This is an on-island test; however, if requests exceed capacity, specimens can be sent to DLS-Hawaii. Consequently, **all orders will begin as an in-house order code 17179G**, and the laboratory will change the code if it will be sent to Hawaii.

Test:	SARS-CoV-2 (COVID-19)
DLS Order code:	17179G
Specimen:	Nasopharyngeal, oropharyngeal, eSwab, nasal swab in transport media or saline
Transport/Stability:	Refrigerated for 48 HOURS or Frozen at -70°F
Turnaround time:	1-2 days (may be impacted due to high volume) Not available STAT

DLS encourages providers to follow public health guidelines, **and those of their respective institutions**. It is important to remember that even if a patient is suspected to have SARS-CoV-2, rapid testing for other common organisms such as influenza remains an integral part of the workup process.

Should you have any questions, please call the laboratory at 646-5770.

<https://www.cdc.gov/coronavirus/2019-ncov/index.html>

<https://health.hawaii.gov/docd/advisories/novel-coronavirus-2019/>