



Technical Bulletin

Performance Characteristics of SARS-CoV-2 (COVID-19) PCR

TO: Medical Staff and Clients

FROM: Dr. Wesley Kim, MD
Medical Director, DLS and QMC West

Dr. Amy Woron, PhD
Manager, DLS Molecular

Dr. A. Christian Whelen, PhD
VP & Technical Director
Microbiology & Molecular

Dr. Ana Ortega-Lopez, MD
Medical Director QMC Punchbowl,
North Hawaii and Molokai

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SUBJECT: Performance characteristics of SARS-CoV-2 (COVID-19) molecular assays performed at DLS

DLS is currently offering SARS-CoV-2 PCR testing on five platforms. Information was provided by manufacturer in Instructions for Use (IFU). All assays have a similar limit of detection, while the Abbott and Cepheid assays have reduced sensitivity. Note: the LOD may differ from IFU based on a differing units of measure. The chart below provides a direct comparison of the five platforms. Turn around time for BD MAX and Roche are given as a range due to batching.

Manufacturer Instrument Assay	Instrument run time	Sensitivity [95% CI]	Specificity [95% CI]	Limit of Detection copies / reaction
Abbott ID NOW COVID-19	13 min***	100% [83.9% - 100%]	100% [88.7% - 100%]	75
Cepheid Xpert SARS-CoV-2	45 min**	100% [83.9% - 100%]	100% [90.1% - 100%]	75
BD MAX SARS-CoV-2	2 - 6 h	92.5% [89.7% - 95%]	100% [89.0% - 100%]	30
Roche 6800 SARS-CoV-2	6-36 h	100% [86.7% - 100%]	100% [96.3% - 100%]	25 - 50
Roche 4800 LDT	6-36 h	99% [94.9% - 100%]	99% [91.0% - 100%]	55

*Total TAT from time received in the lab is longer for accessioning and resulting.

Instrument only runs 1 sample at a time. If 3 specimens arrive at the same time, the first result is in 13 min while the last result is at 39 min.

+ Positives may result faster.

Because these values are based on small numbers of contrived samples, the lower limit of the 95% confidence interval is very important because no test is actually 100%. False positives have been associated with instruments “over-calling” background noise, especially if the prevalence is low, so DLS will report “presumptive positive” and test on a different system. False negatives increases with prevalence, occur at or below the LOD, can be related to sampling such as specimen type, and/or occur in pre-symptomatic infections.

Please refer any questions to Dr, Amy Woron, Manager - DLS Molecular Lab at 441-5436, or DLS Client Services at 589-5101.

Diagnostic Laboratory Services Inc.

99-859 Iwaiwa Street – Aiea, HI 96701
(808) 589-5100 – www.dlslab.com