Technical Bulletin

Performance Characteristics of SARS-CoV-2 (COVID-19) NAAT – Update 1

TO: Medical Staff and Clients

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

DLS is currently offering a variety of SARS-CoV-2 nucleic acid amplification tests (NAAT) tests due to supply constraints. Information summarized below was provided by manufacturer in Instructions for Use (IFU). Note: the LOD may differ from IFU based on a differing units of measure. The chart below provides a direct comparison of the our tests. Turn around time for BD MAX, Roche 6800, and ThermoFisher are given as a range due to batching.

Manufacturer Instrument Assay	Instrument run time	Sensitivity [95% CI]	Specificity [95% CI]	Positive Predictive Value [95% CI] +++	Negative Predictive Value [95% CI] +++	Limit of Detection copies / reaction
Abbott ID NOW COVID-19	13 min*#+	100% [86.9% - 100%]	100% [91.3% - 100%]	50% [0.2% - 50.5%]	100% [99% - 100%]	75
Cepheid Xpert SARS-CoV-2	45 min*+	97.8% [88.4% - 99.6%]	95.6% [85.2% - 98.8%]	18.3% [0.7% – 18.7%]	100% [99% - 100%]	75
Cepheid Xpert SARS/Flu/RSV	45 min*+	97.9% [88.9% - 99.6%]	100% [98.1% - 100%]	49.7% [12.7% - 50.8%]	100% [99.3% - 100%]	131
BD MAX SARS-CoV-2	2 - 6 h	100% [97.3%–100.0%]	96.7% [94.9%–97.9%]	23.4% [13.5% - 23.4%]	100% [99.6% - 100%]	480
Roche Liat SARS-CoV-2 & Flu A/B	21 min*#	100% [93.6% - 100%]	100% [98.4% - 100%] ++	50% [15.4% – 50.5%]	100% [99.3% - 100%]	3++
Roche 6800 SARS-CoV-2	6-48 h	100% [92.9% – 100%]	100% [96.3% - 100%]	50% [13% - 50.5%]	100% [99.2% - 100%]	25 - 50
ThermoFisher TaqPath COVID-19	6-36 h	100% [97.2% – 100%]	100% [96.7% - 100%]	50% [0.2% - 50.5%]	100% [99% - 100%]	5.6

*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.
++ FDA Warning letter about Liat false positives issued March 12, 2021.
+++ Predictive values were based on 1% prevalence and the number of specimens tested for EUA. Also, 100% was reduced to 99% (no test is perfect)

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 if audits of available data suggest possible false positive, 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.