



Technical Bulletin

Interpretation of SARS-CoV-2 (COVID-19) PCR Presumptive Positive

TO: Medical Staff and Clients

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SUBJECT: Interpretation of SARS-CoV-2 (COVID-19) PCR Presumptive Positive results

DLS Central Lab is offering SARS-CoV-2 PCR testing on two platforms, Roche 6800 and ThermoFisher. Result options are Not Detected, Detected and Presumptive Positive. Both platforms have multiple targets for SARS CoV-2. The following examples are general descriptions for each category (other variations occur).

NOT DETECTED:

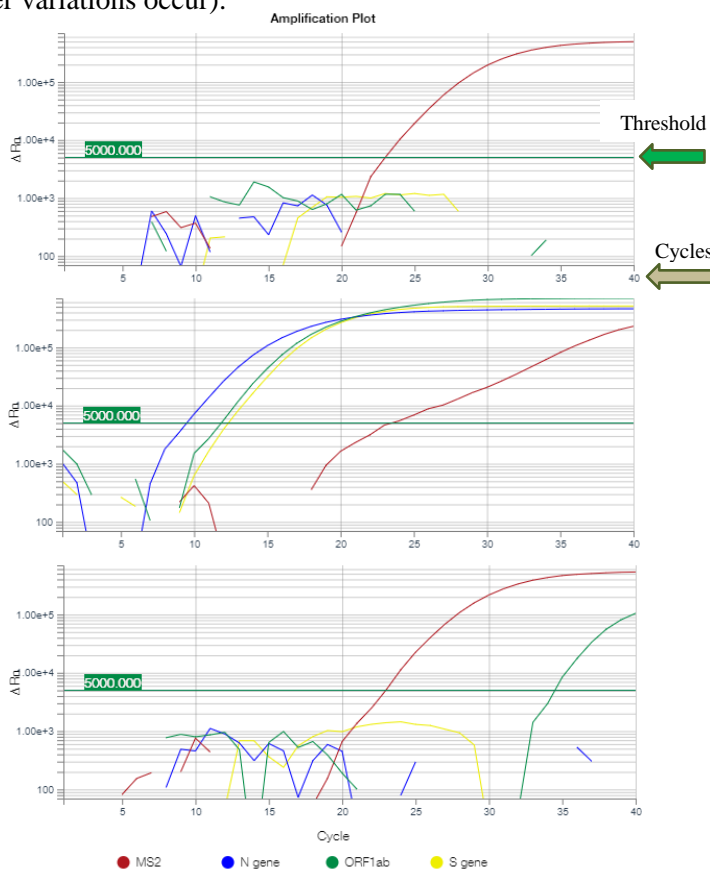
Note the red line (MS2 internal control) exhibiting logarithmic amplification and crossing the green threshold around cycle 23 (also called the cycle threshold, or CT value). None of the 3 SARS CoV-2 targets (blue, green, yellow) show amplification (real-time PCR signal); they do not cross the threshold (no CT).

DETECTED:

Note all 3 SARS CoV-2 targets exhibit logarithmic amplification and cross the threshold at very low CT values. While this is not a quantitative assay, it does indicate a strong positive (high levels of target RNA). Note also the viral targets are stronger (lower CT; left of the red control) and the control curve has flattened because viral targets are out-competing it due to the high amounts of target RNA.

PRESUMPTIVE POSITIVE:

There is detectable real-time PCR signal, but it does not meet the criteria to call the specimen detected. Note only 1 of 3 viral targets are positive and it's a weak signal (CT to the right of the control). If repeating shows similar results, it's a low confidence positive. This may be a true positive very early in infection, or the instrument may be reading poor amplification or background noise. Recollecting in Universal Transport Media (UTM), which is compatible with either assay, may resolve the issue.



We review questionable curves, high CT values, and/or signal not meeting the criteria to be called DETECTED (1 of 2 on Roche, 1 of 3 on ThermoFisher) and often repeat. Retesting is done on an alternate platform when possible, although DNA/RNA Shield transport media is not compatible with Roche 6800.

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