Technical Bulletin

Rapid SARS-CoV-2 (COVID-19) also Includes Roche Liat Combo

TO: Medical Staff, Clients, and Medical Laboratories

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SUBJECT: Roche Liat Combo (SARS & Flu A/B) added as rapid test

The initial "45-minute" test available at Queen's hospital laboratories was the Cepheid GeneXpert, which continues to be on strict allocation. In order to expand capacity in tests that can be performed in this timeframe, DLS has added the Roche cobas Liat SARS-CoV-2 & Influenza A/B. Roche does not make a Liat for SARS-CoV-2 only.

This test is approved by the FDA under Emergency Use Authorization (EUA) and is Clinical Laboratory Improvement Ammendment (CLIA) waived. It tests for 2 target sequences for SARS-CoV-2, but they both signal in the same fluorescent channel. Consequently, we cannot differentiate targets because fluorescence is generated by multiple reactions on the same channel, so we are uncertain what the maximum cycle threshold (Ct) for positive should be.

The Instructions for Use (IFU) claim a limit of detection (LOD) of 3 target copies per ml and 100% correlation with Roche 6800; however, Hansen, et al (SM-JCMB200031 1..8 (asm.org)) reported Liat positive, 6800 negative discrepancies. The authors concluded superior Liat sensitivity, although it was unclear how potential false positives were ruled out.

We know that insruments do not always make the correct interpretation of the data due to software flaws or assumptions. DLS scientists recognized this very early (Possible False Positive SARS-CoV-2 (COVID-19) PCR (dlslab.com), Possible False Positive SARS-CoV-2 (COVID-19) NAAT (dlslab.com), and consequently implemented mandatory audits of any raw data available on all system before results are released. The data available from Liat is very limited.

While the prevalence of COVID-19 in the community is low, the predictive value for a negative is excellent. In order to insure against potential Liat false positives, DLS is implemening no-cost reflexing to another testing platform whenever the result is positive. We expect Lait positives at low Ct will correlate well with supplemental testing: however, we anticipate discrepants at higher Cts.

Results should be used in conjunction with other available information such as other lab data, clinical history, exposure risks, etc., and are not intended to be used as the sole means for diagnostic or patient management decisions.

As more data regarding the performance of all the various methods become available, we will continue to update our community and make adjustments to our protocols and processes to ensure we provide the most accurate results possible to guide appropriate patient care.

If you have any questions, please call Dr. Amy Woron at 441-5436 or DLS client services at 589-5101.