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SHORT COMMUNICATION

Operational Usability Evaluation of the LIAISON® QuantiFERON®-TB Gold Plus Solution in a High Volume Laboratory Setting

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SUMMARY

Background: **Screening for latent tuberculosis infection (LTBI) using interferon gamma release assays has become commonplace for a variety of reasons. Given the high test volume, automated platforms are highly desired.**
Methods: **To this end, we performed an operational usability study using a newly FDA-approved, fully automated, random-access platform.**
Results & Conclusions: **Our results showed that this platform can save time and labor and will be a potential useful addition to streamline LTBI screening. Studies to verify performance characteristics are warranted.**
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KEY WORDS

IGRA, Quantiferon, LIAISON

INTRODUCTION

Recommendations and demand for latent tuberculosis infection testing particularly using interferon-gamma release assays continues to expand [1-3]. A test currently-used by clinical laboratories in addressing this demand is the QIAGEN QuantiFERON®-TB Gold Plus which works through the use of the QuantiFERON®-TB Gold Plus Blood Collection Tubes (BCTs). After an incubation period, the QFT® BCTs are centrifuged, and the interferon-gamma, if present, is measured using the QuantiFERON®-TB Gold Plus Enzyme-linked immunosorbent assay (ELISA). As with all ELISAs, inherent difficulties exist given the processing time and the batched format of the assay, which limits throughput, capacity, and turnaround time. Recently, the QuantiFERON®-TB Gold Plus assay was developed for use on the LIAISON® XL Analyzer, a fully-automated chemiluminescence immunoassay analyzer from DiaSorin Inc. An operational usability evaluation was performed at the Cleveland Clinic Immunopathology Laboratory using the LIAISON® QuantiFERON®-TB Gold Plus solution to test de-identified residual patient samples, previously

tested using a semi-automated microplate analyzer in conjunction with the QIAGEN QuantiFERON®-TB Gold Plus ELISA. The sole purpose of the study was to assess the operational usability of this new technology from the routine laboratory perspective. The study was not aimed at determining performance characteristics of this assay, however, interpretative criteria and cutoff vales remained unchanged.

The Study

Ninety-nine de-identified residual patient samples that had been tested the prior day using the QIAGEN QFT®-Plus ELISA and stored at 2 - 8°C, were chosen for use in this operational usability study. The LIAISON® XL requires unique tube identifiers (ID) for all samples and this laboratory's current QFT® process utilizes a common sample ID on all four BCTs. For this evaluation, it was not feasible to implement new laboratory information system programming to generate unique sample IDs for each set of patient tubes. The LIAISON® QuantiFERON® Software (LQS), developed by DiaSorin as an optional external part of the LIAISON® QuantiFERON®-TB Gold Plus solution, was used to create these unique labels. One tube from the four-tube sample family was scanned into the LQS work-list to generate four unique QFT®-Plus sample IDs, labels were automatically printed, and all tubes were then appropriately relabeled.

Calibration, quality control reagents (provided by the manufacturer), and specimen testing completed in 46 minutes. The samples were placed into the LIAISON® instrument sample racks in no particular order, although samples were kept in "patient family groupings" to maintain consistency with storage procedures. Three sample families (twelve tubes) were loaded and all were completed in 46 minutes including hands-on loading time. Over the six-hour period, 396 total tubes were successfully run, totaling 99 final patient results. This number would have been higher had we used more than one LIAISON instrument over an 8-hour shift. At the end of this process all individual tube results were automatically uploaded to the LQS work-list for calculation of the final patient results. It is important to highlight that in our laboratory currently 12 full ELISA plates (22 patients per plate) are tested every day on three DSX instruments (each test run taking approximately 3.5 hours) carefully watched by a dedicated technologist whereas our LIAISON instruments are also used for several other serological tests using minimal technologist hands-on time. A potential transition would culminate in significant labor-savings. Furthermore, run failures while using batch-testing impose significant extra reagent and cost burden whereas a fully-automated random-access platform obviates the need for such thing. Last but not least, since the new kit includes positive and negative controls, making patient pools to use as in-house controls with each run will also be avoided. Also, of note was the reduction in calibration or standard well testing (eight wells per plate with the ELISA method vs. six replicates required once every 4 weeks with the LIAISON® QFT®-Plus).

In summary, we observed the high throughput of the LIAISON® QFT®-Plus while being user-friendly and, in comparison with the ELISA, reduced reagent handling and improved efficiency with continuous-flow testing capability. Although our results support using this test for high test volume laboratory settings, further studies to verify performance characteristics of the new test are warranted.

Disclaimer:

This was deemed as a quality improvement project by the Cleveland Clinic Foundation institutional review board.

Declaration of Interest:

None declared for KK and MD. GS and RH are DiaSorin Inc. employees.

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