

BACKGROUND: LIAISON® QuantiFERON®-TB Gold Plus (QFT-Plus) is an *in vitro* diagnostic assay for the indirect detection of infection caused by *Mycobacterium tuberculosis* complex (MTBC). QFT-Plus testing consists of four tubes (controls and TB antigens) and detects interferon- γ (IFN- γ) released by host cells when exposed to MTBC peptide antigens using chemiluminescence immunoassay (CIA) technology. Patient's blood can be collected directly into four QFT-Plus tubes or into a single lithium heparin tube. If the one-tube collection process is utilized, blood must be aliquoted into each of the four QFT-Plus tubes prior to testing. In this study, we evaluated the workflow and feasibility of lithium-heparin blood collection and pre-analytical processing using the Copan Universe system for QFT-Plus testing on the LIAISON XL analyzer.

METHODS: Whole blood collected into a 6 mL lithium heparin tube was mixed using a tube rotator prior to processing on the Copan UniVerse, which aliquots 0.9 mL blood into each of four QFT-Plus tubes and label the tubes with patient information. The lithium heparin tube is mixed again immediately prior to aliquoting into each QFT-Plus tube. Different methods of mixing (vortexing vs pipetting) were assessed for efficiency and performance. Walkaway feasibility was also assessed by testing aliquoting efficiency when loading 6, 9, 12 and 18 blood samples at a time. Visual inspection of the QFT-Plus tubes to check accuracy of labels was performed prior to incubation and validation of readability of the barcode labels through the analyzer was performed.

RESULTS: Of 44 blood samples that were pipet mixed, 26 (59.1%), 15 (34.1%) and 3 (6.8%) showed no, slight and moderate hemolysis, respectively. None were grossly hemolyzed. Vortex mixing showed similar results with 61.3% (19/31) and 38.7% (12/31) showed no or slight hemolysis. However, bubble formation, which may interfere with pipetting by the UniVerse, was observed in several tubes when the samples were vortex mixed. The UniVerse appropriately aliquoted 0.9 mL blood and labeled 280 tubes. Only 1 (0.4%) tube had <0.9 mL volume detected. It takes about 20 minutes to aliquot 12 patient samples into four QFT-Plus tubes. Walkaway was possible when loading 18 patients' samples at a time without negative downstream impact on pipetting or appropriate mixing of samples for QFT-Plus testing. All QFT-Plus tubes were labeled accurately with barcodes and accession numbers which were all read and processed through the analyzer.

CONCLUSIONS: Implementation of lithium-heparin blood collection for centralized QFT-Plus testing was feasible when used in conjunction with the Copan UniVerse, which allowed for high throughput specimen processing and mitigated the risk of sample mislabeling.

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A-252 Evaluation of the Use of One-tube Blood Collection and Automated Specimen Processing System for LIAISON® QuantiFERON®-TB Gold Plus Testing at a Large Regional Reference Laboratory

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