

Reinventing blood safety

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Poster Presentation

Performance of the Procleix™ HIV-1/HCV Assay on the Tigris™ Automated Instrument Platform.

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Objective:

Performance of the Procleix™ HIV-1/HCV Assay has been evaluated on the TIGRIS™ instrument at maximum instrument testing capacity.

Design:

The TIGRIS is under development as a fully automated nucleic acid testing system, which integrates sample processing, amplification and detection steps into one instrument. The system is designed to process up to 1000 tests per day and is targeted for high volume screening of blood and plasma donations. In addition to full automation, the system provides features such as specimen barcode reading, compatibility with a wide range of sample tubes, automated worklist creation, a reagent dispense verification system, reagent inventory management and sample ID traceability.

Materials and Methods:

Assay performance was evaluated with sensitivity and specificity panels. To test the maximum working capacity of the system, a 1000 test run was performed. Additionally, worklists of greater than 450 tests each were tested. High positive HIV-1 samples (109 copies/mL) were used to test the system for carry-over.

Results:

Time to complete 1000 tests was approximately 15 hours from start to finish, inclusive of operator interaction and instrument processing. Assay sensitivity obtained with the TIGRIS instrument under high throughput testing conditions was 100% (328/328) for 100 copies/mL HIV-1 and 97.4% (333/342) for 30 copies/mL HIV-1. For HCV virus detection, assay sensitivity was 100% both at 100 copies/mL (328/328) and 30 copies/mL (331/331). No initial reactive results were observed with a negative panel member (0/1,531). The Internal Control failure rate was 0.07% (2/2,860). Equivalent results were obtained with smaller worklists (less than 400 tests). No false positive results were obtained when negative samples were interspersed in the same worklist with high positive HIV-1 samples containing 109 copies/mL.

Conclusion:

The TIGRIS™ system is suitable for medium and high volume screening of blood and plasma donations. This study shows that the TIGRIS™ system meets the Procleix™ HIV-1/HCV Assay specifications of the currently marketed semi-automated system.