

Reinventing blood safety

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Poster Presentation

## A Fully Automated, High Throughput System for Simultaneous Screening of HIV-1, HCV And HBV in Blood Donations

*D. Kolk, J. Linnen, J. Dockter, A. Martinez, A. Binder, J. Knight, A. McElroy, M. Park, A. Broulik, A. Umali, E. Peterson, W. Schneider, D. Cox, S. McDonough, L. T. Mimms, C. Giachetti, J. Macioszek, Gen-Probe Incorporated, San Diego, CA 92121*

### Objective:

To develop a fully automated test for the simultaneous detection of HIV-1, HCV, and HBV nucleic acids (Triplex Assay) for blood/plasma screening. Performance of a Transcription-Mediated Amplification (TMA)-based Triplex Assay on the TIGRIS™ fully automated system was evaluated for specificity, analytical sensitivity and carrier contamination frequency in plasma samples.

### Methods:

To determine the analytical sensitivity of the current Triplex Assay, dilutions of the WHO International Standards for HIV-1, HCV, and HBV were tested. Assay specificity was assessed with 480 replicates of a negative plasma pool, shown previously to be negative for HIV-1, HCV, and HBV nucleic acids. To determine whether there was any carryover contamination on the instrument, a high-titer HBV specimen ( $>10^8$  IU/mL) was interspersed between negative plasma samples in a 500-tube run.

### Results:

Sensitivity studies showed 100% detection at 15 IU/mL and 90% detection at 5 IU/mL of HBV. For HCV, the assay showed 100% detection at 11.1 IU/mL and 90% detection at 3.7 IU/mL. For HIV-1, the Triplex Assay had 100% detection at 33.3 IU/mL and 80% detection at 11.1 IU/mL. Greater than 99.5% specificity was demonstrated for the assay on the fully automated system, similar to the specificity of the FDA-licensed Procleix HIV-1/HCV semi-automated assay. No carryover contamination was observed with the Triplex Assay on TIGRIS.

### Conclusion:

The Triplex Assay run on the TIGRIS instrument system showed sensitivity (for HIV-1 and HCV) and specificity that is very similar to the Procleix HIV-1/HCV Assay. The analytical sensitivity demonstrated for HBV with the Triplex Assay on TIGRIS was similar to that shown in the semi-automated assay. (Partially funded by NHLBI grant no. HB-07148).