

Reinventing blood safety

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Poster Presentation

Sensitivity and Specificity of a TMA-based Triplex Assay for Simultaneous Screening of HIV-1, HCV And HBV in Blood Donations

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Objective:

To assess the analytical sensitivity and specificity of the Transcription-Mediated Amplification (TMA) Triplex Assay, we tested standard panels and negative donor specimens.

Design:

We are developing the TMA Triplex Assay for simultaneously screening blood donations for HIV-1, HCV, and HBV. The TMA Triplex Assay uses the same semi-automated instrumentation and assay procedures as the Procleix HIV-1/HCV Assay, which recently gained US FDA approval. In this study, we tested serial dilutions of the WHO International Standards and genetic variants of HIV-1, HCV, and HBV. To examine assay specificity, we tested negative donor specimens with the Triplex Assay and discriminatory assays for the three viruses.

Methods:

WHO Standards were serially diluted in negative human serum. HBV genotypes A-F, HCV genotypes 1-6, and HIV subtypes A-G, groups O and N (quantitated with commercially available assays) were tested at 100 copies/mL. Negative specimens (N=500 for each assay) were obtained from the Community Blood Center of Greater Kansas City. Each negative specimen was tested in the Triplex and the three discriminatory assays; reactive and invalid results were re-tested.

Results:

Analysis of analytical sensitivity results indicate that the 95% detection level with Triplex Assay for HIV-1 is at about 15 IU/mL, and at 3 and 7 IU/mL for HCV and HBV, respectively. All HIV-1, HCV and HBV genetic variant samples were detected at 100 copies/mL. Results from the specificity study indicate that the Triplex assays have similar specificity as the Procleix HIV-1/HCV Assay and discriminatory assays, with > 99% initial specificity and 100% resolved specificity.

Conclusion:

These results indicate that the sensitivity and specificity of the TMA Triplex Assay are very similar to those of the FDA-cleared Procleix HIV-1/HCV Assay. The analytical sensitivity demonstrated for HBV is sufficient to detect low titers of HBV typically present prior to detection of HBsAg in the seroconversion window. (Partially funded by NHLBI grant HB-07148).