

AABB 57th Annual Meeting, 2004

NAT CROSS-SUPPLEMENTAL ROLE ASSESSMENT OF THE COBAS AMPLISCREEN AND PROCLEIX® HIV-1 AND HCV ASSAYS USING INITIAL REACTIVE DONOR SPECIMENS

G Robertson, V Winkelman*, Jaye Brodsky**, JD McAuley*, Dan Houghton*, S Caglioti*, Susan Stramer** and MP Busch*+.*

**Blood Systems Laboratories, Tempe, AZ. **American Red Cross, Washington, DC. +Blood Centers of the Pacific, San Francisco CA, University of California, San Francisco, CA*

Background:

Serological based donor screening reactive results are supplemented by alternate EIA or confirmatory assays. Although NAT for HIV-1/HCV RNA tests are highly sensitive and specific there is currently no standard method for supplemental testing of reactive samples. There are two manufacturers licensed in blood donor screening. Therefore using initial reactive NAT specimens, we were interested in evaluating the Procleix® Assays with the COBAS AmpliScreen PCR HIV-1 and HCV assays as cross-supplemental NAT confirmatory tests.

Methods:

Procleix® HIV-1/HCV (Mx) Assay initially reactive samples (N=240) were tested for HIV-1 and HCV RNA with one or both of the COBAS AmpliScreen PCR assays: AmpliScreen Standard Specimen Processing (STDPrep) and/or MultiPrep Specimen Process (MLTPrep). A repeat test was performed using the Procleix Mx and Procleix discriminatory assays (dHIV-1, dHCV). Samples were also evaluated by National Genetics Institute (NGI) PCR HIV-1, HCV assays. Samples were considered reactive only if two or more of the methods generated a reactive result. AmpliScreen STDPrep was used to evaluate 179 HIV-1 and 178 HCV samples. MultiPrep Specimen Process (MLTPrep) was used to evaluate 213 HIV-1 and 217 HCV samples. Procleix® discriminatory assays tested 239 HIV-1 and HCV samples. NGI PCR assay was used for 153 HIV-1 and 234 HCV samples.

Results:

Of the 240 specimens evaluated for HIV, 3 specimens (1.3%) were true positive (TP), 180 were true negative (TN) (75%) and 57 (23.7%) had discordant results. Of the 57 discordant specimens, there were 55 false positive (FP) Procleix® Mx (96%), 1 FN STDPrep (2%) and 1 discordant sample (2%): Procleix® Mx Rx, MLTPrep negative. Of the 240 specimens evaluated for HCV, 54 specimens (22.5%) were TP, 176 TN (73.3%), and 10 (4.2%) had discordant results. Of the 10 discordant specimens, there were 6 FP samples: 4 Procleix Mx, 1 STDPrep and 1 NGI; the 2 FN were: 1 dHCV and 1 NGI. The remaining 2 discordant samples were positive by Ampliscreen MLTPrep and STDPrep but negative by Procleix® and NGI. The majority of FP samples were found with the Procleix Mx assay for both HIV-1 and HCV RNA and the NGI assay had some FN samples. Evaluation of MLTPrep assay results with Procleix® discriminatory tests only, found 100% concordance for HIV-1 and 98.8% concordance for HCV.

Conclusion:

The data show there is 100% sensitivity and high concordance between the Procleix® dHIV-1, dHCV and the Ampliscreen MLTPrep PCR HIV-1 and HCV assays, 100% and 98.8% respectively. Therefore, the COBAS MLTPrep and Procleix® discriminatory assays are appropriate for use as cross-supplemental NAT confirmatory tests for blood donor screening. The few discrepancies between the COBAS Ampliscreen results and the Procleix discriminatory results will be investigated further.