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Poster Presentation

**SCREENING OF TISSUE DONORS FOR DETECTION OF HIV-1, HCV AND WNV RNA AND HBV DNA (SP224)**

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**Background:**

Because samples from deceased donors have been associated with invalid tests for nucleic acid, protocols were developed to assure valid assays when performing nucleic acid testing (NAT) for HIV-1, HCV, HBV and WNV on serum or plasma samples from tissue donors.

**Methods:**

Studies with the Gen-Probe Incorporated, Procleix<sup>®</sup> Assays were performed by the American Red Cross (ARC); studies with the Roche Molecular Systems, COBAS Ampliscreen<sup>™</sup> Assays were performed by the Puget Sound Blood Center (PSBC). Testing was performed on single (undiluted) plasma or serum samples collected according to each collection site's routine procedures; samples included for tissue NAT were nonreactive by all routine serologic screening tests. Samples exhibiting inhibition by NAT when tested undiluted were retested following dilution (1 : 5 in saline). The number of donors (samples) tested by the Procleix<sup>®</sup> Assays were: 1,087 for HIV-1/HCV (licensed multiplex), 474 for WNV (investigational), 465 for HBV (investigational); the number tested by the COBAS Ampliscreen<sup>™</sup> assays were: 1,218 for HIV-1 and HCV, and 229 for HBV (all investigational); no WNV testing was performed.

**Results:**

Initial invalid rates for the Procleix<sup>®</sup> Assays were: 1.7% for WNV, 1.5% for HIV-1/HCV and 6.4% for HBV; for the COBAS Ampliscreen<sup>™</sup> Assays, initial invalid rates were: 2.8% for HIV, 1.4% for HCV and 2.2% for HBV. For those samples available for further testing, invalid rates following dilution and retesting were zero except HBV at 7.1% (2 reactive or 28 total reactive) (Procleix<sup>®</sup> Assays) and 0.42% for HIV-1 and 0.85% HBV (Ampliscreen<sup>™</sup> Assays). There were no reactive results by either test system for HIV-1, HCV or HBV. There were two WNV RNA reactive samples. The initial S/CO of one sample was 5.55 with repeat TMA results of 0.28 and 0.25; IgM/IgG negative (Focus Technologies), and therefore false positive. The WNV RNA S/CO of the second sample was 24.44 with repeat RNA results of 2.90 and 0.98. The sample did not confirm by a second NAT assay (PCR; National Genetics Institute) but was reactive (and therefore confirmed) for IgM and IgG (S/COs of 5.22 and 3.02, respectively).

**Conclusion:**

Based on the low false positive rate and the low invalid rate, both assays were found to be efficacious and feasible for use on human serum or plasma samples from tissue donors.