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### **PERFORMANCE OF THE PROCLEIX® HIV-1/HCV ASSAY IN ORGAN AND TISSUE DONOR SERUM SPECIMENS**

*R. Garcia, J. Dockter, W. Schneider, Gen-Probe Incorporated, San Diego, CA, Susan Stramer, American Red Cross, Gaithersburg, MD, M. Kill, S. Haight, American Red Cross Tissue Services, Eagan, MN and C. Giachetti, Gen-Probe Incorporated, San Diego, CA*

#### **Background:**

The Procleix® HIV-1/HCV assay is a licensed test for screening whole blood donations and volunteer source plasma. In this study, we conducted a preliminary evaluation of the performance of the assay in specimens collected from organ and tissue donors, as well as evaluating the effect of highly hemolyzed specimens.

#### **Methods:**

250 banked serum specimens collected from organ and tissue donors were obtained from the American Red Cross Tissue Services. Post-mortem specimens were taken at different times representing the full range typically found in tissue collection services practice. A set of the specimens was tested in the HIV-1/HCV assay to assess overall assay performance with respect to specimen inhibition and specificity. To evaluate assay sensitivity, the remaining specimens were tested in either the HIV-1/HCV assay, the HIV-1 Discriminatory assay or the HCV Discriminatory assay after spiking with low concentrations of HIV-1 or HCV positive plasmas. Additional experiments were performed on whole blood and highly hemolyzed serum samples to qualify a dilution protocol for inhibitory samples and to evaluate the effect of high levels of hemoglobin on assay performance, as often times the cadaveric specimens are highly hemolyzed.

#### **Results:**

Assay inhibition was observed in a small percentage of specimens (approximately 5%). This inhibition was overcome by diluting specimens 1:5 in saline. Whole blood specimens and highly hemolyzed serum (>20,000 mg/dL hemoglobin), also required dilution in saline to overcome inhibition. While this dilution does have some effect on assay sensitivity, in samples containing at least 100 c/mL in the final test sample, >95% detection of HIV-1 and HCV was observed.

#### **Conclusions:**

The HIV-1/HCV assay, HIV-1 Discriminatory assay and the HCV Discriminatory assay are able to detect HIV-1 and HCV RNA in specimens from organ and tissue donors.