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### **SIMULTANEOUS SCREENING FOR HIV-1, HCV AND HBV IN BLOOD DONATIONS ON WITH A HIGH THROUGHPUT FULLY AUTOMATED INSTRUMENT**

***Miyo Park, Michael Deras, Art Martinez, Camila Deza, Tony Dettori, Sherrol McDonough, Cristina Giachetti, Jerzy Macioszek, and Dan Kolk, Gen-Probe Incorporated, San Diego, CA 92121***

#### **Background:**

We are developing a high throughput, fully automated instrument, called TIGRIS™, for use in screening of blood donations. We are also developing a Transcription-Mediated Amplification (TMA) nucleic acid assay, the Procleix® Ultrio™ Assay, that simultaneously detects HIV-1, HCV and HBV in a signal single test. We describe the sensitivity, specificity and throughput of the Ultrio assay on TIGRIS.

#### **Methods:**

Sensitivity studies were performed on plasma panels composed of HIV-1 type B at 100 and at 30 copies/mL, HCV subtype 1a at 100 and at 30 copies/mL, and HBV subtype A at 20 and at 5 IU/mL. The specificity study was done using Nnegative control plasma. Each run was composed of approximately 50 replicates of each positive panel member and 75 replicates of the nNegative panelcontrolcontrol. The study was performed on three separate instruments.

#### **Results:**

With the current assay protocol, the first assay result is obtained in 3 hr and 38 minutes. The system is capable of processing up to 1000 donations samples in less than 14 hrs. With the Ultrio assay, we obtained observed a 99% detection rate of HBV at 20 IU/mL (192/194) and a 80.9% detection rate of HBV @ 5 IU/mL (157/194). We obtained observed a 100% detection rate at both 100 (194/194) and 30 (195/195) copies/mL of HCV 1a. At 100 copies/mL of HIV-1 type B, we obtained observed a 100% (195n/195n) detection rate and 97.4% (190n/195n) detection rate at 30 copies/mL. Specificity was greater than 99.4% (2 reactive out of 341 known negatives).

#### **Conclusion:**

These data indicate that the Ultrio assay on TIGRIS can dramatically increase efficiency of blood screening by combining three separate assays into a single test and providing a full automation on a high throughput instrument. These data also show that the Ultrio assay on TIGRIS has excellent sensitivity and specificity compared to current blood screening assays and is suitable for individual donor testing.

\*The Ultrio™ Assay and the TIGRIS Instrument are both under development at Gen-Probe