

*AABB 56th Annual Meeting, 2003*

## **ASSESSMENT OF A CROSS-SUPPLEMENTAL ROLE FOR THE COBAS AMPLISCREEN AND PROCLEIX® TMA HIV-1/HCV ASSAY USING KNOWN RNA CONTROL SAMPLES**

*JD McAuley\*, V Winkelman\*, RC Williams\*, G Robertson\*, S Caglioti\*, and MP Busch\*+*

*\*Blood Systems Laboratories, Tempe, AZ.*

*+Blood Centers of the Pacific, San Francisco CA, University of California, San Francisco, CA*

### **Background:**

NAT screening for HIV-1 and HCV is now standard practice using minipool (MP) or individual donor testing (IDT). However, there is a need for NAT-based confirmatory assays. We evaluated the feasibility of using the COBAS AmpliScreen PCR HIV-1/HCV assays and the Procleix® discriminatory HIV-1/HCV assays as confirmatory tests for one another (“cross-supplemental NAT”).

### **Methods:**

A total of 908 assay tests were performed on seronegative known RNA copy level standards: 479 on RNA positive standards with 100 to 400,000 copies/mL; 138 on RNA positives with <100 copies/mL and 242 on RNA negative controls; 49 samples were invalid. The AmpliScreen Standard Specimen Processing (STDPrep PCR) was used for 495 samples, the MultiPrep Specimen Processing (MLTPrep PCR) for 293 samples and the Procleix discriminatory Transcription Mediated Amplification (dTMA) assay for 120 samples. The STDPrep isolates HIV-1 and HCV RNA directly from 0.2 mL plasma by lysis of the virus particles followed with alcohol precipitation of RNA, where as the MLTPrep pellets the RNA viral particles by high-speed centrifugation of 1.0 mL plasma, followed by lysis and alcohol precipitation. The COBAS AmpliScreen amplification and detection are automated. Procleix TMA RNA isolation, amplification and detection process occurs within a single tube unit (TTU). Target viral RNAs are captured from 0.5 mL plasma onto magnetic microparticles, which are separated using a magnetic field. All assays use an RNA fragment internal control to verify analyte test validity.

### **Results:**

For known RNA positive samples with >100 copies/mL, MLTPrep PCR and dTMA assays showed 100% sensitivity for both HIV-1 and HCV, whereas STDPrep PCR showed 87.7% and 98.4% sensitivity for HIV-1 and HCV, respectively. For viremic samples with <100 copies/mL, the sensitivities of MLTPrep PCR were 42% and 42.3%, STDPrep PCR 30% and 41%, and dTMA 62% and 58% for HIV-1 and HCV, respectively. HIV-1 specificity was 100% for all three methods; HCV specificity was 100% for STDPrep and dTMA and 98.4% for MLTPrep.

### **Conclusions:**

The AmpliScreen MLTPrep PCR and Procleix dTMA assays showed equal sensitivity, whereas the AmpliScreen STDPrep procedure appears to be less sensitive. The specificity of all assay types was excellent. The high specificity and sensitivity of the COBAS MLTPrep and Procleix TMA assays suggests that they are appropriate to use as cross-supplemental NAT confirmatory tests. Studies applying these assays as cross-supplemental tests on NAT-reactive blood donations with known infection status based on donor follow-up are in progress.