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Oral Presentation

## HEAD TO HEAD COMPARISON OF TWO NEW AUTOMATED NAT SYSTEMS CHIRON PROCLEIX TIGRIS SYSTEM VS ROCHE COBAS S 201 (P-108)

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**Background:** Nucleic acid testing (NAT) of blood donations was implemented in France in 2001 for HIV-1 and HCV with semi-automated systems on pools of 8 (Chiron) or 24 samples (Roche). Recently, two new automated NAT systems became available employing multiplex HBV/HCV/HIV assays, a fully automated system (PROCLEIX<sup>®</sup> TIGRIS<sup>®</sup> System, Chiron) and a modular automated system (Cobas s 201<sup>®</sup>, Roche). A comparative study of these systems can provide valuable information on the performance characteristics of individual donation (ID) or minipool (MP) NAT and the potential of HBV-DNA screening in enhancing blood safety.

**Aims:** To compare the analytical and operational performance characteristics of the TIGRIS and the Cobas s 201 systems.

**Methods:** Testing was done on individual samples (ID NAT) or in minipools of 6 donations (MP NAT) on the TIGRIS and s 201 systems respectively. Analytical sensitivity of the two systems was assessed by comparing 50% and 95% detection limits calculated by probit analysis on replicate tests (n=24) of dilution series of WHO and BBI Accurun standards for HCV, HIV-1 and HBV. The window period reduction (WP) achievable by the ID-NAT and MP-NAT systems in comparison with the current EFS serological test platforms (PRISM-Abbott, Biorad, Ortho) was estimated by testing 5 seroconversion panels (Zeptomatrix, USA) in quadruplicate for each virus (HBV, HCV and HIV-1). The ability of both systems in detecting all genotypes of HBV, HCV and HIV- 1 group was compared by testing 12 replicates of standard dilution panels calibrated in geq/mL (VQC-Acrometrix) and by testing 10-fold dilutions of French plasma samples genotyped and quantified in IU/mL (INTS, Paris, France). The reproducibility was tested by repetitive testing of run control samples. Cross contamination was evaluated by testing negative and high viral load samples. The specificity, reliability and operational and workflow performance was compared by testing 10,000 donations with each system.

**Results:** The 95% LODs expressed in IU/mL for HCV, HIV-1 and HBV using the WHO standards were 8.8, 37.7 and 12.3 respectively for the TIGRIS and 15.4, 41.4 and 3.5 for the s 201 tested by ID NAT. When comparing both systems in ID NAT configuration, there were significant differences in analytical sensitivity between the 2 systems in detecting some of the HBV, HCV and HIV standards of different genotypes. There were no clear differences in the WP reduction, compared with PRISM, for the 3 virus between the 2 systems: 29 to 31 days for HCV, 10 to 12 days for HIV-1 and 7 to 10 days for HBV. The 2 systems showed a 100% reproducibility and specificity. No cross contamination was observed with either system. Of the 19,229 donations tested, none was serologically positive or NAT reactive.

**Conclusions:** Overall, the analytical sensitivities of the 2 systems were comparable at the ID level, although differences were observed for some genotypes. From the workflow perspective, the performances were comparable if samples were tested in mini-pools of 6 on the s 201 and individually on the TIGRIS.