

COMPARISON OF THE CHIRON PROCLEIX TIGRIS AND ROCHE S 201 NUCLEIC ACID TESTING (NAT) SYSTEMS FOR SIMULTANEOUS DETECTION OF HIV/HCV RNA AND HBV DNA (P-128)

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Background: Since July 2002 the Australian Red Cross Blood Service (ARCBS) has performed HIV-1 and HCV nucleic acid testing (NAT) for the Hong Kong Red Cross Blood Transfusion Service (HKRCBTS). The high HBV prevalence in Hong Kong, along with the development of 'multiplex' assays incorporating simultaneous HIV, HCV and HBV nucleic acid detection, motivated the current study.

Aims: The aims of the study were; 1. Estimate the prevalence of HBV DNA positive / HBsAg negative (Yield) donors in the Hong Kong blood donor population. 2. Evaluate the operational performance of two 'multiplex' NAT assays and their respective testing platforms.

Methods: The HBV yield rate was estimated from 10,397 HKRCBTS blood donor samples concurrently tested by ARCBS on Chiron's PROCLEIX[®] ULTRIO[™] assay as individual donor samples using the fully automated TIGRIS[®] platform, and on Roche s Cobas TaqScreen Multiplex (MPX) test in pools of 6 (PDT6) using the modular automated s 201 platform. Reactive samples were assigned a final HIV, HCV and HBV status based on pre-defined viral confirmatory algorithms. Analytical sensitivity was assessed by probit analysis of diluted international standards. Operational performance was compared based on multiple factors, including daily workflow analysis, invalid sample rates and failed run rates.

Results: There were 72 HBV DNA positive samples detected in this study which were also HBsAg positive (Abbott PRISM[®]). Seventy one were detected by the ULTRIO[™] assay and 72 by the TaqScreen MPX test. Each system independently detected 2 HBV NAT yield samples for a combined HBV NAT yield rate of 4 in 10,397 (0.04%). The TaqScreen MPX test detected one additional reactive sample that remains unresolved. The 95% detection limits for HIV-1, HBV and HCV were 42.2, 12.2 and 2.0 IU/mL respectively for the PROCLEIX[®] ULTRIO[™] assay and 50.5, 8.4 and 6.0 IU/mL for the Cobas TaqScreen MPX test using individual donor testing (IDT) on both systems. The invalid test and failed run rates were 0.05% and 2.92% for the TIGRIS[®] system, while preliminary analysis indicates rates of 2.39% and 4.76% for the Cobas s201.

Summary/Conclusions: 1. Based on this study, the estimated HBV NAT yield rate in Hong Kong blood donors is 0.04%. Although implementing either assay alone would be expected to detect only half (0.02%) of these yield donors, the consensus outcome is an incremental increase in blood safety for the HKRCBTS. 2. There appears to be no difference in clinical sensitivity for HBV in Hong Kong blood donors when testing in pools of 6 on the MPX assay and IDT on the ULTRIO[™] assay. 3. When testing in IDT on both systems there was no significant difference between the 95% detection limits for HIV-1 and HBV however the PROCLEIX[®] ULTRIO[™] assay had a significantly ($p < 0.05$) lower 95% detection limit for HCV. 4. Workflow analysis demonstrated that testing completion times for daily workload of 200 donor samples (IDT vs. PDT6) did not differ markedly between the two systems. 5. Based on a lower invalid sample and failed run rate, the TIGRIS[®] system demonstrated better overall operational performance.