

Comparison of Two Automated Nucleic Acid Testing (NAT) Systems for Simultaneous Detection of HIV/HCV RNA and HBV DNA in Hong Kong Blood Donors (S16-030D)

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Background: Recent development of 'multiplex' NAT assays incorporating simultaneous detection of HIV, HCV and HBV nucleic acid has made HBV NAT screening a more feasible option for blood services. This study aimed to compare the performance of two 'multiplex' NAT assays and their automated testing platforms and determine the effects of pooling on HBV DNA detection in the Hong Kong (HK) blood donor population.

Methods: The HBV yield rate was estimated from 10,397 HK donor samples concurrently tested on the PROCLEIX® ULTRIO® (Ultrio) assay as individual donor samples using the TIGRIS® platform, and on the cobas TaqScreen Multiplex (cobas MPX) test in pools of 6 (PDT6) using the s 201 platform. Reactive samples were assigned a final HIV, HCV and HBV status based on pre-defined testing algorithms. Analytical sensitivity was assessed by probit analysis of diluted international standards. Operational performance was compared based on multiple factors.

Results: Each system detected 2 discrete HBV NAT yield samples resulting in a combined yield rate of 4 in 10,397 (0.04%). The cobas MPX test detected one additional reactive sample that remains unresolved. When 3025 cobas MPX (PDT6) negative samples were retested individually, an additional HBV NAT yield sample was detected; when the 2 Ultrio reactive yield samples were retested when diluted 1:4 and 1:8 there was a reduction in the NAT yield detection rate (1/2 for both pool sizes). The 95% detection limits for HIV-1, HBV and HCV were 42.2, 12.2 and 2.0 IU/mL respectively for the Ultrio assay and 50.5, 8.4 and 6.0 IU/mL for the cobas MPX test. Workflow analysis indicated that testing completion times for a workload of 200 samples (IDT vs. PDT6) did not differ markedly between the systems. The invalid test and failed run rates were 0.05% and 2.92% for the TIGRIS and 2.39% and 5.53% for the cobas s 201. Total downtime for the cobas s 201 was lower (24 hours) than the TIGRIS (196 hours) with a shorter average time to repair (6 hours compared to 65 hours).

Conclusion: (1) The data indicates no difference in clinical sensitivity for HBV in HK blood donors when testing in PDT6 on the cobas MPX test and IDT on the Ultrio assay, (2) Testing samples by IDT on the cobas MPX test would increase the HBV DNA yield detection rate while pooled testing on the Ultrio assay would decrease the detection rate, (3) There was no significant difference between the 95% detection limits for HIV-1 and HBV, however the Ultrio assay was significantly ($p < 0.05$) lower for HCV, (4) The TIGRIS demonstrated better overall operational performance based on lower invalid test and failed run rates, however the cobas s 201 had a shorter downtime and average time to repair.