

Relative Performance of Chiron Procleix TIGRIS Vs Roche Cobas S 201 Systems (S17-030D)

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Background: In France, donors have been tested for HCV and HIV-1 by nucleic acid testing (NAT) since 2001, either in pools of 8 (Chiron) or 24 (Roche). With the recent availability of automated NAT systems (Chiron Tigris and Roche cobas s 201) a study was undertaken to compare the performance of these systems for routine blood screening.

Methods: The 50 % and 95 % LODs were determined in IU/ml using dilutions series of the WHO and BBI Accurun standards for HBV, HCV and HIV-1. For genotype detection, 12 replicates of VQC standard dilution panels (geq/mL) and 4 replicates of locally diluted samples were tested. These included HBV genotypes A to G, HCV genotypes 1 to 6 and HIV-1 group M genotypes A to F, O and HIV-2. Cross contamination was assessed by testing alternative negative and high viral load samples while reproducibility was evaluated by repetitive testing of run control samples. For clinical sensitivity, samples were tested individually on the Tigris (ID NAT) or in pools of 6 on the s 201 (MP NAT). Five seroconversion panels (Zeptometrix, USA) for HBV, HCV and HIV-1, were tested in quadruplicate to determine the window period (WP) reduction compared with the current serological tests (Prism, Abbott, Biorad, Ortho). Approximately 10,000 routine donations were tested with each system in order to assess specificity and reliability of the assays. The workflow performance in routine testing was evaluated for each system.

Results: The results of analytical and clinical studies are summarized in the table.

Feature	cobas s201	TIGRIS
Cross contamination	NO	NO
HCV LOD (IU/mL) 95% (50%)	15.4 (2.3)	8.8 (0.9)
HIV-1 LOD (IU/mL) 95% (50%)	41.7 (7.7)	37.7 (5.3)
HBV LOD (IU/mL) 95% (50%)	3.5 (0.7)	12.3 (1.9)
Genotype Detection (HCV, HBV, HIV-1 group M)	All	All
Specificity	100%	100%
WP reduction (days)		
HCV	29	29-31
HIV-1	10-11	12
HBV	7-8	9-10

For HCV and HBV standards, the analytical sensitivities of the two systems were significantly different ($p < 0.0001$). Significant differences were also observed when testing some of the VQC genotype dilution panels. No serological positive or NAT reactive donations were identified in testing 19229 donations.

Conclusion: In ID-NAT configuration the Tigris system was more sensitive for HCV detection compared with the s201 system while for HBV the s 201 was more sensitive. Reproducibility, cross contamination and specificity results indicated that both systems were robust in routine testing. Workflow analysis showed comparable performance of the two systems, when donations were tested in MP NAT (pools of 6) on s 201 and in ID NAT on TIGRIS.