

SIMULTANEOUS SCREENING FOR HCV, HIV-1 AND HBV IN BLOOD DONATIONS WITH THE FULLY AUTOMATED SYSTEM (P-121)

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Background: Nucleic Acid Testing (NAT) for HCV, HIV-1 and HBV has been implemented in many countries to screen blood donations aiming to increase the safety of the blood supply. Since the introduction of NAT screening as routine use, the viral testing need of blood banks was to perform the test on individual donation and to benefit by a fully automated system. The development of the Procleix Triplex assay on TIGRIS instrument is the first advanced technological solution for NAT testing since the system conjugates a high sensitive genome assay with a high level of automation.

Aim: The objective of the work was to assess the analytical sensitivity of the Procleix Ultrio on TIGRIS System and to perform routine screening of blood donations by testing individual specimens.

Materials: The analytical sensitivity was determined by using WHO HCV 96/798, WHO HBV 97/746 and WHO HIV-1 99/634. The standards were each tested at eight dilutions with 24 replicates at each dilution. 95% detection levels was derived from probit analyses. Since September 2005 TIGRIS system was introduced as routine base. 32.600 plasma samples have been run by using different TIGRIS run configurations. The daily workload was ranging between 80 to 400 donations. In the setting of bone marrow transplant, urgent samples, were tested on priority. Initial reactive samples (IRS) were re-tested by Ultrio: when IRS were found twice negative by Ultrio they were assumed as non specific reactive, whereas if IRS were confirmed reactive by Ultrio they were run in Discriminatory assays to identify the specific virus genome. In case of discordant evidence, multiple repeat Ultrio tests and additional HBV serology tests were also performed.

Results: The 95% Detection Limit for the PROCLEIX[®] ULTRIO[™] Assay on TIGRIS was 6.8 IU/mL (4.6-14.4 Fiducial Limits) for HCV, 22 IU/mL (15.4-40.8) for HIV-1 and 12.1 IU/mL (8.6-20.3). 434 runs were performed and 26 runs (5.9%) were invalid due to operator/technical instrument troubles. The data of the screening showed: 11 HCV RNA positive-HCV Ab positive donations, 1 HIV-1 RNA positive-HIV-1 Ag/Ab positive donation, 12 HBV DNA positive-HBsAg positive donations and 2 HBVDNA positive-HBsAg negative donations, whose the former was HBcAb positive whereas the latter did not show any serological HBV marker. Moreover 6 IRS were not found consistent reactive in multiple repeat Ultrio tests (pos/neg), but all the specimens were found HBcAb positive suggesting the possibility of a very low HBV viral load in the corresponding donations. 64 false positive results (0.19%) and 177 invalid results (0.5%) were also observed.

Conclusions: The data indicate that Ultrio assay on TIGRIS has a high analytical sensitivity comparable to the current semi-automate NAT assays. The instrument is reliable in providing a high throughput blood screening system. The detection in some donors of low HBV DNA levels in presence of HBcAb is consistent with the finding of occult hepatitis B suggesting that the individual NAT testing seems to be more appropriate when a simultaneous screening of HBV DNA, in addition to HCV and HIV-1, is performed.