

NAT SCREENING FOR HIV/HCV (PROCLEIX, CHIRON) IN SINGLE DONATION IN COIMBRA, PORTUGAL (2000-2006) (P-135)

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Background: Direct detection of viral nucleic acid HIV-1/HCV RNA can further improve the safety of blood supply by detecting infectious donations prior to seroconversion. Nucleic acid testing (NAT) is estimated to reduce the window period for HIV-1 by 11 days (>50%) and that for HCV by 41-60 days (>85%). A single tube assay was used for simultaneous detection using transcription mediated amplification (TMA) technology. The Portuguese Blood Institute Regional Centre of Coimbra has been performing NAT tests in random blood donations since July 2000. Routine testing of all donations has been carried out as of January 2005. More than 90% of donations are studied within 42 hours of donation. The Regional Centre of Coimbra has approximately 66,000 donations/year.

Aims: To share our experience in NAT testing of HIV-1/HCV by transcription mediated amplification using the Procleix system (Chiron Corporation, USA) from July 2000 to February 2006.

Methods: TMA technology was used with the Procleix HIV-1/HCV Assay kits in single tube testing. Positive samples were tested with the discriminatory probes specific for HIV-1 and HCV. Pelispy HIV RNA 140 geq/ml and Pelispy HCV-RNA 380 geq/ml (VQC-Acrometrix, Netherlands) were used as internal controls for the assays.

Results: In the referred period (July 2000-February 2006) 175,823 donations were studied. A total of 194,395 tests were run including calibrators and controls. Of the total number of tests 290 (0.15%) were invalid. A total of 743 samples were initially reactive. Upon discriminatory testing 94 were proven positive (36 HIV-1 RNA, 59 HCV- RNA, 1 HIV-1/HCV RNA). Serological markers also tested positive for these samples. A total of 2,253 runs were tested with an average of 86 samples per run. An invalid run rate of 0.80% was seen (18/2,253 runs) for Procleix HIV-1/HCV. For discriminatory testing 1/98 runs was seen as invalid.

Conclusions: TMA technology (Procleix Assay, Chiron) for NAT testing of HIV-1/HCV processed 99.63% of blood donations upon first sample testing. After repeat testing a 100% specificity was seen. A very low invalid sample rate was seen (0,15%) throughout testing. Our experience shows that the Procleix HIV-1/HCV Assay demonstrated a high sensitivity, specificity and reproducibility.