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NAT SCREENING FOR HCV HIV HBV IN BLOOD DONORS. ANALITICAL EVALUATION AND MANAGEMENT ONE YEAR AFTER IMPLEMENTATION WITH CHIRON ULTRIO PROCLEIX

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Background

In Piedmont Italy NAT screening for HCV of blood donations was mandatory by DGR 28-3449 since 4.11.2001. In our Blood Transfusion Service we performed NAT screening for HCV-RNA and HIV-RNA with Chiron single-minipool, MP, (8 samples size) technology until 21.06.2004 and, since 22.06.2004 also for HBV-DNA.

Aim

In this work we show our experience with Chiron ULTRIO Procleix test.

Methods

Analytical sensitivity was assessed by testing dilutions series of the ISS (Institute Superior of Health in Italy) standard compared to WHO (World Health Organization) standard for HCV-RNA, HIV-RNA and HBV-DNA. The 95% detection limit (D.L.) was calculated by Probit Analysis. Clinical sensitivity for HBV was estimated by comparison between ULTRIO and PRISM (Abbott) and AXSYM (Abbott) for HBsAg assay testing 10 seroconversion panel (Impath BCA).

Results

Analytical sensitivity in single test: D.L.95%: HIV1-RNA 5,2 UI/ml; HCV-RNA 2,4 UI/ml, HBV-DNA 8,4 UI/ml. Clinical sensitivity for HBV shows precocity of ULTRIO Procleix Assay vs. ABBOTT PRISM HBsAg: undiluted samples 14 days (fiducial limits 11-19) minipool (8 samples size) 11 days (0-17); vs. AXSYM undiluted samples 16 days (10-21), minipool 12 days (0-19).

Feasibility in Routine

55,000 blood units were tested with ULTRIO Procleix Chiron 17,000 test and 500 run were performed. Initially Reactive (I.R.) samples increased from 0,1% with DUPLEX Technology (only for HCV and HIV) to 0,52% with ULTRIO. False Reactive (F.R.) samples increased from 0,03% to 0,43%. Monthly executing of Discriminatory assay increased from 2 runs to 5,3 with the new technology.

Conclusions

ULTRIO Assay demonstrated: very good analytical and clinical sensitivity for HCV-RNA, HIV 1-RNA and HBV-DNA. A window closure by an average of 15 days on neat samples vs. serology screening for HBsAg. ULTRIO did not impact too much the current workload using 8 samples pool, but we had to change our decisional algorithm for I.R. samples and we created a dedicated software to manage HBV results. We will show them at the Congress. Workload to perform discriminatory assay increased of 160%. In several Countries, Japan, Germany, in some Regions in Italy, HBV NAT has been added to HIV1, HCV MP/NAT blood donor screening. However there is controversy over the magnitude of the incremental yield and clinical benefit of HBV MP NAT over serological screening strategies, as well as the impact of implementation of HBV NAT on need for retention of HBsAg and anti HBc screening