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NAT and ELISA Screening: Face to Face in Blood Biological Qualification, a Reality of 5 Years in Routine (SP206)

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Background: In Italy the NAT test encompasses the last 5 years of history, today, in 13 of 20 Italian Regions, NAT screening for HCV, HIV, HBV is mandatory; in 5 Regions NAT for HCV and HIV is mandatory; in 2 Regions the NAT test only for HCV is mandatory. In the case of Hepatitis B serology, only the HbsAg test is mandatory but, in our Region, Piedmont; anti HBc is recommended for all new donors from July 2005. The aim of this work is to give an idea of our realty. We have had about 400,000 blood units validated by NAT and ELISA screening, making a comparison between antibody reactivity and viremia.

Methods: in our lab the NAT test for HCV and HIV has been routine since 11.04.2006 and for HBV from 06.22.2004. Chiron TMA technology uses single samples or pooled samples with a sample pool size of 8. ELISA screening for HIV-Ab, HCV-Ab, HBsAg is performed by ABBOTT PRISM and AXSYM systems. The anti HBc test, only for new donors, (N.D.) has been routine since 04.01.2004.

Results: For HBV: we found 7 cases of chronic hepatitis B in repetitive donors (R.D.), 0.02%; however no cases in window period. 22% of HBV-DNA positive (+) donors are HbsAg negative (-); 90% of HbsAg confirmed positive donors are viremic, in this group 100% are anti HBc +, 96% are N.D., 58% are males and 17% show a raised ALT value. Among HbsAg repetitive reactive cases with a negative or indeterminate supplemental assay only 33% are viremic expressing anti HBc in 100% of cases. For anti HBc cases 7.4% of N.D. are anti HBc +, and 3.5% of them are viremic. Among the R. D. we found 7 (22%) viremic samples without HbsAg (males 46-66 years old). For HCV: 94% of NAT + are HCV-Ab confirmed +. Among RIBA + 75% of cases are viremic. Among RIBA indeterminate cases 7% are viremic. Raised ALT values correlate more with NAT+ than with the positive serologies. All RIBA + RNA + cases express all the bands with a higher prevalence of C33 and C22 (100%), C100 (80%), NS5 (50%), in this group the samples with elevated ALT have a RIBA band score of 4+. For HIV: 100% of NAT + are also HIV Ab +. RIBA +. They show viremia in 91% of cases, RIBA indeterminate or negative cases are not viremic.

Conclusions: The recent introduction of HBV NAT screening shows an unexpectedly high number of viremic donors without HbsAg. Our data provides evidence on which Health Authorities can base specific strategies to address HBV blood safety. This work is comprehensive, including testing, epidemiology, efficiency of screening, residual risk for infectious diseases and their clinical significance. Our study could be a tool for regulators to establish meaningful requirements to ensure the safety of the blood supply.