

HEPATITIS B AND MOLECULAR SCREENING ASSAYS: EVIDENCE FOR DIFFERENT OUTCOMES OF THIS INFECTION (P-061)

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Background: Despite improvements in HBsAg test sensitivity, posttransfusion HBV infection still occurs because HBsAg could be undetectable during the early window phase, or in convalescence core window phase of the infection, or in serologically silent chronic hepatitis or in mutant forms of HBV. The strategy to prevent the residual risk of transmission of HBV by transfusion was in some blood banks the introduction of HBcAb screening and more recently the adoption of HBV-DNA screening by using high sensitive NAT assays. In Latium Region the implementation of HBV-DNA screening addressed to improve blood safety considering the high prevalence of this infection in the Middle and South Italy.

Aim: The aim of the work is to present the data of HBV infections found in blood donors following the extension of nucleic acid testing (NAT) screening to HBV-DNA.

Materials: Since 1st December 2004, 65.162 donations from donors not previously tested for HBcAb have been screened for HBV-DNA. 36.761 donations were tested in mini-pools of 20 samples using the Cobas Ampliscreen HBV assay and 28.401 donations were tested by Ultrio Procleix assay on TIGRIS Instrument as individual donation testing (IDT). The initial reactive samples were re-tested in duplicate and, if screened by Ultrio, Discriminatory HBV assay was also performed. The HBV serology markers were additionally investigated.

Results: The data of the screening revealed 28 HBV-DNA positive- HBsAg positive donors and 13 cases more difficult to assess. Among these 13 cases the following patterns were observed: - 4 donors were HBsAg positive; 2 out of them were positive and 2 were negative when tested by Ultrio as IDT, whereas 3 were HBV-DNA negative in mini-pool by Cobas Ampliscreen but they were found positive when 1 ml of plasma was concentrated by ultracentrifugation before nucleic acid extraction and PCR processing; the fourth donor was found negative by both the Ampliscreen procedures. All donors were HBcAb positive, 2 were also HBeAb positive and 1 was HBsAb weak positive. - 3 donors were HBsAg negative and HBV-DNA consistently reactive by Ultrio and Discriminatory assay; the serology tests showed 1 HBcAb and HBeAb positive, 1 only HBcAb positive and 1 quite negative. - 4 donors were HBsAg negative, Ultrio repeatedly reactive but the Discriminatory assay was not capable of confirming the presence of HBV genome; - 2 donors were found twice positive and twice negative by both Ultrio and HBV Discriminatory assays; the serology tests of these last 6 donors showed that all were HBcAb positive and 3 were also HBsAb positive, 2 out of them at low level. The donors are in follow-up.

Conclusions: The introduction of HBV molecular screening has revealed a higher than expected number of donors with HBV infection. Most of the donors found HBsAg negative and HBcAb positive could be characterized as donors with occult hepatitis B. The introduction of NAT HBV screening of blood donations increases the safety of blood supply but also provides additional information about the knowledge of hepatitis B and increases the protection of donor health by identifying clinically silent infections.