

## **SEROLOGICAL AND MOLECULAR CHARACTERISTICS OF HBV DNA POSITIVE/ HBSAG NEGATIVE BLOOD DONORS. (P-110)**

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**Background:** In Poland, obligatory testing for the release of blood components includes HBsAg, anti-HIV, anti-HCV as well as HCV RNA; since January 2005 also HIV RNA and HBV DNA.

**Aim:** to evaluate the frequency of HBsAg negative/HBV DNA positive donors and HBV infection characteristics from serological and molecular analysis of their follow up and look back samples.

**Methods:** Two methods of HBV DNA screening were used alternatively: 761 666 donations were tested in mini-pools of 24 by Cobas Ampliscreen HBV (Roche Diag) and 250 191 donations were tested individually by PROCLEIX<sup>®</sup> ULTRIO<sup>®</sup> HCV/HIV1/HBV with subsequent testing of positives by Discriminatory tests (Chiron Corp). Donation bags from HBV DNA positive donations and ULTRIO positives/Discriminatory tests negative donations were sent to the reference laboratory for HBV DNA quantitative COBAS Monitor HBV (Roche Diag) or real-time PCR (Arthus) methods. To enhance test sensitivity, DNA was isolated from 1 ml of plasma with centrifugation step in Cobas Monitor procedure or from 2 ml of plasma by Nuclisens Extractor (Biomerieux). If HBV DNA was confirmed, the index donation, follow up and look back samples were tested for HBsAg (Chemiluminescence Ortho test), anti-HBs, anti-HBc total/IgM, HBeAg, anti-HBe by IMX (Abbott) and for HBV DNA. The sequence analysis of S region of HBV DNA from 7 donors was performed.

**Results:** HBV DNA was detected in 28 donors; 8 tested in mini-pools and 20 in single donations (including 11 donors ULTRIO positive/ HIV, HCV and HBV Discrimination tests negative). In 18 donors viremia level was <10 IU/ml; in four -10 to 22 IU/ml and in six - 2x10<sup>2</sup> - 4x10<sup>4</sup> IU/ml. In two donors with viremia 1.8x10<sup>4</sup> and 3.2x10<sup>3</sup> HBsAg was detected by chemiluminescence based test. In the remaining 26 donors, four had no serological HBV markers and 22 had various antibodies to HBV proteins: anti-HBc (9 donors); anti-HBc/anti-HBe (9 donors), anti-HBc/anti-HBs (1 donor), anti-HBc/anti-HBs/ anti-HBe (1 donor) and anti-HBs (2 donors). Mutations in S region of HBV DNA were detected in two donors. In the follow up, window period was confirmed by HBsAg in three donors with no serological markers in index donation and in one donor with anti-HBc.

**Conclusions:** 1/ The frequency of HBV DNA detection in HBsAg negative donors is high (1:36 000), therefore the decision to introduce routine HBV NAT screening is justified. 2/ in all but one donors various stages of HBV infection were confirmed by serological and molecular examination, including 'window period', 'core window period' and chronic infection with mutated HBV.