

THE ADVANTAGES OF EIA WITH IMPROVED SENSITIVITY FOR THE DETECTION OF LOW CONCENTRATIONS OF HBSAG IN SAMPLES WITH MARKERS OF HCV, HBV OR HIV INFECTIONS

N. Egorova¹, S. Igolkinaz, I. Pyrenkova², I. Sharipova¹, V. Puzyrev³, A. Burkov⁴, T. Ulanova⁵

¹HIV, RPC "Diagnostic Systems" Ltd, Nizhny Novgorod, Russia ;

²HBV, RPC "Diagnostic Systems" Ltd, Nizhny Novgorod, Russia ;

³Antigens, RPC "Diagnostic Systems" Ltd, Nizhny Novgorod, Russia ;

⁴General director, RPC "Diagnostic Systems" Ltd, Nizhny Novgorod, Russia ;

⁵Scientific director, DSI S.r.l., Saronno, Italy

Objectives: The aim of the study was to characterize HBV serological profile of the samples from the plasma blood donors rejected because markers of HBV and HCV infections were detected and to evaluate serological profile of the samples from HIV/HBV-coinfected individuals.

Methods: The collection of plasma samples (n=6312) rejected for markers of HBV and HCV infections by blood transfusion stations for 2006-2013 years was evaluated. Comparative evaluation of all specimens was performed by assay with routine sensitivity limit for HBsAg detection 0.05-0.1 IU/ml and by assay with high sensitivity 0.01 IU/ml - DS-EIA-HBsAg-0.01 (CE0483) (Second International Standard for HBsAg subtype adw2, genotype A, NIBSC code number: 00/588). The collection of anti-HIV-positive samples (n=1007) was analyzed by DS-EIA-HBsAg- 0.01. Comparative evaluation HIV/HBsAg-positive specimens was performed by assay with routine level of sensitivity. The presence of HBsAg was confirmed in the reaction of neutralisation. Additionally all HBsAg-positive specimens were characterized for HBV-specific serological markers.

Results: Among 6312 samples 56 were detected as HBsAg-negative in EIA kit with sensitivity 0.05-0.1 IU/ml and were repeatedly HBsAg-reactive in EIA with sensitivity 0.01 IU/ml. So EIA with high sensitivity allowed additionally to reveal 0.9% samples with low concentration of HBsAg. 31 samples of them were HBsAg-positive in high sensitive EIA only and had no other HBV-markers. 20 samples were anti-HBc-positive. The serological profile of 10 samples was compatible with that of an HBV-carrier (anti-HBc, anti-HBe). 6 samples showed the serological profile of acute HBV-infection (anti-HBc, anti-HBc-IgM). The serological markers of 1 sample were compatible with profile of acute HBV infection with active replication (anti-HBc, anti-HBc-IgM, HBeAg). Out of 56 samples 9 were anti-HBs positive. 5 samples were anti-HBc and anti-HBs-positive, 4 of them were additionally anti-HBe-positive. Among 56 samples with HBsAg concentration below limit of sensitivity of most currently available kits (0.05-0.1 IU/ml) 20 samples had markers of HCV-infection. Probably HCV-coinfection suppresses the HBsAg-secretion and is the cause of reducing of HBsAg-concentration in such samples. Among 1007 anti-HIV-positive samples 63 samples were repeatedly reactive with DS-EIA-HBsAg-0.01.

Only 41 samples were detected as HBsAg-positive by commercial available assay with routine sensitivity limit 0.05-0.1 IU/ml. Out of 22 samples which were detected as HBsAg- positive only by high sensitive assay 11 also were additionally anti-HBc-positive, 8 of them additionally contained anti-HBe. Other 11 samples were positive only for HBsAg in low concentration and negative for any other HBV serological markers.

Conclusion: The improvement of sensitivity of the kits for HBsAg detection will allow to reveal more effectively HBsAg in samples which tested negative by most EIA with routine sensitivity, to detect HBsAg both in samples from HIV/HBV-coinfected patients and in samples with markers of HCVcoinfection. More proper diagnostics of latent HBV infection allows apply correct treatment for coinfecting individuals.