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EVALUATION OF DIAGNOSTIC EFFICIENCY OF THE HIGHLY SENSITIVE ENZYME IMMUNOASSAY FOR HBsAg DETECTION

OBJECTIVES: The early stage of HBV infection with HBsAg below the detection limit of the best available EIA kits (0.05–0.1 IU/mL) is one of the main reasons of transfusion-associated hepatitis B. The aim of the study was to evaluate the advantage of highly sensitive (0.01 IU/mL Second International Standard for HBsAg) NIBSC code number: 00/588) assay DS-EIA-HBsAg-0.01 (CE0483) intended for detection and confirmation of HBsAg.

METHODS: The panel of HBV-genotyped/subtyped samples (n = 16) (Paul-Ehrlich-Institut, Germany), the panel of samples containing mutant variants of HBsAg subtypes ayw1 and adw2 (n = 13) (RPC Diagnostic Systems, Russia), seroconversion panels (n = 28) (Boston Biomedica Inc. and ZeptoMetrix Corp.) were used. The total number of reactive specimens in all seroconversion panels was calculated as well as the mean number of days of delay in detection of HBsAg and HBV DNA.

RESULTS: All 16 HBV genotyped/subtyped specimens (A/adw2, B/ayw1, B/adw2, C/adr, D/ayw2, D/ayw3, E/ayw4, F/adw4, G/adw2) highly diluted (concentration of HBsAg equal to 0.031 IU/mL or 0.010 ng/mL) were detected as positive by the DS-EIA-HBsAg-0.01. Data on investigation of mutant variants of HBsAg showed that DS-EIA-HBsAg-0.01 has higher sensitivity in comparison to other CE-marked assay. DS-EIA-HBsAg-0.01 and other most sensitive EIA assays detected 203 and 152 samples as HBsAg positive out of 283 seroconversion samples respectively. About 181 samples were detected as HBV DNA positive. The detection of HBsAg by DS-EIA-HBsAg-0.01 and HBV DNA ranged within 0–133 days with the delay means of 21.85 days and 24.48 days respectively. The detection of HBsAg by other best EIA assays ranged within 0–142 days with the delay means of 28.52 days. DS-EIA-HBsAg-0.01 detected HBsAg in the specimens of eight panels by one bleed earlier and in the specimens of four panels by 2–5 bleeds earlier than the initial detection of HBV DNA (100–400 copies/mL) occurred.

The moments of detection of HBsAg by DS-EIA-HBsAg-0.01 and initial detection of HBV DNA coincided at evaluation of the specimens of 13 panels.

CONCLUSION: The assay with highest level of sensitivity is the most effective both for detection of different HBsAg subtypes and mutants and for early detection of HBV infection. DS-EIA-HBsAg-0.01 allows reducing diagnostic window by 2.63 days in comparison to the HBV DNA assay and 6.67 days in comparison to other best EIA assays.

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