DIAGNOSTIC CHARACTERISTICS OF THE ELISA TEST FOR THE HEPATITIS B VIRUS SURFACE ANTIGEN DETECTION

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The aim of the work was to define the diagnostic ability of the enzyme immunoassay test system DIAHBSAg (PJSC “SPC “Diaprof-Med””), in which the principle of analysis is based on biotin-streptavidin amplification of a specific signal.

The assay performance was studied on WHO Second International Standard for HBsAg, subtype adw2, genotype A (NIBSC code: 00/588) in concentration 0.006 IU/ml; on Capricorn HBsAg standard subtypes ad and ay in concentration 0.006 ng/ml and 0.004 ng/ml respectively. All 14 members of the HBsAg Low Titer Performance Panel PHA 106 (BBI, USA) were detected in DIA-HBsAg with high OD/CO ratio 11.9–40.7.

The DIA-HBsAg sensitivity is similar to the sensitivity of Roche COBAS and Murex HBsAg 3.0 when tested on the HBsAg Mixed Titer Performance Panel PHA 206 (BBI, USA) which consists of sera with various HBsAg concentrations.

The DIA-HBsAg has correctly detected low reactive members of the HBsAg Verification Panel VHA 601 (BBI, USA) with OD/CO ratio 21.0–40.7 whereas the negative member OD/CO was 0.4.

In the evaluation of 174 cross-reactive serum specimens one false positive result was obtained out of 8 sera reactive for IgM to HSV-1/2. The DIA-HBsAg specificity on 1 177 blood donors` specimens was 99.9%.

Key words: ELISA, diagnostics, hepatitis B, analytical and diagnostic sensitivity, specificity.


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