N. EGOROVA, S. IGOLKINA, I. PYRENKOVA, I. SHARIPOVA, V. PUZYREV, A. OBRIADINA, A. BURKOV, T. ULANOVA
Nizhniy Novgorod, RU;
Saronno, IT

THE HIGHLY SENSITIVE ENZYME IMMUNOASSAY FOR HBsAg DETECTION AS THE ALTERNATIVE METHOD TO NUCLEIC ACID TESTING

Background. Enhancement of sensitivity of the currently available EIA assays is very important be-cause the early stage of HBV infection when HBsAg level is below detection limit of the best available EIA kits (0.05-0.1 IU/ml) is one of the main reasons of transfusion-associated hepatitis A. The aim of the study was to evaluate the advantage of highly sensitive assay DS-EIA-HBsAg-0.01 (0.01 IU/ml Second International Standard for HBsAg subtype adw2, genotype A, NIBSC code number: 00/588) for detection of HBsAg during seroconversion period.
Methods. The correlation between HBsAg and HBV DNA presence in seronversion samples has been studied. Twenty eight commercial panels PHM - 911, 925, 926, 927, 928, 929, 930, 931, 932, 933, 934, 935A(M), 935B (Boston Biomedica Inc.) and HBV-6271, 6273, 6275, 6277, 6278, 6279, 6281, 11001, 11002, 11003, 11006, 11008, 11011,11012, 11017 (ZeptoMetrix Corp.) were used. The aggregate score was calculated by summing the total number of reactive specimens in the all panels detected by each test. The mean number of days delay in detection of HBsAg and HBV DNA were also calculated.
Results. DS-EIA-HBsAg-0.01 assay detected 203 samples as HBsAg positive out of 283 seroconversion samples. Only 181 seroconversion samples out of 283 were detected as HBV DNA positive. The detection of HBsAg and HBV DNA ranged 0-133 days with the means delay in detection of HBsAg of 21.85 days and detection of HBV DNA of 24.48 days. DS-EIA-HBsAg-0.01 detected HBsAg in the specimens of the PHM (926, 931, 933), HBV (6277, 6279, 11001, 11012, 11017) panels by one bleed earlier and in the specimens of the panels PHM925, HBV11002, PHM932, HBV6275 by two, two, four and five bleeds, accordingly, earlier than the initial detection of HBV DNA (100-400 copies/ml) occurred. With the use of the DS-EIA-HBsAg-0.01 for evaluation the specimens of the PHM (927, 928, 929, 930, 934, 935A(M)), HBV (6271, 6273, 6281, 11003,11006,11008,11011) panels, the moment of detection of HBsAg coincided in the time of initial detection of HBV DNA. Hence using more highly sensitive assay allows determining HBsAg simultaneously to HBV DNA or even earlier.
Conclusion. Increasing sensitivity EIA for HBsAg detection up to a level comparable to sensitivity of nucleic acid testing (NAT) allows to consider it as the possible alternative to other methods which will raise quality of screening of donor blood, will allow to reduce the risk of posttransfusional hepatitis B infection.

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