G. BOCHKOVA, S. FOMINA, V. PUZYREV, A. OBRIADINA, A. BURKOV, T. ULANOVA

Nizhny Novgorod, RU

THE EVALUATION OF THE ELISA KIT "DS-EIA-ANTI -HCVSPECTR-GM" AS SUPPLEMENTAL ASSAY FOR CONFIRMATION OF ANTI-HCV SCREENING POSITIVE RESULTS

Introduction: The new kit "DS-EIA-anti-HCV-SPECTR-GM" for the detection of antibodies to separate proteins of hepatits C virus in human blood serum or plasma and for the confirmation of anti-HCV screening assay results was developed. The recombinant antigens comprising only diagnostically relevant regions of different variants of native HCV proteins were selected.
Aim: The evaluation of the ELISA kit "DS-EIA-anti-HCV-SPECTRGM".
Objectives and Methods: The various sequences of recombinant antigens comprising HCV Core, NS3, NS4, NS5 were separately adsorbed on the plate. Diagnostic value of the assay was studied by testing 1004 anti-HCV positive samples of patients with confirmed hepatitis C diagnosis, including 338 samples with determined genotype 1−6; samples of 18 commercial seroconversion panels (BBI Inc., ZeptoMetrix), samples of the "Anti-HCV Mixed Titer Performance Panel BBI PHV 206" (BBI Inc.). Additionally sera samples of patients with acute (n = 30) and chronic (n = 439) hepatitis C were studied for the clinical efficiency assessment. Diagnostic specificity was studied by testing samples of healthy blood donor (n = 1657), clinical patients (n = 1225), pregnant women (n = 887).
Results: Out of 127 samples from 18 tested seroconversion panels the "DS-EIA-ANTI-HCV-SPECTR GM" assay confirmed 50 samples (39.4%) as positive and 22 samples (17.3%) as indeterminate. The kit of comparison (immunoblot "DECISCAN HCV Plus", Bio-Rad) detected 35 (27.56%) seroconversion samples as positive and 37 (29.13%) samples as indeterminate. In 21 samples with an indeterminate result HCV-RNA was detected. The diagnostic sensitivity of the new kit at testing anti-HCV positive samples from patients with acute and chronic hepatitis C and samples with different genotypes was 100%. All samples from "Anti-HCV Mixed Titer Performance Panel BBI PHV 206" were detected by "DS-EIA-ANTI-HCV-SPECTR GM" in according to panel data sheet. The study also showed high specificity of the kit "DS-EIAANTI-HCV-SPECTR GM".
Conclusion: The optimal selection of highly immunoreactive epitopes of various HCV-proteins used in the kit allows significantly reduce indeterminate results and by that to increase the reliability of hepatitis C diagnostics.

21th European Congress of Clinical Microbiology and Infection Diseases. – Milan, May 7-10, 2011. – P.2235.