

THE EVALUATION OF THE ELISA KIT "EIA-anti-HCV" WITH NEW RECOMBINANT ANTIGENS

Introduction. High heterogeneity is typical for hepatitis C virus. The new generation enzyme immunoassay "EIA-ANTI-HCV" intended for the detection of antibodies to viral hepatitis C in human serum or plasma was developed. The recombinant antigens comprising only diagnostically relevant regions of different variants of native HCV proteins were specially selected.

Aim. The evaluation of the ELISA kit "EIA-anti-HCV".

Objectives and Methods. The various sequences of recombinant antigens comprising HCV Core, NS3, NS4, NS5 were adsorbed on the microtiter 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 (76 samples of genotype 1, 51 sample of genotype 2, 38 samples of genotype 3, 25 samples of genotype 4, 5 samples of genotype 5, 8 samples of genotype 6); samples of 31 commercial seroconversion panels (BBI Inc., ZeptoMetrix), samples of the "Anti-HCV Mixed Titer Performance Panel BBI PHV 206" (BBI Inc.) 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 donor blood (n = 8107), clinical patients (n = 1225), pregnant women (n = 735), patients with hepatitis B (n = 600).

Results. Out of 259 samples from 31 tested seroconversion panels the kit "EIA-ANTI-HCV" detected 101 samples (40%) as positive. The kit detected 23 positive results and indicated 2 negative results according to data available from insert package of the panel "Anti-HCV Mixed Titer Performance Panel BBI PHV 206". It should be mentioned that the value OD/Cut-off of the most of positive results were higher than the passport date. The diagnostic sensitivity of the kit "EIA-ANTI-HCV" at testing anti-HCV positive samples with clinical diagnosis of acute and chronic hepatitis C was 100%. Sensitivity of the kit during testing the samples with different genotypes was 100%. The study showed high specificity of the kit "EIA-ANTI-HCV".

Conclusion. The received results demonstrated high diagnostic efficiency of ELISA kit in the combination with high specificity.