

THE EVALUATION OF THE NEW ELISA KIT EIA-ANTI -HCV-SPECTRUM-M INTENDED FOR SEPARATE DETECTION OF ANTI-IgM TO DIFFERENT HCV ANTIGENS

INTRODUCTION: The new kit EIA-anti-HCV-SPECTRUM-M intended for separate detection of anti-IgM to different HCV antigens 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 EIA-anti-HCV-SPECTRUM-M.

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 205 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.), 190 samples from infants born to HCV-positive mothers in dynamics, samples from patients with acute (AHCV) (n = 35) and chronic (CHCV) (n = 439) hepatitis C. Diagnostic specificity was studied by testing samples of healthy blood donors (n = 1657), clinical patients (n = 1278), pregnant women (n = 887).

RESULTS: The testing of the kit EIA-anti-HCV-SPECTRUMM showed that about 86.3% of anti-IgG positive samples of patients with AHCV and CHCV have anti-IgM to one or more viral antigens. Good correlation between the presence of HCV RNA and the detection of anti-HCV IgM was revealed. About 95.3% samples with the determined genotype have anti-HCV IgM. More early seroconversion IgM than IgG was detected for two panels BBI 908 and BBI 916(M). The first one appeared anti-IgM to NS4. Anti-IgG were detected earlier than anti-IgM in 11 panels. In the rest five panels anti-IgG were detected simultaneously with anti-IgM. More than 90% of samples from patients with CHCV contain more than one marker of anti-HCV IgM. About 80% of patients with CHCV have anti-HCV IgM to three or four antigens. All samples from babies with AHCV diagnosed in the age of 3–5 months had anti-Core IgM alone or with anti-NS3 IgM and were HCV RNA positive. The significant increase of anti-Core IgM titers was specified to 9–10 months and anti-NS IgM to 9–18 months and indicated to the development of CHCV. The study also showed high specificity of the kit EIAanti-HCV-SPECTRUM-M.

CONCLUSION: The measurement of anti-IgM to different HCV proteins may be important for diagnostics of perinatal transmitted HCV infection and as a predictive factor of persistent infection.