

Development of ELISA method for primary detection of HCV using core antigen

ABSTRACT

Studies show that Hepatitis C Virus (HCV) antigens appear before antibody while the early days of infection. Therefore detecting antigens could lead us to diagnosing the infection on time. The aim of this study was to develop a simple and sensitive enzyme immunoassay for the detection of hepatitis C virus (HCV) core antigen in order to evaluate the role of core antigen as a marker of HCV infection. A total of 280 samples was tested by third generation anti-HCV, and the reverse transcription polymerase chain reaction (RT-PCR) was performed only when the anti-HCV enzyme immunoassay (EIA) was positive. All samples were tested with HCV core antigen using Elisa kits. Among the 280 samples, 95 samples were anti-HCV positive. Among those 95 samples, 75 samples were RT-PCR-positive. The cut-off value was set at 0.15 unit of optical density (equivalent to 2.5 pg/ml of core antigen based on the distribution of healthy subjects (anti-HCV-negative subjects). The difference between the mean optical density values of HCV-ribonucleic acid-positive (HCV-RNA-positive) samples and HCV-RNA-negative samples in the HCV core antigen assay was highly significant (1.4 us 0.08, $p < 0.005$). The sensitivity and specificity of the core antigen assay were 88% and 96%, respectively. The pretreatment of the anti-HCV-positive samples with a solution that contained 1.5 M glycine buffer (pH = 2) increased the sensitivity of the assay (from 57.3% to 88%). This assay is a simple, sensitive, and useful method for use as a screening strategy for HCV infection in anti-HCV-positive or anti-HCV-negative individuals.

Keyword: Hepatitis C virus (HCV); Core antigen; ELISA; Polymerase chain reaction (PCR)