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P.006 The new HBsAg Elisa-kit "DS-EIA-HBsAg-0.01" with the increased sensitivity

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Background and Objectives: The HBsAg is the most commonly used marker of Hepatitis B virus (HBV) infection. Improvements in assay sensitivity have been achieved constantly since introduction of the first commercial test. The current EIA for the detection of HBsAg have an analytical sensitivity equal 0.1 ng/ml. Despite the high performance of screening assays, transfusion-associated HBV infection is still reported. Donation with HBsAg level below the detection limit of currently commercial assays presents a high residual risk of Hepatitis B virus transmission by transfusion. The aim of this present Study was to develop and evaluate EIA test for HBsAg detection with 10-fold increased sensitivity (0.01 ng/ml).

Methods: New EIA one-step diagnostic test based on biotin-streptavidin amplification. Sensitivity of new test was estimated by testing serial dilutions of the Second International Standard for HBsAg (NIBSC 00/588), Hepatitis B HBsAg Sensitivity Panel PHA807 [Boston Biomedica Inc. (BBI). West Bridgewater, MA, USA], Low Titer Performance Panel (BB1 PHA106), Mixed Titer Performance (BBI Panel PHA205), two Seroconversion panels (BBI PHM933 and BBI PHM934). Additionally, serum specimens (n = 494) from patients with HIV infection, the samples of the some recombinant HBsAg mutant (n = 13) have been tested. To challenge the specificity of the new assay, serum samples of healthy blood donors (n = 3348), pregnant women (n = 381), patients with other infections (n = 392) and patients with noninfectious diseases (n = 95) were investigated.

Results: Analytical sensitivity of the "DS-EIA-HBsAg-0.01" assay was estimated equal 0.01 ng/ml. This test showed identical sensitivity for different HBsAg subtypes. All samples from commercial panels demonstrated much higher signal to cutoff ratios than with other assays. The "DS-EIA-HBsAg-0.01" kit permits earlier detection of acute Hepatitis B than the alternative tests. Among anti-HIV positive samples (n = 494) 82 specimens were tested as HBsAg positive.16 of them contained HBsAg in concentrations less than 0.05 ng/ml and had not been detected by other used assays. 9 serum samples from these 16 did not have other markers of HBV infection. 6 serum samples from 3348 healthy donors tested as HBsAg negative in alternative assays were detected as HBsAg positive in the new test. Additionally, the new test has allowed to define mutant forms recombinant HBsAg in much lower concentration. General specificity of the new test among different sample cohorts was equal 99.6%.

Conclusion: The received results demonstrated high diagnostic efficiency of ELISA kit "DS-EIA-HBsAg-0.01". By using this highly sensitive screening assay, risk of posttransfusional Hepatitis B infection can be reduced.

P.150 **Anti-HCV profile in serum specimens from HCV infected patients coinfected with opportunistic diseases**

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Background and Objectives: One of the problems of EIA diagnostic hepatitis C infection (HCV) is associated with the reliable verification screening assays results. Serum samples from HCV infected patients with coinfections may present with atypical results in serological tests.

The purpose of the present study was to evaluate the antibody profile of serum specimens from HCV infected patients coinfected with opportunistic diseases.

Methods: The correlation of anti-HCV antibody profile with presence antibodies to TORCH infections in sera from coinfected patients has been investigated. Well defined anti-HCV positive serum samples (n = 162) were additionally tested on presence of anti-IgG, IgM, IgA to Toxoplasma gondii and Chlamydia trachomatis; anti-IgG to HSV-1 and HSV-2, anti-IgG, IgM to CMV and anti-VGA IgG, anti-VGA IgM, anti-EA, anti-EBNA. As a control group, anti-HCV negative serum samples from healthy blood donors have been used (n = 247). All data were statistically processed.

Results: It has been shown that anti-Toxo IgG in the anti-HCV positive serums meet twice less often than in serums of healthy donors ($p>0.995$). Besides this in serum samples with antibodies to all HCV proteins or with antibodies to three HCV proteins (core, NS3 and NS4) the lower concentration anti-IgG to HSV-1 and HSV-2 is observed ($p>0.966$). Moreover, it has been revealed that in specimens containing antibodies to the structural protein of HCV as a unique marker of Infection or in a combination with antibodies to nonstructural HCV proteins the twice lower concentration of antibodies to a capside antigen (VCA) of the Epstein-Barr (EB) virus is observed ($p>0.95$). In specimens containing antibodies to the core protein of HCV in a combination with NS4 HCV the concentration of antibodies to the NA antigen of EB virus was ($p> 0.902$).
Anti-NS3 is a unique marker of the HCV infection presented in 45% of anti-IgA and 31% of anti-IgG Chlamydia trachomatis positive sera. The combination of anti-NS3 with anti-core or combination of anti-nonstructural HCV proteins only were observed in 55% of anli-IgA and 69% of anti-IgG Chlamydia trachomatis positive sera ($p> 0.995$).
Other statistically significant correlations have no) been revealed.
Conclusion: There is bidirectional influence of the hepatitis C virus and opportunistic infections. Serum specimens from HCV patients coinfected with TORCH infections very often have no complete HCV-antibody spectrum.

P.465 **Prevalence of anti-HEV in veterans who have been at war or have not been at war in Afghanistan In 1979-1989**

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Background and Objectives: Afghanistan is an endemic region for hepatitis E. In 1979-1989, a limited contingent of Soviet Army took part In war actions in Afghanistan. Veterans of this war have had a higher risk of exposure to HEV during their presence in Afghanistan. The aim of this study was to Investigate the current prevalence of anti-HEV In veterans who have been at war in Afghanistan in 1979-1989 and in those who have had their military service in the same years in regions of former USSR, non-endemic for hepatitis E.

Methods: Two groups of veterans were studied: group A — veterans who have had their military service in Afghanistan (n = 317), and group B - veterans who have had their military service in non-endemic for HEV regions of former USSR (n = 208). All individuals currently live in non-endemic for HEV area (Sverdlovsky Region. Russia), are of the same age and have had their military service at the same years (1979-1989). Individuals who have not been in Afghanistan denied any visits in south regions of former USSR.

Anti-HEV testing was performed in ELISA with commercially available assay ("Diagnostic Systems", Russia).

Results: At the time of investigation (2004-2005) the prevalence of anti-HEV in veterans who have had their military service in Afghanistan was 29.97% (95/317) and was significantly higher than that observed in veterans who have had their military service in non-endemic for HEV regions of former USSR (3.8% [8/208], PR [95% Cl] = 7.8 [3.9-15.7]. p < 0.0001). These results suggest that at least approximately 30% of veterans who have been at war in Afghanistan have been exposed to HEV. In none of cases anti-HEV IgM were detected.

Conclusion: The military service in endemic for hepatitis E regions is consistent to a higher risk of HEV-infection and demands preventive measures, including vaccination against hepatitis E.