27th ECCMID Vienna, Austria 22 – 25 April 2017
The congress of ESCMID

Session: EV030 Viral infection & disease

Category: 1g. Diagnostic virology (other than hepatitis & HIV)

22 April 2017, 08:45 - 15:30
EV0575

Improved detection of hepatitis B virus surface antigen by new enzyme immunoassay

Ekaterina Kochina[1], Irina Pyrenkova[2], Yulia Ptitsyna*[2], Natalia Egorova[2], Ekaterina Maiorova[3], Saskia Biallas[4], Philipp Roth[4], Anatoly Burkov[5], Anna Obriadina[5]

[1]*Rpc "diagnostic Systems", Ltd; R&d*

[2]*Rpc Diagnostic Systems Ltd*

[3]*Rpc Diagnostic Systems; Research and Development*

[4]*Ab Diagnostic Systems GmbH*

[5]*Rpc Diagnostic Systems*

Background: The use of high sensitive test for HBsAg detection allows reducing the period of serological window. It will enhance quality of hepatitis B diagnostics. Detection of the most important HBsAg mutations is also necessary. In this study a new "sandwich" solid-phase enzyme immunoassay abia HBsAg was compared to well-established test.

Material/methods: The test kit under evaluation was abia HBsAg, cat. #DK.013.01.3 (AB Diagnostic Systems GmbH, Germany). Murex HBsAg Version 3, cat. #9F80-05 (Murex Biotech Limited, UK) was used as reference assay. 38 seroconversion panels were investigated (ZeptoMetrix Corporation – 33 panels (HBV 6271, 6272, 6275, 6276, 6285, 6288, 6289, 6293, 6290, 6292, 9073, 11000, 11002, 9074, 11006, 11007, 11011, 11008, 11009, 11010, 11012, 11016, 11013,11028, 11017, 11024, 11026, 11027, 11029, 11031, 11052, 11056, 11069) and BBI Diagnostics – 5 (PHM 906, 918, 921, 924, 936)). WHO 3rd International Standard for HBsAg (NIBSC Code: 12/226) was used for determination of analytical sensitivity. Native mutant panel cat. #DH1200, (Trina Bioreactives AG, Germany) was utilized to evaluate mutant detection by abia HBsAg. For specificity assessment 5008 samples from unselected donors were tested by abia HBsAg (Blood donor service from German Red Cross, Frankfurt/Main, Germany).

Results: The analytical sensitivity was evaluated with WHO 3rd International Standard for HBsAg (NIBSC Code: 12/226) and defined at 0.02 IU/ml. It was calculated as limit of detection in accordance with the CLSI document EP17-A2 with a probit regression model.
Seroconversion sensitivity of abia HBsAg and Murex HBsAg Version 3 was evaluated. In this study abia HBsAg detected more panel members (191 of 477) than Murex HBsAg Version 3 (171 of 477).
The native mutant panel (n=48) was tested in abia HBsAg. The panel includes serum samples with different HBV genotypes, HBsAg subtypes and serotypes: A1 (ayw1), A2 (adw2), A3 (ayw1), B4 (ayw1), C (adr), D1 (ayw1 and ayw2), D2 (ayw2 and ayw3), D3 (ayw3), D4 (ayw2), D7 (ayw2), E (ayw3 and ayw4). Samples from this panel represent wide variety of HBsAg mutants: 1) amino acid substitutions at positions 116, 118, 120, 123, 126, 124, 129, 130, 133, 134, 143, 144, 145 2) insertions at amino acid position 116 and 114/115 3) mutation W172-stop outside of main hydrophilic region. All samples were tested undiluted and diluted 1:10 in human negative plasma. The kit abia HBsAg detects ad and ay HBsAg subtypes. All samples with mutation in first and second loops were identified as positive by abia HBsAg.
Total specificity of abia HBsAg with 5008 blood donor specimens was 99.86%.

Conclusions: The kit abia HBsAg permits earlier HBsAg detection than the reference assay. Diagnostic capacity of the studied test system is broad enough. High sensitivity of abia HBsAg does not impair the specificity of the assay.