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

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Material/methods: The kit under evaluation was abia HBsAg, cat. #DK.013.01.3 (AB Diagnostic Systems GmbH, Germany). Murex HBsAg Version 3, cat. #SF80-05 (Murex Biotech Limited, UK) was used as a reference assay. 38 serocorrelation panels were investigated (ZeptoMetrix Corporation – 33 panels (HBV 6272, 6272, 6275, 6276, 6285, 6288, 6289, 6293, 6290, 6292, 9073, 11000, 11002, 9074, 11006, 11007, 11011, 11008, 11009, 11100, 11101, 11013, 11012, 11016, 11013, 11012, 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), Standard for HBsAg, Subtype Ad, 100 U/ml (Paul-Ehrlich-Institut) and Working standard HBsAg subtype Ay, 50 000 U/ml (Paul-Ehrlich-Institut) were used for determination of analytical sensitivity. Native mutant panel cat. #DH1200, (Trina Bioreactives AG, Germany) was utilized to evaluate mutant detection by the abia HBsAg. For specificity assessment 5008 samples from unselected donors were tested by the 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. The abia HBsAg detects both Ad and Ay HBsAg subtypes as positive. The minimal HBsAg concentration detected by the abia HBsAg (A=0.02) was 0.008 IU/ml, according to Standard for HBsAg, Subtype Ad, 100 U/ml (Paul-Ehrlich-Institut) and 0.004 IU/ml according to Working standard HBsAg subtype Ay (Paul-Ehrlich-Institut). Thus, the abia HBsAg demonstrated comparable ability to detect Ad and Ay subtypes. The determination of parallelism and linearity between sets of dose-response data (results of Ad and Ay serial dilution testing) is an integral part of the similarity indication of the substances. Parallelism and linearity between Standard Subtype Ad and Working Standard Subtype Ay dilutions were estimated using One-way analysis of variance.

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