Viral load measurements with results below detection limit in HBV samples with high or low Hepatitis B surface antigen titres

PP-074

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BACKGROUND

Although other biomarkers show a more consistent correlation to the amount of HBV cccDNA (covalently closed circular DNA) than Hepatitis B surface antigen (HBsAg), high levels of HBsAg are usually associated with high levels of cccDNA. In this part of a greater study comparing the performance of the NeuMoDx HBV Quant Assay (QIAGEN) with the Alinity m HBV assay (Abbott) we investigated whether the level of HBsAg has an influence on HBV viral load measurement with the NeuMoDx HBV Quant Assay.

METHODS

300 fresh plasma samples from routine diagnostics were tested with the test of record (Alinity m HBV, Abbott) and had a HBV DNA result below LLOD. Those samples were retested without any freeze thaw cycles within 24 hours with the HBV Quant Assay on the NeuMoDx system (QIAGEN). Of 120 samples HBsAg values were measured either with the qualitative Access HBsAg assay (Beckman Coulter) (n=80) and/or (8 duplicates) with the quantitative LIAISON® XL MUREX HBsAg Quant assay (DiaSorin) (n=48). Values greater than 3000 S/CO or greater than 150 IU/mL, respectively, were considered high positive, values below this were considered low positive.

RESULTS

150 DNA positive samples tested with both assays (viral load range from 0.9 to 9 log IU/mL) a linear regression model showed a slope of 1.02, intercept of -0.30 and a coefficient of determination (R^2) of 0.98. The Bland-Altman Plot resulted in a mean bias of -0.24 log IU/mL (s. Fig. 1+2). For 120 of 150 tested samples with undetectable HBV viral loads there were HBsAg values available. Qualitative HBsAg values ranged from 0 to 6900 S/CO and quantitative results ranged from <0,05 to >1000 IU/mL. Neither HBsAg values above 3000 S/CO (n=46) in the qualitative assay nor values above 150 IU/mL (n=23) in the quantitative test had an influence on the measured HBV viral load. All pre-tested samples that were not detectable with the TOR or <10 IU/mL were "DNA not detected" when tested with the NeuMoDx HBV Quant Assay..

CONCLUSIONS

Despite the correlation between HBsAg and cccDNA and therefore the potential for increased HBV-RNA levels in plasma, the level of HBsAg had no influence on HBV viral load measurement with the NeuMoDx HBV Quant Assay in high positive HBsAg samples.

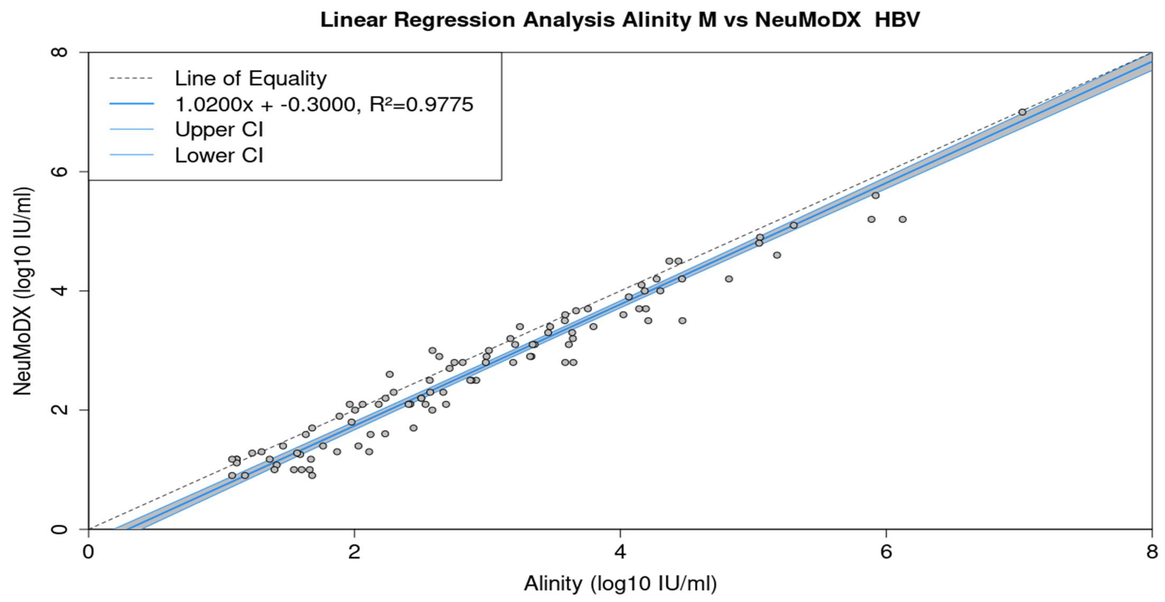

Fig. 1: Deming regression of HBV log IU/mL Alinity M vs. NeuMoDx

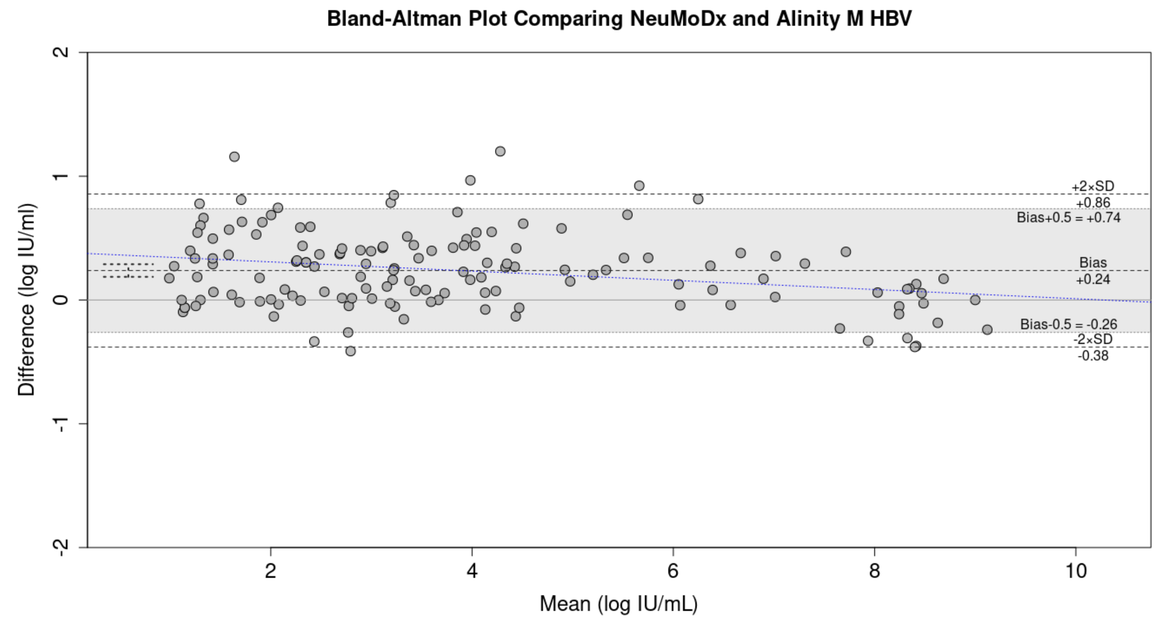

Fig. 2: Bland-Altman Plot of HBV log IU/mL Alinity M vs. NeuMoDx

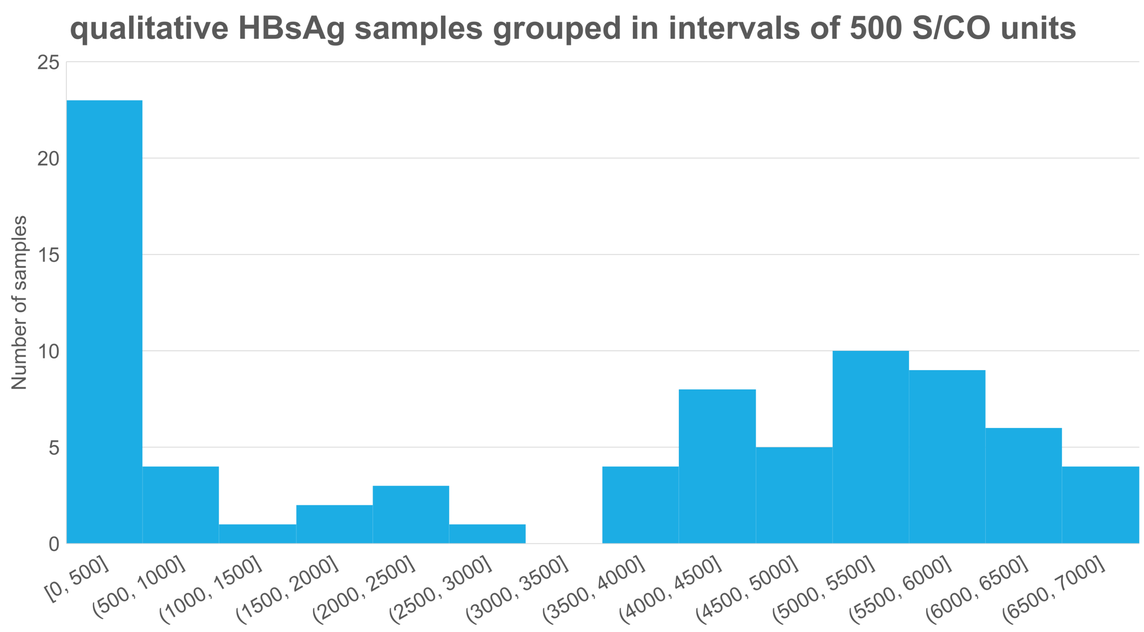

Fig. 3: Number of qualitative HBsAg samples grouped in intervals of 500 S/CO units

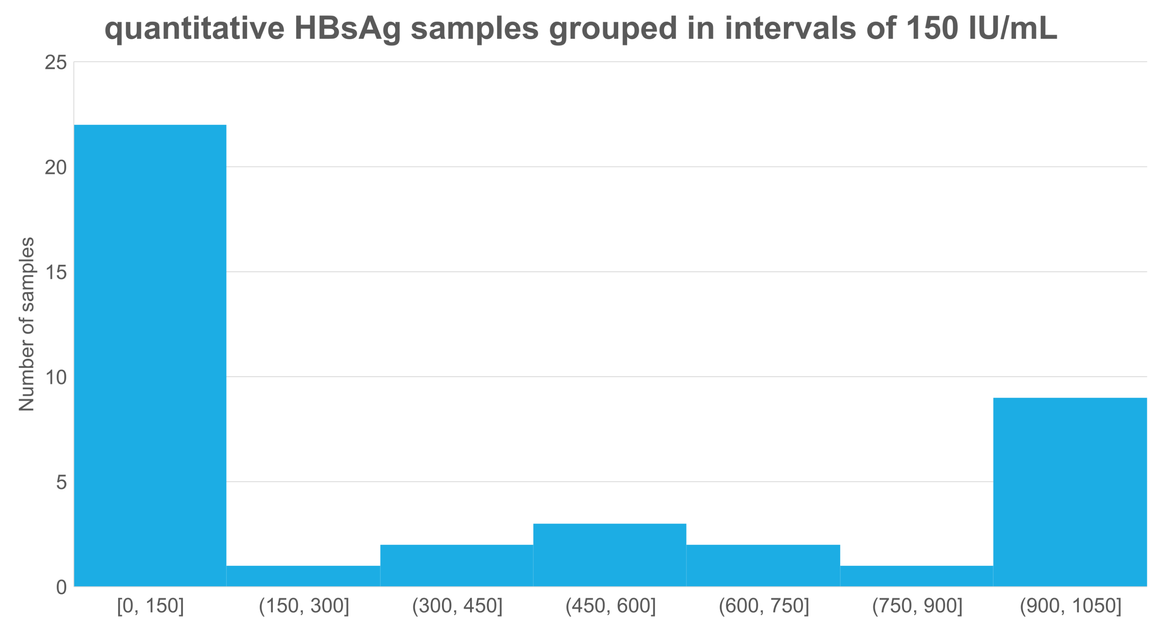

Fig. 4: Number of quantitative HBsAg samples grouped in intervals of 150 IU/mL

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