Comparison of the new Alinity m HBV with the CAP/CTM HBV for quantification of HBV in serum and plasma

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Background

HBV viral load monitoring is vital for guiding treatment decisions, and monitoring of treatment efficacy. Abbott Molecular recently released the Alinity m HBV assay to be run on the Alinity m System, a fully automated, continuous and random access analyser using ReadiFlex™ technology.

Material and Methods

We investigated the performance of the Alinity m HBV assay in comparison to the cobas® AmpliPrep/cobas® Taqman HBV assay, version 2 (CAP/CTM HBV).

Eighty-eight serum and plasma samples with sufficient remaining sample volume after testing with the CAP/CTM HBV, were de-identified and tested with the Alinity m HBV assay. All quantifiable results were available in, or log transformed into, $\log_{10}$ IU/mL for statistical analysis. Deming regression and Bland-Altman analysis were performed to assess correlation and agreement between the quantifiable results obtained with both assays.

Results

Fifty samples (22 plasma, 28 serum) had quantifiable results with both assays. A strong correlation (r = 0.981) was observed between CAP/CTM HBV and Alinity m HBV with Deming regression analysis (Figure 1). Bland-Altman analysis indicated that the mean difference between paired results (Alinity m minus CAP/CTM) was 0.14 $\log_{10}$ IU/mL with a standard deviation (SD) of 0.277 $\log_{10}$ IU/mL (Figure 2).

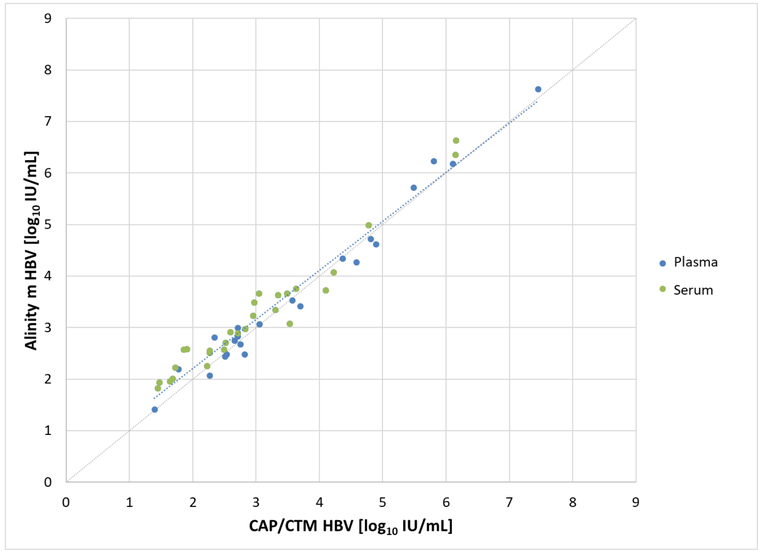

Figure 1. Deming regression analysis for Alinity m HBV and CAP/CTM HBV (n = 50). Slope: 0.97 (95% CI 0.92 – 1.03); Intercept: 0.23 (95% CI 0.04 – 0.42).

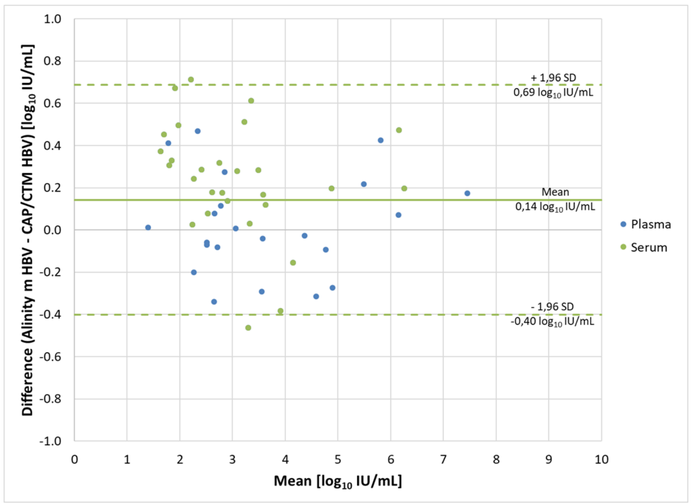

Figure 2. Bland-Altman analysis Alinity m HBV and CAP/CTM HBV (n = 50). Mean difference: 0.14 $\log_{10}$ IU/mL (95% CI 0.06 – 0.22 $\log_{10}$ IU/mL); SD: 0.277 $\log_{10}$ IU/mL.

Only four samples (4/50; 8.0%) had a difference greater than 0.5 $\log_{10}$ IU/mL (difference ranged between 0.51 and 0.71 $\log_{10}$ IU/mL).

Alinity m HBV	CAP/CTM HBV				
	> ULOQ	Quantifiable	< LLOQ	TND	Total
> ULOQ	1				1
Quantifiable	2	50	3	1	56
< LLOQ			5	4	9
TND			2	20	22
Total	3	50	10	25	88

Alinity m HBV ($\log_{10}$ IU/mL)	CAP/CTM HBV ($\log_{10}$ IU/mL)
8.32	> 8.23
8.33	> 8.23

Alinity m HBV ($\log_{10}$ IU/mL)	CAP/CTM HBV ($\log_{10}$ IU/mL)
1.04	< 1.30
1.13	< 1.30
1.51	< 1.30

Alinity m HBV ($\log_{10}$ IU/mL)	CAP/CTM HBV ($\log_{10}$ IU/mL)
1.18	TND

One sample tested above the upper limit of quantification (ULOQ) with both assays, and two samples tested above ULOQ with the CAP/CTM HBV but were quantifiable with the Alinity m HBV. Twenty samples were undetectable with both assays, and a further 5 samples were detected, but unquantifiable with both assays. Four samples were quantified with the Alinity m HBV (range 1.04 – 1.51 $\log_{10}$ IU/mL), but were either undetectable (n = 1) or detected but unquantifiable (n = 3) with the CAP/CTM HBV.

Conclusions

The Alinity m HBV assay compared well with the CAP/CTM HBV. More samples were quantifiable with the Alinity m HBV than the CAP/CTM HBV due to its broader quantification range.

Acknowledgements
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