Comparison of two real-time PCR HBV DNA quantification workflows using Passing-Bablok Regression Test

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Background

Quantification of hepatitis B virus (HBV) DNA is an important test in the management of chronic HBV infection.
Changing quantification workflows requires, among others, the evaluation of possible bias in quantification between assays.

Aim

The comparability in quantification was analyzed with Passing-Bablok (PB) Regression Test for two workflows: AltoStar® HBV PCR Kit 1.5 / AltoStar® Automation System AM16 (AltoStar® HBV workflow) and Alinity m HBV assay / Alinity m Instrument (Alinity m HBV workflow).

Material and Methods

In total 212 individual EDTA plasma samples were analyzed using the AltoStar® HBV workflow (altona Diagnostics GmbH) and compared to the Alinity m HBV workflow (Abbott) at the Institut für Virologie, Universitätsklinikum Freiburg (Freiburg, Germany).

Results

110 samples from patients under HBV therapy gave a positive result with both workflows and all 102 samples without a history of HBV infection gave a negative result with both workflows (Table 1).

Table 1

	Qualitative Results	
Diagnostic sensitivity	100%	CI: 96.70% – 100%
Diagnostic sensitivity	100%	CI: 96.45% – 100%

Data were compared by PB regression. The Cusum test was used to approve the applicability of the PB regression method for the data set (validity criteria: p>0.2); see Figure 1 and Table 2.

Table 2

Result of PB regression	
slope	**0.9778**
Lower 95% CI	0.9273
Upper 95% CI	1.0326
intercept	**0.0791**
Lower 95% CI	−0.132
Upper 95% CI	0.2638

The Bland-Altman Plot, assessing agreement between two data sets, shows an overall bias of 0.05; see Figure 2.

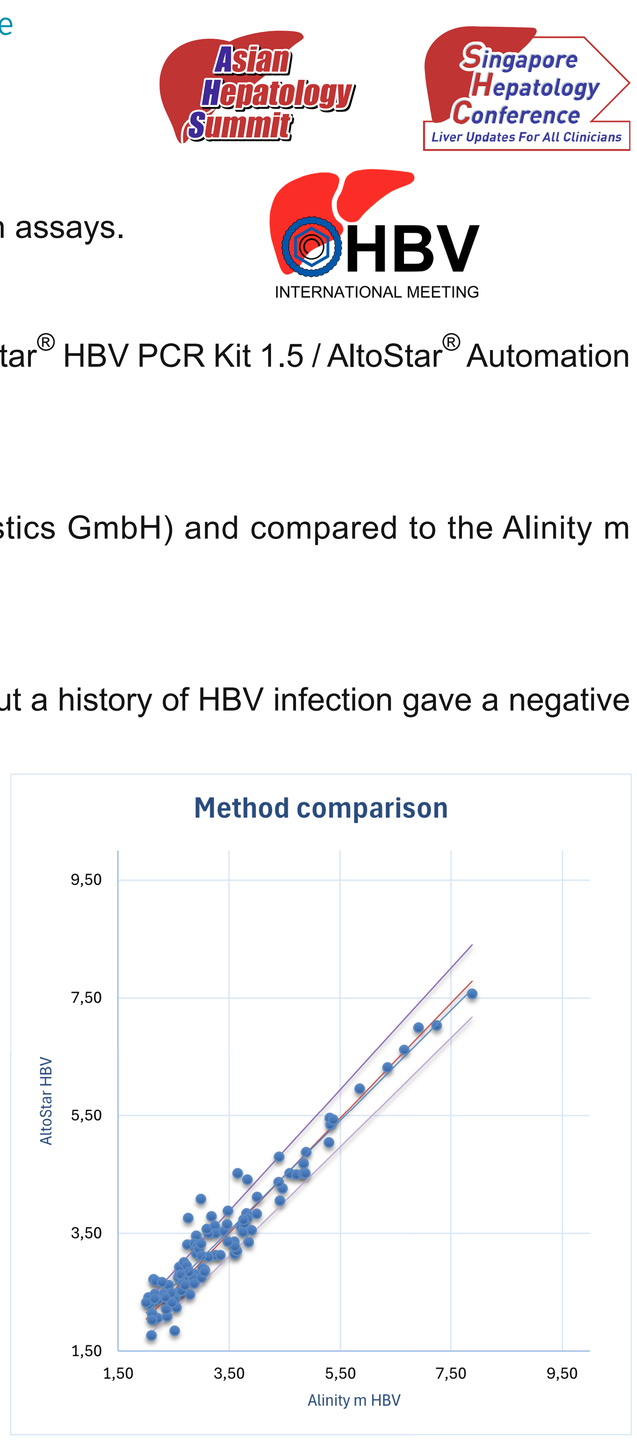

Figure 1: PB regression, scaling in graph in [log_{10} IU(ml]

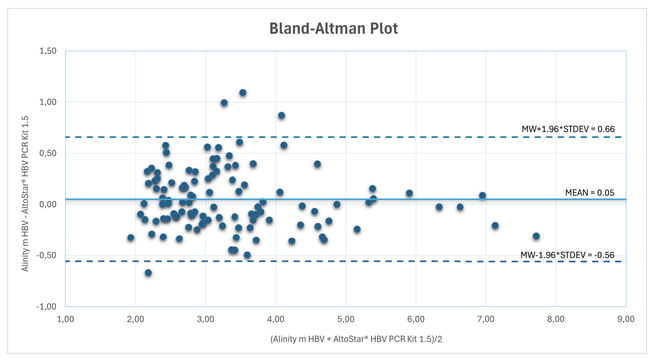

Figure 2: Bland-Altman Plot, scaling in graph in [log_{10} IU(ml]

Discussion

PB regression and Bland-Altman plots are complementary tools. PB results describe how the two methods differ (slope/intercept), while the Bland-Altman plot shows how much they differ (mean bias and spread).
Both analysis methods confirm no statistically significant constant or proportional bias between the AltoStar® HBV workflow and the Alinity m HBV workflow (Abbott).

Conclusion

The AltoStar® HBV PCR Kit 1.5 shows a very good sensitivity and specificity and a very good correlation in quantitative results compared to the Alinity m HBV assay. The AltoStar® HBV PCR Kit 1.5 can be considered as highly accurate in quantification of HBV viral loads.

Notice: The AltoStar® HBV PCR Kit 1.5 is a CE-marked product according to Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices.

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