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Performance evaluation of the AltoStar® HBV PCR Kit 1.5 on the AltoStar® Automation System AM16 platform

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Background

International treatment guidelines like the EASL guideline[1] and the AASLD guideline[2] require HBV DNA viral load assays including quantification of a broad linear range to permit measurement of pre-treatment viral loads that may be in the hundreds of millions, and low viral loads down to 10–20 IU/ml, seen with on-treatment viral response, in inactive carriers or due to drug resistance or occult HBV infections[3,4].

Objectives

Performance evaluation of the novel AltoStar® HBV PCR Kit 1.5 on the AltoStar® Automation System AM16, recently receiving CE-IVD mark.

Materials and methods

We used the 4th WHO International Standard for HBV NAT to determine the limit of detection (LoD). Probit analysis was performed to calculate the LoD.

For testing all relevant HBV genotypes the HBV Genotype Evaluation Panel 01 provided by Qnostics, the 1st WHO International Reference Panel for Hepatitis B Virus Genotypes for Nucleic Acid Amplification provided by the Paul-Ehrlich-Institut (PEI), the AccuSet™ HBV Worldwide Performance C Panel provided by SeraCare and the HBV Genotype H provided by BocaBiolistics were used.

The diagnostic performance of the AltoStar® Automation System was compared to the Abbott RealTi*m*e HBV assay on the Abbott *m*2000 Sample Preparation System.

In total, 460 samples from HCV-infected patients were analyzed. We assessed diagnostic sensitivity and specificity and compared quantitative results by linear regression analysis and Bland-Altman Plot.

Results

The LoD of the AltoStar® workflow for the detection of HBV genotypes A to H in EDTA plasma was 10.2 IU/ml [95% confidence interval 7.6 to 15.8 IU/ml]. The analytical specificity was 100% as assessed on 100 HBV DNA negative samples. The diagnostic sensitivity and specificity of the AltoStar® assay was 100% [95% Conf. Interval: 97.26 to 100] and 95% [95% Conf. Interval: 89.90 to 97.95], respectively. There was very good correlation between quantitative results obtained with the AltoStar® workflow and the Abbott system (correlation coefficient R = 0.96 (R^2 = 0.93).

Conclusions

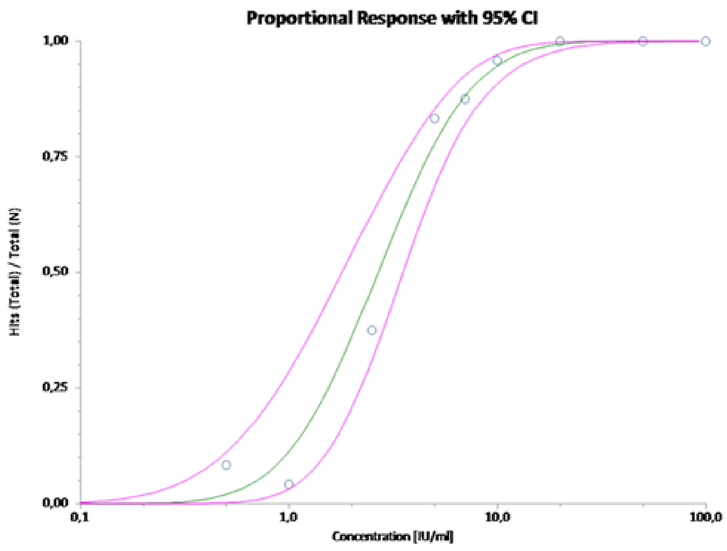
The AltoStar® HBV PCR Kit 1.5 in combination with the AltoStar® Automation System AM16 demonstrated an analytical and diagnostic performance comparable to that of a currently market-leading HBV assay. It may aid clinical decision making and management of HBV infected patients.

[1] https://easl.eu/publication/easl-guidelines-management-of-hepatitis-b/

[2] https://www.aasld.org/publications/practice-guidelines

[3] Park J. *et al.*: Ann Lab Med. 2019 Jan

[4] Sayan M. *et al.*: Pol J Microbiol. 2019



Limit of Detection: The limit of detection is 10.2 IU/ml (95% confidence interval 7.6 to 15.8 IU/ml). A graphical illustration of the probit analysis is shown in the figure above.

4×4 Table:

Comparison of qualitative results for all valid samples above the LoD of both assays included in the analysis.

Total number of samples: 272		Abbott RealTi*m*e HBV	
		POSITIVE	NEGATIVE
AltoStar® HBV PCR Kit 1.5	POSITIVE	133	7
	NEGATIVE	0	132

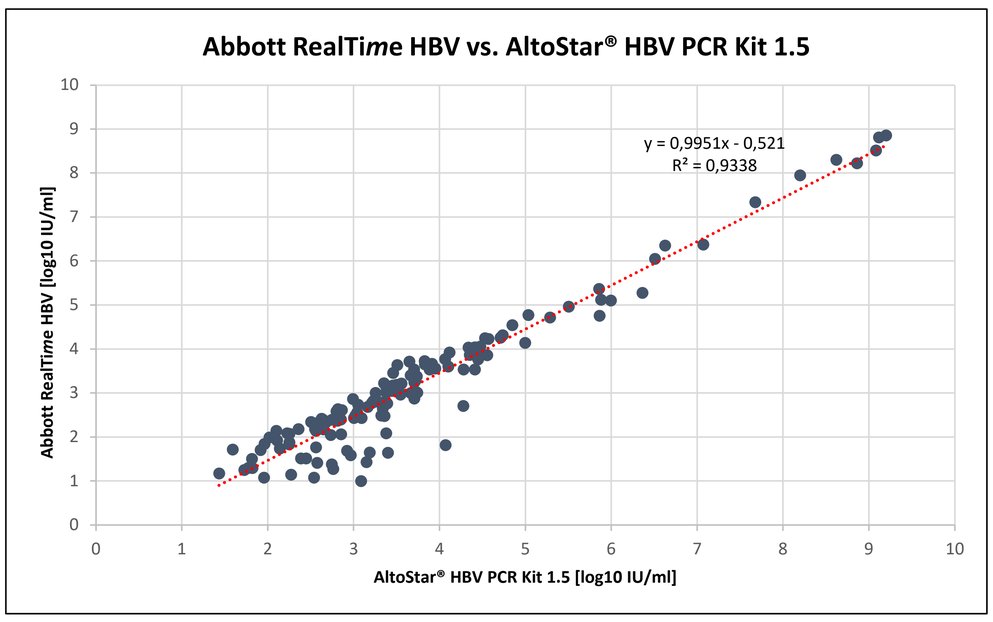


Figure 1: Linear regression of the quantitative results for HBV obtained with the Abbott RealTi*m*e HBV assay (reference) and the AltoStar® HBV PCR Kit 1.5.

The correlation coefficient R determined by the linear regression analysis is 0.96 (R^2 = 0.93). In conclusion, the linear regression analysis shows a very good correlation between the quantitative results generated with the Abbott RealTi*m*e HBV assay (reference) and the AltoStar® HBV PCR Kit 1.5.

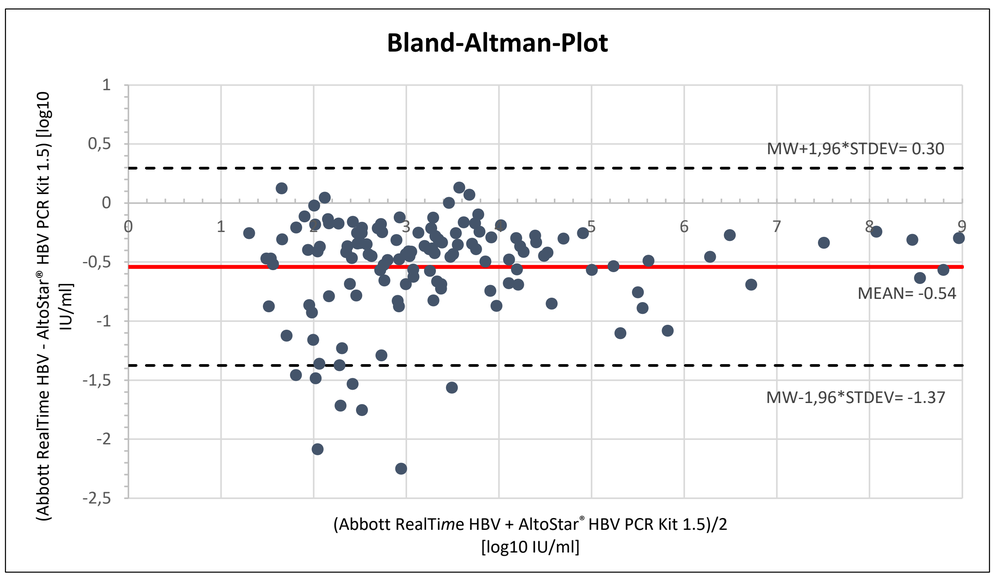


Figure 2: Bland-Altman Plot for comparison of mean differences of quantitative results generated with the Abbott RealTi*m*e HBV assay (reference) and the AltoStar® HBV PCR Kit 1.5.

In addition to the linear regression analysis, a Bland-Altman Plot was generated to evaluate the bias between the quantitative results generated with the AltoStar® HBV PCR Kit 1.5 and the Abbott RealTi*m*e HBV assay (reference) for HBV positive samples (see Figure 2).

The difference in mean Δlog10 IU/ml between the reference (i.e., the Abbott RealTi*m*e HBV assay) and the AltoStar® HBV PCR Kit 1.5 is −0.54.

The Δlog10 values of 124 out of 132 samples (94%) fall within ±1.96 × standard deviation (STDEV = 0.43), showing that there is no systematic difference between both assays and good agreement of quantification results over the entire measuring range.

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POS-AS020150-EN-01_09/2021

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