

HBV ELITE MGB Kit[®] and ELITE InGenius[®]: a new system for the Quantification of HBV DNA in plasma and serum samples

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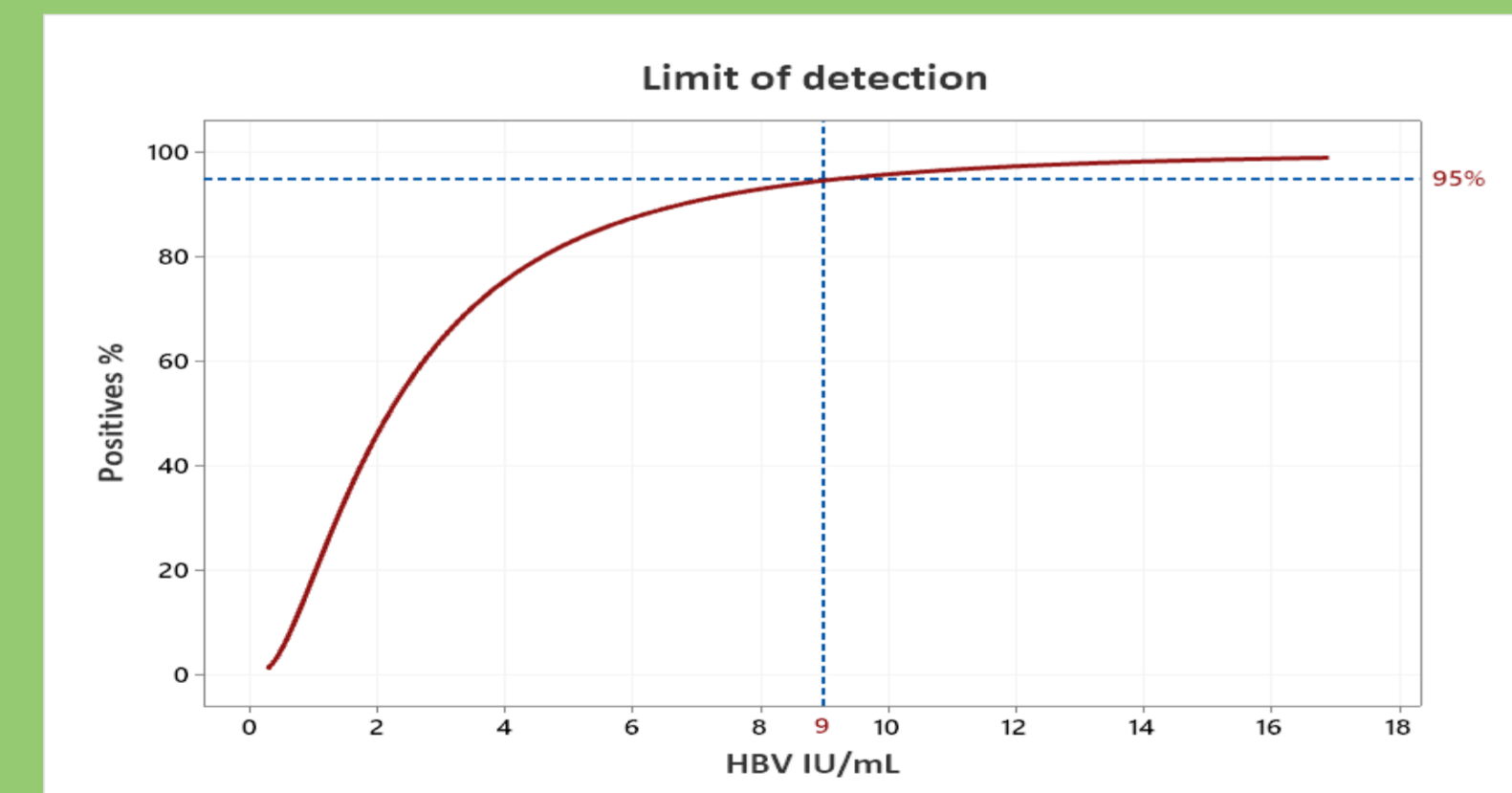
BACKGROUND

HBV viral load quantification is necessary to support clinical decisions in starting and manage anti-HBV treatments. The HBV monitoring is mainly performed at laboratories of major hospitals, with a long sample-to-result time and difficulties in reaching the care centers. This can result in delaying responses to clinicians and losing patients during the follow-up. Integrated, easy-to-use, small-footprint platforms like ELITE InGenius[®] may offer a new tool in HBV monitoring. In this study, we evaluated the analytical and diagnostic performance of the new system HBV ELITE MGB Kit[®] and ELITE InGenius[®] in comparison to the cobas[®] HBV test and cobas[®] 4800 or 6800 System, for the quantification of HBV DNA in plasma and serum samples.

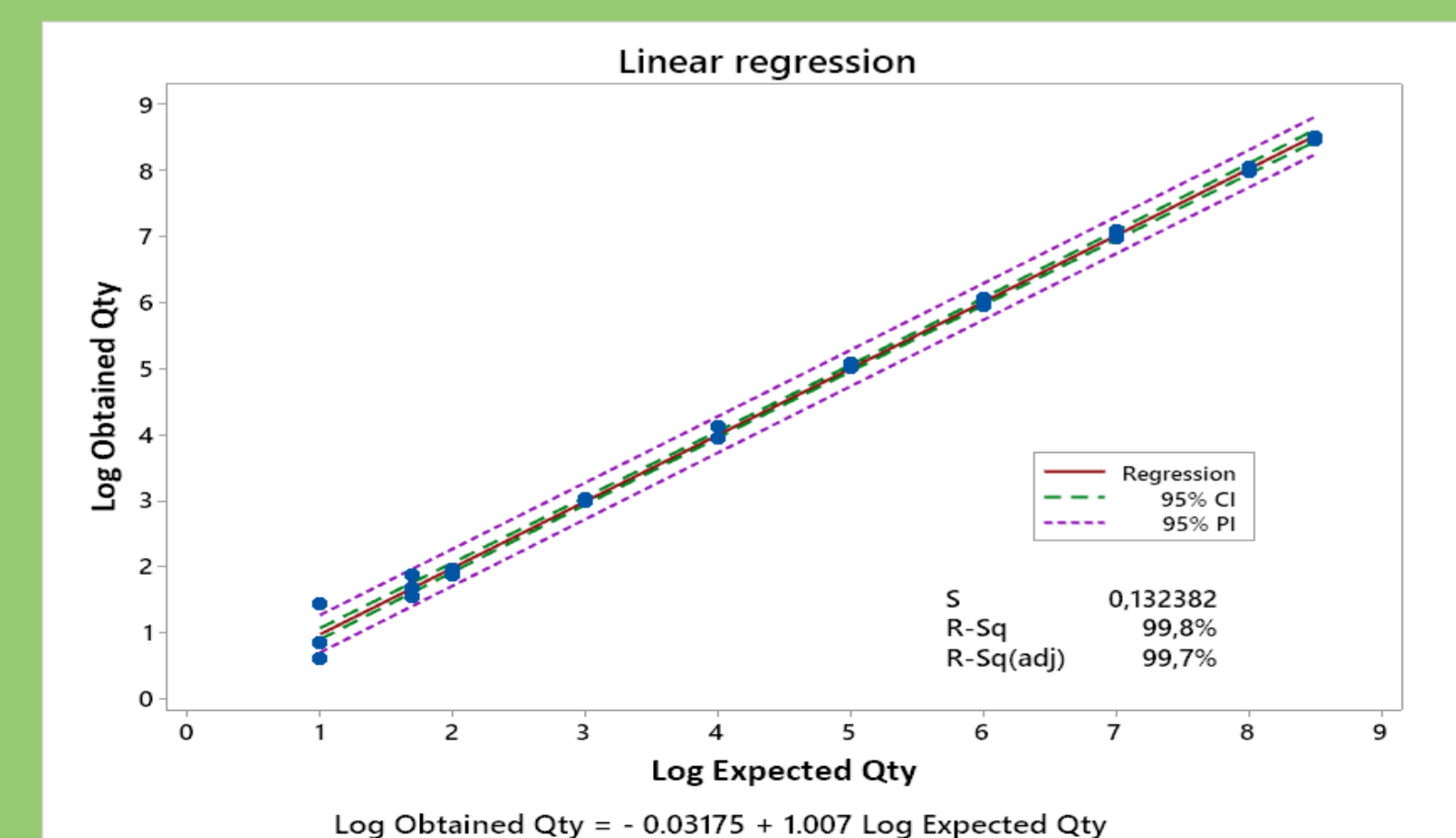
MATERIAL & METHODS

The Limit of detection (LoD) was evaluated by Probit analysis on a serial dilution of the 4th WHO International standard for HBV DNA for NAT on ACD-plasma, and confirmed on EDTA plasma and serum according to the CLSI guideline-EP17-A. The secondary reference material Hepatitis B virus Concentrate (ZeptoMetrix) was used in serial dilutions from 10¹ to about 10^{8.5} IU/mL in EDTA-plasma, to assess the linearity of measurement. The QCMD 2020 Hepatitis B Virus DNA EQA Programme (QCMD Ltd.) was used to assess the system reproducibility. In the performance comparison, 127 HBV negative and 131 positive samples of EDTA-plasma were tested in parallel with HBV ELITE MGB Kit[®] on ELITE InGenius[®] and cobas[®] HBV on cobas[®] 4800/6800 System (Roche Diagnostics). Statistical analysis was performed with MINITAB[®] (SV 19.2020.1).

RESULTS



- The LoD was equal to 9 IU/mL.



- The linearity of measurement ranged from 9 to 3.18 10^{8.5} IU/mL.
- The linearity measurement within clinically relevant concentrations was confirmed for the main HBV genotypes (A, B, C, D, E, F, G) with R2 from 0.979 to 0.996 and quantitative results within ±0.5 Log IU / mL.

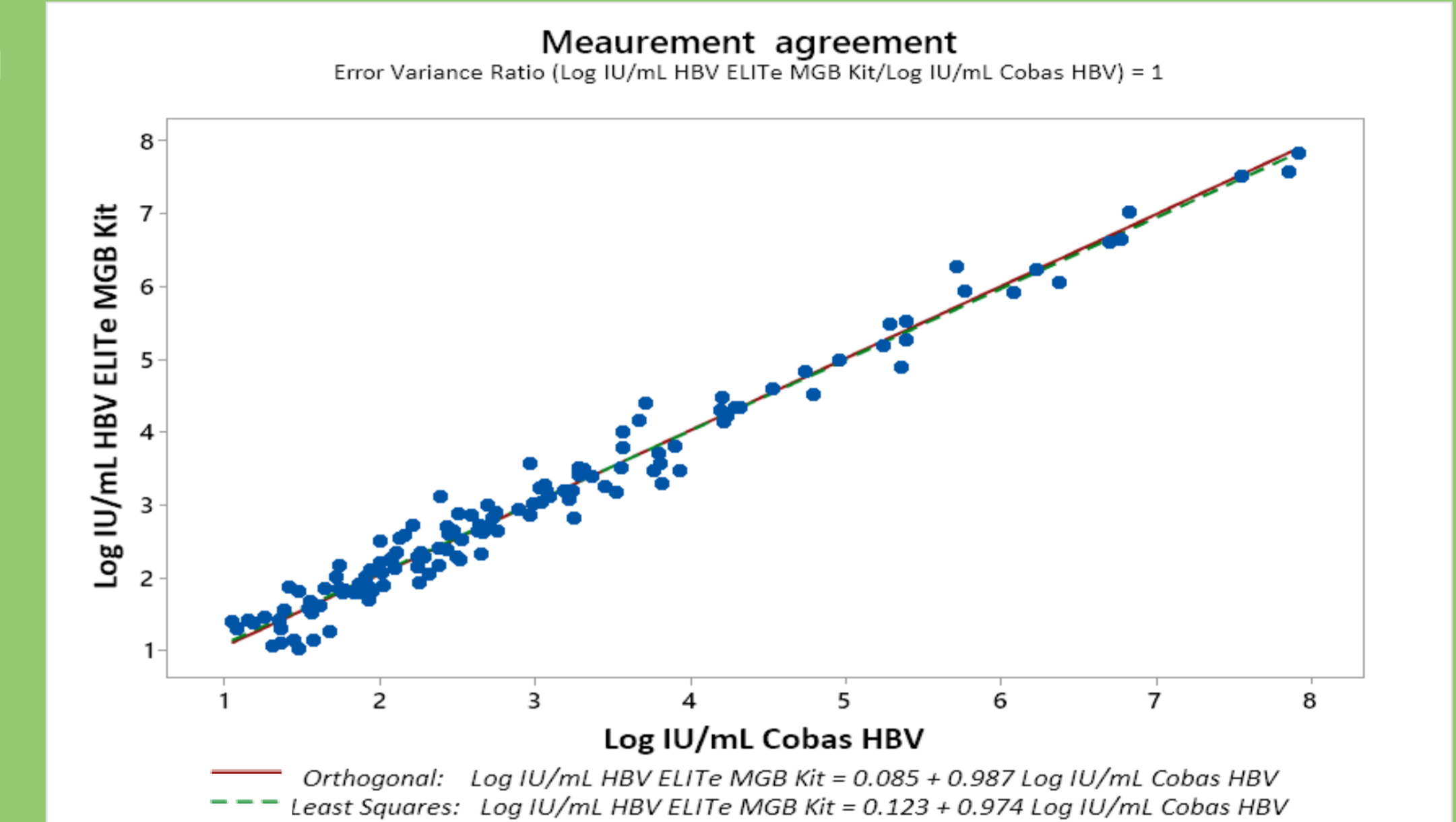


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- The reproducibility of secondary reference material with titers from 1.7 to 3.8 Log IU/mL was within the expected SD range, from ±0.13 to ±0.23.

Sample ID	HBV genotype	Consensus Log UI/ml	SD Log UI/ml	ELITE InGenius Log UI/ml
HBVDNA101S-01	type A	2.823	0.130	2.695
HBVDNA101S-02	type D	2.673	0.148	2.625
HBVDNA101S-03	type D	3.642	0.155	3.579
HBVDNA101S-04	negative	-	-	-
HBVDNA101S-05	type A	1.869	0.229	1.688
HBVDNA101S-06	type A	3.803	0.156	3.781
HBVDNA101S-07	type A	2.848	0.176	2.696
HBVDNA101S-08	type D	1.724	0.227	1.422

- Evaluation over clinical samples showed 97.6% agreement on negative specimens (127) and 100% on positives (131).



- Over 131 plasma samples with titer within the linearity measurement range, regression analysis showed excellent correlation between HBV ELITE MGB Kit[®]-ELITE InGenius[®] and cobas[®] HBV kit, with an intercept equal to 0.085 (95% CI: -0.009 – 0.179), a slope equal to 0.987 (95% IC: 0.959 -1.015) and R2 equal to 0.974.

CONCLUSIONS

HBV ELITE MGB Kit[®] and ELITE InGenius[®] system showed optimal sensitivity in detecting HBV DNA genotypes A, B, C, D, E, F, G, H, I and RF accurate quantitation of HBV DNA over and extensive viral load range. Such performances and the easiness of use make this system an interesting solution for small monitoring routines or backup of high throughput routine.

REFERENCES

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