Reliable HDV RNA quantification of the AltoStar® HDV RT-PCR Kit 1.5* based on EQA programme data from two different suppliers.

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Background

HDV infection leads to a faster progression to cirrhosis and liver failure, as well as higher rates of hepatocellular carcinoma compared to HBV infection alone. Precise quantification of HDV RNA is essential for the diagnosis and management of chronic hepatitis delta.

Aim

EQA programme samples were tested and analysed over 3 consecutive years to prove accuracy of the AM16/AltoStar® HDV RT-PCR Kit 1.5* workflow.

Material and Methods

Working hypothesis H_1: There is a statistically significant bias between the results of AM16/AltoStar® HDV RT-PCR Kit 1.5, and the results provided by the EQA supplier.
Null hypothesis H_0: There is no statistically significant constant or statistically proportional bias.

QCMD EQA Programme 2023, 2024 and 2025
- In total 24 samples.
- Contains dilutions of WHO IS for HDV RNA[1] and dilutions derived from clinical samples.

INSTAND EQA programme 2023, 2024 and 2025
- In total 12 samples.
- Derived from clinical samples

All samples were processed using the AltoStar® Automation System AM16 (Hamilton) and analysed with the AltoStar® HDV RT-PCR Kit 1.5 and compared to provided EQA results.

Results

The Cusum test was used to approve the applicability of the **Passing Bablok (PB) method** for the data set (validity criteria: p >0.05); see Figure 1.
Linearity was given (linear regression: y = 1,0006x-0,064; r = 0,92).
Results of PB analysis are summarized in Table 1.

Discussion

The null hypothesis H_0 for PB regression »there is no statistically significant constant or proportional bias between the results of AM16/AltoStar® HDV RT-PCR Kit 1.5, and the results supplied by the EQA provider« can be accepted.

Conclusion

Following these data, the AltoStar® HDV RT-PCR Kit 1.5 (RUO) can be considered as highly accurate in quantification of HDV viral loads. The assay shows no significant constant bias and no proportional bias in quantification compared to provided results by the EQA supplier.

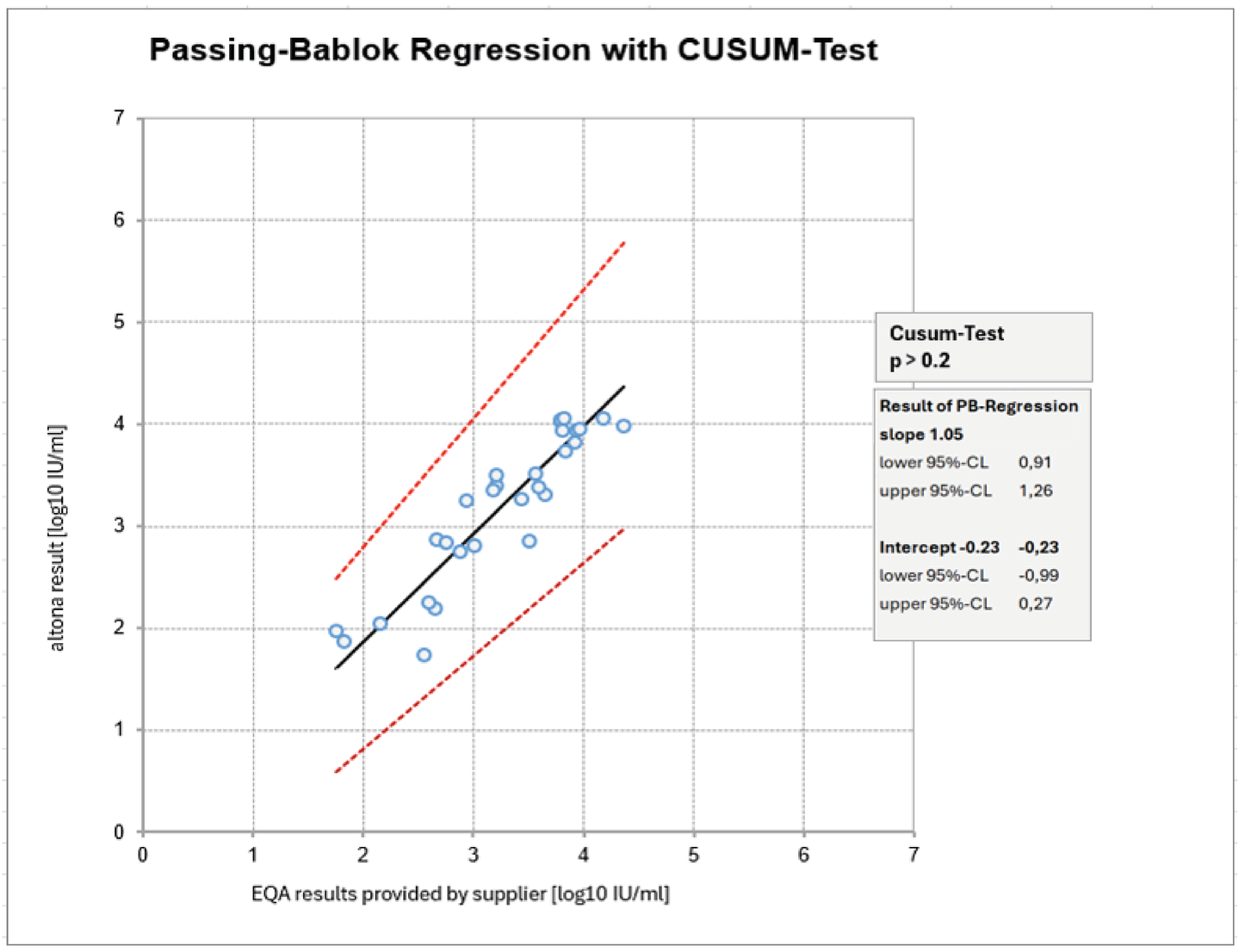

Figure 1: PB regression

Table 1: Acceptance criteria for H0 and results of PB regression

H_0 accepted, if...	intercept [b]	$CI_{95\%}$	includes 0	slope [y]	$CI_{95\%}$	includes 1
		lower level ≤ 0	higher level ≥ 0		lower level ≤ 1	higher level ≥ 1
data set results	intercept [b] **-0.23**	$CI_{95\%}$ includes 0		slope [y] **1.05**	$CI_{95\%}$ includes 1	
		lower level -0.99	higher level 0.27		lower level 0.91	higher level 1.26
H_0 can be accepted for this data set						

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

[1] 1st WHO International Standard for Hepatitis D Virus RNA (PEI code 7657/12)

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