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Poster for you

Clinical evaluation of the Altostar HDV RT-PCR Kit 1.5

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Introduction

- Chronic hepatitis D virus (HDV) infection is considered as the most severe form of viral hepatitis with high rates of liver-related complications [1,2]
- Detection and quantification HDV RNA is essential both for diagnosis and therapeutic management of chronic HDV infection [3]
- The aim of this study was to evaluate the diagnostic performance of the Altostar HDV RT-PCR Kit 1.5 compared to the local quantification standard in real-world clinical samples with and without treatment with bulevirtide (BLV)

Study Design & Methods

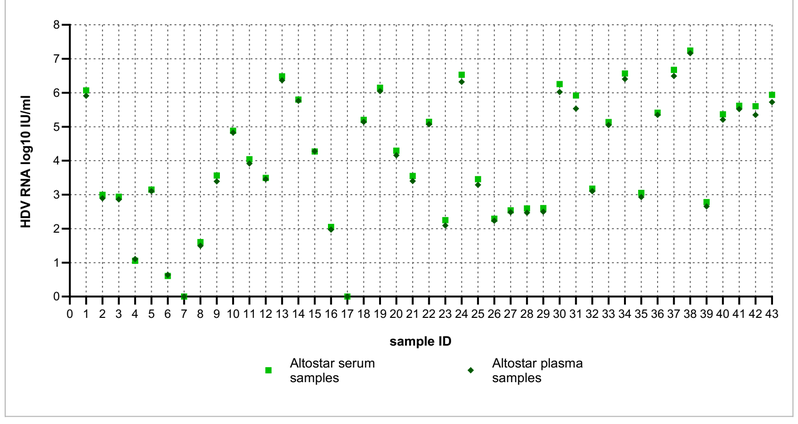
- 54 plasma samples obtained from 40 individual patients with chronic HDV infection were included
- HDV RNA quantification was performed with the Altostar HDV RT-PCR Kit 1.5 (extraction kit: AltoStar Purification Kit 1.5, sample volume 500 µl, elution volume 80 µl) and the RoboGene HDV RNA Quantification Kit 2.0 (extraction kit: QIAamp DNA Blood Mini Kit, sample volume 200 µl, elution volume 100 µl)
- Samples with different viral load levels (target not detected, below the lower limit of quantification and detectable) based on the local quantification standard were included
- Additionally, a comparison of 43 corresponding serum and plasma samples from the same time point was performed
- Baseline (BL) and follow up (FU) plasma samples of 20 patients receiving BLV treatment were analysed to compare virological treatment response rates based on the quantification assay
- Virological response was defined as a ≥ 2log decline of HDV RNA (in IU per ml) or if the target was not detected

Results

Corresponding serum and plasma samples

- HDV RNA quantification was performed in 43 corresponding serum and plasma samples from the same time point
- No significant difference in HDV RNA levels was identified between serum an plasma samples, as the log10 mean difference was 0.11 log10 IU/ml (± 0.08 log10 IU/ml)

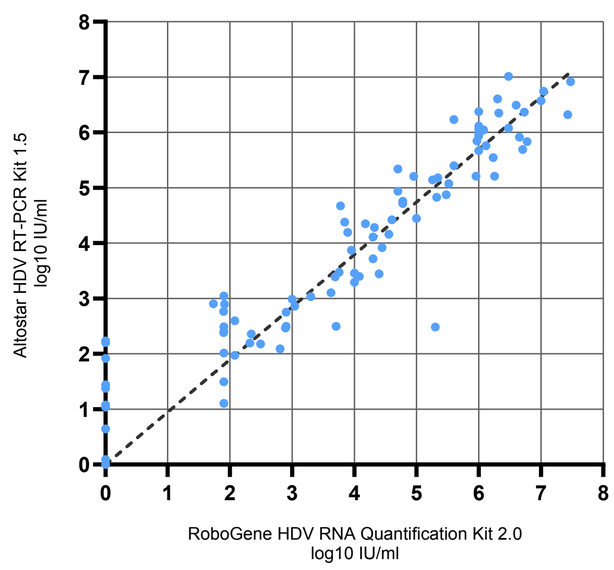
Figure 1 **HDV RNA levels in 43 corresponding plasma and serum samples quantified by Altostar HDV RT-PCR Kit 1.5**



Viral load levels in plasma samples compared to the local standard assay

- Mean HDV RNA levels in plasma samples with detectable viral load quantified by the Altostar HDV RT-PCR Kit 1.5 were similar compared to the quantification with the local standard ($5.04x10^5$ IU/ml [± $1.12x10^6$] vs. $1.72x10^6$ IU/ml [± $4.44x10^6$], p=0.07)
- Two of five samples were undetectable by the local standard, but were detected and quantifiable by Altostar 1.5

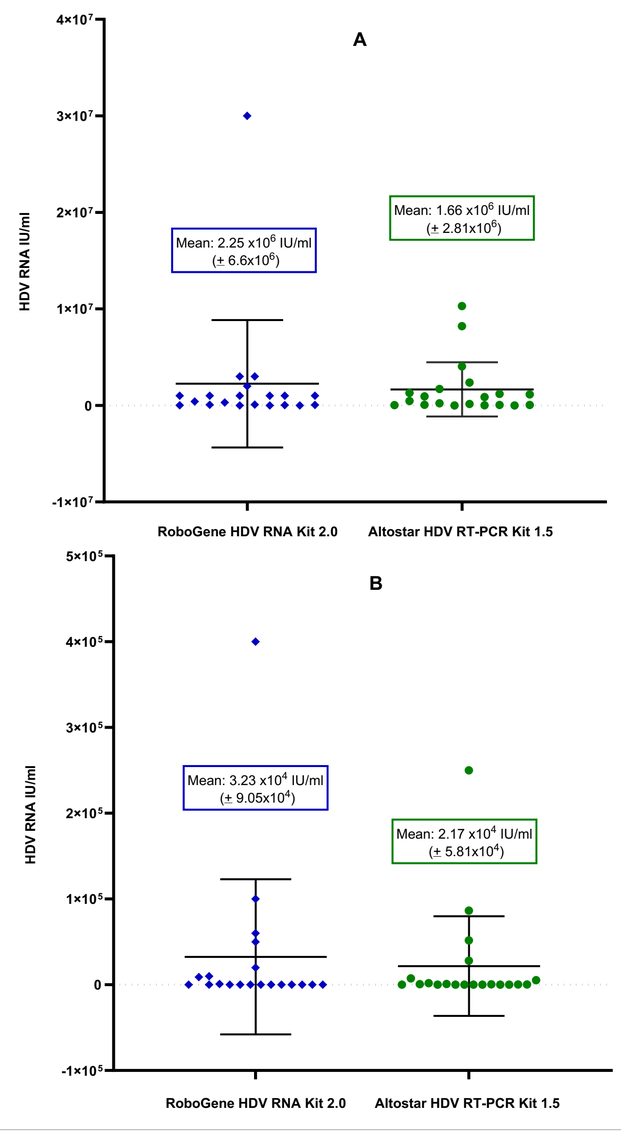
Figure 2 **Comparison of viral load levels quantified by Altostar HDV RT-PCR Kit 1.5 and RoboGene HDV RNA Quantification Kit 2.0**



HDV RNA measurements during antiviral therapy

- HDV RNA was quantified with the Altostar HDV RT-PCR Kit 1.5 and the local standard at BL (A) and after 56 to 65 weeks (B) of treatment with BLV
- Mean HDV RNA levels at BL and FU up were comparable between the Altostar HDV RT-PCR Kit 1.5 and the local standard (BL: p=0.72; FU: p=0.66)

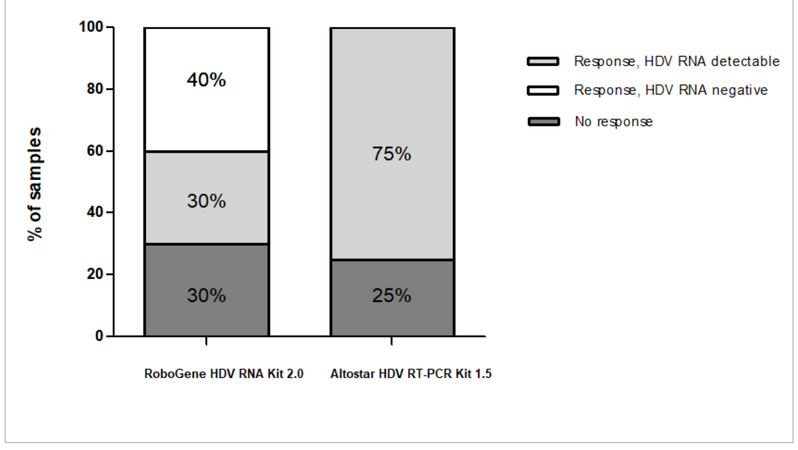
Figure 3 **HDV RNA levels at baseline (A) and after up to 65 weeks of antiviral therapy with BLV (B)**



Virological response rates

- 8 samples (40%, n=8/20) were undetectable with the local standard, but showed quantifiable HDV RNA in the measurement by the Altostar HDV RT-PCR Kit 1.5
- There was no significant difference in the proportion of samples with a virological response to antiviral therapy (75% (n=15/20) as measured by Altostar HDV RT-PCR Kit 1.5 vs. 70% (n=14/20) as quantified by the local standard)

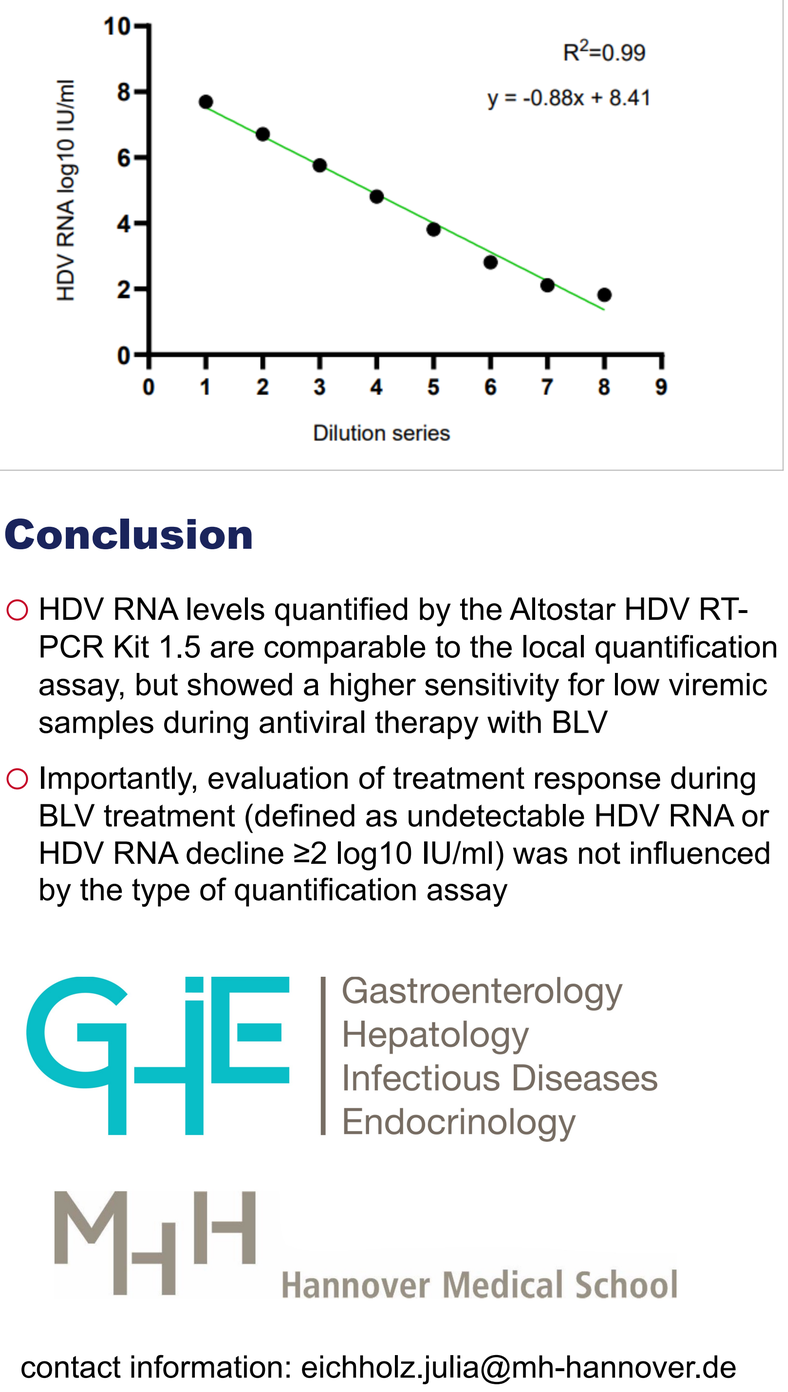
Figure 4 **Proportions of virological response rates to antiviral therapy with BLV measured by RoboGene HDV RNA Quantification Kit 2.0 and Altostar HDV RT-PCR Kit 1.5**



Linearity analysis

- In order to evaluate the linearity of the Altostar HDV RT-PCR Kit 1.5, RNA measurements were performed with a series of dilutions
- The assay demonstrated a linearity up to a dilution factor of 10^6 with a correlation coefficient (R^2) of 0.99

Figure 5 **Linearity of the Altostar HDV RT-PCR Kit 1.5**



Conclusion

- HDV RNA levels quantified by the Altostar HDV RT-PCR Kit 1.5 are comparable to the local quantification assay, but showed a higher sensitivity for low viremic samples during antiviral therapy with BLV
- Importantly, evaluation of treatment response during BLV treatment (defined as undetectable HDV RNA or HDV RNA decline ≥2 log10 IU/ml) was not influenced by the type of quantification assay

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Reference

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