Performance of DxN VERIS System for HBV and HCV viral load quantification in the clinical setting

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INTRODUCTION AND PURPOSE
The goal of current therapy for HBV and HCV infection is the achievement of undetectable viremia: the monitoring of Viral Load (VL) by sensitive, accurate and precise tools is mandatory to characterize such outcome.1,2 DxN VERIS System (Beckman Coulter) is a fully automated, random access, closed molecular diagnostic instrument for Viral Load (VL) quantification. This study aimed to evaluate DxN VERIS HBV and HCV assays performance in the clinical setting.

METHODS
A total of 180 HBsAg- and 180 HCV-Ab-positive plasma samples from blood donors has been collected for specificity assessment. Clinical positive plasma samples at high VL titre for each target have been tested to evaluate linearity through four replicates of serial 1:10 dilutions (10 for HBV, 8 for HCV). The comparison between Beckman DxN VERIS and our routine system (m2000rt by Abbott) has been conducted using plasma sample sets collected from 163 HBsAg- and 94 HCV-Ab-positive patients, harbouring different viral genotypes, during clinical follow-up. The limit of quantification (LOQ) was the same for both assays/systems: 10 and 12 IU/mL for HBV and HCV, respectively.

RESULTS
The specificity resulted 100% (CI 95% = 0.98-1.00) for both assays (fig.1A and 1B). HBV linearity has been evaluated over a range 1.47-7.72 Log IU/mL, with Standard Deviation (SD)<0.09 and a mean SD=0.056 (R2=1) (fig.2A); for HCV the range was 1.68-6.68 Log IU/mL, with SD<0.07 and a mean SD=0.045 (R2=1) (fig.2B).

The method comparison analysis included 71/163 HBV and 69/94 HCV results above the LOQ. The cumulative concordance of the two methods resulted 70.4% and 87.1% for HBV and HCV, respectively; 8 samples provided a difference >0.5 Log IU/mL for both assays, while 1 sample >2.0 Log IU/mL for HCV assay, regardless VL values and viral genotype (fig.3A and 3B).

The correlation analysis resulted R² = 1 for both assays/systems (fig.4A and 4B). In details, for HBV assay: VERIS Log IU/mL = -0.0289+1.0847 Abbott Log IU/mL (Passing-Bablok linear regression) (fig.5A), Spearman Correlation Coefficient (R2)=0.937 (IC 95% = 0.898-0.961) and Mean Difference=0.37 (IC 95% = 0.88-1.61 – Bland Altman analysis) (fig.5B).

CONCLUSIONS
This study showed a good performance of DxN Veris System, in comparison with m2000rt by Abbott: both HBV and HCV assays exhibited high sensitivity, specificity, linearity and reproducibility, regardless the VL levels and the viral genotype. Such characteristics, in addition to the easy-to-use processing, make this system a reliable and useful new solution for molecular biology-based monitoring of HBV and HCV infection.

REFERENCES