Evaluation of a novel hepatitis B virus (HBV) DNA test from fingerstick capillary blood at the point-of-care as a tool to enhance clinical management

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Background: HBV DNA tests are essential for HBV clinical management. Standard-of-care tests in central laboratories are expensive and require venous blood, limiting accessibility. This study assessed the point-of-care Xpert® HBV Viral Load assay performance, using fingerstick capillary blood compared to standard-of-care assay using venous blood.

Method: Participants with chronic HBV were enrolled from six Australian hospitals. Fingerstick capillary blood was collected (diluted 1 in 10) and tested using Xpert® HBV Viral Load assay (adjusted lower limit of quantification: 100 IU/mL). Venipuncture whole blood was collected for standard-of-care testing (gold standard) using COBAS® AmpliPrep/COBAS® TaqMan® HBV DNA Test. Sensitivity and specificity of the Xpert® were evaluated. Agreement measurements of assays were assessed using Bland–Altman bias plot.

Results: To date, we enrolled 178 participants (recruitment ongoing, total n=300), including 46% female, 19% HBeAg positive, 44% on HBV treatment, and 6% with cirrhosis (median age: 46). Gold standard test determined undetectable HBV DNA in 58 participants (33%), detectable <100 IU/mL in 38 (21%), and ≥100 IU/mL in 82 (46%; range: 110 to >180M IU/mL). Sensitivity and specificity of the Xpert® for viral load ≥100 IU/mL (vs. <100 or undetected) was 96.3% (95%CI: 93.6-99.1) and 89.6% (95%CI: 85.1-94.1), respectively. In 13 participants, viral loads detected by two assays were non-concordant (viral loads difference range: 38-388 IU/mL). Across all participants, viral loads detected by Xpert® were a mean of 0.18 log IU/mL higher than those measured by gold standard (95%CI: -0.37, 0.74; Figure).

Conclusion: This interim analysis identified minimal difference in detected HBV viral load between assays. Among participants with non-concordant results, the difference was not sufficient to impact clinical decisions. These results support development of a dedicated Xpert® HBV point-of-care assay to simplify HBV clinical care, particularly in remote and resource-limited settings and hard-to-reach populations, including for treatment decision making in pregnancy.

Disclosure of Interest Statement:

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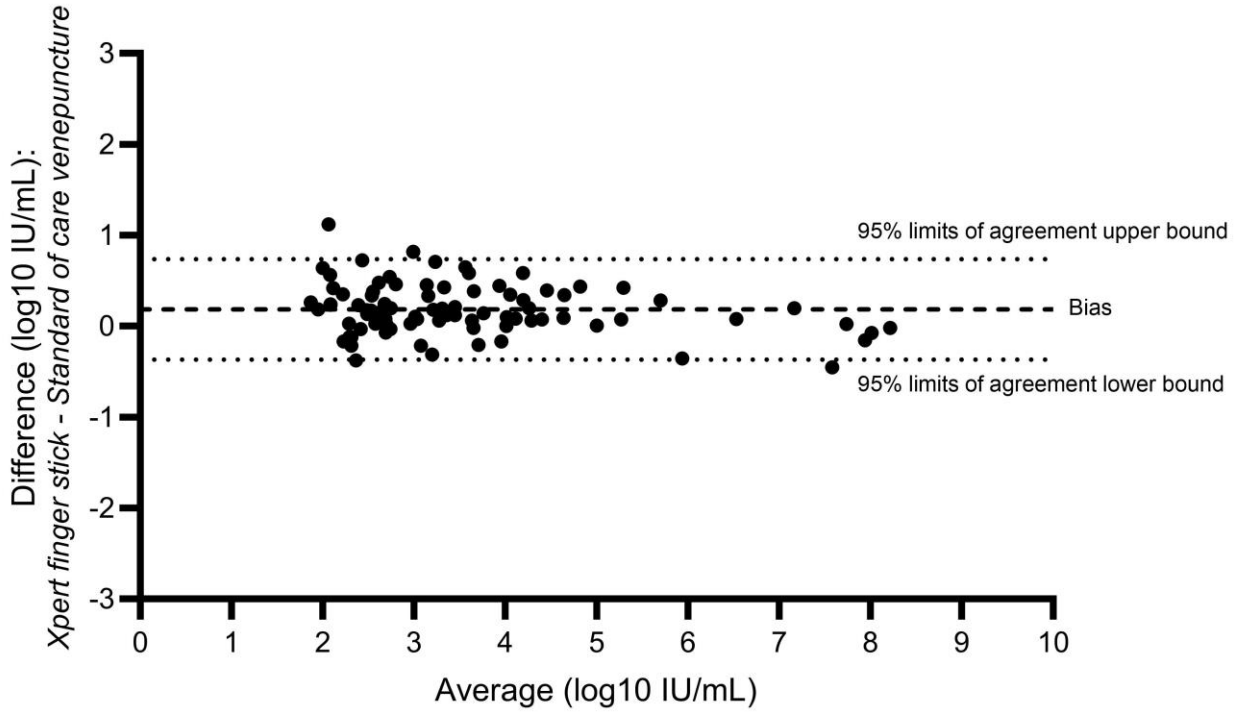

Figure 1: Bland–Altman bias plot of differences between HBV viral loads detected by the Xpert® finger stick and standard-of-care venepuncture assays