

PA-123 **FIELD PERFORMANCE OF POINT-OF-CARE TO DETERMINE HBSAG TEST FOR DIAGNOSIS OF ACTIVE HEPATITIS B VIRUS INFECTION IN ZAMBIA**

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Background In Zambia, we evaluated the field performance of a rapid point-of-care test for hepatitis B surface antigen (HBsAg)

which could support decentralisation and scale-up of care and treatment of chronic hepatitis B virus (HBV) infection in sub-Saharan Africa.

Methods At two urban public health facilities in Zambia's capital Lusaka, we screened a cohort of HIV-infected adults for HBsAg per national guidelines. A subset was tested with both Determine HBsAg (Alere, USA), using finger prick in the clinic, and HBsAg serology (Access2Analyser, Beckman Coulter), using serum sent to a reference laboratory. If either test was reactive, we measured HBV viral load (VL) and determined HBV genotype with Sanger sequencing. We described patient demographic and clinical characteristics (including liver fibrosis biomarkers) and assessed the sensitivity, specificity, positive and negative predictive values (PPV and NPV) of the Determine test. In secondary analyses, we assessed sensitivity among patients with replicating HBV (VL >20 IU/mL) and with high HBV VL (>20,000 IU/mL).

Results Among 412 participants with both HBsAg tests, median age was 34 years, 51% were women, and median CD4 was 208 cells/mm³. By serology, 66 (16%) were HBsAg-positive. HBV genotypes were A1 (n=21; 52.5%) and E (n=19; 47.5%) among successfully sequenced samples. Overall, the Determine test had 87.9% sensitivity (95% CI: 84.7–91.0%), 99.7% specificity, 98.3% PPV, and 97.7% NPV. The majority of patients (6/8) with false negative results had undetectable HBV VL and no evidence of significant liver fibrosis. Test sensitivity increased to 95.9% among the 51 with replicating HBV and to 100% among the 28 with high HBV VL.

Conclusions The Determine HBsAg test accurately diagnosed HBsAg-emia in the majority of field-tested HIV patients, particularly those with higher HBV VL. False negatives tended to have inactive HBV infection further supporting the use of this low-cost test in public health settings in sub-Saharan Africa.

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