

Validation of a novel point-of-care ALT1 test in patients with viral hepatitis: a pilot cohort study

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Background: Alanine aminotransferase (ALT) level is an important marker of liver inflammation, however access to ALT measurement can be challenging in low resource settings. We validated a novel point-of-care (POC) blood test for ALT1.

Methods: The BioPoint® POC ALT1 test antigen immunoassay lateral flow test uses 15µL plasma to provide a quantitative ALT1 result (using Axxin handheld reader) or visual semi-quantitative result (cutoff 40IU/L) <20 minutes. In this cross-sectional pilot study, stored plasma samples and matched clinical/ demographic data from adults > 18 years with viral hepatitis were included; 240 in the Test cohort and 491 in a Validation cohort. Quantitative POC ALT1 results were compared to standard laboratory assay ALT using Spearman correlation. Accuracy of POC ALT1 to detect ALT >40IU/L was calculated by ROC analysis. Sensitivity, specificity, PPV and NPV were determined by confusion matrix.

Results: 731 patients were included: 58% were male, 63% had hepatitis B and 28% had hepatitis C. Median ALT was 26IU/L (18, 45IU/L). There was moderate correlation between POC ALT1 (Axxin reader) and laboratory ALT in both Test ($R^2=0.68$; $p<0.001$) and Validation cohorts ($R^2=0.62$; $p<0.001$). POC ALT1 had good accuracy for laboratory ALT > 40IU/L, with AUROC 0.93 (95% CI 0.89-0.96) in the Test cohort and AUROC 0.92 (95% CI 0.88-0.95) in the Validation cohort. Using a POC ALT1 test cutoff of 0.8, sensitivity for ALT > 40IU/L was 97% and specificity 71% in the Test cohort; in the Validation cohort PPV was 84% and NPV 91%. Visual semi-quantitative POC ALT1 results also had good accuracy for laboratory ALT > 40IU/L in the Validation cohort (AUROC 0.85, 95% CI 0.81-0.90; sensitivity 77%, specificity 93%, PPV 74%, NPV 94%).

Conclusion: BioPoint® POC ALT1 test had good accuracy for elevated laboratory ALT. Further validation of the POC ALT1 test in prospective clinical trials is warranted.

Disclosure of Interest Statement:

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