AN IMMUNOCHROMATOGRAPHIC TEST FOR MEASUREMENT OF ALANINE AMINOTRANSFERASE (ALT) AT POINT OF CARE

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Background: Alanine Aminotransferase (ALT) is widely for detection and management of liver disease, but current ALT tests rely on laboratory instruments, limiting their availability especially for patients in resource-poor settings who represent the majority of the global burden of chronic HBV and HCV. We have developed a rapid, point of care test that provides a visual, semi-quantitative measure of ALT in plasma or whole blood.

Methods: We determined the correlation between the ALT Rapid Test and the "gold standard" enzymatic ALT activity. Samples of 20 µL of plasma were added directly to the prototype ALT Rapid Test, and the amount of ALT was visualized using colloidal gold conjugated antibodies to human ALT1 and quantitated visually and by measuring the line intensity using a portable reader (Axxin AX-2X) after a total test time of 20 minutes. Plasma samples from the Alfred Hospital (n=48; range: 10-276 ALT U/L) and the Jiangsu Provincial Hospital (n=53; range: 9-638 ALT U/L) were coded and run on the ALT Rapid Test at the Burnet Institute or Nanjing BioPoint, respectively.

Results: ALT levels measured using the ALT Rapid Test at both sites showed high levels of correlation with standard clinical laboratory enzymatic ALT for 90% of patients (R^2=0.92, P<0.0001 Melbourne; R^2=0.97, P<0.0001 Nanjing). However 10% of patients with elevated enzymatic ALT (range 38-160 U/L) showed even more pronounced elevation of ALT in the Rapid Test. Whole blood (40 µl) was shown to give equivalent results in pilot studies. In the Melbourne patients where APRI data was available, the ALT Rapid Test also showed quite good correlation with this important marker (R^2=0.66, P<0.0001).

Conclusions: The ALT rapid test shows promise for the detection of elevated ALT levels at the point of care and may be useful in expanded efforts to improve management of liver disease worldwide.

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