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

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Background:
Alanine Aminotransferase (ALT) is widely used 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 as well as metabolic liver disease. We have developed a rapid, point-of-care test (POCT) that provides a visual, semi-quantitative measure of ALT protein in plasma or whole blood in 20 minutes with potential for full quantitation of ALT levels using an optional instrument.

Methods:
We determined the correlation between the ALT POCT and "gold standard" enzymatic ALT activity using coded plasma samples from the Alfred Hospital, Melbourne (n=44; range: 5-361 ALT U/L).

Results: ALT levels measured in plasma using the ALT POCT showed high levels of correlation with standard clinical laboratory enzymatic ALT (R^2=0.88 $p<0.0001$). The ALT POCT also showed surprisingly good correlation with AST-platelet ratio index (APRI) scores (R^2 = 0.61, $p<0.0001$).

Conclusion:
An in-house laboratory evaluation of the ALT POCT on clinical samples demonstrates high correlation with standard enzymatic ALT across the relevant clinical ranges. The measurement of ALT protein provides a robust and accurate POCT that is not temperature or instrument dependent, can be deployed in the field and be useful in expanded efforts to improve management of liver disease worldwide.
This novel approach using protein detection of enzymes or cell associated molecules has potential for improved direct measurement of APRI following modification to detect AST and incorporating platelet count by detecting platelet specific cell surface molecules.