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

Anderson D[1,2],Garcia M[1], Van H[1], Li F[1], Zhang Z[2], Yi F[2], Hellard M[1,3], Doyle J[1,3], Li J [4],

[1]Burnet Institute, Melbourne, VIC, Australia
[2]Nanjing BioPoint Diagnostics, Nanjing, Jiangsu, PR China
[3]Alfred hospital, Melbourne, VIC, Australia
[4]Jiangsu Provincial people's Hospital, Nanjing, PR China

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=48; range: 10-276 ALT U/L) and the Jiangsu Provincial Hospital, Nanjing, China (n=174; range: 9-774 ALT U/L).

Results: ALT levels measured in plasma using the ALT POCT at both sites showed high levels of correlation with standard clinical laboratory enzymatic ALT (R^2=0.86 p<0.0001 Melbourne; R^2=0.97 p<0.0001 Nanjing). In the Melbourne patients where APRI data was available, the ALT Rapid Test also showed surprisingly good correlation with this marker R^2 = 0.64, 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 direct measurement of APRI following modification to detect AST rather than ALT and incorporating platelet count by detecting platelet specific cell surface molecules.