Development of a rapid point-of-care self-test for liver damage

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Background:
The enzyme alanine aminotransferase (ALT) is a key biomarker of liver injury. Measurement of ALT levels, specifically the liver-specific isoform ALT1, is critical to liver disease diagnosis, monitoring, and evaluation of treatment. The objective of this study is to develop a point-of-care self-test to monitor changes in ALT1 levels.

Methods:
Novel anti-ALT1 monoclonal antibodies were generated in alpacas and rabbits. These antibodies combined with in-house produced recombinant ALT1 spiked into blood from healthy volunteers, and plasma clinical samples from adults with chronic liver disease were used to develop the quantitative lateral flow immunoassay.

Results:
The Burnet Diagnostics Initiative has developed a lateral flow test for detection of antigenic ALT1 using 10 µL of finger-prick or venous blood. The 20 min test is housed in the AtomoRapid™ Pascal device, a fully integrated cassette containing a built-in safety lancet, blood collection unit, and buffer delivery mechanism. The accompanying ALT1 test reader can quantify results between 0–5 ng of ALT1 (equivalent to ~0–500 IU/L) and shows good correlation with the standard of care enzymatic ALT test (Pearson r = 0.74). We are conducting further studies to establish the correlation between antigenic and enzymatic ALT.

Conclusion:
We have successfully developed a quantitative integrated lateral flow assay to detect antigenic ALT1 in finger-prick blood. The convenient, easy-to-use test is amenable to frequent ALT monitoring in both healthcare practitioner supervised settings and at-home self-testing.

Disclosure of Interest Statement:
LH, HW, RJC, HED, DAA, FL, HV, MG are inventors on relevant patents (Burnet Institute). RK, IJT, CH are employees of Atomo Diagnostics which manufacture the cassette used in this test.