

PA-058 A RAPID SEROLOGICAL TRIAGE TEST FOR DETECTING ACTIVE TUBERCULOSIS

Nick Borain,¹ Lizette Petersen,² Julianne Du Plessis,¹ Grant Theron,³ Carol Holm-Hansen². ¹Lateral Flow Laboratories, South Africa; ²NIPH, Norway; ³Stellenbosch University, South Africa

10.1136/bmjgh-2016-000260.91

Background A rapid screening test for active tuberculosis (TB) will reduce diagnostic delay and expedite referral for confirmatory testing and treatment. Antigen detection tests, which may utilise a rapid lateral flow (LF) platform suited to point-of-care use, offer a promising alternative to conventional methods for TB diagnosis. To date, the lack of accurate biomarkers has precluded the development of a serological assay.

Methods Sera and saliva were obtained by our consortium partners from culture-positive TB cases and healthy asymptomatic controls in high-burden settings. *Mycobacterium tuberculosis* (Mtb) antigens with diagnostic potential were expressed in eukaryotic and prokaryotic systems, and antigen combinations evaluated for sensitivity/specificity on multiplex, ELISA and LF platforms.

Results Based on a comparison of proteins recognised by antibodies from patients and controls, we have identified a combination of secreted and membrane-associated antigens involved in cell wall/cell processes and lipid metabolism that differentiate between active disease and latent infection. Sensitivities of 84–94% among TB cases and specificities of 97–100% among healthy endemic controls were obtained by screening over 300 samples against combinations of eukaryotic-expressed antigens on different platforms. Results indicating active TB were also observed among samples from symptomatic smear/culture-negative TB suspects. Antibody reactivity was not Mtb strain-specific. Sera from Norwegian latent TB controls yielded negative results. Our LF assay detects TB in the context of HIV co-infection, and is currently being optimised using sera from well-characterised TB suspects in Cape Town.

Conclusions Screening our sample sets against a selected combination of Mtb antigens by multiplex and LF prototype assays yielded sensitivities and specificities superior to that obtained by sputum smear microscopy. Our LF prototype conforms to the WHO target product profile criteria for a community-based triage test. Modification of the lateral flow platform for finger-stick blood and/or saliva samples will further increase assay suitability for use at the health post level.