TB PROTEC

A non-sputum-orientated ultra-sensitive point of care diagnostic device for TB

BACKGROUND

Tuberculosis (TB) is the leading cause of death in Sub-Saharan Africa and South Africa, and globally, 10.4 million new cases are diagnosed annually. It is a stigmatizing disease that marginalizes patients and their families, and the prolonged morbidity and high death rates are economically debilitating. Detection of TB remains a major problem, with a large majority of patients being co-infected with HIV (approximately 60% of the caseload). Currently diagnosis is difficult, with a number of patients being sputum scarce (cannot produce sputum), including 30% of TB-HIV co-infected patients), others being smear negative (low concentration of TB bacilli in the sputum) and the cases of extrapulmonary TB (EPTB) being as high as 50% in HIV co-infection. As such, diagnostics based on sputum have limited success in Africa. There is, therefore, a need for new low cost, point-of-care (POC) diagnostic tools to which a multitude of biological samples can be applied, resulting in a sensitive and specific diagnosis, irrespective of age and HIV status.

TECHNOLOGY DESCRIPTION

TB PROTEC is a sputum-independent POC electrochemical non-reader based lateral flow assay. The platform under development quantitatively detects TB biomarkers in the urine and extra-pulmonary fluids. Signal enhanced biomarker detection is facilitated through nanoparticles. The technology addresses the current problems encountered when using lateral flow assays, namely sub-optimal sensitivity, high inter-reader variability, and lack of compatibility with different types of biological samples.

VALUE PROPOSITION

The resulting diagnostic test incorporates nano-biotechnology to enable biomarker detection. The integrated system is superior to individual point-of-care components, in both sensitivity and specificity, and makes TB-PROTEC an ultrasensitive disruptive technology. The resulting platform is versatile and can be applied to alternative disease states. Therefore, this sputum-independent POC non-reader-based lateral flow assay addresses the drawbacks associated with available POC tests namely: poor sensitivity, inter-reader variability, and limitations in the types of biological fluids that can be tested.

CURRENT STATUS

All individual components have been optimized and integrated into a working proof-of-principle platform that can be used to detect the TB or EPTB biomarkers. This prototype has been subjected to clinical testing (urine and pleural fluid samples) with promising results. The current prototype is undergoing miniaturization, and the resulting devices will be validated internally using a bio-banked cohort of clinical samples.

INTELLECTUAL PROPERTY STATUS & PUBLICATIONS

No publications as yet as we are in the process of filing a patent application.

OPPORTUNITIES

The University of Cape Town and Antrum Biotech are seeking funding for further prototype development and validation (field testing and clinical accuracy) of the diagnostic platform.

FOR MORE INFORMATION PLEASE CONTACT:
saberi.marais@uct.ac.za
+27 (0)21 650 1746
www.rci.uct.ac.za
www.samrc.ac.za/content/innovation-samrc