DEVELOPING A RAPID POINT OF CARE TEST FOR DIAGNOSIS OF ACTIVE SYPHILIS

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Background:
Reported cases of syphilis have increased three-fold in Australia over the past 10 years. Globally, 7.1 million cases were reported worldwide in 2020, with outcomes including 200,000-300,000 neonatal deaths and still births. While treatment of syphilis is relatively straightforward and cost-effective using long-acting penicillin, diagnosis of active syphilis requires complex laboratory diagnosis involving multiple patient interactions with trained health care practitioners. Traditional serological tests for anti-treponemal antibodies cannot distinguish active versus past-treated infections as antibodies persist post-cure. There remains an urgent need to develop simple, quick, point of care tests to diagnose active syphilis to reduce the burden of disease.

Methods:
Treponema pallidum antigens were either purchased or expressed in E. coli, purified by affinity chromatography and used individually and in combination in a lateral flow assay. Clinical samples collected from the Melbourne Sexual Health Centre (Alfred Ethics 625/22) were used to develop the lateral flow assay and select the best performing antigen set for discriminating active and past-treated syphilis. Plasma and serum samples were collected from 40 confirmed cases of active syphilis, 40 past-treated and 17 volunteers with no history of syphilis infection.

Results:
We defined the optimal combination of treponemal antigens to detect anti-treponemal antibodies that differentiate active and past-treated syphilis infection. The final prototype provides 95% sensitivity and 92% specificity in a 30 minute, two step assay. The positive predictive value is 90% and negative predictive value is 96%. The test can utilize serum, plasma or whole blood (venous or finger prick). HIV status did not impact performance of the test.

Conclusion:
We have successfully developed a point of care assay to diagnose active syphilis. In ongoing work, we are simplifying the assay to improve patient usability, by decreasing the number of steps, time to result, and exploring integrating controlled buffer release and sample delivery.

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