A novel point-of-care test for screening and diagnosis of infectious syphilis

Authors:
Pham MD[1,2], Van H[1], Garcia ML[1], Han Y[3,4], Wei WH[3,4], Yin YP[3,4], Chen XS[3,4], Anderson DA[1]

[1] Burnet Institute, [2] School of Public Health and Preventive Medicine, Monash University, [3] China Centre for Disease Control and Prevention, [4] Chinese Academy of Medical Sciences

Background: Serological diagnosis of active (infectious) syphilis requires a combination of treponemal (screening) and non-treponemal (confirmatory) tests. The non-treponemal (RPR) confirmatory tests are often laboratory-based and not always available in low-resource settings. Current commercially available point-of-care tests (POCT) for syphilis cannot distinguish between active and past/treated infections, leading to overtreatment, unnecessary clinical/partner follow-up and/or laboratory testing.

Methods: We have developed a prototype POCT that is able to differentiate active from past syphilis based on the detection of Treponema pallidum Immunoglobulin A (TP-IgA), a new biomarker for infectious syphilis. We used a panel of 458 well-characterised stored plasma samples (154 active syphilis, 153 past/treated syphilis, 151 healthy/no syphilis) to evaluate the diagnostic performance of the TP-IgA against the WHO Target Product Profile of a POCT for diagnosis of active syphilis (TPP). We also perform these samples on two other, commonly used POCTs for syphilis (Visitect® Syphilis and Determine™ Syphilis TP) for comparison.

Results: For active syphilis samples, the TP-IgA achieved 96% sensitivity (148/154) versus 100% for Visitect® and Determine™. The TP-IgA misdiagnosed 3 out of 151 healthy samples (98% specificity) compared to 4 samples for the Visitect® and 1 for the Determine™. More importantly, non-reactivity in the TP-IgA correctly identified 70% (107/153) of the past/treated syphilis samples versus 8% (12/153) and 0% (0/153) for Visitect® and Determine™, respectively.

Conclusion: The TP-IgA met the WHO TPP with >95% sensitivity and >80% specificity for active syphilis with significantly improved capacity to differentiate active from past/treated infections compared to other POCTs on the market. Further clinical studies are warranted to evaluate clinical utilities of the test in real-world settings.

Disclosure of Interest Statement: Van H, Garcia ML, Andersons AD are the test inventors. Pham MD work at the Burnet Institute where the TP-IgA was developed, involved in the development and led the evaluation of the test.