

VALIDATION OF A POINT OF CARE TEST FOR ACTIVE SYPHILIS

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Background:

Syphilis, caused by *Treponema pallidum* (TP), is a sexually transmitted infection (STI) and remains a major global public health concern, especially for high-risk group such as men who have sex with men (MSM). Syphilis cases continue to rise among the population, and many are asymptomatic. Untreated Syphilis infection can cause serious health problems such as brain infections, dementia, lung and heart failure, blindness, and death. However, early diagnosis and timely treatment with penicillin can cure syphilis easily. Point-of-care tests (POCT) detecting total antibodies against *Treponema pallidum* are available, but they cannot distinguish between active and past-treated infections. The Burnet Diagnostics Initiative has developed a 15-minute one-step TP lateral flow test in AtomoRapid™ Pascal Device that shows promise as a point of care test for active syphilis infection.

Methods:

99 pre-characterised (41 active, 41 past-treated, 17 negative) venous whole blood samples were collected at Melbourne Sexual Health Centre (MSHC) and delivered to Burnet institute for evaluation. Performance of Burnet Active Syphilis test was assessed against two commercial tests, Abbott Bioline™ Syphilis 3.0 and Abbott Determine™ Syphilis TP.

Results:

Burnet Active Syphilis prototype demonstrated 95% sensitivity and 92% specificity for detecting active syphilis. Abbott Bioline™ Syphilis 3.0 and Abbott Determine™ Syphilis TP identified 97%, and 100% of active syphilis cases and correctly identified 100% and 94% of never infected patients as negative. However, the two commercial tests identified the majority of past-treated patients (91% and 100%) as positive for syphilis, in comparison to only 12% of past-treated patients misidentified as positive using the Burnet Active Syphilis test.

Conclusion:

The Burnet Active Syphilis test can diagnose active cases of syphilis and could play an important role in diagnosis of active syphilis and accelerating access to treatment.

Disclosure of Interest Statement:

This study was funded by the Burnet Institute. No pharmaceutical grants were received in the development of this study.