

IMPROVED DIAGNOSIS OF ACTIVE SYPHILIS AT THE POINT-OF-CARE

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BACKGROUND: Congenital syphilis affects more newborns than any other infection including HIV and tetanus. Syphilis is easily treated with penicillin but diagnosis requires specialised tests and trained staff. Rapid point-of-care tests (RPOCT) for syphilis are available however they cannot distinguish between active (current) syphilis and past or treated infections. As a result, these tests have limited utility in syphilis control programs.

We have developed a RPOCT that detects IgA antibody to syphilis (IgA Confirm), and can differentiate active syphilis from past treated infections.

AIM: To undertake a laboratory evaluation of the prototype syphilis IgA confirm test and assess its ability to identify active syphilis from a population of syphilis antibody positive and negative serum samples.

METHOD: The IgA Confirm RPOCT was evaluated at the National Center for Sexually Transmitted Disease Control, Nanjing, China in a 'blinded' study using (n=458) stored serum samples classified by rapid plasma reagin (RPR) and *Treponema pallidum* Haemagglutination (TPHA) serology as active syphilis (TPHA positive +RPR titre ≥ 8), past/treated syphilis (TPHA positive, RPR negative) and no evidence of syphilis (TPHA and RPR negative).

RESULTS: The IgA Confirm test demonstrated a sensitivity of 96.1% (148/154) for the active syphilis samples, and 84.7% specificity with patients previously infected or treated for syphilis (71.3% specific, 107/150), or no evidence of syphilis (98% specific, 148/151). Three samples gave indeterminate results and could not be classified in the rapid test

CONCLUSION: This independent evaluation of the IgA Confirm RPOCT has demonstrated that detection of treponemal-specific IgA has the ability to accurately identify active syphilis infections using serum samples classified with the laboratory TPHA and RPR reference tests. The IgA Confirm RPOCT could result in immediate access to diagnosis and significantly increased syphilis treatment uptake, improving maternal and neonatal health outcomes.