

Prospective, Multi-Centre Clinic-Based Evaluation of Four Rapid Diagnostic Tests for Syphilis

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Products Evaluated

Determine Syphilis TP (Inverness Medical)
VisiTect Syphilis (Omega Diagnostics)
Syphicheck-WB (Qualpro Diagnostics)
SD Biotline Syphilis 3.0 (Standard Diagnostics)

Within this study four rapid, point-of-care serological tests for syphilis in prenatal or high risk populations were evaluated. The tests were evaluated prospectively at four sites; Brazil, China, Haiti and Tanzania. Each site evaluated two rapid tests in parallel at both the clinic and the laboratory against a reference standard test of TPPA, TPHA or fluorescent treponemal antibody, absorbed.

Abstract

Objectives: To evaluate prospectively four rapid, point-of-care serological tests for syphilis in prenatal or high risk populations in four countries.

Methods: Tests were performed on consecutive clinic attendees, using whole blood in the clinic, and whole blood and serum in the laboratory. The sensitivity and specificity of each test was evaluated, using a standard treponemal test (*Treponema pallidum* haemagglutination assay (TPHA) or fluorescent treponemal antibody, absorbed (FTA-ABS)) as gold standard. Non-treponemal tests (rapid plasma reagin (RPR) or venereal diseases research laboratory (VDRL) tests) were also performed on all subjects at three sites.

Results: The specificity of each rapid test was >95% at each site. Sensitivities varied from 64%-100% and, in most cases, were lower when whole blood was used rather than serum.

Conclusions: Rapid serological tests for syphilis are an acceptable alternative to conventional laboratory tests. Since they do not require equipment or electricity, they could increase coverage of syphilis screening, and enable treatment to be given at the first clinic visit.

Results

Sensitivity and specificity of the Determine test

	Clinic: Whole blood		Lab: Whole blood		Lab: Serum	
	Sensitivity %	Specificity %	Sensitivity %	Specificity %	Sensitivity %	Specificity %
Tanzania	59.6	99.4	80.7	99.4	91.2	97.9
Brazil	88.5	97.9			88.5	97.9
China	81.9	99.4	77.1	100	100	98.9
Haiti	72.5	98.5	100	95.7	100	95.7

(Results for other point-of-care rapid tests are available from the paper)

Discussion

“The four tests we have evaluated compare favourably with standard treponemal tests for the diagnosis of syphilis. All are highly specific, and most show adequate sensitivity, at least when used with serum. The fact that they can be performed to a high standard on site in the clinic, by staff without laboratory training, and require no equipment or refrigeration means that they can be used in clinics without access to electricity. Their greatest value is likely to be in increasing the coverage of syphilis screening in rural arrears of developing countries. On-site testing will also increase the proportion of cases treated when return rates are low. These tests could also complement syndromic management of STDs in resource-poor areas.”