

Evaluation of the Determine Rapid Syphilis TP assay Using Sera

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Background

The study was carried at the Evandro Chagas Research Institute, Rio de Janeiro, Brazil. The serum samples were collected from patients testing positive, indeterminate and negative by TPHA (haemagglutination assay, BioMérieux) during 2001 and were subject to one freeze thaw cycle at -20°C. VDRL is the Venereal Disease Research Laboratory test also known as rapid plasma reagin test as used in the US.

Abstract

The Abbott Determine Rapid Syphilis TP assay is a treponemal test that can be used in resource-poor settings that lack laboratory facilities. However, this test has not been extensively evaluated. We measured its sensitivity and specificity by using stored serum specimens (n = 567) from all persons who tested Treponema pallidum hemagglutination assay (TPHA) positive (n = 250) or TPHA indeterminate (n = 17) in the year 2001 and the first 300 patients in 2001 who tested TPHA negative at the Evandro Chagas Research Institute in Rio de Janeiro, Brazil. This rapid assay was independently interpreted by three different observers. With TPHA results as the reference, sensitivity ranged between readers from 95.6 to 98.4% and specificity ranged from 97.3 to 95.7%. There was little inter reader variability in the interpretation of results, with approximately 98% agreement for all reader combinations. Of samples from persons with human immunodeficiency virus (HIV) infection (n = 198), sensitivity was 96.9 to 99.2% and it was 94.4 to 96.3% among HIV-negative persons (n = 127). Specificity was 92.4 to 95.5% among HIV-positive persons and 97.2 to 100% among HIV-negative persons. We found this test to have high sensitivity and specificity and little inter reader variability, indicating that it may be easily used in resource-poor settings without laboratory facilities. Further studies are needed using this test on whole blood and under the clinical conditions for which it is intended.

Results

Sensitivity and specificity of Determine Syphilis TP by reader in comparison to TPHA and TPHA/VDRL

	TPHA positive	TPHA Negative	TPHA & VDRL positive	TPHA positive & VDRL negative	TPHA & VDRL negative
	Sensitivity	Specificity	Sensitivity	Sensitivity	Specificity
Reader 1	97.6%	97.2%	97.9%	96.2%	97.3%
Reader 2	98.4%	95.7%	98.5%	98.1%	95.7%
Reader 3	95.6%	96.3%	96.9%	94%	96.3%

Sensitivity and specificity of Determine Syphilis TP by reader in comparison to TPHA and HIV status

	HIV positive		HIV negative	
	Sensitivity	Specificity	Sensitivity	Specificity
Reader 1	98.5%	95.5%	94.4%	100%
Reader 2	99.2%	92.5%	96.3%	97.3%
Reader 3	97.7%	92.5%	94.4%	98.6%

Discussion

“...We found this test to have high sensitivity and specificity, with TPHA as the reference, and low inter reader variability in the interpretation of results, suggesting that this test may be easily used in resource-poor settings without laboratory facilities”

detect... diagnose... determine...