

## Assessment of the rapid test based on an immunochromatography technique for detecting anti-*Treponema pallidum* antibodies

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### Product Evaluated

Determine Syphilis TP (Abbott Diagnostics)

The study was carried at the Department of Sanitary Dermatology of the School of Public Health in São Paulo, Brazil. The serum samples were collected from patients testing positive for Syphilis, positive for other sexually transmitted diseases and negative samples. The status of the samples was determined by serology – VDRL (Behring), FTA-abs (Wama Diagnostica), TPHA (Organon Teknika), Capita Syphilis-M (Centacor) and ELISA IgA, IgM, and IgG for syphilis (Randox)

### Abstract

*A rapid test based on an immunochromatography assay - Determine Syphilis TP (Abbott Lab.) for detecting specific antibodies to Treponema pallidum was evaluated against serum samples from patients with clinical, epidemiological and serological diagnosis of syphilis, patients with sexually transmitted disease other than syphilis, and individuals with negative serology for syphilis. The Determine test presented the sensitivity of 93.6%, specificity of 92.5%, and positive predictive value and negative predictive value of 95.2% and 93.7%, respectively. One serum sample from patient with recent latent syphilis showed a prozone reaction. Determine is a rapid assay, highly specific and easy to perform. This technique obviates the need of equipment and its diagnostic features demonstrate that it may be applicable as an alternative assay for syphilis screening under some emergency conditions or for patients living in remote localities.*

### Results

Sensitivity and specificity of Determine Syphilis TP in serum samples from patients testing both positive and negative results for Syphilis by standard laboratory methods (including VDRL and TPHA)

	%	N/Total N
Sensitivity	93.7%	59/63
Specificity	95.2%	59/62

Sensitivity and specificity of Determine Syphilis TP by reader in comparison to classical serological methods

Group	(n)	Determine		FTA-abs		TPHA		VDRL	
		Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg
Secondary	12	12	0	10	2	11	1	10	2
Recent Latent	28	27	1	27	1	27	1	21	7
Late Latent	23	20	3	20	3	20	3	16	7
Other STD	24	3	21	1	23	2	22	0	24
Negative	38	0	38	0	38	0	38	0	38
Sensitivity		93.7%		90.5%		92.1%		74.6%	
Specificity		95.2%		98.4%		96.8%		100%	

### Discussion

*“The assay yielded rapid results, it was easy to perform without any specialized equipment.”*

*“It is fundamental to carry out the investigation of syphilis at delivery in pregnant women who have not been followed at antenatal care. The conventional serological tests for syphilis are usually time consuming, and commonly the mother and its newborn leave hospital even before the results of serological tests are reported. A rapid test like Determine may be useful to overcome these limitations.”*

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