

## Performance of Rapid Syphilis Tests in Venous and Fingerstick Whole Blood Specimens

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### Product Evaluated

Determine Syphilis TP (Inverness Medical)  
Trep-Strip IV (Phoenix Bio-Tech Corp.)  
One Step (Guardian Biosciences)

The study was carried out using patient samples collected from patients attending the San Francisco City Clinic. Determine Syphilis TP was evaluated with venous whole-blood and fingerstick whole blood samples. The aim of the study was to determine the suitability of rapid tests for the screening of Syphilis.

### Abstract

**OBJECTIVE:** Rapid syphilis screening could facilitate case-identification during U.S. outbreaks. **GOAL:** The goal of this study was to determine the performance of 3 rapid syphilis tests in whole blood specimens in the laboratory and in patients at a sexually transmitted disease (STD) clinic.

**STUDY:** We tested whole blood samples from STD clinic patients with 3 rapid tests and compared results with the serum treponemal pallidum particle agglutination (TP-PA) test. We evaluated the best performing of the 3 rapid tests on fingerstick specimens from STD clinic patients.

**RESULTS:** The Abbott Determine TP (n = 127) had the highest sensitivity (88%; 95% confidence interval [CI], 81-96%) and lowest rate of indeterminate tests (0.8%), followed by Guardian Biosciences One Step (n = 116) (sensitivity 72%; 95% CI, 60-84%; indeterminate 6.5%), and Phoenix Biotech Trep-Strip IV (n = 71) (sensitivity 70%; 95% CI, 54-85%; indeterminate 30.3%). All 3 tests were 100% specific. The Abbott Determine TP showed excellent performance on fingerstick specimens (n = 99), exhibiting 100% sensitivity (95% CI, 93-100%), 100% specificity, and 2.9% indeterminate.

**CONCLUSIONS:** The Abbott Determine TP test was an easy and accurate test that could facilitate rapid detection of syphilis in at-risk patients.

### Results

Sensitivity and Specificity of tests for detection of antibodies to *Treponema pallidum* determined positive and negative by Serodia TP-PA (Fujirebio Inc.)

	Whole Blood		Fingerstick Whole Blood	
	Sensitivity	Specificity	Sensitivity	Specificity
<b>Determine Syphilis TP</b>	<b>88%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>
Trep-Strep IV	70%	100%	N/D	N/D
One Step	72%	100%	N/D	N/D

### Discussion

“... this study suggests that the Abbott determine TP rapid treponemal antibody test could fulfil the need for an inexpensive, non-invasive, rapid screening test for syphilis. In this evaluation, we have documented its consistent performance compared with the serum TP-PA. As a result of its accuracy, price and ease of use, it could be an effective test to help public health departments respond to the current nationwide epidemic”