

## Utility of the Determine Syphilis TP Rapid Test in Commercial Sex Venues in Peru

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The aim of this study was to evaluate the utility of Determine Syphilis TP rapid test for the detection of active syphilis when used in a field-based setting comprised of commercial sex venues and assess the feasibility of integrating rapid syphilis testing into existing health outreach services. In total, 3682 female sex workers were offered syphilis tests during the first two screening cycles (undertaken by PREVEN mobile outreach teams) from February to May 2005.

### Abstract

**Objectives:** This study sought to evaluate the utility of the Determine Syphilis TP test performed in Peruvian commercial sex venues for the detection of active syphilis; and determine the feasibility of integrating rapid syphilis testing for female sex workers (FSW) into existing health outreach services.

**Methods:** We tested 3586 female sex workers for syphilis by Determine in the field using whole blood finger-stick, and by rapid plasma reagin (RPR) and *Treponema pallidum* haemagglutination assay (TPHA) in a central laboratory in Lima using sera.

**Results:** 97.4% of the FSW offered rapid syphilis testing participated; and among those who tested positive, 87% visited the local health centre for treatment. More than twice as many specimens were RPR reactive using serum in Lima (5.7%) than tested positive by whole blood Determine in the field (2.8%) and although most were confirmed by TPHA, only a small proportion (0.7%) were RPR reactive at  $\geq 1:8$  dilutions, and likely indicating active syphilis. Sensitivity, specificity and positive predictive value of the Determine Syphilis TP test in whole blood when compared to serum RPR reactivity at any dilution confirmed by TPHA as the gold standard were 39.3%, 99.2% and 71.4% respectively. Sensitivity improved to 64.0% when using serum RPR  $\geq 1:8$  confirmed by TPHA. Invalid tests were rare (0.3%).

**Conclusions:** Rapid syphilis testing in sex work venues proved feasible, but Determine using whole blood obtained by finger-stick was substantially less sensitive than reported in previous laboratory-based studies using serum. Although easy to perform in outreach venues, the utility of this rapid syphilis test was relatively low in settings where a large proportion of the targeted population has been previously tested and treated.

### Results

Sensitivity, specificity and positive predictive value (PPV) of the Determine Syphilis TP rapid test using whole blood in the field.

	Gold Standard		
	Serum RPR reactive and TPHA positive	Serum RPR $\geq 1:8$ and TPHA positive	Serum RPR $\geq 1:16$ and TPHA positive
Sensitivity	39.3%	64.0%	70.0%
Specificity	99.2%	97.6%	97.4%
PPV	71.4%	16.3%	7.1%

### Discussion

Operationally, the Determine Syphilis TP rapid test was relatively easy to adapt, implement and integrate into existing worksite-based STI prevention services, and was well received by female sex workers. Performance of the test was less sensitive than reported in previous studies. Yet in order to take full advantage of rapid diagnostics tests, studies must evaluate their utility and acceptance in clinics and field-based settings where they are to be used.

*“Our findings indicate relatively low sensitivity of the Determine Syphilis TP test, which may miss a high proportion of whole blood specimens from which serum is reactive by RPR only at low titres, but may detect a higher proportion of active syphilis infections in difficult to reach, high risk populations that would otherwise be over-looked altogether.”*