

Evaluation of Rapid Diagnostic tests for the Detection of Human Immunodeficiency Virus Types 1 and 2, Hepatitis B Surface Antigen, and Syphilis in Ho Chi Minh City, Vietnam

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Products Evaluated

- Determine HIV-1/2, HBsAg, Syphilis *Treponema pallidum* (TP) (Inverness Medical)
- Capillus HIV-1/HIV-2 (Cambridge Biotech Limited)
- Serodia HIV, HIV Blot 2.2, HBsAg, TP, TP-PA (Fujirebio Inc.)
- Dainascreen HBsAg (Inverness Medical)

This study included a total of 710 patients from the Pasteur Institute, Tuberculosis Hospital, Tropical Disease Centre, and Tudo Obstetrical Hospital in Ho Chi Minh City, Vietnam during October-December 1997. The aim of the study was to complete a comparative evaluation of three new rapid diagnostic test kits.

Patient specimens were divided into four groups, including 199 samples to be tested for HIV, 200 samples to be tested for HBsAg, 163 samples to be tested for syphilis and 148 samples from patients with potentially cross-reacting blood components (e.g. pregnancy, Tuberculosis infection), of which 148 were tested for HIV and 128 were tested for HBsAg and Syphilis.

Abstract

*An evaluation of three new rapid diagnostic test kits for human immunodeficiency virus types 1 and 2 (HIV-1/2), hepatitis B surface antigen (HBsAg), and syphilis involved a two-phase comparison of rapid diagnostic assays using prospectively collected from hospitals and clinics in Ho Chi Minh City, Vietnam. After specificity and sensitivity testing, three new rapid diagnostic test kits were tested in parallel with six commonly used diagnostic test kits. The Determine HIV-1/2 test had fewer indeterminate or equivocal results than the Capillus HIV-1/HIV-2 or HIV Blot 2.2 tests. However, the Determine HIV-1/2 test yielded one false-positive result when compared with the Serodia HIV, HIV Blot 2.2, and micro-particle enzyme immunoassay (IMx) HIV tests. The Serodia HBsAg test yielded more false-negative results when compared with the Determine HBsAg diagnostic test kit. The results of the syphilis diagnostic tests evaluated in this clinical trial consistently agreed with those of the rapid plasma regain test for syphilis. The Determine Syphilis *Treponema pallidum* (TP) test had three false-positive results compared with the Serodia TP and the Serodia TP•particle agglutination (PA) tests, which had two false-positive results that were confirmed as negative by an ELISA. Application of these serologic tests within this comparative evaluation framework, using the World Health Organization alternative testing strategies, proved to be an effective way to determine serostatus related to HIV, hepatitis B, and syphilis.*

Results

Comparison of Determine HIV-1/2, Serodia HIV and Capillus HIV-1/HIV-2 diagnostic tests for HIV (n=347).

EIA*	Determine HIV-1/2				Serodia HIV				Capillus HIV-1/HIV-2			
	Positive	Negative	Equivocal	Indeterminant	Positive	Negative	Equivocal	Indeterminant	Positive	Negative	Equivocal	Indeterminant
Positive**	98	0	0	0	98	0	0	0	98	0	0	0
Negative	1**	248	0	0	0	249	0	0	0	248	1§	0

*GenScreen & Abbott enzyme immunoassay (EIA) HIV used as a gold standard confirmatory test.

**Genelabs HIV Blot 2.2 and Abbott HIV-1/HIV-2 EIA used for discordant samples.

§Malaria patient (M1) classified as equivocal by Capillus HIV; indeterminant by HIV Blot 2.2

Comparison of Determine HBsAg, Serodia HBsAg and Dainascreen HBsAg diagnostic test for HBsAg (n=328).

Monolisa Ag HBs*	Determine HBsAg			Serodia HBsAg				Dainascreen HBsAg		
	Positive	Negative	Equivocal	Positive	Negative	Equivocal	Indeterminant	Positive	Negative	Equivocal
Positive	117	0	0	112	3**	1‡	1§	117	0	0
Negative	0	211	0	0	211	0	0	0	211	0

*Monolisa Ag HBs was used as the gold standard test; Abbott IMx HBsAg was used as a confirmatory test for discordant samples.

**Three patient sera yielded false-negative results from confirmed positive specimens with Serodia HBsAg.

‡Patient serum yielded an equivocal result from confirmed positive specimens with Serodia HBsAg.

§Patient serum yielded an indeterminant result from confirmed positive specimens with Serodia HBsAg.

Comparison of Determine and Serodia rapid diagnostic tests for syphilis (n=291)

VDRL RPR*	Carbon Antigen	Determine Syphilis TP			Serodia TP			Serodia TP:PA		
		Positive	Negative	Equivocal	Positive	Negative	Equivocal	Positive	Negative	Equivocal
Positive	72	72	0	0	71	1**	0	71	1**	0
Negative	219	3‡	216	0	2§	217	0	§	217	0
Indeterminant	0	0	0	0	0	0	0	0	0	0

*VDRL Carbon Antigen RPR (Biomérieux) was used as the screening for serostatus; Trepanostika Microelisa (OTC) and FTA-ABS (Kyowa Yakuin Kougyo) were used as the confirmatory tests for discordant samples.

**Tests revealed one false-negative results using Serodia TP/TPPA with confirmed positive serum.

‡Tests revealed three false-positive results using Determine Syphilis TP with confirmed negative sera.

§Tests revealed two false-positive results using Serodia TP/TPPA with confirmed negative sera.

Discussion

“In summary, the three new rapid Determine diagnostic tests (Determine HIV-1/2, Determine HBsAg, and Determine Syphilis TP) evaluated proved to be accurate testing methods, based on sensitivity and specificity measures, when compared with standard clinical laboratory testing. These three tests are rapid, simple and provided excellent screening methods, with comparable sensitivity and specificity to the gold standard methods.”