

Evaluation of three commercial rapid tests for detecting antibodies to human immunodeficiency virus

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Products Evaluated

Chembio HIV STAT-PAK (Chembio Diagnostic Systems, USA)
Determine HIV-1/2 (Inverness Medical)
PenTest HIV (Noventis (S) Pte Ltd)
MEIA HIV-1/2 (Abbott Laboratories)

This study was carried out between August and October 2002 the University of Malaya Medical Centre, Kuala Lumpur. The aim of the study was to determine the sensitivity and specificity of three rapid HIV tests in comparison to the conventional MEIA HIV-1/2 assay.

A total of 200 frozen sera were used of which 92 were HIV-1/2 positive and 108 HIV-1/2 negative, of the 108 negative samples 35 were indeterminate by MEIA and 73 were negative. The 35 indeterminate samples were confirmed as negative by PA HIV-1/2 and Inno-Lia HIV and therefore reported as negative for HIV-1/2 antibodies.

Abstract

Determine HIV-1/2, Chembio HIV-1/2 STAT-PAK and PenTest are simple/rapid tests for the detection of antibodies to HIV-1 and HIV-2 in human whole blood, serum and plasma samples. The assay is one step and the result is read visually within 15 minutes. Using 92 known HIV-1 positive sera and 108 known HIV-1 negative sera, the 3 HIV tests correctly identified all the known HIV-1 reactive and negative samples. The results indicated that Determine HIV-1/2, Chembio HIV-1/2 STAT-PAK and PenTest HIV are as sensitive and specific (100% concordance) as Microparticle Enzyme Immunoassay. The data indicated that these 3 HIV tests are effective testing systems for diagnosis of HIV infection in a situation when the conventional Enzyme Immunoassay is not suitable.

Results

This is a summary of the data reported in the paper comparing the three rapid tests under evaluation to MEIA.

Sample	Determine HIV-1/2		HIV-1/2 STAT_PAK		PenTest HIV	
	Positive	negative	positive	negative	positive	negative
HIV positive (n = 92)	92	0	92	0	92	0
HIV indeterminate (n = 35)	0	35	0	35	0	35
HIV negative (n = 73)	0	73	0	73	0	66

(Only 193 PenTests supplied for evaluation)

Discussion

The paper shows that all three rapid tests were comparable to MEIA for the diagnosis of HIV infection. All indeterminate samples were correctly identified by all three rapid tests as negative.

The paper also shows a 100% sensitivity and specificity compared to conventional screening methodology and 100% concordance to the more complex and technically demanding MEIA.

"We conclude that these 3 simple / rapid HIV-1/2 assays are effective and user-friendly and can be used as a screening HIV test in situation where HIV result and counselling can be given in a single visit"