

**Evaluation of a Rapid Immunochromatographic Test for Detection of Antibodies to Human Immunodeficiency Virus**

Arai H; Petchclai B, Khupulsup K, Kurimura T and Takeda K  
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Product Evaluated

Determine HIV-1/2 (Inverness Medical)  
Serodia HIV (Fujirebio inc.)  
Capillus HIV-1/HIV-2 (Cambridge Biotech Limited)

Determine HIV-1/2 was evaluated with whole-blood, serum, and plasma samples from patients in Ramathibodi Hospital, Bangkok, Thailand, in order to determine the sensitivity, specificity, and clinical utility of this test in emerging and developing countries.

The specimens used in this study were 470 fresh paired samples from HIV-1-infected patients and blood donors, 92 frozen serum and plasma samples from HIV-1-infected patients, 111 specimens from HIV-2-positive patients, and 4 commercial seroconversion panels.

Abstract

*A new immunochromatographic rapid test, Determine HIV-1/2, for the detection of antibodies to human immunodeficiency virus type 1 (HIV-1) and HIV-2 in human whole blood, serum, and plasma was evaluated. Determine HIV-1/2 is a sandwich immunoassay and uses a nitrocellulose strip with a capture site for the patient's results and a procedural control site to confirm the validity of the assay. The results can be read visually, and a positive result is indicated by the formation of a red line within 15 min after sample application. The test showed 100% sensitivity for HIV-1 with 102 whole-blood, 152 serum, and 144 plasma samples obtained from Ramathibodi Hospital, Bangkok, Thailand. The sensitivity of the test for HIV-2 was 100% with 100 serum or plasma samples obtained from Ivory Coast. The sensitivity of the test with 4 anti-HIV-1 seroconversion panels from Boston Biomedica Inc. was equivalent to or better than those of another agglutination assay with serum or plasma and the enzyme immunoassay licensed by the U.S. Food and Drug Administration. The specificity was 100% with 367 sets of whole-blood, serum, and plasma samples from Ramathibodi Hospital. This method had an analytical sensitivity for the detection of HIV-1 equivalent to or better than that of another agglutination assay with serum or plasma. This test had an analytical sensitivity for the detection of HIV-1 better than that of another immunochromatographic test with whole blood. This evaluation demonstrated the excellent performance of this immunochromatographic test with EDTA-anticoagulated whole-blood, serum, and plasma samples. We conclude that this test is suitable for use in emerging countries and is an excellent alternative to HIV antibody testing at remote sites, as well as in traditional laboratories.*

Results

Sensitivity and Specificity of tests for detection of antibodies to HIV-1 & HIV-2 with samples determined positive and negative for HIV-1 with Abbott HIV-1/2 3rd Gen. Plus.

	Sensitivity			Specificity		
	Serum	Plasma	Whole Blood	Serum	Plasma	Whole Blood
<b>Determine HIV-1/2</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>
Serodia HIV	100%	96.8%	N/A	100%	N/D	N/A
Capillus HIV-1/HIV-2	100%	98.4%	N/A	100%	N/D	N/A

Sensitivity of tests for detection of antibodies to HIV-1 & HIV-2 with samples determined positive and negative with HIV-2 samples positive by Abbott HIV-1/2 3rd Gen. Plus.

<b>Determine HIV-1/2</b>	<b>100%</b>
Serodia HIV	100%
Capillus HIV-1/HIV-2	N/D

In addition the sensitivity of the test with the anti-HIV-1 seroconversion panels was shown to be equivalent to or better than those of PA (Serodia HIV).

## Discussion

In comparison to the other assays evaluated in this study, Determine HIV-1/2 had several advantages.

- It requires fewer steps than other assays to achieve results
- It is rapid, results are available 15 min after sample application.
- It does not require any specific instrumentation or any skill or expertise for the reading of the results.

*"All five technicians who evaluated Determine HIV-1/2 at Ramathibodi Hospital commented they had no difficulty in performing Determine HIV-1/2 and in interpreting the results because the test was easy to perform and the signal indicating the results was clear."*

*"Because of its unique features, which are the advantages of the test over the presently used rapid tests, we conclude that this test will allow screening of blood for anti-HIV-1 and anti-HIV-2 antibodies in developing countries and will provide an excellent alternative test for the detection of HIV antibodies at remote sites as well as in traditional laboratories".*