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Evaluation of the Rapid Immunoassay Determine HIV 1/2 for Detection of Antibodies to Human Immunodeficiency Virus Types 1 and 2

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We evaluated the reliability of a rapid human immunodeficiency virus type 1 test for quick clinical decision making, such as in needle-stick accidents. The test was evaluated with 1,160 patients. It proved to be a simple and useful test with 99.6% specificity and 99.4% sensitivity. One patient with late-stage AIDS had a false-negative result.

In needle-stick accidents and clinical situations with a need for immediate human immunodeficiency virus (HIV) testing, rapid tests to detect HIV antibodies facilitate therapeutic and preventive strategies. The Onze Lieve Vrouwe Gasthuis (OLVG) hospital is an HIV referral center situated in the city center of Amsterdam, which has a high HIV seroprevalence (8). In this setting, there is a need for a rapid HIV test. The Determine HIV 1/2 test (Abbott Diagnostic Division, Hoofddorp, The Netherlands) is a rapid immunochromatographic test for the detection of antibodies to HIV types 1 and 2 (HIV-1 and -2, respectively). The performance of this test has been described previously for patients from Thailand and Africa (1, 2, 5). We examined this test in a Dutch population. Between July 1999 and May 2001, 1,160 consecutive patients were tested for HIV antibodies. Fresh serum samples were examined by both rapid test (RT) and a microparticle enzyme immunoassay (MEIA). In case of positivity of one or both tests, a line immunoblot assay was performed. If RT and MEIA results were disconcordant, the tests were repeated immediately. Additionally, these patients were evaluated for risk factors for HIV infection and followed up serologically and/or clinically, if necessary. In a few cases, HIV load was measured in EDTA plasma with the HIV-1 RNA 3.0 assay (bDNA; Bayer Diagnostics, Fernwald, Germany) with a detection level of 50 copies of RNA per ml. The following HIV antibody tests were used. (i) The Determine HIV 1/2 test is a rapid immunochromatographic test that uses either serum, plasma, or whole blood. The results can be read after 15 min, and no special equipment is needed. (ii) The AXSYM HIV 1/2 gO (Abbott) is a microparticle enzyme immunoassay. The cutoff rate is calculated from the mean rate of three index calibrator replicates. A sample rate divided by a cutoff rate (s/co ratio) $\geq$1.00 is considered positive. (iii) The Inno-Lia HIV test (Innogenetics, Ghent, Belgium) is a line immunoblot assay.

All assays were carried out as described by the manufacturers.

For 1,149 of the 1,160 patients (99%), RT and MEIA showed concordant results (988 negative and 161 positive results). In 11 cases, RT and MEIA results were disconcordant (1%; Table 1). We consider 10 of the 11 disconcordant cases to be false positives, with 6 false-positive MEIA results (patients D, F, G, H, J, and K) and 4 false-positive RT results (patients B, C, E, and I). In six patients (B to G), a serological follow-up indicated no infection with HIV. In two patients (G and H), an HIV RNA level of $<$50 copies per ml ruled out infection with HIV-1. Theoretically, a beginning HIV-1 group O or HIV-2 infection cannot be excluded in patient H. However, this is very unlikely in a Dutch population. The other three patients (I, J, and K) had no risk factors for HIV infection and no signs or symptoms of the disease. All six false-positive MEIA samples had an s/co ratio just above the cutoff. Two patients with a false-positive MEIA had concomitant infections (an acute cytomegalovirus infection and an amebic liver abscess) that might be the cause of the false-positive results. False-positive enzyme-linked immunosorbent assays have been described before (3, 4, 6, 7), and cross-reactivity is one of the known causes. A false-negative MEIA did not occur. The reasons for false-positive RT reactions are unknown. The patients remained positive on repeated testing (Table 1).

One patient (A) had a false-negative RT result. He was a 23-year-old man, admitted with *Pneumocystis carinii* pneumonia, oral thrush, and general malaise. The HIV RNA level was 890,000 copies per ml, the CD4 count was 0.02×10^{-9}/liter, and the HIV p24 antigen concentration was 160 pg/ml. The MEIA was reactive, but the RT was negative. The line immunoblot assay was indeterminate. The absence of antibodies to antigens encoded by *gag* and to envelope protein gp120 was notable. Table 2 shows the serological follow-up of this patient. Based on the follow-up, we assumed that the positive tests in all disconcordant samples were false positives, except for patient A. Thus, the MEIA had 100% sensitivity and 99.4% specificity and the rapid Determine HIV 1/2 test had 99.4% sensitivity and 99.6% specificity.

Previous studies of non-Western populations have shown a

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TABLE 1. Results of primary tests and follow-up of patients with discordant results in the rapid Determine HIV 1/2 test and the AXSYM MEIA[a]

Patient	Result of primary tests				Indication to test	Follow-up result[c]				
	RT	MEIA (s/co)	Blot[b]	Viral load (no. of copies/ml)		Interval	RT	MEIA (s/co)	Blot[b]	Viral load (no. of copies/ml)
A	−	12.7	+/−	890,000	*P. carinii* pneumonia					
B	+	−	−		Infertility examination	6 wk	+	−		
C	+	−	−		Victim of needle-stick accident	4 wk	+	−	−	
D	−	3.07	−		Infertility examination	4 wk	−	3.20	−	
E	+	−	−		Malnutrition	10 days	+	−	−	
F	−	1.14	+/−		Source of needle-stick accident	10 days	−	3.0	−	<50
G	−	1.87	−	<50	Amebic liver abscess	6 mo		−		
H	−	1.8	−	<50	Acute cytomegalovirus infection					
I	+	−	−		Semen donor					
J	−	1.02	−		Patient's request					
K	−	1.23	−		Preoperative					

[a] −, negative; +, positive; +/−, indeterminate.
[b] Line immunoblot assay.
[c] For follow-up for patient A, see Table 2. Note that patients J and K were followed up clinically for 4 months and 4 years, respectively.

similar specificity, but in contrast to our study, the sensitivity was 100% (1, 2, 5). Aidoo et al. (1) compared the Determine HIV 1/2 assay and Diagnostic HIV SPOT with a particle agglutination test and a confirmational Western blot as the "gold standard" in 200 specimens. The results revealed 125 HIV-positive patients and 75 HIV-negative patients, with a specificity of 100% for both tests and sensitivities of 100% for the HIV 1/2 assay and 98% for the HIV SPOT assay. Arai et al. (2) had 398 samples from Thailand and 100 samples from Ivory Coast from patients proven to be HIV positive by EIA and confirmed by Western blotting. The Determine HIV 1/2 test showed 100% sensitivity and specificity. Koblavi-Deme et al. (5) compared four rapid assays of 1,216 sera with known HIV serological status. All four rapid tests showed 100% sensitivity and specificities ranging from 99.4 to 100%: Determine HIV 1/2, 99.4%; HIV SPOT, 99.6%, Capillus, 99.7%; and Genie II, 100%. The patient with the false-negative RT result turned out to have end-stage AIDS. The RT apparently lacks sufficient antigenic determinants to detect all patients with end-stage HIV infection.

TABLE 2. Results of the serological follow-up of the patient with HIV infection and a negative rapid Determine HIV 1/2 test

Assay[a]	Result at follow-up time of[b]:			
	Day 0	10 days	3 mo	14 mo
Blot				
gp120	−	−	−	−
gp41	2+	2+	+/−	2+
p31	1+	1+	−	−
p24	−	−	1+	+/−
p17	−	−	−	−
gp105	−	−	−	−
gp36	−	−	−	−
Conclusion	+/−	+/−	+/−	+/−
Rapid test	−	Weakly +	Weakly +	+
MEIA	12.7			

[a] Rapid test, Determine 1/2 HIV rapid test; Blot, line immunoblot assay.
[b] −, negative; +, positive; +/−, indeterminate. Day 0 was the day of admission. At 18 days, highly active antiretroviral treatment was started. At 3 months, the HIV RNA load was 538 copies per ml, and the CD4 cell count was 0.450×10^{-9}/liter.

In summary, the HIV 1/2 rapid test has proven to be a rapid, simple, and useful test for the detection of HIV antibodies. Because of the ability to test immediately, the use of this test with needle-stick accidents has led to an impressive reduction in prescription of postexposure prophylaxis and sick leave in our hospital (8). However, the clinical situation should be taken into account when interpreting the test result because of the possibility of false-negative results in late-stage AIDS.

REFERENCES

1. **Aidoo, S., W. K. Ampofo, J. A. M. Brandful, S. V. Nuvor, J. K. Ansah, N. Nii-Trebi, J. S. Barnor, F. Apeagyei, T. Sata, D. Ofori-Adjei, and K. Ishikawa.** 2001. Suitability of a rapid immunochromatographic test for detection of antibodies to human immunodeficiency virus in Ghana, West Africa. J. Clin. Microbiol. **39:**2572–2575.
2. **Arai, H., B. Petchclai, K. Khupulsup, T. Kurimura, and K. Takeda.** 1999. Evaluation of a rapid immunochromatographic test for detection of antibodies to human immunodeficiency virus. J. Clin. Microbiol. **37:**367–370.
3. **Celum, C. L., R. W. Coombs, M. Jones, V. Murphy, L. Fisher, C. Grant, L. Corey, T. Inui, M. H. Wener, and K. K. Holmes.** 1994. Risk factors for repeatedly reactive HIV 1 EIA and indeterminate Western blots. Arch. Intern. Med. **154:**1129–1137.
4. **Cordes, R. J., and M. E. Ryan.** 1995. Pitfalls in HIV testing. Application and limitations of current tests. Postgrad. Med. **98:**177–180, 185–186, 189.
5. **Koblavi-Dème, S., C. Maurice, D. Yavo, T. S. Sibailly, K. N'Guessan, Y. Kamelan-Tano, S. Z. Wiktor, T. H. Roels, T. Chorba, and J. N. Nkengasong.** 2001. Sensitivity and specificity of human immunodeficiency virus rapid serologic assays and testing algorithms in an antenatal clinic in Abidjan, Ivory Coast. J. Clin. Microbiol. **39:**1808–1812.
6. **Mylonakis, E., M. Paliou, M. Lally, T. P. Flanigan, and J. D. Rich.** 2000. Laboratory testing for infection with the human immunodeficiency virus: established and novel approaches. Am. J. Med. **109:**568–576.
7. **Profitt, M. R., and B. Yen-Lieberman.** 1993. Laboratory diagnosis of human immunodeficiency virus infection. Infect. Dis. Clin. N. Am. **7:**203–219.
8. **Regez, R. M., P. J. G. M. Rietra, C. T. M. van der Linden, P. H. J. Frissen, H. M. Weigel, and K. Brinkman.** 2002. Reducing the risk of blood-transmitted infections of HIV and hepatitis B or C virus in a teaching hospital in Amsterdam: evaluation of a protocol for needle accidents among hospital staff during the period 1997–2001. Ned. Tijdschr. Geneeskd. **46:**617–621.