Retrospective evaluation of the Vidas HIV DUO test for simultaneous detection of anti-HIV antibody and p24 antigen

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SUMMARY

A fourth generation screening assay Vidas HIV DUO (bioMerieux, Lyon, France) which permits a simultaneous detection of anti-HIV-1/2/O antibodies and HIV-1 p24 antigen was evaluated on 927 serum samples with previously determined anti-HIV-1/2 status in a retrospective manner. The Vidas HIV DUO yielded sensitivity, specificity, positive and negative predictive value of 100%, 99.27%, 94.69% and 100%, respectively. The Vidas HIV DUO is a highly specific and sensitive anti-HIV screening assay, suitable for the implementation in the routine laboratory diagnostics of HIV infection.

KEY WORDS

anti-HIV antibody, p24 antigen detection, simoltaneous Vidas HIV DUO test

Introduction

Current laboratory diagnosis of human immunodeficiency virus (HIV) infection is mainly based on the detection of anti-HIV antibodies (1). Since the introduction of anti-HIV screening assays in 1985, their performance has continued to improve. Recently, fourth generation screening assays which permit the simultaneous detection of anti-HIV antibody and HIV-1 p24 antigen have been developed. They are reported to reduce the diagnostic window by at least 6 days compared to third generation assays in cases with symptomatic infections (2-5). Five commercially available fourth generation anti-HIV screening assays are available at the moment: Vidas HIV DUO (HIV4) (bioMérieux, Lyon, France), Vironostika HIV Uni-Form II Ag/Ab (Organon Teknika, Boxtel, Netherlands), Enzymun-Test® HIV Combi (Roche Boehringer Mannheim, Penzberg, Germany), Enzygnost HIV Integral (Dade Behring, Mannheim, Germany) and Genscreen plus HIV Ag-Ab (Biorad, Hercules, USA). According to the results of the first evaluations of the fourth generation HIV screening assays, they represent an important step towards earlier serologic diagnosis of HIV infection (2-5).

Because of an extreme genome variability of HIV-1 and HIV-2, each new anti-HIV screening test or even its variant should be evaluated in local settings before approval is granted by the government and the test is introduced in a routine work (1). Thus, the aim of the

present study was to evaluate a fourth generation anti-HIV screening assay Vidas HIV DUO (bioMerieux, Lyon, France) on serum samples with previously determined anti-HIV-1/2 status, which were carefully selected from the collection of the Slovenian AIDS Reference Center.

Materials and methods

A total of 927 serum samples with previously determined anti-HIV-1/2 status were retrieved from the files of the Slovenian AIDS Reference Center. Serum samples were collected between 1985 and 1998, tested routinely for the presence of HIV-1/2 antibodies and stored at -20 ^{0}C.

All serum samples were previously tested for the presence of anti-HIV-1 and anti-HIV-2 antibodies using at least two different screening enzyme immuno assays in a routine manner. All repeatedly reactive serum samples were supplementary tested with confirmatory Western blot tests. The Western blot results were interpreted according to American Red Cross standards (6).

726 samples were anti-HIV-1/2 negative (they were all obtained from subjects with high risk of HIV infection, none of these samples was obtained from blood donors), 98 samples were anti-HIV-1 positive (51 serotyped as subtype B, five as subtype C, four as subtype A, one as subtype D and one as subtype E, 36 samples were not serotyped) and 9 samples were anti-HIV-2 positive (all obtained from subjects arriving from Central Africa). The most important group of samples consisted of 94 samples which tested anti-HIV reactive in one or more screening assays and anti-HIV-1/2 indeterminate using confirmatory Western blot tests. All these 94 samples were finally determined as anti-HIV-1/2 negative in follow-up testing.

All 927 serum samples included in a retrospective evaluation were tested in August 1998 using the fourth generation assay Vidas HIV DUO (bioMerieux, Lyon, France), according to manufacturer's instructions as described previously (6).

Table 1. Results of the retrospective evaluation of Vidas HIV DUO assay.

VIDAS HIV DUO	Anti-HIV status		
	Negative	Positive	Total
Nonreactive	814	0	814
Reactive	6[a]	107	113
Total	820	107	927

[a] All 6 serum samples belonged to the group of 94 anti-HIV-1/2 indeterminate serum samples which were finally determined as anti-HIV-1/2 negative in follow-up testing (VIDAS HIV DUO false positive results).

Results

A total of 113 serum samples tested initially Vidas HIV DUO positive and 814 tested Vidas HIV DUO negative. After a final evaluation 107 serum samples were defined as Vidas HIV DUO true positive, 6 samples as false positive and 814 as true negative, yielding a sensitivity of Vidas HIV DUO of 100% and specificity of 99.27% (Table 1). All 6 Vidas HIV DUO false positive serum samples belonged to the group of 94 anti-HIV-1/2 Western blot indeterminate serum samples which were finally determined as anti-HIV-1/2 negative in follow-up testing. The positive predictive value of Vidas HIV DUO was 94.69% and the negative predictive value 100%.

Discussion

Recently, the fourth generation of HIV screening assays in which HIV p24 antigen detection is combined with anti-HIV-1, anti-HIV-2 and anti-HIV-1 group O detection have been developed. Comparative evaluations of the fourth generation HIV screening assays performed on the seroconversion panels have shown that the fourth generation HIV screening assays reduced the diagnostic window of HIV infection by an average of 7 days in comparison to the third generation HIV screening assays and that they permit an earlier diagnosis of HIV infection than third generation screening assays, by detecting p24 antigen which may be present in samples from individuals with recent HIV infection prior to seroconversion (2-5, 6-10).

The results of our retrospective evaluation showed 100% sensitivity and a very high specificity of 99.27% of Vidas HIV DUO assay, which is in accordance with the results of earlier evaluations (2, 3, 5, 8). The positive predictive value of the Vidas HIV DUO was very high (94.69%), which was the result of a low number of false positive results and a high prevalence of HIV infection (11.54%) in the artificially created population that was tested in our study. Namely, the number of false positive results decreases with the increase of prevalence of infection and accordingly the positive predictive value of the assay increases.

Since the fourth generation HIV screening assays combine two different test principles in one assay, the potential for nonspecific reactivity might be expected to be higher than with the third generation antibody assays. However, the results of our study did not con-

firm this presumption. Namely, the false-positivity rate of Vidas HIV DUO (6.3%) found in our study among 94 samples which tested anti-HIV reactive in one or more screening assays and anti-HIV-1/2 indeterminate using confirmatory Western blot tests was lower than that of our third generation enzyme immuno assays evaluated on the same samples previously (false-positivity rates ranged from 8.1% to 16.2%, data not shown).

Conclusions

In conclusion, the Vidas HIV DUO is a highly sensitive and specific anti-HIV screening assay. It is completely automated, cost effective, saves technician's time and is therefore suitable for implementation in the routine laboratory diagnostics of HIV infection.

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