DETECTION OF HIV-ANTIBODY EVALUATION OF FOUR COMMERCIALLY AVAILABLE ENZYME IMMUNOASSAYS

Pages with reference to book, From 216 To 217

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ABSTRACT

We evaluated 550 serum samples with four commercially available enzyme immunoassays and Western Blot was used as the confirmatory test for antibodies against human immunodeficiency virus (HIV). The Weilcozyme (Wellcome), Flow HIV-TEK G, and Behring test kits identified all 50 Western Blot positive samples correctly, whereas DuPont failed to detect one sample. None of the kit was able to pickup one sample that showed a faint P24 band on Western Blot strip. The frequency of false positive reaction in the 500 negative serum samples were Wellcome 0%, Behring and DuPont 0.2% and Flow HIV-TEK 0.4% (JPMA 40 : 216, 1990).

INTRODUCTION

Soon after the discovery of human immunodeficiency virus (HIV) commercial test kit became available in 1985. The most accessible of these test kits was the enzyme immunosorbent assay (ELISA)[1]. When these commercial assays were developed and introduced little was known about their quality and efficiency. Many studies have been done to evaluate the performance of these assays[2-4]. In the present study four commercially available enzyme immunoassay test kits working on two different principles of ELISA have been evaluated.

MATERIAL AND METHODS

Sera

a) Four hundred and nintynine sera were collected from the samples which were received for routine biochemical and serological testing. One sample that showed a faint P24 band on Western Blot strip sample was received for confirmation of HIV was also added to this panel.

b) Fifty samples positive for HIV antibodies included the samples which were received from Biomedical Research Unit, Global Programme on AIDS, WHO, Geneva and those which were sent to us for confirmation. Western Blot was used as a confirmatory test in all these samples.

ELISA for HIVAntibody

The four commercially available assays evaluated were from Weilcozyme (Weilcome, Lot No K 707210), Flow HIV-TEK G (Lot No 3860290 B), Behring (Lot No 26229) and DuPont (Lot No 00439249). The ETA were carried out according to the manufacturer's instructions. Wellcozyme and Behring are competitive EIA in which the conjugated antibodies and, if present, human HIV antibodies compete to capture the viral antigen coated on the solid phase whereas, in DuPont and HIV-TEK G which are indirect EIA, viral antigen is present on the solid phase and the bound antibodies are detected by means of enzyme-labelled antibodies against human immunoglobulin. Therefore, the colour development in Weilcozyme and Behring indicates absence of anti-HIV antibodies while in DuPont and Flow HIV-TEK G it indicates the presence of anti-HIV antibodies. Results were read on Multiskan MCC/340.

RESULTS

Of 50 positive serum samples tested, three assays namely Behring, Weilcozyme and Flow HIV-TEK G gave no false negative results (sensitivity 100%); however DuPont gavt one false negative result (sensitivity 98%). Of the 500 negative serum samples (these also included one inconclusive serum sample), Wellcozyme gave no false positive result, Behring and DuPont gave one false positive each whereas Flow HIV-TEK G gave two false positive results (Tables I and II).

TABLE I. Number of false positive and false negative.

Kit	False Positive	False Negative
Behring	1 (0.2%)	Nil
Wellcozyme	Nil	Nil
Flow HIV-TEK G	2 (0.4%)	Nil
DuPont	1 (0.2%)	1 (2%)

TABLE II. Sensitivity specificity and specificity of tests.

Kit	Sensitivity	Specificity	Efficiency of test*
Behring	100%	99.8%	99.8%
Wellcozyme	100%	100%	100%
Flow HIV-TEK G	100%	99.6%	99.6%
DuPont	98%	99.8%	99.8%

*Efficiency of test was calculated by formula:

$$\frac{\text{True Positive + True Negative}}{\text{True Positive + False Positive + False Negative + True Negative.}} \times 100$$

DISCUSSION

Laboratory testing is particularly important in detecting diseases with serious health implications and long "window" periods. If test were perfect, there would be no false positive and false negative results, test sensitivity and test specificity would be 100%. How can one claim to be perfect about testing of a diseasc which is not even a decade old? The four commercially available EIA were sensitive enough to detect 98- 100% of the anti-HJV positive serum samples in this study. The Behring, Flow HIV-TEK G and Wellcozyme correctly picked all the 50 Western Blot confirmed positive samples whereas DuPont did not detect one positive sample. The cause of ELISA false positive results are not clear. It may be due to cross-reaction of antibodies to antigenically related virus or in some cases antibodies to HLA-Type antigens have also been reported[5,6].

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