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The Performance of a Rapid Human Immunodeficiency Virus (HIV) Assay - Genie II HIV-1/HIV-2 in the screening of HIV

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Abstract: HIV testing and counseling is a key strategy in HIV prevention programs because it is considered the gateway to HIV prevention, care, treatment and support interventions. The evolution in diagnostic technology has led to the development of a wide range of simple, rapid HIV assays. (The aim of the present paper was to study the performance of a rapid HIV kit (Genie II HIV-1/HIV-2) in comparison to the gold standard technique.)This study was carried out in the Fitness clinic in the Department of Health in Dubai, UAE on 304 serum samples, to evaluate the performance of a rapid HIV kit (Genie II HIV-1/HIV-2) in comparison to the gold standard technique (ELISA and western blot techniques). The results showed that Genie II HIV-1/HIV-2 assay has a high specificity (100%) and sensitivity (99.3%), which combined with its simple use, providing results in minutes, minimal laboratory equipment and it can be used in resource-limited settings makes it a highly valuable screening tool for HIV. It is concluded from this study that application of such effective rapid techniques for the identification of recent HIV seroconversion will likely facilitate studies designed to derive incidence estimated in different parts of the world especially in resource-limited settings such as rural areas in developing countries. It is recommended that more studies should be carried out on different new rapid HIV assays on larger population in low and high prevalence settings. In addition, combination of test algorithms needs further research work.

INTRODUCTION

The monitoring of individuals for determination of the incidence of human immunodeficiency virus (HIV) infection is important for public health surveillance and prevention programs.[1] Many human immunodeficiency virus (HIV)-infected persons do not get tested until late in their infection, and many persons who are tested do not return to learn their test results.[2] It was reported by the CDC that during a study conducted in 2000, 31% of persons with positive tests for HIV did not return to learn their test results.[3] Many

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persons who learn that they are HIV infected adopt behaviors that might reduce the risk for transmitting HIV[2],[3].

Reasons for HIV testing vary, as was reported by the CDC that in a study conducted on 7,236 persons in whom HIV was newly diagnosed, the reason given most frequently (42%) for seeking the test was illness. Only 10% of HIV-infected men and 17% of HIV-infected women reported that they were tested primarily because the test was offered or recommended by a health-care facility or provider.[2,3]

Antibody testing for HIV began in 1985 with the introduction of the enzyme immunoassay (EIA) for the screening of donated blood. The traditional platform for HIV testing was thus designed to meet the need to protect the blood supply: Tests with high sensitivity, suitable for batch processing of high volumes of specimens in centralized laboratories with specialized equipment were available. Voluntary counseling and testing (VCT) services were soon established to offer HIV antibody testing as a means for high-risk persons to determine their HIV status. Concerns about false-positive results from the use of screening tests in low-prevalence populations[4] led to the implementation of a sequential two-test algorithm: screening with an EIA followed by Western blot as a supplemental test to confirm HIV positivity[5]. The US Public Health Service recommended that no positive test results should be given to patients until the screening test had been repeatedly reactive on the same specimen and the supplemental test had been used to validate those results[6]. In practice, given the time necessary to transport specimens to a laboratory, perform the tests in batches, and transmit test results, tested persons typically must wait 1-2 weeks before they make a second visit to learn their test results.

The EIA and Western blot became the “gold standard” for detection of HIV

antibodies. However, these tests have several disadvantages. EIAs are technically demanding and require sophisticated, regularly maintained equipment (automatic pipettes, incubators, washers, and readers), and a constant electricity supply. This is not feasible for many developing countries where resources are limited and electricity[7] may not be consistently available.[5,6] Efficient use of EIA tests also requires a minimum number of specimens per run, corresponding to the 96-well microtiter plate set up. Small laboratories thus may delay testing until a sufficient number of specimens accumulate. Disadvantages of the Western blot include its high cost, the need for well-trained technicians, lack of consensus in the interpretation criteria, and the occurrence of indeterminate results[7].

For testing to be effective as well as accurate, HIV test results must be available within as short a period of time as possible. When testing is done in centralized laboratories, turnaround times range from several days in developed countries to several months for specimens sent from rural areas in developing countries[8]. Up to 50% of persons testing in VCT and antenatal clinics, including many who are HIV-positive, do not return to collect their results and thus much of the benefit of testing is lost[8,9]. Availability of same-day test results increases both acceptance of voluntary testing and receipt of results.[10] Depending on the setting, even relatively small delays can affect the number of persons who learn their test results. In one study of rapid HIV tests, 55% of patients in an emergency department left before receiving their test results when the mean turnaround time for testing was 107 minutes, compared with 20% when mean turnaround time was 48 minutes[7].

The evolution in diagnostic technology has led to the development of a wide range of simple, rapid HIV assays. Early diagnosis is essential both to link patients

to effective care and to prevent the spread of infection. The CDC estimated that more than half of new HIV infections were spread by HIV-positive people who are unaware of their infidels.[11] In nearly 40 percent of persons who received a diagnosis of HIV infection, AIDS either was concurrently diagnosed or developed within a year.[11,12] Those people had been infected with HIV for about a decade; health care and other institutions missed many opportunities to diagnose their infection. As a result of delayed diagnosis, such patients are sicker when they begin to receive care and will thus die sooner than those whose infection is diagnosed promptly. Many unwittingly spread HIV to their spouses, partners, and others. Once they know their diagnosis, people infected with HIV reduce their practice of high-risk sex by about half, and the risk of heterosexual transmission, at least, is further reduced by treatment that decreases the viral load [12] Voluntary HIV screening and linkage to care should become a normal part of medical practice, similar to screening for other treatable conditions, such as high cholesterol levels, hypertension, diabetes, and breast cancer. Screening and linkage to care are especially important in communities with a high prevalence of HIV infection.[11] Recent breakthroughs in technology have produced tests for human immunodeficiency virus (HIV) antibody that are highly accurate and easy to use and can give a preliminary result in 20 minutes or less. These rapid HIV tests will be used increasingly in labour and delivery wards, emergency departments, urgent care centres, and the primary care office. They have unique applications for health care worker exposures, military operations, public health venues, and developing countries.[13]

AIM OF THE WORK

The aim of the present study was to study the performance of a rapid HIV kit (Genie II

HIV-1/HIV-2) in comparison to the gold standard technique.

MATERIAL AND METHODS

In order to evaluate the performance of the rapid HIV assay Genie II, as a screening test for HIV infection, 152 positive blood samples and 152 negative samples (reported throughout a period of ….Two (Months) after applying the Gold standard test (ELISA then western blot) were selected from the fitness clinic in the Department of Health in Dubai, UAE All selected samples (304) were then tested by Gennie II (Biorad) and the results compared to those of the gold standard test.

Serology:

According to the manufacturer, Genie II HIV-1/HIV-2 is a rapid enzyme immunoassay (EIA) test that uses the immunochromatography principle with recombinant and peptide antigens for the specific detection and differentiation of HIV-1 and HIV-2 antibodies in human serum or plasma. It utilizes ready-to-use reagents and dropper reagent bottles and can provide results in 10 minutes.

Statistical analysis:

The statistical analysis was carried out using the computer programs EPI-Info and SPSS version "13", the following analyses were carried out :

Calculation of sensitivity, specificity, negative predictive value, and positive predictive value. Kappa test was used for testing agreement between the two tests and the Z test was used for testing the significance of Kappa test.

RESULTS

The present study included 304 samples from people who attended the Fitness clinic in the Department of Health in Dubai in which the samples were preliminary screened using ELISA (Veronostika HIV Uni-Form II Ag/Ab – Biomerieux) and were confirmed by the use of New Lav Blot 1 (Biorad) and INNO-LIA HIV1/2 Score (Innogenetics) for HIV.

Results of the Genie II HIV-1/HIV-2 (Biorad) were concordant with the gold standard tests results for 151 of the 152 positive specimens and for 152 out of the 152 negative specimens resulting in a sensitivity of 99.3%, specificity of 100%, negative predictive value of 99.3% and positive predictive value of 100%. The single discordant sample which was negative by the rapid technique was weak reactive by the ELISA and indeterminate by the supplementary tests.

Table (1): Comparative results between the Gold standard and Genie II (Biorad) in the diagnosis of HIV

	Gold standard (ELISA + western blot)		Total
	+	-	
Gennie II (Biorad) +	151	0	151
Gennie II (Biorad) -	1	152	153
Total	152	152	304

Sensitivity: 99.3% Specificity: 100%
Positive predictive value: 100%
Negative predictive value :99.3%
Efficiency: 99.7%
Kappa test = 99 % , Z = 17.32, P<0.05

Table (2) represents the distribution with HIV positive cases according to sociodemographic profile. It was found that the mean age for persons with HIV positive was 35.66 years, the highest percentage was observed among those aged 31 to 40 years (54.6 %), among males 120 (78.95 %) and among people who did not complete high school (40.79 %).

Table (2) Distribution of HIV positive cases according to sociodemographic characteristics.

Socio-demographic characteristics	No. (n= 152)	%
Age		
18 -	31	20.40
30 -	83	54.60
40 +	38	25.00
- X ± SD		
Sex		
Male	120	78.95
Female	32	21.05
Level of education		
Less than high school	62	40.79
High school	49	32.24
Above high school	41	26.97

DISCUSSION

HIV testing and counseling is a key strategy in HIV prevention programs because it is considered the gateway to HIV prevention, care, treatment, and support interventions. Several rapid HIV tests are currently used around the world, and several rapid tests have been approved by the FDA for use in the United States. Current rapid HIV tests provide results within minutes and allow the person being tested to receive their results the same day, decreasing the numbers who remain unaware of their status despite having undergone an HIV test. Rapid HIV tests provide a reliable, quick, and effective strategy to lessen the gap between those who are HIV- infected and prevention services.[14]

Gennie II HIV-1/HIV-2 was approved by the USAID as of January 2008. Our results showed that it has a sensitivity of 99.3% and specificity of 100%. There was

strong significant agreement between the rapid technique and the gold standard (Kappa test = 99 % , Z = 17.32, P<0.05).The present study results are nearly the same as the figures reported by the manufacturer.[15] Similar results were also mentioned by Aghokeng et al., in which they reported specificity of 100%, but the sensitivity 98.9% was a little lower than our study.[16] The most probable reason for the difference in the sensitivity between the two studies, is that in Aghokeng *et al*., study the false positive samples were due to larger number of weak positive or indeterminate samples by the use of the gold standard technique.

Although test sensitivity and specificity are very important tools in the evaluation of a new screening technique but alone they are not sufficient to establish optimal paradigms for HIV screening. Both logistics and economics pose significant challenges to accomplish the three main objective of HIV antibody testing: 1) Screening of donated blood for transfusion safety, 2) diagnosis of infection in individuals and 3) epidemiological surveillance of HIV prevalence. For example, a single HIV screening test may be appropriate in some-resource poor settings if the alternative is no HIV testing at all; initiating testing even when the full diagnostic algorithm cannot be completed can increase the number of persons who ultimately learn their HIV status because persons may be more likely to pursue further testing when advised of suspicious initial results.[17]

Out of the 152 positive cases, 54.6% were aged 31 to 40 years, 78.9% were males, and 40.79% had not completed high school. A study in Nigeria showed similar results in which 49% of their cases were aged 31 to 40 years old and that 72% of the cases were males.[18] Another study showed also similar results, where the majority of the cases were between 31-40 years old and were males.[19] The sociodemographic data is only descriptive

to our data, but are not a representative sample of the HIV positive cases attending the fitness clinic. This is a limitation in the current study as the sample was randomly chosen.

In conclusion and as recommended by the CDC, rapid HIV tests are essential for early access to prevention, care, and support services. Gennie II HIV-1/HIV-2 assay has a high specificity and sensitivity comparable to the Gold standard in the screening of HIV, in addition to providing results in minutes, use of minimal laboratory equipment and can be used in resource-limited settings. Application of such effective rapid techniques for the identification of recent HIV seroconversion will likely facilitate studies designed to derive incidence estimated in different parts of the world especially in resource-limited settings such as rural areas, universities and prisons. As these types of rapid techniques for the detection of HIV are easy to use, they are sometimes performed by personnel with limited or no formal laboratory training, which is a very important factor in areas with limited facilities and staff. Positive samples by such screening techniques should then be sent for confirmation by supplementary techniques in reference laboratories. It is recommended from this study that different new rapid HIV assays should be tried out on larger population in low and high prevalence settings. Moreover, combination of test algorithms needs further research work in the field of HIV screening.

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