

Combination of Three Rapid Tests: An Alternative Approach to Confirmatory Laboratory Diagnosis of HIV Infection in Bangladesh

Dear Editor,

Laboratory diagnosis of human immunodeficiency virus (HIV) infection depends mostly on detection of antibodies against HIV in plasma or serum using a sequential two-test algorithm; Enzyme Linked Immunosorbent Assay (ELISA), followed by the more specific Line Immuno Assay (LIA) / Western blot (WB) test. As recommended, a positive test result must not be given to the patient until the screening test has been repeatedly reactive on the same specimen and a supplemental test like LIA/WB is positive.^[1] In Bangladesh, a country with low prevalence of HIV, WB/LIA is recommended as the confirmatory laboratory test of HIV. However, due to financial constrains, many individuals with positive ELISA results are reluctant to have their diagnosis confirmed by this expensive LIA/WB test. Moreover, since the number of diagnosed HIV cases is low in Bangladesh, LIA/WB tests are performed in batches in order to minimize the cost of the test. As such, the test is performed infrequently at the referral centers. For these reasons, results of LIA/WB tests often take more than a week. During this time, patients experience enormous anxiety, and many fail to return for follow-up.

As the need for HIV testing continues to increase, countries with limited resources such as Bangladesh are increasingly recognizing the need to explore new testing strategies with minimum expenses, which serve the patient's testing needs more effectively. In a randomized

single blinded study conducted at the Department of Virology, Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, Bangladesh, we retrospectively tested specimens from 121 HIV positive and 30 HIV negative individuals collected between July 2004 and April 2005. The specimens tested either positive or negative by ELISA, and were confirmed by LIA analysis. The aim of our study was to assess the feasibility of a combination of rapid tests as an alternative method to LIA/WB for confirming the preliminary positive results of ELISA. All the sera were tested by three rapid test kits (RTK), namely, Determine HIV-1/2 (Abbott Laboratories, IL, USA), Uni-Gold (Trinity Biotech, Ireland) and Capillus HIV-1/HIV-2 (Trinity Biotech, Ireland) according to Strategy III, recommended by the Joint United Nations Program on HIV/AIDS and WHO which involves three rapid assays used for diagnosis and surveillance in low prevalent countries.^[2]

Using this method, we obtained a 100% concordance with the ELISA and LIA results and the three rapid tests [Table 1]. On cost benefit analysis, it was calculated that altogether the three rapid tests required only 11.3 USD, whereas, each WB costs approximately 63.7 USD. However, due to lack of samples, the main limitation of our study was the inability to include sera with discordant WB results. As such, it remains to be determined whether this alternative combination of tests could confirm the discordance of HIV results.

Table 1: Description, result and cost analysis of HIV tests

Name of test	Test principle [#]	Antigen type [*]	Result		Cost/ Assay [*]
			Positive/ Reactive	Negative/ Nonreactive	
ELISA	-	-	121	30	-
LIA			121	30	63.7
RTK					
Determine HIV-1/2	Immuno - chromatography	Recombinant proteins, synthetic peptides	121	30	2.58
Uni-Gold	Immuno - chromatography	Recombinant proteins	121	30	4.36
Capillus HIV1/HIV2	Agglutination	Recombinant proteins	121	30	4.36

[#]The assays can detect IgG antibody only; ^{*}Envelope proteins / peptides of HIV-1 /HIV-2 are used in all these RTKs; ^{*}The prices (in U.S. dollars) of the test materials quoted by the local vendors. Actual prices may vary

Numerous studies have demonstrated that alternative confirmatory strategies using algorithms with combinations of screening tests produce reliable results comparable to those of the standard ELISA and Western blot.^[3-5] Moreover, the United Nations - World Health Organization (WHO) program on HIV/ AIDS currently recommends the routine use of combinations of screening tests for HIV screening, surveillance, and diagnosis.^[2] Hence, we hope that this rapid, cheap, alternative testing strategy will provide an accurate result and reduce the overall cost of HIV diagnosis. Furthermore, HIV positive individuals will be able to get a confirmed result during their second visit. This will not only allow counselling and testing personnel to guide HIV infected individuals more effectively for treatment but also prevent a large number of HIV positive patients from being lost to follow-up. As such, we recommend that resource-limited countries should consider adopting combination of rapid tests as an alternative strategy to LIA/WB for confirmation of HIV infection in their National recommendations.

References

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