HIV

ANTIBODY TESTING:
RECOMMENDED MEASURES TO
GENERATE QUALITY RESULTS

Introduction

With the increasing incidence of HIV infection, there is an increasing number of laboratories testing for HIV antibody. HIV antibody test has played a prominent role in assessing the prevalence and incidence of HIV infection; maintaining the integrity of the blood supply; supporting counselling and testing; and identifying persons who would benefit from early medical intervention for HIV infection.

Because the medical, psychologic and social impact of an inaccurate HIV antibody test result can be devastating, the public expects a perfect test. It is in this context that concerns over technical proficiency, laboratory performance and expertise in test interpretation are being raised frequently.

The following guidelines are written as measures recommended for testing laboratories to generate quality work so that the public could be assured that laboratory HIV testing is of high standards.

Requirements of quality system in a testing laboratory

In a testing laboratory, errors can and do occur at every step of the testing process. To assure the consumers, both doctor and general public, that laboratory diagnosis is of good QUALITY, the followings must be in place in a testing laboratory.

- It must have sufficient personnel having the necessary education, training, technical knowledge and experience. Individual performing laboratory test must be registered with Medical Laboratory Technologist Board of Hong Kong.

- It should have quality manual containing reference to all relevant procedures including quality control.

- It should use reagent kits and reagents which have been evaluated by a known laboratory. Expired reagent kits should not be used.

- It should have appropriate and fully maintained equipment.

- It should have adequate work space so that personnel can do their best work safely. It must be properly ventilated and lighting must be adequate.

- It must participate in external quality assessment (proficiency testing) programme.

- It should have a system for verification of results and appropriate reporting.

- It should have a good record keeping system.

Specimens

- In accordance with the code of practice of Medical Laboratory Technologist Board of Hong Kong, all requests for laboratory investigation must be initiated by registered medical practitioners.

- When a request for HIV testing is received, it is reasonable for a technologist working in a testing laboratory to conclude that the referring clinician has obtained the patient's consent and that testing is voluntary and counselling has been given.

- Specimens should be obtained in a manner which does not cause haemolysis or contamination; they should be correctly labeled and transported expediently and safely to the testing site.

Testing strategy

Sensitivity and specificity are two major factors that determine testing accuracy in distinguishing between infected and uninfected persons. When testing for HIV antibody, the first line or screening tests are optimized for high sensitivity, i.e. they recognize anti-HIV and a range of cross-reacting or non-specific antibodies. Secondary tests are therefore required to distinguish the two groups of reactors. The probability that a test will accurately determine the true infection status of a person being tested depends on the prevalence in the population. The positive predictive value is very low when one tests population of low HIV prevalence. In Hong Kong, the prevalence of HIV infection in the general population is less than 0.1%, it is therefore of utmost importance to confirm every screening reactive specimen.

- At present, the most common strategy for HIV antibody testing uses a highly sensitive enzyme linked immuno-sorbent assay (ELISA) followed by Western blot. Using this strategy, the achievable false positive rate can be as low as <0.001%.

- Alternative strategies using combinations of screening assays including rapid tests based on different antigen preparations and/or different test principles could also provide reliable results (see appendix). The number of assays used depends on the prevalence of HIV infection in the population. In Hong Kong, at least three different assays should be used. In the selection of HIV antibody assays, the first assay used should have the highest sensitivity, whereas the second and third should have higher specificity than the first one. In general, the sensitivity of ELISA is greater than immunodot followed third by rapid agglutination. In cases where test results are equivocal, western blot should be done.

Interpretation

- Results should be interpreted according to the Manufacturer's instructions. All controls' readings should fall within the ranges recommended.

- Reactive results in screening test should not be taken as conclusive. They should be validated by other supplemental tests.

- When interpreting Western blot results, it is recommended to follow the criteria set by CDC i.e. results should be interpreted as positive if any two of p24, gp41 or gp120 bands are present.

- Reporting

- Laboratory results should be reported clearly and concisely, specifying the antibody tests performed are for the detection of HIV-1 or both HIV-1 and HIV-2.

- It reactive result in a screening test without confirmation by other supplemental tests is reported, it should be stressed that the result is only presumptively positive.

- It feasible, second specimen should be requested after an initial confirmed positive result, especially among low risk individuals, to rule out clerical errors.

- HIV test results should not be available for general viewing, and must be kept in a secure location to prevent access by unauthorized individuals.

- HIV test results must only be reported to the submitting physicians, who in turn can appropriately inform and counsel the tested individual.

Appendix

HIV antibody test kits – antigen and test types

Manufacturer	Test kit	Antigen type	Test type
Abbott	Recombinant HIV-1/HIV-2 EIA, 3rd generation	RP	S
	Test Pack	RP	Dot
Agen	SimpliRed	SP	A
Behring	Enzygnost HIV 1/2 EIA	SP	I
Biotest Diagnostics	Biotest Anti HIV 1/2	RP	I
Cambridge Biotech	Recombigen HIV 1/HIV-2	RP	A
Du Pont de Nemours	Du Pont HIV-1/HIV-2 ELISA	SP/RP	I
	HIVCHECK	RP	Dot
Fujirebio	Serodia-HIV	L	A
Murex Diagnostics	Wellcozyme HIV Recombinant	RP	C
	Wellcozyme HIV 1+2 Recombinant	SP/RP	S
	GACELISA HIV 1+2	RP	S
Organon Teknika	Vironostika Mixt	L/SP	I
Roche	Cobas Core	RP	I
Sanofi Diagnostic Pasteur	Genelavia Mixt	SP/RP	I

L   = lysate   A = agglutination

RP = recombinant protein   C = competitive ELISA

SP = synthetic peptide   Dot = dot-immunoassay

                 I   = indirect ELISA

                 S   = sandwich ELISA