

**Recommended principles on the application of
the HIV antibody rapid test in Hong Kong**

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Background

1. HIV antibody testing is an important part of the clinical and public health management of HIV infection. It forms a crucial step prior to the initiation of HIV counselling, medical care, disease surveillance and prevention. The Conventional HIV antibody testing is a two step procedure. Normally, the first step is a screening ELISA assay followed by a confirmatory test with Western Blot. At least 95% of patients become serologically HIV antibody positive within 3 months after infected by the virus.

2. In November 2002, Oraquick Rapid HIV-1 Antibody Test for the diagnosis of HIV infection was approved by the US Food and Drug Administration (FDA). The availability of this rapid test may signify a revolution of our current system of HIV counselling and testing provision and subsequent referral and care.

Purpose

3. This paper summarizes the essential background, pros and cons of the rapid test and its applicability at different settings and serves as a reference for health care workers and community workers in the prevention and care of HIV/AIDS.

Definition & Performances

4. Definition: A rapid test is a easy-to perform, point-of-care investigation for detecting antibody to HIV the result of which is provided at the same setting of the consultation. The test result is normally available within 30 minutes. Oraquick test is the first FDA approved rapid test falling into this category.

5. Performances: The sensitivity of Oraquick is 99.6% and the specificity is 100%. The performances of the test are reproducible in tested specimens from other geographic areas in the world. Compared with other licensed EIA tests, Oraquick has the same capabilities of detecting seroconversion changes.

Advantages of the Rapid Test

6. The advantages of the rapid test are multiple:-

- (a) The test is a single step procedure.
- (b) The test can be offered at the point-of-care setting. This significantly reduces the turnaround time to only 45 minutes.
- (c) The test offers the opportunity to perform more testing, especially in underserved populations like urgent care settings, emergency rooms, and new venues outside of healthcare setting.
- (d) The test provides rapid answers on the clients' HIV status before initiating HAART in case of post exposure prophylaxis and HIV pregnant mother who presents late during delivery.
- (e) The new test ensures that results are promptly obtained by the clients. In US, about 30% of HIV infected people tested by the conventional HIV test did not return for their results. These people did not receive proper care and counselling.
- (f) The test is technically simple to perform. Oraquick is one of the Clinical Laboratory Improvement Amendments (CLIA) waived tests. In the US, CLIA-waived tests can be performed and interpreted in a physician office or other settings without goint through certified laboratory

Limitations of the Rapid Test

7. The rapid test has the following limitations:-

- (a) The accuracy of the test in terms of specificity, sensitivity and predictive values in individual local setting has not been determined. It is extremely important for studies on the feasibility and acceptability of the test to be conducted in local setting.
- (b) The rapid test is still a screening test that requires confirmation.
- (c) Different form of counselling and support services are required as clients may not be prepared for the rapid results, especially in settings like bars and other venues where there is a great influence of drugs and alcohol.
- (d) The advantage of replacing conventional test with rapid test in HIV testing services is not known such as in settings where a low defaulter rate is achieved with conventional HIV test.¹
- (e) The low prevalence of HIV infection at our locality may increase the chance of false positivity of the test.
- (f) The cost of implementing the HIV rapid test into the health care programme may be considerable.

Applications in Hong Kong

8. Rapid test may complement the conventional HIV testing in the following areas.

- (a) Antenatal clinics when HIV infected mother presents late and therefore antenatal care and screening is impossible, e.g. in labour ward. Rapid test HIV antibody can support decision to start antiretroviral therapy in order to prevent mother to child transmission.
- (b) Hospitals or clinics settings where a high risk of acute needle-stick injury is anticipated. Rapid test can be offered both to the source and victim so as to clarify the need for post exposure prophylaxis with antiretroviral therapy at the point-of-care
- (c) Out-reach setting where conventional HIV testing may not reach certain high risk practising peers like the drug addicts, sex workers and homosexuals.
- (d) Conventional HIV care setting where there is a high defaulter rate. The availability of the rapid testing at the point-of-care will reduce the defaulter rate and prevent further spread of the disease.

Requisites for performing the Oraquick Rapid test

9. The following requisites are suggested before performing the rapid test

- (a) All operators must be familiar with standard infection control practice in health care setting.²Universal Precautions for Prevention of Blood-borne pathogens in health-care setting
- (b) For the best performance of the test, a standardized protocol should be developed and followed in each service. Operators should be clearly informed and instructed.
- (c) The test should be performed in the normal office lighting, and allow adequate time for the test process and interpretation.
- (d) Clients enrolled for the test should understand the implications of the test results.
- (e) Pretest counselling is an essential component of the rapid test and must be offered to all clients receiving the test
- (f) After a rapid test positive result has been validated by confirmatory testing, an effective treatment, clinical care and referral should be provided to the client.

¹ Special Preventive Programme and Social Hygiene Service are settings where there is a low defaulter rate

² Guideline of Universal Precautions for Prevention of Blood-borne pathogens in health-care setting