

# Rapid Testing For HIV

## *Preliminary Discussion Document*

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## Introduction

Rapid Testing For HIV involves technology that provides an *HIV antibody screening test* result within thirty minutes. Since the last national testing policy was issued in 1998<sup>1</sup> rapid HIV testing technologies have significantly improved. Rapid testing at the point of care (that is in medical settings) has been introduced in North America (both Canada and the USA) and some European countries.

Rapid HIV testing is often confused with home HIV testing. While home HIV testing often utilises rapid HIV testing technologies, it is quite different from rapid HIV testing when it is administered by a health professional at the point of care. Home HIV testing is not supported by AFAO.

The scope of this paper is restricted to the introduction of rapid HIV testing at the point of medical care. Its purpose is to briefly document some of the significant reasons to seriously consider an expanded use of rapid HIV testing in medical settings and to identify some of the issues that would need to be addressed should broader rapid HIV testing be implemented.

As any broad introduction of rapid testing would have significant implications for all HIV testing and the costs associated with it, and require significant leadership and coordination in its implementation if it was to be introduced, then AFAO feels that an expert led process to make recommendations on rapid HIV testing is a necessary first part of any broad review of national HIV testing policy and guidelines.

## Existing Rapid HIV Testing Policy

The 1998 HIV testing policy<sup>1</sup> recommended the use of rapid HIV testing technologies for:

- Organ donors
- Testing the 'source' in cases of potential occupational exposure
- Individuals presenting with severe, possibly HIV-related illness needing confirmation of diagnosis.

It did not recommend the use of rapid HIV testing in emergency medicine, where universal precautions are recommended

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<sup>1</sup> HIV Testing Policy. Australian National Council on AIDS and Related Diseases (ANCARD) and Intergovernmental Committee on AIDS and Related Diseases (IGCARD). September 1988

## Improved Rapid HIV Tests

When the 1998 national HIV testing policy was developed, the available rapid HIV tests were usually significantly less specific and/or sensitive than standard HIV antibody testing. Now their specificity and sensitivity is very close to the currently used standard HIV combined test. The newer rapid HIV tests are also easier to administer and interpret than the older rapid HIV tests - but there would still need to be initial training and ongoing Quality Assurance (QA) programs should they be introduced.

*Sensitivity* is the probability that the test will be positive if the specimen is truly positive. *Specificity* is the probability that the test will be negative if the specimen is truly negative. At the current time rapid testing technologies have improved to the point where their specificity is equivalent to (or even higher than) currently used HIV testing. Their sensitivity is on the whole still slightly lower (but very close to) currently used HIV testing.

The orally administered Oraquick rapid HIV test for oral fluid approved by the Food and Drug Administration (FDA) in the USA in March 2004, has a specificity of 99.9% and a sensitivity of 99.3%<sup>2</sup>.

The technology is still improving and rapid HIV tests are likely to become more accurate and faster (a new 3-minute test is about to be implemented in South Africa).

This means rapid testing can be used to give a HIV-negative test *result* - but that a positive or seemingly positive test result cannot be considered a final result until confirmatory testing is done. This has implications for the procedures necessary in medical care settings. The meaning of an initially positive screening test will have to be carefully explained, and support may be necessary until the confirmatory result is available. Currently positive HIV test results are not given until confirmatory testing is completed. In low prevalence settings the majority of positive rapid HIV test screening results will be false positive results. Given that, it could be decided to implement rapid testing only in high prevalence settings.

## Rapid HIV Testing Internationally

In the United States and Canada a major impetus for introducing rapid HIV testing at the point of care was the significant number of people with HIV who had a HIV antibody test but did not return for their result. In parts of Canada access to testing facilities was difficult due to geographical isolation or lack of testing facilities. (This situation is common in many developing countries). In Europe rapid HIV testing has often been associated with home HIV testing which is popular because of a lack of capacity in HIV testing facilities and because many people for historical reasons or legal reasons have significant confidentiality concerns.

These same factors do not exist to the same degree within Australia. There is a high rate of return for HIV test results and generally good and equitable access to

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<sup>2</sup> OraQuick Rapid HIV Test for Oral Fluid – Frequently Asked Questions, April, 2004, CDC.  
[http://www.cdc.gov/hiv/rapid\\_testing/materials/oralfluidqandafin1\\_1.pdf](http://www.cdc.gov/hiv/rapid_testing/materials/oralfluidqandafin1_1.pdf)

testing sites. However, there still remain significant reasons to consider a broader use of rapid HIV testing in the Australian context.

### **Some Reasons To Consider Rapid HIV Testing**

When rapid HIV testing was being considered for introduction at the point of care in Canada, the Canadian HIV/AIDS legal network prepared a long and detailed paper<sup>3</sup> canvassing many of the legal and ethical issues potentially associated with its introduction.

The advantages they gave for the introduction of rapid HIV testing were:

- Improved satisfaction with testing for patients and providers
- Easier and safer to administer
- Choice
- More people would receive test results
- Increased access
- Improved prevention
- Possibly, for use preventing perinatal transmission (this was considered both a possible advantage and possible disadvantage of rapid HIV testing depending on how it was implemented).
- Possibly, testing of 'source' in non-occupational exposure (that is the sexual partner(s) or injecting companion(s) of the PEP candidate)

The last two factors were described as 'possible advantages' because depending on how rapid HIV testing was implemented in those contexts, there were perceived to be both advantages and disadvantages.

An issue that they did not consider, but would obviously be of interest to health policy makers, and may be a significant advantage, was cost. There are a number of cost effectiveness studies in the United States that show significant cost-benefit for rapid HIV testing over standard methods. However, these studies assume a far greater number of people with HIV will actually receive their positive results as a result of the introduction of rapid HIV testing so these studies would need to be modified for relevant Australian data.

**Most of these potential advantages are relevant in Australia and AFAO considers that rapid HIV testing would be preferred by many of its constituency.**

Testing messages are included in many HIV prevention messages. In the context of relationships, testing is recommended as part of 'negotiated safety' guidelines. The possibility of obtaining a rapid HIV test result may make using a HIV test in the context of a new relationship more attractive. This period is known to be a period when many HIV seroconversions occur.

The Canadian paper<sup>3</sup> also lists a number of concerns about the introduction of rapid HIV testing including the changed nature of informed consent, the need for parallel rapid confirmatory testing, the changed content and process of counselling and particular legal and ethical concerns relating to rapid HIV testing of women in labour and for PEP in non-occupational settings.

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<sup>3</sup> Rapid HIV Screening at the Point of Care: Legal and Ethical Questions. Richard Elliot and Ralf Jurgens, Canadian HIV/AIDS Legal Network.

## Implementation issues

Widespread rapid HIV Testing using the Oraquick Rapid HIV Test for oral fluid was introduced in the United States during 2004. The CDC produced a number of technical and training documents to accompany its implementation. (See for example the documents at [http://www.cdc.gov/hiv/rapid\\_testing/](http://www.cdc.gov/hiv/rapid_testing/))

This document is more concerned with listing those implementation issues that affect the decision to proceed to introduce rapid HIV testing at the point of care.

These include:

- i) *Rapid Confirmatory testing.* Given a positive screening test result will be given to a patient who will have to wait for a confirmatory result, it is important that confirmatory testing be done as quickly as possible. There are different technologies available for confirmatory tests some of which are quicker than others.
- ii) *The appropriate settings to introduce rapid HIV testing.* In low prevalence settings, most positive screening results would be false positive results. Rapid HIV testing in high prevalence settings produces an outcome very similar to current testing technologies. Therefore it may be less appropriate for rapid HIV testing to be introduced at the point of care for low prevalence settings.
- iii) *The impact on epidemiological data.* Because all HIV-positive tests would still require confirmation then collection of these data should not be affected. However, it would be harder to collect and/ or estimate the number of HIV-negative test results.
- iv) *The technical and training issues associated with any introduction of rapid HIV tests.* Given the wider number of health care professionals who will be administering tests there will be a need for appropriate training in relation to how to administer the test and appropriate counselling protocols.

## Conclusion

AFAO believes that there may be significant reasons to consider the appropriate introduction of rapid HIV tests in some medical settings in Australia. Given any such decision has broad implications for all of Australia's HIV testing policy, AFAO believes an expert group needs to make recommendations on rapid HIV testing as part of any review of HIV testing policy.