# Background Document to 2011 National HIV Testing Policy v1.2

This background document contains issues which are summarised in the HIV Testing Policy. The document was originally developed to assist the Panel in updating the 2006 Policy and developing the current Policy.

The panel has decided, where relevant, to update the background document if this is warranted by issues changing in the Policy. Updated content in the background document is highlighted in each new version.

This background document reflects the process undertaken by the Expert Reference Committee who reviewed the 2006 National HIV Testing Policy from December through to May 2011. It reflects a time and place in the review process where content was removed from the Policy and the decision to use hyperlinks within the Policy to re-direct the reader to supporting documents was made. This allowed for significant changes to the 2006 policy to occur. This document should only be used as evidence of this process and may not include all the recent changes which have since been made to the Policy.

# Background Document to 2011 National HIV Testing Policy v1.2

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# 2011 National HIV Testing Policy

## 1.0 INTRODUCTION

### 1.1 Background and context

Successive *National HIV Strategies* and *Aboriginal and Torres Strait Islander Blood Borne Viruses and Sexually Transmissible Infections Strategies* have identified readily accessible HIV testing as an important tool for minimizing the spread of HIV and facilitating access to treatment. The benefits of reliable, timely testing are numerous, both for the individual and for public health. Detection of HIV infection can effectively reduce onward transmission by empowering people living with HIV (PLHIV) to modify risk behaviour, facilitate contact tracing and protection of the blood, tissue and organ donation supply. Testing is also vital to mapping patterns of HIV transmission and providing the evidence base for public health campaigns and health service planning.

Early detection has significant additional benefit because a person who has contracted HIV is most infectious soon after exposure. Also individuals diagnosed early in the course of their infection have the opportunity to commence treatment at the optimal time.

Compared to other countries, HIV testing rates in Australia are high. However, there is considerable scope for improvement. Recent modelling and behavioural samples suggest that between 10 and 20% of people in Australia living with HIV have not yet been diagnosed. Late diagnoses of HIV are disproportionately represented in those with HIV–associated mortality and morbidity.

The previous HIV Testing Policy was released in 2006. Significant differences in this Policy include:

- change in terminology from pre-test discussion to informed consent
- communication of a HIV negative test result
- provision of framework for point of care (PoC) testing
- web-based provision of policy allowing for regular revision and access to related resources (e.g. related policies, operational guidelines, evidence of best practice)

### 1.2 Purpose, scope and objectives

This Policy sets out the framework for providing quality testing and removing real and perceived barriers to testing. It identifies requirements and provides guidance and/or links regarding procedures for the provision of HIV testing. The audience for the Policy includes all health workers who are able to offer HIV testing services, other professionals whose work relates to HIV testing (e.g. surveillance staff), community-based workers involved in HIV client service delivery/ HIV education and health promotion and policy/program planners. Reference is made in the Policy to other resources (policies, guidelines etc.) that provide additional guidance. A more detailed statement of specific policy objectives and background is provided in Background Document to 2011 National HIV Testing Policy v1.2.

The Policy is aligned with the *National HIV Strategy 2010-2013.* The National HIV Strategy identifies the need for a co-ordinated, accessible and affordable HIV testing system that allows for:

- access to treatment for those diagnosed with HIV to optimise therapeutic effects;

- minimisation of sexual transmission through knowledge of one's status and facilitating the institution of strategies to prevent onward transmission ;
- minimisation of sexual transmission through partner notification;
- protection of the blood supply and of organ and tissue donation;
- prevention of transmission from a mother with HIV infection to foetus and newborn; and
- mapping of the epidemic to aid the development of evidence-based public health interventions.

Changes in the prevention, diagnostics and treatment knowledge base are occurring rapidly. Accordingly, this HIV Testing Policy will undergo periodic review. The Policy is presented as a website with a download and print function as well as linkages to related resources (e.g. related policies, operational guidelines, evidence of best practice).

## 1.3 Principles of HIV testing

The 8 key principles that guide HIV testing in Australia are that:

- testing is demonstrably of the highest possible standard and timely;
- testing **should** be voluntary and performed with informed consent;
- test results will remain confidential (i.e. only the person being tested and the person providing the results will be entitled to information necessary to identify the individual result). Exceptions to this principle are identified in the Policy;
- testing **must** be accessible to all those at risk of HIV infection;
- testing is critical to the interruption of transmission on a population level;
- testing is of benefit to the person being tested and a critical trigger to initiating interventions including treatment;
- testing is critical to understanding the epidemiology of HIV infection in the community;
- anonymous testing **should** be available to individuals subject to the need to obtain sufficient demographic information from those being tested to allow accurate aggregate information to contribute to surveillance.

## 1.4 Policy implementation

Testing policies and practices **must** comply with all relevant Commonwealth and State and Territory anti-discrimination and public health legislation, and other relevant laws and regulations, including those governing Commonwealth funding of pathology tests.

Policies relating to HIV testing, specific to individual states, territories or institutions, **should** be consistent with the purpose, objectives and principles of the National Policy.

### 1.4.1 Voluntary confidential testing

Voluntary confidential testing is the standard form of service delivery for HIV testing in Australia. Testing is provided through a range of settings ranging from general practice to specialist HIV services.

### 1.4.2 Mandatory or compulsory testing

Mandatory testing refers to situations where people may not either participate in certain activities or access certain services unless they agree to be tested. Circumstances in which mandatory testing is currently required under separate policy or legislation and include:

- as a condition of blood, tissue and organ donation;
- under the migration health requirements applicable to specified visa subclasses;

- as a condition for entering training or service in the armed forces; and
- as a condition for purchasing some types of insurance;
- in the context of a legal instruction including in forensic or coronial settings.

To all extents reasonable, the processes involved in mandatory testing **should** be in accordance with the principles in this Policy and basic human rights pertaining to privacy of health information.

**1.4.3 Anonymous delinked testing**
There may be circumstances where, on public health grounds (e.g. prevalence studies), anonymous delinked testing is legitimately performed in accordance with this Policy. Such testing **should** occur only where there is compelling scientific justification *(see section 6.0).* This **must** be independently judged by an ethics committee constituted in accordance with the *National Health and Medical Research Council National Statement on Ethical Conduct in Human Research*.

**1.4.4 Introduction of new technologies and strategies**
Introduction of new technologies or strategies to target new priority populations **must** be accompanied by appropriate workforce development to ensure that those providing or offering HIV testing are equipped with up-to-date information about HIV biology, HIV treatment and management, procedures associated with using any new technology and information related to referral pathways to care and support services (see section 13.0 Point of care tests for HIV in community settings).

## Background

**Background and context**
HIV testing is critical to HIV prevention and treatment. The aim of HIV treatment is to halt viral replication and thus halt disease progression. HIV testing by serology confirms HIV infection. HIV testing is of critical benefit to the person being tested, because it is the trigger for engaging with HIV services, including HIV treatment. In addition people make decisions about risk behaviour at least in part on the basis of assumptions about HIV status.

A person who has contracted HIV is most infectious soon after exposure when the viral load is at its peak. In the untreated patient viral load declines over a period of months up to years, stabilizes at a "set-point" then the viral load begins to climb again as the person becomes immunocompromised. Recent modelling and behavioural samples suggest that between 10 and 20 per cent of people in Australia living with HIV have not yet been diagnosed. Late diagnoses of HIV are disproportionately represented in those with HIV-associated mortality and morbidity.

HIV testing, as soon as possible after exposure, is important for improving treatment outcomes by maximising treatment options. It can also contribute to reducing transmission of HIV because in the absence of an HIV test people may be behaving as though they are HIV negative, at a time when they are actually most infectious.

**Purpose, scope and objectives**
The 2011 National HIV Testing Policy aims to provide high level advice and direction, which will inform more practical and detailed guidelines, protocols and practices. The Policy

outlines the framework for providing quality testing and removing real and perceived barriers to testing so that testing is accessible to all those at risk of HIV infection, transmission of HIV is reduced and timely uptake of treatment and care is facilitated for those infected. Linkages are made to related documents, requirements, standards and approaches, so that, where possible HIV testing is appropriately incorporated into clinical, diagnostic, preventative and pathology practice.

Policies relating to HIV testing, specific to individual states, territories or institutions, should be consistent with the purpose, objectives and principles of the National Policy. This includes providing the education, support, and investment necessary for a high-quality and ethical approach to HIV testing.

Regular review of the Policy will occur annually and additional reviews will occur between these times if necessary. Changes to new editions will be highlighted in the text and summarized on the front page. The Policy will be accessible through a dedicated website with a download and print function.This Policy and the approach taken to its review and updating is endorsed by the Ministerial Advisory Committee on Blood Borne Viruses & Sexually Transmissible Infections and the Blood Borne Viruses Sub-Committee of the Australian Public Health Principal Development Committee. They established an Expert Reference Committee (ERC; see http://testingportal.ashm.org.au/hiv-erc-committee) to respond to agreed Terms of Reference and provide advice to ASHM which has been given the task of facilitating and supporting the ERC and drafting and updating the Policy. There has been broad consultation in the development of this Policy.

**Policy implementation**

State and territory governments should continue to support access to free and de-identified (coded) testing for individuals at risk of HIV infection who would not otherwise access or consent to testing. Further, individuals who do not wish to disclose their name or Medicare number should have access to de-identified testing. Facilities conducting such testing must nonetheless comply with codes of practice and standards designed to ensure that health information is accurately recorded and protected, and that individuals receive their correct results. All testing, whether voluntary or mandatory, should be accompanied by pre- and post-test discussion and conducted with informed consent.

Compulsory testing is required in the context of a legal instruction, such as in certain rare situations where the welfare of others in the community depends on the testing of an individual. These situations are covered by Commonwealth and state and territory legislation and criminal law jurisdictions.

## 2.0 TYPES OF HIV DIAGNOSTIC TESTS – ALSO CALLED IN-VITRO DIAGNOSTIC DEVICES (IVDs)

**Table 1: Categorisation of HIV IVDs for evaluation and use**

| | Test categories | |
|---|---|---|
| **Purpose or uses of IVDs** | **Standard** | **Reference** |
| **Donor Testing** – screening of blood and tissue donations. | Enzyme immunoassay<br>Particle agglutination assay<br>Machine-based immunoassay<br>Nucleic acid amplification test (NAAT) screening tests<br>**Class 4 IVD** | Enzyme immunoassay<br>Western blot<br>Line assay<br>Rapid short incubation assays (PoC)<br>Antigen enzyme immunoassay<br>Discriminatory NAAT assay<br>Qualitative amplification assay<br>Quantitative amplification assay<br>**Class 4 IVD** |
| **Diagnostic Testing** – to determine the infection status of a sample for clinical purposes e.g. diagnosis, antenatal screening, pre-operative, visa, insurance, emergency, testing and supplemental and confirmatory purposes. | Enzyme immunoassay<br>Particle agglutination assay<br>Machine-based immunoassay<br>Rapid short incubation assays (PoC)<br>Assays used with alternative sample types<br>**Class 4 IVD** | |
| **Point of care testing**- the use of rapid/short incubation tests as a screening test for presumptive HIV infection. Not intended to replace conventional diagnostic testing or for home/self -testing | Rapid short incubation assays (PoC)<br>**Class 4 IVD** | |
| **Unlinked epidemiological surveillance** – or definition of infection status of a population where no results are conveyed to individuals from whom samples are taken. | HIV incidence assay<br>Assays used with alternative sample types/ sample collection devices<br>**Class 3 or Class 4 IVD** depending on other intended purposes for the test; epidemiological surveillance is not a therapeutic use. | |
| **Monitoring and management** – quantifies or characterises the virus for clinical management. | | Quantitative nucleic acid (viral load) amplification assay<br>Antigen enzyme immunoassay<br>HIV genotypic drug resistance assays<br>Pharmacogenomic assays for HIV drug susceptibility<br>**Class 3 IVD** |

### (A) Standard tests

Standard tests may be used by laboratories performing diagnostic or screening testing to

identify the HIV-negative antibody status of samples using screening or standard assays. Tests used for screening purposes must be intended for that purpose by the manufacturer and be entered in the Australian Register of Therapeutic Goods (ARTG). IVDs that are entered in the ARTG are evaluated to ensure that their sensitivity and specificity are appropriate to the manufacturer's intended purpose. Those samples yielding non-reactive results do not need to be further tested unless clinical considerations demand it. Reactive samples must be subjected to supplemental testing using venous blood (serum or plasma) to distinguish true reactivity from false reactivity. The reference testing must confirm the presence of specific antibody or virus before the result is accepted as a true positive.

**(B) Reference tests**
Reference tests are used by laboratories to conduct confirmatory or additional special testing. This testing is conducted to confirm true positive status by distinguishing true from false reactivity. Usually this testing is conducted within a diagnostic strategy and a western blot is used; but other reference testing situations occur (e.g. in a setting of possible seroconversion illness) when the first-used reference tests may include nucleic acid tests. Laboratories may also use rapid tests for reference testing in appropriate settings. Other reference tests may be used once the HIV status is confirmed to quantify viral load, characterise the virus or identify sensitivity of the virus to antiretroviral drugs.

**(C) Rapid HIV assays (point of care tests)** will be used as presumptive screening test for HIV infection only, and are not suitable for use as diagnostic tests. While rapid/PoC does provide a quick result, it **must not** be considered a true positive result as supplemental tests are required to confirm any reactive result. If a person being tested shows a reactive result on a rapid HIV test, a venous blood specimen **must** be taken for confirmatory testing at an HIV reference testing laboratory approved by the National Association of Testing Authorities (NATA).

## Background

The medical devices regulatory framework has a separate classification system for IVD medical devices (IVDs). Under this system, IVDs are classified according to the risk posed to the health of the public or an individual, which relates to the risk of an incorrect result arising from the use of the IVD.

The detailed legislation describing the classification of IVDs can be found in:

- Section 41BD of the *Therapeutic Goods Act 1989* (the Act)
- Subregulations 3.2 (2) and 3.3 (2) of the Therapeutic Goods (Medical Devices) Regulations 2002 (the Regulations)
- Schedule 2A of the Regulations.

IVDs are classified according to the principles set out in sub-regulation 3.3 (2) as follows having regard to

- the manufacturer's intended use of the device; and
- the level of risk to the patient and the public (taking into account the likelihood of harm and the severity of that harm):

| Classification | Level of risk |
|---|---|
| Class 1 IVD | no public health risk or low personal risk |
| Class 2 IVD | low public health risk or moderate personal risk |
| Class 3 IVD | moderate public health risk or high personal risk |
| Class 4 IVD | high public health risk |

More specific rules for the classification of IVDs are set out in Schedule 2A. Of importance to the classification of HIV assays are the following clauses in Schedule 2A:

1.1 An IVD intended to be used to detect the presence of, or exposure to, a transmissible agent that causes a serious disease with a high risk of propagation in Australia is a Class 4 IVD or Class 4 in-house IVD.

1.3 An IVD intended to be used in the management of patients suffering from a life-threatening infectious disease is a Class 3 IVD or Class 3 in-house IVD.

Further information on the classification of IVDs can be found on the TGA's website.

## 3.0 INDICATIONS FOR HIV TESTING

HIV testing is indicated in a number of contexts:

- clinical suspicion of HIV infection, *a full list is available here*
  - an opportunistic infection (including tuberculosis)
  - HIV- linked malignancy
  - symptoms and signs consistent with primary HIV infection (e.g. mononucleosis-like syndrome)
  - other HIV indicator conditions (e.g. immune thrombocytopenia)
- inclusion of HIV within the differential diagnosis
- diagnosis of a condition with shared transmission route:
  - sexually transmitted infection (STI)
  - hepatitis B or C
- reported high-risk exposure
- unprotected sexual intercourse with a partner whose HIV status is unknown
- reported reuse of equipment used for skin penetration
- in the setting of contact tracing
- as an early identification and/or prevention initiative e.g. tests based on epidemiological considerations or the opportunity to prevent vertical transmission
  - gay men and other men who have sex with men
  - people who inject drugs
  - people with multiple sex partners/recent partner change
  - people having traveled to countries of high prevalence and engaged in risk behaviour
  - people from high-prevalence countries
  - partners of the above
  - partners of PLHIV
  - pregnant women
  - people who have received a blood transfusion or blood products prior to 1985 in Australia or from overseas
- a patient initiated request to a health care service for an HIV test *(see Background Document to 2011 National HIV Testing Policy v1.2*
- a patient who reports having a reactive result on an unlicensed HIV test
- Health care workers conducting exposure prone procedures. See infection control guidelines and the Communicable Diseases Network of Australia (CDNA) policy on infected health care workers *(see section 11.0 Post Exposure Prophylaxis)*
- in the context of post-exposure prophylaxis which is subject of national and jurisdictional guidelines and policy *(see section 11.0 Post Exposure Prophylaxis*

Jurisdictions should develop guidelines and protocols, based on local epidemiology and demographic data to facilitate testing among populations at higher risk or requiring addition assistance to access testing and related services, for example Aboriginal and Torres Strait Islander communities, culturally and linguistically diverse (CALD) populations and people with cognitive or intellectual disabilities.

### 3.1 Clinical indications

HIV-related illness can affect any organ system and the clinical features can overlap with a

range of other potential diagnoses. HIV testing **should** be offered in any clinically indicated scenario. A list of clinically relevant conditions can be found here.

All people with HIV **should** be tested for tuberculosis and all people with tuberculosis **should** be tested for HIV

### 3.2 Risk assessment and indications for testing

A sexual, drug use and past medical history **should** be conducted to assist in determining whether an HIV test is indicated. Epidemiology in Australia (and country of origin) and the identification of known risk factors will influence the decision to test. The absence of an identified epidemiological or behavioural risk factor should not preclude HIV testing in appropriate clinical circumstances.

### 3.3 Contact tracing

The practitioner organising HIV testing and/or conveying the result of testing has the responsibility to ensure that appropriate contact tracing is initiated.

### 3.4 Screening

Screening refers to performing an HIV test for all persons in a defined population.

There is evidence that significant numbers of people in higher risk populations may be testing less frequently because of the need to return for their test results. The 2011 National HIV Testing Policy allows negative test results to be delivered through non face-to-face communication under certain circumstances *(see section 5.0 Conveying HIV Test Results)* as well as the use of PoC testing for screening purposes (see section13.0 Point of Care Tests for HIV in Community Settings).

### 3.5 Patient initiated testing in the absence of indications

A small number of people will request a test but will not disclose risk factors. In this case, a person's preference not to disclose risk factors **should** be recognised and HIV testing **should** be conducted.

### 3.6 Post-exposure prophylaxis (PEP)

Testing carried out as part of the process of post exposure prophylaxis **must** comply with non-occupational and occupational PEP policies and any relevant state or territory guidelines or operational directives. All testing conducted as part of a prophylaxis protocol **should** meet the principles and conditions of this Policy.

### 3.7 Pre-operative testing:

Routine pre-operative testing for HIV is not supported and **should not** be performed.
In a person with an identified risk of HIV infection and/or clinical indications of infection, pre-operative HIV testing should be performed only if it will benefit the patient, and informed consent has been obtained.

## Background

**Risk assessment and indications for testing**

Male to male sex has been the predominant mode of HIV transmission in Australia. Male to male sex accounts for around 65% of new diagnoses nationally. Recently in some jurisdictions and sub-populations this pattern has changed, and reflects rapid changes in labor-markets and movement to and from countries of high prevalence.

**Contact tracing**
Contact tracing can facilitate case identification and is particularly important in situations where clusters of infections might be identified, irrespective of the mode of transmission. Contact tracing **should** be carried out in line with best practice guidelines and a considerable number of resources exist which are tailored to specific populations, workforces and settings.

**Screening**
Screening is undertaken as a prevention intervention and for the purpose of surveillance.

Many new infections are occurring and have occurred in Australia from people who have only recently been infected or are in the process of seroconverting and believe that they are HIV negative. Routine practitioner-initiated testing of sexually active individuals and campaigns to encourage testing need to be consistently directed at those engaging in high-risk activities. Promotion of safe sex needs to be included in provision of testing and campaigns to encourage testing.

**Patient initiated testing in the absence of indications**
A small number of cases have been reported where people continue to request HIV testing with either repeated HIV negative or positive results. Individual factors should play a role in the discussion between doctor and patient, as well as in the decision whether or not to proceed with an HIV test. Health departments (including local public health units), local sexual health clinics and professional organisations such as ASHM can provide assistance in managing these patients confidentially in a de-identified way.

**Pre-operative testing**
The Infection Control Guidelines for the prevention of transmission of infectious diseases in the health care settings state:

> *"Preoperative testing of a patient for infectious agents should be on the basis of clinical indication, and medical practitioners should exercise their professional judgement in ordering any clinically relevant test. Discretion and patient confidentiality must be maintained in all circumstances"*

The use of rapid testing pre-operatively for elective surgery is not supported.

**Specific Settings**
HIV testing in specific locations and settings are the subject of specific policy directives and **should** be dealt with in accordance to these. Jurisdictional and professional guidelines can also be found at the linkages below:

- testing prior to blood, tissue and organ donation;
- testing for immigration purposes;
- testing as a condition for entering training or service in the armed forces; and
- testing as a condition for purchasing some types of insurance
- testing in the context of a legal instruction including forensic or coronial

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### 4.0 INFORMED CONSENT FOR TESTING

Informed consent for testing means that the person being tested agrees to be tested on the basis of understanding the testing procedures, the reasons for testing and is able to assess the personal implications. Informed consent is required for HIV testing, except for rare occasions when a legal order is made for compulsory testing or in emergency settings. In these rare occasions where informed consent cannot be attained, pre-test discussions and the provision of appropriate information to the patient **should** still take place. The person performing the test **should** use their clinical judgment in securing informed consent. This **should** be based on their understanding of the context in which the test is being performed:

- the features which precipitate testing such as clinical presentation, risk exposure, epidemiology and prevalence and patient initiation,
- an assessment of the person being tested's understanding of the HIV testing process and the consequences of the result.

Relationships between health care providers and patients can be complex. General principles of professional conduct apply in the case of HIV testing and informed consent should not be sought from sexual partner/s or family members.

People involved in HIV testing **should** use whatever additional supports necessary to assist the person considering testing to become adequately informed. The discussion should be appropriate to the gender, culture, behaviour, language and literacy level of the person being tested.

Protocol driven opt-out testing approaches, if used, necessitate special attention to ensure those who choose not to 'opt-out' are free of any form of real or perceived coercion.

In the case of testing a child or person who is incapable of giving consent (perhaps due to mental illness or cognitive disability) then the responsibility for consent rest with the guardian or other person/agency legally authorised to make such decisions on their behalf .

The person being tested needs to be made aware of privacy considerations and protections.

A person **should not** be denied testing because of a lack of capacity to pay for the test or fear of having their name associated with an HIV test.

## Background

HIV testing has significant effects on the psychological/emotional and physical health and welfare of those being tested. Good practice in gaining informed consent and conveying HIV test results can alleviate these effects.

Provision of informed consent is consistent with the right of individuals to manage their own health and can contribute to better public health outcomes. The process of gaining informed

consent facilitates patient understanding of personal HIV risk, implications of HIV infection and reassessment of their own risk practices.

Specific protocols, guidelines and campaigns promoting HIV testing may change over time or for specific populations in response to particular epidemiological circumstances. Testing in these contexts **should** be performed in accordance with this Policy. (For example a campaign promoting HIV testing for all sexual health service attendees, or an HIV testing campaign associated with a gay community event still requires that high quality tests be used and informed consent given.)

People involved in HIV testing **should** use whatever resources and supports are necessary to assist the person considering testing to become adequately informed. This includes the use of interpreters or that information is provided in a culturally, linguistically or age appropriate format. Cognitive disability should also be identified and support given to provide informed consent.

The client's or patient's understanding of HIV and their reason for requesting or considering HIV testing will influence the nature of any discussion related to informed consent.

In the case of testing a child or person who is incapable of giving consent (perhaps due to mental illness or cognitive disability) the responsibility for consent rests with the guardian or other person/agency legally authorised to make such decisions on their behalf.

The person being tested needs to be made aware of privacy considerations and protections (this includes de-identification of data for surveillance purposes). Patient confidentiality is central to the health system generally and particularly important in HIV where there are concerns that stigma may prevent people coming forward for testing.
Standard HIV serological testing sufficient to diagnose HIV infection is now funded by Medicare, but it is one of a number of tests covered by the same item number. Medicare cannot record or report on specific HIV antibody tests associated with a Medicare number.

## 5.0 CONVEYING HIV TEST RESULTS

The process of conveying an HIV test result to the person being tested, irrespective of the specific result, is affected by the type of test performed, the setting of the consultation and testing and the extent, if any, of additional testing required to determine the true HIV status of the person. The person who requests the test is responsible for ensuring that appropriate mechanisms are in place for delivering the test result.

The window period will be determined by the type of test used. More advanced HIV tests can detect infection sooner than others, however not all jurisdictions currently use the more advanced technology. It is important that a practitioner delivering a test result is aware of what test is being used and how soon after infection it can detect infection. If he or she does not have that information then a window period of three months should be used.

### 5.1 Conveying a negative result – in the context of conventional testing

The decision on how a negative HIV test result is provided (e.g. in person, by phone, etc.) **should** be based on clinical judgement by the person responsible for conveying the test. This person should use whatever support is necessary, taking account of the person being tested's level of knowledge, psychological capacity to deal with the outcome of testing and understanding of the testing process is evident at the time of the sample collection.

It is imperative that the clinician makes all attempts to ensure that the result is being provided to the person who was tested.

### 5.2 Conveying a confirmed positive result – in the context of conventional testing

This Policy recognises the significant impact a positive HIV test result can have for an individual and their clinician, and recommends that laboratories provide information and consultation opportunity to assist the clinician and the person being tested at the time the results of confirmatory testing are forwarded. A positive result **should** always be provided in person except in extenuating circumstances such as the possibility that the person who has been tested may not return for the result and/or may engage in risk behaviour based on the wrong assumption that they are HIV negative.

The discussion when conveying a positive result **should** include:

- giving the test result in person and in a manner that is sensitive and appropriate to the gender, culture, behaviour and language of the person who has been tested;
- providing information about and assisting in assessment of support mechanisms and requirements of the person and making provision for immediate referral to a support agency to be accessed at the person's discretion;
- next steps in staging HIV disease and a consideration of potential treatment options: it may be necessary to cover these issues over a period of time in which case a subsequent consultation **should** be arranged at the time of diagnosis;
- contact tracing and partner notification strategies;
- legal obligations relevant to where the diagnosis is made, to disclose HIV status, (refer to the Guide to Australian HIV Laws and Policies for Healthcare Professionals);
- the transmission of HIV and how onward transmission may be prevented.

## 5.3 Conveying the result in the context of point of care testing

In the context of PoC testing, any person performing the test, and interpreting and delivering the test result **must** be appropriately equipped to deal with a reactive as well as a negative result.

It is necessary for venous blood to be collected to enable reference laboratory confirmation of reactive PoC tests, hence collection of blood samples must be able to be undertaken or directly arranged within the consultation.

## 5.4 Challenging cases

### 5.4.1 Indeterminate results

A small number of patients will have indeterminate results where the presence or absence of infection is not established. The laboratory will perform a range of tests to try and make a definite diagnosis but the patient may need to provide an additional sample. Such a result may represent infection that cannot be definitively diagnosed at that point in time or a non-specific test reactivity. This can be a distressing and uncertain time for patients and practitioners can seek additional support from health departments, specialist services and ASHM.

### 5.4.2 Patients unconvinced by a negative or positive result

Patients who fall into this category can be time consuming and may have psychological issues that need to be addressed. Assistance in dealing with these patients can be obtained from specialist services and ASHM who can offer help to refer a patient in this predicament to an alternative service for second opinion.

### 5.4.3 Patients who do not return for positive test results

These patients can place others at risk if they do not know their status. It is important to try to contact these patients. This **should** be done by phone to the individual or in written correspondence. The request **should** be for the individual to re-contact without providing the result per se. The request should use any necessary supports and be appropriate to the gender, culture, behaviour, language and literacy level of the person who was tested. Public health units and sexual health clinics which have experience in contact tracing, can provide assistance.

The decision to stop trying to follow-up a patient can be a difficult one. Attempts to contact patients **should** be documented in the patients file. General practice, in particular has limited capacity to perform patient follow-up and general practitioners **should** pass this responsibility to the local sexual health clinic or public health unit if they have exhausted their resources. Consult state and territory health authorities for further information. The RACGP publishes guidelines for follow-up of pathology results which should also be referred to.

### 5.4.4 Post mortem testing

HIV tests are not validated in the post mortem setting. However, any reactive PoC test should be confirmed by venous sample. A pathologist undertaking HIV testing as part of the process of a coronial examination or other post mortem examination is responsible for ensuring that the other provisions in this Policy are adhered to, including notification and contact tracing. Mortuary staff may need assistance in approaching contact tracing and this can be provided by public health units and sexual health clinics.

## Background

Previous national HIV testing policies and much of the body of knowledge regarding the implications of conveying a HIV test result have been based on conventional testing which requires:

- a venous sample drawn from the patient,
- transfer of the blood sample to the laboratory and testing using an antibody or antigen and antibody test, and then, in the case of a sample which is reactive on the first test -
    - transfer of an aliquot of blood for confirmatory testing in a reference laboratory
    - conduct of appropriate supplementary tests, reporting and data transfer.

In optimal circumstances using conventional, high throughput automated equipment the length of time between the taking of the sample and arrival at a definitive result is potentially only a matter of hours for negative samples and days for those requiring supplementary/ confirmatory testing. However the practicalities of laboratory testing often result in longer periods elapsing between blood draw and result availability. This can be a time of anxiety for the patient.

Based on early experience of the impact of getting a positive HIV antibody test and the caveats related to the "window period" of pre-seroconversion, standard practice has been to give the result, whether positive or negative, in person.

The capacity now, and in the future, to shorten the period between sample collection and generation of a reliable result has the potential to change the fundamental dynamics of the diagnosis process. Those requesting testing, or performing it, should be sensitive to the impact that uncertainty has when test results are conveyed.

Approaches taken to conveying a result need to be developed on the basis of current evidence as it emerges, and not rely on a literature dominated by studies conducted when HIV testing turnaround time was a two week process and when screening tests had significantly longer window periods (now commonly referred to as "eclipse periods" ) extending up to several months.

Recent reviews of long-term testing data reveal that about 50% of HIV test results are given in a hospital or public clinic settings. Late diagnoses presenting with complications of HIV are over-represented in hospitalised cases newly diagnosed with HIV and those diagnosed by specialists. General practitioners make the other 50% of all diagnoses. Of those, half of HIV positive test results are made by doctors who practice in clinics which are significantly involved in the care of people with HIV, predominantly gay men. The other half are made by doctors who have hardly ever previously made an HIV diagnosis. Those doctors characteristically make one or two positive HIV diagnoses per decade. Maintaining updated knowledge of the prognosis, treatment and likely course of HIV is a challenge for those not regularly confronting it in their practice. Peer and expert support in dealing with issues arising from a new diagnosis can facilitate effective involvement of primary care practitioners in case finding and contact tracing.

**Conveying a negative result – in the context of conventional testing**

There is considerable debate about the appropriateness of giving any HIV test result by telephone or in other non-face-to-face settings. While many feel that giving a negative HIV

result over the phone is acceptable, the consequence of this is that if a patient expecting a result is alternatively directed to a face-to-face consultation the patient may assume the test is positive.

The decision on how and by what process a negative HIV test is provided **should** be based on clinical judgement by the person performing the test. This should take account of the patient's level of knowledge and understanding evident at the time of the sample collection, as well as intellectual/cognitive issues, socio-cultural factors and overall capacity to understand the test result. Discussion about possible result scenarios and how the result will be conveyed may form part of the informed consent process.

The post-test discussion when the result is negative should include:

- Discussion of safe sex and safe injecting practices if appropriate
- Discussion of need for further testing

**Conveying a positive result – in the context of conventional testing**

This Policy recognises the potential repercussions, medical and psycho-social, of a positive HIV test result for an individual and their clinician, and recommends that laboratories provide information and consultation opportunity to assist the clinician and the patient at the time the results of confirmatory testing are forwarded.

The 2006 HIV Testing Policy recommended providing support to service providers who have not previously conveyed a positive HIV test result. Providing such support has been well received. Access to this support **should** be expanded.

The post-test discussion when conveying a positive result should:

- be in person and in a manner that is sensitive and appropriate to gender, culture, behaviour and language; and
- provide information about, and assist in assessment of requirements of the person for, support mechanisms. It should make immediate referral to a support agency to be accessed at the person's discretion.

**Conveying the result in the context of point of care testing**

A significant difference between point of care testing and conventional testing is that the one health care provider or a small practice team can:

- be responsible for ensuring informed consent,
- perform the test in real time, usually in the presence of the tested person , and
- be responsible for interpreting and giving the result.

In the context of point of care testing, any person performing the test, and interpreting and delivering the test result **should** be appropriately equipped to deal with a reactive and/or positive result as well as a negative result. A decision to be tested at a POC site may be more likely to be made at the time of testing (rather than a deliberate decision to actively seek testing) and consequently the person being tested may be less prepared for a reactive result. Also the person performing the test will have less time to assess and reflect on the capacity of the person to receive a reactive result.

Persons performing point of care testing **should** be appropriately trained in the mechanics of performing any test offered and in conveying the result.

Accredited training and guidelines **should** be developed to allow for persons performing POCT and giving results. Any training should include provision for the updating of practitioners of point of care testing to allow for:

- changes in the technology used
- changes in confirmatory testing processes, and
- significant developments in HIV management

No health care workers should haves access to a point of care test unless they have the necessary skill to convey a test result which is reactive at point of care.

## 2011 National HIV Testing Policy

## 6.0 SURVEILLANCE AND RESEARCH

Laboratories performing confirmatory testing (the test that defines a sample as truly HIV positive) **must** notify the relevant state and territory health authorities of any new positive laboratory diagnosis in accordance with the relevant legislation/ regulations.

Where information is available to identify and monitor rates of newly acquired HIV infection, determined by either characteristic laboratory evidence of acute/recent HIV infection such as detectable HIV p24 antigen and a negative or indeterminate western blot or through use of specifically designed incidence assays for this purpose, these cases **should** be reported to the local state or territory health authority as appropriate.

### 6.1 Delinked blood surveys

Delinked anonymous surveys are studies in which specimens taken for other purposes (e.g. the neonatal heel prick specimen survey in 1989-90) are tested for HIV infection without consent, after they have been coded so that the results cannot be linked back to the individual who originally provided the specimen. The survey method **should** be considered for Australian surveillance purposes only where there is no other feasible method for reasonably obtaining appropriate data; and **must** be subject to scientific justification and be endorsed by an institutional ethics committee (IEC) in accordance with the requirements prescribed by the National Health and Medical Research Council (NHMRC).

### 6.2 Identity unlinked HIV testing

Research using identity unlinked HIV Testing can provide useful epidemiological data. In such studies specimens the study **must** be endorsed by an appropriate IEC in accordance with requirements prescribed by the NHMRC.

### 6.3 Use of stored blood for research on diagnostic technologies

Retrospective analysis of stored samples, particularly for the testing of new diagnostic technology or testing epidemiological hypotheses **must** only be conducted on delinked or de-identified samples and/or be subject to appropriate ethical review and be endorsed by an IEC in accordance with NHMRC.

### 6.4 Use of unregistered IVDs

In-vitro diagnostic devices (IVDs) not currently in use in Australia may be required to be used in international collaborative research. Application **must** be made to the Therapeutic Goods Administration under the Clinical Trial or Special Access Scheme to allow for use of these IVDs where they are used for a therapeutic purpose, e.g. to diagnose infection or determine treatment for a patient. IVDs to be used for research only, e.g. where results are de-identified and not used to determine patient treatment, are exempt under Clause 1.3, Schedule 4 of the Therapeutic Goods (Medical Devices) Regulations 2002.

## Background

In Australia, surveillance for HIV and AIDS is carried out under the framework of the Australian HIV Surveillance Strategy, initially endorsed at a national level in 1992 and

updated in 2011. It is implemented through the Kirby Institute for infection and immunity in society (previously named National Centre in HIV Epidemiology and Clinical Research) in collaboration with state and territory health departments and a range of other agencies and organisations.

Systematic surveillance of newly diagnosed and newly acquired cases of HIV infection is recognised as a key component of the Australian response to the HIV epidemic. The results of HIV antibody testing have been used to analyse trends in HIV diagnoses, to report on the trends identified in HIV testing carried out at sentinel sites, and for special annual surveys.

Diagnoses of newly acquired HIV infection, defined as cases of newly diagnosed HIV infection with a previous negative test or occurrence of an HIV seroconversion illness within 12 months of HIV diagnosis, provide an indication of the current pattern of HIV transmission in Australia

Diagnoses of newly acquired HIV infection depend on frequent HIV antibody testing or presentation to medical practitioners familiar with the symptoms of HIV seroconversion illness. Surveillance for newly acquired HIV infection provides a lower bound of the extent of HIV transmission. Assays for recent infection such as the detuned, BED and IgG assays provide a more complete indication of the extent of newly acquired HIV infection among cases of newly diagnosed HIV infection.

HIV testing is routinely carried out at a number of sentinel sites such as sexual health clinics, prisons, needle and syringe services and blood donation/ transfusion services. The numbers of people tested, and the proportion with diagnosed HIV infection, are reported on a regular basis from these sites and provide estimates of HIV prevalence and incidence in various population groups.

**Delinked blood surveys**

Delinked anonymous surveys are well accepted overseas for surveillance purposes, but have only rarely been used in the Australian setting. The survey method should be considered for Australian surveillance purposes only where there is no other feasible method for reasonably obtaining appropriate data; and should be subject to scientific justification and be endorsed by an institutional ethics committee in accordance with the requirements prescribed by the National Health and Medical Research Council.

**Identity unlinked HIV testing**

Research may occur in settings where specimens are collected and tested without an ability to link the results to individuals. For example, since 1995, a national network of needle and syringe exchanges has conducted an annual survey of clients over a one week period, which involves obtaining a finger prick blood specimen for HIV testing. The subjects are assured that the specimens are tested under code, so the results cannot be linked back to individuals. Such research should be subject to scientific justification and be endorsed by an institutional ethics committee in accordance with the requirements prescribed by the National Health and Medical Research Council.

**Use of stored blood for research on diagnostic technologies**

IVDs which are not currently in use in Australia may be required to be used in international collaborative research. Where the results of testing undertaken in the research are de-identified and not used to determine patient treatment, the IVDs are exempt under Clause 1.3, Schedule 4 of the Therapeutic Goods (Medical Devices) Regulations 2002. Applications to

use these devices **must** be made to the Therapeutic Goods Administration (TGA) under the Clinical Trial or Special Access Schemes where the results are used for a therapeutic purpose, e.g. to diagnose infection or determine treatment for a patient.

## 2011 National HIV Testing Policy

## 7.0 HEALTH CARE WORKERS

Communicable Diseases Network of Australia (CDNA), professional societies, colleges and registration boards may, from time to time, publish guidelines regarding the testing of health professionals. Any testing done in that context **must** be done in accordance with the 2011 National HIV Testing Policy.

Where testing of a health care worker is undertaken, confidentiality is paramount and **must** be maintained.

Health Care Workers **must** not perform tests on themselves.

### Background

In general the risk of HIV transmission in the Australian health care setting is low, and routine HIV testing of all health care workers is not recommended.

**Exposure prone procedures**

There is a small risk of HIV transmission from an infected health care worker to their patients during the performance of EPPs.

In view of the risk, albeit low, of transmission of HIV from infected health care workers to patients during the performance of EPPs, health care workers who perform EPPs must know their HIV status.

## 2011 National HIV Testing Policy

## 8.0 ANTENATAL AND PERINATAL TESTING

### 8.1 Routine testing

Women contemplating pregnancy or seeking antenatal care **should** be made aware of the benefits of diagnosis of HIV infection and management, and that there is a high risk of mother-to-child transmission which can be almost entirely eliminated with the prevention strategies available for both the mother and the infant.

Antenatal testing **should** be recommended for all women and **must** only be performed with the informed consent of the woman. Should the mother be found to be HIV antibody positive, expert advice must be sought promptly.

Royal Australian & New Zealand College of Obstetricians & Gynaecologists (RANZCOG) guidelines state that, in the absence of complications "all pregnant women should be recommended to have HIV screening at the first antenatal visit" (RANZCOG, 2009). Jurisdictions **should** develop operational directives that support the RANZCOG Guidelines through education, feedback on compliance and periodic auditing of antenatal medical records to provide evidence of recommended best practice.

### 8.2 Testing of infants born to mothers with HIV infection

HIV testing with nucleic acid direct detection tests (such as proviral DNA) on infants of HIV-infected women **should** be performed within the first month after birth, so that appropriate treatment interventions can be implemented quickly. Antibody tests are not helpful due to the persistence of maternal antibodies in the infant for up to 18 months. Diagnosis of HIV infection in infants born to HIV-infected mothers is complex and expert advice **must** be sought promptly.

## Background

**Routine testing**

The primary rationale for antenatal testing for HIV is to prevent mother-to-child transmission of infection. HIV testing of pregnant women is not a useful means of case-finding for HIV in a low prevalence country such as Australia.

It is recommended that during antenatal pre-test and post-test discussions, the clinician assists the woman to identify risks factors for HIV infection. HIV testing must be offered in the context of appropriate risk assessment and discussion. Examples of those at higher risk of infection include:

- female sexual partners of HIV infected men and men at high risk of HIV, including men from countries of high HIV prevalence or who frequently travel to high prevalence countries;
- women with a history of injecting drug use;
- women from countries of high HIV prevalence; and
- women with a history of blood transfusion or who were recipients of other donor tissues in the period prior to May 1985.

Appropriate resources and support should be provided to allow pregnant women to provide informed consent.

Pregnant women should receive materials (in written and other formats) outlining the tests that will be offered and the testing procedure should be explained to the woman by a member of the team involved in her antenatal care. Healthcare workers in antenatal settings should be trained in gaining informed consent and conveying a test result.

Women with limited literacy, or for whom English is a second language, require appropriate educational resources. Material using other media (video, audio, multimedia) and in languages other than English should be made available during the first antenatal appointment or the woman should be referred to a service that can offer such resources.

Women with a first language other than English should be offered access to accredited interpreting services.

**Testing of infants born to mothers with HIV infection**

Diagnosis of HIV infection in infants born to HIV-infected mothers is complex and expert advice is necessary. These infants will acquire IgG antibodies to HIV transplacentally, and will thus show serological reactivity similar or identical to their mothers. These antibodies will be lost progressively over the first 12-18 months of life.

Nucleic acid amplification tests are required to make the diagnosis of HIV infection in an infant. Currently there is no test included on the ARTG that is registered for a purpose that includes diagnosis of HIV infection in an infant.

## 2011 National HIV Testing Policy

## 9.0 ABORIGINAL AND TORRES STRAIT ISLANDER PEOPLE

The Third National Aboriginal and Torres Strait Islander Blood Borne Viruses and Sexually Transmissible Infections Strategy 2010 – 2013 prioritises the testing and treatment of STIs (including HIV) through annual, routine, systematic testing programs. Policies and guidelines **must** be developed locally, so that health care workers are correctly advised and health services generate culturally appropriate policies and programs.

### 9.1Confidentiality

Local health service providers **must** ensure that local guidelines regarding testing have agreed policies and protocols that protect client/patient privacy and confidentiality.

## Background

The Third National Aboriginal and Torres Strait Islander Blood Borne Viruses and Sexually Transmissible Infections Strategy 2010 – 2013 prioritises the testing and treatment of STIs (including HIV) through annual, routine, systematic testing programs. Importantly, it highlights the need for a flexible approach in the frequency of testing and extension of the age group where local epidemiology suggests high community prevalence. Local protocols should be developed in these settings and locally administered patient data management systems that provide the necessary prompts and recalls of when to test should be implemented. The Strategy encourages regular and concurrent opportunistic testing and follow up, and reducing reliance on screening activities alone.

A priority identified in the Implementation Plan for the Sixth National HIV Strategy is to increase the number of people in priority populations who voluntarily seek HIV testing and increase the rate of testing among people at higher risk of exposure to HIV infection to decrease the burden of undiagnosed HIV in the community. At the local level, this may mean the provision of appropriate HIV testing on symptomatic presentation of STIs and also follow up testing of patients who are asymptomatic (and not HIV tested at initial consult) but have positive STI pathology.

Improving access to testing requires an awareness of the differences among groups within Aboriginal and Torres Strait Islander populations and the distinctive barriers that exist for accessing services. Workforce development interventions which increase the awareness of these differences and the barriers to access are essential for all people who work with Aboriginal and Torres Strait Islander people. It may be necessary for local primary health services to develop locally adapted approaches for young people, prisoners, people who inject drugs, women, sex workers, gay and other homosexually active men, and transgendered people, including "Sistergirls" and reflect local HIV transmission routes, risk practices and patterns of health service use.

There is a disproportionate representation of Aboriginal and Torres Strait Islander people in prison settings and juvenile detention centres, and risk of transmission is increased with considerable movement of people in and out of the prison system. Specific state, territory and regional initiatives are needed to improve access to confidential testing and continuity of care for

Aboriginal and Torres Strait Islander people moving through the corrections system. Such initiatives could include improved access to testing in prisons including routine risk assessment conducted in a culturally safe manner, preventive approaches that consist of health promotion and prevention education, and re-entry to the community strategies for prisoners.

Recent trends suggest that Aboriginal and Torres Strait Islander women may be at increased risk of acquiring HIV. It is critical that antenatal testing for Aboriginal and Torres Strait Islander women is conducted in accordance with the guiding principles of this Policy, especially regarding informed consent and pre- and post-test discussions for Aboriginal and Torres Strait Islander women and be consistent with relevant Aboriginal and Torres Strait Islander Health Frameworks.

Coordination and leadership from State and Territory Aboriginal and/or Torres Strait Islander Sexual Health Committees may be needed to encourage partnerships that develop innovative and locally relevant approaches to service provision, address confidentiality concerns in both small communities and in urban areas and raise awareness in Aboriginal and Torres Strait Islander communities about the need for testing, treatment and management of HIV through workforce development initiatives. Workforce development is also required to improve the capacity of primary care and Aboriginal Community Controlled Health Organisations to initiate testing, diagnosing and manage culturally appropriate partner notification.

**Informed consent, conveying HIV test results and confidentiality**

For many Aboriginal and Torres Strait Islander people, high levels of stigma are associated with HIV. The stigma associated with the illness is compounded by its transmission through routes that are also highly stigmatised, such as drug use or same sex activity, or otherwise associated with shame about any sexual activity. Shame for some Aboriginal and Torres Strait Islander people may be incapacitating in the context of HIV testing, particularly if there are differences between the individual and health care worker in terms of race, age and gender. In some areas of the country ceremonial status, moiety and clan may also be important, particularly in contexts where blood has a ceremonial significance. Policies must be developed locally, so that health care workers are correctly advised and health services generate culturally appropriate policies and programs.

Local health service providers need to take these matters into account when developing a testing policy, and in the guidelines around informed consent and delivering HIV test results. Some success has been achieved in clinics providing pre-test information on cassette or CD recorded in local language or plain English, so that the individual can listen to it privately through headphones without shame. The use of interpreters should also be considered.

These approaches will be best developed in the context of strong local partnerships between the Aboriginal community-controlled health sector and mainstream services that specialise in the provision of services to clients at higher risk for HIV, STIs and other blood borne viruses (e.g. sexual health clinics, family planning services, AIDS Councils and services for injecting drug users).

**Confidentiality**

An added complication is that fear of a positive test may include fear of a breach of confidentiality, made worse when the health care provider is known to the person or when the test is provided in a local clinic that employs members of the person's family or community. Particularly in rural and remote clinics, the provision of any pathology test may routinely involve documentation passing through a number of hands, and results may be filed with relatively open access. Any variation to this routine may publicly signal that a "confidential" test is being done and unintentionally breach the person's right to privacy. Such concerns whether realistic or

unwarranted, are likely to provide an additional barrier to someone seeking a test. Local health service providers should ensure that local guidelines regarding testing have agreed protocols on the handling of confidential information.

Informed consent and conveying HIV test results guidelines should take into account local issues of stigma and shame. Fear of breaches of patient confidentiality may be reduced through the development and publication of local confidentiality policies.

The adoption and targeted distribution of a confidentiality policy may assist in reducing this barrier to testing. Such a policy should state that clients' privacy and confidentiality will be respected. It should refer to relevant state or territory legislation that governs privacy and confidentiality and note that all staff have been trained in the confidentiality requirements of providing care in that service. The policy should also outline a grievance procedure if a client feels that their confidentiality has been breached. It may give examples of what will be done with the person's information, and what will not be done with it. It may also detail areas where the person's right to privacy cannot be respected, for example, where mandatory reporting is required under other state or territory legislation.

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## 10.0 HIV TESTING IN PRISON SETTINGS

Australian prisoners are at high risk of contracting blood-borne viruses, including HIV, arising from their engagement in risk behaviours such as injecting drug use, sexual risk behaviours, amateur tattooing, body piercing, and violence. This is reflected in studies showing that rates of HIV and viral hepatitis are many times higher among prisoners than the general community. Australian studies have demonstrated HIV and hepatitis C transmission during incarceration.

During incarceration prisoners have very limited access to means of prevention for all blood-borne viruses including HIV. Condoms are provided on a limited basis to prisoners. Clean needles and syringes are not provided to prisoners in any jurisdiction in Australia, despite evidence that drug use, including injection drug use and needle sharing, continues within prisons.

Offering HIV testing to prisoners during incarceration has the potential to identify new cases of HIV infection, allowing appropriate assessment, treatment, referral post-release, and education to be provided to those individuals who undergo testing. This has clear benefits to the individual, their sexual partners, those with whom they may share injecting equipment and to the wider community.

Australian prisoners **should** be able to access free, confidential, timely, non-discriminatory HIV testing, counselling and treatment services during incarceration. (See section 4 Informed consent.)

(See Background Document to 2011 National HIV Testing Policy v1.2 for references.)

### Background

Prison settings have been identified as a risk environment for transmission of HIV, as well as for other STIs and blood-borne viruses. Strategies to improve access to prevention measures, testing, treatment and care should include provision of continuity of care for those affected by HIV, STIs and hepatitis C.

Australian prisoners are at high risk of contracting blood-borne viruses, including HIV, arising from their engagement in risk behaviours such as injecting drug use, sexual risk behaviours, amateur tattooing, body piercing, and violence.[1,2,3] This is reflected in studies showing that rates of HIV and viral hepatitis are many times higher among prisoners than the general community.[4,5,6] Australian studies have demonstrated HIV and hepatitis C transmission during incarceration.[7,8,9]

During incarceration prisoners have very limited access to means of prevention for all blood-borne viruses including HIV. Condoms are provided on a limited basis to prisoners. Clean needles and syringes are not provided to prisoners in any jurisdiction in Australia, despite evidence that drug use, including injection drug use and needle sharing, continues within prisons.[10]

Offering HIV testing to prisoners during incarceration has the potential to identify new cases of HIV infection, allowing appropriate assessment, treatment, referral post-release, and education to be provided to those individuals who undergo testing. This has clear benefits to the individual, their sexual partners, those with whom they may share injecting equipment and to the wider community.

Australian prisoners **should** be able to access free, confidential, timely, non-discriminatory HIV testing, counselling and treatment services during incarceration.

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## 11.0 POST-EXPOSURE PROPHYLAXIS

Post-exposure prophylaxis (PEP) and non-occupational post-exposure prophylaxis (NPEP) against HIV is the provision of anti-retroviral drugs soon after potential occupational or non-occupational exposure to HIV with the aim of preventing HIV infection. The National Guidelines for Post-Exposure Prophylaxis provide advice on assessment of the potential risk and give detailed protocols for the use of PEP for occupational and non-occupational exposures to HIV. For local implementation consult state and territory guidelines for PEP and NPEP.

### 11.1PEP in health care settings

The Department of Health and Ageing (DoHA) and States and Territories publish guidelines on post-exposure prophylaxis. All testing required as a result of potential exposure to HIV **should** be performed in accordance with this Policy.

If a health care worker is occupationally exposed to blood or body fluids (e.g. through a needlestick injury), testing **must** be offered and performed urgently, for the purposes of guiding PEP prescription. PEP is not indicated if the source is known or established to be HIV negative.

Source patients **should** be encouraged but are not obliged to consent to HIV testing, unless state and territory jurisdictions have established mechanisms under the Public Health Acts to require testing in certain circumstances. Practitioners **should** consult these state and territory guidelines if faced with a source patient who declines HIV testing.

Consent **should** be obtained in accordance with the guiding principles of this Policy. If the patient declines to have an urgent HIV test then it **should** be assumed, for the purposes of PEP prescription, that they have HIV infection. Informed consent **should** be obtained before testing occurs on stored specimens.

## Background

This section is not a comprehensive guide to the use of PEP. Rather, it highlights some aspects of HIV testing that are specific to the PEP situation. The 2006 National Guidelines for Post-exposure Prophylaxis after Non-occupational Exposure to HI V (to be reviewed in 2011) set out detailed protocols for the use of PEP for non-occupational exposures to HIV. Each state and territory has their own NPEP guidelines which can be found on the ASHM website.

Patients may transmit infections to health care workers. The level of risk relates to the transmissibility of the infection, the availability of a route of transmission, the susceptibility of exposed people, and the success of applied control measures (e.g. standard precautions).

All health care workers who have clinical contact with patients can potentially be exposed to blood and other body fluids. Other workers may also be exposed to blood and other body fluids in the course of their work (e.g. laboratory workers, cleaning staff).

POC tests may be particularly useful in this setting.

**Testing of the exposed individual at initial presentation**

There are at least two reasons why it is important for an individual who presents for PEP to receive urgent HIV testing before commencing therapy. First, it is possible that the person already has HIV infection in which case single agent or dual agent PEP may induce resistance emerging in the patient's virus. (In an Australian study of NPEP, approximately 0.5% of those presenting for NPEP were found to be HIV positive at baseline) In such a case, the person should be referred for a full diagnostic workup and consideration of commencement of therapy for HIV, rather than be prescribed PEP. Second, the efficacy of PEP is highly dependent on the duration between HIV exposure and commencement of therapy. It is important that an HIV test result be obtained as quickly as possible.

**2011 National HIV Testing Policy**

## 12.0 QUALITY ASSURANCE OF IVDs FOR HIV TESTING

For more information and background on HIV IVD regulation and quality assurance, refer to *Background Document to 2011 National HIV Testing Policy v1.2 and the* Therapeutic Goods Administration (*TGA).*

### 12.1 Laboratories

Laboratories that perform HIV testing **must:**

- be NATA accredited for Medical Testing;
- participate in a nationally coordinated external quality assessment scheme (EQAS);
- comply with the National Pathology Accreditation Advisory Council (NPAAC) standards.

Laboratories that perform HIV testing **should** contribute testing statistics to NRL to ensure the completeness of test denominator data (See *Background Document to 2011 National HIV Testing Policy v1.2*).

### 12.2 Pre-market quality assurance of HIV IVDs

The TGA has regulatory responsibility for in-vitro diagnostic devices (IVDs) through the *Therapeutic Goods Act 1989* and its associated regulations.

### 12.3 Post-marketing quality assurance of HIV IVDs

IVD manufacturers, sponsors and the TGA have responsibility for post-market monitoring of the IVDs. Corrective action **must** be initiated by the manufacturer and sponsor of an IVD, in consultation with the TGA, as soon as practicable after becoming aware of information relating to any adverse events, malfunction or deterioration in the performance, or inadequacy in the design production and labeling of an IVD.

## Background

**Pre-market quality assurance of HIV IVDs**

From 1 July 2010, all IVDs including IVDs for HIV have been regulated as medical devices under Chapter 4 of the Act and the Therapeutic Goods (Medical Devices) Regulations 2002. Prior to this date, IVDs for HIV and hepatitis C virus (HCV) were regulated as Other Therapeutic Goods (OTGs) under Chapter 3 of the Act and the Therapeutic Goods Regulations 1990. [Under transition provisions in the regulations, IVDs for HIV which were registered in the ARTG, or for which there was an effective application for registration, before 1 July 2010, can continue to be supplied until 1 July 2014 as registered other therapeutic goods.

Under the regulatory framework for OTGs, the TGA has conducted a full pre-market evaluation on IVDs for HIV (and HCV) to demonstrate that they meet the quality, safety and efficacy standards required for registration in the ARTG and supply in Australia. The TGA has contracted the performance section of these evaluations to the National Serology Reference Laboratory Australia.

The new IVD regulatory framework places greater emphasis on the use of appropriate quality management systems for the design and production of IVDs to ensure the ongoing safety of

performance. Under the new framework, all IVD manufacturers will be required to demonstrate compliance with a set of essential principles for quality, safety and performance and the quality management standard *ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes*.

The framework includes a risk-based classification scheme, in which an IVD is assigned to one of four classes, designated 1 to 4, where Class 4 is of highest risk. This risk is assigned according to whether the risk posed by failure applies to an individual and/or to public health in general. IVDs for diagnosis of HIV are classified as Class 4 while IVDs for monitoring, disease staging or selective therapy and management of patients with HIV infection, are Class 3 IVDs.

Class 4 IVDs will undergo a full pre-market evaluation, including performance testing where appropriate, prior to approval for inclusion in the ARTG. IVDs for managing or monitoring treatment of patients with HIV infection (Class 3 IVDs) will undergo pre-market evaluation including a mandatory review of technical documentation to establish performance prior to approval for inclusion in the ARTG.

**Categorisation of HIV IVDs for regulatory purposes**

The TGA has imposed conditions on the registration of products in the ARTG under the old regulatory framework that have categorised HIV IVDs according to their intended use. Tests were classified as standard (or screening) tests (those with a performance that is suitable for blood donor screening and determining the HIV antibody status of a sample), and reference (or supplemental) tests (those that are used to clarify the nature of the reactivity of a sample following initial standard tests).

Under the new IVD regulatory framework, the TGA will not normally impose conditions, related to categorisation of HIV IVDs, on their inclusion in the ARTG. The evaluation and approval of an inclusion in the ARTG will be determined by the manufacturer's intended purpose. The selection of HIV IVDs appropriate for the purpose will be the responsibility of laboratory professionals who undertake the testing.

**Post-market quality assurance of HIV IVDs**

IVD manufacturers, sponsors and the TGA have responsibility for post-market vigilance and monitoring of the IVDs, to reduce the likelihood of adverse events. Corrective action must be initiated by the manufacturer and sponsor of an IVD, in consultation with the TGA, as soon as practicable after becoming aware of information relating to any adverse events, malfunction or deterioration in the performance, or inadequacy in the design production and labeling, of an IVD. Corrective action can include:

- Recall for product correction; or
- Removing the product from the market; or
- Advising users of an issue with an IVD.

The TGA has the power to remove from the market, by suspending or cancelling an entry in the ARTG, any IVD that is not performing to the expected standard or that is known or demonstrated to be defective.

**Laboratories and quality assurance of HIV testing**

The NPAAC *Standards and Guidelines for Laboratory Testing of Antibodies to the Human Immunodeficiency Virus (HIV) and Hepatitis C (HCV)* and the *Laboratory Accreditation*

*Standards and Guidelines for Nucleic Acid Detection and Analysis* provide the frameworks for assessment by NATA/RCPA of the extent to which laboratories must meet the requirements for performance of standard and/or reference HIV testing.

The ability to comply is assessed by the National Association of Testing Authorities, Australia/Royal College of Pathologists of Australasia (NATA/RCPA) Medical Testing Program. It is a NATA requirement that all laboratories must comply with ISO 15189, which includes the requirement to participate, where possible, in an EQAS program. These programs are designed to assess the competency of all laboratory processes involved in the production of an HIV result to the requesting practitioner. EQAS programs are readily available within Australia and are provided by the RCPA QAP Pty Ltd and the NRL.

The legislation, since July 2010, requires laboratories to participate in any nationally coordinated EQAS. The NRL provides a quality control (QC) program to monitor in-field assay performance and provide testing statistics, while national EQAS programs are provided by the NRL EQAS and RCPA Quality Assurance Programs Pty Ltd.

## 13.0 POINT OF CARE TESTS FOR HIV IN COMMUNITY SETTINGS

Rapid PoC tests have in the past been registered in the Australian Register of Therapeutic Goods (ARTG) for use in Australia as supplemental tests in diagnostic or confirmatory testing strategies in a laboratory setting but not for use as standard screening tests that could be used in point of care settings.

A wide range of PoC tests are in use in both comparable developed countries and in developing country settings. This Policy provides parameters and guidelines to ensure that, in the event that a PoC test is registered or included in the ARTG as a screening test, both the appropriate uses and the limitations of PoC testing are clearly outlined.

The particular limitations and strengths of PoC tests include:

- their function as tests for screening rather than definitive diagnostic tests;
- the need to confirm reactive results;
- their high negative predictive value; and
- the longer window period after an HIV exposure required to detect antibodies or antigen compared to laboratory performed test requiring machine based assays.

Confirmatory (reference) testing: all PoC testing sites will need to have guidelines for handling confirmatory testing as a laboratory enzyme immunoassay (EIA) and western blot test is required to distinguish true from false reactivity.

PoC tests are not going to be beneficial at this time in remote communities where community prevalence is very low as the positive predictive value of the test will be low.

### 13.1 Who can perform PoC testing?

Individuals working in organisations which are endorsed by the state or territory in which the service is offered and/or privately employed medical practitioners who:

- have been certified in performing PoC and who have completed appropriate, accredited training;
- have access to clinical support and the infrastructure to perform venous testing and arrange immediate referral for ongoing medical and/or emotional support;
- are able to be appropriately indemnified and compliant with relevant NATA and Medicare arrangements;
- have access to and apply strict protocols which describe and define the application of this Policy.

### 13.2 Accreditation

Supply of PoC tests and reagents **must** be limited to accredited testing sites with certified staff, not individuals. Every prospective PoC testing site **must** meet the following criteria in order to perform PoC tests:

- trained phlebotomist on site;
- minimum of one staff member accredited in the PoC testing (1 or 2 yearly update);
- all services offering PoC testing **should** have procedures in place for rapid despatch

of venous blood samples for confirmatory testing of reactive and/or inconclusive PoC test results;

- before commencing operations, all services offering PoC testing **must** establish a relationship with an HIV testing laboratory that complies with National Pathology Accreditation Advisory Council (NPAAC) standards for HIV testing;
- have either attained National Association of Testing Authorities (NATA) accreditation independently or through a pre-established relationship with a NATA-approved laboratory. If through the latter, the NATA-approved laboratory will provide training and support in the recording of testing data (through the NRL) and quality assurance. If the former, the testing site **must** develop their own recording and denominator data collection procedures and report this directly to the NRL.

### 13.3 Where to test?

Before commencing operations, all sites offering PoC testing **must** establish a formal supervisory relationship with an approved HIV testing laboratory that complies with NATA and NPAAC and specifically HIV testing.[1] Every potential PoC testing site **must** also have the capacity to perform both a finger prick test and venepuncture. The testing environment must be fit for purpose to ensure any related equipment is calibrated and in good working order, all procedures are documented and carried out accurately, efficiently and safely and that the wellbeing and confidentiality of the patient is respected. Special consideration should be given to the security of test records and the treatment of biological waste.

The use of PoC tests **must** be limited to situations where:

- testing is conducted in, or backed up by, a clinical setting;
- testing is conducted under the auspice of a NATA/Royal College of Pathologists of Australasia (RCPA) medical testing accredited laboratory;
- tests that are suitable for use at point of care have been included in the ARTG;
- high-quality information on the tests and their use is available and provided;
- the health worker performing the test is suitably trained in accordance with section 13.1; and
- quality assurance programmes are available to assure ongoing competency of health workers performing the tests and ongoing compliance of any facility.

### 13.4 To whom should a PoC be offered?

PoC testing may be considered for community-based testing interventions for high-risk (gay men) or hard-to-reach populations and individuals (who are resistant to conventional testing). It may also be appropriate for people who might be otherwise reticent to access conventional testing and/or return for test results.

However, a reactive or inconclusive result raises additional difficulties in conveying a result and follow-up care that is not always available in the limited infrastructure environment of rural and remote locations. PoC testing is not currently recommended in remote Aboriginal or Torres Strait Islander communities because of the extremely low prevalence of HIV.

### 13.5 Quality assurance

Jurisdictions **must** ensure that services offering PoC testing develop their own site-specific clinical guidelines and protocols which take into consideration issues such as storage requirements, the limited shelf life of test kits, and operational aspects of providing PoC testing services. These **must** include procedures for the confirmation of reactive results and

links with pathology services, and referral mechanisms for client/patient support. Guidelines **must** also include minimum standards for gaining informed consent, conveying a test result and the training and support of staff, including record keeping and data collection procedures.

### 13.6 Use of rapid HIV testing in a laboratory setting

Laboratories may also use rapid tests for reference testing in appropriate settings. Rapid tests may be used as supplemental tests in validated confirmatory testing strategies and may be useful in adjudication of samples with discordant test results. These tests may be conducted outside reference laboratories as long as they are included in the ARTG for the relevant intended purpose and the tests are used in accordance with a laboratory's accredited testing strategy.

[1] As of September 2011, NPAAC is preparing a set of quality management requirements for use of PoC testing by accredited pathology laboratories (including laboratories operated by medical practitioners). These planned requirements, although likely to adopt similar principles, may differ from those outlined above (NPAAC requirement).

## Background

Screening refers to performing an HIV test for all persons in a defined population. Rapid PoC Tests may be useful for screening because of their ease of use and the possibility of providing an indicative result at time of testing.

Rapid HIV tests perform well in confirming HIV negative status among individuals without very recent HIV risk exposure. The published sensitivities and specificities of the short-incubation tests now approach those of the standard EIAs in positive and negative samples. The negative predictive value of short-incubation tests is such that infection can be confidently excluded if the test is negative. However, these tests are more likely to miss seroconversion because they are less able to detect low levels of antibody. Confirmatory testing, to distinguish false from true positive results, must be performed on each reactive sample.

**Expected ratio of true to false positive results based on test specificity and disease prevalence**

| | **Specificity (%)** | | | |
|---|---|---|---|---|
| **Prevalence (%)** | 98.0% | 98.5% | 99% | 99.5 |
| 10 | 5:1 | 7*:1 | 10:1 | 20:1 |
| 5 | 2*:1 | 3*:1 | 5:1 | 10:1 |
| 0.5 | 1:4 | 1:3 | 1:2 | 1:1 |
| 0.1 | 1:20 | 1:15 | 1:10 | 1:5 |

* Rounded to nearest whole number

There are four rapid HIV PoCT methods for attaining samples. These include finger prick testing, PoCT serum testing, oral fluid and urine.

**Where to test?**

Remote services offering rapid HIV testing should consider the high proportion of false reactive results to true positive results that are likely in settings with low HIV prevalence. A high proportion of false reactive results may outweigh any benefits from the introduction of rapid HIV tests in most settings.

If venepuncture cannot be performed (such as where IVDU induced vein damage has rendered the individual free of accessible peripheral superficial veins , then a second (different brand as supported by the TGA and NRL) of PoCT test could be used. Algorithms will need to be developed in consultation with the NRL for serial POC testing to be implemented in Australia.

**Who should be offered a test**

Populations who should be considered for rapid HIV point of care testing (from ERC Committee focus group meeting, 11 March 2011):

- Gay men and other MSM who have not taken up standard laboratory testing and in whom STI serology is not indicated
- People from and people who travel to high HIV prevalence countries and their partners
- Gay men and other MSM and people from high HIV prevalence populations
- Male sex workers
- People living in rural and remote locations (for example migrant workers and temporary work visa holders in the mining industry )
- Antenatal women presenting with late HIV infection
- People who inject drugs
- Persons involved in occupational and non-occupational exposure situations

**Quality assurance**

Quality assurance checklist for implementation of rapid HIV point of care testing in community settings:

- Rapid HIV POCT accredited staff member – yearly updated
- Testing is conducted under the auspice of a NATA/RCPA Medical Testing accredited laboratory;
- Relationship with an HIV testing laboratory that complies with National Pathology Accreditation Advisory Council (NPAAC) standards for confirmatory testing and TGA license for testing of blood and tissues
- Clinical guidelines should address storage, stock control, and testing algorithms for dealing with clients who report a recent exposure and who receive a reactive result.

**Funding**

Appropriate Commonwealth and jurisdictional legislative bodies should decide on appropriate and feasible arrangements for funding point-of-care testing. Intergovernmental committees may determine interim mechanisms of funding.

**Short - incubation HIV testing in a laboratory setting**

Reference tests are used by laboratories to conduct confirmatory or additional special testing. This testing is conducted to confirm true positive status by distinguishing true from false reactivity. Usually this testing is conducted within a diagnostic strategy and a western blot is used; but other reference testing situations occur (e.g. in a setting of possible seroconversion illness) when the first-used reference tests may include nucleic acid tests for proviral DNA.

## 14.0 HOME BASED TESTING IN AUSTRALIA

Introduction of self-testing for HIV in Australia is not supported. HIV testing in Australia **should** always be performed in a clinically supervised context, where there is an appropriate level of interaction between the individual being tested and a suitably qualified health professional.

Self-testing (also known as home-based testing) as defined in the Therapeutic Goods (Medical Devices) Regulations 2002 refers to a process where HIV testing is conducted:

- in the home or similar environment by a lay person; or
- where a sample is collected by a lay person and, if the sample is tested by another person, the results are returned directly to the person from whom the sample was taken without the direct supervision of a doctor or another health professional who has training in a discipline to which the self-testing relates.

The Therapeutic Goods (Excluded Purposes) Specification 2010 and section 41BEA of the *Therapeutic Goods Act 1989* prohibit the inclusion of self-testing IVDs for HIV in the ARTG.

If an IVD which could be used for self-testing for HIV is included in the ARTG for other purposes (e.g. PoC test or rapid laboratory testing), the TGA will apply a condition on the ARTG entry that the IVD not be supplied or promoted for self-testing.

As home-testing IVDs are currently available for purchase over the internet from overseas suppliers, it is important that access to and use of these tests are monitored through social research, anecdotal reports and observation. Health promotion interventions may be necessary if the practice of home-testing becomes prevalent. Changes in technology and knowledge base in this area are occurring rapidly. This Policy will undergo regular review and make any necessary updates to the Policy as required.

**2011 National HIV Testing Policy**

## 15.0 FUNDING OF HIV TESTING

From 1 November 2005, funding for anti-HIV assays has been made available as a subsidy through the Medicare fee for service arrangements (Medicare Benefits Schedule; MBS). Testing for PoC testing undertaken outside of accredited pathology laboratories is not approved for funding under the MBS. In addition, testing for screening is also specifically excluded for MBS funding purposes.

A person should not be denied testing because of a lack of capacity to pay for the test or fear of having their name associated with an HIV test.

In some situations it may be appropriate to make de-identified testing available free of charge to the individual being tested to ensure that individuals at high risk of HIV infection access and consent to testing. State and territory governments, which prior to 1 November 2005 were responsible for fully funding the cost of HIV antibody testing, **should** ensure that capacity is retained to support provision of free and de-identified testing in such situations.

# 16.0 GLOSSARY

## 16.1 Abbreviations and acronyms

| | |
|---|---|
| ARTG | Australian Register of Therapeutic Goods |
| ASHM | Australasian Society for HIV Medicine |
| BBVSS | Blood Borne Virus and STI Standing committee |
| CALD | culturally and linguistically diverse |
| CDNA | Communicable Diseases Network of Australia |
| DoHA | Department of Health and Ageing |
| EIA | enzyme immuno assay |
| EPP | exposure prone procedures |
| EQAS | external quality assessment scheme |
| HIV | human immunodeficiency virus |
| IEC | institutional ethics committee |
| IVD | in-vitro diagnostic device |
| MACBBVS | Ministerial Advisory Committee on Blood Borne Viruses and Sexually transmissible infections |
| MBS | Medicare benefits schedule |
| NAAT | nucleic acid amplification test |
| NATA | National Association of Testing Authorities |
| NHMRC | National Health and Medical Research Council |
| NPAAC | National Pathology Accreditation Advisory Council |
| NPEP | non-occupational post-exposure prophylaxis |
| NRL | National Serology Reference Laboratory, Australia |
| PEP | post-exposure prophylaxis |
| PLHIV | people living with HIV |
| PoC | point of care |
| RACGP | Royal Australian College of General Practitioners |
| RANZCOG | Royal Australian and New Zealand College of Obstetricians and Gynaecologists |
| RCPA | Royal College of Pathologists of Australasia |
| STI | sexually transmitted infection |
| TGA | Therapeutic Goods Administration |

## 16.2 Glossary

| | |
|---|---|
| compulsory testing | where a person had no choice in being tested e.g. as directed under a public health order |
| EIA | enzyme immuno assay (test allowing detection of an antigen-antibody interaction using enzyme activity as the indicator) |
| mandatory testing | refers to situations where people may not either participate in certain activities or access certain services unless they agree to be tested |
| occupational exposure | an exposure that may place an employee at risk of HIV infection through percutaneous injury (e.g. a needlestick or cut with a sharp object), contact of mucous membranes, or contact of skin with blood, tissues or other potentially infectious body fluids to which universal precautions apply |
| reference laboratory | HIV reference laboratory: specialist pathology laboratory for HIV testing. In Australia, all reactive screening tests are further tested by specialist assays at a reference laboratory to confirm the result. Screening test results will not necessarily be confirmed. |
| reference testing | testing conducted to clarify the nature of samples' reactivity or status following initial tests conducted with standard tests in the same or another laboratory |
| sensitivity | the probability that the person with the disease will have a positive result |
| specificity | the probability that the person without the disease will have a negative result |