

NATIONAL HIV TESTING POLICY v1.1

2011 National HIV Testing Policy

This Policy was written by the National HIV Testing Policy Expert Reference Committee –a joint working party of the Blood Borne Virus and STI Subcommittee (BBVSS) and the Ministerial Advisory Committee on Blood Borne Viruses and Sexually Transmissible Infections (MACBBVS). The review process was coordinated by the Australasian Society for HIV Medicine (ASHM).

The web based provision of the 2011 National HIV Testing Policy allows for regular revision and access to related resources (e.g. related policies, operational guidelines, evidence of best practice) with a download and print function can be found at:

<http://testingportal.ashm.org.au>

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1.0 INTRODUCTION

1.1 Background and context

Successive National HIV 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 minimising 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 an 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 National HIV Testing Policy -Discussion Document to 2011 v10.

The Policy is aligned with the National HIV Strategy 2010–2013. The National HIV Strategy identifies the need for a coordinated, 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 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 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;
- 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/support services (*see section 12.0 Point of care tests for HIV in community settings*).

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

Table 1: Categorisation of HIV IVDs for evaluation and use

Purpose or uses of IVDs	Test categories	
	Standard	Reference
Donor Testing – screening of blood and tissue donations	Enzyme immunoassay Particle agglutination assay Machine-based immunoassay Nucleic Acid Amplification Test (NAAT) screening test Class 4 IVD	Enzyme immunoassay Western Blot Line assay Rapid short incubation assay (PoC) Antigen enzyme immunoassay Discriminatory NAAT assay
Diagnostic Testing – to determine the infection status of a sample for clinical and non-clinical purposes e.g. diagnosis, antenatal screening, visa, insurance testing and supplemental and confirmatory purposes	Enzyme immunoassay Particle agglutination assay Machine-based immunoassay Rapid short incubation assay (PoC) Assay used with alternative sample types Class 4 IVD	Qualitative amplification assay Quantitative amplification assay Class 4 IVD
Point of Care testing – the use of rapid/short incubation test as a screening test for presumptive HIV infection. Not intended to replace conventional diagnostic testing or for home/self testing	Rapid short incubation assay (PoC) 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 Assays used with alternative sample types/sample collection devices 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 Antigen enzyme immunoassay HIV genotypic drug resistance assay Pharmacogenomic assay for HIV drug susceptibility 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 Assay (Point of Care Test)

Will be used as presumptive screening tests 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).

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 (*see Discussion Document to 2011 v1.0*):
 - 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 travelled 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 Discussion Document to 2011 v1.0*)
- 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 for more information. (*see section 10.0 Post Exposure Prophylaxis*)
- in the context of Post-Exposure Prophylaxis (PEP) which is subject to national and jurisdictional guidelines and policy (*see section 10.0 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 additional 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, 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 (*see Discussion Document to 2011 v1.0*)

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 HIV Testing Policy 2011 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 section 12.0*).

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 PEP **must** comply with the Non-occupational and occupational PEP, policies and any relevant State 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.

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. On these rare occasions when informed consent cannot be obtained, 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 judgement 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 by a health care provider from their sexual partner/s or family members.

People involved in HIV testing **should** use whatever additional supports are necessary to assist the person considering testing to become adequately informed.

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 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.

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.

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, 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 that 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 the Australasian Society for HIV Medicine (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 the ASHM who can offer help to refer a patient in this predicament to an alternative service for a 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. 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 patient's file. General practice in particular has limited capacity to perform patient follow-up, and general practitioners **should** pass this responsibility to the local public health unit if they have exhausted their resources. The RACGP publishes guidelines of 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. But 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.

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 department 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 in accordance with the requirements prescribed by the National Health and Medical Research Council (NHMRC) and be endorsed by an Institutional Ethics Committee (IEC) in accordance with the NHMRC.

6.2 Identity unlinked HIV testing

Research using identity unlinked HIV testing can provide useful epidemiological data. In such studies, specimens used **must** be endorsed by an appropriate ethics committee and be endorsed by an IEC in accordance with 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** be conducted only 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 (TGA) 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.

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.

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 which are 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. HIV testing **must** be performed in the context of appropriate risk assessment and discussion. Should the mother be found to be HIV antibody positive, expert advice **must** be sought promptly.

The Royal Australian and New Zealand College of Obstetricians and 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 HIV-infected mothers

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.

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.

9.1 Confidentiality

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

10.0 POST-EXPOSURE PROPHYLAXIS

Post-exposure prophylaxis (PEP) and non-occupational post-exposure prophylaxis (NPEP) against HIV is the provision of antiretroviral drugs soon after potential occupational or non-occupational exposure to HIV with the aim of preventing HIV infection. The 2011 National Guidelines for Post-Exposure Prophylaxis (due for release late 2011) provide advice on assessment of the potential risk and give detailed protocols for the use of PEP for non-occupational exposures to HIV. For local implementation consult State and Territory Guidelines for PEP and NPEP which can be found on the ASHM website.

10.1 Testing of the source

PEP is not indicated if the source is known to be HIV negative. An active attempt **should** be made to assess the HIV status of the source. If the source is contactable, they **should** be invited to have an urgent HIV test. If the source declines to have an urgent HIV test then it **should** be assumed that PEP is required. Under certain circumstances Public Health provisions may be invoked under which consent is not required.

10.2 Testing of the exposed individual at initial presentation

It is important for an individual who presents for PEP to receive urgent HIV testing before commencing therapy. PEP **should** be commenced within 72 hours of exposure, but therapy **should** be commenced as soon as possible, as a delay of a few hours may reduce the efficacy of therapy.

HIV testing with rapid turnaround of results **should** be available in all settings where people are assessed for PEP. Without test results, it **should** be assumed that the source is infected and PEP commenced. In this situation, test results **should** be followed up within 24 hours and PEP stopped or modified if necessary.

10.3 Follow-up testing

Follow-up HIV antibody testing **should** be performed at 2 to 4 weeks after stopping PEP, as HIV infection is likely to become evident at this time in a proportion of cases. Further follow-up testing **should** then occur at 3 months post-exposure.

10.4 PEP 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 jurisdictions have established mechanisms under the Public Health Acts to require testing in certain circumstances. Practitioners **should** consult these State 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.

11.0 QUALITY ASSURANCE OF IVDs FOR HIV TESTING

For more information and background on HIV IVD regulation and quality assurance, refer to *Discussion Document to 2011 v1.0*.

11.1 Pre-market quality assurance of HIV IVDs

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

11.2 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 labelling, of an IVD.

11.3 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; and
- contribute testing statistics to the National Research Laboratory (NRL) to ensure the completeness of test denominator data (*see Discussion Document to 2011 v1.0*)

12.0 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 PoC 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 tests requiring machine-based assays.

Confirmatory (reference) testing: all PoC testing sites will need to have guidelines for handling confirmatory testing as a laboratory enzyme immune assay (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.

12.1 Who can perform PoC Testing?

Individuals working in organizations 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.

12.2 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 data and quality assurance (through the NRL). If the former, the testing site **must** develop their own recording and denominator data collection procedures and report this directly to the NRL.

12.3 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 standards for Medical Testing and specifically HIV testing¹. 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 12.1; and
- quality assurance programmes are available to assure ongoing competency of health workers performing the tests and ongoing compliance of any facility.

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 (see NPAAC requirements).

12.4 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 is not currently recommended in remote Aboriginal or Torres Strait Islander communities because of the extremely low prevalence of HIV.

12.5 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, infection control and links with pathology services, and referral mechanisms for client/patient support. Guidelines **must** also include minimum standards for pre/post test discussion and the training and support of staff, including record keeping and data collection procedures.

12.6 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.

13.0 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.

14.0 FUNDING OF HIV TESTING

From 1 November 2005, additional funding for anti-HIV assays has been made available as a subsidy through the Medicare fee for service arrangements (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.

