National HIV Testing Policy

ADOPTED BY THE ASHM BOARD FEBRUARY 2017

ASHM
1.0 Introduction

1.1 Purpose and Scope

This policy brings together in one place the principles, aims and arrangements for HIV testing in Australia and is consistent with the aims of the Seventh National HIV Strategy 2014-2017. It fulfils three main purposes:

- To bring together and reference standards for registered HIV tests and their usage in Australia
- To explore and describe how Australia will consider new testing technologies as these emerge and provide a framework against which new technologies for HIV diagnosis will be evaluated for use in Australia, and
- To maintain an Expert Reference Group (ERG) which comes together from time to time to consider issues relating to HIV testing and which provides advice to governments and regulators about what is best practice. Its membership reflects the breadth of stakeholders with an interest in HIV testing.

The policy has broad scope and applies to laboratory, point of care and self-testing for HIV infection. It is also flexible, allowing for the consideration of new technologies as these emerge. Through the work of the ERG, it should also allow for the identification of standards, legislation or processes which may need to be modified to keep in step with evolving evidence, expectations and attitudes toward HIV testing.

This policy recognises that HIV testing is vital to stopping the transmission of HIV. It is also a precursor to the initiation of treatment for HIV. It provides a framework for best practice approaches to appropriate high quality HIV testing in the Australian context.

1.2 Background and context

Australia has a high quality, comprehensive multi-sector pathology service. The regulatory and quality framework for HIV testing has evolved with a focus on formal laboratory settings. The advent of point of care HIV testing and the prospect of HIV self-testing has necessitated a review of that framework.

The National Pathology Accreditation Advisory Council (NPAAC) sets quality standards for pathology laboratories and the National Association of Testing Authorities (NATA) and the Royal College of Pathologists of Australasia (RCPA) accredit medical testing facilities against these standards. Accreditation is required in order for pathology services to be eligible for the Medicare Benefits Schedule (MBS) rebates. Professional standards for pathology practice are established by the RCPA.

Tests used in Australia must pass evaluation by the Therapeutic Goods Administration (TGA), prior to entry onto the Australian Register of Therapeutic Goods (ARTG) and the TGA can place conditions on this entry. The Medical Services Advisory Committee (MSAC) advises which tests should be subsidised through the MBS. It also can recommend any restrictions on eligibility. Tests for blood borne viruses including HIV tests undergo the most stringent of pathology test evaluations.

Some tests can be used outside of the laboratory and others may involve self-sample collection and self-interpretation of results. They may therefore be outside the regulatory framework offered by NATA accreditation and/or RCPA standards. TGA has established performance standards for HIV
testing. This policy framework ensures that devices for use outside of the laboratory, like those used within the laboratory:

- are fit for purpose;
- are of an appropriate quality;
- where relevant, are used by individuals who are appropriately trained,
- in the case of self-testing, are supplied with appropriate information and instructions to enable individuals to perform and interpret tests independently, with confidence, and
- are subject to procedures to ensure public safety and confidence.

### 1.3 Principles for HIV Testing

The key principles which guide HIV screening and diagnostic testing in Australia are that testing is conducted ethically, is voluntary and performed with the informed consent of and is beneficial to the person being tested, and provides for an understanding of the epidemiology of HIV infection in the population and a measurement against which to evaluate National Strategy goals.

**In relation to evaluation, quality and performance:**

- Tests are evaluated on the basis of being fit-for-purpose and meet the published sensitivity and specificity criteria established by the TGA.
- Reactive screening tests performed in a laboratory or point-of-care setting, require confirmatory testing from an accredited pathology laboratory.
- Persons performing HIV testing are required to undertake training appropriate to the steps in the process for which they are responsible, including for: gaining informed consent, collecting the sample, interpreting any result, conveying that result and collecting a sample for confirmatory testing if required.

**In relation to access, availability and confidentiality:**

- There should be no barriers to the implementation of quality, cost effective, HIV testing and screening.
- Testing must be accessible to all those at risk of HIV infection.
- 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.
- HIV rapid testing should be targeted to individuals at high risk of HIV infection, who are not currently accessing standard testing or who access it at a suboptimal frequency based on their risk of exposure to HIV.
- All screening and diagnostic test results must remain confidential and only shared with individuals with a clinical need to know in accordance with jurisdictional legal and policy restrictions on sharing of information regarding a person’s HIV positive status.
- Test results should be conveyed to the person being tested in a timely manner which will be contingent of the nature of the test performed.
- Where regulations or legislation allow for restrictions to be placed on individuals who are aware they have HIV\(^1\), a reactive result by the initial HIV test, including an HIV point of care

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\(^1\) Refer to Chapter 15 of the HIV, Viral Hepatitis and STIs: A Guide for Primary Care Practitioners which outlines legal responsibilities across States and Territories
test or HIV self-test, will be considered evidence of HIV infection unless reference testing subsequently shows the individual to be free of HIV. Consequently pending the outcome of confirmatory testing, individuals who are reactive on a screening test should adhere to the transmission restrictions placed upon a person with confirmed HIV infection.

- Testing 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, storage of medical and personal information and confidentiality and privacy protections.

### 2.0 Types of HIV Testing

This policy covers laboratory based testing and non-laboratory based testing. The TGA has produced guidance to assist and inform its evaluation of HIV tests.

- **TGA Clinical Performance Requirements and Risk Mitigation Strategies of HIV Tests**

These set out differential performance requirements for laboratory tests, HIV point of care tests and HIV self-tests. They recognise that a lower performance threshold may be acceptable in a test which is part of a screening protocol, requiring confirmatory testing and that confirmatory testing must be able to demonstrate the highest quality and performance. They also specify the need for training. It is essential that those using any test are familiar with its limitations and can convey these to the person being tested or, in the case of a self-test, that the package insert addresses these limitations. This TGA performance requirements document is prospective and relates to any tests which may be submitted to the TGA for evaluation.

### 2.1 Laboratory based testing

In addition to the performance standards issued by the TGA, laboratories are additionally subject to requirements established by the NPAAC. Laboratory staff are also subject to professional standards established by the RCPA and international standards under which laboratories receive NATA RCPA Accreditation.

- **NPAAC Requirements for Laboratory Testing of Human Immunodeficiency Virus (HIV) and Hepatitis C Virus (HCV)**
- **Royal College of Pathologists of Australasia: Professional Standards**
- **ISO 15189 Standard for Medical Laboratories**

### 2.2 Point of care testing

Point-of-care tests may have a longer window period than laboratory based tests. [In this policy, reference to ‘point of care tests/testing’ refers to rapid HIV tests being used at point of care.]

In addition to the performance standards issued by the TGA, point of care HIV testing services are additionally subject to requirements established by the jurisdictions and medical practitioners performing point of care tests are subject to their own professional standards. Additionally jurisdictions may require those performing HIV point of care tests to contribute to surveillance data collection. Examples of these include:

- **The NSW Standard Operating Procedures for HIV Point of Care Testing**
• The NRL Requirements for Participation in a specific External Quality Assessment Scheme (EQAS) \(^9\)
• The Royal Australian College of Pathologists External Quality Assurance Program.

Sites that perform point of care testing should be enrolled and actively participate in a relevant external quality assurance program and it is recommended that the site contribute to jurisdictional or national data collection.

The application of these requirements is the responsibility of the director of any service which provides HIV testing. The TGA requires that a health professional or appropriately trained user is responsible for performing or supervising all aspects of the testing process from sample collection to test interpretation\(^{10}\). All staff performing HIV point-of-care testing should be able to be able to demonstrate competency in the performance of the tasks for which they are responsible. Training should cover test operation, sample collection and interpretation as well as issues of consent, conveying the result and any confirmatory testing processes. Examples are provided in the following documents:

• National Curriculum for HIV Point of Care Testing (ASHM) (appendix E)
• Competency Standards for HIV Point of Care Test Operators (ASHM) (appendix F)

Staff will also need to receive specific training on the operation of any newly introduced point of care test or sample collection process being used in a facility.

Services providing point of care testing should have a clear linkage to clinical and pathology services for the conduct of confirmatory testing. This includes when point-of-care testing is performed in community-based testing services and in an outreach setting, such as a mobile clinic or pop-up site.

2.3 HIV self-testing
The TGA performance requirements establish baseline criteria against which applications for HIV self-tests will be measured. In addition to performance requirements, the document places on the sponsor requirements to mitigate the risks associated with self-testing\(^{11}\). While no HIV self-test is currently licensed for that purpose on the Australian Register of Therapeutic Drugs, self-tests are the subject of research studies. Australians can also purchase self-tests while travelling overseas or online from overseas suppliers. The TGA performance requirements provide a guide to those performing research and or considering the role of self-test in Australia.

Unlike point-of-care testing, self-testing is performed in the absence of a health care provider or trained operator. It is, therefore, essential that instructions for use (package insert) are sufficiently illustrative and comprehensible so that a user can perform the test correctly and interpret the result. In addition the package insert must explain sensitivity and specificity limitations including the predictive value when used in high and low prevalence populations, the window period, the need for confirmatory testing and referral points.

2.4 Self-sampling for HIV testing
Self-sampling for HIV testing provides opportunities for improving access to testing and increasing frequency of testing among people at risk of HIV infection through minimising the barriers associated with conventional testing e.g. the need to attend a health service to access a test, time
taken for test results to be available, poor access to health care providers, stigma and the risk of discrimination. Self-sampling can also support autonomy, and provide added confidentiality, privacy and convenience for people who may not otherwise engage in HIV testing. Dried blood spot sampling is one form of self-sampling that has been successfully applied for decades in early infant diagnosis of HIV and in monitoring prevalence of HIV among injecting drug users. A successful pilot program targeting high risk groups for HIV was recently implemented in the UK. There is currently no TGA approved dried blood spot test for screening in Australia.

Unlike point-of-care testing, in self-sampling such as dry blood spot testing, the analysis is performed in the laboratory and a confirmed result can be obtained.

2.5 Novel testing technologies and/or sample collection processes
The TGA allows for the importation and/or local sourcing of devices for research purposes. The introduction of novel and innovative approaches to HIV testing is recognised in the 7th National HIV Strategy 2014-2017 as a means of enhancing access to testing for priority populations and thereby increasing the identification of undiagnosed HIV in the Australian community. Nevertheless, prior to its availability in the Australian market, any new testing technology and/or sample collection methods should be evaluated and registered by the TGA and be subject to the documented requirements appropriate to the device.

3.0 Indications for HIV Testing
Jurisdictional and community-based approaches, guidelines and protocols, developed in line with the National HIV Strategy, should reflect local epidemiology and demographic data to facilitate testing frequency among populations at higher risk of HIV.

**HIV testing is indicated in a number of contexts:**

- The presence of any symptom or diagnosis which could be indicative of HIV infection, where HIV would be in the differential diagnosis of a condition or impact the way a disease is managed (such as tuberculosis (TB), or in a condition which shares a transmission route with HIV, such as an sexually transmissible infections (STI), hepatitis B (HBV) or hepatitis C (HCV) has been diagnosed
- A reported high-risk exposure
- Unprotected sexual intercourse with a partner whose HIV status is unknown
- The 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 individual risk factors for HIV infection or the opportunity to prevent vertical transmission

**HIV testing is indicated in the following populations:**

- Gay men and other men who have sex with men (MSM);

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2 A full list of indicator conditions is available at [http://testingportal.ashm.org.au/resources/Indicator_table_v1.1.pdf](http://testingportal.ashm.org.au/resources/Indicator_table_v1.1.pdf) There is also an argument for providing HIV testing to any patient admitted to a hospital with methamphetamine related illness because of the high association of methamphetamine use reported among people who acquire HIV.
• People who inject drugs;
• People with multiple sex partners/recent partner change;
• People who have travelled to countries of high prevalence and engaged in risk behaviour/exposure;
• People from high-prevalence countries;
• Sexual and injecting partners of all the above groups of people, including those coming forward following contact tracing;
• Sexual and injecting partners of people living with HIV (PLHIV);
• Pregnant women;
• People who received a blood transfusion or blood products prior to 1985 in Australia, or from overseas;
• A patient\(^3\) initiated request to a healthcare service for an HIV test;
• An individual who reports having a reactive result on an HIV point of care test, HIV self-test or an HIV test performed overseas;
• A healthcare worker conducting exposure-prone procedures. See infection control guidelines\(^13\) and the Communicable Diseases Network of Australia (CDNA) policy on infected health care workers\(^14\) for more information;
• In the context of post-exposure prophylaxis (PEP), subject to national and jurisdictional guidelines and policy\(^15\);
• As part of an assessment for Pre Exposure Prophylaxis (PrEP) or in the management of a patient taking PrEP\(^16\).

3.1 Normalisation of HIV Testing
Attempts should be made to normalise HIV testing by offering HIV testing, along with STI and viral hepatitis screening, to all patients who have had any risk exposure such as partner change or injecting drug use. HIV testing should accompany STI screening and testing for hepatitis C or identification of incident hepatitis B. The absence of an identified epidemiological or behavioural risk factor should not preclude HIV testing in appropriate clinical circumstances. While a detailed sexual and/or drug use history may elevate the need for HIV testing, obtaining a detailed history is not a prerequisite for testing. HIV testing should be routinely offered to pregnant women as part of the suite of screening tests performed in the first antenatal visit.

3.2 Indicator triggered testing
Inclusion of HIV in a differential diagnosis will help normalise HIV testing. All attempts should be made to make use of existing clinical data to facilitate the identification of HIV in those people who are HIV infected but undiagnosed. This is a hard population to quantify, but the consistent identification of people with advanced un-diagnosed HIV infection in the Australian community makes this a priority population.

The use of pathology results or hospital admission data should be considered to identify indicator diseases and raise greater awareness among clinicians treating diseases which might suggest HIV should be considered.

\(^3\) The term patient is used throughout this document. It refers to the person being tested and should be read interchangeably with the term client. This is done for ease of reading.
3.3 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 respected and HIV testing should be conducted.

3.4 Testing in the context of contact tracing
Individuals may seek testing because they have been contact traced as a person who may have been at risk of exposure to HIV. Most facilities conducting contact tracing establish a communication wall between the identity of the source patient and the contact, see also section 5.1.

These patients are a priority for testing and should be afforded prompt access to testing. They may also be unaware of their potential exposure and may have additional counselling and information needs. They should be tested using a standard laboratory test in addition to any point-of-care test.

3.5 HIV testing in the context of surveillance
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 Surveillance and Research). This must be independently judged by an ethics committee constituted in accordance with the National Health and Medical Research Council’s (NHMRC) National Statement on Ethical Conduct in Human Research.

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

- as a condition of blood, tissue and organ donation;¹⁸
- as a mandatory part of the health requirement assessment for specified visa subclasses;⁴,¹⁹
- as a condition for entering training or service in the armed forces;²⁰ and
- as a condition for purchasing some types of insurance.²¹

Compulsory testing refers to situations where a person has no choice in being tested, e.g. as directed under a public health order, or as authorised under legislation (e.g., in the context of a forensic or coronial inquiry, or under legislation in some jurisdictions that allows for forced testing of individuals accused of certain offences).

The processes involved in securing a sample and conveying any HIV test result, in the context of mandatory and compulsory testing should, be in accordance with the relevant enabling legislation and should be in accordance with the principles in this Policy and basic human rights pertaining to privacy of health information to the extent they do not contradict existing legislation. Situations deemed necessary to impose mandatory or compulsory screening should be closely scrutinised from an evidence-based perspective on a regular basis to ensure that decision-making guidelines are

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¹⁷ The justification for this testing is to assess an applicant’s potential cost burden on the Australian community. As of 2013, a positive HIV test will put an applicant into a cost burden bracket which results in an automatic failure of the health requirement. Waiver of this requirement is available and legal advice should be sought by any migration applicants affected by this Policy.
adequate, and that the breach of the principle that testing be voluntary is still warranted. The decision to use a laboratory or non-laboratory based test will be a decision for the agency requiring that the test to be performed, based on any practical considerations (see section 7.5 Testing in prisons).

3.7 Public health management of HIV
The Department of Health, in consultation with the Communicable Diseases Network of Australia (CDNA) has produced a Series of National Guidelines (SoNGs) on the public health management of HIV. The SoNGs outline the indications for testing in the context of the National Guidelines for the Management of People with HIV who Place Others at Risk22. Individuals identified as contacts of a source patient may require special assistance as they may be unaware of their risk of exposure, see section 3.4 and 5.1.

4.0 Informed consent for HIV testing
As for all pathology testing, informed consent is required for HIV testing, except for rare occasions when a legal order is made for compulsory testing or in emergency settings, see section 3.6

Informed consent23 for HIV testing means that the person being tested agrees to be tested on the basis of understanding the HIV testing procedures, the reasons for testing and is able to assess the personal implications. For some people with a heightened awareness of HIV, routine HIV testing may be a behavioural norm. For others with little understanding of HIV or their potential risk of exposure, HIV testing may be novel, frightening and perceived as highly stigmatising.

The person performing the test should use their professional 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 with respect to their understanding of the HIV testing process and consequences of the result, and
- patients should also be advised how the test result will be conveyed.

Relationships between health care providers and patients can be complex. General principles of professional conduct apply in the case of HIV testing. These issues should be explored in the testing site’s standard operational procedures and each testing site director should make sure that all personnel are supported in developing their professional skills.

4.1 When informed consent cannot be provided by the patient
Professional judgement should be exercised in determining whether a person has capacity to make a decision to undergo an HIV test. In cases where the patient has an appointed guardian, consent must be obtained from that person. Where no formal appointment has been made, consent should be sought from another person or agency legally authorised to make such decisions on behalf of the patient, usually their partner (provided there continues to be a relationship), carer or close relative or friend. The potential impact of the test result on the person being asked to provide consent needs to be considered.
In a life threatening situation, when no guardian or appropriate other person can be identified professional judgement should be used in requesting an HIV test. See the HIV/AIDS Legal Centre matrix for the hierarchy of responsibility in each jurisdiction.

5.0 Conveying HIV test results
The process of conveying an HIV test result to the person who has been 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. Examples are provided for reference in appendices B & C. The site director and the person who requests the test is responsible for ensuring that appropriate mechanisms are in place for delivering the test result.

Community perceptions of HIV have changed over time as has the way people give and receive information. It is preferable that a positive HIV test result is given in person. However, current practice includes the provision of test results by phone, SMS, face-time, text message, email or other mechanism when it is considered appropriate. It will be important for those performing the test to use professional judgement in deciding how results will be delivered and these should be based on the understanding of the person being tested. Counselling may be required by some individuals and should be provided. Operational guidance on conveying positive HIV test results, negative HIV test results and a decision making flow chart are provided for reference in appendices B, C and D.

5.1 Contact tracing and partner notification
There is an onus on the person conveying a positive HIV test result to ensure that the patient is aware of the legal obligations relevant to their jurisdiction; to advise their subsequent partners of their HIV status and to inform former partners that they may have been at risk of exposure to HIV. Site specific approaches to contact tracing will need to be included in standard operating procedures.

Site directors are referred to the Australasian Contact Tracing Website and state and territory policies on contact tracing. Practical assistance can be provided to the health care provider and/or patients by ASHM, the local public health unit or sexual health clinics. Most facilities performing contact tracing should try and create an information wall between the person who gets information from the source patient and the person speaking to the contact. The details of the source patient must be treated confidentially and the contact must not be provided with the source patient’s name or details. Public health facilities, particularly sexual health clinics, are able to assist general practitioners and other private medical practitioners with contact tracing.

5.2 Confidentiality of HIV test results and testing data
HIV pathology results from a pathology laboratory will only be released to the requesting medical practitioner or to the clinical service team responsible for the patient’s care and management. Subject to the arrangement between the site and the reference laboratory, patient information may be shared between a specialist HIV, an s100 prescribing clinician or a sexual health service for the purpose of ensuring that a patient is informed of his or her test result. Part of the informed consent process should involve an explanation of how a patient can expect to receive their result.
Services are responsible for the security of HIV testing data and should develop mechanisms to restrict access to HIV pathology information. For example, there must be a security hierarchy within the information systems to restrict access to this information to those individuals directly involved with the treatment and care of the patient.

It is reasonable to expect that pathology test results are available on a patient’s record and that all staff with a legitimate clinical reason have access to the patient’s HIV test information including the range of non-HIV-related services that may be involved in the patient’s health care.

Any clinical, laboratory, and non-clinical staff involved in HIV testing must not disclose any personal or medical information about a patient to any other person, in accordance with privacy provisions.

5.3 Assistance to doctors new to diagnosing HIV
Some jurisdictions and ASHM provide assistance to doctors who are unfamiliar with diagnosing HIV. This is most easily facilitated by the laboratory performing the HIV test. Services of this nature support the diagnosing doctor and improve the immediate management of the patient, including initiating contact tracing and assessment for treatment. They can also facilitate the collection of routine surveillance data and act to encourage the doctor to engage with the patient’s ongoing HIV management.

6.0 Surveillance and Research
Laboratories performing confirmatory testing must notify the relevant state and territory health authorities of any new positive laboratory diagnosis in accordance with the relevant legislation and regulations.26 Where information is available to identify and monitor rates of newly acquired HIV infection, these cases should be reported to the local state or territory health authority as appropriate. Laboratory evidence of acute or recent HIV infection is useful to monitor rates of incident HIV infection and to evaluate interventions.

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 NHMRC.27

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 IEC in accordance with requirements prescribed by the NHMRC.28

6.3 Data linkage projects
An increasing amount of clinical data is becoming available as a result of the development of electronic data storage. Linkage projects which link to HIV notification data can provide timely and
relevant feedback on practice. Linkage to data including Medicare data, cancer registries, enhanced notification data and treatment and testing data must be endorsed by an appropriate IEC in accordance with requirements prescribed by the NHMRC.  

6.4 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 or be subject to appropriate ethical review and be endorsed by an IEC in accordance with the NHMRC.  

6.5 Use of unregistered in-vitro diagnostic devices
In-vitro diagnostic devices (IVDs) not currently approved by the TGA for in use in Australia may be required to be used in research, e.g. dried blood spot kits and tests which use alternate samples. Application must be made to the 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 screen or 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 Testing in Specific Populations
7.1 Health care workers
CDNA, (Communicable Diseases Network of Australia) professional societies, colleges and registration boards may, from time to time, publish guidelines regarding the testing of health professionals. Any HIV testing done in that context must be done in accordance with this Policy. Where testing of a health care worker is undertaken, confidentiality is paramount and must be maintained.

Previous iterations of the National HIV Testing Policy have stipulated that health care workers must not perform tests on themselves. This was written from the perspective of diagnostic testing when HIV point-of-care tests were not registered in Australia as screening tests. In the event that a test is registered for self-testing, health care workers’ use of such a test would be impossible to regulate. The principle remains that health care workers should be encouraged to seek appropriate clinical care for themselves and not to attempt to self-diagnose or self-manage HIV, and if found to be infected to monitor their health with the aid of an HIV clinician.  

7.2 Routine antenatal testing
Antenatal HIV testing should be recommended for all women and should be included as routine in tests associated with the first antenatal visit, in line with the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) guidelines which state that, in the absence of complications, “all pregnant women should be recommended to have HIV screening at the first antenatal visit” (RANZCOG, 2009). The woman should be informed about the tests being performed as part of the antenatal screen, including HIV testing and provide consent.

Jurisdictions should develop operational directives that support the RANZCOG guidelines through education and feedback on compliance allow for periodic auditing of antenatal medical records to provide evidence of recommended best practice. These should include a clear referral path for
women who are diagnosed with HIV so that they can be managed by appropriate specialist teams\textsuperscript{35,36,37}

7.3 Testing of infants born to HIV positive 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. These tests are not registered for this purpose in Australia, and there is no MBS reimbursement. Antibody tests are not helpful in this context 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.\textsuperscript{38}

7.4 Aboriginal and Torres Strait Islander people
The 4th National Aboriginal and Torres Strait Islander Blood Borne Viruses and Sexually Transmissible Infections Strategy 2014–2017\textsuperscript{39} prioritises testing for and treatment of STIs (including HIV) through annual, routine, systematic testing programs. Policies and guidelines which respect confidentiality must be developed locally, so that health care workers are correctly advised and health services generate culturally appropriate policies and programs.

7.5 Testing in prisons
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. Offering HIV testing to prisoners during incarceration has the potential to identify new cases of HIV infection, allowing for prevention education, appropriate assessment, treatment and referral post-release. This has clear benefits to the individual, their sexual partners, those with whom they may share equipment for skin penetration (including injecting equipment) and to the wider community.

Australian prisoners should be able to access free, voluntary, confidential, timely, non-discriminatory HIV testing, counselling and treatment services during incarceration, in accordance with this Policy. One of the difficulties in testing prisoners is their high rate of mobility between prisons and the difficulty in reliably getting laboratory test results delivered. As a result, offering the use of point of care HIV testing in clinical practice in prisons may increase testing rates and facilitate diagnosis of HIV.

8.0 Quality assurance of in-vitro devices (IVDs) for HIV testing
8.1 Pre-market quality assurance of HIV IVDs
The TGA has regulatory responsibility for IVDs under the Therapeutic Goods Act 1989\textsuperscript{40} and its associated regulations. The TGA has produced a framework to guide the evaluation of HIV tests.\textsuperscript{41}

8.2 Post-market quality assurance of HIV IVDs
IVD manufacturers, sponsors and the TGA have responsibility for post-market monitoring of 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. An adverse event associated with the use of an IVD should be reported by the IVD user through the TGA’s Incident Reporting and Investigation Scheme (IRIS)\textsuperscript{42} There is a different
form for use by medical device manufacturers or authorised representatives for mandatory reporting of adverse events associated with a medical device.

9.0 Funding of HIV testing
The MSAC is responsible for the determination of any MBS reimbursement for any HIV laboratory, rapid HIV test for use at point-of-care or rapid HIV test for self-testing, as well as any sample collection device. Funding for laboratory based anti-HIV screening assays (up-to 4th generation tests) is available as a subsidy through the MBS. Confirmatory and supplementary tests used to confirm initial screening test reactivity (such as western blot) are not funded. States and Territories and other organisations may negotiate the purchase of tests and sample collection devices which have been entered on the ARTG for use in their testing and public health programs. Unregistered tests and sample collection devices can be used for research purposes in line with the TGA conditions.

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.
10.0 References


12 Terrence Higgins Trust, Dean Street and Public Health England (PHE) in the United Kingdom.


28 Ibid.

29 Ibid.

30 Ibid


Appendix A: National HIV Testing Expert Reference Group

1; Terms of Reference
The ERG meets from time to time to review the HIV Testing Policy and to consider what action might be necessary to improve quality, uptake and regulation of HIV Testing in Australia.

The ERG brings together all parties with an interest in HIV testing and provides a forum for discussion of policy matters raised by third parties in relation to HIV testing.

It acts as a forum for identification of barriers and impediments to accessing HIV testing and provides a sounding board for the exploration of how these barriers and impediments might be removed.

The ERG provides background information to jurisdictions and the Commonwealth, the Blood Borne Viruses and Sexually Transmissible Infection Sub-committee (BBVSS) of the Australian Health Protection Principal Committee, regulatory and other advisory bodies.

The ERG provides a voice to raise issues relating to HIV testing with test providers, pathology companies and others.

2; Membership and secretariat
The membership comprises:

National HIV Testing Policy Expert Reference Group Members

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<th>ORGANISATION</th>
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<td>ASHM</td>
<td>BBVSS, Co-chair</td>
<td>Levinia</td>
<td>Crooks</td>
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<td>AFAO</td>
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<td>Darren</td>
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<td>National Aboriginal Community Controlled Health Organisation</td>
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<td>Roger Garsia</td>
<td>Chairman, NSW Ministerial Committee on HIV and STI(CAS); Immunopathologist</td>
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<td>Head, HIV Epidemiology &amp; Prevention Program</td>
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<td>ASHM secretariat</td>
<td>Anna Roberts</td>
<td>Division Manager, National Policy and Education Division</td>
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<td>Peter Kaylock</td>
<td>Senior IVD Evaluator</td>
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<td>TGA</td>
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<td>Michelle McNiven</td>
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Secretariat support to the ERG and to the HIV, HBV and HCV Testing Portal is provided by ASHM.
Appendix B: Conveying Positive HIV Test Results – Features of a Good Diagnosis

Conveying Positive HIV Test Results – Features of a Good Diagnosis

Subtitle: Resource for health practitioners

Date: 4 August 2011

Summary: A brief guide for health professionals when conveying an HIV positive result, including within the context of point of care testing and when encountering challenging cases.

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.

Some laboratories provide information for the diagnosing practitioner to contact a more experienced clinician to discuss the procedure of giving a positive test result at the time the results of confirmatory testing are forwarded. Any practitioner can use the resources listed below if they require support in this situation.

The first step to take before delivering a positive HIV result is to check that the result has been confirmed as a true positive on confirmatory testing by a reference laboratory. Check with the laboratory if you are unsure about whether this has occurred.

A positive result should always be provided in person except in extenuating circumstances.

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

A positive HIV test result has significant implications for an individual and their clinician. A positive result may result in considerable distress for an individual.

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;
* assessing support mechanisms of the person and offering either immediate referral to a support agency, or information to facilitate access at the person’s discretion;
* providing information about the next steps in staging HIV disease and a consideration of potential treatment options;
* arranging appropriate referral for HIV specific medical care;
* discussing contact tracing and partner notification strategies;
* discussing legal obligations relevant to the local jurisdiction about disclosure of HIV status, (see HIV legal resources);
Appendix C: Conveying a Negative HIV Test Result

Conveying a Negative HIV Test Result

Subtitle: Resource for health practitioners

Date: 4 August 2011

Summary: A brief guide for health professionals when providing a negative HIV result, including challenging cases

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.

Conveying a negative result

The decision on how a negative HIV test result is provided (e.g. in person, by phone, etc.) will be based on the clinical judgement of the person responsible for conveying the test result. This decision should take account the level of knowledge about HIV, the understanding of the testing process and psychological capacity to deal with the outcome of testing of the person being tested, as assessed at the time of 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.

It is imperative to recheck that the person understands the duration of the window period of the test performed and the implications this has for that person. It is wise to recheck the risk history at the time the result is provided.

It is important to give advice about the need for further testing in light of the person’s risk history within the window period and ongoing risk of acquiring HIV infection.

It is an opportunity to discuss and reinforce safe sex practices.
Appendix D: Decision Making in HIV

DECISION-MAKING IN HIV

STEP 1: Could it be HIV?
- Who to test: individuals at risk for HIV infection.
- Symptoms: fever, rash, lymphadenopathy, weight loss, diarrhea, opportunistic infections.

STEP 2: Informed consent and testing
- Before testing: assess risk, HIV history, recent sexual activity, recent injection drug use, travel to high-prevalence areas.
- Testing: confirmatory testing, rapid testing, home testing.

STEP 3: Conveying test results
- Positive result: counseling, linkage to care, treatment options.
- Negative result: counseling, follow-up testing, next steps.

IF HIV POSITIVE:
- Positive test results in person:
  - Inform and test to patient needs.
  - Avoid overcrowded environments.
  - Provide immediate assistance.
  - Arrange for a partner to accompany the patient.
  - Make follow-up appointment (within 1 week).
  - Advise patient on adherence and treatment.

IF HIV NEGATIVE:
- Negative result is an opportunity for preventive education:
  - Counseling on risky behaviors.
  - Counseling on the importance of regular testing.

For further details on testing, see the National HIV Testing Policy 2011, available at www.testingportal.ashm.org.au/hiv

www.ashm.org.au
## ASHM HIV Rapid Test Training:
### Certification as an Authorised Operator in a Non-laboratory Setting

### Course Overview

#### Curriculum Outline

<table>
<thead>
<tr>
<th>Module 1: Overview of HIV Infection (online)</th>
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<tr>
<td>• Epidemiology</td>
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<td>• Transmission</td>
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<td>• Prevention</td>
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<td>• Virus lifecycle and disease progression</td>
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<td>• Treatment</td>
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<th>Module 2: Overview of HIV Testing (online)</th>
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<td>• History of HIV testing in Australia</td>
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<td>• National HIV Testing Policy</td>
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<td>• Theory and limitations of HIV rapid tests</td>
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<td>• Appropriate situations and populations for use of HIV rapid tests</td>
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<th>Module 3: Assuring the quality of HIV Rapid Tests (Practical Session delivered in-person)</th>
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<td>This session should, where possible, be run with the supervisory laboratory so that a suitably qualified pathologist or laboratory scientist can respond to questions. It should also involve an individual skilled in the delivery of HIV rapid testing.</td>
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<tr>
<td>• Quality assurance</td>
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<td>• Quality control</td>
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<td>• Standard Operating Procedures for HIV rapid testing</td>
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<td>• Introduction to the tests, equipment, use and storage</td>
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<td>• Infection control and safety</td>
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<td>• Waste management</td>
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<th>Module 4: Performing an HIV Rapid Test (Practical Session delivered in-person)</th>
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<tr>
<td>• Workspace preparation</td>
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<td>• Gaining informed consent</td>
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<td>• Specimen collection</td>
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<td>• Performing the test</td>
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<td>• Interpreting and recording results</td>
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<td>• Conveying a test result</td>
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<td>• Next steps; referrals and patient information</td>
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<td>• Case discussions</td>
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F: Competency Standards for HIV Point of Care Test Operators (ASHM)

Competencies Standards for HIV Rapid Test Authorised Operators in Non-laboratory Settings:

In seeking authorisation an operator will, at the completion of the training be able to demonstrate the following competencies:

a) Describe current HIV epidemiology at local and national levels
b) Demonstrate knowledge and understanding of the mechanism of HIV transmission appropriate to conveying information to a patient seeking HIV rapid testing
c) Demonstrate understanding of behavioural aspects of HIV prevention so as to provide advice to people seeking HIV rapid testing about the prevention of onward transmission
d) Demonstrate understanding of the limitations of HIV rapid testing and how standard laboratory testing is used in confirming HIV rapid test results
e) Demonstrate competence in collecting finger prick or oral samples as required
f) Demonstrate competence in setting up, performing, and interpreting the results of an HIV rapid test
g) Demonstrate understanding of the instructions for use of the HIV rapid test with respect to storage, use, and shelf life of the test device
h) Demonstrate competence in practical considerations associated with performing tests including:
   i. Infection control
   ii. Waste management (of both infectious and non-infectious waste)
   iii. Safety, personal protective equipment and universal precautions
   iv. Records and data collection
   v. Quality control (including performing, understanding and recording results and the participation in external QC programs)
i) Demonstrate competence in talking to people seeking testing and being tested using HIV rapid tests, specifically in:
   i. Gaining informed consent
   ii. Being able to respond to questions about the test and to competently explain concepts such as the window period as it relates to the interpretation and communication of test results.
   iii. Conveying a negative (nonreactive) result and its limitations
   iv. Conveying an invalid result and the next steps in testing
   v. Conveying a reactive result and the next steps in testing
j) Demonstrate understanding of the importance of respect for patients' choices
k) Demonstrate understanding of the procedures specific to the facility in which the HIV rapid tests will be performed and local referral pathways and information sources for people being tested.