

2014 National HIV Testing Policy v1.0

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1.0 INTRODUCTION

1.1 Scope

The National HIV Testing Policy is the principal Standing Committee on Health (SCoH) document that sets out the aims, principles and arrangements for HIV testing in Australia. This Policy is a companion document to the Seventh National HIV Strategy 2014-2017¹ and underpins the regulatory mechanisms, standards, guidelines and operational requirements which are described in other documents².

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This is a foot note here for the PDF version, but will be a hyperlink online.

The Policy has a broad scope and applies to all types of HIV testing and allows for the consideration of new testing technologies which may be developed. It provides a framework for ensuring that quality screening and diagnostic testing become more readily accessible, with the goal of identifying HIV infection in a more timely manner so as to facilitate risk reduction and treatment of infected individuals and thereby a reduction in the risk of onward transmission.

1.2 Background and context

Australia has a high quality, comprehensive multi-sector pathology service. The National Pathology Accreditation Advisory Council (NPAAC) sets quality standards for laboratories and the National Association of Testing Authorities (NATA) and the Royal College of Pathologists of Australasia (RCPA) accredit facilities against these, and this accreditation is required in order to access the Medicare Benefits Scheme (MBS) subsidy. 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) determines which tests can be subsidised through the MBS. It also specifies any restrictions on subsidy eligibility according to the category of requestor and nature of disease under investigation. Tests for blood borne viruses including HIV tests undergo the most stringent of pathology test evaluations. This regulatory framework ensures that settings use quality tests and employ appropriate staff; that procedures are in place to ensure public safety and confidence; and provides testing operators with a strong foundation for professional indemnity.

The regulatory and quality framework for HIV testing has evolved with a focus on formal laboratory settings. In recent years, however, new technology has meant that HIV rapid tests can be reliably performed at the point of care (PoC) or in other non-laboratory settings. Most developed countries have instituted differential regulatory mechanisms to deal with these different types of tests.³ HIV rapid tests can be less specific (i.e. can have more false positives) and can be less sensitive (i.e. can miss more cases of infection) than conventional machine controlled tests used diagnostically, in contemporary laboratory based testing. However, the ease of use of HIV rapid tests and potentially their higher uptake as screening tests, particularly among people who are not accessing conventional testing, has meant that a fit-for-purpose assessment has seen them approved for use in Australia and internationally. Some countries have recently registered self-testing kits for HIV preliminary screening in order to expand testing within populations that may experience barriers to engaging or be otherwise reluctant to engage with the health sector.

³ See appendix B and NPAAC Requirements for Medical Pathology Services and Requirements for the Supervision of Pathology Laboratories.

Early detection of HIV and awareness of one's HIV positive status empowers people to make informed choices regarding treatment commencement and reinforces motivation for modifying risk behaviour, thereby reducing onward transmission. This Policy provides support for the introduction of a quality framework for testing which supports the National Strategies³ and identifies barriers which need to be removed to facilitate appropriate testing. Significant differences between this Policy and its predecessor include:

- Simplification of arrangements for non-laboratory based testing
- Support for all current and new testing technologies, including tests designed for self-testing, to be evaluated and regulated by the TGA using its fit-for-purpose criteria.
- Support for the removal of any overarching legislative restrictions on self-testing for HIV with TGA approved tests
- Removal of sections which are covered under other existing arrangements, requirements, operational guidelines and/or standards.

This Policy is endorsed by all state and territory governments and the Commonwealth through SCoH.

1.3 Definitions^b

This section provides definitions of terms central to this policy and as they relate to HIV testing.

Authorised operator (for HIV rapid tests used in a non-laboratory setting)

An individual who:

1. has training and demonstrable competencies in the operation, monitoring and use of the specific rapid test in use, as set down in manufacturers' manuals, test site manuals and standard operating procedures (SOPs) and any relevant legislation or regulation to perform the functions required at the test site,
2. has had such competency documented; and
3. is authorised to perform the functions required at the test site by the test Site Director.

NOTE: Responsibilities and processes for testing may be shared among a number of individuals at any site and as such each operator should have the competencies required for the specific task they perform.

Competency

The skill, education, training and experience necessary to perform the activities expected within an occupation or function to the standard expected in employment.

Compulsory testing

Refers to situations where a person has no choice in being tested for HIV, e.g. as directed under a public health order or in the context of a legal instruction including in forensic or coronial settings.

Confirmatory testing

Testing which is performed to confirm the results of an HIV screening test and includes:

^b Based on NPAAC taxonomy and definitions

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Definitions will appear in the downloadable PDF version of the Policy. Online on the Testing Portal each occurrence of the term will be underlined and highlighted and the definition will appear in a pop-up when the cursor is hovered over the word as is currently the case.

1. A procedure performed to verify the truth or validity of something thought to be true or valid
2. Testing performed to assure that a result achieved is the correct result or is the final test performed to achieve the true diagnosis.

NOTE: Confirmatory testing is also known as reference testing in some documents.

Diagnostic testing

A measurement or examination of a diagnostic specimen for the purpose of diagnosis, prevention, assessing treatment of any disease, or the assessment of health or impairment of health of an individual patient. In the context of HIV testing this includes the performance of a confirmatory test.

HIV rapid tests

Short incubation immunoassays used for screening and which produces results in twenty minutes or less. HIV rapid tests typically use blood or oral fluid. All reactive results need to be confirmed by reference testing.

NOTE: HIV rapid tests can also be performed in a reference laboratory as part of a confirmatory or reference test algorithm.

Immunoassay

Test which allows the detection of an antigen-antibody interaction.

In-vitro diagnostic devices (IVDs)

Pathology tests and related instrumentation used to carry out testing on human samples, where the results are intended to assist in clinical diagnosis or in making decisions concerning clinical management. IVDs are typically used in diagnostic laboratories, at the point of care, and in the home.

Mandatory testing

Refers to situations where people may not participate in certain activities or roles, or access certain services unless they agree to be tested for HIV.

Occupational exposure

An exposure at the workplace and/or while on duty that may place an employee at risk of HIV infection through percutaneous injury (e.g. a needle stick or cut with a sharp object), contact of mucous membranes, or skin with blood, tissues or other potentially infectious body fluids.

Point of care (PoC) testing

Pathology testing that takes place in close proximity to the patient for the management of the patient during the clinical consultation. In this Policy, PoC testing means HIV testing undertaken in a clinical setting using an HIV rapid test device.

Predictive Values

A measure of the times that the value of a test (positive or negative) is the true value. Predictive values are parameters that define the chance of a reactive tests result being truly positive (the positive predictive value) or a non-reactive test result being truly negative (the negative predictive value) for the substance that a test is designed to detect.

Reference laboratory

An HIV reference laboratory is a specialist pathology laboratory accredited for HIV testing

Reference testing

In Australia, all reactive screening tests are further tested by specialist assays at a reference laboratory using a range of technologies or algorithms to confirm or refute the result.

Reference testing in general includes:

1. A procedure performed to verify the truth or validity of something thought to be true or valid
2. Testing performed to assure that a result achieved is the correct result or is the final test performed to achieve the true diagnosis.

NOTE: Reference testing is also known as confirmatory testing in some documents.

Screening

This is defined as:

1. a test to systematically identify individuals at sufficiently high-risk of a specific disorder to benefit from further investigation or direct preventive action, among persons who have not sought medical attention on account of symptoms of that disorder
2. a test given to defined populations (e.g. newborns) to detect increased risk of a specific condition
3. a method used to evaluate large populations of individuals for the presence of a disease or analyte or substance.

In the context of HIV all reactive screening test results need to be confirmed by reference testing. Non-reactive results can be reported as HIV ½ antibody negative and generally do not proceed to reference testing.

Self-sample collection

This is where the sample collection is performed by the person seeking testing. What differentiates it from self-testing is that the sample is provided to a third party for interpretation and the result of the test will be provided later after analysis. Examples would include:

1. Bowel cancer screen where a sample is collected in the home and mailed to a central facility for screening (laboratory confirmation of any abnormality required)
2. Self-sample collection of a vaginal or anal swab for the purposes of sexually transmissible infection (STI) testing.
3. HIV screening by self-sample collection using a dried blood spot kit or alternate sample and mailed to a laboratory for testing.

Self-testing

This is testing whereby the person both collects the sample and performs the test on him/herself and interprets the results; it is sometimes called home testing. Self-testing kits are manufactured, packaged and labelled with the intended use being for self-testing. What differentiates self-testing from self-sample collection is that in self-testing the individual also interprets the result. Examples would include:

1. Pregnancy tests purchased over the counter and performed at home (clinical review and laboratory confirmation recommended)

2. Blood glucose monitoring performed in the home which may result in insulin dose adjustment or other corrective intervention
3. HIV testing performed on blood or saliva using a test kit purchased from a community pharmacy, over the internet, or from elsewhere.

Site Director (of a service using HIV rapid tests)

The individual who oversees testing and is responsible for ensuring that the conditions set down in this Policy are in place for a test site and that the test site is compliant. He/she will be responsible for ensuring that:

1. all operators have the appropriate training and can demonstrate competency in tasks they are required to perform;
2. appropriate records are kept and any reaccreditation is maintained;
3. any required standard operating procedures are in place and met;
4. a linkage is maintained with a NATA accredited laboratory and reference laboratory;
5. confidentiality of people accessing the site for testing is maintained; and
6. there is participation in an external quality assurance scheme (EQAS).

Sensitivity

The probability that a test will give a reactive result in a person with the disease. For HIV tests; the percentage of results that is correctly positive when HIV is actually present. Tests that are less sensitive can miss cases of HIV infection. (False negatives)

Specificity

The probability that a test will give a non-reactive result in a person without the disease will give a negative result. For HIV tests; the percentage of results that is correctly negative when HIV is not present. Tests that are less specific have higher rates of false positives.

Standard testing

The standard or most common examination performed in the laboratory for a particular area of testing. This examination will most often be the most frequently performed examination for a particular testing area and will consequently generate the highest volume in that testing area. NOTE standard testing is also known as conventional testing in some documents

Window period

Following infection, the period when the test in use does not reliably identify the infection is present.

1.4 Principles of HIV testing

The key principles that guide HIV screening and diagnostic testing in Australia are:

Testing is performed in the context that it is conducted ethically and:

- is voluntary and performed with the informed consent of the person being tested;
- is beneficial to the person being tested and is a critical trigger to initiating interventions including additional testing, prevention activities, decision-making regarding treatment initiation, transmission risk reduction and contact tracing;
- is critical to the interruption of transmission on a population level; and

- provides for an understanding of the epidemiology of HIV infection in the population and a measurement against which to evaluate National Strategy goals.

Evaluation, quality and performance:

- Prior to registration the TGA evaluates all tests on the basis of their being fit-for-purpose applying the relevant legislation and standards. In the case of HIV rapid tests, which are used for screening, lower specificity compared to laboratory based tests may be acceptable as reactive samples trigger confirmatory testing, this will be assessed on a case-by-case basis as part of the evaluation process;
- screening test results which are reactive, whether using standard or rapid tests, require confirmation from a reference laboratory; and
- test results must be conveyed in a timely manner.

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;
- HIV rapid testing should be targeted to individuals who are not currently accessing standard testing or who access it at a suboptimal frequency based on their risk of exposure to HIV;
- 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;
- 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;
- proper records must be retained by all testing sites in accordance with jurisdictional requirements regarding the storage of medical records and information regarding a person's HIV positive status; and
- where regulations or legislation place a restriction on individuals who are aware they have HIV, a reactive result by the initial HIV test, including PoC tests and self-tests, 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, screen-positive subjects should adhere to the restrictions.

2.0 TYPES OF TESTING

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 and storage of medical and personal information.

Policies and operational guidelines relating to HIV testing, specific to individual states, territories or institutions, should be consistent with the purpose, objectives and principles of

this National Policy. A summary of the different HIV tests used in Australia and the purposes for which they are used can be found in [appendix A](#).

2.1 Laboratory based HIV testing

Arrangements for laboratory based HIV testing in Australia are of exceptionally high quality and well established. The NPAAC Requirements for Laboratory Testing for Human Immunodeficiency Virus (HIV) and Hepatitis C Virus (HCV) document sets out standards and guidelines for laboratory based testing. A copy can be found in [appendix B](#).

2.2 Non-laboratory based HIV testing

Arrangements for non-laboratory testing including the development of an appropriate quality framework for regulation are under development in Australia. The first HIV rapid test approved for PoC use in Australia was entered in the ARTG in December 2012.

A wide range of HIV rapid tests are in use in both comparable developed countries and in developing country settings. HIV rapid tests used in a non-laboratory setting are screening tests and as such particular features associated with their use are noteworthy:

- reactive results need to be subjected to confirmatory testing;
- because they are highly sensitive at detecting established infection, they have a high negative predictive value; and
- they can have a longer window period after an HIV exposure to detect antibodies or antigen compared to laboratory-performed tests using machine-based assays.

The TGA, in assessing each HIV rapid test makes a decision as to the appropriate sensitivity and specificity requirements for the test based on the relevant legislation and standards. This may take into consideration the ease of use of the test and its use as a screening test, not as a definitive diagnostic test.

All reactive HIV rapid tests must be confirmed by reference testing on a freshly collected venous blood sample from the individual. All non-laboratory based testing sites must have written standard operating procedures (SOPs) and capacity for promptly collecting samples for confirmatory testing on all reactive and invalid samples to distinguish true from false reactivity. These SOPs will need to be tailored to each site and reference laboratories providing confirmatory testing may place particular requirements on non-laboratory test sites to facilitate the processing of reactive samples. Responsibility for the application of these SOPs will rest with the Site Director who must comply with reasonable audit and documentation review requests from the linked reference laboratory or regulatory authority. Suppliers of HIV rapid test devices must provide timely test sale data to the NRL for inclusion in denominator data of HIV testing.

This Policy does not support the use of HIV rapid tests in populations where prevalence is very low, including remote communities, as the positive predictive value of the test will be low. HIV rapid tests are most appropriately targeted to higher prevalence communities and/or where uptake of standard testing is suboptimal and non-laboratory based testing is part of a broad based strategy to enhance uptake of HIV testing.

2.3 Self-testing

Survey data and clinical opinion indicate that some people at risk of HIV may prefer to self-test, and may not seek testing in conventional settings. A number of countries have

experience in self-testing¹¹ and some research is being conducted domestically.¹² Findings from these activities should help inform policy makers, educators and clinicians as well as self-test users to better understand the place of self-testing. Self-testing should not be viewed as diagnostic. Diagnosis of HIV infection is contingent upon a confirmatory test from a reference laboratory

Australia has recognised that there is room for improvement in its HIV testing patterns. It is estimated that up to 20% of people living with HIV (PLHIV) may be unaware of their infection.¹³ While HIV testing and diagnosis rates were thought to be quite high there continue to be a number of late diagnoses. Frequency of testing among gay men has been decreasing¹⁴ and the overall number of new diagnoses of HIV is increasing.^{c,15} These factors necessitated review of the National HIV Testing Policy. This Policy supports the evaluation of new or novel approaches to testing and/or the introduction of testing strategies that have proved effective at increasing the diagnosis rate of HIV infection in other environments.

This Policy supports the repeal, revocation or amendment of legislation^d prohibiting the supply in Australia of devices intended for self-testing for HIV. These exclusions were developed at a time when the prognosis following an HIV diagnosis was far less promising and the negative consequences of a positive HIV diagnosis were of greater immediate concern. The need for this exclusion is thought to be unnecessary in the current environment. The Policy supports a regulatory framework in which only kits approved by the TGA are permitted to be sold and distributed and it supports the role of the TGA in placing appropriate conditions on suppliers related to the sale of kits in accordance with this Policy. There are a number of limitations to self-testing and consumers need to be protected against these. The TGA may apply specific conditions to the listing of devices for self-testing in an attempt to restrict self-testing to those populations at higher risk of HIV where issues of test specificity are less problematic than in low risk populations.

While the act of performing a self-test is seen as consenting to testing, individuals using the tests may not have considered their options and the consequences of a reactive result. To be favourably evaluated by the TGA for use as self-tests for HIV, tests must have appropriate package inserts, in a range of languages and provide referral to clinical services, including a 24 hour referral service for counselling; inserts must impress on the user the need for confirmatory testing to confirm any reactive result. This will also mitigate against loss of surveillance data and facilitate the linkage of patients to care. Suppliers of kits for self-testing should provide test sale data to the NRL for inclusion in denominator data of HIV testing.

2.4 Other considerations in HIV Testing

2.4.1 Voluntary confidential testing and screening

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

^c It should be noted that some transient increase should be anticipated as a number of campaigns and initiatives are put in place to identify previously undiagnosed HIV. Effort should be made to distinguish chronic from recent infection.

^d [Therapeutic Goods \(Excluded Purposes\) Specification 2010](#)

In addition to these fixed locations, standard and/or HIV rapid testing may be provided in additional sites including non-clinical screening sites that meet the standards outlined in this Policy (i.e. mobile, outreach and pop-up sites). However, any facility performing HIV rapid testing must have a clear linkage to clinical and pathology services for the conduct of confirmatory testing on all reactive samples and access to treatment as necessary.

2.4.2 Mandatory and compulsory screening

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;¹⁴
- as a mandatory part of the health requirement assessment for specified visa subclasses;^{e, 15}
- as a condition for entering training or service in the armed forces;¹⁶ and
- as a condition for purchasing some types of insurance.¹⁷

Compulsory testing refers to situations where a person has no choice in being tested, e.g. as directed under a public health order or in the context of a legal instruction including in forensic or coronial settings.

The processes involved in mandatory and compulsory screening should be in accordance with the principles in this Policy and basic human rights pertaining to privacy of health information. The decision to use laboratory or non-laboratory based screening will be a decision for the individual or organisation requiring the screen be performed based on the test performance characteristics and any practical considerations (see section 8.5 Testing in prisons).

2.4.3 Anonymous delinked screening and 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 7.0 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.¹⁸

2.4.4 Introduction of new technologies and strategies

Introduction of new technologies¹⁹ or strategies to target new priority populations must be accompanied by appropriate workforce development to ensure that those providing or offering HIV screening and diagnostic testing are equipped with up-to-date information about HIV biology, HIV treatment and management, procedures associated with using any new technology and information related to referral pathways to care and support. Where these relate to self-sample collection, such as with dried blood spot kits or alternate samples, appropriate instruction, advice and information for the consumer will be essential.

^e 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.

3.0 A QUALITY FRAMEWORK FOR HIV TESTING

3.1 Testing performed in laboratory settings

The NATA/RCPA accredits laboratories and their staff. Laboratories that conduct HIV testing must:

- be NATA accredited for medical testing;²⁰
- participate in a nationally coordinated external quality assessment scheme (EQAS); and
- comply with NPAAC standards²¹;

and should:

- contribute testing statistics to the National Serology Reference Laboratory, Australia (NRL)²² to ensure the completeness of test denominator data.

3.2 Testing performed in non-laboratory settings

This Policy supports providing for waiver of NATA/RCPA laboratory accreditation requirements for services providing HIV rapid tests in non-laboratory settings in both clinical and non-clinical testing sites.

This Policy supports the establishment by the Department of Health (DoH) of a quality framework for the regulation of HIV rapid testing in clinical and non-clinical testing sites with regulation auspiced under NPAAC, DoH, the Australasian Society for HIV Medicine (ASHM) or other entity. The quality framework must include at a minimum:

- competency standards for HIV rapid test operators in non-laboratory settings (see [appendix A](#))
- a training curriculum for HIV rapid test authorised operator certification (see [appendix B](#))
- requirements for non-laboratory sites performing HIV rapid testing, (see [appendix C](#) for examples from the Centers for Disease Control (CDC) the Public Health Agency of Canada),
- requirements for the site to participate in an appropriate, nationally coordinated EQAS ; and
- a recommendation that the site should contribute testing statistics to the NRL²³ to ensure the completeness of test denominator data.

The quality framework would necessitate the establishment of mechanisms to develop, maintain and document the above items, compliance with which would rest with the Site Director.

This policy supports the accreditation of all specialist HIV facilities, sexual health services and accredited community HIV s100 prescribers to perform HIV rapid testing on the proviso that they meet all the requirements of the quality framework including:

- the designation of a Site Director and
- evidence that operators were trained and are competent to perform the registered test in use

- current documentation of a relationship with a reference laboratory to which they will direct samples for further processing.
-

4.0 INDICATIONS FOR HIV TESTING

This Policy supports the introduction of novel and innovative approaches to HIV testing including through the implementation and reporting of research and the running of campaigns. Jurisdictions should develop approaches, guidelines and protocols, in line with the National HIV Strategy and based on local epidemiology and demographic data to facilitate testing among populations at higher risk of HIV or requiring additional assistance to access testing and related services, for example among men who have sex with men (MSM), Aboriginal and Torres Strait Islander communities,²⁴ culturally and linguistically diverse (CALD) populations²⁵ and people with cognitive or intellectual disabilities.²⁶

The Policy supports increased and targeted testing and the removal of barriers to testing. HIV testing is indicated in a number of contexts:

- presence of any symptom or diagnosis which would be indicative of HIV infection, where HIV would be in the differential diagnosis of a condition, or when a condition with shared transmission route such as an STI, HBV or HCV has been diagnosed. A full list of indicator conditions is available (hyperlink)²⁷
- 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 MSM
 - 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
 - partners of all the above groups of people
 - partners of PLHIV
 - pregnant women
 - people who 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
- a patient/client who reports having a reactive result on an unlicensed HIV test or a test performed overseas
- healthcare workers conducting exposure-prone procedures. See infection control guidelines²⁸ and the Communicable Diseases Network of Australia (CDNA) policy on infected health care workers²⁹ for more information,
- in the context of post-exposure prophylaxis (PEP) which is subject to national and jurisdictional guidelines and policy³⁰

4.1 Public health management of HIV

The DoH in consultation with the CDNA has produced a Series of National Guidelines (SoNGS) on the public health management of HIV. These outline the indications for testing in the context of public health management and can be found in [appendix F](#). Individuals identified as contacts of a source patient may require special assistance as they may be unaware of their risk of exposure.

Comment [LC3]: PLEASE NOTE:
this is draft, but should be available in final form as the Policy progresses

4.2 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.

4.3 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 recognised and HIV testing should be conducted.

5.0 INFORMED CONSENT FOR TESTING

Informed consent³¹ 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.³² 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/client initiation; and
- an assessment of the person being tested with respect to their understanding of the HIV testing process and 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. These issues should be explored in the SOP and the site director should make sure that all personnel are supported in developing their professional skills.

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/client 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/agency legally authorised to make such decisions on behalf of the patient/client, usually their partner (provided there continues to be a relationship), carer or close relative or friend. See the HIV/AIDS Legal Centre matrix³³ for the hierarchy of responsibility in each jurisdiction. More detailed information can be found in the linked documents.

6.0 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.^{84, 35} The site director and/or person who requests the test is responsible for ensuring that appropriate mechanisms are in place for delivering the test result.

This Policy recognises that the community understanding of HIV has changed as has the way people give and receive information. It is preferable that a positive HIV test result is given in person. However, this Policy supports the provision of test results by phone, SMS 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. Operational guidance on conveying different results is provided in [appendix G](#) and a decision making flow chart is provided in [appendix H](#).

6.1 Contact tracing

The individual organising HIV testing and/or conveying the result of testing has the responsibility to ensure that appropriate contact tracing is initiated. Site specific approaches to contact tracing will need to be included in SOPs (see section 3.2 Testing performed in non-laboratory settings). Site directors are referred to the Australasian Contact Tracing Manual, 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 clinic.⁸⁶

6.2 Confidentiality of HIV testing data

HIV pathology results must only be released to the requesting practitioner and/or to the clinical services team responsible for the patient's care and management. It is reasonable that patient information can be shared with a specialist HIV or sexual health service for the purpose of ensuring that a patient is informed of his/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 security hierarchy within laboratory information systems to restrict access to this information to those individuals directly involved with the treatment and care of the patient/client.

It is reasonable to expect that HIV 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/client to any other person.

7.0 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/regulations.³⁷

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

7.1 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.³⁸

7.2 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.³⁸

7.3 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 the NHMRC.³⁸

7.4 Use of unregistered In-vitro diagnostic devices

In-vitro diagnostic devices (IVDs) not currently 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 Scheme³⁹ 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 2002.⁴⁰

8.0 TESTING IN SPECIFIC POPULATIONS

8.1 Health care workers

CDNA,⁴¹ 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 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 tests, which could be used at PoC, were not licensed in Australia. In the event that a test is licensed for home use this would be impossible to regulate. As a general rule health care workers should be encouraged to seek appropriate clinical care for themselves and not to attempt to self-diagnose or self-manage HIV.

8.2 Routine antenatal 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. Should the woman be found to be HIV antibody positive, expert advice must be sought promptly.⁴²

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).⁴³ 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.

8.3 Testing of infants born to mothers with HIV infection

HIV testing with nucleic acid direct detection tests (such as proviral DNA) on infants of HIV-infected women should be performed within the first month after birth, so that appropriate treatment interventions can be implemented quickly. Antibody tests are not helpful due to the persistence of maternal antibodies in the infant for up to 18 months. Diagnosis of HIV infection in infants born to HIV-infected mothers is complex and expert advice must be sought promptly.⁴⁴

8.4 Aboriginal and Torres Strait Islander People

The Fourth National Aboriginal and Torres Strait Islander Blood Borne Viruses and Sexually Transmissible Infections Strategy 2014-2017⁴⁵ 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.

8.5 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 appropriate assessment, treatment, referral post-release, and education to be provided to those

individuals who undergo testing. This has clear benefits to the individual, their sexual partners, those with whom they may share injecting equipment and to the wider community.

Australian prisoners should be able to access free, voluntary, confidential, timely, non-discriminatory HIV testing, counselling and treatment services during incarceration. This Policy supports the use of PoC testing in clinical practice in prisons. as one of the difficulties in testing prisoners is their high rate of mobility and the difficulty in reliably getting laboratory test results delivered.

9.0 QUALITY ASSURANCE OF IN-VITRO DIAGNOSTIC DEVICES (IVDs) FOR HIV TESTING

9.1 Pre-market quality assurance of HIV IVDs

The TGA has regulatory responsibility for IVDs through the Therapeutic Goods Act 1989⁴⁶ and its associated regulations.

9.2 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)⁴⁷.

10.0 FUNDING OF HIV TESTING

From 1 November 2005, additional funding for anti-HIV assays has been made available as a subsidy through the MBS. Funding of HVI rapid test devices for use outside of accredited pathology laboratories is not currently approved under the MBS. In addition, testing for screening is also specifically excluded for MBS funding purposes. The uptake of HIV POC testing in the general practice setting will have limited reach unless HIV rapid tests are subsidised through the MBS.

This Policy supports a review of the current MBS position on the funding of HIV tests with regard to the Seventh National HIV Strategy's emphasis on the place and importance of HIV screening to reducing onward transmission of the virus. Testing is an essential precursor to treatment initiation and knowledge of one's status is a significant motivator for behaviour change. This review should involve an assessment of the cost benefit analysis of making HIV testing more freely available and address the issue of pricing for HIV rapid test devices licenced in Australia.

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.

11.0 ABBREVIATIONS AND ACRONYMS

| | |
|--------|--|
| ARTG | Australian Register of Therapeutic Goods |
| ASHM | Australasian Society for HIV Medicine |
| CALD | culturally and linguistically diverse |
| CDNA | Communicable Diseases Network of Australia |
| DoH | Australian Government Department of Health |
| EQAS | external quality assessment scheme |
| HBV | hepatitis B virus |
| HCV | hepatitis C virus |
| HIV | human immunodeficiency virus |
| IEC | institutional ethics committee |
| IRIS | Incident Reporting and Investigation Scheme |
| IVD | in-vitro diagnostic device |
| MBS | Medicare Benefits Schedule |
| MSAC | Medical Services Advisory Committee |
| MSM | men who have sex with men |
| NATA | National Association of Testing Authorities |
| NHMRC | National Health and Medical Research Council |
| NPAAC | National Pathology Accreditation Advisory Council |
| NRL | National Serology Reference Laboratory, Australia |
| PEP | post-exposure prophylaxis |
| PLHIV | people living with HIV |
| PoC | point of care |
| RAZCOG | Royal Australian and New Zealand College of Obstetricians and Gynaecologists |
| RCPA | Royal College of Pathologists of Australasia |
| SCoH | Standing Committee on Health |
| SoNG | Series of National Guidelines |
| SOP | Standard Operating Procedures |
| STI | sexually transmissible infection |
| TGA | Therapeutic Goods Administration |

12.0 APPENDICES

2.0 Types of testing

- A. Categorisation of HIV IVDs for evaluation and use
- B. Requirements for Laboratory Testing for Human Immunodeficiency Virus (HIV) and Hepatitis C Virus (HCV) (third edition, 2013), NPAAC

3.0 A quality framework for HIV testing

- C. Competency standards for HIV rapid test operators in non-laboratory settings, ASHM

Comment [PR4]: PLEASE NOTE:
Some of these materials are still in draft form or are still in development. Examples from other countries are provided for what will be developed for the Australian context.

D. ASHM HIV Rapid Tests Training Course. (For certification as an Authorised Operator in a non-laboratory setting) – Course Outline

- E. Example requirements for sites performing HIV rapid testing taken from
- To Test or Not to Test? Considerations for Waived Testing, Centers for Disease Control
 - Point-of-Care HIV Testing Using Rapid HIV Test Kits: Guidance for Health-Care Professionals, Public Health Agency of Canada

4.0 Indications for HIV testing

F. Series of National Guidelines (SoNGS) on the public health management of HIV, DoH and CDNA, **NOTE:** Draft in development, will be published here:
<http://www.health.gov.au/cdnasongs>

6.0 Conveying HIV test results

- G. Issues for consideration in conveying test results
H. Examples of flow chart/decision making tree/algorithm

13.0 LINKED DOCUMENTS AND REFERENCES

Comment [PR5]: PLEASE NOTE: To be completed/updated/formatted during style editing once text is finalised, see endnotes for now

¹ 7th National HIV Strategy – **NOTE: Draft in development** will be available here:

<http://www.health.gov.au/internet/main/publishing.nsf/Content/ohp-national-strategies-2010-hiv>

² To Test or Not to Test? Considerations for Waived Testing, Centers for Disease Control

<http://www.cdc.gov/cia/Resources/WaivedTests/default.aspx>

³ **Will need to be updated** Australian Government. Department of Health and Ageing. National HIV strategies and Aboriginal and Torres Strait Islander blood borne viruses and sexually transmissible infections strategies. Available at:

<http://www.health.gov.au/internet/main/publishing.nsf/Content/ohp-bbvs-1> (Accessed 9 March 2012).

⁴ National Anti-Discrimination Information Gateway [internet]. Commonwealth and State and Territory anti-discrimination and public health legislation. Available at:

<http://www.antidiscrimination.gov.au/www/nadig/nadig.nsf> (Cited 9 March 2012).

⁵ Commonwealth funding of pathology tests [internet]. Available at: <http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pathology-aboutus-index.htm> (Cited 9 March 2012).

⁶ <http://www.tga.gov.au/consumers/information-devices-hiv-rapid-tests.htm>

⁷ Prestage G, McCann PD, Hurley M, Bradley J, Down I, Brown G, (2010). Pleasure and Sexual Health: The PASH Study, 2009. Monograph, National Centre in HIV Epidemiology and Clinical Research, Sydney Australia.

<http://www.kirby.unsw.edu.au/sites/default/files/hiv/attachment/PASH2009-final.pdf>

⁸ J Grierson, M Pitts, R Koelmeyer (2013) HIV Futures Seven: The Health and Wellbeing of HIV Positive People in Australia, monograph series number 88, The Australian Research Centre in Sex, Health and Society, La Trobe University, Melbourne, Australia.

http://www.latrobe.edu.au/_data/assets/pdf_file/0007/546037/HIV-Futures-Seven-Report.pdf

⁹ Hull, P., Mao, L., Kao, S.-C., Edwards, B., Prestage, G., Zablotska, I., de Wit, J., & Holt, M. (2013). Gay Community Periodic Survey: Sydney 2013. Sydney: National Centre in HIV Social Research, University of New South Wales. Available at <http://nchr.arts.unsw.edu.au/publications/>

¹⁰ Myers JE, El-Sadr WM, Zerbe A, Branson BM. Rapid HIV self-testing: long in coming but opportunities beckon. AIDS. 2013 Feb 11 <http://www.ncbi.nlm.nih.gov/pubmed/23807269>

-
- ¹¹ Report on the first international symposium on self-testing for HIV: The legal, ethical, gender, human rights and public health implications of self-testing scale-up: Geneva, Switzerland. 8-9 April 2013 http://www.who.int/hiv/pub/vct/self_test/en/
- ¹² <http://www.ncheccsurveys.unsw.edu.au/forth/>
- ¹³ National Blood-borne Virus and Sexually Transmissible Infections Surveillance and Monitoring Report. 2013. The Kirby Institute, the University of New South Wales, Sydney, NSW http://www.kirby.unsw.edu.au/sites/default/files/hiv/resources/NBBVSTI2013_0.pdf
- ¹⁴ Organ Donation. Legislation and guidelines for organ and tissue donation. Available at: <http://www.health.gov.au/internet/main/publishing.nsf/content/health-organ-legislation.htm> (Cited 9 March 2012).
- ¹⁵ Australian Government. Department of Immigration and Citizenship. Fact sheet 22—The health requirement. Available at: <http://www.immi.gov.au/media/fact-sheets/22health.htm> (Cited 9 March 2012).
- ¹⁶ 2011 National HIV Testing Policy. A factsheet for ADF applicants undergoing HIV, hepatitis B and hepatitis C virus screening. Available at: http://www.testingportal.ashm.org.au/resources/TESTING_PORTAL_FactSheet_ADF_AnnexB_V2_FINAL.pdf (Cited 30 January 2013)
- ¹⁷ HIV/AIDS Legal Centre Inc. (NSW). Available at: www.halc.org.au/disclosure.html (Cited 9 March 2012).
- ¹⁸ National Health and Medical Research Council, Australian Research Council, Australian Vice-Chancellors' Committee. National statement on ethical conduct in human research (2007) (updated September 2009). Available at: www.nhmrc.gov.au/files/nhmrc/publications/attachments/e72.pdf (Cited).
- ¹⁹ Australian Government. Department of Health and Ageing. Therapeutic Goods Administration. Medical devices safety. Available at: www.tga.gov.au/safety/information-devices.htm (Cited 9 March 2012).
- ²⁰ National Association of Testing Authorities Australia (NATA). Available at: http://www.nata.asn.au/publications/section/1-accreditation_publications (Updated 2012; cited 23 March 2012).
- ²¹ Australian Government Department of Health and Ageing. National Pathology Accreditation Advisory Council (NPAAC). Requirements for laboratory testing for human immunodeficiency virus (HIV) and hepatitis C virus (HCV). Second edition 2009. Available at: <http://www.health.gov.au/internet/main/publishing.nsf/Content/health-npaac-docs-hivhepc.htm> (Cited 24 January 2013).
- ²² National Reference Laboratory (NRL). EDCnet [portal for collection of testing statistics] Available at: <https://www.nrlqa.net/> (Cited 22 January 2013).
- ²³ National Reference Laboratory (NRL). EDCnet [portal for collection of testing statistics] Available at: <https://www.nrlqa.net/> (Cited 22 January 2013).
- ²⁴ **Will need to be updated to fourth** Australian Government Department of Health and Ageing. Third National Aboriginal and Torres Strait Islander blood borne viruses and sexually transmissible infections strategy 2010 – 2013. March 2010. Available at: <http://www.health.gov.au/internet/main/publishing.nsf/Content/8AF786E7C15CFECA257719NSWHealth.MulticulturalHIVandhepatitiservices.AstatewideservicehostedbySydneyLocalHealthDistrict>. Available at: <http://www.mhahs.org.au/> (Cited 22 January 2013).0002862A/\$File/atsi.pdf (Cited 21 March 2012)
- ²⁵ NSW Health. Multicultural HIV and hepatitis services. A statewide service hosted by Sydney Local Health District. Available at: <http://www.mhahs.org.au/> (Cited 22 January 2013).
- ²⁶ Australian Federation of Disability Organisations. Available at: <http://www.afdo.org.au/> (Cited 21 March 2012).
- ²⁷ http://testingportal.ashm.org.au/resources/Indicator_table_v1.1.pdf
- ²⁸ Australian Government. National Health and Medical Research Council. Australian guidelines for the prevention and control of infection in healthcare (2010) - online version only. Reference number: CD33. Available at: www.nhmrc.gov.au/guidelines/publications/cd33 (Cited 21 March 2012).
- ²⁹ Australian Government. Department of Health and Ageing. Australian National management of health care workers known to be infected with blood-borne viruses. Endorsed 08 February 2012 by AHMAC through the Communicable Diseases Network Australia (CDNA). Available at: www.health.gov.au/internet/main/publishing.nsf/Content/cda-cdna-bloodborne.htm (Cited 27 October 2012).

- ³⁰ Australasian Society for HIV Medicine (ASHM). National guidelines for post exposure prophylaxis after exposure to HIV. Available at: <http://www.ashm.org.au/pep-guidelines> (Cited 21 March 2012).
- ³¹ Australasian Society for HIV Medicine (ASHM). Features of informed consent for HIV testing. A resource for health professionals. 4 August 2011. Available at: http://testingportal.ashm.org.au/resources/practitioners/Informed_Consent_resource_HIV.pdf (Cited 21 March 2012).
- ³² Australasian Society for HIV Medicine (ASHM). Guide to Australian HIV laws and policies for healthcare professionals. Privacy and confidentiality. January 2011. Available at: <http://www.ashm.org.au/HIVLegal/Default.asp?publicationID=2&SectionID=339> (Cited 21 March 2012).
- ³³ HIV/AIDS Legal Centre. State and Territory Guardianship matrix. April 2013. Available at www.ashm.org.au/images/Testing_Portal/TESTING_PORTAL_Factsheet_HALC_V2.pdf (Cited 10 April 2013)
- ³⁴ Australasian Society for HIV Medicine (ASHM). Conveying positive HIV test results: features of a good diagnosis. Resources for health practitioners. August 2011. Available at: http://testingportal.ashm.org.au/resources/practitioners/Conveying_Positive_HIV_Test_Results_resource.pdf (Cited 21 March 2012).
- ³⁵ Australasian Society for HIV Medicine (ASHM). Conveying a negative HIV test result: features of a good diagnosis. Resources for health practitioners. August 2011. Available at: http://testingportal.ashm.org.au/resources/practitioners/Conveying_Negative_HIV_Test_Results_resource.pdf (Cited 21 March 2012).
- ³⁶ Australian Contact Tracing Manual <http://ctm.ashm.org.au/default.asp>
- ³⁷ Australasian Society for HIV Medicine (ASHM). Guide to Australian HIV laws and policies for healthcare professionals. Notification. January 2011. Available at: <http://www.ashm.org.au/HIVLegal/Default.asp?PublicationID=2&ParentSectionID=P2&SectionID=326#linkACT> (Cited 11 March 2012).
- ³⁸ Australian Government. National Health and Medical Research Council. Australian human research ethics. Available at: <http://www.nhmrc.gov.au/health-ethics/human-research-ethics> (Cited 24 January 2013).
- ³⁹ Australian Government. Department of Health and Ageing. Therapeutic Goods Administration. Standards, guidelines and publications: medical devices and IVDs. Available at: <http://www.tga.gov.au/industry/devices-sgp.htm> (Cited 22 March 2012).
- ⁴⁰ Australian Government. ComLaw. Therapeutic Goods (Medical Devices) Regulations 2002: F2012C00424. Available at: <http://www.comlaw.gov.au/Details/F2012C00424> (Cited 24 January 2013).
- ⁴¹ Australian Government. Department of Health and Ageing. Communicable Diseases Network Australia (CDNA). Available at: <http://www.health.gov.au/internet/main/publishing.nsf/content/cda-cdna-index.htm> (Cited 22 March 2012).
- ⁴² Australasian Society for HIV Medicine (ASHM). Making a new HIV diagnosis. Available at: http://www.ashm.org.au/default2.asp?active_page_id=228 (Cited 11 March 2012).
- ⁴³ Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG). Routine antenatal assessment in the absence of pregnancy complications (College statement: C-Obs-3). November 2009. Available at: [http://www.testingportal.ashm.org.au/resources/C-Obs_3_\(b\)_Routine_Antenatal_Assessment_in_the_Absence_of_Pregnancy_Complications_NEW_Mar_13.pdf](http://www.testingportal.ashm.org.au/resources/C-Obs_3_(b)_Routine_Antenatal_Assessment_in_the_Absence_of_Pregnancy_Complications_NEW_Mar_13.pdf) (Cited 24 January 2013).
- ⁴⁴ Sydney Children's Hospital. Paediatric HIV Service. Antenatal screening for HIV. Information for health professionals. December 2011. Available at: http://testingportal.ashm.org.au/resources/practitioners/Antenatal_Screening_on_HIV.pdf (Cited 22 March 2012).
- ⁴⁵ Aboriginal and Torres Strait Islander BBV & STI Strategy 2014 – 2017 **NOTE: Draft in development, cross reference with 24**
- ⁴⁶ Australian Government. ComLaw. Therapeutic Goods Act 1989. C2012C00848. Available at: <http://www.comlaw.gov.au/Details/C2012C00848> (Cited 24 January 2013).
- ⁴⁷ <http://www.tga.gov.au/safety/problem-device.htm#UtljLjbTjuik>