The Expert Reference Committee reconvened on the 07 November 2012 and have made the following amendments to the 2011 National HIV Testing Policy v1.1. These changes have now been accepted into the online version of the policy on the Testing Portal website.

2011 National HIV Testing Policy v1.2

Changes made in v1.2:

- **4.0 Informed consent for testing**
  - Emphasise use of appropriate supports when communicating with people
- **5.0 Conveying HIV test results**
  - Emphasise use of appropriate supports when communicating with people
- **6.0 Surveillance and research**
  - Amend duplication of text
- **8.1 Routine testing**
  - Removed redundant sentence
- **8.2 Testing of infants born to mothers with HIV infection**
  - Amend title
- **10 HIV testing in prisons**
  - Section added
  - Renumbering of subsequent sections
- **11 Post-exposure prophylaxis**
  - Removed potentially confusing sub-sections 11.1, 11.2, 11.3 and instead referred to National PEP policy
  - Renumbering of subsequent sub-sections

Track Changes- 2011 National HIV Testing Policy v1.2

- **11.1 PEP in health care settings**
  - Strengthened obtaining informed consent before testing stored specimens
- **12.0 Quality assurance of IVDs for HIV testing**
  - Renumbered sections to be consistent with hepatitis B and hepatitis C testing policies
- **12.1 Laboratories**
  - Added “should” to laboratories submitting testing statistics
- **13.2 Accreditation**
  - Minor changes to make current

Minor changes were made throughout the policy document for consistency and wording.

The Expert Reference Committee saw these changes as improving the clarity of the document, but not changing its substantive meaning and has notified BBVSS and MACBBVSS of these changes.

4.0 INFORMED CONSENT FOR TESTING

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

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

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

5.4.3 Patients who do not return for positive test results

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

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

5.4.4 Post mortem testing

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

6.1 Delinked blood surveys

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

6.2 Identity unlinked HIV testing

Research using identity unlinked HIV testing can provide useful epidemiological data. In such studies,

specimens used must be endorsed by an appropriate ~~ethics committee and be endorsed by an~~ IEC in accordance with requirements prescribed by the NHMRC.

8.1 Routine testing

Antenatal testing should be recommended for all women and must only be performed with the informed consent of the woman~~. HIV testing must be performed in the context of appropriate risk assessment and discussion.~~ Should the mother be found to be HIV antibody positive, expert advice must be sought promptly.

8.2 Testing of infants born to ~~HIV infected~~ mothers with HIV infection

10.0 HIV testing in prison settings

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

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

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

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

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

11~~0~~.0 POST-EXPOSURE PROPHYLAXIS

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

~~10.1 Testing of the source~~

~~PEP is not indicated if the source is known to be HIV negative. An active attempt should be made to assess the HIV status of the source. If the source is contactable, they should be invited to have an~~

~~urgent HIV test. If the source declines to have an urgent HIV test then it should be assumed that PEP is required. Under certain circumstances public health provisions may be invoked under which consent is not required.~~

~~10.2 Testing of the exposed individual at initial presentation~~

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

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

~~10.3 Follow-up testing~~

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

1~~0~~.14 PEP in health care settings

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

Consent **should** be obtained in accordance with the guiding principles of this policy. If the patient declines to have an urgent HIV test then it should be assumed, for the purposes of PEP prescription, that they have HIV infection.

Informed consent should be obtained before testing occurs on stored specimens.

1~~1~~2.0 QUALITY ASSURANCE OF IVDs FOR HIV TESTING

For more information and background on HIV IVD regulation and quality assurance, refer to ~~Discussion~~ Background Document to the 2011 National HIV Testing Policy ~~v1.0~~v1.2 and the Therapeutic Goods Administration (TGA).

12.1 ~~11.3~~ Laboratories

Laboratories that perform HIV testing **must**:

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

Laboratories that perform HIV testing **should** contribute testing statistics to the NRL to ensure the completeness of test denominator data (See ~~Discussion~~ Background Document to the 2011 National HIV Testing Policy ~~v1.1~~v1.2)

12.2 ~~11.1~~Pre-market quality assurance of HIV IVDs

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

12.3 ~~11.2~~ Post-marketing quality assurance of HIV IVDs

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

13~~2~~.0 POINT OF CARE TESTS FOR HIV IN COMMUNITY SETTINGS

- have either attained National Association of Testing Authorities (NATA) accreditation independently or through a pre-established relationship with a NATA-approved laboratory. If through the latter, the NATA-approved laboratory will provide training and support in the recording of testing data ~~and quality assurance~~ (through the NRL) and quality assurance. If the former, the testing site must develop their own quality assurance ~~recording~~ and denominator data collection procedures and report this directly to the NRL.