



National Screening Unit

# Universal Offer Antenatal HIV Screening Programme

## Policy and Quality Standards

National Screening Unit  
June 2010





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## **Part One – Introduction**

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### **Background to the Programme**

Effective interventions that reduce the risk of perinatal HIV transmission have led to a greater emphasis internationally on antenatal HIV screening (National Health Committee, 2004). It is estimated that if women with HIV are identified during pregnancy and use a combination of interventions, the risk of perinatal transmission can be reduced from as high as 31.5 percent to less than one percent.

In 1997, the Ministry of Health released guidelines for health care practitioners recommending that all pregnant women who were perceived to be at highest risk of acquiring HIV should be assessed (Ministry of Health, 1997). The intention of this recommendation was to reduce the perinatal transmission of HIV by providing appropriate treatments to those women who were found to be HIV positive. The National Health Committee (2004) indicated that this approach had limitations, and that some health professionals did not consistently offer screening to those at risk of HIV infection.

In June 2005, the Ministry of Health announced that New Zealand was moving to a policy of universally offering HIV screening to pregnant women as part of standard antenatal care in line with international practice. As a result, the Universal Offer Antenatal HIV Screening Programme (the “Programme”) has been implemented by all DHBs. All pregnant women in New Zealand should now be offered antenatal HIV screening as part of the Programme.

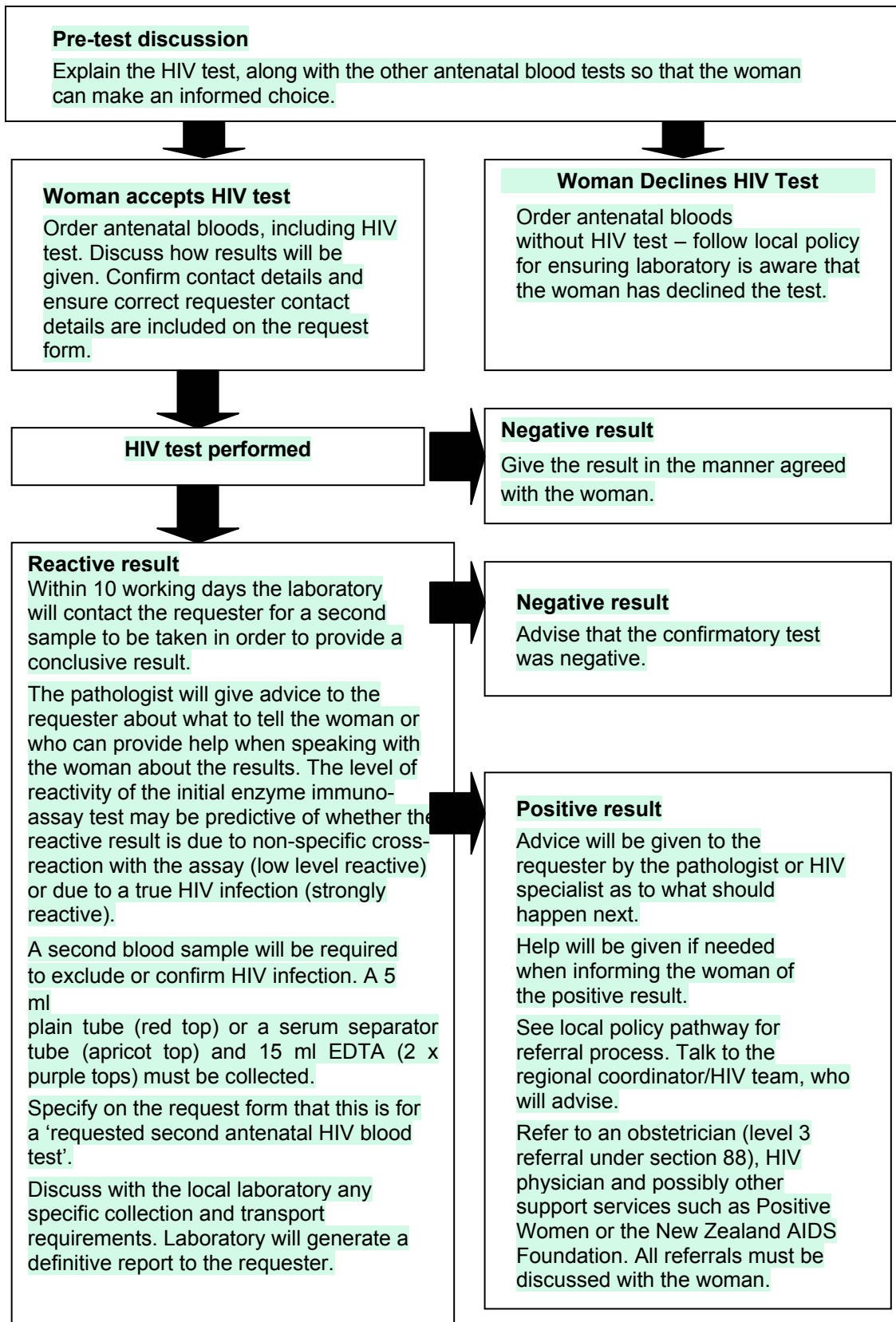
### **Introduction**

The policy and quality standards in this document (the “standards”) replace the December 2008 version developed in consultation with the National Antenatal HIV Screening Implementation Advisory Group (NAHSIAG), which was established to provide advice to the NSU on the implementation of the Programme.

The purpose of the standards is to identify standards of good practice that DHB, Maternity and Laboratory Providers responsible for delivering parts of the Programme must comply with. In addition, these standards will support all those involved in the delivery of the Programme to contribute to the achievement of the Programme’s aims.

## Part Two – Programme Policy

### 1. The Programme Pathway – An Overview



## 2. Programme Aims, Goals and Objectives

The aims of the Programme are:

- prevention of perinatal transmission of HIV
- early detection and appropriate management\* of HIV infected pregnant women
- prevention of transmission within communities
- equitable distribution of health outcomes between population groups.

The goals and objectives of the Programme are:

Goals	Objectives
All pregnant women are universally offered HIV testing.	<ul style="list-style-type: none"> <li>• All pregnant women have an informed opportunity to have an HIV test</li> <li>• Addressing barriers to testing – including provider barriers - to promote high uptake of HIV testing.</li> </ul>
The screening programme does not undermine the concept of pregnancy as a positive experience.	<ul style="list-style-type: none"> <li>• Pregnant women are empowered by the provision of information and options</li> <li>• The Programme is minimally intrusive (requires no additional medical intervention for the majority of women).</li> </ul>
The screening process is appropriate, timely, acceptable, effective and safe.	<ul style="list-style-type: none"> <li>• All pregnant women have the opportunity for informed choice</li> <li>• HIV testing is timely and accurate</li> <li>• Recall for confirmatory testing causes the least harm possible</li> <li>• Minimal delay occurs in conveying the final results</li> <li>• All aspects of the screening process are culturally appropriate and safe</li> <li>• All pregnant women including those that cease being pregnant after the test are given a definitive test result.</li> </ul>
HIV positive women are accurately identified by the programme.	<ul style="list-style-type: none"> <li>• Those pregnant women who are HIV positive at the time of testing are correctly identified</li> <li>• Those pregnant women who are HIV</li> </ul>

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\* While management of HIV positive women falls outside the scope of the screening programme, appropriate management is integral to the Programme's success. Therefore, for the purposes of monitoring and evaluation, its inclusion as one of the aims of the Programme is considered appropriate.

Goals	Objectives
	negative at the time of testing are correctly identified.
Appropriate and timely management of HIV positive women.	<ul style="list-style-type: none"> <li>• Diagnosis is communicated in a sensitive manner</li> <li>• Provision is made for counselling and support (as desired by the woman).</li> </ul>
Perinatal transmission of HIV is minimised.	<ul style="list-style-type: none"> <li>• Timely and co-ordinated referral for expert care and appropriate interventions.</li> </ul>

### 3. Roles and Responsibilities

Maternity Providers are responsible for universally offering the HIV test to pregnant women.<sup>1</sup> District Health Boards provide leadership and oversight of the Programme in each of their regions. It is expected that DHBs will engage with Maternity Providers in their regions in order to implement the Programme and evaluate its effectiveness. District Health Boards will also be responsible for funding laboratory and treatment costs in their regions.

The NSU provides funding to DHBs to deliver the Programme. Programme funding is for training and education, data collection, monitoring and evaluation, and programme co-ordination activities. In addition, the NSU will monitor and evaluate the performance of DHBs, and the Programme. .

### 4. Monitoring and Evaluation

Monitoring and evaluation of the Programme will follow the screening pathway and assess *process* (the organisational aspects of the Programme and policy implementation) and *outcomes* (health outcomes and process utility). The main aspects of monitoring and evaluation will include:

- Screening uptake – by DHB, requester type, age, ethnic group & NZDep score.
- Information provision and informed consent
- Screening results in DHBs: (a) confirmed newly diagnosed HIV positive pregnant women; (b) pregnant women with non-negative results who were not infected.
- Referral management and follow up of women
- Interviews with clinicians and women who had: (a) positive results; (b) required to be retested but were not infected in order to mitigate any adverse effects resulting from the screening process.

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<sup>1</sup> For the purpose of these standards, Maternity Provider means an organisation or a health practitioner that provides primary maternity services (as per the definition of maternity provider in the section 88 Maternity Services Notice), but this may also include other health practitioners, such as GPs, Family Planning and sexual health clinicians, who see pregnant women who miscarry or seek to have a termination.

The potential means of collecting data to monitor and evaluate the Programme include:

- Routine surveillance data
- Surveys of providers and pregnant women
- Interviews with women
- Focus groups
- Audits.

Whilst routine surveillance data provides much of the information required to assess health outcomes, surveys, interviews and focus groups are useful for assessing process and process utility.

## **5. Eligibility**

The 2003 Direction of the Minister of Health (the “Direction”) relating to Eligibility for Publicly Funded Personal and Disability Health Services in New Zealand (the Eligibility Direction) identifies the groups of people who are eligible for publicly funded health and disability services in New Zealand. To be eligible, a person must be lawfully in New Zealand and meet one of the Direction’s specified criteria.

Pregnant women who do not meet the eligibility criteria must still be offered the opportunity to participate in the Programme. If a woman as part of the Programme tests positive with HIV, her antenatal care costs including preventive treatment to limit the risk of perinatal HIV transmission and delivery are publicly funded. However, ineligible women have no entitlement to ongoing publicly funded treatment after delivery; although, their babies are entitled to publicly funded care to prevent perinatal transmission.

## **6. Quality**

The delivery of high quality health care services is an important goal of the Health and Disability Sector. In terms of screening programmes, the Quality Framework for Screening Programmes in New Zealand (National Screening Unit, 2003) underpins quality improvement initiatives for all screening programmes. All providers involved in the delivery of the Programme are expected to adhere to and align their practice with the Quality Framework. Electronic copies of the Quality Framework are available at [www.nsu.govt.nz](http://www.nsu.govt.nz).

## **7. Improving Māori Health**

The New Zealand health and disability strategies, provide an over arching goal for the health and disability sector of improving health and disability outcomes for Māori. The New Zealand Public Health and Disability Act 2000 places a statutory obligation on DHBs to reduce inequalities by improving the health status of Māori, and to increase Māori participation in the health and disability sector. Furthermore, He Korowai Oranga (The Māori Health Strategy) identifies a framework for improving Māori Health. Programme providers are expected to have regard to these strategies, and in the case of DHBs their statutory responsibilities, in the planning and delivery of the Programme to Māori communities.

Core considerations for improving health services for Māori can include:

- ensuring systems/processes are in place to facilitate routine contributions from Māori in service development, planning and delivery
- addressing barriers to access such as financial and geographical barriers
- ensuring services are provided in a culturally appropriate manner.

More information on Māori health can be found on the Ministry of Health's website at [www.moh.govt.nz](http://www.moh.govt.nz).

## **8. Reducing Inequalities in Health**

Health inequalities are differences in health status that are unnecessary, avoidable and unjust (Whitehead, 1990). Like improving the health status of Māori, reducing inequalities is a health and disability sector goal, and efforts to achieve this goal are mandated by a number of instruments including the New Zealand Health Strategy, and in the case of DHBs, the New Zealand Public Health and Disability Act 2000.

Health inequalities can be demonstrated across ethnicity, social position, gender, age and geographic location (Ministry of Health, 2002). As well as these and other factors that impact upon health status, health and disability services can also play a role in health improvement. For this reason, it is important that in delivering the Programme service providers endeavour to contribute to a reduction in health inequalities. Among other things, this can be achieved by providing services in a culturally appropriate manner, ensuring that all pregnant women are offered the test, and where acceptance is given that they are able to have the screening test,<sup>2</sup> and ensuring that if a woman is referred that follow up action is provided to ensure that she has received the follow up service.

More information about health inequalities can be found on the Ministry of Health's website at [www.moh.govt.nz](http://www.moh.govt.nz).

## **9. Groups That May Require Additional Help and Support**

There are likely to be women who, for various reasons, require additional support services. For those women who find it difficult to communicate in English, professional interpreter services should be used when offering the test and giving the results to ensure that a woman fully understands what is being communicated to her. It is not recommended that providers use family members as interpreters.

There may be other groups of women that may require additional support such as women with psychiatric conditions or physical impairments. In such cases, it may be necessary to provide additional support or arrange support services.

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<sup>2</sup> For example, for women who are likely to have difficulties attending a laboratory to have their blood samples taken as a result of socio economic, geographic or cultural factors, it may be necessary to take initial blood samples at the consultation where consent is given rather than making a referral for testing.

## **10. Informed Consent**

It is important that the Programme complies with the Code of Health and Disability Services Consumers' Rights (amended 2004), in particular:

- effective communication (Right 5)
- provision of information (Right 6)
- making an informed choice and giving informed consent (Right 7).

Informed consent applies to all health and disability services in New Zealand, including maternity services. There is a legal framework in the health and disability sector that establishes a consumer's right to make an informed choice and give informed consent.

For maternity providers obtaining informed consent for testing or other interventions is central to good practice. For consent to be ethically and legally valid, women must give their informed consent to what is proposed.

When offering an HIV test to a pregnant woman, Maternity Providers must take reasonable action to ensure that the woman is fully informed. This includes giving women opportunity to ask questions prior to making a decision on whether to have the test. This requirement applies to each antenatal blood test, not just the HIV test.

Pre-test discussion with pregnant women about HIV testing should be clear and comprehensible, and take into account any differences of language and culture. All women should be told how they can access additional advice.

Details of discussions with the pregnant woman, including the information given and her decision, should be recorded in her case notes. Offering HIV testing along with the other antenatal blood tests in pregnancy should be an integral part of the maternity provider's antenatal care, which includes providing information and offering tests for other infections. Written consent for antenatal HIV testing as part of the Programme is not necessary, provided that the information given, and decision made, are clearly recorded.

## **11. Privacy**

Under New Zealand law, when information is collected about an individual the individual must be advised that his or her personal information is being collected and provide authorisation to the collection. The individual must also be informed of how the information that is collected will be stored and used, and who will have access to it. The specific legal requirements in relation to the collection, storage and use of health information are set out in the Health Information Privacy Code 1994 and Programme providers must comply with its requirements.

## **12. Legislative Compliance**

Those involved in the delivery of the Programme must meet their professional and ethical standards as well as their legal obligations, including adherence to the:

- New Zealand Public Health and Disability Act 2000

- Health Act 1956
- Privacy Act 1993 and the Health Information Privacy Code 1994
- Health and Disability Commissioner's (Code of Health and Disability Services Consumer's Rights) Regulations 1996, and
- Health Practitioners Competence Assurance Act 2003
- Public Records Act 2005.

## Part Three – Maternity Provider Responsibilities

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### 1. Pre-test Discussion

#### 1.1 Information About the HIV Test

##### *Standard 1*

Each pregnant woman receives information about the test in a manner that enables her to understand the purpose of it, and to make an informed decision of whether or not to have the screening test.

##### *Criteria*

Maternity Providers must:

1. ensure that the requirements of right 6 and 7 of the Code of Health and Disability Services Consumers' Rights Regulation 1996 are fully met
2. ensure that the current Ministry of Health pamphlet on antenatal HIV testing is given to each pregnant woman and that adequate time is given to discuss information in the pamphlet
3. discuss with pregnant women:
  - a. the purpose of the test
  - b. the potential benefits and limitations of the test
  - c. how long it will take to receive the screening test result and the method by which it will be communicated
  - d. the likelihood of a false negative or false positive test result and what this might mean including the need for confirmatory testing if the initial screening test is reactive
  - e. the potential for, and implications of, a positive result
  - f. the availability of counselling and support services
4. where further information, access to interpreters, additional expertise or time is required, ensure that these are organised
5. ensure that a woman has had the opportunity to ask questions and have them answered and advise that although the test is recommended, she has the right to decline the test.

#### 1.2 Offer to be Screened

##### *Standard 2*

Each pregnant woman is offered the opportunity to be screened for HIV.

##### *Criteria*

Maternity Providers must offer each pregnant woman the opportunity for antenatal HIV screening, this includes:

1. women who present late in pregnancy (also see part five, section 1.5)
2. women who have had a negative HIV test result previously.

### **1.3 Informed Consent**

#### **Standard 3**

Maternity Providers must ensure that those pregnant women that participate or choose to not participate in the Programme have made an informed decision.

#### **Criteria**

Maternity Providers must:

1. ensure that the requirements of the Code of Health and Disability Services Consumers' Rights Regulation 1996, rights 5, 6 and 7 are fully met
2. establish whether a woman consents to have an HIV test as part of the Programme. It is her right to decline the test as with any test offered
3. ensure that a woman is aware of the possibility that she may need confirmatory testing
4. if a woman declines respect her decision and advise that she can change her mind at any time during the pregnancy and have the test at a later date if she chooses
5. document the following in the woman's case notes:
  - a. whether the information recommended in the guidelines was given
  - b. whether the test was offered
  - c. issues that may have been raised, including use of interpreters or other services (if required)
  - d. whether verbal consent was given or declined for the test.

### **1.4 Use of Health Information**

#### **Standard 4**

Maternity Providers ensure that individual clinical records are unique to women, women's health information is accessed and used in accordance with the law, and that they prevent the unauthorised use or unauthorised disclosure of women's health information.

#### **Criteria**

Maternity Providers must ensure that:

1. women's health information and data are collected, used, stored, accessed, and destroyed to a standard that complies with the Health Information Privacy Code 1994.
2. women are fully informed of the purpose, use and recipients of information that is collected about them and any consequences of not supplying such information.

## 2. Obtaining Blood Samples

### Standard 5

Blood samples are obtained in accordance with local policies and processes, as well as accepted standards for the ordering, taking and handling of blood samples.

### Criteria

1. If taking a woman's blood sample, a Maternity Provider must ensure that:
  - a. it is taken and handled in accordance with accepted standards for blood sampling and handling
  - b. where a confirmatory test sample is taken at a location other than a laboratory site, a Maternity Provider should discuss sampling and handling requirements, including timeframes for delivering the sample to the laboratory, with the laboratory prior to taking the sample
  - c. where applicable, comply with the provisions of criteria 2.
2. If referring women for testing, Maternity Providers must ensure that:
  - a. they fill out the laboratory request forms in accordance with section CB13 of the Section 88 Maternity Notice 2007, and:
    - i. indicate on the laboratory form in accordance with the national requirements whether the woman will be having an HIV test as part of her antenatal blood tests
    - ii. indicate on the form whether the test is a first antenatal HIV test, a second or repeated test, or a confirmatory test
  - b. in addition to criteria 2a, ensure that all aspects of request forms are completed correctly and that their contact details (including those of the group/practice they belong to) are legible and accurate
  - c. women are advised of the opening hours and address of the place they should go to have their blood sample taken - including directions
  - d. women are advised that they should have their blood sample taken as soon as possible
  - e. women are advised of the time-frame within which they should expect to receive their results and the method through which results will be communicated (note: this information should be recorded in a woman's case notes)
  - f. ensure that communication systems with relevant laboratories are in place to ensure that results are received in a timely manner.

## 3. Managing Results

### 3.1 Giving Results - If Negative

### Standard 6

Maternity Providers must communicate negative HIV results in a manner that maximises a woman's ability to understand her test result and via the method that was agreed with her.

### Criteria

Maternity Providers must:

1. ensure that a time is arranged with the woman to talk with her about her result

2. ensure that the woman's identity is confirmed prior to communicating the result to her
3. advise the woman that if she thinks she may have been exposed to a risk at any time during her pregnancy, she can have another test if she chooses to
4. ensure that the woman understands her test result
5. record the test result in the woman's case notes.

### **3.2 Giving Results – If the Initial EIA is Reactive**

#### **Standard 7**

Maternity Providers must communicate initial reactive EIA test results in person, in a manner that demonstrates respect and ensures that a woman understands her test result and the importance of confirmatory testing, within five working days of receiving the result.

#### **Criteria**

Maternity Providers must:

1. speak to the laboratory pathologist or HIV (or infectious disease) specialist to discuss the result and the next steps that should be taken
2. ensure that a time is arranged with the woman to talk with her about her reactive EIA test result
3. provide the woman with information (in accordance with criteria one above) to inform her of the reasons for her initial reactive EIA result
4. allow time for discussion and questions regarding the test result
5. ensure that she understands her test result
6. inform her that another blood sample will be needed, in which case:
  - a. refer her in accordance with the lab algorithm for the confirmatory test, and inform her that she should have her blood sample taken as soon as possible
  - b. advise her of the opening hours and address of the place they should go to have their blood sample taken - including directions
  - c. if taking the sample away from a laboratory site, discuss handling requirements with the laboratory prior to taking it, and ensure that it is sent to the laboratory in a timely manner
7. offer access to additional support services if required
8. record the test result, information provided and discussion points in her case notes.

### **3.3 Giving Results – Confirmatory Test Results**

#### **3.3.1 HIV Negative Test Results**

#### **Standard 8**

Maternity Providers must communicate HIV negative test results in a manner that ensures that a woman understands her test result, within five working days of receiving the test result.

#### **Criteria**

Maternity Providers must:

1. ensure that a woman's identity is confirmed prior to communicating the result

2. allow time for discussion and questions regarding the test result
3. ensure that she understands her test result
4. record the test result, information provided and discussion points in her case notes.

### **3.3.2 HIV positive test results**

#### **Standard 9**

Maternity Providers must communicate HIV positive test results in person within five working days of receiving them, in a respectful manner, and in a manner that ensures the woman understands her test result.

#### **Criteria**

Maternity Providers must:

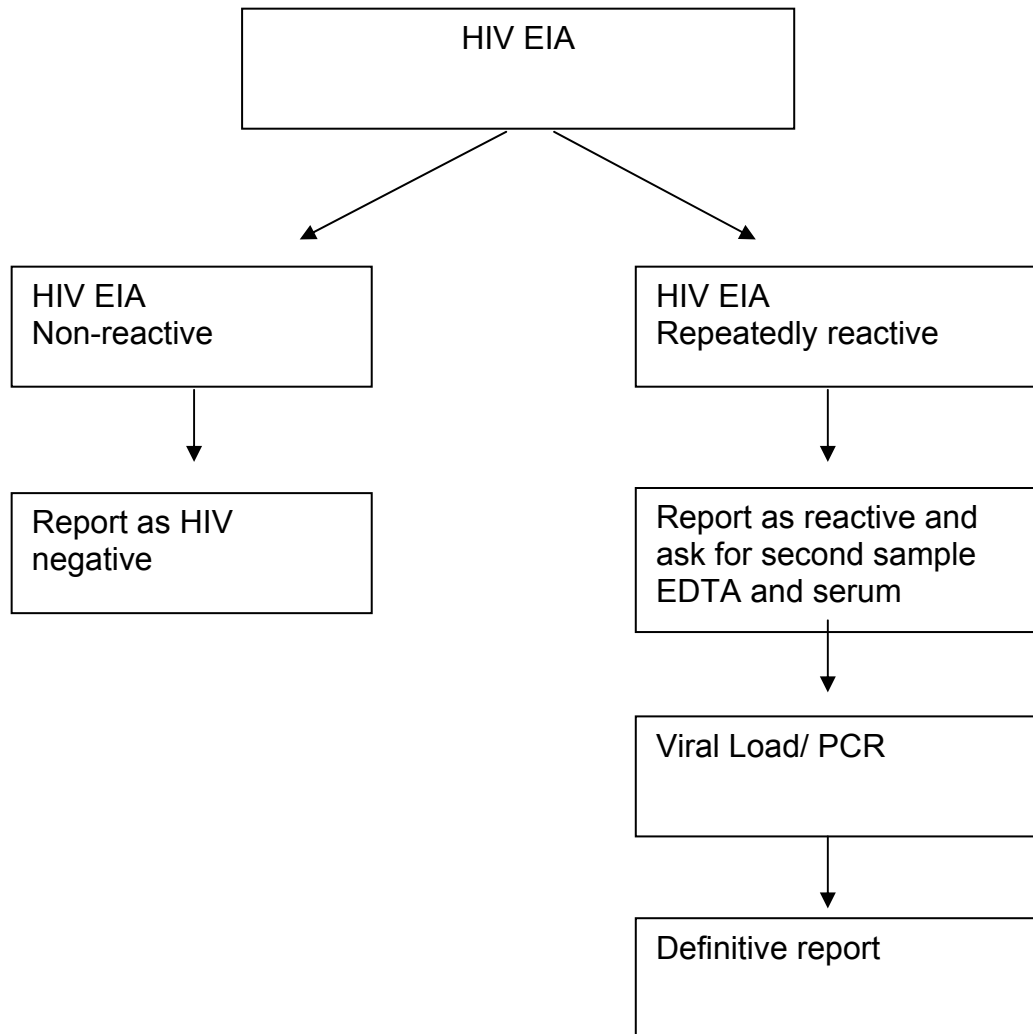
1. speak to the laboratory pathologist or HIV (or infectious disease) specialist to discuss the result and the next steps to be taken
2. speak to the local Programme Coordinator regarding local care pathways and information required for monitoring purposes
3. not give HIV positive results on a Friday or prior to a public holiday, or via a method other than direct contact (i.e. in person)
4. not use family, friends or other persons known to the woman, for the purposes of communicating or translating a test result
5. inform her of her test result in a manner that ensures that she understands her test result, the support services available to her and the next steps to be taken
6. allow adequate time for discussion and questions
7. recommend referral to specialist care including obstetric, infectious diseases and HIV specialists
8. record the test result and information given in her case notes.

Note: As with other level 3 referrals, it may be necessary (particularly in rural areas) for the Maternity Provider to continue to provide antenatal and postnatal care for the mother and her newborn. This should occur after a treatment plan is developed by the woman, her Maternity Provider, an obstetrician and an HIV (or infectious disease) specialist. Any decision regarding such care should be consistent with a DHBs follow up system and processes to monitor HIV exposed newborns.

## Part Four – Laboratory Responsibilities

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### ANTENATAL HIV SCREENING PROGRAMME LABORATORY ALGORITHM



## 1. General

### Standard 10

Laboratories performing sampling and testing in relation to the Programme adhere to ISO 15189:2007 (Medical Laboratories – Particular Requirements for Quality and Competence) and the laboratory algorithm, and have microbiologist or pathologist leadership.

### Criteria

Laboratories performing testing in relation to the Programme must:

1. follow the screening assay protocol as described in the EIA kit insert or an amended protocol that is accredited by IANZ
2. ensure that the assay used has a sensitivity >99.9% and a specificity >99.8%
3. run an internal quality assurance scheme that includes monitoring of reporting times
4. maintain IANZ accreditation
5. code antenatal HIV tests separately from those of other HIV tests
6. provide laboratory order forms for Maternity Providers which meet the national requirements for ordering first antenatal blood tests:
  - a. ideally there are six tick boxes on the laboratory form, one for each of the routine first antenatal blood tests, including Antenatal HIV
  - b. where this cannot be implemented at a minimum there is one tick box for the first five antenatal bloods with the names of these five tests printed alongside the box and a separate tick box for the Antenatal HIV Test.
7. support DHBs to collate relevant data for the purpose of programme monitoring in accordance with NSU requirements.

## 2. Initial Testing of Samples

### Standard 11

All samples are tested and reported in accordance with laboratory protocols and the standards.

### Criteria

1. The laboratory must inform the Maternity Provider of the test result as soon as it becomes available, and:
  - a. if the EIA is non-reactive, the Maternity Provider must be sent the results along with the other antenatal blood test results
  - b. if the EIA is reactive, the laboratory must request a second blood sample.
2. Pathologists must advise and support the referring Maternity Provider on how to explain results to the woman, in particular where this relates to a reactive EIA.
3. The laboratory must inform the Regional Programme Co-ordinator of all reactive EIA test results.

### **3. Confirmatory Testing to Confirm or Exclude HIV**

#### **Standard 12**

Laboratories test samples from women who have had reactive EIA blood samples using nucleic acid amplification testing (NAAT) in the form of HIV viral load or PCR, and inform referrers of reactive EIA test results within ten working days of receiving the sample.

#### **Criteria**

1. Laboratories performing confirmatory testing should be sent from each woman that has a reactive EIA result:
  - a. a 5ml plain tube (red top) or serum separator tube (apricot top)
  - b. 15 ml EDTA (2 purple top).
2. Local collection and transport protocols should be followed.
3. The laboratory must inform the requestor of the reactive test result within ten working days of the specimen being received.
4. If the confirmatory test is HIV positive, the laboratory must also inform the Regional Programme Co-ordinator within ten working days of the sample being received.
5. Pathologists must advise and support the referring Maternity Provider to explain results to the woman, in particular where the HIV infection is confirmed.

## Part Five – District Health Board Responsibilities

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### 1. Regional Programme Management

#### 1.1 Programme Coordination

##### **Standard 13**

District Health Boards ensure that a Programme Coordinator is appointed and that activities required to effectively administer the Programme at a regional level are undertaken.

##### **Criteria**

District Health Boards must ensure that:

1. effective relationships with Programme providers and interested parties are developed and maintained
2. partnerships to promote and achieve the Programme's aims, goals and objectives are developed and maintained with Programme providers
3. the current Ministry of Health pamphlet on antenatal HIV testing is made available
4. systems are designed to ensure privacy, yet allow sharing of information with Programme providers involved in providing care - so as to not compromise safe and effective care.

#### 1.2 Provision of Training Opportunities

##### **Standard 14**

District Health Boards' systematically offer training opportunities, in respect of the Programme, to Programme providers.

##### **Criteria**

District Health Boards must ensure that:

1. training sessions are coordinated and offered to all Programme providers responsible for the delivery of the Programme
2. training sessions cover processes and procedures pertaining to the Programme including:
  - a. eligibility for the Programme
  - b. providing pre-HIV Test discussion and information to pregnant women
  - c. explaining to pregnant women that HIV screening, by way of an HIV test, is recommended but that they can choose not to participate
  - d. discussing the validity and limitations of HIV tests including false positives and false negatives
  - e. when and by what means the pregnant woman can expect the HIV test results to be reported to her
  - f. the lab algorithm and procedures and timeframes for testing samples and requesting second samples if necessary
  - g. the management options available to a woman if her HIV Test result is positive and the effectiveness of those options

- h. the importance of receiving informed consent from each pregnant woman prior to proceeding with the HIV Test and the procedure for recording whether she consents or declines.
- 3. training sessions are conducted on a routine basis.

### 1.3 Data Management

#### Standard 15

All data collected is relevant, accurate, reliable, reported in a consistent and timely manner, and used and stored in a manner that complies with relevant legislative requirements and Government policy on personal health information.

#### Criteria

1. District Health Boards' data management must conform to relevant legislation and to the guiding principles of data collection and management as described in the New Zealand Health Information Service's Guide to the National Health Collections (New Zealand Health Information Service, 2006).
2. District Health Boards must ensure that staff involved in the Programme:
  - a. sign a confidentiality declaration in relation to health information at the commencement of their employment
  - b. know, understand and adhere to all legal, ethical and professional obligations in relation to privacy and confidentiality of patient information and follow the written protocols for the maintenance of the privacy and confidentiality of each woman's information.
3. As a minimum DHBs must record and store in a manner consistent with privacy legislation:
  - a. details of women tested (NHI, name and date of birth)
  - b. name and screen requestor type of the Maternity Provider who ordered the tests
  - c. date the initial sample was collected
  - d. date the initial sample was received at the testing laboratory
  - e. whether an antenatal HIV Test was requested along with the first antenatal blood screen of tests or separately to the first antenatal screening blood tests
  - f. the laboratory that received the blood specimen for the test
  - g. the laboratory that processed the HIV test
  - h. the date the initial HIV test was reported back to the Maternity Provider who ordered the test
  - i. the screening test result (reactive or non-reactive)
  - j. the date, if any, a confirmatory blood sample was requested for confirmatory testing
  - k. the date the second sample for confirmatory testing was collected
  - l. the date the second sample was received at the confirmatory testing laboratory
  - m. the result of the confirmatory test (HIV positive or negative)
  - n. the laboratory that processed the confirmatory test
  - o. the date the confirmatory result was reported back to the referring laboratory

- p. if the confirmatory result was HIV positive, the date the positive confirmatory test result was reported to the Maternity Provider who ordered the test
- q. the date the HIV positive test result was conveyed to the woman
- r. if a woman is confirmed as having HIV, the outcome of her pregnancy
- s. the details of known HIV positive pregnant women who give birth in each calendar month, including:
  - i. whether they were diagnosed prior to or during pregnancy (if during, whether via antenatal screening in accordance with the Programme or otherwise)
  - ii. whether they accepted treatment
  - iii. whether delivery is by caesarean section or vaginal delivery
  - iv. whether they are breast feeding their baby
  - v. any adverse events
- t. the details of babies of known HIV positive pregnant women, including:
  - i. whether the baby is infected with HIV or not
  - ii. what treatment is given
  - iii. any adverse events
- u. the number of pregnant women receiving antenatal care in a DHB region.

## 1.4 Data Collection

### Standard 16

Accurate and reliable data is collected that enables DHBs and the NSU to undertake Programme monitoring and evaluation at both a regional and national level.

### Criteria

District Health Boards must ensure that:

1. data is collected and analysed to:
  - a. regionally and nationally monitor the Programme in accordance with the Programme's monitoring and evaluation plan
  - b. support effective business processes
  - c. inform future policy and Programme development decisions.
2. systems and procedures are developed to ensure that:
  - a. data is captured in a complete, timely and accurate manner
  - b. checks are undertaken to identify any errors that may arise during data entry.
3. regional Programme reports are provided to the NSU each quarter
4. each quarter collated data is provided to the National Screening Unit in accordance with the Programme's monitoring and evaluation plan.

## 1.5 Un-Booked Women Presenting in Labour

### Standard 17

District Health Boards and Maternity Providers should where possible work together to ensure that women presenting un-booked in labour or requiring urgent delivery are offered an HIV test in accordance with these standards, when ever such testing is possible, in a timely manner.

### **Criteria**

1. Women who present unbooked in labour or requiring urgent delivery should, where possible, be offered an HIV screening test in labour if there is an opportunity to obtain informed consent.
2. If it is not possible or appropriate to obtain informed consent prior to the birth, an offer should be made for testing shortly after the baby is born.
3. Where women are to be offered a test in labour they must be informed as part of the pre-test discussion of the potential for a reactive EIA result/positive rapid HIV test followed by a negative confirmatory test, and the treatment that may be recommended while awaiting a confirmatory test result.
4. The test procedure used for screening is EIA testing unless the DHB does not provide a 24 hour laboratory service. In which case a rapid HIV test can be performed within a laboratory by laboratory staff on-call.
5. Women may be offered preventative obstetric care based on a reactive EIA test/positive rapid HIV test and oral and/or intravenous medication may be offered to her and her baby. In such cases, a discussion with a pathologist and specialist team should be sought, so as to create a treatment plan based on the individual test results and the availability of local services.
6. Local recommended referral, testing and treatment algorithms and protocols should be followed in consultation with a consultant obstetrician, a pathologist or infectious diseases/HIV consultant, the maternity provider and the woman.
7. DHBs should carefully consider the risks of offering rapid HIV or EIA testing to women in labour, based on the likely prevalence of HIV within their catchment areas.

## **1.6 Processes to Support, Monitor and Treat Women that are Diagnosed with HIV and HIV exposed Newborns**

### **Standard 18**

District Health Boards must ensure that there are defined systems and processes to support and treat women diagnosed with HIV as part of the Programme and their newborns.

### **Criteria**

District Health Boards will ensure that:

1. a referral and treatment algorithm in respect of HIV positive pregnant women is in place including access to counseling services, infectious disease consultants, or HIV specialists
2. local guidelines regarding the management of pregnant women diagnosed with HIV are available to health care practitioners in each birthing unit
3. a protocol regarding the use of antiretroviral drugs is in place
4. guidelines regarding the pediatric management of HIV exposed newborns, including a system for ruling out HIV infection in HIV exposed newborns are in place.

## **1.7 Serious Adverse Events**

### **Standard 19**

District Health Boards must ensure that there are robust processes for managing serious adverse events.

### **Criteria**

1. DHBs must systematically record all adverse events and report them to the relevant NSU manager.
2. Local and national feedback must be provided to the NSU on cases of transmission/infection despite antenatal diagnosis and on missed cases. Care must be taken to ensure that these activities do not breach privacy laws.
3. If an adverse event occurs, District Health Boards are to manage and evaluate each of these in order that opportunities to improve service delivery can be identified.
4. If an opportunity for improvement is identified, its implementation must be expedited.

## **1.8 Complaints**

### **Standard 20**

District Health Boards must provide a procedure for women, their families and other interested parties to make complaints. This procedure will comply with the Code of Health and Disability Services Consumers' Rights 1994.

### **Criteria**

District Health Boards must ensure that:

1. the complaints procedure is made known to women, their families and other interested parties via pamphlets and Maternity Providers
2. all parties are heard
3. the person handling the complaint is impartial and acts fairly
4. complaints are handled at the level appropriate to the complexity or gravity of the complaint
5. any corrective action required following a complaint is undertaken
6. the complaints procedure sets out the various complaints bodies to whom complaints may be made and the process for doing so. Women will further be advised of their right to direct their complaint to the Health and Disability Commissioner, particularly in the event of the non-resolution of a complaint
7. complaints are handled sensitively with due consideration of cultural or other values
8. complainants who require support, have access to an appropriate support person to support them during the complaints process
9. women who complain must continue to receive Programme services
10. complaints are regularly monitored by the management of the particular service and trends identified in order to improve service delivery
11. complaints are recorded in the Programme monitoring report, which is sent to the NSU.

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