

NSW Framework and Standard Operating Procedure for HIV Point of Care Testing

Summary This Framework has been developed to guide the delivery of high quality, safe, sustainable and appropriate Point of Care Testing (PoCT) for HIV within NSW Health supported non-laboratory settings in NSW in order to increase uptake of HIV testing among high risk groups, increase the proportion of people who receive their test result, and reduce the number of people with undiagnosed HIV infection.

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General Practitioners

NSW FRAMEWORK AND STANDARD OPERATING PROCEDURE FOR HIV POINT OF CARE TESTING

PURPOSE

This Framework has been developed to guide the delivery of high quality, safe, sustainable and appropriate Point of Care Testing (PoCT) for HIV within NSW Health supported non-laboratory settings in NSW in order to increase uptake of HIV testing among high risk groups, increase the proportion of people who receive their test result, and reduce the number of people with undiagnosed HIV infection.

KEY PRINCIPLES

Point of Care Testing (PoCT) is one pathway to increase testing for HIV, particularly among high risk groups who can experience barriers to testing, including the need to attend a health service to access a test, time taken for test results to be available, poor access to health care providers, stigma and the risk of discrimination. PoCT addresses these barriers through increasing access, supporting autonomy, and providing convenience. PoCT should be offered where possible in conjunction with STI screening and/or conventional HIV testing.

Based on the epidemiology of HIV infection, PoCT for HIV is appropriate for gay men and other men who have sex with men (MSM). PoCT for HIV is generally not appropriate in populations with a low prevalence of undiagnosed HIV infection because of the lower positive predictive value of PoCT in these populations.

Only PoCT devices approved by the Therapeutic Goods Administration (TGA) can be used for HIV testing in Australia. Testing must be conducted in accordance with any product specific conditions placed on the test by the TGA. Information on approved tests and product specific conditions is available from the TGA website www.tga.gov.au.

For a PoCT site to be eligible to operate under the NSW Framework and participate in the NSW Health Quality Assurance and Safety package from the St Vincent's NSW State Reference Laboratory for HIV, it is required to use the NSW Health recommended HIV PoCT device.

A PoCT site that elects to operate outside the NSW Health Framework and the NSW Health Quality Assurance and Safety package would require a strong justification for using an alternative HIV PoCT device to that NSW Health recommended device. In these circumstances, each site should be assessed on a case by case basis and would be required to make a submission to NSW Health outlining the relative benefits of the alternative test with regards to service efficiency, client throughout and test performance for the particular site submitting the application.

USE OF THE GUIDELINE

This Framework is for NSW Health, other NSW Government departments, health professionals, others involved in the delivery of health services and non-government organisations involved in providing HIV related services.

REVISION HISTORY

Version	Approved by	Amendment notes
July-2109 (GL2019_010)	Deputy Secretary, Population and Public Health	Revisions to ensure the NSW Framework and SOPs for HIV PoCT are fit for purpose.
December 2015 (GL2015_018)	Deputy Secretary, Population and Public Health	Patient information sheet was replaced.
December 2015 (GL2015_015)	Deputy Secretary, Population and Public Health	Revisions to ensure the NSW Framework and SOPs for HIV PoCT are fit for purpose.
January 2015 (GL2015_003)	Deputy Secretary, Population and Public Health	New guideline.

ATTACHMENTS

1. Framework and Standard Operating Procedure – For the Provision of Point of Care Testing for HIV in Clinical and Non-clinical Settings: Procedure.

Standard Operating Procedures for the Provision of HIV Point-of-Care Testing



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1 BACKGROUND

1.1 Purpose

This Framework has been developed to guide the delivery of high quality, safe, sustainable and appropriate Point of Care Testing (PoCT) for HIV within NSW Health supported non-clinical and clinical settings in order to:

- Increase uptake of HIV testing and frequency of HIV testing among high risk groups, predominantly gay men and other men who have sex with men.
- Increase the proportion of people who receive their test result.
- Reduce the number of people with undiagnosed HIV infection.

Self-testing for HIV is outside the scope of this Framework.

1.2 Context

In NSW, a significant proportion of people infected with HIV are undiagnosed and do not know that they are infected. Undiagnosed individuals are at higher risk of developing HIV related morbidities and pose a risk of transmitting HIV to others.

Increasing the frequency of HIV testing in priority populations in accordance with risk is a key priority of the NSW HIV Strategy 2016-2020. This is essential for early access to treatment and reduced morbidity, mortality and onward transmission of HIV infection.

Under the strategy, NSW has provided a range of testing options to increase access and make it easier to have a HIV test, including Point of Care testing and conventional blood tests.

Point of Care Testing (PoCT), also known as rapid testing, is performed near to, or at the side of a patient by a trained health professional or care provider. PoCT is one pathway to increase testing for HIV; particularly among high risk groups who can experience barriers to testing including the need to attend a health service to access a test, time taken for test results to be available, poor access to health care providers, stigma and the risk of discrimination. PoCT addresses these barriers through increasing access, supporting autonomy, and providing convenience.

1.3 Audience

The audience for this Framework is NSW Health, other NSW Government departments, health professionals, others involved in the delivery of health services and non-government organisations involved in providing HIV related services.

1.4 Service Model

1.4.1 TGA approved tests

Only PoCT devices registered by the Therapeutic Goods Administration (TGA) can be used for HIV testing in Australia¹. Testing must be conducted in accordance with any product specific conditions placed on the test by the TGA. Information on registered tests and conditions is available from the TGA website www.tga.gov.au/conditions-approval-artg-hiv-poct.

1.4.2 NSW Health recommended HIV PoCT device

For a PoCT site to be eligible to operate under the NSW Framework and participate in the NSW Health Quality Assurance and Safety package from the St Vincent's NSW State Reference Laboratory for HIV, it is required to use the NSW Health recommended HIV PoCT device. The recommended HIV PoCT device is nominated by an expert panel who review all TGA registered devices annually against a key quality and performance criteria to ensure best clinical practice for HIV PoCT in NSW. All TGA registered devices will be reviewed on an annual basis by the expert panel to ensure recommendations are contemporary and reflect changes and improvements in performance made by the manufacturer of the device. The key quality and performance criteria for assessing HIV PoCT devices includes Affordability, Sensitivity, Specificity, User-friendliness, Rapidity/time to result and whether the device is robust and Equipment-free.

A PoCT site that elects to operate outside the NSW Health Framework and the NSW Health Quality Assurance and Safety package would require a strong justification for using an alternative HIV PoCT device to that NSW Health recommended device. In these circumstances, each site should be assessed on a case by case basis and would be required to make a submission to NSW Health outlining the relative benefits of the alternative test with regards to service efficiency, client throughput and test performance for the particular site submitting the application.

1.4.3 Populations for whom PoCT may be appropriate

Based on the epidemiology of HIV infection, PoCT for HIV is appropriate for gay men and other men who have sex with men (MSM) in NSW.

PoCT for HIV is generally not appropriate in populations with a low prevalence of undiagnosed HIV infection because of the lower positive predictive value of PoCT in these populations. There is an individual and system cost to the high number of false reactive results that may occur when PoCT for HIV is used for testing individuals with a low pre-test probability of HIV infection. There may be circumstances where there is a decision at a local level that PoCT is clinically appropriate for lower HIV incidence, harder to reach populations, provided they are given appropriate information and support regarding PoCT for HIV. This may be where an individual is diagnosed with a condition that shares a transmission route with HIV and the person is unlikely to access conventional testing.

¹ Non-TGA approved tests may be used in research. See www.tga.gov.au for further information.

1.5 Use of PoCT

PoCT for HIV should be used as a screening test for HIV infection only, and are not suitable for use as a diagnostic test. A PoCT for HIV may be offered without concurrent venepuncture if:

- it can be demonstrated that the benefits to be gained from the use of HIV PoCT outweigh any potential risks arising from its use
- the client is given appropriate information and support regarding the potential disadvantages of HIV PoCT in comparison to a conventional test. A standard patient information sheet for HIV PoCT has been developed for NSW and is located at Appendix G of the attached Standard Operating Procedures (SOP).

If a client has symptoms consistent with a seroconversion illness or may have acquired an HIV infection in the previous 6-12 weeks, PoCT for HIV should not be used and the client should be administered a laboratory-based blood test for HIV or if a PoCT is used a venous sample of blood should be collected at the same time for conventional lab testing. The possibility of recent HIV infection should also be noted on the laboratory test request form. Further details on circumstances where clients should be administered a laboratory-based blood test for HIV is outlined in the attached SOP.

1.5.1 Sites for PoCT

Sites for which PoCT for HIV may be appropriate include within non-clinical and clinical settings. Sites providing PoCT for HIV must comply with the conditions outlined in Section 6 of this Framework and use the NSW Health recommended HIV PoCT device.

Provision of PoCT for HIV may be offered in non-clinical settings:

- to engage individuals in HIV testing for the first time and/or to increase test frequency according to guidelines
- as an innovative or novel testing approach, to raise awareness of the importance of HIV testing

Examples of non-clinical settings include community based services, fixed and temporary shopfront sites, pop-up event based sites and within established commercial businesses such as sex on premises venues.

Provision of PoCT for HIV may be offered in established clinical settings:

- with a medium-high caseload of gay men and/or MSM
- to engage individuals in HIV testing for the first time and/or to increase test frequency according to guidelines
- before prescribing Post Exposure Prophylaxis (PEP). In this instance the client will require a laboratory test in three months.

1.6 Conditions for the provision of safe and high quality PoCT

Provision of safe and high quality PoCT requires that:

- The testing environment is fit for purpose. All equipment is calibrated and in good working order, all procedures are documented and carried out accurately, efficiently and safely and the wellbeing and confidentiality of the client is respected.
- A formal supervisory relationship has been established with an approved HIV testing laboratory that complies with NATA and National Pathology Accreditation Advisory Council (NPAAC) standards for medical testing and specifically HIV testing. In NSW, a Quality Assurance and Safety package from the St Vincent's NSW State Reference Laboratory for HIV to support the delivery of HIV PoCT in NSW has been put in place. An overview of this package is provided in the attached SOP.
- The SOP for HIV PoCT in NSW is adopted by sites providing HIV PoCT (inclusive of clinical and non-clinical settings). The SOP is an attachment of this Framework and includes:
 - establishing appropriate clinical governance
 - the standard workplace health and safety assessment
 - participation and compliance with the NSW Health endorsed quality assurance and safety package
 - the proficient standard for sites.
 - Information ensuring testing is available within or supported by a clinical setting under the auspice of a NATA/Royal College of Pathologists of Australasia medical testing accredited laboratory
 - Information on administering a test and delivering a test result
 - Establishing a mechanism for confirmatory testing for clients who receive a reactive or invalid test result
 - the minimum standard information for clients before verbal consent to undergo the test
 - Involvement of peers where appropriate.
- HIV PoCT is administered and read by an accredited² health professional or by someone trained in PoCT for HIV under the direct supervision of an accredited health professional. Accredited health professionals administering or reading a test, or providing direct supervision to others, must work for an organisation that:
 - has an established relationship with a NATA accredited medical testing laboratory; and
 - participates in an HIV PoCT external quality assurance program; and provides a declaration to the sponsor every 12 months that all health professionals using the device have received training in the delivery and administration of HIV point of care devices.

² A health professional is accredited following completion of an approved training package and completion of site based competency assessments in accordance with the standards set by the St Vincent's NSW HIV State Reference Laboratory.

1.7 Funding

Funding of HIV PoCT is a matter for Local Health Districts and Specialty Health Networks.

1.8 Comprehensive screening

HIV PoCT may be offered alone or in conjunction with STI screening and/or conventional HIV testing. The appropriate model will depend on the population, setting and individual client. The provision of HIV PoCT provides an opportunity to conduct concurrent comprehensive screening for STIs, hepatitis C and hepatitis B. Clients receiving PoCT for HIV in NSW should be offered appropriate testing with the option to opt out as desired. Hepatitis B vaccination should be recommended to those who are not immune to hepatitis B.

1.9 Evaluation and Monitoring

Appropriate evaluation and monitoring must be undertaken for each NSW Health supported site providing PoCT for HIV. This is essential to support best clinical practice and for monitoring the impact and outcomes of implementing PoCT for HIV in NSW. A standard data collection form is located at Appendix I in the attached SOP.

2 SITE DETAILS

The following site details should be recorded and stored at the front of the HIV Point-of-Care Testing (PoCT) site folder provided by The NSW State Reference Laboratory for HIV:

- a. Site name:
- b. Site address:
- c. Site contact number:
- d. Site setting (clinical; non-clinical). If non-clinical please state (fixed shopfront; temporary shopfront; pop-up event; commercial business):
- e. Name of site supervisor and contact details:
- f. Name of clinic director and contact details:
- g. Name of local health district:
- h. HIV PoCT initiation date:
- i. HIV PoCT closing date (date service ceased):
- j. Days and hours of operation:
- k. HIV PoCT used at this site:

See Attachment 1: Site Details Template

3 SERVICE MODEL

3.1 HIV PoCT Proficiency

For a site to be deemed eligible to provide HIV PoCT under this framework, a site is required to use the recommended HIV PoCT device* and meet the proficiency standard for NSW.

**See Section 1.5.1 TGA approved tests, NSW Framework and Standard Operating Procedures for HIV Point-of-Care Testing in Clinical and Non-Clinical Settings, version 2.0*

See Attachment 2: Overview of the NSW Endorsed Training HIV PoCT

See Attachment 3: Operator Competency Assessment Checklist

3.2 HIV PoCT Target Testing Populations

Individuals are eligible for a PoCT for HIV if they self-select as belonging to one of the following risk groups:

- Gay men
- Other men who have sex with men

3.3 Additional HIV Testing Populations

As HIV PoCT is not generally appropriate in populations with a low prevalence of undiagnosed HIV infection, people who do not identify as gay men or other men who have sex with men should be offered a laboratory-based blood test for HIV or referred to a local doctor for a HIV test. These populations include:

- Individuals with signs of seroconversion
- Individuals from a high prevalence country
- Individuals who have engaged in risk behaviour in a high prevalence country
- Individuals who have had multiple sexual partners or a recent partner change

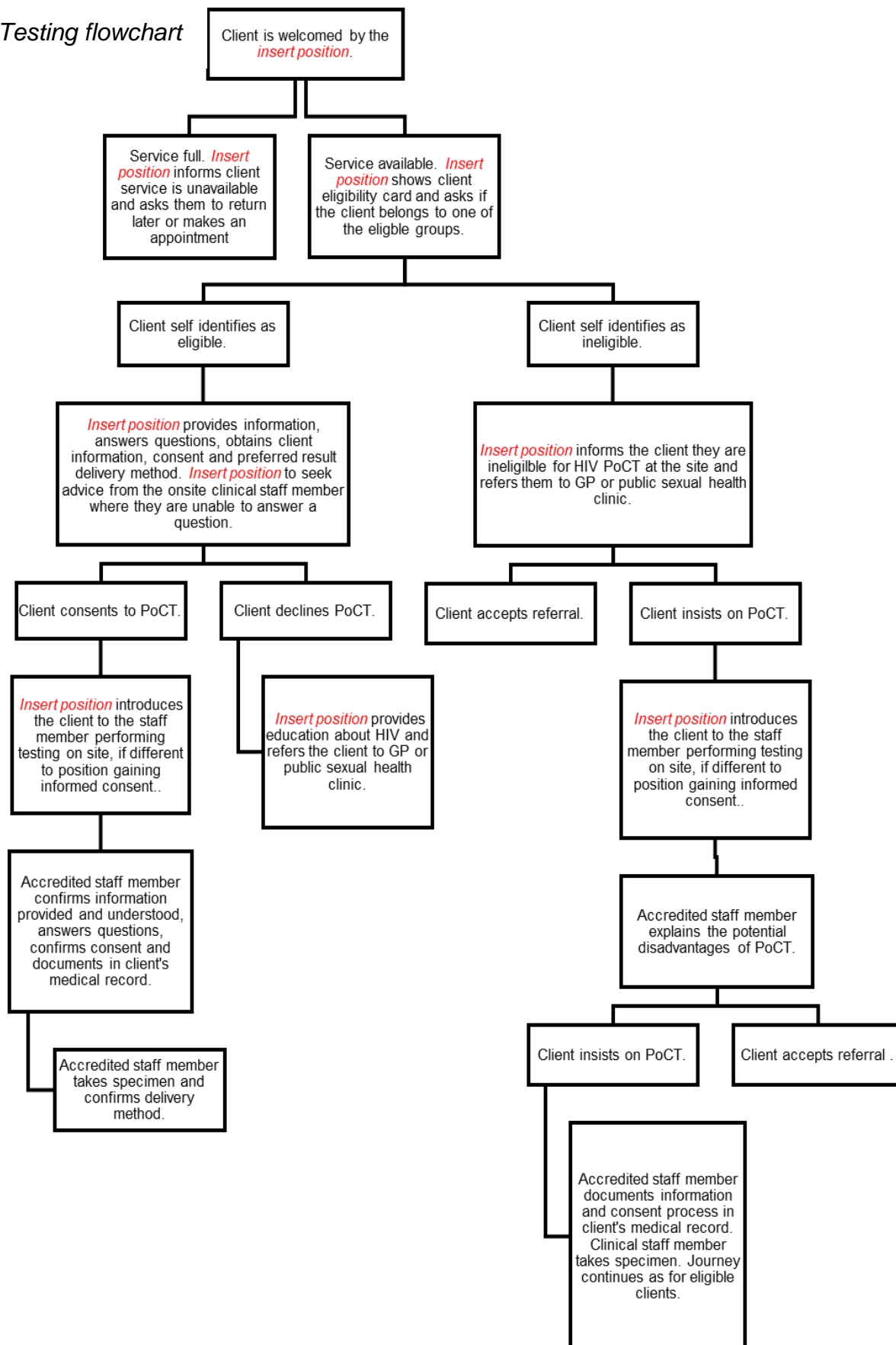
See Attachment 4: High HIV Prevalence Countries

If an individual for whom a laboratory-based blood test for HIV is indicated insists on having an HIV PoCT, they should not be denied a screening test. The potential disadvantages of HIV PoCT should be explained to them with their consent documented in their medical record.

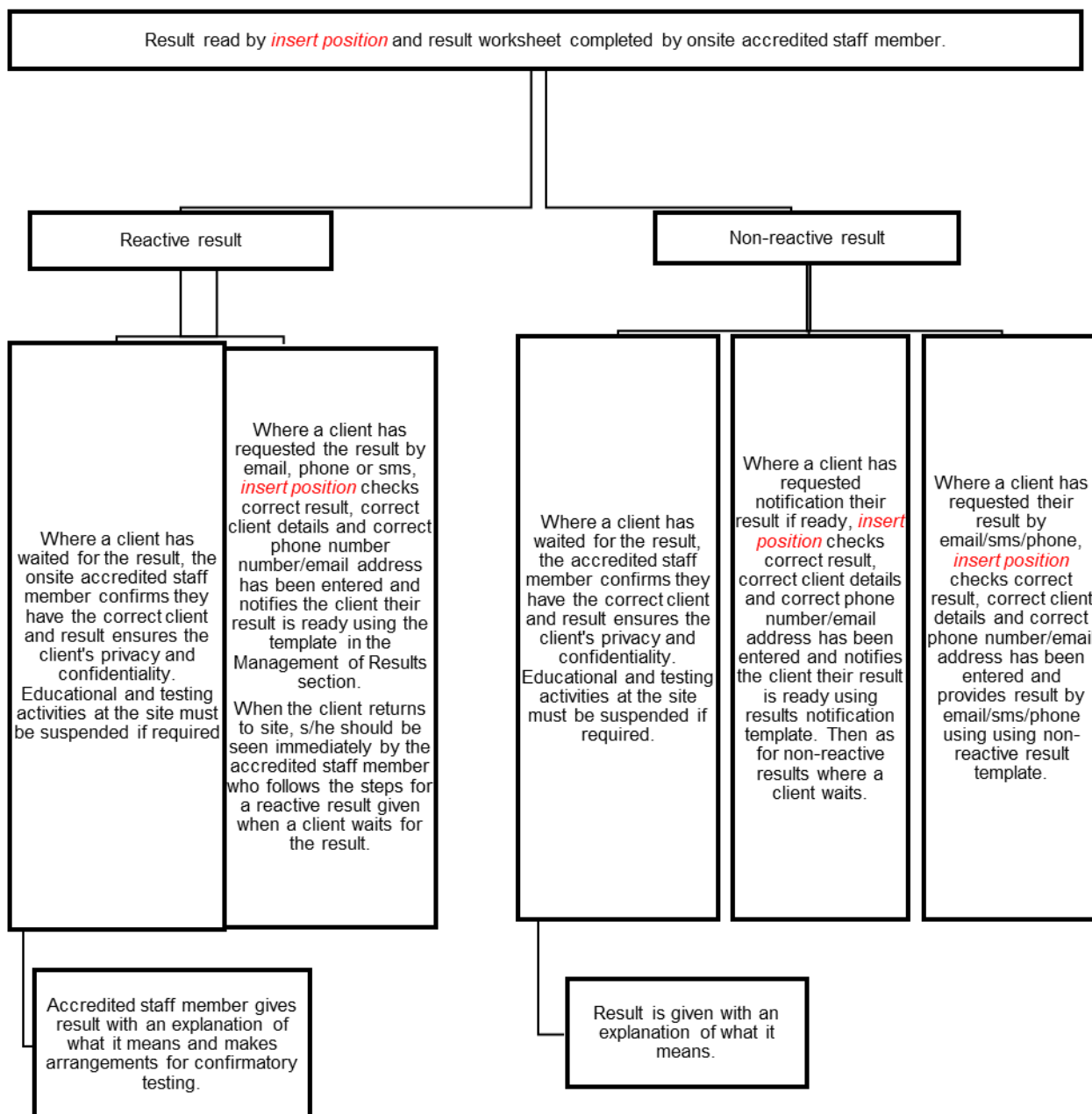
3.4 Client Journey

The testing and results flowcharts detail the steps of the client journey and should be completed for each site. The specific position that will perform each task should be clearly listed. For example, if the staff member is a Registered Nurse, “RN” should replace “*insert position*” in the flowchart.

Testing flowchart



Results flowchart



4 TRAINING, ACCREDITATION AND ONGOING SUPERVISION

A formal agreement has been established between The NSW Ministry of Health and The NSW State Reference Laboratory for HIV, St Vincent's Hospital, Sydney to deliver a quality assurance and safety package to support the provisions of HIV PoCT in NSW. Through this package, sites that meet the proficiency standard to offer HIV PoCT will have access to:

- Competency training for staff
- Quality assurance and site management activities including the distribution of supplies
- Compliance checks with the framework and clinical governance oversight
- Lot release testing and proficiency sample testing
- Site assessments
- Technical and troubleshooting support
- Preparation of site documentation

See Attachment 5: Overview of the Quality Assurance and Safety Package

4.1 Training for HIV PoCT

Individuals must undergo the NSW Ministry of Health endorsed training for HIV PoCT developed by the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine (ASHM). The training program consists of three modules, two online and a third face-to-face practical session, which takes approximately 2.5 hours.

See Attachment 2: Overview of the NSW Endorsed Training for HIV PoCT

Non health-care professionals are required to abide by the Australian Charter of Healthcare Rights and Code of Conduct for Unregistered Health Practitioners.

See Attachment 6: Australian Charter of Healthcare Rights and Code of Conduct for Unregistered Health Practitioners

4.2 Competency Standards

Following successful completion of the approved training program, an operator must complete the operator competency assessment checklist to receive HIV PoCT accreditation. The completed checklist is evidence of training and should be documented and held in the HIV PoCT site folder with a copy emailed to the HIV PoCT Coordinator at the NSW State Reference Laboratory for HIV.

See Attachment 3: Operator Competency Assessment Checklist

4.3 Refresher Training

A site should have documented criteria for when staff require retraining, which may need to occur due to infrequent testing, critical incident generation and/or the implementation of new testing methods.

*NPAAC Guidelines For Point-of-Care Testing, 1st Edition 2015, Section G4, pg11

If a staff member has not performed an HIV PoCT within a 12-month period or there has been a break in service at a site for longer than 12 months, then each trained staff member should undertake an online refresher course provided by ASHM's eLearning website. The certificate generated for the refresher course should be kept by each staff member with a copy kept in the site folder and a copy emailed to the HIV PoCT Coordinator at St Vincent's AMR.

4.4 Training Records

The ASHM training certificate and Operator Competency Assessment Checklist must be retained by each trained operator throughout the duration of their employment with a copy of each filed in the HIV PoCT Site Folder. When a staff member resigns, these documents must remain in the HIV PoCT site folder for a minimum of three years from the date of resignation.

*NPAAC Requirements for the Retention of Laboratory Records and Diagnostic Material, Sixth Edition, 2013

See Attachment 3: Operator Competency Assessment Checklist

The NSW State Reference Laboratory for HIV provides a site folder to each approved site to manage HIV PoCT related procedures, training records and test results. The HIV PoCT folder must be maintained by the site coordinator and will be monitored for compliance with the quality framework by the NSW State Reference Laboratory for HIV annually or as required.

See Attachment 14: Monitoring Report Template

5 QUALITY ASSURANCE

The TGA stipulates a condition of use that all operators and sites performing HIV PoCT are engaged with an approved quality assurance program. External Quality Assurance Programs (EQAS) are mandatory while proficiency testing is best practice. Proficiency test samples will be supplied to PoCT sites in NSW by the NSW State Reference Laboratory for HIV.

5.1 EQAS

- Provided by an external provider two to four times per year usually involving two-five samples each
- In Australia there are two providers of EQAS; National Serology Reference Laboratory (NRL) and the Royal College of Pathologists (RCPA)
- Sites are enrolled with the provider and receive, test and submit test results obtained
- Sites are provided with a unique identification number
- De-identified results are returned to sites in a report which contains results aggregated with other testing sites results. Sites can review their results against consensus to self-identify quality issues.
- EQAS programs involve an enrolment fee of approximately \$400 per annum. The cost of this program is usually supported by the site.

5.2 Proficiency Samples

- Provided with test kits by the NSW State Reference Laboratory for HIV at St Vincent's Hospital, Sydney
- Proficiency samples are known reactive and negative samples and are to be used in training for staff members to retain PoC testing proficiency
- Adequate supplies of the proficiency samples are stored at the site and assist with quality assurance of refrigeration checks
- Each site should perform a proficiency sample test every fortnight, rotating between trained staff members to ensure operator competency

5.3 Data Retention

All documents pertaining to quality assurance and quality management must be retained in the HIV PoCT Site Folder for a minimum of three years from the date of issue as stipulated by NPAAC guidelines. Personnel PoCT training records must be retained in the HIV PoCT Site Folder for the period of employment plus three years following resignation.

*NPAAC Requirements for the Retention of Laboratory Records and Diagnostic Material, Sixth Edition, 2013

6 CLINIC PROCEDURES

6.1 Staffing of the Site

Staff roles must be identified and include staff rostering, staff contact details, and roles responsible for arranging and conducting supervision and competency assessments.

6.2 Standard Operating Procedures for HIV PoCT

The technical procedures for the correct operation and interpretation of the NSW recommended device is provided with the test kit.

6.3 Inclusion Criteria

- Individuals aged 16 years or older

Primary Testing Population

- Gay men
- Other men who have sex with men

Secondary Testing Population

- Individuals with signs of seroconversion
- Individuals from a high prevalence country
- Individuals who have engaged in risk behaviour in a high prevalence country
- Individuals who have had multiple sexual partners or a recent partner change.

The accredited staff member should verbally explain eligibility, show the eligibility card and ask if the individual belongs to one of the groups for who HIV PoCT is appropriate.

See Attachment 7: Eligibility Card

6.4 Informed Consent

Before undergoing testing, individuals must be provided with sufficient information, in a form they can understand, to enable them to make an informed decision about undergoing a HIV PoCT. The minimum information that must be provided before the client consents (or not) to the test is:

- A description of HIV PoCT, including how it differs from laboratory-based HIV testing
- A list of people for whom HIV PoCT may be appropriate
- A description of how the test is conducted
- A description of privacy and confidentiality related to testing and results
- Information about test accuracy, including the window period

- Information about provision and interpretation of results
- The potential implications of not being tested

It may be helpful to provide clients with an information sheet they can take away with them. However, the information sheet does not replace the need to convey the information verbally and confirm with the client that they have understood the information.

See Attachment 8: Patient Information Sheet

Translated material and/or an interpreter must be used where this is required or the person obtaining consent from the client determines that this is appropriate. Verbal consent is required in all cases.

Before taking the sample, the staff member performing the test must confirm with the client that they have been provided with and understand all information about the test with consent documented in the client's medical record. Where the client has requested the test despite a PoCT not being the most appropriate HIV test for her/him, the staff member must document this in the client's medical record.

6.5 Data Collection and Reporting

Each site providing HIV PoCT needs to collect the minimum client information which is located at *Attachment 9* "Standard Data Collection Form". Sites are required to report these data to the NSW Ministry of Health quarterly for monitoring and evaluations purposes.

Standard data collection for service specific data, such as appointment reminder and result delivery preferences, is also located at *Attachment 9*.

6.6 Medical Records

A medical record must be recorded by each site providing HIV PoCT for each client.

See Attachment 10: Medical Record Template

6.7 Supplies

Sites should list all materials being used for HIV PoCT and who is providing them.

6.8 Safe Work Practices for Performing HIV PoCT

Consult *Attachment 11* entitled "Standard Workplace Health and Safety Assessment" for safe work practices.

6.9 Occupational Exposure Procedures

Sites should specify the occupational exposure procedures for their site. The following items specific to the management of occupational exposures should be addressed:

- Occupational exposure policy of the governing/employing institution
- Steps that should be followed for an occupational exposure
- Information on the Needle Stick Hotline, which is available 24 hours on 1800 804 823

6.10 Security

Sites should specify the safety, security and emergency procedures for their site.

7 MANAGEMENT OF RESULTS

The method of results delivery depends on the nature of the result. As this is a screening test the possible results will be non-reactive or reactive. All clients should be given the option to receive their result by email, phone, sms or in person.

7.1 Non-Reactive Result

The client may wait in person or elect to be notified via email, phone or sms of their non-reactive result.

The process for notifying a client that their result is ready is:

- Check correct result and correct patient details
- Check the mobile number entered is correct
- Use the SMS template below. The same information should be provided if a phone call has been requested. The person making the call must check they are speaking with the correct person before providing the result.

Hi, your result is ready, please come back to [insert name of site] and ask for [insert name of person for whom they should ask]

The process for notifying a client of their non-reactive result is:

- Check correct result and correct client details
- Check the phone number or email address is correct
- Use the SMS/email template below. The same information should be provided if a phone call has been requested. The person making the call must check they are speaking with the correct person before providing the result.

*Hi, your test was non-reactive. This means there is no problem as of three months ago. If you have had an exposure within the last three months you will need to be tested again. Qs? Call [insert telephone number]
Regards [Insert name of person providing result]*

Where no telephone contact can be provided, the NSW Sexual Health Infolink number should be provided 1800 451 624.

7.2 Reactive Result

All reactive results must be given in person. The procedure is outlined in the testing flowchart. The same procedure should be followed for clients who elect to be notified their result is ready by email/sms/phone and clients who have elected to receive their result by email/sms/phone.

The procedure is:

- Check correct result and correct client details
- Check the phone number or email address entered is correct
- Use the SMS/email template below. The same information should be provided if a phone call has been requested. The person making the call must check they are speaking with the correct person before providing the result.

Hi, your result is ready, please come back to [insert name of site] and ask for [insert name of person for whom they should ask]

When the client arrives at the testing site, the accredited staff member is responsible for ensuring their privacy and confidentiality. This may mean suspending activities at the site for non-clinical settings. The following management must be initiated immediately:

- Clients with a reactive HIV PoCT are to be seen by the onsite accredited staff member
- Clients must be given the following information by the onsite accredited staff member:
 - Their test result and an explanation of the result
 - The need to have a confirmatory blood test
 - Where and how the confirmatory test will be conducted
 - The need to abstain from any behaviour that puts other people at risk including sex without a condom and sharing needles when injecting drugs or tattooing. It may be helpful to provide the person with written information on the behaviours from which they should abstain until they receive the result of their conventional test
- The onsite accredited staff member must document the information provided in the medical record
- The NSW Health clinical service that provides governance for the site has responsibility for contact tracing where there are immediate public health implications
- The onsite accredited staff member must document the information provided and the actions taken regarding confirmatory testing in the medical record.

Where the client does not return to receive a reactive result, a minimum of four attempts should be made to contact the person. These attempts should be made on different days, at different times using different method (eg. phone, email, letter) within a two-week period. If the client has still not returned, the case should be discussed with the person responsible for clinical governance.

7.3 Invalid Result

An invalid result means the test has not worked. All invalid results must be followed up with clients in person or over the phone.

Where a client has elected to wait for their result, they should be given their result immediately by the accredited staff member in a way that ensures their privacy and confidentiality.

The client should be offered a second PoCT or a confirmatory laboratory test for HIV, with an explanation of the advantages and disadvantages of each option. The information provided and option chosen by the client must be documented in the medical record by the accredited staff member.

The procedure for clients who have elected to be notified by email, phone or sms of their result is ready is:

- Check correct result and correct client details
- Check the phone number or email address entered is correct
- Use the SMS/email template below. The same information should be provided if a phone call has been requested. The person making the call must check they are speaking with the correct person before providing the result.

Hi, your result is ready, please come back to [insert name of site] and ask for [insert name of person for whom they should ask]

When the client returns to the site, the same procedure should be followed as for clients who waited to receive their result.

8 CLINICAL GOVERNANCE

8.1 Lines of Communication

Lines of communication for the test site must be specified.

8.2 Staff Role Descriptions

A role description for each position, including peer educator and on-site accredited staff member where applicable must be specified. The description should include governance lines for non-registered health care professionals.

8.3 Client Complaints/Feedback

The procedure for complaints/feedback from a client or a worker at the site must be specified

9 LIST OF ATTACHMENTS

1. Site Details Template
2. Overview of the NSW Endorsed Training for HIV PoCT
3. Operator Competency Assessment Checklist
4. High HIV Prevalence Countries
5. Overview of the Quality Assurance and Safety Package
6. Australian Charter of Healthcare Rights and Code of Conduct for Unregistered Health Practitioners
7. Eligibility Card
8. Patient Information Sheet
9. HIV Point of Care Testing Standard Data Form
10. Medical Record Template
11. Standard Workplace Health and Safety Assessment
12. Timer Calibration
13. Initiation Visit Template
14. Monitoring Report Template
15. Executive Summary

9.1 Attachment 1: Site Details Template

HIV POINT-OF-CARE TESTING	
SITE DETAILS	
Site Name:	
Site Address:	
Site Contact Number:	
Site Setting:	
PoCT Site Supervisor: Email:	
Clinic Director: Email:	
Local Health District:	
HIV PoCT Initiation Date:	
HIV PoCT Closing Date:	
Days & Hours of Operation:	
PoCT Used At This Site:	

9.2 Attachment 2: Overview of the NSW Endorsed Training for HIV PoCT

Module 1 – Overview of HIV Infection (online)

- The definition and difference between HIV and AIDS
- How HIV is transmitted
- Epidemiology
- The stages of HIV infection and progression
- HIV treatment
- HIV transmission prevention
- Quiz

Module 2 – Overview of HIV Testing (online)

- HIV Testing in Australia
- National HIV Strategy and National HIV Testing Policy
- Conventional and PoCT differences
- Appropriate populations for PoCT use
- PoCT testing devices
- Quiz

Module 3 – Performing HIV PoCT (face-to-face)

- Arrival and welcome
- HIV Point-of-Care Tests
 - Overview and revision of online modules
 - Gaining informed consent for HIV PoCT
- Performing HIV PoCT
 - Specimen collection
 - Performing the test
 - Delivering test results
- Specimen collection (demonstration and practical)
- Performing the test (demonstration and practical)
- Interpreting and recording test results
- Assuring the quality of HIV PoCT
 - Standard operating procedures
 - Staff competency
 - Quality control
- Module 3 quiz
- Evaluation
- Sign out and close

The first two modules will be delivered online and the third module is delivered in a face-to-face and practical session.

Pre-Reading and Course Materials

Trainees should familiarize themselves with the *NSW Framework and Standard Operating Procedures for HIV Point of Care Testing* and the PoCT device package insert located in the HIV PoCT site folder.

Course material will be provided on the day.

In addition, the following information will be useful as pre-reading :

<http://vimeopro.com/ashm/ashm-hiv-point-of-care-testing-module-4-performing-hiv-poct>

These video clips are from the WHO and CDC HIV Rapid Testing training package. They were designed to be generic to be used and adapted worldwide. Therefore some of the information may not be relevant to your specific work site or the HIV point of care test kit used.

You will be asked to review the following questions during the training session:

Initial Steps:

- What are the pre-test preparation steps?
- What safety precautions should you use?
- What should you look for in examining kits before use?
- How do you put your client at ease while performing the test?

Finger Prick:

- How do you ...
 - Position the hand?
 - Decide which finger to use?
 - Clean the fingertip?
 - Use a lancet?
 - Ensure blood flow from your client's fingertip?
- Do you ...
 - Use a previously used lancet on a client?
 - Collect the first drop of blood?

HIV Point of Care Test:

- What preparation is required for the test kit before testing?
- What are the components in the test kit?
- What information needs to be recorded, and where?
- How do you collect blood? What device do you use?
- For how long do you set the timer?
- How many results are possible? How do you read them?

Accreditation and CME Points

Attending the training and an associated competency assessment will be sufficient to provide rapid testing in your clinic.

Everyone wishing to gain accreditation as a PoCT operator (regardless of whether or not they are a clinician), will need to complete two online training modules in addition to the face-to-face training and the associated operator competency assessment.

To access the modules:

1. Click on '<https://lms.ashm.org.au>'
2. Create a log in
3. Click on 'Course Catalogue'
4. Click 'HIV' under course titles
5. Click 'HIV Point-of-Care Testing Training'
6. Complete modules 1 and 2

At the end of each module there is a short quiz. These online modules must be completed prior to the face-to-face practical training day. Please email the HIV PoCT Coordinator when these online modules have been completed.

For people who attend the training and complete the online modules, CME points and other professional development points may be awarded; more details will be provided at the training.

9.3 Attachment 3: Operator Competency Assessment Checklist

Trainee Name: **Type of Training:** Initial ☐ **Revision** ☐

Qualifications:..... **Site:**.....

Element	Operator must understand and explain the rationale and procedural task	Trainee	Supervisor
1. Workplace preparation	1.1. Prepares necessary equipment and supplies 1.2. Ensures workplace is private and comfortable 1.3. Supplies and inventory are adequate for duration of clinic 1.4. Checks expiry dates of tests and accessories (eg. chase buffer) 1.5. Ensures test and supply inventory is managed and records maintained 1.6. Prepares client worksheet or episode record (computer system) for collection of client information 1.7. Timers are available and calibrated	<input type="checkbox"/>	<input type="checkbox"/>
2. Workplace safety	2.1. Workplace design is fit for purpose 2.2. Privacy aspects are adequate 2.3. Understands clinic workflow 2.4. Hand washing / sanitizing between clients 2.5. No eating, drinking, cosmetics, smoking permitted in workplace 2.6. Personal protective equipment (eye protection, gloves) 2.7. Workplace (surface and waste) decontamination procedures 2.8. Disinfectant management/preparation procedures 2.9. Accident/incident reporting 2.10. Site emergency procedures (fire, evacuation) 2.11. Waste disposal procedures (sharps, contaminated, general waste)	<input type="checkbox"/>	<input type="checkbox"/>
3. Client consultation	3.1 Calls next client from waiting list 3.2 In consult room introduces self and designation 3.3 Checks correct client information	<input type="checkbox"/>	<input type="checkbox"/>
4. Communication	4.1 Communicates effectively 4.2 Uses pleasant and respectful manner, uses language appropriate to clients level of understanding, uses open body language 4.3 Establishes rapport via good communication 4.4 Creates non-judgemental environment	<input type="checkbox"/>	<input type="checkbox"/>

	<p>4.5 Avoids language that labels eg. Promiscuous</p> <p>4.6 Discusses confidentiality in relation to medical records and test reports</p> <p>4.7 Understands and clearly communicates pre-test information key messages include:</p> <p>4.8 What to expect from 'finger-prick' sample collection</p> <p>4.9 possible results – 'reactive', 'negative' or 'invalid' results</p> <p>4.10 'window period' and possible false results</p> <p>4.11 Point-of-care tests are not 'diagnostic'</p> <p>4.12 'Reactive' tests need laboratory confirmation</p> <p>4.13 'Invalid' tests are possible and may be repeated</p> <p>4.14 Determines client's level of understanding</p>		
5. Professional conduct	<p>5.1 Understands and operates within the professional conduct of the responsible service</p> <p>5.2 Maintains professional boundaries and does not disclose personal information - maintains client confidentiality</p> <p>5.3 Maintains a professional and friendly demeanour</p>	<input type="checkbox"/>	<input type="checkbox"/>
6. Reviews client history	<p>6.1 Assesses risk of infection and time of last exposure*</p> <p>6.2 Indications for other tests*</p> <p>6.3 If client discloses symptoms or less than 16 years of age seek medical attention</p> <p>6.4 Verifies clinical information and client ID in records*</p>	<input type="checkbox"/>	<input type="checkbox"/>
7. Immediate management plan – performance of test	<p>7.1 Offers HIV point-of-care test</p> <p>7.2 Obtains informed consent from client to perform test</p> <p>7.3 Completes necessary documentation</p> <p>7.4 Prepares test and labels with client ID</p> <p>7.5 Assesses preferred 'finger prick site, decontaminates site, activates lancet</p> <p>7.6 Wipes away first drop of blood</p> <p>7.7 Collection device operation (micro-pipette) – understands adequate volume requirements of test</p> <p>7.8 Applies blood to test followed by chase buffer</p> <p>7.9 Operates timer</p> <p>7.10 Relocates incubating test to separate location (away from client line-of-sight)</p> <p>7.11 Re-engage with client</p> <p>7.12 End of test incubation period - Interprets antibody/antigen and control lines reactivity</p> <p>7.13 Validates test overall result with second operator</p> <p>7.14 Completes Result Worksheet</p> <p>7.15 Conveys 'non-reactive' or negative result to client clearly</p>	<input type="checkbox"/>	<input type="checkbox"/>

	<p>7.16 Conveys 'reactive' point-of-care test result script to client clearly and arranges venous blood collection for confirmation</p> <p>7.17 Arranges ongoing management</p> <p>7.18 Result worksheets files in central location for audit</p> <p>7.19 Results recorded in patient medical record</p>		
8. Quality assurance	<p>8.1 Performs proficiency sample testing once per week – records retained and filed centrally for audit</p> <p>8.2 Proficiency samples are stored appropriately, mixed before use</p> <p>8.3 Reports 'invalid' tests to supervisor</p> <p>8.4 Supervisor reviews proficiency test results periodically</p> <p>8.5 External Quality Assurance programs are enrolled</p> <p>8.6 Results of EQAS are reviewed by all site operators and corrective actions</p> <p>8.7 All equipment is calibrated and monitored. Records kept available on audit.</p>	<input type="checkbox"/>	<input type="checkbox"/>
9. Operator proficiency (observed by supervisor)	9.1 Completes three (3) tests successfully using QC samples (observed)	<input type="checkbox"/>	<input type="checkbox"/>
	9.2 Completes three (3) finger-stick collections successfully (supervised)	<input type="checkbox"/>	<input type="checkbox"/>
	9.3 Completes three (3) clients tests successfully and conveys key messages (supervised)	<input type="checkbox"/>	<input type="checkbox"/>

* Peer Educators are not required to perform the tasks marked with an asterisk.

Trainee:

Trainee:

Signature:

Date:

Supervisor:

Supervisor:

Signature:

Date:

Clinic Director:

Clinic Director:

Signature:

Date:

9.4 Attachment 4: High HIV Prevalence Countries

High HIV prevalence countries are defined as countries where the general population HIV prevalence is greater than 1%.

Country	Adult (15-49) prevalence (%) for 2014
Swaziland	27.7
Botswana	25.2
Lesotho	23.4
South Africa	18.9
Zimbabwe	16.7
Namibia	16
Zambia	12.4
Mozambique	10.6
Malawi	10
Uganda	7.3
Equatorial Guinea	6.2
Kenya	5.3
United Republic of Tanzania	5.3
Cameroon	4.8
Central African Republic	4.3
Gabon	3.9
Guinea-Bissau	3.7
Cote d'Ivoire	3.5
Nigeria	3.2
Congo	2.8
Rwanda	2.8
South Sudan	2.7
Chad	2.5
Angola	2.4
Togo	2.4
Haiti	1.9
Guyana	1.8
Gambia	1.8
Jamaica	1.6
Djibouti	1.6
Guinea	1.6
Ghana	1.5
Mali	1.4
Sierra Leone	1.4
Ukraine	1.2
Belize	1.2
Ethiopia	1.2
Liberia	1.2
Thailand	1.1
Caribbean	1.1
Benin	1.1
Burundi	1.1
Cape Verde	1.1

Source: UNAIDS *How AIDS Changed Everything* Report - 2015

http://www.unaids.org/sites/default/files/media_asset/20150716_HIV2014Estimates_1990-2014.xlsx

9.5 Attachment 5: Overview of the Quality Assurance and Safety Package

1. Training and Preparation of Site Materials:

- Train-the-trainer for PoCT Supervisors at each site
- Coordination of training programs for all PoCT operators to deliver the 3 module training curriculum developed by ASHM
- Development of competency criteria for PoCT operators
- Administer a database of competent operators
- Supply and maintenance of site documentation including document controlled procedures, result worksheets, work instructions, patient information materials.

2. Test kits – Ordering and Distribution:

- Management of procurement of test reagents and accessory supplies for performance of the test.
- Inventory management at supported sites
- Distribution of supplies to sites
- Logistics management
- Test kit pre-release testing to monitor batch lot performance variances

3. Proficiency Sample Testing and Quality Assurance

- Enrolment in External Quality assurance programs (EQAS)
- Procurement and distribution of proficiency samples and management of sample storage
- Proficiency sample testing will be undertaken every 2 weeks at each site by different operators
- Review of EQAS results with sites to identify performance issues
- Proficiency testing for new operators as part of competency assessment
- Monitor reagent in-field reagent batch lot performance (eg. false positive and invalid test rates)

4. Laboratory Confirmatory Referral Services:

- Provision of streamlined referral process for venous samples identified by PoCT tests requiring confirmatory testing by conventional laboratory testing
- Daily confirmatory service for rapid turn-around time for confirmed results
- Pre-printed pathology referral request forms
- Site notification of new positive results

5. Site Audits:

- Periodic review of site for compliance with quality framework
 - i. Site procedures and documentation (site folders)
 - ii. Review of equipment performance and calibration
 - iii. Review of test performance
 - iv. Review of operator performance
 - v. Liaison with PoCT supervisor
 - vi. Training needs and operator competency records
 - vii. Workplace health and safety matters
- Collection of testing denominator data for each site
- Preparation of PoCT testing activity reports prepared for each site and provided to MoH periodically.
- Review of QC test result data

6. Troubleshooting and Technical Advice:

- Support to sites
- Review of abnormal results
- Review of proficiency sample test data
- Retraining for operators having difficulties
- Interpretation of difficult results and confirmatory test results

9.6 Attachment 6: Australian Charter of Healthcare Rights and Code of Conduct for Unregistered Health Practitioners

The Australian Charter of Healthcare Rights can be downloaded at:

<http://www.safetyandquality.gov.au/wp-content/uploads/2012/01/Charter-PDF.pdf>

The Code of Conduct for Unregistered Health Practitioners can be downloaded at:

<https://www.health.nsw.gov.au/phact/Documents/coc-unregistered-practitioners.pdf>

9.7 Attachment 7: Eligibility Card

Eligibility card – Gay men and other men who have sex with men

Rapid HIV tests are screening tests for HIV.

They are recommended for gay men and other men who have sex with men.

A standard HIV test is a better test for people in other groups, because there is a higher possibility that a rapid test will show they have HIV when they do not. A standard HIV test involves a blood sample that can be taken by a GP or *[insert site name or local sexual health clinic as applicable]*.

Please tell the *[insert position]* if you are in one of the groups recommended for rapid HIV testing.

(Insert page break)

Eligibility card – Additional groups

Rapid HIV tests are screening tests for HIV.

They are recommended for gay men and other men who have sex with men.

This site also provides tests for people who are *[insert group(s)]*.

A standard HIV test is a better test for people in other groups, because there is a higher possibility that a rapid test will show they have HIV when they do not. A standard HIV test involves a blood sample that can be taken by a GP or *[insert site name or sexual health clinic as applicable]*.

Please tell the *[insert position]* if you are in one of the groups recommended for rapid HIV testing.

9.8 Attachment 8: Patient Information Sheet

(Original file is attached as a separate document)

RAPID HIV TESTING

WHAT IS A RAPID HIV TEST?

A rapid HIV test is a screening device for HIV which uses either a small drop of blood from a finger prick or oral fluid to provide results within 10-30 minutes. (depending on the test used). They are conducted on-site by a specially trained health professional or care provider and are sometimes referred to as Point-of-Care Tests.

If your rapid test is reactive, there is a chance that you might be HIV positive but that is not certain – you will need a laboratory test to confirm the result. Laboratory HIV tests take longer – a few days to a week. They involve us collecting some of your blood with a needle, and sending it to the laboratory for testing by a technician.

WHO CAN HAVE A RAPID HIV TEST?

Rapid HIV tests are appropriate for groups of people who are at higher risk of HIV infection such as gay men and other men who have sex with men.

For other groups of people, laboratory testing is more suitable and we can refer you to other HIV testing services (please ask us for a list of local services). If you have a doctor you normally see, you could ask him or her about HIV testing.

If you have had a recent risk exposure or if you might be experiencing symptoms of a recent HIV infection (e.g. flu-like symptoms including fever, rash, headache, loss of appetite, muscle aches and swollen lymph nodes), please discuss this with the health provider, as a laboratory test may be better for you.

WHICH RAPID HIV TEST IS USED AT THIS SITE?

Three rapid HIV tests have been registered for use in Australia at this time. The health provider attending to you will be able to tell you which rapid test is being used at the service you are attending.

What are the possible results and what do they mean? There are three possible results:

- Non-reactive (no evidence of HIV infection)
- Reactive (potential evidence of HIV infection, but a laboratory test is needed to confirm if correct; we will arrange a laboratory test today if you have a reactive result)
- Invalid (the test did not work so another test needs to be done)

HOW ACCURATE IS THE RAPID HIV TEST?

Overall, rapid HIV tests are very accurate, however a small number of rapid HIV tests can give a false reactive result (around 1 in every 200 tests). This means the test reacts even though HIV is not present. Confirmation with a laboratory test is used to check whether the rapid test result is correct.

If a rapid test is conducted during the window period (i.e. the period after infection but before the test can detect the presence of the virus), the test may give a false-negative result. A non-reactive test today tells you that you were HIV negative three months ago.

Laboratory HIV tests can detect a recent HIV infection sooner than rapid HIV tests. Some laboratory tests can detect infections within approximately 3-6 weeks. If you have had a very recent risk that you are concerned about, please let us know so we can advise you about the best test for you.

HEALTH.NSW.GOV.AU

HOW DOES THE TEST WORK AND HOW LONG DOES IT TAKE?

A sample will be collected from you to put on the test device, either by oral swab or by pricking your finger with a lancet to obtain a small amount of blood. A solution is then added to the sample and the test allowed to develop.

Depending on the device used, the test may detect the presence of both HIV virus (antigen) and/or the proteins made by the body to fight off the virus (antibodies). The result is available within 10-30 minutes.

WILL MY PRIVACY AND CONFIDENTIALITY BE RESPECTED?

Your result will only be given to you. HIV is a notifiable disease, which means if the laboratory test confirms you have HIV infection, some information is sent to the NSW Ministry of Health. However your name is not provided, only a code.

HOW WILL I GET MY RAPID HIV TEST RESULT?

How you get your result will depend on the service that you are attending. In many cases it is easiest to wait for your result (around 15-30 minutes), particularly if you are having tests for sexually transmissible infections, which can be organised while you wait. In some cases you may be able to get your result by SMS, although if the result is reactive or invalid you will be asked to return to the testing site to get your result and have blood taken for a laboratory test.

WHAT HAPPENS IF I HAVE A REACTIVE RESULT?

If your rapid HIV test is reactive you will need to have a laboratory test for HIV. One of the staff at the testing site will explain the procedure and take the blood sample needed for the test. You will be offered access to support services while you wait for your result.

WHAT COULD HAPPEN IF I DO NOT HAVE A TEST FOR HIV?

You could have HIV and not know that you do. Knowing your HIV status is important for your own health and wellbeing and for preventing HIV being passed on to other people.

CAN I USE THE TEST MYSELF AT HOME?

No. There are no rapid HIV tests suitable for home use that are registered in Australia.

STAYING SAFE

You can protect yourself and others from HIV by always using a condom if you have anal or vaginal sex. Condoms provide effective protection against HIV for you and your partners, and help guard against STIs.



9.9 Attachment 9: HIV Point of Care Testing Standard Data Form

PROGRAMMING INSTRUCTION: # Denotes a compulsory field

Date: _____ Time: _____ Patient ID:

Given Name # _____ Family Name#

Date of Birth# _____ / _____ / _____
Day Month Year

Gender# ☐ Male ☐ Transgender

Street
address# _____

Suburb# _____ Postcode

Email# _____

Mobile Phone Number# _____

Do you identify as: # ☐ Aboriginal ☐ Torres Strait Islander ☐ Both ☐ Neither

Which country were you born in: #

Language spoken at home: #

Have you ever tested for HIV before? # ☐ Yes ☐ No

When was the last time you tested for HIV? #

- ☐ Within the last 3 months
- ☐ 3 to 6 months ago
- ☐ 6 - 12 months ago
- ☐ 1 - 2 years ago
- ☐ 2 - 5 years ago
- ☐ More than 5 years ago

What type of HIV test did you have the last time you tested? (please select more than one option if you had two types of tests at the same time)

- ☐ Laboratory test (my blood was sent to a laboratory)
- ☐ Rapid HIV test
- ☐ Home HIV test
- ☐ I am not sure

Where did you have your last HIV test?

- ☐ GP
☐ Sexual health clinic
☐ a[TEST] (ACON's rapid HIV testing service)
☐ Another rapid HIV testing service, (please name the service or location:
.....)
☐ In a private home
☐ I am not sure

Do you want to have a HIV test today? ☐ Yes ☐ No

Do you have sex with? # ☐ Male ☐ Female ☐ Both

Have you been paid to have sex or worked in the sex industry in the last 12 months? #

- ☐ Yes ☐ No

How many sexual partners have you had in the last 3 and 12 months? (includes vaginal, anal or oral sex) [PROGRAMMING INSTRUCTIONS: (i) the advice to sex workers about not counting clients among partners to appear if 'yes' to sex work in previous 12 months. (ii) the response options for number of female partners in last 3 & 12 months to appear if 'yes' to sex with women above] **Do not count your clients if you are a sex worker.**

Number of Partners In the last 3 months	Number of Partners In the last 12 months
_____ Male sexual partners	_____ Male sexual partners
_____ Female sexual partners	_____ Female sexual partners

In the past 3 months how often did you use condoms for anal sex with any regular male partner/s? #

- ☐ Always (not counting breakages)
☐ More than half the time
☐ Less than half the time
☐ Never
☐ I haven't had anal sex with a regular male partner

[PROGRAMMING INSTRUCTION: If 'yes' to any sex with regular male partners above]
Do you know the HIV status of your regular partner/s?

- ☐ One or more of my regular partner/s are HIV positive ☐ My regular partner/s are HIV negative
☐ I don't know the HIV status of my regular partner/s, or he/they haven't had a HIV test

In the past 3 months how often did you use condoms for anal sex with a casual male partner? #

- ☐ Always (not counting breakages)
☐ More than half the time
☐ Less than half the time

- ☐ Never
- ☐ I haven't had anal sex with casual male partners

[PROGRAMMING INSTRUCTION: Question below only displayed if 'yes' to sex with female partners above]

In the past 3 months how often did you use condoms for anal or vaginal sex with a regular female partner?

- ☐ Always (not counting breakages)
- ☐ More than half the time
- ☐ Less than half the time
- ☐ Never
- ☐ I haven't had anal or vaginal sex with a regular female partner

[PROGRAMMING INSTRUCTION: question below only displayed if 'yes' to sex with female partners above]

In the past 3 months how often did you use condoms for anal or vaginal sex with a casual female partner?

- ☐ Always (not counting breakages)
- ☐ More than half the time
- ☐ Less than half the time
- ☐ Never
- ☐ I haven't had anal or vaginal sex with casual female partners

Have you ever injected drugs? # ☐ Yes ☐ No

[PROGRAMMING INSTRUCTION: If 'yes', to having ever injected:]

Have you injected drugs in the last 12 months ☐ Yes ☐ No

Have you ever been diagnosed with hepatitis C? ☐ Yes ☐ No

Have you been vaccinated for hepatitis B? (The vaccination is a course of 3 injections over a six month time period) #

- ☐ Yes
- ☐ No
- ☐ I am immune through past infection
- ☐ I have chronic hepatitis B
- ☐ Unsure

Have you ever been diagnosed and treated for syphilis? # ☐ Yes ☐ No

Thanks! That's all the questions over.

DO NOT MARK BELOW THIS LINE - FOR [Service name] TEAM ONLY

HIV POCT?

☐ Decline ☐ Yes

HIV POCT Result?

☐ Reactive ☐ Non reactive ☐ Invalid

Peer _____ **start time** _____ **finish**
time _____

Investigations

- ☐ Urine - Chlamydia PCR, Gonorrhoea PCR
- ☐ Rectal swab - Chlamydia, Gonorrhoea PCR
- ☐ Throat swab/PCR - Gonorrhoea PCR
- ☐ Syphilis Immunoassay
- ☐ Syphilis RPR
- ☐ Anti HIV
- ☐ Hepatitis B core antibody
- ☐ Hepatitis C antibody
- ☐ _____
- ☐ _____
- ☐ _____

Clinician _____ **start**

Service Specific Data

How would you like to get your rapid HIV test results today?

- ☐ In person, I will wait
☐ In person, please contact me to return for the results. Please ☐ SMS ☐ Call ☐ Email

How would you like to get your other test results after today? Please choose two options.

#

- ☐ [Insert service name] will telephone me (if I don't answer they will leave a message asking me to call them back)
☐ I will telephone [Insert service name] in 7 days ☐ [Insert service name] will SMS me
☐ [Insert service name] will email me

Would you like to receive a SMS reminder for your next check-up? #

- ☐ No, it's ok I will remember
☐ Yes thanks, I would like a reminder:
☐ 3 months from now ☐ 6 months from now ☐ 12 months from now

'#' Denotes fields that have been compulsory in CASIs

9.10 Attachment 10: Medical Record Template

**Insert Organisation
Logo**

Insert Organisation Name
MRN Sex:
Surname, Given name
DOB: Postcode:

Insert site name

Consultation date: _____

☐ Tested for HIV before

Last tested _____

☐ Test for HIV today

No. of male sex partners Last 3 months _____
Last 12 months _____

No. of female sex partners Last 3 months _____
Last 12 months _____

☐ Client prefers not to answer

Frequency of anal/vaginal sex with a condom in
the past 3 months? _____

☐ Injected drugs ever

☐ Diagnosed with Hepatitis C

HBV status _____

☐ Diagnosed with and treated for Syphilis

Like to received SMS reminder for a check up
___ months from now

Management plan

☐ HIV PoCT

☐ Other _____

Provisional diagnosis

Appointment

Notes:

☐ Informed consent

☐ Window period explained




☐ Suitability for test explained

Results delivery method _____

Clinician _____

Signature _____

9.11 Attachment 11: Standard Workplace Health and Safety Assessment

SWP #:		Name of Task /Equipment: HIV Point of Care Testing			
Department Name:			Facility/Service:		
Risk Assessment No:	Risk Level: e.g. Extreme, High, Med, Low	Date Developed:	Date Review Due:		
	High				
Risk of Injury:					
Occupational exposure to blood and body fluids					
Safety Rules:					
Universal precautions must be used at all time					
Job Steps:					
<p>Prepare the equipment on the clinical workspace before the client enters the room. Ensure the clinical waste bin and sharps bin are readily available for point of generation disposal. Wash hands and don gloves and goggles Perform procedure as per clinical guidelines Dispose of sharps and clinical waste at point of generation Wash hands</p>					
PPE Required:					
					
Approved for use by Manager:					

9.12 Attachment 12: Timer Calibration

1.0 PURPOSE

This document describes the procedure for checking the calibration of timing devices against reference time from Telstra. The procedure is applicable to all timing devices used in the laboratory.

2.0 SCOPE

This procedure applies to all Divisions across SydPath

3.0 RESPONSIBILITIES

Operation Managers are responsible for checking the calibration of timing devices used in their laboratories

4.0 PROCEDURE

4.1 Calibration Schedule

NATA Requirements for the checking of timing devices are specified in the ISO 15189 Application Document as follows:

- The maximum allowable period between successive checks is 6 monthly
- Time is to be checked against the Telstra signal for at least 60 minutes
- New timing devices should be checked prior to being used in the laboratory

4.2 Checking the Calibration Timing Device

- 4.2.1 Refer to the form: Timing Devices Calibration Form. Each timing device should have its own dedicated form
- 4.2.2 Record the timing device number on the top left of the form
- 4.2.3 Record the date when the calibration check is being performed
- 4.2.4 Telephone the reference time (Telstra) on 1194
- 4.2.5 Simultaneously start the timing device and record the reference time
- 4.2.6 Wait a minimum of 60 minutes
- 4.2.7 Telephone the reference time (Telstra) again
- 4.2.8 Simultaneously stop the timing device and record the reference time
- 4.2.9 Calculate the net time which the timing device was running
- 4.2.10 Calculate the net time for the reference time

4.2.11 If the difference between the net time for the timing device and the reference time is less than 1% then the timing device has passed testing. If the difference is greater than 1% then action should be taken. If the timing device is part of an instrument the manufacturer needs to be contacted to make the necessary repairs. A notice should be placed on the instrument stating that the timing device has not passed the calibration check. If it is a stand-alone timer then it should be removed from service until it is repaired or disposed of if it cannot be repaired.

4.2.12 Initial the form

5.0 REFERENCES

ISO 15189 Application Document

9.13 Attachment 13: Initiation Visit Template

NSW State Reference Laboratory for HIV			
HIV PoCT Initiation Visit Report			
Site visited: Date of visit:			
INITIATION MEETING AND STUDY OVERVIEW			
Site director: Site co-ordinator: Ref. Laboratory Staff: Others:		PRESENT <div style="display: flex; justify-content: space-around;"> YES NO </div>	
Comments: None			
SITE/REGULATORY DOCUMENT FILE REVIEW			
LHD approval Final approved subject Information & Consent Form EQAS enrolment Site staff responsibilities & sample signature list Signed and dated CVs for all investigators & study coordinators	YES	NO	
Comments: EQAS enrolment: <i>date:</i>			

FACILITY ASSESSMENT		
A. Clinical space adequate & appropriate.	YES	NO
Comments: None		
TRAINING		
Protocol training Roles/responsibilities and GCP Regulatory training: Site file requirements Source document requirements Informed consent process Monitoring requirements	YES	NO
Comments:		
SUMMARY		
Additional action items:		

SIGNATURE OF MONITOR:

SIGNATURE OF PROJECT LEADER:

SIGNATURE OF HIV PoCT SITE SUPERVISOR

DATE:

9.14 Attachment 14: Monitoring Report Template

NSW State Reference Laboratory for HIV HIV PoCT Monitoring Report		
Site visited: Date of visit: Present at visit: (list site and Ref lab staff present at visit)		
1. Site Status	Open for Recruitment This site administers approximately ?? HIV PoCTs per month	YES/NO
2. Data Review	Has all source data been reviewed, signed and appropriately filed or recorded?	YES/NO
3. Consent	Have all new patients signed consent forms or given verbal consent?	YES/NO
4. Protocol Deviations	Have any protocol deviations been identified at this site?	YES/NO
5. Amendments	Have any protocol amendments been issued or changes made to the patient information document since the last visit?	YES/NO
6. External Quality Assurance Scheme	Has the site enrolled into an EQAS program? EQAS NRL Number:	YES/NO YES/NO

7. Proficiency Sample Testing	<p>Are the proficiency samples being tested for training and coaching?</p> <p>How frequent are the proficiency samples being tested?</p>	YES/NO
8. Training Documents	Does each trained staff member have an ASHM training certificate and a completed operator competency assessment form?	YES/NO
9. Site Folder	<p>Is the site folder up-to-date?</p> <p>Are the timers calibrated and the timer calibration form up-to-date?</p> <p>Are there missing documents?</p>	<p>YES/NO</p> <p>YES/NO</p> <p>YES/NO</p>
10. PoCT Supplies	<p>Are there adequate PoCT devices and supplies on site?</p> <p>PoCT LOT Number:</p> <p>Expiry date:</p>	YES/NO
11. HIV PoCT Staff	Are there staff members that require training?	YES/NO
12. Action Items		
12. Comments		

SIGNATURE OF HIV PoCT COORDINATOR:

SIGNATURE OF OPERATIONS MANAGER:

SIGNATURE OF PoCT SUPERVISOR:

DATE: