New Zealand Best Practice Guidelines

For

Point-of-Care Testing

2014

New Zealand Point-of-Care Testing Advisory Group

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FOREWORD

“His urine is sweet, he has diabetes mellitus” said the physician. Long gone are the days when physicians tasted urine to detect glycosuria, one of the earliest applications of near patient testing. Point-of-care-testing (POCT) has come a long way since, and in the 21st century is transforming the topography of laboratory medicine, with far-reaching potential. It has become an indispensable tool that can expand the capacity of limited-resource health services and that can overcome barriers to access healthcare. POCT constantly challenges professionals who endeavour to keep up with its ever expanding myriad of applications and tests. As we reflect on this we have to consider the scope of governance that regulates POCT and the appropriateness of its applications.

The New Zealand POCT Advisory Group (NZPOCTAG) was born out of the need for bringing together local knowledge and expertise to consult and console on the challenges faced by POCT services and providers in New Zealand. It recognized a need to heighten awareness of the funders and providers both within and outside of the health sector on the necessity for investment in quality processes and clinical risk management. The NZPOCTAG strives towards bridging the gap between the end user and the expert.

Core membership of the group includes laboratory scientists, managers and pathologists who are all involved in the provision of POCT throughout the country, with representation from the Royal College of Pathologists of Australasia and the New Zealand Institute of Medical Scientists, and is chaired by a POCT coordinator. Within 4 years of its establishment in 2009, the NZPOCTAG has realised the need for home-grown nationwide best practice guidelines on POCT.

Solid foundations are essential for establishing a viable POCT framework. The New Zealand Best Practice Guidelines for Point of Care Testing are based on sound international literature and societal guidelines but also draw from local expertise and knowledge of the NZ healthcare needs and environment. This document is written with the intention of helping, guiding and supporting the use of POCT devices and services. The ultimate goal is to secure the safety of the patient, the ultimate benefactor, and ensure appropriate clinical and cost-effective use of POCT. The vision for POCT in NZ is that of a POCT device that is analytically verified, a POC test that is reproducible, accurate and relevant, a POCT result that is safe, beneficial, easily interpretable and seamlessly incorporated in patient-care pathways; and ultimately a POCT service that is governed and managed based on evidence and focused on patient needs.

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1 DEFINITION

Point-of-care testing, also known as near-patient testing, is the analysis of clinical specimens outside the traditional laboratory, near to or at the site of patient care. It may be performed by multiple users including clinical staff whose primary training is not in medical laboratory science. It has an important role to play in the delivery of an efficient healthcare system because of its ability to provide a rapid result near the patient which is able to be acted upon immediately, and which may lead to a diagnosis or a possible change in the care of the patient.

2 SCOPE

There are few randomised controlled trials in point-of-care testing. This document is based on principles of good clinical practice and quality healthcare provision and incorporates the requirements of the following international standards with reference to a number of international point of care statements and documents:

- ISO15189:2012 Medical Laboratories – particular requirements for quality and competence
- ISO22870:2006 Point-of-care testing - Requirements for quality and competence
- Australasian Association of Clinical Biochemists: Point of Care Testing Implementation Guide
- Guidelines for Safe and Effective Management and Use of Point of Care Testing (Ireland) 2007
- MHRA Device Bulletin: Management and use of IVD Point of care Test Device DB2010(D2)
- Royal Australasian College of Pathologists Point of Care Testing Position Statement 2013
- Clinical Laboratory Standards Institute

The purpose of these guidelines is to assist all potential users of point-of-care testing (POCT) but with a particular emphasis on those healthcare professionals without a laboratory background who are required to perform point of care tests or who may be interested in implementing POCT in their facility.

These guidelines can be applied to transcutaneous measurements, the analysis of expired air, and in-vivo monitoring of physiological parameters. Patient self-testing in the home or community setting is excluded, but there are elements of this guide which may be applicable in this setting. These Guidelines have been developed in the interests of clinical safety and are also designed to meet the intentions of the Health and Disability Commission (HDC) Code of Health and Disability Services Consumers' Rights Regulation 1996, in particular Right 4 of the Code, which states that consumers have the Right to Services of an Appropriate Standard.

Disclaimer

The document is intended for guidance purposes only. Therefore, where a particular brand, type or design of technology is mentioned, this is intended to convey meaning by use of an example only, and does not imply specific endorsement of this brand, type or design by the New Zealand Point-of-Care Testing Advisory Group. It is recommended that providers seek advice from an accredited medical laboratory with expertise in POCT when considering implementation of POCT systems.
3 ABBREVIATIONS AND DEFINITIONS

AACB Australasian Association of Clinical Biochemists
CLSI Clinical Laboratory Standards Institute
EQA External Quality Assurance
HDC Health and Disability Commission
HIS Hospital Information System
IANZ International Accreditation New Zealand
ID Identity
IQC Internal Quality Control
LIS Laboratory Information System
NPAAC National Pathology Accreditation Advisory Council
POCT Point-of-care testing or near-patient testing
QC Quality Control
QMS Quality Management System
RCPA Royal College of Pathologists of Australasia
TEG Thrombelastograph or Thrombelastography

Pre-analytical Technical and sample collection procedures which take place before sample analysis

Analytical Technical procedures which take place during sample analysis

Post-analytical Result reporting and sample disposal procedures which take place after sample analysis

Reference Interval This denotes the range of expected values for a particular analyte within which 95% of subjects’ results will fall. For example, a commonly used reference interval for Sodium ion (Na+) is 135 to 145 mmol/L. Note: the reference interval for a particular analyte may vary between different analysers and may also be affected by time of day, fasting status, age and gender. POCT users are advised to check with the local accredited laboratory as to which reference intervals to use for individual devices.

Critical Limits These are limits for a particular analyte which may denote life threatening conditions. For example, a glucose level less than 2.5 mmol/L or a potassium level greater than 6.5 mmol/L may be considered critical limits where clinical staff responsible for the care of the patient should be notified if test results outside these limits are found. POCT users are advised to check with the local accredited laboratory as to which values to use for critical limits.
4 INTRODUCTION / OVERVIEW

Point-of-care testing (POCT) involves the performance of an analytical test outside the conventional laboratory, at the site or in the vicinity of, the patient. It is performed in a variety of locations such as, but not limited to, hospital wards, general practice surgeries, health clinics, pharmacies, law enforcement, ambulance services, and also by patients. The range of testing performed may be as simple as dipstick urinalysis or pregnancy tests, through to testing using more complex instrumentation such as cardiovascular risk screening, anticoagulant monitoring, and blood gas analysis. POCT is also used where it is not practical to send clinical samples to a conventional laboratory for testing i.e. where tests are performed on whole blood samples without anticoagulant and must be processed within a short time frame after collection e.g. samples for Thrombelastography (TEG).

The use of POCT can result in increased clinical effectiveness and improved outcomes for patients, but this is only true if the result is accurate, reliable, cost effective and able to be acted on in a timely manner. POCT should be seen as complementary to, and not as a replacement for conventional laboratory testing.

There are a number of clinical advantages to the provision of POCT and these include:
- improved turnaround time by shortening pre-analytical, analytical and post-analytical steps
- reduced therapeutic turnaround time
- improved monitoring of certain conditions where frequent testing is desirable for diabetes and oral anticoagulant monitoring
- improved convenience and access to service e.g. for elderly patients
- smaller sample volumes which may be less invasive
- availability of rapid results to facilitate patient management
- opportunistic screening of the public for early identification of certain conditions
- ability to provide laboratory tests in remote locations or outside laboratory hours
- economic benefits may also be realised because although some POCT testing is more expensive than conventional laboratory testing, POCT may offer economic benefits in terms of reduced clinic visits, length of hospital stay and hospital admissions.

There are also potential disadvantages which need to be considered, and these include:
- POCT introduction without adequate investigation of clinical need
- inaccurate results due to lack of training, expertise, insufficient quality testing and failure to recognise erroneous results, which may cause patient harm
- problems of comparability of results between different methods (laboratory versus non laboratory)
- increased costs due to additional instrumentation, expensive reagents, enrolment in external quality assurance programs
- inadequate documentation of results and reporting
- increased workload for clinical staff
- the availability of arrays of screening tests which may result in inappropriate testing
- risks to patients as a result of implementation of non-performing devices or failure to recognise limitations of POCT devices.

To overcome the disadvantages requires significant resources and so careful consideration should be given to the clinical need before contemplating this type of testing. The advantages of POCT only hold true if the test result provided is accurate and reliable and improves patient outcomes. It is therefore imperative that all POCT is conducted within a framework of quality
standards which ensures that the quality of results generated is as close as possible to those performed within an accredited laboratory environment.

5 REQUIREMENTS for POCT PROGRAMMES

Where any POCT services are provided, a system for clinical and managerial governance in both hospital based & non-hospital based (rural/remote) service must be established, including a person on site who is designated as responsible and accountable for the service. All POCT devices or technologies should be approved for clinical use by a governance group with executive authority for POCT. Staffing for the POCT service should be proportionate to the level of service in scope, scale and volume.

Appropriate referral criteria should be in place to ensure that where results obtained are unexpected, inconsistent with the clinical picture or outside a defined range, confirmatory testing is performed (methodology of confirmatory testing should be discussed with an accredited medical laboratory) and patients are referred for further medical attention as necessary.

5.1 Governance for POCT

The practice of evidence-based medicine is an essential component of Clinical Governance, which also includes risk management, clinical and cost effectiveness, education, training and continuous professional development of staff, research and audit, and the application of information about patient outcomes. All of these components of clinical governance apply to POCT; Pearson (2006).

POCT may be conducted in a variety of sites: within hospitals (most clinical areas, particularly critical care, maternity, neonatal, surgical and outpatient areas), in the community (ambulances, community physician practices, clinics, pharmacies, other retail outlets, workplace screening) or in patients’ own homes. The management of quality, risk, training and audit is therefore likely to be difficult, especially with the predicted growth of POCT and the increase in self-testing by patients.

The key question which needs to be asked in deciding on whether or not to introduce a point-of-care testing service is:

"What is the clinical problem which needs to be solved by point-of-care testing which cannot be solved by conventional laboratory testing?"

The answer to this question requires input from a range of stakeholders. Formal input is needed from an appropriate POCT governance group or committee with representatives from clinical specialties, pathology, nursing, risk management, finance and logistics. This group will have delegated responsibility, clinical and management expertise to determine if a test intended for use at the point-of-care is appropriate for use in the intended clinical setting. In making this assessment, it is important to ensure that the technology and the test results obtained are compatible with instruments used in the laboratory and how the test results correlate with each other.
5.2 Risk Management

The major risks related to POCT are a result of inadequate operator competency; lack of supervision, governance and accreditation of the POCT service; failure to use quality assurance; inappropriate testing by inexperienced personnel, uncertainty on how to act on results and the use of non-performing devices. Other risks include financial risk and patient harm which may result in increased morbidity and costs of care. These risks can be effectively managed by good clinical governance, the implementation of robust quality management systems and accreditation. A thorough risk assessment of all POCT service activities should be undertaken and advice should be sought from an accredited laboratory.

5.3 Assessment of clinical need

In many cases improving the patient pathway and experience will be major considerations when introducing POCT. To be effective, POCT must deliver an equivalent level of quality and be at least as clinically effective as the alternative and applied within the correct setting. These questions will help in assessing the clinical need for POCT:

- does the current method of providing the service adequately meet the clinical need, and if it does not, what is the problem and can it be rectified?
- is access to the laboratory a problem for patients, and can that be rectified?
- which groups of patients need testing and what test(s) need to be performed?
- will POCT enable more rapid or effective diagnosis, treatment or management?
- will POCT provide a cost-effective alternative to laboratory testing?
- how would a POCT service compare to the current service in terms of quality?
- would any change in quality be appropriate for best management of the patient?
- can you provide evidence that POCT will provide a measurable clinical benefit?

5.4 Inclusion of Laboratory input

The local hospital pathology laboratory should play a key role in the development and management of a POCT service. This is particularly true for secondary care and is recommended in the primary care setting. In the event of unavailability of laboratory support in the primary care setting, POCT should be performed under an adequate Quality Management System (QMS) that should include laboratory trained personnel. Laboratory staff can provide advice on a range of issues which include:

- evaluation and purchase of suitable devices
  - equipment selected should have an independent evaluation report available, preferably performed in Australia or New Zealand
- validation of methodology and test performance
  - tests performed should have a validation report available, preferably performed in an accredited laboratory in Australia or New Zealand
- training of users
  - all individuals who perform POCT must undergo appropriate training and be certified as competent
- result interpretation
  - medical alert/critical/panic values must be defined, and results in these ranges must be communicated immediately to the appropriate carer. For clinically discrepant results, samples should be retested in an accredited laboratory and the discrepancy investigated
• quality control and quality assurance
  o there must be a process in place for routinely monitoring instrument performance.
• documentation and records
  o written policies must be in place for all aspects of POCT. This will include organisational structure, personnel considerations, method/instrument selection, testing procedures, safety/waste disposal, quality control, external quality assurance, maintenance, reporting of results and patient education
• troubleshooting and problem solving
• health and safety

There should be close liaison between users of POCT and an accredited medical laboratory on all issues relating to POCT. It is recommended that this liaison should be formally defined, for example by a service level agreement which specifies the range of products, services, operational details, the responsibilities of the central laboratory, the POCT facility and the user.

5.5 Cost Benefit Analysis

Notwithstanding the clinical benefits, POCT has fiscal implications. These costs may include:

(i) Capital costs
  • initial purchase cost
  • accessories e.g. centrifuges and refrigerators
  • provision of a safe environment e.g. health and safety requirements
  • site alterations to accommodate POCT e.g. operator and storage space
  • depreciation
  • computer interfacing with clinical information management systems
  • complete, accurate and timely records of patient results should be maintained and electronic transfer of POCT results should be implemented.

(ii) Fixed costs
  • routine and preventative maintenance
  • internal quality control material, external quality assessment scheme and regular sample comparison with an accredited medical laboratory.
  • accreditation compliance (if applicable)

(iii) Variable costs
  • consumables
  • record keeping e.g. data-handling system, licence costs
  • waste disposal
  • cleaning

(iv) Professional costs
  • indemnity insurance and legal liability (if applicable)
  • laboratory support
  • management of the POCT programme
  • appropriately qualified designated person acceptable to all stakeholders, responsible for ensuring that the appropriate standards of quality are maintained
  • operator time
  • staff training requirements
6 SELECTION AND VALIDATION OF TECHNOLOGY

Once a clinical need has been established, the next step is to consult your local accredited laboratory to identify the most suitable device before purchase. Considerations in selecting a suitable technology include:

- the availability of an independent evaluation report preferably performed in Australia or New Zealand
- expected workload/throughput
- accuracy and precision of quantitative results
- the clinical environment in which the device will be used e.g. hospital ward, operating theatre, intensive care unit or paediatric clinic
- clinical parameters including sensitivity, specificity and predictive values of the test application
- robustness of the device
- ease of use
- results comparable with a local accredited medical laboratory, in terms of measurement units and expected ranges
- validation must be performed prior to implementation of any devices and full documentation must be available
- adequate space, and appropriate services e.g. power, water, IT requirements, refrigeration
- limitations of testing e.g. measurement range of the device, interfering substances
- connectivity for result recording
- waste disposal requirements

It is important that the device be fit for purpose and an accredited medical laboratory can help and advise in this process. Additional advice on selection procedures for POCT devices can be found in the CLSI document POCT-09A
7 QUALITY MANAGEMENT SYSTEM (QMS)

A quality management system should be set up for any POCT programme in order to ensure that the test results are accurate and precise i.e. clinically reliable at all times and appropriate for patient care. The QMS is a key component of risk management and clinical safety and incorporates the following elements: staff training, competency and certification, quality control, documentation and record keeping, defined roles and responsibilities, audit, adverse event reporting and accreditation.

7.1 Staff training, competency and certification

POCT should only be carried out by healthcare staff who have undergone appropriate initial training and competency certification and who have their competency levels regularly assessed. Training should be organised by a POCT coordinator who ideally should be a registered medical laboratory scientist. Training and competency assessment may be delivered by the POCT coordinator or their nominated representative who may be a registered medical laboratory practitioner, an experienced user of POCT, or the vendor of the device.

A POCT training programme should cover both theory and practice of POCT and include the following aspects as a minimum requirement:

- setting the clinical scene (disease process and pathophysiology)
- clinical utility and significance of the test
- recommended frequency of performing the test
- clinical decision limits or reference intervals
- performance characteristics of the POCT instrument and its technical limitations
- patient preparation and sample collection requirements (including correct preservative or anticoagulant)
- reagent storage and preparation
- how to perform the test on the device (including quality control and calibration)
- how to interpret, report and act on POCT results (including those outside the measuring range of the device and outside the predefined clinical decision limits for the test)
- back up and/or confirmatory procedures for out of range or unexpected results
- the principles and practice of internal quality control (IQC) and external quality assurance (EQA)
- maintenance and common trouble-shooting
- occupational health and safety issues including infection control practices, waste management
- compliance with accreditation requirements (if appropriate).

The practical side of training should include a complete demonstration by the primary trainer of how to use the device and perform a test, how to run QC and EQA samples and how to perform basic maintenance procedures, followed by a hands-on practical session for each person. The practical session should be conducted individually or in small groups, to ensure each trainee gains experience using the POCT technology in a practical ‘hands-on’ sense, and gains confidence prior to commencing patient testing. Train the trainer systems are often used in medium to large facilities to ensure ongoing certification and competency of new and existing staff.

When the formal training is complete, the competency of the trainee should be assessed both practically to ensure a routine POCT test is conducted correctly, and by a written assessment to
ensure key theoretical concepts have been grasped. Competency must be formally and regularly reviewed. For most testing this should be at least annually, depending on the complexity of the POCT, and may consist of retraining and education updates. Regular retraining and competency assessment must be regarded as a mandatory requirement of POCT performance. If a POCT operator fails a competency review then they must immediately cease testing and undergo formal retraining before being recertified.

A register of all persons receiving training and ongoing recertification must be kept and maintained. The maintenance of a competency register may be a requirement of accreditation or POCT testing contract.

7.2 Quality Control

The performance of quality control (QC) testing must be a mandatory component of running a POCT programme. An essential part of performing routine POCT is the regular monitoring of the quality of the analytical performance of the device. This will include both internal quality control (IQC) and external quality assurance (EQA) testing. IQC and EQA are an integral and mandatory part of routine laboratory testing, and are a requirement of laboratory accreditation. It is important that there is an equivalent standard of quality assessment for point of care testing performed outside the laboratory to ensure the validity of the results. IQC and EQA samples are tested in the same manner as a patient sample, and the testing should be performed by POCT operators responsible for performing routine patient testing where practical.

7.2.1 Internal Quality Control (IQC)

The IQC material is an artificial sample which has an assigned or target value, and it is tested in the same way as a patient sample. There are set limits for acceptable performance around the target value. Quality control material may be provided by the manufacturer of the device or obtained from another source. The local laboratory should be able to provide advice on suitable quality control materials. There are generally two or three levels of IQC material which correspond to different concentrations of the analyte or parameter being measured. Only when results are within the acceptable range can there be confidence that the device and consumables are performing correctly. Quality control results must be recorded along with the time and date of testing, operator name, and a comment on the acceptability or otherwise of the result. There must be a process in place to respond to IQC results which are outside the acceptable range.

As a minimum, and depending on the complexity of the testing, IQC testing must be performed prior to any patient testing:

- on each new shipment of reagents/cassettes/strips
- on each new lot number of reagents/cassettes/strips
- in the event of equipment problems or erroneous results
- the frequency of further IQC monitoring is highly dependent on the complexity of the analysis involved, the type of POCT device, stability of consumables and frequency of patient testing. This should be developed in consultation with an accredited medical laboratory and the manufacturer’s guidelines and be fully documented.

IQC testing must be performed by competent operators. The designation for this responsibility will be determined by the complexity of the device and the composition of the suppliers IQC material, the frequency of use and whether or not automated quality control schemes are incorporated in the device.
Consideration should be given to the use of a third party quality control material i.e. provided by a different manufacturer.

While the procedures outlined above are common to most POCT devices, there are other forms of quality control that can check selected parts of the POCT testing process. Electronic quality control assesses the electronic measurement circuitry of a POCT device. It uses a surrogate material (such as a reference cassette, coloured filter, coloured solution or bar code) to generate an electric signal that would normally be produced by a sensor responding to an analyte in a patient sample. Thus, electronic quality control checks only test the ‘reader’ steps in the total testing process and should not be used as a substitute for conventional IQC material. It does not test the analytical process and does not ensure that the reagents/cassettes/strips are functioning correctly.

7.2.2 External Quality Control (EQA)

EQA or proficiency testing, is an essential part of the quality programme, and must be included where there is a suitable programme available. It is a system which objectively assesses the quality of results by comparing performance between different testing sites. EQA samples may be artificial samples provided by an external EQA provider, or if an EQA system is not available, it may be a patient sample exchanged between several sites including laboratories. All participating sites analyse the identical unknown specimen and send the results to the EQA provider who will then send a report to the participating sites detailing their performance. EQA complements the internal QC system to help assure the operator that patient test results are valid. IQC and EQA samples should be commutable (similar in nature to patient samples).

There are a number of national and international EQA programmes available and an accredited medical laboratory can provide advice on suitable programmes.

Where practical, periodic direct comparison tests using patient samples tested on both POCT devices and laboratory analysers should be undertaken to ensure ongoing reliability.

IQC and EQA performance must be regularly monitored to ensure that the analytical performance of the POCT device is clinically acceptable, and long term monitoring will allow early detection of any problems. If required, corrective action must be taken and documented. Review of all quality programmes should be undertaken at regular intervals. It is strongly recommended that this be in consultation with an accredited medical laboratory.

7.3 Documentation and Record Keeping

There must be complete, accurate and timely documentation of all stages of POCT activity.

• Operator training and competency records
  o a register of all persons receiving training and ongoing recertification must be kept and maintained.

• POCT procedure/method manual
  A documented process must be in place for all POCT performed and should include:
  o organisational structure
  o personnel considerations
  o method/instrument selection
  o testing procedures - this may take the form of a laminated “Quick Guide”
  o safety/waste disposal
- quality control and external quality assurance,
- maintenance
- reporting of results
- patient education

- Reagent/Cassette/Test Strip management
  There must be a system in place to record:
  - when reagents/cassettes/straps arrive
  - the batch number
  - date opened
  - use by date
  - expiry date

- Patient results
  It is imperative to keep accurate records of patient results from POCT devices. These records should include:
  - date and time of analysis
  - device type
  - batch numbers
  - test result
  - operator identity
  - patient identity
  - documented policy around correction/amendment of results

- IQC/EQA results
  Most POCT devices will store quality control results in the device memory but it is good practice, where connectivity is not possible or available, to also manually record the results on a work sheet which lists the assigned values and limits for each IQC level. The worksheet should provide space for the date of testing, operator identity and acceptance or not of the result.

- Device maintenance log
  A log should be kept for each POCT device of all problems and maintenance events.

Note: Devices with electronic systems for recording lot numbers of reagents and QC materials, QC performance statistics and troubleshooting logs may simplify the documentation requirements.

### 7.4 Definition of Roles and Responsibilities

It is advisable that there is oversight of the below roles and responsibilities by an appropriate governance group, e.g. POCT Committee. There should be clearly defined lines of responsibility and accountability.

#### 7.4.1 POCT Coordinator

The POCT Coordinator will ideally be an experienced, registered Medical Laboratory Scientist who will:

- be designated by the organisation’s governance group to develop, document, implement and maintain the POCT Quality Management System
• be responsible for ensuring that all POCT is performed to the same standard as would be expected from regular laboratory testing
• maintain a record of all POCT equipment for which they have responsibility.
• be responsible for ensuring that all POCT users have current competency training and documentation
• be responsible for ensuring regular quality assurance is maintained and quality control samples are analysed on POCT devices, with up to date documentation and history;
• maintain (monitor) service records for each device
• be responsible for trouble-shooting of POCT devices and oversee the maintenance of up to date documentation and history
• communicate issues/concerns with the site manager and stakeholders.

7.4.2 Site Manager
A Site Manager will ideally be a registered healthcare professional on the staff of the facility performing POCT and will:
• be responsible for the day to day supervision or oversight of personnel performing POCT and reporting test results
• be responsible for the day to day care of the system and control of environment contamination, and for the maintenance of stocks of consumables and reagents within their shelf life
• ensure that all users of POCT devices are competent and authorised to use the devices
• ensure their area complies with all POCT policy procedures;
• ensure that training records are kept for all users
• ensure that quality control procedures are documented according to the relevant POCT policy
• ensure that the relevant policies and procedures for the use of the device(s) in their area are in place and available to all users.

7.4.3 POCT Trainer
The POCT trainer will be a suitably qualified healthcare professional, who may be the POCT Coordinator or will be designated by them as a trainer. They may be another registered laboratory practitioner, an experienced operator or a representative of the company supplying the device. They are responsible for:
• ensuring that the operator has the knowledge and skills to accurately and reliably perform the task
• assessing and documenting the competency of the operator
• assessing and documenting that the operator has the required theoretical knowledge to perform the test and to recognize any errors or interferences in all stages of the testing process, pre-analytical, analytical or post-analytical
• signing the completed competency and certification records for trainees.

7.4.4 POCT Operator
The users of POCT devices will:
• be trained and certified as competent to use the POCT device
• be individually accountable for their practice and ensure that they acquire and maintain skills in the use of POCT devices. This will require the completion of documented competency processes as required, which will usually be on an annual basis
• use the equipment in a safe and responsible manner
• have a unique identifier (log-in or password) where applicable
• not share their log-in or password with any other person
• keep an accurate and up to date maintenance log for the devices they use
• remove the instrument from use if it becomes non-functional and inform the Site Manager and/or POCT Coordinator as soon as possible
• satisfy the quality control requirements for the device
• document all patient and quality control results according to the protocol.
• ensure the device is left in a fit state for the next user
• ensure all consumables are within expiry date and have been stored correctly as per manufacturer’s recommendations
• ensure that all used items, including but not exclusive to, reagents/cassettes/strips, lancets etc. are disposed of safely in accordance with the standard operating procedure
• sign and acknowledge that they recognise legal responsibility for the tests that they undertake.

7.5 Internal Auditing

Auditing of pre-analytical, analytical and post analytical parameters on a regular basis is essential to ensure continuous quality improvement. Examples include, but are not restricted to: number of clinically discrepant results in total and per user, number of tests performed and EQA performance.

POCT areas should have at least one internal audit per annum by the Laboratory Quality Manager or designate.

Findings of the report need to be reviewed by appropriate personnel.

Clinical audit and the efficacy of POCT on patient outcomes should also be included in the organisation’s clinical audit programme.

7.6 Adverse Event Reporting

An adverse event may cause, or may potentially cause, an unexpected or unwanted effect. In a POCT environment an adverse event may impact on the health and safety of patients, service providers or other persons. For example, an incorrect result may lead to a delay in treatment, inappropriate treatment, a life-threatening illness or injury, a serious deterioration in the state of health, or even death.

Any adverse event involving a POCT device should be reported via the organisational incident reporting system and also must be reported to the supplier of the device. There is a documented process for reporting adverse events to Medsafe and information on the process of reporting may be found on the Medsafe website.

A record of all incidents and actions taken must also be kept at the site/institution of POCT

7.7 Accreditation

Accreditation by an external accreditation agency (such as IANZ) is an important element of risk management. Accreditation against the ISO 15189: 2012 and ISO 22870:2006, standards, while
8 SOURCES OF ERROR

While POCT devices are generally straightforward and easy to use, there are a number of potential sources of error. In order to obtain an accurate result on which to base patient management it is essential that an effective quality management system is established to minimise potential errors. Errors in POCT may occur in all stages of the testing process. These may be pre-analytical, analytical and post-analytical errors.

Errors may occur before the analysis (pre-analytical errors), and include:
- patient identification
  It is essential to properly identify the patient to be tested
- sample collection, timing and delay before testing
  The quality of the sample can have a significant effect on POCT results, (see Appendix 1, Sample Collection Procedures, for information on sample collection)

Errors may occur during the testing process (analytical errors), and include:
- operator training and competency
  All POCT operators must be trained and assessed as competent before commencing patient testing.
- out of date reagents/cassettes/strips
  Document and monitor reagent expiry dates, including open vial/out of refrigeration expiry requirements.
- incorrect storage of equipment and disposables
  Monitor and document temperatures of POCT areas and storage facilities to ensure they meet specifications.
- incorrect operation of the device
  All POCT operators must follow the manufacturer’s instructions/documented methodology for the correct operation of the device.
- failure of the device or consumables
  Ensure that QC/EQA are performed regularly, review and respond to results.
- device not fit for purpose

Errors which may occur after analysis (post-analytical) include:
- result documentation
- result interpretation
- failure to respond to out of range results
- failure to adhere to safety requirements
- failure to effectively incorporate POCT results into a clinical management pathway.

A number of POCT instruments are available which incorporate safeguards to minimise many of these potential sources of error, these may include password protection to exclude untrained operators, expired consumables lockout, QC lockout to ensure that QC is performed regularly and satisfactorily before testing can begin, and connectivity to ensure that results are transmitted directly to the patient record thus eliminating transcription errors.
9 REPORTING OF RESULTS

Results should be expressed in the same stated units of measurement as used by the accredited local medical laboratory. Medical alert/critical/panic values must be defined and results in this range must be communicated to the appropriate carer immediately. All results should be returned to the requesting clinician responsible for the patient and placed in the patient’s notes in a written format with appropriate reference intervals for the POCT device, and recorded in the electronic patient record. It is strongly recommended that devices capable of electronic transfer of results should be used.

POCT generated results must be distinguished from laboratory results and the use of centralised data repositories will also help to ensure that test results are accessible to other providers.

10 POCT INSTRUMENT/DEVICE CONNECTIVITY COMPLIANCE:

INFORMATION TECHNOLOGY REQUIREMENTS

All results obtained from POCT testing must be recorded and become part of the patient health record. It is strongly recommended that POCT1-A2 compliant devices be used. Information technology (IT) capability can aid in minimising some of the potential sources of error in POCT testing and promote compliance with operator and patient identification procedures, test procedures and quality control requirements.

IT capable devices should include software that:
- requires operator identification
- requires patient identification
- checks quality control
- transfers results directly to the patient record.

Other desirable features which should be considered include:
- bidirectional data communication to allow patient data to be uploaded to the device, and results matched with patient information to be fed back to the information system
- devices should be capable of being connected to any database/LIS/HIS system
- access and data should be secure to ensure patient confidentiality
- ability to scan barcodes to facilitate information entry, operator ID, patient ID and lot numbers for disposables
- allow easy and regular monitoring of QC information to continually evaluate system performance
- use common docks, ports and wiring for communication
- wireless connectivity allows more flexibility with regard to location and use of devices and the data capture in different clinical settings
- POCT generated results must be distinguished from laboratory results and the use of centralised data repositories will also help to ensure that test results are accessible to other providers.

11 HEALTH AND SAFETY

The same standard of safety and waste disposal must be observed for the POCT location as for any other laboratory, hospital ward or healthcare facility. The procedures outlined below are for guidance, and are not intended to replace the standards already in place that comply with
accreditation that exists for the location where POCT is performed, where those standards exceed these recommendations.

11.1 Safety

All POCT procedures should be performed in such a manner that there is no compromise to the health and safety of the patient or POCT operator:

- The devices must be operated using the manufacturer’s instructions
- Any electrical components must be checked for safety before the instrument is first used and electrical safety checks carried out annually on those instruments
- The device should be cleaned as per the manufacturers’ instructions at the prescribed time intervals, or immediately after there has been any blood or body fluid contamination
- Devices used on multiple patients must be cleaned after every use.

11.2 Infection Control

It is important to prevent the spread of possible infection at the POCT location and hand hygiene is one of the most important measures to achieve this. All operators must follow universal infection control precautions.

11.2 Decontamination

All devices used between individual patients (e.g. glucose meters) must be decontaminated/disinfected following the manufacturer’s instructions, to prevent cross contamination and nosocomial infection.

The POCT work area should be cleaned and disinfected daily. Decontamination of the work area is necessary in the case of contamination from blood or body fluids.

Any blood and body fluid spills must be cleaned up immediately, following standard organisational protocols.

11.3 Waste Disposal

All biological waste must be considered hazardous and disposed of appropriately.

12 HELP / SUPPORT

The quality of results generated by POCT is directly related to the ability to perform the test correctly in all stages of the process:

- appropriately trained and competent staff
- the patient preparation and sample collection
- the quality and integrity of the consumables
- the performance of the test procedure
- the recognition of any anomaly
- the reporting and interpretation of the result
Many people consider POCT products to be very easy to use and therefore “foolproof”, but there are currently no devices available which meet this goal. Managers of facilities where POCT services are provided must ensure that the help and support required to implement and maintain a quality service is provided to the operators. Because POCT operators are not laboratory based or trained, ongoing support is essential. The degree of help and support required will depend on the technology involved. The formation of a partnership between the POCT facility, the local accredited medical laboratory and the POCT vendor is recommended.

A reputable POCT vendor should be able to provide training for operators, simple to follow instructions for POCT use and other associated documents, and advise on or provide suitable quality control materials for the specific device or process. A number of vendors have call centres with knowledgeable staff who can provide answers to questions about their products raised by POCT facilities and users.

Many accredited medical laboratories now have dedicated POCT laboratory staff to deal with POCT requirements in the secondary care environment, and it is recommended that facilities in primary care pursue a partnership and good working relationship with the local accredited medical laboratory for all areas of POCT support, but particularly for support with QC and quality assurance requirements.

Help and support may be required with:

- the routine operation of the POCT device
- management of consumables and reagents
- review of quality control and quality assurance results
- basic troubleshooting as part of obtaining a reliable result
- identification of pre and post-analytical effects that may affect results
- determining causes of failure of the device to meet specifications
- resolving occasional but inevitable differences between POCT and laboratory results on the same patient.
13 REFERENCES

1 ISO 15189:2012 Medical laboratories – Requirements for quality and competence.


16 Clinical and Laboratory Standards Institute guidelines for best practice.

17 Manufacturer’s product information sheets and manuals for operation of specific equipment, and testing techniques.

18 United Kingdom National External Quality Assessment Service (NEQAS) quality assurance programmes.

19 Royal College of Pathologists of Australasia (RCPA) Quality Assurance Programmes

20 Pearson J. Point-of-care-testing and Clinical Governance
   Clin Chem Lab Med 2006;44(6)765-767

21 The HDC Code of Health and Disability Services Consumers' Rights Regulation 1996


23 Clinical Laboratory Standard Institute POCT04-A2 Point-of-Care In Vitro Diagnostic IVD) Testing; Approved Guideline – Second Edition

24 Clinical Laboratory Standard Institute POCT07 Quality Management: Approaches to Reducing Errors at the Point of Care; Approved Guideline

25 Clinical Laboratory Standard Institute POCT09-A Selection Criteria for Point-of-Care Testing Devices; Approved Guideline

26 Clinical Laboratory Standard Institute GP17-A3 Clinical Laboratory Safety; Approved Guideline – Third Edition

27 Clinical Laboratory Standard Institute Laboratory Quality Control Based on Risk Management; Approved Guideline EP23A

28 Clinical Laboratory Standard Institute POCT1-A2 Point of Care Connectivity Approved Standard - Second Edition
Appendix 1   Sample Collection Procedures

In POCT, the quality of the sample is known to have a significant effect on test results, and training in collection techniques such as fingerprick collection is essential. In accordance with other diagnostic testing, even though POCT is being performed near to the patient, there should be in place the same quality of patient identification, specimen collection and labelling as exists for laboratory testing. Providers are strongly recommended to consult their local accredited laboratory for detailed advice on sample collection procedures.

a)  Collection of Capillary Samples

CLSI states that the skin puncture device should be a sterile, disposable, single-use device with a permanently retractable blade or needle to reduce the possibility of accidental needlestick injuries and reuse. For operator and patient safety do not use a manual lancet, blade or needle without the retractable feature.

Blood obtained via skin puncture is a mixture of blood from arterioles, venules, capillaries, plus interstitial and intracellular fluids.

Proper collection of capillary puncture samples is essential for accurate laboratory test results. Potential sources of errors in capillary sample collection include:

- Incorrect Site selection:
  Choosing the correct site prevents patient harm and ensures adequate sample volume and quality.
  - In Adults and children over one year, the fingertip of the middle and ring fingers on the non-dominant hand are preferred. The tip and sides of the finger are to be avoided as the tissue is half as thick as the central pad. Thumb and index fingers are more likely have calloused skin and in the fifth “pinky” finger the distance to the bone from the skin surface is less. The dominant hand will tend to have thicker skin.
  - Infants under one year, CSLI guidelines recommend a heelprick collection with a device penetrating no deeper than 2.00 mm. To avoid osteomyelitis of the heel bone and nerve damage, the posterior curve of the heel and central arch area must be avoided. The shaded areas on the diagram are the recommended sites for good safe heelprick collection.

- Use of wrong size or type of skin puncture device
  Choose a device designed to deliver the volume of blood required. Poor choices may result in slow or inadequate collection, excessive squeezing, poor specimen quality (haemolysis, clotting) and if high flow devices selected, prolonged bleeding post collection.

- Failure to pre warm the site
  Pre-warming the collection site will increase the blood flow up to seven times. A warm moist towel or warming device, no more than 42°C applied for 3-5 minutes.
  - Capillary blood gas or pH samples must be pre-warmed to arterialise the sample and adequately mixed to prevent clot formation.

- Failure to allow skin to dry after cleansing.
Dry hands after washing and allow alcohol cleansed skin to air dry for effective disinfection.
Residual water or alcohol on the skin may cause haemolysis of the blood sample.
Puncturing the skin through alcohol causes discomfort to the patient.

- Failure to wipe away the appropriate drops of blood
  - Note: Some procedures such as INR require the use of the first drop of blood. Follow manufacturer’s instructions at all times.
    The skin puncture triggers the body’s clotting response with the first platelets aggregating at the collection site. Wiping away this platelet plug prevents an early end to the collection.
    The first drop of blood is potentially contaminated with tissue fluid and skin cells which may cause erroneous results or haemolysis.

- Squeezing too hard, “milking” the heel or digit and scooping/scraping the blood from the skin surface
  Touch the end of the collection device to the drop of blood.
  Excess squeezing and milking of the surrounding tissues will cause contamination with tissue fluid and haemolysis.
  Scooping or scraping blood from the surface of the skin will haemolyse the blood and activate the platelets leading to platelet clumping and micro clots.

- Incorrect or inadequate anticoagulant
  Follow manufacturer’s instructions as to choice of anticoagulant tube for tests required.
  Fill collection tubes to optimal level to prevent excess anticoagulant/blood ratio.
  Overfilled tubes will have insufficient anticoagulant to prevent clotted samples.

- Inadequate mixing
  Thorough mixing at time of collection will ensure anticoagulant is dissolved and dispersed throughout the sample, preventing clot formation. Placing a mixing wire into a capillary blood gas tube before collection will help.
  Mixing of whole blood samples just prior to analysis delivers a homogenous sample for analysis.

- Contamination
  Washing with warm water only is recommended because particular cleansers such as soaps and alcohol wipes are known to interfere with the analysis of certain analytes.
  An exception would be immune compromised patients.
  Uncleaned skin sites may be contaminated with environmental agents such as food that has been handled or creams/oils on baby heels.

- Presence of air bubbles in capillary blood gas samples
  Hold the heparinised capillary tube in a horizontal position. Touch the end of the tube to a well formed drop of blood. Quickly filled capillary tubes from a free flowing puncture site will minimise contact with air.
  Any air bubbles present should not be mixed into the blood sample. To do so will compromise the accuracy of the results.
b) Collection of Arterial Samples

The collection of arterial blood samples is technically difficult and is most sensitive to pre-analytical errors. Training in arterial blood collection by appropriate personnel is essential. Improper collection or handling of arterial blood can lead to erroneous pH and blood gas results. Potential sources of errors in arterial sample collection include:

- Failure to ascertain relevant patient temperature and ventilation status
  Blood gas results may be "corrected" to patient temperature by adjusting the analyser setting to the correct temperature of the patient. Patients who are breathing naturally should be comfortable and in a normal breathing pattern for 5 minutes before the collect. Anxiety, breath holding and crying will affect the results. Patients on supplementary oxygen should be on a stable amount of oxygen for 20 minutes before the collect. Take note of the ventilation status to allow calculation of all blood gas parameters.

- Inadequate sample volume
  Collect sufficient sample volume for the blood gas analyser in use. With 23 gauge or larger needles, the pressure in the artery will force blood into a well-lubricated syringe so that suction is not necessary. Excessive suction lowers the gas pressure of the sample and, therefore, the partial pressure of the individual gases.

- Presence of air bubbles in sample
  Any air in the sample will affect the results, especially pO₂. Expel any air bubbles from the syringe before mixing the sample. Gently tap the sides of the syringe to dislodge bubbles.

- Failure to mix sample after collection
  To prevent clotting, the sample must be promptly and thoroughly mixed after collection. Roll the syringe horizontally between the palms and invert the syringe vertically.

- Clotted sample
  A clotted sample is not representative of the patient’s blood gas status and should not be used. Introducing clots to the blood gas analyser will block the sample analysis of your collect and subsequent samples on the analyser.

- Failure to mix the blood before analysis
  Remix the sample immediately before analysis to introduce a homogenous sample. Whole blood will separate out on standing. Any sample showing visible separation of cells and plasma will need mixing for several minutes.

- Use of the wrong type or amount of anticoagulant
  The use of syringes specific to arterial blood gas collection is recommended. They are usually pre heparinised with dry electrolyte balanced heparin. Liquid heparin dilutes the blood giving erroneous results.

- Failure to remove first drops of blood before analysis
  Blood in the hub of the syringe is difficult to mix and prone to micro clots. Expel the first few drops onto gauze or tissue to prevent introducing clots to the analyser.

- Haemolysis
  Do not store samples directly on ice nor handle vigorously. Ruptured red blood cells will give false electrolyte and calcium results.

- Delay in analysis after collection
  Ideally analyse immediately after collection, delay no longer than 30 minutes. Cell metabolism continues after collection. Prolonged storage gives results that are not representative of the patient’s status. Storage on ice does NOT delay deterioration.
c) Collection of Venous Samples

Improper collection of venous samples for POCT which use whole blood may cause problems which are not as easily detected in the POCT environment as in the laboratory environment where serum or plasma is used. Potential sources of error include:

- Failure to adequately mix sample before analysis
  Remix immediately before analysis to present a homogenous sample for testing.
- Haemolysis due to poor collection technique
  Use of small bore needles and vigorous mixing can cause haemolysis which will not be visible in whole blood samples yet may alter results.
- Use of the incorrect or inadequate anticoagulant
  Follow manufacturer’s instructions as to choice of anticoagulant tube for tests required. Fill collection tubes to optimal level to prevent excess anticoagulant/blood ratio. Overfilled tubes will have insufficient anticoagulant to prevent clotted samples.
- Clotted sample
  A clotted sample is not whole blood. Follow the manufacturer’s instruction for inverting tubes after collection to anticoagulant the blood completely.

d) Collection of Urine Samples

Freshly voided urine or bladder stab specimens may be used for POCT. Catheter and urine bag samples are not suitable.

The urine must be collected in a clean dry container, labelled with patient’s name, NHI number, date and time of collection, and initials of staff collecting sample.

Samples should be tested as soon as possible after collection. If testing cannot be performed within one hour after collection, the specimen should be refrigerated at 2-8°C immediately and returned to room temperature before testing.

e) Collection of Other Samples

The collection of other types of samples must be in accordance with manufacturer’s instructions. These may include but are not restricted to:

- Urine samples for Drug Screening
- Faecal, eye or throat swabs
- Vaginal secretion swabs for prediction of pre-term delivery or pre-eclampsia