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The National Pathology Accreditation Advisory Council (NPAAC) was established in 1979 to advise the Australian, state and territory governments on matters relating to the accreditation of pathology laboratories. A key role of NPAAC is to develop and maintain pathology quality standards for accreditation. NPAAC also advises on pathology accreditation policy initiatives and initiates and promotes education programs about quality in the provision of pathology services.

Publications produced by NPAAC are issued as accreditation materials to provide guidance to medical pathology laboratories and accrediting agencies about minimum standards considered acceptable for good laboratory practice.

Failure to meet these minimum standards may pose a potential risk to public health and patient safety.
Scope

The use of Point of Care Testing (PoCT) in Australia is increasing and will become more widespread in the future. The purpose of this document is to provide guidance to users of the technology and to describe the key quality requirements for the performance of PoCT to ensure the safety and quality of test results.

PoCT is pathology testing performed near the individual by a PoCT operator at the time of the encounter. The results can be used to make immediate informed decisions about individual care.

This document sets out the best practice guidelines for governance, quality systems, staff training, safety, environmental issues, specimen and result integrity, related to the performance of PoCT. The appendices also contain checklists to assist in the interpretation of these Guidelines.

These Guidelines do not cover detailed operations of PoCT devices or training of staff that operate these devices. Self-testing at home and advice on the use and evaluation of specific analytical devices are also outside of the scope of this document.
## Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AS</td>
<td>Australian Standard</td>
</tr>
<tr>
<td>EQA</td>
<td>External Quality Assurance</td>
</tr>
<tr>
<td>ISO</td>
<td>International Organization for Standardization</td>
</tr>
<tr>
<td>NPAAC</td>
<td>National Pathology Accreditation Advisory Council</td>
</tr>
<tr>
<td>PoC</td>
<td>Point of Care</td>
</tr>
<tr>
<td>PoCT</td>
<td>Point of Care Testing</td>
</tr>
<tr>
<td>QC</td>
<td>Quality Control</td>
</tr>
</tbody>
</table>
## Definitions

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allowable error</td>
<td>means the amount of error that is acceptable without invalidating the interpretation of a test result.</td>
</tr>
<tr>
<td>Analyte (or component)</td>
<td>means a substance, component or chemical constituent that is of interest in an analytical procedure.</td>
</tr>
<tr>
<td>Competent</td>
<td>means demonstrated ability to apply knowledge and skills.</td>
</tr>
<tr>
<td>Decision limits</td>
<td>means a limit to decide on a specific level of risk or probability for the presence of a certain disease or condition.</td>
</tr>
<tr>
<td>External Quality Assurance (EQA) (or may be referred to as EQAS or proficiency testing (PT))</td>
<td>means a program in which multiple specimens are periodically sent to a service provider in the program for analysis and the results are reported to the participants and others. Such a program may therefore compare an individual’s PoCT device results with their peer group.</td>
</tr>
</tbody>
</table>
| In vitro diagnostic (IVD) medical device (this definition is adapted from Therapeutic Goods (Medical Devices) Regulations 2002) | means a medical device that is:  
(a) a reagent, calibrator, control material, kit, specimen receptacle, software, instrument, apparatus, equipment or system, whether used alone or in combination with another diagnostic product for in vitro use; and  
(b) intended by the manufacturer to be used in vitro for the examination of a Specimen derived from the human body, solely or principally for:  
(i) giving information about a physiological or pathological state or a congenital abnormality; or  
(ii) determining safety and compatibility with a potential recipient; or  
(iii) monitoring therapeutic measures; and  
(c) not a product that is intended for general laboratory use. |
<table>
<thead>
<tr>
<th><strong>Laboratory</strong>&lt;br&gt;(this definition is adapted from AS ISO 15189 Medical laboratories – Requirements for quality and competence)</th>
<th>means a facility for the biological, microbiological, immunological, chemical, immunohaematological, haematological, biophysical, cytological, pathological or other examination, including genetic testing, of materials for the purpose of providing information for the diagnosis, prevention and treatment of disease in, or assessment of the health of human beings, and which may provide a consultant advisory service covering all aspects of pathology investigation including the interpretation of results and advice on further appropriate investigation.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Point of Care Testing (PoCT)</strong></td>
<td>means pathology testing performed near or at the site of the individual by a PoCT Operator at the time of the consultation or encounter.</td>
</tr>
<tr>
<td><strong>PoCT Operator</strong></td>
<td>means a person who has undergone training and assessment by a recognised training organisation, course or program and is assessed as competent to operate a PoCT device.</td>
</tr>
<tr>
<td><strong>PoCT Supervisor</strong></td>
<td>means the person who is responsible for PoCT.</td>
</tr>
<tr>
<td><strong>Quality Assurance</strong></td>
<td>means a part of a quality system focused on providing confidence that quality requirements will be fulfilled.</td>
</tr>
<tr>
<td><strong>Quality system</strong></td>
<td>means those management activities involved in the direction and control of the organisation with regard to quality.</td>
</tr>
<tr>
<td><strong>Reagent</strong></td>
<td>means a consumable required to perform the testing on a PoCT analyser.</td>
</tr>
<tr>
<td><strong>Validation</strong></td>
<td>means the confirmation by examination and the possession of objective evidence that the particular requirements for a specific intended use are fulfilled.</td>
</tr>
<tr>
<td><strong>Verification</strong></td>
<td>means the application of the validation process only to a nonconforming aspect of an otherwise validated IVD. Verification can comprise activities such as:</td>
</tr>
<tr>
<td></td>
<td>• performing alternative calculations</td>
</tr>
<tr>
<td></td>
<td>• comparing a new design specification with a similar design specification</td>
</tr>
<tr>
<td></td>
<td>• undertaking tests and demonstrations</td>
</tr>
<tr>
<td></td>
<td>• reviewing documentation prior to issue.</td>
</tr>
</tbody>
</table>
**Introduction**

Pathology test results inform diagnostic and treatment decisions that affect health outcomes. Traditionally these tests have been performed in laboratories where systems have developed over time to ensure that results are comparable between different laboratories at different times so that clinicians have confidence that the decisions they make are based on consistent quality. The development of Point of Care (PoC) technology has allowed some pathology testing to be performed at the time of the consultation or encounter.

Point of Care Testing (PoCT) is available for use in pathology laboratories, hospital networks (to allow critical testing to be performed at the bedside or in a clinic), specialist medical retrieval medicine, General Practitioner (GP) practices, Aboriginal and Torres Strait Islander medical services, specialist community health services, and in other situations or community settings, such as pharmacies, sporting venues and law enforcement.

Recognising that PoCT can be used within a traditional pathology Laboratory as well as other healthcare and community settings, there is a need to ensure that any potential risks to patient safety associated with the use of PoCT are appropriately managed. This document sets out the quality framework for the performance of PoCT and provides guidance for any facility performing PoCT. The Guidelines have been developed with reference to relevant current and proposed Australian regulations and other standards. Compliance with the Guidelines ensures patient and client safety is not compromised.

In Australia, all *in vitro* diagnostic medical devices (IVDs) that are used for a therapeutic purpose are subject to regulation under the *Therapeutic Goods Act 1989*. A new regulatory framework for IVDs was implemented on 1 July 2010, following amendments made to the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Regulations) to include IVDs as a subset of medical devices. Any commercial IVDs which are used outside of the manufacturer’s intended purpose equate to “off label use”. In such cases this “off label use” means they are considered in-house IVDs and are required to comply with the regulatory requirements for in-house IVDs ([https://www.tga.gov.au/industry/devices.htm](https://www.tga.gov.au/industry/devices.htm)). Such “off-label use” includes using the device for a clinical purpose other than that originally intended by the manufacturer or not using the device in accordance with the manufacturer’s instructions for use. Careful review of the manufacturer’s instructions for use should be undertaken by the user to ensure the instruments are not used outside of the prescribed intended use. Also some PoCT devices are not intended to be used in a therapeutic setting e.g. breathalysers. Such devices are not subject to the Therapeutic Goods Administration (TGA) IVD regulations.

These Guidelines should be read in conjunction with all relevant national and jurisdictional legislation.

In each section of this document, points deemed important for practice are identified as either ‘Guidelines’ or ‘Commentaries’.

- A Guideline is a consensus recommendation for best practice and should be used if a higher level of practice is appropriate – Guidelines are prefaced with a ‘G’ (e.g. G2.2) and are numbered consecutively through each section. The word ‘must’ is used to indicate Guidelines or recommendations where compliance would be expected for good laboratory practice.
• A Commentary is provided to give clarification to the Standards as well as to provide examples and guidance on interpretation. Commentaries are prefaced with a ‘C’ (e.g. C1.2) and are placed where they add the most value. Commentaries may be normative or informative depending on both the content and the context of whether they are associated with a Standard or not. Where a Commentary contains the word ‘should’ then that commentary is considered to be compulsory.

The Appendices form part of the document and are designed to provide additional information, detailed checklists and further guidance to assist PoCT Operators or those responsible for facilities where PoCT is performed in any of the settings described.


While this document is for use in the accreditation process, comments from users would be appreciated and can be directed to:

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Department of Health Fax: (02) 6289 4028
GPO Box 9848 (MDP 951) Email: npaac@health.gov.au
CANBERRA ACT 2601 Website: www.health.gov.au/npaac
1. Governance

Organisations providing PoCT are accountable for the quality of their service and maintaining a high standard of care.

G1.1 Organisations performing PoCT must have in place a governance framework that actively manages safety and quality risks in the delivery of PoCT.

G1.2 The wellbeing of individuals and their rights must be the primary consideration.

C1.2 The purpose of PoCT is to provide accurate and timely test results that effectively contribute to immediate management decisions.

G1.3 There must be a designated and Competent PoCT Supervisor, who is accountable for the conduct, quality and implementation of the PoCT being performed.

C1.3(i) There must be a documented policy/protocol for the selection, use and application of PoCT tests and for the interpretation of the test results. This must include reference intervals and Decision limits.

C1.3(ii) The PoCT Supervisor must ensure that staff using PoCT are trained and Competent.

G1.4 The analytical and non-analytical characteristics of PoCT and the responsibilities for the delivery of PoCT must be defined in the Quality system.

C1.4(i) The designated PoCT Supervisor under whose direction and control the PoCT operates must be clearly identifiable and accessible, show leadership to promote safe and ethical practice and must have the authority and competence to ensure and take responsibility for:

(a) policy setting and implementation
(b) operational practices and staffing (including training)
(c) determining the range of tests provided, their methods and procedures
(d) regular review of the Quality system and all aspects of performance
(e) provision of medical or scientific consultation
(f) procedures used and the tests performed being within the scope of the education, training, continuing professional development and experience of individual staff members
(g) provision of a clearly defined process for contacting a PoCT Supervisor
(h) Verification of PoCT procedures.

C1.4(ii) Selected tasks may be delegated but must comply with the governance system outlined in C1.4(i).

C1.4(iii) The specific requirements for governance and supervision will differ according to the complexity of testing.

C1.4(iv) Documentation must be available to support C1.4(i) - C1.4(iii).
G1.5 The privacy and confidentiality of individuals must be maintained at all times.

C1.5(i) Consent should be obtained, where possible, from the individual to allow the collection or procedure to be carried out.

C1.5(ii) Consent should also include informed financial consent, where relevant.
2. Preparation, Specimen Integrity and Individual Test Records

The quality of results generated through PoCT relies on the performance of a number of operations; patient or client preparation, testing and record management (also called the pre-analytical, analytical and post-analytical phases of testing – see Appendix D). Test results may be compromised if any of these operations are not considered when implementing PoCT. Failure to recognise and eliminate errors through the entire testing process can jeopardise test results and patient and client safety.

Risk management of these operations is essential. Factors such as patient and client preparation (e.g. fasting), specimen collection, specimen preservative used (if appropriate) and sample application can all affect the quality of the results obtained. Criteria for patient and client safety and quality testing include:

- correct test ordered
- correct patient or client
- correct patient and client preparation
- correct collection technique
- correct specimen and processing
- accurate test result
- correct recording in the patient or client record
- correct clinical interpretation
- correct and timely clinician response.

G2.1 Collection of specimens must be performed in accordance with the manufacturer’s instructions.

G2.2 Collection of specimens must be performed with accurate identification of the patient or client and ensuring traceability of the specimen to the report.

G2.3 The following are examples of records that should be retained to allow traceability:

(a) patient or client demographic data (such as surname, sex, date of birth, unique medical record number), unless de-identification or anonymity is prescribed
(b) date and time of collection
(c) the date and time of performance of the test
(d) validated result data, including the result or printout from the PoCT instrument and any quality control results associated with testing
(e) identity of the location and person issuing the report
(f) the identification of the analyser or device.
3. **Testing Considerations**

In some settings, PoCT may be able to provide a more convenient and accessible service for patients and clients as well as more rapid and accessible test results than can be achieved from Laboratory settings.

Before PoCT is implemented, the analytical performance requirements for the intended purpose must be defined. Participation in Quality Control and External Quality Assurance programs (where available) will ensure appropriate performance. As both Laboratory and PoCT results may be used for patient and client care, it is highly desirable to know how the two methods compare. Reference intervals and clinical Decision limits also need to be clearly defined based on current best practice and the particular characteristics of the PoCT device.

To ensure that the results of testing are correct and that they continue to meet required quality performance criteria, analytical equipment must be checked and verified before use to ensure that its ongoing operation remains within required performance parameters. Records of all quality performance checks must be retained to provide assurance that correct procedures are being maintained.

The RCPA Quality Assurance Programs Pty Ltd has developed a list of allowable limits of performance for a range of therapeutic pathology tests which can be used to guide the process of determining whether a PoCT device is able to meet analytical requirements1 (Refer to Appendix A).

G3.1 **Prior to implementing PoCT, the analytical performance requirements of the test must be defined.**

C3.1 The following **must** be considered when defining analytical performance requirements:

(a) Quantitative analysis such as selectivity, sensitivity, accuracy, precision, trueness, limit of detection and limit of reporting

(b) Qualitative analysis such as sensitivity and specificity.

G3.2 **Testing must be verified by the use of internal quality control material.**

G3.3 **Quality control procedures must be utilised to ensure that all testing is performed using instruments, Reagents and consumables which are working correctly and according to specifications.**

C3.3 There **must** be documented criteria for the acceptance of quality control results. Any results and any action to be taken when these are unacceptable **must** be documented.

G3.4 **An acceptable standard of performance in external proficiency testing programs, where such programs are available, must be achieved.**

C3.4 Where External Quality Assessment programs do not exist for a test method, the validity of the test results **must** be demonstrated by methods such as inter-Laboratory patient or client sample comparisons.
4. **Staff Training**

Operators from both Laboratory and non-Laboratory backgrounds perform routine PoCT in many different situations and locations. However, for patient, client and staff safety, and for the maximum patient and client benefit to be realised, PoCT Operators must be both Competent to perform the test and have confidence in the test result itself. Therefore it is critical that staff have the required skills to perform such testing.

It should be noted that manufacturer’s training of the operation of the device may not be sufficient to ensure competency.

**G4.1** PoCT must only be performed by operators who have undertaken training by a recognised training organisation, course or program and have demonstrated that they are Competent.

- **C4.1(i)** Records of staff PoCT training and retraining must be maintained.
- **C4.1(ii)** Personnel that are undergoing PoCT training must be supervised at all times during the provision of PoCT.
- **C4.1(iii)** There must be documented criteria for when staff require retraining, which may need to occur because of infrequent testing, critical incident generation, or the implementation of new testing methods.
- **C4.1(iv)** The training program should include but not be limited to the following areas:
  (a) procedures for the safe performance of tests and accurate interpretation of results
  (b) pre-analytical errors
  (c) the Quality system
  (d) PoCT work processes and procedures
  (e) confidentiality of patient and client information
  (f) Workplace health and safety.

**G4.2** Personnel must be assessed and deemed as Competent prior to performing patient and client testing and periodically thereafter.

- **C4.2(i)** Competency assessment records must be maintained.
- **C4.2(ii)** Competency must be reassessed following training and when new PoCT devices are deployed.

**G4.3** Personnel involved in the provision of PoCT must participate in continuing education commensurate with the testing provided.
5. **Quality System**

Quality systems describe the systematic approach used by an organisation to direct, control and evaluate the quality of their service. A Quality system aims to consistently monitor and improve the organisation’s ability to produce valid test results. The Quality system for PoCT may be covered by an organisation-wide Quality system.

A Quality system needs to encompass the preparation and sample collection (pre-analytical), the testing process itself (analytical) and reporting of results and sample disposal (post-analytical) phases of the testing cycle and address the organisational structure, responsibilities, policies and procedures and resources needed to achieve a safe service. The scope of the Quality system is usually documented in a quality manual. This should be centrally held and maintained and be available for users of PoCT *(Refer to Appendices B and D).*

**G5.1** There must be a documented Quality system that incorporates PoCT. The Quality system must address the following:

(a) governance
(b) location of PoCT equipment
(c) storage of Reagents and consumables
(d) purchasing and inventory procedures
(e) preparation and sample collection procedures including defined procedures to monitor the traceability and continued integrity of specimens through preparation and sample collection, testing, reporting and sample disposal
(f) test procedures (including reference intervals)
(g) processes for assessing the validity of the test results
(h) record keeping
(i) processes for the timely reporting, interpretation and actioning of test results that contribute to safe care
(j) policies and procedures relating to risk management that ensure the safety of patients, clients, staff and visitors
(k) policies, protocols and procedures to prevent the spread of infection.

**G5.2** There must be a nominated person who is responsible for the Quality system.

**G5.3** There must be periodic review of the PoCT policies and procedures.

C5.3(i) This should occur at least annually.
C5.3(ii) Audits of PoCT operating procedures and staff activities should be conducted to ensure compliance and ongoing suitability of the Quality system.
6. Environment

A safe, secure working environment must be provided to ensure PoCT testing is safely and effectively performed.

G6.1 The PoCT environment must address all facets of PoCT including:

(a) performance of testing  
(b) functioning and maintenance of equipment  
(c) storage of Reagents and consumables  
(d) storage of specimens and records  
(e) undertaking administrative duties  
(f) pre-test counselling  
(g) specimen testing  
(h) post-test reporting  
(i) waste disposal.

G6.2 There must be a documented contingency plan for continued operations in the event of equipment and other failures.

G6.3 Manufacturer’s instructions for the maintenance of instruments and associated equipment must be followed and documented in the PoCT maintenance record.

G6.4 Reagents and consumables must be stored in accordance with the manufacturer’s instructions.

G6.5 PoCT equipment must only be used by a PoCT Operator.
7. **Workplace Health and Safety**

Documentation of accidents, incidents and adverse events; education and training of PoCT staff in the use and performance of PoCT; and the use of PoCT devices is essential to improve practice and protect public health.

Samples tested at PoC must be handled in the same manner as other biological fluids. Every sample may be infectious and staff performing the tests should wear appropriate Personal Protective Equipment (PPE) (e.g. gloves, mask, gown, eye protection).

Additional guidance is provided in Appendix C.

**G7.1** There must be documented policies and procedures relating to Workplace Health and Safety that are consistent with relevant national and jurisdictional workplace health and safety requirements.

- **C7.1(i)** All staff performing PoCT must be vaccinated according to organizational requirements.
- **C7.1(ii)** Equipment or consumables identified as “single use” must not be re-used.

**G7.2** Disposal of biological material, clinical waste and sharps from testing must comply with jurisdictional regulations and the organisation’s waste management policy.

- **C7.2(i)** All samples must be considered to be potentially infectious and handled with this in mind.
- **C7.2(ii)** There must be compliance with all Workplace Health and Safety and other jurisdictional requirements.
- **C7.2(iii)** There must be policies regarding sharps management, biohazard spills and infection control, including standard and transmission based precautions.

**G7.3** Any accidents or incidents must be reported to the PoCT Supervisor with appropriate first aid immediately undertaken and followed up according to local workplace requirements.
Appendix A  Allowable limits of performance (Informative)

<table>
<thead>
<tr>
<th>POINT OF CARE TESTING</th>
<th>Reviewed April 2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albumin</td>
<td>± 2.0 up to 33.0 g/L; 6% &gt; 33.0 g/L</td>
</tr>
<tr>
<td>Alkaline Phosphatase</td>
<td>± 15 up to 125 U/L; 12% &gt; 125 U/L</td>
</tr>
<tr>
<td>ALT</td>
<td>± 5 up to 40 U/L; 12% &gt; 40 U/L</td>
</tr>
<tr>
<td>Amylase</td>
<td>± 10 up to 100 U/L; 10% &gt; 100 U/L</td>
</tr>
<tr>
<td>AST</td>
<td>± 5 up to 40 U/L; 12% &gt; 40 U/L</td>
</tr>
<tr>
<td>Bicarbonate</td>
<td>± 2.0 up to 20.0 mmol/L; 10% &gt; 20.0 mmol/L</td>
</tr>
<tr>
<td>Bilirubin-Total</td>
<td>± 3 up to 25 µmol/L; 12% &gt; 25 µmol/L</td>
</tr>
<tr>
<td>Calcium</td>
<td>± 0.10 up to 2.50 mmol/L; 4% &gt; 2.50 mmol/L</td>
</tr>
<tr>
<td>Chloride</td>
<td>± 3 up to 100 mmol/L; 3% &gt; 100 mmol/L</td>
</tr>
<tr>
<td>Cholesterol</td>
<td>± 0.30 up to 5.00 mmol/L; 6% &gt; 5.00 mmol/L</td>
</tr>
<tr>
<td>Creatine Kinase</td>
<td>± 15 up to 125 U/L; 12% &gt; 125 U/L</td>
</tr>
<tr>
<td>Creatinine</td>
<td>± 8.0 up to 100.0 µmol/L; 8% &gt; 100.0 µmol/L</td>
</tr>
<tr>
<td>Glucose</td>
<td>± 0.4 up to 5.0 mmol/L; 8% &gt; 5.0 mmol/L</td>
</tr>
<tr>
<td>GGT</td>
<td>± 5 up to 40 U/L; 12% &gt; 40 U/L</td>
</tr>
<tr>
<td>HDL Cholesterol</td>
<td>± 0.10 up to 0.80 mmol/L; 12% &gt; 0.80 mmol/L</td>
</tr>
<tr>
<td>Lactate Dehydrogenase</td>
<td>± 20 up to 250 U/L; 8% &gt; 250 U/L</td>
</tr>
<tr>
<td>Magnesium</td>
<td>± 0.10 up to 1.25 mmol/L; 8% &gt; 1.25 mmol/L</td>
</tr>
<tr>
<td>Potassium</td>
<td>± 0.2 up to 4.0 mmol/L; 5% &gt; 4.0 mmol/L</td>
</tr>
<tr>
<td>Protein (Total)</td>
<td>± 3 up to 60 g/L; 5% &gt; 60 g/L</td>
</tr>
<tr>
<td>Sodium</td>
<td>± 3 up to 150 mmol/L; 2% &gt; 150 mmol/L</td>
</tr>
<tr>
<td>Triglyceride</td>
<td>± 0.20 up to 1.60 mmol/L; 12% &gt; 1.60 mmol/L</td>
</tr>
<tr>
<td>Troponin I</td>
<td>± 0.00 up to 0.01 µg/L; 20% &gt; 0.01 µg/L</td>
</tr>
<tr>
<td>Troponin T (Qualitative)</td>
<td>&lt; 50 ng/L Negative</td>
</tr>
<tr>
<td></td>
<td>50-100 ng/L Low</td>
</tr>
<tr>
<td></td>
<td>100-2000 ng/L Quantitative</td>
</tr>
<tr>
<td></td>
<td>&gt;2000 ng/L High</td>
</tr>
<tr>
<td>Troponin T (Quantitative)</td>
<td>± 0 up to 10 ng/L; 20% &gt; 10 ng/L</td>
</tr>
<tr>
<td>Urate</td>
<td>± 0.030 up to 0.380 mmol/L; 8% &gt; 0.380 mmol/L</td>
</tr>
<tr>
<td>Urea</td>
<td>± 0.5 up to 4.0 mmol/L; 12% &gt; 4.0 mmol/L</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>GLYCOHAEMOGLOBIN</th>
<th>Reviewed May 2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>HbA1c (NGSP) (%)</td>
<td>± 0.5 up to 10.0%; 5% &gt; 10.0%</td>
</tr>
<tr>
<td>HbA1c (IFCC) (mmol/mol)</td>
<td>± 4 up to 86 mmol/mol; 5% &gt; 86 mmol/mol</td>
</tr>
</tbody>
</table>

Note: The limits specified in the table above were valid at September 2014. It is recommended that the currency of these limits be checked on the RCPAQAP website: https://www.rcpaqap.com.au/wp-content/uploads/2013/06/chempath/Allowable%20Limits%20of%20Performance.pdf
Appendix B  Implementing and Maintaining PoCT (Informative)

IMPLEMENTING POINT OF CARE TESTING (PoCT) INTO YOUR ORGANISATION - FLOWCHART

1. DETERMINE THE NEED FOR POCT IN YOUR ORGANISATION
   - If YES

2. SELECT THE APPROPRIATE POCT ANALYSER FOR YOUR ORGANISATION
   - Select your device

IMPLEMENTATION OF YOUR POCT SERVICE

- QUALITY ASSURANCE (QA)
  - QUALITY CONTROL (QC)
- RECORDS
  - (e.g. test results, instrument event log, Quality Control log)
- TRAINING/COMPETENCY
  - (e.g. training materials/resources)

ON-GOING PROFESSIONAL SUPPORT
- Manufacturer
- PoCT Network Service Providers
- Accredited Pathology Laboratory
- Professional organisations
A. Test system selection and management

1. Selection

Selection of a test system should be based on intended clinical use and evaluation should be performed accordingly.

Generally test systems fall into three broad categories:

1. Low complexity - simple strip based, tests such as pregnancy test, dipstick and lateral flow.
2. Medium complexity - single use disposable tests such as glucose, INR, troponin, HbA1c.
3. High complexity - laboratory analysers.

PoCT is generally restricted to the first two categories of test systems, although newer PoCT devices may be able to run multiple analytes.

A test system needs to be selected with due regard to the following main points. These points need to be assessed against the manufacturer’s claimed specifications, and will assist in selection of the broad category of test system required.

Considerations:

- why PoCT is a desired testing option
- what type of tests will be performed
- how many tests are anticipated per day or week
- who will be performing the testing
- who will be managing the service
- how the tests will be reported and the results recorded – can they be electronically transferred to hospital/practice/organisational software
- how the test system will be serviced and maintained, if applicable
- what funds are available to support the service.

2. Evaluation and Verification

The purpose of the verification process is to confirm (verify) that the performance of a particular PoC test system, when installed, performs to and meets the manufacturer’s stated specifications, and to validate the results against a known standard.

Verification most commonly occurs by parallel testing, where a number of samples are run firstly on the PoC test system, and then a duplicate, identical sample taken at the same time is sent for analysis by an equivalent laboratory method. The results are then matched and a statistical analysis performed to see how well the two sets of results compare.

The evaluation strategy and statistical analysis employed will be dependent on whether the test result is quantitative (where an absolute level or concentration of analyte is detected, as is the case for most clinical chemistry and haematology PoC tests) or qualitative (where a result is reported as positive or negative, as is the case for most infectious disease and drugs of abuse PoC tests). The key measures of analytical performance for most quantitative PoC tests are accuracy, or trueness of the result, and imprecision, or reproducibility of the measurement, while, for qualitative PoC tests, sensitivity or true positive rate, and the specificity or true negative rate, are more commonly used to assess performance.
3. **Quality Control and Quality Assurance**

Quality Control (QC) is a procedure where the PoCT analyser tests artificial samples where the analyte is present in known quantities, and the PoCT instrument result obtained is expected to be close to this known value +/- the imprecision of the particular test. The quality control samples may be provided by the manufacturer but may also be available from suppliers of external quality control material. The QC process also includes the recording of the QC results, and any subsequent action taken if the quality control result falls outside what is an acceptable range.

QC provides an indication of the performance of an individual analytical system at the time the QC is run and allows confidence in the results of the samples tested during this time.

External Quality Assurance (EQA) involves testing samples where the quantity of analyte or result is not known to the operator at the time of testing. The results obtained from the PoCT analyser are compared to the results obtained by others testing the same EQA sample with the same type of analyser. The target value (often calculated as the mean or median) of all the test results submitted to the EQA program organisers is generally considered to be the expected analyte value, and individual results of all EQA program participants are ranked according to their closeness to the target value.

EQA provides a measure of the robustness of the testing system, and can identify issues such as calibration drift, matrix effects, operator variability, and stability issues that may not be detected by QC alone.

QC and EQA processes will also differ slightly depending on whether the PoCT test is qualitative or quantitative.

**B. Quality Control (QC) testing requirements**

A QC sample should, at a minimum, be tested before each new batch or lot number of reagent or cartridge is put into routine use. Ideally, QC samples should be tested with each group of patient/client tests performed. Frequency of QC samples should be according to the manufacturer’s recommendations.

If a test needs to always be available, a minimum QC testing frequency of once per month is required. For lesser clinical needs, QC testing should be performed immediately before sample testing is undertaken.

Each QC test result should also record the operator identity, the reagent batch number and the test result. With qualitative PoC test results, a system of recording ordinal values (-, +/-, +, ++, ++++) should be introduced. A documented system of acceptance and rejection of QC test results should be established, including what actions are undertaken in the case of rejection.

Many PoC test systems have a number of in-built quality checks. The purpose of these checks may be to check sample integrity, sample flow and sample volume. These may not check the entire testing process. In this situation, another form of QC may need to be undertaken depending on the level of risk to individuals.

Electronic QC is a check of the analyser’s measurement signal only and does not check the analytical part of the system. Therefore it is complementary to physical QC requirements and not a substitute for the minimum QC requirements outlined in this document.
In addition to the regular QC program, QC testing should also be undertaken when:

(a) the lot number of consumables changes
(b) there is a new delivery of consumables
(c) an operator lacks confidence in a result
(d) the healthcare professional does not believe that the PoCT result fits the clinical picture
(e) substantial maintenance procedures have been carried out on the test system
(f) the test system has suffered a physical insult (e.g. dropped, temperature extremes – hot or cold, etc.).

1. **Who should run PoCT quality control samples?**

QC samples simulate actual patient/client samples, so that any likely problem that might affect the correctness of a patient/client sample is also experienced by the QC sample, thereby alerting the operator to the existence of the problem.

For this reason, QC testing for PoCT should be undertaken by the PoCT Operator/s.

2. **Who should be responsible for reviewing quality control results?**

The PoCT Operator undertaking QC testing should immediately review and act on the QC results.

The PoCT Supervisor or delegate must be responsible for review and trend analysis of QC results, taking appropriate corrective action when required. All QC records, reviews and corrective action documentation should be maintained for three years and be available for review.

C. **External Quality Assurance (EQA) testing requirements**

Participation in a recognised EQA program is recommended for each analyte being tested. Monthly parallel sample testing with an accredited Laboratory may be considered as an alternative form of EQA. This mode of EQA may be useful when a commercial program is either unavailable or unsuitable for the instrument in question.

*Note: Users should be aware of limitations of using the parallel sample approach which include a more limited range of analyte concentrations available for testing, issues relating to transport stability and lack of peer comparison.*

1. **Who should run PoCT EQA samples?**

EQA for PoCT must be run by the PoCT Operator.
2. **Who should be responsible for reviewing EQA results?**

The PoCT Supervisor or delegate must be responsible for the review of EQA results and taking appropriate action. All EQA records, reviews and documentation should be available for review and maintained in accordance with the pathology accreditation document *Requirements for the Retention of Laboratory Records and Diagnostic Material*.

**D. Ongoing maintenance**

Manufacturers’ recommendations regarding maintenance must always be followed.

All maintenance activities should be documented (see example below).

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Name........................</th>
<th>Serial No.................</th>
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</thead>
<tbody>
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Appendix C  Workplace Safety (Informative)

All incidents related to PoCT must be recorded and reviewed.

The strategies outlined in this section and the guidance provided have been identified as necessary for successful implementation of practices that ensure patient, client and staff safety.

It is essential that a procedure is in place for the safe disposal of biological waste and/or sharps in accordance with the jurisdictional health and safety and/or infection control legislation.

It is the responsibility of organisations providing PoCT to ensure that appropriate occupational health advice is provided to PoCT Operators. For example, all staff involved in PoCT should be appropriately vaccinated against hepatitis B.

1. Environmental/equipment

1.1 Only PoCT analysers and associated equipment that have satisfied all Workplace Health & Safety requirements can be commissioned.

1.2 Analysers and associated equipment must be located and stored, used and managed according to safe work practices for the testing location.

2. Cleaning of equipment

2.1 In many situations, PoC analysers do not touch the patient or client. However, indirect contact transmission of infectious agents can occur from one patient or client to another, through:

(a) Intermediate contaminated objects (e.g. gloves).
(b) Via individuals (e.g. contaminated hands) (Note: There are many published examples of transmission of hepatitis B through re-use of contaminated glucose meters or sharps).

2.2 Disposable equipment must not be reused.

2.3 Reusable test systems must be cleaned and decontaminated according to the manufacturers’ instructions.

2.4 A relevant and current cleaning manual must be available for all reusable PoCT test systems and equipment.

2.5 Procedural rules for PoCT environment:

(a) Prohibition of activities such as eating, drinking, smoking, and applying cosmetics at testing-sites (due to significant risks of contamination via the hands, and to the items for ingestion or skin application).
(b) Regular and effective disinfection of all work areas in accordance with usage and jurisdictional (and infection control) requirements.
(c) Spills that involve blood, body fluids, other potentially infectious materials, and reagents must be cleaned and decontaminated.
3. **Staff**

3.1 Staff undertaking PoCT must be trained, appropriately vaccinated and knowledgeable regarding the risks of cross-infection and how these can be minimised.

3.2 Staff must comply with organisational infection control policies including:

(a) Hand-washing must occur:
   - before and after patient/client contact
   - after removing gloves
   - after completing work
   - before leaving the testing area
   - before touching eyes, mouth, and glasses
   - before and after using lavatory facilities
   - immediately after contamination with a specimen or reagent
   - after cleaning PoCT test systems.

(b) Glove use including changing gloves between patients, not re-using used gloves, not washing used gloves.

(c) Thorough and effective cleaning and disinfection of testing devices after each use.

(d) Properly labelling and storing PoCT analysers, such that risk of inadvertent analyser use for other patient or client groups is eliminated.

(e) Participating in relevant jurisdictional vaccinations.

3.3 Staff undertaking PoCT must comply with safe work practices including:

(a) Prohibition of needle recapping.

(b) Use of safety needles.

(c) Implementation of special spill-proof, autoclavable, opaque sharps disposal containers (secured to a wall or bench surface, with puncture-resistant design).

(d) Sharps disposal containers, labelled or colour-coded to warn of (potential) biohazards or contamination.

(e) No eating, drinking, smoking, applying cosmetics, changing contact lenses in the PoCT work environment.

3.4 There must be a protocol for the immediate evaluation and subsequent follow-up of occupational body fluid exposure.

3.5 There must be a safety training program for employees who routinely work with blood or other potentially infectious materials.

3.6 There must be a safety manual available on site.

3.7 There must be staff training documentation, maintained according to local regulations or institutional protocols, available for inspection.

4. **Waste disposal**

4.1 Specimens, reagents and other consumables supplies must be handled and disposed of according to safe work practices for the testing location.
(a) Consumables (e.g. lancets, disposable strips, cartridges) and reagents used with hand-held devices or PoCT analysers, require disposal appropriate for biohazardous infectious waste.

(b) Infectious waste (biohazard) containers must be conveniently located and of sufficient number and volume to accommodate the potentially infectious waste generated at the site.

(c) The containers must be constructed of materials appropriate to the type of waste generated.

(d) Biohazard containers must be handled with gloved hands and replaced when the fill-line is reached.

(e) Disposal of medical and infectious waste must comply with all jurisdictional requirements.

5. Other

5.1 There must be a list of emergency contacts, including the names and telephone numbers of appropriate individuals and institutions to inform in an emergency.

5.2 There must be proper reporting procedures for occupational accidents.

5.3 There must be written clean-up procedures for reagent and specimen spills.

5.4 There must be an incident log including the date, time, individual(s) name(s), and type of accident. In the event of a needlestick, the data set must include the source patient/client identifying information, source patient/client contact information and relevant medical diagnoses.
Appendix D  Common errors relating to PoCT  
(Informative)

For PoCT to be conducted safely, a PoCT Operator must perform PoCT according to the test system manufacturer’s instructions and under the Quality system established. Any deviation from those manufacturer instructions has the potential to cause an error in measurement and compromise patient or client safety. In practice, most errors that occur with PoCT are attributable to patient or client preparation and sample collection issues (pre-analytical errors) rather than to the testing process itself (analytical errors) or to the reporting of results (post-analytical errors).

Some of the more common errors that can occur with PoCT are summarised below:

**Preparation or Pre-analytical Errors**

*(a)  Sampling from a venous blood tube containing the wrong preservative*
Manufacturer’s instructions usually specify which blood tube type and preservatives are recommended for a particular PoCT test. If a tube with a different preservative is used to collect a venous sample for PoCT, an error can occur. For example, if blood for the measurement of potassium and calcium by PoCT is collected in a tube containing di-potassium EDTA as the preservative, the sample’s potassium will be falsely elevated due to the presence of potassium in the preservative, while the calcium will be falsely lowered because EDTA binds the calcium in the sample.

*(b)  Finger-prick sampling from unwashed hands*
An important component of finger-prick sample collection is to ensure that an individual’s hands are thoroughly cleaned and dried before sampling is conducted. If the individual’s hands are contaminated by water, chemicals or dirt, then errors in PoCT measurement can potentially occur. For example, if an individual handles a sugar-containing product such as fruit and does not wash his/her hands before having a finger-prick blood glucose test, then the glucose concentration can be falsely elevated (by 10% or higher).

*(c)  Not sampling from first or second drop of finger-prick blood*
It is critical to follow the manufacturer’s specification on which drop of finger-prick blood should be used for analysis. Depending on the test being measured, the first, second or even the third drop of finger-prick blood could be recommended by the manufacturer. For example, for INR testing it is important to use the first drop of blood for analysis as the clotting process may have commenced. For haemoglobin testing, most manufacturers recommend that the first drop of blood is wiped away and the second or third drop of blood is used for this test.
(d) The presence of air bubbles in the sample holder
With many PoCT test systems, if air bubbles are present in the sample when it is placed into a reagent container, there is the possibility of a false PoC test result being generated. For example, urine albumin:creatinine ratio (ACR) is a common PoC test for early renal disease and it is calculated by dividing the urine albumin by the urine creatinine in the sample tested. If an air bubble is present in the sample holder which, for example, takes up one quarter of the recommended sample volume space, then both the urine albumin and the urine creatinine values will be falsely low by a factor of one quarter (although the ACR may be reported correctly). It is therefore important that the full recommended sample volume is collected for PoCT and if air bubbles or sample under-fill occurs, then a new sample is collected.

(e) Wrong units of measurement set on a PoCT analyser
A clinical decision on pathology results is usually made by comparing the PoCT result with a stated reference interval. It is important that the PoCT result and the reference interval are in equivalent units. Many modern PoCT analysers have the ability to report the results of selected tests in more than one unit of measurement. If the PoCT result is set to a different unit of measurement than the reference interval, then an inappropriate clinical decision could be made. For example, blood glucose units can be reported as either mmol/L or mg/dL (but there is an 18-fold difference in numerical value between the two units). Therefore a glucose result of 2.5 mmol/L (which is a value in the hypoglycaemic range) could be reported as 45 (falsely indicating a result in the hyperglycaemic range) if the unit of measurement on the glucose analyser was incorrectly set to mg/dL.

(f) Using quality control materials beyond their expiry date
Most quality control materials used to support PoCT have a well-defined manufacturer shelf life when stored opened or unopened. These expiry dates must be stringently adhered to and once expired, used material must be discarded and replaced with fresh material. For example, if a quality control sample (once opened) has a shelf-life of 3 months and that material continues to be used beyond the recommended 3 month window, then quality control results are likely to trend lower and drift outside the allowable limits set for acceptable quality. These low quality control results are not due to an inherent analytical fault with the analyser but rather due to the material being used inappropriately outside the manufacturer’s recommendations.

(g) Not using the manufacturer’s recommended collection device
Point of care tests have been validated for use with particular sample types and volumes. Different manufacturers provide specific collection devices e.g. capillary tubes, sample loops and loops which standardise the volume of sample applied to test devices. To obtain optimal test results the correct collection device must be used as indicated by the manufacturer’s instructions for use. Using alternate devices may introduce volumetric errors which could affect the validity of the test and its overall performance.
Testing or Analytical Errors

(h) Incorrect timing for manual reading of urine dipsticks
Urine dipsticks are widely used in many clinical settings for qualitative analysis of urine samples. These most basic PoCT analysers commonly rely on the manual reading of colour pads at set time intervals following immersion of the dipstick into a urine sample. The degree of colour change provides an indication of the concentration of the different pathology markers embedded in pads on the dipstick test strip. If the colour pad is read earlier (or later) than the recommended time interval, then the test marker is likely to be either underestimated (or overestimated).

Individual Record or Post-analytical errors

(i) Manual transcription errors
Many modern PoCT analysers have the ability to store and transfer results to an electronic medical record or a laboratory/clinical information system. However some analysers still require manual transcription of results and errors can occur with this mode of result transfer. It is important that the correct PoCT result for each patient or client is taken from the display screen or printout of the PoCT test system and then transcribed accurately into the appropriate individual record.
References

Bibliography


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