Australian Government
Department of Health

NPAAC TIER 4 DOCUMENT

REQUIREMENTS FOR POINT OF CARE TESTING

(Second Edition 2021)

National PATHOLOGY ACCREDITATION Advisory Council

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Content

The National Pathology Accreditation Advisory Council (NPAAC) was established in 1979 to consider and make recommendations to the Australian, state and territory governments on matters related to the accreditation of pathology laboratories, and the introduction and maintenance of uniform standards of practice in pathology laboratories throughout Australia. A function of NPAAC is to formulate Standards and initiate and promote education programs about pathology tests.

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

Failure to meet these minimum Standards may pose a risk to public health and patient safety.

Scope

The *Requirements for Point of Care Testing (Second Edition 2021)* sets out the minimum requirements for governance, management systems, staff training, safety, environmental issues, and specimen and result integrity related to the performance of point of care testing (PoCT).

PoCT is considered to be pathology testing and these minimum practice standards apply to all PoCT used in all healthcare settings.

The document describes the key steps needed to ensure users of point of care technology provide safe, quality-assured PoCT, especially when the results will be used for a patient's healthcare management.

These Requirements *do not* cover details of operating PoCT devices or training staff that operate these devices. The Requirements are also not intended for individuals or carers who perform testing on themselves or someone they care for. Advice on the use, regulation and evaluation of specific analytical devices is also outside the scope of this document.

Abbreviations

Abbreviation	Description
AS	Australian Standard
EQA	External quality assurance
ISO	International Organization for Standardization
IVD	In vitro diagnostic medical device
NPAAC	National Pathology Accreditation Advisory Council
PoCT	Point of care testing
QA	Quality assurance
QC	Quality control
TGA	Therapeutic Goods Administration

Definitions

Term	Definition
Analyte (or component)	means a substance, component or chemical constituent that is of interest in an analytical procedure.
Clinical governance	means a systematic and integrated approach to assuring and reviewing clinical responsibility and accountability that continually improves quality and safety of services provided to patients, resulting in optimal patient outcomes. Clinical governance extends across the boundaries of functions and organisations delivering services along the whole patient care path. Interfaces in, or split responsibility for, delivering patient care are considered points of increased risk of adverse patient outcome.
Competent	means demonstrating the ability to apply knowledge and skills.
Designated person(s)	means a registered medical practitioner with appropriate qualifications, competence and relevant scope of practice who is responsible for the clinical governance of the Medical Pathology Service. The designated person(s) oversees and manages staff and processes to ensure ethical patient care and the provision of accurate and timely test results.
External quality assurance	means results of testing are compared to those reported by an external body on a submitted specimen or the same specimen in a systematic and formal exercise.
In vitro diagnostic medical device	means the same as the definition in the *Therapeutic Goods (Medical Devices) Regulations 2002*.

Term	Definition
Medical Pathology Service	means premises where medical pathology services are performed. A Medical Pathology Service may be a standalone facility or part of a network of laboratories. A Medical Pathology Service may be in a healthcare precinct in which pathology tests in one or more specific disciplines or groups of pathology services are performed. The premises include all locations in the same healthcare precinct where pathology services are performed. Thus a Medical Pathology Service may be part of a medical practice or Indigenous health service using a point of care testing device, or it may be, for example, a chemical pathology laboratory in a large teaching hospital that is part of a pathology service network.
Method validation point of care	means confirming that the performance capabilities of the method under consideration are consistent with a defined analytical requirement.
Point of care testing	means pathology testing performed in close proximity to a patient by a healthcare worker, usually outside the precincts of a traditional laboratory. Testing is undertaken at the time of, and for use during, a consultation or episode of care.
PoCT operator	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.
Quality assurance	means part of a quality system focused on providing confidence that quality requirements will be fulfilled.
Quality system	means management activities involved in directing and controlling quality in an organisation.
Reagent	means a consumable required to perform the testing on a point of care testing device.

Introduction

Pathology test results are used by clinicians to make diagnostic, treatment and management decisions that affect patients' health outcomes. Developments in technology mean that some pathology testing can now be performed at the time of the patient consultation or encounter with healthcare services – known as 'point of care testing', or PoCT. The benefits of PoCT include informed and immediate decision-making about patient care, improved patient compliance with diagnostic testing, and improved access to pathology services, particularly in rural and remote centres. PoCT can be used in healthcare and community settings as well as pathology services and laboratories. Potential risks to patient safety associated with using PoCT need to be appropriately managed in all these settings.

Requirements for Point of Care Testing (Second Edition 2021) sets out the management framework for performing PoCT and provides guidance for any healthcare facility or laboratory-associated facility performing PoCT. Compliance with these Requirements ensures that patient and client safety is not compromised.

Requirements for Point of Care Testing (Second Edition 2021) has been updated with a risk-based approach and reflects current best practice for performing PoCT.

Included in this Standard is the set of requirements developed by the Royal Australian College of General Practitioners (RACGP) to be used in the accreditation of POCT conducted in a general practice setting (***Appendix C***). It should be read in conjunction with the RACGP Standards for General Practices (5th Edition). These Standards contain the same key principles for PoCT as the overarching Standard but are referenced here because they have been contextualised to form a part of the suite of accreditation Standards for General Practices.

Development of these Requirements

Consideration is given to all relevant Australian regulations and standards. In Australia, all in vitro diagnostic medical devices (IVDs) are subject to regulation under the *Therapeutic Goods Act 1989* and *Therapeutic Goods (Medical Devices) Regulations 2002*. IVDs intended for use at the point of care must be included in the Australian Register of Therapeutic Goods (ARTG) before they can be supplied in Australia. Users of PoCT devices should carefully review the manufacturer's instructions to ensure the device is not being used outside of the intended purpose as described in the ARTG. Using a PoCT device in a way that is not consistent with the manufacturer's instructions or intended purpose would equate to 'off-label use'. This is strongly discouraged because the user would assume all responsibility for the off-label performance of the device. Off-label use may also mean that regulatory requirements for 'in-house' IVDs are applicable, for example, use for a clinical purpose other than that originally intended by the manufacturer or not using the device in accordance with the manufacturer's instructions.

These Requirements are intended to serve as minimum standards for the purpose of accreditation. They have been developed with reference to current and proposed Australian regulations and other standards from the International Organization for Standardization (ISO) including:

- AS ISO 15189 *Medical laboratories – Requirements for quality and competence*
- AS ISO 22870 *Point of care testing – Requirements for quality and competence*

Where PoCT is conducted within a medical pathology service, *Requirements for Point of Care Testing (Second Edition 2021)* must be read within the national pathology accreditation framework, including the following NPAAC Requirements:

- **Tier 2 document**
  - *Requirements for Medical Pathology Services*
- **All Tier 3 documents**

All NPAAC documents can be accessed from the pathology accreditation webpage on the Australian Commission on Safety and Quality in Health Care's webpage.

In addition to these Standards, Medical Pathology Services must comply with all relevant state and territory legislation (including any reporting requirements).

Where PoCT is conducted in another healthcare facility, the *Requirements for Point of Care Testing (Second Edition 2021)* should be read in conjunction with the clinical governance Standards of that health service.

Using this document

In each section of this document, points deemed important for practice are identified as either 'Standards' or 'Commentaries'.

- A Standard is the minimum requirement for a procedure, method, staffing resource or facility that is required before a Medical Pathology Service can attain accreditation. Standards are identified by a dark blue box and prefaced with an 'S' (e.g. S2.2). The word '**must**' in each Standard indicates a mandatory requirement for pathology practice.
- A Commentary is provided where necessary to clarify a Standard, 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' (i.e. specifying mandatory requirements) or informative (i.e. providing further information), depending on both the content and the context of whether they are associated with a Standard or not. Note that when a Commentary is expanding on a Standard or referring to other legislation, it assumes the same status and importance as the Standard to which it is attached. As a general rule, a Commentary containing the word '**must**' is considered to be normative.

Please note that appendices attached to this document may be either normative or informative and should be considered as an integral part of this document.

Providing feedback

Comments from users would be appreciated and can be directed to:

Australian Commission on Safety and Quality in Health Care
GPO Box 5480
SYDNEY NSW 2001

Phone: (02) 9126 3600
Email: pathology@safetyandquality.gov.au
Website: https://www.safetyandquality.gov.au/our-work/accreditation/national-pathology-accreditation-scheme

1. Governance

The primary considerations in all healthcare encounters are the safety and quality of patient care, and the patient's rights. The purpose of PoCT is to provide accurate and timely test results that effectively contribute to immediate healthcare decisions. Organisations providing PoCT in the local healthcare setting are accountable for the quality of their service and for maintaining the required standard of care.*

Reducing the risk of a poor patient outcome is the primary aim of the governance standard. The risk can occur because of poor training of the operator, poor patient preparation before the test, the PoCT device not operating to produce an accurate result, poor housekeeping with the use of out-of-date device consumables, misidentifying the patient or reporting the wrong result, not keeping the result in the patient's files, or misinterpreting the result. The risk applies no matter where the PoCT device is used. Refer to ***Appendix B*** for common errors in PoCT.

Regardless of an organisation's structure, the clinical governance process must demonstrate clear accountability and responsibility for supervising PoCT and the delivery of results.

S1.1 There must be one designated person who is a medical practitioner with appropriate qualifications, competencies and scope of practice who is responsible and accountable for the clinical governance and quality of the PoCT service.

S1.2 The designated person 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 management system and all aspects of performance**
- **(e) provision of medical or scientific consultation**
- **(f) tests and procedures used, with the tests performed being within the scope of the education, training, continuing professional development and experience of individual staff members**
- **(g) setting criteria and processes for escalating and communicating incidents that may affect patient safety**
- **(h) verification of PoCT procedures.**

S1.3 Documentation must be available to support Standard 1.

* Standard 4 – *Requirements for Medical Pathology Services (Third Edition 2018)*

S1.4 The PoCT service must document processes, and adhere to those processes, for:

S1.4.1 clinical governance of the PoCT service

C1.4.1(i) A quality framework for performing PoCT should be documented, stating specific roles for staff undertaking PoCT (i.e. the PoCT operators).

C1.4.1(ii) The delegations from the designated person to the PoCT operator **must** be clearly documented.

C1.4.1(iii) A medical practitioner with a relevant scope of practice to safely action all results should be clearly identified.

S1.4.2 a risk-based approach to managing the PoCT service

C1.4.2 A risk-based approach includes assessing risks to patients or operators and mitigating those risks.

S1.4.3 compliance with relevant national (organisational) and jurisdictional legislative requirements

S1.4.4 operational procedures

C1.4.4 Documentation should include (but not be limited to) escalation procedures, staff competencies and training, quality control procedures, range of tests provided, test methods, and procedures to address the clinical need

S1.4.5 the procedure for periodic review of the PoCT service

C1.4.5 Periodic review **must** occur annually or within the accreditation assessment cycle.

S1.5 Before implementing PoCT, the analytical performance requirements of the test must be defined.

C1.5 The following key performance indicators **must** be considered when defining analytical performance requirements:

(a) For quantitative analysis – accuracy, precision, trueness, limit of detection and limit of reporting

(b) For qualitative analysis – sensitivity and specificity.

S1.6 The PoCT service must have a documented incident management system that includes processes for the timely reporting, investigation and follow-up of clinical incidents and adverse events.

C1.6 PoCT services should report relevant adverse events related to the performance of the PoCT device to the TGA)

S1.7 Processes for integrating the results of PoCT into patient care, clinical pathways and processes must be documented.

2. Management system

Management frameworks describe the systematic approach used by an organisation to direct, control and evaluate the quality of their service. General considerations with respect to the implementation and operation of a PoCT service and common errors from failures of process are outlined in ***Appendices A and B***.

S2.1 There must be a documented management system for the PoCT service. The management system and its records must address the following:

(a) the governance framework, including clinical governance

(b) a policy or procedure for purchasing PoCT equipment that is fit for purpose in the clinical setting

(c) location, storage and management of equipment, reagents and consumables

(d) maintenance of the device

(e) preparation and sample collection procedures, including defined procedures for monitoring 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 PoCT results

(h) record-keeping (including confidentiality and privacy compliance)

(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.

S2.2 There must be periodic review of the PoCT policies and procedures.

C2.2(i) PoCT policies and procedures should be reviewed at least annually.

C2.2(ii) PoCT operating procedures and staff activities should be audited to ensure compliance and ongoing suitability of the management system.

3. Training and competency

PoCT operators must be competent to perform PoCT in the local healthcare setting and be able to have confidence in the test result itself. Therefore, it is critical that staff have the necessary training and skills to perform such testing.

S3.1 PoCT must only be performed by operators who have undertaken relevant approved training and demonstrated that they are competent.

C3.1(i) The organisation responsible for providing the PoCT service **must** have an approved training program.

C3.1(ii) The training program **must** include but not be limited to the following areas:

(a) procedures for safely and competently performing patient tests and interpreting the validity of PoCT results

(b) education and training that covers common sources of error, including the source of pre- and post-analytical errors

(c) conducting quality control and quality assurance to regularly assess analytical quality of the PoCT device

(d) general awareness of privacy and confidentiality of patient information

(e) workplace health and safety as it relates to PoCT.

C3.1(iii) Records of staff PoCT training, retraining and competency **must** be maintained.

C3.1(iv) Competency **must** be reassessed after training at regular intervals and when new PoCT devices (different model or manufacturer) are deployed.

C3.1(v) PoCT operators **must** receive training updates when a competency issue with that operator is identified or where the PoCT operator performs testing infrequently.

4. Pre-analytical considerations (before the test)

Risk management of PoCT is essential. Factors such as patient preparation (e.g. fasting), specimen collection, the specimen preservative used (if appropriate) and sample application to the test strip/cartridge of the PoCT device can all affect the quality of PoCT results.

Failure to recognise and eliminate errors at this stage can jeopardise test results, and patient safety and health outcomes.

S4.1 Specimen collection must be in accordance with the instructions for use provided with the PoCT device.

C4.1 Where blood is collected by venepuncture, refer to the NPAAC *Guidelines for Approved Collection Centres (Requirements for Medical Pathology Specimen Collection)*. It is also recommended that *WHO Guidelines on Drawing Blood: Best practices in phlebotomy* be used for collection techniques.

S4.2 The patient or client must be accurately identified during specimen collection to ensure traceability of the specimen through to the results report or entry into the electronic medical record.

S4.3 Records must be retained to allow traceability, including for example:

(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 specimen collection

(c) date and time the test was performed

(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 test site and person issuing the report

(f) identification reference of the PoCT device.

S4.4 Approved test procedures must be documented, authorised and available in the point of care work area in which they are used.

C4.4 Methods for performing PoCT based on the device manufacturer's recommendations **must** be documented.

5. Analytical considerations (during the test)

Before PoCT is implemented in an organisation that intends to offer PoCT services, the analytical and clinical performance requirements for the intended purpose must be defined for the local healthcare setting. The PoCT device or devices selected should be fit for the specific purpose.

S5.1 Quality control (QC) procedures must be used for all testing provided.

C5.1(i) Criteria for QC results that are acceptable for patient testing **must** be documented. Any action to be taken when QC results are unacceptable **must** be documented.

C5.1(ii) A record of all QC results **must** be kept, including:

(a) date and time that QC samples were last tested

(b) QC results and whether they were deemed acceptable

(c) lot number and expiry date of QC samples

(d) name of the PoCT operator performing the QC testing.

S5.2 The PoCT service must participate in external proficiency testing programs where they are available.

C5.2 The purpose of this quality assurance (QA) process is to ensure that the performance of testing using the device is acceptable when compared to the PoCT service's risk analysis (refer to ***Appendix A***).

S5.3 Non-concordant QC and QA results must be investigated and documented, including any impact on the quality of patient results.

6. Post-analytical considerations (after the test)

Breakdown in the communication of information, particularly relating to test results, is one of the contributing factors in serious adverse events in pathology and is a major preventable cause of patient harm.

Where possible, PoCT devices should be connected to electronic information systems to minimise post-analytical errors.

S6.1 Test results must be recorded, and the records must be retrievable.

S6.2 Test results must be communicated in a clear, secure and timely manner to the requesting practitioner and/or others delegated by the requesting practitioner who are responsible for the patient's immediate care and management.

S6.3 Retention of patient data, data on test procedures and equipment records must comply with national and jurisdictional legislative requirements.

7. Environment

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

S7.1 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.

S7.2 There must be a documented contingency plan for continued operations in the event of equipment and other failures.

8. Workplace health and safety

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

Samples tested at point of care 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.

S8.1 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.

C8.1(i) All staff performing PoCT **must** be vaccinated according to organisational requirements.

C8.1(ii) Equipment or consumables identified as 'single use' **must not** be re-used.

S8.2 Disposal of biological material, clinical waste and sharps from testing must comply with jurisdictional regulations and the organisation's waste management policy.

C8.2(i) All samples **must** be considered to be potentially infectious and handled with this in mind.

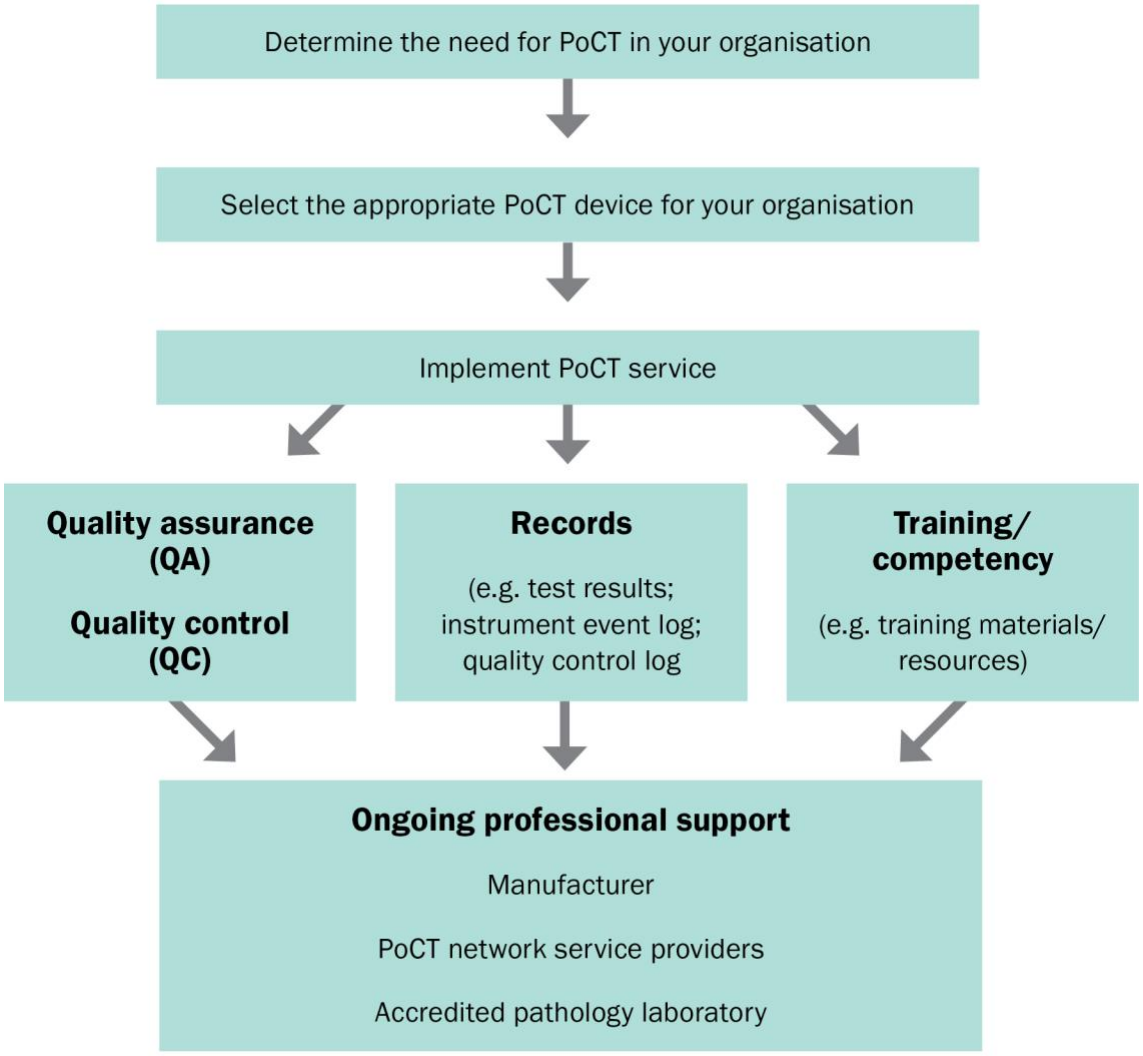
C8.2(ii) There **must** be compliance with all workplace health and safety and other jurisdictional requirements.

C8.2(iii) There **must** be policies regarding sharps management, biohazard spills and infection control, including standard and transmission-based precautions.

S8.3 Any accidents or incidents must be reported to the designated person or delegate, and appropriate first aid must be undertaken immediately and followed up according to local workplace requirements.

Appendix A Implementing and maintaining PoCT (Informative)

Implementing point of care testing (PoCT) into your organisation – flowchart



Test system selection and management

Selection

PoCT devices should be evaluated and selected based on intended clinical use.

Generally, test systems fall into three broad categories:

(a) low complexity – simple strip-based tests such as pregnancy tests, dipstick tests and lateral flow tests (e.g. for syphilis antibodies)

(b) medium complexity – single-use disposable tests such as glucose, International Normalised Ratio (INR), troponin, HbA1c or nucleic acid amplification test–based infectious disease tests

(c) high complexity – laboratory devices.

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

When selecting a test system, consider the following main points:

- 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 how the results will be 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.

These points need to be assessed against the manufacturer's claimed specifications, and will assist in selecting the broad category of test system required.

Evaluation and verification

The purpose of the verification process is to confirm (verify) that a particular PoCT system performs to and meets the manufacturer's stated specifications, and to validate the results against a known standard.

Verification is most commonly done by parallel testing. In this process, a number of samples are run firstly on the PoCT device; a duplicate of each sample, taken at the same time, is then sent for analysis by an equivalent laboratory method. The results are then matched and statistically analysed to see how well the two sets of results compare.

The evaluation strategy and statistical analysis used will depend on whether the PoCT result is quantitative (where an absolute level or concentration of analyte is detected, e.g. for most clinical chemistry and haematology tests) or qualitative (where a result is reported as positive or negative, e.g. for most infectious disease and drugs of abuse tests). The key measures of analytical performance for most quantitative PoCT are accuracy (trueness of the result) and precision (reproducibility of the measurement). For qualitative PoCT, sensitivity (true positive rate) and specificity (true negative rate) are more commonly used to assess performance.

Quality control and quality assurance

Quality control (QC) is a procedure in which the PoCT device tests artificial samples containing an analyte in known quantities. For quantitative tests, the PoCT result is expected to be close to this known value (with some allowance for imprecision of the device). For qualitative tests, the result should be consistent (concordant) with the known value. The QC samples may be available from the device manufacturer or from external suppliers of QC material. The QC process also includes recording QC test results, and any subsequent action taken if the QC result falls outside the acceptable range.

QC indicates the performance of an individual analytical system at the time QC samples are tested, and allows confidence in the results of the patient samples tested during this time.

External quality assurance (EQA) involves testing samples in which the quantity of analyte or expected result is not known to the operator at the time of testing. The results from the PoCT device are compared to results obtained by others testing the same EQA sample with the same type of device. 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; 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. It can identify issues such as problems with the device and device cartridges, operator variability, and stability issues that may not be detected by QC alone.

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

Quality control testing requirements

A QC sample should be tested, at a minimum, 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 testing QC samples should be according to the device manufacturer's recommendations.

If a test needs to always be available, QC testing must be done at least once per month. For PoCT that is done less often, QC testing should be performed immediately before sample testing. For qualitative tests, a minimum of one positive control sample should be analysed.

Each QC test result must be recorded, along with the operator performing the test and the reagent batch number. For qualitative PoCT results, a system of recording ordinal values (−, +/−, +, ++, +++ or 1, 2, 3) should be introduced. A documented system for accepting and rejecting QC test results should be established, including what actions are undertaken in the case of rejection.

Many PoCT 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; however, they may not check the entire testing process. In this situation, another form of QC may be needed depending on the level of risk of the wrong result leading to an adverse outcome for the patient(s).

In some PoCT devices, an electronic QC process checks the device's measurement signal; however, it does not check the analytical part of the system. Therefore, electronic QC is complementary to physical QC requirements and is 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) a delivery of new consumables is received

(c) an operator does not have confidence in the reliability/accuracy of a result

(d) the healthcare professional receiving the result believes that the PoCT result does not fit 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. being dropped, temperature extremes).

Who should run PoCT quality control samples?

QC samples simulate patient samples. Any problem that might affect the correctness of results for a patient sample is also experienced by the QC sample, thereby alerting the operator to the existence of the problem.

For this reason, PoCT of QC samples must be done by the PoCT operator(s).

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 designated person or delegate is responsible for reviewing and analysing trends in QC results, and taking appropriate corrective action when required. All documentation of QC records, reviews and corrective action should be maintained for three years and be available for review by the designated person.

External quality assurance 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 method for EQA. This mode of EQA may be useful when a commercial program is either unavailable or unsuitable for the PoCT device in question.

Note: The parallel sample approach has some limitations including a more limited range of analyte concentrations available for testing, issues relating to transport stability and lack of peer comparison.

Who should run PoCT of EQA samples?

PoCT of EQA samples must be done by the PoCT operator(s).

Who should be responsible for reviewing EQA results?

The designated person or delegate is responsible for reviewing 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*.

Ongoing maintenance

Manufacturers' recommendations regarding maintenance must always be followed.

All maintenance activities should be documented.

Adverse event reporting

Ongoing surveillance of the use of PoCT devices is a very important part of ensuring the safety of POCT services. Any adverse events should be reported to the authorities to allow a systematic review of the device in the marketplace.

Report adverse events to:

- your designated person
- your network service provider/support service
- the manufacturer of the device
- the TGA (within the timeframes specified†).

† See TGA website – Reporting adverse events

Appendix B Common errors relating to PoCT (Informative)

For PoCT to be conducted safely, a PoCT operator must perform PoCT according to the test device manufacturer's instructions and the established management system. Any deviation from the manufacturer's instructions could cause an error in measurement and compromise patient/client safety. In practice, most errors that occur with PoCT arise from patient/client preparation and sample collection issues (pre-analytical errors) rather than the testing process itself (analytical errors) or 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

Sampling from a venous blood tube containing the wrong anticoagulant

Manufacturer's instructions usually specify which blood tube type and anticoagulant are recommended for a particular test. If a tube with a different anticoagulant is used to collect a venous sample for PoCT, an error can occur. For example, if a blood sample for PoCT of potassium and calcium is collected in a tube containing di-potassium EDTA as the anticoagulant, the potassium result will be falsely elevated (because potassium is present in the anticoagulant) while the calcium result will be falsely lowered (because EDTA binds the calcium in the sample).

Finger-prick sampling from unwashed hands

For finger-prick samples, it is important to ensure that the patient's/client's hands are thoroughly cleaned and dried before the sample is collected. If the individual's hands are contaminated by water, chemicals or dirt, errors in PoCT measurement can occur. For example, if the patient/client handles a sugar-containing product such as fruit and does not wash their hands before having a finger-prick blood glucose test, the glucose concentration can be falsely elevated (by 10% or more).

Not sampling from either first or second drop of finger-prick blood

It is critical to follow the manufacturer's specification for which drop of finger-prick blood to use for analysis. Depending on the test, the first, second or even 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 because the clotting process may have already commenced when the second drop is collected. 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.

Using incorrect specimen type

PoCT devices are approved by the TGA for use with specimen types indicated by the manufacturer (e.g. whole blood). Sample types not indicated as suitable by the manufacturer should not be used (e.g. intraosseous blood).

Haemolysed sample

A haemolysed sample may affect test results. Haemolysis can occur when samples are incorrectly collected or handled during venepuncture collections. PoCT operators should

inspect the sample for visible effects of haemolysis (colour assessment) and not proceed with testing if haemolysis is suspected.

Air bubbles present in the sample holder

With many PoCT systems, air bubbles in the sample when it is placed into a sample holder or container could lead to a false test result. For example, urine albumin:creatinine ratio (ACR) is a common 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 in the sample holder takes up, for example, 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 used for PoCT. If a sampled volume is low because of air bubbles or other factors, a new sample must be collected.

Setting wrong units of measurement on a PoCT device

A clinical decision on pathology results is usually made by comparing the PoCT result with a stated reference interval or action limit. For comparison, the PoCT result and the reference interval or action limit must be in equivalent units. Many modern PoCT devices can 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 or action limit, an inappropriate clinical decision could be made. For example, blood glucose results 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 in the hypoglycaemic range) could be reported as 45 (falsely indicating a result in the hyperglycaemic range) if the unit of measurement on the PoCT device was incorrectly set to mg/dL.

Using quality control materials beyond their expiry date

Most quality control (QC) materials used to support PoCT have a well-defined shelf life when stored either opened or unopened. These expiry dates must be stringently adhered to. Once the expiry date is reached, the used material must be discarded and replaced with fresh material. For example, if a QC sample (once opened) has a shelf-life of 3 months, continuing to use that material beyond the recommended 3-month window could cause QC results to trend lower and drift outside the limits set for acceptable quality. These low QC results are not caused by an inherent analytical fault with the PoCT device but by inappropriate use of the QC material outside the manufacturer's recommendations.

Not using the manufacturer's recommended collection device

PoCT methods have been validated for use with particular sample types and volumes. Different manufacturers provide specific collection devices (e.g. capillary tubes, sample loops), which standardise the volume of sample applied to the PoCT device. For optimal test results, the collection device specified by the manufacturer's instructions must be used. Using alternate devices may introduce volumetric errors that could affect the validity of the test and its overall performance.

Testing or analytical errors

Incorrect timing for manual reading of urine dipsticks or immunochromatography tests

Urine dipsticks are widely used in many clinical settings for qualitative analysis of urine samples. These most basic PoCT devices commonly rely on manually reading colour pads at

a set time interval after immersing the dipstick into a urine sample. The degree of colour change indicates the concentration of the different pathology markers embedded in the absorbent 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). Similarly, linear flow immunochromatographic tests, such as quick pregnancy tests, must be read at the manufacturer-recommended time interval to prevent false negative or false positive results.

Individual record or post-analytical errors

Manual transcription errors

PoCT results are generally acted upon within a short time after the test is completed. Patient harm can occur if the result is not clearly and accurately communicated to the clinician. Many modern PoCT devices can store and transfer results to an electronic medical record or a laboratory/clinical information system. However, some devices still require manual transcription of results from the test machine to the patient/client record, which is prone to error. It is important that the correct PoCT result for each patient/client is transcribed accurately from the display screen or printout of the PoCT test system into the appropriate individual record. Whenever possible, a second person should witness or check the result transcription.

Electronic results matched to the incorrect patient

Electronic results transmission from PoCT systems should be validated to ensure that results are sent to the correct patient's/client's electronic medical record. All results must be maintained in the medical record.

Appendix C RACGP *Standards for point-of-care testing* (5th edition) (Normative)

The Royal Australian College of General Practitioners (RACGP) has developed the *Standards for point-of-care testing* (5th edition) (the *Standards for point-of-care testing*) to:

- improve the quality and safety of point-of-care testing performed by health services
- help services identify and address any gaps they have in their systems and processes.

The *Standards for point-of-care testing* is a module of the RACGP *Standards for general practices* (5th edition) and must be read in conjunction with those standards.

The *Standards for point-of-care testing* is available on the RACGP's website at https://www.racgp.org.au/running-a-practice/practice-standards/standards-5th-edition/point-of-care-testing-1

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Professor Mark Shephard

Ms Rosy Tirimacco

Dr Janney Wale

Dr Michael Whiley

NPAAC Document Review & Liaison Committee

National Pathology Accreditation Advisory Council

Further information

Other NPAAC documents are available from:

Australian Commission on Safety and Quality in Health Care
GPO Box 5480
SYDNEY NSW 2001

Phone: (02) 9126 3600
Email: pathology@safetyandquality.gov.au
Website: https://www.safetyandquality.gov.au/our-work/accreditation/national-pathology-accreditation-scheme

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