Australian Commission on **Safety and Quality** in Health Care

NPAAC
National Pathology Accreditation Advisory Council

Point of Care Testing Standard

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Level 5, 255 Elizabeth Street, Sydney NSW 2000
Phone: (02) 9126 3600
Email: mail@safetyandquality.gov.au
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Acknowledgement

We acknowledge the Traditional Owners and Custodians of Country throughout Australia. We recognise their continuing connection to land, waters and community and acknowledge their ongoing contribution to the health system and community. We pay our respects to Elders past and present.

Contents

Background

The Australian Commission on Safety and Quality in Health Care leads and coordinates national improvements in healthcare safety and quality.

About the Australian Commission on Safety and Quality in Health Care

The Australian Commission on Safety and Quality in Health Care (the Commission) partners with the Australian Government, state and territory governments and the private sector to achieve a safe, high-quality, sustainable health system. It also works closely with patients, carers, clinicians, pathologists, medical scientists, technicians, managers, healthcare organisations and policymakers.

Key functions of the Commission include:

- developing national safety and quality standards
- developing clinical care standards to improve the implementation of evidence-based health care
- coordinating work in specific areas to improve outcomes for patients
- providing information, publications and resources about safety and quality.

The Commission works in four priority areas:

- High-quality care in an evolving environment
- Strong outcome-focused clinical governance
- Empowered patients, carers and communities
- An improvement-driven workforce culture.

About the National Pathology Accreditation Advisory Council

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 introduction and maintenance of uniform standards of pathology services throughout Australia.

Introduction

Technological advancements have enabled pathology testing to occur near the patient. This testing is known as pathology point of care testing.

The benefits of point of care testing (POCT) include informed and immediate decision-making about patient care, improved patient compliance with testing, greater patient convenience and improved access to pathology services, especially in rural and remote centres.

The sophistication of POCT systems has increased, making them more accessible to health and aged care service providers working outside the laboratory context. The use of POCT has increased dramatically across these services in Australia. POCT occurs in acute primary, community, residential and domiciliary care settings. While traditionally focused on haematology and biochemistry, POCT has diversified and now includes molecular based medical devices for infectious diseases.

Despite the technical advancements, there are POCT implementation concerns, including quality control, operational documentation, staff training, and results capture. Errors such as patient identification mistakes, sample collection and process issues, accuracy discrepancies between laboratory and POCT results and clinician competency to recognise discrepant results can lead to false results and incorrect medical decisions which pose significant risks to the quality of patient care.

To address these concerns, there needs to be:

- effective governance processes and management systems to ensure the quality, supervision, and support of POCT services
- adequate training that covers testing procedures, sample acquisition, quality control, infection control, and result interpretation
- ongoing monitoring of POCT, routine quality control checks, and proper medical device use
- connectivity of POCT medical devices with the service provider information system and electronic medical records to minimise missing data and transcription errors. Automated data transmission facilitates accurate and timely results reporting, improves data management and monitoring with quality assurance requirements.

NPAAC, as experts in safety and quality pathology standards, have developed the Point of Care Testing Standard (POCT Standard) to describe a nationally consistent quality framework

that service providers should apply to ensure POCT is used as intended and performs as expected.

Developing the POCT standards involved a literature review, an environmental scan, the identification of safety and quality gaps, and reviews of regulations, national, and international standards. The Commission consulted extensively with technicians, scientists, medical practitioners, pathologists, clinicians, consumers, professional and peak bodies, health service organisations, pathology practices, jurisdictions and government agencies.

Application of the standards

Implementing the POCT standards will protect patients from harm and contribute to the overall quality of care delivered by service providers where POCT occurs. The standards describe the key quality elements to implement when providing POCT.

These standards are for health and aged care service providers, not pathology practices. Service providers should read and implement the POCT standards in conjunction with the service provider's safety and quality standards. Service providers take a risk-based approach to implementing the standards.

Out of scope

The standards do not address:

- self-testing, where sample collection is performed by patient or carers without direct supervision from a clinician
- POCT medical devices within a pathology laboratory environment
- the regulation and evaluation of specific POCT in vitro diagnostic medical devices (POCT medical devices).

Overview of the standards

There are seven standards in the POCT standards that address:

1. clinical governance
2. workforce performance and effectiveness
3. partnering with consumers
4. medical devices
5. specimen collection
6. specimen testing
7. results interpretation and reporting.

Structure of the standards

Each standard contains the following:

- a standard statement
- a consumer outcome statement
- a statement of intent
- explanatory notes
- actions that describe what is required to meet each standard.

Terminology

The Commission adopted the following terminology in the Point of Care Testing Standard.

Clinician

A trained health professional, including registered and non-registered practitioners, who provide direct clinical care to patients. Clinicians may provide care within a health service organisation as an employee, a contractor or under other working arrangements. They include nurses, midwives, medical practitioners, allied health professionals, paramedics and other professionals who provide health services, and students who provide health under supervision.

For genetic testing a health professional would also include a genetic counsellor.

Health service provider

A health service provider is a separately constituted organisation that is responsible for implementing clinical governance, administration and financial management of a service unit or service units providing health care at the direction of the governing body. It includes hospitals[1], aged care, community settings, clinicians' rooms, clinics, medical imaging practices and pharmacies.

Point of care testing

A pathology service performed by a clinician outside of a pathology laboratory. Testing occurs near to or at the side of the patient during a patient's consultation or episode of care without the supervision of a trained member of the pathology workforce.

Point of care testing medical device

POCT medical devices are in vitro diagnostic medical devices regulated by the Therapeutic Goods Administration (TGA) and listed on the Australian Register of Therapeutic Goods (ARTG). A POCT medical device is not used solely in a pathology laboratory.

[1] Hospital services not supported by onsite pathology laboratory oversight.

1. Clinical governance

The service provider uses its clinical governance systems to ensure the high-quality and appropriateness of POCT.

Consumer outcome

Patients are confident that the POCT test outcomes will be accurate and result in appropriate, high-quality healthcare decisions.

Intent of this standard

To have a clinical governance framework that accounts for POCT and ensures the testing is of high quality.

Explanatory notes

Governing bodies

Governing bodies are ultimately responsible for ensuring the quality of service providers and maintaining the required standard of care.

Governing bodies must ensure that the governance system that supports POCT delivery operates effectively, and robust monitoring systems focus on continuous quality improvement. Service providers are to continuously measure and improve the quality of POCT and ensure adequate controls are in place for their use, so they are safe, fit for purpose and effective.

Quality improvement

Quality improvement systems are a comprehensive set of policies, procedures and practices used to monitor POCT and ensure reliable results. It is essential to develop a practical quality framework that works effectively in busy service providers.

Evaluating performance

Evaluating the analytical performance of POCT systems, the service provider assesses the sophistication and complexity of these systems, level of connectivity, built-in medical device

quality checks, variability between medical devices, consumables, clinician training and performance, and specimen collection, quality and testing.

Service providers perform regular audits of POCT systems and include patient identification, performance of quality control, result documentation, evidence of result follow-up, compliance with POCT ordering procedures and labelling and storage of reagents.

Quality indicators are used to regularly measure, monitor and report on POCT quality. Quality indicators help to identify systemic issues and contribute to continuous quality improvement. Indicators could measure compliance with positive patient identification procedures, specimen and reagent labelling, the performance of quality control testing, inter-instrument comparison, external quality assurance performance, and policy compliance for results above or below the analytical measuring range.

Actions

Item	Action	
Legislation and standards[2]	1.01	The service provider complies with relevant Commonwealth, state or territory legislation and regulations relating to POCT.
Clinical governance integration	1.02	The service provider uses its governance, patient safety and quality, and clinical performance systems, to implement the POCT standards.
POCT service	1.03	The service provider will describe and keep current the POCT system, including: a the functions of the test and operational range of the equipment b the patient eligibility criteria for testing c the criteria for selecting POCT equipment, tests and testing methods d who can request tests and who can receive the results e the internal quality control, external quality assurance and assurance process in place for the POCT service
POCT supervisor	1.04	The service provider nominates a supervisor for the delivery of POCT who: a has the skills and experience to conduct POCT b is authorised to supervise the POCT

[2] ISO 22583- Requirements and recommendation for supervisors and operators of point-of-care testing (POCT) equipment provides guidance for assessing POCT, test and equipment selection and requirements for technical performance and result interpretation.

		c is responsible for quality, timeliness, accuracy and safe delivery of POCT d ensures clinicians performing POCT work within their roles and responsibilities e is responsible for: i. clinical governance of POCT ii. training of the clinicians performing POCT iii. selection and management of point of care tests, medical devices and inventory iv. specimen collection and testing v. interpreting results, reporting and providing advisory services vi. ensuring there is access to medical experts and laboratory professionals to provide consultation when needed.
Contracted services	1.05	Where the service provider subcontracts to another service provider, pathology practice or other qualified provider, it ensures: a there is an agreement stating the responsibilities of each party b the subcontractor complies with relevant Commonwealth, state or territory legislation and regulations relating to POCT and the requirements set out in this guide c where the subcontractor is a pathology practice, they comply with the NPAAC Standards.
Risk management	1.06	The service provider: a identifies, rates, documents and mitigates patient risks associated with the POCT b regularly reviews POCT risks c reports on POCT risks to the governing body.
Policies and procedures	1.07	The service provider: a makes its policies and processes for POCT readily available to clinicians b monitors and takes action to improve clinician adherence to POCT policies and procedures

		c regularly reviews and maintains the currency and effectiveness of its POCT policies and procedures.
Incident management	1.08	The service provider uses its incident management system to identify and investigate POCT incidents and: a implements corrective action before performing further POCT b inform patients and/or their carer and requester when serious adverse events leading to patient harm involving POCT occur c reports to the TGA adverse events related to a POCT in vitro diagnostic medical device d provides timely feedback on the analysis of adverse events clinicians e reports on POCT adverse events to the governing body.
Quality management	1.09	The service provider uses its quality improvement system to: a identify and collect data on POCT safety and quality measures related including: i. POCT medical device testing ii. patient, specimen and metrological traceability iii. specimen collection, integrity and testing iv. results capture v. adverse incidents and error rates. b implement and monitor POCT safety and quality improvement activities c provide the governing body and clinicians with timely and accessible information on POCT performance and outcomes d involves the clinicians in POCT quality improvement system reviews.
Feedback and complaints	1.10	The service provider uses its feedback and complaints process to: a seek feedback from patients, carers and requesters about the effectiveness and their experience of POCT b receive, acknowledge receipt, track, record and investigate POCT complaints

c ensure the appropriate action is implemented and monitored

d provide the complainant with information on the actions taken, and progress reports, where applicable.

2. Workforce performance and effectiveness

The clinicians have the knowledge, skills and experience to provide patients with high-quality POCT.

Consumer outcome

Patients expect a clinician with the POCT qualifications, skills and experience to undertake their pathology test.

Intent of this standard

To ensure competent and professional clinicians successfully perform and accurately interpret POCT results.

Explanatory notes

The clinicians must be competent to perform POCT and have confidence in the test result. Clinicians performing POCT take ownership of POCT processes, model good practice, challenge poor practice and use what they have learnt to improve patient care.

Adequate training and ongoing competency of clinicians are vital for ensuring accurate results and high-quality healthcare. Comprehensive training programs covering testing procedures, specimen acquisition, quality control, infection control, and result interpretation are essential to minimise errors.

A wide array of POCT training is available in Australia, including accredited courses, online modules, and resources from various organisations.

Where there is a gap between training and patient testing, the service provider identifies a reasonable timeframe where a competence reassessment is required.

Reassessment of competence is planned, and the timing is determined by the clinician's test volume and frequency and the test complexity. Competency is determined against a predetermined set of measurable targets. Low volume, less frequent or more complex testing (more difficult to perform accurately) require more competency assessments.

A significant POCT risk is the failure of the POCT practitioners to follow policies and procedures, which can result in patient safety issues. Regular audits are crucial for identifying non-conformities and improving compliance.

Actions

Item	Action	
Clinician roles and responsibilities	2.01	The service provider has processes to ensure clinicians performing POCT are competent by: a confirming their qualifications, knowledge and skills, and recency of practice to perform, interpret, monitor and produce reliable POCT results b defining and supporting the workforce to fulfil their roles and responsibilities for POCT c monitor clinicians performing POCT to ensure they are operating within their defined scope of practice d review the scope of practice of clinicians when a POCT in vitro diagnostic medical device or service is introduced or substantially altered.
POCT training and performance	2.02	The service provider ensures: a the training delivered accounts for the complexity of the POCT medical devices, the volume of tests, a clinician's frequency of testing and quality assessment data findings b POCT training is provided by a qualified person, requirements for training are defined and training includes: i. specimen labelling ii. process and technique for specimen collection iii. process and procedure to perform testing iv. result interpretation and follow-up v. the recognition and follow-up of critical POCT results vi. result documentation vii. causes of inaccurate results viii. medical device troubleshooting ix. alternative test method processes x. cleaning and maintaining POCT medical devices xi. performance of quality control xii. ordering and storage of reagents, supplies and quality control materials.

c clinicians complete training and are assessed as competent before undertaking POCT

d clinicians undertake continuing development to ensure their POCT skills remain current

e POCT training is reviewed periodically to ensure it remains current and relevant.

3. Partnering with consumers

Service providers develop, implement and maintain systems to deliver person-centred care.

Consumer outcome

Patients and their carers receive person centred care. Clinicians respect the patient's healthcare rights, incorporate the patient's perspectives into the collection process, and obtain informed consent to perform POCT.

Intent of this standard

To ensure service providers understand the importance of communicating with patients and incorporating their needs into POCT.

Explanatory notes

Primary considerations when performing POCT are the patient's rights and the quality of patient care.

Evidence suggests that partnering with patients is associated with positive patient experiences and enhances patient outcomes. Partnerships need to be person centred, respectful and responsive to an individual's needs, values and views. Person-centred care is the gold standard approach.

Actions

Item	Action	
Healthcare rights	3.01	The service provider: a uses a charter of rights consistent with the *Australian Charter of Healthcare Rights* b supports its clinicians to apply the principles of the charter of rights c makes the charter of rights available for patients and their carers.
Informed consent	3.02	The service provider: a implements an informed consent process, including for POCT that complies with legislation and guidelines b ensures financial consent is transparent and completed before the POCT occurs when a patient incurs a cost c has processes and supports clinicians to provide patient centred care and actively involve patients in their care through shared decision making d has processes to identify patients who require support to make decisions and ensures: i. access to the necessary support to make, communicate and participate in decisions ii. inclusion of substitute decision-makers to the degree a patient wants them involved. e obtains patient consent to collect, store and distribute identifiable or de-identified personal data and records for purposes other than patient direct care, quality control and training.
Person-centred communication	3.03	The service provider: a uses communication mechanisms tailored to the diversity of patients it serves b has information about POCT c supports its clinicians to communicate with patients and carers in a manner that meets the patient's needs and preferences

		d provides pre-test counselling when there is a high risk the consequence of the POCT will be severe e provides advice on accessing follow-up care.
POCT service evaluation	3.04	The service provider involves a diverse group of patients and consumers in the governance of and to design, measure and evaluate the POCT service.

4. Medical devices

All POCT in vitro diagnostic medical devices, reagents, and consumables must be appropriate for use and maintained.

Consumer outcome

Patients expect POCT to be performed with reliable in vitro diagnostic medical devices used according to the manufacturer's instructions for use (IFU).

Intent of this standard

To ensure the equipment, reagents, and consumables are safe for patients, meet performance expectations, and provide accurate patient results.

Explanatory notes

POCT medical devices include equipment, reagents and consumables.

Medical device selection

POCT medical devices need to achieve the required performance and comply with the relevant testing specifications. When selecting a POCT medical device, consideration is given to:

- patient outcome evidence on clinical utility
- its appropriateness for the patient testing required
- its ability to prevent patient harm and add to the provision of quality care
- medical device features, specimen types, sample preparation, test performance, quality control functions, software and connectivity, ease of use, cleaning and maintenance.

Lack of understanding of the testing requirements can result in instrument selection that is not fit-for-purpose, which can impact patient safety.

Medical device verification

POCT medical devices are independently verified by the service provider for their analytical performance before clinical use to confirm that their performance is reliable and accurate. The verification focuses on patient care and includes the intended use, methodology, traceability,

sample types and volumes, analytical measuring range, interferences, limitations, and the manufacturer's quality claims. Information about the analytical performance of instruments is usually available in peer-reviewed journals.

Medical device use

To ensure standardised use of POCT systems, standard operating procedures and work instructions must align with the manufacturers' IFU. The instructions identify the critical aspects for all testing stages, so testing is performed consistently. It is important to evaluate standard operating procedures and work instructions, and approve any changes before clinicians use them.

Any use of an in vitro diagnostic medical device outside the scope defined in the manufacturer's IFU constitutes off-label use. Off-label use converts the in vitro diagnostic medical device to an in-house in vitro diagnostic medical device. Off label use requires the service provider to comply with the Therapeutic Goods (Medical Devices) Regulations 2002 and the Essential Principles for safety, quality and performance. This includes:

- liaising with National Association of Testing Authorities to obtain accreditation
- notifying the TGA of Class 1–3 in-house IVDs.
- applying for ARTG inclusion for Class 4 in-house IVDs.

To ensure the continuity of POCT, the service provider should establish relationships with suppliers of POCT goods and services. The suppliers can provide consumables, technical support, maintenance and education.

There is a log that records consumables including lot numbers, expiry dates and monitors and disposes of expired consumables.

Medical device quality assurance

Ongoing external quality assurance practices need to be implemented to ensure accurate POCT medical device performance over time. Regular comparisons between POCT medical devices and pathology laboratory instruments will identify clinically meaningful differences and maintain comparability. Ongoing quality assurance can include, but is not limited to, reagent lot validation across the analytical measuring range, evaluation of quality control material lots, and intra and inter-instrument comparisons.

Regular objective evidence that test results meet the clinical and technical specifications specified at implementation is essential. Appropriate record-keeping is critical in ensuring that POCT medical devices produce quality results.

Actions

Item	Action	
Medical device selection and implementation	4.01	The service provider has a process for POCT medical devices selection and implementation that: a ensures the device is listed on the ARTG b evaluates the device based on its intended clinical use and ensures it is fit for purpose c assesses and verifies the medical device meets the manufacturers claimed specifications by testing results against a known standard d calibrates, quality controls and assures the medical device's performance before implementation e actively manages the risk of aging medical devices and sub-optimal performance of medical devices.
Medical device use	4.02	The service provider: a calibrates, uses quality controls and assures the performance of the POCT medical device before implementation b uses POCT medical devices in accordance with the manufacturer's minimum requirements and instructions for use (IFU) c ensures POCT medical devices are not used outside of the purpose specified by the manufacturer d documents procedures for routine use of POCT medical devices and makes these accessible to clinicians in the testing area e cleans POCT medical devices in accordance with the manufacturer's IFU and when contaminated with body fluids f reports adverse events involving POCT medical devices to the TGA.
Medical device maintenance	4.03	The service provider has processes to ensure its POCT medical devices are safe, fit for their intended purpose and performing optimally including: a maintaining a current and complete POCT medical device inventory

b store the medical devices in accordance with manufacturer's guidelines and to prevent un-authorised use

c ensuring reagents and consumables are in-date and used in-line with manufacturer's IFU

d conducting ongoing quality assurance

e conducting planned maintenance and repair in accordance with the manufacturer's guidelines using appropriately qualified personnel

f performance testing medical devices after maintenance and repair

g maintaining a maintenance and repair log for each medical device.

5. Specimen collection

Service providers document, implement and monitor all aspects of specimen collection.

Consumer outcome

Patients expect to be informed about the purpose and accuracy of the POCT, and the process for collecting and reporting on the test outcome.

Intent of this standard

To correctly identify patients and ensure specimens are correctly managed and prepared according to the manufacturer’s guidelines and procedures.

Explanatory notes

In practice, most errors that occur with POCT arise from misidentifying the patient, patient preparation, specimen collection issues and incorrect sample processing. Failure to recognise and eliminate errors at this stage can jeopardise test results, patient safety and health outcomes.

Patient identification

Specimens must remain positively identified with the patient's details throughout the testing process. Specimens retained following testing must be clearly labelled and stored to retain their original characteristics.

Performing the test in the presence of the patient is preferable as it acts as an additional safeguard to ensure the test results are matched to the right patient. Samples are labelled and it occurs in the patient’s presence. Only one patient sample is processed and tested at a time to reduce sample mix-ups.

Specimen collection

Common specimen collection errors include:

- sampling from a venous blood tube containing the wrong anticoagulant
- finger-prick sampling from unwashed hands

- not sampling from either the first or second drop of finger-prick blood
- using an incorrect specimen type
- air bubbles present in the specimen holder
- not using the manufacturer's recommended collection device.

Actions

Item	Action	
Safe environment	5.01	The service provider maximises the quality of POCT by ensuring: a there is adequate space for instruments, consumables, documentation and waste disposal b the environment and premises are fit for purpose, well maintained c reasonable adjustments can be made to meet the needs of patients, including those with a disability and from diverse backgrounds d patients' privacy, dignity and security.
Patient identification and test matching	5.02	The service provider: a defines and approves at least three unique patient identifiers b uses the approved identifiers to label all specimens, results and reports c correctly matches the patient to their point of care test d takes prompt corrective action when a patient identification and specimen discrepancy is identified e documents identification discrepancies and corrective action in the patient's healthcare record and incident management system.
Patient preparation	5.03	The service provider has processes to ensure the patient is informed about their POCT including, preparation and pre-test counselling.
Specimen collection processes	5.04	The service provider specimen collection processes: a describe the POCT, the purpose and the standard specimen collection procedure b adhere to the manufacturer's instructions for use (IFU)

		c align with best practice guidelines. d are documented and reviewed regularly e are readily accessible to clinicians.
Specimen collection optimisation	5.05	The service provider optimises specimen collection by ensuring the: a POCT medical devices and consumables are available, in date, and easy to locate and use b clinicians maintain specimen integrity through correct preparation and collection.
Infection control	5.06	The service provider has processes: a to comply with Guidelines for the Prevention and Control of Infection in Healthcare b to clean and disinfect surfaces, equipment and medical devices using products listed on the ARTG in a manner consistent with the manufacturers' IFU and at the recommended frequencies c consistent with: i. state or territory work health and safety infection controls regulations ii. the Australian Immunisation Handbook and jurisdictional requirements for vaccine-preventable diseases and workforce immunisation.

6. Specimen testing

Service providers implement documented, explicit procedures for specimen testing.

Consumer outcome

Patients expect clinicians to test their specimens correctly and ensure accurate outputs.

Intent of this standard

To ensure that patients' specimen testing is according to the manufacturer's instructions for use (IFU) and that the quality control and assurance procedures provide certainty that the test results are accurate.

Explanatory notes

Performing the test

The purpose of testing procedures is to ensure patient and operator safety.

POCT medical devices are used according to the manufacturer’s IFU.

Instructions for performing a test are available to clinicians in the testing area. They identify the critical aspects of the testing, so it performs consistently. Instructions include standard operating procedures (SOPs), manufacturer’s IFU, site-specific instructions and quick reference guides.

Each test performed is traceable to a patient, records of quality control, clinician ID and, where applicable, lot numbers of consumables.

POCT performed outside of manufacturer’s IFU (off label), and established quality management systems can lead to inconsistent and unreliable results and pose a risk to patients. Risks include giving wrong results, which can lead to incorrect or inappropriate decisions being made in relation to the health, management or care needs of patients.

Specimen testing errors

Any deviation from the manufacturer's IFU can cause an error in measurement and compromise patient safety.

Common errors include:

- setting the wrong units of measurement on a POCT medical device
- using quality control materials beyond their expiry date
- incorrect timing for manual reading of devices, for example, urine dipsticks or immunochromatography tests.

Reference intervals

For each POCT, there are reference levels and clinical decision limits. POCT manufacturers, pathology practices, international bodies, and professional societies can provide evidence about the clinical and diagnostic purposes, analytical performance and reference data for point of care tests.

Quality control

Quality Control (QC) measurements are essential for all POCT. They provide confidence that the point of care test meets clinical and technical specifications and enables the detection and management of suboptimal performance.

The QC program is completed in accordance with the manufacturer's IFU and verifies the medical device's performance. QC materials with expected values at clinically significant levels should be used wherever possible. When designing the QC program, consider the analytical system, the location of where POCT is conducted and the timing of QC. The acceptable QC range is established during the implementation of the POCT medical device and must fall within the manufacturer's specified limits.

QC usually involves artificial samples with different known analyte levels. POCT manufacturers generally provide QC samples. If not, scientific and medical professional bodies can provide advice, and if samples are unavailable, use patient specimens and results processed in an accredited pathology practice.

Documented criteria for the acceptance and failure of QC shall be available to clinicians.

QC shall be tested at a frequency determined by the stability of the POCT medical device and the potential risk of harm to the patient from an erroneous result. At a minimum, an abnormal QC sample is analysed monthly, and whenever new reagent lot numbers are used. Where two QC samples are available for analysis, one should represent a normal value and the other an abnormal value.

QC samples are reviewed at the time of testing to confirm that the test is performing as expected. When a QC sample is tested, the results are recorded and compared against the acceptable range. Results that fall outside this range are considered unacceptable and can indicate a testing issue. Corrective action is required before proceeding with patient testing.

The QC process requires a regular review as part of a continuous quality improvement system. This includes investigating and documenting unacceptable results and implementing corrective action.

External Quality Assurance

External Quality Assurance (EQA) programs deliver peer reviews of POCT and monitor POCT performance, enabling the detection of issues. Most programs provide identical samples to program participants to test using its routine method. The program collates the results, provides the range of results obtained, and indicates the accuracy of the results. Additionally, it assesses whether the selected method yields results that differ from those obtained by other service providers using the same method.

In the absence of suitable EQA programs, the service provider has alternative quality assurance processes that can include:

- performing patient parallel testing against a reference analyser to test for ongoing alignment of patient results or establish a relationship with a service provider or pathology practice performing the same POCT
- exchanging stable samples with other service providers or pathology practices performing the same POCT to compare results
- analysing reference materials considered to be comparable with patient samples
- comparing the examination results of identical quality control samples against pooled results from service providers or pathology practices using the same quality control samples
- analysing a different lot number of the manufacturer's end-user calibrator or the manufacturer's trueness control material
- analysing microbiological organisms using split/blind testing of the same sample by at least two clinicians, at least two analysers, or at least two methods
- analysing patient samples from clinical correlation studies
- analysing materials from cell and tissue repositories.

Actions

Item	Action	
Analytical and clinical performance requirements	6.01	The service provider, before offering a point of care test, defines each analytical and clinical performance requirement using key indicators for: a quantitative analysis, including accuracy, precision, limits of detection, units of measure and assessment of common interference b qualitative analysis with a reference standard, including estimates of sensitivity and specificity pairs, likelihood ratio of pairs, and receiver operating characteristic analysis c qualitative analysis with a non-reference standard, including positive, negative and overall percent agreement.
Quality control	6.02	The service provider uses QC procedures for POCT and: a ensures all point of care tests have a documented QC process that assesses the test's performance b specifies the acceptable results for patient testing c has the clinicians perform the quality checks d has a review system to analyse results and take corrective action when the QC results are unacceptable

		e documents the QC results, reviews and implements corrective action and maintains these materials in accordance with retention legislation and regulations f ensures QC integrity is maintained when implementing changes to the quality management system.
Frequency of quality control testing	6.03	The service provider ensures the clinicians test quality control samples at a frequency based on the stability and robustness of the examination method, the risk of patient harm and when: a consumables change, including lot number changes b the clinicians do not have confidence in the reliability or accuracy of a result c substantial maintenance has occurred, or the equipment has suffered a physical event.
Specimen test procedures	6.04	The service provider's point of care test procedures: a adhere to the manufacturer's instructions for use (IFU) b include traceability of samples to the original specimen c include reference intervals for identifiable patient groups d are readily available to the clinicians e address management of compromised specimens f are reviewed regularly g are audited regularly to assess clinician compliance with the procedures.
Disposal of biological materials and equipment	6.05	The service provider: a has a waste management policy b handles and disposes of specimens, collection devices, reagents and kits safely c complies with jurisdictional regulations relating to the disposal of biological material from pathology testing.
External quality assurance programs	6.06	The service provider participates in EQA programs, where available, for each point of care test and: a documents the acceptable performance criteria b ensures EQA materials are tested and reported in the same manner as a routine specimen

		c reviews the results to ensure the test's performance is acceptable d has a process which investigates and documents discordant quality assurance results, any impact on the quality of the patient's results and corrective actions.
External quality assurance alternatives	6.07	In the absence of suitable EQA programs, the service provider has alternative quality assurance processes for POCT.

7. Results interpretation and reporting

There are explicit procedures to support the accurate interpretation of test results and processes to communicate and record the results effectively.

Consumer outcome

Patients expect point of care test results to be interpreted accurately, communicated effectively, used to support clinical decision making and recorded.

Intent of this standard

To ensure patients receive accurate results that support clinical decision-making during the episode of care.

Explanatory notes

Reading the result

Timing can be critical to a test result. Timing intervals prescribed by manufacturers are critical and are followed. Results read before the time interval can cause invalid and false negative results due to incomplete reactions while results read after the time interval has passed can lead to either false positive or negative results due to overdevelopment of colour or fading of colour. Timers are available to clinicians at the collection site.

Results

Test results are reported without delay and provide necessary details to enable appropriate patient care. The results contain the unique identifiers that link the result to the patient, date and time of collection, test results with measurement units and reference intervals or decision point, interpretation of results where appropriate and how to access follow up care.

Communication breakdowns, including, misinterpreting the result, reporting the incorrect result to the patient, manual transcription errors, electronic results being matched to the wrong patient, and failing to record the result in the patient's healthcare record can lead to adverse events that result in patient harm.

Recording results

POCT results are usually used immediately for patient management, and therefore, they must be recorded, retained, and become part of the patient's healthcare record. The health record

contains the patient details, unique identifiers, test results, that the result was from a POCT device, reagent lot number, quality control check, name and location, and POCT medical device ID number.

Service providers should use electronic data storage and have connectivity with information systems to optimise quality patient care.

The clinicians have access to relevant healthcare records such as the Event Summary or Shared Health Summary, which is available through My Health Record (MHR).

Critical results

Critical results are defined as results outside critical limits, which may indicate a life-threatening situation and require immediate notification to the service provider. Specific procedures are required to ensure that every reasonable effort is made to contact the service provider, any other service provider responsible for the patient's care, the patient or their carer when necessary, particularly in situations where no service provider is immediately available.

Actions

Item	Action	
Test results	7.01	The service provider has processes to ensure the clinicians that interpret and determine results: a have the skills and qualifications to interpret POCT results b are in an environment with optimal conditions for result interpretation c adhere to the manufacturer's instructions for use (IFU) for result interpretation d have access to reference intervals and clinical decision limits to interpret results e have procedures to check the validity of quality control results and ensure a consistent approach to result interpretation f have access to My Health Record g have access to pathologists who provide advice regarding result interpretation.
Results communication	7.02	The service provider has processes to: a provide accurate and easy to understand results to the patient b complete a written, accurate, clear and concise report which is added to the patient's healthcare record and, where required, provided to the patient's other service providers

		c ensure clinicians are available to interpret results and provide advice to those reviewing the report d to document and report notifiable diseases in accordance with jurisdictional requirements and disease registries.
Reporting critical results	7.03	The service provider has processes for recognising and responding to critical results indicating a life-threatening condition necessitating urgent medical intervention including processes to: a to interpret and report a critical result in a timely manner b promptly notify a responsible service provider, or patient, or their carer when the service provider is not contactable c document the escalation of the critical result and the steps taken to ensure communication of the critical result. d audit critical result process to check compliance.
Result deviations	7.04	The service provider organisation has processes to: a identify and review result errors and deviations b amend reports and document amendments in the healthcare record that are traceable to the original report.
Healthcare records	7.05	The service provider has healthcare records processes that ensure: a test results and related information from the POCT medical device are transferred to the healthcare record, and where possible, this process is automatic b test results are retrievable and retained c patient traceability d patient confidentiality e retention of test results in accordance with retention legislation and regulations.
My Health Record	7.06	The service provider providing information to My Health Record has processes that: a incorporate POCT results into My Health Record b describe how the workforce can access the system, which complies with legislative requirements c maintain the accuracy and completeness of the POCT information it uploads.

Glossary

Term	Definition
Action	Describes what outcome needs to be delivered to meet a criterion.
Accuracy	Closeness of agreement between a measured quantity value and a true quantity value of a measurand.
Adverse event	An incident that results, or could have resulted, in harm to a patient or consumer. A near miss is a type of adverse event.
Analytical performance	The ability of an In house in vitro diagnostic medical device to detect or measure a particular analyte.
Carer	A person who provides personal care, support and assistance to another individual who needs it because they have a disability, medical condition (including a terminal or chronic illness) or mental illness, or they are frail or aged. An individual is not a carer merely because they are a spouse, de facto partner, parent, child, other relative or guardian of an individual, or live with an individual who requires care. A person is not considered a carer if they are paid, a volunteer for an organisation, or caring as part of a training or education program. For Aboriginal and Torres Strait Islander people, there may be a collective approach to carer responsibilities. Confirming who is

Term	Definition
	responsible for different aspects of care is important for ensuring that carer engagement is effective.
Clinical governance	An integrated component of a pathology practice's corporate governance. It ensures that the pathology workforce, everyone from pathology collectors, technicians, scientists, pathologists, designated persons and members of governing bodies, such as boards is accountable to patients and the community for assuring the delivery of safe, effective and high-quality pathology services. Clinical governance systems provide confidence to the community and the pathology practice systems are in place to deliver safe and high-quality pathology care.
Clinical performance	The ability of an in vitro diagnostic medical device to yield results that are correlated with a particular clinical condition/physiological state in accordance with the target population and the intended user.
Collection	Any procedure for obtaining a specimen regardless of technique or source.
Competence	Demonstrated ability to apply knowledge and skills to achieve the intended result.
Confidentiality	The state of keeping or being kept secret or private.
Consumer	A person who has used, or may potentially use, health services, or is a carer for a patient using health services. A healthcare consumer may also act as a consumer representative to provide a consumer perspective, contribute consumer experiences, advocate for the interests of current and potential health service users, and take part in decision-making processes.
Diverse background	The varying social, economic and geographic circumstances of patients having point of care testings and their cultural backgrounds, disability status, religions, beliefs and practices, spoken languages, sexual orientation, gender identity and gender expression, and sex characteristics.
Environment	The context or surroundings in which health care is delivered. The environment can also include other patients, consumers, visitors and the workforce.

Term	Definition
Equipment	Any tools, devices or systems used in health care settings to collect or test samples for the detection, diagnosis or monitoring of disease.
External quality assurance	Is a system for objectively checking a laboratory's performance using an external agency. The external agency provides samples, and the laboratory results are evaluated externally and compared to peers or a reference laboratory who are undertaking the same test with the same methodology.
Governing body	A board, chief executive officer, organisation owner, partnership or other highest level of governance (individual or group of individuals) that has ultimate responsibility for strategic and operational decisions in a pathology practice or health service organisation affecting the safety and quality of the point of care testing.
Hand hygiene	A general term referring to any action of hand cleansing. This includes application of a waterless antimicrobial agent (such as alcohol-based hand rub) to the surface of the hands; and use of soap/solution (plain or antimicrobial) and water.
Harm	Something that impairs or adversely affects a patient physically or mentally.
Health care	The prevention, diagnosis, treatment, and management of illness and injury, and the preservation of mental and physical well-being through the services offered by clinicians.
Healthcare record	A record of the patient's medical history, treatment notes, observations, correspondence, investigations, test results, photographs, prescription records and medication charts for an episode of care. Information in a healthcare record can be sourced from multiple healthcare organisations.
Health outcome	The status of an individual, group of people or population wholly or partially attributable to an action, agent or circumstance.
High-quality health care	Is accessible, effective, integrated, person-centred and safe. At a health system level, it is efficient, sustainable and equitable.
Incident	An event or circumstance that resulted, or could have resulted, in unintended or unnecessary harm to a patient or consumer or loss or damage. An incident may also be a near miss.

Term	Definition
Infection	The invasion and reproduction of pathogenic (disease-causing) organisms inside the body. This may cause tissue injury and disease.
Informed consent	A process of communication between a patient and clinician about options for treatment, care processes or potential outcomes. This communication results in the patient's authorisation or agreement to undergo a specific intervention or participate in planned care, which may include not doing the test. The communication should ensure that the patient understands what will happen, the available options and the expected outcomes, including success rates and side effects for each option.
Instructions for use (IFU)	Means the information provided by the manufacturer for the intended user which details how the device can be used safely for its intended purpose. This may be referred to as directions for use, user guide, or operating manual in some international jurisdictions.
Instrument	A calibrated and validated pathology device, system, or piece of equipment used for the collection, preparation, processing, examination, measurement, or storage of biological specimens.
In vitro diagnostic medical device	Device, whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes and including reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles.
Jurisdictional requirements	Systematically developed statements from state and territory governments about appropriate healthcare or service delivery for specific circumstances. Jurisdictional requirements encompass several document types from state and territory governments, including legislation, regulations, guidelines, policies, directives and circulars.
Likelihood ratios	Are used for assessing the value of performing a diagnostic test. They combine sensitivity and specificity into a single metric that indicates how much a test result shifts the probability that a condition is present.
Manufacturer	The manufacturer is the entity responsible for the design, production, packaging and labelling of the medical device before it is supplied under the entity's name to carry out its defined operations.

Term	Definition

	Or an entity with a view to supplying a medical device that does one or more of the following using ready-made products:
	• Assembles the device.
	• Packages the device.
	• Processes the device.
	• Fully refurbishes the device.
	• Labels the device.
	• Assigns to the device its purpose by means of information supplied, by one or more of the following:
	  ○ The labelling on the device.
	  ○ The instructions for using the device.
	  ○ Any advertising material relating to the device.
	  ○ Technical documentation describing the medical device's mechanism of action.

Medical device	A medical device is defined in the legislation as any instrument, apparatus, implement, machine, appliance, implant, software, material or other similar or related device (including any diagnostic product for in vitro use) that is intended by the manufacturer to be used, alone or in combination, for human beings for the specific purpose of one or more of the following: • diagnosis, prevention, monitoring, treatment or alleviation of disease • diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap • investigation, replacement, modification or support of the anatomy or of a physiological process • supporting or sustaining life • control of conception • disinfection of medical devices • providing information for medical purposes by means of in vitro examination of specimens derived from the human body • does not achieve its principal intended action in or on the human body by pharmacological, immunological or

Term	Definition
	metabolic means, but which may be assisted in its function by such means.
Metrological traceability	Property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty.
Off-label use	Is using a product for a reason not listed as a specific indication or intended use in the ARTG.
Patient	A person or people who are actively receiving health care.
Pathology practice	A separately constituted entity that is responsible for a pathology laboratory or group of laboratories where pathology services, clinical governance, administration and financial management are conducted with the governing body. A pathology practice is an example of an APA, its accredited pathology laboratories, and approved collection centres and pathology practitioners.
Patient privacy	Is the protection of a patient's physical self and their personal health information. It includes respecting a patient's autonomy regarding their body and medical information.
Patient identifiers	Items of information used to unambiguously identify a patient, including family and given names, date of birth, birth sex, address, a healthcare record number and individual healthcare identifiers.
Person centred care	An approach to the planning, delivering and evaluating of health care founded on mutually beneficial partnerships among healthcare providers and patients. Person-centred care is respectful of and responsive to patient and consumers' preferences, needs and values. Key dimensions of person-centred care include respect, emotional support, physical comfort, information and communication, continuity and transition, care coordination, involvement of carers and family, and access to care.
Pre-test counselling	Is a confidential discussion with a patient to provide accurate information about the test and the implications of a positive or negative result. This enables the patient to make an informed choice about having the test and making responsible decisions based on the test outcome.

Term	Definition
Precision	Closeness of agreement between measurement indications or measured quantity values obtained by replicate measurements on the same or similar objects under specified conditions.
Procedure	The set of instructions specific to a pathology practice that operationalises policies and processes.
Process	A series of actions or steps taken to achieve a particular goal.
Quality assurance	Relates to participation in relevant Quality Assurance Programs, performance reviews and corrective actions where performance is unsatisfactory.
Quality control sample	Non-patient derived material such as controls, blanks, and reference materials.
Quality improvement	The combined efforts of the workforce and others – including consumers, patients and their families, researchers, planners and educators – to make changes that will lead to better patient outcomes (health), better system performance (care) and better professional development. Quality improvement activities may be undertaken in sequence, intermittently or continually.
Reagent	A reagent is a compound added to a POCT in vitro diagnostic medical device to test a specimen by causing a reaction.
Receiver operating characteristic analysis	Is an analytical method used to evaluate the performance of a binary diagnostic classification method. Many test results are presented as continuous or ordinal variables, so a cut-off value for diagnosis needs to be set to determine if the disease is present. This analysis is used for this process.
Reference range	Specified interval of the distribution of values taken from a biological reference population.
Report	Is a document prepared to provide information about a patient's condition (description, interpretation and results) to help guide diagnostic and treatment decisions.
Requester	A clinician who communicates to a pathology practice to request that a patient receive specific pathology services.

Term	Definition
Risk	A clinician who communicates to a pathology practice to request that a patient receive specific pathology services.
Risk management	The design and implementation of a program to identify and avoid or minimise risks to patients, employees, volunteers, visitors and the organisation.
Scope of practice	The extent of an individual clinician's approved clinical practice within a particular organisation, based on the clinician's skills, knowledge, performance and professional suitability, and the needs and service capability of the organisation.
Sensitivity	Means the proportion of true positives that are identified as positive by the assay.
Specificity	Ability of an examination procedure to have negative results associated with an absence of a particular disease or condition.
Specimen	Discrete portion of a body fluid or tissue or other sample associated with the human body taken for examination, study or analysis of one or more quantities or characteristics to determine the character of the whole.
Specimen integrity	The necessary conditions required to keep a specimen from becoming compromised. Maintaining integrity involves ensuring that specimens are properly collected, transported, handled and stored to retain their original characteristics, and preventing any changes that could affect the accuracy and reliability of test results.
Specimen traceability	The ability to track all specimens back to a patient or to its origin.
Standard	The agreed attributes and processes to ensure that a product, service or method will perform consistently at a designated level.
Substitute decision-maker	A person appointed or identified by law to make health, medical, residential and other personal (but not financial or legal) decisions on behalf of a patient whose decision-making capacity is impaired. A substitute decision-maker may be appointed by the patient, appointed for (on behalf of) the person, or identified as the default decision-maker by legislation, which varies by state and territory.

Term	Definition
System	Is the resources, policies, processes and procedures that are organised, integrated, regulated and administered to accomplish a stated goal. A system: • brings together risk management, governance, and operational processes and procedures, including education, training and orientation • deploys an active implementation plan, feedback mechanisms including agreed protocols and guidelines, decision support tools and other resource materials • uses incentives and sanctions to influence behaviour and encourage compliance with policies, protocols, regulations and procedures. The workforce is a resource in the system and involved in all elements of system development, implementation, monitoring, improvement, and evaluation. Systems will vary depending on the size of the POCT organisation and the associated POCT risks.
Traceability	The ability to trace the history, application or location of reusable medical devices. Some professional groups may refer to traceability as tracking.
Training	The development of the workforce's knowledge and skills.
Transmission-based precautions	Transmission-based precautions are used with standard precautions and include droplet, contact and airborne precautions or a combination of these based on the infection's transmission route.
Validation	Confirmation through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled.
Verification	Confirmation of truthfulness, through the provision of objective evidence that specified requirements have been fulfilled.
Workforce	Means all people working in a pathology practice, including employed or contracted, locum, agency, student, volunteer, or peer workers. The workforce can be members of the pathology practice or medical company representatives providing technical support.

Australian
Commission on
Safety and Quality
in Health Care

T. +61 2 9126 3600
Level 5, 255 Elizabeth St
Sydney NSW 2000 Australia

safetyandquality.gov.au