



RACGP

Royal Australian College of General Practitioners

Standards for point-of-care testing

5th edition



Standards for point-of-care testing. 5th edition

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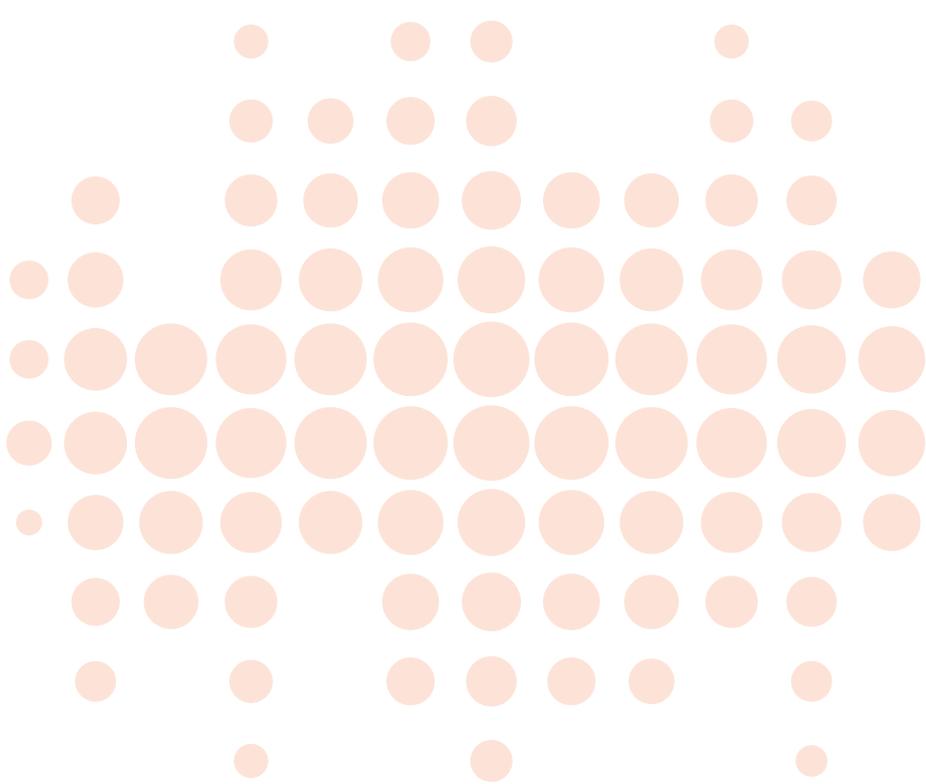
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We acknowledge the Traditional Custodians of the lands and seas on which we work and live, and pay our respects to Elders, past, present and future.



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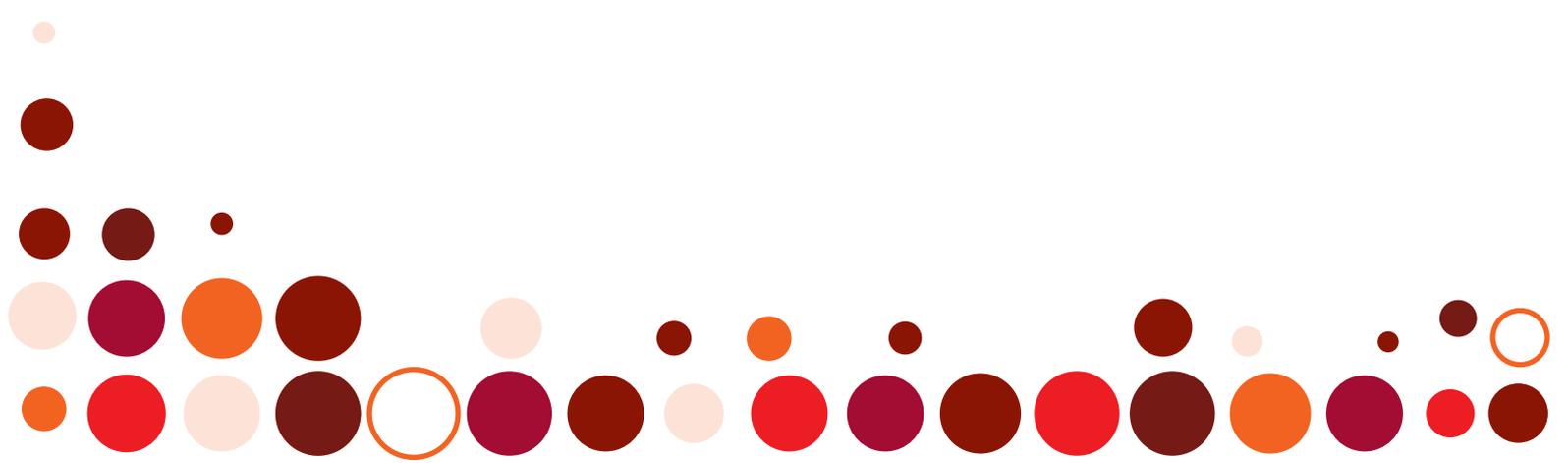
*Standards for
point-of-care testing*

5th edition



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Introduction to the Standards for point-of-care testing (5th edition)

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

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

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

Definition and benefits of PoCT

In this document, PoCT is defined as pathology testing performed at the point or time of care that helps healthcare practitioners make immediate and informed decisions about a patient's management.

The benefits of PoCT include:

- healthcare practitioners' ability to make immediate and informed decisions about patient care, which will result in improved clinical management
- greater patient compliance with pathology requests, especially in at-risk patients
- greater convenience and satisfaction for patients because of the speed of diagnosis and treatment decisions
- more opportunities for patients to engage with the practice team.¹

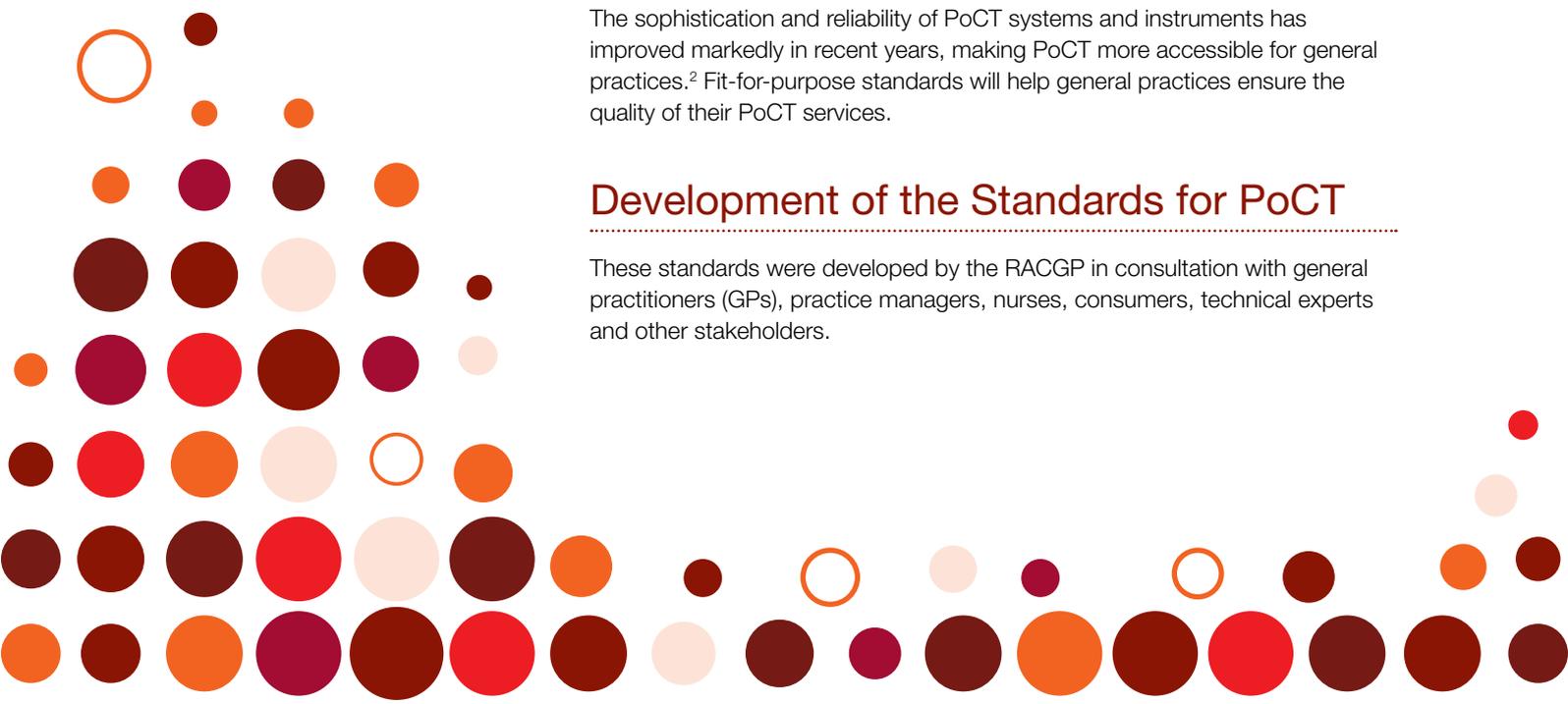
The Standards for PoCT are not intended to apply to simple pathology tests.

Why do we need the Standards for PoCT?

The sophistication and reliability of PoCT systems and instruments has improved markedly in recent years, making PoCT more accessible for general practices.² Fit-for-purpose standards will help general practices ensure the quality of their PoCT services.

Development of the Standards for PoCT

These standards were developed by the RACGP in consultation with general practitioners (GPs), practice managers, nurses, consumers, technical experts and other stakeholders.



Definition of a general practice that performs PoCT

A general practice or health service that performs PoCT is one that:

- operates within the model of general practice described in the RACGP's definition of a general practice, available at www.racgp.org.au/becomingagp/what-is-a-gp/what-is-general-practice
- provides GP services that are predominantly of a general practice nature
- is capable of meeting all mandatory Indicators in the following modules
 - Core
 - Quality improvement
 - General practice
 - Point-of-care testing.

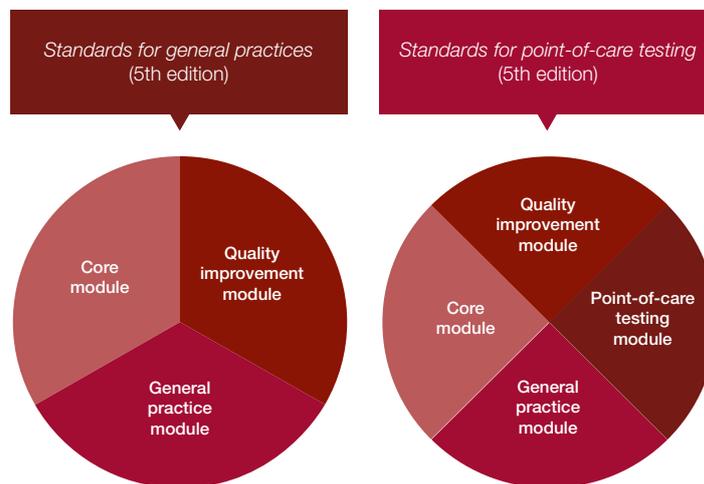


Figure 1. Modular structure of the *Standards for general practices* and *Standards for point-of-care testing*

Accreditation of a general practice that performs PoCT

For your practice to be accredited against the Standards for PoCT:

- you must be accredited against the *Standards for general practices* (5th edition)
- you must be formally assessed against the Standards for PoCT by an accrediting agency approved under the National General Practice Accreditation Scheme (the Scheme), which commenced on 1 January 2017; a list of approved accrediting agencies can be found [here](#).

Please note that your PoCT accreditation visit can occur either concurrently with your general practice accreditation visit, or as a separate process if already accredited.

Surveyor teams

A surveyor team will conduct accreditation visits to assess you against the Standards for PoCT.

Each surveyor team comprises at least two surveyors:

- an appropriately qualified GP surveyor
- an appropriately qualified nurse, practice manager, allied health professional or Aboriginal and Torres Strait Islander health worker/health practitioner with relevant experience in general practice.

Surveyor teams may include a third person, such as a non-health practitioner or consumer who has been appropriately trained in the Standards for PoCT.

At least one member of the surveyor team must have expertise in PoCT.

The RACGP's *Resource guide*

The RACGP's *Standards, 5th edition: Resource guide* contains useful supplementary information that will help your practice meet the Indicators in the Standards for PoCT. The *Resource guide* is available at www.racgp.org.au/download/Documents/Standards/5th%20Edition/resource-guide-racgp-standards-for-general-practices-5th-ed.pdf

PoCT and the Australian Register of Therapeutic Goods

In Australia, PoCT devices and systems are categorised as in-vitro diagnostic medical devices (IVDs) and are therefore regulated as a subset of medical devices by the Therapeutic Goods Administration (TGA).

The Australian Register of Therapeutic Goods (ARTG) lists therapeutic goods that can be legally imported into Australia, or supplied for use in Australia, or exported from Australia.

Unless a specific exemption has been granted, it is a criminal offence under the *Therapeutic Goods Act 1989* to import into, supply in or export from Australia a medical device that is not listed on the ARTG.³

The Standards for PoCT assume that your practice's PoCT devices or systems, including but not limited to consumables, reagents, controls and software, are listed on the ARTG.

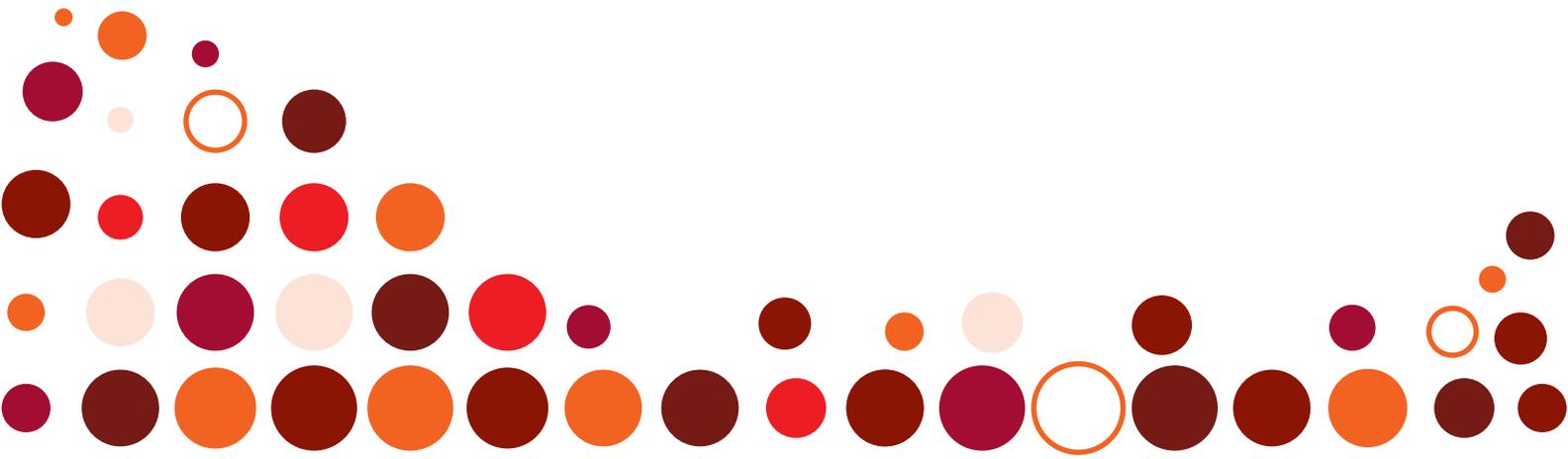
PoCT Standard 1

Clinical governance

Our practice uses clinical governance to establish and review clinical responsibility and accountability.

Effective clinical governance of PoCT ensures that:

- each practice team member takes ownership of PoCT processes, models good practice, and challenges poor practice⁴
- each team member is jointly accountable for patient safety and quality care
- roles, responsibilities and accountabilities for achieving agreed outcomes are clearly allocated to team members, according to each person's scope of practice⁵
- the practice uses what they have learnt to improve patient safety and quality of care.⁶



Criterion PoCT1.1 – Clinical purpose

Indicators

PoCT1.1▶A Our practice can describe the clinical and diagnostic purposes of PoCT based on best practice evidence, and how it can be applied.

PoCT1.1▶B Our practice's specifications for the analytical performance of PoCT are determined by the relevant clinical and diagnostic purposes.

PoCT1.1▶C Our practice uses reference data that is based on best practice evidence to interpret test results.

PoCT1.1▶D Our practice applies quality improvement and risk management processes to PoCT to improve quality of care and to minimise risk to patients.

Why this is important

The purpose of PoCT is to help healthcare practitioners make immediate and informed decisions about a patient's care and management.⁷

How you intend to use PoCT

PoCT can improve the timeliness, efficiency and quality of care in some areas of clinical practice.⁸ When deciding on the clinical and diagnostic purposes where PoCT may benefit your patients, you must consider current best practice evidence.

Because PoCT can be used to diagnose, monitor, manage or screen, your practice needs to define its analytical performance requirements, based on its intended clinical and diagnostic purposes. For example, using PoCT to monitor a patient's diabetes may have different analytical requirements than to diagnose infections with public health implications.⁹

Evaluation of PoCT systems

The quality of PoCT may be affected by many factors, including the storage of consumables, PoCT practitioners, specimen quality and variability between instruments.¹⁰

Your practice needs to assess the impact of these factors by evaluating the analytical performance of your PoCT system. This evaluation will help to confirm that PoCT meets your practice's clinical, diagnostic and other specifications. This evaluation can then provide a benchmark against which you can regularly assess routine analytical performance.

Interpreting test results

You can interpret test results by using reference data obtained from various sources, including PoCT suppliers, pathology providers, international bodies and professional societies.

Your practice must:

- agree on which reference intervals and clinical decision limits you will use to interpret PoCT results
- only use reference intervals and clinical decision limits that are based on current best practice evidence.

Quality use of PoCT

Having a consistent approach to PoCT, which includes having agreed reference intervals and clinical decision limits, may help GPs to interpret test results.

Each GP needs to exercise clinical judgement when:

- deciding whether to use PoCT
- deciding whether to use results of PoCT to make decisions about patient management.

Safe and effective PoCT is possible only if:

- staff have the required skills and receive appropriate training
- PoCT is undertaken often enough to maintain those skills
- the practice records, addresses and reviews non-conformance and adverse events.

Meeting this Criterion

Sources of information and evidence

PoCT suppliers, pathology providers, international bodies, professional societies and other sources can provide evidence about the clinical and diagnostic purposes, analytical performance and reference data for PoCT. Therefore, your practice does not have to generate its own evidence.

It is recommended that you:

- seek information from a range of sources, instead of relying on one source
- select information that is appropriate for your practice's clinical and diagnostic purposes and patient population.

Evaluating PoCT systems' analytical performance

The analytical performance of a test must be evaluated:

- on commissioning
- following major repairs by completing a quality control (QC) test to ensure the instrument is within acceptable ranges
- at other times as needed.

The Australian Point of Care Practitioner's Network (APPN) provides resources to help practices implement a PoCT program.

The APPN also has a resource (*Guidelines for the evaluation of PoCT instruments that provide quantitative results*) that you can refer to when evaluating a PoCT system's analytical performance. This protocol has been endorsed by the Australian Association of Clinical Biochemists (AACB) and IVD Australia.

Quality improvement and risk management

To improve quality of care and to minimise risks to patients:

- apply quality improvement and risk management processes to PoCT
- record and address adverse and non-conformance events in a timely manner

- notify the clinical team member with nominated responsibility for PoCT of adverse and non-conformance events. Adverse and non-conformance events could be included as an agenda item in team meetings
- review adverse and non-conformance events, including how they are addressed. Reviews must occur at least annually and can be conducted internally or externally.

Continuity of care

In the event of unplanned loss of PoCT, you must be able to demonstrate continuity of care for patients.

Related Criteria

Criterion C6.4 – Information security

Criterion QI1.1 – Quality improvement activities

Criterion QI3.1 – Managing clinical risks

Criterion GP2.1 – Continuous and comprehensive care

Meeting each Indicator

PoCT1.1▶A Our practice can describe the clinical and diagnostic purposes of PoCT based on best practice evidence, and how it can be applied.

You must:

- describe the clinical and diagnostic purposes for using PoCT
- ensure the clinical and diagnostic purposes of PoCT are evidence-based.

PoCT1.1▶B Our practice's specifications for the analytical performance of PoCT are determined by the relevant clinical and diagnostic purposes.

You must:

- provide evidence that the analytical performance specifications of each test method are based on the clinical and diagnostic purposes for which they will be used
- demonstrate that the analytical performance of each test method has been evaluated upon commissioning and following major repairs.

PoCT1.1▶C Our practice uses reference data that is based on best practice evidence to interpret test results.

You must:

- describe reference intervals and/or clinical decision limits for interpreting PoCT results
- ensure reference intervals and/or clinical decision limits are evidence-based.

PoCT1.1▶D Our practice applies quality improvement and risk management processes to PoCT to improve quality of care and to minimise risk to patients.

You must:

- record and address adverse and non-conformance events
- annually review adverse and non-conformance events
- demonstrate that your practice can maintain continuity of care if there is an unplanned loss of PoCT.

Criterion PoCT1.2 – Patient needs

Indicator

PoCT1.2▶A Our practice considers our unique requirements for PoCT and how it benefits our patients.

Why this is important

It is important that your practice selects a PoCT system that suits your environment and meets your patients' individual needs.

Patients' needs

PoCT enables equitable access to pathology, regardless of where patients live.¹¹ Some patients may benefit from PoCT more than others. For example, some patients may not be able to attend a pathology collection centre, or may not follow up their results.

Your practice's requirements

Your practice needs to consider how different aspects of a PoCT system may affect your patients' and team members' experience of your practice. Aspects to consider include collecting and storing specimens, turnaround time for results, the use of staff time, and the resources (including IT systems) required to conduct PoCT.

Meeting this Criterion

Your practice must be able to demonstrate that you have considered the specifications and requirements for a PoCT system, in terms of your patients, location, local health infrastructure and other relevant circumstances. These requirements may include specimen type, turnaround time for results, complexity of operations, patterns of testing and staff resources. Practice's can also consider how PoCT can meet these requirements where laboratory pathology services may be limited.

It is best practice to compare the features of various PoCT systems to determine which is most suitable for your practice before you implement PoCT.⁹

Meeting each Indicator

PoCT1.2▶A Our practice considers our unique requirements for PoCT and how it benefits our patients.

You must:

- describe your practice's requirements for PoCT.

You could:

- compare practice requirements with PoCT systems prior to implementation.

Criterion PoCT1.3 – Clinical autonomy

Indicator

PoCT1.3▶A Our practice team has autonomy in decisions concerning the use of PoCT.

Why this is important

Professional autonomy and clinical independence are essential components of high-quality care that supports the patient's best interests.

Individual healthcare practitioners must have the autonomy to determine whether and when to use PoCT, based on their clinical judgement, and to make this decision free from considerations other than the best interests of each individual patient.

Meeting this Criterion

Your practice must ensure that practice team members are free from incentives to use PoCT.

Related Criterion

Criterion C5.2 – Clinical autonomy for practitioners

Meeting each Indicator

PoCT1.3▶A Our practice team has autonomy in decisions concerning the use of PoCT.

You must:

- give clinical team members autonomy to request pathology
- ensure the practice team are free from incentives to use PoCT, including specific instruments or consumables.

Criterion PoCT1.4 – Clinical responsibility

Indicator

PoCT1.4▶A Our practice has at least one member of the clinical team who has primary responsibility, authority and accountability for the quality of PoCT.

Why this is important

The successful implementation of PoCT requires skills, knowledge and time. To ensure results are of a uniformly high quality, your practice needs to properly manage relevant organisational and technical activities. This can be best achieved if one member of the clinical team is responsible for, and oversees, PoCT activities.¹

Meeting this Criterion

A designated member of the clinical team must have ultimate responsibility for PoCT undertaken by the practice.

This person:

- must have an adequate understanding of PoCT, including
 - the diagnostic and technical applications and any limitations
 - these Standards for PoCT
 - your practice's PoCT policies and procedures
- must have completed appropriate PoCT training (eg external courses, in-house programs, 'on the job' training at the practice) that aligns with your practice's PoCT program or system
- can delegate their day-to-day PoCT responsibilities to an appropriately trained PoCT practitioner, but must retain ultimate oversight of PoCT in the practice.

Meeting each Indicator

PoCT1.4▶A Our practice has at least one member of the clinical team who has primary responsibility, authority and accountability for the quality of PoCT.

You must:

- have at least one team clinical team member who has primary responsibility for the implementation, conduct, quality and accreditation of PoCT
- ensure the responsible team member has had appropriate training in PoCT.

You could:

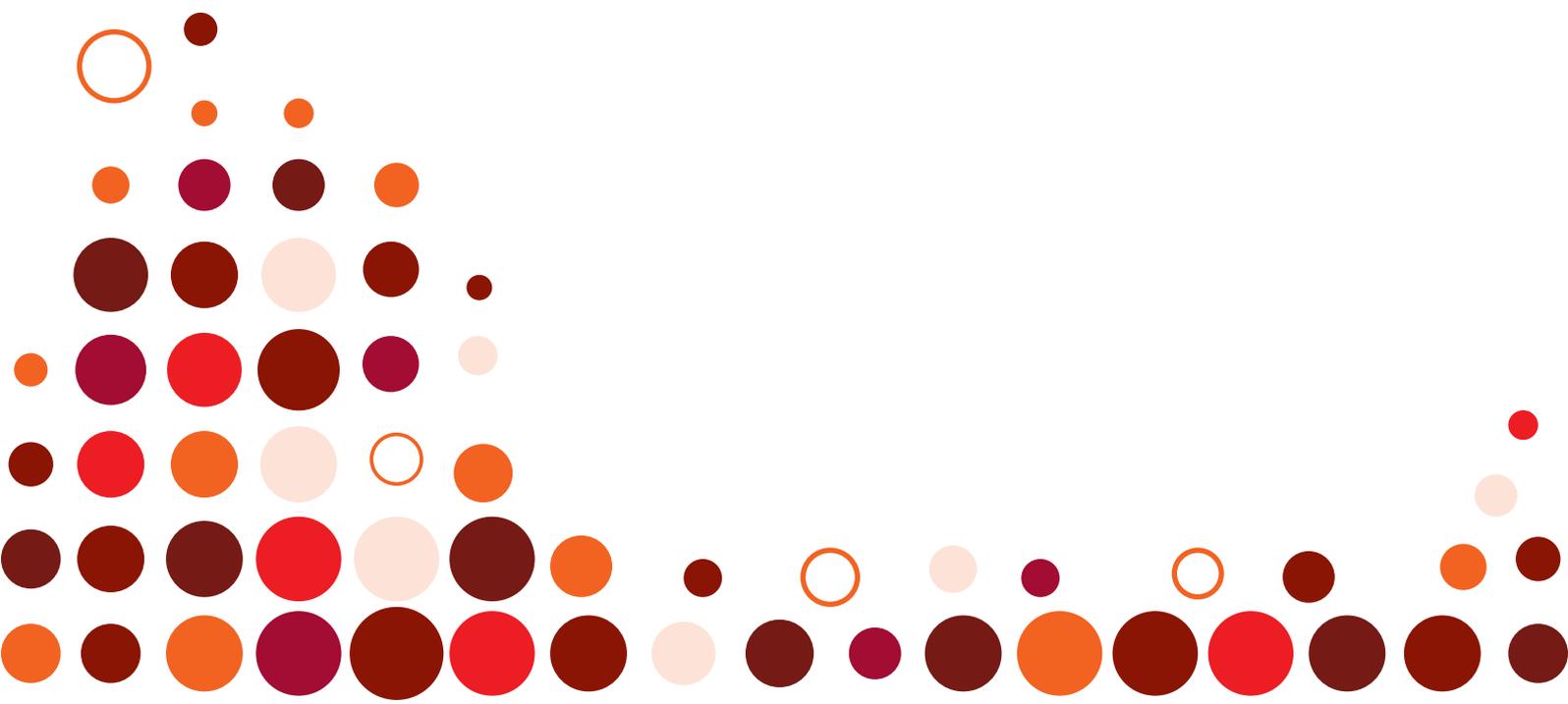
- maintain a clinical governance policy.

PoCT Standard 2

Education and training of PoCT practitioners

Our practice team has the appropriate skills and knowledge to perform PoCT.

The quality of PoCT can be compromised by pre-analytical, analytical and post-analytical errors and issues, especially if performed by inadequately trained PoCT practitioners. This is why team members performing and managing PoCT must be appropriately trained and educated, and must be able to demonstrate competency when assessed.¹²



Criterion PoCT2.1 – Qualifications, education and training of PoCT practitioners

Indicator

PoCT2.1▶A Members of our practice team who perform PoCT:

- have undertaken training
- have completed a competency assessment
- participate in training and education updates.

Why this is important

Having PoCT practitioners who are trained reduces the risk of errors and safeguards the validity of results that inform clinical decision making, ensuring that your practice provides patients with safe, quality care.

All PoCT practitioners must:

- be suitably trained
- maintain the knowledge and skills that enable them to perform PoCT
- work within their scope of practice and competencies.

Meeting this Criterion

Your practice must maintain records demonstrating that the training of PoCT practitioners is appropriate for the PoCT they perform.

All PoCT practitioners must receive updated training if:

- significant changes to the PoCT method/s are introduced
- a new test and/or instrument is introduced.

An individual PoCT practitioner must receive updated training if:

- a competency issue with that practitioner has been identified
- the practitioner has not performed PoCT for more than six months.

Training may cover areas such as the following.

General

- Your practice's policies
- Overview of clinical purposes

PoCT system

- Basic principles of analysis, calibration, bias, precision, range, sensitivity, specificity, interferences, method evaluation and method comparison
- Normal test performance according to the manufacturer's instructions
- Recognition of malfunctions and appropriate actions
- Error messages and actions

- Storage of consumables
- Care, maintenance and decontamination of your PoCT system

Patients and specimens

- Appropriate information for patients
- Patient preparation
- Specimen collection techniques
- Specimen identification and labelling
- Specimen handling and stability
- Recognition of unsuitable specimens
- Patient and staff safety

Results

- Recognition of abnormal, clinically urgent and erroneous results
- Documentation of the testing episode
- Data management

Quality

- Principles and procedures of QC testing and external quality assurance programs
- Assessment of acceptable/unacceptable QC testing and external quality assurance results, and appropriate actions

Assessment of PoCT practitioners

Practice team members must be assessed for competency in all aspects of their PoCT duties and responsibilities.

The Australian Point of Care Practitioner's Network

The APPN is an online platform that provides training, certification and professional development programs for all PoCT practitioners. PoCT practitioners can also maintain an electronic record of their continuing professional development (CPD) on the APPN's portal.

Related Criteria

C8.1 – Education and training of non-clinical staff

GP3.1 – Qualifications, education and training of healthcare practitioners

Meeting each Indicator

PoCT2.1▶A Members of our practice team who perform PoCT:

- have undertaken training
- have completed a competency assessment
- participate in training and education updates.

You must:

- provide evidence that PoCT practitioners are provided with relevant training
- provide evidence that PoCT practitioners are considered competent
- provide evidence that PoCT practitioners receive regular training and education updates
- provide evidence that all PoCT practitioners receive training updates when
 - significant changes to method(s) are introduced
 - new tests and/or instruments are introduced
- provide evidence that individual PoCT practitioners receive training updates when
 - a competency issue with that practitioner has been identified
 - the practitioner has not performed PoCT for more than six months.

You could:

- record each employee's qualifications in your employment files
- keep a training calendar that lists PoCT professional development and training opportunities
- store documents that record training needs and training completed
- conduct annual performance reviews that identify learning and development goals
- keep training logs that record training that PoCT practitioners have completed.

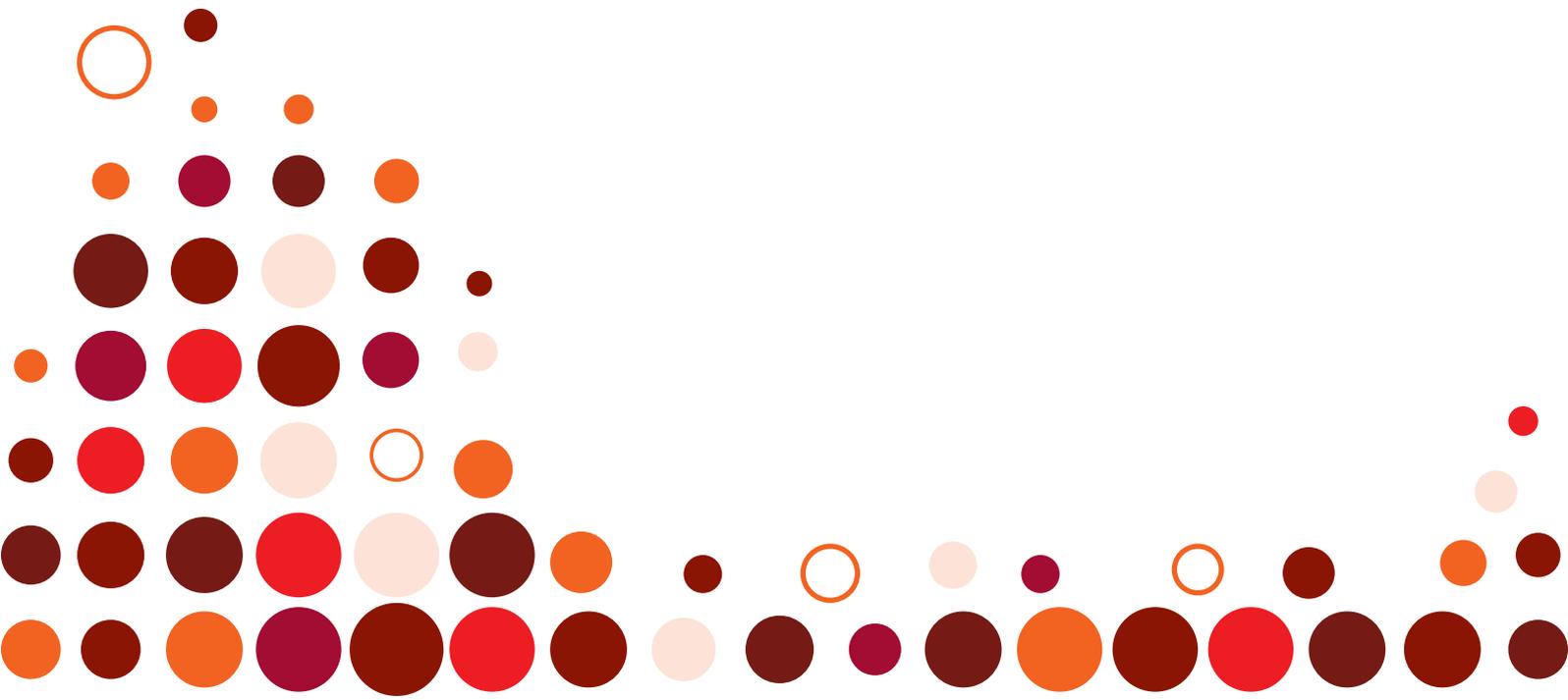
PoCT Standard 3

Implementation and performance

Our practice ensures that the implementation and performance of PoCT is in accordance with manufacturers' recommendations and best practice.

The successful implementation and performance of a PoCT program includes:

- conducting PoCT in a fit-for-purpose environment
- conducting PoCT in accordance with the manufacturers' instructions
- maintaining PoCT equipment in accordance with the manufacturers' instructions
- maintaining PoCT records.



Criterion PoCT3.1 – Facilities for testing

Indicators

PoCT3.1▶A Our practice conducts testing in a safe environment that ensures patient privacy.

PoCT3.1▶B Our practice ensures that instruments and consumables are located and managed to optimise performance.

Why this is important

You need to operate and maintain PoCT instruments and consumables so that:

- they deliver high-quality test results that clinicians can use when making clinical decisions
- the risk of infection is minimised for patients and the practice team.

Meeting this Criterion

Practices must locate PoCT in an area that:

- has adequate space for instruments, consumables, documentation and waste disposal
- does not compromise patient privacy.

Provided that patient privacy is maintained, the area does not need to be solely dedicated to performing PoCT. For example, a consultation or nurse's room may be suitable.

Your practice must also:

- manage a consumables inventory
- store the required quantity of within-date consumables as per the manufacturers' instructions
- use minimum–maximum thermometers to monitor refrigerators where temperature-sensitive consumables are stored.

Related Criteria

Criterion GP4.1 – Infection prevention and control, including sterilisation

Criterion GP5.1 – Practice facilities

Meeting each Indicator

PoCT3.1▶A Our practice conducts testing in a safe environment that ensures patient privacy.

You must:

- demonstrate that testing is performed in a safe area where patients' visual and auditory privacy is ensured.

PoCT3.1►B Our practice ensures that instruments and consumables are located and managed to optimise performance.

You must:

- have a testing area that has appropriate space, lighting, power, security and ambient temperature for sample/specimen handling, testing and documenting
- maintain a consumables inventory, including lot numbers and expiry dates
- store the required quantity of within-date consumables as per the manufacturers' instructions
- dispose of expired consumables in accordance with local, state and federal requirements
- where temperature-sensitive consumables are stored as per the manufacturers' instructions, use a minimum–maximum thermometer to monitor temperature, and keep records of that monitoring.

Criterion PoCT3.2 – Routine testing

Indicators

PoCT3.2▶A Our practice follows the manufacturers' instructions for PoCT.

PoCT3.2▶B Our practice identifies and reviews errors and deviations.

PoCT3.2▶C Our practice ensures that specimens remain positively identified with patients throughout the testing process.

PoCT3.2▶D Our practice documents its requirements for PoCT essential support services.

PoCT3.2▶E Our practice commissions and maintains our PoCT equipment in accordance with each manufacturer's instructions.

Why this is important

The objective of PoCT is to consistently produce results to an analytical standard that meets the benchmark performance defined at implementation.

Consistency is best achieved if your practice documents standard operating procedures and work instructions for all stages of testing, and ensures that they are in accordance with the manufacturers' instructions.

To ensure continuity of PoCT, your practice could have an established arrangement with third-party suppliers of goods and services.

Suppliers of essential PoCT support services are also responsible for providing:

- consumables (directly or via known supplier channels)
- technical support
- maintenance (in addition to the routine maintenance your practice completes)
- education to team members who use their devices.

Meeting this Criterion

Standard operating procedures

Your practice must follow the instructions published by the PoCT manufacturer as they are approved by the TGA. However, it is best practice to also create and maintain your own standard operating procedures or work instructions as the manufacturer's instructions may not include some critical steps such as patient interactions and result management.

Your practice must formally evaluate and approve any proposed changes to the standard operating procedures and work instructions before your practice uses them.

Deviations and errors

Your practice must regularly review deviations and issues encountered during routine testing.

Avoiding transcription errors

Transcription errors are data entry errors that usually occur as a result of typographical mistakes when transferring data and results.

To avoid transcription errors, it is strongly recommended that results are transferred electronically.¹³

Your work instructions could include a distinct step that requires a second person from your practice, preferably another PoCT practitioner, to independently check all steps. If a second person from your practice is not available, the team member performing the PoCT may perform the required checks.

Specimens

Although there is no requirement to label specimens that are to be used completely in the testing process:

- specimens must remain positively identified with the patient throughout the testing process
- if specimens are retained following testing, they must be clearly labelled in accordance with relevant guidelines.

Essential services

When making arrangements with suppliers of essential support services, your practice must consider:

- required frequency and volume of consumables
- required response time for urgent consumables or maintenance
- ownership or leasing arrangements of instruments
- required training of PoCT practitioners
- support for technical updates and trouble-shooting.

If it is appropriate, you could have written agreements with third parties who supply essential support services.

Manufacturers' instructions

Your practice must make records of preventive maintenance, service and calibration as per the manufacturers' instructions and keep these records as required by legislation. These requirements may vary from state to state, so consult with your medical defence organisation to identify specific requirements you must fulfil.

Suppliers of routine maintenance must provide your practice with a record of work and performance checks they undertake. If this is not possible, you must maintain your own records.

Related Criterion

GP5.2 – Practice equipment

Meeting each Indicator

PoCT3.2▶A Our practice follows the manufacturers' instructions for PoCT.

You must:

- demonstrate that your practice follows the manufacturer's instructions for each test method
- demonstrate that your practice checks the accuracy of transfers of data and transcription of results
- demonstrate that your practice records and investigates deviations appropriately.

You could:

- maintain standard operating procedures for each test method
- keep a copy of the relevant procedures/work instructions with each test instrument.

PoCT3.2▶B Our practice identifies and reviews errors and deviations.

You must:

- demonstrate that your practice records and investigates deviations appropriately
- demonstrate that your practice checks the accuracy of transfers of data and transcription of results.

PoCT3.2▶C Our practice ensures that specimens remain positively identified with patients throughout the testing process.

You must:

- demonstrate that specimens remain positively identified with patients throughout the testing process
- clearly identify patient specimens retained for any purpose.

PoCT3.2▶D Our practice documents its requirements for PoCT essential support services.

You must:

- demonstrate that your practice has ongoing arrangements with suppliers of essential support services.

PoCT3.2▶E Our practice commissions and maintains our PoCT equipment in accordance with each manufacturer's instructions.

You must:

- retain records of installation and commissioning
- ensure that maintenance is undertaken by appropriately trained operators
- retain records of maintenance in accordance with the manufacturers' instructions.

Criterion PoCT3.3 – Data management

Indicator

PoCT3.3▶A Our practice maintains records relating to PoCT that are readily accessible and secure.

Why this is important

Records of PoCT results and associated processes must be kept with the relevant patient's health information, in accordance with relevant legislation and guidelines.

Maintaining appropriate records is a way of managing risks.

Your practice needs to demonstrate that you can readily retrieve from your record systems all data related to a patient testing cycle.

Meeting this Criterion

If your practice needs to investigate the reliability of a test result, you may need to:

- identify the PoCT practitioner who conducted the test
- identify the kit or batch of reagents used
- identify whether QC results were within the acceptable range
- review the transcription so that you can rule out errors and non-conformance events.

Therefore, your practice must retain records of the following:

- patient identifiers
- the PoCT practitioner
- who requested the test
- date and time of specimen collection
- test results and unit of measurement
- relevant reference information
- relevant QC results
- external quality assurance results.

Related Criteria

Criterion C6.2 – Patient health records systems

Criterion C7.1 – Content of patient health records

Meeting each Indicator

PoCT3.3▶A Our practice maintains records relating to PoCT that are readily accessible and secure.

You must:

- keep PoCT records, including results and essential related information, in accordance with relevant legislation, including privacy principles.

PoCT Standard 4

Quality outcomes

Our practice performs PoCT using an established quality system to ensure the safety and quality of our patient care.

This standard focuses on the systems that practices need in order to ensure PoCT supports patient safety and high-quality care.



Criterion PoCT4.1 – Quality manual

Indicators

PoCT4.1▶A Our practice maintains a quality manual for PoCT.

PoCT4.1▶B Our practice regularly assesses compliance with PoCT policies and procedures.

Why this is important

A quality manual is a centralised repository of your practice's organisational structure and policies that relate to your PoCT system. Managed by the clinical team member responsible for PoCT, your quality manual is a practical guide to PoCT that helps team members understand their own and other's responsibilities relating to PoCT.

Your quality manual must be accessible to all members of your practice team.

Meeting this Criterion

You must retain a copy of all current PoCT documents, including relevant policies and procedures, in a document detailing how the practice's quality management system operates. It must include detailed descriptions of staff roles and responsibilities, procedures, systems and other information relating to the safe and effective performance of PoCT.

All policies and procedures need to be authorised by the clinical team member responsible for PoCT.

The quality manual must be used as the benchmark for determining how well policies and procedures are being adhered to in routine use. The clinical team member responsible for PoCT must review the quality manual at least annually and review PoCT activities to ensure compliance.¹⁴ The clinical team member must also maintain a record of any non-conformances and ensure they are investigated promptly.

Related Criterion

Criterion QI3.1 – Managing clinical risks

Meeting each Indicator

PoCT4.1▶A Our practice maintains a quality manual for PoCT.

You must:

- maintain a quality manual.

PoCT4.1▶B Our practice regularly assesses our compliance with PoCT policies and procedures.

You must:

- ensure that the member of the clinical team responsible for PoCT reviews, at least annually, how well your practice follows the policies and procedures
- promptly investigate non-conformances.

Criterion PoCT4.2 – Quality control procedures

Indicator

PoCT4.2▶A Our practice uses quality control procedures to ensure the PoCT is functioning optimally.

Why this is important

Quality control (QC) testing helps your practice to:

- be confident that your PoCT is functioning properly
- detect and manage sub-optimal performance.

Meeting this Criterion

QC testing

QC testing is usually performed on artificial samples purchased from PoCT manufacturers or other commercial sources. The samples have different levels of analytes to cover the range that practices might encounter clinically.

You must conduct the QC testing on the samples, record all QC results, then compare them with the target range or acceptable window that you have been given.

Results falling within this range are considered acceptable. Results falling outside this range are unacceptable and may indicate a problem with the testing process.

The APPN quality management function has a platform you can use to enter, review and analyse your QC results.

An acceptable window for QC results is usually determined when you first implement a PoCT device. It is expected that QC results fall within the manufacturer's specified limits.

Standard decision-making rules are used to determine whether to accept or reject the QC results. A patient's result cannot be reported following a rejected QC result.¹⁵

Reviewing QC results

The clinical team member responsible for PoCT must:

- regularly review QC results
- investigate unacceptable results or performance
- record any remedial actions taken.

Meeting each Indicator

PoCT4.2▶A Our practice uses quality control procedures to ensure the PoCT is functioning optimally.

You must:

- demonstrate that all quality control procedures comply with manufacturers' recommendations and applicable regulations
- have standard operating procedures or work instructions that include the acceptable limits for QC testing results and record actions taken in the event of an unacceptable result
- regularly review QC results.

Criterion PoCT4.3 – External quality assurance program

Indicator

PoCT4.3▶A Our practice participates in an external quality assurance program.

Why this is important

External quality assurance programs deliver peer review of your PoCT systems and monitor your PoCT performance, making it more likely that issues that might otherwise go unnoticed are detected early.¹³

Meeting this Criterion

External quality assurance programs provide identical samples to all program participants, who then test the sample using their routine test method. The program collates the results and provides each participant with:

- the range of results achieved
- an indication of whether their method is producing results significantly different to those produced by a different practice using the same method
- details of the accuracy and precision of their results.

If your practice has unacceptable results or performance, you must:

- investigate the reasons for these results or performance
- record any remedial actions taken.

Meeting each Indicator

PoCT4.3▶A Our practice participates in an external quality assurance program.

You must:

- enrol all methods in an approved external quality assurance program
- keep records of participation
- review reports from external quality assurance programs and keep records of action taken if reports indicate poor performance.

Glossary

Definitions of terms used in this document.

Term	Definition
Accuracy	Measure of how close the results of a test come to the true value.
Adverse event/incident	Any event or circumstance arising during care that could have or did lead to unexpected actual harm, loss or damage. Incidents include near misses, sentinel events and unsafe acts.
Analyte	A chemical substance in a fluid or other specimen from the body that is undergoing analysis.
Analytical	Refers to the test.
Analytical performance	The performance of the testing system.
Australian Point of Care Practitioner's Network (APPN)	An online platform developed to provide training, certification and professional development for all PoCT practitioners and to ensure that PoCT instruments and devices are operated within appropriate clinical standards.
Australian Register of Therapeutic Goods (ARTG)	A register of therapeutic goods accepted for importation into Australia, supply for use in Australia, or exportation from Australia. Medical devices generally cannot be imported, supplied in or exported from Australia unless they are included in the ARTG.
Bias	A quantitative measure of inaccuracy or systematic departure from accuracy under specified conditions of analysis.
Calibration	The process of testing and adjustment of an instrument, kit or test system, to provide a known relationship between the measurement response and the value of the substance being measured by the test procedure.
Clinical decision limits	Specific cut-off points or limits for decision about diagnosis or well-defined specific actions, based on guidelines from expert groups.
Consumables	Products required to perform a test, such as cartridges, reagents, calibrators.
Controls	The material used to perform quality control (QC) testing.
Diagnostic test	A test used to establish the presence (or absence) of disease as a basis for treatment in symptomatic or screen-positive people.
External quality assurance program	An external program in which samples are periodically sent to testing sites for analysis.
Instrument	A testing platform, system or device.
In vitro	Outside the body; in a clinical or research laboratory; in an artificial environment such as a test tube or petri dish.
In-vitro diagnostic medical device (IVD)	A medical device (including a reagent, calibrator, control material, kit, specimen receptacle, software, instrument, apparatus, equipment or system) used in vitro (whether alone or in combination with other diagnostic goods) to examine specimens from a human body.
Non-conformance	Departures from standard procedures, or instances where the process or system does not comply with the predetermined specifications.
Point-of-care testing (PoCT)	Pathology testing performed at the point or time of care that helps healthcare practitioners make immediate and informed decisions about a patient's management.

Term	Definition
Post-analytical	Post-testing processes, such as reporting.
Pre-analytical	Pre-testing processes, such as test requests.
Precision	The measure of the closeness of results obtained after analysing the same sample more than once.
Point-of-care testing practitioners (PoCT practitioners)	Members of the practice team who perform PoCT who: <ul style="list-style-type: none">• have undertaken training• have completed a competency assessment• participate in training and education updates.
Quality control	The set of procedures designed to monitor the test method and the results to assure test system performance. These procedures include testing control materials, charting the results and analysing them to identify sources of error, and evaluating and documenting any remedial action taken as a result of this analysis.
Quality manual	A document detailing how the practice's quality management system operates. It must include detailed descriptions of staff roles and responsibilities, procedures, systems and other information relating to the safe and effective performance of PoCT.
Reagent	A substance that produces a chemical reaction in a sample that allows an analyte to be detected and measured.
Reference interval	The reference interval or range for a particular test is expressed as the average value for the 'normal' population group together with the variation around that value (plus or minus two standard deviations from the average). In this way, ranges quoted represent the values found in 95% of individuals in the chosen non-diseased or 'reference' group.
Screen	A test to identify risk factors or the possible presence of an as-yet undiagnosed disease in individuals without signs or symptoms of that disease.
Simple pathology tests	Tests included in Group P9, Category 6 of the Medicare Benefits Schedule; and glucose monitoring.
Test method	A method or procedure that produces a test result.
Transcription errors	Data entry errors that usually occur as a result of typographical mistakes when transferring data and results.

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