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

NPAAC
National Pathology Accreditation Advisory Council

National Pathology Standard

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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 health care 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, medical scientists, 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 Scheme

The National Pathology Accreditation Scheme (NPAS) is an accreditation scheme that requires pathology practices to meet relevant standards for their pathology services to be eligible for Medicare benefits. The *Health Insurance (Accredited Pathology Laboratory-Approval) Principles 2017* (the Approval Principles) underpin NPAS. The Approval Principles set the categories of accredited pathology laboratories, specify the standards to be met and the kind of pathology services provided.

The Approval Principles ensure that pathology practices providing Medicare eligible pathology services met and maintain compliance with the standards. The Approval Principles objectives include:

- supporting the diagnosis and treatment of illness by linking Medicare benefits to pathology services that provide reliable results
- reducing the risk of misdiagnosis from pathology services that provide unreliable results
- maintaining public confidence in pathology services.

The Commission administers the NPAS behalf of the Australian Government Department of Health, Disability and Ageing (the Department). The Department manages the policy and regulatory framework for pathology practice accreditation that are approved to provide Medicare eligible pathology services.

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 accreditation of pathology practices and the introduction and maintenance of uniform standards of practice in pathology practices throughout Australia. NPAAC is responsible for formulating standards which pathology practices are assessed.

The Approval Principles give effect to NPAAC endorsed standards by listing the standards and accreditation materials pathology practices seeking approval to provide Medicare eligible pathology services must meet. The pathology practice's conformity with the standards is assessed by the accrediting agencies defined in the Approved Principles.

Introduction

The National Pathology Standard aim to protect the public from harm and improve the quality of pathology services by describing a nationally consistent framework that pathology practices apply when providing health care.

When fully implemented, patients can be confident that their pathology practice is committed to delivering and continuously improving the safety and quality of pathology services.

Developing the *National Pathology Standard* (NPS) involved mapping with ISO and NPAAC standards, identifying safety and quality gaps, reviewing regulations and national and international standards. The Commission consulted extensively with, scientists, pathologists, consumers, professional and peak bodies, jurisdictions, and government agencies.

The NPS replace the:

- *Requirements for medical pathology services*
- *Requirements for supervision in the clinical governance of medical pathology laboratories*
- *Requirements for the communication of high-risk pathology results*
- *Requirements for the estimation of measurement of uncertainty*
- *Requirements for quality control, external quality assurance and method evaluation*
- *Requirements for medical pathology specimen collection (Guidelines for Approved Pathology Collection Centres)*
- *Requirements for point of care testing*

Application of the standard

A pathology service examines body tissue, blood and other bodily fluids to provide information about patients' health. The results help diagnose and monitor medical conditions, screen for health conditions, and monitor responses to medicines and other treatments. Pathology services underpin medical decision making and their reliable quality and availability are important to the operation of national healthcare services.

Pathology services include specimen examinations using a variety of technologies and supervised by different specialist pathologists. Current specialist services include chemical, cytological, forensic, genetic, microbiological, haematological, immunological, immuno-haematological, and pathological specimen examinations. The NPS apply to all pathology services. Pathology practices that provide Medicare funded pathology services must comply with this standard and other relevant NPAAC standards.

Other laboratories and health services providing pathology services should apply the standard, as it represents a best practice approach to pathology service delivery. The standards provide a structured framework for implementing clinical governance, key elements of quality, identifying and managing risks, and ensuring systems are in place to prevent patient harm and drive quality.

Overview of the standard

The NPS outline the overarching governance requirements for pathology practices. They must be read in conjunction with the last version of the Health Insurance (Accredited Pathology Laboratories – Approvals) Principles 2017.

There are eleven standard topics that address:

- clinical governance
- safety and quality systems
- pathology test supervision
- pathology laboratory supervision
- workforce performance and effectiveness
- partnering with consumers
- communicating for safety
- medical devices.
- specimen collection
- specimen testing
- point of care testing

Structure of the standard

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 and in some actions information and resources to help address the action

Terminology

The Commission adopted the following terminology in the National Pathology Standard.

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 that systems are in place to deliver safe and high-quality pathology care.

Delegation

Is the act of assigning authority for the supervision of a pathology test from a one person to another, the ultimate responsibility for the outcome remaining with the original person.

Designated person

One registered medical practitioner who is responsible for the clinical governance and the safety and quality of a pathology laboratory and its compliance with relevant NPAAC Standards. The designated person has an agreement, arrangement or is employed by a pathology practice and:

- provides advice on appropriate clinical governance systems
- implements the governing body's decisions
- oversees the pathology practice operations
- considers advice from the other medical practitioners with relevant scope of practice

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 the strategic and operational decisions of pathology practices.

An approved pathology provider (APP) is an example of a governing body.

Healthcare vs. health care

The Commission uses the word ‘healthcare’ when referring to an adjective (for example, the ‘healthcare system’) and the words ‘health care’ when referring to a noun (for example, ‘the state of health care in Australia’).

Laboratory categories

Are a set of criteria in the *Health Insurance (Accredited Pathology Laboratories – Approval Principles for accreditation)* which groups pathology laboratories by the medical specialty of the designated person and the pathology laboratory’s governance relationship with other laboratories.

Pathology laboratory

Premises used for the examination of materials derived from the human body for the purpose of providing information for the diagnosis, monitoring, management, prevention and treatment of disease, or assessment of health.

Pathology practice

Is 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 governing body oversight.

A pathology practice is an example of an APA, its accredited pathology laboratories, and approved collection centres and pathology practitioners.

Pathology service

A pathology service is a test completed on a patient specimen by a pathology practice at the request of a clinician.

The Health Insurance Act 1973, Pathology Services Table describes pathology services funded by Medicare.

Pathology test supervision

Is the oversight and management of pre-analytic, analytic, and post-analytic aspects of pathology tests by members of the workforce working within their defined scope of practice and with the appropriate qualifications, skills, and experience.

Patient vs consumer

Patient refers to a person receiving pathology services. The term ‘patient’ encompasses all other relevant terms the pathology sector may use, including ‘client’, ‘person’, and ‘people’.

The term ‘consumer’ refers to a person who has had or may have a pathology service, a consumer representative or an advocate.

Scope of practice

Range of professional activities that a workforce member is educated (qualifications, knowledge and skills) and competent to undertake and within the defined roles, responsibilities and accountability of their position in the pathology practice.

Systems

The NPS rely on pathology providers to establish safety and quality systems. A system includes resources, policies, processes, and procedures that are organised, integrated, regulated, and delivered to accomplish a stated goal. Safety and quality systems will vary depending on the size of the pathology practice and the associated service risks.

Workforce

All people working for a pathology practice inclusive of other employed or contracted locum, agency, student, volunteer or peer workers.

Topics

1. Clinical governance

The pathology practice's governing body establishes and uses clinical governance systems to ensure and continuously improve the safety, quality and appropriateness of its pathology services.

Consumer outcome

Patients are confident that the pathology practice is organised, efficient, and effective, and that it leads to safe, high quality pathology service results, which effectively inform healthcare decisions.

Intent of this standard

To implement a clinical governance framework that ensures pathology services are safe and of high quality.

Explanatory notes

Clinical Governance

Governing bodies or owners are ultimately responsible for ensuring the pathology practice is well-run and delivers safe, high-quality pathology services. They must ensure that the governance system operates effectively and that robust monitoring systems focus on risk management and continuous quality improvement.

Thorough research has identified the effect of good clinical governance on health service performance. Research notes leaders are important to influencing the quality of care provided. Leaders need to support the workforce, shape the future, set direction and monitor risk and safety and quality performance. It is important to engage the workforce in governance, risk and quality improvement activities so that corporate and clinical priorities are aligned.

Clinical governance includes the relationships, roles and responsibilities established by a pathology practice between regulators and funders, managers, executive, owners and governing bodies, healthcare providers, the workforce, patients, consumers and other stakeholders to ensure optimal clinical outcomes.

Designated person

The governing body delegates the responsibility for oversight of the implementation of clinical governance in the organisation to the designated person. The designated person can delegate aspects of their roles and responsibilities to other medical practitioners or clinical scientists with the relevant scope of practice to supervise pathology services.

Sustainability

Sustainability is integrated into pathology practice activities. Human activity impacts on natural environment and a pathology practice can prevent degradation of natural systems and unnecessary use of natural resources. Pathology practices can consider:

- pathology stewardship – improve test ordering, optimise specimen collection and processing, multidisciplinary collaboration, using data and informatics
- waste reduction
- energy conversation
- water systems
- green procurement
- sustainable chemical management

The Royal College of Pathologists of Australasia has released the Environmental Sustainability in Pathology Laboratories Guideline which provides specific examples of sustainability.

Actions

Item	Action	
Governance, leadership and culture	1.01	The governing body: a. is orientated and trained on their clinical governance role, responsibilities and accountabilities b. ensures the pathology practice operates ethically, transparently c. sets priorities and strategic directions for high-quality pathology services and ensures these are communicated effectively to the workforce d. endorses the pathology practice's clinical governance framework and supervision delegation arrangements e. appoints the designated person responsible for the pathology practice under its control f. endorses the risk management framework g. monitors the pathology practices' safety, quality and performance and directs action to improve performance and outcomes h. ensures the pathology practice has a documented clinical governance structure identifying the roles and people who lead, manage and supervise the pathology practice.
Designated person	1.02	The governing body ensures that the: a. delivery of pathology services is under the direction and control of a designated person who

Item	Action	
		i. is a medical practitioner residing in Australia and registered with the Australian Health Practitioner Regulation Agency ii. has the scope of practice to perform the role. b. designated person's responsibilities include: i. implementing the clinical governance framework ii. maintaining the supervision delegation framework iii. delegating supervision iv. maintaining the risk management framework v. overseeing the use of safety and quality systems vi. overseeing workforce performance and effectiveness vii. overseeing pathology services viii. ensuring the workforce has the skills and experience to perform pathology tests ix. determining the range of tests performed, the methods used and procedures for testing x. ensuring the numbers of tests processed are sufficient to maintain competence xi. determining the suitability of referral laboratories xii. overseeing policies and procedures for the identification and communication of critical results.
Delegations	1.03	The pathology practice has: a. formal delegations b. a designated person c. an authorisation process to designate responsibility for aspects of the pathology practice to the workforce with the necessary qualifications and skills and who are working within their scope of practice

Item	Action	
Legislation and standards	1.04	The pathology practice complies with: a. Commonwealth, state or territory legislation and regulations b. NPAAC Standards c. ISO 15189 in the absence of explicit NPAAC standards.
Business decision-making	1.05	The pathology practice: a. prioritises patient safety, quality and the appropriateness of pathology services in its business decisions and business continuity plans b. identifies and addresses conflicts of interest c. addresses and routinely monitors any commercial, financial or other influences that can adversely affect a pathology practice's integrity or pathology services' safety and quality d. has ethical principles it applies to business decisions regarding the design, development and delivery of pathology services.
Ethical practice	1.06	The pathology practice has policies and procedures to: a. address the respectful treatment of patients and deceased patients, their specimens and body parts b. ensure unverified tests only occur in exceptional circumstances for rare or new diseases c. align with the World Health Organisation's Code of Ethics.
Contracted services	1.07	The pathology practice subcontracting pathology services or coordinating pathology services for other organisations ensure: a. subcontractors comply with: i. Commonwealth, state or territory legislation and regulations ii. ISO 15189 and relevant NPAAC standards. b. its designated person or their delegate liaises with scientific, clinical and administrative staff of the subcontractor.

Item	Action	
Referral laboratories	1.08	Where a referral is instigated by the pathology practice it has processes: a. to ensure the referral laboratory, if in Australia complies with ISO15189 and are accredited to relevant NPAAC Standards b. to use accredited international referral laboratories in preference to unaccredited international laboratories c. to consult with the clinicians in the referral laboratory, communicate with patients, and document the consequences[1] d. to retain responsibility for packaging, transport and hand over of specimens being sent internationally e. to manage the risks associated with engaging a referral laboratory and ensure there are processes for: i. receiving pathology reports ii. notification of critical results
Environmental sustainability	1.09	The pathology practice uses its governance systems to implement best practice strategies for reducing its environmental impacts
Information management	1.10	The pathology practice: a. implements electronic health information systems that are interoperable b. ensures Laboratory Information Management Systems (LIMS) and Laboratory Information Systems (LIS) comply with legislation and regulations, so information is: i. secure ii. treated in accordance with privacy principles and legislation iii. is used in accordance with other NPAAC Standards c. implements an information security management system that: i. prevents access from unauthorised users

[1] Including that testing conducted internationally is paid for by the patient and ineligible for Medicare benefits.

Item	Action
	ii. protects information integrity and confidentiality iii. prevents data modification and removal iv. assesses and minimises the vulnerability of the pathology information system v. informs the governing body of vulnerabilities and failures vi. manages and responds to security system failures d. ensures controls are implemented so only authorised workforce access patient information e. Trains the workforce in the use of the laboratory's information system

2. Safety and quality systems

The pathology practice integrates its safety and quality systems into its clinical governance framework to actively manage and improve the safety, quality, and appropriateness of its pathology services.

Consumer outcome

Patients expect pathology practices to have safety and quality systems that support and improve pathology services, that ensure timely, accurate results that support their healthcare provider's decision-making.

The pathology practice seeks, listens to and addresses patient feedback.

Intent of this standard

Using a risk management approach, implement safety and quality systems that ensure delivery of safe and high-quality pathology services.

Explanatory notes

Risk management

Use of a risk management framework permits a considered and proportionate effort by governing bodies, the designated person and the workforce to develop a culture, and processes which support the safety and quality of pathology testing and consultations.

Risk management systems document patient safety risks and issues, the risk level, strategies to mitigate risks and issues, and the implementation status of each mitigation strategy and whether the strategy have successfully addressed the risk or issue.

Action plans and evidence of actions being undertaken helps to establish that a pathology practice has acted to mitigate its risks.

Managing a pathology practice effectively involves identifying and managing risks. It is important that the risk management system is regularly:

- reviewed for effectiveness and information used to improve the system
- audited so material breaches, non-compliance or failure of operation are identified and addressed.

Appropriate care

Although pathology is a referral specialty with limited control on test ordering, pathologists are experts in specimen testing and result interpretation and have a role to encourage appropriate testing that provide clinical utility to patients and optimise healthcare resources.

Pathology practices can focus on improving pathology services by providing advisory services and educational materials, monitoring and discussing with requesters their test ordering practices, withdrawing low value pathology services and introducing services that improve patient diagnosis and management.

Quality management

Quality management systems are an essential component of risk managing a pathology practice. They support high-quality and safe pathology services, patient care and continuous quality improvement. The designated person oversees the quality management system's performance.

A pathology practice's quality management systems include processes to mitigate and manage risks, including those related to workforce, patients, communication, equipment, specimen collection and testing.

Actions

Item	Action	
Policies and procedures	2.01	The pathology practice establishes the policies and processes for its pathology laboratories and services and: a. makes them readily available to the workforce and supports the workforce to use them b. monitors and takes action to improve workforce adherence c. regularly reviews and maintains their currency and effectiveness d. ensures they comply with legislation, regulation, and jurisdictional requirements.
Risk management	2.02	The pathology practice: a. establishes and operates a risk management system to identify, regularly review and mitigate risks b. identifies safety and quality risks in the risk management plan c. uses clinical and other data to support risk assessments d. acts to mitigate risks and issues using quality management and other systems e. supports the workforce involvement in risk identification, assessment and mitigation f. reports on risks to the governing body, designated person and workforce

Item	Action	
		g. regularly reviews and acts to improve the risk management system h. audits the risk management system.
Ongoing service provision	2.03	The pathology practice has business continuity plans that it reviews regularly and improves to ensure provision of pathology services during disruptions, emergencies and disasters.
Appropriate care	2.04	The pathology practice has processes to: a. Identify and introduce best practice technology to improve clinical utility b. Identify and reduce low value pathology services
Quality management systems	2.05	The pathology practice has a quality management system that includes processes: a. to identify and collect data on safety and quality measures, related to: i. specimen collection, specimen integrity and testing ii. testing equipment iii. traceability iv. result interpretation and reporting v. incidents and error rates vi. turnaround times b. to monitor performance c. to implement and monitor safety and quality improvement activities d. for the governing body, designated person and workforce to access information on performance and outcomes e. for involvement of the workforce in quality improvement system reviews f. to audit quality management system effectiveness.

Item	Action	
Incident management systems	2.06	The pathology practice uses an incident management system and has processes to: a. support the workforce to recognise and report incidents and involve them in the review of incidents b. enable patients, carers, families and requesters to communicate concerns or report incidents c. designate a person(s) responsible for investigating an incident and setting timeframes for acting, which is commensurate with the level of risk to patient safety d. escalate significant incidents to the designated person e. document incidents, their investigation, corrective actions, and follow up to determine if corrective action has mitigated risks f. provide timely reports on incidents to the designated person, the workforce and the governing body, including risks identified, actions taken and change in level of risk g. using the information from the analysis of incidents to improve safety and quality h. regularly review and act to improve the effectiveness of the incident management system.
Open disclosure	2.07	The pathology practice: a. uses an open disclosure process consistent with the Australian Open Disclosure Framework b. monitors and acts to improve the use and effectiveness of the open disclosure process
Feedback and complaints management	2.08	The pathology practice has processes to: a. document feedback and complaints from requesters, patients, families and carers to the designated person, and governing body b. escalate, review and take corrective action when communications with requesters, health care providers, patients, families or carers raise the possibility of adverse clinical impacts c. act on feedback and address complaints in a timely way and inform patients, families or carers of the outcome

Item	Action	
		d. provide patients, families and their carers with information on the relevant healthcare complaints authority e. document the timeliness of responses, evaluation and improvements made as a result of feedback and complaints f. analyse feedback and complaints to improve the safety, quality and appropriateness of its pathology services

3. Pathology test supervision

Pathology practices have a supervision framework that demonstrates clear accountability for the supervision of pathology tests.

Consumer outcome

Patients expect a qualified and skilled member of the pathology workforce will supervise the testing of their specimens.

Intent of this standard

Is to use a supervision framework as a key mechanism to control the risks of pathology testing and ensure a person with the appropriate qualifications, skills, experience and scope of practice supervises testing.

Explanatory notes

Supervision is crucial in mitigating the risks to patient safety and welfare that may arise during the provision of pathology services. A key principle of supervision is that a person with the appropriate qualifications, knowledge, skills, and competence personally supervises every test.

The clinical governance structure must demonstrate clear accountability for supervision, and clear criteria and processes for the escalation and communication of incidents that affect patient safety.

Appropriate clinical and scientific pathology test supervision requires a skilled workforce with medical and scientific backgrounds. Risks to patients are best minimised when pathology practices have both a pathologist and clinical scientist working within their scope of practice for each pathology discipline.

Actions

Item		Action
Supervision requirements	3.01	The pathology practice ensures that the workforce with delegation to supervise pathology tests: a. understand their responsibilities and are trained to perform their function b. support requesters with: i. enquires ii. the selection of pathology tests iii. interpretation of results c. support patients with enquiries d. manage the performance, development and education of the workforce related to tests they supervise e. oversee incident management f. identify and manage risk g. manage and review the internal and external quality assurance programs h. address the internal quality control and assurance management i. manage feedback and complaints j. manage equipment and medical devices including selection, implementation, use, review and maintenance k. participate in the audit of the effectiveness of supervision.
Supervision framework	3.02	The pathology practice has a documented supervision framework that is part of clinical governance processes and: a. ensures supervision of every pathology test is delegated to supervising medical practitioners working within their scope of practice b. ensures the make-up of the pathology workforce provides appropriate supervision and oversight of all pathology tests c. document supervision arrangements, including aspects of testing that are delegated to a clinical scientist within their scope of practice by the supervising medical practitioner.

Item		Action
		d. identifies the person with responsibility for the management of testing during operational hours e. audit compliance with supervision arrangements
Workforce and supervision risks	3.03	The pathology practice ensures: a. supervision risks associated with workforce vacancies and extended leave are recorded and rated in the risk management system b. skills and supervisory gaps, associated with a workforce vacancy or extended leave are rated as critical risks and are reported to the accrediting agency c. action is taken to mitigate the identified risks d. the level of risk associated with supervising tests are determined after considering the i. qualifications and experience of the workforce ii. test volume, complexity and acuity iii. number and type of errors, feedback, complaints, and poor outcomes e. the risk management system is routinely reviewed f. the designated person: i. periodically completes a review of the pathology test supervision arrangements ii. mitigates risks from workforce vacancy or supervisory gap iii. mitigates risks when a workforce vacancy and supervisory gap occurs.
	3.04	The pathology practice mitigates supervision risks by: a. actively recruiting to vacancies b. providing access to training and experience to extend the scope of practice of supervising medical practitioners, clinical scientists and scientists

4. Pathology laboratory supervision

Pathology practices have supervision in their laboratories that meet the laboratory category's supervision requirements.

Consumer outcome

Patients expect that, regardless of the pathology services their specimens undergo and where it occurs, testing will be appropriately supervised, and the results will be accurate.

Intent of this standard

Is to address the supervision requirements for different categories of laboratories.

Explanatory notes

The Health Insurance (Accredited Pathology Laboratories—Approval) Principles 2017, Part 4 Categories of premises defines the criteria for each type of pathology laboratory.

The accrediting agency determines the category of a pathology laboratory.

Actions

Item	Action	
GX[2] laboratory	4.01	For a GX laboratory, the pathology practice has a designated person who: a. is a pathologist b. is a fulltime appointment and readily available c. only supervises pathology tests within their scope of practice d. delegates supervision to other pathologists at GX, GY

[2] The Australian Red Blood Cross Network fits into the GX Laboratory category.

and B Laboratories in the same pathology network when:

i. there are pathology tests outside the designated person's scope of practice

ii. the pathologist being delegated supervision responsibilities has the relevant scope of practice.

e. can delegate supervision of laboratory operations, and preanalytical and analytical phases of pathology tests to clinical scientists with an appropriate scope of practice.

4.02 For a GX laboratory, the pathology practice:

a. has at least one full-time equivalent[3] pathologist with the relevant scope of practice, who is on site in a pathology laboratory 80% of the time and readily available with delegated responsibility for supervision of each pathology test.

b. has at least one clinical scientist[4] with a relevant scope of practice with delegated responsibility for the analytical phase for each tissue typing, toxicology, biochemical genetics and genomics[5] test

c. completes a risk assessment[6] on complex pathology tests to determine whether the addition of a clinical scientist to the supervision framework could improve the pathology tests safety and quality

d. has a process to determine the full-time equivalency of the clinical scientist where a clinical scientist is required

GY and B[7] laboratory

4.03 The pathology practice ensures its GY and B laboratories are associated with the GX laboratory in the same pathology network and the GX laboratory's designated person has responsibility for clinical governance.

4.04 For a GY and B laboratory, the pathology practice ensures:

a. it operates in accordance with the pathology network's

[3] In aggregate

[4] The Role of a Pathology Clinical Scientist in Australia Position Statement August 2024 [https://www.rcpa.edu.au/getattachment/aca09d06-db18-49b8-90c2-cf82d25bf0c4/The-Role-of-a-Pathology-Clinical-Scientist-in-Aust.aspx]

[5] Genomics refers to comprehensive analysis of large segments of the genome, including whole genome sequencing and exome sequencing and large panel sequencing

[6] The risk assessment at a minimum addresses test volume, acuity, number and types of error, feedback, complaints and poor outcome

[7] A B laboratory includes B laboratories providing POCT testing

supervision framework, developed by the designated person

b. supervising pathologists within the GY and B laboratories with the appropriate scope of practice provide pathology test supervision where possible and supervising pathologists from within the pathology network address supervisory gaps.

4.05 For a GY and B laboratory, the pathology practice undertakes a regular risk assessment to determine the need for onsite supervision:

a. using criteria including test volume, complexity and acuity, and the number and type of errors, feedback complaints and poor outcomes

b. and where it is necessary, provides appropriate onsite supervision

4.06 The pathology practice:

a. has a common quality management system for GX, GY and B laboratories

b. ensures GY and B laboratories have:

i. effective virtual supervision through at least monthly meetings where there is sufficient time to discuss safety and quality, and operational performance

ii. annual visits by the workforce members with relevant skills and qualifications, who are delegated by the designated person to review the laboratory's operations

iii. onsite managers who are integrated into their network management structure

iv. onsite managers[8] spend a minimum of two full time equivalent[9] days per annum undertaking supervised training or professional development in another laboratory

S laboratory

4.07 The pathology practice with a S laboratory ensures it:

a. performs a limited range of pathology tests for a target patient population that are directly related to the relevant

[8] Excluding onsite managers in B(POCT) laboratories

[9] in aggregate

		qualifications, skills and scope of practice of the designated person b. applies to become a GX laboratory when a wider scope of pathology testing is proposed.
	4.08	For a S laboratory, the pathology practice has a designated person who: a. is a specialist medical practitioner b. works in the pathology laboratory c. can supervise SB laboratories in the same pathology network when onsite supervision is unavailable d. can delegate supervision of the preanalytical and analytical phase of pathology tests to clinical scientists with an appropriate scope of practice.
	4.9	The pathology practice whose S laboratory performs complex genomic testing has both a genetic pathologist and a clinical scientist with relevant scope of practice to supervise the following testing: a. comprehensive analysis of large segments of the genome, including whole genome sequencing and exome sequencing and large panel sequencing b. non-invasive prenatal testing c. genomic profiling of embryos d. cytogenetics.
SB laboratory	4.10	The pathology practice ensures its SB laboratories are associated with a S laboratory in the same pathology network.
	4.11	For a SB laboratory, the pathology practice has: a. full-time supervision and clinical governance from a S laboratory designated person b. the designated person develops the supervision framework for the pathology network c. supervising specialist medical practitioners from SB laboratories with the appropriate scope of practice provide supervision for each test and supervising specialist medical practitioners from within the network address supervisory gaps.

4.12 The pathology practice:

a. has a common quality management system for S and SB laboratories

b. ensures SB laboratories

i. have effective virtual supervision through at least monthly meetings where there is sufficient time to discuss safety and quality and operational performance

ii. have annual visits by persons with relevant qualifications, knowledge and skills who are authorised by a supervisor to review the laboratory's operations.

c. has onsite managers spend a minimum of two full time equivalent days per annum undertaking supervised training or professional development at another laboratory.

M laboratory

4.13 The pathology practice with a M laboratory performs a limited range of pathology tests for the medical practice's patients that are directly related to the relevant qualifications, skills and scope of practice of the designated person.

4.14 A pathology practice with a M laboratory provides:

a. Therapeutic Goods Administration approved pathology tests from the following pathology groups:

i. haematology except immuno-haematology

ii. chemical pathology

iii. general chemistry

iv. microbiology

v. immunology.

4.15 The pathology practice's M laboratory designated person:

a. is competent to provide the pathology tests performed in the laboratory

b. has completed a training program in the operation, monitoring and use of instruments required to undertake the pathology tests as described in the manufacturer and laboratory manuals and any legislative requirements

c. has scientific knowledge and experience using equipment and analytical procedures employed in the

		laboratory.
	4.16	The M laboratory's supervision framework includes delegations that clearly outline who has authority for pathology tests during operational hours.
	4.17	The M laboratory's designated person assesses the skills and competence of the workforce undertaking pathology tests annually.

5. Workforce performance and effectiveness

The workforce has the required qualifications, knowledge, and skills to provide patients with safe, high-quality pathology services.

Consumer outcome

Patients expect a competent workforce to undertake their pathology services.

Intent of this standard

To ensure a competent and professional workforce performs pathology services accurately and effectively.

Explanatory notes

Ensuring the workforce has the right qualifications, knowledge and skills is core to the delivery of safe, high-quality pathology services.

While the workforce has a responsibility to remain competent it is also a pathology practice's responsibility. Roles must be defined, responsibilities allocated, performance monitored, and training provided.

Actions

Item	Action	
Pathology workforce roles and responsibilities	5.01	The pathology practice ensures its workforce's competency by: a. confirming they have the qualifications, knowledge, skills, and recency of practice to effectively perform their role b. defining their functions and responsibilities and supporting them to fulfil their roles c. implementing professional practice mandatory training and a competency assessment process for the non-medical workforce d. supporting participation in quality assurance activities and continuing professional development (CPD) to meet

Item	Action	
		professional requirements e. monitoring the workforce to ensure they operate within their defined roles and scope of practice f. reviewing roles and responsibilities periodically and when medical devices or pathology services are introduced or substantially altered
Training to improve the quality of patient care	5.02	The pathology practice: a. periodically completes a risk assessment to determine the required safety and quality training b. provides its workforce with an orientation to and training in their safety and quality roles on commencement, and when safety and quality responsibilities change c. provides access to training to meet the NPAAC Standards d. monitors workforce participation in training.
Evidence based care	5.03	The pathology practice provides the workforce with ready access to professional and best-practice guidelines, decision-support tools, and resources relevant to their practice, and supports the use of these materials to improve practice.

6. Partnering with consumers

Pathology practices develop, implement and maintain systems to deliver person-centred specimen collection.

Consumer outcome

Patients and their carers receive a person-centred specimen collection. Specimen collectors respect the patient's healthcare rights, incorporate the patient's perspectives into the collection process, and obtain informed consent to collect the specimen.

Intent of this standard

To ensure pathology practices understand the importance of communicating with patients and incorporating their needs into specimen collection.

Explanatory notes

Primary considerations when collecting specimens are the patient's rights and the quality of patient care.

Evidence shows that partnering with patients is linked to positive patient experiences and improves 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.

Pathology practices should provide pathology service information such as specimen preparation, costs, aftercare and obtaining results and consider the communication needs (communication channels, format, clarity and language) of patients.

Actions

Item	Action	
Healthcare rights	6.01	The pathology practice: a. delivers person centred care aligned to a charter of rights consistent with the Australian Charter of Healthcare Rights[10] b. supports its workforce to apply the principles of the charter of rights c. makes the charter of rights available where directly interacting with patients and carers.
Informed consent	6.02	The pathology practice has processes to: a. ensure informed consent complies with legislation and guidelines b. enable patients to consent to specimen collection and where required, for specimen testing and use of data c. provide transparent financial consent including out of pocket expenses, when information of the test and cost are known, before specimen collection commences d. undertaking privacy assessments of the collection, storage and distribution of identifiable or de-identified personal data and results
Decision making	6.03	The pathology practice has processes for collection centres to: a. identify patients who require support to make decisions and ensure: i. access to the necessary support to make, communicate and participate in decisions ii. include substitute decision-makers to the degree a patient wants them involved b. communicating with patients in a way that meets their individual needs

[10] Australian Charter of Healthcare Rights (second edition) - A4 Accessible | Australian Commission on Safety and Quality in Health Care

Accessing specimen collection services	6.04	The pathology practice makes information available to patients and carers, including: a. the pathology collection services accessible at the collection centre b. contact information, location(s), opening hours, appointments bookings and access to the collection service c. access limitations at the collection service d. pre-requisites and preparations for the pathology service, follow-up and aftercare e. easy to understand information and instructions for patients collecting their own specimens that aligns to the pathology practice's specimen collection manuals.
People with diverse care needs	6.05	The pathology practice provides a safe environment and delivers person centred care when collecting specimens from people who are: a. Aboriginal or Torres Strait Islander b. culturally or linguistically diverse c. older people or people with complex care needs d. gender diverse e. living with a disability f. children.

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7. Communicating for safety

The pathology practice establishes and maintains communication system and processes that support effective communication with patients, requesters and healthcare providers so patient care is coordinated, safe and of high quality.

Consumer outcome

Pathology practices communicate with requesters, healthcare providers and patients to ensure patients receive safe and high-quality care.

Intent of this standard

To ensure timely, purpose-driven, effective communication and documentation that support continuous, coordinated safe and high-quality patient care.

Explanatory notes

Communication is a key safety and quality issue in health care.

Accurate patient identification and specimen labelling are crucial to patient safety. Failures in patient identification and labelling are a significant cause of patient morbidity. Breakdowns in the communication of test results also contribute to serious adverse events and are a major preventable cause of patient harm.

The actions relating to communicating for safety recognise the importance of effective communication.

Communication is inherent to patient care, and informal communications will occur throughout healthcare delivery. These actions do not apply to all communication. Instead, the intention is to ensure that systems and processes are in place at crucial times when effective communication is critical to patient safety, such as communicating critical results.

Critical results are defined as results outside critical limits, which may indicate a life-threatening situation and require immediate notification to the requester. Specific procedures are required to ensure that every effort is made to contact the requester, other medical practitioners responsible for treating the patient or the patient or carer directly.

Actions

Item		Action
Supporting requesters	7.01	The pathology practice supports and collaborates with requesters and a patient's other healthcare providers by: a. advising about the available pathology services, pathology request requirements, pathology service appropriateness, limitations, pre-requisites and preparation b. communicating accurate and complete information in a timely manner c. ensuring a competent workforce member is available to address enquiries and provide advice about pathology services d. ensuring the designated person or their delegated supervisors are available for virtual consultations and provide a timely response.
Patient identification and service matching	7.02	The pathology practice ensures unambiguous and traceable identification of a patient by: a. defining and approving at least three patient identifiers for use in the patient record and labelling of the patient's primary specimen b. including national health identifiers c. ensuring the patient checks the identifiers and confirms the accuracy of the labels on the specimen if they are able to do so d. labelling the primary specimen and report with the approved patient identifiers e. linking the primary specimen to the secondary sample unambiguously f. having processes for patients who want to remain anonymous, and to merge and link patient data where there are different identifiers for a single patient g. correctly matching the patient to their pathology specimen and service h. using approved identifiers to confirm the patient's identification when: i. the pathology practice collects the specimen ii. requests are transmitted electronically

Item		Action
		iii. testing the specimen, interpreting results and reporting. i. taking prompt corrective action when a patient identification and specimen discrepancy is identified j. documenting identification discrepancies and corrective action in the patient's healthcare record and incident management system.
Communicating results	7.03	The pathology practice has processes for communicating results that: a. addresses the structure and content of reports, and the communication of results to ensure they contain the: i. unique identifiers ii. patient's demographic data iii. tissue or specimen tested iv. result data v. report date and time vi. identity of any referral pathology practice that performed testing and their interpretive comments b. provide accurate, clear, concise, and verified written reports to requesters, patients and other healthcare providers in a clinically appropriate timeframe c. ensures a competent workforce member is available to interpret results and provide advice to requesters and other healthcare providers d. are provisional, which ensures their interim nature is noted on the report e. ensures reports are only produced in their entirety f. provides reports directly to patients when requested g. ensures patient health information is available in a clinically appropriate timeframe to healthcare providers at the patient's request or acting with the patient's consent h. ensures specimens can be retrieved and reports are retained for the period defined by the relevant jurisdictions and standards i. ensures report amendments are in the reporting system

Item		Action
		and can be traced to the original report j. ensures results containing the necessary information, can be identified and communicated to the requester or patient if the usual communication channel fails k. supports compliance with the reporting policy
Reporting critical results	7.04	The pathology practice has processes for recognising and responding to critical results indicating a life-threatening condition necessitating urgent medical intervention including processes to: a. allow prompt recognition of a critical result, preferably using automated processes b. to interpret and report a critical result in a timely manner c. promptly notify the requester d. promptly notify a responsible healthcare provider, patient, or their carer, when the requester is not contactable e. document the escalation of the critical result and the steps taken to ensure communication of the critical result. f. audit critical results to check process compliance
Healthcare Records	7.05	The pathology practice has processes to collect, store, manage, use and share patient information and pathology records that: a ensure the information and records are complete, accurate and up to date b use national healthcare identifiers[11] when managing clinical information, reports and results c adhere to Standardised Pathology Informatics in Australia (SPIA) and ensure consistent use of standard information structures and terminology d are in accordance with jurisdictional legislation in the event of a laboratory amalgamation, merger or closure e use digital enablers to support sharing point to point

[11] includes the Individual Healthcare Identifier(IHI), Healthcare Provider Identifier – Individual (HPI-I) and Healthcare provider identifier – Organisation (HPI-O)

Item		Action
My Health Record	7.06	The pathology practice contributes to My Health Record and has processes to: a. comply with legislative requirements b. use the available national healthcare identifiers for patients and individual healthcare providers c. support its workforce to upload reports to My Health Record d. ensure the accuracy and completeness of the information uploaded.
Notifiable diseases	7.07	The pathology provider has processes to document and report notifiable diseases in accordance with jurisdictional requirements and disease registries.

8. Medical devices

Pathology practices ensure all medical devices are appropriate for use and well maintained.

Consumer outcome

Patients expect their pathology services will be undertaken with reliable medical devices that provide accurate results.

Intent of this standard

To ensure medical devices are safe for a patient, meet performance expectations and provide accurate patient results.

Explanatory notes

Medical devices include instruments, reagents and consumables.

The pathology practice has the required medical devices to perform pathology services, achieve the required performance and comply with the relevant testing specifications.

The workforce will use the safety and quality systems and processes outlined in Standard 2 to manage the medical devices and ensure the medical devices are used in a safe, and consistent manner.

Actions

Item		Action
Medical device implementation and replacement	8.01	The pathology practice has systems for the replacement and implementation of medical devices that: a. ensures its medical devices are listed on the Australian Register of Therapeutic Goods (ARTG), or, if developed in house, are accredited against ISO 15189 and comply with the *Requirements for the development of in-house invitro diagnostic medical devices* and regulatory requirements and represent industry best practice b. include appropriate consultation and change management

Item		Action
		processes c. assesses the device's ability to meet the requirements for patient care d. assesses the device's ability to meet the manufacturers claimed specifications and verifies the device meets the manufacturer's stated specifications e. uses a known standard to test the device's results f. calibrates, quality controls and assures the medical device's performance before implementation g. actively manages the risk of aging medical devices and medical devices performing sub-optimally.
Medical device use	8.02	The pathology practice: a. uses medical devices for their intended purpose in accordance with the manufacturer's minimum requirements and instructions b. using medical devices outside of their intended purpose complies with the *Requirements for the development of in-house in vitro diagnostic medical devices* and regulatory requirements.
Medical device maintenance	8.03	The pathology practice has processes to ensure its medical devices are safe, fit for their intended purpose and performing optimally by: a. maintaining a current and complete medical device inventory b. storing the devices according to the manufacturer's instructions c. ensuring reagents and consumables are in-date and used in line with manufactures instructions d. conducting planned maintenance and repair according to manufacturer's instructions using appropriately qualified personnel e. performance testing devices after maintenance and repair f. maintaining a device's maintenance and repair log.
In-house invitro diagnostic	8.04	The pathology practice validates the clinical performance of its in-house in vitro diagnostic medical devices and ensures they:

Item		Action
medical device		a. adhere to Therapeutics Goods Administration (TGA) requirements for in-house IVDs. b. are assessed to the current edition of the *Requirements for the development and use of in-house in vitro diagnostic medical devices.*
Adverse medical device events	8.05	The pathology practice reports adverse events involving commercial and in-house invitro diagnostic medical devices to the TGA: a. within the specified time frames b. in the required format c. in line with regulatory requirements.
Artificial intelligence (AI) software and systems	8.06	A pathology practice using clinical decision support software and systems to interpret data or determine results have processes to ensure: a. that commercial AI IVD software and systems are included in the Australian Register of Therapeutic Goods (ARTG). b. in house in vitro diagnostic AI software and systems complies with the *Requirements for the development of in-house invitro diagnostic medical devices,* regulatory requirements and represent industry best practice c. implementation and use occur within a risk management framework that includes management of privacy and cyber security risks. d. they are used for their intended purpose e. they offer a clinical benefit to patients and are used ethically f. acceptance testing and commissioning is in accordance with the approved intended purpose and user population g. AI models are trained on data relevant to the local population, and perform equally well for the intended Australian population h. that a privacy impact assessment is undertaken to assess: i. compliance with Australian privacy law ii. the privacy, confidentiality and security of patient data, including third-party provider data processing is maintained

Item	Action
	iii. inform patient consent requirements i. the workforce is trained to accurately interpret AI results, understand the software's limitations and mitigate risks j. evaluation of the software's performance over time to determine if it is operating within performance expectations k. information is provided transparently to patients and carers on the use of AI for interpreting pathology tests or creating reports that explains why AI is used, the benefits, risks and how risks are mitigated l. the supervision delegation framework identifies workforce members with the appropriate scope of practice to review and where appropriate correct AI generated outputs and approve the results for release m. patient reports describe how AI was used, such as result interpretation or creating the pathology report, and that this does not dimmish the medical practitioner's responsibility for accuracy.

9. Specimen collection

Pathology practices ensure that all aspects of specimen collection are documented, implemented and monitored.

Consumer outcome

Patients expect to be informed about how to prepare for providing a specimen, to have their specimens identified as belonging to them, and to have their specimens correctly collected and stored in preparation for testing so that accurate laboratory testing is assured.

Intent of this standard

To ensure the patients are correctly identified and prepared, specimens are collected according to manufacturer's guidelines and laboratory requirements, and the integrity of the specimen is maintained.

The collection of specimens is undertaken by laboratories and other health services. These requirements apply to pathology services responsible for specimen collection.

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

Actions

Item	Action	
Specimen collection environment	9.01	The pathology practice minimises specimen collection safety and quality risks by: a. complying with regulations and jurisdictional requirements b. ensuring the design, functions and maintenance of the facilities and equipment support safe care c. providing access to an environment, facilities, equipment and devices that are fit for purpose, well-maintained and meet the needs of patients and their carers, including those with a disability and from diverse backgrounds

Item	Action	
		d. facilitating access to the specimen collection areas by providing clear signage and directions e. having space to enable patients and carers to be present and for the patient to be seated or recumbent f. ensuring privacy, dignity and safety of patients g. ensuring fall prevention strategies are in place h. developing strategies to minimise the risks of harm when risk of unpredictable behaviour is identified i. having a clear separation between specimen collection and specimen testing that ensures the patients do not enter testing areas or access pathology supplies, medical devices and specimens.
Infection prevention and control	9.02	The pathology practice has infection prevention and control processes at its collection centres: a. to maintain a clean, safe and hygienic environment consistent with the current edition of *Guidelines for the Prevention and Control of Infection in Health Care* and state or territory requirements b. to clean and disinfect surfaces and medical devices using products listed on the *Australian Register of Therapeutic Goods* in a manner consistent with the manufacturers' instructions for use and at the recommended frequencies c. that comply with state or territory work health and safety regulations on infection prevention and control d. use standard and transmission-based precautions consistent with the current edition of the *Australian Guidelines for the Prevention and Control of Infection in Health Care* e. that are consistent with the National Hand Hygiene Initiative f. that comply with the *Australian Immunisation Handbook* and jurisdictional requirements for vaccine-preventable diseases for the workforce.
Recognising acute deterioration and escalating care	9.03	The pathology practice supports specimen collectors by: a. implementing processes to promptly respond to a patient whose physical or cognitive state acutely deteriorates b. having referral pathways and processes to escalate care

Item	Action	
		according to the identified pathology service risks c. maintaining the specimen collectors' skills to recognise and respond to episodes of acute deterioration d. implementing processes to notify the requester or responsible healthcare provider when a patient's health care is escalated.
Request assessment	9.04	The pathology practice: a. conducts pathology services in response to a documented request that specifies the patient, requesting practitioner and pathology services to be performed and provides relevant clinical information b. assesses requests to be funded by Medicare to ensure they comply with the *Health Insurance Act 1973* legislation c. has a process to manage requests with insufficient or incorrect information d. has a process to document a requester's verbal request for further testing of a specimen and the receipt of a confirmatory documented request.
Specimen collection processes	9.05	The pathology practice's specimen collection processes: a. describe the pathology service, the purpose and the standard specimen collection procedure, whether the specimen requires temperature-controlled storage and the maximum allowable storage time b. are documented and reviewed regularly c. are readily accessible to the workforce d. adhere to the equipment's manufacturer instructions e. align with best practice guidelines f. includes processes for specimen collection in a patient's residence and a patient's collection of the specimen g. specifies the authority required to alter specimen collection.
Optimising specimen collection	9.06	The pathology practice optimises specimen collection by ensuring: a. consumables are available, in date, and easy to locate

Item	Action	
		and use b. the specimen collection workforce maintains specimen integrity through correct preparation, collection, packaging, and transportation c. it has processes for the management of inadequately labelled specimens and specimens where specimen integrity has failed
Specimen storage	9.07	The pathology practice ensures: a. dedicated, suitable and secure specimen storage facilities at the required temperature are available b. appropriate safety protocols, specimen stability and security requirements are followed and documented for specimens retained within a collection centre c. specimens are stored for the least possible time at the collection centre before transportation to a pathology laboratory.
High acuity settings	9.08	The pathology practice ensures: a. high acuity settings know who is responsible for collecting and transporting pathology specimens b. evidence-based approaches are used to collect and transport specimens from high acuity settings, so testing occurs within the clinically optimal timeframe c. there are processes to identify, track, and monitor progress of the high acuity setting samples through the laboratory d. requesters from high acuity settings have access to test turnaround times and the critical results notification process e. there is a process for a requester to inform the laboratory of their suspicion of a critical result, so specimen testing can be expedited and results communicated promptly.

10. Specimen testing

The pathology practice implements explicit procedures for specimen testing and accurate interpretation of results.

Consumer outcome

Patients expect pathology practices to competently test their specimens and report results accurately.

Intent of this standard

To ensure the:

- patient's specimens are tested according to manufacturer's guidelines or validated and authorised pathology practice protocols
- test results are representative by conducting quality control and assurance procedures
- patients and their requesters receive accurate results.

Explanatory notes

Any deviation from the manufacturer's instructions requires validation and authorisation, to prevent measurement error and compromising patient safety.

Actions

Item		Action
Analytical and clinical performance requirements	10.01	Before offering a pathology service, the pathology practice a. defines the clinical performance requirements for morphological analysis b. defines each analytical and clinical performance requirement using key indicators for: i. quantitative analysis, including accuracy, precision, limits of detection, units of measure and assessment of common interference

Item		Action
		ii. qualitative analysis with a reference standard includes estimates of sensitivity and specificity pairs, likelihood ratio of pairs, and receiver operating characteristic analysis iii. qualitative analysis with a non-reference standard includes positive, negative and overall percent agreement. c. ensures the analytical performance meets the assay's clinical application requirements d. ensures validated or verified procedures are used e. has processes to confirm test result comparability when different methods or devices are used f. test procedures are documented, authorised, and readily available to the workforce.
Measurement uncertainty process	10.02	The pathology practice has an estimation of measurement uncertainty (MU) process for quantitative assays that: a. defines the quantity intended to be measured b. indicates the level of confidence a laboratory has in each measurement c. provides information essential for the meaningful interpretation of results and their comparison over time d. identifies clinically appropriate goals for imprecision e. identifies significant sources of measurement uncertainty and opportunities for their reduction.
Measuring uncertainty	10.03	The pathology practice: a. identifies random effects, imprecision, systematic effect and inaccuracy to estimate the measurement uncertainty b. ensures the effort to determine the measurement uncertainty is commensurate with the quality requirements of the clinical application of the results c. sets routine performance goals for measurement of uncertainty and where the goal is not met, identifies and reduces the sources of uncertainty d. uses the measurement uncertainty processes to: i. demonstrate that assays meet the acceptable

Item		Action
		performance goal and are clinically applicable ii. to identify tests where an estimation of measurement uncertainty is not possible and minimises potential risks. e. ensures measurement uncertainty data is available for requesters and other healthcare providers.
Quality control process	10.04	The pathology practice: a. has the designated person oversight quality control (QC) processes including the selection and documentation of laboratory assay performance goals, and consider the measurand, test procedure and clinical situation b. ensures all laboratory assays have a documented QC process that assesses the tests performance c. specifies in the documented QC process: i. the criteria for quality control targets at clinical decision levels and the results acceptable for patient testing ii. alternative quality control mechanisms to ensure validity of testing when internal quality controls are not available. d. follows a documented escalation procedure when there is a QC failure which reviews specimens measured between the last successful QC sample and the first failed QC sample e. has systems to monitor quality control measures, take corrective action and issue reports f. documents the quality control results and keeps them in accordance with the *Requirements for the Retention of Laboratory Records and Diagnostic Material*.
Frequency of quality control testing	10.05	The pathology practice tests QC samples at a frequency based on the stability and robustness of the examination method, the risk of patient harm and when: a. critical consumables change b. confidence in the reliability or accuracy of a result is in question c. substantial maintenance to equipment has occurred or the equipment has sustained damage.

Item		Action
Test procedures	10.06	The pathology practice's test procedures: a. align with best practice guidelines b. adhere to the manufacturer's instructions or pathology practice's validated and authorised variation c. ensure specimen integrity through specimen testing, reporting until disposal d. are conducted according to a documented standard procedure that is traceable to the specimen being tested e. are readily available to the workforce f. are reviewed regularly.
Test results	10.07	The pathology practice has processes to ensure: a. the workforce determining results: i. are competent ii. are in an environment with optimal conditions for result interpretation and have access to the appropriate equipment to optimise result interpretation iii. have access to healthcare records, including My Health Record, when testing and, interpreting outputs, for reporting and historical review iv. have access to evidence-based reference intervals to interpret outputs v. have evidence based clinical decision limits. b. the results are correct, evaluated against internal quality controls, timely, unambiguous, clinically relevant and traceable to the request c. that when a clinically non-validated test is performed, the report indicates that the diagnostic validity has not been established.
Disposal of biological material	10.08	The pathology practice: a. has a waste management policy b. complies with jurisdictional regulations relating to the disposal of biological material from pathology testing.

Item		Action
External quality assurance programs	10.09	The pathology practice participates in external quality assurance (EQA) programs for pre analytical, analytical and post analytical phases for each pathology test or group of tests and has processes that: a. assess whether the EQA program is suitable based on predefined criteria including ISO 17043 b. ensure oversight by the supervising medical practitioner c. ensure EQA materials are tested and reported in the same manner as a routine specimen wherever possible d. document the acceptable performance criteria e. review the results to ensure: i. the test's performance is acceptable when compared to the pathology service's risk analysis ii. discordant quality assurance results are investigated in a timely manner iii. any impact on the quality of the patient's results and care is assessed and corrective action taken. f. ensure the designated person is notified of serious and persistent poor performance.
Morphological external quality assurance programs	10.10	The pathology practice participates in morphological EQA and a. ensures the workforce involved in morphological diagnosis participate in at least one EQA relevant to their practice per year b. retains individual workforce membership participation in morphological EQA, reviews the results and takes appropriate follow-up action where discordance is present c. where morphological EQA programs submissions are collegiate, states this clearly on the response.
Internal quality assurance	10.11	In the absence of suitable EQA programs, the pathology practice has alternative internal quality assurance (IQA) processes for pre-analytic, analytic and post-analytic phases including: a. addressing high risk areas in specimen collection and testing by comparing data with other accredited laboratories b. demonstrating test result validity by analysing reference

Item	Action
	material or comparing across laboratories c. peer review, where formal sample exchange, formal second opinion or informal second opinion is used to compare diagnoses.

11. Point of care testing

The pathology practice's clinical governance, safety and quality, supervision, testing and reporting systems support the delivery of high-quality point of care testing

Consumer outcome

Patients are confident the pathology practice has effectively embedded point of care testing (POCT) into its clinical governance and safety and quality systems, so the trained workforce delivers test results that support high quality healthcare decisions.

Intent of this standard

To ensure the implementation of the key elements required to deliver high quality POCT, including clinical governance, safety and quality systems, a competent workforce, management of medical devices, and a safe environment to perform POCT.

Explanatory notes

Technological advancements have enabled pathology testing to occur near the patient. Known as pathology POCT, the use of POCT has increased dramatically in Australia, as has their sophistication. The benefits of 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.

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, and competency to recognise discrepant results can lead to false results and incorrect medical decisions and pose significant risks to the quality of patient care.

Actions

Item	Action	
Contracted services	11.01	Where the pathology practice coordinates POCT for a health service, it has an agreement a which addresses the responsibilities of each party b accounts for the actions in the *POCT for Health Services.*
Workforce roles and responsibilities	11.02	The pathology practice ensures workforce performing POCT are competent by having processes to: a. confirm they have the qualifications, knowledge and skills, and are operating within their defined scope of practice b. confirm they can perform, interpret, monitor and produce reliable POCT results c. define their POCT roles, responsibilities and accountabilities and support them to fulfil these roles d. review their roles, knowledge and skills when a POCT in vitro diagnostic medical device or service is introduced or substantially altered.
POCT training	11.03	The pathology practice ensures: a. the training delivered accounts for the complexity of the POCT devices and testing, the volume of tests, a workforce member's frequency of testing and quality assessment data findings b. a qualified person provides POCT training, and training requirements are defined, and at a minimum include: 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. device troubleshooting.

		ix. alternative test method processes x. cleaning and maintaining POCT in in vitro medical devices xi. performance of quality control xii. ordering and storage of reagents, supplies and quality control materials. c. the workforce is instructed, has completed relevant POCT training and are deemed competent before undertaking POCT d. the workforce participates in training updates, remains up to date and are recertified competent for POCT e. training is reviewed periodically for suitability.
Performance management	11.04	The pathology practice has reliable processes to: a. review the performance of workforce members undertaking POCT to ensure competence b. identify the POCT training, development and supervision needs of the workforce.
Interprofessional collaboration	11.05	The pathology practice, when coordinating POCT for health services, provides opportunities for interprofessional collaboration between the pathology practice's workforce and clinicians.
POCT test procedures	11.06	In addition to a pathology practice's specimen test procedures, the practice's point of care test procedures: a. include traceability of samples to the original specimen, patient, and POCT medical device b. include reference intervals for identifiable patient groups c. are audited regularly to assess workforce compliance with the procedures.
POCT test results	11.07	The pathology practice has processes that ensure test results and related information from a point of care medical device are included in a patient's healthcare record, and, where possible, this process is automatic.

Glossary

Term	Definition
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.
Artificial intelligence	Artificial intelligence is an area of computer science focused on creating machines that can perceive, synthesise, and infer information and engage in behaviour that is considered intelligent.
Assay	An assay refers to the analytical test or the detailed report of its findings. It is used to determine the composition, quality, or functional activity of a substance.
Audit	Systematic, independent and documented process for obtaining objective evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled.
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 performance	Ability of an in-house in-vitro medical device to yield results that are correlated with a particular clinical condition/physiological state in accordance with target population and intended user.
Clinical scientist	Means a person with the training and competence to perform the functions required, who has at least five years' relevant medical laboratory experience and possesses one or more of the following qualifications: • Fellowship of the Australian Institute of Medical Scientists • Fellowship of the Australian Society for Microbiology (medical microbiology or clinical microbiology) • Fellowship of the Human Genetics Society of Australasia (biochemical genetics, cytogenetics or molecular genetics) • Fellowship of the Faculty of Science of the Royal College of Pathologists of Australasia • Fellowship of the Australian Society of Cytology • Doctor of Philosophy, Australian Qualifications Framework level 101 or equivalent doctoral level degree, in a subject relevant to the scope of diagnostic testing of the laboratory they are supervising • For assisted reproductive technology laboratories, the clinical scientist must meet the criteria in the Reproductive Technology Accreditation Committee code of practice for scientific directors • For bone marrow transplant laboratories, the clinical scientists must meet the requirements of the Bone Marrow Transplant Scientists Association of Australasia • For American Society of Histocompatibility and Immunogenetics accredited laboratories, the clinical scientist must meet the requirements for a general supervisor
Clinician	A trained health professional, including registered and non-registered practitioners, who provides direct clinical care to patients. Clinicians may provide care within a healthcare service as an employee, a contractor or a credentialed healthcare provider, or under other working arrangements. They include nurses, midwives, medical practitioners, allied health professionals, paramedics and other professionals who provide health care, and students who provide health care under supervision.

Term	Definition
	For genetic testing a health professional would also include a genetic counsellor.
Competence	Demonstrated ability to apply knowledge and skills to achieve the intended result.
Complex testing	Testing that requires a high level of technical expertise, interpretative skill and judgment, and rigorous quality assurance.
Confidentiality	The state of keeping or being kept secret or private.
Critical results	Results outside defined limits which may indicate a life-threatening situation and require immediate notification of the referring doctor, nurse or physician's assistant.
Environment	The context or surroundings in which health care is delivered. The environment can include other patients, consumers, visitors and the workforce.
Extended leave	Extended leave is time away from work for a longer than usual period, which is defined as beyond four weeks. It is distinct to ordinary annual leave, short sick leave, or conference leave. It is umbrella term that can cover long service leave, parental leave, extended sick leave, sabbatical leave or leaves of absence.
External quality assurance	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.
Health service	A health service 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, community settings, clinicians' rooms, clinics, medical imaging practices and pharmacies.
Healthcare identifier	A healthcare identifier is a unique number that ensures healthcare providers can accurately match records to the person they are treating. The Healthcare Identifiers Service is a national system for identifying individuals, healthcare providers and organisations, using a healthcare identifier. An Individual Healthcare Identifier (IHI) is a unique 16-digit number used to identify an individual for health care purposes. As part of the HI Service, every Australian resident has a

Term	Definition
	unique IHI.
High acuity setting	A healthcare environment where patients require intensive medical attention because of critical health conditions such as intensive care units, emergency departments and care units. The patients have serious, unstable or complex health issues that necessitate frequent monitoring and rapid interventions. monitoring and intervention due to serious or complex medical conditions.
In vitro diagnostic (IVD) 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.
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.
Integrity	Maintaining the accuracy, completeness, and trustworthiness of scientific data, research processes, and samples throughout their lifecycle. This involves adherence to ethical standards and professional practices to ensure that results are objective, honest, reliable, and reproducible, ultimately maintaining public trust in the laboratory's work.
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

Term	Definition
	• 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 metabolic means, but which may be assisted in its function by such means.
Medical practitioner	A person who has a medical degree and has current registration with AHPRA – Medical Board of Australia.
Pathologist	Pathologists are specialist medical practitioners who study the cause of disease and the ways in which diseases affect our bodies by examining changes in the tissues and in blood and other body fluids. Currently pathology has eight major areas of activity. These relate to either the methods used or the types of disease which they investigate and include: • Anatomical pathology • Chemical pathology • Forensic pathology • General pathology • Genetic pathology • Haematology • Immunopathology • Microbiology
Pathology laboratory	Premises used for the examination of materials derived from the human body for the purpose of providing information for the diagnosis, monitoring, management, prevention and treatment of disease, or assessment of health.
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.
Policies	Documented principles and direction by the pathology practice's governing body and senior leadership that guides the delivery of pathology services. Policies include delegation of authority and

Term	Definition
	supervision.
Premises	Premises used by the pathology practice and, includes pathology laboratories, administrative and collection centres and any other place where the pathology practice conducts business for the purpose of providing a pathology service.
Procedure	The set of instructions specific to a pathology practice that operationalises policies and processes.
Quality assurance	Relates to participation in relevant quality assurance programs, performance reviews and corrective actions where performance is unsatisfactory.
Quality control	Internal procedure which monitors the testing process to verify the system is working correctly and gives confidence that the results are reliable enough to be released.
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.
Quality management system	Set of interrelated or interacting elements of an organisation to establish policies and objectives, and processes to achieve and improve quality.
Recency of practice	Refers to a requirement that members of the pathology workforce demonstrate they have maintained an adequate connection with their profession and recent practice in the scope in which they work.
Report(s)	The provision of results, interpretation and opinions.
Request	A written communication received that identifies the pathology services required and the patients personal and clinical details.
Risk	Combination of the probability of occurrence of harm and the severity of that harm.
Risk management	The design and implementation of a program to identify and avoid or minimise risks to patients, employees, volunteers, visitors and the

Term	Definition
	organisation.
Risk assessment	Overall process comprising risk analysis and evaluation.
Sample	A portion of the specimen assumed to contain the target analytes in the same proportion to that found in the original specimen. Also includes non-patient derived material such as controls, blanks, and reference materials.
Scientist	This person must possess qualifications at Australian Qualifications Framework level 7 or above awarded by an: • Australian University and which contains subjects relevant to pathology • an overseas university recognised as such by local legislation and which is accredited by the Australian Institute of Medical and Clinical Scientists • an overseas university which contains subjects equivalent to those in an accredited degree and who have passed the Australian Institute of Medical and Clinical Scientists professional exam, according to their authority approved by the Minister for Employment, Skills, Small and Family Business.
Specialist	As defined in subsection 3(1) of the *Health Insurance Act 1973*: In relation to a particular specialty (other than general practice), means a medical practitioner in relation to whom there is in force a determination under section 3DB or 3E that the medical practitioner is recognised for the purposes of this Act as a specialist in that specialty, or a medical practitioner who is taken to be so recognised under section 3D.
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 collector	A specimen collector (phlebotomist) is a qualified clinician responsible for obtaining biological specimens from patients for diagnostic testing. A specimen collector must hold, at a minimum, a Certificate III in Pathology Collection or have equivalent experience and competency to meet the level required of a Certificate III in Pathology Collection qualification.
Specimen integrity	The necessary conditions required to keep a specimen from becoming compromised. Maintaining integrity involves ensuring that

Term	Definition
	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.
Standard	The agreed attributes and processes to ensure that a product, service or method will perform consistently at a designated level.
Training	The development of the workforce's knowledge and skills.
Technician	This person must possess qualifications at Australian Qualifications Framework level 5 or above awarded by an: • Australian tertiary level institution which contains subjects relevant to pathology • an overseas institution and which contains subjects assessed by the Australian Institute of Medical and Clinical Scientists as being relevant to pathology and educationally comparable to those in an Australian equivalent qualification • an overseas university which contains subjects equivalent to those in an accredited degree and who have failed the Australian Institute of Medical and Clinical Scientists professional exam, according to their authority approved by the Minister for Employment, Skills, Small and Family Business
Urgent	Means 'requiring immediate attention' as determined by the requesting practitioner or by the laboratory.
Validation	Confirmation through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled.
Verification	Confirms that a standard test method or device performs as expected under specific laboratory conditions, ensuring accuracy and safety in patient diagnosis or product use.

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