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

NPAAC
National Pathology Accreditation Advisory Council

National Pathology Standards

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Acknowledgement

The Australian Commission on Safety and Quality in Health Care pays respect to the Gadigal people as the Traditional Custodians of Country where the Commission's office is located. We extend that respect to all Aboriginal and Torres Strait Islander peoples, and their deep time connections to land, water, and sky.

We recognise that knowledge about healthy Country, community and culture has been developed by Aboriginal and Torres Strait Islander peoples over tens of thousands of years and has been shared for generations. We are committed to partnering with and learning from Aboriginal and Torres Strait Islander peoples through the work that we do.

Contents

Background

The Australian Commission on Safety and Quality in Health Care leads and coordinates national improvements in health care safety and quality. The Commission administers the National Pathology Accreditation Scheme on behalf of the Australian Government Department of Health, Disability and Ageing.

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 nationally consistent 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 provide high-quality care by meeting 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 pathology practice's conformity with the standards is assessed by the accrediting agencies defined in the Approval Principles.

The Approval Principles ensure that pathology practices providing Medicare-eligible pathology services meet 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 on 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 of laboratories that deliver Medicare eligible pathology services.

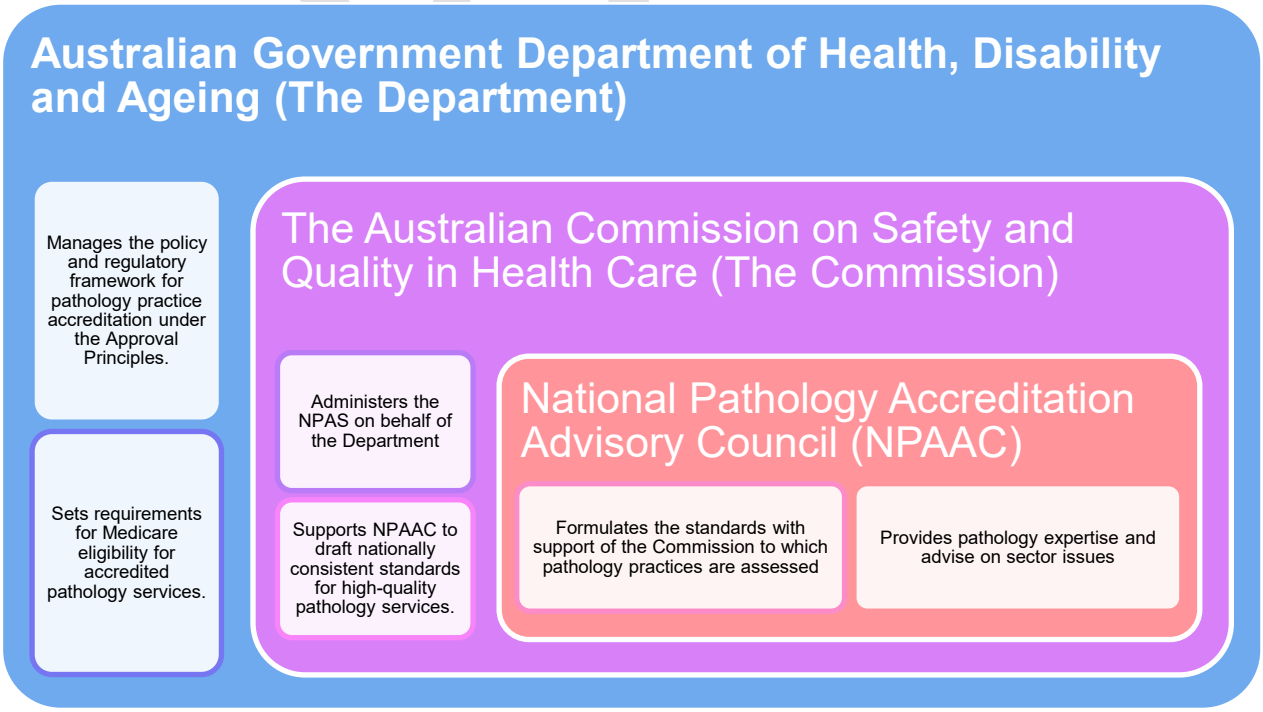
About the National Pathology Accreditation Advisory Council

The National Pathology Accreditation Advisory Council (NPAAC) was established in 1979 to consider and make recommendations to the Australian Government and 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 the standards to which pathology practices are assessed.

Accrediting Agency

NATA is the national accreditation body responsible for assessing pathology practices against the National Pathology Standards. Through independent assessment and ongoing surveillance, NATA provides assurance of a practice's competence and compliance with applicable standards and regulatory requirements. Clinical responsibility and accountability remain with the pathology practice and its medical practitioners.

Roles and responsibilities – National Pathology Accreditation Scheme



Introduction

The National Pathology Standards 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.

Intent of the National Pathology Standards

When fully implemented, patients can be confident that their pathology practice is committed to delivering high-quality pathology services to inform and support clinical decision-making. The intent of the National Pathology Standards is to apply a nationally consistent and streamlined approach to accreditation of laboratories in Australia to ensure access to high-quality pathology services.

Developing the *National Pathology Standards* (NPS)

The Commission consulted extensively with scientists, pathologists, consumers, professional and peak bodies, jurisdictions, and government agencies. The process for development included:

- mapping between current NPAAC requirements and ISO standards
- identifying safety and quality gaps in the current requirements
- reviewing regulations and national and international standards.

The NPS will replace 7 existing requirements (**Box 1**), to reduce duplication and update the requirements to better support modern and high-quality pathology services.

Box 1

Requirements included in the NPS

- 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.

Overview of the National Pathology Standards

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

Structure of the standards

Each standard includes:

- consumer outcome
- intent of the standard
- explanatory notes
- items and actions that describe what is required to meet the standard, and, where applicable, information and resources to support understanding and implementation.

The National Pathology Standards

Pathology Services in Australia

A pathology service examines body tissue, blood and other bodily fluids to provide information about a patient's health. The results help to:

- diagnose and monitor medical conditions,
- screen for health conditions
- monitor responses to medicines and other treatments.

Pathology services underpin medical decision-making and play a critical role in the effective operation of Australia's healthcare system. The reliability, quality and availability of pathology services are essential to diagnosing, monitoring and managing patient conditions and supporting timely, evidence-based clinical care.

Pathology services include the examination of patient specimens using a range of technologies and are supervised by appropriately qualified specialist pathologists. Specialist pathology services currently include andrological, chemical, cytological, forensic, genetic, microbiological, haematological, immunological, immunohaematological and anatomical pathology examinations.

Application of the standards

Pathology practices that provide Medicare-funded pathology services are required to comply with the National Pathology Standards (NPS) and other relevant National Pathology Accreditation Advisory Council (NPAAC) standards.

Other laboratories and healthcare services that provide pathology services should also apply the NPS, as they represent a nationally consistent, best practice approach to pathology service delivery. The standards provide a structured framework for:

- implementing effective clinical governance and key elements of quality
- identifying, assessing and managing risks
- ensuring systems are in place to prevent patient harm and support continuous quality improvement

1. Clinical governance

The pathology practice establishes and uses clinical governance systems to ensure accountability for high-quality pathology services.

Consumer outcome

Patients are confident that the pathology practice delivers high-quality pathology services, to inform healthcare decisions.

Intent of this standard

Pathology services implement a clinical governance framework that ensures the workforce and the governing body understand their accountabilities for the delivery of high-quality pathology.

Explanatory Notes

Clinical Governance

Clinical governance establishes the conditions for high-quality pathology. It is the combination of culture, systems and structures that enables the pathology workforce to deliver pathology services that are consistently high quality and improving (**Figure 1**[1]).

It is the system by which boards, executives, clinical leaders and the workforce are accountable to patients and the community for providing high-quality services.

Figure 1 The foundations of clinical governance

Roles and Responsibilities

Governing bodies, or owners, lead a culture of safety and quality and are ultimately responsible for ensuring the pathology practice is well run and

[1] 2026 National Model for Clinical Governance | Australian Commission on Safety and Quality in Health Care

delivers high-quality pathology services. Leadership is a critical enabler of effective clinical governance. The board and executive provide clear strategic direction while creating an organisational culture in which there is leadership and accountability for providing high-quality pathology services at all levels of the organisation. It is expected that one or more members of the governing body will be available, if required, during an accreditation assessment.

A **clinical governance framework** provides the structure through which the governing body and pathology workforce share responsibility and accountability for maintaining and improving the safety, quality, and effectiveness of pathology services. The outcome of using a clinical governance framework is consistently high-quality pathology services.

It brings together the systems and structures necessary to support:

- clear accountability for clinical and operational decision-making
- safe and effective workforce practice, scope of practice, supervision and training
- risk management, including identification, monitoring and mitigation of patient safety risks
- reliable information management, including accurate reporting and secure handling of patient data
- consumer partnership, ensuring services are person-centred, culturally safe and responsive to diverse needs
- continuous quality improvement, supported by data, incident management, audit, review and feedback loops.

Designated person

The governing body designates 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.

Actions

Item	Action	
Governance, leadership and culture	1.01	The governing body: a. endorses the clinical governance and risk management frameworks b. prioritises patient safety and appropriate use of pathology services in business decisions and continuity planning c. is trained in its governance roles, responsibilities and accountabilities d. ensures the pathology practice operates ethically, transparently, and complies with all relevant legislation and standards e. appoints the designated person(s) responsible for the implementation of the clinical governance framework in the pathology practice under their control

Item	Action	
		f. sets and communicates priorities and strategic directions for high-quality pathology services g. identifies and addresses conflicts of interest h. monitors safety, quality and performance, and directs improvements where required i. ensures a documented clinical governance structure is in place, showing who leads, manages and supervises the practice j. monitors and acts on commercial, financial or other influences that may impact the integrity or quality of pathology services
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: i. is a medical practitioner residing in Australia and registered with the Australian Health Practitioner Regulation Agency ii. has the authority and scope of practice to perform the role b. designated person's responsibilities include: i. implementation of 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. oversight of workforce performance and effectiveness in performing their role vii. ensuring the workforce has the skills and experience to perform pathology tests viii. determining the range of tests performed, the methods used and procedures for testing ix. ensuring the numbers of tests processed are sufficient to maintain competence x. determining the suitability of referral laboratories xi. overseeing policies and procedures for the identification and communication of critical results

Item	Action	
Delegations	1.03	The pathology practice has an authorisation process to delegate 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
Legislation and standards	1.04	The pathology practice complies with applicable: a. Commonwealth, state and territory legislation and regulations b. relevant NPAAC standards c. ISO 15189 where there is no relevant NPAAC standard
Contracted services	1.05	The pathology practice, subcontracting pathology services or coordinating pathology services for other organisations ensure: a. subcontractors are accredited to the relevant NPAAC standards or recognised equivalent international standards, such as ISO 17025, if NPAAC standards are not applicable b. liaison with scientific, clinical and administrative staff of the subcontractor
Referral laboratories	1.06	A pathology practice that instigates referrals has processes: a. to ensure the referral laboratory, if in Australia, is accredited to relevant NPAAC Standards and ISO 15189 b. to preference international referral laboratories that are accredited to ISO 15189 or equivalent over unaccredited international laboratories c. to communicate with the clinicians in the referral laboratory and patients including about costs[2] or other consequences of testing such as data security d. to retain responsibility for packaging, transport and handover of specimens that are sent internationally e. to manage the risks, including turnaround times, associated with engaging a referral laboratory f. for receiving pathology reports g. for agreeing on and documenting the responsibilities for communication of critical results

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

Item	Action	
Environmental sustainability	1.07	The pathology practice uses its governance systems to implement best practice strategies for reducing its environmental impact[3]
Information governance	1.08	The pathology practice uses its information governance to: a. implement health information systems that are interoperable and conformant with relevant national digital health information standards[4] and legislative requirements b. monitor system performance to optimise the accuracy, completeness and quality of the data c. ensure Laboratory Information Management Systems (LIMS) and Laboratory Information Systems (LIS) comply with legislation and regulations[5], so information is i. secure ii. treated in accordance with privacy legislation iii. is used in accordance with other relevant NPAAC Standards d. implement an information security management system that i. ensures that only appropriate users access information that is relevant to the requirement of their role ii. ensures information is protected in transit and when stored iii. is assessed regularly to minimise the vulnerability of the pathology information system iv. informs the governing body of vulnerabilities and failures v. manages and responds to data breaches e. provide orientation to the workforce and monitor compliance with the processes related to the use of information systems and responsibilities for security of information

[3] RCPA guideline - Environmental Sustainability in Pathology Laboratories

[4] Australian Digital Health Agency | Standards search | Digital Health Implementer Hub

[5] **LIMS may be excluded (conditional) from TGA regulation**; however, where software performs diagnostic interpretation or generates diagnostic outputs may be regulated as IVD software and should meet relevant regulatory requirements (see Standard 8).

Item	Action	
		f. implement processes to inform the governing body of vulnerabilities and failures g. assess and mitigate risk to patient safety as a result of delayed adoption of updated and new digital health standards
Artificial Intelligence (AI) Governance	1.09	The pathology practice must implement an AI management system consistent with relevant international standards, such as ISO 42001[6]

[6] ISO/IEC 42001:2023 - AI management systems

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 effectiveness of its pathology services.

Consumer outcome

Patients receive pathology services that are high-quality, giving them confidence that test results are accurate and that clinical decisions based on those results can support safe and effective care

Patient's feedback is actively sought, understood and addressed.

Intent of this standard

To apply a risk-based approach to the implementation of safety and quality systems that support the consistent delivery of high-quality pathology services.

Explanatory notes

Risk management

A strategic approach to risk management informs monitoring, planning and allocation of resources across all part of the organisation. Use of a risk management framework demonstrates a considered and proportionate effort by governing bodies, the designated person and the workforce to develop a culture, and structure for the organisation which supports high-qualitypathology services.

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

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

Risk management systems document:

- patient safety risks
- the risk level
- strategies to mitigate risks
- the implementation status of each mitigation strategy.

Success of the strategies in mitigating risks is monitored. A pathology practice can demonstrate it has acted to mitigate identified risks through action plans and evidence that action has been taken.

Appropriate and sustainable care

Although pathology is a referral specialty and pathologists have limited control over test ordering, they are experts in specimen analysis and results interpretation. As such, pathologists play a critical role in promoting appropriate and sustainable testing that delivers high-quality care for patients while supporting the efficient use of healthcare resources.

Pathology practices can enhance the quality of pathology services by providing advisory support and educational resources to clinicians, monitoring and reviewing test-ordering patterns, and engaging in constructive discussions with requesters. This includes identifying, monitoring, and addressing pathology services that offer low-value care to patients or the health system, as well as introducing contemporary, evidence-based testing to improve diagnostic accuracy and patient management

Quality management

Quality management systems are an essential component of managing risk. They support high-quality 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 have 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 performance 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

Item	Action	
		d. acts to mitigate risks and issues using quality management and other systems e. supports workforce involvement in risk identification, assessment and mitigation f. communicates and reports risks to the governing body, designated person and workforce g. assesses the effectiveness of risk identification and management 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
Adaptable and resilient systems	2.04	The pathology practice must: a. manage software updates and system changes using a change control process[7] b. validate and test any changes that affect regulated software before clinical use c. communicate system outages to staff and users d. regularly review and update systems to meet industry standards
Interoperable information systems	2.05	The pathology practice uses interoperable information systems that: a. use national healthcare identifiers for patients, the organisation and individual healthcare providers[8]

[7] **Change control**
A documented process used to assess, approve, implement, validate and review changes to systems, software or processes in a controlled manner, to ensure changes do not adversely affect patient safety, result accuracy, data integrity or service continuity
What change control covers
Change control applies to changes that may affect laboratory information systems (LIMS / LIS), regulated software that influences test results
interfaces and interoperability messaging, medical device software or firmware, workflows that affect specimen handling, testing, reporting or storage, cybersecurity, access controls or data handling
This includes patching, upgrades and new software versions, configuration changes, system integrations or interface modifications, changes required for regulatory or standards alignment
[8] Healthcare Identifiers and the Healthcare Identifiers Service | Australian Government Department of Health, Disability and Ageing

Item	Action	
		b. ensure consistent use of standard information structures and national terminologies, including those described in the *Standardised Pathology Informatics in Australia* (SPIA) guidelines[9] c. align with jurisdictional and industry interoperability standards for the storage and transmission of information such as the Australian HL7 diagnostic messaging standard[10], and must have processes in place to adopt updated versions or new standards as they become available[11]
Appropriate care	2.06	The pathology practice has processes to: a. identify, assess and implement contemporary, evidence-based pathology services and technologies that improve clinical care b. identify and reduce pathology services that are unnecessary or do not meet required quality standards
Quality management systems	2.07	The pathology practice has a quality management system that includes processes to: a. collect and interpret safety and quality data on: i. specimen collection, integrity, traceability, and testing ii. testing of equipment iii. result interpretation and reporting iv. incident and error rates v. turnaround times b. monitor and report on performance c. monitor and report on safety and quality improvement activities d. facilitate access for the governing body, designated person and workforce to data and reports on performance and quality improvement activities e. involve the workforce in quality improvement reviews

[9] Royal College of Pathologists of Australasia (RCPA). RCPA - SPIA Guidelines and Tools
[10] As of April 2026, Australian Diagnostics and Referral Messaging – Localisation of HL7 Version 2.4 (HL7AUSD-STD-OO-ADRM-2021.1)
[11] This could include monitoring and planning for adoption of FHIR based messaging Where systems support more contemporary architectures, HL7 FHIR may be used to supplement or extend interoperability, particularly for analytics, patient access and modern application integration; however, it does not replace the current HL7 version for core laboratory workflows unless explicitly agreed by all interfacing parties.

Item	Action	
		f. audit quality management system effectiveness
Incident management systems	2.08	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 incident review b. enable consumers and requesters to raise concerns and report incidents c. nominate person(s) responsible for investigating incidents, and set timeframes for action that are proportionate to the risk to patient safety d. escalate significant incidents to the designated person e. document incidents, investigations, corrective actions and follow-up, including whether the corrective actions have reduced risk f. provide timely incident reports to the designated person, the workforce and the governing body, including risks identified, actions taken and any change in the level of risk g. use incident analysis to improve the safety and quality of pathology services h. regularly review and take action to improve the effectiveness of the incident management system
Open disclosure	2.09	The pathology practice: a. uses an open disclosure process consistent with the *Australian Open Disclosure Framework*[12] b. monitors and acts to improve the use and effectiveness of the open disclosure process
Feedback and complaints management	2.10	The pathology practice has processes to: a. document feedback and complaints from requesters, patients, families and carers b. inform the designated person of complaints and feedback

[12] The Australian Open Disclosure Framework | Australian Commission on Safety and Quality in Health Care

Item	Action
	c. escalate, review and take corrective action when communications with requesters, health care providers, patients, families or carers raise the possibility of adverse clinical impacts d. act on feedback, address complaints in a timely way and inform patients, families or carers of the outcome e. provide patients, families and their carers with information on the relevant healthcare complaints authority f. document the timeliness of responses, evaluation and improvements made as a result of feedback and complaints g. analyse feedback, complaints and response processes to improve the safety and quality of 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 are confident that their specimens are tested under the supervision of a qualified and skilled member of the pathology workforce.

Intent of this standard

To manage the risks associated with pathology testing through the application of a supervision framework to ensure that testing is appropriately overseen by a person with the requisite qualifications, skills, experience, and authorised scope of practice, in order to support safe, accurate, and reliable patient results.

Explanatory notes

Supervision

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, experience, skills, and competence 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. enquiries ii. the selection of pathology tests iii. interpretation of results c. manage the performance, development and education of the workforce related to tests they supervise d. oversee incident management e. identify and manage risk f. manage and review the internal and external quality assurance programs g. address the internal quality control and assurance management h. manage feedback and complaints i. manage equipment and medical devices including selection, implementation, use, review and maintenance j. participate in the audit of the effectiveness of supervision
Supervision framework	3.02	The pathology practice has a documented supervision framework 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 d. identifies the person with responsibility for the supervision of testing during operational hours

Item		Action
		e. regularly audits 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 c. action is taken to mitigate the critical 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 designated person: i. periodically completes a review of the pathology test supervision arrangements ii. mitigates risks when a workforce vacancy and supervisory gap occur
	3.04	The pathology practice mitigates supervision risks by: a. actively recruiting to vacancies b. providing access to training and experience to maintain or 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 experience appropriately supervised specimen testing.

Intent of this standard

To ensure pathology laboratories are supervised in accordance with their laboratory category so that clinical governance, test oversight and workforce arrangements are appropriate to the scope, complexity and risks of the services provided, and support safe, accurate and reliable patient results.

Explanatory notes

Supervision requirements

Part 4 of the *Health Insurance (Accredited Pathology Laboratories—Approval) Principles 2017* sets out the premises categories for accredited pathology laboratories and the criteria that distinguish each category (for example, the scope and complexity of testing, the governance relationship with other laboratories, and supervision arrangements).

For accreditation purposes, the accrediting agency assigns (or confirms) the laboratory's category based on the laboratory's services, staffing/supervision model, and how the laboratory operates in practice, against the criteria in Part 4. The category is used to determine the applicable supervision and accreditation requirements for the laboratory.

Where a laboratory's scope of practice, test menu, governance arrangements, or service model changes, the pathology practice should notify the accrediting agency so the laboratory category can be reviewed (and updated if required) to ensure ongoing compliance with the Approval Principles.

Actions

Item	Action
GX[13] laboratory	4.01 For each GX laboratory, the pathology practice has a designated person who: a. is a pathologist b. is a full-time appointment c. only supervises pathology tests within their scope of practice d. delegates supervision to other pathologists at GX, GY 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 scientists and 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[14] pathologist: i. with the relevant scope of practice ii. and who is on-site in a pathology laboratory 80% of the time iii. and is readily available with delegated responsibility for supervision of each pathology test b. completes a risk assessment[15] for complex pathology tests to determine whether the addition of a clinical scientist to the supervision framework could improve the safety and quality of those tests

[13] The Australian Red Cross Lifeblood fits into the GX Laboratory category.

[14] In aggregate

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

Item	Action	
		c. has at least one clinical scientist[16] with a relevant scope of practice and delegated responsibility for the analytical phase of each tissue typing, complex toxicology[17] and complex genomics[18] test d. has a process to determine the full-time equivalency of the clinical scientist, where a clinical scientist is required
	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
GY and B[19] laboratory	4.04	For a GY and B laboratory, the pathology practice ensures: a. it operates in accordance with the pathology network's 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 or B laboratory, the pathology practice must undertake a documented, ongoing risk assessment of the adequacy of onsite supervision. a. The assessment must include: i. test volume

[16] The Role of a Pathology Clinical Scientist in Australia Position Statement August 2024

[17] **Toxicology** refers to specialist or complex toxicology testing that requires advanced scientific oversight due to test complexity, interpretive risk or methodology. This includes but is not limited to drugs of abuse confirmation testing, therapeutic drug monitoring requiring complex interpretation, toxicological testing using mass spectrometry or equivalent high-complexity methodologies.
Toxicology does not include routine, low-complexity assays (for example paracetamol, salicylate or ethanol testing) that are appropriately supervised within existing B, GY or GX laboratory supervision frameworks.

[18] **Large-scale or higher-complexity genomic testing** refers to genomic testing that requires broad, integrative or expert-level analysis of genetic material, including approaches such as karyotyping, genome sequencing, exome sequencing and gene panel sequencing.

Complexity may arise from the breadth of analysis, genetic mechanisms assessed, integration of multiple methods or data sources, limitations of the analytical method, clinical context, or potential for patient harm from incorrect interpretation. It may also arise where expert technical judgement is required to resolve ambiguous or discordant findings, interpret results across multiple assays or loci, or provide an individual interpretative comment because of the nature of the analytical technique. Complexity is not determined solely by the number of genes analysed or technology used, and targeted tests may require Clinical Scientist supervision where expert understanding of the method, its limitations and clinical implications is needed.

Examples of testing not generally considered large-scale or higher-complexity include single-gene testing and focused gene panels for diagnostic indications, NIPT for predefined targets such as common aneuploidies and RhD (excluding NIPT with non-targeted analysis and interpretation), and commercially available assays used without modification and in accordance with manufacturer instructions, where interpretation is limited to predefined variants or outcomes of established clinical significance. These examples are not exhaustive, and any assay may require Clinical Scientist supervision where modification, validation, data integration, method limitations or interpretative requirements increase technical judgement or risk.

[19] A B laboratory includes B laboratories providing PoCT testing

Item	Action	
		ii. testing complexity and acuity iii. workforce composition and capability iv. error and incident data v. feedback and complaints b. Where the risk assessment indicates that patient safety, quality or service integrity may be compromised, the pathology practice must implement appropriate onsite supervision commensurate with the level of risk
GX, GY and B Clinical Governance	4.06	The pathology practice: a. has a common clinical governance 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[20] that spend a minimum of two full time equivalent[21] days per annum undertaking supervised training or professional development in another laboratory[22]
S laboratory	4.07	The pathology practice with an S laboratory ensures it: a. performs a limited range of pathology tests for a target patient population that are related to the designated person's relevant qualifications, skills and scope of practice b. applies for GX laboratory status if a wider scope of pathology testing is planned
	4.08	The pathology practice has a designated person for S

[20] Excluding onsite managers in B(PoCT) laboratories
[21] in aggregate
[22] Routine work undertaken in another laboratory does not constitute training and development.

Item	Action	
S laboratory		laboratories who: a. is a specialist medical practitioner who is not a pathologist b. can supervise SB laboratories in the same pathology network when onsite supervision is unavailable c. can delegate supervision of laboratory operations, and preanalytical and analytical phases of pathology tests to scientists and clinical scientists with an appropriate scope of practice
Complex genomic testing in S laboratories.	4.09	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: 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 each SB laboratory, the pathology practice has: a. full-time supervision and clinical governance from an S laboratory designated person b. a supervision framework developed by the designated person c. supervising specialist medical practitioners with the appropriate scope of practice to provide supervision for each test d. supervising specialist medical practitioners from within the network to address supervisory gaps
	4.12	The pathology practice:

Item	Action	
		a. has a common clinical governance 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, experience 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 an M laboratory performs a limited range of pathology tests for patients of the associated medical practice, consistent with the qualifications, skills, and defined scope of practice of the designated person
	4.14	A pathology practice with an M laboratory provides: a. tests using IVD medical devices that are included in the ARTG or otherwise permitted for supply in Australia under the Therapeutic Goods framework[23] from the following disciplines i. haematology except immuno-haematology ii. chemical pathology iii. microbiology[24] iv. immunology
	4.15	The pathology practice's M laboratory designated person: a. is competent to provide the pathology tests performed in the laboratory and is a medical practitioner b. has completed a training program in the operation, monitoring and use of instruments required to undertake the

[23] Our regulatory framework | Therapeutic Goods Administration (TGA)
[24] The examination and interpretation of clinical specimens for clinically significant microorganisms, including antimicrobial susceptibility testing, to support the diagnosis and management of infectious disease.

Item	Action
	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 have 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, experience, and skills to provide patients with high-quality pathology services.

Consumer Outcome

Patients experience high-quality pathology services delivered by an appropriately trained, competent and qualified workforce, working within their scope of practice.

Intent of this standard

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

Explanatory notes

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

The workforce is responsible for maintaining their own competence, and the pathology practice must support them by clearly defining roles, including the qualifications, skills and experience required, assigning responsibilities, monitoring performance, and providing appropriate training.

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, experience, 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

Item	Action	
		a competency assessment process for the non-medical workforce d. supporting participation in quality assurance activities and continuing professional development (CPD) to meet 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. provides its workforce with an orientation to and training in their safety and quality roles on commencement, and when safety and quality responsibilities change b. provides access to training to meet the NPAAC Standards c. 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 pathology service experience that is equitable and adheres to the Australian Charter of Healthcare Rights.

Intent of this standard

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

Explanatory notes

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

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. This includes consideration of cultural safety

Pathology practices provide pathology service information on:

- specimen preparation
- costs
- aftercare
- results
- health care rights

Pathology practices consider the communication needs (communication channels, format, clarity and language) of patients. This supports patients to make informed decisions about their care.

People with diverse care needs

To provide equitable care, service providers need to consider how a service can support the care needs of the whole population in a way that does not disadvantage or preference one patient group over another. Some patient groups require reasonable adjustments when collecting, testing and reporting on specimens. These groups include, but are not limited to, people who are or identify as:

- Aboriginal and Torres Strait Islander People
- living with disability or frailty
- children
- culturally and linguistically diverse
- gender diverse
- LGBTQA+
- people with complex care needs
- people with cognitive impairment.

Cultural safety

Culturally safe and responsive health care is critical to improving equitable access and outcomes for patients, families and communities.

Cultural Safety

Cultural safety is determined by individuals, families and communities. In health care, culturally safe practise is the ongoing critical reflection of knowledge, skills, attitudes, practising behaviours and power differentials in delivering safe, accessible and responsive health care, free of bias, discrimination and racism.

Although cultural safety is consistently applied in the context of Aboriginal and Torres Strait Islander people, the concept may also be applied to the experiences of people with diverse cultural or social identities.

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[25] b. supports its workforce to apply the principles of the charter of rights

[25] Australian Commission on Safety and Quality in Health Care. Australian Charter of Healthcare Rights (second edition)

		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 processes comply with legislation b. enable patients to consent to specimen collection and where required, for specimen testing c. provide transparent financial information including about out of pocket expenses, when this is known, prior to specimen collection d. undertake privacy assessments on 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[26] and ensure: i. access to the necessary support to make, communicate and participate in decisions[27] ii. supporters and/or substitute decision-makers are involved in decision-making in accordance with the patient's preferences and legislation[28] b. communicate with patients in a way that meets their individual needs
Accessing specimen collection services	6.04	The pathology practice makes information available to patients and carers, including: a. the pathology collection services available 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

[26] For consumers who need assistance, supported decision making, facilitated by family, carers and/or legal guardians can ensure decisions reflect the specific needs and preferences of the person. Supported decision making that includes the consumer to the extent that they are able, also affords them dignity and respect.
[27] People who need support may be able to make some decisions with support from a family member, friend or healthcare professional. This is called supported decision-making
[28] This involves the healthcare professional engaging substitute decision-makers or nominated persons, in line with legislation

		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 f. how to provide feedback and make complaints
People with diverse care needs	6.05	The pathology practice provides a safe environment and delivers person-centred and culturally safe care when collecting specimens and communicating results

7. Communicating for safety

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

Consumer outcome

Patients experience coordinated and high-quality pathology services and have the information they need to make decisions about their care.

Intent of this Standard

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

Explanatory notes

Effective communication is fundamental to safe and high-quality pathology services.

Accurate patient identification and specimen labelling support correct matching of the patient, request, specimen and results. Failures in identification, labelling and result communication are recognised contributors to preventable patient harm, including delays in diagnosis and treatment.

This standard focuses on the points in the pathology process where communication is critical for patient safety, and where clear systems and processes are required (for example, when communicating critical results and when information is transferred between clinical and pathology environments).

While informal communication occurs routinely, the pathology practice should support reliable communication through defined responsibilities, escalation pathways and documentation practices.

Critical results are results outside defined critical limits that may indicate a life-threatening situation and require immediate notification. The pathology practice has procedures to ensure timely communication to the requester, and where the requester cannot be contacted, to other responsible healthcare providers or to the patient or carer, consistent with local arrangements and clinical risk.

Actions

Item	Action
Supporting requesters	The pathology practice supports and collaborates with requesters and the patient's other healthcare providers by: a. providing advice on the available pathology services, pathology request requirements, including the clinical information required for a request, pathology service request 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
Patient identification and service matching	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 when available c. correctly matching the patient to their pathology specimen and service d. ensuring the patient confirms the accuracy of the labels on the specimen if they are able to do so e. labelling the primary specimen and report with the approved patient identifiers f. clearly linking the primary specimen to the secondary sample g. 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 h. using approved identifiers to confirm the patient's identification when i. the pathology practice collects the specimen ii. requests are transmitted electronically iii. testing the specimen, interpreting results and

Item	Action
	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	The pathology practice uses a system and processes for communicating results that: a. supports interoperability by using standardised terminology and structures that align with SPIA guidelines[29] b. addresses the structure and content of reports, and the communication of results c. provides accurate, clear, concise, and verified written reports to requesters, patients and other healthcare providers in a clinically appropriate timeframe[30] d. ensures a competent workforce member is available to interpret results and provide advice to requesters and other healthcare providers e. ensures provisional reports are identified and documented f. ensures final reports are complete when they are communicated g. provides reports directly to patients when requested by the patient and uploads to the national health record, aligned with applicable regulatory requirements h. ensures specimens and reports are retained for the period defined by the relevant jurisdictions and standards i. ensures report amendments are documented and traceable
Reporting critical results[31]	The pathology practice uses processes for recognising and responding to critical results indicating a life-threatening condition or necessitating urgent medical intervention including processes

[29] Royal College of Pathologists of Australasia (RCPA). RCPA - SPIA Guidelines and Tools

30 The pathology practice ensures that "copy to" recipients are not assumed to be responsible for receiving, acknowledging or acting on pathology results. Accountability for result follow-up remains with the requesting practitioner unless explicitly reassigned and documented.

[31]The following resource has been developed by the RCPA - The Communication of critical and unexpected results. https://www.rcpath.org/static/f800366a-e432-47d0-9114154f8a51d3b1/draft-G158-BPR-The-communication-of-critical-and-unexpected-pathology-results.pdf

Item	Action
	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 across all operational periods[32] c. promptly notify the requester of a critical result; if the requester is not contactable, notify a responsible clinician and, where appropriate, the patient or their carer. d. document the escalation process and all steps taken to ensure communication of the critical result. e. monitor, audit and review critical result communication and escalation processes including analysis of failures, delays and near-misses, to support continuous improvement. f. identify and communicate critical results if there is system failure or downtime.
Healthcare Records	The pathology practice uses processes to: a. collect, store, and share patient information and pathology records aligned with national and jurisdictional legislation[33] b. create and maintain health care records, and ensure information is complete, accurate and up to date, aligned with the patient's consent c. ensure consistent use of standard information structures and terminology[34] d. manage healthcare records aligned with jurisdictional legislation in the event of a laboratory amalgamation, merger or closure e. train the workforce in the requirements of creating and maintaining healthcare records
Notifiable diseases	The pathology provider uses processes to document and report notifiable diseases in accordance with jurisdictional requirements

[32]This includes after hours, weekends and public holidays, and accounts for handovers, leave and on-call arrangements to ensure continuity of responsibility.
[33]For further information about sharing by default and requirements for communication: Frequently Asked Questions Modernising My Health Record (Sharing by Default) Act 2025 & Better and Faster Access to health information
[34] Royal College of Pathologists of Australasia. *Standardised Pathology Informatics in Australia (SPIA) Guidelines v4.1*

Item	Action
	and disease registries

8. Medical devices

Pathology practices ensure all medical devices, including in vitro diagnostic (IVD) medical devices are appropriate for use and well maintained.

Consumer outcome

Patients can expect that pathology services are performed using reliable medical devices that consistently generate accurate, precise, and clinically appropriate results to support safe and effective care.

Intent of this standard

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

Explanatory notes

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[35] to ensure they are used in a safe, and consistent manner.

Manufacturer's IFU

For regulated products, the IFU is a legally required document and forms part of the product's official labelling. It ensures users can use the product consistently, safely, and as intended by the manufacturer.

Actions

Item		Action
Medical device implementation and	8.01	The pathology practice uses systems for the replacement and implementation of medical devices to:

[35] Medical devices include reagents, calibrators, control materials, specimen receptacles, software, instruments, and related apparatus.

Item		Action
replacement		a. ensure medical devices are listed on the Australian Register of Therapeutic Goods (ARTG), or, where developed in house, are validated in accordance with ISO 15189 and comply with the relevant NPAAC Standards and regulatory requirements[36] and reflect industry best practice b. include appropriate consultation and change management processes c. assess the device's suitability to meet patient care requirements d. evaluates the device against the manufacturer's claimed specifications and verifies the device meets those specifications e. use recognised reference standards or methods to validate device performance f. ensure appropriate calibration, quality control, and quality assurance processes are completed prior to implementation g. actively monitor and manage the risks associated with ageing devices or devices performing below expected standards h. ensure that device performance is continuously monitored and periodically reviewed, with revalidation or verification undertaken as required following significant changes, emerging evidence, or identified risks
Medical device use	8.02	The pathology practice: a. uses medical devices for their intended purpose in accordance with the manufacturer's IFU b. classifies commercial IVD medical devices used outside their intended purpose[37] (for example, specimen types not specified in the instructions for use) as in-house IVDs c. ensures compliance with relevant NPAAC Standards and TGA requirements
Medical device maintenance	8.03	The pathology practice uses processes to ensure its medical devices are safe, fit for their intended purpose and performing optimally by:

36 Class 4 in-house IVDs are generally required to be included in the ARTG unless an exemption applies. New Class 1–3 in-house IVDs must be notified to the TGA annually (where required). All in-house IVDs must have post-market monitoring arrangements in place, including adverse event reporting.
37 for example, specimen types not specified in the Manufacturer's IFU.

Item		Action
		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 the manufacturer's IFU d. conducting planned maintenance and repair according to the manufacturer's IFU, using appropriately qualified personnel e. performance testing devices after maintenance and repair f. maintaining the device's maintenance and repair log
In-house in vitro diagnostic medical device	8.04	The pathology practice validates the clinical and analytical performance of its in-house in vitro diagnostic (IVD) medical devices and ensures they: a. Comply with the Therapeutics Goods Administration (TGA) requirements for in-house IVDs b. are assessed to the NPAAC Requirements for the development and use of in-house in vitro diagnostic medical devices[38] c. demonstrate, through validation[39], that their clinical and analytical performance is fit for the intended purpose and supports safe and effective patient care

[38] Requirements for the Development and Use of In-House In Vitro Diagnostic Medical Devices (Sixth Edition) | Australian Commission on Safety and Quality in Health Care

[39] **Validation (In-house IVD)** Validation is the documented process of generating objective evidence to demonstrate that an in-house in vitro diagnostic (IVD) is fit for its intended clinical purpose, consistently produces reliable and accurate results, and meets applicable NPAAC performance requirements prior to its use in patient management. As a general principle, validation must be completed before an in-house IVD is used clinically. This requirement also applies to tests or components labelled as "research use only," "not for diagnostic use," or supplied as analyte-specific reagents, where the results are intended to inform diagnosis, treatment, or other aspects of patient management.

Limited exception:

As outlined in NPAAC requirements for in-house IVDs, full validation may be incomplete at the time of clinical use only in circumstances where:

- validation cannot reasonably be completed, and
- no suitable validated alternative assay is available, and
- the test is used in restricted circumstances such as:
  - rare or emerging conditions,
  - uncommon applications where validation requirements cannot be fully met, or
  - urgent public health situations.

In these circumstances:

- the limitations of validation must be clearly disclosed in the patient report,
- a documented validation plan must be in place,

Item		Action
		d. are supported by documented evidence of validation, including methodology, performance characteristics, and acceptance criteria e. are subject to ongoing quality assurance processes to ensure continued performance over time
Adverse medical device events	8.05	The pathology practice reports adverse events involving commercial and in-house in vitro diagnostic medical devices to the TGA: a. within the specified time frames b. in the required format c. in line with regulatory requirements
IVD software and artificial intelligence (AI) systems Governance and Implementation	8.06	The pathology practice uses processes to govern the selection, implementation and management of IVD software, including artificial intelligence (AI) systems, used to interpret data or determine results, to: a. ensure commercial IVD software is included in the Australian Register of Therapeutic Goods (ARTG) b. ensure in-house IVD software, including AI systems used for diagnostic purposes, are managed as in-house IVDs and comply with relevant NPAAC Standards, Therapeutic Goods Administration (TGA) requirements and industry best practice c. ensure selection, implementation and use occur within the pathology practice's clinical governance and risk-management framework, including management of privacy, cyber-security and data-integrity risks d. undertake a privacy impact assessment to: i. ensure compliance with Australian privacy law ii. ensure the privacy, confidentiality and security of patient data, including where third-party providers process data

- all available validation evidence must be retained, and
- validation must be completed within an accreditation cycle, except where there are specific factors that limit the availability of positive samples for a validation study and a risk assessment has been performed by the laboratory.

Item		Action
		e. ensure acceptance testing and commissioning confirm performance for the intended use, user population and clinical context f. ensure AI system performance is evaluated prior to clinical use and monitored over time to confirm it continues to operate within defined performance expectations g. ensure that where training data are not derived from Australian populations, AI system performance is evaluated using data relevant to the intended patient population, with limitations documented and risks mitigated
IVD software and artificial intelligence (AI) systems clinical use and oversight	8.07	The pathology practice must use processes for the safe and appropriate use of IVD software, including artificial intelligence (AI) systems, by: a. ensuring IVD software and AI systems are used only for their intended purpose and are supported by objective evidence of clinical benefit or clinical utility, where this can be reasonably established, or otherwise by evidence that the system improves diagnostic accuracy, efficiency, or clinical decision-making b. ensuring the workforce is trained to use IVD software and AI systems appropriately, understands system limitations, and exercises clinical judgement when reviewing AI-assisted outputs c. monitoring the workforce to ensure they operate within their defined roles and scope of practice when using IVD software and AI systems d. clearly defining responsibility for reviewing, correcting where necessary, and approving AI-assisted results within the supervision and delegation framework e. ensuring information about the use of AI in interpreting pathology tests or generating reports is communicated transparently to patients where clinically appropriate, and does not diminish the medical practitioner's responsibility for the accuracy of results f. ensuring significant AI-related incidents or adverse events are documented, investigated and reported in accordance with regulatory and governance requirements

9. Specimen collection

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

Consumer Outcome

Patients are provided with the information they need about specimen collection, and the collection is undertaken in a safe environment. They can be confident that they are correctly identified and that their specimen is accurately matched to them

Intent of this standard

To ensure that patients are correctly identified and prepared, specimens are collected in accordance with manufacturer's instructions and laboratory requirements, and specimen integrity is maintained.

Explanatory note

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, function and maintenance of the facilities and equipment support safe care

Item	Action	
		c. providing access to an environment, facilities, equipment and devices that are fit for purpose, well-maintained and meet the needs of patients d. facilitating access to the specimen collection areas by providing clear signage and directions e. ensuring privacy, dignity and safety of patients f. ensuring fall prevention strategies are in place g. developing strategies to minimise the risks of harm when risk of unpredictable behaviour is identified h. 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, where possible
Infection prevention and control	9.02	The pathology practice uses infection prevention and control processes in collection centres: a. to maintain a clean, safe and hygienic environment consistent with the *Guidelines for the Prevention and Control of Infection in Health Care*[40] and state or territory requirements b. to clean and disinfect medical devices using products listed on the *Australian Register of Therapeutic Goods*[41] in a manner consistent with the manufacturer's 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[42] f. that comply with the *Australian Immunisation Handbook*[43] and jurisdictional requirements for vaccine-preventable diseases for the workforce
Recognising acute	9.03	The pathology practice supports specimen collectors by:

[40] Australian Guidelines for the Prevention and Control of Infection in Healthcare (2019) | NHMRC
[41] About the Australian Register of Therapeutic Goods (ARTG) | Therapeutic Goods Administration (TGA)
[42] National Hand Hygiene Initiative (NHHI) | Australian Commission on Safety and Quality in Health Care
[43] The Australian Immunisation Handbook

Item	Action	
deterioration and escalating care		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 according to the identified pathology service risks c. maintaining the 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 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 IFU 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
Optimising specimen collection	9.06	The pathology practice optimises specimen collection by ensuring: a. consumables are available, in date, and easy to locate and use

Item	Action	
		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 for specimen integrity failure
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[44] and critical requests[45]	9.08	The pathology practice ensures: d. high acuity settings know who is responsible for collecting and transporting pathology specimens e. evidence-based approaches are used to collect and transport specimens from high acuity settings, so testing occurs within the clinically optimal timeframe f. there are processes to identify, track, and monitor progress of the high acuity setting or critical request samples through the laboratory g. requesters from high acuity settings have access to test turnaround times and the critical results notification process h. there is a process for a requester to inform the laboratory of their suspicion of a critical result, or their confirmation of a critical request, so specimen testing can be expedited and results communicated promptly

[44] **High acuity setting**
A healthcare environment in which patients have serious, unstable or complex clinical conditions requiring urgent assessment, close monitoring and rapid clinical intervention. High acuity settings include, but are not limited to, emergency departments, intensive care units, critical care units, operating theatres and other settings where delays in pathology testing or result communication may pose an immediate risk to patient safety

[45] **Critical request**
A pathology request identified by the requester or the pathology practice as requiring urgent prioritisation because delayed specimen collection, testing or result communication may result in significant patient harm. A critical request is managed through defined processes for prioritisation, tracking, expedited testing and timely communication of results, including escalation where required.

10. Specimen testing

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

Consumer outcome

Patients expect pathology tests to be performed correctly and results to be reported accurately.

Intent of this standard

To ensure:

- patient specimens are tested according to manufacturers' instructions or validated and authorised pathology practice protocols
- quality control and assurance procedures are in place, so test results are representative
- 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 mitigate risks to patient safety. See also Standard 8.

Actions

Item		Action
Analytical and clinical performance requirements	10.01	The pathology practice must have the following documented for all areas of testing: a. analytical performance and clinical performance requirements using key indicators for quantitative analysis, including but not limited to accuracy, precision, limits of detection, units of measure and assessment of common interference. b. analytical and clinical performance and using key indicators for qualitative analysis

Item		Action
	10.02	The pathology practice must: a. ensure the analytical performance meets the assay's clinical application requirements b. ensure that for morphological and interpretive testing, diagnostic performance is supported by peer review, IQA, and EQA activities, ensuring alignment with intended clinical use. c. ensure unverified tests only occur in exceptional circumstances or for rare or new diseases d. ensure that when new or uncommon morphological assessments are undertaken, appropriate peer consultation and review is used to support diagnostic confidence e. have processes to confirm test result comparability when different methods or devices are used f. for morphological analysis, ensure comparability of diagnostic interpretation is supported through documented peer review and case comparison across practitioners, using formal sample exchange, formal second opinion and informal second opinion where relevant g. ensure test procedures are documented, authorised and readily available to the workforce. These include: i. definitions of which diagnostic specimen types and/or diagnoses require mandatory peer review ii. the peer-review processes to be followed iii. procedures for managing discordant diagnoses, including documentation, escalation, and resolution pathways
Measurement uncertainty process	10.03	The pathology practice uses 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 MU and opportunities for their reduction f. uses statistically significant number of replicate measurements, where possible, to ensure accurate

Item		Action
		assessment of MU, or uses statistical methods to account for lower numbers of replicate measurements
Measurement uncertainty	10.04	The pathology practice: a. ensures the effort to determine the MU is commensurate with the quality requirements of the clinical application of the results b. sets routine performance goals for MU and where the goal is not met, identifies and reduces the sources of uncertainty c. uses the MU processes to: i. demonstrate that assays meet the acceptable performance goal and are clinically applicable ii. identify tests where an estimation of MU is not possible and minimise potential risks d. ensures MU data is available for requesters and other healthcare providers e. uses the MU for specific tests, where defined, to inform data monitoring and troubleshooting
Quality control process	10.05	The pathology practice: a. ensures the designated person oversees quality control (QC) processes b. ensures all laboratory assays have a documented QC process that assesses the test's performance c. specifies in the documented QC process d. the criteria for QC targets at clinical decision levels and the results acceptable for patient testing e. alternative QC mechanisms to ensure validity of testing when internal QCs are not available f. 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 i. has systems to monitor quality control performance, take corrective action and issue reports ii. documents quality control results and retains them in accordance with relevant standards
Frequency of quality control	10.06	The pathology practice tests QC samples at a frequency based on the stability and robustness of the examination method, the risk of

Item		Action
testing		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
Test procedures	10.07	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 throughout specimen testing, reporting and 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	10.08	The pathology practice uses 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 evidence-based reference intervals to interpret outputs iv. have evidence-based clinical decision limits[46] b. the results are correct, evaluated against internal quality controls, timely, unambiguous, clinically relevant and traceable to the request

[46] **Evidence-based clinical decision limits**
Clinically validated result thresholds, derived from evidence-based sources, used to inform diagnosis, treatment or clinical action. Clinical decision limits may be derived from clinical guidelines, peer-reviewed literature, regulatory or professional body recommendations, or validated outcome-based studies, and may differ from population-based reference intervals.

Item		Action
		c. that when a clinically non-validated test is performed, the report indicates that the diagnostic validity has not been established d. critical result thresholds end escalation processes are documented
Disposal of biological material	10.09	The pathology practice: a. has a waste management policy b. complies with jurisdictional regulations relating to the disposal of biological material from pathology testing
External quality assurance programs	10.010	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 with EQA programs 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	10.11	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

Item		Action
		c. where morphological EQA programs submissions are collegiate, states this clearly on the response
Internal quality assurance	10.12	In the absence of suitable EQA programs, the pathology practice uses 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 material or comparing across laboratories (for example, sample exchange programs) 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 systems, supervision and testing and reporting systems support the delivery of high-quality point of care testing.

Consumer outcome

Patients receive timely and accurate testing and results using PoCT

Intent of this Standard

To support the delivery of high-quality Point of Care Testing (PoCT). Requirements for PoCT include effective clinical governance, safety and quality systems, a competent workforce, effective management of medical devices, and a safe environment.

Explanatory notes

Technological advances now allow pathology tests to be performed close to the patient, known as pathology point-of-care testing (PoCT). The use of PoCT in Australia has increased significantly, along with the complexity of the tests available. PoCT supports faster clinical decision-making, improves patient convenience and compliance, and increases access to pathology services, particularly in rural and remote areas.

However, despite these advances, PoCT presents implementation challenges. These include maintaining quality control, proper documentation, storage requirements, staff training, and accurate recording of results. Errors such as incorrect patient identification, issues with sample collection or processing, and failure to recognise abnormal or inconsistent results can lead to inaccurate test outcomes and inappropriate clinical decisions, posing risks to patient care

Point of Care Testing

Point-of-care testing (PoCT) refers to pathology or diagnostic testing performed at or near the site of patient care, typically outside the conventional laboratory setting, with results available rapidly to support immediate clinical decision-making during a patient's episode of care

Actions

Item	Action	
Contracted services	11.01	Where the pathology practice coordinates PoCT for a health service, it has an agreement that specifies the roles and responsibilities of each party
Roles and responsibilities	11.02	The pathology practice uses processes to ensure the pathology workforce performing PoCT: a. are sufficiently skilled, competent and working within their scope of practice b. can perform, interpret, monitor and produce reliable PoCT results c. understand their PoCT roles, responsibilities and accountabilities, and supports them to fulfil these roles
PoCT training	11.03	The pathology practice ensures: a. the training delivered to the workforce is dependent on 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 IVD medical device 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 f. a review of roles, knowledge, experience and skills is completed regularly and when a PoCT IVD medical device or service is introduced or altered
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 procedures	11.06	In addition to a pathology practice's specimen test procedures, the practice's PoCT procedures: a. include traceability of samples to the original specimen, patient, and PoCT IVD 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 responsible for different aspects of care is important for ensuring that carer engagement is effective.
Clinical Governance	The combination of organisational culture, systems and structures that enables everyone in a service to deliver consistently high-quality pathology services.
Clinical governance	An integrated component of corporate governance that ensures the pathology workforce understands their roles and accountability for delivering high-quality services. It combines organisational culture, systems, and structures to achieve consistently high-quality, patient-focused care.

Term	Definition
Clinical performance	Ability of an in-house in-vitro diagnostic IVD medical device, including in-house IVDs, 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. a. Fellowship of the Australasian Association of Clinical Biochemistry and Laboratory Medicine. b. Fellowship of the Australian Institute of Medical and Clinical Scientists. c. Fellowship of the Australian Society for Microbiology (medical microbiology or clinical microbiology). d. Fellowship of the Human Genetics Society of Australasia (biochemical genetics, cytogenetics or molecular genetics). e. Fellowship of the Faculty of Science of the Royal College of Pathologists of Australasia (by examination). f. Fellowship of the Australian Society of Cytology. g. Doctor of Philosophy, Australian Qualifications Framework level 10[47] or equivalent doctoral level degree, in a subject relevant to the scope of diagnostic testing of the laboratory they are supervising. h. For assisted reproductive technology laboratories, the clinical scientist must meet the criteria in the Reproductive Technology Accreditation Committee code of practice for scientific directors. i. For haemopoietic cellular therapy laboratories, the clinical scientists must meet the requirements of the Bone Marrow Transplant Scientists Association of Australasia (BMTSAA) including holding appropriate higher degree qualifications, relevant experience in cellular therapy laboratory practice, and documented evidence of competency and ongoing professional development. j. For American Society of Histocompatibility and Immunogenetics accredited laboratories, the clinical scientist must meet the

[47] **Australian Qualifications Framework: second edition**. Adelaide (SA): Australian Qualifications Framework Council; 2013. Available from: https://www.aqf.edu.au/publication/aqf-second-edition

Term	Definition
	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 Aboriginal health practitioners, nurses, midwives, medical practitioners, allied health professionals, paramedics and other professionals who provide health care, and students who provide health care under supervision. For genetic testing, a health professional would also include a genetic counsellor.
Competence	Demonstrated ability to apply the requisite knowledge, skills and judgement to perform duties safely, effectively and in accordance with applicable standards and scope of practice.
Complex testing	Testing that requires a high level of technical expertise, interpretative skill and judgement, and rigorous quality assurance.
Confidentiality	The state of keeping or being kept secret or private. *Protection of information from unauthorised access, use or disclosure.*
Consumer	A person who has had or may have a pathology service, or their representative or advocate.
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.
Delegation	The act of assigning authority for supervision of a pathology test from one person to another, while the original person retains ultimate responsibility for the outcome.
Designated person	A person named under section 23DN of the Health Insurance Act 1973 as responsible for a premises' compliance with standards, including oversight of governance, risk, quality systems, supervision, and critical result communication.
Environment	The context or surroundings in which health care is delivered. The environment can include other patients, consumers, visitors and the workforce.

Term	Definition
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 agency external to the pathology practice. The external agency provides samples, and the laboratory results are evaluated externally and compared to peers or a reference laboratory who are undertaking the same test with the same methodology.
Governing body	The highest level of governance responsible for strategic and operational decisions of pathology practices.
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 unique IHI.
Healthcare vs. health care	Healthcare is used as an adjective; health care is used as a noun.
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.
High-quality care	Pathology services that are person-centred, safe, effective, accessible, integrated, equitable, efficient, and sustainable.

Term	Definition
In vitro diagnostic (IVD) medical device	IVD medical device, or in vitro diagnostic medical device, means a medical device that is: a. a reagent, calibrator, control material, kit, specimen receptacle, software, instrument, apparatus, equipment or system, whether used alone or in combination with another diagnostic product for in vitro use; and b. intended by the manufacturer to be used in vitro for the examination of a specimen derived from the human body, solely or principally for: i. (giving information about a physiological or pathological state or a congenital abnormality; or ii. determining safety and compatibility with a potential recipient; or iii. monitoring therapeutic measures. *(Therapeutic Goods (Medical Devices) Regulations 2002)*
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.
Interoperability	Is the ability to move information easily between people, organisations and systems. It enables a connected healthcare system that shares health information securely, safely and without any special effort from the people and organisations involved.
Laboratory categories	Accreditation criteria grouping laboratories by specialty and governance relationships.
Low-value care	Care that provides little or no benefit, may cause patient harm, or yields marginal benefits at a disproportionately high cost.

Term	Definition
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. a. Diagnosis, prevention, monitoring, treatment or alleviation of disease. b. Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap. c. Investigation, replacement, modification or support of the anatomy or of a physiological process. d. Supporting or sustaining life. e. Control of conception. f. Disinfection of medical devices. g. Providing information for medical purposes by means of in vitro examination of specimens derived from the human body. h. 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 Laboratory Network (See Pathology Network)	A group of pathology laboratories that are under the same APA and governance structure.
Medical practitioner	A person who has a medical degree and has current registration with AHPRA – Medical Board of Australia.
National health care identifier	A unique 16-digit number that is used to identify individuals, clinicians or organisations that deliver healthcare in the Australian healthcare setting. Also known as the individual healthcare identifier.
Pathologist	Specialist medical practitioner who studies 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:

Term	Definition
	a. Anatomical pathology b. Chemical pathology c. Forensic pathology d. General pathology e. Genetic pathology f. Haematology g. Immunopathology h. 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.
Pathology laboratory	Premises where biological samples are examined to support diagnosis, monitoring, and treatment.
Pathology network (Also Medical Laboratory Network)	A group of pathology laboratories that are under the same APA and governance structure.
Pathology practice	An entity overseeing laboratories and collection centres with responsibility for services, governance, and administration.
Pathology service	A test performed on a patient specimen following a clinician's request.
Pathology test supervision	Oversight of all testing phases by qualified staff within their scope of practice.
Patient	A person receiving pathology services.
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.

Term	Definition
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 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.

Term	Definition
Risk assessment	Overall process comprising risk analysis and evaluation.
Risk management	The design and implementation of a program to identify and avoid or minimise risks to patients, employees, volunteers, visitors and the organisation.
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: a. Australian University and which contains subjects relevant to pathology b. an overseas university recognised as such by local legislation and which is accredited by the Australian Institute of Medical and Clinical Scientists c. 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.
Scope of practice	The range of activities a worker is trained and competent to perform.
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

Term	Definition
	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 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.
Sustainability	Embedding environmental responsibility into operations to reduce waste and resource use.
Systems	Organised resources, policies, processes, and procedures used to achieve safety and quality goals.
Technician	This person must possess qualifications at Australian Qualifications Framework level 5 or above awarded by an: a. Australian tertiary level institution which contains subjects relevant to pathology b. 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 c. 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.
Training	The development of the workforce's knowledge and skills.
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

Term	Definition
	patient diagnosis or product use.
Workforce	All individuals contributing to pathology services, including employees and contractors.

Summary of designated person requirements by laboratory category

Category	Designated person	Employment / availability	Delegation and supervision arrangements	Considerations
GX	Pathologist. **See Action** 4.01.	Full-time appointment.	Only supervises tests within their scope of practice. May delegate supervision to other pathologists at GX, GY and B laboratories in the same pathology network when tests are outside their scope and the other pathologist has the relevant scope of practice. May delegate supervision of laboratory operations and pre-analytical/analytical phases to scientists and clinical scientists with appropriate scope of practice.	Each GX laboratory has a designated person. GX designated person has responsibility for clinical governance for associated GY and B laboratories in the same pathology network. **See Actions** 4.01, 4.02.
GY	As for GX (clinical governance responsibility rests with the GX designated person for the network).	Not specified separately in this document (see GX requirements and network supervision framework).	Operates in accordance with the pathology network's supervision framework developed by the designated person. Where possible, supervising pathologists onsite provide test supervision; supervisory gaps are addressed by supervising pathologists from within the pathology network.	Must be associated with a GX laboratory in the same pathology network. **See Actions** 4.03, 4.04, 4.05.
B	As for GX (clinical governance responsibility rests with the GX designated person for the network).	Not specified separately in this document (see GX requirements and network supervision framework).	Operates in accordance with the pathology network's supervision framework developed by the designated person. Where possible, supervising pathologists onsite provide test supervision; supervisory gaps are addressed by supervising pathologists from within the pathology network.	Must be associated with a GX laboratory in the same pathology network. Ongoing risk assessment of adequacy of onsite supervision is required for GY/B laboratories. **See Actions** 4.03, 4.04, 4.05.

Category	Designated person	Employment / availability	Delegation and supervision arrangements	Considerations
S	Specialist medical practitioner who is not a pathologist. **See Action** 4.08.	Not specified as full-time in this document.	May supervise SB laboratories in the same pathology network when onsite supervision is unavailable. May delegate supervision of laboratory operations and pre-analytical/analytical phases to scientists and clinical scientists with appropriate scope of practice.	Performs a limited range of tests for a target patient population related to the designated person's qualifications, skills and scope of practice. Applies to become GX if wider scope is proposed. **See Action** 4.07. Additional requirements apply where complex genomic testing is performed (genetic pathologist plus clinical scientist with relevant scope of practice). **See Action** 4.09.
SB	Clinical governance and full-time supervision provided by an S laboratory designated person (specialist medical practitioner who is not a pathologist).	Full-time supervision and clinical governance from S laboratory designated person.	Designated person develops the supervision framework for the pathology network. Supervising specialist medical practitioners with appropriate scope of practice provide supervision for each test; supervisory gaps addressed by supervising specialists from within the network.	Must be associated with an S laboratory in the same pathology network. **See Action** 4.10.
M	Medical practitioner competent to provide the tests performed in the laboratory.	Not specified as full-time in this document.	Designated person has completed training in the operation, monitoring and use of instruments as described in manufacturer/laboratory manuals and any legislative requirements and has scientific knowledge and experience using the equipment and analytical procedures employed. Supervision framework includes delegations that outline who have authority during operational hours.	Performs a limited range of tests for the medical practice's patients, directly related to the designated person's qualifications, skills and scope of practice. Test disciplines are limited to those listed for M laboratories. **See Actions** 4.13, 4.14, 4.15, 4.16.

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