REQUIREMENTS FOR MEDICAL PATHOLOGY SERVICES
(Second Edition 20XX)

Draft for public consultation - June 2017
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The National Pathology Accreditation Advisory Council (NPAAC) was established in 1979 to consider and make recommendations to the Australian, state and territory governments on matters related to the accreditation of pathology laboratories and the introduction and maintenance of uniform standards of practice in pathology laboratories throughout Australia. A function of NPAAC is to formulate Standards and initiate and promote education programs about pathology tests.

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

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

This is the overarching document outlining the standards for good medical pathology practice, where the primary consideration is patient welfare, and where the needs and expectations of patients, laboratory staff and referrers (both for pathology requests and inter-Laboratory referrals) are safely and satisfactorily met in a timely manner. Providers of Medical Pathology Services must adhere to these and all other NPAAC Requirements in order to achieve accreditation and to ensure the safety, efficacy and quality of all medical pathology testing.

These Tier 2 Requirements are supported by, and must be read in conjunction with, the other NPAAC publications as listed in Tiers 3 and 4 within the NPAAC document hierarchy published on the NPAAC website. Failure to meet these Requirements may pose a risk to the health and safety of both the providers and users of the laboratory.
### Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>ACSQHC</td>
<td>Australian Commission on Safety and Quality in Health Care</td>
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<td>APA</td>
<td>Approved Pathology Authority</td>
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<td>APL</td>
<td>Accredited Pathology Laboratory</td>
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<td>AS</td>
<td>Australian Standard</td>
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<tr>
<td>EQA</td>
<td>External Quality Assurance</td>
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<tr>
<td>ISO</td>
<td>International Organization for Standardization</td>
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<td>IVD</td>
<td>In Vitro Diagnostic Device</td>
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<td>NPAAC</td>
<td>National Pathology Accreditation Advisory Council</td>
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<tr>
<td>NSQHSS</td>
<td>National Safety and Quality Health Service Standards</td>
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<tr>
<td>OH&amp;S</td>
<td>Occupational Health and Safety</td>
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<tr>
<td>QA</td>
<td>Quality Assessment</td>
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<td>RCPA</td>
<td>Royal College of Pathologists of Australasia</td>
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<td>TGA</td>
<td>Therapeutic Goods Administration</td>
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**Definitions**

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<tr>
<th>Term</th>
<th>Definition</th>
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<tr>
<td>Clinical Governance</td>
<td>means a systematic and integrated approach to assurance and review of clinical responsibility and accountability that continually improves quality and safety of services provided to patients resulting in optimal patient outcomes. Clinical governance extends across the boundaries of functions and organisation delivering services along with whole patient care cycle. Interfaces in, or split responsibility for, delivering patient care are considered points of increased risk.</td>
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<td>Clinical Handover (or Communicating for Patient Safety)</td>
<td>means the transfer of professional responsibility and accountability for some or all aspects of a patient's care to another person or professional group on a temporary or permanent basis.</td>
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<tr>
<td>Equipment</td>
<td>means instruments, reference materials, consumables, disposables, reagents, cabinets (incubators, refrigerators), analytical systems and electronic information systems.</td>
</tr>
<tr>
<td>External Quality Assessment</td>
<td>means a program in which specimens are periodically sent to laboratories for analysis and/or identification with each laboratory's results are compared with those of other laboratories in the group and/or with an assigned value, and reported to the participating Laboratory and others. Such a program may also compare an individual’s results with their peer group.</td>
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<tr>
<td>Informative (as applied to Commentaries and Appendices)</td>
<td>means the material is presented to assist in the application or interpretation of the Standards to which it is attached.</td>
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</table>
| Laboratory | means premises where Medical Pathology Services are performed. A laboratory may be stand alone or be part of a network of laboratories.  

A laboratory may be in the same healthcare precinct where pathology services in more than one group of pathology services are performed, or it may be a part of such a laboratory in which pathology tests in a specific discipline or group of pathology services are performed. The premises include all locations in the same healthcare precinct, where pathology services are performed.  

Thus a laboratory may be a medical device in a medical practice or it may be a chemical pathology laboratory in a large teaching hospital, which is part of a pathology laboratory network. |
<table>
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<tr>
<th>Term</th>
<th>Definition</th>
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| Medical Pathology Service                 | means any service whereby pathology testing provides information for –  
• Diagnosis, exclusion and monitoring of disease processes and their treatment  
• health screening  
• epidemiological purposes.                                                                                           |
| Normative (as applied to Commentaries and Appendices) | means prescriptive or mandatory. The material carries the same weight as the Standards to which it is attached.                                                                                      |
| Quality Assessment                        | means a measurement and monitoring function of quality assurance for determining how well health care is delivered in comparison with applicable standards or acceptable bounds of care.                             |
| Quality Assurance                         | means a part of quality management focused on providing confidence that quality requirements will be fulfilled.                                                                                     |
| Quality System                            | means those management activities involved in the direction and control of the organisation with regard to quality.                                                                                   |
| Reference Standards                       | means standards developed to meet a certain requirement.                                                                                                                                             |
| Request-Test-Report Cycle                 | means the initiation of pathology requests, most commonly by a medically qualified individual for the purpose of patient diagnosis or management (Requester), the informed cooperation of the patient, the performance of the requested pathology tests by a pathologist and/or pathology provider (Pathology Provider), and the reporting of the test results and/or professional opinions back to the Requester or their nominated delegate.  
Request means pre-analytical  
Test means analytical  
Report means post-analytical                                                                                       |
| Specimen                                  | means any tissue or fluid from a patient that is submitted to the Laboratory for testing.                                                                                                               |
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Introduction

The first set of National Pathology Accreditation Advisory Council (NPAAC) pathology accreditation standards and guidelines were referenced within the *Health Insurance Act 1973* in 1986, with the introduction of a compulsory accreditation system in relation to Medicare benefits for pathology. The NPAAC accreditation framework has continued to evolve since that time.

The *Requirements for Medical Pathology Services (Second Edition 20XX)* is the Tier 2 document and is the overarching document that outlines the minimum standards acceptable for good laboratory practice that are applicable to all medical pathology testing. The Requirements should be read within the context of the national pathology accreditation legislative framework and *AS ISO 15189 Medical laboratories – Requirements for quality and competence*.

The Requirements have been reviewed to reflect a risk-based approach and current best practice with the aim of ensuring the safe performance of pathology testing and delivery of quality results for the benefit of patient outcomes.

Whilst developing and revising these standards existing NPAAC publications (including those being reviewed at the time) were used as source material. Additional sources of materials included *AS ISO 15189*, *National Safety and Quality Health Service Standards* and the *RCPA Chain of Custody for the Pathology Request-Test-Report Cycle Guidelines*.1

NPAAC Requirements apply to all laboratories seeking accreditation and must be applied in conjunction with jurisdictional and other regulatory requirements.

NPAAC recognises that medical pathology testing is also performed outside the traditional laboratory and thereby the pathology accreditation framework. However, the Requirements should be used for guidance on best practice wherever medical pathology services are provided.

These Requirements are intended to serve as minimum standards in the pathology accreditation process and are aligned with the *National Safety and Quality Health Service Standards* developed by the ACSQHC2, where possible.

These Standards have been developed with reference to current and proposed Australian regulations and other standards from the International Organization for Standardisation (ISO) including:

*AS ISO 15189 Medical laboratories – Requirements for quality and competence*

In each section of the document, points deemed important for practice are identified as ‘Standards’ or ‘Commentaries’.

- A Standard is the minimum requirement for a procedure, method, staffing resource or facility that is required before a Laboratory can attain accreditation – Standards are printed in bold type and prefaced with an ‘S’ (e.g. S2.2). The word ‘**must**’ in each Standard within this document indicates a mandatory requirement for pathology practice.
A Commentary is provided to give clarification to the Standards as well as to provide examples and guidance on interpretation. Commentaries are prefaced with a ‘C’ (e.g. C1.2) and are placed where they add the most value. Commentaries may be normative or informative depending on both the content and the context of whether they are associated with a Standard or not. Note that when comments are expanding on a Standard or referring to other legislation, they assume the same status and importance as the Standards to which they are attached. As a general rule, where a Commentary contains the word ‘must’ then that Commentary is considered to be normative.


While this document is for use in the accreditation process, comments from users would be appreciated and can be directed to:

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All providers of Medical Pathology Services must be familiar with and have access to, the current international standard AS ISO 15189 *Medical laboratories– Requirements for quality and competence* and to the National Safety and Quality Health Service Standards developed and maintained by the Australian Commission on Safety and Quality in Healthcare.

NPAAC Requirements have been developed with consideration of other national and international standards and endeavour to minimise any duplication of standards where possible.
1. The Role of Standards in the Australian Pathology Accreditation Framework

Pathology services can be regarded as a vital clinical service that underpins Australia’s high performing healthcare system. This important role was recognised with the introduction of a mandatory regulatory framework in 1986. The objective of legislation under which NPAAC was established was to ensure the safety of Australians undergoing pathology testing and to promote a consistent standard of practice through the development of Standards for the purpose of accreditation.

NPAAC Standards are developed for application in the Australian legal and regulatory framework and recognise the settings and models of service that exist in Australia. They reference other national standards and international standards where they are suitable for application in the Australian context.

NPAAC applies a risk based approach to the pathology accreditation framework. This approach calls for a focus on areas of high potential risk and on the prevention of harm to patients and to the Australian public more broadly, and support of better health outcomes. The Standards are intended to provide minimum, evidence based standards for best practice in pathology.

NPAAC Standards reference other relevant national and international standards, such as those developed by the Australian Commission for Quality and Safety in Healthcare, and relevant ISO standards, in particular *AS ISO 15189: Medical Laboratories, requirements for quality and competence*.

Australian pathology laboratories must meet NPAAC accreditation standards that are specified in the *Health Insurance (Accredited Pathology Laboratories-Approval) Principles 2002* in order to achieve pathology accreditation and be eligible to receive Medical Benefits Schedule rebates for pathology services. Laboratories are assessed to the NPAAC requirements by an independent assessing body.

**S1.2** Where an NPAAC Standard exists, it must be met for the purposes of accreditation.

**S1.3** In the absence of an explicit NPAAC or referenced standard, the AS ISO 15189 Standard must be met for the purposes of accreditation.

**C1.3** A referenced standard has been developed to meet a special requirement in a field on medical testing by for example a pre-eminent specialist society. An example of this is seen in *Requirements for Transfusion Laboratory Practice* (C14.1).
2. Ethical Practice

S2.1 The wellbeing of patients and their rights must be primary considerations.

C2.1 The patient must be given the opportunity to provide information for the pre-analytical and post-analytical phases of the Request-Test-Report Cycle, for example the provision of information to the patient regarding the test process, associated costs, or when to expect results.*

S2.2 Laboratories must have an open disclosure policy and procedure that allows for a discussion with a patient (and/or their support person(s)) about a patient safety incident that did result or may have resulted in harm to that patient.

S2.3 Patients, their Specimens and body parts must be treated with respect.

C2.3 This Standard also applies to the deceased.

S2.4 Policies and procedures that define ethical standards of laboratory practice must be in place.

C2.4(i) These policies and procedures must address any commercial, financial or other influences which could adversely affect the provision of services, the quality of the work or bring into question the integrity of the laboratory.

C2.4(ii) Conflicts of interest must be assessed, managed and documented through a risk management tool.

S2.5 There must be a policy regarding informed consent consistent with jurisdictional requirements.

C2.5(i) Apart from autopsies ordered by the Coroner, written consent must be obtained from the next of kin or relevant authority for autopsy and Specimen/body part retention. The patient may also give consent ante-mortem.

C2.5(ii) Consent and/or ethical approval may be required for Specimen/body part retention for research, quality activities, and education purposes. In this context it is recognised that de-identified Specimens are retained for quality assurance purposes.

C2.5(iii) It is inferred that informed consent has been obtained from the patient by the referring practitioner when the patient allows the collection or procedure to be carried out. For some tests specified in technical documents, it is the requesting practitioner’s responsibility to obtain written informed consent e.g. genetic testing, HIV testing.

C2.5(iv) Consent should also include informed financial consent.

S2.6 The privacy and confidentiality of patients must be maintained at all times.

* Medical Board of Australia Good Medical Practice: A Code of Conduct for Doctors in Australia
S2.7 APAs must have policies and procedures in place to ensure the ongoing availability and integrity of materials and records in the event of amalgamation, merger or cessation of a laboratory service.

S2.8 Pathology service providers are responsible for retaining or providing storage for pathology records upon closure of their practices in accordance with current relevant state and territory legislation.

C2.8(i) In the event of closure of a laboratory or death of the proprietor, the receiver or estate must ensure compliance with the relevant state and territory legislation in relation to retention of records and materials.†

C2.8(ii) Pathology service providers are obliged to make health information available to another health service provider at the request of the patient, or where requested by an health professional acting for, or on behalf of, the patient.

C2.8(iii) Laboratories should develop a contingency plan for the retention of materials and records in the event of future closure or amalgamation.
3. Risk Management

Contemporary international governmental regulatory practice supports a risk based approach to regulation. This approach calls for a focus on the prevention of harm and the promotion of better health outcomes and prioritises a proactive approach to the prevention of harm over unfocussed compliance processes. This approach supports the attainment of the overall objectives of the legislative mandate. It also acts as a tool for prioritisation and the allocation of resources by the regulated entity and the accrediting body.

S3.1 Laboratories must identify key risks to patient safety, collect data and monitor the performance of the laboratory in managing these risks (refer to Appendix A).

S3.2 Laboratories must demonstrate that there is a regular review of potential risks, and actual adverse incidents to patients generated by failures in the pathology request – test-report cycle and that a proactive approach is taken to the prevent harm and promote better outcomes.

C3.2 There are many resources, including ISO 31000, outlining the elements of a risk management framework. Compliance with a particular standard is not sought as successful risk management ultimately depends on the application of the risk management process to individual decisions.

S3.3 The laboratory must demonstrate that evidence based measures are used to identify and address any failures, including in morphological disciplines, which could cause potential harm to patients and that the success of these measures as durable solutions are monitored.

S3.4 The risk management framework must include a Quality Management Policy and system.
4. Clinical Governance

These Requirements must be considered in conjunction with the Tier 3A document Requirements for Supervision of Medical Pathology Services.

Regardless of the organisational structure, the clinical governance structure must demonstrate clear accountability for the responsibility for supervision, and clear criteria and processes for the escalation and communication of incidents impacting patient safety.

S4.1 The laboratory must have a process of clinical governance that ensures patient safety and quality in the delivery of its services.

S4.2 The laboratory delivering the service must be able to be clearly identified by the requester and the patient.

S4.3 All laboratories must have procedures for the development and clear communication of delegated responsibilities and a protocol for notifying the designated person of relevant events by the delegate.

S4.4 The designated person(s) (who is a medical practitioner) under whose direction and control the laboratory operates must be clearly identifiable and accessible, provide leadership to promote safe and ethical practice and must have the authority and competence to ensure and take active responsibility for:

(a) policy setting and implementation
(b) the identification and management of risk
(c) the implementation and maintenance of the quality management system
(d) compliance with all NPAAC and jurisdictional requirements
(e) operational practices and staffing (including training)
(f) determining the range of tests provided, their methods and procedures taking into account that the numbers processed are sufficient to maintain competence
(g) determining the suitability of referral laboratories
(h) regular review of the quality systems, proficiency testing data, reports, and all aspects of performance
(i) provision of medical and scientific consultation
(j) procedures used and the tests performed being within the scope of the education, training, continuing professional development and experience of individual staff members
(k) determining work suitable to be performed outside normal working hours and that such work is performed by staff who are qualified, trained and competent to work in the absence of an on-site supervisor
(l) provision of a clearly defined process for contacting a supervisor not currently on site.
5. **Quality Management**

Medical pathology services contribute to patient safety and improved clinical outcomes.

S5.1 **The laboratory must have a documented and monitored Quality System in place that ensures the safety of patients and contributes to improved patient outcomes.**

S5.2 **The laboratory must have a designated quality manager who shall have, delegated responsibility and authority that includes:**

   a) ensuring that the quality management system is established, implemented and maintained
   
   b) reporting to laboratory management, at the level at which decisions are made on laboratory policy, objectives, and resources, on the performance of the quality management system and any need for improvement
   
   c) ensuring the promotion of awareness of users’ needs and requirements throughout the laboratory organisation.

S5.3 **The effectiveness of the laboratory Quality System must be audited.**

S5.4 **The services provided by laboratories must be evaluated.**

   C5.4(i) Where practicable, performance measures such as incident and error rates, turn-around times **must** be used for evaluation and improvement purposes.
   
   C5.4(ii) There **must** be protocols to facilitate feedback from patients and referrers and the feedback used for evaluation and improvement purposes.
   
   C5.4(iii) There **must** be protocols for the redress of valid complaints. Complaints and the response **must** be sighted by the person designated in **S4.3**.
6. Personnel

S6.1 There must be sufficient medical, scientific, technical and support staff who have the qualifications, training and competence to provide Medical Pathology Services consistent with the scope of accreditation.

C6.1(i) Laboratories must ensure an appropriate scope of practice for Pathologists and Clinical Scientists for the scope of testing performed in the laboratory and maintain such documentation. Competence requirements for Pathologists are defined by the Medical Board of Australia.

C6.1(ii) All qualified staff involved in the provision of Medical Pathology Services must provide documented evidence of participation in continuing professional development commensurate with their role and responsibilities.

C6.1(iii) Staff must undertake relevant professional activities to enable them to maintain and update the skills required to undertake their individual responsibilities.

C6.1(iv) Where maximum workload measures are specified in technical documents, these must not be exceeded.

S6.2 The laboratory must have a policy for the reporting of critical (high risk) results or results of clinical significance to the requesting practitioner.

C6.2 The requesting practitioner must also be able to obtain advice on issues such as:

(a) patient preparation, the importance of clinical information and the adequacy of the specimen submitted

(b) the precision and accuracy of methods used

(c) the significance of results in relation to the Laboratory’s reference values

(d) the scientific basis of the results

(e) which further investigations may be helpful.

S6.3 The laboratory must have a policy outlining the escalation processes in relation to consultation by relevant clinical staff.
7. Facilities and Equipment

A. Premises

S7A.1 Premises must be an APL that is clearly identified and suitable for activities undertaken.

C7A.1 Approved Collection Centres must meet the NPAAC Guidelines for Approved Pathology Collection Centres (Requirements for Medical Pathology Specimen Collection).

S7A.2 There must be designated space and facilities sufficient for the safe provision of the Medical Pathology Service. This applies to all sectors of the laboratory including testing areas, specimen collection, administrative and mortuary areas.

S7A.3 Access to adequate and up to date educational resources for all staff in the individual pathology disciplines must be provided at the laboratory.

C7A.3 These resources may be textbooks, journals and electronic resources.

B. Equipment

The Tier 3 and Tier 4 NPAAC Requirements identify specific items of equipment. Laboratories must comply with the TGA’s IVD regulatory framework and ensure that commercially supplied IVDs and Class 1-3 are accredited and report any adverse events.

S7B.4 Equipment must be “fit for purpose” and must be maintained to ensure functionality. Associated documents must form part of the Quality System.

C7B.4 Reagents must not be used outside their expiry dates unless extension thereof has been validated.

S7B.5 Electronic information systems must be protected to ensure and maintain integrity of data and to prevent unauthorised access, alteration or destruction of data.

C7B.5 Laboratories must mitigate the risk of electronic data becoming inaccessible due to software redundancy.
8. Request-Test-Report Cycle

Clinical handover is the transfer of information, accountability and professional responsibility for the care of a patient or group of patients. Failure in handover is a major source of preventable patient harm and appropriate clinical handover will maximise patient safety. It is acknowledged that a key feature is standardisation of the process through effective, concise and comprehensive communication. Laboratories must have documented processes in place to ensure that results are communicated to clinicians (clinical handover) in a timely manner.

A. Pre-Analytical

It is recognised that not all specimen collections are done within the control of the laboratory.

SA8.1 The laboratory must ensure that pre analytical procedures and post analytical processes are part of the clinical handover between the laboratory and the clinician.‡

SA8.2 Specimens within the test report cycle must be traceable at all times.

SA8.3 Sufficient information must be available for requesting practitioners and patients about the Medical Pathology Services provided and both parties must be advised about any prerequisites for testing purposes.

SA8.4 Medical Pathology Services provided must be in response to a documented request identifying the patient, the requesting practitioner, the tests requested and relevant clinical information (e.g. any medication history, family history, ancestry).

CA8.4(i) Where there are several different identifiers for the one patient (e.g. baby of . . . , unknown patients, change of maiden to married name, multiple medical record numbers), there must be a policy relating to the merging or linkage of the data.

CA8.4(ii) At times a request may be made verbally by a requestor for further testing when the Specimen is already present in the Laboratory. In these cases, the nature and time of the request must be documented. A confirmatory documented request must be received.

CA8.4(iii) Where a laboratory offers direct-to-consumer testing, the testing must be performed within a documented risk management framework.

Accurate patient identification and specimen labelling are crucial to patient safety. Failure to comply with these requirements is a significant cause of patient morbidity and occasionally mortality.

‡ Australian Commission on Safety and Quality in Health Care Standards - Communicating Patient Safety Standard
SA8.5  Collection of Specimens must be performed with accurate identification of the patient and labelling of Specimens in accordance with written protocols.

CA8.5(i)  Where the request has been transmitted electronically, there must be a documented protocol indicating how the patient is to be identified at the point of collection.

CA8.5(ii)  The identity of the person collecting the primary sample must be traceable in the laboratory records.

CA8.5(iii)  When identifying the patient, three identifiers must be used on the request form. This also applies to unidentifiable and unconscious patients who will need a unique medical record number and two other descriptors e.g. head injury and motorbike accident.

CA8.5(iv)  When labelling the patient’s specimen, two identifiers must be used or three identifiers where practicable.

CA8.5(v)   If there is discordance between the identifiers on the request form and the specimen label there must be a documented process for reconciliation and managing of potential risks to patient safety.

CA8.5(vi)  The specimen must be labelled in the presence of the patient and, if possible, the patient identifiers should be confirmed by the patient.

CA8.5(vii)  The identifiers must include full name and at least one of either date of birth or unique medical record number. Additional identifiers may be the unique accession number or patient address. Alternative identifiers may be used in special circumstances such as patients who wish to remain anonymous.

CA8.5(viii)  Where patients collect their own specimens, they must be provided with instructions in accordance with the collection instructions manual.

CA8.5(ix)  Where requested to accommodate requests for patient de-identification, coding for identification processes must remain unique for the patient and must encompass at least a two-part system (similar to the patient’s name and date of birth currently used); for example, a coded ‘name’ plus the correct date of birth. The same ‘code’ must be used for each patient at subsequent consultations.

CA8.5(x)  If a coded name is used, Standard Australian English alphabet and Arabic numerals should be used in codes, with no spaces between letters or numbers (as spaces may get moved or left out, creating difficulties in finding a person’s code in the Laboratory Information System). Non-standard alphabetical letters should be avoided. Symbols should be avoided in patient coded identities. Arabic numbers should be written clearly to avoid confusion, for example O and 0, 1 and 7, Z and 2.
SA8.6 The laboratory records must include:
(a) three patient identifiers
(b) sex
(c) date and time of collection (where supplied)
(d) date and time of receipt in the Laboratory
(e) anatomical site of tissue Specimens
(f) type of Specimen (e.g. urine, joint aspirate)
(g) clinical status of patient (e.g. fasting), where required
(h) specimen characteristics which may provide information relevant to interpretation of results (e.g. haemolysis)
(i) informed consent where required by legislation or NPAAC documents
(j) the name of the requester.

SA8.7 The laboratory must have a written policy for the management of inadequately labelled Specimens and/or incomplete request forms.

SA8.8 Pathology specimens must be packaged and transported in a manner that assures the integrity of the specimen and safety of the public.

SA8.9 The integrity of the specimen must be ensured prior to testing and/or prior to release of test results.

CA8.9 Examples of compromised integrity include haemolysis, partial clotting of anticoagulated specimens, absence of fixative for tissue Specimens or leaking specimen containers.

B. Analytical

SB8.1 Validated and/or verified recognised procedures must be used.

CB8.1(i) Validation and verification records must be available.

CB8.1(ii) Tests that cannot be fully validated must only be performed where dictated by clinical necessity or public risk and where there is no reasonable access to an alternative validated test. For certain tests laboratories may need to seek advice from the relevant regulatory authority on how to access an unapproved in vitro diagnostic medical device.

SB8.2 There must be evidence to confirm comparability of patient results in a laboratory or network of laboratories when results are produced by different methods and on different instruments.

SB8.2 The analytical performance must meet the requirements for the clinical application of the assay.

SB8.3 Test procedures must be authorised, documented and available in the work area in which they are used.
SB8.4  Acceptable test performance must be confirmed by the ongoing use of internal quality control material.

CB8.4(i)  There must be documented criteria for the acceptance of quality control. Any results and any action to be taken when these are unacceptable must be documented.

CB8.4(ii)  Where internal quality material is available, it must be included in the test system in a manner as close to a patient specimen as possible.

CB8.4(iii)  Where internal quality controls is not available, alternative mechanisms to ensure validity of testing must be carried out, such as specimen exchange with another laboratory.

SB8.5  The laboratory must be enrolled, participate and perform to an acceptable standard in external proficiency testing programs that cover all testing methods performed where such programs are available.

CB8.5(i)  Where External Quality Assessment programs do not exist for a test method, the validity of the test results must be demonstrated by methods such as inter-laboratory comparisons or the analysis of reference material.

CB8.5(ii)  All staff performing Medical Pathology Services must participate in External Quality Assessment programs in accordance with laboratory’s policy and according to their responsibilities. The policy must include frequency of participation.

CB8.5(iii)  In order to minimise risk across the entire test cycle, quality assurance includes extension beyond the analytical aspects of pathology testing into pre- and post-analytical areas.

SB8.6  Non-concordant results must be investigated and the possible ramifications for patient specimen testing must be considered and appropriate actions taken.

SB8.7  Staff must be aware of factors which may give rise to uncertainty about a test result.

CB8.7  There may be pre-analytical sources, software limitations, measurement uncertainty within numerical analytical processes, and post-analytical sources.

SB8.8  Measurement uncertainty must be estimated for each test procedure where relevant and possible.

CB8.8  Where an estimation of uncertainty is not possible, then areas of uncertainty should be identified to minimise any potential risks.

SB8.9  The laboratory must have evidence that its measurement uncertainties meet clinical requirements.

SB8.10  Estimates of measurement uncertainty must be made available to requesters upon request.
C. Post-Analytical

The breakdown in the transfer of information or communication has been identified as one of the contributing factors in serious adverse events and is a major preventable cause of patient harm.

SC8.1 There must be a documented policy for results from test procedures and specimen examinations.

CC8.1(i) The results must be validated to ensure that they are correct, evaluated against internal quality control, timely, clear and unambiguous, clinically relevant and matched to the request form.

CC8.1(ii) If a clinically necessitated non-validated test has been performed, the report must clearly indicate that the diagnostic validity has not been established.

CC8.1(iii) Interpretative and additional comments may be added by identifiable authorised persons.

SC8.2 The reports must contain:

(a) patient demographic data (e.g. name, sex, age)
(b) tissue or fluid tested (e.g. blood, serum, plasma) and, where relevant, its state (e.g. fresh, frozen, fixed)
(c) validated result data
(d) identity of the laboratory issuing the report
(e) unique identifier for each sample episode such as accession number or other unique identifier to allow trace traceability
(f) identity of any referral laboratory that performed part or all of the testing
(g) all interpretive comments provided by the referral laboratory, and
(h) date and time of report release.

CC8.2(i) Provisional/interim reports must be issued according to documented policy and indicate their provisional nature.

CC8.2(ii) Structured reporting must be used where appropriate.

CC8.2(iii) Reports may be paper based or electronically submitted.

CC8.2(iv) Test reports should not be copied or reproduced except in their entirety.

SC8.3 Reports must be communicated in a clear, secure and timely manner to the requesting practitioner and to others delegated by the requesting practitioner responsible for the patient’s immediate care and management.

CC8.3(i) Verbal reports must be given according to documented policy, which must include the name of the person providing and the name of the person receiving the report, the date and time of the communication and a requirement for reading back the verbal report.

CC8.3(ii) Verbal reports must be followed up with an electronic or hard copy as soon as possible.
CC8.3(iii) The laboratory must develop a list of critical results or values, in consultation with relevant referrers, for use by laboratory staff.

CC8.3(iv) Where clinically significant results with the potential to have a serious immediate impact on the patient’s safety and where the requesting practitioner or proxy cannot be contacted, then every effort must be made by the medical director, relevant pathologist or most senior responsible person to contact the patient to arrange management. Referring practitioners should be encouraged to provide after-hours contact numbers. A register of such after-hours contact details should be established.

CC8.3(v) Where there are clinically significant results and these have been verbally communicated to a requesting practitioner directly or through a third party such as a practice nurse or receptionist, the urgency or significance of the results must be made clear.

SC8.4 There must be procedures for:

(a) the reporting of notifiable diseases in accordance with jurisdictional requirements

(b) reporting to disease registries.

SC8.5 Laboratories must have documented procedures for the provision of test results directly to patients.

SC8.6 Retention of patient data, specimens, test procedures and equipment records must comply with NPAAC Requirements§ and jurisdictional requirements.

SC8.7 Disposal of biological material from pathology testing must comply with jurisdictional regulations and the organisation’s waste management policy.

§ NPAAC Requirements for the Retention of Laboratory Records and Diagnostic Material
9. Send away tests

It is recognised that the practice of referring patient specimens from the original collecting laboratory, to other testing laboratories, within the same network, outside the same network or to other national jurisdictions or across borders, is associated with an increased risk of an error which may cause patient harm.

S9.1 The laboratory must have a policy and procedure in the Quality System to document the management of referred specimens.

C9.1(i) Measures of the performance of the send away test function must be monitored and actions taken to reduce potential risks to patient safety are identified.

C9.1(ii) The quality system should address:

(a) quality assurance of the logistics process
(b) documentation of handover(s)
(c) specimen integrity
(d) specimen traceability
(e) accreditation status of the destination laboratory
(f) turnaround times
(g) receipt of the report by the referring laboratory
(h) receipt of the report by the referring doctor.
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APPENDIX A  RISK ASSESSMENT – RISK POINTS (NORMATIVE)

The following risk points must be considered as part of a laboratory’s risk assessment to mitigate potential risks to the delivery of quality pathology services and patient safety.

1. Governance: Clear governance structures will result in prompt corrective action where the accuracy, clinical utility or timeliness of testing has been compromised. They will also promote early notification to the referring doctor about test results or events of clinical significance in the management of the patient.

2. Competency of staff:

3. Patient identification: Clear processes to allow unequivocal identification of the patient promotes the safety and timeliness of testing.

4. Specimen integrity: Processes to address common pre analytical issues, in particular specimen haemolysis, promote the safety and timeliness of testing.

5. Specimen traceability: Processes which enable the traceability of samples promote the safety and timeliness of testing.

6. Specimen analysis: Processes to address failures of Quality Control promote the safety and timeliness of testing.

7. Verification, validation and documentation of methods:

8. Quality Assurance: Participation in Quality Assurance Programs, reviews of performance and corrective actions where performance is unsatisfactory promote the safety and timeliness of testing.

9. Reporting results: Unambiguous reports, current best practice reporting, promote the safety of testing by facilitating timely and appropriate clinical interventions.

10. Turn around times: Turnaround times that allow timely decision making promote good patient outcomes from testing.

11. Communication: Processes for the communication of critical results to clinicians, the management of confidential results, and privacy, promote the safety of testing.

12. Send away tests: Risk management processes which address transport, handovers, specimen integrity, the quality of testing in the referral laboratory, turnaround times and the delivery of reports to the referring doctor and the referring laboratory improve the safety of testing.

13. Reviews of incidents: Processes by which incidents with real or potential adverse outcomes for patients are investigated, corrective actions taken and the efficacy of these actions is monitored, improve the safety of testing. Processes to identify, track and reduce diagnostic errors.
References


Bibliography


*Standards for Accreditation of Medical Laboratories*, 2007 Clinical Pathology Accreditation (UK) Limited.
Acknowledgements

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