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

NPAAC
National Pathology Accreditation Advisory Council

Requirements for information communication and reporting

Sixth Edition

2026

safetyandquality.gov.au

Published by the Australian Commission on Safety and Quality in Health Care

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

ISBN: 978-1-923353-50-3

The Commission's preference is that you attribute this publication (and any material sourced from it) using the following citation:

Australian Commission on Safety and Quality in Health Care. NPAAC Requirements for the development and use of In-house In Vitro Diagnostic Medical Devices. 5th Ed. Sydney: ACSQHC; 2025.

Disclaimer

The content of this document is published in good faith by the Commission for information purposes. The document is not intended to provide guidance on healthcare choices. You should contact your health care provider for information or advice on healthcare choices.

The Commission does not accept any legal liability for any injury, loss or damage incurred using, or reliance on, this document.

Acknowledgement

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

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.

Requirement Edition	Year	Changes
First Edition	1998	First Edition
Second Edition	2007	Reprinted with revisions and name change from Guidelines for data communication
Third Edition	2013	Reprinted and reformatted to be read in conjunction with the Requirements for medical pathology services
Fourth Edition	2020	Reprinted with revisions
Fifth Edition	2022	Revised with amendments to C2.1(iv), delineation of footnote references and explanatory notes (ENs) and updates to referencing and referencing style
Sixth Edition	2026	**Amendment to S4.1** Laboratories must conform with an Australian-approved electronic messaging standard, with the minimum being HL7 Version 2.4 as localised for Australia (ADRM 2021.1 or later). The current approved HL7 Standards are: a. HL7 V2.4 b. HL7 FHIR: i. HL7 Australian Core FHIR Standard ii. HL7 Australian eRequesting FHIR Standards **C4.1a** Laboratories should move towards adopting the Australian-approved HL7 FHIR Standards

Contents

Background

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

About the Australian Commission on Safety and Quality in Health Care

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

Key functions of the Commission include:

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

The Commission works in four priority areas:

- **High-quality care in an evolving environment** – so that high-quality health care is delivered consistently, reliably and equitably for all Australians.
- **Strong outcome focused clinical governance** – so that clinical governance, integrated standards and accreditation drive better patient outcomes
- **Empowered patients, families, carers and communities** – so that health care is designed and delivered with patients and communities.
- **An improvement-driven workforce culture** – because better health care is everyone's responsibility, every day.

About the National Pathology Accreditation Scheme

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

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

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

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

About the National Pathology Accreditation Advisory Council

The National Pathology Accreditation Advisory Council (NPAAC) was established in 1979 to consider and make recommendations to the Australian, state and territory governments on:

- matters related to the accreditation of pathology practices
- the introduction and maintenance of uniform standards of practice in pathology practices throughout Australia.

The Commission supports NPAAC to formulate standards to which pathology practices are assessed.

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

Scope

The *Requirements for information, communication and reporting (sixth edition, 2026)* is a Tier 3B NPAAC document and must be read in conjunction with the Tier 2 document. The latter is the overarching document broadly outlining 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.

Whilst there must be adherence to all the requirements in the Tier 2 document, reference to specific Standards in that document are provided for assistance under the headings in this document.

This document addresses communication of pathology information between pathology laboratories, requesters, consumers and other parties. It emphasises the role of the laboratory and defines the boundary of responsibility of the laboratory, recognising that a laboratory may be limited in its ability to influence requesting practitioners to implement desirable practices, although laboratories must address identified high-risk scenarios.

Throughout these requirements, processes which improve safety, security and privacy, and reduce the risk of harm to patients have been identified within the Standards and Commentary.

The structure and maintenance of databases, data for secondary transmissions, and retention of data are outside the scope of this document.

Abbreviations

Abbreviation	Definition
APUTS	Australian Pathology Units and Terminology Standardisation
AS	Australian Standard
HL7	Health Level 7 standards
HPI-I	Healthcare Provider Identifier – Individual
HPI-O	Healthcare Provider Identifier – Organisation
IHI	Individual Healthcare Identifier
ISO	International Organization for Standardization
LOINC	Logical Observation Identifiers Names and Codes
NPAAC	National Pathology Accreditation Advisory Council
NSPRC	National Structured Reporting of Cancer Project in Australasia
SPRC	Structured Protocols for Reporting Cancer
PKI	Public Key Infrastructure
RCPA	Royal College of Pathologists of Australasia
SNOMED	Systematized Nomenclature of Medicine
SNOMED CT	Systematized Nomenclature of Medicine – Clinical Terms
SNOMED CT-AU	Systematized Nomenclature of Medicine – Clinical Terms Australia
SPIA	RCPA Standards for Pathology Informatics in Australia
UCUM	Unified Code for Units of Measure

Introduction

The *Requirements for information, communication and reporting (sixth edition, 2026)*, is a Tier 3B standard that outlines a framework for the communication of pathology information within the request-test-report cycle.

These requirements set out the minimum standards to ensure the integrity of patient information during the transfer of information with external parties. To manage potential risks, laboratories must be able to ensure the confidentiality, integrity (including authenticity) and availability (collectively known as information security) of messages received and sent to the authorised recipient. This includes recording, storing and, where required, archiving messages and the tracking of access and transmission of these messages.

The Requirements seek to identify the major risks to patient safety associated with information communication and sets standards to mitigate those risks.

Requirements have been developed with reference to current and proposed Australian regulations and other standards from the International Organization for Standardization including:

- AS ISO 15189 Medical laboratories—Requirements for quality and competence
- AS/ISO 27799 ISO/DIS Health informatics—Information security management in health using ISO/IEC 27002
- AS 5552:2013 E-health secure message delivery
- AS 4700.2 Implementation of Health Level Seven Part 2: Pathology and Diagnostic imaging (diagnostics)
- AS 4846: 2014 Person and provider identification in healthcare
- ISO 27001 and ISO 27002 System security processes and methodologies.

As this is a rapidly changing technical environment, standards are likely to be under regular revision and change. Laboratories are encouraged to refer to current best practice standards.

These requirements should be read within the national pathology accreditation framework including the current versions of the following NPAAC documents:

All Tier 2 and Tier 3 Documents

In addition to these standards, laboratories must also comply with all relevant jurisdictional legislation.

Document structure

Each section identifies key points for practice as either Standards (S) or Commentaries (C).

- **Standard**: The minimum requirement for procedures, methods, staffing, or facilities. Standards required before a laboratory can attain accreditation are prefaced with an 'S' (for example, S2.2). The use of "must" indicates a mandatory requirement.
- **Commentary**: Provides clarification to the standards, examples, and guidance. Prefaced with a 'C' (for example, C1.2), commentaries may be normative or informative. If a commentary uses "must", it is considered normative and holds the same weight as a Standard.

Appendices may also be normative or informative and are considered integral to the document.

> Any appendices attached to this document may be either normative or informative and should be considered to be an integral part of this document.

From 1 July 2021, the Commission took over responsibility for administering the NPAS and supporting NPAAC and its subcommittees in their work to develop and maintain the pathology standards.

NPAAC documents can be accessed on the Commission's website.

Comments from users are appreciated and can be directed to:

Australian Commission on Safety and Quality in Health Care

Level 5, 255 Elizabeth Street
Sydney NSW 2001

Phone 1800 304 056

Email pathology@safetyandquality.gov.au

Website Pathology Standards | Australian Commission on Safety and Quality in Health Care

1. Governance

Information governance ensures that information is managed and delivered in an appropriate, secure, and reliable manner

This section addresses information governance, including privacy. Privacy principles must be upheld in all pathology request and report communications. Laboratories must understand the importance of laboratory information systems and structures and adopt a risk-based approach to the management of information assets. Refer to Appendix B.

No.	Standard and commentary
S1.1	The designated person **must** ensure the governance of information communication is clear, appropriate and documented.
	C1.1 (i) If responsibility is assigned to another person within the organisation, the responsibilities **must** be documented.
	C1.1 (i) Where any information communication functions are provided by a third-party provider, the designated person **must** have completed a risk assessment to ensure that risks are managed and there are relevant agreements in place to demonstrate conformance with the necessary requirements.
S1.2	All forms of communication **must** undergo a risk assessment before being implemented or changed.
	C1.2 (i) Investigations of both data breaches and failures to transmit pathology results to the responsible persons should be used to review or update of the laboratory's risks assessment.
S1.3	The laboratory **must** document policies and procedures for the receipt of requests and transmission of reports.

No.	Standard and commentary
	C1.3 (i) The documented policy **must** include: a. the roles and responsibilities of laboratory staff handling pathology requests and reports (including receipt and dispatch) b. details of standards and specific requirements relating to the confidentiality, authenticity, integrity and availability of electronic pathology reports and requests c. access rights and controls, including details about what these are and who they relate to, in relation to transmission of electronic pathology reports and requests d. the processing of electronic request and electronic report message receipt acknowledgements e. storage and archiving requirements, including a record of the transmission of electronic pathology reports and requests f. procedures for internal audits to ensure all processes are operating in accordance with the management system.
S1.4	Incidents and adverse events related to information data breaches **must** be regularly reviewed with the intention of identifying the cause and mitigating the risk of further events. C1.4 (i) The effectiveness of these mitigants **must** be monitored and regularly reviewed.
S1.5	The laboratory **must** ensure the transmission and archiving of pathology messages are supported by trained staff who have been assessed to be competent.
S1.6	All staff **must** have received training in the awareness and treatment of cyber risks.
S1.7	All laboratories **must** have an information security management system, such as that described in ISO 27000.

2. Security of electronic communications

This standard addresses the communication of the content. It sets out the expectations of the level of acknowledgement of the communication.

No.	Standard and commentary
S2.1	For the secure messaging of electronic pathology requests and reports, the laboratory **must** ensure: a. the completeness, accuracy and integrity of electronic messages b. the pathology laboratory message can be authenticated by the recipient. C2.1 (i) Laboratories **must** have a risk-based approach to ensuring the capability to transmit and receive messages. C2.1(ii) The secure messaging protocol is supported by procedures to manage the authentication of the requestor and recipient of the message. C2.1(iii) All communication protocols **must**: a. authenticate the originator of the pathology request b. acknowledge receipt of incoming messages (transport level and application-level acknowledgement) c. c) authenticate the recipient of the pathology report at the initial setup. C2.1(iv) Before first time transmission of results for SMS, email or faxed messaged reports to recipient, an authentication process should be performed and recorded before transmission of the result e.g. sending test message. C2.1(v) The record of receipt of an electronic acknowledgment message is considered to be part of the electronic patient record.

No.	Standard and commentary	
	C2.1(vi)	Electronic report messages cannot be considered successfully delivered until a clinical application acknowledgment message has been received, confirming delivery. It is recognised that clinical software receiving report messages may not send an acknowledgment. However, software vendors should be encouraged to include this feature in their products.
	C2.1(vii)	Laboratory acknowledgment of an electronic request does not constitute a contract to undertake services; it indicates a willingness and capability to enter service agreements to perform or refer the requested services.
S2.2	There **must** be an acknowledgement of outbound communications.	
	C2.2(i)	Laboratories **must** have a transport level acknowledgement to indicate that a message has been received. This is the minimum requirement under this standard.
	C2.2(ii)	There **must** be a procedure for the transmission of high risk and urgent results which ensures this always occurs.
	C2.2(iii)	Laboratories should have application-level acknowledgement. This is generated by the receiving application (e.g. clinical desktop solution) indicating that the message has been received and committed to secure storage for processing by an appropriate clinical application.
	C2.2(iv)	Laboratories should have a clinical level acknowledgement, where available. Given the high risk of the non-review of clinical data, a risk assessment of processes should be undertaken.
S2.3	The laboratory **must** have a procedure to deal with transmission failures in a timeframe relevant to clinical risk and requester expectations.	
	C2.3(i)	A procedure **must** be in place for high risk and urgent results to ensure the effective communication of results and acknowledgement from a person because of the risk of transmission failures.
S2.4	The laboratory **must** define what data needs to be communicated to the recipients of high-risk results.	
	C2.4(i)	The information communicated to the recipient of a high-risk result **must** include the following: a. identity of the notifier b. identity of the patient tested c. date and time that the sample was collected, where given d. test that was performed e. test result (with the units of measurement where relevant) f. reported applicable reference interval for the patient or clinical decision limit(s) for the test, and the offer of pathologist or scientist consultation.
S2.5	Whenever a message is transmitted via a public network, the patient identified clinical information must be encrypted to protect the confidentiality of data and prevent unauthorised access during transmission.	

No.	Standard and commentary	
	C2.5(i)	Accepted transport security protocols, such as Transport Layer Security (TLS) or public key encryption mechanisms such as public key infrastructure (PKI) **must** be used. Use of secure messaging fulfils these requirements.
	C2.5(ii)	Encryption should be considered in private networks as part of information security risk management.
	C2.5(iii)	Unencrypted emails should not be used for identified clinical information without patient consent.

3. Patient and provider identification

There are many patient safety benefits associated with the best practice use of identifiers and terminology.

No.	Standard and commentary	
S3.1	The laboratory must return all identifiers received to confirm identity.	
	C3.1(i)	The laboratory should include the Individual Healthcare Identifier (IHI) in electronic data exchange where the IHI has been provided by a requesting practitioner in electronic form.
	C3.1(ii)	Where a requesting practitioner does not provide the laboratory with an IHI, laboratories are encouraged to obtain the patient's IHI via the health identifier service or previous pathology requests. The laboratory should then use the IHI in electronic data exchange.
S3.2	In electronic data exchange, the laboratory must include the Healthcare Provider Identifier – Individual (HPI I) and Healthcare Provider Identifier – Organisation (HPI O) where it has been provided by a requesting practitioner in electronic form.	

4. Conformance with electronic messaging standards

.

Laboratories should have processes in place for adoption of updated versions of these standards or specifications as they are published by HL7 Australia.

No.	Standard and commentary
S4.1	Laboratories **must** conform with an Australian-approved electronic messaging standard, with the minimum being HL7 Version 2.4 as localised for Australia (ADRM 2021.1 or later). The current approved HL7 Standards are: a. HL7 V2.4 b. HL7 FHIR: i. HL7 Australian Core FHIR Standard ii. HL7 Australian eRequesting FHIR Standard
C4.1(i)	Use of the HL7 standard **must** include testing that demonstrates appropriate use of codes for orderable and results. It must also demonstrate use of patient, provider and organisational identifiers in the messages in accordance with Standard 3 of this document as well as management of message acknowledgments in accordance with Standard 2.
C4.1(ii)	Laboratories should move towards adopting the Australian-approved HL7 FHIR standards

5. Communications audit trail

No.	Standard and commentary
S5.1	Laboratory staff who have access to electronic pathology data and the ability to trigger transmission, change or correction of electronic data **must** use their own individual secure logins.
S5.2	If a paper request is received, then a scanned, hard copy or the original request **must** be stored keeping all the original content, date, time, location and originator of the request. C5.2(i) The same information provided in electronic requests **must** also be stored. C5.2(ii) Any changes to the request **must** be stored as well as the original.
S5.3	When an acknowledgment is received from any transmission (including interim reports), mode of result transmission **must** be recorded. C5.3(i) The audit record **must** include a. request registration b. patient identifier transmissions c. results entry and comments d. results transmission (e.g. date, time and mode) e. patient result access by non-laboratory staff. Alternatively, where it is deemed impractical to include access by such staff into the audit trail then such staff must have received adequate training in the area of jurisdictional privacy legislation f. a record of any subsequent changes to a previously validated report g. key patient demographics changes including at least name, sex and date of birth

No.	Standard and commentary	
	C5.3(ii)	If results are amended, then the audit trail **must** support the collection of all of the above for the subsequent transmission.
S5.4	Laboratories **must** have procedures for the re-transmission of amended results.	
	C5.4(i)	Mode of transmission includes printing, faxing, email and electronic transmission. It also includes verbal reporting by phone.
	C5.4(ii)	Laboratories **must** record the transmission of results by phone in response to result enquiries.
	C5.4(iii)	The audit record is considered part of the patient record.
	C5.4(iv)	Current paper-based and intra-laboratory systems provide for traceability of requests, technical procedures, results and reports. These capabilities **must** be maintained and enhanced in electronic systems, so that access, actions and changes can be traced where and when necessary.
S5.5	The laboratory collecting the audit trail information **must** notify its staff (and any other parties who access patient records): a. that their access to patient records will be recorded on the audit trail b. what personal information is collected (i.e. is it just their name) and a link to the relevant privacy policy of the laboratory that is collecting and disclosing the personal information c. of the purpose and use of the audit trail information d. to whom the audit trail information may be disclosed.	

6. Request and report format requirements

Standardised terminology contributes to patient safety. The format that results are reported can have a significant impact on the way they are interpreted. Differences in reporting formats between laboratories can lead to confusion and misinterpretation. Key requirements for reports are outlined in Appendix A.

No.	Standard and commentary
S6.1	Where the SPIA standard is not used, laboratories **must** undertake a risk assessment that provides assurance for patient safety, in addition to the provision of a list of systems used and reasons.
S6.2	A laboratory **must** ensure that at least one of the observational identifiers used in an electronic report should use the SPIA LOINC coding system, where available, and the associated UCUM units that is in accordance with the SPIA standards when sending to external organisations. C6.2(i) The source of LOINC codes should be those specified in SPIA. C6.2(ii) If SNOMED codes are used in messages, laboratories should use the SNOMED CT-AU code set. C6.2(iii) A laboratory may use non-LOINC observational identifiers.
S6.3	The content and format for cancer reporting must be in accordance with the National Structured Pathology Reporting Protocols. C6.3(i) Published guides for the implementation of structured reporting incorporate a tabulated matrix for different levels of sophistication in reporting. Levels 1–3 relate only to the content and format of a report, all within a single text field. Levels 4–6, in addition, detail progressive levels of electronic implementation. C6.3(ii) Level 3 reporting improves the completeness and clarity of cancer reports and requires only that the content complies with the available NSPRC published datasets and that a structured or synoptic format is used.6

No.	Standard and commentary	
	C6.3(iii)	Level 3 reporting is achievable by all laboratories in Australasia without additional infrastructure or cost and **must** be the minimum level of compliance for reporting of cancers for which published protocols exist.

Glossary

Term	Definition
Access audit trail	A record of views of an individual's health record data without modification by people, recording (as a minimum) date, time, patient identifier and person viewing. Access to data performed regularly as part of routine operations may be recorded to a lower degree of specificity. See also Audit trail.
Application acknowledgement	A computer-generated acknowledgment by the receiving application confirming receipt and processing of data.
Audit trail	A chronological sequence of human readable audit records, each of which contains evidence directly pertaining to and resulting from the execution of a business process or system function.
Authentication	The process that verifies the claimed identity of a station, originator or individual as established by an identification process. Authentication ensures the individual or organisation is who they claim to be. Examples include calling the alleged sender directly or using password protected networks or digital certificates.
Clinical acknowledgement	A record of acknowledgment that a clinician has received and is taking responsibility for acting on results; this may be delivered by any means including phone and clinical application acknowledgement.
Confidentiality	The state of keeping or being kept secret or private.
Edit audit trail	A record of additions and alterations to an individual's health record, including date, time, patient identifier, authorising person, and nature of the edit.
Electronic report	A report message transmitted using computer or electronic device.
Electronic request	A request message transmitted using computer or electronic device.
eRequesting	Submitting a pathology request through an electronic request.
Healthcare Provider Identifier – Individual	The unique identifier used to identify individual healthcare providers in Australia.
Healthcare Provider Identifier – Organisation	The unique identifier used to identify organisations delivering healthcare in Australia.
Individual Healthcare Identifier	The unique identifier used to identify individuals receiving healthcare in Australia.
Integrity	Internal consistency or lack of corruption in electronic data.
Interoperability	The ability of systems to connect and exchange and use patient data to support care.
Message	Communication of requests and reports to and from an external party.

Term	Definition
Patient	An individual receiving pathology tests; may also mean a consumer.
Report	Provision of results, interpretation and opinions from a pathology request.
Request	A requisition received to perform a test.
Requirements for medical pathology services	Document outlining standards for good pathology practice focused on patient welfare.
Security	Protection of digital information and IT assets against threats.
Secure messaging	Capability enabling safe and secure information sharing across healthcare.
Structured reporting	A report format using standard headings and required information.
Synoptic reporting	A structured report in condensed form.
Third-party access	Access by a party other than the original requester.
Third-party enquiry	A request by another entity for a copy of a report.
Transport acknowledgement	A system acknowledgment confirming delivery of an electronic message.
Transport layer security	A protocol providing authentication, privacy and data integrity.
Urgent	Requiring immediate attention as determined by practitioner or laboratory.

Appendices

Appendix A - Report format requirements (Informative)

This appendix is based on the RCPA *Standards for Pathology Informatics in Australia*.

Laboratories should adopt these standards but in circumstances where this is not achievable a risk assessment should be conducted. This should determine what is the likely risk and consequence of that risk and whether effective mitigation strategies can be introduced until the standards are met.

A. Terminology

The standardisation of pathology terminology and units in Australia is desirable and achievable.

A1 Principles

A1.1 No single existing terminology is sufficient.

A1.2 Having well-developed subsets of terms will improve conformance, compliance and efficiency.

A1.3 A high level of knowledge and familiarity with the practice of pathology is required to develop and maintain these subsets.

A1.4 The terms used in Australia will reflect common usage and will be consistent and safe.

A1.5 The terms will be practical and capable of ready implementation.

A1.6 All standardised pathology terminology and associated units will be available in one place.

A1.7 SNOMED-CT should be used as the preferred terminology for requesting pathology.

A1.8 LOINC should be used as the preferred terminology for the highest level test name in reporting pathology.

A1.9 A rendering of the pathology report as the issuing laboratory intends it to be read, should be sent by the laboratory in all electronic messages. Receiving systems should be able to conveniently display this rendering to the reader for review if it is not used as the primary form for display.

A1.10 Combining data for a subject from what appears to be the same test in a time series such as in cumulative reports or graphs, carries with it significant clinical risk of misinterpretation and should only be done after that risk has been properly assessed and in accordance with the guidance provided here.

A1.11 The risk of combination referred to above means caution is required when grouping results from different laboratories, methods or times for research or other statistical purposes.

B. Reporting terminology and codes

B1 Principles

B1.1 A reference terminology set for result names (the question) for each of the disciplines are available:**Error! Bookmark not defined.**

- Anatomical and cytopathology
- Chemical pathology
- Genetic pathology
- Haematology
- Immunopathology
- Microbiology.

B1.2 The context for the use of result name terms (the questions) where the result reported is not a simple question-answer construct is described in information models.

B1.3 In some cases reference sets for terms used as results (the answers to the questions, for example terms and codes for pathogens) have also been created.**Error! Bookmark not defined.**

B2 Implementation

B2.1 Where a code is used to identify a term for electronic communications it should be the code that appears associated with the term in the reference set.

i. Where no such term or code is available a local code may be used provided it is identified as such in the message.

ii. Where no code is available a request for a new code should be made. A temporary code will be issued and that should be used in the interim.

B2.2 Electronic pathology reports should use information models, coded test name concepts and preferred terms from the materials referenced here.

i. Where no appropriate term is available free text may be used to describe the test.

C. Tests to be combined in reports

C1 Principles

There are some tests for which it is both inappropriate and unsafe to compare results between laboratories and/or over time. This can be due to different methods being used, changes to reagents for the same method and/or different clinical conditions.

For safe interpretation of these results it is important that there be an indication with the result for the receiving system if it is unsafe to make these comparisons. The primary way of doing this is with the terminology. When developing the reference sets if methodology was considered to warrant a different reference interval then method dependant codes were assigned. This means that the one test name may have more than one code associated with it. The choice of code is the principal way by which a 'do not combine' signal is conveyed. Results **must** not be combined if they have different LOINC codes.

Test coding alone, however, is not sufficient to identify all of the cases where it would be inappropriate to combine results. As a result a secondary flag and associated coding system was developed to indicate whether it could be safe for tests from different laboratories or from the same laboratory over time to be reported on the same line in a cumulative report or as points in the same line on a graph. The flag for this purpose is called the 'Combining Results Flag'.

Values for the Combining Results Flag, their meaning and the expected action are given below:

Table 1: Values for the Combining Results Flag

Flag	Description
Green	This test is considered safe to combine if harmonised Combine (with caution)
Orange	This test has either not yet been considered or there is uncertainty around comparisons Do not combine
Red	This test is known to be unsafe to make comparisons Do not combine

The Combining Results Flag values for tests where they have been determined are included in the terminology reference sets.

C2 Implementation

C2.1 Tests that have method-dependent terms and codes in the terminology reference sets **must** have the appropriate code applied.

C2.2 Tests that have the same LOINC code, but different units e.g. umol/L and mmol/L **must NOT** be shown as the same test in sequential display whether by graph or cumulative reporting.

C2.3 Tests that have different LOINC codes **must NOT** be shown as the same test in sequential display whether by graph or cumulative reporting.

C2.4 Tests that have a 'Combining Results Flag' with the value of 'Red' or 'Orange' **must NOT** be shown as the same test in sequential display whether by graph or cumulative reporting if they come from different laboratories.

D. Preferred terms

D1 Principles

D1.1 The preferred term is the term preferred for use for the test in Australia for display on paper reports or screens. The test is fully described by the corresponding fully defined name from either SNOMED (for requesting) or LOINC (for reporting).

D1.2 The rules for establishing preferred terms apply for requesting and reporting. Many of the rules are aimed at ensuring safe rendering of the names by various devices and in different circumstances. As an example, the use of special characters such as Greek letters, symbols, super and subscripts that may not be able to be rendered by some devices can lead to misinterpretation and so are ruled against. There is also a general aim to remove redundancy and make the most important element of a name come first.

D2 Implementation

D2.1 Where there is no preferred term available for a test in the reference sets, free text descriptions should conform to the conventions used in developing preferred terms as described here.

E. Units of measure

E1 Principles

E1.1 The standardisation of units used for reporting pathology in Australia is desirable and achievable.

E1.2 All standardised pathology terminology and associated units should be available in one place.

E1.3 A single, test-specific, standardised unit of measure is preferred for use in reports from pathology laboratories.

E1.4 Units should be represented in electronic messages in such a way that receiving systems can readily convert units under the clinical governance of the receivers.

E1.5 The Unified Code for Units of Measure (UCUM) is to be used as the logical representation of units of measure in electronic messages.

E1.6 Numeric results should always have the appropriate units associated with them and they must never be displayed without them.

E2 Implementation

E2.1 Units of measure **must** always be shown where a quantity is shown on pathology reports.

i. The exception is where it is explicit that no units are used for a particular test such as *Human chorionic gonadotropin qual*.

E2.2 Pathology reports should use the units specified in this document for those tests where units have been determined.

E2.3 A single, standardised unit of measure should be used for tests in reports from pathology laboratories.

i. There may, however, be valid exceptions to this rule:

a) in a transition from one preferred unit to another

b) where alternate units are required by legislation or regulation such as for a registry

c) during a period of consensus building as to which will be the preferred unit, but this period should be a short as is practical

d) where a facsimile of an historic report is produced – historic data need not comply.

E2.4 Units should be represented in electronic messages in fields for units in such a way that receiving systems can readily convert units under the clinical governance of the receivers. The Unified Code for Units of Measure (UCUM) should be used where it is the intention to represent units in a computable form (see http://unitsofmeasure.org/).

E2.5 Where the unit is not specified here, UCUM should be used for the unit. UCUM lexical elements such as square brackets ('[' and ']') can be removed in the display format for enhanced clarity. However, the fully defined UCUM syntax should be used in electronic messaging.

E2.6 The caret symbol (^) should be used to represent "raised to a power of". Care must be taken to appropriately "escape" the caret symbol (^) as this symbol is used as a component separator in HL7 messages.

E2.7 Units raised to a power should be indicated in the preferred display unit by the exponent as an integer number written immediately behind the unit term. For example, the preferred display unit for millilitre per minute per 1.73 square metre is mL/min/1.73m^2. Powers of ten should be represented by 10^ e.g. 10^12/. Display example: mL/min/1.73m^2, 6.1x10^12/L; Message example: ml/min/1.73m\S\2, 6.1x10\S\12/L.

F. Rendering of numeric results, ranges, units, previous results, and flagging

F1 Principles

F1.1 Numeric results are incomplete without associated units and guidance for interpretation (e.g. reference intervals) and so these **must** always be shown with the number.

F1.2 Further interpretation of results over time depends on knowing the latest results (and the direction of time) therefore when results are shown in columns, rows or graphically these should be consistent across disciplines and laboratories and the latest results must be differentiated from previous results.

F1.3 Changes to configuration in the rendering of a report should be thoroughly tested in both printed and electronic format to ensure the report is displayed as intended by the receiver.

F1.4 The rendering of the pathology report as the issuing laboratory intends it to be read should be sent by the laboratory in all electronic messages and be able to be displayed to the reader on screen or printed out.

F1.5 When reports are displayed on screen the latest results should be shown on the first display screen to avoid any chance of missing a latest result column or row that is off-screen.

F1.6 Because around 4.5% of the population are colour blind and because some methods of communication remove colour, colour should **not** be used as the only method for highlighting.

F1.7 Multi-level flagging may be used.

F2 Implementation

An example of the application of the standards and guidelines for report rendering is shown for a columnar cumulative report in Figure 3 in the *Australian Pathology Units and Terminology Standards and Guidelines*.

F2.1 Numeric results should be right justified (when shown in columns) and have corresponding guidance values (e.g. reference interval) and units if these exist.

F2.2 Numeric results should have a leading zero where there is no number in the units place (i.e. 0.7 not .7).

F2.3 For columnar cumulative reports the latest result should be shown in the furthest right column of results (i.e. time must go from left to right across the page) or at the top for cumulative reports shown in rows (i.e. time must go from the bottom to the top of the page).

F2.4 The latest result should be differentiated from earlier results by at least two methods one of which is a heading ‘Latest Results’.

i. A box such as that shown in Figure 3 was favoured by 75% of survey respondents for columnar reports.

ii. Bolding of the heading text was considered effective by the Committee.

F2.5 Guidance values should be bounded by parentheses and have no spaces.

i. Italics should not be used.

F2.6 The column showing units should be headed ‘Units’, be left justified and be to the immediate right of the ‘Reference’ column.

F2.7 The numbers used for guidance should be rendered with the same number of decimal places as the related result.

i. For some analytes, such as tumour markers, a result may be orders of magnitude above guidance in which case current practice for some laboratories is to adjust for significant figures because of concern at overstating precision. It is not known whether it is safer to do this or to adopt the number of decimal places for the low range result. If a different number of decimal places is used at different concentrations, the guidance should be rendered to the same number of decimal places as the results of a similar magnitude to the guidance values.

F2.8 Results are considered outside the guidance values if after rounding to the format of the displayed result (and the guidance) the result is greater than the higher number or less than the lower number of the guidance values.

F2.9 Results outside the guidance values should be highlighted by at least two methods one of which is either an ‘L’ or ‘H’ one space to the right of the result (‘L’ for a result lower and ‘H’ for a result higher).

i. A single asterisk (‘*’) and the ‘+’ and ‘-‘ characters should **not** be used for flagging results.

ii. Underlining of results should **not** be used for highlighting results.

iii. Colour was preferred by most respondents in the survey but because of colour blindness and possible loss of colour in some communications, if colour is used, then the font should also be bolded.

iv. Multi-level flagging may be used in which case ‘LL’ or ‘HH' should be used for the second level.

F2.10 Headings should be differentiated from test names.

F2.11 Dates should be shown in the form 30-Jan-14 (i.e. not in the form 30/01/14).

G. Harmonised reference intervals

A set of harmonised reference intervals for reporting pathology in Australia (and New Zealand) is available at the RCPA website. These reference intervals are by age and sex where appropriate and include values used in paediatrics.

G1. Principles

G1.1 Guidance values should be evidence based but as simple and consistent as real biological variation and good medical practice allows.

G1.2 Because common usage for analyte reference limits has both the low and high values included while for age limits the higher value is not included, to avoid any confusion in interpretation of boundary conditions these need to be represented in different ways in reports and tables used outside the laboratory.

G1.3 There is as yet no international standard for representing age intervals and the committee proposes the format '1w to <12y' to show the time interval in a table or on a report. This was done to avoid confusion on reading and with the meaning of mathematical notation.

G1.4 The same method for representing age intervals should be used for adults and children.

G2 Implementation

Where reference intervals other than those provided here are used, laboratories should document their reasons and the evidence that alternate intervals are preferable.

G2.1 Age intervals are calculated in days from date of birth to date of collection starting with day 0 being the day of birth with the result always rounded down.

G2.2 Age intervals should be rendered using days, weeks or years (but not months).[EN3] The Table also provides the interpretation of time ranges for common age intervals.

i. A mixture of days, weeks and years is permissible where it is appropriate (e.g. '7d to <10y').

[EN3] In line with the table under CS8.02 in the *Australian Pathology Units and Terminology Standards and Guidelines*.

Appendix B - Online versions of national, state and territory privacy legislation (Informative)

Jurisdiction	Legislation
National	*Privacy Act 1988* https://www.legislation.gov.au/Details/C2014C00076 *Australian Privacy Principles* https://www.oaic.gov.au/assets/privacy/australian-privacy-principles/the-australian-privacy-principles.pdf *Privacy Regulation 2013* https://www.legislation.gov.au/Details/F2013L02126
Australian Capital Territory	*Health Records (Privacy and Access) Act 1997* http://www.legislation.act.gov.au/a/1997-125/current/pdf/1997-125.pdf
New South Wales	*Privacy and Personal Information Protection Act 1998* https://legislation.nsw.gov.au/view/whole/html/inforce/current/act-1998-133 *Health Records and Information Privacy Act 2002* https://legislation.nsw.gov.au/view/whole/html/inforce/current/act-2002-071
Northern Territory	*Information Act 2002* https://legislation.nt.gov.au/en/Legislation/INFORMATION-ACT-2002
Queensland	*Information Privacy Act 2009* https://www.legislation.qld.gov.au/view/html/inforce/current/act-2009-014
South Australia	*Information Privacy Principles 1989* https://www.dpc.sa.gov.au/resources-and-publications/premier-and-cabinet-circulars/DPC-Circular-Information-Privacy-Principles-IPPS-Instruction.pdf
Tasmania	*Personal Information Protection Act 2004* https://www.legislation.tas.gov.au/view/whole/html/inforce/current/act-2004-046

Victoria	*Information Privacy Act 2000* https://content.legislation.vic.gov.au/sites/default/files/87dc5520-6899-335f-b3b2-87207f40cf1b_00-098a.pdf *Health Records Act 2001* https://content.legislation.vic.gov.au/sites/default/files/2020-08/01-2aa046 authorised.pdf
Western Australia	*Health Act 1911* https://www.legislation.wa.gov.au/legislation/statutes.nsf/main_mrtitle_412_homepage.html **Please note** at the time of publication there was no specific privacy legislation in for Western Australia. Privacy managed through: Western Australia. *Freedom of Information Act 1992 (WA).* Western Australia. *Health Services Act 2016 (WA)*

References

1. Office of the Australian Information Commissioner (OAIC). *Australian Privacy Principles quick reference* [Internet]. Sydney (AU): OAIC; n.d. [cited 2022 Jun 2]. Available from: https://www.oaic.gov.au/privacy/australian-privacy-principles/australian-privacy-principles-quick-reference

2. International Organization for Standardization, International Electrotechnical Commission. *ISO/IEC 27000: Information technology—Security techniques—Information security management systems—Overview and vocabulary* [Internet]. Geneva (CH): ISO/IEC; 2018 [cited 2022 Jun 2]. Available from: https://www.iso.org/standard/73906.html

3. Internet Engineering Task Force (IETF). *The Transport Layer Security (TLS) protocol version 1.3* [Internet]. IETF; 2018 [cited 2022 Jun 2]. Available from: https://datatracker.ietf.org/doc/html/rfc8446

4. Royal College of Pathologists of Australasia (RCPA). *Implementation of structured pathology reporting of cancer* [Internet]. Sydney (AU): RCPA; 2022 [cited 2022 Jun 2]. Available from: https://www.rcpa.edu.au/getattachment/5cdebb47-9308-442a-91c8-22cdd4b93290/Structured-Pathology-Reporting-of-Cancer.aspx

5. Royal College of Pathologists of Australasia (RCPA). *RCPA Standardised Pathology Informatics in Australia (SPIA) guidelines*. Version 4 [Internet]. Sydney (AU): RCPA; 2021 [cited 2022 Jun 2]. Available from: https://www.rcpa.edu.au/getattachment/f306b1de-0ac5-411b-946e-fdeacccd07c8/RCPA-SPIA-GUIDELINES-V4-0.aspx

6. Royal College of Pathologists of Australasia (RCPA). *Structured pathology reporting of cancer* [Internet]. Sydney (AU): RCPA; n.d. [cited 2022 Jun 2]. Available from: https://www.rcpa.edu.au/Library/Practising-Pathology/Structured-Pathology-Reporting-of-Cancer

7. Australian Digital Health Agency (ADHA). *Use of HIs in-health software systems – Conformance requirements v3.1* [Internet]. Australia: ADHA; n.d. [cited 2022 Jun 2]. Available from: https://developer.digitalhealth.gov.au/specifications/national-infrastructure/ep-1826-2014/nehta-1732-2014

8. Standards Australia. *AS/NZS ISO/IEC 17799: Information technology—Code of practice for information security management*. Sydney (AU): Standards Australia; 2001 Jun 8.

9. Standards Australia. *AS 4700.2: Implementation of Health Level 7 (HL7)*. Sydney (AU): Standards Australia; 2004 Mar 19.

10. Standards Australia. *AS 5017: Health care client identification*. Sydney (AU): Standards Australia; 2006 Jun 30.

11. Standards Australia. *AS/NZS ISO/IEC 27002: Information technology—Security techniques—Code of practice for information security management*. Sydney (AU): Standards Australia; 2006 Jul 6.

12. Standards Australia. *HB 262: Guidelines for messaging between diagnostics providers and health service providers*. Sydney (AU): Standards Australia; 2012 Feb 14.

13. Standards Australia. *AS 5552: E-health secure message delivery*. Sydney (AU): Standards Australia; 2013 Dec 17.

14. Standards Australia. *HB 262: Pathology electronic messaging—Guidelines for pathology messaging between pathology providers and health service providers—Implementation guide*. Sydney (AU): Standards Australia; 2002 Jun 20.

Australian
Commission on
Safety and Quality
in Health Care

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

safetyandquality.gov.au