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The Royal College of Pathologists of Australasia

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RCPA STANDARDISED PATHOLOGY INFORMATICS IN AUSTRALIA (SPIA) GUIDELINES V4.0

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Revision History

Rev	Reason for Change	Owner/Author	Date
1.4	Initial APUTS standard, published by the RCPA Pathology Units and Terminology Standardisation Project	Michael Legg and Christiaan Swanepoel	12 Feb 2013
1.5	Updated the RCPA website links to link to the new RCPA website page	Donna Moore	12 Nov 2013
2.07	Complete revision and updated to include the outcomes of PITUS 14 including rewriting of Chapter 4 and addition of Chapters 7 and8	Michael Legg and Donna Moore	8 Jun 2014
2.08	Updated following review by PITUS wg3 and wg4	Michael Legg and Donna Moore	11 Jun 2014
2.09	DRAFT for review by Steering Committee	Michael Legg and Donna Moore	13 Jun 2014
2.1	After public feedback and approval by PITUS steering committee the following changes were made: - corrected spelling and grammar. - added an example into section 4 “Tests not to be combined in reports"	Michael Legg and Donna Moore	6 Nov 2014
2.2	Edits and comments finalised ready for RCPA Board Approval	Michael Legg	10 Nov 2014
2.3	Added Terms of Use for UCUM	Donna Moore	27 May 2016
3.0	These standards are now the Standards for Pathology Informatics in Australia, formerly known as Australian Pathology Units and Terminology Standardisation (APUTS). Updated to include the outcomes of PITUS-16 with new chapters for Safe pathology requesting and	Michael Legg and Donna Moore	17 Jan 2017

	Safe pathology reporting. Other changes include the addition of SNOMED codes for each Combining Results flag (Chapter 4)		
4.0	Document name updated to RCPA Standardised Pathology Informatics in Australia (SPIA) Guidelines with content refined to meet the needs of the main target audience - SPIA implementers. Other updates included outcomes of the PITUS 18-20 Project, particularly with references and URL links to the following resources: - RCPA SPIA Exemplar Reports - SPIA Rendered Report Compliance Checklists - Best Practice Guidelines - NCTS Tool Development Requirements	Vanessa White Vanessa Cameron	23 Jun 2021

Scope and audience

In scope

This document describes the guidelines around terminology, units, and rendering related to requesting and reporting pathology in Australia. This document is intended to be used as a guide for those continuing with the development and implementation of RCPA SPIA resources across all pathology domains.

Out of scope

This document does NOT deal with functional testing such as spirometry or electrocardiography even though these services are provided by some pathology laboratories in Australia.

This document does NOT stipulate the specific components of a requested pathology profile or order set.

Audience

The intended audience for the document and the terminology reference sets, units, rendering and implementation policy includes:

- SPIA implementers
- Pathology laboratories
- Pathology requesters
- All consumers of pathology reports
- Subject matter experts in pathology terminology development and related pathology standards
- Information systems developers
- Researchers and analysts who utilise pathology data.

The intended audience for the chapters on safety is broader and includes:

- All indirect consumers of pathology reports including My Health Record, registries, referrals, etc.
- Surveillance and accreditation bodies
- Government and the general public.

Glossary of terms and acronyms

The table below provides definitions for general or technical terms used in this document. Readers should take particular note of the definitions for ‘guideline’ and ‘commentary’ as these help understand the statement being made for each numbered item.

AS4700.2	AS4700.2 is the Australian messaging Standard for the Implementation of Health Level Seven (HL7) Version 2.4 - Pathology and diagnostic imaging (diagnostics). The standard is available at http://www.e-health.standards.org.au/Home/Publications.aspx
Atomic result	Standardised and structured individual test result that may be numeric or simple / structured text. When data is stored in its atomic form, it can assist with data search, retrieval, analysis and provide value in decision support
CDA	Clinical Document Architecture (CDA) is an HL7 Standard for XML-based mark-up of a document which specifies the encoding, structure and semantics of clinical documents for exchange
Checklist	A combined list of relevant RCPA SPIA, NPAAC, and NATA design elements used to assess rendered pathology report compliance
Code	A code is a unique concept identifier in a terminology that carries no other meaning
Commentary	Commentary is text that clarify the guidelines, provide examples, and helps with interpretation where necessary. Commentary is used to: • define the way an item should be reported, to foster reproducibility • explain why an item is included • cite published evidence in support of the guideline • state any exceptions to a guideline In this document, commentary is prefixed with ‘CG’ (for commentary on a guideline), numbered to be consistent with the relevant guideline, and with sequential alphabetic lettering within each set of commentaries e.g., CG2.05b

Critical risk result	Results requiring immediate medical attention and action with a high risk of imminent death or major patient harm
Differentiated	Differentiated in the context of rendering means that one element is visually distinguished from another. This may be achieved by space, fonts or other graphic design
Exemplar Report	A mock pathology report designed as a visual aide to assist SPIA implementers and laboratories with conformance against RCPA SPIA, NPAAC and NATA design elements
FHIR®	Fast Healthcare Interoperability Resources is a standard describing data formats and elements and an application programming interface for exchanging electronic health records. The standard was created by the Health Level Seven International health-care standards organization.
General commentary	General commentary is text that is not associated with a specific guideline. It is used to provide a brief introduction to a chapter if necessary, for items that are not guidelines but are included as items of potential importance for which there is currently insufficient evidence to recommend their inclusion.
Guideline	Guidelines are recommendations as indicated by the use of the term 'should'. In this document, guidelines are prefixed with 'G' and numbered consecutively within each chapter e.g., G1.10
HB262-2012	HB262-2012 is a handbook published by Standards Australia that gives detailed guidance on how to use AS4700.2. It is available at https://infostore.saiglobal.com/en-us/standards/hb-262-2012-126787_saig_as_as_267654/
High risk result	A collective term used to denote pathology results that require communication in a timely manner i.e. critical risk results, significant risk results and results of critical tests
HL7	Health Level Seven is an organisation involved in the development of international healthcare informatics interoperability standards – http://www.hl7.org/

HL7 v2.x	A set of HL7 standards for electronic messaging to support clinical practice and the management, delivery and evaluation of health services. The most commonly used global set of standards for this purpose, HL7 v2.x messages use a human-readable (ASCII), non-XML encoding syntax based on segments (lines) and one-character delimiters
HL7AUSD-STD-OO-ADRM-2018.1	The Australian localisation of the international HL7 V2 Standard covering the Laboratory/Diagnostics result reporting and laboratory/radiology ordering and referral messaging specification.
HL7 v3 RIM	The Reference Information Model (RIM) is the representation of the HL7 clinical data (domains) and the life cycle of messages or groups of messages which is the foundation of HL7 Version 3. RIM expresses the data content needed in a specific clinical or administrative context and provides an explicit representation of the semantic and lexical connections that exist between the information carried in the fields of HL7 messages
HUGO	Human Genome Organisation (HUGO), through its Gene Nomenclature Committee (HGNC), approves a unique gene name and symbol (or short-form abbreviation) for each known human gene. All approved gene symbols are stored in the HGNC Database – www.genenames.org
IHTSDO	The International Health Terminology Standards Development Organisation (IHTSDO), trading as SNOMED International, is an international non-profit organisation that owns SNOMED CT, a leading clinical terminology used in electronic health records – https://www.snomed.org/
LOINC	Logical Observation Identifiers Names and Codes (LOINC) is a database of terms and standards for identifying medical laboratory observations. It was developed and is maintained by the Regenstrief Institute – http://loinc.org/
MBS	In the context of this document, the Medicare Benefits Schedule (MBS) refers to pathology services subsidised by the Australian Government

NCTS	The National Clinical Terminology Service (NCTS), operated by the Australian Digital Health Agency, is responsible for managing, developing, and distributing national clinical terminologies and related tools and services to support the Australian healthcare community's digital health requirements. This responsibility includes being the Australian National Release Centre for SNOMED CT® on behalf of SNOMED International –https://www.healthterminologies.gov.au/
NPAAC	The National Pathology Accreditation Advisory Council (NPAAC) is responsible for developing and maintaining the accreditation standards that pathology laboratories must meet to be eligible for Medicare. The Pathology Services Table (PST) lists the pathology tests for which Medicare benefits are available, their Schedule fees and conditions for use.
OpenEHR	OpenEHR is an organisation that creates specifications, models and software for electronic health records – www.openehr.org
Pathology report	Reporting of the test results and/or professional opinions back to the requesting clinician or their nominated delegate.
Pathology request	A request to perform a specialised pathology service, most commonly undertaken by a medically qualified individual for patient diagnosis or management
Significant risk result	Pathology results that are not imminently life-threatening but signify significant risk to patient well-being and therefore require medical attention and follow-up action within a clinically justified time limit
SNOMED	SNOMED (Systematized Nomenclature of Medicine) is a systematically organised computer processable collection of medical terms providing codes, synonyms, and definitions covering diseases, findings, procedures, microorganisms, substances, etc. It is owned and maintained by the IHTSDO. Where the term SNOMED is used in this document it is referencing SNOMED CT-AU i.e. SNOMED Clinical Terminology, Australian variant. SNOMED CT-AU is available from Australian Digital Health Agency – https://www.healthterminologies.gov.au/learn/clinical-terminology/snomed-ct-au/index.html

SPIA	Standardised Pathology Informatics in Australia is a guideline of best practice recommendations for pathology requesting, reporting, and report rendering
Standard	In the context of this document, the terms ‘standard(s)’ references documents endorsed by RCPA, NATA or NPAAC for use in the laboratory accreditation process
Structured report	An evidence-based and standardised report which has an associated information model and bound terminology. Structured reports are used to convey a complex pathology report such as that associated with cancer or genetics
Term	Words that in a specific context(s) have specific meaning(s)
Terminology	Terminology is the study of terms and their use. In particular, the labelling of concepts particular to one or more subject fields for the purpose of documenting and promoting consistent usage
UCUM	The Unified Code for Units of Measure is a code system intended to include all units of measures to facilitate unambiguous electronic communication of quantities together with their units – https://ucum.org/trac
Unit	A unit of measurement is a definite magnitude of a physical quantity, defined and adopted by convention and/or by law, that is used as a standard for measurement of the same physical quantity. Units refer to the system used for this measurement and its representation

Introduction

This document describes the background and consensus positions reached by members of the pathology informatics community on the characteristics for requesting, reporting, and rendering of pathology results in Australia.

Interoperability

In the context of this document, interoperability is defined as the ability of a range of health information systems, devices, or applications to connect in a coordinated manner, within and across organisational boundaries, to exchange data or information in a way that preserves shared meaning. Interoperability requires standardisation around: transmission of data; identification policies; information structures; common terminology; common understanding; and behavioural agreement. Interoperability is necessary to deliver safer, more efficient, better quality healthcare for individuals and the community.

Requirement for standardisation

In Australia, most medical practitioners use electronic devices for pathology requesting and reporting. In 1998, a consensus-based Australian Standard for the electronic reporting and requesting of pathology (AS4700) was first published. This is the Standard for the Implementation of Health Level Seven v2.x Pathology and diagnostic imaging (diagnostics) in Australia. AS4700.2 includes recommendations around terminology, but in practice there has been significant variation in the implementation of both the message format and terminology. This remains so despite efforts to improve conformance and compliance by writing a detailed programmer's guide (HB262-2012), curating and publishing subsets of the referenced terminologies on the web, offering trusted example messages and providing a free message testing laboratory.

The Australian experience with e-health standardisation is common, as to date there is no universal standardisation of:

- the grammar used to communicate health care information – despite progress with standards like HL7v2.x and CDA
- information structure – despite progress with models like HL7v3 RIM and OpenEHR
- terminology – despite progress with SNOMED, LOINC, HUGO and many others.

Information structures and terminology

Standardised pathology information structures and terminologies allow improvement in recording, decision support, communication and analysis of pathology results. Interoperability facilitates standardisation by enabling efficient communication through information tools like decision support, improving the safety and quality of pathology data.

In routine chemical pathology, most reporting can be dealt with as a 'question-answer pair' such as 'Sodium = 140 mmol/L'. However, in many disciplines such as microbiology, genetics, and cancer reporting, information structures are required to provide context for terms. To illustrate, for a microbiology result, the sensitivity to an antibiotic class must be related to one organism that has been cultured (often one of a number of organisms) and these are grouped with relevant treatment guidelines provided as a comment. Terms need context to have meaning, and so terminology cannot be developed or assigned without first understanding what it is that has a term bound to it. For example, the term for a diagnosis can mean completely different things if the term is stored in the context of "active problem" or if it is stored in the context of "family history". As natural language uses grammar, context is conveyed by information structures or syntax.

Sets of terms (terminologies) used in context (bound to information structures) are needed for:

- Records - capturing information about a consumer and their interactions with the healthcare system
- Decision Support - gaining access to knowledge, helping with workflow and automating processes such as provision of clinical alerts and warnings, and MBS billing
- Communications - allowing more meaningful health information to be exchanged between clinicians and clinical systems within a practice or facility and with others outside the facility, including consumers and other health services
- Analysis - classification of health information, retrieving and analysing information to improve processes at every level from care of the individual consumer through to public health and health policy.

There are two ways of dealing with the development of terms that cover multiple concepts such as is needed for identifying most tests in pathology:

- Having a grammar that allows for the fundamental terms to be put together to make a compound statement is referred to as **post-coordination**, e.g., *sodium-observation+substance-conc+point-in-time+serum+quant+ISE.* The advantage of this choice is that only the fundamental terms are needed, and they can be combined and matched easily for the specific circumstance. The disadvantage of this approach is that the grammar has to be encoded and meaning implied from the structure. Unless deep knowledge is included, the outcome can be nonsensical e.g., a broken right eyebrow.
- Having a different term for each unique set of combinations of characteristics (concepts) is referred to as **pre-coordination**. The advantage of this choice is that only one field is needed, allowing easy interpretation and manipulation. The disadvantage of this approach is that this can lead to a very large number of codes, known as combinatorial explosion. The Logical Observation Identifiers Names and Codes (LOINC)[1] is a pre-coordinated terminology now used in 176 countries and 12

languages for pathology reports and requests. LOINC has six axes to its pre-coordination. For each code (*e.g., 2951-2*) they are:

- Component (analyte) – *e.g., Sodium*
- Property measured – *e.g., Substance concentration*
- Timing – *e.g., A point in time*
- System – *e.g., Serum or urine*
- Scale – *e.g., Quantitative (mmol/L)*
- Method used – *e.g., ISE,* but this is only used where different methods give clinically significant different results.

Units of measure

While there has been standardisation of sorts on pathology units in Australia since 1973, in practice there is significant variation in the units used for some tests and even more widespread variation in how they are rendered on-screen and paper and how they are represented in electronic messages.

Design of this document

This document contains recommended guidelines for the development and implementation of the RCPA SPIA terminology reference sets and standardised units as indicated by the headings 'Development' and 'Implementation'. The use of Italics throughout the document depicts current pathology examples. The following notation demonstrates guidelines and their commentary:

Gxx.xx which refers to a guideline (recommendation)

CGxx.xx which refers to clarifying commentary on the guideline.

Changes since the last edition

A revision of RCPA SPIA Guidelines was undertaken based on works completed during the PITUS 18-20 Project, implementation experience and to safeguard currency of content. In particular are the incorporation of references to the following resources completed under PITUS 18-20 Project: RCPA SPIA Exemplar Reports, the Best Practice Guidelines, the SPIA Reporting Rendering Compliance Checklists, and the NCTS Tool Development Requirements. The revision concluded the deletion of the use of standards in favour of the use of guidelines as the RCPA is not an authorised body to mandate Pathology Informatics within Australia, rather it is best placed to provide guidance and recommendations.

Acknowledgements

The PUTS and PITUS Steering Committees acknowledge and thank all the pathologists, other clinicians, scientists, informaticians, and subject matter experts who contributed to the discussion around this document. In particular, the RCPA acknowledges the active and diligent contributions of the PITUS Working Group members who provided specialised advice to each PITUS project. The members' time was provided on a voluntary basis, and this contribution by individuals and their employers is both recognised and appreciated.

Stakeholders

The pathology profession was represented through the Royal College of Pathologists of Australasia (RCPA) and other members of Public Pathology Australia and Australian Pathology.

The pathology profession defines and endorses the clinical terminology to be used for pathology in Australia with regard to the customers and colleagues of medical laboratories. The National Clinical Terminology Service (NCTS), operated by the Australian Digital Health Agency (ADHA), is responsible for managing, developing and distributing national clinical terminologies and related tools and services to support the digital health requirements of the Australian healthcare community. This responsibility includes being the Australian National Release Centre for SNOMED CT® on behalf of SNOMED International. HL7 Australia, in particular the Orders and Observations Working Group, provides the main link to Australian and international health informatics standards development, software developers, and users. The Medical Software Industry Association (MSIA) provides a representative connection to the commercial developers of medical information systems.

Development process

Where no reference is provided, the authority utilised in creating this document is the consensus of the pathology informatics experts involved in each PUTS and PITUS Project, with endorsement provided by each Project Steering Committee.

1 Terminology

Below are the guiding principles that have been applied in developing this Guideline, the RCPA SPIA terminology reference sets, and their associated preferred terms. These guiding principles are applicable to each chapter in this Guideline. As such, they are not repeated in subsequent chapters.

Guiding principles

1. The standardisation of pathology terminology and units in Australia is desirable and achievable.
2. No single existing terminology will be sufficient.
3. Having well-developed subsets of terms will improve conformance, compliance, and efficiency.
4. A high level of knowledge and familiarity with pathology practice is required to develop and maintain these subsets.
5. The terms used in Australia should reflect common usage but be consistent and safe.
6. The terms should also be practical and capable of ready implementation.
7. All standardised pathology terminology and associated units should be available in one central repository to facilitate maintenance and ensure currency.
8. SNOMED is to be used as the preferred terminology for requesting pathology.
9. LOINC is to be used as the preferred terminology for the highest-level test name in reporting pathology.
10. 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 if it is not used as the primary form for display.
11. 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. Accordingly, caution is required when grouping results from different laboratories, methods, or times for research or other statistical purposes.

2 Requesting terminology and codes

A set of terms for requesting pathology in Australia and their associated codes is available via a link to the NCTS website from the RCPA website. The RCPA SPIA Requesting Pathology Terminology Reference Set contains the most commonly requested terms used in public and private practice, including specialised tests. With 1285 requesting terms available, users can now facilitate searches by applying filters to the list e.g., Discipline, Specimen, Synonyms etc. In 2019, a new reference set was produced explicitly for requesting specific allergens in response to the gap noted by several laboratories performing allergy testing where the single request for Radioallergosorbent test (RAST) was deemed not only to be too broad, but also redundant, with more advanced methodologies often utilised. The RCPA SPIA Requesting Allergens Terminology Reference Set lists 210 of the most common allergens being reported in Australia.

Development

G2.01 Codes for terms used to request pathology tests should be sourced from well maintained and recognised international terminologies. SNOMED should be the first choice and used where it is adequate.

CG2.01 Where no code is available, a local code may be used, provided it is identified as such in the message, and a request for a new code should be made with the NCTS.

G2.02 If the specimen type is not explicitly specified, then blood, serum, or serum/plasma is the assumed specimen type unless there is a more common specimen type for the particular test e.g., the specimen type for *Frozen section* is always tissue.

CG20.2 Where a specimen type is specified, it should follow the substance in the preferred term e.g., Lactate CSF.

G2.03 Attributes such as the anatomical site or clinical condition should only be included in request test names where it is common practice and to inform the selection of the correct term between similar terms e.g., *Glucose tolerance tests* versus *Glucose tolerance test antenatal.*

Implementation

G2.04 Where a code is used to identify a term from the RCPA SPIA Requesting Pathology Terminology Reference Set for electronic communications,

the associated code should appear with the term contained in the reference set.

GS2.04 Where no such term or code is available, a local code may be used provided it is identified as such in the message.

G2.05 Electronic requests for pathology testing should use coded test concepts and preferred terms from the RCPA SPIA Requesting Pathology Terminology Reference Set or RCPA SPIA Requesting Allergens Terminology Reference Set.

CG2.05 Where no appropriate term is available, free text may be used to describe the test.

3 Reporting terminology and codes

A set of terms for reporting pathology in Australia and their associated codes and preferred units is available on the RCPA website. The RCPA SPIA Reporting Terminology Reference Set contains the most commonly reported terms used in both public and private practice, including specialised tests. A single reporting terminology reference set has been compiled for ease of implementation while discipline-specific Terminology Reference Sets are also available for use as listed below:

- Chemical pathology, including a new set for Blood Gases
- Haematology and Transfusion Medicine
- Immunopathology
- Microbiology, Serology and Molecular Biology.

Development

G3.01 Codes for terms used to report pathology tests should be sourced from well-maintained and recognised international terminologies. LOINC should be the first choice and used where it is adequate.

CG3.01 Where no code is available, a local code may be used, provided it is identified as such in the message, and a request for a new code should be made with LOINC.

Implementation

G3.02 Electronic pathology reports should use information models, coded test name concepts, and preferred terms from the RCPA SPIA terminology reference sets.

CG3.02 Where no appropriate term is available, free text may be used to describe the test.

G3.03 Where a code is used to identify a term from one of the RCPA SPIA reporting terminology reference sets for electronic communications, the associated code should appear with the preferred term or a synonym contained in the reference set.

CG3.03 Where no code is available, a local code may be used, provided it is identified as such in the message, and a request for a new code should be made with LOINC.

4 Tests not to be combined in reports

Background

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 an indication is provided with the receiving system's result if it is unsafe to make these comparisons; the primary method for this is via the terminology. When developing the RCPA SPIA terminology reference sets, if methodology was considered to warrant a different reference interval, then method dependant codes were assigned, meaning one test name may have more than one code associated with it. The choice of code is the principal method by which a 'do not combine' signal is conveyed. Results should never be combined and displayed together if they have different LOINC codes.

However, test coding alone is not sufficient to identify all the cases where it may be inappropriate to combine results. As a result, a secondary flag and associated coding system was developed to indicate whether it was considered 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 provided in Table 1 below:

Value	Meaning	Action
Green	This test is considered safe to combine if harmonised	Combine (with caution) Use SNOMED CT-AU code: 765931000168108 | Combine laboratory test result with caution |
Orange	This test has not yet been considered or there is uncertainty around comparisons	Do not combine Use SNOMED CT-AU code: 765921000168105 | Do not combine laboratory test result |
Red	This test is known to be unsafe to make comparisons	Do not combine Use SNOMED CT-AU code: 765921000168105 | Do not combine laboratory test result |

Table 1 - Values for the Combining Results Flag

The Combining Results Flag values for tests are included in each RCPA terminology reference sets where relevant and where determined.

Implementation

G4.01 Tests with method-dependent terms and codes in the report terminology reference sets should have the appropriate code applied, e.g., *Haemoglobin by oximetry* versus *Haemoglobin calculated*.

G4.02 Tests with different LOINC codes should NOT be shown as the same test in sequential display whether by graph or cumulative reporting e.g., *Desipramine* (LOINC code 3531-1 with reporting in mg/L, recommended unit) versus *Desipramine* (LOINC code 14691-0 with reporting in umol/L).

G4.03 Tests with a ‘Combining Results Flag’ with the value of ‘Red’ or ‘Orange’ should NOT be shown as the same test in sequential display whether by graph or cumulative reporting if they come from different laboratories e.g., *Insulin random*.

5 Preferred terms

Background

The preferred term is used to describe the test to be displayed on pathology reports in Australia. The test is described using the corresponding fully specified name from either SNOMED, typically used for requesting or LOINC for atomic result reporting. The rules for establishing preferred terms apply to both requesting and reporting and aim to ensure safe and accurate rendering of the preferred term. There is also a general aim to ensure the most important element of a preferred term is detailed first.

Development

G5.01 The length of preferred terms should not exceed 40 characters where possible as some report formats may not be able to handle more than 40 characters.

CG5.01a	For routine tests, preferred terms should not exceed 20 characters e.g., *Cervical Co-test.*
CG5.01b	Labels/headers used to identify content in columnar cumulative reports should not exceed 13 characters.

G5.02 The identifier of the substance being measured should come first e.g., *Hepatitis A total Ab* not Total *antibodies, Hepatitis A*.

G5.03 Modifying terms should follow the noun in the test name e.g., *Calcium urine.*

G5.04 Australian English spellings should be used for preferred terms. e.g., *faecal* not *fecal* and *haemoglobin* not *hemoglobin.*

G5.05 Full stops should not be used to end test names.

G5.06 Apostrophes should only be used where grammatically correct e.g., *specific IgE Lamb`s quarters pollen.*

G5.07 Prefixes and numeric ranges should be hyphenated except where the common use of a term would make hyphenation irregular e.g., *17-Hydroxyprogesterone* or *Alpha-1-anti-trypsin.*

G5.08 Commas should not be used within the test name except within a chemical structure e.g., *2,3-diphosphoglycerate.*

G5.09 Numbers should be used according to common usage e.g., *17-Hydroxyprogesterone* or *Factor V.*

G5.10 Abbreviations, including acronyms used in developing preferred terms, should be derived from the list provided in Appendix 2 – Abbreviations and Acronyms.

CG5.10a If the same term is used in different test names but is sometimes abbreviated, the unpredictability will make it more difficult to find the preferred term when searching. For example, the approved abbreviation for *antibody* is *Ab;* as such, the term *antibody* should not appear by itself as a preferred term for any immunopathology test.

CG5.10b Acronyms may be used for test names but only if they are accepted in common use, and there is little risk of confusion e.g., *FBC* for *Full blood count*. Consideration should be given for inclusion as an alternative name (synonym) rather than as the preferred term.

G5.11 Capital letters should only be used for:

- The beginning of a test name e.g., *Sodium, Beta-2-glycoprotein, C peptide*
- Test names that represent a profile e.g., containing more than one test. Each test will start with a capital letter e.g., *Electrolytes Urea Creatinine*
- Eponyms where capitalisation is proper e.g., *Bence Jones protein*
- Acronyms following accepted scientific usage e.g., *IgG* for Immunoglobulin G not *IGG*; and *DNA* for deoxyribonucleic acid not *dna.*

G5.12 The forward slash symbol '/' should be used for ratios in test names not the colon ':' e.g., *Calcium/Creatinine not Calcium:Creatinine.*

CG5.12 A colon may be used in a preferred term where it is a formal part of the test name e.g., *vWF Ag:Ristocetin cofactor.*

G5.13 Greek symbols should be shown as their equivalent roman character if not spelt out e.g., *BOHB (Synonym for Beta hydroxybutyrate).*

CG5.13 In some cases, the abbreviation may hinder searching if a commonly used name is altered, e.g., AFP (*Alpha-fetoprotein)* versus *a-fetoprotein*.

G5.14 Subscripts and superscripts should not be used in test names as they may not be correctly rendered by some software which may lead to misinterpretation e.g., *pCO2 arterial,* not *Partial CO_2* or *Calcium ionised blood not Ca^{2+}.*

G5.15 Brand names should not be used.

CG5.15a Common brand names may be used as a synonym e.g., *Clinistix*™ is a common branded Point of Care Test (PoCT) method for measuring the glucose level in urine but should not be used as a test name.

CG5.15b The generic name of a drug should be used, not the brand or trade name when referring to drug concentrations and antimicrobial susceptibilities, e.g., *Temazepam.* The brand or trade name may be used as a synonym e.g., *Restoril.*

G5.16 For Immunopathology, terms should specify whether the antigen or antibody is being requested or reported, if known, by using the abbreviation *Ab* and *Ag* respectively.

CG5.16a For requesting this may not be known in which case the term '*Serology*' should be used e.g., *Hepatitis B serology*.

CG5.16b The abbreviation Ab should be not be included in the preferred name for IgG, IgM or IgA specific tests e.g., *Barmah Forest virus IgG.*

G5.17 Logical conjunctions such as '*and'* should be used as appropriate, but not the plus symbol (*+)* or ampersand (*&)* e.g., *Clostridium difficile toxin A and B.*

G5.18 Unnecessary qualifiers should not be used. For example, the term *total* is often redundant and should not be used except where it is required as an explicit distinction from a measured level e.g., *Cholesterol* not *Total cholesterol level.*

G5.19 The use of generic terms for classes of compounds should not be used when they do not accurately represent the analyte being measured *e.g., Ethanol* not *alcohol level* and *Glucose,* not *blood sugar level.*

G5.20 Chemical symbols and chemical shorthand should not be used. Commonly accepted terms should be utilised e.g., *Ethanol level* not *EtOH level; Sodium* not *Na.*

G5.21 The anionic name for chemicals should be used not the acid name e.g., *lactate, citrate,* and *urate*, not *lactic acid, citric acid* or *uric acid.*

G5.22 Single-term names for alcohols should be used e.g., *methanol, ethanol* and not *methyl alcohol* or *ethyl alcohol.*

G5.23 OH should be spelt out as *Hydroxy* with no space or hyphen between Hydroxy and additional terms e.g., *17-Hydroxyprogesterone.*

G5.24 The noun form of the target of the antibody should be used e.g., *Myocardium Ab*, not *Myocardial Ab or Meningococcus Ab* not *Meningococcal Ab.*

G5.25 The term *anti* should not be used routinely for naming antibodies e.g., *Cardiolipin Ab* is accepted not *Anti-cardiolipin antibody*.

CG5.25a Exceptions to this rule exist as per common usage e.g., *Antinuclear Ab* and *Anti-D titre.*

CG5.25b *Anti* should be used for inhibitory activity e.g., *anti Xa.*

G5.26 The full taxonomic name of an organism (virus, fungus, bacterium or parasite) should be used, not the disease when describing a test that diagnoses that disease. The disease name should be included as a synonym e.g., *Rickettsia rickettsii Ab* not *Rocky Mountain spotted fever Ab; Herpes simplex virus Ab* not *HSV Ab*.

G5.27 In some tests, antibodies apply to different strains of species e.g., in rickettsial diseases, antibodies are tested for groups like the spotted fever group or the typhus group e.g., *Rickettsia spotted fever group* and *Rickettsia typhus group.*

G5.28 Where the identity of a single species is not known, *sp.* (italicised) should be used e.g., *Enterobacter sp.*

CG5.28 For groups of unknown species within a genus, *spp.* (italicised) should be used *e.g., Staphylococcus cohnii spp. cohnii.*

G5.29 When tests include the name of a bacterium the full bacterial name from the Prokaryotic Names with Standing in the Nomenclature (https://www.bacterio.net/) should be used e.g., *Neisseria gonorrhoeae DNA.*

G5.30 When tests include the name of a virus the viral name as given by International Classification on the Taxonomy of Viruses (https://talk.ictvonline.org/) should be used e.g., *West Nile virus IgM.*

G5.31 For tests performed on specimens other than blood, serum or plasma, the preferred name should include the specimen e.g., *Beta-2-microglobulin CSF* or *Beta-2-microglobulin urine*.

CG5.31 Where the sample most commonly used to perform a test is not blood, serum or plasma, the specimen is not listed in the term e.g., Liquid based cervical cytology which is always performed on a cervical swab.

CG.32 Tests performed on a faeces specimen should use 'faeces' in the preferred name, not the term 'stool' e.g., *Alpha-1-antitrypsin faeces*.

G5.33 For tests performed using more than one method, and where method differentiation/specification assists with clinical decision support, the method should be incorporated into the preferred name e.g., *Influenza B total Ab complement fixation.*

G5.34 For all allergen requesting, terms should be prefixed with specific IgE followed by the specific allergen or allergen mix e.g., *specific IgE Walnut* or *specific IgE Weed pollen mix wv.*

Implementation

G5.35 Guideline G3.01 and Commentary CG3.01 applies.

6 Units of measure

The preferred units of measure to be used in Australia are available by test at the RCPA website. Common Australian Units of Measure with their *Unified Code for Units of Measure*[2] (UCUM) http://unitsofmeasure.org/ representation and standard display form are shown in Table 2.

Background

The preferred unit of measure for a concentration may be represented in three ways, namely:

- the type of unit for the numerator (quantity e.g., grams vs. statement of amount - moles)
- the multiplier (e.g., milli or micro)
- the denominator (e.g., litre). The volume litre is preferred although there are exceptions in common use.

If all these factors indicate the same unit for a specific test, the selection is easy, however where variation occurs, the overriding principle directing choice should focus on patient safety. Considerations should include reducing the number of laboratories needing to change units, aligning reporting units with common reference sources, or selecting units to facilitate calculations. Units of measure used in Australian laboratories are not currently standardised and there is significant variation seen for some tests with respect to how they are rendered electronically and represented in electronic messages. For example, the following units were taken from reports for Creatinine Clearance:

- mL/sec
- mL/min
- mL/min/1.7m2
- mL/s.

Units of measure in Australia use a hybrid of common practices e.g., substance concentration (*mmol/L*) and mass units (*mg/L*) and sometimes its own conventions. The system of units of measure and the way it is rendered can vary, for example:

- mmol/day
- mmol/d
- mmol/24 hrs
- mmol/24hrs
- mmol/24hr
- mmol/24h
- mmol/24 hour.

To address this issue, UCUM has been devised by the Regenstrief Institute. The UCUM system provides one logical, unambiguous way of describing the units. For the example above, the UCUM representation would be mmol/(24.h).

Guiding principles

1. A single, test-specific, standardised unit of measure is preferred for use in reports from pathology laboratories.
2. Units should be represented in electronic messages that facilitates receiving systems to readily convert units under the clinical governance of the receivers. UCUM is to be used as the logical representation of units of measure in electronic messages to allow for Principle 1.
3. Numeric results should always be displayed with their appropriate units and should never be displayed without them.

Development

The following criteria should be used to determine the preferred unit of measure for a test:

G6.01 Common unit usage should be considered. If a test is already reported either entirely, or nearly entirely in a unit type by Australian laboratories, this unit should become the preferred unit.

G6.02 Previous Australian guidelines specifying a unit type should be considered. There are a number of other specific recommendations endorsed by the College and other organisations e.g., *serum creatinine* in *umol/L* and *GFR* in *mL/min.*

G6.03 Use of units in Australian clinical guidelines should be considered. If a unit is commonly used in clinical guidelines and other reference material in Australia then this should become the preferred unit e.g., the use of mmol/L for reporting serum triglycerides and total, LDL, HDL and Non-HLD cholesterol is outlined in the AACB Guideline for Harmonised Lipid Reporting.

G6.04 The implementation of the International System of Units (Système International d'Unités, SI) should be considered. Units conforming to SI should be selected based on the agreed national measurement system. There are currently specific exceptions to this e.g., the use

of mL/min for glomerular filtration rate rather than mL/sec; and U/L for enzyme activity rather than the SI unit, the katal.

G6.05 Units used for related tests should be considered. For example, reporting both total protein and albumin in g/L makes calculation and understanding of globulin results easier. Using the same units in serum and urine facilitates some calculations such as clearance. In general, it would be preferred that similar tests are reported in the same units e.g., all lipids in mmol/L; all drugs in mass units, although exceptions may be required.

G6.06 Use of units in international guidelines and reference sources should be considered. For example, if the clinical oncology guidelines from the American Society of Clinical Oncology use a specific unit for a tumour marker, this may be influential with regard to local use.

G6.07 Units used to define reference standards should be considered. If the primary reference standard for an analyte is defined in a units type e.g., International Units (IU) for hCG, this supports using this unit for reporting test results.

G6.08 Test names should include relevant information to prevent the use of annotations in units; Additional information could appear elsewhere such as on the report or in online manuals. For example, the unit for the Albumin/creatinine ratio is *mg/mmol*. It is clear from the test name that albumin is reported as a ratio to creatinine. Annotating the unit with creatinine is therefore unnecessary i.e. milligrams per millimole of creatinine. Ratios should be reported in the same units as the components of the ratio. For example, the unit for the Albumin/creatinine ratio is *mg/mmol* rather than simplified as *g/mol.*

G6.09 Arbitrary units should be represented by *U* in the preferred display instead of *Arb'U*. For example, *U/mL* (UCUM: *[arb'U]/mL*). Note it is important to transmit the correctly mapped UCUM unit in electronic messages to differentiate arbitrary units from enzyme units, which is also represented by *U*.

CG6.09a Arbitrary units will replace dedicated units unless there is RCPA consensus recommendation to keep a specific unit such as the *Bethesda unit* e.g., u*se arbitrary units (U)* instead of *GPL units (UCUM: [GPL'U])* for the biologic activity of *Cardiolipin IgG*.

CG6.09b Use Bethesda Units with preferred display format *Bethesda U* for *Factor VIII Inhibitor (UCUM: [beth'U]*).

CG6.09c Catalytic activity or enzyme units should be represented by *U* in the preferred display (UCUM: *U*). Note that *U* is also used as the preferred display for arbitrary units.

CG6.09d International Units is a type of arbitrary unit and is represented as *IU* in the preferred display format (UCUM: *[IU]*).

G6.10 *Per 24 hours* should be used instead of *per day* for daily excretion rates represented as */24h* and not according to the UCUM syntax as */(24.h)*. The fully defined UCUM syntax should be used in electronic messaging.

G6.11 *Year* should be represented with *year* and not UCUM: *a, e.g.,* the preferred display unit of “per year” will be */year* not */a.*

G6.12 *Ratios* should have no preferred display unit e.g., INR or Free Kappa/Lambda ratios.

G6.13 For reporting *Haematocrit, Litre/Litre* or *no unit* should be used (*L/L* is endorsed by UK Pathology Harmony).

G6.14 *For pH*, no unit should be displayed as endorsed by UK Pathology Harmony, but the fully defined UCUM syntax *[pH]* should be used in electronic messaging.

Implementation

G6.15 Units of measure should always be displayed where a quantity is shown on pathology reports.

CG6.15 For qualitative reporting, no units are used e.g., *Opiates saliva screen* where the result would typically be reported as *positive*, *negative* or *equivocal*.

G6.16 Pathology reports should use the units specified in this document for those tests where units have been determined.

G6.17 A single, standardised unit of measure should be used for tests in reports from pathology laboratories.

CG6.17 There may be valid exceptions to this rule;

- in a transition from one preferred unit to another

- where alternate units are required by legislation or regulation such as for a registry
- where a historic report is produced – historic data need not comply.

G6.18 Where the unit is not specified in the RCPA SPIA Terminology Reporting Reference Sets, UCUM should be used with the fully defined UCUM syntax for electronic messaging.

G6.19 Superscripts and subscripts should not be used in units e.g., *millilitre per minute per 1.73 square metre* is not represented as *mL/min/1.73m^2*, rather as *mL/min/1.73m2* and as *mL/min/{1.73_m2}* in the UCUM representation in the message.

G6.20 The caret symbol (^) should be used to render "raised to a power of" on the report. Care must be taken to appropriately "escape" the caret symbol (^) as this symbol is used as a component separator in HL7 messages. It should be noted that in UCUM this is represented by the asterisk symbol (*) e.g., *10 raised to the power of 9 would be rendered as 10^9 on the screen and as 10*9 in the UCUM representation in the message.*

G6.21 Units raised to a power should be indicated in the preferred display unit by the exponent as an integer 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.

Unit Description	Preferred Display	UCUM Unit
arbitrary unit	U	[arb'U]
arbitrary unit per millilitre	U/mL	[arb'U]/mL
area under curve	mg.h/L	mg.h/L
Bethesda unit	Bethesda U	[beth'U]
billion per litre	10^9/L	10*9/L
centimetre	cm	cm
copies per millilitre	copies/mL	{copies}/mL
day	d	d
degree Celsius	Cel	Cel
enzyme unit per 24 hour	U/24h	U/(24.h)
enzyme unit per gram	U/g	U/g
enzyme unit per litre	U/L	U/L
enzyme unit per millilitre	U/mL	U/mL
enzyme unit per millimole	U/mmol	U/mmol
femtolitre	fL	fL
femtomole per litre	fmol/L	fmol/L
globules (drops) per high power field	Globules/HPF	{Globules}/[HPF]
gram	g	g
gram per 24 hour	g/24h	g/(24.h)
gram per 72 hour	g/72h	g/(72.h)
gram per decilitre	g/dL	g/dL
gram per litre	g/L	g/L
hour	h	h
international normalised ratio	no unit	{INR}
international unit per gram	IU/g	[IU]/g
international unit per litre	IU/L	[IU]/L
international unit per millilitre	IU/mL	[IU]/mL
kilo arbitrary unit per litre	kU/L	k[arb'U]/L
kilo enzyme unit per litre	kU/L	kU/L
kilo international unit per litre	kIU/L	k[IU]/L
kilo international unit per millilitre	kIU/mL	k[IU]/mL
kilogram	kg	kg
kilopascal	kPa	kPa
litre	L	L
litre per 24 hour	L/24h	L/(24.h)
litre per litre	L/L	L/L
log (base 10) copies per millilitre	Log copies/mL	{Log_copies}/mL
log (base 10) international unit per millilitre	Log IU/mL	{Log_IU}/mL
metre	m	m

Unit Description	Preferred Display	UCUM Unit
microgram	ug	ug
microgram per 24 hour	ug/24h	ug/(24.h)
microgram per decilitre	ug/dL	ug/dL
microgram per gram	ug/g	ug/g
microgram per litre	ug/L	ug/L
microgram per minute	ug/min	ug/min
microlitre	uL	uL
micrometre	um	um
micromole per 24 hour	umol/24h	umol/(24.h)
micromole per gram	umol/g	umol/g
micromole per kilogram	umol/kg	umol/kg
micromole per litre	umol/L	umol/L
micromole per millimole	umol/mmol	umol/mmol
milli enzyme unit per litre	mU/L	mU/L
milli international unit per litre	mIU/L	m[IU]/L
milli international unit per millilitre	mIU/mL	m[IU]/mL
milligram	mg	mg
milligram per 24 hour	mg/24h	mg/(24.h)
milligram per gram	mg/g	mg/g
milligram per litre	mg/L	mg/L
milligram per millimole	mg/mmol	mg/mmol
millilitre	mL	mL
millilitre per minute	mL/min	mL/min
millilitre per minute per 1.73 square metre	mL/min/1.73m2	mL/min/{1.73_m2}
millimetre	mm	mm
millimetre of mercury	mmHg	mm[Hg]
millimetre per hour	mm/h	mm/h
millimole per 24 hour	mmol/24h	mmol/(24.h)
millimole per kilogram	mmol/kg	mmol/kg
millimole per litre	mmol/L	mmol/L
millimole per mole	mmol/mol	mmol/mol
million colony forming units per litre	10*6 CFU/L	10*6.[CFU]/L
million per litre	10*6/L	10*6/L
million per millilitre	10*6/mL	10*6/mL
minute	min	min
multiple of the median	MoM	{M.o.M}
nanogram per litre	ng/L	ng/L
nanomole per 24 hour	nmol/24h	nmol/(24.h)
nanomole per gram	nmol/g	nmol/g

Unit Description	Preferred Display	UCUM Unit
nanomole per litre	nmol/L	nmol/L
nanomole per milligram	nmol/mg	nmol/mg
parts per billion	ppb	[ppb]
per low power field	/LPF	/[LPH]
per high power field	/HPF	/[HPF]
per microlitre	/uL	/uL
per year	/year	/a
percent	%	%
pH	No unit	[pH]
picogram	pg	pg
picomole per litre	pmol/L	pmol/L
ratio	no unit	{ratio}
second	s	s
signal to cutoff ratio	s/co	{s_co_ratio}
titre	titre	{titre}
trillion per litre	10*12/L	10*12/L
umol/gram dry weight divided by the age of patient in years	umol/g/year of life	umol/g/a
week	wk	wk

Table 2 – RCPA SPIA Preferred Units

7 Rendering of numeric results, ranges, units, previous results and flagging

Background

There is anecdotal evidence that existing variation in report formats in Australia has led to the misunderstanding and misreading of results, which is a clinical safety issue. International evidence has shown major inconsistencies between what elements are recommended for inclusion in safe pathology reporting formats and what currently exists. Valenstein[3] reviewed literature from pathology and identified four principles for effective and safe reporting in pathology:

- Use of diagnostic headlines to emphasise key points
- Maintenance of layout continuity with other reports over time
- Optimisation of information density
- Reduction of extraneous information (clutter).

Some of the key usability methods applicable to safety in reporting[4] include:

- Consistency and standardisation relating to the sequence of actions, layout, position and terminology
- Minimalisation – absence of extraneous information which can distract attention
- Clear closure – understanding the bounds of the report, i.e. where it begins and where it ends
- Use of language that is understandable
- Context-sensitive assistance or documentation links to assist report reading.

Results from a survey distributed by the RCPA in 2013 identified significant variation in reporting, in particular, cumulative reporting for Biochemistry, Haematology, and Coagulation tests. Wide variation was observed in the characteristics that were followed up in a subsequent second survey conducted in 2014, examining proposals for specific design elements of a cumulative report. The survey was distributed to a wider audience including general practitioners, specialists and other clinicians, pathologists and health informaticians. The participants were asked to indicate their preference from the binary choices provided and the reasons for those choices. More than 90% of the survey respondents supported standardisation of:

- Time direction for columns on a cumulative report (left or right)
- Highlighting of latest results in cumulative reports
- Flagging of results
- Time direction for rows (up or down).

A further 80% supported the standardisation of the position of reference and units columns. Both surveys were used in forming these Guidelines. To assist LIS software vendors and laboratories to implement the SPIA Guidelines and the RCPA SPIA terminology reference sets, the PITUS 18-20 Project developed the following material: Best Practice Guidelines, SPIA Rendered Report Compliance Checklists (basic and comprehensive), RCPA SPIA Exemplar Reports and the NCTS Tool Development Requirements, all of which are found on the RCPA PITUS website.

Guiding principles

1. Only those aspects of rendering where there is a concern around safety and presentation were supported in developing these guidelines.
2. Numeric results are incomplete without associated units and guidance for interpretation e.g., reference intervals; these should always be displayed with the number.
3. Guidance values may be reference intervals, healthy limits or therapeutic ranges depending upon the test.
4. Further interpretation of results over time depends on knowing the latest results and the direction of time; therefore, when results are displayed in columns, rows or graphically, these should be consistent across disciplines and laboratories and the latest results should be differentiated from previous results.
5. Electronic reports should display the latest results on the first display screen to avoid missing the latest result.
6. Colour-blindness affects 5-10% of the population. With the possible loss of colour in some communications, colour alone cannot be used as the sole method for highlighting attention to specific results; as such, the font should also be bolded.
7. Multi-level flagging may be used.
8. Proposed reporting group names as per the RCPA Best Practice Guidelines: If the requested test is recommended to be reported alone, without any co-requested tests on the same report, the proposed group name is the same as the requesting term. If it is recommended to include additional co-requested tests on the same report, the proposed group name is selected to describe the entire group.

Development

The following guidance is provided for report rendering:

G7.01 The intention is not to stifle innovation in presentation, so only those aspects of rendering should be considered for adoption where there is a concern around safety and broad support for standardisation.

G7.02 The RCPA SPIA Exemplar Reports have been designed to provide laboratory staff and software vendors with visual representations of SPIA compliant reports for a range of disciplines with respect to report formatting as outlined in this chapter. The inclusion or exclusion of tests, preferred terms, reference intervals and the order in which the tests appear on each report are not necessarily meant to be indicative of true report content, merely to demonstrate formatting. The Exemplar Reports are available at https://www.rcpa.edu.au/Library/Practising-Pathology/PTIS/PITUS-18-20.

G7.03 HL7 V2, FHIR and CDA representations of each Exemplar Report are now available to assist software vendors with the design of SPIA compliant messages. Messages for the Exemplar Reports are available at https://www.rcpa.edu.au/Library/Practising-Pathology/PTIS/PITUS-18-20.

G7.04 Two SPIA Rendered Report Compliance Checklists were developed, representing a combination of RCPA SPIA, NPAAC and NATA design elements used to assess rendered pathology report compliance. The basic checklist incorporates 30 report elements while the comprehensive incorporates 62 report elements with additional elements listed for SPRC, Cervical Cytology, Human Medical Genome Testing and Non-invasive Prenatal Screening reports. Both checklists are available at https://www.rcpa.edu.au/Library/Practising-Pathology/PTIS/PITUS-18-20.

Implementation

An example of the application of the guidelines for report rendering is shown for a columnar cumulative report in Figure 1 and a single report in Figure 2.

				Latest Results		
Collection Date:	01-Jun-13	01-Jul-13	01-Aug-13	**11-Aug-13**		
Collection Time:	16:00	10:00	15:00	**09:00**		
Request No:	111111	222222	333333	**444444**	Reference	Units
Chemistry						
Sodium	**132 L**	**134 L**	**130 L**	**131 L**	(135–145)	mmol/L
Potassium	4.5	3.8	**5.6 H**	**7.1 H**	(3.5–5.2)	mmol/L
Chloride	**94 L**	98	**93 L**	95	(95–110)	mmol/L
Bicarbonate	**20 L**	**20 L**	26	**21 L**	(22–32)	mmol/L
Urea	6.8	6.5	7.0	7.3	(3.0-8.5)	mmol/L
Creatinine	74	69	87	73	(60–110)	umol/L
eGFR	66	71	54	67		mL/min/1.73m2
Calcium	2.19	2.28		2.29	(2.10–2.60)	mmol/L
Ca (alb cor)	2.13	2.26		2.27	(2.10–2.60)	mmol/L
Magnesium	0.75	0.74		0.79	(0.70–1.10)	mmol/L
Phosphate	1.31	0.96		1.29	(0.75–1.50)	mmol/L
Osmolality	283					mmol/kg

Figure 1 - Cumulative report illustrating application of the rules for report rendering

Iron studies

		Reference	Units
Ferritin	**26 L**	(30-300)	ug/L
Iron	**9 L**	(11-30)	umol/L
Transferrin	2.6	(1.7-3.6)	g/L
Transferrin saturation	17	(15-45)	**%**

Confirmed iron deficiency.

Figure 2 - Single report illustrating application of the rules for report rendering

G7.06 Numeric results should be right justified when displayed in columns and have corresponding guidance values e.g., reference interval and units if applicable.

G7.07 Numeric results should have a leading zero where there is no number in the units place e.g., *0.7* not *.7.*

G7.08 For columnar cumulative reports, the latest result should be shown in the furthest right column of results i.e. the collection time should be displayed from left to right across the page. For cumulative reports shown in rows, the latest result should be displayed from the top to the bottom of the page.

G7.09 The latest result should be differentiated from earlier results by a minimum of two methods, one of which is a heading 'Latest Results'. Other methods may be either a box surrounding the results as shown in Figure 1 or bolding of the heading text.

G7.10 Guidance values should be bounded by parentheses and have no spaces.

G7.11 Italics should not be used.

G7.12 The column showing units should be headed 'Units', be left justified and be to the immediate right of the 'Reference' column.

G7.13 The numbers used for guidance should be rendered with the same number of decimal places as the related result.

CG7.13 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. 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.

G7.14 Results are considered outside the guidance values if after rounding to the format of the displayed result and the guidance value, the result is greater than the higher number or less than the lower number of the guidance values.

G7.15 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).

CG7.15a A single asterisk ('*') and the '+' and '-' characters should not be used for flagging results.

CG7.15b Underlining should not be used for highlighting results.

	CG7.15c	Colour alone cannot be used as the sole method for highlighting attention to specific results; the font should also be bolded.
	CG7.15d	Multi-level flagging may be used in which case ‘LL’ or ‘HH' should be used for the second level.

G7.16 Headings should be differentiated from test names where practical.

G7.17 Dates should be displayed using the format dd-mmm-yy *e.g., 30-Jan-14,* not *30/01/14.*

8 Harmonised reference intervals

A set of harmonised reference intervals for reporting pathology in Australia and New Zealand is available via the following link on the RCPA Website https://www.rcpa.edu.au/Library/Practising-Pathology/PTIS/APUTS-Downloads.

Background

Harmonisation in the context of pathology testing is described as the actions taken to ensure different laboratories provide consistent information without variation in laboratory process or analytical bias[5]. Scientific evidence supports the use of common reference intervals for many chemistry analytes, particularly those with sound calibration and traceability in place. The AACB Harmonisation Working Group developed a number of common reference intervals by consensus agreement for routine use for adults and children, representing age and sex where appropriate and including values for paediatric use.

Guiding principles

1. Guidance values should be evidence-based but as simple and consistent as real biological variation, and good medical practice allows.
2. Common usage for analyte reference limits has both the low and high values included, whereas for age limits, the higher value is not included.
3. There is as yet no international standard for representing age intervals. The AACB Harmonisation Working Group proposed the format ‘1w to <12y’ to show the time interval in a table or on a report.
4. The same method for representing age intervals should be used for both adults and children.

Development

The following guidance is provided for the development of harmonised guidance values:

G8.03 Guidance values should be evidence-based but as simple and consistent as real biological variation and good medical practice allows.

Implementation

The aim is to have the proposed reference intervals widely used within Australia and New Zealand. The responsibility for use of the intervals lies with the individual laboratory Director but the NATA 15189 field application document supports consideration of the use of common reference intervals such as those referenced here.

G8.01 Age intervals are calculated in days from date of birth to date of collection, starting with the day of birth as day 0, with the result always rounded down.

G8.02 Age intervals should be rendered using days, weeks or years, but not months, in the form shown in Table 3 below. The Table also provides the interpretation of time ranges for common age intervals.

CG8.02 A mixture of days, weeks and years is permissible where it is appropriate (e.g., '7d to <10y').

Age	Interpretation of age (days)
0d to <1w	$0 \le d \le 6$
1w to <4w	$7 \le d \le 27$
1w to <26w	$7 \le d \le 181$
1w to <2y	$7 \le d \le 729$
1w to <18y	$7 \le d \le 6573$
4w to <26w	$28 \le d \le 181$
4w to <2y	$28 \le d \le 729$
26w to <1y	$182 \le d \le 364$
26w to <2y	$182 \le d \le 729$
1y to <4y	$365 \le d \le 1460$
2y to <6y	$730 \le d \le 2190$
2y to <10y	$730 \le d \le 3651$
2y to <18y	$730 \le d \le 6573$
4y to <15y	$1461 \le d \le 5477$
6y to <10y	$2191 \le d \le 3651$
6y to <12y	$2191 \le d \le 4382$
10y to <13y	$3652 \le d \le 4747$
10y to <14y	$3652 \le d \le 5112$
10y to <18y	$3652 \le d \le 6573$
12y to <15y	$4383 \le d \le 5477$
13y to <14y	$4748 \le d \le 5112$
14y to <15y	$5113 \le d \le 5477$
15y to <16y	$5478 \le d \le 5843$
15y to <17y	$5478 \le d \le 6208$

15y to <18y	5478 ≤ *d* ≤ 6573
15y to <19y	5478 ≤ *d* ≤ 6938
16y to <22y	5844 ≤ *d* ≤ 8034
17y to <19y	6209 ≤ *d* ≤ 6938
18y to <120y	6574 ≤ *d* ≤ 43829
19y to <22y	6939 ≤ *d* ≤ 8034
19y to <60y	6939 ≤ *d* ≤ 21914
20y to <120y	7305 ≤ *d* ≤ 43829
22y to <120y	8035 ≤ *d* ≤ 43829

Table 3 – Common Age Intervals

9 Safe pathology requesting

This chapter describes the recommended best practice guidelines for the safe communication of pathology requests for both senders and recipients, focusing on computer-generated paper or electronic pathology requests. It explains the reasoning behind the recommended guidelines and commentary and is intended to be used for current practice as well as for those continuing with the development and implementation of these guidelines across all domains of pathology and healthcare settings.

This document does not include in its scope guidelines for hand-written pathology requests.

Background

The NPAAC *Requirements for Medical Pathology Services (Third Edition 2018)* addresses guiding principles for pathology requesting and sets minimum requirements for the information required within a pathology request. This document is not a replacement, but rather an enhancement of the NPAAC requirements. The NPAAC document states, “accurate patient identification and specimen labelling are crucial to patient safety. Failure to comply with these requirements remains a significant cause of patient morbidity, and occasionally mortality”.

While full use of electronic requesting with advanced clinical decision support has been shown to reduce errors in pathology, it can also introduce errors if not implemented correctly.

Implementation

Electronic pathology request

G9.01 Clinical systems used for requesting pathology should ensure the confidentiality and integrity of patient health records is maintained at all times.

CG9.01a Any device used for pathology ordering should comply with all confidentiality and security requirements.

CG9.01b The pathology ordering system should comply with the RACGP's *Computer and information security standards*.

CG9.01c Electronic data transmission of patient health information should be secure.

G9.02 Pathology requests should be electronically generated where possible.

CG9.02a Research has highlighted that most pathology-related errors occur in the pre-analytical and post-analytical phases. Clinical systems assisting with requesting pathology may help reduce pre-analytical errors and improve the quality of information provided to the laboratory.

CG9.02b Clinical systems should provide the following functionality:

- Test selection using standard terminology;
- Decision support;
- A record of the request details such as:
  - patient and specimen identifiers;
  - tests requested;
  - Date-time of request;
- Secure data transfer which is acknowledged electronically
- Reconciliation of results with the original request.

G9.03 Clinical systems used for requesting pathology should be able to print a paper request form containing all relevant patient demographics and requesting details.

CG9.03a Hand-written request forms may impact patient safety due to misinterpretation of patient information and tests ordered, which could lead to incomplete or incorrect patient information, incorrect specimens collected, and incorrect tests performed.

CG9.03b Hard-copy request forms are necessary for instances where the requesting message is sent electronically, but a laboratory system failure occurs.

G9.04 Pathology requests should be sent and received electronically to reduce data entry effort and the potential for legibility, patient identification and transcription errors.

CG9.04a Clinical systems should be able to send and receive compliant HL7 order messages.

CG9.04b A printed paper request form may be used to supplement the electronic request, e.g., to inform a patient of the location of testing facility, testing preparation e.g., fasting and of the tests being performed.

G9.05 Systems receiving electronic pathology requests should support acknowledgment of the pathology request messages.

CG9.05a Laboratory systems should send acknowledgement messages back to the source to confirm successful receipt of the pathology request message. Electronic request messages cannot be considered as successfully delivered until a transport acknowledgment message has been received, confirming delivery. Refer to http://www.health.gov.au/internet/main/publishing.nsf/Content/health-npaac-docs-InfoComm.htm.

CG9.05b Laboratory acknowledgment of an electronic request does not constitute a contract to undertake services; it indicates a willingness and capability to perform or refer the requested services when appropriate specimens are received by the Laboratory. Refer to http://www.health.gov.au/internet/main/publishing.nsf/Content/health-npaac-docs-InfoComm.htm.

G9.06 Clinical systems used for requesting pathology or decision support should allow for the capture and display of pertinent clinical information and patient information should be visible in the electronic pathology ordering system.

CG9.06a Patient demographics such as name, address, date of birth and sex should be clearly displayed in the electronic pathology ordering system to minimise errors related to misidentification.

CG9.06b The system used for electronic ordering should provide the ability for the clinician to input relevant clinical issues at the time of ordering; this information should be visible on the screen.

CG9.06c The patient's relevant clinical information should be included in the electronic order to provide the laboratory with pertinent clinical information for the requested test(s).

CG9.06d Relevant coded patient information should be provided such as: pregnant; diabetic; therapeutic drug monitoring; prostate cancer, etc. The clinical information should be provided back to the clinician on the report.

CG9.06e The clinical system should display tests previously requested, including the date of request, enabling the clinician to order tests appropriately.

G9.07 The electronic ordering system should clearly indicate the steps to complete a request.

CG9.07a The minimum information necessary to complete an electronic request includes: patient identity (surname, given name, date of birth, sex and patient identifier); requesting practitioner name; clinical information; date and time of request; tests requested.

CG9.07b The system should provide a step approach and clearly indicate mandatory fields required to complete a request and provide suitable highlighting/alert to indicate any missing information to reduce the risk of delay to the order.

CG9.07c Alert messages in the electronic ordering system should be clear, appropriate and unambiguous. Unclear alert messages and excessive use of alerts may reduce their effectiveness and may be misinterpreted, resulting in clinicians missing important alerts.

CG9.07d When entering a request, suitable alerts should indicate issues with eligibility of the test being added, such as when a duplicate test is requested, or when it is an inappropriate test for the patient's age or sex (e.g., PSA test on a female), etc.

CG9.07e The clinician should be alerted to the status of the electronic pathology request.

G9.08 Clinical systems used for requesting pathology should support the use of standardised terminology for pathology tests to reduce the risk of misinterpretation or misunderstanding of the requested test.

CG9.08a Using recognised standardised terminology sources when requesting pathology tests will improve communication between the clinician and laboratory staff e.g., the RCPA SPIA Requesting Terminology Reference Set published coded test concepts and preferred terms for pathology tests.

CG9.08b Where there is no suitable term available, free text may be used to describe the test, but should be avoided when practical as it may result in the inability to reconcile requested tests. Strategies should be incorporated in the system to minimise the use of free text requesting, such as:

- The use of standardised coded pathology tests
- The use of common synonyms
- Listing all commonly requested tests
- Providing search functionality e.g., the use of dropdown lists and natural language or voice processing mechanism to search for a test.

CG9.08c Receiving systems should make an appropriate response to text in a free text request field e.g., ensure the field is read and acted on.

G9.09 The clinician should have access to appropriate knowledge or clinical support systems to assist with requesting relevant tests.

CG9.09a Online authoritative information resources can reduce the risk of errors and improve patient care by providing up-to-date information on pathology tests. Such information resources include the RCPA Manual; RCPA Genetic Tests and Laboratories; Lab Tests Online; RACGP Guidelines for preventive activities in general practice 9th edition; or by contacting the laboratory.

Decision Support

G9.10 Electronic requesting systems should incorporate decision support.

CG9.10a There is proven value in providing decision support for test requesting. The best quality practice would indicate the following attributes are required:

- Decision support should be based on good evidence, which is reviewed promptly. The review should include expert clinical input to ensure accuracy and clinical context;
- Expert knowledge should be appropriately managed, including version control;
- Decision support should be configurable to allow systems to match the requester knowledge and expertise of the user;
- Ability to generate an alert when the test is being requested e.g.,
  - to indicate a breach of Medicare Benefit Schedule (MBS) rules or that the test is not on the MBS schedule so the requester knows possible billing implications;
  - when it is an inappropriate test for the patient's age or sex e.g., PSA test on a female;
  - when the test is being requested too soon e.g., Hepatitis serology requested in the previous week, etc.
- The system may include the generation of a reminder to prompt for screening or regular requesting of tests that may not have been requested in the current request. e.g.,
  - diabetic patient overdue for annual HbA1c test;
  - cervical screen overdue;
  - a patient with previously abnormal liver function tests without follow-up to check current status;
- Ability to apply condition-based testing to turn a condition into a set of recommended set of tests e.g., Antenatal screen;
- Provision of algorithms or pathways based on clinical condition, patient demographics and previous results.

10 Safe pathology reporting

This chapter describes the guidelines for best practice communication of pathology reports, both printed and electronic, for senders and recipients.

Background

The NPAAC *Requirements for Medical Pathology Services (Third Edition 2018)* addresses guiding principles for pathology reporting and sets minimum requirements for the information contained within a pathology report. RCPA SPIA is not a replacement, rather an enhancement of the NPAAC requirements.

In the EHR-enabled environment, providers rely on technology to support and manage the reporting and follow-up of test results. The RCPA SPIA offers recommended practices related to the content and communication of test results to the clinician, as well as recommended practices related to the follow-up of test results. To manage optimal patient safety, attention needs to be paid to monitoring the safe use of informatics, decision support and pathology IT.

Implementation

G10.01 Data should be sent in a rendered format and may be accompanied by atomic results which should be coded.

CG10.01 Meaning is conveyed by spatial association and arrangement of headings, results, comments, and other text on a rendered report. Therefore, it is essential to have a means of assurance that a report is being viewed in the manner in which the issuing laboratory intended.

G10.02 Pathology reports should be stored in the receiving system in the same format as they are received; this refers to structured reports as well as atomic results.

CG10.02a Rending in the same format will reduce the risk of misinterpretation.

CG10.02b The report should be sent in the same format as that produced by the issuing laboratory. If pathology results are forwarded or shared to other clinicians, electronic health record etc., they should also be sent in the format provided by the issuing laboratory.

CG10.02c Retaining the same format for atomic results is required to enable use of the information for data search, retrieval, aggregation, analysis or decision support.

CG10.02d If the data are standardised, then the atomic results can be sent in addition to the rendered report.

G10.03 Data should be stored in receiving systems as atomic results using standardised terminology and units.

CG10.03a Sending and receiving systems should use the published standardised terminology and units described here where possible.

CG10.03b Report responses should be stored as atomic results in addition to any supplied narrative text as transmitted by the sending system.

CG10.03c Care should be taken when storing text as results and where coded comments are attached to numeric results.

G10.04 Receiving systems should be capable of rendering results in the manner intended by the sending system, which should be consistent with Guidelines described in Chapter 7.

CG10.04a For structured reports, the formatted report should be the default display.

CG10.04b For atomic results, the receiving system should always display results and units in the same format as provided by the sending system; results should not be converted to other units of measure for initial interpretation.

CG10.04c All numeric results should always be displayed with relevant units.

CG10.04d Results for the same test should only be displayed together and combined (cumulative or graphical) where the tests have the same LOINC codes and there is no flag to indicate that results should not be combined as outlined in Chapter 4.

G10.05 Data should be stored as structured reports using standardised terminology published in the RCPA SPRC protocols if received in that manner.

CG10.05a Receiving systems should store atomic results as intended by the sending system to enable the information to be used for data search, retrieval, aggregation, analysis or decision support.

CG10.05b The College has published SPRC protocols (SPRC) for 48 cancers, equivalent to 89% of all cancers. Click here to download the SPRC protocols[6]. These standards are not restricted to cancer reporting as other disciplines such as genetics are developing similar reporting standards.

G10.06 Text and/or interpretation of coded results should be preserved in receiving systems.

CG10.06a When displaying reports from multiple episodes, perhaps from different laboratories, it is beneficial to display results mapped to a standardised reference template. Refer to Chapter 4 for full details.

G10.07 The system used to store a patient's health record should have the ability to track the status of a patient's requested tests.

CG10.07a On receiving the request form and specimen, the laboratory should send an electronic 'receipt' message which contains the date and time of specimen collection and the date and time of receipt into the laboratory.

CG10.07b Where results may be significantly delayed beyond usual times, the laboratory should send a message indicating a delay in the result availability.

G10.08 The report should contain the name and contact details of the requester and other clinicians involved in the follow-up of test results.

CG10.08a Name and contact details for the primary clinician involved in the patient care and follow-up of test results should be recorded on the request form.

CG10.08b Name and contact details for any other clinician(s) involved in care of the patient and follow-up of test results should be recorded on the report and will be stored as a 'copy to' in the laboratory information system, meaning they will receive a copy of the report.

G10.09 Amendments made to a pathology report should be clearly identified on both the atomic and rendered report. Results that are subsequently changed carry a significant potential for delayed or wrong treatment based on outdated or incorrect results[7].

CG10.09a Modified results and the amended status should be clearly identified on both electronic and printed reports.

CG10.09b For atomic results, the system should update the stored result and provide a mechanism to alert the

clinician of the change; this may be done by the accompanying rendered report.

CG10.09c The pathology laboratory is responsible for ensuring the amended report is issued in a timely manner to the requesting clinician and all known ‘copy to’ recipients.

CG10.09d If the variation in the result is clinically significant, the pathology laboratory should treat it as an urgent report by communicating directly with the requesting clinician[8].

CG10.09e The receiving system should have a method of alerting electronic receipt of an amended report.

CG10.09f The receiving system should clearly indicate that the original report has been superseded with a warning message or via an alternate, unambiguous mechanism. The preferred mechanism is to archive the original report to reduce the risk of subsequent misinterpretation.

CG10.09g If the entire original report was forwarded to a secondary clinician or specialist in a referral letter, the referrer is responsible for ensuring the amended report is forwarded to the secondary clinician or specialist.

CG10.09h If an individual result from within a report is transferred, copied or extracted to another medium e.g., doctor’s referral letter, related database, registry etc., the person who made the initial transfer should consider whether the amended result should overwrite the first and whether urgent notification is required.

G10.10 Preliminary or interim reports should be clearly identified on both the atomic and rendered report followed by a clearly marked final report.

CG10.10a Preliminary or interim reports are those issued prior to final validation or full information being available to provide rapid communication of information likely to be of clinical value. Examples may include

preliminary microscopy results prior to full specimen culture and identification, or blood count results from an analyser prior to review of the blood film.

CG10.10b Results that are subsequently changed may carry a significant potential for delayed or wrong treatment based on outdated results[7].

CG10.10c The preliminary or interim status should be clearly visible on the electronic and printed report and should be issued according to documented policy, indicating their provisional nature.

CG10.10d For atomic results, the system should update the stored preliminary result if needed and provide a mechanism of alerting the clinician of the change. This may be done by the accompanying rendered report that notifies of the change.

CG10.10e If the entire original preliminary or interim report was forwarded to a secondary clinician or specialist in a referral letter, the referrer is responsible for ensuring the final report is provided to the secondary clinician or specialist.

CG10.10f If an individual result from within a report is transferred, copied or extracted to another medium e.g., doctor's letter, related database, registry etc., the person who made the initial transfer should consider whether the final result should overwrite the first and whether urgent notification of the final report is required.

CG10.10g If the variation in the result in the final report is clinically significant, this should be drawn to the attention of all report recipients and where appropriate, escalated via a high-risk notification pathway.

G10.11 Laboratories should provide timely communication and follow-up management of "Sendaway" tests i.e. those referred to other laboratories, to ensure the safety of the patient.

CG10.11a It is recognised that referring tests to another laboratory introduces variation in reporting.

CG10.11b With multiple communication interfaces for reporting from referral laboratories, there is an increase in the risk of reporting issues and misinterpretations;

CG10.11c If the expected turnaround time for a “sendaway” test is known to be prolonged, this information should be made available to the requesting physician as soon as possible.

CG10.11d “Sendaway” test results should be electronically communicated directly to the requesting clinician. The use of electronic and paper reports should be avoided.

G10.12 The receiving system should have a method for recording whether the requesting clinician or delegate has reviewed a report.

CG10.12a All pathology reports, whether printed or electronic, should be reviewed and signed off by the requesting clinician or their delegate.

CG10.12b The receiving system should provide an audit trial of those who have reviewed a report, including the individual login used and related date/timestamp.

G10.13 The receiving system should provide a method for actioning a report by the requesting clinician or delegate.

CG10.13a The requesting clinician or delegate should action the report in the receiving system to acknowledge they have reviewed it. The report should remain in the user’s electronic “inbox” until the clinician has assigned an action; this also applies to paper reports.

CG10.13b Atomic results may be reported at different times. Each new result will require review, and the clinician or delegate reviewing each result should be recorded each time.

G10.14 The receiving system should have a method to identify, follow up and review patients with at risk results.

CG10.14a Test results should be able to be sorted in the clinician's 'inbox' according to clinically relevant criteria e.g., clinical importance, patient name, request date/time, report date/time, location or urgent flag[7].

CG10.14b The receiving system should have a method of prioritising and highlighting pathology reports containing clinically significant results.

CG10.14c The recommended method for recognising and flagging critical risk results is addressed in the Best Practice Guidelines.

G10.15 The receiving system should support a process for the transfer of information, accountability and responsibility from the requesting clinician to a backup clinician.

CG10.15a The clinical information system should have the capability to compile a list of cases for review, whether by the original clinician or their delegate.

CG10.15b The receiving system should track the login of the clinician who actioned a report and the date/time the report was actioned; each time a report is actioned it should be tracked.

CG10.15c A method should be available for the requesting clinician to be able to forward a pathology report electronically to another clinician, and a record tracked to indicate the transfer.

CG10.15d When a report is forwarded to another clinician, the pathology report should be copied or reproduced in its entirety.

CG10.15e The receiving system should have a method for the requesting clinician or proxy to acknowledge that the high-risk results have been seen and provide an appropriate audit trial of the event.

G10.16 Numeric results outside guidance values should be clearly highlighted. Refer to Chapter 7 Rendering of numeric results, ranges, units, previous results and flagging.

CG10.16a Guidance values may be reference intervals, healthy limits or therapeutic ranges depending on the test, and should be in the context (clinical history) of the subject of the report where this context is known and relevant.

CG10.16b 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).

CG10.16c A single asterisk (‘*’) and the ‘+’ and ‘-‘ characters should not be used for flagging results.

CG10.16d Underlining of results should not be used for highlighting results.

CG10.16e If colour is used to highlight results, the font should also be bolded.

CG10.16f Multi-level flagging may be used in which case ‘LL’ or ‘HH' should be used for the second level.

G10.17 The rendered report should be easily accessible, visible, comprehensible, and clear.

CG10.17a The rendered report may contain different result types such as numeric, coded or narrative text, images, and graphical; all result types should be understood by the person interpreting the results.

CG10.17b The rendering of a report should be displayed and printed according to the rules described in Chapter 7.

CG10.17c The receiving system should render the pathology report as the laboratory intended e.g., by displaying the PDF rendering, etc.

CG10.17d The receiving system should ensure that pathology reports are easily accessible and the status e.g., Interim, Final, etc. is clearly visible on the report.

CG10.17e A rendered report should be sent and the above commentary applied, including atomic data.

CG10.17f Where a rendered report cannot be displayed in the receiving system, care should be taken to ensure all results are displayed correctly and as the pathology laboratory intended.

CG10.17g Rendered reports containing numerical results for more than one episode may either be complete for all episodes e.g., contain all comments and appropriate reference intervals, or a complete report for the latest episode with previous results provided to assist with interpretation only. The report should be annotated to reflect which of these conditions is used.

G10.18 Reports should remain in the clinician's electronic inbox until actioned by the clinician or their delegate.

CG10.18 The receiving system should provide a mechanism for the clinician to action each report individually.

G10.19 Clinician to clinician interpretation of pathology results should be placed in context when results are included in a referral letter, discharge summary, etc.

CG10.19a When forwarding a subset of pathology results to another clinician, the person producing the letter/report is responsible for selecting the results of significance and placing these results in context.

CG10.19b Appropriate metadata should be included when forwarding a subset of pathology results to another clinician, i.e. date of test, test name, reference interval and units. Results may be provided in the body of the letter or as an attached report. If results are provided without reference interval or units, it is recommended to identify the pathology laboratory that performed the test allowing the receiving clinician to request a copy of the pathology report.

CG10.19c If preliminary or interim results are forwarded to another clinician, the status of these results should be clearly stated. This is important so no tests are unnecessarily repeated or missed.

G10.20 The full pathology report should be made available to the clinician seeing the referred patient.

CG10.20a When referring a patient to another clinician, the referring clinician should append or make available the full copy of the pathology report or indicate the testing laboratory so the receiving clinician is able to request a copy of the report.

CG10.20b The clinical management system should be able to send a request for a report to another system e.g., MyHR. This request would be sent to the testing laboratory, then the testing laboratory would send a 'copy to' the other system. When the testing laboratory is aware of all recipients of a report, the laboratory should ensure all recipients are updated when results become available or are amended.

G10.21 Care should be taken when combining test results on a cumulative report or graph.

CG10.21a 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 significant clinical risk of misinterpretation and should only be done after that risk has been properly assessed.

CG10.21b Appropriately comparable test results from different laboratories can be combined on a cumulative report or graph but should be clearly indicated to the reader. Note - Results from other laboratories may have different reference intervals; if so, they should NOT be combined on a report.

CG10.21c Atomic data should be used when combining tests results on a cumulative report or graph. Screen scraping and other similar techniques should NOT be used as this introduces a level of risk of incorrect results being displayed.

CG10.21d Tests with different LOINC codes should NOT be shown as the same test in sequential display whether by graph or cumulative reporting – refer to Chapter 4.

G10.22 The clinician's inbox in the receiving system should have the ability to sort pathology test records according to clinically relevant criteria e.g., date/time, hospital/location, or patient.

CG10.22 There is an inherent risk of sorting using the test result flag or report flag, as there is known variation for flagging urgency, results out of range, clinically significant results, etc.

G10.23 The receiving system used to store a patient's health record should allow the clinician to set reminders for follow-up tasks.

CG10.23 a The clinician should set reminders for any recalls, follow-up tasks, or one-time recurring test follow-up.

CG10.23 b The reminders should be accessible and monitored by any authorised personnel as a recall phone call or letter to the patient may be required.

G10.24 The laboratory and the receiving organisation should report pathology incidents or issues involving the following scenarios:

- there are missing or mishandled test results;
- a report was sent to the wrong clinician;
- a report was not received by the correct clinician;
- clinically significant results were not phoned, or phoned in a timely manner;
- clinically significant results were not acted on by the requesting clinician or their delegate;
- reports were not reviewed by the requesting clinician or delegate in a timely manner;
- patients reported not receiving adequate follow-up on their pathology tests.

G10.25 Clinical system data back-up policy and procedures, restoration time frames, and alternative methods of communication should be in place to ensure business continuity during mechanical or communication downtime.

G10.26 The receiving system should ensure the confidentiality and integrity of patient health records is maintained at all times.

CG10.26a	The management of the data by the receiving system and personnel should comply with national and state privacy regulations.
CG10.26b	Any devices used to retain data should also comply with all confidentiality and security requirements.
CG10.26c	The receiving systems should comply with the RACGP's *Computer and information security standards - For general practices and other office-based practices*[9]*.*
CG10.26d	Electronic data transmission of patient health information should be secure.

Appendix 1 – Links

ADHA - http://www.digitalhealth.gov.au/

Lab Tests Online AU - http://www.labtestsonline.org.au/

LOINC - http://loinc.org/

NCTS Tool Development Requirements - https://www.rcpa.edu.au/getattachment/17b65c86-e8a4-4aa7-9f28-8a735c4ab006/NCTS-Tool-development-Requirements.aspx

RCPA - http://www.rcpa.edu.au

RCPA Best Practice Guidelines - https://www.rcpa.edu.au/getattachment/0415ea8b-65b0-4557-bb70-62d3c7de448a/Best-practice-guidelines.aspx

RCPA Catalogue of Genetic Tests and Laboratories - http://genetictesting.rcpa.edu.au/

RCPA Manual - https://www.rcpa.edu.au/Library/Practising-Pathology/RCPA-Manual/Home

RCPA SPIA Compliance Checklists - https://www.rcpa.edu.au/Library/Practising-Pathology/PTIS/PITUS-18-20

RCPA SPIA Exemplar Reports - https://www.rcpa.edu.au/Library/Practising-Pathology/PTIS/PITUS-18-20

SNOMED - http://www.ihtsdo.org/

UCUM - http://unitsofmeasure.org/

Appendix 2– Abbreviations and Acronyms used throughout this document and in SPIA Preferred terms

Abbreviation or Acronym	Term
a-	Alpha
AFP	Alpha-fetoprotein
Ab	Antibody/Antibodies
Ag	Antigen/s
AACB	Australasian Association for Clinical Biochemistry and Laboratory
ADHA	Australian Digital Health Agency
b-	Beta
CSF	Cerebrospinal fluid
DNA	Deoxyribonucleic acid
EtOH	Ethanol
FBC	Full blood count
HbA1c	Haemoglobin A1c
HDL	High density lipoprotein
hCG	Human chorionic gonadotropin
Ig	Immunoglobulin
IgA	Immunoglobulin A
IgE	Immunoglobulin E
IgG	Immunoglobulin G
IgM	Immunoglobulin M
INR	International Normalised Ratio
IU	International Unit(s)
ISE	Ion Selective Electrode
LDL	Low density lipoprotein
MSIA	Medical Software Industry Association
MyHR	My Health Record
Na	Sodium
O2	Oxygen
OH	Hydroxy
MSIA	Medical Software Industry Association
PDF	Portable Document Format
PoCT	Point of Care Testing
PSA	Prostate specific antigen
RACGP	The Royal Australian College of General Practitioners
RAST	Radioallergosorbent test
RCPA	The Royal College of Pathologists of Australasia
SI unit(s)	The International System of Units / Système International d'Unités
SPIA	Standardised Pathology Informatics in Australia
sp.	Species (genus)

Abbreviation or Acronym	Term
spp.	Species (class)
SPRC	Structured Pathology Reporting of Cancers
vWF	Von Willebrand factor

References

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4 Nielsen J. Usability inspection methods. In CHI '94 Conference Companion on Human Factors in Computing Systems ACM; 1994; New York. p. 413-414

5 Tate J, Johnson R, Barth J, Panteghini M. Harmonization of Laboratory Testing - A global activity. Clinica Chimica Acta. 2014 May; 432: p. 1-166

6 RCPA website – Structured Pathology Reporting of Cancer Protocols

7 Safety Assurance Factors for EHR resilience Self assessment: Test Results Reporting and Follow-Up Assessment

8 National Pathology Accreditation Advisory Council (NPAAC), Tier 3B Document Requirements for information communication. (2013)

9 RACGP Computer and information security standards - For general practices and other office-based practices 2nd ed

Other suggested reading:

1 RCPA policy: Clinical Handover and after hours pathology results

2 RACGP Standards for general practices 4th Ed

3 RACGP Guidelines for preventive activities in general practice 8th edition 2012

4 Australian Healthcare Messaging Laboratory