NATA Assessment year x for ADRM and SPIA

Derek Holzhauser







How are laboratories accredited?

- In 1986, the Australian Government introduced compulsory accreditation for pathology laboratories.
- To claim benefits under Medicare as an accredited provider, pathology laboratories must be assessed to and meet the National Pathology Accreditation (NPA) standards.
- The NPA Scheme operates as part of the Medicare rebatable pathology services under the Health Insurance Act 1973.
- The pathology accreditation standards that underpin the accreditation requirements specified in the Act under *Health Insurance* (Accredited Pathology Laboratories—Approval) Principles 2017



NPAAC



- The National Pathology Accreditation Advisory Council (NPAAC) is responsible for developing and maintaining the NPA standards for Australian pathology labs.
- The standards are categorised into 4 main tiers
- Tier 1 The Principles
 - Tier 2 Overarching standards for all pathology services
 - Tier 3A Supervisory requirements for pathology laboratories
 - Tier 3B Technical and specific detailed requirements for good medical practice in all pathology services
 - Tier 4 Technical publications for specific areas of pathology



Assessment

- We have a single approved pathology accrediting agency NATA (National Association of Testing Authorities)
- NATA use volunteer technical assessors to assess against the NPAAC standards





AUSTRALIAN COMMISSION
ON SAFETY AND QUALITY IN HEALTH CARE

NPXXC

TRIM: D22-32436

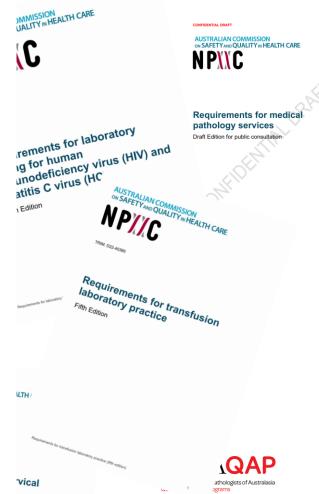
Requirements for information communication and reporting

Fifth Edition

Requirements for the pack and transport of pathology specimens and associated materials

Fifth Edition

TRIM: D22-47232



Requirements for the packaging and transport of pathology specimens and assignding)

Purpose

This document outlines how pathology information should be communicated between labs, requesters, consumers, and others.

AUSTRALIAN COMMISSION
ON SAFETY AND QUALITY IN HEALTH CARE



TRIM: D22-32436

Requirements for information communication and reporting

Fifth Edition

Requirements for information communication and reporting (fifth edition)



Why is it important

to use standardised terminology and messaging?



The following story is based on true events

Only the names have been changed to protect the innocent





Doctor receives results from lab electronically

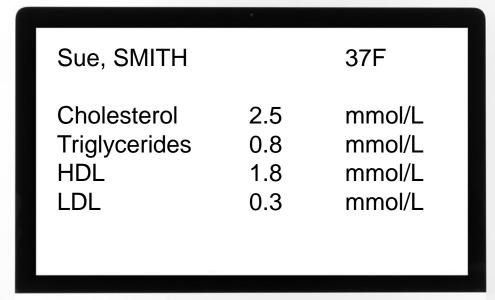
Calls patient to discuss

Chol 2.5 mmol/L

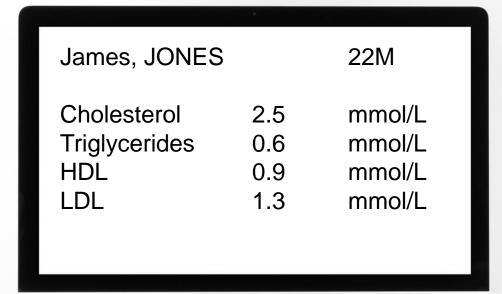


Phillip, PETERS		45M
Cholesterol	2.5	mmol/L
Triglycerides	2.8 H	mmol/L
HDL	1.0	mmol/L
LDL	2.4	mmol/L





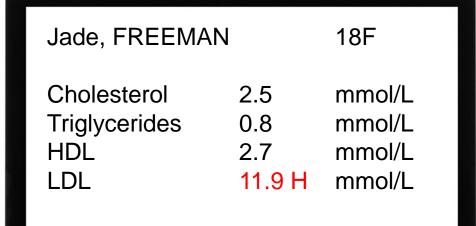






Kate, TAYLOR		27F
Cholesterol Triglycerides HDL LDL	2.5 1.1 0.7 1.3	mmol/L mmol/L mmol/L mmol/L









Doctor calls pathology lab

"Why do all my patients have a cholesterol of 2.5 mmol/L when tested at your lab?"



Ultimate Pathology

Local Road Medical Practice

Local Road

WEST NILE VIC 3095

DOB/Age/Sex:

001-02-03 10/06/74 45 years Male Location: Local Road Medical Practice

PETERS, Phillip

Doctor: SMITH. J

Copies to:

12345 Your Ref: Accession No.: 19-001-00001

CLINICAL CHEMISTRY

Chemistry

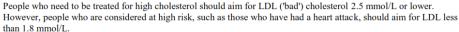
Cholesterol	<5.5	mmol/L	6.0 H
Triglycerides	< 2.0	mmol/L	2.8 H
HDL	1.8-3.2	mmol/L	1.0
LDL	0.0-4.0	mmol/L	2.4

01/08/19 14:12 LDL Cholesterol:

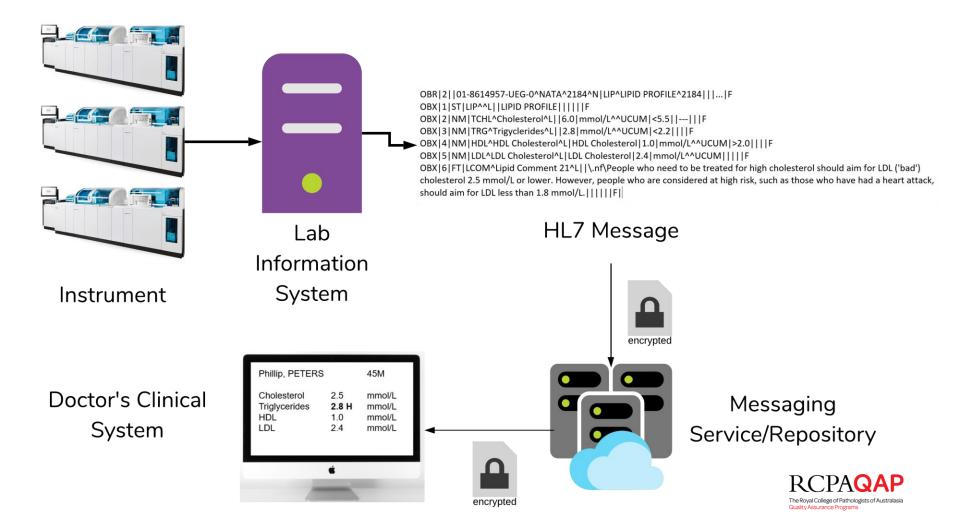
People who need to be treated for high cholesterol should aim for LDL ('bad') cholesterol 2.5 mmol/L or lower. However, people who are considered at high risk, such as those who have had a heart attack, should aim for LDL less than 1.8 mmol/L.

CHOICEGO	~~.~		V.V
Triglycerides	< 2.0	mmol/L	2.8 H
HDL	1.8-3.2	mmol/L	1.0
LDL	0.0-4.0	mmol/L	2.4









OBX|2|NM|TCHL^Cholesterol^L||6.0|mmol/L^^UCUM|<5.5||---|||F

nstrument Syste

Doctor's Clinical
System



Messaging Service/Repositor

RCPAQAP
The Royal College of Pathologists of Australasia

Ultimate Pathology

Local Road Medical Practice Local Road

DOB/Age/Sex:

001-02-03 10/06/74 45 years Male Location: Local Road Medical Practice

PETERS, Phillip

WEST NILE VIC 3095

Doctor: SMITH. J Copies to:

12345 Your Ref: Accession No.: 19-001-00001

CLINICAL CHEMISTRY

Chemistry

Cholesterol	< 5.5	mmol/L	6.0 H
Triglycerides	< 2.0	mmol/L	2.8 H
HDL	1.8-3.2	mmol/L	1.0
LDL	0.0-4.0	mmol/L	2.4

01/08/19 14:12 LDL Cholesterol:

People who need to be treated for high cholesterol should aim for LDL ('bad') cholesterol 2.5 mmol/L or lower. However, people who are considered at high risk, such as those who have had a heart attack, should aim for LDL less than 1.8 mmol/L.

CHOICECTOI	-0.0		0.0
Triglycerides	< 2.0	mmol/L	2.8 H
HDL	1.8-3.2	mmol/L	1.0
LDL	0.0-4.0	mmol/L	2.4



People who need to be treated for high cholesterol should aim for LDL ('bad') cholesterol 2.5 mmol/L or lower. However, people who are considered at high risk, such as those who have had a heart attack, should aim for LDL less than 1.8 mmol/L.



How can we prevent this?



We are speaking the same language (HL7)



LOINC (Logical Observation Identifiers Names and Codes)



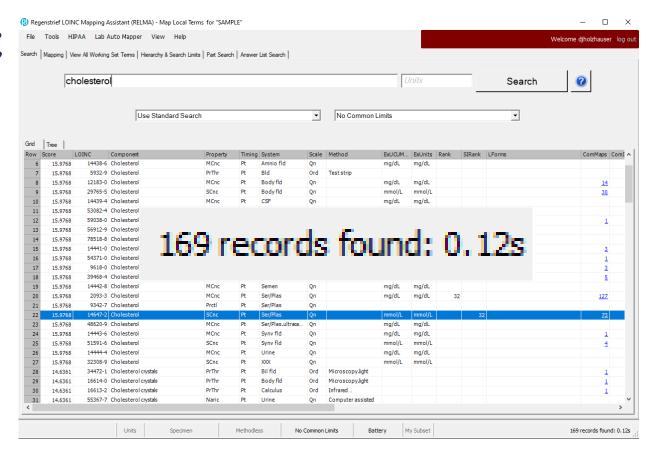
OBX|2|NM|14647-2^Cholesterol^LN^TCHL^Cholesterol^ULTP||6.0|mmol/L^^UCUM|<5.5||---|||F



Easy, everybody just use LOINC codes?



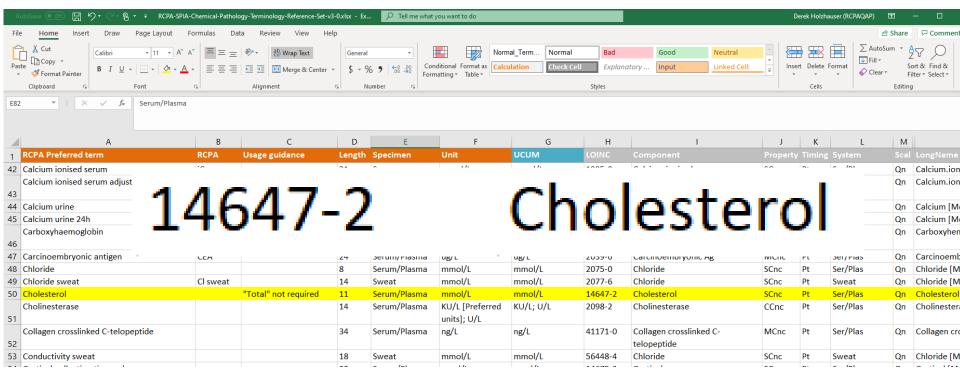
LOINC



https://loinc.org



Terminology Reference Set





4. Conformance with electronic messaging standards

Laboratories should have in place processes to adopt updated versions of these standards as they are published by HL7 Australia.

- S4.1 Laboratories **must** use the HL7 Standard as defined by the HL7 V 2.4 as set out in <u>HL7AUSD-STD-OO-ADRM-2017.1</u> the Australian Pathology Messaging – Localisation of HL7 Version 2.4 2017.
 - C4.1(i) Use of the HL7 standard **must** include testing that demonstrates appropriate use of codes for orderables and results as well as use of patient, provider and organisation identifiers in the messages in accordance with Standard 3 of this document as well as management of message acknowledgments in accordance with Standard 2.



4. Conformance with electronic messaging standards

C4.1(ii) When this HL7 Standard is updated in Australian Standards laboratories are required to move towards adopting the new version.

HL7 Australia

Australian Diagnostics and Referral Messaging - Localisation of HL7 Version 2.4

HL7AUSD-STD-OO-ADRM-2021.1

ADRM 2021.1

https://hl7.com.au/



6. Request and report format requirements

- A laboratory **must** ensure that at least one of the observational identifiers used in an electronic report should use the SPIA LOINC coding system, where available, and the associated UCUM units that is in accordance with the SPIA standards⁵ when sending to external organisations.
 - C6.2(i) The source of LOINC codes should be those specified in SPIA.⁶
 - C6.2(ii) If SNOMED codes are used in messages, laboratories should use the SNOMED CT-AU code set.
 - A laboratory may use non-LOINC observational identifiers. C6.2(iii)
- You can use local codes in messages, but you must also use a SPIA LOINC code
- If SNOMED codes are used, they should be from the SPIA SNOMFD-CT AU set



What is ADRM?

- Australian Diagnostics and Referral Messaging Localization of HL7
 Version 2.4 (Current version 2021.1)
- Addresses HL7 Orders, Results and Referrals Messages for use in Australia
- "Formalisms" Prescribed Non-Clinical Data in prescribed places e.g. (HL7au:000040) MSH-12 Version ID Field Conformance Points
- HL7 v2 Segments Allowed or Prohibited in Pathology Messages Australia
- Data Type Structures, Field / Component / Subcomponent Structures
- Required or Recommended Values for Coded Data for use in Australia



HL7 Australia

Australian Diagnostics and Referral Messaging - Localisation of HL7 Version 2.4

HL7AUSD-STD-OO-ADRM-2021.1

548 pages

~300 Technical conformance points





RCPAQAP Tools

- RCPAQAP HL7 Validation Orchestrator
- RCPAQAP SPIA eRequesting Terms Lookup Tool
- RCPAQAP SNOMED Code & Terms Lookup Tool
- RCPAQAP LOINC Code Lookup Tool
- RCPAQAP SPIA Coding Performance Reporting Tool
- RCPAQAP Conformant Order Generator App
- RCPAQAP Conformant Result Generator App (WIP)



What can they do?

- Checks HL7 messages for compliance with ADRM, SPIA (& QAP)
- Produces a (very) detailed report (with references)
- SPIA SNOMED/LOINC compliance summary
- Generate and ADRM conformant order message
- Generate an ADRM conformant result message
- SNOMED & LOINC code lookup



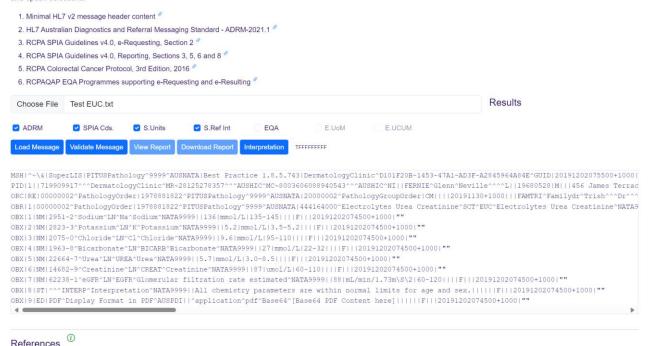




HL7 v2 Diagnostic Messaging in Australia

Validate Orders and Results Messages ^

Select a file containing a HL7 v2 Delimited message which to validate for conformance with one or more of the implemented conformance profiles, depending on the message type and option selections:



- Orders and Results, including Colorectal Cancer Reporting (ORM^O01, ORU^R01)
 - The minimal message header content requirements that permit messages to be parsed and attributed
 - The Australian Diagnostics and Referral Messaging Localisation of HL7 Version 2.4 (ADRM-2021.1) Standard See ADRM 2021.1 Validation Rules for implementation notes



(i) about:blank



HL7 v2 Message Validation Report A 🖣 🖣

Message validation was performed on 2024-05-14, at 20:36:05.

The message was checked for conformance with the requirements of the RCPAQAP HL7 Conformance Profile for the Australian Diagnostics and Referral Messaging - Localisation of HL7 Version 2.4 (ADRM-2021.1) Standard. The HL7 Message does NOT conform to the requirements of the ADRM-2021.1 Standard.

The message was checked for conformance with the requirements of the RCPAQAP HL7 Conformance Profile for the Royal College of Pathologists of Australasia RCPA Standardised Pathology Informatics in Australia (SPIA), Guidelines v4.0 for Reporting. The HL7 Message does NOT conform to the requirements of the RCPA SPIA Guidelines v4.0.

Message Identification Details

- Sending Facility: PITUSPathology 9999
- Message Control Id: E48CFF2E-CF87-486B-B679-10101034AC29
- Date/Time of Message: 20191202075500+1000
- HL7 Message Source: HL7 message body from Web Service Request
- Conformance Profile Id: "TFFFFTTTFF" / "TFFFFTTTFF"

Message Validation Results

This message Does NOT conform to the requirements of the HL7AUSD-STD-OO-ADRM-2021.1 - Australian Diagnostics and Referral Messaging - Localisation of HL7 Version 2.4 Standard, profiled in the RCPAQAP HL7 Conformance Profile for Pathology Ordering and Observation Reporting in Australia.

This message Does NOT conform to the requirements of the Royal College of Pathologists of Australasia RCPA Standardised Pathology Informatics in Australia (SPIA), Guidelines v4.0 for Reporting profiled in the RCPAQAP HL7 Conformance Profile for Pathology Ordering and Observation Reporting in Australia.

The table below describes issues identified in the message.

Entry Id	Element Type			Validation Diagnostics
0	Message			ERROR Required PVI Segment is missing Failing HL7AUSD-STD-00-ADRM-2021.1 conformance point HL7au:00046.5 (r2) Conformance Point Text: Receiving implementations when receiving HL7 messages and converting their contents to data values must treat segments that were expected but are not present as an error.
1	Segment	MSH		ERROR Component MSH.12.2 Internationalization Code is not valued Failing HL7AUSD-STD-00-ADRM-2021.1 conformance point HL7au:000040.2 (r2) Conformance Point Text: MSH-12 Version ID component must be valued "AUS&Australia&ISO3166_1"
2	Segment	MSH		ERROR Component MSH.12.3 internal version ID is not valued Failing HL7AUSD-STD-OO-ADRM-2021.1 conformance point HL7au:000040.3 Conformance Point Text: MSH-12 Version ID component must be valued as "HL7AU-OO-2017018.&L"
3	Segment	MSH		ERROR Field MSH.19 - Principal Language Of Message is not valued Failing HL7AUSD-STD-OO-ADRM-2021.1 conformance point HL7au:000042 Conformance Point Text: MSH-19 must be valued as "en^English^ISO639".
4	Segment	MSH	1	ERROR MSH-16 Application acknowledgement type (ID) must be AL. It is NE

match the OBX.6.1 Units value [mL/min/1	./3m^2]	 Failing validation for conformance with the expectations of the SPIA_Guid 	elines_v4.0, Section
Units of measure, Guideline G6			

- 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.

100 Component	OBX.3.3	12 ERROR Component obx[8] 3.3 Name Of Coding System is not populated - continuing validation of this component for conformance with the expectations of the SPIA, Guidelines 44.0, Section 3 Reporting terminology and codes, Guideline G3.01 Guideline lext. 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
101 Component	OBX.3.1	12 ERROR Component obx(8) 3.1 Identifier is not populated - Failing validation for conformance with the expectations of the SPIA_Guidelines_v4.0, Section 3 Reporting terminology and codes, Guideline G3.01

Guideline Text

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

HL7 Message

- 1: MSH|/~\&|SuperLIS|PITUSPathology/9999^AUSNATA|Best Practice 1.8.5.743|DermatologyClinic/D101F208-1453-47A1-AD3F-A2845964A84E^GUID|20191202075500+1000||0
- 2: PID|1||719909917^^^Dermatologyclinic^MR~28125278357^^^AUSHIC^MC~8003606088940543^^AUSHIC^NI||FERNIE^Glenn^Neville^^^AL||19680528|M|||456 James Terrace^A
- 3: ORC|RE|00000002/Pathology0rder|1978881822/PITUSPathology/9999/AUSNATA|20000002/PathologyGroupOrder|CM|||20191130+1000|||FAMTRIAFamilydr/Trish/^^NA
- 4: OBR|1|00000002/PathologyOrder|1978881822/PITUSPathology/9999/AUSNATA|444164000/Electrolytes Urea Creatinine/SCT/EUC/Electrolytes Urea Creatinine/NATA999
- 5: OBX|1|NM|2951-2^Sodium^LN^Na^Sodium^NATA9999||136|mmo1/L|135-145||||F|||20191202074500+1000|""
- 6: OBX|2|NM|2823-3^Potassium^LN^K^Potassium^NATA9999||5.2|mmol/L|3.5-5.2||||F|||20191202074500+1000|""
- 7: OBX|3|NM|2075-0^chloride^LN^Cl^chloride^NATA9999||9.6|mmol/L|95-110||||F||20191202074500+1000|"
- 8: OBX|4|NM|1963-8^Bicarbonate^LN^BICARB^Bicarbonate^NATA9999||27|mmo7/L|22-32||||F|||20191202074500+1000|"
- 9: OBX|5|NM|22664-7/Urea/LN/UREA/Urea/NATA9999||5.7|mmol/L|3.0-8.5||||F|||20191202074500+1000|"
- 10: 08X|6|NM|14682-9^Creatinine^LN^CREAT^Creatinine^NATA9999||87|umo1/L|60-110||||F|||20191202074500+1000|""
- 11: OBX|7|NM|62238-1^eGFR^LN^EGFR^G]omerular filtration rate estimated^NATA9999||88|mL/min/1.73m\s\2|60-120||||F|||20191202074500+1000|""
- 12: OBX|8|ST|^^Interpretation^NATA9999||All chemistry parameters are within normal limits for age and sex.|||||||||||20191202074500+1000|""
- 13: OBX|9|ED|PDF^Display Format in PDF^AUSPDI||^application^pdf^8ase64^[Base64 PDF Content here]|||||F|||20191202074500+1000|""

References ®

- SPIA Terminology Reference Sets and Information Models
- · Relevant Requesting Pathology SPIA resources:
- RCPA SPIA RequestingAllergens Terminology Reference Set v4.0
- RCPA SPIA Requesting Pathology Terminology Reference Set v4.2

RCPAQAP HL7 Conformance Profile for selected Pathology HL7 messages was developed using the Caristix Conformance tool.

The message was validated using the RCPAQAP's QAP Validation Orchestrator which wraps the Carisitx Validate Live service with additional functionality.

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SPIA Coding Performance Summary Table

Prepared: 09/05/2024, 8:04:54 pm

Test/Panel Group	Test/Panel	SPIA Preferred Term	SPIA LOINC Code	Identified as LOINC	SPIA Reporting Unit	UCUM Unit	Identified as UCUM	SPIA SNOMED-CT Code	Identified as SCT	
EUC	Potassium	Yes (Potassium)	Yes (2823-3)	No	Yes (mmol/L)	Yes (mmol/L)	No	No (2921244)	No	
EUC	Chloride	Yes (Chloride)	Yes (2075-0)	No	Yes (mmol/L)	Yes (mmol/L)	No	No (2921244)	No	
EUC	Bicarbonate	Yes (Bicarbonate)	Yes (1963-8)	No	Yes (mmol/L)	Yes (mmol/L)	No	No (2921244)	No	
EUC	Anion Gap	Yes (Anion Gap)	Yes (1863-0)	No	Yes (mmol/L)	Yes (mmol/L)	No	No (2921244)	No	Preferred Term: Anion gap 4
EUC	Urea	No (Urea)*	No (14937-7)*	No	No (mmol/L)*	No (mmol/L)*	No	No (2921244)	No	* LOINC Code 14937-7 not fi
EUC	Creatinine	Yes (Creatinine)	Yes (14682-9)	No	Yes (umol/L)	Yes (umol/L)	No	No (2921244)	No	
FBC	Haemoglobin	Yes (Haemoglobin)	Yes (718-7)	No	Yes (g/L)	Yes (g/L)	No	No (23707965)	No	
FBC	White Cell Count	No (White Cell Count)	Yes (6690-2)	No	No (x10^9/L)	No (x10^9/L)	No	No (23707965)	No	
FBC	Platelet Count	No (Platelet Count)	Yes (777-3)	No	No (x10^9/L)	No (x10^9/L)	No	No (23707965)	No	
FBC	Red Cell Count	No (Red Cell Count)	Yes (789-8)	No	No (x10^12/L)	No (x10^12/L)	No	No (23707965)	No	
FBC	Haematocrit	Yes (Haematocrit)	Yes (4544-3)	No	Yes (L/L)	Yes (L/L)	No	No (23707965)	No	
FBC	MCV	Yes (MCV)	Yes (787-2)	No	Yes (fL)	Yes (fL)	No	No (23707965)	No	Preferred Term: Mean cell vo
FBC	MCH	Yes (MCH)	Yes (785-6)	No	Yes (pg)	Yes (pg)	No	No (23707965)	No	Preferred Term: Mean cell ha
FBC	MCHC	Yes (MCHC)	Yes (786-4)	No	Yes (g/L)	Yes (g/L)	No	No (23707965)	No	Preferred Term: Mean cell ha
FBC	RDW	No (RDW)*	No (788-0)*	No	No (%)*	No (%)*	No	No (23707965)	No	* LOINC Code 788-0 not four
FBC	Mean Platelet Volume	No (Mean Platelet Volume)*	No (23708748)*	No	No (fL)*	No (fL)*	No	No (23707965)	No	* LOINC Code 23708748 not
FBC	Neutrophils %	No (Neutrophils %)*	No (770-8)*	No	No (%)*	No (%)*	No	No (23707965)	No	* LOINC Code 770-8 not four
FBC	Neutrophils	No (Neutrophils)*	No (751-8)*	No	No (x10^9/L)*	No (x10^9/L)*	No	No (23707965)	No	* LOINC Code 751-8 not four
FBC	Lymphocytes %	No (Lymphocytes %)*	No (736-9)*	No	No (%)*	No (%)*	No	No (23707965)	No	* LOINC Code 736-9 not four
FBC	Lymphocytes	No (Lymphocytes)*	No (731-0)*	No	No (x10^9/L)*	No (x10^9/L)*	No	No (23707965)	No	* LOINC Code 731-0 not four
FBC	Monocytes %	No (Monocytes %)*	No (5905-5)*	No	No (%)*	No (%)*	No	No (23707965)	No	* LOINC Code 5905-5 not for
FBC	Monocytes	No (Monocytes)*	No (742-7)*	No	No (x10^9/L)*	No (x10^9/L)*	No	No (23707965)	No	* LOINC Code 742-7 not four
FBC	Eosinophils %	No (Eosinophils %)*	No (713-8)*	No	No (%)*	No (%)*	No	No (23707965)	No	* LOINC Code 713-8 not four
FBC	Eosinophils	No (Eosinophils)*	No (711-2)*	No	No (x10^9/L)*	No (x10^9/L)*	No	No (23707965)	No	* LOINC Code 711-2 not four
FBC	Basophils %	No (Basophils %)*	No (706-2)*	No	No (%)*	No (%)*	No	No (23707965)	No	* LOINC Code 706-2 not four
FBC	Basophils	No (Basophils)*	No (704-7)*	No	No (x10^9/L)*	No (x10^9/L)*	No	No (23707965)	No	* LOINC Code 704-7 not four
GLURNDM	Fasting	No (Fasting)*	No (32073711)*	No	No ()*	No ()*	No	No (26641647)	No	* LOINC Code 32073711 not
GLURNDM	Glucose	No (Glucose)	Yes (14749-6)	No	Yes (mmol/L)	Yes (mmol/L)	No	No (26641647)	No	
HBA1CIFCC	HbA1c	No (HbA1c)	Yes (59261-8)	No	Yes (mmol/mol)	Yes (mmol/mol)	No	No (21978844)	No	
HBA1CIFCC	HbA1c %	No (HbA1c %)*	No (17856-6)*	No	No (%)*	No (%)*	No	No (21978844)	No	* LOINC Code 17856-6 not fi
HBA1CIFCC	HbA1c Comment	No (HbA1c Comment)*	No (30902987)*	No	No ()*	No ()*	No	No (21978844)	No	* LOINC Code 30902987 not
HEPB	Hepatitis B virus surface Ab	No (Hepatitis B virus surface Ab)*	No (30526113)*	No	No ()*	No ()*	No	No (22787696)	No	* LOINC Code 30526113 not
HEPB	Hepatitis B virus surface Ab IU/L	No (Hepatitis B virus surface Ab IU/L)*	No (30524297)*	No	No (IU/L)*	No (IU/L)*	No	No (22787696)	No	* LOINC Code 30524297 not
INR	Prothrombin Time	No (Prothrombin Time)*	No (5902-2)*	No	No (s)*	No (s)*	No	No (28626361)	No	* LOINC Code 5902-2 not for
INR	INR	Yes (INR)	Yes (6301-6)	No	No (ratio)	No (ratio)	No	No (28626361)	No	
IRNSTD	Fasting	No (Fasting)*	No (32073711)*	No	No ()*	No ()*	No	No (22787835)	No	* LOINC Code 32073711 not
IRNSTD	Iron	Yes (Iron)	Yes (14798-3)	No	Yes (umol/L)	Yes (umol/L)	No	No (22787835)	No	

Acknowledgments

Michael Czapski (Czapski IT)

Ray Oreo (RCPAQAP)

Rizzi De Leon (RCPAQAP)

Anthony Green (RCPAQAP)

Tony Badrick (RCPAQAP)

Vanessa Cameron (RCPA)

Vanessa White (RCPA)

