Australian Government
Australian Digital Health Agency

Pathology Test Result
Detailed Clinical Model Specification
Version 3.2

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Approved for external use

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Document Information

Key Information

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Product Version History

Product version	Date	Release comments
1.0	29 May 2007	Initial public release.
2.0	23 Aug 2011	New version created in accordance with the archetype from NEHTA Clinical Knowledge Manager[1].
2.1	22 Dec 2011	This version of the specification is published to support the Structured Content Specifications published (at the end of 2011) that use the versions of the DCMs included in this specification. Changes to the DCMs, included in this specification, are primarily to support the Consolidated View in the PCEHR.
3.0	18 Dec 2015	Updated to support Pathology Report Structured Content Specification in the PCEHR R5.
3.1	18 Dec 2015	This version of the specification is published to support the Structured Content Specifications published (in the first half of 2015), primarily Event Summary in the PCEHR R5.
3.2	5 Aug 2016	This version of the specification is published to support the Service Referral structured content specification. It includes rebranding for the Australian Digital Health Agency.

Related Documents

Name	Version/Release Date
Participation Data Specification	Version 3.2, Issued 20 July 2011

Included Detailed Clinical Models

This specification contains the following detailed clinical models:

- Pathology Test Result, version 3.2

[1] http://dcm.nehta.org.au/ckm

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Regenstrief Institute (LOINC)

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1 Introduction

1.1 Purpose and Scope

This detailed clinical model (DCM) specification forms part of a suite of data specifications that the Australian Digital Health Agency (the Agency) is developing for the Australian health informatics community. The suite comprises specifications for a range of health topics (represented as data groups), which are considered to be the most critical to support the work programme given to the Agency and to realise the benefits derived from Level 4 (semantic) interoperability[1] in the Australian healthcare setting.

We value your questions and comments about this document. Please direct your questions or feedback to help@digitalhealth.gov.au.

1.2 Intended Audience

This document is intended to be read by jurisdictional information and communication technology (ICT) managers, clinicians involved in clinical information system specifications, software architects and developers, and implementers of clinical information systems in various healthcare settings.

This is a technical document; the audience should be familiar with the language of health data specification and also have some familiarity with health information standards and specifications. Definitions and examples are provided to clarify relevant terminology, usage, and intent.

1.3 Background

One area of priority for us is the identification of digital health data to be communicated and its structure. We are addressing this through data specifications, which detail the data elements (logically grouped) and their associated value domains.

Data specifications need to be independent of messaging formats. They are concerned with providing an information framework in which to achieve semantic interoperability.

Data specifications have been developed based on priorities identified by jurisdictions and clinicians, incorporating clinical examples of use to enhance utility and adoption. These specifications are intended to:

- suit the Australian model for a shared electronic health record;
- define collections of related information, e.g. event summaries, data groups, data elements;
- be human readable (with information enhanced by the hierarchical structure);
- provide a set of clinical terminologies specific to the requirements of the Australian healthcare system; and
- allow for expansion and extension as electronic systems mature.

While the My Health Record system is referred to in these documents, implementation within the system is not dealt with here.

1.4 Terminology

Our National Clinical Terminology Service (NCTS) is defining a national approach to clinical terminology. Consistent and accurate articulation and interpretation of clinical terms is critical to the process of safe exchange.

[1] Level 4 interoperability is described in *The Value Of Health Care Information Exchange And Interoperability [WALJ2005a]*.

We recommend the SNOMED CT as the preferred clinical terminology for Australia and this has been endorsed by the Australian, state and territory governments. SNOMED CT is considered to be the most comprehensive multilingual health terminology in the world. It is owned, maintained and distributed by the International Health Terminology Standards Development Organisation (IHTSDO).

Our NCTS is the Australian National Release Centre for SNOMED CT and is also responsible for managing, developing and distributing national clinical terminologies, such as SNOMED CT Australian Release (SNOMED CT-AU), the Australian Medicines Terminology (AMT), and related tools and services.

SNOMED CT-AU provides local variations and customisation of terms relevant to the Australian healthcare community. It includes the international resources, along with all Australian-developed terminology for implementation in Australian clinical information technology systems. The AMT provides a consistent approach to the identification and naming of medicines, and supports medicines management and activity across the Australian healthcare domain. The AMT is now included within SNOMED CT-AU, with even closer integration planned for the future.

Reference sets listed as value domains within this document have been developed taking into account data element and data group definitions, as well as how they align with and complement the SNOMED CT concept model.

SNOMED CT-AU has been available for software developers to use in their Australian products since 1 July 2006. It is updated monthly and is freely available under a dual licensing arrangement – namely the SNOMED CT Affiliate License and Australian National Terminology License.

For further information regarding terminology and the development of reference sets, please visit http://-www.healthterminologies.gov.au. Email *help@digitalhealth.gov.au* with questions or feedback.

2 Pathology Test Result Detailed Clinical Model

This chapter describes version 3.2 of the *Pathology Test Result* Detailed Clinical Model.

2.1 Purpose

To record the findings and interpretation of pathology tests performed on tissues and body fluids. This is typically done in a laboratory, but may be done in other environments, such as at the point of care.

2.2 Use

Use to record any pathology test result, including the result of a test on a specimen taken as part of a composite procedure or operation.

Multi-analyte panels can be represented using templates or specialised DCMs.

More complex tests, such as histopathology or microbiology, should be represented using specialised DCMs where additional report content is required.

The content of instances of this DCM will normally be reported back to the requesting clinician as one component within the context of an overall structured document.

2.3 Misuse

Not to be used for reporting on non-pathology test results, such as diagnostic imaging, ECG or respiratory function tests.

Not to be used to represent an entire cumulative report. This *Pathology Test Result* DCM represents only one of the result sets that is usually viewed as a vertical in a cumulative test report. A cumulative report is a view that is constructed from the results represented by multiple DCMs.

This DCM is suitable for representation of general pathology test results, but is not intended to cover full synoptic reports. For these, additional specialised DCMs are required to represent the data.

2.4 UML Class Diagrams

The following figures represent the data hierarchy using UML 2.0 class diagrams. The diagrams display data groups and data elements, together with their names, data types and multiplicities. Data elements are displayed as attributes; data groups are displayed as classes; their label names are represented as association role names. Association role names are only displayed if they differ from the associated class name. When a data element has a choice of data types, the data type of the attribute that represents it is an abstract interface class generalised from the individual data types. The diagrams show the data hierarchy excluding the details of participation. The default multiplicity is 1..1.

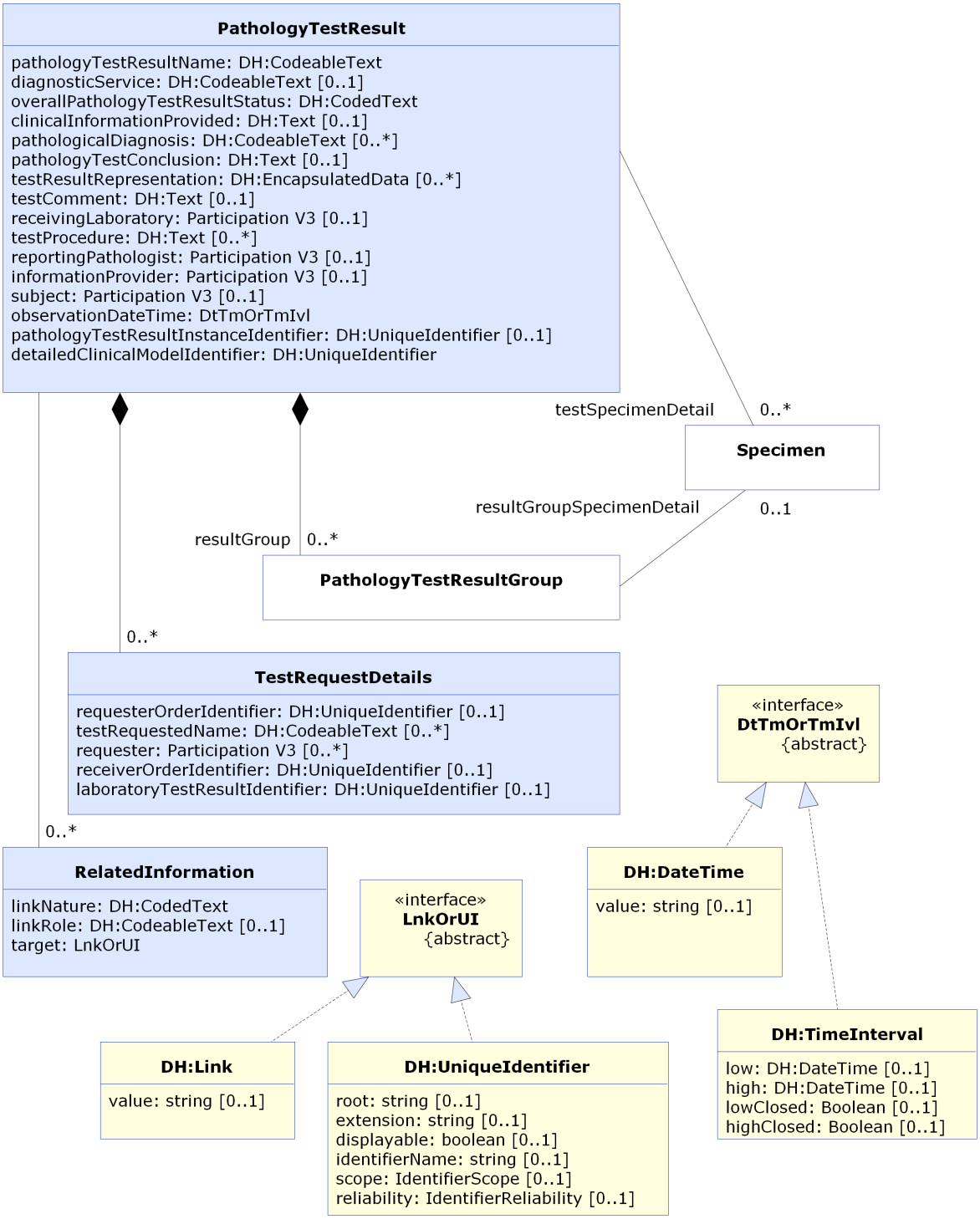

Figure 2.1. Pathology Test Result - part 1

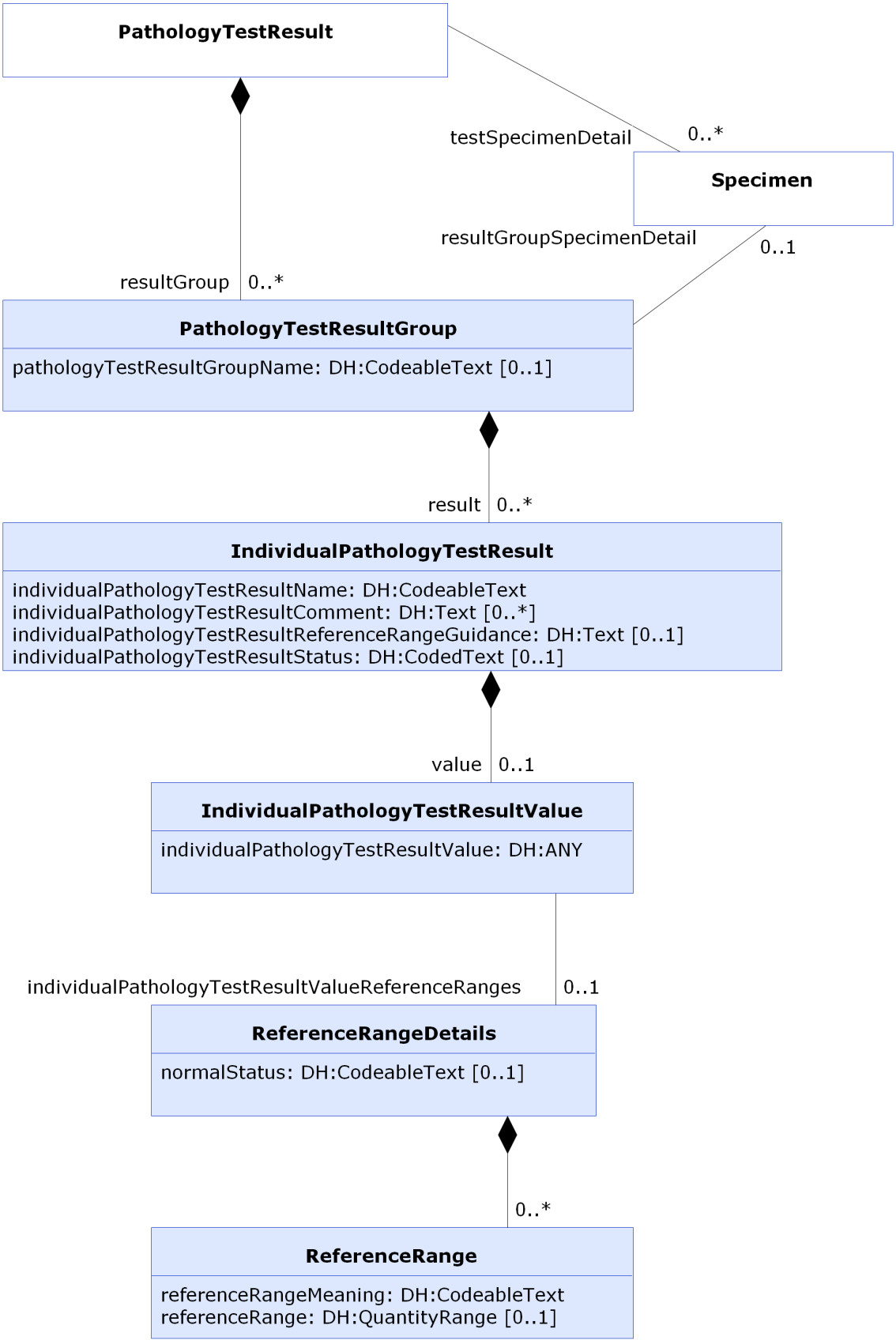

Figure 2.2. Pathology Test Result - part 2

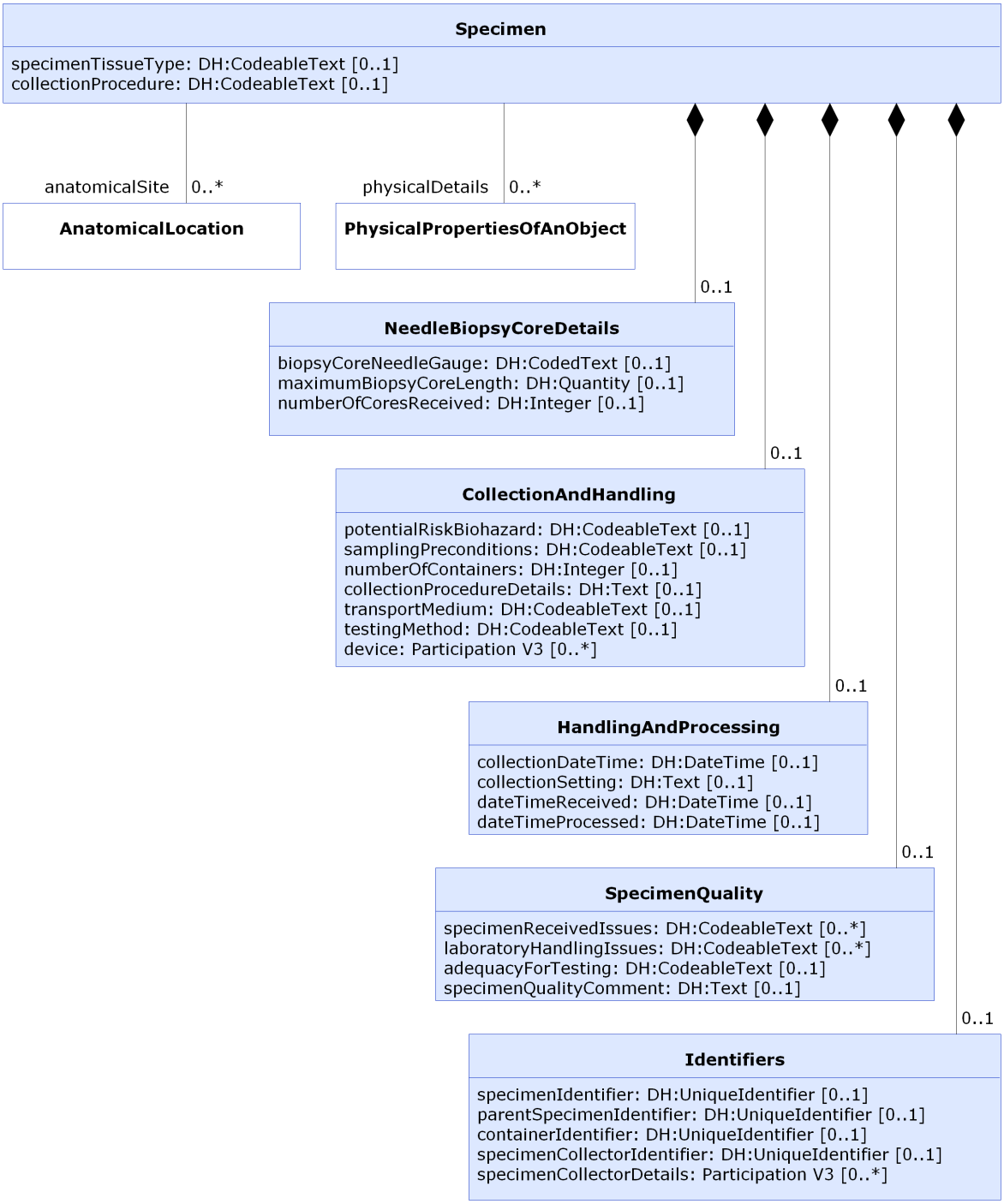

Figure 2.3. Specimen - part 1

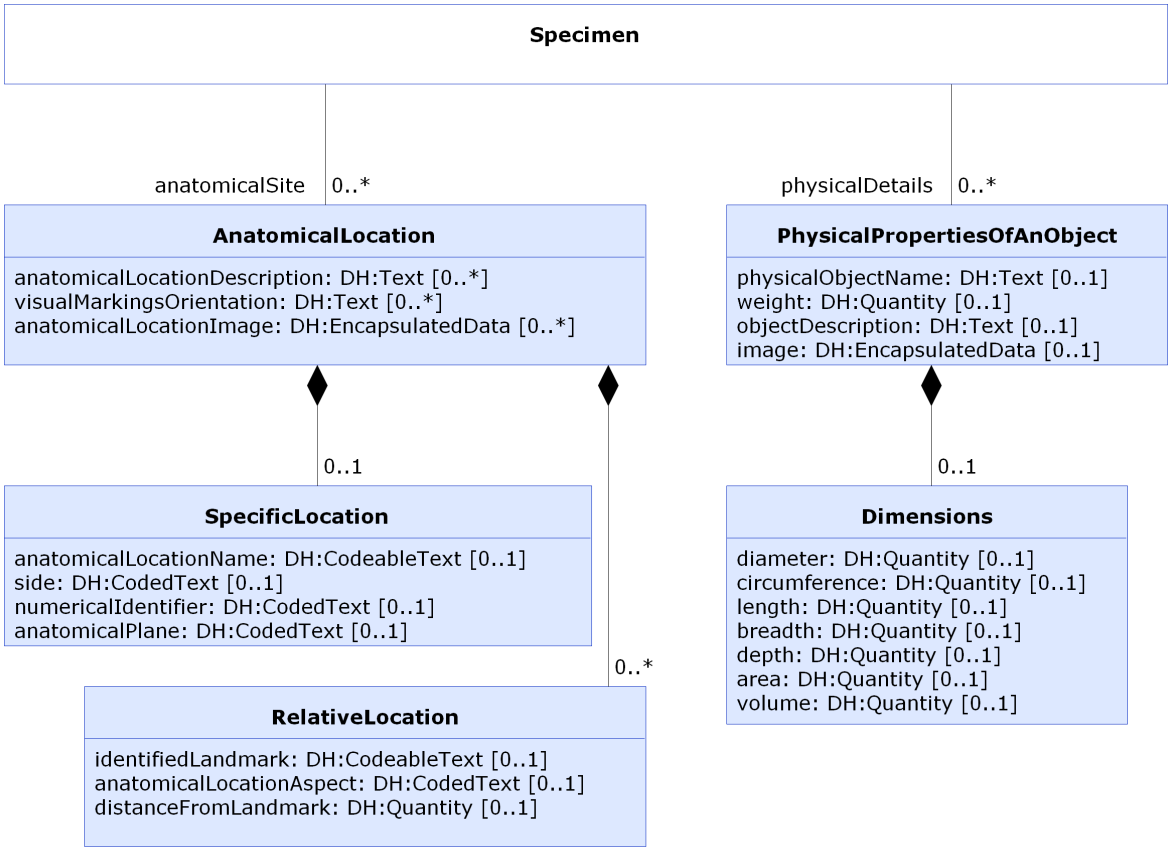

Figure 2.4. Specimen - part 2

2.5 PATHOLOGY TEST RESULT

Identification

Label	PATHOLOGY TEST RESULT
Metadata Type	Data Group
Identifier	DG-16144
OID	1.2.36.1.2001.1001.101.102.16144

Definition

Definition	Findings and interpretation of pathology tests performed on one or more specimens obtained from a person or environment.
Definition Source	Australian Digital Health Agency
Synonymous Names	Lab Test Pathology Biochemistry Haematology Microbiology Immunology
Notes	This `data group` may be used to record a single valued test, but will often be used to represent multiple value or “panel” tests.

Data Hierarchy

Note

Items below whose text is lighter (mid-blue and mid-grey) are technical identifiers whose purpose is to facilitate interoperability, sharing of data and secondary use. Typically, such identifiers will be generated internally by systems and not displayed to users since they rarely have clinical significance.

PATHOLOGY TEST RESULT					
	Test Result Name (Pathology Test Result Name)				1..1
	Diagnostic Service				0..1
	Test Specimen Detail (SPECIMEN)				0..*
		Specimen Tissue Type			0..1
		Collection Procedure			0..1
		Anatomical Site (ANATOMICAL LOCATION)			0..*
			SPECIFIC LOCATION		0..1

					Anatomical Location Name	0..1
					Side	0..1
					Numerical Identifier	0..1
					Anatomical Plane	0..1
				RELATIVE LOCATION		0..*
					Identified Landmark	0..1
					Anatomical Location Aspect	0..1
					Distance From Landmark	0..1
				Anatomical Location Description		0..*
				Visual Markings/Orientation		0..*
				Anatomical Location Image		0..*
			Physical Details (PHYSICAL PROPERTIES OF AN OBJECT)			0..*
				Name (Physical Object Name)		0..1
				Weight		0..1
				DIMENSIONS		0..1
					Diameter	0..1
					Circumference	0..1
					Length	0..1
					Breadth	0..1
					Depth	0..1
					Area	0..1
					Volume	0..1
				Description (Object Description)		0..1
				Image		0..1
			NEEDLE BIOPSY CORE DETAILS			0..1

				Biopsy Core Needle Gauge	0..1
				Maximum Biopsy Core Length	0..1
				Number of Cores Received	0..1
			COLLECTION AND HANDLING		0..1
				Potential Risk / Biohazard	0..1
				Sampling Preconditions	0..1
				Number of Containers	0..1
				Collection Procedure Details	0..1
				Transport Medium	0..1
				Testing Method	0..1
				DEVICE	0..*
			HANDLING AND PROCESSING		0..1
				Date and Time of Collection (Collection DateTime)	0..1
				Collection Setting	0..1
				Date and Time of Receipt (DateTime Received)	0..1
				Date and Time Processed (DateTime Processed)	0..1
			SPECIMEN QUALITY		0..1
				Specimen Received Issues	0..*
				Laboratory Handling Issues	0..*
				Adequacy for Testing	0..1
				Comment (Specimen Quality Comment)	0..1
			IDENTIFIERS		0..1
				Specimen Identifier	0..1
				Parent Specimen Identifier	0..1
				Container Identifier	0..1

				Specimen Collector Identifier			0..1
				SPECIMEN COLLECTOR DETAILS			0..*
	Overall Pathology Test Result Status						1..1
	Clinical Information Provided						0..1
	Result Group (PATHOLOGY TEST RESULT GROUP)						0..*
		Pathology Test Result Group Name					0..1
		Result (INDIVIDUAL PATHOLOGY TEST RESULT)					0..*
			Individual Pathology Test Result Name				1..1
			Result Value (INDIVIDUAL PATHOLOGY TEST RESULT VALUE)				0..1
				Individual Pathology Test Result Value			1..1
				Individual Pathology Test Result Value Reference Ranges (REFERENCE RANGE DETAILS)			0..1
					Normal Status		0..1
					REFERENCE RANGE		0..*
						Reference Range Meaning	1..1
						Reference Range	0..1
			Individual Pathology Test Result Comment				0..*
			Individual Pathology Test Result Reference Range Guidance				0..1
			Individual Pathology Test Result Status				0..1
		Result Group Specimen Detail (SPECIMEN)					0..1
			Specimen Tissue Type				0..1
			Collection Procedure				0..1
			Anatomical Site (ANATOMICAL LOCATION)				0..*
				SPECIFIC LOCATION			0..1
					Anatomical Location Name		0..1
					Side		0..1

						Numerical Identifier	0..1
						Anatomical Plane	0..1
					RELATIVE LOCATION		0..*
						Identified Landmark	0..1
						Anatomical Location Aspect	0..1
						Distance From Landmark	0..1
					Anatomical Location Description		0..*
					Visual Markings/Orientation		0..*
					Anatomical Location Image		0..*
				Physical Details (PHYSICAL PROPERTIES OF AN OBJECT)			0..*
					Name (Physical Object Name)		0..1
					Weight		0..1
					DIMENSIONS		0..1
						Diameter	0..1
						Circumference	0..1
						Length	0..1
						Breadth	0..1
						Depth	0..1
						Area	0..1
						Volume	0..1
					Description (Object Description)		0..1
					Image		0..1
				NEEDLE BIOPSY CORE DETAILS			0..1
					Biopsy Core Needle Gauge		0..1
					Maximum Biopsy Core Length		0..1

					Number of Cores Received	0..1
				COLLECTION AND HANDLING		0..1
					Potential Risk / Biohazard	0..1
					Sampling Preconditions	0..1
					Number of Containers	0..1
					Collection Procedure Details	0..1
					Transport Medium	0..1
					Testing Method	0..1
					DEVICE	0..*
				HANDLING AND PROCESSING		0..1
					Date and Time of Collection (Collection DateTime)	0..1
					Collection Setting	0..1
					Date and Time of Receipt (DateTime Received)	0..1
					Date and Time Processed (DateTime Processed)	0..1
				SPECIMEN QUALITY		0..1
					Specimen Received Issues	0..*
					Laboratory Handling Issues	0..*
					Adequacy for Testing	0..1
					Comment (Specimen Quality Comment)	0..1
				IDENTIFIERS		0..1
					Specimen Identifier	0..1
					Parent Specimen Identifier	0..1
					Container Identifier	0..1
					Specimen Collector Identifier	0..1
					SPECIMEN COLLECTOR DETAILS	0..*

		Pathological Diagnosis		0..*
		Conclusion (Pathology Test Conclusion)		0..1
		Test Result Representation		0..*
		Test Comment		0..1
		RECEIVING LABORATORY		0..1
		TEST REQUEST DETAILS		0..*
			Requester Order Identifier	0..1
			Test Requested Name	0..*
			REQUESTER	0..*
			Receiver Order Identifier	0..1
			Laboratory Test Result Identifier	0..1
		Test Procedure		0..*
		REPORTING PATHOLOGIST		0..1
		INFORMATION PROVIDER		0..1
		SUBJECT		0..1
		Observation DateTime		1..1
		Pathology Test Result Instance Identifier		0..1
		RELATED INFORMATION		0..*
			Link Nature	1..1
			Link Role	0..1
			Target	1..1
		Detailed Clinical Model Identifier		1..1

2.6 Pathology Test Result Name

Identification

Label	Test Result Name
Metadata Type	Data Element
Identifier	DE-11017
OID	1.2.36.1.2001.1001.101.103.11017

Definition

Definition	Identification of the pathology test performed, sometimes including specimen type.
Definition Source	Australian Digital Health Agency
Notes	The test name can refer to a single test, for example Glycosylated Haemoglobin (HbA1c), or to a test group such as electrolytes, Full Blood Count (FBC) or coagulation tests. When a *Pathology Test Result* record contains only a single individual test, this name may be the same as the name of the individual test.
Data Type	CodeableText
Value Domain	Pathology Test Result Name Values

Usage

Examples	1) Sputum microscopy and culture 2) FBC 3) Serum bilirubin 4) HbA1c
Exceptional Values	Absent values are **PROHIBITED**.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	PATHOLOGY TEST RESULT	1..1

2.7 Pathology Test Result Name Values

Identification

Label	Pathology Test Result Name Values
Metadata Type	Value Domain
Identifier	VD-11017
OID	1.2.36.1.2001.1001.101.104.11017
External Identifier	SNOMED CT-AU Concept Id: 2021000036107

Definition

Definition	Set of values for the names of pathology tests requested or performed.
Definition Source	Australian Digital Health Agency
Notes	A pathology test may be performed on a pathology specimen or a person. The codes recommended for pathology terminology by the Royal College of Pathologists of Australasia (RCPA) are included in the various Pathology reference sets that can be found at https://www.digitalhealth.gov.au/implementation-resources/terminology-access/#pathology[1] (accessed 28 July 2016).

Value Domain

Source	RCPA

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Test Result Name (Pathology Test Result Name)	1..1

[1] https://www.digitalhealth.gov.au/implementation-resources/terminology-access/#pathology

2.8 Diagnostic Service

Identification

Label	Diagnostic Service
Metadata Type	Data Element
Identifier	DE-16149
OID	1.2.36.1.2001.1001.101.103.16149

Definition

Definition	The diagnostic service that performs the examination.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	CodeableText
Value Domain	Diagnostic Service Values

Usage

Examples	1) Microbiology 2) Haematology

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	PATHOLOGY TEST RESULT	0..1

2.9 Diagnostic Service Values

Identification

Label	Diagnostic Service Values
Metadata Type	Value Domain
Identifier	VD-16148
OID	1.2.36.1.2001.1001.101.104.16148
External Identifier	2.16.840.1.113883.12.74

Definition

Definition	Set of values for the type of diagnostic service.
Definition Source	Australian Digital Health Agency

Value Domain

Source	HL7 Table 0074 (Diagnostic service section ID)

Relationships

Parents

Data Type	Name	**Occurrences** (child within parent)
	Diagnostic Service	1..1

2.10 SPECIMEN

Identification

Label	Test Specimen Detail
Metadata Type	Data Group
Identifier	DG-16156
OID	1.2.36.1.2001.1001.101.102.16156

Definition

Definition	Details about specimens to which this test result refers.
Definition Source	Australian Digital Health Agency
Synonymous Names	Laboratory Specimen Sample Collection
Notes	Do not include specimens described in *PATHOLOGY TEST RESULT GROUP*.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	PATHOLOGY TEST RESULT	0..*

Children

Data Type	Name	Occurrences
	Specimen Tissue Type	0..1
	Collection Procedure	0..1
	Anatomical Site (ANATOMICAL LOCATION)	0..*
	Physical Details (PHYSICAL PROPERTIES OF AN OBJECT)	0..*
	NEEDLE BIOPSY CORE DETAILS	0..1
	COLLECTION AND HANDLING	0..1
	HANDLING AND PROCESSING	0..1
	SPECIMEN QUALITY	0..1

Data Type	Name	Occurrences
	IDENTIFIERS	0..1

2.11 Overall Pathology Test Result Status

Identification

Label	Overall Pathology Test Result Status
Metadata Type	Data Element
Identifier	DE-16155
OID	1.2.36.1.2001.1001.101.103.16155

Definition

Definition	The status of the pathology test result as a whole.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	CodedText
Value Domain	Pathology Test Result Status Values

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for CodedText.
Exceptional Values	Absent values are **PROHIBITED**. Abnormal values are **PROHIBITED**.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	PATHOLOGY TEST RESULT	1..1

2.12 Pathology Test Result Status Values

Identification

Label	Pathology Test Result Status Values
Metadata Type	Value Domain
Identifier	VD-16488
OID	1.2.36.1.2001.1001.101.104.16488

Definition

Definition	Set of values for the pathology test result status.
Definition Source	Australian Digital Health Agency
Notes	The *HL7 Table 0085 - Observation result status codes interpretation* is intended to be used at the result or record level, while the *HL7 Table 0123 - Result status* is intended to be used for the overall report status. Having to source values from two HL7 tables and determine which one to apply in a situation is a potential cause of confusion. Consequently we provide a value set that is applicable across report level and individual result level status values. The single value set has been assessed to be adequate for the My Health Record-based use cases. This approach reduces the chances of confusion and errors in the use of status values.

Value Domain

Source	NCTIS Pathology Test Result Status Values	
Permissible Values	1, Registered	No result yet available.
	2, Interim	This is an initial or interim result: data may be missing or verification has not been performed.
	3, Final	The result is complete and verified by the responsible pathologist.
	4, Amended	The result has been modified subsequent to being Final, and is complete and verified by the responsible pathologist.
	5, Cancelled/Aborted	The result is unavailable because the test was not started or not completed.
	Values sourced by the Agency from *HL7 Table 0085 - Observation result status codes interpretation*, *HL7 Table 0123 - Result status* and other sources.	

Usage

Conditions of Use	In situations where *NCTIS Pathology Test Result Status Values* is not available, *HL7 v2.x Table 0123 (Result status)* [OID:2.16.840.1.113883.12.123] **MAY** be used.
Conditions of Use Source	Australian Digital Health Agency

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Overall Pathology Test Result Status	1..1

2.13 Clinical Information Provided

Identification

Label	Clinical Information Provided
Metadata Type	Data Element
Identifier	DE-16397
OID	1.2.36.1.2001.1001.101.103.16397

Definition

Definition	Description or summary of relevant, prior clinical information that may help in determining the test(s) to be performed, or interpreting the result when compiling or reading the report.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	This would typically be a summarised restatement of any clinical information provided by the original requester of the test for any of the following reasons: • to justify the request; • to help the pathologist or laboratory scientist determine whether a better test should be performed; • to help the pathologist or laboratory scientist determine whether any additional tests are needed; and • to help interpret the result when reporting or reading the report.
Data Type	Text

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for Text.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	PATHOLOGY TEST RESULT	0..1

2.14 PATHOLOGY TEST RESULT GROUP

Identification

Label	Result Group
Metadata Type	Data Group
Identifier	DG-16469
OID	1.2.36.1.2001.1001.101.102.16469

Definition

Definition	A group of results that form all or part of a recognisable pathology test.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	Results may be grouped by specimen, or by some other name or code to describe what binds all the results together.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	PATHOLOGY TEST RESULT	0..*

Children

Data Type	Name	Occurrences
	Pathology Test Result Group Name	0..1
	Result (INDIVIDUAL PATHOLOGY TEST RESULT)	0..*
	Result Group Specimen Detail (SPECIMEN)	0..1

2.15 Pathology Test Result Group Name

Identification

Label	Pathology Test Result Group Name
Metadata Type	Data Element
Identifier	DE-16428
OID	1.2.36.1.2001.1001.101.103.16428

Definition

Definition	The name of a group of pathology test results.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	CodeableText
Value Domain	Pathology Test Result Name Values

Usage

Examples	1) Full blood count 2) Liver function tests

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Result Group (PATHOLOGY TEST RESULT GROUP)	0..1

2.16 INDIVIDUAL PATHOLOGY TEST RESULT

Identification

Label	Result
Metadata Type	Data Group
Identifier	DG-16489
OID	1.2.36.1.2001.1001.101.102.16489

Definition

Definition	Specific detailed result of a pathology test, including both the value of the result item, and additional information that may be useful for clinical interpretation.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	Many specific data items that pathology labs report as part of a clinical service are treated as results; results are not confined to measurements. Individual results are identified by *Individual Pathology Test Result Name*. If a result is not grouped with others, it is recorded as the only result in a nameless result group.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Result Group (PATHOLOGY TEST RESULT GROUP)	0..*

Children

Data Type	Name	Occurrences
	Individual Pathology Test Result Name	1..1
	Result Value (INDIVIDUAL PATHOLOGY TEST RESULT VALUE)	0..1
	Individual Pathology Test Result Comment	0..*
	Individual Pathology Test Result Reference Range Guidance	0..1
	Individual Pathology Test Result Status	0..1

2.17 Individual Pathology Test Result Name

Identification

Label	Individual Pathology Test Result Name
Metadata Type	Data Element
Identifier	DE-16571
OID	1.2.36.1.2001.1001.101.103.16571

Definition

Definition	The name of an individual pathology test result.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	CodeableText
Value Domain	Individual Pathology Test Result Name Values

Usage

Examples	1) Serum glucose level 2) Haemoglobin concentration 3) Hepatitis B surface antibody titre 4) Prothrombin time

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Result (INDIVIDUAL PATHOLOGY TEST RESULT)	1..1

2.18 Individual Pathology Test Result Name Values

Identification

Label	Individual Pathology Test Result Name Values
Metadata Type	Value Domain
Identifier	VD-16571
OID	1.2.36.1.2001.1001.101.104.16571

Definition

Definition	Set of values for the names of individual pathology tests performed.
Definition Source	Australian Digital Health Agency
Notes	The codes recommended for pathology terminology by the Royal College of Pathologists of Australasia (RCPA) are included in Requesting Pathology reference set which can be found at http://www.rcpa.edu.au/Library/Practising-Pathology/PTIS/APUTS-Downloads (accessed 24 March 2014). Most codes are LOINC codes.

Value Domain

Source	RCPA Requesting Pathology reference set

Usage

Conditions of Use	Values **SHOULD** be codes recommended for pathology terminology by the Royal College of Pathologists of Australasia.
Conditions of Use Source	Australian Digital Health Agency

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Individual Pathology Test Result Name	1..1

2.19 INDIVIDUAL PATHOLOGY TEST RESULT VALUE

Identification

Label	Result Value
Metadata Type	Data Group
Identifier	DG-11023
OID	1.2.36.1.2001.1001.101.102.11023

Definition

Definition	Value of the result, with reference range information.
Definition Source	Australian Digital Health Agency
Synonymous Names	

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Result (INDIVIDUAL PATHOLOGY TEST RESULT)	0..1

Children

Data Type	Name	Occurrences
	Individual Pathology Test Result Value	1..1
	Individual Pathology Test Result Value Reference Ranges (REFERENCE RANGE DETAILS)	0..1

2.20 Individual Pathology Test Result Value

Identification

Label	Individual Pathology Test Result Value
Metadata Type	Data Element
Identifier	DE-11023
OID	1.2.36.1.2001.1001.101.103.11023

Definition

Definition	The actual value of the result.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	Most result values will be numerical measurements, but others may be coded concepts or free text. It is recommended that data types without units, e.g. Text or Integer, are avoided where possible so that machine-level semantic interoperability is not compromised.
Data Type	Any

Usage

Examples	1) 140 2) ++ 3) Neg

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Result Value (INDIVIDUAL PATHOLOGY TEST RESULT VALUE)	1..1

2.21 REFERENCE RANGE DETAILS

Identification

Label	Individual Pathology Test Result Value Reference Ranges
Metadata Type	Data Group
Identifier	DG-16325
OID	1.2.36.1.2001.1001.101.102.16325

Definition

Definition	One or more reference ranges applicable to the *Individual Pathology Test Result Value*.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	A reference range is particular to the patient and context, e.g. sex, age, and any other factor that affects ranges. May be used to represent normal, therapeutic, dangerous, critical and other such clinical ranges.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Result Value (INDIVIDUAL PATHOLOGY TEST RESULT VALUE)	0..1

Children

Data Type	Name	Occurrences
	Normal Status	0..1
	REFERENCE RANGE	0..*

2.22 Normal Status

Identification

Label	Normal Status
Metadata Type	Data Element
Identifier	DE-11028
OID	1.2.36.1.2001.1001.101.103.11028

Definition

Definition	An indication of the degree of diagnostically significant abnormality of the value, based on available clinical information.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	Available clinical information includes the reference range. The term “normal” is **not** statistical normality, but rather what would normally be considered healthy for the individual concerned. As such, this `data element` represents the health risk for the individual, which is indicated by the observation or measurement and the nature and criticality of that health risk.
Data Type	CodeableText
Value Domain	*Not specified.* In the absence of national standard code sets, the code sets used **SHALL** be registered code sets, i.e. registered through the HL7 code set registration procedure[2] with an appropriate object identifier (OID), and **SHALL** be publicly available. When national standard code sets become available, they **SHALL** be used and the non-standard code sets **SHALL** be deprecated.

Usage

Examples	1) Below normal 2) Above normal 3) Critically low 4) Critically high

[2] http://www.hl7.org/oid/index.cfm

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Individual Pathology Test Result Value Reference Ranges (REFERENCE RANGE DETAILS)	0..1

2.23 REFERENCE RANGE

Identification

Label	REFERENCE RANGE
Metadata Type	Data Group
Identifier	DG-11024
OID	1.2.36.1.2001.1001.101.102.11024

Definition

Definition	A named range to be associated with any quantity datum.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	The obligations on this data group imply that if this data group occurs only once, the *Reference Range* `data element` is optional, otherwise it is essential.

Usage

Conditions of Use	If this data group occurs only once, its contents **SHALL** span the observed value. If this data group occurs more than once, its contents **SHOULD** include all of the ranges in a single set. If this data group occurs more than once, the *Reference Range* `data element` is **ESSENTIAL**. All reference ranges **SHALL** come from the one set of reference ranges.
Conditions of Use Source	Australian Digital Health Agency

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Individual Pathology Test Result Value Reference Ranges (REFERENCE RANGE DETAILS)	0..*

Children

Data Type	Name	Occurrences
	Reference Range Meaning	1..1
	Reference Range	0..1

2.24 Reference Range Meaning

Identification

Label	Reference Range Meaning
Metadata Type	Data Element
Identifier	DE-16574
OID	1.2.36.1.2001.1001.101.103.16574

Definition

Definition	Term whose value indicates the meaning of this range.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	CodeableText
Value Domain	*Not specified.* In the absence of national standard code sets, the code sets used **SHALL** be registered code sets, i.e. registered through the HL7 code set registration procedure[3] with an appropriate object identifier (OID), and **SHALL** be publicly available. When national standard code sets become available, they **SHALL** be used and the non-standard code sets **SHALL** be deprecated.

Usage

Examples	1) Normal 2) Critical 3) Therapeutic
Exceptional Values	Absent values are **PROHIBITED**.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	REFERENCE RANGE	1..1

[3] http://www.hl7.org/oid/index.cfm

2.25 Reference Range

Identification

Label	Reference Range
Metadata Type	Data Element
Identifier	DE-11024
OID	1.2.36.1.2001.1001.101.103.11024

Definition

Definition	The data range for the associated *Reference Range Meaning* `data element`.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	QuantityRange

Usage

Examples	1) 15 - 58 g/L 2) < 15 mmol/L 3) 2.5 - 3.5 kg 4) 23 - 45 cm

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	REFERENCE RANGE	0..1

2.26 Individual Pathology Test Result Comment

Identification

Label	Individual Pathology Test Result Comment
Metadata Type	Data Element
Identifier	DE-16466
OID	1.2.36.1.2001.1001.101.103.16466

Definition

Definition	Comments that may include statements about significant, unexpected or unreliable values, or information about the source of the value where this may be relevant to the interpretation of the result.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	Text

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for Text.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Result (INDIVIDUAL PATHOLOGY TEST RESULT)	0..*

2.27 Individual Pathology Test Result Reference Range Guidance

Identification

Label	Individual Pathology Test Result Reference Range Guidance
Metadata Type	Data Element
Identifier	DE-16467
OID	1.2.36.1.2001.1001.101.103.16467

Definition

Definition	Additional advice on the applicability of the reference range.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	Text

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for Text.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Result (INDIVIDUAL PATHOLOGY TEST RESULT)	0..1

2.28 Individual Pathology Test Result Status

Identification

Label	Individual Pathology Test Result Status
Metadata Type	Data Element
Identifier	DE-11029
OID	1.2.36.1.2001.1001.101.103.11029

Definition

Definition	The status of the result value.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	Allows a report with more than one result to be issued and allows each result to have a different status associated with it. The status of a result is included in the report to inform the requester or receiver whether it is final or there is more to expect, or whether amendments have been made. This may be of use to the clinician in deciding how to respond to the report.
Data Type	CodedText
Value Domain	Pathology Test Result Status Values

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for CodedText.
Exceptional Values	Absent values are **PROHIBITED**. Abnormal values are **PROHIBITED**.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Result (INDIVIDUAL PATHOLOGY TEST RESULT)	0..1

2.29 SPECIMEN

Identification

Label	Result Group Specimen Detail
Metadata Type	Data Group
Identifier	DG-16156
OID	1.2.36.1.2001.1001.101.102.16156

Definition

Definition	Details about the individual specimen to which these result group test results refer, where testing of multiple specimens is required.
Definition Source	Australian Digital Health Agency
Synonymous Names	Laboratory Specimen Sample Collection

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Result Group (PATHOLOGY TEST RESULT GROUP)	0..1

Children

Data Type	Name	Occurrences
001011001	Specimen Tissue Type	0..1
001011001	Collection Procedure	0..1
	Anatomical Site (ANATOMICAL LOCATION)	0..*
	Physical Details (PHYSICAL PROPERTIES OF AN OBJECT)	0..*
	NEEDLE BIOPSY CORE DETAILS	0..1
	COLLECTION AND HANDLING	0..1
	HANDLING AND PROCESSING	0..1
	SPECIMEN QUALITY	0..1

Data Type	Name	Occurrences
	IDENTIFIERS	0..1

2.30 Pathological Diagnosis

Identification

Label	Pathological Diagnosis
Metadata Type	Data Element
Identifier	DE-16402
OID	1.2.36.1.2001.1001.101.103.16402

Definition

Definition	Single word, phrase or brief description representing the diagnostic statement as asserted by the reporting pathologist.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	CodeableText
Value Domain	*Not specified.* In the absence of national standard code sets, the code sets used **SHALL** be registered code sets, i.e. registered through the HL7 code set registration procedure[4] with an appropriate object identifier (OID), and **SHALL** be publicly available. When national standard code sets become available, they **SHALL** be used and the non-standard code sets **SHALL** be deprecated.

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for CodeableText.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	PATHOLOGY TEST RESULT	0..*

[4] http://www.hl7.org/oid/index.cfm

2.31 Pathology Test Conclusion

Identification

Label	Conclusion
Metadata Type	Data Element
Identifier	DE-16403
OID	1.2.36.1.2001.1001.101.103.16403

Definition

Definition	Concise and clinically contextualised narrative interpretation of the pathology test results.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	Text

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for Text.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	PATHOLOGY TEST RESULT	0..1

2.32 Test Result Representation

Identification

Label	Test Result Representation
Metadata Type	Data Element
Identifier	DE-16159
OID	1.2.36.1.2001.1001.101.103.16159

Definition

Definition	Rich text representation of the entire result as issued by the diagnostic service.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	The report is a verbatim copy of the report as issued. The results reported may also, or instead, be supplied in a machine-readable structured form. As some structured pathology information is unable to be stored and displayed correctly by receiving systems at this time, some structured pathology information (such as microbiology results) is sent in the same way as free text or images. Resistance to structured formatting has been expressed in some quarters. These concerns may be due to the perceived difficulty in ensuring the results are maintained in their entirety as intended by the reporting provider. The nature and intent of DCMs to constrain information and provide context may help to alleviate this problem. In the meantime, the *Pathology Test Result* `data group` represents the non-numerical pathology results as a single data element. This is similar to the approach taken by *Pathology Result Report Structured Document Template [NEHT2009s]*, which is HL7 based.
Data Type	EncapsulatedData

Usage

Conditions of Use	Multiple formats are allowed but they **SHALL** be semantically equivalent.
Conditions of Use Source	Australian Digital Health Agency
Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for EncapsulatedData.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	PATHOLOGY TEST RESULT	0..*

2.33 Test Comment

Identification

Label	Test Comment
Metadata Type	Data Element
Identifier	DE-16468
OID	1.2.36.1.2001.1001.101.103.16468

Definition

Definition	Additional narrative about the test that is not captured in other fields.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	Text

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for Text.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	PATHOLOGY TEST RESULT	0..1

2.34 RECEIVING LABORATORY

Identification

Label	RECEIVING LABORATORY
Metadata Type	Data Group
Identifier	DG-10296
OID	1.2.36.1.2001.1001.101.102.10296

Definition

Definition	Laboratory that received the test request.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	The receiving laboratory may either perform the test or refer it to another laboratory.

Usage

Conditions of Use

This is a reuse of the *PARTICIPATION* `data group`, which is described in *Participation Data Specification [NEHT2011v]*.

The following constraints are additional to those specified in *Participation Data Specification [NEHT2011v]*. Constraints are explained in Appendix B, *Specification Guide for Use*.

Additional obligation and occurrence constraints:

- Participation Period is **PROHIBITED**.
- LOCATION OF PARTICIPATION is **PROHIBITED**.
- Entity Identifier is **ESSENTIAL**.
- ADDRESS is **ESSENTIAL**.
- ELECTRONIC COMMUNICATION DETAIL is **ESSENTIAL**.
- ENTITLEMENT is **PROHIBITED**.
- Qualifications is **PROHIBITED**.

Other additional constraints:

- Participation Type **SHALL** have an implementation-specific value equivalent to “Receiving Laboratory”.
- Role **SHALL** have an implementation-specific null flavour.
- The value of one Entity Identifier **SHALL** be an Australian HPI-O.
- PERSON OR ORGANISATION OR DEVICE **SHALL** be instantiated as an ORGANISATION.

Conditions of Use Source	Australian Digital Health Agency

Relationships

Parents

Data Type	Name	**Occurrences** (child within parent)
	PATHOLOGY TEST RESULT	0..1

2.35 TEST REQUEST DETAILS

Identification

Label	TEST REQUEST DETAILS
Metadata Type	Data Group
Identifier	DG-16160
OID	1.2.36.1.2001.1001.101.102.16160

Definition

Definition	Details concerning a single requested pathology test.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	Usually there is one test request for each result; however, in some circumstances multiple test requests may be represented using a single *Pathology Test Result*.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	PATHOLOGY TEST RESULT	0..*

Children

Data Type	Name	Occurrences
	Requester Order Identifier	0..1
	Test Requested Name	0..*
	REQUESTER	0..*
	Receiver Order Identifier	0..1
	Laboratory Test Result Identifier	0..1

2.36 Requester Order Identifier

Identification

Label	Requester Order Identifier
Metadata Type	Data Element
Identifier	DE-11006
OID	1.2.36.1.2001.1001.101.103.11006

Definition

Definition	The local identifier assigned to the order by the order requester.
Definition Source	Australian Digital Health Agency
Synonymous Names	Request Order Number Order Number Request Number (Requester)
Notes	Assigning an identifier to a request by the clinical information system enables the progress of the request to be tracked and enables requests to be linked to results. *Request Order Identifier* is equivalent to the Placer Order Identifier.
Data Type	UniqueIdentifier

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for UniqueIdentifier.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	TEST REQUEST DETAILS	0..1

2.37 Test Requested Name

Identification

Label	Test Requested Name
Metadata Type	Data Element
Identifier	DE-16404
OID	1.2.36.1.2001.1001.101.103.16404

Definition

Definition	Identification of the pathology test that was requested.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	CodeableText
Value Domain	Pathology Test Result Name Values

Usage

Conditions of Use	This `data element` **SHOULD NOT** be used if its value is equal to the value of the Pathology Test Result Name `data element`.
Conditions of Use Source	Australian Digital Health Agency
Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for CodeableText.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	TEST REQUEST DETAILS	0..*

2.38 REQUESTER

Identification

Label	REQUESTER
Metadata Type	Data Group
Identifier	DG-10296
OID	1.2.36.1.2001.1001.101.102.10296

Definition

Definition	Details of the clinician or organisation requesting the laboratory test.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Scope	Generally only used when the recorder needs to make the requester explicit. Otherwise composer, author or organisation of the enclosing Structured Document is assumed.
Scope Source	Australian Digital Health Agency
Notes	This can be a person or an organisation. Types of sources include: • the clinician; and • a healthcare provider or organisation.

Usage

Conditions of Use	This is a reuse of the *PARTICIPATION* `data group`, which is described in *Participation Data Specification [NEHT2011v]*. The following constraints are additional to those specified in *Participation Data Specification [NEHT2011v]*. Constraints are explained in Appendix B, *Specification Guide for Use*. • Participation Type **SHALL** have an implementation-specific value equivalent to “Requester”. • PERSON OR ORGANISATION OR DEVICE **SHALL** be instantiated as a PERSON or ORGANISATION.
Conditions of Use Source	Australian Digital Health Agency

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	TEST REQUEST DETAILS	0..*

2.39 Receiver Order Identifier

Identification

Label	Receiver Order Identifier
Metadata Type	Data Element
Identifier	DE-11007
OID	1.2.36.1.2001.1001.101.103.11007

Definition

Definition	The local identifier assigned to the test order by the order filler, usually by the laboratory information system (LIS).
Definition Source	Australian Digital Health Agency
Synonymous Names	Request Number (Laboratory)
Context	Assigning an identifier to a request by the laboratory information system enables the progress of the request to be tracked and enables requests to be linked to results. It also provides a reference to assist with enquiries.
Context Source	Australian Digital Health Agency
Assumptions	The laboratory information system is able to assign an identifier to each request on receipt. *Receiver Order Identifier* is usually equivalent to the DICOM Accession Number and the Filler Order Identifier.
Assumptions Source	Australian Digital Health Agency
Data Type	UniqueIdentifier

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for UniqueIdentifier.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	TEST REQUEST DETAILS	0..1

2.40 Laboratory Test Result Identifier

Identification

Label	Laboratory Test Result Identifier
Metadata Type	Data Element
Identifier	DE-11018
OID	1.2.36.1.2001.1001.101.103.11018

Definition

Definition	The identifier given to the laboratory test result of a pathology investigation.
Definition Source	Australian Digital Health Agency
Synonymous Names	Lab Number
Notes	Assigning an identification code to a result allows the result to be linked to a request in the laboratory.
Data Type	UniqueIdentifier

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for UniqueIdentifier.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	TEST REQUEST DETAILS	0..1

2.41 Test Procedure

Identification

Label	Test Procedure
Metadata Type	Data Element
Identifier	DE-16632
OID	1.2.36.1.2001.1001.101.105.16632

Definition

Definition	Details of pathology test methodologies followed for the test.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	This free text data element is currently a placeholder for further structured data that is as yet undefined. See Appendix A, *Known Issues* for further information.
Data Type	Text

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for Text.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	PATHOLOGY TEST RESULT	0..*

2.42 REPORTING PATHOLOGIST

Identification

Label	REPORTING PATHOLOGIST
Metadata Type	Data Group
Identifier	DG-10296
OID	1.2.36.1.2001.1001.101.102.10296

Definition

Definition	Pathologist who is responsible for the pathology test result.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	The author of the content of the report. The date the pathology test result is generated is contained in the *Participation Period* of the *Reporting Pathologist*.

Usage

Conditions of Use	This is a reuse of the *PARTICIPATION* `data group`, which is described in *Participation Data Specification [NEHT2011v]*. The following constraints are additional to those specified in *Participation Data Specification [NEHT2011v]*. Constraints are explained in Appendix B, *Specification Guide for Use*. Additional obligation and occurrence constraints: • LOCATION OF PARTICIPATION is **PROHIBITED**. • Entity Identifier is **ESSENTIAL**. • ADDRESS is **ESSENTIAL**. • ELECTRONIC COMMUNICATION DETAIL is **ESSENTIAL**. • Relationship to Subject of Care is **PROHIBITED**. • EMPLOYMENT DETAIL is **ESSENTIAL**. • EMPLOYER ORGANISATION is **ESSENTIAL**. • EMPLOYER ORGANISATION.Entity Identifier is **ESSENTIAL**. • DEMOGRAPHIC DATA is **PROHIBITED**. Other additional constraints: • Participation Type **SHALL** have an implementation-specific value equivalent to “Reporting Pathologist”. • Role **SHOULD** have a value chosen from *1220.0 - ANZSCO - Australian and New Zealand Standard Classification of Occupations, First Edition, Revision 1 [ABS2009]*.

	However, if a suitable value in this set cannot be found, then any code set that is both registered with HL7 and is publicly available **MAY** be used. • The value of one Entity Identifier **SHOULD** be an Australian HPI-I. • The value of one EMPLOYER ORGANISATION.Entity Identifier **SHOULD** be an Australian HPI-O. • AUSTRALIAN OR INTERNATIONAL ADDRESS **SHALL** be instantiated as an AUSTRALIAN ADDRESS. • PERSON OR ORGANISATION OR DEVICE **SHALL** be instantiated as a PERSON.
Conditions of Use Source	Australian Digital Health Agency

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	PATHOLOGY TEST RESULT	0..1

2.43 INFORMATION PROVIDER

Identification

Label	INFORMATION PROVIDER
Metadata Type	Data Group
Identifier	DG-10296
OID	1.2.36.1.2001.1001.101.102.10296

Definition

Definition	Source of the information.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Scope	Only used when the recorder needs to make it explicit. Otherwise, it is assumed to be the subject of care of the enclosing structured document.
Scope Source	Australian Digital Health Agency
Notes	This does not have to be a person and, in particular, does not have to be a healthcare provider. Types of sources include: • an agent of a subject of care, e.g. parent, guardian; • a clinician; • a device or software; and • the subject of the DCM, when not the subject of care of the enclosing structured document.

Usage

Conditions of Use	This **SHALL NOT** be used if the source of the information is the *SUBJECT OF CARE* of the enclosing structured document. This is a reuse of the *PARTICIPATION* `data group`, which is described in *Participation Data Specification [NEHT2011v]*. Further constraints on this data group that apply to this reuse of it are listed below. • Participation Type **SHALL** have an implementation-specific value equivalent to “Information Provider”. • PERSON OR ORGANISATION OR DEVICE **SHALL** be instantiated as a PERSON or as a DEVICE. Terms used in obligation and occurrence constraints are explained in Appendix B, *Specification Guide for Use*.
Conditions of Use Source	Australian Digital Health Agency

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	PATHOLOGY TEST RESULT	0..1

2.44 SUBJECT

Identification

Label	SUBJECT
Metadata Type	Data Group
Identifier	DG-10296
OID	1.2.36.1.2001.1001.101.102.10296

Definition

Definition	The individual about whom the laboratory test information is being recorded.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Scope	Only used when the recorder needs to make it explicit. Otherwise, it is assumed to be the subject of care of the enclosing structured document.
Scope Source	Australian Digital Health Agency
Notes	An example of use is: When the *Subject of Care* is the recipient of a donor organ, the *SUBJECT* of a *Pathology Test Result* could be the person from whom the organ was extracted.

Usage

Conditions of Use	This **SHALL NOT** be used if the subject of the information is the *SUBJECT OF CARE* of the enclosing structured document. This is a reuse of the *PARTICIPATION* `data group`, which is described in *Participation Data Specification [NEHT2011v]*. Further constraints on this data group that apply to this reuse of it are listed below. • Participation Type **SHALL** have an implementation-specific value equivalent to “Subject”. • PERSON OR ORGANISATION OR DEVICE **SHALL** be instantiated as a PERSON. Terms used in obligation and occurrence constraints are explained in Appendix B, *Specification Guide for Use*.
Conditions of Use Source	Australian Digital Health Agency

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	PATHOLOGY TEST RESULT	0..1

2.45 Observation DateTime

Identification

Label	Observation DateTime
Metadata Type	Data Element
Identifier	DE-15561
OID	1.2.36.1.2001.1001.101.103.15561

Definition

Definition	Date, and optionally time, when an observation is clinically significant to the condition of the subject of the observation.
Definition Source	Australian Digital Health Agency
Synonymous Names	Clinically Significant DateTime Effective DateTime
Context	For a *Pathology Test Result* the value is the date, and optionally time, of collection of the specimen.
Context Source	Australian Digital Health Agency
Notes	Associated with every observation of a subject are two different times that often, but not always, coincide, and are consequently often conflated: the time that the activity of observing occurred (the time the subject **was** observed, the *measuring time*), and the time that the subject was the way it looked (the time the subject was **as** observed, the *state time*.) Generally, there is no delay between a person being in a state, and an observation of the person being in that state. For example, if a pulse of 72 bpm is recorded at 13:45 on 12 February 2015, one can assume that the heart rate was 72 bpm at that time. (Pulse is a surrogate for heart rate.) In such cases the *measuring time* and the *state time* are the same. Sometimes, when there is a delay between the time the person is in a state and the time when they are measured, the delay is important. For example, if a sample is taken from a person and its testing is completed over a period of days, the test results will provide information about the state of the person at the time the sample was taken, not the time the test was completed. The clinically significant time in all clinical observations is the time that the person was as observed, the *state time*. In observations involving specimens, the time that the specimen was taken is the closest practicable proxy for the *state time*. The meaning of *Observation DateTime* is always the time that the person was **as** observed. This approach follows that of openEHR.
Data Type	DateTime TimeInterval

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for DateTime, and TimeInterval.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	PATHOLOGY TEST RESULT	1..1

2.46 Pathology Test Result Instance Identifier

Identification

Label	Pathology Test Result Instance Identifier
Metadata Type	Data Element
Identifier	DE-16714
OID	1.2.36.1.2001.1001.101.103.16714

Definition

Definition	A globally unique identifier for each instance of a *Pathology Test Result* observation.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	UniqueIdentifier

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for UniqueIdentifier.
Exceptional Values	Absent values are **PROHIBITED**. Abnormal values are **PROHIBITED**.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	PATHOLOGY TEST RESULT	0..1

2.47 RELATED INFORMATION

Identification

Label	RELATED INFORMATION
Metadata Type	Data Group
Identifier	DG-16692
OID	1.2.36.1.2001.1001.101.102.16692

Definition

Definition	Information held elsewhere that is relevant to this instance of *Pathology Test Result*.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	Items of related information include, but are not limited to, documents, parts of documents, images and web pages. “Elsewhere” includes elsewhere in the same document. 1:1 and 1:N relationships between instances of DCMs can be expressed by using one, or more than one, respectively, links. Chains of links can be used to see problem threads or other logical groupings of items. Links are only to be used between instances of DCMs or documents, i.e. between objects representing complete domain concepts. This is because relationships between sub-elements of whole concepts are not necessarily meaningful and may be confusing. When the item of related information is a complete document (including images) or a web page (or part thereof) an appropriate specialisation of the *Related Information* `data group` should be used. The document or other data component instance containing the *Related Information* `data group` is called the *source*. The related information is called the *target*.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	PATHOLOGY TEST RESULT	0..*

Children

Data Type	Name	Occurrences
	Link Nature	1..1

Data Type	Name	Occurrences
	Link Role	0..1
	Target	1..1

2.48 Link Nature

Identification

Label	Link Nature
Metadata Type	Data Element
Identifier	DE-16698
OID	1.2.36.1.2001.1001.101.103.16698

Definition

Definition	The general semantic category of the relationship between this instance of this detailed clinical model (DCM), i.e. the source, and the target DCM instance or target document.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	This is one of two attributes that together communicate the semantics of the relationship between the source and target DCMs or document. This attribute is intended to be a coarse-grained category that can be used to enable interoperability between sender and receiver.
Data Type	CodedText
Value Domain	Link Nature Values

Usage

Examples	1) is related to 2) is confirmed by or authorised by 3) is related to the same problem or health issue
Exceptional Values	Absent values are **PROHIBITED**. Abnormal values are **PROHIBITED**.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	RELATED INFORMATION	1..1

2.49 Link Nature Values

Identification

Label	Link Nature Values
Metadata Type	Value Domain
Identifier	VD-16698
OID	1.2.36.1.2001.1001.101.104.16698
External Identifier	LINK_NATURE

Definition

Definition	Set of values for the general semantic category of the relationship between this instance of this DCM, i.e. the source, and the target DCM instance or target document.
Definition Source	Australian Digital Health Agency

Value Domain

Source	ISO 13606-3:2009
Permissible Values	The permissible values are those specified in Termlist LINK_NATURE in *ISO 13606-3:2009 Health informatics - Electronic health record communication - Part 3: Reference archetypes and term lists [ISO2009a]*. The values are listed here with brief descriptions.

LINK-A0, is related to	The most general category of Link.
LINK-B0, is confirmed by or authorised by	The link target contains an instance of a DCM or document that is either a legal or authoritative basis for what is documented in the source DCM instance, or is a declaration of intent to provide (or not provide) requested care.
LINK-C0, is related to the same problem or health issue	The target instance of a DCM or document describes health or healthcare that concerns the same clinical situation as the source DCM instance.
LINK-D0, is related to the same care plan, act or episode	The source and the target instances of DCMs or documents both describe parts of the same care plan, act or episode.
LINK-E0, is a related documentation	The target instance of a DCM or document is an alternative documentary form of the source DCM instance. For example, a re-expression of the same clinical information or supplementary explanatory information.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Link Nature	1..1

2.50 Link Role

Identification

Label	Link Role
Metadata Type	Data Element
Identifier	DE-16699
OID	1.2.36.1.2001.1001.101.103.16699

Definition

Definition	The detailed semantic description of the relationship between this instance of this detailed clinical model (DCM), i.e. the source, and the target DCM instance or target document.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	This is one of two attributes that together communicate the semantics of the relationship between the source and target DCMs. This attribute provides for a specific description of the actual role played by the target in relation to the source. This attribute may be populated from any suitable terminology and therefore might support human readership better than interoperable automated processing.
Data Type	CodeableText
Value Domain	Link Role Values

Usage

Examples	1) unspecified link 2) suggests 3) endorses 4) evidence for 5) outcome 6) is documented by 7) excerpts

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	RELATED INFORMATION	0..1

2.51 Link Role Values

Identification

Label	Link Role Values
Metadata Type	Value Domain
Identifier	VD-16699
OID	1.2.36.1.2001.1001.101.104.16699
External Identifier	LINK_ROLE

Definition

Definition	Set of values for the detailed semantic description of the relationship between this instance of this DCM, i.e. the source, and the target DCM instance or target document.
Definition Source	Australian Digital Health Agency
Context	These values are used within the context of the value of the *Link Nature* `data element`. They provide greater specificity and may be selected more for human readership than for interoperable automated processing.
Context Source	Australian Digital Health Agency

Value Domain

Source	ISO 13606-3:2009
Permissible Values	Values **SHOULD** be from Termlist LINK_ROLE in ISO 13606-3:2009 [ISO2009a]. Values **MAY** be from any suitable terminology. Some values from Termlist LINK_ROLE in *ISO 13606-3:2009 Health informatics - Electronic health record communication - Part 3: Reference archetypes and term lists [ISO2009a]*, together with brief descriptions, are: LINK-A1, unspecified link — This can be used to say explicitly “there is no semantic information available for this Link”. LINK-B1, endorses — The source endorses (agrees with, confirms or verifies) the situation (or interpretation) described in the target. LINK-C3, evidence for — The source describes evidence for the situation (or interpretation) described in the target. LINK-D1, outcome — The source describes an outcome of the situation (or interpretation) that the target describes. LINK-E1, documented by — The source is a less formal description of the situation (or interpretation) documented by the target. LINK-E4, excerpts — The source is an extract (copy) of part or all of the information contained within the target. LINK-E5, derived from — The source contains information that has been derived (e.g. calculated) from information in the target.

Usage

Conditions of Use	Each of the values in LINK_ROLE from ISO 13606-3:2009 identifies a subcategory of a corresponding value in *Link Nature Values*. That correspondence is indicated by the first letter after the code string “LINK-”. For example, the term LINK-A1 is a subcategory of term LINK-A0. If a term in this list is used for the *Link Role* `data element`, the appropriate corresponding value **SHALL** be used for *Link Nature Values*.
Conditions of Use Source	ISO 13606-3:2009

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Link Role	1..1

2.52 Target

Identification

Label	Target
Metadata Type	Data Element
Identifier	DE-16700
OID	1.2.36.1.2001.1001.101.103.16700

Definition

Definition	The “linked to” or identified information.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	Link UniqueIdentifier

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for Link, and UniqueIdentifier.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	RELATED INFORMATION	1..1

2.53 Detailed Clinical Model Identifier

Identification

Label	Detailed Clinical Model Identifier
Metadata Type	Data Element
Identifier	DE-16693
OID	1.2.36.1.2001.1001.101.103.16693

Definition

Definition	A globally unique identifier for this detailed clinical model.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	UniqueIdentifier

Usage

Conditions of Use	The value of this item **SHALL** be either the default value or a semantically equivalent value from an appropriate code system.
Conditions of Use Source	Australian Digital Health Agency
Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for UniqueIdentifier.
Default Value	1.2.36.1.2001.1001.101.102.16144
Exceptional Values	Absent values are **PROHIBITED**. Abnormal values are **PROHIBITED**.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	PATHOLOGY TEST RESULT	1..1

3 Specimen Data Group

This chapter describes version 2.2 of the *Specimen* Data Group.

3.1 Purpose

To record details of a laboratory specimen. Will often be used in different contexts e.g. within an instruction DCM to describe the specimen that has to be taken, or describing the specimen which accompanies the laboratory request. It may occur within an action DCM e.g. describing specimens taken as part of a surgical procedure. It will finally be used within a Pathology Test Result DCM to describe the specimen being reported.

3.2 Use

Generally used within the Pathology Test Result DCM and other laboratory-related instruction and action DCMs.

3.3 SPECIMEN

Identification

Label	Test Specimen Detail
Metadata Type	Data Group
Identifier	DG-16156
OID	1.2.36.1.2001.1001.101.102.16156

Definition

Definition	Details of a specimen.
Definition Source	Australian Digital Health Agency
Synonymous Names	Laboratory Specimen Sample Collection

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	PATHOLOGY TEST RESULT	0..*

Children

Data Type	Name	Occurrences
	Specimen Tissue Type	0..1
	Collection Procedure	0..1
	Anatomical Site (ANATOMICAL LOCATION)	0..*
	Physical Details (PHYSICAL PROPERTIES OF AN OBJECT)	0..*
	NEEDLE BIOPSY CORE DETAILS	0..1
	COLLECTION AND HANDLING	0..1
	HANDLING AND PROCESSING	0..1
	SPECIMEN QUALITY	0..1
	IDENTIFIERS	0..1

3.4 Specimen Tissue Type

Identification

Label	Specimen Tissue Type
Metadata Type	Data Element
Identifier	DE-11008
OID	1.2.36.1.2001.1001.101.103.11008

Definition

Definition	The type of specimen to be collected.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	This is the actual specimen being submitted to the laboratory for analysis.
Data Type	CodeableText
Value Domain	*Not specified.* In the absence of national standard code sets, the code sets used **SHALL** be registered code sets, i.e. registered through the HL7 code set registration procedure[1] with an appropriate object identifier (OID), and **SHALL** be publicly available. When national standard code sets become available, they **SHALL** be used and the non-standard code sets **SHALL** be deprecated.

Usage

Examples	1) Venous blood 2) Prostate tissue, left base 3) Urine 4) Sputum 5) Scraping 6) Catheter tip 7) Single core (yellow-tan) liver tissue

[1] http://www.hl7.org/oid/index.cfm

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Test Specimen Detail (SPECIMEN)	0..1
	Result Group Specimen Detail (SPECIMEN)	0..1

3.5 Collection Procedure

Identification

Label	Collection Procedure
Metadata Type	Data Element
Identifier	DE-16111
OID	1.2.36.1.2001.1001.101.103.16111

Definition

Definition	The method of collection to be used.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	CodeableText
Value Domain	*Not specified.* In the absence of national standard code sets, the code sets used **SHALL** be registered code sets, i.e. registered through the HL7 code set registration procedure[2] with an appropriate object identifier (OID), and **SHALL** be publicly available. When national standard code sets become available, they **SHALL** be used and the non-standard code sets **SHALL** be deprecated.

Usage

Examples	1) Venepuncture 2) Biopsy 3) Resection

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Test Specimen Detail (SPECIMEN)	0..1
	Result Group Specimen Detail (SPECIMEN)	0..1

[2] http://www.hl7.org/oid/index.cfm

3.6 ANATOMICAL LOCATION

Identification

Label	Anatomical Site
Metadata Type	Data Group
Identifier	DG-16150
OID	1.2.36.1.2001.1001.101.102.16150

Definition

Definition	The anatomical site from where the specimen was taken.
Definition Source	Australian Digital Health Agency
Synonymous Names	

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Test Specimen Detail (SPECIMEN)	0..*
	Result Group Specimen Detail (SPECIMEN)	0..*

Children

Data Type	Name	Occurrences
	SPECIFIC LOCATION	0..1
	RELATIVE LOCATION	0..*
	Anatomical Location Description	0..*
	Visual Markings/Orientation	0..*
	Anatomical Location Image	0..*

3.7 SPECIFIC LOCATION

Identification

Label	SPECIFIC LOCATION
Metadata Type	Data Group
Identifier	DG-16151
OID	1.2.36.1.2001.1001.101.102.16151

Definition

Definition	Specific and identified anatomical location.
Definition Source	Australian Digital Health Agency
Synonymous Names	

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Anatomical Site (ANATOMICAL LOCATION)	0..1

Children

Data Type	Name	Occurrences
	Anatomical Location Name	0..1
	Side	0..1
	Numerical Identifier	0..1
	Anatomical Plane	0..1

3.8 Anatomical Location Name

Identification

Label	Anatomical Location Name
Metadata Type	Data Element
Identifier	DE-16153
OID	1.2.36.1.2001.1001.101.103.16153

Definition

Definition	The name of the anatomical location.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	CodeableText
Value Domain	Body Structure Foundation Reference Set

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for CodeableText.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	SPECIFIC LOCATION	0..1

3.9 Body Structure Foundation Reference Set

Identification

Label	Body Structure Foundation Reference Set
Metadata Type	Value Domain
Identifier	VD-16152
OID	1.2.36.1.2001.1001.101.104.16152
External Identifier	SNOMED CT-AU Concept Id: 32570061000036105

Definition

Definition	The set of values for named anatomical locations.
Definition Source	Australian Digital Health Agency

Value Domain

Source	SNOMED CT-AU

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Anatomical Location Name	1..1

3.10 Side

Identification

Label	Side
Metadata Type	Data Element
Identifier	DE-16336
OID	1.2.36.1.2001.1001.101.103.16336

Definition

Definition	Laterality of the anatomical location.
Definition Source	Australian Digital Health Agency
Synonymous Names	Laterality
Data Type	CodedText
Value Domain	Laterality Reference Set

Usage

Examples	1) Right 2) Left 3) Bilateral
Exceptional Values	Absent values are **PROHIBITED**. Abnormal values are **PROHIBITED**.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	SPECIFIC LOCATION	0..1

3.11 Laterality Reference Set

Identification

Label	Laterality Reference Set
Metadata Type	Value Domain
Identifier	VD-16312
OID	1.2.36.1.2001.1001.101.104.16312
External Identifier	SNOMED CT-AU Concept Id: 32570611000036103

Definition

Definition	The set of values for identifying the laterality of an anatomical location.
Definition Source	Australian Digital Health Agency

Value Domain

Source	SNOMED CT-AU

Relationships

Parents

Data Type	Name	**Occurrences** (child within parent)
	Side	1..1

3.12 Numerical Identifier

Identification

Label	Numerical Identifier
Metadata Type	Data Element
Identifier	DE-16338
OID	1.2.36.1.2001.1001.101.103.16338

Definition

Definition	Ordinal value used with anatomical site or part name to identify a specific anatomical site in a collection of enumerable sites, such as vertebrae or ribs.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	CodedText
Value Domain	*Not specified.* In the absence of national standard code sets, the code sets used **SHALL** be registered code sets, i.e. registered through the HL7 code set registration procedure[3] with an appropriate object identifier (OID), and **SHALL** be publicly available. When national standard code sets become available, they **SHALL** be used and the non-standard code sets **SHALL** be deprecated.

Usage

Conditions of Use	This **SHALL** be an ordinal number between first and eighteenth.
Conditions of Use Source	Australian Digital Health Agency
Examples	1) First, as in 'first rib'. 2) Second, as in 'second toe'. 3) Third, as in 'third lumbar vertebra'.
Exceptional Values	Absent values are **PROHIBITED**. Abnormal values are **PROHIBITED**.

[3] http://www.hl7.org/oid/index.cfm

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	SPECIFIC LOCATION	0..1

3.13 Anatomical Plane

Identification

Label	Anatomical Plane
Metadata Type	Data Element
Identifier	DE-16340
OID	1.2.36.1.2001.1001.101.103.16340

Definition

Definition	Line describing the position of a vertical anatomical plane in the body.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	CodedText
Value Domain	*Not specified.* In the absence of national standard code sets, the code sets used **SHALL** be registered code sets, i.e. registered through the HL7 code set registration procedure[4] with an appropriate object identifier (OID), and **SHALL** be publicly available. When national standard code sets become available, they **SHALL** be used and the non-standard code sets **SHALL** be deprecated.

Usage

Examples	1) Midline 2) Midclavicular 3) Midaxillary 4) Midscapular
Exceptional Values	Absent values are **PROHIBITED**. Abnormal values are **PROHIBITED**.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	SPECIFIC LOCATION	0..1

[4] http://www.hl7.org/oid/index.cfm

3.14 RELATIVE LOCATION

Identification

Label	RELATIVE LOCATION
Metadata Type	Data Group
Identifier	DG-16341
OID	1.2.36.1.2001.1001.101.102.16341

Definition

Definition	Qualifier(s) to identify a non-specific location.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	An example is: 5cm (distance) inferior (aspect) to the tibial tuberosity (landmark). More than one relative location may be required to provide a cross-reference.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Anatomical Site (ANATOMICAL LOCATION)	0..*

Children

Data Type	Name	Occurrences
	Identified Landmark	0..1
	Anatomical Location Aspect	0..1
	Distance From Landmark	0..1

3.15 Identified Landmark

Identification

Label	Identified Landmark
Metadata Type	Data Element
Identifier	DE-16343
OID	1.2.36.1.2001.1001.101.103.16343

Definition

Definition	Identified anatomical landmark from which to specify the relative anatomical location.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	CodeableText
Value Domain	*Not specified.* In the absence of national standard code sets, the code sets used **SHALL** be registered code sets, i.e. registered through the HL7 code set registration procedure[5] with an appropriate object identifier (OID), and **SHALL** be publicly available. When national standard code sets become available, they **SHALL** be used and the non-standard code sets **SHALL** be deprecated.

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for CodeableText.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	RELATIVE LOCATION	0..1

[5] http://www.hl7.org/oid/index.cfm

3.16 Anatomical Location Aspect

Identification

Label	Anatomical Location Aspect
Metadata Type	Data Element
Identifier	DE-16345
OID	1.2.36.1.2001.1001.101.103.16345

Definition

Definition	Qualifier to identify which direction the anatomical location is in relation to the identified landmark.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	CodedText
Value Domain	*Not specified.* In the absence of national standard code sets, the code sets used **SHALL** be registered code sets, i.e. registered through the HL7 code set registration procedure[6] with an appropriate object identifier (OID), and **SHALL** be publicly available. When national standard code sets become available, they **SHALL** be used and the non-standard code sets **SHALL** be deprecated.

Usage

Examples	1) Medial to 2) Lateral to 3) Anterior to 4) Above
Exceptional Values	Absent values are **PROHIBITED**. Abnormal values are **PROHIBITED**.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	RELATIVE LOCATION	0..1

[6] http://www.hl7.org/oid/index.cfm

3.17 Distance From Landmark

Identification

Label	Distance From Landmark
Metadata Type	Data Element
Identifier	DE-16346
OID	1.2.36.1.2001.1001.101.103.16346

Definition

Definition	Distance of location from the identified landmark.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	Quantity

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for Quantity.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	RELATIVE LOCATION	0..1

3.18 Anatomical Location Description

Identification

Label	Anatomical Location Description
Metadata Type	Data Element
Identifier	DE-16319
OID	1.2.36.1.2001.1001.101.103.16319

Definition

Definition	Description of the anatomical location.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	Text

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for Text.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Anatomical Site (ANATOMICAL LOCATION)	0..*

3.19 Visual Markings/Orientation

Identification

Label	Visual Markings/Orientation
Metadata Type	Data Element
Identifier	DE-16407
OID	1.2.36.1.2001.1001.101.103.16407

Definition

Definition	Description of any visual markings used to orient the viewer.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	Text

Usage

Examples	1) External reference points 2) Special sutures 3) Ink markings

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Anatomical Site (ANATOMICAL LOCATION)	0..*

3.20 Anatomical Location Image

Identification

Label	Anatomical Location Image
Metadata Type	Data Element
Identifier	DE-16199
OID	1.2.36.1.2001.1001.101.103.16199

Definition

Definition	An image or images used to identify a location.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Context	This element is intended to be an image, e.g. a photo of the anatomical site such as a wound on the leg.
Context Source	Australian Digital Health Agency
Data Type	EncapsulatedData

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for EncapsulatedData.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Anatomical Site (ANATOMICAL LOCATION)	0..*

3.21 PHYSICAL PROPERTIES OF AN OBJECT

Identification

Label	Physical Details
Metadata Type	Data Group
Identifier	DG-16166
OID	1.2.36.1.2001.1001.101.102.16166

Definition

Definition	Record of physical details, such as weight and dimensions, of a body part, device, lesion or specimen.
Definition Source	Australian Digital Health Agency
Synonymous Names	

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Test Specimen Detail (SPECIMEN)	0..*
	Result Group Specimen Detail (SPECIMEN)	0..*

Children

Data Type	Name	Occurrences
	Name (Physical Object Name)	0..1
	Weight	0..1
	DIMENSIONS	0..1
	Description (Object Description)	0..1
	Image	0..1

3.22 Physical Object Name

Identification

Label	Name
Metadata Type	Data Element
Identifier	DE-16326
OID	1.2.36.1.2001.1001.101.103.16326

Definition

Definition	The object concerned.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	May be a body part, device or specimen.
Data Type	Text

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for Text.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Physical Details (PHYSICAL PROPERTIES OF AN OBJECT)	0..1

3.23 Weight

Identification

Label	Weight
Metadata Type	Data Element
Identifier	DE-16327
OID	1.2.36.1.2001.1001.101.103.16327

Definition

Definition	Property of a body – commonly, but inadequately, defined as the quantity of matter in it – to which its inertia is ascribed, and expressed as the weight of the body divided by the acceleration due to gravity.
Definition Source	Macquarie Dictionary (2010)
Synonymous Names	
Data Type	Quantity

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for Quantity.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Physical Details (PHYSICAL PROPERTIES OF AN OBJECT)	0..1

3.24 DIMENSIONS

Identification

Label	DIMENSIONS
Metadata Type	Data Group
Identifier	DG-16328
OID	1.2.36.1.2001.1001.101.102.16328

Definition

Definition	The dimensions of the object.
Definition Source	Australian Digital Health Agency
Synonymous Names	

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Physical Details (PHYSICAL PROPERTIES OF AN OBJECT)	0..1

Children

Data Type	Name	Occurrences
	Diameter	0..1
	Circumference	0..1
	Length	0..1
	Breadth	0..1
	Depth	0..1
	Area	0..1
	Volume	0..1

3.25 Diameter

Identification

Label	Diameter
Metadata Type	Data Element
Identifier	DE-16329
OID	1.2.36.1.2001.1001.101.103.16329

Definition

Definition	The diameter of the object.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	Quantity

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for Quantity.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	DIMENSIONS	0..1

3.26 Circumference

Identification

Label	Circumference
Metadata Type	Data Element
Identifier	DE-16330
OID	1.2.36.1.2001.1001.101.103.16330

Definition

Definition	The circumference of the object.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	Quantity

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for Quantity.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	DIMENSIONS	0..1

3.27 Length

Identification

Label	Length
Metadata Type	Data Element
Identifier	DE-16331
OID	1.2.36.1.2001.1001.101.103.16331

Definition

Definition	The length of the object.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	Quantity

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for Quantity.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	DIMENSIONS	0..1

3.28 Breadth

Identification

Label	Breadth
Metadata Type	Data Element
Identifier	DE-16332
OID	1.2.36.1.2001.1001.101.103.16332

Definition

Definition	The measure or dimension of the object from side to side.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	Quantity

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for Quantity.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	DIMENSIONS	0..1

3.29 Depth

Identification

Label	Depth
Metadata Type	Data Element
Identifier	DE-16333
OID	1.2.36.1.2001.1001.101.103.16333

Definition

Definition	The depth of the object.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	Quantity

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for Quantity.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	DIMENSIONS	0..1

3.30 Area

Identification

Label	Area
Metadata Type	Data Element
Identifier	DE-16334
OID	1.2.36.1.2001.1001.101.103.16334

Definition

Definition	The amount of two-dimensional space; typically a measure of the outermost surface of an object.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	Quantity

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for Quantity.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	DIMENSIONS	0..1

3.31 Volume

Identification

Label	Volume
Metadata Type	Data Element
Identifier	DE-16335
OID	1.2.36.1.2001.1001.101.103.16335

Definition

Definition	Size, measure or amount of anything in three dimensions; space occupied by a body or substance measured in cubic units.
Definition Source	Macquarie Dictionary (2010)
Synonymous Names	
Data Type	Quantity

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for Quantity.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	DIMENSIONS	0..1

3.32 Object Description

Identification

Label	Description
Metadata Type	Data Element
Identifier	DE-16621
OID	1.2.36.1.2001.1001.101.103.16621

Definition

Definition	A description of other physical characteristics of the object.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	Text

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for Text.
Misuse	This data element **SHALL NOT** be used to record characteristics that might affect the quality of a test interpretation; use *Specimen Received Issues* in the *Specimen* `data group` for that purpose.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Physical Details (PHYSICAL PROPERTIES OF AN OBJECT)	0..1

3.33 Image

Identification

Label	Image
Metadata Type	Data Element
Identifier	DE-16199
OID	1.2.36.1.2001.1001.101.103.16199

Definition

Definition	A picture of the object.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	EncapsulatedData

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for EncapsulatedData.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Physical Details (PHYSICAL PROPERTIES OF AN OBJECT)	0..1

3.34 NEEDLE BIOPSY CORE DETAILS

Identification

Label	NEEDLE BIOPSY CORE DETAILS
Metadata Type	Data Group
Identifier	DG-16161
OID	1.2.36.1.2001.1001.101.102.16161

Definition

Definition	Details of the needle used to take the needle biopsy.
Definition Source	Australian Digital Health Agency
Synonymous Names	

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Test Specimen Detail (SPECIMEN)	0..1
	Result Group Specimen Detail (SPECIMEN)	0..1

Children

Data Type	Name	Occurrences
	Biopsy Core Needle Gauge	0..1
	Maximum Biopsy Core Length	0..1
	Number of Cores Received	0..1

3.35 Biopsy Core Needle Gauge

Identification

Label	Biopsy Core Needle Gauge
Metadata Type	Data Element
Identifier	DE-16163
OID	1.2.36.1.2001.1001.101.103.16163

Definition

Definition	The diameter of the core obtained via needle biopsy expressed using the needle gauge used to take the specimen.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	CodedText
Value Domain	*Not specified.* In the absence of national standard code sets, the code sets used **SHALL** be registered code sets, i.e. registered through the HL7 code set registration procedure[7] with an appropriate object identifier (OID), and **SHALL** be publicly available. When national standard code sets become available, they **SHALL** be used and the non-standard code sets **SHALL** be deprecated.

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for CodedText.
Exceptional Values	Absent values are **PROHIBITED**. Abnormal values are **PROHIBITED**.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	NEEDLE BIOPSY CORE DETAILS	0..1

[7] http://www.hl7.org/oid/index.cfm

3.36 Maximum Biopsy Core Length

Identification

Label	Maximum Biopsy Core Length
Metadata Type	Data Element
Identifier	DE-16164
OID	1.2.36.1.2001.1001.101.103.16164

Definition

Definition	The length of the core obtained by needle biopsy.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	Quantity

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for Quantity.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	NEEDLE BIOPSY CORE DETAILS	0..1

3.37 Number of Cores Received

Identification

Label	Number of Cores Received
Metadata Type	Data Element
Identifier	DE-16165
OID	1.2.36.1.2001.1001.101.103.16165

Definition

Definition	The number of needle biopsy cores received.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	Integer

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for Integer.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	NEEDLE BIOPSY CORE DETAILS	0..1

3.38 COLLECTION AND HANDLING

Identification

Label	COLLECTION AND HANDLING
Metadata Type	Data Group
Identifier	DG-16167
OID	1.2.36.1.2001.1001.101.102.16167

Definition

Definition	Collection and handling requirements.
Definition Source	Australian Digital Health Agency
Synonymous Names	

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Test Specimen Detail (SPECIMEN)	0..1
	Result Group Specimen Detail (SPECIMEN)	0..1

Children

Data Type	Name	Occurrences
	Potential Risk / Biohazard	0..1
	Sampling Preconditions	0..1
	Number of Containers	0..1
	Collection Procedure Details	0..1
	Transport Medium	0..1
	Testing Method	0..1
	DEVICE	0..*

3.39 Potential Risk / Biohazard

Identification

Label	Potential Risk / Biohazard
Metadata Type	Data Element
Identifier	DE-16169
OID	1.2.36.1.2001.1001.101.103.16169

Definition

Definition	Any risk or biohazard associated with collecting or handling the specimen.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	CodeableText
Value Domain	*Not specified.* In the absence of national standard code sets, the code sets used **SHALL** be registered code sets, i.e. registered through the HL7 code set registration procedure[8] with an appropriate object identifier (OID), and **SHALL** be publicly available. When national standard code sets become available, they **SHALL** be used and the non-standard code sets **SHALL** be deprecated.

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for CodeableText.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	COLLECTION AND HANDLING	0..1

[8] http://www.hl7.org/oid/index.cfm

3.40 Sampling Preconditions

Identification

Label	Sampling Preconditions
Metadata Type	Data Element
Identifier	DE-16171
OID	1.2.36.1.2001.1001.101.103.16171

Definition

Definition	Any conditions to be met before the sample should be taken.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	Can also be used to document any known deviations from collection or handling instructions, or any special instructions on the handling or immediate processing of the sample.
Data Type	CodeableText
Value Domain	*Not specified.* In the absence of national standard code sets, the code sets used **SHALL** be registered code sets, i.e. registered through the HL7 code set registration procedure[9] with an appropriate object identifier (OID), and **SHALL** be publicly available. When national standard code sets become available, they **SHALL** be used and the non-standard code sets **SHALL** be deprecated.

Usage

Examples	1) centrifuge on receipt 2) fasting 3) full bladder 4) sterile field 5) patient was not fasted

[9] http://www.hl7.org/oid/index.cfm

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	COLLECTION AND HANDLING	0..1

3.41 Number of Containers

Identification

Label	Number of Containers
Metadata Type	Data Element
Identifier	DE-16526
OID	1.2.36.1.2001.1001.101.103.16526

Definition

Definition	The total number of containers holding this specimen.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	Integer

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for Integer.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	COLLECTION AND HANDLING	0..1

3.42 Collection Procedure Details

Identification

Label	Collection Procedure Details
Metadata Type	Data Element
Identifier	DE-16527
OID	1.2.36.1.2001.1001.101.103.16527

Definition

Definition	Additional detailed description of method of sample collection.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	Text

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for Text.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	COLLECTION AND HANDLING	0..1

3.43 Transport Medium

Identification

Label	Transport Medium
Metadata Type	Data Element
Identifier	DE-16173
OID	1.2.36.1.2001.1001.101.103.16173

Definition

Definition	Any special preservative or transport medium requirements.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	CodeableText
Value Domain	*Not specified.* In the absence of national standard code sets, the code sets used **SHALL** be registered code sets, i.e. registered through the HL7 code set registration procedure[10] with an appropriate object identifier (OID), and **SHALL** be publicly available. When national standard code sets become available, they **SHALL** be used and the non-standard code sets **SHALL** be deprecated.

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for CodeableText.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	COLLECTION AND HANDLING	0..1

[10] http://www.hl7.org/oid/index.cfm

3.44 Testing Method

Identification

Label	Testing Method
Metadata Type	Data Element
Identifier	DE-11025
OID	1.2.36.1.2001.1001.101.103.11025

Definition

Definition	The test method used to arrive at the result.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	The method used has a critical impact in the comparability of results. A decision on diagnosis can be affected by the method used, based on the likelihood of false or true positives and negatives related to sensitivities and specificities of tests. This is associated with the result observable name. The method is chosen by the performing pathologist or pathology laboratory. This may be recorded or reported at the overall test level or for an individual result.
Data Type	CodeableText
Value Domain	Testing Method Reference Set

Usage

Conditions of Use	To be used to describe the method used, especially in cases where the method has a bearing on the result interpretation.
Conditions of Use Source	Australian Digital Health Agency
Examples	1) 54826005 - Chromatography measurement 2) 117259009 - Microscopy

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	COLLECTION AND HANDLING	0..1

3.45 Testing Method Reference Set

Identification

Label	Testing Method Reference Set
Metadata Type	Value Domain
Identifier	VD-11025
OID	1.2.36.1.2001.1001.101.104.11025
External Identifier	SNOMED CT-AU Concept Id: 3021000036100

Definition

Definition	The set of values for the specific method(s) used by the laboratory to perform the analyses and produce the reported test results.
Definition Source	Australian Digital Health Agency

Value Domain

Source	SNOMED CT-AU

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Testing Method	1..1

3.46 DEVICE

Identification

Label	DEVICE
Metadata Type	Data Group
Identifier	DG-10296
OID	1.2.36.1.2001.1001.101.102.10296

Definition

Definition	Details of the device used to perform the test.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Scope	Only used when the recorder needs to make it explicit. Otherwise, device of the enclosing structured document is assumed.
Scope Source	Australian Digital Health Agency

Usage

Conditions of Use	This **SHALL NOT** be used unless the device is different to the *Device* of the enclosing Structured Document. This is a reuse of the *PARTICIPATION* `data group`, which is described in *Participation Data Specification [NEHT2011v]*. Further constraints on this data group that apply to this reuse of it are listed below. • Participation Type **SHALL** have an implementation-specific value equivalent to “Device”. • PERSON OR ORGANISATION OR DEVICE **SHALL** be instantiated as a DEVICE. Terms used in obligation and occurrence constraints are explained in Appendix B, *Specification Guide for Use*.
Conditions of Use Source	Australian Digital Health Agency

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	COLLECTION AND HANDLING	0..*

3.47 HANDLING AND PROCESSING

Identification

Label	HANDLING AND PROCESSING
Metadata Type	Data Group
Identifier	DG-16528
OID	1.2.36.1.2001.1001.101.102.16528

Definition

Definition	Workflow of specimen processing or handling.
Definition Source	Australian Digital Health Agency
Synonymous Names	

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Test Specimen Detail (SPECIMEN)	0..1
	Result Group Specimen Detail (SPECIMEN)	0..1

Children

Data Type	Name	Occurrences
	Date and Time of Collection (Collection DateTime)	0..1
	Collection Setting	0..1
	Date and Time of Receipt (DateTime Received)	0..1
	Date and Time Processed (DateTime Processed)	0..1

3.48 Collection DateTime

Identification

Label	Date and Time of Collection
Metadata Type	Data Element
Identifier	DE-11013
OID	1.2.36.1.2001.1001.101.103.11013

Definition

Definition	The date and time that the collection has been ordered to take place or has taken place.
Definition Source	Australian Digital Health Agency
Synonymous Names	Collected Date/Time
Notes	This provides a point-in-time reference for linking of result data to request data, and a point-in-time reference within a health record that the clinician may refer to.
Data Type	DateTime

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for DateTime.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	HANDLING AND PROCESSING	0..1

3.49 Collection Setting

Identification

Label	Collection Setting
Metadata Type	Data Element
Identifier	DE-16529
OID	1.2.36.1.2001.1001.101.103.16529

Definition

Definition	Identification of the setting at which the specimen was collected from a subject of care.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	The specimen is often collected by a healthcare provider, but may be collected directly by the patient or carer at home. This specifies the specimen collection location within the healthcare environment. It enables the laboratory to ask questions about the collection of the specimen, if required. The specimen collection setting may provide additional information relevant to the analysis of the result data.
Data Type	Text

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for Text.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	HANDLING AND PROCESSING	0..1

3.50 DateTime Received

Identification

Label	Date and Time of Receipt
Metadata Type	Data Element
Identifier	DE-11014
OID	1.2.36.1.2001.1001.101.103.11014

Definition

Definition	The date and time that the sample was received at the laboratory.
Definition Source	Australian Digital Health Agency
Synonymous Names	Received Date/Time
Notes	This provides a point-in-time reference for linking of result data to request data, and a point-in-time reference within a health record that the clinician may refer to.
Data Type	DateTime

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for DateTime.

Relationships

Parents

Data Type	Name	**Occurrences** (child within parent)
	HANDLING AND PROCESSING	0..1

3.51 DateTime Processed

Identification

Label	Date and Time Processed
Metadata Type	Data Element
Identifier	DE-16176
OID	1.2.36.1.2001.1001.101.103.16176

Definition

Definition	The date and time that the specimen was processed by the laboratory.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	DateTime

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for DateTime.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	HANDLING AND PROCESSING	0..1

3.52 SPECIMEN QUALITY

Identification

Label	SPECIMEN QUALITY
Metadata Type	Data Group
Identifier	DG-16530
OID	1.2.36.1.2001.1001.101.102.16530

Definition

Definition	An assessment of the quality of the specimen received by the pathology service, especially regarding the suitability of the specimen for testing or analysis.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	Assessment of quality is important for proper analysis to be done by the pathology laboratory. If a tissue sample is crushed or too small, assessment will not be optimal, so an indication of the quality of the sample must be given. This data group provides an indication of whether the specimen is suitable for the required laboratory testing.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Test Specimen Detail (SPECIMEN)	0..1
	Result Group Specimen Detail (SPECIMEN)	0..1

Children

Data Type	Name	Occurrences
	Specimen Received Issues	0..*
	Laboratory Handling Issues	0..*
	Adequacy for Testing	0..1
	Comment (Specimen Quality Comment)	0..1

3.53 Specimen Received Issues

Identification

Label	Specimen Received Issues
Metadata Type	Data Element
Identifier	DE-16178
OID	1.2.36.1.2001.1001.101.103.16178

Definition

Definition	Specific issue with a received specimen.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	CodeableText
Value Domain	*Not specified.* In the absence of national standard code sets, the code sets used **SHALL** be registered code sets, i.e. registered through the HL7 code set registration procedure[11] with an appropriate object identifier (OID), and **SHALL** be publicly available. When national standard code sets become available, they **SHALL** be used and the non-standard code sets **SHALL** be deprecated.

Usage

Examples	1) Haemolysed: The specimen was haemolysed. 2) Lipaemic: The specimen was lipaemic. 3) Incorrect transport medium: An incorrect preservative was used when transporting the specimen. 4) Insufficient sample: An insufficient sample was given to undertake measurement.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	SPECIMEN QUALITY	0..*

[11] http://www.hl7.org/oid/index.cfm

3.54 Laboratory Handling Issues

Identification

Label	Laboratory Handling Issues
Metadata Type	Data Element
Identifier	DE-16182
OID	1.2.36.1.2001.1001.101.103.16182

Definition

Definition	Issue arising with handling or processing of the specimen within the laboratory.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	CodeableText
Value Domain	*Not specified.* In the absence of national standard code sets, the code sets used **SHALL** be registered code sets, i.e. registered through the HL7 code set registration procedure[12] with an appropriate object identifier (OID), and **SHALL** be publicly available. When national standard code sets become available, they **SHALL** be used and the non-standard code sets **SHALL** be deprecated.

Usage

Examples	1) Handling error: An error arose when handling the specimen. 2) Age: The specimen was too old to analyse accurately. 3) Laboratory accident: An accident occurred with the sample in the laboratory. 4) Technical failure: The specimen could not be analysed for technical reasons.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	SPECIMEN QUALITY	0..*

[12] http://www.hl7.org/oid/index.cfm

3.55 Adequacy for Testing

Identification

Label	Adequacy for Testing
Metadata Type	Data Element
Identifier	DE-16183
OID	1.2.36.1.2001.1001.101.103.16183

Definition

Definition	Indication of the adequacy of the sample for testing.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	CodeableText
Value Domain	*Not specified.* In the absence of national standard code sets, the code sets used **SHALL** be registered code sets, i.e. registered through the HL7 code set registration procedure[13] with an appropriate object identifier (OID), and **SHALL** be publicly available. When national standard code sets become available, they **SHALL** be used and the non-standard code sets **SHALL** be deprecated.

Usage

Examples	1) Satisfactory: The specimen is of sufficient quality to allow reporting. 2) Unsatisfactory - processed: The specimen is unsatisfactory but has been processed. 3) Unsatisfactory - not processed: The specimen is unsatisfactory and has not been processed.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	SPECIMEN QUALITY	0..1

[13] http://www.hl7.org/oid/index.cfm

3.56 Specimen Quality Comment

Identification

Label	Comment
Metadata Type	Data Element
Identifier	DE-16181
OID	1.2.36.1.2001.1001.101.103.16181

Definition

Definition	An additional text comment on the quality of the received specimen.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	Text

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for Text.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	SPECIMEN QUALITY	0..1

3.57 IDENTIFIERS

Identification

Label	IDENTIFIERS
Metadata Type	Data Group
Identifier	DG-16186
OID	1.2.36.1.2001.1001.101.102.16186

Definition

Definition	Sample identifications.
Definition Source	Australian Digital Health Agency
Synonymous Names	

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Test Specimen Detail (SPECIMEN)	0..1
	Result Group Specimen Detail (SPECIMEN)	0..1

Children

Data Type	Name	Occurrences
	Specimen Identifier	0..1
	Parent Specimen Identifier	0..1
	Container Identifier	0..1
	Specimen Collector Identifier	0..1
	SPECIMEN COLLECTOR DETAILS	0..*

3.58 Specimen Identifier

Identification

Label	Specimen Identifier
Metadata Type	Data Element
Identifier	DE-11012
OID	1.2.36.1.2001.1001.101.103.11012

Definition

Definition	Unique identifier of the specimen, normally assigned by the laboratory.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	The assignment of an identification code to a specimen allows the tracking of the specimen through receipt, processing, analysis, reporting and storage within the laboratory. This identifier may be placed on several vials of the same specimen type collected at the same time, as in the case of blood vials.
Data Type	UniqueIdentifier

Usage

Conditions of Use	Each specimen **SHOULD** have an identifier.
Conditions of Use Source	Australian Digital Health Agency
Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for UniqueIdentifier.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	IDENTIFIERS	0..1

3.59 Parent Specimen Identifier

Identification

Label	Parent Specimen Identifier
Metadata Type	Data Element
Identifier	DE-16187
OID	1.2.36.1.2001.1001.101.103.16187

Definition

Definition	Unique identifier of the parent specimen where the specimen is split into sub-samples.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	UniqueIdentifier

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for UniqueIdentifier.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	IDENTIFIERS	0..1

3.60 Container Identifier

Identification

Label	Container Identifier
Metadata Type	Data Element
Identifier	DE-16188
OID	1.2.36.1.2001.1001.101.103.16188

Definition

Definition	Unique identifier given to the container in which the specimen is transported or processed.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	UniqueIdentifier

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for UniqueIdentifier.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	IDENTIFIERS	0..1

3.61 Specimen Collector Identifier

Identification

Label	Specimen Collector Identifier
Metadata Type	Data Element
Identifier	DE-16534
OID	1.2.36.1.2001.1001.101.103.16534

Definition

Definition	Identifier of the person or agency responsible for collecting the specimen.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	UniqueIdentifier

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for UniqueIdentifier.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	IDENTIFIERS	0..1

3.62 SPECIMEN COLLECTOR DETAILS

Identification

Label	SPECIMEN COLLECTOR DETAILS
Metadata Type	Data Group
Identifier	DG-10296
OID	1.2.36.1.2001.1001.101.102.10296

Definition

Definition	The person or organisation responsible for collecting the specimen.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	This can be a person or an organisation. Types of sources include: • the clinician; and • a healthcare provider or organisation.

Usage

Conditions of Use	This is a reuse of the *PARTICIPATION* `data group`, which is described in *Participation Data Specification [NEHT2011v]*. The following constraints are additional to those specified in *Participation Data Specification [NEHT2011v]*. Constraints are explained in Appendix B, *Specification Guide for Use*. • Participation Type **SHALL** have an implementation-specific value equivalent to "Specimen Collector Details". • PERSON OR ORGANISATION OR DEVICE **SHALL** be instantiated as a PERSON or ORGANISATION.
Conditions of Use Source	Australian Digital Health Agency

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	IDENTIFIERS	0..*

Appendix A. Known Issues

This appendix lists known issues with this specification at the time of publishing. We are working on solutions to these issues and encourage comments to help us develop these solutions.

Reference	Description
Links to external resources	Certain combinations of web browsers and PDF readers have problems opening URL links (usually found in reference sections) that span more than one line.
Data Hierarchy	Only the parts of these detailed clinical models (DCMs) required for current structured content specifications have been mapped to HL7 CDA. Mapping the remaining parts to CDA may reveal inconsistencies in the data hierarchies, requiring normative change.
Undefined Value Domains	The following data elements lack a defined value domain: *Normal Status*, *Reference Range Meaning*, *Pathological Diagnosis*, *Specimen Tissue Type*, *Collection Procedure*, *Numerical Identifier*, *Anatomical Plane*, *Identified Landmark*, *Anatomical Location Aspect*, *Biopsy Core Needle Gauge*, *Potential Risk / Biohazard*, *Sampling Preconditions*, *Transport Medium*, *Specimen Received Issues*, *Laboratory Handling Issues*, and *Adequacy for Testing*. We are in the process of developing national code sets for these items. In the meantime, you are free to use your own code sets, providing any code set used **SHALL** be registered, i.e. registered through the HL7 code set registration procedure with an appropriate object identifier (OID), and **SHALL** be publicly available. Note that when national standard code sets do become available, they **SHALL** be used and the non-standard code sets **SHALL** be deprecated.
Undefined Data Structures	The following data components lack a defined data structure: *Test Procedure*. A free text data element is currently used as an interim solution.
Reference Range	This element is of data type *QuantityRange*. It is possible that the data type should be widened to allow a wider choice of data types.
Dimensions	There is no provision to include measurements other than volume, in particular for tissue specimens where at least length, width/breath and depth are required.
Observation DateTime	No guidance is provided on how the value of *Observation DateTime* is related to the value of specimen *Collection DateTime* (14.29 Collection DateTime and 14.74 Collection DateTime) when there is more than one instance of *Collection DateTime*. We seek feedback from early implementers.
Information Provider	We are considering making *Information Provider* one of a pair of data components: *Information Provider* for the source of the information, typically the subject of care of the enclosing structured document and *Reporter* for the author of the information, typically the author of the enclosing structured document. *Reporter* has not been added to this DCM. More investigation is needed to make a decision.
Non-normalised structure	This structure has not been normalised, meaning that while some common groupings of information are easy, other groupings of information are very difficult. An example is that every Result is part of a Result Group. Another is that a specimen may be associated with a Result Group, but not a Result. The information model for this concept needs to be restructured, even if none of the data elements change.

Reference	Description
Detailed Clinical Model	This DCM has a number of known shortcomings, including a) its lack of suitability for histopathology; b) the complex data structure makes it very cumbersome to use for reporting a simple test; and c) the inability to have more than one level of grouping. As a result, it is intended that the Agency will re-design this DCM to address these (and other) issues. The timeline for this re-design is undecided at present, but the Agency will provide suitable notification of any implementation-affecting changes.
Use of test name data elements	There is no guidance on how to deal with the various levels of test names; for example how to capture detailed data such as the result value and reference range data when only one test is completed.
Device	Scope statement requires further clarification, in particular whether the “device of the enclosing structured document” is the *Document Author*.

Appendix B. Specification Guide for Use

B.1 Overview

Each detailed clinical model (DCM) and structured content specification (SCS) is designed to be a shared basis for data interpretation. It specifies rigorous business and technical definitions of data that systems may need to share. It is intended to be a logical specification of the data to be persisted within or communicated between systems. It is also the foundation for the compliance, conformance, and declaration process. Our CDA implementation guides are guides to the implementation of HL7 CDA R2 messages based upon these DCMs and SCSs.

Each DCM specifies all of the data components required for any use of a clinical concept; for instance, an entry in a medical record such as a procedure or an imaging test. As such, they are maximal data sets. DCMs are building blocks, which are trimmed to size for use in the construction of SCSs.

Each SCS describes a template of a Structured Document. It specifies the data for a single type of clinical document or information exchange, such as a discharge summary. It is assembled using DCMs that have been constrained to eliminate data components not relevant to the particular context. For example, *Procedure* in a discharge summary uses only some of the data components required by *Procedure* in a specialist report.

B.2 The Structured Content Specification Metamodel

Our metamodel for structured content specifications (see Figure 1) is used to specify the overall structure of a structured content specification. The structure is a tree, so every item in the tree, other than the root node, has a parent node. For an SCS, the root node is a Structured Document. For a DCM, the root node is a Data Group.

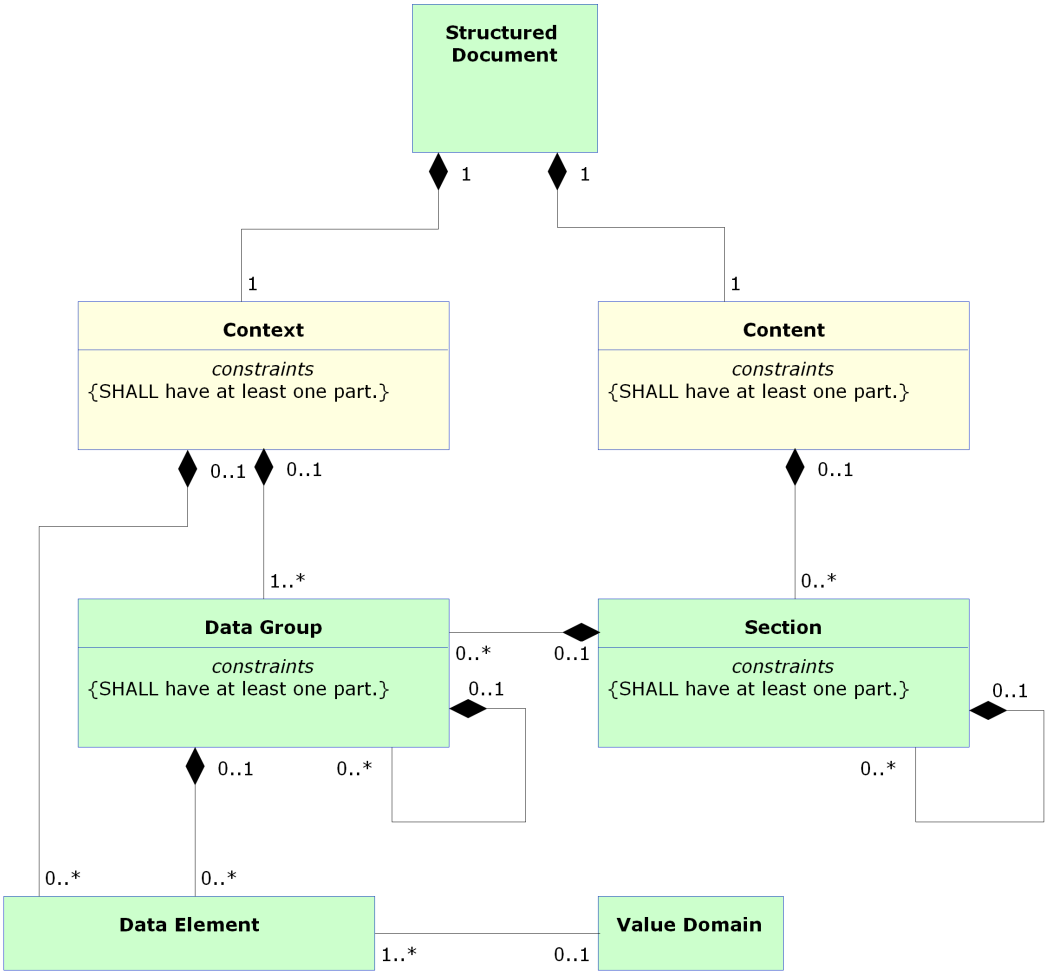

Figure 1: SCS Metamodel

There are two main items used to organise information within an SCS as follows:

Context: This contains information related to the overall context of the document.

Content: This contains information that changes between different SCSs, but is always structured as shown in Figure 1, and consists of the following data components:

- Section
- Data Group
- Data Element
- Value Domain

These data components are described in more detail below.

Structured Document

A structured document is a collection of health information about a subject of care that is relevant to the ongoing care of that person. They are composed of one or more data groups and data elements that are organised into

sections. Examples of structured documents are *Discharge Summary*, *Shared Health Summary*, and *Advance Care Directive Custodian Record*.

Context

The purpose of the context is to identify and classify the document and to provide subjects of care and involved healthcare providers with the information related to the relevant healthcare events.

Content

Content contains a collection of personal information and health information pertinent to a subject of care that is derived from the healthcare event described in the document. The detail is organised into one or more data groups, which are optionally grouped into sections.

Section

A section is composed of data groups, other sections, or both. It is an organising container that cues the reader about expected content. A section organises information in a manner suitable for the primary purpose for which it is collected and provides a way to navigate through the data components within the document, thereby enabling more efficient querying. It is recommended that the section support safe reuse for secondary purposes, e.g. clinical coding or inclusion in a summarised form in an electronic health record. A section is context-specific to the document in which it resides.

Data Group

Each data group is used to represent one concept. A data group consists of other data groups, data elements, or both. Some data groups are reused across DCMs.

Every instance of a data group **SHALL** have at least one child data component instantiated.

Participation

Participation is a special case of a data group that is based on a data group template, which is reused throughout the DCMs and SCSs. Participations are an amalgam of the Actors (see below) operating within a defined healthcare domain and the Roles they are playing within that domain.

A Participant has been defined to align with the concepts of the Agency's *Interoperability Framework [NEHT2007b]*. It equates to an *Entity* that is related to the action described in an SCS as an *Actor*. A Participant can be a human, an organisation, or an IT system.

Our *Participation Data Specification [NEHT2011v]* defines the full Participation specification.

Choice

Choice represents a selection, to be made at run-time, of a single member from a set of data groups, where the set is defined at design-time, i.e. one and only one member of the set is chosen for each instance of the choice.

For example, at design-time a healthcare provider provides a service, but it is not until run-time that a decision can be made as to whether the provider is a person or an organisation. Hence, when a healthcare provider *Participant* is instantiated, it will contain either an instance of the *Person* data group or an instance of the *Organisation* data group.

Data Element

A data element is the smallest named unit of information in the model that can be assigned a value. For example, *DateTime of Observation* and *Observation Note*. Data elements are bound to data types (see Data Types Legend). Some data elements are reused in different data groups.

While all data elements are constrained by their data type, some data elements are further constrained by value domains (see Value Domain below).

Value Domain

A value domain constrains the permissible values for a data element. The values are often a subset of values based on a generic data type.

Value domains are reusable items, therefore the same value domain can be referred to by different data elements in different contexts. Value domains are often specified with reference to a *reference set*. A reference set is a constrained list of SNOMED CT-AU concepts that are appropriate to a particular context or use. Since many of these reference sets have been developed specifically for the context in which they appear, it is recommended that an assessment of fitness for purpose be undertaken before using any of the reference sets in another context.

Value domains constrain either by specifying a lower or upper bound (or both) on the range of permissible values or by specifying a finite set of prescribed values. Such a set of prescribed values can be specified directly within the definition of the data element, or in a separate but associated specification, or else by reference to one or more vocabulary or terminology reference sets. The table below provides some examples of value domains.

Table 1: Value Domain Examples

<table>
<tr><th>Data Element</th><th>Data Type</th><th>Example of Value Domain</th></tr>
<tr><td>Sex</td><td>CodedText</td><td>Standards Australia AS 4846 (2006) – Health Care Provider Identification [SA2006a] and Standards Australia AS 5017 (2006) – Health Care Client Identification [SA2006b] derive their values from METeOR 287316, which includes values such as:

<table><tr><th>Value</th><th>Meaning</th></tr><tr><td>1</td><td>Male</td></tr><tr><td>2</td><td>Female</td></tr><tr><td>3</td><td>Intersex or Indeterminate</td></tr><tr><td>9</td><td>Not Stated/Inadequately Described</td></tr></table></td></tr>
<tr><td>Diagnosis</td><td>CodeableText</td><td>A SNOMED CT-AU reference set that references concepts such as “Bronchitis” (Concept ID: 32398004).</td></tr>
<tr><td>Therapeutic Good Identification</td><td>CodeableText</td><td>An AMT reference set that references concepts such as “Ibuprofen Blue (Herron) (ibuprofen 200 mg) tablet: film-coated, 1 tablet” (Concept ID: 54363011000036107).</td></tr>
<tr><td>Individual Pathology Test Result Name</td><td>CodeableText</td><td>A LOINC subset that references concepts such as “Cholesterol [Moles/volume] in Serum or Plasma” (ID: 14647-2).</td></tr>
</table>

B.3 Icon Legend

These legends describe all icons that are used in the Agency's DCMs and SCSs.

Metadata Types Legend

The following table explains each of the icons used to represent the metadata types within DCMs and SCSs.

Table 2: Metadata Types Legend

Icon	Metadata Types
	Structured Document
	Section
	Data Group
	Participation
	Choice

Data Types Legend

The following table explains each of the icons used to represent the data types bound to each data element in the SCSs. These data types are a profile of the **ISO 21090-2011** data types as specified in *Data Types in NEHTA Specifications: A Profile of the ISO 21090 Specification [NEHT2010c]*.

Table 3: Data Types Legend

Icon	Data type	Explanation
	Any (ISO 21090: ANY)	Use of this icon indicates that instances of the data element can be of any concrete data type. There are no limitations on the data type of the data element. The values that can be required will vary considerably depending on the context. This is an abstract data type that is the basis for all data types and **SHOULD NOT** be used in an actual implementation.
	Boolean (ISO 21090: BL)	A data type, sometimes called the logical data type, having one of the two values: *true* and *false*. Many systems represent true as *non-zero* (often 1, or -1) and false as *zero*. **Usage/Examples** • An actual value entered by a user might be “yes” or could be chosen by a mouse click on an icon such as ☑.

CodeableText

(ISO 21090: CD)

Coded text *with* exceptions; supports various ways of holding text, both free text and coded text.

Often used to support compliance for early adopters of the structured content specifications.

While it is recommended that the values in this data type come from the bound value domain, it allows other value domains to also be used (with or without translations to the bound value domain) or free text alternatives. This is useful when it is not possible to define an entire value domain for a complex concept (e.g. *Diagnosis*) and when there are competing code sets in existence. Note that within exchange specifications or message profiles this data type **MAY** be constrained to mandate compliance with the bound value domain.

Usage/Examples

- The Australian Institute of Health and Welfare (AIHW) defines a data element concept *Episode of admitted patient care-separation mode* (the status at separation of a subject of care and the place to which they are released). An early adopter could have a similar concept (coded or otherwise) that maps to this data element but does not strictly comply with the AIHW values.
- A SNOMED CT-AU coded/complex expression that embodies single or multiple concepts. The SNOMED CT-AU concepts behind these CodeableText data elements are specified in the structured content specification value domains.

CodedText

(ISO 21090: CD)

Coded text *without* exceptions; text with code mappings. Values in this data type **SHALL** come from the bound value domain, with no exceptions.

Often used for reference sets with only a small number of applicable values, e.g. Gender and Document Status.

Usage/Examples

Standards Australia AS 5017 (2006) – Health Care Client Identification [SA2006b] specifies the following value domain representing a type of address:

Value	Meaning
1	Business
2	Mailing or Postal
3	Temporary Accommodation
4	Residential (permanent)
9	Not Stated/Unknown/Inadequately Described

DateTime

(ISO 21090: TS)

A single date, optionally with a time of day.

Has the ability to indicate a level of precision, but not whether the date or time is estimated. Cannot represent a time alone.

String representations of known dates **SHALL** conform to the format within the **ISO 21090-2011** standard without the use of extensions, i.e. YYYY[MM[DD[HH[MM[SS[.U[U[U[U]]]]]]]]][+|-ZZzz].

Usage/Examples

- Partial dates: 2008, 20081001.
- To indicate 1:20 pm on May the 31st, 1999 for a time zone that is 10 hours ahead of Coordinated Universal Time (UTC): 19990531132000+1000.

 Duration (ISO 21090: PQ.TIME)	The period of time during which something continues. Consists of a value and a unit that represents the time value, e.g. hours, months. Compound durations are not allowed, e.g. 10 days 3 weeks 5 hours. **Usage/Examples** • 3 hours • 6 months • 1 year
 EncapsulatedData (ISO 21090: ED)	Data that is primarily intended for human interpretation or for further machine processing outside the scope of this specification. This includes unformatted or formatted written language, multimedia data, or structured information as defined by a different standard (e.g. XML signatures). **Usage/Examples** • JPEG images • HTML documents • [RFC1521] MIME types
 Integer (ISO 21090: INT)	The mathematical data type comprising the exact integral values. **Usage/Examples** • 1 • -50 • 125
 Link (ISO 21090: TEL)	A general link, reference or pointer to an object, data or application that exists logically or is stored electronically in a computer system. **Usage/Examples** • URL (Uniform Resource Locator) – the World Wide Web address of a site on the internet, such as the URL for the Google internet search engine – *http://www.google.com*. • An absolute or relative path within a file or directory structure – e.g. in the Windows operating system, the “link” or absolute path to a particular letter could be *C:\Documents and Settings\GuestUser\MyDocuments\letter.doc*
 Quantity (ISO 21090: PQ)	A magnitude value with a unit of measurement. This is used for recording many real world measurements and observations. As the default unit of measure is 1, even counts of items can be recorded with *Quantity*. **Usage/Examples** • 100 centimetres • 25.5 grams • 3 per month

 QuantityRange (ISO 21090: IVL)	A range of *Quantity* values. It may be identified using a combination of an optional minimum *Quantity* and an optional maximum *Quantity* (i.e. lower and upper bounds). This is typically used for defining the valid range of values for a particular measurement or observation. Unbounded quantity ranges can be identified by not including a minimum or a maximum *Quantity* value. **Usage/Examples** • -20 to 100 Celsius • 30-50 mg • >10 kg • 2-3 hours
 QuantityRatio (ISO 21090: RTO)	A relative magnitude of two *Quantity* values. Usually recorded as numerator and denominator. **Usage/Examples** • 25 mg / 500 ml • 200 mmol per litre
 Real (ISO 21090: REAL)	A computational approximation to the standard mathematical concept of real numbers. These are often called floating-point numbers. **Usage/Examples** • 1.075 • -325.1 • 3.14157
 Text (ISO 21090: ST)	A character string (with optional language) containing any combination of alpha, numeric, or symbols from the Unicode character set. Also referred to as *free text*. **Usage/Examples** “The patient is a 37 year old man who was referred for cardiac evaluation after complaining of occasional palpitations, racing heart beats and occasional dizziness.”
 TimeInterval (ISO 21090:IVL)	An interval in time. It is identified using a combination of an optional start *DateTime*, an optional end *DateTime*, and an optional *Duration*. **Usage/Examples** • 20080101+1000 - 20081231+1000 • 200801010130+1000 - 200801011800+1000 • 200801010130+1000, duration=16.5 hours

	UniqueIdentifier (ISO 21090: II)	A unique value used to identify a physical or virtual object or concept. In using this data type, the attributes of the UniqueIdentifier data type **SHOULD** be populated from the identifiers as defined in *AS 4846 (2006) – Health Care Provider Identification [SA2006a]* and *AS 5017 (2006) – Health Care Client Identification [SA2006b]* as follows: • *root*: a globally unique object identifier that identifies the combination of geographic area, issuer and type. If no such globally unique object identifier exists, it **SHALL** be created. • *extension*: a unique identifier within the scope of the root that is directly equivalent to the identifier designation element. • *identifierName*: a human readable name for the namespace represented by the root that is populated with the issuer or identifier type values, or a concatenation of both, as appropriate. The content of this attribute is not intended for machine processing and **SHOULD NOT** be used for that purpose. • *identifierScope*: the geographic span or coverage that applies to or constrains the identifier. It is directly equivalent to the geographic area element. The content of this attribute is not intended for machine processing and **SHOULD NOT** be used as such. Also, the following constraints apply on the UniqueIdentifier data type: 1) The *root* attribute **SHALL** be used. 2) For an Entity Identifier, the *root* attribute **SHALL** be an OID that consists of a node in a hierarchically assigned namespace, formally defined using the ITU-T's ASN.1 standard. 3) For an Entity Identifier, the *root* attribute **SHALL NOT** be a UUID. 4) The *extension* attribute **SHALL** be used. **Usage/Examples** Australian health identifiers (e.g. IHI, HPI-I and HPI-O) and patient hospital medical record numbers are examples of identifiers that may be carried by data elements of this data type.

Keywords Legend

Where used in this document and in DCMs and SCSs, the keywords **SHALL, SHOULD, MAY, SHALL NOT** and **SHOULD NOT** are to be interpreted as described in *Key Words for Use in RFCs to Indicate Requirement Levels [RFC2119]*. Our specifications use the terms **SHALL** in place of “MUST” and **SHALL NOT** in place of “MUST NOT”. The key word definitions in RFC 2119, adjusted to remove the key words not used in the Agency specifications, are presented in the following table.

Table 4: Keywords Legend

Keyword	Definition
SHALL	This word means that the statement is an absolute requirement of the specification.
SHOULD	This word means that there may exist valid reasons in particular circumstances to ignore a particular data component, but the full implications must be understood and carefully weighed before choosing a different course.

MAY	This word means that a data component is truly optional. One implementer may choose to include the data component because a particular implementation requires it, or because the implementer determines that it enhances the implementation, while another implementer may omit the same data component. An implementation that does not include a particular option shall be prepared to interoperate with another implementation that does include the option, perhaps with reduced functionality. In the same vein, an implementation that does include a particular option shall be prepared to interoperate with another implementation that does not include the option (except of course, for the feature the option provides).
SHALL NOT	This phrase means that the statement is an absolute prohibition of the specification.
SHOULD NOT	This phrase means that there may exist valid reasons in particular circumstances when the particular behaviour is acceptable or even useful, but the full implications should be understood and the case carefully weighed before implementing any behaviour described with this label.

Obligation Legend

In DCMs and SCSs obligations on a data component specify whether or not it **SHALL** be populated in the logical record architecture of a message. We intend that all data components that are not **PROHIBITED** will be implemented.

Obligations in statements about values specify whether or not certain values are permitted.

Implementation guides specify the rules and formats for implementing and populating data components in specific messaging formats.

The following table defines the obligations.

Table 5: Obligations Legend

Keyword	Interpretation
ESSENTIAL	Indicates that the data component is considered a mandatory item of information and **SHALL** be populated. **Usage/Examples:** The Participant data component for a Subject of Care **SHALL** include an Entity Identifier data component in order to hold the IHI.
OPTIONAL	Indicates that the data component is not considered a mandatory item of information and **MAY** be populated. **Usage/Examples:** Such data components will be implemented, only inclusion and population are optional. This is only needed when a DCM incorrectly asserts that a data component is **ESSENTIAL**. It will be used with a note stating that the DCM needs revision.
PROHIBITED	On a data component this indicates that the data component is considered a forbidden item of information and **SHALL NOT** be included. In a statement about values this indicates that the use of the specified values is considered forbidden and they **SHALL NOT** be used. **Usage/Examples:** Within a Participation data group depicting a Subject of Care, the Participation Healthcare Role **SHALL NOT** be populated.

CONDITIONAL	Indicates that a data component is considered **ESSENTIAL** only on satisfaction of a given condition. Individual data components specify the obligation of the data component when the condition is not met. When a condition is met, the data component is considered to be **ESSENTIAL** and **SHALL** be populated. When a condition is not met, the data component may be considered **PROHIBITED**, or the data component may be considered **OPTIONAL**. **Usage/Examples:** Within a Pathology Result Report, the *Specimen Detail* `data group` is **ESSENTIAL** if the requested test is to be performed on a specimen; otherwise it **SHALL NOT** be included.

Obligations follow the usual scope rules: where **ESSENTIAL** child data components are contained within **OPTIONAL** parent data components, the child data components **SHALL NOT** be included when the parent is not included.

B.4 Exceptional Values

Occasionally a data element will have an exceptional value: an abnormal value (i.e. the value cannot be described using the expected set of values) or an absent value (i.e. no value is provided). Some abnormal values are only relevant to data elements of certain data types (e.g. positive infinity is relevant to numbers but not Booleans).

Unless otherwise specified, all data elements are permitted to have exceptional values. Constraints on the use of exceptional values are contained in the Exceptional Values row of the Usage section, except for instances of Participation, when they are in the Conditions of Use row. The most common statements constraining exceptional values are:

- Absent values are **PROHIBITED**.
- Abnormal values are **PROHIBITED**.

The commonly used implementation specifications ISO 21090 and HL7 CDA R2 use *nullFlavor* to manage abnormal and absent values.

The following table provides a classification of nullFlavor values as abnormal or absent.

Table 6: Classification of ISO 21090 nullFlavor values as absent or abnormal

Level	Code	Term	Abnormal	Absent
1	NI	No information		Absent
2	INV	Invalid	Abnormal	
3	OTH	Other	Abnormal	
4	PINF	Positive infinity	Abnormal	
4	NINF	Negative infinity	Abnormal	
3	UNC	Unencoded	Abnormal	
3	DER	Derived	Abnormal	
2	UNK	Unknown		Absent
3	ASKU	Asked but unknown		Absent
4	NAV	Temporarily unavailable		Absent
3	NASK	Not asked		Absent
3	QS	Sufficient quantity	Abnormal	

Level	Code	Term	Abnormal	Absent
3	TRC	Trace	Abnormal	
2	MSK	Masked		Absent
2	NA	Not applicable		Absent

B.5 Information Model Specification Parts Legends

This section illustrates the format and parts used to define each section, data group and data element within the Agency's DCMs and SCSs, and identifies when each part is applicable.

Chapter Name

Each section, data group, data element, value domain or choice has its own eponymous chapter. The chapter name is used in all data hierarchies.

Identification Section Legend

The following table illustrates the layout of the Identification section and describes the various parts of the section.

Table 7: Identification Section Legend

Label	A suggested display name for the data component.
Metadata Type	The type of the data component, e.g. section, data group or data element.
Identifier	An Agency-assigned internal identifier of the data component. Note that if one data component is used twice (e.g. *Therapeutic Good Identification* is used in both *Medication Instruction* and *Medication Action*), both uses of the data component will have the same identifier. A data component identifier identifies a data component, not a **use** of a data component.
OID	An object identifier equivalent to the data component identifier.
External Identifier	An identifier of the concept represented by the data component that is assigned by an organisation other than the Agency.

Definition Section Legend

The following table illustrates the layout of the Definition section and describes the various parts of the section.

Table 8: Definition Section Legend

Definition	The meaning, description or explanation of the data component. For data groups used in a particular context, the definition **MAY** be a refinement of the generic data group definition.
Definition Source	The authoritative source for the Definition statement.
Synonymous Names	A list of any names the data component may also be known as.

	Implementers may prefer to use synonymous names to refer to the data component in specific contexts.
Scope	Situations in which the data component may be used, including the Scope circumstances where specified data are required or recommended. For example, Medication Instruction (data group) has a scope that includes all prescribable therapeutic goods, both medicines and non-medicines. This item is not relevant to data elements or value domains.
Scope Source	The authoritative source for the Scope statement.
Context	The environment in which the data component is meaningful, i.e. the circumstance, purpose and perspective under which this data component is defined or used. For example, Street Name has a context of Address. This item is applicable only to data elements.
Assumptions	Suppositions and notions used in defining the data component.
Assumptions Source	The authoritative source for the Assumptions statement.
Notes	Informative text that further describes the data component, or assists in the understanding of how the data component can be used.
Data Type	The data type (or data types) of the data element, e.g. DateTime or Text. The valid data types are specified in the Data Types Legend. This item is applicable only to data elements.
Value Domain	The name of the Value Domain used to define the range of values of the data element, or a statement describing what values to use in the absence of a defined value domain for the related data element. The statement is: In the absence of national standard code sets, the code sets used **SHALL** be registered code sets, i.e. registered through the HL7 code set registration procedure with an appropriate object identifier (OID), and **SHALL** be publicly available. When national standard code sets become available, they **SHALL** be used and the non-standard code sets **SHALL** be deprecated. This item is applicable only to data elements with data type CodedText or CodeableText.

Data Hierarchy

The top-level data components (a Structured Document in an SCS or Data Groups in a DCM) contain a data hierarchy. Each row contains information about a single data component. The entries are nested to represent inclusion of one data component in another. Each entry contains at least three occupied cells. The left-most cell contains an icon to indicate the entry's data type. The next cell to the right contains the label of the data component (if the label is different from the name, the name is displayed in brackets after the label). The next cell to the right contains the multiplicity range for the data component.

If a row is shaded grey, this indicates that the data component **SHOULD NOT** be used. This will be because analysis of requirements either did not find reasons to use it or found reasons to not use it.

If the text in a row is in a ~~strike through~~ font and the multiplicity is 0..0, this indicates that the data component **SHALL NOT** be used. This will be because analysis of requirements found reasons to prohibit the use of it.

In some documents the right-hand side of the data hierarchy contains one or more columns under the heading “Core Requirement”. Each column contains information for one document exchange scenario. A cell that is empty indicates that the data component on that row is **OPTIONAL** to implement. That is, software that creates documents made in conformance with this specification **MAY** exclude the data component, and software that reads documents made in conformance with this specification **MAY** ignore the data component. All other data components **SHALL** be implemented.

Sample SCS Data Hierarchy

Note

Items below whose text is lighter (mid-blue and mid-grey) are technical identifiers whose purpose is to facilitate interoperability, sharing of data and secondary use. Typically, such identifiers will be generated internally by systems and not displayed to users since they rarely have clinical significance.

Items below with a grey background are data components that are included in the relevant detailed clinical model specification, but whose use is discouraged in this particular scenario.

	SPECIALIST LETTER			
CONTEXT				
		SUBJECT OF CARE		1..1
		DOCUMENT AUTHOR		1..1
		ENCOUNTER		1..1
			DateTime Subject of Care Seen (DateTime Health Event Started)	1..1
			DateTime Health Event Ended	0..0
			HEALTHCARE FACILITY	0..0
		Document Instance Identifier		0..1
		RELATED INFORMATION		0..0
		Document Type		1..1
CONTENT				
		RESPONSE DETAILS		1..1
			Diagnosis (PROBLEM/DIAGNOSIS)	0..*
				Diagnosis Name (Problem/Diagnosis Identification) 1..1
				Clinical Description 0..0
	and more			

Value Domain Section Legend

The following table illustrates the layout of the Value Domain section and describes the various parts of the section.

Table 9: Value Domain Section Legend

Source	The name of the terminology or vocabulary from which the value domain's permissible values are sourced, e.g. SNOMED CT-AU, LOINC.
Version Number	Version number of the value domain source.
Permissible Values	A specification of the permissible values in the value domain. This may be a list of codes. (Each code is typically presented as a triple with code values, text equivalent, and description) for example: 1, Registered No result yet available. This may be a conformance statement (e.g. "The permissible values are the members of the following seven AMT reference sets: ...").

Usage Section Legend

The following table illustrates the layout of the Usage section and describes the various parts of the section.

Table 10: Usage Section Legend

Examples	Sample values for the data element, with or without notes about sample values. Where a data element has an associated value domain, examples representative of that domain are used where possible. Where the value domain is yet to be determined, indicative examples are provided. Implementation guides may contain specific examples of how data elements may be populated and how they relate to each other. This item is applicable only to data elements.
Conditions of Use	Prerequisites, provisos or restrictions for use of the data component.
Conditions of Use Source	The authoritative source for the Conditions of Use statement.
Misuse	Incorrect, inappropriate or wrong uses of the data component.
Default Value	A common denomination, or at least a usable denomination, from the Value Domain where available or applicable, typically assigned at the creation of an instance of the data component.
Exceptional Values	A statement of limitations on the use of exceptional values, see Exceptional Values. Unless otherwise specified, all data elements are permitted to have exceptional values. The most common statements constraining exceptional values are: • Abnormal values are **PROHIBITED**. • Absent values are **PROHIBITED**. This item is applicable only to data elements.

Relationships Section Legend

The Relationships section specifies the cardinality between parent and child data components.

The following table illustrates the layout of the Parent relationships table. Note that the occurrences in the relationships described by this table are from the parent to the child data component, i.e. from the data component listed in the table to the data component described by the section.

Table 11: Parent Legend

Data Type	**Name**	**Occurrences** (child within parent)
The icon illustrating the metadata type or data type.	Parent Data Component Name	The minimum and maximum number of instances of the data component described on this page that **SHALL** occur.

The following table illustrates the layout of the Children relationships table.

Table 12: Children Legend

Data Type	**Name**	**Occurrences**
The icon illustrating the metadata type or data type.	Child Data Component Name	The minimum and maximum number of instances of the data component described on this page that **SHALL** occur.

Appendix C. Change History

A summary of changes from one document version to the next. Changes to the change history were excluded.

C.1 Changes Since Version 3.1 - 18 December 2015

Generic changes

Various changes to rebrand the document from the National E-Health Transition Authority (NEHTA) to the Australian Digital Health Agency (the Agency):

- Definition Source, Scope Source, Context Source, Condition of Use Source and Value Domain Source updated from “NEHTA” to “Australian Digital Health Agency”;
- references to “National E-Health Transition Authority” and “NEHTA” have been replaced with references to the “Australian Digital Health Agency” and “the Agency” respectively; and
- all NEHTA URLs have been updated to redirect to the Agency website.

Preliminary Pages

Document Information section has been changed to include the latest release details.

Chapter 1 Introduction

Various editorial changes to presentation and wording, including replacing the expression “PCEHR” with “My Health Record”.

Chapter 2 Pathology Test Result Detailed Clinical Model

The version of the DCM used has changed from 3.1 to 3.2.

The UML Class Diagrams have been split into more diagrams.

Guidance on data elements with exceptional values has been added. This affects all uses of the following data elements:

- *PATHOLOGY TEST RESULT > Pathology Test Result Name*;
- *PATHOLOGY TEST RESULT > Overall Pathology Test Result Status*;
- *PATHOLOGY TEST RESULT > PATHOLOGY TEST RESULT GROUP > INDIVIDUAL PATHOLOGY TEST RESULT > INDIVIDUAL PATHOLOGY TEST RESULT VALUE > REFERENCE RANGE DETAILS > REFERENCE RANGE > Reference Range Meaning*;
- *PATHOLOGY TEST RESULT > PATHOLOGY TEST RESULT GROUP > INDIVIDUAL PATHOLOGY TEST RESULT > Individual Pathology Test Result Status*;
- *PATHOLOGY TEST RESULT > Pathology Test Result Instance Identifier*;

- *PATHOLOGY TEST RESULT > RELATED INFORMATION > Link Nature*; and
- *PATHOLOGY TEST RESULT > Detailed Clinical Model Identifier*.

In 2.7 Pathology Test Result Name Values, the external identifier was added for SNOMED CT-AU. There were also various editorial changes to the notes. The notes also now point to an Agency website where codes recommended for pathology terminology can be found.

In 2.10 SPECIMEN, three synonymous names were added.

In 2.12 Pathology Test Result Status Values, the term “PCEHR” was replaced with “My Health Record”.

In 2.17 Individual Pathology Test Result Name, there was an editorial change to one of the examples.

In 2.20 Individual Pathology Test Result Value, the datatype of “any”was added. Consequently, the section on result value values was removed. A note was added and standard text referencing the appendix was added to the examples.

In 2.22 Normal Status, there was an editorial change to the definition and notes.

In 2.28 Individual Pathology Test Result Status, there were editorial changes to the notes.

In 2.29 SPECIMEN, three synonymous names were added.

In 2.37 Test Requested Name, there was an editorial change to the definition.

In 2.43 INFORMATION PROVIDER, this follows current design for specifying Information Provider.

In 2.44 SUBJECT, there were editorial changes to the scope and conditions of use.

In 2.45 Observation DateTime, there was an editorial change to the example text referencing the appendix.

In 2.49 Link Nature Values, there were editorial changes to the permissible values.

In 2.50 Link Role, there was an editorial change to the notes.

In 2.51 Link Role Values, the permissible values have been updated and editorial changes have been made in the condition of use.

Chapter 3 Specimen Data Group

The version of the DCM used has changed from 2.1 to 2.2.

Guidance on data elements with exceptional values has been added. This affects all uses of the following data elements:

- *SPECIMEN > ANATOMICAL LOCATION > SPECIFIC LOCATION > Side*;
- *SPECIMEN > ANATOMICAL LOCATION > SPECIFIC LOCATION > Numerical Identifier*;
- *SPECIMEN > ANATOMICAL LOCATION > SPECIFIC LOCATION > Anatomical Plane*;
- *SPECIMEN > ANATOMICAL LOCATION > RELATIVE LOCATION > Anatomical Location Aspect*; and
- *SPECIMEN > NEEDLE BIOPSY CORE DETAILS > Biopsy Core Needle Gauge*.

In 3.10 Side, there was an editorial change to the definition.

In 3.12 Numerical Identifier, there were clarifying changes to the definition.

In 3.14 RELATIVE LOCATION, there were editorial changes to the notes.

In 3.16 Anatomical Location Aspect, the examples were simplified.

In 3.19 Visual Markings/Orientation, there was an editorial change to the definition.

In 3.46 DEVICE, there were editorial changes to the scope and conditions of use.

In 3.48 Collection DateTime, there was an editorial change to the example text referencing the appendix.

In 3.50 DateTime Received, there was an editorial change to the example text referencing the appendix.

In 3.51 DateTime Processed, there was an editorial change to the example text referencing the appendix.

Appendix A. Known Issues

Four known issues were added.

Appendix B. Specification Guide for Use

Various editorial changes.

Renamed the section B.4 “Abnormal and Absent Values” to “Exceptional Values” and updated explanatory text throughout accordingly.

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