Integrating the Healthcare Enterprise

IHE Pathology and Laboratory Medicine (PaLM) Technical Framework

Volume 3 (PaLM TF-3) Content Modules

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CONTENTS

1 Introduction

This document, Volume 3 of the IHE Pathology and Laboratory Medicine (PaLM) Technical Framework, defines content modules used in the IHE Pathology and Laboratory Medicine profiles.

1.1 Introduction to IHE

Integrating the Healthcare Enterprise (IHE) is an international initiative to promote the use of standards to achieve interoperability among health information technology (HIT) systems and effective use of electronic health records (EHRs). IHE provides a forum for care providers, HIT experts and other stakeholders in several clinical and operational domains to reach consensus on standards-based solutions to critical interoperability issues.

The primary output of IHE is system implementation guides, called IHE profiles. IHE publishes each profile through a well-defined process of public review and trial implementation and gathers profiles that have reached final text status into an IHE Technical Framework, of which this volume is a part.

For more general information regarding IHE, refer to www.ihe.net. It is strongly recommended that, prior to reading this volume, the reader familiarizes themselves with the concepts defined in the *IHE Technical Frameworks General Introduction,* which is published on this page.

1.2 Intended Audience

The intended audience of IHE Technical Frameworks Volume 3 is:

- IT departments of healthcare institutions
- Technical staff of vendors participating in the IHE initiative
- Experts involved in standards development

1.3 Overview of Technical Framework Volume 3

Volume 3 is comprised of several distinct sections:

- Section 1 provides background and reference material.
- Section 2 presents the conventions used in this volume to define the content modules.
- Section 3 provides an overview of Content Modules and the terminology used.
- Section 4 is reserved for domain unique Content Module specifications.

- Section 5 lists the namespaces and identifiers defined or referenced and the vocabularies defined or referenced herein.
- Section 6 defines the PaLM domain's HL7®[1] V3 CDA®[2] Content Modules in detail.
- Section 7 defines the PaLM domain's DICOM®[3] content modules in detail.
- Section 8 defines other types of content modules.

The appendices in Volume 3 provide clarification of technical details of the IHE data model and transactions. A glossary of terms and acronyms used in the IHE Technical Framework, including those from relevant standards, is provided in the IHE Technical Frameworks General Introduction published on this page. Due to the length of the document, some domains may divide Volume 3 into smaller volumes labeled 3a, 3b, etc. In this case, the Volume 3 appendices are gathered in Volume 3x. Code and message samples may also be stored on the IHE ftp server. In this case, explicit links to the ftp server will be provided in the transaction text.

1.4 Comment Process

IHE International welcomes comments on this document and the IHE initiative. They can be submitted by sending an email to the co-chairs and secretary of the Pathology and Laboratory Medicine domain committees at palm@ihe.net.

1.5 Copyright Licenses

[1] HL7 is the registered trademark of Health Level Seven International.

[2] CDA is the registered trademark of Health Level Seven International.

[3] DICOM is the registered trademark of the National Electrical Manufacturers Association for its standards publications relating to digital communications of medical information.

1.5.1 Copyright of Base Standards

IHE technical documents refer to and make use of a number of standards developed and published by several standards development organizations. All rights for their respective base standards are reserved by these organizations. This agreement does not supersede any copyright provisions applicable to such base standards.

Health Level Seven, Inc. has granted permission to IHE to reproduce tables from the HL7 standard. The HL7 tables in this document are copyrighted by Health Level Seven, Inc. All rights reserved. Material drawn from these documents is credited where used.

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1.7 Disclaimer Regarding Patent Rights

Attention is called to the possibility that implementation of the specifications in this document may require use of subject matter covered by patent rights. By publication of this document, no position is taken with respect to the existence or validity of any patent rights in connection therewith. IHE International is not responsible for identifying Necessary Patent Claims for which a license may be required, for conducting inquiries into the legal validity or scope of Patents Claims or determining whether any licensing terms or conditions provided in connection with submission of a Letter of Assurance, if any, or in any licensing agreements are reasonable or non-discriminatory. Users of the specifications in this document are expressly advised that determination of the validity of any patent rights, and the risk of infringement of such rights, is entirely their own responsibility. Further information about the IHE International patent disclosure process including links to forms for making disclosures is available at http://www.ihe.net/Patent_Disclosure_Process. Please address questions about the patent disclosure process to the secretary of the IHE International Board: secretary@ihe.net.

1.8 History of Document Changes

This section provides a brief summary of changes and additions to this document.

Date	Document Revision	Change Summary
July 2016	7.0	Adoption of IHE_TF_Template_Vol3_Rev1.0_2014-07-01 No other change in the content.
June 2017	7.1	Republished without change

2 Conventions

This document has adopted the following conventions for representing the framework concepts and specifying how the standards upon which the IHE Technical Framework is based shall be applied.

2.1 Content Module Modeling and Profiling Conventions

In order to maintain consistent documentation, modeling methods for IHE content modules and profiling conventions for frequently used standards are maintained as an appendix in the *IHE Technical Frameworks General Introduction* published on this page. Methods described include the standards conventions DICOM, HL7 v2.x, HL7 Clinical Document Architecture (CDA) Documents, etc. These conventions are critical to understanding this volume and should be reviewed prior to reading this text.

2.2 Additional Standards Profiling Conventions

This section defines profiling conventions for standards which are not described in the *IHE Technical Frameworks General Introduction*.

Not Applicable.

3 Content Modules Overview and Terminology

In the future, an appendix to the *IHE Technical Frameworks General Introduction* will provide an overview of Content Modules. In the interim, information may be available on the IHE wiki at http://wiki.ihe.net/index.php?title=Profiles.

The Pathology and Laboratory Medicine content modules are listed in the table below:

Table 3-1: Pathology and Laboratory Medicine Content Modules

Content Module Acronym	Type of Content Module	Semantic	Status
XD-LAB	CDA R2 medical document	Clinical laboratory structured report	Final Text
APSR	CDA R2 medical document	Anatomic pathology structured report	Trial implementation

4 IHE Pathology and Laboratory Medicine Bindings

4.1 Medical Document Binding to XDS, XDM and XDR

The bindings of the content modules of the PaLM domain leverage the bindings specified by the Patient Care Coordination domain, in PCC TF-2:4, with the addition of the constraints specified below.

4.1.1 XDSDocumentEntry Metadata

4.1.1.1 XDSDocumentEntry.eventCodeList

The XD-LAB Content Module further constrains the XDSDocumentEntry.eventCodeList as specified below:

XDSDocumentEntry			
Attribute	**Usage**	**Source Type**	**Source/ Value**
eventCodeList	R2[1]	SAT	ClinicalDocument / component / structuredBody / component / section / entry / act / entryRelationship / organizer (templateId="1.3.6.1.4.1.19376.1.3.1.1")/ component / observation(templateId="1.3.6.1.4.1.19376.1.3.1.1.1")/value AND ClinicalDocument / component / structuredBody / component / section / entry / act / subject / code If the document has Reportable Condition, then this code SHALL be among those listed in the eventCodeList. Additionally, if the document contains information about a Non-Human Subject, then the code that indicates what this subject is SHALL be among those listed in the eventCodeList. Thus, this attribute has been enhanced from the XDS Profile from O to R2.

4.1.1.2 XDSDocumentEntry.formatCode

For the XD-LAB content module, The XDSDocumentEntry.formatCode SHALL be **urn:ihe:lab:xd-lab:2008**

The associated codingScheme SHALL be **1.3.6.1.4.1.19376.1.2.3**

4.1.1.3 XDSDocumentEntry.parentDocumentRelationship

For the XD-LAB content module XDSDocumentEntry.parentDocumentRelationship is constrained to the "RPLC" value. When there is a parent document the current document is a new version of the parent document, replacing it.

5 IHE Namespaces and Vocabularies

This section lists the namespaces and identifiers defined or referenced by the IHE PaLM Technical Framework and the vocabularies defined or referenced herein.

Eventually, *IHE Technical Frameworks General Introduction Appendix G* when available on this page, will contain the namespace and vocabulary listings for all domains and will act as a central repository for information. In the interim, this information is listed in this section.

The following vocabularies are referenced in this document. An extensive list of registered vocabularies can be found at http://hl7.amg-hq.net/oid/frames.cfm.

codeSystem	codeSystemName	Description
2.16.840.1.113883.6.1	LOINC	Logical Observation Identifier Names and Codes
2.16.840.1.113883.6.96	SNOMED-CT	SNOMED Controlled Terminology
1.3.6.1.4.1.19376.1.5.3.2	IHEActCode	Small interim vocabulary defined by the Patient Care Coordination domain of IHE. See PCC TF-2:5.1.2
1.3.6.1.4.1.19376.1.3.2		Namespace OID used for extensions to CDA Release 2.0 brought by IHE PaLM
1.3.6.1.4.1.19376.1.3.4		Root identifier used by example instances of documents in the PaLM domain

5.1.1 IHE Format Codes

The table below lists the format codes, template identifiers and media types used by the IHE profiles specified in the PaLM Technical Framework.
Note that the code system for these codes is **1.3.6.1.4.1.19376.1.2.3** as assigned by the ITI Domain for codes used for the purposes of cross-enterprise document sharing (XDS). For more information see XDS Coding System (1.3.6.1.4.1.19376.1.2.3).

Profile	Format Code	Media Type	Template ID
PaLM Profiles			
CDA Laboratory Report	urn:ihe:lab:xd-lab:2008	text/xml	1.3.6.1.4.1.19376.1.3.3 (Laboratory Report)

6 PaLM HL7 V3 CDA Content Modules

6.1 Conventions

HL7 V3 CDA Conventions are defined in the IHE Technical Frameworks General Introduction Appendix E published on this page.

6.2 Folder Modules

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6.3 Content Modules

This section defines each IHE Pathology and Laboratory Medicine Content Module in detail, specifying the standards used and the information defined.

6.3.1 CDA Document Content Modules

All persons (including the patient) and organizations mentioned in the CDA Document Content Modules SHALL include the elements `name`, `addr` and `telecom`.

6.3.1.1 Clinical Laboratory Report Content Module

This content module describes a laboratory report as an electronic document, both human readable and machine-processable.

Such an electronic document contains the set of releasable results produced by a clinical laboratory or by a public health laboratory in fulfillment of an order or an order group**.** The human rendering of the laboratory report defined in this Integration Profile is compatible with laboratory regulations in numerous countries, including CLIA in the USA, GBEA in France. The content of the report is also encoded in machine-processable entry elements that can be imported and interpreted by the Content Consumer system.

6.3.1.1.1 Standards

HL7 CDA Release 2

6.3.1.1.2 Conformance

CDA Release 2.0 documents that conform to the requirements of this content module shall indicate their conformance by the inclusion of the templateId 1.3.6.1.4.1.19376.1.3.3 in the header of the document, as shown below:

```
<ClinicalDocument xmlns="urn:hl7-org:v3" xmlns:lab="urn:oid:1.3.6.1.4.1.19376.1.3.2"
    xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
    <realmCode code="FR"/>
    <typeId root="2.16.840.1.113883.1.3" extension="POCD_HD000040"/>
    <templateId root="1.3.6.1.4.1.19376.1.3.3"/>
    …
```


6.3.1.1.3 Specification

The Clinical Laboratory Report content module contains header content modules, section content modules and entry content modules listed in Table 6.3.1.1-1

300 **Table 6.3.1.1.3-1: Defined or Referenced Content Modules for Clinical Laboratory Report**

Template Id	CDA Element	Usage	Description
1.3.6.1.4.1.19376.1.3.3	ClinicalDocument	R	Template specifying the CDA R2 laboratory report.
1.3.6.1.4.1.19376.1.3.3.1.2	ClinicalDocument/ recordTarget	R2	Non-Human Subject template in the CDA header
1.3.6.1.4.1.19376.1.3.3.1.3	ClinicalDocument/ recordTarget	R2	Human (Patient) paired with Non-Human Subject template in the CDA header
1.3.6.1.4.1.19376.1.3.3.1.4	ClinicalDocument/ intendedRecipient	O	Intended Recipient template in the CDA header
1.3.6.1.4.1.19376.1.3.3.1.5	ClinicalDocument/ authenticator, entry/act/.../participant ('AUTHEN')	O	Laboratory Results Validator template in the CDA header and in an entry of the CDA body
1.3.6.1.4.1.19376.1.3.3.1.6	ClinicalDocument/ Participant ('REF')	O	Ordering Provider template in the CDA header
1.3.6.1.4.1.19376.1.3.3.1.7	ClinicalDocument/ documentationOf/ serviceEvent/performer, entry/act/.../performer	O	Laboratory Performer template in the CDA header and in an entry of the CDA body
1.3.6.1.4.1.19376.1.3.3.2.1	ClinicalDocument/ component/structuredBody/ component/ section	R	Laboratory Specialty Section template in the CDA body
1.3.6.1.4.1.19376.1.3.3.2.2	ClinicalDocument/ component/structuredBody/ component/ section/component/section	O	Laboratory Report Item Section template in the CDA body
1.3.6.1.4.1.19376.1.3.1	ClinicalDocument/ component/structuredBody/ component/ section/ …/entry	R	Laboratory Data Processing Entry template in the CDA body
1.3.6.1.4.1.19376.1.3.1.2	ClinicalDocument/ component/structuredBody/ component/ section/ …/ entry /act/…/ entryRelationship/procedure	R2	Specimen Collection template in an entry of the CDA body (6.3.4.5)
1.3.6.1.4.1.19376.1.3.1.3	ClinicalDocument/ component/structuredBody/ component/ section/ …/ entry /act/…/ entryRelationship/procedure/ entryRelationship/act	R2	Specimen Received template in an entry of the CDA body

Template Id	CDA Element	Usage	Description
1.3.6.1.4.1.19376.1.3.1.1	ClinicalDocument/ component/structuredBody/ component/ section/ …/ entry/act/…/entryRelationship /organizer	R2	Notification Organizer template in an entry of the CDA body
1.3.6.1.4.1.19376.1.3.1.1.1	ClinicalDocument/ component/structuredBody/ component/ section/ …/ entry/act/…/entryRelationship /organizer/component/ observation	R2	Notifiable Condition template in an entry of the CDA body
1.3.6.1.4.1.19376.1.3.1.1.2	ClinicalDocument/ component/structuredBody/ component/ section/ …/ entry/act/…/ entryRelationship/organizer/ component/observation	R2	Case Identifier template in an entry of the CDA body
1.3.6.1.4.1.19376.1.3.1.1.3	ClinicalDocument/ component/structuredBody/ component/ section/ …/ entry/act/…/ entryRelationship/organizer/ component/observation	R2	Outbreak Identifier template in an entry of the CDA body
1.3.6.1.4.1.19376.1.3.1.5	ClinicalDocument/ component/structuredBody/ component/ section/ …/ entry/act/…/ entryRelationship/organizer	R2	Laboratory Isolate Organizer template in an entry of the CDA body
1.3.6.1.4.1.19376.1.3.1.4	ClinicalDocument/ component/structuredBody/ component/ section/ …/ entry/act/…/ entryRelationship/organizer	R2	Laboratory Battery Organizer template in an entry of the CDA body
1.3.6.1.4.1.19376.1.3.1.6	ClinicalDocument/ component/structuredBody/ component/ section/ …/ entry/act/…/ entryRelationship/observation	R	Laboratory Observation template in an entry of the CDA body
1.3.6.1.4.1.19376.1.5.3.1.4.2	ClinicalDocument/ component/structuredBody/ component/ section/ …/ entry /act/…/ entryRelationship/act	O	Annotation Comment in an entry of the CDA body (6.3.4.15). This template is defined in PCC TF-2: 6.4.4.6

6.3.1.1.3.1 Contraints on the body of the laboratory medicine report

The report SHALL have a `structuredBody`. This body is organized as a tree of up to two levels of sections, delivering the human-readable content of the report:

Top level sections represent laboratory specialties. A top level section SHALL contain:

- either one `text` block carrying all the human-readable results produced for this specialty along with a single Laboratory Data Processing Entry ;
- or a set of Laboratory Report Item Sections.

In the first case the specialty section happens to also be a leaf section. In the latter case, each (second level) leaf section contained in the (top level) specialty section represents a **Report Item**: i.e., a battery, a specimen study, or an individual test.

Every leaf section SHALL contain a single Laboratory Data Processing Entry containing the observations of that section in a machine-readable format.

6.3.1.2 Anatomic Pathology Structured Report Content Module

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6.3.2 CDA Header Content Modules

6.3.2.1 realmCode

This element SHALL be present and is valued from the RealmOfUse [2.16.840.1.113883.1.11.11050] subset, within the VocabularyDomainQualifier value set.

In the international context the realm code SHALL be `<realmCode code="UV"/>` (universal).

Whenever a national extension has been defined and is used, the realm code SHALL identify this national extension. Example for a French extension: `<realmCode code="FR"/>`

6.3.2.2 typeId

This element is a technology-neutral explicit reference to the standard CDA R2. It SHALL be present and valued as follows:

ClinicalDocument/typeId@root = "2.16.840.1.113883.1.3" (which is the OID for HL7 Registered models);

ClinicalDocument.typeId@extension = "POCD_HD000040" (which is the unique identifier for the CDA, Release Two Hierarchical Description).

```
<typeId root="2.16.840.1.113883.1.3" extension="POCD_HD000040"/>
```

6.3.2.3 templateId

This element is identifying the set of constraints applied to the CDA R2 standard by this IHE specification of a clinical laboratory report. The following templateId SHALL be present and valued as follows to indicate compliance with this specification:

```
<templateId root="1.3.6.1.4.1.19376.1.3.3"/>
```

6.3.2.4 Unique Instance Identifier of the Document

id SHALL be present. It represents the unique instance identifier of the clinical document. The combination of the root and extension attributes SHALL provide a globally unique identifier, in accordance with CDA R2, without further constraints.

Example using the extension attribute: `<id root="1.3.6.1.4.1.19376.1.3.4" extension="abc2"/>`

Example without the extension attribute: `<id root="1.3.6.1.4.1.19376.1.3.4.1232669"/>`

6.3.2.5 Type of Clinical Document

ClinicalDocument/code SHALL be present. The laboratory report can be either a multi-disciplinary report or a single discipline report.

6.3.2.5.1 Multi-disciplinary Laboratory Report

The LOINC code identifying the type of document as a (potentially) multidisciplinary laboratory report (presenting results from many specialties) is:

```
<code codeSystem="2.16.840.1.113883.6.1"
       codeSystemName=”LOINC”
       code="11502-2" displayName="LABORATORY REPORT.TOTAL"/>
```

6.3.2.5.2 Single Discipline Laboratory Report

Use the appropriate LOINC code as listed in table “Laboratory Specialties” in 6.3.3.1.1.

6.3.2.6 effectiveTime

ClinicalDocument/effectiveTime SHALL be present. It contains the creation date & time of the laboratory report as an electronic document. In case this is a new revision replacing a previous version (identified in `parentDocument`), this is the date & time of the new revision.

```
<effectiveTime value="20080624131933.0000-0500"/>
```

6.3.2.7 confidentialityCode

ClinicalDocument/confidentialityCode SHALL be present in accordance with the HL7 CDA R2 standard.

6.3.2.8 languageCode

ClinicalDocument/languageCode SHALL be present in accordance with the HL7 CDA R2 standard.

Example of a report authored in American English:

```
<languageCode code="en-US" codeSystem="2.16.840.1.113883.6.121"/>
```

Example of a report authored in French:

```
<languageCode code="fr-FR" codeSystem="2.16.840.1.113883.6.121"/>
```


6.3.2.9 Common Identifier to all Revisions of the Clinical Document

ClinicalDocument/setId SHALL be present to enable further updates of the clinical document. It is an identifier that is common across all revisions of the document.

Example: `<setId root="1.3.6.1.4.1.19376.1.3.4" extension="abc2"/>`

6.3.2.10 versionNumber

ClinicalDocument/versionNumber MAY be present. As requested by the CDA standard, it is an integer value used as versioning for the document.

6.3.2.11 recordTarget

ClinicalDocument/recordTarget SHALL be present and SHALL conform to the Human Patient, Non-Human Subject or Human Patient with Non-Human Subject templates defined below. There are three varieties of laboratory reports:

- Human (patient): The document reports laboratory observations produced on specimens collected exclusively from the patient.
- Non-Human Subject: The document reports laboratory observations produced on specimens collected from a non-human material (e.g., water, milk, etc.) or living subject (e.g., animal).
- Human (patient) paired with Non-Human Subject: The document reports laboratory observations produced on a non-human specimen with a relationship to a human patient (e.g., peanut butter eaten by a patient, a ferret that bit a patient).

These three varieties are represented by three templates applied to recordTarget element:

6.3.2.11.1 Human Patient

In accordance with the HL7 CDA R2 standard and further constrained by this specification, XD-LAB requires the presence of `name`, `addr` and telecom for all entities in the document including the human patient. Additionally, the following SHALL be present.

- **<id/> -** The patientRole/id SHALL be present.
- **<administrativeGenderCode/>** - The patientRole/patient/administrativeGenderCode SHALL be present.
- **<birthTime/>** - The patientRole/patient/birthTime SHALL be present.


```
<recordTarget typeCode="RCT">
  <patientRole classCode="PAT">
    <id extension="sw54321" root="1.3.6.1.4.1.19376.1.3.4"/>
    <addr>
      <streetAddressLine>1313 Mockingbird Lane</streetAddressLine>
      <city>Janesville</city><state>WI</state><postalCode>53545</postalCode>
      <country>USA</country>
    </addr>
    <telecom value="tel:608-555-5555"/>
    <patient classCode="PSN">
      <name><family>Winters</family><given>Shelly</given></name>
      <administrativeGenderCode code="F"/>
      <birthTime value="19401213000000.0000-0500"/>
    </patient>
  </patientRole>
</recordTarget>
```

Figure 6.3.2.11.1-1: Human Patient Example a

In the event a unit of information about the patient is not known or has been de-identified, the use of nullFlavor is appropriate:

```
<recordTarget typeCode="RCT">
  <patientRole classCode="PAT">
  <id extension="sw54321" root="1.3.6.1.4.1.19376.1.3.4"/>
    <addr>
      <streetAddressLine nullFlavor="MSK"/> <!-- masked value -->
      <city nullFlavor="MSK"/> <!-- masked value -->
      <state nullFlavor="MSK"/> <!-- masked value -->
      <postalCode>53545</postalCode>
      <country>USA</country>
    </addr>
    <telecom nullFlavor="UNK"/> <!-- unknown value -->
    <patient classCode="PSN">
      <name nullFlavor="MSK"/> <!-- masked value -->
      <administrativeGenderCode code="F"/>
      <birthTime value="19401213000000.0000-0500"/>
    </patient>
  </patientRole>
</recordTarget>
```

Figure 6.3.2.11.1-2: Human Patient Example b

6.3.2.11.2 Non-Human Subject 1.3.6.1.4.1.19376.1.3.3.1.2

When the subject of the observations in the report is a sample exclusively taken from a non-human subject, such as an animal, a lake, soil or other environmental element, the following SHALL be present.

- **<templateId root="1.3.6.1.4.1.19376.1.3.3.1.2"/> -** The `templateId` element identifies this `recordTarget` as a non-human subject of laboratory testing. The templateId SHALL have `root="1.3.6.1.4.1.19376.1.3.3.1.2"`.
- **<id/> -** /patientRole/id SHALL be present and SHALL represent the id of the non-human subject.
- **<patient@nullFlavor/> -** The recordTarget/patientRole SHALL have a patient sub-element and its `nullFlavor` SHALL be set to "`OTH`". This indicates that other information pertaining to the non-human subject can be found in the body of the document.
- **<structuredBody> mark-up -** In addition to the elements specified in the CDA header for the non-human subject, this non-human subject SHALL be represented in a Subject element in level 3 entries in the `structuredBody` as described in (6.3.4.3).

```
<recordTarget typeCode="RCT">
  <templateId root="1.3.6.1.4.1.19376.1.3.3.1.2"/>
  <patientRole classCode="PAT">
    <id extension="66373839" root="1.3.6.1.4.1.19376.1.3.4"/>
    <patient nullFlavor="OTH"/>
  </patientRole>
</recordTarget>
```

Figure 6.3.2.11.2-1: Non-Human Subject Example

6.3.2.11.3 Human Patient with Non-Human Subject 1.3.6.1.4.1.19376.1.3.3.1.3

When the report assembles observations for a human (patient) with observations produced using a non-human specimen, the recordTarget SHALL represent the human patient. In accordance with the HL7 CDA R2 standard and further constrained by this specification, the presence of `name`, `addr` and `telecom` is required for all entities in the document including the human patient. Additionally, the following SHALL be present.

- **<templateId root="1.3.6.1.4.1.19376.1.3.3.1.3"/> -** The `templateId` element identifies this `recordTarget` as a human patient directly impacted by a non-human subject of laboratory testing. The templateId SHALL have `root="1.3.6.1.4.1.19376.1.3.3.1.3"`.
- **<id/> -** recordTarget/patientRole/id SHALL be present. It SHALL be representative of the id of the human patient. In this template, the id of the non-human subject is not provided in the header. On a special note, at present, if the document contains a patient and a subject (as in the case of rabies, for example), documentation of the id of the subject cannot be accomplished without an extension to CDA.
- **<administrativeGenderCode/>** - The patientRole/patient/administrativeGenderCode SHALL be present.
- **<birthTime/>** - The patientRole/patient/birthTime SHALL be present.

- **<structuredBody> mark-up -** In addition to the elements specified in the CDA header for the patient, the non-human subject SHALL be represented in a Subject element in level 3 entries in the `structuredBody` as described in (6.3.4.4).

```
<recordTarget typeCode="RCT">
  <templateId root="1.3.6.1.4.1.19376.1.3.3.1.3"/>
  <patientRole classCode="PAT">
    <id extension="sw54321" root="1.3.6.1.4.1.19376.1.3.4"/>
    <addr>
      <streetAddressLine>1313 Mockingbird Lane</streetAddressLine>
      <city>Janesville</city><state>WI</state><postalCode>53545</postalCode>
      <country>USA</country>
    </addr>
    <telecom value="tel:608-555-5555"/>
    <patient classCode="PSN">
      <name><family>Winters</family><given>Shelly</given></name>
      <administrativeGenderCode code="F"/>
      <birthTime value="19401213000000.0000-0500"/>
    </patient>
  </patientRole>
</recordTarget>
```

Figure 6.3.2.11.3-1: Human patient paired with Non-Human Subject Example

As in the Human Patient template, a unit of information about the patient unknown or de-identified, is signaled with the nullFlavor attribute.

6.3.2.12 author

At least one ClinicalDocument/author SHALL be present with a `time` in accordance with the HL7 CDA R2 standard and further constrained by this specification to require the presence of `name`, `addr` and `telecom`. The `author/time` element carries the date&time the laboratory report was produced. The laboratory report can be authored by a software system or by a person or by both.

```
<author>
  <time value="20080124171911.0425-0500"/>
  <assignedAuthor>
    <id extension="1" root="1.3.6.1.4.1.19376.1.3.4"/>
    <addr>
      <streetAddressLine>21 North Ave</streetAddressLine>
      <city>Burlington</city><state>MA</state><postalCode>01803</postalCode>
      <country>USA</country>
    </addr>
    <telecom value="tel:555-1212" use="DIR"/>
    <assignedAuthoringDevice>
      <softwareName>Pretty Good Lab System</softwareName>
    </assignedAuthoringDevice>
  </assignedAuthor>
</author>
```


Figure 6.3.2.12-1: Example of Report Authored by a System

```
<author>
  <time value="20080124171911.0425-0500"/>
  <assignedAuthor>
    <id extension="1" root="1.3.6.1.4.1.19376.1.3.4"/>
    <addr>
      <streetAddressLine>21 North Ave</streetAddressLine>
      <city>Burlington</city><state>MA</state><postalCode>01803</postalCode>
      <country>USA</country>
    </addr>
    <telecom value="tel:555-1212" use="DIR"/>
    <assignedPerson>
      <name>
        <prefix>Dr.</prefix><given>GP</given><family>Physician</family>
      </name>
    </assignedPerson>
    <representedOrganization>
      <name>Good Practice</name>
    </representedOrganization>
  </assignedAuthor>
</author>
```

Figure 6.3.2.12-2: Example of Report Authored by a Person

6.3.2.13 custodian

ClinicalDocument/custodian SHALL be present with an `id` in accordance with the HL7 CDA R2 standard and further constrained by this specification to require the presence of `name`, `addr` and `telecom`. It represents the organization that is in charge of maintaining the laboratory report.

```
<custodian>
  <assignedCustodian>
    <representedCustodianOrganization>
      <id extension="1" root="1.3.6.1.4.1.19376.1.3.4"/>
      <name>Good Health Clinic</name>
      <telecom value="tel:555-1212" use="DIR"/>
      <addr>
        <streetAddressLine>21 North Ave</streetAddressLine>
        <city>Burlington</city>
      </addr>
    </representedCustodianOrganization>
  </assignedCustodian>
</custodian>
```

Figure 6.3.2.13-1: Example of a Custodian

6.3.2.14 intended Recipient 1.3.6.1.4.1.19376.1.3.3.1.4

ClinicalDocument/informationRecipient MAY be present. When present, it SHALL be in accordance with the HL7 CDA R2 standard and further constrained by this specification to require the presence of `name` (on the `informationRecipient` and/or `receivedOrganization`), `addr` and `telecom`. Additionally, it SHALL have the following:

- **<templateId root="1.3.6.1.4.1.19376.1.3.3.1.4"/> -** The `templateId` element identifies this `participant` as an intended recipient. The templateId SHALL have `root="1.3.6.1.4.1.19376.1.3.3.1.4"`.

The informationRecipient/intendedRecipient element can be multiple. It introduces an intended recipient of the laboratory report, other than the Ordering Provider (described as a referrer participant). These elements carry the list of the originally intended recipients of the laboratory report, i.e., those who were known at the time the report was created and published for sharing.

```
<informationRecipient>
  <templateId root="1.3.6.1.4.1.19376.1.3.3.1.4"/>
  <intendedRecipient>
    <id extension="0000" root="1.3.6.1.4.1.19376.1.3.4"/>
    <addr>
      <streetAddressLine>1600 Clifton Road</streetAddressLine>
      <city>Atlanta</city><state>GA</state><postalCode>30333</postalCode>
    </addr>
    <telecom value="tel:404-639-3535"/>
    <informationRecipient>
      <name><family>Angulo</family><given>Fred</given></name>
    </informationRecipient>
    <receivedOrganization>
      <id extension="0000" root="1.3.6.1.4.1.19376.1.3.4"/>
      <name>FoodNet</name>
      <telecom value="tel: 404-639-3535"/>
      <addr>
        <streetAddressLine>1600 Clifton Road</streetAddressLine>
        <city>Atlanta</city><state>GA</state><postalCode>30333</postalCode>
      </addr>
    </receivedOrganization>
  </intendedRecipient>
</informationRecipient>
```

Figure 6.3.2.14-1: Intended Recipient Example

6.3.2.15 legalAuthenticator

The ClinicalDocument/legalAuthenticator MAY be present. When present, it SHALL be in accordance with the HL7 CDA R2 standard and further constrained by this specification to require the presence of `name`, `addr` and `telecom`. This element carries the person who has legally authenticated the report, and the organization represented by this person. The sub-element time carries the date&time this legal authentication took place. The sub-element signatureCode carries the “signed” (S) status.

If this entity happens also to be one of the validators of the laboratory results in the report, it SHALL also be documented as a validator as described in Section 6.3.2.16.

```
<legalAuthenticator>
  <time value="20080124171911.0425-0500"/>
  <signatureCode code="S"/>
  <assignedEntity>
    <id extension="1" root="1.3.6.1.4.1.19376.1.3.4"/>
    <addr>
      <streetAddressLine>21 North Ave</streetAddressLine>
      <city>Burlington</city>
    </addr>
    <telecom value="tel:555-1212" use="DIR"/>
    <assignedPerson>
      <name><given>Mike</given><family>Roscopp</family></name>
    </assignedPerson>
  </assignedEntity>
</legalAuthenticator>
```

Figure 6.3.2.15-1: Legal Authenticator Example

6.3.2.16 Laboratory Results Validator 1.3.6.1.4.1.19376.1.3.3.1.5

The ClinicalDocument/authenticator element MAY be present. When present it represents the clinical expert who performed the clinical validation (see the entries "validator" and "clinical expert" in the glossary in LAB TF-1:1.11) of the report or of a subset of its results, also called the validator. This element SHALL be in accordance with the HL7 CDA R2 standard and further constrained by this specification to require the presence of `name`, `addr` and `telecom`.

There MAY be more than one validator of the report. All the validators SHALL appear in the report header as `authenticator` elements AND, in the case of multiple validators, each individual validator SHALL be associated with the particular sections of the report he or she validated. In this case, the validator of a section SHALL also appear in the `entry` this section is derived from. The validator SHALL appear as a `participant` with `typeCode="AUTHEN"`. Additionally, the laboratory results validator SHALL have the following:

- **<templateId root="1.3.6.1.4.1.19376.1.3.3.1.5"/> -** The `templateId` element identifies this `authenticator` or `participant` as a laboratory results validator. The templateId SHALL have `root="1.3.6.1.4.1.19376.1.3.3.1.5"`.


```
<!-- Single validator (authenticator) -->
<ClinicalDocument>
  ...
  <authenticator>
    <templateId root="1.3.6.1.4.1.19376.1.3.3.1.5"/>
    <time value="20080124171911.0425-0500"/>
    <signatureCode code="S"/>
    <assignedEntity>
      <id extension="274" root="1.3.6.1.4.1.19376.1.3.4"/>
      <addr>
        <streetAddressLine>7000 Laboratory Drive</streetAddressLine>
        <city>Chicago</city><state>IL</state><postalCode>60622</postalCode>
        <country>USA</country>
      </addr>
      <telecom value="tel:312-555-5555"/>
      <assignedPerson>
        <name>
          <family>Technologist</family><given>274</given>
        </name>
      </assignedPerson>
      <representedOrganization>
        <id extension="rm83747" root="1.3.6.1.4.1.19376.1.3.4"/>
        <name>Laboratory</name>
        <telecom value="tel:312-555-5555"/>
        <addr>
          <streetAddressLine>1234 Laboratory Drive</streetAddressLine>
          <city>Chicago</city>
          <state>IL</state>
          <postalCode>60622</postalCode>
          <country>USA</country>
        </addr>
      </representedOrganization>
    </assignedEntity>
 </authenticator>
 ...
</ClinicalDocument>
```

Figure 6.3.2.16-1: Laboratory Results Single Validator Example


```
<!-- Multiple Validators (authenticator) -->
<ClinicalDocument>
  ...
  <authenticator>
    <templateId root="1.3.6.1.4.1.19376.1.3.3.1.5"/>
    <time value="20080124171911.0425-0500"/>
    <signatureCode code="S"/>
    <assignedEntity>
      <id extension="274" root="1.3.6.1.4.1.19376.1.3.4"/>
      <addr><!-- address 1 content here --></addr>
      <telecom value="tel:312-555-5555"/>
      <assignedPerson>
        <name><!-- name 1 content here --></name>
      </assignedPerson>
    </assignedEntity>
  </authenticator>
  <authenticator>
    <templateId root="1.3.6.1.4.1.19376.1.3.3.1.5"/>
    <time value="20080124171911.0425-0500"/>
    <signatureCode code="S"/>
    <assignedEntity>
      <id extension="332" root="1.3.6.1.4.1.19376.1.3.4"/>
      ...
    </assignedEntity>
  </authenticator>
  ...
  <structuredBody>
    ...
   <section>
    ...
    <entry>
      <act>
        ...
        <entryRelationship>
          <observation>
            ...
            <participant typeCode="AUTHEN">
              <templateId root="1.3.6.1.4.1.19376.1.3.3.1.5"/>
              <time value="20080123211000.007-0500"/>
              <participantRole>
                <id extension="332" root="1.3.6.1.4.1.19376.1.3.4"/>
                <addr> <!-- address 2 content here --></addr>
                <telecom value="tel:312-555-5555"/>
                <playingEntity>
                  <name><!-- name 2 content here --></name>
                </playingEntity>
              </participantRole>
            </participant>
          </observation>
        ...
     </entry>
    </section>
    <section>
     ...
     <entry>
          ...
            <participant typeCode="AUTHEN">
              <templateId root="1.3.6.1.4.1.19376.1.3.3.1.5"/>
              <time value="20080123211000.007-0500"/>
              <participantRole>
                <id extension="274" root="1.3.6.1.4.1.19376.1.3.4"/>
            ...
     </entry>
    </section>
  </structuredBody>
</ClinicalDocument>
```

Figure 6.3.2.16-2: Laboratory Results Multiple Validators Example

6.3.2.17 Ordering Provider 1.3.6.1.4.1.19376.1.3.3.1.6

ClinicalDocument/participant(s) MAY be present. When present, this element SHALL be in accordance with the HL7 CDA R2 standard with a `time` element and further constrained by this specification to require the presence of `name`, `addr` and `telecom`.

In particular, when the ordering provider of the order (or group of orders) fulfilled by this laboratory report is present in the CDA, it SHALL be documented as a participant with the attribute `typeCode` valued "`REF`" (referrer). Additionally, the ordering provider SHALL have the following:

- **<templateId root="1.3.6.1.4.1.19376.1.3.3.1.6"/> -** The `templateId` element identifies this `participant` as an ordering physician. The `templateId` SHALL have `root="1.3.6.1.4.1.19376.1.3.3.1.6"`.

Note: In the v2.5 messaging structures this participant corresponds to the "ordering provider" represented by OBR-16 or ORC-12.

```
<participant typeCode="REF">
  <templateId root="1.3.6.1.4.1.19376.1.3.3.1.6"/>
  <time value="20080123211000.007-0500"/>
  <associatedEntity classCode="AGNT">
    <id extension="1" root="1.3.6.1.4.1.19376.1.3.4"/>
    <addr>
      <streetAddressLine>21 North Ave</streetAddressLine>
      <city>Burlington</city>
    </addr>
    <telecom value="tel:555-1212" use="DIR"/>
    <associatedPerson>
      <name><given>Good</given><family>Orderer</family></name>
    </associatedPerson>
    <scopingOrganization>
      <id extension="rm83747" root="1.3.6.1.4.1.19376.1.3.4"/>
      <name>Hospital</name>
      <telecom nullFlavor="UNK"/>
      <addr nullFlavor="UNK"/>
    </scopingOrganization>
  </associatedEntity>
</participant>
```

Figure 6.3.2.17-1: Ordering Provider Example

6.3.2.18 inFulfillmentOf/order

The `inFulfillmentOf/order` element MAY be present. It represents the Placer Order or the Placer Group that was fulfilled, the id of which is carried by `inFulfillmentOf/order/id`.

Note: A laboratory report MAY fulfill an Order Group or an Order (see definitions of these terms in the IHE Technical Framework Glossary available on http://ihe.net/TF_Intro_Appendices.aspx). In v2.5 messages the Placer Group corresponds to field ORC-4 "placer group number", the Placer Order corresponds to field ORC-2 "placer order number"

6.3.2.19 documentationOf/serviceEvent

ClinicalDocument/documentationOf(s) MAY be present. The `documentationOf/serviceEvent` represents the main Act being documented, that is an act of reporting Result Event(s) produced by a laboratory (See Result Event RMIM in the Laboratory domain of HL7 V3).

Use of sub element `documentationOf/serviceEvent/effectiveTime` to document the time boundaries of events in the document is appropriate.

This laboratory report content module adds the optional sub element `documentationOf/serviceEvent/statusCode` to enable the sharing of non-final reports. A report is considered as non-final (e.g., a preliminary report) if and only if it documents an Act, which is still in the status "active" (i.e., `serviceEvent/statusCode@code="active"`).

The statusCode sub element is an extension to the CDA R2 schema further described in section A.3 of this volume. This sub-element is optional. When it is not there, the documented Act is assumed to be completed and the report is assumed to be a final report.

```
<documentationOf>
  <serviceEvent>
    <effectiveTime>
      <low value="20080104000000.0000-0500"/>
      <high value="20080108000000.0000-0500"/>
    </effectiveTime>
  </serviceEvent>
</documentationOf>
```

Figure 6.3.2.19-1: documentationOf – Example of a final report

```
<documentationOf>
  <serviceEvent>
    <lab:statusCode code="active"/>
    <effectiveTime>
      <low value="20080104000000.0000-0500"/>
      <high value="20080108000000.0000-0500"/>
    </effectiveTime>
  </serviceEvent>
</documentationOf>
```

Figure 6.3.2.19-2: DocumentationOf – Example of a non-final report

6.3.2.20 Laboratory Performer 1.3.6.1.4.1.19376.1.3.3.1.7

Laboratory Performers MAY be present. See this entry in the glossary (LAB TF-1:1.11)

Documentation of laboratories having performed the reported tests can be done in multiple levels of the document to reflect performance scope. In the case where there is a single Laboratory Performer, this entity SHALL be documented in CDA header as `ClinicalDocument/documentationOf/serviceEvent/performer`. In the case where multiple Laboratory Performers participated in the lab testing process, they SHALL instead be

documented in the `structuredBody` at the entry level, organizer level or observation level, depending on the scope of the subset they performed.

A Laboratory Performer, when present, SHALL be in accordance with the HL7 CDA R2 standard with a `time` element and further constrained by this specification to require the presence of `name`, `addr` and `telecom`. Additionally, the laboratory performer SHALL have the following:

- **<templateId root="1.3.6.1.4.1.19376.1.3.3.1.7"/> -** The `templateId` element identifies this `performer` as a laboratory performer. The `templateId` SHALL have `root="1.3.6.1.4.1.19376.1.3.3.1.7"`.

```
<!-- Single Laboratory Performer -->
<ClinicalDocument>
  ...
  <documentationOf>
    <serviceEvent>
      <performer typeCode="PRF">
        <templateId root="1.3.6.1.4.1.19376.1.3.3.1.7"/>
       <time value="20080123211000.007-0500"/>
        <assignedEntity>
          <id extension="kd83736" root="1.3.6.1.4.1.19376.1.3.4"/>
          <addr>
            <streetAddressLine>7000 Hospital Drive</streetAddressLine>
            <city>Chicago</city><state>IL</state><postalCode>60622</postalCode>
            <country>USA</country>
          </addr>
          <telecom value="tel:312-555-5555"/>
          <assignedPerson>
            <name>
              <family>Dawson</family><given>Kim</given><prefix>Dr.</prefix>
            </name>
          </assignedPerson>
          <representedOrganization>
            <id extension="72899" root="1.3.6.1.4.1.19376.1.3.4"/>
            <name>Hospital Laboratory</name>
            <telecom value="tel:312-555-5555"/>
            <addr>
              <streetAddressLine>7000 Hospital Drive</streetAddressLine>
              <city>Chicago</city><state>IL</state><postalCode>60622</postalCode>
              <country>USA</country>
            </addr>
          </representedOrganization>
        </assignedEntity>
      </performer>
    </serviceEvent>
  </documentationOf>
</ClinicalDocument>
```

Figure 6.3.2.20-1: Laboratory Single Performer Example


```
<!— Multiple Laboratory Performers, this one has performed a single observation -->
<structuredBody>
  ...
  <entry>
    <act>
      ...
      <entryRelationship>
        <observation>
          ...
          <performer typeCode="PRF">
            <templateId root="1.3.6.1.4.1.19376.1.3.3.1.7"/>
           <time value="20080123211000.007-0500"/>
            <assignedEntity>
              <id extension="rm83747" root="1.3.6.1.4.1.19376.1.3.4"/>
              <addr>
                <streetAddressLine>7000 Hospital Drive</streetAddressLine>
                <city>Chicago</city><state>IL</state>postalCode>60622</postalCode>
                <country>USA</country>
              </addr>
              <telecom value="tel:312-555-5555"/>
              <assignedPerson>
                <name>
                  <family>Trenton</family><given>Douglas</given><prefix>Dr.</prefix>
                </name>
              </assignedPerson>
              <representedOrganization>
                <id extension="rm83747" root="1.3.6.1.4.1.19376.1.3.4"/>
                <name>Hospital Laboratory</name>
                <telecom value="tel:312-555-5555"/>
                <addr>
                  <streetAddressLine>7000 Hospital Drive</streetAddressLine>
                  <city>Chicago</city><state>IL</state><postalCode>60622</postalCode>
                  <country>USA</country>
                </addr>
              </representedOrganization>
            </assignedEntity>
          </performer>
        </observation>
      </entryRelationship>
      ...
    </act>
  </entry>
  ...
</structuredBody>
```

Figure 6.3.2.20-2: Multiple Laboratory Performers Example

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6.3.2.21 relatedDocument/parentDocument

This element SHALL be present in case of an update replacement of a previous report. In this case `relatedDocument@typeCode` attribute SHALL be valued `"RPLC"`, the new report replacing the parent one.

```
<relatedDocument typeCode="RPLC">
  <parentDocument>
    <id root="1.3.6.1.4.1.19376.1.3.4" extension="abc2"/>
  </parentDocument>
</relatedDocument>
```

Figure 6.3.2.21-1: Related Parent Document Example

Note 1:A non-final laboratory report published in an XDS infrastructure will likely be replaced afterwards by the final report. When this event occurs, the Content Creator SHALL apply the following rules:

- ClinicalDocument/setId SHALL have the same value in the new report as in the replaced report.
- ClinicalDocument/versionNumber SHALL be incremented in the replacing report (i.e., the final one).
- ClinicalDocument/relatedDocument@typeCode attribute SHALL be valued ”RPLC”
- ClinicalDocument/relatedDocument/parentDocument/id in the new report SHALL be equal to ClinicalDocument/ id of the replaced document.

The Document Source SHALL apply the following rules on XDSDocumentEntry metadata:

- The final report SHALL be associated with the previously published one, using RPLC relationship and the previous report SHALL be “Deprecated” as described in ITI TF-2:4.1.6.1.

Note 2:A non-final report can also be replaced by a more recent, albeit still non-final report. The rules above also apply in this case.

Note 3:A final report can also be replaced by a corrective final report. The rules above also apply in this case.

6.3.2.22 componentOf/encompassingEncounter

The ClinicalDocument/componentOf/encompassingEncounter element MAY be present. It describes the encounter during which the reported lab observations were ordered.

When present the encounter SHALL:

- be identified with an id element: `encompassingEncounter/id`
- The encounter SHALL have an effective time that represents the time interval (possibly still running, e.g., an inpatient current stay) of the encounter or a point in time at which the encounter took place (e.g., an outpatient consultation): `encompassingEncounter/effectiveTime`

The encounter MAY provide any number of encounter participants (`encompassingEncounter/encounterParticipant/assignedEntity`). When present, encounter participants SHALL be in accordance with the HL7 CDA R2 standard with a `time` and further constrained by this specification to require the presence of `name`, `addr` and `telecom`. Additionally, the encounter participant SHALL have a `typeCode` with one the values selected from the x_EncounterParticipant domain:

The encounter MAY precise the patient location during this encounter. This is the healthcare facility in which the patient was located when the reported lab test observations were ordered: `encompassingEncounter/location/healthCareFacility`. This healthcare facility can be represented as a physical place (e.g., room, floor, building, office) or as an organization (e.g., service, department, team) or both: `healthCareFacility/location`, `healthCareFacility/serviceProviderOrganization`.

```
<componentOf>
  <encompassingEncounter>
    <id extension="73920282" root="1.3.6.1.4.1.19376.1.3.4"/>
    <effectiveTime>
      <low value="20080123211000.0000-0500"/>
    </effectiveTime>
  </encompassingEncounter>
</componentOf>
```

Figure 6.3.2.22-1: Example of an Encompassing Encounter

6.3.3 CDA Section Content Modules

6.3.3.1 Laboratory Specialty Section 1.3.6.1.4.1.19376.1.3.3.2.1

6.3.3.1.1 List of Laboratory Specialties

Every Laboratory Report SHALL contain at least one Laboratory Specialty Section. Each top section represents a specialty. A laboratory report MAY be composed of test results from a single specialty (e.g., a virology report), or from any number of specialties. The structure of the template allows both kinds of reports.

The Laboratory Specialty Sections use the LOINC codes defined as report subject identifier codes. A laboratory report SHALL contain one or more of these sections, in any order. Laboratory Specialty Sections SHALL NOT be nested:

Table 6.3.3.1.1-1: Laboratory Specialties

LOINC code	Name
18717-9	BLOOD BANK STUDIES
18718-7	CELL MARKER STUDIES
18719-5	CHEMISTRY STUDIES
18720-3	COAGULATION STUDIES
18721-1	THERAPEUTIC DRUG MONITORING STUDIES
18722-9	FERTILITY STUDIES
18723-7	HEMATOLOGY STUDIES
18724-5	HLA STUDIES
18725-2	MICROBIOLOGY STUDIES
18727-8	SEROLOGY STUDIES
18728-6	TOXICOLOGY STUDIES

LOINC code	Name
18729-4	URINALYSIS STUDIES
18767-4	BLOOD GAS STUDIES
18768-2	CELL COUNTS+DIFFERENTIAL STUDIES
18769-0	MICROBIAL SUSCEPTIBILITY TESTS
26435-8	MOLECULAR PATHOLOGY STUDIES
26436-6	LABORATORY STUDIES
26437-4	CHEMISTRY CHALLENGE STUDIES
26438-2	CYTOLOGY STUDIES

Note 1:26436-6 (LABORATORY STUDIES) enables issuing a report putting together observations from multiple specialties (disciplines) in the same text block, allowing delivery of a global interpretation comment at the end of the text block that will be rendered at the end of the report.

Note 2:18721-1 (THERAPEUTIC DRUG MONITORING STUDIES) will be used for a section carrying pharmacology observations on a patient.

Note 3:Mycology and parasitology, as well as bacteriology, are part of the 18725-2 (MICROBIOLOGY STUDIES) specialty.

Note 4:Virology MAY be included in 18725-2 (MICROBIOLOGY STUDIES) specialty or 18727-8 (SEROLOGY STUDIES) or split between both specialties, depending upon the Content Creator's choice.

6.3.3.1.2 Specification

Every Laboratory Report SHALL contain at least one Laboratory Specialty Section, identified with its LOINC specialty code.

```
<templateId root="1.3.6.1.4.1.19376.1.3.3.2.1"/>
```

The `templateId` element identifies this `section` as a Laboratory Specialty Section. The `templateId` SHALL be present with `root="1.3.6.1.4.1.19376.1.3.3.2.1"`.

```
<code code=" " codeSystem=" " codeSystemName=" " displayName=" "/>
```

The Laboratory Specialty Section SHALL identify the LOINC laboratory specialty. The `code`, `codeSystem`, and `displayName` attributes SHALL be present. The `codeSystemName` MAY also be present.

`<title/> - The Laboratory Specialty Section <title>` MAY be present. It is the local translation of the `code@displayName`.

The semantic content of each specialty `section` is not constant between countries. The relationship between **Report Items** and **Specialties** varies from country to country, and MAY even vary in the same country, from a healthcare organization to another. A **Report Item** can be a battery (or test panel), an individual test, or the complete study of a specimen (for instance in the MICROBIOLOGY STUDIES specialty). Realm extensions of this profile MAY further constrain these definitions.

A Laboratory Specialty Section SHALL contain either a list of Laboratory Report Item Section(s) or a single `text` and `entry` element to represent the **Report Items**.

Choice 1: Laboratory Report Item Section - With this option, this Laboratory Specialty Section SHALL contain neither a top level `text` nor `entry` elements. Each **Report Item** is contained in a corresponding Laboratory Report Item Section which contains the Lab Report Data Processing Entry. See Section 6.3.4.2.

Choice 2: Text and Entry - With this option, the Laboratory Specialty Section `text` SHALL be present and not blank.

This narrative block SHALL present to the human reader, all the observations produced for this Specialty, using the various structures available in the CDA Narrative Block schema (NarrativeBlock.xsd): tables, lists, paragraphs, hyperlinks, footnotes, references to attached or embedded multimedia objects. The layout of the results in this narrative block should conform to the recommendations stated in § 6.3.3.2.2.

The narrative block is fully derived from the `entry` containing the machine-readable result data. Additionally, a single Laboratory Report Data Processing Entry SHALL be present with attribute typeCode="DRIV". This `entry` contains the machine-readable result data from which the narrative block of this section is derived.

A laboratory report may contain multiple Laboratory Specialty Sections, which need not adhere to the same choice of representation: there can be a mixture of choice 1 and choice 2 representations across multiple Laboratory Specialty Sections.


```
<ClinicalDocument>
  ...
  <component typeCode="COMP">
    <structuredBody classCode="DOCBODY" moodCode="EVN">
      <component typeCode="COMP">
        <section classCode="DOCSECT">
          <templateId root="1.3.6.1.4.1.19376.1.3.3.2.1"/>
          <!-- Example Specialty Section that holds a leaf section. -->
          <code code="18723-7" codeSystem="2.16.840.1.113883.6.1"
           codeSystemName="LOINC" displayName="HEMATOLOGY STUDIES"/>
          <title>Laboratory Hematology Results</title>
          <component>
            <section>
              <templateId root="1.3.6.1.4.1.19376.1.3.3.2.2"/>
              <!-- Example Leaf Section that holds one Report Item. -->
              <code code="16931-8" codeSystem="2.16.840.1.113883.6.1"
               codeSystemName="LOINC" displayName="Hemoglobin/Hematocrit"/>
              <text><table>...</table></text>
              <entry typeCode="DRIV">
                <templateId root="1.3.6.1.4.1.19376.1.3"/>
                <act classCode="ACT" moodCode="EVN">
                  ...
                </act>
              </entry>
            </section>
          </component>
        </section>
      </component>
      <component typeCode="COMP">
        <section classCode="DOCSECT">
          <templateId root="1.3.6.1.4.1.19376.1.3.3.2.1"/>
          <!-- Example Specialty Section that holds Report Items directly as a
               Laboratory Report Data Processing Entry-->
          <code code="18719-5" codeSystem="2.16.840.1.113883.6.1"
           codeSystemName="LOINC" displayName="CHEMISTRY STUDIES"/>
          <title>Laboratory Chemistry Results</title>
          <text><table>...</table></text>
          <entry typeCode="DRIV">
            <templateId root="1.3.6.1.4.1.19376.1.3"/>
            <act classCode="ACT" moodCode="EVN">
              ...
            </act>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
  ...
</ClinicalDocument>
```

Figure 6.3.3.1.2-1: Laboratory Specialty Section Example

6.3.3.2 Laboratory Report Item Section 1.3.6.1.4.1.19376.1.3.3.2.2

At the second level (nested in one specialty `section`), each leaf `section` represents a **Report Item**. It can be a battery (or test panel), an individual test, or the complete study of a specimen. A Laboratory Report Item Section under a Laboratory Specialty Section SHALL represent only one **Report Item**.

6.3.3.2.1 Specification

```
<templateId root="1.3.6.1.4.1.19376.1.3.3.2.2"/>
```

The `templateId` element identifies this `section` as a Laboratory Report Item Section under a Laboratory Specialty Section. The `templateId` SHALL be present with `root="1.3.6.1.4.1.19376.1.3.3.2.2"`.

```
<code code=" " codeSystem=" " codeSystemName=" " displayName=" "/>
```

The Laboratory Report Item Section SHALL identify the single **Report Item** uniquely using the `<code>` element. For example, a LOINC test code. The `code`, `codeSystem`, and `displayName` SHALL be present. One MAY also populate `codeSystemName` and `orginalText`.

`<title/>` **-** The Leaf Section `title` MAY be present, it is the local translation of the `code@displayName`.

`<text/>` **-** The Laboratory Report Item Section `text` SHALL be present and not blank. This narrative block SHALL present to the human reader and represent the observations produced for this **Report Item**, using the various structures available in the CDA Narrative Block schema (NarrativeBlock.xsd): tables, lists, paragraphs, hyperlinks, footnotes, references to attached or embedded multimedia objects. The narrative block is fully derived from the `entry` containing the machine-readable result data.

```
<entry typeCode="DRIV">
```

The Laboratory Report Item Section SHALL contain a Lab Report Data Processing Entry. This `entry` contains the machine-readable result data from which the narrative block of this section is derived.


```
<ClinicalDocument>
  ...
  <component typeCode="COMP">
    <structuredBody classCode="DOCBODY" moodCode="EVN">
      <component typeCode="COMP">
        <section classCode="DOCSECT">
          <templateId root="1.3.6.1.4.1.19376.1.3.3.2.1"/>
          <!-- Example Specialty Section that holds two leaf sections. -->
          <code code="18723-7" codeSystem="2.16.840.1.113883.6.1"
            codeSystemName="LOINC" displayName="HEMATOLOGY STUDIES"/>
          <title>Laboratory Hematology Results</title>
          <component>
            <section>
              <templateId root="1.3.6.1.4.1.19376.1.3.3.2.2"/>
              <!-- Leaf Section that holds one Report Item. -->
              <code code="16931-8" codeSystem="2.16.840.1.113883.6.1"
                codeSystemName="LOINC" displayName="Hemoglobin/Hematocrit"/>
              <text><table/>...</table></text>
              <entry typeCode="DRIV">
                <templateId root="1.3.6.1.4.1.19376.1.3"/>
                <act classCode="ACT" moodCode="EVN">
                  ...
                </act>
              </entry>
            </section>
          </component>
          <component>
            <section>
              <templateId root="1.3.6.1.4.1.19376.1.3.3.2.2"/>
              <!-- Leaf Section that holds one Report Item. -->
              <code code="14196-0" codeSystem="2.16.840.1.113883.6.1"
                codeSystemName="LOINC" displayName="Reticulocytes"/>
              <text><table>...</table></text>
              <entry typeCode="DRIV">
                <templateId root="1.3.6.1.4.1.19376.1.3"/>
                <act classCode="ACT" moodCode="EVN">
                  ...
                </act>
              </entry>
            </section>
          </component>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 6.3.3.2.1-1: Laboratory Report Item Section Example

6.3.3.2.2 Recommendations for Narrative Text

6.3.3.2.2.1 Presenting the Laboratory Results in the Narrative Text

For each test result the narrative block presents the following items, some of which will be common to all the tests performed on the same specimen:

The date/time of the observation, which is the relevant physiological date/time, i.e., when the specimen was drawn from the patient, or the best approximation to it.

The name of the analyte or finding.

The observation value (numeric, coded, textual or multimedia).

The unit of measure is present if relevant, and is represented with the Unified Code for Units of Measure (UCUM) [http://aurora.rg.iupui.edu/UCUM].

The reference range if known and relevant, with optional criteria pre-conditioning it (e.g., "newborn age < 6 weeks").

The interpretation code if known and relevant, using HL7 V3 vocabulary domain ObservationInterpretation (e.g., D = decreased, L = low, A = abnormal, R = resistant…)

The specimen type if it is not implied by the test. If it is present it SHALL use the HL7 V3 vocabulary domain SpecimenEntityType or another international standard terminology (e.g., SNOMED CT) and it SHALL NOT conflict with the specimen inherent to the test code[4], when using a test vocabulary that implies the specimen type, (like LOINC does with its "SYSTEM" property). This constraint can be verified by conformance testing, only if the conformance testing tool is able to map both vocabularies.

The specimen source site if relevant (e.g., swab on left foot in microbiology).

The testing method if relevant. If it is present it SHALL NOT conflict with the method inherent to the test code (like LOINC does with its "METHOD_TYP" property).

In case the tests were subcontracted, the mention of the subcontractor lab's name, address, telecom and director's name.

The collecting method if relevant. (e.g., catheter, fine needle aspirate).

Zero or more previous values obtained for the same test on the same patient. Previous results MAY appear only if they are clearly comparable, i.e., produced with the same method on the same specimen type, and expressed with the same unit.

[4] For instance, the LOINC test code 16904-5 GLUCOSE^1ST SPECIMEN POST XXX CHALLENGE is inherent to a Urine specimen. If the specimen type is mentioned in the section, it has to be a urine specimen (e.g., « Urine » or « Urine clean catch »); it cannot be a « Serum » or a « Sweat » specimen type.

The physiologically relevant date/time of these previous values

When all the tests of a battery share the same specimen the following items SHALL be present once in the section:

date/time of the observation (since it represents the specimen collection time)

specimen type (if not inherent to the section)

specimen source site (if relevant)

In case the previous observations for these tests were also obtained on one single specimen: the date/time of the previous value SHALL also be mentioned only once.

The general rule to be applied by the Content Creator is to put the specimen at the highest possible level in the hierarchy of the document.

6.3.3.2.2.1.1 Reporting a Single Specimen Battery

This structure fits the presentation of results of a battery performed on a single specimen. The presentation is designed in priority for numeric results, but it also fits coded and textual results. For each test, the current observation is compared with the reference ranges when relevant, and the results obtained on previous Filler Orders.

The narrative block MAY contain:

Zero or more initial `paragraph` delivering contextual information on the battery: Pertinent information. Reason for ordering this battery. Information related to the specimen (specimen observation, specimen collection procedure, specimen target site). Method used by the battery (if it is common to all the tests belonging to it). Name and phone of the verifier of the results, with date of validation, etc.

a `table` with the test results belonging to the battery. The following columns MAY be used:

Name of analyte.

Method

Unit

Current observation with the date/time of specimen collection as header. This column is emphasized with Bold `styleCode`.

Reference to footnote comments (`footnoteRef` if any comments accompany some of the observations)

Reference range

Criteria for reference range

Interpretation code (e.g., abnormality flag)

Optionally, previous observations with the date/time of specimen collection as header. This column MAY be repeated as many times as there are previous specimens to represent.

Columns MAY be amalgamated as required. (e.g., name of analyte and units).

Zero or more `footnote` referenced from the table, delivering comments (annotations) on some of the observations.

Zero or more concluding `paragraph` delivering global interpretative comments to this battery.

6.3.3.2.2.1.2 Reporting an Individual Test

This structure fits the presentation of a test ordered or promised individually. The presentation is designed in priority for numeric results, but it also fits coded and textual results. The current observation is compared with the reference ranges when relevant, and the results obtained on previous Filler Orders.

The narrative block contains:

Zero or more initial `paragraph` delivering contextual information on the test: Pertinent information. Reason for ordering this test. Information related to the specimen (specimen observation, specimen collection procedure, specimen target site). Method. Name and phone of the verifier of the results, with date of validation…

The complete observation MAY be rendered in a `paragraph`, with name of the test, unit, current result, unit, reference range, criteria, interpretation flag, annotation, dated previous results. Alternatively it MAY be rendered in a `table` defined below:

an OPTIONAL `table` with one single data row presenting the test result. The following columns MAY be used:

Name of analyte.

Method

Unit

Current observation with the date/time of specimen collection as header. This column is emphasized with bold `styleCode`.

Reference range

Criteria for reference range

Interpretation code (e.g., abnormality flag)

Optionally, previous observations with the date/time of specimen collection as header. This column MAY be repeated as many times as there are previous specimens to represent.

Columns MAY be amalgamated as required. (e.g., name of analyte and units).

Zero or more concluding `paragraph` delivering interpretative comments of the result.

6.3.4 CDA Entry Content Modules

6.3.4.1 Specification Tables for CDA Level 3 Content Module

All CDA level 3 content modules are positioned in a tree hierarchy. The tables specifying each of these content modules reflect this hierarchy.

- The 1st left column "Lvl" counts the number of nodes traversed in the tree to reach an element, n representing the top element of the current content module.
- The 2nd column "Card" gives the cardinality of an element.
- The 3rd column contains the name of the element, preceded by the name of its parent.
- The 4th column lists the attributes usable on an element.
- The 5th column lists the authorized values for an attribute. When a single value is listed, the attribute is mandatory and must have this value.
- The 6th column gives comments, and indicates whether an attribute is mandatory or not.

Notes below the table deliver additional precisions. Elements of the CDA document not explicitly referenced in a table SHALL rely on the HL7 CDA R2 specification.

6.3.4.2 Laboratory Report Data Processing Entry 1.3.6.1.4.1.19376.1.3.1

One Laboratory Report Data Processing Entry SHALL be present in each leaf section of the report. The `entry` element SHALL be present and have its `root` attribute valued `"1.3.6.1.4.1.19376.1.3.1"`. The `entry` SHALL contain a single `act` sub-element. This `act` is hereafter referred to as the **Specimen Act**. All other CDA level 3 content modules are nested in this one `act`. The **Specimen Act** shall contain at least one Laboratory Observation. If all observations of the `entry` have been produced on the same specimen, this specimen SHALL be attached to the top **Specimen Act** as a specimen collection `procedure` sub-element.

A particular section of the laboratory report MAY carry results more confidential than the rest of the report (e.g., the section of the HIV serology). This is expressed with the confidentialityCode sub-element of the **Specimen Act**.

The Laboratory Report Data Processing Entry SHALL conform to statements here and those made in the following tables and sections.

Table 6.3.4.2-1: Structure of Laboratory Report Data Processing Entry

Lvl	Card	Parent/element	Attribute	Value	Comments
n	[1..1]	section/entry	typeCode	DRIV	Mandatory and fixed. Indicates that the narrative block is derived from the entry.
n+1	[1..1]	entry/templateId	root	1.3.6.1.4.1.19376.1.3.1	Mandatory and fixed. Identifies this entry as a Laboratory Report Data Processing Entry.

Lvl	Card	Parent/element	Attribute	Value	Comments
Report Item from which the section text is derived					
n+1	[1..1]	entry/act	classCode	ACT	The 'Specimen Act'. Mandatory and fixed.
			moodCode	EVN	Mandatory and fixed.
n+2	[1..1]	act/code			Mandatory. When section is a Specialty Section, code is a LOINC Specialty. When section is a Report Item Section, code is a Report Item code.
n+2	[1..1]	act/statusCode	code	{completed | active | aborted}	Mandatory. 'completed' when all expected results are in a final state. 'active' if not all expected results are present 'aborted' if the tests of this section did not reach completion. Some results MAY be there, but not all.
Subject in case of a non-human subject attached to the report					
n+2	[0..1]	act/subject	typeCode	SBJ	→ See (6.3.4.3, 6.3.4.4)
performer participation used if different from the performer of the header, to supersede it for this section.					
n+2	[0..*]	act/performer	typeCode	PRF	→ See 6.3.2.20
author used if different from the author of the header, to supersede it for this section.					
n+2	[0..*]	act/author			
Other participants such as validator (AUTHEN) **or responsible party** (RESP) **or device** (DEV)					
n+2	[0..*]	act/participant	typeCode	{AUTHEN| RESP|DEV}	AUTHEN for validator (See 6.3.2.16) , RESP for responsible party DEV for device (e.g., lab analyzer)
Laboratory Result Content					
n+2	[1..*]	act/entryRelationship	typeCode	COMP	→ Specimen Collection (6.3.4.5) → Specimen Received (6.3.4.6) → Notification Organizer (6.3.4.7) → Notifiable Condition (6.3.4.8) → Case Identifier (6.3.4.9) → Outbreak Identifier (6.3.4.10) →Laboratory Isolate Organizer (6.3.4.11) →Laboratory Battery Organizer (6.3.4.12) → Laboratory Observation (6.3.4.13) → Multimedia Embedded Content (6.3.4.14) → Annotation Comment (6.3.4.15)


```
<entry typeCode="DRIV">
  <templateId root="1.3.6.1.4.1.19376.1.3.1"/>
  <act classCode="ACT" moodCode="EVN">
    <!-- Specialty Level Entry : LOINC Specialty Code -->
    <code code="18719-5" codeSystem="2.16.840.1.113883.6.1"
      codeSystemName="LOINC" displayName="Chemistry Studies"/>
    <statusCode code="completed"/>
    <effectiveTime value="200806180512">
    <entryRelationship typeCode="COMP">
      ...
    </entryRelationship>
    ...
  </act>
</entry>
```

Figure 6.3.4.2-1: Laboratory Report Data Processing Entry within a Specialty Section

```
<entry typeCode="DRIV">
  <templateId root="1.3.6.1.4.1.19376.1.3.1"/>
  <act classCode="ACT" moodCode="EVN">
    <!-- Report Item Level Entry : Result Item Code -->
    <code code="12814-0" codeSystem="2.16.840.1.113883.6.1"
     codeSystemName="LOINC" displayName="POTASSIUM" originalText="Serum potassium"/>
    <statusCode code="completed"/>
    <effectiveTime value="200806180512">
    <entryRelationship typeCode="COMP">
      ...
    </entryRelationship>
    ...
  </act>
</entry>
```

Figure 6.3.4.2-2: Laboratory Report Data Processing Entry within a Report Item Section

6.3.4.3 Non-Human Subject 1.3.6.1.4.1.19376.1.3.3.1.2.1

When the subject of the observations in the report is a specimen taken from a non-human subject, such as an animal, a lake, soil or other environmental element, the following SHALL be present. In addition to the elements specified in the CDA body for the non-human subject, this non-human subject SHALL be represented in the CDA header as specified in 6.3.2.11.2.

Table 6.3.4.3-1: Non-Human Subject

Lvl	Card	Parent/element	Attribute	Value	Comments
n	[0..1]	subject			
n+1	[1..1]	subject/ templateId	root	1.3.6.1.4.1.19376.1.3.3.1.2.1	Mandatory and fixed
n+1	[1..1]	subject/ relatedSubject			

Lvl	Card	Parent/element	Attribute	Value	Comments
n+2	[1..1]	relatedSubject/ code			Code characterizing the non-human subject (animal species, material…)
n+2	[1..1]	relatedSubject/ addr			Address of the non-human subject

```
<subject>
  <templateId root="1.3.6.1.4.1.19376.1.3.3.1.2.1"/>
  <relatedSubject>
    <code code="226955001" codeSystem="2.16.840.1.113883.6.96"
      codeSystemName="SNOMED-CT" displayName="Chicken">
      <qualifier>
        <name code="105590001" codeSystem="2.16.840.1.113883.6.96"
          codeSystemName="SNOMED-CT" displayName="Substance"/>
        <value code="255620007" codeSystem="2.16.840.1.113883.6.96"
          codeSystemName="SNOMED-CT" displayName="Food"/>
      </qualifier>
    </code>
    <addr>
      <streetAddressLine>304 Portola Road</streetAddressLine>
      <city>San Jose</city><state>CA</state><postalCode>95120</postalCode>
      <country>USA</country>
    </addr>
  </relatedSubject>
</subject>
```

Figure 6.3.4.3-1: Example of a non-human subject

6.3.4.4 Human Patient with Non-Human Subject 1.3.6.1.4.1.19376.1.3.3.1.3.1

When the subject of the observations in this part of the report is a specimen taken from a non-human subject, such as an animal, water, soil or other environmental element, while other parts of the report are related to the human patient, the following SHALL be present. In addition to the elements specified in the CDA body for the non-human subject, this non-human subject SHALL be represented in the CDA header as specified in 6.3.2.11.2.

Table 6.3.4.4-1: Human Patient with Non-Human Subject

Lvl	Card	Parent/element	Attribute	Value	Comments
n	[0..1]	subject			
n+1	[1..1]	subject/ templateId	root	1.3.6.1.4.1.19376.1.3.3.1.3.1	Mandatory and fixed
n+1	[1..1]	subject/ relatedSubject			
n+2	[1..1]	relatedSubject/ code			Code characterizing the non-human subject (animal species, material…)

Lvl	Card	Parent/element	Attribute	Value	Comments
n+2	[1..1]	relatedSubject/ addr			Addr of the non-human subject

```
<subject>
  <templateId root="1.3.6.1.4.1.19376.1.3.3.1.3.1"/>
  <relatedSubject>
    <code code="18998007" codeSystem="2.16.840.1.113883.6.96"
      codeSystemName="SNOMED-CT" displayName="Ferret species">
      <qualifier>
        <name code="105590001" codeSystem="2.16.840.1.113883.6.96"
          codeSystemName="SNOMED-CT" displayName="Substance"/>
        <value code="39866004" codeSystem="2.16.840.1.113883.6.96"
          codeSystemName="SNOMED-CT" displayName="Animal"/>
      </qualifier>
    </code>
    <addr>
      <streetAddressLine>304 Portola Road</streetAddressLine>
      <city>San Jose</city><state>CA</state><postalCode>95120</postalCode>
      <country>USA</country>
    </addr>
  </relatedSubject>
</subject>
```

Figure 6.3.4.4-1: Human Patient Paired with Non-Human Subject Example

6.3.4.5 Specimen Collection 1.3.6.1.4.1.19376.1.3.1.2

Specimen Collection, when present, SHALL be recorded under the **Specimen Act** in an `entryRelationship` under the Laboratory Data Processing Entry. The table below shows how the information for this element is coded, and further constraints are provided in the following sections.

Table 6.3.4.5-1: Specimen Collection

Lvl	Card	Parent/element	Attribute	Value	Comments
Specimen Collection					
n	[1..1]	procedure	classCode	PROC	
			moodCode	EVN	
n+1	[1..1]	procedure/templateId	root	1.3.6.1.4.1. 19376.1.3.1.2	Mandatory and fixed
n+1	[0..1]	procedure/code	code codeSystem	33882-2	LOINC specimen collection code
n+1	[1..1]	procedure/effectiveTime			Date & time of specimen collection
n+1	[0..1]	procedure/ targetSiteCode			Specimen Source
Specimen Collection Participants					

Lvl	Card	Parent/element	Attribute	Value	Comments
n+1	[0..1]	procedure/performer			Specimen collection organization
n+1	[1..1]	procedure/participant	typeCode	PRD	
n+2	[1..1]	participant/participantRole	classCode	SPEC	
n+3	[1..1]	participantRole/id			Specimen ID, Required
n+3	[1..1]	participantRole/playingEntity/code			Specimen Type, Required
Specimen Received					
n+1	[0..1]	procedure/ entryRelationship/act			→ Specimen Received (2.3.5.6)

```
<entry typeCode="DRIV">
  <templateId root="1.3.6.1.4.1.19376.1.3.1"/>
  <act classCode="ACT" moodCode="EVN">
    ...
    <entryRelationship typeCode="COMP">
      <procedure classCode="PROC" moodCode="EVN">
        <templateId root="1.3.6.1.4.1.19376.1.3.1.2"/>
        <code code="33882-2" codeSystem="2.16.840.1.113883.6.1"
              codeSystemName="LOINC" displayName="Specimen Collection"/>
        <effectiveTime nullFlavor="UNK"/>
        <targetSiteCode/>
        <performer>
          <assignedEntity>
            <id/>
            <representedOrganization>
              <name/>
              <telecom/>
              <addr>...</addr>
            </representedOrganization>
          </assignedEntity>
        </performer>
        <participant typeCode="PRD">
          <participantRole classCode="SPEC">
            <id extension="55584739" root="1.3.6.1.4.1.19376.1.3.4"/>
            <playingEntity>
              <code/>
            </playingEntity>
          </participantRole>
        </participant>
      </procedure>
    </entryRelationship>
    ...
```

Figure 6.3.4.5-1: Specimen Collection Example

6.3.4.6 Specimen Received 1.3.6.1.4.1.19376.1.3.1.3

Specimen Received, when present, SHALL be recorded under the **Specimen Act** in an `entryRelationship` under the Specimen Collection Procedure. The table below shows how the

information for this element is coded, and further constraints are provided in the following sections.

865 **Table 6.3.4.6-1: Specimen Received**

Lvl	Card	Parent/element	Attribute	Value	Comments
n		procedure/ entryRelationship	typeCode	COMP	
n+1		entryRelationship/ act	classCode	ACT	
			moodCode	EVN	
n+2	[1..1]	act/templateId	root	1.3.6.1.4.1. 19376.1.3.1.3	
n+2	[1..1]	act/code	code codeSystem codeSystemName	SPRECEIVE 1.3.5.1.4.1. 19376.1.5.3.2 IHEActCode	Code representing the specimen reception in the laboratory
n+2	[1..1]	act/effectiveTime			Date & time of specimen reception


```
<entry typeCode="DRIV">
  <templateId root="1.3.6.1.4.1.19376.1.3.1"/>
  <act classCode="ACT" moodCode="EVN">
    ...
    <entryRelationship typeCode="COMP">
      <procedure classCode="PROC" moodCode="EVN">
        <templateId root="1.3.6.1.4.1.19376.1.3.1.2"/>
        <code code="33882-2" codeSystem="2.16.840.1.113883.6.1"
              codeSystemName="LOINC" displayName="Specimen Collection"/>
        <effectiveTime nullFlavor="UNK"/>
        <targetSiteCode/>
        <performer>
          ...
        </performer>
        <participant typeCode="PRD">
          ...
        </participant>
        <entryRelationship typeCode="COMP">
          <act classCode="ACT" moodCode="EVN">
            <templateId root="1.3.6.1.4.1.19376.1.3.1.3"/>
            <code code="SPRECEIVE" codeSystem="1.3.5.1.4.1.19376.1.5.3.2"
                  codeSystemName="IHEActCode" displayName="Receive Time"/>
            <effectiveTime value="20080408000000.0000-0700"/>
          </act>
        </entryRelationship>
      </procedure>
    ...
  </act>
</entry>
```

Figure 6.3.4.6-1: Specimen Received Example

6.3.4.7 Notification Organizer 1.3.6.1.4.1.19376.1.3.1.1

870 The document MAY contain a Notification Organizer in an `entryRelationship` under the **Specimen Act** of a Laboratory Data Processing Entry as demonstrated. This `organizer` SHALL be present when any of the following Notifications are present: Notifiable Condition, Case Identification, Outbreak Identification. Notifications SHALL be present when dictated by local public health requirements.

875 **Table 6.3.4.7-1: Notification Organizer**

Lvl	Card	Parent/element	Attribute	Value	Comments
n		organizer	classCode	CLUSTER	
			moodCode	EVN	
n+1	[1..1]	organizer/templateId	root	1.3.6.1.4.1. 19376.1.3.1.1	
n+1	[1..1]	organizer/statusCode	code	{completed |nullify}	A status of completed means the patient has been associated with the given notification. A status of nullify means that the notification was done in error.
n+1	[1..*]	organizer/component			Contains one or more of the following Notifications: Notifiable Condition, Case Identification, Outbreak Identification.


```
<entry typeCode="DRIV">
  <templateId root="1.3.6.1.4.1.19376.1.3.1"/>
  <act classCode="ACT" moodCode="EVN">
    <entryRelationship typeCode="COMP">
      <organizer classCode="CLUSTER" moodCode="EVN">
        <templateId root="1.3.6.1.4.1.19376.1.3.1.1"/>
        <statusCode code="completed"/>
        <component>
          <observation classCode="COND" moodCode="EVN">
            <templateId root="1.3.6.1.4.1.19376.1.3.1.1.1"/>
            ...
          </observation>
        </component>
        <component>
          <observation classCode="CASE" moodCode="EVN">
            <templateId root="1.3.6.1.4.1.19376.1.3.1.1.2"/>
            ...
          </observation>
        </component>
        <component>
          <observation classCode="OUTB" moodCode="EVN">
            <templateId root="1.3.6.1.4.1.19376.1.3.1.1.3"/>
              ...
          </observation>
        </component>
      </organizer>
    </entryRelationship>
  </act>
</entry>
```

Figure 6.3.4.7-1: Notification Organizer Example

6.3.4.8 Notifiable Condition 1.3.6.1.4.1.19376.1.3.1.1.1

Notifiable Condition, when present, SHALL be recorded as an `observation` under the Notification Organizer (see 6.3.4.7) as demonstrated. Notifiable Condition SHALL be present when dictated by local public health requirements.

Table 6.3.4.8-1: Notifiable Condition

Lvl	Card	Parent/element	Attribute	Value	Comments
n		observation	classCode	COND	
			moodCode	EVN	
n+1	[1..1]	observation/ templateId	root	1.3.6.1.4.1. 19376.1.3.1.1.1	
n+1	[0..*]	observation/id			
n+1	[1..1]	observation/code			Code is used to identify this observation as the one for 'Notifiable Condition'.
n+2	[1..1]	code/qualifier			

Lvl	Card	Parent/element	Attribute	Value	Comments
n+3	[1..1]	qualifier/name	code codeSystem codeSystemName displayName		Qualifies the code with the source of specimen
n+3	[1..1]	qualifier/value	code codeSystem codeSystemName displayName		Identifies the specimen source of the condition – patient, food, soil, …
n+1	[1..1]	observation/ statusCode	code	{completed |aborted}	A status of completed means the patient has been associated with the given notifiable condition. A status of aborted means the patient was associated with the notifiable condition in error.
n+1	[0..1]	observation/ effectiveTime			
n+1	[1..1]	observation/value	xsi:type code codeSystem codeSystemName displayName	"CE"	This is the value of the notifiable condition. It SHALL use the type "CE"


```
<entry typeCode="DRIV">
  <templateId root="1.3.6.1.4.1.19376.1.3.1"/>
  <act classCode="ACT" moodCode="EVN">
    <entryRelationship typeCode="COMP">
      <organizer classCode="CLUSTER" moodCode="EVN">
        <templateId root="1.3.6.1.4.1.19376.1.3.1.1"/>
        <statusCode code="completed"/>
        <component>
          <observation classCode="COND" moodCode="EVN">
            <templateId root="1.3.6.1.4.1.19376.1.3.1.1.1"/>
            <id extension="SALM" root="1.3.6.1.4.1.19376.1.3.4"/>
            <code code="170516003" codeSystem="2.16.840.1.113883.6.96"
              codeSystemName="SNOMED-CT" displayName="Notification of Disease">
              <qualifier>
                <name code="246087005" codeSystem="2.16.840.1.113883.6.96"
                  codeSystemName="SNOMED-CT" displayName="Source of Specimen"/>
                <value code="116154003" codeSystem="2.16.840.1.113883.6.96"
                  codeSystemName="SNOMED-CT" displayName="Patient"/>
              </qualifier>
            </code>
            <statusCode code="completed"/>
            <effectiveTime value="20080408000000.0000-0400"/>
            <value xsi:type="CE" code="27268008"
              codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED-CT"
              displayName="Salmonella"/>
          </observation>
        </component>
        ...
      </organizer>
    </entryRelationship>
  </act>
</entry>
```

Figure 6.3.4.8-1: Notifiable Condition Example

6.3.4.9 Case Identification 1.3.6.1.4.1.19376.1.3.1.1.2

Case Identification, when present, SHALL be recorded as an `observation` under the Notification Organizer (see 6.3.4.7) as demonstrated. Case Identification SHALL be present when dictated by local case identification reporting requirements.

Table 6.3.4.9-1: Case Identification

Lvl	Card	Parent/element	Attribute	Value	Comments
n		observation	classCode	CASE	
			moodCode	EVN	
n+1	[1..1]	observation/templateId	root	1.3.6.1.4.1. 19376.1.3.1.1.2	
n+1	[0..*]	observation/id			This is the local case identification.

Lvl	Card	Parent/element	Attribute	Value	Comments
n+1	[1..1]	observation/code			Code is used to identify this observation as the one for 'Case Identification'.
n+1	[1..1]	observation/statusCode	code	{completed |aborted}	A status of completed means the patient has been associated with the given case number. A status of aborted means the patient was associated with the case number in error.
n+1	[0..1]	observation/ effectiveTime			
n+1	[1..1]	observation/value			Must be type “CE”

```
<ClinicalDocument>
  ...
  <entry typeCode="DRIV">
    <templateId root="1.3.6.1.4.1.19376.1.3.1"/>
    <act classCode="ACT" moodCode="EVN">
      <entryRelationship typeCode="COMP">
        <organizer classCode="CLUSTER" moodCode="EVN">
          <templateId root="1.3.6.1.4.1.19376.1.3.1.1"/>
          <statusCode code="completed"/>
          <component>
            <observation classCode="CASE" moodCode="EVN">
              <templateId root="1.3.6.1.4.1.19376.1.3.1.1.2"/>
              <id extension="SALM_83747" root="1.3.6.1.4.1.19376.1.3.4"/>
              <code="416341003" codeSystem="2.16.840.1.113883.6.96
                codeSystemName="SNOMED-CT" displayName="Case Started">
              <statusCode code="completed"/>
              <effectiveTime value="20080408000000.0000-0400"/>
              <value xsi:type="CE" code="27268008"
                codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED-CT"
                displayName="Salmonella"/>
            </observation>
          </component>
          ...
        </organizer>
      </entryRelationship>
    </act>
  </entry>
  ...
</ClinicalDocument>
```

Figure 6.3.4.9-1: Case Identification Example

6.3.4.10 Outbreak Identification 1.3.6.1.4.1.19376.1.3.1.1.3

Outbreak Identification, when present, SHALL be recorded as an `observation` under the Notification Organizer (see 6.3.4.7) as demonstrated. Outbreak Identification SHALL be present when dictated by local outbreak identification reporting requirements.

Table 6.3.4.10-1: Outbreak Identification

Lvl	Card	Parent/element	Attribute	Value	Comments
n		observation	classCode	OUTB	
			moodCode	EVN	
n+1	[1..1]	observation/templateId	root	1.3.6.1.4.1. 19376.1.3.1.1.3	
n+1	[0..*]	observation/id			This is the local outbreak identification.
n+1	[1..1]	observation/code			Code is used to identify this observation as the one for 'Outbreak Identification'.
n+1	[1..1]	observation/statusCode	code	{completed |aborted}	A status of completed means the patient has been associated with the given outbreak. A status of aborted means the patient was associated with the outbreak in error.
n+1	[0..1]	observation/ effectiveTime			
n+1	[1..1]	observation/value			Must be type “CE”


```
<ClinicalDocument>
  ...
  <entry typeCode="DRIV">
    <templateId root="1.3.6.1.4.1.19376.1.3.1"/>
    <act classCode="ACT" moodCode="EVN">
      <entryRelationship typeCode="COMP">
        <organizer classCode="CLUSTER" moodCode="EVN">
          <templateId root="1.3.6.1.4.1.19376.1.3.1.1"/>
          <statusCode code="completed"/>
          <component>
            <observation classCode="OUTB" moodCode="EVN">
              <templateId root="1.3.6.1.4.1.19376.1.3.1.1.3"/>
                <id extension="SALM_SPINACH459" root="1.3.6.1.4.1.19376.1.3.4"/>
                <code code="416534008" codeSystem="2.16.840.1.113883.6.96"
                  codeSystemName="SNOMED-CT" displayName="Outbreak">
                <statusCode code="completed"/>
                <effectiveTime value="20080421000000.0000-0400"/>
                <value xsi:type="CE" code="79153007"
                  codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED-CT"
                  displayName="Salmonella tennessee 6,7,14;z29;1,2,7">
            </observation>
          </component>
          ...
        </organizer>
      </entryRelationship>
    </act>
  </entry>
  ...
</ClinicalDocument>
```

Figure 6.3.4.10-1: Outbreak Identification Example

6.3.4.11 Laboratory Isolate Organizer 1.3.6.1.4.1.19376.1.3.1.5

The Laboratory Isolate Organizer SHALL be used only if the entry represents a microbiology specimen study with isolates discovered on the specimen. The isolate is represented by the Isolate role played by the Isolate entity. The isolate identification is carried by the code attribute of the Isolate entity.

Table 6.3.4.11-1: Laboratory Isolate Organizer

Lvl	Card	Parent/element	Attribute	Value	Comments
SpecimenObservationCluster_Organizer used only in microbiology to capture the findings on an **isolate**					
n	[1..1]	organizer	classCode	CLUSTER	Mandatory and fixed
			moodCode	EVN	Mandatory and fixed
n+1	[1..1]	organizer/templateId	root	1.3.6.1.4.1.19376.1.3.1.5	Mandatory and fixed

Lvl	Card	Parent/element	Attribute	Value	Comments
n+1	[0..1]	organizer/id			
n+1	[0..1]	organizer/code			
n+1	[1..1]	organizer/statusCode	code	{completed |active |aborted}	'completed' when all expected results for this isolate are in a final state.. 'active' if some are missing 'aborted' if the findings on the isolate did not reach completion. Some results MAY be there.
n+1	[0..1]	organizer/ effectiveTime	value		Time of results on this isolate.
subject in case of a non-human subject attached to the **isolate**					
n+1	[0..1]	organizer/subject	typeCode	SBJ	→ See Tables 6.3.4.3-1 and 6.3.4.4-1
participation of the isolate i.e., the specific sub-specimen on which a microorganism was isolated and cultivated					
n+1	[1..1]	organizer/specimen	typeCode	SPC	type of participation "specimen"
n+2	[1..1]	specimen/specimenRole	classCode	SPEC	This represents an isolate here.
n+3	[0..1]	specimenRole/id			unique identifier for this isolate, known to the laboratory
n+3	[1..1]	specimenRole/ specimenPlayingEntity	classCode	MIC	The entity is a microorganism
n+4	[1..1]	specimenPlayingEntity /code			Identification of the microorganism, in a standard vocabulary
			code		
			codeSystem		
			codeSystemName		
			displayName		Name of the organism reported in the narrative block.
performer participation used if specific performer on this **isolate**, to supersede all performers of higher level.					
n+1	[0..*]	organizer/performer	typeCode	PRF	
author participation used if specific author on this **isolate**, to supersede all authors of higher level.					
n+1	[0..*]	organizer/author	typeCode	AUT	
Other participants such as verifier (AUTHEN) **or responsible party** (RESP)					
n+1	[0..*]	organizer/participant	typeCode	{AUTHEN |RESP |DEV}	→ See 6.3.4.16 AUTHEN for verifier, RESP for responsible party DEV for device (e.g., lab analyzer)
Content of the SpecimenObservationCluster _Organizer: any number of Observations, Battery_Organizers, Multimedia					
n+1	[1..*]	organizer/component	typeCode	COMP	→ Battery (6.3.4.12) → Observation (6.3.4.13) → Multimedia (6.3.4.14) → Annotation Comment (6.3.4.15)

910 **Note 1**:The SpecimenObservationCluster_Organizer can have for components any number of Battery Organizer (represented by organizer element with classCode="BATTERY") and any number of Observation (represented by observation element).

Note 2:If the Report_Entry is “completed”, then the SpecimenObservationCluster_Organizer cannot be “active”.

```
<section classCode="DOCSECT">
  <templateId root="1.3.6.1.4.1.19376.1.3.3.2.1"/>
  ...
  <entry typeCode="DRIV">
    <templateId root="1.3.6.1.4.1.19376.1.3.1"/>
    <act classCode="ACT" moodCode="EVN">
      ...
      <entryRelationship typeCode="COMP">
        <organizer classCode="CLUSTER" moodCode="EVN">
          <templateId root="1.3.6.1.4.1.19376.1.3.1.5"/>
          <statusCode code="completed"/>
          <effectiveTime value="20071108000000.0000-0500"/>
          <specimen typeCode="SPC">
            <specimenRole classCode="SPEC">
              <id extension="55584739" root="1.3.6.1.4.1.19376.1.3.4"/>
              <specimenPlayingEntity classCode="MIC">
                <code code="79153007" codeSystem="2.16.840.1.113883.6.96"
                  codeSystemName="SNOMED-CT"
                  displayName="Salmonella tennessee 6,7,14;z29;1,2,7"/>
              </specimenPlayingEntity>
            </specimenRole>
          </specimen>
          <performer typeCode="PRF">
            <templateId root="1.3.6.1.4.1.19376.1.3.3.1.7"/>
            ...
          </performer>
          <author typeCode="AUT">
            ...
          </author>
          <participant typeCode="AUTHEN">
            <templateId root="1.3.6.1.4.1.19376.1.3.3.1.5"/>
            ...
          </participant>
          <participant typeCode="RESP">
            ...
          </participant>
          <participant typeCode="DEV">
            ...
          </participant>
          <component>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="1.3.6.1.4.1.19376.1.3.1.6"/>
              <code code="89029-0" codeSystem="2.16.840.1.113883.6.1"
                codeSystemName="LOINC" displayName="Microbiology Culture"/>
              ...
            </observation>
          </component>
          <component>
            <organizer classCode="BATTERY" moodCode="EVN">
              <templateId root="1.3.6.1.4.1.19376.1.3.1.4"/>
              <code code="29576-6" codeSystem="2.16.840.1.113883.6.1"
                codeSystemName="LOINC" displayName="Microbiology Susceptibility">
              ...
            </organizer>
          </component>
          ...
        </organizer>
      </entryRelationship>
    </act>
  </entry>
```

915 **Figure 6.3.4.11-1: Laboratory Isolate Organizer Example**

6.3.4.12 Laboratory Battery Organizer 1.3.6.1.4.1.19376.1.3.1.4

A Laboratory Battery Organizer is used to group Laboratory Observations for a battery of tests. Laboratory Battery Organizer, when present, SHALL be recorded as an `organizer` under the Laboratory Data Processing Entry as demonstrated.

920 **Table 6.3.4.12-1: Laboratory Battery Organizer**

Lvl	Card	Parent/element	Attribute	Value	Comments
Battery_Organizer Holds a battery and its set of observations and annotations, plus an optional specimen					
n	[1..1]	organizer	classCode	BATTERY	Mandatory and fixed
			moodCode	EVN	
n+1	[1..1]	organizer/templateId	root	1.3.6.1.4.1.19376.1.3.1.4	Mandatory and fixed
n+1	[0..1]	organizer/id			If present, represents the lab filler order number (ORC-3 and OBR-3 in HL7 v2.5) for this battery
n+1	[0..1]	organizer/code			Unique code for the battery in the appropriate vocabulary (e.g., SNOMED CT)
n+1	[1..1]	organizer/statusCode	code	{completed |aborted}	'completed' when all expected results for this battery are in a final state.. 'aborted' if the battery did not reach the end of testing. Some results MAY be there.
n+1	[0..1]	organizer/ effectiveTime	value		Time of results on this battery
Subject in case of a non-human subject attached to the **Battery**					
n+1	[0..1]	organizer/subject	typeCode	SBJ	→ See Tables 6.3.4.3-1 and 6.3.4.4-1
performer participation. Performer to supersede those recorded at higher level.					
n+1	[0..*]	organizer/performer	typeCode	PRF	
author participation used to supersede the authors of higher level.					
n+1	[0..*]	organizer/author	typeCode	AUT	
Other participants such as verifier (AUTHEN) **or responsible party** (RESP)					
n+1	[0..*]	organizer/ participant	typeCode	{AUTHEN |RESP |DEV}	→ See 6.3.4.16 AUTHEN for verifier, RESP for responsible party DEV for device (e.g., lab analyzer)
content of the Battery_Organizer: any number of observations and or multimedia					
n+1	[0..*]	organizer/component	typeCode	COMP	→ Specimen Collection (6.3.4.5) → Observation (6.3.4.13) → Multimedia (6.3.4.14) → Annotation Comment (6.3.4.15)

Note 1:If the Battery_Organizer hangs below the Report_Entry, n = 4. Otherwise the Battery Organizer hangs below the SpecimenObservationCluster_Organizer and n = 6.

Note 2:A Battery Organizer MAY be related to a specimen if it does not inherit this relationship from an upper level.

Note 3:A battery contains at least one observation. The only case where the battery MAY have no observations at all, in a final report, is when it is reported as aborted.

```
<entry typeCode="DRIV">
    <templateId root="1.3.6.1.4.1.19376.1.3.1"/>
    <act classCode="ACT" moodCode="EVN">
      ...
      <entryRelationship typeCode="COMP">
        <organizer classCode="BATTERY" moodCode="EVN">
          <templateId root="1.3.6.1.4.1.19376.1.3.1.4"/>
          <code code="29576-6" codeSystem="2.16.840.1.113883.6.1"
            codeSystemName="LOINC" displayName="Microbiology Susceptibility">
            <originalText><reference value="susceptibilityTest"/></originalText>
          </code>
          <statusCode code="completed"/>
          <effectiveTime value="20071108000000.0000-0500"/>
          <performer typeCode="PRF">
            <templateId root="1.3.6.1.4.1.19376.1.3.3.1.7"/>
            ...
          </performer>
          <author typeCode="AUT">
            ...
          </author>
          <participant typeCode="AUTHEN">
            <templateId root="1.3.6.1.4.1.19376.1.3.3.1.5"/>
            ...
          </participant>
          <component>
            <procedure classCode="PROC" moodCode="EVN">
              <templateId root="1.3.6.1.4.1.19376.1.3.1.2"/>
              ...
              <entryRelationship typeCode="COMP">
                <act classCode="ACT" moodCode="EVN">
                  <templateId root="1.3.6.1.4.1.19376.1.3.1.3"/>
                  ...
                </act>
              </entryRelationship>
            </procedure>
          </component>
          <component>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="1.3.6.1.4.1.19376.1.3.1.6"/>
              ...
            </observation>
          </component>
          <component>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="1.3.6.1.4.1.19376.1.3.1.6"/>
              ...
            </observation>
          </component>
         <component>
           <act classCode="ACT" moodCode="EVN">
             <templateId extension="1.3.6.1.4.1.19376.1.5.3.1.4.2"/>
             <code code="48767-8" codeSystem="2.16.840.1.113883.6.1"
               codeSystemName="LOINC" displayName="Annotation Comment"/>
             <text><reference value="organizerComment"/></text>
             <statusCode code="completed"/>
           </act>
         </component>
        </organizer>
      </entryRelationship>
    </act>
</entry>
```

Figure 6.3.4.12-1: Laboratory Battery Organizer Example

6.3.4.13 Laboratory Observation 1.3.6.1.4.1.19376.1.3.1.6

Table 6.3.4.13-1: Laboratory Observation

Lvl	Card	Parent/element	Attribute	Value	Comments
Observation with related previous results, reference range, participants, comments					
n	[1..1]	observation	classCode	OBS	Mandatory and fixed
			moodCode	EVN	Mandatory and fixed
n+1	[1..1]	observation/ templateId	root	1.3.6.1.4.1.19376.1.3.1.6	Mandatory and fixed
n+1	[0..1]	observation/id			
n+1	[1..1]	observation/code			Unique test code in an international standard (LOINC or SNOMED CT) or a national standard (e.g., JC10 in Japan)
n+1	[1..1]	observation/ statusCode	code	{completed |aborted }	'completed' when the result is present. 'aborted' if the test could not be performed.
n+1	[0..1]	observation /effectiveTime	value		Physiologically relevant time
n+1	[0..1]	observation/value			The result obtained for this test using the appropriate data type. Numeric results use data type PQ, which includes the unit. The result is absent in case of 'aborted' observation.
n+1	[0..1]	observation/ interpretationCode			One or more codes interpreting the result, expressed with ObservationInterpretation vocabulary (e.g., H = high, L = low) In case of a antimicrobial susceptibility test in microbiology, the vocabulary domain is ObservationInterpretationSusceptibility: S = susceptible R = resistant I = intermediate SDD = susceptible dose dependent
n+1	[0..1]	observation/ methodCode	code		method used for this observation expressed with ObservationMethod vocabulary (CWE)
Subject in case of a non-human subject attached to the Observation					
n+1	[0..1]	observation/subject	typeCode	SBJ	→ See Tables 6.3.4.3-1 and 6.3.4.4-1
performer participation. Performer to supersede those recorded at higher level.					
n+1	[0..*]	observation/ performer	typeCode	PRF	
author participation used to supersede the authors of higher level.					

Lvl	Card	Parent/element	Attribute	Value	Comments
n+1	[0..*]	observation/author	typeCode	AUT	
Other participants such as verifier (AUTHEN) **or responsible party** (RESP)					
n+1	[0..*]	observation/ participant	typeCode	{AUTHEN |RESP |DEV}	→ See 6.3.4.16 AUTHEN for verifier, RESP for responsible party DEV for device (e.g., lab analyzer)
Specimen or **Comment** on this Observation					
n+1	[0..*]	observation/ entryRelationship			→ Specimen Collection (6.3.4.5) → Annotation Comment (6.3.4.15)
Previous observations obtained for the same patient, test, same method, same unit (1)					
n+1	[0..*]	observation/ entryRelationship	typeCode	REFR	Refers to a previous observation for the same test code on a previous specimen.
n+2	[1..1]	entryRelationship/ observation	classCode	OBS	
			moodCode	EVN	
n+3	[1..1]	observation/code			The same test code
n+3	[1..1]	observation/ statusCode	code	completed	
n+3	[1..1]	observation/ effectiveTime	value		The clinically relevant date/time of the previous result obtained for this test.
n+3	[1..1]	observation/value			The previous result obtained for this test
Reference range for the current test result					
n+1	[0..1]	observation/ referenceRange	typeCode	REFV	
n+2	[1..1]	referenceRange/ observationRange	classCode	OBS	
			moodCode	EVN.CRT	
n+5	[0..1]	observationRange/ value			interval (IVL) representation
n+5	[1..1]	observationRange/ interpretationCode	code	N	These are normal ranges
n+5	[0..*]	observationRange/ preCondition	typeCode	PRCN	Extension to CDA Clinical statement
n+6	[1..1]	precondition/ criterion	classCode	COND	
			moodCode	EVN	
n+7	[1..1]	criterion/code	code		Code of the criterion (e.g., age, sex)
n+7	[1..1]	criterion/value	value		Value of the criterion

930 **Note 1**:An Observation MAY be complemented by any number of previous results as pertinent information related to it. This is represented with an entryRelationship of typeCode=”REFR” pointing to an observation element delivering the previous result, and carrying the same test code. In case there is more than one previous result, the entryRelationship elements are sorted in reverse chronological order, and numbered from 1 to n by sequenceNumber.


```
<observation classCode="OBS" moodCode="EVN">
  <templateId root="1.3.6.1.4.1.19376.1.3.1.6"/>
  <code code="11273-0" codeSystem="2.16.840.1.113883.6.1"
    codeSystemName="LOINC" displayName="ERYTHROCYTES"/>
  <statusCode code="completed"/>
  <effectiveTime value="20060321063000.0000-0500"/>
  <value xsi:type="PQ" value="4.95" unit="10*6/mm3"/>
  <interpretationCode code="N" codeSystem="2.16.840.1.113883.5.83"/>
  <entryRelationship typeCode="COMP">
    <procedure classCode="PROC" moodCode="EVN">
      <!-- Specimen collection -->
      <templateId root="1.3.6.1.4.1.19376.1.3.1.2"/>
      ...
      <entryRelationship typeCode="COMP">
        <act classCode="ACT" moodCode="EVN">
          <templateId root="1.3.6.1.4.1.19376.1.3.1.3"/>
          ...
        </act>
      </entryRelationship>
    </procedure>
  </entryRelationship>
  <entryRelationship typeCode="REFR">
    <!-- Previous result 4.85 from Mar 12, 2006 08:15 -->
    <observation classCode="OBS" moodCode="EVN">
      <code code="11273-0" codeSystem="2.16.840.1.113883.6.1"/>
      <statusCode code="completed"/>
      <effectiveTime value="20060312081500.0000-0500"/>
      <value xsi:type="PQ" value="4.85" unit="10*6/mm3"/>
    </observation>
  </entryRelationship>
  <!--       reference range given patient sex -->
  <referenceRange typeCode="REFV">
    <observationRange classCode="OBS" moodCode="EVN.CRT">
      <interpretationCode code="N"/>
      <value xsi:type="IVL_PQ">
        <low value="4.50" unit="10*6/mm3"/>
        <high value="6.00" unit="10*6/mm3"/>
      </value>
      <lab:precondition typeCode="PRCN">
        <lab:criterion classCode="COND">
          <lab:code code="SEX"/>
          <lab:value xsi:type="CD" code="M" codeSystem="2.16.840.1.113883.5.1"/>
        </lab:criterion>
      </lab:precondition>
    </observationRange>
  </referenceRange>
</observation>
```

Figure 6.3.4.13-1: Laboratory Observation Example

6.3.4.14 Multimedia Embedded Content

The embedding of multimedia content (e.g., a small image of an electrophoresis chart) in a Laboratory Report is consistent with the CDA R2 Standard. The CDA schema allows both embedded multimedia objects and referenced external multimedia objects. However, this content module restrains the use to embedded multimedia objects only. Additionally, the embedded

content SHALL be B64 encoded. This is indicated by setting `observationMedia/value/representation="B64"`. This profile supports only small images in *gif*, *jpeg*, *png* or *bmp* format, which are in most cases, not real pictures but simple graphics, such as an electrophoresis chart, embedded in the report, or an illustration of the test results. The sharing of real images (e.g., a picture taken from a microscope, such as the picture of a kariotype) will be addressed in the future by an extension of the Laboratory Technical Framework.

```
<section>
  <text>
    ...
    <renderMultimedia referencedObject="ELECTRO"/>
    ...
  </text>
  <entry>
    ...
    <observationMedia classCode="OBS" moodCode="EVN" ID="ELECTRO">
      <value mediaType="image/gif" representation="B64">Here is the inline B64
        multimedia content</value>
    </observationMedia>
    ...
  </entry>
</section>
```

Figure 6.3.4.14-1: Multimedia Content Example

6.3.4.15 Annotation Comment (PCC) 1.3.6.1.4.1.19376.1.5.3.1.4.2

This content module is defined in PCC TF-2:6.3.4.6. It enables representation of a comment at any level within the entry.


```
<section>
  <text>
    <table>
      <thead ID="isolateTest">
        ...
      </thead>
      <tfoot>
        <tr ID="isolateTestComment0">
          <td>Salmonella is a Public Health notifiable condition.
              A report has been forwarded.</td>
        </tr>
        <tr ID="isolateTestComment1">
          ...
        </tr>
      </tfoot>
      ...
    </table>
  </text>
  <entry>
    ...
    <component>
      <observation classCode="OBS" moodCode="EVN">
        <templateId root="1.3.6.1.4.1.19376.1.3.1.6"/>
          ...
          <entryRelationship typeCode="COMP">
            <act classCode="ACT" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.40"/>
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.2"/>
              <code code="48767-8" codeSystem="2.16.840.1.113883.6.1"
                codeSystemName="LOINC" displayName="Annotation Comment"/>
              <text><reference value="isolateTestComment0"/></text>
              <statusCode code="completed"/>
            </act>
          </entryRelationship>
      </observation>
    </component>
  </entry>
</section>
```

Figure 6.3.4.15-1: Comment on Observation Example

6.3.4.16 Additional Participant

This content module represents a participant, which can be either a validator (typeCode="AUTHEN"), a responsible party (typeCode="RESP") or a device like the analyzer that performed the tests (typeCode="DEV"), associated to any object (Report_Entry, SpecimenObservationCluster, Battery, Observation) in the `entry`.

The participant MAY be:

- The validator (typeCode="AUTHEN") of the observations of this part of the report. See 6.3.2.16 for more information on "validator".

- A device (typeCode=”DEV”), which was used to produce this set of results, for instance an analyzer.
- The person responsible (typeCode=”RESP”) for the provision of the observations of this part of the report. In the case where a subset of the observations is subcontracted to an external laboratory, this external laboratory (with its address and telecom) and the actual performer is represented by a `performer` element, whereas the Director of this subcontractor laboratory is carried by a `participant@typeCode=”RESP”/participantRole/playingentity/name`
- the `participant` element being attached to the same level as the `performer` element.

This module is consistent with the CDA standard regarding participant and requires in addition the `name`, `addr` and `telecom` for all participants.

6.4 Section not applicable

This heading is not used in a CDA document.

6.5 PaLM Value Sets

Intentionally left blank.

Appendices

Appendix A – Extensions to CDA R2

A.1 General Rules Respected by PaLM Extensions to CDA R2

The extension brought to the CDA model, for follows the same rules as those defined in the "Care Continuity Document" (CCD®[5]) implementation guide:

- An extension is a collection of element or attribute declarations and rules for their application to the CDA Release 2.0.
- All extensions are optional. An extension **MAY** be used, but **NEED NOT** be.
- A single namespace for all extension elements or attributes that **MAY** be used by this profile is defined as follows:
  - `urn:oid:1.3.6.1.4.1.19376.1.3.2`
- This namespace **SHALL** be used as the namespace for any extension elements or attributes that are defined by this implementation guide.
- Each extension element **SHALL** use the same HL7 vocabularies and data types used by CDA Release 2.0.
- Each extension element **SHALL** use the same conventions for order and naming as is used by the current HL7 tooling.
- An extension element **SHALL** appear in the XML where the expected RIM element of the same name would have appeared had that element not been otherwise constrained from appearing in the CDA XML schema.

A.2 Pre-condition Criterion on Reference Range

The Clinical Statement of CDA does not support the association of a criterion with a reference range, thus forbidding expressing in a Laboratory Report that a reference range is conditioned by the patient's sex, and/or the patient's age.

The extension to express these criteria is the same that has been adopted by the "Care Continuity Document" implementation guide: It adds a precondition actRelationship between ObservationRange class and Criterion class of the CDA entry model, as shown on the figure below:

[5] CCD is the registered trademark of Health Level Seven International.

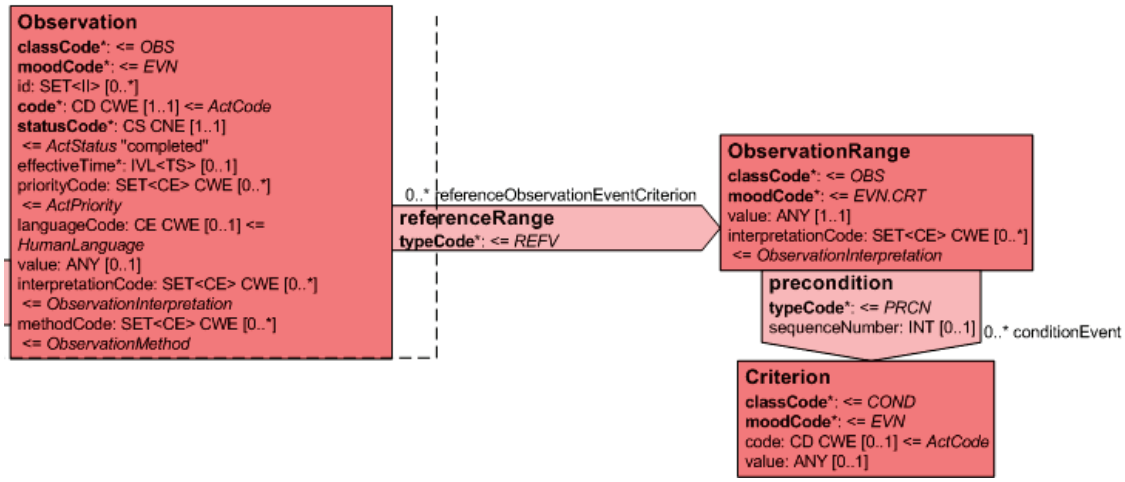

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Figure A.2-1: Associating criteria to the reference range of an observation

```
<ClinicalDocument xmlns="urn:hl7-org:v3" xmlns:lab="urn:oid:1.3.6.1.4.1.19376.1.3.2"
  xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
  ...
  <!-- The appropriate reference range is selected according to patient sex and age
       (2 criteria)-->
  <referenceRange typeCode="REFV">
    <observationRange classCode="OBS" moodCode="EVN.CRT">
      <value xsi:type="IVL_PQ">
        <low value="4.50" unit="10*6/mm3"/>
        <high value="6.00" unit="10*6/mm3"/>
      </value>
      <lab:precondition typeCode="PRCN">
        <lab:criterion classCode="COND">
          <lab:code code="SEX"/>
          <lab:value xsi:type="CD" code="M" codeSystem="2.16.840.1.113883.5.1"/>
        </lab:criterion>
      </lab:precondition>
      <lab:precondition typeCode="PRCN">
        <lab:criterion classCode="COND">
          <lab:code code="AGE"/>
          <lab:value xsi:type="IVL_PQ">
            <lab:low value="35" unit="Y"/>
            <lab:high value="55" unit="Y"/>
          </lab:value>
        </lab:criterion>
      </lab:precondition>
    </observationRange>
  </referenceRange>
  ...
</ClinicalDocument>
```

Figure A.2-2: Pre-Condition Criterion Example

A.3 statusCode of Documented serviceEvent

A laboratory report can be final or non-final. To distinguish between the two, the `statusCode` element has been added to the `documentationOf/serviceEvent` element. A non-final report is a report documenting a `serviceEvent`, which is in the status `"active"`.

This sub-element `serviceEvent/statusCode` is optional. When it is not present the `serviceEvent` is assumed to be in the status `"completed"`.

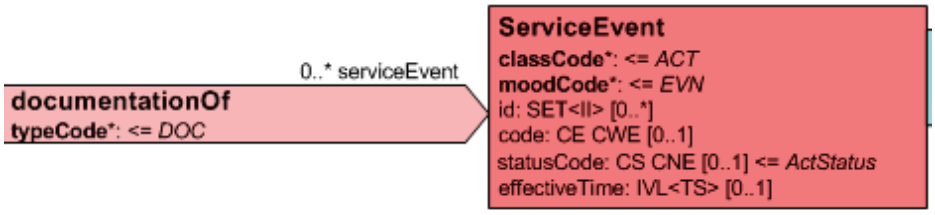

Figure A.3-1: StatusCode added to serviceEvent in the CDA header

```
<ClinicalDocument xmlns="urn:hl7-org:v3"
      xmlns:lab="urn:oid:1.3.6.1.4.1.19376.1.3.2"
      xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
   ...
   <documentationOf>
       <serviceEvent>
         <lab:statusCode code=”active”>
         <performer>
            ...
         </performer>
       </serviceEvent>
   </documentationOf>
   ...

</ClinicalDocument>
```

Figure A.3-2: Example of usage in a non-final laboratory report

Glossary

The IHE Glossary can be found as an appendix to the *IHE Technical Frameworks General Introduction*, available on this page.

