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1 Introduction

1.1 Overview of IHE

Integrating the Healthcare Enterprise (IHE) is an initiative designed to stimulate the integration of the information systems that support modern healthcare institutions. Its fundamental objective is to ensure that in the care of patients all required information for medical decisions is both correct and available to healthcare professionals. The IHE initiative is both a process and a forum for encouraging integration efforts. It defines a technical framework for the implementation of established interoperability standards to achieve specific clinical goals. It includes a rigorous testing process for the implementation of this framework, organizes educational sessions, exhibits at major meetings of medical professionals to demonstrate the benefits of this framework and encourage its adoption by industry and users.

The approach employed in the IHE initiative is to support the use of existing standards, e.g., HL7, ASTM, DICOM, ISO, IETF, OASIS, CLSI and others as appropriate, rather than to define new standards. IHE profiles further constrain configuration choices where necessary in these standards to ensure that they can be used in their respective domains in an integrated manner between different actors. When clarifications or extensions to existing standards are necessary, IHE refers recommendations to the relevant standards bodies.

1.2 Overview of the Laboratory Technical Framework

1.2.1 Production

This document, the Laboratory Technical Framework (LAB TF), defines specific implementations of established standards to achieve integration goals of clinical laboratories with other components of a healthcare enterprise or with a broader community of healthcare providers, hereafter called a healthcare community.

This document is updated annually, following a period of public review, and maintained regularly through the identification and correction of errata. The current version, rev. 5.0 Final Text, specifies the IHE transactions defined and implemented as of November 2013. The latest version of the document is always available via the Internet at http://www.ihe.net/Technical_Framework.

It has been produced with the help of the following organizations:

- CAP (College of American Pathologists)
- ASIP Santé (Agence des Systèmes d’Information Partagés de Santé) formerly GMSIH (Groupement pour la Modernisation du Système d’Information Hospitalier)
- JAHIS (Japanese Association of Healthcare Information Systems Industry)
- IHE-J (IHE Japan)
- SFIL (Société Française d’Informatique de Laboratoire)
- HL7 and its affiliate organizations
1.2.2 How the Laboratory Technical Framework is Organized

The IHE Laboratory Technical Framework identifies a subset of the functional components of the healthcare enterprise or healthcare community, called IHE actors, and specifies their interactions in terms of a set of coordinated, standards-based transactions. It describes this body of transactions in progressively greater depth, and is organized in volumes:

- **Volume 1** of the Laboratory Technical Framework (LAB TF-1) provides a high-level view of IHE functionality, showing the transactions organized into functional units called integration profiles that highlight their capacity to address specific integration requirements for clinical purposes.

- **Volumes 2a, 2b, and 2x** of the Laboratory Technical Framework (LAB TF-2a, Lab TF-2b, LAB TF-2x) provide a detailed technical description of each message-based transaction and its messages.

- The present volume, **Volume 3** of the Laboratory Technical Framework (LAB TF-3) provides a detailed technical description of each document-based transaction, its persistent content and binding. Currently, Volume 3 describes one single document-based transaction designed for the sharing of laboratory reports. One single content module is provided, namely the laboratory report as a CDA document.

- **Volume 4** of the Laboratory Technical Framework (LAB TF-4) has been deprecated.

1.3 Audience

The intended audience of this document is:

- Technical staff of vendors participating in the IHE initiative.
- IT managers of healthcare institutions and healthcare communities.
- Experts involved in standards development.
- Anyone interested in the technical aspects of integrating healthcare information systems.

1.4 Relationship to Standards

The IHE Laboratory Technical Framework identifies functional components of a distributed healthcare environment (referred to as IHE actors), solely from the point of view of their interactions in the healthcare enterprise. At its current level of development, it defines a coordinated set of transactions based on HL7, IETF, ISO, CLSI, OASIS and W3C standards. As the scope of the IHE initiative expands, transactions based on other international standards MAY be included as required.

In some cases, IHE recommends selection of specific options supported by these standards; however, IHE does not introduce technical choices that contradict conformance to these standards. If errors in or extensions to existing standards are identified, IHE’s policy is to report them to the appropriate standards bodies for resolution within their conformance and standards evolution strategy.
IHE is therefore an implementation framework, not a standard. Conformance claims for products must still be made in direct reference to specific standards. In addition, vendors who have implemented IHE integration capabilities in their products MAY publish IHE Integration Statements to communicate their products’ capabilities. Vendors publishing IHE Integration Statements accept full responsibility for their content. By comparing the IHE Integration Statements from different products, a user familiar with the IHE concepts of actors and integration profiles can determine the level of integration between them.

### 1.5 Relationship to Real-world Architectures

The IHE Actors and transactions are abstractions of the real-world healthcare information system environment. While some of the transactions are traditionally performed by specific product categories (e.g., Hospital Information System, Electronic Patient Record, Clinical Information System, Laboratory Information System, Laboratory Automation System, Analyzer, Robotic Transportation System and other pre and post-analytic process equipment), the IHE Laboratory Technical Framework intentionally avoids associating functions or actors with such product categories. For each actor, the IHE Laboratory Technical Framework defines only those functions associated with integrating information systems. The IHE definition of an actor should therefore not be taken as the complete definition of any product that might implement it, nor should the framework itself be taken to comprehensively describe the architecture of a healthcare information system.

### 1.6 Comments

IHE International welcomes comments on this document and the IHE initiative. They should be directed to the co-chairs of the IHE Laboratory Committee, using the address lab@ihe.net.

### 1.7 Copyright Permissions

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.

IHE grants permission to Health Level Seven Inc. and its affiliate organizations to reproduce either parts of this document or the document in its entirety.

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IHE grants permission to CLSI to reproduce either parts of this document or the document in its entirety.

### 1.8 IHE Technical Framework Development and Maintenance Process

The IHE Laboratory Technical Framework is being continuously extended and maintained by the IHE Laboratory Technical committee. The development and maintenance process of the Framework follows a number of principles to ensure stability of the specification so that both vendors and users MAY use it reliably in specifying, developing and acquiring systems with IHE integration capabilities.
The first of these principles is that any extensions, clarifications and corrections to the Technical Framework must maintain backward compatibility with previous versions of the framework in order to maintain interoperability with systems that have implemented IHE Actors and Integration Profiles defined there.

1.9 Technical Framework Cross-references

When references are made to another section within a Technical Framework volume, a section number is used by itself. When references are made to other volumes or to a Technical Framework in another domain, the following format is used:

\(<\text{domain designator}>\) TF-<volume number>: <section number>, where

\(<\text{domain designator}>\) is a short designator for the IHE domain (ITI = IT Infrastructure, PCC = Patient Care Coordination, LAB = Laboratory)

<volume number> is the applicable volume within the given Technical Framework (e.g., 1, 2, 3),

<section number> is the applicable section number.

For example: ITI TF-1: 3.1 refers to Section 3.1 in volume 1 of the IHE IT Infrastructure.

When references are made to Transaction numbers in the Technical Framework, the following format is used:

\([<\text{domain designator}>]<\text{transaction number}>\], where

<transaction number> is the transaction number within the specified domain. For example: [LAB-1] refers to Transaction 1 from the IHE Laboratory Technical Framework, [ITI-30] refers to Transaction 30 from the IT Infrastructure Technical Framework.

1.10 Glossary

The glossary of all terms, acronyms and abbreviations used in any volume of the Laboratory Technical Framework is in section 1.11 of Volume 1: LAB TF-1:1.11
2 Sharing Laboratory Reports (XD-LAB) Content Module

This Content Integration Profile describes a laboratory report as an electronic document to be published towards a document sharing resource such as an Electronic Health Record (EHR) or Personal Health Record (PHR) shared by a community of care providers, using one of the document sharing profiles defined in ITI-TF.

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 (see definition of these terms in LAB TF-1:3.5.3) for a patient. The report is shared in a human-readable format. In addition, this electronic laboratory report SHALL contain test results in a machine-readable format, to facilitate the integration of these observations in the database of a consumer system.

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 laboratory report described in this profile, with its set of test results in a machine-readable format, MAY also be used to share historical results with appropriate content anonymization and patient identification pseudonymization to create shared distributed repositories of laboratory information.

2.1 Referenced Standards and Profiles

HL7 CDA Release 2.0 (denoted HL7 CDA R2, or just CDA, in subsequent text)

2.2 XDS Metadata

XD-LAB is a CDA R2 document and thus conforms to the XDS Metadata requirements in PCC TF-2: 5 unless otherwise specified below.

2.2.1 XDSDocumentEntry

XD-LAB leverages the XDS DocumentEntry Metadata requirements in PCC TF-2: 5.1.1.1.1, unless otherwise specified below.

2.2.1.1 XDSDocumentEntry.eventCodeList

XD-LAB documents further constrain the XDSDocumentEntry.eventCodeList to the following:
### XDSDocumentEntry

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Usage</th>
<th>Source Type</th>
<th>Source/ Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>eventCodeList</td>
<td>R2(^1)</td>
<td>SAT</td>
<td>ClinicalDocument / component / structuredBody / component / section / entry / act / entryRelationship / organizer (templateId=&quot;1.3.6.1.4.1.19376.1.3.1.1&quot;)/ component / observation(templateId=&quot;1.3.6.1.4.1.19376.1.3.1.1.1&quot;)/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.</td>
</tr>
</tbody>
</table>

Note 1: The usage requirement ‘R2’ is a synonym of the usage requirement code ‘RE’ which appears in the volume 2 of this TF. R2 is retained in this volume 3 for consistency with all other content profiles specifications across IHE domains.

#### 2.2.1.2 XDSDocumentEntry.formatCode

The XDSDocumentEntry.formatCode SHALL be **urn:ihe:lab:xd-lab:2008**

The associated codingScheme Slot SHALL be 1.3.6.1.4.1.19376.1.2.3

#### 2.2.1.3 XDSDocumentEntry.parentDocumentRelationship

XD-LAB only permits the “replace” relationship between instances of XD-LAB documents. Thus, XDSDocumentEntry.parentDocumentRelationship is constrained to only the "RPLC" value.

#### 2.2.2 XDSSubmissionSet

No additional constraints. For more information, see PCC TF-2: 5.1.1.1.2.

#### 2.2.3 XDSFolder

No additional requirements. For more information, see PCC TF-2: 5.1.1.1.3.

#### 2.3 Specification

CDA Release 2.0 documents that conform to the requirements of this content module SHALL indicate their conformance by the inclusion of the appropriate **templateId** elements in the header of the document. This is shown in the sample document below. A CDA Document MAY conform to more than one template. Additionally, all persons (including the patient) and all organizations mentioned in the document SHALL be represented with elements **name**, **addr** and **telecom**. If in the event a unit of information about an entity is not known or has been de-identified, the use of **nullFlavor** is appropriate.
2.3.1 Identifiers Defined or Referenced by the Laboratory Report

The Content Modules of the Laboratory Technical Framework define or reference the following template identifiers:

<table>
<thead>
<tr>
<th>Template Id</th>
<th>CDA Element</th>
<th>Usage</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.3.6.1.4.1.19376.1.3.3</td>
<td>ClinicalDocument</td>
<td>R</td>
<td>Template specifying the CDA R2 laboratory report. (2.3.3.5)</td>
</tr>
<tr>
<td>1.3.6.1.4.1.19376.1.3.3.1.2</td>
<td>ClinicalDocument/recordTarget</td>
<td>R2</td>
<td>Non-Human Subject template in the CDA header (2.3.3.13.2 and 2.3.5.3)</td>
</tr>
<tr>
<td>1.3.6.1.4.1.19376.1.3.3.1.3</td>
<td>ClinicalDocument/recordTarget</td>
<td>R2</td>
<td>Human (Patient) paired with Non-Human Subject template in the CDA header (2.3.3.13.3 and 2.3.5.4)</td>
</tr>
<tr>
<td>1.3.6.1.4.1.19376.1.3.3.1.4</td>
<td>ClinicalDocument/intendedRecipient</td>
<td>O</td>
<td>Intended Recipient template in the CDA header (2.3.3.16)</td>
</tr>
<tr>
<td>1.3.6.1.4.1.19376.1.3.3.1.5</td>
<td>ClinicalDocument/ authenticator, entry/act/.../participant (‘AUTHEN’)</td>
<td>O</td>
<td>Laboratory Results Validator template in the CDA header (2.3.3.18) and in an entry of the CDA body</td>
</tr>
<tr>
<td>1.3.6.1.4.1.19376.1.3.3.1.6</td>
<td>ClinicalDocument/ Participant (‘REF’)</td>
<td>O</td>
<td>Ordering Provider template in the CDA header (2.3.3.19)</td>
</tr>
<tr>
<td>1.3.6.1.4.1.19376.1.3.3.1.7</td>
<td>ClinicalDocument/ documentationOf/ serviceEvent/performer, entry/act/.../performer</td>
<td>O</td>
<td>Laboratory Performer template in the CDA header and in an entry of the CDA body (2.3.3.22)</td>
</tr>
<tr>
<td>1.3.6.1.4.1.19376.1.3.3.2.1</td>
<td>ClinicalDocument/ component/structuredBody/ component/ section</td>
<td>R</td>
<td>Laboratory Specialty Section template in the CDA body (2.3.4.1)</td>
</tr>
<tr>
<td>1.3.6.1.4.1.19376.1.3.3.2.2</td>
<td>ClinicalDocument/ component/structuredBody/ component/ section/component/section</td>
<td>O</td>
<td>Laboratory Report Item Section template in the CDA body (2.3.4.2)</td>
</tr>
<tr>
<td>1.3.6.1.4.1.19376.1.3.1</td>
<td>ClinicalDocument/ component/structuredBody/ component/ section/.../entry</td>
<td>R</td>
<td>Laboratory Data Processing Entry template in the CDA body (2.3.5.2)</td>
</tr>
<tr>
<td>1.3.6.1.4.1.19376.1.3.1.2</td>
<td>ClinicalDocument/ component/structuredBody/ component/ section/.../entry/act/.../ entryRelationship/procedure</td>
<td>R2</td>
<td>Specimen Collection template in an entry of the CDA body (2.3.5.5)</td>
</tr>
<tr>
<td>1.3.6.1.4.1.19376.1.3.1.3</td>
<td>ClinicalDocument/ component/structuredBody/ component/ section/.../entry/act/.../ entryRelationship/procedure/ entryRelationship/act</td>
<td>R2</td>
<td>Specimen Received template in an entry of the CDA body (2.3.5.6)</td>
</tr>
<tr>
<td>Template Id</td>
<td>CDA Element</td>
<td>Usage</td>
<td>Description</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>------------------------------------------------------------------------------</td>
<td>-------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>1.3.6.1.4.1.19376.1.3.1.1.1</td>
<td>ClinicalDocument/component/structuredBody/component/.../entry/act/.../entryRelationship/organizer</td>
<td>R2(^1)</td>
<td>Notification Organizer template in an entry of the CDA body (2.3.5.7)</td>
</tr>
<tr>
<td>1.3.6.1.4.1.19376.1.3.1.1.1</td>
<td>ClinicalDocument/component/structuredBody/component/.../entry/act/.../entryRelationship/organizer/component/observation</td>
<td>R2(^1)</td>
<td>Notifiable Condition template in an entry of the CDA body (2.3.5.7.1)</td>
</tr>
<tr>
<td>1.3.6.1.4.1.19376.1.3.1.1.2</td>
<td>ClinicalDocument/component/structuredBody/component/section/.../entry/act/.../entryRelationship/organizer/component/observation</td>
<td>R2(^1)</td>
<td>Case Identifier template in an entry of the CDA body (2.3.5.7.2)</td>
</tr>
<tr>
<td>1.3.6.1.4.1.19376.1.3.1.1.3</td>
<td>ClinicalDocument/component/structuredBody/component/section/.../entry/act/.../entryRelationship/organizer/component/observation</td>
<td>R2(^1)</td>
<td>Outbreak Identifier template in an entry of the CDA body (2.3.5.7.3)</td>
</tr>
<tr>
<td>1.3.6.1.4.1.19376.1.3.1.1.5</td>
<td>ClinicalDocument/component/structuredBody/component/section/.../entry/act/.../entryRelationship/organizer</td>
<td>R2(^1)</td>
<td>Laboratory Isolate Organizer template in an entry of the CDA body (2.3.5.8)</td>
</tr>
<tr>
<td>1.3.6.1.4.1.19376.1.3.1.1.4</td>
<td>ClinicalDocument/component/structuredBody/component/section/.../entry/act/.../entryRelationship/organizer</td>
<td>R2(^1)</td>
<td>Laboratory Battery Organizer template in an entry of the CDA body (2.3.5.9)</td>
</tr>
<tr>
<td>1.3.6.1.4.1.19376.1.3.1.1.6</td>
<td>ClinicalDocument/component/structuredBody/component/section/.../entry/act/.../entryRelationship/observation</td>
<td>R</td>
<td>Laboratory Observation template in an entry of the CDA body (2.3.5.10)</td>
</tr>
<tr>
<td>1.3.6.1.4.1.19376.1.5.3.1.4.2</td>
<td>ClinicalDocument/component/structuredBody/component/section/.../entry/act/.../entryRelationship/act</td>
<td>O</td>
<td>Annotation Comment in an entry of the CDA body (0). This template is defined in PCC TF-2: 6.4.4.6</td>
</tr>
</tbody>
</table>

Note 1: The usage requirement ‘R2’ is a synonym of the usage requirement code ‘RE’ which appears in the volume 2 of this TF. R2 is retained in this volume 3 for consistency with all other content profiles specifications across all IHE domains.

In addition, this IHE Laboratory Technical Framework uses the two following identifiers:

<table>
<thead>
<tr>
<th>OID</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.3.6.1.4.1.19376.1.3.2</td>
<td>Namespace protecting the single extension brought to the CDA R2 standard</td>
</tr>
<tr>
<td>1.3.6.1.4.1.19376.1.3.4</td>
<td>Root identifier used by example instances of documents</td>
</tr>
</tbody>
</table>
2.3.2 Vocabularies Used by the Laboratory Report

2.3.2.1 LOINC
265 codeSystem: 2.16.840.1.113883.6.1
266 codeSystemName: LOINC
267 Description: Logical Observation Identifier Names and Codes
268 A LOINC tests codes subset is provided in Volume 4 of the Laboratory Technical Framework: IHE LAB TF-4 “LOINC Laboratory Test Code Set”.
269 In addition, this specification uses LOINC codes to define types of laboratory reports in the CDA header, and types of sections in the CDA body.

2.3.2.2 Use of SNOMED CT Terminology
270 codeSystem: 2.16.840.1.113883.6.96
271 codeSystemName: SNOMED-CT
272 Description: SNOMED Controlled Terminology
273 Some countries will take from SNOMED CT some of the vocabulary domains needed by the entries of the Laboratory Report. (e.g., specimen types, isolates, antibiotics). The usage of SNOMED CT in a laboratory report is not constrained by this specification. These tasks are left up to realms.

2.3.2.3 Use of IHEActCode Vocabulary
276 codeSystem: 1.3.5.1.4.1.19376.1.5.3.2
277 codeSystemName: IHEActCode
278 Description: A small vocabulary of clinical acts defined in PCC TF-2:6.1.1

2.3.3 Content Modules for CDA Header (Level 1)
279 This section describes the CDA header of the clinical laboratory report.
280 Most of the constraints on this CDA header are derived from national regulations and conventions, and therefore are defined in the context of a realm (e.g., a country). Being international, this IHE content profile does not supersede constraints that have been (or will be) defined by realm implementation guides.
281 For instance, most of the constraints on the header provided by the Continuity of Care Document (CCD) CDA Implementation Guide for the US realm, will also apply to the Clinical Laboratory Report in the US. Similarly, the constraints on the CDA header provided by the French “Guide d’Implémentation de l’entête CDA” will also apply to the Clinical Laboratory Report in France.
282 The header identifies the patient, the clinical laboratory that produced the report, the physician that ordered the tests, the encounter in which this act was performed, and other participants to this document (author, custodian, legal authenticator…). This information SHALL be rendered to the human reader of the electronic document, together with the content of the body. Seeing the body of the document without the header makes no sense.
Table 2.3.3-1: CDA Header Templates

<table>
<thead>
<tr>
<th>Template Id</th>
<th>CDA Element</th>
<th>Usage</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.3.6.1.4.1.19376.1.3.3</td>
<td>ClinicalDocument</td>
<td>R</td>
<td>Template specifying the CDA R2 laboratory report. (2.3.3.5)</td>
</tr>
<tr>
<td>1.3.6.1.4.1.19376.1.3.3.1.2</td>
<td>ClinicalDocument/recordTarget</td>
<td>R2(^i)</td>
<td>Non-Human Subject template in the CDA header (2.3.3.13.2 and 2.3.5.3)</td>
</tr>
<tr>
<td>1.3.6.1.4.1.19376.1.3.3.1.3</td>
<td>ClinicalDocument/recordTarget</td>
<td>R2(^i)</td>
<td>Human (Patient) paired with Non-Human Subject template in the CDA header (2.3.3.13.3 and 2.3.5.4)</td>
</tr>
<tr>
<td>1.3.6.1.4.1.19376.1.3.3.1.4</td>
<td>ClinicalDocument/intendedRecipient</td>
<td>O</td>
<td>Intended Recipient template in the CDA header (2.3.3.16)</td>
</tr>
<tr>
<td>1.3.6.1.4.1.19376.1.3.3.1.5</td>
<td>ClinicalDocument/authorenticator,entry/act/.../participant (‘AUTHEN’)</td>
<td>O</td>
<td>Laboratory Results Validator template in the CDA header and in an entry of the CDA body (2.3.3.18)</td>
</tr>
<tr>
<td>1.3.6.1.4.1.19376.1.3.3.1.6</td>
<td>ClinicalDocument/Participant (‘REF’)</td>
<td>O</td>
<td>Ordering Provider template in the CDA header (2.3.3.19)</td>
</tr>
<tr>
<td>1.3.6.1.4.1.19376.1.3.3.1.7</td>
<td>ClinicalDocument/documentationOf/serviceEvent/performer, entry/act/.../performer</td>
<td>O</td>
<td>Laboratory Performer template in the CDA header and in an entry of the CDA body (2.3.3.22)</td>
</tr>
</tbody>
</table>

Note 1: The usage requirement ‘R2’ is a synonym of the usage requirement code ‘RE’ which appears in the volume 2 of this TF. R2 is retained in this volume 3 for consistency with all other content profiles specifications across all IHE domains.

2.3.3.1 General Constraints on Persons and Organizations Mentioned

All persons (including the patient) and organizations mentioned in the document SHALL provide elements name, addr and telecom.

2.3.3.2 ClinicalDocument

The root of a clinical laboratory report SHALL be a ClinicalDocument element from the urn:hl7-org:v3 namespace.

2.3.3.3 ClinicalDocument/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 of this profile used as it is without any further extension, 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 US extension: <realmCode code="USA"/>  
Example for a French extension: <realmCode code="France"/>
2.3.3.4 ClinicalDocument/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"/>

2.3.3.5 ClinicalDocument/templateId

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

<templateId root="1.3.6.1.4.1.19376.1.3.3"/>

2.3.3.6 ClinicalDocument/id

ClinicalDocument/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. In this case the OID populated in the root attribute is the unique instance identifier itself (The OID in this example is constructed from the OID dedicated to all examples in IHE LAB TF: 1.3.6.1.4.1.19376.1.3.4):  

<id root="1.3.6.1.4.1.19376.1.3.4.1232669"/>

2.3.3.7 ClinicalDocument/code

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

2.3.3.7.1 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"/>
2.3.3.7.2 Single Discipline Laboratory Report

Use the appropriate LOINC code as listed in table “Laboratory Specialties” in section 2.3.4.1.1.

2.3.3.8 ClinicalDocument/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.

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

2.3.3.9 ClinicalDocument/confidentialityCode

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

2.3.3.10 ClinicalDocument/languageCode

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

Example of a report authored in American English:
```xml
<languageCode code="en-US" codeSystem="2.16.840.1.113883.6.121"/>
```

Example of a report authored in French:
```xml
<languageCode code="fr-FR" codeSystem="2.16.840.1.113883.6.121"/>
```

2.3.3.11 ClinicalDocument/setId

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

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

2.3.3.12 ClinicalDocument/versionNumber

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

2.3.3.13 ClinicalDocument/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:

2.3.3.13.1 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 2.3.3.13.1-1a: 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:
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 (2.3.5.3).

```
<recordTarget typeCode="RCT">
  <patientRole classCode="PAT">
    <id extension="66373839" 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="PSH">
      <name nullFlavor="MSK"/> <!-- masked value -->
      <administrativeGenderCode code="F"/>
      <birthTime value="19401213000000.0000-0500"/>
    </patient>
  </patientRole>
</recordTarget>
```
2.3.3.13.3 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 (2.3.5.4).

```
<recordTarget typeCode="RCT">
  <templateId root="1.3.6.1.4.1.19376.1.3.3.1.3"/>
  <patientRole classCode="PAT">
    <id extension="sw53421" 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="19401213000000-0500"/>
    </patient>
  </patientRole>
</recordTarget>
```

**Figure 2.3.3.13.3-1: 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.
2.3.3.14 ClinicalDocument/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.

```xml
<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 2.3.3.14-1: Example of Report Authored by a System

```xml
<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 2.3.3.14-2: Example of Report Authored by a Person
2.3.3.15 ClinicalDocument/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.

```xml
<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"/>
    </representedCustodianOrganization>
    <addr>
      <streetAddressLine>21 North Ave</streetAddressLine>
      <city>Burlington</city>
    </addr>
  </assignedCustodian>
</custodian>
```

Figure 2.3.3.15-1: Example of a Custodian

2.3.3.16 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.
2.3.3.17 ClinicalDocument/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 2.3.3.18.
2.3.3.18 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".

---

**Figure 2.3.3.17-1: Legal Authenticator Example**

```xml
<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 2.3.3.18-1: Laboratory Results Single Validator Example
Figure 2.3.3.18-2: Laboratory Results Multiple Validators Example
2.3.3.19 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.

```xml
<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 2.3.3.19-1: Ordering Provider Example

2.3.3.20 ClinicalDocument/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 Glossary: LAB TF-1:1.11 and in “Product Implementation” section: LAB TF-1:3.5.3). 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”

2.3.3.21 ClinicalDocument/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 <code>documentationOf/serviceEvent/effectiveTime</code> to document the time boundaries of events in the document is appropriate.

This laboratory report content module adds the optional sub element <code>documentationOf/serviceEvent/statusCode</code> 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., <code>serviceEvent/statusCode@code="active"</code>). The statusCode sub element is an extension to the CDA R2 schema further described in section 2.3.5 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.

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

Figure 2.3.3.21-1: DocumentationOf – Example of a final report

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

Figure 2.3.3.21-2: DocumentationOf – Example of a non-final report

More requirements regarding replacement of a report by a new version are provided in notes 1, 2 and 3 of section 2.3.3.23.
2.3.3.22 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".

```xml
<!-- 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>
                <documentationOf>
                  <ClinicalDocument>
                </documentationOf>
              </performer>
            </assignedEntity>
          </representedOrganization>
        </representedOrganization>
      </assignedEntity>
    </performer>
  </serviceEvent>
</documentationOf>
</ClinicalDocument>
```

Figure 2.3.3.22-1: Laboratory Single Performer Example
Figure 2.3.3.22-2: Laboratory Multiple Performers Example
**2.3.3.23 ClinicalDocument/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 2.3.3.23-1: 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 Actor 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"

The Document Source Actor 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.
2.3.3.24 ClinicalDocument/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 2.3.3.24-1: Example of an Encompassing Encounter
2.3.4 Content Modules for CDA Sections (Level 2)

A laboratory 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 text 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 (especially in microbiology), or an individual test.

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

### Table 2.3.4-1: CDA Section Templates

<table>
<thead>
<tr>
<th>Template Id</th>
<th>CDA Element</th>
<th>Usage</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.3.6.1.4.1.19376.1.3.3.2.1</td>
<td>ClinicalDocument/component/structuredBody/component/section</td>
<td>R</td>
<td>Laboratory Specialty Section template in the CDA body (2.3.4.1)</td>
</tr>
<tr>
<td>1.3.6.1.4.1.19376.1.3.3.2.2</td>
<td>ClinicalDocument/component/structuredBody/component/section/component/section</td>
<td>O</td>
<td>Laboratory Report Item Section template in the CDA body (2.3.4.2)</td>
</tr>
</tbody>
</table>

2.3.4.1 Laboratory Specialty Section 1.3.6.1.4.1.19376.1.3.3.2.1

2.3.4.1.1 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 microbiology report, a virology report), or from any number of specialties (a report from a multidisciplinary laboratory). The structure of the report 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 2.3.4.1.1-1: Laboratory Specialties

<table>
<thead>
<tr>
<th>LOINC code</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>18717-9</td>
<td>BLOOD BANK STUDIES</td>
</tr>
<tr>
<td>18718-7</td>
<td>CELL MARKER STUDIES</td>
</tr>
<tr>
<td>18719-5</td>
<td>CHEMISTRY STUDIES</td>
</tr>
<tr>
<td>18720-3</td>
<td>COAGULATION STUDIES</td>
</tr>
<tr>
<td>18721-1</td>
<td>THERAPEUTIC DRUG MONITORING STUDIES</td>
</tr>
<tr>
<td>18722-9</td>
<td>FERTILITY STUDIES</td>
</tr>
<tr>
<td>LOINC code</td>
<td>Name</td>
</tr>
<tr>
<td>------------</td>
<td>-------------------------------------------</td>
</tr>
<tr>
<td>18723-7</td>
<td>HEMATOLOGY STUDIES</td>
</tr>
<tr>
<td>18724-5</td>
<td>HLA STUDIES</td>
</tr>
<tr>
<td>18725-2</td>
<td>MICROBIOLOGY STUDIES</td>
</tr>
<tr>
<td>18727-8</td>
<td>SEROLOGY STUDIES</td>
</tr>
<tr>
<td>18728-6</td>
<td>TOXICOLOGY STUDIES</td>
</tr>
<tr>
<td>18729-4</td>
<td>URINALYSIS STUDIES</td>
</tr>
<tr>
<td>18767-4</td>
<td>BLOOD GAS STUDIES</td>
</tr>
<tr>
<td>18768-2</td>
<td>CELL COUNTS+DIFFERENTIAL STUDIES</td>
</tr>
<tr>
<td>18769-0</td>
<td>MICROBIAL SUSCEPTIBILITY TESTS</td>
</tr>
<tr>
<td>26435-8</td>
<td>MOLECULAR PATHOLOGY STUDIES</td>
</tr>
<tr>
<td>26436-6</td>
<td>LABORATORY STUDIES</td>
</tr>
<tr>
<td>26437-4</td>
<td>CHEMISTRY CHALLENGE STUDIES</td>
</tr>
<tr>
<td>26438-2</td>
<td>CYTOLOGY STUDIES</td>
</tr>
</tbody>
</table>

**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 Actor’s choice.

### 2.3.4.1.2 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 (particularly 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 2.3.4.2.

• **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 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.

Should a Laboratory Report contain multiple Laboratory Specialty Sections they need not adhere to the same choice of representation, that is, one MAY expect a mixture of choice 1 and choice 2 representations among multiple Laboratory Specialty Sections.
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.
(particularly in the MICROBIOLOGY STUDIES specialty). A Laboratory Report Item Section under a Laboratory Specialty Section SHALL represent only one **Report Item**.

- `<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.
2.3.4.3 Recommendations for Narrative Text

2.3.4.3.1 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, if relevant. It is specified in the Unified Code for Units of Measure (UCUM) [http://aurora.rg.iupui.edu/UCUM]. Realms MAY choose the uppercase or mixed case variants as necessary.

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, 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, arterial blood for blood gas)

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.

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)

---

1 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.
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 Actor is to put the specimen at the highest possible level in the hierarchy of the document.

### 2.3.4.3.2 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:

1. 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.

2. 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).

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

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

### 2.3.4.3.3 Reporting of 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.
2.3.5 Content Modules for CDA Entries (Level 3)

2.3.5.1 General Considerations

2.3.5.1.1 Derivation of the Text Block of a Section from the Data of an Entry

Each leaf section of the structuredBody of a laboratory report SHALL contain exactly one entry containing the machine-readable result data rendered in the section. The narrative block is entirely derived from that entry; thus the entry@typeCode attribute SHALL be “DRIV”.

2.3.5.1.2 Alignment with “Result Event” RMIM from V3 Laboratory Domain

The level 3 entries must be compatible with the results contained in message type POLB_MT004000 of the Laboratory Domain. Thus, a laboratory information system able to produce HL7 V3 results messages will easily produce lab reports from the same data. The equivalence with POLB_MT004000 is as follows:

<table>
<thead>
<tr>
<th>Result Event RMIM class</th>
<th>CDA object</th>
</tr>
</thead>
<tbody>
<tr>
<td>ObservationReport</td>
<td>ACT</td>
</tr>
<tr>
<td>ObservationBattery</td>
<td>Organizer</td>
</tr>
<tr>
<td>SpecimenObservationCluster</td>
<td>Organizer</td>
</tr>
<tr>
<td>ObservationEvent</td>
<td>Observation</td>
</tr>
</tbody>
</table>

To cope with a current limitation of vocabulary in the CDA R2 entry model, we chose to represent the ObservationReport class (classCode ENTRY) by an ACT (ACT) rather than by an ORGANIZER (CLUSTER). Although this is not the ideal solution, it is a practical and semantically appropriate solution, which avoids an extension to the x_ActClassDocumentEntryOrganizer domain vocabulary from the CDA R2 normative edition.

2.3.5.1.3 List of Content Modules Available for Level 3

<table>
<thead>
<tr>
<th>Template Id</th>
<th>CDA Element</th>
<th>Usage</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.3.6.1.4.1.19376.1.3.1.1</td>
<td>ClinicalDocument/ component/structuredBody/ component/ section/ entry</td>
<td>R</td>
<td>Laboratory Data Processing Entry template in the CDA body (2.3.5.2)</td>
</tr>
<tr>
<td>1.3.6.1.4.1.19376.1.3.1.2</td>
<td>ClinicalDocument/ component/structuredBody/ component/ section/ entry/ act.../ entryRelationship/procedure</td>
<td>R2¹</td>
<td>Specimen Collection template in the CDA body (2.3.5.5)</td>
</tr>
<tr>
<td>1.3.6.1.4.1.19376.1.3.1.3</td>
<td>ClinicalDocument/ component/structuredBody/ component/ section/ entry/ act.../ entryRelationship/procedure/ entryRelationship/act</td>
<td>R2¹</td>
<td>Specimen Received template in the CDA body (2.3.5.6)</td>
</tr>
</tbody>
</table>
### 2.3.5.1.4 Specification Tables for CDA Level 3 Content Module

All CDA level 3 content modules described in this section 2.3.5 are potentially nested under the Laboratory Report Data Processing Entry and constitute 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.
  - A cardinality of [1..1] means that the element SHALL be present once and only once.
• A cardinality \([1..\ast]\) means that the element SHALL be present at least once.
• A cardinality \([0..1]\) means the element MAY be present.
• A cardinality \([0..\ast]\) means the element MAY be present zero or more times.

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 one 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 remain as specified by the HL7 CDA R2 specification.

2.3.5.2 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 2.3.5.2-1: Structure of Laboratory Report Data Processing Entry

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

Report Item from which the section text is derived.

<table>
<thead>
<tr>
<th>n+1</th>
<th>[1..1]</th>
<th>entry/act</th>
<th>classCode</th>
<th>ACT</th>
<th>The ‘Specimen Act’. Mandatory and fixed.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>moodCode</td>
<td>EVN</td>
<td>Mandatory and fixed.</td>
</tr>
</tbody>
</table>

| 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. |

41
<table>
<thead>
<tr>
<th>Lvl</th>
<th>Card</th>
<th>Parent/element</th>
<th>Attribute</th>
<th>Value</th>
<th>Comments</th>
</tr>
</thead>
</table>
| 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**

<table>
<thead>
<tr>
<th>Lvl</th>
<th>Card</th>
<th>Parent/element</th>
<th>Attribute</th>
<th>Value</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>n+2</td>
<td>[0..1]</td>
<td>act/subject</td>
<td>typeCode</td>
<td>SBJ</td>
<td>(\rightarrow) See 2.3.5.3, 2.3.5.4</td>
</tr>
</tbody>
</table>

**performer participation** used if different from the performer of the header, to supersede it for this section.

<table>
<thead>
<tr>
<th>Lvl</th>
<th>Card</th>
<th>Parent/element</th>
<th>Attribute</th>
<th>Value</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>n+2</td>
<td>[0..*]</td>
<td>act/performer</td>
<td>typeCode</td>
<td>PRF</td>
<td>(\rightarrow) See 2.3.3.22</td>
</tr>
</tbody>
</table>

**author** used if different from the author of the header, to supersede it for this section.

<table>
<thead>
<tr>
<th>Lvl</th>
<th>Card</th>
<th>Parent/element</th>
<th>Attribute</th>
<th>Value</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>n+2</td>
<td>[0..*]</td>
<td>act/participant</td>
<td>typeCode</td>
<td>{AUTHEN</td>
<td>RESP</td>
</tr>
</tbody>
</table>

**Laboratory Result Content**

<table>
<thead>
<tr>
<th>Lvl</th>
<th>Card</th>
<th>Parent/element</th>
<th>Attribute</th>
<th>Value</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>n+2</td>
<td>[1..*]</td>
<td>act/entryRelationship</td>
<td>typeCode</td>
<td>COMP</td>
<td>(\rightarrow) Specimen Collection (2.3.5.5) (\rightarrow) Specimen Received (2.3.5.6) (\rightarrow) Notification Organizer (2.3.5.6) (\rightarrow) Notifiable Condition (2.3.5.7.1) (\rightarrow) Case Identifier (2.3.5.7.2) (\rightarrow) Outbreak Identifier (2.3.5.7.3) (\rightarrow) Laboratory Isolate Organizer (2.3.5.8) (\rightarrow) Laboratory Battery Organizer (2.3.5.9) (\rightarrow) Laboratory Observation (2.3.5.10) (\rightarrow) Multimedia Embedded Content (2.3.5.11) (\rightarrow) Annotation Comment (2.3.5.12)</td>
</tr>
</tbody>
</table>

```
<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>
```
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. 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 described in 2.3.3.13.2.

Table 2.3.5.3-1: Non-Human Subject

<table>
<thead>
<tr>
<th>Level</th>
<th>Card</th>
<th>Parent/element</th>
<th>Attribute</th>
<th>Value</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>[0..1]</td>
<td>subject</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n+1</td>
<td>[1..1]</td>
<td>subject/templatedId</td>
<td>root</td>
<td>1.3.6.1.4.1.19376.1.3.3.1.2.1</td>
<td>Mandatory and fixed</td>
</tr>
<tr>
<td>n+1</td>
<td>[1..1]</td>
<td>subject/relatedSubject</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n+2</td>
<td>[1..1]</td>
<td>relatedSubject/code</td>
<td></td>
<td></td>
<td>Code characterizing the non-human subject (animal species, material...)</td>
</tr>
<tr>
<td>n+2</td>
<td>[1..1]</td>
<td>relatedSubject/addr</td>
<td></td>
<td></td>
<td>Address of the non-human subject</td>
</tr>
</tbody>
</table>
Figure 2.3.5.3-1: Example of a non-human subject
2.3.5.4 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 sample taken from a non-human subject, such as an animal, a lake, 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 described in 2.3.3.13.3.

Table 2.3.5.4-1: Human Patient with Non-Human Subject

<table>
<thead>
<tr>
<th>Lvl</th>
<th>Card</th>
<th>Parent/element</th>
<th>Attribute</th>
<th>Value</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>[0..1]</td>
<td>subject</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n+1</td>
<td>[1..1]</td>
<td>subject/ templateId</td>
<td>root</td>
<td>1.3.6.1.4.1.19376.1.3.3.1.3.1</td>
<td>Mandatory and fixed</td>
</tr>
<tr>
<td>n+1</td>
<td>[1..1]</td>
<td>subject/ relatedSubject</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n+2</td>
<td>[1..1]</td>
<td>relatedSubject/ code</td>
<td></td>
<td></td>
<td>Code characterizing the non-human subject (animal species, material...)</td>
</tr>
<tr>
<td>n+2</td>
<td>[1..1]</td>
<td>relatedSubject/ addr</td>
<td></td>
<td></td>
<td>Addr of the non-human subject</td>
</tr>
</tbody>
</table>

Figure 2.3.5.4-1: Human Patient Paired with Non-Human Subject Example

```xml
<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>
    </addr>
  </relatedSubject>
</subject>
```
2.3.5.5 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>
<thead>
<tr>
<th>Lvl</th>
<th>Card</th>
<th>Parent/element</th>
<th>Attribute</th>
<th>Value</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>specimen</td>
<td>classCode</td>
<td>PROC</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>moodCode</td>
<td>EVN</td>
<td></td>
</tr>
<tr>
<td>n+1</td>
<td>[1..1]</td>
<td>procedure</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n+1</td>
<td>[1..1]</td>
<td>procedure/templateId</td>
<td>root</td>
<td>1.3.6.1.4.1.19376.1.3.1.2</td>
<td>Mandatory and fixed</td>
</tr>
<tr>
<td>n+1</td>
<td>[0..1]</td>
<td>procedure/code</td>
<td>codeSystem</td>
<td>33882-2</td>
<td>LOINC specimen collection code</td>
</tr>
<tr>
<td>n+1</td>
<td>[1..1]</td>
<td>procedure/effectiveTime</td>
<td></td>
<td>Date &amp; time of specimen collection</td>
<td></td>
</tr>
<tr>
<td>n+1</td>
<td>[0..1]</td>
<td>procedure/targetSiteCode</td>
<td>Specimen Source</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Specimen Collection Participants

<table>
<thead>
<tr>
<th>Lvl</th>
<th>Card</th>
<th>Parent/element</th>
<th>Attribute</th>
<th>Value</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>n+1</td>
<td>[0..1]</td>
<td>procedure/performer</td>
<td></td>
<td>Specimen collection organization</td>
<td></td>
</tr>
<tr>
<td>n+1</td>
<td>[1..1]</td>
<td>procedure/participant</td>
<td>typeCode</td>
<td>PRD</td>
<td></td>
</tr>
<tr>
<td>n+2</td>
<td>[1..1]</td>
<td>participant/participantRole</td>
<td>classCode</td>
<td>SPEC</td>
<td></td>
</tr>
<tr>
<td>n+3</td>
<td>[1..1]</td>
<td>participantRole/id</td>
<td></td>
<td>Specimen ID, Required</td>
<td></td>
</tr>
<tr>
<td>n+3</td>
<td>[1..1]</td>
<td>participantRole/playingEntity/code</td>
<td>Specimen Type, Required</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Specimen Received

<table>
<thead>
<tr>
<th>Lvl</th>
<th>Card</th>
<th>Parent/element</th>
<th>Attribute</th>
<th>Value</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>n+1</td>
<td>[0..1]</td>
<td>procedure/entryRelationship/act</td>
<td></td>
<td>Specimen Received (2.3.5.6)</td>
<td></td>
</tr>
</tbody>
</table>
2.3.5.6 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.

<table>
<thead>
<tr>
<th>Lvl</th>
<th>Card</th>
<th>Parent/element</th>
<th>Attribute</th>
<th>Value</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td></td>
<td>procedure/entryRelationship</td>
<td>typeCode</td>
<td>COMP</td>
<td></td>
</tr>
<tr>
<td>n+1</td>
<td></td>
<td>entryRelationship/act</td>
<td>classCode</td>
<td>ACT</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>moodCode</td>
<td>EVN</td>
<td></td>
</tr>
<tr>
<td>n+2</td>
<td>[1..1]</td>
<td>act/templateId</td>
<td>root</td>
<td>1.3.6.1.4.1.19376.1.3.1.3</td>
<td></td>
</tr>
</tbody>
</table>

Figure 2.3.5.5-1: Specimen Collection Example
<table>
<thead>
<tr>
<th>Lvl</th>
<th>Card</th>
<th>Parent/element</th>
<th>Attribute</th>
<th>Value</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>n+2</td>
<td>[1..1]</td>
<td>act/code</td>
<td>code</td>
<td>SPRECEIVE</td>
<td>Code representing the specimen reception in the laboratory</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>codeSystem</td>
<td>1.3.5.1.4.1.19376.1.5.3.2 IHEActCode</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>codeSystemName</td>
<td>19376.1.5.3.2</td>
<td></td>
</tr>
<tr>
<td>n+2</td>
<td>[1..1]</td>
<td>act/effectiveTime</td>
<td></td>
<td></td>
<td>Date &amp; time of specimen reception</td>
</tr>
</tbody>
</table>

```xml
<entry typeCode="DRIV">
  <templateId root="1.3.6.1.4.1.19376.1.3.1"/>
  <act classCode="ACT" moodCode="EVN">
    ...
    <entryRelationship typeCode="COMP">
      <templateId root="1.3.6.1.4.1.19376.1.3.1.2"/>
      <procedure classCode="PROC" moodCode="EVN">
        <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>
      </procedure>
      <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 2.3.5.6-1: Specimen Received Example
2.3.5.7 Notification Organizer 1.3.6.1.4.1.19376.1.3.1.1

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 (See 2.3.5.7.1), Case Identification (See 2.3.5.7.2), and/or Outbreak Identification (See 2.3.5.7.3). Notifications SHALL be present when dictated by local public health requirements.

Table 2.3.5.7-1: Notification Organizer

<table>
<thead>
<tr>
<th>Lvl</th>
<th>Card</th>
<th>Parent/element</th>
<th>Attribute</th>
<th>Value</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td></td>
<td>organizer</td>
<td>classCode</td>
<td>CLUSTER</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>moodCode</td>
<td>EVN</td>
<td></td>
</tr>
<tr>
<td>n+1</td>
<td>[1..1]</td>
<td>organizer/templateld</td>
<td>root</td>
<td>1.3.6.1.4.1.19376.1.3.1.1</td>
<td></td>
</tr>
<tr>
<td>n+1</td>
<td>[1..1]</td>
<td>organizer/statusCode</td>
<td>code</td>
<td>{completed | nullify}</td>
<td>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.</td>
</tr>
<tr>
<td>n+1</td>
<td>[1..*]</td>
<td>organizer/component</td>
<td></td>
<td>Contains one or more of the following Notifications: Notifiable Condition, Case Identification, Outbreak Identification.</td>
<td></td>
</tr>
</tbody>
</table>
Notifiable Condition, when present, SHALL be recorded as an observation under the Notification Organizer (See 2.3.5.7) as demonstrated. Notifiable Condition SHALL be present when dictated by local public health requirements.

### Table 2.3.5.7.1-1: Notifiable Condition

<table>
<thead>
<tr>
<th>Lvl</th>
<th>Card</th>
<th>Parent/element</th>
<th>Attribute</th>
<th>Value</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td></td>
<td>observation</td>
<td>classCode</td>
<td>COND</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>moodCode</td>
<td>EVN</td>
<td></td>
</tr>
<tr>
<td>n+1</td>
<td>[1..1]</td>
<td>observation/</td>
<td>root</td>
<td>1.3.6.1.4.1.19376.1.3.1.1.1</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>templateId</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n+1</td>
<td>[0..*]</td>
<td>observation/id</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n+1</td>
<td>[1..1]</td>
<td>observation/code</td>
<td></td>
<td></td>
<td>Code is used to identify this observation as the one for 'Notifiable Condition'.</td>
</tr>
<tr>
<td>n+2</td>
<td>[1..1]</td>
<td>code/qualifier</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lvl</td>
<td>Card</td>
<td>Parent/element</td>
<td>Attribute</td>
<td>Value</td>
<td>Comments</td>
</tr>
<tr>
<td>-----</td>
<td>--------</td>
<td>------------------------</td>
<td>----------------------------</td>
<td>-------------------------------</td>
<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td>n+3</td>
<td>[1..1]</td>
<td>qualifier/name</td>
<td>code</td>
<td></td>
<td>Qualifies the code with the source of specimen</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>codeSystem</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>codeSystemName</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>displayName</td>
<td></td>
<td></td>
</tr>
<tr>
<td>n+3</td>
<td>[1..1]</td>
<td>qualifier/value</td>
<td>code</td>
<td></td>
<td>Identifies the specimen source of the condition – patient, food, soil, …</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>codeSystem</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>codeSystemName</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>displayName</td>
<td></td>
<td></td>
</tr>
<tr>
<td>n+1</td>
<td>[1..1]</td>
<td>observation/statusCode</td>
<td>code</td>
<td>{completed</td>
<td>aborted}</td>
</tr>
<tr>
<td>n+1</td>
<td>[0..1]</td>
<td>observation/effectiveTime</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n+1</td>
<td>[1..1]</td>
<td>observation/value</td>
<td>xsi:type</td>
<td>“CE”</td>
<td>This is the value of the notifiable condition. It SHALL use the type “CE”</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>code</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>codeSystem</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>codeSystemName</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>displayName</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
<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 2.3.5.7.1-1: Notifiable Condition Example
2.3.5.7.2 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 2.3.5.7) as demonstrated. Case Identification SHALL be present when dictated by local case identification reporting requirements.

<table>
<thead>
<tr>
<th>Lvl</th>
<th>Card</th>
<th>Parent/element</th>
<th>Attribute</th>
<th>Value</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td></td>
<td>observation</td>
<td>classCode</td>
<td>CASE</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>moodCode</td>
<td>EVN</td>
<td></td>
</tr>
<tr>
<td>n+1</td>
<td>[1..1]</td>
<td>observation/templateld</td>
<td>root</td>
<td>1.3.6.1.4.1.19376.1.3.1.1.2</td>
<td></td>
</tr>
<tr>
<td>n+1</td>
<td>[0..*]</td>
<td>observation/id</td>
<td></td>
<td></td>
<td>This is the local case identification.</td>
</tr>
<tr>
<td>n+1</td>
<td>[1..1]</td>
<td>observation/code</td>
<td></td>
<td></td>
<td>Code is used to identify this observation as the one for 'Case Identification'.</td>
</tr>
<tr>
<td>n+1</td>
<td>[1..1]</td>
<td>observation/statusCode</td>
<td>code</td>
<td>{completed</td>
<td>A status of completed means the patient has been associated with the given case number.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>aborted}</td>
<td>A status of aborted means the patient was associated with the case number in error.</td>
</tr>
<tr>
<td>n+1</td>
<td>[0..1]</td>
<td>observation/effectiveTime</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n+1</td>
<td>[1..1]</td>
<td>observation/value</td>
<td></td>
<td></td>
<td>Must be type “CE”</td>
</tr>
</tbody>
</table>
Figure 2.3.5.7.2-1: Case Identification Example
2.3.5.7.3 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 2.3.5.7) as demonstrated. Outbreak Identification SHALL be present when dictated by local outbreak identification reporting requirements.

<table>
<thead>
<tr>
<th>Lvl</th>
<th>Card</th>
<th>Parent/element</th>
<th>Attribute</th>
<th>Value</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td></td>
<td>observation</td>
<td>classCode</td>
<td>OUTB</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>moodCode</td>
<td>EVN</td>
<td></td>
</tr>
<tr>
<td>n+1</td>
<td>[1..1]</td>
<td>observation/templateId</td>
<td>root</td>
<td>1.3.6.1.4.1.19376.1.3.1.1.3</td>
<td></td>
</tr>
<tr>
<td>n+1</td>
<td>[0..*]</td>
<td>observation/id</td>
<td></td>
<td></td>
<td>This is the local outbreak identification.</td>
</tr>
<tr>
<td>n+1</td>
<td>[1..1]</td>
<td>observation/code</td>
<td></td>
<td></td>
<td>Code is used to identify this observation as the one for 'Outbreak Identification'.</td>
</tr>
<tr>
<td>n+1</td>
<td>[1..1]</td>
<td>observation/statusCode</td>
<td>code</td>
<td>{completed, aborted}</td>
<td>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.</td>
</tr>
<tr>
<td>n+1</td>
<td>[0..1]</td>
<td>observation/effectiveTime</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n+1</td>
<td>[1..1]</td>
<td>observation/value</td>
<td></td>
<td></td>
<td>Must be type “CE”</td>
</tr>
</tbody>
</table>
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 2.3.5.8-1: Laboratory Isolate Organizer

<table>
<thead>
<tr>
<th>Lvl</th>
<th>Card</th>
<th>Parent/element</th>
<th>Attribute</th>
<th>Value</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>[1..1]</td>
<td>organizer</td>
<td>classCode</td>
<td>CLUSTER</td>
<td>Mandatory and fixed</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>moodCode</td>
<td>EVN</td>
<td>Mandatory and fixed</td>
</tr>
<tr>
<td>n+1</td>
<td>[1..1]</td>
<td>organizer/templateId</td>
<td>root</td>
<td>1.3.6.1.4.1.19376.1.3.1.5</td>
<td>Mandatory and fixed</td>
</tr>
<tr>
<td>n+1</td>
<td>[0..1]</td>
<td>organizer/id</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n+1</td>
<td>[0..1]</td>
<td>organizer/code</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### SpecimenObservationCluster_Organizer

<table>
<thead>
<tr>
<th>Lvl</th>
<th>Card</th>
<th>Parent/element</th>
<th>Attribute</th>
<th>Value</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>n+1</td>
<td>[1..1]</td>
<td>organizer/statusCode</td>
<td>code</td>
<td>{completed [active [aborted]}</td>
<td>‘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.</td>
</tr>
<tr>
<td>n+1</td>
<td>[0..1]</td>
<td>organizer/effectiveTime</td>
<td>value</td>
<td></td>
<td>Time of results on this isolate.</td>
</tr>
<tr>
<td>n+1</td>
<td>[0..1]</td>
<td>organizer/subject</td>
<td>typeCode</td>
<td>SBJ</td>
<td>See tables 2.3.5.3-1 and 2.3.5.4-1</td>
</tr>
<tr>
<td>n+1</td>
<td>[1..1]</td>
<td>organizer/specimen</td>
<td>typeCode</td>
<td>SPC</td>
<td>type of participation “specimen”</td>
</tr>
<tr>
<td>n+2</td>
<td>[1..1]</td>
<td>specimen/specimenRole</td>
<td>classCode</td>
<td>SPEC</td>
<td>This represents an isolate here.</td>
</tr>
<tr>
<td>n+3</td>
<td>[0..1]</td>
<td>specimenRole/id</td>
<td>classCode</td>
<td></td>
<td>unique identifier for this isolate, known to the laboratory</td>
</tr>
<tr>
<td>n+3</td>
<td>[1..1]</td>
<td>specimenRole/specimenPlayingEntity</td>
<td>classCode</td>
<td>MIC</td>
<td>The entity is a microorganism</td>
</tr>
<tr>
<td>n+4</td>
<td>[1..1]</td>
<td>specimenPlayingEntity//code</td>
<td>code</td>
<td></td>
<td>Identification of the microorganism, in a standard vocabulary</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>codeSystem</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>codeSystemName</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>displayName</td>
<td></td>
<td>Name of the organism reported in the narrative block.</td>
</tr>
</tbody>
</table>

**performer participation** used if specific performer on this isolate, to supersede all performers of higher level.

<table>
<thead>
<tr>
<th>Lvl</th>
<th>Card</th>
<th>Parent/element</th>
<th>Attribute</th>
<th>Value</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>n+1</td>
<td>[0..*]</td>
<td>organizer/performer</td>
<td>typeCode</td>
<td>PRF</td>
<td></td>
</tr>
</tbody>
</table>

**author participation** used if specific author on this isolate, to supersede all authors of higher level.

<table>
<thead>
<tr>
<th>Lvl</th>
<th>Card</th>
<th>Parent/element</th>
<th>Attribute</th>
<th>Value</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>n+1</td>
<td>[0..*]</td>
<td>organizer/author</td>
<td>typeCode</td>
<td>AUT</td>
<td></td>
</tr>
</tbody>
</table>

**Other participants such as verifier (AUTHEN) or responsible party (RESP)**

<table>
<thead>
<tr>
<th>Lvl</th>
<th>Card</th>
<th>Parent/element</th>
<th>Attribute</th>
<th>Value</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>n+1</td>
<td>[0..*]</td>
<td>organizer/participant</td>
<td>typeCode</td>
<td>{AUTHEN [RESP [DEV]}</td>
<td>See 2.3.5.13 AUTHEN for verifier, RESP for responsible party DEV for device (e.g., lab analyzer)</td>
</tr>
</tbody>
</table>

**Content of the SpecimenObservationCluster_Organizer:**

any number of Observations, Battery_Organizers, Multimedia

<table>
<thead>
<tr>
<th>Lvl</th>
<th>Card</th>
<th>Parent/element</th>
<th>Attribute</th>
<th>Value</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>n+1</td>
<td>[1..*]</td>
<td>organizer/component</td>
<td>typeCode</td>
<td>COMP</td>
<td>Battery (2.3.5.9) Observation (2.3.5.10) Multimedia (2.3.5.11) Annotation Comment (2.3.5.12)</td>
</tr>
</tbody>
</table>

---

**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”.

---

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Figure 2.3.5.8-1: Laboratory Isolate Organizer Example
### 2.3.5.9 Laboratory Battery Organizer 1.3.6.1.4.1.19376.1.3.1.4

A Laboratory Battery Organizer is used to group Laboratory Observations (See 2.3.5.10) for a battery of tests. Laboratory Battery Organizer, when present, SHALL be recorded as an organizer under the Laboratory Data Processing Entry as demonstrated.

#### Table 2.3.5.9-1: Laboratory Battery Organizer

<table>
<thead>
<tr>
<th>Lvl</th>
<th>Card</th>
<th>Parent/element</th>
<th>Attribute</th>
<th>Value</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>[1..1]</td>
<td>organizer</td>
<td>classCode</td>
<td>BATTERY</td>
<td>Mandatory and fixed</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>moodCode</td>
<td>EVN</td>
<td></td>
</tr>
<tr>
<td>n+1</td>
<td>[1..1]</td>
<td>organizer/templateId</td>
<td>root</td>
<td>1.3.6.1.4.1.19376.1.3.1.4</td>
<td>Mandatory and fixed</td>
</tr>
<tr>
<td>n+1</td>
<td>[0..1]</td>
<td>organizer/id</td>
<td></td>
<td></td>
<td>If present, represents the lab filler order number (ORC-3 and OBR-3 in HL7 v2.5) for this battery</td>
</tr>
<tr>
<td>n+1</td>
<td>[0..1]</td>
<td>organizer/code</td>
<td></td>
<td></td>
<td>Unique code for the battery in the appropriate vocabulary (e.g., SNOMED CT)</td>
</tr>
<tr>
<td>n+1</td>
<td>[1..1]</td>
<td>organizer/statusCode</td>
<td>code</td>
<td>{completed</td>
<td>‘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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>aborted}</td>
<td></td>
</tr>
<tr>
<td>n+1</td>
<td>[0..1]</td>
<td>organizer/effectiveTime</td>
<td>value</td>
<td></td>
<td>Time of results on this battery</td>
</tr>
</tbody>
</table>

**Subject** in case of a non-human subject attached to the Battery

| n+1 | [0..1]| organizer/subject | typeCode | SBJ | \(\rightarrow\) See tables 2.3.5.3-1 and 2.3.5.4-1 |

**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 | \(\rightarrow\) See 2.3.5.13 |
|     |      |                        |         | [RESP | AUTHEN for verifier, |
|     |      |                        |         | [DEV} | 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 | \(\rightarrow\) Specimen Collection (2.3.5.5) |
|     |      |                        |         |      | \(\rightarrow\) Observation (2.3.5.10) |
|     |      |                        |         |      | \(\rightarrow\) Multimedia (2.3.5.11) |
|     |      |                        |         |      | \(\rightarrow\) Annotation Comment (2.3.5.12) |

**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.
Figure 2.3.5.9-1: Laboratory Battery Organizer Example
2.3.5.10 Laboratory Observation 1.3.6.1.4.1.19376.1.3.1.6

The document SHALL contain at least one Laboratory Observation within each Laboratory Report Data Processing Entry (See 2.3.5.2).

Table 2.3.5.10-1: Laboratory Observation

<table>
<thead>
<tr>
<th>Lvl</th>
<th>Card</th>
<th>Parent/element</th>
<th>Attribute</th>
<th>Value</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>[1..1]</td>
<td>observation</td>
<td>classCode</td>
<td>OBS</td>
<td>Mandatory and fixed</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>moodCode</td>
<td>EVN</td>
<td>Mandatory and fixed</td>
</tr>
<tr>
<td>n+1</td>
<td>[1..1]</td>
<td>observation/ templatedId</td>
<td>root</td>
<td>1.3.6.1.4.1.19376.1.3.1.6</td>
<td>Mandatory and fixed</td>
</tr>
<tr>
<td>n+1</td>
<td>[0..1]</td>
<td>observation/id</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n+1</td>
<td>[1..1]</td>
<td>observation/code</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n+1</td>
<td>[1..1]</td>
<td>observation/ statusCode</td>
<td>code</td>
<td>{completed</td>
<td>aborted}</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n+1</td>
<td>[0..1]</td>
<td>observation/ effectiveTime</td>
<td>value</td>
<td></td>
<td></td>
</tr>
<tr>
<td>n+1</td>
<td>[0..1]</td>
<td>observation/value</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n+1</td>
<td>[0..1]</td>
<td>observation/ interpretationCode</td>
<td></td>
<td>One or more codes interpreting the result, expressed with ObservationInterpretation vocabulary (e.g., H = high, L = low)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Subject in case of a non-human subject attached to the Observation
<table>
<thead>
<tr>
<th>Lvl</th>
<th>Card</th>
<th>Parent/element</th>
<th>Attribute</th>
<th>Value</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>n+1</td>
<td>[0..1]</td>
<td>observation/subject</td>
<td>typeCode</td>
<td>SBJ</td>
<td>→ See tables 2.3.5.3-1 and 2.3.5.4-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>performer participation. Performer to supersede those recorded at higher level.</td>
</tr>
<tr>
<td>n+1</td>
<td>[0..*]</td>
<td>observation/performer</td>
<td>typeCode</td>
<td>PRF</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>author participation used to supersede the authors of higher level.</td>
</tr>
<tr>
<td>n+1</td>
<td>[0..*]</td>
<td>observation/author</td>
<td>typeCode</td>
<td>AUT</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Other participants such as verifier (AUTHEN) or responsible party (RESP)</td>
</tr>
<tr>
<td>n+1</td>
<td>[0..*]</td>
<td>observation/participant</td>
<td>typeCode</td>
<td>{AUTHEN [RESP [DEV]}</td>
<td>→ See 2.3.5.13</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>AUTHEN for verifier, RESP for responsible party DEV for device (e.g., lab analyzer)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Specimen or Comment on this Observation</td>
</tr>
<tr>
<td>n+1</td>
<td>[0..*]</td>
<td>observation/entryRelationship</td>
<td>typeCode</td>
<td>REFR</td>
<td>→ Specimen Collection (2.3.5.5)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>→ Annotation Comment (2.3.5.12)</td>
</tr>
<tr>
<td>n+2</td>
<td>[1..1]</td>
<td>entryRelationship/observation</td>
<td>classCode</td>
<td>OBS</td>
<td></td>
</tr>
<tr>
<td>n+2</td>
<td>[1..1]</td>
<td>entryRelationship/observation</td>
<td>moodCode</td>
<td>EVN</td>
<td></td>
</tr>
<tr>
<td>n+3</td>
<td>[1..1]</td>
<td>observation/code</td>
<td>code</td>
<td></td>
<td></td>
</tr>
<tr>
<td>n+3</td>
<td>[1..1]</td>
<td>observation/statusCode</td>
<td>moodCode</td>
<td>EVN</td>
<td></td>
</tr>
<tr>
<td>n+4</td>
<td>[1..1]</td>
<td>observation/effectiveTime</td>
<td>value</td>
<td></td>
<td></td>
</tr>
<tr>
<td>n+3</td>
<td>[1..1]</td>
<td>observation/value</td>
<td>value</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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   |          |
| n+3 | [1..1] | observation/code             | code      |        | The same test code |
| n+3 | [1..1] | observation/statusCode       | moodCode  | EVN   |          |
| 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            | 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   |          |
| n+5 | [0..1] | observationRange/value       | moodCode  | EVN.CRT | 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  |          |
| n+6 | [1..1] | precondition/criterion       | 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 |

**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.
Figure 2.3.5.10-1: Laboratory Observation Example
2.3.5.11 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 karyotype) will be addressed in the future by an extension of the Laboratory Technical Framework.

```xml
<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 2.3.5.11-1: Multimedia Content Example
2.3.5.12 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 2.3.5.12-1: Comment on an Observation Example
Figure 2.3.5.12-2: Comment on an Organizer Example
2.3.5.13 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 2.3.3.18 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.
2.3.6 Extensions to CDA R2

This Laboratory Report Content Module brings two extensions to CDA R2.

2.3.6.1 General Rules Respected by Laboratory Report Extensions

The extension brought to the CDA model, for follows the same rules as those defined in the “Care Continuity Document” (CCD) 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
- 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.

2.3.6.2 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 proposed 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:
Figure 2.3.6.2-1: Associating criteria to the reference range of an observation

```xml
<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 2.3.6.2-2: Pre-Condition Criterion Example
2.3.6.3 statusCode of Documented serviceEvent

This Laboratory Report Content Module can express both final and non-final reports. 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".

![Diagram](image)

Figure 2.3.6.3-1: StatusCode added to serviceEvent in the CDA header

```xml
<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 2.3.6.3-2: Example of usage in a non-final laboratory report
3 Open issues

Refer to wiki.ihe.net for issues to be addressed in the future.

4 Closed issues

What is the process to identify a template? What is the OID for the root of a template id? How to choose the extension? Solution: Use an OID assigned by the IHE Laboratory committee.

Representing the previous results obtained for the same test and the same patient, considered as a pertinent information accompanying the current observation:

The Laboratory Result Event RMIM (POLB_RM004000) would use an outbound ActRelationship pertinentInformation to the CMET

A_SupportingClinicalInformation using the specialization

A_ObservationGeneral from this CMET, with value being the previous result, code being the same code as in the ObservationEvent and effectiveTime being the date/time of this previous result.

In CDA, a previous result is another observation related to the current one by an entryRelationship. The currently more convenient value for entryRelationship.typecode is “REFR” (refers to).

There is no real discrepancy between CDA representation and LAB domain representation: Both of them allow the previous result to be an observation pointed by an outbound ActRelationship from the current observation.

How to extract the subset “Common Lab Tests” from LOINC? This is related to the restriction on LOINC test codes that we intend to bring. From Regenstrief’s answer, this information is internal to the RELMA tool, and therefore not usable.

Representation of comment of an observation or a battery. (e.g., Annotation on a CBC or on the hematocrit analyte):

Adopt comment template from PCC.

Spotting the Ordering Provider in the header of the document.

We use a <participant typeCode="REF">. The physician who is the referrer.

In case a part of the report has been produced from a subcontractor lab, this part of the report SHALL contain the name of the Director of this lab, as well as the name, address and telecom of this lab.

Two solutions are useable in this profile, based on the element <performer> associated with the subcontracted part, alone or in conjunction with an element <participant typeCode="RESP">.

Issue closed.

Usage code R2 versus RE

IHE uses R2 (mostly), Lab-TF is consistent with HL7 and uses RE – solution, create a Note in the document for readers highlighting this discrepancy
Dealing with preliminary and final reports. Extension to CDA R2: serviceEvent/statusCode