GMSIH, SFIL, IHE-J, JAHIS and RSNA

Integrating the Healthcare Enterprise

Laboratory
Technical Framework

Volume 3
(LAB TF-3)
Document-based transactions

Revision 2.0 – For Trial Implementation
August 16, 2007

Contents:

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 messaging 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 (aka medical 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. 2.0 for Trial Implementation, specifies the IHE transactions defined and implemented as of July 2007.

The latest version of the document is always available via the Internet at www.ihe.net/Technical Framework, www.ihe-europe.fr, www.gmsih.fr/IHE

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

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

RSNA (Radiological Society of North America)

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 5 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.
- **Volume 2** of the Laboratory Technical Framework (LAB TF-2) provides a detailed technical description of each message-based transaction and of 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: The laboratory report as a CDA document.
- **Volume 4** of the Laboratory Technical Framework (LAB TF-4) provides a subset of LOINC (Logical Observations Identifiers, Names and Codes) usable in all profiles of this Laboratory Technical Framework.
- **Volume 5** of the Laboratory Technical Framework (LAB TF-5) will be dedicated to national extensions that some countries may wish to build on top of this Laboratory Technical Framework.

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

JAHIS, GMSIH , SFIL, IHE-J and RSNA welcome comments on this document and the IHE initiative. They should be directed to the cochairs of the IHE Laboratory Committee, namely:

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1.7 Copyright permissions

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:

<domain designator> TF-<volume number>: <section number>, where

<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:

[<domain designator>-<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

See Glossary section in Volume 1: LAB TF-1:1.11

2 IHE Transactions

This section describes the options available in the transaction "Share Content" for a Content Consumer Actor.

2.1 Content Consumer Options

2.1.1 View Option

A Content Consumer that supports the View Option shall be able to:

1) Use the appropriate XD* transactions to obtain the document along with associated necessary metadata.
2) Render the document for viewing. This rendering shall meet the requirements defined for CDA Release 2 content presentation semantics (See Section 1.2.4 of the CDA Specification: Human readability and rendering CDA Documents). CDA Header information providing context critical information shall also be rendered in a human readable manner. This includes at a minimum the ability to render the document with the stylesheet specifications provided by the document source, if the document source provides a stylesheet. Content Consumers may optionally view the document with their own stylesheet, but must provide a mechanism to view using the source stylesheet.
3) Support traversal of links for documents that contain links to other documents managed within the sharing framework.
4) Print the document to paper.

2.1.2 Document Import Option

This Option requires that the View Option be supported. In addition, the Content Consumer that supports the Document Import Option shall be able to support the storage of the entire document (as provided by the sharing framework, along with sufficient metadata to ensure its later viewing) both for discharge summary or referral documents. This Option requires the proper tracking of the document origin. Once a document has been imported, the Content Consumer shall offer a means to view the document without the need to retrieve it again from the sharing framework. When viewed after it was imported, a Content Consumer may choose to access the sharing framework to find out if the related Document viewed has been deprecated, replaced or addended.

Note: For example, when using XDS, a Content Consumer may choose to query the Document Registry about a document previously imported in order to find out if this previously imported document may have been replaced or has received an addendum. This capability is offered to Content Consumers by this Integration Profile, but not required, as the events that may justify such a query are extremely implementation specific.

2.1.3 Section Import Option

This Option requires that the View Option be supported. In addition, the Content Consumer that supports the Section Import Option shall be able to support the import of one or more sections of the document (along with sufficient metadata to link the data to its source) both for discharge summary or referral. This Option requires the proper tracking of the document section origin. Once sections have been selected, a Content Consumer shall offer a means to copy the imported section(s) into local data structures as free text. This is to support the display of section level information for comparison or editing in workflows such as medication reconciliation while discrete data import is not possible. When viewed again after it is imported, a Content Consumer may chose to access the sharing framework to find out if the related information has been updated.

Note: For example, when using XDS, a Content Consumer may choose to query the Document Registry about a document whose sections were previously imported in order to find out if this previously imported document may have been replaced or has received an addendum. This capability is offered to Content Consumers by

this Integration Profile, but not required, as the events that may justify such a query are extremely implementation specific.

This Option does not require, but does not exclude the Content Consumer from offering a means to select and import specific subsets of the narrative text of a section.

2.1.4 Discrete Data Import Option

This Option does not require that the View, Import Document or Section Import Options be supported. The Content Consumer that supports the Discrete Data Import Option shall be able to support the storage of the structured content of one or more sections of the document. This Option requires that the user be offered the possibility to select among the specific sections that include structured content a set of clinically relevant record entries (e.g. a problem or an allergy in a list) for import as part of the local patient record with the proper tracking of its origin.

Note: This note discusses an example of an implementation in an EMR supporting these options. The EMR implements a Content Consumer Actor for this XDS-MS Integration Profile that retrieves medical summary documents and allows the EMR user to use a number of import choices. One of them could be to save the retrieved document to the EMR system. This would be the support of the Document Import Option (See Section 3.4.2.2). If this implementation supports in addition the "Discrete Data Import" Option, the user may be offered the ability (implicitly or not) to have the document parsed for allergy, problem, and medication lists and all such structured entries found in the imported document are placed in quarantine for review by healthcare providers. A provider reviewing these quarantined items may decide to add some of them as discrete data items to the patient's local EMR record.

Note: This Discrete Data Import Option does not require the support of the View, Import Document or Import Sections Options so that it could be used alone to support implementations of Content Consumers other than EMRs, such as Public Health Data or Clinical Research systems that would want to aggregate and anonymize specific population healthcare information data as Document Consumer Actors, but one which no care provider actually views the medical summaries. It is expected that most EMR supporting the Discrete Data Import Option would select also one of the View, Import Document or Import Sections Options.

When discrete data is accessed after it was imported, a Content Consumer may choose to check if the document related to the discrete data viewed has been deprecated, replaced or addended.

Note: For example, using XDS, a Content Consumer may choose to query the Document Registry about a document from which discrete data was previously imported in order to find out if this previously imported document may have been replaced or has received an addendum. This capability is offered to Content Consumers by this Integration Profile, but not required, as the events that may justify such a query are extremely implementation specific.

3 IHE Bindings

This section describes how the payloads used in IHE transactions are related to and/or constrained by the data elements contained within the content sent or received in those transactions. This section is where any specific dependencies between the content and transaction are defined.

3.1 Laboratory Report Binding to XDS, XDM and XDR

This binding is defined hereafter for two of the XDS objects: XDSDocumentEntry and XDSSubmissionSet. The use of the third object, XDSFolder is left up to the Affinity Domain in which the transactions take place.

The columns of the following tables are:

- **<XXX> attribute** – name of an XDS attribute, followed by any discussion of the binding detail.
- **Usage** - Indicates the required status of the XDS attribute, and is one of R (Required), RE (Required if available), or O (optional). This column is filled with the values specified in the XDS Profile as a convenience.
- **Source Type** – Will contain one of the following values:

Source Type	Description
SA	**Source document Attribute** – value is copied directly from source document. The Source/Value column identifies where in the source document this attribute comes from. Specify the location in XPath when possible.
SAT	**Source document Attribute with Transformation** – value is copied from source document and transformed. The Source/Value column identifies where in the source document this attribute comes from. Specify the location in XPath when possible. Extended Discussion column must not be empty and the transform must be defined in the extended discussion
FM	**Fixed (constant) by Mapping** - for all source documents. Source/Value column contains the value to be used in all documents.
FAD	**Fixed by Affinity Domain** – value configured into Affinity Domain, all documents will use this value.
CAD	**Coded in Affinity Domain** – a list of acceptable codes are to be configured into Affinity Domain. The value for this attribute shall be taken from this list.
CADT	**Coded in Affinity Domain with Transform -** a list of acceptable codes are to be configured into Affinity Domain. The value for this attribute shall be taken from this list.
n/a	**Not Applicable** – may be used with an optionality R2 or O attribute to indicate it is not to be used.
DS	**Document Source** – value comes from the Document Source actor. Use Source/Value column or Extended Discussion to give details.
O	**Other** – Extended Discussion must be 'yes' and details given in an Extended Discussion.

- **Source/Value** –This column indicates the source or the value used.

3.1.1 XDSDocumentEntry metadata

XDSDocumentEntry Attribute	Usage	Source Type	Source/ Value
authorSpecialty This metadata element should be based on a detailed defined classification system for healthcare providers such as those found in SNOMED-CT, or the HIPPA Healthcare Provider Taxonomy.	RE	DS	
authorInstitution	RE	SA	/ClinicalDocument/author /assignedAuthor /representedOrganization/ name

authorPerson
The author can be formatted using the following XPath expression, where **$person** in the expression below represents the author.
`concat(`
`  $person/id/@extension,"^",`
`  $person/assignedPerson/name/family,"^",`
`  $person/assignedPerson/name/given,"^",`
`  $person/assignedPerson/name/middle,"^",`
`  $person/assignedPerson/name/suffix,"^",`
`  $person/assignedPerson/name/prefix,"^",`
`  $person/assignedPerson/name/degree,"^^&",`
`  $person/id/@root,"&ISO"`
`)`
	RE	SAT	$person <= /ClinicalDocument/author

availabilityStatus	R	DS	Value assigned at point of submission.
classCode Derived from a mapping of /ClinicalDocument/code/@code to an Affinity Domain specified coded value to use and coding system. Affinity Domains are encouraged to use the appropriate value for Type of Service, based on the LOINC Type of Service (see Page 53 of the LOINC User's Manual).	R	CADT	Must be consistent with /ClinicalDocument/code/ @code
classCodeDisplayName DisplayName of the classCode derived. Derived from a mapping of /ClinicalDocument/code/@code to the appropriate Display Name based on the Type of Service.	R	CADT	Must be consitent with /ClinicalDocument/code/ @code
confidentialityCode Derived from a mapping of /ClinicalDocument/confidentialityCode/@code to an Affinity Domain specified coded value and coding system.	R	CADT	/ClinicalDocument/ confidentialityCode/@code
creationTime	R	SA	/ClinicalDocument/ effectiveTime
eventCodeList These values express a collection of keywords that may be relevant to the consumer of the documents in the registry.	O	CADT	
eventCodeDisplayNameList These are the display names for the collection of keywords described above.	R (if event Code is valued)	CADT	
formatCode The format code shall be the OID associated with the template identifier used to identify the content module that the document conforms to. See PCC TF-2:5.1.2 for a list of values that can be	R	FM	ClinicalDocument/templateId Fixed value is: 1.3.6.1.4.1.19376.1.3.3

XDSDocumentEntry Attribute	Usage	Source Type	Source/ Value
used as format codes.			
healthcareFacilityTypeCode A fixed value assigned to the Document Source and configured form a set of Affinity Domain defined values.	R	O	Must be concistent with /clinicalDocument/code
healthcareFacility TypeCodeDisplay Name	R	O	Must be concistent with /clinicalDocument/code

intendedRecipient
The intendedRecipient can be formatted using the following XPath expression, where **$person** in the expression below represents the intendedRecipient.
`concat(`
`  $person/id/@extension,"^",`
`  $person/assignedPerson/name/family,"^",`
`  $person/assignedPerson/name/given,"^",`
`  $person/assignedPerson/name/middle,"^",`
`  $person/assignedPerson/name/suffix,"^",`
`  $person/assignedPerson/name/prefix,"^",`
`  $person/assignedPerson/name/degree,"^^&",`
`  $person/id/@root,"&ISO"`
`)`
	RE	SAT	$person <= /ClinicalDocument/ intendedRecipient

languageCode	R	SA	/ClinicalDocument/ languageCode

legalAuthenticator
The legalAuthenticator can be formatted using the following XPath expression, where **$person** in the expression below represents the legalAuthenticator.
`concat(`
`  $person/id/@extension,"^",`
`  $person/assignedPerson/name/family,"^",`
`  $person/assignedPerson/name/given,"^",`
`  $person/assignedPerson/name/middle,"^",`
`  $person/assignedPerson/name/suffix,"^",`
`  $person/assignedPerson/name/prefix,"^",`
`  $person/assignedPerson/name/degree,"^^&",`
`  $person/id/@root,"&ISO"`
`)`
	O	SAT	$person <= /ClinicalDocument/ legalAuthenticator

mimeType	R	FM	text/xml
parentDocumentRelationship	R (when applicable)	SA	/ClinicalDocument/ relatedDocument/@typeCode
parentDocumentId The parentDocumentId can be formatted using the following XPath expression, where **$docID** in the expression below represents the identifier. `concat($docID/@root,"^", $docID/@extension)`	R (when parent Document Relationship is present)	SAT	$docID <= /ClinicalDocument/ relatedDocument/ parentDocument/id
patientId The patientId can be formatted using the following XPath expression, where **$patID** in the expression below represents the appropriate identifier.	R	SAT	$patID <= /ClinicalDocument/ recordTarget/patientRole/id

XDSDocumentEntry Attribute	Usage	Source Type	Source/ Value
`concat($patID/@extension,"^^^&", $patID/@root, "&ISO")`			
practiceSettingCode This elements should be based on a coarse classification system for the class of specialty practice. Recommend the use of the classification system for Practice Setting, such as that described by the Subject Matter Domain in LOINC.	R	CAD	
practiceSettingCodeDisplayName This element shall contain the display names associated with the codes described above.	R	CAD	
serviceStartTime	RE	SA	/ClinicalDocument/ documentationOf/ serviceEvent/effectiveTime/ low/@value
serviceStopTime	RE	SA	/ClinicalDocument/ documentationOf/ serviceEvent/effectiveTime/ high/@value
sourcePatientId	R	DS	
sourcePatientInfo	R	DS	
Title	O	SA	/ClinicalDocument/title
typeCode	R	SA	/ClinicalDocument/code/ @code
typeCodeDisplayName	R	SA	/ClinicalDocument/code/ @displayName
uniqueId The uniqueId can be formatted using the following XPath expression, where **$docID** in the expression below represents the identifier. `concat($docID/@root,"^", $docID/@extension)`	R	SAT	$docID <= /ClinicalDocument/id

3.1.2 XDSSubmissionSet metadata

XDSSubmissionSet Attribute	Usage	Source Type	Source/ Value
authorDepartment This metadata element should be based on a detailed defined classification system for healthcare providers such as those found in SNOMED-CT, or the HIPPA Healthcare Provider Taxonomy.	RE	CAD	
authorInstitution	RE	SA	/ClinicalDocument/author/ assignedAuthor/ representedOrganization/ name
authorPerson The author can be formatted using the following XPath expression, where $person in the expression below represents the author.	RE	SAT	$person <= /ClinicalDocument/author

`concat(`
`  $person/id/@extension,"^",`
`  $person/assignedPerson/name/family,"^",`
`  $person/assignedPerson/name/given,"^",`
`  $person/assignedPerson/name/middle,"^",`
`  $person/assignedPerson/name/suffix,"^",`
`  $person/assignedPerson/name/prefix,"^",`
`  $person/assignedPerson/name/degree,"^^&",`
`  $person/id/@root,"&ISO"`
`)`			

comments	RE		
contentTypeCode	R	CAD	
contentTypeCodeDisplayName	R	CAD	

patientId
 	
The patientId can be formatted using the following XPath expression, where $patID in the expression below represents the appropriate identifier.
 	
`concat($patID/@extension,"^^^&",`
`$patID/@root, "&ISO")`
	R	SAT	$patID <= /ClinicalDocument/ recordTarget//patientRole/id

sourceId	R	DS	
submissionTime	R	DS	
uniqueId	R		

4 CDA Release 2.0 Content Module for the Laboratory Report

4.1 Level 1: Header of the laboratory report

This section describes the CDA header of the clinical laboratory report.

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.

For instance, most of the constraints on the header provided by the Care Record Summary 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.

4.1.1 Header rendering

The header identifies the patient, the clinical laboratory that produced the report, the physician that ordered the tests performed, 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.

4.1.2 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`.

4.1.3 ClinicalDocument

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

4.1.4 ClinicalDocument/realmCode

This element SHALL be present.

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="US"/>`

Example for a French extension: `<realmCode code="FR"/>`

4.1.5 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"/>
```


4.1.6 ClinicalDocument/templateId

This element is identifying the set of constraints applied to the CDA R2 standard by this IHE specification of a laboratory report. One occurrence SHALL be present and valued as follows:

```
<templateId root="1.3.6.1.4.1.19376.1.3.3"
            extension="Lab.Report.Clinical.Document"/>
```

4.1.7 ClinicalDocument/id

This element 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.

Example:

```
<id root="2.16.840.1.113883.19.4" extension="abc266"/>
```

4.1.8 ClinicalDocument/code

The laboratory report can be either a multi-disciplinary report or a single discipline report.

4.1.8.1 Multi-disciplinary lab report

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

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

Note 1: The Veneto project of lab report in Italy chose 11488-4 that is “Consultation Note”.

Note 2: The US Claim attachment uses a general “Report Subject Identifier” 26436-6, with the meaning “Laboratory Studies”.

The SNOMED CT code identifying the type of document as a multi-disciplinary laboratory report is:

```
<code codeSystem="2.16.840.1.113883.6.96"
      codeSystemName=”SNOMED-CT”
      code="197431000000109" displayName="laboratory report"/>
```

4.1.8.2 Single discipline laboratory report

LOINC: Use the appropriate LOINC code as listed in table “Laboratory specialties” in section 4.2.1.1.

SNOMED CT does not distinguish various categories of laboratory reports.

4.1.9 ClinicalDocument/effectiveTime

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.

4.1.10 ClinicalDocument/confidentialityCode

This code indicates the level of confidentiality of the laboratory report. The three possible values are:

code	*Meaning*
N	Normal confidentiality rules apply, according to the healthcare domain policies (e.g. the regional healthcare network).
R	Restricted access
V	Very restricted access

Example:
```
<confidentialityCode code="N" codeSystem="2.16.840.1.113883.5.25"/>
```

The confidentialityCode can be raised at a higher level than the one declared in the header (i.e. from N to R or V, from R to V) for a particular `section`. In that case, the content of the `section` will be protected accordingly. The confidentialityCode will be carried by the level 3 `entry` from which this `section` is derived.

4.1.11 ClinicalDocument/languageCode

The main language in which the report is authored.
Example of a report authored in American English:
```
<languageCode code="en-US" codeSystem=" 2.16.840.1.113883.6.121"/>
```

4.1.12 ClinicalDocument/setId

An identifier that is common across all revisions of this laboratory report.

This element SHALL be present to enable further updates of the clinical document.

4.1.13 ClinicalDocument/versionNumber

An integer value used as versioning.

4.1.14 ClinicalDocument/recordTarget

This element encapsulates the patient, target of this laboratory report, with its ID, demographics, address and telecom.

4.1.15 ClinicalDocument/author

The author(s) of the laboratory report.

The `author/time` element carries the date&time the laboratory report was produced.

The laboratory report can be produced by a software system or by a person or by both.

`Example of report authored` by a system:

```
<author>
    <time value="2005032922441+0500"/>
    <assignedAuthor>
        <id extension="1" root="1.3.6.4.1.4.1.2835.1"/>
        <assignedAuthoringDevice>
            <softwareName>Pretty Good Lab System</softwareName>
        </assignedAuthoringDevice>
    </assignedAuthor>
</author>
```

Example of report authored by a person:


```
<author>
    <time value="200503300830+0500"/>
    <assignedAuthor>
        <id extension="1" root="1.3.6.4.1.4.1.2835.1"/>
        <addr>
            <streetAddressLine>21 North Ave</streetAddressLine>
            <city>Burlington</city>
            <state>MA</state>
            <postalCode>01803</postalCode>
            <country>USA</country>
        </addr>
        <telecom value="tel:(999)555-1212" use="DIR"/>
        <assignedPerson>
            <name>
                <prefix>Dr.</prefix>
                <given>GP</given>
                <family>Physician</family>
            </name>
        </assignedPerson>
    </assignedAuthor>
    <representedOrganization>
        <name>Good Practice</name>
    </representedOrganization>
</author>
```

4.1.16 ClinicalDocument/custodian

The organization that is in charge of maintaining the laboratory report (i.e. replacing it by a new revision, or deprecating it). This organisation is placed in the following element:

`custodian/assignedCustodian/representedCustodianOrganization`,

with the following mandatory sub-elements:

`id`	Unique identifier of this organization in the affinity domain.
`name`	Name
`addr`	Address
`telecom`	Phone, and/or other telecom address (email, fax…)

In this Integration Profile, the role of custodian is devoted to the organization operating the Content Creator Actor that shares the laboratory report in the common Document Repository and Document Registry. (See § **Erreur ! Source du renvoi introuvable.**). For instance in use case **Erreur ! Source du renvoi introuvable.**, it will be the hospital; in use case **Erreur ! Source du renvoi introuvable.** it will be the private laboratory; in use case **Erreur ! Source du renvoi introuvable.** it will be the ambulatory physician.

Example (taken from normative edition of HL7 v3):

```
<custodian>
    <assignedCustodian>
        <representedCustodianOrganization>
            <id extension="1" root="1.3.6.4.1.4.1.2835.3"/>
            <name>Good Health Clinic</name>
            <telecom value="tel:(999)555-1212" use="DIR"/>
            <addr>
                <streetAddressLine>21 North Ave</streetAddressLine>
                <city>Burlington</city>
            </addr>
        </representedCustodianOrganization>
    </assignedCustodian>
</custodian>
```


4.1.17 informationRecipient/intendedRecipient

The informationRecipient element can be multiple. It introduces an intended recipient of the laboratory report, other than the ordering physician (described as a participant as shown in §).

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.

An `informationRecipient/intendedRecipient` will appear in this Profile with the following mandatory sub-elements:

`id`	Unique identifier of this person in the affinity domain.
`addr`	Address of the person
`telecom`	Phone, and/or other telecom address (email, fax…) of the person
`informationRecipient`	
`name`	Name of the person

Example:

```
<informationRecipient>
    <intendedRecipient>
        <id extension="1" root="1.3.6.4.1.4.1.2835.3"/>
        <informationRecipient>
            <name>
                <prefix>Dr.</prefix>
                <given>Specialist</given>
                <family>Physician</family>
            </name>
        </informationRecipient>
        <addr>
            <streetAddressLine>21 North Ave</streetAddressLine>
            <city>Burlington</city>
        </addr>
        <telecom value="tel:(999)555-1212" use="DIR"/>
    </intendedRecipient>
</informationRecipient>
```

4.1.18 ClinicalDocument/legalAuthenticator

Carries the person who has verified and 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.


```
<legalAuthenticator>
    <time value="20050329224512+0500"/>
    <signatureCode code="S"/>
    <assignedEntity>
        <id extension="1" root="1.3.6.4.1.4.1.2835.1"/>
        <addr>
            <streetAddressLine>21 North Ave</streetAddressLine>
            <city>Burlington</city>
        </addr>
        <telecom value="tel:(999)555-1212" use="DIR"/>
        <assignedPerson>
            <name>
                <given>Mike</given>
                <family>Roscopp</family>
            </name>
        </assignedPerson>
    </assignedEntity>
</legalAuthenticator>
```

4.1.19 ClinicalDocument/authenticator

This element is used to carry the verifier of the report when this verifier is not the legal authenticator. This person is represented with its name, address and telecom, as in the following example:

```
<authenticator>
    <time value="20050329224512+0500"/>
    <signatureCode code="S"/>
    <assignedEntity>
        <id extension="1" root="1.3.6.4.1.4.1.2835.1"/>
        <addr>
            <streetAddressLine>21 North Ave</streetAddressLine>
            <city>Burlington</city>
        </addr>
        <telecom value="tel:(999)555-1212" use="DIR"/>
        <assignedPerson>
            <name>
                <given>Bio</given>
                <family>Surveillance</family>
            </name>
        </assignedPerson>
    </assignedEntity>
</authenticator>
```

There may be more than one verifier of the report. Depending upon realm conventions, all the verifiers may appear in the report header as authenticators, or each verifier may be associated with the particular sections of the report he or she verified. In the latter case, the verifier of a section SHALL also appear in the <entry> this section is derived from. It will appear as a participant with participationType “VRF”.

4.1.20 ClinicalDocument/participant carries the ordering physician

This element is used to carry other types of participants to the laboratory report.

In particular, the ordering physician of the Placer Order (or group of orders) fulfilled by this laboratory report, may be carried by a `participant` element with the attribute `typeCode` valued “REF” (referrer), as in the following example:


```
<participant typeCode="REF">
    <time value="20050329224512+0500"/>
    <associatedEntity>
        <id extension="1" root="1.3.6.4.1.4.1.2835.1"/>
        <addr>
            <streetAddressLine>21 North Ave</streetAddressLine>
            <city>Burlington</city>
        </addr>
        <telecom value="tel:(999)555-1212" use="DIR"/>
        <associatedPerson>
            <name>
                <given>Good</given>
                <family>Orderer</family>
            </name>
        </associatedPerson>
    </associatedEntity>
</participant>
```

In that case, The `time` element represents the date&time the order was placed.

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

4.1.21 inFulfillmentOf/order

The `inFulfillmentOf/order` element MAY be present. It represents the Placer Order[1] that was fulfilled, the id of which is carried by `inFulfillmentOf/order/id`

4.1.22 documentationOf/serviceEvent

`documentationOf/serviceEvent` represents the main Act being documented, that is a Result Event produced by a clinical laboratory (See Result Event RMIM in the Laboratory domain of HL7 V3).

This element SHALL be present when the report documents a Result Event performed by a single laboratory. In other situations (e.g. report aggregating observations from multiple laboratories) this element may not be present in the header, but carried instead in the body of the document at the entry level (level 3), and reported as textual information in the sections.

4.1.23 serviceEvent/statusCode

This element in an extension to CDA R2 added by this Profile. The purpose is to indicate whether the report is preliminary or final.

A final report documents a serviceEvent that is completed:

```
<statusCode code="completed">
```

A preliminary report documents a serviceEvent that is not completed (hence active):

```
<statusCode code="active">).
```

The `statusCode` element is optional as all extensions brought to CDA by this Profile. IHE and HL7 strongly recommend not to use this subelement in conjunction with the `id` subelement or the `code` subelement[2].

See section 4.5 for a detailed discussion of all extensions brought by this profile to CDA R2.

---

[1] The Placer Order is either a group of order items (modeled as PlacerGroup in the Placer Order RMIM of the V3 Laboratory domain, and represented by field ORC-4 "placer group number" in v2.5 messages) or a single item ordered (modeled as ObservationRequest in the same RMIM and represented by ORC-2 "placer order number" in v2.5). .

[2] The `statusCode` carries the status of completeness of the laboratory promise, and the `id` does not identify a FulfillerPromise. Similarly the `code` does not represent the FulfillerPromise.

4.1.24 serviceEvent/performer

The `serviceEvent/performer` represents the person (i.e. the biomedical scientist or the Director) scoped by the organization (i.e. the laboratory) who produced the Result Event documented by the report.

The `performer/assignedEntity/representedOrganization` represents the clinical laboratory that produced the report.

4.1.25 relatedDocument/parentDocument

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

4.1.26 authorization/consent

This element carries the patient's consent to share this report in the healthcare network, to other care providers participating to this network (affinity domain), and having the proper access rights to the longitudinal record of this patient, according to the policies that rule this affinity domain.

```
<authorisation>
        <consent classCode="CONS" moodCode="EVN">
                <code code="XXX" codeSystem="YYYY"/>
                <statusCode code="completed"/>
        </consent>
</authorization>
```

The optional `code` element enables to qualify the type of consent. It is a CE (coded with equivalent) datatype with coding strengh CWE (coded with extensions). Therefore the code set can be defined by realms in national extensions of that profile.

4.1.27 componentOf/encompassingEncounter

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

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 precise the responsible party in charge with the patient during that encounter:

`encompassingEncounter/responsibleParty/assignedEntity`

The encounter MAY provide any number of encounter participants:

`encompassingEncounter/encounterParticipant/assignedEntity`

The <encounterParticipant> element SHALL have its "typeCode" attribute provided, with one of these values, selected from the x_EncounterParticipant domain:

ADM for admitter

ATND for attender

REF for referrer

DIS for discharger

CON for consultant

A responsible party as well as an encounter participant SHALL provide an assigned person or a represented organization or both:

`assignedEntity/assignedPerson`

`assignedEntity/representedOrganization`

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`

Minimal content of an encounter:

```
<componentOf>
        <encompassingEncounter>
                <id extension="9876543" root="oid of assigning authority"/>
                <effectiveTime>
                        <low value="200605230910"/>
                </effectiveTime>
        </encompassingEncounter>
</componentOf>
```

4.2 Level 2: human-readable Body of the report

A clinical 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 may contain either one text block carrying all the results produced for this specialty or a set of leaf sections. In the first case the specialty section happens to be also a leaf section. In the latter case, each (second level) leaf section contained in the (top level) specialty section represents a reported item: i.e. a battery, a specimen study (especially in microbiology), or an individual test.

In addition, any leaf section SHALL contain a level 3 entry that contains the observations of that section in a machine-readable format.

4.2.1 Top level sections: specialties

4.2.1.1 List of specialties

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 “specialty”sections use the LOINC codes defined as report subject identifier codes for the US claim attachment A clinical laboratory report SHALL contain one or more of these sections, in any order. These “specialty” sections SHALL NOT be nested:

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

Table 4.2-1: Laboratory specialties

Note 1: 26436-6 (LABORATORY STUDIES) enables to issue a report putting together observations from multiple specialties (disciplines) in the same text block, allowing to deliver 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.

4.2.1.2 Template of a "specialty" section

A top level `section` element SHALL contain:

- A MANDATORY `code` element using one of the codes listed in the table above. This element carries the following sub-elements:
  - `code` is MANDATORY
  - `codeSystem` is MANDATORY
  - `codeSystemName` is OPTIONAL
  - `displayName` is MANDATORY
- An OPTIONAL `title` element.
- Either:
  - One or more `component` elements, each of which introduces a leaf `section` representing a reported item: battery, specimen study, or individual tests, with its related observations.
- Or:
  - One `text` block with non-blank text, representing the whole report for that specialty.
  - One MANDATORY `entry` containing the full structured data of that report in a machine-readable format.

4.2.2 Relationship between specialties and reported items

The semantic content of each specialty `section` is not constant between countries. The relationship between **reported items** (batteries, specimen studies or individual tests) and **specialties** varies from country to country, and may even vary in the same country, from a healthcare organization to another. This profile does not constrain this relationship. The choice of locating a battery or a test below the appropriate specialty `section` is left up to the Content Creator Actor. Realm extensions of this profile MAY further constrain these relationships, depending upon chosen vocabularies (e.g. LOINC, SNOMED CT, national vocabularies).

4.2.3 Leaf sections: Reported items

At the second level (nested in one specialty `section`), each leaf `section` represents a reported 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 leaf `section` element contains:

- A MANDATORY `code` element identifying the reported item. It represents a battery, an individual test or a microbiology study. This element carries the following sub-elements:
  - `code` is MANDATORY
  - `codeSystem` is MANDATORY
  - `codeSystemName` is OPTIONAL
  - `displayName` is MANDATORY
  - `originalText` is OPTIONAL. The original text exists in a scenario where an originator of the information does not assign a code, but where the code is assigned later by a coder (post-coding.).

    The rule of priority between `displayName` and `originalText` in the rendering should be defined by realms in national extensions of this profile. Some countries may consider `originalText` as the translation of `displayName`, therefore superseding it.
- An OPTIONAL `title` element for the reported item. It is the local translation of the display name for the code.
- A MANDATORY `text` block with non-blank text. This narrative block SHALL present to the human reader, the observations produced for this reported 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. The `entry.typeCode` attribute SHALL be valued "`DRIV`".
- A MANDATORY `entry` containing an `observationMedia` for each multimedia item to be rendered in the narrative block. This `entry` does not exist if there is no multimedia object in the narrative block.
- A MANDATORY `entry` containing the machine-readable result data from which the narrative block of this section is derived.

4.2.3.1 General rules for presenting the results in the narrative block

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 MANDATORY date/time of the observation, which is the relevant physiologic date/time, i.e. when the specimen was drawn from the patient.
- The MANDATORY name of the analyte or finding.
- The MANDATORY 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[3], 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 SHOULD be present once in the section:

- date/time of the observation (since it represents the specimen collection time)
- specimen type (if not inherent to the section)
- specimen source site (if relevant)
- In case the previous observations for these tests were also obtained on one single specimen: the date/time of the previous value SHOULD also be mentioned only once.

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

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

4.2.3.2 Templates for leaf sections

4.2.3.2.1 Leaf section reporting a single specimen battery

4.2.3.2.1.1 Scope

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.

4.2.3.2.1.2 Structure

The narrative block contains:

- Zero or more initial `paragraph` delivering contextual information on the battery: Pertinent information. Reason for ordering this battery. Information related to the specimen (specimen observation, specimen collection procedure, specimen target site). Method used by the battery (if it is common to all the tests belonging to it). Name and phone of the verifier of the results, with date of validation…etc
- a MANDATORY `table` with the test results belonging to the battery. The following columns MAY be used:
    - Name of analyte.
    - Method
    - Unit
    - Current observation with the date/time of specimen collection as header. This column is emphasized with Bold `styleCode`.
    - Reference to footnote comments (`footnoteRef` if any comments accompany some of the observations)
    - Reference range
    - Criteria for reference range
    - Interpretation code (.e.g abnormality flag)
    - Optionally, previous observations with the date/time of specimen collection as header. This column MAY be repeated as many times as there are previous specimens to represent.

  Columns may be amalgamated as required. (e.g. name of analyte and units).
- Zero or more `footnote` referenced from the table, delivering comments (annotations) on some of the observations.
- Zero or more concluding `paragraph` delivering global interpretative comments to this battery.

4.2.3.2.1.3 Example 1: A Complete Blood Count

```
<section>
    <code code="18768-2" codeSystem="2.16.840.1.113883.6.1"
        displayName="CELL COUNT+DIFFERENTIAL STUDIES" originalText="CELL COUNT+DIFFERENTIAL"/>
    <component>
        <section>
            <code code="24317-0" codeSystem="2.16.840.1.113883.6.1"
                                displayName="HEMOGRAM & PLATELETS PANEL"/>
            <text>
                <table border="1">
                    <thead align="center">
                        <tr>
                            <th colspan="5" align="left">
                                <content styleCode="Bold">CBC + Platelets Bld</content>
                            </th>
                        </tr>
                        <tr>
                            <th/>
                            <th><content styleCode="Bold">Mar 21, 2006 07:10</content></th>
                            <th>Reference range</th>
                            <th>Int.c.</th>
                            <th> Mar 12, 2006 08:15</th>
                        </tr>
                    </thead>
                    <tbody align="center">
                        <tr>
                            <td align="left">erythrocytes count (10*6/mm3)</td>
                            <td><content styleCode="Bold">4.95</content></td>
                            <td>4.50-6.00</td>
                            <td/>
                            <td>4.85</td>
                        </tr>
                        <tr>
                            <td align="left">hemoglobin (g/dL)</td>
                            <td><content styleCode="Bold">13.4</content></td>
                            <td>11.5-14.5</td>
                            <td/>
                            <td>13.3</td>
                        </tr>
                        <tr>
                            <td align="left">hematocrit (%)</td>
                            <td><content styleCode="Bold">45</content></td>
                            <td>40.0-54.0</td>
                            <td/>
                            <td>45</td>
                        </tr>
                        <tr>
                            <td align="left">mean corpuscular volume(fL)</td>
                            <td><content styleCode="Bold">97</content></td>
                            <td>80-95</td>
                            <td>H, U</td>
                            <td>90</td>
                        </tr>
                            :
                    </tbody>
                </table>
                <paragraph>No sign of anemia</paragraph>
            </text>
        </section>
    </component>
</section>
```


Rendering:

CELL COUNT + DIFFERENTIAL

CBC + Platelets Bld				
	Mar 21, 2006 07:10	Reference range	Int.c.	Mar 12, 2006 08:15
erythrocytes count (10*6/mm3)	**4.95**	4.50-6.00		4.85
hemoglobin (g/dL)	**13.4**	11.5-14.5		13.3
hematocrit (%)	**45**	40-54		46
mean corpuscular volume (fL)	**97**	80-95	H, U	94
…				

No sign of anemia

4.2.3.2.1.4 Example 2: A chemistry serum electrolyte


```
<section>
    <code code="18719-5" codeSystem="2.16.840.1.113883.6.1" displayName="CHEMISTRY STUDIES"
                originalText=" CHEMISTRY "/>
    <component>
        <section>
            <code code="34554-6" codeSystem="2.16.840.1.113883.6.1"
                displayName="ELECTROLYTES HCFA 98 & VENOUS PH PANEL"
                originalText=" Serum electrolyte"/>
            <text>
                <table border="1">
                    <thead align="center">
                        <tr>
                            <th colspan="8" align="left"><content styleCode="Bold">Lytes</content></th>
                        </tr>
                        <tr>
                            <th/>
                            <th><content styleCode="Bold">Mar 21, 2006 07:10</content></th>
                            <th>Ann.</th>
                            <th>Reference range</th>
                            <th>Int.c.</th>
                            <th>Mar 12, 2006 08:15</th>
                            <th>Jan 01, 2006 05:12</th>
                            <th>Dec 21, 2005 08:10</th>
                        </tr>
                    </thead>
                    <tbody align="center">
                        <tr>
                            <td>Na (mmol/L)</td>
                            <td><content styleCode="Bold">140</content></td>
                            <td/>
                            <td>135 -145</td>
                            <td/>
                            <td>141</td>
                            <td/>
                            <td/>
                        </tr>
                        <tr>
                            <td>K (mmol/L)</td>
                            <td><content styleCode="Bold">3.4</content></td>
                            <td><footnoteRef IDREF="N1"/>(1)</td>
                            <td>3.5 - 5.0</td>
                            <td>L</td>
                            <td/>
                            <td>3.3</td>
                            <td>3.2</td>
                        </tr>
                        <tr>
                            <td>Cl (mmol/L)</td>
                            <td><content styleCode="Bold">99</content></td>
                            </td>
                            <td>98 - 106</td>
                            <td/>
                            <td/>
                            <td/>
                            <td>100</td>
                        </tr>
                            :
                    </tbody>
                </table>
                <footnote ID="N1">(1) Result controlled with a second run</footnote>
            </text>
        </section>
    </component>
</section>
```


Rendering:

CHEMISTRY

Serum electrolyte

Lytes							
	Mar 21, 2006 07:10	Ann.	Reference range	Int.c.	Mar 12, 2006 08:05	Jan 01, 2006 05:12	Dec 21, 2005 08:10
Na (mmol/L)	**140**		135-145		141		
K (mmol/L)	**3.4**	(1)	3.5-5.0	L		3.3	3.2
Cl (mmol/L)	**99**		98-106				100
…							

(1) Result controlled with a second run

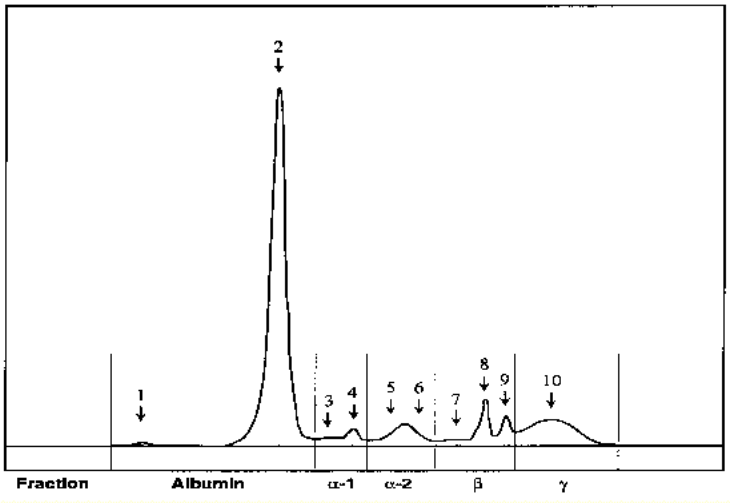
4.2.3.2.1.5 Example 3 including an image: Protein electrophoresis

```
<section>
    <code code="12851-2" codeSystem="2.16.840.1.113883.6.1" displayName="PROTEIN PATTERN"
          originalText="Protein electrophoresis"/>
    <text>
        <table border="1">
            <thead align="center">
                <tr>
                    <th colspan="3" align="left">
                        <content styleCode="Bold">Electrophoretic fraction</content>
                    </th>
                </tr>
                <tr>
                    <th/>
                    <th><content styleCode="Bold">Mar 21, 2006 07:10</content></th>
                    <th>Reference range</th>
                </tr>
            </thead>
            <tbody align="center">
                <tr>
                    <td>Total protein</td>
                    <td><content styleCode="Bold">72</content></td>
                    <td>64 - 80</td>
                </tr>
                <tr>
                    <td>Albumin</td>
                    <td><content styleCode="Bold">40</content></td>
                    <td>38 - 50</td>
                </tr>
                <tr>
                    <td>Alpha 1</td>
                    <td><content styleCode="Bold">4</content></td>
                    <td>3 - 5</td>
                </tr>
                <tr>
                    <td>Alpha 2</td>
                    <td><content styleCode="Bold">5</content></td>
                    <td>3 - 7</td>
                </tr>
                <tr>
                    <td>Beta</td>
                    <td><content styleCode="Bold">8</content></td>
                    <td>6 - 10</td>
                </tr>
                <tr>
                    <td>Gamma</td>
                    <td><content styleCode="Bold">11</content></td>
                    <td>7 - 14</td>
                </tr>
            </tbody>
        </table>
        <renderMultimedia referencedObject="ELECTRO"/>
    </text>
    <entry>
        <observationMedia classCode="OBS" moodCode="EVN" ID="ELECTRO">
            <id root="2.16.840.1.113883.19.2.1"/>
            <value mediaType="image.gif" representation="B64">Here is the inline B64 content</value>
        </observationMedia>
    </entry>
</section>
```


Rendering:

Protein electrophoresis

Electrophoretic fraction		
	Mar 21, 2006 07:10	Reference range
Total protein (g/L)	**72**	64 - 80
Albumine (g/L)	**40**	38 - 50
Alpha 1 (g/L)	**4**	3 - 5
Alpha 2 (g/L)	**5**	3 - 7
Beta (g/L)	**8**	6 - 10
Gamma (g/L)	**11**	7 - 14



1. pre-albumin
2. Albumin
3. alpha 1-Acid-Glycoprotein
4. alpha 1-Antitrrypsin
5. Haptoglobin
6. alpha2 macroglobulin
7. Hemopexin
8. Transferrin
9. Complement
10. Gamma

4.2.3.2.2 Leaf section reporting an individual test

4.2.3.2.2.1 Scope

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.

4.2.3.2.2.2 Structure

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.

4.2.3.2.2.3 Example: A serum potassium

```
<section>
    <code code="18719-5" codeSystem="2.16.840.1.113883.6.1" displayName="CHEMISTRY STUDIES"
          originalText="CHEMISTRY"/>
    <component>
        <section>
            <code code="12814-0" codeSystem="2.16.840.1.113883.6.1"
                  displayName="POTASSIUM" originalText=" Serum potassium "/>
            <text>
                <table border="1">
                    <thead align="center">
                        <tr>
                            <th/>
                            <th><content styleCode="Bold">Mar 21, 2006 07:10</content></th>
                            <th>Reference range</th>
                            <th>Int.c.</th>
                            <th>Mar 12, 2006 08:15</th>
                            <th>Jan 01, 2006 05:12</th>
                        </tr>
                    </thead>
                    <tbody align="center">
                        <tr>
                            <td>K (mmol/L)</td>
                            <td><content styleCode="Bold">3.4</content></td>
                            <td>3.5 - 5.0</td>
                            <td>L, D</td>
                            <td>4.6</td>
                            <td>3.3</td>
                        </tr>
                    </tbody>
                </table>
                <paragraph>Result controlled with a second run</paragraph>
            </text>
        </section>
    </component>
</section>
```

Rendering:

CHEMISTRY

Serum Potassium

	Mar 21, 2006 07:10	Reference range	Int.c.	Mar 12, 2006 08:05	Jan 01, 2006 05:12
K (mmol/L)	**3.4**	3.5 - 5.0	L, D	4.6	3.3

Result controlled with a second run

4.2.3.2.3 Leaf section reporting a challenge study (DFT)

4.2.3.2.3.1 Scope

This structure fits the presentation of the results of a battery that represents a challenge study. A challenge study is a multi-specimen battery, including an initial pre-condition and a temporal sequence of specimen, collected at defined time interval from the origin. It is also called a DFT (Dynamic Function Test). Typical examples of such batteries are found in the specialty "CHEMISTRY CHALLENGE STUDIES".

4.2.3.2.3.2 Structure

The narrative block contains:

- Zero or more introductory `paragraph` delivering contextual information on the battery, including the date/time of the current observations, and other pre-conditions of the challenge.
- One `table` with the sequence of observations obtained during the study. Each row in the table represents one point in time of the challenge.
- Zero or more concluding `paragraph` delivering an interpretative comment on the observations.

4.2.3.2.3.3 Example of a glucose tolerance study

```
<section>
    <code code="XXXXXXX" codeSystem="2.16.840.1.113883.6.1"
                         displayName="GLUCOSE TOLERANCE STUDY POST 75 G GLUCOSE PO"
                         originalText=" Glucose tolerance study "/>
    <text>
        <paragraph>Current observation: Mar 21, 2006 07:10</paragraph>
        <paragraph>Glucose absorbed: 75 g </paragraph>
        <table border="1">
            <thead align="center">
                <tr>
                    <th>Specimen rank</th><th>Time</th><th>blood glucose (mmol/L)</th>
                </tr>
            </thead>
            <tbody align="center">
                <tr>
                    <td>T0</td><td>08:00</td><td>5.55</td>
                </tr>
                <tr>
                    <td>T1</td><td>08:30</td><td>6.66</td>
                </tr>
                <tr>
                    <td>T2</td><td>09:05</td><td>7.77</td>
                </tr>
                <tr>
                    <td>T3</td><td>09:45</td><td>7.22</td>
                </tr>
                <tr>
                    <td>T4</td><td>10:15</td><td>5.00</td>
                </tr>
            </tbody>
        </table>
        <paragraph>Normal reaction</paragraph>
    </text>
</section>
```


Rendering:

Glucose tolerance study per ora
Current observation: Mar 21, 2006 08:00
Glucose absorbed: 75 g

Specimen rank	Time	blood glucose (mmol/L)
T0	08:00	5.55
T1	08:30	6.66
T2	09:05	7.77
T3	09:45	7.22
T4	10:15	5.00

Normal reaction

4.2.3.2.4 Specialty section embedding a whole report

This structure is not constrained. It uses freely the features offered by the narrative block schema (NarrativeBlock.xsd). It allows delivery of a global comment applying to the whole report, at the end of the `text` block.

4.2.3.2.5 Leaf section reporting a microbiology study

4.2.3.2.5.1 Scope

This structure reports all the microbiology observations produced from a specimen during a microbiology study. It includes microbial susceptibility tests: clinical values obtained by MIC (minimal inhibiting concentration) or disk width or any other method.

4.2.3.2.5.2 Structure

The narrative block contains:

- Zero or more introducing paragraphs.
- One table with:
  - 1st column naming the actions, and subtitles delimiting the various phases of the study (microscopy, gram stain, culture, antibiotic sensitivity).
  - 2nd column displaying the observations obtained on the initial specimen. This second column can be split in to any number of columns to accommodate the targeted rendering (see the examples below).
- Zero or more concluding paragraphs.

4.2.3.2.6 Example of a urine microscopy, culture and antibiotic testing

The following examples should be considered as illustrations of possible rendering for microbiology studies. They are not normative: There are many different ways of reporting a microbiology study, depending upon the specimen type (urine, blood culture, swab…) but most of all depending of the author of the report, and of the capabilities of the system used to issue this document.

First example: Showing a cross table of isolates / antibiotic sensitivity:

```
<section>
    <code code="????" codeSystem="2.16.840.1.113883.6.1" displayName="Microbiology on Urine"/>
    <text>
        <table border="1">
            <thead>
                <tr>
                    <th>Action</th>
                    <th align="center" colspan="4">Observation on urine specimen collected 03/21/06 07:25</th>
                </tr>
            </thead>
            <tbody align="center">
                <tr><td>Specimen site & localization</td><td align="center" colspan="4">Urine mid stream</td></tr>
            <tr><td>Direct examination:</td><td colspan="4"/></tr>
                <tr><td/><td align="center" colspan="4">Color: straw</td></tr>
                <tr><td/><td align="center" colspan="4">Appearance: clear</td></tr>
                <tr><td>Microscopy:</td><td colspan="4"/></tr>
                <tr><td>Leukocytes</td><td align="center" colspan="4">500 /mL</td>          </tr>
                <tr><td>Erythtocytes</td><td align="center" colspan="4">200 /mL</td></tr>
            <tr><td>Epithelial cells</td><td align="center" colspan="4">absence</td></tr>
            <tr>
                    <td>Gram stain</td>
                    <td align="center" colspan="4">numerous Gram - ; some Gram +</td>
                </tr>
                <tr><td>Aerobic culture</td><td colspan="4">Positive</td></tr>
                <tr><td>Isolate:</td><td colspan="2">Escherichia coli</td><td colspan="2">Streptococcus D.</td></tr>
            <tr><td>Microorganism count:</td><td colspan="2">100,000 /mL</td><td colspan="2">200,000 /mL</td></tr>
            <tr><td>Microbial suceptibility:</td><td>MIC (mg/L)</td><td>clinical</td><td>MIC (mg/L)</td>
                    <td>clinical</td></tr>
                <tr><td>Amoxicillin:</td><td>12</td><td>R</td><td/><td/></tr>
                <tr><td>Ampicillin:</td><td/><td/><td>6</td><td>I</td></tr>
                <tr><td>Fosfomycin:</td><td>1.3</td><td>S</td><td>2.5</td><td>S</td></tr>
                :
            </tbody>
        </table>
    </text>
</section>
```

Rendering:

Microbiology on Urine

Action	**Observation on urine specimen collected 03/21/06 07:25**			
Specimen site & localization	Urine mid stream			
Direct examination:				
	color: straw			
	appearance: clear			
Microscopy:				
Leukocytes	500 /mL			
Erythrocytes	200 /mL			
Epithelial cells	absence			
Gram stain	numerous gram - ; some gram +			
Aerobic culture:	Positive			
Isolate:	**Escherichia coli**		**Streptococcus D.**	
Microorganism count	100,000 /mL		200,000 /mL	
Microbial susceptibility:	**MIC (mg/L)**	**clinical**	**MIC (mg/L)**	**clinical**
Amoxicillin	12	R		
Ampicillin			6	I
Fosfomycin	1.3	S	2.5	S
…				

Second example: More textual, showing each isolate individually:

```
<section>
    <code code="????" codeSystem="2.16.840.1.113883.6.1" displayName="Microbiology on Urine"/>
    <text>
        <table border="1">
            <paragraph>Urine mid stream collected on March 21<sup>st</sup>2006, 07:25</paragraph>
            <paragraph><caption>Direct examination:</caption> Appearance clear, color straw</paragraph>
            <br/>
            <thead><tr><th>Action</th><th>Observation</th></tr></thead>
            <tbody align="center">
                <tr><td>Microscopy:</td><td colspan="2"/> </tr>
                <tr><td>Leukocytes</td><td align="center" colspan="2">500 /mL</td>          </tr>
                <tr><td>Erythtocytes</td><td align="center" colspan="2">200 /mL</td></tr>
                <tr><td>Epithelial cells</td><td align="center" colspan="2">absence</td></tr>
                <tr>
                    <td>Gram stain</td>
                    <td align="center" colspan="4">numerous Gram - ; some Gram +</td>
                </tr>
                <tr><td>Aerobic culture</td><td colspan="2">Positive</td></tr>
                <tr><td>Isolate:</td><td colspan="2">Escherichia coli</td></tr>
                <tr><td>Microorganism count:</td><td colspan="2">100,000 /mL</td></tr>
                <tr><td>Microbial suceptibility:</td><td>MIC</td><td>clinical</td></tr>
                <tr><td>Amoxicillin:</td><td>12</td><td>R</td></tr>
                <tr><td>Fosfomycin:</td><td>1.3</td><td>S</td></tr>
                <tr><td>Isolate:</td><td colspan="2">Streptococcus D.</td></tr>
                <tr><td>Microorganism count:</td><td colspan="2">200,000 /mL</td></tr>
                <tr><td>Microbial suceptibility:</td><td>MIC</td><td>clinical</td></tr>
                <tr><td>Ampicillin:</td><td>6</td><td>I</td></tr>
                <tr><td>Fosfomycin:</td><td>2.5</td><td>S</td></tr>
                :
            </tbody>
        </table>
    </text>
```

Rendering:

Microbiology on Urine
Urine mid-stream collected on March 21st 2006, 07:25
Direct examination:
Appearance clear, color straw

Action	Observation	
Microscopy:		
Leukocytes	500 /mL	
Erythrocytes	200 /mL	
Epithelial cells	absence	
Gram stain	numerous gram - ; some gram +	
Aerobic culture:	Positive	
Isolate:	**Escherichia coli**	
Microorganism count	100,000 /mL	
Microbial susceptibility:	**MIC**	**clinical susceptibility**
Amoxicillin	12	R
Fosfomycin	1.3	S
…		
Isolate:	**Streptococcus D.**	
Microorganism count	200,000 /mL	
Microbial susceptibility:	**MIC**	**clinical susceptibility**
Ampicillin	6	I
Fosfomycin	2.5	S
…		

4.3 Level 3 entries dedicated to multimedia rendering

A leaf section of the Laboratory Report MAY have optional entries to carry the multimedia objects mentioned in level 2 narrative block, and provide their rendering. Multimedia rendering is based on the `observationMedia` element in an `entry` dedicated to that purpose.

The CDA schema allows both embedded multimedia objects and referenced external multimedia objects. This content Integration Profile restrains the use to embedded multimedia objects only. The purpose of this restriction is to facilitate the digital signature process, and let the digital signature apply to the whole report, multimedia objects included.

The multimedia object is encoded in BASE 64 in the `observationMedia/value` element:

```
<text>
    :
    :
    <renderMultimedia referencedObject="ELECTRO"/>
    :
    :
</text>
<entry>
    <observationMedia classCode="OBS" moodCode="EVN" ID="ELECTRO">
        <id root="2.16.840.1.113883.19.2.1"/>
        <value mediaType="image/gif" representation="B64">Here is the inline B64 multimedia content</value>
    </observationMedia>
</entry>
```

This Integration Profile supports only small images in gif, jpeg, png or bmp[4] format, which are in most cases, not real pictures but simply graphics, like an electrophoresis chart, embedded in the report, as an illustration of the test results.

The sharing of real images (e.g. a picture taken from a microscope, the picture of a kariotype) may be addressed in the future by a dedicated profile of the Laboratory Technical Framework.

4.4 Level 3 entry dedicated to data-processing

4.4.1 Global model and general rules

Each leaf section of the `structuredBody` of a laboratory report SHALL contain 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 is valued "`DRIV`".

Alignment with the objects of the "Result Event" RMIM from the Laboratory Domain:

The level 3 entries must be compatible with the results contained in message type POLB_MT004000 carried by the trigger event Result Complete (POLB_TE004200) or Result Corrected (POLB_TE004201) of the Laboratory Domain. Thus, a LIS able to produce HL7 V3 results messages will easily produce lab reports from the same data. The equivalence with POLB_MT004000 is as follows:

Result Event RMIM class	CDA object
ObservationReport (classCode ENTRY)	ACT (classCode ACT)
ObservationBattery (classCode BATTERY)	Organizer (classCode BATTERY)
SpecimenObservationCluster (classCode CLUSTER)	Organizer (classCode CLUSTER)
ObservationEvent (classCode OBS)	Observation (classCode OBS)
Annotation (classCode ACT)	Act (classCode ACT)

[4] This list of image formats can further be refined by national extensions of this profile.

Result Event RMIM class	CDA object
Process (classCode PROC)	Procedure (classCode PROC)

To cope with a current limitation of vocabulary in the CDA R2 entry model, we chose to represent the Lab 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.

A laboratory observation `entry` is based on the constrained clinical statement model below:

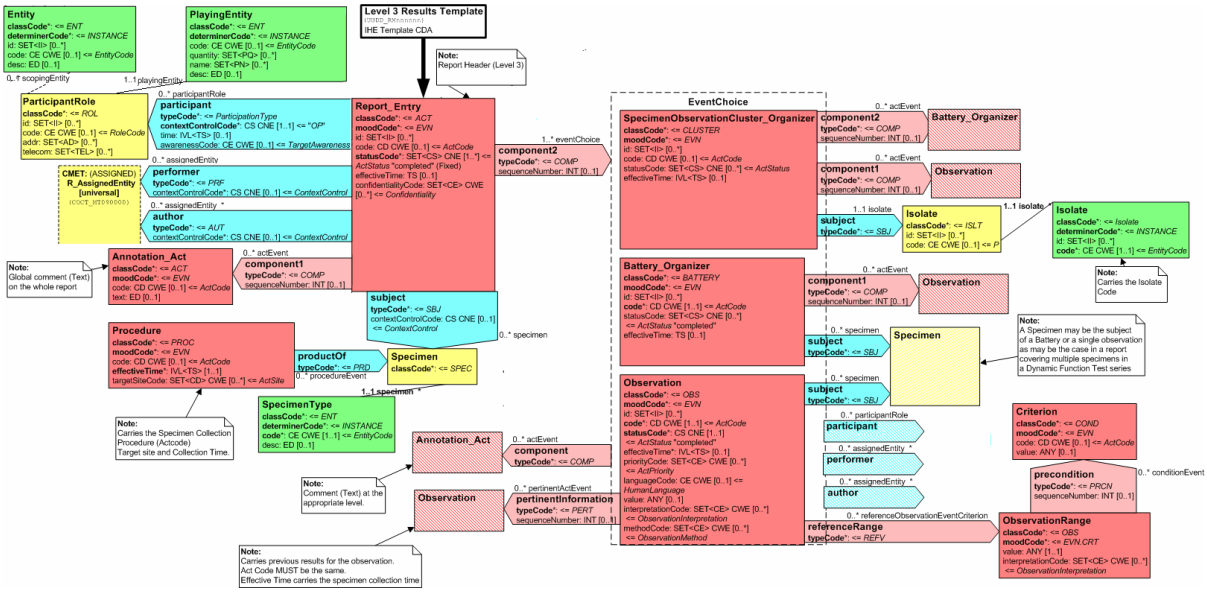


Figure 4.4-1: representation of a machine-processable entry

The figure above uses more expressive names than those appearing in the clinicalStatement of CDA entries. Its purpose is only to provide a clear synopsis view of the `entry` template built hereafter as a restriction of a CDA `entry`, with four extensions to the CDA Clinical Statement model. The figure is split into its left and right parts, zoomed in sequence hereafter.

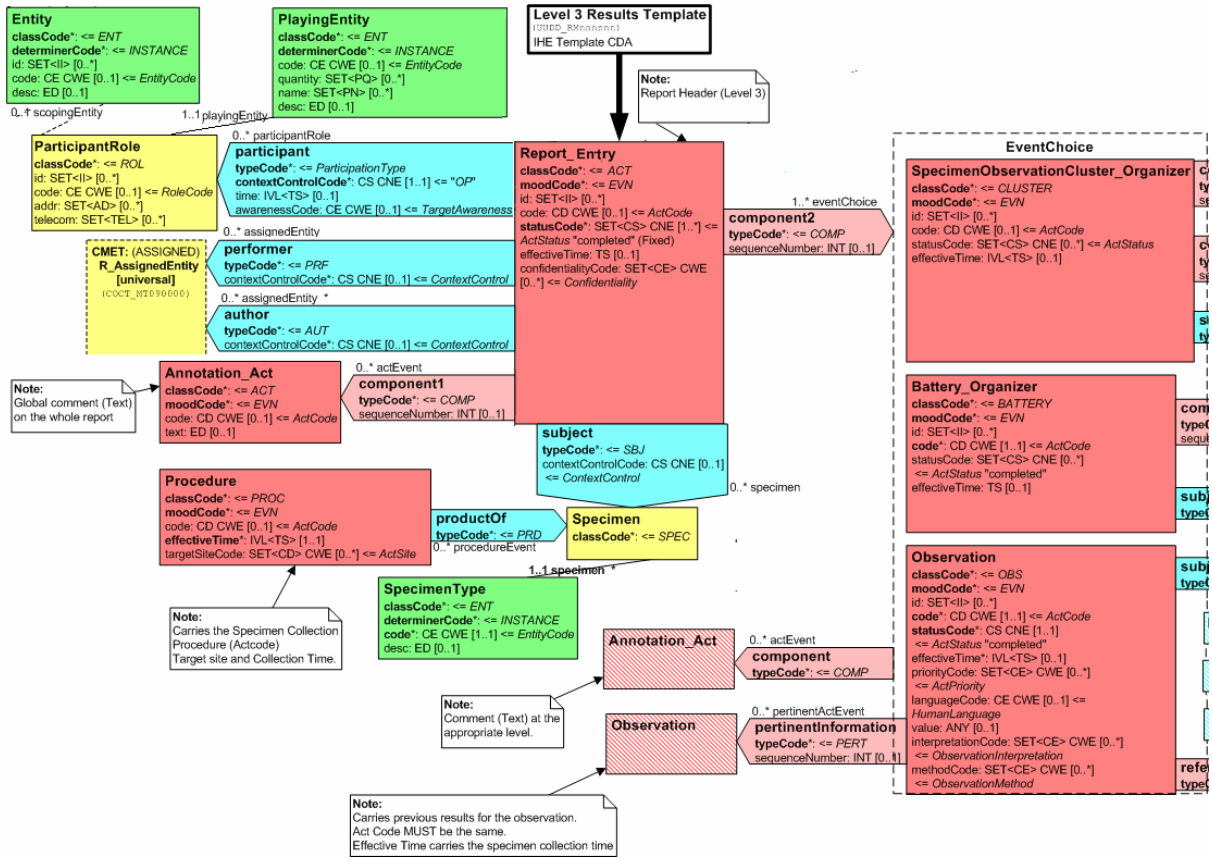


Figure 4.4-2: Left part of the machine-processable entry

Comments:

Report_Entry: The `entry` MUST start with this element. It holds the global content of the leaf `section` to which this `entry` is hanging. And it carries the general properties of that `section`. It will be represented in the CDA `entry` by: a `<act classCode="ACT">` element.

It can contain one of these items:

- A single specimen battery as shown in § 4.2.3.2.1
- A single test as shown in § 4.2.3.2.2
- A multi-specimen DFT as shown in § 4.2.3.2.3
- A whole report embedded in a specialty section as explained in § 4.2.3.2.4
- A microbiology study performed on a specimen, as shown in § 4.2.3.2.5

In case of a report aggregating observations from multiple laboratories, or multiple specialties with a different biomedical scientist for each, a leaf `section` may have a performer and an author different from those declared in the header of the document. This is expressed with the participations "performer" and "author" to the Report_Entry.

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 property of Report_Entry, which in that case will be valued with a code requiring a restricted access ("R") or a very restricted access ("V").

This Report_Entry (`<act classCode="ACT">`) MAY contain any number of objects appearing in the EventChoice choice box:

- SpecimenObservationCluster_Organizer encapsulates an isolate, and contains the batteries and observations performed on that isolate, as well as the microorganism identification. It is represented by an `organizer` element, with `classCode="CLUSTER"`.
- Battery_Organizer is used to report the observations belonging to a battery and is represented by an `organizer` element, with `classCode="BATTERY"`.
- Observation is used to report the result of a single test and is represented by an `observation` element.

Both the Report_Entry and any of the elements of the choice box MAY be commented with an Annotation_Act represented with a `<entryRelationship typeCode="COMP">` element having an `act` sub-element. The comment is delivered by the `text` sub-element if it is purely textual, or by the `code` sub-element for a coded comment.

Example of a textual comment:

```
<entryRelationship typeCode="COMP">
    <act classCode="ACT" moodCode="EVN">
        <text>No sign of anemia</text>
    </act>
</entryRelationship>
```

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"`[5] 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`.

Example of a current result with 2 previous results attached to it:

[5] "REFR" ("refers to") is the menemonic available in the x_ActRelationshipEntryRelationship vocabulary domain, most appropriate to this reference to a previous result. The mnemonic "PREV" ("has previous") would have been more appropriate, but is not available in this vocabulary domain.


```
<observation classCode="OBS" moodCode="EVN">
    <code code="11273-0" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
                                displayName="ERYTHROCYTES"/>
    <statusCode code="completed"/>
    <!-- Current result 4.95  -->
    <value xsi:type="PQ" value="4.95" unit="10*6/mm3"/>
    <interpretationCode code="N" codeSystem="2.16.840.1.113883.5.83"/>
    <!—Introduces the previous result 4.85 from Mar 12, 2006 08:15 -->
    <entryRelationship typeCode="PERT">
        <sequenceNumber value="1"/>
        <observation classCode="OBS" moodCode="EVN">
            <code code="11273-0" codeSystem="2.16.840.1.113883.6.1"/>
            <statusCode code="completed"/>
            <effectiveTime value="20060312"/>
            <value xsi:type="PQ" value="4.85" unit="10*6/mm3"/>
        </observation>
    </entryRelationship>
    <entryRelationship typeCode="PERT">
        <sequenceNumber value="2"/>
        <observation classCode="OBS" moodCode="EVN">
            <code code="11273-0" codeSystem="2.16.840.1.113883.6.1"/>
            <statusCode code="completed"/>
            <effectiveTime value="20051031"/>
            <value xsi:type="PQ" value="4.70" unit="10*6/mm3"/>
        </observation>
    </entryRelationship>
</observation>
```


If all observations of the entry have been produced on the same specimen, this specimen SHALL be attached to the top Report_Entry through a subject participation represented by a `specimen` element in CDA Clinical Statement.

This Specimen is the productOf a specimen collection Procedure represented by a `procedure` element introduced by a `productOf` participation.[6] This `procedure` encapsulates:

- A `code` which represents the particular method employed to collect the specimen.
- An `effectiveTime`, which represents the date & time of specimen collection.
- The `targetSiteCode` which carries the source site of the specimen (e.g. urine natural mid-stream).

The specimen entity SpecimenType brings the type of specimen. It is represented by a `specimenPlayingEntity` element and its `code` attribute. The recommended vocabulary domain is the HL7 v3 SpecimenEntityType. Alternatively, other standard vocabularies can be used, like SNOMED CT.

```
<entry typeCode="DRIV">
    <templateId root="1.3.6.1.4.1.19376.1.3" extension="Lab.Report.Data.Processing.Entry"/>
    <!--Report_Entry -->
    <act classCode="ACT" moodCode="EVN">
        <id root="2.16.840.1.113883.19" extension="1234"/>
        <code code="xxxxx" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
                displayName="MICROBIOLOGY URINE STUDY"/>
        <statusCode code="completed"/>
        <effectiveTime value="200603210725"/>
    <!--subject participation -->
        <specimen typeCode="SPC">
            <!--specimen role -->
            <specimenRole classCode="SPEC">
                < !--specimen playing entity -->
                <specimenPlayingEntity>
                    < !--specimen type -->
                    <code code="UR" codeSystem="OID for HL7 vocab domain"
                                    codeSystemName="specimenEntityType" displaName="urine"/>
                </specimenPlayingEntity>
                <productOf typeCode="PRD">
                    <!-- Specimen collection procedure, carrying also the target site -->
                    <procedure classCode="PROC" moodCode="EVN">
                        <effectiveTime value="200603210725"/>
                        <targetSiteCode code="xxxxxxx" displaName="natural mid-stream"/>
                    </procedure>
                </productOf>
            </specimenRole>
        </specimen>
```

[6] This is an extension to CDA R2. See Chapter 4.5 for discussion on the proposed extensions to CDA R2.

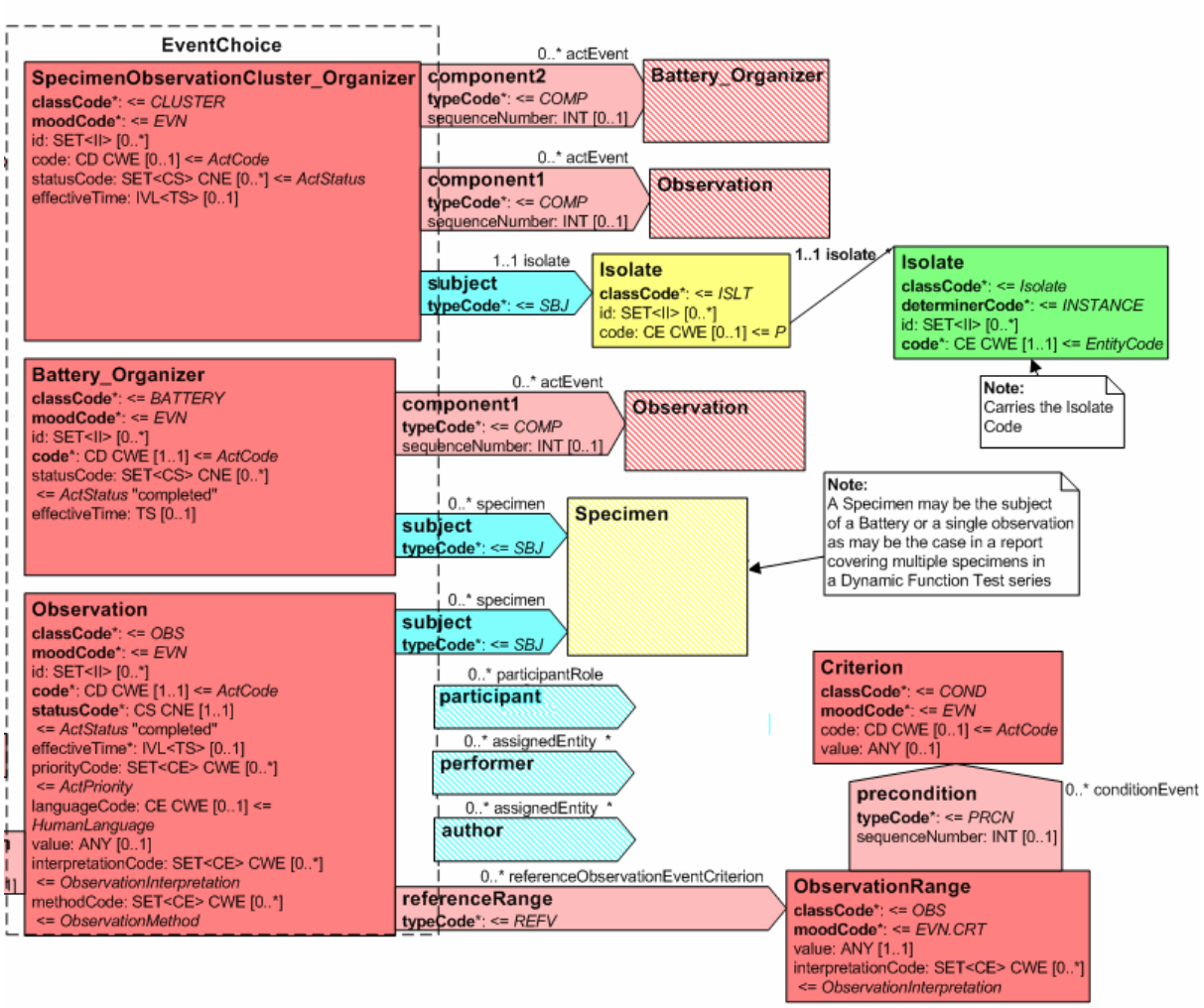


Figure 4.4-3: Right part of the machine-processable entry

Comments:

Below the Report_Entry, any number of SpecimenObservationCluster_Organizer, Battery_Organizer, Observation, can be found.

SpecimenObservationCluster_Organizer is an `organizer` element with `classCode="CLUSTER"`, only used 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. The mapping with CDA schema is as follows:

artifact on the figure	CDA element or attribute
SpecimenObservationCluster_Organizer	<organizer classCode="CLUSTER">
subject participation	<specimen>
Isolate role	<specimenRole classCode="ISLT">
Isolate playing entity	<specimenPlayingEntity>
code attribute of Isolate playing entity	<code> using any available vocabulary domain (e.g. SNOMED CT) to code the microorganism.

Example of isolate identification:

```
<organizer classCode="CLUSTER" moodCode="EVN">
    <specimen typeCode="SPC">
        <specimenRole classCode="ISLT">
            <specimenPlayingEntity>
                <code code="E-coli" displayName="Escherichia  coli"/>
            </specimenPlayingEntity>
        </specimenRole>
    </specimen>
```

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).

A Battery_Organizer may be related to a specimen if it does not inherit this relationship from an upper level.

A Battery_Organizer can have for components any number of Observations (`observation` element).

An Observation may be related to a specimen if it does not inherit this relationship from an upper level.

A battery, an observation, a study of an isolate, may have an author and/or a performer differing from those declared at a higher level. These will be described using respectively the "author" and "performer" participations connected to the choice box.

Unless it is aborted, an Observation usually has a `value`, which is the result.

The observation may have an `interpretationCode`, and may have a `methodCode`.

An Observation may have a reference range attached. The reference range is represented as a value, not as a text (since it is machine-processable data).

The reference range may be qualified by preconditions, each of which brings a criterion.

```
<observation classCode="OBS" moodCode="EVN">
    <code code="30428-7" codeSystem="2.16.840.1.113883.6.1" displayName="MCV"/>
    <statusCode code="completed"/>
    <value xsi:type="PQ" value="97" unit="fL"/>
    <interpretationCode code="H" codeSystem="2.16.840.1.113883.5.83"/>
    <interpretationCode code="U" codeSystem="2.16.840.1.113883.5.83"/>
    <referenceRange typeCode="REFV">
        <observationRange classCode="OBS" moodCode="EVN.CRT">
            <value xsi:type="IVL_PQ">
                <low value="80" unit="fL"/>
                <high value="95" unit="fL"/>
            </value>
        </observationRange>
        <precondition typeCode="PRCN">
            <criterion classCode="COND">
                <code code="SEX"/>
                <value xsi:type="CD" code="M" codeSystem="2.16.840.1.113883.5.1"/>
            </criterion>
        </precondition>
        <precondition typeCode="PRCN">
            <criterion classCode="COND">
                <code code="AGE"/>
                <value xsi:type="IVL_PQ">
                    <low value="35" unit="Y"/>
                    <high value="55" unit="Y"/>
                </value>
            </criterion>
        </precondition>
    </referenceRange>
```


4.4.2 Template "Report_Entry" : An entry of a laboratory report

The hierarchy of tables below describes the structure of the data-processing `entry` template for a section of a laboratory report, according to the data model described above in 4.4.1:

Table 4.4-1: Structure of Report_Entry

Lvl	Card	Parent/element	Attribute	Value	Comments
1	[0..1]	section/entry			
			typeCode	DRIV	The narrative block should be entirely derived from the entry
2	[1..1]	entry/templateId			
			root	1.3.6.1.4.1. 19376.1.3.1	OID assigned to the template Report_Entry
			extension	Lab.Report. Data. Processing. Entry	Extension of the Template identifier assigned by the IHE Laboratory domain.
Report_Entry from which the section is derived					
2	[1..1]	entry/act			
			classCode	ACT	fixed
			moodCode	EVN	fixed
3	[0..1]	act/id			
3	[1..1]	act/code			Unique code from which section/code is derived
3	[1..1]	act/statusCode			
			code	{completed |active |aborted |obsolete}	'completed' when all expected results are present. 'active' if not all expected results are present (in a preliminary report) 'aborted' if the tests of this section did not reach completion. Some results may be there, but not all. 'obsolete' if the whole set of observations of this section is replaced by a new one. i.e. this obsolete entry is replaced by a new one in this new revision of the laboratory report.
3	[0..1]	act/effectiveTime			
			value		Date & time the content of the entry was issued
3	[0..1]	act/confidentialityCode			
			code	{R|V}	Supersedes confidentialityCode of the document for this particular section. Used only to restrict access to the content of the section. If valued, the value must be more restrictive than that of the header (R = Restricted, V = Very restricted). If it exists, then section/confidentialityCode is derived from it.
specimen participation hangs to Report_Entry if one single specimen for the whole section.					
3	[0..1]	act/specimen			→ See Table 4.4-5
			typeCode	SPC	
performer participation used if different from the performer of the header, to supersede it for this section.					
3	[0..*]	act/performer			→ See Table 4.4-6
			typeCode	PRF	
author participation used if different from the author of the header, to supersede it for this section.					
3	[0..*]	act/author			→ See Table 4.4-7

Lvl	Card	Parent/element	Attribute	Value	Comments
			typeCode	AUT	
participant used for other participants such as verifier (VRF) or responsible party (RESP)					
3	[0..*]	act/participant			→ See Table 4.4-8
			typeCode	{VRF|RESP|DEV}	VRF for verifier, RESP for responsible party DEV for device (e.g. lab analyzer)
content of the Report_Entry: any number of SpecimenObservationCluster_Organizer, Battery_Organizer, Observation. Each of these is described in one of the tables below.					
3	[1..*]	act/entryRelationship			→ Isolate = Table 4.4-2 → Battery = Table 4.4-3 → Observation = Table 4.4-4
			typeCode	COMP	
Global comments of the Report_Entry that will comment the section, at the bottom of it.					
3	[0..*]	act/entryRelationship			
			typeCode	COMP	
4	[1..1]	entryRelationship/act			
			classCode	ACT	
			moodCode	EVN	
5	[1..1]	act/text			Text of the comment.

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Table 4.4-2: Structure of SpecimenObservationCluster_Organizer

Lvl	Card	Parent/element	Attribute	Value	Comments
SpecimenObservationCluster_Organizer used only in microbiology to capture the findings on an **isolate**					
4	[1..1]	organizer			
			classCode	CLUSTER	fixed
			moodCode	EVN	fixed
5	[0..1]	organizer/id			
5	[0..1]	organizer/code			
5	[1..1]	organizer/statusCode			
			code	{completed|active|aborted|obsolete}	'completed' when all expected results are present for this isolate. 'active' if not all expected results are present (in a preliminary report) 'aborted' if the findings on the isolate did not reach completion. Some results may be there. 'obsolete' if the whole set of observations on this isolate is replaced by a new one. i.e. this obsolete isolate is replaced by a new one in the same entry under the same Report_Entry, in this new revision of the laboratory report.
5	[0..1]	organizer/effectiveTime			
			value		Time of results on this isolate.
participation of the isolate i.e. the specific sub-specimen on which a microorganism was isolated and cultivated					
5	[1..1]	organizer/specimen			
			typeCode	SPC	type of participation "specimen"
6	[1..1]	specimen/specimenRole			
			classCode	ISLT	represents an isolate
7	[0..1]	specimenRole/id			unique identifier for this isolate, known to the laboratory

Lvl	Card	Parent/element	Attribute	Value	Comments
7	[1..1]	specimenRole /specimenPlayingEntity			
			classCode	MIC	The entity is a microorganism
8	[1..1]	specimenPlayingEntity /code			Identification of the microorganism, in a standard vocabulary
			code		
			codeSystem		
			codeSystemName		
			displayName		Name of the organism reported in the narrative block.
performer participation used if specific performer on this isolate, to supersede all performers of higher level.					
5	[0..*]	organizer/performer			→ See Table 4.4-6
			typeCode	PRF	
author participation used if specific author on this isolate, to supersede all authors of higher level.					
5	[0..*]	organizer/author			→ See Table 4.4-7
			typeCode	AUT	
participant used for other participants such as verifier (VRF) or responsible party (RESP)					
5	[0..*]	act/participant			→ See Table 4.4-8
			typeCode	{VRF|RESP|DEV}	VRF for verifier, RESP for responsible party DEV for device (e.g. lab analyzer)
content of the SpecimenObservationCluster _Organizer: any number of Battery_Organizer, Observation.					
5	[1..*]	organizer/component			→ Battery = Table 4.4-4 → Observation = Table 4.4-5
			typeCode	COMP	
Global comments on this isolate					
5	[0..*]	organizer/ entryRelationship			
			typeCode	COMP	
6	[1..1]	entryRelationship/act			
			classCode	ACT	
			moodCode	EVN	
7	[1..1]	act/text			Text of the comment.

Table 4.4-3: Structure of Battery_Organizer

Lvl	Card	Parent/element	Attribute	Value	Comments
Battery_Organizer Holds a battery and its set of observations and annotations, plus an optional specimen					
n([7])	[1..1]	organizer			
			classCode	BATTERY	fixed
			moodCode	EVN	fixed
n+1	[0..1]	organizer/id			If present, represents the lab filler order number (ORC-3 and OBR-3 in HL7 v2.5) for this battery
n+1	[0..1]	organizer/code			Unique code for the battery in the appropriate vocabulary (e.g. SNOMED CT)
n+1	[1..1]	organizer/statusCode			
			code	{completed|aborted|obsolete}	'completed' when all expected results are present. 'aborted' if the battery did not reach the end of testing. Some results may be there. 'obsolete' if this battery is replaced by a new one (following it) in this new revision of the laboratory report.
n+1	[0..1]	organizer/effectiveTime			
			value		Time of results on this battery
specimen participation if this battery uses a specific specimen not recorded at a higher level.					
n+1	[0..1]	organizer/specimen			→ See Table 4.4-5
			typeCode	SPC	
performer participation. Performer to supersede those recorded at higher level.					
n+1	[0..*]	organizer/performer			→ See Table 4.4-6
			typeCode	PRF	
author participation used to supersede the authors of higher level.					
n+1	[0..*]	organizer/author			→ See Table 4.4-7
			typeCode	AUT	
participant used for other participants such as verifier (VRF) or responsible party (RESP)					
5	[0..*]	act/participant			→ See Table 4.4-8
			typeCode	{VRF|RESP|DEV}	VRF for verifier, RESP for responsible party DEV for device (e.g. lab analyzer)
content of the Battery_Organizer: any number of Observation.					
3	[0..*]	organizer/component			→ Observation = Table 4.4-4 ([8])
			typeCode	COMP	
Global comments of the Battery_Organizer that will comment the battery at the bottom of it.					
3	[0..*]	organizer/ entryRelationship			
			typeCode	COMP	
4	[1..1]	entryRelationship/act			
			classCode	ACT	
			moodCode	EVN	
5	[1..1]	act/text			Text of the comment.

[7] If the Battery_Organizer hangs below the Report_Entry, n = 4. Otherwise the Battery_Organizer hangs below the SpecimenObservationCluster_Organizer and n = 6.

[8] A battery has 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.

Table 4.4-4: Structure of Observation

Lvl	Card	Parent/element	Attribute	Value	Comments
Battery_Organizer Holds a battery and its set of observations and annotations, plus an optional specimen					
n([9])	[1..1]	observation			
			classCode	OBS	fixed
			moodCode	EVN	fixed
n+1	[0..1]	observation/id			
n+1	[1..1]	observation/code			Unique test code in an international standard (LOINC or SNOMED CT) or a national standard (e.g. JC10 in Japan)
n+1	[1..1]	observation/statusCode			
			code	{completed |aborted |obsolete}	'completed' when the result is present. 'aborted' if the test could not be performed. 'obsolete' if this test is replaced by a new one (following it) in this new revision of the laboratory report.
n+1	[0..1]	observation /effectiveTime			
			value		Relevant clinical time (equal time of the collection of the specimen used for this test)
n+1	[0..1]	observation/value			The result obtained for this test using the appropriate data type. Numeric results use data type PQ, which includes the unit. The result is absent in case of 'obsolete' or 'aborted' observation.
n+1	[0..1]	observation/ interpretationCode			One or more codes interpreting the result, expressed with ObservationInterpretation vocabulary (e.g. H = high, L = low) In case of a antimicrobial susceptibility test in microbiology, the vocabulary domain is ObservationInterpretationSuscep-tibility: S = susceptible R = resistant I = intermediate VS = very susceptible MS = moderately susceptible
			code		
n+1	[0..1]	observation/methodCode			method used for this observation expressed with ObservationMethod vocabulary (CWE)
			code		
specimen participation if this observation uses a specific specimen not recorded at a higher level.					
n+1	[0..1]	observation/specimen			→ See Table 4.4-5
			typeCode	SPC	
performer participation. Performer to supersede those recorded at higher level.					
n+1	[0..*]	observation/performer			→ See Table 4.4-6
			typeCode	PRF	
author participation used to supersede the authors of higher level.					
n+1	[0..*]	observation/author			→ See Table 4.4-7
			typeCode	AUT	

[9] If the Observation hangs below the Report_Entry, n = 4. If the Observation hangs below a SpecimenObservationCluster_Organizer, n = 6. If the Observation hangs below a Battery_Organizer below the Report_Organize, n = 6. If If the Observation hangs below a Battery_Organizer below a SpecimenObservationCluster_Organizer, n = 8.

Lvl	Card	Parent/element	Attribute	Value	Comments
			typeCode	COMP	
participant used for other participants such as verifier (VRF) or responsible party (RESP)					
5	[0..*]	act/participant			→ See Table 4.4-8
			typeCode	{VRF|RESP|DEV}	VRF for verifier, RESP for responsible party DEV for device (e.g. lab analyzer)
Comments on this Observation					
n+1	[0..*]	observation/ entryRelationship			Extension to CDA Clinical Statement (See **Erreur ! Source du renvoi introuvable.**)
			typeCode	COMP	
n+2	[1..1]	entryRelationship/act			
			classCode	ACT	
			moodCode	EVN	
n+3	[1..1]	act/text			Text of the comment.
Previous observations obtained for the same patient, test, same method, same unit					
n+1	[0..*]	observation/ entryRelationship			
			typeCode	REFR	Refers to a previous observation
n+2	[1..1]	entryRelationship/ observation			
			classCode	OBS	
			moodCode	EVN	
n+3	[1..1]	observation/code			The same test code
n+3	[1..1]	observation/statusCode			
			code	completed	
n+3	[1..1]	observation/ effectiveTime			
			value		The clinically relevant date/time of the previous result obtained for this test.
n+3	[1..1]	observation/value			The previous result obtained for this test
Reference range for the current test result					
n+1	[0..1]	observation/ referenceRange			
			typeCode	REFV	
n+2	[1..1]	referenceRange/ observationRange			
			classCode	OBS	
			moodCode	EVN.CRT	
n+5	[0..1]	observationRange/value			interval (IVL) representation
n+5	[1..1]	observationRange/ interpretationCode			
			code	N	These are normal ranges
n+5	[0..*]	observationRange/ preCondition			Extension to CDA Clinical statement (see 0)
			typeCode	PRCN	
n+6	[1..1]	precondition/criterion			
			classCode	COND	
			moodCode	EVN	
n+7	[1..1]	criterion/code			
			code		Code of the criterion (e.g. age, sex)
n+7	[1..1]	criterion/value			
			value		Value of the criterion

Table 4.4-5: Specimen for Report_Oganizer or Battery_Organizer or Observation

Lvl	Card	Parent/element	Attribute	Value	Comments
specimen participation					
n	[0..1]	specimen			
			typeCode	SPC	type of participation "specimen"
n+1	[1..1]	specimen/specimenRole			
			classCode	SPEC	type of role: specimen
n+2	[0..1]	specimenRole/id			specimen identifier known to the laboratory
n+2	[1..1]	specimenRole /specimenPlayingEntity			
n+3	[1..1]	specimenPlayingEntity/code			The specimen type coded with HL7 vocabulary SpecimenEntityType or another standard vocabulary
n+2	[0..1]	specimenRole/productOf			Extension to CDA Clinical Statement (see 4.5.2)
			typeCode	PRD	specimen is produced by
n+3	[0..1]	productOf/procedure			specimen collection process
			classCode	PROC	
			moodCode	EVN	
n+4	[0..1]	procedure/code			specimen collection procedure code
n+4	[1..1]	procedure/effectiveTime			date/time of specimen collection
n+4	[0..1]	procedure/targetSiteCode			source site of the specimen

Table 4.4-6: Performer at any level

Lvl	Card	Parent/element	Attribute	Value	Comments
performer participation used to supersede the performer of the higher level					
n	[0..*]	performer			
			typeCode	PRF	"performer" type of participation
n+1	[0..1]	performer/time			Time interval of the performer's act.
n+1	[1..1]	performer/assignedEntity			
			classCode	ASSIGNED	
n+2	[1..1]	assignedEntity/id			Identifier of the performing role
n+2	[1..1]	assignedEntity/addr			Address
n+2	[1..1]	assignedEntity/telecom			telephone, fax, email, …
n+2	[0..1]	assignedEntity/ assignedPerson			The person who performed the tests of this section.
n+3	[1..1]	assignedPerson/name			Name of the person
n+2	[0..1]	assignedEntity/ representedOrganization			The organization represented by this person.
n+3	[1..1]	representedOrganization /name			Name of the organization

This participation is used to mention a person who performed the tests, different from the one indicated at a higher level, including the header.

In particular, when a part of the tests has been performed by a subcontractor laboratory, the element `performer/assignedEntity/assignedPerson/name` may carry the name of the subcontractor laboratory Director. This is possible if the hypothesis below is verified for the realm:

> From the standpoint of the laboratory issuing the global report including these subcontracted test results, The Director of the subcontractor laboratory was indeed the assigned person who received the order to perform these tests, and is the only person that need to be mentioned in the global report.
>
> If this hypothesis is incompatible with the realm, then use a responsible participant, as described below table 9.2-8.

Table 4.4-7: Author at any level

Lvl	Card	Parent/element	Attribute	Value	Comments
author participation used to supersede the author of the higher level. Constraint: The `assignedAuthor` is either an `assignedPerson` or an `assignedAuthoringDevice`.					
n	[0..*]	`author`			
			`typeCode`	`AUT`	"author" type of participation
n+1	[0..1]	`author/functionCode`			Function code of the author
n+1	[0..1]	`author/time`			Time interval of authoring
n+1	[1..1]	`author/assignedAuthor`			
			`classCode`	`ASSIGNED`	
n+2	[1..1]	`assignedAuthor/id`			Identifier of the authoring role
n+2	[1..1]	`assignedAuthor/addr`			Address
n+2	[1..1]	`assignedAuthor/telecom`			telephone, fax, email, …
n+2	[0..1]	`assignedAuthor/` `assignedPerson`			Either the person who authored the content of this section.
n+3	[1..1]	`assignedPerson/name`			
n+2	[0..1]	`assignedAuthor/` `assignedAuthoringDevice`			Or the device that authored the content of this section.
n+3	[1..1]	`assignedAuthoringDevice` `/manufacturerModelName`			Name of the device
n+3	[1..1]	`assignedAuthoringDevice` `/softwareName`			Name of the software system
n+2	[1..1]	`assignedAuthor/` `representedOrganization`			The organization represented by this person.
n+3	[0..1]	`representedOrganization` `/name`			Name of the person

Table 4.4-8: additional Participant at any level

Lvl	Card	Parent/element	Attribute	Value	Comments
participant used for other participants Constraint: Types of participants limited to verifier (VRF) or responsible party (RESP)					
n	[0..*]	`participant`			
			`typeCode`	`{VRF|RESP|` `DEV}`	VRF for verifier, RESP for responsible party DEV for device (e.g. analyzer)
n+1	[1..1]	`participant` `/participantRole`			
			`classCode`	`ASSIGNED`	
n+2	[1..1]	`participantRole/id`			Identifier of the participant role
n+2	[1..1]	`participantRole/addr`			Address
n+2	[1..1]	`participantRole/telecom`			telephone, fax, email, …
n+2	[0..1]	`participantRole/` `playingEntity`			Appears only if VRF or RESP: The person who verified the content of this part and is responsible for it
n+3	[1..1]	`playingEntity/name`			Name of the person
n+2	[0..1]	`participantRole/` `playingDevice`			Appears only if DEV: The analyzer or other laboratory device used to produce the results
n+3	[1..1]	`playingDevice/code`			code of the analyzer or other device
n+3	[1..1]	`playingDevice/` `manufacturerModelName`			Name of the analyzer or other device
n+2	[0..1]	`participantRole/` `scopingEntity`			The organization (laboratory, facility, team) the person belongs to
n+3	[1..1]	`scopingEntity/id`			Organization identifier

The participant may be:

a) The verifier of the observations of this part of the report. In the case where a laboratory report has multiple verifiers. Each verifier is attached to the subset of observations he or she verified, by the means of a `participant` element.

b) A device or equipment, which was used to produce this set of results (e.g. an analyzer).

c) The person responsible 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.

4.4.3 Examples of machine-processable entries

4.4.3.1 CBC

The example described in section 4.2.3.2.1.3 is derived from the following entry:

```
<entry typeCode="DRIV">
    <templateId root="1.3.6.1.4.1.19376.1.3.1" extension="Lab.Report.Data.Processing. Entry"/>
    <!--      Report_Entry from which the section is derived -->
    <act classCode="ACT" moodCode="EVN">
        <code code="24317-0" codeSystem="2.16.840.1.113883.6.1" displayName="HEMOGRAM &amp;amp; PLATELETS
PANEL"/>
        <statusCode code="completed"/>
        <!-- Blood total specimen used for the observations of the entire section -->
        <specimen typeCode="SPC">
            <specimenRole classCode="SPEC">
                <!-- Specimen unique ID assigned by the laboratory -->
                <id root="1.3.6.4.1.4.1.2835.1" extension="0321123456"/>
                <!-- Type of specimen : venous blood -->
                <specimenPlayingEntity>
                    <code code="BLDV" codeSystem="2.16.840.1.113883.XXX.YYY" displayName="blood venous"/>
                </specimenPlayingEntity>
                <lab:productOf typeCode="PRD">
                    <lab:procedure classCode="PROC" moodCode="EVN">
                        <!-- Date time of specimen collection  6:30 a.m. on March 21 2006 -->
                        <lab:effectiveTime value="200603210630"/>
                    </lab:procedure>
                </lab:productOf>
            </specimenRole>
        </specimen>
        <!--      Battery Hemogram and platelets     -->
        <entryRelationship typeCode="COMP">
            <organizer classCode="BATTERY" moodCode="EVN">
                <id root="1.3.6.4.1.4.1.2835.1" extension="060321123456"/>
                <code code="24317-0" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
displayName="HEMOGRAM &amp;amp; PLATELETS PANEL"/>
                <statusCode code="completed"/>
                <!-- Date time of final results for this battery  7:10 a.m. on March 21 2006 -->
                <effectiveTime value="200603210710"/>
                <!--      First analyte: Erythrocytes  -->
                <component>
                    <observation classCode="OBS" moodCode="EVN">
                        <code code="11273-0" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
displayName="ERYTHROCYTES"/>
                        <statusCode code="completed"/>
                        <!-- Clinically relevant time for the observation =  specimen collection  time -->
                        <effectiveTime value="200603210630"/>
                        <!-- Current result 4.95  -->
                        <value xsi:type="PQ" value="4.95" unit="10*6/mm3"/>
                        <interpretationCode code="N" codeSystem="2.16.840.1.113883.5.83"/>
                        <entryRelationship typeCode="REFR">
                            <!-- Previous result 4.85 from Mar 12, 2006 08:15 -->
                            <observation classCode="OBS" moodCode="EVN">
                                <code code="11273-0" codeSystem="2.16.840.1.113883.6.1"/>
                                <statusCode code="completed"/>
                                <effectiveTime value="200603120815"/>
                                <value xsi:type="PQ" value="4.85" unit="10*6/mm3"/>
                            </observation>
                        </entryRelationship>
```



```
                        <!--    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>
                            </observationRange>
                            <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>
                        </referenceRange>
                    </observation>
                </component>
                <!--    2nd analyte: Hemoglobin -->
                <component>
                    <observation classCode="OBS" moodCode="EVN">
                        <code code="20509-6" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
displayName="HEMOGLOBIN"/>
                        <statusCode code="completed"/>
                        <!-- Clinically relevant time for the observation =  specimen collection  time -->
                        <effectiveTime value="200603210630"/>
                        <value xsi:type="PQ" value="13.4" unit="g/dL"/>
                        <interpretationCode code="N" codeSystem="2.16.840.1.113883.5.83"/>
                        <entryRelationship typeCode="REFR">
                            <!-- Previous result 13.3 from Mar 12, 2006 08:15 -->
                            <observation classCode="OBS" moodCode="EVN">
                                <code code="20509-6" codeSystem="2.16.840.1.113883.6.1"/>
                                <statusCode code="completed"/>
                                <effectiveTime value="200603120815"/>
                                <value xsi:type="PQ" value="13.3" unit="g/dL"/>
                            </observation>
                        </entryRelationship>
                        <!-- The appropriate reference range, precondition not mentioned -->
                        <referenceRange typeCode="REFV">
                            <observationRange classCode="OBS" moodCode="EVN.CRT">
                                <value xsi:type="IVL_PQ">
                                    <low value="11.5" unit="g/dL"/>
                                    <high value="14.5" unit="g/dL"/>
                                </value>
                            </observationRange>
                        </referenceRange>
                    </observation>
                </component>
                <!-- 3rd analyte: Hematocrit -->
                <component>
                    <observation classCode="OBS" moodCode="EVN">
                        <code code="20570-8" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
displayName="HEMATOCRIT"/>
                        <statusCode code="completed"/>
                        <!-- Clinically relevant time for the observation =  specimen collection  time -->
                        <effectiveTime value="200603210630"/>
                        <value xsi:type="PQ" value="45" unit="%"/>
                        <interpretationCode code="N" codeSystem="2.16.840.1.113883.5.83"/>
                        <entryRelationship typeCode="REFR">
                            <!-- Previous result 45 from Mar 12, 2006 08:15 -->
                            <observation classCode="OBS" moodCode="EVN">
                                <code code="20570-8" codeSystem="2.16.840.1.113883.6.1"/>
                                <statusCode code="completed"/>
                                <effectiveTime value="200603120815"/>
                                <value xsi:type="PQ" value="45" unit="%"/>
```



```
                        </observation>
                    </entryRelationship>
                    <!--    The appropriate reference range, precondition not mentioned -->
                    <referenceRange typeCode="REFV">
                        <observationRange classCode="OBS" moodCode="EVN.CRT">
                            <value xsi:type="IVL_PQ">
                                <low value="40.0" unit="%"/>
                                <high value="54.0" unit="%"/>
                            </value>
                        </observationRange>
                    </referenceRange>
                </observation>
            </component>
            <!-- 4th analyte: mean corpuscular volume -->
            <component>
                <observation classCode="OBS" moodCode="EVN">
                    <code code="30428-7" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
displayName="MCV"/>
                    <statusCode code="completed"/>
                    <!-- Clinically relevant time for the observation =  specimen collection  time -->
                    <effectiveTime value="200603210630"/>
                    <value xsi:type="PQ" value="97" unit="fL"/>
                    <interpretationCode code="H" codeSystem="2.16.840.1.113883.5.83"/>
                    <interpretationCode code="U" codeSystem="2.16.840.1.113883.5.83"/>
                    <entryRelationship typeCode="REFR">
                        <!-- Previous result 94 from Mar 12, 2006 08:15 -->
                        <observation classCode="OBS" moodCode="EVN">
                            <code code="30428-7" codeSystem="2.16.840.1.113883.6.1"/>
                            <statusCode code="completed"/>
                            <effectiveTime value="200603120815"/>
                            <value xsi:type="PQ" value="94" unit="fL"/>
                        </observation>
                    </entryRelationship>
                    <!-- The appropriate reference range  -->
                    <referenceRange typeCode="REFV">
                        <observationRange classCode="OBS" moodCode="EVN.CRT">
                            <value xsi:type="IVL_PQ">
                                <low value="80" unit="fL"/>
                                <high value="95" unit="fL"/>
                            </value>
                        </observationRange>
                    </referenceRange>
                </observation>
            </component>
            <!-- End of the battery-->
        </organizer>
    </entryRelationship>
    <!-- Global interpretative annotation on the section -->
    <entryRelationship typeCode="COMP">
        <act classCode="ACT" moodCode="EVN">
            <text>No sign of anemia</text>
        </act>
    </entryRelationship>
</act>
</entry>
```

4.4.3.2 Single serum potassium

The example presented in section 4.2.3.2.2.3 is derived from the following entry:

```
<entry typeCode="DRIV">
    <templateId root="1.3.6.1.4.1.19376.1.3.1" extension="Lab.Report.Data.Processing. Entry"/>
    <!--    Report_Entry from which the section is derived -->
    <act classCode="ACT" moodCode="EVN">
        <code code="12814-0" codeSystem="2.16.840.1.113883.6.1" displayName="POTASSIUM" originalText=" Serum
potassium "/>
        <statusCode code="completed"/>
        <entryRelationship typeCode="COMP">
            <observation classCode="OBS" moodCode="EVN">
                <code code="12814-0" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC" originalText="K"/>
                <statusCode code="completed"/>
                <!-- Clinically relevant time for the observation (= specimen collection  time) -->
                <effectiveTime value="200603210710"/>
                <!-- Current result 3.4  -->
```



```
                    <value xsi:type="PQ" value="3.4" unit="mmol/L"/>
                    <!-- 2 interpretation codes : Low, Significant decrease -->
                    <interpretationCode code="L" codeSystem="2.16.840.1.113883.5.83"/>
                    <interpretationCode code="D" codeSystem="2.16.840.1.113883.5.83"/>
                    <entryRelationship typeCode="REFR">
                        <!-- Previous result 4.6 from Mar 12, 2006 08:05 -->
                        <observation classCode="OBS" moodCode="EVN">
                            <code code="11273-0" codeSystem="2.16.840.1.113883.6.1"/>
                            <statusCode code="completed"/>
                            <effectiveTime value="200603120805"/>
                            <value xsi:type="PQ" value="4.6" unit="mmol/L"/>
                        </observation>
                    </entryRelationship>
                    <entryRelationship typeCode="REFR">
                        <!-- Previous result 3.3 from Jan 1st, 2006 05:12 -->
                        <observation classCode="OBS" moodCode="EVN">
                            <code code="11273-0" codeSystem="2.16.840.1.113883.6.1"/>
                            <statusCode code="completed"/>
                            <effectiveTime value="200601010512"/>
                            <value xsi:type="PQ" value="4.6" unit="mmol/L"/>
                        </observation>
                    </entryRelationship>
                    <!-- Reference range for this patient: [3.5 - 5.0] -->
                    <referenceRange typeCode="REFV">
                        <observationRange classCode="OBS" moodCode="EVN.CRT">
                            <value xsi:type="IVL_PQ">
                                <low value="3.5" unit="mmol/L"/>
                                <high value="5.0" unit="mmol/L"/>
                            </value>
                        </observationRange>
                    </referenceRange>
                </observation>
            </entryRelationship>
            <!-- Comment for the section represented by this entry -->
            <entryRelationship typeCode="COMP">
                <act classCode="ACT" moodCode="EVN">
                    <text>Result controlled with a second run</text>
                </act>
            </entryRelationship>
        </act>
    </entry>
```

4.4.3.3 Urine microbiology study

The example presented in section 4.2.3.2.6 is derived from the following entry:

```
<entry typeCode="DRIV">
    <templateId root="1.3.6.1.4.1.19376.1.3.1" extension="Lab.Report.Data.Processing.Entry"/>
    <act classCode="ACT" moodCode="EVN">
        <id root="2.16.840.1.113883.19" extension="1234"/>
        <code code="18725-2" displayName="MICROBIOLOGY URINE STUDY"/>
        <statusCode code="completed"/>
        <!-- Time in which this entry (section) was reported-->
        <effectiveTime value="200603231500"/>
        <specimen typeCode="SPC">
            <specimenRole classCode="SPEC">
                <specimenPlayingEntity>
                    <code code="UR" codeSystem="OID for HL7 EntityType vocab domain"
codeSystemName="specimenEntityType" displayName="urine"/>
                </specimenPlayingEntity>
                <lab:productOf typeCode="PRD">
                    <lab:procedure classCode="PROC" moodCode="EVN">
                        <!-- Date time of specimen collection  6:30 a.m. on March 21 2006 -->
                        <lab:effectiveTime value="200603210630"/>
                        <targetSiteCode codeSystem="2.16.840.1.113883.2.1.3.2.4.15" code="225271002"
displayName="mid-stream urine"/>
                    </lab:procedure>
                </lab:productOf>
            </specimenRole>
        </specimen>
        <entryRelationship typeCode="COMP">
            <organizer classCode="BATTERY" moodCode="EVN">
                <code code="xxxxx" displayName="DIRECT EXAMINATION"/>
                <!-- Time of direct examination -->
```



```
                <statusCode code="completed"/>
                <effectiveTime value="200603210825"/>
                <!-- 2 Observations: color = straw, appearance = clear -->
                <component>
                    <observation classCode="OBS" moodCode="EVN">
                        <code code="xxxxx" codeSystem="2.16.840.1.113883.6.1" displayName="Color"/>
                        <value xsi:type="ST">straw</value>
                    </observation>
                </component>
                <component>
                    <observation classCode="OBS" moodCode="EVN">
                        <code code="xxxxx" codeSystem="2.16.840.1.113883.6.1" displayName="Appearance"/>
                        <value xsi:type="ST">clear</value>
                    </observation>
                </component>
            </organizer>
        </entryRelationship>
        <entryRelationship typeCode="COMP">
            <organizer classCode="BATTERY" moodCode="EVN">
                <code code="xxxxx" displayName="MICROSCOPY"/>
                <statusCode code="completed"/>
                <!-- Time of microscopy -->
                <effectiveTime value="200603210829"/>
                <!-- 4 Observations: Leukocytes, Erythrocytes, Epithelial cells, Gram stain -->
                <component>
                    <observation classCode="OBS" moodCode="EVN">
                        <code code="24122-4" codeSystem="2.16.840.1.113883.6.1" displayName="Leukocytes"/>
                        <value xsi:type="PQ" value="500" unit="/mL"/>
                    </observation>
                </component>
                <component>
                    <observation classCode="OBS" moodCode="EVN">
                        <code code="14290-1" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
displayName="Erythrocytes"/>
                        <value xsi:type="PQ" value="200" unit="/mL"/>
                    </observation>
                </component>
                <component>
                    <observation classCode="OBS" moodCode="EVN">
                        <code code="20453-7" codeSystem="2.16.840.1.113883.6.1" displayName="Epithelial cells"/>
                        <value xsi:type="ST">absence</value>
                    </observation>
                </component>
                <component>
                    <observation classCode="OBS" moodCode="EVN">
                        <code code="653-6" codeSystem="2.16.840.1.113883.6.1" displayName="Gram stain"/>
                        <value xsi:type="ST">numerous Gram - ; some Gram +</value>
                    </observation>
                </component>
            </organizer>
        </entryRelationship>
        <entryRelationship typeCode="COMP">
            <organizer classCode="BATTERY" moodCode="EVN">
                <code code="xxxxx" displayName="Aerobic culture"/>
                <statusCode code="completed"/>
                <!-- Time of culture observation -->
                <effectiveTime value="200603220910"/>
                <!-- 1 Observation: growth of something -->
                <component>
                    <observation classCode="OBS" moodCode="EVN">
                        <code code="xxxxx" codeSystem="2.16.840.1.113883.6.1" displayName="Aerobic culture"/>
                        <value xsi:type="ST">Positive</value>
                    </observation>
                </component>
            </organizer>
        </entryRelationship>
        <!-- First isolate: Escherichia  coli -->
        <entryRelationship typeCode="COMP">
            <organizer classCode="CLUSTER" moodCode="EVN">
                <statusCode code="completed"/>
                <!-- Time of final reporting on isolate -->
                <effectiveTime value="200603231100"/>
                <specimen typeCode="SPC">
                    <specimenRole classCode="ISLT">
```



```
                        <specimenPlayingEntity>
                            <code code="E-coli" codeSystemName="A vocabulary for isolates" displayName="Escherichia
coli"/>
                        </specimenPlayingEntity>
                    </specimenRole>
                </specimen>
                <component>
                    <!-- Culture amount -->
                    <observation classCode="OBS" moodCode="EVN">
                        <code code="xxxxx" codeSystem="2.16.840.1.113883.6.1" displayName="Microorganism count"/>
                        <statusCode code="completed"/>
                        <effectiveTime value="200603220815"/>
                        <value xsi:type="PQ" value="100000" unit="/mL"/>
                    </observation>
                </component>
                <component>
                    <!-- Battery sensitivity -->
                    <organizer classCode="BATTERY" moodCode="EVN">
                        <code code="xxxxx" displayName="Microbial suceptibility"/>
                        <!-- One antibiotic tested. -->
                        <component>
                            <observation classCode="OBS" moodCode="EVN">
                                <code code="xxxxx" displayName="amoxicillin"/>
                                <value xsi:type="PQ" value="12" unit="mg/L"/>
                                <interpretationCode code="R" codeSystem="2.16.840.1.113883.5.83"/>
                                <methodCode code="MIC"/>
                            </observation>
                        </component>
                        <!-- One antibiotic tested. -->
                        <component>
                            <observation classCode="OBS" moodCode="EVN">
                                <code code="xxxxx" displayName="Fosfomycin"/>
                                <value xsi:type="PQ" value="1.3" unit="mg/L"/>
                                <interpretationCode code="S" codeSystem="2.16.840.1.113883.5.83"/>
                                <methodCode code="MIC"/>
                            </observation>
                        </component>
                    </organizer>
                </component>
            </organizer>
        </entryRelationship>
        <!-- Second isolate: Streptococcus D. -->
        <entryRelationship typeCode="COMP">
            <organizer classCode="CLUSTER" moodCode="EVN">
                <statusCode code="completed"/>
                <!-- Time of final reporting on isolate -->
                <effectiveTime value="200603231300"/>
                <specimen typeCode="SPC">
                    <specimenRole classCode="ISLT">
                        <specimenPlayingEntity>
                            <code code="Strep-D" codeSystemName="A vocabulary for isolates" displayName="Streptococcus
D."/>
                        </specimenPlayingEntity>
                    </specimenRole>
                </specimen>
                <component>
                    <!-- Culture amount -->
                    <observation classCode="OBS" moodCode="EVN">
                        <code code="xxxxx" codeSystem="2.16.840.1.113883.6.1" displayName="Microorganism count"/>
                        <statusCode code="completed"/>
                        <effectiveTime value="200603220815"/>
                        <value xsi:type="PQ" value="200000" unit="/mL"/>
                    </observation>
                </component>
                <component>
                    <!-- Battery sensitivity -->
                    <organizer classCode="BATTERY" moodCode="EVN">
                        <code code="xxxxx" displayName="Microbial suceptibility"/>
                        <!-- One antibiotic tested. -->
                        <component>
                            <observation classCode="OBS" moodCode="EVN">
                                <code code="xxxxx" displayName="ampicillin"/>
                                <value xsi:type="PQ" value="6" unit="mg/L"/>
                                <interpretationCode code="I" codeSystem="2.16.840.1.113883.5.83"/>
```



```
                                <methodCode code="MIC"/>
                            </observation>
                        </component>
                        <!-- One antibiotic tested. -->
                        <component>
                            <observation classCode="OBS" moodCode="EVN">
                                <code code="xxxxx" displayName="Fosfomycin"/>
                                <value xsi:type="PQ" value="2.5" unit="mg/L"/>
                                <interpretationCode code="S" codeSystem="2.16.840.1.113883.5.83"/>
                                <methodCode code="MIC"/>
                            </observation>
                        </component>
                    </organizer>
                </component>
            </organizer>
        </entryRelationship>
    </act>
</entry>
```

4.5 Extensions to CDA R2

This Laboratory Report Content Integration Profile is aligning its CDA level 3 entries with the structure of the "Result Event" RMIM of the Laboratory Domain.

The main rationale to enforce this alignment is to ensure that an application able to produce (Order Fulfiller) or to integrate (Result Receiver) messages derived from the Result Event RMIM, will have no difficulties in dealing with the machine-processable entries of a CDA laboratory report.

In the process of this alignment, two issues appeared, caused by some discrepancies between the release of Clinical Statement used by CDA and the newer release of Clinical Statement leveraged by the Laboratory Domain. These issues were solved by two extensions brought to the CDA R2 entry format.

An additional extension was brought to the header of CDA R2 to distinguish a final report from a preliminary report.

4.5.1 General rules respected by laboratory report extensions

The extensions proposed to the CDA entry model, for a better expression of a Laboratory Report, follow the same rules as those defined in the 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 under this Integration Profile.
- A single namespace for all extension elements or attributes that **MAY** be used by this Profile is defined as follows:

  urn:oid:1.3.6.1.4.1.19376.1.3.2

- This namespace **SHALL** be used as the namespace for any extension elements or attributes that are defined by this implementation guide.
- Each extension element **SHALL** use the same HL7 vocabularies and data types used by CDA Release 2.0.
- Each extension element **SHALL** use the same conventions for order and naming as is used by the current HL7 tooling.

- An extension element **SHALL** appear in the XML where the expected RIM element of the same name would have appeared had that element not been otherwise constrained from appearing in the CDA XML schema.

4.5.2 Missing specimen target site and collection time

4.5.2.1 Issue

The **specimen target site** is not explicitly represented in CDA. This information is often crucial in microbiology (e.g. " swab from left ear, external"), and also useful in many cases in other specialties, especially when the laboratory report is coding specimen properties using SNOMED CT terminology. Similarly, the specimen collection time is of key interest in most cases: It is the clinically relevant time of all observations produced on this specimen for the patient.

- In the Result Event RMIM, this information is represented in the R_Specimen universal CMET by the attribute "targetSiteCode" of the specimen collection Process class attached to the Specimen role through the participation "productOf".
- In CDA the specimen collection Process cannot be attached to the Specimen role. This is because the current version of Clinical Statement leveraged by CDA does not offer the R_Specimen CMET.

4.5.2.2 Proposed extension

The proposed extension to solve this issue consists in adding a "productOf" participation of the Specimen role to a Procedure. The figure below is a zoom of figure 9-1 :

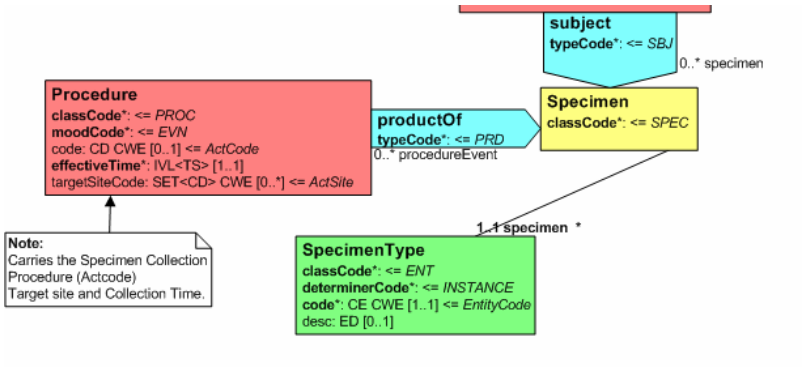

Figure 4.5-1: Adding a participation to the specimen collection procedure

4.5.2.3 Example

```
<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">

….
<specimen typeCode="SPC">
    <specimenRole classCode="SPEC">
        <specimenPlayingEntity>
            <code code="UR" codeSystemName="specimenEntityType" displayName="urine"/>
        </specimenPlayingEntity>
        <lab:productOf typeCode="PRD">
            <lab:procedure classCode="PROC" moodCode="EVN">
                <!-- Date time of specimen collection  6:30 a.m. on March 21 2006 -->
                <lab:effectiveTime value="200603210630"/>
                <targetSiteCode codeSystem="2.16.840.1.113883.2.1.3.2.4.15" code="225271002" displayName="mid-stream
urine"/>
            </lab:procedure>
        </lab:productOf>
    </specimenRole>
</specimen>
```


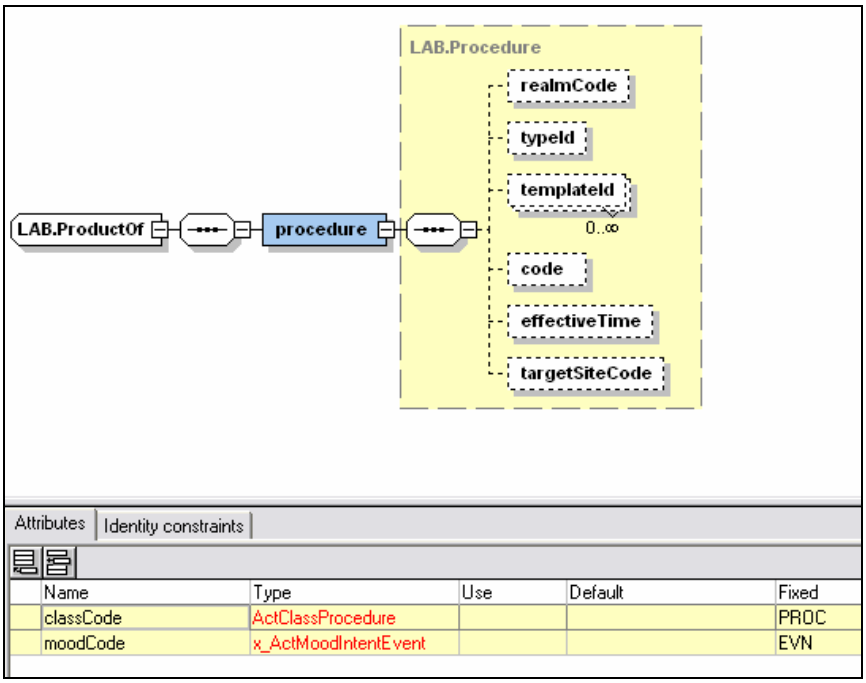

Figure 4.5-2: Schema snippet for the lab:productOf extension

4.5.3 Missing pre-condition criterion on reference range

4.5.3.1 Issue

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

4.5.3.2 Proposed extension

The proposed extension 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, which is a zoom of figure 9-1:

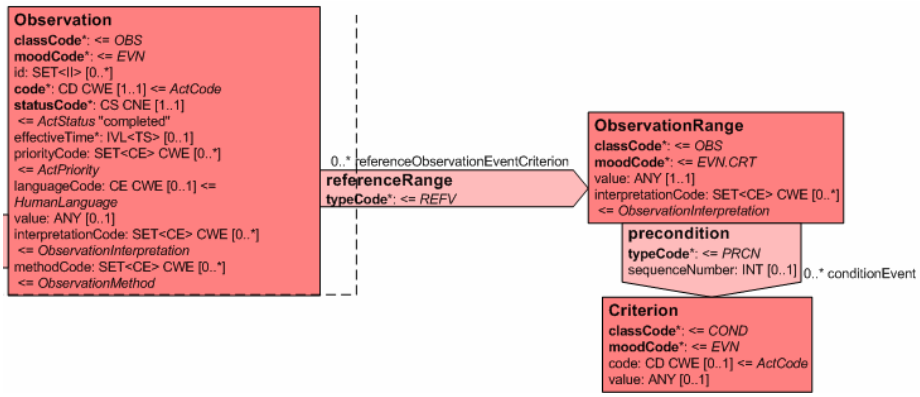

Figure 4.5-3: Associating criteria to the reference range of an observation

4.5.4 Example

```
<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>
    </observationRange>
    <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>
</referenceRange>
```

4.5.5 statusCode of the documented serviceEvent in the header

This profile supports the sharing of both final and preliminary reports. To distinguish between the two, the `statusCode` element has been added to the `documentationOf/serviceEvent` element. A preliminary report documents a `serviceEvent` in the status "active" whereas as final report document a "completed" `serviceEvent`.

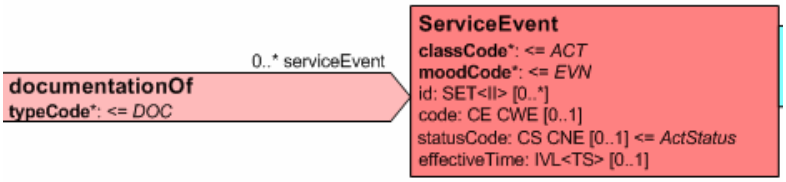

Figure 4.5-4: StatusCode added to serviceEvent in the header

Example of a preliminary laboratory report:

```
<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">
            <effectiveTime value="200603210630"/>
            <performer>
                ...
```


5 Vocabularies

5.1 Selected subset of LOINC test codes

The laboratory LOINC tests code subset is provided in Volume 4 of the Laboratory Technical Framework: IHE LAB TF-4 “LOINC Laboratory Test Code Set”.

5.2 Use of SNOMED CT terminology

Some countries will take from SNOMED CT most of the vocabulary domains needed by the entries of the Laboratory Report. (e.g. batteries, specimen types, tests, isolates, antibiotics…). The appropriate subsets of SNOMED CT to be used in a laboratory report, are not defined nor constrained by this Integration Profile. These tasks are left up to realms.

6 OIDs assigned to artefacts of this Content Integration Profile

This “Sharing Laboratory Reports” Content Profiles uses the following OIDs:

OID	Description
1.3.6.1.4.1.19376.1.3.1	Template Report_Entry
1.3.6.1.4.1.19376.1.3.2	Namespace associated with elements ans attributes of extensions brought to CDA R2 by this XD-LAB Profile.
1.3.6.1.4.1.19376.1.3.3	Template for the ClinicalDocument/templateID representing a CDA laboratory report. Also associated to the metadata XDSDocumentEntry.formatCode

Table 6-1: OIDs assigned to the XD-LAB Content Profile

7 Open issues

Topic	Rationale
LOINC codes for challenge studies	Will have to create LOINC codes for these with the initial condition (e.g lactose charge) being an observation itself, and variable time intervals for further observations. Challenge protocols are very variable among healthcare organizations. So the LOINC codes with fixed pre-condition and fixed time intervals are not usable. (Discussion with Martine Marchand)
OID for HL7 vocabulary domains	Some OIDs in the examples are still missing. To be checked with the HL7 OID registry.
Digital signature	embedded or by-reference using DGS profile in the context of XDS.

8 Closed issues

1) 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.

2) 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. The issue is then closed.

3) 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. Issue closed.

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

   Following Result Event RMIM of LAB Domain, a comment is an `Annotation` having an inbound ActRelationship `subjectOf` to the `ObservationBattery` or to the `ObservationEvent`.

   In CDA representation: There is currently no dedicated representation of `Annotation` in the entry choice-box of CDA because comments are usually represented only at level 2 in CDA documents. But in this « Lab report » profile a section is derived from an entry. Therefore the comment must be represented in the entry. We will adopt this solution :

   - General comment on a battery: Since we represent the battery with an `Organizer`, we have to represent the comment through a `component` relationship to an `Act`.

- Comment on an observation: We have to represent the comment through an `entryRelationship` to an `Act`.

  In LAB Domain and in CDA the comment is written in the text attribute of the `Annotation/Act` element. Even if the CDA representation is less precise than the LAB Domain one, there is no incompatibility between the two. The issue is closed.

5) Spotting the ordering physician in the header of the document.

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

6) 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.

