

## **Integrating the Healthcare Enterprise**



# **IHE Laboratory Technical Framework Supplement 2006-2007**

## **Sharing Laboratory Reports (XD\*-LAB)**

### **Trial Implementation**

**September 14, 2006**

**Contents**

25	<b>1 INTRODUCTION.....</b>	<b>7</b>
	1.1 SCOPE .....	7
	1.2 STANDARDS .....	7
	1.3 REFERENCES .....	8
	1.4 STYLE CONVENTIONS .....	9
30	1.5 APPROACH .....	9
	<b>2 USE CASES.....</b>	<b>10</b>
	2.1 HOSPITAL PHYSICIAN FEEDING THE PATIENT RECORD OF AN AFFINITY DOMAIN .....	10
	2.2 PRIVATE LABORATORY SHARES A REPORT TO THE PATIENT RECORD OF AN AFFINITY DOMAIN .....	11
	2.3 AMBULATORY PHYSICIAN SHARES A LAB REPORT FROM A PATIENT IN AN AFFINITY DOMAIN .....	11
35	2.4 REPORTS SYSTEMATICALLY SHARED BY A PRIVATE OR HOSPITAL LAB.....	11
	2.5 CUMULATIVE REPORT BUILT AND SHARED AT DISCHARGE TIME .....	12
	<b>3 LINKS WITH NATIONAL PROJECTS.....</b>	<b>13</b>
	3.1 ITALY .....	13
	3.2 US.....	13
40	3.3 FRANCE.....	13
	3.4 JAPAN.....	13
	<b>4 LINKS WITH WORKFLOW MESSAGING .....</b>	<b>14</b>
	4.1 LINKS WITH THE IHE LABORATORY SCHEDULED WORKFLOW .....	14
	4.2 ALIGNMENT WITH THE LABORATORY DOMAIN OF HL7 V3 .....	14
45	<b>5 ACTORS AND TRANSACTIONS FOR THE XD*-LAB INTEGRATION PROFILE .....</b>	<b>16</b>
	5.1 ACTOR/TRANSACTION RELATIONSHIPS.....	16
	5.2 XD*-LAB INTEGRATION PROFILE OPTIONS .....	16
	5.2.1 <i>View Document Option</i> .....	17
	5.2.2 <i>Document Import Option</i> .....	17
50	5.2.3 <i>Section Import Option</i> .....	17
	5.2.4 <i>Discrete Data Import Option</i> .....	17
	5.3 DEPENDENCIES OF XD*-LAB TOWARDS OTHER INTEGRATION PROFILES.....	17
	5.4 CONTENT BINDINGS WITH XDS, XDM AND XDR .....	18
	<b>6 LEVEL 1: HEADER OF THE LABORATORY REPORT .....</b>	<b>20</b>
55	6.1 HEADER RENDERING .....	20
	6.2 GENERAL CONSTRAINTS ON PERSONS AND ORGANIZATIONS MENTIONED.....	20
	6.3 CLINICALDOCUMENT .....	20
	6.4 CLINICALDOCUMENT/REALMCODE.....	20
	6.5 CLINICALDOCUMENT/CODE .....	20
60	6.5.1 <i>Multi-disciplinary lab report</i> .....	21
	6.5.2 <i>Single discipline laboratory report</i> .....	21
	6.6 CLINICALDOCUMENT/EFFECTIVETIME.....	21
	6.7 CLINICALDOCUMENT/CONFIDENTIALITYCODE .....	21
	6.8 CLINICALDOCUMENT/LANGUAGECODE .....	21
65	6.9 CLINICALDOCUMENT/SETID.....	22
	6.10 CLINICALDOCUMENT/VERSIONNUMBER .....	22
	6.11 CLINICALDOCUMENT/RECORDTARGET .....	22
	6.12 CLINICALDOCUMENT/AUTHOR.....	22
	6.13 CLINICALDOCUMENT/CUSTODIAN .....	23
70	6.14 INFORMATIONRECIPIENT/INTENDEDRECIPIENT .....	24
	6.15 CLINICALDOCUMENT/LEGALAUTHENTICATOR .....	24
	6.16 CLINICALDOCUMENT/AUTHENTICATOR .....	25
	6.17 CLINICALDOCUMENT/PARTICIPANT CARRIES THE ORDERING PHYSICIAN .....	25
	6.18 INFULFILLMENTOF/ORDER .....	26
75	6.19 DOCUMENTATIONOF/SERVICEEVENT .....	26

	6.20	SERVICEEVENT/STATUSCODE .....	26
	6.21	SERVICEEVENT/PERFORMER.....	27
	6.22	RELATEDDOCUMENT/PARENTDOCUMENT.....	27
	6.23	AUTHORIZATION/CONSENT .....	27
80	6.24	COMPONENTOF/ENCOMPASSINGENCOUNTER.....	27
<b>7</b>		<b>LEVEL 2: HUMAN-READABLE BODY OF THE REPORT .....</b>	<b>29</b>
	7.1	TOP LEVEL SECTIONS: SPECIALTIES .....	29
	7.1.1	List of specialties .....	29
	7.1.2	Template of a "specialty" section .....	30
85	7.2	RELATIONSHIP BETWEEN SPECIALTIES AND REPORTED ITEMS .....	30
	7.3	LEAF SECTIONS: REPORTED ITEMS .....	30
	7.3.1	Additional constraints on the content of a leaf section .....	31
	7.3.2	General rules for presenting the results in the narrative block .....	31
	7.3.3	Templates for leaf sections .....	33
90	7.3.3.1	Leaf section reporting a single specimen battery .....	33
	7.3.3.1.1	Scope .....	33
	7.3.3.1.2	Structure.....	33
	7.3.3.1.3	Example 1: A Complete Blood Count .....	34
	7.3.3.1.4	Example 2: A chemistry serum electrolyte .....	35
95	7.3.3.1.5	Example 3 including an image: Protein electrophoresis .....	36
	7.3.3.2	Leaf section reporting an individual test .....	37
	7.3.3.2.1	Scope .....	37
	7.3.3.2.2	Structure.....	37
	7.3.3.2.3	Example: A serum potassium .....	38
100	7.3.3.3	Leaf section reporting a challenge study (DFT).....	39
	7.3.3.3.1	Scope .....	39
	7.3.3.3.2	Structure.....	39
	7.3.3.3.3	Example of a glucose tolerance study .....	39
	7.3.3.4	Specialty section embedding a whole report .....	40
105	7.3.3.5	Leaf section reporting a microbiology study .....	41
	7.3.3.5.1	Scope .....	41
	7.3.3.5.2	Structure.....	41
	7.3.3.5.3	Example of a urine microscopy, culture and antibiotic susceptibilities .....	41
<b>8</b>		<b>LEVEL 3 ENTRIES DEDICATED TO MULTIMEDIA RENDERING.....</b>	<b>44</b>
110	<b>9</b>	<b>LEVEL 3 ENTRY DEDICATED TO DATA-PROCESSING.....</b>	<b>45</b>
	9.1	GLOBAL MODEL AND GENERAL RULES .....	45
	9.2	TEMPLATE "REPORT_ENTRY" : AN ENTRY OF A LABORATORY REPORT .....	52
	9.3	EXAMPLES OF MACHINE-PROCESSABLE ENTRIES .....	60
	9.3.1	CBC .....	60
115	9.3.2	Single serum potassium .....	63
	9.3.3	Glucose tolerance study.....	63
	9.3.4	Urine microbiology study.....	64
<b>10</b>		<b>EXTENSIONS TO CDA R2.....</b>	<b>67</b>
	10.1	GENERAL RULES RESPECTED BY LABORATORY REPORT EXTENSIONS .....	67
120	10.2	MISSING SPECIMEN TARGET SITE AND OTHER PROPERTIES .....	68
	10.2.1	Issue .....	68
	10.2.2	Proposed extension .....	68
	10.2.3	Example .....	68
	10.3	MISSING PRE-CONDITION CRITERION ON REFERENCE RANGE.....	69
125	10.3.1	Issue .....	69
	10.3.2	Proposed extension .....	69
	10.3.3	Example .....	69
	10.4	STATUSCODE OF THE DOCUMENTED SERVICEEVENT IN THE HEADER .....	70
<b>11</b>		<b>VOCABULARIES .....</b>	<b>71</b>
130	11.1	SELECTED SUBSET OF LOINC TEST CODES.....	71
	11.2	USE OF SNOMED CT TERMINOLOGY .....	71

12	OIDs ASSIGNED TO ARTEFACTS OF THIS CONTENT INTEGRATION PROFILE.....	71
13	OPEN ISSUES.....	72
14	CLOSED ISSUES .....	72

135

## Foreword

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. And it organizes educational sessions and 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 not to define new integration standards, but rather to support the use of existing standards, HL7, DICOM, IETF, and others, as appropriate in their respective domains in an integrated manner, defining configuration choices when necessary. IHE maintain formal relationships with several standards bodies and refers recommendations to them when clarifications or extensions to existing standards are necessary.

This initiative has numerous sponsors and supporting organizations in different medical specialty domains and geographical regions. In North America the primary sponsors are the American College of Cardiology (ACC), the Healthcare Information and Management Systems Society (HIMSS) and the Radiological Society of North America (RSNA). IHE Canada has also been formed. IHE Europe (IHE-EUR) is supported by a large coalition of organizations including the European Association of Radiology (EAR) and European Congress of Radiologists (ECR), the Coordination Committee of the Radiological and Electromedical Industries (COCIR), Deutsche Röntgengesellschaft (DRG), the EuroPACS Association, Groupement pour la Modernisation du Système d'Information Hospitalier (GMSIH), Société Française de Radiologie (SFR), Société Française d'Informatique de Laboratoires (SFIL), Società Italiana di Radiologia Medica (SIRM), the European Institute for health Records (EuroRec), the European Society of Cardiology (ESC) and the Israeli Medical Information Association. In Japan IHE-J is sponsored by the Ministry of Economy, Trade, and Industry (METI); the Ministry of Health, Labor, and Welfare; and MEDIS-DC; cooperating organizations include the Japan Industries Association of Radiological Systems (JIRA), the Japan Association of Healthcare Information Systems Industry (JAHIS), Japan Radiological Society (JRS), Japan Society of Radiological Technology (JSRT), and the Japan Association of Medical Informatics (JAMI). Other organizations representing healthcare professionals are invited to join in the expansion of the IHE process across disciplinary and geographic boundaries.

The IHE Technical Frameworks for the various domains (IT Infrastructure, Cardiology, Laboratory, Radiology, etc.) defines specific implementations of established standards to achieve integration goals that promote appropriate sharing of medical information to support optimal patient care. It is expanded annually, after a period of public review, and maintained

regularly through the identification and correction of errata. The current version for these Technical Frameworks may be found at [www.ihe.net/Technical\\_Framework](http://www.ihe.net/Technical_Framework).

180 The IHE Technical Framework identifies a subset of the functional components of the healthcare enterprise, 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. The volume I 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 clinical needs. The subsequent volumes provide  
185 detailed technical descriptions of each IHE transaction.

**This supplement to the IHE Laboratory Technical Framework V1.2 is published for Trial Implementation.**

**Comments may be submitted to:**

190 <http://forums.rsna.org> under the “*IHE*” forum

Select the “*Laboratory Supplements for Public Review*” sub-forum.

## Revision History

Author: François Macary: AGFA HealthCare

195 Methodology facilitator: Keith W Boone: GE Medical Systems

Domain content: Sarah Glamm: EPIC

Domain modeling facilitator: Patrick Michell-Jones: Connecting for Health

LOINC test codes restriction: Martine Marchand: University hospital Robert Debré (Paris), SFIL

Reviewer: Keith Naylor: iSOFT

Version	Date	Changes
0.1	March 13, 2006	Initial Release: Description of level 2
0.2	March 22, 2006	Level 1 & 2 continuation
0.3	March 27, 2006	§ on US projects added by CP. LOINC code for Lab Report fixed
0.4	April 3, 2006	Improve level 2 microbiology example, add electrophoresis example
0.5	April 5, 2006	Correction of location of the <entry> with image file for electrophoresis (7.2.6)
0.6	April 25, 2006	Comments by Rob taken into account. + Simplification of microbiology example + added serology and virology example. First proposal of level 3 by Sarah Glamm.
0.7	May 2, 2006	Rearranging the structure of the documents. Introduction. Level 2 and level 3 templates.
0.8	May 4, 2006	Comments by Keith Boone, minor corrections by FM
0.9	May 8, 2006	Template for "specialty" top level section Templates for the microbiology entry, sensitivity battery, microbiology observation Streamline the tables describing the level 3 templates Index of all templates created by this document, using the IHE Lab OID as "root" and a structured mnemonic as "extension"
0.10	May 11, 2006	Complements on microbiology entry <ul style="list-style-type: none"> <li>- Fix the vocabulary: "reported item", "single-specimen battery"</li> <li>- Show MIC in microbio section</li> <li>- Split the entry templates</li> <li>- Only 3 templates for &lt;observation&gt;</li> <li>- Chart for each use case</li> </ul>
0.11	May 12, 2006	Post working session Friday May 12 with Karen Sieber, René Spronk, Dick Harding, Sarah Glamm, Patrick Loyd, Ann Hueber... <ul style="list-style-type: none"> <li>- 2 more use cases added for US (2.4 and 2.5)</li> <li>- Level 2: Alternative rendering for microbiology, separating the various isolates and using more textual layout.</li> </ul>
0.12	May 24, 2006	Global update during IHE Lab ftf meeting. Participants: Nobuyuki Chiba, Nicola Ferrari, Nick Harrison, Yoshimi Hirasawa, François Macary, Martine Marchand, Patrick Mitchell-Jones, Keith Naylor, George Philp <ul style="list-style-type: none"> <li>- Precision on the scope regarding excluded specialties</li> <li>- Precisions on the use cases</li> <li>- Multiple kinds of lab reports</li> <li>- More flexible level 2 templates</li> <li>- Global model for a level 3 entry → Merge all entry templates into one</li> <li>- More details on the header (encounter, documentationOf...)</li> </ul>
PC	June 15, 2006	Examples of entries completed, LOINC subset, foreword, minor language corrections. Introduction and Standards sections complemented. For Public Comment release
TI	September 14, 2006	Reconciliation of the comments received during the public comment period.

# 1 Introduction

## 1.1 Scope

This supplement introduces a Content Integration Profile that will constitute Volume 3 of the IHE Laboratory Technical Framework.

205 It describes a clinical laboratory report as an electronic document. Such an electronic document contains the set of releasable results produced by a clinical laboratory in fulfillment of one or more test orders for a patient. The intention is to share this human-readable laboratory report, in an Electronic Health Record (EHR) or in a Personal Health Record (PHR), so that healthcare professionals taking care of the patient may access it and read it. In  
210 addition, this electronic laboratory report SHALL contain test results in a machine-readable format, to facilitate the integration of these observations in the database of a consumer system.

This Content Integration Profile is focussed on the sharing of sets of laboratory results in the form of a laboratory report structured document.

215 The scope covers the specialties already addressed by the IHE Laboratory Technical Framework: All laboratory specialties working on in-vitro specimens, including microbiology. The anatomic pathology specialty is not included in the scope of this profile. Anatomic Pathology has its dedicated domain in IHE. Blood bank specialty is restricted to non-stock associated testing; results for blood banks (e.g. ABO blood group) are included.

220 The human rendering of the laboratory report defined in this Integration Profile is compatible with laboratory regulations in numerous countries, including CLIA in the USA.

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

## 1.2 Standards

This content Integration Profile is based upon the standard Clinical Document Architecture Release 2 (CDA R2), as in the HL7 V3 normative edition. The CDA R2 standard has been  
230 approved by ANSI in 2006, and is planned to be submitted for ISO endorsement in 2006.

The choice of HL7 CDA R2 has been made for multiple reasons, among which:

- It is already endorsed and used by several national projects around the world.
- It is the basis for the US HIPAA NPRM for laboratory Claim Attachments, which completed its review in 2006 and is slated for publication in 2007. This  
235 Integration Profile takes into account the NPRM requirements (e.g. LOINC codes) and is expected to be provided to the HL7 Claim Attachment SIG.

An electronic laboratory report is a CDA R2 document. This profile describes a laboratory report using a set of templates constraining the CDA R2 schema.

240 Particularly, this Integration Profile provides a single template for the entries (i.e. the level 3 machine-processable data in the CDA schema) of a laboratory report, and this entry template

is aligned with the HL7 V3 Laboratory data model, to ensure simple mapping between test results in a complete laboratory result message and a persistent CDA document.

245 This Integration Profile is also aligned with the definition of the Laboratory data extracts of the CDA Continuity of Care Document resulting from the ASTM CCR/HL7 CDA convergence, to ensure that selected laboratory results from such a laboratory report may be directly placed into a CCD medical summary.

250 The laboratory test results data structures and codes that may be conveyed are semantically compatible with those defined in the US-ELINCS specification, so that complete test results communicated via ELINCS messages to an ambulatory EHR, may be afterwards persisted for historical access using this Integration Profile without any semantic loss.

255 Similarly, the data structures and codes that may be conveyed are semantically compatible with those defined in the LAB-3 transaction from the Laboratory Scheduled WorkFlow (LSWF) Integration Profile, so that complete test results messages communicated via LAB-3 by a hospital laboratory to the laboratory results tracker of the hospital, may be authored afterwards in a persistent laboratory report without any semantic loss.

### 1.3 References

- “Clinical Document Architecture Release 2” CDA R2 (from HL7 V3 normative edition)
- HL7 V3 “Laboratory” Domain (from May 2006 Ballot)
- 260 - HL7 V3 “Specimen” Domain (from May 2006 Ballot)
- XDS Integration Profile in IHE Infrastructure Technical Framework: The laboratory report is produced by a Content Creator Actor, shared in a Document Repository and registered in a Document Registry for further access by Content Consumer Actors.
- 265 - NAV Integration Profile in IHE Infrastructure Technical Framework: At time of registration in the Document Registry, the laboratory report may be notified by the Notification Sender coupled with Content Creator to a Notification Receiver coupled with Content Consumer.
- XDR (Cross-Enterprise Document Reliable Interchange), supplement 2006 of the IHE Infrastructure Technical Framework. A laboratory report may be interchanged by email, using the XDR profile.
- 270 - XDM (Cross-Enterprise Document Media Interchange), supplement 2006 of the IHE Infrastructure Technical Framework. A laboratory report may be interchanged using a CD, a USB key, using the XDM profile.
- PCC (Patient Care Continuity) Technical Framework
- 275 - LSWF Integration Profile in IHE Laboratory Technical Framework: The Content Creator Actor issuing the laboratory report may be coupled with either an Order Filler Actor (in use cases where the laboratory information system shares a lab report) or an Order Result Tracker (ORT) (in use cases where the clinical system of a hospital or a physician shares a lab report).
- 280 - CCD (HL7/ASTM Implementation Guide for CDA Release 2 – Continuity of Care Document).



- ELINCS (EHR-Laboratory Interoperability and Connectivity Specification from California HealthCare Foundation)

## 1.4 Style conventions

- 285 The CDA XML element and attribute names embedded in the text, will be styled with this font throughout the document:

`someCDAelement`                      `someCDAattribute`

## 1.5 Approach

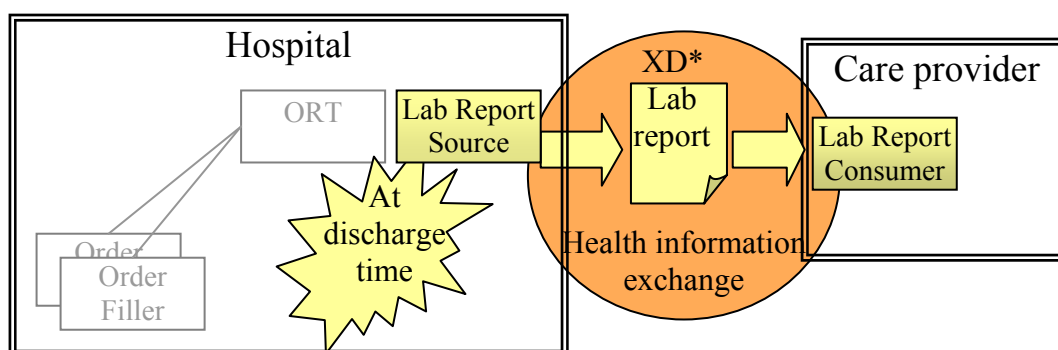
- 290 A bottom up approach has been used to build this content profile, starting from a set of representative paper laboratory reports, then defining the common characteristics of the CDA Header for a laboratory report and the structure of the human-readable body. Then we defined the various level 2 templates needed for a laboratory report. Lastly, we defined the level 3 template for the machine-readable entries, working with the **cda.xsd** schema and the
- 295 laboratory “Result Event” RMIM **POLB\_RM004000** in parallel. The level 3 entries require a common terminology for laboratory tests. This profile recommends the use of a common terminology, which can be LOINC, SNOMED CT, or any appropriate national vocabulary enforced by a national extension of this profile.

## 2 Use cases

### 2.1 Hospital physician feeding the patient record of an affinity domain

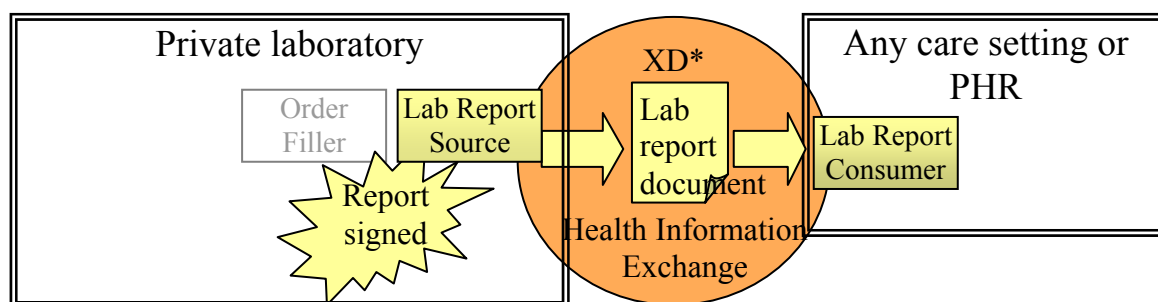
During his stay in a hospital, patient John Smith has had several clinical laboratory orders. At discharge time, a hospital physician selects the most significant reports produced by various facilities, including lab reports, and issues these reports individually to a health information exchange (e.g. XDS Affinity Domain) shared by a number of healthcare enterprises and primary care providers. Thus later on, during a new episode of care, the care provider of John Smith (e.g. his family doctor) will be able to access the previous lab reports of the patient through a health information exchange (e.g. XDS Affinity Domain).

In this example, the electronic laboratory report is produced by the system that played the role of Order Result Tracker, and sent to the external health information exchange upon request from the medical staff preparing the discharge summary.



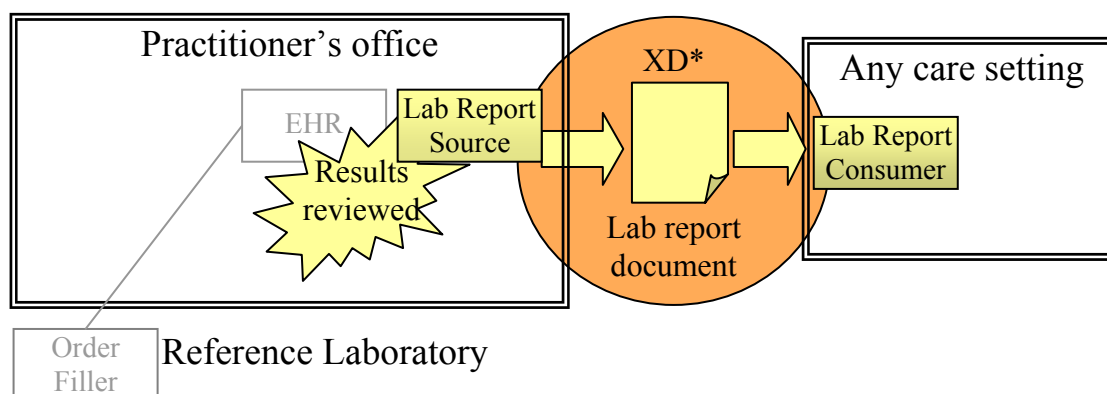
## 2.2 Private laboratory shares a report to the patient record of an affinity domain

Patient Jane Smith with a suspected urinary infection has been sent by her family doctor to any private laboratory downtown, with an order for a CBC and a urine microscopy and culture. Jane Smith enters into the nearest laboratory with a urine specimen, sees a phlebotomist who collects a venous blood specimen from her, and then leaves the laboratory. In this laboratory all the work on the request (hematology and microbiology) is reported together. Two days later the clinical laboratory addresses its paper report to Jane's family doctor (outside of this use case) and in the same time sends this report in an electronic format to the national EHR to feed the record of Jane Smith.



## 2.3 Ambulatory physician shares a lab report from a patient in an affinity domain

Patient Jane Smith, with a suspected urinary infection is seen by her family doctor who collects a urine sample and sends it to a reference laboratory with an order for a urine microscopy and culture. The laboratory returns the tests results (outside of this use case) to the family doctor who reviews the results, and notifies Jane Smith of her treatment. The doctor, as requested by Jane Smith, shares this laboratory report in Jane's personal health record in an electronic format.

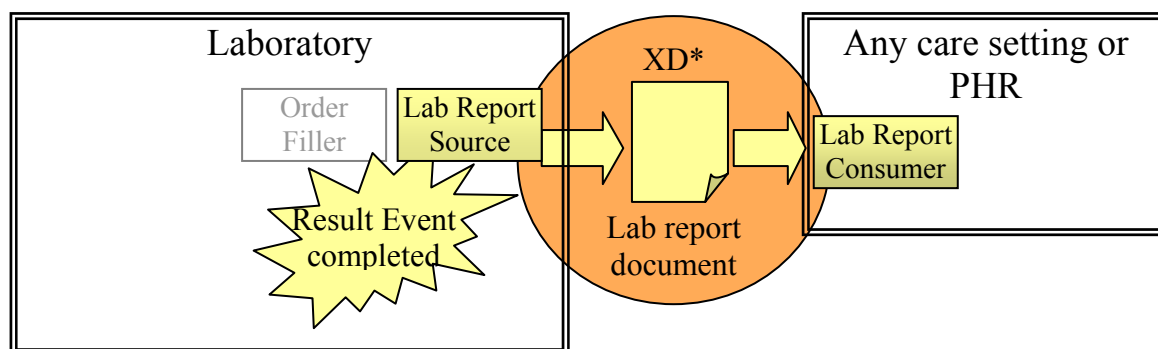


## 2.4 Reports systematically shared by a private or hospital lab

A community or hospital laboratory, systematically (with some degree of automatism) shares its reports with a regional healthcare network. The trigger event for this is the decision to

issue any releasable laboratory report, at which point a copy is sent to the regional healthcare network repository.

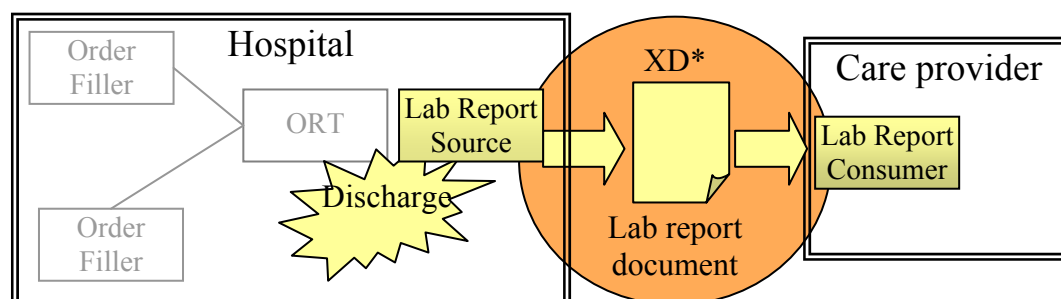
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## 2.5 Cumulative report built and shared at discharge time

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At discharge time of an inpatient, a hospital physician selects the most significant lab results, produced by one or more laboratories of the healthcare enterprise, and builds a cumulative report sent to an health info exchange shared by a number of healthcare enterprises and primary care providers. This cumulative report aggregates the observations related to one or more order groups. It is made available to anybody having access to the EHR, for instance the patient's family doctor.



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- Note 1: A Content Integration Profile for discharge summaries will be built by PCC domain. This use case and the cumulative laboratory report it carries, is intended for deployment where the PCC discharge summary is not utilized. It is not a replacement for a full multi-disciplinary discharge summary. The structure of the body of a cumulative laboratory report is also candidate to be used as the laboratory results section of a PCC discharge summary.
- Note 2: This cumulative laboratory report may be produced at other times than discharge time (e.g. Multi-Disciplinary Team meetings, patient referral)

### 3 Links with national projects

#### 3.1 Italy

Italy was the first country experimenting CDA R2 to build a laboratory report, with its project TeleMed ESCAPE experimented in the Veneto region since 2005.

#### 3.2 US

In the USA, the American Health Information Community (AHIC) and the Office of National Coordinator (ONC) have identified among their three breakthrough use cases the “deployment of standardized, widely available, secure solution for accessing laboratory results in a patient-centric manner for clinical care by authorized parties”. This is further refined to include “the retrieval of historical lab results by providers of care”. This IHE use case where lab reports are encapsulated in a CDA document and may be queried and retrieved from repositories on-demand by XDS document sharing, precisely addresses this access to historical lab data.

Part of this use case will need to be consistent with the EHR to Lab Information Communication Specification (ELINCS) in the USA which includes a results coding vocabulary (Subset of LOINC or SNOMED). ELINCS focuses only on the communication of results back to and under the control of the ordering provider. ELINCS and IHE-North America are under discussions to join their efforts in the lab area.

#### 3.3 France

Use cases 2.1, 2.2, 2.4 and 2.5 cover the needs of sharing laboratory reports in the national personal record DMP (“*Dossier Médical Personnel*”). This patient personal record is document oriented, and will rely on IHE XDS profile for the sharing infrastructure, using a set of central document repositories and registries. The unique key of a personal record will be based on the national health identifier of the person (NIS “Numéro Identifiant de Santé”) authenticated with the patient electronic healthcare card (“carte Vitale”). The patient will manage his or her record and the access to it by healthcare providers who identify themselves through the X509 certificate of their professional electronic card (CPS). The patient can also delegate this access management to his or her officially declared family doctor (“médecin traitant”). The clinical documents stored in the patient’s record, including laboratory reports, will be digitally signed using the X509 certificate of the healthcare provider authenticating the document.

Another requirement addressed by this profile is the sharing of laboratory reports in multi-disciplinary collaboration meetings focused on a cancer case, required by another national project DCC (“*Dossier Communicant en Cancérologie*”) driven by the National Institute of Cancer (INCA).

#### 3.4 Japan

Japan has no use case for direct sharing of laboratory reports. Instead, Japan is likely to use the content of the `structuredBody` of the laboratory report defined in this profile, as a “laboratory result section” of the CDA R2 based “Patient Referral Document” currently being standardized in this country.

## 4 Links with Workflow messaging

### 4.1 Links with the IHE Laboratory Scheduled WorkFlow

In all use cases above, the laboratory report document is built and published towards an EHR, generally after the order (or order group) is fulfilled. It is usually a final report. Yet in some cases a preliminary report can also be shared. In all cases the laboratory report document will not be carried by the laboratory results messages of the Laboratory Scheduled WorkFlow.

In all use cases above, the laboratory report is built with a set of releasable results. The report may be preliminary or final. Further updates of this report must be supported (e.g. replace, deprecate).

In use cases 2.2, 2.4 the report is produced by the LIS that played the role of Order Filler during the laboratory scheduled workflow. The Content Creator Actor is coupled with the Order Filler Actor.

In use cases 2.1 and 2.5 the report is produced by the application that played the role of Order Result Tracker during the laboratory scheduled workflow. The Content Creator Actor is coupled with the Order Result Tracker Actor.

### 4.2 Alignment with the Laboratory Domain of HL7 V3

The HL7 V3 Laboratory Domain supports messaging related to the laboratory test workflows. As already stated above, this content profile is not involved in the laboratory workflows.

Rather, the laboratory report documents an Act (documentationOf/ServiceEvent in the CDA header) performed by a clinical laboratory. This Act is modeled as the **Result Event** in the **Result Event** RMIM in the HL7 V3 Laboratory Domain.

Furthermore, this IHE Content Integration Profile describes a laboratory report. Thus in the **Result Event** RMIM of the Laboratory Domain each result in the report would be represented by the **ObservationEvent** class, that will map with an **observation** element in the level 3 <entry> machine-readable part of the CDA report.

In many cases, the laboratory report organizes the observations within “battery” sections. A battery in the report represents a set of tests reported together. In the **Result Event** RMIM of the Laboratory Domain, a battery would be represented by the **ObservationBattery** class. In the level 3 machine-readable part of the CDA report, this battery is represented by an **organizer** element, with classCode attribute valued “BATTERY”.

Microbiology full studies are represented in the **Result Event** RMIM of the Laboratory Domain by a tree-structure with a **ObservationReport** class as root element. This tree is thoroughly reflected in the level 3 machine-readable part of the CDA report associated with this microbiology study.

Yet, CDA R2 is relying on a version of the Clinical Statement model, which is not fully compatible with the newer version of this model leveraged by the Lab Result Event RMIM. Hence there are some pieces of data captured by a Lab result message, which are missing in the CDA <entry> schema.

440 Some of these gaps are of minor concern, where the missing data, which is of key interest during the result reporting workflow, appears of less interest in the report resulting from this workflow, produced for sharing purposes.

This profile fills the major gaps by extending the <entry> schema of CDA R2. These extensions are described in section 10 of this document.

## 5 Actors and Transactions for the XD\*-LAB Integration Profile

This section references two other IHE Technical Frameworks:

- 445                   • IT Infrastructure Technical Framework
- PCC Technical Framework.

Both are available here: [http://www.ihe.net/Technical\\_Framework/](http://www.ihe.net/Technical_Framework/).

### 5.1 Actor/Transaction Relationships

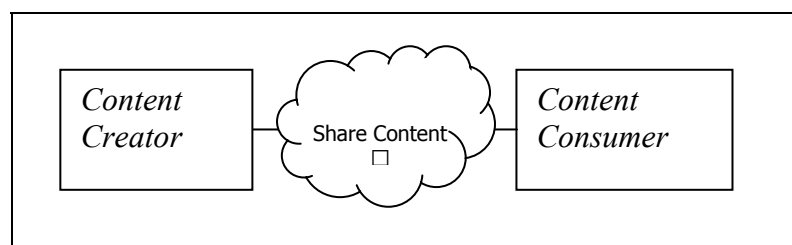
There are two actors in this profile, the Content Creator and the Content Consumer.

- 450   **Content Creator**       A Content Creator Actor is responsible for the creation of content and transmission to a Content Consumer.

**Content Consumer**   A Content Consumer Actor is responsible for viewing, import, or other processing of content created by a Content Creator Actor

- 455   Content (i.e. a laboratory report) is created by a Content Creator and is to be consumed by a Content Consumer. The sharing or transmission of content from one actor to the other is addressed by the appropriate use of IHE profiles described below, and is out of scope of this profile. A Document Source or a Portable Media Creator may embody the Content Creator Actor. A Document Consumer, a Document Recipient or a Portable Media Importer may embody the Content Consumer Actor.

- 460   The sharing or transmission of laboratory reports or updates from one actor to the other is addressed by the use of appropriate IHE profiles described by section 5.4 Content Bindings with XDS, XDM and XDR below.



**Figure 5.1-1 XD\*-LAB Actors**

### 5.2 XD\*-LAB Integration Profile Options

- 465   Table 5.2-1 summarizes the options that actors may take for this Integration Profile. Dependencies between options when applicable are specified in notes. These options are summarized below the table, and further detailed in PCC TF Volume 2, section 3.1, as indicated in the right column of the table.

Actor	Options	Domain, Vol & Section
Content Consumer	<i>View Option (1)</i>	PCC TF-2: 3.1.1
	<i>Document Import Option (1)</i>	PCC TF-2: 3.1.2
	<i>Section Import Option (1)</i>	PCC TF-2: 3.1.3
	<i>Discrete Data Import Option (1)</i>	PCC TF-2: 3.1.4

**Table 5.2-1 Actors and Options**

- 470   Note 1: The Actor shall support at least one of these options.



### **5.2.1 View Document Option**

This option defines the processing requirements placed on Content Consumers for providing access, rendering and management of the Medical Summary. See PCC TF-2:3.1.1 for more details on this option.

- 475 A Content Creator Actor of Laboratory Report should provide access to a style sheet that ensures consistent rendering of the report content when displayed by the Content Consumer Actor (See PCC TF-2:5.4.1.1.2.1).

The Content Consumer Actor must be able to present a view of the document using this style sheet if present.

### **480 5.2.2 Document Import Option**

This option defines the processing requirements placed on Content Consumers for providing access, and importing the entire laboratory report and managing it as part of the patient record. See PCC TF-2: 3.1.2 for more details on this option.

### **5.2.3 Section Import Option**

- 485 This option defines the processing requirements placed on Content Consumers for providing access to, and importing the selected section of the laboratory report and managing them as part of the patient record. See PCC TF-2:3.1.3 for more details on this option.

### **5.2.4 Discrete Data Import Option**

- 490 This option defines the processing requirements placed on Content Consumers for providing access, and importing discrete data from selected sections of the laboratory report and managing them as part of the patient record. See PCC TF-2:3.1.4 for more details on this option.

## **5.3 Dependencies of XD\*-LAB towards other Integration Profiles**

- 495 Dependencies among IHE Integration Profiles exist when implementation of one integration profile is a prerequisite for achieving the functionality defined in another integration profile. Table 5.3-1 defines these dependencies in tabular form. Some dependencies require that an actor supporting one profile be grouped with one or more actors supporting other integration profiles. For example, Sharing Laboratory Reports (XD\*-LAB) requires that different
- 500 participating actors support the Cross-Enterprise Document Sharing (XDS) Integration Profile as well as that its actors be grouped with a Secured Node Actor of the Audit Trail and Node Authentication (ATNA) Integration Profile. The dependency exists because XD\*-LAB and XDS actors must support a secured communication channel with proper auditing of the
- 505 exchange of patient identified information in order to function properly in an environment where protection of patient privacy is critical.

Integration Profile	Depends on	Dependency Type	Purpose
Sharing Laboratory Reports (XD*-LAB)	<i>Cross-Enterprise Document Sharing (XDS)</i>	Implementers of XD*-LAB Content Profile may implement the XDS Profile to enable sharing of the laboratory reports within an XDS Affinity Domain. When the XDS profile is used to provide document interchange, the Content Creator must be grouped with an XDS Document Source actor, and the Content Consumer must be grouped with an XDS Document Consumer actor.	Ensure that the sharing of laboratory reports within an XDS Affinity Domain can co-exist with the sharing of other types of documents (e.g. imaging, ECG, etc.)
Sharing Laboratory Reports (XD*-LAB)	<i>Cross-Enterprise Document Media Interchange (XDM)</i>	Implementers of XD*-LAB Content Profile may implement the XDM Profile to enable sharing of the laboratory reports using media. When the XDM profile is used to provide document interchange, the Content Creator must be grouped with an XDM Portable Media Creator actors, and the Content Consumer must be grouped with an XDM Portable Media Consumer.	Ensure that the sharing of laboratory reports on media can co-exist with the sharing of other types of documents (e.g. imaging, ECG, etc.)
Sharing Laboratory Reports (XD*-LAB)	<i>Cross-Enterprise Document Reliable Interchange (XDR)</i>	Implementers of XD*-LAB Content Profile may implement the XDR Profile to enable sharing of the laboratory reports using reliable point-to-point network messages. When the XDR profile is used to provide document interchange, the Content Creator must be grouped with an XDR Document actor, and the Content Consumer must be grouped with an XDR Document Recipient.	Ensure that the sharing of laboratory reports through reliable point-to-point messages can co-exist with the sharing of other types of documents (e.g. imaging, ECG, etc.)
Sharing Laboratory Reports (XD*-LAB)	<i>Audit Trail and Node Authentication (ATNA)</i>	Content Creator and Content Consumer actors shall be grouped with the ATNA Secured Node Actor	Required to manage audit trail of exported PHI, node authentication, and transport encryption.
Sharing Laboratory Reports (XD*-LAB)	<i>Consistent Time (CT)</i>	Content Creator and Content Consumer actors shall be grouped with the Time Client Actor	Required to manage and resolve conflicts in multiple updates.

**Table 5.3-1 XD\*-LAB Integration Profiles Dependencies**

To support a dependent profile, an actor must implement all required transactions in the prerequisite profiles in addition to those in the dependent profile. In some cases, the prerequisite is that the actor selects any one of a given set of profiles.

## 5.4 Content Bindings with XDS, XDM and XDR

It is expected that the sharing of laboratory reports will occur in an environment where the physician offices and hospitals have a coordinated infrastructure that serves the information sharing needs of this community of care. Several mechanisms are supported by IHE profiles:

- A registry/repository-based infrastructure is defined by the IHE Cross-Enterprise Document Sharing (XDS) and other IHE Integration Profiles such as patient identification (PIX & PDQ), and notification of availability of documents (NAV).
- A media-based infrastructure is defined by the IHE Cross-Enterprise Document Media Interchange (XDM) profile.

- 520
- A reliable messaging-based infrastructure is defined by the IHE Cross-Enterprise Document Reliable Interchange (XDR) profile.
  - All of these infrastructures support Security and privacy through the use of the Consistent Time (CT) and Audit Trail and Node Authentication (ATNA) profiles.

For more details on these profiles, see the IHE IT Infrastructure Technical Framework

- 525 Such an infrastructure is assumed by the use cases described in this Profile, in section 2.

A content binding 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. The Sharing Laboratory Reports Profile applies one binding, which is used when grouping the Content Creator with the IHE ITI XDS, XDM or XDR Integration

- 530 Profiles. This binding is defined in PCC Technical Framework Volume 2, section 4.1.

Content	Binding	Actor	Optionality
Laboratory Report	Medical Document Binding to XD* <i>PCC TF-2:4.1</i>	Content Creator	R
		Content Consumer	R

**Table 5.4-1 Content Bindings**

## 6 Level 1: Header of the laboratory report

535 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.

540 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.

### 545 6.1 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  
550 with the content of the body. Seeing the body of the document without the header makes no sense.

### 6.2 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.

### 555 6.3 ClinicalDocument

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

### 6.4 ClinicalDocument/realmCode

This element SHALL be present.

560 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"/>`

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

### 6.5 ClinicalDocument/code

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

### 6.5.1 Multi-disciplinary lab report

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

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

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

575 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:

580 

```
<code codeSystem="2.16.840.1.113883.2.1.3.2.4.15"
    code="197431000000109" displayName="laboratory report" />
```

### 6.5.2 Single discipline laboratory report

LOINC: Use the appropriate LOINC code as listed in table "[Laboratory specialties](#)" in section 7.1.1.

SNOMED CT does not distinguish various categories of laboratory reports.

## 585 6.6 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.

## 6.7 ClinicalDocument/confidentialityCode

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

<i>code</i>	<i>Meaning</i>
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"/>
```

595 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.

## 6.8 ClinicalDocument/languageCode

The main language in which the report is authored.

600 Example of a report authored in American English:

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

## 6.9 ClinicalDocument/setId

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

## 6.10 ClinicalDocument/versionNumber

605 An integer value used as versioning.

## 6.11 ClinicalDocument/recordTarget

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

## 610 6.12 ClinicalDocument/author

The author(s) of the laboratory report.

In use cases 2.2 and 2.4, the laboratory report is produced by a software system represented by the element:

615 author/assignedAuthor/assignedAuthoringDevice/softwareName. The author/time element carries the date&time the laboratory report was produced by the 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>
```

620 In use cases 2.1, 2.3 and 2.5 the report is prepared by a physician who is the assignedPerson.

```
<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>
```

## 6.13 ClinicalDocument/custodian

- 625 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.
630	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 § 5). For instance in use case 2.1, it will be the hospital; in use case 2.2 it will be the private laboratory; in use case 2.3 it will be the ambulatory physician.

635

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>
```

## 6.14 informationRecipient/intendedRecipient

640 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.

645 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
650	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>
```

## 655 6.15 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>
```

## 660 6.16 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>
```

665 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”.

## 670 6.17 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 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>
```

675

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

## 6.18 inFulfillmentOf/order

The `inFulfillmentOf/order` element MAY be present. It represents the Placer Order<sup>1</sup> that was fulfilled.

## 680 6.19 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).

685 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.

## 6.20 serviceEvent/statusCode

690 This element is 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">).
```

695 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<sup>2</sup>.

---

<sup>1</sup> The Placer Order is either a group of order items (modeled as PlacerGroup in the Placer Order RMIM of the Laboratory domain) or a single order item (modeled as ObservationRequest in the same RMIM).

<sup>2</sup> 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.

See section 10 for a detailed discussion of all extensions brought by this profile to CDA R2.

## 6.21 serviceEvent/performer

- 700 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.

## 6.22 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.

## 6.23 authorization/consent

- 710 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>
```

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

## 6.24 componentOf/encompassingEncounter

- 720 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`

- 725 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`

- 730 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

735 ATND for attender

REF for referrer

DIS for discharger

CON for consultant

740 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:

745 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

750 Minimal content of an encounter:

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

## 7 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:

- 755 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.
- 760 In addition, any leaf section SHALL contain a level 3 entry that contains the observations of that section in a machine-readable format.

### 7.1 Top level sections: specialties

#### 7.1.1 List of specialties

- 765 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.

- 770 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:

<i>LOINC code</i>	<i>Name</i>
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 7-1: Laboratory specialties**

- 775 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.

- 780      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.

### 7.1.2 Template of a “specialty” section

785    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:
  - o `code` is MANDATORY
  - o `codeSystem` is MANDATORY
  - 790      o `codeSystemName` is OPTIONAL
  - o `displayName` is MANDATORY
- An OPTIONAL `title` element.
- Either:
  - 795      o 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. Some of these leaf `section` elements may have an associated level 3 `entry`.
- Or:
  - 800      o One `text` block with non-blank text, representing the whole report for that specialty.
  - o Additionally, one optional `entry` containing the full structured data of that report in a machine-readable format.

## 7.2 Relationship between specialties and reported items

805    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

810    relationships, depending upon chosen vocabularies (e.g. LOINC, SNOMED CT, national vocabularies).

## 7.3 Leaf sections: Reported items

815    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:

- 820
  - o `code` is MANDATORY
  - o `codeSystem` is MANDATORY
  - o `codeSystemName` is OPTIONAL
  - o `displayName` is MANDATORY
  - o `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.).
- 825

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
- 830

`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.
- 835
- 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.
- 840
- An OPTIONAL `entry` containing the machine-readable result data from which the narrative block of this section is derived.

### 7.3.1 Additional constraints on the content of a leaf section

- 845 If the `entry` containing the machine-readable result data is present and the narrative block is fully derived from it, then the `entry.typeCode` attribute is valued "DRIV". Otherwise (i.e. when the text block contains additional text that does not come from the entry) "COMP" is used. For example a non-codable specimen site such as "top of incision on left thigh", may not be coded in the `entry` (depending upon which terminology is used), whereas it appears in the `text` block.

### 850 7.3.2 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.
- 855
- 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.
- 860 - 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...)
- 865 - 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<sup>3</sup>, when using a test vocabulary that implies the specimen type, (like LOINC does with its “SYSTEM” property). This constraint can be verified
- 870 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).
- 875 - 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.
- 880 - 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:

- 885 - 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.
- 890 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

---

<sup>3</sup> 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.



### 7.3.3 Templates for leaf sections

#### 7.3.3.1 Leaf section reporting a single specimen battery

##### 7.3.3.1.1 Scope

895 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.

##### 7.3.3.1.2 Structure

900 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).  
905 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:

- o Name of analyte.
- o Method
- 910 o Unit
- o Current observation with the date/time of specimen collection as header. This column is emphasized with Bold styleCode.
- o Reference to footnote comments (footnoteRef if any comments accompany some of the observations)
- 915 o Reference range
- o Criteria for reference range
- o Interpretation code (.e.g abnormality flag)
- o Optionally, previous observations with the date/time of specimen collection as header. This column MAY be repeated as many times as there are previous  
920 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  
925 this battery.

### 7.3.3.1.3 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" styleCode="Bold">CBC + Platelets Bld </th>
            </tr>
            <tr>
              <th/><th styleCode="Bold">Mar 21, 2006 07:10</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 styleCode="Bold">4.95</td><td>4.50-6.00</td><td/><td>4.85</td>
            </tr>
            <tr>
              <td align="left">hemoglobin (g/dL)</td>
              <td styleCode="Bold">13.4</td><td>11.5-14.5</td><td/><td>13.3</td>
            </tr>
            <tr>
              <td align="left">hematocrit (%)</td>
              <td styleCode="Bold">45</td><td>40.0-54.0</td><td/><td>45</td>
            </tr>
            <tr>
              <td align="left">mean corpuscular volume (fL)</td>
              <td styleCode="Bold">97</td><td>80-95</td><td>H, U</td><td>90</td>
            </tr>
            <tr>
              <td align="left">...</td>
              <td></td><td></td><td></td><td></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)	<b>4.95</b>	4.50-6.00		4.85
hemoglobin (g/dL)	<b>13.4</b>	11.5-14.5		13.3
hematocrit (%)	<b>45</b>	40-54		46
mean corpuscular volume (fL)	<b>97</b>	80-95	H, U	94
...				

No sign of anemia

## 930 7.3.3.1.4 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" styleCode="Bold">Lytes</th>
            </tr>
            <tr>
              <th/><th styleCode="Bold">Mar 21, 2006 07:10</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 styleCode="Bold">140</td><td/>
              <td>135 - 145</td><td/><td>141</td><td/><td/>
            </tr>
            <tr>
              <td>K (mmol/L)</td><td styleCode="Bold">3.4</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 styleCode="Bold">99</td><td/>
              <td>98 - 106</td><td/><td/><td/><td>100</td>
            </tr>
            <tr>
              <td>:</td><td/><td/><td/><td/><td/><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)	<b>140</b>		135-145		141		
K (mmol/L)	<b>3.4</b>	(1)	3.5-5.0	L		3.3	3.2
Cl (mmol/L)	<b>99</b>		98-106				100
...							

(1) Result controlled with a second run

## 7.3.3.1.5 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" styleCode="Bold">Electrophoretic fraction</th></tr>
        <tr><th/><th styleCode="Bold">Mar 21, 2006 07:10</th><th>Reference range</th></tr>
      </thead>
      <tbody align="center">
        <tr><td>Total protein</td><td styleCode="Bold">72</td><td>64 - 80</td></tr>
        <tr><td>Albumin</td><td styleCode="Bold">40</td><td>38 - 50</td></tr>
        <tr><td>Alpha 1</td><td styleCode="Bold">4</td><td>3 - 5</td></tr>
        <tr><td>Alpha 2</td><td styleCode="Bold">5</td><td>3 - 7</td></tr>
        <tr><td>Beta</td><td styleCode="Bold">8</td><td>6 - 10</td></tr>
        <tr><td>Gamma</td><td styleCode="Bold">11</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>

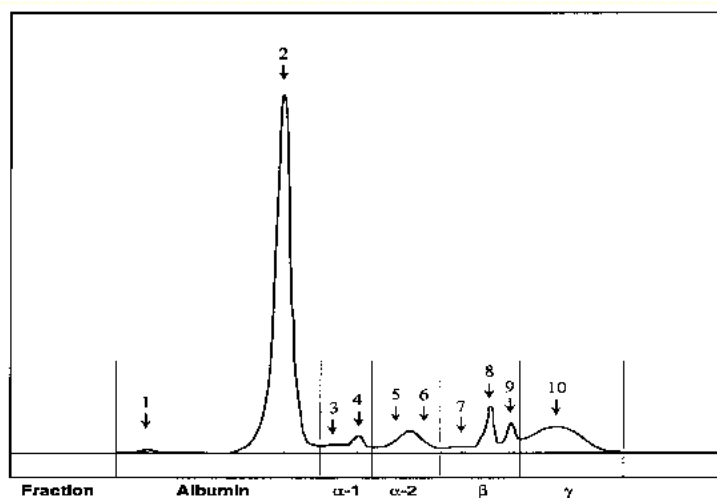
```

935

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

### 7.3.3.2 Leaf section reporting an individual test

#### 7.3.3.2.1 Scope

940 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.

#### 7.3.3.2.2 Structure

945 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...

950 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:

- 955     o Name of analyte.
- o Method
- o Unit
- o Current observation with the date/time of specimen collection as header. This column is emphasized with bold styleCode.
- 960     o Reference range
- o Criteria for reference range
- o Interpretation code (.e.g abnormality flag)
- o Optionally, previous observations with the date/time of specimen collection as header. This column MAY be repeated as many times as there are previous
- 965     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.

### 7.3.3.2.3 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 styleCode="Bold">Mar 21, 2006 07:10</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 styleCode="Bold">3.4</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>

```

970

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)	<b>3.4</b>	3.5 - 5.0	L, D	4.6	3.3

Result controlled with a second run

### 7.3.3.3 Leaf section reporting a challenge study (DFT)

#### 975 7.3.3.3.1 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  
980 specialty "CHEMISTRY CHALLENGE STUDIES".

#### 7.3.3.3.2 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  
985 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.

#### 990 7.3.3.3.3 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

995 **7.3.3.4 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.



### 7.3.3.5 Leaf section reporting a microbiology study

#### 1000 7.3.3.5.1 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.

#### 7.3.3.5.2 Structure

1005 The narrative block contains:

- Zero or more introducing paragraphs.
- One table with:
  - 1<sup>st</sup> column naming the actions, and subtitles delimiting the various phases of the study (microscopy, gram stain, culture, antibiotic sensitivity).
  - 2<sup>nd</sup> 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.

1010

#### 7.3.3.5.3 Example of a urine microscopy, culture and antibiotic susceptibilities

1015 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.

1020 Examples of variations:

- The cross table isolate/antibiotic in the first example might choose not to report the MIC but only their clinical interpretation, and might choose to reference each isolate by a number to narrow the columns:

Isolates:		
Escherichia coli: 1		
Streptococcus D.: 2		
	1	2
Culture amount:		
Microorganism count (/mL)	100,000	200,000
Microbial susceptibility:		
Amoxicillin	R	
Ampicillin		I
Fosfomycin	S	S
...		

1025

**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"></td></tr>
        <tr><td></td><td align="center" colspan="4">Color: straw</td></tr>
        <tr><td></td><td align="center" colspan="4">Appearance: clear</td></tr>
        <tr><td>Microscopy:</td><td colspan="4"></td></tr>
        <tr><td>Leukocytes</td><td align="center" colspan="4">500 /mL</td></tr>
        <tr><td>Erythrocytes</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 susceptibility:</td><td>MIC (mg/L)</td><td>clinical</td><td>MIC (mg/L)</td><td></td>
          <td>clinical</td></tr>
        <tr><td>Amoxicillin:</td><td>12</td><td>R</td><td></td><td></td></tr>
        <tr><td>Ampicillin:</td><td></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"></td></tr>
        <tr><td>Leukocytes</td><td align="center" colspan="2">500 /mL</td></tr>
        <tr><td>Erythrocytes</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="2">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>
        <tr><td>:</td><td colspan="2"></td></tr>
      </tbody>
    </table>
  </text>

```

1030

Rendering:

<b>Microbiology on Urine</b>		
Urine mid-stream collected on March 21 <sup>st</sup> 2006, 07:25		
Direct examination:		
Appearance clear, color straw		
<b>Action</b>	<b>Observation</b>	
<b>Microscopy:</b>		
Leukocytes	500 /mL	
Erythrocytes	200 /mL	
Epithelial cells	absence	
Gram stain	numerous gram - ; some gram +	
<b>Aerobic culture:</b>	Positive	
<b>Isolate:</b>	<b>Escherichia coli</b>	
Microorganism count	100,000 /mL	
<b>Microbial susceptibility:</b>	<b>MIC</b>	<b>clinical susceptibility</b>
Amoxicillin	12	R
Fosfomycin	1.3	S
...		
<b>Isolate:</b>	<b>Streptococcus D.</b>	
Microorganism count	200,000 /mL	
<b>Microbial susceptibility:</b>	<b>MIC</b>	<b>clinical susceptibility</b>
Ampicillin	6	I
Fosfomycin	2.5	S
...		

## 8 Level 3 entries dedicated to multimedia rendering

1035 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.

1040 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>
```

1045 This Integration Profile supports only small images in gif, jpeg, png or bmp<sup>4</sup> 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.

1050 The sharing of real images (e.g. a picture taken from a microscope, the picture of a karyotype) may be addressed in the future by a dedicated profile of the Laboratory Technical Framework.

---

<sup>4</sup> This list of image formats can further be refined by national extensions of this profile.

## 9 Level 3 entry dedicated to data-processing

### 9.1 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)
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:

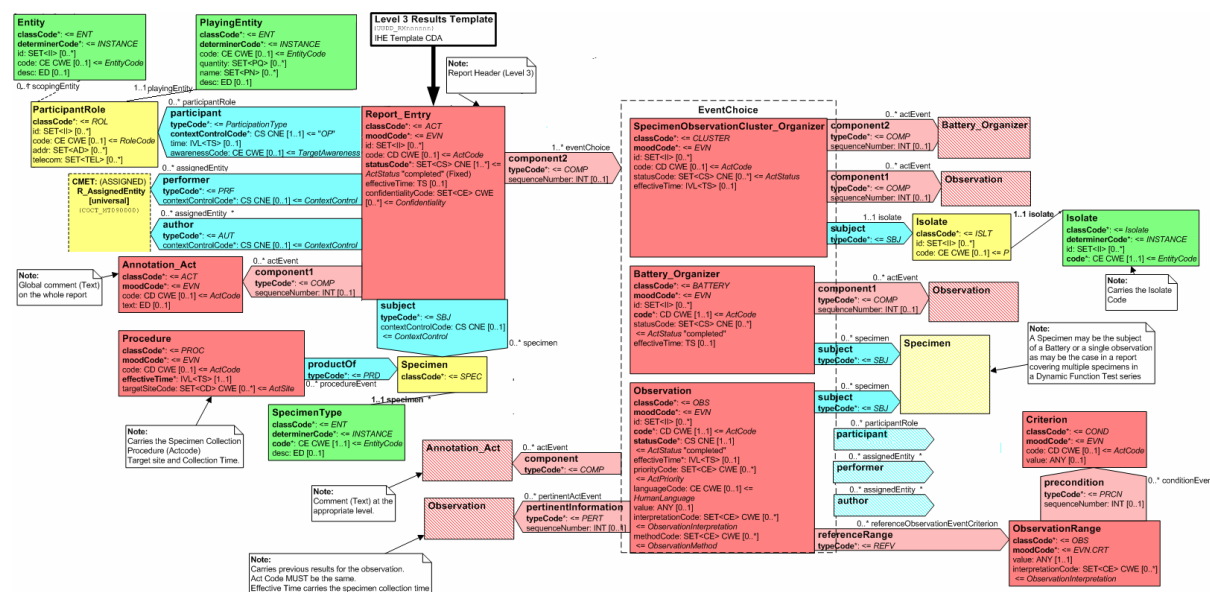


Figure 9-1: representation of a machine-processable entry



1095 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:

- 1100 - SpecimenObservationCluster\_Organizer is only used in the context of a microbiology study. It 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".
- 1105 - 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 1110 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>
```

1115 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"<sup>5</sup> 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.

1120 Example of a current result with 2 previous results attached to it:

---

<sup>5</sup> "REFR" ("refers to") is the mnemonic 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>
```



1125 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.<sup>6</sup> This procedure encapsulates:

- o A code which represents the particular method employed to collect the specimen.
- 1130 o An effectiveTime, which represents the date & time of specimen collection.
- o The targetSiteCode which carries the source site of the specimen (e.g. urine natural mid-stream).

1135 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" displayName="urine"/>
      </specimenPlayingEntity>
      <productOf typeCode="PRD">
        <!-- Specimen collection procedure, carrying also the target site -->
        <procedure classCode="PROC" moodCode="EVN">
          <effectiveTime value="200603210725"/>
          <targetSiteCode code="xxxxxxx" displayName="natural mid-stream"/>
        </procedure>
      </productOf>
    </specimenRole>
  </specimen>
</entry>
```

---

<sup>6</sup> This is an extension to CDA R2. See Chapter 10 for discussion on the proposed extensions to CDA R2.



## 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>
</organizer>
```

- 1150 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.

- 1155 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.

- 1160 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).

- 1165

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>
</observation>
```

## 9.2 Template “Report\_Entry” : An entry of a laboratory report

1170 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 9.1:

**Table 9.2-1: Structure of Report\_Entry**

L v l	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.
<b>Report_Entry from which the section is derived</b>					
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.
<b>specimen participation</b> hangs to Report_Entry if one single specimen for the whole section.					
3	[0..1]	act/specimen	typeCode	SPC	→ See Table 9.2-5
<b>performer participation</b> used if different from the performer of the header, to supersede it for this section.					
3	[0..*]	act/performer			→ See Table 9.2-6

L v l	Card	Parent/element	Attribute	Value	Comments
			typeCode	PRF	
<b>author participation</b> used if different from the author of the header, to supersede it for this section.					
3	[0..*]	act/author			→ See Table 9.2-7
			typeCode	AUT	
<b>participant</b> used for other participants such as verifier (VRF) or responsible party (RESP)					
3	[0..*]	act/participant			→ See Table 9.2-8
			typeCode	{VRF RESP}	VRF for verifier, RESP for responsible party
<b>content of the Report_Entry:</b> 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 9.2-2 → Battery = Table 9.2-3 → Observation = Table 9.2-4
			typeCode	COMP	
<b>Global comments of the Report_Entry</b> 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.

**Table 9.2-2: Structure of SpecimenObservationCluster\_Organizer**

L v l	Card	Parent/element	Attribute	Value	Comments
<b>SpecimenObservationCluster_Organizer</b> 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.
<b>participation of the isolate</b> 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”

L v l	Card	Parent/element	Attribute	Value	Comments
6	[1..1]	specimen/specimenRole			
			classCode	ISLT	type of role: isolate
7	[0..1]	specimenRole/id			unique identifier for this isolate, known to the laboratory
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.
<b>performer participation</b> used if specific performer on this isolate, to supersede all performers of higher level.					
5	[0..*]	organizer/performer			→ See Table 9.2-6
			typeCode	PRF	
<b>author participation</b> used if specific author on this isolate, to supersede all authors of higher level.					
5	[0..*]	organizer/author			→ See Table 9.2-7
			typeCode	AUT	
<b>participant</b> used for other participants such as verifier (VRF) or responsible party (RESP)					
5	[0..*]	act/participant			→ See Table 9.2-8
			typeCode	{VRF RESP}	VRF for verifier, RESP for responsible party
<b>content of the SpecimenObservationCluster Organizer:</b> any number of Battery Organizer, Observation.					
5	[1..*]	organizer/component			→ Battery = Table 9.2-4 → Observation = Table 9.2-5
			typeCode	COMP	
<b>Global comments on this isolate</b>					
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 9.2-3: Structure of Battery\_Organizer**

Lvl	Card	Parent/element	Attribute	Value	Comments
<b>Battery Organizer</b> Holds a battery and its set of observations and annotations, plus an optional specimen					
n <sup>(7)</sup>	[1..1]	organizer	classCode	BATTERY	fixed
			moodCode	EVN	fixed
n+1	[0..1]	organizer/id			
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
<b>specimen participation</b> if this battery uses a specific specimen not recorded at a higher level.					
n+1	[0..1]	organizer/specimen	typeCode	SPC	→ See Table 9.2-5
<b>performer participation.</b> Performer to supersede those recorded at higher level.					
n+1	[0..*]	organizer/performer	typeCode	PRF	→ See Table 9.2-6
<b>author participation</b> used to supersede the authors of higher level.					
n+1	[0..*]	organizer/author	typeCode	AUT	→ See Table 9.2-7
<b>participant</b> used for other participants such as verifier (VRF) or responsible party (RESP)					
5	[0..*]	act/participant	typeCode	{VRF RESP}	→ See Table 9.2-8 VRF for verifier, RESP for responsible party
<b>content of the Battery_Organizer:</b> any number of Observation.					
3	[0..*]	organizer/component	typeCode	COMP	→ Observation = Table 9.2-4 <sup>(8)</sup>
<b>Global comments of the Battery_Organizer</b> 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.

<sup>7</sup> If the Battery\_Organizer hangs below the Report\_Entry, n = 4. Otherwise the Battery\_Organizer hangs below the SpecimenObservationCluster\_Organizer and n = 6.

<sup>8</sup> 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 9.2-4: 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 <sup>(9)</sup>	[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 9.2-5
			typeCode	SPC	
performer participation. Performer to supersede those recorded at higher level.					
n+1	[0..*]	observation/performer			→ See Table 9.2-6
			typeCode	PRF	

<sup>9</sup> 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 the Observation hangs below a Battery\_Organizer below a SpecimenObservationCluster\_Organizer, n = 8.



Lvl	Card	Parent/element	Attribute	Value	Comments
<b>author participation</b> used to supersede the authors of higher level.					
n+1	[0..*]	observation/author	typeCode	AUT	→ See Table 9.2-7
			typeCode	COMP	
<b>participant</b> used for other participants such as verifier (VRF) or responsible party (RESP)					
5	[0..*]	act/participant	typeCode	{VRF RESP}	→ See Table 9.2-8
					VRF for verifier, RESP for responsible party
<b>Comments on this Observation</b>					
n+1	[0..*]	observation/ entryRelationship	typeCode	COMP	Extension to CDA Clinical Statement (See <b>Erreur ! Source du renvoi introuvable.</b> )
n+2	[1..1]	entryRelationship/act	classCode	ACT	
			moodCode	EVN	
n+3	[1..1]	act/text			Text of the comment.
<b>Previous observations obtained for the same patient, test, same method, same unit</b>					
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
<b>Reference range for the current test result</b>					
n+1	[0..1]	observation/ referenceRange	typeCode	REFV	
n+2	[1..1]	referenceRange/ observationRange	classCode	OBS	
			moodCode	EVN.CRT	
n+5	[0..1]	observationRange/value			interval (IVL) representation
n+5	[1..1]	observationRange/ interpretationCode	code	N	These are normal ranges
n+5	[0..*]	observationRange/ preCondition	typeCode	PRCN	Extension to CDA Clinical statement (see 10.3)
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 9.2-5: Specimen for Report\_Organizer or Battery\_Organizer or Observation**

Lvl	Card	Parent/element	Attribute	Value	Comments
<b>specimen participation</b>					
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	typeCode	PRD	<b>Extension to CDA Clinical Statement</b> (see 10.2) specimen is produced by
n+3	[0..1]	productOf/procedure	classCode	PROC	specimen collection process
			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

1185

**Table 9.2-6: Performer at any level**

Lvl	Card	Parent/element	Attribute	Value	Comments
<b>performer participation</b> 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

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:

1190

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.

1195

If this hypothesis is incompatible with the realm, then use a responsible participant, as described below table 9.2-8.

**Table 9.2-7: Author at any level**

Lvl	Card	Parent/element	Attribute	Value	Comments
<b>author participation</b> 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 9.2-8: additional Participant at any level**

Lvl	Card	Parent/element	Attribute	Value	Comments
<b>participant</b> used for other participants					
Constraint: Types of participants limited to verifier (VRF) or responsible party (RESP)					
n	[0..*]	participant			
			typeCode	{VRF RESP}	VRF for verifier, RESP for responsible party
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			The person who verified the content of this section or who is responsible for providing this content
n+3	[1..1]	playingEntity/name			Name of the person
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:

- 1200      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.
- 1205      b) 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

1210 the participant element being attached to the same level as the performer element.

## 9.3 Examples of machine-processable entries

### 9.3.1 CBC

The example described in section 7.3.3.1.3 is derived from the following entry:

```

1215 <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 & PLATELETS
1220 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 -->
1225 <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>
1230 <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>
1235 </lab:productOf>
                </specimenRole>
            </specimen>
            <!-- Battery Hemogram and platelets -->
            <entryRelationship typeCode="COMP">
1240 <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 & PLATELETS PANEL"/>
                <statusCode code="completed"/>
1245 <!-- 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">
1250 <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"/>
1255 <!-- 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 -->
1260 <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"/>
1265 </observation>
                        </entryRelationship>
                    </component>
                </organizer>
            </entryRelationship>
        </act>
    </entry>

```

```

criteria) -->
1270      <!-- The appropriate reference range is selected according to patient sex and age (2
      <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>
1275        </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"/>
1280          </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>
1285          </lab:criterion>
        </lab:precondition>
      </referenceRange>
    </observation>
  </component>
1295  <!-- 2nd analyte: Hemoglobin -->
  <component>
    <observation classCode="OBS" moodCode="EVN">
      <code code="20509-6" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
1300      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"/>
1305      <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"/>
1310          <effectiveTime value="200603120815"/>
          <value xsi:type="PQ" value="13.3" unit="g/dL"/>
        </observation>
      </entryRelationship>
      <!-- The appropriate reference range, precondition not mentioned -->
1315      <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>
1320        </observationRange>
      </referenceRange>
    </observation>
  </component>
1325  <!-- 3rd analyte: Hematocrit -->
  <component>
    <observation classCode="OBS" moodCode="EVN">
      <code code="20570-8" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
1330      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"/>
1335      <entryRelationship typeCode="REFR">
        <!-- Previous result 45 from Mar 12, 2006 08:15 -->

```

```
1340      <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>
1345    <!-- 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>
1355 <!-- 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"
1360 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"/>
1365 <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"/>
1370 <statusCode code="completed"/>
        <effectiveTime value="200603120815"/>
        <value xsi:type="PQ" value="94" unit="fL"/>
      </observation>
    </entryRelationship>
1375 <!-- 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>
1385 <!-- End of the battery-->
</organizer>
</entryRelationship>
1390 <!-- Global interpretative annotation on the section -->
<entryRelationship typeCode="COMP">
  <act classCode="ACT" moodCode="EVN">
    <text>No sign of anemia</text>
  </act>
</entryRelationship>
1395 </act>
</entry>
```

### 9.3.2 Single serum potassium

The example presented in section 7.3.3.2.3 is derived from the following entry:

```

1400 <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="
1405 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"
1410 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"/>
1415 <!-- 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 -->
1420 <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"/>
1425 </observation>
                    </entryRelationship>
                    <entryRelationship typeCode="REFR">
                        <!-- Previous result 3.3 from Jan 1st, 2006 05:12 -->
1430 <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"/>
1435 </observation>
                        </entryRelationship>
                        <!-- Reference range for this patient: [3.5 - 5.0] -->
                        <referenceRange typeCode="REFV">
                            <observationRange classCode="OBS" moodCode="EVN.CRT">
1440 <value xsi:type="IVL_PQ">
                                    <low value="3.5" unit="mmol/L"/>
                                    <high value="5.0" unit="mmol/L"/>
                                    </value>
                            </observationRange>
                        </referenceRange>
1445 </observation>
                    </entryRelationship>
                    <!-- Comment for the section represented by this entry -->
                    <entryRelationship typeCode="COMP">
                        <act classCode="ACT" moodCode="EVN">
1450 <text>Result controlled with a second run</text>
                        </act>
                    </entryRelationship>
                </act>
    </entry>

```

### 1455 9.3.3 Glucose tolerance study

(postponed)

### 9.3.4 Urine microbiology study

The example presented in section 7.3.3.5.3 is derived from the following entry:

```
1460 <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"/>
1465        <statusCode code="completed"/>
        <!-- Time in which this entry (section) was reported -->
        <effectiveTime value="200603231500"/>
        <specimen typeCode="SPC">
          <specimenRole classCode="SPEC">
1470            <specimenPlayingEntity>
              <code code="UR" codeSystem="OID for HL7 EntityType vocab domain"
codeSystemName="specimenEntityType" displayName="urine"/>
              </specimenPlayingEntity>
              <lab:productOf typeCode="PRD">
1475                <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"
1480 displayName="mid-stream urine"/>
                  </lab:procedure>
                </lab:productOf>
              </specimenRole>
            </specimen>
            <entryRelationship typeCode="COMP">
1485              <organizer classCode="BATTERY" moodCode="EVN">
                <code code="xxxxx" displayName="DIRECT EXAMINATION"/>
                <!-- Time of direct examination -->
                <statusCode code="completed"/>
                <effectiveTime value="200603210825"/>
1490                <!-- 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>
1495                  </observation>
                </component>
                <component>
                  <observation classCode="OBS" moodCode="EVN">
                    <code code="xxxxx" codeSystem="2.16.840.1.113883.6.1" displayName="Appearance"/>
1500                    <value xsi:type="ST">clear</value>
                  </observation>
                </component>
              </organizer>
            </entryRelationship>
            <entryRelationship typeCode="COMP">
1505              <organizer classCode="BATTERY" moodCode="EVN">
                <code code="xxxxx" displayName="MICROSCOPY"/>
                <statusCode code="completed"/>
                <!-- Time of microscopy -->
                <effectiveTime value="200603210829"/>
1510                <!-- 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"/>
1515                    <value xsi:type="PQ" value="500" unit="mL"/>
                  </observation>
                </component>
                <component>
                  <observation classCode="OBS" moodCode="EVN">
1520                    <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>
1525                  <observation classCode="OBS" moodCode="EVN">
```



```

1530         <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>
1535        </observation>
    </component>
    </organizer>
</entryRelationship>
<entryRelationship typeCode="COMP">
1540    <organizer classCode="BATTERY" moodCode="EVN">
        <code code="xxxxx" displayName="Aerobic culture"/>
        <statusCode code="completed"/>
        <!-- Time of culture observation -->
        <effectiveTime value="200603220910"/>
1545        <!-- 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>
1550            </observation>
        </component>
    </organizer>
</entryRelationship>
<!-- First isolate: Escherichia coli -->
1555 <entryRelationship typeCode="COMP">
    <organizer classCode="CLUSTER" moodCode="EVN">
        <statusCode code="completed"/>
        <!-- Time of final reporting on isolate -->
        <effectiveTime value="200603231100"/>
1560        <specimen typeCode="SPC">
            <specimenRole classCode="ISLT">
                <specimenPlayingEntity>
                    <code code="E-coli" codeSystemName="A vocabulary for isolates"
1565                    displayName="Escherichia coli"/>
                </specimenPlayingEntity>
            </specimenRole>
        </specimen>
        <component>
            <!-- Culture amount -->
1570            <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"/>
1575                <value xsi:type="PQ" value="100000" unit="mL"/>
            </observation>
        </component>
    </component>
    <!-- Battery sensitivity -->
1580    <organizer classCode="BATTERY" moodCode="EVN">
        <code code="xxxxx" displayName="Microbial suceptibility"/>
        <!-- One antibiotic tested. -->
        <component>
            <observation classCode="OBS" moodCode="EVN">
1585                <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>
1590        </component>
        <!-- One antibiotic tested. -->
        <component>
            <observation classCode="OBS" moodCode="EVN">
1595                <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>
1605 <!-- Second isolate: Streptococcus D. -->
    <entryRelationship typeCode="COMP">
      <organizer classCode="CLUSTER" moodCode="EVN">
        <statusCode code="completed"/>
        <!-- Time of final reporting on isolate -->
        <effectiveTime value="200603231300"/>
1610 <specimen typeCode="SPC">
          <specimenRole classCode="ISLT">
            <specimenPlayingEntity>
              <code code="Strep-D" codeSystemName="A vocabulary for isolates"
1615 displayName="Streptococcus D."/>
            </specimenPlayingEntity>
          </specimenRole>
        </specimen>
      <component>
        <!-- Culture amount -->
1620 <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"/>
1625 <value xsi:type="PQ" value="200000" unit="mL"/>
        </observation>
      </component>
    </component>
    <!-- Battery sensitivity -->
1630 <organizer classCode="BATTERY" moodCode="EVN">
      <code code="xxxxx" displayName="Microbial suceptibility"/>
      <!-- One antibiotic tested. -->
      <component>
        <observation classCode="OBS" moodCode="EVN">
1635 <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">
1645 <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>
1650 </act>
1655 </entry>
```

## 10 Extensions to CDA R2

1660 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.

1665 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.

1670 An additional extension was brought to the header of CDA R2 to distinguish a final report from a preliminary report.

### 10.1 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:

- 1675
  - 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:

1680 **`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.
- 1685
  - 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.

## 10.2 Missing specimen target site and other properties

### 10.2.1 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.

- 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.

### 10.2.2 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 :

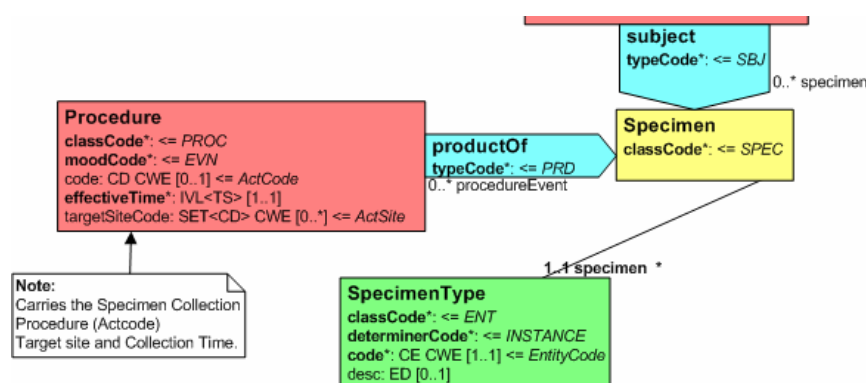


Figure 10-1: Adding a participation to the specimen collection procedure

### 10.2.3 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">
```

....

```
<specimenRole classCode="SPEC">
  ...
  <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>
```

## 10.3 Missing pre-condition criterion on reference range

### 10.3.1 Issue

1725 The Clinical Statement of CDA does not support the association of a criterion with a reference 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.

### 10.3.2 Proposed extension

1730 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:

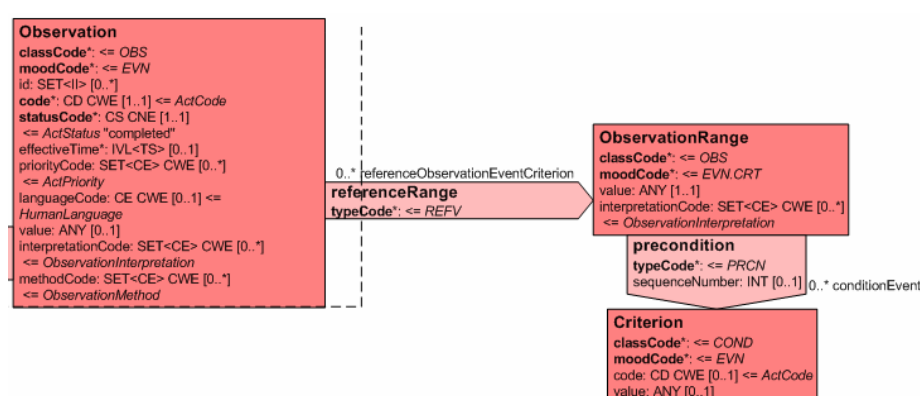


Figure 10-2: Associating criteria to the reference range of an observation

### 10.3.3 Example

```

1735 <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">
      ....
1740   <!--
        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">
1745            <low value="4.50" unit="10*6/mm3"/>
            <high value="6.00" unit="10*6/mm3"/>
          </value>
        </observationRange>
        <lab:precondition typeCode="PRCN">
1750          <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>
1755        <lab:precondition typeCode="PRCN">
          <lab:criterion classCode="COND">
            <lab:code code="AGE"/>
            <lab:value xsi:type="IVL_PQ">
1760              <lab:low value="35" unit="Y"/>
              <lab:high value="55" unit="Y"/>
            </lab:value>
          </lab:criterion>
        </lab:precondition>
      </referenceRange>
  
```

## 10.4 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.

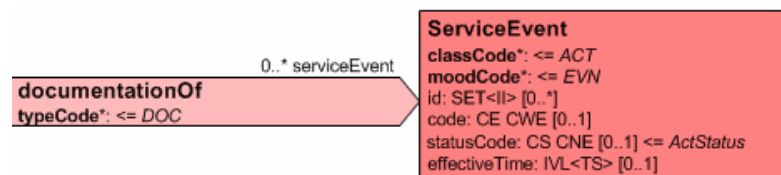


Figure 10-3: StatusCode added to serviceEvent in the header

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>
          ...
        
```

## 11 Vocabularies

### 11.1 Selected subset of LOINC test codes

1790 The laboratory LOINC tests code subset is provided in the following external document, that represents Volume 4 of the Laboratory Technical Framework:

IHE LAB TF-4 LOINC Laboratory Test Terminology Trial Implementation.

### 11.2 Use of SNOMED CT terminology

1795 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.

## 12 OIDs assigned to artefacts of this Content Integration Profile

1800 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 and attributes of extensions brought to CDA R2 by this Profile.

**Table 12-1: OIDs assigned to the XD\*-LAB Content Profile**

## 13 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	We have to list these OIDs in the document. Some are missing
Digital signature	embedded or by-reference using DGS profile in the context of XDS.

## 14 Closed issues

- 1805 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.
- 1810 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.
- 1815 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).
- 1820 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.
- 1825 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.
- 1830 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.



1835 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`.
- 1840 - 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.

1845 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.

1850 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.