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

2.3.3.4 ClinicalDocument/typeId

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

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

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

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

2.3.3.5 ClinicalDocument/templateId

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

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

2.3.3.6 ClinicalDocument/id

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

Example using the extension attribute:

```
<id root="1.3.6.1.4.1.19376.1.3.4" extension="abc2"/>
```

Example without the extension attribute. In this case the OID populated in the root attribute is the unique instance identifier itself (The OID in this example is constructed from the OID dedicated to all examples in IHE LAB TF: `1.3.6.1.4.1.19376.1.3.4`):

```
<id root="1.3.6.1.4.1.19376.1.3.4.1232669"/>
```

2.3.3.7 ClinicalDocument/code

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

2.3.3.7.1 Multi-disciplinary Laboratory Report

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

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


2.3.3.7.2 Single Discipline Laboratory Report

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

2.3.3.8 ClinicalDocument/effectiveTime

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

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

2.3.3.9 ClinicalDocument/confidentialityCode

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

2.3.3.10 ClinicalDocument/languageCode

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

Example of a report authored in American English:

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

Example of a report authored in French:

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

2.3.3.11 ClinicalDocument/setId

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

Example:

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

2.3.3.12 ClinicalDocument/versionNumber

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

2.3.3.13 ClinicalDocument/recordTarget

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

- Human (patient): The document reports laboratory observations produced on specimens collected exclusively from the patient.
- Non-Human Subject: The document reports laboratory observations produced on specimens collected from a non-human material (e.g., water, milk, etc.) or living subject (e.g., animal).

- Human (patient) paired with Non-Human Subject: The document reports laboratory observations produced on a non-human specimen with a relationship to a human patient (e.g., peanut butter eaten by a patient, a ferret that bit a patient).

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

2.3.3.13.1 Human Patient

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

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

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

Figure 2.3.3.13.1-1a: Human Patient Example a

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

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

Figure 2.3.3.13.1-1b: Human Patient Example b

2.3.3.13.2 Non-Human Subject 1.3.6.1.4.1.19376.1.3.3.1.2

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

- **<templateId root="1.3.6.1.4.1.19376.1.3.3.1.2"/> -** The `templateId` element identifies this `recordTarget` as a non-human subject of laboratory testing. The templateId SHALL have `root="1.3.6.1.4.1.19376.1.3.3.1.2"`.
- **<id/> -** /patientRole/id SHALL be present and SHALL represent the id of the non-human subject.
- **<patient@nullFlavor/> -** The recordTarget/patientRole SHALL have a patient sub-element and its `nullFlavor` SHALL be set to "`OTH`". This indicates that other information pertaining to the non-human subject can be found in the body of the document.
- **<structuredBody> mark-up -** In addition to the elements specified in the CDA header for the non-human subject, this non-human subject SHALL be represented in a Subject element in level 3 entries in the `structuredBody` as described in (2.3.5.3).

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

Figure 2.3.3.13.2-1: Non-Human Subject Example

2.3.3.13.3 Human Patient with Non-Human Subject 1.3.6.1.4.1.19376.1.3.3.1.3

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

- **<templateId root="1.3.6.1.4.1.19376.1.3.3.1.3"/> -** The `templateId` element identifies this `recordTarget` as a human patient directly impacted by a non-human subject of laboratory testing. The templateId SHALL have `root="1.3.6.1.4.1.19376.1.3.3.1.3"`.
- **<id/> -** recordTarget/patientRole/id SHALL be present. It SHALL be representative of the id of the human patient. In this template, the id of the non-human subject is not provided in the header. On a special note, at present, if the document contains a patient and a subject (as in the case of rabies, for example), documentation of the id of the subject cannot be accomplished without an extension to CDA.
- **<administrativeGenderCode/>** - The patientRole/patient/administrativeGenderCode SHALL be present.
- **<birthTime/>** - The patientRole/patient/birthTime SHALL be present.
- **<structuredBody> mark-up -** In addition to the elements specified in the CDA header for the patient, the non-human subject SHALL be represented in a Subject element in level 3 entries in the `structuredBody` as described in (2.3.5.4).

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

Figure 2.3.3.13.3-1: Human patient paired with Non-Human Subject Example

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

2.3.3.14 ClinicalDocument/author

At least one ClinicalDocument/author SHALL be present with a `time` in accordance with the HL7 CDA R2 standard and further constrained by this specification to require the presence of

name, addr and telecom. The author/time element carries the date&time the laboratory report was produced. The laboratory report can be authored by a software system or by a person or by both.

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

Figure 2.3.3.14-1: Example of Report Authored by a System

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

Figure 2.3.3.14-2: Example of Report Authored by a Person

2.3.3.15 ClinicalDocument/custodian

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


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

Figure 2.3.3.15-1: Example of a Custodian

2.3.3.16 Intended Recipient 1.3.6.1.4.1.19376.1.3.3.1.4

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

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

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

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

Figure 2.3.3.16-1: Intended Recipient Example

2.3.3.17 ClinicalDocument/legalAuthenticator

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

If this entity happens also to be one of the validators of the laboratory results in the report, it SHALL also be documented as a validator as described in section 2.3.3.18.

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

Figure 2.3.3.17-1: Legal Authenticator Example

2.3.3.18 Laboratory Results Validator 1.3.6.1.4.1.19376.1.3.3.1.5

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

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

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


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

515 **Figure 2.3.3.18-1: Laboratory Results Single Validator Example**

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

Figure 2.3.3.18-2: Laboratory Results Multiple Validators Example

2.3.3.19 Ordering Provider 1.3.6.1.4.1.19376.1.3.3.1.6

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

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

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

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

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

Figure 2.3.3.19-1: Ordering Provider Example

2.3.3.20 ClinicalDocument/inFulfillmentOf/order

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

Note: A laboratory report MAY fulfill an Order Group or an Order (see definitions of these terms in the Glossary: LAB TF-1:1.11 and in "Product Implementation" section: LAB TF-1:3.5.3). In v2.5 messages the Placer Group corresponds to field ORC-4 "placer group number", the Placer Order corresponds to field ORC-2 "placer order number"

2.3.3.21 ClinicalDocument/documentationOf/serviceEvent

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

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

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

The statusCode sub element is an extension to the CDA R2 schema further described in section 2.3.6.3 of this volume. This sub-element is optional. When it is not there, the documented Act is assumed to be completed and the report is assumed to be a final report.

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

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

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

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

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

2.3.3.23 ClinicalDocument/relatedDocument/parentDocument

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

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

Figure 2.3.3.23-1: Related Parent Document Example

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

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

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

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

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

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

2.3.4 Content Modules for CDA Sections (Level 2)

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

Top level sections represent laboratory specialties. A top level section SHALL contain either one `text` block carrying all the text results produced for this specialty along with a single Laboratory Data Processing Entry or a set of Laboratory Report Item Sections. In the first case the specialty section happens to also be a leaf section. In the latter case, each (second level) leaf section contained in the (top level) specialty section represents a **Report Item**: i.e., a battery, a specimen study (especially in microbiology), or an individual test.

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

Table 2.3.4-1: CDA Section Templates

Template Id	CDA Element	Usage	Description
1.3.6.1.4.1.19376.1.3.3.2.1	ClinicalDocument/ component/structuredBody/ component/section	R	Laboratory Speciality Section template in the CDA body (2.3.4.1)
1.3.6.1.4.1.19376.1.3.3.2.2	ClinicalDocument/ component/structuredBody/ component/section/component/section	O	Laboratory Report Item Section template in the CDA body (2.3.4.2)

2.3.4.1 Laboratory Specialty Section 1.3.6.1.4.1.19376.1.3.3.2.1

2.3.4.1.1 List of Laboratory Specialties

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

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

Table 2.3.4.1.1-1: Laboratory Specialties

LOINC code	Name
18717-9	BLOOD BANK STUDIES
18718-7	CELL MARKER STUDIES
18719-5	CHEMISTRY STUDIES
18720-3	COAGULATION STUDIES
18721-1	THERAPEUTIC DRUG MONITORING STUDIES
18722-9	FERTILITY STUDIES
18723-7	HEMATOLOGY STUDIES
18724-5	HLA STUDIES

LOINC code	Name
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

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

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

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

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

2.3.4.1.2 Specification

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

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

<code code=" " codeSystem=" " codeSystemName=" " displayName=" "/> - The Laboratory Specialty Section SHALL identify the LOINC laboratory specialty. The `code`, `codeSystem`, and `displayName` attributes SHALL be present. The codeSystemName MAY also be present.

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

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

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


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

Figure 2.3.4.1.2-1: Laboratory Specialty Section Example

2.3.4.2 Laboratory Report Item Section 1.3.6.1.4.1.19376.1.3.3.2.2

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

- The 1st left column "Lvl" counts the number of nodes traversed in the tree to reach an element, n representing the top element of the current content module.
- The 2nd column "Card" gives the cardinality of an element.
  - A cardinality of [1..1] means that the element SHALL be present once and only once.
  - A cardinality [1..*] means that the element SHALL be present at least once.
  - A cardinality [0..1] means the element MAY be present.
  - A cardinality [0..*] means the element MAY be present zero or more times.
- The 3rd column contains the name of the element, preceded by the name of its parent.
- The 4th column lists the attributes usable on an element.
- The 5th column lists the authorized values for an attribute. When one single value is listed, the attribute is mandatory and must have this value.
- The 6th column gives comments, and indicates whether an attribute is mandatory or not.

Notes below the table deliver additional precisions. Elements of the CDA document not explicitly referenced in a table SHALL remain as specified by the HL7 CDA R2 specification.

2.3.5.2 Laboratory Report Data Processing Entry 1.3.6.1.4.1.19376.1.3.1

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

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

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

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

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

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

Figure 2.3.5.2-1: Laboratory Report Data Processing Entry within a Specialty Section

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

Figure 2.3.5.2-2: Laboratory Report Data Processing Entry within a Report Item Section

2.3.5.3 Non-Human Subject 1.3.6.1.4.1.19376.1.3.3.1.2.1

When the subject of the observations in the report is a sample exclusively taken from a non-human subject, such as an animal, a lake, soil or other environmental element, the following SHALL be present. In addition to the elements specified in the CDA body for the non-human subject, this non-human subject SHALL be represented in the CDA header as described in 2.3.3.13.2.

Table 2.3.5.3-1: Non-Human Subject

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

2.3.5.4 Human Patient with Non-Human Subject 1.3.6.1.4.1.19376.1.3.3.1.3.1

When the subject of the observations in this part of the report is a sample taken from a non-human subject, such as an animal, a lake, soil or other environmental element, while other parts of the report are related to the human patient, the following SHALL be present. In addition to the elements specified in the CDA body for the non-human subject, this non-human subject SHALL be represented in the CDA header as described in 2.3.3.13.3.

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

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

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

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

2.3.5.13 Additional Participant

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

The participant MAY be:

The validator (typeCode="AUTHEN") of the observations of this part of the report. See 2.3.3.18 for more information on "validator".

A device (typeCode="DEV"), which was used to produce this set of results, for instance an analyzer.

The person responsible (typeCode="RESP") for the provision of the observations of this part of the report. In the case where a subset of the observations is subcontracted to an external laboratory, this external laboratory (with its address and telecom) and the actual performer is represented by a `performer` element, whereas the Director of this subcontractor laboratory is carried by a `participant@typeCode="RESP"/participantRole/playingentity/name`

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

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

2.3.6 Extensions to CDA R2

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

2.3.6.1 General Rules Respected by Laboratory Report Extensions

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

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

2.3.6.2 Pre-condition Criterion on Reference Range

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

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

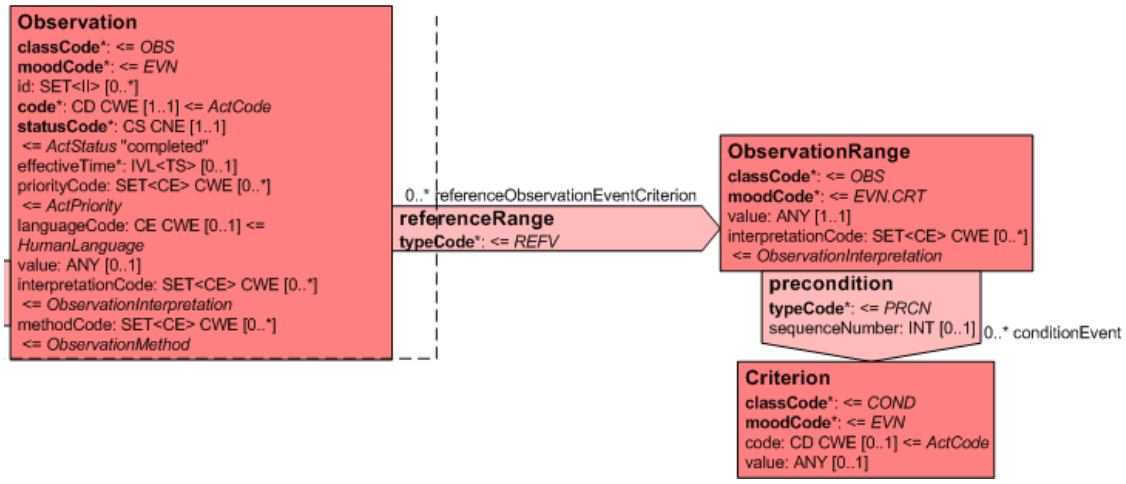

Figure 2.3.6.2-1: Associating criteria to the reference range of an observation

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

Figure 2.3.6.2-2: Pre-Condition Criterion Example

2.3.6.3 statusCode of Documented serviceEvent

This Laboratory Report Content Module can express both final and non-final reports. To distinguish between the two, the `statusCode` element has been added to the `documentationOf/serviceEvent` element. A non-final report is a report documenting a `serviceEvent`, which is in the status `"active"`.

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

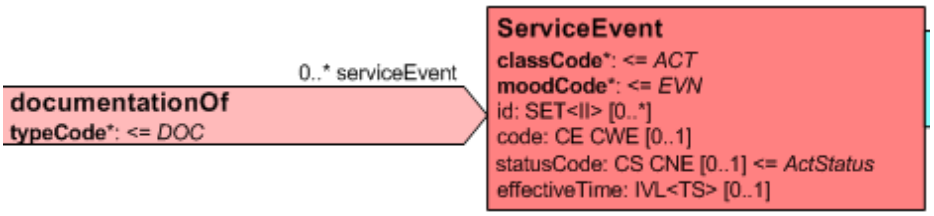

Figure 2.3.6.3-1: StatusCode added to serviceEvent in the CDA header

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

</ClinicalDocument>
```

Figure 2.3.6.3-2: Example of usage in a non-final laboratory report

3 Open issues

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

4 Closed issues

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

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

The Laboratory Result Event RMIM (POLB_RM004000) would use an outbound ActRelationship `pertinentInformation` to the CMET `A_SupportingClinicalInformation` using the specialization `A_ObservationGeneral from this CMET`, with `value` being the previous result, `code` being the same code as in the `ObservationEvent` and `effectiveTime` being the date/time of this previous result.

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

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

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

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

Adopt comment template from PCC.

Spotting the Ordering Provider in the header of the document.

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

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

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

Usage code R2 versus RE

IHE uses R2 (mostly), Lab-TF is consistent with HL7 and uses RE – solution, create a Note in the document for readers highlighting this discrepancy

Dealing with preliminary and final reports. Extension to CDA R2: serviceEvent/statusCode

