Implementation Guide for CDA Release 2 ONC/HL7/IHE Consolidation Project

Results Section (working draft)

The Office of the National Coordinator for
Health Information Technology

DRAFT: FOR DEVELOPMENT USE ONLY
(Consolidated Developer Documentation)

Contents

Acknowledgments

HITSP Diagnostic Results

Diagnostic Results Section

[Section: templateId `2.16.840.1.113883.3.88.11.83.122`]

The Diagnostic Results Section contains information about the results from diagnostic procedures the patient received.

1. **SHALL** conform to *CDA Section*
2. **SHALL** conform to *IHE Coded Results Section* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.3.28`)
3. [IHE] **SHALL** contain [1..1] `code/@code` = "30954-2" *STUDIES SUMMARY* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC)
4. [IHE] **SHALL** contain [1..*] `procedureEntry`, such that it
   a. contains *IHE Procedure Entry*
5. [IHE] **SHOULD** contain [1..*] `entry`, such that it
   a. contains *IHE External Reference* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.4`)
6. [IHE] **MAY** contain [0..*] `entry`, such that it
   a. contains *IHE Simple Observation* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.13`)
7. [HITSP] **SHALL** contain [1..*] `entry`, such that it
   a. contains *Procedure* (templateId: `2.16.840.1.113883.3.88.11.83.17`) (C83-[CT-122-2])
8. [HITSP] **SHALL** contain [1..*] `entry`, such that it
   a. contains *Result* (templateId: `2.16.840.1.113883.3.88.11.83.15`) (C83-[CT-122-2])

```xml
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.28"
assigningAuthorityName="IHE Coded Results Section"/>
          <templateId root="2.16.840.1.113883.3.88.11.83.122"
assigningAuthorityName="HITSP Diagnostic Results Section"/>
          <code code="30954-2" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="STUDIES SUMMARY"/>
          <title>STUDIES SUMMARY</title>
          <entry>
            <procedure>
              <templateId root="2.16.840.1.113883.10.20.1.29"/>
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.19"/>
              <templateId root="2.16.840.1.113883.3.88.11.83.17"
assigningAuthorityName="HITSP Procedure"/>
              <id root="4ab040d3-8646-4293-96d0-21dc9a741003"/>
              <code/>
              <text/>
              <statusCode code="completed"/>
              <effectiveTime>
                <low value="1972"/>
                <high value="2008"/>
              </effectiveTime>
              <approachSiteCode/>
```

```
                    <targetSiteCode codeSystem="2.16.840.1.113883.6.96"
codeSystemName="SNOMEDCT"/>
            </procedure>
          </entry>
          <entry>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.31"
assigningAuthorityName="CCD Result Observation"/>
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.13"
assigningAuthorityName="IHE Simple Observation"/>
              <templateId root="2.16.840.1.113883.3.88.11.83.15"
assigningAuthorityName="HITSP Result"/>
              <id root="0da948f9-a254-4b2b-89df-6fa67b8ce473"/>
              <code/>
              <statusCode code="completed"/>
              <effectiveTime>
                <low value="1972"/>
                <high value="2008"/>
              </effectiveTime>
              <interpretationCode/>
              <methodCode/>
            </observation>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 1: Diagnostic Results Section example

Procedure

[Procedure: templateId `2.16.840.1.113883.3.88.11.83.17`]

Defines a coded entry describing a procedure performed on a patient.

1. **SHALL** conform to *IHE Procedure Entry*
2. **SHALL** conform to *CCD Procedure Activity*
3. **SHALL** conform to *CDA Clinical Statement*
4. **SHALL** conform to *CDA Procedure*
5. **SHALL** conform to *CCD Procedure Activity Procedure* template (templateId: `2.16.840.1.113883.10.20.1.29`)
6. **SHALL** conform to *IHE Procedure Entry Procedure Activity Procedure* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.19`)
7. [CDA] Contains [1..1] `@classCode`, where its data type is ActClass
8. [CDA] Contains [1..1] `@moodCode`, where its data type is x_DocumentProcedureMood
9. [IHE] **SHALL** contain [1..*] `id`
10. [IHE] **SHALL** contain [1..1] `statusCode`

   • The <statusCode> element shall be present when used to describe a procedure event. It shall have the value 'completed' for procedures that have been completed, and 'active' for procedures that are still in progress. Procedures that were stopped prior to completion shall use the value 'aborted', and procedures that were cancelled before being started shall use the value 'cancelled'.

11. [IHE] **SHOULD** contain [1..1] `effectiveTime`
12. [IHE] **SHALL** contain [1..1] `code`

   • Contains a code describing the type of procedure.

13. [IHE] **MAY** contain [0..*] `approachSiteCode`

   • This element may be present to indicate the procedure approach.

14. [HITSP] **SHOULD** contain [1..1] `targetSiteCode`, which **SHOULD** be selected from ValueSet 2.16.840.1.113883.3.88.12.3221.8.9 Body Site Value Set STATIC 2 (C83-[DE-17-CDA-3])
15. [IHE] **SHALL** contain [1..1] `text`
16. [IHE] **SHALL** satisfy: The <text> element shall contain a reference to the narrative text describing the procedure.

   - `[OCL]: not self.text.reference.oclIsUndefined()`

17. [IHE] **MAY** satisfy: entryRelationship with typeCode='COMP' may be present to point to the encounter in which the procedure was performed, and shall contain an internal reference to the encounter.
18. [IHE] **MAY** satisfy: entryRelationship with typeCode='RSON' may be present. A <procedure> act may indicate one or more reasons for the procedure. These reasons identify the concern that was the reason for the procedure via an Internal Reference to the concern. The extension and root of each observation present must match the identifier of a concern entry contained elsewhere within the CDA document.
19. [HITSP] **SHOULD** satisfy: The code/@code attribute is present.

   - `[OCL]: not self.code.code.oclIsUndefined()`

20. [HITSP] **SHALL** satisfy: The code/originalText/reference/@value is present.

   - `[OCL]: not self.code.originalText.reference.value.oclIsUndefined()`

21. [HITSP] **SHOULD** satisfy: Contains the procedure provider in performer / assignedEntity.

   - `[OCL]: self.performer->forAll(perf : cda::Performer2 | not perf.oclIsUndefined() and perf.assignedEntity->size() > 0)`

```xml
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <procedure>
              <templateId root="2.16.840.1.113883.10.20.1.29"/>
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.19"/>
              <templateId root="2.16.840.1.113883.3.88.11.83.17"
 assigningAuthorityName="HITSP Procedure"/>
              <id root="fd05534a-2548-477a-93d7-7385990b9242"/>
              <code/>
              <text/>
              <statusCode code="completed"/>
              <effectiveTime>
                <low value="1972"/>
                <high value="2008"/>
              </effectiveTime>
              <approachSiteCode/>
              <targetSiteCode codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMEDCT"/>
            </procedure>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 2: Procedure example

Result

[Observation: templateId `2.16.840.1.113883.3.88.11.83.15`]

This module contains current and relevant historical result observations for the patient. The scope of "observations" is broad with the exception of "vital signs" which are contained in the Vital Signs section.

1. **SHALL** conform to *IHE Simple Observation* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.13`)
2. **SHALL** conform to *CDA Clinical Statement*
3. **SHALL** conform to *CDA Observation*
4. **SHALL** conform to *CCD Result Observation* template (templateId: `2.16.840.1.113883.10.20.1.31`)
5. [CDA] Contains [1..1] `@classCode`, where its data type is ActClassObservation
6. [CCD] **SHALL** contain [1..1] `@moodCode` = "EVN" (CONF-408)
7. [CCD] **SHALL** contain [1..*] `id` (CONF-409)
8. [CCD] **SHALL** contain [1..1] `statusCode` (CONF-410)
9. [HITSP] **SHALL** contain [1..1] `code`
10. [HITSP] **SHALL** contain [1..1] `effectiveTime`
11. [CCD] **MAY** contain [0..1] `methodCode` (CONF-414)

    • Included if the method isn't inherent in code or if there is a need to further specialize the method in code.
12. [CCD] **SHOULD** contain [0..*] `interpretationCode` (CONF-418)

    • Can be used to provide a rough qualitative interpretation of the observation, such as 'N' (normal), 'L' (low), 'S' (susceptible), etc. Interpretation is generally provided for numeric results where an interpretation range has been defined, or for antimicrobial susceptibility test interpretation.
13. [HITSP] **SHALL** contain [1..1] `value`

    • The Result value records the desired result in a goal or recorded event, and will not present when recording an intent, request or proposal to measure a result.
14. [CCD] **SHOULD** satisfy: The value for 'code' SHOULD be selected from LOINC (codeSystem 2.16.840.1.113883.6.1) or SNOMED CT (codeSystem 2.16.840.1.113883.6.96), and MAY be selected from CPT-4 (codeSystem 2.16.840.1.113883.6.12). (CONF-413)
15. [CCD] **SHALL** satisfy: The methodCode SHALL NOT conflict with the method inherent in code (CONF-415)
16. [CCD] **SHALL** satisfy: Where value is a physical quantity, the unit of measure SHALL be expressed using a valid Unified Code for Units of Measure (UCUM) expression. (CONF-417)
17. [CCD] **SHOULD** satisfy: Contain one or more referenceRange to show the normal range of values for the observation result (CONF-419)

    • `[OCL]: not self.referenceRange->isEmpty()`
18. [CCD] **SHALL** satisfy: SHALL NOT contain referenceRange / observationRange / code, as this attribute is not used by the HL7 Clinical Statement or Lab Committee models. (CONF-420)

    • `[OCL]: self.referenceRange->forAll(range : cda::ReferenceRange |`
      `range.observationRange.code.code.oclIsUndefined())`
19. [CCD] **SHALL** satisfy: Contains one or more sources of information. (CONF-421)

    • `[OCL]: not self.informant->isEmpty()`
      `or not self.getSection().informant->isEmpty()`
      `or not self.getClinicalDocument().informant->isEmpty()`
      `or self.reference->exists(ref : cda::Reference | ref.typeCode =`
      `vocab::x_ActRelationshipExternalReference::XCRPT)`
      `or (self.entryRelationship->exists(rel : cda::EntryRelationship |`
      `rel.typeCode = vocab::x_ActRelationshipEntryRelationship::REFR`
      `and rel.observation.code.code = '48766-0'))`
20. [HITSP] **SHOULD** satisfy: Result Type SHOULD be selected from LOINC (codeSystem 2.16.840.1.113883.6.1) or SNOMED CT (codeSystem 2.16.840.1.113883.6.96) (C154-[DE-15.03-1])
21. [HITSP] **SHOULD** satisfy: Result Type for laboratory results SHOULD be coded as specified in HITSP/C80 Section 2.2.3.6.1 Laboratory Observations. (C154-[DE-15.03-2])

22. [HITSP] **SHALL** satisfy: Result Value SHALL be present when the observation/@moodCode is EVN or GOL, and SHALL NOT be present when observation/@moodCode is INT or PRP. (C83-[DE-15.05-CDA-1])

- [OCL]: (self.moodCode = vocab::x_ActMoodDocumentObservation::EVN or
     self.moodCode = vocab::x_ActMoodDocumentObservation::EVN)
        implies (not self.value->isEmpty()) and
     (self.moodCode = vocab::x_ActMoodDocumentObservation::INT or
     self.moodCode = vocab::x_ActMoodDocumentObservation::PRP)
      implies (self.value->isEmpty())

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.31"
 assigningAuthorityName="CCD Result Observation"/>
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.13"
 assigningAuthorityName="IHE Simple Observation"/>
              <templateId root="2.16.840.1.113883.3.88.11.83.15"
 assigningAuthorityName="HITSP Result"/>
              <id root="df204fab-5aa2-4cc7-9d68-19cd0edb11c3"/>
              <code/>
              <statusCode code="completed"/>
              <effectiveTime>
                <low value="1972"/>
                <high value="2008"/>
              </effectiveTime>
              <interpretationCode/>
              <methodCode/>
            </observation>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 3: Result example

External Reference

[Act: templateId 1.3.6.1.4.1.19376.1.5.3.1.4.4]

1. **SHALL** conform to *CDA Clinical Statement*
2. **SHALL** conform to *CDA Act*
3. [IHE] **SHALL** contain [1..1] @classCode = "ACT"
4. [IHE] **SHALL** contain [1..1] @moodCode = "EVN"
5. [CDA] Contains [1..1] code, where its data type is CD

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section
```

```
            <entry>
              <act classCode="ACT" moodCode="EVN">
                <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.4"
 assigningAuthorityName="IHE External Reference"/>
              </act>
            </entry>
          </section>
        </component>
      </structuredBody>
    </component>
</ClinicalDocument>
```

Figure 4: External Reference example

CCD Results

Results Section

[Section: templateId `2.16.840.1.113883.10.20.1.14`]

This section contains the results of observations generated by laboratories, imaging procedures, and other procedures. The scope includes hematology, chemistry, serology, virology, toxicology, microbiology, plain x-ray, ultrasound, CT, MRI, angiography, cardiac echo, nuclear medicine, pathology, and procedure observations. The section may contain all results for the period of time being summarized, but should include notable results such as abnormal values or relevant trends.

Lab results are typically generated by laboratories providing analytic services in areas such as chemistry, hematology, serology, histology, cytology, anatomic pathology, microbiology, and/or virology. These observations are based on analysis of specimens obtained from the patient, submitted to the lab.

Imaging results are typically generated by a clinician reviewing the output of an imaging procedure, such as where a cardiologist reports the left ventricular ejection fraction based on the review of a cardiac echo.

Procedure results are typically generated by a clinician wanting to provide more granular information about component observations made during the performance of a procedure, such as where a gastroenterologist reports the size of a polyp observed during a colonoscopy.

1. **SHALL** conform to *CDA Section*
2. [CCD] **SHALL** contain [1..1] `code/@code` = "30954-2" *Relevant diagnostic tests and/or laboratory data* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC) (CONF-389)
3. [CCD] **SHALL** contain [1..1] `title` (CONF-391)
4. [CCD] **SHOULD** contain [1..*] `entry`, such that it

    a. contains *Result Organizer* (templateId: `2.16.840.1.113883.10.20.1.32`) (CONF-388)
5. [CCD] **SHALL** contain [1..1] `text` (CONF-388)
6. [CCD] **SHOULD** satisfy: Contains a case-insensitive language-insensitive string containing 'results'. (CONF-392)

```xml
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <templateId root="2.16.840.1.113883.10.20.1.14"
assigningAuthorityName="CCD Results Section"/>
          <code code="30954-2" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Relevant diagnostic tests and/or
laboratory data"/>
          <title>Relevant diagnostic tests and/or laboratory data</title>
          <entry>
            <organizer moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.32"
assigningAuthorityName="CCD Result Organizer"/>
              <id root="f267faa9-089c-4e1b-b699-152f49c7697c"/>
              <code/>
              <statusCode/>
            </organizer>
          </entry>
        </section>
      </component>
    </structuredBody>
```

```
    </component>
</ClinicalDocument>
```

Figure 5: Results Section example

Result Organizer

[Organizer: templateId `2.16.840.1.113883.10.20.1.32`]

The result organizer identifies an observation set, contained with the result organizer as a set of result observations. It contains information applicable to all of the contained result observations.

Results in ASTM CCR and CCD are structured similarly to the HL7 Version 2 ORU Observation message, where there is an outer result organizer (templateId 2.16.840.1.113883.10.20.1.32), analogous to the HL7 Version 2 OBR Observation Result Segment, which contains one or more result observations (templateId 2.16.840.1.113883.10.20.1.31), analogous to the HL7 Version 2 OBX Observation/Result Segment.

1. **SHALL** conform to *CDA Clinical Statement*
2. **SHALL** conform to *CDA Organizer*
3. [CDA] Contains [1..1] @classCode, where its data type is x_ActClassDocumentEntryOrganizer
4. [CCD] **SHALL** contain [1..1] @moodCode = "EVN" (CONF-394)
5. [CCD] **SHALL** contain [1..1] statusCode (CONF-396)
6. [CCD] **SHALL** contain [1..*] component, such that it

   a. contains *Result Observation* (templateId: `2.16.840.1.113883.10.20.1.31`) (CONF-405)
7. [CCD] **SHOULD** contain [1..*] specimen, such that it

   a. contains *CDA Specimen* (CONF-399)

   • Should be included if the specimen isn't inherent in code value.
8. [CCD] **SHALL** contain [1..*] id (CONF-395)
9. [CCD] **SHALL** contain [1..1] code (CONF-397)
10. [CCD] **SHOULD** satisfy: The value for 'code' in a result organizer SHOULD be selected from LOINC (codeSystem 2.16.840.1.113883.6.1) or SNOMED CT (codeSystem 2.16.840.1.113883.6.96), and MAY be selected from CPT-4 (codeSystem 2.16.840.1.113883.6.12) or ValueSet 2.16.840.1.113883.1.11.20.16 ResultTypeCode STATIC. (CONF-398)
11. [CCD] **SHALL** satisfy: The specimen element SHALL NOT conflict with the specimen inherent in code (CONF-400)
12. [CCD] **SHOULD** satisfy: specimen / specimenRole / id SHOULD be set to equal a Procedure / specimen / specimenRole / id to indicate that the Results and the Procedure are referring to the same specimen. (CONF-401)
13. [CCD] **SHALL** satisfy: Contains one or more component (CONF-402)

    • `[OCL]: not self.component->isEmpty()`
14. [CCD] **MAY** satisfy: The target of one or more result organizer component relationships MAY be a procedure, to indicate the means or technique by which a result is obtained, particularly if the means or technique isn't inherent in code or if there is a need to further specialize the code value. (CONF-403)
15. [CCD] **MAY** satisfy: A result organizer component / procedure MAY be a reference to a procedure described in the Procedure section. (CONF-404)
16. [CCD] **SHALL** satisfy: Contains one or more sources of information. (CONF-406)

    • `[OCL]: not self.informant->isEmpty()`
      `or not self.getSection().informant->isEmpty()`
      `or not self.getClinicalDocument().informant->isEmpty()`
      `or self.reference->exists(ref : cda::Reference | ref.typeCode =`
      ` vocab::x_ActRelationshipExternalReference::XCRPT)`

```xml
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
```

```
      <component>
        <section>
          <entry>
            <organizer moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.32"
assigningAuthorityName="CCD Result Organizer"/>
              <id root="cdefc18c-de20-41f8-840c-7c1ac6a9d5fa"/>
              <code/>
              <statusCode/>
              <component>
                <observation classCode="OBS" moodCode="EVN">
                  <templateId root="2.16.840.1.113883.10.20.1.31"
assigningAuthorityName="CCD Result Observation"/>
                  <id root="3d5d24b8-544a-4842-95f5-2dfc09a38bf7"/>
                  <code/>
                  <statusCode/>
                  <effectiveTime>
                    <low value="1972"/>
                    <high value="2008"/>
                  </effectiveTime>
                  <interpretationCode/>
                  <methodCode/>
                </observation>
              </component>
            </organizer>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 6: Result Organizer example

Result Observation

[Observation: templateId `2.16.840.1.113883.10.20.1.31`]

1. **SHALL** conform to *CDA Clinical Statement*
2. **SHALL** conform to *CDA Observation*
3. [CDA] Contains [1..1] `@classCode`, where its data type is ActClassObservation
4. [CCD] **SHALL** contain [1..1] `@moodCode` = "EVN" (CONF-408)
5. [CCD] **SHALL** contain [1..1] `code` (CONF-412)
6. [CCD] **SHALL** contain [1..*] `id` (CONF-409)
7. [CCD] **SHOULD** contain [1..1] `effectiveTime` (CONF-411)

   • Represents the biologically relevant time (e.g. time the specimen was obtained from the patient).
8. [CCD] **SHALL** contain [1..1] `statusCode` (CONF-410)
9. [CCD] **MAY** contain [0..1] `methodCode` (CONF-414)

   • Included if the method isn't inherent in code or if there is a need to further specialize the method in code.
10. [CCD] **SHOULD** contain [0..*] `interpretationCode` (CONF-418)

   • Can be used to provide a rough qualitative interpretation of the observation, such as 'N' (normal), 'L' (low), 'S' (susceptible), etc. Interpretation is generally provided for numeric results where an interpretation range has been defined, or for antimicrobial susceptibility test interpretation.
11. [CCD] **SHALL** contain [1..1] `value` (CONF-416)
12. [CCD] **SHOULD** satisfy: The value for 'code' SHOULD be selected from LOINC (codeSystem 2.16.840.1.113883.6.1) or SNOMED CT (codeSystem 2.16.840.1.113883.6.96), and MAY be selected from CPT-4 (codeSystem 2.16.840.1.113883.6.12). (CONF-413)

13. [CCD] **SHALL** satisfy: The methodCode SHALL NOT conflict with the method inherent in code (CONF-415)

14. [CCD] **SHALL** satisfy: Where value is a physical quantity, the unit of measure SHALL be expressed using a valid Unified Code for Units of Measure (UCUM) expression. (CONF-417)

15. [CCD] **SHOULD** satisfy: Contain one or more referenceRange to show the normal range of values for the observation result (CONF-419)

- [OCL]: `not self.referenceRange->isEmpty()`

16. [CCD] **SHALL** satisfy: SHALL NOT contain referenceRange / observationRange / code, as this attribute is not used by the HL7 Clinical Statement or Lab Committee models. (CONF-420)

- [OCL]: `self.referenceRange->forAll(range : cda::ReferenceRange | range.observationRange.code.code.oclIsUndefined())`

17. [CCD] **SHALL** satisfy: Contains one or more sources of information. (CONF-421)

- [OCL]: `not self.informant->isEmpty()`
  `or not self.getSection().informant->isEmpty()`
  `or not self.getClinicalDocument().informant->isEmpty()`
  `or self.reference->exists(ref : cda::Reference | ref.typeCode = vocab::x_ActRelationshipExternalReference::XCRPT)`
  `or (self.entryRelationship->exists(rel : cda::EntryRelationship | rel.typeCode = vocab::x_ActRelationshipEntryRelationship::REFR and rel.observation.code.code = '48766-0'))`

```xml
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.31"
 assigningAuthorityName="CCD Result Observation"/>
              <id root="b3a7eb89-a547-4d2c-a302-ae2585cabeb1"/>
              <code/>
              <statusCode/>
              <effectiveTime>
                <low value="1972"/>
                <high value="2008"/>
              </effectiveTime>
              <interpretationCode/>
              <methodCode/>
            </observation>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 7: Result Observation example