

- a. This code **SHALL** contain exactly one [1..1] @code="77301-0" Reason care action performed or not (CONF:4537-11362).
 - b. This code **SHALL** contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.1" (CodeSystem: LOINC urn:oid:2.16.840.1.113883.6.1) (CONF:4537-27028).
6. **SHALL** contain exactly one [1..1] statusCode (CONF:4537-11364).
 - a. This statusCode **SHALL** contain exactly one [1..1] @code="completed" (CodeSystem: HL7ActStatus urn:oid:2.16.840.1.113883.5.14) (CONF:4537-11365).
7. **SHALL** contain exactly one [1..1] effectiveTime (CONF:4537-11366).
 - a. This effectiveTime **SHALL** contain exactly one [1..1] low (CONF:4537-27551).
 - b. This effectiveTime **MAY** contain zero or one [0..1] high (CONF:4537-27552).
8. **SHALL** contain exactly one [1..1] value with @xsi:type="CD" (CONF:4537-11367).

Figure 50: Reason (V4) Example (Reason for something that did not occur)

```

<!-- Contained in a Procedure that was not performed (example) -->
<entryRelationship typeCode="RSON">
  <!-- ** Reason (V4) ** -->
  <observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.24.3.88" extension="2023-05-01" />
    <id root="5750a5bb-6a01-4b99-9b1c-cda56b1dce0c" />
    <code code="77301-0"
          codeSystem="2.16.840.1.113883.6.1"
          displayName="Reason care action performed or not"
          codeSystemName="LOINC" />
    <statusCode code="completed" />
    <effectiveTime>
      <low value="20230926"/>
    </effectiveTime>
    <value xsi:type="CD"
          code="57054005"
          codeSystem="2.16.840.1.113883.6.96"
          codeSystemName="SNOMED CT"
          displayName="Acute myocardial infarction" />
  </observation>
</entryRelationship>

```

3.22 Result Observation (V4)

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.2:2023-05-01 (open)]

This template represents the results of a laboratory, radiology, or other study performed on a patient. The result observation includes a statusCode to allow recording the status of an observation. “Pending” results (e.g., a test has been run but results have not been reported yet) should be represented as “active” ActStatus.

Table 74: Result Observation (V4) Constraints Overview

XPath	Card.	Verb	Data Type	CONF#	Value
observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.2:2023-05-01)					
@classCode	1..1	SHALL		4537-7130	urn:oid:2.16.840.1.113883.5.6 (HL7ActClass) = OBS
@moodCode	1..1	SHALL		4537-7131	urn:oid:2.16.840.1.113883.5.1001 (HL7ActMood) = EVN
templateId	1..1	SHALL		4537-7136	
@root	1..1	SHALL		4537-9138	2.16.840.1.113883.10.20.22.4.2
@extension	1..1	SHALL		4537-32575	2023-05-01
id	1..*	SHALL		4537-7137	
code	1..1	SHALL		4537-7133	urn:oid:2.16.840.1.113883.6.1 (LOINC)
statusCode	1..1	SHALL		4537-7134	
@code	1..1	SHALL		4537-14849	urn:oid:2.16.840.1.113883.11.20.9.39 (Result Status)
effectiveTime	1..1	SHALL		4537-7140	
value	1..1	SHALL		4537-7143	
interpretationCode	0..*	SHOULD		4537-7147	urn:oid:2.16.840.1.113883.1.11.78 (Observation Interpretation (HL7))
methodCode	0..1	MAY	SET<CE>	4537-7148	
targetSiteCode	0..1	MAY	SET<CD>	4537-7153	
specimen	0..*	MAY		4537-32611	
specimenRole	1..1	SHALL		4537-32612	
specimenPlayingEntity	1..1	SHALL		4537-32613	
code	1..1	SHALL		4537-32614	urn:oid:2.16.840.1.113762.1.4.1099.54 (Specimen type)
author	0..*	SHOULD		4537-7149	Author Participation (identifier: urn:oid:2.16.840.1.113883.10.20.22.4.119)
referenceRange	0..*	SHOULD		4537-7150	

XPath	Card.	Verb	Data Type	CONF#	Value
observationRange	1..1	SHALL		4537-7151	
code	0..0	SHALL NOT		4537-7152	
value	1..1	SHALL		4537-32175	

1. **SHALL** contain exactly one [1..1] **@classCode**="OBS" Observation (CodeSystem: HL7ActClass urn:oid:2.16.840.1.113883.5.6 **STATIC**) (CONF:4537-7130).
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" Event (CodeSystem: HL7ActMood urn:oid:2.16.840.1.113883.5.1001 **STATIC**) (CONF:4537-7131).
3. **SHALL** contain exactly one [1..1] **templateId** (CONF:4537-7136) such that it
 - a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.2" (CONF:4537-9138).
 - b. **SHALL** contain exactly one [1..1] **@extension**="2023-05-01" (CONF:4537-32575).
4. **SHALL** contain at least one [1..*] **id** (CONF:4537-7137).
5. **SHALL** contain exactly one [1..1] **code**, which **SHOULD** be selected from CodeSystem LOINC (urn:oid:2.16.840.1.113883.6.1) (CONF:4537-7133).
 - a. This code **SHOULD** be a code from the LOINC that identifies the result observation. If an appropriate LOINC code does not exist, then the local code for this result **SHALL** be sent (CONF:4537-19212).
6. **SHALL** contain exactly one [1..1] **statusCode** (CONF:4537-7134).
 - a. This statusCode **SHALL** contain exactly one [1..1] **@code**, which **SHALL** be selected from ValueSet [Result Status](#) urn:oid:2.16.840.1.113883.11.20.9.39 **STATIC** (CONF:4537-14849).
7. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:4537-7140).
Note: Represents the clinically relevant time of the measurement (e.g., the time a blood pressure reading is obtained, the time the blood sample was obtained for a chemistry test).
8. **SHALL** contain exactly one [1..1] **value** (CONF:4537-7143).

NOTE: The base CDA R2.0 standard requires **@unit** to be drawn from UCUM, and best practice is to use case sensitive UCUM units

- a. If Observation/value is a physical quantity (**xsi:type**="PQ"), the unit of measure **SHOULD** be selected from ValueSet **UnitsOfMeasureCaseSensitive** urn:oid:2.16.840.1.113883.1.11.12839 **DYNAMIC** (CONF:4537-31484).
 - b. A coded or physical quantity value **MAY** contain zero or more [0..*] translations, which can be used to represent the original results as output by the lab (CONF:4537-31866).
 - c. If Observation/value is a CD (**xsi:type**="CD") the value **SHOULD** be SNOMED-CT (CONF:4537-32610).
9. **SHOULD** contain zero or more [0..*] **interpretationCode**, which **SHALL** be selected from ValueSet [Observation Interpretation \(HL7\)](#) urn:oid:2.16.840.1.113883.1.11.78 **DYNAMIC** (CONF:4537-7147).

10. **MAY** contain zero or one [0..1] **methodCode** (CONF:4537-7148).

11. **MAY** contain zero or one [0..1] **targetSiteCode** (CONF:4537-7153).

Laboratory observations are expected to include the specimen participant. The specimen included at specimenPlayingEntity/code must be consistent with the observation/code.

12. **MAY** contain zero or more [0..*] **specimen** (CONF:4537-32611).

a. The specimen, if present, **SHALL** contain exactly one [1..1] **specimenRole** (CONF:4537-32612).

i. This specimenRole **SHALL** contain exactly one [1..1] **specimenPlayingEntity** (CONF:4537-32613).

1. This specimenPlayingEntity **SHALL** contain exactly one [1..1] **code**, which **SHOULD** be selected from ValueSet [Specimen type](#) urn:oid:2.16.840.1.113762.1.4.1099.54 **DYNAMIC** (CONF:4537-32614).

13. **SHOULD** contain zero or more [0..*] Author Participation (identifier: urn:oid:2.16.840.1.113883.10.20.22.4.119) (CONF:4537-7149).

14. **SHOULD** contain zero or more [0..*] **referenceRange** (CONF:4537-7150).

a. The referenceRange, if present, **SHALL** contain exactly one [1..1] **observationRange** (CONF:4537-7151).

i. This observationRange **SHALL NOT** contain [0..0] **code** (CONF:4537-7152).

ii. This observationRange **SHALL** contain exactly one [1..1] **value** (CONF:4537-32175).

Table 75: Result Status

Value Set: Result Status urn:oid:2.16.840.1.113883.11.20.9.39 (Clinical Focus: The processing status of a laboratory test or panel),(Data Element Scope:),(Inclusion Criteria:),(Exclusion Criteria:) This value set was imported on 4/24/2019 with a version of 20190103. Value Set Source: https://vsac.nlm.nih.gov/valueset/2.16.840.1.113883.11.20.9.39/expansion			
Code	Code System	Code System OID	Print Name
aborted	HL7ActStatus	urn:oid:2.16.840.1.113883.5.14	aborted
active	HL7ActStatus	urn:oid:2.16.840.1.113883.5.14	active
cancelled	HL7ActStatus	urn:oid:2.16.840.1.113883.5.14	cancelled
completed	HL7ActStatus	urn:oid:2.16.840.1.113883.5.14	completed
held	HL7ActStatus	urn:oid:2.16.840.1.113883.5.14	held
suspended	HL7ActStatus	urn:oid:2.16.840.1.113883.5.14	suspended

Table 76: UnitsOfMeasureCaseSensitive

Value Set: UnitsOfMeasureCaseSensitive urn:oid:2.16.840.1.113883.1.11.12839 (Clinical Focus: Common UCUM units. This value set is based on the Common UCUM set.),(Data Element Scope: unit of measure),(Inclusion Criteria: all valid UCUM units case sensitive),(Exclusion Criteria:) This value set was imported on 6/29/2019 with a version of 20180509. Value Set Source: https://vsac.nlm.nih.gov/valueset/2.16.840.1.113883.1.11.12839/expansion			
Code	Code System	Code System OID	Print Name
%	UCUM	urn:oid:1.3.6.1.4.1.12009.10.3.1	percent
%{Hb}	UCUM	urn:oid:1.3.6.1.4.1.12009.10.3.1	percent hemoglobin
%{RBCs}	UCUM	urn:oid:1.3.6.1.4.1.12009.10.3.1	percent of red blood cells
%{WBCs}	UCUM	urn:oid:1.3.6.1.4.1.12009.10.3.1	percent of white blood cells
%{abnormal}	UCUM	urn:oid:1.3.6.1.4.1.12009.10.3.1	percent abnormal
%{activity}	UCUM	urn:oid:1.3.6.1.4.1.12009.10.3.1	percent activity
%{aggregation}	UCUM	urn:oid:1.3.6.1.4.1.12009.10.3.1	percent aggregation
%{at_60_min}	UCUM	urn:oid:1.3.6.1.4.1.12009.10.3.1	percent at 60 minute
%{bacteria}	UCUM	urn:oid:1.3.6.1.4.1.12009.10.3.1	percent of bacteria
%{basal_activity}	UCUM	urn:oid:1.3.6.1.4.1.12009.10.3.1	percent basal activity
...			

Table 77: Observation Interpretation (HL7)

Value Set: Observation Interpretation (HL7) urn:oid:2.16.840.1.113883.1.11.78 (Clinical Focus: Codes specifying a rough qualitative interpretation of the observation, such as "normal", "abnormal", "below normal", "change up", "resistant", "susceptible", etc.), (Data Element Scope:), (Inclusion Criteria: all reportable codes in the code system ObservationInterpretation), (Exclusion Criteria: Collector codes in the code system) This value set was imported on 4/24/2019 with a version of 20190104. Value Set Source: https://vsac.nlm.nih.gov/valueset/2.16.840.1.113883.1.11.78/expansion			
Code	Code System	Code System OID	Print Name
<	ObservationInterpretation	urn:oid:2.16.840.1.113883.5.83	Off scale low
>	ObservationInterpretation	urn:oid:2.16.840.1.113883.5.83	Off scale high
A	ObservationInterpretation	urn:oid:2.16.840.1.113883.5.83	Abnormal
AA	ObservationInterpretation	urn:oid:2.16.840.1.113883.5.83	Critical abnormal
AC	ObservationInterpretation	urn:oid:2.16.840.1.113883.5.83	Anti-complementary substances present
B	ObservationInterpretation	urn:oid:2.16.840.1.113883.5.83	Better
CAR	ObservationInterpretation	urn:oid:2.16.840.1.113883.5.83	Carrier
Carrier	ObservationInterpretation	urn:oid:2.16.840.1.113883.5.83	Carrier
D	ObservationInterpretation	urn:oid:2.16.840.1.113883.5.83	Significant change down
DET	ObservationInterpretation	urn:oid:2.16.840.1.113883.5.83	Detected
...			

Table 78: Specimen type

Value Set: Specimen type urn:oid:2.16.840.1.113762.1.4.1099.54 (Clinical Focus: This set of values includes all potentially relevant specimen types for a human result observation.),(Data Element Scope: The intent of this set of values is to represent clinically relevant specimens that may be used for laboratory or other pathology studies.),(Inclusion Criteria: Any specimen that could be relevant in a human clinical use case),(Exclusion Criteria: Excludes a decapitated animal head specimen) This value set was imported on 11/7/2022 with a version of Latest. Value Set Source: https://vsac.nlm.nih.gov/valueset/2.16.840.1.113762.1.4.1099.54/expansion			
Code	Code System	Code System OID	Print Name
110893002	SNOMED CT	urn:oid:2.16.840.1.113883.6.96	Cutaneous cytologic material (specimen)
110894008	SNOMED CT	urn:oid:2.16.840.1.113883.6.96	Mammary cytologic material (specimen)
110896005	SNOMED CT	urn:oid:2.16.840.1.113883.6.96	Subcutaneous cytologic material (specimen)
110897001	SNOMED CT	urn:oid:2.16.840.1.113883.6.96	Bone marrow cytological material (specimen)
110898006	SNOMED CT	urn:oid:2.16.840.1.113883.6.96	Lymph node cytologic material (specimen)
110899003	SNOMED CT	urn:oid:2.16.840.1.113883.6.96	Breast nipple cytologic material (specimen)
110900008	SNOMED CT	urn:oid:2.16.840.1.113883.6.96	Skeletal muscle cytologic material (specimen)
110901007	SNOMED CT	urn:oid:2.16.840.1.113883.6.96	Bone cytologic material (specimen)
110902000	SNOMED CT	urn:oid:2.16.840.1.113883.6.96	Upper respiratory tract cytologic material (specimen)
110903005	SNOMED CT	urn:oid:2.16.840.1.113883.6.96	Nasal cytologic material (specimen)
...			

Figure 51: Result Observation (V4) Example

```
<observation classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.22.4.2" extension="2023-05-01" />
  <id root="7c0704bb-9c40-41b5-9c7d-26b2d59e234f" />
  <code code="20570-8" displayName="Hematocrit" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" />
  <statusCode code="completed" />
  <effectiveTime value="200803190830-0800" />
  <value xsi:type="PQ" value="35.3" unit="%" />
  <interpretationCode code="L" codeSystem="2.16.840.1.113883.5.83" />
  <author>
    <time value="200803190830-0800" />
    <assignedAuthor>
      <id extension="333444444" root="1.1.1.1.1.1.4" />
      <addr>
        <streetAddressLine>1017 Health Drive</streetAddressLine>
        <city>Portland</city>
        <state>OR</state>
        <postalCode>99123</postalCode>
        <country>US</country>
      </addr>
      <telecom use="WP" value="tel:+1(555)555-1017" />
      <assignedPerson>
        <name>
          <given>William</given>
          <given qualifier="CL">Bill</given>
          <family>Beaker</family>
        </name>
      </assignedPerson>
      <representedOrganization>
        <name>Good Health Laboratory</name>
      </representedOrganization>
    </assignedAuthor>
  </author>
  <referenceRange>
    <observationRange>
      <text>Low</text>
      <value xsi:type="IVL_PQ">
        <low value="34.9" unit="%" />
        <high value="44.5" unit="%" />
      </value>
      <interpretationCode code="L" codeSystem="2.16.840.1.113883.5.83"/>
    </observationRange>
  </referenceRange>
</observation>
```

3.23 Result Organizer (V4)

```
[organizer: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.1:2023-05-01
(open)]
```

This template provides a mechanism for grouping result observations. It contains information applicable to all of the contained result observations. The Result Organizer code categorizes the