

**United States Core Data for Interoperability (USCDI)
ONDEC (ONC Data Element and Class) Submission
CAP Comments**

The College of American Pathologists (CAP) appreciates the opportunity to comment on USCDI version 4. As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the CAP serves patients, pathologists and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine.

Data sharing through widely accepted standards is critical to ensure that health information is available and comprehensible across care settings for use in patient care, public health, and emergency (eg, pandemic) preparedness and response. For broader sharing of electronic health information, the USCDI is critical to establishing foundational standards to support patient care. In that spirit, the CAP recommends that USCDI align with the CLIA Test Report requirements¹ in the Clinical Laboratory Improvement Amendments (CLIA) of 1988. CLIA requirements are required for clinical laboratories, and those elements should consequently be the basis for developing a foundation for the standardized sharing and reporting of laboratory information to support patient care. Aligning the USCDI with CLIA requirements will support interoperability by building on existing standards and patterns of use while avoiding contradictory or duplicative reporting requirements.

Therefore, the CAP provides the following recommendations for data elements and vocabulary standards that should be added to USCDI ver. 4.

USCDI Level 2 Laboratory Elements:

- **Data Element: Laboratory results: date and timestamps**
 - **Corresponding CLIA Reporting Requirement:** The test report date
 - **Description:** The CAP supports the inclusion of this Level 2 data element into USCDI v4, corresponding to the time of result transmission. This inclusion will align the USCDI with CLIA's Test Report Date reporting requirement. The CLIA requirements are required for laboratory reporting and should be used as the basis for laboratory and public health reporting standards. For future iterations of USCDI, we would suggest collapsing this data element with the Laboratory Test Performed Date data element called "Date/time of the analysis," which is the name of the OBX-19 field of the HL7 2.5.1 standard. The CAP may submit this new data element for USCDI v5 in 2023.
 - **Vocabulary Standard:** The CAP recommends replacing the listed standards for this data element with the value format from the OBX-19 field in HL7 2.5.1, which is a version of the Health Level Seven (HL7) standard that defines methods for transferring and sharing data between various healthcare systems and providers. HL7 2.5.1 OBX-19 is aligned with the ISO 8601 international standard for communicating date and time information.

¹ 42 CFR § 493.1291(c)

- **Data Element: Laboratory Test Performed Date**
 - **Corresponding CLIA Reporting Requirement:** The test report date
 - **Description:** The CAP supports the inclusion of this Level 2 data element into USCDI v4. This inclusion will align the USCDI with CLIA’s Test Report Date reporting requirement. The CLIA reporting requirements are required for clinical laboratory reporting and should be used as the basis for laboratory and public health reporting standards. For future iterations of USCDI, we would suggest collapsing this data element with the Laboratory results: date and timestamps data element called “Date/time of the analysis,” which is the name of the OBX-19 field of the HL7 2.5.1 standard. The CAP may submit this new data element for USCDI v5 in 2023.
 - **Vocabulary Standard:** The CAP recommends replacing the listed standards in this data element with the value format from the OBX-19 field in HL7 2.5.1, which is a version of the Health Level Seven (HL7) standard that defines methods for transferring and sharing data between various healthcare systems and providers. The CAP supports the use of the HL7 2.5.1 standard because the standard was designed to help laboratories comply with CLIA requirements. HL7 2.5.1 OBX-19 is aligned with the ISO 8601 international standard for communicating date and time information.

- **Data Element: Specimen collection date/time**
 - **Description:** The CAP supports the inclusion of this Level 2 data element into USCDI v4. While this is not a CLIA requirement, the specimen collection time defines the clinically applicable time of the result, which is crucial for correct interpretation of the result by care providers and correct response by public health agencies in emergency (eg, pandemic) preparedness and response settings. For future iterations of USCDI, we may recommend replacing this data element with two data elements corresponding to the OBX-14 and SPM-17 fields in HL7 2.5.1. The data elements should be named “Date/time of the observation” which is the name of OBX-14, and “Date/time of specimen collection,” which is a minor variation on the name of SPM-17. Date/time of the observation refers to the clinically-relevant date/time associated with the measurement. When there is testing of a specimen, HL7 2.5.1 specifies that the content of OBX-14 and SPM-17 should be identical. Having these two data elements allows for documentation of specimen collection time in rare cases where the clinically relevant time and specimen collection time might differ. The CAP may submit these new data elements for USCDI v5 in 2023.
 - **Vocabulary Standard:** The CAP recommends the value format from the SPM-17 field in HL7 2.5.1, which is a version of the Health Level Seven (HL7) standard that defines methods for transferring and sharing data between various healthcare systems and providers. The CAP supports the use of the HL7 2.5.1 standard because the standard was designed to help laboratories comply with CLIA requirements. HL7 2.5.1 SPM-17 is aligned with the ISO 8601 international standard for communicating date and time information.

- **Data Element: Laboratory Result Value:**

- **Corresponding CLIA Reporting Requirement:** The test result and, if applicable, the units of measurement or interpretation, or both
 - **Description:** The CAP supports replacing the Laboratory Result/Value element in USCDI with this Level 2 data element. This data element aligns with CLIA's requirement to report the test result and, if applicable, the units of measurement or interpretation, or both. The CLIA requirements are required for laboratory reporting and should be used as the basis for laboratory and public health reporting standards.
 - **Vocabulary Standard:** The CAP suggests replacing the listed standards with the UCUM standard for quantitative results units and the SNOMED CT standard for qualitative results. The CAP supports the use of the UCUM standard because it is well-established and because a common standard for units of measure will reduce errors related to translation of units of measure from one system to another. The CAP supports the use of the SNOMED CT standard for qualitative data because it is a relatively complete, well-curated, and actively-managed medical ontology that has excellent coverage of concepts appropriate for qualitative laboratory results and supports a rich array of hierarchical and other concept relationships.
- **Data Element: Specimen Source Site**
 - **Corresponding CLIA Reporting Requirement:** Specimen source
 - **Description:** The CAP supports the inclusion of this Level 2 data element into USCDI v4 to align with CLIA's Specimen Source reporting requirement. The CLIA requirements are required for laboratory reporting and should be used as the basis for laboratory and public health reporting standards.
 - **Vocabulary Standard:** For the content of the data element, the CAP recommends replacing the LOINC standard with the SNOMED CT standard. LOINC does not adequately represent specimen types or anatomic locations and relationships necessary to represent specimens and their sources, and is not intended for that purpose. SNOMED CT is a relatively complete, well-curated, and actively-managed medical ontology that has excellent coverage of concepts appropriate for description of laboratory specimens and specimen sources, and supports a rich array of hierarchical and other concept relationships.

USCDI Level 1 Laboratory Elements:

- **Data Element: Test Interpretation (Abnormal Flag)**
 - **Corresponding CLIA Reporting Requirement:** Test result interpretation
 - **Description:** The CAP supports this data element as written and urges that it be brought up to Level 2 and ideally included in USCDI v4. The CAP supports this data element to align with CLIA's test interpretation reporting requirement. The CLIA-defined reporting requirements are required for laboratory reporting and should be used as the basis for laboratory and public health reporting standards. Because laboratories already communicate test result interpretations along with reference ranges to the Centers for Medicare & Medicaid Services (CMS), this data element is already in wide usage and should be classified Level 2 at a minimum.

Proposed Laboratory Data Elements:

The CAP has submitted four new proposed data elements for the Laboratory class through the ONDEC system. For convenience, the CAP lists these new data elements here. They are a work in progress and the CAP urges that the vocabulary standards listed be considered for a future version of USCDI:

- **Reference Range**
 - **Corresponding CLIA Reporting Requirement:** Reference Range. CLIA regulations, Test Report: Standard, 42 CFR 493:1291(d).
 - **Data Element Name:** Reference Range
 - **Description:** The CAP is proposing this data element to align with CLIA's Reference Range reporting requirement. The CLIA requirements are required for laboratory reporting and should be used as the basis for laboratory and public health reporting standards. This data element describes the interval of laboratory results for numerical results or an expected value for qualitative results that would be considered "normal" as determined by the laboratory performing the tests.
 - **Similar elements in the USCDI?** No
 - **Standards:** The CAP proposes that the content of this data element follow the OBX-7 field from the HL7 2.5.1 standard. The CAP supports the use of the HL7 2.5.1 standard because the standard was designed to help laboratories comply with CLIA requirements. For numerical values, the CAP also proposes the Unified Code for Units of Measure (UCUM) standard. The CAP supports the use of the UCUM standard because it is well-established and because a common standard for units of measure will reduce errors related to translation of units of measure from one system to another.
 - **Use Cases:** The primary use cases for this data element in the USCDI are routine communication of laboratory results to healthcare providers and public health agencies in support of test result interpretation. These use cases are similar to existing use cases for OBX-7 that are described in detail in the following documentation.
 - HL7 Version 2.5.1 Implementation Guide: Laboratory Results Interface, Release 1 STU Release 3 - US Realm (https://www.hl7.org/implement/standards/product_brief.cfm?product_id=279)
 - HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) (https://www.hl7.org/implement/standards/product_brief.cfm?product_id=98)
 - HL7 Version 2.5.1 Implementation Guide: Orders and Observations; Interoperable Laboratory Result Reporting to EHR, Release 1 (https://www.hl7.org/implement/standards/product_brief.cfm?product_id=94).
 - The number of stakeholders who would capture, access, use, or exchange this data element or data class:
 - **Answer:** The data element would be used with all laboratory result messages sent between laboratories and data recipients

including public health agencies, and in messages sent between provider organizations that contained laboratory results. Since there are around 330,000 CLIA-certified laboratories in the United States that are information sources, the usage floor including laboratories and their communication partners would be substantially above that number.

- Does this data element support the following aims in healthcare?
 - Improving patient experience of care (quality and/or satisfaction) **Yes**
 - Improving the health of populations **Yes**
 - Reducing the cost of care **Yes**
 - Improving provider experience of care **Yes**
- Are there additional technical specifications such as an implementation guide (IG) or profile using this data element?
 - HL7 Version 2.5.1 Implementation Guide: Laboratory Results Interface, Release 1 STU Release 3 - US Realm (https://www.hl7.org/implement/standards/product_brief.cfm?product_id=279)
 - HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) (https://www.hl7.org/implement/standards/product_brief.cfm?product_id=98)
 - HL7 Version 2.5.1 Implementation Guide: Orders and Observations; Interoperable Laboratory Result Reporting to EHR, Release 1 (https://www.hl7.org/implement/standards/product_brief.cfm?product_id=94).
- Which of the following best describes the use of this data element?
 - **Answer:** This data element has been used at scale between multiple different production environments...
 - **Supporting Artifact:** HL7 Version 2.5.1 Implementation Guide: Laboratory Results Interface, Release 1 STU Release 3 - US Realm (https://www.hl7.org/implement/standards/product_brief.cfm?product_id=279)
- Has this data element been electronically exchanged with external organizations or individuals (including patients)?
 - **Answer:** Five or more.
 - **Supporting Artifact:** HL7 Version 2.5.1 Implementation Guide: Laboratory Results Interface, Release 1 STU Release 3 - US Realm (https://www.hl7.org/implement/standards/product_brief.cfm?product_id=279)
- Any restrictions on the standardization of this data element:
 - **Answer:** None
- Describe any restrictions on the use of this data element (e.g., licensing, user fees).
 - **Answer:** None
- Describe any privacy and security concerns with the use and exchange of this data element.
 - **Answer:** None

- Please provide an estimate of overall burden to implement. Overall estimate of burden to implement, including those not affected by the primary use case(s)
 - **Answer:** No burden. Laboratories are already required to report this information as part of CLIA.
- **Name and Address of Laboratory Location**
 - **Corresponding CLIA Reporting Requirement:** The name and address of the laboratory location where the test was performed. CLIA regulations, Test Report: Standard, 42 CFR 493:1291(c)(2).
 - **Data Element:** Laboratory identifier
 - **Similar data elements in the USCDI?** No
 - **Description:** The CAP is proposing this data element to align with CLIA's requirement to report the name and address of the laboratory location where the test was performed. The CLIA-defined requirements are required for laboratory reporting and should be used as the basis for laboratory and public health reporting standards.
 - **Standard:** In lieu of a non-standard and inefficient textual description of a name and address, the CAP is proposing the use of the CLIA identification number as the data element content. All laboratories performing clinical testing have a CLIA identification number and are required to be able to report it, so the use of this number is not burdensome. The name and location of a laboratory can be determined quickly from the CLIA number using available online resources (for example, <https://www.cdc.gov/clia/LabSearch.html>)
 - **Use Cases:** Routine communication of laboratory results to healthcare providers and public health agencies in support of test result interpretation.
 - The number of stakeholders who would capture, access, use or exchange this data element or data class
 - The data element would be used with all laboratory result messages sent between laboratories and data recipients including public health agencies, and in messages sent between provider organizations that contained laboratory results. Since there are around 330,000 CLIA-certified laboratories in the United States that are information sources, the usage floor including laboratories and their communication partners would be substantially above that number.
 - Does this data element support the following aims in healthcare?
 - Improving patient experience of care (quality and/or satisfaction) **Yes**
 - Improving the health of populations **Yes**
 - Reducing the cost of care **Yes**
 - Improving provider experience of care **Yes**
 - Are there additional technical specifications such as an implementation guide (IG) or profile using this data element?
 - Data elements representing laboratory identity are included in the following HL7 2.5.1 Implementation Guides.
 - HL7 Version 2.5.1 Implementation Guide: Laboratory Results Interface, Release 1 STU Release 3 - US Realm

- **Description:** The CAP is proposing this data element to align with CLIA's requirement to report any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. The CLIA-defined requirements are required for laboratory reporting and should be used as the basis for laboratory and public health reporting standards. This data element is used to indicate whether a specimen was unacceptable for testing. It is proposed to contain two codes, the first representing the condition of the specimen and the second representing the reason for rejection (if appropriate).
- **Standard:** The CAP proposes the use of SNOMED CT for data element content. SNOMED CT is a relatively complete, well-curated, and actively-managed medical ontology that has excellent coverage of concepts appropriate for description of laboratory specimens, specimen sources, and conditions, and supports a rich array of hierarchical and other concept relationships.
- **Use cases:** Routine communication of laboratory results to healthcare providers and public health agencies in support of test result interpretation.
- The number of stakeholders who would capture, access, use or exchange this data element or data class
 - The data element would be used with all laboratory result messages sent between laboratories and data recipients including public health agencies, and in messages sent between provider organizations that contained laboratory results. Since there are around 330,000 CLIA-certified laboratories in the United States, there is a usage floor of approximately 660,000 organizations assuming each laboratory sends data to at least one other organization.
- Does this data element support the following aims in healthcare?
 - Improving patient experience of care (quality and/or satisfaction) **Yes**
 - Improving the health of populations **Yes**
 - Reducing the cost of care **Yes**
 - Improving provider experience of care **Yes**
- Are there additional technical specifications such as an implementation guide (IG) or profile using this data element?
 - Analogous data elements are discussed in the HL7 v. 2.5.1 documentation, see below. HL7 uses two fields to carry this information, SPM-21 and SPM-24. The contents of these fields are HL7 code sets, with extensions allowed. The CAP is proposing similar concepts but using SNOMED CT for data representation.
 - HL7 Version 2.5.1 Implementation Guide: Laboratory Results Interface, Release 1 STU Release 3 - US Realm (https://www.hl7.org/implement/standards/product_brief.cfm?product_id=279)
 - HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) (https://www.hl7.org/implement/standards/product_brief.cfm?product_id=98)

- HL7 Version 2.5.1 Implementation Guide: Orders and Observations; Interoperable Laboratory Result Reporting to EHR, Release 1
(https://www.hl7.org/implement/standards/product_brief.cfm?product_id=94).
 - Which of the following best describes the use of this data element?
Please cite supporting artifacts
 - **Answer:** The best response is “This data element has been used at scale between multiple different production environments...” However, note that the usage has been with the two HL7 fields and the HL7 value sets, which are strongly analogous to but not identical with what is proposed here.
 - **Supporting Artifact:** HL7 Version 2.5.1 Implementation Guide: Laboratory Results Interface, Release 1 STU Release 3 - US Realm
(https://www.hl7.org/implement/standards/product_brief.cfm?product_id=279), see SPM-21 and SPM-24.
 - Has this data element been electronically exchanged with external organizations or individuals (including patients)? How many?
 - **Answer:** The data elements have been tested at scale (“5 or more...”) but not in exactly the form proposed.
 - **Supporting Artifact:** For analogous HL7 data elements, see HL7 Version 2.5.1 Implementation Guide: Laboratory Results Interface, Release 1 STU Release 3 - US Realm
(https://www.hl7.org/implement/standards/product_brief.cfm?product_id=279).
 - Any restrictions on the standardization of this data element
 - **Answer:** None
 - Describe any restrictions on the use of this data element (e.g., licensing, user fees).
 - **Answer:** None
 - Describe any privacy and security concerns with the use and exchange of this data element.
 - **Answer:** None
 - Please provide an estimate of overall burden to implement. Overall estimate of burden to implement, including those not affected by the primary use case(s)
 - **Answer:** None
- **Test Result Harmonization Status**
 - **Data Element:** Result harmonization status.
 - **Description:** The CAP is proposing this data element to further promote interoperability. Harmonization status indicates equivalency of results across platforms and vendors, ie, a harmonized test for a particular analyte and specimen yield results equivalent to other harmonized tests for that analyte and specimen. Harmonization is required for full clinical interoperability of test results. Results from harmonized tests may be interpreted and trended together, and may use the same calculation and decision support rules. Machine learning models may be trained and applied to data sets from different test platforms and vendors if the tests are harmonized. Tests that are not harmonized do not yield comparable

results and should be interpreted and processed separately, not in aggregate with other tests. Incorrect assumption of harmonization status is a serious patient safety risk, and lack of harmonization information impedes public health interpretation of test results.

- **Standard:** This is the first proposal of a harmonization status data element, and examples do not exist in other health data standards. Recently the ISO defined standard methods for harmonizing laboratory tests (see ISO 17511:2020 and 21151:2020). The CAP proposes development of a standard representation of these methods as content for this data element.
- Use cases: The primary use case for harmonization status is in sharing data for clinical interpretation and use. If a test result from an external site has a harmonization status matching local tests, the harmonized results could be displayed in the same line of a flow sheet, and trended and processed with local results. A non-harmonized result would not be clinically compatible with local results and should be displayed and processed separately. In a public health setting, harmonized results could be grouped for surveillance processing, statistical analysis, and machine learning applications. Non-harmonized results should be kept separate.
- The number of stakeholders who would capture, access, use or exchange this data element or data class
 - Because the data element would be needed to meet any current or future clinical interoperability requirements, the CAP anticipates that it would become a routine component of laboratory result reporting. Since there are around 330,000 CLIA-certified laboratories in the United States that are information sources, the usage floor including laboratories and their communication partners would be substantially above that number.
- Does this data element support the following aims in healthcare?
 - Improving patient experience of care (quality and/or satisfaction) **Yes, and is critical for patient safety**
 - Improving the health of populations **Yes**
 - Reducing the cost of care **Yes**
 - Improving provider experience of care **Yes**
- Are there additional technical specifications such as an implementation guide (IG) or profile using this data element?
 - **Answer:** To our knowledge, this is the first proposal of a data element to represent result harmonization.
- Which of the following best describes the use of this data element? Please cite supporting artifacts
 - **Answer:** Not currently captured or accessed.
- Has this data element been electronically exchanged with external organizations or individuals (including patients)? Please cite supporting artifacts.
 - **Answer:** No.
- Any restrictions on the standardization of this data element
 - **Answer:** None per se. There could be a dependence on ISO standards, which are proprietary, depending on how that information is used.
- Describe any restrictions on the use of this data element (e.g., licensing, user fees).

- **Answer:** None
- Describe any privacy and security concerns with the use and exchange of this data element.
 - **Answer:** None
- Please provide an estimate of overall burden to implement. Overall estimate of burden to implement, including those not affected by the primary use case(s)
 - **Answer:** Laboratories would need to define the content of an additional data field when building result messages. The content of the field is likely to be selected a limited number of alternatives and therefore should be of limited additional burden.

Please contact hduncan@cap.org or htran@cap.org as needed for any follow up on this commentary.