Comments on USCDI+ Laboratory Data Exchange Use Case

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Commenter Organization: American Clinical Laboratory Association

Comments on Proposed Data Elements		
Data Element Name/Definition	**Comment, e.g., name change, description change, removal. Please include the revised language that you are proposing**	**Rationale for the Proposed Change**
Accession Number -- The unique identifier for a single instance of a specimen received by a laboratory and its analysis.	ACLA supports. [We will not comment on this element]	
Laboratory Results -- Date and Timestamps -- Date and timestamps associated with the completion of laboratory results, that are meta data associated with laboratory results.	ACLA supports. [We will not comment on this element]	
Laboratory Test Performed Date -- The clinically relevant date/time of the observation. In the case of observations taken directly from a subject, it is the actual date and time the observation was obtained. In the case of a specimen-associated study, this field shall represent the date and time the specimen was collected or obtained	ACLA comments: The American Clinical Laboratory Association appreciates the opportunity to comment on the Data Element, Laboratory Test Performed Date. A portion of this data element is redundant with the Data Element: Specimen Collection Date and Time (i.e., for a "specimen-associated study"). It is redundant to include specimen collect date and time in two categories. ACLA recommends the laboratory test performed date should be limited to patient observations only.	
Laboratory Test/Panel Code -- An identifier for the analysis of specimens derived from humans which provide information for the	ACLA supports. [We will not comment on this element]	

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diagnosis, prevention, treatment of disease, or assessment of health.		
Result Interpretation -- Categorical assessment of a laboratory value, often in relation to a test's reference range. Examples include but are not limited to high, low, critical high, and normal.	ACLA comments: The American Clinical Laboratory Association appreciates the opportunity to comment on the data element, Result Interpretation. Normal results typically do not require interpretation.	
Result Reference Range -- Upper and lower limit of quantitative test values expected for a designated population of individuals. Usage note: Reference range values may differ by patient characteristics, laboratory test manufacturer, and laboratory test performer.	ACLA comments: The American Clinical Laboratory Association appreciates the opportunity to comment on the data element, Result Reference Range. ACLA comments pertain to the burden of using the Unified Code for Units of Measure (UCUM). Using only the UCUM as a standard is problematic and the burden on laboratories would be very high. The UCUM cannot be used when it is not supported by the analytic procedure's documentation for an FDA authorized, cleared, or approved method. Existing interfaces should not be required to update to the UCUM. (Note: the FDA approved units must be used for reporting, regardless of the standard used).	
Result Status -- State or condition of a laboratory test.	ACLA comments: The American Clinical Laboratory Association appreciates the opportunity to comment on the data element, Result Status. ACLA comments pertain to the burden of using the Unified Code for Units of Measure (UCUM).	

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	Using only the UCUM as a standard is problematic and the burden on laboratories would be very high. The UCUM cannot be used when it is not supported by the analytic procedure's documentation for an FDA authorized, cleared, or approved method. Existing interfaces should not be required to update to the UCUM. (Note: the FDA approved units must be used for reporting, regardless of the standard used). Please clarify the result status element and whether it is for the panel or each individual test. For example, a Complete Blood Count (CBC) is the panel, and the White Blood Count (WBC) is one individual test within the panel. The standards referenced in the original submission do not include HL7 Version 2.5.1 Implementation Guide: Lab Results Interface (LRI); Release 1 (US Realm) which was required by Meaningful Use Stage 2 and the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) required for Meaningful Use Stage 1 and currently used for COVID-19 and other STLT health department reporting. When ONC cites vocabulary standards, we suggest the HL7 V2 terminology referenced in the LRI and ELR be cited as a required terminology since these terminologies are currently used for laboratory result reporting. LRI: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=279 ELR: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=98	
Result Unit of Measure -- Unit of measurement to report laboratory test results.	ACLA comments: The American Clinical Laboratory Association (ACLA) appreciates the opportunity to comment on the data element, Result Unit of Measure.	

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	These comments pertain to the burden of using the Unified Code for Units of Measure (UCUM). Using only the UCUM as a standard is problematic and the burden for laboratories would be very high. The UCUM cannot be used when it is not supported by the analytic procedure's documentation for an FDA authorized, cleared, or approved method. Existing interfaces should not be required to update to the UCUM. (Note: the FDA approved units must be used for reporting, regardless of the standard used).	
Specimen Collection Date/Time -- Date/time when clinical specimen was collected from subject patient.	ACLA comments: Please refer to the ACLA comments for Laboratory Test Performed Date.	
Specimen Condition Acceptability -- Information regarding a specimen, including the container, that does not meet a laboratory's criteria for acceptability. Examples include but are not limited to hemolyzed, clotted, container leaking, and missing patient name. Usage note: This may include information about the contents of the container, the container, and the label.	ACLA comments: The American Clinical Laboratory Association (ACLA) appreciates the opportunity to comment on the data element, Specimen Condition Acceptability. ACLA does not support this data element for Public Health. Laboratories do not perform testing on specimens that do not meet a laboratory's criteria for acceptability. This should not be a Public Health data element.	
Specimen Identifier -- Sequence of characters assigned by a laboratory for an individual specimen. Example includes but is not limited to accession number.	ACLA supports. [We will not comment on this element]	
Specimen Source Site -- Body location from where a specimen was	ACLA supports. [We will not comment on this element]	

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obtained. Examples include but are not limited to right internal jugular, left arm, and right eye.		
Specimen Type -- Substance being sampled or tested. Examples include but are not limited to nasopharyngeal swab, whole blood, serum, urine, and wound swab.	ACLA supports. [We will not comment on this element]	
Test Kit Unique Identifier -- Uniquely identifies the type of test (at minimum by using test name and manufacturer (similar to the make and model of a car)) that was used to obtain the Test Result Value. It is a device identifier and should be referenced using Device Identifiers (DI), when available. The DI is contained within the unique device identifier (UDI), created by manufacturer (Manufacturer requests UDI issuance, then provides DI, or can be pulled from GUDID database (https://accessgudid.nlm.nih.gov/).	ACLA comments: The American Clinical Laboratory Association (ACLA) appreciates the opportunity to comment on the data element, Test Kit Unique Identifier. This is not currently supported by most laboratories and would impact technology and operational aspects of their business. We suggest that ONC work with FDA, CMS/CLIA, public health agencies, laboratories, and instrument manufacturers to establish a practical roadmap. Additionally, inclusion of this data element would be problematic for laboratory developed tests (LDTs) because they have generally not been regulated as devices and do not currently have UDIs. FDA's proposed rule to regulate LDTs as devices would not require the adoption of UDIs for LDTs prior to 2 years after the final rule (likely April 2026). Until then, there is no mechanism for obtaining UDIs for LDTs not regulated as devices, and multiple devices with multiple device identifiers may be used in the performance of an LDT.	
Values/Results -- Documented findings of a tested specimen including structured and unstructured components.	ACLA comments: The American Clinical Laboratory Association (ACLA) appreciates the opportunity to comment on the data element, Values/Results.	

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	The only applicable standard listed is SNOMED but not all Values/Results have SNOMED. ACLA recommends allowing coding systems other than SNOMED.	