Laboratory Reporting

This document was developed by the Data Standardization Work Group (DSWG) of the Council of State and Territorial Epidemiologists (CSTE) Surveillance Practice and Implementation Subcommittee (SPIS) as a part of a larger data harmonization effort. It will be published and maintained in a repository on the CSTE website.

More information about the DSWG and data harmonization can be found here: [link to DSWG Core Surveillance Project Brief (pending)].

Background

Laboratory (Lab) data is a primary source of information in the world of public health surveillance. These data are often the first notification a public health agency receives of a potential case of disease or infection and, as such, are a key part of the case surveillance lifecycle. Lab reports typically include important patient information as well as test details, such as test type, results, specimen type, and collection/result dates. These data are crucial to move case investigations forward, to determine any need for public health actions, and to accurately classify cases according to condition case definitions. These data are also a vital part of the case notifications sent from jurisdictions to the CDC as part of the National Notifiable Diseases Surveillance System (NNDSS).

Jurisdictional health departments may receive lab reports from facilities such as electronic files or paper-based reports sent via fax, mail or other means. Electronic files can be received in either standard HL7 formats or as flat files; both can be considered Electronic Lab Reports (ELR). Although the majority of lab reports are received as HL7 ELR, complete receipt of all lab results via ELR has not been achieved by all jurisdictions from all reporters, so lab reports still need to be hand entered into disease surveillance systems. The challenges of manual entry can hinder the transmission of large amounts of lab data to CDC within case notifications. Few surveillance systems include the direct ability to receive and parse HL7 messages; most rely on external integration engines. The ability to capture lab results in surveillance systems based on standard codes varies and for some this makes it difficult to include lab information in case notifications without additional work.

The current standard for ELR used by many (but not all) submitters is in the HL7 Version 2.5.1 Implementation Guide (IG): Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) (HL7 2.5.1 ELR IG). It is possible that jurisdictions are able to pass information directly from ELRs sent according to this well-defined standard into case notification messages without the need for extensive mapping. Unfortunately, not all laboratories are sending the 2.5.1 standard; some are still sending according to the HL7 Version 2.3.1 and others send in other electronic formats such as csv flat files. These non-2.5.1 formats may require additional work by jurisdictions to extract and transform the data.

The HL7 2.5.1 ELR IG specifies the use of several well-defined data standards for use in ELR, although local codes can and are used in systems as well. Logical Observation Identifiers Names and Codes (LOINC) is the standard coding system indicated for the lab test performed (OBX-3). Unified Code for Units of Measure (UCUM) is the code system required for transmission of Units (OBX-6). Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT) is the standard used for the transmission of

coded results in the Observation Value (OBX-5) field. Because these standards exist and are in use, they can be used as the basis for lab data elements for case notifications.

The inclusion of lab data in NNDSS case notifications has been tricky due to the aforementioned lab data entry and ELR integration challenges. For example, the message mapping guide (MMG) "lab template" was a mechanism developed with the idea that data from ELR might be mapped directly to case notifications. However, this mechanism still required a significant amount of data transformation and mapping at jurisdictions in order for the data to be received without error at CDC. In addition, CDC program areas weren't yet ready to receive this level of data and, therefore, the lab template was abandoned.

Currently, lab data are transmitted in NNDSS case notifications through condition-specific repeating groups. These repeating groups capture the most epidemiologically important information from case investigations. However, the structure and content of these lab repeating groups vary greatly across condition MMGs. Different data element names and descriptions are often used to capture the same information, some examples of which are shown in Table 1. In addition, most data elements have different value sets depending on the condition and can require a considerable amount of data mapping at the jurisdiction level to successfully transmit lab data to CDC. Currently there are 53 data elements used across all MMGs with 85 associated value sets.

Table 1. Laboratory Repeating Group Data Elements Currently in Three Message Mapping Guides

Data Element	MMGs	Description	Value Set
Test Type	Arboviral	List of Arboviral tests - PCR, PRNT, IgM, Immunohistochemical staining	[Condition-specific value sets]
	STD*	Epidemiologic interpretation of the type of test(s) performed for this case.	
	TB**	Epidemiologic interpretation of the type of test(s) performed for this case. Please provide a response for each of the main test types (culture, smear, pathology/cytology, NAA, TST, IGRA, HIV, diabetes) If test was not done please indicate so.	
Test Result	TB	Epidemiologic interpretation of the results of the test(s) performed for this case - This is a qualitative test result. (e.g, positive, detected, negative)	[Condition-specific value sets]
	STD		
Test Result / Interpretation	Arboviral	Interpretation of test results associated with the lab tests such as positive, negative, equivocal, test not done.	[Condition-specific value set]
Test Result Quantitative	TB	Quantitative test result value	N/A - Text
	STD		
Units of Measure	STD	Units of measure for the quantitative test result value.	[Condition-specific value sets]
Result Units	TB		
Organism Name	Arboviral	Species identified through testing	[Condition-specific value sets]
	STD		
Specimen Type	Arboviral	If "Other Arbovirus PCR (Not serum / CSF) was selected as test type, specify the specimen type. List of specimens that are used for Arboviral lab tests - Serum, CSF, Amniotic Fluid, Urine, Semen, Cord blood	[Condition-specific value set]
Specimen Source	STD	Anatomic site or specimen type from which lab specimen was collected.	[Condition-specific value set]
Specimen Source Site	TB	This indicates the anatomical source of the specimen tested.	[Condition-specific value set]
Specimen Collection Date	Arboviral	Specimen collection date would be used to identify the first or second specimen and would be useful for Serum Paired Antibody result too.	N/A – Date
	STD	Date of collection of laboratory specimen	
Specimen Collection Date/Time	TB	Date of collection of laboratory specimen used for diagnosis of health event reported in this case report. Time of collection is an optional addition to date.	N/A – DateTime
Date of Lab Result	STD	Date of collection of laboratory specimen	N/A – Date
Date/Time of Lab Result	TB	Date result sent from reporting laboratory. Time of result is an optional addition to date.	N/A – DateTime
Performing Lab Type	Arboviral	Type of labs that were used to test for Arboviral lab tests - CDC Lab, State Public Health Lab, Commercial Lab	[Condition-specific value set]

*Sexually Transmitted Disease (SD)

**Tuberculosis (TB)

Core Surveillance Laboratory Data Elements for Routine Case Notifications

The DSWG came to consensus that laboratory information be included as a repeating group of core data elements for case notification to CDC. The seven data elements below are those that the DSWG recommended for inclusion in a laboratory repeating group. For each of the recommended data elements, there is a possibility for information to be routed from an ELR to a case notification message, most commonly after routing the ELR through an integration engine. Specimen Collectoin Date/Time and Date/Time of Lab Result align with definitions in the *CSTE Data Standardization: Dates of Importance to Public Health Surveillance*. Refer to Tables 2-8 below for definitions and additional information for each data element.

- Test Performed
- Test Result
- Units of Measure
- Specimen Type
- Specimen Source Site
- Specimen Collection Date/Time
- Date/Time of Lab Result

The following data elements were also discussed, but there was no consensus to include them as core surveillance data elements for routine case notifications to CDC. Some data element discussions were augmented with a survey sent to jurisdictional partners to elicit details from individuals who may not be as widely represented on the DSWG calls, such as informaticians and staff more familiar with jurisdiction data policies.

- Test Result Reference Range
- Performing Laboratory Type
- Performing Laboratory Specimen ID
- Sequencing ID

Reference range can be helpful for CDC primarily from a data quality perspective; however, jurisdictions noted difficulty in mapping the values which are sent in ELR, if values are sent at all. Performing Laboratory Type data was determined to be of limited use to jurisdictions while also requiring considerable work to maintain in their system or populate accurately. Jurisdictional representatives suggested that a less granular value set might make implementation of this data element less burdensome, but this solution was also noted by CDC program representatives to reduce the utility of the data.

Two specimen identifiers were suggested for inclusion in a core lab repeating group. Performing Laboratory Specimen ID is a data element sent via ELR and considered important for specimen/patient data linkage. While this type of linkage would be helpful for CDC programs, there are privacy concerns about transmitting this data element within a case notification. Sequencing ID was ruled out from the core surveillance repeating group due to the limited number of conditions to which it applies and the fact that the ID alone without the associated database name might not be useful.

Consideration was also given to whether there are barriers to sending test results of all types - Coded, Qualitative, or Quantitative - in the same data element field (INV291). In the proposal discussed, the data type (CWE, NM, SN, or ST) of the test result in OBX-5 would be required to be specified in the OBX-

2 of the OBX segment for INV291 in each repeating group. Feedback from jurisdictional partners, including subject matter experts from outside the DSWG membership, was solicited in order to assess any potential technical barriers to this approach and the results were mixed. While several jurisdictions said this would be no issue, others cited concerns over lab results which were still manually entered, or which enter their surveillance system in a format less conducive to direct mapping of ELR fields to case notification messages.

The ability of a jurisdiction to send lab data pulled directly from ELR is linked to how fully these ELR are integrated into the case surveillance system. Some systems are streamlined to accept ELR data relatively unchanged, while others have no direct input of lab data into the case surveillance event from which case notification messages are built. This document outlines data elements recommended for inclusion in a lab repeating group, but no definitive recommendation is made about how to send more than one lab result data type.

Table 2. Core Surveillance Data Element for Routine CDC Case Notification – Test Performed

Test Performed	
Definition	Code for the lab test or analysis that was performed on the specimen.
Standard Code for Transmission to CDC	INV290 – Test Type
Value Set or Coding System for Transmission to CDC	• LOINC • Other, specify
Abstracted/ Derived/ Created	Abstracted
Derived from (examples)	N/A
Recommendations for Input Data Source(s)	Laboratory Reports (including, but not exclusively, ELR) eCR
Notes	Also referred to as "Resulted Test Name"
Data Source Details*	
eCR CDA	HL7 CDA R2 Implementation Guide: Public Health Case Report, Release 2 STU Release 1.1 - US Realm • ClinicalDocument/component/ResultsSection/ResultOrganizer/ResultObservation/code HL7 CDA R2 Implementation Guide: Public Health Case Report – eICR Release 2, STU Release 3.1 - US Realm • ClinicalDocument/component/ResultsSection/ResultOrganizer/ResultObservation/code
eCR FHIR	US Public Health Laboratory Result Observation Profile • Observation.code • "The test that was performed. A LOINC **SHALL** be used if the concept is present in LOINC."
ELR	Observation identifier (OBX-3) • Unique identifier for the type of observation. • OBX-3 together with OBX-4 Observation Sub-ID should uniquely identify the OBX pertinent to the test performed. • LOINC is the strongly preferred coding system for this field unless there is no applicable LOINC in which case local codes are allowed
USCDI v5	Laboratory Data Class: • Tests: Analysis of specimens derived from humans which provide information for the diagnosis, prevention, treatment of disease, or assessment of health. • Applicable Vocabulary Standard: LOINC version 2.77
USCDI+ Public Health: Case Reporting Use Case	Laboratory Test/Panel Code • Definition: An identifier for the analysis of specimens derived from humans which provide information for the diagnosis, prevention, treatment of disease, or assessment of health. • Maybe too high-level if a test panel code is used instead of the test code. **Also included in the USCDI+ Laboratory Data Exchange Use Case**

* Additional information on input data sources for laboratory data can be found in Appendix A.

Table 3. Core Surveillance Data Element for Routine CDC Case Notification – Test Result

Test Result	
Definition	Qualitative or quantitative results for test performed. This can include various types of results such as numeric, coded, text, or other types relevant to the specific result.
Standard Code for Transmission to CDC	PHIN Questions: INV291 – Test Result
Value Set or Coding System for Transmission to CDC	For Coded results: • SNOMED-CT (including the APHL SCT extension codes) • Other, specify (to capture non-SNOMED codes)
Abstracted/ Derived/ Created	Abstracted
Derived from (examples)	N/A
Recommendations for Input Data Source(s)	Laboratory Reports (including, but not exclusively, ELR) eCR
Notes	In an HL7 format, the Test Result data type would be sent in the OBX-2 of the HL7 segment transmitting the Test Result (INV291) data element.
Data Source Details*	
eCR CDA	HL7 CDA R2 Implementation Guide: Public Health Case Report, Release 2 STU Release 1.1 - US Realm • ClinicalDocument/component/ResultsSection/ResultOrganizer/ResultObservation/value HL7 CDA R2 Implementation Guide: Public Health Case Report – eICR Release 2, STU Release 3.1 - US Realm • ClinicalDocument/component/ResultsSection/ResultOrganizer/ResultObservation/value
eCR FHIR	US Core Lab Results Observation Profile • Observation.value[x] *or* Observation.component.value[x] • The Laboratory result value. • *Note:* Observation.component.value[x] may be relevant depending on the test results. US Public Health Laboratory Result Observation Profile • Observation.value[x] • "The Laboratory result value. If a coded value, the valueCodeableConcept.code **SHOULD** be selected from SNOMED CT if the concept exists. If a numeric value, valueQuantity.code **SHALL** be selected from UCUM."
ELR	Observation value (OBX-5) • Test results appear here. • For laboratory-based reporting, SNOMED is required for OBX-5 whenever the CE/CWE data type is indicated in OBX-2.
USCDI v5	Laboratory Data Class: • Values/Results: Documented findings of a tested specimen including structured and unstructured components • Applicable Vocabulary Standard: SNOMED CT, U.S. Edition, March 2024 Release
USCDI+ Public Health: Case	Laboratory Data Class: • Values/Results: Documented findings of a tested specimen including structured and unstructured components

Reporting Use Case	• Applicable Vocabulary Standard: SNOMED CT, U.S. Edition, March 2024 Release **Also included in the USCDI+ Laboratory Data Exchange Use Case**

* Additional information on input data sources for laboratory data can be found in Appendix A.

Table 4. Core Surveillance Data Element for Routine CDC Case Notification – Units of Measure

Units of Measure	
Definition	Units of measure for the test result value, if applicable.
Standard Code for Transmission to CDC	OBX-6 for INV291
Value Set or Coding System for Transmission to CDC	• Unified Code for Units of Measure (UCUM)
Abstracted/ Derived/ Created	Abstracted
Derived from (examples)	N/A
Recommendations for Input Data Source(s)	Laboratory Reports (including, but not exclusively, ELR) eCR
Notes	
Data Source Details*	
eCR CDA	HL7 CDA R2 Implementation Guide: Public Health Case Report, Release 2 STU Release 1.1 - US Realm • ClinicalDocument/component/ResultsSection/ResultOrganizer/ResultObservation/value HL7 CDA R2 Implementation Guide: Public Health Case Report – eICR Release 2, STU Release 3.1 - US Realm • ClinicalDocument/component/ResultsSection/ResultOrganizer/ResultObservation/value
eCR FHIR	US Public Health Laboratory Result Observation Profile • Observation.valueQuantity.unit *or* Observation.component.valueQuantity.unit • Unit representation
ELR	Units (OBX-6) • UCUM is the required code system for this segment.
USCDI v5	Laboratory Data Class: • Result Unit of Measure: Unit of measurement to report quantitative values. • Applicable Vocabulary Standard: The Unified Code of Units for Measure, Revision 2.1
USCDI+ Public Health: Case Reporting Use Case	Laboratory Data Class: • Result Unit of Measure: Unit of measurement to report quantitative values. • Applicable Vocabulary Standard: The Unified Code of Units for Measure, Revision 2.1 **Also included in the USCDI+ Laboratory Data Exchange Use Case**

* Additional information on input data sources for laboratory data can be found in Appendix A.

Table 5. Core Surveillance Data Element for Routine CDC Case Notification – Specimen Type

Specimen Type	
Definition	The type of specimen used in testing the resulted lab test
Standard Code for Transmission to CDC	LOINC: 66746-9 – Specimen type
Value Set or Coding System for Transmission to CDC	• SNOMED-CT Specimen hierarchy • Other, specify
Abstracted/ Derived/ Created	Abstracted
Derived from (examples)	N/A
Recommendations for Input Data Source(s)	Laboratory Reports (including, but not exclusively, ELR) eCR
Notes	If the SPM-4 field of a received ELR message contains data that describe both the specimen type (e.g., blood, urine) and the specimen source site (e.g., nasopharynx, skin), it is acceptable to transmit this information to CDC in its current, combined format; i.e., the full content of the SPM-4 field can be sent to the CDC as is for this data element.
Data Source Details*	
eCR CDA	HL7 CDA R2 Implementation Guide: Public Health Case Report, Release 2 STU Release 1.1 - US Realm • /ClinicalDocument/component/structuredBody/component/section/entry/organizer/component/procedure/participant/participantRole/playingEntity/code/@code HL7 CDA R2 Implementation Guide: Public Health Case Report – eICR Release 2, STU Release 3.1 - US Realm • /ClinicalDocument/component/structuredBody/component/section/entry/organizer/component/procedure/participant/participantRole/playingEntity/code/@code • ClinicalDocument/component/ResultsSection/ResultOrganizer/ResultObservation/value
eCR FHIR	US Core Lab Results Observation Profile • Specimen.type • Kind of material that forms the specimen US Public Health Laboratory Result Observation Profile • Observation.specimen • Only used when specimen type is not specifically denoted in the Performed Test name.
ELR	Specimen Type (SPM-4) • "Description of the precise nature of the entity that is the source material for the observation."
USCDI v5	Laboratory Data Class: • Specimen Type: Substance being sampled or tested. • Applicable Vocabulary Standard: SNOMED CT, U.S. Edition, March 2024 Release
USCDI+ Public Health: Case Reporting Use Case	Laboratory Data Class: • Specimen Type: Substance being sampled or tested. • Applicable Vocabulary Standard: SNOMED CT, U.S. Edition, March 2024 Release **Also included in the USCDI+ Laboratory Data Exchange Use Case**

* Additional information on input data sources for laboratory data can be found in Appendix A.

Table 6. Core Surveillance Data Element for Routine CDC Case Notification – Specimen Source Site

Specimen Source Site	
Definition	Indicator of the anatomical source of the specimen tested
Standard Code for Transmission to CDC	LOINC: 31208-2 – Specimen Source identified
Value Set or Coding System for Transmission to CDC	• SNOMED-CT Body Structure hierarchy • Other, specify
Abstracted/ Derived/ Created	Abstracted
Derived from (examples)	N/A
Recommendations for Input Data Source(s)	Laboratory Reports (including, but not exclusively, ELR) eCR
Notes	
Data Source Details*	
eCR CDA	HL7 CDA R2 Implementation Guide: Public Health Case Report, Release 2 STU Release 1.1 - US Realm • ClinicalDocument/component/ResultsSection/ResultOrganizer/ResultObservation/ targetSiteCode HL7 CDA R2 Implementation Guide: Public Health Case Report – eICR Release 2, STU Release 3.1 - US Realm • ClinicalDocument/component/ResultsSection/ResultOrganizer/ResultObservation/targetSiteCode
eCR FHIR	US Core Lab Results Observation Profile • Specimen.collection.bodySite • Anatomical location from which the specimen was collected (if subject is a patient). This is the target site. This element is not used for environmental specimens.
ELR	Specimen Source Site (SPM-8) • "Source from which the specimen was obtained. … For biological samples, it may represent the anatomical site from which the specimen was collected."
USCDI v5	Laboratory Data Class: • Specimen Source Site: Body location from where a specimen was obtained. • Applicable Vocabulary Standard: SNOMED CT, U.S. Edition, March 2024 Release
USCDI+ Public Health: Case Reporting Use Case	Laboratory Data Class: • Specimen Source Site: Body location from where a specimen was obtained. • Applicable Vocabulary Standard: SNOMED CT, U.S. Edition, March 2024 Release **Also included in the USCDI+ Laboratory Data Exchange Use Case**

* Additional information on input data sources for laboratory data can be found in Appendix A.

Table 7. Core Surveillance Data Element for Routine CDC Case Notification – Specimen Collection Date/Time

Specimen Collection Date/Time	
Definition	Date (and time as available) a clinical specimen was collected from the person for the laboratory testing relevant to the disease or condition being reported to a public health agency.
Standard Code for Transmission to CDC	LOINC: 68963-8 Collection date and time of Specimen
Value Set or Coding System for Transmission to CDC	N/A – DateTime
Abstracted/ Derived/ Created	Abstracted
Derived from (examples)	N/A
Recommendations for Input Data Source(s)	Laboratory Reports (including, but not exclusively, ELR) eCR
Notes	Data element aligns with that of the same name defined in the *CSTE Data Standardization: Dates of Importance to Public Health Surveillance*.
Data Source Details*	
eCR CDA	HL7 CDA R2 Implementation Guide: Public Health Case Report, Release 2 STU Release 1.1 - US Realm • ClinicalDocument/component/ResultsSection/ResultOrganizer/ResultObservation/effective.time HL7 CDA R2 Implementation Guide: Public Health Case Report – eICR Release 2, STU Release 3.1 - US Realm • ClinicalDocument/component/ResultsSection/ResultOrganizer/ResultObservation/effective.time • ClinicalDocument/component/ResultsSection/InitialCaseReportTriggerCodeResultOrganizer/ ResultOrganizer/ResultObservation/effective.time – Only applicable to laboratory results which are included in the Reportable Condition Trigger Codes.
eCR FHIR	US Core Lab Results Observation Profile • Specimen.collection.collected[x] • "Time when specimen was collected from subject – the physiologically relevant time." US Public Health Laboratory Result Observation Profile • Observation.effective[x] • "For lab tests this is the specimen collection date."
ELR	Observation Date/Time (OBR-7) • "For specimen-based observations, the date/time the specimen was collected." Date/Time of the Observation (OBX-14) • Intended to carry the clinically relevant time of an observation • "For specimen-based laboratory reporting, the specimen collection date and time." Specimen Collection Date/Time (SPM-17) • A time range over which the specimen was collected. • The First component of the date range must match OBR-7.
USCDI v5	No relevant data element is present in USCDI v5. Present in USCDI as Level 0 is the following data element:

	• Specimen Collection Date/Time: Date/time when clinical specimen was collected from subject patient.
USCDI+ Public Health: Case Reporting Use Case	Specimen Collection Date/Time • Definition: Date and time the test sample was collected. **Also included in the USCDI+ Laboratory Data Exchange Use Case**

* Additional information on input data sources for laboratory data can be found in Appendix A.

Table 8. Core Surveillance Data Element for Routine CDC Case Notification – Date/Time of Lab Result

Date/Time of Lab Result	
Definition	Date (and time as available) the latest result was released for reporting.
Standard Code for Transmission to CDC	LOINC: 90056-3 Date and time lab result reported
Value Set or Coding System for Transmission to CDC	N/A – DateTime
Abstracted/ Derived/ Created	Abstracted
Derived from (examples)	N/A
Recommendations for Input Data Source(s)	Laboratory Reports (including, but not exclusively, ELR) eCR
Notes	Data element aligns with that of the same name defined in the *CSTE Data Standardization: Dates of Importance to Public Health Surveillance*.
Data Source Details*	
eCR CDA	N/A
eCR FHIR	N/A
ELR	Date/Time of the Analysis (OBX-19) • "Time at which the testing was performed."
USCDI v5	No relevant data element is present in USCDI v5. Present in USCDI as Level 0 is the following data element: • Laboratory Results: Date and Timestamps: Date and timestamps associated with the completion of laboratory results, that are meta data associated with laboratory results.
USCDI+ Public Health: Case Reporting Use Case	Laboratory Results: Date and Timestamps • Definition: Date and timestamps associated with the completion of laboratory results, that are meta data associated with laboratory results. **Also included in the USCDI+ Laboratory Data Exchange Use Case**

* Additional information on input data sources for laboratory data can be found in Appendix A.

Appendix A. Input Data Sources for Laboratory Data

Electronic Case Reporting (eCR)

Although the ideal electronic data source for laboratory data is ELR, eCR can contain lab information that may not have been transmitted to a public health agency otherwise.

The CDA Implementation Guide (IG) for eCR defines components of an electronic Initial Case Report (eICR) that communicate results data, which includes but is not limited to laboratory results. The Results Section contains observation of results which are generated by any number of healthcare procedures. This section is built to specifically note things such as abnormal values, units and reference ranges.

- Results Section (entries required) – contains observations of results which are generated by any number of healthcare procedures. This section is built to specifically note things such as abnormal values, units and reference ranges.
- Results Organizer – provides a template for grouping related result observations. This provides a place to include information related to a group of observations including statusCode and effectiveTime.
- Results Observation – provides a template for capturing the results of a study performed on a patient, including a laboratory test. This template enables capture of information such as effectiveTime, value, referenceRange, and interpretationCode.

The CDA IG specifies several places to capture dates or times related to laboratory testing; however, these dates are not defined well enough to allow for a clear recommendation that one be used over another to gather Date/Time of Lab Result.

The US Public Health Laboratory Result Observation profile in the eCR FHIR specification also defines components transmitting laboratory data. The more clearly defined data elements have been included in the appropriate tables early in this document; however, neither this profile nor the more broad US Core Laboratory Observation profile provide an obvious data element to recommend for collection of Date/Time of Lab Result.

Electronic Laboratory Reporting (ELR)

ELR are the gold standard for transmission of lab data from any lab to public health agencies. As noted earlier, the current standard for ELR submitters can be found in the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm). All data elements recommended in this document are able be found in messages sent according to this standard.

USCDI and USCDI+

USCDI has contained a Laboratory data class since version 1 which at that time contained two data elements, Tests and Value/Results. As of version 5, ten data elements are included. Laboratory-related data elements are included in both the Case Reporting and Laboratory Data Exchange use cases of USCDI+. Table 9 outlines the laboratory data elements included in both use cases and their related USCDI development level if relevant.

Table 9. Laboratory-related Data Elements included in USCDI+

Data Element	Description	Laboratory Data Exchange	Case Reporting	USCDI level/ version
Accession Number	The unique identifier for a single instance of a specimen received by a laboratory and its analysis.	X		0
Laboratory Result Test Name	Analysis of specimens derived from humans which provide information for the diagnosis, prevention, treatment of disease, or assessment of health.		X	N/A
Laboratory Results: Date and Timestamps	Date and timestamps associated with the completion of laboratory results, that are meta data associated with laboratory results.	X	X	0
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.	X	X	0
Laboratory Test/Panel Code	An identifier for the analysis of specimens derived from humans which provide information for the diagnosis, prevention, treatment of disease, or assessment of health.		X	2
Placer Order Number	Identifier for the laboratory order from the encounter.		X	N/A
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.	X		USCDI V5
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.	X		USCDI V5
Result Status	State or condition of a laboratory test.	X	X	USCDI V5
Result Unit of Measure	Units of measurement for the lab test	X		USCDI V5
Specimen Collection Date/Time	Date and time the test sample was collected	X	X	0
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.	X		USCDI V5
Specimen Identifier	Sequence of characters assigned by a laboratory for an individual specimen. Example includes but is not limited to accession number.	X	X	USCDI V5

Specimen Source Site	Body location from where a specimen was obtained. Examples include but are not limited to right internal jugular, left arm, and right eye.	X	X	USCDI V5
Specimen Type	Substance being sampled or tested. Examples include but are not limited to nasopharyngeal swab, whole blood, serum, urine, and wound swab.	X	X	USCDI V5
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/).	X		0
Values/Results	Documented findings of a tested specimen including structured and unstructured components	X	X	USCDI V5