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 data is a primary source of information in the world of public health surveillance. Laboratory, or lab, data are often the first notifications a public health agency receives of a potential case of disease. As such, these data are a key part of the case surveillance lifecycle. Lab reports often 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 moving case investigations forward, to determine any need for public health actions, and to accurately classify cases according to condition case definition. These data are also a vital part of the 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 as either as Electronic Lab Reports (ELR) in an HL7 format or as paper-based reports, sent via fax, mail, or other means. Currently, the vast majority of lab reports are received as ELR. However this is a relatively new state and, until recently, most lab reports would have had to be hand entered into disease surveillance systems, thus hindering the transmission of large amounts of lab data to CDC within case notifications. Unfortunately, many surveillance systems weren't initially built to receive ELR into their case management dataflows and some systems are still unable to easily integrate this information into their case notifications without external processes which may include manual data entry.

The current standard for ELR used by many (but not all) submitters can be found in the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm). It is possible that jurisdictions will be 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 files. These non-2.5.1 formats require additional work by jurisdictions to extract and transform the data.

The message mapping guide (MMG) "lab template" was a mechanism developed with the idea that data from ELR might be ported directly into a case notification. Unfortunately, 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. Unfortunately, many surveillance systems weren't initially built to receive ELR into their case management dataflows and some systems are still unable to easily integrate this information into their case notifications without external processes which may include manual data entry.

Most lab data are currently transmitted in case notifications through condition-specific repeating groups. These repeating groups capture the most epidemiologically important information from case investigations. These lab repeating groups vary greatly across condition MMGs with different data element names and descriptions used to capture the same information as shown in Table 1. In addition, most data elements have different value sets depending on the condition requiring a considerable amount of data mapping at the jurisdiction level in order to transmit lab data to CDC.

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 Observation Identifier (OBX-3) which conveys information related to Test Type. 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 a recommended standard used for the transmission of coded results in the Observation Value (OBX-5) field though this is not included in the 2.5.1 IG. Because these standards exist and are in use, they can be used as the basis for lab data elements for case notifications as well.

Table 1. Laboratory Repeating Group Data Elements Currently in 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]

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 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 directly from an ELR to a case notification message. 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.

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

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 this proposal, the data type of the test result (CWE, NM, SN, or ST) would be required to be sent in the OBX-2 of the OBX segment for INV291 in each repeating group. Feedback from external jurisdictional partners was solicited in order to assess any 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. The ability of a jurisdiction to send lab data in this way is directly linked to how integrated incoming ELR are with the case surveillance system. Some systems are fully integrated while others have no direct input of lab data into the case surveillance event from which case notification messages are built.

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 (to capture local 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	
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. Part of the Laboratory data class.

* 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 • 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 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 strongly recommended for OBX-5 whenever the CE 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

* 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

* 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	
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

* 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 Site 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

* 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 patient 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 – Date
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/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. • 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.

* 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 – Date
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	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.

* 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 for eCR defines components of an 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 deifines 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.

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
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	X		0

	DI, or can be pulled from GUDID database (https://accessgudid.nlm.nih.gov/).			
Values/Results	Documented findings of a tested specimen including structured and unstructured components	X	X	USCDI V5