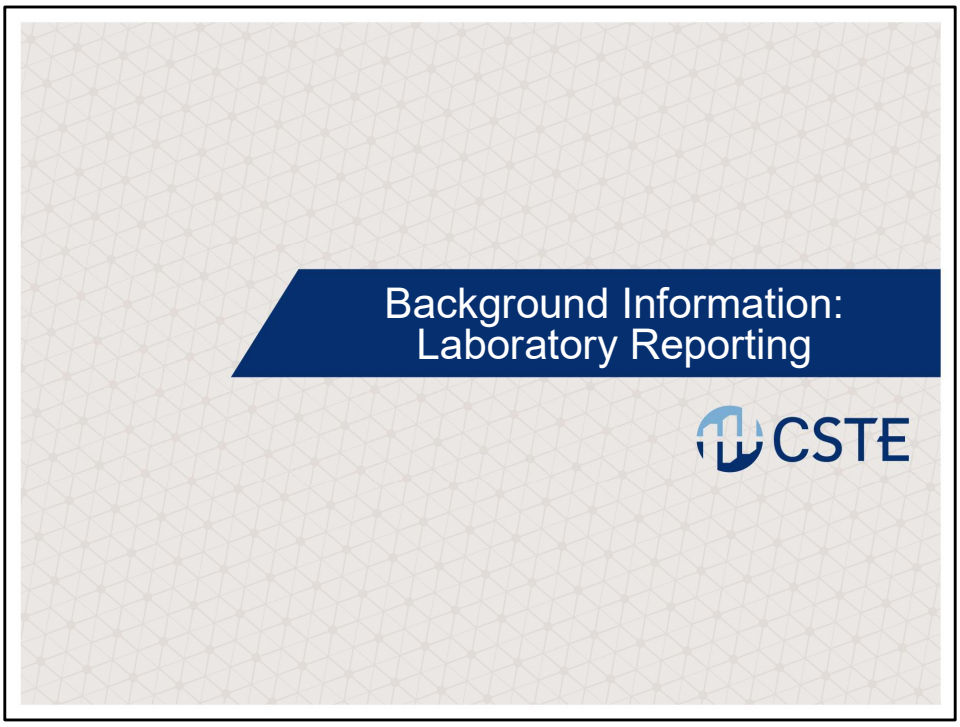
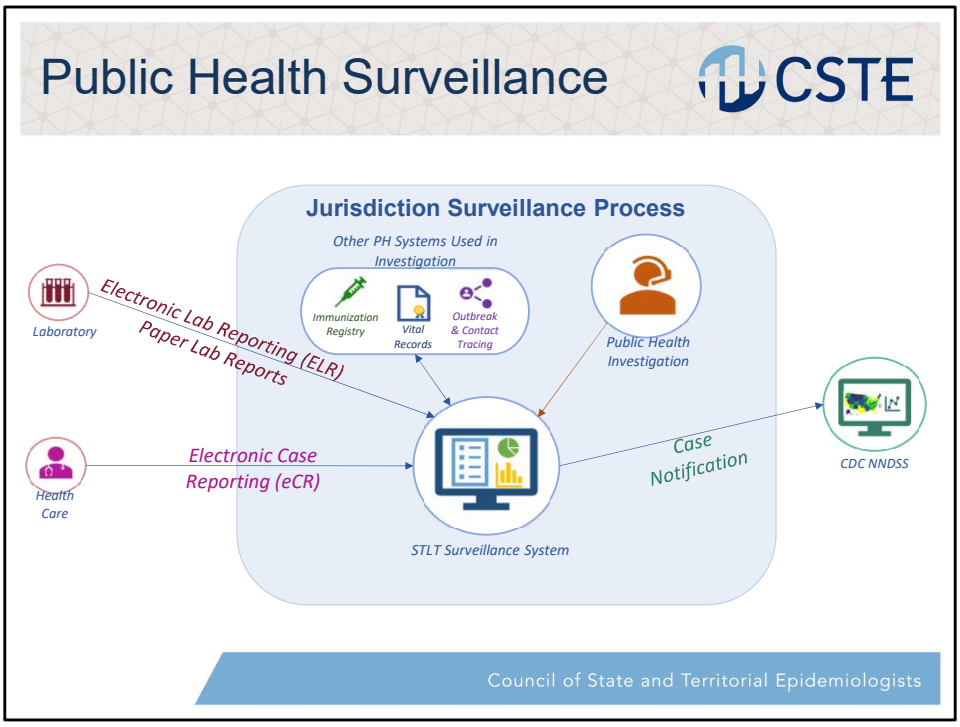


Welcome to the background recording for Laboratory Reporting data class.



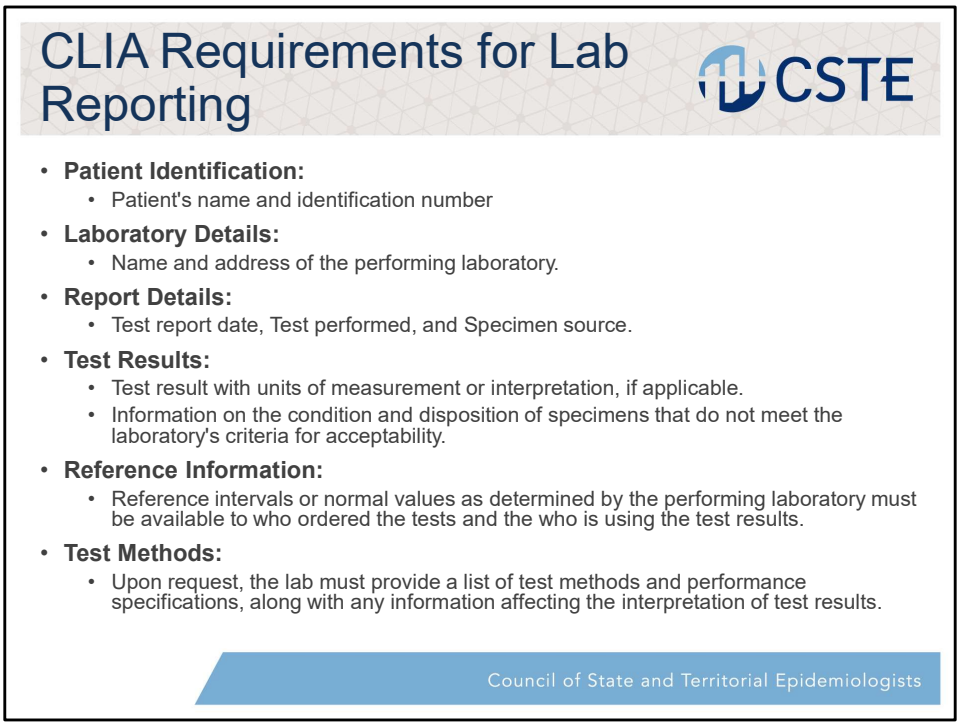
A primary source of information in the world of public health surveillance are laboratory, or lab, reports. Lab data is indispensable in public health as it can inform the entire case surveillance lifecycle. A lab report can be the first notification of a case of disease to a public health agency, can confirm diagnoses, and can provide proof of clearance of the condition. Accuracy and timeliness of lab data is essential to public health action.

Many different types of laboratories or healthcare organizations send lab reports to public health agencies. As noted, these reports often provide the first case information to these agencies. Lab reports include detailed information on the patient and the test, such as test type, results, specimen type, and collection/result dates. This data is crucial for thorough case investigations and for maintaining accurate public health records. It is also a vital part of the data sent from jurisdictions to the CDC as part of the National Notifiable Diseases Surveillance System (NNDSS).

The data flow from laboratories to public health systems and then to CDC NNDSS is depicted above, highlighting the interconnected nature of these data flows.

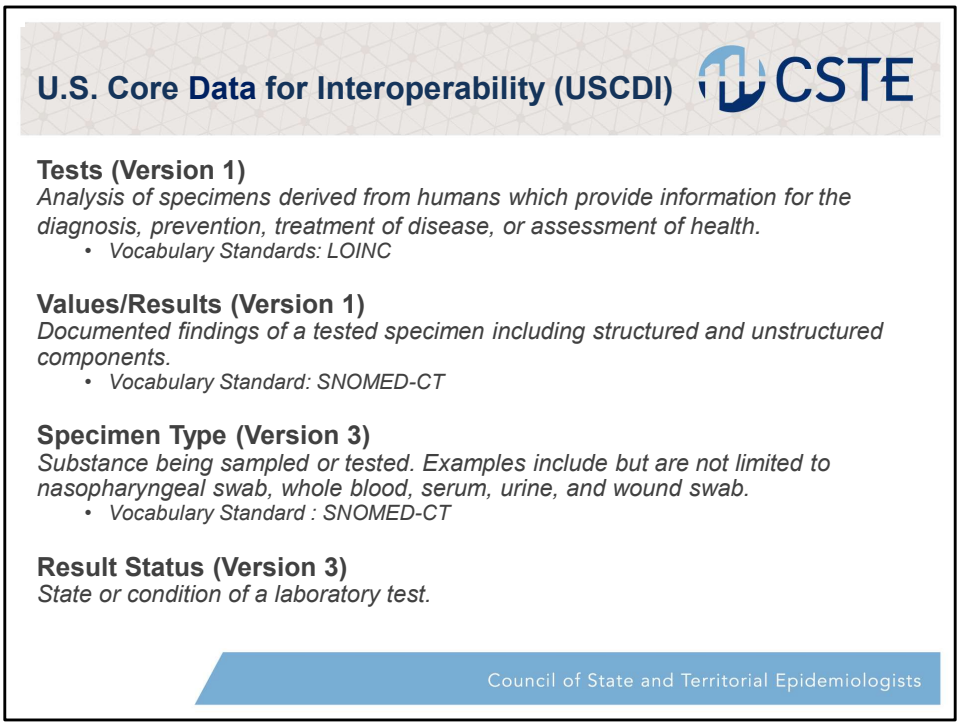
In the subsequent slides, we'll dive into the reporting of lab results to jurisdictions,

the sending of those results to CDC, and some of the regulations and standards that inform that data transmission.



There are several regulations and standards that work together to ensure laboratories operate with high levels of accuracy, safety, and reliability. One of the key regulations is the Clinical Laboratory Improvement Amendments, known as CLIA. Established to ensure the quality and reliability of laboratory testing in the United States, compliance with CLIA requirements is mandatory for all laboratories that test human specimens for health assessment or to diagnose, prevent, or treat disease. Key requirements for lab reporting under CLIA include the necessity for each report to contain specific information such as the patient's name and identification number, the laboratory's name and address, the dates of specimen collection and reporting, and the test's methods and results along with reference ranges.

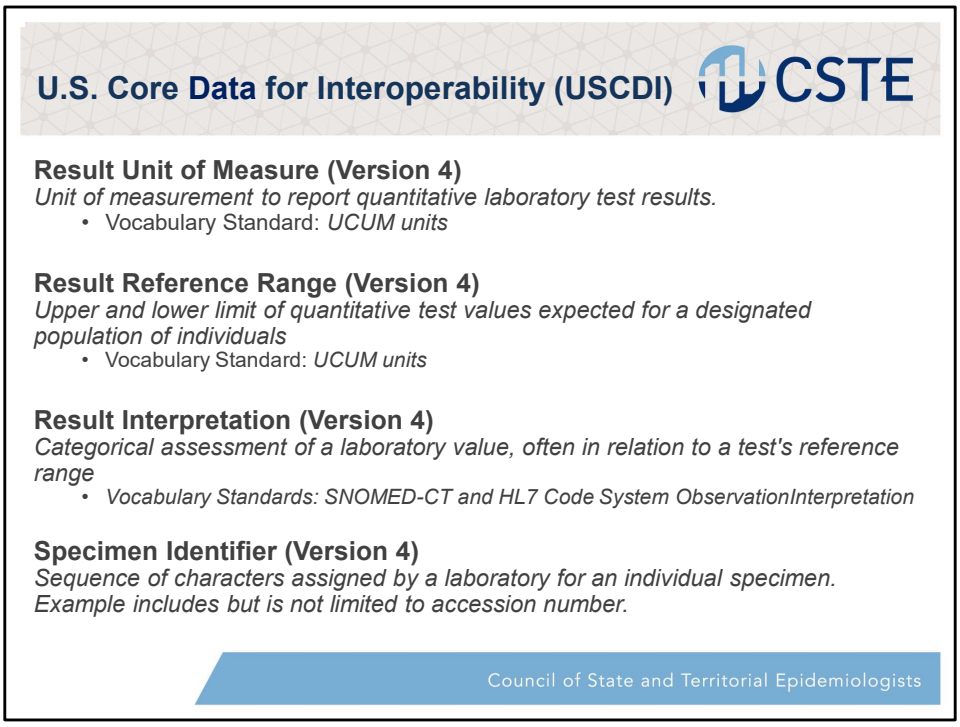
Regulations such as CLIA inform and shape various standards used in laboratories. These standards ensure that regulatory requirements are met and that the data collected and reported is accurate and reliable. In the next few slides, we will look at some of these standards, starting with the United States Core Data for Interoperability (USCDI).



As a data class, Lab was first included in USCDI in v1. In this first version, only two DEs were included - tests and values/results. This has expanded over time to now include 10 data elements in v4 of USCDI.

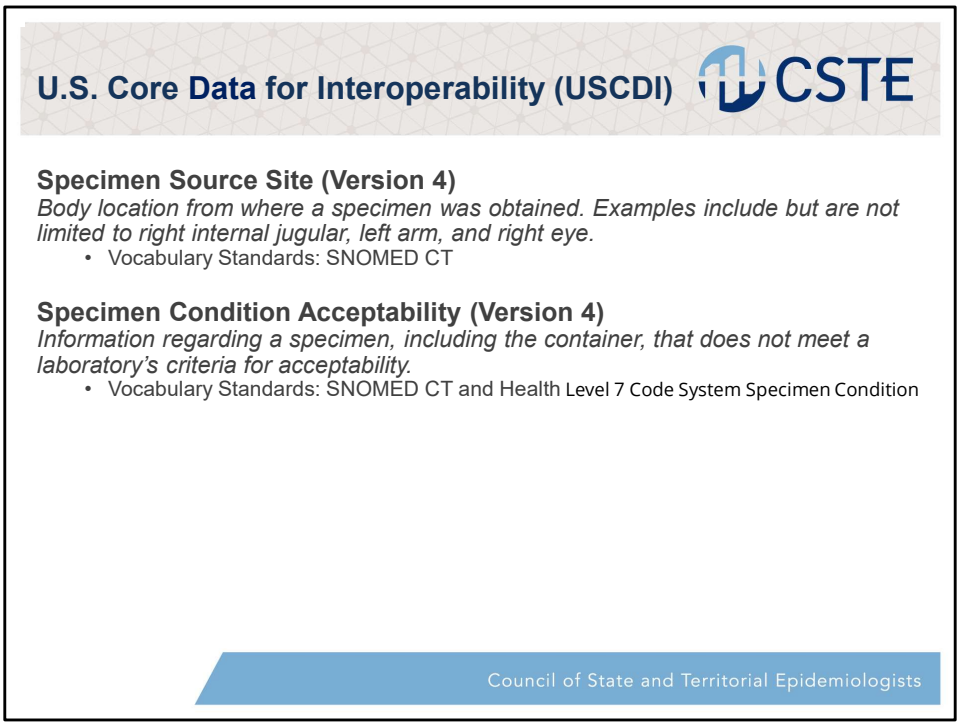
These data elements include:

- **Tests**: Indicates the analysis of specimens derived from humans to provide information for diagnosing, preventing, or treating disease, or assessing health. USCDI recommends using LOINC as the vocabulary standard for tests.
- **Values/Results**: Provides documented findings of a tested specimen, both structured and unstructured, using SNOMED-CT as the vocabulary standard.
- **Specimen Type**: Has information on the substance being sampled or tested, such as whole blood, serum, urine, or wound swab, with SNOMED-CT as the vocabulary standard.
- **Result Status**: Represents the status or condition of a lab test. While USCDI does not provide a specific value set for this element, ELR as well as the FHIR observation profile include concepts like final, corrected, and preliminary .



Also included in USCDI v4 laboratory data class are

- Result unit of measure and result reference range, both of which use Unified Code for Units of Measure, or UCUM, units to capture units of quantitative lab test results and upper and lower limits of quantitative test values, respectively.
- Result interpretation – which is the Categorical assessment of a laboratory value, often in relation to a test's reference range
- Specimen identifier – which is used to uniquely identify a specimen.

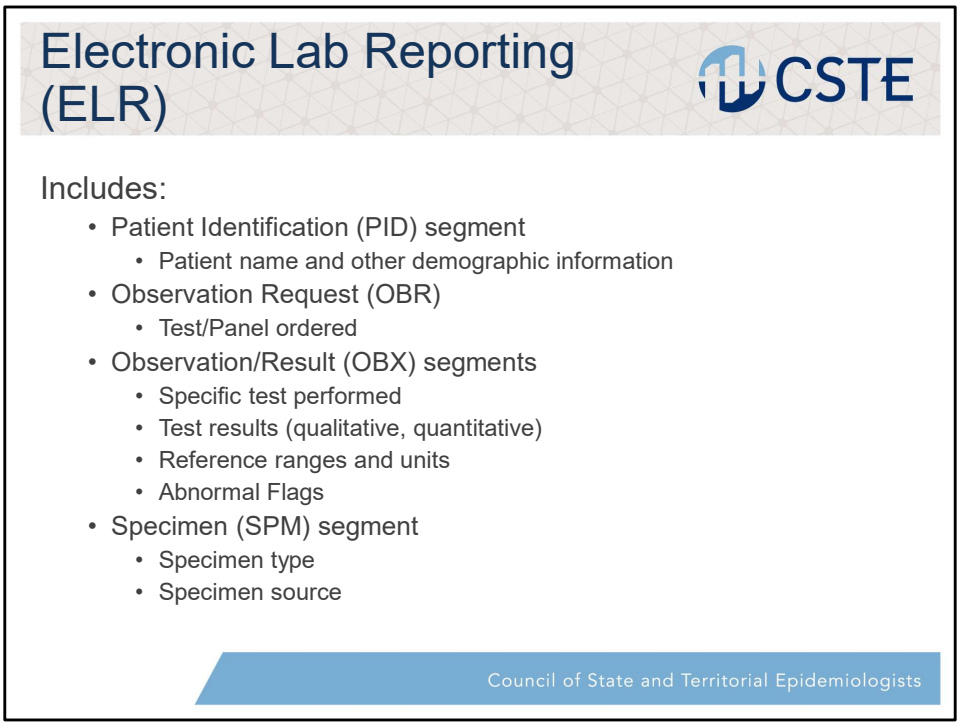


Lastly, USCDI includes specimen source site and specimen condition acceptability in the v4 laboratory data class.

- Specimen source site is the body location from where a specimen was obtained. USCDI includes SNOMED-CT as the vocabulary standard for this.
- Specimen condition acceptability contains information regarding a specimen that does not meet a laboratory's criteria for acceptability. Recommended vocabulary standards include SNOMED-CT and HL7 Specimen Condition

Additional data elements exist in draft V5 and at levels 0,1, and 2 of maturity, including the Test Kit Unique Device Identifier found in draft v5. However most of these data elements are not part of NNDSS Message Mapping Guides and will not be discussed here.

The exception is the Specimen Collection Date/Time. This element is at level 2 and captures the date and time when a clinical specimen was collected from the patient.



Electronic Laboratory Reporting (ELR) is the primary source of laboratory information for jurisdictions. For the purposes of public health, ELR is the digital transmission of lab reports from laboratories to public health partners. ELR automates a key part of the reporting process and is crucial for both routine surveillance and in response to outbreaks. By converting information into an electronic message that can be automatically sent and processed, ELR allows for rapid reporting of cases.

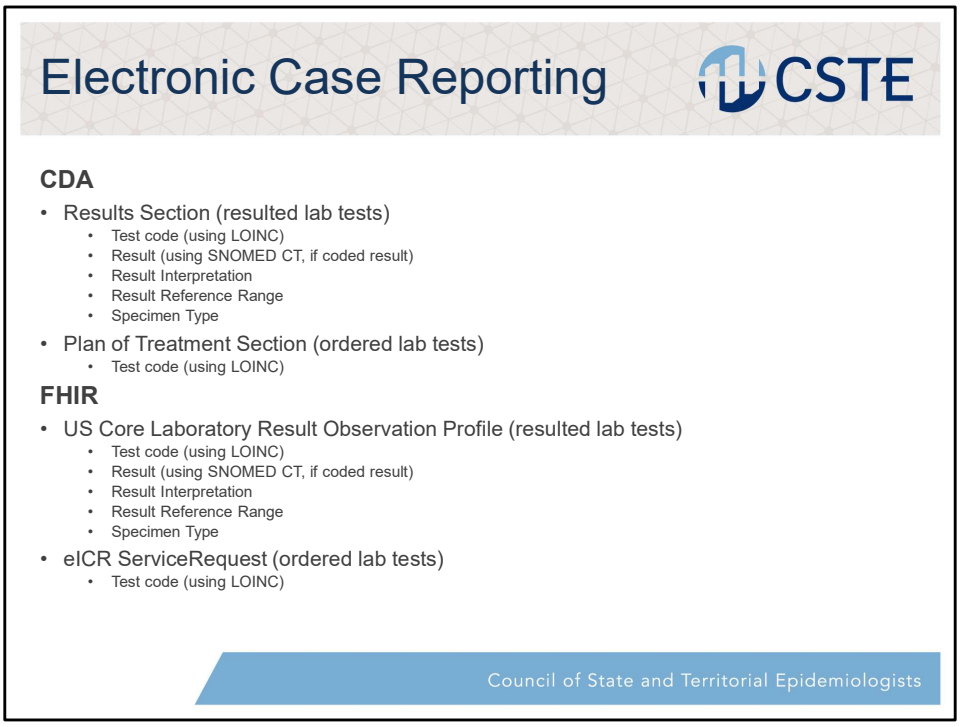
Through this message, public health partners can identify which laboratory conducted a test, the patient for whom it was ordered, the types of tests conducted, the results, and the specimen type. This information can either supplement an existing case or initiate a new case investigation.

ELR messages are structured according to the HL7 Version 2.5.1 Implementation Guide for Electronic Laboratory Reporting, which includes:

- **The Patient Identification (or PID) Segment:** Captures patient information, including name, date of birth, and address.
- **The Observation Request (or OBR) Segment:** Captures information on what test or tests were ordered for the patient primarily using LOINC codes.
- **The Observation/Result (or OBX) Segment:** Capture information on the test

performed, usually using LOINC codes. The **OBX** segment also records test results, reference ranges, and units of measure. Test results can be quantitative or coded, with coded results typically using SNOMED-CT codes.

- **The Specimen (or SPM) Segment:** Captures details about the specimen, including type, source, and collection time.



Laboratory data can also be included in electronic case reporting. Across both CDA and FHIR electronic case reporting, similar information is captured. This information includes

- test codes, which should be a LOINC, if an applicable LOINC code exists,
- a test result, which can be a coded result or a quantity. If coded, the code should be a SNOMED-CT code, and if a quantity, this should include units of measure.
- Result interpretation
- Reference range
- Specimen type

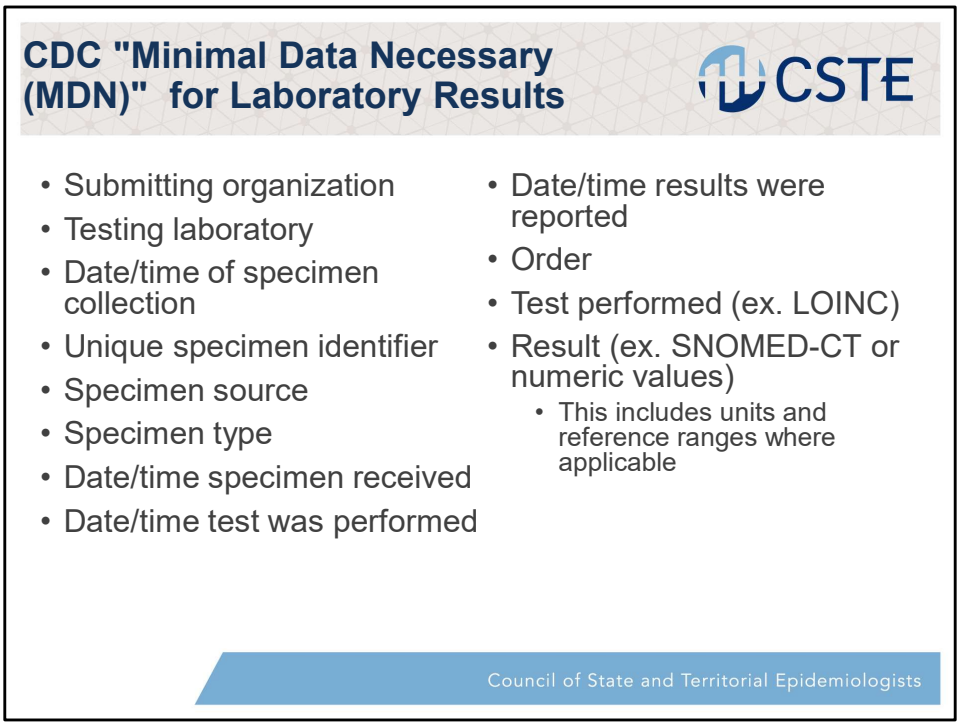
For CDA, resulted lab tests can be found in the Results Section and ordered lab tests can be found in the plan of treatment section.

For FHIR, information on resulted tests is captured in the US Core Laboratory Result Observation Profile which contains the US Core Specimen Profile. Information on ordered tests is captured in the eICR ServiceRequest profile.

In CDA, if the lab test caused the triggering of the electronic initial case report, lab results can also be found in additional “trigger code” templates including the Initial

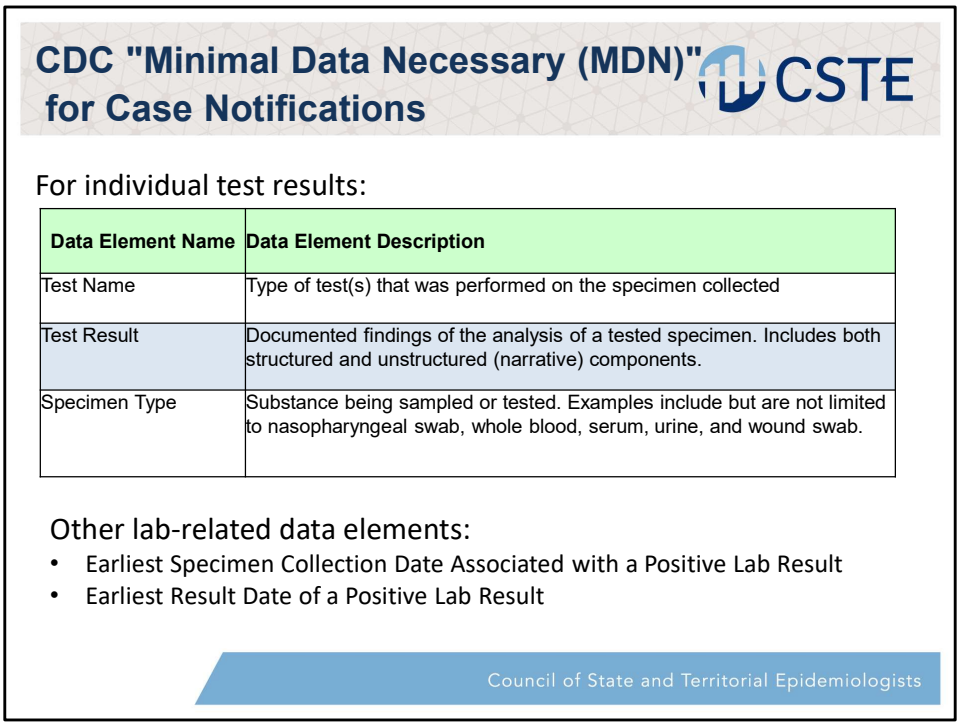
Case Report Trigger Code Lab Test Order template or the Initial Case Report Trigger Code Result Observation template, depending on whether the test was ordered or resulted.

FHIR is a bit different and instead has an eICR Trigger Code Flag Extension that can be sent with the US Core Laboratory Result Observation Profile or the eICR ServiceRequest Profile that is used to identify when a code(s) in a resource is the trigger code that led to creation of the eICR.



In November 2022, the CDC Advisory Committee to the Director Data and Surveillance Workgroup recommended defining the **Minimal Data Necessary (MDN)** for Public Emergency Response. Laboratory-based diagnostic testing data was one of the core data sources identified. The Public Health Data Strategy, released in April 2023, emphasized the importance of laboratory data as a core data source, stating that "including test results and test types enables public health agencies to track disease trends, identify outbreaks or exposures, and help frontline providers diagnose and treat health conditions."

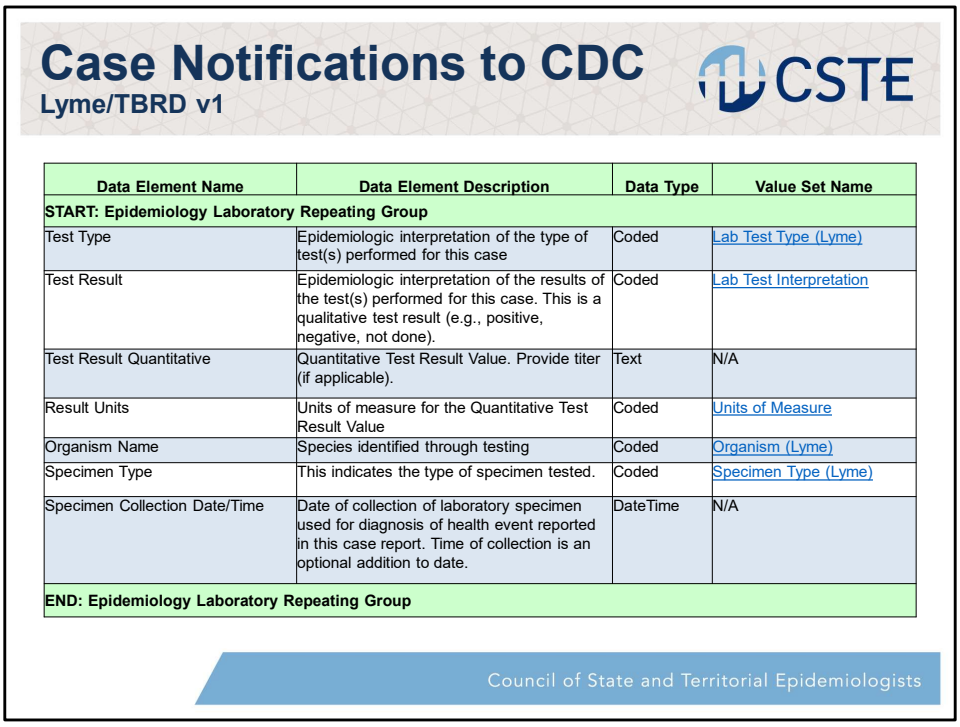
The minimal lab data required for any laboratory data shared with the CDC are listed here and were developed collaboratively. These are based on national standards, including ELR and Laboratory Result Interface (LRI). When implemented, the data dictionary for this will be straight from the ELR standards. These are just the higher-level concepts.



The MDN has more than one domain in which it defines what should be sent to CDC in cases of emergency response. The previous slide was specifically related to Laboratory Reporting.

This slide refers to the CDC defined MDN for case notifications. These are the lab-related fields which would be included in case notifications at the beginning of a public health response. These data elements would be requested to be included in the case notification for all cases reported to CDC in addition to other epidemiological information. These data elements transmit information on tests associated with the case, including information on the test name, test result, and specimen type.

In addition to information about individual test results, the MDN for case notification includes Earliest Specimen Collection Date Associated with a Positive Lab Result and the Earliest Result Date of a Positive Lab Result.



Case Notifications to CDC

Lyme/TBRD v1

CSTE

Data Element Name	Data Element Description	Data Type	Value Set Name
START: Epidemiology Laboratory Repeating Group			
Test Type	Epidemiologic interpretation of the type of test(s) performed for this case	Coded	Lab Test Type (Lyme)
Test Result	Epidemiologic interpretation of the results of the test(s) performed for this case. This is a qualitative test result (e.g., positive, negative, not done).	Coded	Lab Test Interpretation
Test Result Quantitative	Quantitative Test Result Value. Provide titer (if applicable).	Text	N/A
Result Units	Units of measure for the Quantitative Test Result Value	Coded	Units of Measure
Organism Name	Species identified through testing	Coded	Organism (Lyme)
Specimen Type	This indicates the type of specimen tested.	Coded	Specimen Type (Lyme)
Specimen Collection Date/Time	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.	DateTime	N/A
END: Epidemiology Laboratory Repeating Group			

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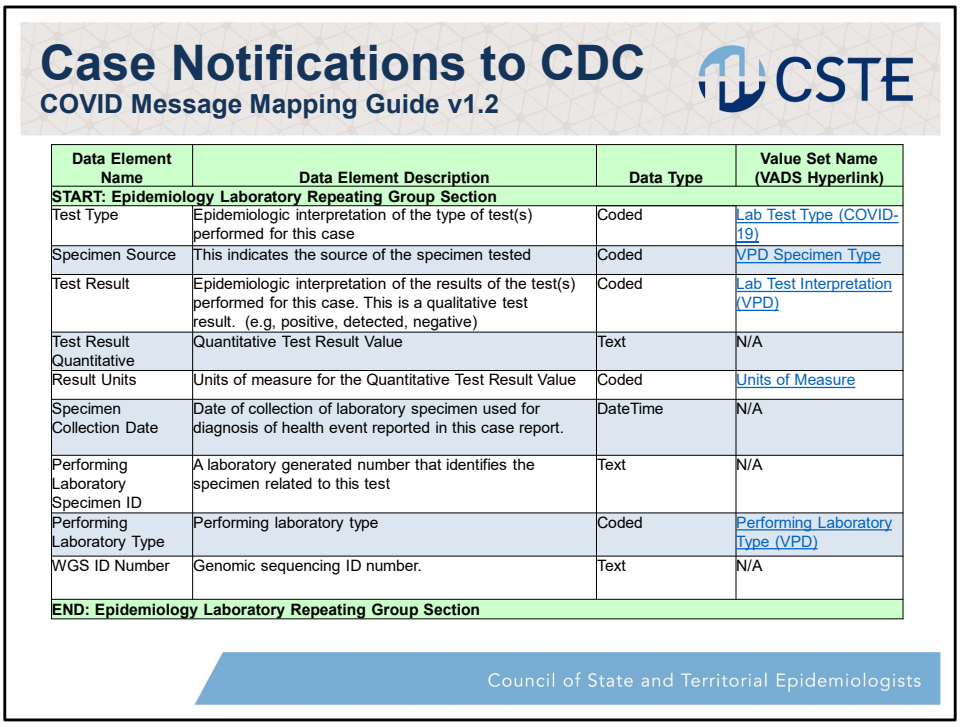
Within NNDSS, CDC requests laboratory data through what is often labeled as an epidemiology laboratory repeating group. This repeating group is included in all currently published MMGs.

All such repeating groups ask for a test type and then a result. The set of allowable test type values vary by MMG, but can include LOINC codes, CDC codes, or both. Value sets can range in size from as a few as 8 codes to hundreds of codes, depending on the type of codes requested.

Test results are separated into three categories: interpretive (such as positive, negative, not done), coded organism (such as Borrelia burgdorferi or Borrelia mayonii) and quantitative. Each of the three result categories is captured in a separate data element, with each MMG including 2-3 of them.

Beyond test type and test result, each repeating group captures a variety of additional data elements. Most capture specimen type, specimen source, and specimen collection date. Additional data elements captured include performing laboratory type, test method, serotype, genotype, specimen ID, and whether specimen was sent to CDC for testing.

Currently, each Epidemiology Laboratory Repeating Group is condition-specific and reflects the data needs of that CDC program. Shown above is an example from the Lyme/TBRD MMG. The test type value set consists of 24 LOINC codes and an option to specify “other” test types. All three categories of test type are included in test result, test result quantitative, and organism name. Beyond test type and result, specimen type and specimen collection date/time are included.



Case Notifications to CDC

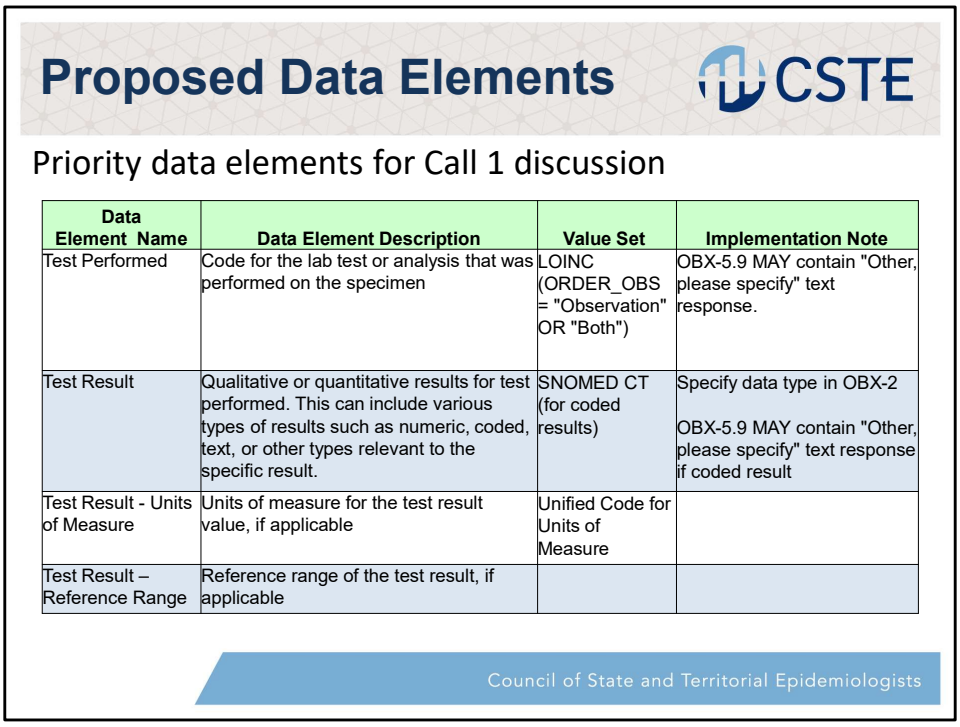
COVID Message Mapping Guide v1.2

CSTE

Data Element Name	Data Element Description	Data Type	Value Set Name (VADS Hyperlink)
START: Epidemiology Laboratory Repeating Group Section			
Test Type	Epidemiologic interpretation of the type of test(s) performed for this case	Coded	Lab Test Type (COVID-19)
Specimen Source	This indicates the source of the specimen tested	Coded	VPD Specimen Type
Test Result	Epidemiologic interpretation of the results of the test(s) performed for this case. This is a qualitative test result. (e.g, positive, detected, negative)	Coded	Lab Test Interpretation (VPD)
Test Result Quantitative	Quantitative Test Result Value	Text	N/A
Result Units	Units of measure for the Quantitative Test Result Value	Coded	Units of Measure
Specimen Collection Date	Date of collection of laboratory specimen used for diagnosis of health event reported in this case report.	DateTime	N/A
Performing Laboratory Specimen ID	A laboratory generated number that identifies the specimen related to this test	Text	N/A
Performing Laboratory Type	Performing laboratory type	Coded	Performing Laboratory Type (VPD)
WGS ID Number	Genomic sequencing ID number.	Text	N/A
END: Epidemiology Laboratory Repeating Group Section			

Council of State and Territorial Epidemiologists

Here is the Epidemiology Laboratory Repeating Group from the Covid MMG. This test type value set includes a combination of LOINC and CDC codes. Test results include epidemiological interpretive and quantitative test results. Beyond that, specimen source, specimen collection date, performing lab specimen ID, performing lab type, and WGS ID Number are included.



The overall goal for this data class is to determine core data elements requested for use across all conditions, that aligns with standards, minimizes burden on jurisdictions, and provides CDC programs with the information that they need.

On the first call, we want to focus on test performed and test result data elements. We will also discuss the associated units of measure and reference range elements. Other lab data elements will be discussed on future calls.

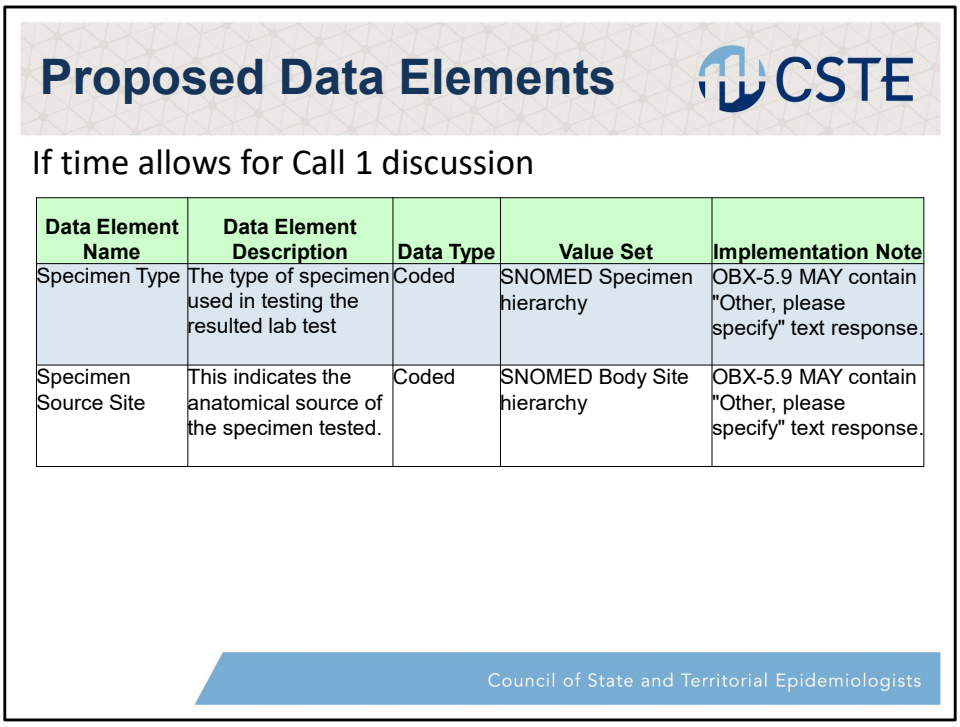
This slide shows a summary of our proposal for the test performed and test result data elements:

- For the Test Performed: We recommend moving away from condition-specific value sets to accepting all valid LOINC codes, whenever they are available. Local codes would not be accepted.
- For the Test Result, we suggest a move to a single data element for results. Coded results are recommended to be sent as SNOMED-CT (SCT) codes. This would include the APHL Snomed-CT extension codes (previously PLR codes) for qualitative lab results including organism detection, serotype identification, and antimicrobial susceptibility profiles. This approach eliminates the need for the NNDSS to maintain

condition-specific lists of test result codes that states must select from. Code data type would be specified in OBX-2.

Please consider the following for the first call:

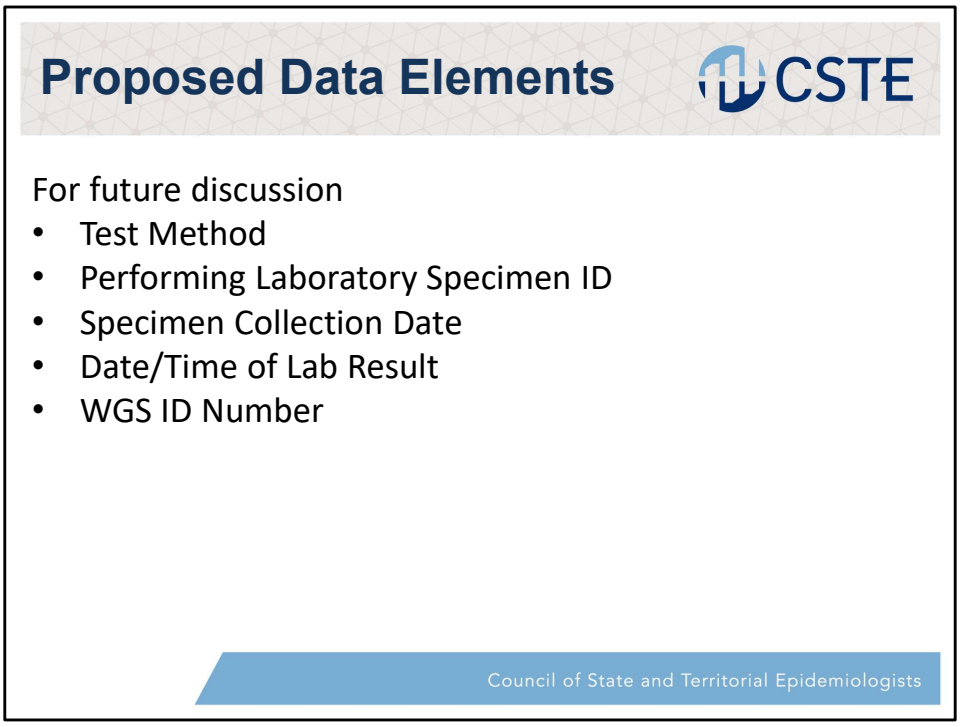
1. Are these definitions useful and clear?
2. Are the value sets implementable?
3. Is the concept of sending all result types in one data elements a reasonable one for jurisdictions?
4. Do these data elements convey useful information to the CDC program areas?
5. Are Units of Measure and Reference Range considered core components for data transmission.



If there is sufficient time on the first call, we can begin to discuss specimen type and specimen source.

Specimen Type and Specimen Source as core data elements are recommended to be included in a standardized laboratory reporting block. This information would only be expected if these fields were populated in an HL7 message SPM segment and there would be no expectation that specimen source would need to be pulled out of a LOINC code. Coded values are preferred but text could be sent in “other, specify”.

For is if these data elements should be part of the standardized lab block and if the value sets are useful and reasonable for implementation.



The other data elements to be discussion on a second call are shown here and will be discussed further at that time.

We look forward to hearing your thoughts about the proposed laboratory data elements on August 9.
Thank you!