The Association of Public Health Laboratories (APHL) is pleased to provide the following comments regarding Draft USCDI V6 for consideration. APHL is an organization that works to strengthen laboratory systems serving the public's health in the US and globally. APHL member laboratories, i.e., state and local governmental laboratories in the US, protect the public's health by monitoring and detecting infectious and foodborne diseases; environmental contaminants; biological, chemical, and radiological agents; genetic disorders in newborns; and other diverse health threats. Should you have any questions about APHL's feedback, please do not hesitate to contact us; inquiries can be directed to Melanie Kourbage, Lead Informatics Specialist, at melanie.kourbage@aphl.org.

Date/timestamps: ASTP's current approach is to use a single procedure performance date/time element in USCDI to cover all lab relevant date/timestamps, which include: Specimen collection date/time; Specimen received date time; Test performed date/time; Report released date/time. This approach does not align with how these data elements are managed by health IT systems in practice. APHL raises the concern that most systems don't model specimen collection, specimen receipt, lab tests and report creation as procedures. APHL recommends at a minimum adding data elements to capture Specimen Collection Date/time (Specimen Collection Date/Time, Specimen Receipt at Lab Date/time (submitted to USCDI+ for the PH Lab Reporting Use case, but not available on the USCDI+ website yet), Laboratory Test Performed Date/time (Laboratory Test Performed Date/Time), and Report Released Date/time (submitted to USCDI+ for the PH Lab Reporting Use case as a corollary to eCR report date element, but not available on the USCDI+ website yet https://uscdiplus.healthit.gov/uscdiplus?id=uscdi_record&table=x_g_sshh_uscdi_uscdi_elements&sys_id=04a7ba8a1b367d1094626318624bcbf3&view=sp). Of these suggested elements, Specimen Collection Date/time, Report Released Date/time and Laboratory Test Performed Date/time are the most critical, though the effort on the part of health IT vendors should be minimal. The vast majority of EHRs already track this information as distinct data elements. Indeed, Laboratory Test Performed date/time has been a recognized data element in HL7 since 1988 and Report Released Date/time is used to identiy the latest version of a report. We therefore do not anticipate that the inclusion of these data elements in USCDI V6 would cause a burden on health IT software vendors, but it would substantially increase the precision and quality of the laboratory data that is conveyed.

Performance date/time is included in the Procedure class of data elements but not in the Laboratory class. This classification has resulted in unintended confusion as developers create data models, deciding to model lab tests as procedures, which is not necessarily the right approach. The addition of laboratory-specific date/timestamps, explicitly named as indicated above, would alleviate this confusion, make it easier for health IT developers to follow the standards as intended, and promote overall system interoperability.

At a minimum, ASTP should provide implementation guidance for developers to make it clear that classes in USCDI are a convenience grouping and should not be considered indicative of modeling choices. Thus, developers are encouraged to use the appropriate FHIR resources when modeling USCDI content, for example using ServiceRequest when modeling a lab order. As an additional note, ASTP should make this implementation guidance easier for developers to find

on the ASTP website, to avoid developers misinterpreting USCDI content, resulting in incorrect data element modeling. If class is a convenience grouping, we suggest ASTP create references from several classes to the same data element - for example “Laboratory Orders” should be referenced in both the Orders class and the Laboratory class. Having the element “Laboratory Orders” in the Orders class and not in the Laboratory Class may result in developers overlooking that data element. This guidance facilitates the role of the developer, streamlines data modeling and promotes ASTP’s goal of system interoperability.

Furthermore, the inclusion of these date/timestamps is directly relevant to a laboratory’s CLIA review. To meet CLIA requirements and continue its operations, a laboratory must demonstrate that laboratory results in the EHRs map to what is in the source system i.e., the LIS/LIMS. Clearly identifying these date/timestamps in USCDI in the laboratory class would facilitate this mapping. It would also ensure that US Core interpretation covers all required lab date/time elements. US Core currently captures Specimen Collection Date/time as optional (Specimen.collection.collectedDateTime), and this information may end up in several different resources: Observation.effectiveDateTime, DiagnosticReport.effectiveDateTime, meaning that the DE is not included in the key elements view. Laboratory Test Performed Date/time does not have a dedicated home in the base FHIR observation resource. The V2-to-FHIR mapping project handled Laboratory Test performed Date/time by mapping to an extension (HL7 FHIR Analysis Date/Time), which is not used in US Core today. The Report Released Date/time (i.e. when the lab results are verified and released for reporting) is currently supported in US Core as DiagnosticReport.issued.

Assigning Authority: APHL recommends ASTP include the assigning authority with ANY identifier data element (in all HL7 products this is part of the various supported identifier type data types). This comment applies to Identifier (https://www.healthit.gov/isp/uscdi-data/identifier), Specimen Identifier (Specimen Identifier), Medical Record Number (https://www.healthit.gov/isp/uscdi-data/medical-record-number), and Medicare Patient Identifier (https://www.healthit.gov/isp/uscdi-data/medicare-patient-identifier). We recommend that the definitions for these data elements include the following language: "Alphanumeric value that uniquely identifies the declared identifier type over time, at minimum within one organization, ideally at the national level, including a means to identify the organization or system that assigned it."

Ideally, the complete identifier should consist of the alphanumeric string, the assigning authority, and the identifier type code. This combination would promote data interoperability by allowing data modelers to confidently merge identifiers that are identical. Just because the alphanumeric string in the Identifier field in two different messages is identical, the data modeler cannot assume that the patient is the same. It may be that the string refers to a medical record number in one and a different patient identifier in another, or to medical record numbers from two different EHR systems that just happen to be the same. A more complete identifier with assigning authority and identifier type code would eliminate this confusion and lead to more transparent, interoperable and ultimately actionable data. This also supports USCDI’s vision of defining generic data elements that can be reused across different classes. The specializations of identifier like Specimen Identifier, Medical Record Number and Medicare Patient Identifier all are essentially taking the identifier type code and putting it in their name.

DE	APHL Draft Comment February 2025
Unique Device Identifier	APHL also offers feedback on whether Unique Device Identifier (UDI) should be captured as one or two data elements (Unique Device Identifier—Implantable and Unique Device Identifier—Non-implantable). Having 2 data elements (implantable and non-implantable) may be helpful to accommodate a phased approach for certification, but the modeling of both should be the same. APHL supports the expansion from implantable only to any device in principle, but requests more guidance on what devices should be tracked in the various areas; for the laboratory we suggest ASTP focus on the instrument (Instrument Unique Identifier) and testkit (Test Kit Unique Identifier) which would be covered by this expansion. Identifiers for instrument and testkit will allow better tracking, accountability, and interpretation of laboratory results, resulting in higher quality data and more reliable analyses and fewer redundant tests. Most useful would be the tracking at the model level (not the serial number), though tracking the full UDI of the device (not its packaging) will include the device identifier aspect and may be easier when the data can be acquired by scanning the product barcode. Currently many data producing systems are not capable of storing and exchanging this data element; capturing this data in source systems and near-source intermediaries such as instruments, LIS, RIS, PoCs automatically and be able to include them into downstream communications is required before it can be required in EHR certification. APHL notes that all HL7 products can accommodate the exchange of device information including the full UDI, as well as parts of the UDI like the device Identifier, and the instrument interfacing IHE LAW specification (CLSI AUTO-16) supports “manufacturer” and “model” as well as the serial number for the transactions between instruments and analyzer managers. Thus, once the issue of capturing it at the source or source-intermediary level is resolved, the UDI information can be exchanged. At the same time, ASTP should take steps to ensure that EHRs are ready to accommodate UDI once the source systems have been updated. In order to fully support laboratory data exchange, the capability to track and send UDI (non-implantable) should be added as a criterion in future EHR certifications, which is why splitting them into two elements might make sense to support this phased approach.

Specimen Condition Acceptability	APHL requests that ASTP rename this element to "Specimen Condition" and use the improved valuesets defined by the HL7 Orders & Observations Workgroup, with APHL's support, for specimen condition. https://confluence.hl7.org/display/OO/Specimen+Condition+and+Specimen+Reject+Reason+Vocabulary). APHL made similar comments in September 2024 (Comment 14135), April 2024 (Comment 13837), and September 2023 (Comment 13519). The problem with the current data element is that is combines two preanalytical workflow steps: the evaluation of the specimen itself and then the evaluation of whether or not the specimen can be used for the test that was ordered. The condition is often reported when the testing can be performed, but the interpretation of the result is limited by the specimen condition; the condition is also reported when the test cannot be done at all, but usually in a different clinical context. To retain the clinical context of condition vs reject reason requires two different data elements.

Laboratory Test Performed Date	APHL requests an update to the definition to actually define what the name implies which is the "Date (and optionally time) when testing was conducted by the testing laboratory." In HL7 V2, this element maps to OBX-19 (Date and Time of Analysis) (https://www.hl7.eu/refactored/segOBX.html#1480). In HL7 CDA, it does not map cleanly to a single data element; most people use observation.effective, but that is really the specimen collection date time). And in HL7 FHIR, the element unfortunately only exists as an extension (HL7 FHIR Analysis Date/Time). APHL made similar comments in September 2024 (Comment 14139) and September 2022 (Comment 11646). ASTP's current approach is to use a single procedure performance date/time element in USCDI to cover all lab relevant date/time elements, which include: Specimen Collection Date/time; Specimen Received in Lab Date time; Test Performed Date/time; Report Released Date/time. APHL raises the concern that most systems don't model lab tests as procedures. APHL is confident that most EHRs already track and have the capability to receive Laboratory Test Performed Date/time, and so including it in USCDI V6 should not impose a burden on vendors. Because of its widespread use in EHRs this element should at minimum be elevated to level 2. APHL recommends at a minimum adding data elements to USCDI's Laboratory Class to capture Specimen Collection Date/time; Test Performed Date/time and Report Released Date/time to better align with how these data elements are used in practice and tracked by current health IT software.

Specimen Collection Date/Time	ASTP's current approach is to use a single procedure performance date/time element in USCDI to cover all lab relevant date/time, which include: Specimen Collection Date/time; Specimen Received in Lab Date time; Test Performed Date/time and Report Released date/time. APHL raises the concern that systems might not model specimen collection as a procedure, so might not consider using the Procedure Performance Date/time as a choice to represent this data element. The specimen collection date/time is clinically relevant as it provides the temporal aspect for the patient's care, so is important when sharing patient data with other physicians or public health. It is used by the lab to determine specimen acceptability for testing and is required to be tracked for CLIA accreditation. Performance time can be broad, as in a surgery that can last multiple hours. In contrast, a specimen collection usually occurs at a specific moment in time, when the specimen physically leaves the body (though specimen that are collected after they leave the body can be collected over a period of time, e.g. 24-hour urine). This data element is also in USCDI+ for the Public Health Pab Reporting Use case: https://uscdiplus.healthit.gov/uscdiplus?id=uscdi_record&table=x_g_sshh_uscdi_uscdi_elements&sys_id=798cd3d81bd5b110f7052f84604bcb3d&view=sp APHL is confident that most EHRs already track and have the capability to send/receive Specimen Collection Date/time, and so including it in USCDI V6 should not impose a burden on vendors. Because of its widespread use in EHRs this element should at minimum be elevated to level 2. An alternative name for this data element could be Performance time of specimen Collection. APHL recommends at a minimum adding data elements to USCDI's Laboratory Class to capture Specimen Collection Date/time; Test Performed Date/time and Report Released Date/time to better align with how these data elements are used in practice and tracked by current health IT software.

ADD: Specimen Received date/time	ASTP's current approach is to use a single procedure performance date/time element in USCDI to cover all lab relevant date/time, which include: Specimen Collection Date/time; Specimen Received in Lab Date/time; Test Performed Date/time; Report Released Date/time. APHL raises the concern that most systems don't model specimen receipt as a procedure. In a laboratory setting, the Specimen Received Date/time is important for understanding potential reject reasons and to calculate the turnaround time for lab results. APHL is confident that most EHRs already track and have the capability to receive Specimen Received in Lab date/time, and so including it in USCDI V6 should not impose a burden on vendors. APHL submitted this data element to USCDI+ for the PH Lab Reporting Use case, but it is not visible on the USCDI+ website yet.

ADD: Report Released Date/time	The definition for this data element should be: “The date and time at which the LIMS system releases the results to the provider and other recipients.” This date/time applies to any report, whether preliminary, final or corrected. This data element is critical in establishing the temporal context of reports, specifically when updates are received; it is commonly used by EHRs to identify the most recent version of a report and thus adding it would be supporting existing EHR functionality. ASTP’s current approach is to use a single procedure performance date/time element in USCDI to cover all lab relevant date/time, which include: Specimen Collection Date/time; Specimen Received in Lab date time; Test Performed Date/time; Report Released Date/time. APHL raises the concern that most systems don’t track Report Release date/time as a procedure or an observation. APHL is confident that most EHRs already track and have the capability to receive Report Released Date/time, and so including it in USCDI V6 should not impose a burden on vendors. APHL submitted this data element to USCDI+ for the PH Lab Reporting Use case as a corollary to eCR report date element, but it is not visible on the USCDI+ website yet. APHL recommends at a minimum adding these data elements to USCDI to capture Specimen Collection Date/time, Laboratory Test performed data/time, and Report Released date/time as distinct data elements to USCDI V6 to advance the quality and usability of laboratory data.

Medical Record Number	APHL recommends ASTP include the assigning authority with ANY identifier data element (in all HL7 products this is part of the various supported identifier type data type). Thus we propose to update the definition to: "Alphanumeric value that uniquely identifies the patient's health record over time, at minimum within one organization, ideally at the national level, including a means to identify the organization or system that assigned it." Other partners, including CSTE, echoed this recommendation in September 2024 (Comment 14174). APHL made similar comments in September 2024 (Comment 14144). APHL is confident that all EHRs heavily use Medical Record Number and so including it in USCDI V6 should not impose a burden on vendors. Because of its widespread use in EHRs this element should at minimum be elevated to level 2.
Specimen Identifier	APHL requests that ASTP update the definition text to "Alphanumeric value to uniquely (at minimum, within one organization) identify an individual specimen, including a means to identify the organization or system that assigned it. Example includes but is not limited to accession number." APHL made similar comments in September 2024 (Comment 14137), April 2024 (Comment 13836), and September 2023 (Comment 13464) APHL is confident that most EHRs already track and have the capability to assing and also receive Specimen Identifiers, and so including it in USCDI V6 should not impose a burden on vendors. Because of its widespread use in EHRs this element should at minimum be elevated to level 2.
Identifier	APHL recommends ASTP include the assigning authority with ANY identifier data element (in all HL7 products this is part of the various supported identifier type data type). Thus we propose ASTP update the definition to: "Alphanumeric value that should uniquely identify the patient over time - at minimum within one organization, ideally at the national level), including a means to identify the organization or system that assigned it." APHL made similar comments in September 2024 (Comment 14142).

Laboratory Order	The current definition of this data element: “Provider-authored request for the performance of a laboratory test.” is ambiguous. APHL interprets the assignment of LOINC vocabulary as the indication that it is represents the ordered test(s) (not the entire requisition as defined in CLIA), warranting an update to the name to match USCDI+ Laboratory Test/Panel Code (https://uscdiplus.healthit.gov/uscdi?id=uscdi_record&table=x_g_sshh_uscdi_uscdi_elements&sys_id=808c53d81bd5b110f7052f84604bcbb5&view=sp)). We therefore suggest a new name of Ordered Laboratory Test / Panel Code and new definition of ”A code that identifies the test or group of tests (panel) being ordered for the analysis on a specimen derived from humans, animals or the environment, which provide information for the diagnosis, prevention, treatment of disease or assessment of health.” This definition would match the coded version of the CLIA element in §493.1291(c)(4) in CLIA 42 CFR 493.1291 - Test Report (http://www.ecfr.gov/cgi-bin/text-idx?SID=1248e3189da5e5f936e55315402bc38b&node=pt42.5.493&rgn=div5#se42.5.493_11291)). APHL supports the selection of LOINC for Laboratory orders, though not every order may have an appropriate LOINC.