ASTP Assistant Secretary for Technology Policy

REPORT TO CONGRESS

Standards for Electronic Ordering and Reporting of Laboratory Test Results

December 19, 2024

Prepared by:

The Office of the Assistant Secretary for Technology Policy
Office of the National Coordinator for Health Information Technology
United States Department of Health and Human Services
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Statutory Requirement:

- The Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act, or the PREVENT Pandemics Act under Title II of Division FF, Subtitle E of the Consolidated Appropriations Act of 2023 (Pub. L. 117–328), requires the Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology Office of the National to conduct a study to review the use of standards for electronic ordering and reporting of laboratory test results, and submit a report to Congress.

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I. Executive Summary

This report to Congress was prepared in response to the Consolidated Appropriations Act, 2023 (Pub. L. 117-328). The law requires the Office of the National Coordinator for Health Information Technology to conduct a study to review the use of standards for electronic ordering and reporting of laboratory test results and issue a report on its findings with a focus on the following concentration areas:

1. Determine the extent to which clinical laboratories are using standards for electronic ordering and reporting of laboratory test results;
2. Assess trends in laboratory compliance with standards for ordering and reporting laboratory test results and the effect of such trends on the interoperability of laboratory data with public health data systems;
3. Identify challenges related to collection and reporting of demographic and other data elements with respect to laboratory test results;
4. Identify any challenges associated with using or complying with standards and reporting laboratory test results with data elements identified in standards for electronic ordering and reporting of such results; and,
5. Review other relevant areas determined appropriate by the Office of the National Coordinator for Health Information Technology.

The Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology (hereafter ASTP) approached this report by addressing each of the five concentration areas above in sections that detailed each step in a complete laboratory workflow, from ordering through sharing the results with public health agencies. At each stop along the workflow path, the report discusses the adoption of standards for terminology and exchange, the impact of adoption rate on clinical care and on public health action, and the associated challenges with standards implementation. The report also discusses, throughout each section, the challenges with documenting and exchanging complete patient demographic and contact information, and the effects downstream—particularly on public health assessment and action—when that does not happen. Lastly, in each section, the report suggests areas for improvement and a future vision that could be achieved with additional federal authorities and aligned funding to incentivize broader adoption of laboratory terminology and exchange standards across the ecosystem.

Laboratory information is critical to clinical care, population health, public health activities, and clinical research. Healthcare providers rely on laboratory results as an indicator to diagnose and treat patients. The timely and precise reporting of laboratory results enables healthcare providers to make informed decisions, thereby reducing the risk of diagnostic error and enhancing the overall quality of care. Laboratory results are often the primary signal shared with public health agencies to alert them to potential public health events. This information can indicate the emergence of diseases, show local trends on outbreaks, identify hotspots, and provide public health officials the information they need to minimize disease spread through case investigation and contact tracing. Laboratory data are also a critical component of real-world data used in clinical investigations and research to improve healthcare practices. The success of laboratory data exchange can vary based on the ability of a wide range of organizations to share data, including clinicians sending complete demographic and contact information within laboratory orders; the consistent adoption of standards for both terminology and exchange; and the variability in system capabilities.

Despite the importance of laboratory information and the need for seamless, real-time exchange to keep our country healthy and safe, there are many roadblocks today to laboratory data interoperability. While there are federal and state policies related to laboratories and their associated workflows, these do not currently cover all the components needed to solve challenges and drive wider adoption of standards.

This report includes independent research, consultation with subject matter experts, and interviews and input from across the laboratory ecosystem. The report is designed to walk through a laboratory workflow: from clinician order to the laboratory receiving the order and specimen, the testing within the laboratory, the result from the testing, the sending of the result to the ordering clinician, and, when appropriate, the sending of the result to a public health agency and/or to a health information network (HIN). Within each workflow step, the report discusses the systems and standards involved, the challenges with adoption of technology and the relevant standards, the current state of regulation and incentives, and concludes each section with areas for improvement and a vision for the future.

The report proposes several solutions to challenges across workflow steps that have many similarities—a lack of incentives to do resource-heavy upgrades, habitual use of local or custom codes, a delay in the creation and updates of terminology and exchange standards, and a lack of available training and support. Expanding regulatory authority where needed, broadening the scope of current laboratory regulatory programs, and providing incentives and associated support can help address the challenges identified throughout each step. A summary of the proposed Federal solutions is below, and a complete table of solutions can be found in Table. 2 Options for Action.

1. Finalize new ONC Health IT Certification Program (Certification Program) requirements for standardized sending and receiving of laboratory orders and results.

    a. This action could help ensure that systems are capable of sending and receiving laboratory orders and results conformant to common standards. This will better align systems across the ecosystem to advance in tandem.

2. Where legally permissible, include conditions on U.S. Department of Health and Human Services (HHS) grant funding that require use of ONC-certified systems, which reference HHS-adopted standards for laboratory data exchange.

    a. An example of this could be the Centers for Disease Control and Prevention (CDC), as well as other HHS grant making- agencies, introducing grant funding with conditions to use ONC-certified health IT and standards where appropriate. This would help provide incentives for public health laboratories that have not been part of prior incentive programs for advancing health information technology. Upgrading and maintaining laboratory systems and standards can be a resource-intensive lift, and additional funding could help with the costs associated with upgrading and maintaining systems and standards.

3. Invest in efforts to modernize public health laboratory technology and advance standards adoption.

    a. CDC has been making significant investments in both its own systems and by supporting state and local public health laboratory systems. Additional investments could provide an opportunity to build on existing mechanisms and continue to adopt newer functions and standards as outlined in the Certification Program. These investments could help offset costs for state and local public health laboratories with limited resources for technology upgrades.

4. Federal authorities should work together to develop an incentive program for non-hospital-based laboratories.

    a. Federal programs, like the Medicare Promoting Interoperability Program, provide monetary incentives for practices that enable interoperability to eligible providers. The Medicare Clinical Laboratory Fee Schedule, which provides payment for non-hospital-based laboratories, does not include incentives for interoperability practices or technology under current CMS authority. There is opportunity for future programs to support non-hospital laboratories in similar programs that support other providers.

5. The Food and Drug Administration (FDA) should continue its partnership with federal agencies and key stakeholders (including federal, academia, and industry) in the Systemic Harmonization and Interoperability Enhancement for Laboratory Data (SHIELD) collaboration.

    a. The SHIELD program is working to develop a platform to improve the quality and portability of laboratory data, through the innovative harmonization of data standards such as SNOMED Clinical Terms (SNOMED CT) (a standard nomenclature of medical terms) and Logical Observation Identifiers Names and Codes (LOINC) (a standard coding system for identifying health measurements, observations, and documents). More on both terminology standards below. Standardized and harmonized coding could contribute to improving the quality of laboratory data available across the ecosystem to support evidence-based decision making and public health activities.

6. Federal agencies should encourage laboratories and health care providers to participate in the Trusted Exchange Framework and Common Agreement (TEFCA™) to receive more complete and timely laboratory information through a nationwide governance framework for health information networks.

    a. TEFCA has a national scope and reach, includes shared governance, and can facilitate standards-based exchange of laboratory data. This could also allow for laboratory orders and results being available not only for providers for treatment and care purposes, but also to public health agencies (PHAs) and individuals as well. Further, using a single point of connection through this nationwide hub for providers and healthcare organizations could help reduce burden and associated maintenance costs.

II. The Laboratory Ecosystem

Laboratory testing is a critical part of the United States healthcare system. It is estimated that billions of laboratory tests are performed every year.[1] Virtually every person who has received medical care has experienced some type of laboratory testing, whether it is a blood test for cholesterol, sputum analysis for infection, or another form of test. Laboratory test results contribute significantly to clinical care (e.g., diagnosing infections and diseases) to preventive health (e.g., monitoring cholesterol levels and medication effectiveness) and to public health (e.g., aiding analysis of disease prevalence and trends in populations). Consequently, laboratory test results play a role in our healthcare system - every minute, hour, and day.

[1] Centers for Disease Control and Prevention, About DLS. https://www.cdc.gov/csels/dls/about-us.html

Despite the critical role of laboratory data in healthcare, ensuring its accessibility through electronic data exchange remains a significant challenge. For example, over the past decade, there has been a notable rise in the electronic transmission of laboratory results from hospital laboratories to healthcare providers. In 2022, approximately 75% of hospital laboratories were electronically sending their results,[2] a substantial increase from less than a third in 2013.[3] Despite this progress, clinical laboratories still struggle with widespread adoption and consistent implementation of data standards for both content and exchange.

Data standards create a shared understanding of data across systems, which is foundational for timely and reliable access to laboratory data.

Table 1. Health Data Standards

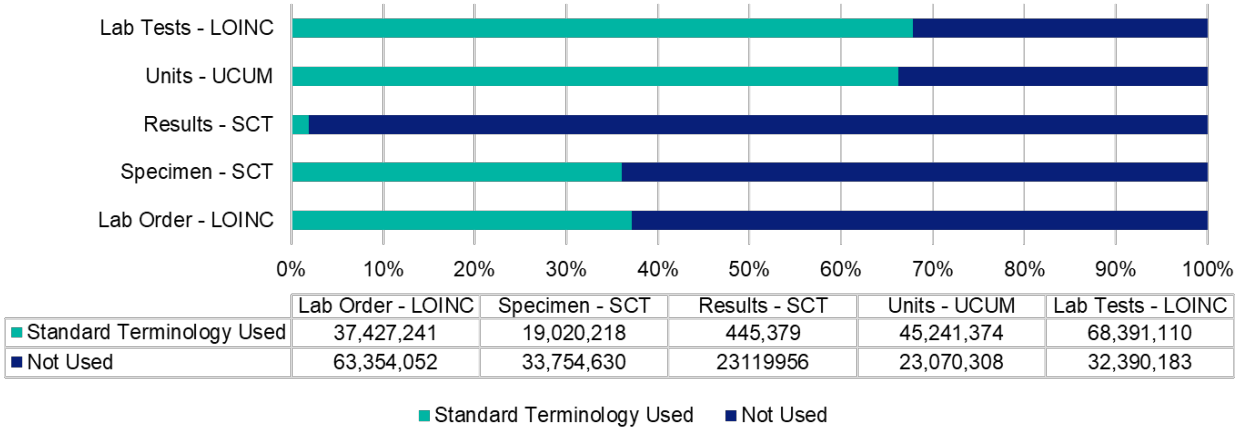
Terminology Standards	Logical Observation Identifiers Names and Codes (LOINC®): Paired concepts and codes used to create shared understanding of tests and measurements.
	SNOMED Clinical Terms (SNOMED CT®): Paired concepts and codes used to create shared understanding of clinical content.
	Unified Codes for Units of Measure (UCUM®): Represents units of measures for unambiguous sharing of quantities and units together.
Exchange Standards	Health Level 7® Version 2 (HL7v2): Defines the structure and organization of health data to facilitate exchange across systems. First released in 1987 and used in 95% of US healthcare organizations.
	HL7 Clinical Document Architecture (CDA®): Defines the structure and semantics of electronic clinical documents for the purpose of exchange.
	HL7 Fast Healthcare Interoperability Resources (FHIR®): Defines the structure and organization of health data and includes specification for an application programming interface (API). First released in 2012 and designed to be easier and less resource intensive to implement than other HL7 exchange standards.

In early 2024, ASTP measured how often electronic laboratory test results are represented with terminology standards using 90 days of deidentified data from participants across different healthcare

[2] Richwine C and Patel V. (2022, October 26). *ONC LOINC Annual Meeting Presentation*. 2022 LOINC Annual Conference, Les Pensières Center for Global Health, Annecy, France and Online. https://loinc.org/conference/france-2022/

[3] Patel V, McNamara L, Dullabh P, Sawchuk ME, Swain M. Variation in interoperability across clinical laboratories nationwide. Int J Med Inform. 2017 Dec; 108:175-184

segments, covering over 100 million laboratory results. The analysis found varied use of terminology standards, with broad use of LOINC to represent the laboratory test performed and Unified Codes for Units of Measure (UCUM) to represent quantitative units. The use of SNOMED CT ("SCT" in Figure 1) was limited, especially for the representation of qualitative laboratory results, at only 1%. Robust use of all these standards is needed to create widespread shared understanding of laboratory tests and results between laboratories, providers, public health, researchers, and more.



	Lab Order - LOINC	Specimen - SCT	Results - SCT	Units - UCUM	Lab Tests - LOINC
Standard Terminology Used	37,427,241	19,020,218	445,379	45,241,374	68,391,110
Not Used	63,354,052	33,754,630	23119956	23,070,308	32,390,183

Figure 1. Use of terminology standards in electronic laboratory test results

Achieving accuracy and efficiency in laboratory data exchange is complex but essential for patient safety.[4] Without the timely transmission of accurate laboratory information, healthcare providers may lack the information they need to make decisions regarding diagnosis and treatment. Incomplete or inaccurate laboratory information could lead to incorrect or missed diagnoses, medication errors and adverse reactions, or a patient's condition worsening due to treatment delays. Furthermore, if this occurs, providers may lose trust in laboratory data and consequently lose an important factor in providing clinical care.

[4] Massachusetts Institute of Technology (MIT). "FDA System Safety within Laboratory Data Exchanges: End of Base Year Report." Department of Aeronautics and Astronautics, MIT, 2023, aeroastro.mit.edu/wp-content/uploads/2023/12/FDA_System_Safety_within_Laboratory_Data_Exchanges_End_of_Base_Year_Report.pdf.

Laboratory tests are a crucial part of medical research and innovation. The 21st Century Cures Act (Pub. L. 114-255) directed FDA to establish programs to evaluate real-world evidence to support new indications for a drug to satisfy post-approval study requirements.[5] Ensuring interoperability of laboratory data is critical for this purpose because studies are combining data generated across different laboratories and health systems.

Laboratory test results are also essential to inform population and public health analyses. PHAs—including state and local health departments—rely on test results from hospitals, doctors' offices, laboratories, and other healthcare facilities to inform a range of public health initiatives. Laboratory diagnostic test ordering is an important indicator of clinical suspicion of a disease on the front lines, and laboratory test results are often a leading indicator shared with PHAs and can alert them to potential public health events. This information can indicate the emergence of diseases, show local trends on outbreaks, identify hotspots, and provide public health officials the information they need to minimize disease spread through case investigation and contact tracing. Laboratory test results were the first indicator in several high-profile outbreaks—Salmonella in peanut butter,[6] Listeria in ice cream,[7] lead in packaged apple sauce,[8] and increased cases of measles in 2019.[9] Laboratory test results also help identify outbreaks before they become more widespread and can aid in the development of vaccines and treatment options, as was the case with Zika and Mpox.

While the COVID-19 pandemic highlighted longstanding complexities in the laboratory reporting ecosystem, work was already underway to address these challenges long before the pandemic increased the volume and stress on an already underdeveloped and underfunded technology infrastructure. Without the existing electronic laboratory reporting (ELR) infrastructure prior to the pandemic, the public health response could have been significantly hampered, leading to delays in data collection and response times. The existing systems not only facilitated the transmission of laboratory results to health departments but also provided a framework to further grow and mature interoperability capabilities that proved invaluable during the public health emergency for COVID-19. This experience underscored the importance of such systems, prompting further expansion and enhancement of the infrastructure to improve future health surveillance and response efforts. Even before the pandemic significantly expanded the amount of testing done in non-traditional sites—like pop-up labs in parking lots to address testing

[5] H.R.34 - 114th Congress (2015-2016): 21st Century Cures Act. (2016, December 13). https://www.congress.gov/bill/114th-congress/house-bill/34/titles

[6] Centers for Disease Control and Prevention, 2022 Salmonella Outbreak Linked to Peanut Butter, https://archive.cdc.gov/#/details?url=https://www.cdc.gov/salmonella/senftenberg-05-22/index.html

[7] Centers for Disease Control and Prevention, Listeria Outbreak Linked to Ice Cream - August 2023, https://www.cdc.gov/listeria/outbreaks/ice-cream-08-23.html?CDC_AAref_Val

[8] Centers for Disease Control and Prevention, Lead and Chromium Poisoning Outbreak Linked to Cinnamon Applesauce Pouches, https://www.cdc.gov/lead-prevention/news/outbreak-applesauce-pouches.html

[9] Centers for Disease Control and Prevention, Measles Cases and Outbreaks, https://www.cdc.gov/measles/data-research/index.html#cdc_data_surveillance_section_1-measles-cases-in-2024

needs—laboratory test results received by PHAs were often missing relevant follow-up data and data necessary for further population stratification, such as patient demographics or contact information. Outdated technology further contributed to data challenges during the pandemic. PHAs often received laboratory results manually by fax and PDF, which left public health officials with time-consuming work to reenter results into their systems and introduced opportunities for error and delays in identifying trends and reporting to federal partners.[10,11]

Further complicating public health reporting for laboratory test results, different states—and sometimes, even counties and cities—have different laws and mandates governing what tests for which conditions are reportable, and how, what, when, and where to report. For example, New York state requires reporting of certain conditions—like measles or syphilis—immediately by phone, while other conditions—including Hepatitis B and C, or toxic shock syndrome—have a twenty-four-hour reporting expectation.[12] The same conditions in other states, however, may have other timelines and expectations. Missouri requires syphilis to be reported within one day to either the local or state health department, and Alabama requires Hepatitis B and C to be reported within three days.[13] Further, only a handful of states require laboratory results reporting using electronic means, and often include exceptions to electronic reporting. California requires electronic reporting of laboratory results, but within that, allows for certain conditions to be sent via comma-separated values (CSV) file in addition to HL7 messages, and still requires phone calls for immediate reporting of certain high-priority conditions.[14] Wisconsin, on the other hand, allows reporting to be done via either electronic means, fax, or mail.[15]

Given the variability in federal, state, and local laws, laboratories and healthcare organizations often develop different workflows and reporting practices, including manual processes, such as filling out paper forms and making phone calls for many reportable conditions. The burden to stay compliant amongst all this variation, particularly for organizations that operate in multiple states, is costly and often leads to delays.[16]

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[10]Faxes and the Coronavirus: How America's Love Affair with an Outdated Technology Complicates the Response to COVID-19, N.Y. Times (2020), https://www.nytimes.com/2020/07/13/upshot/coronavirus-response-fax-machines.html

[11]Council of State and Territorial Epidemiologists. (2019). Driving public health in the fast lane: The urgent need for a 21st century data superhighway. https://cdn.ymaws.com/www.cste.org/resource/resmgr/pdfs/pdfs2/Driving_PH_Print.pdf

[12]New York State Department of Health, Communicable Disease Reporting Requirements, https://www.health.ny.gov/forms/instructions/doh-389_instructions.pdf

[13]Alabama Department of Public Health, Reportable Diseases, https://www.alabamapublichealth.gov/blog/assets/nd-reportable-diseases.pdf

[14]California Department of Public Health, CalREDIE Laboratory Reporting, https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/CalREDIE-Lab-Reporting.aspx

[15]Wisconsin Department of Health Services, Disease Reporting, https://www.dhs.wisconsin.gov/disease/reporting.htm

[16]Council of State and Territorial Epidemiologists. (2019). *Driving Public Health in the Fast Lane: The Urgent Need for a 21st Century Data Superhighway.* ymaws.com/www.cste.org/resource/resmgr/pdfs/pdfs2/Driving_PH_Print.pdf

III. Data Flows Across the Laboratory Ecosystem

Laboratory data flows are complex, involving multiple steps and numerous actors. Even seemingly basic tests – hemoglobin A1C or cholesterol – require all the steps in Figure 2. Given the complexity, there are many opportunities for error along the way, particularly given the various staff, systems, connections, and gaps in applicable requirements at each step. To identify areas to catalyze improvement in laboratory interoperability, the sections below walk through the data journey, the use of data standards, the authorities that apply to standards use, the areas for improvement, and a vision for more seamless data exchange in the future.

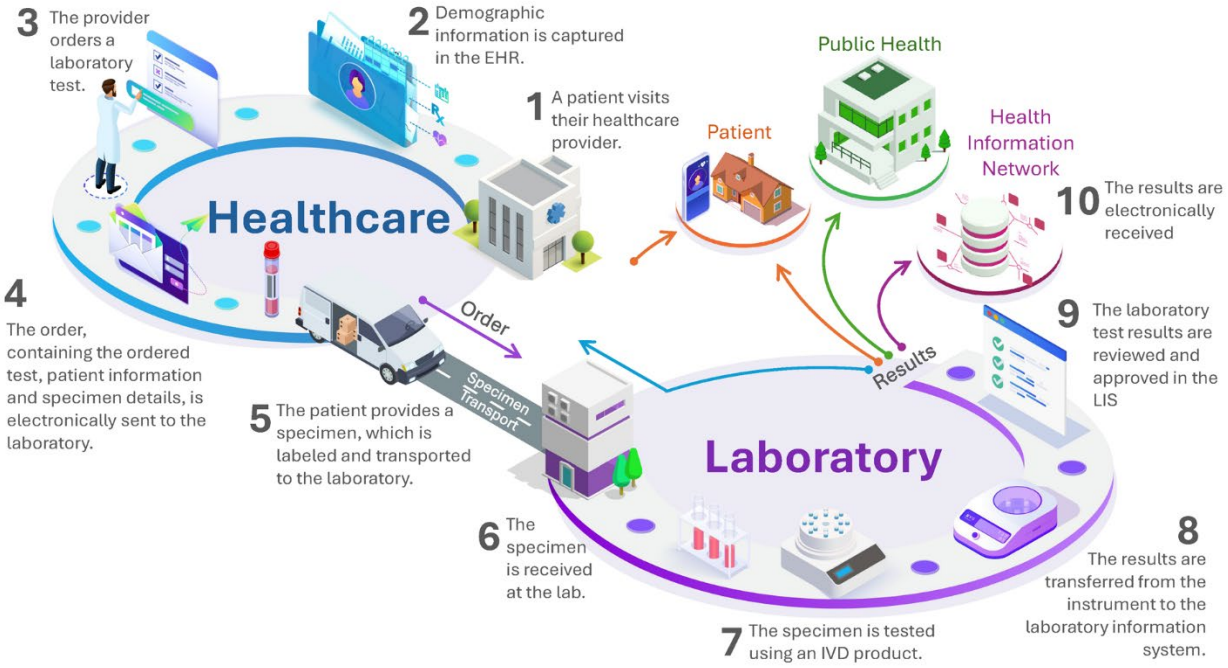

Figure 2. Laboratory Data Flow

Like most other data in healthcare, laboratory data begins its journey through the health system when a person visits their healthcare provider (Step 1). Upon intake, the patient's personal information, including patient demographics, is usually captured and recorded within the provider's electronic health record (EHR) (Step 2). If the patient's healthcare provider determines that a laboratory test is required, the provider may be able to use their EHR to electronically order the test (Step 3) and include necessary details like specimen specifics and patient information (Step 4). In some instances, providers collect specimens (e.g., blood, urine, or tissue) from patients and send them to the laboratory, while in others, patients visit the laboratory for specimen collection (Step 5). After the specimen reaches the laboratory and the order information is received by the laboratory information system (LIS) (Step 6), in vitro diagnostic (IVD) products or laboratory developed tests (LDTs) are used to analyze the specimen (Step 7). Results of the analysis are transferred to the LIS either manually or electronically (Step 8). Once

approved (Step 9), the laboratory test results are shared with the ordering provider, patient, and sometimes PHAs and HINs (Step 10).[17]

A. PROVIDER ORDERS

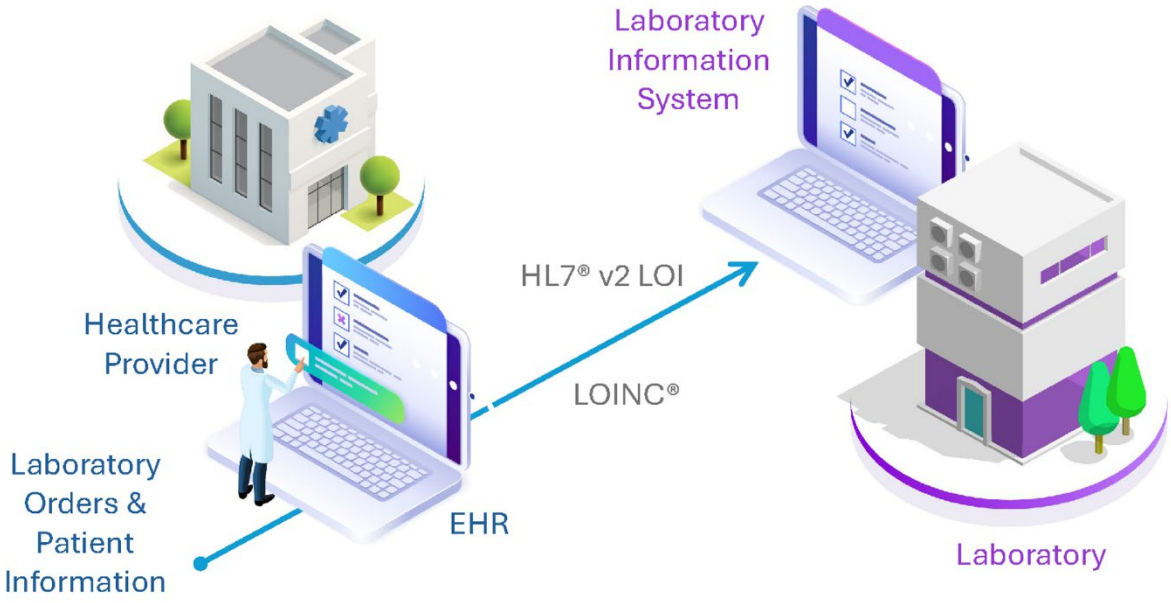

Figure 3. Laboratory Orders. Despite the availability of LOINC and specification HL7 Version 2.5.1 Implementation Guide: Laboratory Order from EHR (LOI)[18], there is little to no adoption of data standards for laboratory orders.

LOINC can be used in the electronic transmission of laboratory orders from the EHR to the LIS; however, the ASTP analysis of standards use[19] and interviews with laboratory leaders demonstrate little to no use of standard terminology in orders. While LOINC can be used as a terminology standard for laboratory orders,[20] providers primarily order sets or panels of laboratory tests, and the numerous possible permutations of these sets make it unrealistic to represent all possibilities.

[17]Figure 2 is intended to represent a general data flow of electronic laboratory order and results, but there are also administrative steps that can affect the movement of data. For example, for tests requiring prior authorization, the administrative process may take place at the clinician office (preferred), but if not completed by the clinician, the laboratory may be required to complete this step in order to be paid by insurance.

[18]Health Level Seven International (HL7). "HL7 Version 2.5.1 Implementation Guide: Laboratory Orders from EHR (LOI) Edition 5 - US Realm" https://www.hl7.org/implement/standards/product_brief.cfm?product_id=152

[19]Appendix C. Measurement of Laboratory Data Standards Use

[20]Regenstrief Institute. (2022, February 22). *Universal Laboratory Order Codes from LOINC*. LOINC. https://loinc.org/usage/orders/

Similar to the minimal use of terminology standards, there is low adoption of the exchange specifications that support the standardization of laboratory orders:

- HL7 Version 2.5.1 Implementation Guide: Laboratory Order from EHR (LOI), which defines structure and organization for laboratory orders sent from EHRs or LIS's to the LIS performing the test.
- HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Test Compendium Framework (eDOS)[21], which enables laboratory test catalogs to be integrated into EHRs to streamline ordering.

During interviews, several laboratory leaders representing different areas of the healthcare ecosystem stated that implementing interfaces for laboratory data exchange requires a large investment of time and resources. Therefore, once systems are in place, there is little incentive to make the changes necessary to stay current. As one academic medical center laboratory personnel stated, "we don't update the… interfaces. Once they are working, they're set and we keep [them] going." Another representative from a large reference laboratory stated, "once you've built it, it [requires] a lot of resource activity to go back and make changes and modify and redo it again."

While national terminology and exchange standards for laboratory orders exist, federal regulatory mechanisms are limited in their ability to require use of these standards. Relatedly, there are no federal requirements to mandate laboratory orders are sent electronically or using specified standards. Without such requirements, laboratories must support a wide range of methods for providers and other ordering clinicians to submit orders, including non-standardized and non-electronic ways. This variability limits potential efficiencies, can delay analysis, and may also have an impact on health equity. Further, research demonstrates that with low adoption of standards for orders, many laboratory orders are missing key patient demographic data.[22]

The HL7 v2 LOI exchange standard includes the exchange of certain patient demographics and information, including race, ethnicity, sex, and contact information. However, despite the value of this additional patient information, these fields are often blank, and the adoption of this standard is low. This is not because providers are not collecting this information—a study conducted from 2005 through 2014 found that address was documented in EHRs 94% of the time and phone numbers 76% of the time; in

[21]Health Level Seven International (HL7), HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Test Compendium Framework (eDOS), Release 2 – US Realm, https://www.hl7.org/implement/standards/product_brief.cfm?product_id=151

[22]Spangler, K.R., Levy, J.I., Fabian, M.P. et al. Missing Race and Ethnicity Data among COVID-19 Cases in Massachusetts. J. Racial and Ethnic Health Disparities 10, 2071–2080 (2023). https://doi.org/10.1007/s40615-022-01387-3

addition, by 2014, email address was available in 54% of cases.[23] Widespread adoption of the LOI standard would reduce variability in interoperable information, and help laboratories receive more complete information—which, in turn, can help ensure more complete information throughout the workflow, and reduce burden on laboratories, public health, and other downstream users related to calling providers or patients to collect missing information. The challenge for providers is not necessarily the collection or documentation of the data, but rather in the costs and associated burden of updating systems to comply with standards that require demographic information. Given that there is no federal or state requirements or incentive to implement new or updated interfaces, there is little drive from laboratories to spend the resources—both time and financial—to replace functional connections with this new standard.

The Certification Program, a voluntary program established in 2010, establishes functional and standards-based certification criteria for health IT.[24] Included in the Certification Program is a criterion for Computerized Provider Order Entry (CPOE) for Laboratory Orders, which specifies functionality for clinicians to electronically enter a laboratory order. However, the criterion does not currently point to a standard for this functionality, and it does not include any associated requirements for submitting the order to a laboratory. Due to feedback from the laboratory community about low adoption of standards-based exchange for laboratory orders, ASTP has proposed as part of the Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) Proposed Rule[25] to update the Certification Program to include the LOI implementation guide as part of the certification criterion for the transmission of orders from certified health IT to laboratories and their respective systems.

ASTP's stewardship of the United States Core Data for Interoperability (USCDI) also influences laboratory data exchange by establishing a baseline set of data classes and data elements that certified health IT certified to particular certification criteria must be capable of exchanging. USCDI defines data elements with respective terminology standards, where appropriate, including several that are important for sending laboratory orders: patient demographics, laboratory tests, and diagnoses, among others.

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[23]Culbertson, A., Goel, S., Madden, M. B., Safaeinili, N., Jackson, K. L., Carton, T., Waitman, R., Liu, M., Krishnamurthy, A., Hall, L., Cappella, N., Visweswaran, S., Becich, M. J., Applegate, R., Bernstam, E., Rothman, R., Matheny, M., Lipori, G., Bian, J., Hogan, W., Kho, A. (2017). The Building Blocks of Interoperability. A Multisite Analysis of Patient Demographic Attributes Available for Matching. *Applied clinical informatics*, *8*(2), 322–336. https://doi.org/10.4338/ACI-2016-11-RA-0196.

[24]Office of the National Coordinator for Health Information Technology, About the ONC Health IT Certification Program. https://www.healthit.gov/topic/certification-ehrs/about-ONC-health-it-certification-program.

[25]Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability Proposed Rule (89 FR 63498), https://www.federalregister.gov/d/2024-14975

The Certification Program is voluntary and depends on corresponding federal programs to drive the adoption and meaningful use of certified health IT and standards through various incentives and payment reductions. Two such programs are the Medicare Promoting Interoperability Program and the Merit-based Incentive Payment System (MIPS) Promoting Interoperability performance category, the successors of the Medicare EHR Incentive Program under the Health Information Technology for Economic and Clinical Health Act (HITECH Act) of 2009 (Pub. L. 111-5). The Medicare EHR Incentive Program initially contributed to widespread adoption of certified health IT, use of standards, and improved electronic exchange among eligible clinicians, eligible hospitals, and critical access hospitals (CAHs). However, to date, the Medicare Promoting Interoperability Program and MIPS Promoting Interoperability performance category have not included measures or other requirements that have directly incentivized the use of standards for the exchange of these orders, as such standards have not been included in certified health IT, as discussed above.

In addition to payment programs, CMS also sets quality standards for clinical laboratories through the Clinical Laboratory Improvement Amendments (CLIA)[26] and its implementing regulations. While CLIA regulations set criteria for quality control, personnel requirements, and categories based on the complexity of tests performed[27], they do not require electronic transmission or receipt of laboratory orders or results and do not reference terminology or exchange standards, such as LOINC and the LOI implementation guide. However, CLIA regulations include general requirements for test requests (i.e., orders) received by the laboratory, which include either a "written or electronic request for patient testing from an authorized person."[28] Further, they require that the laboratory ensure that the test order includes, among other elements, the following information: the name and address of the authorized person requesting the test; the patient's name or identifier; the sex and age or date of birth of the patient; the test to be performed; and any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.[29]

Much like the lack of federal policy requiring electronic exchange mechanisms or standards for laboratory orders, states do not dictate the manner in which clinicians must send orders to laboratories. While states do govern *who* can order laboratory tests via state medical boards or health departments, these requirements do not dictate the mechanism for such ordering. Therefore, while state law or policy may

[26]All laboratories that perform clinical testing reported to the patient's medical record are required to get a CLIA certificate. CLIA assigns each laboratory a category based on the type of clinical laboratory test systems they perform (Provider Performed Microscopy (PPM), waived, moderate, and high complexity). Facilities performing only waived tests must obtain a CLIA certificate, but other CLIA requirements do not apply.

[27]Department of Health and Human Services. 42 CFR 493.1241(a). https://www.ecfr.gov/current/title-42/section-493.1241

[28]Department of Health and Human Services. 42 CFR 493.1241(a). https://www.ecfr.gov/current/title-42/section-493.1241

[29]Department of Health and Human Services. 42 CFR 493.1241(c)(1)-(8). https://www.ecfr.gov/current/title-42/section-493.1241

dictate if nurse practitioners, physician assistants, or pharmacists are legally allowed to place laboratory orders—and which laboratory tests require a provider order—they do not extend to how these orders are placed.

Areas for improvement and vision for the future

Laboratory orders often lack patient demographic and contact information because they typically include only the necessary information to perform, result, and receive payment for a test. Providers generally do not include patient demographic information in laboratory orders, regardless of whether the order is sent electronically or through a paper requisition form.

Additionally, not all LISs are able to receive complete patient demographic information from electronically shared orders. Some LISs only have a single field to store contact information meaning that even if both the provider's and patient's phone numbers are included, only the provider's number can be stored.

The lack of patient demographics and contact information in laboratory orders means that laboratories may not always receive data elements relevant to public health. Consequently, laboratories are unable to include demographics such as race, sex, or occupation in subsequent reportable results, even when the data is readily available in a provider's EHR or other clinical system.

For laboratories to receive information relevant to appropriately resulting specimens according to applicable reference ranges, or for PHAs to receive complete demographic information to perform needed outreach, those data elements must be captured using established national standards at an appropriate "upstream" point (e.g., at admission or intake) and systems must have the technical capabilities of exchanging the data.

State and Federal action and associated incentives, penalties, and enforcement that require consistent implementation of national standards, including complete patient demographic information as required within the LOI specification, can help improve the likelihood that accurate and complete data is available throughout the entire workflow.

B. LABORATORY RECEIVES ORDER AND SPECIMEN

Laboratories receive orders from providers via electronic feeds into their LIS, and/or through portal, mail, phone, or fax. Manual orders need to be entered into LIS, creating an additional step and potential opportunity for error. As discussed above, in addition to the type of test ordered, it may also be important for laboratories to receive patient demographics and information, particularly elements like age and sex, to help identify the patient and to inform the appropriate reference range for laboratory tests. For example, a patient's date of birth is necessary for laboratory tests that have different "normal" ranges based on the patient's age. Additionally, laboratories must follow reporting requirements, that often include patient demographics, when sending results to public health agencies, and these demographics are often only available to the laboratory if sent by the provider.

As discussed above in the context of sending of orders, similarly, today there are no requirements for a laboratory order to be received electronically or that electronic submissions to a laboratory must conform to a specific national standard. When it comes the receipt of orders, CLIA's implementing regulations require certain processes and quality control measures, as well as the collection of certain data elements—including patient identification information, test name, reference range, and more[30]—it does not point to or mandate the use of terminology standards or exchange standards, such as LOINC and the LOI implementation guide, for the collection, receipt, or exchange of these elements.

Areas for improvement and vision for the future

The Certification Program has certification criteria that cover the sending or transmitting of information, such as medication prescriptions, as well as accompanying requirements for certified health IT to receive information. In the HTI-2 Proposed Rule, ASTP proposed updating the Certification Program to include a new certification criterion for the receipt of electronic laboratory orders adhering to the LOI standard focused on public health information systems. This would be in alignment with the proposed certification criterion for documenting and sending orders. However, this alone would likely not move the needle due to the voluntary nature of the Certification Program. To move the needle, state and Federal action and associated incentives, penalties, and enforcement—which should require consistent implementation of national standards—would need to accompany Certification Program criteria to make a substantial difference in the laboratory ecosystem. Doing so would result in orders that laboratories receive being more complete, timely, and more easily able to be ingested and processed within their systems.

[30]Department of Health and Human Services. 42 CFR 493.1241(a). https://www.ecfr.gov/current/title-42/section-493.1241

C. TESTING WITHIN THE LABORATORY

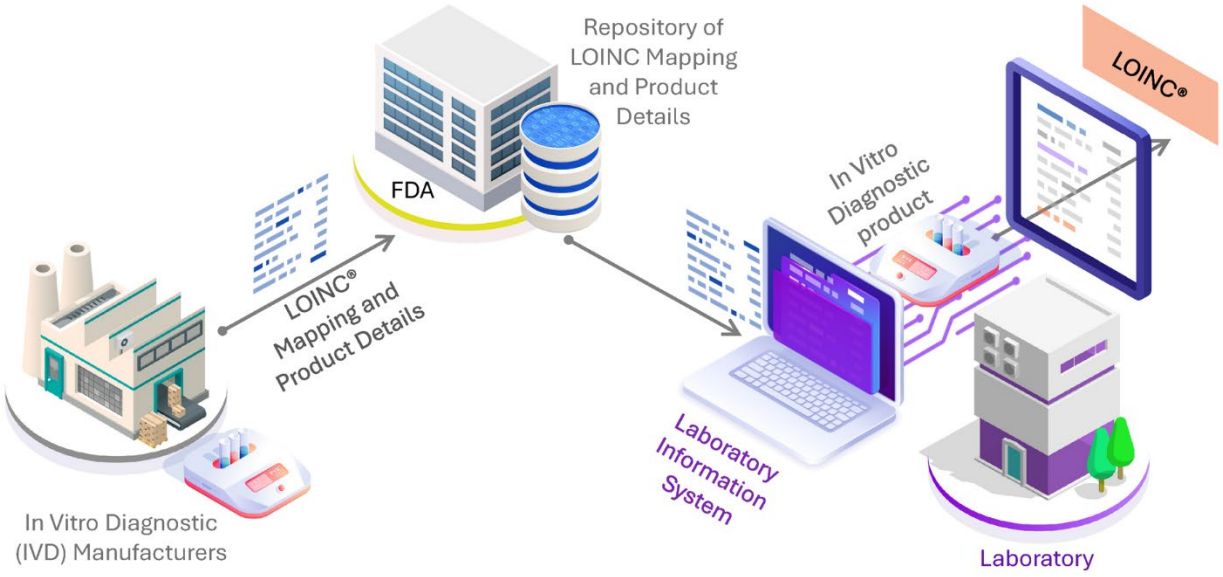

Figure 4. Laboratory Mapping. In response to the public health emergency, the Coronavirus Aid, Relief, and Economic Security (CARES) Act required all SARS-CoV-2 laboratory testing to be reported to the United States Health and Human Services (HHS) using the terminology specified in the LOINC In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests[31]. Currently, LIVD is also available for Lyme Disease, HIV, and Monkeypox testing, but beyond the mandated SARS-CoV-2 use-case, there is very little reported adoption of the LIVD Implementation Guide.

Every laboratory has a catalog of tests they can perform based on the type of diagnostic devices and resources in the laboratory. Laboratory personnel use diagnostic devices to prepare and examine specimens taken from the patient.[32] Each laboratory test is performed to answer a question(s) about a patient, such as measuring the level of cholesterol in a patient's blood. The answers may be numeric (i.e., quantitative), like a cholesterol measurement, or qualitative, like the color of urine or the name of bacteria present in the specimen.

[31]COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115. Department of Health and Human Services. January 8, 2021. https://cd2h.org/node/324

[32]U.S. Food and Drug Administration, Overview of IVD Regulation, https://www.fda.gov/medical-devices/ivd-regulatory-assistance/overview-ivd-regulation

To enable interoperability, laboratory and LIS personnel assign (or map) the tests in a test catalog to terminology data standards (see Table 1. Data Standards). Consistent with HHS adopted standards, the laboratory test performed is assigned a LOINC code, the descriptive qualitative test result is assigned a SNOMED CT code, and the quantitative tests results are reported with a standardized UCUM unit.

However, mapping the laboratory tests catalog to standard LOINC codes is a complex and time-consuming task, often prone to human error. This process requires a deep understanding of the LOINC model, including the LOINC naming rules and multiaxial hierarchy.[33] The LOINC naming model uses specific acronyms, such as MFr for mass fraction, and naming conventions, such as using the species name for allergy tests (e.g., Brazil nut is *Bertholletia excelsa*). LOINC creates different concept codes for each type of method used to conduct a test, and LOINC creates codes without a specified method that can be used when the method is unknown. Although both a method-specific code and a method-less code may be technically correct, different organizations may have incongruent policies for applying these codes. Even with extensive knowledge and training, laboratories may map their local codes to LOINC differently due to LOINC's varying levels of granularity. Studies of accuracy of LOINC mapping vary greatly; some reporting error rates of less than 5%[34,35] and others reporting error rates of up to 40%.[36]

Laboratory representatives described challenges with LIS systems supporting terminology standards. One laboratory representative reported that LISs were not "designed to support standards that didn't exist when they were built." As reported in a 2023 compendium of LISs by the College of American Pathologists (CAP), LIS capabilities to support laboratory data exchange using standardized formats vary, with most providing a field in each test definition for LOINC codes (95%) and about three-quarters of LISs supporting the use of SNOMED CT for qualitative answers. Given this, the majority of LISs have the *capability* to support LOINC and SNOMED CT; however, there are not requirements or standardized approaches for the implementation of these terminology standards.[37] Understanding the barriers to consistent implementation and use of data standards can help inform Standards Development Organizations (SDO), such as HL7, about unmet needs and how they can help.

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[33]LOINC Users' Guide; https://loinc.org/kb/users-guide/; 2024

[34]Lin, M. C., Vreeman, D. J., McDonald, C. J., & Huff, S. M. (2010). Correctness of Voluntary LOINC Mapping for Laboratory Tests in Three Large Institutions. AMIA ... Annual Symposium proceedings. AMIA Symposium, 2010, 447–451.

[35]McDonald, C. J., Baik, S. H., Zheng, Z., Amos, L., Luan, X., Marsolo, K., & Qualls, L. (2023). Mis-mappings between a producer's quantitative test codes and LOINC codes and an algorithm for correcting them. Journal of the American Medical Informatics Association : JAMIA, 30(2), 301–307. https://doi.org/10.1093/jamia/ocac215.

[36]Stram, M., Seheult, J., Sinard, J. H., Campbell, W. S., Carter, A. B., de Baca, M. E., Quinn, A. M., Luu, H. S., & Members of the Informatics Committee, College of American Pathologists (2020). A Survey of LOINC Code Selection Practices Among Participants of the College of American Pathologists Coagulation (CGL) and Cardiac Markers (CRT) Proficiency Testing Programs. Archives of pathology & laboratory medicine, 144(5), 586–596. https://doi.org/10.5858/arpa.2019-0276-OA

[37]College of American Pathologists (CAP). "Laboratory Information Systems: 2023." CAP Today, www.captodayonline.com/laboratory-information-systems-2023/.

Laboratories have also experienced difficulty in utilizing terminology standards due in part to the protracted timelines to issue codes for new tests. As science evolves, laboratories add new tests to their catalogs, necessitating the creation of new LOINC codes that LIS and other vendors then need to make available in the system. Laboratories have reported that this process can take up to half a year or more to update both the data standard and the health IT system using the standard—creating a lag between the availability of a new laboratory test and a standardized way to order that test.

When terminology development lags months behind the need for new codes in health IT systems, data quality suffers. During the COVID-19 pandemic, LOINC and SNOMED joined a small group of experts from CDC, FDA, and industry to review emerging testing techniques and rapidly create new codes. In fact, LOINC was able to create and publish new codes within a matter of days, in some cases. These codes were made available almost immediately via an emergency release of the new standards. The ability to respond quickly during an emergency demonstrates that the capacity for timely turnaround exists when appropriate resources are dedicated to do so.[38] Leveraging these lessons learned, there is an opportunity for terminology standards development organizations (SDOs) and Federal authorities to collaborate to develop a rapid response process for public health and patient safety needs.

ASTP's analysis of laboratory standards adoption indicates that although LOINC is widely adopted across systems exchanging laboratory test results, the extent of LOINC utilization varies significantly (see Figure 5).

[38]LOINC, Annual Report 2020, https://loinc.org/annual-reports/year-2020/

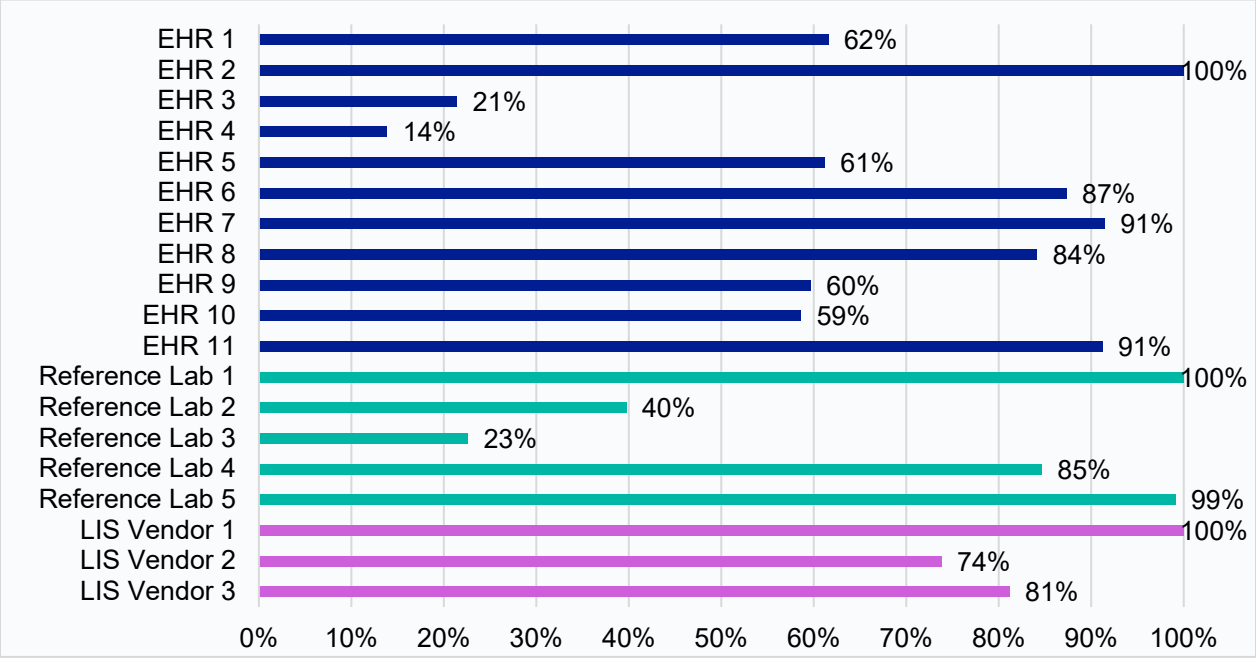

Figure 5. Laboratory Tests Assigned a LOINC Code Across Source Type[39]

The FDA's role in health information technology centers around ensuring the safety and effectiveness of medical devices, including in vitro diagnostic products (IVDs). FDA ensures that IVDs generate test data that meets the standards for reasonable assurance of safety and effectiveness, including validation that the IVD test systems are generating and providing accurate results, and post-market surveillance address issues or adverse events that are discovered after initial approval. However, FDA does not regulate subsequent transmission and exchange of those data.[40]

FDA regulation is meant to reasonably assure the safety and effectiveness of IVD devices, which can include ensuring that the data generated is sent in a way that can be interpreted by other systems, as appropriate for a given device's technology or intended use. While FDA does not require a specific coding system for IVD tests, FDA strongly encourages the use of consensus standards for coding of IVD tests and specifically recognizes the utility of LOINC for this purpose.[41] FDA also supports the efforts by federal and non-federal partners to improve the standardization of laboratory data. For example, FDA is collaborating with federal partners on the LOINC In Vitro Diagnostic (LIVD) Test Code Mappings. The LIVID files, maintained by the CDC in collaboration with federal partners, map the device identifier to appropriate LOINC and SNOMED CT codes. FDA also supported development of the HL7 FHIR Implementation Guide: LOINC – IVD Test Code (LIVD) which can be used by IVD software systems to implement these mappings[42].

[39]Appendix C. Measurement of Laboratory Data Standards Use

[40]According to the 21st Century Cures Act, software functions that transfer, store, convert formats, or display medical device data are not FDA regulated medical devices. See: https://www.fda.gov/media/88572/download

[41]Logical Observation Identifiers Names and Codes for In Vitro Diagnostic Tests | FDA

[42]Health Level Seven International (HL7), LOINC – IVD Test Code (LIVD) Mapping. 0.3.0 https://build.fhir.org/ig/HL7/livd/

FDA would support the use of a more computable, comprehensive, and agile evolution of the LIVD mappings, including the unique device identifier (UDI), as well as several other pertinent data elements (e.g., specimen ID, units of measure, etc.). If adopted nationwide as a standard for laboratory data transfer, this evolved LIVD form would ensure that laboratory test results are more consistently encoded by linking each test result to the IVD device that was used to generate it, leading to improved public health analytics, patient safety, and real-world data quality.

The Shield Collaborative Community is comprised of key stakeholders from more than 70 organizations (including federal, academia and industry) from across the laboratory data ecosystem to build, implement, and support a comprehensive solution that addresses clinical and semantic device interoperability of IVDs across the nation. Continued investment in these community partnerships could contribute to the adoption of a definitive reference source for laboratories when choosing which code to use for a given test and would tie those codes in with a variety of specimen, analyte, and other granular details that existing standards (e.g., LOINC or SNOMED CT) do not currently represent.

The Certification Program requires the use of USCDI in interoperable data exchange certification criteria. Associated terminology standards like LOINC, SNOMED CT, and UCUM are identified for certain data elements—and in the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Final Rule, ASTP established that as of January 1, 2026, USCDI v3 will be the only USCDI version required within the Certification Program. USCDI v3 identifies applicable terminology standards for documenting and exchanging relevant laboratory data elements. For example, USCDI v3 includes laboratory tests as a data element, and identifies LOINC version 2.72 as the applicable vocabulary standard for that data element.[43]

Areas for improvement and vision for the future

HHS and other partners across the care continuum should facilitate the adoption and improved use of terminology standards, including:

- Move the assignment of tests to standard LOINC, SNOMED CT, and UCUM codes to the IVD manufacturers;
- Support SDOs to develop standards and resources for LIS to relate local codes to standard terminology including more timely processes for new codes; and,
- Incentivize complete and accurate standards adoption.

[43]Office of the National Coordinator for Health Information Technology, United States Core Data for Interoperability (USCDI) Version 3, https://www.healthit.gov/isp/taxonomy/term/676/uscdi-v3

Move upstream: Moving the assignment of standard terminology to the IVD manufacturers that develop the test could reduce coding errors, reduce burden on laboratories, and increase data quality. When IVD manufacturers provide the LOINC, SNOMED CT and UCUM codes in a definitive reference source for encoding guidance (e.g., LIVD specifications or similar), laboratory personnel and laboratory applications will have standard terminology information from the most upstream source, the creator of the test.

Support SDOs: To be effective, health data standards need to evolve with the ecosystem over time. Continued, predictable funding for the SDOs that create the terminology standards LOINC and SNOMED CT, Regenstrief Institute and SNOMED International respectively, allows standards to grow and adapt and aid in the development of tools to support users. For example, Regenstrief Institute has begun creating a standard process for rapidly developing LOINC codes to meet urgent needs, similar to the one used for COVID-19.

Incentivize standards adoption: Lowering the complexity of standards is likely not enough to sufficiently increase the comprehensive and accurate application of terminology standards. For widespread improvement in the accurate encoding and transmission of laboratory data, HHS agencies may need to implement policy changes, coordinate regulatory activities, and consider financial and non-financial incentives to lower barriers to laboratory use of standards.

For example, CLIA's technical standards and laboratory practice guidelines do not currently require the use of health data standards. Mandated use of terminology standards and best-practice guidelines for training and relating local codes to standard terminology would catalyze growth in accurate and consistent LOINC, SNOMED CT and UCUM use. Additionally, as discussed above, a program similar to the Medicare Promoting Interoperability Program that focuses on laboratories could drive LIS developers to better enable the use of health data standards in their products.

These efforts in laboratories and LISs would necessitate a mechanism to assess and monitor the use of data standards in the laboratory ecosystem. Standards testing tools can enable systems to check how well they have assigned and used standard terminologies and allow regulators and accreditation organizations to evaluate performance.

D. LABORATORY RESULTS

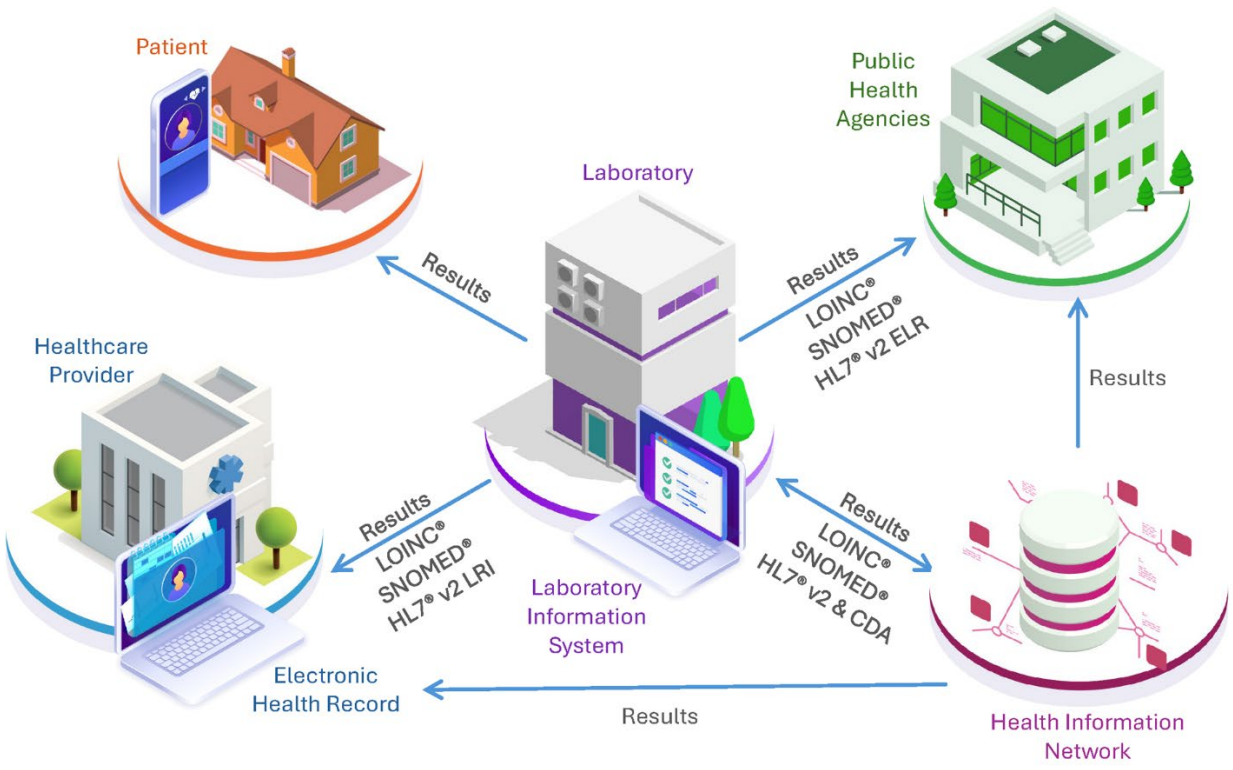

Figure 6. Laboratory Results. The terminology standards LOINC and UCUM are widely adopted by provider and laboratory organizations. SNOMED CT, recommended for reporting qualitative laboratory test results, shows low uptake and laboratories report insufficient LIS capabilities for using SNOMED CT. Regarding exchange standard adoption, Health Level 7 Version 2 (HL7v2) and Consolidated Clinical Document Architecture (C-CDA) is used extensively across the ecosystem. EHRs have moderately implemented the HL7v2 Implementation Guides included in the Certification Program, including HL7 Version 2.5.1 Implementation Guide: Laboratory Results Interface (LRI), and HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting (ELR) to Public Health.

After completing the testing and assigning a standard code to the results, the laboratory packages the results into various formats to send the information to the ordering provider[44] and, if applicable, the patient, public health agencies, or health information networks. CLIA regulations regarding test reports require that laboratories have systems in place to ensure test results and other patient-specific data are

[44]ASTP recognizes that providers performing tests under a Certificate of Waiver (COW) may themselves be considered “laboratories" under CLIA regulations. For simplicity, however, we are focusing on the most common flow of laboratory information.

accurately, reliably, and in a timely manner sent from the point of data entry to final report destination.[45] However, they do not require that those systems be electronic, or that laboratory results sent electronically conform to specific exchange standards. In addition, CLIA requirements for the content of the test report are limited to a minimum set of elements needed for accountability, attribution, and results interpretation.[46]

The attribution of qualitative results (e.g., "positive," "present," or "Staphylococcus aureus") to SNOMED CT can create shared understanding of the result and reduces the burden of manual review. For example, the results "positive" and "negative" may be represented very differently between organizations—one organization might use "detected" and "not detected," while another might use "positive" and "negative."

There are two HL7 implementation guides that could be used when sending laboratory results depending on the use case: electronic laboratory reporting to public health (ELR), or laboratory results interface (LRI). As the name suggests, the ELR implementation guide is specified for sending results to PHAs, while LRI has flexibility about the recipient. While these implementation guides are included in Certification Program criteria, there are no programs that incentivize or require non-hospital based laboratories to use certified health IT in the way that programs incentivize and require providers to use certified EHRs. As a result, there is only moderate adoption of these implementation guides.

Sending results to providers

Each recipient of the laboratory results may have different capabilities to receive electronic information, and the laboratory's technical capabilities may limit the ways in which they transmit results. An academic medical center laboratory pointed to this challenge becoming larger for them. Because laboratories are working with more EHRs—especially small practices using a variety of different EHRs—and as they try to transition from faxing of laboratory reports to electronic exchange, they find that they are creating multiple interfaces. One laboratory specialist share that it would be nice to be able to have… some kind of generic interface that we could set up that we don't have to… recreate each one specifically for each location. [Effectively] the more integrated we become, the more work that ends up being [to create and maintain]." When point-to-point interfaces are in place, the resource lift needed to update all of the individualized connections is so high that the benefit of the updates is often not worth the lift—particularly without any requirements or incentives to do so.

Certain healthcare provider types, such as skilled nursing facilities, did not receive incentives similar to the incentives provided under the Medicare EHR incentive programs for eligible hospitals, CAHs, and

[45]Department of Health and Human Services. 42 C.F.R. § 493.1291(a). https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493#493.1291

[46]Department of Health and Human Services. 42 C.F.R. § 493.1291(c). https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493#493.1291

eligible clinicians, which required use of ONC-certified health IT to receive incentive payments. These providers are more likely to use methods like fax and phones for receiving laboratory results. Similarly, some laboratories may use fax and phone to send laboratory test results due to the high cost of electronic systems or because they primarily serve healthcare organizations that do not receive results electronically.

Sending results to PHAs

There are more requirements regarding the sending of laboratory *results* for reportable public health conditions than there are for sending or receiving laboratory orders. However, the scope and enforcement of these requirements are minimal, and variability remains in the implementation of the existing standards. Currently, the Certification Program certifies health IT to have the functionality to electronically transmit reportable results to PHAs,[47] adhering to the ELR standard for exchange and using LOINC and SNOMED CT terminology.

Conditions that are reportable to PHAs through laboratory results include infectious diseases, respiratory illnesses, sexually transmitted infections, and other conditions that could have public health consequences. Reportable conditions are driven by state law, and there may be variations across the country. Examples include tuberculosis; Hepatitis A, B, and C; syphilis; measles; rabies; and foodborne illness.

There are plenty of laboratory tests that are *not* reportable. Standard blood tests taken at annual physicals, lipid panels, thyroid tests, A1C—these are commonly performed lab tests that do not need to be reported to PHAs.

Currently, federal regulatory mechanisms are limited in their ability to set requirements for how non-reportable laboratory results are exchanged. While there are policies that require laboratory results be made available to the ordering provider and to the patient, these do not mandate the *how.* This means laboratories are not required by Federal or state law to use terminology or exchange standards when sharing laboratory results with providers or patients.

Providers to PHAs

The Medicare Promoting Interoperability Program has long included a measure for eligible hospitals and CAHs to attest that they are in “active engagement” with a PHA to submit electronic laboratory results. CMS has taken steps to strengthen the impact of this measure in recent years, moving the measure from optional to required, increasing the overall point value associated with meeting measures under the public health and clinical data exchange objective, and limiting the time that eligible hospitals and CAHs can remain in pre-production and validation stages to one year.[48] As part of its Fiscal Year 2025 Hospital

[47] Department of Health and Human Services. 45 CFR 170.315(f)(3). https://www.ecfr.gov/current/title-45/section-170.315. See also, https://www.healthit.gov/test-method/transmission-public-health-agencies-reportable-laboratory-tests-and-valueresults.

[48] See program resources, including measure specification sheets, at https://www.cms.gov/medicare/regulations-guidance/promoting-interoperability-programs/resource-library.

Inpatient Prospective Payment System and Long-Term Care Hospital Prospective Payment System Notice of Proposed Rule-Making, CMS issued a Request for Information describing goals and principles for the Medicare Promoting Interoperability Program's Public Health and Clinical Data Reporting objective and soliciting feedback in response to a series of questions related to that objective and related topics.[49]

Under its Public Health Laboratory Electronic Test Orders and Results initiative (ETOR), CDC is collaborating with the nation's public health laboratories (PHLs) and other partners to build a technical architecture that uses a centralized platform for receiving test orders in different formats from many healthcare facilities and routing these to public health laboratories. This same infrastructure will be used to return test results back to providers quickly and seamlessly.

Laboratories to PHAs

While CMS's recent actions represent important progress, under current statutory authority, current programs do not include non-hospital-based laboratories (e.g., commercial and/or reference laboratories) and only include certain eligible clinicians, eligible hospitals, and CAHs, thereby reducing the volume of laboratory transmissions affected by this regulation. While there are state regulations that require laboratories to transmit reportable laboratory values and results, these requirements do not often require the use of electronic mechanisms nor mandate terminology or exchange standards. Given that laboratories are neither addressed through incentive programs nor required to adopt electronic, standards-based reporting to PHAs, that reporting happens using a variety of mechanisms: electronically utilizing HL7 standards, web portal entry, fax, mail, or phone.

Reporting to CDC

In addition to providers and laboratories reporting to local and state PHAs, CDC also receives laboratory results for certain reportable conditions. For example, in public health emergencies, or for certain nationally reportable conditions, CDC will receive laboratory results either from states, or in some cases, hospitals or laboratories directly (with personal identifiable information removed). Depending on the disease category, information is submitted to different CDC programs, such as the National Syndromic Surveillance Program (NSSP) and the National Health Safety Network (NHSN). While CDC recommends the use of standardized terminologies and electronic reporting to these and other systems, it is not mandated.

Areas for improvement and vision for the future

Laboratories and providers have state requirements to send reportable results to PHAs, but many laboratories—and PHAs—struggle with the costs and burden associated with using electronic exchange

[49]Centers for Medicare & Medicaid Services, FY 2025 Hospital Inpatient Prospective Payment System (IPPS) and Long-Term Care Hospital Prospective Payment System (LTCH PPS) Proposed Rule - CMS-1808-P Fact Sheet, https://www.cms.gov/newsroom/fact-sheets/fy-2025-hospital-inpatient-prospective-payment-system-ipps-and-long-term-care-hospital-prospective

and the most updated standards. Even where standards have been implemented and electronic exchange is in place, variability in implementation and usage of data elements and standard terminologies create additional burden in implementation and maintenance.

Laboratories and public health agencies need similar incentive programs to clinicians and hospitals—or to be incorporated into existing programs—to aid in the implementation, adoption, and maintenance of certified systems that use electronic exchange with the most up to date national standards. Similarly, laboratories and public health agencies need training and technical assistance to implement certified systems and follow implementation guides, all of which could help contribute to more consistent, timely, and complete transmission of laboratory results and values to PHAs. Further, as Federal requirements and incentives are rolled out, states could also work to align their own reporting requirements to support the same standards-based electronic exchange.

Correspondingly, functions and capabilities need to be expanded in the Certification Program to ensure that all components of the laboratory reporting workflow are covered.[50] As part of this approach, ASTP recently proposed certification criteria that require both the electronic exchange and receipt of laboratory orders that adhere to consistent terminology and exchange standards. Additionally, in the HTI-2 Proposed Rule, ASTP proposed to expand the Certification Program to include a similar proposal for laboratory results—both the exchange *and* the receipt of results that adhere to the same terminology and exchange standards.

E. ORDERING PROVIDER RECEIVES LABORATORY TEST RESULTS

Healthcare providers use laboratory test results to make clinical decisions, including assigning a diagnosis, initiating treatment, or determining other tests to perform. Coded laboratory data enables features of EHRs that improve patient care and safety and reduce costs and provider burden. Examples include graphs of the patient's previous results, tools that alert clinicians to best practices, and AI-based decision support technologies. Providers and researchers may also use laboratory test results to learn about groups of patients for research purposes or to inform care practices. In those cases, patient data is aggregated and patient identifying information is removed.

These uses of laboratory test results are predicated on the data being of high quality and trustworthy. Inconsistencies and potential errors in encoding upstream can lead to downstream patient care impacts, such as the misinterpretation of test results critical for diagnosing and treating medical conditions. For example, incorrect data encoding might result in the wrong medication being prescribed or the wrong dosage being administered, potentially causing adverse reactions or ineffective treatment. These errors can further propagate through EHRs, affecting other clinical decisions made by healthcare providers. This

[50] Department of Health and Human Services. 45 CFR 170.102. https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-D/part-170/subpart-A/section-170.102

not only compromises patient safety, but also undermines the trust in healthcare systems, leading to increased costs due to the need for additional tests and treatments to correct initial errors.

While there are both federal and state regulations that cover other components of receiving results—particularly around privacy and security—they do not include requirements around the technical functions of providers receiving results from a laboratory or ensuring the quality and consistency of the result data[51].

Patient Safety Concern: A 2014 case study showed that a woman was misdiagnosed with a liver condition and prescribed unnecessary medication due to conflicting test results from multiple laboratories. Upon further investigation, clinicians discovered that the local hospital, regional reference laboratory, and national reference laboratories all used different instruments, test kits, and reference ranges tests for tests with the *same name*, but this granular data was not included in the exchange with the patient care team. This case highlights an instance in which inclusion of critical data elements aligned with interoperability standards may have helped to prevent unnecessary testing and ensured appropriate patient care.[52]

As mentioned in the prior section about laboratories sending results, ASTP has proposed new certification criteria for health IT that will encompass the electronic *receipt* of laboratory results according to standards (specifically, the LRI implementation guide). This proposal could help drive the industry to more consistently adopt standards-based exchange and potentially help improve the completeness of the information included in results received by providers, patients, and PHAs. This program update, when accompanied with the others discussed above, will cover the functions across laboratory workflows—covering the sending and receipt of both orders and results, according to the same standards for terminology and exchange.

Areas for improvement and vision for the future

The Certification Program is a voluntary program, making it necessary to align federal incentives and requirements to drive widespread adoption. Much like the Medicare Promoting Interoperability Program for eligible hospitals and CAHs, laboratories will need to be incentivized, and have these requirements enforced, through similar mechanisms. For example, EHR reporting programs could be extended to laboratories, tied to payment under the Medicare Clinical Laboratory Fee Schedule, and require use of certified Health IT Modules. Federal funding earmarked for laboratory standards and improved

[51] H.R.34 - 114th Congress (2015-2016): 21st Century Cures Act. (2016, December 13). https://www.congress.gov/bill/114th-congress/house-bill/34/titles

[52] John R Mills, Dina N Greene, James Bainton, Thomas S Lorey, Nikola A Baumann, Fluctuating Serum Aspartate Aminotransferase Activity in a Complicated Pregnancy, Clinical Chemistry, Volume 61, Issue 10, 1 October 2015, Pages 1241–1244, https://doi.org/10.1373/clinchem.2014.228247

interoperability could create levers to ensure that laboratory results are being exchanged and received using terminology and exchange standards.

F. PUBLIC HEALTH AGENCY RECEIVES LABORATORY TEST RESULTS

Laboratories are required by local, state, and federal regulations to share specific types of reportable test results with public health agencies. Public health agencies use health information, including laboratory test results, to monitor and support population health, and conduct case investigations.

Standards for the transmission of electronic laboratory results to PHAs is the area where there is the most Federal and state regulation today. However, it has been one-sided: it covers the systems and the users that *send* results to PHAs. There are no Federal requirements today that cover the corresponding requirements for how public health systems *receive* laboratory results.

PHAs use laboratory results to initiate case investigations, conduct contact tracing, understand disease spread, and identify potential outbreaks before they escalate. If results are faxed, mailed, shared over a phone call, or entered through a portal, public health officials may need to manually enter the results into their systems—where they can then perform case investigations and perform analysis, among other outreach. Manual work is expensive, creates additional opportunities for error, and is slower, all of which could negatively affect public health outcomes and follow-ups. The delays introduced with non-standardized reporting mechanisms can cause public health officials' understanding of pandemics or other health issues to lag their real-time effects. This, in turn, presents challenges for making informed decisions on quarantines, public education campaigns, school closures, reopening after a pandemic, and many other essential public health decisions. In many outbreaks, time is of the essence, and it is vital to get results into systems, with complete information, in as near real-time as possible.

In addition to delays in receiving and entering these data, public health officials also are often left with missing information that they must find through other sources to do their jobs. Laboratory results are often missing demographic information, as well contact information like phone number, email, or address, that are needed for contact tracing, and are also important components for patient matching. Research found that such demographic information was missing in 40% of COVID-19 results, and prior to the pandemic, patient's phone numbers were found to be missing in over half of laboratory reports.[53,54] Race and ethnicity data are also commonly missing in laboratory reports: one study found race was missing more

[53]HealthIT.gov. (2020, July 1). Health IT Advisory Committee (Meeting transcript). https://www.healthit.gov/hitac/events/health-it-advisory-committee-29

[54]B. Dixon et al., "Electronic Health Information Quality Challenges and Interventions to Improve Public Health Surveillance Data and Practice," *Public Health Reports* 128, no. 6 (2013): 546-53, http://europepmc.org/article/PMC/3804098.

than one-third of the time, and ethnicity was present less than one-fifth of the time.[55] Without race and ethnicity data, health inequities in communities will remain unidentified, and can create further disparities in health outcomes. Further, without race and ethnicity data, resources may not be adequately allocated to the communities that need them the most. Using standards-based exchange for sending orders (LOI) and receiving results (ELR or LRI) could help improve completeness of demographic and contact information, as the implementation guides for these standards require these critical data elements.

Another component to issues related to receipt, delays, and missing data is that many PHA systems—including those that receive and monitor laboratory results—often lack basic electronic functionalities needed to receive and process results. PHAs and the systems they use have not had adequate funding to support training, technical assistance, upgrades, or implementation of new systems that include capabilities for electronic receipt and exchange.

In an effort to address the above, the federal advisory committee that makes recommendations to the National Coordinator, the Health Information Technology Advisory Committee (HITAC), convened a Public Health Data Systems Task Force in 2021 and 2022 to develop recommendations on how to modernize public health infrastructure and improve interoperability among public health, healthcare, and laboratories. The 2021 Task Force recommended the inclusion of "certification of information systems for both senders and receivers" for public health data.[56] The 2022 Task Force built on this recommendation, and further endorsed establishing certification criteria that focused on improving interoperability through electronic, standards-based exchange.

CDC's Advisory Committee to the Director (ACD) similarly recommended that a certification program for health IT for public health would help address core problems with data infrastructure and exchange.[57] The ACD recommendations included that CDC and ASTP should work together to develop and implement an approach for certifying health IT for public health, grounded in the use of shared data standards. Both the ACD and the HITAC recommendations highlight the need to develop standards-based requirements to improve the availability and exchange of data for both clinical care and public health purposes.

These recommendations informed the proposed Certification Program updates and additions discussed previously. While the additional certification criteria proposed in the HTI-2 Proposed Rule encompass *all* laboratory orders and results, regardless of if they are required to be reported to a PHA, there is also a

[55]Electronic health information quality challenges and interventions to improve public health surveillance data and practice. - Abstract - Europe PMC. https://europepmc.org/article/PMC/3804098

[56]Final Report of the Health Information Technology Advisory Committee's Public Health Data Systems Task Force 2021. https://www.healthit.gov/sites/default/files/page/2021-08/2021-07-14_PHDS_TF_2021_HITAC%20Recommendations%20Report_Signed_508_0.pdf

[57]Centers for Disease Control and Prevention, CDC Advisory Committee to the Director (ACD) Data and Surveillance Workgroup (DSW), https://www.cdc.gov/about/pdf/advisory/dsw-recommendations-report.pdf

specific proposed certification criterion that covers systems in place at public health agencies to be able to receive laboratory results, following the same standards for sending those results.[58]

CDC is also taking steps to help ensure PHAs and public health laboratories have the people, policies, processes, and technologies in place to receive and exchange laboratory data using federal health IT standards. CDC's Epidemiology and Laboratory Capacity for Prevention and Control of Emerging Infections (ELC) program provides CDC with a mechanism to help monitor ELR implementations within funded jurisdictions.[59] Through its Public Health Infrastructure Grant (PHIG), CDC has invested in a number of efforts that are intended to move laboratory data faster, create higher data quality, and reduce reporting burden for partners. These investments include:

- $200M under the Laboratory Data Exchange (LDX) category to sustain or improve laboratory information systems and advance laboratory data exchange for improved response time to disease outbreaks, and prevention;
- $425M under the broader Data Modernization category to support health department efforts build and evolve the capacity and data infrastructure they need to maintain, improve, and modernize their approach to acquire, manage, share, and use data for public health action; and,
- $255M to establish Implementation Centers that will help state, territorial, local, and tribal PHAs adopt more flexible, advanced data sharing methods, including participation in TEFCA.

Through this combination of investments, as well as ongoing training and technical assistance offerings,[60] CDC is also well positioned to help PHAs and public health laboratories meet Certification Program criteria for exchange of laboratory data.

Areas for improvement and vision for the future

Interoperable standards-based requirements for documentation or exchange are necessary to address the high amount of variability in the way PHAs receive test results. However, even when using electronic exchange, variability remains due to the customization and optionality within implementation guides—for example, some organizations may require fields that the implementation guide deems as optional, while others may not include those same elements. In an assessment of incoming results in Virginia in 2022,

[58]Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability Proposed Rule (89 FR 63498), https://www.federalregister.gov/d/2024-14975

[59]Centers for Disease Control and Prevention, Implementing ELR, https://www.cdc.gov/electronic-lab-reporting/php/public-health-strategy/?CDC_AAref_Val=

[60]Through the ELR Technical Assistance (ELRTA) initiative, CDC and APHL offer technical assistance to public health agencies and laboratories to implement and advance electronic laboratory reporting with diverse messaging partners. ELR allows laboratories and public health agencies to exchange data using a fast and potentially more streamlined process. ELRTA enables ELR capability on a larger scale, supporting commercial labs with a HL7 lab results message in addition to public health agencies and public health laboratories. This program is providing technical assistance to many jurisdictions, and more are in the pipeline.

there was significant variation in formatting when it came to common data elements: timestamp, phone number, and address.[61] In order to reduce some of this variation, national agreement on implementation, IVD manufacturers providing standard terminology, and corresponding training and technical assistance, could help with greater consistency and widespread adoption.

CDC awards grants to state and large local health agencies, as well as public health associations, and often requires adherence to certain approaches, practices, or standards as part of the funding. CDC grant funding on the adoption and use of ONC-certified health IT and the use of standards-based electronic exchange could help incentivize and support to PHAs to use modern approaches and systems that have foundational capabilities. Greater consistency in the way in which state and local PHAs implement standards would, in turn, reduce variability across jurisdictions, and reduce burden on the laboratories that must set up multiple connections.

G. HEALTH INFORMATION NETWORK (HIN) RECEIVES LABORATORY TEST RESULTS

HINs act as regional hubs for sharing and accessing health information across providers and places of care, and contain demographic information for more than 92% of the population.[62] Given that HINs have demographic information on many patients, states and localities could use these systems to supplement laboratory data with any incomplete information for the individual. At least seven states launched specific projects to utilize HINs amidst the pandemic, and more widespread utilization of HINs could fill an important data gap on a larger scale.[54]

Further, since the COVID-19 pandemic, ASTP has invested support in expanding connections between HINs and public health agencies.[63] Specifically, Strengthening the Technical Advancement & Readiness of Public Health via Health Information Exchange Program (The STAR HIE Program) has made great strides in supporting public health agencies' ability to exchange health information during times of emergency. This program was able to improve real-time data sharing between regional HINs and immunization information systems, as well as provided increased access to laboratory data available in the HIN to participating PHAs.[64] Further, through the use of HINs, clinicians and healthcare organizations can set up single connections for reporting, rather than multiple connections for different use cases and recipients.[54] For example, HealthShare Exchange of Southeastern Pennsylvania collaborated with local

[61] Centers for Disease Control and Prevention, A Prototype of Modernized Public Health Infrastructure for All: Findings from a Virginia Pilot, https://github.com/CDCgov/phdi/blob/main/publications/DMI_VAWhitePaper_V3.pdf

[62] J. Drees, "7 State Data Exchanges That Launched New Projects to Combat COVID-19," Becker's Healthcare, May 14, 2020, https://www.beckershospitalreview.com/healthcare-information-technology/7-state-data-exchanges-that-launched-new-projects-to-combat-covid-19.html

[63] For purposes of this report, ASTP is using HIE and HIN interchangeably, as they are describing the same method of information sharing, but different programs have chosen different terms.

[64] Assistant Secretary for Technology Policy, The STAR HIE Program Shines, https://www.healthit.gov/buzz-blog/health-information-exchange-2/the-star-hie-program-shines

PHAs to enhance COVID-19 surveillance and successfully increased timely ELR data feeds and onboarded more facilities for reporting. KONZA developed a solution that allowed providers to electronically report COVID-19 laboratory results to their PHA. The product is called Translate Ambulatory Electronic Lab Reporting which is intended to improve the health infrastructure by turning laboratory messages used by health information exchanges into compliant laboratory messages for public health reporting. Similarly, Contexture (formerly Health Current) in Arizona improved reporting during the COVID-19 pandemic by engaging hospitals through their HIN infrastructure. Despite challenges with automated data extraction, they pivoted to initiatives that facilitated better coordination between the Arizona Department of Health Services and Arizona Health Care Cost Containment System. This allowed for improved social service coordination and contact tracing across disparate systems, enhancing the state's public health response capabilities.[65] These programs are strong examples of how access to an HIN can aid in real-time availability of needed information for public agencies, while simultaneously reducing reporting burden for clinicians and healthcare organizations.

Laboratory Data Exchange Nationwide via TEFCA

Building on the success of HINs—the reduced connections, the availability of necessary information for care and public health purposes, and improved timeliness—TEFCA provides a nationwide governance framework for health information exchange networks and was authorized by the 21st Century Cures Act. The goals of TEFCA are to establish a governance, policy, and technical floor for nationwide interoperability; simplify connectivity for organizations; and enable individuals to gather their health information from disparate sources.

There are currently six exchange purposes under TEFCA's Common Agreement that identify reasons information could be requested or shared through the network, several of which could include laboratory data. TEFCA's value depends heavily on participant adoption and use of defined standards, as outlined in the exchange purposes. Like the Certification Program, TEFCA is a voluntary program. While TEFCA contains a framework and Common Agreement regarding standards for exchange, only entities that choose to participate are impacted by them. Given this, while HINs and other intermediaries can be a helpful tool to reduce burden, supplement information, and facilitate exchange, given the lack of requirement for use, they will not be the sole answer for advancing laboratory interoperability on a national level.

[65] UCSF Center for Clinical Informatics and Improvement Research. (2023). Program evaluation for the Strengthening the Technical Advancement and Readiness of Public Health via Health Information Exchange (STAR HIE) final report. Prepared for U.S. Department of Health and Human Services, Office of the National Coordinator for Health IT. https://www.healthit.gov/sites/default/files/page/2024-03/STAR%20HIE%20Program%20Evaluation_Final%20Report_508.pdf

Areas for Improvement and vision for the future

The adoption of national standards, and their common use, provides an opportunity in TEFCA to enable timely, complete, and accessible exchange of information across the healthcare ecosystem. Given the national reach and scope of TEFCA, the framework can facilitate standards-based exchange of laboratory data and ensure that necessary orders and results are available not only to providers for treatment purposes, but also to PHAs and to individuals directly. With single connections, healthcare entities could send—and have access to—laboratory data from across the ecosystem.

Supporting public health reporting, including through the exchange of laboratory results, can similarly simplify exchange through a reduction in one-off connections. A single point of connection for public health reporting via TEFCA can also encourage the use of electronic reporting methods over fax, paper, or phone, improving efficiency and reducing manual burden on PHAs.[66] Further, this single point would be a bidirectional connection, allowing for PHAs to query for allowed information to support public health functions, as well as to send messages to providers regarding public health concerns.[67]

While interest and engagement has been positive since TEFCA went live in December of 2023—including several public health agencies live and using information via TEFCA as of July 2024—incentives for participation could help with greater adoption and use. As more organizations and entities choose to participate in TEFCA, more complete information will be accessible, and, over time, laboratory data could become more readily available within the network, reducing the need for organizations to maintain single point-to-point connections to exchange orders and results. Incentives for participation, or support for implementation, could help increase participation in these networks.

IV. Conclusion

This report addressed the five concentration areas specified by Congress through quantitative and qualitative inputs that give a detailed view of standards use at each step of the laboratory workflow, from ordering through sharing the results to public health agencies. At each stop along the workflow, the report discussed the adoption of standards for terminology and exchange, the impact of adoption rate on clinical care and on public health action, and the associated challenges with standards implementation. The report also discussed, throughout each section, the challenges with documenting and exchanging complete patient demographic and contact information, and the effects downstream—particularly on public health assessment and action—when it is not. Lastly, in each section, the report suggested areas for improvement and a future vision that could be achieved with additional federal authorities and aligned funding to incentive broader adoption of laboratory terminology and exchange standards across the ecosystem.

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[66] Sequoia Project, TEFCA Benefits for State Governments and Public Health, https://rce.sequoiaproject.org/benefits-for-state-governments-and-public-health/

[67] Ibid

The complexity of the laboratory ecosystem and its existing IT infrastructure means that improving laboratory interoperability will require a multi-faceted approach with iterative improvements over many years. The solutions discussed above will need Federal agencies—ASTP, CMS, CDC, and FDA— as well as states and the private sector to continue to collaborate on a coordinated strategy to ensure that regulations and incentives for adoption are aligned. Many of these solutions will require additional funding—and in some cases, additional authorities—granted to these agencies to provide incentives to laboratories and others to adopt and implement the interoperability standards. Additional funding to standards development organizations to develop and support educational and training resources will also help facilitate the upfront implementation and real-world usage of these standards.

The proposed solutions, highlighted in the table below, can reduce complexity and close gaps with standards, require foundational capabilities for systems, and incentivize adoption, without greatly disrupting the ecosystem. With the right support—funding and authorities—these changes could help drive meaningful and lasting change across the laboratory ecosystem, improve interoperability, and ready the ecosystem before the next public health emergency.

Table 2. Options for action

Opportunity	Feasibility	Pros	Cons	Require Congressional Action?
Increase use of data standards				
Conditions on HHS grant funding that require use of standards for laboratory data exchange	**High**, as there is precedent and acceptance with funding conditions	• Precedent exists • Financial incentive for states and localities	• Does not address the upstream needs discussed in this report • Challenges designing and applying conditions in a way that meets all funding objectives	**No**

Opportunity	Feasibility	Pros	Cons	Require Congressional Action?
CDC data modernization investments on laboratory technology and standards adoption	**Medium,** as CDC is already making significant investments in its own systems and those of state/local agencies and public health labs	• Opportunity to build on mechanisms and investments already in place • Investments directed by the Public Health Data Strategy, CDC's goal-driven, two-year plan providing accountability for data, technology, policy and administrative actions	• Future investments predicated on ongoing funding and level of such funding	**Yes**, additional and sustained funding
New ONC Certification Program certification criteria for standardized sending and receiving of laboratory orders and results	**High**, though will need to be done in concert with other enforcement mechanisms *(a bove and below)*	• Ensures technical functionality in place before regulatory requirements	• Lengthy process • Incentives for adoption would need to come from other Federal partners • Likely to face opposition by vendors	**No**

Opportunity	Feasibility	Pros	Cons	Require Congressional Action?
Similar to the Medicare Promoting Interoperability Program, a program to incentivize standards use in non-hospital based laboratories	**Low,** as associated costs would be significant and require Congressional approval	• Medicare Promoting Interoperability Program is an established exemplar program, and could help reduce financial burden for technology upgrades	• Likely reticence from laboratories on new requirements	**Yes,** and additional funding would be needed for these programs and incentives
Improve the accuracy of data standards use				
FDA prompts device manufacturers to provide encoding guidance for the devices they manufacture	**Medium,** as FDA would need to develop mechanisms for IVDs to provide information about assigning terminology standards to their tests	• Terminology standards information direct from IVD manufacturers would have a huge impact the accuracy of standards use across laboratory ecosystem	• IVD manufacturers may not participate without regulatory enforcement or incentives	**No**

Opportunity	Feasibility	Pros	Cons	Require Congressional Action?
CMS adds measures to other quality reporting programs	**Medium,** as measures would need to be created and added to these reporting programs, which would require formal rulemaking	• Adding quality measures under other pay for reporting programs—such as LTCHQRP[68], ESRD QIP[69]—could cover providers that are not eligible clinicians, eligible hospitals, or CAHs, yet do a significant amount of testing in certain patient populations	• Measure development and rule-making processes take time	**No,** but additional funding would be needed for these programs to expand incentives
Introduce new interoperability standards as part of laboratory accreditation programs	**Medium**, as requires willingness of and collaboration with accrediting organizations like the Joint Commission and the College of American Pathologists	• Accreditation programs can introduce requirements that go beyond baseline requirements of the CLIA regulations	• Not a universal solution • Requires buy in by accrediting organizations and (likely) some investment to create appropriate standards	**No**

[68]Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP)
[69]End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP)

Opportunity	Feasibility	Pros	Cons	Require Congressional Action?
Future proof laboratory interoperability				
HINs and other third parties to supplement missing demographic data and other data critical to safe, high quality patient care and timely, equitable public health action	**High**, as HINs already contain patient demographic information and are a known resource	• HIN infrastructure already in place; TEFCA's launch extends scope and reach nationally • States have authorities to act on their own	• Certain jurisdictions not covered by some types of HINs operating outside the TEFCA network • Potential privacy concerns with direct laboratory connections • Only applies to data completeness, not electronic exchange	**No**
Expand and sustain CDC supported interoperability solutions (AIMS70)	**High**, as critical infrastructure is already in place and delivering value	• Infrastructure is already in place and operational. • Network is growing • Offers a solution that avoids need for point-to-point connections • Reduces burden on senders and receivers that struggle with or do not have the expertise to map to appropriate standardized codes	• Future investments require continued funding sufficient to sustain—and ultimately expand—this infrastructure	**No**

[70]APHL Informatics Messaging Services (AIMS)

Opportunity	Feasibility	Pros	Cons	Require Congressional Action?
State policies on reportable laboratory results to require ONC certification and associated standards for laboratory exchange	**Low**, as all states would need to update existing policy regarding transmission of laboratory results/values to, and receipt by, to public health agencies	• Laboratories already comply with state policy, and standardization across states would be beneficial and reduce compliance burden	• State policy would need to align with federal policy, and be updated accordingly • State policy for laboratory results reporting often only covers public health reportable conditions, which is only a subset of laboratory results	**No**

V. Appendix A. Health Data Standards in the Laboratory Ecosystem

Standard	Description
Logical Observation Identifiers Names and Codes (LOINC®)	★ A health data standard that consists of paired codes and concepts used to create shared understanding of tests and measurements. LOINC codes represent the "question" for a test or measurement. *Example: 2085-9 | Cholesterol in HDL [Mass/volume] in Serum or Plasma*
Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®)	★ A health data standard that consists of an ontology of paired codes and concepts used to create shared understanding of clinical content. SNOMED CT codes represent the "answer" for a test of measurement. *Example: 112283007 | Escherichia coli (organism)*
Unified Codes for Units of Measure (UCUM®)	★ A health data standard that represents units of measures for unambiguous sharing of quantities and units together. *Example: mg/L | milligram per liter*
Health Level 7 Version 2 (HL7v2)	A health data messaging standard that defines the structure and organization of data to facilitate exchange of data across systems. According to HL7, this standard, first released in 1987, is used in 95% of US healthcare organizations.[71] Key specifications for use of HL7v2 for laboratory data exchange*: • ★ *HL7 Version 2.5.1 Implementation Guide: Laboratory Order from EHR (LOI)*: Specification for laboratory orders sent from EHRs or LIS Ito the laboratory LIS performing the test. • ★ *HL7 Version 2.5.1 Implementation Guide: Laboratory Results Interface (LRI)*: Specification for laboratory results from LIS. Contains component profile for public health reporting of laboratory results. • ★ *HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting (ELR) to Public Health, Release 1:* Standard governing electronic laboratory reporting from EHR/LIS to PHAs.

[71]HL7. "HL7 Version 2 Product Suite." Retrieved on 6/18/2024 from https://www.hl7.org/implement/standards/product_brief.cfm?product_id=185.

Standard	Description
HL7 Clinical Document Architecture (CDA®)	A standard that defines the structure and semantics of electronic clinical documents for the purpose of exchange. • ★ Consolidated Clinical Document Architecture (C-CDA) is a library of CDA templates that harmonizes development efforts. • ★ *HL7 CDA R2 Implementation Guide: Public Health Case Report - the Electronic Initial Case Report (eICR)*: Specification for electronic submission of public health case reports. • ★ *HL7 CDA R2 Implementation Guide: Healthcare Associated Infection (HAI) Reports*: Specification for electronic submission of healthcare associated infection reporting to CDC's National Healthcare Safety Network.
Fast Healthcare Interoperability Resources (FHIR®)	An exchange standard with a content model and specification for an application programming interface (API). FHIR is the newest of the HL7 specifications, first released in 2012, and is designed to be easier and less resource intensive to implement. FHIR uses web standards to be compatible with mobile phone apps, cloud communications, EHR-based data sharing, server communication, and more. • ★ *HL7 FHIR Implementation Guide: Electronic Case Reporting (eCR)*: Specification for electronic submission of public health case reports. • *HL7 FHIR Implementation Guide: LOINC – IVD Test Code (LIVD)Mapping*: Digital format for publication of In Vitro Test laboratory result mappings to LOINC and result values to SNOMED CT.

★ Included in ONC Health IT Certification Program

* Exchange standard specifications listed here are key examples and are from a snapshot in time.

VI. Appendix B. Actors in the Laboratory Ecosystem

Clinical Laboratory	A healthcare facility that examines patient samples for the purpose of healthcare. Types of clinical laboratories include: • Commercial reference laboratory: for-profit, independent clinical laboratory serving a large regional or national population. • Academic medical center laboratory: clinical laboratory primarily serving an academic medical center hospital and associated clinics. • Small independent laboratory: clinical laboratory serving a regional or local population. • Critical access hospital laboratory: hospital-based clinical laboratory serving a single, regional critical access hospital. • Public health laboratory: specialized governmental health laboratories working at the federal, state, and local level that monitor and detect disease and public health threats. Laboratories receive orders and patient information and send out test results and patient information. To facilitate electronic capture and exchange of orders and results, laboratories use health IT systems called Laboratory Information System (LIS) and Laboratory Information Management System (LIMS).
Healthcare provider	A medical professional authorized to provide medical care or treatment, including requests for clinical laboratory testing. Some categories of healthcare providers who request laboratory testing in the care of patients include doctors, nurse practitioners, and physician assistants. Providers send orders or requests for laboratory tests on behalf of the patient, and providers receive the results of laboratory tests. Providers use EHRs to facilitate the capture, display, and exchange of healthcare data, including order and result exchange with LISs in laboratories.
Public Health Agency (PHA)	A government organization tasked with safeguarding and improving the health of a population through disease surveillance, health promotion, and outbreak response. They work closely with federal agencies, healthcare providers, and community organizations to address local health needs, enforce health regulations, and implement public health policies tailored to their specific jurisdictions. PHAs can operate at the state, territorial, local, tribal, or federal level. PHAs collect and analyze health data, including laboratory results, to identify trends and develop strategies for addressing public health challenges. Some PHAs have health IT systems that can electronically receive health data from EHRs and LISs.

Standards Development Organization (SDO)	An organization responsible for the development, curation, and publication of data standards that enable seamless exchange of health data between systems.
In Vitro Diagnostic Product Manufacturer	Companies that create and distribute in vitro diagnostic products. In vitro diagnostic products are those reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body. These products are devices as defined in section 201(h)(1) of the Federal Food, Drug, and Cosmetic Act (the act) and may also be biological products subject to section 351 of the Public Health Service Act, including when the manufacturer of these products is a laboratory. (21 CFR 809.3(a)). Laboratories use IVD products for detecting diseases, monitoring health conditions, and assessing treatment efficacy.
Health Information Network	An infrastructure that facilitates the electronic exchange of health information, such as laboratory results and patient information. These networks leverage health data standards to enable sharing among healthcare stakeholders, including providers, payers, patients, and public health agencies.
Government Agencies	
Office of the Assistant Secretary for Technology Policy (ASTP) /Office of the National Coordinator for Health Information Technology (ONC)	ASTP is the federal agency responsible for coordinating nationwide efforts to implement and advance the use of health information technology (IT). ASTP establishes standards and policies that facilitate seamless transmission of health data, including laboratory data, between healthcare providers, laboratories, and other stakeholders. ASTP provides the voluntary ONC Health IT Certification Program (referenced throughout as the Certification Program) which ensures that Certified Health Information Technology meets the technological capability, functionality, and security requirements adopted by the U.S. Department of Health and Human Services (HHS).

Centers for Disease Control and Prevention (CDC)	CDC is tasked with protecting national public health and safety. CDC collects, analyzes, and disseminates health data, including laboratory results, to monitor disease outbreaks, track public health trends, and inform policy decisions. CDC, in partnership with CMS and FDA, also supports the Clinical Laboratory Improvement Amendments (CLIA) program and clinical laboratory quality. CDC's responsibilities for the national CLIA program include: • Providing analysis, research, and technical assistance • Developing technical standards and laboratory practice guidelines • Conducting laboratory quality improvement studies • Developing and distributing professional information and educational resources • Managing the Clinical Laboratory Improvement Advisory Committee (CLIAC)
Food and Drug Administration (FDA)	FDA is responsible for, among other things, protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices. FDA regulates medical products such as in vitro diagnostic (IVD) tests and laboratory equipment. FDA oversees the premarket review process for new drugs, biologics, and medical devices, conducts inspections of manufacturing facilities, and monitors the post-market safety of regulated products. FDA, in partnership with CDC and CMS, also supports the CLIA program, in partnership with CDC and CMS, through completion of complexity categorizations for in vitro diagnostic tests.
Centers for Medicare & Medicaid Services (CMS)	CMS administers the Medicare and Medicaid programs, and it uses various payment and regulatory levers to incentivize/require adoption of federal interoperability standards among healthcare providers, plans, and payers. In addition to overseeing these programs, CMS regulates laboratory testing (except research) performed on humans in the United States through CLIA, which ensures the quality and accuracy of laboratory test results.
State and Local Health Authorities	State and Local Health Authorities oversee public health initiatives, health and safety regulations, and services at regional levels. They work closely with federal agencies, healthcare providers, and community organizations to address local health needs, enforce health regulations, and implement public health policies tailored to their specific jurisdictions.

VII. Appendix C. Measurement of Laboratory Data Standards Use

The ASTP engaged subject matter experts to collect sample electronic laboratory result records from multiple health care entities and analyze their content for compliance to health data standards. The data was to be provided as either redacted HL7 ORU messages or via extract reports from stored HL7 OBR (observation request) and OBX (observation/result) records. Below is a summary of data standards used in the ORU (observation result) data. This data does not determine the underlying consistency or correctness of encoding the laboratory data, just if any code from the designated standard was used.

Source	Total Tests	LOINC Tests	Not LOINC	LOINC Orders	Not LOINC	Has Units	UCUM Units	Not UCUM	Coded Result	SCT Result	Not SCT
LIS 1	148,302	119,063	29,239	-	148,302	104,864	73,430	31,434	39,214	-	39,214
LIS 2	31,848	23,496	8,352	775	31,073	26,269	18,879	7,390	7,074	-	7,074
LIS 3	1,842	1,842	-	1,682	160	-	-	-	1,842	1,506	336
Re Lab 1	11,346,325	9,601,767	1,744,558	-	11,346,325	7,920,931	5,010,201	2,910,730	3,767,193	-	3,767,193
Ref Lab 2	437,431	98,778	338,653	345,804	91,627	220,627	161,334	59,293	87,694	-	87,694
Ref Lab 3	259,542	257,137	2,405	-	259,542	222,662	144,905	77,757	51,414	-	51,414
Ref Lab 4	161,311	161,282	29	-	161,311	125,153	80,904	44,249	49,066	-	49,066
Ref Lab 5	2,155	682	1,473	2,155	-	-	-	-	2,155	-	2,155
EHR 1	21,302,378	18,581,065	2,721,313	10,039,046	11,263,332	15,505,811	10,328,117	5,177,694	4,763,586	3,073	4,760,513
EHR 2	5,214,037	3,189,243	2,024,794	49,365	5,164,672	4,138,238	2,384,949	1,753,289	462,596	354	462,242
EHR 3	4,002,046	2,344,834	1,657,212	1,299,793	2,702,253	2,439,898	1,487,144	952,754	881,782	22,943	858,839
EHR 4	1,635,474	1,006,636	628,838	1,315,870	319,604	844,720	606,835	237,885	340,229	-	340,229
EHR 5	853,115	118,063	735,052	-	853,115	625,246	414,878	210,368	138,156	-	138,156
EHR 6	832,671	759,270	73,401	474,464	358,207	690,089	510,746	179,343	122,654	-	122,654
EHR 7	751,575	632,233	119,342	-	751,575	586,716	403,348	183,368	108,458	2,460	105,998
EHR 8	616,635	367,827	248,808	517,452	99,183	401,444	289,864	111,580	69,062	12,375	56,687
EHR 9	195,227	195,227	-	174,258	20,969	159,178	3	159,175	29,709	4,189	25,520
EHR 10	84,569	77,324	7,245	81,391	3,178	53,607	-	53,607	79,058	-	79,058