Informatics Self-Assessment Tool

for Public Health Laboratories 2013

APHL ASSOCIATION OF PUBLIC HEALTH LABORATORIES

LEI LABORATORY EFFICIENCIES INITIATIVE
Transforming to a Sustainable Public Health Laboratory System

CDC CENTERS FOR DISEASE CONTROL AND PREVENTION

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Abbreviations

Below are the most common abbreviations used in the text. Abbreviations used less frequently are identified in context, or in the endnotes of the relevant capability area. The glossary provides additional definitions and explanations of many concepts and terms mentioned in the tool.

APHL	Association of Public Health Laboratories
CA	Capability Area
CDC	Centers for Disease Control and Prevention
CLIA	Clinical Laboratory Improvement Amendments
COOP	Continuity of Operations Plan
CS	Capability Statement
EHR	Electronic Health Record
ELR	Electronic Laboratory Reporting
ETOR	Electronic Test Order and Reporting
HIE	Health Information Exchange
HL7	Health Level 7
IT	Information Technology
L-SIP	Laboratory System Improvement Program

LIMS	Laboratory Information Management System
LOINC	Logical Observation Identifier Names and Codes
PHII	Public Health Informatics Institute
PHIN MS	Public Health Information Network Messaging System
PHL	Public Health Laboratory
QA	Quality Assurance
QC	Quality Control
QMS	Quality Management System
SLA	Service Level Agreement
SME	Subject Matter Expert
SOP	Standard Operating Procedure
SPHL	State Public Health Laboratory

Introduction

The purpose of this self-assessment tool is to enable Public Health Laboratories (PHLs) to have a comprehensive understanding and assessment of their current informatics capabilities. Use of this tool will help PHLs identify key gaps in their informatics capabilities, identify actions they may wish to take to strengthen those capabilities, and demonstrate improvement in efficiencies to policymakers.

Informatics is critically important to PHLs' efficiency and their vital role in protecting Americans from infectious diseases, environmental dangers, and other health threats. But rapidly evolving information technology, restructuring of the nation's health system, and strained government budgets pose complex challenges to attaining essential informatics capability. Further, the limited funding available for public health laboratory informatics has focused on program-specific applications, not on a laboratory's cross-cutting informatics system.

This self-assessment tool gives PHL professionals new ability to identify and plan in a comprehensive, systems-oriented manner for the informatics capabilities they need. This is also the first initiative that has sought to measure overall informatics capabilities in PHLs. This tool will help PHL professionals prioritize the use of existing resources, document and communicate laboratory priorities to policymakers, and monitor laboratories' informatics capabilities on an on-going basis. Because concerned PHL directors, senior staff, and informatics experts guided development of the self-assessment, this tool can be seen as representing best-practice benchmarks and standards.

The Laboratory Efficiencies Initiative (LEI)

The self-assessment tool was created as a key part of the Laboratory Efficiencies Initiative (LEI). The Association of Public Health Laboratories (APHL) and the Laboratory Science Policy and Practice Program Office (LSPPPO) at the Centers for Disease Control and Prevention (CDC) cosponsor the LEI. The goal of the LEI is to assure long-term sustainability of the nation's public health laboratory system by improving the efficiency of state, local, and territorial PHLs.

PHLs participate in the LEI on a voluntary basis and can use the self-assessment tool, like other resources created through the LEI, to address the goals and priorities their leaders identify as most important. Additional information about the LEI is available from APHL at http://www.aphl.org/aphlprograms/lss/Laboratory-Efficiencies-Initiative/Pages/default.aspx and CDC at http://www.cdc.gov/osels/lspppo/lei/index.html..

Tool Development Process

The self-assessment tool had its genesis in a meeting that APHL and LSPPPO convened in December 2011. The purpose of the meeting was to identify strategies to improve PHLs' informatics capabilities nationally as a critical element of the LEI. Participants in this subject-matter expert (SME) group included state PHL directors and PHL informatics experts, APHL and CDC staff, and technical consultants. The participants' unanimous conclusion was that a critical first step toward designing those strategies would be development of a resource that laboratory leaders could use to identify—in a comprehensive and systematic manner—strengths and weaknesses in their existing informatics capabilities.

A representative working group, formed shortly thereafter, drafted an initial framework for the tool based upon the "Requirements for Public Health Laboratory Information Management Systems (LIMS)" published by APHL in 2003 and the associated 16 business processes that provide the framework for a PHL's LIMS. (APHL, 2003) The SME group reviewed this framework and provided comments and recommendations for further development. Over a period of several months the tool underwent four reviews by the SME group, followed by a formal technical review by three PHLs (i.e., PHLs in Alabama, Kentucky, and New York City). Four PHLs (i.e., PHLs in Alabama, Kentucky, New York City, and West Virginia) beta-tested an advanced draft of the tool in December 2012 and provided detailed feedback to the working group. The self-assessment tool was finalized and published in spring 2013 and was presented to the PHL community at the June 2013 APHL annual meeting.

Appendix 1 identifies participants in the tool development process.

Organization of the Tool

The tool is organized into 19 Capability Areas (CAs) (see Table 1). Collectively, the CAs represent the principal laboratory functions that an information system supports. The CAs closely track the 16 business processes identified by APHL's 2003 report. In addition, the SME group added 3 CAs to reflect functions related to data exchange and interoperability, core Information Technology (IT) services, and policies and procedures.

Table 1: 19 Capability Areas

CA #1	Laboratory Test Request and Sample receiving
CA #2	Test Preparation, LIMS Processing, Test Results Recording and Verification
CA #3	Report Preparation and Distribution
CA #4	Laboratory Test Scheduling
CA #5	Prescheduled Testing
CA #6	Specimen and Sample Tracking/Chain of Custody
CA #7	Media, Reagents, Controls: Manufacturing and Inventory
CA #8	Interoperability and Data Exchange
CA #9	Statistical Analysis and Surveillance
CA #10	Billing for Laboratory Services
CA #11	Contract and Grant Management
CA #12	Training, Education and Resource Management
CA #13	Laboratory Certifications/Licensing
CA #14	Customer Relationship Management
CA #15	Quality Control (QC) and Quality Assurance (QA) Management
CA #16	Laboratory Safety and Accident Investigation
CA #17	Laboratory Mutual Assistance/Disaster Recovery
CA #18	Core IT Services: Hardware, Software and Services
CA #19	Policies and Procedures, including Budgeting and Funding

Introduction

Each CA section includes a title, a brief description, a guidance statement, and one or more capability statements (CSs). Some CAs include pertinent endnotes. The guidance statement describes the specific abilities covered in the CA and explains how these abilities are integrated into the laboratory's operations; it also provides an overview of the benchmarks that a laboratory would meet to reach the highest level of maturity in that CA. Each guidance statement presents a bulleted list of the desired informatics capabilities covered in that CA. The CS represents the capability of a laboratory that has reached full maturity. The associated indicator statements describe laboratories in various stages of maturity (see Table 2). Note that most CSs are ranked on a three-point scale, others on a two-point scale. Laboratories can use these levels as 'milestones' to measure current status and progress towards full maturity. Users can also select "Not Applicable" (N/A) if a particular capability statement is not relevant.

The self-assessment tool includes a number of supplements. Abbreviations used in the text three or more times are listed in on page 1; abbreviations used less frequently are identified in the notes section of each CA. A general glossary provides definitions for terms and examples. Users can locate the full reference to all citations within the text and the CAs in the bibliography.

Figure 1: Format of each Capability Area

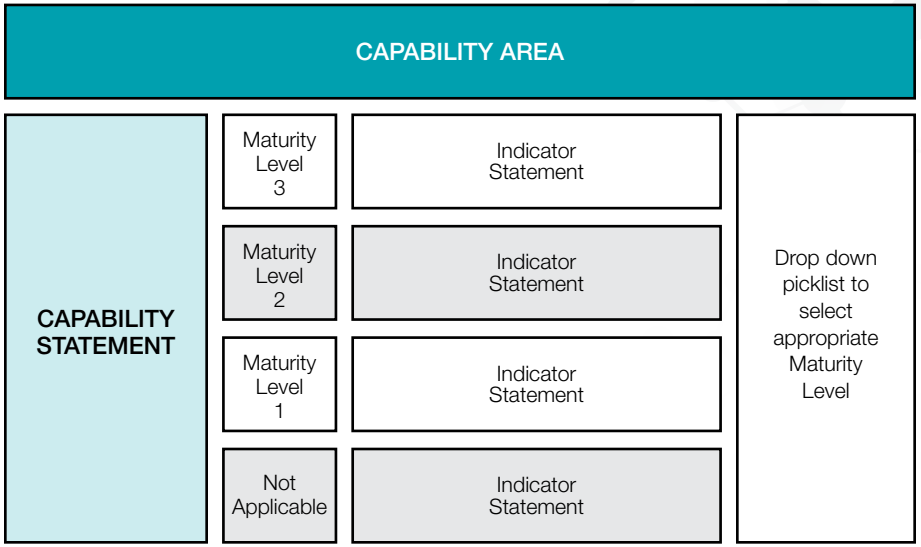

Table 2: Levels of Maturity

Level 3	Technology and process in place/extended to execute the functions described beyond the local business domain.
Level 2	Minimal required technology and process in place to execute the functions described.
Level 1	No/very little current ability to execute the functions described.
N/A	Not applicable to this laboratory.

Suggestions for Using the Self-Assessment Tool

The self-assessment tool was designed for use primarily by PHL leadership, laboratory scientists, informatics staff, and quality managers. PHL directors and other leaders can use the output from this tool to provide strategic direction for informatics investments to improve operations and inform policy.

Three state PHLs and one city PHL beta-tested the tool in the winter of 2013. All reported that they found it valuable. Their collective experience indicates several points that users may consider when implementing the tool.

- **Team Approach:** While this tool was designed so that any user, regardless of informatics background, can navigate through the capabilities described, completion of the tool may require the joint effort of several laboratory staff members to ensure that it accurately captures the laboratory's current capabilities. A team with members representing leadership, administration, programs, informatics/IT, quality management, and possibly other domains within the laboratory, can bring all the relevant perspectives to the self-assessment process.
- **Planning:** Laboratory leadership and the assessment team will want to develop a common understanding of their goals, how they will conduct the assessment, and how they intend to use the results when the assessment has been completed.
- **The Assessment Process:** Each of the 4 beta tests was completed in a single-day session. Team members familiarized themselves with the tool and the CAs in advance. The teams devoted between 6 and 8 hours to the assessment.
- **Reporting Results:** The tool was designed to capture the 'maturity level' that the team designates for each capability statement as the team proceeds through the 19 sections. This metric produces a detailed record that can be used in reporting the results of the assessment and determining follow-up steps.

While the organization of the tool allows for flexibility in the selection of capability areas to be completed, users are encouraged to set aside sufficient time to read through each capability statement and work with appropriate staff in their laboratories to select the most appropriate response. Therefore, it is recommended that each laboratory select a user to peruse all 19 capability areas first, before beginning the self-assessment, to help select appropriate staff to participate in the assessment. This preparation will allow the laboratory to complete the self-assessment efficiently and accurately. Furthermore, it is important that the user understand the key functionalities of a capability area before completing the assessment for that area. Therefore, it is suggested that the user review the associated guidance statement before completing the assessment for each CA.

To complete the self-assessment, users can record answers using the dropdown menu to the right of each capability statement. For each capability statement, users can select the level of maturity that best reflects current operations at their laboratory. If the capability is not relevant for that particular laboratory, users may select 'Not Applicable'. Please refer to the scenario examples below for further guidance in completing the assessment. Users may decide to progress from one capability area to the next sequentially or in a different order. Some may choose not to complete every CA. Within a given CA, however, a laboratory's assessment will be most effective if the users work through the CSs sequentially.

To obtain the most benefit from the tool, users can rank their laboratory's capabilities based on the capabilities that are currently present and in use in the laboratory. In certain cases, laboratories may have the infrastructure necessary to implement additional capabilities, but if these capabilities are not in use, they do not accurately reflect the laboratory's current capability level. Responses based on a laboratory's potential will not provide laboratories with the granularity they need to assess their true maturity level and subsequently progress from one level to the next within a capability area.

Introduction

At the end of each CA assessment, the tool automatically calculates a laboratory's total grade and percentage grade. For an accurate percentage, users will need to select the appropriate level for each CS within a given CA. Laboratories that function at Level 3 for every CS described would have the maximum possible maturity level for that CA. Note that there is no overall "grade" or "score" for all the 19 CAs. It is important to remember that the percentage or numeric score is not indicative of a "Pass" or "Fail" determination. As the priorities and business needs of laboratories vary, the percentage grade can help identify the areas on which to focus attention (as discussed in the "Outcomes and Value Added" section below).

The tool also includes a summary worksheet that provides users a condensed representation of their maturity level through total and percentage scores for each CA. In addition, a User Information Sheet (Appendix 5) captures details about the laboratory staff who completed the assessment and the approach used.

Users can complete the assessment as many times as they want. Once the laboratory has implemented some changes to its information systems, it may be useful to repeat the assessment to see how the laboratory's capabilities have progressed

The tool allows for flexibility in whether a user completes it from the perspective of a specific LIMS implemented in one section of the laboratory, or from the aspect of the overall capability of the laboratory and the services it is able to provide. This flexibility enables a user to target systems or services, and even specific sections within the laboratory. If using the tool to assess change in capabilities over time, it is important for the longitudinal data present in the tool to consistently have the same interpretation. Therefore, if users wish to compare responses over time, they are encouraged to use the same approach every time they fill out the tool in order to maintain consistency.

Scenario Examples

Example 1

Capability Statement	Level	Description of Levels	Select from drop down menu below
Capability Statement #1.3 The laboratory is able to receive data using one or more standard message types (e.g., HL7 orders). Data include sample metadata, auxiliary data, test orders, test results, etc.	Level 3	The laboratory is able to receive data on samples using one or more standard message types, and data include sample metadata, auxiliary data, test orders, etc.	
	Level 2	The laboratory is able to receive data using nonstandard formats but cannot receive data on samples using standard message types.	
	Level 1	The laboratory is able to receive data on samples only via paper, e-mail or spreadsheets.	
	N/A	Not applicable to this laboratory.	

The above capability statement is drawn from Capability Area 1, which focuses on laboratory test requests and sample receiving. As you complete the assessment, you will determine whether the laboratory functions at Level 1, Level 2, or Level 3, as described in the indicator statements; if this CS is not relevant to your laboratory, you would select option N/A.

Scenario: In this example, you are completing this assessment on behalf of a microbiology laboratory. The laboratory is able to receive test requests in PDF and doc formats via email or via paper-based formats. These requests are then entered into the LIMS. The laboratory cannot receive test requests only using standard message types, such as Health Level 7 (HL7 Interface Engine). Based on this information, your laboratory currently functions at Level 1 with respect to Capability Statement 1.3.

Next Steps: The guidance statement printed at the beginning of Capability Area 1 provides guidance regarding the laboratory test requests and sample receiving functionalities that a laboratory is often expected to have. After taking the assessment and reading the guidance statement, you may decide to explore the standard message types that are most applicable to you based on your program's priorities. You also might talk with colleagues in laboratories that have already added this functionality to see if they can offer additional guidance.

Example 2

Capability Statement	Level	Description of Levels	Select from drop down menu below
Capability Statement #8.11 The laboratory is able to provide data electronically through a web portal for data and information exchange (e.g., turn-around information, result reporting, samples in-house, ad hoc queries, etc.).	Level 3	The laboratory is able to provide data electronically through a web portal for data and information exchange.	
	Level 2	The laboratory has some capability to provide data electronically through a web portal for data and information exchange.	
	Level 1	The laboratory is not able to provide data electronically through a web portal for data and information exchange.	
	N/A	Not applicable to this laboratory.	

The above capability statement is drawn from Capability Area 8, which focuses on data exchange and interoperability. Users grade their laboratories on the capabilities described in Capability Statement 8.11 using a three-point scale; you will determine whether the laboratory functions at Level 1, Level 2, or Level 3, as described in the indicator statements; if this CS is not relevant to your laboratory, you would select option N/A.

Scenario: In your Newborn Screening laboratory, authorized pediatricians can view results of some tests for their patients on your website. Your laboratory also posts the average turnaround time for these tests so providers can estimate when results might be ready. Because the laboratory does not have the capability to provide all their results electronically through their website, pediatricians often have to call the laboratory asking for results. Besides providing results and turnaround time, your laboratory does not make any other information available electronically through the website. Based on this information, your laboratory currently functions at Level 2.

Next Steps: The guidance statement at the beginning of Capability Area 8 provides a roadmap for improving data exchange and interoperability functionality. After completing the assessment and reading the guidance statement, you may decide to prioritize working with informatics and laboratory staff to use the web portal effectively to provide data to clients and partners.

Example 3

Capability Statement	Level	Description of Levels	Select from drop down menu below
Capability Statement #17.8 The laboratory manages and routinely updates a catalog of capacities and services offered by partners, and a documented schedule to test effectiveness of partners' capabilities in disaster recovery and emergency situations.	Level 3	The laboratory manages and routinely updates both a catalog of capacities and services offered by partners and a documented schedule to test effectiveness of partners' capabilities.	
	Level 2	The laboratory manages and updates a partial catalog but not a regular documented schedule to test effectiveness of partners' capabilities.	
	Level 1	The laboratory maintains neither a catalog nor a regular documented schedule to test effectiveness of partners' capabilities.	
	N/A	Not applicable to this laboratory.	

This capability statement is part of Capability Area 17, which describes functionalities associated with mutual assistance and disaster recovery. Again, you will determine whether your laboratory functions at Level 1, 2, or 3, based on the indicator statements; if this CS is not relevant to your laboratory, you would select option N/A.

Scenario: Your laboratory was recently affected by a hurricane that disrupted normal operations for several days. Just before the storm, your laboratory had received several specimens that had a short turnaround time for testing. To maintain the integrity of these samples, it was essential to transfer them to your partner laboratories so they could be tested in a timely way. However, the information you found on these partners was somewhat scattered, and you could not determine which laboratories would be able to perform the required testing. Your laboratory does not maintain a current catalog of partners' capabilities. Therefore, your response to Capability Statement 17.8 would be Level 1.

Next Steps: The guidance statement at the beginning of Capability Area 17 1 provides guidance regarding the mutual assistance and disaster recovery functionalities that a laboratory is often expected to have. After reviewing this assessment and the associated guidance statements, you may decide to work with informatics and laboratory scientists to assemble information about your partners, the tests they can do, and the workload they can handle, into a regularly updated document.

Outcomes and Value Added

The self-assessment tool can help laboratories accomplish several objectives. First, PHLs can assess their current informatics capabilities, thus establishing a baseline. Second, PHLs can measure the maturity of their informatics capabilities against desired levels. These measurements will also enable future comparison of informatics capabilities. Third, the tool provides PHLs with a step-wise approach to reaching these benchmarks. Use of this tool will help PHLs identify gaps in their capabilities while also providing them with guidance on steps they can take to achieve the desired standard.

It became evident during the beta-testing of the tool that laboratories can use self-assessment results to improve processes in the laboratory and enhance the use of informatics. Beta-testing sites indicated that the tool and its results can be applied to quality improvement, quality assurance, and customer relations (see Appendix 4 for additional feedback from these beta-testing sites). While a laboratory may determine that it does possess a specific capability, completing the assessment can help it recognize flaws in current processes or in the manner in which the capability has been implemented, and thereby provide a roadmap for re-implementing these capabilities with greater efficiency.

> **We found the tool to be insightful, engaging and well worth the time.**
>
> - New York City PHL

> **We were able to quickly determine what areas needed our focus. I would recommend all PHLs to use the tool.**
>
> - West Virginia SPHL

The tool also helps to ensure a common understanding of informatics processes and efficiencies. For example, the tool can help laboratories distinguish between redundancy and backups. Laboratories can use this distinction to ensure that appropriate measures are in place to safeguard their data while still managing for redundancy.

The tool as a whole can serve as a means to evaluate the LIMS. Laboratories that are in the process of procuring a LIMS can use the assessment tool as a guide to ensure the LIMS has all, or at least the key, capabilities they want. At the same time, laboratories that have implemented a LIMS can use the tool to measure its LIMS capabilities and ensure that the LIMS is being used to improve laboratory efficiency.

PHLs can use assessment results to prioritize upgrades to their existing capabilities. Laboratories may choose to focus efforts first on capabilities that are at lower levels. Prioritization can highlight important gaps in a laboratory's request for allocation of resources. The PHLs that beta-tested the self-assessment tool reported that citing the results of an objective tool developed by CDC and APHL may give added credence to requests for resources.

> **The tool is a comprehensive and informative informatics measuring tool as well as a great 'workshop' style document for lab leaders.**
>
> - Kentucky SPHL

> **It is the first tool that I have seen that allows an SPHL director to evaluate the maturity of their LIMS across all functional areas of their lab.**
>
> - Alabama SPHL

Assessment findings can also be used to develop and inform policies within the laboratory, as well as with external partners. Policies and processes evolve with the needs of the laboratory, and this tool can help the laboratory evaluate and improve on existing policies and processes.

Completing the assessment creates a baseline against which the laboratory can measure progress. Laboratories can repeat the assessment at intervals to identify trends in capabilities. This periodic reassessment can help laboratories evaluate ongoing informatics activities and validate changes that the laboratory has implemented to its information systems. Laboratories can use this reevaluation to guide the direction of future enhancements to their capabilities.

Capability Areas

CA 1: Laboratory Test Request and Sample Receiving

Description

This capability area addresses informatics capabilities related to the business processes associated with initial test sample request and receiving.

Guidance Statement

Purpose: Laboratories need efficient processes to receive a sample and its associated test requests. These processes play a critical role in a laboratory's ability to report results proficiently. Laboratories can best perform these processes by exchanging data electronically, including test ordering and reporting (ETOR), and by leveraging systems such as laboratory information management systems (LIMS).

What: LIMS allow laboratories to take advantage of informatics capabilities and established data standards. Many LIMS accept multiple message types, create a flexible vocabulary model to utilize different standards, input and edit necessary data, and accommodate various transport mechanisms for receiving data. Other informatics efficiency measures for sample receiving and accessioning include the utilization of barcode scanning, radio frequency identification[1], robotics[2], and enterprise accessioning across multiple laboratory disciplines.

How: Informatics has allowed the modern laboratory to move from paper-based requisitions to electronic test orders. As data sharing abilities advance with technology, the ability to use standards, the flexibility to accommodate ever-changing transport mechanisms, and the need to validate the content and ensure the security of electronic data exchange, are becoming critical to PHL success.

A laboratory that has the desired informatics capabilities to receive the sample and the associated request can:

- Receive an electronic test request package message from a submitter and process the message. To process the workflow completely, PHLs would follow an agreed upon standard/format, verify the submitter, verify an established relationship with the submitter, separate acceptable requests from problematic ones, match acceptable requests to pre-scheduled submissions, edit the data record for completeness, and send an acknowledgment to the submitter about the message and physical sample when received.
- Receive and send data using one or more standard message types as stipulated in state and federal regulations (e.g., Meaningful Use)[3]. Data include sample metadata, test orders, and test results.
- Meet multiple transport protocols (e.g., Direct[4] [HIE[5] Service/Protocol], CONNECT[6], PHIN MS[7], and SOAP[8]).
- Use multiple standardized vocabulary formats and function as an integration broker; integrate local and new codes and vocabulary standards; and flexibly utilize vocabulary standards across parties, e.g., using different codes to report the same test to different entities (from submitter to state to CDC).
- Apply informatics efficiency measures during sample receiving and accessioning.
- Electronically define and capture required identifiers/core data elements (submitter information, package, sample, tests, etc.) in the LIMS to initiate handling of any samples received or prepared, and add new data elements (e.g., metadata and demographics).

CA 1: Laboratory Test Request and Sample Receiving

Capability Statement	Level	Description of Levels	Select from drop down menu below
Capability Statement #1.1 The laboratory is able to receive an electronic test request message from a submitter for all tests.	Level 3	The laboratory is able to receive an electronic test request message from a submitter for all tests.	
	Level 2	The laboratory is able to receive an electronic test request message for some tests and paper-based requisitions for other tests.	
	Level 1	The laboratory is able to receive only paper-based requisitions for tests.	
	N/A	Not applicable to this laboratory.	
Capability Statement #1.2 The laboratory is able to receive an individual electronic test request or package request message from a submitter and process the workflow.	Level 3	The laboratory is able to receive an individual electronic test request or package request message from a submitter and process the workflow completely.	
	Level 2	The laboratory is able to receive an individual electronic test request or package request message from a submitter and process the workflow partially.	
	Level 1	The laboratory is able to receive a paper, e-mail, or fax, but not an electronic test order request message.	
	N/A	Not applicable to this laboratory.	
Capability Statement #1.3 The laboratory is able to receive data using one or more standard message types[9] (e.g., HL7[10] orders). Data include sample metadata, auxiliary data, test orders, test results, etc.	Level 3	The laboratory is able to receive data on samples using one or more standard message types, and data include sample metadata, auxiliary data, test orders, etc.	
	Level 2	The laboratory is able to receive data using nonstandard formats but cannot receive data on samples using standard message types.	
	Level 1	The laboratory is able to receive data on samples only via paper, e-mail or spreadsheets.	
	N/A	Not applicable to this laboratory.	
Capability Statement #1.4 The laboratory is able to send data using one or more standard message types (e.g., PHLIP[11], SDWIS[12], EDWR[13], ERLN[14] and LIMSi[15]). Data include sample metadata, auxiliary data, test orders, test results, etc.	Level 3	The laboratory is able to send data on samples using one or more standard message types, and data include sample metadata, auxiliary data, test results, etc.	
	Level 2	The laboratory is able to send data on samples using nonstandard formats but cannot send data on samples using standard message types.	
	Level 1	The laboratory is able to send data on samples only via paper, e-mail or spreadsheets.	
	N/A	Not applicable to this laboratory.	

Capability Statement	Level	Description of Levels	Select from drop down menu below
Capability Statement #1.5 The laboratory is able to use multiple secure transport protocols, e.g., Direct[4] (HIE[5] Service/ Protocol), CONNECT[6], PHIN MS[7], SOAP[8], etc.	Level 3	The laboratory is able to use multiple secure transport protocols	
	Level 2	The laboratory is able to use at least one secure transport protocol.	
	Level 1	The laboratory is unable to use any transport protocols.	
	N/A	Not applicable to this laboratory.	
Capability Statement #1.6 The laboratory is able to generate messages using multiple standardized vocabulary formats; integrate local and new codes and vocabulary standards[16]; and flexibly use vocabulary standards across parties, e.g., use different codes to report the same test to different entities (from submitter to state to CDC).	Level 3	The laboratory is able to integrate vocabulary standards and local and new codes, including mapping local codes to national standards.	
	Level 2	The laboratory is able to use multiple vocabulary standards but cannot integrate new codes and vocabulary standards.	
	Level 1	The laboratory uses only local coding standards but not multiple vocabulary formats.	
	N/A	Not applicable to this laboratory.	
Capability Statement #1.7 The laboratory evaluates and applies informatics efficiency measures during specimen receiving and accessioning. Examples are provided below.			
a) Barcode scanners	Level 3	Yes	
	Level 2	The laboratory has evaluated this measure and opted not to implement.	
	Level 1	No	
	N/A	Not applicable to this laboratory	
b) Flatbed scanners to read hard copy forms and transfer to electronic format to be stored as image/PDF files	Level 3	Yes	
	Level 2	The laboratory has evaluated this measure, and opted not to implement.	
	Level 1	No	
	N/A	Not applicable to this laboratory.	

Capability Statement	Level	Description of Levels	Select from drop down menu below
c) Radio-frequency identification (RFID)[1]	Level 3	Yes	
	Level 2	The laboratory has evaluated this measure, and opted not to implement.	
	Level 1	No	
	N/A	Not applicable to this laboratory.	
d) Robotics[2]	Level 3	Yes	
	Level 2	The laboratory has evaluated this measure and opted not to implement.	
	Level 1	No	
	N/A	Not applicable to this laboratory	
e) Central accessioning	Level 3	Yes	
	Level 2	The laboratory has evaluated this measure, and opted not to implement.	
	Level 1	No	
	N/A	Not applicable to this laboratory.	
f) Consistent accessioning practices across the laboratory	Level 3	Yes	
	Level 2	The laboratory has evaluated this measure, and opted not to implement.	
	Level 1	No	
	N/A	Not applicable to this laboratory.	
g) Web-based test order entry by submitter	Level 3	Yes	
	Level 2	The laboratory has evaluated this measure and opted not to implement.	
	Level 1	No	
	N/A	Not applicable to this laboratory	

Capability Statement	Level	Description of Levels	Select from drop down menu below
h) Distributing barcoded sample collection container/card	Level 3	Yes	
	Level 2	The laboratory has evaluated this measure, and opted not to implement.	
	Level 1	No	
	N/A	Not applicable to this laboratory.	
Capability Statement #1.8 The laboratory is able to electronically define and capture required identifiers/core data elements (submitter information, package, sample, tests) in the LIMS to initiate handling of any samples received or prepared and can also add new data elements (e.g., metadata and pass through auxiliary data).	Level 3	The laboratory is able to electronically define and capture required identifiers/core data elements in the LIMS to initiate handling of any samples received or prepared and can also add new data elements.	
	Level 2	The laboratory is able to electronically define and capture required identifiers and core data elements in the LIMS, to initiate handling of any samples received or prepared, but does not have the ability to add new data elements on an ad hoc basis.	
	Level 1	The laboratory is able to capture required identifiers and core data elements on paper only.	
	N/A	Not applicable to this laboratory.	

Total for this Capability Area	0
Percentage for this Capability Area	0.0%

Notes to Capability Area 1

1. **RFID:** RFID technology has multiple applications in a laboratory. Examples include, tracking (proximity tracking, location tracking as a part of Chain of custody), automated accessioning purposes, and inventory management in high volume laboratories.

2. **Robotics:** For example, liquid handlers connected to LIMS, automated EIA plate readers, and other automated analytical instruments in the laboratory.

3. **Meaningful Use (MU):** Applies to the minimum requirements (as defined by the final rule issued by the Centers for Medicare and Medicaid Services) that providers must meet through their use of certified Electronic Heath Record technology in order to qualify for incentives under the Health Information Technology for Economic and Clinical Health (HITECH) Act. (HealthIt.hhs.gov)

4. **Direct:** "The Direct Project specifies a simple, secure, scalable, standards-based way for participants to send authenticated, encrypted health information directly to known, trusted recipients over the Internet." (The Direct Project, 2010)

5. **Health Information Exchange (HIE):** "The term 'health information exchange (HIE) actually encompasses two related concepts:
   - "Verb: the electronic sharing of health-related information among organizations
   - "Noun: An organization that provides services to enable the electronic sharing of health-related information." (HealthIT.gov, "Health Information Exchange")

6. **CONNECT:** Open-source software for health information exchange.

7. **Public Health Network Messaging System (PHIN MS):** PHIN MS is a service that is used for creating standards, and HL7 2.x messages, for surveillance, message exchange between laboratories, public health jurisdictions and CDC. The goal is interoperability among public health systems.

8. **Simple Object Access Protocol (SOAP):** "A lightweight protocol for exchange of information in a decentralized, distributed environment." (Box et al., 2000)

9. **Message types:** The type of a message (messages are communicated between systems) specifies its name, structure and content data type.

10. **HL7:** "HL7 and its members provide a framework (and related standards) for the exchange, integration, sharing, and retrieval of electronic health information. These standards define how information is packaged and communicated from one party to another, setting the language, structure and data types required for seamless integration between systems. HL7 standards support clinical practice and the management, delivery, and evaluation of health services, and are recognized as the most commonly used in the world." (HL7, 2012).

11. **Public Health Laboratory Interoperability Project (PHLIP):** A collaborative effort between APHL, state PHLs, CDC Office of Infectious Diseases, and CDC PHITPO. The purpose of PHLIP is two-fold. (1) To accomplish exchange of laboratory reference test orders and results (ETOR) through HL7 messaging from LIMS to LIMS among states, and between state PHLs and CDC. (2) To accomplish laboratory reporting of surveillance test results to CDC programs, also via HL7 messaging from LIMS to a CDC database. (CDC, 2012)

12. **Safe Drinking Water Information System (SDWIS):** EPA developed SDWIS as a database to store information about drinking water.

13. **Electronic Drinking Water Report (EDWR):** An EPA initiative that established electronic data exchange between laboratories and state drinking water programs.

14. **Environmental Response Laboratory Network (ERLN):** Established by EPA as a network of laboratories that could be enlisted to support large-scale environmental responses by providing a range of laboratory services. (ERLN, 2011)

15. **Laboratory Information Management System Integration (LIMSi):** a project of the Laboratory Response Network that is helping laboratories connect their LIMS to CDC. (LIMSi, 2012)

16. **Vocabulary standards:** "Standard vocabularies and systems of encoding data have been defined by various standards development organizations (SDOs). Reliance on these standards for terminology and coding of data greatly improves semantic understanding and therefore the value of the data to analysis and decision making. Where they exist, preparedness systems should use these standard vocabularies and coding systems. As additional standards are defined, they should be accepted and implemented." (PHIN, 2005). Examples include, Standardized Nomenclature of Medicine – Clinical Terms (SNOMED CT), Logical Observation Identifiers Names and Codes (LOINC), Chemical Abstracts Service (CAS) Registry Numbers, etc.

CA 2: Test Preparation, LIMS Processing, Test Results Recording and Verification

Description

This capability area addresses informatics capabilities related to the business processes associated with initial sample test request and receiving.

Guidance Statement

Purpose: A critical function of an environmental, clinical, or public health laboratory is to receive requests for laboratory testing from an authorized submitter, process them and validate the results obtained, then issue reports to the submitter; and, when required, submit results reports to a local or state or federal public health agency. Traditionally, such requests and reports were exchanged manually, in paper form, via fax, email, or by postal service. Computerized LIMS with the capability to securely transfer encrypted request and result messages between data systems via national standard messaging formats, codes and terms, can achieve significant efficiencies in accuracy, time, and cost.

What: This capability area addresses test preparation, LIMS processing, test results recording and verification, and the progress achieved in implementing data system interoperability (i.e., the ability to receive test requests, verify and return test results and forward laboratory reports for notifiable diseases to public health agencies using secure electronic messaging).

How: The process of moving from an entirely paper-based work flow system to a secure electronic work flow system using standard messaging formats, codes, and terms can be a lengthy one requiring careful planning and staging of activities. Availability of resources to carry out this process also influences the timeline for achieving full interoperability.

A laboratory that has the desired informatics capabilities to efficiently manage the process for sample receiving and test requests can:

- Receive samples and associated electronic test requests from submitting laboratories and can perform pre-processing of the sample for testing individually, or in batches, through LIMS and integrated systems.
- Assign one or more samples to individual tests or combinations of tests, instruments, runs and batches, prepare test queue, and prioritize through LIMS and/or other integrated systems.
- Populate test results data [sample and Quality Control (QC)[1]] from instruments back into LIMS through a seamless integrated process.
- Send test order data from LIMS to an instrument in an automated manner.
- Perform verification for QC and test results for individual samples or batches within the LIMS and report QC parameters through the LIMS.
- Automatically flag and auto-assign tests to samples that need retesting (individual or batch), and review and update samples and their results through the LIMS.
- Auto-assign reflex testing to samples either individually or in a batch.
- Track reports created, the receiver of the report, the version it was created in, and maintain those logs.
- Export all sample associated data in flexible formats for further manipulation and analysis.
- Grant users permission by laboratory sections, to approve, edit (amend and correct), and view a report.
- Block electronic messaging for samples which should not be reported (e.g., proficiency samples, and validation samples).

CA 2: Test Preparation, LIMS Processing, Test Results Recording and Verification

Capability Statement	Level	Description of Levels	Select from drop down menu below
Capability Statement #2.1 The laboratory is able to receive samples and associated electronic test requests from submitters (including other laboratories) and can perform pre-processing[2] of the samples for testing individually or in batches through the LIMS and integrated systems[3].	Level 3	The laboratory is able to perform these functions electronically through the LIMS and integrated systems.	
	Level 2	The laboratory is able to perform some of these functions electronically.	
	Level 1	The laboratory uses a paper-based system to perform these functions.	
	N/A	Not applicable to this laboratory.	
Capability Statement #2.2 The laboratory is able to assign one or more samples to individual or combinations of tests, instruments, runs and batches[4], prepare test queue, and prioritize through the LIMS and/or other integrated systems.	Level 3	The laboratory is able to perform these functions through the LIMS and/or other integrated systems.	
	Level 2	The laboratory is able to perform some of these functions electronically.	
	Level 1	The laboratory uses a paper-based system to perform these functions.	
	N/A	Not applicable to this laboratory.	
Capability Statement #2.3 The laboratory is able to populate test results data (sample and QC[1]) from instruments back into LIMS through a seamless integrated process.	Level 3	The laboratory is able to electronically receive both sample and QC results in their LIMS.	
	Level 2	The laboratory is able to electronically receive sample results but not QC.	
	Level 1	The laboratory enters sample and QC results manually.	
	N/A	Not applicable to this laboratory.	
Capability Statement #2.4 The laboratory's LIMS is able to build an analytical sequence for instrument integration (e.g., create run queue for the instrument and upload it to the instrument).	Level 3	The laboratory is able to perform this function.	
	Level 1	The laboratory is unable to perform this function.	
	N/A	Not applicable to this laboratory.	

CA 2: Test Preparation, LIMS Processing, Test Results Recording and Verification

Capability Statement	Level	Description of Levels	Select from drop down menu below
Capability Statement #2.5 The laboratory is able to perform verification for QC and test results for individual samples or batches within LIMS and send QC parameters and instrument name to LIMS from the instrument.	Level 3	The laboratory is able to perform these functions.	
	Level 2	The laboratory is able to perform some of these functions.	
	Level 1	The laboratory is unable to perform these functions.	
	N/A	Not applicable to this laboratory.	
Capability Statement #2.6 The laboratory is able to automatically flag and auto assign tests to samples that need retesting (individual or batch) and can review and update samples and results through the LIMS.	Level 3	The laboratory is able to perform these functions through the LIMS.	
	Level 1	The laboratory is unable to perform these functions through the LIMS.	
	N/A	Not applicable to this laboratory.	
Capability Statement #2.7 The laboratory is able to auto-assign reflex or repeat testing[5] to samples either individually or in a batch	Level 3	The laboratory is able to perform this function.	
	Level 1	The laboratory is unable to perform this function.	
	N/A	Not applicable to this laboratory.	
Capability Statement #2.8 The laboratory is able to identify samples received for individual patients and maintain a local master patient index that can be used to detect discrepancies and support ongoing treatment management and monitoring efforts of public health submitters[6].	Level 3	The laboratory maintains a master patient index for samples where it is appropriate to do so, and can automatically detect potential matches and discrepancies.	
	Level 2	The laboratory maintains a master patient index for samples where it is appropriate to do so.	
	Level 1	The laboratory is not able to electronically identify multiple samples for individual patients.	
	N/A	Not applicable to this laboratory.	

Total for this Capability Area	0
Percentage for this Capability Area	0.0%

Notes to Capability Area 2

1. **Quality Control (QC) data:** "QC measures are intended to reflect the quality of the PHL's testing processes and the accuracy and reliability of the test results." (APHL, 2003)

2. **Sample Pre-processing:** The preparation and handling of samples before laboratory tests are performed on them.

3. **Integrated Systems:** A system that functions seamlessly and in real time with the LIMS.

4. **Runs and Batches:** A batch is a collection of test samples for processing. A run is a "continuous analytical sequence consisting of prepared samples and all associated QA measurements as required by the method." (ERLN, 2011)

5. **Reflex testing:** Occurs when initial test results are positive or outside normal parameters and indicate that a second related test is clinically appropriate. In order to avoid performing unnecessary reflex tests, laboratories may want to design their requisition form in a way that would only allow for the reflex test when necessary. Therefore, requisition forms should clearly indicate the condition under which the reflex test will be performed. Laboratories may wish to adopt a similar policy for confirmation testing, which may be mandatory. (HHS/OIG).

6. In some cases, the laboratory may want to integrate with a local Electronic Medical Record (EMR) provider to validate patient information.

CA 3: Report Preparation and Distribution

Description

This capability area addresses informatics capabilities related to electronic report preparation, electronic submission of test results, and auxiliary data report format and content, transport and distribution, and tracking.

Guidance Statement

Purpose: In order to meet the needs of their clients, PHLs are expected to provide valid and relevant results rapidly, and package these results for electronic consumption [e.g., for electronic health records (EHRs) within hospitals]. The ability to meet these needs depends on having a LIMS capable of providing the information electronically, the technical infrastructure necessary to package and transmit the results securely, and the skills to implement and manage that process.

What: This capability area assesses the ability to meet the typical electronic delivery needs of most PHLs. These capabilities are dependent on a laboratory's level of implementation of pre-analytical steps from CA 1 and CA 2. In addition to collection, storage, and retrieval of analytical test result data and additional data to support validation (e.g., quality control data for some tests), the laboratory collects and stores associated client-specific metadata and auxiliary data. These data must be available in an electronic format before they are added into the results message. While it is helpful to be able to "begin with the end in mind" when implementing data exchange technologies, often this may be difficult, as many PHL clients have different and evolving electronic data "end" requirements. Until more universal standardization of PHL data occurs, the PHL's capability to meet multiple data consumer needs may depend on its ability to address different electronic data message formats, vocabularies, and transport mechanisms as needed.

How: A PHL can benefit greatly from the use of an "interface engine" between its LIMS and external clients. This interface engine provides the PHL with the ability to scale its messaging infrastructure according to its needs, and insulate its LIMS from the security and performance hazards of having messaging functionality coupled with LIMS functionality.

In addition, the ability to exchange an electronic results message in the correct format requires personnel with special skill sets that include messaging and vocabulary. This exchange often includes partnership between laboratory and informatics SMEs who are capable of understanding the results well enough to translate them into their electronic format correctly and without loss of important detail. Many laboratories have found it beneficial to invest in training of laboratory staff to specialize in this area and obtain the necessary skills and experience.

A laboratory that has the desired Informatics capabilities related to report preparation, electronic submission of test results, report validation, distribution, and tracking, can:

- Create an electronic message for test results using agreed-upon standards and vocabulary for message creation.
- Send an electronic message for test results using agreed-upon standards and vocabulary for message transmission.
- Receive an acknowledgement about delivery of the electronic message using agreed-upon standards and vocabulary for message receiving.
- Electronically modify and verify submitters and data requestors authorized to receive results by referencing a test/data requestor index.
- Modify and verify submitters and data requestors authorized to receive results through LIMS and keep a log of submitters.
- Comply with submitters' data exchange format requirements for electronic results submittal and reporting based on different business rules.
- Submit results via a secure electronic message format.
- Electronically submit results of tests performed on the sample to recipients.
- Electronically authenticate test results.

CA 3: Report Preparation and Distribution

Capability Statement	Level	Description of Levels	Select from drop down menu below
Capability Statement #3.1 The laboratory is able to create an electronic message for test results using agreed-upon standards and vocabulary for message creation.	Level 3	The laboratory is able to perform this function.	
	Level 2	The laboratory is able to perform this function on a limited basis.	
	Level 1	The laboratory is unable to perform this function.	
	N/A	Not applicable to this laboratory.	
Capability Statement #3.2 The laboratory is able to send an electronic message for test results using agreed-upon standards and vocabulary for message transmission.	Level 3	The laboratory is able to send a new or ad hoc electronic message for test results using agreed-upon standards and vocabulary.	
	Level 2	The laboratory is able to perform this function on a limited basis using some of the agreed upon standards and vocabulary.	
	Level 1	The laboratory is unable to perform this function.	
	N/A	Not applicable to this laboratory.	
Capability Statement #3.3 The laboratory is able to receive an acknowledgement of delivery of the electronic message using agreed-upon standards and vocabulary for message receiving.	Level 3	The laboratory is able to perform this function.	
	Level 2	The laboratory is able to perform this function on a limited basis using some of the agreed-upon standards and vocabulary.	
	Level 1	The laboratory is unable to perform this function.	
	N/A	Not applicable to this laboratory.	
Capability Statement #3.4 The laboratory is able to route results electronically to requestors other than original submitters based upon test results.	Level 3	Yes	
	Level 1	No	
	N/A	Not applicable to this laboratory.	
Capability Statement #3.5 The laboratory maintains an electronic log of receivers of test results.	Level 3	Yes	
	Level 1	No	
	N/A	Not applicable to this laboratory.	

CA 3: Report Preparation and Distribution

Capability Statement	Level	Description of Levels	Select from drop down menu below
Capability Statement #3.6 The laboratory is able to comply with submitters' data exchange format requirements for electronic results submittal and reporting based on different business rules[1].	Level 3	The laboratory is able to comply with submitters' data exchange format requirements for electronic results submittal and reporting based on different business rules.	
	Level 2	The laboratory is able to comply with some of the data exchange and reporting format requirements of submitters.	
	Level 1	The laboratory is unable to comply with submitters' data exchange format requirements.	
	N/A	Not applicable to this laboratory.	
Capability Statement #3.7 The laboratory is able to electronically submit results of all tests performed on a particular sample or patient to recipients.	Level 3	The laboratory is able to electronically submit results of all tests performed on a particular sample or patient to recipients.	
	Level 2	The laboratory is able to electronically submit results for some tests performed on that sample to recipients, but cannot include results of any previous testing done on the patient.	
	Level 1	The laboratory is only able to submit results manually and/or by fax/mail.	
	N/A	Not applicable to this laboratory.	
Capability Statement #3.8 The laboratory is able to track reports created, the receiver of the report, time of transmission, and version it was created in, and maintain those logs.	Level 3	The laboratory is able to perform all these functions for the workflow of the report generation and transmission process.	
	Level 2	The laboratory is able to perform some of these functions for the workflow of the report generation and transmission process.	
	Level 1	The laboratory is able to track reports through disparate paper-based systems	
	N/A	Not applicable to this laboratory.	
Capability Statement #3.9 The laboratory is able to export all sample-associated data in flexible formats for further manipulation and analysis.	Level 3	The laboratory is able to export all sample associated data in flexible formats for further manipulation and analysis.	
	Level 2	The laboratory is able to export some sample associated data (e.g., results and some QC data or metadata) in a limited number of formats.	
	Level 1	The laboratory cannot export data in specified/ desired formats.	
	N/A	Not applicable to this laboratory.	

CA 3: Report Preparation and Distribution

Capability Statement	Level	Description of Levels	Select from drop down menu below
Capability Statement #3.10 The laboratory is able to grant users permission by laboratory sections to approve, edit (amend and correct), and view a report	Level 3	The laboratory is able to grant users permission by laboratory sections to approve, edit, and view a report.	
	Level 2	The laboratory is able to grant internal users permission to view reports but not to approve or edit.	
	Level 1	The laboratory cannot grant permissions.	
	N/A	Not applicable to this laboratory.	
Capability Statement #3.11 The laboratory is able to filter out electronic messaging for samples that should not be reported (e.g., proficiency samples, validation samples).	Level 3	The laboratory is able to perform this function.	
	Level 1	The laboratory is unable to perform this function.	
	N/A	Not applicable to this laboratory.	

Total for this Capability Area	0
Percentage for this Capability Area	0.0%

Notes to Capability Area 3

1. **Business rules:** "Anything that captures and implements business, policies and practices and can be used to: 1) enforce policy (e.g., program hierarchy, exception handling), 2) make a decision (e.g., eligibility determination, point in time verification), and/or 3) infer new data from existing data (e.g., persons with the same address live in the same household." (HealthIT.gov, 2010)

CA 4: Laboratory Test Scheduling

Description

This capability area addresses informatics capabilities which encompass prioritizing and processing the test workload for samples received. This CA includes the addition and prioritization of test requests and removal of completed requests. It also provides the basis for activating mutual assistance agreement.

Guidance Statement

Purpose: The ability to efficiently organize samples and manage the testing process is important in any modern laboratory. Parameters such as holding time, instrument availability, laboratory workload, and courier pickup are some of the variables that laboratories often consider to effectively prioritize and manage workflows. Overarching needs, like activating mutual assistance, often have significant impact on these priorities, especially for PHLs. Creating and managing these changing priorities often requires the use of informatics.

What: A test's priority can be changed in a LIMS by adding or removing the test from various testing schedules. Some systems have the ability to provide additional complex algorithms directly within the application based on many of the above parameters. These algorithms aid staff in building schedules. Similarly, the delivery of samples to a mutual assistance laboratory can also be automated within the information system. For example, the system can automatically place selected tests into a send-out queue, generate a shipping manifest, and electronically order the requested tests.

How: Streamlining testing workflows improves overall efficiency and maximizes resources. A laboratory that has the desired informatics capabilities to achieve these objectives can:

- Electronically add test requests, add to test schedules, and prioritize these test requests using laboratory-specified criteria.
- Remove and restore completed requests and transfer samples from active queue.
- Select tests and associated metadata for diversion to a mutual assistance laboratory.
- Capture specific data elements associated with process improvement indicators regarding test schedule.
- Create reports of test processing time by priority.
- Create test status reports (e.g., turnaround time).

CA 4: Laboratory Test Scheduling

Capability Statement	Level	Description of Levels	Select from drop down menu below
Capability Statement #4.1 The laboratory is able to electronically add test requests received or generated in-house; add to existing test schedule; and prioritize requests with respect to test type, submitter, turn-around time, etc.	Level 3	The laboratory is able to perform all of these functions.	
	Level 2	The laboratory is able to perform some of these functions.	
	Level 1	The laboratory is unable to perform these functions electronically.	
	N/A	Not applicable to this laboratory.	
Capability Statement #4.2 The laboratory is able to electronically remove and restore completed requests and transferred samples from active queue through the LIMS or other integrated systems[1].	Level 3	The laboratory is able to perform these functions through the LIMS or other integrated systems.	
	Level 1	The laboratory is unable to perform these functions electronically.	
	N/A	Not applicable to this laboratory.	
Capability Statement #4.3 The laboratory is able to electronically select tests for diversion to a mutual assistance laboratory and transmit metadata associated with tests/sample.	Level 3	The laboratory is able to perform these functions electronically.	
	Level 2	The laboratory is able to electronically select some but not all tests for diversion to a mutual assistance laboratory and transmit metadata associated with tests/sample.	
	Level 1	The laboratory is unable to perform these functions electronically.	
	N/A	Not applicable to this laboratory.	
Capability Statement #4.4 The laboratory is able to electronically generate a real-time test schedule by calculating daily processing capacity and tracking test load; flag overdue test requests; and notify submitter through LIMS and/or integrated information systems.	Level 3	The laboratory is able to perform all of these functions through LIMS and/or integrated information systems.	
	Level 2	The laboratory is able to perform some of these functions electronically through LIMS and/or integrated information systems, depending on test type.	
	Level 1	The laboratory is unable to perform these functions electronically.	
	N/A	Not applicable to this laboratory.	

CA 4: Laboratory Test Scheduling

Capability Statement	Level	Description of Levels	Select from drop down menu below
Capability Statement #4.5 The laboratory is able to electronically a) capture specific data elements associated with process improvement indicators[2] regarding test schedule; b) create reports of test processing time by priority; and c) create test status reports such as pending lists and turnaround time.	Level 3	The laboratory is able to perform all of these functions.	
	Level 2	The laboratory is able to perform some of these functions, though it is unable to create reports by priority.	
	Level 1	The laboratory is unable to perform these functions electronically.	
	N/A	Not applicable to this laboratory.	

Total for this Capability Area	0
Percentage for this Capability Area	0.0%

Notes to Capability Area 4

1. **Integrated systems:** A system that functions seamlessly and in real time with the LIMS.

2. **Process improvement indicators:** Statistics that track results and efficiencies gained in a laboratory following the modification of laboratory testing business processes

CA 5: Prescheduled Testing

Description

This capability area addresses informatics capabilities related to receipt of prescheduled samples in an efficient and timely manner to help with workload management.

Guidance Statement

Purpose: Data systems that have the ability to not only preschedule samples but also receive them and manage associated information on these samples can increase the efficiency of workload management in a laboratory.

What: Automating the process of prescheduling samples and receiving these samples back in the laboratory can have a significant impact on the manual processes used by a laboratory to manage its workload.

How: A laboratory that has the desired informatics capabilities to receive prescheduled samples in an efficient and timely manner can:

- Automate the process of scheduling either one-time or recurring requests.
- Automate receipt and processing of prescheduled samples.
- Automatically track distribution of kits (for testing and/or sample collection), their expiration dates and associated forms (received and completed), and receipt of related specimen/samples.
- Use the LIMS to predict and adjust workload based on the distribution schedule and corresponding tests received.

CA 5: Prescheduled Testing

Capability Statement	Level	Description of Levels	Select from drop down menu below
Capability Statement #5.1 The laboratory is able to schedule single (one-time) requests or recurring requests and manage receipt and processing of the prescheduled samples with partners in an automated manner.	Level 3	The laboratory is able to schedule single (one-time) requests or recurring requests and manage receipt and processing of the prescheduled samples with other partners in an automated manner.	
	Level 2	The laboratory is able to schedule single (one-time) requests or recurring requests and manage receipt and processing of the prescheduled samples with other partners in a partly automated manner.	
	Level 1	The laboratory is not able to schedule one-time or recurring requests in an automated manner.	
	N/A	Not applicable to this laboratory.	
Capability Statement #5.2 The laboratory is able to automatically track a) distribution of kits (for testing and/or sample collection); b) the kits' expiration date and associated forms (received and completed); and c) receipt of related sample/samples	Level 3	The laboratory is able to perform all of these functions electronically.	
	Level 2	The laboratory is able to perform some of these functions electronically.	
	Level 1	The laboratory uses a paper-based system to perform these functions.	
	N/A	Not applicable to this laboratory.	
Capability Statement #5.3 The laboratory is able to use LIMS to predict and adjust workload based on the distribution schedule[1] and corresponding tests received.	Level 3	The laboratory is able to use LIMS to predict and adjust workload based on the distribution schedule and corresponding tests received.	
	Level 2	The laboratory is able to predict workload; however the sources of these data reside in disparate systems and therefore the laboratory is unable to use LIMS to make an accurate prediction.	
	Level 1	The laboratory is unable to predict and adjust workload.	
	N/A	Not applicable to this laboratory.	

Total for this Capability Area	0
Percentage for this Capability Area	0.0%

Notes to Capability Area 5

1. **Distribution schedule:** Sample collection kits may be distributed as part of agreements with submitting laboratories and thus be a leading indicator of anticipated test sample submission.

CA 6: Specimen and Sample Tracking/Chain of Custody

Description

This capability area addresses informatics capabilities related to the laboratory's ability to create accurate and timely specimen and sample tracking and chain of custody documentation.

Guidance Statement

Purpose: A key aspect of ensuring quality testing and management of samples in any laboratory is the ability to know the status of a sample at any point in time, track the chain of custody[1], and determine the impact of the state of the sample on quality.

What: Informatics tools can provide a laboratory with the ability to readily and seamlessly determine the state and location of a sample, its disposition, who handled the sample, and any results associated with the sample.

How: A laboratory that has the desired informatics capabilities to ensure that samples are tracked efficiently and accurately and that chain of custody is appropriately documented can:

- Track the sample and its associated aliquots, their locations, and all steps in the sample's lifecycle[2]. This includes sample storage, the duration for which a sample was removed for testing, and sample disposition.
- Track aliquot hierarchy, including what tests were performed on which aliquot.
- Track and document custody of the sample from sample receipt to disposal, storage, or return to submitter.
- Record digital signatures of all staff that handled the sample.
- Link demographic data on samples with data on chain of custody, sample integrity, sample handling and defined storage parameters.
- Route the sample to a laboratory section.
- Track creation of aliquots.
- Assign an identifier (batch number, worksheet number) to a group of samples that were analyzed together, and assign associated identifiers for the instruments used for these analyses.

CA 6: Specimen and Sample Tracking/Chain of Custody

Capability Statement	Level	Description of Levels	Select from drop down menu below
Capability Statement #6.1 The laboratory is able to uniquely identify and track the location and associated dates of a sample and its aliquots at any step in the sample lifecycle[2] (including storage, time out for testing, and sample disposition) electronically.	Level 3	The laboratory is able to perform these functions electronically.	
	Level 2	The laboratory is able to track some of these attributes electronically.	
	Level 1	The laboratory is only able to track these attributes manually (i.e., external to LIMS).	
	N/A	Not applicable to this laboratory.	
Capability Statement #6.2 The laboratory is able to demonstrate chain of custody[1] by electronically documenting custody of the sample from receipt to disposal or return to submitter, including recording of digital signatures of sample custodians and analysts.	Level 3	The laboratory is able to perform these functions electronically.	
	Level 2	The laboratory is able to partly demonstrate chain of custody and partly track the sample, analyst, location, and time.	
	Level 1	The laboratory only tracks sample, analyst, location, and time manually.	
	N/A	Not applicable to this laboratory.	
Capability Statement #6.3 The laboratory is able to link data on samples with data on chain of custody, sample integrity[3], sample handling, and defined storage parameters including date range and temperature.	Level 3	The laboratory is able perform this sample tracking electronically.	
	Level 2	The laboratory is able to perform some of this sample tracking electronically.	
	Level 1	The laboratory can only track manually.	
	N/A	Not applicable to this laboratory.	
Capability Statement #6.4 The laboratory is able to associate and track the sample (e.g., Sample Identification) with one or more test requests, route the sample to a laboratory section.	Level 3	The laboratory is able to perform this sample tracking electronically.	
	Level 2	The laboratory is able to perform some of this sample tracking electronically.	
	Level 1	The laboratory can only track manually.	
	N/A	Not applicable to this laboratory.	

CA 6: Specimen and Sample Tracking/Chain of Custody

Capability Statement	Level	Description of Levels	Select from drop down menu below
Capability Statement #6.5 The laboratory is able to create, track, and maintain a sample aliquot hierarchy through the LIMS throughout all sections of the laboratory.	Level 3	The laboratory is able to perform this aliquot tracking through the LIMS.	
	Level 2	The laboratory is able to perform some of this aliquot tracking electronically.	
	Level 1	The laboratory uses a paper-based system to perform this tracking.	
	N/A	Not applicable to this laboratory.	

Total for this Capability Area	0
Percentage for this Capability Area	0.0%

Notes to Capability Area 6

1. **Chain of custody (rule set):** "Procedures and documents that account for the integrity of an item of evidence by tracking its handling and storage from its point of collection to its final disposition." (FBI, 2006)

2. **Sample lifecycle:** A comprehensive description of all sample processes, sample management, transfers, and data collection, with their corresponding LIMS actions throughout the period the laboratory interacts with the sample. This covers processes such as sample receipt, pre-testing activities (e.g., scheduling, measurements, dilution, aliquoting, etc.), testing, analysis, reporting, re-testing, storage, disposal, and destruction.

3. **Sample Integrity:** The physical, chemical, and biological characteristics of a sample that ensure it would yield accurate and representative test results.

CA 7: Media, Reagents, Controls: Manufacturing and Inventory

Description

This capability area addresses informatics capabilities related to the use of electronic and real-time management of all inventory-related activities within the laboratory.

Guidance Statement

Purpose: Laboratories are responsible for meeting logistical demands tied to their operational activities. Examples include providing materials for sample collection, sample transportation emergency response, and producing packaging for the needed chemicals, media, reagents, stains, controls, and kits. Whether this production is carried out by the laboratory or by third party suppliers, the laboratory may require the ability to provide these resources in adequate quantities based on laboratory need and in coordination with the inventory, supply, and logistics activities within the laboratory.

What: This capability area addresses informatics capabilities related to the receiving and processing of orders from internal laboratory sections and inventory control, lot manufacturing that may require other items to be manufactured to assemble the final ordered item, and creation of Quality Control data sets linked to each item or batch manufactured. It includes the use of informatics to associate QC data sets to inventory lots, trigger in-house manufacturing of items, sell inventory items to other laboratories, and track maximum and minimum inventory levels of items used in testing.

How: The ability to electronically track and forecast inventory and supply levels, as well as testing demands within the laboratory helps guide laboratories to begin in-house production of needed materials, and to identify the need for raw materials and other supplies.

From a process perspective, the laboratory management system would benefit from being able to effectively track the quantity, quality, location/storage, and oversight of all laboratory materials relevant to the manufacturing process across the relevant phases of the manufacturing lifecycle. The relevant steps in the product manufacturing lifecycle are:

- Formulation/design
- Planning (needs forecasts)
- Procurement
- Manufacture/production
- Quality testing
- Use, sale, or disposal/destruction

The system should be able to track product quality as products are used, moved, or stored for the duration of their shelf life, and provide alerts and information to initiate relevant action based on the state of these materials. The LIMS thus links manufacturing with the following functions: procurement, inventory, logistics, supplies, testing, quality management, accounts, and waste management. The information provided by the system can also be used to monitor the availability and cost effectiveness of in-house manufacturing.

CA 7: Media, Reagents, Controls: Manufacturing and Inventory

Capability Statement	Level	Description of Levels	Select from drop down menu below
Capability Statement #7.1 The laboratory is able to electronically track, manage, and maintain inventory[1], including maximum and minimum inventory levels for items used in testing, such as chemicals, media, reagents, control, etc.	Level 3	The laboratory is able to electronically track, manage, and maintain inventory, including maximum and minimum inventory levels for items used in testing.	
	Level 2	The laboratory is able to track, manage, and maintain inventory levels partly electronically and partly manually.	
	Level 1	The laboratory has only manual inventory tracking capability.	
	N/A	Not applicable to this laboratory.	
Capability Statement #7.2 The laboratory management systems[2] are able to associate Quality Control[3] (QC) data sets to inventory items and lots in an automated manner (e.g., batches or items manufactured, QC information, replace output by expiration dates).	Level 3	The laboratory management systems are able to perform this function in an automated manner.	
	Level 2	The laboratory management systems are able to perform this function in a partly automated manner.	
	Level 1	The laboratory uses a paper-based system to perform these functions.	
	N/A	Not applicable to this laboratory.	
Capability Statement #7.3 The laboratory management systems a) automate the control of manufacturing protocols; b) store and maintain electronic formulae of raw ingredients needed for manufacturing; and c) track lot information, including re-inventorying finished goods and synchronization with raw materials usage in the inventory system.	Level 3	The laboratory management systems are able to perform all of these functions.	
	Level 2	The laboratory management systems are able to perform some of these functions.	
	Level 1	The laboratory uses a paper-based system to perform these functions.	
	N/A	Not applicable to this laboratory.	

Total for this Capability Area	0
Percentage for this Capability Area	0.0%

Notes to Capability Area 7

1. **Inventory tracking:** Inventory management of items that directly support the testing process (not general inventory management). These items include internally manufactured items, such as reagents and media and purchased items, such as kit components. (APHL, 2003)

2. **Laboratory management systems:** Systems that help support the management of both testing and non-testing laboratory functions.

3. **Quality control:** "The overall system of technical activities and checks that measure the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements within prescribed limits established by the customer, operational techniques, and activities that are used to fulfill requirements for quality." (RLN, 2012)

CA 8: Data Exchange and Interoperability

Description

This capability area focuses on systematically addressing electronic interoperability and data exchange.

Guidance Statement

Purpose: Data exchange and interoperability are two significant capabilities for PHLs. Interoperable public health data systems and standards are a platform for exchange of information across all associated entities and create opportunities for improvement and efficiencies in public health.

What: A key issue for PHLs is the type, quality, and security of data exchange methods and interoperability between systems enabling the safe and secure transmission of data following agreed upon standards. This capability area addresses the types of data exchange, the quality of data including the ability to map to standardized codes, the security of information while its being transported, and the ability to reformat the same data based on partner's need.

How: As data sharing abilities advance with technology, the ability to utilize standards, the flexibility to accommodate ever-changing transport mechanisms, and the need to validate the content and ensure security of electronic data exchange are becoming critical tools. A laboratory that has the desired Informatics capabilities with regard to data exchange and interoperability can:

- Exchange data electronically with various entities such as other PHLs and federal, state, and local partners.
- Exchange bidirectional data, such as receiving electronic orders and test results with health facilities, sending electronic orders, and receiving results (exchange with CDC and other PHLs).
- Provide data electronically through a web portal for data and information exchange.
- Create and manage data exchange channels in partnership with state and national efforts such as statewide HIEs[1].
- Meet external reporting requirements of public health agencies and health departments. These requirements include the ability to:
    - Identify reportable laboratory events.
    - Adopt required message specifications (e.g., Meaningful Use)2.
    - Deliver secure automated electronic laboratory reports (ELR)3 to public health authorities.
    - Generate required HL74 messages for ELR messaging.
    - Use secure ELR transport mechanisms.
- Meet external reporting requirements of public health agencies and health departments using required ELR standards.
- Send automated electronic results to partners based on agreed-upon protocols.
- Send messages using different secure transports such as Virtual Private Network (VPN)[5], PHIN MS[6], or HIE Direct[7].
- Map Logical Observation Identifiers Names and Codes (LOINC)[8] for tests and Standardized Nomenclature of Medicine (SNOMED)[9] codes for test results to national and local notifiable diseases and conditions by integrating with Nationally Notifiable Conditions Tables (i.e., RCMT[10] within PHIN VADS[11]).
- Interface the LIMS with a message broker that maps local codes to standard codes, validates that all required data elements are present, generates valid message structure and content, and securely transmits the message using the agreed-upon transport mechanism. The message broker/integration engine can be a separate stand-alone capability or integrated with the LIMS.
- Participate in APHL advocacy initiatives (e.g., PHLIP[12], PHLISSA[13], ELR TA[14], NewSTEPS[15]).

CA 8: Data Exchange and Interoperability

Capability Statement	Level	Description of Levels	Select from drop down menu below
Capability Statement #8.1 The laboratory is able to exchange data electronically with various entities, such as with other PHLs and federal, state and local partners, and is able to meet external reporting requirements of public health agencies and health departments.	Level 3	The laboratory is able to perform these functions.	
	Level 2	The laboratory has limited ability to perform these functions.	
	Level 1	The laboratory is unable to exchange data with partners electronically, mostly reporting to partners manually (e.g., by mail/fax).	
	N/A	Not applicable to this laboratory.	
Capability Statement #8.2 The laboratory has or intends to develop software as part of its information system that will enable it to identify and message reportable laboratory events[16] to public health.	Level 3	Yes	
	Level 1	No	
	N/A	Not applicable to this laboratory.	
Capability Statement #8.3 The laboratory has or intends to develop the message specification for Meaningful-Use (MU)[2] -approved Automated Electronic Laboratory Reporting Implementation Guide (e.g., ORU^R01 HL7 2.5.1).	Level 3	Yes	
	Level 2	The laboratory has evaluated this measure, and opted not to implement.	
	Level 1	No	
	N/A	Not applicable to this laboratory.	
Capability Statement #8.4 The laboratory delivers or intends to deliver secure automated electronic laboratory reports to a designated public health authority consistent with the MU requirements on an agreed-upon schedule.	Level 3	Yes	
	Level 2	The laboratory has evaluated this measure, and opted not to implement.	
	Level 1	No	
	N/A	Not applicable to this laboratory.	

CA 8: Data Exchange and Interoperability

Capability Statement	Level	Description of Levels	Select from drop down menu below
Capability Statement #8.5 The laboratory generates HL7[4] messages directly, without conversion.	Level 3	Yes	
	Level 1	No	
	N/A	Not applicable to this laboratory.	
Capability Statement #8.6 The laboratory uses automated validation tools to assure that ELR[3] messages meet structural and content guidelines[17].	Level 3	Yes	
	Level 1	No	
	N/A	Not applicable to this laboratory.	
Capability Statement #8.7 The laboratory uses CDC's PHIN MS[6] for secure transport messaging of reportable laboratory tests to public health.	Level 3	The laboratory currently has PHIN-MS implemented.	
	Level 2	The laboratory has plans to implement PHIN-MS.	
	Level 1	The laboratory does not use PHIN-MS and has no plans to implement it.	
	N/A	Not applicable to this laboratory.	
Capability Statement #8.8 The laboratory uses secure ELR transport mechanisms.	Level 3	The laboratory currently participates in NHIN or connects through some HIE.	
	Level 2	The laboratory uses secure electronic transport mechanisms and proprietary point-point connections.	
	Level 1	The laboratory cannot use secure electronic transport mechanisms.	
	N/A	Not applicable to this laboratory.	
Capability Statement #8.9 The laboratory's ELR software solution employs business rules to automatically select/filter identified reportable data.	Level 3	Yes	
	Level 1	No	
	N/A	Not applicable to this laboratory.	

CA 8: Data Exchange and Interoperability

Capability Statement	Level	Description of Levels	Select from drop down menu below
Capability Statement #8.10 The laboratory is able to exchange transactional data[18] between systems (e.g., ETORs[19]).	Level 3	The laboratory is able to receive transactional data and process it.	
	Level 2	The laboratory is able to receive a transaction but the transaction is not integrated with the process.	
	Level 1	The laboratory is not able to receive these transactions.	
	N/A	Not applicable to this laboratory.	
Capability Statement #8.11 The laboratory is able to provide data electronically through a web portal for data and information exchange (e.g., turn-around information, result reporting, samples in-house, ad hoc queries, etc.).	Level 3	The laboratory is able to provide data electronically through a web portal for data and information exchange.	
	Level 2	The laboratory has some capability to provide data electronically through a web portal for data and information exchange.	
	Level 1	The laboratory is not able to provide data electronically through a web portal for data and information exchange.	
	N/A	Not applicable to this laboratory.	
Capability Statement #8.12 The laboratory is involved with state and national efforts, such as statewide HIEs and relevant standards development organizations (SDOs)[20], to create and manage data exchange channels.	Level 3	The laboratory is able and is involved with state and national efforts to create and manage data exchange channels.	
	Level 2	The laboratory is aware of the standards bodies and activities around these efforts but is not an active participant.	
	Level 1	The laboratory is not involved in these efforts.	
	N/A	Not applicable to this laboratory.	
Capability Statement #8.13 The laboratory supports other "environmental" and non-clinical data exchange/data submittal networks.	Level 3	Yes	
	Level 1	No	
	N/A	Not applicable to this laboratory.	

CA 8: Data Exchange and Interoperability

Capability Statement	Level	Description of Levels	Select from drop down menu below
Capability Statement #8.14 The laboratory performs data exchange electronically with the PH Newborn Screening[21] program.	Level 3	Yes	
	Level 1	No	
	N/A	Not applicable to this laboratory.	
Capability Statement #8.15 The laboratory performs data exchange electronically through HIE[1] or direct connections.	Level 3	Yes	
	Level 1	No	
	N/A	Not applicable to this laboratory.	
Capability Statement #8.16 The laboratory exchanges blood lead data for CLPPPs[22].	Level 3	Yes	
	Level 1	No	
	N/A	Not applicable to this laboratory.	
Capability Statement #8.17 The laboratory's software solution integrates Nationally Notifiable Conditions Tables and Local Tables (e.g., RCMT[10]) within PHIN VADS[11], with mappings of LOINC[8] test codes to national and local notifiable diseases/conditions.	Level 3	Yes	
	Level 1	No	
	N/A	Not applicable to this laboratory.	

CA 8: Data Exchange and Interoperability

Capability Statement	Level	Description of Levels	Select from drop down menu below
Capability Statement #8.18 The laboratory actively participates with public health jurisdictions[23] to create and develop listings of unique conditions that are reportable, and is able to proactively upgrade its capabilities to accommodate these changes.	Level 3	Yes	
	Level 1	No	
	N/A	Not applicable to this laboratory.	
Capability Statement #8.19 The laboratory supports the electronic reporting of the SACHDNC[24] screening panel of 31 core conditions and 26 secondary conditions.	Level 3	Yes	
	Level 1	No	
	N/A	Not applicable to this laboratory.	
Capability Statement #8.20 The laboratory uses an enterprise integration engine[25] that validates, filters, and maps the data, converting local codes to standard codes, checks that all required data elements are present, and generates valid message structure and content before securely transmitting the message to the public health authorities using the agreed-upon transport mechanisms.	Level 3	Yes	
	Level 1	No	
	N/A	Not applicable to this laboratory.	

CA 8: Data Exchange and Interoperability

Capability Statement	Level	Description of Levels	Select from drop down menu below
Capability Statement #8.21 The laboratory is able to electronically support the ICLN[26] networks where possible, and for each one, data exchange occurs automatically. (Please respond in regards to your laboratory's ability to participate directly or indirectly through your partners.)	Level 3	The laboratory is able to electronically support ICLN networks where possible.	
	Level 2	The laboratory is able to participate manually.	
	Level 1	The laboratory is unable to support this operation.	
	N/A	Not applicable to this laboratory.	
Capability Statement #8.22 The laboratory actively participates in APHL advocacy initiatives, such as PHLIP[12], PHLISSA[13], ELR TA[14], and NewSTEPS[15].	Level 3	Yes	
	Level 1	No	
	N/A	Not applicable to this laboratory.	

Total for this Capability Area	0
Percentage for this Capability Area	0.0%

Notes to Capability Area 8

1. **Health Information Exchange (HIE):** "The term 'health information exchange (HIE) actually encompasses two related concepts:
   - **"Verb:** the electronic sharing of health-related information among organizations
   - **"Noun:** An organization that provides services to enable the electronic sharing of health-related information." (HealthIT.gov, "Health Information Exchange")

2. **Meaningful Use (MU):** Applies to the minimum requirements (as defined by the final rule issued by the Centers for Medicare and Medicaid Services) that providers must meet through their use of certified Electronic Heath Record (EHR) technology in order to qualify for the incentives under the Health Information Technology for Economic and Clinical Health (HITECH) Act. (HealthIt.hhs.gov)

3. **Electronic Laboratory Reporting (ELR):** The automated transmission of laboratory-related data from commercial, public health, hospital, and other laboratories to state and local public health departments through an electronic health records (EHR) system or a Laboratory Information Management System (LIMS). ELR helps identify reportable conditions determined by confirmatory testing and supports case reporting at the state or local level.

4. **HL7:** HL7 and its members provide a framework (and related standards) for the exchange, integration, sharing, and retrieval of electronic health information. These standards define how information is packaged and communicated from one party to another, setting the language, structure and data types required for seamless integration between systems. HL7 standards support clinical practice and the management, delivery, and evaluation of health services, and are recognized as the most commonly used in the world. (HL7, 2012)

5. **Virtual Private Network (VPN):** A private network that extends across public networks (e.g., the Internet).

6. **Public Health Network Messaging System (PHIN MS):** PHIN MS is a service that is used for creating standards, and HL7 2.x messages, for surveillance, message exchange between laboratories, public health jurisdictions and CDC. The goal is interoperability among public health systems.

7. **Direct:** "The Direct Project specifies a simple, secure, scalable, standards-based way for participants to send authenticated, encrypted health information directly to known, trusted recipients over the Internet." (Direct, 2010)

8. **Logical Observation Identifier Names and Codes (LOINC):** "Universal data identifiers for laboratory results and clinical observations, e.g., vital signs, outcomes management, and research." (APHL L-SIP)

9. **Standardized Nomenclature of Medicine – Clinical Terms (SNOMED):** "Comprehensive, defined, and controlled clinical terminology created for the indexing of the entire medical record, under the International Health Terminology Standards Development Organization." (APHL L-SIP)

10. **RCMT:** Reportable Conditions Mapping Table.

11. **PHIN VADS:** Public Health Information Network (PHIN) Vocabulary and Distribution System.

12. **Public Health Laboratory Interoperability Project (PHLIP):** A collaborative effort between APHL, state PHLs, CDC Office of Infectious Diseases, and CDC PHITPO. The purpose of PHLIP is two-fold. (1) To accomplish exchange of laboratory reference test orders and results (ETOR) through HL7 messaging from LIMS to LIMS among states, and between state PHLs and CDC. (2) To accomplish laboratory reporting of surveillance test results to CDC programs, also via HL7 messaging from LIMS to a CDC database. (CDC, 2012)

13. **Public Health Laboratory Interoperability Solutions and Solution Architecture (PHLISSA):** A project to develop Electronic Laboratory Test Order and a Result Reporting Service Oriented Architecture supporting sharing of information between clinical care and public health. (CDC, 2012)

14. **Electronic Laboratory Reporting Technical Assistance (ELR TA):** A collaborative effort between APHL, states, and CDC PHITPO. This program provides public health agencies and their laboratory partners technical assistance to implement and enhance ELR capabilities.

15. **Newborn Screening Technical assistance and Evaluation Program (NewSTEPS):** Will provide quality improvement initiatives for newborn screening systems, a new innovative data repository, technical and educational resources, policy guidance, and program evaluation to state newborn screening programs and stakeholders, and also serve as a central link for access to newborn screening information, data and resources for the country. (APHL NewSTEPS, 2012)

16. **Reportable disease:** Laboratories are required, through statute, ordinance, or administrative rule, to report to a public health agency when certain conditions are diagnosed in individuals. (CDC NNDSS, 2012).

17. **ELR Guidelines:** Guidelines include NIST validation requirements and CDC's Message Quality Framework. The PHIN Message Quality Framework (MQF) is a testing tool that can assess whether messages follow the appropriate message and vocabulary standard. PHIN MQF validates the structure of the message, confirms that the message follows all business rules defined for it, and verifies that the vocabulary used in the message is correct. By using PHIN MQF, organizations can test whether their systems are producing correctly formatted messages that receivers will be able to unload and use. (CDC DISO https://phinmqf.cdc.gov)

18. **Transactional data:** Transaction data is data derived from organizational operational processes involving exchange between entities. It provides data to describe transaction events such as ETOR, sales, purchases, data reporting, etc.

19. **ETOR:** Electronic Test Order and Reporting.

20. **Standards Development Organization (SDO):** "A domestic or international organization that plans, develops, establishes, or coordinates voluntary consensus standards using procedures that incorporate the attributes of openness, balance of interests, due process, an appeals process, and consensus." (108th US Congress, 2004)

21. **Newborn screening (NBS):** The practice of testing every newborn for certain harmful or potentially fatal conditions that are not otherwise apparent at birth. Newborn screening tests take place before the newborn leaves the hospital and identifies serious or life-threatening conditions before symptoms begin. (APHL L-SIP)

22. **CLPPP:** Childhood Lead Poisoning Prevention Program.

23. **Jurisdiction:** Refers to any area within geopolitical boundaries such as a city, a county, multiple counties, a state, a region or nation, within which a governmental agency has legal authority to perform a clearly defined function.

24. **SACHDNC:** Secretary's Advisory Committee on Heritable Disorders in Newborns and Children. These core and secondary conditions are also known as the "Recommended Uniform Screening Panel" or RUSP. (HHS HRSA, 2012)

25. **Integration Engine:** "Software which works as a go-between for different systems. They monitor different types of interfaces and communication points and perform actions according to rules defined by the organization." (HL7 Interface Engine) Examples include Mirth, Rhapsody, etc. Note that APHL and CDC do not endorse or specifically recommend the use of the listed vendor products. These have been provided as examples to assist the user's understanding of enterprise integration engines.

26. **ICLN:** Integrated Consortium of Laboratory Networks.

CA 9: Statistical Analyis and Surveillance

Description

This capability area encompasses informatics capabilities related to the laboratory's ability to perform statistical analyses and support surveillance activities.

Guidance Statement

Purpose: A key part of collection, recording, and reporting data on specimens is the ability to use these data for decision making. This applies to data associated with diagnostic, referral testing as well as surveillance activities.

What: In order to use its data effectively, the laboratory may wish to conduct statistical analyses efficiently. This effective use of data includes the ability to study trends, analyze customer feedback, conduct ad hoc queries, and carry out exploratory analyses.

How: A laboratory that has the desired informatics capabilities to conduct statistical analyses and support surveillance activities, can:

- Electronically capture and store both demographic data/metadata associated with specimens/samples from submitters and non-test-specific data.
- Add metadata fields and electronically transmit these data to specified users.
- Electronically query flagged data to perform statistical analyses.
- Apply statistical methods for all samples (e.g., clinical, food and environmental) and analyze test results and data patterns.
- Query and create user-defined extracts of data on an ad hoc basis for electronic transmittal to specified formats.
- Perform analyses and study trends on performance data.
- Study customer feedback data using statistical methods and tools.
- Integrate GIS data on samples, specimen data, test results, and tabulated results for a given geographic area.

CA 9: Statistical Analyis and Surveillance

Capability Statement	Level	Description of Levels	Select from drop down menu below
Capability Statement #9.1 The laboratory is able to electronically capture and store both demographic data/metadata associated with specimens/samples from submitters and non-test-specific data, add metadata fields, and electronically transmit these data to specified users.	Level 3	The laboratory is able to perform all of these functions electronically.	
	Level 2	The laboratory is able to capture and store these data electronically but cannot transmit electronically.	
	Level 1	The laboratory cannot electronically capture and store or transmit these data.	
	N/A	Not applicable to this laboratory.	
Capability Statement #9.2 The laboratory is able to electronically query flagged data to perform statistical analyses across the entire laboratory information system in a standard manner.	Level 3	The laboratory is able to perform these functions electronically.	
	Level 2	The laboratory is able to either query flagged data to perform statistical analyses for one laboratory information system or create standard reports across multiple systems.	
	Level 1	The laboratory is unable to perform statistical analyses electronically.	
	N/A	Not applicable to this laboratory.	
Capability Statement #9.3 The laboratory is able to analyze test result and data patterns and data visualization, and apply complex statistical methods for all samples (e.g., clinical, food and environmental).	Level 3	The laboratory is able to perform these functions electronically.	
	Level 2	The laboratory is able to analyze results from all samples but cannot apply complex statistical analyses methods.	
	Level 1	The laboratory is only able to do simple statistical methods for analyses.	
	N/A	Not applicable to this laboratory.	
Capability Statement #9.4 The laboratory is able to query and create user-defined extracts of data on an ad hoc basis for electronic transmittal to specified formats.	Level 3	The laboratory is able to perform these functions electronically.	
	Level 2	The laboratory is able to perform some of these functions electronically.	
	Level 1	The laboratory is unable to query and extract data electronically.	
	N/A	Not applicable to this laboratory.	

CA 9: Statistical Analyis and Surveillance

Capability Statement	Level	Description of Levels	Select from drop down menu below
Capability Statement #9.5 The laboratory is able to perform analyses and study trends on performance data (including turnaround time, reagent tracking, and QC of samples) and customer feedback data using statistical methods and tools.	Level 3	The laboratory is able to perform these analyses in an automated manner (e.g., through the LIMS).	
	Level 2	The laboratory is able to collect this information electronically and perform these analyses manually	
	Level 1	The laboratory uses a paper-based system to collect this information and performs these analyses manually.	
	N/A	Not applicable to this laboratory.	
Capability Statement #9.6 The laboratory is able to integrate spatial data on samples, sample data, test results, and tabulated results for a given geographic area.	Level 3	The laboratory is able to integrate spatial data on samples, sample data, test results, and tabulated results for temporal and spatial analyses using visualization software, data modeling techniques, etc.	
	Level 2	The laboratory is able to integrate spatial data on samples, sample data, test results, and tabulated results but has limited ability to analyze the data.	
	Level 1	The laboratory is unable to integrate spatial data on samples, sample data, test results, and tabulated results.	
	N/A	Not applicable to this laboratory.	

Total for this Capability Area	0
Percentage for this Capability Area	0.0%

CA 10: Billing for Laboratory Services

Description

This capability area addresses the informatics capability of a laboratory to perform standard billing/revenue management functions for testing and non-testing services, use of data from different sources, and the expediency and efficiency with which these functions can be performed.

Guidance Statement

Purpose: PHLs handle various financial transactions as part of routine operations for which accounting infrastructure and support is required. There is an increasing need for PHLs to generate revenue by charging for the services and products they provide, including laboratory testing, manufactured products, certification, and oversight responsibilities. The varied nature of these activities may necessitate the linking of accounting systems within the laboratory to other operational and accounting systems within and outside the laboratory. Laboratories benefit from the informatics capability to electronically link these systems in order to assure accountability and efficient management of their financial resources. It is unlikely that most LIMS would be able to handle all the financial transactions performed by the laboratory. It is therefore important to facilitate electronic linkage between the LIMS and accounting systems. Similarly, laboratories may consider implementing accounting systems within the laboratory that can receive, read, and share data (interoperably) with all relevant systems whose operations have or may have financial implications for the laboratory.

What: This CA addresses the informatics ability of a laboratory to perform standard billing and revenue management functions for testing and non-testing services. Customers for non-test services may include other laboratories certified by the PHL; purchasers of training supplied by the PHL; purchasers of items that are manufactured by the PHL, such as reagents; and purchasers of inventory items, such as sample collection kits, that are assembled by the PHL. The CA describes the relevant systems that may be used to link the laboratory with overarching jurisdiction fiscal management to provide a forecast of revenues and expenditures, compare actual financial operations with the forecast, and establish cost constraints for laboratory operations. Examples include modeling how the business of laboratory services might perform financially if certain strategies, events, and plans are carried out. The CA also addresses the use of data from different sources, and the expediency and efficiency with which these functions can be performed.

How: A laboratory that has the desired Informatics capabilities to address its billing needs can:

- Comprehensively account for all existing sources of financial inflow to the laboratory.
- Describe all relevant systems related to cost accounting tasks and how they relate to each other within the informatics environment of the laboratory.
- Approach the consolidation or upgrade of system capabilities from an enterprise-wide perspective within the laboratory and in full consideration of its financial partners and obligations.
- Maintain the capability to compile and combine data from these different systems for statistical analysis. Analysis may link billing for services to fiscal considerations and reliably inform management on trends that influence the budgets.
- Take the human resource implications of billing into account. Laboratories may wish to bill for the effort involved in providing laboratory services.
- Maintain the human resource capacity to handle the interoperability, data integration, and financial analysis aspects of a comprehensive billing system.

CA 10: Billing for Laboratory Services

Capability Statement	Level	Description of Levels	Select from drop down menu below
Capability Statement #10.1 Regardless of whether it can bill for services or receive dedicated revenue, the laboratory is able to electronically generate discrete chargeables[1]/ values of laboratory services and other products (e.g., ability to generate accounts receivable[2] through a system integrated with the LIMS).	Level 3	The laboratory is able to perform this function electronically.	
	Level 2	The laboratory is partly able to perform this function electronically.	
	Level 1	The laboratory is not able to perform this function electronically.	
	N/A	Not applicable to this laboratory.	
Capability Statement #10.2 The laboratory is able to conduct electronic billing in a flexible, automated, and on-demand manner to insurance or other clearing house entities[3], and to customers (e.g., local government entities, hospitals, private laboratories, and private citizens).	Level 3	The laboratory is able to conduct electronic billing in a flexible, automated, and on-demand manner to insurance or other clearing house entities, and to customers.	
	Level 2	The laboratory is able to invoice customers electronically but is unable to conduct electronic billing to insurance or clearing house entities.	
	Level 1	The laboratory conducts billing activities using a paper-based system.	
	N/A	Not applicable to this laboratory.	
Capability Statement #10.3 The laboratory is able to automatically bill customers for non-test services provided.	Level 3	The laboratory is able to conduct billing for non-test services in an electronic and automated manner.	
	Level 2	The laboratory is able to conduct billing for non-test services in a partly automated manner.	
	Level 1	The laboratory conducts all billing for non-test services using a paper-based system.	
	N/A	Not applicable to this laboratory.	
Capability Statement #10.4 The laboratory's information system collects and stores data to support and manage cost/resource accounting[4] for batch and non-batch analytical services.	Level 3	The laboratory's information system is able to perform these functions.	
	Level 2	The laboratory's information system is able to perform some of these functions.	
	Level 1	The laboratory is unable to perform these functions.	
	N/A	Not applicable to this laboratory.	

CA 10: Billing for Laboratory Services

Capability Statement	Level	Description of Levels	Select from drop down menu below
Capability Statement #10.5 The laboratory's information system collects and stores necessary financial data and supports the management of cost recovery and budgeting[5] of laboratory resources.	Level 3	The laboratory's information system is able to perform these functions.	
	Level 2	The laboratory's information system is able to perform some of these functions.	
	Level 1	The laboratory's information system is unable to perform these functions.	
	N/A	Not applicable to this laboratory.	

Total for this Capability Area	0
Percentage for this Capability Area	0.0%

Notes to Capability Area 10

1. **Chargeables:** Services for which the laboratory generates a billing charge for its clients/customers.
2. **Accounts receivable:** The tracking of payments owed to the laboratory from the provision of goods and services, and the management of invoices generated for clients and customers.
3. **Clearing house entities:** Financial institutions responsible for managing transactions between various commercial entities.
4. **Cost accounting and resource accounting:** These data provides transparent accountability of costs/resources needed to perform analytical services and support management efforts to be productive and efficient with existing resources. The data include costs based on the individual cost of each production step as well as the value of capital assets representing fixed costs in the production process.
5. **Budgeting:** Developing plans for the laboratory's anticipated income and expenditures.

CA 11: Contract and Grant Management

Description

This capability area concerns the use of informatics for all aspects of contract and grant management in the laboratory, and the management of all informatics contracts and grants.

Guidance Statement

Purpose: Most PHLs use mechanisms such as contracts and grants in providing services. The ability to manage these mechanisms and link them to the services provided is an informatics function interrelated with other processes, such as the collection of specimens; the scheduling, processing, tracking, and reporting of test results; and billing for laboratory services.

What: This capability area concerns the use of informatics for all aspects of contract and grant[1] management in the laboratory. It also addresses the management of informatics-related contracts and grants.

How: A laboratory that has the desired informatics capabilities with regard to contract and grant management can:

- Determine a single source for managing all contractual and grant data, with estimates and timelines for how these relate to testing and billing functions and other laboratory services.
- Follow an enterprise-wide approach to information systems implementation.
- Combine budget, personnel, legal, and laboratory procedures with informatics functions.
- Incorporate features such as tracking of contract-related events (e.g., provision of billable tests and services), management (e.g., burnrates, notifications, and alerts), personnel roles, and links to contractual instruments.

CA 11: Contract and Grant Management

Capability Statement	Level	Description of Levels	Select from drop down menu below
Capability Statement #11.1 The organization has a centralized electronic information system or document management system that tracks and stores grants, agreements, and project management artifacts[2].	Level 3	The organization has a centralized electronic information system or document management system to track and store these artifacts.	
	Level 2	The organization has electronic and paper-based systems to track and store these artifacts.	
	Level 1	All of these artifacts are paper-based.	
	N/A	Not applicable to this laboratory.	
Capability Statement #11.2 The laboratory is able to organize, monitor and track all its agreements with outside parties using electronic processes.	Level 3	The laboratory is able to organize, monitor and track all its agreements with outside parties using electronic processes.	
	Level 2	The laboratory is able to organize, monitor and track all its agreements with outside parties using some electronic processes.	
	Level 1	The laboratory is only able to organize, monitor and track its agreements with outside parties using manual processes.	
	N/A	Not applicable to this laboratory.	
Capability Statement #11.3 The laboratory and organization have personnel[3] whose primary role is managing the informatics portions of grants, contracts, and informatics-related agreements with vendors and partners.	Level 3	The laboratory and organization have personnel whose primary role is managing these operations and procedures.	
	Level 2	The laboratory and organization have personnel whose secondary role is managing these operations and procedures.	
	Level 1	The organization does not have roles or procedures for managing these operations.	
	N/A	Not applicable to this laboratory.	

CA 11: Contract and Grant Management

Capability Statement	Level	Description of Levels	Select from drop down menu below
Capability Statement #11.4 The laboratory uses contractual instruments[4] to ensure that the support required for services is in place.	Level 3	All interactions with IT vendors and data exchange partners are guided by contractual instruments and data exchange agreements, respectively.	
	Level 2	Some interactions with IT vendors and data exchange partners are guided by contractual instruments and data exchange agreements.	
	Level 1	The laboratory has no contractual instruments or data exchange agreements.	
	N/A	Not applicable to this laboratory.	

Total for this Capability Area	0
Percentage for this Capability Area	0.0%

Notes to Capability Area 11

1. **Contracts and grants:** "From a system design perspective, the major distinction between a grant and a contract is that under a grant, the monies are given to the PHL in a lump sum at the beginning of the grant, or according to a set disbursement schedule. With a contract, the PHL typically draws down the contract dollars as services defined in the contract are performed. In most other aspects, grants and contracts are similar." (APHL BP#10)

2. **Artifacts:** A by-product of a technology development process, in this case referring to all the project management documents, software development documents, technical documentation, source codes, etc.

3. **Contract and grant personnel:** These may include the contract manager and vendor liaison. Contract Manager: An individual responsible for managing the portfolio of informatics-related contracts involving the laboratory. Vendor Liaison: An individual/office that coordinates the relationships between the laboratory and its vendors, partners, including vetting, registration, and scheduling of vendors, and ensuring that activities involving vendors do not affect the mission and integrity of the PHL.

4. **Contractual instruments:** These include Service Level Agreements (SLA) which define the level of service expected from the provider as part of a service contract; memoranda of understanding (MOU); binding contractual agreements with IT and other vendors; and data exchange agreements with data exchange partners, etc.

CA 12: Training, Education and Resource Management

Description

This capability area focuses on informatics aspects of training, education and resource management activities within the laboratory.

Guidance Statement

Purpose: Maintaining a well-trained and suitably qualified laboratory workforce is a principal concern of every PHL. To accomplish this, the PHL endeavors to accurately estimate the human resource (HR) implications of its roles and responsibilities and support the continuous development of its workforce capabilities in order to effectively meet current and future challenges. This capability lends itself to innovative ways of keeping an up-to-date workforce, with timely information guiding the implementation of comprehensive HR management policies. HR management and the ability to manage information resources as part of a broader knowledge management strategy help make PHLs efficient and competitive. PHLs may require access to a wide array of competencies required for the efficient management of routine, ad-hoc, project-based, and mid-to-long term activities and goals.

What: This capability area focuses on informatics aspects of training, education and resource management activities within the laboratory.

How: A laboratory that has the desired informatics capabilities to ensure a well-trained and competent laboratory workforce has generally implemented the following:

- A clearly defined workforce strategy that links workforce needs and required competencies to organizational goals. This strategy may also reflect expectations imposed by regulatory standards.
- An information system that tracks the overall skills and competencies mix in the laboratory, and addresses different aspects of training, performance measurement, and professional development.
- Assigned roles and responsibilities for designated staff to ensure that laboratory personnel are up-to-date on their proficiency and professional training requirements and needs, and opportunities are created to address observed competency gaps.
- Access to good quality data that are indispensable in shaping the laboratory workforce of the future while remaining competitive and efficient. This access could inform on trends and forecast challenges and expectations that the PHL may face, in order to guide appropriate action.
- Maintenance of a balance between internal and external human resources (e.g., contracts and outsourced services) in an efficient manner that promotes organizational learning and sustainable institutional capacity.
- Evaluation of training and its impact on laboratory policy and practice.

CA 12: Training, Education and Resource Management

Capability Statement	Level	Description of Levels	Select from drop down menu below
Capability Statement #12.1 The laboratory is able to electronically create, manage, maintain, and track a comprehensive electronic master record[1], which includes training, proficiency[2], competency[3], and skill levels for each laboratorian, and is able to generate reports across capabilities and training.	Level 3	The laboratory is able to create, manage, maintain and track this master record electronically.	
	Level 2	The laboratory has electronic records on laboratorian training, proficiency, competency and associated data; however they are not in a centralized location and the laboratory is not able to generate aggregate reporting.	
	Level 1	The laboratory tracks laboratorian training, proficiency, competency and associated data manually.	
	N/A	Not applicable to this laboratory.	
Capability Statement #12.2 The laboratory routinely manages laboratory operations using up-to-date information on laboratory resources (including personnel, instrument availability, supplies, etc.) through summarized management reports, ad hoc reports, and real time queries.	Level 3	The laboratory routinely manages laboratory operations using up-to-date information on laboratory resources through summarized management reports, ad hoc reports and real time queries; these reports allow for capacity assessment and balancing of workloads.	
	Level 2	The laboratory routinely manages laboratory operations using data on laboratory resources managed using multiple systems or non-integrated systems that can capture the information electronically.	
	Level 1	The laboratory manages laboratory operations using paper-based systems.	
	N/A	Not applicable to this laboratory.	
Capability Statement #12.3 The laboratory maintains fully qualified and dedicated human resources, has financial resources for developing and ensuring a well-trained and up-to-date workforce, and identifies further opportunities for training, and tracks them electronically. Training is aligned with the business needs and directions for service in the laboratory and the personal growth of the laboratorian.	Level 3	The laboratory meets all of these requirements.	
	Level 2	The laboratory has limited training resources and capability, and tracks training received and provided in a partly automated manner.	
	Level 1	The laboratory does not have dedicated training management resources, has limited training capability, and manually tracks training received and provided.	
	N/A	Not applicable to this laboratory.	

CA 12: Training, Education and Resource Management

Capability Statement	Level	Description of Levels	Select from drop down menu below
Capability Statement #12.4 The laboratory maintains documentation, in electronic format, of training activities provided by the staff to external partners.	Level 3	The laboratory maintains documentation of training activities in an electronic format.	
	Level 2	The laboratory maintains documentation of training activities in a partly electronic format.	
	Level 1	The laboratory maintains documentation of training activities, in a paper-based format.	
	N/A	Not applicable to this laboratory.	
Capability Statement #12.5 The laboratory has plans and implements them for continuing education[4], upgrading and maintaining competencies, refresher training, and all other relevant aspects of informatics training[5].	Level 3	The laboratory has plans and implements them for continuing education, upgrading and maintaining competencies, refresher training, and all other relevant aspects of informatics training.	
	Level 2	The laboratory has plans for certain areas of informatics training and has implemented some of these plans, but has not addressed all relevant aspects of informatics training.	
	Level 1	The laboratory lacks a structured plan for informatics-related trainings.	
	N/A	Not applicable to this laboratory.	
Capability Statement #12.6 The laboratory has an ongoing informatics training program focused on the entire workforce up through the various levels of informatics competencies.	Level 3	The laboratory provides basic informatics training for its entire workforce and offers training for specialized informatics roles.	
	Level 2	The laboratory provides basic informatics training for its entire workforce.	
	Level 1	The laboratory provides no training or a basic informatics training for a portion of its workforce	
	N/A	Not applicable to this laboratory.	
Capability Statement #12.7 The laboratory implements a comprehensive Knowledge Management (KM)[6] strategy and demonstrates improved KM practices organizationally, has developed KM performance measures, and manages this information electronically.	Level 3	The laboratory has implemented a comprehensive KM strategy that addresses all of these functions	
	Level 2	The laboratory has implemented a comprehensive KM strategy that addresses some of these functions.	
	Level 1	The laboratory does not have a comprehensive and detailed KM strategy.	
	N/A	Not applicable to this laboratory.	

CA 12: Training, Education and Resource Management

Capability Statement	Level	Description of Levels	Select from drop down menu below
Capability Statement #12.8 The laboratory implements a comprehensive Lifecycle management strategy[7] for IT investments, including IT project management[8] resources, and a functional coordinating project management office (if needed).	Level 3	The laboratory implements a comprehensive Lifecycle management strategy for IT investments, including IT project management resources, and a functional coordinating project management office.	
	Level 2	The laboratory implements a comprehensive Lifecycle management strategy for IT investments, including IT project management resources.	
	Level 1	The laboratory does not have any of these capabilities.	
	N/A	Not applicable to this laboratory.	
Capability Statement #12.9 The laboratory has adopted a strategy, including assigned roles and responsibilities, for communications with senior agency officials, policymakers, and stakeholders about the laboratory's informatics capabilities and strategic resourcing priorities.	Level 3	The laboratory has adopted all of these strategies.	
	Level 2	The laboratory has adopted some of these strategies.	
	Level 1	The laboratory has adopted none of these strategies.	
	N/A	Not applicable to this laboratory.	
Capability Statement #12.10 The laboratory has a dedicated, comprehensive and sustainable team to support informatics activities/projects (IT, technical scientists, management).	Level 3	The laboratory has a dedicated, comprehensive and sustainable team to support informatics activities/projects and can prioritize the use of these resources.	
	Level 2	The laboratory has some of these resources available in a sustainable manner and can prioritize the use of these resources.	
	Level 1	An adequate component of informatics system resources is not available.	
	N/A	Not applicable to this laboratory.	

Total for this Capability Area	0
Percentage for this Capability Area	0.0%

Notes to Capability Area 12

1. **Master record:** A record containing a comprehensive profile, credentials, and other details about an individual or organization associated with the laboratory.

2. **Proficiency:** Mastery of a specific behavior or skill demonstrated by consistently superior performance, measured against established or popular standards. (Businessdictionary.com)

3. **Competency:** "Action-oriented statements that delineate the essential knowledge, skills, and abilities in the performance of work responsibilities. Competencies are describable and observable." (CDC and CSTE, 2008)

4. **Continuing education (CE):** "Refers to an array of opportunities by which professionals can augment existing knowledge and skills. CE is essential for professional competence, career development, and compliance with licensing rules and other regulations. CE is offered through a variety of auspices, methods, and venues. Advances in instructional technology and electronic communication have further expanded access to CE opportunities." (APHL L-SIP)

5. **Informatics Training:** Examples include LIMS functionality, Data Exchange, future data needs, refresher courses, and end user training.

6. **Knowledge Management (KM):** "Refers to how best to leverage knowledge internally and externally…It deals with creating a process for generating value-added benefits from an organization's intellectual assets." (Leibowitz et al., Knowledge Management, 2009).

7. **Lifecycle Management Strategy:** The continuous process of managing the laboratory's IT investments and its procedures for testing, modifying, and implementing changes to existing computing systems including hardware, software, and documentation or installing new systems throughout their lifecycle. (ERLN, 2011)

8. **Project Management:** The practice of planning and managing laboratory projects to ensure that they stay within scope, time, and cost limits.

CA 13: Laboratory Certifications, Accreditations and Licensure

Description

This capability area addresses informatics capabilities related to fulfilling state and other regulatory certification/licensing and, where appropriate, oversight responsibilities assigned to the PHL.

Guidance Statement

Purpose: It is critical for laboratories to possess the informatics capabilities needed to deliver high quality services to their customers in a secure, cost effective and efficient manner, while remaining compliant with all state and federal laws.

What: Laboratories obtain and maintain certification by successfully completing the requirements for certification as stipulated under state and federal regulations (e.g., CLIA-88, TNI, state certification of drinking water, etc.). Accreditation is generally given only by organizations to laboratories conducting activities within the scope of that organization's interests. Licensure is usually granted by governments (federal or state) to entities such as hospitals, laboratories, and individuals to conduct a specific scope of activities within relevant jurisdictions.

How: A laboratory that has the desired informatics capabilities to fulfill state, federal and other regulatory requirements to procure and maintain appropriate certification, accreditation, and licensure, can:

- Comply with all applicable data processing standards associated with local, state, and federal certification/accreditation/licensing and other requirements associated with analytical testing performed in the laboratory (e.g., CLIA, CAP, NCCLS/CLSI, PHIN, TNI, ISO, ASCLD-Laboratory, SDWA, FDA, etc.)[1]
- Comply with various state, federal and other security and regulatory standards pertaining to privacy and security of personal health, medical, and other identifiable information.
- Electronically create and modify reports, and electronically manage all data associated with laboratory certifications, accreditations, and licensure.

CA 13: Laboratory Certifications, Accreditations and Licensure

Capability Statement	Level	Description of Levels	Select from drop down menu below
Capability Statement #13.1 The laboratory complies with all applicable data processing standards associated with local, state, and federal certification/ accreditation/ licensing and requirements associated with analytical testing performed in the laboratory (e.g., CLIA, CAP, NCCLS/CLSI, PHIN, TNI, ISO, ASCLD-Laboratory, SDWA, FDA)[1].	Level 3	The laboratory demonstrates compliance in its LIMS with all of these accreditation/ standards and requirements.	
	Level 2	The laboratory demonstrates data processing compliance in its LIMS or other electronic system for some of the accreditation/standards but not all.	
	Level 1	The laboratory is unable to demonstrate compliance electronically.	
	N/A	Not applicable to this laboratory.	
Capability Statement #13.2 The laboratory complies with security standards and regulations (e.g., HIPAA[2] standards, CDC bioterrorism and chemical standards, select agent and Nuclear Regulatory Commission regulations) and other federal and state regulations pertaining to privacy and medical transactions containing personal health information.	Level 3	The laboratory has documents, policies and procedures, and electronic systems to comply with security standards and regulations and manages compliance electronically.	
	Level 1	The laboratory has documents, policies and procedures to comply with security standards and regulations but lacks an electronic system to manage compliance.	
	N/A	Not applicable to this laboratory.	
Capability Statement #13.3 The laboratory creates ad hoc reports, modifies reports, and manages data on certification of other laboratories electronically based on properly documented processes, in a system designed to support the complete process.	Level 3	The laboratory performs all of these functions electronically.	
	Level 2	The laboratory performs some of these functions electronically.	
	Level 1	The laboratory performs these functions using a paper-based system.	
	N/A	Not applicable to this laboratory.	

CA 13: Laboratory Certifications, Accreditations and Licensure

Capability Statement	Level	Description of Levels	Select from drop down menu below
Capability Statement #13.4 The laboratory meets PHIN Requirements and Certification Criteria[3] (e.g., LRN-B[4]).	Level 3	The laboratory meets current PHIN certifications requirements.	
	Level 2	The laboratory is in process to meet PHIN certification requirements.	
	Level 1	The laboratory does not meet PHIN certification requirements.	
	N/A	Not applicable to this laboratory.	

Total for this Capability Area	0
Percentage for this Capability Area	0.0%

Notes to Capability Area 13

1. **CLIA, CAP, NCCLS, CLSI, PHIN, NELAC, ISO, ASCLD, SDWA, FDA:**
   - Clinical Laboratory Improvement Amendments (CLIA)
   - College of American Pathologists (CAP)
   - National Committee for Clinical Laboratory Standards (NCCLS)
   - Clinical and Laboratory Standards Institute (CLSI)
   - Public Health Information Network (PHIN)
   - The NELAC Institute (TNI). National Environmental Laboratory Accreditation Conference (NELAC)
   - International Organization for Standardization (ISO)
   - American Society of Crime Laboratory Directors Laboratory Accreditation Board (ASCLD/LAB)
   - Safe Drinking Water Act (SDWA)
   - Food and Drug Administration (FDA) (for food and pharmaceutical requirements).
2. **HIPAA:** Health Insurance Portability and Accountability Act
3. **Public Health Information Network (PHIN) Certifications:** Evaluation for each PHIN Certification includes demonstrating the required capability and compliance with the applicable certification criteria. Each PHIN Certification includes the certification criteria for PHIN Requirement #5 (Security and Availability). (CDC PHIN 2012)
4. **LRN-B:** Laboratory Response Network-Biological.

CA 14: Customer Relationship Management

Description

This capability area focuses on the electronic management and use of information received from customer feedback on the laboratory's activities, performance and services.

Guidance Statement

Purpose: The purpose of this capability area is to ensure that the laboratory can improve its efficiency through the electronic management and use of information received from customer feedback on the laboratory's activities, performance and services.

What: Efficient customer relationship management is key to maintaining a laboratory's performance goals. As a part of customer relationship management, PHLs collect and analyze all necessary data from multiple sources related to operations, billing, etc. Laboratories can use this data to manage their customer relationships by: reducing costs and increasing efficiencies in overall operation; increasing effectiveness by identifying customer needs and providing the correct services; and building and maintaining customer loyalty through relevant and timely communications, etc.

How: A laboratory that has the desired informatics capabilities to fulfill all activities associated with customer relationship management can:

- Maintain an electronic system that manages customer and employee feedback and complaints.
- Maintain an electronic system to manage laboratory errors and information requests.
- Maintain an electronic system to record corrective actions and generate ad hoc queries and reports.

CA 14: Customer Relationship Management

Capability Statement	Level	Description of Levels	Select from drop down menu below
Capability Statement #14.1 The laboratory maintains an electronic system that manages customer feedback and complaints, laboratory errors, and information requests; records corrective actions; generates ad hoc queries and reports; and examines and uses quantitative measurements of performance such as turnaround times to improve service.	Level 3	The laboratory is able to perform these functions electronically.	
	Level 2	The laboratory is able to perform some of these functions electronically, but does not perform quantitative performance measurements or tuning of service.	
	Level 1	The laboratory performs these functions using a paper-based system.	
	N/A	Not applicable to this laboratory.	

Total for this Capability Area	0
Percentage for this Capability Area	0.0%

CA 15: Quality Control (QC) and Quality Assurance (QA) Management

Description

This capability area addresses the informatics capability of a laboratory to be able to perform and provide appropriate QC and QA services integrated into all aspects of the performance of the laboratory testing process, performance tracking, validation of results, and exchange of data.

Guidance Statement

Purpose: Laboratory analysts take steps to ensure and monitor the precision and accuracy of results, and to maintain their Quality Control (QC) data efficiently. The laboratory also conducts Quality Assurance (QA) activities and integrates both QC and QA efficiently into the entire testing process.

What: QC and QA services can be integrated into many aspects of the laboratory testing process, including performance tracking, result validation, reporting, and data exchange.

How: A laboratory that has the desired informatics capabilities to perform and provide appropriate QC and QA services can:

- Use the LIMS or other integrated systems to electronically set up and capture raw data associated with sample testing, including QC parameters and associated data elements (e.g., the creation and maintenance of a master record for each QC test by instrument/method, parameters for reagent, and sample conditions).
- Electronically extract and transmit QC data associated with sample results.
- Use the LIMS or other integrated system to execute a comprehensive document control system[1] to capture standard operating procedures (SOP) with respect to instrument/test/method and version control.
- Use the LIMS or other integrated system to track, analyze, trend, export, and create reports, and electronically verify all QC measures associated with all tests and samples.
- Collect QC data associated with analytical sequences within the LIMS and validate results prior to reporting by comparing QC data to method measurement quality objectives (e.g., recovery percent, completion of requested tests, frequency and sequence of blanks, spikes, and duplicates, etc.).
- Electronically capture QC data in the LIMS or other system and revise output formats and data as required for trending, analyses, and reporting.
- When appropriate, use the LIMS to validate data and provide qualifiers for test results qualifiers that indicate whether test results fail to meet QC requirements, meet QC requirements with notation, or fully meet QC requirements.
- Implement an electronic quality management system (QMS)[2] that coordinates organizational structure, procedures, processes, and resources.

CA 15: Quality Control (QC) and Quality Assurance (QA) Management

Capability Statement	Level	Description of Levels	Select from drop down menu below
Capability Statement #15.1 The laboratory uses the LIMS and/or integrated system to set up and capture raw data associated with sample testing, including QC parameters or associated data elements (e.g., creation and maintenance of a master record for each QC test by instrument/method, parameters for reagents, sample conditions, etc.) for laboratory and third party generated samples, analytes and submitted samples.	Level 3	The laboratory is able to perform all of these functions through the LIMS and/or integrated systems.	
	Level 2	The laboratory is able to perform some of these functions through LIMS and/or third party integrated systems.	
	Level 1	The laboratory performs these functions using a paper-based system.	
	N/A	Not applicable to this laboratory.	
Capability Statement #15.2 The laboratory electronically extracts and transmits QC data associated with sample results for all business purposes and the QC range determines any auto trigger and follow-up action.	Level 3	The laboratory is able to perform these functions electronically.	
	Level 2	The laboratory is able to perform some of these functions electronically.	
	Level 1	The laboratory cannot electronically extract and transmit QC data.	
	N/A	Not applicable to this laboratory.	
Capability Statement #15.3 The laboratory is able to execute a comprehensive document control system[1] (to capture SOPs with respect to instrument/test/method and version control) through the LIMS and/or integrated systems.	Level 3	The laboratory is able to execute a comprehensive document control system through the LIMS and/or integrated systems.	
	Level 2	The laboratory has a document control system in stored network folders and can execute this via a third party system using standalone or external systems.	
	Level 1	The laboratory has a manual document control system.	
	N/A	Not applicable to this laboratory.	

CA 15: Quality Control (QC) and Quality Assurance (QA) Management

Capability Statement	Level	Description of Levels	Select from drop down menu below
Capability Statement #15.4 The laboratory is able to track, analyze, trend, export, create QMS[2] reports, and electronically verify all QC measures associated with all tests and samples through the LIMS and/or integrated systems.	Level 3	The laboratory is able to perform all of these functions through the LIMS and/or integrated systems.	
	Level 2	The laboratory has limited ability to track, analyze, trend, and create QMS reports, and electronically verify all QC measures associated with all tests and samples through the LIMS and/or integrated systems and may require a third party system.	
	Level 1	The laboratory cannot perform any of these functions electronically.	
	N/A	Not applicable to this laboratory.	
Capability Statement #15.5 The LIMS collects QC data associated with analytical sequences (batches) and is able to validate results prior to reporting (automated data review) by comparing these QC data to method measurement quality objectives[3] (e.g., % recovery, completion of tests requested and frequency and sequence of blanks, spikes, and duplicates).	Level 3	The laboratory is able to perform flexible (ad hoc) automated data reviews for all tests by comparing QC data to multiple method measurement quality objectives.	
	Level 2	The laboratory is able to provide limited automated data reviews for some tests by comparing QC data to limited method measurement quality objectives.	
	Level 1	The laboratory is unable to provide automated data review/validation of results.	
	N/A	Not applicable to this laboratory.	
Capability Statement #15.6 The laboratory is able to electronically capture QC data in the LIMS or other information system and revise output formats and data when appropriate (trending, analyses and reporting).	Level 3	The laboratory is able to electronically capture QC data in the LIMS or other information system and revise output formats and data when appropriate.	
	Level 2	The laboratory has limited ability to capture QC data in the LIMS and to revise output formats, and may require other information to perform this function.	
	Level 1	The laboratory manually captures and reports out QC data.	
	N/A	Not applicable to this laboratory.	
Capability Statement #15.7 The LIMS is able to provide QC qualifiers to test results using automated configurable rules-based functionality.	Level 3	The LIMS is able to provide QC qualifiers to test results using automated configurable rules-based functionality.	
	Level 2	The LIMS is able to provide QC qualifiers to test results using manual functionality.	
	Level 1	The LIMS is unable to provide QC qualifiers to test results.	
	N/A	Not applicable to this laboratory.	

CA 15: Quality Control (QC) and Quality Assurance (QA) Management

Capability Statement	Level	Description of Levels	Select from drop down menu below
Capability Statement #15.8 The laboratory is able to use informatics technologies to facilitate the analytics of the QMS.	Level 3	The laboratory is able to use informatics technologies to facilitate the analytics of the QMS.	
	Level 2	The laboratory is able to use informatics technologies to facilitate some analytics of the QMS.	
	Level 1	The laboratory is unable to electronically coordinate its QMS practices.	
	N/A	Not applicable to this laboratory.	

Total for this Capability Area	0
Percentage for this Capability Area	0.0%

Notes to Capability Area 15

1. **Document control system:** An electronic system for tracking and storing electronic documents. This tracking function includes version control, and different types of documents could be stored including images, and scanned copies.

2. **Quality Management System (QMS):** "A set of interrelated or interacting elements that organizations use to direct and control how quality policies are implemented and quality objectives are achieved." (Praxiom, 2013)

3. **Measurement quality objectives:** "Statements that define the specific measurement goals needed to meet the Data Quality Objectives (DQOs); they are quantitative thresholds or qualitative statements of performance characteristics. In general, the MQOs do not specify the methods, but provide criteria for describing different aspects of data quality. DQO are Qualitative/quantitative statements that clarify objectives, define appropriate data, and specify tolerable levels of decision error for monitoring programs. They are used to determine the quality and quantity of data needed." (Flotemersch 2006)

CA 16: Laboratory Safety and Accident Investigation

Description

This capability area focuses on the use of informatics capabilities to ensure the safety of all laboratory activities.

Guidance Statement

Purpose: Ensuring the safety[1] of all laboratory activities is critical for successful laboratory operations.

What: A laboratory can use informatics capabilities to enhance and more effectively maintain the safety of all laboratory activities.

How: A laboratory that has the desired informatics capabilities to ensure the safety of laboratory activities can:

- Link electronic hazardous materials master records, and storage location records, and use current practice standards in tracking laboratory materials of safety concern.
- Use the LIMS to track laboratory materials considered to be safety hazards, including tracking disposal of used hazardous materials.
- Provide appropriate Material Safety Data Sheets (MSDS) and standard operating procedures (SOP) used by laboratory personnel.
- Maintain electronic security for infectious and toxic agents, associated media, reagents, and inventory, with access restricted to personnel with appropriate federal security clearances.
- Analyze, track, and maintain electronic records on safety incidents, errors, violations, and laboratory accidents in a centralized system.
- Electronically manage, maintain, track, and identify laboratory safety and accident investigation procedures, take corrective actions, perform root cause analysis, and disseminate appropriate safety standards and procedures across the laboratory.
- Maintain a detailed task workflow analysis[2] of processes within the laboratory that pose a safety risk to ensure compliance with safety standards.

CA 16: Laboratory Safety and Accident Investigation

Capability Statement	Level	Description of Levels	Select from drop down menu below
Capability Statement #16.1 The laboratory links electronic hazardous materials[3] master records and storage location records and is able to track laboratory materials of safety concern. The LIMS tracks laboratory materials considered to be safety hazards, (including tracking disposal of used hazardous materials) and the laboratory is able to provide appropriate MSDS[4] and SOP used by laboratory personnel.	Level 3	The laboratory is able to perform all of these functions.	
	Level 2	The laboratory is able to perform some of these functions.	
	Level 1	The laboratory tracks hazardous materials using a paper-based system.	
	N/A	Not applicable to this laboratory.	
Capability Statement #16.2 The laboratory maintains electronic security for infectious and toxic agents, associated media[5], reagents, and inventory in a centralized system, with access restricted to personnel with appropriate federal security clearances[6].	Level 3	The laboratory is able to maintain electronic security for infectious and toxic agents, associated media, reagents, and inventory in a centralized system, with access restricted to personnel with appropriate federal security clearances.	
	Level 2	The laboratory is able to maintain electronic security for infectious and toxic agents, associated media, reagents, inventory in disparate systems, with access restricted to personnel with appropriate federal security clearances	
	Level 1	The laboratory maintains a paper-based process for managing security for infectious and toxic agents and access for authorized personnel.	
	N/A	Not applicable to this laboratory.	
Capability Statement #16.3 The laboratory is able to securely and confidentially analyze, track and maintain electronic records on safety incidents, errors, violations, and laboratory accidents in a centralized system.	Level 3	The laboratory is able to securely and confidentially analyze, track, and maintain electronic records on safety incidents, errors, violations, and laboratory accidents in a centralized system.	
	Level 2	The laboratory is able to securely and confidentially analyze, track, and maintain electronic records on safety incidents, errors, violations and laboratory accidents, with data residing in disparate systems.	
	Level 1	The laboratory manually analyzes, tracks, and maintains records on safety incidents, errors, violations, and laboratory accidents (e.g., paper-based).	
	N/A	Not applicable to this laboratory.	

CA 16: Laboratory Safety and Accident Investigation

Capability Statement	Level	Description of Levels	Select from drop down menu below
Capability Statement #16.4 The laboratory is able to securely and confidentially electronically manage, maintain, track, and identify laboratory safety and accident investigation procedures, take corrective actions, perform root cause analysis[7], and disseminate appropriate safety standards and procedures across the laboratory.	Level 3	The laboratory is able to securely and confidentially perform all of these functions.	
	Level 2	The laboratory is able to securely and confidentially perform some of these functions electronically.	
	Level 1	The laboratory manages laboratory safety and investigation procedures manually (e.g., paper-based).	
	N/A	Not applicable to this laboratory.	
Capability Statement #16.5 The laboratory is able to electronically manage alerts associated with hazardous materials and can generate appropriate package and sample labels once an alert is received.[8]	Level 3	The laboratory is able to perform all of these functions.	
	Level 2	The laboratory has limited ability to perform these functions.	
	Level 1	The laboratory uses a paper-based system to manage information on hazardous materials.	
	N/A	Not applicable to this laboratory.	

Total for this Capability Area	0
Percentage for this Capability Area	0.0%

Notes to Capability Area 16

1. **Safety:** Procedures, equipment, personal protective equipment, and work practices that are capable of protecting employees from the health hazards presented by hazardous biologic materials. (Delany 2011)

2. **Workflow analysis:** "The analysis of processes (made up of tasks) and their interactions through process mapping, or flowcharting, which involves diagramming all of the tasks required to carry out a process, and identifying the points at which one process intersects with another. Workflow analysis addresses inefficiencies and bottlenecks revealed by the process mapping." (Kushinska 2011)

3. **Hazardous materials:** Materials that pose a safety risk. They include biologic materials, research animals, chemical materials, radiologic materials, and the physical environment. (Delany 2011)

4. **MSDS:** The Material Safety Data Sheet (MSDS) is a fact sheet summarizing information regarding material identification for a chemical product or mixture, including hazardous ingredients; health, physical, and fire hazards; first aid; chemical reactivities and incompatibilities; spill, leak, and disposal procedures; and protective measures required for safe handling and storage. (Delany, 2011)

5. **Media:** Substances used in growing (culturing) microorganisms.

6. **Federal security clearance:** An administrative determination based upon the results of a favorably adjudicated background investigation that an individual is trustworthy and may be granted access to a specified level of classified national security information as required in the performance of assigned duties. (HHS)

7. **Root cause analysis:** "A family of methods, applying a sequence of component methods: (1) schematic representation of the incident sequence and its contributing conditions, (2) identification of critical events or active failures or conditions in the incident sequence, and (3) systematic investigation of the management and organizational factors that allowed the active failure to occur" (Livingston, 2001)

8. **Examples of alert-associated activity:** Examples of activities associated with hazardous material alerts include labeling potential toxic and/or infectious materials or kit preparation if a toxic preservative is to be added.

CA 17: Laboratory Mutual Assistance and Disaster Recovery

Description

This capability area focuses on informatics capabilities, plans and agreements for laboratory mutual assistance, emergency preparedness, surge management and disaster recovery, assurance of continuity of operations, and related policies.

Guidance Statement

Purpose: As part of emergency preparedness, public health laboratories are responsible for rapidly and efficiently resuming essential operations. Planning for operations under the most extreme conditions can serve as an aid in mitigation with respect to agency personnel, facilities, IT infrastructure and the overall mission. Therefore, PHLs would benefit from preparing and maintaining a continuity of operations plan (COOP)[1] that provides guidelines for the continuation of critical operations in the event of any disaster/emergency event.

What: COOP guidelines can be documented in such a way that the most critical operations are identified, the command structure and succession plan is communicated, continuity teams are identified, and location and resources are spelled out, to support the continuation of the laboratory's mission critical processes. The PHL's COOP ensures:

- The capability of implementation with or without warning.
- The ability to perform essential functions within the recommended period upon COOP activation.
- The capability to maintain essential functions for up to the maximum recommended time period following COOP activation.
- Regularly scheduled testing, training, and exercising of agency personnel, equipment, systems, processes and procedures used to support the PHL in a disaster fire, and other emergency event.
- Locations are identified as alternate facilities and there is regular risk analysis of those facilities.

How: The laboratory's COOP can support the identification and documentation of temporary operation procedures which would enable the performance of essential function and promote development, maintenance and annual review of the plan's capabilities. Therefore, a laboratory that has the desired informatics capabilities with regard to this capability area has implemented the following:

- Memoranda of Agreement (MOAs)[2]/Memoranda of Understanding (MOUs)[3]/Service Level Agreements (SLAs)[4] for all IT maintenance and support services and appropriate management of all documentation related to the agreements.
- MOUs and MOAs with out of state and outsourced IT services including data sharing and service level agreements and processes/procedures to routinely monitor these services to ensure compliance with the MOUs and MOAs.
- MOUs with other laboratories for mutual assistance during emergency response and surge testing, including data-sharing agreements for secure electronic data exchange which are compliant with state and federal standards, and signed agreements in place to support putting the mutual assistance agreements.
- Exercises and drills conducted according to a documented schedule, at least annually, to test the effectiveness of the MOAs /MOUs/protocols described above and produce after action reports (AARs) designed to improve the process.
- Established policies, protocols, resources and requirements for IT infrastructure and support services for emergency and disaster recovery operations with clearly documented duration and extent to which IT supports will be required.
- Defined policies and procedures for continuity of operations plan (COOP) with respect to restoring informatics support including IT services.

- Documentation supporting the existing agreements (i.e. MOU/MOA/SLAs) that is routinely updated and managed.
- A catalogue of capacities and services offered by partners, that is managed and routinely updated and a documented schedule to test the effectiveness of these capabilities in disaster recovery and emergency situations.

The presentation delivered at the 2012 National Emergency Response Meeting, speaks to the importance of developing and exercising a COOP (http://www.aphl.org/aphlprograms/lss/Laboratory-Efficiencies-Initiative/Pages/Informatics.aspx).

CA 17: Laboratory Mutual Assistance and Disaster Recovery

Capability Statement	Level	Description of Levels	Select from drop down menu below
Capability Statement #17.1 The laboratory has memoranda of agreement (MOA)[2]/ memoranda of understanding (MOU)[3]/ service level agreements (SLAs)[4] for all IT maintenance and support services.	Level 3	The laboratory has MOA/MOU/SLAs for all IT maintenance and support services.	
	Level 2	The laboratory has MOA/MOU/SLAs for some IT maintenance and support services.	
	Level 1	The laboratory has no MOA/MOU/SLA for IT maintenance and support services.	
	N/A	Not applicable to this laboratory.	
Capability Statement #17.2 The laboratory has MOU/MOA, including data sharing agreements and SLAs, with out of state and outsourced IT services, and has processes/ procedures to routinely monitor these services to ensure compliance with MOU/MOA.	Level 3	The laboratory has MOU/MOA, including data sharing agreements and SLAs, with out of state and outsourced IT services, and has processes/ procedures to routinely monitor these services to ensure compliance with MOU/MOA.	
	Level 2	The laboratory has MOU/MOA (but not data sharing agreements or SLAs) with out of state and outsourced IT services, and has some processes/ procedures to routinely monitor these services to ensure compliance with MOU/MOA.	
	Level 1	The laboratory does not have MOU/MOA with out of state and outsourced IT services.	
	N/A	Not applicable to this laboratory.	
Capability Statement #17.3 The laboratory has MOU with other laboratories for mutual assistance during emergency response and surge testing; data sharing agreements for secure electronic data exchange; and signed agreements to support putting these agreements into practice. All agreements are compliant with state and federal standards.	Level 3	The laboratory has all of these items.	
	Level 2	The laboratory has some of these items.	
	Level 1	The laboratory does not have MOU or agreements for mutual assistance.	
	N/A	Not applicable to this laboratory.	

CA 17: Laboratory Mutual Assistance and Disaster Recovery

Capability Statement	Level	Description of Levels	Select from drop down menu below
Capability Statement #17.4 The laboratory routinely conducts exercises and drills following a documented schedule, at least annually, to test the effectiveness of the MOA/MOU described in 17.3 and performs After Action Reviews (AARs) designed to improve the process.	Level 3	The laboratory routinely conducts these exercises and drills following a documented schedule, at least annually.	
	Level 2	The laboratory conducts these exercises on an ad hoc basis.	
	Level 1	The laboratory does not conduct any exercise to test the effectiveness of these MOA/MOU/protocols.	
	N/A	Not applicable to this laboratory.	
Capability Statement #17.5 The laboratory has established policies, protocols, resources, and requirements for IT infrastructure and support services for emergency and disaster recovery operations with clearly documented duration and extent of required IT supports.	Level 3	The laboratory has established these policies, protocols, resources, and requirements.	
	Level 2	The laboratory has some of these policies, protocols, resources, and requirements.	
	Level 1	The laboratory has none of these, policies, protocols, resources, or requirements.	
	N/A	Not applicable to this laboratory.	
Capability Statement #17.6 The laboratory has defined policies and procedures for continuity of operations plan (COOP)[1] to restore informatics support including IT services.	Level 3	The laboratory has defined policies and procedures for COOP to restore informatics support including IT services.	
	Level 2	The laboratory has some policies and procedures for COOP to restore critical informatics services.	
	Level 1	The laboratory lacks defined policies and procedures for COOP to restore IT and informatics services.	
	N/A	Not applicable to this laboratory.	
Capability Statement #17.7 The laboratory manages and routinely updates all documentation supporting existing agreements (i.e., MOU/MOA/SLAs) pertaining to disaster recovery and mutual assistance.	Level 3	The laboratory manages and routinely updates all documentation supporting existing agreements.	
	Level 1	The laboratory does not manage or routinely update all documentation supporting existing agreements.	
	N/A	Not applicable to this laboratory.	

CA 17: Laboratory Mutual Assistance and Disaster Recovery

Capability Statement	Level	Description of Levels	Select from drop down menu below
Capability Statement #17.8 The laboratory manages and routinely updates a catalogue of capacities and services offered by partners, and a documented schedule to test effectiveness of partners' capabilities in disaster recovery and emergency situations.	Level 3	The laboratory manages and routinely updates both a catalogue of capacities and services offered by partners, and a documented schedule to test effectiveness of partners' capabilities.	
	Level 2	The laboratory manages and updates a partial catalogue but not a regular documented schedule to test effectiveness of partners' capabilities.	
	Level 1	The laboratory maintains neither a catalogue nor a regular documented schedule to test effectiveness of partners' capabilities.	
	N/A	Not applicable to this laboratory.	

Total for this Capability Area	0
Percentage for this Capability Area	0.0%

Notes to Capability Area 17

1. **Continuity of Operations Plan (COOP):** "A plan that details the how essential functions of an agency will be handled during any emergency or situation that may disrupt normal operations." (APHL L-SIP)
2. **Memorandum of Agreement (MOA):** A document describing in detail the specific responsibilities of, and actions to be taken by, each of the parties so that their goals may be accomplished. A MOA may also indicate the goals of the parties, to help explain their actions and responsibilities. (HHS, 2003)
3. **Memorandum of Understanding (MOU):** A document that describes very broad concepts of mutual understanding, goals and plans shared by the parties (HHS, 2003)
4. **Service Level Agreement (SLA):** A contractual agreement between an internal or external service provider .and their customer specifying performance guarantees with associated penalties should the service note be performed as contracted. (HS, Practices Guide)

CA 18: Core IT Services: Hardware, Software, and Services

Description

This capability area addresses the breadth and maturity of laboratory information systems including informatics, interoperability, information and communications technology hardware, software and services.

Guidance Statement

Purpose: Once thought of as a support function, the delivery of laboratory IT services has evolved to the extent that electronic recordkeeping and automated data management are mission-critical components of PHL operations. The rapid expansion of LIMS and support technologies has prompted the need for laboratories to manage multiple business processes and maintain interoperable networks with other laboratories. Interoperability requires that laboratories grapple with a new set of technologies that transcend individual laboratories.

What: IT service arrangements can take many forms. For example, IT services can follow a decentralized model, with the laboratory managing most IT services, a consolidated or 'centralized' model, or shared services hybrid model, with aspects of centralization and decentralization. Whatever the form of IT service arrangements, laboratory managers are encouraged to recognize that the totality of the laboratory's IT infrastructure is more than just the LIMS.

Though familiar to virtually all governmental laboratory directors, the LIMS is only the most visible component of the laboratory's IT infrastructure. To be sure, technologies such as the LIMS and associated hardware and software are critical assets. However, the larger IT infrastructure (e.g., informatics) also includes:

- **Governance functions,** such as contract oversight, budgeting for IT products and services, policymaking, and other management activities.
- **Technical support,** including software customization, staff training, trouble-shooting and other activities to implement commercial technologies and otherwise assist end-users.

It is critical for successful laboratory operations that laboratory managers understand each of these components, along with associated costs, risks, metrics, and implementation strategies. Laboratory operations may benefit from negotiations with many IT partners and leaders outside of the "laboratory". The memoranda of understanding (MOUs)[1] and service level agreements (SLAs)[2] can facilitate productive negotiations and help document essential IT activities. These documents may be written in the language of the IT professional and convey the importance and functions of laboratory services through clear business case models.

Many compliance agencies, such as Select Agent Rule[3], CAP[4] and TNI (The NELAC Institute)[5], require that PHLs be able to provide specific proof of policies and procedures regarding IT security, reliability, and accountability. While the ultimate responsibility for these tasks resides with the laboratory director, the tasks themselves and the associated monitoring activities are performed by IT staff, with important components completed by entities other than the local laboratory administration. It is therefore crucial that laboratory leadership establish clear and specific governance policies and operational procedures to meet and monitor the required metrics and procedures for regulatory compliance.

"The Brave New World," a white paper developed by the APHL Informatics Committee, provides laboratories with guidance to identify, distinguish, and negotiate components of operational agreements to successfully employ consolidated IT services. This paper, publicly available on aphl.org, may be useful to laboratory and IT leaders. (APHL, 2011)

How: A laboratory that has the desired informatics capabilities to achieve breadth and maturity in their laboratory information systems, including informatics, interoperability, information and communications technology hardware, software, and services, can:

- Operate an enterprise-wide LIMS solution that handles all information processes within the laboratory and is available 24/7 and 365 days/year.
- Access an IT help desk and assure IT support for the laboratory.

- Maintain fully mature and fully functional IT functions.
- Define functional requirements and translate them into software development and configuration as needed and also have the capacity for change management.
- Capture data using a standard enterprise integration engine (e.g., messaging, vocabulary).
- Access, search, and avail legacy data online and integrate the legacy system into the LIMS.
- Use the LIMS to communicate with other systems besides legacy systems and maintain real-time electronic access to the data residing in those systems (e.g., Pulse Net[6]).
- Monitor audit trails to its LIMS and other information systems.
- Support routine needs (e.g., maintenance and upgrade of its LIMS, modernization of legacy systems, IT security enhancement, and records management) through capital and operational resources and mandated policies and procedures.
- Extend capital budgets over 5-6 years.
- Preserve instrument data in the event of a network or system failure so they can be reprocessed when the system is restored.

CA 18: Core IT Services: Hardware, Software, and Services

Capability Statement	Level	Description of Levels	Select from drop down menu below
Capability Statement #18.1 a) The laboratory has an enterprise-wide Laboratory Information Management System solution that is inclusive of Enterprise Resource Planning (ERP)[7] capabilities.	Level 3	The laboratory has a fully functional enterprise-wide LIMS solution, serving as part of the Enterprise Resource Planning System1 and/or policies.	
	Level 2	The laboratory has a functional enterprise-wide LIMS, but the LIMS does not serve as part of the Enterprise Resource Planning System.	
	Level 1	The laboratory does not currently have an enterprise-wide LIMS.	
	N/A	Not applicable to this laboratory.	
a) The enterprise-wide LIMS is available 24/7, 365 days/year (with the exception of scheduled downtime.	Level 3	The LIMS is available 24/7, 365 days/year with the exception of scheduled downtime.	
	Level 1	The LIMS is not available 24/7, 365 days/year.	
	N/A	Not applicable to this laboratory.	
Capability Statement #18.2 The laboratory is able to access an IT help desk on-site/off-site and on-call, and can assure IT operational support for the laboratory.	Level 3	The laboratory is able to access a fully functional IT help desk and assures 24/7, 365/ year operational IT support for the laboratory.	
	Level 2	The laboratory is able to access a fully functional IT helpdesk during traditional business hours for the applicable time zone.	
	Level 1	The laboratory does not have access to an IT help desk or operational IT support across its IT domains.	
	N/A	Not applicable to this laboratory.	
Capability Statement #18.3 The laboratory has IT functions that are fully mature and fully functional.	Level 3	IT is supportive of the laboratory's needs.	
	Level 2	IT is able to support some of the laboratory's needs.	
	Level 1	The laboratory does not have IT abilities internally to support its needs.	
	N/A	Not applicable to this laboratory.	
Capability Statement #18.4 The laboratory is able to incorporate change management and follow a software development life cycle (SDLC)[8], which includes defining functional requirements[9], and translating these into software development and configuration.	Level 3	The laboratory is able to perform these functions.	
	Level 2	The laboratory is able to perform some of these functions.	
	Level 1	The laboratory is unable to perform these functions.	
	N/A	Not applicable to this laboratory.	

CA 18: Core IT Services: Hardware, Software, and Services

Capability Statement	Level	Description of Levels	Select from drop down menu below
Capability Statement #18.5 The laboratory has a standard enterprise integration engine (e.g., messaging, vocabulary) to capture data.	Level 3	The laboratory has a standard integration engine function to capture data.	
	Level 2	The laboratory is able to integrate with an Integration Broker.	
	Level 1	The laboratory does not have integration capability OR cannot communicate with external systems.	
	N/A	Not applicable to this laboratory.	
Capability Statement #18.6 The laboratory has legacy data that are accessible, searchable and available online, and the legacy system[10] is integrated into the LIMS.	Level 3	The laboratory has legacy data that are accessible, searchable and available online, and the legacy system is integrated into the LIMS.	
	Level 2	Legacy systems are accessible but not integrated into the LIMS.	
	Level 1	Legacy data are not available electronically.	
	N/A	Not applicable to this laboratory.	
Capability Statement #18.7 The LIMS communicates with other non-legacy systems (e.g., Pulse Net[6]) and maintains real-time electronic access to the data residing in these systems.	Level 3	The LIMS communicates with other non-legacy systems and maintains real-time electronic access to these data.	
	Level 2	The LIMS communicates with other non-legacy systems on an ad hoc basis and cannot maintain real-time electronic access to these data.	
	Level 1	The LIMS does not communicate with other non-legacy systems.	
	N/A	Not applicable to this laboratory.	
Capability Statement #18.8 The laboratory routinely collects and maintains detailed access and audit records on all its information systems, and can review and sort these records to assure satisfaction of compliance metrics.	Level 3	The laboratory routinely collects and maintains detailed access and audit records on its information systems, and can review and sort these records to assure satisfaction of compliance metrics.	
	Level 2	The laboratory routinely collects and maintains detailed access and audit records on its information systems, but cannot easily review or report these for compliance purposes.	
	Level 1	The laboratory has no means of tracking access and audit activities on its information systems.	
	N/A	Not applicable to this laboratory.	

Capability Statement	Level	Description of Levels	Select from drop down menu below
Capability Statement 18.9 The laboratory is able to preserve instrument data and reprocess them when the system is restored following a network or system failure.	Level 3	Yes, for all instruments interfaced to the LIMS.	
	Level 2	Yes, for some of the instruments interfaced to the LIMS.	
	Level 1	No	
	N/A	Not applicable to this laboratory.	

Total for this Capability Area	0
Percentage for this Capability Area	0.0%

Notes to Capability Area 18

1. **Memorandum of Understanding (MOU):** A document that describes very broad concepts of mutual understanding, goals and plans shared by the parties (HHS, 2003)
2. **Service Level Agreement (SLA):** A contractual agreement between an internal or external service provider and its customer specifying performance guarantees with associated penalties should the service not be performed as contracted. (DHS, Practices Guide)
3. **Select Agent Rule:** "The Federal Select Agent Program is jointly comprised of the Centers for Disease Control and Prevention/Division of Select Agents and Toxins and the Animal and Plant Health Inspection Services/Agricultural Select Agent Program. The Federal Select Agent Program oversees the possession, use and transfer of biological select agents and toxins, which have the potential to pose a severe threat to public, animal or plant health or to animal or plant products." (NSAR, 2013)
4. **CAP:** College of American Pathologists.
5. **The National Environmental Laboratory Accreditation Conference [NELAC Institute (TNI)]:** An accreditation program for environmental measurement data that is coordinated by the NELAC Institute, a non-profit organization.
6. **PulseNet:** A national network of public health and food regulatory agency laboratories coordinated by CDC.
7. **Enterprise Resource Planning System:** A system that supports an enterprise approach to information management by integrating information from separate systems.
8. **Software Development Life Cycle (SDLC):** A guideline for developing systems or software that involves progressive phases spanning the life cycle of the system from initiation to disposition.
9. **Functional requirements:** "This describes the behavior and information that a solution will manage. They describe the capabilities the solution will be able to perform in terms of operations and behavior specific Information Technology application actions or responses." (BABOK Guide)
10. **Legacy Systems:** An old or outmoded system being maintained because it contains historical data or other business intelligence purposes.

CA 19: Policies and Procedures, Including Budgeting and Funding

Description

This capability area addresses overarching informatics-related policies and procedures, and management of information systems within the laboratory.

Guidance Statement

Purpose: A laboratory professional requires standard operating procedures (SOPs) to conduct laboratory tests, and every informatics business process relies on associated policies and clear procedural guidelines. The successful planning and implementation of informatics in a PHL is guided by having policies and aligned procedures that link informatics activities to the laboratory's broader aims, while also spelling out the details of activities that are necessary to assure efficient functioning of the laboratory. Having appropriate policies in place becomes particularly critical for newly-introduced informatics processes and technology to succeed and to be integrated into the laboratory's functions.

What: Consensus on the procedural steps to be followed is important in developing informatics policies within the laboratory that impact the ability to exchange, share and view data from partner laboratories. This includes memoranda of understanding (MOU), memoranda of agreement (MOA), SOPs, data sharing agreements and policy instruments that are essential for effective routine and emergency functioning of the laboratory.

Procedures for planning budgets and aligning them with varying stakeholder financial cycles are necessary for ensuring sustainable and other resources for the laboratory. These policies may include strategies that ensure any covenants tied to funding sources that are used for capital acquisition, are commensurate with the laboratory's long-term goals. These goals can help advance informatics capabilities, rather than simply meeting short-term, externally driven objectives, such as grant deliverables. It is also crucial that the laboratory's informatics policies and procedures address the need for reliable resources streams for operation and maintenance of systems. These policies may also include a plan to sunset systems and informatics capabilities responsibly, should the laboratory no longer be able to feasibly maintain and operate them.

It is important that PHLs that have relationships with external informatics entities, such as central IT agencies, be able to build and monitor agreements with those entities. Development of these agreements requires effective communication streams and dedicated personnel time to manage the relationship on an ongoing basis.

How: A laboratory that has the desired informatics capabilities to ensure informatics-related policies and procedures are successfully implemented can:

- Facilitate centralized access to the respective policies and procedures.
- Communicate clearly and address concerns using language common to both laboratory and informatics.
- Train staff to assure that competencies exist to address informatics policies and procedures.
- Employ feedback mechanisms to support change management, obtain lessons learned, and acquire evidence for reviewing and updating the policies and procedures.
- Have a common understanding of requirements for policy making (e.g., informatics related SOPs, SLAs, MOUs, data-sharing agreements, budget planning, and strategies to secure short-term and long-term funding for sustainability and upgrade/expansion).
- Ensure that informatics agreements include metrics, monitoring, and accountability for performance goals.
- Identify gaps in existing policies and have a requirement for drafting/implementing new policies.
- Ensure documentation of existing policies is complete and updated.
- Implement new policies and ensure continuation of implemented policies.
- Evaluate the efficacy of implemented policies based on measurement of outcomes.

CA 19: Policies and Procedures, Including Budgeting and Funding

Capability Statement	Level	Description of Levels	Select from drop down menu below
Capability Statement #19.1 The laboratory has clearly defined processes for informatics policy making[1]. These policies include signed, documented MOUs, data sharing agreements, SOPs and other policies that affect routine and special functions within the laboratory.	Level 3	The organization has clearly defined processes for informatics policy making.	
	Level 2	The laboratory has clearly defined processes for some aspects of informatics policy making.	
	Level 1	The laboratory does not have clearly defined processes for informatics policy making.	
	N/A	Not applicable to this laboratory.	
Capability Statement #19.2 The laboratory has adopted policies, procedures, and a defined timeline to manage change control[2], and metrics to assure compliance.	Level 3	The laboratory has adopted policies, procedures, and a defined timeline to manage change control, and metrics to assure compliance.	
	Level 2	The laboratory has adopted some policies and procedures consistently, with some defined timelines to manage change control, and some metrics to assure compliance.	
	Level 1	The laboratory does not have policies and processes to manage change control.	
	N/A	Not applicable to this laboratory.	
Capability Statement #19.3 The laboratory has complete documentation for all standardized laboratory IT processes. This documentation is centrally located and accessible to laboratory and IT staff and management 24/7 both in electronic and paper format.	Level 3	The laboratory has complete documentation for these processes and stores this documentation in a central location that is accessible to laboratory and IT staff and management 24/7 both in electronic and paper format.	
	Level 2	The laboratory has a timeline for completing this documentation and storing it centrally where it will be accessible to laboratory and IT staff and management 24/7 both in electronic and paper format.	
	Level 1	The laboratory has incomplete documentation for these processes and no timeline for completing this documentation or storing it centrally.	
	N/A	Not applicable to this laboratory.	
Capability Statement #19.4 The laboratory has a sustainable operational budgeting strategy that anticipates the short- and long- term service/maintenance needs of its informatics systems and services.	Level 3	Yes	
	Level 1	No	
	N/A	Not applicable to this laboratory.	

CA 19: Policies and Procedures, Including Budgeting and Funding

Capability Statement	Level	Description of Levels	Select from drop down menu below
Capability Statement #19.5 The laboratory executes capital budgeting[3] to plan, request, and set aside resources for information systems and other services.	Level 3	The laboratory executes capital budgeting, wherein it plans, requests and sets aside resources for information systems and other services.	
	Level 2	The laboratory executes capital budgeting, but does not specifically set aside resources for information systems and other services.	
	Level 1	The laboratory does not perform capital budgeting activities.	
	N/A	Not applicable to this laboratory.	
Capability Statement #19.6 The laboratory has adequate non-grant operational resources for routine needs (e.g., maintenance, upgrade of its LIMS, modernization of legacy systems, IT security enhancement, records management, etc.).	Level 3	The laboratory has adequate non-grant operational resources for routine needs.	
	Level 2	The laboratory has non-specified stop gap resources for routine needs.	
	Level 1	The laboratory does not have resources or mandates for routine needs.	
	N/A	Not applicable to this laboratory.	
Capability Statement #19.7 The laboratory has a data system/ component/ equipment replacement policy and budget for replacing equipment and updating/replacing data systems at a pre-determined timespan according to the expected service life of the system/ component/equipment.	Level 3	The laboratory has a policy and budget for fulfilling these needs.	
	Level 2	The laboratory has a partial plan for fulfilling these needs.	
	Level 1	The laboratory lacks a data system/ component/equipment replacement policy and plan.	
	N/A	Not applicable to this laboratory.	

CA 19: Policies and Procedures, Including Budgeting and Funding

Capability Statement	Level	Description of Levels	Select from drop down menu below
Capability Statement #19.8 The laboratory has partnership channels and processes to facilitate grant procurement for informatics needs.	Level 3	The laboratory has established partnership channels and processes for informatics needs.	
	Level 2	The laboratory has ad hoc partnership channels and processes to facilitate grant procurement for informatics needs.	
	Level 1	The laboratory has no partnership channels or processes to facilitate grant procurement for informatics needs.	
	N/A	Not applicable to this laboratory.	

Total for this Capability Area	0
Percentage for this Capability Area	0.0%

Notes to Capability Area 19

1. **Policy Making:** The means by which problem identification, technical knowledge of possible solutions and societal values converge to set a course of action. As such policy development is an outgrowth of the assessment and monitoring activities described with respect to all other Essential Services. Policy development is not synonymous with the development of laws, rules, and regulations. Laws, rules, and regulations may be adopted as tools among others to implement policy. Policy development is a process that enables informed decisions to be made concerning issues related to the public's health. (APHL L-SIP)

2. **Change control:** A process for implementing changes to software or other IT solutions using a coordinated approach.

3. **Capital budgeting:** The process of planning funding for long-lived assets such as equipment and buildings.

SELF-ASSESSMENT USER SUMMARY WORKSHEET

CA 1: Laboratory Test Request and Sample Receiving	Test Score:	0
	Percentage Score:	0.0%
CA 2: Test Preparation, LIMS Processing, Test Results Recording and Verification	Test Score:	0
	Percentage Score:	0.0%
CA 3: Report Preparation and Distribution	Test Score:	0
	Percentage Score:	0.0%
CA 4: Laboratory Test Scheduling	Test Score:	0
	Percentage Score:	0.0%
CA 5: Prescheduled Testing	Test Score:	0
	Percentage Score:	0.0%
CA 6: Specimen and Sample Tracking/Chain of Custody	Test Score:	0
	Percentage Score:	0.0%
CA 7: Media, Reagents, Controls: Manufacturing and Inventory	Test Score:	0
	Percentage Score:	0.0%
CA 8: Interoperability and Data Exchange	Test Score:	0
	Percentage Score:	0.0%
CA 9: Statistical Analysis and Surveillance	Test Score:	0
	Percentage Score:	0.0%
CA 10: Billing for Laboratory Services	Test Score:	0
	Percentage Score:	0.0%

CA 11: Contract and Grant Management	Test Score:	0
	Percentage Score:	0.0%
CA 12: Training, Education and Resource Management	Test Score:	0
	Percentage Score:	0.0%
CA 13: Laboratory Certifications/Licensing	Test Score:	0
	Percentage Score:	0.0%
CA 14: Customer Relationship Management	Test Score:	0
	Percentage Score:	0.0%
CA 15: Quality Control (QC) and Quality Assurance (QA) Management	Test Score:	0
	Percentage Score:	0.0%
CA 16: Laboratory Safety and Accident Investigation	Test Score:	0
	Percentage Score:	0.0%
CA 17: Laboratory Mutual Assistance/ Disaster Recovery	Test Score:	0
	Percentage Score:	0.0%
CA 18: Core IT Services: Hardware, Software and Services	Test Score:	0
	Percentage Score:	0.0%
CA 19: Policies and Procedures, including Budgeting and Funding	Test Score:	0
	Percentage Score:	0.0%

Glossary

Term	Description
Capability	"A capability may be delivered with any combination of properly planned, organized, equipped, trained, and exercised personnel who achieve the intended outcome." (HSEEP DHS)
Chemical Abstracts Service (CAS) Registry Number	"When you need to positively identify a chemical substance, you can rely on the authoritative source for chemical names and structures of CAS REGISTRY. You can also identify your substance of interest by its CAS Registry Number®, which is universally used to provide a unique, unmistakable identifier for chemical substances." (CAS REGISTRY)
Competencies	"Action-oriented statements that delineate the essential knowledge, skills, and abilities in the performance of work responsibilities. Competencies are describable and observable." (CDC and CSTE, 2008)
Continuity of Operations Plan	A plan that details the how essential functions of an agency will be handled during any emergency or situation that may disrupt normal operations. (APHL L-SIP)
Electronic Health Record (EHR)	"A longitudinal electronic record of patient health information generated by one or more encounters in any care delivery setting." (HIMSS)
Electronic Laboratory Reporting (ELR)	"The automated transmission of laboratory-related data from commercial, public health, hospital, and other laboratories to state and local public health departments through an electronic health records (EHR) system or a Laboratory Information Management System (LIMS). ELR helps identify reportable conditions determined by confirmatory testing and supports case reporting at the state or local level." (CDC NNDSS, 2012)
Electronic Medical Record (EMR)	"The EMR is the legal record created in hospitals and ambulatory environments that is the source of data for the EHR." (Garets and Davis, HIMSS, 2006)
Enterprise-wide	Affecting the entire organization

Glossary

Term	Description
Health Information Exchange (HIE)	"The term 'health information exchange (HIE) actually encompasses two related concepts: "Verb: the electronic sharing of health-related information among organizations "Noun: An organization that provides services to enable the electronic sharing of health-related information." (HealthIT.gov, "Health Information Exchange")
HL7	"HL7 and its members provide a framework (and related standards) for the exchange, integration, sharing, and retrieval of electronic health information. These standards define how information is packaged and communicated from one party to another, setting the language, structure and data types required for seamless integration between systems. HL7 standards support clinical practice and the management, delivery, and evaluation of health services, and are recognized as the most commonly used in the world." (HL7, 2012)
Informatics	"A broad field encompassing human-computer interaction, information science, information technology, algorithms, and social science. Information Science – the study of the processing, management and retrieval of information. Information Technology – the study, design, implementation, support or management of computer-based information systems. Algorithms – a process or set of rules to be followed in calculations or other problem solving operations, especially by a computer. Social Science – the scientific study of human society and social relationships." (APHL MRC)
Laboratory Practice	"Evidence base (screening and testing, reference and special testing, state-of-the-art testing, etc.), epidemic investigation, best practices and case studies, research." (APHL MRC)
Laboratory Services	"All the testing and associated activities conducted by public and private laboratories in the support of primary health care, population-based public health and environmental protection for the purpose of disease surveillance, prevention and control." (APHL L-SIP)
Meaningful Use (MU) Requirements	Issued by the Centers for Medicare and Medicaid Services, the meaningful use rule defines the minimum requirements that providers must meet through their use of certified EHR technology in order to qualify for incentive payments under the Health Information Technology for Economic and Clinical Health (HITECH) Act. (HealthIt.hhs.gov)

Glossary

Term	Description
Operations	"Condition of functioning or being active; the operations or backbone of the day to day structure of the laboratory such as Organization (or administration), Customer focus (service), Facilities and safety, Personnel, Purchasing and Inventory, Equipment, Process management (SOPs), documents and records, information management, nonconformance management, assessments (CLIA and CAP) and continual improvement." (APHL MRC)
PHIN MS	The Public Health Information Network Messaging System is a service that is used for creating standards, and HL7 2.x messages, for surveillance, message exchange between laboratories, public health jurisdictions and CDC. The goal is interoperability among public health systems.
Public Health	"What we, as a society, do collectively to assure the conditions in which people can be healthy." (IOM, 1988)
Public Health Laboratory (PHL)	"A scientific facility with the equipment and staff needed to conduct ongoing public health assessments and to respond to emergency public health issues." (APHL L-SIP)
Standard	"A level of quality or excellence used as a criterion by which actual attainments are judged." (APHL L-SIP)
Standard Operating Procedures (SOP)	"Detailed, written instructions to achieve uniformity of the performance of a specific function." (ICHGCP)
State Public Health Laboratory (SPHL)	"A governmental facility that performs analytical testing for personal health and/or environmental health surveillance and disease prevention and control." (APHL L-SIP)
State Public Health Laboratory System	"A partnership between public health laboratories and other state agencies, private laboratories, and other organizations and health care providers to assure laboratory services essential to the health of the public." (APHL L-SIP)
Surveillance	"The ongoing systematic collection, analysis, and interpretation of data (e.g., regarding agent/hazard, risk factor, exposure, health event) essential to the planning, implementation, and evaluation of public health practice, closely integrated with the timely dissemination of these data to those responsible for prevention and control." (APHL L-SIP)

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Appendix

Appendix 1: Acknowledgements

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Appendix 2: Chronology of Tool Development Milestones

Milestone	Reference	Activity	Outcome
Milestone 1			
Consultation meeting, December 2011	See Participants on page 94	PHLs agreed on the need for a self-assessment tool to determine current informatics capabilities in terms of the overall information system enterprise, an inventory of systems, hardware, software, costs incurred, and depreciating factors and how they affect PHLs.	A core SME group was formed comprising APHL informatics committee members and CDC.
Milestone 2			
Consultation meeting, May 2012	See participants on page 95	The group reviewed the progress made on the self-assessment tool to date and provided recommendations on content and design.	Feedback was incorporated and 2 more rounds of reviews were conducted by conference call with the SME group.
Milestone 3			
Review of 7 Capability Areas by 3 laboratories, August-September 2012	See participants on page 95	The 3 selected states reviewed the content of the tool and answered a questionnaire on the format of each of the 7 Capability Areas, associated statements and indicators.	The tool was improved by incorporating this feedback.
Milestone 4			
Final review of tool by subset of SME group with CDC, December 2012	See participants on page 95	3 SMEs participated in a final review of the entire tool before it was beta-tested	Tool was updated with this feedback.
Milestone 5			
Beta testing of tool by 4 laboratories, December 2012 – January 2013	See participants on page 95	4 PHLs participated in a beta test of all 19 Capability Areas of the tool and completed a questionnaire about the format and design of the overall tool.	Tool was updated with this feedback.
Milestone 6			
Final Release of Tool	Spring 2013		

Appendix 3: Additional Acknowledgements

The writers wish to acknowledge Dr. May C. Chu, Director of the Laboratory Science, Policy and Practice Program Office (LSPPPO), and members of the APHL Informatics Committee for their support during the development of the self-assessment tool.

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Appendix 4: Stakeholder Feedback

As described in the introduction, the self-assessment tool has been reviewed by leadership at CDC and APHL. In addition, four PHLs beta-tested the tool and provided valuable feedback to the workgroup. Several of these stakeholders contributed insightful comments about the tool's purpose and value.

"This assessment will be a valuable tool for all State Public Health Lab directors as it is used and reused over the next several years. It is extremely detailed, yet very user friendly. It is the first tool that I have seen that allows an SPHL director to evaluate the maturity of their LIMS across all functional areas of their lab. This will give the lab director valuable insight into areas that still need improvement and will assist them in writing project justifications in their grants to improve deficiencies. I think it will also highlight areas where grant money has been well spent in the past"

- Alabama State Public Health Laboratory

"Our laboratory found the LEI SA tool to be a comprehensive and informative informatics measuring tool as well as a great 'workshop' style document for lab leaders. This tool not only provides laboratories a scale to rank or measure their informatics maturity level but it can also be used alone or alongside existing laboratory self-awareness and growth tools."

- Kentucky State Public Health Laboratory

The 19 Capability Areas provide the most definitive assessment yet and place a level of standardization which will prove very useful to all PHLs and their supporting agencies. Gap related information can be inserted into strategic plans, annual objectives and used as substantive budget justification. We found the tool to be insightful, engaging and well worth the time."

- New York City Public Health Laboratory

"Although it did take some time to complete the assessment, we felt as if it was an advantageous use of our time. It helped us evaluate our weaknesses and discover our strengths. We were able to quickly determine what areas needed our focus. I would recommend all PHLs to use the tool."

- West Virginia Public Health Laboratory

Appendix 5: User Information Sheet

Laboratories may use or modify this sheet to record information about the laboratory, the approach used in completing the self-assessment, the dates on which the assessment was done, and the staff members who helped complete the tool.

Laboratory Information

Laboratory Name / Division / Unit		
Address		
City	State / Territory	Zip Code
Main Contact Name	Contact Phone #	Contact Email Address

Assessment Details

Date(s) Assessment Started

Date(s) Assessment Completed

Systems Evaluated

- ☐ One LIMS (state name)
- ☐ Multiple LIMS (state the name of each)
- ☐ Other systems (state name and description)

Use the space provided to indicate the specific systems in use in the laboratory that were evaluated as part of this assessment (e.g., LIMS).

The focus of the assessment was on one or more of the following:

- ☐ Overall informatics capabilities
- ☐ Laboratory services
- ☐ Capabilities of specific section within the laboratory
- ☐ Capabilities of a specific LIMS
- ☐ Other

Use the space provided to indicate the focus of the assessment, whether overall informatics capabilities, the laboratory's services, the capabilities of specific section within the laboratory, the capabilities of a particular LIMS, etc. (see the How to Use the Tool section of the introduction for further guidance.

Omitted Capability Areas

Use the space provided to indicate why, if applicable, the laboratory did not complete an assessment of all Capability Areas.

Appendix 5: User Information Sheet

Participants

Use the space provided to list the staff members who contributed to the tool's completion		
Name	Title	Capability Areas
Name	Title	Capability Areas
Name	Title	Capability Areas
Name	Title	Capability Areas
Name	Title	Capability Areas

Notes

Use the space provided to record any additional notes about how, when, and why the laboratory completed the self-assessment tool.