PHIN Preparedness

CONNECTING LABORATORY SYSTEMS FUNCTIONAL REQUIREMENTS AND PROCESS FLOWS

Version 1.0

4/26/2005

TABLE OF CONTENTS

1 INTRODUCTION 3

2 REQUIREMENTS 4

2.1 Identifiers and Linkages 4

2.1.1 Subject Identifiers 5

2.1.2 Specimen Identifiers 5

2.1.3 Linkages 6

2.2 Message Content 7

2.3 System Integration and Data Exchange 8

2.4 Chain of Custody 8

2.5 Vocabulary Standards 9

2.6 Operations 10

2.7 System Security and Availability 10

2.8 Privacy 10

3 ELECTRONIC INTERACTIONS 11

3.1 Electronic Laboratory Reporting 11

3.2 Mutual Assistance - Electronic Laboratory Test Requests 12

1 INTRODUCTION

This document describes Public Health Information Network (PHIN) functional requirements and general workflow for systems managing and reporting requests for and results of laboratory testing. Public health laboratories are a critical asset in safeguarding the public's health. Working in collaboration with other public health organizations and disciplines, public health laboratories ensure the rapid identification of biological, chemical, radiological, and nuclear agents in clinical (human and animal), environmental and food specimens and inform an effective and timely response to contain and minimize their impact on the health of communities. Public health laboratories are leading-edge organizations, equipped to tackle the most advanced science available today in performing diagnostic testing, disease surveillance, and research.

To ensure the nation's readiness in detecting and responding to both natural and man-made outbreaks of disease, the Laboratory Response Network (LRN) was formed in 1999 by a broad coalition of scientific partners including the Centers for Disease Control and Prevention, the Association of Public Health Laboratories, the Department of Defense, the Federal Bureau of Investigation, the Food and Drug Administration, United States Department of Agriculture and the Environmental Protection Agency.

During the anthrax events of 2001 the LRN laboratories tested 125,000 samples representing more than 1 million separate laboratory tests. The management of data and test results associated with this event was enormously complex and largely unsupported by any form of standardized electronic reporting between participating organizations. As successful as the laboratory testing activity was, the reporting, aggregation, and analysis of the results from the many labs performing the testing was anything but systematic.

What became apparent from this experience was the need to develop and broadly adopt common specifications and processes for information exchange among the nation's public health laboratories and their partner organizations. As clinical laboratories and healthcare organizations also participate in these events the need for standard electronic interchange of laboratory results and test requests is even more important.

The remainder of this document presents essential PHIN interoperability requirements to support coordinated laboratory services and response across local, state and federal public health jurisdictions. This document does not present requirements for specific applications (e.g., Laboratory Information Management Systems) but rather focuses on the interface of systems supporting CLS to other systems both internal and external to the public health and LRN laboratories.

2 REQUIREMENTS

The following requirements describe baseline functionality for the PHIN functional area of Connecting Laboratory Systems.

2.1 Identifiers and Linkages: Laboratory data must be assigned unambiguous identifiers and support traceable linkages among related data.

2.2 Message Content: Messages exchanged by systems supporting CLS must adhere to the appropriate PHIN standards and message implementation guides, and contain the appropriate information to assist the laboratory and the message recipients in interpreting the messages.

2.3 System Integration and Data Exchange: Public health laboratory data must be communicated reliably and securely between partner organizations. All public health organizations need be interconnected with the appropriate technology to support these secure, electronic communications.

2.4 Chain of Custody: Often originating outside the public health laboratory, a detailed record must be kept of the movement of the specimen/sample from the collection point through the testing and result reporting process.

2.5 Vocabulary Standards: Standard coding systems and data structures have been defined by standards organizations. Where they exist, connected laboratory systems should use them. As additional standards are defined, they should be accepted and implemented.

2.6 Operations: Personnel, roles, and responsibilities necessary to support laboratory data exchange should be clearly defined.

2.7 System Security and Availability: Security of laboratory data includes the protection of data from corruption and access by unauthorized individuals, as well as the protection of a laboratory system itself from sabotage or other failure. There must be a plan for continuing activities when connected laboratory systems are unavailable.

2.8 Privacy: Patients, organizations, and personnel must be protected from fraudulent and unauthorized use of their information.

2.1 IDENTIFIERS AND LINKAGES

Laboratory data is frequently communicated to other public health organizations, where it is aggregated and linked with data from other sources. To aggregate and link data, it must contain identifiers that are unique across organizations. This "global uniqueness" is only possible when all organizations consistently follow predefined strategies for identifying organizations, subjects and test specimens/samples. The namespace is a globally unique identifier for the system or entity assigning an identifier. Namespace examples include a specific LIMS system, a state's Master Person Index (MPI), and a jurisdiction's surveillance system. Object identification requirements that span PHIN functional areas are separately defined and should be reviewed in "PHIN Preparedness Cross Functional Components Requirements", available at www.cdc.gov/phin.

2.1.1 Subject Identifiers

2.1.1.1 Each subject (e.g., person, place, animal, object) of laboratory testing must be identified with an identifier (i.e., Subject ID) that is unique within the namespace assigning the identifier. It will be assumed by external systems that subjects with the same identifier are indeed the same, and that subjects with different identifiers are indeed different.

2.1.1.2 To provide global uniqueness, subject identifiers must be combined with an object identifier (OID) for the assigning namespace whenever reported externally to public health partners.

Example:

- Subject ID: 556-094560
  Uniquely identifies Martha Smith in the state public health lab LIMS system.
- OID: 2.16.840.1.11422.4.3.2.2.1.100.1
  Identifies the specific LIMS system in the state laboratory in Columbus, Ohio that assigned the Subject ID to the subject.
- Globally Unique ID: 2.16.840.1.11422.4.1.100.1 556-094560
  Combined OID + Subject ID creates a globally unique identifier for the subject that will not collide with any other identifier for the subject assigned by any other system or organization world-wide.

2.1.1.3 Systems supporting CLS must maintain the subject identifier assigned by an external requestor of laboratory services.

2.1.1.4 Laboratory results must be reported with the subject identifier assigned by the requestor of laboratory services.

2.1.2 Specimen Identifiers

2.1.2.1 Samples and specimens undergoing laboratory testing must be identified with an identifier (i.e., Specimen ID) that is unique within the namespace assigning the identifier. It will be assumed by external systems that specimens with the same identifier are indeed the same, and that specimens with different identifiers are indeed different.

2.1.2.2 To provide global uniqueness, specimen identifiers must be combined with an OID for the assigning namespace whenever reported externally to public health partners.

Example

- Specimen ID: PQ8907
  Unique accession number assigned to a blood specimen collected by a public health worker and accessioned by a LIMS system in the state public health lab in Columbus, Ohio.
- OID: 2.16.840.1.11422.4.3.2.2.1.100.1
  Identifies the specific LIMS system in the state laboratory in Columbus, Ohio that assigned the Specimen ID to the specimen.
- Globally Unique ID: 2.16.840.1.11422.4.3.2.2.1.100.1 PQ8907
  Combined OID + Specimen ID creates a globally unique identifier for the specimen that will not collide with any other specimen identifier assigned by any other system or organization world-wide.

2.1.2.3 Laboratory systems must maintain the specimen identifier assigned by an external requestor of laboratory services.

2.1.2.4 Laboratory results must be reported with the specimen identifier assigned by the requestor of laboratory services.

2.1.2.5 Laboratory systems must store all identifiers that are assigned to a specimen/sample. This includes field assigned as well as lab assigned specimen identifiers.

2.1.2.5.a Specimens/samples collected in the field should be accessioned using centrally assigned numbers to reduce the number of identifiers associated with a given specimen/sample.

2.1.2.6 When additional specimens/samples are created from a parent specimen/sample, such as aliquots and new specimen types created from a source sample, the child specimens/samples must be assigned specimen identifiers that can be linked to the original specimen's identifier.

2.1.3 Linkages

2.1.3.1 Laboratories must track specimens/samples from receipt to result reporting.

2.1.3.2 Specimens/samples common to a subject should be traceable back to that subject.

2.1.3.3 Field assigned specimen identifiers must be stored and linked to the lab assigned specimen identifiers if they are different.

2.1.3.4 It should be possible to associate a subject's epidemiology data with samples and specimens, although laboratory data and epidemiological data may reside in separate information stores. This may be supported through the assignment of a subject or case identifier to the specimen/sample.

2.1.3.5 Laboratories must retain use of the original subject and specimen identifiers throughout the course of testing and link them to any child specimens created from the specimen. Examples of child specimens are aliquots, split samples, and new specimen types created from source samples.

2.1.3.6 Where child specimens are created, the relationship between the child and the original parent specimen must be maintained through multiple generations (e.g., parent, child, grandchild).

2.1.3.6.a If the child specimen is assigned a postscript identifier, the parent-child linkage for each child must be specifically captured.

Example

- Specimen ID: PQ8907
  The accession number assigned to a 5.0 ml blood specimen.
- Specimen ID: PQ8907-01
  The accession number assigned to a 1.0 ml aliquot of the original blood specimen.
- The parent-child relationship is maintained in the LIMS system.

  Parent Specimen ID: PQ8907

  ↓

  Child Specimen ID: PQ8907-01

2.1.3.7 The parent and child specimen identifiers must be reported with all laboratory results returned to an external requestor so that all testing associated with an original (root) specimen can be easily aggregated for review and analysis.

2.2 MESSAGE CONTENT

2.2.1 Message content must comply with the PHIN Preparedness message implementation guides, available at *www.cdc.gov/phin.*

2.2.2 Laboratory test request messages must include packing and shipping information.

2.2.3 Laboratory result messages should include quality control data when that information is appropriate and available.

2.2.4 Laboratory results messages must include the result status (e.g., initial, final, partial, corrected) of the laboratory result.

2.2.5 Laboratory test request and test results messages should specify if the testing is for confirmatory purposes.

2.2.6 Laboratory results messages should contain information to assist the recipient in directing the results to the correct program area once received.

2.3 SYSTEM INTEGRATION AND DATA EXCHANGE

Systems integration requirements specific to systems supporting CLS are included in the section below and describe the types of data that CLS should be able to send and receive. This section is limited to describing the types of data exchange that CLS must support; not the requirements for transporting the data. Bi-directional, secure exchange of data with partner organizations supports public health investigations across all levels of public health. Message construction and parsing, and secure data transport requirements that span PHIN functional areas are separately defined and should be reviewed in "PHIN Preparedness Cross Functional Components Requirements", available at www.cdc.gov/phin.

2.3.1 Systems supporting CLS must exchange messages for laboratory results. This requirement is identified as a key performance measure for assessing preparedness as described in *PHIN Preparedness Key Performance Measures*, available at *www.cdc.gov/phin*.

2.3.2 Systems supporting CLS must exchange messages for laboratory test requests. This requirement is identified as a key performance measure for assessing preparedness as described in *PHIN Preparedness Key Performance Measures*, available at *www.cdc.gov/phin*.

2.3.3 Systems supporting CLS should be able to exchange messages for acknowledging acceptance or indicating refusal of the test request, in accordance with *PHIN Laboratory Test Order Response Message Implementation Guide*, available at *www.cdc.gov/phin*.

2.3.4 Laboratory results for test requests that were forwarded to another facility should be reported to the original requestor. Test requests may be forwarded because of capacity or capability constraints, or because specimens/samples were split across multiple testing facilities.

2.3.5 Data collected by systems supporting CLS should be linkable to data in other systems that contain demographic or epidemiologic data, such as a state's Master Person Index (MPI) or a jurisdiction's surveillance system.

2.4 CHAIN OF CUSTODY

2.4.1 The laboratory should support chain of custody records for routine specimens/samples handled internal to the laboratory, or redirected or transferred to external testing facilities.

2.4.2 The laboratory must support chain of custody records for forensic and select agent samples handled internal to the laboratory, or redirected or transferred to external testing facilities.

2.4.3 Chain of custody for forensic and select agent samples must document the movement of the specimen/sample through the lab and include the following:

- Identifier of each individual who handles the specimen/sample from its arrival at a lab through its ultimate disposition,
- Date and time of collection for each specimen/sample,

- Date and time of each redirection or transfer for each specimen/sample,
- Tracking of the specimen/sample into and out of primary storage,
- Specimen/sample disposition, including destruction date and individual who destroyed the specimen/sample, and
- Unique identifier of the subject.

2.4.4 The laboratory must be able to document custody of the specimen/sample from receipt through its disposal or return to the submitter or other agency, including unique identification of the specimen/sample and all its children, transfer to other facilities for confirmatory testing or overflow, and appropriate digital signatures from all custodians.

2.5 VOCABULARY STANDARDS

It is recommended that standards be used across systems supporting CLS; however, it is required that vocabulary standards be used when exchanging data. Vocabulary requirements specific to systems supporting connecting laboratory systems are included in the section below. Vocabulary requirements that span PHIN functional areas are separately defined and should be reviewed in "PHIN Preparedness Cross Functional Components Requirements", available at www.cdc.gov/phin.

2.5.1 Laboratory test results produced and reported externally by public health laboratories must use the Logical Observation Identifiers, Names and Codes® (LOINC) coding system for test names and codes wherever these codes are available. More information about LOINC is available at *http://www.loinc.org.*

2.5.2 Laboratory test results reported to organizations outside the public health laboratory must use the Systemized Nomenclature of Medicine Clinical Terms® (SNOMED CT) coding system for encoding laboratory findings wherever these codes are available. More information about SNOMED is available at *http://www.snomed.org.*

2.5.3 Laboratory test requests must use the Logical Observation Identifiers, Names and Codes® (LOINC) coding system for test names and codes where the codes are available. More information about LOINC is available at *http://www.loinc.org*.

2.5.4 Human genomic information should use the Human Gene Nomenclature (HGNC) sponsored by the Human Genome Organization (HUGO). More information about HGNC is available at *http://www.gene.ucl.ac.uk/nomenclature/guidelines.html*.

2.5.5 Adherence to standards may be accomplished either by mapping local codes to standard codes such as LOINC and SNOMED, by directly implementing standard codes, or by a combination of direct implementation and mapping. Mappings of local codes to standards should be maintained at local sites and the mappings do not need to be shared or registered with PHIN.

2.5.6 There are occasions when a new assay method is recommended but does not have an assigned LOINC code, or an organism is reported but does not have a corresponding SNOMED code. In these cases the laboratory must be able to support creation of local test and results codes that are consistently identified. The local structure must contain the ability to map to a standard code as it becomes available.

2.6 OPERATIONS

Operational requirements, such as system backup policies and procedures, continuity of operations, system monitoring, and employee training ensure that public health partners can effectively support activities in connecting laboratory systems and other PHIN functional areas. Operational requirements specific to connecting laboratory systems are defined below. Operational requirements that span PHIN functional areas are separately defined and should be reviewed in "PHIN Preparedness Cross Functional Components Requirement", available at www.cdc.gov/phin.

2.6.1 Laboratories must be able to monitor test capacity, recognize when capacity has been exceeded and redirect test requests to partner labs that have capacity.

2.6.1.1 Redirection of specimens must be traceable, including when, why and where a specimen was redirected as described in section *2.4 Chain of Custody* of this document.

2.6.1.2 Laboratories should be able to communicate test capacity with partner organizations, and during public health emergencies, provide updates to allow national capacity to be assessed.

2.6.2 Laboratories must have policies and procedures in place to match incoming and outgoing specimens/samples with the appropriate laboratory test request(s).

2.6.3 Laboratories should have practices and policies in place to ensure data quality.

2.7 SYSTEM SECURITY AND AVAILABILITY

Systems and data supporting CLS must be protected from sabotage, corruption and unauthorized access, and must be available subsequent to a catastrophic event. Security and Availability requirements that span PHIN functional areas should be reviewed in "PHIN Preparedness Cross Functional Components Requirements", available at www.cdc.gov/phin.

2.8 PRIVACY

Privacy requirements ensure that sensitive information is not accessible to unauthorized users. Privacy requirements are broadly defined because they span all PHIN functional areas. These requirements should be reviewed in "PHIN Preparedness Cross Functional Components Requirements", available at www.cdc.gov/phin.

3 ELECTRONIC INTERACTIONS

3.1 ELECTRONIC LABORATORY REPORTING

Public health laboratories must be able to report laboratory findings to CDC, their state or territorial department of health and other partner organizations appropriate to the situation. The electronic interchange associated with laboratory test results reporting is diagrammed in Figure 3-1

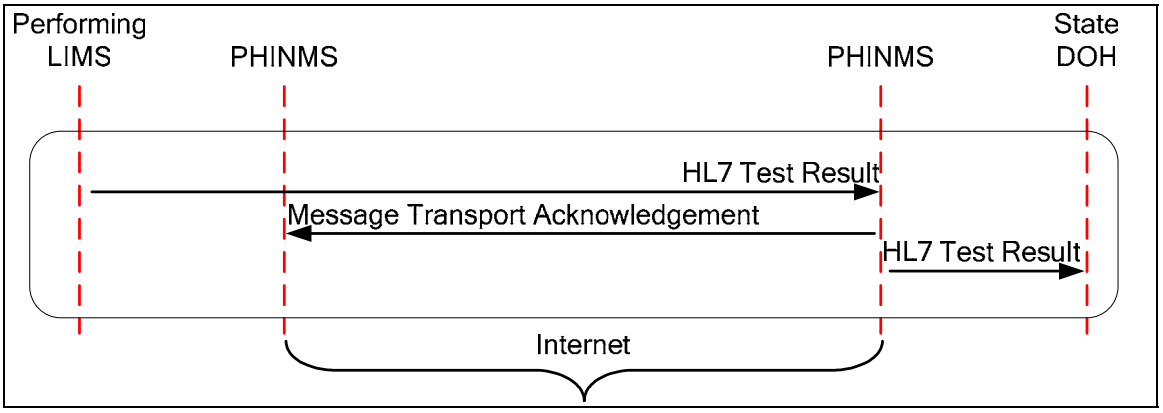

Figure 3- 1 Electronic Laboratory Reporting

3.2 MUTUAL ASSISTANCE - ELECTRONIC LABORATORY TEST REQUESTS

In an emergency public health labs must be able to assist other labs that have reached or exceeded their testing capacity. To do so, PHIN compliant public health laboratories must be able to receive electronic requests for laboratory testing and electronically return results via PHIN standard HL7 messages.

The electronic interchange associated with laboratory test requests is diagrammed in Figure 3-2, and illustrates the following functionality:

- Upon receipt of HL7 laboratory test request messages, a public health laboratory will validate, parse, and store this message for processing by a LIMS system.
- Electronic laboratory test requests are acknowledged as received with an HL7 acknowledgement message.
- Electronic laboratory test requests are acknowledged as accepted or refused for testing.
- Upon receipt of the HL7 laboratory response message indicating acceptance or refusal of the test request, the requesting laboratory will validate, parse and store the message content reporting the acceptance or refusal of the test request.
- A public health laboratory can act as the requestor or the performing lab.

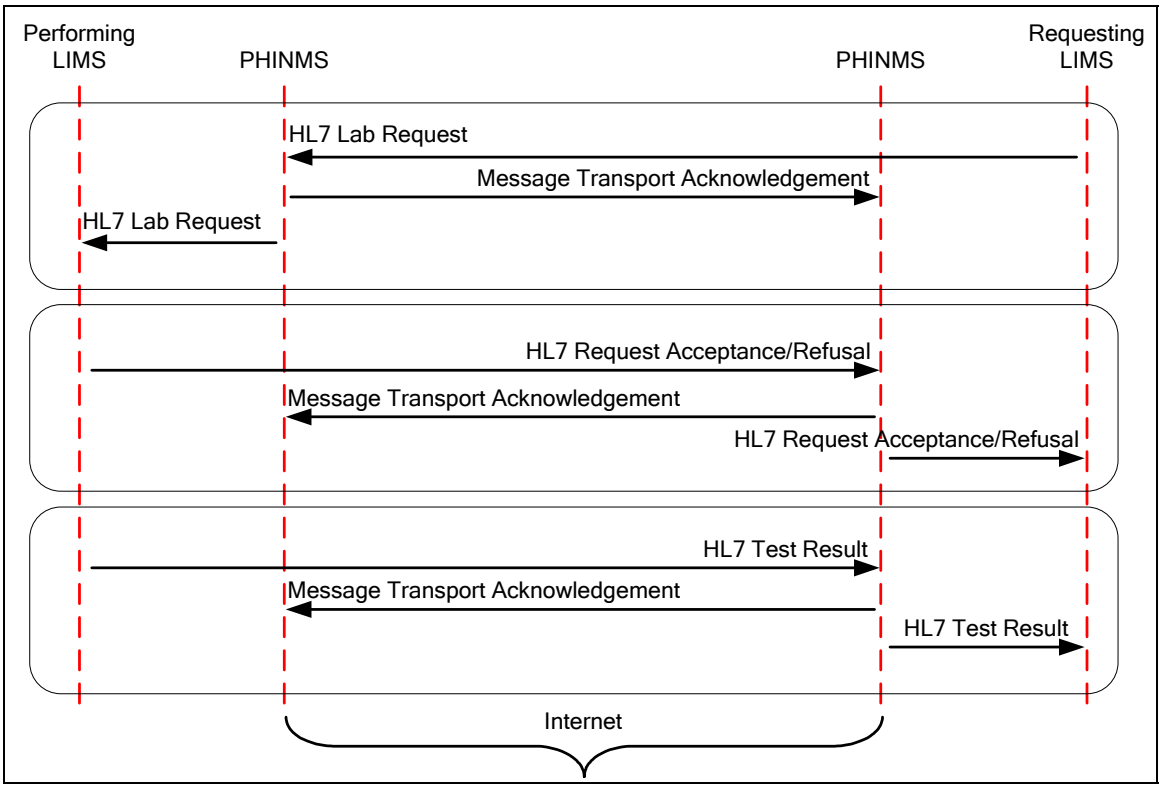

Figure 3- 2 Mutual Assistance- Electronic Laboratory Test Requests