Public Health Information Network

LABORATORY SYSTEMS
FUNCTIONAL REQUIREMENTS

Version 0.2 Draft

05/28/2004

VERSION HISTORY

Version #	Prepared By	Revision Date	Approved By	Approval Date	Reason
0.1	David Groves	05/19/2004	<name>	<mm/dd/yy>	Initial Draft
0.2	David Groves	5/28/2004			Minor corrections

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1 INTRODUCTION

This document describes PHIN functional requirements and general workflow for systems managing and reporting the 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 disease agents and threats 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. In some cases they may have even broader capabilities and may additionally perform chemical and environmental testing, food testing, and animal testing.

To ensure the nation's readiness in detecting and responding to both natural and man-made outbreaks of disease, the Laboratory Response Network 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 American Society for Microbiology, the Department of Defense, the Federal Bureau of Investigation, the Food and Drug Administration, the Lawrence Livermore National Laboratory in the Department of Energy, the National Veterinary Service Laboratory, and the Environmental Protection Agency. The LRN now consists of over 120 laboratories nationwide operating at laboratory safety levels BSL-2, BSL-3, and BSL-4 and are organized as sentinel, confirmatory reference labs, and National labs.

Standardized methods, reagents, equipment, and training are essential elements of the LRN's concept of operations. Proficiency testing and QC/QA procedures ensures laboratory results are reliable and trustworthy. During the anthrax events of 2001 the LRN laboratories tested over 125,000 samples representing over 1 million separate laboratory tests. The management of data and test results associated with this event were 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 clear from this experience is the need to develop and broadly adopt common standards and methods for information exchange between the nation's public health laboratories and their partner organizations. As clinical laboratories and healthcare organizations also come into play in these events this need for standard electronic interchange of laboratory results and service requests is ever 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 Laboratory Information Systems (LIMS) themselves but rather focuses on the interface of these systems to other systems both internal and external to the public health laboratory.

2 REQUIREMENTS

2.1 PATIENT IDENTIFIERS

- Human subjects of laboratory testing must be identified with a unique identifier within the namespace assigning the identifier. It will be assumed by external systems that patients with the same identifier are indeed the same person.
- To provide global uniqueness, patient identifiers must be combined with an Object Identifier (OID) for the assigning namespace whenever reported externally to public health partners. A namespace might refer to the several possible entities, including the Department of Health, the laboratory, or a particular LIMS system.
    - Example:
        - Patient ID: 556-094560
          Uniquely identifies Martha Smith in the state public health lab
        - OID: 2.16.840.1.11422.4.1.100
          Identifies the state laboratory in Columbus, Ohio as the assigning authority for the patient ID. In this case patient identifiers are assigned at the laboratory level and not by individual LIMS systems. A patient in two LIMS systems within this state laboratory is always identified with the same number.
        - Globally Unique ID: 556-094560 2.16.840.1.11422.4.1.100
          Combined Patient ID + OID creates a globally unique ID for the patient that will not collide with any other patient ID assigned by any other system or organization world-wide.
- Laboratory systems must maintain the patient identifier assigned by an external requestor of laboratory services.
- Laboratory results must be reported with the patient identifier assigned by the requestor of laboratory services.

2.2 SPECIMEN IDENTIFIERS

- Samples and specimens undergoing laboratory testing must be identified with a unique identifier within the namespace assigning the identifier. It will be assumed by external systems that specimens with the same identifier are indeed the same specimen. It will also be assumed that specimens with different identifiers are different specimens.
- To provide global uniqueness, specimen identifiers must be combined with an Object Identifier (OID) whenever reported externally to public health partners.
    - Example:
        - Specimen ID: PQ8907
          The 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 accession number to the specimen.
- Globally Unique ID: PQ8907 2.16.840.1.11422.4.3.2.2.1.100.1
  Combined Patient ID + OID creates a globally unique ID for the specimen that will not collide with any other specimen ID assigned by any other system or organization world-wide.

- Laboratory systems must maintain the specimen identifier assigned by an external requestor of laboratory services.
- Laboratory results must be reported with the specimen identifier assigned by the requestor of laboratory services.

2.3 SPECIMEN LINKAGES

- New specimens may be produced through testing or culturing in the laboratory. Specimen lineage must be maintained by laboratory systems. Parent and child relationships between specimens must be maintained.
- Where aliquots and splits are assigned new accession numbers the system must maintain the relationship between the aliquot and the original parent specimen. Even where the aliquot is being assigned a postscript ID, the parent child linkage must be specifically recorded in the LIMS and not simply inferred by the form of the accession number.
  - Example:
    - Specimen ID: PQ8907
      The accession number assigned to a 5.0 ml blood sample
    - Specimen ID: PQ8907-01
      The accession number assigned to a 1ml aliquot of the original blood specimen.
    - The parent child relationship is maintained in the LIMS system

      Parent: PQ8907
      ↓
      Child: PQ8907-01
- The parent and child specimen IDs must be reported with all laboratory results returned to an external requestor. In this way all testing associated with an original (root) specimen can be easily rolled up for review and analysis.

2.4 TEST NAMES AND CODES

- Test results produced and reported externally by public health laboratories must utilize the Logical Observation Identifiers, Names and Codes (LOINC) coding system for test names and codes.

- Where LOINC is not used internally for test names and codes the laboratory must map to LOINC codes when creating external electronic results. See http://www.loinc.org/ for more information on LOINC.

2.5 LABORATORY RESULTS CODING

- Electronic test results reported externally to the public health laboratory must use the SNOMED CT coding system for encoding laboratory findings.
- Where SNOMED CT coding is not used internal to a public health LIMS system, LIMS provided codes must be mapped to SNOMED CT when creating external electronic results. See http://www.snomed.org/ for more information on SNOMED.

2.6 HL7 MESSAGING

- Public health laboratories must be able to produce the following PHIN standard HL7 messages for relating to laboratory services. Message implementation guides may be found at http://www.cdc.gov/phin/messaging/index.htm .

  - BT Laboratory Result Message – ORU_R01
    (For LRN labs doing bioterrorism related testing including BioWatch)
  - ELR Laboratory Results – ORU_R01
    (For reporting laboratory-reportable findings to state, territorial, and federal public health agencies)
  - Environmental and Food Test results – OUL_R22
    (For test results including human, environmental and food testing)
  - Laboratory Order Request – OML_O21
  - Laboratory Order Response – OMF_O22

2.7 MESSAGE ADDRESSING

- Public health laboratories must have the ability to target HL7 messages to the appropriate recipients. Messages may be addressed automatically via information available in the laboratory information system (such as “test requestor”), or may be addressed individually through a user interface.

Note: The PHIN message standard for BT related results and notifiable disease results are available now. A full set of PHIN laboratory messages under the HL7 version 2.5 standard are being developed now for release by Q4 of 2004.

- Public health LIMS systems must be able to address multiple targets for any laboratory result.
- Public health LIMS systems must be able to ensure an appropriately "identified" or "de-identified" result message for each addressed party.

2.8 SECURE MESSAGE TRANSPORT

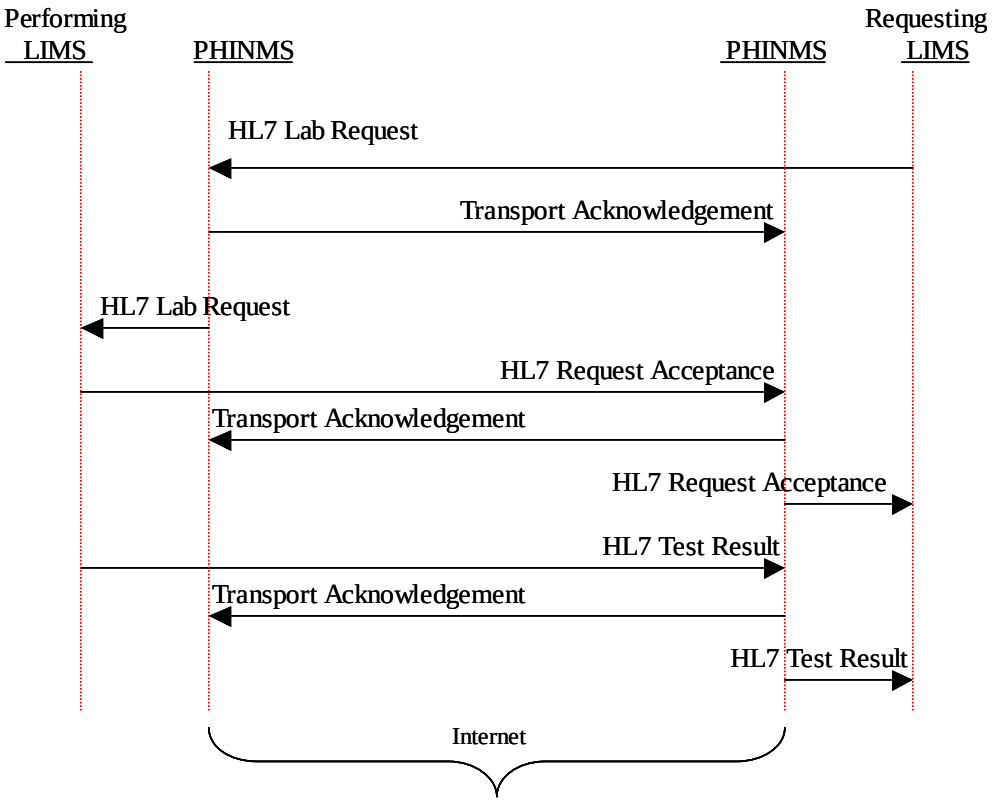
- Public health laboratory systems must message partner organizations using PHIN standards for secure, reliable messaging. PHINMS fully implements PHIN standards for secure messaging and is available from CDC. More information on PHINMS is available at http://www.cdc.gov/phin/messaging/index.htm . PHINMS however is not required so long as the laboratory can meet the following several interoperability requirements in another way.
- PHIN compliant organizations must use the ebXML Messaging Service (ebMS) standard for message transport across the public internet. The ebMS standard is a set of layered extensions on the Simple Object Access Protocol (SOAP). For more information on ebXML and ebMS see http://www.oasis-open.org/ .
- PHIN compliant organizations must be able to easily configure new collaboration protocol agreements (CPA) to create new messaging partners. When available, laboratories must be able to access a PHIN messaging registry to search for potential messaging partners and to download a CPA from the registry.
- PHIN compliant organizations must be able to both send and directly receive messages from public health partners on a 24X7 basis.
- PHIN compliant organizations must be able to encrypt HL7 messages utilizing public key infrastructure (PKI). The public key of the intended message recipient is used to encrypt the message. They will later decrypt the message using their private key.
- PHIN compliant organizations must be able to digitally sign an HL7 message using a digital certificate. .
- PHIN compliant organizations must be able to acknowledge receipt of all messages. PHIN compliant organizations must be able to automatically resend messages that failed transport or were not acknowledged as received.

3 PROCESS FLOWS

3.1 MUTUAL ASSISTANCE - ELECTRONIC LABORATORY 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.
- Upon receipt of HL7 test request messages Public health laboratories must be able to validate, parse, and store this message for processing by a LIMS system.
- Electronic laboratory requests must be acknowledged as received with an HL7 acknowledgement message.
- Electronic laboratory requests must be acknowledged as accepted or denied for testing.
- The requesting Laboratory must be able to validate, parse and store the message content reporting the acceptance or denial of the test request.
- Public health laboratories must be able to perform the electronic interchange associated with laboratory requests diagrammed in Figure 3.1 and must be able to perform at various times as the requestor or the performing lab.

Figure 3.1



3.2 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.
- Test result reporting should be implemented as shown in the diagram in Figure 3.2

Figure 3.2