

CALINX LAB IMPORT Toolkit

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CALINX LAB STANDARD TOOLKIT

Introduction and Roadmap

This toolkit provides an overview of the *CALINX Laboratory Data Standard* and the CALINX LAB IMPORT tool. The CALINX LAB IMPORT tool enables providers to process complex HL7 messages and import and convert those messages into a flat file format for subsequent processing and storage. It gives many organizations the capability to process lab data without the accompanying cost and complexity of a general-purpose interface engine.

HL7 is an important and widely used standard for transmitting data by clinical laboratories. HL7 messages use a hierarchically nested and repeating structure that is not directly supported by the import tools available with most database systems. CALINX LAB IMPORT is an interface engine that transforms the contents of HL7 messages for lab results into formats that are more readily understood and processed.

Read this guide to learn more about:

CALINX background and mission

Who benefits from lab standards

CALINX Laboratory Data Standard and import tool overview

How lab result data can be used (data warehousing, pay for performance, and disease registry)

Understanding lab result data

HL7 and the CALINX Lab Standard

The CALINX message structure

Working with the CALINX LAB IMPORT tool

CALINX LAB IMPORT and HIPAA

Frequently asked questions

Contact information

CALINX Background and Mission

In the spring of 2004, members of the California health care community established the California Clinical Data Project: Setting Standards Initiative. Setting Standards is a collaborative composed of provider organizations, health plans, commercial labs, hospitals, community clinics, purchasers, and state government dedicated to establishing uniform pharmacy and laboratory data exchange standards. These standards have been designed to facilitate the exchange of clinical data and provide clinicians with greater access to timely clinical information.

The goal is to:

Address underlying barriers to the access and use of integrated clinical data to support chronic disease management

Establish a set of uniform processes and procedures for clinical data exchange

Ensure that lab data is consistently transferred in a standardized format

You can find additional information on the Setting Standards initiative's goals and objectives at <http://www.iha.org/calinx/overview.htm>.

Who Benefits from Lab Standards

Having a uniform laboratory standard, agreed upon rules of exchange, and software to ensure compliance benefits a range of stakeholders, including: provider organizations, health plans, labs, hospital systems, clinics, state government, purchasers, and patients. Some of the benefits of uniform standards are:

Standardized and timely lab results data helps provider organizations self-report Pay for Performance clinical measures and increases the likelihood of substantial quality incentives.

Provider organizations with limited resources can more easily integrate clinical data and devote more resources to health and quality improvement efforts such as disease management and disease registry development.

Better access to clinical data helps provider organizations target the sickest patients for treatment and follow-up care.

Health plans can more easily acquire lab data from provider organizations treating their members.

Labs and hospitals can support only a single laboratory results data exchange standard. Currently, many provider groups request a format from their lab partners and those labs must code and support each format.

Additional support (laboratory data validation and conversion tools as well as technical advisors) are available to groups requesting data, which helps minimize provider group requests for assistance from labs and hospitals.

The lab data exchange standard complies with HL7 standards.

Clinics with in-house labs can exchange lab data using a single standard and provide these results to entities with whom they contract.

Better access to timely clinical data means providers can build their own quality improvement or outreach programs tailored specifically to the needs of their patients.

Patients benefit from their clinician's access to timely, essential health care information. Clinicians are able to rely less on the patient's recollection of test results.

Accurate and timely information improves disease management programs and allows for targeted interventions to those most in need.

CALINX Laboratory Data Standard and Lab Import Tool Overview

Through consultation with health plans, laboratories, and medical groups, the California HealthCare Foundation has developed an HL7- compliant laboratory standard as part of the California Clinical Data Project. The *CALINX Laboratory Data Standard* is designed to contain commonly used data elements found in laboratory transmissions that are useful for medical groups and health plans for a variety of purposes. The standard is designed to be a small *subset* of all possible HL7 messages, thereby limiting complexity while maximizing utility and promoting adoption of the standard.

The goal of the standard is to provide a format for reporting test results that is useful for population-based data aggregation and patient-level data analysis. Although clinical laboratories are providing test result files for data analysis today, no standard format exists for this process. The creation and statewide adoption of a single format for this purpose improves the quality, efficiency, and timeliness with which these data are reported.

The purpose of the CALINX LAB IMPORT tool is to provide the data-transformation capabilities that many organizations need to process CALINX-HL7 lab data, without the accompanying cost and complexity of a general-purpose interface engine. Specifically, the import tool accepts lab result data encoded in the CALINX variant of HL7 and converts the data to an arbitrary flat-file format, suitable for loading into applications and database management systems. The tool accepts all HL7 messages, but processes only those compliant with the CALINX Lab Standard. Making this tool available for no charge facilitates the use of CALINX-HL7 by the largest possible group of organizations in California.

Platform and Hardware Requirements

CALINX LAB IMPORT can be used with the following operating systems:

Windows 2000 (all versions)

Windows XP (Professional)

The following hardware is recommended:

1 GHz Intel Pentium processor

256 MB RAM (128 MB possible)

16KB internal cache

200 MB disk space for installation

How Lab Results Data Can Be Used

The CALINX LAB IMPORT tool allows medical groups to more effectively participate in Pay for Performance and registry development for lab data stored in a data warehouse.

Data Warehousing

Medical groups process high volumes of laboratory data, with rates of up to 750,000 result records per month. These results are typically sent monthly via transport of physical media (large batch files on CDs). There is no standard system environment across medical groups for handling this data: systems range from mainframes to desktops for processing and storing the data.

Medical groups currently receive laboratory data from hospitals and commercial laboratories generally in the form of large flat files. The format of these files varies from laboratory to laboratory, requiring the receiving medical groups to negotiate individually with each laboratory and handle multiple formats of data. Streaming HL7 is sometimes received for encounter data, but is rarely used for results data. Thus, HL7 formatted laboratory data is an unknown quantity at most medical groups. Most laboratories, however, are quite familiar with producing HL7 data for transmission of laboratory data both internally and externally.

The consistency and rigor applied to validating files of laboratory data vary across medical groups. Some work with raw files, while others load data into unconstrained databases for subsequent checking using SQL or database tools. The data is then checked for errors and compliance with a predefined format, and decisions are made about how to proceed. Data is typically transformed from incoming flat files into formats adequate for loading into relational database end targets.

Pay for Performance

Pay for Performance (P4P) is a physician incentive program in California that rewards provider organizations for achieving specific benchmarks and ultimately improving the quality and reducing the cost of care. Groups are evaluated using a common set of measures to validate the quality of clinical care for preventative services and treatment of chronic conditions (such as diabetes). Groups are rated on how much they invest in and adopt new technology to improve patient care (such as patient registries for people with chronic illnesses and reminder systems), and on "patient satisfaction" scores that are obtained in an annual survey administered by PBGH (known as the Consumer Assessment Survey or CAS).

The CALINX LAB IMPORT tool enables physician groups to format and report test results for population-based data aggregation and patient-level data analysis. When groups self-report clinical measures, the health plan typically takes the better of the two scores (the one the provider group reports and the one the health plan reports for that group). Since 2005, some of the P4P measures require lab results (see www.IHA.org for a list of measures). These results can only be obtained from lab results files collected from rendering labs/hospitals, not from claims encounter data sent from the provider groups to the health plans.

Registry Development

Computerized disease registries are affordable and practical systems for physicians and provider groups who seek to improve chronic care. A registry is an effective tool for improving management of chronic conditions, such as asthma and diabetes. Disease registries capture and track key patient information to assist providers in proactively monitoring clients with chronic conditions. Chronic conditions such as diabetes, asthma, and coronary artery disease are the major cause of illness, disability, and death in the United States. In 2000, the medical cost of treating chronic disease amounted to 75 percent of health care spending.

An overview and purchasing guide of disease registries is available for download at: <http://www.chcf.org/documents/chronicdisease/ChronicDiseaseRegistryReview.pdf>

Registries can be used in the following situations:

Point of care: to provide patient-specific information such as lab results, and advice to support decision making

Between patient visits: to identify patients with gaps in care

Periodically: to provide population reports to improve care delivery

Medical groups who have implemented disease registries can use the CALINX LAB IMPORT tool to convert HL7 lab results into standard flat files.

Understanding Lab Result Data

Lab tests and other clinical observations use the Logical Observation Identifiers Names and Codes (LOINC) standard, a non-proprietary coding system. LOINC codes uniquely identify tests based on a combination of their features, including the “analyte” (the specific substance being measured or detected), the specimen being tested, and the test methodology being used. Over 25,000 LOINC codes exist for laboratory tests. You can download the LOINC downloadable database free of charge at <http://www.regenstrief.org/loinc/loinc/download/>.

Note: Lab tests can be done separately or in a panel. For example, HgbA1c% is a separate lab test, while CBC is a panel containing multiple lab results.

In the *CALINX Laboratory Data Standard*, the set of tests that require special coding corresponds exactly to the set of tests that are used in the calculation of HEDIS measures. Approximately 60 such tests have been designated. This set of tests was selected for special coding because it represents:

Tests that are most useful for quality-improvement programs related to HEDIS and Pay-for-Performance (P4P).

A manageable set of tests for Laboratories to LOINC encode in a reasonable time.

Each year, NCQA specifies the LOINC codes for all lab tests used in that year’s HEDIS measures, so laboratory result data that is LOINC encoded in CALINX messages may be used directly in the calculation of HEDIS and P4P measures.

HL7 and the CALINX Lab Standard

The HL7 Standard was created with the assumption that real world healthcare events create the need for data to flow between systems. The mission of the group who created and maintains the HL7 standard is “To provide standards for the exchange, management and integration of data that support clinical patient care and the management, delivery and evaluation of healthcare services. Specifically, to create flexible, cost effective approaches, standards, guidelines, methodologies, and related services for interoperability between healthcare information systems.”

The CALINX Lab Standard is focused exclusively on the retrospective reporting of laboratory results in the context of outpatient services. It is based on the HL7 version 2.4 messaging standard and the LOINC laboratory coding standard. Specifically, it is a *message profile* for the HL7 ORU message type and it mandates LOINC codes for identifying certain tests.

Refer to the California Clinical Data Project *CALINX Laboratory Data Standard* (available at <http://www.iha.org/calinx/calinxrxlab.htm>) for detailed information on the structure of CALINX messages and the contents of individual data fields. Although this document describes the elements of HL7 messages as they relate to the CALINX Lab Standard, it does not constitute an introduction to HL7. Readers unfamiliar with HL7 may wish to first review Appendix A (Introduction to HL7 Message Encoding) in the California Clinical Data Project *CALINX Laboratory Data Standard* and/or the extensive materials describing the HL7 2.4 standard, available at www.hl7.org.

HL7 Terms and Concepts

CALINX LAB IMPORT tool users don't need to be HL7 experts to understand and utilize the tool, but it is helpful to have a high-level understanding of the common HL7 terms and concepts described in this section.

Trigger Events

In HL7, a trigger event is a real world event. For example, when an observation is available for a patient (for example, a CBC result), that observation may need to be sent to a number of other systems. This observation is the trigger event.

Messages

A message is the unit of data transferred between systems. Each HL7 message has a message type that defines its purpose. For example, the message type ORU is used to communicate lab data information from one system to another.

Messages have headers that define the intent, source, destination, and some specifics of the syntax of a message. Messages consist of data fields that are of variable length and separated by a field separator character. Rules describe how the various data types are encoded within a field and when an individual field may be repeated.

Segments

A segment is a logical grouping of data fields. Segments of a message may be required or optional. They may occur only once in a message or they may be allowed to repeat. Each segment is given a name and is identified by a unique three-character code known as the Segment ID.

Note the following about segments:

Segments are separated by carriage-return characters.

Each segment begins with a three-character literal value that identifies it within a message.

Segments may be defined as required or optional and may be permitted to repeat.

Individual data fields are found in the message by their position within their associated segments.

Encoding Characters

The following special characters are used in HL7 messages:

Field separator (|) which separates two adjacent data fields in a segment and separates the segment ID from the first data field in each segment from the first data field in each segment.

Component separator, which separates adjacent components of data fields where allowed. The default character is ^.

Subcomponent separator, which separates adjacent subcomponents of data fields where allowed. The default character is &.

Repetition separator, which separates multiple occurrences of a field where allowed. The default character is ~.

Escape character, which is used to include special formatting information in a text field. The default character is \.

HL7 Message Hierarchy

HL7 messages have an implicit hierarchy of segments. Some segments, fields, and components are optional—and some may repeat.

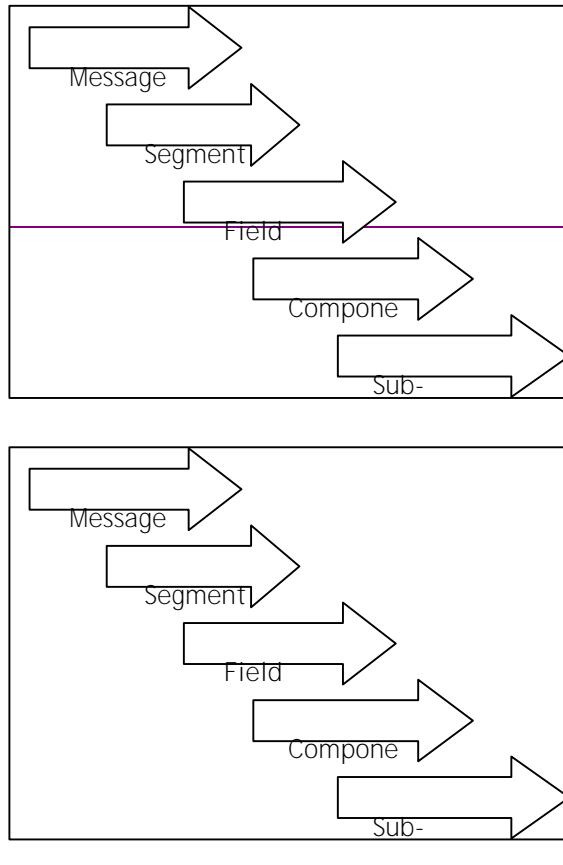


Figure 1: HL7 Message Hierarchy

The structure of HL7 messages is defined in special notation that lists the segment IDs in the order they would appear in the message. The following notations are used:

Braces {...} indicate one or more repetitions of the enclosed group of segments

Brackets [...] show that the enclosed group of segments is optional. If a group of segments is optional and may repeat, it is enclosed in brackets and braces.

Note: [...]} and {[...]} are equivalent.

The following example shows the HL7 message hierarchy notation for an ORU message, listing only those segments used by CALINX. MSH is the message header at the top of the hierarchy; PID is the segment Patient Identification, which is one level below MSH. OBR is the Observations Report ID, which is nested below the PID segment. For each OBR, there may be one or more OBX segments reporting the test result(s).

<u>Segment ID</u>	<u>Segment Name</u>
MSH	Message Header
{	
PID	Patient Identification
{	
OBR	Observations Report ID
[NTE]	Notes and comments
{	
OBX	Observation/Result
[NTE]	Notes and comments
}	
[FT1]	Financial Transaction
}	
}	

Figure 2: HL7 Notation

The CALINX Message Structure

Only one HL7 message profile is used in the CALINX LAB IMPORT tool, the ORU message. This is a general-purpose message that can be used to report any clinical observations, including, lab results, radiology reports, and physical exam findings. The ORU message can also be used in various clinical contexts, including inpatient admissions, outpatient visits, and clinical trials.

The typical ORU message represents laboratory results as a three-level hierarchy, with the Patient Identification segment (PID) at the upper level, an order segment (OBR) at the next level and one or more observation segments (OBX) at the lowest level.

Not all parts (segments) of the standard HL7 ORU message are relevant, and certain optional segments in the ORU message are not needed by the CALINX Lab Standard. Also, certain segments that are relevant to the CALINX Lab Standard have restrictions on their optionality or ability to repeat that vary from the HL7 standard. These variations are intended to simplify the message structure and insure that CALINX messages contain required information. Note that even if there are variations, the message structure is fully compliant with the HL7 ORU message and can be processed by standard HL7 interface engines.

Refer to the California Clinical Data Project *CALINX Laboratory Data Standard* for complete information on the segments that are relevant to the CALINX Lab Standard. See "Example of How an HL7 Message Get Converted to a Flat File" in this document for an illustration of how the CALINX LAB IMPORT tool allows you to translate the hierarchical message to individual, flat-file records.

Segments used in the CALINX Lab Standard

The following sections describe the segments used in the CALINX Lab Standard.

PID Segment

The PID segment is used to communicate patient identification information for lab results transmitted in the CALINX Lab Standard. This segment contains permanent patient identifying and demographic information that, for the most part, is not likely to change frequently.

OBR Segment

In the reporting of clinical observations, the OBR segment serves as the report header. It describes an entire set of observations. The details of each individual observation appear in nested OBX segments (see Section 3.6 of the California Clinical Data Project *CALINX Laboratory Data Standard*). In the case of laboratory results, the OBR segment describes the relevant lab-order information, including the date/time that the specimen was collected.

OBX Segment

The OBX segment is used to transmit a single lab-result value. It represents the smallest indivisible unit of a laboratory report. When the results of laboratory panels are reported, the ordered panel is typically reported in the OBR segment, and the results of each test performed in the panel are reported as individual OBX segments nested beneath the OBR segment. When the results of individually ordered tests are reported, there is a single OBX segment for each OBR segment. Each unique OBX observation in a given HL7 message becomes a unique record in the flat file.

The LOINC coding system must be used as the coding system in the Observation Identifier field for certain lab tests. The list of tests that require LOINC coding is listed in Appendix B of the California Clinical Data Project *CALINX Laboratory Data Standard*.

NTE Segment

The NTE segment is commonly used for sending notes and comments that accompany test-result data. Note that, depending on its position in the ORU message, this segment may be associated with an OBR segment or with an OBX segment.

FT1 Segment

The FT1 segment typically contains the detail data necessary to post charges, payments, adjustments, etc. to patient accounting records. However, in the CALINX Lab Standard, the FT1 segment is used primarily to transmit information about the diagnosis code(s) associated with a test result. The FT1 segment may also be used to transmit information about the patient's insurance plan, if available.

FHS Segment

The FHS segment is used to begin a file containing multiple CALINX laboratory messages, per the CALINX batch file structure, as described in Section 2.3 of the California Clinical Data Project *CALINX Laboratory Data Standard*. This segment and the batch file structure only apply when data is sent in a batch file.

Working with the CALINX LAB IMPORT Tool

The CALINX LAB IMPORT tool accepts lab result data encoded in the CALINX variant of HL7 and converts the data to an arbitrary flat-file format, suitable for loading into applications and database management systems. All HL7 messages are accepted, but only those compliant with the CALINX Lab Standard are processed.

CALINX LAB IMPORT features an interactive interface you can use to:

Assess data quality by testing whether an input file conforms to the specifications of the CALINX Lab Standard, and report data that are missing or improperly formatted. It identifies any variations from the standard and displays/logs them.

Specify the transformation of data from HL7 messages to flat file records. For example, you can specify which fields from CALINX-HL7 messages should be copied to flat-file records and what the sequence of fields should be in those records.

Convert CALINX-HL7 messages into flat file records in the specified formats. You can view and browse the structured content of a data file and preview its flat file conversion, based on the configuration file you select. This lets you access the contents of a file and confirm the correct transformation in a flat file format.

It also supports command-line and programmatic API interfaces to accomplish validation and conversion of CALINX files to facilitate the use of a tool in automated processing environments. It runs as a standalone software application on a single workstation or server, with no requirements for Internet or other network connectivity.

The following diagram illustrates how repeating segments and fields for one HL7 message are converted to records in a flat file output format.

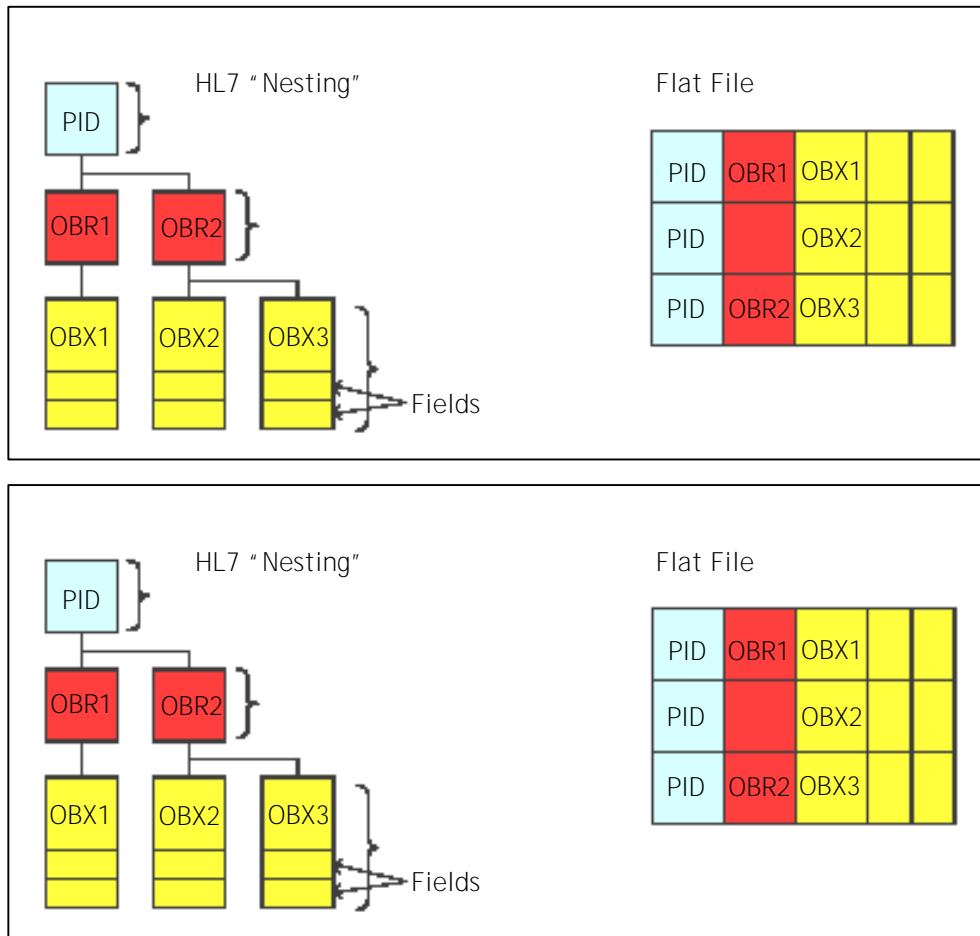


Figure 3: HL7 "Nesting" Converted to Flat File

Example of How an HL7 Message Gets Converted to a Flat File

The following graphic shows the HL7 message for two lab tests:

LDL Cholesterol (1 OBR 1 OBX)

CBC (1 OBR 2 OBXs)

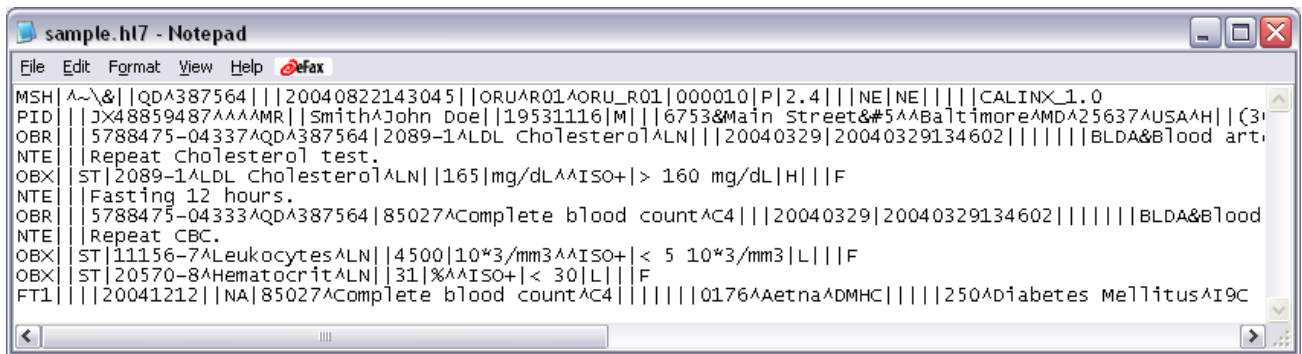


Figure 4: Sample HL7 Message

When this message is converted by CALINX LAB IMPORT tool, the lab data in the resulting flat file can be loaded into a relational database for processing. Observe how in the flat file, the three OBX segments produced three rows containing information on the three lab results received.

The information in the *Medical Record Number, Identifier Type Code, Last Name, and First Name* columns comes from the PID segment.

The information in the *Order ID Text* column comes from the parent OBR segment associated with each lab result (OBX). Note how the OBX results are matched to their parent OBR test orders in the flat file.

The information in the *Lab Identifier, Lab ID Text, Coding System, Observation Value, Result Identifier, Reference Range, Abnormal Flags, and Result Status* come from fields in the OBX segments for each test result.

CALINX LAB IMPORT tool reports whether the message is a valid CALINX message in the *Message Status* column.

CALINX LAB IMPORT lets users configure which data is converted and in which order it is entered in the flat file. The labels of the columns are also configurable.

	A	G	H	I	U	V	W	X	Y	Z	AB	AC	AE	AF
	Medical Record Number	Identifier Type Code	Last Name	First Name	Order ID Text	Lab Identifier	Lab ID Text	Coding System	Observation Value	Result Identifier	Reference Range	Abnormal Flags	Result Status	Message Status
1	JX48859487	MR	Smith	John Doe	LDL Cholesterol	2089-1	LDL Cholesterol	LN	165	mg/dL	> 160 mg/dH		F	Valid
2	JX48859487	MR	Smith	John Doe	Complete blood count	11156-7	Leukocytes	LN	4500	10*3/mm3	< 5 10*3/m	L	F	Valid
3	JX48859487	MR	Smith	John Doe	Complete blood count	20570-8	Hematocrit	LN	31	%	< 30	L	F	Valid
4														
5														

Figure 5: Sample Flat File

CALINX LAB IMPORT and HIPAA

CALINX LAB IMPORT lab data is intended to help improve access to more accurate and timely lab data. CALINX LAB IMPORT data is only intended to be exchanged between contracted entities, or between “covered entities” and “business associates” as defined in the Health Insurance Portability and accountability Act of 1996, or HIPAA.

The HIPAA transaction standard requires that only standards recognized in the *Federal Register* be used for *financial* and *administrative transactions* to enable health information to be exchanged electronically. Standards are required for the following transactions:

1. Health care claims or equivalent encounter information
2. Health care payment and remittance advice
3. Coordination of benefits
4. Health care claim status
5. Enrollment and disenrollment in a health plan
6. Eligibility for a health plan
7. Health plan premium payments

8. Referral certification and authorization
9. First report of injury
10. Health claims attachments
11. Other transactions that the Secretary may prescribe by regulation

A transaction is defined in § 160.103 of the Final Rule as the exchange of data for one of the enumerated specific purposes. For example, one type of health care claim or equivalent encounter information transaction is the exchange of information between a health care provider and a health plan about services provided to a patient to obtain payment. Data submissions or exchanges for purposes other than those designated in this regulation are not transactions and therefore do not require use of the standards.

The regulations define a health care claim or encounter transaction as the transmission of:

- a) A request to obtain payment, and the necessary accompanying information from a health care provider to a health plan for health care or;
- b) If there is no direct claim, because the reimbursement contract is based on a mechanism other than charges or reimbursement rates for specific services (e.g., capitation), the transaction is the transmission of encounter information for the purpose of reporting health care.

CALINX LAB IMPORT is NOT a request for payment of any kind; it is a file format for transmitting clinical information to providers of care. As such, the CALINX Lab Standard does not fall under the transaction rule of HIPAA. The Privacy and Security regulations of HIPAA must however still be observed to maintain patient confidentiality.

Frequently Asked Questions

What is CALINX?

CALINX (which stands for CALifornia INformation eXchange) is a standard or file format for exchanging lab results. CALINX Rx 2.0 is also a standard for exchanging pharmacy utilization data. The standard provides information about lab results and can be used for disease registries, electronic health records, disease management, and Pay-4-Performance initiatives.

What does the CALINX LAB IMPORT tool do?

CALINX LAB IMPORT tool enables providers to process complex HL7 messages which conform to the *CALINX Laboratory Data Standard*, and import and convert those messages into a flat file format for subsequent processing and storage. It gives many organizations the capability to process lab data without the accompanying cost and complexity of a general-purpose interface engine.

Where can I get the CALINX LAB IMPORT tool?

The tool is free and will be available from <http://www.iha.org/calinx/calinxrxlreg.htm>.

What is HL7?

Health Level 7 (HL7) is an important and widely used standard for transmitting data by clinical laboratories.

What are LOINC codes?

Lab tests and other clinical observations use the Logical Observation Identifiers Names and Codes (LOINC) standard, a non-proprietary coding system. LOINC codes uniquely identify tests based on a combination of their features, including the "analyte" (the specific substance being measured or detected), the specimen being tested, and the test methodology being used. Over 25,000 LOINC codes exist for laboratory tests. In the CALINX LAB IMPORT tool, the LOINC coding system must be used as the coding system in the Observation Identifier field for certain lab tests.

What is the difference between a hierarchical file and a flat file?

In a hierarchical file, such as an HL7 message, data is nested and repeated in a prescribed method. In a flat file, data is listed in tables that can be loaded into relational databases.

Who can I talk to about getting lab data?

See the "Contact Information" section in this document if your provider group contracts with any of the listed organizations. If the appropriate organization is not listed, contact any other contracted lab providers or hospitals/clinics and request files in the CALINX format.

Will the toolkit or data validation software help with member matching?

Neither the toolkit nor the software will help with member matching. Groups will have to internally develop their own algorithms or purchase software designed specifically for member matching.

Is this standard HIPAA compliant?

The CALINX Lab Standard does not fall under the HIPAA transaction standard rule. The CALINX LAB IMPORT tool is intended for the transmission of health care information for quality and health improvement purposes, NOT for payment purposes. Because CALINX Rx data has protection health information (PHI) such as patient names and dates of birth, it does fall under HIPAA privacy and security rules, and must be exchanged accordingly (between covered entities and business associates in a secure manner).

Contact Information

For questions regarding the use of lab data, the CALINX Lab Standard, or the CALINX LAB IMPORT tool, contact the appropriate health plan involved in the *California Clinical Data Project: Setting Standards* initiative.

Organization	Name	e-mail	Phone
Integrated Healthcare Association	Dolores Yanagihara	dyanagihara@iha.org	510-208-1740
LabCorp	Lisa Birkett	birketl@labcorp.com	336-436-7744
Quest Diagnostics	Andy Shaw	andrew.l.shaw@questdiagnostics.com	916-679-3930 x 6062