

# **NIST Testing Approach Overview: Using the HL7 V2 LOI Validation Tool**

Laboratory Order Interface (LOI) – Ambulatory EHR-S

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# Purpose

- Provide an additional resource to explain the process of EHR testing related to HL7 V2 Laboratory Orders Interface (LOI) Messaging
- Describe NIST approach for assessing and validating the test messages
- Provide an overview of the testing requirements

# Table of Contents

- List of Resources
- Scope of NIST LOI Testing
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- Explanation of Test Scenarios and Test Cases
- Example Test Case Documents
- Explanation of Test Data Categorization/Validation
- Test Tool Overview and Example Test Tool Screen
- FAQ for LOI Test Tool
- Additional Resources

# Resources

- LOI Test Plan (on Documentation Tab)
- Test Tool Web Site (<http://hl7v2-loi-r1-testing.nist.gov>) Beta Version
  - Validation Tools
  - User Documentation
    - S&I Framework Lab Order Interface (LOI) Implementation Guide ([http://www.hl7.org/implement/standards/product\\_brief.cfm?product\\_id=152](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=152))
    - LOI Tool Quick Reference Guide (In Process)
    - LOI Tool Tutorial (In Process)
  - Release Notes for each version of Test Tool  
(on Documentation Tab)
- LOI Test Tool Google Group for submitting questions to the Test Tool developers  
(<https://groups.google.com/forum/?hl=en#!forum/hl7v2-lab-orders-interface-testing>)

# Scope of NIST Testing

NIST testing is directed at an EHR product, not specific instances (implementations) of an EHR system

- NIST LOI testing focuses on the capability of the EHR product to electronically create lab order messages in accordance with standards for electronic transmission from ambulatory EHRs
- Transmission of the messages is not being tested
- Receiving LIS\* are not being tested using the LOI Context-based validation tool; however, the receiving LIS should be capable of processing the data included in the LOI test message

\*Laboratory Information Systems

Testing focus and scope is narrow

- Testing encompasses only the specific use case indicated in the LOI implementation guide
- Testing does not attempt to address the entire spectrum of use cases found in practice or specified in implementation guides

NIST testing is driven by the test data

- NIST is testing the capability of an EHR product to create lab order messages for transmission from ambulatory EHRs using specific data
- The Test Cases provided do not cover the full extent of use cases specified in the implementation guide; through consultation with clinical laboratory experts, a subset of key lab tests were selected for testing
- The testing will not demonstrate complete conformance to the implementation guide, as it is not practical for this testing to be exhaustive

Clinical laboratory subject matter experts, in collaboration with the National Institute of Standards and Technology (NIST), provided the Test Scenarios, Test Cases, and Test Data for the NIST Laboratory Order Interface testing

# NIST Lab Order Interface Testing

- Evaluates the capability for an ambulatory EHR technology to electronically create laboratory orders for electronic transmission to laboratory information systems
  - Using HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Orders from EHR (Referred to as LOI)
  - Using LOINC® version 2.40 (at a minimum)
  - With all the information for a test requisition as specified at 42 CFR 493.1241(c)(1) through (c)(8)
- The LOI Test Tool targets the *create* aspect, evaluating the capability of the EHR to electronically create the LOINC-encoded laboratory test result message in a conformant HL7 v2.5.1 format
- The testing focuses on the proper implementation of the LOI specification; *how* the laboratory order is sent from an ambulatory EHR to an LIS is not within the scope



# Referenced Standards - Lab Order Interface

- **42 CFR 493.1241 Standard: Test request. (c) The laboratory must ensure the test requisition solicits the following information:**
  - (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values.
  - (2) The patient's name or unique patient identifier.
  - (3) The sex and age or date of birth of the patient.
  - (4) The test(s) to be performed.
  - (5) The source of the specimen, when appropriate.
  - (6) The date and, if appropriate, time of specimen collection.
  - (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy.
  - (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.
- **Implementation specifications for exchanging electronic health information**
  - HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Orders from EHR
- **Vocabulary standards for representing electronic health information**
  - Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.40, a universal code system for identifying laboratory and clinical observations produced by the Regenstrief Institute, Inc.

# Referenced Standards Documents

V251\_IG\_SIF\_LABORDERS\_DSTU\_R1\_2013DEC



## HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Orders from EHR, Release 1 - US Realm

### Draft Standard for Trial Use

December 2013

Publication of this draft standard for trial use and comment has been approved by Health Level Seven International (HL7). This draft standard is not an accredited American National Standard. The comment period for use of this draft standard shall end 12 months from the date of publication. Suggestions for revision should be submitted at <http://www.hl7.org/dstucomments/index.cfm>.

Following this 12 month evaluation period, this draft standard, revised as necessary, will be submitted to a normative ballot in preparation for approval by ANSI as an American National Standard. Implementations of this draft standard shall be viable throughout the normative ballot process and for up to six months after publication of the relevant normative standard.

Sponsored by:  
Orders and Observations Work Group  
in collaboration with the Health and Human Services Standards  
and Interoperability Framework Laboratory Orders Interface Working Group

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## HL7 2.5.1 LOI Implementation Guide Release 1 DSTU

[http://www.hl7.org/implement/standards/product\\_brief.cfm?product\\_id=152](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=152)



# Referenced Standards Documents

## § 493.1241

approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in § 493.1249 for each specialty and sub-specialty of testing performed.

### § 493.1241 Standard: Test request.

(a) The laboratory must have a written or electronic request for patient testing from an authorized person.

(b) The laboratory may accept oral requests for laboratory tests if it solicits a written or electronic authorization within 30 days of the oral request and maintains the authorization or documentation of its efforts to obtain the authorization.

(c) The laboratory must ensure the test requisition solicits the following information:

(1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values.

(2) The patient's name or unique patient identifier.

(3) The sex and age or date of birth of the patient.

(4) The test(s) to be performed.

(5) The source of the specimen, when appropriate.

(6) The date and, if appropriate, time of specimen collection.

(7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy.

(8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.

(d) The patient's chart or medical record may be used as the test requisition or authorization but must be available to the laboratory at the time of testing and available to CMS or a CMS agent upon request.

## 42 CFR Ch. IV (10-1-11 Edition)

(e) If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately.

### § 493.1242 Standard: Specimen submission, handling, and referral.

(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable:

(1) Patient preparation.

(2) Specimen collection.

(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source.

(4) Specimen storage and preservation.

(5) Conditions for specimen transportation.

(6) Specimen processing.

(7) Specimen acceptability and rejection.

(8) Specimen referral.

(b) The laboratory must document the date and time it receives a specimen.

(c) The laboratory must refer a specimen for testing only to a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by CMS.

(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section.

### § 493.1249 Standard: Preanalytic systems quality assessment.

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at §§ 493.1241 through 493.1242.

(b) The preanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and

## 42 CFR 493.1241 Standard: Test request.

<http://www.gpo.gov/fdsys/granule/CFR-2011-title42-vol5/CFR-2011-title42-vol5-sec493-1241/content-detail.html>

# Referenced Standards Web Site

The screenshot shows the LOINC website homepage. At the top, the LOINC logo is displayed with the tagline "From Regenstrief". Navigation links include Downloads, Documentation, News, About, and Go Premium. A search bar is present with a "search" button and a dropdown menu set to "All of loinc.org". Below the navigation bar, a large blue text block reads: "A universal code system for tests, measurements, and observations." Below this, a handwritten-style text asks "How do you say glucose?" above a laptop screen. The laptop screen displays the LOINC logo and the text "the clinical data exchange lingua franca", surrounded by various flags and the word "Glucose" in multiple languages. Below the laptop, a text block states: "More than 29,000 people in 158 countries use LOINC to make bridges across their islands of health data." At the bottom, it says "It's free, but invaluable." On the right side of the page, there are sections for "Current Versions" (listing LOINC 2.46 and RELMA 6.4, both released 2013-12-26, with a "Download" button), "Recent Forum Posts" (with links to "Chemistry | Re: What time is specified by concept 58645-3 ?" and "Other Lab | Re: Microbiology culture order=result, awkward?"), and "Follow LOINC on Twitter" (showing a tweet from @djvreeman about a presentation).

LOINC® Database version 2.40 (at a minimum)

<http://loinc.org/>

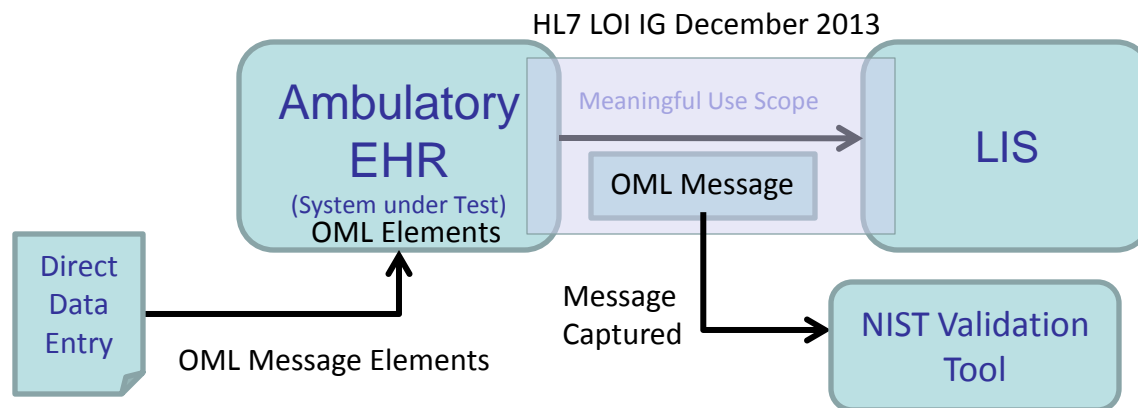
# LOI Validation Tool Overview

Purpose: The tool validates LOI messages created by EHR technology

## Tool Key Capabilities

<b>LOI Context-free Validation</b>	<b>(No Test Cases - Test any LOI message created by EHR senders)</b> <ul style="list-style-type: none"><li>• Context (e.g. type and results of lab test) is unknown to validation tool</li><li>• Provides a simple and convenient method for testing message structure and most vocabulary</li></ul>
<b>LOI Context-based Validation</b>	<b>(Test Cases - Test LOI message associated with a specific test scenario)</b> <ul style="list-style-type: none"><li>• Context (e.g. type and results of lab test) is known to validation tool</li><li>• All conformance requirements of LOI implementation guide can be assessed</li></ul> <b>(Context-base Validation is used for certifying EHR technology for Meaningful Use)</b>
<b>Profile Viewer</b>	Provides a browsable version of the conformance profile which encapsulates the requirements. Can be used to assist in the interpretation of errors.
<b>Vocabulary Browser</b>	Provides a browsable view of the vocabulary requirements. Can be used to assist in the interpretation of value set errors.
<b>Documentation</b>	Provides access to documents which will assist in using the tool (including test plans, data sheet and juror document supplements).

# Lab Orders from Ambulatory EHR Testing Procedure

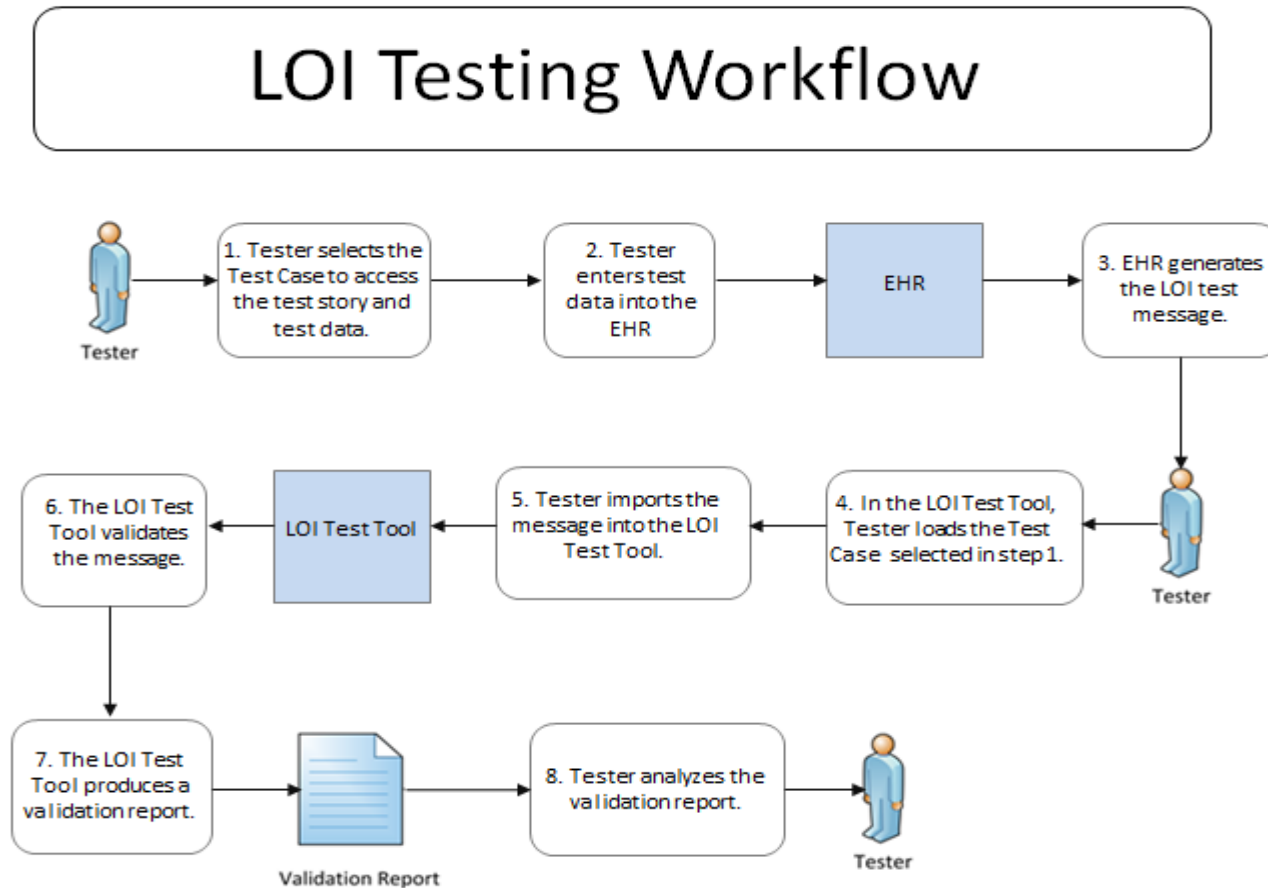


1. The Ambulatory EHR is the system being tested. The EHR system is required to create messages that conform to the referenced standards (See previous slides).
2. Test data can be entered into EHR directly via the EHR's user interface or can be imported via some other method
3. The EHR is expected to process the test data to create a message. This message is captured and uploaded into the testing tool for validation.
4. Test data are available in the Test Tool via the Test Cases in the Context-based Validation. Each Test Case includes a Test Story that provides the context, a Test Data Specification that lists the test data, and a Message Content Data Sheet that shows a conformant message (in a table format) including a detailed profile of the required elements

# Testing Workflow Diagram for Context-based Validation

This diagram shows

- How the major steps of the context-based test are sequenced
- When the Test Tool is to be used





# Test Scenarios and Associated Test Cases

- Each of the LOI test cases
  - Addresses a specific test scenario
  - Consists of a Test Story, Test Data Specification sheet, and Message Content sheet
  - Includes LOI test data for lab tests ordered by an EHR-S in the ambulatory setting
- One test case is a “smoke test” for demonstration of basic LOI capabilities and should be completed prior to beginning the other test cases
- Test cases and specific test data are provided for four profile options defined in the LOI implementation guide (see next slide for details about these profile options)



# Test Scenarios and Associated Test Cases (cont'd)

- The HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Orders from EHR (LOI) interoperability standard defines four profile options that are relevant for NIST Context-based Validation
- These profile options are composed of Pre-Coordinated OIDs or combinations of Component OIDs used to populate MSH.21 (Message Profile Identifier)

LOI Profile	Pre-Coordinated OID	Component OIDs	Component Name
LOI_GU_PRU_Profile	2.16.840.1.113883.9.85	2.16.840.1.113883.9.66 2.16.840.1.113883.9.78 2.16.840.1.113883.9.82	LOI_Common_Component LOI_GU_Component LAB_PRU_Component
LOI_GU_PRN_Profile	2.16.840.1.113883.9.86	2.16.840.1.113883.9.66 2.16.840.1.113883.9.78 2.16.840.1.113883.9.81	LOI_Common_Component LOI_GU_Component LAB_PRN_Component
LOI_NG_PRU_Profile	2.16.840.1.113883.9.87	2.16.840.1.113883.9.66 2.16.840.1.113883.9.79 2.16.840.1.113883.9.82	LOI_Common_Component LOI_NG_Component LAB_PRU_Component
LOI_NG_PRN_Profile	2.16.840.1.113883.9.88	2.16.840.1.113883.9.66 2.16.840.1.113883.9.79 2.16.840.1.113883.9.81	LOI_Common_Component LOI_NG_Component LAB_PRN_Component

The PRN profiles apply only to the GHP and Creatinine Clearance test cases in the LOI test tool

- For the purpose of NIST Context-based Validation, the Vendor will declare which one of the four profile options they are claiming for conformance
- The test cases are grouped in the test tool by GU or NG

# Test Scenarios and Associated Test Cases (cont'd)

- Context-free Validation in the LOI test tool may be used to evaluate messages containing the following additional *optional* profile components:

Component OIDs	Component Name	
2.16.840.1.113883.9.80	LAB_FI_Component	(Financial Information)
2.16.840.1.113883.9.94	LOI_PH_COMPONENT	(Public Health)

- Example messages containing these optional components are available on the Documentation tab in the LOI test tool

# Test Scenarios and Associated Test Cases (cont'd)

- Depending on which profile is claimed by the Vendor
  - The Tester shall use the NG test cases, and shall use either NG\_PRU or NG\_PRN for the GHP (Initial Order) and Creatinine Clearance test cases or
  - The Tester shall use the GU test cases, and shall use either GU\_PRU or GU\_PRN for the GHP (Initial Order) and Creatinine Clearance test cases

Test Scenario	NG Test Cases	GU Test Cases
Minimally Populated Prothrombin Time – Initial Order (Smoke Test)	LOI_0.0_1.1-NG	LOI_0.0_1.1-GU
Typically Populated Sed Rate message – Initial Order via Ambulatory EHR	LOI_1.0_1.1-NG	LOI_1.0_1.1-GU
Typically Populated Sed Rate message – Order Cancelled via Ambulatory EHR	LOI_1.0_2.1-NG	LOI_1.0_2.1-GU
Typically Populated Sed Rate message – Order Cancelled by Lab	LOI_1.0_3.1-NG	LOI_1.0_3.1-GU
Typically Populated CBC – Initial Order	LOI_2.0_1.1-GU	LOI_2.0_1.1-GU
Typically Populated Lipid Panel – Initial Order	LOI_3.0_1.1-NG	LOI_3.0_1.1-GU
Typically Populated Lipid Panel – Initial Order	LOI_3.1_1.1-NG	LOI_3.1_1.1-GU
Typically Populated Culture and Susceptibility – Microbiology – Initial Order	LOI_4.0_1.1-NG	LOI_4.0_1.1-GU
Typically Populated Hepatitis – Reflex – Initial Order	LOI_5.0_1.1-NG	LOI_5.0_1.1-GU
Typically Populated Pap Smear – Anatomical Pathology – Initial Order	LOI_6.0_1.1-NG	LOI_6.0_1.1-GU
Typically Populated GHP – Initial Order	LOI_7.0_1.1-NG_PRU OR	LOI_7.0_1.1-GU_PRU OR
	LOI_7.0_1.1-NG_PRN	LOI_7.0_1.1-GU_PRN
Typically Populated GHP – Add-On Order	LOI_7.0_2.1-NG	LOI_7.0_2.1-GU
Typically Populated Creatinine Clearance – Initial Order	LOI_9.0_1.1-NG_PRU OR	LOI_9.0_1.1-GU_PRU OR
	LOI_9.0_1.1-NG_PRN	LOI_9.0_1.1-GU_PRN
Typically Populated Prostate Biopsy – Anatomical Pathology – Initial Order	LOI_10.0_1.1-NG	LOI_10.0_1.1-GU

# The Test Data Documents for Each Test Case

Each Test Case includes a narrative Test Story that describes a real world situation and provides context for the Test Case

NIST Test Data : Laboratory Orders Interface

**NIST Test Data**  
**Laboratory Orders Interface**

Version 1.2

11th July, 2014

National Institute of Standards and Technology (NIST)

NIST Test Data : Laboratory Orders Interface

**LOI Test Case LOI\_1.0\_1.1-GU**

**Sed\_Rate**

National Institute of Standards and Technology (NIST)

NIST Test Data : Laboratory Orders Interface

**Test Story**

Description

Mr. William A. Jones is a 51 year old white male who presented with pain, swelling, and redness in several joints including his elbows, wrists, knees, and hips on March 31, 2011 at 2:05 PM PST. In order to screen for rheumatoid diseases, Dr. Nicholas Radon ordered an erythrocyte sedimentation rate (ESR or Sed Rate) blood test using the GoodHealth Clinic's EHR system, specifying that the laboratory's patient service center was to draw the blood specimen from the patient who was scheduled to arrive at 3:00 PM PST. Dr. Radon also requests that the results be CC'd to Dr. Pafford M. Hamlin Sr, a specialist to which he is referring Mr Jones as well as Dr. Daniel Davison who is Mr Jones' regular doctor.

Comments

This test order message corresponds to the LRI test result message 'LRI\_1.0\_Sed\_'.  
This is a new order of a single test.  
Sample is collected by the laboratory.  
Results to be copied to other providers.

PreCondition

The lab provided a list of test codes - LODNC, local or both. There is agreement that these codes will be used in the order messages.

PostCondition

No PostCondition.

TestObjectives

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Example: Test Data pdf document for the  
LOI\_1.0\_1.1-GU\_PRU Sed Rate Order Test Case

# The Test Data Documents for Each Test Case (cont'd)

NIST Test Data : Laboratory Orders Interface

### Test Data Specification

**Patient Information**

Element name	Data
Name	William A Jones JR
Date/time of birth	1961-06-15
Administrative gender	Male
Race	White
Address	2100 Kewwood Ave Apt 41 Los Angeles CA 90067

**Order Information**

Element name	Data
<b>Ordering Provider</b>	
Name	Nicholas Radon
NPI identifier	5742200012
Call Back Phone Number	213-7865600 ext 3312
<b>General order information</b>	
Placer Order Number	ORD10
Placer Group Number	GORD874211
Order Control	New order/service
Date/Time of Transaction	2011-03-31 2:30pm
Advanced Beneficiary Notice	Advanced Beneficiary Notice has not been signed
Advanced Beneficiary Notice Override Reason	Patient not asked

**Timing/Quantity Information**

Element name	Data
Start date and time	2011-03-31 3:00pm-08:00
Priority	Routine

**Observation request details**

Element name	Data
<b>Universal service identifier</b>	
Code	500

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NIST Test Data : Laboratory Orders Interface

Test	Erythrocyte sedimentation rate
Coding system	99U01
Alternate code	90341-2
Alternate text	Erythrocyte sedimentation rate
Alternate coding system	LN
Alt Handling	Carbon Copy

**Remarks**

Element name	Data
Comments	Patient is extremely anxious about needles used for drawing blood. If patient is overly frightened, nervous, or anxious please reschedule blood draw.

**Remarks**

Element name	Data
Comments	Patient is allergic to latex

**Prescription Information**

Element name	Data
Prescription Instance ID	1
Prescriber NPI identifier	10092000194
Prescriber name	Pattford Humlin
Address	555 Tennessee Ave Suite 120 Huntington Park CA 90255 USA
Phone number	323-5555555
Email address	DocPattford@gooddr.com
Phone number(s)	310-5465550 ext 19

**Prescription Information**

Element name	Data
Prescription Instance ID	2
Prescriber NPI identifier	2129416824
Prescriber name	Daniel Davison
Address	7014 West Arbor Vitae St Suite 120 Inglewood CA 90313 USA

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- Each Test Case includes a Test Data Specification that
  - Lists data associated with the Test Story
  - Consists of typical information found in the clinical setting
  - Along with the Test Story, provides sufficient information to be entered into the EHR for the Test Case
- A test message is generated using these data and the EHR functions

Example: Test Data pdf document for the  
LOI\_1.0\_1.1-GU\_PRU Sed Rate Order Test Case



# The Test Data Documents for Each Test Case (cont'd)

NIST Test Data : Laboratory Orders Interface

## Message Content Data Sheet

Test Case Information

NIST-LOI_1.0_1.1-GU - Sed_Rate	
Test Case ID	LOI_1.0_1.1-GU

MSH :

Location	Data Element	Data	Categorization
MSH.1	Field Separator		IG Fixed Data
MSH.2	Encoding Characters	^~&#	IG Fixed Data
MSH.3	Sending Application		
MSH.3.1	Namespace ID	NIST EHR	Configurable Data
MSH.3.2	Universal ID	2.16.840.1.113883.3.72.5.22	Configurable Data
MSH.3.3	Universal ID Type	ISO	IG Fixed Data
MSH.4	Sending Facility		
MSH.4.1	Namespace ID	NIST EHR.Facility	Configurable Data
MSH.4.2	Universal ID	2.16.840.1.113883.3.72.5.23	Configurable Data
MSH.4.3	Universal ID Type	ISO	IG Fixed Data
MSH.5	Receiving Application		
MSH.5.1	Namespace ID	NIST Test Lab APP	Configurable Data
MSH.5.2	Universal ID	2.16.840.1.113883.3.72.5.20	Configurable Data
MSH.5.3	Universal ID Type	ISO	IG Fixed Data
MSH.6	Receiving Facility		
MSH.6.1	Namespace ID	NIST Lab Facility	Configurable Data
MSH.6.2	Universal ID	2.16.840.1.113883.3.72.5.21	Configurable Data
MSH.6.3	Universal ID Type	ISO	IG Fixed Data
MSH.7	Date/Time of Message		
MSH.7.1	Time	20130211184101-0500	System Generated
MSH.9	Message Type		
MSH.9.1	Message Code	OML	IG Fixed Data
MSH.9.2	Trigger Event	021	IG Fixed Data
MSH.9.3	Message Structure	OML_021	IG Fixed Data

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NIST Test Data : Laboratory Orders Interface

PRT :

Location	Data Element	Data	Categorization
PRT.1	Participation Instance ID		
PRT.1.1	Entry Identifier	1	Changeable Data
PRT.1.2	Namespace ID	NIST EHR	Configurable Data
PRT.1.3	Universal ID	2.16.840.1.113883.3.72.5.22	Configurable Data
PRT.1.4	Universal ID Type	ISO	IG Fixed Data
PRT.2	Action Code	AD	IG Fixed Data
PRT.4	Participation		
PRT.4.1	Identifier	RCT	Test Case Fixed Data
PRT.4.2	Text	Result Copies To	Changeable Data
PRT.4.3	Name of Coding System	HL70912	IG Fixed Data
PRT.4.7	Coding System Version ID		
PRT.4.8	Alternate Coding System Version ID		
PRT.4.9	Original Text	Copy to	Changeable Data
PRT.5	Participation Person		
PRT.5.1	ID Number	10092060184	Changeable Data
PRT.5.2	Family Name		
PRT.5.2.1	Surname	Hamlin	Changeable Data
PRT.5.3	Given Name	Pafford	Changeable Data
PRT.5.9	Assigning Authority		
PRT.5.9.1	Namespace ID	NPI	Configurable Data
PRT.5.9.2	Universal ID	2.16.840.1.113883.4.6	Configurable Data
PRT.5.9.3	Universal ID Type	ISO	IG Fixed Data
PRT.5.10	Name Type Code	L	Changeable Data
PRT.5.13	Identifier Type Code	NPI	Changeable Data
PRT.14	Participation Address		
PRT.14.1	Street Address		
PRT.14.1.1	Street or Mailing Address	555 Tennessee Ave	Changeable Data
PRT.14.2	Other Designation	suite 120	Changeable Data
PRT.14.3	City	Huntington Park	Changeable Data
PRT.14.4	State or Province	CA	Changeable Data
PRT.14.5	Zip or Postal Code	90255	Changeable Data
PRT.14.6	Country Code	USA	Changeable Data
PRT.14.7	Address Type	B	Changeable Data

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Each Test Case includes a Message Content Data Sheet that shows a conformant message instance

The category of the test data is listed in the Categorization column

Example: Test Data pdf document for the LOI\_1.0\_1.1-GU\_PRU Sed Rate Order Test Case



# Test Data Categorization and Validation

- The Message Content Data Sheet shows the categorization of the test data that are provided for each Location
- The category assigned to the data is directly related to how the associated message content is validated by the Test Tool, as shown in the table below

Data Categorization	Description	Validation
<b>Configurable</b>	Data typically that is configured by the system (customer-definable). Example data is provided.	Validate for the presence of data
<b>System Generated</b>	Data typically generated automatically by the system, for example, message time. Example data is provided.	Validate for the presence of data
<b>IG Fixed</b>	Data that is fixed by the implementation guide; data can't be changed. Specific data is provided.	Validate for the presence and data content
<b>Test Case Fixed</b>	Data that is specific and fixed by the test case; data should not be changed. Specific data is provided	Validate for the presence and selectively validate for data content
<b>Changeable</b>	Data where the exact content is not relevant for the Test Case and can be changed for the purposes of testing. Example data is provided.	Validate for the presence of data

# Test Data Validation

- The Test Tool validates a message for the *presence and exact content* of the data for Locations assigned to the **IG Fixed** category and the **Test Case Fixed** category
- The Test Tool validates a message for the *presence* of data for Locations assigned to any of the other categories
  - These data are necessary for the transaction, but the exact content is either not relevant for the Test Case or may be system-dependent
  - Example: Universal ID for the Performing Organization

Location	Value	Category	Assessment
PRT.4.1	RTC	Test Case Fixed Data	Content must be <u>present and exactly</u> “RTC”
PRT.4.2	Result Copies To	Changeable Data	Content must be <u>present</u> and should be a value equivalent to “Result Copies To”
PRT.4.3	HL70912	IG Fixed Data	Content must be <u>present and exactly</u> “HL70912”
MSH.3.1	NIST EHR	Configurable Data	Content must be <u>present</u> and should be an equivalent value
MSH.3.3	ISO	IG Fixed Data	Content must be <u>present and exactly</u> “ISO”

- The testing laboratory may also inspect the message during validation; the Inspection Test Guides in the Test Procedure document provide guidance

# LOI Validation Tool Overview

Purpose: The tool validates LOI messages created by EHR technology

## Tool Key Capabilities

<b>LOI Context-free Validation</b>	<b>(No Test Cases - Test any LOI message created by EHR senders)</b> <ul style="list-style-type: none"><li>• Context (e.g. type and results of lab test) is unknown to validation tool</li><li>• Provides a simple and convenient method for testing message structure and most vocabulary</li></ul>
<b>LOI Context-based Validation</b>	<b>(Test Cases - Test LOI message associated with a specific test scenario)</b> <ul style="list-style-type: none"><li>• Context (e.g. type and results of lab test) is known to validation tool</li><li>• All conformance requirements of LOI implementation guide can be assessed</li></ul>
<b>Profile Viewer</b>	Provides a browsable version of the conformance profile which encapsulates the requirements. Can be used to assist in the interpretation of errors.
<b>Vocabulary Browser</b>	Provides a browsable view of the vocabulary requirements. Can be used to assist in the interpretation of value set errors.
<b>Documentation</b>	Provides access to documents which will assist in using the tool (including test plans, data sheet and juror document supplements).

No registration or log-in credentials are needed. Simply click link on the link below and send/paste/load message into tool to obtain a Validation Report.

<http://hl7v2-loi-r1-testing.nist.gov>

NOTE: The Test Tool (.war file) can also be downloaded and installed locally.

NOTE: Web Application is compatible with Internet Explorer versions 8 and 9, Firefox, and Chrome. Recommended browsers are Internet Explorer 9, Firefox and Chrome.

Register to Google Group at: <https://groups.google.com/forum/?hl=en#!forum/hl7v2-lab-orders-interface-testing> to ask questions and provide feedback.

# Example LOI Test Tool Screen

LOI Tool Tutorial (In Process) provides a full guide

The screenshot displays the LOI Test Tool interface. The top navigation bar includes links for Home, Context-free Validation, Context-based Validation, Profile Viewer, Vocabulary, Documentation, Settings, and About. Below this, a secondary bar shows Test Case, Validation, and Report. The main area is divided into two panes: Message Tree on the left and Message Content on the right. The Message Tree pane shows a hierarchical structure of message elements, including MSH, PID, ORC, and PRT. The Message Content pane displays the raw HL7 message text. At the bottom, the Message Validation Result section shows a table of errors. Four numbered callouts provide additional context: 1. Context-free or Context-based Validation. 2. Uploaded test message displays. 3. If message fails validation, errors will display in Message Validation Result section of page. 4. Click on location link to highlight the data element causing the error within the Message Tree and Content.

1 Context-free or Context-based Validation.

2 Uploaded test message displays.

3 If message fails validation, errors will display in Message Validation Result section of page.

4 Click on location link to highlight the data element causing the error within the Message Tree and Content.

Note: Location link may not be available if the message element location does not map to a message element in the message tree.

Message Tree

- MSH[1]: Message Header R [1,1]
- PID[1]: Patient Identification R [1,1]
- ORC[1]: Common Order R [1,1]
- Quantity [1,1]
- Observation Request R [1,1]
- Notes and Comments RE [0,1]
- Notes and Comments RE [0,1]
- PRT[1]: Abstract C [0,5]
- PRT[2]: Abstract C [0,5]

Message Content

```
MSH|^~\&#NIST EHR*2.16.840.1.113883.3.72.5.22*ISO|NIST EHR Facility*2.16.840.1.113883.3.72.5.23*ISO|NIST Test Lab APP*2.16.840.1.113883.3.72.5.20*
PID|1||PATID1234***NIST MPI*2.16.840.1.113883.3.72.5.30.2*ISO*MR||Jones*William*A*JR***L||19610615|B||2106-3*White*HL70005|2100 Kennwood Ave*Apt 41
ORC|ERT|ORD10*NIST EHR*2.16.840.1.113883.3.72.5.24*ISO||GORD874211*NIST EHR*2.16.840.1.113883.3.72.5.24*ISO||||201103311430||5742200012*Radon*Nic
TQ1|1||||201103311500-0800||R**HL70485
OBR|1|ORD10*NIST EHR*2.16.840.1.113883.3.72.5.24*ISO||500*Erythrocyte sedimentation rate*990SI*11111-1*Erythrocyte sedimentation rate*LN*20130421*2
NTE|1||Patient is extremely anxious about needles used for drawing blood.\E\br\E\If patient is overly frightened, nervous, or anxious please resch
NTE|1||Patient is allergic to latex
PRT|1*NIST EHR*2.16.840.1.113883.3.72.5.22*ISO|AD||RCT*Result Copies To*HL70912*****Copy to|10092000194*Hamlin*Pafford*****NPI*2.16.840.1.113883.
PRT|2*NIST EHR*2.16.840.1.113883.3.72.5.22*ISO|AD||RCT*Result Copies To*HL70912*****Send carbon copies to|2129416824*Davison*Daniel*****NPI*2.16.
```

Message Validation Result

Errors (5)

Description	Line	Column	Location
[NIST-9] If OBR-4.6 (Name of Coding System) value is "LN", OBR-4.4 (Identifier) SHALL be a valid LOINC code identifier format. No assertion description is provided	5	55	OBR[1].4[1]
The value 'B' specified in the message does not match any of the values in the table 'HL70001'	2	100	PID[1].8[1]
The value 'ERT' specified in the message does not match any of the values in the table 'LOI_HL70119'	3	5	ORC[1].1[1]

# FAQ –Lab Order Interface

## Frequently Asked Questions

What is the difference between context-free and context-based validation?

With the context-based validation method, the messages created by the EHR technology are populated using the Test Data provided in the Test Cases associated with specific Test Scenarios. These Test Scenarios and Test Cases are accessed via the Context-based Validation part of the Test Tool, and this "context" (along with all conformance requirements of the LOI implementation guide) is "known" to the validation tool. The Context-free Validation method may be used to test any lab order message created by an EHR. It provides an easy way to test message structure and most vocabulary, but the context (Test Scenario, etc.) is unknown to the Test Tool.

In the Message Content sheet, what does "Changeable Data" mean?

"Changeable data" means the exact content of the data for the data element is not relevant to the testing. The NIST Test Tool will check for the presence of data to verify that the system supports the particular data element, but the tool does not check for specific content. NIST provides example values in the Test Data, but anticipates that local installations would provide their local values.

In the Message Content sheet, what does "Configurable Data" mean?

"Configurable Data" indicates data that typically are system-defined. The NIST Test Tool will check for the presence of data to verify that the system supports the particular data element, but the tool does not check for specific content. NIST provides example values in the Test Data.

What is the difference between "R", "RE", and "O" Usage for data elements?

"R" means that the data element is "Required", and it **must be populated** in the test messages for certification testing.

"RE" means that the data element is "Required, but may be empty", and it **must be populated** in the test messages for certification testing IF TEST DATA ARE PROVIDED FOR THE DATA ELEMENT.

"O" means that the data element is "Optional", and it is **not in-scope** for certification testing.



# Resources

- Test Tool Web Site (<http://hl7v2-loi-r1-testing.nist.gov>) provides
  - Test Tool (API, Web Application, and Desktop)
  - Test Cases / Test Stories / Message Content Details / Test Data / User Documentation
  - Test Plan
  - Example messages
  - Testing Artifacts
    - Message Profile
    - Value Sets
- Contact
  - Rob Snelick ([rsnelick@nist.gov](mailto:rsnelick@nist.gov))