NIST Normative Test Process Document: Electronic Lab Reporting (ELR) Test Tool

Test Tool and Test Descriptions to Conduct ONC 2015 Edition Certification
Version 2.3 for Public Comment
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Developed by the National Institute of Standards and Technology (NIST) in collaboration with the Center for Disease Control and Prevention (CDC), the Council of State and Territorial Epidemiologists (CSTE), and the Association of Public Health Laboratories (APHL)

DRAFT FOR REVIEW

National Institute of Standards and Technology

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Document History

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NIST Normative Test Process Document for §170.315(f)(3) Transmission to public health agencies – reportable laboratory tests and values/results

This document explains the testing process for which a National Institute of Standards and Technology (NIST) validation test tool is used in evaluating conformance of a health information technology module (Health IT Module) to the certification criterion §170.315(f)(3) Transmission to public health agencies – reportable laboratory tests and values/results defined in 45 CFR Part 170 of the Office of the National Coordinator for Health Information Technology (ONC), Department of Health and Human Services (HHS) 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications Final Rule.

For the ONC Approved §170.315(f)(3) Transmission to public health agencies – reportable laboratory tests and values/results test procedure visit
http://confluence.oncprojectracking.org/pages/viewpage.action?pageId=8389422

For detailed certification criterion verbiage, please consult ONC's 2015 Edition Certification Companion Guide for Electronic Lab Reporting https://www.healthit.gov/sites/default/files/2015Ed_CCG_f3-Trans-PHA-reportable-lab-tests-values-results.pdf

EXPLANATION OF TERMS

Key for Names and Terms Used Frequently in this Document	
Referenced Names and Terms	**Equivalent Used in Document**
HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 with Errata and Clarifications, and ELR 2.5.1 Clarification Document for EHR Technology Certification.	**ELR Messaging Guide and associated Errata and Clarifications**
IHTSDO SNOMED CT® International Release July 2012 and US Extension to SNOMED CT® March 2012 Release	**"SNOMED CT" or "SNOMED"**
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.	**LOINC**
Health IT Module	**"HIT Module" or "Module"**
HL7 v2.5.1 Context-based capability of the NIST ELR Test Tool	**Tool**

INFORMATIVE TEST DESCRIPTION

This section provides key background information for conducting the certification testing. The *Understanding ELR ONC Certification Testing 2015 Edition* document is available via the Documentation tab in the NIST ELR Messaging Test Tool; this document is an additional resource that explains the process of Health IT Module certification testing for HL7 v2 ELR messaging.

This document has been developed to be used by the ONC- Accredited Testing Laboratories (ATLs) in certification of Health IT Modules for the ONC. The term 'Tester', when used in this document, refers to a person (such as an ATL employee) acting on behalf of an ATL for certification testing of a Vendor's HIT Module. In addition, a Vendor may use this document to test their own HIT Modules in preparation for certification testing by an ATL.

The test evaluates the capability for a Health IT Module to create HL7 v2 laboratory results messages for transmission to public health agencies that

- Are conformant to the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) (using the "ELR Receiver Usage" column – see below) with Errata, and ELR 2.5.1 Clarification Document for EHR Technology Certification
- At minimum, use the IHTSDO SNOMED CT® International Release July 2012 and US Extension to SNOMED CT® March 2012 Release; and the Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.40

Only the "**ELR Receiver Usage" column** in the ELR guide is used, because this is the relevant profile for the use case to be tested – the Sender Profile, the result of combining all receiver profiles (ELR, NHSN, Lab to EHR) into a single profile to eliminate the need on the sender side for multiple profiles as part of the harmonization strategy. Since the other receiver profiles are not considered for certification, the sender will only have to conform to the ELR Receiver Profile.

The NIST ELR Messaging Test Tool includes a total of ten Test Scenarios, counting 5A and 5B. Test Scenarios one through four and six through nine have **three** Test Cases, and Test Scenarios 5A and 5B have **two** Test Cases. (The Vendor has the option of supporting either Test Scenario 5A or 5B (support of both is preferred, but not required)). For the certification test, the Tester shall select at minimum one Test Case from **each** of nine Test Scenarios.

The Centers for Disease Control and Prevention (CDC), in collaboration with the Council of State and Territorial Epidemiologists (CSTE) and the Association of Public Health Laboratories (APHL) and NIST, provided the Test Scenarios, Test Cases, and Test Data for the ELR testing process.

Listed in the **Test Data section** of this document are the Test Cases that have been developed for the NIST testing process. Test Data PDF Documents, which are accessible from the NIST ELR Test Tool identified in the **Conformance Test Tools section** of this testing process document, contain the test data that are specific to each Test Case. Instructions for use of the provided test data are listed in the **Normative Test Description** and **Test Data sections** of this testing process document.

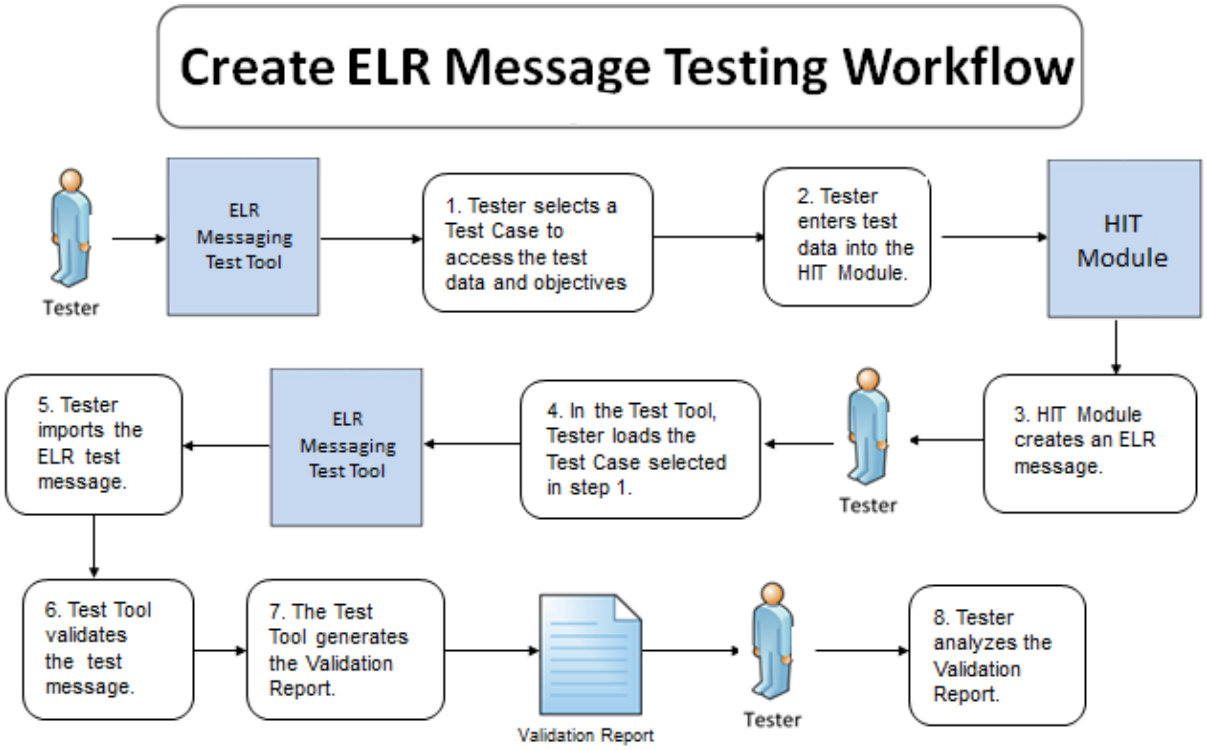
NORMATIVE TEST DESCRIPTION

Derived Test Requirement

ELR_DTR - 1: Electronically Create Reportable Laboratory Test Values/Results Messages

ELR_DTR - 1: Electronically Create Reportable Laboratory Test Values/Results Messages

Figure 1 Create Reportable Laboratory Test Values/Results Messages



The instructions in the testing process listed below reference the numbered test steps in **Figure 1**.

Required Vendor Information

1. Vendor shall identify the Health IT Module function(s) that are available to 1) input the test data into the Module for the test patients, 2) create ELR messages using the test data, and 3) import[1] the ELR messages into the NIST ELR Messaging Test Tool

[1] During certification testing, the mechanism by which the ELR test message is imported (sent) from or to the Health IT Module being tested is not specified. The ATL may have their own utility, they may allow the Module vendor to use a utility created by that vendor, or the message can be cut from the Module and pasted into the NIST Test Tool or cut from the NIST Test Tool and pasted into the Module. For certification testing, the key requirement is for the Module to demonstrate real time/dynamic import.

2. Vendor shall provide the mechanism necessary to capture and import ELR messages into the NIST ELR Messaging Test Tool

Required Testing Actions

1. Using the capabilities provided by the NIST ELR Messaging Test Tool identified in the **Conformance Test Tools section** of this testing process document, Tester shall select an ELR Test Case [Figure 1, Step 1]
2. Using the capabilities in the Health IT Module, the Tester shall
   a) Input the provided ELR test data for the selected Test Step (input can be performed using a manual or automated process) [Figure 1, Step 2]
   b) Cause the Module to generate the indicated ELR message [Figure 1, Step 3]
4. In the NIST ELR Messaging Test Tool, the Tester shall load the selected Test Case and import the ELR message generated by the HIT Module [Figure 1, Steps 4 & 5]
5. Using the **Inspection Test Guide**, the Tester shall verify that the ELR message is conformant to the **Referenced Standards** and that the message includes the specified ELR information

Inspection Test Guide

1. Using the **Validation Report** produced by the NIST ELR Messaging Test Tool**,** the Tester shall analyze the Report and verify that the message created by the Health IT Module meets the conformance requirements in the **Referenced Standards** [Figure 1, Steps 6, 7, and 8]

TEST DATA

Test data are provided for the testing process to ensure that the applicable requirements identified in the ONC criteria can be adequately evaluated for conformance, as well as to provide consistency in the testing process across multiple National Voluntary Laboratory Accreditation Program (NVLAP) - Accredited Testing Labs (ATLs). The provided test data focus on evaluating the basic capabilities required of the Health IT Module, rather than exercising the full breadth/depth of capability that installed Health IT Modules might be expected to support. The test data are formatted for ease of use by the Tester during the testing process; the format is not intended to prescribe the design of the display presented to the end-user for viewing the data. No additional requirements should be drawn from the format.

The Tester shall use and apply the provided test data during the testing, without exception, unless one of the following conditions exists:

- The Tester determines that the Health IT Module is sufficiently specialized that the provided test data need to be modified in order to conduct an adequate test. Having made the determination that some modification to the provided test data is necessary, the Tester shall record the modifications made as part of the test documentation.
- The Tester determines that changes to the test data will improve the efficiency of the testing process (for example, using consistent demographic data throughout the testing workflow). The Tester shall ensure that the functional and interoperable requirements identified in the criterion

can be adequately evaluated for conformance, and that the modified test data provide a comparable level of robustness.

- The Tester determines that the LOINC or SNOMED CT code in a message created by the Health IT Module is a **valid code** for a data item (e.g., lab test) even though it is different from the LOINC or SNOMED CT code provided for that data item in the test data for that message

Any departure from the provided test data shall focus on meeting the basic capabilities required of the Health IT Module relative to the certification criterion rather than exercising the full breadth/depth of capability that the installed Module might be expected to support.

The testing process requires that the Tester enter the applicable test data into the HIT Module being evaluated for conformance. The intent is that the Tester fully controls the process of entering the test data in order to ensure that the data are correctly entered as specified in the testing process. If a situation arises where it is impractical for a Tester to enter the test data directly, the Tester, at the Tester's discretion, may instruct the Vendor to enter the test data, so long as the Tester remains in full control of the testing process, directly observes the test data being entered by the Vendor, and validates that the test data are entered correctly as specified in the testing process document.

For ONC Health IT Module certification testing, the primary purpose of the provided test data is to assist the Tester in verifying that the vendor's HIT Module is capable of supporting the required functions; verifying the ability to support specific content is applicable only when the data are categorized as "IG Fixed Data" and in certain instance when the data are categorized as "Test Case Fixed Data" (see How to Interpret the Message Content Data Sheet section below). The clinical test data are relevant for the given Test Stories; however, these data should not be expected to represent standards of practice.

Test data for certification testing related to the §170.315(f)(3) Transmission to public health agencies – reportable laboratory tests and values/results ONC criterion are available in the NIST ELR Test Tool (see the Conformance Test Tools section of this testing process document for instructions on how to access the Test Tool).

NAVIGATING A TEST SCENARIO

An ELR Test Case consists of a Test Story, a Test Data Specification, and a Message Content Data Sheet. All of these artifacts are accessible via the NIST ELR Test Tool.

- The Test Story describes a real-world situation that provides the context for the Test Case.
- The Test Data Specification provides the data associated with the Test Story and lists the information that would typically be available for a given situation in the specified clinical setting. Together, the Test Story and the Test Data Specification provide sufficient information for the Testers and Health IT Module Vendors to enter into the Module in order to create the ELR message for a particular Test Step. The message is to be created using these data and the Health IT Module functions.
- The Message Content Data Sheet shows a conformant message instance for the Test Case. The message content is organized in a table format that provides the HL7 v2 message elements and

the data associated with the message elements for a given Test Case. The Message Content Data Sheet may provide assistance to the Tester and Health IT Module Vendor for resolving issues discovered during conformance testing. This data sheet can be thought of as the "answer" to the scenario ("question") provided by the Test Story and the Test Data Specification.

For this test procedure the Tester shall select one Test Case (and, hence, its associated test data) from **each** of the nine test scenarios listed:

1 – Maximally Populated Final Quantitative Result
2 – Final Quantitative Result
3 – Preliminary Multiple Coded Culture Results
4 – Final Single Coded Culture Result with Susceptibility Testing
5A – Final Quantitative Result with Reflex Testing*
5B – Final Quantitative Result with Reflex Testing*
6 – Final Titer Result
7 – Final Qualitative Result
8 – Final Multiple Qualitative Results
9 – Final Single Coded Culture Result

* The Vendor has the option of supporting either Test Scenario 5A or 5B (support of both is preferred, but not required).

The Tester shall follow the Normative Test Procedure to conduct these tests. **Table 1** below (ELR Test Scenarios and Associated Test Cases) lists the **ten** test scenarios, and identifies **three** Test Cases for scenarios one through four and six through nine and **two** Test Cases for scenarios 5A and 5B. Details of the Test Cases, including the test story, test objectives, and test data are provided in PDF files and also are accessible in the Conformance Test Tool (See the "Context-based Validation" tab).

Table 1 ELR Test Scenarios and Associated Test Cases

Test Scenarios	Test Case 1	Test Case 2	Test Case 3
1 – Maximally Populated Final Quantitative Result	ELR_1_1.1_Max	ELR_1_1.2_Max	ELR_1_1.3_Max
2 – Final Quantitative Result	ELR_2_1.1_Typ	ELR_2_1.2_Typ	ELR_2_1.3_Typ
3 – Preliminary Multiple Coded Culture Results	ELR_3_1.1_Typ	ELR_3_1.2_Typ	ELR_3_1.3_Typ
4 – Final Single Coded Culture Result with Susceptibility Testing	ELR_4_1.1_Typ	ELR_4_1.2_Typ	ELR_4_1.3_Typ
5A – Final Quantitative Result with Reflex Testing*	ELR_5A_1.1_Typ	Removed	ELR_5A_1.3_Typ
5B – Final Quantitative Result with Reflex Testing*	ELR_5B_1.1_Typ	Removed	ELR_5B_1.3_Typ
6 – Final Titer Result	ELR_6_1.1_Typ	ELR_6_1.2_Typ	ELR_6_1.3_Typ
7 – Final Qualitative Result	ELR_7_1.1_Typ	ELR_7_1.2_Typ	ELR_7_1.3_Typ
8 – Final Multiple Qualitative Results	ELR_8_1.1_Typ	ELR_8_1.2_Typ	ELR_8_1.3_Typ
9 – Final Single Coded Culture Result	ELR_9_1.1_Typ	ELR_9_1.2_Typ	ELR_9_1.3_Typ

* The Vendor has the option of supporting either Test Scenario 5A or 5B (support of both is preferred, but not required).

Details for each Test Case, including the test story, test objectives, test data, and example HL7 message, are provided via the tabs that are displayed when a user selects a Test Case in the Context-based feature of the Test Tool, and also are available in PDF files accessible via the tabs displayed with the Test Case as well as via the Test Tool Documentation tab. The Tester shall follow the instructions in the **Normative Test Description** section of this testing process document to conduct the certification testing.

HOW TO INTERPRET THE MESSAGE CONTENT DATA SHEET

The Message Content Data Sheet indicates the data that are to be included in the HL7 v2 message based on the test data entered into the Health IT Module for a particular Test Step. **Table 2** shows a portion of a Message Content Data Sheet.

Table 2 Message Content Data Sheet for PID Segment

PID : Patient Identification Segment

Location	Data Element	Data	Categorization
PID.1	**Set ID - PID**	1	IG Fixed Data
PID.3[1]	**Patient Identifier List**		
PID.3[1].1	ID Number	18547545	Changeable data
PID.3[1].4	Assigning Authority		
PID.3[1].4.1	Namespace ID	NIST MPI	Changeable data
PID.3[1].4.2	Universal ID	2.16.840.1.113883.3.72.5.30.2	Configurable Data
PID.3[1].4.3	Universal ID Type	ISO	IG Fixed Data
PID.3[1].5	Identifier Type Code	MR	Changeable Data
PID.3[1].6	Assigning Facility		
PID.3[1].6.1	Namespace ID	University H	Changeable Data
PID.3[1].6.2	Universal ID	2.16.840.1.113883.3.0	Configurable Data
PID.3[1].6.3	Universal ID Type	ISO	IG Fixed Data
PID.3[2]	**Patient Identifier List**		
PID.3[2].1	ID Number	111111111	Changeable data
PID.3[2].4	Assigning Authority		
PID.3[2].4.1	Namespace ID	SSN	Changeable data
PID.3[2].4.2	Universal ID	2.16.840.1.113883.4.1	Configurable Data
PID.3[2].4.3	Universal ID Type	ISO	IG Fixed Data
PID.3[2].5	Identifier Type Code	SS	Changeable Data
PID.3[2].6	Assigning Facility		
PID.3[2].6.1	Namespace ID	SSA	Changeable Data
PID.3[2].6.2	Universal ID	2.16.840.1.113883.3.184	Configurable Data
PID.3[2].6.3	Universal ID Type	ISO	IG Fixed Data

The information in the ***Location*** column indicates the canonical element location in the HL7 v2 message. For example, PID-3[1].5 represents the 5th component in the first occurrence of the 3rd field of the PID segment. The ***Data Element*** column indicates the name of the data element as specified by the *HL7 v2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 with Errata and Clarifications, and ELR 2.5.1 Clarification Document for EHR Technology Certification* standard. The ***Test Data*** column lists the data to be included for each Data Element in the message created by the Health IT Module.

The ***Categorization*** column indicates the type and expected source of the data as well as how the Context-based feature in the NIST Tool will validate the data for the given Data Element in the message. In some cases the test tool validator simply examines the message element for the presence of data, whereas in other cases the validator examines the message element for the presence of data and for exact content. **Table 3** shows the descriptions of the test data Categories and their associated Qualifiers. Additional information about the test data Categories and Qualifiers is available in the *Understanding ELR Messaging ONC Certification Testing Edition 2015* document, which is accessed via the Documentation tab in the NIST ELR Test Tool.

Table 3 Description of Data Categorization and Validation

Category	Description	Validation
Configurable	Data typically that is configured by the system (customer-definable). Example data is provided.	Validate for the presence of data
System Generated	Data typically generated automatically by system, for example, message time. Example data is provided.	Validate for the presence of data
IG Fixed	Data that is fixed by the implementation guide; data can't be changed. Specific data is provided.	Validate for the presence and data content
Test Case Fixed	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.
Changeable	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

Along with the Test Data Specification, the Message Content Data Sheet can be used to assist the Tester and Health IT Module Vendor in loading the test data into the Module for a given Test Step.

The Test Cases and the Context-based feature in the NIST ELR Test Tool are tightly-coupled. In addition to validating message conformance, the test tool performs selective content validation based on the test data provided, and deviation from the test data may cause the test tool to issue Error notifications. For this reason, the Tester should use the test data as specified.

CONFORMANCE TEST TOOLS

The following testing tools are available to evaluate conformance to the standards referenced in this testing process document:

- HL7v2 Edition 2014 & 2015 Electronic Laboratory Reporting (ELR) Validation Tool – an HL7v2 messaging validation tool; designed to support the NIST testing process for ONC Health IT Certification testing as well as other ELR message testing
- The tool is available as a Web Application
- The application can be downloaded for local installation
- The ELR Test Tool Web Application is available at:
  http://hl7v2-elr-testing.nist.gov

Support for these tools is available by submitting questions to the following user's group:
https://groups.google.com/d/forum/hl7v2-reportable-lab-testing

Inquiries may also be sent to this user group via email: hl7v2-reportable-lab-testing@googlegroups.com

Several browsers may be used to access the HL7 v2 ELR Test Tool; IE 8, IE 9, Firefox, and Chrome are the supported browsers. The Test Tool uses non-standard ports. If your firewall blocks HTTP traffic on non-standard ports, this tool may not be accessible. Please retry access from a location without a firewall that blocks non-standard ports. Alternatively users may download and run a local version of the tool.

The following information is provided to assist the Tester in interpreting the Validation Reports generated by the HL7 v2 ELR Messaging Test Tool:

The Context-based capability in the HL7 v2 ELR Test Tool evaluates conformance requirements that are specified or have been derived from the standards and implementation guides identified in the 2015 Edition of the ONC Final Rule and the test data provided for this testing process. The Test Tool evaluates the submitted HL7 message for each conformance requirement, and then produces a Validation Report.

The Tester should consider a Report that contains only Affirmative and Warning messages to be indicative of a sufficient level of conformance to the standard and test data expectations. If reported, Errors should be considered significant departures from the standard or test data requirements, and these Errors must be corrected in order to claim conformance. ATLs will need to further analyze each Error to determine if, in the context of meeting the criterion and overall meaningful use objective, the Error results in a failure of the testing process by the Health IT Module.

The NIST context-based testing performs specific content validation depending on the Category/Qualifier combination assigned to the Data Elements in the message (see How to Interpret the Message Content Data Sheet section for more details). In some cases, in order to perform this type of validation the NIST Tool expects the segments/segment groups in the message to be sequenced in a certain order. The complexity of automatically evaluating specific content

necessitates this approach. If the Message Validation Result generated by the NIST Tool indicates content-related errors, the ATL may change the order of the segments/segment groups in the test message to match the Test Case once the message has been loaded into the Message Content window of the Test Tool. These kinds of content-related errors do not imply a failure of the vendor product nor a requirement to create the message with the segments/segment groups in a certain order (beyond the base message structure).

Document History

Version Number	Description of Change	Date Published
2.0	Released for public comment	November 17, 2015
2.1	Updated with ONC feedback • List of Content updated • Informative Test Description Section o Detailed Test Steps removed o Definition of “Tester” inserted • Normative Test Description Section o “Import” footnote added	November 24, 2015
2.2	Track Changes accepted	December 1, 2015
2.3	Conformance Test Tool Section • url for ELR Test Tool changed	December 3, 2015