Test Procedure for §170.314.b.6 Transmission of electronic laboratory tests and values/results to ambulatory providers – inpatient setting only

This document describes the test procedure for evaluating conformance of Complete EHRs or EHR modules to the certification criteria defined in 45 CFR Part 170 Subpart C of the Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule. The document[1] is organized by test procedure and derived test requirements with traceability to the normative certification criteria as described in the Overview document located at [available when final]. The test procedures may be updated to reflect on-going feedback received during the certification activities.

The HHS/Office of the National Coordinator for Health Information Technology (ONC) has defined the standards, implementation guides and certification criteria used in this test procedure. Applicability and interpretation of the standards, implementation guides and certification criteria to EHR technology is determined by ONC. Testing of EHR technology in the Permanent Certification Program, henceforth referred to as the ONC HIT Certification Program[2], is carried out by National Voluntary Laboratory Accreditation Program-Accredited Testing Laboratories (ATLs) as set forth in the final rule establishing the Permanent Certification Program (*Establishment of the Permanent Certification Program for Health Information Technology, 45 CFR Part 170; February 7, 2011*.)

Questions or concerns regarding the ONC HIT Certification Program should be directed to ONC at ONC.Certification@hhs.gov.

CERTIFICATION CRITERIA

This certification criterion is from the Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule issued by the Department of Health and Human Services (HHS) on September 4, 2012.

170.314(b)(6) Inpatient setting only – transmission of electronic laboratory tests and values/results to ambulatory providers. EHR technology must be able to electronically create laboratory test reports for electronic transmission in accordance with the standard specified in § 170.205(j) and with laboratory tests expressed in accordance with, at a minimum, the version of the standard specified in § 170.207(c)(2).

[1] Disclaimer: Certain commercial products may be identified in this document. Such identification does not imply recommendation or endorsement by ONC.

[2] Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule

Per Section III.A of the preamble of the Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule, the 2014 Edition of this certification criterion is classified as new from the 2011 Edition. This certification criterion meets at least one of the factors of new certification criteria: (1) The certification criterion only specifies capabilities that have never been included in previously adopted certification criteria; or, (2) The certification criterion was previously adopted as "mandatory" for a particular setting and subsequently adopted as "mandatory" or "optional" for a different setting.

Per Section III.A of the preamble of the Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule where the transmission of electronic laboratory tests and values/results to ambulatory providers certification criterion is discussed:

- "After consideration of public comments, CMS has included a corresponding objective and measure in the MU Stage 2 menu set and the adoption of this certification criterion will support that objective and measure."
- "We believe that the S&I Framework LRI implementation guide is mature enough for adoption and inclusion in this certification criterion…the LRI implementation guide has been undergoing balloting by HL7. The LRI implementation guide was approved by HL7 as a Draft Standard for Trial Use (DSTU) in July 2012. This confirms its adoption as a consensus-based standard ready for use. This DSTU version of the standard updates the version we proposed by correcting errors and clarifying requirements. These corrections and clarifications will assist EHR technology developers in implementing the standard and will improve testing to the standard."
- "The adopted LRI specification for the ambulatory setting is intended to provide the desired interface uniformity commenters have noted for the receipt of laboratory test results. We believe this standard is appropriate and mature for the purposes of EHR technology certification. As we have indicated in other responses in this final rule certification addresses the technical capabilities that EHR technology must include. It does not address how it must be used, once certified."
- "For the purposes of testing and certification, we expect that EHR technology will be evaluated based on its ability to use most commonly reported LOINC® codes. We expect that the test procedure developed for this certification criterion will leverage LOINC® materials published by the Regenstrief Institute and available through the National Library Medicine16, which in this case would be the "LOINC® Top 2000+ Lab Observations and Mapper's Guide."
- "We have established a process for adopting certain vocabulary standards, including LOINC®, which permits the use of newer versions of those standards than the one adopted in regulation. We refer readers to section IV.B for a discussion of "minimum standards" code sets and our new more flexible approach for their use in certification and upgrading certified Complete EHRs and certified EHR Modules."
- "The LRI specification's message header includes a required date/time stamp and the result segment (OBX) includes a test performed date/time stamp that is required if it exists.

- "We…did not propose specific transport approaches to require for certification and intend to focus certification on the proper implementation of the LRI specification."
- "This certification criterion focuses on the proper implementation of the LRI specification. How or by what means the laboratory test report gets to an EP is not currently within the scope the certification criterion and, in part, is likely dictated by other regulatory requirements, such as the CLIA rules."

INFORMATIVE TEST DESCRIPTION

This section provides an informative description of how the test procedure is organized and conducted. It is not intended to provide normative statements of the certification requirements.

In this test procedure, "inpatient EHR technology" and "inpatient EHR function(s)" refer to clinical laboratory resulting capabilities.

The test procedures are developed to be used by the ATLs in certification of EHR technology for the ONC. The term 'Tester', when used in the test procedure, refers to a person (such as an ATL employee) acting on behalf of an ATL for certification testing of a Vendor's EHR technology. In addition, an EHR Vendor may use the test procedures to test their own EHR technology in preparation for certification testing by an ATL.

This test evaluates the capability for a Complete EHR or EHR Module to generate laboratory test reports for electronic transmission to ambulatory provider's EHR systems using the

- HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface interoperability standards (Referred to as LRI) (Note: when differences in requirements are given for Sender and Receiver profile, use the **Sender** profile requirements);
- HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Release 1 Errata and Guidance September 2012 document[3]; and
- 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.

The HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface (LRI) interoperability standard defines four profile options relevant for certification testing:

- LRI_GU_RU_Profile ID: 2.16.840.1.113883.9.17
- LRI_GU_RN_Profile ID: 2.16.840.1.113883.9.18
- LRI_NG_RU_Profile ID: 2.16.840.1.113883.9.19
- LRI_NG_RN_Profile ID: 2.16.840.1.113883.9.20

[3] See Referenced Standards section of this test procedure for details about how to use this document for testing

For the purpose of certification testing the Vendor has the option to declare which profile they are claiming conformance to—only one is required. Test Cases (and hence specific test data) are provided for each profile option. See the implementation guide for more information on the definition and organization of the profile options.

The ONC Standards and Interoperability Framework Laboratory Results Interface (LRI) Validation Suite Work Group, in coordination with NIST, provided the test scenarios and test cases for this test procedure.

Eight Test Scenarios are listed in the Test Data section for this test procedure, and each Test Scenario has one Test Case for each of the four LRI profile options. The test data for the Test Cases are provided in the Test Case PDF documents associated with this test procedure. For the certification test, the Tester shall execute the Test Case provided for **each** of the eight Test Scenarios for the given profile option the Vendor selected. Additional instructions for use of the provided test data are listed in the Normative Test Procedure and test data sections of this test procedure document.

The test procedure is organized into one section:

- Create – evaluates the capability of the inpatient EHR technology to electronically generate conformant HL7 messages for clinical laboratory tests and values/results reports
    - Using the Vendor-identified inpatient EHR function(s), the Tester inputs the provided clinical lab tests and values/results test data for the test patients (input can be performed using a manual or automated process)
    - Using the Vendor-identified inpatient EHR function(s) and the provided test data, the Tester causes the EHR to generate the indicated LRI HL7 v2.5.1 ORU^R01 lab result messages using:
        - The HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface interoperability standards;
        - HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Release 1 Errata and Guidance September 2012 document[4]; and
        - The Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.40
    - Using the Vendor-identified inpatient EHR function(s), the Tester exports the messages from the inpatient EHR technology and imports the messages into the NIST Laboratory Results Interface (LRI) Conformance Test Tool
    - Using the Validation Report produced by the NIST LRI Conformance Test Tool, the Tester verifies that the Implementation Guide conformance requirements tested are met and that the LOINC codes are appropriate for the imported test data

[4] See Referenced Standards section of this test procedure for details about how to use this document for testing

REFERENCED STANDARDS

§170.205 Content exchange standards and implementation specifications for exchanging electronic health information.	Regulatory Referenced Standard
The Secretary adopts the following content exchange standards and associated implementation specifications:	
(j) Electronic incorporation and transmission of lab results. Standard. HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, (incorporated by reference in § 170.299).	
§170.207 Vocabulary standards for representing electronic health information.	**Regulatory Referenced Standard**
The Secretary adopts the following code sets, terminology, and nomenclature as the vocabulary standards for the purpose of representing electronic health information:	
(c) Laboratory tests. (2) Standard. 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. (incorporated by reference in § 170.299).	

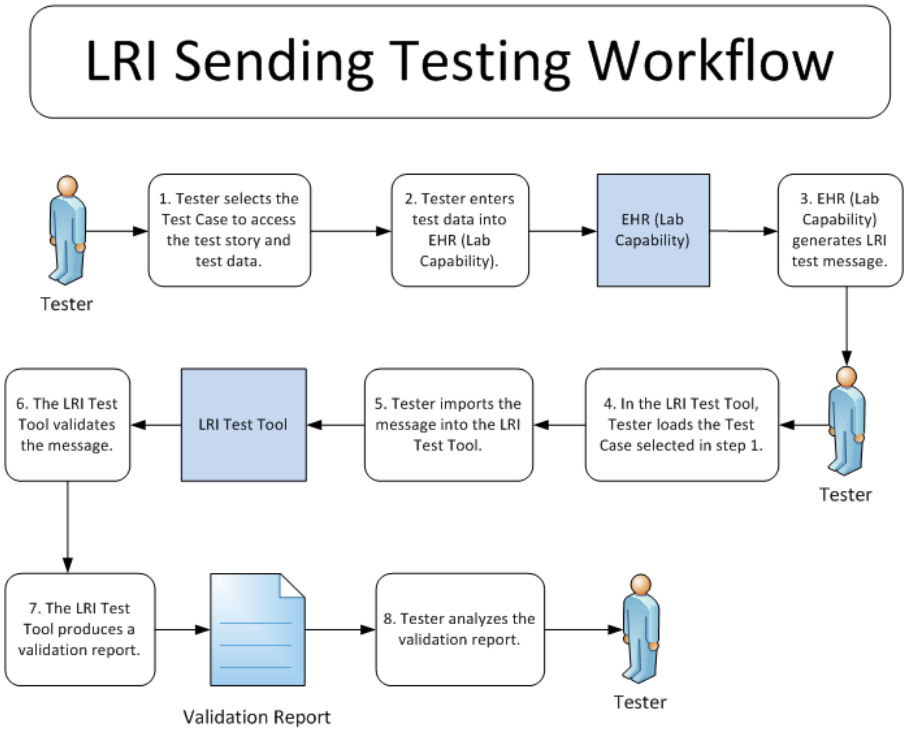
The HL7 Laboratory Results Interface Work Group developed a set of *recommended* corrections and modifications to the currently published "HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Release 1 – US Realm". These recommended corrections and modifications are referred to in this test procedure as "the **HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Release 1 Errata and Guidance September 2012 document**". For 2014 Edition ONC EHR certification testing, this document should be used only as a clarification document for the HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface interoperability standard. A future balloted and published version of the Implementation Guide will contain these recommended changes.

NORMATIVE TEST PROCEDURES

Derived Test Requirements

DTR170.314.b.6 - 1: Electronically Create Laboratory Test Reports

Figure 1: Test Flow for 170.314.b.6 – Lab Results Interface Validation



The instructions in the derived test procedure listed below reference the numbered test steps in Figure 1 above.

DTR170.314.b.6 - 1: Electronically Create Laboratory Test Reports

Required Vendor Information

VE170.314.b.6 – 1.01: Vendor shall identify the EHR function(s) that are available to 1) input the Test Data into the EHR technology for the test patients, 2) create the LRI HL7 v2.5.1 ORU^R01 message using the Test Data, 3) export the message, and 4) demonstrate support for any named value sets

VE170.314.b.6 – 1.02: Vendor shall provide the mechanism necessary to capture and import the LRI HL7 v2.5.1 ORU^R01 message into the NIST LRI Conformance Test Tool

Required Test Procedure

For each of the **eight** Test Scenarios provided in the Test Data section of this test procedure, follow the steps below:

TE170.314.b.6 – 1.01: Tester shall select the Test Case (that has associated Test Data) consisting of test values/results, specimen information, patient demographic information, and provider information. [Figure 1, Step 1]

TE170.314.b.6 – 1.02: Using the Vendor-identified inpatient EHR function(s), the Tester shall input the provided test data for the Test Case selected in TE170.314.b.6 – 1.01 (input can be performed using a manual or automated process) [Figure 1, Step 2]

TE170.314.b.6 – 1.03: Using the Vendor-identified inpatient EHR function(s) and the selected clinical lab tests and values/results test data, the Tester shall

- Cause the inpatient EHR technology to generate the indicated LRI HL7 v2.5.1 ORU^R01 message for the test patient [Figure 1, Step 3] based on
  - The HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface interoperability standards
  - The HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Release 1 Errata and Guidance September 2012 document[5]
  - The Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.40 for the vocabulary standard
- Load the Test Case selected in TE170.314.b.6 – 1.01 into the NIST LRI Conformance Test Tool identified in the Conformance Test Tools section of this test procedure [Figure 1, Step 4]
- Import the LRI v2.5.1 ORU^R01 message into the NIST LRI Conformance Test Tool [Figure 1, Step 5]

TE170.314.b.6 – 1.04: Using the Inspection Test Guide, the Tester shall verify that the LRI HL7 v2.5.1 ORU^R01 message is conformant to the requirements in the named standards tested for the selected Test Case

Inspection Test Guide

IN170.314.b.6 – 1.01: Using the Validation Report produced by the NIST LRI Conformance Test Tool identified in the Conformance Test Tools section of this test procedure, the Tester shall verify that the LRI Implementation Guide conformance requirements tested are met [Figure 1, Step 6, 7 & 8]

IN170.314.b.6 – 1.02: The Tester shall inspect the inpatient EHR technology to verify the capability of the Vendor to support the named LOINC vocabulary standard and the value sets specified in the HL7 Version 2.5.1 Implementation Guide and the HL7 Version 2.5.1 Implementation Guide Errata document[6]

[5] See Referenced Standards section of this test procedure for details about how to use this document for testing
[6] See Referenced Standards section of this test procedure for details about how to use this document for testing

- Using the Vendor-identified inpatient EHR function(s), the Vendor shall demonstrate to the Tester that their EHR supports the Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.40 vocabulary standard
- Using the Vendor-identified inpatient EHR function(s) and the NIST LRI Conformance Test Tool (Vocabulary Tab), the Vendor shall demonstrate to the Tester that their inpatient EHR technology supports the HL7 Table 0078-Observation Interpretation value set as specified for abnormal/interpretation flag data field
- At their discretion, the Tester may select another value set specified in the HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface interoperability standard, and, using the Vendor-identified inpatient EHR function(s) and the NIST LRI Conformance Test Tool (Vocabulary Tab), the Vendor shall demonstrate that their inpatient EHR technology supports the selected value set as specified

TEST DATA

Test data are provided with the test procedure to ensure that the functional and interoperability requirements identified in the criteria can be adequately evaluated for conformance, as well as to provide consistency in the testing process across multiple NVLAP-Accredited Testing Labs (ATLs). The provided test data focus on evaluating the basic capabilities of required EHR technology, rather than exercising the full breadth/depth of capability that installed EHR technology might be expected to support. The test data are formatted for readability of use within the testing process. The format is not prescribing a particular end-user view or rendering. No additional requirements should be drawn from the format

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

- The Tester determines that the Vendor product is sufficiently specialized that the provided test data needs 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; primarily through 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 test data provides a comparable level of robustness.

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

The test procedures require that the Tester enter the test data into the EHR technology 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 test procedure. If a situation arises where it is impractical for a Tester to directly enter the test data, 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 test procedure.

For this test procedure the Tester shall execute all **eight** Test Cases (and hence it's associated test data) listed:

1. Maximally Populated SED Rate message - Final Results
2. Maximally Populated SED Rate message - Corrected Results
3. Rejected SED Rate Message (No OBX segment; OBR.25 = X)
4. Typically Populated CBC message - Final Results
5. Typically Populated Lipid Panel message - Final Results
6. Culture-Escherichia coli, Salmonella, Shigella – Parent – Preliminary
7. Culture-Escherichia coli, Salmonella, Shigella – Parent/Child – Susceptibility – Final
8. Reflex - Hepatitis

The Tester shall follow the normative test procedure to conduct these tests. Table 1 (LRI Test Scenarios and Associated Test Cases) lists the **eight** Test Scenarios and identifies one Test Case for each scenario. 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).

The HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface (LRI) interoperability standard defines four profile options relevant for certification testing:

- LRI_GU_RU_Profile ID: 2.16.840.1.113883.9.17
- LRI_GU_RN_Profile ID: 2.16.840.1.113883.9.18
- LRI_NG_RU_Profile ID: 2.16.840.1.113883.9.19
- LRI_NG_RN_Profile ID: 2.16.840.1.113883.9.20

For the purpose of certification testing, the Vendor has the option to declare which profile they are claiming conformance to—only one is required. Test Cases (and hence specific test data) are provided for each profile option. When selecting the NG option, the Tester shall conduct the NG Test Cases 1 through 6 and NG Test Cases 7 and 8 depending on the RU or RN profile conformance claim of the Vendor. Likewise, when selecting the GU option, the Tester shall conduct the GU Test Cases 1 through 6 and GU Test Cases 7 and 8 depending on the RU or RN profile conformance claim of the Vendor.

Table 1: Lab Results Interface Test Scenarios and Associated Test Cases

Test Scenarios	NG Test Cases	GU Test Cases
1. Maximally Populated SED Rate message - Final Results	LRI_1.0-NG	LRI_1.0-GU
2. Maximally Populated SED Rate message - Corrected Results	LRI_1.1-NG	LRI_1.1-GU
3. Rejected SED Rate Message (No OBX segment; OBR.25 = X)	LRI_1.2-NG	LRI_1.2-GU
4. Typically Populated CBC message - Final Results	LRI_2.0-NG	LRI_2.0-GU
5. Typically Populated Lipid Panel message - Final Results	LRI_3.0-NG	LRI_3.0-GU
6. Culture-Escherichia coli, Salmonella, Shigella - Parent – Preliminary	LRI_4.0-NG	LRI_4.0-GU
7. Culture-Escherichia coli, Salmonella, Shigella - Parent/Child Susceptibility – Final	LRI_4.1-NG-RU OR LRI_4.2-NG-RN	LRI_4.1-GU-RU OR LRI-4.2-GU-RN
8. Reflex - Hepatitis	LRI_5.0-NG-RU OR LRI_5.1-NG-RN	LRI_5.0-GU-RU OR LRI-5.1-GU-RN

NAVIGATING A TEST CASE

A Test Case consists of a narrative Test Story and a Test Data Specification. The Test Story gives a real world scenario that provides the context for the test case. The Test Data Specification provides the data associated with the Test Story and consists of typically available information in the clinical setting. Together the Test Story and the Test Data Specification provide sufficient information that is to be entered into the EHR for a particular test case. Using this data and the EHR functionality a message is to be generated.

Another artifact called the Message Content Data Sheet is provided that 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. If necessary the message content may be used to help the Vendor select the correct option provided by the EHR technology. It may also be used to provide assistance to the Tester and Vendor to resolve issues discovered in conformance testing. In short, the Message Content Data Sheet can be thought of as the "answer" to the Test Case ("question") articulated by the Test Story and the Test Data Specification.

HOW TO INTERPRET THE MESSAGE CONTENT DATA SHEET

The Message Content Data Sheet indicates the location and data of the message for a particular Test Case. The Message Content Datasheet can be used to assist the Tester in loading the EHR with the test case specific data and provides a classification of the data. This classification indicates the type and the

expected source of the data. How the data is classified is directly related to how the message content is validated. In some cases, the validator is examining the message element for the presence or absence of data whereas in other cases it is examining the message element for both the presence of data and exact content.

The information in the ***Location*** column indicates the canonical element location in the HL7 V2 message. For example, MSH-9.3 represents the 3rd component in the 9th field of the MSH segment. The ***Data Element*** column indicates the name of the data element as specified by The Receiver Profile contained in the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 with Errata and Clarifications.

The ***Test Data*** column provides the expected data (if applicable) for that message element. The ***Data Classification*** column indicates the categorization of the data. See the table below for a description of the data categorization and how each data class is being validated.

Table 2 Description of Data Classification and Validation

Data Categorization	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 the system, e.g., 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 can't be changed. Specific data is provided.	Validate for the presence and 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

The Test Cases and the context-based validation test tool are tightly-coupled. In addition to validating message conformance, the test tool performs selective content validation based on the Test Story and Test Data Specification provided. Deviation from the test data may cause the test tool to issue Errors. For this reason, the Tester should use the test data as specified.

The HL7 V2 standard provides flexibility in messaging—several different message instances for a given test case can be considered conformant. The test tool is designed to support all such instances; however, it is not a certainty. If the test tool issues an Error for a message instance, the Vendor shall provide evidence of equivalency to the Tester.

CONFORMANCE TEST TOOLS

The following testing tools are available to evaluate conformance to the standards referenced in this test procedure:

- HL7 V2 – NIST provides an HL7 V2 validation tool designed specifically to support this test procedure. The tool is available as a Web Application
- Use the LIS Validation Tab for this test procedure
- The application can be downloaded for local installation
- NIST is making available the web-site for pre-testing
- The web application validation service is available at:
  http://lri.sipilotdevelopment.org/lri-dstu/
  (NOTE: This is a temporary site for the public comment period. Updates to the tool will be made without notice during this period).

Support for these tools is available by submitting questions to the following user's group:

http://groups.google.com/group/hl7v2-lab-testing

The following information is provided to assist the Tester in interpreting the conformance reports generated by the NIST conformance testing tools.

The NIST HL7 conformance test tool evaluates conformance requirements which are specified or have been derived from the standards and implementation guides identified in the Final Rule and the test data provided in this test procedure. The conformance test tool evaluates the submitted HL7 message for each conformance requirement, and then produces a conformance report. The Tester should consider that a report containing only Affirmative and Warning messages indicates a sufficient level of conformance to the standard and test data expectations. If reported, errors should be considered as significant departures from the standard or test data requirements which need to 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 test procedure by the EHR technology.

Document History

Version Number	Description	Date Published
1.0	Released for public comment	November 7, 2012