Test Procedure for §170.314(f)(4) Inpatient setting only – transmission of reportable laboratory tests and values/results

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(f)(4) Inpatient setting only—transmission of reportable laboratory tests and values/results. EHR technology must be able to electronically create reportable laboratory tests and values/results for electronic transmission in accordance with:

(i) The standard (and applicable implementation specifications) specified in § 170.205(g); and

(ii) At a minimum, the versions of the standards specified in § 170.207(a)(3) and (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 revised from the 2011 Edition. This certification criterion meets at least one of the three factors of revised certification criteria: (1) the certification criterion includes changes to capabilities that were specified in the previously adopted certification criterion, (2) the certification criterion has a new mandatory capability that was not included in the previously adopted certification criterion, or (3) the certification criterion was previously adopted as "optional" for a particular setting and is subsequently adopted as "mandatory" for that 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 reportable laboratory tests and values/results certification criterion is discussed:

- "We are not, however, adopting the certification criterion we proposed that focused on data capture. For similar reasons as expressed in the syndromic surveillance certification criterion, we have dropped this requirement because we believe it is not necessary to focus on for the purposes of EHR technology certification. We agree with commenters regarding HIEs and noted in the Proposed Rule that our approach to the public health certification criteria could enable additional EHR technologies (likely in the form of EHR Modules) to be certified and provides additional pathways and flexibility to EPs, EHs, and CAHs to have EHR technology that can be used to satisfy the proposed revised definition of CEHRT."
- "We have adopted the proposed certification criterion, including the proposed standards and implementation guide with errata and clarifications and a recently published supplement to the implementation guide, titled "ELR 2.5.1 Clarification Document for EHR Technology Certification." The supplement was not available when the Proposed Rule was published. It does not specify additional substantive requirements. Rather, it clarifies conformance requirements and other aspects of Release 1 with errata and clarifications that will improve testing and certification to the implementation guide."
- "We have established a process for adopting certain vocabulary standards, including SNOMED CT® and LOINC®, which permits the use of newer versions of those standards than the one adopted in regulation."
- "A commenter expressed concern about the ongoing volatility of the LOINC® and SNOMED CT® code sets and the burden that will be placed on laboratory staff. The commenter further stated that the failure to adopt national standards for that coding may result in less than optimal interstate sharing of laboratory results.... We are not familiar with the "volatility" that the commenter references and believe that LOINC® and SNOMED CT® constitute consensus-based national standards."
- "Another commenter noted that the mapping of local codes to our standard codes is needed but little guidance is provided…The CDC has published the Reportable Condition Mapping Table

(RCMT) that provides a subset of LOINC® and SNOMED CT® codes associated with reportable conditions. RCMT can be obtained from CDC vocabulary server PHIN VADS (http://phinvads.cdc.gov). The CDC vocabulary team provides guidance to implementers regarding the implementation of RCMT and mapping of LOINC® and SNOMED CT® codes to local lab tests. CDC vocabulary team can be reached directly via e-mail at phinvs@cdc.gov or through the CDC Meaningful Use technical assistance team (meaningfuluse@cdc.gov). In addition, the LOINC® SDO has created a tool known as "RELMA," which helps to map the local tests to standard LOINC® laboratory tests. LOINC® SDO provides RELMA training twice a year and, through a partnership with LOINC® SDO, the CDC provides RELMA training to the public health community at least twice a year with a special focus on microbiology lab tests."

- "We want to make clear that we do not require EHR technology to be certified to any transport standard, including Direct, to meet this certification criterion. There is no consensus transport standard that states and public health agencies use for the reporting of laboratory test and values/results. Therefore, we believe that it is appropriate for EHR technology developers to have the flexibility to include in their EHR technology and implement the transport standards that permit EPs, EHs, and CAHs to report in their states and to local public health agencies."

Per Section III.D of the preamble of the Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, Final Rule where the reportable lab results certification criterion is discussed:

- "We clarify that the certification criterion does not specify, and is not intended to specify, the requirements for how the reports are to be triggered nor the periodicity of the reporting requirements. As a certification criterion, it only specifies capabilities necessary for certification."
- "Each public health jurisdiction maintains its list of diseases or conditions that require notification of public health authorities by law. The CDC and the Council of State and Territorial Epidemiologists also maintain a list of nationally notifiable conditions (www.cdc.gov/ncphi/disss/nndss/phs/infdis.htm). We reiterate, the adoption of this certification criterion is not intended to affect applicable Federal or state law concerning public health authority notification requirements."
- "We clarify that we do not expect Certified EHR Technology to natively (or internally) support LOINC in its entirety...". "…we agree with commenters that we should not require a LOINC code that has been received, to then be displayed." "…we expect Certified EHR Technology to be able to reuse a LOINC code once it has been received and is accessible to Certified EHR Technology. We do not expect…that Certified EHR Technology will have to crosswalk or map internal or local codes to LOINC codes." "This response is applicable to similar comments we received on other certification criteria that also referenced the use of LOINC codes."

CHANGES FROM 2011 TO 2014 EDITION

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 reportable laboratory tests and values/results certification criterion is discussed:

- "We proposed two certification criteria for reportable laboratory tests and values/results that were essentially a split of the 2011 Edition EHR certification criterion for reportable lab results (§ 170.306(g)).
    - We proposed one certification criterion that focused just on the capabilities to electronically record, change, and access laboratory tests and values/results (data capture) and another that focused on the capability to electronically create reportable laboratory tests and values/results for electronic transmission in accordance with specified standards.
    - We discussed these two proposed certification criteria together in the Proposed Rule for simplicity and to prevent confusion, but noted that we do not consider the certification criterion we proposed to focus on data capture to be a revised certification criterion. Rather, we stated that we believed that the certification criterion would constitute an unchanged certification criterion because all the capabilities included in the criterion were the same as the capabilities included in the corresponding 2011 Edition EHR certification criterion (§ 170.306(g)).
- Commenters supported our proposed "two certification criteria approach.""

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.

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 electronically generate reportable laboratory test values and results information for electronic transmission to public health agencies using the Receiver Profile contained in the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) with Errata and Clarifications, and ELR 2.5.1 Clarification Document for EHR Technology Certification; and using, at minimum, 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, a universal code system for identifying laboratory and clinical observations produced by the Regenstrief Institute, Inc.

Only the **Receiver Profile** 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 CDC, in collaboration with the Council of State and Territorial Epidemiologist (CSTE) and the Association of Public Health Laboratories (APHL) and in coordination with NIST, provided the test scenarios and Test Cases for this test procedure.

Nine Test Scenarios are listed in the Test Data section for this test procedure, and each Test Scenario has three Test Cases. 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 select one Test Case from **each** of the nine Test Scenarios. 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 EHR technology to electronically generate conformant HL7 messages for reportable laboratory test values/results
  - Using the Vendor-identified EHR function(s), the Tester inputs the provided reportable laboratory test 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 reportable laboratory test values/results message using
    - The **Receiver Profile** contained in the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) with Errata and Clarifications, and ELR 2.5.1 Clarification Document for EHR Technology Certification interoperability standards
    - The IHTSDO SNOMED CT® International Release July 2012 and US Extension to SNOMED CT® March 2012 Release vocabulary standard
    - The Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.40 vocabulary standard
  - Using the Vendor-identified EHR function(s), the Tester exports the message from the EHR and imports the message into the NIST ELR Conformance Test Tool

- Using the Validation Report produced by the NIST ELR Conformance Test Tool, the Tester verifies that:
  - The Implementation Guide conformance requirements tested are met and
  - That the SNOMED CT and LOINC codes are appropriate for the reportable laboratory results message

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:	
(g) Electronic transmission of lab results to public health agencies. Standard. HL7 2.5.1 (incorporated by reference in § 170.299). Implementation specifications. HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) (incorporated by reference in § 170.299) with Errata and Clarifications, (incorporated by reference in § 170.299) and ELR 2.5.1 Clarification Document for EHR Technology Certification, (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:	
(a)(3)Standard. IHTSDO SNOMED CT® International Release July 2012 (incorporated by reference in § 170.299) and US Extension to SNOMED CT® March 2012 Release (incorporated by reference in § 170.299).	
(c)(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).	

Note: For the purposes of this test procedure, the Receiver Profile contained in the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) shall be used (even though the EHR technology is performing the role of the Sender).

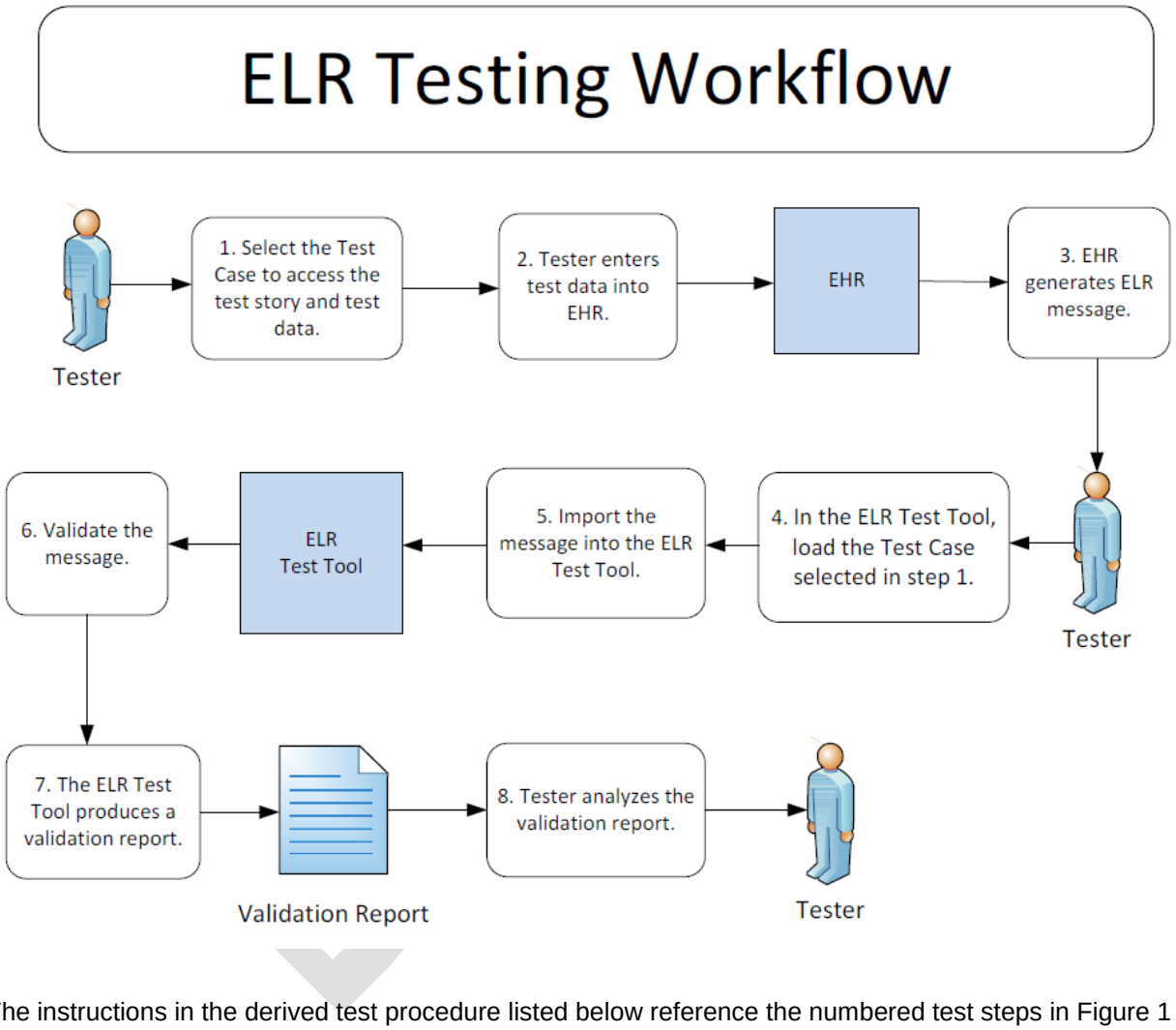
Note: For the purposes of this test procedure, the ELR 2.5.1 Clarification Document for EHR Technology Certification listed above for §170.205(g) is Release 1.1.

NORMATIVE TEST PROCEDURES

Derived Test Requirements

DTR170.314.f.4 – 1: Electronically Create Reportable Laboratory Tests and Values/Results

Figure 1



The instructions in the derived test procedure listed below reference the numbered test steps in Figure 1 above. Note the ELR Testing Workflow applies to the execution of a single Test Scenario.

DTR170.314.f.4 – 1: Electronically Create Reportable Laboratory Tests and Values/Results

Required Vendor Information

VE170.314.f.4 – 1.01: Vendor shall identify the EHR function(s) that are available to 1) input the test data into the EHR for the selected Test Case, 2) create an HL7 Version 2.5.1: ORU^R01 messages using the test data provided, 3) import the HL7 Version 2.5.1: ORU^R01 messages into the NIST ELR Conformance Test Tool, and 4) demonstrate support for the named standard vocabulary value sets

VE170.314.f.4 – 1.02: Vendor shall provide the mechanism necessary to capture and import the HL7 Version 2.5.1: ORU^R01 messages into the NIST ELR Conformance Test Tool

Required Test Procedure

For each of the **nine** test scenarios provided in the test data section of this test procedure, follow the steps below:

TE170.314.f.4 – 1.01: Tester shall select a Test Case (that has associated test data) which includes test values/results, specimen information, patient demographic information, and provider information. [Figure 1, Step 1]

TE170.314.f.4 – 1.02: Using the Vendor-identified EHR function(s), the Tester shall input the test data for the Test Case selected in TE170.314.f.4 – 1.01 (input can be performed using a manual or automated process) [Figure 1, Step 2]

TE170.314.f.4 – 1.03: Using the Vendor-identified EHR function(s) and the selected Test Case, the Tester shall

- Cause the EHR to generate an HL7 Version 2.5.1: ORU^R01 message [Figure 1, Step 3] based on
  - The **Receiver Profile** contained in the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) with Errata and Clarifications, and ELR 2.5.1 Clarification Document for EHR Technology Certification interoperability standards
  - The IHTSDO SNOMED CT® International Release July 2012 and US Extension to SNOMED CT® March 2012 Release vocabulary standard
  - The Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.40 vocabulary standard
- Import the HL7 Version 2.5.1: ORU^R01 message into the NIST ELR Conformance Test Tool identified in the Conformance Test Tools section of this test procedure [Figure 1, Steps 4 & 5]

TE170.314.f.4 – 1.04: Using the Inspection Test Guide, the Tester shall verify that the HL7 Version 2.5.1: ORU^R01 message is conformant to the requirements in the named standards tested for the selected Test Case

Inspection Test Guide

IN170.314.f.4 – 1.01: Using the Validation Report produced by the NIST ELR Conformance Test Tool identified in the Conformance Test Tools section of this test procedure**,** the Tester shall verify that:

- The ELR Implementation Guide conformance requirements tested are met for the selected Test Case [Figure 1, Steps 6, 7, & 8]

IN170.314.f.4 – 1.02: The Tester shall inspect the EHR to verify the capability of the Vendor to support the named vocabulary standards and the value sets specified in The Receiver Profile contained in the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) with Errata and Clarifications, and ELR 2.5.1 Clarification Document for EHR Technology Certification interoperability standards

- Using the Vendor-identified EHR function(s) the Vendor shall demonstrate to the Tester that their EHR supports the named SNOMED CT vocabulary standard for coded results, specimen related data fields.
- Using the Vendor-identified EHR function(s) the Vendor shall demonstrate to the Tester that their EHR supports the named LOINC vocabulary standard for resulted test data fields
- Using the Vendor-identified EHR function(s) and the NIST ELR Conformance Test Tool (Vocabulary Tab), the Vendor shall demonstrate to the Tester that their EHR 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 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) with Errata and Clarifications, and ELR 2.5.1 Clarification Document for EHR Technology Certification interoperability standards, and, using the Vendor-identified EHR function(s) and the NIST ELR Conformance Test Tool (Vocabulary Tab), the Vendor shall demonstrate that their EHR supports that selected value set as specified

TEST DATA

Test data are provided in 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 select one Test Case (and hence it's 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 Case 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 **nine** test scenarios and identifies **three** Test Cases 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).

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	ELR_5A_1.2_Typ	ELR_5A_1.3_Typ
5B – Final Quantitative Result with Reflex Testing*	ELR_5B_1.1_Typ	ELR_5B_1.2_Typ	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 Case 5A or 5B (support of both is preferred, but not required).

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.
- 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//mu-elr
  (NOTE: This is a temporary site for the public comment period. Updates to the tool will be made without notice during this period).

The HL7 v2 service 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.

Support for these tools is available by contacting:

Rob Snelick (robert.snelick@nist.gov)
Computer Scientist
National Institute of Standards and Technology (NIST)
Information Technology Laboratory

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	For public comment	October 17, 2012