Test Procedure for §170.314(b)(5)(A) Incorporate laboratory tests and values/results

This document describes the test procedure for evaluating conformance of EHR technology 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 http://www.healthit.gov/certification (navigation: 2014 Edition Test Method). The test procedures may be updated to reflect on-going feedback received during the certification activities.

The Department of Health and Human Services (HHS)/Office of the National Coordinator for Health Information Technology (ONC) have 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 Health Information Technology (HIT) Certification Program[2], is carried out by National Voluntary Laboratory Accreditation Program (NVLAP)-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)(5) Incorporate laboratory tests and values/results.

[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.

(i) Receive results.

(A) Ambulatory setting only.

(1) Electronically receive and incorporate clinical laboratory tests and values/results in accordance with the standard specified in § 170.205(j) and, at a minimum, the version of the standard specified in § 170.207(c)(2).

(2) Electronically display the tests and values/results received in human readable format.

(B) Inpatient setting only. Electronically receive clinical laboratory tests and values/results in a structured format and electronically display such tests and values/results in human readable format.[3]

(ii) Electronically display all the information for a test report specified at 42 CFR 493.1291(c)(1) through (7).

(iii) Electronically attribute, associate, or link a laboratory test and value/result with a laboratory order or patient record.

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 (September 4, 2012), 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.

2014 Edition Preamble Language

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 (September 4, 2012) where the incorporate laboratory tests and values/results certification criterion is discussed:

- "…by requiring ambulatory EHR technology to be capable of receiving laboratory tests and values/results formatted in accordance with the HL7 2.5.1 standard and the LRI implementation guide, it would be significantly easier and more cost effective for electronic laboratory results interfaces to be set up in an ambulatory setting (that is, minimal additional configuration and little to no additional/custom mapping). Moreover, we stated that it would increase the likelihood that data would be properly incorporated into ambulatory EHR technology upon receipt and thus, facilitate the subsequent use of the data by the EHR technology for other purposes, such as CDS."
- "Because we have specified a standard by which EHR technology designed for an ambulatory

[3] This test procedure does not address part (i)(B) of the §170.314(b)(5) criterion; part (i)(B) is addressed in the §170.314(b)(5)(B) Incorporate laboratory tests and values/results test procedure document.

setting must be capable of receiving lab results, we clarify that testing and certification for this setting will examine whether EHR technology can properly extract lab tests results/values and incorporate the data from the LRI specification for subsequent use."

- "…because this certification criterion only focuses on receipt and not transmission of laboratory orders we decline to modify this certification criterion in response to the commenter's recommendation that we reference a transport standard for transmission of laboratory orders."
- "…the only additional modification we have made in response to public comment was to reinsert the phrase "attribute, associate, or link" in 170.314(b)(5)(iii) to reflect the 2011 Edition version of this certification criterion due to the confusion we caused by overloading the term "incorporate."
- "We do not intend to specify a particular profile or limit the use of the LRI specification to only one profile at this time. We understand that the LRI specification was drafted to create a path toward more constrained and specific implementations, the most rigorous being the Base + GU + RU (GU = Globally Unique Identifiers and RU = Unique Filler or Order Number Required). We intend to move toward this direction in our future rulemakings. We also seek to clarify for EHR technology developers that we do not expect the optional portions of the LRI specification/profile to be tested."
- "This certification criterion only applies to the electronic receipt of laboratory tests and does not focus on the transmission of orders."
- "The CLIA rules do not specify how results can be viewed by a provider, just that they can be accurately, timely, confidentially and reliably transmitted to the final destination. Laboratories need to verify that this occurred, as well as that the CLIA required elements were sent, but there is no requirement in the CLIA rules that a provider must be able to immediately view all of the information. Thus, we did not modify this certification criterion in response to the additional requirements suggested by the commenters as they would artificially lead to design limits that are unnecessary to impose as part of certification. We do, however, encourage EHR technology developers to present the laboratory test data in a format that is most useful to the provider who will use them."

2011 Edition Preamble Language

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 (July 28, 2010) where the reportable lab results certification criterion is discussed:

- "Human readable format means a format that enables a human to read and easily comprehend the information presented to him or her regardless of the method of presentation (e.g., computer screen, handheld device, electronic document)."

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 (September 4, 2012) where the incorporate laboratory tests and values/results certification criterion is discussed:

- "…although the HITSC did not recommend that we revise the "incorporate laboratory test results" certification criterion (adopted as part of the 2011 Edition EHR certification criteria at 45 CFR 170.302(h)), we believed that we should leverage the significant progress made by the S&I Framework LRI initiative. We believed that we could achieve this by proposing revisions to this certification criterion for the ambulatory setting."

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 an EHR technology to electronically receive, incorporate, and display clinical laboratory tests and values/results in human readable format. The clinical laboratory tests and values/results must be electronically received using the

- HL7 Version 2.5.1 Implementation Guide: S&I[4] Framework Lab Results Interface interoperability standards (Referred to as LRI)
- HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Release 1 Errata and Guidance September 2012 document[5]
- 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.

[4] Standards and Interoperability

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

This test also evaluates the capability for an EHR technology to associate a received laboratory test and value/result with a lab order or patient record, and to display, at a minimum, the following seven components of test report information for each of the clinical laboratory tests and results listed in the Referenced Standards section[6] (see Special Note sub-section in the Informative Test Description section of this test procedure for detailed explanations about each of the following data elements):

(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number
(2) The name and address of the laboratory location where the test was performed
(3) The test report date
(4) The test performed
(5) Specimen source, when appropriate
(6) The test result and, if applicable, the units of measurement or interpretation, or both
(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability

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. See the implementation guide for more information on the definition and organization of the profile options.

The test procedure is not prescriptive about the protocol used to send/receive the clinical laboratory tests and values/results messages to/by the EHR technology during the "Receive" steps of the certification testing process. For example, the Vendor may choose to use MLLP (Minimum Lower Level Protocol) or may choose another protocol to send/receive the messages.

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 (September 4, 2012) where the Explanation and Revision of Terms Used in Certification Criteria is discussed, "when the

[6] Display of the following data elements in the test report is not specified as the minimum requirement in the ONC certification criterion §170.314(b)(5)(ii) [42 CFR 493.1291(c)(1)-(7)]; however, these additional data elements in the test report are required by CLIA, are considered to be "best practice" with respect to meaningful use of EHR technology: Date of Birth or Age; Gender; Laboratory Director; Test report time; Specimen Date/Time or Collection Date/Time; Reference Range; Result/Report Status

term incorporate is used within a certification criterion it is intended to mean to electronically process structured information from another source such that it is combined (in structured form) with information maintained by EHR technology and is subsequently available for use within the EHR technology by a user."

ONC 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 LRI four 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.

This test procedure is organized into three sections:

- Receive, incorporate, and display – evaluates the capability of the ambulatory EHR technology to electronically receive and incorporate clinical laboratory tests and values/results using the:
    - HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface interoperability standard;
    - HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Release 1 Errata and Guidance September 2012 document[7] and; Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.40 vocabulary standard; and evaluates the capability of the ambulatory EHR technology to electronically display, in human readable format, the clinical laboratory tests and values/results that were received.
    - The ambulatory EHR Vendor creates test patient records in their EHR
    - Using the capabilities provided by the NIST Laboratory Results Interface (LRI) Conformance Test Tool and the provided HL7 v2.5.1 ORU^R01 laboratory results test message, the Tester imports the test message into the ambulatory EHR
    - Using the Vendor-identified EHR function(s) and a NIST-supplied Juror Document, the Tester signs on to the ambulatory EHR and verifies that:
    - The laboratory tests and values/results data elements that are required by the HL7 V2.5.1 LRI Implementation Guide are received and incorporated into the ambulatory EHR the laboratory tests[8] and values/results[9] received and incorporated into the

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

[8] Fourth component in the information for a test report specified at 42 CFR 493.1291(c)(1) through (7)

[9] Sixth component in the information for a test report specified at 42 CFR 493.1291(c)(1) through (7)

ambulatory EHR are displayed in a human readable format

(With respect to the requirement for human readability, the test procedure considers this requirement to be satisfied if the required sections of the laboratory test result can be evaluated for conformance by the Tester using the rendering technology on the device or system identified by the Vendor)

- Display test report information – evaluates the capability of the ambulatory EHR technology to electronically display the following seven components of test report information for the clinical laboratory tests and values/results:
  (1) For positive patient identification, either the patient's name and identification number or a unique patient identifier and identification number
  (2) The name and address of the laboratory location where the test was performed
  (3) The test report date
  (4) The test performed
  (5) Specimen source, when appropriate
  (6) The test result and, if applicable, the units of measurement or interpretation, or both
  (7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability

  - Using the Vendor-identified ambulatory EHR function(s) and the NIST-supplied Juror Document, the Tester signs on to the EHR and views the clinical laboratory test report information exported in the “Receive, incorporate, and display” step

The Tester verifies that the seven named components (applicable for the Test Case) of the test report information are displayed for the clinical laboratory tests and values/results

- Attribute, associate, or link – evaluates the capability of the ambulatory EHR technology to electronically attribute, associate, or link a lab test and value/result with the appropriate lab order or with the appropriate patient record

  - Using the Vendor-identified ambulatory EHR function(s), the Tester signs on to the EHR and verifies that at least one of the lab tests and its values/results (obtained in the “Receive, incorporate, and display” step) is attributed/associated/linked to the appropriate lab order or is attributed/associated/linked with the appropriate patient record

SPECIAL NOTE FOR 170.314.B.5.II REGARDING 42 CFR 493.1291.C.1 THROUGH 7
(Reviewed and approved by CMS CLIA desk)

When testing compliance with the 2014 Edition electronic health record certification criterion[10] adopted at

[10] Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition [45 CFR 170.314(b)]

45 CFR §170.314.b.5, EHR technology is required at **§170.314.b.5.ii** to display the data elements that include, at a minimum, the information specified in §170.314.b.5.ii, 42 CFR 493.1291.c.1 through 7[11]

For the purposes of paragraph 170.314.b.5.ii, **a laboratory "test report"** is meant to comprise all of the data elements specified at 42 CFR 493.1291.c.1 through 7. These data are meant to be displayed concurrently in their entirety by the EHR technology under test, and the content must be presented in a human readable format[12].

When all of the required data elements cannot be displayed concurrently in their entirety (for example, due to complexity or IT limitations), additional electronic display screens are to be permitted. When multi-page electronic display screens are utilized, they should follow these characteristics:

- Identify individual electronic display screens unambiguously as part of the same report and as belonging to the specific patient
- Indicate on each electronic display screen the continuation of the report on additional display screens
- Provide additional information with ideally no more than two motions for electronic displays, e.g., hover, click, scroll, pan, zoom

Other presentations of laboratory information may be present in the EHR technology such as a flow sheet or summary reports.

To assist with certification testing related to 170.314(b)(5) ii, the following information provides details about the **data elements** specified at 42 CFR 493.1291.c.1 through 7 [Note: text below in bold italic is quoted directly from 42 CFR 493.1291.c]:

1) 42 CFR 493.1291.c.1 "***For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number.***"
    - Patient name that includes, when available, the patient's legal name consisting of a first name, middle name or initials, and the last name [PID-5] **OR** unique patient Identification number assigned by the ordering facility (may be used when the patient name is not available) [PID-3] **AND** identification number [PID-3 (additional identifier) / ORC-2 (OBR-2) or ORC-4 (if present) / ORC-3], which may contain either numbers or letters or both
    - If the laboratory test and value/result have been successfully and unambiguously linked to a patient record as required by **§170.314.b.5.iii,** then the patient name, unique patient identifier and identification number displayed may be from the EHR patient record

[11] Clinical Laboratory Improvement Amendments of 1988 [42 CFR 493.1291]

[12] *Human readable format* means a format that enables a human to read and easily comprehend the information presented to him or her regardless of the method of presentation. [45 CFR 170.102]

2) 42 CFR 493.1291.c.2 "***The name and address of the laboratory location where the test was performed.***"
   - The actual name of the laboratory as indicated on the CLIA certificate (OBX-23)
   - The actual physical location of the laboratory facility or location within the facility (including room, suite, floor as applicable) where testing is performed, as indicated on the CLIA certificate [OBX-24]
3) 42 CFR 493.1291.c.3 "***The test report date.***"
   - The date (e.g. mm/dd/yyyy) the test report/status change was finalized by the laboratory [OBR-22]
4) 42 CFR 493.1291.c.4 "***The test performed.***"
   - The specific name of the test/analyte that is assigned by the laboratory [OBR.4/OBX.3]. A coded value received from the laboratory may be translated in the EHR to an equivalent test description prior to display
5) 42 CFR 493.1291.c.5 "***Specimen source, when appropriate.***"
   - The type of specimen submitted for testing and/or the collection site/method of collection as applicable [SPM-4]. The coded values received from the laboratory may be translated in the EHR to an equivalent description prior to display
6) 42 CFR 493.1291.c.6 "***The test result and, if applicable, the units of measurement or interpretation, or both.***"
   - The corresponding test result, and interpretation (where available) for the requested analyte/test in numeric or text format [OBX-5]
   - Where available, the corresponding units of measure for the requested analyte/test identified and used by the laboratory [OBX-6]
   - Where available, the laboratory's interpretation communicated by defined text/symbols indicating test results that do not fall within the established reference/normal range [OBX-8]. The coded values received from the laboratory may be translated in the EHR to an equivalent description prior to display
   - The laboratory's additional, miscellaneous notes, comments, interpretations regarding the test/analyte/report [NTE-3]
7) 42 CFR 493.1291.c.7 "***Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.***"
   - When available, the laboratory's defined comment(s) denoting specimen suitability or not for testing [any of OBX-5/NTE-3/SPM-21]. The coded values received from the laboratory may be translated in the EHR to an equivalent description prior to display
   - When available, the laboratory's comment(s) denoting the condition of the specimen (hemolysis, lipemia, icterus, clotted, etc.) [any of OBX-5/NTE-3/SPM-24]. The coded values received from the laboratory may be translated in the EHR to an equivalent description prior to display

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).	42 CFR 493.1291 (c) The test report must indicate the following: (1)For positive patient identification, either the patient's name and identification number, or a unique patient identification number, or a unique patient identifier and identification number. (2)The name and address of the laboratory location where the test was performed. (3) The test report date. (4) The test performed. (5) Specimen source, when appropriate. (6) The test result and, if applicable, the units of measurement or interpretation, or both. (7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability
§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". The 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

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

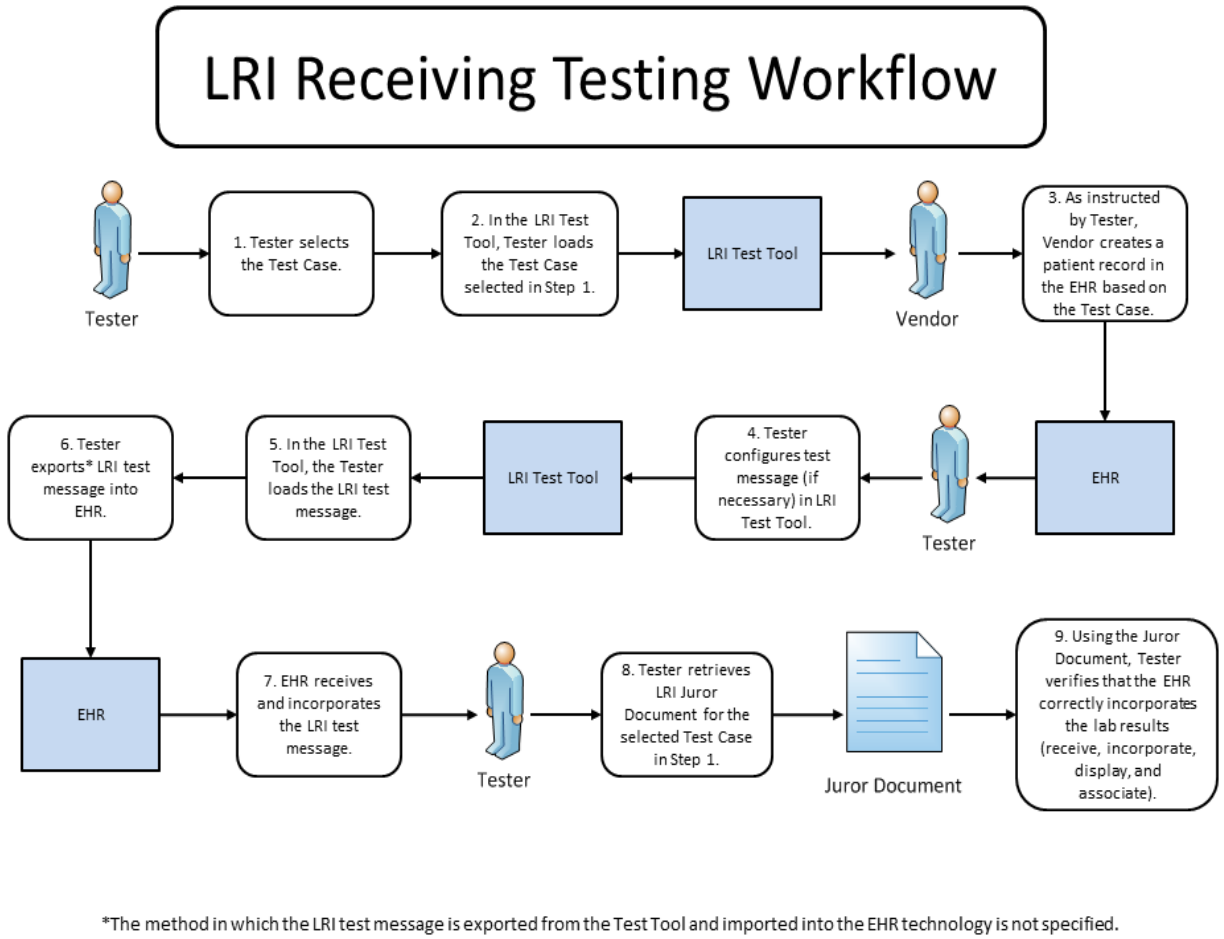
DTR170.314(b)(5)(A) - 1: Electronically Receive, Incorporate[13], and Display Clinical Laboratory Tests and Values/Results

DTR170.314(b)(5)(A) - 2: Electronically Display Test Report Information

DTR170.314(b)(5)(A) - 3: Electronically Attribute/Associate/Link a Laboratory Test and Value/Result with a Laboratory Order or Patient Record

[13] Electronically process structured information from another source such that it is combined (in structured form) with information maintained by EHR technology and is subsequently available for use within the EHR technology by a user.

Figure 1:



*The method in which the LRI test message is exported from the Test Tool and imported into the EHR technology is not specified.

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

DTR170.314(b)(5)(A) – 1: Electronically Receive, Incorporate, and Display Clinical Laboratory Tests and Values/Results

Required Vendor Information

VE170.314(b)(5)(A) – 1.01: The Vendor shall identify the EHR function(s) that are available to 1) select the test patients' records, 2) view laboratory tests and values/results in human readable format when received from an external source, 3) display all of the required sections of a laboratory Test Report, and 4) demonstrate that the ambulatory EHR has attributed/associated/linked a laboratory test and value/result with a laboratory order or patient record

VE170.314(b)(5)(A) – 1.02: The Vendor shall identify the mechanism used to import the LRI HL7 v2.5.1 ORU^R01 test messages to the ambulatory EHR

Required Test Procedure

TE170.314(b)(5)(A) – 1.01: Using the capabilities provided by the NIST LRI Conformance Test Tool identified in the Conformance Test Tools section of this test procedure, the Tester shall select a Test Case [Figure 1, Step 1]

TE170.314(b)(5)(A) – 1.02: Using the capabilities provided by the NIST LRI Conformance Test Tool, the Tester shall load the Test Case selected in TE170.314.b.5.A – 1.01 [Figure 1, Step 2]

TE170.314(b)(5)(A) – 1.03: Using the provided test data as determined by the Test Case, the Vendor shall create a test patient(s) and configure the LRI test message (if necessary—e.g., the patient identifier) in the ambulatory EHR [Figure 1, Steps 3 &4]

TE170.314(b)(5)(A) – 1.04: Using the capabilities provided by the NIST LRI Conformance Test Tool, the Tester shall load and export (that is, send directly) to the ambulatory EHR the LRI test message for the Test Case loaded in TE170.314.b.5.A – 1.02 [Figure 1, Steps 5, 6]

TE170.314(b)(5)(A) – 1.05: Using the Vendor-identified function(s), the Tester shall observe the ambulatory EHR receiving and incorporating the LRI test message that was loaded and exported in TE170.314.b.5.A – 1.04 [Figure 1, Step 7]

TE170.314(b)(5)(A) – 1.06: Using the capabilities provided by the NIST LRI Conformance Test Tool, the Tester shall retrieve an LRI Juror Document for the Test Case selected in TE170.314.b.5.A – 1.01 [Figure 1, Step 8]

TE170.314(b)(5)(A) – 1.07: Using the Inspection Test Guide, the Tester shall verify that the ambulatory EHR incorporates the laboratory tests values/results information correctly and shall verify that the ambulatory EHR electronically displays the laboratory tests values/results information in human readable format [Figure 1, Step 9]

Inspection Test Guide

IN170.314(b)(5)(A) – 1.01: Using the Vendor-identified ambulatory EHR function(s), the test patient(s) created in TE170.314(b)(5)(A) – 1.03, the provided test data, and the Juror

Document retrieved from the NIST LRI Conformance Test Tool for the Test Case selected in TE170.314(b)(5)(A) – 1.01, the Tester shall sign on to the ambulatory EHR and shall [Figure 1, Step 9]

- Verify that the LRI test message data elements exported from the NIST LRI Conformance Test Tool to the EHR are received by the EHR and incorporated into the records for the test patient(s)
- Verify that the laboratory test results received from the NIST LRI Conformance Test Tool are complete and accurate and are displayed in a human readable format
- Verify that the LOINC codes are received and incorporated by the ambulatory EHR in TE170.314(b)(5)(A) – 1.05, and that they are valid and correct

DTR170.314(b)(5)(A) – 2: Electronically Display Test Report Information

Required Vendor Information

VE170.314(b)(5)(A) – 2.01: The Vendor shall identify the ambulatory EHR function(s) that are available to display all of the required and applicable sections of the laboratory Test Report

Required Test Procedures

TE170.314(b)(5)(A) – 2.01: Using the Vendor-identified ambulatory EHR function(s), the test patient's records and the associated laboratory tests and values/results used in the DTR170.314(b)(5)(A) - 1: Electronically Receive, Incorporate, and Display Clinical Laboratory Tests and Values/Results test, the Tester shall display the received information in a laboratory Test Report

TE170.314(b)(5)(A) – 2.02: Using the Inspection Test Guide, the Tester shall verify that all of the required and applicable components of the laboratory Test Report are accurate and complete

Inspection Test Guide

IN170.314(b)(5)(A) – 2.01: Using the test data from the Test Case selected for DTR170.314(b)(5)(A) - 1: Electronically Receive, Incorporate, and Display Clinical Laboratory Tests and Values/Results test**,** and using the Juror Document retrieved from the NIST LRI Conformance Test Tool for the Test Case selected in TE170.314(b)(5)(A) – 1.01**,** the Tester shall verify that the displayed laboratory test report includes all of the following sections and information (see "Special Note for 170.314(b)(5) ii" in the Informative Test Description section of this test procedure for detailed explanations about each section):

- either the patient's name and identification number, or a unique patient
- identifier and identification number
- the name and address of the laboratory location where the test was performed
- the test report date

- the test performed
- specimen source, when appropriate
- the test result and, if applicable, the units of measurement or interpretation, or both
- any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability

DTR170.314(b)(5)(A) - 3: Electronically Attribute/Associate/Link a Laboratory Test and Value/Result with a Laboratory Order or Patient Record

Required Vendor Information

VE170.314(b)(5)(A) – 3.01: The Vendor shall indicate whether the ambulatory EHR uses an automatic process or user functions to associate the received laboratory test result with a laboratory order or the patient's record in the EHR. If the association is accomplished by the user, the Vendor shall identify the EHR function(s) available to establish the association

VE170.314(b)(5)(A) – 3.02: The Vendor shall identify the ambulatory EHR function(s) that are available to verify that the received laboratory test result are attributed or associated or linked with a laboratory order or the patient's record in the EHR

Required Test Procedures

If the Vendor indicates that an automatic process is used to create the association, the Tester will perform TE170.314(b)(5)(A) – 3.01, otherwise the Tester will perform TE170.314(b)(5)(A) – 3.02. The EHR is not required to conform to both test procedures.

TE170.314(b)(5)(A) – 3.01: Automatic Process – Using Vendor-identified ambulatory EHR function(s) and the Inspection Test Guide, the Tester shall verify that a received laboratory test value/result is associated with the appropriate laboratory order or with the appropriate patient's record

TE170.314(b)(5)(A) – 3.02: End-User Process - Using Vendor-identified ambulatory EHR function(s) and the Inspection Test Guide, the Tester shall associate the received laboratory test result with the appropriate laboratory order or with the appropriate patient's record

Inspection Test Guide

IN170.314(b)(5)(A) – 3.01: Using the test data in the Test Case selected for the DTR170.314(b)(5)(A) - 1: Electronically Receive, Incorporate, and Display Clinical Laboratory Tests and Values/Results test, and using the Juror Document from the NIST LRI Conformance Test Tool, the Tester shall verify that the received laboratory tests and values/results are associated with the appropriate laboratory order or with the appropriate patient's record

- Laboratory Order – verify that the laboratory values/results are viewable via

the appropriate laboratory order. Since each EHR may associate the lab test values/results with the lab order in a different way, the exact sequence of actions is not being evaluated in this test; the test only evaluates that a user-recognizable association exists between the order and lab test values/results

- Patient's Record – verify that the laboratory values/results are viewable via the appropriate patient's record. Each EHR may have various ways to navigate to and display the laboratory test values/results via the patient's record. The method used by the EHR to navigate the user to the laboratory test values/results is not being evaluated during this test

TEST DATA

ONC supplied test data are provided with the test procedure to ensure that the applicable requirements identified in the criteria can be adequately evaluated for conformance, as well as, to provide consistency in the testing process across multiple National Voluntary Laboratory Accreditation Program-Accredited Testing Laboratories (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. See table 2 below for guidance on allowable changes to data.
- 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. 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.

Test Data for §170.314(b)(5)(A) Incorporate laboratory tests and values/results is available through the conformance tool (reference Conformance Tool Section for tool access).

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 procedure requires that the Tester imports the test message into the EHR technology being evaluated for conformance. If a situation arises where it is impractical for a Tester to directly import the test message, the Tester, at the Tester's discretion, may instruct the Vendor to enter the test message, so long as the Tester remains in full control of the testing process, directly observes the test message being entered by the Vendor, and validates that the test message is entered correctly as specified in the test procedure.

For ONC EHR certification testing, the primary purpose of the provided test data is to assist the Tester in verifying that the vendors' EHR technologies are capable of supporting the required functions; verifying the ability to support the specific content is not the primary purpose of the test data. Such testing and verification is more appropriate for local installations of the EHR technologies. The clinical test data are relevant for the given test stories; however, these data should not be expected to represent standards of practice.

The Date/Time data provided in the test data for the lab tests and values/results messages (Date/Time of the Observation, Date/Time of the Analysis, etc.) are examples showing the format of these data, but are not necessarily to be used during the certification testing. The Tester may use their discretion in determining the appropriate Date/Time data for each lab tests and values/results message

For this test procedure the Tester shall execute all **eight** Test Cases (and hence their 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, test data, and the inspection document are provided in PDF files and also are accessible in the Conformance Test Tool (See the "EHR 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: LRI Test Scenarios and Associated Test Cases

Test Scenario	NG Test Cases	GU Test Cases
Maximally Populated SED Rate message - Final Results	LRI_1.0-NG_Final	LRI_1.0-GU_Final
Maximally Populated SED Rate message - Corrected Results	LRI_1.1-NG_Corrected	LRI_1.1-GU_Corrected
Rejected SED Rate Message (No OBX segment; OBR.25 = X)	LRI_1.2-NG_Rejected	LRI_1.2-GU_Rejected
Typically Populated CBC message - Final Results	LRI_2.0-NG_Typ	LRI_2.0-GU_Typ
Typically Populated Lipid Panel message - Final Results	LRI_3.0-NG_Typ	LRI_3.0-GU_Typ
Culture-Escherichia coli, Salmonella, Shigella – Parent – Preliminary	LRI_4.0-NG_Parent	LRI_4.0-GU_Parent
Culture-Escherichia coli, Salmonella, Shigella - Parent/Child Susceptibility – Final	LRI_4.1-NG-RU_Parent_Child OR LRI-4.2-NG-RN_Parent_Child	LRI_4.1-GU-RU_Parent_Child OR LRI-4.2-GU-RN_Parent_Child
Reflex – Hepatitis	LRI_5.0-NG-RU_Parent_Child OR LRI-5.1-NG-RN_Parent_Child	LRI_5.0-GU-RU_Parent_Child OR LRI-5.1-GU-RN_Parent_Child

NAVIGATING A TEST CASE

A test case consists of a test story, test data specification, test message, and juror document. 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 is what is typically available in the clinical setting. Based on the test story and data a test message is provided. The test message is imported (for example, sent) to the EHR technology. For each test case indicated, the test tool provides a test message. The Juror Document is a test case specific checklist that the Tester uses to assess and record that the test message is correctly incorporated into the EHR. The process utilizes an inspector to ascertain if the lab results sent in the test message is incorporated appropriately in the EHR technology. The Juror Document guides the inspector through the assessment process. This is a visual inspection where verification may include viewing the EHR display or an *extended* (for example, data base view) inspection.

HOW TO INTERPRET AND USE THE JUROR DOCUMENT

The Juror Document categorizes test data according to how data incorporation into the EHR is verified. The Table 2 describes the categorizations. Note that not all message elements sent require explicit verification and therefore the "Implied and No Verification" data will not appear in the Juror Document.

Table 2 Data Element Incorporation Categorization

Category	Description	Example
Display Verification	Verify data is *displayed*[14] on EHR user interface	Lab Result (OBX.3)
Incorporate Verification	Verify data is *persisted*[15] in the EHR (e.g., inspection of the data base; however, a specific method for attestation is not prescribed); Note, Display Verification can be used for data classified as Incorporate Verification in the Juror Document[16]	Unique patient identification (PID.3) including support for assigning authority (for the GU profile)
Implied Verification	Verify the appropriate data associations and subsequent rendering if applicable	Linking of parent/child results (OBX.4 – Sub ID)
No Verification	Data verification not relevant	Processing of the Message Type (MSH.9)

The Juror Document is composed of a set of tables listing the data that are required to be verified for a given test case. One set of tables (labeled "Display Verification") illustrates the data that are required to be verified by "Display". The Juror Documents for Test Cases LRI_1.0-GU_Final and LRI_1.0-NG_Final include a second set of tables (labeled "Incorporate Verification") illustrates the data that are required to

[14] Displayed and associated

[15] Stored or otherwise derived/retrievable and associated

[16] For example, gender is not required to be displayed; however, if gender is displayed along with the patient record and lab result, then this satisfies this incorporate verification requirement

be verified by "Incorporate". For testing efficiency, the EHR technology being tested only needs to demonstrate the ability to incorporate the data listed in the Incorporate Verification tables for the LRI_1.0-GU_Final or LRI_1.0-NG_Final Test Case. The ATL may perform an additional "spot check" for a Test Case for which the Juror Document doesn't include the Incorporate Verification set of tables. Implied Verification is built into the Juror Document, for example, grouping of data. Not all elements contained in the message are subject to verification; these fall into the No Verification category and are not provided on the Juror Document.

CONFORMANCE TEST TOOLS

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

- HL7v2 Laboratory Results Interface (LRI) Validation Tool – an HL7v2 validation tool is designed specifically to support this test procedure.
- The tool is available as a Web Application
- Use the EHR Validation Tab for this test procedure
- The application can be downloaded for local installation
- The web application validation service is available at:
- http://hl7v2-lab-testing.nist.gov

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

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

Multiple browsers may be used to access this tool; if the tool does not load completely using Internet Explorer 8 or Internet Explorer 9, alternative browsers such as Firefox, Google Chrome, or Safari are recommended. The HL7v2 Laboratory Results Interface (LRI) Validation 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 conformance reports generated by the HL7v2 Laboratory Results Interface (LRI) Validation Tool.

The HL7v2 validation 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 HL7v2 Laboratory Results Interface (LRI) Validation 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 of Change	Date Published
1.0	Released for public comment	November 19, 2012
1.1	Delivered for National Coordinator Approval	December 3, 2012
1.2	Posted Approved Test Procedure	December 14, 2012
1.3	Posted Updated Approved Test Procedure Updates: • Certification Criteria language bullets (ii) and (iii) realigned to be in line with bullet (i) • Test data reference moved and modified in Informative Test Description • Footnote 7 added to Receive, incorporate and display section of the Informative Test Description and typo removed • Language corrected in Special Note, section 1) 42 CFR 493.1291.c.1 to indicate patient's name and identification number are required (instead of "or") • Bullet removed in Test Data section referring to Vendor-selected message format • Reference to Table 2 added to first bullet of Test Data section • Full name of certification criterion updated in reference to test data access sentence of Test Data section • Paragraph in Test Data section indicating that Vendor may enter test data updated with appropriate verbiage: "enter" replaced with "import"; "data" replaced with "message"; sentence indicating "intent" of test procedure removed • Added paragraph to Test Data section about primary purpose of test data	January 16, 2013
1.4	Posted Updated Approved Test Procedure Updates: • Provided clarification in the "How to Interpret and Use the Juror Document" section of Test Data section	February 22, 2013