Test Procedure for §170.302 (h) Incorporate Laboratory Test Results

This document describes the draft test procedure for evaluating conformance of complete EHRs or EHR modules[1] to the certification criteria defined in 45 CFR Part 170 Subpart C of the Final Rule for Health Information Technology: Initial Set of standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology as published in the Federal Register on July 28, 2010. The document[2] 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://healthcare.nist.gov/docs/TestProcedureOverview_v1.pdf. 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. Test procedures to evaluate conformance of EHR technology to ONC's requirements are defined by NIST. Testing of EHR technology is carried out by ONC-Authorized Testing and Certification Bodies (ATCBs), not NIST, as set forth in the final rule establishing the Temporary Certification Program (*Establishment of the Temporary Certification Program for Health Information Technology, 45 CFR Part 170; June 24, 2010*.)

Questions about the applicability of the standards, implementation guides or criteria should be directed to ONC at ONC.Certification@hhs.gov. Questions about the test procedures should be directed to NIST at hit-tst-fdbk@nist.gov. Note that NIST will automatically forward to ONC any questions regarding the applicability of the standards, implementation guides or criteria. Questions about functions and activities of the ATCBs should be directed to ONC at ONC.Certification@hhs.gov .

CERTIFICATION CRITERIA

This Certification Criterion is from the Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology Final Rule issued by the Department of Health and Human Services (HHS) on July 28, 2010.

§170.302 (h) Incorporate laboratory test results.

1) Receive results. Electronically receive clinical laboratory test results in a structured format and display such results in human readable format.
2) Display test report information. Electronically display all the information for a test report specified at 42 CFR 493.1291(c)(1) through (7).

[1] Department of Health and Human Services, 45 CFR Part 170 Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, Final Rule, July 28, 2010.

[2] Disclaimer: Certain commercial products are identified in this document. Such identification does not imply recommendation or endorsement by the National Institute of Standards and Technology.

3) Incorporate results. Electronically attribute, associate, or link a laboratory test result to a laboratory order or patient record.

Per Section III.C 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 definition of human readable 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)."

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.

This test evaluates the capability for a Complete EHR or EHR Module to receive electronically transmitted laboratory test results, display them in human readable format, display all required sections of the test report and associate the laboratory test result to a laboratory order or patient's record.

The test procedure is organized into two sections:

- Receive and Display Test Report Information - evaluates the capability to receive and display a laboratory test result in the EHR when received in a structured format. The Final Rule does not require a specific standard for the structured format.
    - The Vendor identifies the structured format of the laboratory message to use for this test.
    - The Tester sends the NIST-supplied laboratory test results in the format selected by the Vendor to the EHR
    - Using Vendor-identified EHR functions, the Tester displays the received laboratory test data, validates that the rendered data are correct and that all required sections of the test report are displayed as defined at 42 CFR 493.1291(c)(1) through (7)
    - With respect to the requirement for human readability, The test procedures 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

- Incorporate Results – evaluates the capability of the EHR to electronically associate the received laboratory test report with a laboratory order or a patient's record in the EHR. The word "associate" is used in the test procedure as a placeholder for the entire phrase "attribute, associate, or link" in the criteria.
    - Using Vendor-defined EHR functions, the Tester verifies that the received laboratory test result is associated with a laboratory order or patient record in the EHR. If the EHR provides an automated process to establish this association, the Tester verifies that the association is present in the EHR. If the EHR does not provide an automated process, the

Tester uses Vendor-defined EHR functions to create the association between the received laboratory test result and a laboratory order or patient record in the EHR

REFERENCED STANDARDS

§170.205/207 Content exchange and vocabulary standards for exchanging electronic health information	Regulatory Referenced Standard
None specified	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 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.

NORMATIVE TEST PROCEDURES

Derived Test Requirements

DTR170.302.h - 1: Electronically Receive and Display Laboratory Test Report Information

DTR170.302.h - 2: Electronically Associate Laboratory Test Result with Laboratory Order or Patient Record

DTR170.302.g - 1: Electronically Receive and Display Laboratory Test Report Information

Required Vendor Information

VE170.302.h – 1.01: Vendor shall identify the structured format for the laboratory test results to be used for this test

VE170.302.h – 1.02: Vendor shall identify a patient with an existing record in the EHR to be used for this test

VE170.302.h – 1.03: Vendor shall provide communications configuration information and patient identifiers necessary to send laboratory test result data to the EHR in the Vendor-identified structured format

VE170.302.h – 1.04: Vendor shall identify the EHR function(s) that are available to 1) select an existing patient record, 2) view a laboratory test result in human readable format when received from an external source, 3) display all of the required sections of the laboratory report

Required Test Procedure

TE170.302.h – 1.01: Tester shall select laboratory test result test data from NIST-supplied test data set TD170.302.h

TE170.302.h – 1.02: Tester shall transmit laboratory test result test data in the Vendor-selected structured format to the EHR

TE170.302.h – 1.03: Using the EHR function(s) and existing patient record identified by the Vendor and using the NIST-supplied Inspection Test Guide, the Tester shall select the patient record, display and verify that the laboratory test results information received by the EHR are complete and correct

TE170.302.h – 1.04: Tester shall verify that all of the required test report sections are present and correctly populated with the laboratory test results

Inspection Test Guide

IN170.302.h – 1.01: Tester shall verify that the laboratory test results test data are received by the EHR

IN170.302.h – 1.02: Using the data in the NIST-supplied Test Data set TD170.302.h, Tester shall verify that the received laboratory test results test data are complete and correct

IN170.302.h – 1.03: Tester shall verify that the displayed laboratory test result includes all of the following sections and data, including:

- 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

DTR170.302.h - 2: Electronically Associate Laboratory Test Result with Laboratory Order or Patient Record

Required Vendor Information

VE170.302.h – 2.01: Vendor shall indicate whether the 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 functions available to establish the association

Required Test Procedures

If the Vendor indicates that an automatic process is used to create the association, the Tester will perform TE170.302.h – 2.01, otherwise the Tester will perform TE170.302.h – 2.02. The EHR is not required to conform to both test procedures.

TE170.302.h – 2.01: Automatic Process – Using EHR function(s) identified by the Vendor, the Tester shall verify that the received laboratory test result is associated with a laboratory order or with the patient's record

TE170.302.h – 2.02: End-User Process - Using EHR function(s) identified by the Vendor, the Tester shall associate the received laboratory test result with a laboratory order or with the patient's record

Inspection Test Guide

IN170.302.h – 2.01: Tester shall verify that the received laboratory test result is associated with a laboratory order or with the patient's record

- Patient's Record – verify that the laboratory result is viewable from within the patient's record. The EHR may have various ways to navigate and display the laboratory test result from within the patient's record. There are no specific requirements on the method used by the EHR to navigate the user to the laboratory test result from within the patient's chart
- Laboratory Order – verify that the laboratory result is viewable from the laboratory order. Since the EHR may associate the lab result with the lab order in different ways, the exact sequence of actions is not being evaluated in this test, only that there is a user-recognizable association between the order and result

TEST DATA

Test data is provided by NIST in the Test Procedure to ensure that the functional and interoperable requirements identified in the criteria can be adequately evaluated for conformance, as well as, to provide consistency in the testing process across multiple ONC-Authorized Testing and Certification Bodies (ATCBs). The NIST-supplied 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 is 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 NIST-supplied test data during the test, without exception, unless one of the following conditions exist:

- The Tester determines that the Vendor product is sufficiently specialized that the NIST-supplied test data needs to be modified in order to conduct an adequate test. Having made the determination that some modification to the NIST-supplied 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 NIST-supplied 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 control 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.

TD170.302.h: Test Data Sets

Data Set #1

Test Data Element	Test Data
Patient ID Information	
Patient Family Name	(Vendor-supplied)
Patient Given Name	(Vendor-supplied)
Patient ID Number (e.g, medical record #)	(Vendor-supplied)
Test Lab Information	
Lab Facility Name	Milton Street Laboratory
Lab Facility Street Address	40025 Milton Street
Lab Facility City	Aurora
Lab Facility State	Colorado
Lab Facility Zip Code	80011
Test Result Information	
Test Report Date	(ATCB-defined)[3]
Test Type	Chemistry
LOINC Code	14771-0
Test Name (and Normal Range)	Fasting Blood Glucose (70–100 mg/dl)
Test Result Value	178
Test Result Unit of Measure	mg/dl
Test Specimen Source	Arterial catheter
Condition/Disposition of Specimen	Hemolyzed
Test Report Date	(ATCB-defined)
Test Type	Chemistry

[3] Test date needs to be greater than or equal to admission/registration date of the patient (vendor registers the patient; ATCB sets the test report date to T+ n days at their discretion.

Test Data Element	Test Data
LOINC Code	14682-9
Test Name (and Normal Range)	Creatinine (0.5–1.4 mg/dl)
Test Result Value	1.0
Test Result Unit of Measure	mg/dl
Test Specimen Source	Arterial catheter
Condition/Disposition of Specimen	Hemolyzed
Test Report Date	(ATCB-defined)
Test Type	Chemistry
LOINC Code	14937-7
Test Name (and Normal Range)	BUN (7–30 mg/dl)
Test Result Value	18
Test Result Unit of Measure	mg/dl
Test Specimen Source	Arterial catheter
Condition/Disposition of Specimen	Hemolyzed

Data Set #2

Test Data Element	Test Data
Patient ID Information	
Patient Family Name	(Vendor-supplied)
Patient Given Name	(Vendor-supplied)
Patient ID Number (e.g, medical record #)	(Vendor-supplied)
Test Lab Information	
Lab Facility Name	Oakton Crest Laboratories
Lab Facility Street Address	5570 Eden Street
Lab Facility City	Oakland
Lab Facility State	California
Lab Facility Zip Code	94607
Test Result Information	
Test Report Date	(ATCB-defined)
Test Type	Chemistry
LOINC Code	2951-2
Test Name (and Normal Range)	Serum Sodium (135–146 mg/dl)
Test Result Value	141
Test Result Unit of Measure	mg/dl
Test Specimen Source	Not Applicable
Condition/Disposition of Specimen	Not Applicable
Test Report Date	(ATCB-defined)
Test Type	Chemistry

Test Data Element	Test Data
LOINC Code	2823-3
Test Name (and Normal Range)	Serum Potassium (3.5–5.3 mg/dl)
Test Result Value	4.3
Test Result Unit of Measure	mg/dl
Test Specimen Source	Not Applicable
Condition/Disposition of Specimen	Not Applicable

Data Set #3

Test Data Element	Test Data
Patient ID Information	
Patient Family Name	(Vendor-supplied)
Patient Given Name	(Vendor-supplied)
Patient ID Number (e.g, medical record #)	(Vendor-supplied)
Test Lab Information	
Lab Facility Name	Aloha Laboratories
Lab Facility Street Address	575 Luau Street
Lab Facility City	Honolulu
Lab Facility State	Hawaii
Lab Facility Zip Code	96813
Test Result Information	
Test Report Date	(ATCB-defined)
Test Type	Chemistry
LOINC Code	14647-2
Test Name (and Normal Range)	Total cholesterol (<200 mg/dl)
Test Result Value	162
Test Result Unit of Measure	mg/dl
Test Specimen Source	Not Applicable
Condition/Disposition of Specimen	Hemolyzed
Test Report Date	(ATCB-defined)
Test Type	Chemistry
LOINC Code	14646-4
Test Name (and Normal Range)	HDL cholesterol (≥40 mg/dl)
Test Result Value	43
Test Result Unit of Measure	mg/dl
Test Specimen Source	Not Applicable
Condition/Disposition of Specimen	Hemolyzed
Test Report Date	(ATCB-defined)
Test Type	Chemistry

Test Data Element	Test Data
LOINC Code	2089-1
Test Name (and Normal Range)	LDL cholesterol (<100 mg/dl)
Test Result Value	84
Test Result Unit of Measure	mg/dl
Test Specimen Source	Not Applicable
Condition/Disposition of Specimen	Hemolyzed
Test Report Date	(ATCB-defined)
Test Type	Chemistry
LOINC Code	14927-8
Test Name (and Normal Range)	Triglycerides (<150 mg/dl)
Test Result Value	127
Test Result Unit of Measure	mg/dl
Test Specimen Source	Not Applicable
Condition/Disposition of Specimen	Hemolyzed

Data Set #4

Test Data Element	Test Data
Patient ID Information	
Patient Family Name	(Vendor-supplied)
Patient Given Name	(Vendor-supplied)
Patient ID Number (e.g, medical record #)	(Vendor-supplied)
Test Lab Information	
Lab Facility Name	Mid-town Laboratories
Lab Facility Street Address	908 Drue Street
Lab Facility City	Eklutna
Lab Facility State	Alaska
Lab Facility Zip Code	99567
Test Result Information	
Test Report Date	(ATCB-defined)
Test Type	Hematology
LOINC Code	26449-9
Test Name (and Normal Range)	Eosinophil Count (1 – 3 %)
Test Result Value	2
Test Result Unit of Measure	%
Test Specimen Source	Not Applicable
Condition/Disposition of Specimen	Not Applicable
Test Report Date	(ATCB-defined)
Test Type	Hematology

Test Data Element	Test Data
LOINC Code	718-7
Test Name (and Normal Range)	Hemoglobin (male: 14-18 g/dl female: 12-16 g/dl)
Test Result Value	16
Test Result Unit of Measure	g/dl
Test Specimen Source	Not Applicable
Condition/Disposition of Specimen	Not Applicable
Test Report Date	(ATCB-defined)
Test Type	Hematology
LOINC Code	4544-3
Test Name (and Normal Range)	Hematocrit (male: 40-54% female: 36-48%)
Test Result Value	45
Test Result Unit of Measure	%
Test Specimen Source	Not Applicable
Condition/Disposition of Specimen	Not Applicable

Data Set #5

Test Data Element	Test Data
Patient ID Information	
Patient Family Name	(Vendor-supplied)
Patient Given Name	(Vendor-supplied)
Patient ID Number (e.g, medical record #)	(Vendor-supplied)
Test Lab Information	
Lab Facility Name	Colton Street Laboratories
Lab Facility Street Address	5050 Colton Street
Lab Facility City	Shawville
Lab Facility State	Pennsylvania
Lab Facility Zip Code	16873
Test Result Information	
Test Report Date	(ATCB-defined)
Test Type	Chemistry
LOINC Code	2823-3
Test Name (and Normal Range)	Serum Potassium (3.5–5.3 mg/dl)
Test Result Value	4.5
Test Result Unit of Measure	mg/dl
Test Specimen Source	Not Applicable
Condition/Disposition of Specimen	Not Applicable
Test Report Date	(ATCB-defined)
Test Type	Chemistry

Test Data Element	Test Data
LOINC Code	14647-2
Test Name (and Normal Range)	Total cholesterol (<200 mg/dl)
Test Result Value	180
Test Result Unit of Measure	mg/dl
Test Specimen Source	Not Applicable
Condition/Disposition of Specimen	Not Applicable
Test Report Date	(ATCB-defined)
Test Type	Chemistry
LOINC Code	14646-4
Test Name (and Normal Range)	HDL cholesterol (≥40 mg/dl)
Test Result Value	38
Test Result Unit of Measure	mg/dl
Test Specimen Source	Not Applicable
Condition/Disposition of Specimen	Not Applicable
Test Report Date	(ATCB-defined)
Test Type	Chemistry
LOINC Code	2089-1
Test Name (and Normal Range)	LDL cholesterol (<100 mg/dl)
Test Result Value	120
Test Result Unit of Measure	mg/dl
Test Specimen Source	Not Applicable
Condition/Disposition of Specimen	Not Applicable
Test Report Date	(ATCB-defined)
Test Type	Chemistry
LOINC Code	14927-8
Test Name (and Normal Range)	Triglycerides (<150 mg/dl)
Test Result Value	187
Test Result Unit of Measure	mg/dl
Test Specimen Source	Not Applicable
Condition/Disposition of Specimen	Not Applicable

CONFORMANCE TEST TOOLS

None

Document History

Version Number	Description	Date Published
0.4	Original draft version	April 20, 2010
1.0	Updated to reflect Final Rule	July 21, 2010
1.0	Updated to remove “Pending” from header	August 13, 2010