

Test Procedure for §170.302 (g) Incorporate laboratory test results

This document describes the draft 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 Interim Final Rule (IFR) as published in the Federal Register on January 13, 2010. The document 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. These test procedures will be updated to reflect the certification criteria defined in the ONC Final Rule.

Note: This test procedure is scoped only to the criteria defined in 45 CFR Part 170 Subpart C of the Interim Final Rule (IFR) as published in the Federal Register on January 13, 2010. This test procedure will be updated to reflect updates to the criteria and standards as published in the ONC Final Rule. Questions about the criteria and standards should be directed to ONC.

CERTIFICATION CRITERIA

§170.302 (g) 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 codes in readable format. Electronically display in human readable format any clinical laboratory tests that have been received with LOINC® codes.
- 3) Display test report information. Electronically display all the information for a test report specified at 42 CFR 493.1291(c)(1) through (7).
- 4) Update. Enable a user to electronically update a patient's record based upon received laboratory test results.

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 Module¹ to receive electronically transmitted laboratory test results, display them in human readable format, display all required sections of the test report and update the patient's record with the received laboratory test results.

The test procedure is organized into three sections:

- Receive and Display - evaluates the capability to receive and display (render) a laboratory test result in the EHR when received in a structured format containing LOINC codes. Per the IFR, there is no specific requirement identified for the type of structured format to be used in the test. NIST will provide test messages in HL7v2, HL7 CCD and ASTM CCR formats. If the Vendor chooses to use a

¹ Department of Health and Human Services, 45 CFR Part 170 Proposed Establishment of Certification Programs for Health Information Technology, Proposed Rule, March 10, 2010.

structured format other than those listed above, the ATCB conducting the test will determine whether the Vendor's structured format can be created for this test.

- The Vendor identifies the structured format of the laboratory message which they wish 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 and validates that the rendered data is complete and presented in human readable format

Per ONC guidance, the requirement for displaying structured data and vocabulary coded values in human readable form requires that the received structured data be rendered in some way which does not display the message in raw delimited or XML format to the user. In addition, the standardized text associated with the LOINC coded values must be displayed to the user. There is no requirement that the actual coded values be displayed to the user, however, the Vendor may choose to do so. The Vendor may also choose to display locally defined text descriptions of the LOINC codes, however, the standardized text must always be displayed.

Display test report information – evaluates the capability of the EHR to display all of the required sections of laboratory test result data as defined at 42 CFR 493.1291(c)(1) through (7):

- 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.

Update – evaluates the capability of the EHR to electronically update a patient's record based upon the received laboratory test result.

- Using Vendor-identified functions, the Tester updates the patient's record with the received laboratory test result

REFERENCED STANDARDS

§170.205 Content exchange and vocabulary standards
for exchanging electronic health information.

Regulatory Referenced Standard

(iii) Laboratory orders and results

(A) Standard. Logical Observation Identifiers Names and Codes (LOINC®) version 2.27, when such codes were received within an electronic transaction from a laboratory (incorporated by reference in §170.299).

**§170.205 Content exchange and vocabulary standards
for exchanging electronic health information.**

Regulatory Referenced Standard

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.g - 1: Electronically Receive and Display Laboratory Test Results

DTR170.302.g - 2: Electronically Display Test Report Information

DTR170.302.g - 3: Electronically Update Patient Record

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

Required Vendor Information

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

VE170.302.g – 1.02: Vendor shall provide communications configuration information and patient identifiers necessary to send laboratory test result data to the EHR

VE170.302.g – 1.03: Vendor shall identify a patient with an existing record in the EHR to be used for this test

VE170.302.g – 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, and 3) to update the patient's record with the received laboratory test results

Required Test Procedure

TE170.302.g – 1.01: Tester shall select laboratory test result test data from NIST-supplied test data sets

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

TE170.302.g – 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 an existing patient record, and display and verify that the laboratory test results information received by the EHR are complete and correct.

Inspection Test Guide

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

IN170.302.g – 1.02: Tester shall verify that the received laboratory test results test data are complete, correct and viewable in the EHR in human readable format, and that the received test data are conformant to the referenced content and vocabulary standards including:

- Delimited or structured data are presented to the user in narrative English language description form
- The appropriate LOINC standard text is displayed for any laboratory test results containing LOINC codes

DTR170.302.g - 2: Electronically Display Test Report Information

Required Vendor Information

- As defined in DTR170.302.g -1, no additional information is required

Required Test Procedure

TE170.302.g – 2.01: Tester shall verify that all of the required test report sections are present and populated with the laboratory test results received in the Receive and Display Test

Inspection Test Guide

IN170.302.g – 2.01: 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.g - 3: Electronically Update Patient Record

Required Vendor Information

- As defined in DTR170.302.g - 1, no additional information is required

Required Test Procedures

TE170.302.g – 3.01: Using the EHR function(s) identified by the Vendor, the Tester shall select and update the patient's existing record with the laboratory test results received during the Receive and Display Test

TE170.302.g – 3.02: Using EHR function(s) identified by the Vendor, the Tester shall verify that the patient's existing record has been updated with the laboratory test results

Inspection Test Guide

IN170.302.g – 3.01: Tester shall verify that all of the patient summary record test data are stored in the patient's record, 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

EXAMPLE TEST DATA

Data Set #1

Test Data Element	Test Data
Patient ID Information	
Patient Family Name	Barnaby
Patient Given Name	Jonas
Patient ID Number (e.g, medical record #)	969988999
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	09/16/2009
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	Not Applicable
Condition/Disposition of Specimen	Not Applicable
Test Report Date	09/16/2009
Test Type	Chemistry
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	Not Applicable
Condition/Disposition of Specimen	Not Applicable
Test Report Date	09/16/2009
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	Not Applicable
Condition/Disposition of Specimen	Not Applicable

Data Set #2

Test Data Element	Test Data
Patient ID Information	
Patient Family Name	Flint
Patient Given Name	Robert
Patient ID Number (e.g, medical record #)	9813624798
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	09/16/2009
Test Type	Chemistry
LOINC Code	2951-2
Test Name (and Normal Range)	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	09/16/2009
Test Type	Chemistry
LOINC Code	2823-3
Test Name (and Normal Range)	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	Simpson
Patient Given Name	Barbara
Patient ID Number (e.g, medical record #)	9688675266
Test Lab Information	
Lab Facility Name	Aloha Laboratories

Test Data Element	Test Data
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	09/16/2009
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	Not Applicable
Test Report Date	09/16/2009
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	Not Applicable
Test Report Date	09/16/2009
Test Type	Chemistry
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	Not Applicable
Test Report Date	09/16/2009
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	Not Applicable

Data Set #4

Test Data Element	Test Data
Patient ID Information	
Patient Family Name	Ellerby
Patient Given Name	Susan
Patient ID Number (e.g, medical record #)	925377799
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	12/22/2009
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	12/22/2009
Test Type	Hematology
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	12/22/2009
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	Stone
Patient Given Name	Johnathan
Patient ID Number (e.g, medical record #)	988772587
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	07/15/2009
Test Type	Chemistry
LOINC Code	2823-3
Test Name (and Normal Range)	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	07/15/2009
Test Type	Chemistry
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	07/15/2009
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 Data Element	Test Data
Test Report Date	07/15/2009
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	07/15/2009
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