

Test Procedure for §170.314(b)(5)(B) 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 document¹ 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 Program², 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.

- (i) Receive 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.

(A) Ambulatory setting only³.

(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)

(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.

(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 unchanged with refinements in the inpatient setting from the 2011 Edition. This certification criterion meets the three factors of unchanged certification criteria: (1) the certification criterion includes only the same capabilities that were specified in previously adopted certification criteria, (2) the certification criterion's capabilities apply to the same setting as they did in previously adopted certification criteria, and (3) the certification criterion remains designated as "mandatory," or it is re-designated as "optional," for the same setting for which it was previously adopted certification criterion.

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

- "...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."
- "This certification criterion only applies to the electronic receipt of laboratory tests and does not focus on the transmission of orders."

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

- “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 (for example, 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 transmission of reportable 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 in human readable format clinical laboratory tests and values/results. The clinical laboratory tests and values/results must be electronically received in a structured format. The 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 results⁴ (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 test procedure is not prescriptive about the protocol used to send the clinical laboratory tests and values/results messages to 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 the messages.

ONC provides the test data for this test procedure.

This test procedure is organized into three sections:

- Receive and display – evaluates the capability of the inpatient EHR technology to electronically receive clinical laboratory tests and values/results in a structured format as

⁴ 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 and 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

discrete data elements and display them in human readable format (the ONC Final Rule does not require a specific standard for the structured format)

- The inpatient EHR Vendor creates test patient records in their EHR
 - The inpatient EHR Vendor identifies the structured format and the messaging protocol for the clinical laboratory tests and results/values message(s)
 - The Tester electronically sends the provided clinical laboratory tests and values/results messages in the structured format selected by the Vendor to the inpatient EHR
 - Using the Vendor-identified EHR function(s), the Tester signs on to the inpatient EHR and verifies that the clinical laboratory tests⁵ and values/results⁶ that were sent are displayed as discrete data elements 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 inpatient EHR technology to electronically display, at a minimum, 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 EHR function(s), the Tester signs on to the inpatient EHR and views the clinical laboratory tests and values/results test report information sent in the “Receive and display” step
 - The Tester validates that the seven named components of the test report information are displayed for the clinical laboratory tests and values/results
- Attribute, associate, or link – evaluates the capability of the inpatient EHR technology to electronically incorporate (attribute, associate, or link) a lab test and value/result with the appropriate lab order or with the correct patient record

⁵ Fourth component in the information for a test report specified at 42 CFR 493.1291(c)(1) through (7)

⁶ Sixth component in the information for a test report specified at 42 CFR 493.1291(c)(1) through (7)

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

SPECIAL NOTE FOR 170.314(B)(5) 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 criterion⁷ adopted at **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 7⁸.

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 format⁹.

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, for example, 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 or identification number, or a unique patient identifier and identification***”

⁷ Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition [\[45 CFR 170.314\(b\)\]](#)

⁸ Clinical Laboratory Improvement Amendments of 1988 [\[42 CFR 493.1291\]](#)

⁹ *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. [\[45 CFR 170.102\]](#)

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 **OR** unique patient Identification number assigned by the ordering facility (may be used when the patient name is not available) **AND** identification number, 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
- 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
 - 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
- 3) 42 CFR 493.1291.c.3 “**The test report date.**”
- The date (for example, mm/dd/yyyy) the test report/status change was finalized by the laboratory
- 4) 42 CFR 493.1291.c.4 “**The test performed.**”
- The specific name of the test/analyte that is assigned by the laboratory. 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. 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
 - Where available, the corresponding units of measure for the requested analyte/test identified and used by the laboratory
 - Where available, the laboratory's interpretation communicated by defined text/symbols indicating test results that does not fall within the established reference/normal range. 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
- 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. 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.). 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. §170.207 Vocabulary standards for representing 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

- DTR170.314(b)(5)(B) - 1: Electronically Receive and Display Clinical Laboratory Tests and Values/Results
- DTR170.314(b)(5)(B) - 2: Electronically Display Test Report Information
- DTR170.314(b)(5)(B) - 3: Electronically Attribute/Associate/Link a Laboratory Test and Value/Result with a Laboratory Order or Patient Record

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

Required Vendor Information

- VE170.314(b)(5)(B) – 1.01: The Vendor shall identify a patient with an existing record in the inpatient EHR to be used for this test
- VE170.314(b)(5)(B) – 1.02: The Vendor shall identify the inpatient 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 the laboratory test report, and 4) demonstrate that the EHR has attributed/associated/linked (incorporated) a laboratory test and value/result with a laboratory order or patient record
- VE170.314(b)(5)(B) – 1.03: The Vendor shall identify the structured format and messaging protocol used to send the clinical laboratory tests and values/results messages to the inpatient EHR

Required Test Procedures

- TE170.314(b)(5)(B) – 1.01: The Tester shall select laboratory tests and values/results test data from one of the provided test data sets in TD170.314(b)(5)(B) [See associated test data document]
- TE170.314(b)(5)(B) – 1.02: Using the Vendor-identified structured format, the Tester shall create the laboratory tests and values/results message(s) based on the test data selected in TE170.314(b)(5)(B) – 1.01
- TE170.314(b)(5)(B) – 1.03: Using the Vendor-identified messaging protocol, the Tester shall send the laboratory tests and values/results message(s) created in TE170.314(b)(5)(B) – 1.02 to the inpatient EHR
- TE170.314(b)(5)(B) – 1.04: Using the Vendor-identified inpatient EHR function(s), the Tester shall sign on to the EHR as a clinical user, select the test patients and view the laboratory tests and values/results sent to the EHR in TE170.314(b)(5)(B) – 1.03
- TE170.314(b)(5)(B) – 1.05: Using the Inspection Test Guide, the Tester shall verify that the inpatient EHR receives and displays the laboratory tests values/results information correctly

Inspection Test Guide

- IN170.314(b)(5)(B) – 1.01: Using the test data selected in TE170.314(b)(5)(B) – 1.01 and the test patients selected in TE170.314(b)(5)(B) – 1.04, the Tester shall verify that the laboratory test values/results received by the inpatient EHR are complete, accurate, and are displayed as discrete data elements in a human readable format

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

Required Vendor Information

- As defined in DTR170.314(b)(5)(B) – 1, no additional information is required

Required Test Procedures

TE170.314(b)(5)(B) – 2.01: Using the Vendor-identified inpatient EHR function(s), the test patients' records and the associated laboratory tests and values/results used in the DTR170.314(b)(5)(B) - 1: Electronically Receive and Display Clinical Laboratory Tests and Values/Results, the Tester shall display the information for the laboratory test report received by the EHR

TE170.314(b)(5)(B) – 2.02: Using the Inspection Test Guide, the Tester shall verify that all of the required lab test report sections are correctly and accurately populated with the laboratory test values/results information

Inspection Test Guide

IN170.314(b)(5)(B) – 2.01: Using the test data and the test patients selected for the DTR170.314(b)(5)(B) - 1: Electronically Receive and Display Clinical Laboratory Tests and Values/Results test, 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 of the following data elements):

- 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)(B) - 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)(B) – 3.01: The Vendor shall indicate whether the inpatient 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)(B) – 3.02: The Vendor shall identify the inpatient 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)(B) – 3.01, otherwise the Tester will perform TE170.314(b)(5)(B) – 3.02. The EHR is not required to conform to both test procedures.

- TE170.314(b)(5)(B) – 3.01: Automatic Process – Using Vendor-identified inpatient 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)(B) – 3.02: End-User Process - Using Vendor-identified inpatient 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)(B) – 3.01: Using the test data and the test patients selected for the DTR170.314(b)(5)(B) - 1: Electronically Receive and Display Clinical Laboratory Tests and Values/Results test, 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 inpatient 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 inpatient 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 is 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 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 provided test data during the test, without exception, unless one of the following conditions exists:

- The Tester determines that the Vendor-selected message format requires some modification to the test data.
- 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. 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)(B) Incorporate lab tests available at <http://www.healthit.gov/certification>
(navigation: 2014 Edition Test Method)

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.

CONFORMANCE TEST TOOLS

None

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