

NIST Normative Test Process Document: Immunization Test Tool

Test Tool and Test Descriptions to Conduct ONC Certification*

NIST Approved Version 1.4

Date: March 25, 2024

*Previously called “ONC 2015 Edition Certification”. Any reference to “2015 Edition” or “Edition 2015” in this document should be disregarded.

For several reasons outlined in the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Final Rule, ONC determined it was no longer necessary to maintain an “edition” naming convention or to adopt entirely new editions of certification criteria to update the Certification Program over time. Instead, ONC established a single set of certification criteria, which will be updated in an incremental fashion that is more closely aligned with standards development cycles and regular health IT development timelines. As of the HTI-1 Final Rule effective date, all certification criteria will be referred to simply as ONC Certification Criteria for Health IT.

**Developed by the National Institute of Standards and Technology (NIST) in
collaboration with the Center for Disease Control and Prevention (CDC)**

List of Contents

Explanation of Terms

A table containing a key of equivalents for names and terms used frequently in this document

Informative Test Description

Key background information for conducting the certification testing; includes information about

- Definition of “Tester” for this document
- Care settings and profiles that are in-scope for the testing
- Capabilities the Health IT Module must be able to demonstrate during the certification testing

Normative Test Description

Detailed description of the testing process, including Derived Test Requirement(s), Testing Workflow Diagram(s), Required Vendor Information, Required Testing Actions, and Inspection Test Guide

Test Data

Detailed description of the purpose and use of the provided test data, including allowed exceptions

Navigating a Test Case

Detailed description of the information and instructions available in the NIST Test Tool related to the Test Cases

How to Interpret the Message Content Data Sheet

Detailed description of the purpose of and information available in the Message Content Data Sheet, including the meaning of the NIST Test Data Categories and Qualifiers

Conformance Test Tools

Links to the web-based NIST Test Suite and Support sites, as well as information to assist the Tester in interpreting the Validation Reports generated by the Tool

Document History

Listing of Version Numbers and Publication Dates for the final published versions of the NIST Testing Process document

NIST Normative Test Process Document for §170.315(f)(1) Transmission to immunization registries

This document explains the testing process for which a National Institute of Standards and Technology (NIST) validation test tool is used in evaluating conformance of a health information technology module (Health IT Module) to the certification criterion §170.315(f)(1) Transmission to immunization registries defined in 45 CFR Part 170 of the Office of the National Coordinator for Health Information Technology (ONC), Department of Health and Human Services (HHS) 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications Final Rule.

For the ONC Approved §170.315(f)(1) Transmission to immunization registries test procedure visit <https://www.healthit.gov/policy-researchers-implementers/2015-edition-test-method>

For detailed certification criterion verbiage, please consult ONC's 2015 Edition Certification Companion Guide for Immunization Messaging https://www.healthit.gov/sites/default/files/2015Ed_CCG_f1-Trans-immunization-registries.pdf

EXPLANATION OF TERMS

Key for Names and Terms Used Frequently in this Document	
Referenced Names and Terms	Equivalent Used in Document
HL7 v2.5.1 Implementation Guide for Immunization Messaging, Release 1 and HL7 v2.5.1 Implementation Guide for Immunization Messaging (Release 1.5)—Addendum, July 2015	Immunization Messaging Guide and associated Addendum
HL7 Standard Code Set CVX—Vaccines Administered, updates through August 17, 2015	“CVX Standard Code Set” or “CVX”
National Drug Code Directory (NDC)—Vaccine NDC Linker, updates through August 17, 2015	“NDC Standard” or “NDC”
Health IT Module	“HIT Module” or “Module”
HL7 v2.5.1 Context-based capability of the NIST Immunization Test Suite	Tool

INFORMATIVE TEST DESCRIPTION

This section provides key background information for conducting the certification testing. The *Understanding Immunization Messaging ONC Certification Testing Edition 2015* document is available via the Documentation tab in the NIST Immunization Test Suite; this document is an additional resource that explains the process of Health IT Module certification testing for HL7 V2 Immunization Messaging.

This document has been developed to be used by the ONC- Accredited Testing Laboratories (ATLs) in certification of Health IT Modules for the ONC. The term 'Tester', when used in this document, refers to a person (such as an ATL employee) acting on behalf of an ATL for certification testing of a Vendor's HIT Module. In addition, a Vendor may use this document to test their own HIT Modules in preparation for certification testing by an ATL.

The test evaluates the capability for a Health IT Module to

- a) Create messages for electronic transmission that
 - Contain patient immunization information
 - Are conformant to the HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.5, and the HL7 Version 2.5.1 Implementation Guide for Immunization Messaging Release 1.5 Addendum
 - At minimum, use the HL7 Standard Code Set CVX – Vaccines Administered vocabulary standard (updates through August 17, 2015) for vaccines in an historical record
 - At minimum, use the National Drug Code Directory – Vaccine Codes (updates through August 17, 2015) for administered vaccines
- b) Receive and process electronic acknowledgement messages from an immunization registry that
 - Indicate whether any errors were found during the course of processing the patient immunization information message
 - Are conformant to the Immunization Messaging Guide and associated Addendum
- c) Create messages for electronic transmission to an immunization registry that
 - Request a patient's evaluated immunization history and immunization forecast
 - Are conformant to the Immunization Messaging Guide and associated Addendum
- d) Receive and process electronic response messages from an immunization registry that
 - Provide information related to a patient's evaluated immunization history and immunization forecast
 - Are conformant to the Immunization Messaging Guide and associated Addendum
 - Are populated with
 - Evaluated immunization history and immunization forecast information for the patient requested OR
 - Information indicating that no matches were found for the patient requested OR
 - Information indicating that too many matches were found for the patient requested

- e) Electronically display to the user the information received in the electronic response message (with information from the Health IT Module, if applicable¹) including
 - The evaluated immunization history and immunization forecast for the patient requested OR
 - A notification that no matches were found for the patient requested OR
 - A notification that too many matches were found for the patient requested

The ONC 2015 Edition Final Rule specifies the HL7 2.5.1 Implementation Guide for Immunization Messaging Release 1.5 and the associated Addendum as the messaging standard. This standard defines eight profiles, of which the following subset-pairs are in-scope for the certification testing process:

Table 1 In-Scope Immunization Profiles

Profile Pair	Description	Message Pair
Z22/Z23	Send Immunization/ACK	VXU/ACK
Z44/Z42	Query Evaluated History & Forecast/Respond Evaluated History & Forecast	QBP/RSP
Z44/Z33	Query Evaluated History & Forecast/Respond Person Not Found	QBP/RSP
Z44/Z33	Query Evaluated History & Forecast/ Respond Too many matches Found	QBP/RSP

The Test Cases included in the Context-based feature of the Tool provide pairs of Test Steps, which match up each Z22 VXU message with a corresponding Z23 ACK message and each Z44 QBP message with a corresponding Z42 RSP or Z33 RSP message.

The Centers for Disease Control and Prevention (CDC), in collaboration with the American Immunization Registries Association (AIRA) and NIST, provided the Test Cases and Test Data for this testing process.

Listed in the **Test Data section** of this document are the Test Cases that have been developed for the NIST testing process. Test Data PDF Documents, which are accessible from the NIST Immunization Test Suite identified in the **Conformance Test Tools section** of this testing process document, contain the test data that are specific to each Test Step in the Test Cases. Instructions for use of the provided test data are listed in the **Normative Test Description** and **Test Data sections** of this testing process document.

Note: Regarding Use of MVX Codes for Immunization Messages

ONC did not adopt MVX (Manufacturers of Vaccines) codes for vaccine manufacturers in the 2015 Edition Health IT Certification Criteria Final Rule and did not include MVX codes in their list of code sets. For the purposes of administered vaccines, ONC requires that the NDC (National Drug Code) be sent in the VXU

¹ This test verifies that the Health IT Module is capable of displaying the specified information in the message transmitted by the IIS. The Module may display information from the Health IT Module itself as well, but the information transmitted in the message from the IIS MUST BE displayed (since the message is processed in a test environment, the Module is only expected to know about the message the NIST Test Tool returns).

message [RXA-5] when an immunization is reported at the time it is administered when the actual product is known; and states that CVX (Vaccines Administered) codes are to be sent [RXA-5] when reporting historical vaccines. The NIST HL7 Context-based validation in the 2015 Edition Immunization Test Suite used for ONC certification testing will verify that the Health IT Module supports NDC for new immunization records and CVX for historical immunization records in HL7 immunization messages, and the Test Cases in the Test Suite (ONC 2015 Test Plan) will reflect this requirement.

A question has arisen regarding whether the MVX code should be included in the VXU message [RXA-17] when an immunization is reported at the time it is administered, since the NDC is required to be sent and an NDC typically includes the identification of the vaccine manufacturer (Note: if the NDC identifies the repackager of the vaccine, the identification of the actual vaccine manufacturer may not be readily available or apparent via that NDC).

The Immunization Messaging Guide and associated Addendum require the MVX code be sent conditionally in RXA-17 of the VXU. The Condition Predicate that triggers populating RXA-17 with the MVX code is the first occurrence of RXA-9.1 (Administration Notes-Identifier) being valued "00" (New Immunization Record, i.e., newly administered vaccine) and RXA-20 (Completion Status) being valued "CP" (Complete) or "PA" (Partially Administered).

Though ONC does not require use of MVX codes in the VXU messages created by certified Health IT Modules, the Immunization Messaging Guide does require use of MVX codes if the Condition Predicate is met. Immunization registries (IIS), which are not included in CMS Meaningful Use and are not incented to conform to the ONC health IT certification requirements, are likely to be following the Immunization Messaging Guide and associated Addendum rather than the ONC 2015 Edition Final Rule regarding use of MVX codes. To facilitate interoperability, the NIST test cases include MVX codes in accordance with the requirement in the Immunization Messaging Guide and associated Addendum, therefore, the NIST Immunization Test Suite verifies that the health IT being tested supports MVX codes for RXA-17 as well as NDC for RXA-5 (for New Immunization Records) even though certain data available via the NDC and MVX code may be redundant.

Note: Regarding Display of IIS Evaluated History and Forecast Information

- Work Flow and Pre-conditions
 - A test patient is created in the HIT Module for the Evaluated History and Forecast Test Case
 - Tester verifies that this patient has no current immunization information in their electronic record
 - Tester causes Module to create a Query for Evaluated History and Forecast, and the IIS (simulated by the NIST Test Tool) sends a Response
 - Module must display the Evaluated History and Forecast Response information returned by the IIS
- ONC Certification Testing Scope – Evaluated History and Forecast
 - ONC requirement is for the HIT Module to display Evaluated History and Forecast from IIS

- Testing environment is set up so this information sent in the RSP message from the Test Tool is the only available immunization information in the patient's electronic record
- This information must be displayed, and only display of this information for the Evaluated History and Forecast is valid for ONC certification testing
- HIT Modules can be designed to display the immunization Forecast based on data stored in the Module, but this capability is out-of-scope for ONC certification testing
- Scope of ONC certification testing is focused on verifying that the HIT Module is able to display the Evaluated History and Forecast received **from the IIS**
- Substitution of a Forecast produced from patient immunization data stored in the HIT Module is not acceptable for the ONC certification testing; the Testers will check to make sure the electronic record for the test patient has no immunization information prior to creation of the Evaluated History and Forecast Query (see first action under Required Testing Actions in **IZ_DTR - 3: Create Evaluated Immunization History and Forecast Query Messages**)
- The Juror Document used for assessing the Evaluated History and Forecast Response step indicates what information from the RSP message must be displayed, not how this information is to be displayed

NORMATIVE TEST DESCRIPTION

Using the NIST Immunization Test Tool, conformance testing can be completed in either of the following two ways:

- Single message (step by step) testing
- Multiple message (multiple step) testing

Single message (step by step) testing is a separate validation of each message in an *opened* Test Scenario or Test Case. After accessing the ONC 2015 Test Plan, *opening* a Test Scenario and then *opening* a Test Case, the Tester will *select* each of the Test Steps in their given sequence, will click on “Load Test Step”, and validate each message individually. Using the features provided on the Test Execution page of the Tool, the Tester is able to keep the default Validation Result value produced by the Tool or use the drop-down menu to select a different value; the Tester also is able to enter free-text into the Comments field by clicking on the pen icon that displays there and then typing into the field. These Validation Result values and free-text Comments become part of the Validation Report generated by the Tool. The Derived Test Requirements (DTR) listed in this document provide the detailed explanation regarding how single message is performed.

Multiple message (multiple step) testing is similar to single message (step by step) testing, except with the capability of loading a complete Test Case (all Test Steps) at once instead of selecting individual Test Steps. After accessing the ONC 2015 Test Plan and *opening* a Test Scenario, the Tester will click on a Test Case, and then will click on the “Load Test Case” button to load the complete Test Case. This mode allows the Tester to progress from one Test Step to another by clicking the “Next” button after each Test Step message is validated. Using the features provided on the Test Execution page of the Tool, the Tester is able to keep the default Validation Result value produced by the Tool or use the drop-down menu to select a different value; the Tester also is able to enter free-text into the Comments field by clicking on the pen icon that displays there and then typing into the field. These Validation Result values and free-text Comments become part of the Validation Report generated by the Tool. When all Test Steps have been validated, the Tester will click on the “Test Summary” button to complete the testing of the Test Case and download the validation reports.

Derived Test Requirements

The following two Test Requirements are to be tested as a pair using Test Steps 1 and 2 from each of the Test Cases in the **Administration Group** of the ONC 2015 Test Plan in the Tool:

IZ_DTR - 1: Create Immunization Information Messages

IZ_DTR - 2: Receive and Process Acknowledgement (ACK) Messages

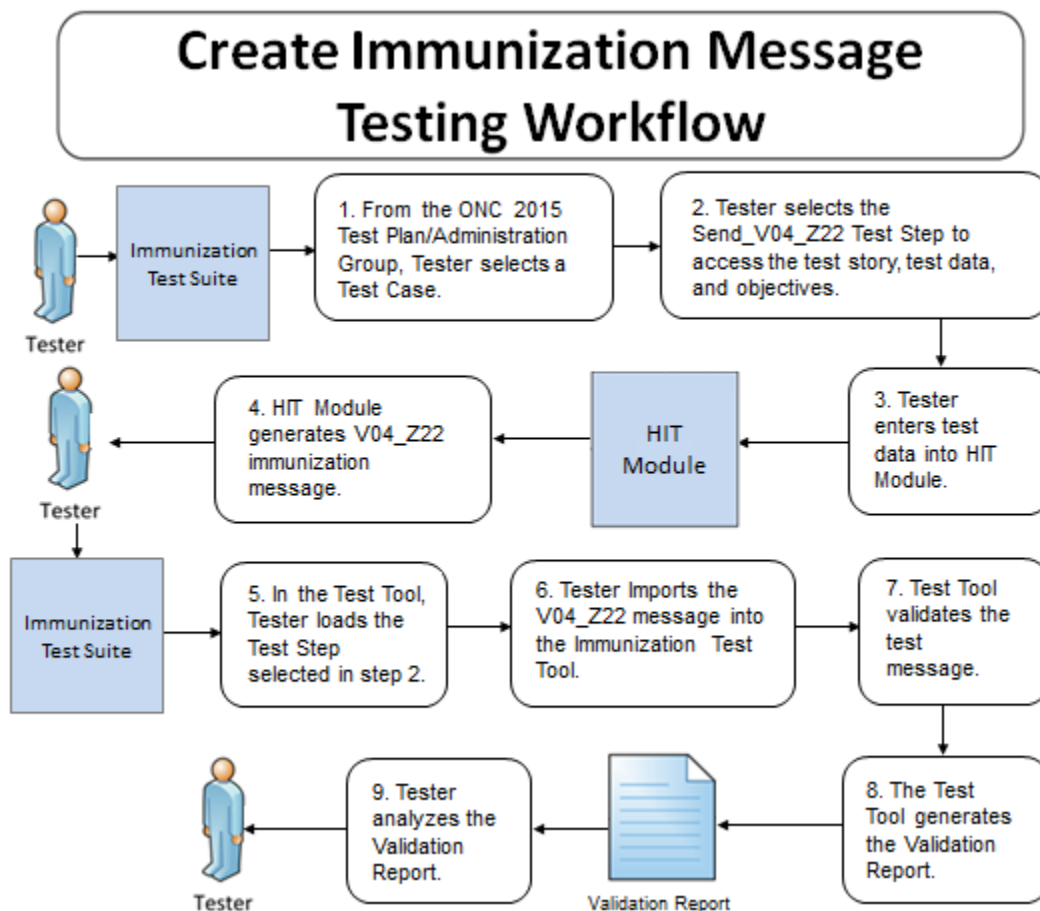
The following two Test Requirements are to be tested as a pair using Test Steps 1 and 2 from each of the Test Cases in the **Evaluated History and Forecast Group** of the ONC 2015 Test Plan in the Tool:

IZ_DTR - 3: Create Evaluated Immunization History and Forecast Query Messages

IZ_DTR - 4: Receive and Display Evaluated Immunization History and Forecast Response Messages

IZ_DTR - 1: Create Immunization Information Messages

Figure 1 Create HL7 v2.5.1 VXU Z22 Messages



The instructions in the testing process listed below reference the numbered test steps in **Figure 1**.

Required Vendor Information

1. Vendor shall identify the Health IT Module function(s) that are available to 1) create patient records in the Health IT Module and input the test data for the test patients, 2) create immunization information messages using the test data, 3) import the immunization information messages to the Tool, and 4) demonstrate support for the named standard vocabulary value sets
2. Vendor shall provide the mechanism necessary to capture and import immunization messages into the Tool

Required Testing Actions

1. Using the HL7 Context-based capability provided in the Tool identified in the **Conformance Test Tools section** of this testing process document, the Tester shall access the **ONC 2015 Test Plan** and
 - a) Select a Test Case in the Administration Group [Figure 1, Step 1]
 - b) Select the Send_V04_Z22 Test Step consisting of immunization information [Figure 1, Step 2]
2. Using the capabilities in the Health IT Module, the Tester shall
 - a) Input the provided immunization information test data using the Test Data Specification in the Tool for the Test Step (input can be performed using a manual or automated process) [Figure 1, Step 3]
 - b) Cause the Health IT Module to generate the indicated immunization information message [Figure 1, Step 4]
3. In the Tool, the Tester shall load the selected Send_V04_Z22 Test Step and import² the immunization information message generated by the Health IT Module [Figure 1, Steps 5 & 6]
4. Using the **Inspection Test Guide**, the Tester shall verify that the immunization information message is conformant to the **Referenced Standards** and that the message includes the specified immunization information

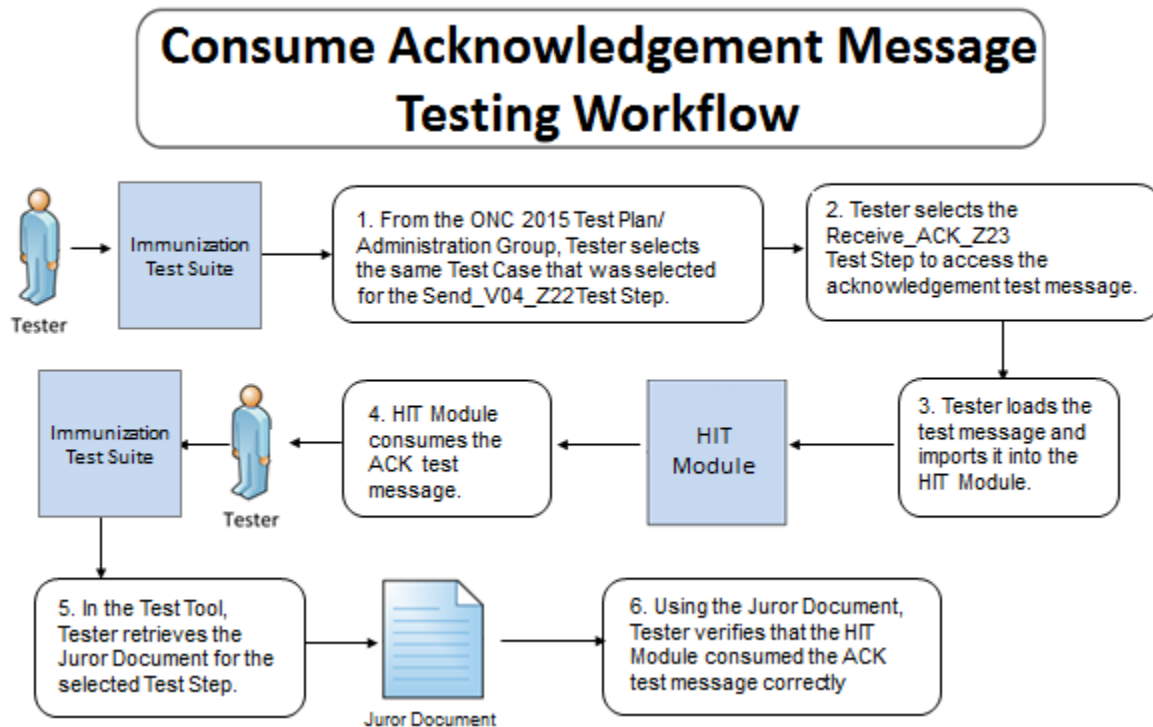
Inspection Test Guide

1. Using the Validation Report produced by the Tool, the Tester shall analyze the Report and verify that the message created by the Health IT Module meets the conformance requirements in the **Referenced Standards** [Figure 1, Step 7, 8, & 9]
2. Once during the certification testing for this criterion, the Tester shall inspect the Health IT Module to verify its ability to support the named HL7 Standard Code Set CVX -- Vaccines Administered, the National Drug Code Directory – Vaccine Codes vocabulary standard, and the value sets specified in the HL7 v2.5.1 Implementation Guide for Immunization Messaging, Release 1.5 interoperability standard
 - a) Using the functions of the Health IT Module and Tool, the Vendor shall demonstrate to the Tester that their Health IT Module supports
 - The HL7 Standard Code Set CVX -- Vaccines Administered vocabulary standard for vaccines **in an historical record**
 - The National Drug Code Directory – Vaccine Codes **for administered vaccines**
 - The CDC-defined NIP003 – Observation Identifier value set specified in the HL7 v2.5.1 Implementation Guide for Immunization Messaging, Release 1.5 interoperability standard
 - Another value set specified in the HL7 v2.5.1 Implementation Guide for Immunization Messaging, Release 1.5 interoperability standard and **selected at the tester's discretion**

² During certification testing, the mechanism by which the immunization test message is imported (sent) from or to the Health IT Module being tested is not specified. The ATL may have their own utility, they may allow the Module vendor to use a utility created by that vendor, or the message can be cut from the Module and pasted into the NIST Test Tool or cut from the NIST Test Tool and pasted into the Module. For certification testing, the key requirement is for the Module to demonstrate real time/dynamic import.

IZ_DTR - 2: Receive and Process Acknowledgement (ACK) Messages

Figure 2 Receive and Process HL7 v2.5.1 ACK Z23 Messages



The instructions in the testing process listed below reference the numbered test steps in **Figure 2**.

Required Vendor Information

- Vendor shall identify the Health IT Module function(s) that are available to 1) import the Acknowledgement messages into the Health IT Module, and 2) verify that the Acknowledgement messages are processed according to the referenced standard
- Vendor shall provide the mechanism necessary to import the Acknowledgement messages into the Health IT Module

Required Testing Actions

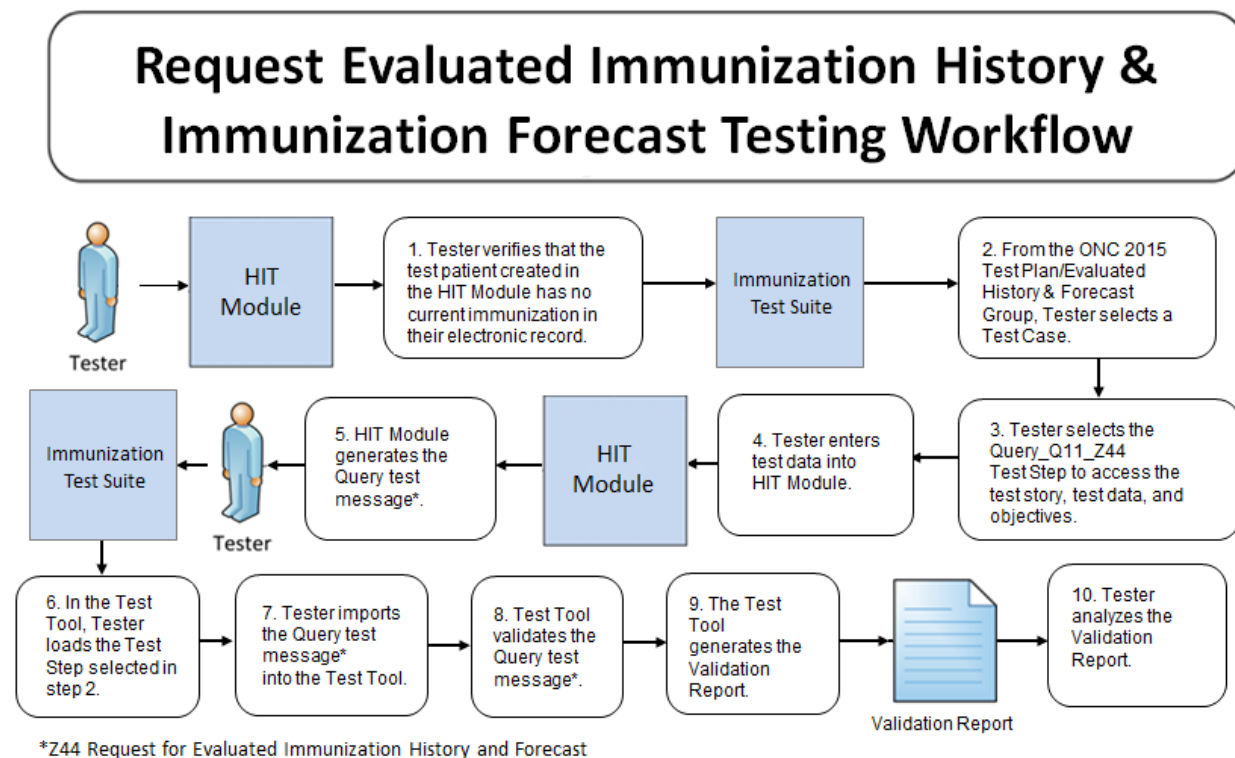
1. In the Tool, Tester shall access the same Test Case selected previously for **IZ-DTR - 1: Create Immunization Information Messages** [Figure 2, Step 1] and shall
 - a) Select the Receive_ACK_Z23 Test Step [Figure 2, Step 2]
 - b) Load the test message [Figure 2, Step 3]
2. Using the capabilities in the Health IT Module, the Tester shall import the Acknowledgement message into the Health IT Module, and the Module will consume the message [Figure 2, Steps 3 & 4]
3. In the Tool, the Tester shall retrieve the Juror Document for the selected Receive_ACK_Z23 Test Step [Figure 2, Step 5]
4. Using the **Inspection Test Guide**, the Tester shall verify that the Health IT Module consumed the Acknowledgement message correctly

Inspection Test Guide

1. Using the Test Step-specific Juror Document retrieved from the Tool, the Tester shall inspect the Health IT Module and verify that the Module processed the Acknowledgement message according to the conformance requirements in the **Referenced Standards** as indicated by the instructions in the Juror Document [Figure 2, Step 6]
 - a) For a positive Acknowledgement message, no notification need be made visible in the Health IT Module unless the Module was unable to process the message
 - i. The first six of the ten Test Cases in the Administration Group have positive acknowledgement messages; i.e., no errors are reported back to the HIT Module being tested; the Tester may choose to use only one of these first six Test Cases to complete that part of the certification testing
 - b) For Acknowledgement messages with ERR segments, the issue(s) identified in the error notification must be made visible in some manner in the Health IT Module
 - i. The last four of the ten Test Cases in the Administration Group have negative acknowledgement messages; i.e., errors or warnings are reported back to the HIT Module being tested; the Tester must use all of these last four Test Cases to complete that part of the certification testing

IZ_DTR - 3: Create Evaluated Immunization History and Forecast Query Messages

Figure 3 Create HL7 v2.5.1 Z44 Query Messages



The instructions in the testing process listed below reference the numbered test steps in **Figure 3**.

Required Vendor Information

1. Vendor shall identify the Health IT Module function(s) that are available to 1) create patient records in the Health IT Module and input the test data for the test patients, 2) create evaluated immunization history and forecast query messages using the test data, and 3) import the query messages into the Tool
2. Vendor shall provide the mechanism necessary to capture and import evaluated immunization history and forecast query messages into the Tool

Required Testing Actions

1. Using the capabilities in the Health IT Module, the Tester shall verify that the test patient used for this DTR has no current immunization information stored in their electronic record [Figure 3, Step 1]
2. In the Tool, Tester shall access the ONC 2015 Test Plan and
 - a) Select a Test Case in the Evaluated History and Forecast Group [Figure 3, Step 2]
 - b) Select the Query_Q11_Z44 Test Step [Figure 3, Step 3]
3. Using the capabilities in the Health IT Module, the Tester shall
 - a) Input the provided immunization information test data using the Test Data Specification in the Tool for the Test Step (input can be performed using a manual or automated process) [Figure 3, Step 4]

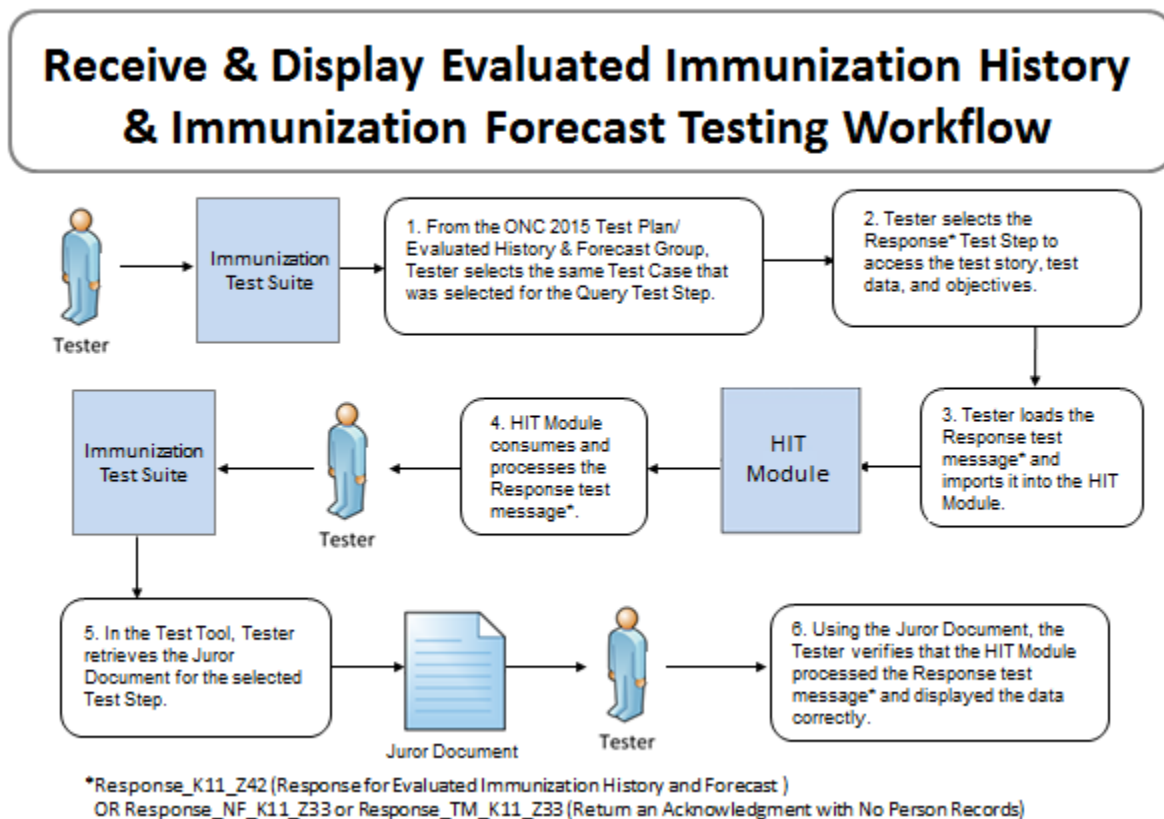
- b) Cause the Health IT Module to generate the indicated Evaluated Immunization History and Forecast query message [Figure 3, Step 5]
4. In the Tool, the Tester shall load the selected Query_Q11_Z44 Test Step and import the Evaluated Immunization History and Forecast query message generated by the Health IT Module [Figure 3, Steps 6 & 7]
5. Using the **Inspection Test Guide**, the Tester shall verify that the Evaluated Immunization History and Forecast query message is conformant to the **Referenced Standards** and that the message includes the specified query information

Inspection Test Guide

1. Using the Validation Report produced by the Tool, the Tester shall analyze the Report and verify that the Evaluated Immunization History and Forecast query message created by the Health IT Module meets the conformance requirements in the **Referenced Standards** [Figure 3, Step 8, 9, & 10]

IZ_DTR - 4: Receive and Display Evaluated Immunization History and Forecast Response Messages

Figure 4 Receive and Process HL7 v2.5.1 Z42 or Z33 Messages



The instructions in the testing process listed below reference the numbered test steps in **Figure 4**.

Required Vendor Information

1. Vendor shall identify the Health IT Module function(s) that are available to 1) import the HL7 response messages into the Health IT Module, and 2) verify that the HL7 response messages are processed according to the referenced standard
2. Vendor shall provide the mechanism necessary to import the HL7 response messages into the Health IT Module

Required Testing Actions

1. In the Tool, Tester shall access the same Test Case selected previously for **IZ-DTR - 3: Create Evaluated Immunization History and Forecast Query Messages** [Figure 4, Step 1] and shall
 - a) Select the Response (Response_K11_Z42, Response_NF_K11_Z33, or Response_TM_K11_Z33) Test Step [Figure 4, Step 2]
 - b) Load the Response test message [Figure 4, Step 3]
2. Using the capabilities in the Health IT Module, the Tester shall import the Response test message into the Health IT Module, and the Module will consume the message [Figure 4, Steps 3 & 4]
3. In the Tool, the Tester shall retrieve the Juror Document for the selected Send Response Test Step [Figure 4, Step 5]
4. Using the **Inspection Test Guide**, the Tester shall verify that the Health IT Module consumed the Response message correctly

Inspection Test Guide

1. Using the Test Step-specific Juror Document retrieved from the Tool, the Tester shall inspect the Health IT Module and verify that the Module processed the Response message according to the requirements derived from the Immunization Messaging Guide and associated Addendum as indicated by the instructions in the Juror Document [Figure 4, Step 6]
 - a) For a Response message that contains Evaluated Immunization History and Forecast information, the Health IT Module shall process the Response message and display the patient immunization information contained in the message (in a real-world setting, the patient immunization information in the message could be combined with information that is in the Health IT Module)
 - b) For a Response message that contains *no matching records were found* information, the Health IT Module shall process the Response message and display a notification indicating that the query for the Evaluated Immunization History and Immunization Forecast is complete but no matching records were found for the person in the query
 - c) For a Response message that contains *too many matches were found* information, the Health IT Module shall process the Response message and display a notification indicating that the query for the Evaluated Immunization History and Immunization Forecast is complete but too many matches were found for the patient requested

TEST DATA

Test data are provided for the testing process to ensure that the applicable requirements identified in the ONC criteria can be adequately evaluated for conformance, as well as to provide consistency in the testing process across multiple National Voluntary Laboratory Accreditation Program (NVLAP)-Accredited Testing Labs (ATLs). The provided test data focus on evaluating the basic capabilities required of the Health IT Module, rather than exercising the full breadth/depth of capability that installed Health IT Modules might be expected to support. The test data are formatted for ease of use by the Tester during the testing process; the format is not intended to prescribe the design of the display presented to the end-user for viewing the data. No additional requirements should be drawn from the format.

The Tester shall use and apply the provided test data during the testing, without exception, unless one of the following conditions exists:

- The Tester determines that the Health IT Module is sufficiently specialized that the provided test data need 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 (for example, 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 modified test data provide a comparable level of robustness.

Any departure from the provided test data shall focus on meeting the basic capabilities required of the Health IT Module relative to the certification criterion rather than exercising the full breadth/depth of capability that installed Health IT Module might be expected to support.

Using the exact test data provided for the **Evaluated Immunization History and Forecast** Query and Response messages is imperative in order to support patient matching performed by the HIT Module being tested. The NIST RSP test message is populated with fixed data based on the data expected to be in the Module. If the exact test data provided for the Query message are altered, the test data in the Response message would need to be altered exactly the same way.

The testing process requires that the Tester enter the applicable test data into the Health IT Module 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 testing process. If a situation arises where it is impractical for a Tester to enter the test data directly, 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 testing process document.

For ONC Health IT Module certification testing, the primary purpose of the provided test data is to assist the Tester in verifying that the vendor's Health IT Module is capable of supporting the required functions; verifying the ability to support the specific content is applicable only when the test data are categorized as, for example, "Value-Profile-Fixed" (see How to Interpret the Message Content Data Sheet section below for additional details about the categorization of test data). The clinical test data are relevant for the given Test Stories; however, these data should not be expected to represent standards of practice.

Test data for certification testing related to the §170.315(f)(1) Transmission to immunization registries ONC criterion are available in the Tool (see the Conformance Test Tools section of this test process document for instructions on how to access the Test Tool).

NAVIGATING A TEST CASE

An Immunization Messaging Test Case contains multiple Test Steps, each consisting of a Test Story, a Test Data Specification, a Message Content Data Sheet, and (if applicable) a Juror Document. All of these artifacts are accessible via the ONC 2015 Test Plan in the Tool.

- The Test Story describes a real-world situation that provides the context for the Test Step.
- The Test Data Specification provides the data associated with the Test Story and lists the information that would typically be available for a given situation in the specified clinical setting. Together, the Test Story and the Test Data Specification provide sufficient information for the Testers and Health IT Module Vendors to enter into the Module in order to create the HL7 v2.5.1 message for a particular Test Step. The message is to be created using these data and the Health IT Module functions.
- The Message Content Data Sheet shows a conformant message instance for the Test Step. The message content is organized in a table format that provides the HL7 v2.5.1 message elements and the data associated with the message elements for a given Test Step. The Message Content Data Sheet may provide assistance to the Tester and Health IT Module Vendor for resolving issues discovered during conformance testing. This data sheet can be thought of as the "answer" to the scenario ("question") provided by the Test Story and the Test Data Specification.
- The Juror Document provides a checklist for the Tester to use during certification testing for assessing the Health IT Module's ability to display required data elements from the information received in the immunization message. Additional data from the message or from the Health IT Module are permitted to be displayed by the Module. Grayed-out fields in the Juror Document indicate where no data for a given data element were included in the message for the particular Test Case. The format of the Juror Document is for ease-of-use by the Tester and does not indicate how the Health IT Module display must be designed.

For the Immunization Messaging ONC certification testing process, the Tester shall select the **ONC 2015 Test Plan** in the **HL7 Context-based** capability of the Tool. The ONC 2015 Test Plan consists of two Groups of Test Cases:

- 10 Administration Test Cases

- 4 Evaluated History and Forecast Test Cases

Each Test Case listed in the two Groups consists of a pair of Test Steps that are to be used together to test the Health IT Module for Message Created and Message Returned capabilities (the Test Steps provide data that may be used for an ambulatory or an inpatient Health IT Module). **Table 2** (Immunization Test Cases and Associated Test Steps) lists the two Groups, the Test Cases, and the two Test Steps for each Test Case.

Note:

- The first six of the ten Test Cases in the Administration Group have positive acknowledgement messages; i.e., no errors are reported back to the HIT Module being tested; the Tester may choose to use only one of these first six Test Cases to complete that part of the certification testing
- The last four of the ten Test Cases in the Administration Group have negative acknowledgement messages; i.e., errors or warnings are reported back to the HIT Module being tested; the Tester must use all of these last four Test Cases to complete that part of the certification testing

Table 2 Immunization Test Cases and Associated Test Steps

Test Cases	Message Created – Step 1	Message Returned – Step 2
Administration Group	Send Administration Message	Consume Acknowledgement Message
IZ-AD-1 Admin Child	IZ-AD-1.1 Send_V04_Z22	IZ-AD-1.2 Receive_ACK_Z23
IZ-AD-2 Admin Adult	IZ-AD-2.1 Send_V04_Z22	IZ-AD-2.2 Receive_ACK_Z23
IZ-AD-3 Child No Consent	IZ-AD-3.1 Send_V04_Z22	IZ-AD-3.2 Receive_ACK_Z23
IZ-AD-4 Delete Record	IZ-AD-4.1 Send_V04_Z22	IZ-AD-4.2 Receive_ACK_Z23
IZ-AD-5 Refusal	IZ-AD-5.1 Send_V04_Z22	IZ-AD-5.2 Recieve_ACK_Z23
IZ-AD-6 Update Record	IZ-AD-6.1 Send_V04_Z22	IZ-AD-6.2 Receive_ACK_Z23
IZ-AD-7 Historical IIS Error	IZ-AD-7.1 Send_V04_Z22	IZ-AD-7.2 Receive_ACK_Z23
IZ-AD-8 Admin IIS Warning	IZ-AD-8.1 Send_V04_Z22	IZ-AD-8.2 Receive_ACK_Z23
IZ-AD-9 Admin IIS 2Warnings	IZ-AD-9.1 Send_V04_Z22	IZ-AD-9.2 Receive_ACK_Z23
IZ-AD-10 Historical IIS SysError	IZ-AD-10.1 Send_V04_Z22	IZ-AD-10.2 Receive_ACK_Z23
Evaluated History and Forecast Group	Send Query Message	Receive Response Message
IZ-QR-1 Query Child	IZ-QR-1.1 Query_Q11_Z44	IZ-QR-1.2 Response_K11_Z42
IZ-QR-2 Query Adult	IZ-QR-2.1 Query_Q11_Z44	IZ-QR-2.2 Response_K11_Z42
IZ-QR-3 Query No Patients	IZ-QR-3.1 Query_Q11_Z44	IZ-QR-3.2 Response_NF_K11_Z33
IZ-QR-4 Query Too Many	IZ-QR-4.1 Query_Q11_Z44	IZ-QR-4.2 Response_TM_K11_Z33

Details for each Test Step, including the test story, test objectives, test data, example HL7 message, and (if applicable) the Juror Document, are provided via the tabs that are displayed when a user selects a Test Step in the Context-based feature of the Tool, and also are available in PDF files accessible via the tabs displayed with the Test Step as well as via the Test Suite Documentation tab. The Tester shall follow the instructions in the **Normative Test Description** section of this testing process document to conduct the certification testing.

HOW TO INTERPRET THE MESSAGE CONTENT DATA SHEET

The Message Content Data Sheet indicates the data that are to be included in the immunization test message based on the test data entered into the Health IT Module for a particular Test Step. **Table 3** shows a portion of a Message Content Data Sheet.

Table 3 Message Content Data Sheet Excerpt for PID Segment in an Immunization Message

Location	Data Element	Data	Categorization
PID-1	Set ID - PID	1	Value-Profile Fixed
PID-3	Patient Identifier List		
PID-3.1	ID Number	3123	Presence-Content Indifferent
PID-3.3	Check Digit Scheme		Indifferent
PID-3.4	Assigning Authority		
PID-3.4.1	Namespace ID	WcEHR	Presence-Content Indifferent
PID-3.4.2	Universal ID		Indifferent
PID-3.4.3	Universal ID Type		Indifferent
PID-3.5	Identifier Type Code	MR	Presence-Content Indifferent
PID-5	Patient Name		
PID-5.1	Family Name		
PID-5.1.1	Surname	Richardson	Presence-Content Indifferent
PID-5.1.2	Own Surname Prefix		
PID-5.1.3	Own Surname		
PID-5.1.4	Surname Prefix From Partner/Spouse		
PID-5.1.5	Surname From Partner/Spouse		
PID-5.2	Given Name	Russell	Presence-Content Indifferent
PID-5.3	Second and Further Given Names or Initials Thereof	Clint	Presence-Content Indifferent
PID-5.7	Name Type Code	L	Presence-Content Indifferent
PID-6	Mother's Maiden Name		
PID-6.1	Family Name		
PID-6.1.1	Surname	Billington	Presence-Content Indifferent
PID-6.1.2	Own Surname Prefix		
PID-6.1.3	Own Surname		
PID-6.1.4	Surname Prefix From Partner/Spouse		
PID-6.1.5	Surname From Partner/Spouse		
PID-6.7	Name Type Code	M	Value-Profile Fixed
PID-7	Date/Time of Birth		
PID-7.1	Time	20150415	Presence-Content Indifferent
PID-8	Administrative Sex	M	Presence-Content Indifferent
PID-10	Race		
PID-10.1	Identifier	1002-5	Presence-Content Indifferent

The information in the **Location** column indicates the canonical element location in the HL7 V2 message. For example, PID-3.5 represents the 5th component in the 3rd field of the PID segment. The **Data Element** column indicates the name of the data element as specified by the Immunization Messaging Guide. The **Test Data** column lists the data to be included for each Data Element in the immunization message created by the Health IT Module.

The **Categorization** column indicates the type and expected source of the data as well as how the Context-based feature in the Tool will validate the data for the given Data Element in the immunization message. In some cases the test tool validator simply examines the message element for the presence of data, whereas in other cases the validator examines the message element for the presence of data and for exact content. **Table 4** shows descriptions of the test data Categories and their associated Qualifiers. Additional information about the test data Categories and Qualifiers is available in the *Understanding Immunization Messaging ONC Certification Testing Edition 2015* document, which is accessed via the Documentation tab in the NIST Immunization Test Suite.

Table 4 Test Data Categories, Associated Qualifiers, and Descriptions

Test Data Categorization	Description	Qualifier	Description
Indifferent	No content is specified.	None	None
Presence	Example content is specified.	Content Indifferent	Content is expected to be present in the message, but not a specific value.
		Configuration	Content is expected to be present in the message, but not a specific value. The value is usually determined at installations.
		System Generated	Content is expected to be present in the message, but not a specific value. The value is system generated.
		Test Case Proper	Content is expected to be present in the message, but not a specific value. However, content is expected to be consistent with the clinical test story.
Presence-Length	Example content is specified to a minimum length.	Same qualifiers as for Presence	Content of a minimum length is expected to be present in the message, but not a specific value.
Value	Specific content is specified.	Profile Fixed	Content is defined as a constant in the conformance profile. The constant is specified in the test data.
		Profile Fixed - List	Content is defined as a set of allowable values in the conformance profile. One value from the allowable set is specified in the test data.
		Test Case Fixed	Content that is defined as a constant in the test case.
		Test Case Fixed - List	Content is defined as a set of allowable values in the test case. One value from the allowable set is specified in the test data.
Non-presence	No content is explicitly specified.	None	None

Along with the Test Data Specification, the Message Content Data Sheet can be used to assist the Tester and Health IT Module Vendor in loading the test data into the Module for a given Test Step.

The Test Cases and the Context-based feature in the Tool are tightly-coupled. In addition to validating message conformance, the test tool performs selective content validation based on the test data provided, and deviation from the test data may cause the test tool to issue Error notifications. For this reason, the Tester should use the test data as specified.

CONFORMANCE TEST TOOLS

The following testing tools are available to evaluate conformance to the standards referenced in this testing process document:

- HL7 v2 Immunization Test Suite – an HL7v2 messaging validation tool; designed to support the NIST testing process for ONC Health IT Certification testing as well as other immunization message testing
- The tool is available as a Web Application
- The application can be downloaded for local installation
- The Immunization Test Suite Web Application is available at:
<http://hl7v2-iz-r1-5-testing.nist.gov>

Support for these tools is available by submitting questions to the following user's group:

<https://groups.google.com/d/forum/hl7v2-immunization-testing>.

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

Several browsers may be used to access the HL7 v2 Immunization Test Suite tool; Firefox or Google Chrome are the supported browsers. The Test Suite 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 Validation Reports generated by the HL7v2 Immunization Test Suite tool:

The Context-based capability in the HL7v2 Immunization Test Suite tool evaluates conformance requirements that are specified or have been derived from the standards and implementation guides identified in the 2015 Edition of the ONC Final Rule and the test data provided for this testing process. The Test Suite tool evaluates the submitted HL7 message for each conformance requirement, and then produces a Validation Report.

The Tester should consider a Report that contains only Affirmative and Warning messages to be indicative of a sufficient level of conformance to the standard and test data expectations. If reported, Errors should be considered significant departures from the standard or test data requirements, and these Errors must 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 testing process by the Health IT Module.

Document History

Version Number	Description of Change	Date Published
1.0	Approved Normative Test Process Document	January 21, 2016
1.1	<p>Normative Test Description Section</p> <p>IZ_DTR - 1: Create Immunization Information Messages</p> <p><u>Inspection Test Guide</u></p> <p>2) a)</p> <ul style="list-style-type: none"> The CDC-defined NIP003 – Immunization information source value set specified in the HL7 v2.5.1 Implementation Guide for Immunization Messaging, Release 1.5 interoperability standard <p>Changed to</p> <ul style="list-style-type: none"> The CDC-defined NIP003 – Immunization observation identifier value set specified in the HL7 v2.5.1 Implementation Guide for Immunization Messaging, Release 1.5 interoperability standard 	January 21, 2016
1.2	<p>Normative Test Description Section</p> <p>IZ_DTR - 1: Create Immunization Information Messages</p> <p><u>Inspection Test Guide</u></p> <p>2) a)</p> <ul style="list-style-type: none"> The CDC-defined NIP003 – Immunization observation identifier value set specified in the HL7 v2.5.1 Implementation Guide for Immunization Messaging, Release 1.5 interoperability standard <p>Changed to</p> <ul style="list-style-type: none"> The CDC-defined NIP003 – Observation Identifier value set specified in the HL7 v2.5.1 Implementation Guide for Immunization Messaging, Release 1.5 interoperability standard 	February 22, 2016
1.3	<p>Normative Test Description Section</p> <ul style="list-style-type: none"> Verbiage was added at the beginning of this section to explain in detail the two ways that the ONC Certification testing can be completed using the Immunization Test Tool, including: <ul style="list-style-type: none"> Single message (step by step) testing Multiple message (multiple step) testing <p>Conformance Test Tools Section</p> <ul style="list-style-type: none"> Verbiage explaining about required sequencing of fields/segments/segment groups in the message was deleted; this design has been changed and the specified sequencing is no longer required 	May 5, 2016
1.4	<p>“2015 Edition” removed from Cover Page</p> <p>“Edition 2015” removed from Page Headings</p> <p>Explanatory note added to Cover Page</p> <p>URL to NIST Immunization Test Suite updated on page 21</p>	March 25, 2024