

HITSP Lab Result Message Component

HITSP/C36



Healthcare Information Technology Standards Panel

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1.0 INTRODUCTION

1.1 OVERVIEW

The purpose of this document is to describe the specification for a constrained Health Level Seven (HL7) Version 2.5.1 ORU – Unsolicited Observation Message – (Event R01). The goals supported by this Component specification are stated in the AHIC Electronic Health Record (EHR) and Biosurveillance Use Cases:

- Transmission of complete, preliminary, final and updated laboratory results to the EHR system (local or remote) of the ordering clinician
- Transmission of complete, preliminary, final and updated (or notification of) laboratory results to the EHR system (local or remote) or other clinical data system of designated providers of care (with respect to a specific patient)
- Transmission of laboratory result data from electronically enabled healthcare delivery and public health systems in standardized and anonymized format to authorized Public Health Agencies with less than one day lag time

The Use Cases note that there are obstacles to achieving the stated goals. In particular, the following obstacle is delineated:

- Lack of harmonization among data interoperability standards including vocabulary, laboratory and other messaging standards

This Healthcare Technology Standards Panel (HITSP) Lab Result Message Component is the result of a considered assessment of the current practices in electronic laboratory results reporting and the requirements of the Use Case. Following the EHR Use Case as used by HITSP in consultation with the Department of Health and Human Services (HHS), the Office of the National Coordinator (ONC) and the American Health Information Community (AHIC), this scope includes laboratory results and interpretations from ambulatory, inpatient and other care settings. In order to encourage rapid and widespread adoption of this Component, HITSP placed emphasis on the message content in current implementations and the ease with which current implementations can become compliant. HL7 Version 2.x message-based laboratory result reporting is the most common electronic interface in existence today and HITSP did not want to invalidate those interfaces.

1.2 COPYRIGHT PERMISSIONS

COPYRIGHT NOTICE

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1.3 REFERENCE DOCUMENTS

This section provides a list of key reference documents and background material.

A list of key reference documents and background material is provided in the table below. These documents can be retrieved from www.hitsp.org.

Table 1-1 Reference Documents

Reference Document	Document Description
HITSP Acronyms List	Lists and defines the acronyms used in this document
HITSP Glossary	Provides definitions for relevant terms used by HITSP documents



Reference Document	Document Description
TN900 - Security and Privacy	TN900 is a reference document that provides the overall context for use of the HITSP Security and Privacy constructs
TN903 – Data Architecture	TN903 is a reference document that provides the overall context for use of the HITSP Data Architecture constructs

1.4 CONFORMANCE

This section describes the conformance criteria, which are objective statements of requirements that can be used to determine if a specific behavior, function, interface, or code set has been implemented correctly.

As this Component is based upon an HL7 message standard, the provided tools available for conformance checking (Message Workbench) rely on HL7 interpretations of these usage indicators. HL7 V2.5.1 does not support a unique instance identifier for an OBX. Therefore, until after the HL7 Implementation Guide is updated to v.2.6+, this means only “snapshot” mode will exist in the current edition of the specification.

1.4.1 CONFORMANCE CRITERIA

In order to claim conformance to this construct specification, an implementation must satisfy all the requirements and mandatory statements listed in this specification, the associated HITSP Interoperability Specification, its associated construct specifications, as well as conformance criteria from the selected base and composite standards. A conformant system must also implement all of the required interfaces within the scope, subset or implementation option that is selected from the associated Interoperability Specification.

Claims of conformance may only be made for the overall HITSP Interoperability Specification or Capability with which this construct is associated.

1.4.2 CONFORMANCE SCOPING, SUBSETTING AND OPTIONS

A HITSP Interoperability Specification must be implemented in its entirety for an implementation to claim conformance to the specification. HITSP may define the permissibility for interface scoping, subsetting or implementation options by which the specification may be implemented in a limited manner. Such scoping, subsetting and options may extend to associated constructs, such as this construct. This construct must implement all requirements within the selected scope, subset or options as defined in the associated Interoperability Specification to claim conformance.



2.0 COMPONENT DEFINITION

2.1 CONTEXT OVERVIEW

This Component specification is based on the HL7 U.S. Realm - Interoperability Specification: Lab Result Message to EHR (ORU^R01) (HL7 Version 2.5.1), which successfully passed ballot in November 2007. It has also been informed by IHE Laboratory Technical Framework Supplement 2006-2007 Revision 1.0 (XD*-Lab) and the extensive experience of HITSP members in developing laboratory interfaces using HL7 messages.

The HL7 Lab Result Message specification describes the structure and data fields for the HL7 Version 2.5.1 ORU – Unsolicited Observation Message – (Event R01) as constrained for the AHIC EHR and Biosurveillance Use Cases. In order to satisfy both Use Cases some segments and data fields are included that are needed by only one of the Use Cases, but since both require the same core information, they were combined. This allows a laboratory to implement a single message for both situations. The fields not required by either the EHR or Biosurveillance Use Cases are shown with a usage of Optional (O). This allows existing implementations to continue to utilize these fields for local purposes.

The context for the Lab Result Message has the premise that a laboratory has received an order to perform a test. The test has been performed and the results, preliminary or final, are releasable to be reported back to the ordering clinician. It does not matter if the order was a paper order or an electronic order. If it is a paper order, the laboratory enters the order information into the Laboratory Information System (LIS), including the placer order number and then the LIS collects the results from the instruments or through manual data entry.

2.1.1 COMPONENT CONSTRAINTS

Table 2-1 Component Constraints

Constraint	Constraint Section
HITSP has applied constraints to message content	See Table 2-3

2.1.2 COMPONENT DEPENDENCIES

Table 2-2 Component Dependencies

Standard/HITSP Component	Depends On (Name of standard/HITSP Component that it depends on)	Dependency Type (Pre-condition, Post-condition, General)	Purpose (Reason for this dependency)
HITSP/C36-Lab Result Message	HITSP/C35-Lab Result Terminology	General	Supplies required vocabulary guidance information to be applied within the exchange
HITSP/C36-Lab Result Message	HL7 U.S. Realm - Interoperability Specification: Lab Result Message to EHR (ORU^R01) (HL7 Version 2.5.1)	General	Defines data structure requirements
HITSP/C36-Lab Result Message	HITSP/C154 HITSP Data Dictionary	General	Identifies HITSP Data Elements that map to the HL7 Data Elements constrained by this Component

2.2 RULES FOR IMPLEMENTING

The HL7 U.S. Realm - Interoperability Specification: Lab Result Message to EHR (ORU^R01) (HL7 Version 2.5.1) specification provides the implementation requirements for this Component. The specification also defines all of the fields necessary to report microbiology results, but the mechanism for encoding these results in the HL7 Version 2.5.1 ORU – Unsolicited Observation Message – (Event R01)



is complicated. It involves linking segments within a message and linking parent messages to children messages. This complication is necessary to allow the flexibility to report multiple organisms and multiple susceptibilities for each organism while still providing an unambiguous method for updating results. Additional explanation for the linking is provided in Appendix A. "HL7 Reporting of Culture and Susceptibilities" of the HL7 Lab specification.

Further considerations are as follows:

- Before this message can be sent, the order and specimen must have been received by the laboratory and the ordered test performed. Information about the patient, the order, the specimen and the test is releasable by the sender of this message
- The trigger for this message varies depending on the circumstance. It may be a routine report from a laboratory to the ordering provider or it may be something more complicated like a report to a public health agency. These triggers are described in higher-level specifications that include this Component
- The post-condition for this message transmission is that the receiver is able to accept the transmission and parse the content. Additional post-conditions may be described in higher level specifications that include this Component
- The output from this message transmission is the message itself. The use of the information is dependent on the circumstances. These circumstances are described in higher level specifications that include this Component

2.2.1 DATA MAPPING

C36-[MSG-1-1] Implementations **SHALL** support the Health Level Seven (HL7) U.S. Realm - Interoperability Specification: Lab Result Message to EHR (ORU^R01) (HL7 Version 2.5.1) September, 2007

C36-[MSG-1-2] Implementations **SHALL** follow the minimum data set for all fields and segments as specified by the Health Level Seven (HL7) U.S. Realm - Interoperability Specification: Lab Result Message to EHR (ORU^R01) (HL7 Version 2.5.1) September, 2007, as well as any additional fields required by local usage

2.2.1.1 GUIDANCE ON SECTION 5.1.2 SPM – SPECIMEN SEGMENT

The HL7 specification does not provide guidance on optional fields. However the following table provides additional guidance for the Specimen Collection Site data element in the Specimen Message Segment (SPM):

Table 2-3 Specimen Message Segment

HL7 V2 Data Element	HITSP Data Element Identifier and Name	Optionality ¹	Additional Specification
SPM.10 - Specimen Collection Site	17.06 Body Site	O	C36-[DE-17.06-1] The Site SHALL be coded as specified in HITSP/C80 Section 2.2.3.2.1 Body Site

¹ Optionality = "R" for Required, "R2" for Required if Known or "O" for Optional, or "C" for Conditional.



2.3 STANDARDS

2.3.1 REGULATORY GUIDANCE

Table 2-4 Regulatory Guidance

Standard	Description
Clinical Laboratory Improvement Amendments (CLIA) of 1988	Establishes quality standards for all laboratory testing to ensure the accuracy, reliability, and timeliness of patient test results regardless of where the test is performed. The Centers for Medicare and Medicaid Services (CMS) regulates all laboratory testing (except research) performed on humans in the U.S. based on CLIA. For more information visit http://www.fda.gov and http://www.cms.hhs.gov

2.3.2 SELECTED STANDARDS

Table 2-5 Selected Standards

Standard	Description
Health Level Seven (HL7) U.S. Realm - Interoperability Specification: Lab Result Message to EHR (ORU^R01) (HL7 Version 2.5.1) September, 2007	This guide contains the necessary specifications for clinical laboratory results reporting to EHRs for use in the U.S. Realm. For more information visit www.hl7.org
Health Level Seven (HL7) Version 2.5.1	The HL7 Version 2.5.1 Messaging Standard is an application protocol for electronic data exchange in healthcare. It and prior versions have widespread use in the U.S. and internationally. Both message formats and value sets / code tables (e.g., diagnosis type, gender, patient class, result status, specimen collection method, abnormal flags, observation result status codes interpretation, timestamp format) are contained in the standard. Of particular focus for HITSP Interoperability Specifications are message formats described in Chapters 2, 3, 4, 5, and 7 including patient demographic (ADT) and lab result reporting. These are also used within composite standards from IHE for Patient Identity Cross-Referencing and Feed (PIX), Patient Demographics Query (PDO) and Acknowledgements. They are also used in HL7 order messages. For more information visit www.hl7.org
International Health Terminology Standards Development Organisation (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®)	SNOMED CT consists of a technical design, core content architecture, and Core content. SNOMED CT Core content includes the technical specification of SNOMED CT and fully integrated multi-specialty clinical content. The Core content also includes a concepts table, description table, relationships table, history table, ICD-9-CM mapping, and Technical Reference Guide. Additionally, SNOMED CT provides a framework to manage language dialects, clinically relevant subsets, qualifiers and extensions, as well as concepts and terms unique to particular organizations or localities. For more information visit www.ihtsdo.com

2.3.3 INFORMATIVE REFERENCE STANDARDS

Table 2-6 Informative Reference Standards

Standard Name	Description/Reason for Use
No applicable informative reference standards	



3.0 APPENDIX

The following sections include relevant materials referenced throughout this document.

- A listing of all HITSP Constraints defined within this document.

3.1 HITSP CONSTRAINTS DEFINED IN THIS DOCUMENT

C36-[MSG-1-1] Implementations **SHALL** support the Health Level Seven (HL7) U.S. Realm - Interoperability Specification: Lab Result Message to EHR (ORU^R01) (HL7 Version 2.5.1) September, 2007

C36-[MSG-1-2] Implementations **SHALL** follow the minimum data set for all fields and segments as specified by the Health Level Seven (HL7) U.S. Realm - Interoperability Specification: Lab Result Message to EHR (ORU^R01) (HL7 Version 2.5.1) September, 2007, as well as any additional fields required by local usage

C36-[DE-17.06-1] The Site SHALL be coded as specified in HITSP/C80 Section 2.2.3.2.1 Body Site



4.0 CHANGE HISTORY

The following sections provide the history of changes made to this document.

4.1 DECEMBER 13, 2007

Upon approval by the HITSP Panel on December 13, 2007, this document is now Released for Implementation.

4.2 MARCH 19, 2008

This document has been updated to include the HITSP Security and Privacy constructs and has been updated to reflect the new template.

The following changes have been made to the construct:

- Update HL7 reference in section 2.2
- Moved text from section 2.2 to 2.2.1 per reviewer comment
- Deleted Section 2.1.3 – Technical Interfaces –interfaces already documented in IS Table 3.2.1-1
- Removed HIPAA and CLIA from Table 2.3-1 as these are guiding regulations, not standards

4.3 MARCH 27, 2008

Upon approval by the HITSP Panel on March 27, 2008, this document is now Released for Implementation.

4.4 AUGUST 20, 2008

This document has been modified to reflect the updated HITSP approach to categorizing standards as Regulatory Guidance, Selected Standards, and Informative References.

The following standard was added as Regulatory Guidance:

- Clinical Laboratory Improvement Amendments (CLIA) of 1988

The following standard was added as Selected:

- International Health Terminology Standards Development Organisation (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®)

4.5 AUGUST 27, 2008

Upon approval by the HITSP Panel on August 27, 2008, this document is now Released for Implementation.

4.6 JUNE 30, 2009

Minor editorial changes were made to this document. Removed boilerplate text for simplification. The term “actor” was replaced with “interface”.

4.7 JULY 8, 2009

Upon approval by the HITSP Panel on July 8, 2009, this document is now Released for Implementation.

4.8 SEPTEMBER 30, 2009

This document has been modified to reflect HITSP TN903 Data Architecture approach.



The following changes have been made:

- Section 1.3 Table 1-1 Addition of TN903 as a reference
- Section 2.1.1 Table 2-1 update of Component Constraints
- Section 2.1.2 Table 2-2 added reference to HITSP/C154 Data Dictionary
- Section 2.2.1 Formatting of Message Data Mapping requirements to Message Constraints
- Section 2.2.1.1 Table 2-3 Formatting of Data Element Mapping and Constraint Requirements
- Section 3.0 Addition of HITSP Constraints in this document as a reference

