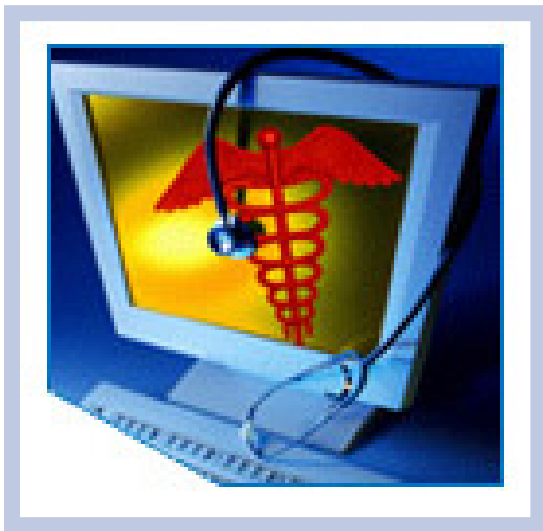


HITSP Lab Result Message Component

HITSP/C36



Submitted to:

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Submitted by:

Care Management and Health Records Domain Technical Committee



DOCUMENT CHANGE HISTORY

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1.0 INTRODUCTION

As an introduction to the HITSP Lab Result Message Component, this section provides a high level overview of the information sharing scenario enabled by following this specification, provides a document map of the construct relationships for this specification, acknowledges the copyright protections that pertain and provides a list of key reference documents and background material. If you are already familiar with this information, proceed to Section 2.0 Component Definition.

1.1 OVERVIEW

This section describes the contents of this specification and provides a high level definition of this Component and background information about the underlying standards that the Component is based on.

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 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, the HITSP Technical Committee 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

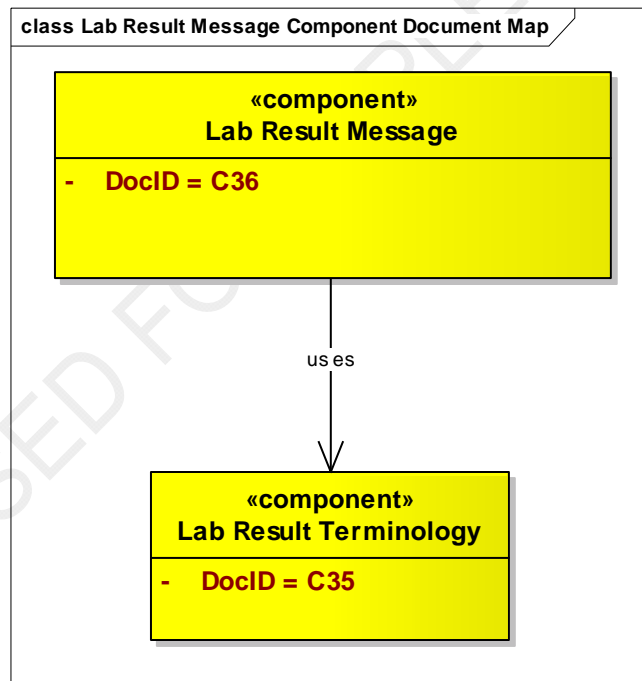


the most common electronic interface in existence today and the HITSP Technical Committee did not want to invalidate those interfaces.

1.2 COMPONENT DOCUMENT MAP

Each HITSP specification describes a suite of constructs that, taken as a whole, define how to integrate and constrain existing standards and specifications that will satisfy the requirements for the HITSP construct. There are four types of HITSP constructs called Interoperability Specifications (IS), Transaction Packages (TP), Transactions (T), and Components (C). Interoperability Specifications define the context(s) in which any other HITSP construct may be used. The current Lab Result Message Component specification is used with other constructs to meet the requirements of one or more ISs. Review Section 1.2 Interoperability Specification Document Map from the relevant IS to better understand the context, dependencies, and relationships between the constructs used to meet the IS requirements. The Document Map in Figure 1.2-1 depicts how this construct integrates and constrains HITSP constructs to support the information exchange, within the defined context of this document. Implementers should read the documents that describe the constructs depicted in the diagram for their details and specific uses.

Figure 1.2-1 Component Document Map



1.3 COPYRIGHT PERMISSIONS

COPYRIGHT NOTICE

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Certain materials contained in this document are reproduced from HL7 Version 2.5.1 and HL7 U.S. Realm – Interoperability Specification: Lab Result Message to EHR with permission of Health Level Seven, Inc. No part of the material may be copied or reproduced in any form outside of the Interoperability Specification documents, including an electronic retrieval system, or made available on the Internet without the prior written permission of Health Level Seven, Inc. Copies of standards included in this Interoperability Specification may be purchased from the Health Level Seven, Inc. Material drawn from these standards is credited where used.

This material includes SNOMED Clinical Terms(r) (SNOMED CT(r)) which is used by permission of the International Health Terminology Standards Development Organisation (IHTSDO). All rights reserved. SNOMED CT(r) was originally created by The College of American Pathologists. "SNOMED" and "SNOMED CT" are registered trademarks of the IHTSDO.

1.4 REFERENCE DOCUMENTS

This section provides a list of key reference documents and background material. If you are already familiar with this information, proceed to Section 2.

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

Table 1.4-1 Reference Documents

Reference Document	Document Description
HITSP Interoperability Specification Overview	Provides background information about the HITSP and its role in the overall U.S. efforts to realize large scale interoperability of health information. The document also provides a description of the HITSP process for healthcare standards harmonization and explains how to use the Interoperability Specifications and other related documents to inform your health IT product development or product refinement
HITSP Conventions List	Describes the conventions that are used to convey the full descriptions and usage of standards in the HITSP specifications
HITSP Acronyms List	Lists and defines the acronyms used in this document
HITSP Glossary	Provides definitions for relevant terms used by HITSP documents
HITSP Harmonization Framework	Describes the current framework within which the Interoperability Specifications are built



Reference Document	Document Description
TN900 - Security and Privacy Technical Note	<p>Developed as a reference document to provide the overall context for use of the HITSP Security and Privacy constructs. It includes the following:</p> <ul style="list-style-type: none"> • The scope, reference policy background, and Security and Privacy principles used in the development of the constructs • A detailed description and schematics of the conceptual relationship between the Security and Privacy constructs • A mapping of existing standards and constructs to be used in meeting the stated requirements of the AHIC Use Cases • A list of identified gaps and the recommended approaches to resolving those gaps • A roadmap for how the Security and Privacy constructs will evolve and eventually align with other HITSP Interoperability Specifications • A conceptual framework for Security and Privacy management, including reference information on privacy policies, risk assessment, and risk management • A glossary of terms used in all the Security and Privacy construct documents • A description of the application of the Security and Privacy constructs to the HITSP Interoperability Specifications for the three initial AHIC Use Cases – Biosurveillance, Electronic Health Records - Laboratory Results Reporting, and Consumer Empowerment <p>HITSP will periodically update this Technical Note as required by the introduction of new contexts for use.</p>



2.0 COMPONENT DEFINITION

A Component defines atomic constructs used to support an information exchange or to meet an infrastructure requirement. This is accomplished by:

- (a) Referencing one or more underlying standards
- (b) Specifying constraints and other rules for using the standards

2.1 CONTEXT OVERVIEW

This section provides a general description of the Component. It includes a detailed definition of the Component and the reason for its use. It also provides all the necessary background information that further describes the context in which the Component is needed and the base or composite standard that the Component is based on.

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 the HITSP panel 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

This section describes the constraints that limit the context in which the Component may be used. A constraint describes a rule that limits the use of the actors, actions or data within the given context or to which the interactions must conform to be used within the described context. It is a description of the



limits and scope of the interactions and can describe actions or events that are not part of the initial definition for the context.

Table 2.1.1-1 Component Constraints

Constraint	Constraint Section
No applicable component constraints	

2.1.2 COMPONENT DEPENDENCIES

This section describes any specific mapping criteria for the standards underlying the Component. It elaborates on the relationships between different standards used by this Component and how they map to each other. Additional required mapping criteria not currently enforced by the underlying standards and any specific elements that are required for this mapping to succeed are also provided.

Table 2.1.2-1 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

2.2 RULES FOR IMPLEMENTING

The following section documents the content of the Component. It provides the basic elements and secondary standards that are supported by this Component and the constraints that are being placed on those standards. Specifically, it describes the subset or constraints that are required for this Component and the minimum attributes of the Component as it relates to the base or composite standards on which it is based.

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 has also attempted to define 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

This section describes the specific data elements used by this Component. Due to the potentially large number of data elements in a particular standard, only the fields that HITSP is constraining differently from the standard will be described here.

The data structure is defined in “HL7 U.S. REALM - INTEROPERABILITY SPECIFICATION: LAB RESULT MESSAGE TO EHR (ORU^R01) (HL7 Version 2.5.1)”. The specification defines all the necessary data structure requirements and contains the field-level detail for the data elements in a laboratory result message. The HL7 implementation guide also defines constraints on the HL7 Version 2.5.1 ORU – Unsolicited Observation Message – (Event R01) by indicating fields that a vendor or system implementer must implement to be conformant with the AHIC Use Cases. The minimum data set is represented by all fields and segments set to “R”, “RE”, “C” or “CE”. In addition, it contains fields that may be present depending on local usage, but are not required by the AHIC Use Cases. The inclusion of “Not Supported” and/or “Optional” elements in a message should not cause the message to be rejected.

2.2.1.1 GUIDANCE ON IG SECTION 5.1.2 SPM – SPECIMEN SEGMENT

The HL7 Implementation Guide 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 2.2.1.1-1 Specimen Message Segment

Seq	Data Element	Len	DT	Optionality	Requirements/Pre-conditions	Additional Specification for Component
10	Specimen Collection Site		CWE	O	HITSP selects SNOMED CT as the specified vocabulary	



2.3 STANDARDS

It is important to understand that the standards selected here are within the context of the specific Use Case requirements and do not necessarily reflect selection in other contexts. The standards used by this Component specification fall into the following categories:

- Regulatory guidance is a legal or other authoritative declaration that HITSP must abide by in standards selection (see Section 2.3.1)
- Selected standards are necessary for interoperability. These are standards that are used to meet information exchange requirements of associated constructs. For example, they are used to realize direct information exchange, to provide the transport mechanism, to specify the content, or to address security (see Section 2.3.2)
- Informative reference standards provide additional background information or guidance, and are not required for interoperability. These standards are not required to implement the Component specification (see Section 2.3.3)

2.3.1 REGULATORY GUIDANCE

The following table provides a list of legal or other authoritative guidelines that HITSP must abide by, or has agreed to use as guidance in the selection of standards. Note that only the referenced sections of the regulations are relevant to this Component specification.

Table 2.3.1-1 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

The following table provides a list of standards that are used to meet information exchange requirements of the Component specification, and a detailed description of each standard.

Table 2.3.2-1 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



Standard	Description
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 (PDQ) 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

The following table lists standards that provide additional background information or guidance; however, they are not required for the implementation of the Component specification.

Table 2.3.3-1 Informative Reference Standards

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



3.0 TECHNICAL IMPLEMENTATION

3.1 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.

3.1.1 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 be constrained as specified in Table 2.1.1-1 and implement all of the required actors, where defined, 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 with which this construct is associated.

3.1.2 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 actor 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.



4.0 APPENDIX

The following sections include relevant materials referenced throughout this document.

No additional information at this time

RELEASED FOR IMPLEMENTATION



5.0 CHANGE HISTORY

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

5.1 DECEMBER 13, 2007

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

5.2 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 Actors – actors 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

5.3 MARCH 27, 2008

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

5.4 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®)

5.5 AUGUST 27, 2008

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



RELEASED FOR IMPLEMENTATION

