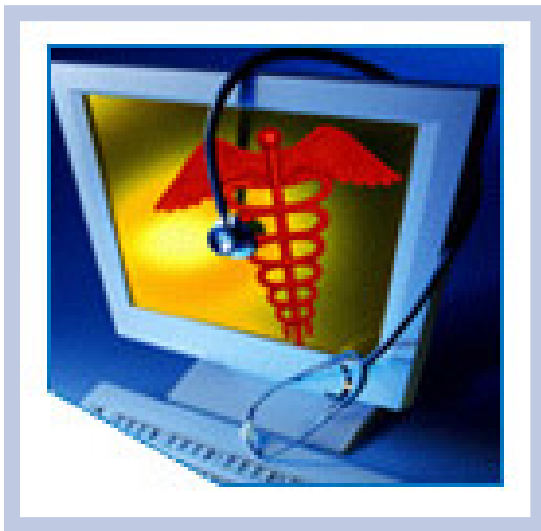


# HITSP Lab Result Message Component

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HITSP/C36



Submitted to:

**Healthcare Information Technology Standards Panel**

Submitted by:

**Care Delivery Technical Committee  
Population Health Technical Committee**



## DOCUMENT CHANGE HISTORY

Version Number	Description of Change	Name of Author	Date Published
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delivered based on the requirements for health information exchange. The next phase will be to connect the prototypes and state and regional health information exchange efforts in trial implementations. These activities share the goal of widespread adoption of interoperable electronic health records within 10 years through public-private collaboration.

### ***HITSP's Role within Nationwide Interoperability Efforts***

The HITSP<sup>2</sup> is a multi-stakeholder coordinating body designed to provide the process within which affected parties can identify, select, and harmonize standards for communicating healthcare information throughout the healthcare spectrum. As used by HITSP, the term "standard" refers, but is not limited to Specifications, Implementation Guides, Code Sets, Terminologies, and Integration Profiles. A standard should be produced through a well defined approach that supports a business process and

1. has been agreed upon by a group of experts
2. has been publicly vetted
3. provides rules, guidelines, or characteristics
4. helps to ensure that materials, products, processes, and services are fit for their intended purpose
5. is available in an accessible format

HITSP functions as a partnership of the public and private sectors and operates with a neutral and inclusive governance model administered by the American National Standards Institute. The goal of the Panel is to:

- Facilitate the development of harmonized Interoperability Specifications and information policies, including Standards Development Organization (SDO) work products (e.g., standards, technical reports). These policies, profiles and work products are essential for establishing privacy, security and interoperability among healthcare software applications
- Coordinate, as appropriate, with other national, regional and international groups addressing healthcare informatics to ensure that the resulting standards are globally relevant
- Be Use Case driven, using information from stakeholders and basing decisions on industry needs

The work of the HITSP is conducted through formally chartered Technical Committees and Work Groups. The artifact of the Technical Committee and Work Group activities is an Interoperability Specification (IS) and related documents referred to as IS Transaction Packages, IS Transactions, or IS Components. For additional information on these constructs, please refer to the HITSP Harmonization Framework.

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<sup>2</sup> [www.hitsp.org](http://www.hitsp.org)



This HITSP document pertains to the Interoperability Specification for the following:

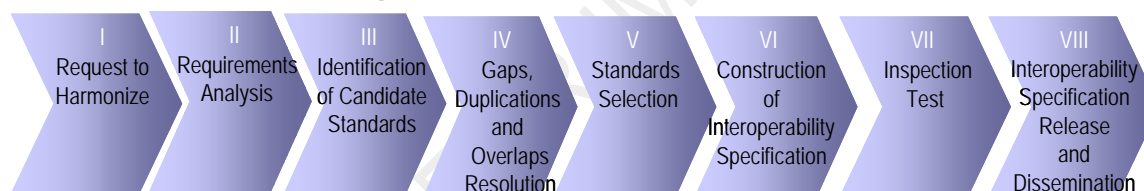
Use Case	Specific Scope of this Use Case
Biosurveillance	Transmit essential ambulatory care and emergency department visit, utilization, and laboratory result data from electronically enabled healthcare delivery and public health systems in standardized and anonymized format to authorized Public Health Agencies with less than one day lag time.
Electronic Health Records - Laboratory Results Reporting	Allow ordering clinicians to electronically access laboratory results, and allow non-ordering authorized clinicians to electronically access historical and other laboratory results for clinical care.

In its final state, this Interoperability Specification provides unambiguous instructions for how two or more systems should exchange information within this specific context of the Use Case.

### ***How Use Cases and HITSP Interoperability Specifications are Developed***

The American Health Information Community, as the representative of public and private health sector stakeholders, identified the three Use Cases (available at [hitsp.org](http://hitsp.org)) that drove the efforts of the HITSP. Nationwide public and private health sector priorities continue to focus the efforts of the HITSP. The Use Case driven HITSP harmonization process is implemented by formally chartered Technical Committees. The volunteers that comprise a Technical Committee follow an 8 step process, depicted below.

**Figure 1.0-1 HITSP Harmonization Process Steps**



### ***How to Read this Interoperability Specification***

Each HITSP Interoperability Specification (IS) is comprised of a suite of constructs that, taken as a whole, define how to integrate and constrain existing standards and specifications that will satisfy the requirements imposed by a given Use Case. The IS groups specific actions and actors to describe the relevant contexts using HITSP constructs that further identify and constrain standards where necessary. There are four types of HITSP constructs called Interoperability Specifications (IS), Transaction Packages (TP), Transactions (T), and Components (C). 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 Construct Roadmap) from the relevant IS to better understand the context, dependencies, and relationships between the constructs that are used to meet the IS requirements. The roadmap in Figure 1.2-1 depicts primary standards that are selected, constrained, or referenced to define the atomic constructs used in an information exchange, or to meet an infrastructure requirement. Implementers should read the documents that describe the standards represented in the diagram for their details and specific uses.



## 2.0 INTRODUCTION

As an introduction to the Laboratory Result Message Component, this section provides a high level overview of the information sharing scenario enabled by following this specification, outlines the technical scope of the specification, describes the intended audience for the technical content of the document, acknowledges the copyright protections that pertain, provides Internet links to the acronym list and an explanation of the conventions used to convey the full descriptions and usage of standards. If you are already familiar with this information, proceed to section 3.0 Referenced Standards.

### 2.1 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 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 and laboratory and other messaging standards

This 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 HHS ONC and 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 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 committee did not want to invalidate those interfaces.

This Component specification describes the structure and data fields for the HL7 Version 2.5.1 ORU – Unsolicited Observation Message – (Event R01) as constrained for the HITSP 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 vocabulary for the coded attributes in this Component is described in a related Component document:

**Table 2.1-1 Document Relationships**

Related Documents	Document Description
HITSP/C35	HITSP EHR Lab Terminology Component

## **2.2 TECHNICAL ASSUMPTIONS AND SCOPE**

This Interoperability Specification focuses on a set of constrained standards for information interchange that address the core requirements of the Use Case described above. It does not define all functions, constructs and standards necessary to implement a conforming system in a real world environment. In particular, an implementer must provide the technical infrastructure and security framework necessary to support operations in accordance with law, regulation, best practices and business agreements. The following paragraphs provide the HITSP principals with regard to several critical topics to ensure consistent interpretation of the Interoperability Specifications.

### **2.2.1 INTEROPERABILITY SPECIFICATIONS NOT FUNCTIONAL SPECIFICATIONS**

The HITSP Interoperability Specification defines how two or more systems exchange standard data content in a standard manner. Interoperability Specifications define the necessary business and technical actors, the Transactions between them including the message, content and terminology standards for the actual information exchange. Interoperability Specifications do not specify the functional requirements or behaviors of the systems or applications.

### **2.2.2 ARCHITECTURAL NEUTRALITY**

HITSP Interoperability Specifications, unless otherwise noted, are not intended to define or prescribe any system architecture or implementation. At the most basic level, the Interoperability Specifications define specific information exchange standards that are to be used by any two systems. Information exchange must be placed within the context of a transaction between defined technical actors which fulfill higher level business requirements derived from the Use Case. In some cases the necessary technical actors may require some architectural structure or make some assumptions involving synchronous or asynchronous data exchanges, or require specific type of exchange, such as a message or document. These requirements may constrain to some degree the total range of choices regarding system



architectures. When constraints are necessary to meet the Use Case requirements, the Interoperability Specification will note this and will retain as much architectural neutrality as possible. When appropriate, the Interoperability Specifications may provide architectural examples and discuss considerations of such examples.

### 2.2.3 THE USE OF MESSAGES AND DOCUMENTS AS APPROPRIATE

Within healthcare information there is an ongoing debate concerning the proper role of messages and documents as methods of exchanging data. Messages are typically non-persistent encapsulations of highly structured data that require external context. Documents are persistent encapsulations of both data and context which may be authenticated to insure non-repudiation. Persistence as defined by HL7 means that a clinical document continues to exist in an unaltered state for a time period defined by local and regulatory requirements. Non-repudiation, as defined by ISO adapted from ASTM E31, means a service that provides proof of the integrity and origin of data (both in an unforgeable relationship), which can be verified by any party. HITSP recognizes that requirements for both messages and documents exist and where consistent with harmonization will support both. For example, depending on specific phases of the workflow, a laboratory result might be exchanged as a message, as a document, or both. Business requirements may define which format is more effective.

### 2.2.4 SECURITY AND PRIVACY

The Health Insurance Portability and Accountability Act (HIPAA) and its Administrative Simplification sections establish the minimum federal requirements for security and privacy of individually identifiable health information (IIHI). HIPAA requires that “covered entities” establish and maintain secure systems that protect IIHI from unauthorized disclosures while ensuring its availability for authorized uses. Most providers, health plans and intermediaries, and by contract their business associates, are covered by HIPAA regulation. However, HIPAA does not cover personal health records unless they are held by a covered entity, nor an individual’s use of their own health information.

Currently, HITSP is charged by ONC to harmonize standards based on Use Cases derived from AHIC requirements and priorities. Implicitly and in some cases explicitly, the Use Cases require a secure infrastructure and certain security or privacy functions. Because of time and resource constraints and the need for further information as described below, HITSP has decided to defer specifying most security requirements, instead treating these as a pre-condition for implementing the core information exchanges. The underlying premise is that HITSP, based upon prioritization by AHIC and ONC, will in the future identify and constrain the standards needed for a standards-based security framework that provides the mechanisms needed to protect patient privacy and maintain confidentiality of information about the patient. This standards-based security framework will need to accommodate federal, state, local, and healthcare enterprise security and privacy policies and processes. Exceptions to the deferral that are addressed in this first release are secure web-based messaging and pseudonymization and anonymization.



There is a special case for the CE Use Case. In the first year of HITSP's work, the Consumer Empowerment TC is to provide an Interoperability Specification for sharing of demographic data, medication lists, and allergies *based on patient consent*. Patient consent is clearly within the scope of the CE Use Case. However, HITSP requires further guidance on patient consent, particularly since patient consent is not addressed by HIPAA in the case of a personal health record (PHR) nor is it established within widely accepted PHR standards. Therefore HITSP identifies patient consent as a necessary pre-condition for successful implementation of a PHR that contains personal demographic data and medication histories. Patient consent will be documented as a pre-condition in the Consumer Empowerment and Access to Clinical Information via Networks Interoperability Specification. Work on patient consent has been deferred until the second year of HITSP work.

## 2.3 AUDIENCE

The Interoperability Specification is designed to be used by analysts who need to understand the interoperability requirements for the described Use Case, and by implementers working to develop interoperable applications. Understanding and using the relevant interoperability set of specifications is a key requirement for establishing interoperability compliance.

## 2.4 COPYRIGHT PERMISSIONS

### COPYRIGHT NOTICE

© 2007 ANSI. This material may be copied without permission from ANSI only if and to the extent that the text is not altered in any fashion and ANSI's copyright is clearly noted.

HL7 materials used in this document have been extracted from relevant copyrighted materials with permission of Health Level Seven (HL7). Copies of this standard may be purchased from the Health Level 7 website at [www.hl7.org](http://www.hl7.org).

## 2.5 ACRONYMS

The acronyms used in this document are contained in the HITSP Acronyms List.

## 2.6 CONVENTIONS

The Conventions are used to convey the full descriptions and usage of standards in the Interoperability Specification and are contained in the HITSP Conventions List.



## 2.7 REFERENCE DOCUMENTS

This section contains links to key reference documents and background material.

The HITSP Glossary provides definitions for relevant terms used by HITSP documents.



### 3.0 REFERENCED STANDARDS

It is the HITSP policy to incorporate only standards that have been approved according to the formal policy of standards organization, as defined by HITSP, which publishes the standard. HITSP interprets approval to include Draft Standards for Trial Use. The objective is to incorporate only standards that are managed within a formal life cycle process as defined by the standards organization. In some cases, where we believe a standard that is not yet approved may best meet the requirements of an Interoperability Specification, HITSP may provide a roadmap of its future intent conditional on future actions by either or both the standards organizations and the HITSP Technical Committee. Thus there are four classes of HITSP-committed standards.

- Approved for Use – standards included for unconditional use within a HITSP construct
- Interim – standards included for use now within a HITSP construct but for a defined time period or conditional on future actions, e.g., “Intended for Use” standard is available
- Provisional - standards that are not yet but expected to be approved by the Standards Organization by the time that the Interoperability Specification is released by HITSP. A "Provisional" standard becomes an "Approved for Use" standard only if:
  - It is approved by the Standards Organization by the time that the Interoperability Specification is released by HITSP and
  - It is substantially the same as it was when it was provisionally used and
  - It requires no further action by the Technical Committee
- Intended for Use – proposed standards that are roadmapped for future use pending actions by the TC and/or the standards organization. Therefore a standard is defined as “Intended for Use” because it will not be approved by the time that the HITSP construct is released but is sufficiently defined to enable detailed evaluation of how well it will meet technical and business requirements

HITSP may continue to use “Provisional” or “Interim” standards as they existed when incorporated into the HITSP construct if the expected conditions are not satisfied until such time as HITSP can replace it with a more suitable standard. In this circumstance, the standards organization would have no responsibility to maintain or correct this artifact. If a standard “Intended for Use” is not developed and approved in terms of time frame or content as expected by the TC at the time of its initial selection, it may be replaced. All standards used by HITSP must meet the HITSP selection criteria. The use of interim and intended for use standards will be weighed against the alternative of simply declaring a gap for HITSP and the standards organizations to resolve.



### 3.1 LIST OF STANDARDS

This Component specification is drawn directly from the HL7 Version 2.5.1 standard.

**Table 3.1-1 List of Standards**

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. Visit <a href="http://www.fda.gov/cdrh/clia">www.fda.gov/cdrh/clia</a> and <a href="http://www.cms.hhs.gov/clia">www.cms.hhs.gov/clia</a> for more information.
Health Insurance Portability and Accountability Act (HIPAA) -- Administrative Simplification	A listing of national standards plus rules adopted by federal regulation for electronically communicating specified administrative and financial healthcare transactions, and protecting the security and privacy of healthcare information, as applied to the three types of defined covered entities: health plans, healthcare clearinghouses, and healthcare providers who conduct any of the specified healthcare transactions. See the Code of Federal Regulations, Title 45, Parts 160, et. seq. for more information.
Health Level Seven (HL7) Version 2.5/2.5.1	The HL7 Version 2.5 and 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), Pharmacy/Treatment Orders 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 such as Visit <a href="http://www.hl7.org">www.hl7.org</a> for more information.
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. Visit <a href="http://www.hl7.org">www.hl7.org</a> for more information.



## 4.0 COMPONENT

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.

### 4.1 CONTEXT OVERVIEW

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 the LIS collects the results from the instruments or through manual data entry.

#### 4.1.1 CONTEXTUAL CONSTRAINTS

This Component is based directly on the HL7 V2.5.1 standard. As is typical with all HL7 interfaces, this specification places constraints on the individual fields in the message to guarantee a certain amount of predictability in obtaining the required information for the HITSP Use Cases. Optional use of elements has been retained for fields that are not of interest to HITSP, but may already exist in current implementations. Further, a number of elements are optional to allow for additional constraints to be applied in other HITSP constructs. It is not the intent of this specification to invalidate current implementations because they contain useful information that is not needed in the HITSP Use Cases.

This specification has 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 this linking is provided at Appendix 6.1.

#### 4.1.2 TECHNICAL ACTORS

The technical actors for this Component are:

**Table 4.1.2-1 Technical Actors**

Actor	Description
Lab Result Sender	A system that has laboratory result information and has a need to communicate that information with another system



Actor	Description
Lab Result Receiver	A system that has a requirement to process laboratory results and receives those results from another source

## 4.2 INFORMATION INTERCHANGE COMPONENTS: RULES FOR IMPLEMENTING

The Lab Result Message Component contains the field-level detail for the data elements in a laboratory result message. It 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 HITSP Use Cases. In addition, it contains fields that may be present depending on local usage, but are not required by the HITSP Use Cases. The inclusion of “Not Supported” and/or “Optional” elements should not cause the message to be rejected.

### 4.2.1 CONFORMANCE CONDITIONS

Full conformance with this IS requires implementation of only those data elements (segment, field, component, subcomponent) that are identified in this document as having usage specified as R, RE, C, CE. These usage indicators are defined in HL7 2.5.1 Chapter 2, Section 2.12 Conformance Using Message Profiles.

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 v 2.5.1 does not support a unique instance identifier for an OBX. Therefore, until after this specification is updated to v.2.6+, this means only “snapshot” mode will exist in this edition of the specification.

### 4.2.2 PROCESS PRE-CONDITIONS

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.

#### 4.2.2.1 PROCESS TRIGGERS

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.





#### 4.2.3 PROCESS POST-CONDITIONS

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.

##### 4.2.3.1 PROCESS OUTPUTS

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.

#### 4.2.4 DATA STRUCTURE

The data structure is defined in "HL7 U.S. REALM - INTEROPERABILITY SPECIFICATION: LAB RESULT MESSAGE TO EHR (ORU^R01) (HL7 Version 2.5.1)"

#### 4.2.5 MINIMUM DATA-SET

See above message structure and data element table for usage requirements. The minimum data set is represented by all fields and segments set to "R", "RE", "C" or "CE".

#### 4.2.6 ADDITIONAL SPECIFICATIONS

##### 4.2.6.1 GUIDANCE ON IG SECTION 5.1.2 SPM – SPECIMEN SEGMENT

The HL7 IG does not provide guidance on optional fields, however HITSP states that for SPM-10 (Specimen Collection Site) SNOMED CT is to be the specified vocabulary.



## 5.0 CONSTRAINTS FOR REUSE

This Component may be reused by any set of communicating applications where the required fields are necessary and sufficient. In addition, optional fields may be populated and used between communicating applications without impairing the intended use by HITSP.



## 6.0 CHANGE HISTORY

The following sections provide the history of all changes made to this document since the last publication.

### 6.1 DECEMBER 22, 2006

The changes in this cycle address the following comments received during the September 2006 public review and comment period:

1573, 1576, 1674, 1678

### 6.2 DECEMBER 5, 2007

- Minor edits to synchronize this specification with the final HL7 IG documentation (document titles, versions, and dates, etc.)
- Removed additional redundant information that now exists in the IG, e.g., the appendix with examples, pre-adopted vocabulary tables

### 6.3 DECEMBER 13, 2007

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

