

HITSP Communicate Lab Results Message Capability

HITSP/CAP126



Healthcare Information Technology Standards Panel

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1.0 INTRODUCTION

This Healthcare Information Technology Standards Panel (HITSP) document is divided into Requirements Analysis, External Capability Options, Design Specifications and Standards sections which may be used by analysts, architects and implementers. Analysts refer to this document to determine if the Capability satisfies their requirements. Architects and system implementers refer to this document as the architectural specifications for a system design, while software developers will use a Capability as the source of the design for interoperable information exchange. The Appendix lists requirements satisfied by this Capability.

All sections may be useful to analysts and architects. However as shown in Table 1-1, different readers may find specific sections of greater interest and utility. This table is provided as an aid to readers to assist them in identifying sections to focus on. Readers are encouraged to review all sections of this document to further their understanding of HITSP's work.

Table 1-1 Reader's Guide for Capability

Document Section	Section Number	Intended Audience	Information Contained
Section 2.0 Requirements Analysis	2.1 Introduction	Policy Managers Policy Analysts Executive Leadership	Provides an overview of the requirements which this Capability addresses, and identifies the system roles supported by the Capability
	2.2 Requirements	Program Managers Policy Analysts Executive Leadership Architects Business Analysts	Defines the actual information exchanges supported by the Capability in terms of exchange actions and exchange content. It shows how these roles can be assigned at a higher level to real world systems, such as an Electronic Health Record
Section 3.0 External Capability Options	3.1 Security and Privacy	Policy Analysts Architects Business Analysts Developers	Describes the integrated and optional security and privacy functions supported by the Capability
Section 4.0 Design Specification	4.1 Requirements Mapped to Constructs	Program Managers Architects Business Analysts Developers	Maps the information exchanges developed in requirements to the actual HITSP construct used by the Capability to support the exchange
	4.2 Constraints and Assumptions	Business Analysts Developers	Lists the context that is necessary to use the Capability, including constraints, assumptions, pre-conditions, post-conditions and triggers
	4.3 Specified Interfaces by System Role	Business Analysts Developers	Identifies the constructs and their interfaces assigned to each system role. It also lists the implementation conditions for use
Section 5.0 Standards	5.1 Standards Used	Program Managers Policy Analysts Architects Business Analysts Developers	Lists regulatory guidance, selected standards and informative references used by the Capability and all its supporting constructs
	5.2 Standards Gaps and Overlaps	Program Managers Policy Analysts Architects Business Analysts Developers	Identifies gaps or overlaps in standards to implement the Capability including a plan to resolve issues

1.1 CAPABILITY OVERVIEW

This Capability addresses interoperability requirements that support the sending of a set of laboratory test results. Ordering Providers of Care receive results as a laboratory results message. The communication



of the order is out of scope for this Capability but is addressed in HITSP/CAP99 – Communicate Laboratory Orders.

The content of these test results may be either or both:

- General Laboratory Test Results
- Microbiology Test Results

1.2 SCOPE

A Capability enables business and policy requirements for a business need to be implemented through information exchanges specified in HITSP constructs. The objective of a Capability is to provide the bridge between the business, policy and implementation disciplines by defining a set of information exchanges at a level relevant to policy and business decisions and specifying the use of HITSP constructs sufficiently for implementation. A Capability supports stakeholder requirements and business processes and includes information content, infrastructure, security and privacy. The design of Capabilities leverages existing HITSP constructs and communication methodologies. As new constructs become available, the scope of this Capability may be extended.

The scope of this Capability is the sending of lab result messages from a Laboratory Result Sender to a Laboratory Result Receiver and the associated communications of these transactions.

1.3 COPYRIGHT PERMISSIONS

COPYRIGHT NOTICE

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1.4 REFERENCE DOCUMENTS

A list of key reference documents and background material is provided in the table below. HITSP-maintained reference documents can be retrieved from the [HITSP Web Site](#).

Table 1-2 Reference Documents

Reference Documents	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
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
TN904 – Harmonization Framework and Exchange Architecture	TN904 is a reference document that provides the overall context for use of the HITSP Harmonization Framework and Exchange Architecture constructs

1.5 GUIDANCE FOR USE OF A CAPABILITY

NOTE: For questions related to details on HITSP Capabilities and HITSP System Roles, please refer to HITSP/TN904 Harmonization Framework and Exchange Architecture Technical Note.

To use a HITSP Capability, a HITSP Interoperability Specification or an implementation conformance statement must assign specific systems to one or more HITSP Capability System Roles and identify how the HITSP Capability Options are to be addressed. In order to assign systems to HITSP System Roles, the reader uses Table 2-3 Supported Information Exchanges to determine what systems can support the specific information exchanges required. For an example of how HITSP System Roles and systems are mapped, readers can consult a HITSP Interoperability Specification Table 3-3 Orchestration of



Capabilities by System. In the case of an Implementation Guide, systems can be assigned to HITSP System Roles using a similar methodology.

The use of a HITSP Capability implies that these specific rules will be followed:

- For each HITSP Capability System Role listed in Table 2-2 Capability System Roles, the defined responsibilities of that HITSP Capability System Role are supported. Responsibilities for the HITSP Capability System Role are defined as support for the HITSP Construct interfaces listed in Section 4.3 Specified Interfaces by System Role. Support implies that the system assigned to the HITSP Capability System Role makes the associated HITSP construct interfaces available for use by other systems. For those HITSP construct interfaces in Section 4.3 that have associated content optionality, the HITSP Capability System Role must comply with the optionality condition listed in Table 4-6 Implementation Conditions.
- Responsibilities also include the constraints and assumptions associated with use of a Capability, as outlined in Table 4-3 Context. For those Capabilities with Section 3.2 options, the following additional rules apply:
 1. Each topology option listed in Table 3-2 Topology Related Options should be supported by the implementation
 2. Each content import option listed in Table 3-3 Content Import Options should be supported by the implementation
 3. Each document content option listed in Table 3-4 Document Content Options should be supported by the implementation



2.0 REQUIREMENTS ANALYSIS

The following table is provided as an aid to readers to assist them in identifying the parts of this section to focus on. Readers are encouraged to review all sections of this document to further their understanding of HITSP's work.

Table 2-1 Reader's Guide for Section 2.0

Document Section	Section Number	Intended Audience	Information Contained
Section 2.0 Requirements Analysis	2.1 Introduction	Policy Managers Policy Analysts Executive Leadership	Provides an overview of the requirements which this Capability addresses, and identifies the system roles supported by the Capability
	2.2 Requirements	Program Managers Policy Analysts Executive Leadership Architects Business Analysts	Defines the actual information exchanges supported by the Capability in terms of exchange actions and exchange content. It shows how these roles can be assigned at a higher level to real world systems, such as an Electronic Health Record

2.1 INTRODUCTION

Table 2-2 summarizes the system roles of the Capability. Section 2.2 identifies how these system roles participate in the set of information exchanges.

Table 2-2 Capability System Roles

System Role	System Role Definition
Result Sender	The system which sends the laboratory result message
Result Receiver	The system which receives the laboratory result message

2.2 REQUIREMENTS

2.2.1 INFORMATION EXCHANGES

Table 2-3 defines each of the Information Exchanges supported by this Capability in terms of the Exchange Action (EA) or Exchange Content (EC) used.

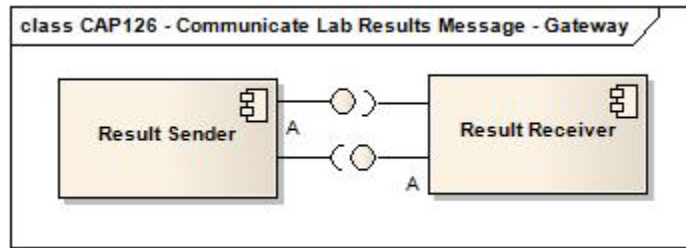
Table 2-3 Supported Information Exchanges

Information Exchange Identifier	Exchange Action	Exchange Content
A	Send	Lab Result Message

Figure 2-1 identifies how this Capability supports various system roles within multiple system architectures. For example, either an Electronic Health Record (EHR) system or a Health Information Exchange (HIE) might fill a document repository system role in an information exchange. In an implementation architecture, system roles may be combined locally (e.g., Hospital EHR System) and in others, the system roles may be provided by multiple-distributed trusted third parties (e.g., pharmacies within an HIE).



Figure 2-1 Information Exchanges Between System Roles



3.0 EXTERNAL CAPABILITY OPTIONS

The following table is provided as an aid to readers to assist them in identifying the parts of this section to focus on. Readers are encouraged to review all sections of this document to further their understanding of HITSP's work.

Table 3-1 Reader's Guide for Section 3.0

Document Section	Section Number	Intended Audience	Information Contained
Section 3.0 External Capability Options	3.1 Security and Privacy	Policy Analysts Architects Business Analysts Developers	Describes the integrated and optional Security and Privacy functions supported by the Capability

This section is primarily for architects, engineers and analysts. It allows those who consider using this Capability to evaluate and/or constrain the options that are externally made available for the Capability implementers.

Interoperability among system roles defined by this Capability often requires the selection of consistent options.

3.1 SECURITY AND PRIVACY

The application of Security and Privacy is highly influenced by the security and privacy policies. The HITSP Security and Privacy Technical Note (HITSP/TN900) provides a detailed discussion of the Security and Privacy constructs, including consideration and appropriate context for needed security and privacy related policy decisions. Security and Privacy constructs are integrated comprehensively into the Service Collaborations. The actual constructs used and the way in which the constructs are used is dependent on the policies and physical setting. Conformance claims are against the Security and Privacy constructs that are chosen to enforce the policies.



4.0 DESIGN SPECIFICATION

The following table is provided as an aid to readers to assist them in identifying the parts of this section to focus on. Readers are encouraged to review all sections of this document to further their understanding of HITSP's work.

Table 4-1 Reader's Guide for Section 4.0

Document Section	Section Number	Intended Audience	Information Contained
Section 4.0 Design Specification	4.1 Requirements Mapped to Constructs	Program Managers Architects Business Analysts Developers	Maps the information exchanges developed in requirements to the actual HITSP construct used by the Capability to support the exchange
	4.2 Constraints and Assumptions	Business Analysts Developers	Lists the context that is necessary to use the Capability, including constraints, assumptions, pre-conditions, post-conditions and triggers
	4.3 Specified Interfaces by System Role	Business Analysts Developers	Identifies the constructs and their interfaces assigned to each system role. It also lists the implementation conditions for use

4.1 REQUIREMENTS MAPPED TO CONSTRUCTS

4.1.1 CONSTRUCTS

Table 4-2 defines the mapping of the Information Exchanges supported by this Capability in terms of the Exchange Action (EA), Exchange Content (EC) and any Constraints applied to the Information Exchange with specific initiating and/or responding system interfaces. This provides the traceability of constructs to the information exchanges identified in Section 2.0 above. Content modules and terminology components are not listed here because they are referenced by other constructs, but do not provide an interface. HITSP/TN903 discusses how content modules and terminology components are referenced by other constructs.

Table 4-2 Information Exchanges Mapped to Constructs

Information Exchange Identifier	Exchange Type	Construct Identifier	Description
A – Send Laboratory Result Message	Action	HITSP/SC115 – HL7 Messaging	The HITSP HL7 Messaging Service Collaboration provides the Capability to send and receive HL7 messages. The Service Collaboration applies the necessary Security and Privacy constructs
A – Send Result Laboratory Message	Content	HITSP/C36 – Lab Results Message	The HITSP Lab Result Message Component describes the use of a constrained Health Level Seven (HL7) Version 2.5.1 ORU – Unsolicited Observation Message for electronic laboratory results reporting

4.2 CONSTRAINTS AND ASSUMPTIONS

Table 4-3 specifies the context that must be provided in order to use the Capability, identifying any assumptions, pre-conditions, post-conditions, and triggers relevant for use of the Capability.

Table 4-3 Context

Assumptions, Pre-conditions, Post-conditions, and Triggers	Type of Context
Laboratory results are sent only to the ordering clinician and copy to clinicians specified in the order; other clinicians receive notification.	Assumption
An order for a laboratory test has been created and accepted by the performing laboratory	Pre-condition



Assumptions, Pre-conditions, Post-conditions, and Triggers	Type of Context
The order contains an electronic address of all authorized electronic recipients	Pre-condition
Result is received and is viewable or can be processed	Post-condition

4.3 SPECIFIED INTERFACES BY SYSTEM ROLE

This section specifies the HITSP Capability interfaces in terms of the System Roles identified in Table 2-2 Capability's System Roles.

Table 4-4 below specifies interfaces for the result sender system role as defined in Table 2-2.

Table 4-4 Result Sender System Role Mapped to HITSP Construct Interfaces

Construct Interface	Interface Type	T/TP/SC or Content	T/SC/Content Optionality
Request HL7 Message	Initiating	HL7 Messaging(HITSP/SC115)	R
	Initiating	Lab Result Message(HITSP/C36)	R

Optionality Legend: "R" for Required, "O" for Optional, or "C" for Conditional

Table 4-5 below specifies interfaces for the result receiver system role as defined in Table 2-2.

Table 4-5 Result Receiver System Role Mapped to HITSP Construct Interfaces

Construct Interface	Interface Type	T/TP/SC or Content	T/SC/Content Optionality
Respond to HL7 Message	Responding	HL7 Messaging(HITSP/SC115)	R
	Responding	Lab Result Message(HITSP/C36)	R

Optionality Legend: "R" for Required, "O" for Optional, or "C" for Conditional

Table 4-6 specifies optionality conditions referenced in Table 4-4 through Table 4-5 above.

Table 4-6 Implementation Conditions

Condition ID	Condition Description
No Applicable Implementation Conditions	



5.0 STANDARDS

The following table is provided as an aid to readers to assist them in identifying the parts of this section to focus on. Readers are encouraged to review all sections of this document to further their understanding of HITSP's work.

Table 5-1 Reader's Guide for Section 5.0

Document Section	Section Number	Intended Audience	Information Contained
Section 5.0 Standards	5.1 Standards Used	Program Managers Policy Analysts Architects Business Analysts Developers	List regulatory guidance, selected standards and informative references used by the Capability and all its supporting constructs
	5.2 Standards Gaps and Overlaps	Program Managers Policy Analysts Architects Business Analysts Developers	Identifies gaps or overlaps in standards to implement the Capability including a plan to resolve issues

5.1 STANDARDS USED

5.1.1 REGULATORY GUIDANCE

Table 5-2 lists any regulatory guidance that determines or constrains use of standards. Laboratories are expected to comply with any of their local regulatory or accreditation requirements in addition to those listed in this section.

Table 5-2 Regulatory Guidance

Regulation	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

5.1.2 SELECTED STANDARDS

Table 5-3 lists the standards selected as relevant to this Capability.

Table 5-3 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 http://www.hl7.org



Standard	Description
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

5.1.3 INFORMATIVE REFERENCE STANDARDS

Table 5-4 includes reference standards that inform the overall semantic interoperability.

Table 5-4 Informative Reference Standards

Standard	Description
No applicable informative reference standards	

5.2 STANDARDS GAPS AND OVERLAPS

Table 5-5 identifies the information exchange requirements and known standards gaps, along with the recommended resolutions to the gaps.

Table 5-5 Information Exchange Requirements (IER) and Associated Standards Gaps

IER Gap Description	Responsible HITSP TC	Design Approach	Required Standards Now Unavailable for Constructs	SDO Working on Unavailable Standards	Expected Availability
None					

Table 5-6 lists any standards overlaps and describes plans to resolve each of the overlaps.

Table 5-6 Information Exchange Requirements (IER) and Associated Standards Overlaps

IER Number	Summary Description	Standard Overlap	Recommended Resolution
None			



6.0 APPENDIX

This section may include additional materials referenced throughout this document, such as requirements analysis tables and figures. If the Capability is yet to be implemented, it may contain the candidate standards for Tier 2 evaluations.

The following legacy Interoperability Specifications were used to create this Capability:

- HITSP/IS01 – Electronic Health Records Laboratory Results Reporting
- HITSP/IS02 – Biosurveillance
- HITSP/IS08 – Personalized Healthcare
- HITSP/IS09 – Consultation and Transfers of Care
- HITSP/IS11 – Public Health Case Reporting



7.0 DOCUMENT UPDATES

The following sections provide the details of updates made to this document.

7.1 NOVEMBER 9, 2009

No changes. This is the first published version of the document.

7.2 JANUARY 18, 2010

7.2.1 UPDATES FROM PUBLIC COMMENT

The changes in this cycle address the following comments received during the November 2009 public comment period:

- Incorporated all of the 11 Public Comment TC dispositions into the document
- Added additional statement to Section 1.2 Scope to clarify the scope of this Capability
- Changed text of Assumption in Table 4-3 to clarify which clinicians receive the result message
- Updated Section 1.1 Capability Overview to reference HITSP/CAP99 – Communicate Laboratory Orders for laboratory orders
- Added statement in Section 5.1.1 Regulatory Guidance that Laboratories are expected to comply with any of their local regulatory or accreditation requirements in addition to those listed in this section
- Reformatted the document content to adhere to the new HITSP document template
- Added diagrams and tables based on the new HITSP document templates
- Removed sections which only pertain to CDA documents

The associated comment numbers for these updates are as follows:

- 8400, 9006, 9017, 9018, 9019

The full text of the comments along with the Technical Committee's disposition can be reviewed on the [HITSP Public Web Site](#).

Updated document to HITSP Capability Template Version 2.3

7.3 JANUARY 25, 2010

Upon approval by the HITSP Panel on January 25, 2010, this document is now Released for Implementation.

