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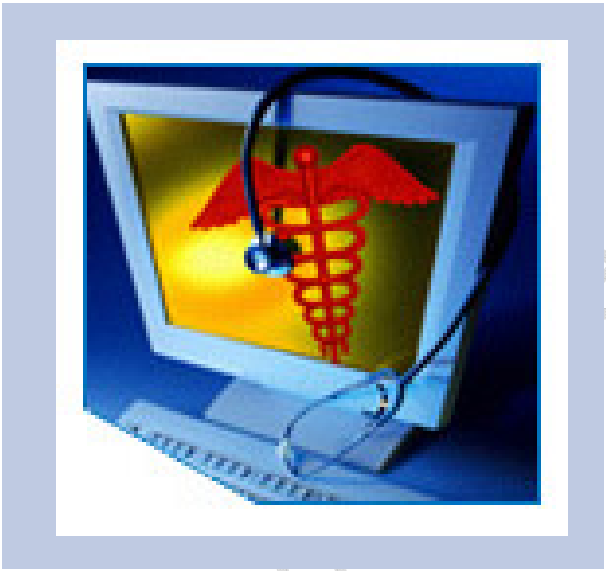
HITSP Interoperability Specification: Send Lab Result Message to Ordering Clinician and Provider of Care Transaction Package

HITSP/ISTP-14



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1.0 FOREWORD

Healthcare Information Technology Standards Panel (HITSP) 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. 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 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, utilize information from stakeholders and base its decisions on industry needs.

The HITSP shall serve the public good by working to ensure that the combined work of various healthcare information standards organizations supports interoperability, accurate use, access, privacy and security of shared health information.

In order to advance the goal of expanding harmonized interoperability specifications and information policies, HITSP was tasked with developing interoperability specifications for three main use case "breakthrough areas" in which specific, near term value to the health care consumer could be realized. The harmonized use case areas are:

1.	Biosurveillance	Transmit essential ambulatory care and emergency department visit, utilization, and lab result data from electronically enabled health care delivery and public health systems in standardized and anonymized format to authorized Public Health Agencies with less than one day lag time.
2.	Consumer Empowerment	Allow consumers to establish and manage permissions access rights and informed consent for authorized and secure exchange, viewing, and querying of their linked patient registration summaries and medication histories between designated caregivers and other health professionals.
3.	Electronic Health Record	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.

The interoperability specification provides a detailed mapping of existing standards and specifications such as implementation guides, integration profiles to actions and actors that satisfy the requirements

imposed by the relevant use cases. It identifies and constrains standards where necessary, and creates groupings of specific actions and actors to further describe the relevant contexts. Where gaps and overlaps are identified, the interoperability specification provides recommendations and a roadmap for corrections to be made.

2.0 INTRODUCTION

The purpose of this document is to describe the package of transactions and components that make up the specification for sending a lab result message to the ordering clinician, other providers of care, and authorized public health agencies. The goals supported by this Transaction Package specification are stated in the EHR and Biosurveillance Use Cases:

- Transmission of complete, preliminary, final and updated lab results to the EHR system (local or remote) of the ordering clinician;
- Transmission of complete, preliminary, final and updated (or notification) to the EHR system (local or remote) or other clinical data system of designated providers of care (with respect to a specific patient)
- Transmit lab result data from electronically enabled health care 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 Transaction Package is the result of a considered assessment of the current practices in electronic laboratory results reporting and the requirements of the Use Case. In order to encourage rapid and widespread adoption of this package, the committee placed emphasis on the operations and process flows of current implementations and the ease with which current implementations can become compliant. HL7 Version 2.x message-based lab result reporting is the most common electronic interface in existence today and the committee did not want to invalidate those interfaces.

2.1 OVERVIEW

This specification includes by reference the transactions and components that comprise the Lab Result Message package. It describes the processes supported by these structures and the work that is accomplished by implementing this transaction package. In order to describe the complete package and how it is expected to be implemented, the Patient Matching and ID Cross-Referencing Transaction Package is also included as an optional structure under the Lab Result Message Transaction Package.

Related Documents	Document Description	Document Name and Location
HITSP/ISC-36	Interoperability Specification for the HL7 V2.5 Lab Result Message Component as constrained by HITSP	ISC_HITSP_36_v1.0_2006
HITSP/ISC-35	Interoperability Specification for the Terminology for Lab Results as constrained by HITSP	ISC_HITSP_35_v1.0_2006
HITSP/IST-22	Patient ID Cross-Referencing Transaction Package	IST_HITSP_22_V1.0_2006

2.2 AUDIENCE

The audience for this specification is expected to be vendors and technical staff responsible for implementing a message-based laboratory result reporting application. This specification does not require any specialized knowledge, but a familiarity with HL7 Version 2.x is desirable.

2.3 TERMS AND DEFINITIONS

The definitions used for the purposes of this document can be found in the glossary. Refer to appendix 4.0 for the Common Terms and Definitions Document.

2.4 CONVENTIONS

This specification uses the following to convey the full descriptions and usage of standards:

UML sequence and activity diagrams

In these diagrams, the actors and transactions are highlighted within the framework of the specific scenario or context. The actors involved in the specified use-scenario or context are mapped out, and the interactions between each action and actor for a particular context, and the flow of data are provided through the use of arrows. Diagrams are named according to the section in which they reside, and will use the following naming convention:

Figure <section number>-<consecutive number for the diagram, e.g. 1, 2, 3, etc.>. <Short name/description of diagram>. For example, a diagram residing in section 3.1.3 showing the Actor Interactions for the Send Lab Results transaction package is named:

Figure 3.1.3-1. Send Lab Results Transaction Package

Tables

Tables are used to indicate standards categorizations, as well as dependencies and constraints between constructs. Tables are named according to the section in which they reside, and will use the following naming convention:

Table <section number>-<consecutive number for the table, e.g. 1, 2, 3, etc.>. <Short name/description of table>. For example, a table residing in section 2.7.1 showing the Dependencies between the transactions for the Send Lab Results transaction package is named:

Table 2.7.1-1. Send Lab Results Transaction Package dependencies

References

When references are made to another section within an Interoperability Specification a section number is used by itself. When references are made to other constructs that are related to the Interoperability Specification, such as Transaction Packages, Components or Composite Standards, the HITSP document short name and section number are displayed as follows:

<HITSP Document short name or Composite Standard Short Name>-<Volume Number>: <section number>

where:
<HITSP document short name> is a short designator for the construct (e.g. HITSP/ISTP-013)
<Composite Standard Short Name> is a short designator for the composite standard (e.g. IHE-ITI TF)
<Volume Number> is the applicable volume within the given composite standard (e.g. 1)
<section number> is the applicable section number (e.g. 3.1)

For example: HITSP/ISTP-013: 3.1 refers to Section 3.1 in the Interoperability Specification for a Transaction Package, IHE-ITI TF-2: 4.33 refers to Section 4.33 in volume 2 of the IHE IT Infrastructure Technical Framework.

Reproductions

Where large sections of composite standards or base standards are reproduced within a HITSP specification, the reproduced sections are cited with introductory text containing the reference information for the composite or base standard. In addition, the beginning and ending of the reproduced text are respectively shown using a beginning statement:

The text for the <composite or base standard name> specification begins here:

And an ending statement:

The text for the <composite or base standard name> ends here.

2.5 COMMENTS

To submit comments for this interoperability specification, please download the Comment Submission sheet from the HITSP site at www.hitsp.org and provide all relevant information, and then email the completed document to hitspcomments@ansi.org. Comments are consolidated periodically and sent to the Technical Committees for review.

2.6 COPYRIGHT PERMISSIONS

COPYRIGHT NOTICE

2.7 LIST OF TRANSACTIONS AND COMPONENTS

The following list of transactions and their definitions are used by the transaction package specification.

Transaction Name	Description	Document Name	Date Added
Lab Result Message Transaction	The transaction that sends a lab result message using HL7 Version 2.5.	ISC_HITSP_36_V1.0_2006	August 18, 2006
Patient ID Cross-Referencing Transaction (PIX)	The PIX transaction in a package that supports the retrieval of a patient ID through a matching of patient traits or ID cross referencing.	ISC_HITSP_11_V1.0_2006	August 18, 2006
Message Acknowledgement	Acknowledgement of message at application level.	ISC_HITSP_45_V1.0_2006	August 18, 2006

Table 2.7-1 List of Transactions

2.7.1 DEPENDENCIES

The following table shows a list of transactions with their existing dependencies. Dependencies usually exist when there are some additional pre-requisites for a specific transaction specification.

Transaction Name	Depends On (Name of transaction that it depends on)	Dependency Type (Pre-condition, post-condition, general)	Purpose (Reason for this dependency)
Patient ID Cross-Referencing	Lab Result Message Transaction	Pre-condition	Optionally, the Patient ID from the lab result message is sent to the cross-referencing Service by the recipient.
Lab Result Message	Lab Order	Pre-condition	The lab order is echoed in the lab result message.
Message Acknowledgement	Lab Result Message	Pre-condition	Acknowledges receipt of Lab Result message.

Table 2.7.1-1 Dependencies

2.7.2 CONSTRAINTS

The following table identifies the constraints identified for included transactions and transaction packages:

Transaction Name	Constraint	Constraint Type (Pre-condition, post-condition, general)	Purpose (Reason for this constraint)
Lab Result Message	The order contained the unambiguous addresses of the other providers of care.	Pre-condition	The sender must rely on the order to identify the addresses of the other providers of care.
Lab Result Message	Authorized public health agencies have been identified to the lab.	Pre-condition	Public health agencies must be known to the lab and associated with a particular type of test or result.
Patient ID Cross-Referencing (PIX)	When needed, the patient is registered in the Patient Matching and ID Cross-Referencing service with the appropriate local IDs.	Pre-condition	The cross-referencing service must already have the patient and the local IDs in order to return a result.

Table 2.7.2-1 Constraints

3.0 TRANSACTION PACKAGES

3.1 CONTEXT OVERVIEW

The functionality supported by this transaction package, send lab result message to and receive acknowledgement from authorized recipients with optional patient ID cross-referencing, operates within a defined context. That context assumes that an order has been received and accepted by the lab and the lab has processed the order. The initial state of this transaction package is that the electronic laboratory result has been deemed releasable. In addition to the normal return to the ordering clinician, this transaction package also supports reporting the results to other authorized providers of care and authorized public health agencies.

3.1.1 CONTEXTUAL CONSTRAINTS

The constraints on this transaction package are imposed for various reasons. In part, the reasons for the constraints are due to a lack of infrastructure. For example, a provider registry or a registry of public health agencies is not in practice at the time of this writing. The constraints identified for this transaction package are as follows:

- The order itself as an electronic message is not part of this specification.
- Authorized recipients must be uniquely identified by the sending system
    a. For clinical care, the copy-to list of authorized providers of care was part of the order
    b. When legally authorized, public health agencies are authorized recipients.

- All messages in this transaction package conform to HITSP lab terminology. The electronic lab result may have been transformed, mapped and/or translated into the set of target terminologies and vocabularies prior to transmission. The technology exists to translate between terminologies and some terminologies have been cross-mapped by the NLM. This would allow the lab to report using one terminology and the receiver could translate into another. While this technology exists, it is not widely used and the mappings are not yet complete.

3.1.2 TECHNICAL ACTORS

The technical actors for this transaction package are associated with one of two interactions:

- The lab result message or
- The Patient ID cross-referencing query and response.

A given business actor may assume the identity of different technical actors depending on the nature of the interaction. For example, as shown in the diagram below, the clinician is the Lab Result Receiver for the Lab Result Message transaction and also the Patient Identifier Cross Reference Consumer for the PIX transaction. The table below identifies the technical actors involved in this transaction package:

Actor	Description
Lab Result Message Sender	The holder of a lab result who is communicating a lab result message to another actor.
Lab Result Message Receiver	An authorized entity that is receiving a lab result message.
Patient Identifier Cross Reference Manager	This system is invoked by the receiving system to retrieve a local patient ID from a cross-reference mapping of all IDs for a patient.
Patient Identifier Cross Reference Consumer	The user of a cross-referencing service who needs to map a foreign ID to a locally understood ID

Table 3.1.2-1 Technical Actors

3.1.3 ACTOR INTERACTIONS

The relationship between the business actors and the technical actors is shown in the UML sequence diagram below. This transaction package includes the PIX query and response from the Patient Matching and ID Cross Referencing Transaction Package as an option to the receiving clinician when the clinician's locally-understood ID is not returned with the result. The technical actors from that package are shown here in addition to the actors from the Send Lab Result transaction. It is also important to note that the ordering clinician and the other providers of care are combined under the Clinician business actor. The results message will be sent to the other providers of care based on the cc list in the order.

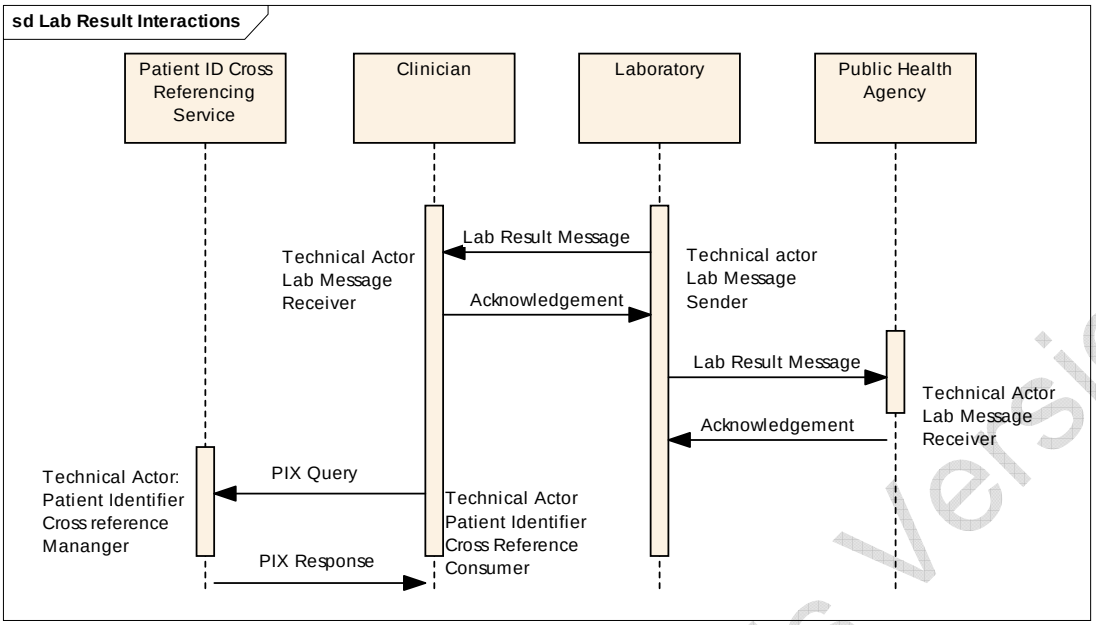
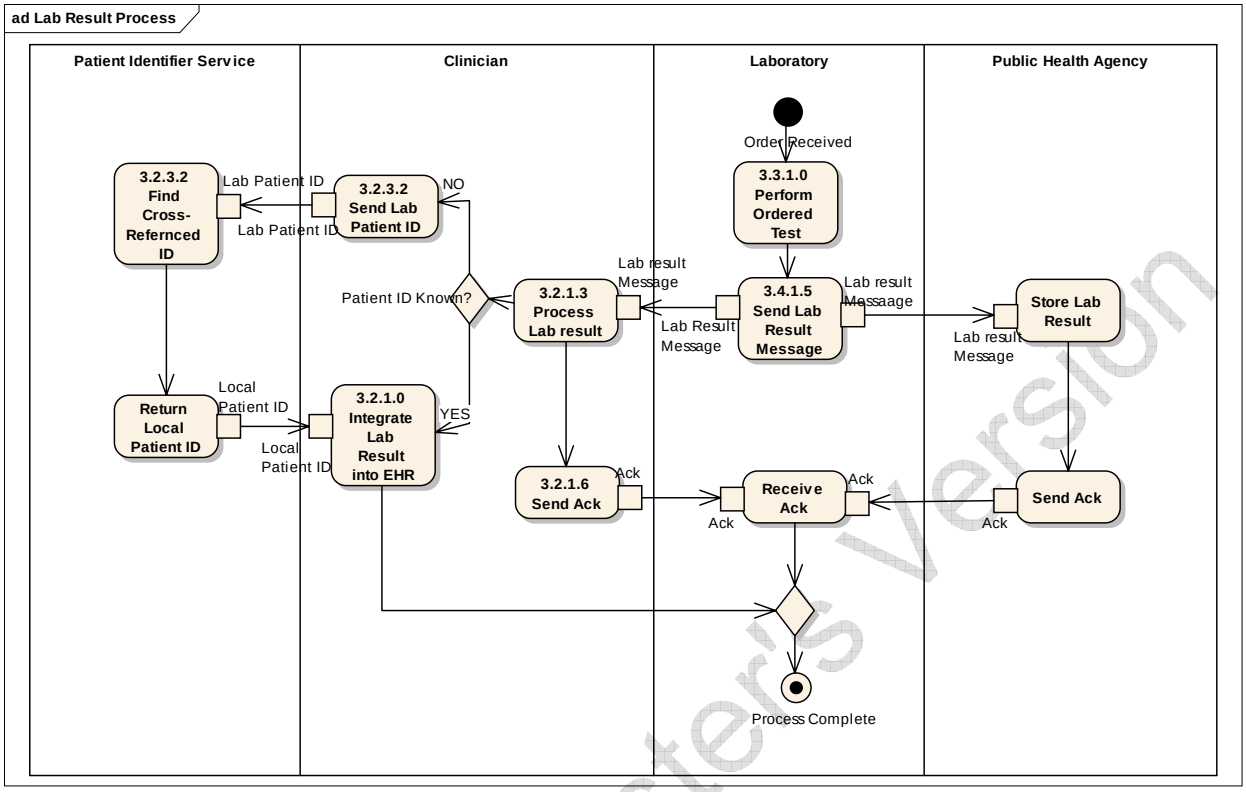


Figure 3.1.3-1 Actor Interactions

3.2 PROCESS FLOWS

This transaction package is in support of the traditional HL7 Version 2.x interface and as such, it supports the direct reporting from the lab to the ordering clinician and other providers of care. The inclusion of the optional Patient ID Cross-Referencing is intended to be used for sending the electronic lab result to authorized recipients other than the ordering clinician. It is assumed that the result sent to the ordering clinician contains the Patient ID provided on the order. The event codes in the following diagram refer to the ONC Harmonized EHR Use Case.



255 Figure 3.2-1 Process Flows

Change “Integrate into EHR” to “Receive Results in Local or Remote EHR or Other Clinical System”; “send ACK” after integrating into local system; combine 3.2.4.0 and 3.2.1.0

3.2.1 PROCESS PRE-CONDITIONS

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The following pre-conditions are assumed to be in place for the successful execution of this transaction package:

- The order contains the unambiguous names and electronic addresses for the other authorized providers of care.
- 265 When needed, the patient is registered in a patient ID cross-referencing system and that system includes both the lab patient ID and the clinician’s patient ID.
- On the electronic lab result, the lab has transformed any local codes into HITSP-specified terminologies before transmission.
- The lab is aware of the authorized public health agencies that require reports through either the
- 270 order or some other medium.

3.2.1.1 PROCESS TRIGGERS

There are two categories of trigger events supported by this transaction package. The first set of trigger
275 events focuses on the status of the lab result:

- A lab result (preliminary or final) is releasable.

- A lab result update is available.
- A lab result requires correction.
-

The second category of subsequent trigger events, typically for recipients other than the ordering clinician, focuses on the fact that the receiving system's patient ID may not be known to the sending system. This may necessitate a query to a patient ID cross-referencing service to locate the receiving system's local ID and an appropriate response. From the IHE IT Infrastructure Technical Framework, volume 2:

- A Patient Identifier Cross-reference Consumer's need to get the patient identifier associated with a domain for which it needs patient related information will trigger the request for corresponding patient identifiers message based on the following HL7 trigger event: Q23 – Get Corresponding Identifiers
- The Patient Identifier Cross-reference Manager's response to the Get Patient Identifiers message will trigger the following HL7 message: K23 – Corresponding patient identifiers

3.2.2 PROCESS POST-CONDITIONS

The desired post conditions for this transaction package are:

- The patient was successfully identified unambiguously
- The electronic lab result was successfully made available for clinical care in a manner that could be merged into a local or remote EHR system.
- Where appropriate, the authorized public health agency has received the lab result in a manner that could be merged into a biosurveillance system.

3.2.2.1 PROCESS OUTPUTS

The outputs from the processes supported by this transaction package are the successful receipt of the message acknowledgements.

3.3 DATA FLOWS

Data flows are depicted above.

4.0 APPENDIX

4.1 GLOSSARY

Included is the common interoperability glossary that is used for all the Use Cases. This is the HITSP glossary that spans all the interoperability specifications, which can be found in the following folder on the HITSP site:
http://publicaa.ansi.org/sites/apdl/Documents/Forms/AllItems.aspx?RootFolder=http%3a%2f%2fpublicaa%2eansi%2eorg%2fsites%2fapdl%2fDocuments%2fStandards%20Activities%2fHealthcare%20Informatics%20Technology%20Standards%20Panel