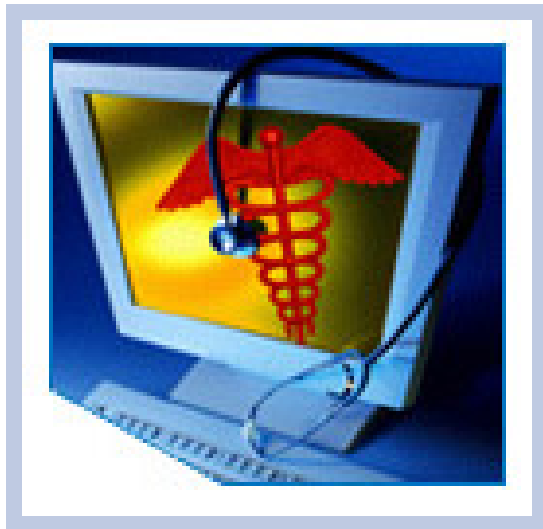


HITSP Send Laboratory Result Message to Ordering Clinician and Providers of Care Transaction Package

HITSP/TP14



Submitted to:

Healthcare Information Technology Standards Panel

Submitted by:

Care Delivery Technical Committee



DOCUMENT CHANGE HISTORY

Version Number	Description of Change	Name of Author	Date Published
1.0	Final Draft	Electronic Health Record Technical Committee	August 18, 2006
1.1	Ready for Public Comment	Electronic Health Record Technical Committee	September 12, 2006
1.2	Ready for Implementation Testing	Electronic Health Record Technical Committee	October 20, 2006
1.3	Review Copy	Care Delivery Technical Committee	April 27, 2007
2.0	Released for Implementation	Care Delivery Technical Committee	May 11, 2007
2.0.1	Review Copy	Care Delivery Technical Committee	December 5, 2007
2.1	Released for Implementation	Care Delivery Technical Committee	December 13, 2007



TABLE OF CONTENTS

1.0	FOREWORD	5
2.0	INTRODUCTION	8
2.1	Overview	8
2.2	Technical Assumptions and Scope	9
2.2.1	Interoperability Specifications Not Functional Specifications	9
2.2.2	Architectural Neutrality	9
2.2.3	The Use of Messages and Documents as Appropriate.....	10
2.2.4	Security and Privacy	10
2.3	Audience.....	11
2.4	Copyright Permissions.....	11
2.5	Acronyms.....	11
2.6	Conventions.....	11
2.7	Reference Documents.....	11
2.8	List of Transactions and Components.....	11
2.8.1	Dependencies.....	12
2.8.2	Constraints	12
3.0	TRANSACTION PACKAGES.....	13
3.1	Context Overview	13
3.1.1	Contextual Constraints	13
3.1.2	Actor Interactions.....	14
3.2	Process Flows	15
3.2.1	Process Pre-conditions.....	15
3.2.2	Process Post-conditions	16
3.3	Data Flows.....	16
4.0	CHANGE HISTORY	17
4.1	December 5, 2007	17
4.2	December 13, 2007	17



FIGURES AND TABLES

Figure 1.0-1 HITSP Harmonization Process Steps	7
Figure 3.1.2-1 Actor Interactions.....	14
Figure 3.2-1 Process Flows	15
Table 2.1-1 Related Documents	9
Table 2.8-1 List of Transactions and Components	12
Table 2.8.1-1 Dependencies.....	12
Table 2.8.2-1 Constraints.....	12
Table 3.1.1-1 Technical Actors	14



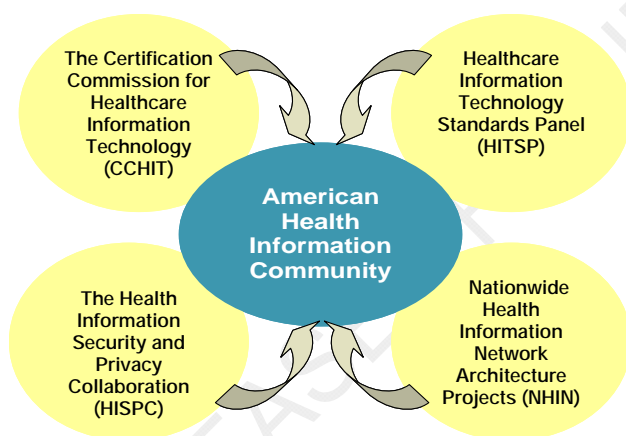
1.0 FOREWORD

This document is referred to as a Transaction Package and is an artifact of the Healthcare Information Technology Standards Panel (HITSP).

The following paragraphs provide background information about the HITSP and its role in the overall U.S. efforts to realize large scale interoperability of health information. It also describes the HITSP process for healthcare standards harmonization and explains how to use this document and other related documents to inform your health IT product development or product refinement. If you are familiar with HITSP and HITSP artifacts, please proceed to Section 2.0.

U.S. Nationwide Health Information Interoperability

Studies published by the Institute of Medicine and others have raised awareness of the extent to which the fragmented nature of clinical information adversely impacts the quality of care across the U.S. Health Information Technology (IT) can be used to enable better integration of clinical information. However, as of 2007, only a small number of U.S. healthcare providers have fully adopted health IT due, in part, to technical barriers associated with a lack of unambiguous and nationally recognized Interoperability Standards.



The American Health Information Community¹ (AHIC), a 2005 federally-chartered commission made up of leaders from public and private health sectors, was formed to provide recommendations on how to make health records digital and interoperable, and assure that the privacy and security of those records are protected, in a smooth, market-led way. At the same time, the Department of Health and Human Services, through the Office of the National Coordinator for Health IT (ONC) awarded contracts to 1) identify Interoperability Standards to facilitate the exchange of patient data

(HITSP), 2) define a process for certifying that health IT products comply with appropriate standards through the Certification Commission for Healthcare Information Technology (CCHIT), and 3) develop a series of prototypes to establish the requirements of a Nationwide Health Information Network (NHIN). Under a renewed second year contract, HITSP scheduled activities will include identifying and constraining 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, as well as further work in additional Use Case priority areas recommended by AHIC. This year, CCHIT is expanding its certification efforts to inpatient, or hospital, electronic health record products. In

¹ <http://www.hhs.gov/healthit/ahic.html>



January 2007, four NHIN prototypes were 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 HITSP² 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
6. is subject to an ongoing review and revision process

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 information 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 constructs referred to as Transaction Packages, Transactions, or Components. For additional information on these constructs, please refer to the HITSP Harmonization Framework.

² www.hitsp.org



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 Use Cases (available at www.hitsp.org) that drove the initial 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 followed an 8 step process, depicted below.

Figure 1.0-1 HITSP Harmonization Process Steps



How to Read this Interoperability Specification

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 Send Lab Result Message Transaction Package 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 used to meet the IS requirements. The roadmap in Figure 1.2-1 depicts how this construct integrates and constrains HITSP constructs and existing standards selected or referenced to support the information exchange between two or more systems, 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.



2.0 INTRODUCTION

As an introduction to the HITSP Transaction Package: Send Laboratory Result Message to Ordering Clinician and Providers of Care, this section provides a high level overview of an 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 HITSP Acronyms List and an explanation of the conventions used to convey the full descriptions and usage of standards.

2.1 OVERVIEW

The purpose of this document is to describe the package of Transactions and Components that make up the specification for sending a laboratory result message to the ordering clinician and other providers of care. The goals supported by this Transaction Package specification are stated in the Electronic Health Record (EHR) Use Case:

- 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 laboratory results (or notification of the availability 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)

The Use Case notes 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 an 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 Care Delivery TC placed emphasis on the operations and process flows of current implementations and the ease with which current implementations can become compliant. Health Level (HL7) Version 2.x³ message-based laboratory result reporting is the most common electronic interface in existence today and the TC did not want to invalidate those interfaces.

This specification includes by reference the Transactions and Components that comprise the Laboratory Result Message Transaction Package. It describes the processes supported by these structures and the

³ HITSP references HL7 2.5.1 messaging for lab results reporting and HL7 2.5 for other messages. Future maintenance work will move toward referencing a single HL7 version across HITSP documents.



work that is accomplished by implementing this Transaction Package. This Transaction Package is an initial step in establishing a baseline of performance for all stakeholders. It raises everyone to a modern version of HL7 2.x and establishes some discipline in identity management and vocabulary.

In order to describe the complete package and how it is expected to be implemented, the Patient ID Cross-Referencing Transaction Package is also included as an optional structure under the Laboratory Result Message Transaction Package.

Table 2.1-1 Related Documents

Related Documents	Document Description
HITSP/C36	HITSP Laboratory Result Message Component
HITSP/C35	HITSP EHR Laboratory Terminology Component
HITSP/TP22	HITSP Patient ID Cross-Referencing Transaction Package

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 may not define all functions, constructs and standards necessary to implement a conforming system in a real world environment. The following paragraphs provide the HITSP principles 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 standardized 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 nonrepudiation. Persistence as defined by Health Level Seven (HL7) means that a clinical document continues to exist in an unaltered state for a time period defined by local and regulatory requirements. Nonrepudiation, as defined by ISO adapted from ASTM E31, means a service that provides proof of the integrity and origin of data, 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 deferred requirements that are addressed in this first release are secure web-based messaging, pseudonymization and anonymization.



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 set of Interoperability 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.

Certain material contained in this Interoperability Specification are reproduced from Health Level Seven (HL7) Version 2.5/2.5.1 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.

IHE materials used in this document have been extracted from relevant copyrighted materials with permission of Integrating the Healthcare Enterprise (IHE). Copies of this standard may be retrieved from the IHE Web Site at www.ihe.net.

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

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

2.8 LIST OF TRANSACTIONS AND COMPONENTS

The following list of Transactions and their definitions are used by this Transaction Package specification.



Table 2.8-1 List of Transactions and Components

Transaction Name	Description
HITSP/C36	HITSP Laboratory Result Message Component
HITSP/C35	HITSP EHR Laboratory Result Terminology Component
HITSP/TP22	HITSP Patient ID Cross-Referencing Transaction Package

2.8.1 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.

Table 2.8.1-1 Dependencies

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	Laboratory 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	Laboratory Order	Pre-condition	The lab order is echoed in the lab result message.

2.8.2 CONSTRAINTS

The following table identifies the constraints identified for included Transactions and Transaction Packages:

Table 2.8.2-1 Constraints

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.
Patient ID Cross-Referencing	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.



3.0 TRANSACTION PACKAGES

3.1 CONTEXT OVERVIEW

The functionality supported by this Transaction Package to send laboratory result messages to the ordering clinicians and providers of care and to receive acknowledgement from authorized recipients, with optional patient ID cross-reference information, operates within a defined context. That context assumes that an order has been received and accepted by the laboratory and the laboratory 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.

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 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. The copy-to list of authorized providers of care is provided in the order
- All messages in this Transaction Package conform to HITSP laboratory terminology

NOTE:

The electronic laboratory 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 National Library Medicine (NLM). This would allow the laboratory to report using one terminology and the receiver to translate into another. While this technology exists, it is not widely used and the mappings are not yet complete. In the long term, mappings are prone to losses of information and discouraged.

TECHNICAL ACTORS

The technical actors for this Transaction Package are associated with one of three interactions:

- The Laboratory Result Message
- The Patient ID Cross-Referencing Query
- 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 Laboratory Result Receiver for the Laboratory Result Message Transaction and also the Patient Identifier Cross Reference



Consumer for the transaction. The table below identifies the technical actors involved in this Transaction Package:

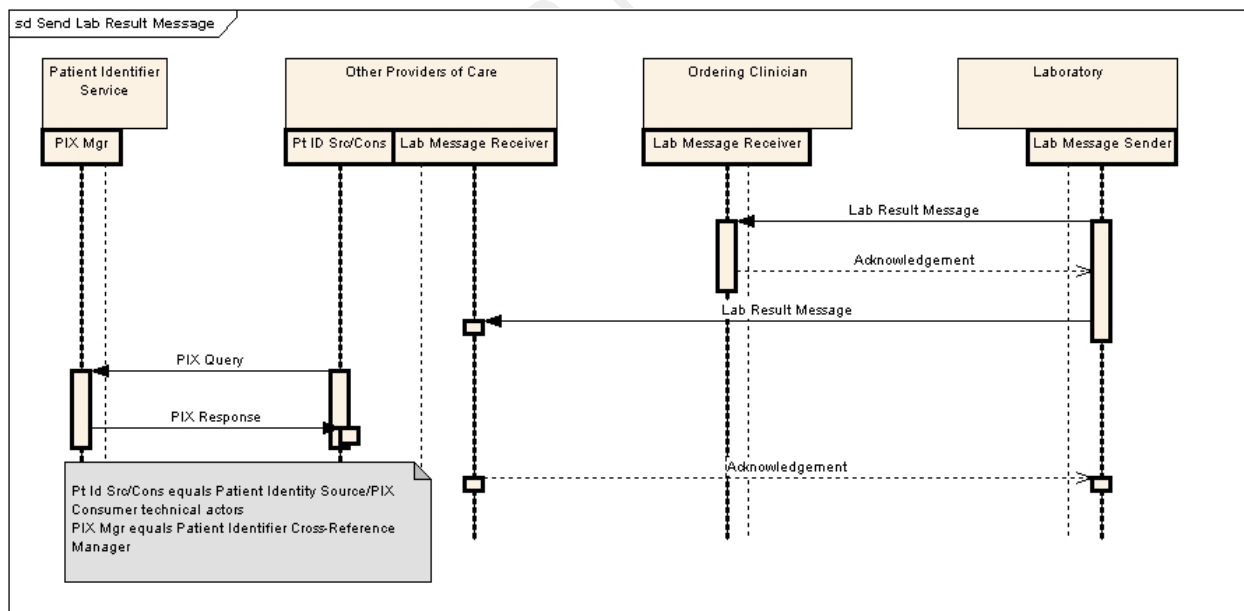
Table 3.1.1-1 Technical Actors

Actor	Description
Laboratory Result Message Sender	The holder of a laboratory result who is communicating a laboratory result message to another actor.
Laboratory Result Message Receiver	An authorized entity that is receiving a laboratory 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.

3.1.2 ACTOR INTERACTIONS

The relationship between the business actors and the technical actors is shown in the Unified Modeling Language (UML) sequence diagram below. This Transaction Package includes the Patient Identifier Cross-Referencing (PIX) query and response from the Patient ID Cross-Referencing Transaction Package HITSP/TP22 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 Laboratory Result Transaction. The results message will be sent to the other providers of care based on the carbon copy list in the order.

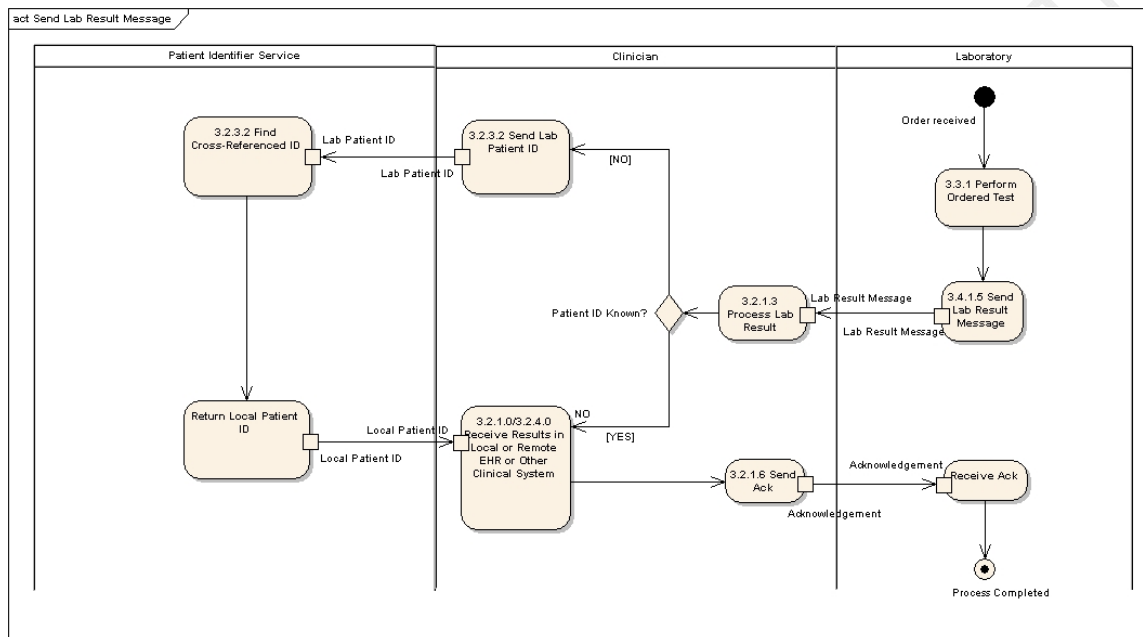
Figure 3.1.2-1 Actor Interactions



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 laboratory to the ordering clinician and other providers of care. The inclusion of the optional Patient ID Cross-Referencing manager is intended to be used for sending the electronic laboratory 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 EHR Use Case.

Figure 3.2-1 Process Flows



3.2.1 PROCESS PRE-CONDITIONS

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
- When needed, the patient is registered in a Patient ID Cross-Referencing system and that system includes both the laboratory patient ID and the clinician's patient ID
- On the electronic laboratory result, the laboratory has transformed any local codes into HITSP-specified terminologies before transmission

3.2.1.1 PROCESS TRIGGERS

There are two categories of trigger events supported by this Transaction Package. The first set of trigger events focuses on the status of the laboratory result:



- A laboratory result (preliminary or final) is releasable
- A laboratory result update is available
- A laboratory 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 laboratory result was successfully made available for clinical care in a manner that could be merged into a local or remote EHR 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 (see Figure 3.2-1 Process Flow).



4.0 CHANGE HISTORY

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

4.1 DECEMBER 5, 2007

- Removed footnote regarding informative nature of C36 as that construct is now complete
- Removed references to *C45 - Acknowledgements*, this construct is no longer required; the topic is covered in the referenced HL7 Implementation Guide in *C36 - Lab Message*
- Updated UML Diagrams

4.2 DECEMBER 13, 2007

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

