Project: Lab Information Systems – Standards

Project No.: ITC-11-522

Deliverable: AHS Laboratory Report CDA Specification – Business Overview

Reviewed/Approved by	Name
Approver	Lab Report CDA Working Group

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V0.2	March 12, 2014 Added content to Section III – Business Context. Minor edits to other sections as tracked.
V3.0	April 2, 2014 Edits based on feedback from the Lab Working Group.

Reference Documents

The following documents are for reference material purposes to provide context to support information included in this document.

Document
Lab Standardization Project – Lab Report CDA Project Charter

Acknowledgements

These specifications were developed in collaboration with the Alberta Laboratory Report CDA Specification Working Group:

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TABLE OF CONTENTS

List of Figures

List of Tables

I INTRODUCTION

1.1 Background

The Lab Information Systems Standards Project seeks to normalize laboratory messaging and terminologies through the adoption of relevant pan-Canadian and Provincial standards.

In early 2013, the project conducted a Laboratory Standardization Assessment to determine the extent to which the Canada Health Infoway pan-Canadian Laboratory Messaging and Nomenclature (pCLMN) Specification could be used in Alberta. The recommendation included a hybrid solution – leveraging the HL7v2 Lab Test Result Delivery Specification (Release 2) and aspects of the pCLMN for terminologies (e.g. SNOMED CT® , pCLOCD, HL7 Value Sets, etc.) and the HL7v3 domain constraints for the Lab Report clinical document.

To produce this standard message, the Laboratory Message Transformation Service will restructure the incoming HL7v2 messages from 11 Laboratory Information Systems, transforming data, normalizing with appropriate terminology, and building a standard HL7v2.4 message and a CDA-compliant clinical document.

The Business Overview provides the business context for the Lab Report Clinical Document (HL7v3 Clinical Document Architecture) and HL7v2.4 LTRD Release 2 Specifications. This specification will enable the rendering and display of lab reports in a consistent way for all consuming systems.

1.2 Document Purpose

These specifications include HL7 v2.4 messaging specifications and a CDA laboratory report document template. This Document is intended to collect common information including business background, process information as well as other common Implementation Guidance relevant to implementers of either or both of the v2.4 along with the CDA content.

1.3 Document Audience

This audience includes technical and business readers who will use the guide to develop implementations and validate that these implementations conform to the Specifications and to the requirements of the associated stakeholder organizations.

Readers are assumed to be familiar with HL7 specifications generally and HL7 v2.4 and v3 specification frameworks specifically as well as the HL7 CDA Standard. For further information on these standards please consult http://www.hl7.org.

In addition readers should be familiar with prevailing Alberta Health Information standards. For further information on these standards please consult http://www.health.alberta.ca/about/HISCA.html.

Finally, readers may benefit from broad awareness of pan-Canadian standards. For further information on these standards please consult https://www.infoway-inforoute.ca/standards-collaborative.

1.4 Specification Structure

These specifications have been layered into multiple documents and technical artifacts which, together, provide implementation direction and establish conformance requirements.

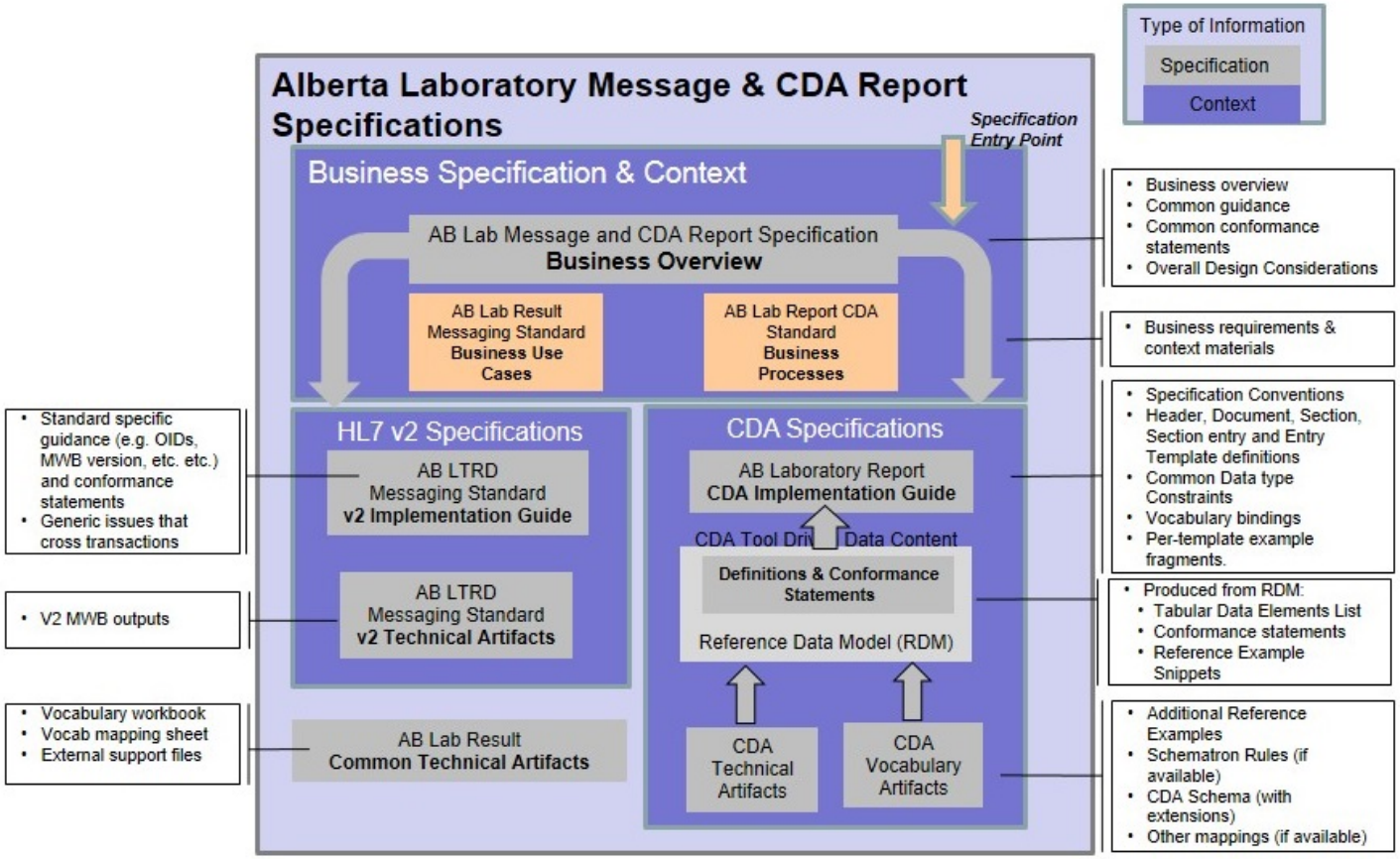


Figure 1: Specification Structure

These documents have been structured to minimize duplication and to streamline access to information for prospective implementers. Moreover, recognizing that certain implementers will likely need to support v2.4 and CDA based interoperability, these specification documents aim to offer an integrated view for both specifications.

Each of these specification sets has been stratified and it is recommended that readers approach these layers in order as follows:

- ***V2.4 Implementation Guide:*** This guide is intended to provide clear direction to implementers about the in-scope interoperability transactions and provides both guidance and normative direction about how to implement the specifications.
- ***CDA Implementation Guide:*** This document is intended to provide the technical information required to implement the specification. It includes an outline of the specification conventions and overall technical requirements. The implementation guide then includes the detailed requirements for the in-scope documents, all of the document sections, and templates that are used to build the specifications. The implementation guide consists of both tabular as well as conformance-statement oriented views of the requirements and includes the testable conformance statements for the specification which conformant systems are expected to support as well as specific business rules and data obligations. Where applicable the formal CDA conformance statements are incorporated or referenced.
- ***v2 Conformance Profiles***: The HL7v2.4 **Conformance Profile** document outlines the in-scope transactions which conformant systems are expected to support as well as specific business rules and data obligations for each transaction. Where applicable a formal conformance profile (e.g. HL7 Message Profile) is referenced.
- ***Technical Artifacts***. Each specification includes appropriate technical artifacts as outlined in Appendix B of this document. Broadly speaking, the following artifacts are included:
  - HL7 v2.4: Applicable HL7 Message Workbench files; and
  - HL7 CDA: non-normative eXtensible Markup Language (XML) Schema files (.XSD) files to extend the HL7 CDA schema (if applicable).

Finally, these specifications are published with a set of common artifacts including a normative vocabulary specification contained in the ***Lab Report - Data Model and Mapping Workbook***. This is intended to consolidate valid vocabulary pertaining to the message portion of the specification in a convenient, machine processable manner. Vocabulary pertaining to the Clinical Document Architecture (CDA) portion of these specifications is fully integrated into the CDA Implementation Guide.

Please consult section V (Conformance Approach) for further details about how these specification documents are intended to be formally interpreted so as to maximize clarity and to enable the effective development and validation of conformant solutions.

II DEVELOPMENT METHODOLOGY

2.1 Preamble

The process used to select and settle the specific in-scope transactions as well as the data used within the various transactions may be helpful context for implementers as they aim to understand why certain choices were made by the designers and the stakeholders charged with development of the specification. This section provides a high level overview.

2.2 Business Requirements

2.2.1 Business Context

The first step in the development methodology was to develop a common understanding of the business context within which the lab standards would be used. This understanding is reflected in the following Business Context Diagram. The scope of this specification covers the transactions and clinical documents for laboratory result reporting. At this time, laboratory order management is out of scope. This diagram illustrates the key processes and actors in the overall simplified Laboratory Business Model.

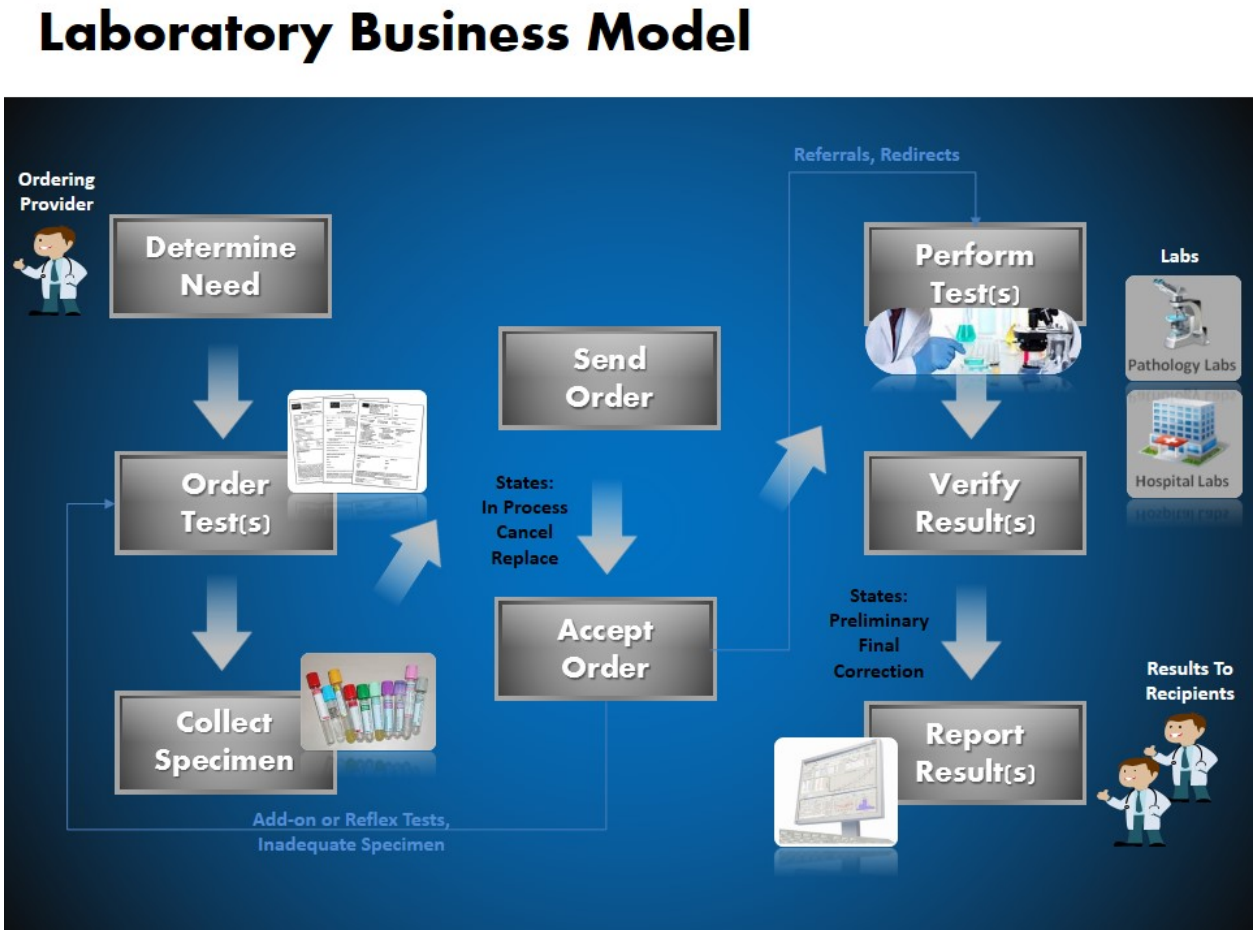


Figure 2: Business Model Diagram

Below is the basic workflow:

- The ordering provider completes the Test Requisition and provides direction to the patient/client to present to the lab for the Specimen to be collected or the specimen may be collected at the Service Delivery location and forwarded to the Laboratory for processing.
- Subsequent to collection, the Order is provided to the patient for collection of the Specimen(s) by the Laboratory. Note: the specimen is sometimes collected prior to the creation of the Order.
- The Specimen is sent to the Laboratory for processing.
- Orders can be In Process, Cancelled or Replaced.
- The Laboratory may accept the Order as is, may add-on tests, or may indicate that the Specimen is inadequate. One or more of the tests may also be referred to another lab or the entire Order may be re-directed.
- The performing Laboratory runs the tests, verifies the results and distributes the results to the Ordering Provider and Copies to.
- Results can be Preliminary, Final or Corrected. Only Preliminary Results can be Cancelled.
- Receiving Providers may either receive pushed results or need to query the Alberta Netcare Portal to obtain the results. Corrections to Results in the Alberta Netcare Portal are re-bolded to alert Providers of changes to the records.

2.3 Transaction Framework

The Process Flow and Use Cases identified three Transaction Groups required to support the full Laboratory Test Order and Result Management Workflow. Only one Transaction Group is in scope for these specifications.

Table 1: Transaction Group List

ID	Transaction Group
TG01	**Laboratory Result Reporting**
a) Send Laboratory Result (Preliminary or Final) b) Revise Laboratory Result (Corrected, When a Final is replacing a Preliminary; Amendments, Addendums) c) Cancel Laboratory Results d) Notification of Changes to Laboratory Results in the Alberta Netcare Portal (re-bolding in the CDV)	
TG02	**Laboratory Order Management**
Out of scope	
TG03	**Laboratory Report Clinical Document Query**
See Shared Health Record Project Specifications.	

2.3.1 Lab Result Design Pattern

The design pattern for the Lab Result transaction group includes a combination of HL7 messaging and HL7 Clinical Document Architecture documents. The purpose of the HL7 message component is to communicate the workflow data elements needed to process the Lab Result. The purpose of the document component is to communicate the displayable, clinically attested content that is relevant to the Lab Report.

There are many elements that will be duplicated in the message, because they are necessary for workflow, and in the document, because they are part of the clinical content.

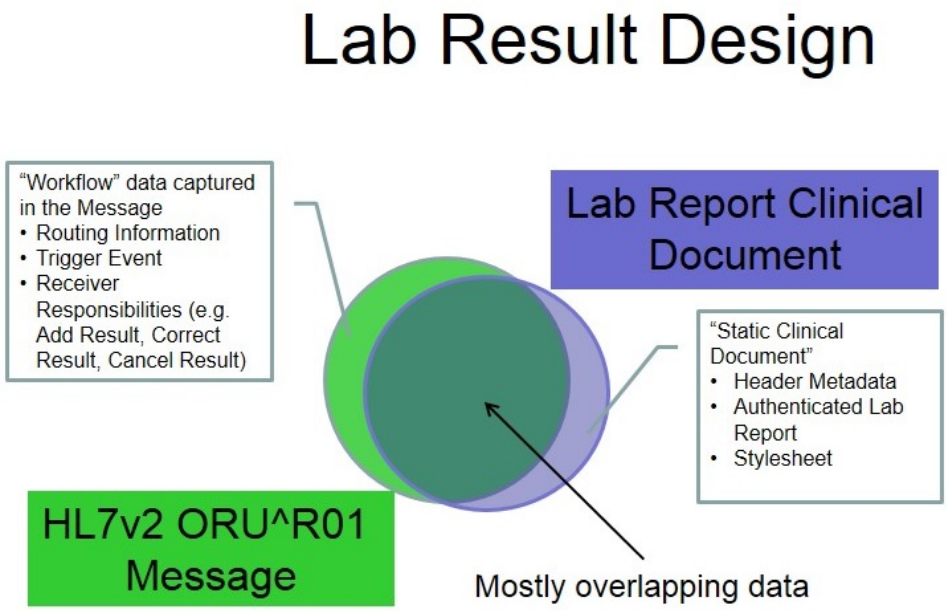


Figure 3: Lab Result Design Pattern

Within the Message and Document there are distinct conceptual components. The approach for each conceptual component is outlined in the following figure:

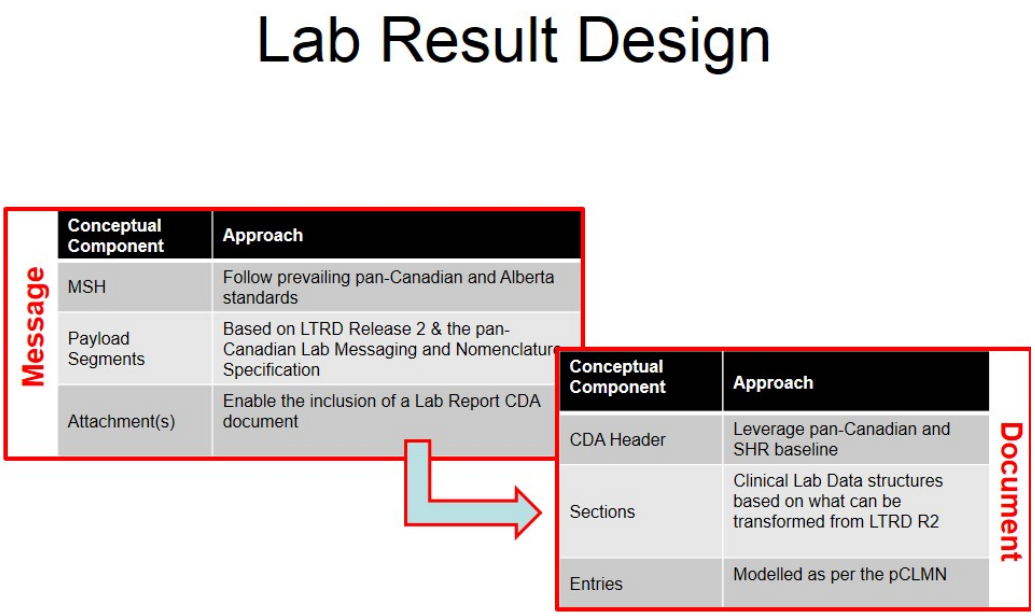


Figure 4: Lab Result Design Approach

2.4 Data Framework

2.4.1 Messaging Layer

The data framework for the messaging layer will be summarized in the ***Lab Result Data Model and Mapping Workbook***.

A series of data elements may need to be added to meet technical / processing requirements and to ensure HL7 v2.4 / CDA interoperability. For further details please consult chapter IV.

2.4.2 Document Layer

The data framework for the document layer is fully outlined in the CDA Implementation Guide.

III BUSINESS CONTEXT

3.1 Laboratory Result Types

3.1.1 General Lab

For purposes of this specification, General Lab covers tests more familiar to the general public; such as blood cell counts, coagulation studies, urinalysis, blood glucose level determinations. Its subsections include chemistry, hematology, immunology, urinalysis.

3.1.2 Microbiology

Microbiology is the study of microscopic organisms, either unicellular (single cell), multicellular (cell colony), or acellular (lacking cells). Microbiology encompasses numerous sub-disciplines including virology, mycology, parasitology, and bacteriology.

3.1.3 Bloodbank

Bloodbank-related tests refer to the blood typing and screening of blood products for use in future transfusions,

3.1.4 Anatomic Pathology

Anatomical pathology is a medical specialty that is concerned with the diagnosis of disease based on the gross, microscopic, chemical, immunologic and molecular examination of organs, tissues, and rarely whole bodies (autopsy). Sub-disciplines in scope of this specification include surgical pathology and cytopathology.

3.2 Business Processes

The following table list the business processes in scope for this specification.

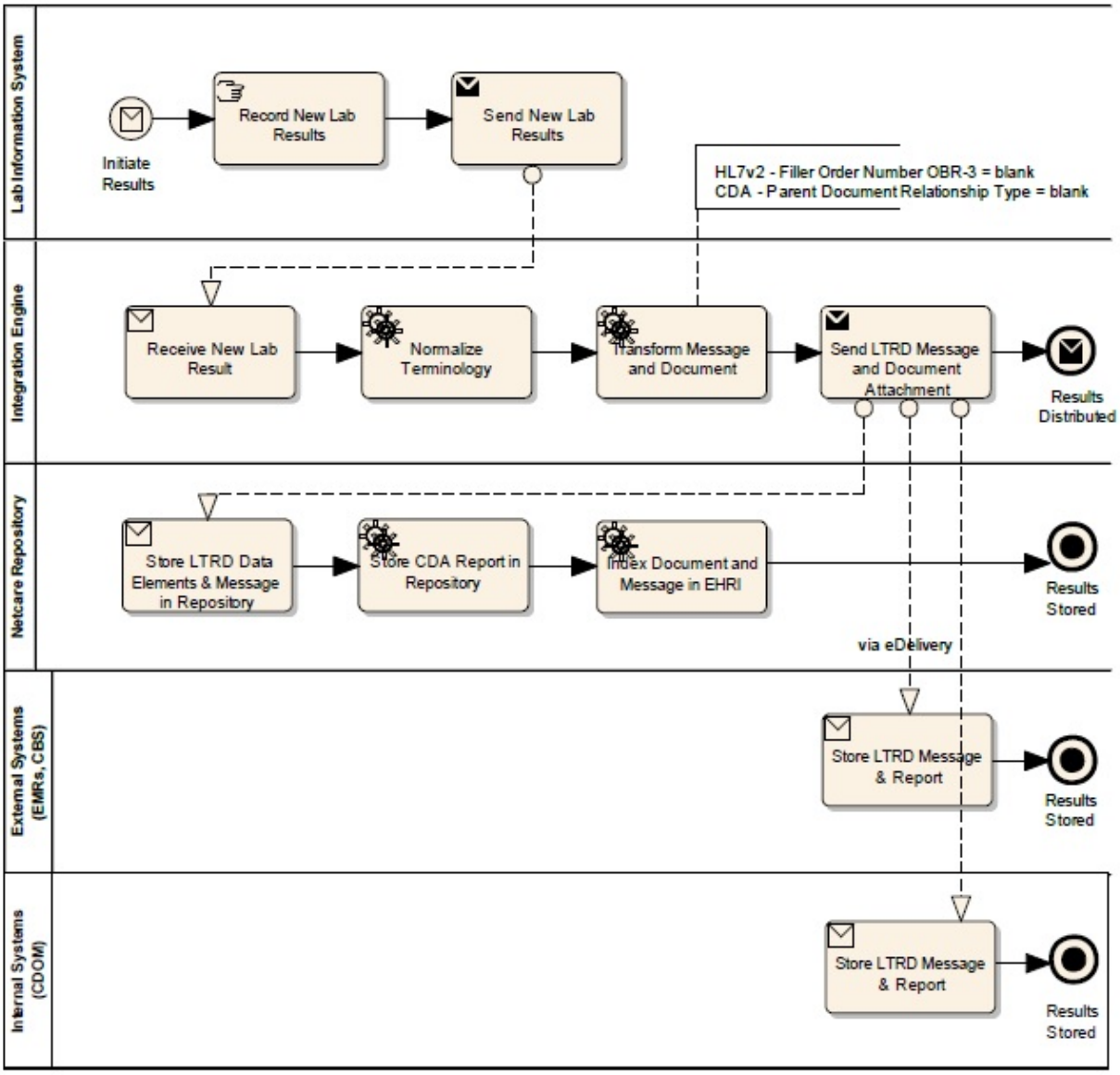
Process Name	Identifier	Process Purpose
Laboratory Result Create	**[T01]**	Send a Lab Result to the EHR and/or other consuming systems using the Lab Message Transformation Service.
Laboratory Result Update	**[T02]**	Send an update Lab Result to the EHR and/or other consuming systems using the Lab Message Transformation Service. This could include corrections, replacements of Preliminary with Final results or addition of information (i.e. Append).
Laboratory Result Cancel	**[T03]**	Send a request to cancel one or more tests for a Lab Result to the EHR and/or other consuming systems using the Lab Message Transformation Service.
Laboratory Result Deletion	**N/A**	Laboratory Results cannot be deleted. If they are in error and Preliminary, they will be cancelled. If they are in error and Final, they will be corrected.

Notifications of changes to Laboratory Results (e.g. Corrections or Cancellations) propagated to the Alberta Netcare Portal will follow the existing Netcare processes whereby documents on the Clinical Document View tree will re-bold when a change of any kind occurs.

3.2.1 T01 – Laboratory Result Create

The basic process flow for the distribution of new laboratory results is common across all 4 lab disciplines in scope, namely, general lab, microbiology, anatomic pathology and bloodbank. The diagram below illustrates the key actors and activities in this process flow.

3.2.1.1 Process Flow



Narrative

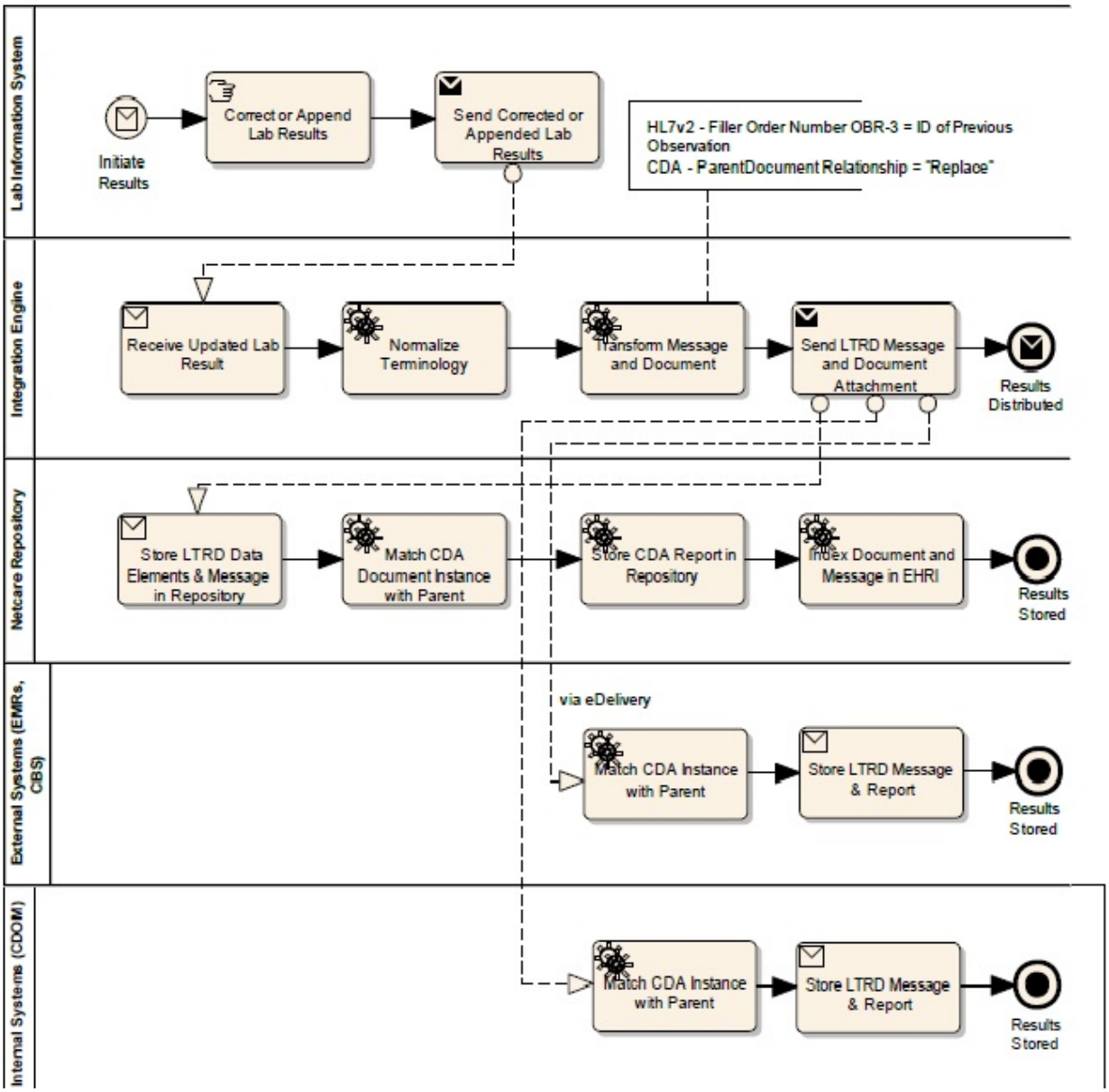
- New lab results are recorded in the LIS and sent to the Integration Engine.
- The Integration Engine logs the message invokes the Message Transformation Service.
- The Message Transformation Service transforms the message and creates a lab report document.
- The standardized message and document attachment are sent directly to the consuming systems from the Integration Engine.

- The standardized message and document attachment are sent to Netcare Repository. Netcare will index the document (and the message in EHRI and the XDS registry for later retrieval.
- Netcare stores the LTRD message and discrete data in the Lab Repository and the CDA Report in the Document Repository for viewing in the Netcare Portal.
- All providers may view the new result through Alberta Netcare Portal.
- The CDA Lab Report may also be accessed via XDS mechanisms.

3.2.2 T02 – Laboratory Result Update

The basic process flow for the distribution of updates to laboratory results (i.e. corrections, amendments, addendums) is common across all 4 lab disciplines in scope, namely, general lab, microbiology, anatomic pathology and bloodbank. The diagram below illustrates the key actors and activities in this process flow.

3.2.2.1 Process Flow



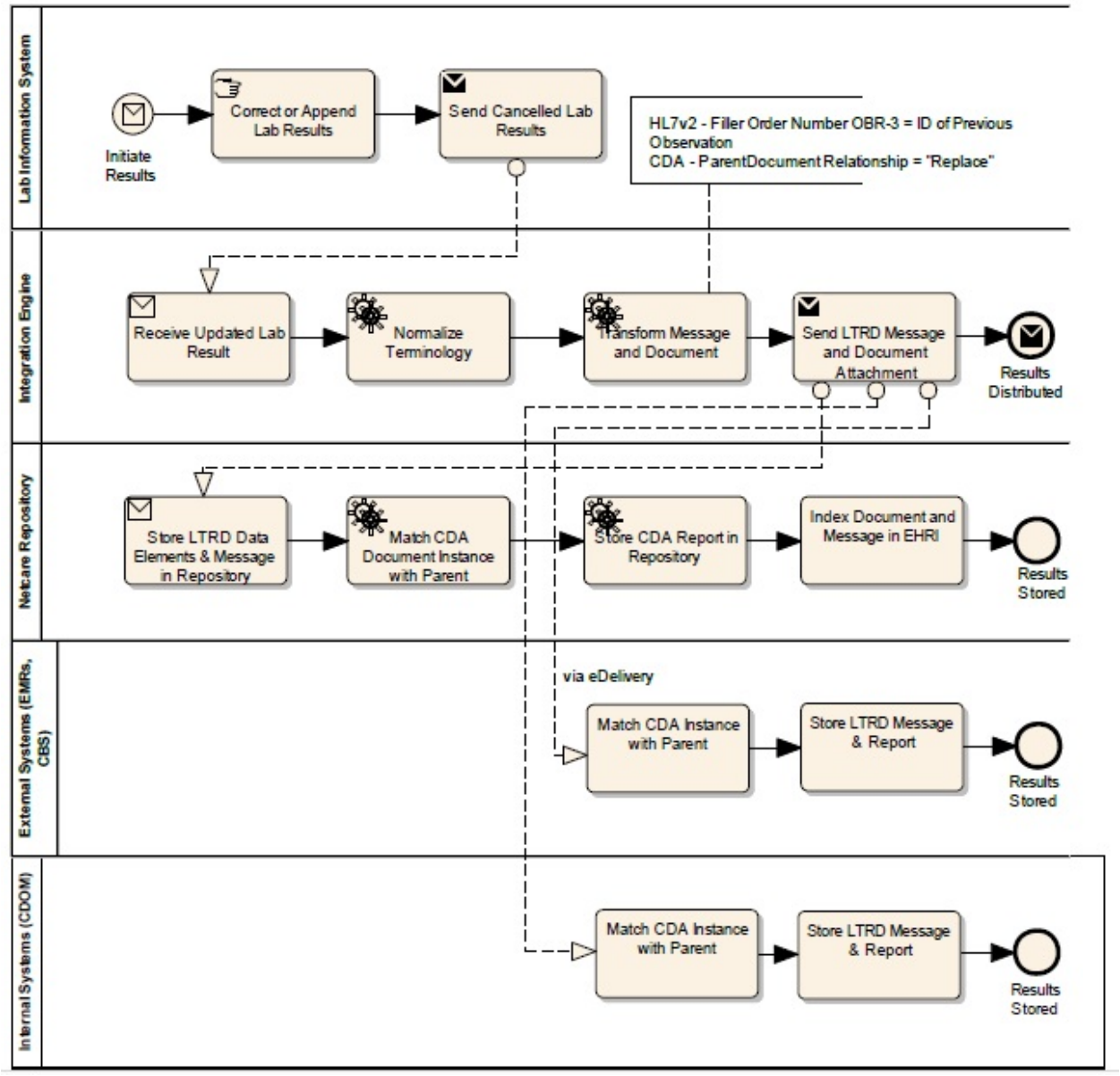
Narrative

- Updated lab results are recorded in the LIS and sent to the Integration Engine.
- The Integration Engine logs the message invokes the Message Transformation Service.
- The Message Transformation Service transforms the message and creates a lab report document.
- The standardized message and document attachment are sent directly to the consuming systems from the Integration Engine.
- The standardized message and document attachment are sent to the Netcare Repository. Netcare will index the document (and the message in EHRI and the XDS registry for later retrieval.
- Netcare matches to the original results using OBR-3 identifier and stores the LTRD message in the Lab Repository and the CDA Report in the Document Repository for viewing in the EHR. The CDA Report is to replace the previous report as indicated by the ParentDocument Relationship id. The original Report would still be available in the Repository for historical tracking purposes.
- Providers will be notified of the Corrected Lab Result through existing mechanisms (e.g. eDelivery). For the Alberta Netcare Portal, the records will be re-bolded in the Clinical Document View.

3.2.3 T03 – Laboratory Result Cancel

The basic process flow for the distribution of cancellations to preliminary laboratory results is common across all 4 lab disciplines in scope, namely, general lab, microbiology, anatomic pathology and bloodbank. Note: Final results cannot be cancelled. The diagram below illustrates the key actors and activities in this process flow.

3.2.3.1 Process Flow



Narrative

- Cancelled preliminary lab results are recorded in the LIS and sent to the Integration Engine.
- The Integration Engine logs the message and invokes the Message Transformation Service.
- The Message Transformation Service transforms the message and creates a lab report document.
- The standardized message and document attachment are sent directly to the consuming systems from the Integration Engine.
- The standardized message and document attachment are sent to the Netcare Repository. Netcare will index the document and the message in EHRI and the XDS registry for later retrieval.
- Netcare matches to the original results using OBR-3 identifier and stores the LTRD message in the Lab Repository and the CDA Report in the Document Repository for viewing in the EHR. The CDA Report is to replace the previous report as indicated by the ParentDocument Relationship id.

- Providers will be notified of the Cancelled Lab Result through the Netcare Portal. That is, records will be re-bolded in the Clinical Document View. Subscribers to the Document Repository will be notified of a replacement report through the existing Shared Health Record Infrastructure.

3.1 Overarching Pre-Conditions, Post-Conditions & Assumptions

3.1.1 Pre-Conditions

The following pre-conditions apply to usage of all transactions:

1. Users have appropriate permissions and security to perform the tasks (i.e. the in-scope systems will have appropriate mechanisms to authenticate users and control access to privileged operations).
2. Point of service systems are authenticated with AHS network security and are able to access Netcare and other applicable central resources via the Regional Integration Engines or the Provincial Health Information Exchange (pHIE).
3. Providers are licensed and are recorded in the provincial Provider Registry.
4. Locations where health services are delivered are registered in the provincial Delivery Site Registry.
5. The patient's identity and Unique Lifetime Identifier (ULI) will have been confirmed by the provider.
6. The regional integration infrastructure has received an HL7 result message from a Laboratory Information System and invoked the Lab Message Transformation Service.

3.1.2 Post-Conditions

The following post-conditions apply to usage of all transactions:

1. The HL7 message as received has been normalized and transformed and sent to the systems that can consume it; the original message has been delivered to other consuming systems.

3.2 Use Cases

The following table outlines some key use cases for the sending, updating and cancellation of the various lab results for each of the 4 disciplines.

Use Case Name	Use Case ID	Use Case Diagram	OBR-3 Filler Order Number	OBR-25 Lab Result Status	OBX-11 Lab Obs Status	CDA Relationship Type
General Lab						
Send Final General Lab Results	**UC001**	**[UC01]**	Not duplicated	F	F	No relation to another Document
Send Corrected General Lab Results	**UC002**	**[UC02]**	Matches Original	F	C	Replace
Cancel Preliminary General Lab Results	**UC003**	**[UC03]**	Matches Original	X	X	Replace
Microbiology						
Send Preliminary Microbiology Results	**UC004**	**[UC01]**	Not duplicated	P	P	No relation to another Document

Use Case Name	Use Case ID	Use Case Diagram	OBR-3 Filler Order Number	OBR-25 Lab Result Status	OBX-11 Lab Obs Status	CDA Relationship Type
Send Final Microbiology Results (to replace preliminary)	**UC005**	**[UC02]**	Matches Original	F	F	Replace
Send Corrected Final Microbiology Results	**UC006**	**[UC02]**	Matches Original	F	C	Replace
Cancel Microbiology Results	**UC007**	**[UC03]**	Matches Original	X	X	Replace
Pathology Reporting						
Send Preliminary Pathology Report	**UC008**	**[UC08]**	Not duplicated	P	P	No relation to another Document
Send Final Pathology Report (to replace preliminary)	**UC009**	**[UC11]**	Matches Original	F	F	Replace
Send Corrected Pathology Report	**UC0010**	**[UC11]**	Matches Original	F	C	Replace
Cancel Pathology Report	**UC0011**	**[UC03]**	Matches Original	X	X	Replace
Bloodbank Results						
Send Final Bloodbank Results (for Blood Typing and Screening)	**UC0012**	**[UC01]**	Not duplicated	F	F	No relation to another Document
Send Corrected Bloodbank Results	**UC0013**	**[UC02]**	Matches Original	F	C	Replace

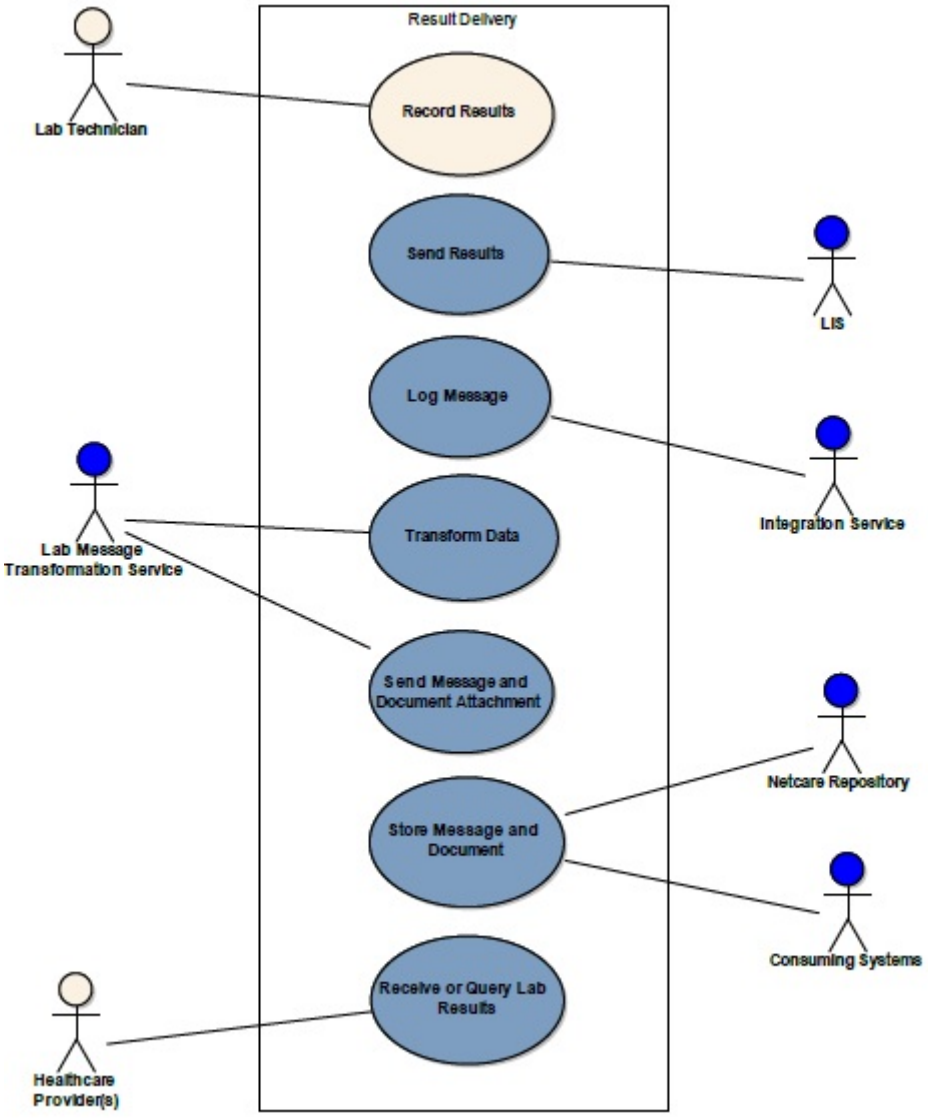
3.2.1 UC001: Send Final General Lab Results

3.2.1.1 Description

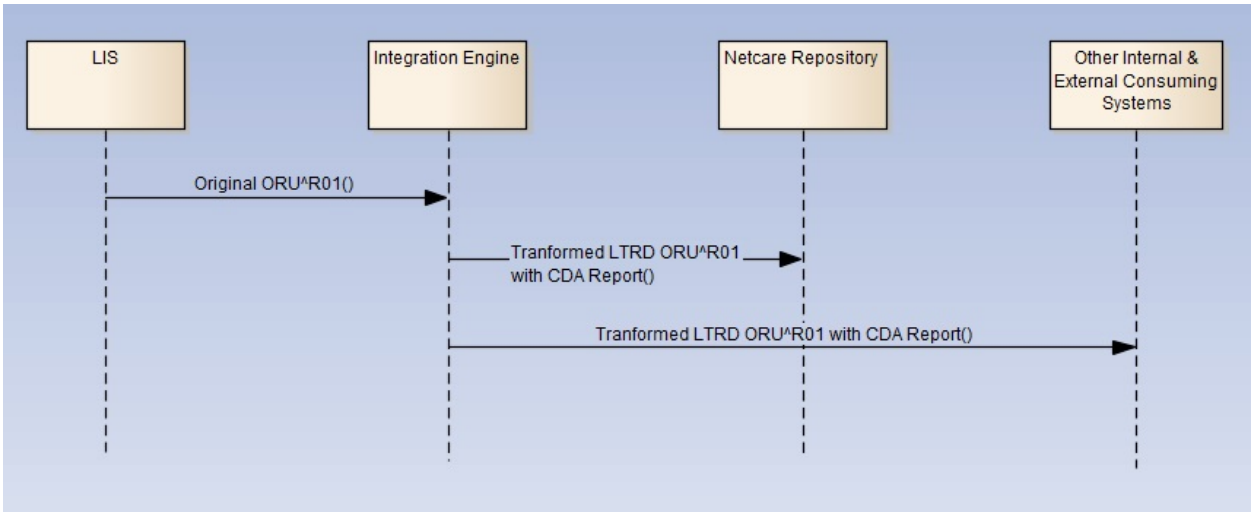
This use case describes the scenario where a Laboratory Information System sends Final General Lab Results (e.g. Sodium) to Netcare and other Consuming Systems via the Regional Integration Engine.

In this scenario, there was no Preliminary result previously sent and therefore no matching to the Filler Order Number (i.e. OBR-3) or replacement functions are required.

3.2.1.2 Use Case Diagram



3.2.1.3 Sequence Diagram



Caveats:

- Some consuming systems will receive the Original message; not LTRD compliant; not with a CDA Report as per existing mechanisms
- The external systems (e.g. FCC EMR) may or may not receive the LTRD v2 (TBD…could be an HL7v3 message)

3.2.1.4 Pre-Conditions

- See 3.1.1.
- No preliminary results were sent.

3.2.1.5 Post-Conditions

- See 3.1.2.
- Providers can query for the Lab Result message through the Netcare Portal.
- The LTRD compliant message with the CDA Lab Report attachment are sent directly to consuming systems (e.g. CDOM).

3.2.1.6 Basic Flow

1. The Laboratory Information System send the Final General Lab Result to the Integration Engine. The message is in local HL7v2 ORU^R01 format with non-standardized terminology. The Lab Result Status is set to ‘F’ for Final (OBR-25). The Observation Result Status(s) are set to ‘F’ for Final (OBX-11).
2. The Integration Service logs the receipt of the message.
3. The Message Transformation Service is invoked.
4. The data is normalized and the message is transformed to an LTRD compliant message with a CDA Lab Report attachment.
5. The LTRD message and CDA Lab Report attachment are sent to Netcare.
6. The message (and discrete data elements) and the CDA Lab Report are stored in the Repository.

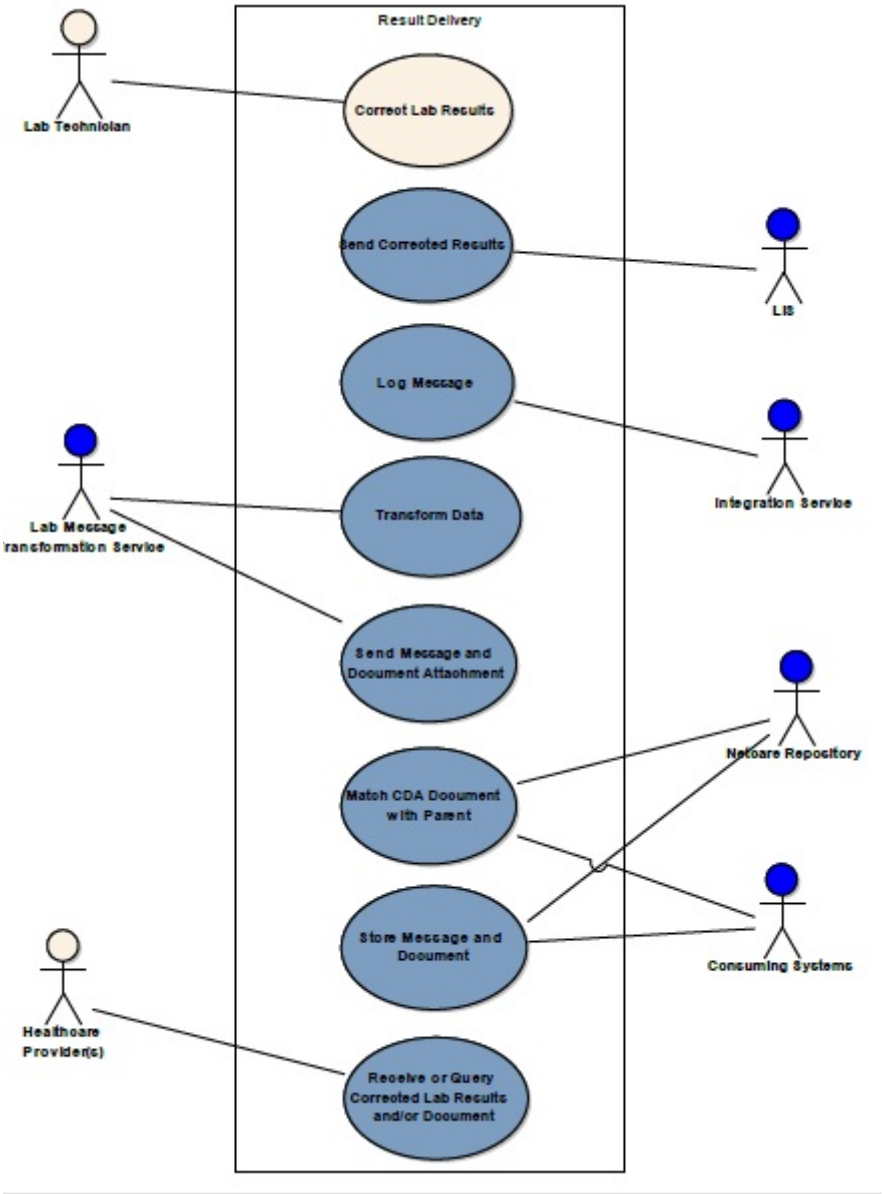
3.2.2 UC002: Send Corrected General Lab Results

3.2.2.1 Description

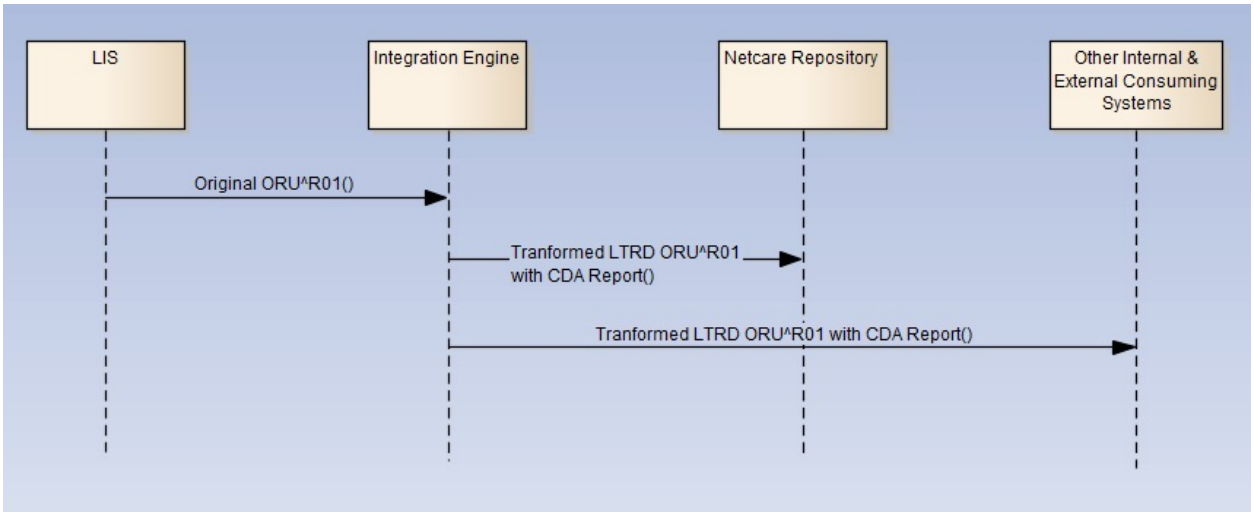
This use case describes the scenario where a Laboratory Information System sends a Correction to a previously sent Final General Lab Results (e.g. Sodium) to Netcare and other Consuming Systems via the Regional Integration Engine.

In this scenario, the Filler Order Number (i.e. OBR-3) must match the previous Sodium result.

3.2.2.2 Use Case Diagram



3.2.2.3 Sequence Diagram



3.2.2.4 Pre-Conditions

- See 3.1.1.
- A previous result was sent that is now to be corrected.

3.2.2.5 Post-Conditions

- See 3.1.2.
- The LTRD compliant message with the CDA Lab Report attachment are sent directly to consuming systems (e.g. CDOM).
- Providers will be notified of the Corrected Lab Result through the Netcare Portal. That is, the record will be re-bolded in the Clinical Document View. Subscribers to the Document Repository will be notified of a replacement report through the existing eDelivery Infrastructure.

3.2.2.6 Basic Flow

1. The Laboratory Information System sends a correction to the Final General Lab Result previously sent to the Integration Engine. The message is in local HL7v2 ORU^R01 format with non-standardized terminology. The Lab Result Status is set to 'F' for Final (OBR-25). The Observation Result Status(s) are set to 'C' for Correction (OBX-11).
2. The Integration Service logs the receipt of the message.
3. The Message Transformation Service is invoked.
4. The data is normalized and the message is transformed to an LTRD compliant message with a CDA Lab Report attachment.
5. The LTRD message and CDA Lab Report attachment are sent to Netcare.
6. The message is matched to the previous result using the Filler Order Number (i.e. OBR-3) and stored in the Repository as a correction. The CDA Lab Report is matched to the previous document using the ParentRelatinshipType.ParentDocument.id field and stored in the Repository as a Replacement to the previous Report.

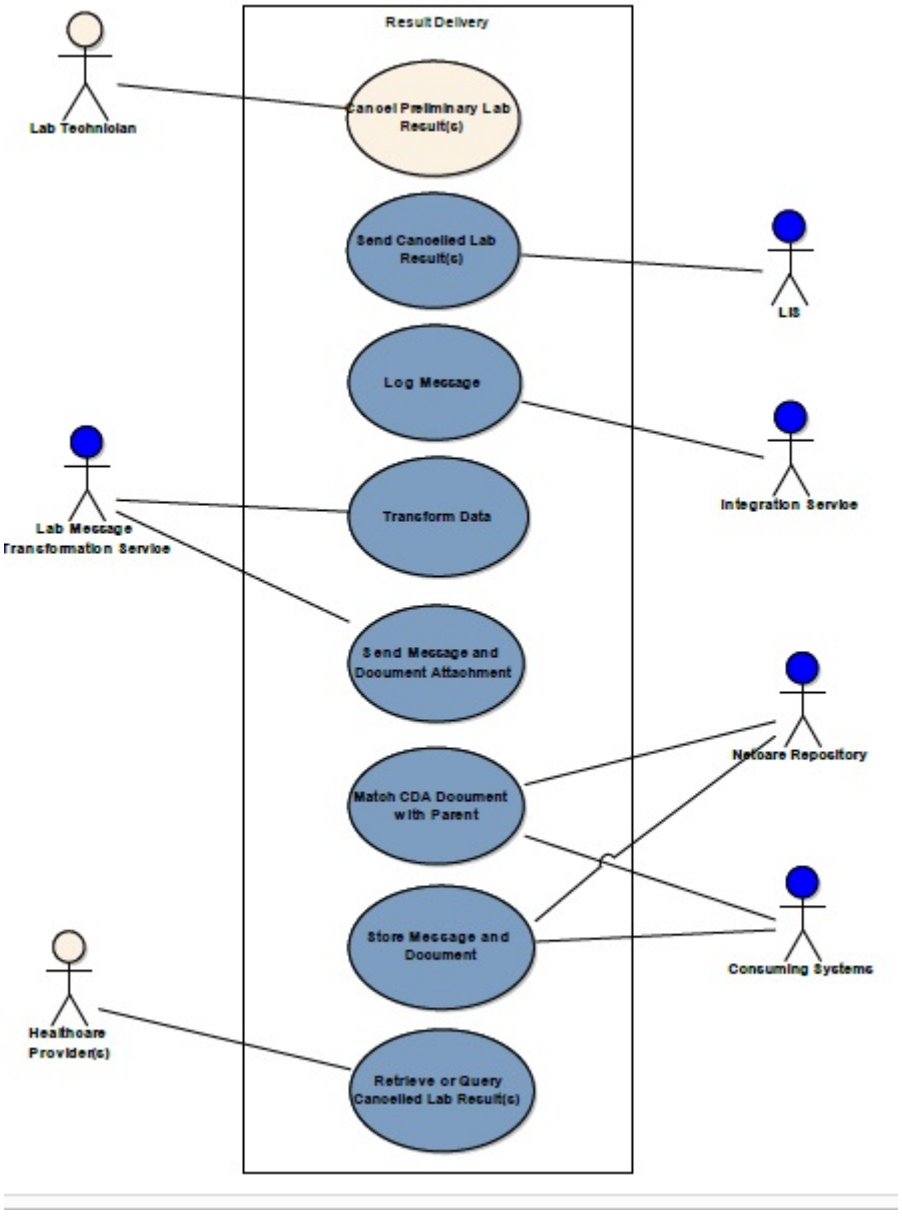
3.2.3 UC003: Send Cancelled Preliminary General Lab Results

3.2.3.1 Description

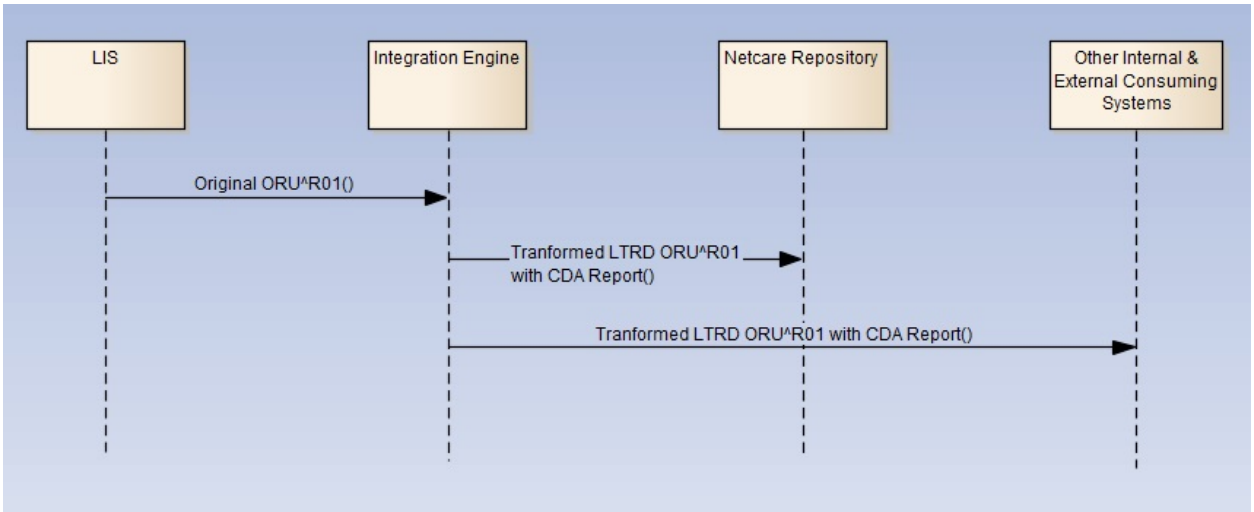
This use case describes the scenario where a Laboratory Information System sends a Cancellation to a previously sent Preliminary General Lab Results (e.g. Glucose) to Netcare and other Consuming Systems via the Regional Integration Engine.

In this scenario, the Filler Order Number (i.e. OBR-3) must match the previous Glucose result.

3.2.3.2 Use Case Diagram



3.2.3.3 Sequence Diagram



3.2.3.4 Pre-Conditions

- See 3.1.1.
- A previous Preliminary Result was sent that is now to be cancelled. Note: Final Results cannot be cancelled.
- The LTRD compliant message with the CDA Lab Report attachment are sent directly to consuming systems (e.g. CDOM).

3.2.3.5 Post-Conditions

- See 3.1.2.
- Providers will be notified of the Cancelled Preliminary Lab Result through the Netcare Portal. That is, the record will be re-bolded in the CDV. Subscribers to the Document Repository will be notified of a replacement report through the existing eDelivery Infrastructure.

3.2.3.6 Basic Flow

1. The Laboratory Information System sends a cancellation to a Preliminary General Lab Result previously sent to the Integration Engine. The message is in local HL7v2 ORU^R01 format with non-standardized terminology. The Lab Result Status is set to 'X' for Order Cancelled (OBR-25). The Observation Result Status(s) are set to 'X' for Results Cannot be Obtained (OBX-11).
2. The Integration Service logs the receipt of the message.
3. The Message Transformation Service is invoked.
4. The data is normalized and the message is transformed to an LTRD compliant message with a CDA Lab Report attachment.
5. The LTRD message and CDA Lab Report attachment are sent to Netcare.
6. The message is matched to the previous result using the Filler Order Number (i.e. OBR-3) and stored in the Lab Repository as a correction. The CDA Lab Report is matched to the previous document using the ParentRelatinshipType.ParentDocument.id field and stored in the Document Repository as a Replacement to the previous Report.

3.2.4 UC004: Send Preliminary Microbiology Results

3.2.4.1 Description

This use case describes the scenario where a Laboratory Information System sends Preliminary Microbiology Results (e.g. Stool Bacterial Culture) to Netcare and other Consuming Systems via the Regional Integration Engine.

In this scenario, there was no result previously sent and therefore no matching to the Filler Order Number (i.e. OBR-3) or replacement functions are required.

3.2.4.2 Use Case Diagram

See Common Lab Result Create Use Case Diagram for UC001.

3.2.4.3 Sequence Diagram

See Common Sequence Diagram for UC001.

3.2.4.4 Pre-Conditions

- See 3.1.1.
- No preliminary results were sent.

3.2.4.5 Post-Conditions

- See 3.1.2.
- The LTRD compliant message with the CDA Lab Report attachment are sent directly to consuming systems (e.g. CDOM).
- Providers can query for the Lab Result message through the Netcare Portal.

3.2.4.6 Basic Flow

1. The Laboratory Information System send the Preliminary Microbiology Results to the Integration Engine. The message is in local HL7v2 ORU^R01 format with non-standardized terminology. The Lab Result Status is set to 'P' for Preliminary (OBR-25). The Observation Result Status(s) are set to 'P' for Preliminary (OBX-11).
2. The Integration Service logs the receipt of the message.
3. The Message Transformation Service is invoked.
4. The data is normalized and the message is transformed to an LTRD compliant message with a CDA Lab Report attachment.
5. The LTRD message and CDA Lab Report attachment are sent to Netcare.
6. The message and CDA Lab Report are stored in the Repository.

3.2.5 UC005: Send Final Microbiology Results

3.2.5.1 Description

This use case describes the scenario where a Laboratory Information System sends Final Microbiology Results in replacement of Preliminary results (e.g. Stool Bacterial Culture) to Netcare and other Consuming Systems via the Regional Integration Engine.

In this scenario, the Filler Order Number (i.e. OBR-3) must match that of the Preliminary result.

3.2.5.2 Use Case Diagram

See Common Lab Result Update Use Case Diagram for UC002.

3.2.5.3 Sequence Diagram

See Common Sequence Diagram for UC002.

3.2.5.4 Pre-Conditions

- See 3.1.1.
- Preliminary results were sent.

3.2.5.5 Post-Conditions

- See 3.1.2.
- The LTRD compliant message with the CDA Lab Report attachment are sent directly to consuming systems (e.g. CDOM).
- Providers will be notified of Final Microbiology Result through the Netcare Portal. That is, the record will be re-bolded in the CDV. Subscribers to the Document Repository will be notified of a replacement report through the existing eDelivery Infrastructure.

3.2.5.6 Basic Flow

1. The Laboratory Information System sends the Final Microbiology Results to the Integration Engine. The message is in local HL7v2 ORU^R01 format with non-standardized terminology. The Lab Result Status is set to 'F' for Final (OBR-25). The Observation Result Status(s) are set to 'F' for Final (OBX-11). If the status are Final, but the Filler Order Number (i.e. OBR-3) is a duplicate to the previous Report, then a replacement is implied.
2. The Integration Service logs the receipt of the message.
3. The Message Transformation Service is invoked.
4. The data is normalized and the message is transformed to an LTRD compliant message with a CDA Lab Report attachment.
5. The LTRD message and CDA Lab Report attachment are sent to Netcare.
6. The message is matched to the previous result using the Filler Order Number (i.e. OBR-3) and stored in the Repository as a replacement. The CDA Lab Report is matched to the previous document using the ParentRelatinshipType.ParentDocument.id field and stored in the Repository as a Replacement to the previous Report.

3.2.6 UC006: Send Corrected Microbiology Results

3.2.6.1 Description

This use case describes the scenario where a Laboratory Information System sends Corrected Microbiology Results (e.g. Stool Bacterial Culture) to Netcare and other Consuming Systems via the Regional Integration Engine.

In this scenario, the Filler Order Number (i.e. OBR-3) must match that of the Preliminary result.

3.2.6.2 Use Case Diagram

See Common Lab Result Update Use Case Diagram for UC002.

3.2.6.3 Sequence Diagram

See Common Sequence Diagram for UC002.

3.2.6.4 Pre-Conditions

- See 3.1.1.
- Previous Preliminary or Final results were sent.

3.2.6.5 Post-Conditions

- See 3.1.2.
- Providers will be notified of Corrected Microbiology Result through the Netcare Portal. That is, the record will be re-bolded in the CDV. Subscribers to the Document Repository will be notified of a replacement report through the existing eDelivery Infrastructure.
- The LTRD compliant message with the CDA Lab Report attachment are sent directly to consuming systems (e.g. CDOM).

3.2.6.6 Basic Flow

1. The Laboratory Information System sends the Corrected Microbiology Results to the Integration Engine. The message is in local HL7v2 ORU^R01 format with non-standardized terminology. The Lab Result Status is set to 'F' for Final (OBR-25). The Observation Result Status(s) are set to 'C' for Corrected (OBX-11).
2. The Integration Service logs the receipt of the message.
3. The Message Transformation Service is invoked.
4. The data is normalized and the message is transformed to an LTRD compliant message with a CDA Lab Report attachment.
5. The LTRD message and CDA Lab Report attachment are sent to Netcare.
6. The message is matched to the previous result using the Filler Order Number (i.e. OBR-3) and stored in the Repository as a replacement. The CDA Lab Report is matched to the previous document using the ParentRelatinshipType.ParentDocument.id field and stored in the Repository as a Replacement to the previous Report.

3.2.7 UC007: Send Cancelled Microbiology Results

3.2.7.1 Description

This use case describes the scenario where a Laboratory Information System sends a Cancellation to a previously sent Microbiology Results (e.g. Stool Bacterial Culture) to Netcare and other Consuming Systems via the Regional Integration Engine.

In this scenario, the Filler Order Number (i.e. OBR-3) must match the previous Glucose result.

3.2.7.2 Use Case Diagram

See Common Lab Result Update Use Case Diagram for UC003.

3.2.7.3 Sequence Diagram

See Common Sequence Diagram for UC003.

3.2.7.4 Pre-Conditions

- See 3.1.1.
- A previous Microbiology Result was sent that is now to be cancelled. Note: Final Results cannot be cancelled.

3.2.7.5 Post-Conditions

- See 3.1.2.
- Providers will be notified of the Cancelled Microbiology Result through the Netcare Portal. That is, the record will be re-bolded in the CDV. Subscribers to the Document Repository will be notified of a replacement report through the existing eDelivery Infrastructure.
- The LTRD compliant message with the CDA Lab Report attachment are sent directly to consuming systems (e.g. CDOM).

3.2.7.6 Basic Flow

1. The Laboratory Information System sends a cancellation to a Microbiology Result previously sent to the Integration Engine. The message is in local HL7v2 ORU^R01 format with non-standardized terminology. The Lab Result Status is set to 'X' for Order Cancelled (OBR-25). The Observation Result Status(s) are set to 'X' for Results Cannot be Obtained (OBX-11).
2. The Integration Service logs the receipt of the message.
3. The Message Transformation Service is invoked.
4. The data is normalized and the message is transformed to an LTRD compliant message with a CDA Lab Report attachment.
5. The LTRD message and CDA Lab Report attachment are sent to Netcare.
6. The message is matched to the previous result using the Filler Order Number (i.e. OBR-3) and stored in the Repository as a correction. The CDA Lab Report is matched to the previous document using the ParentRelatinshipType.ParentDocument.id field and stored in the Repository as a Replacement to the previous Report.

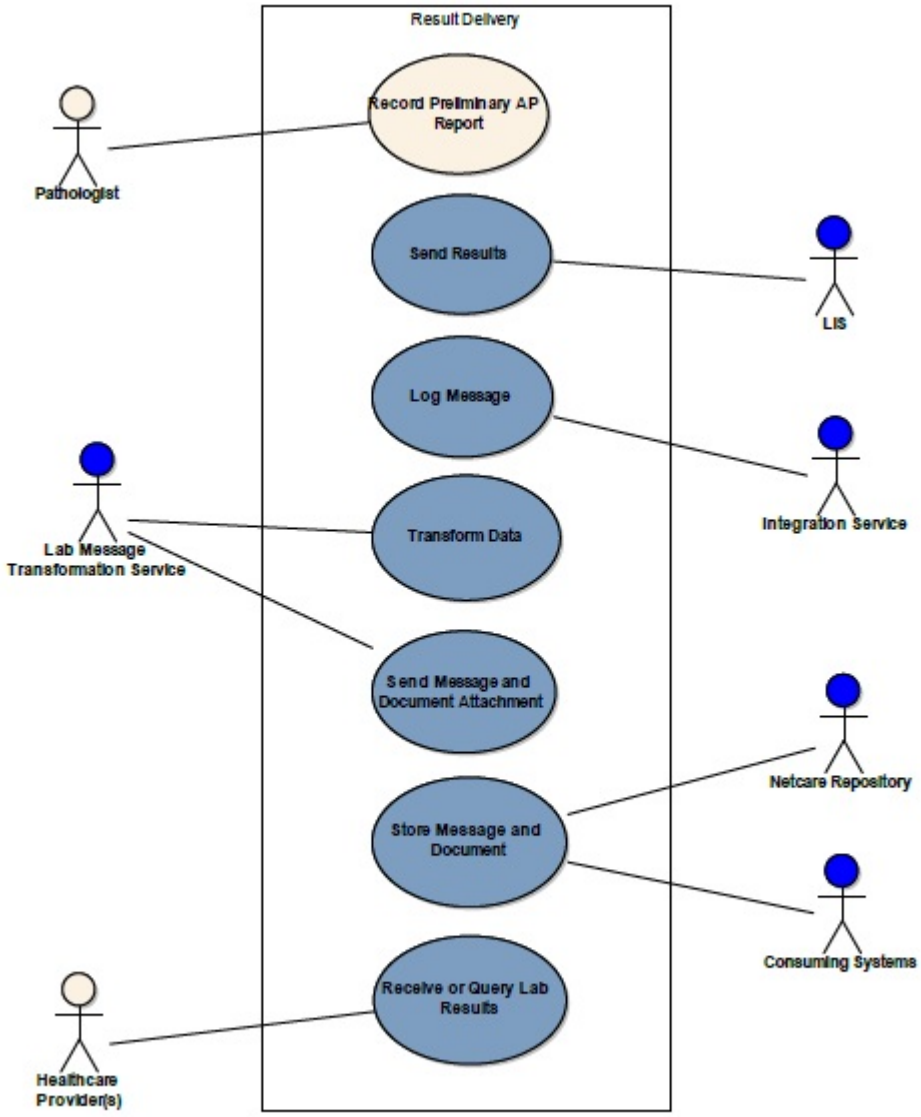
3.2.8 UC008: Send Preliminary Anatomic Pathology Report

3.2.8.1 Description

This use case describes the scenario where a Laboratory Information System sends Preliminary Anatomic Pathology Report (e.g. Surgical Pathology Report) to Netcare and other Consuming Systems via the Regional Integration Engine.

In this scenario, the Filler Order Number (i.e. OBR-3) is new and does not need to be matched to any previous reports.

3.2.8.2 Use Case Diagram



3.2.8.3 Sequence Diagram

See Common Sequence Diagram for UC001.

3.2.8.4 Pre-Conditions

- See 3.1.1.

3.2.8.5 Post-Conditions

- See 3.1.2.
- The LTRD compliant message with the CDA Lab Report attachment are sent directly to consuming systems (e.g. CDOM).
- Providers can query for the AP Result message through the Netcare Portal.

3.2.8.6 Basic Flow

1. The Laboratory Information System sends a Preliminary Anatomic Pathology Report to the Integration Engine. The message is in local HL7v2 ORU^R01 format with non-standardized terminology. The Lab Result Status is set to 'P' for Preliminary (OBR-25). The Observation Result Status(s) are set to 'P' for Preliminary (OBX-11).
2. The Integration Service logs the receipt of the message.
3. The Message Transformation Service is invoked.
4. The data is normalized and the message is transformed to an LTRD compliant message with a CDA Lab Report attachment.
5. The LTRD message and CDA Lab Report attachment are sent to Netcare.
6. The message and the CDA Lab Report are stored in the Repository.

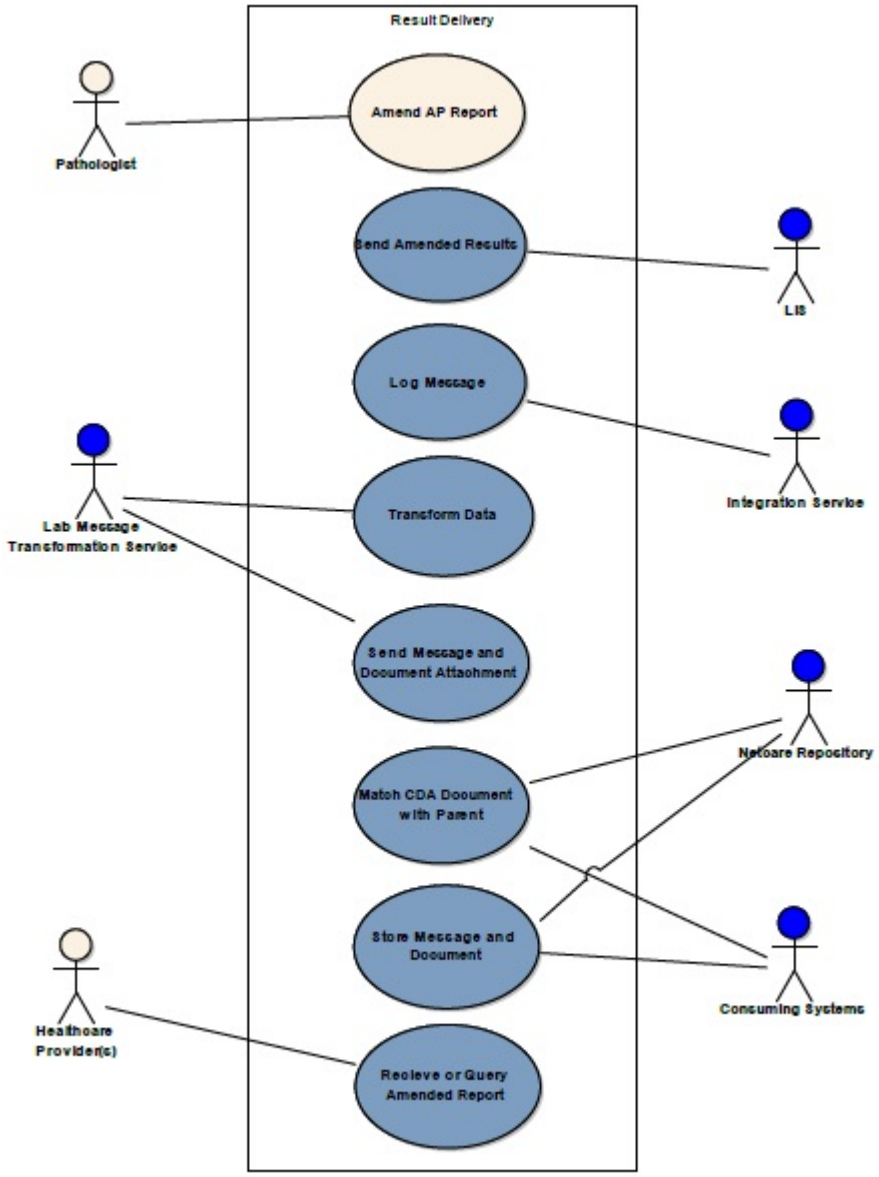
3.2.9 UC009: Send Final Anatomic Pathology Report

3.2.9.1 Description

This use case describes the scenario where a Laboratory Information System sends Final Report in replacement of a previously sent Preliminary Anatomic Pathology Report (e.g. Surgical Pathology Report) to Netcare and other Consuming Systems via the Regional Integration Engine.

In this scenario, the Filler Order Number (i.e. OBR-3) must match the previous AP Report.

3.2.9.2 Use Case Diagram



3.2.9.3 Sequence Diagram

See Common Sequence Diagram for UC002.

3.2.9.4 Pre-Conditions

- See 3.1.1.
- A previous Preliminary Report was sent that is now to be replaced with the Final Report.

3.2.9.5 Post-Conditions

- See 3.1.2.
- The LTRD compliant message with the CDA Lab Report attachment are sent directly to consuming systems (e.g. CDOM).

- Providers will be notified of the Final AP Report through the Netcare Portal. That is, the record will be re-bolded in the CDV. Subscribers to the Document Repository will be notified of Final Report (in replacement of the Preliminary Report) through the existing eDelivery Infrastructure.

3.2.9.6 Basic Flow

1. The Laboratory Information System sends Final Anatomic Pathology Report to replace a previously sent Preliminary Report sent to the Integration Engine. The message is in local HL7v2 ORU^R01 format with non-standardized terminology. The Lab Result Status is set to 'F' for Final (OBR-25). The Observation Result Status(s) are set to 'F' for Final (OBX-11). If the status are Final, but the Filler Order Number (i.e. OBR-3) is a duplicate to the previous Report, then a replacement is implied.
2. The Integration Service logs the receipt of the message.
3. The Message Transformation Service is invoked.
4. The data is normalized and the message is transformed to an LTRD compliant message with a CDA Lab Report attachment.
5. The LTRD message and CDA Lab Report attachment are sent to Netcare.
6. The message is matched to the previous Report using the Filler Order Number (i.e. OBR-3) and stored in the Repository as a replacement. The CDA Lab Report is matched to the previous document using the ParentRelatinshipType.ParentDocument.id field and stored in the Repository as a Replacement to the previous Report.

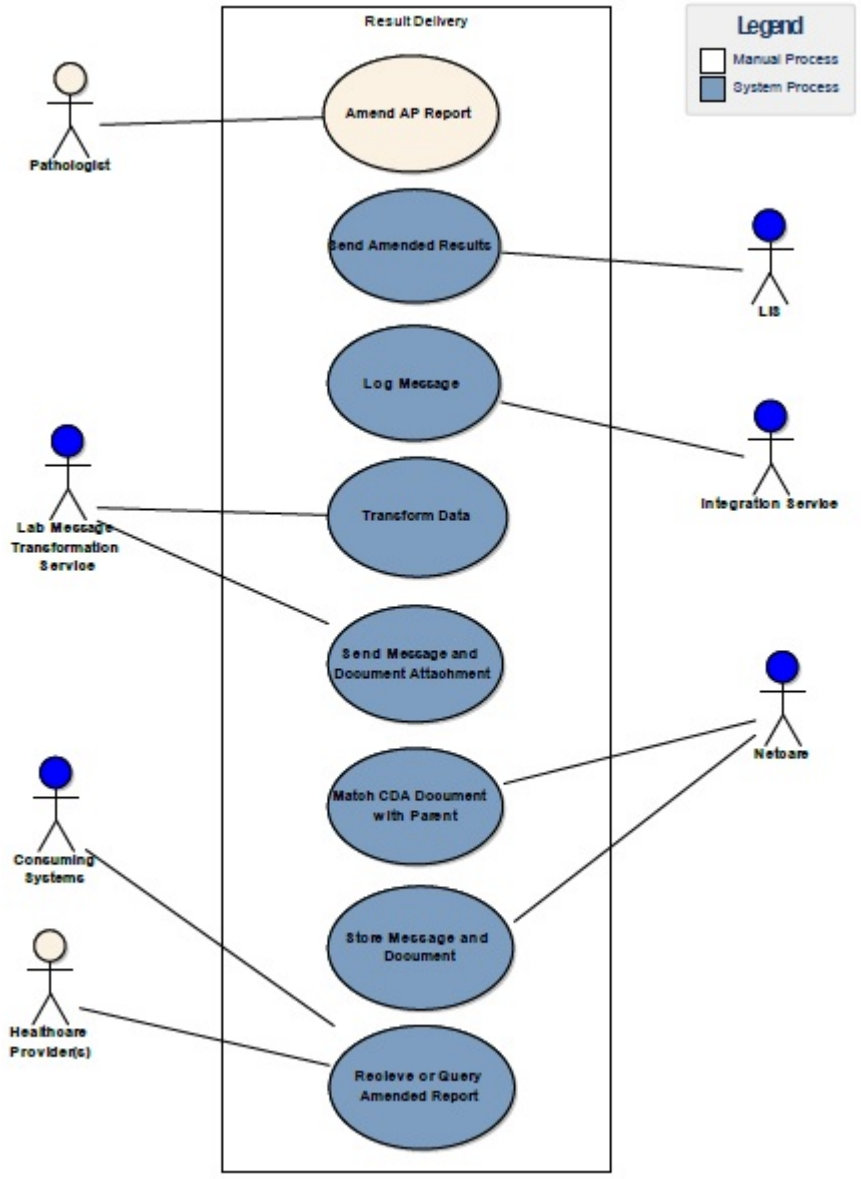
3.2.10 UC010: Send Amended Anatomic Pathology Report

3.2.10.1 Description

This use case describes the scenario where a Laboratory Information System sends an Amendment to a previously sent Anatomic Pathology Report (e.g. Surgical Pathology Report) to Netcare and other Consuming Systems via the Regional Integration Engine.

In this scenario, the Filler Order Number (i.e. OBR-3) must match the previous AP Report.

3.2.10.2 Use Case Diagram



3.2.10.3 Sequence Diagram

See Common Sequence Diagram for UC001.

3.2.10.4 Pre-Conditions

- See 3.1.1.
- A previous Report was sent that is now to be amended.

3.2.10.5 Post-Conditions

- See 3.1.2.
- The LTRD compliant message with the CDA Lab Report attachment are sent directly to consuming systems (e.g. CDOM).

- Providers will be notified of the Amended AP Report through the Netcare Portal. That is, the record will be re-bolded in the CDV. Subscribers to the Document Repository will be notified of an amendment to the report through the existing eDelivery Infrastructure.

3.2.10.6 Basic Flow

1. The Laboratory Information System sends an Amendment to the Anatomic Pathology Report previously sent to the Integration Engine. The message is in local HL7v2 ORU^R01 format with non-standardized terminology. The Lab Result Status is set to 'F' for Final (OBR-25). The Observation Result Status(s) are set to 'C' for Corrected (OBX-11).
2. The Integration Service logs the receipt of the message.
3. The Message Transformation Service is invoked.
4. The data is normalized and the message is transformed to an LTRD compliant message with a CDA Lab Report attachment.
5. The LTRD message and CDA Lab Report attachment are sent to Netcare.
6. The message is matched to the previous Report using the Filler Order Number (i.e. OBR-3) and stored in the Repository as a replacement. The CDA Lab Report is matched to the previous document using the ParentRelatinshipType.ParentDocument.id field and stored in the Repository as a Replacement to the previous Report.

3.2.10.7 Alternative Flow

3.2.11 UC011: Send Cancelled Preliminary Anatomic Pathology Report

3.2.11.1 Description

This use case describes the scenario where a Laboratory Information System sends a Cancellation to a previously sent Preliminary Anatomic Pathology Report (e.g. Surgical Pathology Report) to Netcare and other Consuming Systems via the Regional Integration Engine.

In this scenario, the Filler Order Number (i.e. OBR-3) must match the previous AP Report.

3.2.11.2 Use Case Diagram

See Common Use Case Diagram UC003.

3.2.11.3 Sequence Diagram

See Common Sequence Diagram for UC001.

3.2.11.4 Pre-Conditions

- See 3.1.1.
- A previous Preliminary Report was sent that is now to be cancelled.

3.2.11.5 Post-Conditions

- See 3.1.2.
- The LTRD compliant message with the CDA Lab Report attachment are sent directly to consuming systems (e.g. CDOM).
- Providers will be notified of the Cancelled AP Report through the Netcare Portal. That is, the record will be re-bolded on the CDV. Subscribers to the Document Repository will be notified of the cancellation of the report through the existing eDelivery Infrastructure.

3.2.11.6 Basic Flow

1. The Laboratory Information System sends an Cancellation to the Preliminary Anatomic Pathology Report previously sent to the Integration Engine. The message is in local HL7v2 ORU^R01 format with non-standardized terminology. The Lab Result Status is set to 'X' for Cancelled (OBR-25). The Observation Result Status(s) are set to 'X' for Results could not be obtained (OBX-11).
2. The Integration Service logs the receipt of the message.
3. The Message Transformation Service is invoked.
4. The data is normalized and the message is transformed to an LTRD compliant message with a CDA Lab Report attachment.
5. The LTRD message and CDA Lab Report attachment are sent to Netcare.
6. The message is matched to the previous Report using the Filler Order Number (i.e. OBR-3) and stored in the Repository as a replacement. The CDA Lab Report is matched to the previous document using the ParentRelatinshipType.ParentDocument.id field and stored in the Repository as a Replacement to the previous Report.

3.2.11.7 Alternative Flow

3.2.12 UC012: Send Final Bloodbank Results

3.2.12.1 Description

This use case describes the scenario where a Laboratory Information System sends Final Bloodbank Results (e.g. Blood Typing and Screening) to Netcare and other Consuming Systems via the Regional Integration Engine.

In this scenario, there was no result previously sent and therefore no matching to the Filler Order Number (i.e. OBR-3) or replacement functions are required.

3.2.12.2 Use Case Diagram

See Common Lab Result Create Use Case Diagram for UC001.

3.2.12.3 Sequence Diagram

See Common Sequence Diagram for UC001.

3.2.12.4 Pre-Conditions

- See 3.1.1.
- No preliminary results were sent.

3.2.12.5 Post-Conditions

- See 3.1.2.
- The LTRD compliant message with the CDA Lab Report attachment are sent directly to consuming systems (e.g. CDOM).
- Providers can query for the Lab Result message through the Netcare Portal. The CDA Lab Report is available to subscribed providers as per the eDelivery Infrastructure.

3.2.12.6 Basic Flow

1. The Laboratory Information System send the Final Bloodbank Results to the Integration Engine. The message is in local HL7v2 ORU^R01 format with non-standardized terminology. The Lab Result Status is set to 'F' for Final (OBR-25). The Observation Result Status(s) are set to 'F' for Final (OBX-11).

2. The Integration Service logs the receipt of the message.
3. The Message Transformation Service is invoked.
4. The data is normalized and the message is transformed to an LTRD compliant message with a CDA Lab Report attachment.
5. The LTRD message and CDA Lab Report attachment are sent to Netcare.
6. The message and the CDA Lab Report are stored in the Repository.

3.2.13 UC013: Send Corrected Bloodbank Results

3.2.13.1 Description

This use case describes the scenario where a Laboratory Information System sends Corrected Bloodbank Results (e.g. Blood Typing and Screening) to Netcare and other Consuming Systems via the Regional Integration Engine.

In this scenario, the Filler Order Number (i.e. OBR-3) must match that of the original result.

3.2.13.2 Use Case Diagram

See Common Lab Result Update Use Case Diagram for UC002.

3.2.13.3 Sequence Diagram

See Common Sequence Diagram for UC002.

3.2.13.4 Pre-Conditions

- See 3.1.1.
- Previous Preliminary or Final results were sent.

3.2.13.5 Post-Conditions

- See 3.1.2.
- The LTRD compliant message with the CDA Lab Report attachment are sent directly to consuming systems (e.g. CDOM).
- Providers will be notified of Corrected Bloodbank Result through the Netcare Portal. That is, the record will be re-bolded in the CDV. Subscribers to the Document Repository will be notified of a replacement report through the existing eDelivery Infrastructure.

3.2.13.6 Basic Flow

1. The Laboratory Information System sends the Corrected Bloodbank Results to the Integration Engine. The message is in local HL7v2 ORU^R01 format with non-standardized terminology. The Lab Result Status is set to ‘F’ for Final (OBR-25). The Observation Result Status(s) are set to ‘C’ for Corrected (OBX-11).
2. The Integration Service logs the receipt of the message.
3. The Message Transformation Service is invoked.
4. The data is normalized and the message is transformed to an LTRD compliant message with a CDA Lab Report attachment.
5. The LTRD message and CDA Lab Report attachment are sent to Netcare.
6. The message is matched to the previous result using the Filler Order Number (i.e. OBR-3) and stored in the Lab Repository as a replacement. The CDA Lab Report is matched to the previous document using the ParentRelatinshipType.ParentDocument.id field and stored in the Document Repository as a Replacement to the previous Report.

IV KEY DESIGN DECISIONS

This section highlights key design decisions that will drive the development of these specifications. Information here may be repeated in other areas of the specification within the context of the specific v2 or CDA specifications.

The developers of the Message Specification do not assert that the set of implementation considerations and guidelines are complete.

4.1 Use of Clinical Document Architecture

The HL7 Clinical Document Architecture (CDA) is an XML-based markup standard intended to specify the encoding, structure and semantics of clinical documents for exchange.

CDA is part of the HL7 version 3 standard and it is based on the HL7 Reference Information Model (RIM) and the HL7 Version 3 Data Types. The CDA specifies that the content of the document consists of a mandatory textual part (which ensures human interpretation of the document contents) and optional structured parts (for software processing).

4.1.1 Transporting CDA

The CDA standard does not specify how clinical documents should be transported. For this specification, the Lab Report (as described in the ***CDA Implementation Guide***) will be transported with HL7 v2.4 messages.

The constrained CDA document can be embedded in a v2 payload as a Multipurpose Internet Mail Extension (MIME) package as described in section 3 (CDA Document Exchange in HL7 Messages) of the CDA R2 specification.

The querying of the Lab Report Document will be handled by the Shared Health Record specification infrastructure (i.e. using HL7v3 query/response messaging).

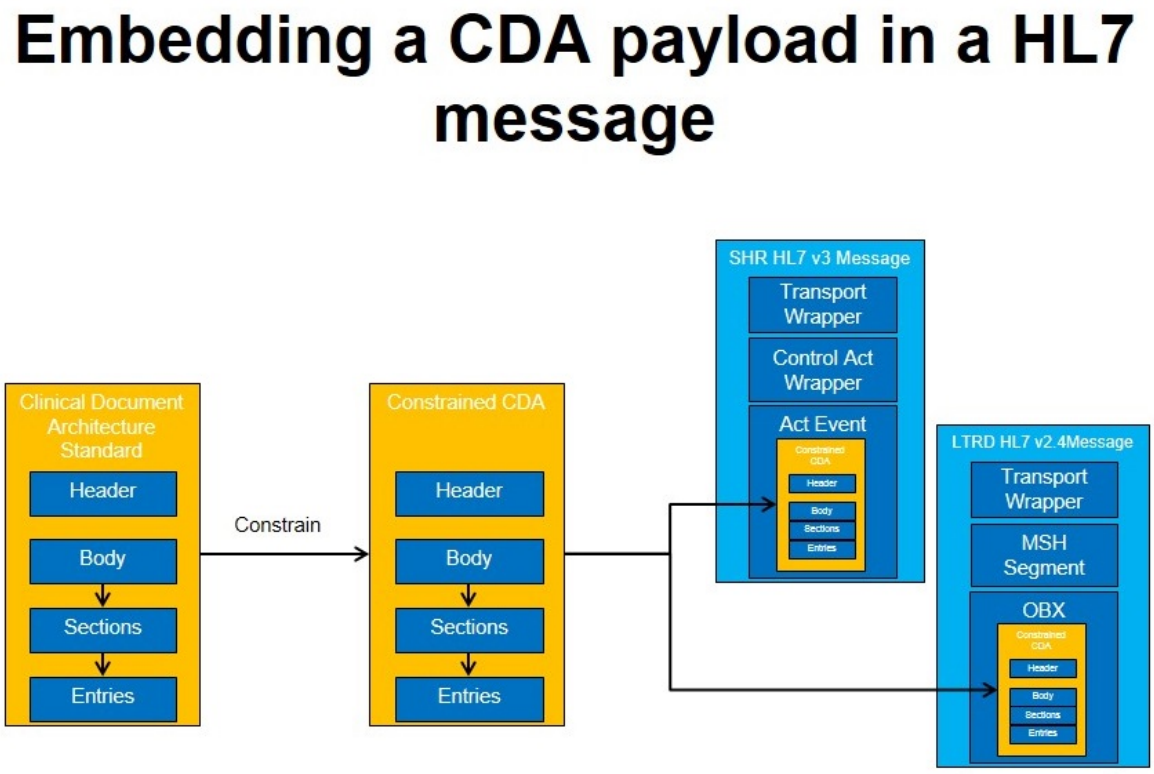


Figure 5: Embedding a CDA payload in a message

V CONFORMANCE APPROACH

5.1 Preamble

Interoperability specifications, such as the Lab Result Messaging and Document Specifications, are intended to enable systems from multiple vendors to interoperate in order to meet stated business objectives. The goal of the specifications is to be the basis for a standard, once approved by the Health Information Standards Committee for Alberta (HISCA) that will minimize costs over non-standardized, one-of many-to-many interfaces while ensuring that key business rules and data standards are followed in the various technical implementations.

The specification should aim to minimize the need for negotiations among trading partners during initial implementation and as part of ongoing operations by providing, whenever possible, unambiguous guidance. The degree to which this can be achieved is directly related to a number of factors:

- ***Strength of Core Specification Framework***: The strength of the specification frameworks - in this case HL7 v2.4 and CDA - to clearly and concisely convey interoperability requirements;
- ***Specification Quality and Completeness***: The quality of the specification (both in terms of design and completeness of the associated artifacts).
- ***Stakeholder Direction***: The ability of stakeholders to reach consensus about key design decision points.

Subject to these considerations, this specification aims to establish clear expectations for the development, testing/certification and deployment of conformant solutions.

5.2 Conformance Language

HL7 establishes formal language to establish the conformance obligation, among other things, for individual attributes within messages and clinical documents. Readers are assumed to be familiar with this language for HL7 v2.4 and HL7 CDA.

In addition, the various documents that provide additional information and guidance may use additional key words which are intended to clarify expectations for conformant systems. Specifically, the (capitalized) key words "MUST", "MUST NOT", "SHALL", "SHALL NOT", "SHOULD", "SHOULD NOT" and "MAY" in these specifications are to be interpreted as follows[1]:

- **MUST**: This word, or the terms "REQUIRED" or "SHALL", mean that the statement is an absolute requirement of the specification.
- **MUST NOT:** This phrase, or the phrase "SHALL NOT", mean that the statement is an absolute prohibition of the specification.
- **SHOULD:** This word, or the adjective "RECOMMENDED", mean that there may exist valid reasons in particular circumstances to ignore a particular item, but the full implications must be understood and carefully weighed before choosing a different course.
- **SHOULD NOT**: This phrase, or the phrase "NOT RECOMMENDED" mean that there may exist valid reasons in particular circumstances when the particular behavior is acceptable or even useful, but the full implications should be understood and the case carefully weighed before implementing any behavior described with this label.
- **MAY**: This word, or the adjective "OPTIONAL", mean that an item is truly optional. One vendor may choose to include the item because a particular marketplace requires it or because the vendor feels that it enhances the product while another vendor may omit the same item. An implementation which does not include a particular option MUST be prepared to interoperate with another implementation which does include the option, though perhaps with reduced functionality.

[1] Definitions have been adapted from RFC 2119 (http://www.ietf.org/rfc/rfc2119.txt)

In the same vein an implementation which does include a particular option MUST be prepared to interoperate with another implementation which does not include the option (except, of course, for the feature the option provides.)

5.3 Precedence Hierarchy

In order to ensure consistent interpretation of these specifications conformant implementers MUST apply the following precedence hierarchy:

Table 2: Specification Precedence Hierarchy

#	HL7 v2	HL7 CDA
1	Business Overview	
2	v2.4 Implementation Guide document	CDA Implementation Guide (through explicit Definitions & Conformance Statements)
3	v2.4 Conformance Profile document	
5	Vocabulary Specification tabs within the ***Lab Report Data Model and Mapping Workbook*** Note that for domains or value sets referenced by these specifications for which neither the Lab vocabulary specification nor the specification documents below provide clear direction, conformant implementers SHALL utilize the applicable value set from the pan-Canadian Master Terminology Worksheet.	
6	v2.4 Message Profiles document HL7 Conformance Profile (as generated by Message Workbench)	CDA Schemas
7	Sample instances	

In case of conflict between the materials in the table above, the document or artifact higher in Table 2 (i.e. with a lower number) SHALL prevail. In cases where these apparent conflicts are purposeful refinements, every effort has been made to ensure that this is clearly indicated.

5.4 Attribute Conformance Cross Reference

The following table cross references the type of data element or attribute based conformance statements with the formal conformance language of HL7 v2.x and v3/CDA respectively:

Table 3: Attribute Conformance Cross Reference

HL7 v2.x Conformance	CDA Conformance	Interpretation
Required	Mandatory	The (v3) mandatory inclusion flag indicates whether or not a particular element MUST be present in each instance of an HL7 message. A value must be present in each message, that value SHALL NOT include OTH (Other) nor UNK (Unknown).
	Populated	A value MUST be present in each message, that value includes OTH (Other) nor UNK (Unknown).
Required but may be Empty	Required	In message instances, a (v3) required element need not always be sent by an application. If the data exists, the sending application SHALL send it as a non-null value or a non-empty element.

HL7 v2.x Conformance	CDA Conformance	Interpretation
Conditional	Conditional	In message instances, a conditional element is present according to accompanying rules.
Conditional but it may be empty [Not used]		
Optional	Optional	A value may be present in each message. Values are allowed to be ignored.

5.5 Conformance Profiles

A significant body of work exists pertaining to the establishment and use of conformance profiles. Conceptually a conformance profile is intended to provide precise and unambiguous direction for conformant systems on the following two integration perspectives:

- ***Dynamic Perspective***: The dynamic perspective outlines which transactions (or messages) a conformant system must support (as sender, receiver or both) and, for senders, under which circumstances the transactions must be initiated.
- ***Static Perspective***: For a given transaction, the static perspective provides clear direction on the data that is to be included in a transaction; although, again, this may vary for certain business circumstances, these circumstances must be predictable.

HL7 has gone some way to define a series of specification constructs to provide both dynamic and static clarity. For example, HL7 establishes and defines a v2.x *message profile* as follows:

> An HL7 V2.x Message Profile is a precise and unambiguous specification of a standard HL7 message that has been analyzed for use within a particular set of requirements. It is a particular style or usage of a standard HL7 message, driven by use case analysis and interaction modeling.
>
> An HL7 V2.x Message Profile defines both the **static** structure and content of the message and the **dynamic** interaction, which involves the communication of the message from the sending application to one or more receiving applications.[2]

HL7 CDA is solely a **static** structure and consequently only provides direction on the data that is to be included in the document; although, again, this may vary for certain business circumstances, these circumstances must be predictable.

[2] HL7 Version 2.x Message Profiling Specification, Version 2.2, November 30, 2000.

VI COMMON IMPLEMENTATION GUIDANCE

6.1 Technical Considerations

6.1.1 Object Identifiers

Conformant systems MUST apply the OID designated in Appendix D of this document for data attributes as specified in the CDA Implementation Guide.

6.1.2 Coded Element to Identifier Mapping

The following table lists the data elements where there is a variance between the data type being coded or an instance identifier between the Business Data type as defined in the Data Set, and the Data type used in the HL7 v2.4 and CDA.

Table 4: Coded Element to Identifier Mapping

ID	Data Element Name	Business Data type	HL7 2.4 Data Type	HL7 3.x CDAA Data type
	Lab Repository Location	ID	CE	II.BUS
	Patient Identifier	ID	CX	SET<II.PUBLIC>
	Care Team Provider ID	ID	CM	II.PUBLIC
	Source Provider IDs	ID	CM	II.PUBLIC
	Source Location ID	ID	CM	II.PUBLIC
	Destination Provider ID	ID	CM	II.PUBLIC
	Destination Location ID	ID	CM	II.PUBLIC
	Document Category	CODE	IS	CV
	Document Status	CODE	ID	CS
	Document Masking Indicator	CODE	BL	CV

Appendix A. TECHNICAL ARTIFACTS

A.1 HL7 v2.4 Artifacts

A.1.1 Overview

The HL7 v2.4 technical artifacts include the following source materials:

Table 5: HL7 v2.4 Artifacts

Artifact / Artifact Type	Format	Description
Data Types Specification	(Included in Implementation Guide)	The applicable data types are described in the HL7 v2.3 Implementation Guide.
Message Profiles	MWB outputs (.MWB, .XML and .HTM)	The various Message Workbench profiles

A.2 Common Artifacts

A number of common artifacts apply to both the HL7 v2.4 specifications as follows:

Table 6: Common Artifacts

Artifact / Artifact Type	Format	Description
Data Model and Mapping Workbook	Excel (.XLS)	A common workbook which includes: • Data element listing • Terminology usage • Data element mapping to HL7 v2.4 HL7 v3 models
Source Diagrams	.VDX and .PPT	Files containing the source diagrams for the various business documents.

Appendix B. EXTERNAL ARTIFACTS

A number of external artifacts are being distributed with these specifications for implementer convenience. Please note that this leads to licensing considerations when distributing these specifications. In general, the consumers of these specifications should be members of the *Infoway* Standards Collaborative and/or HL7 International Inc.

The following sections list these artifacts:

MR2009 pan-Canadian Data Type Specifications

File	SC-3002-EN - Data Type Specification - R02.04.03 - 20100831.zip
Source	Canada Health Infoway Standards Collaborative
Source URL (if available)	See https://www.infoway-inforoute.ca/index.php/programs-services/standards-collaborative/overview for further details.
Description	The definition of data types as used in the pan-Canadian Specifications.
Purpose	These data types are the normative data types for the HL7 v3 CDA portion of this specification. This is included for implementer convenience.

MR2009 Terminology Worksheet

File	SC-3004-EN - Terminology Worksheet - R02.04.03 – 20100831
Source	Canada Health Infoway Standards Collaborative
Source URL (if available)	See https://www.infoway-inforoute.ca/index.php/programs-services/standards-collaborative/overview for further details.
Description	The vocabulary definitions used in the pan-Canadian Specifications.
Purpose	These vocabulary domains and values apply to the HL7 v3 CDA Specification unless overridden by the terminology noted in Laboratory Vocabulary Worksheet.

Appendix C. SPECIFICATION TOOLING

HL7 v2.4

Message Modelling

Name	HL7 Message Workbench
Source	HL7 International
Source URL (if available)	http://gforge.hl7.org/gf/project/mwb/
Description	The Messaging Workbench is a multipurpose productivity tool for HL7 V2.x implementers. It facilitates rapid development of specifications and reports. It also incorporates an online message validation service, and message generator for use in testing. For purposes of this project, we will be using the Workbench to apply constraints to the HL7v2.4 ORU^R01 message and generate the Conformance Profile.

HL7 CDA

CDA Implementation Guide Generator

Name	GPi CDA Implementation Guide Generator
Source	Gordon Point Informatics Ltd.
Source URL (if available)	N/A
Description	Used to generate editable MS-Word-based CDA implementation guides.

Appendix D. **OBJECT IDENTIFIERS**

D.1 **Background**

A key challenge in distributed information processing is the globally unique identification of records or objects. HL7 version 3 address this through the use of Universal Object Identifiers (OIDs). These OIDs are used in three areas:

- As the root for all identifiers (using the II datatype);
- As the means of identifying code systems when using one of the code datatypes; and
- As the means of identifying value sets for use in constraint statements.

OIDs are a hierarchical identification scheme designed to ensure that identifiers are globally unique. "Structurally, an OID consists of a node in a hierarchically-assigned namespace, formally defined using the ITU-T's ASN.1 standard."[3] Each OID consist of a series of integers separated by decimal points. These can be interpreted from left to right to progressively identify an 'assigning authority' and a hierarchy of objects. If the rules defined by the International Standards Organization (ISO) are appropriately followed, there is no chance that the same OID will be issued to more than one object. Conversely, if an OID is known, then it the object to which the OID corresponds is also known, although this may require a lookup of the OID in a repository.

Any person or organization can be issued an OID by an OID registrar. Once issued, that OID is permanently and irrevocably assigned to identify that person or organization. The person or organization can then issue additional OIDs below their particular node by appending further levels. For example, as per the diagram in Figure 6, the internet has the OID "1.3.6.1". It in turn is the assigning authority for the node "mgmt" which has the OID "1.3.6.1.2". Similarly HL7's OID is 2.16.840.1.113883.

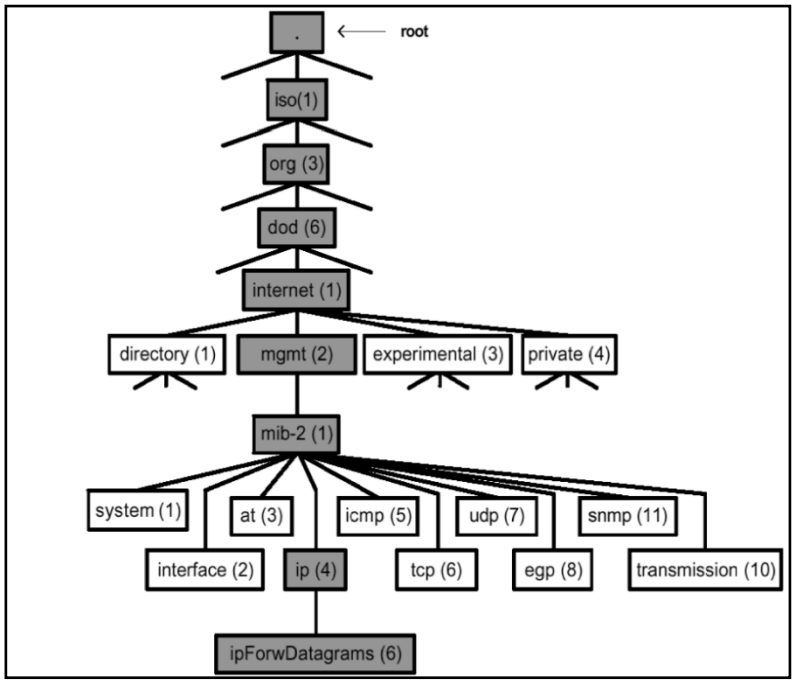


Figure 6: ISO OID Hierarchy

[3] WikiPedia Object Identifier entry, accessed May 1, 2012.

D.2 Use of OIDs

D.2.1 Vocabulary

D-2.1.1 Code Systems

OIDs for all code systems are assigned or registered when HL7 registers a particular code system. Once registered, the assigned or registered OID is the only OID allowed to be used for that code system. Implementers **SHALL** only use code systems, including local code systems, which have been registered with HL7 and been assigned an OID or which have a designated OID.

D-2.1.2 Value Sets

Value set OIDs are defined primarily to allow implementation guides such as this to provide definitive guidance as to the set of allowable values.

D.2.2 Instance Identifiers

In HL7 v3, all instance identifiers are required to be globally unique. Globally unique means that the identifier points to only one thing no matter what system the identifier is used in anywhere in the world. Any system which constructs identifiers which are not globally unique cannot claim HL7 v3 conformance.

The II Datatypes consists of two principle components: A mandatory OID root and an optional extension. The combination of the root and the extension form the universally unique identifier. In other words, the combination of the root and the extension must refer to only one thing worldwide.

The reason for the extension component of II is that many “real-world” identifiers do not reflect the conventions of the OID (string of digits separated by periods) format. Real world identifiers such as health numbers, provider ids, lab order ids and others tend to contain alphabetic characters, punctuation or other structures that cannot be conveyed as an OID. In this case, the ‘root’ element will contain an OID which defines the ‘namespace’ for the ‘real-world’ identifier being conveyed in the extension. A unique OID applies to each unique namespace. If the namespace changes (e.g. changing from an 8 digit sequence to a 9 digit sequence), a new OID would apply. For example, the root might represent the concept “Canadian Social Insurance Number beginning January, 1932”.

The root refers to the “unique number-space” of the identifier, not to the assigning organization. For example, if the Alberta College of Nursing were responsible for licensing both Licensed Practical Nurses (LPNs) and Registered Nurses (RNs), there might be two OIDs (one for each type of nurse) or one OID (for all nurses) depending on whether the license numbers issued were drawn from two separate pools or one pool.

The “unique number-space” does not necessarily correspond to a single application. Multiple applications might draw on a common database which tracks issued identifiers and thus use a single OID. On the other hand, a single application might issue multiple identifiers. Some order entry systems will use the same number-space for all orders, whether lab, pharmacy or imaging and would thus use the same OID for all. Others would use a separate OID, and might even use different number-spaces and OIDs for orders issued from each ward.

The hierarchy in which an OID is situated conveys no semantics about the meaning of an identifier. Identifiers registered under the Canadian OID node can refer to items that exist in other countries and vice versa. Registering an OID for an item does not imply control over that item, merely knowledge of the item’s unique existence. If the organization responsible for issuing an identifier splits or merges or is renamed, the OID remains the same so long as the number pool from which the extensions are issued remains the same. For example, if the Alberta College of Nursing were to spin off a separate organization for LPNs, the same OID would continue to be used for LPN identifiers unless the new organization started issuing different identifiers.

Nothing prevents numerous OIDs from being issued for the same identifier. To minimize the mapping issues resulting from two organizations using different OIDs for the same type of identifier, HL7 allows organizations to ‘register’ OIDs of common identifiers with HL7. Common identifiers are those identifiers

where it is reasonable to expect an identifier to be captured by multiple systems without those systems having an explicit business relationship with the issuer of the identifier. For example, many systems will need to capture the concept of an "Alberta Unique Lifetime Identifier (ULI)" or a "BC Personal Health Number (PHN)" without necessarily having a direct relationship with either the Alberta Department of Health or the BC Ministry of health. These types of identifiers have therefore been registered. HL7 will only allow one OID to be registered for a given concept. The OID that is first registered for a particular concept is the OID that **SHALL** be used when communicating that concept in HL7 version 3 message or document instances. Systems which use other OIDs cannot claim conformance with either HL7 v3 nor with this specification.

When the OID for an identifier is registered, the format for capturing the identifier is also specified. For example, whether the extension should be in upper-case or lower case, whether there should be any punctuation or spacing, and whether there should be leading digits. The general rule is upper-case with only that punctuation and spacing needed to prevent duplication. (e.g. if 123-456 and 12-3456 constitute different identifiers, then the dash needs to be sent as part of the identifier.)

While the mechanism described ensures that v3 applications will reference the same identifier object in a consistent manner it is important to note that absolute identifier uniqueness will always depend on the integrity of the assignment process for the underlying real world identifiers (i.e. the extension portion).

D.3 OIDs Used In this Specification

D.3.1 Patient, Provider and Location Identifiers

The following table lists OIDS for common public identifiers:

Table 7: OIDs for Patient and Provider Identifiers

Identifier	Description	OID root
Patient – ULI	The patient's Unique Lifetime Identifier	2.16.840.1.113883.4.20
Provider – HSPID	The provider's jurisdictional provider identifier	2.16.840.1.113883.4.322
Provider Organization Identifier	Identifier for a provider organization such as a provider consulting group	2.16.840.1.113883.3.163.11.2.1
Service Delivery Location – DSR ID	The jurisdictional identifier associated with the service delivery location	2.16.840.1.113883.4.289

For a formal list of Alberta OIDs please consult the following Intranet URL:

https://healthshare.gov.ab.ca/sites/isg/oids/Background%20Information/AH_Internal_OID_Listing.xls.

D.3.2 Lab Report CDA OIDs

D.3.3 CDA Assigned Identifiers

The following convention has been established for OIDs that are explicitly assigned as part of the development of the CDA components of these specifications:

Table 8: OID Tree

OID Branch	Usage
2.16.840.1.113883.3.163.99.4.*	This is the root for identifiers pertaining to these consolidated CDA specifications.
2.16.840.1.113883.3.163.99.4.1.*	Document level template identifiers.
2.16.840.1.113883.3.163.99.4.2.*	Section level template identifiers.
2.16.840.1.113883.3.163.99.4.3.*	Section Entry level template identifiers.
2.16.840.1.113883.3.163.99.4.4.*	Entry level template identifiers.
2.16.840.1.113883.3.163.99.4.6.*	Code System identifiers.
2.16.840.1.113883.3.163.99.4.7.*	Header template identifiers.
2.16.840.1.113883.3.163.99.4.8.*	Value Set identifiers.
2.16.840.1.113883.3.163.99.4.9.*	Instance identifiers.

D.3.4 Implementer Assigned Identifiers

A number of identifiers referenced by the specification pertain to fields where the sending system reflects the source of truth. For example, various record identifiers or local client/patient identifiers are assumed to be generated within each sending system. In order to make these globally unique each implementer will require an OID at implementation time and said OID will need to be used when communicating these types of identifiers.

Guidance for OID establishment will rest with the Health Information Standards Committee for Alberta (HISCA).

D.3.5 Instance Identifier OIDs

The following table summarizes a non-exhaustive subset of well-known identifier OIDs relevant to this implementation guide. Since these OIDs are formally established through the HL7 OID registry, in case of discrepancy between this list and the registry, the latter SHALL prevail.

Table 9: Common Identifier OIDs

OID	Symbolic Name	Description
2.16.840.1.113883.4.32	ab-coMDTT-LN	Alberta College of Medical Diagnostic and Therapeutic Technologists license number
2.16.840.1.113883.4.31	ab-coMLT-LN	Alberta College of Medical Laboratory Technologists license number
2.16.840.1.113883.4.39	ab-coPHARM-LN	Alberta College of Pharmacists license number
2.16.840.1.113883.4.47	ab-coSW-LN	Alberta College of Social Workers license number
2.16.840.1.113883.4.48	ab-coSLPA-LN	Alberta College of Speech-Language Pathologists and Audiologists license number
2.16.840.1.113883.4.27	ab-coDEN-LN	Alberta Dental Association License Number (ab-coDEN-LN)
2.16.840.1.113883.4.600	ca-abDLN	Alberta, Canada (Ministry of Transportation of Alberta, Canada)

OID	Symbolic Name	Description
		Driver's Licence
2.16.840.1.113883.4.50	ca-bcPHN	British Columbia Personal Health Number
2.16.840.1.113883.4.597	ca-bcDLN	British Columbia, Canada ICBC (Insurance Corporation of British Columbia, Canada) Driver's Licence
2.16.840.1.113883.4.44	ab-coRN-LN	College and Association of Registered Nurses of Alberta license number
2.16.840.1.113883.4.46	ab-coRT-LN	College and Association of Respiratory Therapists of Alberta license number
2.16.840.1.113883.4.21	ab-coRAC-LN	College of Acupuncturists of Alberta license number (ab-coRAC-LN)
2.16.840.1.113883.4.24	ab-coDENA-LN	College of Alberta Dental Assistants license number (ab-coDENA-LN)
2.16.840.1.113883.4.28	ab-coDENT-LN	College of Alberta Denturists license number (ab-coDENT-LN)
2.16.840.1.113883.4.26	ab-coRDT-LN	College of Dental Technologists of Alberta license number (ab-coRDT-LN)
2.16.840.1.113883.4.43	ab-coRD-LN	College of Dieticians of Alberta license number
2.16.840.1.113883.4.29	ab-coHAP-LN	College of Hearing Aid Practitioners of Alberta license number (ab-coHAP-LN)
2.16.840.1.113883.4.33	ab-coRM-LN	College of Midwives of Alberta license number
2.16.840.1.113883.4.34	ab-coNPD-LN	College of Naturopathic Doctors of Alberta license number
2.16.840.1.113883.4.36	ab-coRO-LN	College of Opticians of Alberta license number
2.16.840.1.113883.4.40	ab-coPT-LN	College of Physical Therapists of Alberta license number
2.16.840.1.113883.4.41	ab-coMD-LN	College of Physicians and Surgeons of Alberta license number
2.16.840.1.113883.4.25	ab-coRDH-LN	College of Registered Dental Hygienists of Alberta license number (ab-coRDH-LN)
2.16.840.1.113883.4.45	ab-coRPN-LN	College of Registered Psychiatric Nurses of Alberta license number
2.16.840.1.113883.4.377	cschn	Correctional Service Canada Health Number
2.16.840.1.113883.4.378	inachn	Indian & Northern Affairs Canada Health Number
2.16.840.1.113883.4.12	mhphin	Manitoba Health Personal Health Identification Number - MHPHIN
2.16.840.1.113883.4.599	ca-mbDLN	Manitoba, Canada Driver's Licence
2.16.840.1.113883.4.601	ca-nbDLN	New Brunswick, Canada Driver's Licence
2.16.840.1.113883.4.51	ca-nbPHN	New Brunswick, Canada Personal Health Number
2.16.840.1.113883.4.596	ca-nlDLN	Newfoundland and Labrador, Canada Driver's Licence
2.16.840.1.113883.4.52	ca-nlPHN	Newfoundland and Labrador, Canada Personal Health Number
2.16.840.1.113883.4.602	ca-ntDLN	Northwest Territories, Canada (Ministry of Transportation Northwest Territories, Canada) Driver's Licence
2.16.840.1.113883.4.54	nwtCPHN	Northwest Territories, Canada Personal Health Number
2.16.840.1.113883.4.606	ca-nsDLN	Nova Scotia, Canada (Registry of Motor Vehicles Nova Scotia, Canada) Driver's Licence
2.16.840.1.113883.4.53	nsCPHN	Nova Scotia, Canada Personal Health Number
2.16.840.1.113883.4.603	ca-nuDLN	Nunavut, Canada Driver's Licence
2.16.840.1.113883.4.55	ca-nuPHN	Nunavut, Canada Personal Health Number
2.16.840.1.113883.4.595	ca-onDLN	Ontario, Canada MTO (Ministry of Transportation of Ontario, Canada) Driver's License
2.16.840.1.113883.4.604	ca-peDLN	Prince Edward Island, Canada Driver's Licence
2.16.840.1.113883.4.13	peiphni	Prince Edward Island, Canada Personal Health Number Identifier (PEIPHNI)

OID	Symbolic Name	Description
2.16.840.1.113883.4.11	mbcpn	Provider Registry Common Party Number - Manitoba, Canada (MBCPN)
2.16.840.1.113883.4.594	ca-qcDLN	Quebec, Canada (Société de l'assurance automobile du Quebec, Canada) Driver's Licence
2.16.840.1.113883.4.379	rcmphn	Royal Canadian Mounted Police Health Number
2.16.840.1.113883.4.598	ca-skDLN	Saskatchewan, Canada Driver's Licence
2.16.840.1.113883.4.35	ab-coOT-LN	The Alberta College of Occupational Therapists license number
2.16.840.1.113883.4.37	ab-coOPT-LN	The Alberta College of Optometrists license number
2.16.840.1.113883.4.38	ab-coPMD-LN	The Alberta College of Paramedics license number
2.16.840.1.113883.4.42	ab-coPSYCH-LN	The College of Alberta Psychologists license number
2.16.840.1.113883.4.22	ab-coCHIRO-LN	The College of Chiropractors of Alberta license number (ab-coCHIRO-LN)
2.16.840.1.113883.4.23	ab-coCLXT-LN	The College of Combined Laboratory and X-Ray Technologists license number (ab-coCLXT-LN)
2.16.840.1.113883.4.376	vachn	Veteran's Affairs Canada Health Number
2.16.840.1.113883.4.605	ca-ytDLN	Yukon, Canada Driver's Licence

D.3.6 Code System OIDs

OIDs for code systems are noted in the vocabulary section of the ***Laboratory - Data Model and Mapping Workbook.***

Appendix E. GLOSSARY

Table 10: Glossary Terms and Acronyms

Term / Acronym	Description
AH	Alberta Health
AHS	Alberta Health Services
Clinical Document Architecture (CDA)	This is part of the HL7 Version 3 standard and describes an XML- based mark-up standard intended to specify the encoding, structure and semantics of clinical documents.
EMR	Electronic Medical Record
HISCA	Health Information Standards for Alberta
HL7	Health Level Seven
LOINC®	Logical Observation Identifiers Names and Codes
POS	Point of Service
SME	Subject Matter Expert
SNOMED CT®	Systematized Nomenclature of Medicine -- Clinical Terms

Appendix F. MAINTENANCE CONSIDERATIONS

F.1 Overview

There are several key drivers for change to these specifications including the following:

- ***Business change:*** The Lab Report CDA Business Overview outlines the core business framework for electronic laboratory result reporting. As/when the materials change in response to business or legislative changes within Alberta, this specification will likely need to change in response.
- ***Development experience***: As implementers begin to develop interfaces based on these specifications, it is possible (and, during early implementations, highly likely) that errors will be surfaced in these specifications. These errors will require updates to the specifications and, depending on the extent to which implementations are in production, changes to operational systems and environments.
- ***Operational experience***: As conformant systems begin to exchange encounter data it is possible (and, during early production implementations, somewhat likely) that errors will be surfaced in these specifications. These errors will require updates to the specifications and, depending on the extent to which implementations are in production, changes to operational systems and environments.

F.2 Maintenance Life Cycle

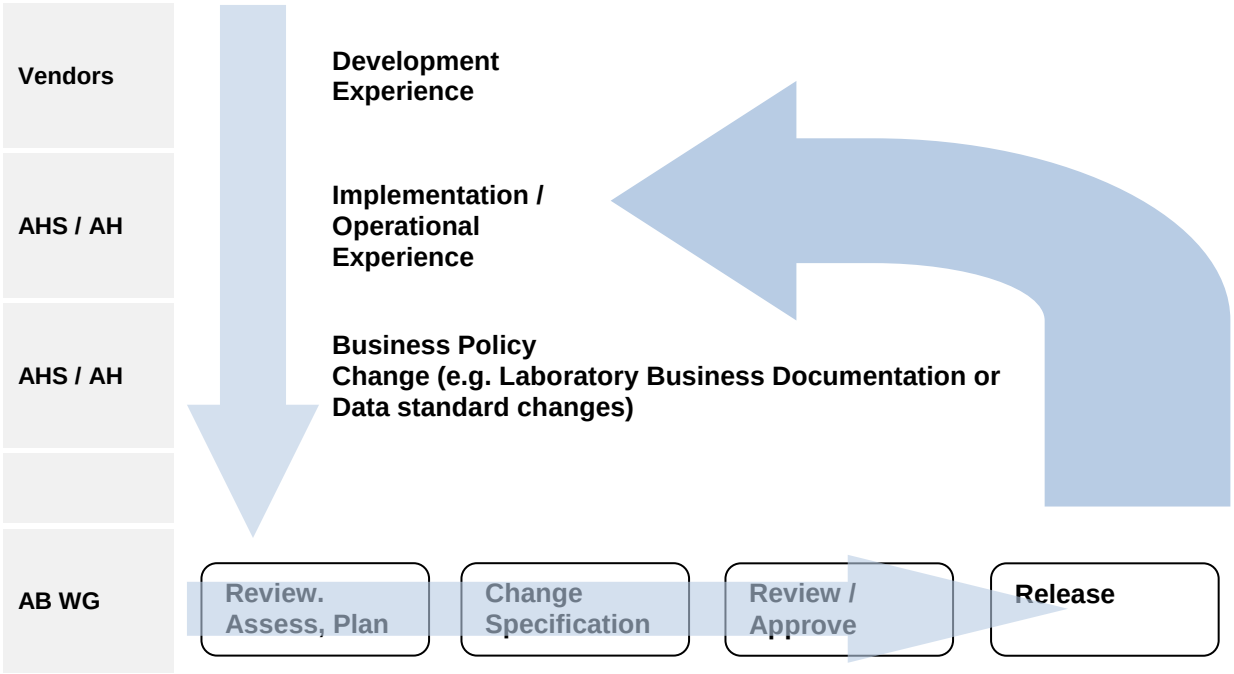


Figure 7: Maintenance Life Cycle