Kingdom of Saudi Arabia
Ministry of Health

National eHealth Strategy and Change Management Office
(SCMO)

Enabling Standards-Based eHealth Interoperability

IS0003
Saudi eHealth Core Interoperability Specification for Sharing Coded Laboratory Results

Version 1.0
February 22, 2015

Document Control Number: IS0003 Saudi eHealth Core Interoperability Specification for Sharing Coded Laboratory Results

THIS PAGE INTENTIONALLY LEFT BLANK

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

CONFIDENTIALITY STATEMENT:

The Ministry of Health (MOH) of the Kingdom of Saudi Arabia grants to any user of this document, perpetual, royalty-free, nontransferable, nonexclusive, license under its copyrights to access and read the Saudi eHealth Specification. You may not reproduce or use this document or any portion of it, without prior written consent from the MOH. The licenses covered are only to those parts owned or controlled by the MOH itself. If parts of the Saudi eHealth Specification include materials owned or controlled by other parties, licenses to use those products would have to be obtained from that other party.

The MOH offers the licensed material as-is and as-available, and makes no representations or warranties of any kind concerning the licensed material, whether express, implied, statutory, or other. This includes, without limitation, warranties of title, merchantability, fitness for a particular purpose, non-infringement, absence of latent or other defects, accuracy, or the presence or absence of errors, whether or not known or discoverable. To the extent possible, in no event will the authors and licensor be liable on any legal theory (including, without limitation, negligence) or otherwise for any direct, special, indirect, incidental, consequential, punitive, exemplary, or other losses, costs, expenses, or damages arising out of this public license or use of the licensed material, even if the licensor has been advised of the possibility of such losses, costs, expenses, or damages.

Document Revision History

Version	Date	Type of update	Prepared
1.0	February 22, 2015	First Release	eHealth Strategy Management Office – eHealth Standards Department

1. INTRODUCTION

1.1 DOCUMENT PURPOSE

The purpose of this document is to address the Saudi eHealth Core Interoperability Specification for Sharing Coded Laboratory Results. It forms a set of requirements that complements the set of IHE Profiles, HL7 and LOINC Standards required by this specification with Saudi eHealth specific constraints. It also aligns with the Saudi e-Government Interoperability Standards (YEFI) to expedite national adoption.

This Interoperability Specification is applicable to existing and new information systems to be connected to the national Saudi eHealth Exchange (SeHE) platform.

1.2 DESCRIPTION

This Core Interoperability Specification describes the technical requirements for the interface to share coded Laboratory Results Reports via the Saudi eHealth Exchange (SeHE). These laboratory test results are generally used by primary and hospital care providers but may also be used by MOH Business Applications, including public health/MOH business organizations.

Laboratory results reports are grouped as they are produced by laboratories. Reports contain information such as:

- General information about the laboratory order
- The performing laboratory
- Information about the sample
- The set of releasable results produced by a clinical laboratory in the fulfillment of one or more test orders for a patient

The Laboratory Results Report is created in a format that supports both human-readable rendering and machine processing (i.e. coded results data).

1.3 SCOPE

In Scope:

The scope of this document is the specification of the Sharing of Coded Laboratory Results.

Please note that specification of the content of the Laboratory Results Report is found in the supporting document: IS0105 *Saudi eHealth Laboratory Results and Orders Content Interoperability Specification.*

The scope of this document is further constrained as follows:

- Laboratory results may only be shared for patients with KSA-Wide Health IDs
- Laboratory test results may only be shared by a provider and/or organization authorized by the KSA

Out of scope:

The following is a list of content and specifications that are specifically out of scope for this Interoperability Specification:

- Medical Practices for identifying authorized Healthcare Providers and/or Organizations
- The User Interface for querying and retrieving Laboratory Results Reports
- Verification of the reading of a Laboratory Results Report by the ordering Healthcare Provider and/or Organization.
- Notification of available Laboratory Results Reports for recipients other than the ordering Healthcare Provider/Organization (It is expected that the local systems responsible for ordering the laboratory tests will handle additional recipient notifications)
- The content of the documentation that must be included in amended/corrected Laboratory Results Report
- The content of the documentation that must be included in a partial results laboratory result reports
- How the Laboratory Results Reports are rendered to the physician is out of scope for this document. This includes the ability to brand or provide a logo on the Laboratory Results Report. Local applications are responsible to process coded laboratory data, filter the subset of interest to the health professional and provide a user friendly layout in context with other information needed to deliver care
- Laboratory sub-contracting is out of scope for this document. As such, existing local laboratory processes will be used to handle sub-contracted laboratory work, and the primary Laboratory will be responsible for updating the laboratory order and reporting the results report(s).

1.4 RELATIONSHIP BETWEEN LABORATORY ORDERS AND RESULTS REPORTS

The operation of the sharing of Laboratory Orders and Results Reports is covered by two different interoperability specifications: one specification addressing orders and the second addressing results. The specification of the Laboratory order workflow (i.e. the placement of a laboratory order and completion of a laboratory order) as well as Laboratory Order interoperability are covered by IS0004 *Saudi eHealth Core Interoperability Specification for Coded Laboratory Orders*. The specification of the Laboratory Results Report creation (including updates and access) as well as the Laboratory Results Report interoperability are covered by this Interoperability Specification: IS0003 *Saudi eHealth Core Interoperability Specification for Sharing Coded Laboratory Results*. Figure 1.4-1: Overview of Relationship between Shared Coded Lab Results and Coded Lab Orders Interoperability Specifications shows the interplay between the major activities associated with the creation and execution of a laboratory order and the creation of the Laboratory Results Report. The diagram also shows the associated workflow and how the requirements for the interoperability specification are divided up.

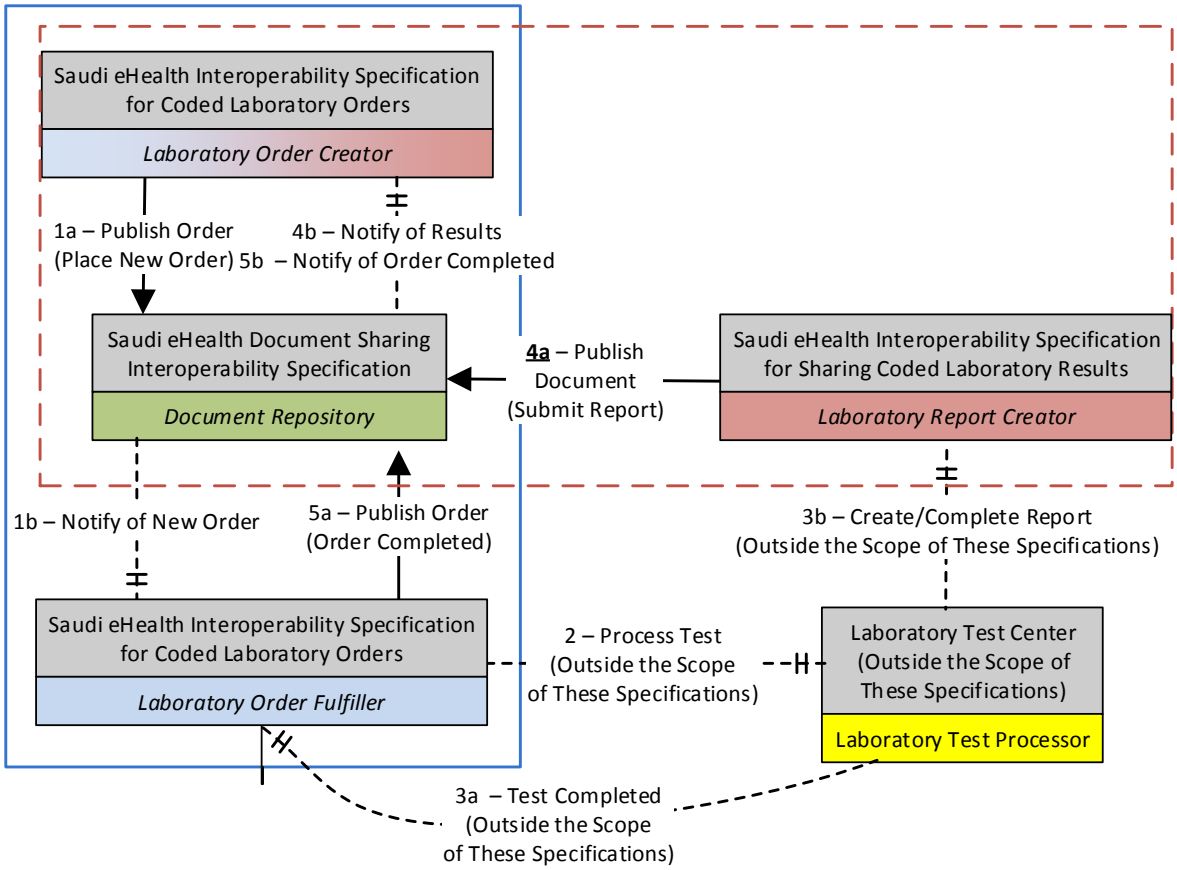

FIGURE 1.4-1: OVERVIEW OF RELATIONSHIP BETWEEN SHARED CODED LAB RESULTS AND CODED LAB ORDERS INTEROPERABILITY SPECIFICATIONS

1.5 METHODOLOGY

This Interoperability Specification has been developed with input from various Saudi stakeholders collected during several months through workshops and teleconferences. Stakeholders included leaders from numerous laboratories handling laboratory workflows in facilities.

The development of a Core Interoperability Specification relies on the high-level requirements set by the associated Use Case. These high-level requirements are not restated in this specification and readers may consider reviewing the related Use Case document for more information.

1.6 HOW TO READ THIS DOCUMENT

1.6.1 Where to Find Information

This document contains six normative sections, as well as informative appendices for your convenience. The document is structured as follows:

Section 1: Contains an introduction to the Interoperability Specification (IS). This section contains a summary of the IS purpose and scope, as well as other content to help orient the first time reader to the topic of the IS and how it relates to other specifications in the SeHE System.

Section 2: Describes the Use Case, including design constraints and assumptions and the flows of information that will be specified in this IS. Section 2 also introduces scenarios that describe how the specified flows may be used in the Saudi eHealth context.

Section 3: Provides an overview of how the interoperability requirements fit into the overall context of the Use Case.

Section 4: Establishes the Core Interoperability Requirements for the Interoperability Specification. . Diagrams within this section show only cross business actor transactions. Actions internal to the business actors have been omitted from the diagrams for brevity and clarity.

Section 5: Establishes the Conformance Requirements for the Interoperability Specification.

Section 6: Describes the constraints on the transactions and actors used for sharing Laboratory Results Reports.

Section 7: Describes the related Saudi eHealth Interoperability Specifications, as well as the international standards which underpin this Interoperability Specification.

Appendix A: Illustrates example messages and documents used with this Specification.

1.6.2 Related Documents

The Saudi eHealth Interoperability Core Specification (IS) is the sole entry point for the technology developers, the compliance assessment testing and certification, and the purchaser of IT systems in terms of technical requirements.

It references a number of Supporting Interoperability Specifications:

- IS0004 *Saudi eHealth Core Interoperability Specification for Coded Laboratory Orders*
- IS0101 *Saudi eHealth Security and Privacy Interoperability Specification*
- IS0102 *Saudi eHealth Document Sharing Interoperability Specification*
- IS0105 *Saudi eHealth Laboratory Results and Orders Content Interoperability Specification*
- IS0106 *Saudi eHealth Clinical Documents Constrains Interoperability Specifications*
- IS0200 *Saudi eHealth Terminology Repository*

The above Saudi eHealth Interoperability Specifications include precise references to internationally adopted profiles and standards as well as Saudi specific constraints. See Section 7 Referenced Documents and Standards for more information on these Interoperability Specifications.

Implementations are required to conform to the requirements within this Interoperability Specification as well as all referenced Interoperability Specifications and the standards and profiles they specify. This document fits into an overall specification framework described in Figure 1.4-1: Overview of Relationship between Shared Coded Lab Results and Coded Lab Orders Interoperability Specifications.

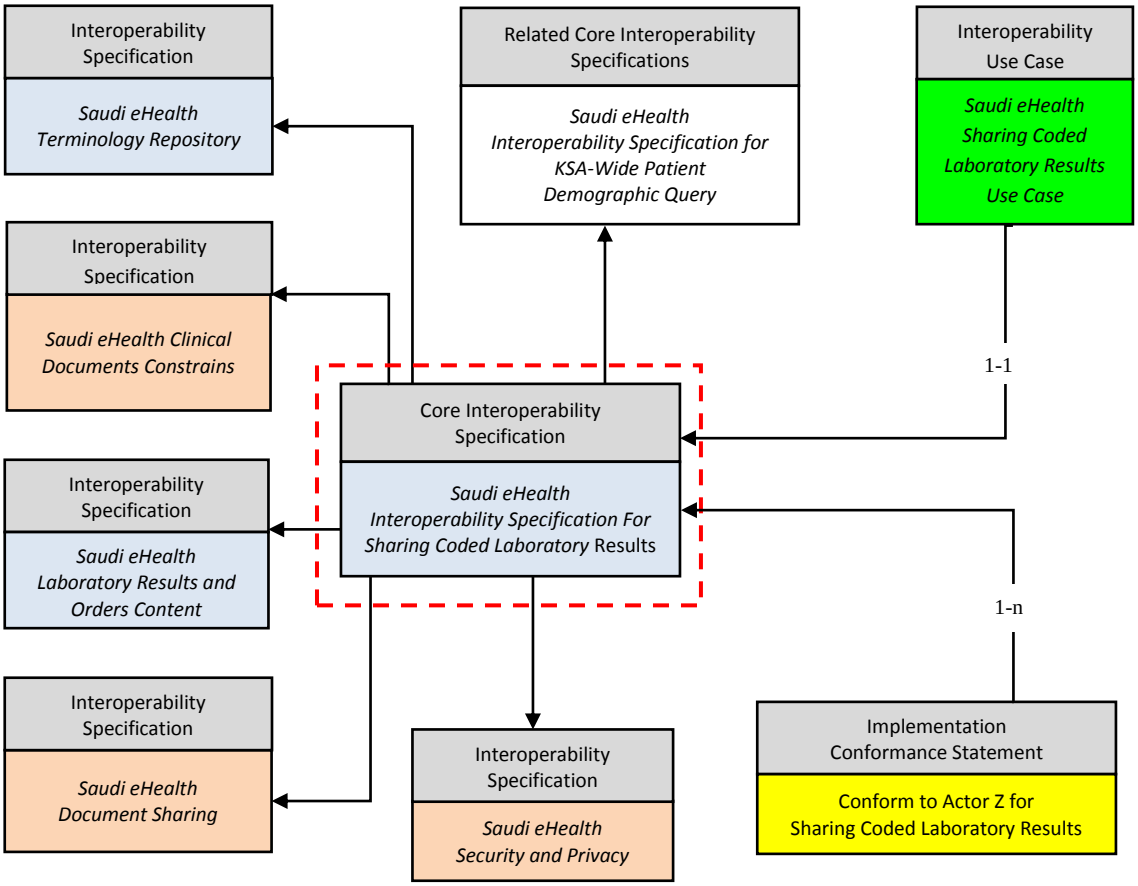

FIGURE 1.6.2-1 SHARING CODED LABORATORY RESULTS DOCUMENT ORGANIZATION

1.6.3 Document Conventions

1.6.3.1 REQUIREMENTS NUMBERING CONVENTIONS:

All Saudi eHealth Interoperability Specifications contain numbered requirements that follow this format:

- [ABCD-###], where ABCD is a three or four letter acronym unique to that Interoperability Specification for convenient purposes, and ### is the unique number for that requirement within the Interoperability Specification.
- Where a specific value set or code is required to be used, it can be found in the "IS0200 Saudi eHealth Terminology Repository". The location and process to access the terminology repository will be specified in mechanisms external to this document.

Saudi eHealth numbered requirements are the elements of the Interoperability Specification that the system can conform to. In other words, in order to implement a system that fully supports the Use Case and Interoperability Specification, the system shall be able to demonstrate that it conforms to every numbered requirement for the system actors to which it is claiming conformance.

Please note that all Saudi eHealth numbered requirements are numbered uniquely, however numbered requirements are not always sequential.

1.6.3.2 REQUIREMENTS LANGUAGE

Throughout this document the following conventions[1] are used to specify requirement levels:

- **SHALL:** the definition is an absolute requirement of the specification. (Note: "SHALL …… IF KNOWN" means that the tag must be sent. However, if there were no information, then this tag should be sent with a <nullflavor>).
- **SHALL NOT:** the definition is an absolute prohibition of the specification.
- **SHOULD:** 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:** 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** or **OPTIONAL**: means 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.

[1] Definitions based upon RFC 2119

2. USE CASE

2.1 USE CASE ACTORS AND SERVICES

The Use Case Actors and the Services that are used by this Core Interoperability Specification are described at a functional level in the *Saudi eHealth Interoperability Specification for Sharing Coded Laboratory Results Use Case* document. A brief description is provided in the following tables.

TABLE 2.1-1 USE CASE ACTORS

ACTOR NAME	DESCRIPTION
Document Repository	This Repository stores the Laboratory Results Reports that include the coded laboratory tests and maintains metadata about each registered laboratory report. Most often the system hosting a Repository includes a Document Registry that maintains the location of the Documents within this or additional Document Repositories.
Laboratory Report Creator	This Actor is responsible for the creation of laboratory content of the electronic document and publishing the report to the Document Repository. It also is responsible to manage the updates to lab report documents, such as replace, amend and/or deprecate.
Laboratory Report Consumer	This Actor is responsible for querying and retrieving Laboratory Results Reports for viewing, importing, or other processing of content from the Document Repository.
Laboratory Order Creator	This Actor is responsible for the creation of coded laboratory orders as an electronic order and publishing the order to the Document Repository. It also manages the order status such as new order or cancelled.
Laboratory Order Fulfiller	This Actor is responsible for querying and retrieving coded laboratory orders from the Document Repository for their fulfillment. It is also responsible to provide updates to the order, such as completed or aborted.

TABLE 2.1-2 USE CASE SERVICES

SERVICE NAME	DESCRIPTION
Publish Document(s)	Publish Document(s) is used to provide a set of Laboratory Results Reports to a Document Repository. It also requests that the Document Repository store these reports and then register them with a Document Registry. Documents may be managed such as replaced, amended and/or deprecated.
Query/Retrieve Document(s)	Query the Document Repository for information about Laboratory Results Reports stored and indexed in a registry. This also includes the retrieval of one or more reports.
Notification of Document Availability	This service is issued by the Document Repository to notify a Laboratory Report Consumer Actor of a laboratory report of interest that is available to be retrieved.

2.2 DESIGN CONSTRAINTS AND ASSUMPTIONS

The following design principles underlie this interoperability specification:

- It is expected that all services initiated or provided by these Actors operate in accordance to the Saudi Health Information Exchange Polices.
- Laboratories have the ability to share a Laboratory Results Report even if the original laboratory order is not shared.
- Only verified results report(s) will be shared.
- As a result of a shared laboratory order (See IS0004 *Saudi eHealth Core Interoperability Specification for Coded Laboratory Orders*), test results that have been produced will be available for the ordering Healthcare Provider and/or Organization (as well as other potential health professionals and possibly the patient). Such test results are ready to be shared in SeHE through this Interoperability Specification.
- Laboratory results reports for patients without KSA-Wide Health IDs are excluded from being shared in SeHE and are expected to be stored locally.
- It is the responsibility of the receiving system (Laboratory Report Consumer) to reconcile their local patient IDs and laboratory coded data elements with the KSA-Wide Health ID, and nationally specified Laboratory Test and Results codes as well as other coded information in the laboratory report.
- Configuration of the Document Metadata Subscription to enable receipt of notifications is expected to happen at the install/configuration time. This simplifies implementation until specific need for dynamic subscription has been identified. For further details, see the IS0102 *Saudi eHealth Document Sharing Interoperability Specification*.

2.3 USE CASE FLOW OF EVENTS

The Saudi eHealth Interoperability Use Case document describes the key workflows that are supported by this Core Interoperability Specification. A brief summary of the Use Case flows are provided below. For an in-depth understanding of the Use Case flows, it is recommended to read the Use Case document.

- **Main Flow:** A Laboratory Report Creator creates Laboratory Results Reports and publishes them to the Document Repository. The Document Repository resides in the SeHE System platform. The edge systems that are consumers of Laboratory Results Reports retrieve Laboratory Results Reports from the Document Repository.
- **Alternative Flow of Events:** Edge systems that are consumers of Laboratory Results Reports may be notified when the Laboratory Results Reports are accessible within the Document Repository. This includes the Healthcare Provider or Organization who may have requested the laboratory tests and wish to be notified when the Laboratory Results Reports are available.
- **Alternative Flow of Events:** If the laboratory that created the original Laboratory Results Report determines it needs to amend/correct the results report (e.g. important

information was left out, additional test results need to be added, etc.). The Laboratory Report Creator queries and retrieves the original Laboratory Results Report from the Document Repository, and locally creates an amended Laboratory Results Report. The authorized Laboratory Report Creator publishes the amended Laboratory Results Report to the Document Repository. The amended Laboratory Results Report references and replaces the original Laboratory Results Report (See IS0102 *Saudi eHealth Document Sharing Interoperability Specification* Section 2.2.2 for detail on how this is accomplished).

.

2.3.1 Specific Workflow Scenarios

The following sections provide various scenarios that complement the Use Case flow of events by using the defined transactions in a specific way. Some of these scenarios highlight variants to the Use Case flow of events while others describe local workflow situations that are beyond the scope of the Use Case but consistent with it. These workflow scenarios are not intended to be an exhaustive list.

2.3.1.1 SCENARIO 1: LABORATORY CREATES A LABORATORY RESULTS REPORT FOR A SHARED CODED LABORATORY ORDER

A laboratory performs the requested tests for a shared coded laboratory order (See IS0004 *Saudi eHealth Core Interoperability Specification for Coded Laboratory Orders* Section 2.3.1.1). The laboratory may choose to include a comment to communicate additional information to the ordering Healthcare Provider or Organization. As part of this process, the Laboratory Report Creator creates a Laboratory Results Report and publishes it to the Document Repository.

> Note: To ensure that the shared laboratory order and the shared Laboratory Results Report are linked, the information identifying the shared laboratory order is included in the Laboratory Results Report.

This scenario is a sub-set of the Use Case main flow of events.

2.3.1.2 SCENARIO 2: LABORATORY CREATES A PARTIAL LABORATORY RESULTS REPORT FOR A SHARED CODED LABORATORY ORDER

A laboratory begins performing the requested tests for a shared coded laboratory order. Laboratory protocol indicates that the partial test results should be shared with the Healthcare Provider or Organization (e.g. a wound culture indicates that a given bacteria is present, but further testing is required to determine the susceptibility). The Laboratory Report Creator creates a local Laboratory Results Report with the available laboratory results and a comment indicating the reason for publishing the partial results. Prior to creating a shareable Laboratory Results Report the Laboratory Results Report is validated either by clinician or by an associated medical device. The Laboratory Report Creator publishes the partial Laboratory Results Report to the Document Repository.

> Note: Preliminary results which have not been validated by the laboratory should not be made shareable within the Document Repository. The workflow associated with releasing partial

Laboratory Results Reports may be found in the IS0004 *Saudi eHealth Core Interoperability Specification for Coded Laboratory Orders* Section 2.3.1.9. This scenario is a sub-set of the Use Case main flow of events.

2.3.1.3 SCENARIO 3: LABORATORY AMENDS A PARTIAL LABORATORY RESULTS REPORT WITH THE FINAL REPORTABLE RESULTS

A laboratory completes the requested tests for a shared coded laboratory order, which has previously released a shareable Laboratory Results Report (e.g. a wound culture indicates that a given bacteria is present without the susceptibility information) (See IS0004 *Saudi eHealth Core Interoperability Specification for Coded Laboratory Orders* Section 2.3.1 for details on the workflow associated with this activity). Now that all of the test results are available, the existing Laboratory Results Report needs to be amended with the additional results. The Laboratory Report Creator queries and retrieves the existing Laboratory Results Report and locally amends the laboratory report with the additional test results and a comment documenting the addition of the additional test results. The Laboratory Report Creator publishes the amended Laboratory Results Report to the Document Repository. The amended results report references the original results report and replaces the original (both versions of the Laboratory Results Report remain accessible through the Document Repository). (See IS0102 *Saudi eHealth Document Sharing Interoperability Specification* Section 2.2.2 for details on this mechanism). This scenario is a sub-set of the Use Case Alternative Flow 2 flow of events.

2.3.1.4 SCENARIO 4: LABORATORY AMENDS/CORRECTS A FINAL LABORATORY RESULTS REPORT

An authorized laboratory determines that a final Laboratory Results Report that has already been shared to the Document Repository needs to be corrected/amended (e.g. wrong patient linked to results report, erroneous information needs to be corrected, defective interpretation) (See IS0004 *Saudi eHealth Core Interoperability Specification for Coded Laboratory Orders Section* 2.3.1 for details on the workflow associated with this activity). The Laboratory Report Creator query and retrieves the existing Laboratory Results Report and locally amends the Laboratory Results Report with the corrections/additions, providing comments to document the changes that have been made to the report. The Laboratory Report Creator publishes it to the Document Repository. The amended Laboratory Results Report references the original Laboratory Results Report and replaces the original (both versions of the Laboratory Results Report remain accessible through the Document Repository). (See IS0102 *Saudi eHealth Document Sharing Interoperability Specification* Section 2.2.2 for details on this mechanism). This scenario is a sub-set of the Use Case Alternative Flow 2 flow of events.

2.3.1.5 SCENARIO 5: LABORATORY ORDER TO BE SHARED REQUIRES LABORATORY RESULTS REPORTS FROM MULTIPLE SPECIALTIES

A Healthcare Provider creates a laboratory order which requires laboratory tests from multiple laboratory specialty areas to be performed (e.g. Cerebrospinal fluid requested tests for culture and chemistry results). Shared laboratory orders are created for each of the laboratory specialty areas (e.g. Chemistry and Microbiology) and published to the Document Repository (See IS0004 *Saudi eHealth Core Interoperability Specification for Coded Laboratory Orders* Section 2.3.1.8

for details on the workflow associated with this activity). Each of the laboratories performs the requested test(s) and creates a Laboratory Results Report, which the Laboratory Report Creator sends to the Document Repository. This scenario is a sub-set of the Use Case main flow of events.

> Note: The local Laboratory Order Creator is responsible for linking the individual shared laboratory orders with the original laboratory order (a process which is out of scope for the Shared Laboratory Results and Laboratory Order Use Case).

2.3.1.6 SCENARIO 6: LABORATORY SHARES A LABORATORY RESULTS REPORT FOR A NON-SHARED CODED LABORATORY ORDER

A request has been made to share a patient's Laboratory Results Report for a previously created local laboratory order. The Laboratory Report Creator creates a shareable Laboratory Results Report and sends it to the Document Repository so that it may be accessed within the SeHE system. This scenario is a sub-set of the Use Case main flow of events.

> Note: The Laboratory Report Creator will be responsible for creating a version of the Laboratory Results Report which provides KSA-Wide Health ID identifiers. This includes such items as the Patient ID, the Placer Order ID when available and the Filler Order ID.

2.3.1.7 SCENARIO 7: ACCESS TO PRIOR LABORATORY RESULTS REPORT(S) FROM THE DOCUMENT REPOSITORY

A Healthcare Provider needs to access Laboratory Results Reports produced by a Laboratory Report Creator. The Healthcare Provider may have been the original Ordering Healthcare Provider (See the IS0004 *Saudi eHealth Order Core Interoperability Specification for Coded Laboratory Orders*) or simply need them for historical laboratory results. When shared Laboratory Results Reports are created, they are stored in the Document Repository with key metadata. This metadata can be used to filter the Laboratory Results Reports returned from a Document Repository query. The Healthcare Provider is able to query and retrieve shared results reports using filtering mechanisms managed by the Document Repository or its local applications.

This interoperability specification supports two levels of filtering. The first level of filtering is by specification of query metadata including:

- Patient KSA-Wide Health ID
- KSA-Wide Order Placer Number
- Lab specialty (biochemistry, microbiology, etc.)
- Time of service when tests were performed
- Specific Ordered Test

Additional filtering may be applied on the returned metadata for the reports, including report author, institution, et cetera.

> Note: If Laboratory Results Reports have a confidentiality level associated with them (e.g. a Restricted test, such as an HIV Test), a Healthcare Provider that may only access Laboratory Results Reports with a lower confidentiality level, may not be able to access the data from restricted Laboratory results reports associated with the Patient although the filters at the above

levels would not have excluded them (See IS0101 *Saudi eHealth Security and Privacy Interoperability Specification*).

2.3.1.8 SCENARIO 8: ACCESS ALL VERSIONS OF A LABORATORY RESULTS REPORT

There are cases where deprecated versions of a Laboratory Results Report may need to be retrieved from the Document Repository (e.g. Quality Assurance).

The query and filtering methods used to retrieve all versions of a document from the Document Repository are discussed in the IS0102 *Saudi eHealth Document Sharing Interoperability Specification* Section 5.

This scenario is a sub-set of the Use Case Alternative Flow 2 flow of events.

2.3.1.9 SCENARIO 9: LABORATORY RESULTS REPORT IS AMENDED AFTER PRE-FETCH HAS OCCURRED TO LOCAL SYSTEM

A request may be made to the Document Repository to receive notification of an update to the Laboratory Results Report. This is recommended when the time between the Laboratory Results Report retrieval and its usage differ. Alternatively, if Laboratory Results Reports are pre-fetched and stored locally, it is recommended that the Laboratory Report Consumer re-query the Document Repository to verify that it has not been deprecated and replaced by an amended Laboratory Results Report.

This scenario is a sub-set of the Use Case Alternative Flow 1 flow of events.

3. OVERVIEW OF SHARED LABORATORY RESULTS REPORTS

3.1 SHARED LABORATORY DOCUMENT REQUIREMENTS

Shared Laboratory Results Reports publishing differs from the standard in-house Laboratory publishing in that the Laboratory updates are made available on a more limited basis, and must include KSA-Wide identifiers in order to ensure interoperability. Furthermore, a laboratory may choose to exclude information that is stored in the shared Laboratory Results Report (e.g. internal personnel involved in performing the laboratory), based upon laboratory protocol. The following section describes the publishing of the shared Laboratory Results Report and identifies the KSA-Wide identifiers which are critical for shared Laboratory Results Reports.

3.1.1 Publishing Laboratory Results Reports

The ability for a Laboratory Report Creator to create and modify a shared Laboratory Results Report depends in part on the laboratory order status of the shared Laboratory Order. See Table 3.1-1 IS0004 *Saudi eHealth Core Interoperability Specification for Coded Laboratory Orders* for the details. Table 3.1.1-1: Clinical Laboratory Report Status shows the clinical status of the Laboratory Results Report and how they are used within the Saudi eHealth Enterprise.

TABLE 3.1.1-1: CLINICAL LABORATORY REPORT STATUS

CLINICAL REPORT STATUS	DEFINITION	SHARED LABORATORY RESULTS REPORT SUPPORT
Preliminary Report	Report which is released prior to undergoing the process of report validation by the laboratory.	Not supported

CLINICAL REPORT STATUS	DEFINITION	SHARED LABORATORY RESULTS REPORT SUPPORT
Partial Report	Report which is released prior to all of the requested tests being completed. The report validation process has been performed prior to the partial report being released.	Supported prior to the completion of the laboratory order. Laboratory must include documentation on why the laboratory is releasing partial results.
Amended Partial Report	Report which is released and then updated prior to all of the requested tests being completed. The report validation process has been performed prior to the partial report being released and again before the amended report is released.	Supported prior to the completion of the laboratory order. Laboratory must include documentation on why the laboratory is releasing partial results. Laboratory must also include documentation on to why the partial report was amended and what was changed.
Final Report	Report which is released after all of the requested tests have been completed.	Supported Note: When a test is Aborted, a Final Report should be returned indicating that the test was Aborted and the reason why
Amended Report	New report which is released after a completed report has been sent that provides additional information not in the original report	Supported Laboratory must also include documentation on to why the final report. was amended and what was changed.
Corrected Report	Corrected report which is released after a completed report has been sent that changes information in that original report.	Supported Laboratory must also include documentation on the correction to the final report and what was changed.

When a Laboratory Results Report is updated for whatever reason, all versions of the shared Laboratory Results Report must be maintained within Document Repository. The process of replacing the original shared Laboratory Results Report with a new version is known as deprecation.

3.1.2 Use of KSA-Wide Identifiers within Shared Laboratory Results Reports

As a part of the interoperability of shared Laboratory Results Reports, the Laboratory Report Creator must provide KSA-Wide identifiers rather than local identifiers. The identifiers critical for linking the laboratory order to the results report are the Placer Order ID and the Filler Order ID. The Placer Order ID is the identifier assigned to a laboratory order at the time of its creation. Organizations typically provide a mechanism to ensure that within the organization the Placer Order ID is unique. In order to ensure that the Placer Order ID for a shared laboratory order is unique, the KSA-Wide Organization identifier becomes a part of the Placer Order ID for a shared laboratory order Likewise, the Filler Order ID is the identifier assigned the Laboratory Results

Report at the time of its creation, and it has the same requirements. In order to link the laboratory order with the laboratory results, the Laboratory Report Creator must include the KSA-Wide Placer Order ID in the shared Laboratory Results Report. When a Laboratory Results Report is updated, the Placer Order ID and Filler Order ID **SHALL** not change.

4. CORE INTEROPERABILITY SPECIFICATION REQUIREMENTS

4.1 ACTOR MAPPING TO SAUDI EHEALTH IS SPECIFICATIONS

A system conforming to this Core Interoperability Specification shall claim conformance at the level of a Use Case Actor. A system may claim conformance to one or more Use Case Actors. Multiple systems may fulfill a Use Case Actor,

The Actors and the Services they support are described at a functional level in the Saudi eHealth Interoperability Use Case document. Services may be required, conditional or optional. The Use Case Actor, Service(s) and Optionality are conveyed in the first three columns of Interoperability Conformance Requirement tables shown below.

The second part of the table (columns 4-7) provides the mapping for the Use Case Actor to the detailed specifications (such as IHE Profiles, Technical Actors, Optionality) that systems shall implement to exchange healthcare information in the context of this Use Case.

For a selected Use Case Actor (a single row in the table), all the requirements listed in the second part of the table (columns 4-7) shall be implemented. This includes the referenced profiles and the standards specified (terminology or other). For each Technical Actor (whether required or optional), the last column references the detailed specification that constrain and extend of the implementation of this profile for KSA specific requirements. These specifications may be found in Appendices to this core specification or in other referenced KSA eHealth Interoperability Specifications (e.g. IS0101 *Saudi eHealth Security and Privacy Interoperability Specification,* etc.).

TABLE 4.1-1 INTEROPERABILITY CONFORMANCE REQUIREMENTS FOR LABORATORY REPORT CREATOR

SHARING CODED LABORATORY RESULTS			MAPPING TO TECHNICAL CONSTRUCTS OF SAUDI EHEALTH INTEROPERABILITY SPECIFICATIONS			
USE CASE ACTOR	SERVICE SUPPORTED	OPT	TECHNICAL ACTOR	OPT	PROFILE/ STANDARD	REFERENCED SPECIFICATION
Laboratory Report Creator	Publish Document(s)	R	Content Creator	R	IHE – Sharing Laboratory Reports (XD-LAB)	IS0105 Saudi eHealth Laboratory Results and Orders Content Interoperability Specification - Section 3.2
			Document Source	R	IHE – Cross-Enterprise Document Sharing (XDS.b)	IS0102 Saudi eHealth Document Sharing Interoperability Specification – Section 3.2
			Secure Node	R	IHE Audit Trail and Node Authentication (ATNA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.2

						and 3.3.2
			Time Client	R	IHE Consistent Time (CT)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.1.2

R=Required, O = Optional, C= Conditional

TABLE 4.1-2 INTEROPERABILITY CONFORMANCE REQUIREMENTS FOR LABORATORY REPORT CONSUMER

SHARING CODED LABORATORY RESULTS			MAPPING TO TECHNICAL DOCUMENTS OF SAUDI EHEALTH INTEROPERABILITY SPECIFICATIONS			
USE CASE ACTOR	SERVICE SUPPORTED	OPT	TECHNICAL ACTOR	OPT	PROFILE/ STANDARD	REFERENCED SPECIFICATION AND COMMENTS
Laboratory Report Consumer	Query/Retrieve Documents(s)	R	Document Consumer	R	IHE – Cross-Enterprise Document Sharing (XDS.b)	IS0102 Saudi eHealth Document Sharing Interoperability Specification – Section 3.3
			Content Consumer	R	IHE – Sharing Laboratory Reports (XD-LAB)	IS0105 Saudi eHealth Laboratory Results and Orders Content Interoperability Specification - Section 3.2
			X-Service User	R	IHE – Cross-Enterprise User Assertion (XUA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.4.1
			Secure Node	R	IHE Audit Trail and Node Authentication (ATNA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.2 and 3.3.2
			Time Client	R	IHE Consistent Time (CT)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.1.2
	Notification of Document Availability	O	Document Metadata Notification Recipient	R	IHE - Document Metadata Subscription (DSUB)	IS0102 Saudi eHealth Document Sharing Interoperability Specification
			Secure Node	R	IHE Audit Trail and Node Authentication (ATNA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.2 and 3.3.2
			Time Client	R	IHE Consistent	IS0101 Saudi eHealth

SHARING CODED LABORATORY RESULTS			MAPPING TO TECHNICAL DOCUMENTS OF SAUDI EHEALTH INTEROPERABILITY SPECIFICATIONS			
USE CASE ACTOR	SERVICE SUPPORTED	OPT	TECHNICAL ACTOR	OPT	PROFILE/ STANDARD	REFERENCED SPECIFICATION AND COMMENTS
					Time (CT)	Security and Privacy Interoperability Specification

R=Required, O = Optional, C= Conditional

TABLE 4.1-3 INTEROPERABILITY CONFORMANCE REQUIREMENTS FOR DOCUMENT REPOSITORY

SHARING CODED LABORATORY RESULTS			MAPPING TO TECHNICAL DOCUMENTS OF SAUDI EHEALTH INTEROPERABILITY SPECIFICATIONS			
USE CASE ACTOR	SERVICE SUPPORTED	OPT	TECHNICAL ACTOR	OPT	PROFILE/ STANDARD	REFERENCED SPECIFICATION AND COMMENTS
Document Repository	Publish Document(s)	R	Document Repository	R	IHE – Cross-Enterprise Document Sharing (XDS.b)	IS0102 Saudi eHealth Document Sharing Interoperability Specification – Section 3.4
			Secure Node	R	IHE Audit Trail and Node Authentication (ATNA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.2 and 3.3.1
			Time Client	R	IHE Consistent Time (CT)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification
	Query/Retrieve Document(s)	R	Document Registry and Document Repository	R	IHE – Cross-Enterprise Document Sharing (XDS.b)	IS0102 Saudi eHealth Document Sharing Interoperability Specification – Section 3.4
			X-Service Provider	R	IHE – Cross-Enterprise User Assertion (XUA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.41
			Secure Node	R	IHE Audit Trail and Node Authentication (ATNA)	S0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.2 and 3.3.1

SHARING CODED LABORATORY RESULTS			MAPPING TO TECHNICAL DOCUMENTS OF SAUDI EHEALTH INTEROPERABILITY SPECIFICATIONS			
USE CASE ACTOR	SERVICE SUPPORTED	OPT	TECHNICAL ACTOR	OPT	PROFILE/ STANDARD	REFERENCED SPECIFICATION AND COMMENTS
			Time Client	R	IHE Consistent Time (CT)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.1.2
	Notification of Document Availability	R	Document Metadata Notification Broker	R	IHE - Document Metadata Subscription (DSUB)	IS0102 Saudi eHealth Document Sharing Interoperability Specification – Section 4.1
			Secure Node	R	IHE Audit Trail and Node Authentication (ATNA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.2 and 3.3.1
			Time Client	R	IHE Consistent Time (CT)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.1.2

R=Required, O = Optional, C= Conditional

4.2 INTEROPERABILITY SEQUENCE DIAGRAMS

The following Sequence diagrams provide an overview of the combined flow of transactions resulting from the above selected profiles and standards. These sequence diagrams are not intended to cover all cases and variants of information exchange between the Actors.

The Coded Laboratory Results sequence diagrams provide a high-level sequence of events for the exchange of information for sharing a patient's Laboratory Results Reports. It also illustrates typical security exchanges for authorized network communications and audit trail of patient information access.

4.2.1 Main Flow Sequence Diagram

The main flow sequence diagram is a scenario between a laboratory and a Healthcare Provider or Organization where a laboratory creates a Laboratory Results Report; and a Healthcare Provider or Organizations retrieves the patient's shared Laboratory Results Report. This figure depicts a number of transactions between IHE Profile Actors specified in the multiple tables in Section 4. The sequence diagrams show only transactions that operate across business actors. Transactions that operate between actors within business actors are omitted for brevity. For a complete outline

of the transactions necessary for implementation of the Specification, consult Table 4.1-1 Interoperability Conformance Requirements for Laboratory Report Creator, Table 4.1-2 Interoperability Conformance Requirements for Laboratory Report Consumer and Table 4.1-3 Interoperability Conformance Requirements for Document Repository.

Steps 1 – 5 are shown in Figure 4.2.1-1 Coded Laboratory Results Sequence Diagram (1).

1. Time synchronization occurs independently. These transactions may take place at any time and are shown at the beginning of the sequence diagram [IHE CT Profile: Maintain Time ITI-1].
2. Laboratory test(s) are ordered for a patient. The laboratory test(s) are performed and the local Laboratory Results Report is created. The Laboratory Report Creator determines that the Laboratory Results Report must be shared, and creates a shared version of the Laboratory Results Report to send to the Document Repository. Before the exchange can take place, an authentication process takes place between the Document Source/Secure Node Actor and the Document Repository/Secure Node Actor occurs [IHE ATNA Profile: Authenticate Node ITI-19].

Note: The shared Laboratory Results Report must contain KSA-Wide identifiers. This includes the requirements on how to obtain a patient's KSA-wide Health ID and key patient demographics which are defined in IS0001 *KSA-Wide Core Interoperability Specification for Patient Demographic Query Core*. The Health ID and key patient demographics attributes are used to identify the patient for which the Laboratory Results Reports are shared. This ensures KSA-wide identification of the patient in health records. This is not shown is the diagram and details to accomplish this are defined in IS0001 *Saudi eHealth Core Interoperability Specification for KSA-Wide Patient Demographic Query*.

3. Following node authentication, the Document Source transmits the Laboratory Results Report to Document Repository. [IHE XDS.b: Profile: Provide and Register Document Set – b ITI-41]. The format of the report is defined by [IHE Profile: Sharing Laboratory Reports (XD-LAB)]. The Document Repository stores the report.
4. The Document Repository registers the laboratory report with the Document Registry [IHE XDS.b: Register Document Set – b ITI-42].

   Note: The IHE XDS.b: [Register Document Set – b ITI-42] transaction is listed without first performing the authentication between the two systems [IHE ATNA Profile: Authenticate Node ITI-19]. This is because it is very common that the Document Repository and Registry are implemented within the same system. If these Actors are implemented in separate systems the authentication transaction would be required.

5. The Document Source/Secure Node generates a local audit record of the release of patient health information [using the data content as defined by IHE ATNA Profile and Section 5.1]and the Document Repository/Secure Node generates an audit record of the receipt of patient health information [IHE ATNA Profile: Record Audit Event ITI-20].

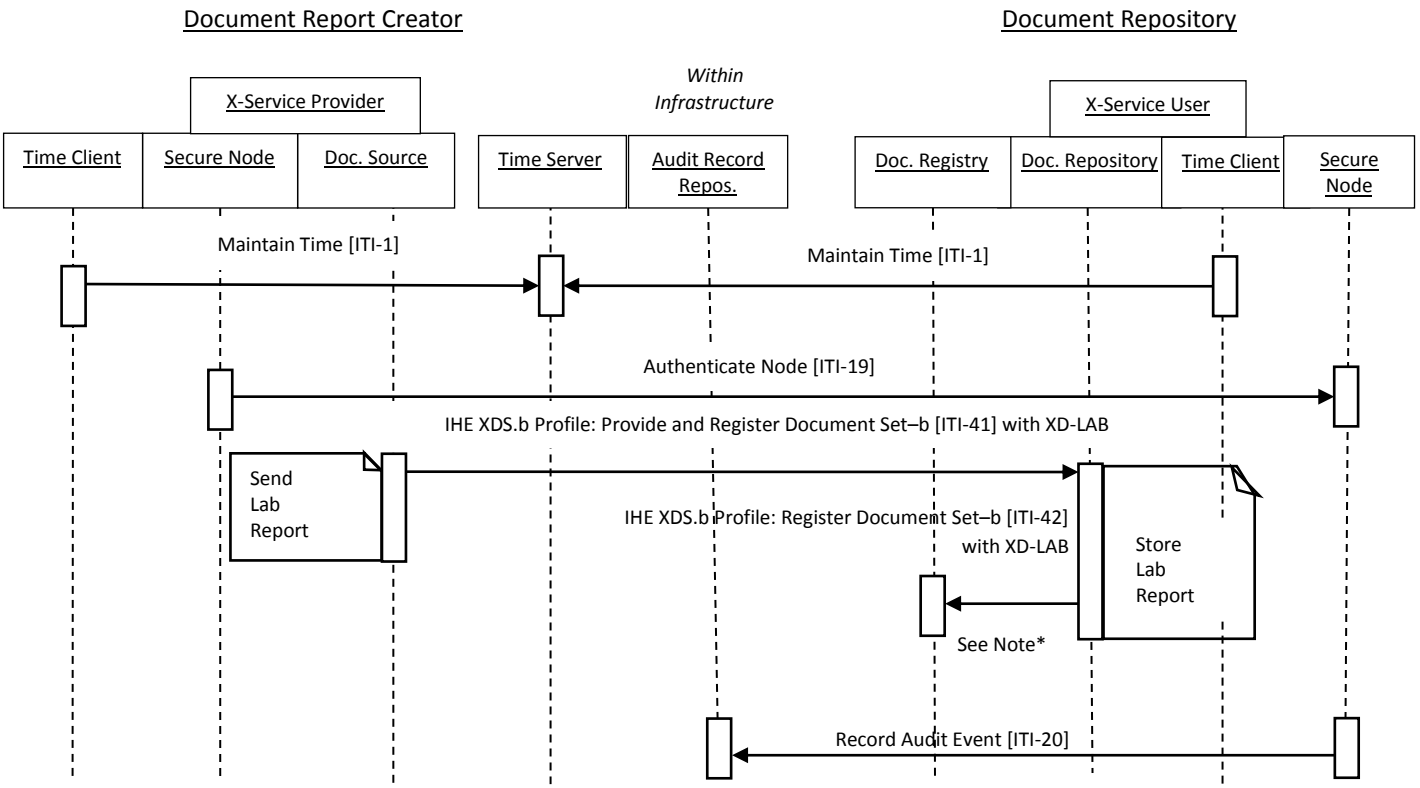

FIGURE 4.2.1-1 CODED LABORATORY RESULTS SEQUENCE DIAGRAM (1)

Steps 6 – 14 related to access to shared laboratory results are shown in Figure 4.2.1-2 Coded Laboratory Results Sequence Diagram (2).

Please note that Time Client and Time Server Actors have been omitted due to limited space on the diagram. The systems need to perform on-going time synchronization [IHE CT Profile: Maintain Time ITI-1] as shown in Step 1.

6. The Healthcare Provider or Organization needs to review the laboratory results. Its supporting system queries the Document Registry to determine if Laboratory Results Reports are available. Before the information exchange can take place, an authentication process between the Laboratory Report Consumer/Secure Node Actor and the Document Registry/Secure Node Actor takes place [IHE ATNA Profile: Authenticate Node ITI-19].
7. The Laboratory Report Consumer/X-Service User queries the Document Registry/X-Service Provider using the patient's KSA-Wide Health ID to determine if the patient's reports are available. As part of the query request, a user assertion is conveyed to verify that the Healthcare Provider or Organization is an authorized user to obtain patient information [IHE XDS-b: Registry Stored Query ITI-18] and [IHE XUA: Provide X-User Assertion ITI-40].

8. The Laboratory Report Consumer/Secure Node generates a local audit record of the access to patient health information [using the data content as defined by IHE ATNA Profile and Section 5.1].
9. The Document Registry processes the query and responds with the information needed to retrieve the Laboratory Results Report [IHE XDS-b: Registry Stored Query ITI-18].
10. The Document Registry/Secure Node generates an audit record of the access to patient health information [IHE ATNA Profile: Record Audit Event ITI-20].
11. The Healthcare Provider or Organization uses the Laboratory Report Consumer to retrieve the laboratory report. Before the information exchange can take place, an authentication process between the Laboratory Report Consumer/Secure Node Actor and the Document Repository/Secure Node Actor takes place [IHE ATNA Profile: Authenticate Node ITI-19].
12. The Laboratory Report Consumer/X-Service User retrieves the laboratory report. As part of the retrieve, a user assertion is conveyed to verify that the Healthcare Provider or Organization is an authorized user to obtain patient information [IHE XDS-b: Retrieve Document Set ITI-43] and [IHE XUA: Provide X-User Assertion ITI-40].
13. The Document Repository/Secure Node generates an audit record of the access to patient health information [IHE ATNA Profile: Record Audit Event ITI-20].
14. The Laboratory Results Report is available, with the coded laboratory results it contains, for the Healthcare Provider or Organization for review.

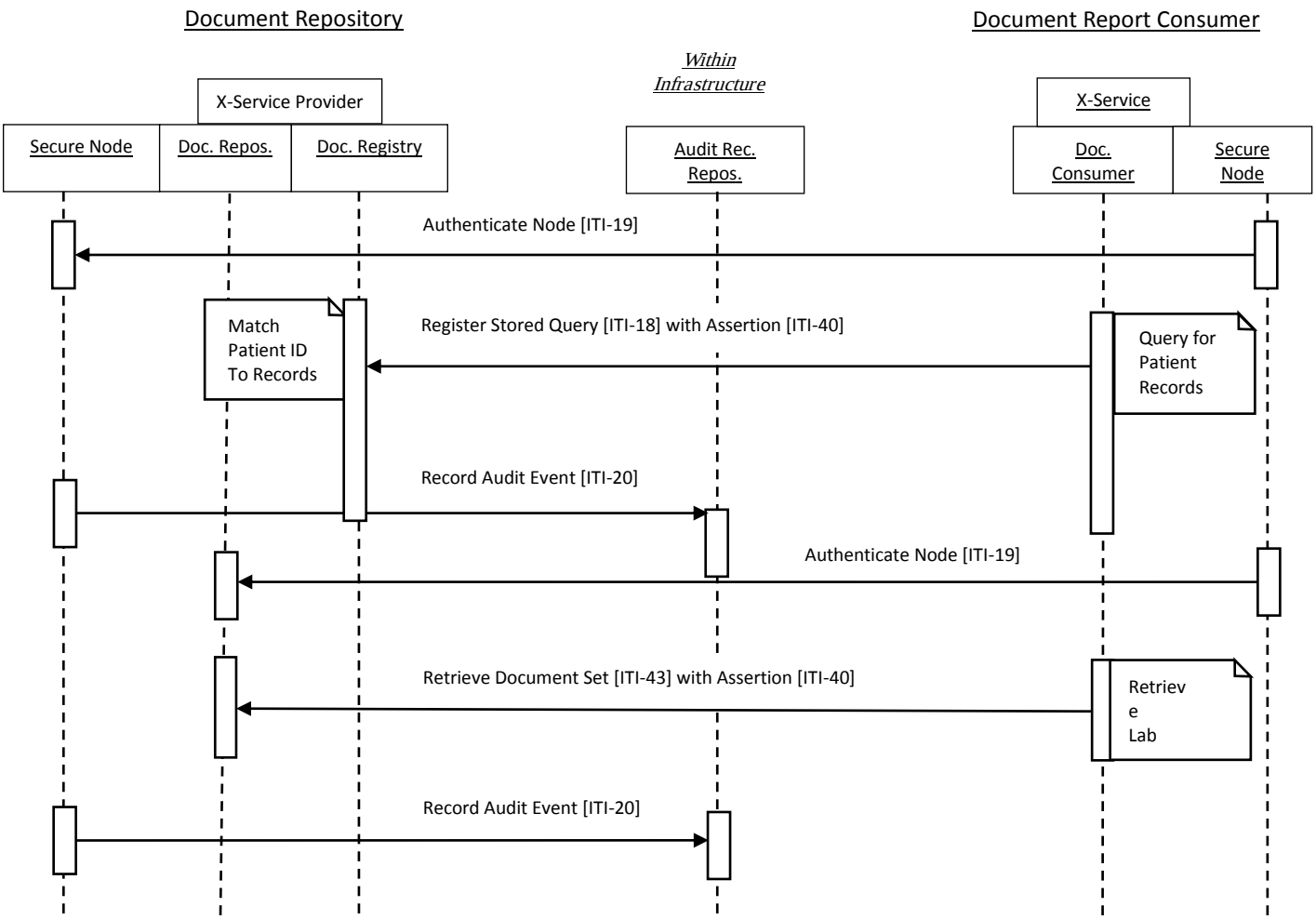

FIGURE 4.2.1-2 CODED LABORATORY RESULTS SEQUENCE DIAGRAM (2)

4.2.2 Amended Report (with optional Notification) Sequence Diagram

The amended report sequence diagram is for the scenario when a Laboratory Results Report has been updated via an amended report. It also includes the optional interaction to provide an automatic notification when the amended Laboratory Results Report is available for sharing. The main flow sequence diagram is a pre-condition to creating an amended Laboratory Results Report and is not repeated in this diagram. This figure depicts a number of transactions between IHE Profile Actors specified in the multiple tables in Section 4.

Steps 1 – 4 are shown in Figure 4.2.1-3 Amended Report with Optional Notification Sequence Diagram (1)

1. Time synchronization is not shown but occurs as shown in other diagrams [IHE CT Profile: Maintain Time ITI-1].

2. The authorized laboratory that creates the original Laboratory Results Report determines that the Laboratory Results Report needs to be amended (addition of final results for previously published partial results, correction to final Laboratory Results Report, etc.). Using the Laboratory Report Creator, the laboratory creates an amended Laboratory Results Report to add/modify the laboratory results information. The Laboratory Results Report includes comments which document the reason for the Laboratory Results Report amendment as well as documentation on what was updated per laboratory protocol. The Laboratory Report Creator shares the amended report with the Document Repository. Before this can take place, an authentication process between the Laboratory Report Creator/Secure Node Actor and the Document Repository/Secure Node Actor occurs [IHE ATNA Profile: Authenticate Node ITI-19].

   Note: When the amended report is published, the source system informs the Document Repository that it is a replacement to the original, a previously shared document. This information is used by the Document Repository to manage the two versions (i.e. deprecate the original laboratory report and provide a link with the amended report).

3. Following node authentication, the amended laboratory report is transmitted [IHE XDS.b Profile: Provide and Register Document Set – b ITI-41]. The format of the Laboratory Results Report is defined by [IHE – Sharing Laboratory Reports (XD-LAB)]. The Document Repository stores the report and deprecates the old version. However the old version of the report is still maintained in the document repository.

4. The Laboratory Report Creator generates a local audit record of the release of patient health information [using the data content as defined by IHE ATNA Profile and Section 5.1] and the Document Repository/Secure Node generates an audit record of the receipt of patient health information [IHE ATNA Profile: Record Audit Event ITI-20].

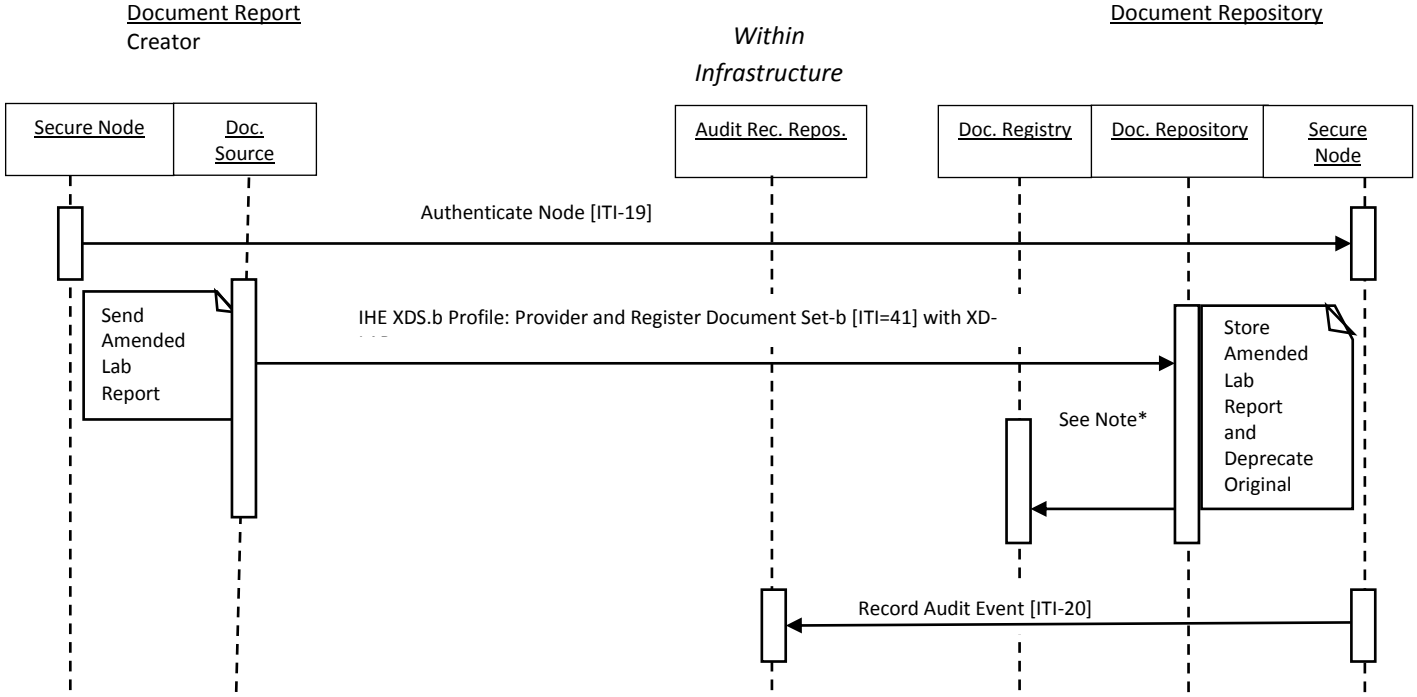

FIGURE 4.2.1-3 AMENDED REPORT WITH OPTIONAL NOTIFICATION SEQUENCE DIAGRAM (1)

Steps 5 – 11 are shown in Figure 4.2.1-4 Amended Report with Optional Notification Sequence Diagram (2).

5. The Document Repository/Document Metadata Notification Broker notifies the Laboratory Report Consumer that an amended Laboratory Results Report was created based on the intendedRecipient metadata field found in the Provide and Register Document Set in step 3 transaction. Before the information exchange can take place, an authentication process between the Document Repository/ Document Metadata Notification Broker/Secure Node Actor and the Laboratory Report Consumer/Document Metadata Notification Recipient/Secure Node Actor occurs [IHE ATNA Profile: Authenticate Node ITI-19].
6. Following node authentication, the notification of document availability is transmitted [IHE DSUB Profile: Document Metadata Notify ITI-53]. The Laboratory Report Consumer has been notified that the amended report is available.
7. The Document Repository generates an audit record of the access to patient health information [IHE ATNA Profile: Record Audit Event ITI-20].
8. Upon the successful transmission of the notification, the receiving system uses the Laboratory Report Consumer Actor to retrieve the amended Laboratory Results Report. Before the information exchange can take place, an authentication process between the Laboratory Report Consumer /Secure Node Actor and the Document Repository/Secure Node Actor takes place [IHE ATNA Profile: Authenticate Node ITI-19].
9. The Laboratory Report Consumer/X-Service User retrieves the amended Laboratory Results Report. As part of the retrieve, an assertion process to verify that the Healthcare Provider or Organization is an authorized user to obtain patient information [IHE XDS.b: Retrieve Document Set ITI-43] and [IHE XUA: Provide X-User Assertion ITI-40].
10. The Document Repository/Secure Node generates an audit record of the access to patient health information [IHE ATNA Profile: Record Audit Event ITI-20].
11. The Healthcare Provider or Organization reviews the amended Laboratory Results Report and provides follow up healthcare.

Note: The IHE XDS.b: [Register Document Set – b ITI-42] transaction is listed without first performing the authentication between the two systems [IHE ATNA Profile: Authenticate Node ITI-19]. This is because it is very common that the Document Repository and Registry are implemented within the same systems. If these Actors are implemented in separate systems the authentication transaction would be required.

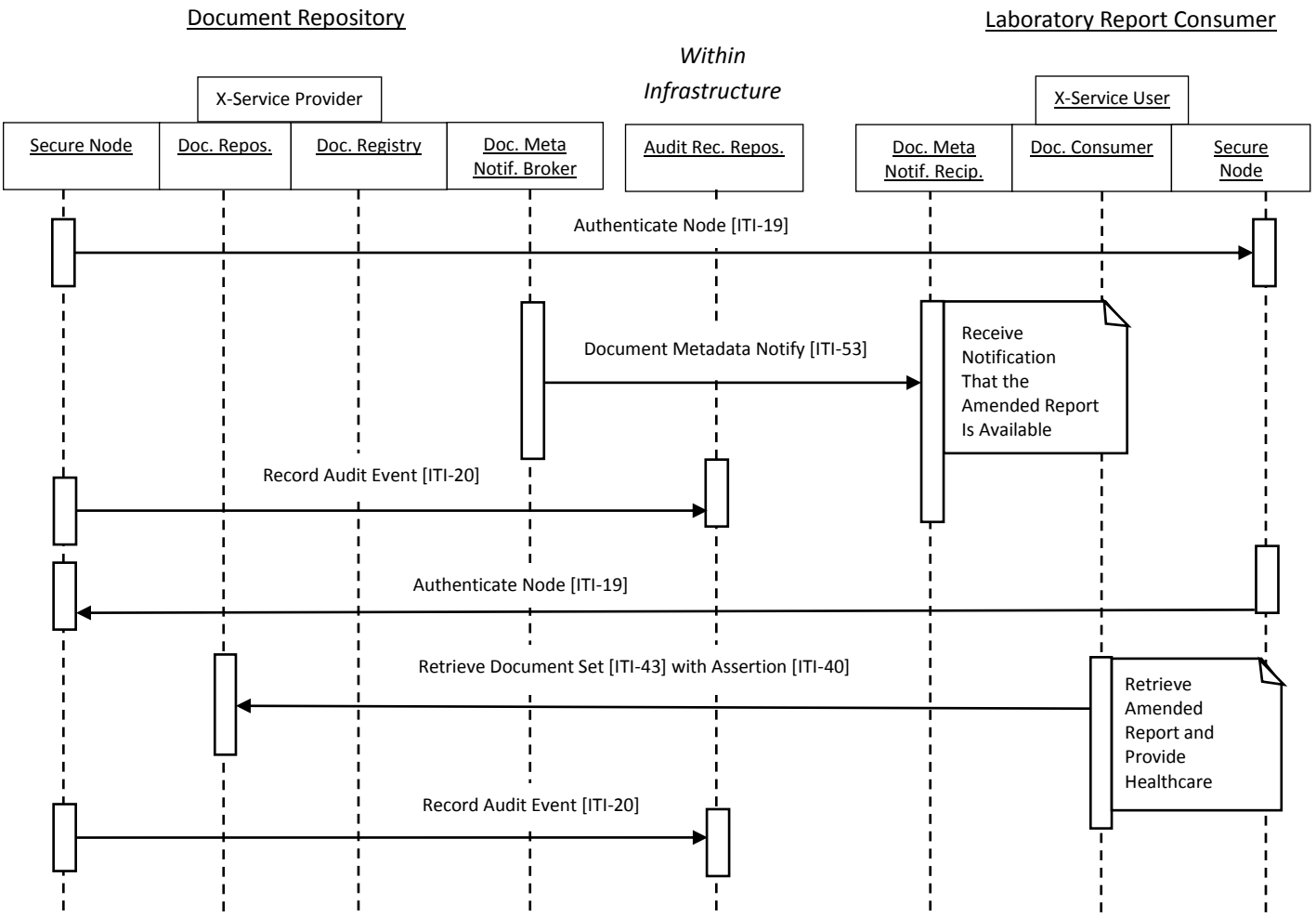

FIGURE 4.2.1-4 AMENDED REPORT WITH OPTIONAL NOTIFICATION SEQUENCE DIAGRAM (2)

5. CONFORMANCE REQUIREMENTS

5.1.1 Laboratory Report Creator Conformance

Systems may claim conformance to IS0003 *Saudi eHealth Core Interoperability Specification for Sharing Coded Laboratory Results* as a Laboratory Report Creator as follows:

"Sharing Code Laboratory Results as a Laboratory Report Creator Actor"

This requires:

- to support the Publish Document(s) Service by conforming to:
  - [CLR-001] - IHE Sharing Laboratory Reports (XD-LAB) Content Profile as a Content Creator Actor with the additional constraints specified in:
  - IS0105 *Saudi eHealth Laboratory Results and Orders Content Interoperability Specification* - Section 3.2
  - [CLR-002] - IHE Cross-Enterprise Document Sharing (XDS.b) Integration Profile as a Document Source Actor with the additional constraints specified in:
    - IS0102 *Saudi eHealth Document Sharing Interoperability Specification* – Section 3.2
  - [CLR-003] - IHE Audit Trail and Node Authentication (ATNA) Integration Profile as a Secure Node Actor with the additional constraints specified in:
    - IS0101 *Saudi eHealth Security and Privacy Interoperability Specification – Section* 3.2 and 3.3.2
  - [CLR-004] – IHE Consistent Time (CT) Integration Profile as a Time Client Actor with the additional constraints specified in:
    - IS0101 *Saudi eHealth Security and Privacy Interoperability Specification – Section* 3.1.2

5.1.2 Laboratory Report Consumer Conformance

Systems may claim conformance to the Sharing Coded Laboratory Results Interoperability Specification as a Laboratory Report Consumer as follows:

"Sharing Coded Laboratory Results as a Laboratory Report Consumer Actor"

This requires:

- To support the Query/Retrieve Document(s) Service by conforming to:
  - [CLR-005]- IHE Cross-Enterprise Document Sharing (XDS.b) Integration Profile as a Document Consumer Actor with the additional constraints specified in:
    - IS0102 *Saudi eHealth Document Sharing Interoperability Specification* – Section 3.3
  - [CLR-006] - IHE Sharing Laboratory Reports (XD-LAB) as an Document Consumer with the additional constraints specified in:

- IS0105 *Saudi eHealth Laboratory Results and Orders Content Interoperability Specification* - Section 3.2
- [CLR-007] - IHE Cross-Enterprise User Assertion (XUA) Integration Profile as a X-Service User Actor with the additional constraints specified in:
    - IS0101 *Saudi eHealth Security and Privacy Interoperability Specification – Section* 3.4.1
- [CLR-008] - IHE Audit Trail and Node Authentication (ATNA) Integration Profile as a Secure Node Actor with the additional constraints specified in:
    - IS0101 *Saudi eHealth Security and Privacy Interoperability Specification – Section* 3.2 and 3.3.2
- [CLR-009] – IHE Consistent Time (CT) Integration Profile as a Time Client Actor with the additional constraints specified in:
    - IS0101 *Saudi eHealth Security and Privacy Interoperability Specification – Section* 3.1.2

➢ To optionally support the Notification of Document Availability Service by conforming to:

- [CLR-010] – IHE Document Metadata Subscription (DSUB) Integration Profile as a Document Metadata Notification Recipient Actor with the additional constraints specified in:
    - IS0102 *Saudi eHealth Document Sharing Interoperability Specification* - Section 4.2
- [CLR-011] - IHE Audit Trail and Node Authentication (ATNA) Integration Profile as a Secure Node Actor with the additional constraints specified in:
    - IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.2 and 3.3.2
- [CLR-012] – IHE Consistent Time (CT) Integration Profile as a Time Client Actor with the additional constraints specified in:
    - IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.1.2

5.1.3 Document Repository Conformance

Systems may claim conformance to the Sharing Coded Laboratory Results Interoperability Specification as a Document Repository as follows:

"Sharing Coded Laboratory Results Reports as a Document Repository Actor"

This requires:

➢ To support the Publish Document(s) Service by conforming to::

- [CLR-013]- IHE Cross-Enterprise Document Sharing (XDS.b) Integration Profile as an Document Repository with the additional constraints specified in:

  - IS0102 *Saudi eHealth Document Sharing Interoperability Specification* – Section 3.4

- [CLR-014] - IHE Audit Trail and Node Authentication (ATNA) Integration Profile as a Secure Node Actor with the additional constraints specified in:
  - IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.2 and 3.3.1
- [CLR-015] – IHE Consistent Time (CT) Integration Profile as a Time Client Actor with the additional constraints specified in:
  - IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.1.2

➢ To support the Query/Retrieve Document(s) Service by conforming to:

- [CLR-016]- IHE Cross-Enterprise Document Sharing (XDS.b) Integration Profile as a Document Registry and Document Repository Actor with the additional constraints specified in:
  - IS0102 *Saudi eHealth Document Sharing Interoperability Specification* – Section 3.4
- [CLR-017] - IHE Cross-Enterprise User Assertion (XUA) Integration Profile as a X-Service Provider Actor with the additional constraints specified in:
  - IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.4.2
- [CLR-018] - IHE Audit Trail and Node Authentication (ATNA) Integration Profile as a Secure Node Actor with the additional constraints specified in:
  - IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.2 and 3.3.1
- [CLR-019] – IHE Consistent Time (CT) Integration Profile as a Time Client Actor with the additional constraints specified in:
  - IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.1.2

➢ To support the Notification of Document Availability Service by conforming to::

- [CLR-020] – IHE Document Metadata Subscription (DSUB) Integration Profile as a Document Metadata Notification Broker Actor with the additional constraints specified in:
  - IS0102 *Saudi eHealth Document Sharing Interoperability Specification* - Section 4.1
- [CLR-021] - IHE Audit Trail and Node Authentication (ATNA) Integration Profile as a Secure Node Actor with the additional constraints specified in:
  - IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.2 and 3.3.1

- [CLR-022] – IHE Consistent Time (CT) Integration Profile as a Time Client Actor with the additional constraints specified in:
    - IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.1.2

6. SAUDI EHEALTH CONSTRAINTS ON THE SHARING OF LABORATORY INFORMATION

This section defines required behavior rules for Use Case Actors defined in this Core Interoperability Specification.

The XDS Metadata associated with a Laboratory Results Report is defined by two parts: non-laboratory specific XDS Metadata and laboratory specific XDS Metadata.

- [CLR-040] The non-laboratory specific metadata **SHALL** conform to the requirements specified in the IS0102 *Saudi eHealth Document Sharing Interoperability Specification* - Section 4.2.1.

6.1 REQUIREMENTS FOR LABORATORY REPORT CREATOR

The following rules shall be supported for the conformance to the Laboratory Report Creator Actor:

- [CLR-050] The Laboratory Report Creator **SHALL** support the creation of shared Laboratory Results Reports along with XDS Metadata that shall include the following attributes:
  - [CLR-052] An eventCodeList Attribute **SHALL** be created and contain the "Laboratory Specialty code" with one of the coded value defined in the "KSA Laboratory Department" value set.
  - [CLR-069] A Document Title Attribute **SHALL** be created and contain the "Laboratory" display name with one of the "Print Name" values defined in the "Laboratory Department" value set.
- [CLR-053] A documentClass Attribute **SHALL** contain the coded value "REPORTS" as defined in the "KSA Class Code" value set.
- [CLR-054] A practiceSetting Attribute **SHALL** contain the "practiceSetting" coded value with a value of "Laboratory" as defined in the "KSA Organization Specialty" value set.
- [CLR-055] A referenceIdList Attribute (See IHE ITI TF-3 Section 4.2.3.2.28) **SHALL** contain the "KSA-Wide Filler Order Number" value issued by the system that placed the Order (e.g. local ordering system or Laboratory Order Creator). The structure of this KSA-Wide Filler Order Number is specified in the IS0105 *Saudi eHealth Laboratory Results and Orders Content Interoperability Specification*
  Note: When no Filler Order Number is available because the order was placed manually, no referenceIdList Attribute is needed.
  - [CLR-056] The typeCode Attribute **SHALL** contain one coded value for the requested Laboratory Test Code which is identical to the type code of the Laboratory Results Report document. The coded values are defined by the "KSA Laboratory Studies" value set.
- [CLR-063] The mimeType attribute shall contain one coded value which shall be "text/xml" as described in the "MIME Type" value set.

- [CLR-064] The formatCode attribute shall contain one coded value which shall be "urn:ihe:lab:xd-lab:2008" as described in the "KSA Format Code" value set.
- [CLR-058] All other XDS Metadata Attributes **SHALL** contain values as specified in the IS0102 *Saudi eHealth Document Sharing Interoperability Specification*.
- [CLR-059] All other XDS Metadata Attributes with corresponding data elements in the Laboratory Results Report document **SHALL** be consistent with the values in the Laboratory Results Report document.

- [CLR-060] When a Laboratory Report Creator creates a shared Laboratory Results Report, the shared Laboratory Results Report **SHALL** contain requested laboratory tests from a single laboratory specialty (laboratory department).

- [CLR-061] The Laboratory Report Creator **MAY** include a comment within the Laboratory Results Report (See IS0105 *Saudi eHealth Laboratory Results and Orders Content Interoperability Specification*) documenting additional notes for the Laboratory Report Consumer.

- [CLR-062] When partial results are shared, the Laboratory Report Creator **SHALL** include a comment documenting the reason for releasing the partial results within the Laboratory Results Report (IS0105 *Saudi eHealth Laboratory Results and Orders Content Interoperability Specification*).

- [CLR-065] The Laboratory Report Creator **SHALL** support the update (replace) of a shared Laboratory Results Report, by replacing a shared Laboratory Results Report with an updated Laboratory Results Report.
  - [CLR-066] The associated XDS Metadata shall include the attributes specified in [CLR-050] with identical values
  - [CLR-067] If a Laboratory Results Report is amended or corrected, the Laboratory Report Creator **SHALL** include a comment documenting the modifications and reason, within the Laboratory Results Report.

- [CLR-070] If a laboratory Results Report has been published and assigned to an incorrect patient, the Laboratory Report Creator (the XDS document source actor is grouped with an XDS Document Administrator Actor-See KXDS-072 in IS0102 *Saudi eHealth Document Sharing Interoperability Specification*) **SHALL** correct the error by using the [IHE XDS.b Supplement – Metadata Update: Delete Document Set Request ITI-62] to deprecate the original Report, and a new Report (and associated results, if any) shall be published and assigned to the correct patient. (See IS0102 *Saudi eHealth Document Sharing Interoperability Specification*).

- [CLR-075] The Laboratory Report Creator **MAY** request that a notification be sent to the Lab Report Consumer that ordered the laboratory test in order to provide timely notification. This notification request is performed by placing the address of the target Use Case Actor to be notified in the intendedRecipient XDS Metadata

Attribute of the Provide and Register Document Set Transaction – b (IHE ITI-41) used to send the Laboratory Results Report to the Document Repository. The format of the address shall meet the specifications of IS0102 *Saudi eHealth Document Sharing Interoperability Specification* (See Section 4).

Note: The Lab intendedRecipient can be determined by inspection of the submission set transaction that produced the original order.

6.2 REQUIREMENTS FOR LABORATORY REPORT CONSUMER

The following rules **SHALL** be supported for the conformance to the Laboratory Report Consumer Actor:

- [CLR-100] When retrieving a patient's Laboratory results report, it is the responsibility of the Laboratory Report Consumer to rely on the Metadata associated with the Laboratory results report to reconcile the KSA-Wide information with its local information and conventions. At a minimum, it **SHALL** reconcile:
  - [CLR-101] The KSA-Wide Health ID with the local Patient ID
  - [CLR-102] The Saudi eHealth Laboratory Test Codes with the corresponding local Laboratory Test Codes when available
  - [CLR-103] The KSA-Wide Filler Order ID with a corresponding local Filler Order ID when available
- [CLR-105] When retrieving a patient's Laboratory Results Report, the Report Consumer **SHALL** be able to receive them in such a way that the user on the receiving system is able to display and process its content.

- [CLR-110] The Laboratory Report Consumer **MAY** receive notifications (Lab Report Consumer Notification Option) triggered by the Laboratory Report Creator that created the Laboratory Results Report as a PARTIAL or FINAL report, or an updated laboratory results Report as a PARTIAL, AMENDED PARTIAL, FINAL, AMENDED or CORRECTED report. This notification is triggered by placing the address of the Laboratory Report Creator in the intendedRecipient XDS Metadata Attribute in the Provide and Register Document Set Transaction – b (IHE ITI-41) used to send the created or updated Report to the Document Repository. The format of the address **SHALL** meet the specifications in the IS0102 *Saudi eHealth Document Sharing Interoperability Specification.*

6.3 REQUIREMENTS FOR DOCUMENT REPOSITORY

The following rules **SHALL** be supported for the conformance to the Document Repository Actor:

- [CLR-080] When responding to a query, a Document Registry **SHALL** be able to support the return of several Reports for the same patient. Results filtering **SHALL** support the use of the KSA-Wide Order Placer ID stored in a referenceIdList slot (See IHE ITI TF-3 Section 4.2.3.2.28).

- [CLR-081] The following stored queries **SHALL** be supported by the XDS Document Registry:
    - FindDocuments
    - FindSubmissionSets
    - GetAll
    - GetDocuments
    - GetAssociations
    - GetDocumentsAndAssociations
    - GetSubmissionSets
    - GetSubmissionSetAndContents
    - GetRelatedDocuments

  Folder related transaction may be optionally supported:
    - FindFolders
    - GetFolders
    - GetFolderAndContents
    - GetFoldersForDocument

Note: Information about the allowed query parameters and examples of how those parameters are used may be found in IHE IT Infrastructure Technical Framework Volume 2a describing transaction ITI-18 Registry Stored Query.

- [CLR-122] The Document Repository **SHALL** support the [IHE XDS.b Supplement – Metadata Update: Delete Document Set Request ITI-62] to deprecate an active or deprecated document. This is used to correct an error when a document has been published and assigned to an incorrect patient (See IS0102 *Saudi eHealth Document Sharing Interoperability Specification* Section 4.2.8 for details).

7. REFERENCED DOCUMENTS AND STANDARDS

The following Saudi eHealth documents are referenced by this Interoperability Specification.

TABLE 7-1 INTERNAL REFERENCES

MOH DOCUMENT	DESCRIPTION
IS0001 Saudi eHealth Core Interoperability Specification for KSA-Wide Patient Demographic Query	Documents the specifications required to obtain patient IDs and demographic information for the patient. It is used to ensure that the nationwide Health ID is used to register laboratory orders for the correct patient.
IS0004 Saudi eHealth Core Interoperability Specification for Coded Laboratory Orders	Establishes the initiation of a coded laboratory order and making the order accessible via the SeHE platform. It addresses two types of laboratory orders: 1. Laboratory Orders that are created by primary care providers and Healthcare Organizations to perform laboratory tests on their patients. Laboratory test facilities (i.e. hospital, private and national laboratory centers) access the coded orders and fulfill the order. 2. Laboratory Orders created by laboratories that rely on other laboratories to perform tests that cannot be performed locally. For example, small Healthcare Organization laboratories typically only perform common tests and use a regional or national lab for advanced tests.
IS0101 Saudi eHealth Security and Privacy Interoperability Specification	Specifies the interoperability standards and profiles along with the Saudi specific constraints that are required to provide the technical security measures, data protection, and privacy management that will facilitate the implementation of the Saudi eHealth Policies for Health Information Exchange in the Kingdom of Saudi Arabia among communicating IT systems.
IS0102 Saudi eHealth Document Sharing Interoperability Specification	Forms a “container” for set of requirements that complements the IHE XDS Profile with Saudi eHealth specific constraints when it is called upon by any of the Core Interoperability Specifications.
IS0105 Saudi eHealth Laboratory Results and Orders Content Interoperability Specification	Specifies the clinical content for cross-enterprise sharing of laboratory orders and results based upon the IHE XD-LAB Content Profile. This interoperability specification focuses on the Saudi eHealth specific constraints.
IS0106 Saudi eHealth Clinical Documents Constrains Interoperability Specifications	Specifies common constraints for clinical documents such as data elements of document headers that are common across the Saudi eHealth Project.
IS0200 Saudi eHealth Terminology Repository.	Specifies the terminology concepts and associated coded value sets for data elements used throughout the Saudi eHealth Interoperability Specifications.
UC0003 Saudi eHealth Laboratory Interoperability Use Case	Provides the ability to share laboratory test results and to initiate a coded laboratory order, and making them accessible via the SeHE platform.

MOH DOCUMENT	DESCRIPTION
Saudi Health Information Exchange Policies	Contains the policies and supporting definitions that support the security and privacy aspects of the Saudi Health Information Exchange. The Saudi Health Information Exchange Policies apply to all individuals and organizations that have access to the Saudi Health Information Exchange managed health records, including those connected to the Saudi Health Information Exchange, their Business Associates, as well as any subcontractors of Business Associates. These policies apply to all information provided to or retrieved from the Saudi Health Information Exchange. .

TABLE 6-2 EXTERNAL REFERENCES

STANDARD	DESCRIPTION
Health Level Seven (HL7) Clinical Document Architecture Release 2 (CDA R2)	The HL7 Clinical Document Architecture (CDA) Release 2 is an XML-based document markup standard that specifies the structure and semantics of clinical documents for the purpose of exchange. CDA R2 further builds upon the Version 3.0 Reference Information Model (RIM) Standard. For more information see http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7
IHE IT Infrastructure (ITI) Technical Framework – Volume 1 (ITI TF-1) Integrations Profiles, Section 10 Cross-Enterprise Document Sharing (XDS.b)	The Cross-Enterprise Document Sharing (XDS.b) IHE Integration Profile facilitates the registration, distribution and access across health enterprises of patient electronic health records. This profile is focused on providing a standards-based specification for managing the sharing of documents between healthcare enterprises, ranging from a private physician office to a clinic to an acute care in-patient facility. May be obtained at http://www.ihe.net/Technical_Frameworks/#iti
IHE IT Infrastructure (ITI) Technical Framework – Volume 1 (ITI TF-1) Integration Profiles, Supplement -- XDS Metadata Update	This supplement updates the XDS and XDR profiles to add support for the updating and deleting of metadata. May be obtained at http://www.ihe.net/Technical_Frameworks/#iti
IHE IT Infrastructure (ITI) Technical Framework – Volume 3 (ITI TF-3) Integrations Profiles, Section 4 Metadata used in Document Sharing profiles	Describes the metadata that is used in IHE profiles designed for sharing documents (Document Sharing profiles). The Document Sharing profiles are implementing the Document Sharing concept outlined in the ITI whitepaper entitled Health Information Exchange: Enabling Document Sharing Using IHE Profiles May be obtained at http://www.ihe.net/Technical_Frameworks/#iti
IHE Laboratory (LAB) Technical Framework – Volume 1 (IHE LAB TF-1) Integrations Profiles, Section 9 – Sharing Laboratory Reports (XD-LAB)	The Sharing Laboratory Reports (XD-LAB) content profile defines the laboratory report as an electronic content to be shared in a community of healthcare settings and care providers. Such an electronic document contains the set of releasable results produced by a clinical laboratory or by a public health laboratory in fulfillment of one or more test Orders for a patient. The report is shared in a human-readable format. In addition, this electronic laboratory report contains test results in a machine-readable format, to facilitate the integration of these observations in the database of a consumer system. May be obtained at http://www.ihe.net/Technical_Frameworks/#laboratory

8. APPENDIX A – EXAMPLE MESSAGES/DOCUMENT

EXAMPLES WILL BE PROVIDED AS PART OF THE IS SPECIFICATION VALIDATION PROCESS. UNTIL THEN THIS SECTION WILL REMAIN BLANK.