

Kingdom of Saudi Arabia
Ministry of Health



National eHealth Strategy and Change Management Office
(SCMO)

Enabling Standards-Based eHealth Interoperability

IS0105

Saudi eHealth Laboratory Results and Orders Content
Interoperability Specification

Version 1.2
February 22, 2015

Document Control Number: IS0105 Saudi eHealth Laboratory Results and Orders Content
Interoperability Specification

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Document Revision History

Version	Date	Type of update	Prepared/Revised by
1.0	February 22, 2015	First release	eHealth - Strategy Management Office

1. INTRODUCTION

1.1 DOCUMENT PURPOSE

The purpose of this document is to specify the clinical content for cross-enterprise sharing of Laboratory Orders and results reports using IHE Laboratory Technical Framework Volume 1 (LABTF-1) Section 9 (XD-LAB). IHE LABTF-1 Section 9 (XD-LAB) supports the sharing of Laboratory Results Reports, and includes information on the original Laboratory Order. This interoperability specification focuses on the specification of a Laboratory Order document using concepts borrowed from IHE LABTF-1 Section 9 (XD-LAB) and the specification of the Saudi eHealth specific constraints for both the shared Laboratory Order document and the shared Laboratory Results Report. It is a specification that is referenced by the IS0004 *Saudi eHealth Core Interoperability Specification for Coded Laboratory Orders* and IS0003 *Saudi eHealth Core Interoperability Specification for Sharing Coded Laboratory Results*. It also aligns with the Saudi e-Government Interoperability Standards (YEFI) to expedite national adoption.

This document content is applicable to existing and new information systems, the systems which will be connected to the national Saudi eHealth Exchange (SeHE) System.

1.2 DESCRIPTION

This Interoperability Specification outlines the clinical content for cross-enterprise sharing of laboratory orders and results reports using IHE Laboratory Technical Framework Volume 3 (LABTF-3) Content Section 2 (XD-LAB). IHE LABTF-3 Content supports the sharing of Laboratory Results Reports, and includes information on the original laboratory order.

1.3 SCOPE

In Scope:

The scope of this document is the specification of the content structure for laboratory results and Laboratory Orders to be shared by Healthcare Organizations and regional laboratories in support of the *Laboratory Sharing Use Case*.

Out of Scope:

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.

The intent of this specification is to document the constraints that are in addition to those constraints already specified in the HL7 CDA R2 Standard or LAB TF-1 Section 9 (XD-LAB). Implements are expected to conform to the constraints of those specifications in addition to the constraints found herein.

1.4 METHODOLOGY

This Interoperability Specification has been developed with input from various Saudi stakeholders collected during several months through workshops and teleconferences.

This specification was developed in response to the *Laboratory Sharing Use Case*.

A 3-day face-to-face meeting at the Ministry of Health was held with the Stakeholders to review the Use Case, discuss workflows and review necessary data content, available standards and terminology which could be utilized for this Use Case. During the face to face meeting, numerous lab reports were analyzed to identify data element requirements for Laboratory Orders and results reports. Comparisons were made between these data elements and those found in International specifications, including HL7 Version 2 Standard, HL7 Version 3 Standard, and the IHE Laboratory Technical Framework.

Using this comparison work, constraints appropriate to each of these data elements were reviewed, and several standards and value sets were agreed upon at the face to face meeting. The remainder of the decisions were either deferred to the MOH Architecture team, or a general direction on future development was agreed upon. A focus group was formed from the face-to-face participants and other MOH selected experts. This focus group met approximately every two weeks between mid-April and the beginning of July. The focus group reviewed and approved the descriptions of each of the data elements, and upon the principles used for selecting the value sets used to record their content. An additional face-to-face workshop was held with all of the participants to verify the work of the focus group and to provide further guidance. The contents of *IS0105 Saudi eHealth Laboratory Results and Orders Content Interoperability Specification* is a culmination of this effort.

1.5 HOW TO READ THIS DOCUMENT

1.5.1 Where to Find Information

This document contains four normative sections, as well as informative appendices. 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: Establishes the Core Interoperability Requirements for the Interoperability Specification.

Section 3: Establishes the Content Requirements for the Interoperability Specification.

Section 4: Lists the Saudi eHealth reference documents, as well as the international standards which underpin the Interoperability Specification.

Appendix A: Illustrates sample documents.

1.5.2 Related Documents

A Saudi eHealth Interoperability Specification (IS) is targeted to be the sole entry point for the technology developers, the compliance assessment testing and certification, and the purchaser of IT systems in term of technical requirements that will ensure interoperability.

From this Interoperability Specification a number of related Interoperability Specifications are referenced:

- IS0101 *Saudi eHealth Security and Privacy Interoperability Specification*
- IS0003 *Saudi eHealth Core Interoperability Specification for Sharing Coded Laboratory Results*
- IS0004 *Saudi eHealth Core Interoperability Specification for Coded Laboratory Order*
- 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.

Further descriptions and references for the documents identified above are provided in Section 4 Referenced Documents and Standards.

Implementations are required to conform to the requirements within this Interoperability Specification; all Saudi eHealth referenced Interoperability Specifications and the standards and profiles they specify.

1.5.3 Document Conventions

1.5.3.1 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.

1.5.3.2 REQUIREMENTS LANGUAGE

Throughout this document the following conventions¹ are used to specify requirement levels:

¹ Definitions based upon RFC 2119

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.

1.6 DESIGN CONSTRAINTS AND ASSUMPTIONS

The Saudi eHealth Project for Laboratory Orders and Results is built upon the foundation of a number of existing HL7 Standards and IHE Technical Frameworks which already constrain the content of the Laboratory Orders and Laboratory Results Report. Additional general design constraints have been created as a result of requirements set forth by the project, and apply to all of the Saudi eHealth Content Interoperability Specifications. These design constraints are specified in IS0106 *Saudi eHealth Clinical Documents Constrains Interoperability Specifications* and referenced by this document. Section 3 of that specification defines additional constraints on datatypes that apply across data elements. This specification does not repeat the required constraints found in the all of the referenced specifications. It is assumed that the implementer of products that create Laboratory Orders and/or Laboratory Results Reports will take into account all of the constraints in this specification and the other referenced specifications.

As part of the Saudi eHealth Project, a Laboratory Order document definition has been created which specifies the requirements for the Laboratory Order content. The attributes and constraints that apply to the Laboratory Order document content are based entirely upon the foundation of the Saudi eHealth Laboratory Results Report, with some adjustments being made to take into account content which is specific to the Laboratory Order document.

2. CONFORMANCE REQUIREMENTS

Systems **SHALL NOT** claim conformance to this Interoperability Specification. Systems **SHALL** claim conformance to the requirements defined in the Core Interoperability Specifications that reference this document. The Core Interoperability Specifications deliver a user-relevant set of requirements corresponding to an Interoperability Use Case.

3. STRUCTURE OF LABORATORY ORDER AND RESULTS REPORTS

This section is an introduction to how the Laboratory Order document and Laboratory Results Reports are organized, including the necessary data elements identified by the stakeholders.

Both the Laboratory Order document and the Laboratory Results Report are to be expressed as a Clinical Document using the HL7 Clinical Document Architecture (CDA) Release 2 (R2).

An HL7 CDA R2 document consists of two parts: the header and the body. The header identifies and classifies the document and provides information on the authentication, the encounter, the patient, and the involved providers. The body contains the clinical order and/or results information, organized into sections whose narrative content can be encoded using standard vocabularies. An HL7 CDA R2 document consists of a single header and a body containing sections and content modules.

By defining the requirements for a specific HL7 CDA R2 document type, one has the ability to enable interoperability between systems. This is accomplished by providing a set of HL7 CDA R2 templates which constrain the CDA specification within a particular implementation and provide validating rule sets that check conformance to these constraints.

A number of the requirements that have been encountered in the development of this specification are held in common with other Saudi eHealth specifications. This includes the specification of such data types as person names, date/time and identifiers for Organizations and Professional Practitioners. These data type requirements are specified in the CDA Data Type Attributes and Constraints section in the *IS0106 Saudi eHealth Clinical Documents Constrains Interoperability Specifications*

[LABC-001] The HL7 CDA R2 constraints for data types and CDA structures found in *IS0106 Saudi eHealth Clinical Documents Constrains Interoperability Specifications* **SHALL** apply to all Laboratory Order and Result Report documents.

Requirements of the HL7 Clinical Document Architecture Release 2 (CDA R2) **SHALL** apply to all Laboratory Order and Result Report documents.

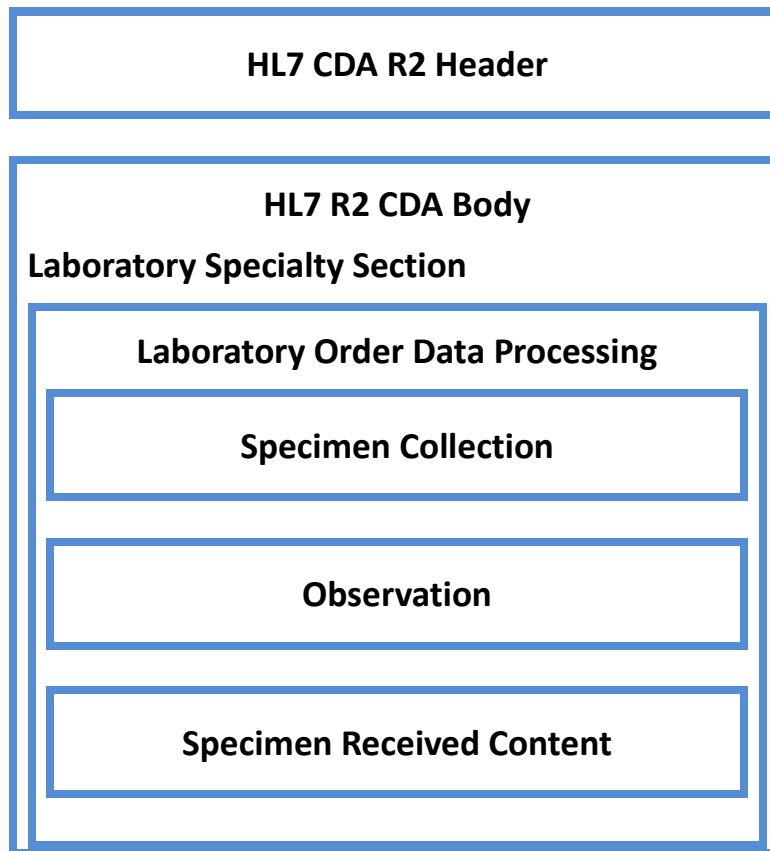
Constraints in IHE Laboratory Technical Framework Volume 1 (LABTF-1) Section 9 (XD-LAB) **SHALL** apply to all Laboratory Order and Result Report documents.

3.1 THE STRUCTURE OF A LABORATORY ORDER

For the purposes of exchanging Laboratory Orders and laboratory result reports within SeHE, a new HL7 CDA R2 document Template is defined for the SeHE Laboratory Order document, while the existing HL7 CDA R2 Template defined by IHE LABTF-3 Content , with additional constraints, is used for the SeHE Laboratory Results Report. The Laboratory Order document for Saudi eHealth borrows its content from IHE LABTF-1 Section 9 (XD-LAB) which already contains certain items about the Laboratory Order.

FIGURE 3.1-1 depicts the high level organization of the Laboratory Order document as it will be used by Saudi eHealth.

FIGURE 3.1-1 HL7 CDA R2 COMPONENTS FOR A LABORATORY ORDER DOCUMENT



By design, a SeHE Laboratory Order document can only contain Lab Order Requests (i.e. lab test, panel of tests, or test profile) from a single Laboratory Specialty (i.e., a laboratory department). Within the Laboratory Order Specialty Section there are four different types of content modules which are used to organize the Laboratory Order information, and have the same content modules as defined in LABTF-1 Section 9 (XD-LAB).

A **Laboratory Order Data Processing Content Module** exists for each Lab Order Request. All of the details associated with a given Lab Order Request are nested within a single Laboratory Order Data Processing Content Module. This includes information on the Specimen as well as

additional Laboratory Order information that the Ordering Healthcare Provider needs to relay. The Laboratory Order document may contain multiple Laboratory Order Data Processing Content Modules known as leaf sections.

A **Specimen Collection Content Module** exists for every Specimen associated with a Lab Order Request. It is nested within the Laboratory Order Data Processing leaf of the Laboratory Order document. Since the Specimen may be collected at the time the SeHE Laboratory Order is created, or by the Laboratory prior to claiming the SeHE Laboratory Order, there is no requirement that the Specimen information be available when the SeHE Laboratory Order is created. There may be multiple Specimens associated with a single Laboratory Order Request. This includes the case where there is a need to re-collect a specimen because of issues with the existing specimen already associated with the Laboratory Order.

A **Specimen Received Content Module** allows the Laboratory to document information about the receipt of the Specimen.

An **Observation Module** contains additional information about the Laboratory Order that is not already specified as coded information. In the case of the SeHE Laboratory Orders, there are a number of Saudi eHealth specific Laboratory Order data requirements which require the use of the **Observation Module**, such as Patient Age and Patient Nationality.

In addition to the Content Modules specified above, under some conditions the Laboratory Order document may be required to include a comment indicating why a Laboratory Order was not completed. To accomplish this, the Laboratory Order document will also support the **Annotation Comment Module**.

The sub-sections below provide information on the data elements present in the Laboratory Order document and which are called out in IS0004 *Saudi eHealth Core Interoperability Specification for Coded Laboratory Orders*.

TABLE 1.5.3-1 LABORATORY ORDER DOCUMENT ATTRIBUTES

ENTRY ATTRIBUTE	ATTRIBUTE DEFINITION	CDA LOCATION	SECTION REF.
Laboratory Order Document	Document describing a Laboratory Order	/ClinicalDocument [templateId/@root='2.16.840.1.113883.3.3731.1.105.1']	
Test Order Metadata	Metadata for the test order	.	3.1.1
Patient Demographics Information	Data elements that identify the patient.	./recordTarget/patientRole	3.1.2
Encounter Information	Information about the encounter in which the laboratory work was ordered.	./componentOf/encompassingEncounter	3.1.3
Laboratory Order Information	The Laboratory Order Information is a group of data elements which provides all of the detailed information for a single laboratory discipline order.	./section[templateId/@root='1.3.6.1.4.1.19376.1.3.3.2.1']	3.1.4
Specimen Collection Entry	The Specimen Collection entry is a group of data elements which describe the specimen, how it was collected and the methods/timing of its handling.	./section/entry/act/entryRelationship/procedure	3.1.5
Additional Order	Additional information may be provided with the	./section/entry/observation	3.1.6

ENTRY ATTRIBUTE	ATTRIBUTE DEFINITION	CDA LOCATION	SECTION REF.
Information Observation	Order in order to help with the laboratory analysis, or is required for SeHE Laboratory Orders.		
[LABC-003]	A Laboratory Order document SHALL contain Test Order Metadata		
[LABC-002]	A Laboratory Order document SHALL contain exactly one [1..1] Patient Demographics Information		
[LABC-004]	When an order is placed during a clinical encounter, the Laboratory Order document SHALL contain exactly one [1..1] Encounter Information		
[LABC-005]	A Laboratory Order document SHALL contain exactly one [1..1] Laboratory Order Information [templateId/@root = '1.3.6.1.4.1.19376.1.3.3.2.1']		
[LABC-006]	A Laboratory Order document MAY contain zero to many [0..n] Specimen Collection Entries		
[LABC-007]	A Laboratory Order document MAY contain zero to many [0..n] Additional Order Information Observations		
[LABC-008]	A Laboratory Order Data Processing Module MAY contain [0..n] Specimen Collection Module [templateId/@root = 1.3.6.1.4.1.19376.1.3.2].		
[LABC-009]	A Laboratory Order Data Processing Module SHALL contain [1..n] Observation Module(s) [templateId/@root = 1.3.6.1.4.1.19376.1.3.1.6].		
[LABC-010]	A Laboratory Order Data Processing Module MAY contain [0..n] Annotation Comment Module(s) [templateId/@root = 1.3.6.1.4.1.19376.1.5.3.1.4.2].		

3.1.1 Test Order Metadata

The Test Order Metadata are a group of data elements which relays information about metadata associated with the test order, including the identity of the ordering physician and the status and identifier of the order. This metadata are used when querying for Laboratory Order documents.

Test order information appears in the Header of the CDA Document, as shown in the table below.

TABLE 3.1.1-1 TEST ORDER METADATA

ENTRY ATTRIBUTE	ATTRIBUTE DEFINITION	CDA LOCATION	SECTION REF.
Laboratory Order Document	Document describing a Laboratory Order	/ClinicalDocument [templateId/@root='2.16.840.1.113883.3.3731.1.105.1']	
Laboratory Order Document Type	The code specifying the particular kind of Laboratory Order document.	./code	3.1.1.1
Laboratory Ordering Provider	The Ordering Provider is a set of attributes including the name, identifier and contact information for the ordering provider.	./author/assignedAuthor	3.1.1.2

ENTRY ATTRIBUTE	ATTRIBUTE DEFINITION	CDA LOCATION	SECTION REF.
Laboratory Ordering Facility	This field is the name and identifier for the facility in which the ordering provider works where applicable.	./author/assignedAuthor/representedOrganization	3.1.1.3
Laboratory Order Status	The Laboratory Order Status is a coded value used to manage the SeHE Laboratory Order workflow (see Section 3 of IS0004 Saudi eHealth Core Interoperability Specification for Coded Laboratory Orders).	./documentationOf/serviceEvent/lab:statusCode	3.1.1.4
Placer Order Number	This field is the order number assigned by the ordering provider or their information system when the order was placed.	./documentationOf/serviceEvent/id	3.1.1.5

3.1.1.1 LABORATORY DOCUMENT REPORT TYPE

See section 3 of IS0004 *Saudi eHealth Core Interoperability Specification for Coded Laboratory Orders*.

[LABC-012] The **Laboratory Order Document Type** SHALL be present and contain exactly one [1..1] code whose value is 57832-8 (Prescription for diagnostic or specialist care) from the LOINC code system.

3.1.1.2 LABORATORY ORDERING PROVIDER

Only Providers registered in the KSA Provider Registry may place SeHE Laboratory Orders.

[LABC-013] The **Laboratory Ordering Provider** SHOULD contain exactly one [1..1] id populated with a valid id from the "KSA Provider Registry".

3.1.1.3 LABORATORY ORDERING FACILITY

Only Providers registered in the KSA Provider Registry may place SeHE Laboratory Orders.

[LABC-014] The **Laboratory Ordering Facility** SHOULD contain exactly one [1..1] id populated with a valid id from the "KSA Provider Registry".

3.1.1.4 LABORATORY ORDER STATUS

[LABC-015] The **Laboratory Order Status** SHALL be present.

[LABC-016] The **Laboratory Order Status** SHALL contain exactly one [1..1]lab:statusCode/@code that comes from the "**KSA Order Status**" value set.

3.1.1.5 PLACER ORDER NUMBER

[LABC-017] The **Placer Order Number** SHALL contain exactly one [1..1] id

[LABC-096] The **Placer Order Number** SHALL contain exactly one [1..1]id/@root that is set to an OID assigned by SeHE at deployment time to each system ensuring a unique order identifier.

3.1.2 Patient Demographics Information

The Patient demographics are a group of data elements which identify the patient, and provide additional information about them (e.g., Gender) that may be used to help determine normal ranges for results. They are described in the table below. This information appears in the Laboratory Order document and in the Laboratory Results Report in the same fashion.

TABLE 3.1.2-1 PATIENT DEMOGRAPHICS ATTRIBUTES

ENTRY ATTRIBUTE	ATTRIBUTE DEFINITION	CDA LOCATION	SECTION REF.
Patient Demographics Information	Data elements that identify the patient.	/ClinicalDocument/recordTarget / patientRole	3.1.2
Patient Identifier	This is used to link results to the correct patient. This will be the KSA Patient Identifier.	./id	3.1.2.1
Patient Name	Patient name is used to help confirm the identity of the patient. Today this is typically stored using a Romanized representation of the name, regardless of the original name spelling.	./patient/name	3.1.2.2
Patient Gender	Gender is used both to facilitate interpretation of the result, and as an aid to determining unique patient identity.	./patient/administrativeGenderCode	3.1.2.3

3.1.2.1 PATIENT IDENTIFIER

A Laboratory Order or Laboratory Results Report cannot be uploaded to SeHE without a KSA Patient Identifier.

- [LABC-018] The **Patient Identifier** SHALL be present.
- [LABC-019] The **Patient Identifier** SHALL contain exactly one [1..1] **id/@extension** set to the KSA Patient Identifier.
- [LABC-020] The **Patient Identifier** SHALL contain exactly one [1..1] **id/@root** set to the KSA Patient Identifier Domain OID.

3.1.2.2 PATIENT NAME

- [LABC-021] The **Patient Name** SHALL be present.

3.1.2.3 PATIENT GENDER

- [LABC-022] The **Patient Gender** SHALL be present.
- [LABC-023] The **Patient Gender** SHALL contain exactly one [1..1] **administrativeGenderCode/@code** containing a value from the KSA Gender Value Set.

3.1.3 Encounter Information

Encounter information describes the encounter in which the order was placed, including the ordering provider, facility, and location. This information may be used to confirm order details, report results, or support additional communication as needed

TABLE 3.1.3-1 ENCOUNTER INFORMATION ATTRIBUTES

ENTRY ATTRIBUTE	ATTRIBUTE DEFINITION	CDA LOCATION	SECTION REF.
Encounter	Information about the encounter in which the laboratory work was ordered.	/ClinicalDocument/componentOf/encompassingEncounter	
Patient Encounter Identifier	The identifier of the patient encounter.	./id	3.1.3.1
Patient Facility	The facility where the patient is being treated is communicated on inpatient tests to facilitate communication, and to support secondary uses (e.g., infection control).	./location/healthCareFacility	3.1.3.2
Patient Facility Identifier	The identifier of the facility	./location/healthCareFacility/id	3.1.3.2
Patient Facility Organization Name	The name of the healthcare facility Organization	./location/healthCareFacility/serviceProviderOrganization	3.1.3.2
Patient Facility Location	The patient location within the facility where the patient is being treated is communicated on inpatient tests to facilitate communication, and to support secondary uses (e.g., infection control).	./location/healthCareFacility/location/name	3.1.3.3

3.1.3.1 PATIENT ENCOUNTER/VISIT IDENTIFIER

- [LABC-024] The **Patient EncounterIdentifier** SHALL contain exactly one [1..1] id
- [LABC-025] The **Patient EncounterIdentifier** SHALL contain exactly one [1..1]id/@extensioncontaining the local encounter identifier.
- [LABC-026] The **Patient EncounterIdentifier** SHALL contain exactly one [1..1]id/@root that is set to an OID assigned by SeHE at deployment time to each system ensuring a unique encounter identifier.

3.1.3.2 PATIENT FACILITY

- [LABC-027] The **Patient FacilityIdentifier** SHALL contain exactly one [1..1] id
- [LABC-028] The **Patient FacilityIdentifier** SHOULD contain exactly one [1..1] id/@extension set to the MOH assigned facility identifier.
- [LABC-029] The **Patient FacilityIdentifier** SHOULD contain exactly one [1..1] id/@root set to 2.16.840.1.113883.3.3731.1.2.2 for the OID representing 'MOH' as the issuing authority OID for facility identifiers.
- [LABC-030] The **Patient Facility Organization Name** SHALL contain exactly one [1..1] name.
The Patient Facility details should be consistent with the information returned by the Healthcare Provider Directory Actor described in the Saudi eHealth Interoperability Specification IS0002 *Saudi eHealth Core Interoperability Specification for KSA-Wide Healthcare Provider Directory Query*.
- [LABC-031] The **Patient Facility Organization Name** SHALL NOT be null.

3.1.3.3 PATIENT FACILITY LOCATION

For the purpose of SeHE Orders, typically only the Patient Facility location is necessary. However, the department/ward information can be provided as free text.

- [LABC-032] The **Patient Location** MAY be present.

3.1.4 Laboratory Order Information

This body section of the CDA document describes the test or tests that are being ordered. The Laboratory Order Information is used to encapsulate information on a SeHE Laboratory Order

The table below provides the section attributes for which unique constraints exist for all types of Laboratory Order documents.

TABLE 3.1.4-1 LABORATORY ORDER INFORMATION ATTRIBUTES

ENTRY ATTRIBUTE	ATTRIBUTE DEFINITION	CDA LOCATION	SECTION REF.
Laboratory Order Information	The Laboratory Order Information is a group of data element which provides all of the detailed information for a single laboratory discipline.	//section[templateId/@root='1.3.6.1.4.1.19376.1.3.3.2.1']	
Laboratory Specialty Code	This code specifies the laboratory specialty (discipline or department) for the laboratory work to be performed.	./code	3.1.4.1
Laboratory Order Data Processing Entry	The Laboratory Order Data Processing Entry is a group of data elements which provides all of the detailed information associated with a Laboratory Order Request	./entry[templateId/@root='2.16.840.1.113883.3.3731.1.105.3']/act[@moodCode='RQO']	3.1.4.2
Laboratory Order Identifier	This identifier represents the ID of the Laboratory Order or order group to be performed (Placer Order Number).	./id	3.1.4.3
Laboratory Test Requested Code	This code specifies the type of Laboratory work being requested.	./code	3.1.4.4
Laboratory Order Status	Orders can have some, but not all results available; be cancelled, completed, discontinued, replaced, or in-process. The order status is a code that indicates the current status of an order.	./statusCode	3.1.4.5
Laboratory Order Priority	This is a code identifying the priority in which the test result must be determined. For the purpose of SeHE Orders, the order priority may be Routine or ASAP. ASAP tests must be turned around as soon as possible in accordance with laboratory policies. Tests with routine priority are performed as planned.	./entry/act/priorityCode	3.1.4.6
Specimen Information	The Specimen Information is a group of data elements which describe the specimen, how it was collected and the methods/timing of its handling.	./entry/act/entryRelationship/procedure	3.1.5
Additional Order Information	Additional Information may be provided with the order in order to help with the laboratory analysis.	./entry/observation	3.1.6

3.1.4.1 LABORATORY SPECIALTY CODE

For the purposes of sharing, the SeHE Laboratory Orders and results reports must be for a single laboratory specialty.

- [LABC-033] The **Laboratory Specialty Section** SHALL contain exactly one [1..1] **Laboratory Specialty Code**.
- [LABC-034] The **Laboratory Specialty Code** SHALL be selected from the "KSA Laboratory Department" Value Set.

3.1.4.2 LABORATORY ORDER DATA PROCESSING ENTRY

The Laboratory Order data processing entry is patterned after the Laboratory Data Processing Entry in the IHE XD-LAB specification, but conveys information about the test requested in the order in the Laboratory Order document, rather than the test as performed that appears in the result report.

- [LABC-035] At least one [1..n] **Laboratory Order Data Processing Entry** SHALL appear in a **Laboratory Specialty Section**.
- [LABC-111] The **Laboratory Order Data Processing Entry** SHALL contain exactly one [1..1] templateId where @root='2.16.840.1.113883.3.3731.1.105.3'[LABC-036] The **Laboratory Order Data Processing Entry** SHALL contain exactly one [1..1] act/@moodCode which shall be RQO.

3.1.4.3 LABORATORY ORDER IDENTIFIER

- [LABC-037] The **Laboratory Order Identifier** SHALL contain exactly one [1..1] **id**
- [LABC-097] The **Laboratory Order Identifier id** SHALL be set to the local identifier used by the organization and SHALL include a unique organization root OID assigned by SeHE at deployment time to each system issuing order identifiers to ensure uniqueness.

3.1.4.4 LABORATORY TEST REQUESTED CODE

- [LABC-038] The **Laboratory Test Requested Code** SHALL contain exactly one [1..1] code
- [LABC-039] The **Laboratory Test Requested Code** SHALL be selected from the "KSA Laboratory Order and Results" Value Set.

3.1.4.5 LABORATORY ORDER PRIORITY

- [LABC-040] The **Laboratory Order Priority** SHALL contain exactly one [1..1] priorityCode .
- [LABC-041] The **Laboratory Order Priority** priorityCode SHALL be selected from the "KSA LAB Order Priority" Value Set.

3.1.4.6 LABORATORY ORDER STATUS

- [LABC-042] The **Laboratory Order Status** SHALL contain exactly one [1..1] statusCode and SHALL NOT be null.
- [LABC-043] The **Laboratory Order Status** statusCode SHALL be selected from the "KSA Order Status" Value Set.

3.1.5 Specimen Information

The Specimen Information is a group of data elements which describe the specimen, how it was collected and the methods/timing of its handling.

TABLE 3.1.5-1 SPECIMENT INFORMATION

ENTRY ATTRIBUTE	ATTRIBUTE DEFINITION	CDA LOCATION	SECTION REF.
Specimen Collection Entry	The Specimen Collection Entry is where the specimen information is placed. It is used to express information on the specimen collected as part of the laboratory test being performed.	//procedure[templateID/@root='1.3.6.1.4.1.19376.1.3.1.2']	
Specimen Identifier	The identifier unique to this specimen and which distinguishes it from all others within SeHE.	./participant[@typeCode='PRD']/participantRole/id	3.1.5.1
Specimen Type	This is a coded field which describes the type of specimen that is provided with the order (e.g., blood, bodily fluid, tissue sample, et cetera).	./participant[@typeCode='PRD']/participantRole[@classCode='SPEC']/playingEntity/code	3.1.5.2
Specimen Source	This text field describes the location on the patient from where the specimen came. It is applicable when the location can be one of various places on the body (e.g., for a wound swab). The specimen source may be implicit for some specimen types (e.g., nasal swab), and need not be applicable for all specimens (e.g., blood sample).	./targetSiteCode	3.1.5.3
Specimen Handling	The Specimen Handling indicates how the specimen needs to be handled.	./entryRelationship/observation[code/@code='01908']	3.1.5.4
Specimen Handling Comment	Free text indicating how the specimen needs to be handled.	./text	3.1.5.4
Specimen Risks	The Specimen Risks indicates the various precautions that should be taken with the specimen	./entryRelationship/observation	3.1.5.5
Specimen Risk Code	The code identifying the observation as a specimen risk	./code[@code='01903']	3.1.5.5
Specimen Risks Value	The value of the Specimen Risks using locally defined vocabulary.	./value	3.1.5.5
Specimen Risks Comment	Free text indicating risks associated with the specimen.	./text	3.1.5.5
<u>Specimen Collection Procedure</u>	<u>The procedure by which the specimen was collected.</u>	<u>./entryRelationship/procedure[templateID/@root='1.3.6.1.19376.1.3.1.2']</u>	<u>3.1.5.6</u>
Specimen Received Entry	The Specimen Received Entry is used to express information on the specimen received as part of the laboratory test performed.	./entryRelationship/act[templateID/@root='1.3.6.1.19376.1.3.1.3']	3.1.5.6
Specimen Time	The date and time when the specimen was received.	./effectivetime	0
Specimen Receiver	The name and identifier of the person receiving the specimen	./performer	3.1.5.8
Specimen Receipt Organization	Information about the Organization receiving the Specimen, including location information.	./performer/representedOrganization	3.1.5.9

3.1.5.1 SPECIMEN IDENTIFIER

- [LABC-044] The **Collection Entry** SHALL contain exactly one [1..1] **Specimen Identifier**
 [LABC-045] The **Specimen Identifier** SHOULD be set to the local identifier used by the organization and SHALL include a unique organization root OID assigned by MOH to the identifier issuing organization.

3.1.5.2 SPECIMEN TYPE

- [LABC-046] The **Collection** SHALL contain exactly one [1..1] **Specimen Type**
 [LABC-047] The **Specimen Type Code** SHALL be selected from the "Laboratory Specimen Type" Value Set

3.1.5.3 SPECIMEN SOURCE

- [LABC-048] The **Specimen Source** SHALL contain zero or one [0..1] targetSiteCode
 [LABC-049] The **targetSiteCode** SHALL contain a value from the "Specimen Source" Value Set.

3.1.5.4 SPECIMEN HANDLING

- [LABC-050] The **Specimen Handling** SHALL contain exactly one [1..1] **Specimen Handling Comment**

3.1.5.5 SPECIMEN RISKS

- [LABC-098] The **Specimen Risk Entry** SHALL contain exactly one [1..1] **Specimen Risk Code**.
 [LABC-099] The **Specimen Risk Code** SHALL contain exactly one [1..1] code/@code='01903'
 [LABC-100] The **Specimen Risk Code** SHALL contain exactly one [1..1] code/@codeSystem='2.16.840.1.113883.3.3731.1.105.2'
 [LABC-051] The **Specimen Entry** MAY contain zero or more [0..*] **Specimen Risks**.
 [LABC-052] The **Specimen Risks** MAY contain zero or one [0..1] **Specimen Risk Value**.
 [LABC-101] The **Specimen Risk Value** SHALL contain a value from the "Specimen Risk" Value Set.
 [LABC-053] The **Specimen Risk** MAY contain exactly one [1..1] **Specimen Risk Comment**.

3.1.5.6 SPECIMEN RECEIVED ENTRY

- [LABC-054] The **Specimen Received Entry** MAY appear at most one [0..1] in a **Specimen Collection Entry**.
 [LABC-133] The **Specimen Collection Procedure** SHALL have at most one [0..1] methodCode element specifying the **Specimen Collection Method**.
 [LABC-136] The **Specimen Collection Method** SHALL contain a value from the "Specimen Collection Method" Value Set.

3.1.5.7 SPECIMEN TIME

There are no additional constraints on the **Specimen Time**.

3.1.5.8 SPECIMEN RECEIVER

There are no additional constraints on the *Specimen Receiver*.

3.1.5.9 SPECIMEN RECEIPT ORGANIZATION

There are no additional constraints on the *Specimen Receipt Organization*.

3.1.6 Additional Order Information

Additional Information may be provided with the order in order to help with the laboratory analysis. This group of data elements was specifically identified by the Saudi eHealth Project. The Laboratory Observation Entry is used to express observations about the Laboratory Order being performed.

TABLE 3.1.6-1 ADDITIONAL ORDER INFORMATION ATTRIBUTES

ENTRY ATTRIBUTE	ATTRIBUTE DEFINITION	CDA LOCATION	SECTION REF.
Additional Order Information	Additional information may be provided with the Order in order to help with the laboratory analysis, or is required for SeHE Laboratory Orders.	observation	
Preliminary/Admission Diagnosis	This is the working diagnosis associated with the patient. It may be relevant to the interpretation of the test results. This diagnosis is not necessarily a confirmed or final diagnosis.	observation [code/@code='148006']/value	3.1.6.1
Pre-existing Conditions	This is a previously confirmed diagnosis, symptom or other condition associated with the patient. This information may also be relevant to interpretation of the test results.	observation [code/@code='102478008']/value	3.1.6.2
Other Risk Factors	There are a variety of other risk factors that may be relevant to interpretation of test results including possible exposures, other existing symptoms, etc.	observation [code/@code='80943009']/value	3.1.6.3
Patient Age	Patient date of birth is frequently what is transmitted in electronic messages, but what is reported on the lab report (and in various order forms) is the patient age. The age is important in interpretation of the result (e.g., to determine appropriate normal values). The birth date is often used to help confirm the identity of the patient, and carries with it both age and identity information.	observation [code/@code='424144002']/value	3.1.6.4
Patient Height	Patient height may be necessary to transmit on a Laboratory Order for appropriate interpretation of laboratory results.	observation [code/@code='50373000']/value	3.1.6.5
Patient Weight	Patient weight may be necessary to transmit on a Laboratory Order for appropriate interpretation of laboratory results.	observation [code/@code='363808001']/value	3.1.6.6
Patient is Fasting	This value should be sent when fasting status is important to understand for interpretation of laboratory results, and the patient is fasting.	observation [code/@code='16985007']	3.1.6.7

ENTRY ATTRIBUTE	ATTRIBUTE DEFINITION	CDA LOCATION	SECTION REF.
Patient is not Fasting	This value should be sent when fasting status is important to understand for interpretation of laboratory results, and the patient is NOT fasting.	observation [code/@code='440565004']	3.1.6.8
Patient Nationality	This field contains a code that identifies the nation or national grouping to which the person belongs.	observation [code/@code='365456003']/ value	3.1.6.9
Other Relevant Observations	Other observations can be included in a Laboratory Order.	observation	3.1.6.10

3.1.6.1 PRELIMINARY/ADMISSION DIAGNOSIS

- [LABC-055] The **Preliminary/Admission Diagnosis Code** SHALL be “148006” (preliminary diagnosis) from the SNOMED CT coding system (2.16.840.1.113883.6.96) and **SHALL NOT** be null.
- [LABC-130] The **Preliminary/Admission Diagnosis** Code MAY be present.
- [LABC-056] The **Preliminary/Admission Diagnosis Value** SHALL be selected from the **"KSA Problem" Value Set** and **SHALL NOT** be null.

3.1.6.2 PRE-EXISTING CONDITIONS

- [LABC-057] The **Pre-existing Conditions Code** SHALL be “102478008” (preexisting condition) from the SNOMED CT coding system (2.16.840.1.113883.6.96) and **SHALL NOT** be null.
- [LABC-140] The **Pre-existing Conditions** Code MAY be present
- [LABC-058] The **Pre-existing Conditions value** SHALL be selected from the **"KSA Problem" Value Set** and **SHALL NOT** be null.

3.1.6.3 OTHER RISK FACTORS

- [LABC-059] The **Other Risk Factors Code** SHALL be “80943009” (risk factors) from the SNOMED CT coding system (2.16.840.1.113883.6.96) and **SHALL NOT** be null.
- [LABC-141] The **Other Risk Factors Code** MAY be present
- [LABC-060] The **Other Risk Factors Value** SHOULD be selected from the **"KSA Problem" Value Set** and **SHALL NOT** be null.

3.1.6.4 PATIENT AGE

For the purposes of the SeHE Laboratory Orders, the Patient's Age shall be provided with the Laboratory Order. Because Laboratory Orders cannot be shared without a known patient identity, patient age will always be known.

- [LABC-061] **Patient Age code** SHALL be 424144002 (Current Chronological Age) from the SNOMED CT coding system (2.16.840.1.113883.6.96) and **SHALL NOT** be null.
- [LABC-062] The **Patient Age value** SHALL contain exactly one [1..1] value and **SHALL** contain exactly one [1..1] unit and **SHALL NOT** be null.
- [LABC-063] The **Patient Age value** SHALL contain exactly one [1..1] unit selected from the **"KSA Time Units" Value Set**.

3.1.6.5 PATIENT HEIGHT

- [LABC-102] **Patient Height code** SHALL be 50373000(Body Height Measure) from the SNOMED CT coding system (2.16.840.1.113883.6.96) and **SHALL NOT** be null.
- [LABC-142] **Patient Height code** *MAY be present*
- [LABC-103] The **Patient Height value** SHALL contain exactly one [1..1] value and **SHALL** contain exactly one [1..1] unit and **SHALL NOT** be null.
- [LABC-104] The **Patient Height value** SHALL contain exactly one [1..1] unit selected from the **"KSA Height Units" Value Set**.

3.1.6.6 PATIENT WEIGHT

- [LABC-105] **Patient Weight code** SHALL be 363808001 (Body Weight Measure) from the SNOMED CT coding system (2.16.840.1.113883.6.96) and **SHALL NOT** be null.
- [LABC-143] **Patient Weight code** *MAY be present*
- [LABC-106] The **Patient Weight value** SHALL contain exactly one [1..1] value and **SHALL** contain exactly one [1..1] unit and **SHALL NOT** be null.
- [LABC-107] The **Patient Weight value** SHALL contain exactly one [1..1] unit selected from the **"KSA Weight Units" Value Set**.

3.1.6.7 PATIENT IS FASTING

- [LABC-131] The **Patient Fasting Code** *MAY* be present.
- [LABC-110] At most one of **Patient is Fasting or Patient is NOT Fasting code** SHALL be present. Neither need be present.
- [LABC-108] **Patient Fasting code** SHALL be 16985007 (Fasting) from the SNOMED CT coding system (2.16.840.1.113883.6.96) and **SHALL NOT** be null.

3.1.6.8 PATIENT IS NOT FASTING

- [LABC-109] **Patient is NOT Fasting code** SHALL be 440565004 (Nonfasting) from the SNOMED CT coding system (2.16.840.1.113883.6.96) and **SHALL NOT** be null.

3.1.6.9 PATIENT NATIONALITY

For the purpose of the SeHE Laboratory Orders the Nationality **SHALL** be provided with the Laboratory Order.

- [LABC-132] There **SHALL** be one **Patient Nationality** code
- [LABC-064] The **Patient Nationality code** **SHALL** be "365456003" (ethnicity / related nationality data - finding) from the SNOMED CT coding system (2.16.840.1.113883.6.96) and **SHALL NOT** be null.
- [LABC-065] The **Patient Nationality value** **SHALL** be selected from the **"Nationality Value Set"** **SHALL NOT** be null.

3.1.6.10 OTHER RELEVANT OBSERVATIONS

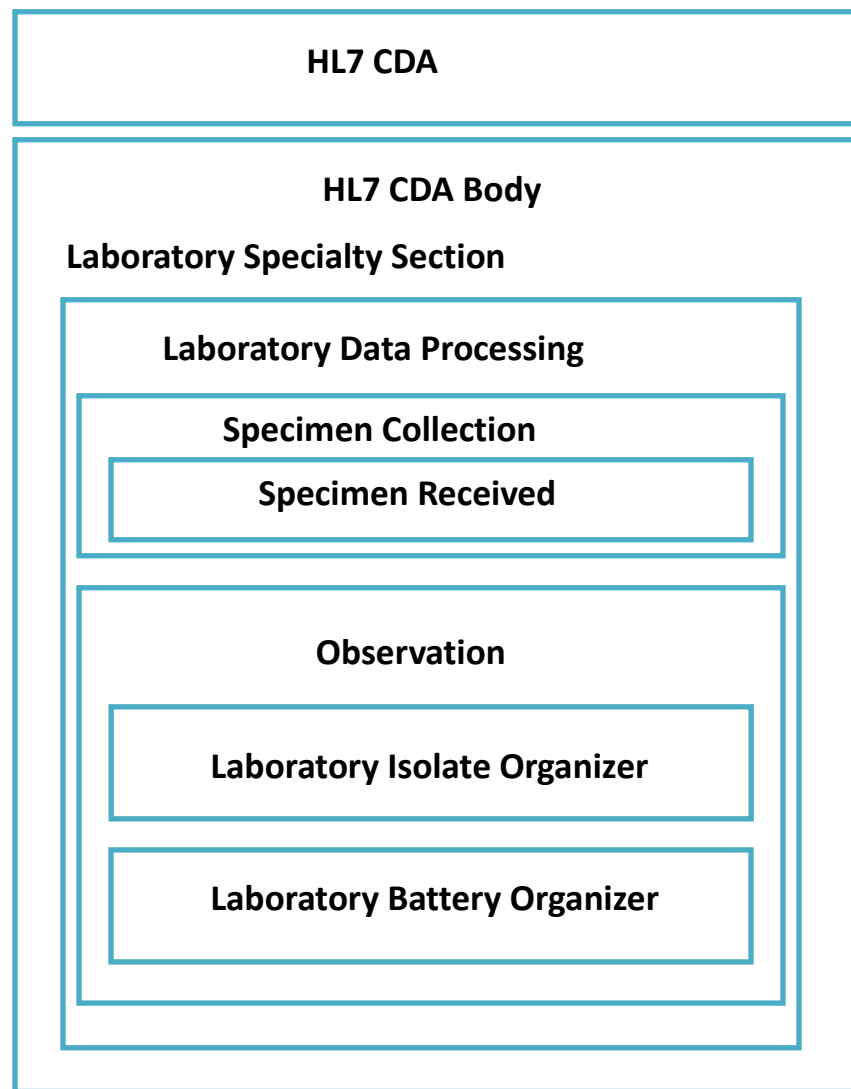
Other relevant observations can be encoded in the order using SNOMED CT to identify the observable value.

- [LABC-066] The **Observation code** SHALL come from the SNOMED CT coding system (2.16.840.1.113883.6.96).
- [LABC-067] The **Observation value** SHALL NOT be null.

3.2 THE STRUCTURE OF A LABORATORY RESULTS REPORT

This section describes the specific constraints across all Saudi eHealth Cross Enterprise Shared Laboratory Results Reports. The Laboratory Results Report for Saudi eHealth is a further constrained use of LABTF-1 Section 9 (XD-LAB) *Profile*. FIGURE 3.2-1 depicts the high level organization of the Laboratory Results Report as it will be used by the Saudi eHealth Project.

FIGURE 3.2-1 HL7 CDA R2 COMPONENTS FOR A LABORATORY RESULTS REPORT



The Laboratory Results Report includes much of the same information found in the Laboratory Order described previously and data elements describing the results of the tests performed. Many

of the same Section and Content Modules from the Laboratory Order document appear in the Laboratory Results Report. However, some of the constraints are different. It should also be noted that the Laboratory Test Requested may not be identical to the Laboratory Test Performed, and that this will be reflected in the Laboratory Results Report.

At the time a Laboratory claims the SeHE Laboratory Order, a Specimen must be present in the Laboratory Order. Typically this will be updated in the SeHE Laboratory Order and can be reflected in the SeHE Laboratory Results Report. However, it is not required that the information on the Specimen be specified in the SeHE Laboratory Results Report, as this information may only be maintained locally to the Laboratory.

The following Content Modules only pertain to the Laboratory Results Report:

A Laboratory Data Processing Module exists for all Laboratory Result Reports. It is a group of data elements which provides all of the detailed information associated with a Laboratory Order Request.

A **Laboratory Isolate Organizer Content Module** exists only for microbiology specimen studies with isolates discovered on the specimen, and is used to provide results on the isolate. Multiple microorganisms can be associated with a specimen.

[LABC-135] When an observation within the Laboratory Isolate Organizer Content Module describes the susceptibility of the organism to a drug, it shall use values from the "**HL7 Observation Interpretation Susceptibility**" Value Set.

A **Laboratory Battery Organizer Content Module** is only relevant for group Laboratory Observations where a report is being created based upon a battery of tests (e.g., a Lipid Panel or CBC).

The following sub-sections provide a high-level overview these data elements which are called out in IS0003 *Saudi eHealth Core Interoperability Specification for Sharing Coded Laboratory Results*.

TABLE 3.1.6-1 LABORATORY RESULTS REPORT ATTRIBUTES

ENTRY ATTRIBUTE	ATTRIBUTE DEFINITION	CDA LOCATION	SECTION REF.
Laboratory Results Report Document	Document describing a Laboratory Results Report	/ClinicalDocument[templateId/@root='1.3.6.1.4.1.19376.1.3.3']	
Laboratory Results Metadata	Metadata for the Laboratory Results	.	3.2.1
Patient Demographics Information	Data elements that identify the patient.	./recordTarget/patientRole	3.1.2
Encounter Information	Information about the encounter in which the laboratory work was ordered.	./componentOf/encompassingEncounter	3.1.2
Laboratory Results Information	The Laboratory Specialty Section is a group of data element which provides all of the detailed Laboratory Order information for a single laboratory discipline.	./section[templateId/@root='1.3.6.1.4.1.19376.1.3.3.2.1']	0

[LABC-068] **The Laboratory Report SHALL** contain exactly one [1..1] templateId where @root = 1.3.6.1.4.1.19376.1.3.3

- [LABC-120] The **Laboratory Report** SHALL contain **Laboratory Results Metadata**.
- [LABC-121] The **Laboratory Report** SHALL contain **Patient Demographics Information**. The patient demographics shall be consistent with the patient demographics provided by the Client Registry in IS0001 *Saudi eHealth Core Interoperability Specification for KSA-Wide Patient Demographic Query*.
- [LABC-122] The **Laboratory Report** MAY contain **Encounter Information**.
- [LABC-123] The **Laboratory Report** SHALL contain **Laboratory Results Information**.

The sub-sections below describe the data elements identified by the laboratory focus group in more detail

3.2.1 Laboratory Result Metadata

The Laboratory Result Metadata are a group of data elements which relays information about metadata associated with the test result, including the identity of the processing laboratory and the status and identifier of the result. These metadata are used when querying for Laboratory Result Reports.

TABLE 3.2.1-1 LABORATORY RESULT METADATA

ENTRY ATTRIBUTE	ATTRIBUTE DEFINITION	CDA LOCATION	SECTION REF.
Laboratory Result Report	Document describing a Laboratory Results Report	/ClinicalDocument/	3.2.1
Laboratory Result Report Type	The code specifying the particular kind of Laboratory Result Report.	./code	3.2.1.1
Laboratory Result Report Author	This is a set of attributes including the name, identifier and contact information for the Laboratory Result Report Author.	./author/assignedAuthor	3.2.1.2
Laboratory Result Report Author Organization	The name and identifier of the laboratory that produced the Laboratory Result Report.	./author/assignedAuthor/representedOrganization	3.2.1.3
Laboratory Result Status	The status of the Laboratory Result Report.	./documentationOf/serviceEvent/lab:statusCode	3.2.1.4
Order Identifiers	The placer and filler order identifiers.	./inFulfillmentOf/order/id	3.2.1.5

3.2.1.1 LABORATORY RESULT REPORT TYPE

- [LABC-075] The **Laboratory Result Report Type** SHALL be present and contain exactly one [1..1] code from LOINC describing the type of laboratory report contained in the result report.

3.2.1.2 LABORATORY REPORT AUTHOR

- [LABC-076] The **Laboratory Report Author** SHALL be present.

3.2.1.3 LABORATORY REPORT AUTHOR ORGANIZATION

Only Laboratories registered in the KSA Laboratory Registry may fill SeHE Laboratory Orders.

- [LABC-077] The **Laboratory Report Author Organization** SHALL be present per the requirements of [KHPD-038] specified in IS0002 *Saudi eHealth Core*

Interoperability Specification for KSA-Wide Healthcare Provider Directory Query.

- [LABC-078] The **Laboratory Report Author Organization** id **SHALL** be present and be populated with the author organization's KSA Organization Identifier per the requirements of [KHPD-019] specified in IS0002 *Saudi eHealth Core Interoperability Specification for KSA-Wide Healthcare Provider Directory Query*.

3.2.1.4 LABORATORY RESULT STATUS

- [LABC-079] The **Laboratory Result Status** **SHALL** be present.

3.2.1.5 ORDER IDENTIFIERS

As part of the Laboratory Order and Laboratory Results Report linkage, both the Filler Order Number and the Placer Order Number are provided in the Laboratory Results Report order identifiers fields.

- [LABC-081] Two **Order Identifier** **SHOULD** be present representing the placer order identifier (The unique identifier assigned by the Ordering Healthcare Provider or their information system when the order was placed) and filler order identifier (The unique identifier assigned by the laboratory or their information system when the tests were performed (e.g. accession number)). These identifiers **SHALL** include a unique organization root OID assigned by SeHE at deployment time to each system issuing order identifiers to ensure uniqueness.

```
<inFulfillmentOf>
<order>
<id extension="PLACER" root="2.36.3.24.36.2"/>
<id extension="FILLER" root="2.36.3.24.36.3"/>
</order>
</inFulfillmentOf>
```

3.2.2 Laboratory Results Information

This body section of the Laboratory Results Report describes the test or tests that are being reported upon. The Laboratory Specialty Section is used to encapsulate information on a SeHE Laboratory Results Report. These are described in further detail in the table below.

TABLE 3.2.2-1 LABORATORY SPECIALTY SECTION ATTRIBUTES

ENTRY ATTRIBUTE	ATTRIBUTE DEFINITION	CDA LOCATION	SECTION REF.
Laboratory Specialty Section	The Laboratory Specialty Section is a group of data element which provides the detailed laboratory result information for a single laboratory discipline.	//section[templateId/@root='1.3.6.1.4.1.19376.1.3.3.2.1']	
Laboratory Specialty Code	This code specifies the laboratory specialty (discipline or department) for the laboratory work to be performed.	./code	3.1.4.1
Laboratory Order Data Processing Entry	This is a set of attributes including the name, identifier and contact information for the Laboratory Result Report Author	//entry[templateId/@root='2.16.840.1.113883.3.3731.1.105.3	3.1.4.2

ENTRY ATTRIBUTE	ATTRIBUTE DEFINITION	CDA LOCATION	SECTION REF.
		/act[@moodCode='RQO']	
Laboratory Data Processing Entry	The Laboratory Data Processing Entry is used to describe the test performed.	./entry[templateId/@root='1.3.6.1.4.1.19376.1.3.1']/act[@moodCode='EVN']	3.2.2.1
Laboratory Test Performed Code	This is the test that was performed, and may be different from, or more specific than, the test that was ordered	./code	3.2.2.2
Specimen Information	The Specimen Information is a group of data elements which describe the specimen, how it was collected and the methods/timing of its handling.	./entry/act/entryRelationship/procedure	3.1.5
Additional Order Information	Additional Information that may have been provided with the order to help with the laboratory analysis.	./entry/observation	3.1.6
Laboratory Test Result	The Lab Test Result is a group of data elements which describe the Results of the Laboratory Analysis.	./entry/observation[templateId/@root='1.3.6.1.4.1.19376.1.3.1.6']	3.2.3

3.2.2.1 LABORATORY DATA PROCESSING ENTRY

The Laboratory Data Processing Entry in a Laboratory Results Report is similar to the Laboratory Order Data Processing Entry in the Laboratory Order, but has different content requirements. There are no KSA specific Laboratory Data Processing Entry requirements.

3.2.2.2 LABORATORY TEST PERFORMED CODE

The test performed may have been changed from the Laboratory Test Requested Code because the lab specified more details about the specific method used to perform the test (and updated the Order to a more specific code), the order was changed by the lab or provider based on medical practice, or because the lab was unable to perform the requested test and performed as best as it was able to complete the order (based on medical practice).

- [LABC-082] The **Laboratory Test Performed Code** SHALL contain exactly one [1..1] code
 [LABC-083] The **Laboratory Test Performed Code** SHALL be selected from the "KSA Laboratory Orders and Results" Value Set.

3.2.3 Lab Test Result

The Lab Test Result is a group of data elements which describe the Results of the Laboratory Analysis. For the purposes of sharing, the SeHE Laboratory Results Report **SHALL** be for a single laboratory specialty.

- [LABC-134] For the purposes of sharing, the SeHE Laboratory Orders and results reports **SHALL** be for a single laboratory specialty.

TABLE 3.2.3-1 LABORATORY OBSERVATION ENTRY ATTRIBUTES UNIQUE TO LABORATORY RESULTS REPORT

ENTRY ATTRIBUTE	ATTRIBUTE DEFINITION	CDA LOCATION	SECTION REF.
Laboratory Observation Entry	The Laboratory Observation Entry is used to express observations test results	observation[templateId/@root='1.3.6.1.4.1.19376.1.3.1.6']	

ENTRY ATTRIBUTE	ATTRIBUTE DEFINITION	CDA LOCATION	SECTION REF.
Observation Code	This is a code and a description of the test result. The code may be the same value as the test ordered and/or test performed, or it can be different when the result is for a panel or profile (e.g., one result of several produced by a single test).	./code	3.2.3.1
Observation Value	The observation value represents a quantitative or qualitative measurement result.	./value	3.2.3.2
Interpretation Code	The interpretation of the result will follow one of several forms, depending on the type of test.	./interpretationCode	3.2.3.3
Test Performer	This indicates the person or device that performed the test.	./performer	3.2.3.4
Test Performer Identifier	The identifier of the person performing the test.	./assignedEntity/id	
Test Performer Name	The name of the person performing the test.	./assignedEntity/assignedPerson/name	
Test Performer Organization	The name and identifier of the organization represented by the individual performing the test (the performing laboratory).	./assignedEntity/representedOrganization	
Test Verifier	Information about the individual verifying the test result.	./participant[@typeCode='AUTHEN']	3.2.3.5
Test Verifier Identifier	The identifier for the individual reviewing or verifying the test result.	./participantRole/id	
Test Verifier Name	The name for the individual verifying the test result.	./participantRole/playingEntity/name	

3.2.3.1 OBSERVATION CODE

[LABC-084] The **Observation Code** SHALL be present and SHALL come from the "KSA Laboratory Orders and Results" Value Set.

Note: The KSA Laboratory Result Value Set uses codes from LOINC. The Point of Service may add local codes or request codes from LOINC during the onboarding process to support coding of results that are not supported by LOINC.

3.2.3.2 OBSERVATION VALUE

A Quantitative Measurement will provide a value as a real number, and have associated units. A Qualitative Result can include either coded or non-coded (narrative or textual) results of the test performed.

[LABC-085] The **Observation Value** SHALL be present.

3.2.3.3 INTERPRETATION CODE

A test for presence will have an interpretation that the substance is present (POS), absent (NEG), or cannot be determined (IND). A quantitative result may indicate that the result is low, high or within the normal range, or above or below alert limits, or off-scale (high or low).

[LABC-086] The **Interpretation Code** MAY be present.

[LABC-087] The ***Interpretation Code*** SHALL come from the HL7 Version 3 Code System Observation Interpretation.

3.2.3.4 TEST PERFORMER

[LABC-088] The **Test Performer** SHALL be present.

3.2.3.5 TEST VERIFIER

Note that not all tests need to be verified. For example, some labs do not verify negative results for certain tests due to medical practice.

[LABC-089] The **Test Verifier** SHALL be present when known.

3.2.4 Laboratory Battery Organizer Entry

The Laboratory Battery Organizer Entry is used to group Laboratory Observations for a battery of tests. The SeHE Laboratory Results Report has no additional constraints.

3.2.5 Microbiology Results

The Microbiology Results is a group of data elements which describe the additional Results that are relevant for a Microbiology Laboratory Test.

TABLE 3.2.5-1 MICROBIOLOGY RESULTS METADATA

ENTRY ATTRIBUTE	ATTRIBUTE DEFINITION	CDA LOCATION	SECTION REF.
Microbiology Observation	Entry specifying information on the microbiology specimen study with isolates discovered on the specimen by the Laboratory	./entryRelationship/organizer[templateId/@root='1.3.6.1.4.1.19376.1.3.1.5']	
Isolate	The isolate being examined for susceptibility.	./specimen/specimenRole/	
Organism	The kind the organism found.	specimenPlayingEntity/code	3.2.5.1
Susceptibility Observation	A susceptibility observation on the isolate.	./observation [code/@code='29576-6']	3.2.5.2
Antimicrobial Medication	This is the type of antibiotic or antifungal agent that is being used to test the organism sensitivity. (Microbiology ONLY)	./methodCode/code	3.2.5.3
Susceptibility Interpretation	This is an interpretation of the susceptibility, indicates whether the organism is susceptible or not to the treatment agent.	./interpretationCode	3.2.5.4

3.2.5.1 ORGANISM

[LABC-090] The **Organism** SHALL be present.

[LABC-091] The **Organism** SHALL be coded using the "KSA Micro-organism" Value Set.

3.2.5.2 SUSCEPTIBILITY OBSERVATION

A susceptibility observation is identified by the presence of the LOINC Code for susceptibility test in an observation or organizer.

[LABC-092] A **Susceptibility Observation** SHALL be identified using 29576-6 from the LOINC coding system.

3.2.5.3 ANTIMICROBIAL MEDICATION

- [LABC-093] The ***Antimicrobial Medication*** SHALL be present.
- [LABC-094] The ***Antimicrobial Medication*** SHALL be coded using the "KSA Antimicrobial" Value Set.

3.2.5.4 SUSCEPTIBILITY INTERPRETATION

The susceptibility is reported as the interpretation of the test result.

- [LABC-095] The ***Susceptibility Interpretation*** SHOULD be present.
- [LABC-144] The ***Susceptibility Interpretation*** SHALL be coded using the HL7 ObservationInterpretationSusceptibility coding system.

4. REFERENCED DOCUMENTS AND STANDARDS

The following documents and standards were referenced during the development of this Interoperability Specification.

TABLE 4-1 INTERNAL REFERENCES

DOCUMENT OR STANDARD	DESCRIPTION
IS0003 Saudi eHealth Core Interoperability Specification for Sharing Coded Laboratory Results	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. Note that policies may require that patient information be pseudonymized for use in MOH business applications.
IS0004 Saudi eHealth Core Interoperability Specification for Coded Laboratory Order	Establishes the initiation of a coded laboratory order and making the order accessible via the SeHE platform. It addresses two types of laboratory orders: 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. 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.
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 specific data elements used for the laboratory domain.
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.
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 4-2 EXTERNAL REFERENCES

DOCUMENT OR STANDARD	DESCRIPTION
Health Level Seven (HL7) Clinical Document Architecture Release 2 (CDA R2)	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 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
IHE Laboratory Technical Framework Volume 3 (LABTF-3) Content	This Content Integration Profile describes a clinical laboratory report as an electronic document to be published towards a document sharing resource such as an Electronic Health Record (EHR) or a Personal Health Record (PHR) shared by a community of care providers, using one of the document sharing profiles defined in ITI-TF. Such an electronic document contains the set of releasable results produced by a clinical laboratory in fulfillment of one or more test Orders for a patient. The report is both human-readable and importable in the consumer systems so as to consolidate their patient medical records. The scope of this profile covers all laboratory specialties except anatomic pathology. May be obtained at http://www.ihe.net/Technical_Frameworks/#laboratory .
IHE IT Infrastructure (ITI) Technical Framework – Volume1 (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

5. APPENDIX A – SAMPLE LABORATORY DOCUMENTS

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

5.1 SAMPLE LABORATORY ORDER

This example provides a sample laboratory Order.

5.2 SAMPLE LABORATORY RESULTS

This example provides a sample laboratory results.

5.3 SAMPLE AGE OBSERVATION

FIGURE 5.3-1 AGE OBSERVATION EXAMPLE

```
<observation classCode="OBS" moodCode="EVN">
<templateId root="2.16.840.1.113883.10.20.22.4.31"/>
<!-- Age observation template -->
<code code="397659008" codeSystem="2.16.840.1.113883.6.96"
displayName="Age"/>
<statusCode code="completed"/>
<value xsi:type="PQ" value="57" unit="a"/>
</observation>
```