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HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Release 1, DSTU Release 2 - US Realm

Draft Standard for Trial Use

September 2015

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SNOMED CT	International Healthcare Terminology Standards Developing Organization (IHTSDO) http://www.ihtsdo.org/snomed-ct/get-snomed-ct or info@ihtsdo.org
Logical Observation Identifiers Names & Codes (LOINC)	Regenstrief Institute
International Classification of Diseases (ICD) codes	World Health Organization (WHO)
NUCC Health Care Provider Taxonomy code set	American Medical Association. Please see 222.nucc.org. AMA licensing contact: 312-464-5022 (AMA IP services)

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Questions or comments regarding this document should be directed to the Orders and Observations Workgroup **(ord@lists.hl7.org)**

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1 INTRODUCTION

The *HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Release 1 DSTU Release 2 – US Realm* is the result of collaborative efforts between HL7 and the Office of the National Coordinator (ONC) Standards and Interoperability (S&I) Framework Laboratory Results Interface (LRI) Initiative. By consensus the HL7 V2.5.1 ORU^R01 Message was selected as the basis to define the profile constraints expressed in this guide to meet the requirements of the transmission of laboratory results. The Standards and Interoperability (S&I) Framework's Laboratory Result Interface Use Case was leveraged and revised, where agreed upon by the working group, to provide the Use Case content, diagrams and foundation for this Implementation Guide. Capabilities made available through HL7 V2.8.2 were selectively applied to further support the use case requirements.

1.1 Purpose

The Laboratory Results Interface Initiative identifies the requirements, defines specifications and standards to provide implementation guidance for electronic reporting of laboratory test results to ambulatory care providers in the US Realm. The scope of the Laboratory Results Interface Use Case includes requirements to enable the incorporation of clinical laboratory test results into an Electronic Health Record System (EHR-S) as standardized structured data using the defined inter-organizational laboratory transaction. The Use Case requirements are directed at laboratory test results reporting between a Laboratory Information System (LIS) and an ambulatory EHR-S in different organizational entities, e.g., different corporate structure, ownership or governance.

1.2 Audience

This guide is designed for use by analysts and developers who require guidance on data elements and components of the *HL7 Version 2.5.1 ORU Unsolicited Observation Message* relative to the Laboratory Results Interface (LRI) initiative. Users of this guide must be familiar with the details of HL7 message construction and processing starting with HL7 Version 2.5.1 through HL7 Version 2.8.2. This guide is not intended to be a tutorial on that subject.

1.2.1 RELEVANT LABORATORY IMPLEMENTATION GUIDES

There are multiple Implementation Guides that have been developed under the Office of the National Coordinator's (ONC) Standards and Interoperability Framework Initiative (S&I Framework). These guides have been created using the same processes, are stylistically similar and designed to work together. The set includes but is not limited to:

- This publication; the *HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Results Interface Implementation Guide, Release 1 DSTU Release 2 – US Realm* (LRI) in support of the lab result reporting to ambulatory care providers;
- *HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Orders from EHR, Release 1 DSTU Release 1 – US Realm,* (LOI)[1] in support of the lab test ordering from ambulatory care providers and to provide data needed for reporting to Public Health;

[1] Note that HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Orders from EHR, Release 1 DSTU Release 2 - US Realm is expected to be published in Q3 2015 and contains significant improvements; it is recommended implementers refer to that guide when available as it has been harmonized with this release of the LRI.

- *HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Test Compendium Framework, Release 2, DSTU Release 2* (eDOS) in support of the transmission of a laboratory's directory of services to an EHR using HL7 Master File messages;
- *HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 2 (US Realm)* (ELR) as a constrained profile of the LRI Implementation Guide;
- *HL7 Version 2 Implementation Guide: Laboratory Value Set Companion Guide, Release 1-US Realm, September 2015,* providing cross-IG value set definitions and harmonized requirements.

The EHR System and LIS will conform to this family of Implementation Guides; a laboratory that receives an order conforming to the LOI IG should be capable of reporting results with a conformant LRI message.

1.2.2 REQUISITE KNOWLEDGE

- HL7 V2.5.1 through V2.8.2 Messaging (www.HL7.org)
- SNOMED CT (http://www.ihtsdo.org/snomed-ct)
- LOINC (http://loinc.org)
- UCUM (http://unitsofmeasure.org)
- OIDS (http://www.hl7.org/oid)
- Standards and Interoperability Laboratory Results Interface Use Case, *Laboratory Results Reporting to Primary Care Providers (in an Ambulatory Setting) v1.0*

1.3 Organization of this Guide

1.3.1 CONVENTIONS

This guide adheres to the following conventions:

- The guide is constructed assuming the implementer has access to the 2.5.1 through 2.8.2 versions of the HL7 Standard. Where there are variations from 2.5.1 the version that is used is referenced. Although some information from the standard is included in this Implementation Guide, much information from the standard has not been repeated here.
- The rules outlined in *HL7 2.7.1*, *Chapter 2B*, *Section 2B5*, *Conformance Using Message Profiles*, were used to document the use case for, and constraints applied to, the messages described in this guide.
- Data types have been described separately from the fields that use the data types.
- No conformance information is provided for optional message elements ("O") or unsupported ("X"). This includes cardinality, value sets and descriptive information. Implementers who want to use optional message elements should refer to the base HL7 V2.5.1 Standard to determine how these optional message elements will be used. Conformance information is provided when a conditional predicate resolves to an "R" or "RE" on either the "a" or "b" part of the expression, regardless of the opposite value, e.g., C(R/O).
- This guide uses "X" as a conformance usage indicator very sparingly. Where the underlying standard indicates the segments/field/component is present for backwards compatibility ("B") or withdrawn ("W") an "X" will be used. A small number of other message elements that are clearly

out of scope for the use case have been given the "X" usage. All other message elements have either been further constrained to R/RE/C(a/b) or have been left as "O" to enable trading partners to explore additional capabilities. Labs would have insufficient information to populate these fields and if they would it would cause potential confusion with information present on the provider's system. Note that without a clearly agreed to complementary profile between trading partners, a Lab does not have to send any elements marked as an "O", nor does a receiver of a lab result have to process any elements marked as an "O". Neither trading partners can mandate the other to accept any such complementary profiles to enable basic laboratory results interfacing "out-of-the-box". The recipient should not return an error unless there is a clinical or regulatory impact as a result of discarding optional information.

1.3.2 MESSAGE ELEMENT ATTRIBUTES

The following table describes the various attributes used by this guide to document data type attribute tables, message structure attribute tables and segment attribute tables. Not all attributes apply to all attribute tables.

TABLE 1-1. MESSAGE ELEMENT ATTRIBUTES

Attribute	Definition
SEQ	Sequence of the elements as numbered in the HL7 message element. The SEQ attribute applies to the data type attribute table and the segment attribute table.
Component Name	Short name for the component.
Segment	Three-character code for the segment and the abstract syntax (e.g., the square and curly braces). [XXX] Optional and singular { XXX } Required and may repeat XXX Required and singular [{ XXX }] Optional and may repeat Note that for segment groups there is no segment code present, but the square and curly braces will still be present. The Segment attribute only applies to the Message attribute table.
DT	Data type used by this profile for HL7 element. The data type attribute applies to data type attribute tables and segment attribute tables.
Usage	Usage of the message element for this profile. Indicates whether the message element (segment, segment group, field, component, or subcomponent) is R, RE, O, X or C(a/b) in the corresponding message element. Usage applies to the message attribute table, data type attribute table and the segment attribute table, see Section 1.3.4 Usage Conformance Rules.
Cardinality	Minimum and maximum number of times the element may appear. [0..0] Element never present. [0..1] Element may be omitted and can have, at most, one occurrence. [1..1] Element must have exactly one occurrence. [0..n] Element may be omitted or may repeat up to *n* times. [1..n] Element must appear at least once, and may repeat up to *n* times. [0..*]Element may be omitted or repeat an unlimited number of times. [1..*] Element must appear at least once, and may repeat unlimited number of times. [m..n] Element must appear at least *m*, and at most, *n* times. Cardinality applies only to message attribute tables and segment attribute tables.

TABLE 1-1. MESSAGE ELEMENT ATTRIBUTES	
Attribute	Definition
Value Set	The set of coded values to be used with the field. The value set attribute applies only to the data type attribute tables and the segment attribute tables. The value set may equate with an entire code system part of a code system, or codes drawn from multiple code systems.
Name	HL7 descriptor of the message element. Name applies to the message attribute table, data type attribute table and the segment attribute table.
Description/Comments	Context and usage for the element. Description/Comments applies to the message attribute table, data type attribute table and the segment attribute table.

1.3.3 KEYWORDS

The key words "**MUST**", "**MUST NOT**", "**REQUIRED**", "**SHALL**", "**SHALL NOT**", "**SHOULD**", "**SHOULD NOT**", "**RECOMMENDED**", "**MAY**", and "**OPTIONAL**" in this document are to be interpreted as described in RFC 2119[2]. The following definitions are excerpted from the RFC:

> **"MUST"** or the terms "**REQUIRED**" or "**SHALL**", mean that the definition is an absolute requirement of the specification.
>
> **"MUST NOT"** or the phrase "**SHALL NOT**", mean that the definition is an absolute prohibition of the specification.
>
> **"SHOULD"** or the adjective "**RECOMMENDED**", mean that there may exist valid reasons in particular circumstances to ignore a particular item, but the full implications must be understood and carefully weighed before choosing a different course.
>
> **"SHOULD NOT"** or the phrase "**NOT RECOMMENDED**" mean that there may exist valid reasons in particular circumstances when the particular behavior is acceptable or even useful, but the full implications should be understood and the case carefully weighed before implementing any behavior described with this label.
>
> **"MAY"** or the adjective "**OPTIONAL**", mean that an item is truly optional. One software supplier may choose to include the item to enable certain capabilities while another software supplier may omit the same item. In either case, the communication partner cannot be expected to either provide it (sender) or process it (receiver) without clear and voluntary agreement between the partners.

Any further constraining of optional segments/fields/components must be agreed to by both parties and cannot be made pre-requisite to sending/receiving messages to achieve the basic interoperability described in this guide. Therefore, a sender shall not require a receiver to accept any segments/fields/components marked as optional to successfully send a message. Likewise, a receiver shall not require a sender to send any segment/fields/components marked as optional to successfully receive such a message.

1.3.4 USAGE CONFORMANCE RULES

The following text is pre-adopted from the HL7 V2.7.1 Conformance (Chapter 2B, 2.B.7.5). Please refer to the base standard documentation for a full explanation of conformance concepts. Usage is

[2] http://www.ietf.org/rfc/rfc2119.txt

described here as it introduces the revised approach to conditional element handling; upon successful ballot and publication this material will be replaced with a reference to the normative documentation.

---------- *start citation*---------

2.B.7.5 Usage

Message content is governed by the cardinality specification associated (explicitly or implicitly) with each element of an HL7 message. Usage rules govern the expected behavior of the sending application and receiving application with respect to the element. The usage codes expand/clarify the optionality codes defined in the HL7 standard. Usage codes are employed in a message profile to constrain the use of elements defined in the standard. The usage code definitions are given from a sender and receiver perspective and specify implementation and operational requirements.

The standard allows broad flexibility for the message structures that HL7 applications must be able to receive without failing. But while the standard allows that messages may be missing data elements or may contain extra data elements, it should not be inferred from this requirement that such messages are conformant. In fact, the usage codes specified in a message profile place strict conformance requirements on the behavior of the application.

Definition of Conditional Usage

The conditional usage is defined as follows:

C(a/b) - “a” and “b” in the expression are placeholders for usage codes representing the true (“a”) predicate outcome and the false (“b”) predicate outcome of the condition. The condition is expressed by a conditional predicate associated with the element (“See section 2.b.7.9, "Condition predicate"). “a” and “b” shall be one of “R”, “RE”, “O” and/or “X”. The values of “a” and “b” can be the same.

The example C(R/RE) is interpreted as follows. If the condition predicate associated with the element is true then the usage for the element is R-Required. If the condition predicate associated with the element is false then the usage for the element is RE-Required but may be empty.

There are cases where it is appropriate to value “a” and “b” the same. For example, the base standard defines the usage of an element as “C” and the condition predicate is dependent on the presence or non-presence of another element. The profile may constrain the element that the condition is dependent on to X; in such a case the condition should always evaluate to false. Therefore, the condition is profiled to C(X/X) since the desired effect is for the element to be not supported. Note it is not appropriate to profile the element to X since this breaks the rules of allowable usage profiling (see table HL7 Optionality and Conformance Usage).

Usage Rules for a Sending Application

Optionality /Usage Indicator	Description	Implementation Requirement	Operational Requirement
R	Required	The application shall implement “R” elements.	The application shall populate “R” elements with a non-empty value.
RE	Required but may be empty	The application shall implement “RE” elements.	The application shall populate “RE” elements with a non-empty value if there is relevant data. The term “relevant” has a confounding interpretation in

Optionality /Usage Indicator	Description	Implementation Requirement	Operational Requirement
			this definition[3].
C(a/b)	Conditional	An element with a conditional usage code has an associated condition predicate (See section 2.B.7.9, "Condition predicate" that determines the operational requirements (usage code) of the element. If the condition predicate associated with the element is true, follow the rules for ***a*** which shall be one of "R", "RE", "O" or X": If the condition predicate associated with the element is false, follow the rules for ***b*** which shall be one of "R", "RE", "O" or X". ***a*** and ***b*** can be valued the same.	
X	Not supported	The application (or as configured) shall not implement "X" elements.	The application shall not populate "X" elements.
O	Optional	None. The usage indicator for this element has not yet been defined. For an implementation profile all optional elements must be profiled to R, RE, C(a/b), or X.	Not Applicable.

Usage Rules for a Receiving Application

Optionality /Usage Indicator	Description	Implementation Requirement	Operational Requirement
R	Required	The application shall implement "R" elements.	The receiving application shall process (save/print/archive/etc.) the information conveyed by a required element. A receiving application shall raise an exception due to the absence of a required element. A receiving application shall not raise an error due to the presence of a required element,
RE	Required but may be empty	The application shall implement "RE" elements.	The receiving application shall process (save/print/archive/etc.) the information conveyed by a required but may be empty element. The receiving application shall process the message if the element is omitted (that is, an exception shall not be raised because the element is missing).
C(a/b)	Conditional	The usage code has an associated condition predicate true (See section 2.B.7.9, "Condition predicate"). If the condition predicate associated with the element is true, follow the rules for ***a*** which shall one of "R", "RE", "O" or X": If the condition predicate associated with the element is false, follow the rules for ***b*** which shall one of "R", "RE", "O" or X". ***a*** and ***b*** can be the same.	

[3] There are multiple interpretations of "RE" when a value is known. One is "the capability must always be supported and a value is sent if known", the other is "the capability must always be supported and a value may or may not be sent even when known based on a condition external to the profile specification. The condition may be noted in the profile but cannot be processed automatically". This is what can be interpreted from the "relevant" part of the definition. Regardless of the interpretation the "RE" usage code, a set of test circumstances can be developed to sufficiently test the "RE" element. See the "Conformity Assessment of Conformance Constructs" section for more details.

Optionality /Usage Indicator	Description	Implementation Requirement	Operational Requirement
X	Not supported	The application (or configured) shall not implement "X" elements.	None, if the element is not sent. If the element is sent the receiving application may process the message, shall ignore the element, and may raise an exception. The receiving application shall not process (save/print/archive/etc.) the information conveyed by a not-supported element.
O	Optional	None. The usage indicator for this element has not yet been defined. For an implementation profile all optional elements must be profiled to R, RE, C(a/b), or X.	None.

--------- *end citation* ---------

1.4 Key Technical Decisions

One of the primary features of this Implementation Guide is its focus on key points of broad interoperability. The HL7 Implementation Guides in Sections 1.2.1 Relevant Laboratory Implementation Guides and 1.5 Referenced Profiles - Antecedents have informed the content of this specification as analysis indicated that none of the candidate guides could satisfy the use case requirements without some adjustment. This guide is the result of combining the best practices from the current body of work while making further adjustment to meet the needs of ambulatory reporting and preparing for increased consistency of lab result reporting across care settings.

1.4.1 PROFILE AND COMPONENT ARCHITECTURE

This guide extensively uses constrainable profiles to define a minimum set of requirements to enable the successful exchange of laboratory orders. The main objective is to ensure that an EHR-S and an LIS can exchange laboratory orders with minimum if any modifications from one combination to another combination of software, while maintaining flexibility to enable software developers to provide more capabilities using the same core message definitions. Section 3 Conformance to this Guide describes the mandatory and optional profiles to be used, as well as the rules on further constraining the guide.

1.4.2 USE OF ISO OBJECT IDENTIFIER (OID)

OIDs, or Object Identifiers, provide a strong identifier that uniquely identifies the object in question and is global in scope. Examples of information that OIDs can identify are items about patients, orders, providers and organizations. This means the identifier includes enough information to remain unique when taken out of the context within which the identifier was created. The ISO OID specification (ISO/IEC 8824:1990(E)) is the globally accepted technology for this purpose and is recommended as the means to satisfy the requirement for a universally unique identifier.

This guide defines a Globally Unique Component (LRI_GU_Component) (see Section 3.3.1) that prescribes the use of an ISO Object Identifier (OID) for a specific set of fields.

HL7 has developed an Implementation Guide for the use of OIDs, "HL7 Implementation Guidance for Unique Object Identifiers (OIDs), Release 1"[4], which provides guidance on how organizations can use and manage OIDs.

1.4.3 USE OF VOCABULARY STANDARDS

This guide calls for specific vocabulary standards for the exchange of laboratory information such as LOINC and SNOMED CT. Standard vocabularies, particularly coded laboratory results, enable automated decision support for patient healthcare, as well as for public health surveillance of populations. Terminology is updated periodically and it is best practice to use the most current version of the coding system.

1.4.4 FIELD LENGTH AND TRUNCATION

This guide is silent as to the field length definition conventions, lengths, and truncation rules and directs the reader to HL7 Version 2.7.1, Chapter 2 Control for informative guidance.

The sole exception to truncation guidance in the base specification is that OBX-5 (Observation Value) **SHALL NOT** be truncated.

1.4.5 CONFORMANCE STATEMENTS

This guide includes conformance statements to clarify the requirements that will be tested to determine conformance to this guide and the profiles it defines; note the following conventions are followed in this guide:

- Conformance IDs have the naming convention of AAA-NN where AAA is the mnemonic of the IG in which the statement is made, e.g., LRI-, LOI-, and NN is a number to uniquely identify the statement from all others.
- Conformance IDs are not reused, and they do not imply any sequence.

1.4.6 DATA TYPE FLAVORS

A particular data type can be referenced by different fields. Depending on the field's purpose, specific use of the associated data type may vary. For example, an observation identifier in the OBX segment using CWE may not require the same components or value sets as an HL7 error code in the ERR segment. Rather than providing data type specifications in-line with each field within a segment, we opted to create data type flavors. Whenever a data type is used differently depending on the field referencing it, a new flavor is created, e.g., TS_0 (where TS is the data type and _0 indicates the flavor). Different fields can reference the same data type flavor. This approach will reduce the number of data type definitions, thus reducing the size of this Implementation Guide.

1.4.7 VALUE SETS

This Implementation Guide provides detailed value set definitions for each component and field where they are used in a separate publication. See Section 3 Conformance to this Guide for the minimum version associated with the release of this document.

This separation is intended to set a minimum release version to be associated with the release of a Laboratory US Realm Implementation Guide such that the value sets can be versioned over time

[4] The current version of the HL7 Implementation Guidance for Unique Object Identifiers (OIDs), Release 1 is available from HL7 (www.hl7.org). Members may obtain a copy without charge in the Members-only area of the site, others may purchase a copy for a nominal fee via the HL7 Store

without always requiring a revision of the referring Implementation Guide. Thus the value set version stated at the time of Implementation Guide publication OR NEWER can be used to satisfy the requirements of this IG at the time of implementation.

This additional documentation includes introductory material, and a master index that links to a spreadsheet for each value set. This spreadsheet contains the detailed requirements for each component or field in each Implementation Guide.

1.4.7.1 VALUE USAGE REQUIREMENTS

The spreadsheets describe the detailed usage requirement indicators for implementations intending to be conformant to this guide (e.g., required values, permitted values). These concepts are fully detailed in the Companion Document.

In the case of a single fixed value, e.g., the value of MSH-12.1 (Version ID.Version ID) the table is listed but is also constrained by a Conformance Statement. Other code systems such as LOINC, SNOMED CT, USPS, etc. are also listed with additional constraints noted.

Note: this guide does **NOT** address coordination of use of updates between trading partners. See the Value Set Companion Guide for full details on how values sets are created, managed, and the scope and expectations for use.

1.4.7.2 BINDING STRENGTH

Value Sets declared in this Implementation Guide in the Value Set column of the Data Type and Segment definitions are considered to have a binding strength of 'R' (Required) unless otherwise declared to be Suggested or Recommended. The interpretation of 'R' is that values MUST be drawn from the identified set whereas implementations may choose to use an alternate code system than those that are suggested or recommended.

When implementing optional fields, this guide recommends use of the code system(s) defined for the field in companion Lab IGs (if present). E.g., if Field A is optional in Guide A but required in Guide B with a defined value set, implementers are encouraged to adopt the value set as defined in Guide B.

1.4.8 SCOPE OF IMPLEMENTATION

The base standard indicates that receiving applications "…shall process (save/print/archive/etc.)…". For order-specific segments, e.g., ORC, OBR, SPM, this typically means saving that data. For other segments, e.g., MSH, the receiving application may not always have to save the data as the segment is focused on ensuring the order-specific data arrives in the appropriate place and therefore may have shorter-term value.

Due to receiving system variations and need, this guide does not specifically indicate for each field whether to store it or not. This is left to the individual system's scope and purpose.

1.4.9 SNAPSHOT MODE

Result messages shall always be sent in snapshot mode, meaning that all information related to the smallest individually identifiable unit are complete. For this message type that would be the OBR and all related segments (OBX, NTE and SPM, OBX). I.e., if a correction and/or status update to at least one of the OBX segments under one OBR is necessary, all OBX segments, even if previously sent, shall be resent with the correction and/or current status and/or current values. For example, when a Complete Blood Count with manual differential is ordered, the blood count will be released

and then at a later time the manual differential will be performed and released. When the blood count is released the report will provide only the count as final results. When the differential is completed, Snap Shot Reporting will send all previous results as well as the new results, in this case the blood count and the differential.

1.5 Referenced Profiles - Antecedents

This specification documents a message profile for Laboratory Reporting Interface (LRI) profile for Senders and Receivers based on the HL7 version 2.5.1[5]. Other laboratory results profiles were referenced and used as source materials in the development of this guide, including:

- *HL7 Ambulatory Care Laboratory Result Implementation Guide: EHR-Laboratory Interoperability And Connectivity Specification (ELINCS) - Release 1*, July 1, 2008
- *HL7 Version 2.5.1 Implementation Guide: Orders And Observations; Interoperable Laboratory Result Reporting To EHR (US Realm), Release 1*, November, 2007
- *HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1.1 (US Realm),* May 2014

This document should not be considered the source of truth for any statement or assertion in regards to the referenced profiles. They are provided here as antecedent documentation and are not required for successful implementation of this Guide.

[5] The referenced documents are all available from HL7 (www.hl7.org) – Members may obtain a copy without charge in the Members-only area of the site, others may purchase a copy for a nominal fee via the HL7 Store.

2 USE CASE – RESULTS FOR AMBULATORY CARE

A laboratory is defined as any facility which performs laboratory testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention, treatment of disease, or impairment of, or assessment of health[6]. In this Use Case, the Laboratory provides results based on a request for laboratory services from an authorized Provider. It is assumed that the receiving system is an EHR-S that can receive lab results even if it is not aware of the request, as there is no assumption that the receiving EHR-S provided the request for lab services.

2.1 Scope

The scope is the sending of lab results from a laboratory to an ambulatory provider. The implementation design is as a series of constraining profiles on a base specification, itself a constraint on the HL7 V2.5.1 Message standard, for future use case expansion.

2.1.1 IN SCOPE

- Defining the core data elements required for ambulatory care clinical laboratory test results.
- Reporting of clinical laboratory test results for ambulatory care in the US Realm.
- Sending clinical laboratory test results as standardized structured data so they can be incorporated that way into an EHR-S.
- Supporting ONC certification criteria and Meaningful Use (MU) requirements by developing requirements for an interface that enables the incorporation of clinical laboratory test results into an EHR-S when data is sent as standardized structured data.
- Reporting test results for an order that was placed either manually or electronically.
- Some order specific data has been included to enable the receiving EHR-S to correlate the results back to the originating order.
- Covering all CLIA reporting requirements.
- Receiving of laboratory results by a non-ordering provider, e.g., copy-to provider.
- Advanced error messages related to application transport.

2.1.2 OUT OF SCOPE

- Specifications and implementation guidance on laboratory ordering transactions. However, the establishment of requirements in the laboratory result message that will allow the matching of the reported result to an existing order initiated from the ordering clinician's EHR-S is within the scope of this effort.
- Querying for laboratory results.
- Querying for historical laboratory results.
- Receiving historical laboratory results.

[6] Derived from the CLIA definition (https://www.cms.gov/CLIA/07_Program_Descriptions_Projects.asp - TopOfPage). Future Use Cases may require expansion to include non-human subjects.

- Secondary use of laboratory data (i.e., public health or bio surveillance uses of the reported laboratory results).
- In hospital ordering and reporting of laboratory results.
- Results not transmitted using a standardized structured format, e.g., scanned documents, direct entry into EHR.

2.2 Actors

There are two actors that have responsibilities related to the conformance profiles defined in this document

- Laboratory Result Sender – A sender of laboratory result messages that declares conformance to a profile defined in this guide.
- Laboratory Result Receiver – A receiver of laboratory result messages that declares conformance to a profile defined in this guide.

2.3 Results for Ambulatory Care Use Case and Context Diagrams

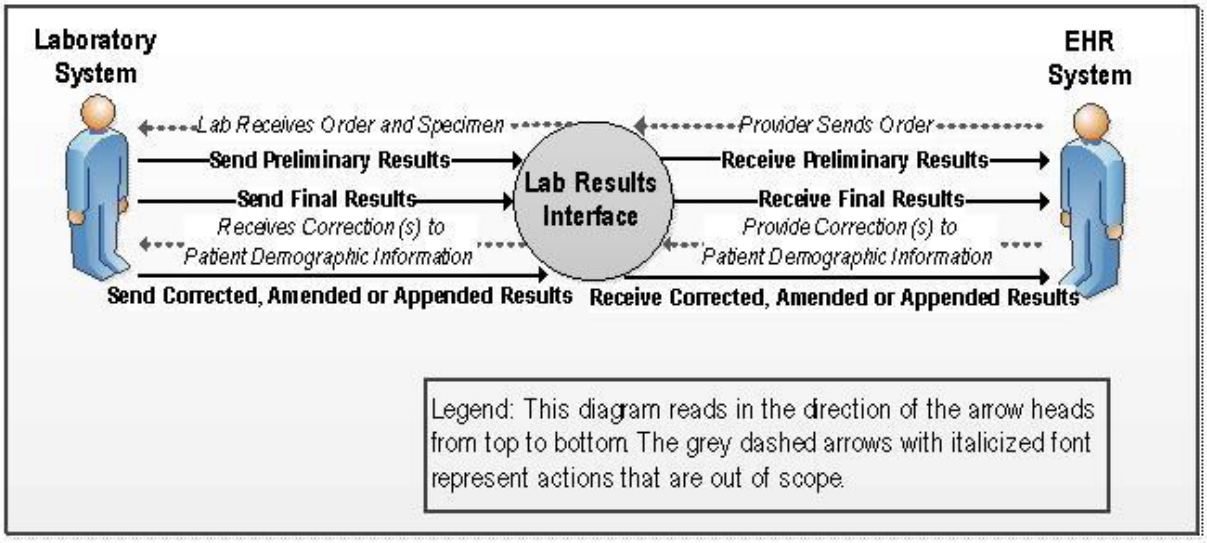

Figure 2-1. Context Diagram

2.4 User Story

A Provider (order placer) may enter a laboratory order into an ambulatory EHR-S. A laboratory requisition is generated (paper or electronic) and is communicated to the laboratory. The information in the laboratory requisition is entered manually or captured electronically into the LIS. After the specimen(s) has been collected and, if necessary, shipped or delivered to the laboratory, the laboratory processes the specimen(s). If the specimen is satisfactory for testing the laboratory will attempt to perform the test. Prior to successful completion of a test, communication may be necessary to indicate cancellation, failure to perform the test and the related reasons; for example if the specimen is either not appropriate for the ordered test, or otherwise unsatisfactory, the rejection of the specimen will be communicated using the result message in this IG.

If testing is successful, results are obtained and entered/released in the LIS. An authorized person at the laboratory reviews and approves the laboratory test results, or the certifying laboratory reviewer of record in the case of an auto-verification process, to be sent to the ordering provider.

The laboratory's LIS (results sender) transmits the results to the provider's EHR-S (results receiver). The EHR-S incorporates the results into the patient's electronic record. The provider logs into his/her EHR-S and views the laboratory results in order to inform patient care decisions.

2.5 Use Case Assumptions

- Providers securely access clinical information through an EHR-S.
- Appropriate security and transport protocols; patient identification methodology; requisition (order) identification methodology; consent; privacy and security procedures; coding, vocabulary and normalization standards have been agreed to by all relevant participants.
- This Use Case only addresses the exchange of laboratory results that are associated with the In Scope laboratory tests.
- All relevant parties have agreed on a structured laboratory test results message format.
- This Use Case covers all CLIA reporting requirements.
- For the specimen collection process the data included in the dataset considerations table[7] are assumed to be available and reported in the result.
- Legal and governance issues regarding data access authorizations, data ownership, and data use are in effect.
- Established network and policy infrastructure to enable consistent, appropriate, and accurate information exchange across provider systems, data repositories and locator services. This includes, but is not limited to:
  - Methods to identify and authenticate users;
  - Methods to identify and determine Providers of care;
  - Methods to enforce data access authorization policies;
  - Methods to ensure the veracity of data;
- Detailed audit trails are kept as necessary by all participating systems.
- Security and privacy policies, procedures and practices are commonly implemented to support acceptable levels of patient privacy and security; i.e. HIPAA, HITECH and EHR certification criteria.
- A LIS will be the sender of laboratory test results while an EHR will be the receiver.
- The transport mechanism will provide guaranteed delivery and error handling.
- This Use Case acknowledges the variations in requirements for reporting across local, state, tribal, and territorial boundaries as well as voluntary versus mandatory requirements.
- Laboratories meet accreditation criteria according to jurisdiction requirements or agency criteria.

[7] Section 13.0 - LRI Use Case: http://wiki.siframework.org/LRI - FINAL Use Case

2.5.1 PRE-CONDITIONS

- An order has been generated by an Ordering Provider for one or more laboratory tests results to be produced.
- When indicated, the Laboratory receives request to send laboratory results to a non-order placer.
- The Laboratory receives an order (electronic, paper, etc.) or the Laboratory receives a request to re-run (repeat) a test, or determines a need to re-run a test for possible correction, or determines that reflex testing (which is based on criteria set by the medical review board) is required or determines the need to amend a test result based on erroneous information.
- The Laboratory receives the appropriate clinical information to perform the ordered test.
- Laboratory has entered, manually or through the interface, pertinent (or corrected) data from an order into the LIS
- Laboratory has received and processed properly identified specimen(s) related to the ordered test(s).
- Laboratory entered or received from the ordering EHR-S, pertinent data from/about the specimen into the LIS.
- Laboratory performed the ordered tests on received specimens and/or incorporated calculated and reference data to produce the results to be exchanged.
- The laboratory result message contains both the appropriate patient information and the originating order information to associate the laboratory results to the correct patient and original order.
- The LIS is capable of and ready to send laboratory results electronically and in standardized structured format.
- EHR-S is in place and capable of receiving laboratory results electronically and in standardized structured format.
- The laboratory result is verified and ready for release.

2.5.2 POST CONDITION

- Laboratory results are accurately reported and successfully transmitted electronically from the LIS to the Ordering Provider's (*order placer's*) EHR-S, module or other results receiver.
- The provider's EHR-S has electronically received the laboratory results, incorporated in a standardized structured format, and if available, associated with a patient and laboratory order.

2.5.3 FUNCTIONAL REQUIREMENTS

TABLE 2-1. INFORMATION INTERCHANGE REQUIREMENTS

Initiating System	Action	Requirement	Action	Receiving System
Laboratory Information System	Sends	Laboratory Test Result	Receives	Electronic Health Record System

TABLE 2-2. SYSTEM REQUIREMENTS	
System	System Requirement
Laboratory Information System	Form a laboratory message with standardized structured data[8] meeting CLIA and other federal and state regulatory requirements.
Electronic Health Record System	Incorporate test data from the laboratory message as standardized structured data.

2.6 Sequence Diagram

Figure 1-3 shows the interactions between the Lab Results Sender and the Lab Results Receiver in the order that they occur. The horizontal lines are used to identify the specific activity between the systems. The solid lines represent the data being transmitted using an ORU message while the dotted lines represent the return acknowledgements. Each step has a number associated with it to emphasize the order of the events. Internal Lab system functions (retry, next and log options) are shown as closed loops on the side of the Lab Results Sender.

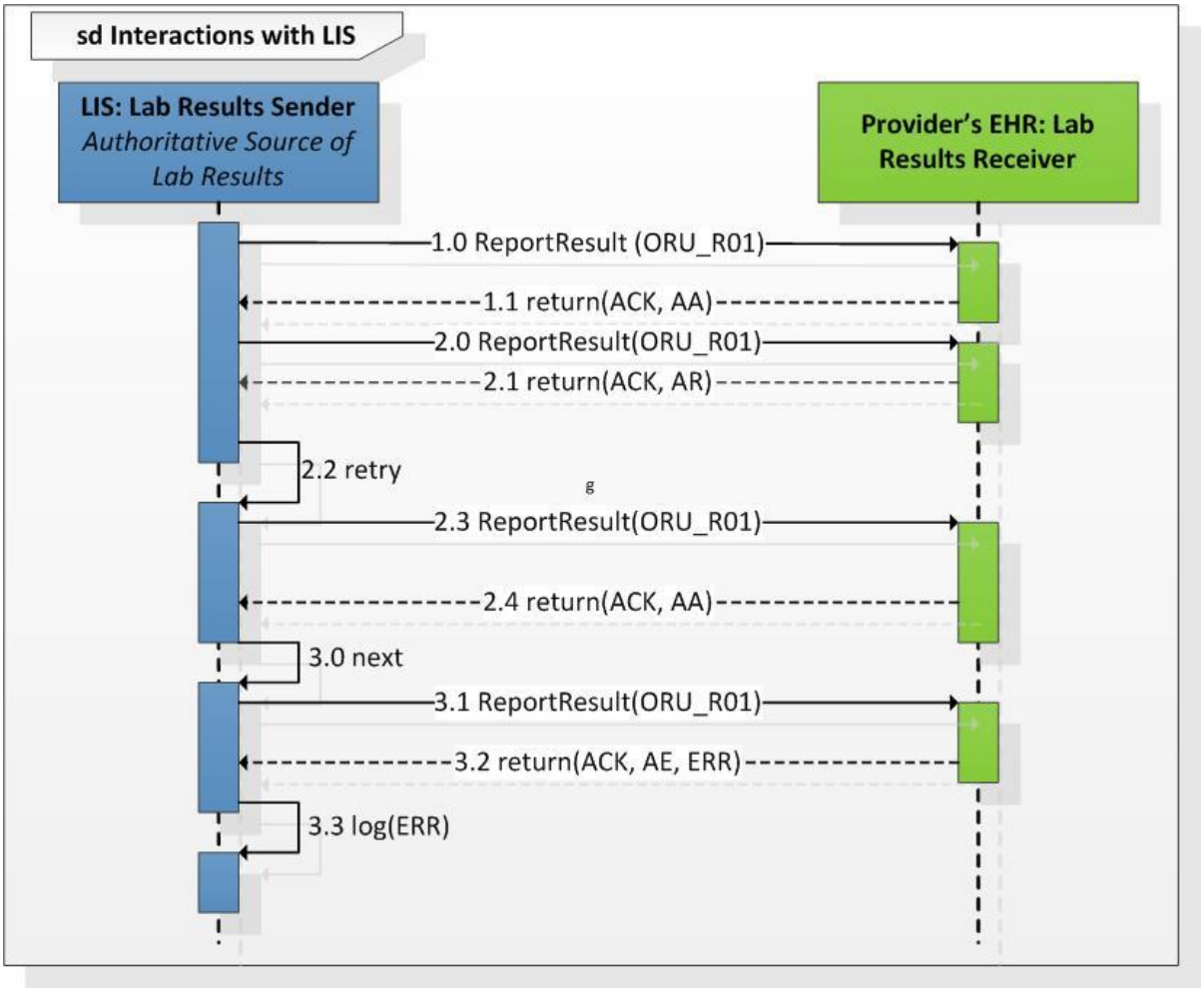

Figure 2-2. Sequence Diagram

[8] See the S&I LRI Use Case, Section 2.3 Structured Data Definition

The sequence begins with the Lab Results Sender transmitting a message to the EHR (1.0) which is positively acknowledged (AA) by the EHR (1.1).

A subsequent results transaction (2.0) is rejected (AR) through an acknowledgement transaction (2.1) that leads the Lab to fix the problem and retry (2.2). The resulting transaction (2.3) is positively acknowledged (2.54).

The third result transaction (3.1) contains serious errors resulting in an error message (3.2) being returned to the Lab system which then logs the error (3.3).

2.6.1 ACKNOWLEDGEMENTS

This guide requires support for Acknowledgement messages in general. In order to guarantee end-to-end delivery to the intended recipient in an environment with possible multiple intermediaries, this guide uses the enhanced acknowledgement mode. This requires use of both the accept acknowledgement as well as the application acknowledgement.

2.6.1.1 ACCEPT ACKNOWLEDGEMENT

Node-to-Node delivery notification is required and that is accomplished by using the enhanced acknowledgment mode, whereby the accept acknowledgment is used by the receiver system to state that it has taken responsibility for the transmitted message (or that it cannot do that). In detail this means:

1. In the LRI result message (ORU^R01) as well as in the Application Acknowledgement message (ACK^R01), for any non-batch transmission method, the MSH-15 (Accept Acknowledgment Type) is valued "AL" and each receiving system along a communication route (Node) must respond appropriately to the system which sent the transaction to it by synchronously returning an Accept Acknowledgement of either "CA" or "CR" to the immediately preceding sender. This applies to intermediaries between a Laboratory Result Sender and an EHR-S such as HIEs and interface engines, as well as to the final EHR-S destination.
2. In the returned Accept Acknowledgement messages (ACK^R01) the MSH-15 (Accept Acknowledgment Type) is valued 'NE' to avoid an infinite loop.

2.6.1.2 APPLICATION ACKNOWLEDGMENT

End-to-end delivery and error notification is also required and that is accomplished by using the enhanced acknowledgment mode, whereby the intended EHR-S receiver application responds to the receipt of the result message. To ensure end-to-end acknowledgement of delivery and error notification, this guide requires that MSH-16 (Application Acknowledgement Type) must be valued "AL" in all result messages from the Laboratory Result Sender and that the result message are responded to with an Application Acknowledgement of "AA", "AR", or "AE" by the intended destination to verify successful delivery and indicate application level acceptance or application level acceptance errors.

The diagram in summarizes the flow of Acknowledgements from the results sender (LIS) to the results receiver (EHR-S) and back through the different gateways.

The numbers for R = Result indicate the step in the respective flow. For example the step marked R2 indicates that for the flow of the Result message – the solid green arrow labeled ORU and its related Access ACK, the dotted black arrow between Gateway 2 and Gateway 1 – would be step 2.

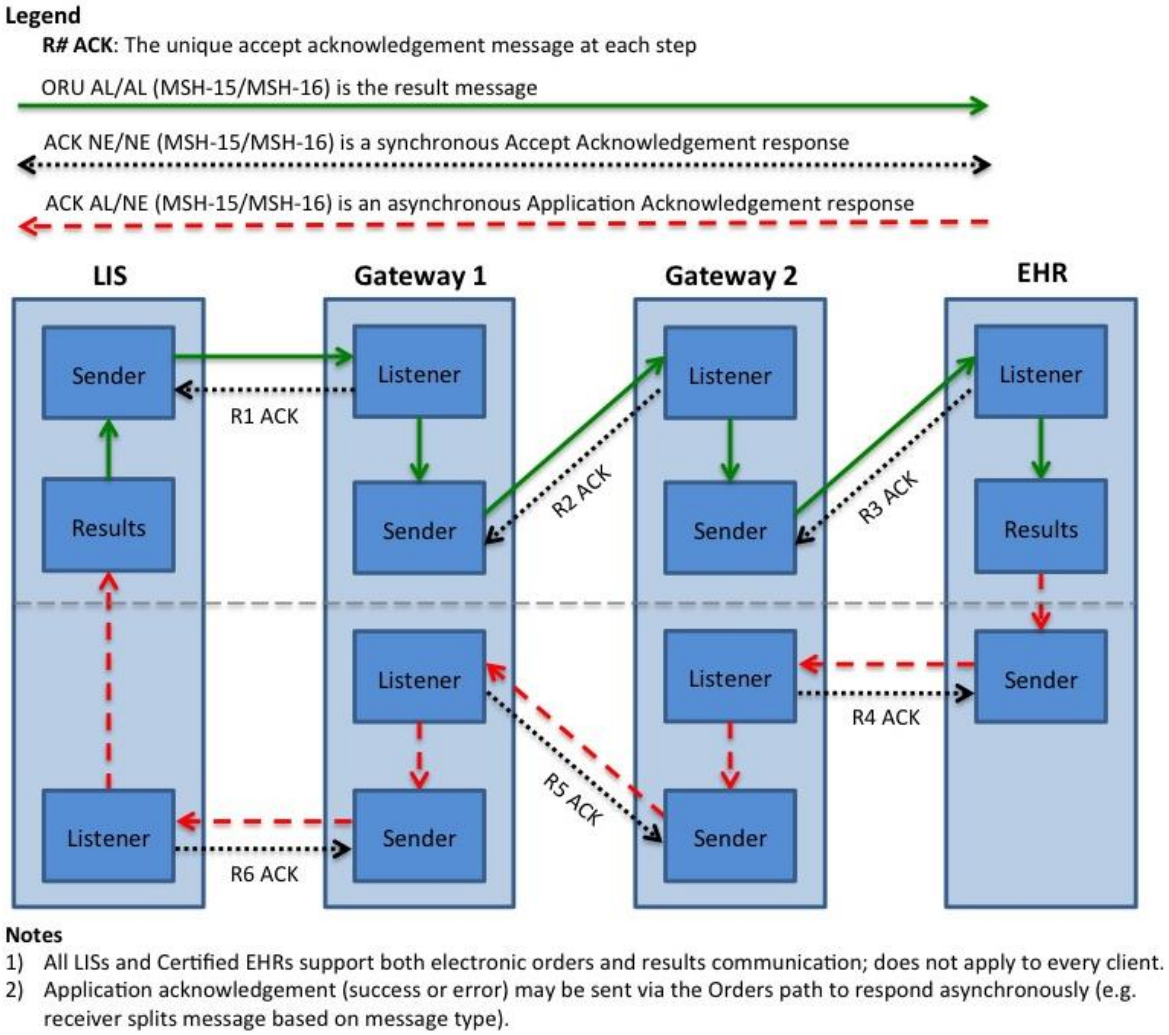

Figure 2-3. LRI Message and Guaranteed Delivery Notification Flow

The values used in MSH-15 (Accept Acknowledgement Type) and MSH-16 (Application Acknowledgement Type) will depend on the type of message sent.

2.6.1.3 ACKNOWLEDGEMENT CODES IN MSH-15 AND MSH-16 FOR THE ORU MESSAGE

Use the result message (ORU^R01) with the following code combinations:

TABLE 2-3. ORU ACKNOWLEDGEMENT CODES

Requirement	MSH-15	MSH-16
SHALL support	AL	AL
MAY support	AL	ER
MAY support*	NE	AL

*ONLY in point-to-point environments, where the transport protocol guarantees delivery to the intended recipient.

All other values and combinations are NOT allowed.

2.6.1.4 ACKNOWLEDGEMENT CODES IN MSH-15 AND MSH-16 FOR THE ACCEPT ACKNOWLEDGEMENT MESSAGE

Use the Accept Acknowledgement message (ACK^R01) with the following code combinations:

TABLE 2-4. ACCEPT ACKNOWLEDGEMENT CODES		
Requirement	MSH-15	MSH-16
SHALL support	NE	NE

All other values and combinations are NOT allowed.

2.6.1.5 ACKNOWLEDGEMENT CODES IN MSH-15 AND MSH-16 FOR THE APPLICATION ACKNOWLEDGEMENT MESSAGE

Use the Application Acknowledgement message (ACK^R01) with the following code combinations:

TABLE 2-5. APPLICATION ACKNOWLEDGMENT CODES		
Requirement	MSH-15	MSH-16
SHALL support	AL	NE
MAY support	NE	NE

All other values and combinations are NOT allowed.

2.6.2 ERROR HANDLING

EHR-System functional requirements to support this Implementation Guide will be published as the *HL7 EHR-S Implementation Guide: S&I Framework Lab Results Interface (LRI) Functional Requirements, Release 1, DSTU Release 1 – US Realm (EHR-FR-LR)* (in production at release time of this publication), which defines responses to specific error types. An excerpt is included below:

---------- *begin citation* ----------

After receiving an LRI message the EHR responds with an Accept Acknowledgment Message to the immediately preceding sender, returning a Communication Accept code in MSA-1 of "CA" or a Communication Reject code "CR". If the message is rejected (MSA-1 = "CR") the EHR-S has completed the message acknowledgement workflow for the message.

If the message is accepted (MSA-1 = "CA"), the EHR-S evaluates the ORU message for both conformance to the LRI guide and whether it is able to consume and associate the message contents, and finally the EHR-S consumes and stores the message contents. If all of these steps succeed without an error, the EHR-S responds with an Application Acknowledgment Message to the originating system returning an Application Accept code in MSA-1 of "AA". If there are hard errors, the processing of the message is aborted at any of these steps and the EHR-S responds with an Application Acknowledgment Message to the originating system returning an Application Reject code in MSA-1 of "AR" with the error(s) listed in fields ERR-3 and/or ERR-5. If there are soft errors the EHR-S responds, after consuming and storing the message, with an Application Acknowledgment Message to the originating system returning an Application Error code in MSA-1 of "AE" with the error(s) listed in fields ERR-3 and/or ERR-5. This is illustrated in Figure 2-4.

There are two error severity categories:

Hard Error – stop; suspend processing and notify sender, do not commit data to patient record

Soft Error – notify (as directed) but continue to process message unless a hard error is encountered prior to end of message processing; may commit data to patient record while informing sender of soft errors.

Errors can be reported at two levels:

HL7 error code (ERR-3) - These are errors in the structure or the message content that can be identified during validation against the guide profile.

Application error code (ERR-5) – These are errors related to the message content that are not computable from the guide profile, but related to the receiving application's functionality, or are not related to the message or its content, but report on other application failures.

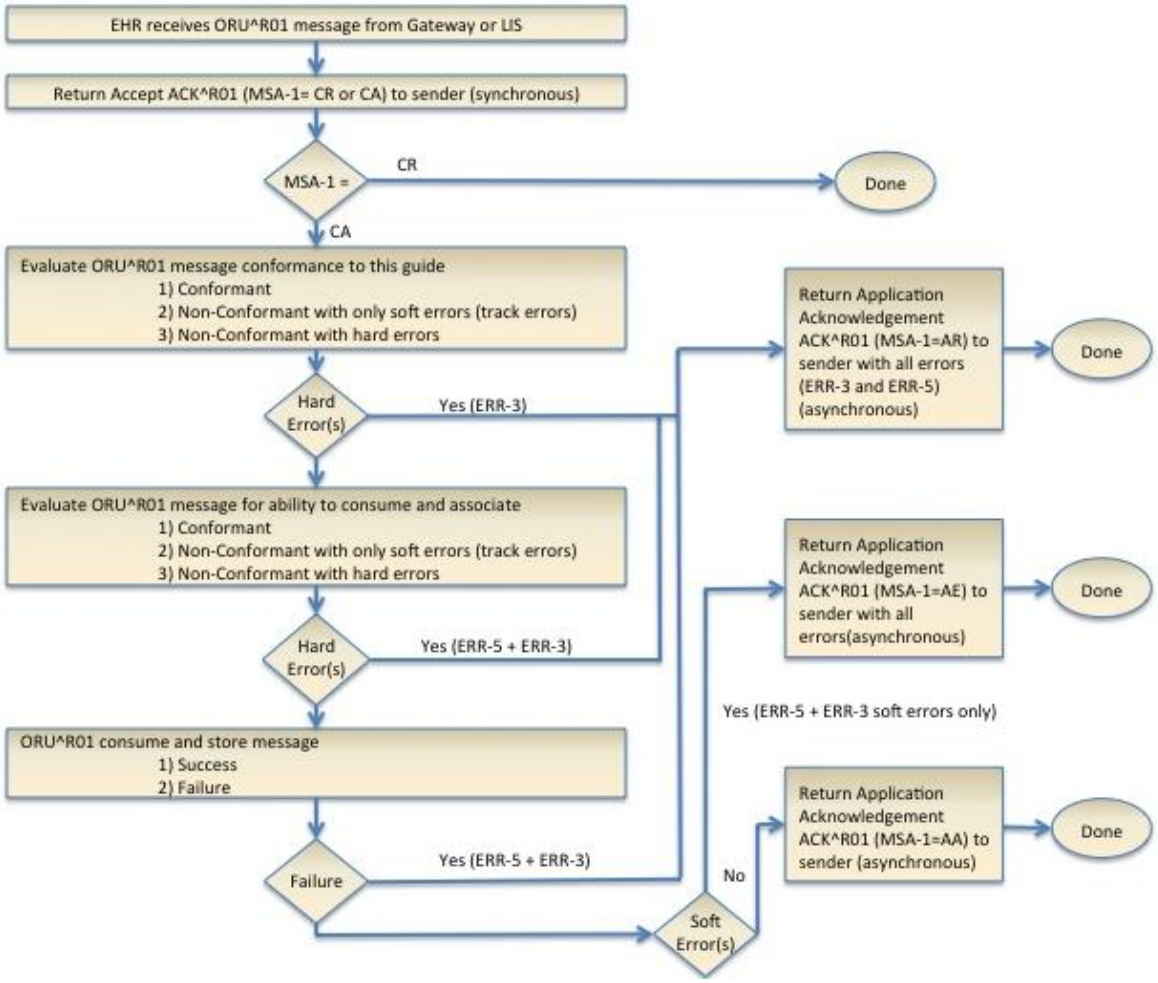

Figure 2-4. LRI Message Evaluation In EHR

---------- *end citation* ----------

3 CONFORMANCE TO THIS GUIDE

3.1 Value Sets

Conformance to this guide requires an implementation to adhere to sets of constraints as defined in the profile components and profiles below, as well as the Value Set requirements as set forth in the companion publication *HL7 Laboratory US Realm Value Set Companion Guide, Release 1, September 2015.*

Note that newer versions of the Value Set Companion Guide may be used with this IG and be considered compatible.

3.2 Profiles and Profile Components

This Implementation Guide defines profile components that are then combined as profiles to define specific conformance requirements. Profile components and profiles can be specific to a very narrow set of requirements for an IG, or broadly defined for use in all US Realm Lab interactions. This latter set is referred to as "domain" profile components in this guide.

As part of this design, some components are prefaced by LAB_, LOI_ or LRI_, which indicates the following use:

- LAB_*xxx* – the component declares behaviors and constraints that apply to all guides.
- LOI_*xxx* – the component declares behaviors and constraints that apply specifically to laboratory orders.
- LRI_*xxx* – the component declares behaviors and constraints that apply specifically to laboratory results.
- eDOS_*xxx* – the component declares behaviors and constraints that apply specifically to laboratory directories of service.
- PH-*xxx* - the component declares behaviors and constraints that apply specifically to reporting for public health (ELR)

The profile components must be combined to create a valid profile for a particular transaction by populating MSH-21 (Message Profile Identifier) with a valid set of identifiers. Multiple profiles or profile components can be present in MSH-21 provided the combined requirements do not conflict with each other. Additional definitions and guidance for MSH-21 can be found in Section 5.3.1 MSH – Message Header Segment.

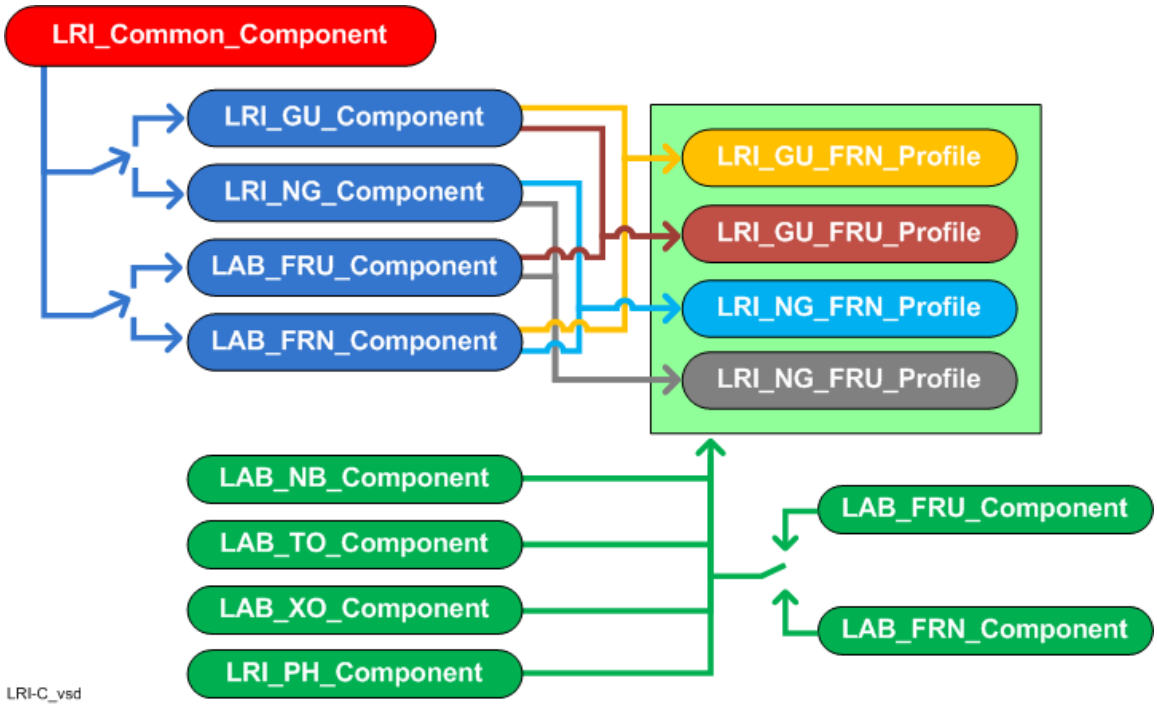

Figure 3-1. Profile and Component Architecture

As of this version a valid profile consists of a minimum of three profile components:

1. The LRI_Common_Component (red) – this component is always present)
2. The LRI_GU_Component **OR** the LRI_NG_Component (blue) – at least one of these
3. The LAB_FRU_Component **OR** the LAB_FRN_Component (blue) – at least one of these

Additional components can be provided to further define the message structure and use. This guide defines six such components (green):

1. The LAB_PRU_Component **OR** the LAB_PRN_Component
2. LAB_NB_Component – Newborn
3. LAB_TO_Component – Time Offset
4. LAB_XO_Component – Exclusions
5. LRI_PH_COMPONENT – Public Health Reporting[9]

As illustrated above, users must choose which of the four basic profiles they will use, and optionally may have additional profile components.

Additional definitions and guidance for MSH-21 can be found in Section 5.3.1 MSH – Message Header Segment.

3.3 Result Profile Components

The result profile components that can be assembled into profiles are:

[9] Refer to the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 2 (US Realm) for full requirements for this component.

3.3.1 LRI_COMMON_COMPONENT – ID: 2.16.840.1.113883.9.16

This profile component indicates that the message adheres to the rules set out in this Implementation Guide.

Note: This profile component sets the minimum constraints on the base specification for all profiles defined by this guide and may be further constrained by additional profile components.

3.3.2 LRI_GU_COMPONENT – ID: 2.16.840.1.113883.9.12

This profile component indicates that the following fields use Globally Unique Identifiers through ISO OID according to Section 1.4.2 Use of ISO Object Identifier (OID) for at least the assigning authority within the data type used.

- MSH-3 – Sending Application
- MSH-4 – Sending Facility
- MSH-6 – Receiving Facility
- PID-3 – Patient Identifier List
- ORC-2 – Placer Order Number
- ORC-3 – Filler Order Number
- ORC-4 – Placer Group Number
- ORC-12 – Ordering Provider
- OBR-2 – Placer Order Number
- OBR-3 – Filler Order Number
- OBR-16 – Ordering Provider
- OBR-28 – Result Copies To
- OBR-29 – Parent
- OBX-16 – Responsible Observer
- OBX-23 – Performing Organization Name
- OBX-25 – Performing Organization Medical Director
- SPM-2 – Specimen ID

These fields must use the GU version of their data type definition.

3.3.3 LRI_NG_COMPONENT – ID: 2.16.840.1.113883.9.13

This profile component indicates that the identification method has been negotiated between the trading partners where none or some may use ISO OIDs according to Section 1.4.2 Use of ISO Object Identifier (OID) while others use any of the identification methods allowed through the base standard. Consequently, these identifiers are not guaranteed to be globally unique.

- MSH-3 – Sending Application
- MSH-4 – Sending Facility
- MSH-6 – Receiving Facility
- PID-3 – Patient Identifier List

- ORC-2 – Placer Order Number
- ORC-3 – Filler Order Number
- ORC-4 – Placer Group Number
- ORC-12 – Ordering Provider
- OBR-2 – Placer Order Number
- OBR-3 – Filler Order Number
- OBR-16 – Ordering Provider
- OBR-28 – Result Copies To
- OBR-29 – Parent
- OBX-16 – Responsible Observer
- OBX-23 – Performing Organization Name
- OBX-25 – Performing Organization Medical Director
- SPM-2 – Specimen ID

These fields must use the NG version of their data type definition.

3.3.4 LAB_FRU_COMPONENT (UNIQUE FILLER NUMBER) – ID: 2.16.840.1.113883.9.83

This profile component indicates that the filler order number uniquely identifies the test ordered. No additional information is necessary, such as the universal service identifier, since the identifier on its own is unique. This profile component can only be declared in MSH-21 by the filler and subsequently copied if the copier (e.g., placer upon responding, or another party forwarding the message) did not change the filler order number value.

3.3.5 LAB_FRN_COMPONENT (NON-UNIQUE FILLER NUMBER) – ID: 2.16.840.1.113883.9.84

This profile component indicates that the test shall be identified using the universal service identifier in conjunction with the filler order number and, if available, the placer order number. The order numbers (placer/filler) must be combined with the universal service identifier to uniquely identify the order. This must also be taken into account when creating parent – child relationships in subsequent messages.

3.3.6 LAB_PRU_COMPONENT (UNIQUE PLACER ORDER NUMBER) – ID: 2.16.840.1.113883.9.82

This profile component indicates that the placer order number uniquely identifies the test ordered. No additional information is necessary, such as the universal service identifier, since the identifier on its own is unique. This profile component can only be declared in MSH-21 by the placer and subsequently copied if the copier (e.g., filler upon responding, or another party forwarding the message) did not change the placer order number value.

3.3.7 LAB_PRN_COMPONENT (NON-UNIQUE PLACER ORDER NUMBER) – ID: 2.16.840.1.113883.9.81

This profile component indicates that the test shall be identified using the universal service identifier in conjunction with the filler order number and, if available, the placer order number. The order numbers (placer/filler) must be combined with the universal service identifier to uniquely identify the order. This must also be taken into account when creating parent – child relationships in subsequent messages.

3.3.8 LAB_NB_COMPONENT – ID: 2.16.840.1.113883.9.24

This profile component indicates that the data type TS_3 is used in PID-7 (Date/Time of Birth) to support Newborn Screening.

Note: For the purposes of this guide Newborn is defined as up to 28 days, see Section 11 Glossary.

3.3.9 LAB_TO_COMPONENT – ID: 2.16.840.1.113883.9.22

This profile component requires the time zone component of the TS/DTM data type. Note that the base standard's default use of MSH-7 (Date/Time of Message) time zone offset dictates that if the time zone offset is present in MSH-7 it becomes the default time zone for the message instance and applies to all other date/time fields in that same message instance where a time zone offset is not valued. This profile component requires that all date/time fields indicated below carry a time zone offset if the time is included.

Note: this is a lab domain profile component and the following fields may or may not be required in this IG.

- MSH-7 (Date/Time of Message)
- PID-7 – Date/Time of Birth - If NB Screening profile component is used, then TO profile component applies.
- ORC-19 (Date/Time of Transaction)
- OBR-7 – Observation Date/Time
- OBR-8 – Observation End Date/Time
- OBR-22 – Results Rpt/Status Chng – Date/Time
- TQ1-7 – Start Date/Time
- TQ1-8 – End Date/Time
- OBX-5 – Observation Value (when OBX-2 is “TM”)
- OBX-14 – Date/Time of the Observation
- OBX-19 – Date/Time of the Analysis
- SPM-17 – Specimen Collection Date/Time
- IN1-18 – Insured’s Date of Birth

It is important that the sending application has appropriately resolved the time zone offsets for PID-7, TQ1-7, TQ1-8, OBR-7, OBR-8, and SPM-17 as these date/times may be managed through ADT/Registration and Orders interfaces.

3.3.10 LAB_XO_COMPONENT – ID: 2.16.840.1.113883.9.23

One of the basic premises of this guide is to enable senders to compose transactions that may satisfy multiple purposes, e.g., multiple Implementation Guides that share the same required fields and vocabulary. They therefore may populate any of the fields/components marked ‘O’ (optional). At the same time this Implementation Guide wants to expressly reinforce that if data is sent in optional fields/segments, the receiver can completely ignore those. Therefore, the usage code ‘X’ (Not Supported) is used sparingly, while the usage code ‘O’ is mostly used when the field/component is not necessary for the use case at hand. The rationale is according to the definition of ‘X’ per the base standard "For conformant sending applications, the element shall not be sent. Conformant receiving applications may ignore the element if it is sent, or may raise an application error."

However to accommodate those implementations where the population of any optional fields remaining is not desirable, the LAB_XO_Component is defined to indicate that all of the remaining optional segments and fields that are marked ‘O’ are now considered to be marked with an ‘X’. Its use yields, in combination with the other profile components, a fully implementable profile in accordance with Chapter 2B. Note though that this profile component is strictly voluntary and its use cannot be mandated by either trading partner to enable a successful results transaction.

3.3.11 LRI_PH_COMPONENT – ID: 2.16.840.1.113883.9.195.3.5

This profile component indicates support for Public Health Reporting, see Section 1.2.1 Relevant Laboratory Implementation Guides.

3.4 Result Profiles (Pre-Coordinated Components)

One may either enumerate the profile component IDs in MSH-21 (in no particular order), or use one of the profile IDs provided for each of the valid combinations,

3.4.1 LRI_GU_FRU_PROFILE – ID: 2.16.840.1.113883.9.195.3.1

This profile component is used to identify an ORU that is conformant to the combined constraints of the LRI_Common_Component, the LRI_GU_Component and the LAB_FRU_Component as defined within this Guide.

3.4.2 LRI_GU_FRN_PROFILE – ID: 2.16.840.1.113883.9.195.3.2

This profile component is used to identify an ORU that is conformant to the combined constraints of the LRI_Common_Component, the LRI_GU_Component, and the LAB_FRN_Component as defined within this Guide.

3.4.3 LRI_NG_FRU_PROFILE – ID: 2.16.840.1.113883.9.195.3.3

This profile component is used to identify an ORU that is conformant to the combined constraints of the LRI_Common_Component, the LRI_NG_Component, and the LAB_FRU_Component as defined within this Guide.

3.4.4 LRI_NG_FRN_PROFILE – ID: 2.16.840.1.113883.9.195.3.4

This profile component is used to identify an ORU that is conformant to the combined constraints of the LRI_Common_Component, the LRI_NG_Component, and the LAB_FRN_Component as defined within this Guide.

Note that the PRN, PRU, TO, XO and NB profile components are not included in the pre-coordinated profiles; rather they should also be declared in MSH-21 when applicable, e.g., the

LAB_NB_Component would be included to support the level of precision a Newborn use case requires on time-related data elements.

3.5 Response Components

3.5.1 LRI_ACKNOWLEDGEMENT_COMPONENT – ID: 2.16.840.1.113883.9.26

This profile component indicates that the acknowledgement message adheres to the rules set out in this Implementation Guide.

Note: This profile component sets the minimum constraints on the base specification for the acknowledgement and may be further constrained by additional profile components.

3.5.2 GU_ACKNOWLEDGEMENT_COMPONENT – ID: 2.16.840.1.113883.9.21

This profile component is used to identify an ACK that is constrained for the profiles defined within this Guide in response to the ORU message where MSH-21 contains '2.16.840.1.113883.9.195.3.1' (LRI_GU_FRU_Profile), OR '2.16.840.1.113883.9.195.3.2' (LRI_GU_FRN_Profile), OR '2.16.840.1.113883.9.12' (LRI_GU_Component).

3.5.3 NG_ACKNOWLEDGEMENT_COMPONENT – ID: 2.16.840.1.113883.9.25

This profile component is used to identify an ACK that is constrained for the profiles defined within this Guide in response to the ORU message where MSH-21 contains '2.16.840.1.113883.9.195.3.3' (LRI_NG_FRU_Profile), **OR** '2.16.840.1.113883.9.195.3.4' (LRI_NG_FRN_Profile), **OR** '2.16.840.1.113883.9.13' (LRI_NG_Component).

3.6 Response Profiles (Pre-Coordinated Components)

One may either enumerate the profile component IDs in MSH-21 (in no particular order), or use one of the profile IDs provided for each of the valid combinations:

3.6.1 LRI_GU_RESPONSE_PROFILE – ID: 2.16.840.1.113883.9.28

This profile pre-coordinates the use of the LRI_Acknowledgement_Component and GU_Acknowledgement_Component.

3.6.2 LRI_NG_RESPONSE_PROFILE – ID: 2.16.840.1.113883.9.27

This profile pre-coordinates the use of the LRI_Acknowledgement_Component and NG_Acknowledgement_Component.

3.7 Extended Profile Use

The sender may create other profile components or profiles that are defined outside of this Implementation Guide for use in conjunction with the profiles and profile components defined in this guide. However, those profiles and profile components are strictly voluntary and shall be properly constrained against the base standard and the profiles and profile components defined in Sections 1.11.1 through 1.11.3. Neither the sender nor the receiver shall require the use of any additional profiles and profile components in combination with the profiles and profile components defined in this guide to achieve a successful send or receive of Lab Results.

3.8 Scope of Implementation

The base standard indicates that receiving applications "…**SHALL** process (save/print/archive/etc.)…". For results-specific data segments, e.g., OBR, OBX, SPM, this typically

means saving that data. For other segments, e.g., MSH, the receiving application may not always have to save the data as the segment is focused on ensuring the results-specific data arrives in the appropriate place and therefore may have shorter-term value.

3.9 Relationship to Orders

This Implementation Guide imposes no constraints on data elements where the origination of the content for those data elements is a lab order. For all such data elements, the expectation is that the result message will support those elements as defined in the guide with the expectation that the lab will provide back in the result message either the original value from the order, or the most current available value the lab is aware of at the time the result message is generated. Note that this only involves data that is sent in fields that are marked in the LOI as 'R', 'RE', or 'C(a/b)' where (a) or (b) is 'R' or 'RE'. Any other fields valued, i.e., those marked O in the LOI guide, may be returned, but the Laboratory is under no obligation to do so unless specifically agreed to with the order sender The definition of a common order is outside the scope of this Guide; see the companion specification "HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Orders from EHR, DSTU Release 2 US Realm [HL7 Version 2.5.1: OML^O21] DSTU Ballot September 2014" available at http://www.hl7.org.

4 DATA TYPES

Data types are further defined in this Implementation Guide for all fields that have a usage of 'R', 'RE', or 'C(a/b)'. Data types used only for optional fields, or where this IG does not further constrain the base, are not included. Please refer to the base standard for those data types.

Depending on the profile components used, the usage of data type components for some data types varies. To clearly indicate when to use specific data type components, each data type that has a varying definition based on profile components will be documented with multiple flavors, e.g., CX_GU and CX_NG. Composite data types indicate which variety of the component's data type is applicable, while the data type of a field is marked as "varies" where the comment indicates the data type choices based on the declared profile or component.

Note that the CE data type has been deprecated in V2.5.1, use CWE or CNE as appropriate.

4.1 CWE – Coded With Exceptions

Note the following rules for display purposes only when more than one triplet is available in the specific flavor of CWE in use:

1) CWE.9 (Original Text) should not contain an entry unless it is different from what is in either triplet and then it must be used for the display.
2) If there is only one triplet, use it;
3) If two triplets, use the triplet containing the local code;
4) Where two triplets are present with two local or two non-local codes, the receiver should use the first triplet.
5) Additional constraints may apply, see individual elements using CWE.

4.1.1 CWE_CRE – CODED WITH EXCEPTIONS – CODE REQUIRED, BUT MAY BE EMPTY

Note: Pre-adoption of components 10-22 from V2.7.1

TABLE 4-1. CODED WITH EXCEPTIONS – CODE REQUIRED BUT MAY BE EMPTY

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Identifier	ST	RE		
2	Text	ST	C(RE/X)		Condition Predicate: If CWE_CRE.1 (Identifier) is valued. It is strongly recommended that text be sent to accompany any identifier. When a coded value is not known, the original text element (CWE_CRE.9) is used to carry the text, not the text (CWE_CRE.2) element.
3	Name of Coding System	ID	C(R/X)	HL70396	Condition Predicate: If CWE_CRE.1 (Identifier) is valued.
4	Alternate Identifier	ST	C(RE/X)		Condition Predicate: If CWE_CRE.1 (Identifier) is valued. The alternate identifier (from the alternate coding system) should be the closest match for the identifier found in CWE_CRE.1.

TABLE 4-1. CODED WITH EXCEPTIONS - CODE REQUIRED BUT MAY BE EMPTY					
SEQ	Component Name	DT	Usage	Value Set	Comments
5	Alternate Text	ST	C(RE/X)		Condition Predicate: If CWE_CRE.4 (Alternate Identifier) is valued. It is strongly recommended that alternate text be sent to accompany any alternate identifier.
6	Name of Alternate Coding System	ID	C(R/X)	HL70396	Condition Predicate: If CWE_CRE.4 (Alternate Identifier) is valued.
7	Coding System Version ID	ST	C(RE/O)		Condition Predicate: If CWE_CR.3 (Name of Coding System) is not an HL7 defined table or user defined.
8	Alternate Coding System Version ID		O		
9	Original Text	ST	C(R/RE)		Condition Predicate: If CWE_CRE.1 (Identifier) is not valued. Original Text is used to convey the text that was the basis for coding. If neither the first or second triplet has values, this contains the text of the field.
10	Second Alternate Identifier		O		
11	Second Alternate Text		O		
12	Second Name of Alternate Coding System		O		
13	Second Alternate Coding System Version ID		O		
14	Coding System OID		O		
15	Value Set OID		O		
16	Value Set Version ID		O		
17	Alternate Coding System OID		O		
18	Alternate Value Set OID		O		
19	Alternate Value Set Version ID		O		
20	Second Alternate Coding System OID		O		
21	Second Alternate Value Set OID		O		
22	Second Alternate Value Set Version ID		O		

Usage Note

The sender shall always populate the first triplet before populating other triplets; the receiver shall examine all triplets to find relevant values.

The CWE_CRE data type is used where it is necessary to communicate a code, text, coding system and the version of coding system the code was drawn from. It also allows the

communication of an alternate code drawn from another coding system. Many coded fields in this specification identify coding systems or value sets that must be used for the field.

Note: When populating the CWE_CRE data type with these values, this guide does not give preference to the triplet in which the standard code should appear.

4.1.2 CWE_CRE1 – CODED WITH EXCEPTIONS – CODE REQUIRED, BUT MAY BE EMPTY – SECOND TRIPLET OPTIONAL

Note: Components 10-22 are pre-adopted from V2.7.1 CWE.

TABLE 4-2. CODED WITH EXCEPTIONS – CODE REQUIRED BUT MAY BE EMPTY – SECOND TRIPLET OPTIONAL (CWE_CRE1)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Identifier	ST	RE		
2	Text	ST	C(RE/X)		Condition Predicate: If CWE_CRE1.1 (Identifier) is valued. It is strongly recommended that text be sent to accompany any identifier. When a coded value is not known, CWE_CRE1.9 (Original Text Element) is used to carry the text, not CWE_CRE1.2 (Text) element.
3	Name of Coding System	ID	C(R/X)	HL70396	Condition Predicate: If CWE_CRE1.1 (Identifier) is valued.
4	Alternate Identifier		O		
5	Alternate Text	ST	C(RE/X)		Condition Predicate: If CWE_CRE1.4 (Alternate Identifier) is valued. It is strongly recommended that alternate text be sent to accompany any alternate identifier.
6	Name of Alternate Coding System	ID	C(R/X)	HL70396	Condition Predicate: If CWE_CRE1.4 (Alternate Identifier) is valued.
7	Coding System Version ID	ST	C(RE/O)		Condition Predicate: If CWE_CRE1.3 (Name of Coding System) is not an HL7 defined table or user defined..
8	Alternate Coding System Version ID		O		
9	Original Text	ST	C(R/RE)		Condition Predicate: If CWE_CRE1.1 (Identifier) and CWE_CRE1.4 (Alternate Identifier) are not valued. Original Text is used to convey the text that was the basis for coding. If neither the first or second triplet has values, this contains the text of the field.
10	Second Alternate Identifier		O		
11	Second Alternate Text		O		
12	Second Name of Alternate Coding System		O		

TABLE 4-2. CODED WITH EXCEPTIONS – CODE REQUIRED BUT MAY BE EMPTY – SECOND TRIPLET OPTIONAL (CWE_CRE1)					
SEQ	Component Name	DT	Usage	Value Set	Comments
13	Second Alternate Coding System Version ID		O		
14	Coding System OID		O		
15	Value Set OID		O		
16	Value Set Version ID		O		
17	Alternate Coding System OID		O		
18	Alternate Value Set OID		O		
19	Alternate Value Set Version ID		O		
20	Second Alternate Coding System OID		O		
21	Second Alternate Value Set OID		O		
22	Second Alternate Value Set Version ID		O		

Usage Note

The CWE_CRE1 data type is used where it is necessary to communicate a code, text, or coding system and the version of the coding system the code was drawn from and alternate codes drawn from another coding system. Many coded fields in this specification identify coding systems or value set attributes that must be used for the field. When populating the CWE_CRE1 data types with these values, this guide does not give preference to the triplet in which the standard code should appear. The receiver is expected to examine the coding system names in components CWE_CRE1-3 (Name of Coding System) and, if valued, CWE_CRE1-6 (Alternate Name of Coding System) and, if valued, CWE_CRE1-20 (Second Alternate Name of Coding System) to determine if it recognizes the coding system or value set.

4.1.3 CWE_CR – CODED WITH EXCEPTIONS – CODE REQUIRED

Note: Pre-adoption of Components 10-22 from V2.7.1

TABLE 4-3. CODED WITH EXCEPTIONS – CODE REQUIRED – (CWE_CR)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Identifier	ST	R		
2	Text	ST	RE		It is strongly recommended that text be sent to accompany any identifier.
3	Name of Coding System	ID	R	HL70396	
4	Alternate Identifier	ST	RE		The alternate identifier (from the alternate coding system) should be the closest match for the identifier found in CWE_CR.1.
5	Alternate Text	ST	RE		It is strongly recommended that alternate text be sent to accompany any alternate identifier.
6	Name of Alternate Coding System	ID	C(R/X)	HL70396	Condition Predicate: If CWE_CR.4 (Alternate Identifier) is valued.

TABLE 4-3. CODED WITH EXCEPTIONS - CODE REQUIRED - (CWE_CR)					
SEQ	Component Name	DT	Usage	Value Set	Comments
7	Coding System Version ID	ST	C(RE/O)		Condition Predicate: If CWE_CR.3 (Name of Coding System) is not an HL7 defined table or user defined.
8	Alternate Coding System Version ID		O		
9	Original Text	ST	RE		Original Text is used to convey the text that was the basis for coding.
10	Second Alternate Identifier		O		
11	Second Alternate Text		O		
12	Second Name of Alternate Coding System		O		
13	Second Alternate Coding System Version ID		O		
14	Coding System OID		O		
15	Value Set OID		O		
16	Value Set Version ID		O		
17	Alternate Coding System OID		O		
18	Alternate Value Set OID		O		
19	Alternate Value Set Version ID		O		
20	Second Alternate Coding System OID		O		
21	Second Alternate Value Set OID		O		
22	Second Alternate Value Set Version ID		O		

Usage Note

The sender shall always populate the first triplet before populating other triplets; the receiver shall examine all triplets to find relevant values.

The CWE_CR data type is used where it is necessary to communicate a code, text, coding system and the version of coding system the code was drawn from. It also allows the communication of an alternate code drawn from another coding system. Many coded fields in this specification identify coding systems or value sets that must be used for the field. When populating the CWE_CR data types with these values, this guide does not give preference to the triplet in which the standard code should appear.

4.1.4 CWE_CR1 – CODED WITH EXCEPTIONS – CODE REQUIRED – SECOND TRIPLET OPTIONAL

Note: Components 10-22 are pre-adopted from V2.7.1 CWE.

TABLE 4-4. CODED WITH EXCEPTIONS – CODE REQUIRED 1 – SECOND TRIPLET OPTIONAL (CWE_CR1)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Identifier	ST	R		
2	Text	ST	RE		It is strongly recommended that text be sent to accompany any identifier.
3	Name of Coding System	ID	R	HL70396	
4	Alternate Identifier		O		
5	Alternate Text		O		
6	Name of Alternate Coding System	ID	C(R/X)	HL70396	Condition Predicate: If CWE_CR1.4 (Alternate Identifier) is valued.
7	Coding System Version ID	ST	C(RE/O)		Condition Predicate: If CWE_CR1.3 (Name of Coding System) is not an HL7 defined table.
8	Alternate Coding System Version ID		O		
9	Original Text	ST	RE		Original Text is used to convey the text that was the basis for coding.
10	Second Alternate Identifier		O		
11	Second Alternate Text		O		
12	Second Name of Alternate Coding System		O		
13	Second Alternate Coding System Version ID		O		
14	Coding System OID		O		
15	Value Set OID		O		
16	Value Set Version ID		O		
17	Alternate Coding System OID		O		
18	Alternate Value Set OID		O		
19	Alternate Value Set Version ID		O		
20	Second Alternate Coding System OID		O		
21	Second Alternate Value Set OID		O		
22	Second Alternate Value Set Version ID		O		

Usage Note

The sender shall always populate the first triplet before populating other triplets; the receiver shall examine all triplets to find relevant values.

The CWE_CR1 data type is used where it is necessary to communicate a code, text, coding system and the version of coding system the code was drawn from. It also allows the communication of an alternate code drawn from another coding system. Many coded fields in this specification identify coding systems or value sets that must be used for the field. When populating the CWE_CR1 data types with these values, this guide does not give preference to the triplet in which the standard code should appear.

4.2 CX – Extended Composite ID with Check Digit

4.2.1 CX_GU – EXTENDED COMPOSITE ID WITH CHECK DIGIT (GLOBALLY UNIQUE)

TABLE 4-5. EXTENDED COMPOSITE ID WITH CHECK DIGIT (CX_GU)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	ID Number	ST	R		
2	Check Digit		O		
3	Check Digit Scheme		O		
4	Assigning Authority	HD_GU	R		The Assigning Authority component is used to identify the system, application, organization, etc. that assigned the ID Number in component 1.
5	Identifier Type Code	ID	R	HL70203_USL	
6	Assigning Facility		O		
7	Effective Date		O		
8	Expiration Date		O		
9	Assigning Jurisdiction		O		
10	Assigning Agency or Department		O		

Usage Note

The CX_GU data type is used to carry identifiers. The GU profile requires that assigning authorities accompany all identifiers and that all identifiers carry an identifier type. This method allows the exchange of universally unique identifiers for the associated object across organizational and enterprise boundaries, enabling broad interoperability.

Although the Identifier Type Code component is required, it is not a part of the actual identifier. Rather, it is metadata about the identifier. The ID Number and Assigning Authority component, together, constitute the actual identifier. The reason for this requirement is to promote forward compatibility with HL7 Version 3 identifiers, where there is no concept of identifier type codes.

4.2.2 CX_NG – EXTENDED COMPOSITE ID WITH CHECK DIGIT (NON-GLOBALLY UNIQUE)

TABLE 4-6. EXTENDED COMPOSITE ID WITH CHECK DIGIT (CX_NG)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	ID Number	ST	R		
2	Check Digit	ST	O		

TABLE 4-6. EXTENDED COMPOSITE ID WITH CHECK DIGIT (CX_NG)					
SEQ	Component Name	DT	Usage	Value Set	Comments
3	Check Digit Scheme		O		
4	Assigning Authority	HD_NG	RE		
5	Identifier Type Code	ID	R	HL70203_USL	
6	Assigning Facility		O		
7	Effective Date		O		
8	Expiration Date		O		
9	Assigning Jurisdiction		O		
10	Assigning Agency or Department		O		

Usage Note

The CX_GU data type is used to carry identifiers. The GU profile component requires that assigning authorities accompany all identifiers and that all identifiers carry an identifier type. This method allows the exchange of universally unique identifiers for the associated object across organizational and enterprise boundaries, enabling broad interoperability.

Although the Identifier Type Code component is required, it is not a part of the actual identifier. Rather, it is metadata about the identifier. The ID Number and Assigning Authority component, together, constitute the actual identifier. The reason for this requirement is to promote forward compatibility with HL7 Version 3 identifiers, where there is no concept of identifier type codes.

4.3 DR – Date/Time Range

TABLE 4-7. DATE/TIME RANGE (DR)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Range Start Date/Time	TS_4	RE		
2	Range End Date/Time	TS_5	RE		

4.4 DT – Date

TABLE 4-8. DATE (DT)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Date	-	R		Format: YYYY[MM[DD]]

4.5 DTM – Date/Time

TABLE 4-9. DATE/TIME (DTM)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Date/Time	-	R		Format: YYYY[MM[DD[HH[MM[SS[.S[S[S[S]]]]]]]]][+/-ZZZZ]

Usage Note

It is strongly recommended that the time zone offset always be included in the DTM particularly if the granularity includes hours, minutes, seconds, etc. Specific fields in this Implementation

Guide may require Date/Time to a specific level of granularity, which may require the time zone offset. The granularity of the DTM as well as whether the time zone offset is required is defined in the Time Stamp patterns starting in Section 4.25 TS – Time Stamp.

4.6 ED – Encapsulated Data

TABLE 4-10. ENCAPSULATED DATA (ED)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Source Application	HD	O		
2	Type of Data	ID	R	HL70191_USL	
3	Data Subtype	ID	RE	HL70291_USL	
4	Encoding	ID	R	HL70299_USL	
5	Data	TX	R		

Usage Note

The ED data type is required to send a pre-formatted version of a report, e.g., a PDF file.

4.7 EI – Entity Identifier

4.7.1 EI_GU – ENTITY IDENTIFIER (GLOBALLY UNIQUE)

TABLE 4-11. ENTITY IDENTIFIER (EI_GU)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Entity Identifier	ST	R		
2	Namespace ID	IS	RE		
3	Universal ID	ST	R		
4	Universal ID Type	ID	R		Fixed to “ISO”.

Usage Note

The EI_GU data type is used to carry identifiers. The GU profile component requires that all entity identifiers be accompanied by assigning authorities. This allows the exchange of unique identifiers for the associated object across organizational and enterprise boundaries, enabling broad interoperability.

In the EI data type, the Namespace ID, Universal ID and Universal ID type correspond to the HD data type identified elsewhere. These types, together, are commonly considered the assigning authority for the identifier.

Conformance Statements: LRI_GU Profile

LRI-2: EI_GU.3 (Universal ID) **SHALL** be valued with an ISO-compliant OID.

LRI-3: EI_GU.4 (Universal ID Type) **SHALL** contain the value “ISO” drawn from the code system HL70301.

4.7.2 EI_NG – ENTITY IDENTIFIER (NON-GLOBALLY UNIQUE)

TABLE 4-12. ENTITY IDENTIFIER (EI_NG)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Entity Identifier	ST	R		
2	Namespace ID	IS	C(R/O)		Condition Predicate: If EI_NG.3 (Universal ID) is not valued.
3	Universal ID	ST	C(R/O)		Condition Predicate: If EI_NG.2 (Namespace ID) is not valued.
4	Universal ID Type	ID	C(R/X)	HL70301_USL	Condition Predicate: If EI_NG.3 (Universal ID) is valued.

Usage Note

The EI_NG data type accommodates identifiers that are not globally unique and therefore may not have the assigning authority (components 3-4) populated. Local arrangements determine how uniqueness is established.

4.8 EIP – Entity Identifier Pair

4.8.1 EIP_GU – ENTITY IDENTIFIER PAIR (GLOBALLY UNIQUE)

TABLE 4-13. ENTITY IDENTIFIER PAIR (EIP_GU)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Placer Assigned Identifier	EI_GU	RE		
2	Filler Assigned Identifier	EI_GU	C(R/RE)		Condition Predicate: If EIP_GU.1 is not valued.

4.8.2 EIP_NG – ENTITY IDENTIFIER PAIR (NON-GLOBALLY UNIQUE)

TABLE 4-14. ENTITY IDENTIFIER PAIR (EIP_NG)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Placer Assigned Identifier	EI_NG	RE		
2	Filler Assigned Identifier	EI_NG	C(R/RE)		Condition Predicate: if EIP_NG.1 is not valued.

4.9 ERL – Error Location

TABLE 4-15. ERROR LOCATION (ERL)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Segment ID	ST	R		
2	Segment Sequence	NM	R		Absolute position of this segment in the message (e.g. 3rd NTE in message, regardless of the number or type of intervening segments).
3	Field Position	NM	RE		Not used, when entire segment is referred to
4	Field Repetition	NM	RE		If not specified repetition is assumed 1
5	Component Number	NM	RE		Not used, when entire field is referred to
6	Sub-component Number	NM	RE		Not used, when entire component is referred to

4.10 FN – Family Name

TABLE 4-16. FAMILY NAME (FN)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Surname	ST	R		
2	Own Surname Prefix		O		
3	Own Surname		O		
4	Surname Prefix From Partner/Spouse		O		
5	Surname From Partner/Spouse		O		

4.11 FT – Formatted Text Data

TABLE 4-17. FORMATTED TEXT DATA (FT)					
SEQ	Component Name	DT	Usage	Value Set	Comments
	Formatted Text Data	-	R		

Usage Note

For NTE segments, or when this data type is used in OBX-2 (Value Type), one should consider that specific formatting (e.g., tabular data) may be included in either NTE-3 (Comment) or OBX-5 (Observation Value) based on a mono-spaced font. If the receiver must preserve this type of formatting, both parties must agree on how to preserve this mono-spaced font in the final display. The sender may not assume that such formatting is preserved without specific agreement with the receiver. The receiver is not obligated to conform to this guide to preserve that type of formatting.

The FT data type allows use of the formatting escape sequences documented in *HL7 Version 2.5.1, Chapter 2, Section 2.7.1 - Use of Escape Sequences in Text Fields*. In this Implementation Guide, the only allowed escape sequences are those allowed in *HL7 Version 2.5.1, Chapter 2, Section 2.7.4 - Special Characters*. These are the escape sequences for the message delimiters (i.e., |^&~\ or |^&~\#).

4.12 HD – Hierarchic Designator

4.12.1 HD_GU – HIERARCHIC DESIGNATOR (GLOBALLY UNIQUE)

TABLE 4-18. HIERARCHIC DESIGNATOR (HD_GU)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Namespace ID	IS	RE		The value of HD_GU.1 reflects a local code that represents the combination of HD_GU.2 and HD_GU.3.
2	Universal ID	ST	R		
3	Universal ID Type	ID	R		Fixed to “ISO”.

Usage Note

The HD data type is used directly to identify objects such as applications or facilities. It is used also as a component of other data types, where it is typically an assigning authority for an identifier. Where this capability is used in this specification, the usage is described separately.

Note that the HD data type has been constrained to carry an OID identifying an application, a facility, or an assigning authority.

Conformance Statements: LRI_GU Profile

LRI-4: HD_GU.2 (Universal ID) **SHALL** be valued with an ISO-compliant OID.

LRI-5: HD_GU.3 (Universal ID Type) **SHALL** contain the value "ISO" drawn from the code system HL70301.

4.12.2 HD_NG – HIERARCHIC DESIGNATOR (NON-GLOBALLY UNIQUE)

TABLE 4-19. HIERARCHIC DESIGNATOR (HD_NG)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Namespace ID	IS	C(R/O)		Condition Predicate: If HD_NG.2 (Universal ID) is not valued.
2	Universal ID	ST	C(R/O)		Condition Predicate: If HD_NG.1 (Namespace ID) is not valued.
3	Universal ID Type	ID	C(R/X)	HL70301_USL	Condition Predicate: If HD_NG.2 (Universal ID) is valued.

Usage Note

The actual value of and use of components must be negotiated between trading partners for each of the fields where this data type is used.

The HD_NG data type is used directly to identify objects such as applications or facilities. It is used also as a component of other data types, where it is typically an assigning authority for an identifier. Where this capability is used in this specification, the usage is described separately.

4.13 ID – Coded Value for HL7-Defined Tables

TABLE 4-20. CODED VALUE FOR HL7-DEFINED TABLES (ID)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Coded Value for HL7-Defined Tables	-	R		

4.14 IS – Coded Value for User-Defined Tables

TABLE 4-21. CODED VALUE FOR USER-DEFINED TABLES (IS)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Coded Value for User-Defined Tables	-	R		

4.15 MSG – Message Type

TABLE 4-22. MESSAGE TYPE (MSG)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Message Code	ID	R	HL70076_USL	
2	Trigger Event	ID	R	HL70003_USL	
3	Message Structure	ID	R	HL70354_USL	

4.16 NM – Numeric

TABLE 4-23. NUMERIC (NM)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Numeric	-	R		

4.17 OG - Observation Grouper

TABLE 4-24. OBSERVATION GROUPER (OG)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Original Sub-Identifier	ST	O		
2	Group	NM	R		
3	Sequence	NM	R		
4	Identifier	ST	RE		

4.18 PRL – Parent Result Link

Note: the OG data type is pre-adopted from V2.8.2.

TABLE 4-25. PARENT RESULT LINK (PRL)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Parent Observation Identifier	CWE_CR	R		
2	Parent Observation Sub-Identifier	OG	RE		
3	Parent Observation Value Descriptor		O		

Usage Note

See Section 8.1.1 Parent/Child Linking for details on how this data type and the EIP data type are used in parent/child result linking. Use of data type CWE_CR for sequence 1 reflects a pre-adoption of *HL7 Version 2.7.1* standard.

4.19 PT – Processing Type

TABLE 4-26. PROCESSING TYPE (PT)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Processing ID	ID	R	HL70103_USL	
2	Processing Mode		O		

4.20 SAD – Street address

TABLE 4-27. STREET ADDRESS (SAD)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Street or Mailing Address	ST	R		
2	Street Name		O		
3	Dwelling Number		O		

4.21 SI – Sequence ID

TABLE 4-28. SEQUENCE ID (SI)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Sequence ID	-	R		

4.22 SN – Structured Numeric

TABLE 4-29. STRUCTURED NUMERIC (SN)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Comparator	ST	RE		
2	Num1	NM	RE		
3	Separator/Suffix	ST	RE		
4	Num2	NM	RE		

Usage Note

The SN data type carries a structured numeric result value. Structured numeric values include intervals (^0^-^1), ratios (^1^/^2 or ^1^:^2), inequalities (<^10).

4.23 ST – String Data

TABLE 4-30. STRING DATA (ST)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	String Data	-	R		

Usage Note

The ST data type is normally used for short text strings. No leading blanks (space characters) are permitted. Trailing blanks are permitted. In this Implementation Guide, the only allowed escape sequences are those allowed in *HL7 Version 2.5.1, Chapter 2, Section 2.7.4 - Special Characters*. These are the escape sequences for the message delimiters (i.e., |^&~\ or |^&~\#).

When this data type is used in OBX-2 (Value Type), one should consider that formatting may be included in OBX-5(Observation Value) based on a monospaced font. If this type of formatting must be preserved by the receiver, both parties must agree on how to preserve this monospaced font in the final display. The sender may not assume that such formatting is preserved without specific agreement with the receiver. The receiver is not obligated to conform to this guide to preserve that type of formatting.

4.24 TM – Time

TABLE 4-31. TIME (TM)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Time	-	R		

4.25 TS – Time Stamp

4.25.1 TS_0 – TIME STAMP

TABLE 4-32. TIME STAMP (TS_0)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Time	DTM	R		
2	Degree of Precision	ID	X		Excluded for this Implementation Guide, see Section 1.3.1.
The DTM component of this Time Stamp has the following constraints:					
	YYYY	DTM	R		
	MM	DTM	O		
	DD	DTM	O		
	HH	DTM	O		
	MM	DTM	O		
	SS	DTM	O		
	[.S[S[S[S]]]]	DTM	O		
	+/- ZZZZ	DTM	O		

4.25.2 TS_1 – TIME STAMP

TABLE 4-33. TIME STAMP (TS_1)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Time	DTM	R		
2	Degree of Precision	ID	X		Excluded for this Implementation Guide, see Section 1.3.1.
The DTM component of this Time Stamp has the following constraints:					
	YYYY	DTM	R		
	MM	DTM	R		
	DD	DTM	R		
	HH	DTM	R		
	MM	DTM	R		
	SS	DTM	R		
	[.S[S[S[S]]]]		O		
	+/- ZZZZ		Varies		LAB_TO_Component Usage: 'R' All other profiles Usage: 'O'

4.25.3 TS_2 – TIME STAMP

TABLE 4-34. TIME STAMP (TS_2)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Time	DTM	R		

TABLE 4-34. TIME STAMP (TS_2)					
SEQ	Component Name	DT	Usage	Value Set	Comments
2	Degree of Precision	ID	X		Excluded for this Implementation Guide, see Section 1.3.1.
The DTM component of this Time Stamp has the following constraints:					
	YYYY	DTM	R		
	MM	DTM	RE		
	DD	DTM	RE		
	HH		O		
	MM		O		
	[SS[.S[S[S[S]]]]]		O		
	+/- ZZZZ		O		

4.25.4 TS_3 – TIME STAMP

TABLE 4-35. TIME STAMP (TS_3)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Time	DTM	R		
2	Degree of Precision	ID	X		Excluded for this Implementation Guide, see Section 1.3.1.
The DTM component of this Time Stamp has the following constraints:					
	YYYY	DTM	R		
	MM	DTM	RE		
	DD	DTM	RE		
	HH	DTM	RE		
	MM	DTM	RE		
	[SS[.S[S[S[S]]]]]		O		
	+/- ZZZZ	DTM	Varies		LAB_TO_Component Usage: 'RE' All other profiles Usage: 'O'

4.25.5 TS_4 – TIME STAMP

TABLE 4-36. TIME STAMP (TS_4)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Time	DTM	R		
2	Degree of Precision	ID	X		Excluded for this Implementation Guide, see Section 1.3.1.
The DTM component of this Time Stamp has the following constraints:					
	YYYY	DTM	R		
	MM	DTM	C(R/X)		Condition Predicate: If TS_4.1 (YYYY) is not valued '0000'.
	DD	DTM	C(R/X)		Condition Predicate: If TS_4.1 (YYYY) is not valued '0000'.
	HH	DTM	C(RE/X)		Condition Predicate: If TS_4.1 (YYYY) is not valued '0000'.

TABLE 4-36. TIME STAMP (TS_4)					
SEQ	Component Name	DT	Usage	Value Set	Comments
	MM	DTM	C(RE/X)		Condition Predicate: If TS_4.1 (YYYY) is not valued '0000'.
	[SS[.S[S[S[S]]]]]	DTM	C(O/X)		Condition Predicate: If TS_4.1 (YYYY) is not valued '0000'.
	+/- ZZZZ	DTM	Varies		LAB_TO_Component Usage: 'RE' All other profiles Usage: 'O'

Usage Note

When the time is not known, then use YYYY = '0000' and leave everything else empty.

4.25.6 TS_5 – TIME STAMP

TABLE 4-37. TIME STAMP (TS_5)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Time	DTM	R		
2	Degree of Precision	ID	X		Excluded for this Implementation Guide, see Section 1.3.1.
The DTM component of this Time Stamp has the following constraints:					
	YYYY	DTM	R		
	MM	DTM	R		
	DD	DTM	R		
	HH	DTM	RE		
	MM	DTM	RE		
	[SS[.S[S[S[S]]]]]		O		
	+/- ZZZZ		Varies		LAB_TO_Component Usage: 'RE' All other profiles Usage: 'O'

4.25.7 TS_6 – TIME STAMP

TABLE 4-38. TIME STAMP (TS_6)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Time	DTM	R		
2	Degree of Precision	ID	X		Excluded for this Implementation Guide, see Section 1.3.1.
The DTM component of this Time Stamp has the following constraints:					
	YYYY	DTM	R		
	MM	DTM	R		
	DD	DTM	R		
	HH	DTM	R		
	MM	DTM	R		
	[SS.S[S[S[S]]]]		O		
	+/- ZZZZ		Varies		LAB_TO_Component Usage: 'R' All other profiles Usage: 'O'

4.26 TX – Text Data

TABLE 4-39. TEXT DATA (TX)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Text Data	-	R		

Usage Note

The TX data type is used to carry string data intended for display purposes. It can contain leading blanks (space characters). In this Implementation Guide, the only allowed escape sequences are those allowed in HL7 Version 2.5.1, Chapter 2, Section 2.7.4 - Special Characters. These are the escape sequences for the message delimiters (i.e., |^&~\ or |^&~\#).

When this data type is used in OBX-2 (Value Type), one should consider that formatting may be included in OBX-5 (Observation Value) based on a mono-spaced font. If the receiver must preserve this type of formatting, both parties must agree on how to preserve this mono-spaced font in the final display. The sender may not assume that such formatting is preserved without specific agreement with the receiver. The receiver is not obligated to conform to this guide to preserve that type of formatting.

4.27 VID – Version Identifier

TABLE 4-40. VERSION IDENTIFIER (VID)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Version ID	ID	R	HL70104_USL	
2	Internationalization Code		O		
3	International Version ID		O		

4.28 XAD – Extended Address

TABLE 4-41. EXTENDED ADDRESS (XAD)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Street Address	SAD	RE		
2	Other Designation	ST	RE		
3	City	ST	RE		
4	State or Province	ST	RE	USPS_USL	
5	Zip or Postal Code	ST	RE		.
6	Country Code	ID	RE	HL70399_USL	Use 3-character (alphabetic) form of ISO 3166 for HL7 Table 0399 as defined in HL7 Chapter 2, Section 2.15.9.17.
7	Address Type	ID	RE	HL70190_USL	
8	Other Geographic Designation		O		
9	County/Parish Code	IS	RE	FIPS_6-4	
10	Census Tract		O		

TABLE 4-41. EXTENDED ADDRESS (XAD)					
SEQ	Component Name	DT	Usage	Value Set	Comments
11	Address Representation Code		O		
12	Address Validity Range		X		Excluded for this Implementation Guide, see Section 1.3.1.
13	Effective Date		O		
14	Expiration Date		O		

4.29 XCN – Extended Composite ID Number and Name for Persons

4.29.1 XCN_GU – EXTENDED COMPOSITE ID NUMBER AND NAME FOR PERSONS (GLOBALLY UNIQUE)

TABLE 4-42. EXTENDED COMPOSITE ID NUMBER AND NAME FOR PERSONS (XCN_GU)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	ID Number	ST	RE		The ID Number component combined with the Assigning Authority (XCN_GU.9) must uniquely identify the associated person. **Note:** Despite the component being named "ID Number" this component is an ST string data type, not numeric, so the component is not limited to just numbers.
2	Family Name	FN	RE		
3	Given Name	ST	RE		I.e., first name.
4	Second and Further Given Names or Initials Thereof	ST	RE		
5	Suffix (e.g., JR or III)	ST	RE		
6	Prefix (e.g., DR)	ST	RE		
7	Degree (e.g., MD)	IS	X		Excluded for this Implementation Guide, see Section 1.3.1.
8	Source Table		O		
9	Assigning Authority	HD_GU	C(R/X)		Condition Predicate: If XCN_GU.1 (ID Number) is valued. The Assigning Authority component is used to identify the system, application, organization, etc. that assigned the ID Number in component 1.
10	Name Type Code	ID	RE	HL70200_USL	
11	Identifier Check Digit		O		
12	Check Digit Scheme	ID	C(O/X)		Note that the condition predicate will be established when this profile is constrained further.
13	Identifier Type Code	ID	C(R/X)	HL70203_USL	Condition Predicate: If XCN_GU.1 (ID Number) is valued.

TABLE 4-42. EXTENDED COMPOSITE ID NUMBER AND NAME FOR PERSONS (XCN_GU)					
SEQ	Component Name	DT	Usage	Value Set	Comments
14	Assigning Facility		O		
15	Name Representation Code		O		
16	Name Context		O		
17	Name Validity Range		X		Excluded for this Implementation Guide, see Section 1.3.1.
18	Name Assembly Order		O		
19	Effective Date		O		
20	Expiration Date		O		
21	Professional Suffix		O		
22	Assigning Jurisdiction		O		
23	Assigning Agency or Department		O		

4.29.2 XCN_NG – EXTENDED COMPOSITE ID NUMBER AND NAME FOR PERSONS (NON-GLOBALLY UNIQUE)

TABLE 4-43. EXTENDED COMPOSITE ID NUMBER AND NAME FOR PERSONS (XCN_NG)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	ID Number	ST	RE		**Note:** Despite the component being named "ID Number" this component is an ST string data type, not numeric, so the component is not limited to just numbers.
2	Family Name	FN	RE		
3	Given Name	ST	RE		I.e., first name.
4	Second and Further Given Names or Initials Thereof	ST	RE		
5	Suffix (e.g., JR or III)	ST	RE		
6	Prefix (e.g., DR)	ST	RE		
7	Degree (e.g., MD)		X		Excluded for this Implementation Guide, see Section 1.3.1.
8	Source Table		O		
9	Assigning Authority	HD_NG	C(RE/X)		Condition Predicate: If XCN_NG.1 (ID Number) is valued. The Assigning Authority component is used to identify the system, application, organization, etc. that assigned the ID Number in component 1.
10	Name Type Code	ID	RE	HL70200_USL	
11	Identifier Check Digit		O		

TABLE 4-43. EXTENDED COMPOSITE ID NUMBER AND NAME FOR PERSONS (XCN_NG)					
SEQ	Component Name	DT	Usage	Value Set	Comments
12	Check Digit Scheme	ID	C(O/X)		Note that the condition predicate will be established when this profile is constrained further.
13	Identifier Type Code	ID	C(R/X)	HL70203_USL	Condition Predicate: If XCN_NG.1 (ID Number) is valued.
14	Assigning Facility		O		
15	Name Representation Code		O		
16	Name Context		O		
17	Name Validity Range		X		Excluded for this Implementation Guide, see Section 1.3.1.
18	Name Assembly Order		O		
19	Effective Date		O		
20	Expiration Date		O		
21	Professional Suffix		O		
22	Assigning Jurisdiction		O		
23	Assigning Agency or Department		O		

4.30 XON – Extended Composite Name and Identification Number for Organizations

4.30.1 XON_GU – EXTENDED COMPOSITE NAME AND IDENTIFICATION NUMBER FOR ORGANIZATIONS (GLOBALLY UNIQUE)

TABLE 4-44. EXTENDED COMPOSITE NAME AND IDENTIFICATION NUMBER FOR ORGANIZATIONS (XON_GU)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Organization Name	ST	RE		
2	Organization Name Type Code		O		
3	ID Number		X		Excluded for this Implementation Guide, see Section 1.3.1.
4	Check Digit		O		
5	Check Digit Scheme		C(O/X)		
6	Assigning Authority	HD_GU	C(R/X)		Condition Predicate: If XON_GU.10 (Organization Identifier) is valued. The Assigning Authority component is used to identify the system, application, organization, etc. that assigned the ID in component 10.
7	Identifier Type Code	ID	C(R/X)	HL70203_USL	Condition Predicate: If XON_GU.10 (Organization Identifier) is valued.

TABLE 4-44. EXTENDED COMPOSITE NAME AND IDENTIFICATION NUMBER FOR ORGANIZATIONS (XON_GU)					
SEQ	Component Name	DT	Usage	Value Set	Comments
8	Assigning Facility		O		
9	Name Representation Code		O		
10	Organization Identifier	ST	C(R/RE)		Condition Predicate: If XON_GU.1 (Organization Name) is not valued.

Usage Note

Both XON.1 and XON.10 may be populated, but at least one of them must be valued.

4.30.2 XON_NG – EXTENDED COMPOSITE NAME AND IDENTIFICATION NUMBER FOR ORGANIZATIONS (NON-GLOBALLY UNIQUE)

TABLE 4-45. EXTENDED COMPOSITE NAME AND IDENTIFICATION NUMBER FOR ORGANIZATIONS (XON_NG)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Organization Name	ST	RE		
2	Organization Name Type Code		O		
3	ID Number		X		Excluded for this Implementation Guide, see Section 1.3.1.
4	Check Digit		O		
5	Check Digit Scheme	ID	C(O/X)		Note that the condition predicate will be established when this profile is constrained further.
6	Assigning Authority	HD_NG	C(RE/X)		Condition Predicate: If XON_NG.10 (Organization Identifier) is valued. The Assigning Authority component is used to identify the system, application, organization, etc. that assigned the ID in component 10.
7	Identifier Type Code	ID	C(R/X)	HL70203_USL	Condition Predicate: If XON_NG.10 (Organization Identifier) is valued.
8	Assigning Facility		O		
9	Name Representation Code		O		
10	Organization Identifier	ST	C(R/RE)		Condition Predicate: If XON_NG.1 (Organization Name) is not valued.

Usage Note

Both XON.1 and XON.10 may be populated, but at least one of them must be valued.

4.31 XPN – Extended Person Name

TABLE 4-46. EXTENDED PERSON NAME (XPN)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Family Name	FN	RE		
2	Given Name	ST	RE		I.e., first name.
3	Second and Further Given Names or Initials Thereof	ST	RE		
4	Suffix (e.g., JR or III)	ST	RE		
5	Prefix (e.g., DR)		O		
6	Degree (e.g., MD)		X		Excluded for this Implementation Guide, see Section 1.3.1.
7	Name Type Code	ID	R	HL70200_USL	
8	Name Representation Code		O		
9	Name Context		O		
10	Name Validity Range		X		Excluded for this Implementation Guide, see Section 1.3.1.
11	Name Assembly Order		O		
12	Effective Date		O		
13	Expiration Date		O		
14	Professional Suffix		O		

5 MESSAGES

The following sections detail the structure of each message, including segment name, usage, cardinality and description, as well as the definition of each segment used in the message structure.

Note that the first column (Segment) is listing the cardinality and optionality according to the base standard, the second column (Name) provides the segment or group name from the base standard, while the remaining columns (Usage, Cardinality, Description) define the constraints for this Implementation Guide. It is therefore possible that the base standard defines a segment as optional with a cardinality of up to 1, while this Implementation Guide defines the segment in the Usage column as R thus a cardinality of [1..1].

5.1 ORU^R01^ORU_R01

The ORU^R01 message is constrained for transmitting laboratory results from the testing source to the Receiver as defined in each Use Case.

TABLE 5-1. ORU^R01^ORU_R01 ABSTRACT MESSAGE SYNTAX

Segment	Name	Usage	Cardinality	Description
MSH	Message Header	R	[1..1]	The message header (MSH) segment contains information describing how to parse and process the message. This includes identification of message delimiters, sender, receiver, message type, timestamp, etc.
[{SFT}]	Software Segment	O		
{	***PATIENT_RESULT Begin***	R	[1..1]	
[	***PATIENT Begin***	R	[1..1]	
PID	Patient Identification	R	[1..1]	The patient identification (PID) segment is used to provide basic demographics regarding the subject of the testing. The subject shall be a person.
[PD1]	Additional Demographics	O		
[{NTE}]	Notes and Comments for PID	O		
[{NK1}]	Next of Kin/Associated Parties	O		
[	***VISIT Begin***	O		
PV1	Patient Visit	R	[1..1]	HL7 requires that the patient visit (PV1) segment be present if the VISIT group is present.
[PV2]	Patient Visit – Additional Information	O		
]	***VISIT End***			
]	***PATIENT End***			

TABLE 5-1. ORU^R01^ORU_R01 ABSTRACT MESSAGE SYNTAX				
Segment	Name	Usage	Cardinality	Description
{	***ORDER_OBSERVATION Begin***	R	[1..*]	The ORDER_OBSERVATION is required and can repeat.
[ORC]	Order Common	R	[1..1]	The common order (ORC) segment identifies basic information about the order for testing of the specimen. This segment includes identifiers of the order, who placed the order, when it was placed, what action to take regarding the order, etc.
OBR	Observations Request	R	[1..1]	The observation request (OBR) segment is used to capture information about one test being performed on the specimen. Most importantly, the OBR identifies the type of testing to be performed on the specimen, and ties that information to the order for the testing.
[{NTE}]	Notes and Comments for OBR	RE	[0..*]	
[{	***TIMING_QTY Begin***	RE	[0..1]	
TQ1	Timing/Quantity	R	[1..1]	
[{TQ2}]	Timing/Quantity Order Sequence	O		
}]	***TIMING_QTY End***			
[CTD]	Contact Data	O		
[{	***OBSERVATION Begin***	C(R/O)	[0..*]	Condition Predicate: If OBR-25 (Result Status) is valued 'A', 'C', 'F', 'P', or 'M'. Multiple Observation groups, each containing a single OBX and a potentially repeating NTE, may be associated with a single order.
OBX	Observation related to OBR	R	[1..1]	The observation/result (OBX) segment contains information regarding a single observation (analyte) result. This includes identification of the specific type of observation, the result for the observation, when the observation was made, etc.
[{NTE}]	Notes and Comments	RE	[0..*]	The notes and comment (NTE) segment may carry comments related to the result being reported in the OBX segment.
}]	***OBSERVATION End***			
[{FTI}]	Financial Transaction	O		
{[CTI]}	Clinical Trial Identification	O		
[{	***SPECIMEN Begin***	RE	[0..*]	The specimen group is required if known in the ORU and is used to carry specimen information that is no longer contained in the OBR segment. Each specimen group documents a single sample.
SPM	Specimen Information related to OBR	R	[1..1]	The specimen information (SPM) segment describes the characteristics of a single sample. The SPM segment carries information regarding the type of specimen, where and how it was collected, and some basic characteristics of the specimen.

TABLE 5-1. ORU^R01^ORU_R01 ABSTRACT MESSAGE SYNTAX				
Segment	Name	Usage	Cardinality	Description
[{OBX}]	Observation related to Specimen	O		
}]	***SPECIMEN End***			
}	***ORDER_ OBSERVATION End***			
}	***PATIENT_RESULT End***			
[DSC]	Continuation Pointer	X		Excluded for this Implementation Guide, see Section 1.3.1.

5.2 ACK^R01^ACK

There are two kinds of Acknowledgement messages in use in the LRI guide – the Accept Acknowledgement and the Application Acknowledgement – both use the same message structure.

They can be differentiated by the value used in MSA-1: Accept Acknowledgments will use “CA” or “CR”, while Application Acknowledgments will use “AA”, AR” or “AE”.

TABLE 5-2. ACK^R01^ACK ABSTRACT MESSAGE SYNTAX				
Segment	Name	Usage	Cardinality	Description
MSH	Message Header	R	[1..1]	The message header (MSH) segment contains information describing how to parse and process the message. This includes identification of message delimiters, sender, receiver, message type, timestamp, etc.
[{SFT}]	Software Segment	O		
MSA	Message Acknowledgment	R	[1..1]	The Message Acknowledgment Segment (MSA) contains the information sent as acknowledgment to the result message received by an EHR-S.
[{ ERR }]	Error	C(R/O)	[0..*]	Condition predicate: If MSA-1 (Message Acknowledgement) is not valued ‘AA’ or ‘CA’.

5.3 Segment and Field Descriptions

This messaging guide provides notes for required (non-optional) fields for each of the non-optional segments. For each segment the segment table defines the applicable constraints on usage for its fields for this Implementation Guide (see Section 1.3.2 Message Element Attributes for a description of the columns in the Segment Attribute Tables.) All the relevant conformance statements and general usage notes are located at the end of each table.

Note that any optional segments that are brought forward from the base will have to be used within the constraints set forth in this guide, e.g., constraint statements will be required to use the GU or NG profile components, and agreement about which data type flavors to use (e.g., CWE_CRE or CWE_CR) needs to be reached.

5.3.1 MSH – MESSAGE HEADER SEGMENT

TABLE 5-3. MESSAGE HEADER SEGMENT (MSH)

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Field Separator	ST	R	[1..1]		
2	Encoding Characters	ST	R	[1..1]		
3	Sending Application	Varies	RE	[0..1]	HL70361_USL	GU data type: HD_GU NG data type: HD_NG
4	Sending Facility	Varies	R	[1..1]	HL70362_USL	GU data type: HD_GU NG data type: HD_NG This facility will receive any related acknowledgment message.
5	Receiving Application		O			
6	Receiving Facility	Varies	RE	[0..1]	HL70362_USL	GU data type: HD_GU NG data type: HD_NG This facility originates any related acknowledgment message.
7	Date/Time Of Message	TS_1	R	[1..1]		If the time zone offset is included in MSH-7 it becomes the default time zone for the message instance and applies to all other date/time fields in that same message instance where a time zone offset is not valued, except as otherwise indicated through the use of the LAB_TO_Component profile as defined in Section 3.3.9 in MSH-21 (Message Profile Identifier).
8	Security		O			
9	Message Type	MSG	R	[1..1]		
10	Message Control ID	ST	R	[1..1]		String that identifies the message instance from the sending application. Example formats for message control IDs include GUID, timestamp plus sequence number, OID plus sequence number or sequence number. The important point is that care must be taken to ensure that the message control id is unique within the system originating the message.
11	Processing ID	PT	R	[1..1]		
12	Version ID	VID	R	[1..1]		HL7 version number used to interpret format and content of the message. Note that receivers must examine MSH-21 (Message Profile Identifier) to understand which message profile the message instance conforms with.
13	Sequence Number		O			
14	Continuation Pointer		O			

TABLE 5-3. MESSAGE HEADER SEGMENT (MSH)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
15	Accept Acknowledgment Type	ID	R	[1..1]	HL70155_USL	The value set constraints are described in Sections 2.6.1.1 for the ORU, 2.6.1.4 for the Accept Acknowledgement, and 2.6.1.5 for the Application Acknowledgment.
16	Application Acknowledgment Type	ID	R	[1..1]	HL70155_USL	The value set constraints are described in Sections 2.6.1.1 for the ORU, 2.6.1.4 for the Accept Acknowledgement, and 2.6.1.5 for the Application Acknowledgment.
17	Country Code		O			
18	Character Set		O			
19	Principal Language Of Message		O			
20	Alternate Character Set Handling Scheme		O			
21	Message Profile Identifier	EI_GU	R	[1..*]		The sender asserts that the message conforms to a given profile and/or valid combination of components.

5.3.1.1 LRI RESULT PROFILE COMBINATIONS

The MSH-21 field shall identify exclusively one lab result interface profile and shall not be populated with conflicting LRI profiles or LRI profile components. Additional compatible profiles or components can be present in MSH-21; for example, if an LRI profile or profile component is further constrained.

The sequence of the elements in MSH-21 is not important and cannot be relied on. To improve readability, implementers are encouraged to start with the base lab result ID followed by additional profiles and/or profile component IDs that add constraints.

The table below indicates valid MSH-21 combinations for declaring conformance to a particular pre-coordinated LRI profile or the equivalent set of profile components.

TABLE 5-4. MSH 21 PROFILE COMBINATIONS			
LRI Profile	Pre-Coordinated OID	Profile Component OIDs	Component Name
LRI_GU_FRU_Profile	2.16.840.1.113883.9.195.3.1	2.16.840.1.113883.9.16	LRI_Common_Component
		2.16.840.1.113883.9.12	LRI_GU_Component
		2.16.840.1.113883.9.83	LAB_FRU_Component

TABLE 5-4. MSH 21 PROFILE COMBINATIONS			
LRI Profile	Pre-Coordinated OID	Profile Component OIDs	Component Name
LRI_GU_FRN_Profile	2.16.840.1.113883.9.195.3.2	2.16.840.1.113883.9.16 2.16.840.1.113883.9.12 2.16.840.1.113883.9.84	LRI_Common_Component LRI_GU_Component LAB_FRN_Component
LRI_NG_FRU_Profile	2.16.840.1.113883.9.195.3.3	2.16.840.1.113883.9.16 2.16.840.1.113883.9.13 2.16.840.1.113883.9.83	LRI_Common_Component LRI_NG_Component LAB_FRU_Component
LRI_NG_FRN_Profile	2.16.840.1.113883.9.195.3.4	2.16.840.1.113883.9.16 2.16.840.1.113883.9.13 2.16.840.1.113883.9.84	LRI_Common_Component LRI_NG_Component LAB_FRN_Component

For each of the combinations illustrated, the following additional profile component identifiers may be specified:

- LAB_TO_Component – 2.16.840.1.113883.9.22
- LAB_XO_Component – 2.16.840.1.113883.9.23
- LAB_NB_Component – 2.16.840.1.113883.9.24
- LAB_PRU_COMPONENT – 2.16.840.1.113883.9.82
- LAB_PRN_COMPONENT – 2.16.840.1.113883.9.81
- LRI_PH_COMPONENT – 2.16.840.1.113883.9.195.3.5

Example: LRI_NG_FRN_Profile Using Component OIDs

```
MSH…|||||LRI_Common_Component^^2.16.840.1.113883.9.16^ISO~LRI_NG_Component^^2.16.840.
1.113883.9.13^ISO~LAB_FRN_Component^^2.16.840.1.113883.9.84^ISO
```

Example: LRI_NG_FRN_Profile Pre-Coordinated Profile OID

```
MSH…|||||LRI_NG_FRN_Profile^^2.16.840.1.113883.9.195.3.4^ISO
```

Example: LRI_NG_FRN_Profile using Pre-Coordinated Profile OID and the LAB_NB_Component

```
MSH…||||LRI_NG_FRN_Profile^^2.16.840.1.113883.9.195.3.4^ISO~LAB_NB_Component^^2.16.8
40.1.113883.9.24^ISO
```

Conformance Statements: LRI_Common_Component

LRI-6: MSH-1 (Field Separator) **SHALL** contain the constant value '|'.

LRI-7: MSH-2 (Encoding Characters) **SHALL** contain the constant value '^~\&' or the constant value '^~\&#'.

LRI-72: MSH-9.1 (Message Type.Message Code) **SHALL** contain the constant value 'ORU_R01' drawn from the code system HL70076.

LRI-73: MSH-9.2 (Message Type.Event Trigger) **SHALL** contain the constant value 'R01' drawn from the code system HL70003.

LRI-8: MSH-9.3 (Message Type.Message Structure) **SHALL** contain the constant value 'ORU_R01' drawn from the code system HL70354.

LRI-9: MSH-12.1 (Version ID.Version ID) **SHALL** contain the constant value '2.5.1' drawn from code system HL70104.

Conformance Statements: LRI_GU_FRU_Profile

LRI-10: An occurrence of MSH-21 (Message Profile Identifier) **SHALL** be valued with '2.16.840.1.113883.9.195.3.1' (LRI_GU_FRU_Profile) or three occurrences **SHALL** be valued with '2.16.840.1.113883.9.16 (LRI_Common_Component), '2.16.840.1.113883.9.12' (LRI_GU_Component) and '2.16.840.1.113883.9.83' (LAB_FRU_Component) in any order.

Note: Additional occurrences of MSH-21 (Message Profile Identifier) may be valued with '2.16.840.1.113883.9.81' (LAB_PRN_Component) **OR** '2.16.840.1.113883.9.82' (LAB_PRU_Component) and/or '2.16.840.1.113883.9.22' (LAB_TO_Component), and/or '2.16.840.1.113883.9.23' (LAB_XO_Component), and/or '2.16.840.1.113883.9.24' (LAB_NB_ Component) and/or 2.16.840.1.113883.9.195.3.5 (LRI_PH_Component).

Conformance Statements: LRI_GU_FRN_Profile

LRI-56: An occurrence of MSH-21 (Message Profile Identifier) **SHALL** be valued with '2.16.840.1.113883.9.195.3.2' (LRI_GU_FRN_Profile) or three occurrences **SHALL** be valued with '2.16.840.1.113883.9.16 (LRI_Common_Component), '2.16.840.1.113883.9.12' (LRI_GU_Component) and '2.16.840.1.113883.9.84' (LAB_FRN_Component) in any order.

Note: Additional occurrences of MSH-21 (Message Profile Identifier) may be valued with '2.16.840.1.113883.9.81' (LAB_PRN_Component) **OR** '2.16.840.1.113883.9.82' (LAB_PRU_Component) and/or '2.16.840.1.113883.9.22' (LAB_TO_Component), and/or '2.16.840.1.113883.9.23' (LAB_XO_Component), and/or '2.16.840.1.113883.9.24' (LAB_NB_ Component) and/or 2.16.840.1.113883.9.195.3.5 (LRI_PH_Component).

Conformance Statements: LRI_NG_FRU_Profile

LRI-11: An occurrence of MSH-21 (Message Profile Identifier) **SHALL** be valued with '2.16.840.1.113883.9.195.3.3' (LRI_NG_FRU_Profile) or three occurrences **SHALL** be valued with '2.16.840.1.113883.9.16' (LRI_Common_Component), '2.16.840.1.113883.9.13' (LRI_NG_Component) and '2.16.840.1.113883.9.83' (LAB_FRU_Component) in any order.

Note: Additional occurrences of MSH-21 (Message Profile Identifier) may be valued with '2.16.840.1.113883.9.81' (LAB_PRN_Component) **OR** '2.16.840.1.113883.9.82' (LAB_PRU_Component) and/or '2.16.840.1.113883.9.22' (LAB_TO_Component), and/or '2.16.840.1.113883.9.23' (LAB_XO_Component), and/or '2.16.840.1.113883.9.24' (LAB_NB_ Component) and/or 2.16.840.1.113883.9.195.3.5 (LRI_PH_Component).

Conformance Statements: LRI_NG_FRN_Profile

LRI-12: An occurrence of MSH-21 (Message Profile Identifier) **SHALL** be valued with '2.16.840.1.113883.9.195.3.4' (LRI_NG_FRN_Profile) or three occurrences **SHALL** be valued with '2.16.840.1.113883.9.16' (LRI_Common_Component), '2.16.840.1.113883.9.13' (LRI_NG_Component) and '2.16.840.1.113883.9.84' (LAB_FRN_Component) in any order.

Note: Additional occurrences of MSH-21 (Message Profile Identifier) may be valued with '2.16.840.1.113883.9.81' (LAB_PRN_Component) **OR** '2.16.840.1.113883.9.82' (LAB_PRU_Component) and/or '2.16.840.1.113883.9.22 (LRI_TO_Component) and/or 2.16.840.1.113883.9.23 (LAB_XO_Component), and/or 2.16.840.1.113883.9.24 (LAB_NB_ Component) and/or 2.16.840.1.113883.9.195.3.5 (LRI_PH_Component).

5.3.1.2 LRI ACKNOWLEDGEMENT COMPONENTS

When the initial results transaction uses the GU profile in MSH.21 (Message Profile Identifier) this means that a defined set of fields, including MSH-3 (Sending Application), MSH-4 (Sending Facility), and MSH-6 (Receiving Facility), are considered globally unique by the sender. Therefore, when providing an accept acknowledgement to that result transaction and the acknowledgement uses the exact same values from MSH-3, MSH-4, and MSH-6 to populate the appropriate MSH fields in the acknowledgement message and any fields under the control of the acknowledgement transaction sender are also globally unique, then MSH-21 can assert that the GU profile is used.

As long as MSH-3, MSH-4, and/or MSH-6 are echoed back as-is and MSH-21 indicates the use of the GU profile, it is not necessary to validate that MSH-3, MSH-4, and/or MSH-6 are, in fact, unique.

When the acknowledgement sender populates fields referenced by the GU profile without using MSH-3, MSH-4, and MSH-6 originally received then the acknowledgement sender has all the knowledge to determine whether their values are considered globally unique or not and can populate MSH-21 accordingly.

The table below indicates valid MSH-21 combinations for declaring conformance to a particular pre-coordinated LRI acknowledgement profile or its equivalent set of profile components.

TABLE 5-5. MSH 21 ACKNOWLEDGMENT PROFILE COMBINATIONS			
LRI Profile	Pre-Coordinated OID	Profile Component OIDs	Component Name
LRI_GU_Response_Profile	2.16.840.1.113883.9.28	2.16.840.1.113883.9.26 2.16.840.1.113883.9.21	LRI_Acknowledgement_Component GU_Acknowledgement_Component
LRI_NG_Response_Profile	2.16.840.1.113883.9.27	2.16.840.1.113883.9.26 2.16.840.1.113883.9.25	LRI_Acknowledgement_Component NG_Acknowledgement_Component

Conformance Statements: LRI_Acknowledgement_Component

LRI-13: MSH-1 (Field Separator) **SHALL** contain the constant value '|'.

LRI-14: MSH-2 (Encoding Characters) **SHALL** contain the constant value '^~\&' or the constant value '^~\&#'.

LRI-15: MSH-9 (Message Type) **SHALL** contain the constant value 'ACK^R01^ACK'.

LRI-16: MSH-12.1 (Version ID) **SHALL** contain the constant value '2.5.1'.

Conformance Statements: GU_Acknowledgement_Component

LRI-18: MSH-21 (Message Profile Identifier) **SHALL** be valued with '2.16.840.1.113883.9.21' (GU_Acknowledgment_Profile) when acknowledging ORU GU Profiles where MSH-21 contains '2.16.840.1.113883.9.195.3.1' (LRI_GU_FRU_Profile), or '2.16.840.1.113883.9.195.3.2' (LRI_GU_FRN_Profile), or '2.16.840.1.113883.9.12' (LRI_GU_Component).

Conformance Statements: NG_Acknowledgement_Component

LRI-19: MSH-21 (Message Profile Identifier) **SHALL** be valued with '2.16.840.1.113883.9.25' (NG_Acknowledgment_Profile) when acknowledging LRI IG conformant results messages ORU NG Profiles where MSH-21 contains '2.16.840.1.113883.9.195.3.3' (LRI_NG_FRU_Profile), or '2.16.840.1.113883.9.195.3.4' (LRI_NG_FRN_Profile), or '2.16.840.1.113883.9.13' (LRI_NG_Component).

5.3.2 MSA – ACKNOWLEDGEMENT SEGMENT

TABLE 5-6. ACKNOWLEDGMENT SEGMENT (MSA)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Acknowledgment Code	ID	R	[1..1]	HL70008_USL	
2	Message Control ID	ST	R	[1..1]		
3	Text Message		X			Excluded for this Implementation Guide, see Section 1.3.1.
4	Expected Sequence Number		O			

TABLE 5-6. ACKNOWLEDGMENT SEGMENT (MSA)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
5	Delayed Acknowledgment Type		X			Excluded for this Implementation Guide, see Section 1.3.1.
6	Error Condition		X			Excluded for this Implementation Guide, see Section 1.3.1.

5.3.3 ERR – ERROR SEGMENT

TABLE 5-7. ERROR SEGMENT (ERR)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Error Code and Location		X			Excluded for this Implementation Guide, see Section 1.3.1.
2	Error Location	ERL	RE	[0..1]		To reduce ambiguity, each error will have an individual ERR segment.
3	HL7 Error Code	CWE_CR1	R	[1..1]	HL70357_USL	Used to identify issues based on conformance profile in message (structure and vocabulary) or to indicate an application error was identified and is communicated in ERR-5 (Application Error Code).
4	Severity	ID	R	[1..1]	HL70516_USL	
5	Application Error Code	CWE_CR1	C(R/O)	[0..1]	HL70533_USL	Condition Predicate: If ERR-3.1 (Identifier) is valued '999'. Used to indicate error in content; there is nothing wrong with the message structure, but system cannot use the data.
6	Application Error Parameter		O			
7	Diagnostic Information	TX	R	[1..1]		Use to help IT personnel fix the error. Gives additional detail to ERR-3 (HL7 Error Code) and ERR-5 (Application Error Code).
8	User Message	TX	R	[1..1]		Use to display error/instructions to user of the system. Information may differ from that in ERR-7 (Diagnostic Information).
9	Inform Person Indicator		O			
10	Override Type		O			
11	Override Reason Code		O			
12	Help Desk Contact Point		O			

Usage Note

ERR-2.2 (Error Location.Segment Sequence)

Identifies the occurrence of the segment identified in ERR-2.1 (Error Location.Segment ID) within the message. The following example illustrates how ERR-2.2 (Error Location.Segment Sequence) is valued '3' since the error occurred in the third occurrence of an NTE segment. Note that this is not the same as the segment's Set ID element.

Example ERL data type: |NTE^3|

```
MSH...
...
ORC|RE|...
OBR|1|...
OBX|1|...
NTE|1|...
NTE|2|...
OBX|2|...
NTE|1|... ***invalid NTE segment***
SPM|1|...
```

Message sent / received

Bold text indicates errors

```
MSH|^~\&#|||LIS^2.16.840.1.113883.19^ISO|||20150901104930||ORU^R01^ORU_R01|1234567890
|…..
PID|1|…..
ORC|XY|…..
OBR|1|…..
OBX|1|…..
OBX|2|…..
OBX|3|…..
ORC|RE|…..
OBR|2||12345|abc^^LNC|…..
OBX|1|…..
OBX|2|…..
OBX|3|…..
ORC|RE|…..
OBR|3|…..
OBX|1|…..
OBX|2|…..
OBX|3|DT|xyz^^LN|…..
```

Application Level Response

```
MSH|^~\&#|||EHR^2.16.840.1.113883.20^ISO|||20150901105030||ACK^R01^ACK|9876543210|…..
MSA|AE|1234567890|…..
ERR||ORC^1|203|E|||Control code XY is not supported.||
ERR||OBR^2^4|999|E|201||Coding system LNC is not supported.||
ERR||OBX^9^3^^1|999|E|201||xyz was not found|We do not support xyz|
```

5.3.4 PID – PATIENT IDENTIFICATION SEGMENT

TABLE 5-8. PATIENT IDENTIFICATION SEGMENT (PID)

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Set ID – PID	SI	R	[1..1]		

TABLE 5-8. PATIENT IDENTIFICATION SEGMENT (PID)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
2	Patient ID		X			Excluded for this Implementation Guide, see Section 1.3.1.
3	Patient Identifier List	Varies	R	[1..*]		GU data type: CX_GU NG data type: CX_NG
4	Alternate Patient ID – PID		X			Excluded for this Implementation Guide, see Section 1.3.1.
5	Patient Name	XPN	R	[1..1]		
6	Mother's Maiden Name		O			
7	Date/Time of Birth	Varies	RE	[0..1]		Base Profile: TS_2 LAB_NB Profile: TS_3 Note: If NB Screening profile component is used, then TO profile component applies.
8	Administrative Sex	IS	R	[1..1]	HL70001_USL	Patient's gender.
9	Patient Alias		X			Excluded for this Implementation Guide, see Section 1.3.1.
10	Race	CWE_CR1	RE	[0..*]	HL70005_USL	Note that state and/or national regulations may dictate other behaviors, e.g., may prohibit the collection of this data. The PID-10 (Race) value is provided for demographic/billing purposes, not clinical use.
11	Patient Address		O			
12	County Code		X			Excluded for this Implementation Guide, see Section 1.3.1.
13	Phone Number – Home		O			
14	Phone Number – Business		O			
15	Primary Language		O			
16	Marital Status		O			
17	Religion		O			
18	Patient Account Number	CX	RE	[0..1]		
19	SSN Number – Patient		X			Excluded for this Implementation Guide, see Section 1.3.1.
20	Driver's License Number – Patient		X			Excluded for this Implementation Guide, see Section 1.3.1.
21	Mother's Identifier		O			

TABLE 5-8. PATIENT IDENTIFICATION SEGMENT (PID)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
22	Ethnic Group		O			
23	Birth Place		O			
24	Multiple Birth Indicator		O			
25	Birth Order		O			
26	Citizenship		O			
27	Veterans Military Status		O			
28	Nationality		X			Excluded for this Implementation Guide, see Section 1.3.1.
29	Patient Death Date and Time		O			
30	Patient Death Indicator		O			
31	Identity Unknown Indicator		O			
32	Identity Reliability Code		O			
33	Last Update Date/Time		O			
34	Last Update Facility		O			
35	Species Code		O			
36	Breed Code		X			Excluded for this Implementation Guide, see Section 1.3.1.
37	Strain		X			Excluded for this Implementation Guide, see Section 1.3.1.
38	Production Class Code		X			Excluded for this Implementation Guide, see Section 1.3.1.
39	Tribal Citizenship		O			

Conformance Statements: Base Profile

LRI-20: PID-1 (Set ID - PID) **SHALL** be valued with the constant value '1'.

5.3.5 ORC – COMMON ORDER SEGMENT

TABLE 5-9. COMMON ORDER SEGMENT (ORC)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Order Control	ID	R	[1..1]	HL70119_USL	

TABLE 5-9. COMMON ORDER SEGMENT (ORC)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
2	Placer Order Number	Varies	RE	[0..1]		GU data type: EI_GU NG data type: EI_NG
3	Filler Order Number	Varies	R	[1..1]		GU data type: EI_GU NG data type: EI_NG
4	Placer Group Number	Varies	RE	[0..1]		GU data type: EI_GU NG data type: EI_NG
5	Order Status		O			
6	Response Flag		O			
7	Quantity/Timing		X			Excluded for this Implementation Guide, see Section 1.3.1.
8	Parent		O			
9	Date/Time of Transaction		O			
10	Entered By		O			
11	Verified By		O			
12	Ordering Provider	Varies	R	[1..1]		Providers should be identified using their NPI. GU data type: XCN_GU NG data type: XCN_NG
13	Enterer's Location		O			
14	Call Back Phone Number		O			
15	Order Effective Date/Time		O			
16	Order Control Code Reason		O			
17	Entering Organization		O			
18	Entering Device		O			
19	Action By		O			
20	Advanced Beneficiary Notice Code		X			Excluded for this Implementation Guide, see Section 1.3.1.
21	Ordering Facility Name		O			
22	Ordering Facility Address		O			
23	Ordering Facility Phone Number		O			

TABLE 5-9. COMMON ORDER SEGMENT (ORC)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
24	Ordering Provider Address		O			
25	Order Status Modifier		O			
26	Advanced Beneficiary Notice Override Reason		C(X/X)			Excluded for this Implementation Guide, see Section 1.3.1.
27	Filler's Expected Availability Date/Time		O			
28	Confidentiality Code		O			
29	Order Type		O			
30	Enterer Authorization Mode		O			
31	Parent Universal Service Identifier	Varies	Varies	[0..1]		Contains the universal service identifier of the parent order. PRU and FRU, or PRU only, or FRU only – Usage: 'O'; PRU and FRN, or PRN and FRU, or PRN and FRN, or PRN only, or FRN only – Usage: 'C(R/X) Condition Predicate: If OBR-29 (Parent) is valued. Data type: CWE_CR

Usage Note

ORC-4 (Placer Group Number)

A result message may have an ORC-4 (Placer Group Number) populated, even when the ORC-2 (Placer Order Number) is blank. Two examples of result message that may meet this situation are reflex results, and Add-on orders. Reflex results by their nature, are not an order from the placer, and therefore have no ORC-2 (Placer Order Number); however ORC-4 (Placer Group Number) can be derived from the parent result. Add-on orders can be submitted in a variety of ways. When called in, the order placer may not have access to a placer order number at time of the order. Because the result is part of a group, the resulting system may be able to accurately identify and apply ORC-4 (Placer Group Number), even when the ORC-2 (Placer Order Number) is unavailable.

Conformance Statements: Base Profile

LRI-23: The value of ORC-2 (Placer Order Number) **SHALL** be identical to the value of OBR-2 (Placer Order Number) within the same Order_Observation Group instance.

LRI-24: The value of ORC-3 (Filler Order Number) **SHALL** be identical to the value of OBR-3 (Filler Order Number) within the same Order_Observation Group instance.

LRI-25: The value of ORC-12 (Ordering Provider) **SHALL** be identical to the value of OBR-16 (Ordering Provider) within the same Order_Observation Group instance.

Conformance Statements: LAB_FRN Profile

LRI-26: The value of ORC-31 (Parent Universal Service Identifier) **SHALL** be identical to the value of OBR-50 (Parent Universal Service Identifier) within the same Order_Observation Group instance.

Conformance Statements: LAB_FRU Profile

LRI-28: The value of ORC-3 (Filler Order Number), excluding those in the Prior Result group(s), **SHALL NOT** be valued identical to another instance of ORC-3 (Filler Order Number) in the same message.

Note: The conformance statements for ORC-2 do not apply when either of those fields is empty.

5.3.6 OBR – OBSERVATION REQUEST SEGMENT

TABLE 5-10. OBSERVATION REQUEST SEGMENT (OBR)

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Set ID - OBR	SI	R	[1..1]		
2	Placer Order Number	Varies	RE	[0..1]		GU data type: EI_GU NG data type: EI_NG
3	Filler Order Number	Varies	R	[1..1]		GU data type: EI_GU NG data type: EI_NG
4	Universal Service Identifier	CWE_CR	R	[1..1]	LOINC	LOINC shall be used as the standard vocabulary to identify the ordered test in OBR-4 (Universal Service Identifier) when an applicable LOINC code is available and provided by the laboratory. When no valid orderable LOINC code exists, the local code may be the only code sent.
5	Priority – OBR		X			Excluded for this Implementation Guide, see Section 1.3.1
6	Requested Date/Time		X			Excluded for this Implementation Guide, see Section 1.3.1
7	Observation Date/Time	TS_4	R	[1..1]		This reflects the specimen collection date/time when the test involves a specimen. Since a test may also involve drawing specimens at different times, e.g., tolerance tests, this date/time only covers the draw of the first specimen. All other specimen collection date/times, including the first one, are communicated in the SPM segment For unknown collection date/time use "0000".

TABLE 5-10. OBSERVATION REQUEST SEGMENT (OBR)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
8	Observation End Date/Time	TS_5	Varies	[0..1]		Sender Usage: 'O' Receiver Usage: 'RE' **Note:** Future versions of this guide will constrain the usage of this element to 'RE'.
9	Collection Volume		O			
10	Collector Identifier		O			
11	Specimen Action Code	ID	RE	[0..1]	HL70065_USL	
12	Danger Code		O			
13	Relevant Clinical Information	CWE_CR1	RE	[0..1]	HL70916_USL	This field pre-adopts the V2.7.1 definition. Constrained to indicate Fasting only.
14	Specimen Received Date/Time		X			Excluded for this Implementation Guide, see Section 1.3.1
15	Specimen Source		X			Excluded for this Implementation Guide, see Section 1.3.1
16	Ordering Provider	Varies	R	[1..1]		Providers should be identified using their NPI. Note that ORC-12 Ordering Provider is constrained to contain the same value as this field. GU data type: XCN_GU NG data type: XCN_NG
17	Order Call-back Phone Number		O			
18	Placer Field 1		O			
19	Placer Field 2		O			
20	Filler Field 1		O			
21	Filler Field 2		O			
22	Results Rpt/Status Chng - Date/Time	TS_1	R	[1..1]		
23	Charge to Practice		O			
24	Diagnostic Service Sect ID		O			
25	Result Status	ID	R	[1..1]	HL70123_USL	The value of OBR-25 is derived from the OBX-11 values that follow the OBR as outlined in section 5.3.6.3 below.

TABLE 5-10. OBSERVATION REQUEST SEGMENT (OBR)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
26	Parent Result	PRL	C(R/RE)	[0..1]		Condition Predicate: If OBR-11 (Specimen Action Code) is valued “G”.
27	Quantity/Timing		X			Excluded for this Implementation Guide, see Section 1.3.1.
28	Result Copies To	Varies	C(R/X)	[0..*]		Condition Predicate: If CWE_CRE.1 (Identifier) or CWE_CRE.4 (Alternate Identifier) of at least one occurrence of OBR-49 (Result Handling) is valued ‘CC’ or ‘BCC’ GU Profile: XCN_GU NG Profile: XCN_NG
29	Parent	Varies	C(R/RE)	[0..1]		Condition Predicate: If OBR-11 (Specimen Action Code) is valued “G”. GU Profile: EIP_GU NG Profile: EIP_NG See Section 8.1.1 Parent/Child Linking, of this document for more information on linking parent/child results.
30	Transportation Mode		O			
31	Reason for Study		O			
32	Principal Result Interpreter		O			
33	Assistant Result Interpreter		O			
34	Technician		O			
35	Transcriptionist		O			
36	Scheduled Date/Time		O			
37	Number of Sample Containers		O			
38	Transport Logistics of Collected Sample		O			
39	Collector's Comment		O			
40	Transport Arrangement Responsibility		O			
41	Transport Arranged		O			
42	Escort Required		O			
43	Planned Patient Transport Comment		O			

TABLE 5-10. OBSERVATION REQUEST SEGMENT (OBR)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
44	Procedure Code		O			
45	Procedure Code Modifier		O			
46	Placer Supplemental Service Information		O			
47	Filler Supplemental Service Information	CWE_CR1	RE	[0..*]	HL70411_USL	As defined in this guide, this field is used with the values from the table to indicate the type of test result structure being sent, i.e, the use of the 'MIC' value indicates the subsequent data will be structured as microbiology results.
48	Medically Necessary Duplicate Procedure Reason		O			
49	Result Handling	CWE_CRE1	RE	[0..3]	HL70507_USL	
50	Parent Universal Service Identifier	Varies	Varies	[0..1]		Contains the universal service identifier of the parent order. PRU and FRU, or PRU only, or FRU only – Usage: 'O'; PRU and FRN, or PRN and FRU, or PRN and FRN, or PRN only, or FRN only – Usage: 'C(R/X) Condition Predicate: If OBR-29 (Parent) is valued. Data type: CWE_CR

Usage Note

OBR-3 (Filler Order Number)

In the circumstance where some of the lab results are generated by the lab but others are performed by a reference lab, the sending lab can choose what filler order number to use in OBR-3. The Filler ID for a single orderable must be the same for all messages for that orderable, e.g., the filler ID must be the same for the ORC/OBR pair reporting a preliminary, final or corrected result. Whichever filler order number is used, the sending lab is expected to be able to trace all the observations in the lab result back to the appropriate source lab based on the filler order number provided in OBR-3 (Filler Order Number).

OBR-13 (Relevant Clinical Information)

Note that CWE has been pre-adopted from V2.7.1.

OBR-7 (Observation Date/Time), OBR-8 (Observation End Date/Time), SPM-17.1 (Range Start Date/Time), SPM-17.2 (Range End Date/Time)

If any of OBR-7 (Observation Date/Time), OBR-8 (Observation End Date/Time), SPM-17.1 (Range Start Date/Time) or SPM-17.2 (Range End Date/Time) contain time zone offset then all must contain a time zone offset.

OBR-25 (Result Status)

When nothing has been reported under an OBR and the LRI message is used to communicate a cancellation, the reason for cancellation, including wrong patient or wrong specimen, is reported in an NTE under the OBR and the OBR-25 is valued 'X' and follows the cancellation path.

If any result is reported on the OBR it must be issued as a corrected report with OBR-25 valued 'M' or 'C'.

OBR-47 (Filler Supplemental Service Information)

Special handling of parent/child resulting for reflexing as well as micro susceptibility:

1. When a parent is non-micro, but it reflexes to a micro with susceptibilities, the non-micro parent should not have "MIC" in OBR-47 (Filler Supplemental Service Information), however the reflex and all susceptibilities should be valued with "MIC" in OBR-47.
2. When the parent is valued "MIC" in OBR-47, all child OBRs should be flagged as micro via the "MIC" in OBR-47.
3. Child OBRs, should be flagged to match the parent indicator for all susceptibilities.

Conformance Statements: Base Profile

LRI-29: For linking Parent/Child results OBR-26.1 (Parent Observation Identifier) of a child observation **SHALL** be valued with the parent OBX-3 (Observation Identifier).

LRI-30: For linking Parent/Child results OBR-26.2 (Parent Observation Sub-identifier) of a child observation **SHALL** be valued with the parent OBX-4 (Observation Sub-ID).

LRI-31: For linking Parent/Child results OBR-29.1 (Placer Assigned Identifier) in a child observation **SHALL** be valued with the parent OBR-2 (Placer Order Number), if OBR-2 is populated.

LRI-32: For linking Parent/Child results OBR-29.2 (Filler Assigned Identifier) in a child observation **SHALL** be valued with the parent OBR-3 (Filler Order Number).

LRI-33: If present, OBR-8 (Observation End Date/Time) **SHALL** be equal to or later than OBR-7 (Observation Date/Time).

LRI-34: The value of OBR-1 (Set ID – OBR) **SHALL** be valued sequentially starting with the value '1' across the Order_Observation Groups.

Note: For the first occurrence of the OBR segment, the Sequence number shall be one (1), for the second occurrence, the Sequence number shall be two (2), etc., as shown in the example below:

```
MSH|...<cr>
PID|...<cr>
// First order group
ORC|NW|...<cr>
OBR|1|...<cr>
SPM|1|...<cr>
SPM|2|...<cr>
// end first order group
// Second order group
ORC|NW|...<cr>
OBR|2|...<cr>
SPM|1|...<cr>
SPM|2|...<cr>
//end second order group
```

Conformance Statements: LAB_FRU Profile

~~**LRI-44: Deprecated as of Aug 18, 2012** OBR-2 (Placer Order Number) when present **SHALL** be unique for each OBR segment in the message.~~

~~**LRI-45: Deprecated as of Aug 18, 2012** OBR-3 (Filler Order Number) **SHALL** be unique for each OBR segment in the message.~~

LRI-40: The value of OBR-3 (Filler Order Number) **SHALL NOT** be valued identical to another instance of OBR-3 (Filler Order Number) in the message.

Conformance Statements: LAB_FRN Profile

LRI-41: The value of OBR-50 (Parent Universal Service Identifier) **SHALL** be identical to the value of ORC-31 (Parent Universal Service Identifier).

LRI-42: For linking Parent/Child results OBR-50 (Parent Universal Service Identifier) in a child observation **SHALL** be valued with the parent OBR-4 (Universal Service Identifier).

5.3.6.1 REPORTING RESULTS WITH A PARENT/CHILD RELATIONSHIP (SUCH AS REFLEX RESULTS AND MICROBIOLOGY CULTURE WITH SUSCEPTIBILITY)

When communicating results with a parent/child relationship, such as microbiology results and reflex tests, the use of the right segments and fields is essential to consistently convey the structure and content of the culture, organisms, and susceptibilities. This guide opted for one of

potentially 3-4 ways to communicate these results. The following diagrams summarize the concepts and are followed by the formal conformance statements that implement that.

The challenge at hand is to express a microbiology report, shown on the left in first diagram, into the ORU message structure summarized on the right.

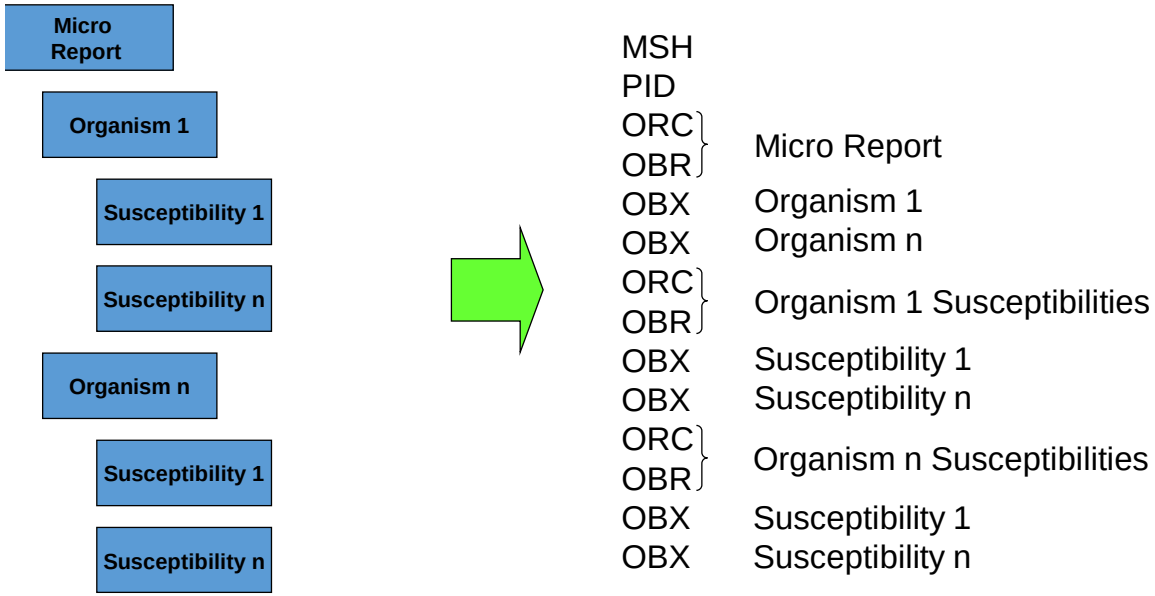

Figure 5-1. Sample Report Structure Represented as Message Structure

Figure 5-2 shows the use of the ORC, OBR, and OBX segments. The arrows illustrate how the child Organism refers to value in the parent OBR and OBX to clearly link the child to the parent. (For example the dark blue line illustrates how the value in the child's OBR-26 matches the value of its parents OBX-3 and OBX-4.)

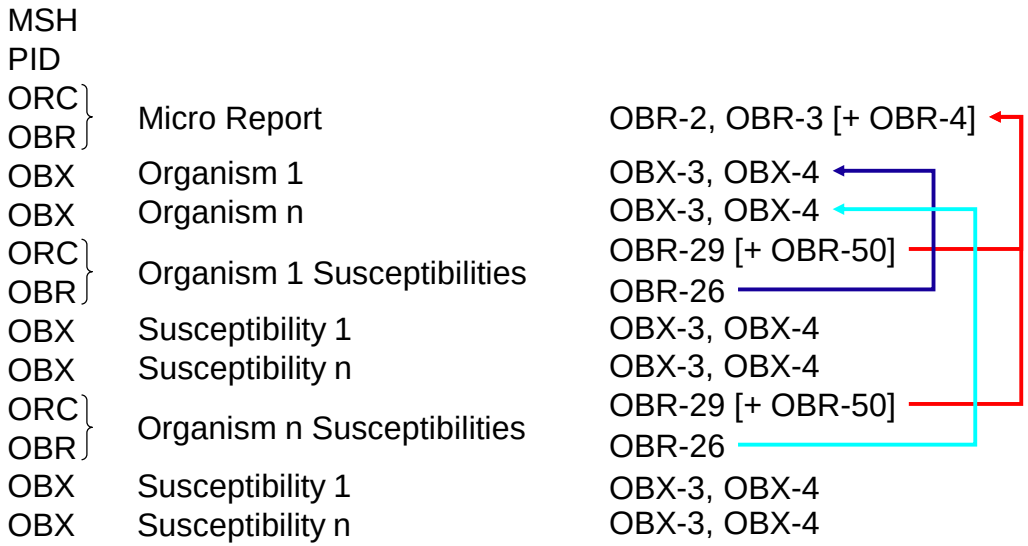

Figure 5-2. Parent-Child Relationships

The following conformance statements express this more formally.

Conformance Statements: LRI_FRU and LRI_PRU Profiles

LRI-43: Results with a Parent/Child relationship (as defined in Section 8.1 Parent/Child Reporting for Reflex and Culture/Susceptibility Testing), such as Microbiology and Reflex Results **MUST** provide proper linking from the Child result to the Parent OBR and OBX as detailed below:

Parent OBR matching: Any OBR with a value of 'G' in OBR-11 (Specimen Action Code) and/or a value in OBR-26 (Parent Result), henceforth referred to as the Child OBR, **SHALL** be successfully matched to a Parent OBR in a previously occurring Order Observation Group in the following ways:

The child OBR-29.1 (Placer Assigned Identifier) is valued the same as the Parent OBR-2 (Placer Order Number) value (taking into account the conversion of component delimiters into sub-component delimiters.)

AND

The child OBR-29.2 (Filler Assigned Identifier) is valued the same as the Parent OBR-3 (Filler Order Number) value (taking into account the conversion of component delimiters into sub-component delimiters.)

Parent OBX matching: Any OBR with a value of 'G' in OBR-11 (Specimen Action Code) or a value in OBR-26 (Parent Result), henceforth referred to as the Child OBR, **SHALL** be successfully matched to an OBX segment within the previously identified Parent Order Observation Group in the following ways:

The child OBR-26.1 (Parent Observation Identifier) is valued the same as the Parent OBX-3 value (taking into account the conversion of component delimiters into sub-component delimiters.)

AND

The child OBR-26.2 (Parent Observation Sub-Identifier) is valued the same as the Parent OBX-4 (Observation Sub-Identifier) valuet (taking into account the conversion of component delimiters into sub-component delimiters.)

Conformance Statements: LRI_FRN and LRI_PRN Profiles

LRI-57: Results with a Parent/Child relationship (as defined in section 6.1.1), such as Microbiology and Reflex Results must provide proper linking from the Child result to the Parent OBR and OBX as detailed below:

Parent OBR matching: Any OBR with a value of 'G' in OBR-11 (Specimen Action Code) or a value in OBR-26 (Parent Result), henceforth referred to as the Child OBR, **SHALL** be successfully matched to a Parent OBR in a previously occurring Order Observation Group in the following ways:

Child OBR-29.1 (Placer Assigned Identifier) is valued the same as the Parent OBR-2 (Placer Order Number) value (taking into account the conversion of component delimiters into sub-component delimiters.)

AND

The child OBR-29.2 (Filler Assigned Identifier) is valued the same as the Parent OBR-3 (Filler Order Number) value (taking into account the conversion of component delimiters into sub-component delimiters.)

AND

The child OBR-50 (Parent Universal Service Identifier) is valued the same as the Parent OBR-4 value.

Parent OBX matching: Any OBR with a value of "G" in OBR-11 or a value in OBR-26, henceforth referred to as the Child OBR, SHALL be successfully matched to an OBX segment within the previously identified Parent Order Observation Group in the following ways:

The child OBR-26.1 (Parent Observation Identifier) is valued the same as the Parent OBX-3 value (taking into account the conversion of component delimiters into sub-component delimiters.)

AND

The child OBR-26.2 (Parent Observation Sub-Identifier) is valued the same as the Parent OBX-4 (Observation Sub-Identifier) value (taking into account the conversion of component delimiters into sub-component delimiters.)

Examples conforming to **LRI-43** and **LRI-57** can be found in Section 8.2.5 Examples of Culture and Susceptibility Results

5.3.6.2 RESULTS HANDLING AND RESULT COPIES TO

In this Implementation Guide OBR-28 (Result Copies to) is populated based on the value in OBR-49 (Result Handling) based on two values 'BCC' (Blind copy) and 'CC' (Copy to) in OBR-49. When the order is submitted to the laboratory, the Ordering Provider includes the identifier (typically the NPI) and the name of the colleagues (up to five[10]) that the provider would like to also receive the patient's results.

When the laboratory prepares the report, the one sent back to the original ordering provider will include in OBR-28 all the copy to colleagues that were requested to receive the reports and the flag in OBR-49 will be set as 'CC'.

For all other reports, defined as the copy to, the receiving colleague will get the report with OBR-28 containing only the colleague's information and OBR-49 will have 'BCC'.

Example: Physician_1 orders a CBC and Electrolytes for a patient. Because Physician_1 intends to go on vacation starting tomorrow and three other colleagues have agreed to a rotating coverage, Physician_1 requests that the lab also report the results to Colleague_A, Colleague_B and Colleague_C. This will create four reports with unique values in OBR-28 and OBR-49 as noted below:

TABLE 5-11. OBR-16, -28, -49 EXAMPLES

Report	OBR-16	OBR-28	OBR-49
Primary report	Physician_1	Colleague_A, _B, _C	CC
Copy to report to Colleague_A	Physician_1	Colleague_A	BCC
Copy to report to Colleague_B	Physician_1	Colleague_B	BCC
Copy to report to Colleague_C	Physician_1	Colleague_C	BCC

5.3.6.3 RELATIONSHIP BETWEEN OBR-25 (RESULT STATUS) AND THE OBX-11 (OBSERVATION RESULTS STATUS) VALUE THAT FOLLOW THE OBR

The OBR-25 (Result Status) is a summary of the OBX-11 statuses that follow the OBR. This is most easily understood in the case where an OBR contains only one OBX with an 'F' (Final), one would naturally expect the OBR-25 value to be 'F' (Final) as well. This guide will prescribe the expected OBR-25 value given multiple and various combinations of OBX-11 values.

Before we can discuss how OBR-25 is derived from the OBX-11 values we must first examine the value set for OBR-25, and understand in what order the values can (or cannot) transition from one value to the same or another value in a series of transactions. That is described in the following section.

[10] More than five recipients can be sent as part of an order see the Laboratory Orders IG - LOI_RC_Component (Results Copies).

5.3.6.3.1 ALLOWED RESULT STATUS (OBR-25) TRANSITIONS

The status of the results under an order (ORC/OBR) is defined by the value of OBR-25. The following table defines the allowed and prohibited transitions from one transaction to the next transaction that contains the same ORC/OBR.

How to Read This Table

First row: An existing OBR-25 valued 'I' can take on the following values in a subsequent transaction: 'I', 'A', 'P', 'F' or 'X'. It cannot be changed to 'M' or 'C'.

Second row: An existing OBR-25 valued 'A' can take on the following values in a subsequent transaction: 'A', 'P', 'F', 'M'. It cannot be changed to 'I', 'C' or 'X'.

Third row: An existing OBR-25 valued 'P' can take on the following values in a subsequent transaction: 'A', 'P', 'F', 'M' or 'C'. It cannot be changed to 'I' or 'X'.

Fourth row: An existing OBR-25 valued 'F' can take on the following values in a subsequent transaction: 'C' and 'F'. It cannot be changed to 'I', 'A', 'P', 'M' or 'X'.

Fifth row: An existing OBR-25 valued 'M' can take on the following values in a subsequent transaction: 'M' or 'C'. It cannot be changed to 'I', 'A', 'P', 'F' or 'X'.

Sixth row: An existing OBR-25 valued 'C' can remain ONLY 'C' on the following values in a subsequent transaction. It cannot be changed to 'I', 'A', 'P', 'F', 'M' or 'X'.

Seventh row: An existing OBR-25 valued 'X' can remain ONLY 'X' on the following values in a subsequent transaction. It cannot be changed to 'I', 'A', 'P', 'F', 'M', or 'C'.

Table Legend

Not Allowed
A=Allowed

TABLE 5-12. ALLOWED OBR-25 TO OBR-25 TRANSITIONS

From OBR-25 (existing result)		TO OBR-25						
		I	A	P	F	M [2]	C	X
I	In Process	A	A	A	A			A
A	Partial		A	A	A	A	A	

TABLE 5-12. ALLOWED OBR-25 TO OBR-25 TRANSITIONS								
From OBR-25 (existing result)		TO OBR-25						
		I	A	P	F	M (2)	C	X
P	Preliminary		A	A	A	A	A	
F	Final				A (1)		A	
M (2)	Corrected, not final					A	A	
C	Corrected, final						A	
X	No Results Available, Order Canceled							A

Notes

(1) Only allowed if the date in OBR-22 (Results Rpt/Status Chng – Date/Time) does not change and there is no change in any OBX.

(2) This value has been added to the HL70123_USL value set.

Example: If an ORC/OBR has been reported with an OBR-25 status of F (Final), then the next time it is reported with any changes, the allowed OBR-25 status may be 'F' or 'C', but not 'I', 'A', 'P', or 'X' – see row 4 for this example.

5.3.6.3.2 OBR-25 (RESULT STATUS) VALUES BASED UPON POSSIBLE COMBINATIONS OF OBX-11 VALUES

The previous section addressed the transitional state of the OBR-25, this section will prescribe how the OBR-25 is to be valued when multiple and varying OBX-11 values exist under the respective OBR segment.

The table below provides a visual depiction of the following conformance rules prescribing the evaluation of OBX-11 values in the determination the value of OBR-25.

How to Read This Table

1.) The combination of OBX-11 values determines the allowable OBR-25 value.
2.) When viewing the possible OBR-25 values (column), the value is only valid if there is an OBX-11 status that is marked 'R'.
3.) The status of the report is indicated in OBR-25 status. Only certain OBX-11 combinations are allowed for specific OBR-25 values.
    a. For example the OBR-25 value 'M' requires that at least one of the OBX-11 is valued 'C', 'A', or 'B' as well as at least another, that is valued either 'I' or 'P'. If there are multiple OBX segments and their OBX-11 values are limited to only 'P' and 'I', the table below shows that this combination matches the OBR-25 values of 'P' and 'M', but the absence of any OBX-11 valued with 'C', 'A', or 'B' prohibits the use of the value 'M', thus making the correct OBR-25 value 'P'.

First column: An order (ORC/OBR) with multiple analytes (OBXs) is reported via LRI, where all OBXs have OBX-11 valued 'I'. The status for the order in OBR-25 shall be 'I' indicating work in progress, without available results.

Second column: An order (ORC/OBR) with multiple analytes (OBXs) is reported via LRI, where one or more OBX has OBX-11 valued 'F' and the other OBXs have a status of 'I'. None of the OBXs have an OBX-11 status of 'P', 'C', 'A', 'B', or 'W'. The status for the order in OBR-25 shall be 'A' indicating a partial report.

Third column: An order (ORC/OBR) with multiple analytes (OBXs) is reported via LRI, where one or more OBX has OBX-11 valued 'P' and the other OBXs are valued either 'F' or 'I'. None of the OBXs have an OBX-11 status of 'C', 'A', 'B', or 'W'. The status for the order in OBR-25 shall be 'P' indicating a preliminary report.

Fourth column: An order (ORC/OBR) with multiple analytes (OBXs) is reported via LRI, where one or more OBX has OBX-11 valued 'F'. None of the OBXs have an OBX-11 status of 'I', 'P', 'C', 'A', 'B', or 'W'. The status for the order in OBR-25 shall be 'F' indicating a final report.

Fifth column: An order (ORC/OBR) with multiple analytes (OBXs) is reported via LRI where one or more OBX has OBX-11 valued 'C', 'A', 'B' or 'W'. At least one of the other OBXs has a status indicating either a 'P' or 'I'. The status for the order in OBR-25 shall be 'M', indicating a correction in a partial or preliminary report.

Sixth column: An order (ORC/OBR) with multiple analytes (OBXs) is reported via LRI, where one or more OBX has OBX-11 valued 'C', 'A', 'B' or 'W'. **No** OBX has a status indicating either a 'P' or 'I'. The status for the order in OBR-25 shall be 'C' indicating a correction in a final report.

Seventh column: An order (ORC/OBR) with multiple analytes (OBXs) is reported via LRI, where one or more OBX has OBX-11 valued 'N', 'D' or 'X'. None of the OBXs have an OBX-11 status of 'I', 'P', 'F', 'C', 'A', 'B', or 'W'. The status for the order in OBR-25 shall be 'X' indicating a cancelation of the order.

Table Legend

Not Allowed
A=Allowed
R=Required

TABLE 5-13. REQUIRED/ALLOWED OBX-11, AND OBR-25 VALUES IN SAME ORDER								
From OBX-11		OBR-25						
		I	A	P	F	M	C	X
I	In Process	R	R	A		R (3)		
P	Preliminary			R		R (3)		
F	Final		A (1)	A	R	A	A	
C	Corrected					R (1)	R (1)	
A	Amended					R (1)	R (1)	
B	Appended					R (1)	R (1)	
N (2)	Not Asked		A (1)	A	A	A	A	A
X (2)	Not Possible		A (1)	A	A	A	A	A
D (2)	Delete	A	A	A	A	A	A	A
W	Wrong					R (1)	R (1)	

Notes

(1) Requires at least one of the OBXs present under the OBR to have the specified OBX-11 to affect the order level result status (OBR-25).

(2) OBX-11 values 'N', 'X', and 'D' are allowed on several message types but are irrelevant to the determination of OBR-25 unless all OBX-11s consist of a combination of the three. In that case the value of OBR-25 will be 'X'.

(3) Requires at least one of the OBXs present under the OBR to be valued either 'I' or 'P' in OBX-11 to affect the order level result status

Conformance Statements

LRI- 58: Any OBR-25 valued 'I' with any related OBX-11 not valued 'I'or 'D' **SHALL** be a hard error

LRI- 59: Any OBR-25 valued 'A' without any related OBX-11 valued 'F', 'N' or 'X' **SHALL** be a hard error.

LRI- 60: Any OBR-25 valued 'A' without any related OBX-11 valued 'I' **SHALL** be a hard error.

LRI- 61: Any OBR-25 valued 'A' with any related OBX-11 valued 'P', 'C', 'A', 'B' or 'W' **SHALL** be a hard error.

LRI- 62: Any OBR-25 valued ‘P’ without any related OBX-11 valued ‘P’ **SHALL** be a hard error.

LRI- 63: Any OBR-25 valued ‘P’ with any related OBX-11 valued ‘C’, ‘A’, ‘B’ or ‘W’ **SHALL** be a hard error.

LRI- 64: Any OBR-25 valued ‘F’ without any related OBX-11 valued ‘F’ **SHALL** be a hard error.

LRI- 65: Any OBR-25 valued ‘F’ with any related OBX-11 valued ‘I’, ‘P’, ‘C’, ‘A’, ‘B’ or ‘W’ **SHALL** be a hard error.

LRI- 66: Any OBR-25 valued ‘M’ without any related OBX-11 valued ‘C’, ‘A’, ‘B’, or ‘W’ **SHALL** be a hard error.

LRI- 67: Any OBR-25 valued ‘M’ without any related OBX-11 valued ‘I’ or ‘P **SHALL** be a hard error.

LRI- 68: Any OBR-25 valued ‘C’ without any related OBX-11 valued ‘C’, ‘A’, ‘B’ or ‘W’ **SHALL** be a hard error.

LRI- 69: Any OBR-25 valued ‘C’ with any related OBX-11 valued ‘I’ or ‘P’ **SHALL** be a hard error.

LRI- 70: Any OBR-25 valued ‘X’ with any related OBX-11 value except for ‘D’, ‘N’ or ‘X’ **SHALL** be a hard error.

5.3.7 TQ1 – TIMING/QUANTITY SEGMENT

TABLE 5-14. TIMING/QUANTITY SEGMENT FOR ORDER GROUP

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Set ID - TQ1	SI	R	[1..1]		
2	Quantity		O			
3	Repeat Pattern		O			
4	Explicit Time		O			
5	Relative Time and Units		O			
6	Service Duration		O			
7	Start date/time	TS_5	RE	[0..1]		The start date should be the expected date the order should begin or the anticipated date when the order will be fulfilled by the patient arriving at the Patient Service Center (PSC). If this is a future order this should have a date, otherwise it may be empty. A future order is an order with a start date/time where that start date/time indicates the earliest time the specimen can be collected. Leaving this field empty would indicate the earliest available date or when the patient arrives to have specimen drawn.
8	End date/time	TS_5	RE	[0..1]		The latest date and time by which the specimen should be collected.
9	Priority	CWE_CR1	R	[1..1]	HL70485_USL	
10	Condition text		O			

TABLE 5-14. TIMING/QUANTITY SEGMENT FOR ORDER GROUP						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
11	Text instruction		O			
12	Conjunction		X			Excluded for this Implementation Guide, see Section 1.3.1
13	Occurrence duration		O			
14	Total occurrence's		O			

Usage Note

Since the TQ group can only appear once in each Observation Group use of the conjunction field is not permitted, including further constrained profiles as this would conflict with TQ group only appearing once.

Conformance Statements: Base Profile

LRI-44: The value of TQ1-1 (Set ID – TQ1) **SHALL** be valued '1'.

5.3.8 OBX – OBSERVATION/RESULT SEGMENT

Note: Components 26-29 are pre-adopted from V2.8.1

TABLE 5-15. OBSERVATION RESULT SEGMENT (OBX)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Set ID – OBX	SI	R	[1..1]		
2	Value Type	ID	C(R/X)	[0..1]	HL70125_USL	Condition Predicate: If OBX-5 (Observation Value) is valued. This field identifies the data type used for OBX-5.
3	Observation Identifier	CWE_CR	R	[1..1]	Logical Observation Identification Name and Codes (LOINC)	LOINC shall be used as the standard coding system for this field if an appropriate LOINC code exists. Appropriate status is defined in the LOINC Manual Section 11.2 Classification of LOINC Term Status. If a local coding system is in use, a local code should also be sent to help with identification of coding issues. When no valid LOINC exists the local code may be the only code sent. When populating this field with values, this guide does not give preference to the triplet in which the standard (LOINC) code should appear.
4	Observation Sub-ID	OG	C(R/RE)	[0..1]		Condition Predicate: If there are multiple OBX segments associated with the same OBR segment that have the same OBX-3 values for (OBX-3.1 and OBX-3.3) or (OBX-3.4 and OBX-3.6). Note: This field is pre-adopted from V2.8.2.

TABLE 5-15. OBSERVATION RESULT SEGMENT (OBX)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
5	Observation Value	Varies	RE	[0..1]		**Note:** If value is coded, ST should not be used. See Section 6.2 SNOMED CT for guidance on how to value this field for Microbiology.
6	Units	CWE_CRE	RE	[0..1]		See Section 6.5 UCUM
7	References Range	ST	RE	[0..1]		Guidance: It is not appropriate to send the reference range for a result in an associated NTE segment. It would be appropriate to send additional information clarifying the reference range in an NTE associated with this OBX-
8	Abnormal Flags	IS	RE	[0..*]	HL70078_USL	This field will be populated from Table 0078 when appropriate. Therefore, if a laboratory populates OBX-8 with a coded interpretation, regardless of the coded interpretation sent, the EHR shall consume and display it. Microbiology example: Ceftazidime susceptibility (LOINC 133-9) value = |<=^1|, units = ug/ml, Abnormal flag = S
9	Probability		O			
10	Nature of Abnormal Test		O			
11	Observation Result Status	ID	R	[1..1]	HL70085_USL	
12	Effective Date of Reference Range		O			
13	User-Defined Access Checks		O			
14	Date/Time of the Observation	TS_5	RE	[0..1]		For specimen-based test, if OBX-14 (Date/Time of Observation) is valued it must be the same as SPM-17.1 (Range Start Date/Time). If SPM-17.2 (Range End Date/Time) is present and relates to the same observation, then OBX-14 must be within the DR range.
15	Producer's Reference		O			
16	Responsible Observer		O			
17	Observation Method		O			
18	Equipment Instance Identifier		O			
19	Date/Time of the Analysis	TS_6	RE	[0..1]		Be as precise as appropriate and available.

TABLE 5-15. OBSERVATION RESULT SEGMENT (OBX)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
20	Reserved for harmonization with Version 2.6.		X			Excluded for this Implementation Guide, see Section 1.3.1
21	Reserved for harmonization with Version 2.6.		X			Excluded for this Implementation Guide, see Section 1.3.1
22	Reserved for harmonization with Version 2.6.		X			Excluded for this Implementation Guide, see Section 1.3.1
23	Performing Organization Name	Varies	R	[1..1]		GU data type: XON_GU NG data type: XON_NG The information for producer ID is recorded as an XON data type.
24	Performing Organization Address	XAD	R	[1..1]		
25	Performing Organization Medical Director	Varies	RE	[0..1]		GU data type: XCN_GU NG data type: XCN_NG
26	Patient Results Release Category		O			
27	Root Cause		O			
28	Local Process Control		O			
29	Observation Type	ID	R	[1..1]	HL70936_USL	Note: This field is pre-adopted from v2.8.2
30	Observation Sub-Type	ID	RE	[0..1]	HL70937_USL	Note: This field is pre-adopted from v2.8.2

Usage Note

OBX-17 (Observation Method) can further specify information about the specific method to a more granular level than what is defined by the LOINC used in OBX-3 (Observation Identifier). There are two vocabularies available for use at this time, SNOMED CT procedure hierarchy codes and V3 Observation Method codes, and work to make these more complete as well as to provide a cross-mapping between them is in development.

Conformance Statements: Base Profile

LRI-45: The value of OBX-5 (Observation Value) **SHALL NOT** be truncated.

LRI-46: The value of OBX-1 (Set ID – OBX) **SHALL** be valued sequentially starting the value '1' within a given segment group.

LRI-47: If there are multiple OBX segments associated with the same OBR segment that have the same OBX-3 (Observation Identifier) values for OBX-3.1 (Observation Identifier.Identifier) + OBX-3.3 (Observation Identifier.Name of Coding System) or OBX-3.4 (Observation Identifier.Alternate Identifier) + OBX-3.6 (Observation Identifier.Name of Alternate Coding System), a combination of (OBX-3.1 + OBX3.3) or (OBX-3.4 + OBX-3.6) and OBX-4 **SHALL** create a unique identification under a singl**e** OBR**.**

LRI-48: If OBX-2 (Value Type) is valued, then the data type format for OBX-5 (Observation Value) **SHALL** conform to the corresponding constrained data type identified in the "comment" column of HL70125_USL.

5.3.8.1 OBSERVATION IDENTIFIERS, OBSERVATION VALUES, INTERPRETATIONS AND COMMENTS

Laboratory results fall into several broad categories or types of results. The first type of result is a quantitative measure of some property of a specimen and is typically numerical in nature. Often these numeric results are also associated with some sort of interpretation, typically in terms of the normality or abnormality of the measured quantity in relationship to a reference range or normal range. Another type of result is a qualitative result related to the testing of a specimen. This is typically coded or textual in nature. Qualitative results may actually be interpretations of more detailed quantitative measurement (see Section 9.2 CLSI Definitions – Quantitative, Semi-quantitative, Qualitative Results). Both quantitative and qualitative results may have comments associated with them (usually delivered in NTE segments.) These comments may provide additional clarification, information regarding how the result was obtained, etc.

This guide assumes that LOINC is normally being used for the identification of observations if an appropriate LOINC code exists. Appropriate status is defined in the LOINC Manual Section 11.2 Classification of LOINC Term Status. LOINC identifiers can easily be classified as quantitative or qualitative. The LOINC scale property QN (quantitative) indicates that the LOINC identifier is quantitative. All other LOINC identifiers can be treated as qualitative for the purpose of this discussion. Those OBX's associated with quantitative LOINC identifiers should be using OBX-5 with either the NM (numeric), SN (structured numeric), TS (timestamp), DT (date) or TM (time) data types. These quantitative results are usually accompanied by a simple interpretation. Coded interpretations should be reported using OBX-8 (abnormal flags) when the values have been drawn from HL70078_USL.

The LOINC scale property for qualitative results can fall into four types:

a) Ordinal (ORD): OBX-3 observations with qualitative LOINC test codes using ordinal result scales may fully specify the analyte/component measured in OBX-3, thus only requiring a ranked ordered set of answers such as reactive, weakly reactive, non-reactive or a "Presence/Absence" code to fully specify the observation.

b) Nominal (NOM): OBX-3 observations with "presence or identity" LOINC test codes using nominal result scales to fully specify the observation.

   - Bacterial cultures may require a SNOMED CT concept from the "organism" hierarchy

c) Narrative (NAR): OBX-3 observations with narrative LOINC test codes use ST or TX data type in OBX-5.

d) Ordinal or Quantitative (OrdQn): This type is used by Susceptibility tests that may be reported as qualitative (i.e. susceptible, resistant) or as quantitative, numeric results (e.g. Minimum Inhibitory Concentration MIC).

In laboratory test result reporting, the LOINC code in OBX-3 describes what is being tested for and the value (result) in OBX-5 answers either the question of what was found or how much of it. So in chemistry, the serum glucose test answers the how much of it question; telling you how much glucose the serum contains. Microbiology is more interested in the "what was found" kind of questions mostly, what organisms(s) were found. Two different categories of "what was found tests" exist.

The first category of targets only a single organism or species and reports only whether that organism or species was found in the specimen. The name of that target organisms is carried in the analyte part of the LOINC name and the Scale of the LOINC name will be ordinal (ORD). These tests targeted towards identification of a specific organism are typically immuno assays, nucleic acid tests or organism specific cultures and they can only speak to whether the targeted organisms was found or not. So the value of the test would be reported in OBX-5 with SNOMED CT codes of detected/not detected or some analogous SNOMED CT codes. Some ordinal tests may also report codes for equivocal or other such codes between detected and not detected for which SNOMED CT codes should also be used.

The second category carries tests that can detect many different organisms from within a class of organisms and the OBX-5 reports which of these organisms were detected (if any). In this case the analyte part of the LOINC name is at a broader level than individual species, e.g. Bacteria identified, the LOINC scale is "nominal" (NOM), which means, roughly, that the test reports "names" of things. The LOINC name can include further constrains identifying the method and or the system. A good example is the blood culture. The results of blood cultures will be reported as SNOMED CT codes that name the organism(s) that grew in the blood culture, or "no growth" (or something similar), when nothing grew as the final results. We have oversimplified a bit in this example, because blood cultures will report preliminary results such as "no organisms detected after 24 hours", and early indications of the kinds of organisms that are growing, e.g. , gram positive cocci; these findings would also be reported using appropriate SNOMED CT codes.

The above discussion has focused on actual clinical findings, whether they are quantitative or qualitative. Often, additional clarifying documentation is sent along with the clinical findings. Depending on the content, these should be handled either as additional OBX segments grouped together or as comments, conveyed in one or more NTE segment(s) following the OBX in question.

Additonal OBXs can cover coded information:

- Ask at Order entry questions needed to properly interpret the result
- Reference Sequences used in genetic testing

Comments typically fall into the following categories:

- Comments about how a clinical finding was reached
- Additional information clarifying the meaning of a clinical finding
- Additional information not directly related to the clinical finding such as contact information for the lab, disclaimers, etc.
- Most canned, or boilerplate text associated with a result falls into the comment category.

The following table gives examples of how the different fields in the OBX segment interact to create the complete observation.

TABLE 5-16. OBSERVATION IDENTIFIERS						
Testing Situation Discussion	OBX-2 Observation Type	OBX-3 Observation Identifier: LOINC part = scale	OBX-5 Observation value	OBX-6 Units	OBX-7 Reference Range	NTE Segment
Numeric result	NM	QN	number	Should be populated.	Should be populated	May be populated with comments, not clinical findings.
Numerical intervals, ratios, inequalities	SN	QN	structured numeric	May be populated.	May be populated	May be populated with comments, not clinical findings.
Time like quantitative result	TM, DT, DTM	QN	timestamp, time or date	May be empty.	May be populated	May be populated with comments, not clinical findings.
Conveys ordinal value	CWE	ORD	Ordinal as a code using CWE_CR. For receivers: SNOMED CT SHALL be supported when received. For senders: SNOMED CT SHOULD be used for Microbiology results at a minimum, and other coded results as negotiated with trading partners; otherwise a local code.	Should be empty.	May be populated	May be populated with comments, not clinical findings.
Conveys ordinal value	SN	ORD	Ordinal as structured numeric	May be populated.	Required	May be populated with comments, not clinical findings.

TABLE 5-16. OBSERVATION IDENTIFIERS						
Testing Situation Discussion	OBX-2 Observation Type	OBX-3 Observation Identifier: LOINC part = scale	OBX-5 Observation value	OBX-6 Units	OBX-7 Reference Range	NTE Segment
Conveys observation	CWE	NOM	Coded observation using CWE_CR. For receivers: SNOMED CT SHALL be supported when received. For senders: SNOMED CT SHOULD be used for Microbiology results at a minimum, and other coded results as negotiated with trading partners; otherwise a local code.	Empty	May be populated	May be populated with comments, not clinical findings.
Conveys observation	FT, TX or ST	NAR	text	Empty	May be populated	May be populated with comments, not clinical findings.
Conveys numeric or ordinal value	NM	ORDQN	Number	May be populated.	May be populated	May be populated with comments, not clinical findings.
Conveys numeric or ordinal value	CWE	ORDQN	Ordinal as a code using CWE_CR. For receivers: SNOMED CT SHALL be supported when received. For senders: SNOMED CT SHOULD be used for Microbiology results at a minimum, and other coded results as negotiated with trading partners; otherwise a local code.	Empty	May be populated	May be populated with comments, not clinical findings.
Conveys observation	FT, TX or ST	MULTI	text	Empty	May be populated	May be populated with comments, not clinical findings.

TABLE 5-16. OBSERVATION IDENTIFIERS						
Testing Situation Discussion	OBX-2 Observation Type	OBX-3 Observation Identifier: LOINC part = scale	OBX-5 Observation value	OBX-6 Units	OBX-7 Reference Range	NTE Segment
Conveys imbedded object (ED) or pointer to object (RP)	ED, RP	*	Object pointer or imbedded object	Empty	[empty]	May be populated with comments, not clinical findings.

Usage Note

This guide **recommends** the use of SNOMED CT for senders, with a reminder, that a future release of this guide will require the use of SNOMED CT for result reporting.

If either OBX-3.3 or OBX-3.6 is 'LN' (LOINC) then the data type identified in OBX-2 should be drawn from Table 5-17. Data Types for LOINC Scale Part based on the LOINC Scale Part of the code in OBX-3.1 or OBX-3.4, except when OBX-11 equals 'X' or 'N'.

* At this time it is not yet clear how LOINC supports inclusion of documents. We anticipate having clarity by the time this document is moved to a normative state.

TABLE 5-17. DATA TYPES FOR LOINC SCALE PART	
LOINC Scale Part	OBX-2 Value Type
QN - Quantitative	NM, SN, TS, TM, DT
ORD - Ordinal	CWE, SN
NOM – Nominal	CWE
NAR – Narrative	ED, FT, TX or ST
ORDQN - Quantitative or Ordinal	NM, SN, TS, TM, DT, CWE
MULTI - Multi	FT, TX or ST
DOC	ED

5.3.8.2 GROUPING OF RELATED OBX SEGMENTS

Groups are a specific collection of OBX segments that are reported in a pre-determined sequence for display or processing order within the Group. Starting with V2.8.2 a new OG (Observation Grouper) datatype was created and OBX-4 (Observation Sub-ID) datatype ws changed

from ST to OG to enable improved structured grouping of observation segments. This IG is pre-adopting this data type for use in OBX-4 (Observation Sub-ID)

Group Identification – where grouping is important, a unique identifier (in OBX-4) that declares membership in a group.

- OG-1 remains the ST data type for backwards compatibility
- OG-2 (NM) identifies the group and sequence within the OBR
- OG-3 (NM) Sequence within a Group – Individual OBXs within the group should have the means to declare an unambiguous sequence in which they should be processed, validated, displayed or for any other reason the sender and receiver may have negotiated.
- OG-4 (NM) An optional identifier to a result component. For example, an isolate identifier in a microbiology message.

Uniqueness – OBX-4 is the location to declare a unique identifier, OG.2 and OG.3 plus OBX-3.3 will provide uniqueness

- The LRI and LOI implementation guides would then constrain the Group Order component as C(R/RE) with "Condition Predicate: If Group Member Sequence is valued" to ensure a unique and valid value is always present.

Example: Grouping with sequence declared and isolates identified using the OG datatype in OBX-4.

Note: For an example showing the parent child structure in more detail see Section 8.1.1 Parent/Child Linking.

Test: Culture, Respiratory with antibiotic sensitivities

Specimen: Sputum

Gram Stain: Many WBCs

Moderate Gram Positive Rods

Moderate Gram Positive Cocci in chains

Many Gram Negative Rods

Many Gram Positive Cocci in Clusters

Culture Result: Moderate Growth Normal Respiratory Flora

Isolate 1: Heavy Growth

Klebsiella pneumonia

Sensitive to Ampicillin, Ciprofloxacillin and Gentamicin

Isolate 2: Heavy Growth

Staphylococcus aureus

Sensitive to Ampicillin, Ciprofloxacillin and Gentamicin

```
...(Parent Respiratory Culture ORC/OBR Group)
OBX|1|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM STAIN|^1^1|MNY^Many^L^...
OBX|2|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM STAIN|^1^2|WBCS^WBCS^L^..
OBX|3|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM STAIN|^2^1|MOD^Moderate^L^...
OBX|4|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM STAIN|^2^2|GPR^Gram Positive Rods^L^...
OBX|5|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM STAIN|^3^1|MOD^Moderate^L^...
OBX|6|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM STAIN|^3^2|GPCCH^Gram Positive Cocci in
chains^L^...
OBX|7|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM STAIN|^4^1|MNY^Many^L^...
OBX|8|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM STAIN|^4^2|GNR^Gram Negative Rods^L^...
OBX|9|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM STAIN|^5^1|MNY^Many^L^...
OBX|10|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM STAIN|^5^2|GPCCL^Gram Positive Cocci in
clusters^L^...
OBX|11|CWE|624-7^Bacteria Spt Resp Cul^LN^...|^6^1|263812008^Moderate growth^SCT^...
OBX|12|CWE|624-7^Bacteria Spt Resp Cul^LN^...|^6^2|23506009^Normal flora^SCT^...
OBX|13|CWE|624-7^Bacteria Spt Resp Cul^LN^...|^7^1^1|655938018^Heavy growth^SCT^...
OBX|14|CWE|624-7^Bacteria Spt Resp Cul^LN^...|^7^2^1|56415008^Klebsiella pneumonia^SCT^...
OBX|13|CWE|624-7^Bacteria Spt Resp Cul^LN^...|^8^1^2|655938018^Heavy growth^SCT^...
OBX|14|CWE|624-7^Bacteria Spt Resp Cul^LN^...|^8^2^2|3092008^Staphylococcus aureus^SCT^...
...(Child Klebsiella Sensitivity ORC/OBR Group)
OBX|1|SN|28-1^ Ampicillin Islt MIC ^LN^...|^1^1^1|<^0.06|ug/mL^^UCUM^...
OBX|2|SN|185-9^ Ciprofloxacin Islt MIC ^LN^...|^1^2^1|<^0.05|ug/mL^^UCUM^...
OBX|3|SN|267-5^Gentamicin Islt MIC^LN^...|^1^3^1|<^0.05|ug/mL^^UCUM^...
...(Child Staphylococcus Sensitivity ORC/OBR Group)
OBX|1|SN|28-1^ Ampicillin Islt MIC ^LN^...|^1^1^2|<^0.06|ug/mL^^UCUM^...
```

```
OBX|2|SN|185-9^ Ciprofloxacin Islt MIC ^LN^...|^1^2^2|<^0.05|ug/mL^^UCUM^...
OBX|3|SN|267-5^Gentamicin Islt MIC^LN^...|^1^3^2|<^0.05|ug/mL^^UCUM^...
```

5.3.8.3 ALLOWED OBX-11 TRANSITIONS

The following is a description of how the OBX-11 (Observation Result Status) can transition from one value to another value.

This is the status on one OBX, depending on when a change occurs in that OBX; when an OBX is sent unaltered in an update message the status remains the same.

Example: If an OBX has been reported with an OBX-11 status of P (Preliminary), then the next time it is reported with any changes, the allowed OBX-11 status may be P, F or W, but not I, C, A, B, N, D or X.

How to Read The Table

First row: An existing OBX-11 valued 'I' can take on the following values in a subsequent transaction: 'I', 'P', 'F', 'N', 'X', 'D' or 'W'. It cannot be changed to 'C', 'A' or 'B'.

Second row: An existing OBX-11 valued 'P' can take on the following values in a subsequent transaction: 'P', 'F' or 'W'. It cannot be changed to 'I', 'C', 'A', 'B', 'N', 'X' or 'D'.

Third row: An existing OBX-11 valued 'F' can take on the following values in a subsequent transaction: 'F', 'C', 'A', 'B' or 'W'. It cannot be changed to 'I', 'P', 'N', 'X' or 'D'.

Fourth row: An existing OBX-11 valued 'C' can take on the following values in a subsequent transaction: 'C' or 'W'. It cannot be changed to 'I', 'P', 'F', 'A', 'B', 'N', 'X' or 'D'.

Fifth row: An existing OBX-11 valued 'A' can take on the following values in a subsequent transaction: 'C', 'A' or 'W'. It cannot be changed to 'I', 'P', 'F', 'B', 'N', 'X' or 'D'.

Sixth row: An existing OBX-11 valued 'B' can take on the following values in a subsequent transaction: 'C', 'A', B' or 'W'. It cannot be changed to 'I', 'P', 'F', 'N', 'X' or 'D'.

Seventh row: An existing OBX-11 valued 'N' can take on the following values in a subsequent transaction: 'N' or 'W'. It cannot be changed to 'I', 'P', 'F', 'C, 'A', 'B', 'X' or 'D'.

Eighth row: An existing OBX-11 valued 'X' can take on the following values in a subsequent transaction: 'X' or 'W'. It cannot be changed to 'I', 'P', 'F', 'C, 'A', 'B', 'N' or 'D'.

Ninth row: An existing OBX-11 valued 'D' can take on the following values in a subsequent transaction: 'D' or 'W'. It cannot be changed to 'I', 'P', 'F', 'C, 'A', 'B', 'X' or 'N'.

Ninth row: An existing OBX-11 valued 'W' can ONLY remain 'W'. It cannot be changed to 'I', 'P', 'F', 'C, 'A', 'B', 'X', 'N' or 'D'.

Table Legend

Not Allowed
A=Allowed

TABLE 5-18. ALLOWED OBX-11 TRANSITIONS											
OBX-11 (EXISTING RESULT)		TO OBX-11 (NEW RESULT)									
		I	P	F	C	A	B	N	X	D	W
I	In Process	A	A	A				A	A	A	A
P	Preliminary		A	A							A
F	Final			A	A	A	A				A
C (1)	Corrected				A						A
A	Amended				A	A	A				A
B	Appended				A	A	A				A
N	Not Asked							A			A
X	Not Possible								A		A
D	Delete									A	A
W	Wrong										A

Notes

(1) Once Corrected, always Corrected – 'C' status can only progress to 'W'.

5.3.9 SPM – SPECIMEN SEGMENT

TABLE 5-19. SPECIMEN SEGMENT (SPM)

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Set ID – SPM	SI	R	[1..1]		
2	Specimen ID	Varies	R	[1..1]		GU data type: EIP_GU NG data type: EIP_NG
3	Specimen Parent IDs		O			
4	Specimen Type	CWE_CRE	R	[1..1]	SNOMED CT and/or HL70487_USL	Either HL70487 or SNOMED CT Specimen hierarchy codes may be used. It should be noted that in the future SNOMED CT Specimen hierarchy may become the only recommended value set so trading partners should consider moving in that direction.
5	Specimen Type Modifier		O			
6	Specimen Additives		O			
7	Specimen Collection Method		O			
8	Specimen Source Site		O			
9	Specimen Source Site Modifier		O			
10	Specimen Collection Site		O			
11	Specimen Role		O			
12	Specimen Collection Amount		O			
13	Grouped Specimen Count		O			
14	Specimen Description		O			
15	Specimen Handling Code		O			
16	Specimen Risk Code		O			

TABLE 5-19. SPECIMEN SEGMENT (SPM)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
17	Specimen Collection Date/Time	DR	RE	[0..1]		SPM-17.1 must use TS_4 for the data type definition. SPM-17.2 must use TS_5 for the data type definition. For specimen-based test, if only SPM-17.1 (Range Start Date/Time) is valued it must be the same as OBX-14 (Date/Time of the Observation). If both SPM-17.1 and SPM-17.2 (Range End Date/Time) are present and relates to the same observation, then OBX-14 must be within this DR range.
18	Specimen Received Date/Time		O			
19	Specimen Expiration Date/Time		O			
20	Specimen Availability		O			
21	Specimen Reject Reason	CWE_CRE	RE	[0..*]	HL70490_USL	SPM-21 should not be interpreted as the cancel reason.
22	Specimen Quality		O			
23	Specimen Appropriateness		O			
24	Specimen Condition	CWE_CRE	RE	[0..5]	HL70493_USL	
25	Specimen Current Quantity		O			
26	Number of Specimen Containers		O			
27	Container Type		O			
28	Container Condition		O			
29	Specimen Child Role		O			

Usage Note

When reporting child results, the children do not always inherit the specimen information reported on the parent. Each child OBR should include the specimen segment(s) for the observation it reports. For example, microbiology culture and susceptibility results.

Conformance Statements: Base Profile

LRI-50: The value of SPM-1 (Set ID – SPM) **SHALL** be valued sequentially starting the value '1' within a given segment group.

LRI-53: If one or more SPM segments are present for the same OBR, then the earliest SPM-17.1 (Range Start Date/Time) **SHALL** be equal to or before OBR-7 (Observation Date/Time) and OBR-7 (Observation Date/Time) **SHALL** be equal to or before the latest SPM-17.2 (Range End Date/Time).

LRI-54: If one or more SPM segments are present for the same OBR and if OBR-8 (Observation End Date/Time) is present, OBR-8 (Observation End Date/Time) **SHALL** be equal to or before the latest SPM-17.2 (Range End Date/Time).

LRI-71: SPM-2 shall not repeat with in a given order group.

5.3.9.1 GUIDANCE FOR RESULT MESSAGES DESCRIBING SPECIMEN REJECTION REASON AND SPECIMEN CONDITION

SPM-21 can be used for communicating the specimen rejection reason in a codified manor. This IG has identified HL70490_USL as the value set for SPM-21, though the content needs improvement. The SNOMED finding hierarchy also has some appropriate terms, but is not complete. Future work on these vocabularies could expand the content. Disposition of the specimen is a CLIA requirement which needs to be retained and displayed in the patient record and incorporated into any type of report regardless of the medium of that report (paper, display on screen).

Use of SPM-24 can be very useful for communicating specimen condition information that does not meet the laboratory's standard for acceptability (HL70493_USL). The SNOMED CT finding hierarchy also has some appropriate terms, but is not complete. Future work on these vocabularies could expand the content.

Since changes are needed to expand the current vocabularies and since SPM-21 and SPM-24 are only sufficient for conveying the cancelation reason when all analytes are cancelled for a single specimen related reason and only one specimen is present for the order, it will be necessary to use OBX-5 and NTE segment(s), which follow the same display/report rules as SPM-21, to convey the specimen rejection information.

For normally coded values OBX-5 will carry a code to indicate that the test could not be performed – for example `SNOMED: 373121007^Test not done (qualifier value)^SCT`. For non-coded values expect a string in OBX-5 indicating that the test was not performed. OBX-11 will contain the 'X' canceled result status code. The OBR -25 value is dependent on all the OBX-11 values in the ORC/OBR pair.

The NTE immediately following that OBX will then describe the reason the test could not be performed.

Example cancellation message

```
MSH…

PID…

ORC…

OBR|1|15810^H_Dx_2_0|16699480030^MB|123^Erythrocyte sedimentation rate^L|||20110331150551-
0800|||||||||^Smith^John||15810||008847||20110615102200|||X||||OBX|1|CE|30341-2^Erythrocyte
sedimentation rate^LN||373121007^Test not done (qualifier value^SCT^TNP^test not
performed^L||||||X|||20110331140551-
0800||33445566^Levin^Henry^^^^^^&2.16.840.1.113883.3.72.5.30.1&ISO^L^^^EN|||20110331150551-
0800||||Century Hospital^^^^^&2.16.840.1.113883.3.72.5.30.1&ISO^XX^^^987|2070 Test Park^^Los
Angeles^CA^90067^^B|2343242^Knowsalot^Phil^J.^III^Dr.^^^&2.16.840.1.113883.3.72.5.30.1&ISO^L^^^DN
NTE|1||Blood in tube was clotted, resulting in a rejection of the specimen and leaving the lab
unable to perform this test. Please resubmit a new specimen, if test is still desired.|
SPM|1|||119297000^BLD^SCT^BldSpc^Blood^99USA^^^Blood
Specimen||||||||||||20110103143428||||RC^Clotting^HL70490^CLT^Clotted^99USA^^^Blood clotted in
tube|||CLOT^Clotted^HL70493^CLT^Clotted^99USA^^^clotted blood
```

Example using OBX-5 and NTE segment for the same test, specimen and rejection reason

```
MSH…

PID…

ORC…

OBR|1|15810^H_Dx_2_0|16699480030^MB|123^Erythrocyte sedimentation rate^L|||20110331150551-
0800|||||||||^Smith^John||15810||008847||20110615102200|||F||||

OBX|1|ST|30341-2^Erythrocyte sedimentation rate^LN||test not performed||||||X|||20110331140551-
0800||33445566^Levin^Henry^^^^^^&2.16.840.1.113883.3.72.5.30.1&ISO^L^^^EN|||20110331150551-
0800||||Century Hospital^^^^^&2.16.840.1.113883.3.72.5.30.1&ISO^XX^^^987|2070 Test Park^^Los
Angeles^CA^90067^^B|2343242^Knowsalot^Phil^J.^III^Dr.^^^&2.16.840.1.113883.3.72.5.30.1&ISO^L^^^DN

NTE|1||Blood in tube was clotted, resulting in a rejection of the specimen and leaving the lab unable
to perform this test. Please resubmit a new specimen, if test is still desired.|

SPM|1|||119297000^BLD^SCT^BldSpc^Blood^99USA^^^Blood Specimen||||||||||||20110103143428
```

5.3.10 NTE – NOTES AND COMMENTS SEGMENT

The Notes and Comments Segment (NTE) is used to convey additional comments regarding the associated segment. The NTE segment is not intended for automatic processing. The contents of the NTE segment are primarily intended for human use. Automated process should not be based upon the contents of NTE-3 (Comment); rather the content of that field should be displayed to humans.

TABLE 5-20. NOTES AND COMMENTS SEGMENT (NTE)

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Set ID – NTE	SI	R	[1..1]		
2	Source of Comment		O			
3	Comment	FT	R	[1..1]		Comment contained in the segment. Note: This Implementation Guide disallows the use of '~', hexadecimal or local escape sequences as a line break indicator.
4	Comment Type		O			

Usage Note

One NTE segment shall contain a single complete comment. If several distinct comments are to be conveyed in the message, one NTE segment shall be used for each comment. The use of formatting commands in the base standard V2.7.1, Section 2.7.6, allows for appropriate formatting of the comment within the NTE-3 (Comment) field if desired. Specifically for representation of line breaks use the formatting command "\.br\" as defined in the base standard V2.7.1, section 2.7.6. Use of '~', hexadecimal, or local escape sequences as a line break indicator is NOT allowed.

The receiver shall not concatenate separate NTEs in any way that displays any part of multiple NTEs on the same line; see the EHR-S FR Implementation Guide.

Reports generated by the lab using the LRI message transaction must follow the LRI IG; reports generated by an external lab and received by an EHR via an LIS-LIS interface may contain additional NTEs and OBXs that must be accommodated for some period of time. This must be managed through local trading partner agreements.

Examples of valid formatted text within a single NTE

Option 1:

```
…
NTE|1||result should be interpreted in conjunction with other laboratory and \.br\ clinical data
available to the clinician.
NTE|2||Identification performed by DLS Laboratories, Aiea, HI.
NTE|3||Susceptibility performed by Focus Diagnostics, Inc., Cypress, CA
…
```

Option 3 implies that these are NOT 3 distinct concepts, but rather are to be considered together:

```
…
NTE|1||result should be interpreted in conjunction with other laboratory and \.br\ clinical data
available to the clinician. \.br\ Identification performed by DLS Laboratories, Aiea, HI.
\.br\ Susceptibility performed by Focus Diagnostics, Inc., Cypress, CA
…
```

Conformance Statements: Base Profile

LRI-55: NTE.1 (Set ID - NTE) **SHALL** be valued sequentially starting with the value '1' within a given segment group.

6 CODE SYSTEMS

Successful message implementation requires that transmitted messages (message instances) contain valid values for coded fields. It is important to note that code sets are relatively dynamic and subject to change between publications of these Implementation Guides.

Every code value passed in a message instance is drawn from a code system that either may have a globally unique identifier, such as an OID, an HL7 identifier (Table 0001), or a locally defined identifier. In general, the coded values allowed in a field (a) may be drawn from more than one code system, and (b) may be a subset of the codes from a given coding system. Combining (a) and (b) makes it possible for the allowed code value to be a combination of multiple subsets drawn from multiple coding systems. In most cases, only subsets of the codes defined in a code system are legal for use in a particular message.

The subsets of the codes that are allowed for a particular field is identified by an HL7 construct known as a "value set." A value set is a collection of coded values drawn from code systems. Value sets serve to identify the specific set of coded values for the message from the universe of coded values across all coding systems.

The segment tables in previous sections identify the value set or coding system used for each supported field containing a coded value. Some of these pre-coordinated value sets must be updated, or new ones created, as new needs are identified.

Value sets may have a unique identifier but this identifier is not transmitted in the message. The identifier or code for the coding system from which the value is derived is sent in the message. However, the value set identifier is useful and important when vocabulary items are modified or replaced.

When extending an open value set by adding new codes to it, the code system chosen for the new code(s) is based upon the following rules:

> HL7 Table 0396 defines the standard coding systems recognized by HL7. Any code/coding system not defined in HL7 Table 0396 is considered a “local” coding system from the HL7 perspective and identified with an ‘L’ or the use of ‘99zzz’ where ‘zzz’ represents a three-character string identifying the specific non-standard coding system. Therefore, if the new code belongs to a code system defined in HL7 Table 0396, use that code system, otherwise use either ‘L’ or ‘99zzz’.
>
> Other than those code systems specified in the value sets associated with this Implementation Guide, all other code systems in HL7 Table 0396 are considered to be ‘P’ (Permitted), see http://www.hl7.org/special/committees/vocab/table_0396/index.cfm

6.1 LOINC

The use of the Logical Observation Identifiers Names and Codes (LOINC) vocabulary is required where a LOINC code is available for the test being resulted. The LOINC terms transmitted by the sender in OBX-3 must be valid but it is not the intent of this guide to specify LOINC values for a given test.

LOINC shall be used as the standard coding system to identify the Resulted Test in the Observation Identifier (OBX-3) if an appropriate LOINC code exists. Appropriate status is defined in the LOINC Manual Section 11.2 Classification of LOINC Term Status. If a local coding system is in use, a local

code should also be sent to help with identification of coding issues. When no valid LOINC exists the local code may be the only code sent.

While data storage requirements in the EHR will not be addressed in this guide, it is recommended that LOINC codes be stored in or accessible by the EHR for the following reasons:

1. If the result is related to a reportable condition and the laboratory provides a LOINC code, Meaningful Use Stage 1 requires the EHR to send the LOINC code to public health.

2. If the LOINC code is the only code sent to the EHR in OBX-3, then the EHR must store and retain that code to satisfy CLIA reporting requirements.

3. LOINC codes may be used for secondary data exchange purposes and other partner exchange agreements.

For further information on LOINC, request codes for new tests, and access to tools, please visit http://loinc.org/

6.2 SNOMED CT

For receivers, SNOMED CT is a required vocabulary for Microbiology related results reported as Coded With Exception (CWE) data types in OBX.5 (and identified as CWE in OBX-2). When received, certified EHR technology shall be capable of supporting SNOMED CT codes (Concept ID, and if sent, Description as provided by IHTSDO.

For senders, SNOMED CT is the recommended vocabulary in this release of the Implementation Guide. It is the intent of this Guide to move toward requiring the use of SNOMED CT on the sender side in a future release. Senders are highly encouraged to implement SNOMED CT support as soon as possible.

For results other than Microbiology, the use of SNOMED CT would need to be negotiated between trading partners, but its use is recommended.

If a SNOMED CT code is not published for a Microbiology coded result, it is acceptable to use an alternate or local coding system (and identified as CWE in OBX-2) by itself.

When SNOMED CT is used in OBX-5, CWE_CR.9 shall contain the laboratory's original text which is used for printing and/or display to satisfy CLIA reporting requirements. CWE_CR.2 and CWE_CR.9 may contain the same value, when the coded description is also the original text.

6.3 Example HL7 Messages

General Format for OBX-2 = CWE (SNOMED CT required when available code is published)

```
OBX|1|CWE|LOINC code^Loinc Longname^LOINC code systemID||
CWE.1=SNOMED CT ConceptID^CWE.2=description^CWE.3=SNOMED CT code
systemID^CWE.4=alt. code ^CWE.5=alt. description^CWE.6=alt. code
system^CWE.7=SNOMED CT code system version^CWE.8=alt. code system
version^CWE.9=original text||||||F|||200808151030-
0700|||0086^Bacterial identification^OBSMETHOD^^^^501-
20080815||200808161030-0700||||Reliable Labs,
Inc^L^^^^CLIA&2.16.840.1.113883.19.4.6&ISO^XX^^^1236|3434 Industrial
Loop^^Ann
Arbor^MI^99999^USA^B|9876543^Slide^Stan^S^^^^^NPPES&2.16.840.1.113883
.19.4.6&ISO^L^^^NPI
```

SNOMED CT-Specific Format for OBX-2 = CWE (SNOMED CT required for receivers/recommended for senders when available code is published)

Example of organism finding with generic LOINC in Nominal scale:

```
OBX|1|CWE|600-7^Bacteria identified in Blood by Culture^LN||
112283007^Escherichia coli^SCT^ECO^Escherichia coli
^L^20110731^1^beta-hemolytic streptococcus
isolated||||||F|||200808151030-0700|||0086^Bacterial
identification^OBSMETHOD^^^^501-20080815||200808161030-
0700||||Reliable Labs,
Inc^L^^^^CLIA&2.16.840.1.113883.19.4.6&ISO^XX^^^1236|3434 Industrial
Loop^^Ann
Arbor^MI^99999^USA^B|9876543^Slide^Stan^S^^^^^NPPES&2.16.840.1.113883
.19.4.6&ISO^L^^^NPI
```

Example of substance finding with generic LOINC in Nominal scale:

```
OBX|1|CWE|34175-0^Analgesics [Identifier] in Serum or Plasma^LN||
387494007^Codeine^SCT^COD^Codeine^L^20110731^1^Codeine
cdetected||||||F|||200808151030-0700|||0086^Bacterial
identification^OBSMETHOD^^^^501-20080815||200808161030-
0700||||Reliable Labs,
Inc^L^^^^CLIA&2.16.840.1.113883.19.4.6&ISO^XX^^^1236|3434 Industrial
Loop^^Ann
Arbor^MI^99999^USA^B|9876543^Slide^Stan^S^^^^^NPPES&2.16.840.1.113883
.19.4.6&ISO^L^^^NPI
```

Example for presence finding with organism specific LOINC in Ordinal scale:

```
OBX|1|CWE|546-2^Streptococcus.beta-hemolytic [Presence] in Throat by
Organism specific culture^LN||46651001^isolated^SCT^ISO^Iisolated^
^L^20110731^1^beta-hemolytic streptococcus
isolated||||||F|||200808151030-0700|||0086^Bacterial
identification^OBSMETHOD^^^^501-20080815||200808161030-
```

```
0700|||Reliable Labs,
Inc^L^^^^CLIA&2.16.840.1.113883.19.4.6&ISO^XX^^^1236|3434 Industrial
Loop^^Ann
Arbor^MI^99999^USA^B|9876543^Slide^Stan^S^^^^^NPPES&2.16.840.1.113883
.19.4.6&ISO^L^^^NPI
```

General Format for OBX-2 = CWE

```
OBX|1|CWE|546-2^Streptococcus.beta-hemolytic [Presence] in Throat by
Organism specific culture^LN^^^^||53490009^beta-hemolytic
streptococcus^SCT^^^^^beta-hemolytic streptococcus
isolated||||||F|||200808151030-0700|||0086^Bacterial
identification^OBSMETHOD^^^^501-20080815||200808161030-
0700|||Reliable Labs,
Inc^L^^^^CLIA&2.16.840.1.113883.19.4.6&ISO^XX^^^1236|3434 Industrial
Loop^^Ann
Arbor^MI^99999^USA^B|9876543^Slide^Stan^S^^^^^NPPES&2.16.840.1.113883
.19.4.6&ISO^L^^^NPI
```

TABLE 6-1. EXAMPLES OF SNOMED CT CODES FOR FREQUENTLY REPORTED ORGANISMS

Description	SNOMED SCT (CUI) Code	SNOMED CT Text
ESBL Escherichia coli	409800005	ESBL Escherichia coli
Escherichia coli	112283007	Escherichia coli
Staphylococcus aureus	3092008	Staphylococcus aureus
MRSA	115329001	methicillin resistant Staphylococcus aureus
Pseudomonas aeruginosa	52499004	Pseudomonas aeruginosa
Group B Streptococcus	43492007	Streptococcus agalactiae
Proteus mirabilis	73457008	Proteus mirabilis
coagulase-negative staphylococcus	116197008	Staphylococcus, coagulase negative
Enterococcus faecium	90272000	Enterococcus faecium
VRE	113727004	vancomycin resistant enterococcus

Note: SNOMED CT not required

6.4 Specimen Type

SNOMED CT is a suggested vocabulary for specimen source terms in SPM-4 (Specimen type) when a SNOMED CT code is available for the specimen source, pending the outcome of pilot testing. Specimen type/source terms in SPM-4 should be drawn from the specimen hierarchy in SNOMED CT or may be drawn from HL7 Table 0487 as it is a commonly used vocabulary (until deprecated by HL7).

Note: Pending the outcome of successful pilot testing, the workgroup anticipates that SNOMED CT would be the recommended vocabulary for specimen type/source concepts in the long term.

Further information on SNOMED CT can be found at the National Library of Medicine.

6.5 UCUM

UCUM (Unified Code for Units of Measure) is the preferred standard for reporting units of measure when it is supported by the analytic procedure's documentation for an FDA 510k approved method. (Note: the FDA approved units must be used for reporting, regardless of the standard used)

While this version of the guide does not require UCUM reporting units for test results, we encourage moving to the UCUM standard over time, specifically using case-sensitive abbreviations as the coded value.

For dimensionless units the UCUM representation "{any string}" can be used, e.g., for a titer the UCUM representation is "{titer}^titer^UCUM". Only the string in the curly braces should be considered the "UCUM" unit. To communicate that an analyte has "No units", OBX-6 should be empty.

A table of commonly used example UCUM units for electronic messaging is available here: http://loinc.org/downloads/usage/units.

Further information on UCUM can be found at http://unitsofmeasure.org/

7 LABORATORY RESULT MESSAGE DEVELOPMENT RESOURCES

Examples should not be used as the basis for implementing the messages in the Implementation Guide. Examples are handcrafted and as such are subject to human error.

The National Institute of Standards and Technology (NIST) has established a website (healthcare.nist.gov) to support the HIT developer community. The site has a number of tools and related materials to assist implementers with the development and testing of software in preparation for ONC Certification.

To support the Laboratory Messaging community, a repository has been established to function as a dynamic library of V2.x.x example messages, technical corrections, and other materials with the intent of providing continuous growth of resources without being time bound to future publications of this guide.

The repository is available at http://hl7v2-lab-testing.nist.gov/mu-lab/.

7.1 Cardinality Testing

As part of testing message elements with unlimited cardinality, minimum testing limits have been established and are defined in a spreadsheet that will be accessible on the National Institute of Standards and Technologies HIT testing site (see link above).

Depending on the element, a failure to consume all repeats can result in either a hard or a soft error; the error type is also indicated in the spreadsheet. The error(s) must be communicated to the sender using the application acknowledgement.

A system that passes cardinality testing limits but cannot handle more than the number of tested repeats will be considered non-conformant. Trading partners shall set up error resolution protocols to handle these situations.

7.2 Length Testing

Some message elements do not have a length constraint – specifically per the underlying standard these are the FT and TX data types. For testing purposes length for these elements has been limited to 64k characters.

7.3 Attached File Size Testing

For PDF files and other attachments, testing will use 40MB as the “reasonable file size” test target.

8 ADDITIONAL IMPLEMENTATION GUIDANCE – REFLEX AND CULTURE/SUSCEPTIBILITY TESTING

8.1 Parent/Child Reporting for Reflex and Culture/Susceptibility Testing

Release Note: Revised examples will be provided for this section that are conformant to the statements in the final publication of this Release (D1). The examples in the shaded boxes below are all subject to changes as a result of ballot.

8.1.1 PARENT/CHILD LINKING

This section presents a brief discussion on Parent/Child Linking and how the use of PRU, FRU, PRN, and FRN effect which fields may be required to properly identify the link between parent and child.

8.1.1.1 HIGH LEVEL DESCRIPTION OF PARENT/CHILD LINKING

It must be understood that an observation can be the catalyst for additional tests, e.g., reflex tests. When looking at those tests, it is important to understand which observation was the originator (Parent), and which observation was generated (Child). Note that there is no information in the Parent that indicates the presence of a Child. It is the function of the Child pointing to a Parent that defines the relationship.

Both parent and child(ren) must be in the same message and the parent must precede its child(ren).

8.1.1.2 FRU, FRN, GU AND NG PROFILE COMPONENT CONSIDERATIONS

The specific combination of RU flavor (PRU or FRU), RN flavor (PRN or FRN), GU and NG components impact the specific combination of fields, components and sub-components that must be correctly populated in a message to support linking Child with Parent. As a reminder, the various profile components are repeated here:

- GU - This profile component indicates the use of Globally Unique Identifiers through ISO OID as described in Section 1.4.2 Profile and Component Architecture
- NG - This profile component indicates that the identification method has been negotiated between the trading partners and is not required to guarantee global uniqueness
- PRU and FRU - These profile components indicates that the test can be identified using the placer order number (PRU) or using the filler order number (FRU). No additional information is necessary since either identifier on its own is unique.
- PRN and FRN - These profile components indicates that the test can be only be identified using the placer order number (PRN) or the filler order number (FRN) in combination with the Parent Universal Service Identifier

When using the FRU Component, because of the uniqueness of the placer order number and/or filler order number, fewer fields are needed to link the Child to its Parent. When the PRN and FRN Components are both used in a single message, the non-unique placer order numbers and filler order numbers require a Parent Universal Service Identifier be used along with the non-unique order number to uniquely link the Child to the Parent. Use of the GU and NG profile components dictates

what data type components must be populated for the EI & EIP data types used to link the Child to its Parent. The following table shows the potential profile component combinations. This section will provide examples illustrating parent/child result linking for each of these combinations.

TABLE 8-1 COMPONENT COMBINATIONS

	FRN	RU
GU	FRN + GU	FRU + GU
NG	FRN + NG	FRU + NG

8.1.1.3 DETAILED EXPLANATION OF HOW PARENT/CHILD RESULT LINKING WORKS

Order processing of the child is beyond the scope of this document, it is important to note that the Child observations will have its own Common Order (ORC)/Observation Request (OBR) group. The Child's "Parent Result" field (OBR-26), and "Parent" field (OBR-29) are used to link to the Parent as described below.

8.1.1.3.1 OBR-26 – PARENT RESULT

OBR-26 is populated in the Child observations, and this provides a link between the Child OBR, and the OBX in the Parent that generated the new tests. It will contain the two subfields, the first (OBR-26.1) will be valued with the Parent's "Observation Identifier" (OBX-3), and the second (OBR-26.2) will be valued with the Parent's "Observation Sub-ID" (OBX-4). (Please

Note: The Parent's "Observation Identifier" (OBX-3) component separators will need to be converted to sub-component separators when placed into the Child's OBR.

Note that OBR-26 Parent Result link works the same across each component profile combination. Also note that OBR-26 alone is insufficient to identify the OBR the parent OBX is associated with. OBR-29 (Parent) and potentially OBR-50 (Parent Universal Service Identifier) are needed to identify the specific parent OBR that the parent OBX is associated with.

Parent OBX

```
OBX|1|TX|008847^Urine Culture, Routine^99zzz^630-4^Bacteria
identified^LN^^^Bacteria identified|1|L-99990^Gram negative
rods^ORM||||||F|20031013163200||20110615100900|…
```

Child OBR

```
OBR|2|15810^H_Dx_2_0|16699480030^MB|997135^Antimicrobial
Susceptibility^99zzz|||20110614160000||||G|||||^Family^Fay||15810||||
20110615102200|||F|008847&Urine Culture, Routine&99zzz&630-4&Bacteria
identified&LN&&&Bacteria identified^1|…
```

8.1.1.3.2 OBR-29 – PARENT

OBR-29 is populated in the Child observations, and this provides a link between the Child OBR, and the Parent OBR. The Child's OBR-29 shall contain two fields the first (OBR-29.1) will be populated with the Parent's OBR-2 value, and the second field (OBR-29.2) will be populated with the Parent's

OBR-3 value. (Please note: The Parent's OBR-2, and OBR-3, component separators will need to be converted to sub-component separators when placed into the Child's OBR.)

Regardless of profile component, OBR-29 is required if OBR-11 (Specimen Action Code) is populated with a G indicating the OBR is associated with a generated or reflex order).

For the messages with either the PRU or FRU component profile, OBR-29 is sufficient to link the child OBR to the correct parent OBR- The two examples below show how OBR-29 is used in the PRU-FRU-NG and PRU-FRU-GU profile combinations.

Example: FRU-NG Profile

Parent OBR

```
OBR|1|15810^H_Dx_2_0|16699480030^MB|008847^Urine Culture,
Routine^99zzz|||20110614160000||||||^SRC:CL
CATCH|||^Family^Fay||||||20110615102200|||F|…
```

Child OBR

```
OBR|2|15811^H_Dx_2_0|16699480031^MB|997135^Antimicrobial
Susceptibility^99zzz|||20110614160000||||G||||||^Family^Fay||||||20110
615102200|||F|008847&Urine Culture,
Routine&99zzz^1|||15810&H_Dx_2_0^16699480030&MB|…
```

Example: FRU-GU Profile

Parent OBR

```
OBR|1|15810^^2.16.840.1.113883.19.3.1.1^ISO|16699480030^^2.16.840.1.1
13883.19.3.1.2^ISO|008847^Urine Culture,
Routine^99zzz|||20110614160000||||||^SRC:CL
CATCH|||^Family^Fay||||||20110615102200|||F|…
```

Child OBR

```
OBR|2|15811^^2.16.840.1.113883.19.3.1.1^ISO|16699480031^^2.16.840.1.1
13883.19.3.1.2^ISO|997135^Antimicrobial
Susceptibility^99zzz|||20110614160000||||G||||||^Family^Fay||||||20110
615102200|||F|008847&Urine Culture,
Routine&99zzz^1|||15810&&2.16.840.1.113883.19.3.1.1&ISO^16699480030&&
2.16.840.1.113883.19.3.1.2&ISO|…
```

Notes

1) The PRU and FRU profiles require that the OBR be uniquely identified by the OBR-2 (in the case of the PRU) and/or the OBR-3 (in the case of the FRU). This means that use of either the PRU or FRU component provides uniqueness at the OBR level. Remember the Child's result uses the parent's OBR-2 AND OBR-3 values for identification, so as long as one of them are unique per OBR, the combination of the two will also be unique.

2) The examples show OBR-2 populated in both the Parent and Child OBR's. In many circumstances, the Child OBR-2 will likely be empty as the placer is unlikely to assign a placer order number for the child result. Since all profiles have OBR-2 list as RE (required but may be empty) this is not normally a problem. However, use of null OBR-2 would cause problems with matching the Child result to a parent if the profile components where a combination of PRU and FRN. (Filler order number is not unique, and the Placer Order Number is empty, effectively also not unique.) In a situation where the component profiles are PRU and FRN, and the filler can send empty OBR-2 values, then OBR-50 is required, just as if the message where using the PRN and FRN component profiles. (More on this can be found below.)

3) OBR-11 (Specimen Action Code) is valued with G (generated or reflex order) of the second OBR in each example. When OBR-11 is valued G, OBR-29 becomes required.

When the PRN and FRN Components are both used (or PRU and FRN with the possibility of an empty OBR-2 as described above), an additional identifier is needed to overcome the lack of uniqueness in the order numbers and filler order numbers. To obtain the uniqueness that the Child result needs to successfully identify its Parent, the non-unique order number(s) are combined with the Parent's Universal Service Identifier (OBR-4) as described below:

8.1.1.3.3 OBR-50 – PARENT UNIVERSAL SERVICE IDENTIFIER

OBR-50 of the Child is used in combination with the parent's universal service identifier OBR-4 to uniquely identify linking relationship, specifically when working with single requisition identifiers used on multiple ordered tests (the PRN and FRN Components). When the FRU component is used, then OBR-50 is not needed for linking the Child to the Parent OBR, as OBR-26 is sufficient to this task. If PRU is used theoretically OBR-50 would not need to be supported, but as previously noted, in some reflex situations the value of OBR-2 is empty, and as such use of the PRU may not provide the uniqueness required to identify the Parent OBR. In that case OBR-50 becomes required.

Example: FRN-NG

Non-Parent OBR, followed by Parent OBR (single requisition example, as potentially found in RN Component)

```
OBR|1|15810^H_Dx_2_0|16699480030^MB|007204^Amikacin Peak,
Serum^99zzz|||20110614160000|||||||||^Family^Fay|||||2011061510
2200|||F||||
OBR|1|15810^H_Dx_2_0|16699480030^MB|008847^Urine Culture,
Routine^99zzz|||20110614160000||||||
|||^Family^Fay||||||20110615102200|||F||||
```

Child OBR

```
OBR|2|15810^H_Dx_2_0|16699480030^MB|997135^Antimicrobial
Susceptibility^99zzz|||20110614160000||||G|||||^Family^Fay||||||
20110615102200|||F|008847&Urine Culture,
Routine&99zzz^1|||15810&H_Dx_2_0^16699480030&MB||||||||||||||||
||||008847^Urine Culture, Routine^99zzz
```

Example: FRN-GU Profile

Non-Parent OBR, followed by Parent OBR (single requisition example, as potentially found in FRN Component):

```
OBR|1|15810^^2.16.840.1.113883.19.3.1.1^ISO|16699480030^^
2.16.840.1.113883.19.3.1.2^ISO|007204^Amikacin Peak,
Serum^99zzz|||20110614160000|||||||||^Family^Fay||||||2011061510
2200|||F||||
OBR|1|15810^^2.16.840.1.113883.19.3.1.1^ISO|16699480030^^
2.16.840.1.113883.19.3.1.2^ISO|008847^Urine Culture,
Routine^99zzz|||20110614160000||||||
|||^Family^Fay||||||20110615102200|||F||||
```

Child OBR

```
OBR|2|15810^^2.16.840.1.113883.19.3.1.1^ISO|16699480030^^2.16.84
0.1.113883.19.3.1.2^ISO|997135^Antimicrobial
Susceptibility^99zzz|||20110614160000||||G|||||^Family^Fay||||||
20110615102200|||F|008847&Urine                                Culture,
Routine&99zzz^1|||15810&&2.16.840.1.113883.19.3.1.1&ISO^16699480
030&&2.16.840.1.113883.19.3.1.2&ISO||||||||||||||||||||008847
Urine Culture, Routine^99zzz
```

8.1.1.3.4 SPECIMEN INHERITANCE

When reporting child results, the specimen information reported on its parent are not automatically assumed to be inherited by the children. Each child OBR must include the relevant specimen segment(s) for the observations being reported.

8.2 Culture and Susceptibilities Reporting

Section 6.1 describes the general use of parent-child result linking which may apply to any sort of reflex testing. This section focuses on parent/child result linking for the purpose of reporting microbiology culture and susceptibilities.

8.2.1 INTRODUCTION

Culture and sensitivities (e.g., reporting of multi-resistant tuberculosis or drug-resistant gonococcus or pneumococcus) can be reported using the HL7 electronic messaging standard in a number of different ways. Consequently, many vendors and large laboratories use varying methods to account for variations in the systems with which they work while still staying within the standard definitions. To improve consistency when implementing new or upgrading existing laboratory results interfaces, and considering that culture and susceptibilities reporting is a critical component of electronic, laboratory-based public health reporting, this IG requires a specific approach, using parent-child relationship, when reporting microbiology results for this message profile that shall be supported.

Both parent and child(ren) must be in the same message and the parent must precede its child(ren).

8.2.2 TEMPLATE FOR CULTURE RESULTS

A template report for the initial identification of three organisms from a single stool culture is presented below. For each field (*i.e.*, the space between the pipes, "|"), a description of what should appear in that particular field is given, along with the segment-field number in parentheses (*e.g.*, OBR-3) for some of the fields. Note that these examples use the ORU^R01 message type.

Example

```
MSH|…

PID|…

ORC|…

OBR|1| Placer number (OBR-2)| Filler number (OBR-3)| Identifier
    code for the requested test or panel of tests(OBR-4)|…

TQ1|…

OBX|1|CWE| Other identifier (OBX-3) | Sub-id for the first
    observation group (OBX-4) | Observation on the specimen (OBX-5)
    |… |Observation type= 'RSLT' (OBX-29)| Observation Sub-Type =
    'MNIR'(OBX-30)

…

OBX|n|CWE| Specific organism identifier (OBX-3) | Sub-id for the
    first organism (OBX-4) | Description of organism (OBX-5)
    |…|Observation type= 'RSLT' (OBX-29)| Observation Sub-Type =
    'MIR'(OBX-30)

OBX|n+1|CWE| Other identifier (OBX-3) | Sub-id for the first
    organism (OBX-4) | Observation on the organism (OBX-5) |…
    |Observation type= 'RSLT' (OBX-29)| Observation Sub-Type =
    'MIRM'(OBX-30)

OBX|n+2|CWE| Specific organism identifier (OBX-3) | Sub-id for the
    second organism (OBX-4) | Description of organism (OBX-5) |…
    |Observation type= 'RSLT' (OBX-29)| Observation Sub-Type =
    'MIR'(OBX-30)

OBX|n+3|CWE| Other identifier (OBX-3) | Sub-id for the second
    organism (OBX-4) | Observation on the Organism (OBX-5) |…
    |Observation type= 'RSLT' (OBX-29)| Observation Sub-Type =
    'MIRM'(OBX-30)

OBX|n+4|CWE| Specific organism identifier (OBX-3) | Sub-id for the
    third organism (OBX-4) | Description of organism (OBX-5) |…|
    Observation type= 'RSLT' (OBX-29)| Observation Sub-Type =
    'MIR'(OBX-30)

OBX|n+5|CWE| Other identifier (OBX-3) | Sub-id for the third
    organism (OBX-4) | Observation on the organism (OBX-5) |…
    |Observation type= 'RSLT' (OBX-29)| Observation Sub-Type =
```

```
    'MIRM'(OBX-30)
SPM|1| Specimen identifier for the specimen being tested|
```

This report has the MSH (Message Header), the PID (Patient Identification Segment), a single OBR (Observation Request Segment), and six OBX (Observation/Results) segments, and a single SPM (Specimen Segment). Note that the Set ID in the first field of each OBX is sequential, while the Sub-ID in the fourth field of each OBX is not sequential, but acts as a link for all of the OBX segments that are reporting information for a related observation. The Sub-ID field in the template above has the words "first," "second" and "third" in **bold** and highlighted in green. This is done to show that the identification of the first organism is the relating observation for the first two OBX segments (*e.g.*, Set-ID numbers 1 and 2). The identification of the second organism is the relating observation for the second two segments (*e.g.*, Set-ID numbers 3 and 4), and so on. An example using the template above is presented below.

8.2.3 EXAMPLES OF CULTURE RESULTS

Example

Note that the use of OBX-4 Sub-ID is independent of the component profile combination. For this example, message details have been omitted to emphasize the salient fields.

```
MSH|...
PID|...
ORC|RE|RP723234^...|250401^...|RGP12356^...
OBR|1|RP723234^...|250401^...|624-7^Bacteria Spt Resp Cul^LN^...
TQ1|1|...
OBX|1|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
    STAIN|^1^1|MNY^Many^L^...|...||RSLT|MNIR
OBX|2|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
    STAIN|^1^2|WBCS^WBCS^L^...|...||RSLT|MNIR
OBX|3|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
    STAIN|^2^1|MOD^Moderate^L^...|...||RSLT|MNIR
OBX|4|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
    STAIN|^2^2|GPR^Gram Positive Rods^L^...|...||RSLT|MNIR
OBX|5|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
    STAIN|^3^1|MOD^Moderate^L^...|...||RSLT|MNIR
OBX|6|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
    STAIN|^3^2|GPCCH^Gram Positive Cocci in chains^L^...
    |...||RSLT|MNIR
OBX|7|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
    STAIN|^4^1|MNY^Many^L^...|...||RSLT|MNIR
OBX|8|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
```

```
    STAIN|^4^2|GNR^Gram Negative Rods^L^...|...||RSLT|MNIR
OBX|9|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
    STAIN|^5^1|MNY^Many^L^...|...||RSLT|MNIR
OBX|10|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
    STAIN|^5^2|GPCCL^Gram Positive Cocci in clusters^L^...
    |...||RSLT|MNIR
OBX|11|CWE|624-7^Bacteria Spt Resp Cul^LN^...
    |^6^1|263812008^Moderate growth^SCT^...|...||RSLT|MNIR
OBX|12|CWE|624-7^Bacteria Spt Resp
    Cul^LN^...|^6^2|23506009^Normal flora^SCT^...|...||RSLT|MNIR
OBX|13|CWE|624-7^Bacteria Spt Resp Cul^LN^...
    |^7^1^1|655938018^Heavy growth^SCT^...|...||RSLT|MIRM
OBX|14|CWE|624-7^Bacteria Spt Resp Cul^LN^...
    |^7^2^1|56415008^Klebsiella pneumonia^SCT^...|...||RSLT|MIR
OBX|13|CWE|624-7^Bacteria Spt Resp Cul^LN^...
    |^8^1^2|655938018^Heavy growth^SCT^...|...||RSLT|MIRM
OBX|14|CWE|624-7^Bacteria Spt Resp Cul^LN^...
    |^8^2^2|3092008^Staphylococcus aureus^SCT^...|...||RSLT|MIR
SPM|1|^C448&...||45710003^Sputum specimen^SCT^...|...
```

8.2.4 TEMPLATE FOR CULTURE AND SUSCEPTIBILITY RESULTS

The template and example in Section 8.2 Culture and Susceptibilities Reporting describe a report for a culture. The following template shows how antimicrobial susceptibility results are reported for the culture described in that section. The connection of the culture to the susceptibilities is a "parent-child" relationship, where the culture is the parent result and the susceptibilities are the child results. This means that there can be many child results for a single parent result. In other words, there can be multiple OBR child segments for the single OBR parent segment. The template for the report containing the culture and susceptibilities appears below. The titles in ***Bold Italics*** are given to highlight the individual parent and child segments and are not found in an actual HL7 message transmission. It is important to note that each of the OBR child segment references the parent result. These reference fields are OBR-26 (Parent Result), OBR-29 (Parent Number) and, for the FRN component, ORC-31 and OBR-50 (Parent Universal Service Identifier).

Example

Message Header and Patient Identification Segment for the Parent-Child Message

```
MSH|…
PID|…
```

Parent ORC/OBR Group

ORC|RE|Placer number (OBR-2)|Filler number (OBR-3)|…

OBR|1| Placer number (OBR-2)| Filler number (OBR-3)| Identifier code for the requested test or panel of tests(OBR-4)|…

TQ1|…

Parent OBX Segments for Non-Isolate Related Specimen Observations

OBX|1|CWE| Other identifier (OBX-3) | Sub-id for the first observation group (OBX-4) | Observation on the specimen (OBX-5) |… |Observation type= 'RSLT' (OBX-29)| Observation Sub-Type = 'MNIR'(OBX-30)

…

Parent OBX Segments for First Organism Identified

OBX|n|CWE| Specific organism identifier (OBX-3) | Sub-id for the first organism (OBX-4) | Description of organism (OBX-5) |…|Observation type= 'RSLT' (OBX-29)| Observation Sub-Type = 'MIR'(OBX-30)

OBX|n+1|CWE| Other identifier (OBX-3) | Sub-id for the first organism (OBX-4) | Observation on the organism (OBX-5) |… |Observation type= 'RSLT' (OBX-29)| Observation Sub-Type = 'MIRM'(OBX-30)

Parent OBX Segments for Second Organism Identified

OBX|n+2|CWE| Specific organism identifier (OBX-3) | Sub-id for the second organism (OBX-4) | Description of organism (OBX-5) |… |Observation type= 'RSLT' (OBX-29)| Observation Sub-Type = 'MIR'(OBX-30)

OBX|n+3|CWE| Other identifier (OBX-3) | Sub-id for the second organism (OBX-4) | Observation on the Organism (OBX-5) |… |Observation type= 'RSLT' (OBX-29)| Observation Sub-Type = 'MIRM'(OBX-30)

Parent OBX Segments for Third Organism Identified

OBX|n+4|CWE| Specific organism identifier (OBX-3) | Sub-id for the third organism (OBX-4) | Description of organism (OBX-5) |…| Observation type= 'RSLT' (OBX-29)| Observation Sub-Type = 'MIR'(OBX-30)

OBX|n+5|CWE| Other identifier (OBX-3) | Sub-id for the third organism (OBX-4) | Observation on the organism (OBX-5) |… |Observation type= 'RSLT' (OBX-29)| Observation Sub-Type = 'MIRM'(OBX-30)

SPM Segment

SPM|1| Specimen identifier for the specimen being

tested|||**clinical specimen type**|…

Child ORC/OBR Group for First Organism identified

ORC|RE||Filler number (OBR-3)|…|Parent Universal Service Identifier**(ORC-31) The parent identifier code for the requested test or panel of tests (OBR-4 of Parent OBR)**

OBR|2| Placer number (OBR-2)| Filler order number (OBR-3) | Identifier code for the requested test or panel of tests (OBR-4) |...| Specimen Action Code='G'(OBR-11) |…| Parent Result**(OBR-26) The parent OBX segment that contained the identification of the first organism**|||**Parent(OBR-29) The parent placer and/or filler order numbers for the requested test or panel of tests (OBR-2 and OBR-3 of Parent OBR)**|…|**Parent identifier code for the requested test or panel of tests (OBR-4 of Parent OBR)**|...

Child OBX Segments for Susceptibilities of First Organism Identified

OBX|n|CE|Specific susceptibility identifier for first antimicrobial (OBX-3) |Sub-id (OBX-4)| Susceptibility finding (OBX-5) ||| Susceptibility interpretation (OBX-8) |…|Observation type= 'RSLT' (OBX-29)| Observation Sub-Type = 'SUR'(OBX-30)

OBX|n+1|CE|Specific susceptibility identifier for second antimicrobial (OBX-3) | Sub-id (OBX-4)| Susceptibility finding (OBX-5) ||| Susceptibility interpretation (OBX-8) |…|Observation type= 'RSLT' (OBX-29)| Observation Sub-Type = 'SUR'(OBX-30)

OBX|n+2|CE|Specific susceptibility identifier for third antimicrobial (OBX-3) | Sub-id (OBX-4)| Susceptibility finding (OBX-5) ||| Susceptibility interpretation (OBX-8) |…|Observation type= 'RSLT' (OBX-29)| Observation Sub-Type = 'SUR'(OBX-30)

SPM Segment

SPM|1|Specimen identifier for the specimen being tested||Isolate|…

Child ORC/OBR Group for Second Organism identified

ORC|RE||Filler number (OBR-3)|…|Parent Universal Service Identifier**(ORC-31) The parent identifier code for the requested test or panel of tests (OBR-4 of Parent OBR)**

OBR|3| Placer number (OBR-2)| Filler order number (OBR-3) | Identifier code for the requested test or panel of tests (OBR-4) |...| Specimen Action Code='G'(OBR-11) |…| Parent Result**(OBR-26) The parent OBX segment that contained the identification of the** second **organism**|||**Parent(OBR-29) The parent placer and/or filler order numbers for the requested test or panel of tests (OBR-2 and OBR-3 of Parent OBR)**|…|

Parent identifier code for the requested test or panel of tests (OBR-4 of Parent OBR)|...

Child OBX Segments for Susceptibilities of Second Organism Identified

OBX|n|CE|Specific susceptibility identifier for first antimicrobial (OBX-3) | Sub-id (OBX-4)| Susceptibility finding (OBX-5) ||| Susceptibility interpretation (OBX-8) |…|Observation type= 'RSLT' (OBX-29)| Observation Sub-Type = 'SUR'(OBX-30)

OBX|n+1|CE|Specific susceptibility identifier for second antimicrobial (OBX-3) | Sub-id (OBX-4)| Susceptibility finding (OBX-5) ||| Susceptibility interpretation (OBX-8) |…|Observation type= 'RSLT' (OBX-29)| Observation Sub-Type = 'SUR'(OBX-30)

OBX|n+2|CE|Specific susceptibility identifier for third antimicrobial (OBX-3) | Sub-id (OBX-4)| Susceptibility finding (OBX-5) ||| Susceptibility interpretation (OBX-8) |…|Observation type= 'RSLT' (OBX-29)| Observation Sub-Type = 'SUR'(OBX-30)

SPM Segment

SPM|1| Specimen identifier for the specimen being tested||Isolate|…

Child ORC/OBR Group for** Third **Organism identified

ORC|RE||Filler number (OBR-3)|…|Parent Universal Service Identifier**(ORC-31) The parent identifier code for the requested test or panel of tests (OBR-4 of Parent OBR)**

OBR|4| Placer number (OBR-2)| Filler order number (OBR-3) | Identifier code for the requested test or panel of tests (OBR-4) |...| Specimen Action Code='G'(OBR-11) |…| Parent Result**(OBR-26) The parent OBX segment that contained the identification of the** third **organism**|||**Parent(OBR-29) The parent placer and/or filler order numbers for the requested test or panel of tests (OBR-2 and OBR-3 of Parent OBR)**|…| **Parent identifier code for the requested test or panel of tests (OBR-4 of Parent OBR)**|...

Child OBX Segments for Susceptibilities of Third Organism Identified

OBX|n|CE|Specific susceptibility identifier for first antimicrobial (OBX-3) | Sub-id (OBX-4)| Susceptibility finding (OBX-5) ||| Susceptibility interpretation (OBX-8) |…|Observation type= 'RSLT' (OBX-29)| Observation Sub-Type = 'SUR'(OBX-30)

OBX|n+1|CE|Specific susceptibility identifier for second


```
    antimicrobial (OBX-3) | Sub-id (OBX-4)| | Susceptibility
    finding (OBX-5) ||| Susceptibility interpretation (OBX-8)
    |…|Observation type= 'RSLT' (OBX-29)| Observation Sub-Type =
    'SUR'(OBX-30)

OBX|n+2|CE|Specific susceptibility identifier for third
    antimicrobial (OBX-3) | Sub-id (OBX-4)| Susceptibility
    finding (OBX-5) ||| Susceptibility interpretation (OBX-8)
    |…|Observation type= 'RSLT' (OBX-29)| Observation Sub-Type =
    'SUR'(OBX-30)

SPM Segment

SPM|1| Specimen identifier for the specimen being
tested||Isolate|…
```

8.2.5 EXAMPLES OF CULTURE AND SUSCEPTIBILITY RESULTS

Using the template above, this example shows a report of three pathogens identified from a stool specimen with their respective antimicrobial susceptibility tests. Examples are provided for the FRU and FRN component profile combinations. Fields bolded and highlighted in **green** are used for linking parent and child results as identified in the template above. For these examples, message details have been omitted to emphasize the salient fields.

8.2.5.1 EXAMPLE FRU-GU PROFILE COMBINATION

In the FRU profile combinations (FRU-GU and FRU-GN) the order number alone is sufficient to uniquely identify the parent OBR. This means the child ORC(s) need only include the parent order number in OBR-29 to uniquely identify the parent OBR.

Example

```
MSH|...

PID|...

ORC|RE|RP723234^...|250401^...|RGP12356^...

OBR|1|RP723234^...|250401^...|624-7^Bacteria Spt Resp Cul^LN^...

TQ1|1|...

OBX|1|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
    STAIN|^1^1|MNY^Many^L^...|...||RSLT|MNIR

OBX|2|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
    STAIN|^1^2|WBCS^WBCS^L^...|...||RSLT|MNIR

OBX|3|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
    STAIN|^2^1|MOD^Moderate^L^...|...||RSLT|MNIR

OBX|4|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
    STAIN|^2^2|GPR^Gram Positive Rods^L^...|...||RSLT|MNIR

OBX|5|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
```

```
    STAIN|^3^1|MOD^Moderate^L^...|...||RSLT|MNIR
OBX|6|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
    STAIN|^3^2|GPCCH^Gram Positive Cocci in
    chains^L^...|...||RSLT|MNIR
OBX|7|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
    STAIN|^4^1|MNY^Many^L^...|...||RSLT|MNIR
OBX|8|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
    STAIN|^4^2|GNR^Gram Negative Rods^L^...|...||RSLT|MNIR
OBX|9|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
    STAIN|^5^1|MNY^Many^L^...|...||RSLT|MNIR
OBX|10|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
    STAIN|^5^2|GPCCL^Gram Positive Cocci in
    clusters^L^...|...||RSLT|MNIR
OBX|11|CWE|624-7^Bacteria Spt Resp
    Cul^LN^...|^6^1|263812008^Moderate
    growth^SCT^...|...||RSLT|MNIR
OBX|12|CWE|624-7^Bacteria Spt Resp
    Cul^LN^...|^6^2|23506009^Normal flora^SCT^...|...||RSLT|MNIR
OBX|13|CWE|624-7^Bacteria Spt Resp
    Cul^LN^...|^7^1^1|655938018^Heavy
    growth^SCT^...|...||RSLT|MIRM
OBX|14|CWE|624-7^Bacteria Spt Resp Cul^LN^...
    |^7^2^1|56415008^Klebsiella pneumonia^SCT^...|...||RSLT|MIR
OBX|15|CWE|624-7^Bacteria Spt Resp
    Cul^LN^...|^8^1^2|655938018^Heavy
    growth^SCT^...|...||RSLT|MIRM
OBX|16|CWE|624-7^Bacteria Spt Resp Cul^LN^...
    |^8^2^2|3092008^Staphylococcus aureus^SCT^...|...||RSLT|MIR
SPM|1|^C448&...||45710003^Sputum specimen^SCT^...|...
ORC|RE||S-2010733^...|RGP12356^...|...
OBR|2||S-2010733^...|50545-3^Bacterial susceptibility panel:-
    :MIC:Isolate:OrdQn:MIC^LN^...|...|G|...|F|624-7&Bacteria Spt
    Resp Cul&LN&...^ &7&2&1^Klebsiella
    pneumonia|||RP723234&...|…
TQ1|1|...
OBX|1|SN|28-1^Ampicillin Islt
    MIC^LN^...|^1^1^1|<^0.06|ug/mL^^UCUM^...||S|||F|...||RSLT|SU
    R
OBX|2|SN|185-9^Ciprofloxacin Islt
    MIC^LN^...|^1^2^1|<^0.05|ug/mL^^UCUM^...||S|||F|...||RSLT|SU
```

```
    R
OBX|3|SN|267-5^Gentamicin Islt
    MIC^LN^...|^1^3^1|<^0.05|ug/mL^^UCUM^...||S|||F|...||RSLT|SU
    R
SPM|1|^C448-1&...||119303007^Microbial isolate
    specimen^SCT^...|...
ORC|RE||S-2010734^...|RGP12356^...|...
OBR|3||S-2010734^...|50545-3^Bacterial susceptibility panel:-
    :MIC:Isolate:OrdQn:MIC^LN^...|...|G|...|F|624-7&Bacteria Spt
    Resp Cul&LN&...^ &8&2&2^Staphylococcus
    aureus|||RP723234&...|...
TQ1|1|...
OBX|1|SN|28-1^Ampicillin Islt
    MIC^LN^...|^1^1^2|<^0.06|ug/mL^^UCUM^...||S|||F|...||RSLT|SU
    R
OBX|2|SN|185-9^Ciprofloxacin Islt
    MIC^LN^...|^1^2^2|<^0.05|ug/mL^^UCUM^...||S|||F|...||RSLT|SU
    R
OBX|3|SN|267-5^Gentamicin Islt
    MIC^LN^...|^1^3^2|<^0.05|ug/mL^^UCUM^...||S|||F|...||RSLT|SU
    R
SPM|1|^C448-2&...||119303007^Microbial isolate
    specimen^SCT^...|...
```

8.2.5.2 EXAMPLE FRN PROFILE COMBINATIONS

In the FRN profile combinations (FRN-GU and FRN-GN) the order number in conjunction with the universal service identifier are necessary to uniquely identify the parent OBR- This means the child ORC(s) must include ORC-31 and OBR(s) must include OBR-50 (Parent Universal Service Identifier) along with the parent order number in OBR-29 to uniquely identify the parent OBR. OBR-26 identifies the result that the follow up order is based upon, if needed. For this example, message details have been omitted to emphasize the salient fields.

Example

```
MSH|...
PID|...
ORC|RE|RP723234^...|250401^...|RGP12356^...
OBR|1|RP723234^...|250401^...|624-7^Bacteria Spt Resp Cul^LN^...
TQ1|1|...
OBX|1|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
```

```
    STAIN|^1^1|MNY^Many^L^...|...||RSLT|MNIR
OBX|2|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
    STAIN|^1^2|WBCS^WBCS^L^...|...||RSLT|MNIR
OBX|3|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
    STAIN|^2^1|MOD^Moderate^L^...|...||RSLT|MNIR
OBX|4|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
    STAIN|^2^2|GPR^Gram Positive Rods^L^...|...||RSLT|MNIR
OBX|5|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
    STAIN|^3^1|MOD^Moderate^L^...|...||RSLT|MNIR
OBX|6|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
    STAIN|^3^2|GPCCH^Gram Positive Cocci in
    chains^L^...|...||RSLT|MNIR
OBX|7|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
    STAIN|^4^1|MNY^Many^L^...|...||RSLT|MNIR
OBX|8|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
    STAIN|^4^2|GNR^Gram Negative Rods^L^...|...||RSLT|MNIR
OBX|9|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
    STAIN|^5^1|MNY^Many^L^...|...||RSLT|MNIR
OBX|10|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
    STAIN|^5^2|GPCCL^Gram Positive Cocci in
    clusters^L^...|...||RSLT|MNIR
OBX|11|CWE|624-7^Bacteria Spt Resp
    Cul^LN^...|^6^1|263812008^Moderate
    growth^SCT^...|...||RSLT|MNIR
OBX|12|CWE|624-7^Bacteria Spt Resp
    Cul^LN^...|^6^2|23506009^Normal flora^SCT^...|...||RSLT|MNIR
OBX|13|CWE|624-7^Bacteria Spt Resp
    Cul^LN^...|^7^1^1|655938018^Heavy
    growth^SCT^...|...||RSLT|MIRM
OBX|14|CWE|624-7^Bacteria Spt Resp Cul^LN^...
    |^7^2^1|56415008^Klebsiella pneumonia^SCT^...|...||RSLT|MIR
OBX|15|CWE|624-7^Bacteria Spt Resp
    Cul^LN^...|^8^1^2|655938018^Heavy
    growth^SCT^...|...||RSLT|MIRM
OBX|16|CWE|624-7^Bacteria Spt Resp Cul^LN^...
    |^8^2^2|3092008^Staphylococcus aureus^SCT^...|...||RSLT|MIR
SPM|1|^C448&...||45710003^Sputum specimen^SCT^...|...
ORC|RE||S-2010733^...|RGP12356^...|…|624-7^Bacteria Spt Resp
    Cul^LN^...
OBR|2||S-2010733^...|50545-3^Bacterial susceptibility panel:-
```

```
    :MIC:Isolate:OrdQn:MIC^LN^...|...|G|...|F|624-7&Bacteria Spt
    Resp Cul&LN&...^ &7&2&1^Klebsiella
    pneumonia|||RP723234&...|…|624-74^Bacteria Spt Resp
    Cul^LN^...
TQ1|1|...
OBX|1|SN|28-1^Ampicillin Islt
    MIC^LN^...|^1^1^1|<^0.06|ug/mL^^UCUM^...||S|||F|...||RSLT|SUR
OBX|2|SN|185-9^Ciprofloxacin Islt
    MIC^LN^...|^1^2^1|<^0.05|ug/mL^^UCUM^...||S|||F|...||RSLT|SUR
OBX|3|SN|267-5^Gentamicin Islt
    MIC^LN^...|^1^3^1|<^0.05|ug/mL^^UCUM^...||S|||F|...||RSLT|SUR
SPM|1|^C448-1&...||119303007^Microbial isolate
    specimen^SCT^...|...
ORC|RE||S-2010734^...|RGP12356^...|...|624-7^Bacteria Spt Resp
    Cul^LN^...
OBR|3||S-2010734^...|50545-3^Bacterial susceptibility panel:-
    :MIC:Isolate:OrdQn:MIC^LN^...|...|G|...|F|624-7&Bacteria Spt
    Resp Cul&LN&...^ &8&2&2^Staphylococcus
    aureus|||RP723234&...|…|624-74^Bacteria Spt Resp Cul^LN^...
TQ1|1|...
OBX|1|SN|28-1^Ampicillin Islt
    MIC^LN^...|^1^1^2|<^0.06|ug/mL^^UCUM^...||S|||F|...||RSLT|SUR
OBX|2|SN|185-9^Ciprofloxacin Islt
    MIC^LN^...|^1^2^2|<^0.05|ug/mL^^UCUM^...||S|||F|...||RSLT|SUR
OBX|3|SN|267-5^Gentamicin Islt
    MIC^LN^...|^1^3^2|<^0.05|ug/mL^^UCUM^...||S|||F|...||RSLT|SUR
SPM|1|^C448-1&...||119303007^Microbial isolate
    specimen^SCT^...|...
```

8.3 Confirmatory and Reflex Testing

Definition: Additional laboratory testing included in the original test request by reference to specific follow-up testing, e.g. “Urinalysis w/Culture Reflex” as opposed to “Urinalysis” ordered as a standalone test. The decision to perform the reflex or confirmatory test is based upon the results of the initial test and application of a predetermined local or national practice guideline, approved protocol or legal requirement.

- **Example:** A Urinalysis with elevated WBCs signals the potential for bacterial infection and a confirmatory Urine Culture is ordered on the same specimen as a reflex test. Depending on the laboratory standard operating procedure, LIS and nature of the reflexed or confirmatory test one or more of the following may be generated: a new accession number, new test codes and additional charges.

- **CLIA Compliance:** The initial test request received in the laboratory is adequate to demonstrate an order for both the initial and the additional testing for CLIA compliance and CMS auditing purposes.
    - **LIS Process:** The LIS shall report the reflexed test as one of the following:
        1. one or more additional OBXs as part of an existing OBR or
        2. one or more additional OBR/OBX(s) or
        3. a new accession.

In the event method two or three is used (one or more additional OBR/OBX(s), or a new accession), then the new OBR(s) shall be referenced to the original OBR using the parent-child relationship via the unique identifier in OBR-2 or using OBR-2/OBR-4 if OBR-2 is not unique. In addition date specimen was collected or obtained, OBR-7, in the new OBR shall be the same as OBR-7 in the original OBR.

- **EHR Process:** The EHR should support all three methods of reporting a reflexed test (see above) and associate it with the original test request for the specimen.

8.4 Add-On Testing

Definition: Additional laboratory testing is requested by an authorized provider (as defined by CLIA and state law) on an existing specimen after the original test request has been submitted to the laboratory. The decision to request additional testing is individual provider driven and based on any number of factors not limited to a test result.

- **Example:** A physician orders a Complete Blood Count and Basic Metabolic Panel on an outpatient who presented in the office with symptoms of fatigue and a low-grade fever following a camping trip to Wisconsin. After consultation with an infectious disease physician later in the day, he calls the laboratory and requests the addition of a Lyme's Disease Antibody test to the specimens already in the laboratory.
- **CLIA Compliance:** CLIA requires the laboratory to obtain a written or electronic test request for the add-on testing from the authorized provider for its records. If the test request is verbal the laboratory must document its efforts to receive a written or electronic test request within 30 days. [42CFR493.1241(b)]
- **LIS Process:** The LIS shall report the add-on test as one of the following:
    - one or more additional OBR/OBX(s) or
    - a new order.
- **EHR Process:** The EHR should support both methods of reporting an add-on test (see above).

9 ADDITIONAL IMPLEMENTATION GUIDANCE – OTHER

9.1 Clinical Laboratory Improvement Amendments Considerations

In the United States, clinical laboratory testing of human specimens is regulated by the Clinical Laboratory Improvements Amendments of 1988 (CLIA). Several sections of the regulations implementing CLIA impact how electronic laboratory data is formatted for the US Realm and these are outlined in this section. Impacted areas include mandatory reporting requirements, report retention and display, and those authorized to receive a report. Specifics on the CLIA Regulation are found at http://www.cdc.gov/clia/. Interpretative Guidelines on the elements required in a report may be found at http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Interpretive_Guidelines_for_Laboratories.html.

9.1.1 MANDATORY REPORTING REQUIREMENTS

The CLIA Regulations at 42 CFR 493.1291 - Test Report define the items that must appear on a clinical laboratory report. Note that the value(s) of some items that are supplied on the order and flow through to the Test Report are defined in 42 CFR 493.1241 - Test Request.

Specific report fields impacted include the following:

TABLE 9-1. MANDATORY REPORTING REQUIREMENTS

CLIA Reference	CLIA Requirement, Additional Guidance	Segment/Field Description
§493.1291(a) §493.1241(c)(3) §493.1241(c)(6) §493.1241(c)(7)	"... patient-specific data are accurately and reliability send [*sic*] from point of data entry (whether interfaced or entered manually) to final report destination..." 493.1241 (c) (3) "The sex and age or date of birth of the patient" 42 CFR 493.1241 (c) (6) "The date and, if appropriate, time of specimen collection" 42 CFR 493.1241 (c) (7) "Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable" Note: For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment or biopsy.	PID-7 – Date/Time of Birth PID-8 – Administrative Sex OBR-7 – Observation Date/Time NTE-3 – Comment OBR-13 – Relevant Clinical Information OBX-5 – Observation Value (AOE, Prior Results) OBX-3 – Observation Identifier OBR-4 – Universal Service Identifier

TABLE 9-1. MANDATORY REPORTING REQUIREMENTS		
CLIA Reference	CLIA Requirement, Additional Guidance	Segment/Field Description
§493.1291(c)(1)	"For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number." Clarification: Patient name includes, when available, the patient's legal name consisting of a first name, middle name or initial, and last name [PID-5] The unique patient Identification number assigned by the facility (may be used when the patient name is not available) and the unique identification number for the order [PID-3] which may contain either numbers or letters or both numbers and letters.	PID-3 – Patient Identifier List PID-5 – Patient Name
§493.1291(c)(2)	"The name and address of the laboratory location where the test was performed." Clarification: The name of the laboratory as indicated on the CLIA certificate [OBX-23] and The actual physical location of the laboratory facility or location within the facility (including room, suite, floor as applicable) where testing is performed, as indicated on the CLIA certificate [OBX-24]. Note: Populating with the CLIA ID Number in OBX-23 meets the requirement **if** the receiving EHR-S has the ability to populate the Organization Name and Address in the Laboratory Test Report based on the CLIA ID Number.	OBX-23 – Performing Organization Name OBX-24 – Performing Organization Address
§493.1291(c)(3)	"The test report date." Clarification: The date (e.g. mm/dd/yyyy hh/mm) the test report/status change was finalized by the laboratory	OBR-22 – Results Rpt/Status Chng Date/Time

TABLE 9-1. MANDATORY REPORTING REQUIREMENTS		
CLIA Reference	CLIA Requirement, Additional Guidance	Segment/Field Description
§493.1291(c)(4)	"The test performed." Clarification: The specific name of the test/analyte that is assigned by the laboratory. Use of LOINC codes for additional tests is strongly encouraged. Addition of a local laboratory code is allowed. For certain tests CLIA requires additional information: Laboratories using manufacturer's instruments, kits or test systems labeled for "investigational use only" or "research use only" must clearly state that the test results are not to be used for treatment or diagnostic purposes. If results of such tests are being reported without a disclaimer statement, or are being used by the provider for patient care, they are in the same category as in-house developed tests and the laboratory must establish performance specifications in accordance with §493.1253. The disclaimer for Analyte Specific Reagents (ASR) should state, "This test was developed and its performance characteristics determined by (Laboratory Name). It has not been cleared or approved by the U.S. Food and Drug Administration." The ASR disclaimer on the test report is required by the FDA under *21 CFR, Part 809.30, "Restrictions on the sale, distribution and use of analyte-specific reagents."*	OBR-4 – Universal Service Identifier OBX-3 – Observation Identifier
§493.1291(c)(5)	"Specimen source, when appropriate." Clarification: The type of specimen submitted for testing and/or the collection site/method of collection as applicable. The coded values received from the laboratory may be translated in the EHR to an equivalent description prior to display. CLIA reporting requirements call for the specimen source, which equates at minimum to the Specimen Type in the SPM segment. Additional Information may be provided by Ask at Order Questions (AOE)	SPM-4 – Specimen Type OBX-5 – Specimen Source (AOE)

TABLE 9-1. MANDATORY REPORTING REQUIREMENTS		
CLIA Reference	CLIA Requirement, Additional Guidance	Segment/Field Description
§493.1291(c)(6)	"The test result and, if applicable, the units of measurement or interpretation, or both." Clarification: The corresponding test result value, and interpretation (where available) of that value for the requested analyte/test in numeric or text format [OBX-5]. Where available, the corresponding units of measure for the requested analyte/test identified and used by the performing laboratory [OBX-6] Where available, the laboratory's interpretation communicated by defined text/symbols indicating test results that do not fall within the established reference/normal range [OBX-8]. The coded values received from the laboratory may be translated in the EHR to an equivalent description prior to display. The laboratory's additional, miscellaneous notes, comments, interpretations regarding the test/analyte/report [NTE-3].	OBX-5 – Observation Value OBX-6 – Units OBX-8 – Abnormal Flags NTE-3 – Comment
§493.1291(c)(7)	"Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability." Clarification: When available, the laboratory's defined comment(s) denoting specimen suitability or not for testing [any of OBX-5/NTE-3/SPM-21]. The coded values received from the laboratory may be translated in the EHR to an equivalent description prior to display. When available, the laboratory's comment(s) denoting the condition of the specimen (hemolysis, lipemia, icterus, clotted, etc.) [any of OBX-5/NTE-3/SPM-24]. The coded values received from the laboratory may be translated in the EHR to an equivalent concept prior to display. Additional Notes: SPM-21: Use this field in connection with OBX-11 if a test is cancelled for specimen related reason. SPM-24: Use this field in combination with SPM-21 to further specify the reason for specimen rejection.	OBX-5 – Observation Value NTE-3 – Comment SPM-21 – Specimen Reject Reason SPM-24 – Specimen Condition
§493.1291(d)	"Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the test, must be available to the authorized person who ordered the test and, if applicable, the individual responsible for using the test results" Clarification: The "reference intervals" or "normal" values that are determined by the performing laboratory and correspond to the particular test/analyte result [OBX-7]	OBX-7 – Reference Range

TABLE 9-1. MANDATORY REPORTING REQUIREMENTS		
CLIA Reference	CLIA Requirement, Additional Guidance	Segment/Field Description
§493.1291(k)	"When errors in the reported patient test results are detected, the laboratory must do the following... (2) Issue corrected reports..." Clarification: The laboratory's status of the test result/report (preliminary, partial, final, corrected, etc.) [OBX-11/OBR-25]. The coded values received from the laboratory may be translated in the EHR to an equivalent concept prior to display.	OBX-11 – Observation Result Status OBR-25 – Result Status

9.1.2 LABORATORY TEST REPORT

The Laboratory Test Report is comprised of all of the CLIA required data elements. Such data are intended to be concurrently displayed in their entirety by the EHR technology and the content must be presented in a human readable format.

When all of the required data elements cannot be concurrently displayed in their entirety on a single display (for example, due to complexity or technology limitations), additional electronic display screens are permitted. When multi-page electronic display screens are utilized, they shall follow these characteristics:

- Identify individual electronic display screens unambiguously as part of the same report and as belonging to the specific patient.
- Indicate on each electronic display screen the continuation of the report on additional display screens.
- Provide each additional display of information with no more than two user actions for electronic displays, e.g., hover, click, scroll, pan, zoom.

9.1.3 REGULATORY COMPLIANCE

There may be local, state or federal regulations where the electronic message from a performing laboratory is presumed to be the legal report of the tests performed. Hence, the receiver may be required to save the format or content of the message for the same time period as required for any other legal document.

9.1.4 AUTHORIZED PARTIES

Local laws, generally at the State level, govern who is authorized to receive laboratory reports. CLIA restricts the availability of those authorized to receive laboratory reports to just those approved at the local level and sets no national standards. Testing laboratories may not report results to unauthorized parties under CLIA.

Testing laboratories either have a trusted relationship with the ordering party or presume that the ordering party is authorized to receive results. However, testing laboratories need not have knowledge of the appropriateness of others requested to receive results, such as "Copy to" recipients. To maintain CLIA compliance, a laboratory may choose to restrict its reports to only those recipients authorized and verified to receive them. Hence, a testing laboratory need not send copies of a result. Note that CLIA places no restrictions on the receiver of a laboratory report regarding its retransmission of the report to others.

9.2 CLSI Definitions – Quantitative, Semi-quantitative, Qualitative Results

The following definitions were derived from the CLSI website:

http://www.clsi.org/Content/NavigationMenu/Resources/HarmonizedTerminologyDatabase/Harmonized_Terminolo.htm

9.2.1 QUANTITATIVE

4) A characterization applied to laboratory tests that give results expressing a numerical amount or level (concentration) of an analyte in a specimen;
NOTE 1: It is usually compared to an accredited recognized standard;
NOTE 2: This is in contrast to qualitative tests.

5) When used to describe a test, means a test that produces a result that is numerical. For example, a point-of-care blood glucose test might generate a result of 120 mg/dL (1.20 g/L). In contrast, a qualitative test generates a non-numerical result such as 'positive' or 'detected.' A subset of quantitative tests called semiquantitative provides results either over a range of values, such as a urine dipstick that results in glucose ranges of 0–40, 40–100, and >100 mg/dL (0–0.4, 0.4–1, and >1 g/L), or as a series of relative values, such as the same multiple test urine dipstick that results in hemoglobin as 0, +, ++, +++, and ++++.

9.2.2 SEMI-QUANTITATIVE

6) A test that has a dose-response gradient that may be included in the reported result, but for which no authoritative calibration scale exists to determine inaccuracy and imprecision; tests that yield results in an approximate range of values (e.g., trace, moderate);
Note: This definition includes tests with subjective readout of quantification such as IF-ANA titers, and it includes tests with an instrumental readout of quantification such as ELISA-ANA when the instrument scale cannot be referenced to an authoritative calibration scale.

7) Tests that yield results in an approximate range of values (e.g., trace, moderate).

9.2.3 QUALITATIVE

8) When used to describe a test, means a test that produces a result that is descriptive rather than numerical. For example, a urine pregnancy test might generate a result of 'positive' or 'negative' for urinary hCG. In contrast, a quantitative test generates a numerical result. The quality control and reporting procedures differ significantly for quantitative and qualitative tests.

9) Characterization applied to laboratory tests that detect and/or identify a particular analyte, constituent, or condition;
NOTE 1: This term is applied to tests that detect whether a particular analyte, constituent, or condition is present or absent, and is sometimes assigned a positive degree (ie, 1+, 2+);
NOTE 2: It may also be called semiquantitative tests;
NOTE 3: Specific identification may be performed.

10 COMPONENT AND PROFILE OIDS

This appendix provides a list of all OIDs used in this IG.

TABLE C-1. RESULT PROFILE COMPONENTS		
Section	Name	OID
3.3.1	LRI_Common_Component	2.16.840.1.113883.9.16
3.3.2	LRI_GU_Component	2.16.840.1.113883.9.12
3.3.3	LRI_NG_Component	2.16.840.1.113883.9.13
3.3.4	LAB_FRU_Component (Unique Filler Number)	2.16.840.1.113883.9.83
3.3.5	LAB_FRN_Component (non-Unique Filler Number)	2.16.840.1.113883.9.84
3.3.6	LAB_PRU_Component (Unique Placer Order Number)	2.16.840.1.113883.9.82
3.3.7	LAB_PRN_Component (Non-Unique Placer Order Number)	2.16.840.1.113883.9.81
3.3.8	LAB_NB_Component	2.16.840.1.113883.9.24
3.3.9	LAB_TO_Component	2.16.840.1.113883.9.22
3.3.10	LAB_XO_Component	2.16.840.1.113883.9.23
3.3.11	LRI_PH_Component	2.16.840.1.113883.9.195.3.5

TABLE C-2. RESULT PROFILES (PRE-COORDINATED COMPONENTS)		
Section	Name	OID
3.4.1	LRI_GU_FRU_Profile	2.16.840.1.113883.9.195.3.1
3.4.2	LRI_GU_FRN_Profile	2.16.840.1.113883.9.195.3.2
3.4.3	LRI_NG_FRU_Profile	2.16.840.1.113883.9.195.3.3
3.4.4	LRI_NG_FRN_Profile	2.16.840.1.113883.9.195.3.4

TABLE C-3. RESPONSE COMPONENTS		
Section	Name	OID
3.5.1	LRI_Acknowledgement_Component	2.16.840.1.113883.9.26
3.5.2	GU_Acknowledgement_Component	2.16.840.1.113883.9.21
3.5.3	NG_Acknowledgement_ Component	2.16.840.1.113883.9.25

TABLE C-4. RESPONSE PROFILES (PRE-COORDINATED COMPONENTS)		
Section	Name	OID
3.6.1	LRI_GU_Response_Profile	2.16.840.1.113883.9.28
3.6.2	LRI_NG_Response_Profile	2.16.840.1.113883.9.27

11 GLOSSARY

TABLE 11-1. GLOSSARY

Term	Definition
Analyte	Component represented in the name of a measurable quantity. It is the most granular level at which measurements are made and always represented using a single OBX.
Cancellation	Act of cancelling the order.
Electronic Health Record	Clinical information for a specific patient that is stored electronically within an EHR-S
Electronic Health Record System (EHR-S)	A software application that is capable of managing clinical patient information.
Future Order	A future order is an order with a start date/time where that start date/time indicates the earliest time the specimen can be collected.
Laboratory	A facility or organization that performs laboratory testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention, treatment of disease, or impairment or assessment of health.
Laboratory Information System (LIS)	An information system that receives, processes, and stores information related to laboratory processes. LIS may interface with HIS and EHR applications. To meet the requirements of the LOI Use Case the LIS, at minimum, must have the following characteristics: • Data model that includes discrete representations of patients, clinician end-users, laboratory test requisitions, laboratory tests (including panels), and laboratory test results (at the level of an individual analyte); • Capability to receive electronic messages that communicate a laboratory order from a physician; • Capability to send electronic messages that report the status and results of laboratory tests that have been ordered; This definition is very minimal and omits many features and capabilities that are typically associated with laboratory information systems. This minimal characterization is intentional, as to include the broadest possible set of LIS systems in the use case. The minimal nature of the definition by no means excludes LIS with significantly greater capabilities.
Laboratory Message	An electronic communication between a Laboratory Order System and a Laboratory Information System related to laboratory testing. Laboratory messages may be used to request that one or more tests be performed, to change previous requests for testing, to report the cancellation of requested tests, or to report the results of requested tests.
Laboratory Order	Synonymous with a Requisition when referring to a single ORC/OBR pair.
Laboratory Order System	Software, either stand-alone or as part of an EHR system, used by a Provider *(Order Placer)* to manage a laboratory order, including generating the laboratory requisition, sending it to a laboratory, and monitoring/tracking of the status of the laboratory order. Typically a laboratory order system is an integral part of an order management system that enables users to manage orders for many different types of services, procedures, supplies, etc. Since we only focus on data exchange relative to laboratory orders we are purposely using a very limited definition.

TABLE 11-1. GLOSSARY	
Term	**Definition**
Laboratory Requisition	A set of information that constitutes an official request for one or more laboratory tests to be performed on an individual patient. A laboratory requisition is specified in a clinical setting and communicated to a laboratory as a discrete paper or electronic artifact. Laboratory requisitions always include at least one test order. In terms of an HL7 order transaction it represents one or more orders (ORC/OBR pairs) transmitted as part of the same OML^O21^OML_O21 new or append order message.
Newborn	A human infant from the time of birth through the 28th day of life per Mosby's Medical Dictionary, 8th edition. © 2009, Elsevier, and the World Health Organization standardization for perinatal definitions.
Orderable Test or Test	A request to perform an individual test or panel. It always refers to an single ORC/OBR pair and may have one or more associated analytes (OBXs).
Panel	While there are differences in the meanings of the terms “panel” among various laboratories, for the purposes of this guide, it is defined as a grouping of procedures that measure multiple analytes from a single specimen and can be requested through one laboratory order. This is also referred to as battery. For example, a CBC or a urinalysis may be referred to as a panel.
Request for Cancellation (RFC)	Request by the Provider *(Order Placer)* not to perform the order.
Test	A medical procedure or named set of related procedures that involves analyzing one analyte using a single sample of blood, urine, or other specimen from a patient for the purpose of diagnosing a disease or medical condition, planning or evaluating treatment, or monitoring the course of a disease.