V251_IG_LB_LABRPTPH_R2_DSTU_R1.1_2014MAY

HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 2 (US Realm)

Draft Standard for Trial Use, Release 1.1

May 2014

Publication of this draft standard for trial use and comment has been approved by Health Level Seven International (HL7). This draft standard is not an accredited American National Standard. The comment period for use of this draft standard shall end 24 months from the date of publication. Suggestions for revision should be submitted at http://www.hl7.org/dstucomments/index.cfm.

Following this 24 month evaluation period, this draft standard, revised as necessary, will be submitted to a normative ballot in preparation for approval by ANSI as an American National Standard. Implementations of this draft standard shall be viable throughout the normative ballot process and for up to six months after publication of the relevant normative standard.

IMPORTANT NOTES:

HL7 licenses its standards and select IP free of charge. **If you did not acquire a free license from HL7 for this document,** you are not authorized to access or make any use of it. To obtain a free license, please visit http://www.HL7.org/implement/standards/index.cfm.

If you are the individual that obtained the license for this HL7 Standard, specification or other freely licensed work (in each and every instance "Specified Material"), the following describes the permitted uses of the Material.

A. HL7 INDIVIDUAL, STUDENT AND HEALTH PROFESSIONAL MEMBERS, who register and agree to the terms of HL7's license, are authorized, without additional charge, to read, and to use Specified Material to develop and sell products and services that implement, but do not directly incorporate, the Specified Material in whole or in part without paying license fees to HL7.

INDIVIDUAL, STUDENT AND HEALTH PROFESSIONAL MEMBERS wishing to incorporate additional items of Special Material in whole or part, into products and services, or to enjoy additional authorizations granted to HL7 ORGANIZATIONAL MEMBERS as noted below, must become ORGANIZATIONAL MEMBERS of HL7.

B. HL7 ORGANIZATION MEMBERS, who register and agree to the terms of HL7's License, are authorized, without additional charge, on a perpetual (except as provided for in the full license terms governing the Material), non-exclusive and worldwide basis, the right to (a) download, copy (for internal purposes only) and share this Material with your employees and consultants for study purposes, and (b) utilize the Material for the purpose of developing, making, having made, using, marketing, importing, offering to sell or license, and selling or licensing, and to otherwise distribute, Compliant Products, in all cases subject to the conditions set forth in this Agreement and any relevant patent and other intellectual property rights of third parties (which may include members of HL7). No other license, sublicense, or other rights of any kind are granted under this Agreement.

C. NON-MEMBERS, who register and agree to the terms of HL7's IP policy for Specified Material, are authorized, without additional charge, to read and use the Specified Material for evaluating whether to implement, or in implementing, the Specified Material, and to use Specified Material to develop and sell products and services that implement, but do not directly incorporate, the Specified Material in whole or in part.

NON-MEMBERS wishing to incorporate additional items of Specified Material in whole or part, into products and services, or to enjoy the additional authorizations granted to HL7 ORGANIZATIONAL MEMBERS, as noted above, must become ORGANIZATIONAL MEMBERS of HL7.

Please see http://www.HL7.org/legal/ippolicy.cfm for the full license terms governing the Material.

Acknowledgements, Copyrights

Sponsored by:
Public Health Emergency and Response Workgroup

PHER Work Group Co-chair:	Joginder Madra, Gordon Point Informatics Ltd.
PHER Work Group Co-chair:	John Roberts, Tennessee Department of Health
PHER Work Group Co-chair:	Ken Pool, MD, Oz Systems
PHER Work Group Co-chair:	Rob Savage MS, Rob Savage Consulting
Principal Author:	Eric Haas, TSJG Contractor for Association of Public Health Laboratories
Principal Author:	Riki Merrick, Contractor for Association of Public Health Laboratories
Principal Author	Rita Altamore, Washington Department of Health
Principal Author	Erin Holt, Tennessee Department of Health
Principal Author:	Austin Kreisler, SAIC - Science Applications International Corp

Questions or comments regarding this document should be directed to the Public Health Emergency and Response Workgroup (pher@lists.hl7.org).

Acknowledgements, Copyrights

Acknowledgments

The authors of this document wish to recognize the many participants from across laboratory, vendor, and public health community and HL7 working groups who contributed their time and expertise to the development of this guide and the *HL7 Version 2.5.1 Implementation Guide: Laboratory Results Interface for US Realm, Release 1 (US Realm).*

We would like to acknowledge the efforts and support for development of this guide by the Association of Public Health Laboratories (APHL). APHL and this publication are supported by Cooperative Agreement # U60HM000803 from the Centers for Disease Control and Prevention (CDC) and/or Assistant Secretary for Preparedness and Response. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of CDC and/or Assistant Secretary for Preparedness and Response.

Copyrights

TABLE OF CONTENTS

TABLE OF CONTENTS

TABLE OF CONTENTS

TABLE OF CONTENTS

TABLE OF CONTENTS

TABLE OF CONTENTS

INDEX OF TABLES

INDEX OF TABLES

INDEX OF TABLES

INDEX OF FIGURES

1 INTRODUCTION

This guide merges the additional constraints, comments and elements necessary for laboratory reporting to public health with the *HL7 Version 2.5.1 Implementation Guide: Laboratory Results Interface for US Realm, Release 1 (US Realm)* (LRI). Any variations that are specific to Public Health are identified by placing them in separate subsections where appropriate and prefacing them with "**PH Component**". Usage notes and comments that are specific to Public Health are simply prefaced with "**PH Component**". Together LRI and the PH Component form the Electronic Laboratory Result to Public Health Release 2 (ELR R2) guide.

The *HL7 Version 2.5.1 Implementation Guide: Laboratory Results Interface for US Realm, Release 1 (US Realm)* is the result of collaborative efforts between HL7 and the Health and Human Services Standards and Interoperability Framework Laboratory Results Interface 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 reports. 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.

1.1 PH Component

Laboratory Results Interface Public Health Profile (LRI_PH) is the public health profile component for use with the *HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Release 1 – US Realm Draft Standard for Trial Use, July 2012 (LRI)*. This profile component describes the additional constraints and guidance needed to transmit reportable laboratory observations to appropriate local, state, territorial and federal health agencies using the HL7 2.5.1 ORU^R01 message. It is also sometimes called ELR R2.

LRI_PH in combination with the Laboratory Results Interface base component (LRI) is the successor to The *HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health (US Realm), Release 1(*ELR251R1). It is the product of several related efforts that directly impacted ELR251R1 as well as a wealth of experience gained through the implementation of Release 1. The ELR251R1 errata and clarifications document, that was approved and published in September of 2011[1], was incorporated into this profile. Also incorporated is the 2.5.1 Clarification Document for EHR Technology Certification V1.1 that was created for 2014 EHR certification criteria.[2] Although every attempt was made to be backward compatible to ELR251R1, it was not always possible. In light of the developments in the laboratory messaging space in the US Realm, the decision was made to align rather than preserve backwards compatibility, where a choice had to be made. Section 11 provides a link to additional resources that summarize in detail the differences between ELR251 R1 and LRI + LRI-PH and where backwards compatibility was not possible.

[1] R1 Errata Document is available as part of the ELR251 R1 download from Hl7

[2] http://www.cdc.gov/ehrmeaningfuluse/Docs/1ELR251_Clarification_EHR_Tech_Cert_v1_1-20121016.pdf.

1.2 Purpose

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. Future versions of this Guide may harmonize with existing guides to extend interoperability of laboratory results across care settings, e.g., acute care and public health.

1.2.1 PH COMPONENT

The LRI combined with the LRI_PH component are intended to meet the needs and requirements of implementation guidance for reporting to Public Health entities, replacing the previous documentation regarding Electronic Laboratory Reporting to Public Health (ELR-PH). ELR-PH is a specific piece in a larger test order - test result process. When a laboratory result is sent to public health, additional data is required to be sent along in the result message when compared to the LRI use case. The LRI_PH component included in this guide facilitates the inclusion of information necessary for public health reporting in the larger test order - test result process between ordering providers/laboratories and performing laboratories to ensure that the data is available to be sent to PH when necessary. Harmonizing the technical specifications (format and vocabulary) for the test order (order placer sends order to lab), test result (lab sends result to order placer), and reportable test result (lab sends result to PH) enhances interoperability and data quality thus improving the overall laboratory result reporting process for both the sender and the receiver.

The LRI_PH component used in conjunction with the LRI guide contains the necessary specifications for laboratory results reporting to local, state, territorial and federal health agencies including messaging content and dynamics related to the transmission of Reportable Result Messages. The message described in this guide is not specific to any pathogen or reportable condition and is applicable for most biological and chemistry reportable laboratory observations. Each state and territory has requirements for laboratories to report certain findings to health officials. Authority to establish a list of reportable conditions and to specify the content of those reports resides with the individual public health jurisdiction. Reports made to Public Health come in two forms: case reports (not the subject of this guide), and laboratory reports related to reportable conditions.

Reporters can access further information about reportable conditions at the website for their own Public Health jurisdiction relevant to their service area. (For information about a national Reportable Condition Knowledge Management System see Appendix A) Additionally, the LRI_PH Component does not replace the need for each public health jurisdiction to document the constraints of their specific implementation. Further guidance on how to create a derived profile from this guide is given in Chapter 2b of the HL7 Messaging Standard v2.7.1.

1.3 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. This guide is not intended to be a tutorial on that subject

1.3.1 PH COMPONENT

In addition 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 *Public Health Lab Result/ELR Use Case*.

1.4 Requisite Knowledge

- HL7 V2.5.1, V2.7, V2.7.1 Messaging (www.HL7.org)
- SNOMED (www. 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*

1.5 Organization of this Guide

1.5.1 CONVENTIONS

This guide adheres to the following conventions:

- The guide is constructed assuming the implementer has access to the 2.5.1 and 2.7.1 versions of the HL7 Standard. 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.
- 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".

1.5.1.1 PH COMPONENT

- This guide merges the additional constraints, comments and elements necessary for laboratory reporting to public health with the *HL7 Version 2.5.1 Implementation Guide: Laboratory Results Interface for US Realm, Release 1 (US Realm)* (LRI). Components and Sections from LRI that are not supported by the LRI_PH_Component are omitted from this document.

1.5.2 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 1.5.4 Usage Conformance Testing Recommendations.

TABLE 1-1. MESSAGE ELEMENT ATTRIBUTES	
Attribute	**Definition**
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.
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. Constrained tables are included in Section 4.7 Constrained HL7 Tables
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.

1.5.3 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[3]. 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.

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

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.

An implementation which does not include a particular segment/field/component marked as optional **MUST** be prepared to interoperate with another implementation which does include the optional segment/field/component, though perhaps with reduced functionality. In the same vein an implementation which includes a particular segment/field/component marked as optional **MUST** be prepared to interoperate with another implementation which does not include the optional segment/field/component.

1.5.4 USAGE CONFORMANCE TESTING RECOMMENDATIONS

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 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 this definition[4].
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	The application (or as	The application shall not populate “X” elements.

[4] 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
	supported	configured) shall not implement "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.	

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* ---------

1.6 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.

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 Stage 2 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 as a non-order placer.

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.
- 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.
- Advanced error messages related to application transport.
- Results not transmitted using a standardized structured format.

1.6.1 PH COMPONENT

The following scope statements are in addition to those listed above. For ELR-PH, the receiving system is the Public Health Disease Surveillance System, defined as ELR-PH Receiver below, and not the Electronic Health Record System (EHR-S).

In Scope

- Defining the core data elements required for electronic laboratory reporting of reportable laboratory test results to Public Health.
- Reporting of clinical laboratory test results to public health in the US Realm
    - Including results from public health laboratories.
    - Including the use case where public health is the originator of the order for testing.
- Sending laboratory test results as standardized structured data so they can be incorporated that way into a Public Health Disease Surveillance System.
- Stage 3 certification criteria in support of the Meaningful Use (MU) program.
- Harmonization of data elements that are used in both laboratory orders and results.
- Batch processing.
- Laboratory results for individual living subjects (persons and animals).

Out of Scope

- Reporting of results from laboratory to laboratory.
- Querying patient demographics.
- The use case for public health laboratory test orders.
- Reporting of results to Cancer Registries.
- Results from nonliving subjects (water, food, air).
- Reporting of Healthcare Associated Infections (HAI) to the National Healthcare Safety Network (NHSN).

1.7 Results for Ambulatory Care Use Case and Context Diagrams

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[5]. 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.

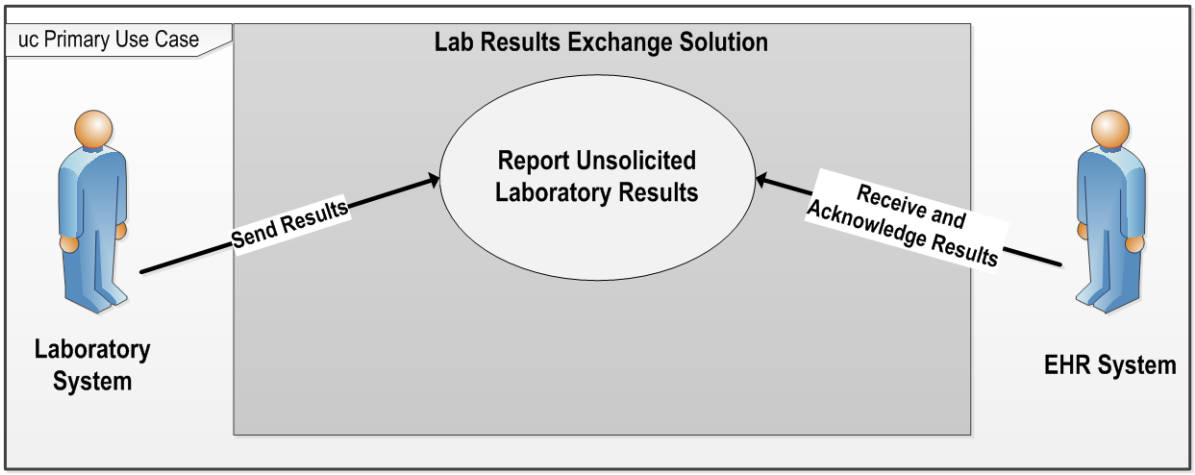

Figure 1-1. Use Case Diagram

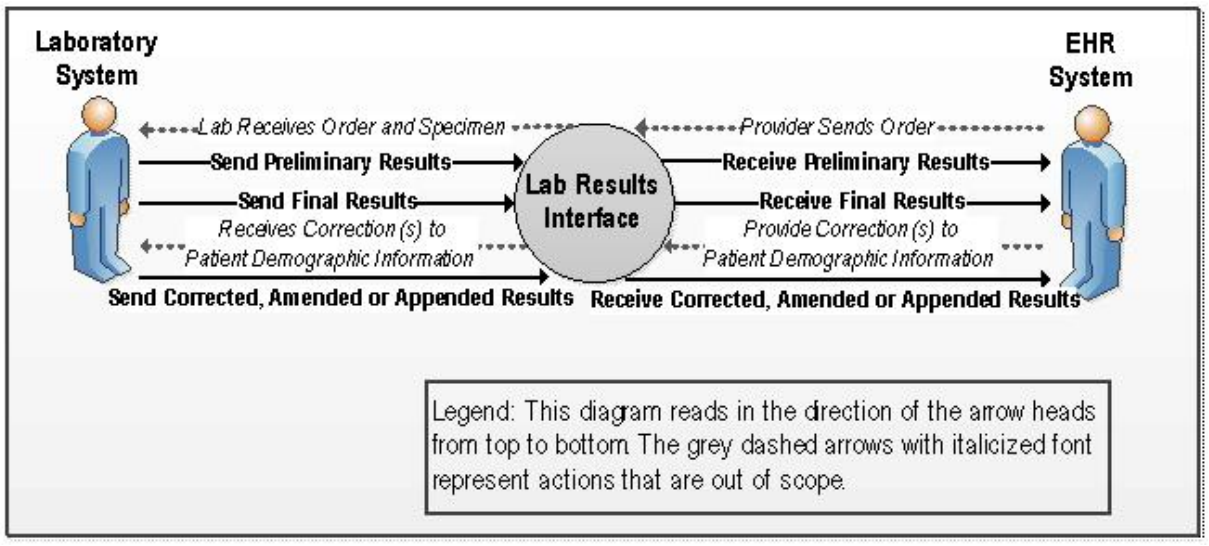

Figure 1-2. Context Diagram

[5] 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.

1.7.1 PH COMPONENT

For ELR-PH, the receiving system is the Public Health Disease Surveillance System, defined as ELR-PH Receiver below, not the Electronic Health Record System (EHR-S).

ELR-PH Receiver – The ELR-PH Receiver is a public health application capable of receiving results of laboratory testing, optionally transmitting an acknowledgment and optionally capable of receiving a batch of laboratory result messages. The ELR-PH Receiver may be associated with the local, state, territorial or federal health agency that requires access to the results. Note that the ELR-PH Receiver should not be confused with the "Placer" of the laboratory order that the laboratory results are associated with. The placer of the order is typically a provider who is responsible for treating the patient. In this case, the ELR-PH Receiver is an interested party who receives a copy of the results.

1.8 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 perform the test. Prior to successful completion of a test, communication may also 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. Order cancellation notifications should be communicated using order messages. Until an Ambulatory Orders IG is available these communications will mostly use the results message described in this IG or be otherwise arranged with each business partner. The laboratory performs or attempts to perform the test(s). 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.

1.8.1 PH COMPONENT

The laboratory result is determined to be a reportable laboratory result for the patient's and/or the provider's public health jurisdiction. The results sender, e.g., LIS or EHR, transmits the results to the appropriate public health jurisdiction. The public health jurisdiction's ELR-PH Receiver incorporates the results in their disease surveillance system allowing for the appropriate follow up by the public health jurisdiction.

1.9 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 table6 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.

1.9.1 PH COMPONENT

- Each public health jurisdictional entity has previously defined the reportable conditions appropriate to its jurisdiction.
- Laboratory result senders are responsible for the setup of their system with the reportable conditions appropriate to its jurisdiction.

1.9.2 PRE-CONDITIONS

- An order has been generated by an Ordering Provider for one or more laboratory tests results to be produced.

---

[6] Section 13.0 - LRI Use Case: http://sibrowser.siframework.org/siclient/view?type=artifact&id=39481918-9dc7-4f55-aa77-f978b4c13d8b&name=SIFramework_LRI_UC.docx

- 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.

1.9.2.1 PH COMPONENT

For ELR-PH, the receiving system is the ELR-PH Receiver and not the EHR-S.

1.9.3 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.

1.9.3.1 PH COMPONENT

For ELR-PH, the receiving system is the ELR-PH Receiver and not the EHR-S.

1.9.4 FUNCTIONAL REQUIREMENTS

TABLE 1-2. INFORMATION INTERCHANGE REQUIREMENTS

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

TABLE 1-3. SYSTEM REQUIREMENTS	
System	System Requirement
Laboratory Information System	Form a laboratory message with standardized structured data[7] meeting CLIA and other federal and state regulatory requirements
Electronic Health Record System	Incorporate test data from the laboratory message as standardized structured data.

1.9.4.1 PH COMPONENT

For ELR-PH, the receiving system is the ELR-PH Receiver and not the EHR-S.

1.10 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.

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

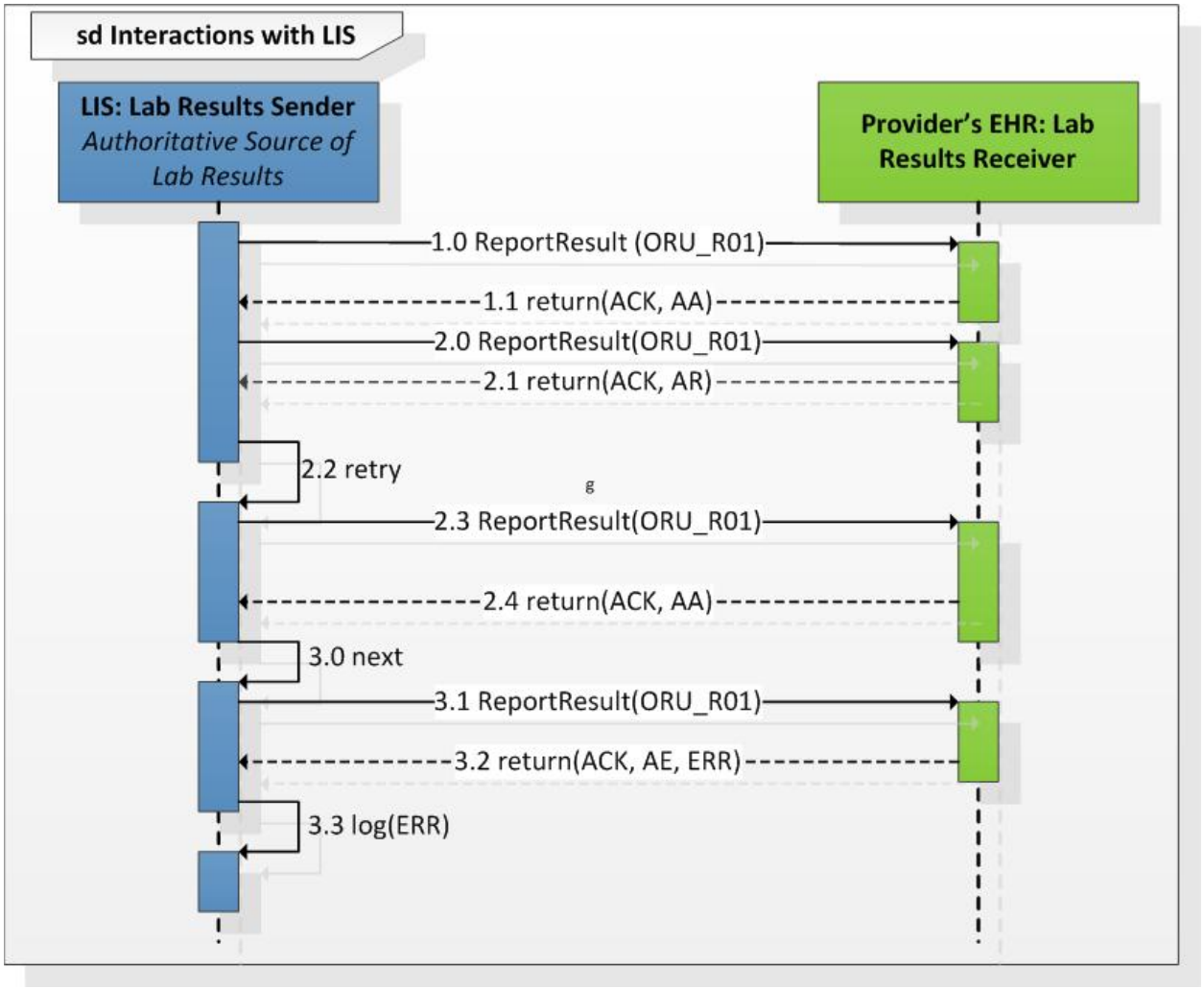

Figure 1-3. Sequence Diagram

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 acknowledged as correct (2.5).

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

1.10.1 PH COMPONENT

1.10.1.1 SINGLE ORU MESSAGE

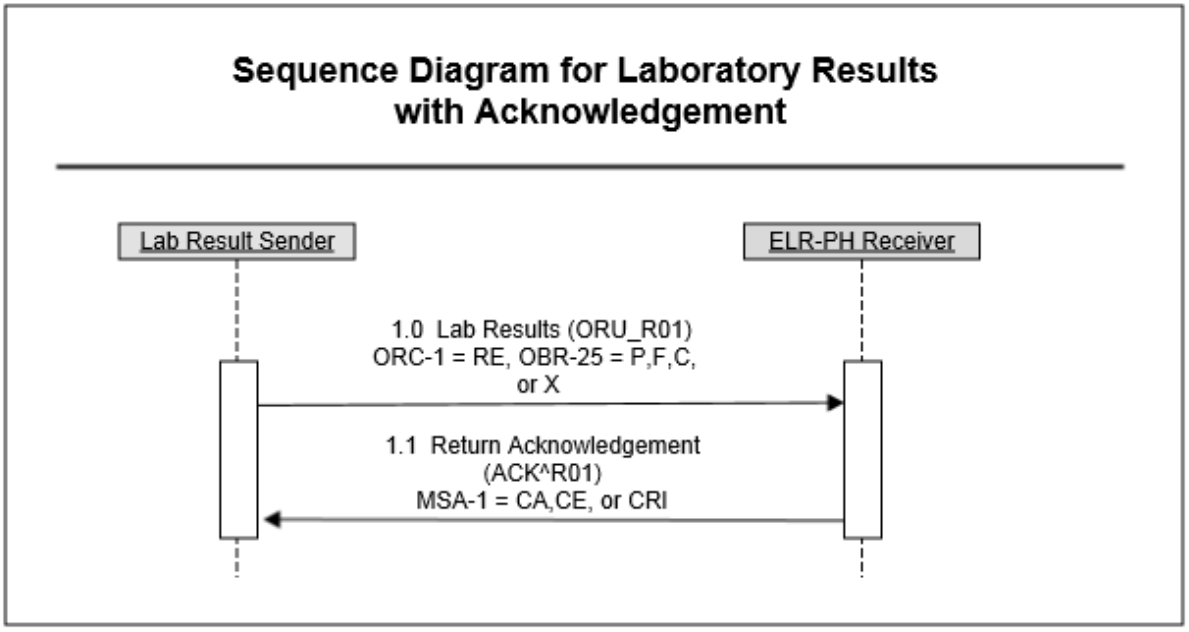

Figure 1-4. Sequence Diagram for Laboratory Result with Acknowledgement – messages rejected

The sequence begins with the Lab Results Sender transmitting an ORU^R01^ORU_R01 message (ORC-1=RE) to the ELR-PH Receiver (1.0). The message is either Preliminary (OBR-25=P), Final (OBR-25=F), Corrected (OBR-25=C), or No Results Available (OBR-25=X).

Upon receipt of the message, an acknowledgement is sent by the ELR-PH Receiver to the Lab Result Sender using the ACK^R01^ACK message type (1.1)

The ELR Receiver either accepts (MSA-1=CA), rejects (MSA-1 = CR) , or errors the message (MSA-1= CR).

1.10.1.2 BATCH MESSAGE

Transmission of ELR-PH messages using batch protocol is optional and not a requirement of this guide.

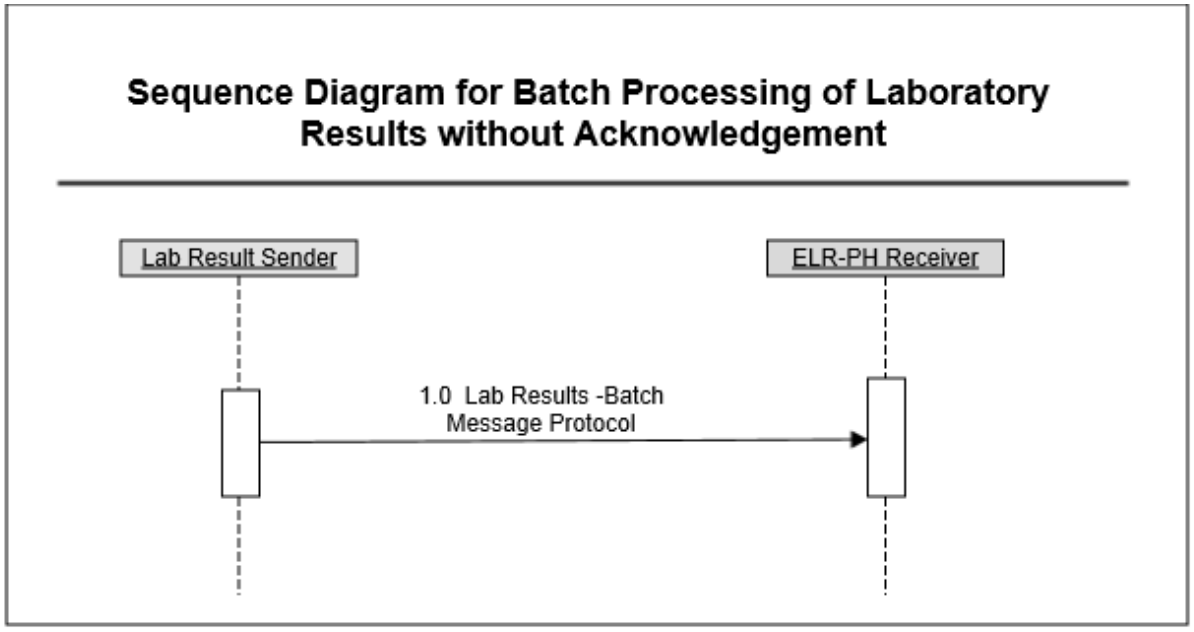

Figure 1-5. Sequence Diagram for Batch Processing of Laboratory Result without Acknowledgement

The sequence consists of Lab Results Sender transmitting zero or more ORU^R01^ORU_R01 messages to the ELR-PH Receiver (1.0) using the batch protocol.

No acknowledgement is sent by the ELR-PH Receiver.

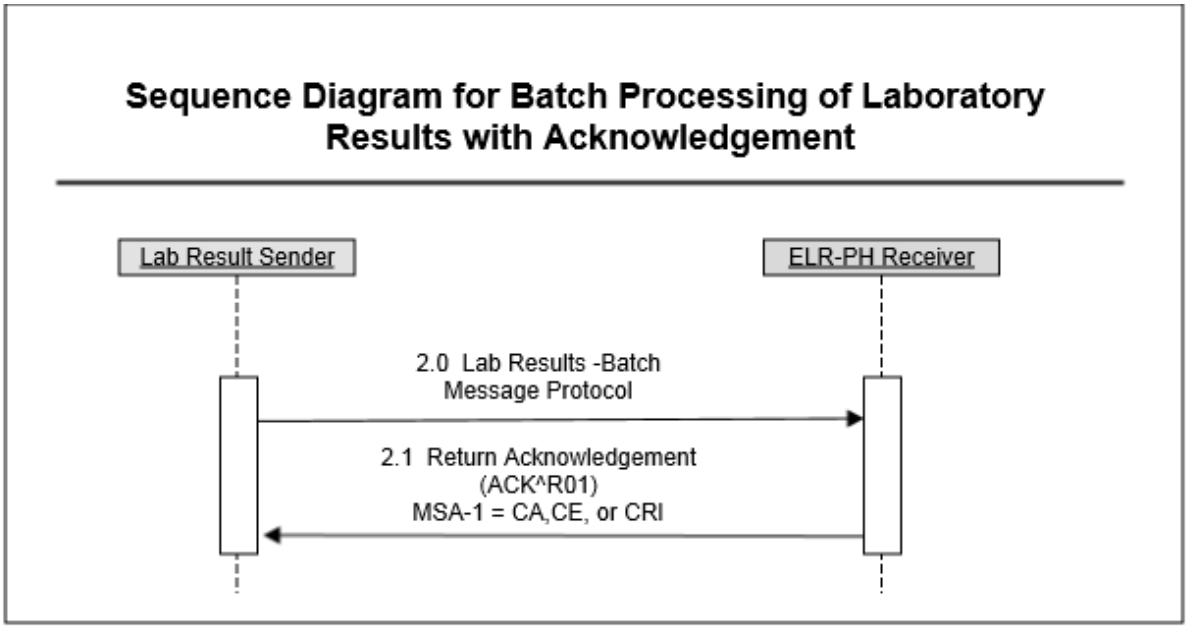

Figure 1-6. Sequence Diagram for Batch Processing of Laboratory Result with Acknowledgement

The sequence consists of Lab Results Sender transmitting zero or more ORU^R01^ORU_R01 messages to the ELR-PH Receiver using the batch protocol (2.0).

Upon receipt of the message, a single acknowledgement is sent by the ELR-PH Receiver to the Lab Result Sender for the batch message using the ACK^R01^ACK message type (2.1) .

The ELR receiver either accepts (MSA-1=CA), rejects (MSA-1 = CR) , or errors the message (MSA-1= CR).

1.11 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 Section 1.12-Referenced Profiles 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.

1.11.1 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 1.14.2.1) 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"[8], which provides guidance on how organizations can use and manage OIDs.

1.11.1.1 PH COMPONENT

The following organization OIDs below are provided for the reader's convenience.

TABLE 1-4. COMMON ORGANIZATION OIDS

Organization	OID	Notes
NPI	2.16.840.1.113883.4.6	U.S. National Provider Identifier
CLIA	2.16.840.1.113883.4.7	The Centers for Medicare & Medicaid Services (CMS) regulates all laboratory testing (except research) performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments (CLIA).

As of this publication, there is no single registry for US Realm OIDs for healthcare. One source for obtaining an OID for your organization's use or registering existing OIDs is the HL7 OID Registry.9

1.11.2 USE OF VOCABULARY STANDARDS

This guide calls for specific vocabulary standards for the exchange of laboratory information such as LOINC and SNOMED. 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.

1.11.3 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

[8] The current version of the HL7 Implementation Guidance for Unique Object Identifiers (OIDs), Release 1 is available from HL7 (www.hl7.org).

[9] http://www.hl7.org/oid/index.cfm

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.

1.11.4 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.

1.12 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 [10]. 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 (US Realm)

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.

1.12.1 PH COMPONENT

In addition, the following documents were used as source materials in the development of the PH Component:

- Harmonized Use Case for Electronic Health Records (Laboratory Result Reporting)
- Implementation Guide for Transmission of Laboratory-Based Reporting of Public Health Information using version 2.3.1 of Health Level Seven (HL7) Standard Protocol, March 2005.
- HL7 Version 3 Standard: Abstract Transport Specification, Normative Edition 2009
- HL7 Version 2.5.1 Implementation Guide: Laboratory Results Interface for US Realm, Release 1, HL7 Version 2.5.1: ORU^R01, Draft Standard for Trial Use, July 2012
- Standards and Interoperability Laboratory Results Interface Use Case, Laboratory Results Reporting to Primary Care Providers (in an Ambulatory Setting) v1.0

[10] The referenced documents are all available from HL7 (www.hl7.org)

- HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Orders from EHR, Release 1 – US Realm January 2013 10 HL7 DSTU Ballot

1.13 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.

1.14 Conformance to this Guide

This implementation guide defines components that are combined into profiles to define specific conformance requirements.

1.14.1 PH COMPONENT

This implementation guide defines components that are combined into profiles to define specific conformance requirements.

The Components must be combined to create a valid Profile for a particular transaction. As of this version a valid profile consists of a minimum of three components:

1. LRI_Common_Component
2. LRI_GU_Component
3. LAB_RU_Component
4. LRI_PH_COMPONENT – Public Health Reporting

Additional components can be provided to further define the message structure and use. This guide defines three such components:

1. LAB_NB_Component – Newborn
2. LRI_TO_Component – Time Offset
3. LAB_XO_Component – Exclusions

Additional definitions and guidance for MSH-21 can be found in Section 3.4.1 MSH – Message Header Segment.

1.14.2 RESULT PROFILE COMPONENTS

The result components that can be assembled into profiles are:

1.14.2.1 LRI_COMMON_COMPONENT – ID: 2.16.840.1.113883.9.16

This component indicates that the message adheres to the rules set out in this implementation guide.

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

1.14.2.2 LRI_GU_COMPONENT – ID: 2.16.840.1.113883.9.12

This component indicates that the following fields use Globally Unique Identifiers through ISO OID according to Section 1.11.1 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-28 – Result Copies To
- OBR-16 – Ordering Provider
- OBR-29 – Parent
- OBX-16 – Responsible Observer
- OBX-23 – Performing Organization Name
- OBX-25 – Performing Organization Medical Director

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

1.14.2.3 LAB_RU_COMPONENT – ID: 2.16.840.1.113883.9.14

This component indicates that the test can be identified using the placer order number or using the filler order number. No additional information is necessary since either identifier on its own is unique.

1.14.2.4 LAB_NB_COMPONENT – ID: 2.16.840.1.113883.9.24

This 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 9 Appendix A – Glossary

1.14.2.5 LAB_TO_COMPONENT – ID: 2.16.840.1.113883.9.22

This component indicates the time zone component of the TS/TM data type used for the following fields is required. 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 requires that all date/time fields indicated below carry a time zone offset.

- PID-7 – Date/Time of Birth
- 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” or “TS”)
- OBX-14 – Date/Time of the Observation
- OBX-19 – Date/Time of the Analysis
- SPM-17 – Specimen Collection Date/Time

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 are managed through ADT/Registration and Orders interfaces.

1.14.2.6 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 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 that according to the definition of X per the base standard is "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 (Optional) are now considered to be marked with an X (Not Supported). Its use yields, in combination with the other profile components, a fully implementable profile in accordance with Chapter 2B. Note though that this component is strictly voluntary and cannot be mandated by either trading partner to be used to enable a successful results transaction.

1.14.2.7 LRI_PH_COMPONENT - ID: 2.16.840.1.113883.9.63

When a laboratory result is sent to public health, additional data is required. The PH component facilitates the inclusion of information necessary for public health. This profile is used to identify those fields that are to be considered for Public Health according to table attributes and conformance statements referencing this profile component are identified as “ELR-xx”, where xx is an increasing number, starting with ‘1’.

Note: LRI supports additional profile components ,LRI_GN_Component and the LAB_RN_Component. These components are **not** supported when using the LRI_PH_Component.

The fields that are effectively added and/or modified by this profile are:

- MSH-3- Sending Application
- MSH-4 - Sending Facility
- MSH-5 - Receiving Application
- MSH-6 - Receiving Facility
- MSH-7 - Date/Time Of Message
- MSH-15-Accept Acknowledgment Type
- MSH-16-Application Acknowledgment Type
- SFT-1 - Software Vendor Organization
- SFT-2 - Software Certified Version or Release Number
- SFT-3 - Software Product Name
- SFT-4 - Software Binary ID
- SFT-5 - Software Product Information
- SFT-6 - Software Install Date
- ERR-3 - HL7 Error Code
- PID-6 - Mother’s Maiden Name
- PID-7 - Date/Time of Birth
- PID-10 - Race
- PID-11 - Patient Address
- PID-13 - Phone Number – Home
- PID-14 - Phone Number – Business
- PID-22 - Ethnic Group
- PID-29 - Patient Death Date and Time
- PID-30 - Patient Death Indicator
- PID-33 - Last Update Date/Time
- PID-34 - Last Update Facility
- NK1-1 - Set ID – NK1
- NK1-2 - Name
- NK1-3 - Relationship

- NK1-4 - Address
- NK1-5 - Phone Number
- NK1-7 - Contact Role
- NK1-13 - Organization Name – NK1
- NK1-30 - Contact Person's Name
- NK1-31 - Contact Person's Telephone Number
- NK1-32 - Contact Person's Address
- PV1-1 - Set ID - PV1
- PV1-2 - Patient Class
- PV1-4 - Admission Type
- PV1-44 - Admit Date/Time
- PV1-45 - Discharge Date/Time
- ORC-12 - Ordering Provider
- ORC-14 - Call Back Phone Number
- ORC-21 - Ordering Facility Name
- ORC-22 - Ordering Facility Address
- ORC-23 - Ordering Facility Phone Number
- ORC-24 - Ordering Provider Address
- OBR-4 - Universal Service Identifier
- OBR-16 - Ordering Provider
- OBR-17 - Order Callback Phone Number
- OBR-31 - Reason for Study
- OBR-32 - Principal Result Interpreter
- OBR-3 - Observation Identifier
- OBR-5 - Observation Value
- OBR-8 - Interpretation Codes
- OBR-14 - Date/Time of the Observation
- OBR-17 - Observation Method
- OBR-29 - Observation Type
- SPM-2 - Specimen ID
- SPM-4 - Specimen Type
- SPM-5 - Specimen Type Modifier
- SPM-6 - Specimen Additives
- SPM-7 - Specimen Collection Method
- SPM-8 - Specimen Source Site
- SPM-9 - Specimen Source Site Modifier
- SPM-17 - Specimen Collection Date/Time
- SPM-18 - Specimen Received Date/Time

- NTE-2 - Source of Comment
- NTE-4 - Comment Type
- FHS-1 - File Field Separator
- FHS-2 - File Encoding Characters
- FHS-6 - File Receiving Facility
- FHS-7 - File Creation Date/Time
- FHS-8 - File Security
- FHS-10 - File Header Comment
- FHS-11 - File Control ID
- FHS-12 - Reference File Control D
- FTS-1 - File Batch Count
- FTS-2 - File Trailer Comment
- BHS-1 - Batch Field Separator
- BHS-2 - Batch Encoding Characters
- BHS-8 - Batch Security
- BHS-10 - Batch Comment
- BHS-11 - Batch Control ID
- BHS-12 - Reference Batch Control D
- BTS-1 - Batch Message Count
- BTS-2 - Batch Comment
- BTS-3 - Batch Totals

1.14.3 RESULT PROFILES (PRE-COORDINATED COMPONENTS)

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

Note that the TO, XO and NB components are not included in the pre-coordinated profiles; rather they are included 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.

1.14.3.1 LRI_GU_RU_PROFILE ID: 2.16.840.1.113883.9.17

This profile pre-coordinates the use of the LRI_Common_Component, LRI_GU_Component, and the LAB_RU_Component.

1.14.4 RESPONSE COMPONENTS

1.14.4.1 LRI_ACKNOWLEDGEMENT_COMPONENT – ID: 2.16.840.1.113883.9.26

This component indicates that the acknowledgement message adheres to the rules set out in this implementation guide.

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

1.14.4.2 GU_ACKNOWLEDGEMENT_COMPONENT – ID: 2.16.840.1.113883.9.21

This profile ID 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 2.16.840.1.113883.9.17 (LRI_GU_RU_Profile), OR 2.16.840.1.113883.9.12 (LRI_GU_Component)

1.14.5 RESPONSE PROFILES (PRE-COORDINATED COMPONENTS)

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

1.14.5.1 LRI_GU_RESPONSE_PROFILE ID: 2.16.840.1.113883.9.28

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

1.14.6 EXTENDED PROFILE USE

The sender may create other components or profiles that are defined outside of this implementation guide for use in conjunction with the profiles / components defined in this guide. However, those profiles / components are strictly voluntary and shall be properly constrained against the base standard and the profiles / 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 / components in combination with the profiles / components defined in this guide to achieve a successful send or receive of Lab Results.

1.14.7 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.

1.14.8 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 best value the lab is aware of at the time the result message is generated. The definition of a common order is outside the scope of this Guide.

2 DATA TYPES

Data types are further defined in this implementation guide for all fields that have a usage of R, RE, C(a/b). Data types used only for optional fields are not included. Please refer to the base standard for those data types.

Depending on the 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 will be documented with multiple variations, e.g., HD_GU or HD_GU-PH. 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.

2.1 CE – Coded Element

TABLE 2-1. CODED ELEMENT (CE)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Identifier	ST	RE		
2	Text	ST	C(R/RE)		Condition Predicate: If CE.1 (Identifier) is not valued It is strongly recommended that text be sent to accompany any identifier. When a coded value is not known, text can still be sent, in which case no coding system should be identified.
3	Name of Coding System	ID	C(R/X)	HL70396	Condition Predicate: If CE.1 (Identifier) is valued
4	Alternate Identifier	ST	RE		The alternate identifier (from the alternate coding system) should be the closest match for the identifier found in component 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 CE.4 (Alternate Identifier) is valued

Usage Note

Triplet population order

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

Conformance Statements: LRI_COMMON_COMPONENT

LRI-1: If data is available for only one Coded Element then the triplet of CE.1 (Identifier), CE.2 (Text), and CE.3 (Name of Coding System) **SHALL** be valued in accordance with the rules given for CE.1, CE.2, and CE.3.

2.2 PH Component: CE-PH - Coded Element – Public Health

TABLE 2-2. CODED ELEMENT (CE-PH)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Identifier	ST	R		
2	Text	ST	RE		
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 component 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 CE.4 (Alternate Identifier) is valued

Usage Note

The CE-PH is used in OBX-5 (Observation Value) when OBX-2 (Value Type) is valued "CE".

2.3 PH Component: CNN – Composite ID Number and Name Simplified

TABLE 2-3. COMPOSITE ID NUMBER AND NAME SIMPLIFIED (CNN)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	ID Number	ST	RE		The ID Number component combined with the Assigning Authority – Universal ID component (component 10) 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	ST	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	O	HL70360	
8	Source Table		C(O/X)		Condition Predicate: If CNN.1 (Identifier) is valued.

TABLE 2-3. COMPOSITE ID NUMBER AND NAME SIMPLIFIED (CNN)					
SEQ	Component Name	DT	Usage	Value Set	Comments
9	Assigning Authority – Namespace ID	IS	C(RE/X)	Local	Condition Predicate: If CNN.1 (Identifier) is valued.. The coding system for this component is locally managed.
10	Assigning Authority - Universal ID	ST	C(R/X)		Condition Predicate: If CNN.1 (Identifier) is valued.
11	Assigning Authority - Universal ID Type	ID	C(R/X)	HL70301	Condition Predicate: If CNN.10 (Assigning Authority - Universal ID) is valued.

Conformance Statements: LRI_PH COMPONENT

ELR-2: CNN.10 (Assigning Authority - Universal ID) **SHALL** be valued with an ISO-compliant OID.

ELR-3: CNN.11 (Assigning Authority - Universal ID Type) **SHALL** contain the value "ISO".

2.4 CWE_CRE – Coded with Exceptions – Code Required, but May Be Empty

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

TABLE 2-4. CODED WITH EXCEPTIONS - CODE REQUIRED BUT MAY BE EMPTY (CWE_CRE)					
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.
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.

TABLE 2-4. CODED WITH EXCEPTIONS - CODE REQUIRED BUT MAY BE EMPTY (CWE_CRE)					
SEQ	Component Name	DT	Usage	Value Set	Comments
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		O		
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 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.

Triplet population order

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

CWE Statuses

The CWE data type allows communication CWE Statuses that indicate whether the value is known or not, not applicable, or not available (HL7 Table 0353). The full set of allowable values and its use is in Chapter 2A, Section 2.A.13 under Data Missing. This will be allowed for all uses of CWE_CRE, except in SPM-4.

PH Component

CWE_CRE is used with SPM-4 (Specimen Type), SPM-8 (Specimen Source Site) and OBX-6 (Units).

2.5 CWE_CR – Coded with Exceptions – Code Required

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

TABLE 2-5. 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
7	Coding System Version ID		O		
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		

TABLE 2-5. CODED WITH EXCEPTIONS - CODE REQUIRED (CWE_CR)					
SEQ	Component Name	DT	Usage	Value Set	Comments
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_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.

Triplet population order

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

CWE Statuses

The CWE_CR data type allows communication of "null flavors", referred to as CWE Status(es), where the values are drawn from HL7 Table 0353. The CWE Statuses are supported in this guide for all uses of CWE_CR.

PH Component

CWE-CR is used with OBR-4(Universal Service Identifier), OBX-3(Observation Identifier) and in the data type element PRL-1(Parent Observation Identifier).

2.6 CWE_CRO – Coded with Exceptions – Code and Original Text Required

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

TABLE 2-6. CODED WITH EXCEPTIONS - CODE AND ORIGINAL TEXT REQUIRED (CWE_CRO)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Identifier	ST	R		

TABLE 2-6. CODED WITH EXCEPTIONS - CODE AND ORIGINAL TEXT REQUIRED (CWE_CRO)

SEQ	Component Name	DT	Usage	Value Set	Comments
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_CRO.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_CRO.4 (Alternate Identifier) is valued
7	Coding System Version ID		O		
8	Alternate Coding System Version ID		O		
9	Original Text	ST	R		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 CWE_CRO 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. CWE_CRO.9 is always sent in this CWE_CRO type. When used in OBX-5

CWE_CRO.9 is expected to be the print text to comply with CLIA regulation of matching result statements between reports of record at both sender and receiver systems.

Triplet population order

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

CWE Statuses

The CWE_CRO data type allows communication of "null flavors", referred to as CWE Status(es), where the values are drawn from HL7 Table 0353. The CWE Statuses are supported in this guide for all uses of CWE_CRO, except for OBX-5 (Observation Value).

PH Component

CWE_CRO is used with OBX-5 (Observation Value). CWE_CRO.9 (Original Text) is expected to be the print text to comply with CLIA regulation of matching result statements between reports of record at both sender and receiver systems and can be the same as text in CWE.2 (Text).

2.7 CX_GU – Extended Composite ID with Check Digit (Globally Unique)

TABLE 2-72-8. 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		C(O/X)		
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	
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 all identifiers be accompanied by assigning authorities 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.

CX_GU.5 (Identifier Type Code)

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.

2.8 DR – Date/Time Range

TABLE 2-92-10. 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		

2.9 DT – Date

TABLE 2-112-12. DATE (DT)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Date	-	R		Format: YYYY[MM[DD]]

2.10 DTM – Date/Time

TABLE 2-13. 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 as defined in the Time Stamp patterns starting in Section 2.34.

2.11 EI_GU – Entity Identifier (Globally Unique)

TABLE 2-14. ENTITY IDENTIFIER (EI_GU)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Entity Identifier	ST	R		

TABLE 2-14. ENTITY IDENTIFIER (EI_GU)					
SEQ	Component Name	DT	Usage	Value Set	Comments
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. This GU profile 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_COMPONENT

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”.

2.12 EIP_GU – Entity Identifier Pair (Globally Unique)

TABLE 2-15. 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.

2.13 ERL – Error Location

TABLE 2-16. ERROR LOCATION (ERL)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Segment ID	ST	R		
2	Segment Sequence	NM	R		
3	Field Position		O		
4	Field Repetition		O		
5	Component Number		O		
6	Sub-component Number		O		

2.14 FN – Family Name

TABLE 2-17. 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		

2.15 FT – Formatted Text Data

TABLE 2-18. FORMATTED TEXT DATA (FT)

SEQ	Component Name	DT	Usage	Value Set	Comments
	Formatted Text Data	-	R		

Usage Note

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*.

Formatting Considerations

For NTE segments, or when this data type is used in OBX-2 Value Type, one should consider that formatting may be included in either NTE-3, Comment, or 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.

2.16 HD_GU – Hierarchic Designator (Globally Unique)

TABLE 2-19. 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		

TABLE 2-19. HIERARCHIC DESIGNATOR (HD_GU)					
SEQ	Component Name	DT	Usage	Value Set	Comments
3	Universal ID Type	ID	R		Fixed to “ISO”

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 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_COMPONENT

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”.

2.17 PH Component: HD_GU-PH – Hierarchic Designator (Public Health)

TABLE 2-20. HIERARCHIC DESIGNATOR (HD_GU-PH)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Namespace ID	IS	RE		The value of HD_GU-PH.1 reflects a local code that represents the combination of HD_GU-PH.2 and HD_GU-PH.3
2	Universal ID	ST	R		Must be an OID except for Sending Facility (MSH-4) where a CLIA identifier is allowed.
3	Universal ID Type	ID	R		PH Component: Fixed to ‘ISO’ except for Sending Facility (MSH-4) where the value ‘CLIA’ is allowed.

Conformance Statement: LRI_PH Component

ELR-7: HD_GU-PH.3 (Universal ID Type) If element is in MSH-4 (Sending Facility), then HD_GU-PH.3 (Universal ID type) **SHALL** contain the value "ISO" OR "CLIA", ELSE HD_GU-PH.3 (Universal ID type) **SHALL** contain the value "ISO".

ELR-73: If HD_GU-PH.3(Universal ID type) value is "CLIA", then HD_GU-PH.2 (Universal ID) **SHALL** be a valid CLIA identifier format.

ELR-74: If HD_GU-PH.3(Universal ID type) value is "ISO", then HD_GU-PH.2 (Universal ID) **SHALL** be a valid ISO OID format.

2.18 ID – Coded Value for HL7-Defined Tables

TABLE 2-21. CODED VALUE FOR HL7-DEFINED TABLES (ID)

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

2.19 IS – Coded Value for User-Defined Tables

TABLE 2-22. Coded Value for User-Defined Tables (IS)

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

2.20 MSG – Message Type

TABLE 2-23. Message Type (MSG)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Message Code	ID	R	HL70076 (constrained)	
2	Trigger Event	ID	R	HL70003	
3	Message Structure	ID	R	HL70354 (constrained)	

2.21 PH Component: NDL - Name With Date And Location

TABLE 2-24. NDL - NAME WITH DATE AND LOCATION

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Name	CNN	R		
2	Start Date/time		O		
3	End Date/time		O		
4	Point of Care		O		
5	Room		O		
6	Bed		O		
7	Facility		O		

TABLE 2-24. NDL - NAME WITH DATE AND LOCATION					
SEQ	Component Name	DT	Usage	Value Set	Comments
8	Location Status		O		
9	Person Location Type		O		
10	Building		O		
11	Floor		O		

2.22 NM – Numeric

TABLE 2-25. NUMERIC (NM)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Numeric	-	R		

2.23 PRL – Parent Result Link

TABLE 2-26. PARENT RESULT LINK (PRL)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Parent Observation Identifier	CWE_CR	R		
2	Parent Observation Sub-Identifier	ST	RE		
3	Parent Observation Value Descriptor		O		

Usage Note

See Section 6.1.1 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 for sequence 1 reflects a pre-adoption of *HL7 Version 2.7.1* standard.

2.24 PT – Processing Type

TABLE 2-27. Processing Type (PT)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Processing ID	ID	R	HL70103	
2	Processing Mode		O		

2.25 SAD – Street address

TABLE 2-28. 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		

2.26 SI – Sequence ID

TABLE 2-29. SEQUENCE ID (SI)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Sequence ID	-	R		

2.27 SN – Structured Numeric

TABLE 2-30. 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), or categorical results (^2^+)

Conformance Statements: LRI_PH Component

ELR-8: SN.1 (Comparator) **SHALL** contain the value ">" or "<" or ">=" or "<=" or "=" or "<>".

ELR-9: SN.3 (Separator/Suffix) **SHALL** contain the value "-" or "+" or "/" or "." or ":".

2.28 ST – String Data

TABLE 2-31. 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*.

Formatting Considerations

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.

2.29 TM – Time

TABLE 2-32. Time (TM)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Time	-	R		Format: HH[MM[SS[.S[S[S[S]]]]]][+/-ZZZZ]

Usage Note

PH Component

It is strongly recommended that the time zone offset always be included in the TM. Specific fields in this implementation guide may require time to a specific level of granularity, which may require the time zone offset.

2.30 TS_0 – Time Stamp

TABLE 2-33. 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 1.5.1
The DTM component of this Time Stamp has the following constraints:					
	YYYY		R		
	MM		O		
	DD		O		
	HH		O		
	MM		O		
	SS		O		

TABLE 2-33. Time Stamp (TS_0)					
SEQ	Component Name	DT	Usage	Value Set	Comments
	[.S[S[S[S]]]]		O		
	+/- ZZZZ		Varies		TO Component Usage: 'C(R/O)' All other profiles Usage: 'O'

2.31 TS_1 – Time Stamp

TABLE 2-34. 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 1.5.1
The DTM component of this Time Stamp has the following constraints:					
	YYYY		R		
	MM		R		
	DD		R		
	HH		R		
	MM		R		
	SS		R		
	[.S[S[S[S]]]]		O		
	+/- ZZZZ		Varies		TO Component Usage: 'C(R/O)' All other profiles Usage: 'O'

2.32 TS_2 – Time Stamp

TABLE 2-35. Time Stamp (TS_2)					
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 1.5.1
The DTM component of this Time Stamp has the following constraints:					
	YYYY		R		
	MM		RE		
	DD		RE		

TABLE 2-35. Time Stamp (TS_2)					
SEQ	Component Name	DT	Usage	Value Set	Comments
	HH		O		
	MM		O		
	[SS[.S[S[S[S]]]]]		O		
	+/- ZZZZ		Varies		TO Component Usage: 'C(R/O)' All other profiles Usage: 'O'

2.33 TS_3 – Time Stamp

TABLE 2-36. 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 1.5.1
The DTM component of this Time Stamp has the following constraints:					
	YYYY		R		
	MM		RE		
	DD		RE		
	HH		RE		
	MM		RE		
	[SS[.S[S[S[S]]]]]		O		
	+/- ZZZZ		Varies		TO Component Usage: 'C(R/O)' All other profiles Usage: 'O'

2.34 TS_4 – Time Stamp

TABLE 2-37. 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 1.5.1
The DTM component of this Time Stamp has the following constraints:					
	YYYY		R		
	MM		C(R/X)		Condition Predicate: If TS_4.1 (YYYY) is not valued '0000'
	DD		C(R/X)		Condition Predicate: If TS_4.1 (YYYY) is not valued '0000'

TABLE 2-37. Time Stamp (TS_4)					
SEQ	Component Name	DT	Usage	Value Set	Comments
	HH		C(RE/X)		Condition Predicate: If TS_4.1 (YYYY) is not valued '0000'
	MM		C(RE/X)		Condition Predicate: If TS_4.1 (YYYY) is not valued '0000'
	[SS[.S[S[S[S]]]]]		C(O/X)		Condition Predicate: If TS_4.1 (YYYY) is not valued '0000'
	+/- ZZZZ		Varies		TO Component Usage: 'C(R/O)' All other profiles Usage: 'O'

Usage Note

Default value

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

2.35 TS_5 – Time Stamp

TABLE 2-38. 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 1.5.1
The DTM component of this Time Stamp has the following constraints:					
	YYYY		R		
	MM		R		
	DD		R		
	HH		RE		
	MM		RE		
	[SS[.S[S[S[S]]]]]		O		
	+/- ZZZZ		Varies		TO Component Usage: 'C(R/O)' All other profiles Usage: 'O'

2.36 TS_6 – Time Stamp

TABLE 2-39. 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 1.5.1
The DTM component of this Time Stamp has the following constraints:					

TABLE 2-39. TIME STAMP (TS_6)					
SEQ	Component Name	DT	Usage	Value Set	Comments
	YYYY		R		
	MM		R		
	DD		R		
	HH		R		
	MM		R		
	SS		R		
	[.S[S[S[S]]]]		O		
	+/- ZZZZ		Varies		TO Component Usage: 'C(R/O)' All other profiles Usage: 'O'

2.37 PH Component: TX_7– Time Stamp

TABLE 2-40. STAMP 7 (TS_7)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Time	DTM	R		
2	Degree of Precision		X		Excluded for this Implementation Guide, see Section 1.5.1.
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	DTM	R		

2.38 TX – Text Data

TABLE 2-41. 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.

Formatting Considerations

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.

2.39 VID – Version Identifier

TABLE 2-42. VERSION IDENTIFIER (VID)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Version ID	ID	R	HL70104	
2	Internationalization Code		O		
3	International Version ID		O		

2.40 XAD – Extended Address

TABLE 2-43. 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 Alpha State Codes	
5	Zip or Postal Code	ST	RE		.
6	Country Code	ID	RE	HL70399	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	
8	Other Geographic Designation		O		
9	County/Parish Code	IS	RE	FIPS_6-4	
10	Census Tract		O		
11	Address Representation Code		O		
12	Address Validity Range		X		Excluded for this Implementation Guide, see Section 1.5.1
13	Effective Date		O		

TABLE 2-43. EXTENDED ADDRESS (XAD)					
SEQ	Component Name	DT	Usage	Value Set	Comments
14	Expiration Date		O		

2.41 XCN_GU – Extended Composite ID Number and Name for Persons (Globally Unique)

TABLE 2-44. 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 1.5.1
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	
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	Condition Predicate: If XCN_GU.1 (ID Number) is valued
14	Assigning Facility		O		
15	Name Representation Code		O		
16	Name Context		O		

TABLE 2-44. EXTENDED COMPOSITE ID NUMBER AND NAME FOR PERSONS (XCN_GU)

SEQ	Component Name	DT	Usage	Value Set	Comments
17	Name Validity Range		X		Excluded for this Implementation Guide, see Section 1.5.1
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		

2.42 XON_GU – Extended Composite Name and Identification Number for Organizations Globally Unique)

TABLE 2-45. 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	NM	X		Excluded for this Implementation Guide, see Section 1.5.1
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	Condition Predicate: If XON_GU.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_GU.1 (Organization Name) is not valued

Usage Note

How to populate XON_GU.1 - Organization Name or XON_GU.10 - Organization Identifier

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

2.43 XPN – Extended Person Name

TABLE 2-46. 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 1.5.1
7	Name Type Code	ID	RE	HL70200	
8	Name Representation Code		O		
9	Name Context		O		
10	Name Validity Range		X		Excluded for this Implementation Guide, see Section 1.5.1
11	Name Assembly Order		O		
12	Effective Date		O		
13	Expiration Date		O		
14	Professional Suffix		O		

2.44 PH Component: XTN - Extended Telecommunication Number

TABLE 2-47. XTN – EXTENDED TELECOMMUNICATION NUMBER

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Telephone Number		X		Not supported.
2	Telecommunication Use Code	ID	O		
3	Telecommunication Equipment Type	ID	R	HL70202	
4	Email Address	ST	C(R/X)		Condition Predicate: If XTN-3 (Telecommunication Equipment Type) is valued ‘X.400’ or ‘Internet’.

TABLE 2-47. XTN - EXTENDED TELECOMMUNICATION NUMBER					
SEQ	Component Name	DT	Usage	Value Set	Comments
5	Country Code	NM	O		
6	Area/City Code	NM	C(R/X)		Condition Predicate: If XTN-3 (Telecommunication Equipment Type) is valued 'PH', 'CP', 'SAT', 'FX' or 'TDD'.
7	Local Number	NM	C(R/X)		Condition Predicate: If XTN-3 (Telecommunication Equipment Type) is valued 'PH', 'CP', 'SAT', 'FX'or 'TDD'.
8	Extension	NM	C(RE/X)		Condition Predicate: If XTN-3 (Telecommunication Equipment Type) is valued 'PH', 'CP', 'SAT', 'FX' or 'TDD'.
9	Any Text	ST	RE		For example: "Regular hours 8 am to 5 pm."
10	Extension Prefix		O		
11	Speed Dial Code		O		
12	Unformatted Telephone number		C(O/X)		Condition Predicate: If XTN-3 (Telecommunication Equipment Type) is valued 'PH', 'CP', 'SAT', 'FX' or 'TDD'.

Usage Note

How to populate XTN.4 - Email Address and XTN.7 - Local Number

Component 4 (Email Address) and component 7 (Local Number) are mutually exclusive. You must populate one or the other, but not both in a single repeat of this data type.

XTN.1 - Telephone Number

Components five through nine reiterate the basic function of the first component in a delimited form that allows the expression of both local and international telephone numbers. As of V2.3, the recommended form for the telephone number is to use the delimited form rather than the unstructured form supported by the first component (which is left in for backward compatibility only).

3 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].

3.1 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 3-1. 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	Varies	[1..*]	PH Component Usage: 'R' All other profiles Usage: 'O' PH Component: The first repeat (i.e., the Laboratory Result Sender actor that generated the message) is required. Any other application that transforms the message must add an SFT segment for that application. Other applications that route or act as a conduit may add an SFT but are not required to do so. Just being "HL7 aware" is not enough to put in SFT. They actually have to manipulate the data in the transaction beyond routing.
{	*PATIENT_RESULT Begin*	R	[1..1]	
[	*PATIENT Begin*	R	[1..1]	

TABLE 3-1. ORU^R01^ORU_R01 ABSTRACT MESSAGE SYNTAX				
Segment	Name	Usage	Cardinality	Description
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	Varies	[0..*]	PH Component Usage: 'RE' All other profiles Usage: 'O' PH Component: This notes and comments (NTE) segment should contain notes or comments pertaining to the patient identified in the PID segment. It should not contain order or result related comments.
[{NK1}]	Next of Kin/Associated Parties	Varies	[0..*]	PH Component Usage: 'RE' All other profiles Usage: 'O' PH Component: The next of kin (NK1) segment can be used to document the patient's next of kin, employer, guardian, etc. Particular jurisdictions may require the NK1 segment to contain parent/guardian information when reporting lead testing results for children. When reporting results of animal testing (for example testing animals for rabies) the NK1 segment can be used to identify the owner of the animal.
[	*VISIT Begin*	Varies		PH Component Usage: 'RE' All other profiles Usage: '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*			
{	*ORDER_OBSERVATION Begin*	R	[1..*]	The ORDER_OBSERVATION is required and can repeat.

TABLE 3-1. ORU^R01^ORU_R01 ABSTRACT MESSAGE SYNTAX				
Segment	Name	Usage	Cardinality	Description
[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/X)	[0..*]	Condition Predicate: If OBR-25 (Result Status) is valued “A”, “C”, “F”, “P”, or “R” 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. For laboratory testing, the OBX is normally reporting the results of a test performed on a specimen, Because the ORU^R01^ORU_R01 message structure allows multiple specimens to be associated with a single OBR, there is no direct way to tell which specimen this OBX is associated with. There are other HL7 messages for laboratory results where this ambiguity does not exist, but were not chosen for this implementation guide.

TABLE 3-1. ORU^R01^ORU_R01 ABSTRACT MESSAGE SYNTAX				
Segment	Name	Usage	Cardinality	Description
[{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. PH Component: The specimen group is required at least one time in the message and is used to carry specimen information that is no longer contained in the OBR segment.
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, who collected it, and some basic characteristics of the specimen.
[{OBX}]	Observation related to Specimen	Varies	[0..*]	PH Component Usage: 'RE' All other profiles Usage: 'O' PH Component: The Observation related to Specimen is generally used to report additional characteristics related to the specimen. It is not used to report the results of the requested testing identified in OBR-4 (Universal Service ID). The observations associated with the specimen are typically information that the ordering providing sends with the order. The laboratory forwards that information as part of the result message
}]	*SPECIMEN End*			
}	*ORDER_ OBSERVATION End*			
}	*PATIENT_RESULT End*			

TABLE 3-1. ORU^R01^ORU_R01 ABSTRACT MESSAGE SYNTAX				
Segment	Name	Usage	Cardinality	Description
[DSC]	Continuation Pointer	X		Excluded for this Implementation Guide, see Section 1.5.1

Conformance Statements: LRI_PH Component

ELR-64: Specimen (Specimen Group) **SHALL** be present in at least one occurrence of one ORDER_OBSERVATION Group.

3.2 ACK^R01^ACK

Guaranteed delivery is required. Where use of an ACK is appropriate for the transport mechanism it should be used as described in this guide. All other acknowledgement methods are beyond the scope of this document (e.g., acknowledgement of batches using the HL7 batch methods).

TABLE 3-2. 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	Varies	[1..*]	PH Component Usage: 'R' All other profiles Usage: 'O' PH Component: The first repeat (i.e., the Laboratory Result Sender actor that generated the message) is required. Any other application that transforms the message must add an SFT segment for that application. Other applications that route or act as a conduit may add an SFT but are not required to do so. Just being "HL7 aware" is not enough to put in SFT. They actually have to manipulate the data in the transaction beyond routing.
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

3.3 PH Component: HL7 Batch Protocol

Note: Transmission of ELR-PH messages using batch protocol is optional and not a requirement of this guide. Details such as the frequencies of batch transmissions are left to specific implementations. For further guidance regarding the Batch Protocol refer to Section 2.10.3 HL7 batch protocol in Chapter 2 of the HL7 v2.5.1 Standard.

TABLE 3-3. BATCH PROTOCOL

Segment	Name	Usage	Cardinality	Description/Comments
[FHS]	File Header Segment	R	[1..1]	
{	Batch Begin	R	[1..1]	
[BHS]	Batch Header Segment	R	[1..1]	
{[	Message Begin	RE	[0..*]	A batch containing zero HL7 messages may be sent to meet a requirement for periodic submission of batches when there are no messages to send.
MSH	Message Header Segment	R	[1..1]	
…				
[]}	Message End			
[BTS]	Batch trailer Segment	R	[1..1]	
}	Batch End			
[FTS]	File Trailer Segment	R	[1..1]	

3.4 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 1.5.2 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 profiles, and agreement about which CWE data type to use needs to be reached.

3.4.1 MSH – MESSAGE HEADER SEGMENT

TABLE 3-4. 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]		Constrained to the literal values '^~\&' or '^~\&#', always appearing in the same order.
3	Sending Application	HD_GU	Varies	Varies	HL70361	PH Component Usage: 'R' Cardinality: [1..1] All other profiles Usage: RE' Cardinality: [0..1]
4	Sending Facility	Varies	R	[1..1]	HL70362	GU Datatype: HD_GU PH Component: HD_GU-PH If acknowledgments are in use, this facility will receive any related acknowledgment message. PH Component: For laboratories originating messages, the CLIA identifier is allowed for the Universal ID component of the HD_GU data type. Non-laboratory facilities taking on the Laboratory Result Sender actor role will use an OID for this field.
5	Receiving Application	HD_GU	Varies	[1..1]	HL70361	PH Component Usage: 'R' All other profiles Usage: 'O'
6	Receiving Facility	HD_GU	Varies	Varies	HL70362	PH Component Usage: 'R' Cardinality: [1..1] All other profiles Usage: RE' Cardinality: [0..1] If acknowledgments are in use, this facility originates any related acknowledgment message.
7	Date/Time Of Message	Varies	R	[1..1]		PH Component Datatype: 'TS_7' All other profiles Usage: 'TS_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 LRI_TO_Component profile as defined in Section 1.14.2.7 in MSH-21 (Message Profile Identifier). PH Component: Note that the time zone offset is required and applies to all other date/time fields in the same message instance where a time zone offset is not valued

TABLE 3-4. MESSAGE HEADER SEGMENT (MSH)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
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. Constrained to the literal value '2.5.1'. 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			
15	Accept Acknowledgment Type	ID	R	[1..1]	HL70155 (constrained)	Fixed to 'AL'
16	Application Acknowledgment Type	ID	R	[1..1]	HL70155 (constrained)	Fixed to 'NE'
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.

Usage Notes

MSH-21 - Message Profile Identifier

MSH-21 (Message Profile Identifier) shall identify exclusively one lab results interface profile (i.e., MSH-21 shall not be populated with conflicting LRI profile or LRI components).

Additional compatible profiles or components can be present in MSH-21; for example, if an LRI profile or component is further constrained.

PH Component

When a laboratory result is sent to public health, additional data is required. The PH Component facilitates the inclusion of information necessary for public health. The table below indicates valid MSH-21 combinations for declaring conformance to LRI_PH_COMPONENT profile.

TABLE 3-5. MSH 21 - RESULT PROFILE COMBINATIONS

Component Name	Component OIDs	Description/Comments
LRI_GU_RU_Profile + LRI_PH_Component	2.16.840.1.113883.9.17 2.16.840.1.113883.9.63	Message is conformant to the pre-coordinated LRI_GU_RU profile and Public Health component, which support the (ELR) Laboratory Result with Acknowledgement use case.
LRI_Common_Component + LRI_GU_Component + LAB_RU_Component + LRI_PH_Component	2.16.840.1.113883.9.16 2.16.840.1.113883.9.12 2.16.840.1.113883.9.14 2.16.840.1.113883.9.63	Message is conformant to the post-coordinated LRI_GU_RU profile and Public Health component, which support the (ELR) Laboratory Result with Acknowledgement use case.

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

- LRI_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

When the initial results transaction uses the GU profile in MSH.21 this means that a defined set of fields, including MSH-3, MSH-4, and MSH-6, 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 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 in fact are 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.

Example: LRI_GU_RU_Profile using pre-coordinated component OID and the LRI_PH_Component

```
MSH…|||||LRI_GU_RU_Profile^^2.16.840.1.113883.9.17^ISO~LRI_PH_Component^^2.16.840.1.113883.9.
63^ISO
```

Example: LRI_Common_Component + LRI_GU_Component + LAB_RU_Component + LRI_PH_Component using Component OIDs

```
MSH…|||||LRI_Common_Component^^2.16.840.1.113883.9.16^ISO~
LRI_GU_Component^^2.16.840.1.113883.9.12^ISO~
LRI_RU_Component^^2.16.840.1.113883.9.14^ISO~LRI_PH_Component^^2.16.840.1.113883.9.63^ISO
```

Example: LRI_RU_GU_Profile using pre-coordinated component OID and the LRI_PH_Component and the LAB_NB_Component

```
MSH…|||||LRI_GU_RU_Profile^^2.16.840.1.113883.9.17^ISO~LRI_PH_Component^^2.16.840.1.113883.9.
63^ISO~LAB_NB_Component^^2.16.840.1.113883.9.24^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-8: MSH-9 (Message Type) **SHALL** contain the constant value 'ORU^R01^ORU_R01'.

LRI-9: MSH-12.1 (Version ID) **SHALL** contain the constant value '2.5.1'.

LRI-10: MSH-15 (Accept Acknowledgement Type) **SHALL** contain the constant value 'AL'.

LRI-11: MSH-16 (Application Acknowledgement Type) **SHALL** contain the constant value 'NE'.

Conformance Statements: LRI_GU_RU_Profile

LRI-15: An occurrence of MSH-21 (Message Profile Identifier) **SHALL** be valued with 2.16.840.1.113883.9.17 (LRI_GU_RU_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 2.16.840.1.113883.9.14 (LAB_RU_Component) in any order.

Note: Additional occurrences of MSH-21 (Message Profile Identifier) may be valued with 2.16.840.1.113883.9.22 (LRI_TO_Component), 2.16.840.1.113883.9.23 (LAB_XO_Component), and/or 2.16.840.1.113883.9.24 (LAB_NB_Component).

Conformance Statements: LRI_PH_Component

LRI-15: An occurrence of MSH-21 (Message Profile Identifier) **SHALL** be valued with 2.16.840.1.113883.9.17 (LRI_GU_RU_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 2.16.840.1.113883.9.14 (LAB_RU_Component) in any order.

ELR-71: An occurrence of MSH-21 (Message Profile Identifier) **SHALL** be valued with 2.16.840.1.113883.9.63 (LRI_PH_Component).

Acknowledgement Profile Combinations

The table below indicates valid MSH-21 combinations for declaring conformance to a particular LRI acknowledgement profile.

TABLE 3-6. MSH 21 ACKNOWLEDGMENT PROFILE COMBINATIONS			
LRI Profile	Pre-Coordinated OID	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

Conformance Statements: LRI_Acknowledgement_Component

LRI-16: MSH-1 (Field Separator) **SHALL** contain the constant value '|'.

LRI-17: MSH-2 (Encoding Characters) **SHALL** contain the constant value '^~\&' or the constant value '^~\&#'.

LRI-18: MSH-9 (Message Type) **SHALL** contain the constant value 'ACK^R01^ACK'.

LRI-19: MSH-12.1 (Version ID) **SHALL** contain the constant value '2.5.1'.

LRI-20: MSH-15 (Accept Acknowledgement Type) **SHALL** contain the constant value 'NE'.

Conformance Statements: GU_Acknowledgement_Component

LRI-22: MSH-21 (Message Profile Identifier) **SHALL** contain either 2.16.840.1.113883.9.28 (LRI_GU_Response_Profile) or both 2.16.840.1.113883.9.21 (GU_Acknowledgment_Component) and 2.16.840.1.113883.9.26 (LRI_Acknowledgement_Component) when acknowledging ORU GU Profiles where MSH-21 contains 2.16.840.1.113883.9.17 (LRI_GU_RU_Profile), or 2.16.840.1.113883.9.18 (LRI_GU_RN_Profile), or 2.16.840.1.113883.9.12 (LRI_GU_Component).

3.4.2 PH COMPONENT: SFT – SOFTWARE SEGMENT

The software segment provides information about the sending application or other applications that manipulate the message before the receiving application processes the message. In this guide, the Laboratory Result Sender actor is required to populate the first SFT segment. Any other application that transforms the message must add an SFT segment for that application. Other applications that route or act as a conduit may add an SFT but are not required to do so. Based on that discussion, an HL7 Application (including gateways) is required to populate an SFT segment, while bridges and intermediaries may add an SFT but are not required to do so.

TABLE 3-7. SFT – SOFTWARE SEGMENT						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Software Vendor Organization	XON	R	[1..1]		
2	Software Certified Version or Release Number	ST	R	[1..1]		
3	Software Product Name	ST	R	[1..1]		
4	Software Binary ID	ST	R	[1..1]		
5	Software Product Information		O			
6	Software Install Date		O			

3.4.3 MSA – ACKNOWLEDGEMENT SEGMENT

TABLE 3-8. ACKNOWLEDGMENT SEGMENT (MSA)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Acknowledgment Code	ID	R	[1..1]	HL70008	
2	Message Control ID	ST	R	[1..1]		
3	Text Message		X			Excluded for this Implementation Guide, see Section 1.5.1.
4	Expected Sequence Number		O			
5	Delayed Acknowledgment Type		X			Excluded for this Implementation Guide, see Section 1.5.1.
6	Error Condition		X			Excluded for this Implementation Guide, see Section 1.5.1.

3.4.4 ERR – ERROR SEGMENT

TABLE 3-9. 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 1.5.1.

TABLE 3-9. ERROR SEGMENT (ERR)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
2	Error Location		O			
3	HL7 Error Code	CWE_CR	R	[1..1]	HL70357	
4	Severity	ID	R	[1..1]	HL70516	
5	Application Error Code		O			
6	Application Error Parameter		O			
7	Diagnostic Information	TX	RE	[0..1]		
8	User Message		O			
9	Inform Person Indicator		O			
10	Override Type		O			
11	Override Reason Code		O			
12	Help Desk Contact Point		O			

3.4.5 PID – PATIENT IDENTIFICATION SEGMENT

TABLE 3-10. PATIENT IDENTIFICATION SEGMENT (PID)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Set ID – PID	SI	R	[1..1]		Constrained to the literal value '1'.
2	Patient ID		X			Excluded for this Implementation Guide, see Section 1.5.1.
3	Patient Identifier List	CX_GU	R	[1..*]		
4	Alternate Patient ID – PID		X			Excluded for this Implementation Guide, see Section 1.5.1.
5	Patient Name	XPN	R	[1..*]		

TABLE 3-10. PATIENT IDENTIFICATION SEGMENT (PID)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
6	Mother's Maiden Name	XPN	Varies	[0..1]		PH Component Usage: 'RE' All other profiles Usage: 'O' PH Component: May be included for identification purposes. XPN.7 (Name type code) is constrained to the value "M."
7	Date/Time of Birth	Varies	RE	[0..1]		LRI_COMMON_COMPONENT: TS_2 Newborn Screening Profile: TS_3 PH Component: Patient's date of birth. Note that the granularity of the birth date may be important. For a newborn, birth date may be known down to the minute, while for adults it may be known only to the date. Note: If a birth date is not provided in the PID, then the patient age must be reported as an observation associated with the Order.
8	Administrative Sex	IS	R	[1..1]	HL70001	Patient's gender.
9	Patient Alias		X			Excluded for this Implementation Guide, see Section 1.5.1.
10	Race	Varies	RE	[0..*]	HL70005	PH Component Datatype: 'CWE_CRE' All other profiles Datatype: 'CE' Note that state regulations may dictate other behaviors.
11	Patient Address	XAD	Varies	[0..*]		PH Component Usage: 'RE' All other profiles Usage: 'O'
12	County Code		X			Excluded for this Implementation Guide, see Section 1.5.1.
13	Phone Number – Home	XTN	Varies	[0..*]		PH Component Usage: 'RE' All other profiles Usage: 'O'
14	Phone Number – Business	XTN	Varies	[0..*]		PH Component Usage: 'RE' All other profiles Usage: 'O'

TABLE 3-10. PATIENT IDENTIFICATION SEGMENT (PID)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
15	Primary Language		O			
16	Marital Status		O			
17	Religion		O			
18	Patient Account Number		O			
19	SSN Number – Patient		X			Excluded for this Implementation Guide, see Section 1.5.1.
20	Driver's License Number – Patient		X			Excluded for this Implementation Guide, see Section 1.5.1.
21	Mother's Identifier		O			
22	Ethnic Group	CWE_CRE	Varies	[0..*]	HL70189	PH Component Usage: 'RE' All other profiles Usage: '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 1.5.1.
29	Patient Death Date and Time	TS_3	Varies	[0..1]		PH Component Usage: 'C(RE/X)' Condition Predicate: If PID-30 (Patient Death Indicator) is valued 'Y'. All other profiles Usage: 'O'
30	Patient Death Indicator	ID	Varies	[0..1]	HL70136	PH Component Usage: 'RE' All other profiles Usage: 'O'
31	Identity Unknown Indicator		X			Excluded for this Implementation Guide, see Section 1.5.1.
32	Identity Reliability Code		O			

TABLE 3-10. PATIENT IDENTIFICATION SEGMENT (PID)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
33	Last Update Date/Time	TS_5	Varies	[0..1]		PH Component Usage: 'RE' All other profiles Usage: 'O' PH Component: The intent of this field is to serve as flag for messages with updated demographic information.
34	Last Update Facility	HD_GU	Varies	[0..1]		PH Component Usage: 'C(RE/0)' Condition Predicate: If PID-33 (Last Update Date/Time) is valued. All other profiles Usage: 'O' PH Component: This is the facility that originated the demographic update.
35	Species Code	CWE_CRE	Varies	[0..1]	PHVS_Animal_CDC	PH Component Usage: 'RE' All other profiles Usage: 'O' PH Component: Population of this field supports animal rabies testing by public health laboratories.
36	Breed Code		X			Excluded for this Implementation Guide, see Section 1.5.1.
37	Strain		X			Excluded for this Implementation Guide, see Section 1.5.1.
38	Production Class Code		X			Excluded for this Implementation Guide, see Section 1.5.1.
39	Tribal Citizenship		X			Excluded for this Implementation Guide, see Section 1.5.1.

Usage Note

PH Component

The Patient Identification Segment (PID) is used to provide basic demographics regarding the subject of the testing. For ELR the subject may be a person or an animal.

Conformance Statements: LRI_Common_Component

LRI-24: PID-1 (Set ID - PID) **SHALL** be valued with the constant value '1'.

LRI-25: If PID-5 (Patient Name) is unknown then the first occurrence of PID-5 **SHALL NOT** be valued.

LRI-26: If PID-5 (Patient Name) is unknown then the second occurrence of PID-5 **SHALL** be valued and only PID-5.7 (Name Type Code) **SHALL** be valued with the constant value "U" (i.e., PID-5 shall be valued as |~^^^^^^U|).

Conformance Statements: LRI_PH_Component

ELR-25: If valued, PID-6.7 (Name Type Code) **SHALL** contain the constant value 'M'.

3.4.6 PH COMPONENT: NK1 – NEXT OF KIN SEGMENT

If the subject of the testing is something other than a person i.e. an animal, the NK1 will document the person or organization responsible for or owning the subject. For patients who are persons, the NK1 documents the next of kin of the patient. This is particularly important for lead testing of minors, since the NK1 is used to document information about the parent or guardian

TABLE 3-11. NK1 - NEXT OF KIN SEGMENT

SEQ	HL7 Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Set ID – NK1	SI	R	[1..1]		
2	Name	XPN	C(R/X)	[0..*]		Condition Predicate: If NK1-13 (Organization Name – NK1) is not valued. Name of the next of kin or associated party. If next of kin or associated party is a person use this field, otherwise, use field NK1-13.
3	Relationship	CWE_CRE	RE	[0..1]	HL70063	Description of the relationship between the next of kin/related party and the patient. It is of particular importance when documenting the parent or guardian of a child patient or the owner of an animal patient.
4	Address	XAD	RE	[0..*]		Field that may contain the address of the next of kin/associated party.
5	Phone Number	XTN	RE	[0..*]		Field that may contain the telephone number or email address of the next of kin/associated party. Multiple phone numbers are allowed.
6	Business Phone Number		O			

TABLE 3-11. NK1 - NEXT OF KIN SEGMENT						
SEQ	HL7 Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
7	Contact Role	CWE_CRE	RE	[0..1]	HL70131	
8	Start Date		O			
9	End Date		O			
10	Next of Kin / Associated Parties Job Title		O			
11	Next of Kin / Associated Parties Job Code/Class		O			
12	Next of Kin / Associated Parties Employee Number		O			
13	Organization Name – NK1	XON	C(R/X)	[0..1]		Condition Predicate: If NK1-2 (Name) is NOT valued. If next of kin or associated party is an organization use this field, otherwise, use field NK1-2.
14	Marital Status		O			
15	Administrative Sex		O			
16	Date/Time of Birth		O			
17	Living Dependency		O			
18	Ambulatory Status		O			
19	Citizenship		O			
20	Primary Language		O			
21	Living Arrangement		O			
22	Publicity Code		O			
23	Protection Indicator		O			
24	Student Indicator		O			

TABLE 3-11. NK1 - NEXT OF KIN SEGMENT						
SEQ	HL7 Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
25	Religion		O			
26	Mother's Maiden Name		O			
27	Nationality		O			
28	Ethnic Group		O			
29	Contact Reason		O			
30	Contact Person's Name	XPN	C(R/X)	[0..*]		Condition Predicate: If NK1-13 (Organization Name) is valued.
31	Contact Person's Telephone Number	XTN	C(RE/X)	[0..*]		Condition Predicate: If NK1-13 (Organization Name) is valued.
32	Contact Person's Address	XAD	C(RE/X)	[0..*]		Condition Predicate: If NK1-13 (Organization Name) is valued.
33	Next of Kin/Associated Party's Identifiers		O			
34	Job Status		O			
35	Race		O			
36	Handicap		O			
37	Contact Person Social Security Number		O			
38	Next of Kin Birth Place		O			
39	VIP Indicator		O			

Conformance Statements: LRI_PH_Component

ELR-33: NK1-1 (Set ID – NK1) **SHALL** be valued sequentially starting with the value '1'.

3.4.7 PH COMPONENT: PV1 – PATIENT VISIT INFORMATION

This segment contains basic inpatient or outpatient encounter information.

TABLE 3-12. PV1 - PATIENT VISIT INFORMATION

SEQ	HL7 Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Set ID - PV1	SI	R	[1..1]		
2	Patient Class	IS	R	[1..1]	HL70004	A gross identification of the classification of patient's visit
3	Assigned Patient Location		O			
4	Admission Type	IS	RE	[0..1]	HL7007	
5	Preadmit Number		O			
6	Prior Patient Location		O			
7	Attending Doctor		O			
8	Referring Doctor		O			
9	Consulting Doctor		O			
10	Hospital Service		O			
11	Temporary Location		O			
12	Preadmit Test Indicator		O			
13	Re-admission Indicator		O			
14	Admit Source		O			
15	Ambulatory Status		O			
16	VIP Indicator		O			
17	Admitting Doctor		O			
18	Patient Type		O			

TABLE 3-12. PV1 - PATIENT VISIT INFORMATION						
SEQ	HL7 Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
19	Visit Number		O			
20	Financial Class		O			
21	Charge Price Indicator		O			
22	Courtesy Code		O			
23	Credit Rating		O			
24	Contract Code		O			
25	Contract Effective Date		O			
26	Contract Amount		O			
27	Contract Period		O			
28	Interest Code		O			
29	Transfer to Bad Debt Code		O			
30	Transfer to Bad Debt Date		O			
31	Bad Debt Agency Code		O			
32	Bad Debt Transfer Amount		O			
33	Bad Debt Recovery Amount		O			
34	Delete Account Indicator		O			
35	Delete Account Date		O			
36	Discharge Disposition		O			
37	Discharged to Location		O			
38	Diet Type		O			
39	Servicing Facility		O			

TABLE 3-12. PV1 - PATIENT VISIT INFORMATION						
SEQ	HL7 Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
40	Bed Status		X			Excluded for this Implementation Guide, see Section 1.5.1.
41	Account Status		O			
42	Pending Location		O			
43	Prior Temporary Location		O			
44	Admit Date/Time	TS_5	RE	[0..1]		Date and time patient arrived for services.
45	Discharge Date/Time	TS-5	RE	[0..1]		Date and time patient services ended.
46	Current Patient Balance		O			
47	Total Charges		O			
48	Total Adjustments		O			
49	Total Payments		O			
50	Alternate Visit ID		O			
51	Visit Indicator		O			
52	Other Healthcare Provider		X			Excluded for this Implementation Guide, see Section 1.5.1.

Conformance Statements: LRI_PH_Component

ELR-30: PV1-1 (Set ID - PV1) **SHALL** contain the constant value '1'.

3.4.8 ORC – COMMON ORDER SEGMENT

TABLE 3-13. COMMON ORDER SEGMENT (ORC)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Order Control	ID	R	[1..1]	HL70119	

TABLE 3-13. COMMON ORDER SEGMENT (ORC)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
2	Placer Order Number	EI_GU	RE	[0..1]		
3	Filler Order Number	EI_GU	R	[1..1]		
4	Placer Group Number	EI_GU	RE	[0..1]		
5	Order Status		O			
6	Response Flag		O			
7	Quantity/Timing		X			Excluded for this Implementation Guide, see Section 1.5.1.
8	Parent		O			
9	Date/Time of Transaction		O			
10	Entered By		O			
11	Verified By		O			
12	Ordering Provider	XCN_GU	R	[1..1]		PH Component: If available, a NPI should be used as the identifier.
13	Enterer's Location		O			
14	Call Back Phone Number	XTN	Varies	[0..2]		PH Component Usage: 'RE' All other profiles Usage: 'O' PH Component: This should be a phone number or other contact information associated with the original ordering provider.
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 1.5.1.

TABLE 3-13. COMMON ORDER SEGMENT (ORC)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
21	Ordering Facility Name	XON	Varies	[1..1]		PH Component Usage: 'R' All other profiles Usage: 'O' PH Component: This field should contain the name of the facility where the order was originally placed by the provider (even if a sample is being referred by the filler lab to another lab). If the order was placed in a single provider office, the value in this field may be the same as in ORC-12.
22	Ordering Facility Address	XAD	Varies	[1. 1]		PH Component Usage: 'R' All other profiles Usage: 'O' PH Component: The address of the ordering facility identified in ORC.21.
23	Ordering Facility Phone Number	XTN	Varies	[1..*]		PH Component Usage: 'R' All other profiles Usage: 'O' PH Component: The telephone number or other contact information associated with the ordering facility identified in ORC.21.
24	Ordering Provider Address	XAD	Varies	[0..*]		PH Component Usage: 'RE' All other profiles Usage: 'O' PH Component: This should be the address associated with the original ordering provider identified in OBR.16 / ORC 12.
25	Order Status Modifier		O			
26	Advanced Beneficiary Notice Override Reason		C(X/X)			Excluded for this Implementation Guide, see Section 1.5.1.
27	Filler's Expected Availability Date/Time		O			
28	Confidentiality Code		O			

TABLE 3-13. COMMON ORDER SEGMENT (ORC)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
29	Order Type		O			
30	Enterer Authorization Mode		O			
31	Parent Universal Service Identifier		O	]		

Conformance Statements: LRI_COMMON_COMPONENT

LRI-27: The value of ORC-2 (Placer Order Number) **SHALL** be identical to the value of OBR-2 (Placer Order Number).

LRI-28: The value of ORC-3 (Filler Order Number) **SHALL** be identical to the value of OBR-3 (Filler Order Number).

LRI-29: The value of ORC-12 (Ordering Provider) **SHALL** be identical to the value of OBR-16 (Ordering Provider).

Conformance Statements: LAB_RU_COMPONENT

LRI-31: The value of ORC-2 (Placer Order Number) **SHALL NOT** be valued identical to another instance of ORC-2 (Placer Order Number) in the message.

LRI-32: The value of ORC-3 (Filler Order Number) **SHALL NOT** be valued identical to another instance of ORC-3 (Filler Order Number) in the message.

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

Conformance Statements: LRI_PH_Component

ELR-34: ORC-1 (Order Control) **SHALL** contain the constant value 'RE'.

ELR-38: ORC-14 (Call Back Phone Number) **SHALL** be the same value as OBR-17 (Call Back Phone Number) within same Order_Observation Group.

3.4.9 OBR – OBSERVATION REQUEST SEGMENT

TABLE 3-14. OBSERVATION REQUEST SEGMENT (OBR)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments

TABLE 3-14. OBSERVATION REQUEST SEGMENT (OBR)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Set ID - OBR	SI	R	[1..1]		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.
2	Placer Order Number	EI_GU	RE	[0..1]		
3	Filler Order Number	EI_GU	R	[1..1]		
4	Universal Service Identifier	CWE_CR	R	[1..1]	Varies (see comments)	PH Component Value Set: LOINC All other profiles Value Set: not defined PH Component: OBR.4 (Universal Service) Identifier is a test, panel or battery code for the requested observation. For lab test orders in general LOINC SHOULD be used as the standard coding system for this field if an appropriate LOINC code exists. A local code and local test name 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.
5	Priority – OBR		X			Excluded for this Implementation Guide, see Section 1.5.1
6	Requested Date/Time		X			Excluded for this Implementation Guide, see Section 1.5.1

TABLE 3-14. OBSERVATION REQUEST SEGMENT (OBR)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
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". NOTE: Even when a specimen is not involved, the Observation Date/Time is always relevant.
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 (constrained)	
12	Danger Code		O			
13	Relevant Clinical Information	CWE_CRE	RE	[0..*]	HL70916	CWE is pre-adopted from V2.7.1 and can only contain values that were originated on the original order.
14	Specimen Received Date/Time		X			Excluded for this Implementation Guide, see Section 1.5.1
15	Specimen Source		X			Excluded for this Implementation Guide, see Section 1.5.1
16	Ordering Provider	XCN_GU	R	[1..1]		Note that ORC-12 Ordering Provider is constrained to contain the same value as this field. PH Component: If available, a NPI should be used as the identifier.

TABLE 3-14. OBSERVATION REQUEST SEGMENT (OBR)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
17	Order Call-back Phone Number	XTN	Varies	[0..2]		PH Component Usage: RE All other profiles Usage: O PH Component: This should be a phone number or other contact information associated with the original ordering provider..
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_6	R	[1..1]		
23	Charge to Practice		O			
24	Diagnostic Service Sect ID		O			
25	Result Status	ID	R	[1..1]	HL70123 (constrained)	
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 1.5.1
28	Result Copies To	XCN_GU	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 is valued CC or BCC
29	Parent	EIP_GU	C(R/RE)	[0..1]		Condition Predicate: If OBR-11 (Specimen Action Code) is valued “G” See Section 6.1.1 Parent/Child Linking, of this document for more information on linking parent/child results.
30	Transportation Mode		O			

TABLE 3-14. OBSERVATION REQUEST SEGMENT (OBR)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
31	Reason for Study	CWE_CRE	Varies	[0..*]	ICD-9CM or ICD-10-CM and/or CORE Problem List Subset of SNOMED CT.	PH Component Usage: 'RE' All other profiles Usage: 'O'
32	Principal Result Interpreter	NDL	Varies	[0..1]		PH Component Usage: 'RE' All other profiles Usage: 'O' PH Component: Used for pathology results.
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			
44	Procedure Code		O			
45	Procedure Code Modifier		O			

TABLE 3-14. OBSERVATION REQUEST SEGMENT (OBR)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
46	Placer Supplemental Service Information		O			
47	Filler Supplemental Service Information		O			
48	Medically Necessary Duplicate Procedure Reason		O			
49	Result Handling	CWE_CRE	RE	[0..*]	HL70507	
50	Parent Universal Service Identifier		O			

Usage Note

OBR-7 – Date/Time of Observation

The date/time of those OBXs that relate to the actual result should have OBX-14 (Date/Time of the Observation) equal to OBR-7 (Observation Date/Time).

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. 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

For OBR-13 (Relevant Clinical Information), note that CWE has been pre-adopted from V2.7.1 and can only contain values that were in the original order.

Conformance Statements: LRI_COMMON_COMPONENT

LRI-33: 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-34: 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-35: 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).

LRI-36: 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-37: If present, OBR-8 (Observation End Date/Time) **SHALL** be equal or later than OBR-7 (Observation Date/Time).

LRI-38: The value of OBR-1 (Set ID – OBR) **SHALL** be valued sequentially starting with the value '1' within a given segment group.

LRI-39: The value of OBR-2 (Placer Order Number) **SHALL** be identical to the value of ORC-2 (Placer Order Number).

LRI-40: The value of OBR-3 (Filler Order Number) **SHALL** be identical to the value of ORC-3 (Filler Order Number).

LRI-41: If valued, OBR-11 (Specimen Action Code) **SHALL** be a value with "A", "G", "L", or "O".

LRI-42: The value of OBR-16 (Ordering Provider) **SHALL** be identical to the value of ORC-12 (Ordering Provider).

Conformance Statements: LAB_RU_COMPONENT

LRI-46: The value of OBR-2 (Placer Order Number) **SHALL NOT** be valued identical to another instance of OBR-2 (Placer Order Number) in the message.

LRI-47: 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.

Note: The conformance statements for OBR-2 do not apply when those fields are empty.

3.4.9.1 REPORTING A MICROBIOLOGY CULTURE WITH SUSCEPTIBILITY

The approach described here is required for use in reporting microbiology results for the profiles supported in this guide.

Report a microbiology culture with susceptibility where:

1) The parent result contains the culture result including an OBX identifying an organism AND

2) The child result contains a susceptibility battery linked to the organism identified in the parent result.

The following conformance statements are intended to support these requirements.

Conformance Statements: LRI_COMMON_COMPONENT

LRI-50: The implementer **SHALL** report microbiology results as follows:

PART A: The ORU^R01 shall contain One (1..1) ORDER_OBSERVATION group containing one (1..1) OBR with OBR-4 field populated with a code for a Culture with Susceptibility

AND

PART B: one or more (1..*) OBSERVATION groups containing an OBX segment with OBX-3 field populated with a code indicating the identification of an organism

AND

PART C: One or more (1..*) additional ORDER_OBSERVATION groups each containing:

PART C1: one (1..1) OBR with OBR-4 field populated with a code for Susceptibility battery and OBR-11 field populated with the value "G" and OBR-26 valued such that it links to one of the OBX segments in **PART B**

AND

PART C2: one or more (1..*) OBSERVATION groups containing an OBX segment with OBX-3 field populated with a code for a specific antibiotic susceptibility

AND

PART D: the ORU^R01 shall conform to one of the following profiles:

LRI_GU_RU_Profile

- **LRI-33**
- **LRI-34**
- **LRI-35**
- **LRI-36**

Note: Examples conforming to **LRI-50** can be found in Section 6.2.5 Examples of Culture and Susceptibility Results

3.4.9.2 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) 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 3-15. OBR-16, -28, -49 EXAMPLES

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

3.4.10 TQ1 – TIMING/QUANTITY SEGMENT

TABLE 3-16. 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_3	RE	[0..1]		
8	End date/time	TS_3	RE	[0..1]		
9	Priority		O			
10	Condition text		O			
11	Text instruction		O			
12	Conjunction		X			Excluded for this Implementation Guide, see Section 1.5.1
13	Occurrence duration		O			
14	Total occurrence's		O			

Usage Note

TQ1-12 - Conjunction

Since the TQ group can only appear once in each Observation_Group, none of the values in TQ1-12 make sense, thus should not be sent.

Conformance Statements: LRI_Common_Component

LRI-51: The value of TQ1-1 (Set ID – TQ1) **SHALL** be valued '1'.

3.4.11 OBX – OBSERVATION/RESULT SEGMENT

TABLE 3-17. OBSERVATION RESULT SEGMENT (OBX)

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Set ID – OBX	SI	R	[1..1]		For the first repeat of the OBX segment, the sequence number shall be one (1), for the second repeat, the sequence number shall be two (2), etc.
2	Value Type	ID	C(R/X)	[0..1]	HL70125 (constrained)	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. PH Component: For Ask at Order Entry (AOE) questions refer to the Section 8.1 below.
4	Observation Sub-ID	ST	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).

TABLE 3-17. 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 4.2 SNOMED CT for guidance on how to value this field for Microbiology. PH Component: See Section 0, HL7 Table 0125 for the data types that will be supported for this field. For coded lab test results, SNOMED CT shall be used as the standard coding system for this field if an appropriate SNOMED CT code exists. See Section Error! Reference source not found. below for further guidance. For AOE question responses refer to the Guidance Section 8.1 below
6	Units	CWE_CRE	C(R/RE)	[0..1]		Condition Predicate: If OBX-2 (Value Type) is valued “NM” or “SN” and OBX-11 is not valued “X” or “N” Note: If there is not a unit of measure available while the Condition Predicate is True, the value “NA” shall be used in CWE_CRE.1 and “HL70353” in CWE_CRE.3 Note: UCUM (Unified Code for Units of Measure) will be evaluated during the pilot for potential subsequent inclusion. As part of the pilot test, for dimensionless units the UCUM representation could be {string}, e.g., for titer the pilot might use {titer} to test feasibility. When sending units of measure as text, they must be placed in the correct component of OBX-6 (CWE_CRE.9). PH Component: UCUM (Unified Code for Units of Measure) should be used for reporting units of measure.
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-

TABLE 3-17. OBSERVATION RESULT SEGMENT (OBX)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
8	Abnormal Flags	Varies	RE	[0..*]	Varies	PH Component Datatype: 'CWE_CRE' All other profiles Datatype: 'IS' PH Component Value Set: HL70078 (V2.7.1) All other profiles Value Set: Extended HL70078 (V2.5.1) The Laboratory determines based on policy whether a result is accompanied by a coded interpretation in OBX-8. 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 Note that this IG is adopting HL70078 from V2.5.1, see Section 4.7.4 for value set. PH Component: ELR-PH has pre-adopted the CWE data type for this field from HL7 v2.7 and constrained HL70078 from v2.7.1 for the value set. Example for Microbial Sensitivity: "S^Susceptible^HL70078" Examples for Numeric Results: "H^Above high normal^HL70078"
9	Probability		O			
10	Nature of Abnormal Test		O			
11	Observation Result Status	ID	R	[1..1]	HL70085 (V2.8)	
12	Effective Date of Reference Range		O			

TABLE 3-17. OBSERVATION RESULT SEGMENT (OBX)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
13	User-Defined Access Checks		O			
14	Date/Time of the Observation	Varies	RE	[0..1]		PH Component Datatype: 'TS_4' All other profiles Datatype: 'TS_5' For specimen based test, if it is valued it must be the same as SPM-17.1 If SPM-17.2 is present and relates to the same observation, then OBX-14 must be within the DR range. PH Component: The date/time testing was performed should be reported in OBX-19 (Date/Time of the Analysis)
15	Producer's Reference		O			
16	Responsible Observer		O			
17	Observation Method	CWE_CRE	Varies	RE	HL7 V3 Observation Method and/or SNOMED CT Procedure Hierarchy	PH Component Usage: 'RE' All other profiles Usage: 'O' PH Component: If the LOINC code in OBX-3 (Observation Identifier) is methodless, this field should be populated.
18	Equipment Instance Identifier		O			
19	Date/Time of the Analysis	TS_5	RE	[0..1]		Be as precise as appropriate and available.
20	Reserved for harmonization with *Version 2.6.*		X			Excluded for this Implementation Guide, see Section 1.5.1
21	Reserved for harmonization with *Version 2.6*.		X			Excluded for this Implementation Guide, see Section 1.5.1

TABLE 3-17. OBSERVATION RESULT SEGMENT (OBX)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
22	Reserved for harmonization with *Version 2.6*.		X			Excluded for this Implementation Guide, see Section 1.5.1
23	Performing Organization Name	XON_GU	R	[1..1]		The information for producer ID is recorded as an XON data type. PH Component:: • Example using a CLIA Identifier in OBX-23.10 (Organization Identifier) `University Hospital Chem Lab^L^^^^CLIA&2.16.840.1.113883.4.7&ISO^XX^^^01D1111111`
24	Performing Organization Address	XAD	R	[1..1]		
25	Performing Organization Medical Director	XCN_GU	RE	[0..1]		
26	Patient Results Release Category		O			PH Component: This field is being pre-adopted from HL7 v2.8.1
27	Root Cause		O			PH Component: This field is being pre-adopted from HL7 v2.8.1
28	Local Process Control		O			PH Component: This field is being pre-adopted from HL7 v2.8.1
29	Observation Type	ID	[1..1]	R	HL70396 (V2.8.1)	PH Component: This field is being pre-adopted from HL7 v2.8.1 . This field indicates the type of observation to enable systems to distinguish between observations sent along with an order, (e.g. Ask at Order questions or AOEs) versus observations sent as the result to an order.

Usage Note

OBX-14 – Date/Time of Observation

For an OBX that reflects an actual result for the test requested, rather than including additional information such as ask at order entry responses, OBX-14 (Date/Time of the Observations should be identical to OBR-7 (Observation Date/Time).

OBX-17 – Observation Method

For OBX-17 (Observation Method): This can be useful to further specify information about the specific method to a more granular level than what is defined by the LOINC used in OBX-3. There are two vocabularies available for use at this time, SNOMED 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.

PH Component

An OBX can reflect an actual result for the test requested, additional information such as AOE responses, or other epidemiologically important information or observations related to the specimen.

Conformance Statements: LRI_COMMON_COMPONENT

LRI-52: The value of OBX-5 (Observation Value) **SHALL NOT** be truncated.

LRI-53: The value of OBX-1 (Set ID – OBX) **SHALL** be valued sequentially starting the value '1' within a given segment group.

LRI-54: If there are multiple OBX segments associated with the same OBR segment that have the same OBX-3 values for (OBX-3.1 + OBX-3.3) or (OBX-3.4 + OBX-3.6), a combination of (OBX-3.1 + OBX-3.3) or (OBX-3.4 + OBX-3.6) and OBX-4 **SHALL** create a unique identification under a singl**e** OBR**.**

LRI-55: If OBX-2 (Observation Type) is valued, then the data type format for OBX-5 **SHALL** conform to the corresponding constrained data type identified in the "Data Type Flavor" column of Table 4-9. HL7 Table 0125 – Value Type (V2.5.1) in this guide.

LRI-56: If OBX-5 (Observation Value) is CE (as indicated in OBX-2), then CE.1 (Identifier) and CE.3 (Name of Coding System) or CE. 4 (Alternate Identifier) and CE.6 (Name of Alternate Coding System) **SHALL** be valued.

Conformance Statements: LRI_PH_COMPONENT

ELR-77: OBX-5 (Observation Value) **MUST** be valued If OBX-8 (Abnormal Flags) is empty AND OBX-11 (Observation Result Status) is not valued 'X' or 'N'.

ELR-78: OBX-8 (Abnormal Flags) **MUST** be valued If OBX-5 (Observation Value) is empty AND OBX-11 (Observation Result Status) is not valued 'X' or 'N'.

ELR-72: OBX-14 (Date/Time of the Observation) For observation related to testing of specimen (OBX's following the OBR), **SHALL** be identical to an occurrence of SPM-17.1 (Range Start Date/Time) value within the same ORDER_OBSERVATION Group.

3.4.11.1 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 7.2 CLSI Definitions – Quantitative, Semi-quantitative, Qualitative Results). Both quantitative and qualitative results may have comments associated with them. 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 can be accompanied by an interpretation. Coded interpretations should be reported using OBX-8 (abnormal flags) when the values have been drawn from HL7 table 0078.

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 "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.

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

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

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).

Both quantitative and qualitative results may have comments associated with them. These comments may provide additional clarification, information regarding how the result was obtained, etc.

In laboratory test result reporting, the semantic relationship between OBX-3 (Observation Identifier) and OBX-5 (Observation Value) is that the asserted value in OBX-5 "refines" or "qualifies" the meaning of the laboratory test that is specified in OBX-3. In other words how a particular result should be reported using the OBX segment above depends upon what is being used as an observation identifier for OBX-3. This is true regardless of whether SNOMED-CT is used. When SNOMED CT is used for a coded result value in OBX-5, this understanding of the semantic relationship is consistent with the use of qualifiers and refinement as specified in the SNOMED CT Concept Model. It supports the use of SNOMED CT concepts (codes) from the "qualifier value" or another appropriate SNOMED CT hierarchy matching the "semantic type" of the laboratory test specified by the LOINC code in OBX-3 for Microbiology results. These result value concepts may specify a presence/absence value, an organism name or an organism-related substance (e.g. toxin, RNA, DNA, antigen).

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. These should be handled as comments, conveyed in an NTE segment(s) following the OBX in question. Comments typically fall into the following categories:

- Comments about how a clinical finding was reached
- Clarification regarding 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 boiler plate 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 3-18. 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	PH Component: OBX.8 Abnormal Flags	NTE Segment
Numeric result	NM	QN	number	Required unless OBX-11 = 'X' or'N'.'	May be populated	May be populated with an Interpretation Code. Examples: "H^Above high normal^HL70078" or RR^Reactive^HL70078	May be populated with comments, not clinical findings.
Numerical intervals, ratios, inequalities	SN	QN	structured numeric	Required unless OBX-11 = 'X' or'N'.	May be populated	May be populated with an Interpretation Code. See above examples	May be populated with comments, not clinical findings.
Time like quantitative result	TS, TM, DT	QN	timestamp, time or date	[empty]	May be populated	May be populated with an Interpretation Code. See above examples	May be populated with comments, not clinical findings.

TABLE 3-18. 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	PH Component: OBX.8 Abnormal Flags	NTE Segment
Conveys ordinal value	CWE	ORD	Ordinal as a code 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. PH Component: For coded ordinal test results SNOMED CT shall be used if a suitable code exist. The ELR Ordinal Value Set is provided in the vocabulary section as an informative value set..	[empty]	May be populated	May be populated with an Interpretation Code. Example: "A^Abnormal^HL70078"	May be populated with comments, not clinical findings.
Conveys ordinal value	SN	ORD	Ordinal as structured numeric PH Component: example ^2^+	Required unless OBX-11 = 'X' or 'N'. **	Required	May be populated with an Interpretation Code. See above examples	May be populated with comments, not clinical findings.

TABLE 3-18. 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	PH Component: OBX.8 Abnormal Flags	NTE Segment
Conveys observation	CWE	NOM	Coded observation. 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. PH Component: For coded nominal test results SNOMED CT shall be used if a suitable code exist.	[empty]	May be populated	May be populated with an Interpretation Code. See above examples	May be populated with comments, not clinical findings.
Conveys observation	FT, TX or ST	NAR	text	[empty]	May be populated	May be populated with an Interpretation Code. See above examples	May be populated with comments, not clinical findings.
Conveys numeric or ordinal value	NM	ORDQN	Number	Required unless OBX-11 = 'X' or'N'. **	May be populated	May be populated with an Interpretation Code. Example for Microbial Sensitivity: "S^Susceptible^HL70078"	May be populated with comments, not clinical findings.

TABLE 3-18. 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	PH Component: OBX.8 Abnormal Flags	NTE Segment
Conveys numeric or ordinal value	CWE	ORDQN	Ordinal as a code. 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. PH Component: For coded Ordinal test results see comments above	[empty]	May be populated	May be populated with an Interpretation Code. See above examples"	May be populated with comments, not clinical findings.
Conveys observation	FT, TX or ST	MULTI	text	[empty]	May be populated	May be populated with an Interpretation Code. See above examples	May be populated with comments, not clinical findings.
Conveys imbedded object (ED) or pointer to object (RP)	ED, RP	*	Object pointer or imbedded object	[empty]	[empty]	May be populated with an Interpretation Code. See above examples	May be populated with comments, not clinical findings.

PH Component

HL7 Message examples for OBX segments:

LOINC QN:

```
OBX|1|NM|5671-3^Lead [Mass/volume] in Blood^LN^PB^lead blood^L^2.40^V1||=^9.2|ug/dL^microgram per
deciliter^UCUM^ug/dl^microgram per deciliter^L^1.1^V1|0.0 - 5.0|H^Above High
Normal^HL70078^H^High^L^2.7^V1|||F|…
```

LOINC QN:

```
OBX|2 SN|6812-2^Dengue virus IgM Ab [Titer] in Serum^LN^3752^Dengue Fever - IGM AB
EIA^L^2.40^v1||^1^:^256|{titer}^titer^UCUM^titer^titer^L^1.8.2|<1:64|H^Above High Normal^HL70078|||F|…
```

LOINC ORD:

```
OBX|3|SN|38382-8^FLUBV XXX Ql Cult^LN^1234^Flu B Culture ||^2^+|{growth}^^UCUM|no growth|A|||F|…
```

LOINC ORD:

```
OBX|4|CWE|23826-1^Bordetella pertussis DNA [Presence] in Unspecified specimen by Probe and target
amplification method^LN^BPRP^Bordetella pertussis PCR^L^2.40||10828004^Positive (qualifier
value)^SCT^BPPOS^Positive^L^20120131^^Positive||||||F|
```

LOINC ORDQN:

```
OBX|5| SN|48177-0^Streptomycin 1 ug/mL [Susceptibility] by Method for Slow-growing
mycobacteria^LN^STRP^Streptomycin 1.0 ug/mL^L^2.40||<^100|[arb'U]^arbitrary unit^UCUM^growth
units^growth units^L||S^Susceptible^HL70078^^^^2.5.1|||F|…
```

LOINC ORDQN:

```
OBX|6| CWE|48177-0^Streptomycin 1 ug/mL [Susceptibility] by Method for Slow-growing
mycobacteria^LN^STRP^Streptomycin 1.0 ug/mL^L^2.40||131196009 ^Susceptible (qualifier
value)^SCT^SUS^susceptible^L^2012013^^Susceptible||||||F|…
```

LOINC NOM:

```
OBX|7| CWE|6463-4^Bacteria identified in Unspecified specimen by Culture^LN^TCX^Throat
Culture^L^2.40||5851001^Corynebacterium diphtheriae^SCT^^^^^^Corynebacterium diphtheriae
isolated|||||F|…
```

Usage Note

SNOMED CT

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.

PH Component

For coded test results SNOMED CT **shall** be used, if a suitable code exist.

OBX-2 – Observation Type and LOINC scale Relationship

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 3-20. 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.

** When using SN or NM to report ordinal values where there are no appropriate units of measure, use of the CWE status ‘NA’ for CWE.1 and ‘HL7 0353’ for CWE.3 is allowed, indicating there are no applicable units of measure. See OBX-6 in Table 3-19. Observation Identifiers.

TABLE 3-19. 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	FT, TX or ST

TABLE 3-19. DATA TYPES FOR LOINC SCALE PART	
LOINC Scale Part	OBX-2 Value Type
ORDQN - Quantitative or Ordinal	NM, SN, TS, TM, DT, CWE
MULTI - Multi	FT, TX or ST

3.4.12 SPM – SPECIMEN SEGMENT

TABLE 3-20. SPECIMEN SEGMENT (SPM)

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Set ID – SPM	SI	R	[1..1]		
2	Specimen ID	EIP_GU	Varies	[1..1]		PH Component Usage: 'R' All other profiles Usage: 'O' PH Component: Unique identifier for the specimen as referenced by the Placer application, the Filler application, or both. Note that the specimen ID is not the same thing as the placer/filler order number. Order numbers identify the specific test to be performed on a specimen. A particular specimen may be associated with multiple orders (and multiple placer/filler order numbers). The specimen ID may be the same as an accession number, depending on how the particular lab assigns accession numbers.
3	Specimen Parent IDs		O			

TABLE 3-20. SPECIMEN SEGMENT (SPM)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
4	Specimen Type	CWE_CRE	R	[1..1]	SNOMED CT and/or HL70487	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. PH Component: The standard vocabulary for this field should be based upon the SNOMED CT Specimen hierarchy. Although it is not required to send information about the original specimen, when sending information, the original clinical specimen type/source (e.g. Stool) in SPM.4 is preferred over reporting a derivative of the specimen (e.g. an isolate , DNA, or RNA).
5	Specimen Type Modifier	CWE_CRE	Varies	[0..*]	SNOMED CT	PH Component Usage: 'C(RE/X)' Condition Predicate: If SPM-4.3 (Name of Coding System) or SPM-4.6 (Alternate Coding System ID) is valued 'SCT' All other profiles Usage: 'O' PH Component: Modifiers or qualifiers for Specimen type. This allows use of post-coordinated expressions for specimen type.
6	Specimen Additives	CWE_CRE	Varies	[0..*]	SNOMED CT and/or HL70371	PH Component Usage: 'RE' All other profiles Usage: 'O'
7	Specimen Collection Method	CWE_CRE	Varies	[0..1]	SNOMED CT procedure hierarchy and/or HL70488	PH Component Usage: 'RE' All other profiles Usage: 'O'

TABLE 3-20. SPECIMEN SEGMENT (SPM)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
8	Specimen Source Site	CWE_CRE	Varies	[0..1]	SNOMED CT anatomical structure hierarchy	PH Component Usage: 'RE' All other profiles Usage: 'O' PH Component: Source from which the specimen was obtained. For biological samples, it represents the anatomical site from which the specimen was collected.
9	Specimen Source Site Modifier	CWE_CRE	Varies	[0..*]	SNOMED CT topographical modifier hierarchy	PH Component Usage: 'C(RE/X)' Condition Predicate: If SPM-8.3 (Name of Coding System) or SPM-8.6 (Alternate Coding System ID) is valued 'SCT' All other profiles Usage: 'O' PH Component: Topographical modifier (such as "left" or "right") for the specimen source site (SPM-8). Only used if SPM-8 is a SNOMED code. This allows use of post-coordinated expression for specimen source site.
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 3-20. SPECIMEN SEGMENT (SPM)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
17	Specimen Collection Date/Time	DR	Varies	Varies		PH Component Usage: 'R' Cardinality: [1..1] All other profiles Usage: 'RE' Cardinality: [0..1] LRI: 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 OBXs reporting observations based on this specimen, OBX-14 should contain the same value as component 1 of one of the SPM-17.1 values under the OBR.
18	Specimen Received Date/Time	TS_5	Varies	[1..1]		PH Component Usage: 'R' All other profiles Usage: 'O'
19	Specimen Expiration Date/Time		O			
20	Specimen Availability		O			
21	Specimen Reject Reason	Varies	Varies	[0..*]	HL70490	Sender Usage: O using CWE Receiver Usage: RE using CWE_CRE Note: Future versions of this guide will constrain the sender usage of this element to RE.
22	Specimen Quality		O			
23	Specimen Appropriateness		O			
24	Specimen Condition	Varies	Varies	[0..*]	HL70493	Sender Usage: O using CWE Receiver Usage: RE using CWE_CRE Note: Future versions of this guide will constrain the sender usage of this element to RE.
25	Specimen Current Quantity		O			
26	Number of Specimen Containers		O			
27	Container Type		O			

TABLE 3-20. SPECIMEN SEGMENT (SPM)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
28	Container Condition		O			
29	Specimen Child Role		O			

Usage Note

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

Conformance Statements: LRI_Common_Component

LRI-57: The value of SPM-1 (Set ID – SPM) **SHALL** be valued sequentially starting the value '1' within a given segment group.

LRI-58: SPM-4.3 (Name of Coding System) **SHALL NOT** be valued with HL70353.

LRI-59: SPM-4.6 (Name of Alternate Coding System) **SHALL NOT** be valued with HL70353.

LRI-60: 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-61: 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)

Conformance Statements: LRI_PH_Component

ELR-75: The earliest SPM-17.1 (Range Start Date/Time) value **SHALL** be equal to or before OBR-7 (Observation Date/Time) value within the same ORDER_OBSERVATION Group.

ELR-76: If present, the latest SPM-17.2 (Range End Date/Time) value **SHALL** be equal to or after OBR-7 (Observation Date/Time) value within the same Order_Observation Group.

ELR-30: If present, the latest SPM-17.2 (Range End Date/Time) value **SHALL** be equal to or after OBR-8 (Observation End Date/Time) value within the same ORDER_OBSERVATION Group

Guidance for result messages describing specimen rejection

As best practice in the future, a combination of SPM-21 and SPM-24 should be used to provide the most detailed coded information about the specimen reject reason and the specific specimen condition, if applicable.

Use of SPM-21 is the ideal way to communicate when a test order is canceled due to specimen rejection as it codifies the reason for cancellation. Because disposition of a specimen is a CLIA requirement this reason 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, displayed on screen). The IG has identified HL70490 table 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 will expand the content.

Use of SPM-24 can be very useful for communicating specimen condition information that does not meet the laboratory's standard for acceptability (HL70493). The SNOMED finding hierarchy also has some appropriate terms, but is not complete. Future work on these vocabularies will expand the content.

If a laboratory system cannot use SPM-21 and SPM-24, then this information shall be communicated using OBX-5 and NTE segment(s), which has to follow the same display / report rules as SPM-21. How specimen rejection is handled needs to be negotiated between trading partners.

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 any other result expect a string in OBX-5 indicating that the test was not performed.

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

Example of ideal specimen rejection 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||||SPM|1|||119297000^BLD^SCT^BldSpc^Blo
od^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
```

3.4.13 NTE – NOTES AND COMMENTS SEGMENT

TABLE 3-21. NOTES AND COMMENTS SEGMENT (NTE)

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Set ID – NTE	SI	R	[1..1]		For the first repeat of the NTE segment, the sequence number shall be one (1), for the second repeat, the sequence number shall be two (2), etc.
2	Source of Comment	ID	Varies	[0..1]	HL70105	PH Component Usage: 'RE' All other profiles Usage: 'O'
3	Comment	FT	R	[1..*]		Comment contained in the segment.
4	Comment Type	CWE_CRE	Varies	[0..1]	HL70364	PH Component Usage: 'RE' All other profiles Usage: 'O'

Conformance Statements: LRI_PH_Component

ELR-53:NTE.1 (Set ID - NTE) **SHALL** be valued sequentially starting with the value '1' within a given segment group.

3.4.14 PH COMPONENT: FHS – FILE HEADER SEGMENT

TABLE 3-22. FHS – FILE HEADER SEGMENT

SEQ	HL7 Element Name	DT	Cardinality	Usage	Value Set	Description/Comments
1	File Field Separator	ST	[1..1]	R		
2	File Encoding Characters	ST	[1..1]	R		
3	File Sending Application			O		
4	File Sending Facility			O		
5	File Receiving Application			O		
6	File Receiving Facility	HD_GU	[1..1]	R		Unique identifier of the facility that is to receive the message. This field has the same definition as the corresponding field in the MSH segment.
7	File Creation Date/Time	TS_7	[1..1]	R		
8	File Security			X		Excluded for this Implementation Guide, see Section 1.5.1

TABLE 3-22. FHS - FILE HEADER SEGMENT						
SEQ	HL7 Element Name	DT	Cardinality	Usage	Value Set	Description/Comments
9	File Name/ID			O		
10	File Header Comment			X		Excluded for this Implementation Guide, see Section 1.5.1
11	File Control ID			X		Excluded for this Implementation Guide, see Section 1.5.1
12	Reference File Control D			X		Excluded for this Implementation Guide, see Section 1.5.1

Conformance Statements: LRI_PH_Component

ELR-31: FHS-1 (Field Separator) **SHALL** contain the constant value '|'.

ELR-32: FHS-2 (Encoding Characters) **SHALL** contain the constant value '^~\&' or the constant value '^~\&#'.

3.4.15 PH COMPONENT: FTS – FILE TRAILER SEGMENT

TABLE 3-23. FTS - FILE TRAILER SEGMENT						
SEQ	HL7 Element Name	DT	Cardinality	Usage	Value Set	Description/Comments
1	File Batch Count	NM	[1..1]	R		The number of batches contained in this file. Since this interface is constrained to one batch per file, this number should always be '1'.
2	File Trailer Comment			X		Excluded for this Implementation Guide, see Section 1.5.1

3.4.16 PH COMPONENT: BHS – BATCH HEADER SEGMENT

TABLE 3-24. BHS - BATCH HEADER SEGMENT						
SEQ	HL7 Element Name	DT	Cardinality	Usage	Value Set	Description/Comments
1	Batch Field Separator	ST	[1..1]	R		
2	Batch Encoding Characters	ST	[1..1]	R		
3	Batch Sending Application			O		

TABLE 3-24. BHS - BATCH HEADER SEGMENT						
SEQ	HL7 Element Name	DT	Cardinality	Usage	Value Set	Description/Comments
4	Batch Sending Facility			O		
5	Batch Receiving Application			O		
6	Batch Receiving Facility			O		
7	Batch Creation Date/Time			O		
8	Batch Security			X		Excluded for this Implementation Guide, see Section 1.5.1
9	Batch Name/ID/Type			O		
10	Batch Comment			X		Excluded for this Implementation Guide, see Section 1.5.1
11	Batch Control ID			X		Excluded for this Implementation Guide, see Section 1.5.1
12	Reference Batch Control D			X		Excluded for this Implementation Guide, see Section 1.5.1

Conformance Statements: LRI_PH_Component

ELR-33: BHS-1 (Field Separator) **SHALL** contain the constant value '|'.

ELR-34:BHS-2 (Encoding Characters) **SHALL** contain the constant value '^~\&' or the constant value '^~\&#'.

3.4.17 PH COMPONENT: BTS – BATCH TRAILER SEGMENT

TABLE 3-25. BTS - BATCH TRAILER SEGMENT						
SEQ	HL7 Element Name	DT	Cardinality	Usage	Value Set	Description/Comments
1	Batch Message Count	NM	[1..1]	R		This is the total number of messages contained in the batch.
2	Batch Comment			X		Excluded for this Implementation Guide, see Section 1.5.1
3	Batch Totals			X		Excluded for this Implementation Guide, see Section 1.5.1

4 CODE SYSTEMS AND VALUE SETS

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 0396), 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.

A unique identifier identifies value sets, 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.

4.1 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 lab 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 and access to tools, please visit http://loinc.org/

4.1.1 PH COMPONENT

The LOINC long common name SHOULD be sent in addition to the LOINC in order to facilitate debugging and message validation between the sender and the public health agency. See Section 8.2 below for further guidance and examples when a valid LOINC does not exist.

4.2 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 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.

4.2.1 PH COMPONENT

Where a SNOMED CT code is available, SNOMED CT SHALL be used for coded reportable laboratory results using either CWE with the CWE_CRO usage, or CE; in OBX.5. Each SNOMED CT Concept has a permanent unique numeric Identifier which is known as the "Concept ID" and only these shall be used for this IG[11]. In other words, SNOMED alphanumeric legacy codes shall not be used for this IG.

[11] From Section 3.1.2. Concept Identifiers SNOMED CT User Guide- July 2012 International Release (US English), (www.snomed.org/ug.pdf).

The majority of coded results for reportable laboratory results fall into three categories: microorganism names (e.g. 88274000^Trypanosoma cruzi^SCT), presence or absence findings (e.g. 260373001^Detected^SCT), and, less commonly, substances (255835006 ^ Shiga toxin^SCT). When SNOMED CT is used in OBX-5, CWE_CRO.9 shall contain the laboratory's original text which is used for printing and/or display to satisfy CLIA reporting requirements. The original text may be different than or the same as the text describing the standard and/or local code.

4.3 Example HL7 Messages

4.3.1 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
```

4.3.2 SNOMED-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|626-2^Bacteria identified in Throat by Culture^LN||413643004^Beta-
hemolytic Streptococcus, group A^SCT^bstrep^beta hemolytic
Streptococci^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|6551-6^Streptococcus agalactiae Ag [Presence] in Throat by
Immunofluorescence^LN||260208006^Group B Streptococcus
antigen^SCT^bstrepAG^beta hemolytic Streptococci Antigen
identified^L^20110731^1^beta-hemolytic streptococcus antigen
detected||||||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^bstrep^beta hemolytic
Streptococci^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
```

4.3.3 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^SN^^^^^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 4-1. EXAMPLES OF SNOMED CODES FOR FREQUENTLY REPORTED ORGANISMS			
Description	SNOMED SCT (CUI) Code	SNOMED SCT2 (Legacy) Code	SNOMED Text
ESBL Escherichia coli	409800005	R-005C1	ESBL Escherichia coli
Escherichia coli	112283007	L-15601	Escherichia coli
Staphylococcus aureus	3092008	L-24801	Staphylococcus aureus
MRSA	115329001	L-24852	methicillin resistant Staphylococcus aureus
Pseudomonas aeruginosa	52499004	L-23401	Pseudomonas aeruginosa
Group B Streptococcus	43492007	L-25107	Streptococcus agalactiae
Proteus mirabilis	73457008	L-16802	Proteus mirabilis
coagulase-negative staphylococcus	116197008	L-24853	Staphylococcus, coagulase negative
Enterococcus faecium	90272000	L-1E602	Enterococcus faecium
VRE	113727004	L-1E621	vancomycin resistant enterococcus

Note: SNOMED CT not required

4.4 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 can be found at the National Library of Medicine.

4.4.1 PH COMPONENT

SNOMED CT drawn from the specimen hierarchy in SNOMED CT should be used for SPM-4 (Specimen type). A cross-mapping between HL70487 and SNOMED CT is available at PHIN-VADS. (see Appendix B: Resources).

4.5 UCUM

UCUM (Unified Code for Units of Measure) appears to be a viable option for reporting units of measure but must be pilot tested in order to understand the impact of key issues identified by various stakeholders. This guide does not preclude the use of UCUM coding where senders and receivers have localized this guide by mutual agreement.

A list of examples is available at http://loinc.org/usage, see the bottom of that page. As this is a dynamic set, please refer to this site for the most current set of example codes.

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

4.5.1 PH COMPONENT

UCUM (Unified Code for Units of Measure) SHOULD be used for reporting units of measure.

For dimensionless units the UCUM representation {any string} can be used, e.g. for a titer the UCUM representation is {titer}^titer^UCUM.

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

4.6 Vocabulary Constraints

Table 4-2. Value Set/Code System Summary shows the various value sets/code systems used in this IG. It also provides information about the source of the vocabulary and an identifier for the vocabulary. The name found in the Value Set/Code System Name column corresponds with the value set identified in the Value Set column of the data type and segment attribute tables found above.

4.6.1 PH COMPONENT

Table 4-2 LEGEND:

- **Name**: Description of the Value Set attribute found in the data type and segment tables above.
- **Source ID/Reference**: For HL7 tables, this is the same as the Value Set attribute in the data type and segment table above.
- **Source**: The coding system (including version for HL7). Value Sets may be composed of more than as single source.
- **Unique Identifier**: The OID for the Value set, if available. This identifier is not transmitted in the message; however, the identifier is useful and important when vocabulary items are modified or replaced.
- **Comments**: Additional information regarding the Value Set which may include constraints, URL links, and other information.

TABLE 4-2. VALUE SET/CODE SYSTEM SUMMARY

Name	Value Set	Source	Unique Identifier	Comments
Administrative Sex	HL70001	HL7 Version 2.5.1	2.16.840.1.113883.12.1	
Marital Status	HL70002	HL7 Version 2.5.1	2.16.840.1.113883.12.2	
Event Type	HL70003	HL7 Version 2.5.1	2.16.840.1.113883.12.3	Constrained to 'R01'

TABLE 4-2. VALUE SET/CODE SYSTEM SUMMARY				
Name	Value Set	Source	Unique Identifier	Comments
Patient Class	HL70004	HL7 Version 2.5.1	2.16.840.1.113883.12.4	
Race Category	HL70005	HL7 Version 2.5.1	2.16.840.1.113883.12.5	
Admission Type	HL70007	HL7 Version 2.5.1	2.16.840.1.113883.12.7	PH Component
Acknowledgment Code	HL70008	HL7 Version 2.5.1	2.16.840.1.113883.12.8	
Check Digit Scheme	HL70061	HL7 Version 2.5.1	2.16.840.1.113883.12.61	
Relationship	HL70063	HL7 Version 2.5.1	2.16.840.1.113883.12.63	PH Component
Specimen Action Code	HL70065	HL7 Version 2.7.1	2.16.840.1.113883.12.65	Constrained to A, G, L, O
Message Type	HL70076	HL7 Version 2.5.1	2.16.840.1.113883.12.76	Constrained to ORU, ACK
Observation Interpretation	HL70078	HL7 Version 2.7.1	2.16.840.1.113883.12.78	PH Component: Previously known as Abnormal Flag. Note LRI support an extended v2.5.1 HL7 Table 0078
Observation Result Status	HL70085	HL7 Version 2.8	2.16.840.1.113883.12.85	
Processing ID	HL70103	HL7 Version 2.5.1	2.16.840.1.113883.12.103	
Version ID	HL70104	HL7 Version 2.5.1	2.16.840.1.113883.12.104	Constrained to '2.5.1'
Source of Comment	HL70105	HL7 Version 2.5.1	2.16.840.1.113883.12.105	PH Component
Order Control	HL70119	HL7 Version 2.5.1	2.16.840.1.113883.12.119	
Result Status	HL70123	HL7 Version 2.5.1	2.16.840.1.113883.12.123	Constrained to: A, C, F, I, O, P, R, S, X
Value Type	HL70125	HL7 Version 2.5.1	2.16.840.1.113883.12.125	Constrained to: 'R' for CE, DT, NM, SN, ST, TM, TS, TX, FT, CWE; 'RE' for CX, ED, RP (requires agreement between trading partners)
Contact Role	HL70131	HL7 Version 2.5.1	2.16.840.1.113883.12.131	PH Component
Accept/Application Acknowledgment Condition	HL70155	HL7 Version 2.5.1	2.16.840.1.113883.12.155	Constrained to 'AL', 'NE'
Ethnic Group	HL70189	HL7 Version 2.5.1	2.16.840.1.113883.12.189	
Address Type	HL70190	HL7 Version 2.5.1	2.16.840.1.113883.12.190	.
Type of Referenced Data	HL70191	HL7 Version 2.5.1	2.16.840.1.113883.12.191	
Name type	HL70200	HL7 Version 2.5.1	2.16.840.1.113883.12.200	

TABLE 4-2. VALUE SET/CODE SYSTEM SUMMARY				
Name	Value Set	Source	Unique Identifier	Comments
Telecommunication Equipment Type	HL70202	HL7 Version 2.5.1	2.16.840.1.113883.12.202	PH Component
Identifier type	HL70203	HL7 Version 2.7.1	2.16.840.1.113883.12.203	
Subtype of referenced data	HL70291	HL7 Version 2.7.1	2.16.840.1.113883.12.291	
Encoding	HL70299	HL7 Version 2.5.1	2.16.840.1.113883.12.299	
Universal ID type	HL70301	HL7 Version 2.7.1	2.16.840.1.113883.12.301	
CWE Status Codes	HL70353	HL7 Version 2.5.1	2.16.840.1.113883.12.353	See Section 4.7.12 for values
Message structure	HL70354	HL7 Version 2.5.1	2.16.840.1.113883.12.354	Constrained to ORU_R01, ACK
Message Error Condition Codes	HL70357	HL7 Version 2.5.1	2.16.840.1.113883.12.357	
Coding Systems	HL70396	HL7	2.16.840.1.113883.12.396	HL7 Table 0396 defines the standard coding systems recognized by HL7. The table defines a mechanism by which locally defined codes can be transmitted. Any code/coding system not defined in HL7 Table 0396 is considered a “local” coding system from the HL7 perspective. Coding systems that are identified in this implementation guide will be identified according to the recommended HL7 nomenclature from table 0396 as “99-zzz” where “zzz” represents a string identifying the specific non-standard coding system. HL7 now maintains HL7 table 0396 “real time”. This means that values may be added to the table at any time so that implementers can have an up-to-date source of truth for the codes to be used to identify coding systems in any 2.x message.

TABLE 4-2. VALUE SET/CODE SYSTEM SUMMARY				
Name	Value Set	Source	Unique Identifier	Comments
Country Value Set	HL70399	HL7 Version 2.5.1		Refer to HL7 V2.5.1 Message, Chapter 2, Section 2.15.9.1 This identifies the codes for the representation of names of countries, territories and areas of geographical interest. The complete set of 3166-1 codes. http://www.iso.org/iso/iso-3166-1_decoding_table
Specimen Type	HL70487	HL7 Version 2.5.1	2.16.840.1.113883.12.487	
Sequence Condition Code	HL70504	HL7 Version 2.5.1	2.16.840.1.113883.12.504	
Cyclic Entry/Exit Indicator	HL70505	HL7 Version 2.5.1	2.16.840.1.113883.12.505	
Service Request Relationship	HL70506	HL7 Version 2.5.1	2.16.840.1.113883.12.506	
Observation Result Handling	HL70507	HL7 Version 2.71	2.16.840.1.113883.12.507	
Error severity	HL70516	HL7 Version 2.5.1	2.16.840.1.113883.12.516	
LOINC		LOINC	2.16.840.1.113883.6.1 (code system)	Logical Observation Identifiers Names and Codes http://www.loinc.org
Relevant Clinical Information	HL70916	HL7 Version 2.7.1		
Observation Type	HL70936	HL7 Version 2.8.1		Used to indicate if the OBX conveys results or other clinical supplemental information including AsK at Order Entry (AOE) questions
County	FIPS 6-4		2.16.840.1.114222.4.11.829	Codes representing county of origin, address county, reporting county Also referred to as HL70289
ELR Ordinal Value Set		SNOMED CT		PH Component: This is an informative only value set of suggested SNOMED CT concepts related to reporting of qualitative laboratory test. See Section 4.7.17 for values.

TABLE 4-2. VALUE SET/CODE SYSTEM SUMMARY				
Name	Value Set	Source	Unique Identifier	Comments
Observation Method		HL7 V3 Observation Method and/or SNOMED CT procedure hierarchy (108252007)		PH Component: Either HL7 V3 Observation Method and/or SNOMED CT procedure hierarchy may be used. Note: Code System for HL7 V3 Observation Method is “OBSMETHOD”.
Reason For Study		ICD- 9-CM and/or ICD-10-CM and/or CORE Problem List Subset of SNOMED CT		PH Component: Either ICD-9CM and/or ICD-10-CM and/or CORE Problem List Subset of SNOMED CT may be used. The CORE Problem List Subset of SNOMED CT is available from Unified Medical Language System (UMLS) Terminology Service at https://uts.nlm.nih.gov//home.html .
SNOMED CT		SNOMED CT	2.16.840.1.113883.6.96	SNOMED CT http://www.nlm.nih.gov/research/umls/Snomed/snomed_main.html
Species		PHVS_Animal_CDC	2.16.840.1.114222.4.11.1074	PH Component: Animal Type based on SNOMED CT
Specimen Additives		SNOMED CT and/or HL70371		PH Component: Either HL70371 and/or SNOMED CT may be used. It should be noted that in the future a SNOMED CT subset may become the only recommended value set so trading partners should consider moving in that direction.

TABLE 4-2. VALUE SET/CODE SYSTEM SUMMARY				
Name	Value Set	Source	Unique Identifier	Comments
Specimen Collection Method		HL70488 and/or SNOMED CT procedure hierarchy		PH Component: Either HL7 Table 0488 and/or SNOMED CT Procedure (128927009) hierarchy may be used. A constrained SNOMED CT value set for this field is under development and may replace this in the future.
Specimen Source Site		SNOMED CT Anatomical Structure hierarchy (91723000)		PH Component
Specimen Source Site Modifier		SNOMED CT Topographical modifier hierarchy (106233006)		PH Component
Specimen Type		SNOMED CT and/or HL70487 PH Component: SNOMED CT Specimen hierarchy (12303009) and/or HL70487		Either HL70487 or SNOMED CT Specimen hierarchy 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. A cross mapping from HL7 table Hl7086 to SNOMED CT is available at PHIN-VADS (see resources in Appendix B below)
Specimen Type Modifier		SNOMED CT	2.16.840.1.113883.6.96	PH Component: A constrained SNOMED CT value set for this field is under development and may replace this in the future.

TABLE 4-2. VALUE SET/CODE SYSTEM SUMMARY				
Name	Value Set	Source	Unique Identifier	Comments
State Value Set	USPS	USPS		Identifies addresses within the United States are recorded using the USPS two-letter alphabetic codes for the State, District of Columbia, or an outlying area of the United States or associated area. See http://pe.usps.com/text/pub28/28apb.htm
Unified Code for Units of Measure (UCUM)		Regenstrief Institute, Inc.	2.16.840.1.113883.3.88.12.80.29	Units of measure concepts that includes atomic UCUM units as well as UCUM expression. Commonly used UCUM units of measure concepts can be obtained from UCUM Web Site http://www.regenstrief.org/medinformatics/ucum A tool for converting non-UCUM units of measure to the equivalent UCUM units is available at: http://www.regenstrief.org/medinformatics/ucum/unit-conversion-tool

4.7 Constrained HL7 Tables

This section provides values for only those HL7 tables that are constrained by this IG. HL7 tables in this guide are as specified in the HL7 Version 2.5.1 Standard, except as noted below.

- HL7 Table 0065-Specimen Action Code is pre-adopted from HL7 Version 2.7.1
- HL7 Table 0301-Universal ID Type is pre-adopted from HL7 Version 2.7.1
- HL7 Table 0507-Observation Result Handling is pre-adopted from HL7 Version 2.7.1

4.7.1.1 PH COMPONENT

- HL7 Table0396-Observation Type is pre-adopted from HL7 Version 2.8.1

4.7.2 HL7 TABLE 0065 – SPECIMEN ACTION CODE (V2.7.1)

TABLE 4-3. HL7 TABLE 0065 SPECIMEN ACTION CODE (V2.7.1)

Value	Description	Comment
A	Add ordered tests to the existing specimen	
G	Generated order; reflex order	
L	Lab to obtain specimen from patient	
O	Specimen obtained by service other than Lab	

4.7.3 HL7 TABLE 0076 – MESSAGE TYPE (V2.5.1)

TABLE 4-4. HL7 TABLE 0076 MESSAGE TYPE (V2.5.1)

Value	Description	Comment
ORU	Unsolicited transmission of an observation message	
ACK	General acknowledgment message	

4.7.4 HL7 TABLE 0085 - OBSERVATION RESULT STATUS (V2.8)

TABLE 4-5. HL7 TABLE 0085 - OBSERVATION RESULT STATUS (V2.8)

Value	Description	Comment
A	Some, but not all, results available	
C	Correction to results	
F	Final results; results stored and verified. Can only be changed with a corrected result.	
I	No results available; specimen received, procedure incomplete	
O	Order received; specimen not yet received	
P	Preliminary: A verified early result is available, final results not yet obtained	
R	Results stored; not yet verified	
S	No results available; procedure scheduled, but not done	
X	No results available; Order canceled.	

4.7.5 HL7 TABLE 0123 – RESULTS STATUS

TABLE 4-6. HL7 TABLE 0123 - RESULT STATUS

Value	Description	Comment

TABLE 4-6. HL7 TABLE 0123 – RESULT STATUS		
Value	Description	Comment
A	Some, but not, all results available	
C	Correction to results	
F	Final results; results stored and verified. Can only be changed with a corrected result.	
I	No results available; specimen received, procedure incomplete	
O	Order received; specimen not yet received	
P	Preliminary: A verified early result is available, final results not yet obtained	
R	Results stored; not yet verified	
S	No results available; procedure scheduled, but not done	
X	No results available; Order canceled.	

4.7.6 HL7 TABLE 0125 – VALUE TYPE (V2.5.1)

TABLE 4-7. HL7 TABLE 0125 – VALUE TYPE (V2.5.1)				
Value	Description	Usage	Data Type	Comment
CE	Coded Entry	R		When sending text data in OBX-5, use either the ST, TX or FT data types. PH Component: The Use of CE datatypes for coded results is discouraged in preference to CWE_CRO.
CWE	Coded with Exceptions	R	CWE_CRO	Data type to be used where it is important to communicate the coding system and coding system version with the coded result being reported. Pre-adopted from *Version 2.6.* This Implementation Guide has specially constrained versions of the CWE data type in Section 2.2 through 2.6. The CWE_CRO format shall be used for OBX-5. When sending text data in OBX-5, use either ST, TX or FT data types. PH Component: CWE_CRO.9 is expected to be the print text to comply with CLIA regulation of matching result statements between reports of record at both sender and receiver systems and can be the same as text in CWE.2.
CX	Extended Composite ID With Check Digit	O	CX-GU	

TABLE 4-7. HL7 TABLE 0125 – VALUE TYPE (V2.5.1)				
Value	Description	Usage	Data Type	Comment
DT	Date	R		
ED	Encapsulated Data	O		When using the Source Application ID component it should use the HD data type formatting considerations outlined in the base standard, not the constrained HD definitions in this IG.
FT	Formatted Text (Display)	R		Field using the FT data type to carry a text result value. This is intended for display. The text may contain formatting escape sequences as described in the data types section. Numeric results and numeric results with units of measure should not be reported as text. These should be reported as NM or SN numeric results, with the units of measure in OBX-6.
NM	Numeric	R		Field using the NM data type to carry a numeric result value. The only non-numeric characters allowed in this field are a leading plus (+) or minus (-) sign. The structured numeric (SN) data type should be used for conveying inequalities, ranges, ratios, etc. The units for the numeric value should be reported in OBX-6. PH Component: The units for the numeric value shall be reported in OBX-6
RP	Reference Pointer	O		When using the Application ID component it should use the HD data type formatting considerations outlined in the base standard, not the constrained HD definitions in this IG.
SN	Structured Numeric	R		Field using the SN data type to carry a structured numeric result value. Structured numeric include intervals (^0^-^1), ratios (^1^/^2 or ^1^:^2), inequalities (<^10), or categorical results (^2^+). The units for the structured numeric value should be reported in OBX-6. PH Component: The units for the numeric value shall be reported in OBX-6.
ST	String Data	R		Field using the ST data type to carry a short text result value. Numeric results and numeric results with units of measure should not be reported as text. These shall be reported as NM or SN numeric results, with the units of measure in OBX-6.
TM	Time	R		The time zone offset shall adhere to the use of the LRI_TO_COMPONENT profile.
TS	Time Stamp (Date & Time)	R	TS_0	The time zone offset shall adhere to the use of the LRI_TO_COMPONENT and associated discussion if the granularity involves HH or “more”.
TX	Text Data (Display)	R		Field using the TX data type to carry a text result value this is intended for display. Numeric results and numeric results with units of measure should not be reported as text. These should be reported as NM or SN numeric results, with the units of measure in OBX-6.

4.7.7 HL7 TABLE 0155 – ACCEPT/APPLICATION ACKNOWLEDGMENT CONDITION

(V2.5.1)

TABLE 4-8. HL7 TABLE 0155 - ACCEPT/APPLICATION ACKNOWLEDGMENT CONDITION (V2.5.1)

Value	Description	Usage	Comment
AL	Always	R	Constrained for MSH-15 use only
NE	Never	R	Constrained for MSH-16 use only

4.7.8 HL7 TABLE 0301 – UNIVERSAL ID TYPE (V2.7.1)

TABLE 4-9. HL7 TABLE 0301 - UNIVERSAL ID TYPE (V2.7.1)

Value	Description	Usage	Comments
CLIA	Clinical Laboratory Improvement Amendments. Allows for the ability to designate organization identifier as a "CLIA" assigned number (for labs)	RE	
DNS	An Internet dotted name. Either in ASCII or as integers	C(X/O)	Condition Predicate: If Component GU is used on the field using this value set
GUID	Same as UUID.	C(X/O)	Condition Predicate: If Component GU is used on the field using this value set
CEN	The CEN Healthcare Coding Scheme Designator. (Identifiers used in DICOM follow this assignment scheme.)	C(X/O)	Condition Predicate: If Component GU is used on the field using this value set
HL7	Reserved for future HL7 registration schemes	C(X/O)	Condition Predicate: If Component GU is used on the field using this value set
ISO	An International Standards Organization Object Identifier	R	Used as the Universal ID Type in the CNN, EI and HD data types.
L,M,N	These are reserved for locally defined coding schemes.	C(X/O)	Condition Predicate: If Component GU is used on the field using this value set
Random	Usually a base64 encoded string of random bits. The uniqueness depends on the length of the bits. Mail systems often generate ASCII string _unique names," from a combination of random bits and system names. Obviously, such identifiers will not be constrained to the base64 character set.	C(X/O)	Condition Predicate: If Component GU is used on the field using this value set
URI	Uniform Resource Identifier	R	Used as the Universal ID Type in the RP data type
UUID	The DCE Universal Unique Identifier	C(X/O)	Condition Predicate: If Component GU is used on the field using this value set

TABLE 4-9. HL7 TABLE 0301 - UNIVERSAL ID TYPE (V2.7.1)			
Value	Description	Usage	Comments
x400	An X.400 MSH format identifier	C(X/O)	Condition Predicate: If Component GU is used on the field using this value set
x500	An X.500 directory name	C(X/O)	Condition Predicate: If Component GU is used on the field using this value set

4.7.9 HL7 TABLE 0353 – CWE STATUS CODES

TABLE 4-10. HL7 TABLE 0353 - CWE STATUS CODES			
Value	Description	Usage	Comments
U	Unknown	R	
UASK	Asked but Unknown	R	
NAV	Not available	R	
NA	Not applicable	R	
NASK	Not asked	R	

Usage Note

This table is not constrained for this implementation guide. It is however constrained on where the table can be used. Table HL70353 can be used for coded values **except** for elements OBX-5 and SPM-4.

4.7.10 HL7 TABLE 0354 – MESSAGE STRUCTURE (V2.5.1)

TABLE 4-11. HL7 TABLE 0354 (V2.5.1)			
Value	Description	Usage	Comments
ORU_R01	Unsolicited transmission of an observation message	R	Required for Profiles: LRI_GU_RU_Profile
ACK	General Acknowledgment Message for unsolicited transmission of an observation message	R	Required for Profiles: LRI_Acknowledgement_Component GU_Acknowledgement_Component

4.7.11 HL7 TABLE 507 – OBSERVATION RESULT HANDLING (V2.7.1)

TABLE 4-12. HL7 TABLE 0507 - OBSERVATION RESULT HANDLING (V2.7.1)		
Value	Description	Comments

TABLE 4-12. HL7 TABLE 0507 - OBSERVATION RESULT HANDLING (V2.7.1)		
Value	Description	Comments
F	Film-with-patient	
N	Notify provider when ready	
A	Alert provider when abnormal	
CC	Copies Requested	
BCC	Blind Copy	

4.7.12 HL7 TABLE 0834 – MIME TYPE (V2.7.1)

TABLE 4-13. HL7 TABLE 0834 - MIME TYPE			
Value	Description	Usage	Comments
application	Application data	O	
audio	Audio data	O	
image	Image data	R	
model	Model data	O	
text	Text data	R	
video	Video data	O	
multipart	MIME multipart package	O	

4.7.13 HL7 TABLE 0916 – RELEVANT CLINICAL INFORMATION CODE

TABLE 4-14. HL7 TABLE 0916 - RELEVANT CLINICAL INFORMATION CODE		
Value	Description	Comment
F	Patient was fasting prior to the procedure	
N	The patient indicated they did not fast prior to the procedure	
NG	Not given - patient was asked at the time of the procedure	NOTE: This is the recommended description for this value.
FNA	Fasting not asked of the patient at time of procedure	

4.7.14 PH COMPONENT: HL7 TABLE 0936 – OBSERVATION TYPE

TABLE 4-15. PH COMPONENT: HL7 TABLE 0936 - OBSERVATION TYPE (V2.8.1)		
Value	Description	Comment
SCI	Supporting Clinical Information	Includes Ask at Order Entry (AOE) questions

TABLE 4-15. PH COMPONENT: HL7 TABLE 0936 - OBSERVATION TYPE (V2.8.1)		
Value	Description	Comment
RSLT	Result	

4.7.15 PH COMPONENT: ELR ORDINAL RESULTS VALUE SET (INFORMATIVE ONLY)

TABLE 4-16. PH COMPONENT: ELR ORDINAL RESULTS VALUE SET		
Value	Description	Comment
260347006	+	
260348001	++	
260349009	+++	
260350009	++++	
260373001	Detected	
263776006	Heavy growth	
7882003	Identified	
46651001	Isolated	
263812008	Moderate growth	
10828004	Positive	
260411009	Presence findings	
52101004	Present	
89292003	Rare	
11214006	Reactive	
260405006	Trace	
260408008	Weakly positive	
373066001	Yes	
272519000	Absence findings	
2667000	Absent	
281297005	Analyte not detected	
260385009	Negative	
373067005	No	
264868006	No growth	
27863008	No organisms seen	
131194007	Non-Reactive	
17621005	Normal	

TABLE 4-16. PH COMPONENT: ELR ORDINAL RESULTS VALUE SET		
Value	Description	Comment
23506009	Normal flora	
280413001	Normal result	
260415000	Not detected	
264887000	Not isolated	
47492008	Not seen	
42425007	Equivocal	
280414007	Equivocal result	
419984006	Inconclusive	
82334004	Indeterminate	
280416009	Indeterminate result	

5 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-elr-r2-testing.nist.gov/.

6 ADDITIONAL IMPLEMENTATION GUIDANCE – REFLEX AND CULTURE/SUSCEPTIBILITY TESTING

6.1 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.

6.1.1 PARENT/CHILD LINKING

This section presents a brief discussion on Parent/Child Linking.

6.1.1.1 HIGH LEVEL DESCRIPTION OF PARENT/CHILD LINKING

It must be understood that an observation can be the catalyst for additional tests, (reflex tests for example). 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).

6.1.1.2 RU AND GU PROFILE COMPONENT CONSIDERATIONS

The specific combination of RU and GU 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, only the RU and GU profile components used with the LRI_PH_Component are repeated here:

- GU - This profile component indicates the use of Globally Unique Identifiers through ISO OID as described in Section 1.11.1 Use of ISO Object Identifier (OID)
- RU - This profile component indicates that the test can be identified using the placer order number or using the filler order number. No additional information is necessary since either identifier on its own is unique.

6.1.1.3 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.

6.1.1.3.1 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 (OBX-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|…
```

6.1.1.3.2 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 v alue. (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 RU component profile, OBR-29 is sufficient to link the child OBR to the correct parent OBR.

Example: RU-GU Profile

Parent OBR

```
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||||||^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.
113883.19.3.1.2^ISO|997135^Antimicrobial
Susceptibility^99zzz|||20110614160000||||G|||||^Family^Fay||||||2011
0615102200|||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|…
```

Things to **Note:**

- The RU profile requires that each OBR be uniquely identified by OBR-2/OBR-3, which means that these identifiers must be different in each OBR segment in the message.
- 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.
- 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.

6.1.1.3.3 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.

6.2 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.

6.2.1 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).

6.2.2 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 | Filler number | Identifier code for the requested
    test or panel of tests(OBR-4) |…

TQ1|…

OBX|1|CE| Specific organism identifier (OBX-3) | Sub-id for the first
    organism (OBX-4) | Description of organism (OBX-5) |…

OBX|2|SN| Other identifier (OBX-3) | Sub-id for the first organism (OBX-
    4) | Observation on the organism (OBX-5) |…

OBX|3|CE| Specific organism identifier (OBX-3) | Sub-id for the second
```

```
    organism (OBX-4) | Description of organism (OBX-5) |…

OBX|4|SN| Other identifier (OBX-3) | Sub-id for the second organism
    (OBX-4) | Observation on the Organism (OBX-5) |…

OBX|5|CE| Specific organism identifier (OBX-3) | Sub-id for the third
    organism (OBX-4) | Description of organism (OBX-5) |…

OBX|6|SN| Other identifier (OBX-3) | Sub-id for the third organism (OBX-
    4) | Observation on the organism (OBX-5) |…

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.

6.2.3 EXAMPLES OF CULTURE RESULTS

In this example, Reliable Labs, Inc. is sending preliminary results of a stool. Three pathogens have been identified: Campylobacter jejuni, Salmonella and Shigella.

This example shows the use of the Sub-ID in OBX-4 to connect related observations. The Sub-ID is shown in bolded letters and highlighted in green, as presented in the previous template. In this example, numbers are used for the Sub-ID. However, a text identifier such as "isolate1" could be used. The HL7 standard has defined the Sub-ID (*e.g.*, OBX-4) as a "string" data type. Thus, it can be either a number or text.

In this example, the information about colony counts in OBX segments with Set IDs 2, 4, and 6 is provided to show how the Sub-ID is used to relate the associated OBX segments to each other (*e.g.*, 1 and 2, 3 and 4, 5 and 6). Some laboratories may not have this additional information and would therefore transmit only the identification of the organisms (*e.g.*, OBX segments 1, 3 and 5).

Whenever possible, identified organisms should be reported as coded data instead of text data Coded data enables machine processing of results. String data can normally be interpreted only by humans.

Example

Note that the use of OBX-4 Sub-ID is independent of the component profile combination. This particular example uses the RU-GU profile combination.

```
MSH|^~\&|^2.16.840.1.113883.3.72.5.20^ISO|^2.16.840.1.113883.3.72.5.21^I
    SO||^2.16.840.1.113883.3.72.5.23^ISO|20110531140551-
    0500||ORU^R01^ORU_R01|NIST-LRI-GU-
    004.00|T|2.5.1|||AL|NE|||||LRI_Common_Component^^2.16.840.1.113883.9
    .16^ISO~LRI_GU_Component^^2.16.840.1.113883.9.12^ISO~LAB_RU_Componen
    t^^2.16.840.1.113883.9.14^ISO

PID|1||PATID1234^^^&2.16.840.1.113883.3.72.5.30.2&ISO^MR||Everyman^Adam|
    |19610615|M||2106-3^White^HL70005

ORC|RE|ORD723222-4^^2.16.840.1.113883.3.72.5.24^ISO|R-783274-
    4^^2.16.840.1.113883.3.72.5.25^ISO|GORD874211^^2.16.840.1.113883.3.7
    2.5.24^ISO||||||||57422^Family^Fay^^^^^^&2.16.840.1.113883.3.72.5.30
    .1&ISO^L^^^NPI

OBR|1|ORD723222-4^^2.16.840.1.113883.3.72.5.24^ISO|R-783274-
    4^^2.16.840.1.113883.3.72.5.25^ISO|625-4^Bacteria
    identified^LN^3456543^CULTURE STOOL^99USI^^^Bacteria
    identified|||20110530123551-
    0500|||||787.91^DIARRHEA^I9CDX^^^^^^Changeable
    Data|||57422^Family^Fay^^^^^^&2.16.840.1.113883.3.72.5.30.1&ISO^L^^^
    NPI||||||20110531140428-
    0500|||P|||10092^Osler^Otto^^^^^^&2.16.840.1.113883.3.72.5.30.1&ISO

OBX|1|CWE|625-4^Bacteria identified^LN^^^^^^Bacteria
    identified|1|66543000^Campylobacter jejuni^SCT^^^^^^Campylobacter
    jejuni||||||P|||20110530123551-0500|||||20110531130655-0500||||Good
    Health Hospital^^^^^&2.16.840.1.113883.3.72.5.30.1&ISO^XX^^^987|1000
    Hospital Lane^^Ann
    Arbor^MI^99999^^B|9876543^Slide^Stan^S^^^^^&2.16.840.1.113883.3.72.5
    .30.1&ISO^L^^^NPI

OBX|2|SN|564-5^COLONY COUNT^LN^^^^^^COLONY COUNT|1|^10000^-
    ^90000|1^^UCUM|||||P|||20110530123551-0500|||||20110531130655-
    0500||||Good Health
    Hospital^^^^^&2.16.840.1.113883.3.72.5.30.1&ISO^XX^^^987|1000
    Hospital Lane^^Ann
    Arbor^MI^99999^^B|9876543^Slide^Stan^S^^^^^&2.16.840.1.113883.3.72.5
    .30.1&ISO^L^^^NPI
```

```
OBX|3|CWE|625-4^Bacteria identified^LN^^^^^^Bacteria
    identified|2|302620005^Salmonella group B phase 1 a-
    e^SCT^^^^^^Salmonella group B phase 1 a-e||||||P|||20110530123551-
    0500||||20110531130655-0500||||Good Health
    Hospital^^^^^&2.16.840.1.113883.3.72.5.30.1&ISO^XX^^^987|1000
    Hospital Lane^^Ann
    Arbor^MI^99999^^B|9876543^Slide^Stan^S^^^^^&2.16.840.1.113883.3.72.5
    .30.1&ISO^L^^^NPI

OBX|4 SN|564-5^COLONY COUNT^LN^^^^^^COLONY
    COUNT|2|>^100000|1^^UCUM|||||P|||20110530123551-
    0500||||20110531130655-0500||||Good Health
    Hospital^^^^^&2.16.840.1.113883.3.72.5.30.1&ISO^XX^^^987|1000
    Hospital Lane^^Ann
    Arbor^MI^99999^^B|9876543^Slide^Stan^S^^^^^&2.16.840.1.113883.3.72.5
    .30.1&ISO^L^^^NPI

OBX|5|CWE|625-4^Bacteria identified^LN^^^^^^Bacteria
    identified|3|77352002^Shigella^SCT^^^^^^Shigella||||||P|||2011053012
    3551-0500||||20110531130655-0500||||Good Health
    Hospital^^^^^&2.16.840.1.113883.3.72.5.30.1&ISO^XX^^^987|1000
    Hospital Lane^^Ann
    Arbor^MI^99999^^B|9876543^Slide^Stan^S^^^^^&2.16.840.1.113883.3.72.5
    .30.1&ISO^L^^^NPI

OBX|6|SN|564-5^COLONY COUNT^LN^^^^^^COLONY
    COUNT|3|<^1000|1^^UCUM|||||P|||20110530123551-
    0500||||20110531130655-0500||||Good Health
    Hospital^^^^^&2.16.840.1.113883.3.72.5.30.1&ISO^XX^^^987|1000
    Hospital Lane^^Ann
    Arbor^MI^99999^^B|9876543^Slide^Stan^S^^^^^&2.16.840.1.113883.3.72.5
    .30.1&ISO^L^^^NPI

SPM|1|||119339001^Stool
    specimen^SCT^^^^^^Stool||||||||||||20110530123551-0500
```

6.2.4 TEMPLATE FOR CULTURE AND SUSCEPTIBILITY RESULTS

The template and example in Section 6.2.3 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 *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 in each of the OBR child segments there is a pointer back to the parent result. This pointer is found in OBR-26 (Parent Result) and in OBR-29 (Parent Number).

Example

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

MSH|…

PID|…

ORC|…

Parent OBR Segment

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

TQ1|…

Parent OBX Segments for First Organism Identified

OBX|1|CE| Specific organism identifier (OBX-3) | Sub-id for the first
    organism (OBX-4) | Description of organism (OBX-5) |…

OBX|2|SN| Other identifier (OBX-3) | Sub-id for the first organism (OBX-
    4) | Observation on the organism (OBX-5) |…

Parent OBX Segments for Second Organism Identified

OBX|3|CE| Specific organism identifier (OBX-3) | Sub-id for the second
    organism (OBX-4) | Description of organism (OBX-5) |…

OBX|4|SN| Other identifier (OBX-3) | Sub-id for the second organism
    (OBX-4) | Observation on the Organism (OBX-5) |…

Parent OBX Segments for Third Organism Identified

OBX|5|CE| Specific organism identifier (OBX-3) | Sub-id for the third
    organism (OBX-4) | Description of organism (OBX-5) |…

OBX|6|SN| Other identifier (OBX-3) | Sub-id for the third organism (OBX-
    4) | Observation on the organism (OBX-5) |…
```

SPM Segment

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

Child OBR for First Organism identified

ORC|…

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 |||||||||||||| **A pointer back to the parent OBX segment that contained the identification of the first organism, see below for description of "Pointers" (OBR-26)** ||| **Parent order number (OBR-29)** ||||||||||||||||||||...

Child OBX Segments for Susceptibilities of First Organism Identified

OBX|1|CE|Specific susceptibility identifier for first antimicrobial (OBX-3) || Susceptibility finding (OBX-5) ||| Susceptibility interpretation (OBX-8) |…

OBX|2|CE|Specific susceptibility identifier for second antimicrobial (OBX-3) || Susceptibility finding (OBX-5) ||| Susceptibility interpretation (OBX-8) |…

OBX|3|CE|Specific susceptibility identifier for third antimicrobial (OBX-3) || Susceptibility finding (OBX-5) ||| Susceptibility interpretation (OBX-8) |…

Child OBR Segment for Susceptibilities of Second Organism Identified

ORC|…

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 |||||||||||||| **A pointer back to the parent OBX segment that contained the identification of the second organism, see below for description of "Pointers" (OBR-26)** ||| **Parent order number (OBR-29)** ||||||||||||||||||||...

Child OBX Segments for Susceptibilities of Second Organism Identified

OBX|1|CE|Specific susceptibility identifier for first antimicrobial (OBX-3) || Susceptibility finding (OBX-5) ||| Susceptibility interpretation (OBX-8) |…

OBX|2|CE|Specific susceptibility identifier for second antimicrobial


```
    (OBX-3) || Susceptibility finding (OBX-5) ||| Susceptibility
    interpretation (OBX-8) |…

OBX|3|CE|Specific susceptibility identifier for third antimicrobial
    (OBX-3) || Susceptibility finding (OBX-5) ||| Susceptibility
    interpretation (OBX-8) |…
```

Child OBR Segment for Susceptibilities of Third Organism Identified

```
ORC|…

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 |||||||||||||| A pointer back to the parent
    OBX segment that contained the identification of the third organism,
    see below for description of "Pointers" (OBR-26) ||| Parent order
    number (OBR-29)|...
```

Child OBX Segments for Susceptibilities of Third Organism Identified

```
OBX|1|CE|Specific susceptibility identifier for first antimicrobial
    (OBX-3) || Susceptibility finding (OBX-5) ||| Susceptibility
    interpretation (OBX-8) |…

OBX|2|CE|Specific susceptibility identifier for second antimicrobial
    (OBX-3) || Susceptibility finding (OBX-5) ||| Susceptibility
    interpretation (OBX-8) |…

OBX|3|CE|Specific susceptibility identifier for third antimicrobial
    (OBX-3) || Susceptibility finding (OBX-5) ||| Susceptibility
    interpretation (OBX-8) |…
```

6.2.5 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 RU-GU profile combination. Fields bolded and highlighted in **green** are used for linking parent and child results as identified in the template above.

6.2.5.1 EXAMPLE RU-GU PROFILE COMBINATION

In the RU-GU profile combination the order number alone is sufficient to uniquely identify the parent OBR-In this profile combination, OIDs are used to scope the various identifiers (including placer and filler order numbers).

Example

```
MSH|^~\&|^2.16.840.1.113883.3.72.5.20^ISO|^2.16.840.1.113883.3.72.5.21^I
    SO||^2.16.840.1.113883.3.72.5.23^ISO|20110531140551-
    0500||ORU^R01^ORU_R01|NIST-LRI-GU-RU-
    004.01|T|2.5.1|||AL|NE|||||LRI_Common_Component^^2.16.840.1.113883.9
    .16^ISO~LRI_GU_Component^^2.16.840.1.113883.9.12^ISO~LAB_RU_Componen
    t^^2.16.840.1.113883.9.14^ISO

PID|1||PATID1234^^^&2.16.840.1.113883.3.72.5.30.2&ISO^MR||Everyman^Adam|
    |19610615|M||2106-3^White^HL70005

ORC|RE|ORD723222-4^^2.16.840.1.113883.3.72.5.24^ISO|R-783274-
    4^^2.16.840.1.113883.3.72.5.25^ISO|GORD874211^^2.16.840.1.113883.3.7
    2.5.24^ISO|||||||57422^Family^Fay^^^^^^&2.16.840.1.113883.3.72.5.30
    .1&ISO^L^^^NPI

OBR|1|ORD723222-4^^2.16.840.1.113883.3.72.5.24^ISO|R-783274-
    4^^2.16.840.1.113883.3.72.5.25^ISO|625-4^Bacteria
    identified^LN^3456543^CULTURE STOOL^99USI^^^Bacteria
    identified|||20110530123551-
    0500|||||787.91^DIARRHEA^I9CDX^^^^^^Changeable
    Data|||57422^Family^Fay^^^^^^&2.16.840.1.113883.3.72.5.30.1&ISO^L^^^
    NPI||||||20110531140428-
    0500|||F|||10092^Osler^Otto^^^^^^&2.16.840.1.113883.3.72.5.30.1&ISO

OBX|1|CWE|625-4^Bacteria identified^LN^^^^^^Bacteria
    identified|1|66543000^Campylobacter jejuni^SCT^^^^^^Campylobacter
    jejuni||||||F|||20110530123551-0500|||||20110531130655-0500||||Good
    Health Hospital^^^^^&2.16.840.1.113883.3.72.5.30.1&ISO^XX^^^987|1000
    Hospital Lane^^Ann
    Arbor^MI^99999^^B|9876543^Slide^Stan^S^^^^^&2.16.840.1.113883.3.72.5
    .30.1&ISO^L^^^NPI

OBX|2|SN|564-5^COLONY COUNT^LN^^^^^^COLONY COUNT|1|^10000^-
    ^90000|1^^UCUM|||||F|||20110530123551-0500|||||20110531130655-
    0500||||Good Health
    Hospital^^^^^&2.16.840.1.113883.3.72.5.30.1&ISO^XX^^^987|1000
    Hospital Lane^^Ann
```

```
    Arbor^MI^99999^^B|9876543^Slide^Stan^S^^^^^&2.16.840.1.113883.3.72.5
    .30.1&ISO^L^^^NPI

OBX|3|CWE|625-4^Bacteria identified^LN^^^^^^Bacteria
    identified|2|302620005^Salmonella group B phase 1 a-
    e^SCT^^^^^^Salmonella group B phase 1 a-e||||||F|||20110530123551-
    0500||||20110531130655-0500||||Good Health
    Hospital^^^^^&2.16.840.1.113883.3.72.5.30.1&ISO^XX^^^987|1000
    Hospital Lane^^Ann
    Arbor^MI^99999^^B|9876543^Slide^Stan^S^^^^^&2.16.840.1.113883.3.72.5
    .30.1&ISO^L^^^NPI

OBX|4|SN|564-5^COLONY COUNT^LN^^^^^^COLONY
    COUNT|2|>^100000|1^^UCUM|||||F|||20110530123551-
    0500||||20110531130655-0500||||Good Health
    Hospital^^^^^&2.16.840.1.113883.3.72.5.30.1&ISO^XX^^^987|1000
    Hospital Lane^^Ann
    Arbor^MI^99999^^B|9876543^Slide^Stan^S^^^^^&2.16.840.1.113883.3.72.5
    .30.1&ISO^L^^^NPI

OBX|5|CWE|625-4^Bacteria identified^LN^^^^^^Bacteria
    identified|3|77352002^Shigella^SCT^^^^^^Shigella||||||F|||2011053012
    3551-0500||||20110531130655-0500||||Good Health
    Hospital^^^^^&2.16.840.1.113883.3.72.5.30.1&ISO^XX^^^987|1000
    Hospital Lane^^Ann
    Arbor^MI^99999^^B|9876543^Slide^Stan^S^^^^^&2.16.840.1.113883.3.72.5
    .30.1&ISO^L^^^NPI

OBX|6|SN|564-5^COLONY COUNT^LN^^^^^^COLONY
    COUNT|3|<^1000|1^^UCUM|||||F|||20110530123551-
    0500||||20110531130655-0500||||Good Health
    Hospital^^^^^&2.16.840.1.113883.3.72.5.30.1&ISO^XX^^^987|1000
    Hospital Lane^^Ann
    Arbor^MI^99999^^B|9876543^Slide^Stan^S^^^^^&2.16.840.1.113883.3.72.5
    .30.1&ISO^L^^^NPI

SPM|1|||119339001^Stool
    specimen^SCT^^^^^^Stool||||||||||||20110530123551-0500

ORC|RE||R-783274-
    5^^2.16.840.1.113883.3.72.5.25^ISO|GORD874211^^2.16.840.1.113883.3.7
    2.5.24^ISO|||||||57422^Family^Fay^^^^^^&2.16.840.1.113883.3.72.5.30
    .1&ISO^L^^^NPI

OBR|2||R-783274-5^^2.16.840.1.113883.3.72.5.25^ISO|50545-3^Bacteria
```

```
    susceptibility^LN^^^^^^Bacteria susceptibility|||20110530123551-
    0500||||G|||||57422^Family^Fay^^^^^^&2.16.840.1.113883.3.72.5.30.1&I
    SO^L^^^NPI||||||20110531140428-0500|||F|625-4&Bacteria
    identfied&LN&&&&&&Bacteria
    identfied^1||10092^Osler^Otto^^^^^^&2.16.840.1.113883.3.72.5.30.1&IS
    O|ORD723222-4&&2.16.840.1.113883.3.72.5.24&ISO^R-783274-
    4&&2.16.840.1.113883.3.72.5.25&ISO

OBX|1|SN|6979-
    9^AMPICILLIN^LN^^^^^^AMPICILLIN|1|<^0.06|ug/mL^^UCUM||S|||F|||201105
    30123551-0500|||||20110531130655-0500||||Good Health
    Hospital^^^^^&2.16.840.1.113883.3.72.5.30.1&ISO^XX^^^987|1000
    Hospital Lane^^Ann
    Arbor^MI^99999^^B|9876543^Slide^Stan^S^^^^^&2.16.840.1.113883.3.72.5
    .30.1&ISO^L^^^NPI

OBX|2|SN|7016-
    9^GENTAMICIN^LN^^^^^^GENTAMICIN|1|^0.05|ug/mL^^UCUM||S|||F|||2011053
    0123551-0500|||||20110531130655-0500||||Good Health
    Hospital^^^^^&2.16.840.1.113883.3.72.5.30.1&ISO^XX^^^987|1000
    Hospital Lane^^Ann
    Arbor^MI^99999^^B|9876543^Slide^Stan^S^^^^^&2.16.840.1.113883.3.72.5
    .30.1&ISO^L^^^NPI

OBX|3|SN|7002-
    9^CIPROFLOXACIN^LN^^^^^^CIPROFLOXACIN|1|^0.05|ug/mL^^UCUM||S|||F|||2
    0110530123551-0500|||||20110531130655-0500||||Good Health
    Hospital^^^^^&2.16.840.1.113883.3.72.5.30.1&ISO^XX^^^987|1000
    Hospital Lane^^Ann
    Arbor^MI^99999^^B|9876543^Slide^Stan^S^^^^^&2.16.840.1.113883.3.72.5
    .30.1&ISO^L^^^NPI

ORC|RE||R-783274-
    6^^2.16.840.1.113883.3.72.5.25^ISO|GORD874211^^2.16.840.1.113883.3.7
    2.5.24^ISO|||||||57422^Family^Fay^^^^^^&2.16.840.1.113883.3.72.5.30
    .1&ISO^L^^^NPI

OBR|3||R-783274-6^^2.16.840.1.113883.3.72.5.25^ISO|50545-3^Bacteria
    susceptibility^LN^^^^^^Bacteria susceptibility|||20110530123551-
    0500||||G|||||57422^Family^Fay^^^^^^&2.16.840.1.113883.3.72.5.30.1&I
    SO^L^^^NPI||||||20110531140428-0500|||F|625-4&Bacteria
    identfied&LN&&&&&&Bacteria
    identfied^2||10092^Osler^Otto^^^^^^&2.16.840.1.113883.3.72.5.30.1&IS
    O|ORD723222-4&&2.16.840.1.113883.3.72.5.24&ISO^R-783274-
```



```
     4&&2.16.840.1.113883.3.72.5.25&ISO

OBX|1|SN|6979-
     9^AMPICILLIN^LN^^^^^^AMPICILLIN|1|<^0.06|ug/mL^^UCUM||S|||F|||201105
     30123551-0500|||||20110531130655-0500||||Good Health
     Hospital^^^^^&2.16.840.1.113883.3.72.5.30.1&ISO^XX^^^987|1000
     Hospital Lane^^Ann
     Arbor^MI^99999^^B|9876543^Slide^Stan^S^^^^^&2.16.840.1.113883.3.72.5
     .30.1&ISO^L^^^NPI

OBX|2|SN|7016-
     9^GENTAMICIN^LN^^^^^^GENTAMICIN|1|^0.05|ug/mL^^UCUM||S|||F|||2011053
     0123551-0500|||||20110531130655-0500||||Good Health
     Hospital^^^^^&2.16.840.1.113883.3.72.5.30.1&ISO^XX^^^987|1000
     Hospital Lane^^Ann
     Arbor^MI^99999^^B|9876543^Slide^Stan^S^^^^^&2.16.840.1.113883.3.72.5
     .30.1&ISO^L^^^NPI

OBX|3|SN|7002-
     9^CIPROFLOXACIN^LN^^^^^^CIPROFLOXACIN|1|^0.05|ug/mL^^UCUM||S|||F|||2
     0110530123551-0500|||||20110531130655-0500||||Good Health
     Hospital^^^^^&2.16.840.1.113883.3.72.5.30.1&ISO^XX^^^987|1000
     Hospital Lane^^Ann
     Arbor^MI^99999^^B|9876543^Slide^Stan^S^^^^^&2.16.840.1.113883.3.72.5
     .30.1&ISO^L^^^NPI

ORC|RE||R-783274-
     7^^2.16.840.1.113883.3.72.5.25^ISO|GORD874211^^2.16.840.1.113883.3.7
     2.5.24^ISO|||||||57422^Family^Fay^^^^^^&2.16.840.1.113883.3.72.5.30
     .1&ISO^L^^^NPI

OBR|4||R-783274-7^^2.16.840.1.113883.3.72.5.25^ISO|50545-3^Bacteria
     susceptibility^LN^^^^^^Bacteria susceptibility|||20110530123551-
     0500|||G|||||57422^Family^Fay^^^^^^&2.16.840.1.113883.3.72.5.30.1&I
     SO^L^^^NPI||||||20110531140428-0500|||F|625-4&Bacteria
     identfied&LN&&&&&&Bacteria
     identfied^3||10092^Osler^Otto^^^^^^&2.16.840.1.113883.3.72.5.30.1&IS
     O|ORD723222-4&&2.16.840.1.113883.3.72.5.24&ISO^R-783274-
     4&&2.16.840.1.113883.3.72.5.25&ISO

OBX|1|SN|6979-
     9^AMPICILLIN^LN^^^^^^AMPICILLIN|1|<^0.06|ug/mL^^UCUM||S|||F|||201105
     30123551-0500|||||20110531130655-0500||||Good Health
     Hospital^^^^^&2.16.840.1.113883.3.72.5.30.1&ISO^XX^^^987|1000
     Hospital Lane^^Ann
```



```
    Arbor^MI^99999^^B|9876543^Slide^Stan^S^^^^^&2.16.840.1.113883.3.72.5
    .30.1&ISO^L^^^NPI

OBX|2|SN|7016-
    9^GENTAMICIN^LN^^^^^^GENTAMICIN|1|^0.05|ug/mL^^UCUM||S|||F|||2011053
    0123551-0500||||20110531130655-0500|||Good Health
    Hospital^^^^^&2.16.840.1.113883.3.72.5.30.1&ISO^XX^^^987|1000
    Hospital Lane^^Ann
    Arbor^MI^99999^^B|9876543^Slide^Stan^S^^^^^&2.16.840.1.113883.3.72.5
    .30.1&ISO^L^^^NPI

OBX|3|SN|7002-
    9^CIPROFLOXACIN^LN^^^^^^CIPROFLOXACIN|1|^0.05|ug/mL^^UCUM||S|||F|||2
    0110530123551-0500||||20110531130655-0500|||Good Health
    Hospital^^^^^&2.16.840.1.113883.3.72.5.30.1&ISO^XX^^^987|1000
    Hospital Lane^^Ann
    Arbor^MI^99999^^B|9876543^Slide^Stan^S^^^^^&2.16.840.1.113883.3.72.5
    .30.1&ISO^L^^^NPI
```

6.3 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.

6.4 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 reflexed test as one of the following:
  - one or more additional OBR/OBX(s) or
  - a new accession.

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 both methods of reporting a reflexed test (see above) and associate it with the original test request for the specimen

7 ADDITIONAL IMPLEMENTATION GUIDANCE – OTHER

7.1 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://wwwn.cdc.gov/clia/regs/toc.aspx.

7.1.1 MANDATORY REPORTING REQUIREMENTS

Section 493.1291 of the CLIA Regulations defines items that must appear on a clinical laboratory report (http://wwwn.cdc.gov/clia/regs/subpart_k.aspx493.1291). Interpretative Guidelines on the elements required in a report may be found at http://www.cms.hhs.gov/CLIA/downloads/apcsubk2.pdf. Specific report fields impacted include the following:

TABLE 7-1. MANDATORY REPORTING REQUIREMENTS

Segment	Field	CLIA Impact
PID-3	Patient Identifier List	A unique patient identification number is required
PID-5	Patient Name	Positive patient identification required. If the patient's name is known, this must be that name. If it is not known, a unique patient identifier must be assigned.
OBX-3	Observation Identifier[12]	Unique identification of the test performed is required. See Section 4.1 LOINC for vocabulary use. Use of LOINC codes for additional tests is strongly encouraged. See 4.1 for more details. 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

[12] While CLIA requires a laboratory to maintain positive identification of a specimen reporting, that information as part of the result is not required.

TABLE 7-1. MANDATORY REPORTING REQUIREMENTS		
Segment	Field	CLIA Impact
		sale, distribution and use of analyte -specific reagents."
OBX-5	Observation Value	The laboratory result is required. No regulatory requirements are specified, outside of readability, regarding result appearance.
OBX-6	Units	Units, if required, or an interpretation must be given. For tests such as genetic screens the interpretation may actually be the test result. See Section 4.5 UCUM for vocabulary use.
OBX-7	Reference Range	When available reference range shall be valued.
OBX-8	Abnormal Flag	A laboratory may use this field as part of its interpretation guidance. If reported, it should be displayed by an EHR. See Section 4.7.4 HL7 Table 0078 – Interpretation Codes for vocabulary use.
OBX-11	Observation Result Status	Used to reflect CLIA required conditions such as specimen acceptability, result corrections, cancellations as well as report status (§493.1291 (c)(7) and (k)(1,2). See SPM-21 and -24 below.
OBX-19	Date/Time of Analysis	This field is used to transfer the time stamp associated with generation of the analytical result by the instrument specified in Equipment Instance Identifier.
OBX-23, 24, 25	Laboratory Identification Fields	The identification of the performing laboratory is required. Populating with the CLIA ID Number in OBX-23 meets the requirement if this receiving EHR-S has access to a look-up table that will convert the CLIA ID number to full demographics comprising OBX-23,Performing Organization Name; OBX-24, Performing Organization Address; and OBX-25, Performing Organization Medical Director. If the CLIA ID number is not used, all demographic fields (OBX-23, OBX-24 and OBX-25) must be populated with appropriate information.
SPM-4	Specimen Type	Reporting requirements call for the specimen source, which equates at minimum to the Specimen Type in the SPM segment. See Section 3.5 SPM – Specimen Segment for vocabulary use.
SPM-21	Specimen Reject Reason	Use this field in connection with OBX-11 if a test is cancelled for specimen related reason. (Future may be RE for Sender, see SPM-21)
SPM-24	Specimen Condition	Use this field in combination with SPM-21 to further specify the reason for specimen rejection. (Future may be RE for Sender, see SPM-24)

7.1.2 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.

7.1.3 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.

7.2 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

7.2.1 QUANTITATIVE

- 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.
- 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 semi-quantitative 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 ++++.

7.2.2 QUALITATIVE

1) 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.
2) 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 semi-quantitative tests;
NOTE 3: Specific identification may be performed.

7.2.3 SEMI-QUANTITATIVE

1) A test that has a dose-response gradient that may be included in the reported result, but for which no authorative 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.
2) Tests that yield results in an approximate range of values (e.g., trace, moderate).

8 PH COMPONENT: ADDITIONAL IMPLEMENTATION GUIDANCE FOR PUBLIC HEALTH REPORTING

8.1 PH Component: Epidemiological important information from Ask at Order Entry responses

There are several common data elements that have been identified as important data elements for Public Health laboratory reporting that do not have a supported field in the ELR251 message. This data may be available in the ELR Sender system as Ask at Order Entry (AOE) responses for a particular test order. See the Section 2.6.5 of the *HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Orders from EHR, Release 1 – US Realm* for further discussion of AOE observations and how they relate to ordering.

For this profile, appropriate AOE answers should be sent along to the local public health jurisdiction as an observation in an OBX segment under the respective Order_ Observation group (ORC/OBR segment pair). In addition, OBX-29 (Observation Type) should be valued "AOE" to flag this as an AOE answer rather than an actual result. A table of example AOE questions is provided in Appendix B in the *HL7 Version 2.5.1 Implementation Guide: Laboratory Test Compendium Framework, Release 2, US Realm, November 2013 (eDOS)*.

The following Testing scenario gives context for the example ELR message below (The ellipses represent omitted details)

A clinician orders a Hepatitis B Virus Surface antigen test. As part of the submission, she must answer a question (an AOE) about female patient's pregnancy status. The patient is pregnant and this information is entered into the electronic order. The results of the test are positive which triggers an ELR message to be sent to the local public health jurisdiction. If asked by the laboratory as an AOE, the answer regarding pregnancy status is sent along with the laboratory reportable result.

```
MSH...

…

OBX|1|CWE|5195-3^Hepatitis B virus surface Ag [Presence] in
Serum^LN...|1|11214006^Reactive^SCT...|F|

OBX|2|CWE|11449-6^Pregnancy status^LN...|| 77386006^Patient currently
pregnant^SCT…|AOE Code|

…
```

8.2 PH Component: Reference test results

There may be occasions when the sending laboratory (Filler) needs to transmit and ELR message for reportable results that did not originate from their facility. Examples include when the specimen is forwarded by the Filler

to a reference lab or to another lab as a “pass-through” test. The criterion for reporting results that did not originate with the sender is subject to the discretion of the local public health jurisdiction.

The laboratory where the reportable laboratory results originated from must be identified in OBX-23 (Performing Organization Name) and OBX-24 (Performing Organization Address). Additionally, if populated, OBX-25 (Performing Organization Medical Director) must be the name associated with the same laboratory listed in OBX-23 and OBX-24.

The following Testing scenario gives context for the example ELR message below (The ellipses represent omitted details)**:**

A Clinician submits a stool sample the Filler lab for an enteric culture. The Filler lab performs the necessary culture, isolates Salmonella, and forwards the isolate and original sample to their state public health lab for confirmation and serotyping. The state public health sends a report back the Filler lab identifying Salmonella typhimurium. The Filler lab sends an ELR message to their local health jurisdiction with both their findings and the state lab’s findings.

```
MSH…
…
OBR|1…
OBX|1|CWE|625-4^Bacteria identified in Stool by Culture^LN…||
27268008^Salmonella^SCT...|…|Filler Lab Name^…|123 Filler Lab
Street^…|Director^Filler^L^^Dr.…
OBX|2|CWE|20951-0^Salmonella sp serotype [Identifier] in Isolate by
Agglutination…||50136005^Salmonella Typhimurium^SCT...|…|State Lab
Name^…|123 State Lab Street^…|Director^State^L^^Dr.….
...
```

Usage note

Specimen sent for further testing

The Sender may want to report to the jurisdiction the fact that they are sending a sample for further testing to a reference lab. The following SNOMED result code may be used as a coded observation:

```
415564008^Specimen sent to reference laboratory for testing
```

8.3 PH Component: How to populate CWE datatype flavors

8.3.1 CWE_CRE

If you have both a standard and a local code you should populate both coding triplets to help with identification of coding issues. When populating this field with values, this guide does not give preference to the triplet in which the standard code should appear.

Example for SPM-4 (Specimen type):

```
SPM|1|…|| |258450006^Cerebrospinal fluid sample^SCT^CSF^Cerebrospinal
Fluid^L^07/31/2012||…
```

If you have a local code but no valid standard code exists then populate then the first triplet must be populated with the local code.

Example for SPM-4 (Specimen type):

```
SPM|1|…||SS^Some Specimen^L…|…
```

The sender may have an un-coded (text only) element or a free text entry. If neither a valid standard nor a local code exists then **CWE_CRE.9 (Original text)** must be populated with the local text.

Example for SPM-4 (Specimen type):

```
SPM|1|…||^^^^^^^^Some Specimen|…
```

8.3.2 CWE_CR

If you have both a standard and a local code you should populate both coding triplets to help with identification of coding issues. When populating this field with values, this guide does not give preference to the triplet in which the standard code should appear.

Example for OBX-3 (Observation Identifier)

```
OBX|1|…|43305-2^Neisseria gonorrhoeae rRNA [Presence] in
   Unspecified specimen by Probe and target amplification
   method^LN^2334^APTIMA GC^L^2.44|||…
```

If you have a local order code but no valid LOINC exists then the first triplet must be populated with the local code.

Example for OBX-3 (Observation Identifier)

```
OBX|1|…|123^Reportable test name^L…|||…
```

8.3.3 CWE_RO FOR CODED RESULTS IN OBX.5:

For OBX.5 CWE data type, the first triplet and original text field (CWE.1, CWE.3 and CWE.9 =R) must be populated. CWE_CRO.9 is expected to be the print text to comply with CLIA regulation of matching result statements between reports of record at both sender and receiver systems and can be the same as text in CWE.2.

If you have both a standard and a local code you should populate both coding triplets to help with identification of coding issues. When populating this field with values, this guide does not give preference to the triplet in which the standard code should appear.

Example for OBX-5 (Observation Value)

```
OBX|1|CWE|…|10828004^Positive^SCT^POS^Positive^L^07/31/2012^^Positive|
…
```

When a standard SNOMED CT concept ID is not available, the local code must populate the first triplet, the original text field must also be populated.

Example for OBX-5 (Observation Value):

```
OBX|1|CWE|20951-0^Salmonella sp serotype [Identifier] in Isolate by
Agglutination^LN…||167^Salmonella subspecies
I:Rough:i:1,2^L^^^^V1^^Salmonella subspecies I:Rough:i:1,2||…
```

The sender may have an un-coded (text only) element or a free text entry. For a non-numeric result, if neither a valid standard nor a local code exists, OBX-2 (Value type) must be either ST (String), TX (Text) or FT(Formatted Text) and OBX-5 (Observation Value) is populated with a text only entry.

Example for OBX-5 (Observation Value):

```
OBX|1|ST|20951-0^Salmonella sp serotype [Identifier] in Isolate by
Agglutination^…||Salmonella subspecies I:Rough:i:1,2||…
```

8.4 PH Component: Examples of partial, Final and corrected messages

Refer to Section 1.11.3 for a discussion of snapshot mode.

The following Testing scenario provides context for the example Partial and Final and Corrected messages below **(**The ellipses represent omitted details**):**

Partial Message

A Clinician orders a complete blood count with manual differential. The specimen is collected and the laboratory completes and releases the automated blood count as a partial report prior to completion of the manual differential on 11/06/2014 at 10:26. Only the blood count results are marked as "F" final in OBX-11(Observation Results Status).

```
MSH…

…
```

```
OBR|1|...| 57782-5^CBC with Ordered Manual Differential panel in Blood^LN...
    |20141106102631|||P|...

OBX|1|NM|26453-1^Erythrocytes [#/volume] in Blood^LN...|4.41|10*6/uL^million
    per microliter^UCUM|4.3 to 6.2|N|||F|...

…

OBX|10|…|F|…

…
```

Final Message

When the manual differential is completed, the report is generated on 11/06/2014 at 11:26. The entire message is resent along with any additional results. OBR-22 (ResultsRpt/Status Chng - Date/Time) is updated. The order is marked as final in OBR-25(Resutl Status). All the differential and the blood count results are marked as "F" final in OBX-11(Observation Results Status).

```
MSH…

…

OBR|1|...| 57782-5^CBC with Ordered Manual Differential panel in
    Blood^LN...|20141106112601|||F|...

OBX|1|NM|26453-1^Erythrocytes [#/volume] in Blood^LN...|4.41|10*6/uL^million
    per microliter^UCUM|4.3 to 6.2|N|||F|...

…

OBX|24|TX|779-9^Poikilocytosis [Presence] in Blood by Light microscopy^|None
    seen|...|F|...

…
```

Corrected Message

*On 11/06/2014 at 13:26, an error is detected for poikilocytes results and the **entire** message is resent once again with the correction. The order and the poikilocytes results are marked as "C" corrected and the rest of the results marked as "F" final and*

```
MSH…

…
```

```
OBR|1|...| 57782-5^CBC with Ordered Manual Differential panel in Blood^LN...
|20141106132601|||C|...

OBX|1|NM|26453-1^Erythrocytes [#/volume] in Blood^LN...|4.41|10*6/uL^million
per microliter^UCUM|4.3 to 6.2|N|||F|...

…

OBX|24|TX|779-9^Poikilocytosis [Presence] in Blood by Light
microscopy^|Moderate Poikilocytosis|...|C|...

…
```

8.5 PH Component: How to Further constrain this Constrainable profile

The purpose of this section is to provide guidance to a public health agency for developing a conformant implementation profile that meets the needs of their jurisdiction. It is important to realize that the Sender may message ELR messages to multiple jurisdictions, therefore, in order to maintain this interoperability, further constraints imposed upon this profile by one jurisdiction must preserve the underlying base profile conformance requirements. If the underlying conformance is not taken into consideration then the same message may cause an error if it is sent to a neighboring jurisdiction. Please refer to the HL7 V2.8 CH 2.B ballot document for a full discussion of conformance, constrainable profiles, and implementable profiles.

Ground rules for creating a fully implementable profile and maintaining interoperability across jurisdictions:

- Redefining Usage for elements: Listed below are the allowable constraints for usage types to maintain conformance with this IG:

  R → R

  RE→ R, RE

  C(a/b) → (a, b follow same rules for R, RE, O, X – e.g. C(R/RE) → C(R/RE), R)

  O → R, RE, C(a/b), X

  X→X

- Cardinality: Usage Rules above outlines the cardinalities allowed for various usage constraints. Refer to the cardinality table from the V2.7.1 Section 2.B.7.4 base standard. Additionally, for the purposes of creating an implementable profile from this guide, consider the cardinalities as the minimum allowed. If the receiver is expecting fewer repetitions of an element that the bound set by the implementable profile, the burden is on the receiver to determine which repetitions it is interested in receiving.
- Length: For the purposes of creating an implementable profile from this guide, the upper limit of allowed length published above will be considered the conformance length. Truncation characters (#, =) can be assigned a to all lengths not already defined.

- Data types: the data types cannot be changed, except IS can be extended to CWE (example is OBX-8) and ID can be extended to CNE.
- Vocabulary: The vocabulary can be further constrained and still maintain broad interoperability. If on the other hand, a jurisdiction need to locally extend the vocabulary to meet their requirements, the local vocabulary may not be compatible with neighboring jurisdictions and the sender should be made aware of this.
- Repurposing or redefining existing elements: The elements as defined in the standard and this IG should not be repurposed or redefined in a local implementation.

9 APPENDIX A – GLOSSARY

TABLE 9-1. 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. [Get definition from HL7, et al]
Electronic Health Record System (EHR-S)	A software application that is capable of managing clinical patient information. [Get definition from HL7, et al]
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 9-1. 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.
Profile	A set of laboratory orders that involve multiple tests and panels and that may require multiple specimens, but can be requested as a single unit for convenience. For example, a “diabetic profile” might include a CBC, a glycosylated hemoglobin test, and a urinalysis. This term is frequently used interchangeably with “order set”, thus a profile that contains a variety of laboratory test orders may be on its own or be combined with other test orders (e.g., radiology image, consult, etc.) be considered an order set. *Profiles shall not be communicated to the laboratory.*
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.

10 PH COMPONENT: APPENDIX B ELR-PH RESOURCES

Below are links to additional resources to help with implementation of the LRI_PH_Component:

10.1 PHIN-VADS

PHIN-VADS ELR VALUE SET RESOURCE

The Public Health Information Network Vocabulary Access and Distribution System (PHIN VADS) is based upon Whitehouse E-Gov Consolidated Health Informatics (CHI) domain recommendations and its main purpose is to distribute the vocabulary subsets that are needed for public health. PHIN VADS allows implementers to browse, search, and download the value sets associated with an implementation guide. PHIN VADS has the capability to host multiple versions of value sets and implementation guide vocabulary. PHIN VADS provides vocabulary metadata that are needed for HL7 messaging or CDA implementations.

PHIN VADS listed below and those listed in the LRI guide. Additionally, an *ELR IG to VADS Vocabulary Mapping* table is available that cross references the ELR values sets to the PHIN VADS value sets. These resources and others can be accessed on the PHIN VADS home page:

- PHIN-VADS home page: http://phinvads.cdc.gov/vads/SearchVocab.action
- Reportable Condition Mapping Tables (RCMT): https://phinvads.cdc.gov/vads/ViewCodeSystemConcept.action?oid=2.16.840.1.114222.4.5.274&code=RCMT

10.2 VSAC

The Value Set Authority Center (VSAC) is provided by the National Library of Medicine (NLM), in collaboration with the Office of the National Coordinator for Health Information Technology and the Centers for Medicare & Medicaid Services. It is the declared source of truth for value sets related to Clinical Quality Measures under the meaningful use regulations and its content may be extended in the future to house other value sets related to meaningful use regulations. For more information see: https://vsac.nlm.nih.gov/

10.3 Reportable Condition Knowledge Management System (RCKMS):

A joint Centers for Disease Control and Prevention (CDC) – Council of State and Territorial Epidemiologists (CSTE) project is underway, which has the goal of creating a national knowledge management system, identified as Reportable Condition Knowledge Management System (RCKMS), containing this information. For information contact CSTE at http://www.cste.org/group/SPI

11 PH COMPONENT: APPENDIX C SUMMARY OF CHANGES BETWEEN ELR-PH R1 AND ELR-PH R2

11.1 Introduction

The following section summarizes the differences between Release 2 and Release 1 of the ELR-PH 251 IGs. Although every attempt was made to be backwards compatible with the earlier release it was not always possible. Backwards Compatibility means a Release 1 ELR-PH 251 message can be received by an ELR-PH Release 2 Receiver without the potential of causing the receiving application to raise an exception as described in HL7 V2.7.1 Conformance (Chapter 2B, 2.B.7.5). Note that an ELR-PH Receiver may or may not raise exceptions depending on its individual business rules. Note also that this is an informative summary and not a substitute for reading the guide.

11.2 Edits to Synch with LOI and LRI Implementation Guides:

11.2.1 CREATED LRI_PH_COMPONENT TO SYNCH WITH LRI/LOI PROFILES

Only the additional constraints, usage notes, condition predicates and conformance statements and guidance were retained from Release 1 and merged with the LRI IG to create this IG.

11.2.2 CHANGED CONFORMANCE STATEMENTS

Several additions, deletions and edits to the “Conformance Statements from 2.5.1 Clarification Document for EHR Technology Certification V1.1” have been made in this release. The numbering of the conformance statements for the LRI_PH_Component has been retained from the Clarification document where the conformance statements are unchanged.

TABLE 11-1. ELR R1 CONFORMANCE STATEMENT REPRESENTED IN ELR R2

Conformance statement in ELR R1	Appears in ELR R2 as:
ELR-4:EI.3 (Universal ID) SHALL be valued with an ISO-compliant OID.	LRI-2: EI_GU.3 (Universal ID) SHALL be valued with an ISO-compliant OID.
ELR-5:EI.4 (Universal ID Type) SHALL contain the value 'ISO'.	LRI-3: EI_GU.4 (Universal ID Type) SHALL contain the value “ISO”.
ELR-10:XAD.4 (State or Province) SHALL use the FIPS 5-2 two letter alphabetic codes.	is covered by the code system format check
ELR-11:XAD.5 (Zip or Postal Code) SHALL be formatted as 99999[-9999] for US Zip or ZIP +4 codes or as A9A9A9 for Canadian postal codes.	is covered by the code system format check
ELR-12:MSH.1 (Field Separator) SHALL contain the constant value '|'.	LRI-6: MSH-1 (Field Separator) SHALL contain the constant value ‘|’.

TABLE 11-1. ELR R1 CONFORMANCE STATEMENT REPRESENTED IN ELR R2	
Conformance statement in ELR R1	Appears in ELR R2 as:
ELR-13:MSH.2 (Encoding Characters) SHALL contain the constant value '^~\&#'.	LRI-7: MSH-2 (Encoding Characters) SHALL contain the constant value '^~\&' or the constant value '^~\&#'.
ELR-14:MSH.7 (Date/Time Of Message) SHALL follow the format YYYYMMDDHHMMSS[.S[S[S[S]]]]+/-ZZZZ	Is now handled in TS data type
ELR-15:MSH.9.1 SHALL contain the constant value 'ORU'	LRI-8: MSH-9 (Message Type) SHALL contain the constant value 'ORU^R01^ORU_R01'.
ELR-16:MSH.9.2 (Trigger Event) SHALL contain the constant value 'R01'	LRI-8: MSH-9 (Message Type) SHALL contain the constant value 'ORU^R01^ORU_R01'.
ELR-17:MSH.9.3 (Message Structure) SHALL contain the constant value 'ORU_R01'	LRI-8: MSH-9 (Message Type) SHALL contain the constant value 'ORU^R01^ORU_R01'.
ELR-18:MSH.12.1 (Version ID) SHALL contain the constant value '2.5.1'.	LRI-9: MSH-12.1 (Version ID) SHALL contain the constant value '2.5.1'.
ELR-19:MSH.15 (Accept Acknowledgment Type) SHALL contain the constant value 'AL' IF any occurrence of MSH.21.1 (Entity Identifier) is 'PHLabReport-Ack' , ELSE, if valued, SHALL contain the constant value 'NE'.	no longer needed - handled using MSH-15
ELR-20:MSH.16 (Application Acknowledgement Type) SHALL contain the constant value 'AL', 'NE', 'ER', or 'SU' ,'SU',IF any occurrence of MSH.21.1 (Entity Identifier) is 'PHLabReport-Ack', ELSE, if valued, SHALL contain the constant value 'NE' .	no longer needed - handled using MSH-15
ELR-21:MSH.21.1 (Entity Identifier) of an occurrence of MSH.21 (Message Profile Identifier) SHALL be valued with 'PHLabReport-Ack' OR 'PHLabReport-NoAck' OR 'PHLabReport-Batch'	no longer needed - handled using MSH-15
ELR-22:MSH.21.3 (Universal ID) of an occurrence of MSH.21 (Message Profile Identifier) SHALL contain the value " 2.16.840.1.113883.9.11"	LRI-15: An occurrence of MSH-21 (Message Profile Identifier) SHALL be valued with 2.16.840.1.113883.9.17 (LRI_GU_RU_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 2.16.840.1.113883.9.14 (LAB_RU_Component) in any order.
ELR-22:MSH.21.3 (Universal ID) of an occurrence of MSH.21 (Message Profile Identifier) SHALL contain the value " 2.16.840.1.113883.9.11"	ELR-71: An occurrence of MSH-21 (Message Profile Identifier) SHALL be valued with 2.16.840.1.113883.9.63 (LRI_PH_Component).
ELR-23:SFT.6 (Software Install Date) SHALL follow the format YYYY[MM[DD[HH[MM[SS[.S[S[S[S]]]]]]]]][+/-ZZZZ]	field is now 'O'

TABLE 11-1. ELR R1 CONFORMANCE STATEMENT REPRESENTED IN ELR R2	
Conformance statement in ELR R1	Appears in ELR R2 as:
ELR-24:PID.1 (Set ID - PID) SHALL contain the constant value '1'.	LRI-24: PID-1 (Set ID - PID) SHALL be valued with the constant value '1'.
ELR-26:If valued, PID-7 (Date/Time of Birth) SHALL follow the format YYYY[MM[DD[HH[MM[SS[.S[S[S[S]]]]]]]]][+/-ZZZZ]	Is now handled in TS data type
ELR-27:If PID-7 (Date/Time of Birth) is not valued, then an OBX segment associated with the SPM segment SHALL be present to report patient age at specimen collection.	see comment in PID-7, not tested.
ELR-28:PID.29 (Patient Death Date and Time) SHALL follow the format YYYY[MM[DD[HH[MM[SS[.S[S[S[S]]]]]]]]][+/-ZZZZ]	Is now handled in TS data type
ELR-29:PID.33 (Last Update Date/Time) SHALL follow the format YYYY[MM[DD[HH[MM[SS[.S[S[S[S]]]]]]]]][+/-ZZZZ]	Is now handled in TS data type
ELR-31:PV1.44 (Admit Date/Time) SHALL follow the format YYYY[MM[DD[HH[MM[SS[.S[S[S[S]]]]]]]]][+/-ZZZZ]	Is now handled in the TS data type
ELR-32:PV1.45 (Discharge Date/Time) SHALL follow the format YYYY[MM[DD[HH[MM[SS[.S[S[S[S]]]]]]]]][+/-ZZZZ]	Is now handled in the TS data type
ELR-35:ORC.2 (Placer Order Number) SHALL be the same value as OBR.2 within same Order_Observation Group.	LRI-27: The value of ORC-2 (Placer Order Number) SHALL be identical to the value of OBR-2 (Placer Order Number).
ELR-36:ORC.3 (Filler Order Number) SHALL be the same value as OBR.3 (FIller Order Number) within same Order_Observation Group.	LRI-28: The value of ORC-3 (Filler Order Number) SHALL be identical to the value of OBR-3 (Filler Order Number).
ELR-37:ORC.12 (Ordering Provider) SHALL be the same value as OBR.16 within same Order_Observation Group.	LRI-29: The value of ORC-12 (Ordering Provider) SHALL be identical to the value of OBR-16 (Ordering Provider).
ELR-39:OBR.1 (Set ID - OBR) SHALL be valued sequentially starting with the value '1'	LRI-38: The value of OBR-1 (Set ID – OBR) SHALL be valued sequentially starting with the value '1' within a given segment group.
ELR-40:OBR.3 (Filler Order Number) SHALL NOT contain the same value as another occurrence of OBR.3 (Filler Order Number) in the message.	LRI-47: 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.
ELR-41:OBR-7 (Observation Date/Time) SHALL follow the format YYYYMMDD[HH[MM[SS[.S[S[S[S]]]]]]][+/-ZZZZ] OR contain the value "0000" when the collection date/time is unknown.	Is now handled in TS data type

TABLE 11-1. ELR R1 CONFORMANCE STATEMENT REPRESENTED IN ELR R2	
Conformance statement in ELR R1	Appears in ELR R2 as:
ELR-43:OBR-8 (Observation End Date/Time) SHALL follow the format YYYYMMDD[HH[MM[SS[.S[S[S[S]]]]]]][+/-ZZZZ] OR contain the value "0000" when the collection date/time is unknown.	Is now handled in TS data type
ELR-47:OBR.22 (Results Rpt/Status Chng - Date/Time) SHALL follow the format YYYYMMDDHHMM[SS[.S[S[S[S]]]]]+/-ZZZZ	Is now handled in TS data type
ELR-48:OBX.1 (Set ID - OBX) SHALL be valued sequentially starting with the value '1' within a given Order Observation Group (OBX following the OBR).	LRI-53: The value of OBX-1 (Set ID – OBX) SHALL be valued sequentially starting the value ‘1’ within a given segment group.
ELR-49:OBX-14 (Date/Time of the Observation) SHALL follow the format YYYYMMDD[HH[MM[SS[.S[S[S[S]]]]]]][+/-ZZZZ] OR contain the value "0000"" when the collection date/time is unknown.	Is now handled in TS data type
ELR-51:OBX.14 (Date/Time of the Observation) For observation related to testing of specimen (OBX's following the OBR), SHALL be identical to OBR.7 (Observation Date/Time) value within the same Order_Observaton Group.	ELR-72: OBX-14 (Date/Time of the Observation) For observation related to testing of specimen (OBX's following the OBR), SHALL be identical to an occurrence of SPM-17.1 (Range Start Date/Time) value within the same ORDER_OBSERVATION Group.
ELR-52:OBX.19 (Date/Time of the Analysis) SHALL follow the format YYYY[MM[DD[HH[MM[SS[.S[S[S[S]]]]]]]]][+/-ZZZZ]	Is now handled in TS data type
ELR-54:SPM.1 (Set ID - SPM) SHALL contain the constant value '1'.	LRI-57: The value of SPM-1 (Set ID – SPM) SHALL be valued sequentially starting the value ‘1’ within a given segment group.
ELR-55:SPM-17.1 (Range Start Date/Time) SHALL follow the format YYYYMMDD[HH[MM[SS[.S[S[S[S]]]]]]][+/-ZZZZ] OR contain the value "0000"" when the collection date/time is unknown.	Is now handled in TS data type
ELR-57:SPM.17.1 (Range Start Date/Time) SHALL be identical to OBR.7 (Observation Date/Time) value within the same Order_Observation Group.	ELR-75: The earliest SPM-17.1 (Range Start Date/Time) value SHALL be equal to or before OBR-7 (Observation Date/Time) value within the same ORDER_OBSERVATION Group.
ELR-58:SPM.17.2 (Range End Date/Time) SHALL follow the format YYYYMMDD[HH[MM[SS[.S[S[S[S]]]]]]][+/-ZZZZ] OR contain the value "0000".	Is now handled in TS data type

TABLE 11-1. ELR R1 CONFORMANCE STATEMENT REPRESENTED IN ELR R2	
Conformance statement in ELR R1	Appears in ELR R2 as:
ELR-59:SPM.17.2 (Range End Date/Time) SHALL be identical to OBR.8 (Observation End Date/Time) value within the same Order_Observation Group.	ELR-76: If present, the latest SPM-17.2 (Range End Date/Time) value SHALL be equal to or after OBR-7 (Observation Date/Time) value within the same ORDER_OBSERVATION Group.
ELR-60:SPM.18 (Specimen Received Date/Time) SHALL follow the format YYYYMMDD[HH[MM[SS[.S[S[S[S]]]]]]][+/-ZZZZ]	Is now handled in TS datatype
ELR-62:IF HD.3(Universal ID type) value is "CLIA", SHALL be a valid CLIA identifier format	ELR-73: IF HD.3(Universal ID type) value is "CLIA", then HD.2 (Universal ID) SHALL be a valid CLIA identifier format.
ELR-63:IF HD.3(Universal ID type) value is "ISO", SHALL be a valid ISO OID format.	ELR-74: IF HD.3(Universal ID type) value is "ISO", then HD.2 (Universal ID) SHALL be a valid ISO OID format.
ELR-65:OBX.5(Observation Value) Must be valued IF OBX.8 (Abnormal Flags) is empty AND OBX.11 (Observation Result Status) is not valued 'X'	ELR-77: OBX-5 (Observation Value) MUST be valued IF OBX-8 (Abnormal Flags) is empty AND OBX-11 (Observation Result Status) is not valued 'X' or 'N'.
ELR-66:OBX.8 (Abnormal Flags) Must be valued IF OBX.5(Observation Value) is empty AND OBX.11 (Observation Result Status) is not valued 'X'	ELR-78: OBX-8 (Abnormal Flags) MUST be valued IF OBX-5 (Observation Value) is empty AND OBX-11 (Observation Result Status) is not valued 'X' or 'N'.
ELR-67:XAD.9 (County/Parish Code) SHALL be formatted as 99999	is covered by the code system format
ELR-68:OBX.1 (Set ID - OBX) SHALL be valued sequentially starting with the value '1' within a given Specimen Group (OBX following the SPM).	LRI-53: The value of OBX-1 (Set ID – OBX) SHALL be valued sequentially starting the value '1' within a given segment group.
ELR-69:IF CWE.3 (Name of Coding System) value is "LN", SHALL be a valid LOINC code identifier format.	is covered by the code system format check
ELR-70:IF CWE.6 (Name of Alternate Coding System) value is "LN", SHALL be a valid LOINC code identifier format.	is covered by the code system format check

11.2.3 CHANGED USAGE TO 'O' WHERE APPROPRIATE.

This includes changing Usage of 'X' Not Supported to 'O' where appropriate to align with LRI and LOI. In addition several elements were determined not to be clinically relevant and their usage was changed to 'O'. The following table summarizes where this occurs in the field and datatype elements. These changes are backwards compatible as defined above.

TABLE 11-2. ELR R2 USAGE CHANGE TO 'O' (OPTIONAL) FROM ELR R1		
Message or Datatype Element	ELRR2_Usage	ELRR1_Usage
CNN_7 : Degree (e.g. MD)	O	RE
CQ_1 : Quantity	O	R
CQ_2 : Units	O	RE
CWE: Coding System Version ID	O	RE
CWE_8 : Alternate Coding System Version ID	O	RE
CWE_15 : Value Set OID	O	X
CWE_16 : Value Set Version ID	O	X
CWE_17 : Alternate Coding System OID	O	X
CWE_18 : Alternate Value Set OID	O	X
CWE_19 : Alternate Value Set Version ID	O	X
CWE_20 : Second Alternate Coding System OID	O	X
CWE_21 : Second Alternate Value Set OID	O	X
CWE_22 : Second Alternate Value Set Version ID	O	X
CX_GU_6 : Assigning Facility	O	RE
ERR_3 Field Position	O	C(RE/X)
ERR_4 Field Repetition	O	C(RE/X)
ERR_5 Component Number	O	C(RE/X)
ERR_6 Sub-component Number	O	RE
NDL_2 : Start Date/time	O	X
NDL_3 : End Date/time	O	X
NDL_4 : Point of Care	O	X
NDL_5 : Room	O	X
NDL_6 : Bed	O	X
NDL_7 : Facility	O	X
NDL_8 : Location Status	O	X
NDL_9 : Patient Location Type	O	X
NDL_10 : Building	O	X
NDL_11 : Floor	O	X
XCN_GU_14 : Assigning Facility	O	RE

TABLE 11-2. ELR R2 USAGE CHANGE TO 'O' (OPTIONAL) FROM ELR R1		
Message or Datatype Element	ELRR2_Usage	ELRR1_Usage
XCN_GU_21 : Professional Suffix	O	RE
XON_GU_2 : Organization Name Type Code	O	RE
XPN_GU_5 : Prefix (e.g. DR)	O	RE
XPN_GU_14 : Professional Suffix	O	RE
XTN_2 : Telecommunication Use Code	O	RE
XTN_5 : Country Code	O	C(RE/X)
XTN_10 : Extension Prefix	O	X
XTN_11 : Speed Dial Code	O	X
SFT_6 : Software Install Date	O	RE
ERR_8 User Message	O	RE
ERR_9 Inform Person Indicator	O	X
ERR_10 Override Type	O	X
ERR_11 Override Reason Code	O	X
ERR_12 Help Desk Contact Point	O	RE
NK1_6 : Business Phone Number	O	X
NK1_8 : Start Date	O	X
NK1_9 : End Date	O	X
NK1_10 : Next of Kin / Associated Parties Job Title	O	X
NK1_11 : Next of Kin / Associated Parties Job Code/Class	O	X
NK1_12 : Next of Kin / Associated Parties Employee Number	O	X
NK1_14 : Marital Status	O	X
NK1_15 : Administrative Sex	O	X
NK1_16 : Date/Time of Birth	O	X
NK1_17 : Living Dependency	O	X
NK1_18 : Ambulatory Status	O	X
NK1_19 : Citizenship	O	X
NK1_21 : Living Arrangement	O	X
NK1_22 : Publicity Code	O	X
NK1_23 : Protection Indicator	O	X
NK1_24 : Student Indicator	O	X
NK1_25 : Religion	O	X

TABLE 11-2. ELR R2 USAGE CHANGE TO 'O' (OPTIONAL) FROM ELR R1		
Message or Datatype Element	ELRR2_Usage	ELRR1_Usage
NK1_26 : Mother's Maiden Name	O	X
NK1_27 : Nationality	O	X
NK1_28 : Ethnic Group	O	X
NK1_29 : Contact Reason	O	X
NK1_33 : Next of Kin/Associated Party's Identifiers	O	X
NK1_34 : Job Status	O	X
NK1_35 : Race	O	X
NK1_36 : Handicap	O	X
NK1_37 : Contact Person Social Security Number	O	X
NK1_38 : Next of Kin Birth Place	O	X
NK1_39 : VIP Indicator	O	X
PV1_13 : Re-admission Indicator	O	X
PV1_15 : Ambulatory Status	O	X
PV1_16 : VIP Indicator	O	X
PV1_21 : Charge Price Indicator	O	X
PV1_22 : Courtesy Code	O	X
PV1_23 : Credit Rating	O	X
PV1_24 : Contract Code	O	X
PV1_25 : Contract Effective Date	O	X
PV1_26 : Contract Amount	O	X
PV1_27 : Contract Period	O	X
PV1_28 : Interest Code	O	X
PV1_29 : Transfer to Bad Debt Code	O	X
ORC_20 : Advanced Beneficiary Notice Code	O	X
OBR_9 : Collection Volume	O	X
OBR_30 : Transportation Mode	O	X
OBR_37 : Number of Sample Containers *	O	X
OBR_40 : Transport Arrangement Responsibility	O	X
OBR_41 : Transport Arranged	O	X
OBR_42 : Escort Required	O	X
OBR_43 : Planned Patient Transport Comment	O	X
SPM_12 : Specimen Collection Amount	O	RE

11.2.4 CHANGED "O" USAGE TO 'X' WHERE APPROPRIATE

The Usage for the optional elements listed below was changed to X to either align with LRI and LOI or the base standard. Since these elements were optional in Release 1 of the ELR IG these changes may or may not be backwards compatible as defined above depending on the individual local implementation.

TABLE 11-3. ELR R2 USAGE CHANGE TO 'X' (NOT SUPPORTED) FROM ELR R1

Message or Datatype Element	ELRR2_Usage	ELRR1_Usage
XCN_GU_7 : Degree (e.g. MD)	X	O
XPN_GU_6 : Degree (e.g. MD)	X	O
PID_31 : Identity Unknown Indicator	X	O
PID_36 : Breed Code	X	O
PID_37 : Strain	X	O
PID_38 : Production Class Code	X	O
PID_39 : Tribal Citizenship	X	O
PV1_52 : Other Healthcare Provider	X	O

11.2.5 CHANGED FROM "O" OR "X" TO OTHER USAGE

The Usage for the elements listed below was changed from O or X to some other usage in Release 2 to align with LRI and LOI and/or the base standard or technical corrections from Release 1. Many of these changes are technical in nature and do not change the real world usage of the element. However, some of these changes are additional elements to ELR-PH message and not backwards compatible as defined above.

TABLE 11-4. ELR R1 USAGE CHANGE FROM 'O' (OPTIONAL) OR 'X' (NOT SUPPORTED) TO OTHER IN ELR R2

Message or Datatype Element	ELRR2_Usage	ELRR1_Usage
CE_1 : Identifier	R	***
CE_2 : Text	RE	***
CE_3 : Name of Coding System	R	***
CE_4 : Alternate Identifier	RE	***
CE_5 : Alternate Text	RE	***
CE_6 : Name of Alternate Coding System	C(R/X)	***
CNN_8 : Source Table	C(O/X)	X
EIP_GU_1 : Placer Assigned Identifier	RE	O

TABLE 11-4. ELR R1 USAGE CHANGE FROM 'O' (OPTIONAL) OR 'X' (NOT SUPPORTED) TO OTHER IN ELR R2		
Message or Datatype Element	ELRR2_Usage	ELRR1_Usage
XCN_GU_12 : Check Digit Scheme	C(O/X)	O
XON_GU_5 : Check Digit Scheme	C(O/X)	O
XTN_12 : Unformatted Telephone number	C(O/X)	X
NK1_7 : Contact Role	RE	X
ORC_26 : Advanced Beneficiary Notice Override Reason	C(X/X)	X
OBR_11 : Specimen Action Code	RE	O
OBR_28 : Result Copies To	C(R/X)	O
OBR_49 : Result Handling	RE	O
TQ1_1 : Set ID - TQ1	R	O
TQ1_7 : Start date/time	RE	O
TQ1_8 : End date/time	RE	O
OBX_26 Patient Results Release Category	O	****
OBX_27 Root Cause	O	****
OBX_28 Local Process Control	O	****
OBX_29 Observation Type	R	****
SPM_24 : Specimen Condition	VARIES	O

*** Usage not defined in Release 1

****Not present in Release since pre-adopted from v2.8.1

11.2.6 CHANGED TO "R" REQUIRED USAGE

The Usages for the elements listed below was changed from some other usage to "R" in Release 2 to align with LRI and LOI. These changes are an added constraint on the message and not backwards compatible as defined above.

TABLE 11-5. ELR R2 USAGE CHANGE TO 'R' (REQUIRED)		
Message or Datatype Element	ELRR2_Usage	ELRR1_Usage
XTN_3 : Telecommunication Equipment Type	R	RE
MSH_15 : Accept Acknowledgment Type	R	C(R/RE)
MSH_16 : Application Acknowledgment Type	R	C(R/RE)
PID_8 : Administrative Sex	R	RE

TABLE 11-5. ELR R2 USAGE CHANGE TO 'R' (REQUIRED)		
Message or Datatype Element	ELRR2_Usage	ELRR1_Usage
ORC_12 : Ordering Provider	R	C(R/X)
OBR_16 : Ordering Provider	R	RE

11.2.7 ELEMENTS CONDITIONAL USAGE CHANGES

The Usages for the elements listed below were changed to or from some conditional usage to some other usage to align with LRI and LOI or for a technical correction or clarification of usage. Refer to the Condition Predicates in the IG above. In general, when the usage is more constrained the change is not backwards compatible.

TABLE 11-6. ELR R2 USAGE CHANGE TO OR FROM 'C' (CONDITIONAL)		
Message or Datatype Element	ELRR2_Usage	ELRR1_Usage
CNN_9 : Assigning Authority - Namespace ID	C(RE/X)	RE
EIP_GU_2 : Filler Assigned Identifier	C(R/RE)	R
XON_GU_1 : Organization Name	RE	C(R/RE)
XON_GU_10 : Organization Identifier	C(R/RE)	RE
XTN_6 : Area/City Code	C(R/X)	C(RE/X)
PID_29 : Patient Death Date and Time	C(RE/X)	RE
PID_34 : Last Update Facility	C(R/O)	C(R/X)
NK1_31 : Contact Person's Telephone Number	C(RE/X)	RE
NK1_32 : Contact Person's Address	C(RE/X)	RE
ORC_2 : Placer Order Number	RE	C(R/X)
ORC_14 : Call Back Phone Number	RE	C(R/X)
OBR_8 : Observation End Date/Time	RE	C(R/X)
OBR_26 : Parent Result	C(R/RE)	CE
OBR_29 : Parent	C(R/RE)	CE
OBX_4 : Observation Sub-ID	C(R/RE)	C(R/X)
OBX_5 : Observation Value	RE	C(RE/X)
OBX_6 : Units	C(R/RE)	C(R/X)
OBX_8 : Interpretation Codes	RE	C(RE/X)
OBX_14 : Date/Time of the Observation	RE	CE
SPM_9 : Specimen Source Site Modifier	C(RE/X)	RE

11.2.8 MESSAGE STRUCTURE CHANGES

The Usages for the message structure elements listed below were changed to align with LRI and LOI or for a technical correction. The first three rows are more constrained usages in Release 2 and not backwards compatible as defined above.

TABLE 11-7. ELR R2 USAGE CHANGE IN THE MESSAGE STRUCTURE

ORU Segment Name	ELRR2_Usage	ELRR1_Usage
Order Common Segment (ORC)	R	CE
TIMING_QTY Group Begin	RE	O
OBSERVATION Group Begin	C(R/X)	C(R/RE)
SPECIMEN Group Begin	RE	CE

11.2.9 TS (TIME STAMP) FLAVORS

TS data type for Release 1 elements are revised in Release 2 to synch with the appropriate TS flavor data types used in LRI. Refer to Section 2 above for a detailed description of the TS flavors. The table below summarizes the changes listing the TS flavor alongside the data element Note that Conformance Statements defined in the Clarifications Guide[13] constrained the TS format in Release 1.

TABLE 11-8. ELR R2 TIME STAMP FLAVORS REPLACE ELR R1 CONFORMANCE STATEMENTS

Field Element Name	ELRR2_TS flavor	ELRR1_CS number
MSH.7 : Date/Time Of Message	TS_7	ELR-14
PID.7 : Date/Time of Birth	TS_2 or TS_3	ELR-26
PID.29 : Patient Death Date and Time	TS_3	ELR-28
PID.33 : Last Update Date/Time	TS_5	ELR-29
PV1.44 : Admit Date/Time	TS_5	ELR-31
PV1.45 : Discharge Date/Time	TS_5	ELR-32
OBR.7 : Observation Date/Time	TS_4	ELR-41
OBR.8 : Observation End Date/Time	TS_5	ELR-43
OBR.22 : Results Rpt/Status Chng - Date/Time	TS_6	ELR-47
OBX.14 : Date/Time of the Observation	TS_5	ELR-49
OBX.19 : Date/Time of the Analysis	TS_5	ELR-52

[13] http://www.cdc.gov/ehrmeaningfuluse/Docs/1ELR251_Clarification_EHR_Tech_Cert_v1_1-20121016.pdf.

TABLE 11-8. ELR R2 TIME STAMP FLAVORS REPLACE ELR R1 CONFORMANCE STATEMENTS		
Field Element Name	ELRR2_TS flavor	ELRR1_CS number
SPM.17 : Specimen Collection Date/Time	SPN-17.1 : TS_4 SPM-17.2: TS_5	ELR-55 ELR-58
SPM.18 : Specimen Received Date/Time	TS_5	ELR-60

11.2.10 CWE (CODED WITH EXCEPTION) FLAVORS.

CWE data type for Release 1 elements are revised in Release 2 to synch with the appropriate CWE flavor data types used in LRI. Refer to Sections 2 and Section 8.2 above for a detailed description of the CWE flavors. The table below summarizes the changes, listing the CWE flavor alongside the data element.

TABLE 11-9. ELR R2 CWE FLAVORS REPLACE CWE IN ELR R1		
Field Element Name	ELRR2_Datatype	ELRR1_Datatype
PID.10 : Race	CWE_CRE	CWE
PID.22 : Ethnic Group	CWE_CRE	CWE
PID.35 : Species Code	CWE_CRE	CWE
NTE.4 : Comment Type	CWE_CRE	CWE
NK1.3 : Relationship	CWE_CRE	CWE
OBR.4 : Universal Service Identifier	CWE_CR	CWE
OBR.13 : Relevant Clinical Information	CWE_CRE	ST
OBR.31 : Reason for Study	CWE_CRE	CWE
OBR.49 : Result Handling	CWE_CRE	IS
OBX.3 : Observation Identifier	CWE_CR	CWE
OBX.5: Results (coded)	CWE_CRO	CWE for OBX.5
OBX.6 : Units	CWE_CRE	CWE
OBX.8 : Interpretation Codes	CWE_CRE	CWE
OBX.17 : Observation Method	CWE_CRE	CWE
SPM.4 : Specimen Type	CWE_CRE	CWE
SPM.5 : Specimen Type Modifier	CWE_CRE	CWE
SPM.6 : Specimen Additives	CWE_CRE	CWE
SPM.7 : Specimen Collection Method	CWE_CRE	CWE
SPM.8 : Specimen Source Site	CWE_CRE	CWE
SPM.9 : Specimen Source Site Modifier	CWE_CRE	CWE

TABLE 11-9. ELR R2 CWE FLAVORS REPLACE CWE IN ELR R1		
Field Element Name	ELRR2_Datatype	ELRR1_Datatype
SPM.11 : Specimen Role	CWE_CRE	CWE
SPM.21 : Specimen Reject Reason	CWE_CRE	CWE
SPM.24 : Specimen Condition	CWE_CRE	CWE

12 PH COMPONENT: APPENDIX D ELR R2. RELEASE 1.0 TO 1.1

This section summarize the changes between HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 2 - US Realm (published November, 2013) and HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health R2, Release 1.1 - US Realm (published March, 2014).

The changes in DSTU R1.1 are a collection of publishing and technical corrections to the guide.

Section	Revised	Comment
Various	Typos and formatting	
1.14.2.5	LAB_TO_COMPONENT OID	Updated OID from 2.16.840.1.113883.9.XX to 2.16.840.1.113883.9.22
3.4.1	ELR-71	Updated OID from 2.16.840.1.113883.9.NNN to 2.16.840.1.113883.9.63
3.4.1	LRI-22	Approved errata for LRI DSTU (OO CR151) Update Conformance Statement.
3.4.5	Table 3-11: PID-34 Usage for PH Component	Technical correction/errata: Changed "PH Component Usage: to 'C(RE/O)' Usage did not match condition predicate listed for this field
3.4.6	Table 3-12: NK1-2 Comment	Technical correction: Remove comment repeated from base standard for consistency with other fields containing the XPN datatype.
3.4.12	Table 3-21, SPM-5 Usage	Update usage for consistent treatment of modifier fields in SPM segment.
5	Hyperlink	Technical correction: Update link