

# Michigan Department of Health and Human Services

---

*HL7 Version 2.5.1 Implementation Guide: Lab Results – Bureau of Laboratories*

FOR PILOT AND TRIAL IMPLEMENTATIONS ONLY

This Implementation Guide is being released for Pilot and Trial implementations ONLY.  
Changes are expected prior to final release for general implementations.

Version 0.5



## Table of Contents

1.	Introduction.....	7
1.1.	Audience.....	7
1.1.1.	Requisite Knowledge.....	7
1.2.	Organization of this Guide.....	8
1.2.1.	Conventions.....	8
1.2.2.	Message Element Attributes.....	8
1.2.3.	Keywords.....	9
1.2.4.	Usage Conformance Testing Recommendations.....	10
1.2.5.	Relationship to Orders.....	12
1.3.	MDHHS Point of Contact.....	12
1.4.	Revisions of this Document.....	12
1.5.	Copyright Information.....	12
2.	Messages.....	14
2.1.	ORU^R01^ORU_R01.....	14
2.2.	ACK^R01^ACK.....	16
2.3.	Segment and Field Descriptions.....	16
2.3.1.	MSH – Message Header Segment.....	16
2.3.2.	SFT – Software Segment.....	20
2.3.3.	MSA – Acknowledgement Segment.....	20
2.3.4.	ERR – Error Segment.....	20
2.3.5.	PID – Patient Identification Segment.....	21
2.3.6.	PV1 – Patient Visit Segment.....	22
2.3.7.	ORC – Common Order Segment.....	24
2.3.8.	OBR – Observation Request Segment.....	26
2.3.9.	OBX – Observation/Result Segment.....	29
2.3.10.	SPM – Specimen Segment.....	36
2.3.11.	NTE – Notes and Comments Segment.....	39
3.	Special Cases and Error Conditions.....	41
3.1.	Special Cases.....	41
3.1.1.	Test Referred to CDC for Testing.....	41
3.2.	Error Conditions.....	41
3.2.1.	Delivery Failure.....	41
4.	Message Transport and On Boarding.....	41
4.1.	Message Transport Options.....	41
4.2.	On-boarding Instructions.....	41
4.2.1.	Pre-Production Onboarding.....	41
4.2.2.	Production.....	42
4.2.3.	Testing After Entering into Production.....	42
4.2.4.	Required Retesting.....	42
5.	Code Systems and Value Sets.....	43
5.1.	LOINC.....	43
5.2.	SNOMED CT.....	44

- 5.3. Example HL7 Messages ..... 44
  - 5.3.1. General Format for OBX-2 = CWE (SNOMED CT required when available code is published)..... 44
  - 5.3.2. SNOMED-Specific Format for OBX-2 = CWE ..... 44
  - 5.3.3. General Format for OBX-2 = CWE..... 45
- 5.4. Specimen Type..... 46
- 5.5. UCUM ..... 46
- 5.6. Vocabulary Constraints..... 46
- 5.7. Constrained HL7 Tables ..... 51
  - 5.7.1. HL7 Table 0065 – Specimen Action Code (V2.7.1) ..... 51
  - 5.7.2. HL7 Table 0076 – Message Type (V2.5.1)..... 51
  - 5.7.3. HL7 Table 0078 – Interpretation Codes (V2.5.1) ..... 51
  - 5.7.4. HL7 Table 0123 – Results Status (V2.5.1) ..... 52
  - 5.7.5. HL7 Table 0125 – Value Type (V2.5.1)..... 52
  - 5.7.6. HL7 Table 0203 – Identifier Type (V2.7.1) ..... 54
  - 5.7.7. L7 Table 0291 – Subtype of Referenced Data (V2.7.1)..... 56
  - 5.7.8. HL7 Table 0301 - Universal ID Type (V2.7.1) ..... 56
  - 5.7.9. HL7 Table 0353 – CWE Status Codes ..... 57
  - 5.7.10. HL7 Table 0354 – Message Structure (V2.5.1) ..... 57
  - 5.7.11. HL7 Table 507 – Observation Result Handling (V2.7.1)..... 57
  - 5.7.12. HL7 Table 0834 – MIME Type (V2.7.1) ..... 58
- 6. Laboratory Result Message Development Resources ..... 59
- 7. Additional Implementation Guidance – Other ..... 60
  - 7.1. Clinical Laboratory Improvement Amendments Considerations ..... 60
  - 7.2. Mandatory Reporting Requirements ..... 60
    - 7.2.1. Regulatory Compliance..... 61
  - 7.3. Authorized Parties ..... 61
  - 7.4. CLSI Definitions – Quantitative, Semi-quantitative, Qualitative Results..... 62
    - 7.4.1. Quantitative..... 62
    - 7.4.2. Qualitative ..... 62
    - 7.4.3. Semi-quantitative ..... 62
- Appendix A: Data Types..... 63
  - CE – Coded Element ..... 63
  - CWE\_CRE – Coded with Exceptions – Code Required, but May Be Empty ..... 63
  - CWE\_CR – Coded with Exceptions – Code Required..... 65
  - CWE\_CRO – Coded with Exceptions – Code and Original Text Required..... 66
  - CX\_NG – Extended Composite ID with Check Digit (Non-Globally Unique)..... 67
  - DR – Date/Time Range ..... 68
  - DT – Date ..... 68
  - DTM – Date/Time ..... 68
  - EI\_NG – Entity Identifier (Non-Globally Unique)..... 68
  - EIP\_NG – Entity Identifier Pair (Non-Globally Unique)..... 69
  - ERL – Error Location ..... 69
  - FN – Family Name..... 69

- FT – Formatted Text Data ..... 69
- HD\_NG – Hierarchic Designator (Non-Globally Unique) ..... 69
- ID – Coded Value for HL7-Defined Tables ..... 70
- IS – Coded Value for User-Defined Tables..... 70
- MSG – Message Type ..... 70
- NM – Numeric ..... 70
- PRL – Parent Result Link ..... 70
- PT – Processing Type ..... 70
- SAD – Street address ..... 71
- SI – Sequence ID ..... 71
- SN – Structured Numeric..... 71
- ST – String Data ..... 71
- TM – Time..... 71
- TS\_0 – Time Stamp ..... 71
- TS\_1 – Time Stamp ..... 72
- TS\_2 – Time Stamp ..... 72
- TS\_3 – Time Stamp ..... 73
- TS\_4 – Time Stamp ..... 73
- TS\_5 – Time Stamp ..... 73
- TS\_6 – Time Stamp ..... 74
- TX – Text Data..... 74
- VID – Version Identifier ..... 74
- XAD – Extended Address ..... 74
- XCN\_NG – Extended Composite ID Number and Name for Persons (Non-Globally Unique) ..... 75
- XON\_NG – Extended Composite Name and Identification Number for Organizations (Non-Globally Unique) . 76
- XPN – Extended Person Name..... 76
- Appendix B: Use Case ..... 78
  - Scope ..... 78
  - Results for Ambulatory Care Use Case and Context Diagrams ..... 78
  - User Story ..... 79
  - Use Case Assumptions..... 80
  - Pre-Conditions ..... 81
  - Post Condition ..... 81
  - Functional Requirements ..... 81
  - Sequence Diagram..... 82
  - Key Technical Decisions..... 83
  - Use of ISO Object Identifier (OID) ..... 83
  - Use of Vocabulary Standards ..... 83
  - Snapshot Mode ..... 83
  - Field Length and Truncation..... 84
  - Referenced Profiles - Antecedents..... 84
  - Actors..... 84
  - Conformance to this Guide ..... 84

Result Profile Components .....	85
Result Profiles (Pre-Coordinated Components) .....	86
Response Components .....	87
Response Profiles (Pre-Coordinated Components) .....	87
Extended Profile Use .....	87
Scope of Implementation .....	87
Relationship to Orders .....	87
APPENDIX C - Error Conditions and Related Codes .....	88
APPENDIX D - Revision History .....	89
- END OF DOCUMENT - .....	89

## List of Table

Table 1 - Message Element Attributes .....	8
Table 2 - ORU^R01^ORU_R01 Abstract Message Syntax .....	14
Table 3 - ACK^R01^ACK Abstract Message Syntax .....	16
Table 4 - MSH – Message Header Segment .....	16
Table 5 -MSH 21 Response Profile Combinations .....	18
Table 6 - MSH 21 Acknowledgment Profile Combinations .....	19
Table 7 - MSA – Acknowledgement Segment .....	20
Table 8 - ERR – Error Segment .....	20
Table 9 - PID – Patient Identification Segment .....	21
Table 10 - PV1 - Patient Visit Segment .....	22
Table 11 - ORC – Common Order Segment .....	24
Table 12- OBR – Observation Request Segment .....	26
Table 13 - OBR-16, -28, Examples .....	29
Table 14 - OBX – Observation/Result Segment .....	29
Table 15 - Observation Identifiers .....	34
Table 16 - Data Types for LOINC Scale Part .....	36
Table 17 - SPM – Specimen Segment .....	36
Table 18 - Notes and Comments Segment (NTE) .....	40
Table 19 - Examples of SNOMED Codes for Frequently Reported Organisms .....	45
Table 20- Value Set/Code System Summary .....	47
Table 21 - HL7 Table 0065 – Specimen Action Code .....	51
Table 22 - HL7 Table 0076 – Message Type .....	51
Table 23 - HL7 Table 0078 – Interpretation Codes .....	52
Table 24 - HL7 Table 0123 – Results Status .....	52
Table 25 - HL7 Table 0125 – Value Type .....	52
Table 26 - HL7 Table 0203 – Identifier Type .....	54
Table 27 - HL7 Table 0291 – Subtype of Referenced Data .....	56
Table 28 - HL7 Table 0301 - Universal ID Type .....	56
Table 29 - HL7 Table 0353 – CWE Status Codes .....	57
Table 30- HL7 Table 0354 – Message Structure .....	57
Table 31 - HL7 Table 507 – Observation Result Handling .....	57

Table 32 - HL7 Table 0834 – MIME Type .....	58
Table 33 - Mandatory Reporting Requirements.....	60
Table 34 - CE – Coded Element.....	63
Table 35 - CWE_CRE – Coded with Exceptions – Code Required, but May Be Empty .....	63
Table 36 - CWE_CR – Coded with Exceptions – Code Required .....	65
Table 37 - CWE_CRO – Coded with Exceptions – Code and Original Text Required .....	66
Table 38 - CX_NG – Extended Composite ID with Check Digit (Non-Globally Unique) .....	67
Table 39 - DR – Date/Time Range.....	68
Table 40 - DT – Date .....	68
Table 41 - DTM – Date/Time .....	68
Table 42 - EI_NG – Entity Identifier (Non-Globally Unique).....	68
Table 43 - EIP_NG – Entity Identifier Pair (Non-Globally Unique).....	69
Table 44 - ERL – Error Location.....	69
Table 45 - FN – Family Name .....	69
Table 46 - FT – Formatted Text Data .....	69
Table 47 - HD_NG – Hierarchic Designator (Non-Globally Unique) .....	69
Table 48 - ID – Coded Value for HL7-Defined Tables.....	70
Table 49 - IS – Coded Value for User-Defined Tables.....	70
Table 50 - MSG – Message Type.....	70
Table 51 - NM – Numeric.....	70
Table 52 - PRL – Parent Result Link .....	70
Table 53 - PT – Processing Type .....	70
Table 54 -SAD – Street address .....	71
Table 55 -SI – Sequence ID .....	71
Table 56 - SN – Structured Numeric.....	71
Table 57 - ST – String Data.....	71
Table 58 - TM – Time .....	71
Table 59 - TS_0 – Time Stamp .....	71
Table 60 - TS_1 – Time Stamp .....	72
Table 61 - TS_2 – Time Stamp .....	72
Table 62 - TS_3 – Time Stamp .....	73
Table 63 - TS_4 – Time Stamp .....	73
Table 64 - TS_5 – Time Stamp .....	73
Table 65 - TS_6 – Time Stamp .....	74
Table 66 -TX – Text Data.....	74
Table 67 - VID – Version Identifier.....	74
Table 68 - XAD – Extended Address .....	74
Table 69 - XCN_NG – Extended Composite ID Number and Name for Persons (Non-Globally Unique) .....	75
Table 70 - XON_NG – Extended Composite Name and Identification Number for Organizations (Non-Globally Unique).....	76
Table 71 - XPN – Extended Person Name.....	76
Table 72 - Information Interchange Requirements.....	81
Table 73 - System Requirement .....	82

## 1. Introduction

As the health care community moves to an electronic and interoperable environment, the health care community desires to send lab orders from the provider Electronic Health Records (EHR) system and receive lab results from the Michigan Department of Health and Human Services (MDHHS) Bureau of Laboratories (BOL) systems via the Michigan HIE platform. In order to streamline interoperability, MDHHS has adopted the Office of the National Coordinator’s (ONC), Standards and Interoperability Framework Initiative (S&I Framework) Laboratory Orders Interface Implementation Guide with the following selected profiles.

- LRI\_COMMON\_COMPONENT
- LRI\_NG\_COMPONENT
- LRI\_RN\_COMPONENT
- LRI\_TO\_COMPONENT

In addition to those profiles, there are some Michigan specific items. These include:

- Michigan HIE platform-related routing requirements. See Section 4.
- OBR.4 Universal Service Identifier will use panel codes created and maintained by MDHHS instead of using LOINC.
- PV1 segment: PV1.15 will be used by MDHHS to indicate if patient was reported to be pregnant. Other fields in the PV1 segment are not supported.

The document that follows is largely a copy of the S&I Framework Laboratory Results Interface Implementation Guide adjusted for the selected profiles and Michigan specific items. It also includes on-boarding and testing instructions along with special cases and Michigan HIE platform-related items.

NOTE: Although the S&I Framework Laboratory Results Interface Implementation Guide is written in HL7 version 2.5.1, several items have been pre-adopted from versions 2.7.1 and 2.8.1. These pre-adopted items are noted throughout this guide.

This document takes advantage of in-document linking for easy navigation. For example: “See Table 8 - ERR – Error Segment.” The “Table 8 - ERR – Error Segment” text links to the corresponding table.

### 1.1. 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 with BOL. 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.

#### 1.1.1. Requisite Knowledge

- Michigan Department of Health and Human Services HL7 Version 2.5.1 Implementation Guide: Lab Orders – Bureau of Laboratories
- HL7 V2.5.1, V2.7, V2.7.1 Messaging ([www.HL7.org](http://www.hl7.org))
- SNOMED (<http://browser.ihtsdo.org/>)

- 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](#)

## 1.2. Organization of this Guide

### 1.2.1. 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”.

### 1.2.2. 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 - 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 1.2.4 Usage Conformance Testing Recommendations.
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 <i>n</i> times. [1..n] Element must appear at least once, and may repeat up to <i>n</i> 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 <i>m</i> , and at most, <i>n</i> 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 5.7 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.

### 1.2.3. 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<sup>1</sup>. The following definitions are excerpted from the RFC:

**MUST** or the terms "**REQUIRED**" or "**SHALL**", mean that the definition is an absolute requirement of the specification.

**MUST NOT** or the phrase "**SHALL NOT**", mean that the definition is an absolute prohibition of the specification.

**SHOULD** or the adjective "**RECOMMENDED**", mean that there may exist valid reasons in particular circumstances to ignore a particular item, but the full implications must be understood and carefully weighed before choosing a different course.

**SHOULD NOT** or the phrase "**NOT RECOMMENDED**" mean that there may exist valid reasons in particular circumstances when the particular behavior is acceptable or even useful, but the full implications should be

<sup>1</sup> <http://www.ietf.org/rfc/rfc2119.txt>

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.

### 1.2.4. 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 <sup>2</sup> .
C(a/b)	Conditional	<p>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.</p> <p>If the condition predicate associated with the element is true, follow the rules for <i>a</i> which shall be one of “R”, “RE”, “O” or X”:</p> <p>If the condition predicate associated with the element is false, follow the rules for <i>b</i> which shall be one of “R”, “RE”, “O” or X”.</p> <p><i>a</i> and <i>b</i> can be valued the same.</p>	
X	Not supported	The application (or as configured) shall not implement “X” elements.	The application shall not populate “X” elements.
O	Optional	None. The usage indicator for this element has not yet been defined. For an implementation profile all optional elements must be profiled to R, RE, C(a/b), or X.	Not Applicable.

Usage Rules for a Receiving Application

Optionality /Usage Indicator	Description	Implementation Requirement	Operational Requirement
R	Required	The application shall implement “R” elements.	<p>The receiving application shall process (save/print/archive/etc.) the information conveyed by a required element.</p> <p>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,</p>
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).

<sup>2</sup> 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
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 <i>a</i> which shall be one of "R", "RE", "O" or "X": If the condition predicate associated with the element is false, follow the rules for <i>b</i> which shall be one of "R", "RE", "O" or "X". <i>a</i> and <i>b</i> can be the same.	
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 -----

### 1.2.5. 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. See the corresponding BOL implementation guide for Lab Orders for all of those details.

### 1.3.MDHHS Point of Contact

Questions or comments should be directed to the MDHHS BOL by email: LIMS\_HELP@michigan.gov or (517) 335-9604 during normal business hours.

### 1.4.Revisions of this Document

This document will be reviewed and possibly revised on an annual basis. Submitters are advised to monitor the web site for new versions. Revisions, along with major items changed, are tracked in APPENDIX D - Revision History.

### 1.5.Copyright Information

This material includes SNOMED Clinical Terms<sup>®</sup> (SNOMED CT<sup>®</sup>) which is used by permission of the International Health Terminology Standards Development Organization (IHTSDO). All rights reserved. SNOMED CT was originally created by The College of American Pathologists. "SNOMED<sup>®</sup>" and "SNOMED CT<sup>®</sup>" are registered trademarks of the IHTSDO.

This material contains content from LOINC<sup>®</sup> (<http://loinc.org>). The LOINC table, LOINC codes, and LOINC panels and forms file are copyright (c) 1995-2013, Regenstrief Institute, Inc. and the Logical Observation Identifiers Names and Codes (LOINC) Committee and available at no cost under the license at <http://loinc.org/terms-of-use>.

This material contains references and citations to various publications from the Health Level Seven International (HL7). Members may obtain a copy of the referenced materials without charge in the Members-only area of the site. Non-members are referred to the HL7 Intellectual Property Policy to determine if a no-cost license is available, otherwise a copy can be obtained for a nominal fee via the HL7 Store at [www.hl7.org](http://www.hl7.org).

## 2. 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].

### 2.1.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 2 - 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	RE	[0..1]	
{	<i>PATIENT_RESULT Begin</i>	R	[1..1]	
[	<i>PATIENT Begin</i>	R	[1..1]	
PID	Patient Identification	R	[1..1]	The patient identification (PID) segment is used to provide basic demographics regarding the subject of the testing. The subject shall be a person.
[PD1]	Additional Demographics	X		
[[NTE]]	Notes and Comments for PID	O		
[[NK1]]	Next of Kin/Associated Parties	X		
[	<i>VISIT Begin</i>	X		
PV1	Patient Visit	RE	[0..1]	
[PV2]	Patient Visit – Additional Information	X		
]	<i>VISIT End</i>			
]	<i>PATIENT End</i>			
{	<i>ORDER_OBSERVATION Begin</i>	R	[1..*]	The ORDER_OBSERVATION is required and can repeat.

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..*]	
{	<i>TIMING_QTY Begin</i>	X		
TQ1	Timing/Quantity	X		
[[TQ2]]	Timing/Quantity Order Sequence	X		
}	<i>TIMING_QTY End</i>			
[CTD]	Contact Data	O		
{	<i>OBSERVATION Begin</i>	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.
[[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.
}	<i>OBSERVATION End</i>			
[[FTI]]	Financial Transaction	X		
[[CTI]]	Clinical Trial Identification	X		
-{	<i>SPECIMEN Begin</i>	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. It also provides a place for the specimen number. Each specimen group documents a single sample.
SPM	Specimen Information related to OBR	R	[1..1]	The specimen information (SPM) segment describes the characteristics of a single sample. The SPM segment carries information regarding the type of specimen, where and how it was collected, who collected it, and some basic characteristics of the specimen.

Segment	Name	Usage	Cardinality	Description
[[OBX]]	Observation related to Specimen	O		
}}	<i>SPECIMEN End</i>			
}	<i>ORDER_ OBSERVATION End</i>			
}	<i>PATIENT_RESULT End</i>			
[DSC]	Continuation Pointer	X		Excluded for this Implementation Guide

## 2.2. 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 - ACK^R01^ACK Abstract Message Syntax

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

## 2.3. Segment and Field Descriptions

This messaging guide provides notes for required (non-optional) fields for each of the non-optional segments. For each segment the segment table defines the applicable constraints on usage for its fields for this implementation guide. All the relevant conformance statements and general usage notes are located at the end of each table.

### 2.3.1. MSH – Message Header Segment

Table 4 - MSH – Message Header Segment

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_NG	RE	[0..1]	HL70361	

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
4	Sending Facility	HD_NG	R	[1..1]	HL70362	This facility will receive any related acknowledgment message.
5	Receiving Application		O			Due to the network of network HIE environment within Michigan, this field may be changed by the HIE(s) to properly address/route the message. Contact your HIE for more information on what this field will include.
6	Receiving Facility	HD_NG	RE	[0..1]	HL70362	Due to the network of network HIE environment within Michigan, this field may be changed by the HIE(s) to properly address/route the message. Contact your HIE for more information on what this field will include.  If acknowledgments are in use, this facility originates any related acknowledgment message.
7	Date/Time Of Message	TS_1	R	[1..1]		If the time zone offset is included in MSH-7 it becomes the default time zone for the message instance, and applies to all other date/time fields in that same message instance where a time zone offset is not valued, except as otherwise indicated through the use of the LRI_TO_Component profile as defined in Section 0 in MSH-21 (Message Profile Identifier).
8	Security		O			
9	Message Type	MSG	R	[1..1]		
10	Message Control ID	ST	R	[1..1]		String that identifies the message instance from the sending application. Example formats for message control IDs include GUID, timestamp plus sequence number, OID plus sequence number or sequence number. The important point is that care must be taken to ensure that the message control id is unique within the system originating the message.
11	Processing ID	PT	R	[1..1]		
12	Version ID	VID	R	[1..1]		HL7 version number used to interpret format and content of the message. 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	
16	Application Acknowledgment Type	ID	R	[1..1]	HL70155	
17	Country Code		O			
18	Character Set		O			

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
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) 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. The table below indicates valid MSH-21 combinations for declaring conformance to a particular LRI response profile or LRI components.

**Table 5 -MSH 21 Response Profile Combinations**

LRI Profile	Pre-Coordinated OID	Component OIDs	Component Name
LOI_NG_PRN_Profile	2.16.840.1.113883.9.20	2.16.840.1.113883.9.16	LOI_Common_Component
		2.16.840.1.113883.9.13	LOI_NG_Component
		2.16.840.1.113883.9.14	LOI_RU_Component

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

**Example: LOI\_NG\_PRN\_Profile Using Component OIDs**

MSH...|||LRI\_Common\_Component^^2.16.840.1.113883.9.16^ISO~LRI\_NG\_Component^^2.16.840.1.113883.9.13^ISO~LRI\_RU\_Component^^2.16.840.1.113883.9.14^ISO

**Example: LOI\_NG\_PRN\_Profile Pre-Coordinated Profile OID**

MSH...|||LOI\_NG\_PRN\_Profile^^2.16.840.1.113883.9.20^ISO

**Conformance Statements: LOI\_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: LOI\_NG\_PRN\_Profile**

**LRI-14:** An occurrence of MSH-21 (Message Profile Identifier) **SHALL** be valued with 2.16.840.1.113883.9.20 (LRI\_NG\_RN\_Profile) or three occurrences **SHALL** be valued with 2.16.840.1.113883.9.16 (LRI\_Common\_Component), 2.16.840.1.113883.9.13 (LRI\_NG\_Component) and 2.16.840.1.113883.9.15 (LRI\_RN\_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 (LRI\_XO\_Component), and/or 2.16.840.1.113883.9.24 (LRI\_NB\_Component).

**Note:** Additional occurrences of MSH-21 (Message Profile Identifier) may be valued with 2.16.840.1.113883.9.22 (LRI\_TO\_Component),

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

**Table 6 - MSH 21 Acknowledgment Profile Combinations**

LRI Profile	Pre-Coordinated OID	Component OIDs	Component Name
LRI_NG_Response_Profile	2.16.840.1.113883.9.27	2.16.840.1.113883.9.26 2.16.840.1.113883.9.25	LRI_Acknowledgement_Component NG_Acknowledgement_Component

**Conformance Statements: LRI\_Acknowledgement\_Component**

**LRI-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 (Version ID) **SHALL** contain the constant value ‘2.5.1’.

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

**LRI-21:** MSH-16 (Application Acknowledgement Type) **SHALL** contain the constant value ‘NE’.

**Conformance Statements: NG\_Acknowledgement\_Component**

**LRI-23:** MSH-21 (Message Profile Identifier) **SHALL** be valued with 2.16.840.1.113883.9.25 (NG\_Acknowledgment\_Profile) when acknowledging ORU NG Profiles where MSH-21 contains 2.16.840.1.113883.9.20 (LRI\_NG\_RN\_Profile), or 2.16.840.1.113883.9.13(LRI\_NG\_Component).

### 2.3.2. 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. This guide imposes no additional constraints on the base specification HL7 v2.5.1, Chapter 2.

### 2.3.3. MSA – Acknowledgement Segment

The Message Acknowledgment Segment (MSA) contains the information sent as acknowledgment to the result message received by an Electronic Health Record System.

Table 7 - MSA – Acknowledgement Segment

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
4	Expected Sequence Number		O			
5	Delayed Acknowledgment Type		X			Excluded for this Implementation Guide
6	Error Condition		X			Excluded for this Implementation Guide

### 2.3.4. ERR – Error Segment

The ERR segment is used to add error comments to acknowledgment messages. See MiHIN HL7 Message Acknowledgement & Error Handling for more details [[http://mihin.org/wp-content/uploads/2013/07/MiHIN\\_HL7\\_Message\\_Acknowledgement\\_Error\\_Handling\\_v1.2.pdf](http://mihin.org/wp-content/uploads/2013/07/MiHIN_HL7_Message_Acknowledgement_Error_Handling_v1.2.pdf) or [mihin.org](http://mihin.org)].

Table 8 - ERR – Error Segment

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Error Code and Location		X			Excluded for this Implementation Guide
2	Error Location		O			
3	HL7 Error Code	CWE	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			

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
9	Inform Person Indicator		O			
10	Override Type		O			
11	Override Reason Code		O			
12	Help Desk Contact Point		O			

### 2.3.5. PID – Patient Identification Segment

The Patient Identification Segment (PID) is used to provide basic demographics regarding the subject of the testing.

Table 9 - PID – Patient Identification Segment

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
3	Patient Identifier List	CX_NG	RE	[0..1]		
4	Alternate Patient ID – PID		X			Excluded for this Implementation Guide
5	Patient Name	XPN	RE	[0..1]		
6	Mother's Maiden Name		O			
7	Date/Time of Birth	TS_2	RE	[0..1]		
8	Administrative Sex	IS	R	[1..1]	HL70001	Patient's gender.
9	Patient Alias		X			Excluded for this Implementation Guide
10	Race	CE	RE	[0..*]	HL70005	Note that state regulations may dictate other behaviors.
11	Patient Address		O			
12	County Code		X			Excluded for this Implementation Guide
13	Phone Number – Home		O			
14	Phone Number – Business		O			
15	Primary Language		O			
16	Marital Status		O			
17	Religion		O			
18	Patient Account Number		O			
19	SSN Number – Patient		X			Excluded for this Implementation Guide
20	Driver's License Number – Patient		X			Excluded for this Implementation Guide
21	Mother's Identifier		O			
22	Ethnic Group		O			

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
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
29	Patient Death Date and Time		O			
30	Patient Death Indicator		O			
31	Identity Unknown Indicator		X			Excluded for this Implementation Guide
32	Identity Reliability Code		O			
33	Last Update Date/Time		O			
34	Last Update Facility		O			
35	Species Code		X			Excluded for this Implementation Guide
36	Breed Code		X			Excluded for this Implementation Guide
37	Strain		X			Excluded for this Implementation Guide
38	Production Class Code		X			Excluded for this Implementation Guide
39	Tribal Citizenship		X			Excluded for this Implementation Guide

**Conformance Statements: Base Profile**

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

**2.3.6. PV1 – Patient Visit Segment**

The Patient Visit Segment (PV1) is only used to indicate if the patient was reported to be pregnant. Only PV1-15 is used, all other fields are optional and will be blank.

**Table 10 - PV1 - Patient Visit Segment**

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Set ID - PV1	SI	R	[1..1]		
2	Patient Class	IS	O		HL70004	
3	Assigned Patient Location		O			
4	Admission Type		O			
5	Preadmit Number		O			
6	Prior Patient Location		O			

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
7	Attending Doctor		O			
8	Referring Doctor		O			
9	Consulting Doctor		X			Excluded for this Implementation Guide
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		C(R/O)			This field is used to indicate if the patient was reported to be pregnant. This does not mean that the BOL tested for pregnancy or confirmed what was reported.
16	VIP Indicator		O			
17	Admitting Doctor		O			
18	Patient Type		O			
19	Visit Number		O			
20	Financial Class	FC	O	[1..1]	HL70064	
21	Charge Price Indicator		O			
22	Courtesy Code	CWE	O	[0..1]	HL70045	
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			

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
39	Servicing Facility		O			
40	Bed Status		X			Excluded for this Implementation Guide
41	Account Status		O			
42	Pending Location		O			
43	Prior Temporary Location		O			
44	Admit Date/Time		O			
45	Discharge Date/Time		O			
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

### 2.3.7. ORC – Common Order Segment

The Common Order Segment (ORC) identifies basic information about the order for testing of the specimen. This segment includes identifiers for the order, who placed the order, when it was placed, what action to take regarding the order, etc.

Table 11 - ORC – Common Order Segment

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Order Control	ID	R	[1..1]	HL70119	
2	Placer Order Number	EI_NG	RE	[0..1]		
3	Filler Order Number	EI_NG	R	[1..1]		
4	Placer Group Number	EI_NG	RE	[0..1]		
5	Order Status		O			
6	Response Flag		O			
7	Quantity/Timing		X			Excluded for this Implementation Guide
8	Parent		O			
9	Date/Time of Transaction		O			
10	Entered By		O			

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
11	Verified By		O			
12	Ordering Provider	XCN_NG	RE	[0..1]		
13	Enterer's Location		O			
14	Call Back Phone Number		O			
15	Order Effective Date/Time		O			
16	Order Control Code Reason		O			
17	Entering Organization		O			
18	Entering Device		O			
19	Action By		O			
20	Advanced Beneficiary Notice Code		X			Excluded for this Implementation Guide
21	Ordering Facility Name		O			
22	Ordering Facility Address		O			
23	Ordering Facility Phone Number		O			
24	Ordering Provider Address		O			
25	Order Status Modifier		O			
26	Advanced Beneficiary Notice Override Reason		X			Excluded for this Implementation Guide
27	Filler's Expected Availability Date/Time		O			
28	Confidentiality Code		O			
29	Order Type		O			
30	Enterer Authorization Mode		O			
31	Parent Universal Service Identifier	Varies	C(R/X )	[0..1]		Contains the universal service identifier of the parent order. Condition Predicate: If OBR-29 (Parent) is valued

**Conformance Statements: Base Profile**

**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).

**Conformance Statements: LRI\_RN Profile**

**LRI-30:** The value of ORC-31 (Parent Universal Service Identifier) **SHALL** be identical to the value of OBR-50 (Parent Universal Service Identifier).

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

### 2.3.8. OBR – Observation Request Segment

The Observation Request Segment (OBR) 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.

**Table 122- OBR – Observation Request Segment**

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_NG	RE	[0..1]		GU Data Type: EI_GU
3	Filler Order Number	EI_NG	R	[1..1]		GU Data Type: EI_GU
4	Universal Service Identifier	CWE_CR	R	[1..1]		
5	Priority – OBR		X			Excluded for this Implementation Guide
6	Requested Date/Time		X			Excluded for this Implementation Guide
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	RE	[0..1]		
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..*]		

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
14	Specimen Received Date/Time		X			Excluded for this Implementation Guide
15	Specimen Source		X			Excluded for this Implementation Guide
16	Ordering Provider	XCN_NG	RE	[0..1]		Note that ORC-12 Ordering Provider is constrained to contain the same value as this field.
17	Order Call-back Phone Number		O			
18	Placer Field 1		O			
19	Placer Field 2		O			
20	Filler Field 1		O			
21	Filler Field 2		O			
22	Results Rpt/Status Chng - Date/Time	TS_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
28	Result Copies To	XCN_NG	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 NG
29	Parent	EIP_NG	C(R/RE)	[0..1]		Condition Predicate: If OBR-11 (Specimen Action Code) is valued "G"
30	Transportation Mode		O			
31	Reason for Study		O			
32	Principal Result Interpreter		O			
33	Assistant Result Interpreter		O			
34	Technician		O			
35	Transcriptionist		O			
36	Scheduled Date/Time		O			
37	Number of Sample Containers		O			
38	Transport Logistics of		O			

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
	Collected Sample					
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			
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	CWE_CR	C(R/X)	[0..1]		Contains the universal service identifier of the parent order. Condition Predicate: If OBR-29 (Parent) is valued

### Usage Note

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

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.

### Conformance Statements: Base Profile

**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”.

**2.3.8.1. Results Handling and Results Copy To**

When the order is submitted to the laboratory, the Ordering Provider includes the identifier (StarLIMS Agency ID) and the name of the colleagues that the provider would like to also receive the patients results, up to five (5).

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.

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.

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 4 reports with unique values in OBR-28 as noted below:

**Table 13 - OBR-16, -28, Examples**

Report	OBR-16	OBR-28
Primary report	Physician_1	Colleague_A, Colleague_B and Colleague_C
Copy to report	Physician_1	Colleague_A
Copy to report	Physician_1	Colleague_B
Copy to report	Physician_1	Colleague_C

**2.3.9. OBX – Observation/Result Segment**

The Observation/Result Segment (OBX) contains information regarding a single observation related to a single test (OBR) or specimen (SPM). This includes identification of the specific type of observation, the result for the observation, when the observation was made, etc.

**Table 14 - OBX – Observation/Result Segment**

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.

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
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.
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).
5	Observation Value	Varies	RE	[0..1]		Note: If value is coded, ST should not be used
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).
7	References Range	ST	RE	[0..1]		Guidance: It is not appropriate to send the reference range for a result in an associated NTE segment. It would be appropriate to send additional information clarifying the reference range in an NTE associated with this OBX-
8	Abnormal Flags	IS	RE	[0..*]	HL70078 (2.5.1)	Microbiology example: Ceftazidime susceptibility (LOINC 133-9) value =  <= <sup>^</sup> 1 , units = ug/ml, Abnormal flag = S Note that this IG is adopting HL70078 from 2.5.1, see Section 5.7.3 HL7 Table 0078 – Interpretation Codes (V2.5.1) for value set.
9	Probability		O			

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
10	Nature of Abnormal Test		O			
11	Observation Result Status	ID	R	[1..1]	HL70085	
12	Effective Date of Reference Range		O			
13	User-Defined Access Checks		O			
14	Date/Time of the Observation	TS_5	RE	[0..1]		
15	Producer's Reference		O			
16	Responsible Observer		O			
17	Observation Method		O			
18	Equipment Instance Identifier		O			
19	Date/Time of the Analysis	TS_5	RE	[0..1]		Be as precise as appropriate and available.
20	Reserved for harmonization with <i>Version 2.6</i> .		X			Excluded for this Implementation Guide
21	Reserved for harmonization with <i>Version 2.6</i> .		X			Excluded for this Implementation Guide,
22	Reserved for harmonization with <i>Version 2.6</i> .		X			Excluded for this Implementation Guide
23	Performing Organization Name	XON_NG	R	[1..1]		The information for producer ID is recorded as an XON data type.
24	Performing Organization Address	XAD	R	[1..1]		
25	Performing Organization Medical Director	XCN_NG	RE	[0..1]		

### Usage Note

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).

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.

### **Conformance Statements: Base Profile**

**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 + OBX3.3) or (OBX-3.4 + OBX-3.6) and OBX-4 **SHALL** create a unique identification under a **single** 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 HL7 Table 0125 found in Section 5.7.5 HL7 Table 0125 – Value Type (V2.5.1) of 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.

#### **2.3.9.1. 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 7.4 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.
  - Bacterial cultures may require a SNOMED CT concept from the "organism" hierarchy.
- c. Narrative (NAR): OBX-3 observations with narrative LOINC test codes use ST or TX data type in OBX-5.
- d. Ordinal or Quantitative (OrdQn): This type is used by Susceptibility tests that may be reported as qualitative (i.e. susceptible, resistant) or as quantitative, numeric results (e.g. Minimum Inhibitory Concentration MIC).

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 15 - Observation Identifiers**

Testing Situation Discussion	OBX-2 Observation Type	OBX-3 Observation Identifier: LOINC part = scale	OBX-5 Observation value	OBX-6 Units	OBX-7 Reference Range	NTE Segment
Numeric result	NM	QN	number	Required unless OBX-11 = 'X'	May be populated	May be populated with comments, not clinical findings.
Numerical intervals, ratios, inequalities	SN	QN	structured numeric	Required unless OBX-11 = 'X'	May be populated	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 comments, not clinical findings.
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.	[empty]	May be populated	May be populated with comments, not clinical findings.
Conveys ordinal value	SN	ORD	Ordinal as structured numeric	Required unless OBX-11 = 'X' **	Required	May be populated with comments, not clinical findings.

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.	[empty]	May be populated	May be populated with comments, not clinical findings.
Conveys observation	FT, TX or ST	NAR	text	[empty]	May be populated	May be populated with comments, not clinical findings.
Conveys numeric or ordinal value	NM	ORDQN	Number	Required unless OBX-11 = 'X' **	May be populated	May be populated with comments, not clinical findings.
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.	[empty]	May be populated	May be populated with comments, not clinical findings.
Conveys observation	FT, TX or ST	MULTI	text	[empty]	May be populated	May be populated with comments, not clinical findings.
Conveys imbedded object (ED) or pointer to object (RP)	ED, RP	*	Object pointer or imbedded object	[empty]	[empty]	May be populated with comments, not clinical findings.

### Usage Note

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

If either OBX-3.3 or OBX-3.6 is “LN” (LOINC) then the data type identified in OBX-2 should be drawn from Table 3-15. 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 3-11 above.

**Table 16 - 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
ORDQN - Quantitative or Ordinal	NM, SN, TS, TM, DT, CWE
MULTI - Multi	FT, TX or ST

### 2.3.10. SPM – Specimen Segment

The Specimen Information Segment (SPM) 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.

**Table 17 - SPM – Specimen Segment**

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Set ID – SPM	SI	R	[1..1]		
2	Specimen ID		O			
3	Specimen Parent IDs		O			
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.
5	Specimen Type Modifier		O			
6	Specimen Additives		O			
7	Specimen Collection Method		O			
8	Specimen Source Site		O			

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
9	Specimen Source Site Modifier		0			
10	Specimen Collection Site		0			
11	Specimen Role		0			
12	Specimen Collection Amount		0			
13	Grouped Specimen Count		0			
14	Specimen Description		0			
15	Specimen Handling Code		0			
16	Specimen Risk Code		0			
17	Specimen Collection Date/Time	DR	RE	[0..1]		SPM-17.1 must use TS_4 for the data type definition. SPM-17.2 must use TS_5 for the data type definition. For 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		0			
19	Specimen Expiration Date/Time		0			
20	Specimen Availability		0			
21	Specimen Reject Reason	CWE	RE	[0..*]	HL70490	
22	Specimen Quality		0			
23	Specimen Appropriateness		0			
24	Specimen Condition	CWE	RE	[0..*]	HL70493	
25	Specimen Current Quantity		0			
26	Number of Specimen Containers		0			
27	Container Type		0			
28	Container Condition		0			

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
29	Specimen Child Role			0		

**Conformance Statements: Base Profile**

**LRI-57:** The value of SPM-1 (Set ID – SPM) **SHALL** be valued sequentially starting the value ‘1’.

**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.

**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^Blood^99USA^^^Blood
Specimen|||||20110103143428|||RC^Clotting^HL70490^CLT^Clotted^99USA^^^Bloo
d 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^Erythrocytesedimentation 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^^LosAngeles^CA^90067^^B|2343242^Knows alot^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
```

### 2.3.11. NTE – Notes and Comments Segment

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

Table 18 - 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		O			
3	Comment	FT	R	[1..*]		Comment contained in the segment.
4	Comment Type		O			

## 3. Special Cases and Error Conditions

### 3.1. Special Cases

In addition to the items below, as Special Cases and Error Conditions emerge, the most current information may be found on the Laboratory Services Guide website at [http://www.michigan.gov/mdhhs/0,5885,7-339-71551\\_2945\\_5103\\_26138-362966--,00.html](http://www.michigan.gov/mdhhs/0,5885,7-339-71551_2945_5103_26138-362966--,00.html)

#### 3.1.1. Test Referred to CDC for Testing

For orders that get referred to the CDC for testing, HL7 orders are accepted, but the paper copy of the “CDC Test Request Form” is required to accompany the specimen(s) or sent via fax. Also, HL7 results are NOT available for specimens tested at the CDC.

### 3.2. Error Conditions

#### 3.2.1. Delivery Failure

In the event that the receiving facility’s EHR or LIMS system is not available when result messages are sent, the MDHHS Data Hub will attempt multiple times to send the message but will timeout and fail after 5 attempts. If this happens, HL7 results may not be available and the results may be delivered by mail or fax.

## 4. Message Transport and On Boarding

### 4.1. Message Transport Options

Messages must be sent through Michigan’s Health Information Exchange (HIE) infrastructure or other MDHHS approved methods to MDHHS’s Data Hub. Michigan’s HIE infrastructure includes the Michigan Health Information Network (MiHIN) Shared Services and its related Health Information Exchanges (a.k.a., Qualified Organizations). To learn more, visit <http://mihin.org/exchanges/>. For additional information, contact the staff listed in Section 1.3 MDHHS Point of Contact.

Out-of-state providers may use the HIE infrastructure or contact the staff listed in Section 1.3 MDHHS Point of Contact for other options.

### 4.2. On-boarding Instructions

The on-boarding process is designed to ensure that all messages are complete and of good quality prior to allowing a new submitter to enter into production. It is a multi-step process, described below.

#### 4.2.1. Pre-Production Onboarding

Prior to entering into full production, submitters are required to go through a data/message quality phase for Pre-Production Onboarding. During this phase, real messages are sent, just as in production, but MSH-11 “Processing ID” is to be set to the literal value of “T”. Messages are reviewed for completeness and quality by BOL staff. Only after correcting any quality issues with the message are submitters allowed to enter full production. During Pre-Production Onboarding, submitters may be required to report BOL items via a different process. All Pre-Production Onboarding must be coordinated with BOL staff. Contact the BOL staff listed in Section 1.3 MDHHS Point of Contact to start pre-production testing and onboarding.

#### 4.2.2. Production

Once a submitter has completed Pre-Production Onboarding and received the approval to enter into production from BOL staff, they must change MSH-11 “Processing ID” to be set to the literal value of “P”. **Submitters are advised to include this requirement in any internal project scope or contract with an external organization conducting the configuration of the HL7 interface.**

#### 4.2.3. Testing After Entering into Production

If for any reason a submitter wishes to test messages after entering into production (e.g., during an EHR upgrade), they may request an additional round of Pre-Production Onboarding testing. This must be coordinated with BOL staff, and the MSH-11 “Processing ID” must be set to the literal value of “T” for any test message. Production messaging can continue during additional rounds of Pre-Production Onboarding testing as long as the MSH-11 “Processing ID” is set to the literal value of “P” for production messages, and BOL staff have approved.

#### 4.2.4. Required Retesting

Submitters are required to go through Pre-Production Onboarding retesting when switching from one EHR or interface engine product to another. Submitters are encouraged to undergo Pre-Production Onboarding retesting for any major EHR or interface engine version upgrade. All retesting must be coordinated with BOL staff.

## 5. 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.

### 5.1.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 as part of the CLIA report of record.
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/>

## 5.2. 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 regulation of report on record. CWE\_CR.2 and CWE\_CR.9 may contain the same value, when the coded description is also the original text.

## 5.3. Example HL7 Messages

### 5.3.1. 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&2.16.840.1.1
13883.19.4.6&ISO^L^^^^NPI
```

### 5.3.2. 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 4 Industrial Loop^^Ann Arbor^MI^99999^USA^B|9876543^Slide^Stan^S^^^^^NPPES&2.16.840.1.113883.19.4.6&ISO^L^^^NPI

**5.3.3. 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 19 - Examples of SNOMED Codes for Frequently Reported Organisms

Description	SNOMEDSCT (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

### 5.4. 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, for example in use with NAACCR (until deprecated by HL7). A cross-mapping is under development.

**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](http://www.nlm.nih.gov/loinc/).

### 5.5. 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/>

### 5.6. Vocabulary Constraints

Table 20 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.

Table 20- Value Set/Code System Summary

Name	Source ID/ Reference	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. <a href="http://www.iso.org/iso/iso-3166-1_decoding_table">http://www.iso.org/iso/iso-3166-1_decoding_table</a>
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'
Patient Class	HL70004	HL7 Version 2.5.1	2.16.840.1.113883.12.4	
Race Category	HL70005	HL7 Version 2.5.1	2.16.840.1.113883.6.238	
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	
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 2.5.1	2.16.840.1.113883.12.78	See Section 5.7.3 for values
Observation Result Status	HL70085	HL7 Version 2.5.1	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'
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

MDHHS HL7 Version 2.5.1 Implementation Guide: Lab Results – Bureau of Laboratories

Name	Source ID/ Reference	Source	Unique Identifier	Comments
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)
Accept/Application Acknowledgment Condition	HL70155	HL7 Version 2.5.1	2.16.840.1.113883.12.155	
Ethnic Group	HL70189	HL7 Version 2.5.1	2.16.840.1.113883.6.238	
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	
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	
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	

Name	Source ID/ Reference	Source	Unique Identifier	Comments
Coding Systems	HL70396	HL7 <a href="http://www.hl7.org/special/committees/vocab/table_0396/index.cfm">http://www.hl7.org/special/committees/vocab/table_0396/index.cfm</a>	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.
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	
MIME Types	HL70834	HL7 Version 2.7.1	2.16.840.1.113883.12.834	Imported Table 0834

Name	Source ID/ Reference	Source	Unique Identifier	Comments
LOINC		LOINC	2.16.840.1.113883.6.1 (code system)	Logical Observation Identifiers Names and Codes <a href="http://www.loinc.org">http://www.loinc.org</a>
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
SNOMED CT		SNOMED CT	2.16.840.1.113883.6.96	SNOMED CT <a href="http://www.nlm.nih.gov/research/umls/Snomed/snomed_main.html">http://www.nlm.nih.gov/research/umls/Snomed/snomed_main.html</a>
Specimen Type Value Set		SNOMED CT 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.
State Value Set	USPS	USPS <a href="http://pe.usps.com/text/pub28/28apb.htm">http://pe.usps.com/text/pub28/28apb.htm</a>		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. <a href="http://pe.usps.com/text/pub28/28apb.htm">http://pe.usps.com/text/pub28/28apb.htm</a>

Name	Source ID/ Reference	Source	Unique Identifier	Comments
Unified Code for Units of Measure (UCUM)		Regenstrief Institute, Inc. <a href="http://unitsofmeasure.org/trac">http://unitsofmeasure.org/trac</a>	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 <a href="http://www.regenstrief.org/m edinformatics/ucum">http://www.regenstrief.org/m edinformatics/ucum</a> A tool for converting non-UCUM units of measure to the equivalent UCUM units is available at: <a href="http://www.regenstrief.org/m edinformatics/ucum/unit-conversion-tool">http://www.regenstrief.org/m edinformatics/ucum/unit-conversion-tool</a>

### 5.7. 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 0203-Identifier Type is pre-adopted from HL7 Version 2.7.1
- HL7 Table 0291-Subtype of referenced data 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
- HL7 Table 0834-MIME Types is pre-adopted from HL7 Version 2.7.1

#### 5.7.1. HL7 Table 0065 – Specimen Action Code (V2.7.1)

Table 21 - HL7 Table 0065 – Specimen Action Code

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	

#### 5.7.2. HL7 Table 0076 – Message Type (V2.5.1)

Table 22 - HL7 Table 0076 – Message Type

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

#### 5.7.3. HL7 Table 0078 – Interpretation Codes (V2.5.1)

The values LU and HU are added to the values listed in the V2.5.1 User Defined table to support the LRI use case.

No further extensions are allowed. HL7 has been requested to add these values to a future V2 base standard version.

**Table 23 - HL7 Table 0078 – Interpretation Codes**

Value	Description	Comment
L	Below low normal	
H	Above high normal	
LU	Low Urgent	Between L and LL
HU	High Urgent	Between H and HH
LL	Below lower panic limits	
HH	Above upper panic limits	
<	Below absolute low-off instrument scale	
>	Above absolute high-off instrument scale	
N	Normal (applies to non-numeric results)	
A	Abnormal (applies to non-numeric results)	
AA	Very abnormal (applies to non-numeric units, analogous to panic limits for numeric units)	
null	No range defined, or normal ranges don't apply	
U	Significant change up	
D	Significant change down	
B	Better—use when direction not relevant	
W	Worse—use when direction not relevant	
S	Susceptible. Indicates for microbiology susceptibilities only.	
R	Resistant. Indicates for microbiology susceptibilities only.	
I	Intermediate. Indicates for microbiology susceptibilities only.	
MS	Moderately susceptible. Indicates for microbiology susceptibilities only.	
VS	Very susceptible. Indicates for microbiology susceptibilities only.	

### 5.7.4. HL7 Table 0123 – Results Status (V2.5.1)

**Table 24 - HL7 Table 0123 – Results 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.	

### 5.7.5. HL7 Table 0125 – Value Type (V2.5.1)

**Table 25 - HL7 Table 0125 – Value Type**

Value	Description	Usage	Data Type Flavor	Comment
CE	Coded Entry	R		When sending text data in OBX-5, use either the ST, TX or FT data types.
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 <i>Version 2.6</i> . This Implementation Guide has specially constrained versions of the CWE data type in Section 0 through 0. The CWE_CR format shall be used for OBX-5. When sending text data in OBX-5, use either the ST, TX or FT data types.
CX	Extended Composite ID With Check Digit	O	Varies	Use the appropriate CX flavor (CX-GU or CX-NG or base standard) depending on the format of the observation value and as agreed to between the sender/receiver.
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.
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 ( $^0\text{--}^1$ ), ratios ( $^1\text{--}^2$ or $^1\text{--}^2$ ), inequalities ( $<^10$ ), or categorical results ( $2^+$ ). The units for the structured numeric value should 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 TimeZone Offset profile.

Value	Description	Usage	Data Type Flavor	Comment
TS	Time Stamp (Date & Time)	R	TS_0	The time zone offset shall adhere to the use of the TimeZone Offset profile 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.

### 5.7.6. HL7 Table 0203 – Identifier Type (V2.7.1)

Table 26 - HL7 Table 0203 – Identifier Type

Value	Description	Comment
AM	American Express	
AN	Account number	
ANC	Account number Creditor	
AND	Account number Debitor	
ANON	Anonymous identifier	
ANT	Temporary Account Number	
APRN	Advanced Practice Registered Nurse number	
BA	Bank Account Number	
BC	Bank Card Number	
BR	Birth registry number	
BRN	Breed Registry Number	
CC	Cost Center number	
CY	County number	
DDS	Dentist license number	
DEA	Drug Enforcement Administration registration number	
DFN	Drug Furnishing or prescriptive authority Number	
DI	Diner_s Club card	
DL	Driver_s license number	
DN	Doctor number	
DO	Osteopathic License number	
DPM	Podiatrist license number	
DR	Donor Registration Number	
DS	Discover Card	
EI	Employee number	
EN	Employer number	
FI	Facility ID	
GI	Guarantor internal identifier	
GL	General ledger number	
GN	Guarantor external identifier	
HC	Health Card Number	
IND	Indigenous/Aboriginal	
JHN	Jurisdictional health number (Canada)	

Value	Description	Comment
LI	Labor and industries number	
LN	License number	
LR	Local Registry ID	
MA	Patient Medicaid number	
MB	Member Number	
MC	Patient's Medicare number	
MCD	Practitioner Medicaid number	
MCN	Microchip Number	
MCR	Practitioner Medicare number	
MD	Medical License number	
MI	Military ID number	
MR	Medical record number	
MRT	Temporary Medical Record Number	
MS	MasterCard	
NE	National employer identifier	
NH	National Health Plan Identifier	
NI	National unique individual identifier	
NII	National Insurance Organization Identifier	
NIIP	National Insurance Payor Identifier (Payor)	
NNxxx	National Person Identifier where the xxx is the ISO table 3166 3-character (alphabetic) country code	
NP	Nurse practitioner number	
NPI	National provider identifier	
OD	Optometrist license number	
PA	Physician Assistant number	
PCN	Penitentiary/correctional institution Number	
PE	Living Subject Enterprise Number	
PEN	Pension Number	
PI	Patient internal identifier	
PN	Person number	
PNT	Temporary Living Subject Number	
PPN	Passport number	
PRC	Permanent Resident Card Number	
PRN	Provider number	
PT	Patient external identifier	
QA	QA number	
RI	Resource identifier	
RN	Registered Nurse Number	
RPH	Pharmacist license number	
RR	Railroad Retirement number	
RRI	Regional registry ID	
SID	Specimen identifier	
SL	State license	
SN	Subscriber Number	
SR	State registry ID	

Value	Description	Comment
SS	Social Security number	
TAX	Tax ID number	
TN	Treaty Number/ (Canada)	
U	Unspecified identifier	
UPIN	Medicare/CMS (formerly HCFA)_s Universal Physician Identification numbers	
VN	Visit number	
VS	VISA	
WC	WIC identifier	
WCN	Workers_ Comp Number	
XX	Organization identifier	

### 5.7.7. L7 Table 0291 – Subtype of Referenced Data (V2.7.1)

Table 27 - HL7 Table 0291 – Subtype of Referenced Data

Value	Description	Comment
	Source RFC 2046	MIME media subtypes established in accordance with RFC 2046 ( <a href="http://ietf.org/rfc/rfc2046.txt">http://ietf.org/rfc/rfc2046.txt</a> ) and registered with the Internet Assigned Numbers Authority ( <a href="http://www.iana.org/numbers.html">http://www.iana.org/numbers.html</a> ). Note that the MIME media subtype values are case-insensitive, in accordance with RFC 2045.
x-hl7-cda-level-one	HL7 Clinical Document Architecture Level One document	Not supported.

### 5.7.8. HL7 Table 0301 - Universal ID Type (V2.7.1)

Table 28 - HL7 Table 0301 - Universal ID Type

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

Value	Description	Usage	Comments
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
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

### 5.7.9. HL7 Table 0353 – CWE Status Codes

Table 29 - 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.

### 5.7.10. HL7 Table 0354 – Message Structure (V2.5.1)

Table 30- HL7 Table 0354 – Message Structure

Value	Description	Usage	Comments
ORU_R01	Unsolicited transmission of an observation message	R	Required for Profiles: LRI_NG_RN_Profile
ACK	General Acknowledgment Message for unsolicited transmission of an observation message	R	Required for Profiles: LRI_Acknowledgement_Component NG_Acknowledgement_Component

### 5.7.11. HL7 Table 507 – Observation Result Handling (V2.7.1)

Table 31 - HL7 Table 507 – Observation Result Handling

Value	Description	Comments
F	Film-with-patient	

Value	Description	Comments
N	Notify provider when ready	
A	Alert provider when abnormal	
CC	Copies Requested	
BCC	Blind Copy	

### 5.7.12. HL7 Table 0834 – MIME Type (V2.7.1)

Table 32 - 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	

## 6. 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](http://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.

## 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.

### 7.2. 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/regulatory/default.aspx>). Interpretative Guidelines on the elements required in a report may be found at <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html>. Specific report fields impacted include the following:

Table 33 - 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 <sup>3</sup>	Unique identification of the test performed is required. See Section 5.1 LOINC for vocabulary use. Use of LOINC codes for additional tests is strongly encouraged. Addition of a local laboratory code is allowed. For certain tests CLIA requires additional information: Laboratories using manufacturer's instruments, kits or test systems labeled for "investigational use only" or "research use only" must clearly state that the test results are not to be used for treatment or diagnostic purposes. If results of such tests are being reported without a disclaimer statement, or are being used by the provider for patient care, they are in the same category as in-house developed tests and the laboratory must establish performance specifications in accordance with §493.1253. The disclaimer for Analyte Specific Reagents (ASR) should state, "This test was developed and its performance characteristics determined by (Laboratory Name). It has not been cleared or approved by the U.S. Food and Drug Administration." The ASR disclaimer on the test report is required by the FDA under 21 CFR, Part 809.30, "Restrictions on the sale, distribution and use of analyte -specific reagents."
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 5.5 UCUM for vocabulary use.
OBX-7	Reference Range	When available reference range shall be valued.

<sup>3</sup> While CLIA requires a laboratory to maintain positive identification of a specimen reporting, that information as part of the result is not required.

Segment	Field	CLIA Impact
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 5.7.3 HL7 Table 0078 – Interpretation Codes (V2.5.1) 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 2.3.10 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)

### 7.2.1. 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.

### 7.3. 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.

## 7.4.CLSI Definitions – Quantitative, Semi-quantitative, Qualitative Results

The following definitions were derived from the CLSI website: <http://www.clsi.org>

### 7.4.1. Quantitative

- 1) 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.
- 2) 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 ++++.

### 7.4.2. 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 (i.e., 1+, 2+);  
NOTE 2: It may also be called semi-quantitative tests;  
NOTE 3: Specific identification may be performed.

### 7.4.3. Semi-quantitative

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

## Appendix A: 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., CX\_GU vs. CX\_NG. Composite data types indicate which variety of the component's data type is applicable, while the data type of a field is marked as "varies" where the comment indicates the data type choices based on the declared profile or component.

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

### CE – Coded Element

Table 34 - CE – Coded Element

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

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

#### Conformance Statements: Base Profile

**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.

### CWE\_CRE – Coded with Exceptions – Code Required, but May Be Empty

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

Table 35 - CWE\_CRE – Coded with Exceptions – Code Required, but May Be Empty

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Identifier	ST	RE		
2	Text	ST	C(RE/X)		Condition Predicate: If CWE_CRE.1 (Identifier) is valued It is strongly recommended that text be sent to accompany any identifier. When a coded value is

SEQ	Component Name	DT	Usage	Value Set	Comments
					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.
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 sender shall always populate the first triplet before populating other triplets; the receiver shall examine all triplets to find relevant values.

The CWE\_CRE data type is used where it is necessary to communicate a code, text, coding system and the version of coding system the code was drawn from. It also allows the communication of an alternate code drawn from another coding system. Many coded fields in this specification identify coding systems or value sets that must be used for the field. **When populating the CWE\_CRE data type with these values, this guide does not give preference to the triplet in which the standard code should appear.** The receiver is expected to examine the coding system names in components 3 and 6 to determine if it recognizes the coding system.

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.

### CWE\_CR – Coded with Exceptions – Code Required

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

Table 36 - CWE\_CR – Coded with Exceptions – Code Required

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		
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		

SEQ	Component Name	DT	Usage	Value Set	Comments
20	Second Alternate Coding System OID		O		
21	Second Alternate Value Set OID		O		
22	Second Alternate Value Set Version ID		O		

### Usage Note

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

The CWE\_CR data type is used where it is necessary to communicate a code, text, coding system and the version of coding system the code was drawn from. It also allows the communication of an alternate code drawn from another coding system. Many coded fields in this specification identify coding systems or value sets that must be used for the field. **When populating the CWE\_CR data types with these values, this guide does not give preference to the triplet in which the standard code should appear.** The receiver is expected to examine the coding system names in components 3 and 6 to determine if it recognizes the coding system.

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.

## CWE\_CRO – Coded with Exceptions – Code and Original Text Required

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

**Table 37 - CWE\_CRO – Coded with Exceptions – Code and Original Text Required**

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	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		

SEQ	Component Name	DT	Usage	Value Set	Comments
13	Second Alternate Coding System Version ID		O		
14	Coding System OID		O		
15	Value Set OID		O		
16	Value Set Version ID		O		
17	Alternate Coding System OID		O		
18	Alternate Value Set OID		O		
19	Alternate Value Set Version ID		O		
20	Second Alternate Coding System OID		O		
21	Second Alternate Value Set OID		O		
22	Second Alternate Value Set Version ID		O		

**Usage Note**

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

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. **When populating the CWE\_CRO data types with these values, this guide does not give preference to the triplet in which the standard code should appear.** The receiver is expected to examine the coding system names in components 3 and 6 to determine if it recognizes the coding system.

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.

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).

**CX\_NG – Extended Composite ID with Check Digit (Non-Globally Unique)**

Table 38 - CX\_NG – Extended Composite ID with Check Digit (Non-Globally Unique)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	ID Number	ST	R		
2	Check Digit	ST	O		
3	Check Digit Scheme		C(O/X)		
4	Assigning Authority	HD_NG	RE		
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		O		

Department
------------

### Usage Note

The CX\_NG data type is used to carry identifiers. This guide requires that assigning authorities accompany all identifiers if known, and that all identifiers carry an identifier type. This method allows the exchange of unique identifiers for the associated object across organizational and enterprise boundaries, enabling broad interoperability.

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

## DR – Date/Time Range

Table 39 - DR – Date/Time Range

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Range Start Date/Time	TS_4	RE		
2	Range End Date/Time	TS_5	RE		

## DT – Date

Table 40 - DT – Date

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

## DTM – Date/Time

Table 41 - DTM – Date/Time

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 0 TS\_0 – Time Stamp.

## EI\_NG – Entity Identifier (Non-Globally Unique)

Table 42 - EI\_NG – Entity Identifier (Non-Globally Unique)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Entity Identifier	ST	R		
2	Namespace ID	IS	C(R/O)		Condition Predicate: If EI_NG.3 (Universal ID) is not valued
3	Universal ID	ST	C(R/O)		Condition Predicate: If EI_NG.2 (Namespace ID) is not valued
4	Universal ID Type	ID	C(R/X)	HL70301 (V2.7.1)	Condition Predicate: If EI_NG.3 (Universal ID) is valued

### Usage Note

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

**EIP\_NG – Entity Identifier Pair (Non-Globally Unique)**

Table 43 - EIP\_NG – Entity Identifier Pair (Non-Globally Unique)

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

**ERL – Error Location**

Table 44 - ERL – Error Location

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		

**FN – Family Name**

Table 45 - FN – Family Name

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		

**FT – Formatted Text Data**

Table 46 - FT – Formatted Text Data

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*. These are the escape sequences for the message delimiters (i.e., |^&~\ or |^&~\#).

**HD\_NG – Hierarchic Designator (Non-Globally Unique)**

Table 47 - HD\_NG – Hierarchic Designator (Non-Globally Unique)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Namespace ID	IS	C(R/O)		Condition Predicate: If HD_NG.2 (Universal ID) is not valued
2	Universal ID	ST	C(R/O)		Condition Predicate: If HD_NG.1 (Namespace ID) is not valued
3	Universal ID Type	ID	C(R/X)	HL70301 (V2.7.1)	Condition Predicate: If HD_NG.2 (Universal ID) is valued

**Usage Note**

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

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

### ID – Coded Value for HL7-Defined Tables

Table 48 - ID – Coded Value for HL7-Defined Tables

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

### IS – Coded Value for User-Defined Tables

Table 49 - IS – Coded Value for User-Defined Tables

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

### MSG – Message Type

Table 50 - MSG – Message Type

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)	

### NM – Numeric

Table 51 - NM – Numeric

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Numeric	-	R		

### PRL – Parent Result Link

Table 52 - PRL – Parent Result Link

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		

### PT – Processing Type

Table 53 - PT – Processing Type

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Processing ID	ID	R	HL70103	
2	Processing Mode		O		

## SAD – Street address

Table 54 -SAD – Street address

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Street or Mailing Address	ST	R		
2	Street Name		O		
3	Dwelling Number		O		

## SI – Sequence ID

Table 55 -SI – Sequence ID

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

## SN – Structured Numeric

Table 56 -SN – Structured Numeric

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 ( $^0^{\wedge}-^1$ ), ratios ( $^1^{\wedge}/^2$  or  $^1^{\wedge}:^2$ ), inequalities ( $<^10$ ), or categorical results ( $2^{\wedge}+$ )

## ST – String Data

Table 57 -ST – String Data

SEQ	Component Name	DT	Usage	Value Set	Comments
1	String Data	-	R		

### Usage Note

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

## TM – Time

Table 58 -TM – Time

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

## TS\_0 – Time Stamp

Table 59 -TS\_0 – Time Stamp

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Time	DTM	R		
2	Degree of Precision	ID	X		Excluded for this Implementation Guide
The DTM component of this Time Stamp has the following constraints:					
	YYYY		R		
	MM		O		
	DD		O		

SEQ	Component Name	DT	Usage	Value Set	Comments
	HH		O		
	MM		O		
	SS		O		
	[.S[S[S[S]]]]		O		
	+/- ZZZZ		C(R/O)		Condition Predicate: If an occurrence of MSH-21 is valued 2.16.840.1.113883.9.22 (LRI_TO_Component)

### TS\_1 – Time Stamp

Table 60 - TS\_1 – Time Stamp

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Time	DTM	R		
2	Degree of Precision	ID	X		Excluded for this Implementation Guide
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		C(R/O)		Condition Predicate: If an occurrence of MSH-21 is valued 2.16.840.1.113883.9.22 (LRI_TO_Component)

### TS\_2 – Time Stamp

Table 61 - TS\_2 – Time Stamp

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Time	DTM	R		
2	Degree of Precision	ID	X		Excluded for this Implementation Guide
The DTM component of this Time Stamp has the following constraints:					
	YYYY		R		
	MM		RE		
	DD		RE		
	HH		O		
	MM		O		
	[SS[.S[S[S[S]]]]]		O		
	+/- ZZZZ		C(RE/O)		Condition Predicate: If an occurrence of MSH-21 is valued 2.16.840.1.113883.9.22 (LRI_TO_Component)

### TS\_3 – Time Stamp

Table 62 - TS\_3 – Time Stamp

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Time	DTM	R		
2	Degree of Precision	ID	X		Excluded for this Implementation Guide
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		C(RE/O)		Condition Predicate: If an occurrence of MSH-21 is valued 2.16.840.1.113883.9.22 (LRI_TO_Component)

### TS\_4 – Time Stamp

Table 63 - TS\_4 – Time Stamp

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Time	DTM	R		
2	Degree of Precision	ID	X		Excluded for this Implementation Guide
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'
	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		C(RE/O)		Condition Predicate: If an occurrence of MSH-21 is valued 2.16.840.1.113883.9.22 (LRI_TO_Component)

#### Usage Note

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

### TS\_5 – Time Stamp

Table 64 - TS\_5 – Time Stamp

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Time	DTM	R		
2	Degree of Precision	ID	X		Excluded for this Implementation Guide
The DTM component of this Time Stamp has the following constraints:					
	YYYY		R		
	MM		R		
	DD		R		
	HH		RE		

SEQ	Component Name	DT	Usage	Value Set	Comments
	MM		RE		
	[SS[.S[S[S[S]]]]]		O		
	+/- ZZZZ		C(RE/O)		Condition Predicate: If an occurrence of MSH-21 is valued 2.16.840.1.113883.9.22 (LRI_TO_Component)

## TS\_6 – Time Stamp

Table 65 - TS\_6 – Time Stamp

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Time	DTM	R		
2	Degree of Precision	ID	X		Excluded for this Implementation Guide
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		C(RE/O)		Condition Predicate: If an occurrence of MSH-21 is valued 2.16.840.1.113883.9.22 (LRI_TO_Component)

## TX – Text Data

Table 66 - TX – Text Data

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

### Usage Note

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

## VID – Version Identifier

Table 67 - VID – Version Identifier

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

## XAD – Extended Address

Table 68 - XAD – Extended Address

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	

SEQ	Component Name	DT	Usage	Value Set	Comments
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
13	Effective Date		O		
14	Expiration Date		O		

### XCN\_NG – Extended Composite ID Number and Name for Persons (Non-Globally Unique)

Table 69 - XCN\_NG – Extended Composite ID Number and Name for Persons (Non-Globally Unique)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	ID Number	ST	RE		Note: despite the component being named “ID Number” this component is an ST string data type, not numeric, so the component is not limited to just numbers.
2	Family Name	FN	RE		
3	Given Name	ST	RE		I.e., first name.
4	Second and Further Given Names or Initials Thereof	ST	RE		
5	Suffix (e.g., JR or III)	ST	RE		
6	Prefix (e.g., DR)	ST	RE		
7	Degree (e.g., MD)		X		Excluded for this Implementation Guide
8	Source Table		O		
9	Assigning Authority	HD_NG	C(RE/X)		Condition Predicate: If XCN_NG.1 (ID Number) is valued The Assigning Authority component is used to identify the system, application, organization, etc. that assigned the ID Number in component 1.
10	Name Type Code	ID	RE	HL70200	
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_NG.1 (ID Number) is valued
14	Assigning Facility		O		
15	Name Representation Code		O		
16	Name Context		O		
17	Name Validity Range		X		Excluded for this Implementation Guide
18	Name Assembly Order		O		
19	Effective Date		O		

SEQ	Component Name	DT	Usage	Value Set	Comments
20	Expiration Date		O		
21	Professional Suffix		O		
22	Assigning Jurisdiction		O		
23	Assigning Agency or Department		O		

## XON\_NG – Extended Composite Name and Identification Number for Organizations (Non-Globally Unique)

Table 70 - XON\_NG – Extended Composite Name and Identification Number for Organizations (Non-Globally Unique)

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
4	Check Digit		O		
5	Check Digit Scheme	ID	C(O/X)		Note that the condition predicate will be established when this profile is constrained further.
6	Assigning Authority	HD_N G	C(RE/ X)		Condition Predicate: If XON_NG.10 (Organization Identifier) is valued The Assigning Authority component is used to identify the system, application, organization, etc. that assigned the ID in component 10.
7	Identifier Type Code	ID	C(R/X)	HL70203	Condition Predicate: If XON_NG.10 (Organization Identifier) is valued
8	Assigning Facility		O		
9	Name Representation Code		O		
10	Organization Identifier	ST	C(R/R E)		Condition Predicate: If XON_NG.1 (Organization Name) is not valued

### Usage Note

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

## XPN – Extended Person Name

Table 71 - XPN – Extended Person Name

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
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

MDHHS HL7 Version 2.5.1 Implementation Guide: Lab Results – Bureau of Laboratories

SEQ	Component Name	DT	Usage	Value Set	Comments
11	Name Assembly Order		0		
12	Effective Date		0		
13	Expiration Date		0		
14	Professional Suffix		0		

## Appendix B: Use Case

### 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 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.

### 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<sup>4</sup>. In this Use Case, the Laboratory provides results based on a request for

---

<sup>4</sup> Derived from the CLIA definition ([https://www.cms.gov/CLIA/07\\_Program\\_Descriptions\\_Projects.asp](https://www.cms.gov/CLIA/07_Program_Descriptions_Projects.asp)). Future Use

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.

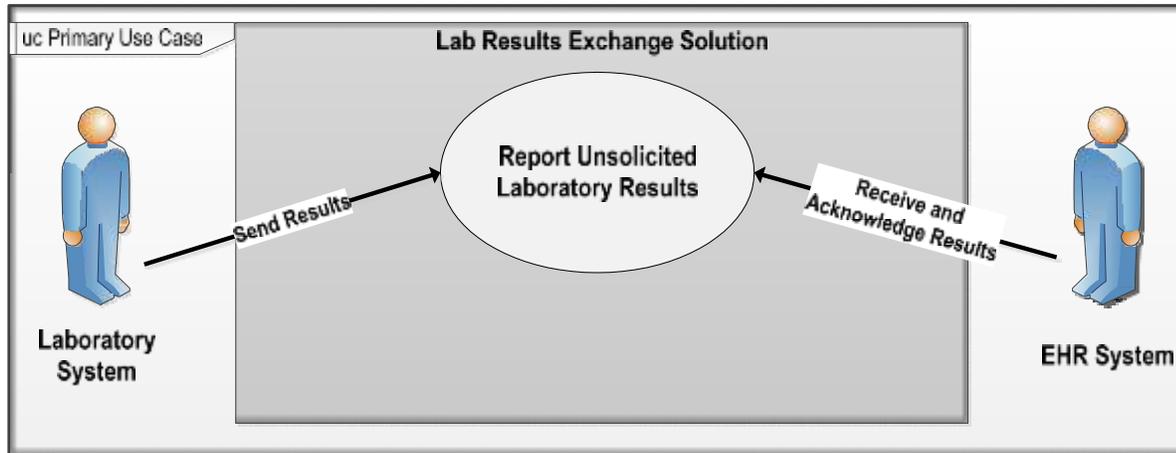


Figure 1 - Use Case Diagram

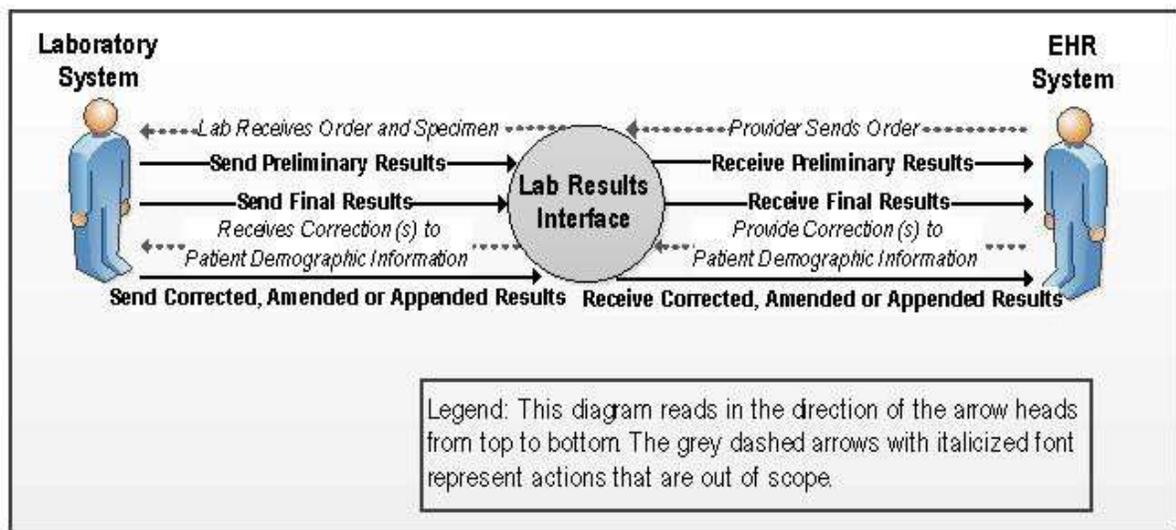


Figure 2 - Context Diagram

### 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

Cases may require expansion to include non-human subjects.

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.

### Use Case Assumptions

- Providers securely access clinical information through an EHR-S.
- Appropriate security and transport protocols; patient identification methodology; requisition (order) identification methodology; consent; privacy and security procedures; coding, vocabulary and normalization standards have been agreed to by all relevant participants.
- This Use Case only addresses the exchange of laboratory results that are associated with the In Scope laboratory tests.
- All relevant parties have agreed on a structured laboratory test results message format.
- This Use Case covers all CLIA reporting requirements.
- For the specimen collection process the data included in the dataset considerations table<sup>5</sup> 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.

---

<sup>5</sup> Section 13.0 - LRI Use Case: :

<http://wiki.siframework.org/LRI+Use+Case+%26+Requirements+%28UCR%29+WG>

- Laboratories meet accreditation criteria according to jurisdiction requirements or agency criteria.

### Pre-Conditions

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

### 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.

### Functional Requirements

Table 72 - Information Interchange Requirements

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

Table 73 - System Requirement

System	System Requirement
Laboratory Information System	Form a laboratory message with standardized structured data <sup>6</sup> meeting CLIA and other federal and state regulatory requirements
Electronic Health Record System	Incorporate test data from the laboratory message as standardized structured data.

### Sequence Diagram

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

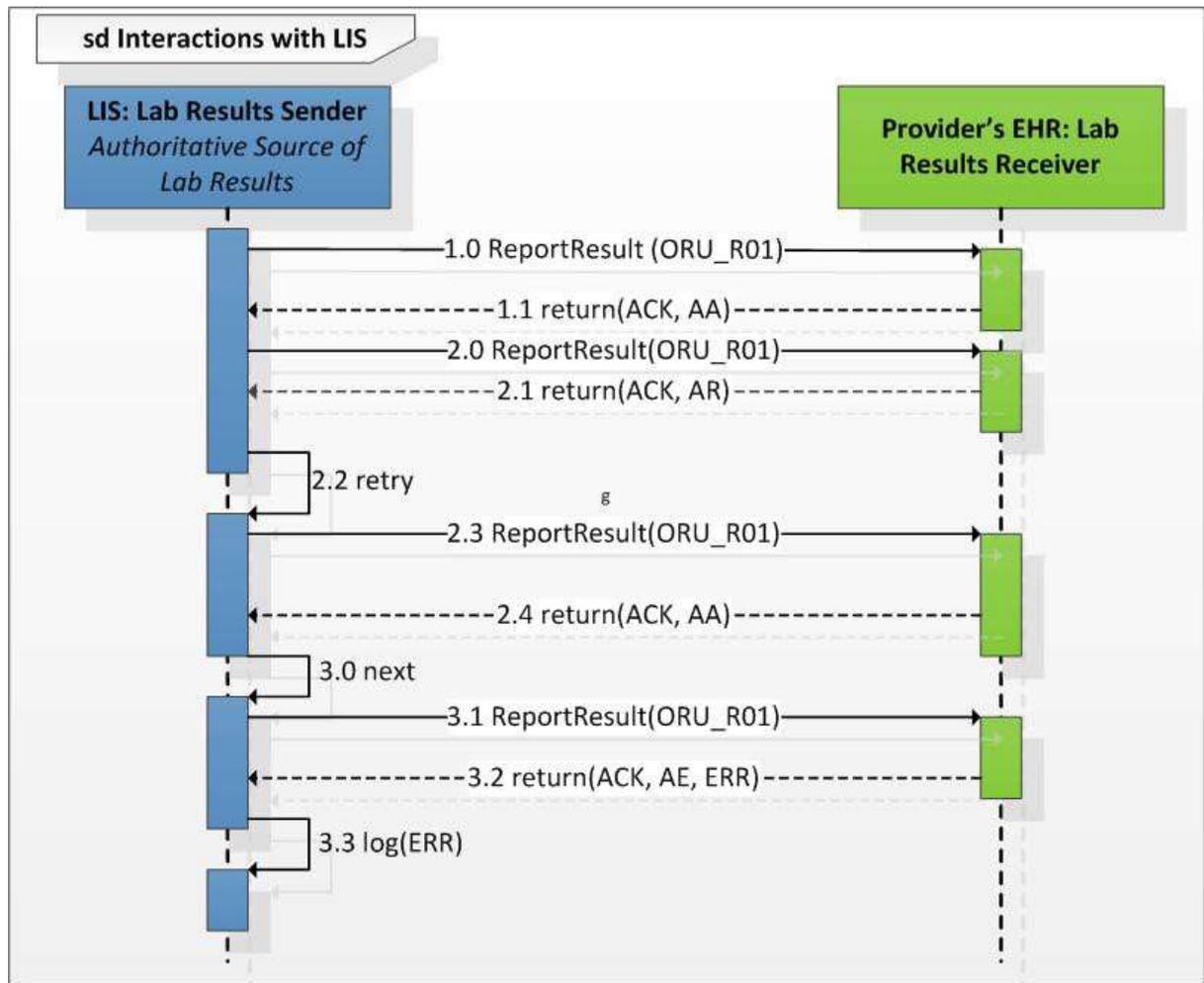


Figure 3 - Sequence Diagram

<sup>6</sup> See the <http://wiki.siframework.org/LRI+-+Structured+Data+Text+to+Include+as+Part+of+Scope>

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 (2.3). The resulting transaction is acknowledged as correct (2.4).

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

## 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 Referenced Profiles - Antecedents 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.

## 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 0) 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”<sup>7</sup>, which provides guidance on how organizations can use and manage OIDs.

## 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.

## 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

---

<sup>7</sup> The current version of the HL7 Implementation Guidance for Unique Object Identifiers (OIDs), Release 1 is available from HL7 ([www.hl7.org](http://www.hl7.org)). Members may obtain a copy without charge in the Members-only area of the site, others may purchase a copy for a nominal fee via the HL7 Store

segments (OBX, NTE and SPM, OBX). I.e., if a correction and/or status update to at least one of the OBX segments under one OBR is necessary, all OBX segments, even if previously sent, shall be resent with the correction and/or current status and/or current values. For example, when a Complete Blood Count with manual differential is ordered, the blood count will be released and then at a later time the manual differential will be performed and released. When the blood count is released the report will provide only the count as final results. When the differential is completed, Snap Shot Reporting will send all previous results as well as the new results, in this case the blood count and the differential.

### 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.

### 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<sup>8</sup>. 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.

### 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.

### Conformance to this Guide

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

---

<sup>8</sup> The referenced documents are all available from HL7 ([www.hl7.org](http://www.hl7.org)) – Members may obtain a copy without charge in the Members-only area of the site, others may purchase a copy for a nominal fee via the HL7 Store.

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. The LRI\_Common\_Component
2. The LRI\_NG\_Component
3. The LRI\_RN\_Component

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

1. LRI\_TO\_Component – Time Offset

Additional definitions and guidance for MSH-21 can be found in Section 2.3.1 MSH – Message Header Segment.

### Result Profile Components

The result components that can be assembled into profiles are:

#### 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.

#### LRI\_NG\_COMPONENT – ID: 2.16.840.1.113883.9.13

This component indicates that the identification method has been negotiated between the trading partners where none or some may use ISO OIDs according to Section 0 Use of ISO Object Identifier (OID) while others use any of the identification methods allowed through the base standard. Consequently, these identifiers are not guaranteed to be globally unique.

- MSH-3 – Sending Application
- MSH-4 – Sending Facility
- MSH-6 – Receiving Facility
- PID-3 – Patient Identifier List
- ORC-2 – Placer Order Number
- ORC-3 – Filler Order Number
- ORC-4 – Placer Group Number
- 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-25 – Performing Organization Medical Director

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

**LRI\_RN\_COMPONENT – ID: 2.16.840.1.113883.9.15**

This component indicates that the test shall be identified by using the universal service identifier in conjunction with the filler order number and, if available, the placer order number. The order numbers (placer/Filler) must be combined with the universal service identifier to uniquely identify the order.

**LRI\_TO\_COMPONENT – ID: 2.16.840.1.113883.9.22**

This component indicates the time zone component of the TS/DTM 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”)
- 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.

### **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:

2. LOI\_Common\_Component + LOI\_GU\_Component + LOI\_GU\_Component
  - a. LOI\_GU\_PRU\_Profile ID: 2.16.840.1.113883.9.17
3. LOI\_Common\_Component + LOI\_GU\_Component + LOI\_RC\_Component
  - a. LOI\_GU\_PRN\_Profile ID: 2.16.840.1.113883.9.18
4. LOI\_Common\_Component + LOI\_NG\_Component + LOI\_GU\_Component
  - a. LOI\_NG\_PRU\_Profile ID: 2.16.840.1.113883.9.19
5. LOI\_Common\_Component + LOI\_NG\_Component + LOI\_RC\_Component
  - a. LOI\_NG\_PRN\_Profile ID: 2.16.840.1.113883.9.20

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

## Response Components

### 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.

### NG\_ACKNOWLEDGEMENT\_COMPONENT - ID: 2.16.840.1.113883.9.25

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 2.16.840.1.113883.9.19 (LOI\_NG\_PRU\_Profile), **OR** 2.16.840.1.113883.9.20 (LOI\_NG\_PRN\_Profile), **OR** 2.16.840.1.113883.9.13 (LOI\_NG\_Component).

## 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. LOI\_Acknowledgement\_Component + NG\_Acknowledgement\_Component
  - a. LOI\_NG\_Response\_Profile ID - 2.16.840.1.113883.9.27

## 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 Section 0. 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.

## Scope of Implementation

The base standard indicates that receiving applications “...**SHALL** process (save/print/archive/etc.)...”. While for results specific data on the OBR, OBX, SPM, etc. this typically means saving that data, for other segments’ data, e.g., MSH data the receiving application may not always have to save it as the data is focuses on ensuring the data arrives in the appropriate place and therefore have shorter-term value.

## 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.

## **APPENDIX C - Error Conditions and Related Codes**

## APPENDIX D - Revision History

Version	Date	Author	Comments
0.5	07/11/2016	J. Shaw	First draft released for “Pilot and Trial Implementations Only”

**- END OF DOCUMENT -**