# Michigan Department of Health and Human Services

HL7 Version 2.5.1 Implementation Guide: Lab Orders – Bureau of Laboratories

Version 1.0



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#### 1. Introduction

This document has been developed by the Michigan Department of Health and Human Services (MDHHS) Bureau of Laboratories (BOL) in accordance with the policies and requirements of the State of Michigan (SOM). 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 SOM system via the Michigan Health Information Exchange (HIE) platform. To streamline interoperability, the SOM has developed local orders and results implementation guides adapted from the "HL7 Version 2.5.1 Implementation Guide: Laboratory Orders from EHR (LOI) Edition 5 - US Realm" and the "HL7 Version 2.5.1 Implementation Guide: Laboratory Results Interface (LRI), Edition 5 - US Realm".

The guide that follows is largely adapted from the "HL7 Version 2.5.1 Implementation Guide: Laboratory Orders from EHR (LOI) Edition 5 - US Realm", adjusted for the selected profiles provided below and Michigan specific items. It also includes onboarding and testing instructions along with special cases and Michigan HIE platform-related items.

- LOI\_Common\_Component
- LOI\_NG\_Component (Non-Globally Unique)
- LAB\_PRN\_Component (Non-Unique Placer Order Number)
- LAB\_FRN\_Component (Non-Unique Filler Order Number)
- LAB FI COMPONENT (Financial Information)
- LOI PH COMPONENT (Public Health)
- LAB\_TO\_COMPONENT (Time Offset)

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

- Date/Time of Birth (PID-7) is modified to data type TS-5 and shall include year, month, and day and may include hours, minutes, and seconds.
- Species Code (PID-35) and Breed Code (PID-36) are not supported; HL7 orders and results are limited to human testing.
- The SOM will ignore Result Handling (OBR-49).
- The incoming order message must include the Ordering Facility's StarLIMS Agency ID (ORC-21.10), and the related Assigning Authority (ORC-21.6) must indicate StarLIMS Agency ID. See <u>Table 14 - ORC –</u> Common Order Segment.
- The SOM does not support the Test Code Details (TCD) segment.
- The required use of Reason for Study (OBR-31) is to capture the primary reason for testing, such as diagnosis, surveillance, or outbreak. See Table 15 OBR Observation Request Segment.
- The required use of Ask at Order Entry responses for some tests. See <u>Section 4.2.2</u>. <u>Asked at Order Entry</u> (AOE) Observations.
- The required use of Specimen Information. See <u>APPENDIX D SPM Requirement</u>.
- The use of Release Information Code (IN1-27) is to indicate confidential testing, see <u>Section 4.2.5.</u> Confidential Testing.
- Cancelling and appending an order is only supported <u>before the specimen has been received</u>. After that, orders can only be changed or cancelled by contacting the lab directly. See <u>Section 4.2.1</u>. <u>Order</u> <u>Cancellation or Add-On Request After Specimen Received</u>.
- Includes Michigan HIE platform-related routing requirements. See <u>Section 4.4. Health Information</u>

#### Exchanges (HIE) and Related Requirements and Section 5.2. Onboarding Instructions.

This document takes advantage of webpage linking to ensure submitters have the most up-to-date
locally defined value sets and Test Compendium data. Hyperlinks to the SOM BOL Laboratory
Services Guide website will be prefixed with 'BOL'. For example, <u>BOL Test Orders (OML) and Results</u>
(ORU) by HL7 Messaging

NOTE: although the "HL7 Version 2.5.1 Implementation Guide: Laboratory Orders from EHR (LOI) Edition 5 - US Realm" is based on 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.

#### 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 OML Laboratory Order Message* relative to the Laboratory Orders Interface with the SOM. 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

- HL7 V2.5.1, V2.7, V2.7.1, V2.8.1 Messaging (www.HL7.org)
- SNOMED ( <a href="http://browser.ihtsdotools.org/">http://browser.ihtsdotools.org/</a>)
- LOINC (http://loinc.org)
- OIDS (http://www.hl7.org/oid)
- HL7 Version 2.5.1 Implementation Guide: Laboratory Orders from EHR (LOI) Edition 5 US Realm
- HL7 Version 2.5.1 Implementation Guide: Laboratory Results Interface (LRI), Edition 5 US Realm

# 1.2. Organization of this Guide

# 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.

Attribute	Definition
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. [00] Element never present.  [01] Element may be omitted and can have, at most, one occurrence. [11] Element must have exactly one occurrence.  [0n] Element may be omitted or may repeat up to "n" times.  [1n] Element must appear at least once, and may repeat up to "n" times. [0*] Element may be omitted or repeat an unlimited number of times.  [1*] Element must appear at least once, and may repeat unlimited number of times. [mn] Element must appear at least "m", and at most, "n" times.  Cardinality applies only to message attribute tables and segment attribute tables.
Value Set	The set of coded values to be used with the field. The value set attribute applies only to the data type attribute tables and the segment attribute tables. The value set may equate with an entire code system, part of a code system, or codes drawn from multiple code systems.  Unconstrained, Constrained, and User Defined tables are listed or included in Section 5. Code Systems and Value Sets
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 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 that includes a particular segment/field/component marked as optional **MUST** be prepared to interoperate with another implementation that does not include the optional segment/field/component.

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

### 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.

----- 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 requirement 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	An element with a conditional usage code has an associated condition predicate (See section 2.B.7.9, "Condition predicate" that determines the operational requirements (usage code) of the element.					
		If the condition predicate associated with the element is true, follow the rules for <b>a</b>					
		which shall be one of "R", "RE", "O" or X":					
		If the condition predicate associated with the element is false, follow the rules for <b>b</b>					
		which shall be one of "R", "RE", "O" or X".					
		a and b can be valued the same.					
Х	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.				

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<sup>&</sup>lt;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 of 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.

# Usage Rules for a Receiving Application

Optionality /Usage Indicator	Description	Implementation Requirement	Operational Requirement				
R	Required	The application shall implement "R" elements.	The receiving application shall process (save/print/archive/etc.) the information conveyed by a required element.				
			A receiving application shall raise an exception due to the absence of a required element. A receiving application shall not raise an error due to the presence of a required element,				
RE	Required but may be empty	The application shall implement "RE" elements.	The receiving application shall process (save/print/archive/etc.) the information conveyed by a required (but may be empty) element. The receiving application shall process the message if the element is omitted (that is, an exception shall not be raised because the element is missing).				
C(a/b)	Conditional	The usage code has an associated condition predicate true (See section 2.B.7.9, "Condition predicate").					
		If the condition predicate associated with the element is true, follow the rules for <b>a</b>					
		which shall be one of "R", "RE", "O" or X":					
		If the condition predicate associated with the element is false, follow the rules for <b>b</b>					
		which shall be one of "R", "RE", "O" or X".					
		<b>a</b> and <b>b</b> 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				
0	Optional	None. The usage indicator for this element has	information conveyed by a not-supported element.  None.				
	Ορτιοπαι 	not yet been defined. For an implementation profile all optional elements must be profiled to R, RE, C(a/b), or X.	INOTIG.				

----- end citation -----

#### 1.3. HL7 Version

This guide is written for version 2.5.1; however, several items have been pre-adopted from versions 2.7.1 and 2.8.1. These pre-adopted items are noted throughout this guide.

Submission of version 2.5.1 messages is required.

#### 1.4. SOM Point of Contact

Questions or comments should be directed to the MDHHS BOL by email: LIMS HELP@michigan.gov.

#### 1.5. Revisions of this Document

This document will be reviewed and possibly revised on an annual basis. Submitters are advised to monitor the SOM BOL Laboratory Services Guide web site: <a href="https://www.michigan.gov/mdhhs/doing-business/providers/labservices/labservicesguide/test-orders-oml-and-results-oru-by-hl7-messaging">https://www.michigan.gov/mdhhs/doing-business/providers/labservices/labservicesguide/test-orders-oml-and-results-oru-by-hl7-messaging</a> for new versions. Revisions, along with major items changed, are tracked in APPENDIX G — Revision History.

#### 1.6. Copyright Information

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This material contains references and citations to various publications from the Health Level Seven International (HL7). HL7 artifacts as well as information on the HL7 Intellectual Property Policy are available free of charge on the HL7 Standards-based Product Grid

# 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 "O" (optional) with a cardinality of up to 1, while this implementation guide defines the segment in the Usage column as "R" (required) thus a cardinality of [1..1].

The OML^O21^OML O21 message is constrained for transmitting laboratory orders from the Sender to the Receiver as defined in each Use Case.

### OML^021^OML\_021: Laboratory Order Message - New and Append Order

This message structure supports the use cases of Electronic Ordering of New or Scheduled Laboratory Test(s) and Electronic Ordering of Add-On Laboratory Test(s).

Table 2 - OML^O21^OML\_O21 New and Append Order

Segment	Name	Usage	Cardinality	Description
MSH	Message Header	R	[11]	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	0		
[{NTE}]	Notes and Comments for Header	Χ		Excluded for this Implementation Guide
[	PATIENT Begin	R	[11]	
PID	Patient Identification	R	[11]	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	0		
[{NTE}]	Notes and Comments for PID	0		
[{NK1}]	Next of Kin/Associated Parties	RE	[05]	Sender usage: 'RE'; Receiver usage: '0'
				The Next of Kin/Associated Parties is used to communicate the patient's other related parties. This is particularly important for lead testing of minors, since the NK1 is used to document information about the parent or guardian.
[	VISIT Begin	0		
PV1	Patient Visit	0		
[PV2]	Patient Visit – Additional Information	0		
]	VISIT End			

Segment	Name	Usage	Cardinality	Description
[{	INSURANCE Begin	C(R/O)	[01]	Condition Predicate: if the test ordered is a billed test. See the Laboratory Services Guide available on the BOL website for the list of BOL Billed Tests.
IN1	Insurance	C(R/O)	[01]	Condition Predicate: if the test ordered is a billed test. See the Laboratory Services Guide available on the BOL website for the list of BOL Billed Tests.
[IN2]	Insurance – Additional Information	0		
[IN3]	Insurance – Additional Information – Cert.	0		
}]	INSURANCE End			
[GT1]	Guarantor	0		
[{AL1}]	Allergy Information	0		
]	PATIENT End			
{	ORDER Begin	R	[1*]	
ORC	Order Common	R	[11]	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.  See Section 4.2.7. Laboratory Requisition for additional information.
[{	TIMING_QTY Begin	Х		Excluded for this Implementation Guide
TQ1	Timing/Quantity	Х		Excluded for this Implementation Guide
[{TQ2}]	Timing/Quantity Order Sequence	Х		Excluded for this Implementation Guide
}]	TIMING_QTY End			
	OBSERVATION_REQUEST Begin	R	[11]	
OBR	Observations Request	R	[11]	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.
[TCD]	Test Code Details	Х		Excluded for this Implementation Guide
[{NTE}]	Notes and Comments for Detail	RE	[0*]	
[{PRT}]	Participation (for Obs Request)	C(R/O)	[05]	Condition Predicate: If OBR-28 (Result Copies To) is valued.  Note: There should be one PRT for each repeat of OBR-28 (Result Copies To). Sender and receiver must also support PRT where PRT-4 is 'RCT'.
[CTD]	Contact Data	0		
[{DG1}]	Diagnosis	C(R/RE)	[0*]	Condition Predicate: if the test ordered is a billed test. See the Laboratory Services Guide available on the BOL website for the list of BOL Billed Tests.

Segment	Name	Usage	Cardinality	Description
[{	OBSERVATION Begin	RE	[0*]	
OBX	Observation/Result	R	[11]	
[TCD]	Test Code Details	0		
[{NTE}]	Notes and Comments for Details	0		
}]	OBSERVATION End			
{	SPECIMEN Begin	R	[1*]	The specimen group is required at the time of the order placement, i.e., when the provider collects the specimen. See <u>APPENDIX D – SPM Requirement</u> for details.
SPM	Specimen Information	R	[11]	The specimen information (SPM) segment describes the characteristics of a single sample. The SPM segment carries information regarding the type of specimen, where and how it was collected, who collected it, and some basic characteristics of the specimen.
[{OBX}]	Observation related to Specimen	0		
[{	CONTAINER Begin	Χ		Excluded for this Implementation Guide
SAC	Specimen Container	Χ		Excluded for this Implementation Guide
[{OBX}]	Observation related to Container	Χ		Excluded for this Implementation Guide
}]	CONTAINER End	Χ		Excluded for this Implementation Guide
}	SPECIMEN End			
	OBSERVATION_ REQUEST End			
[{FTI}]	Financial Transaction	0		
{[CTI]}	Clinical Trial Identification	0		
[BLG]	Billing Segment	0		
}	ORDER End			

### **USAGE NOTE**

When placing an add-on order, the specimen information that the order is intended to be added onto SHALL be included, i.e., when the provider adds an order to the specimen that they collected.

# OML^021\*OML\_021: Laboratory Order Message - Cancel Order

This message structure supports the use case of Requesting the Cancellation of a Previously Placed Laboratory Order.

Table 3 - OML^O21^OML\_O21 Cancel Order - Ordering Provider Initiated

Segment	Name	Usage	Cardinality	Description
MSH	Message Header	R	[11]	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	0		
[{NTE}]	Notes and Comments for Header	Х		Excluded for this Implementation Guide
[	PATIENT Begin	R	[11]	
PID	Patient Identification	R	[11]	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	Х		Excluded for this Implementation Guide
[{NTE}]	Notes and Comments for PID	X		Excluded for this Implementation Guide
[{NK1}]	Next of Kin/Associated Parties	Х		Excluded for this Implementation Guide
	VISIT Begin	Х		Excluded for this Implementation Guide
PV1	Patient Visit	Х		Excluded for this Implementation Guide
[PV2]	Patient Visit – Additional Information	Х		Excluded for this Implementation Guide
VISIT End		-	-	
[{	INSURANCE Begin	Х		Excluded for this Implementation Guide
IN1	Insurance	Х		Excluded for this Implementation Guide
[IN2]	Insurance – Additional Information	Х		Excluded for this Implementation Guide
[IN3]	Insurance – Additional Information – Cert.	Х		Excluded for this Implementation Guide
}]	INSURANCE End			
[GT1]	Guarantor	Х		Excluded for this Implementation Guide
[{AL1}]	Allergy Information	Х		Excluded for this Implementation Guide
]	PATIENT End			
{	ORDER Begin	R	[1*]	
ORC	Order Common	R	[11]	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.

Segment	Name	Usage	Cardinality	Description
[{	TIMING_QTY Begin	Х		Excluded for this Implementation Guide
TQ1	Timing/Quantity	Х		Excluded for this Implementation Guide
[{TQ2}]	Timing/Quantity Order Sequence	Х		Excluded for this Implementation Guide
}]	TIMING_QTY End			
	OBSERVATION_REQUEST Begin	R	[11]	
OBR	Observations Request	R	[11]	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.
[TCD]	Test Code Details	X		Excluded for this Implementation Guide
[{NTE}]	Notes and Comments for Detail	RE	[0*]	
[CTD]	Contact Data	X		Excluded for this Implementation Guide
[{DG1}]	Diagnosis	X		Excluded for this Implementation Guide
[{	OBSERVATION Begin	X		Excluded for this Implementation Guide
OBX	Observation/Result	Х		Excluded for this Implementation Guide
[TCD]	Test Code Details	X		Excluded for this Implementation Guide
[{NTE}]	Notes and Comments for Details	Х		Excluded for this Implementation Guide
}]	OBSERVATION End			
{	SPECIMEN Begin	R	[1*]	
SPM	Specimen Information	R	[11]	
[{OBX}]	Observation related to Specimen	Х		Excluded for this Implementation Guide
[{	CONTAINER Begin	X		Excluded for this Implementation Guide
SAC	Specimen Container	Х		Excluded for this Implementation Guide
[{OBX}]	Observation related to Container	X		Excluded for this Implementation Guide
}]	CONTAINER End			
}	SPECIMEN End			
	OBSERVATION_ REQUEST End			
[{FTI}]	Financial Transaction	Х		Excluded for this Implementation Guide
{[CTI]}	Clinical Trial Identification	0		
[BLG]	Billing Segment	Х		Excluded for this Implementation Guide
}	ORDER End			

### ACK^021^ACK: Laboratory Order Message - Accept Acknowledgement

This message structure supports accept level acknowledgment to indicate that the SOM has received the order message or where there has been an error that precludes application processing.

This document requires the use of HL7 Enhanced Mode processing as described in Chapter 2 of the HL7 base standard. That is, MSH-15 (Accept Acknowledgment Type) and MSH-16 (Application Acknowledgement Type) are valued by the message sender and control the creation of an accept level message and an application level acknowledgement message by the message receiver, or a node that enables transmission of the message across the various systems that may be between the sender and receiver (e.g., integration engines, HIEs, etc.). In addition to the processing outcome (MSA-1), it may also contain additional data regarding errors and warnings identified during processing by SOM. All OML^O21 messages will receive an ACK.

Table 4 - ACK^O21^ACK Abstract Message Syntax

Segment	Name	Usage	Cardinality	Description
MSH	Message Header	R	[11]	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	0		
MSA	Message Acknowledgment	R	[11]	The Message Acknowledgment Segment (MSA) contains the information sent as acknowledgment to the order message received by SOM.
[{ERR }]	Error	C(R/O)	[0*]	Condition predicate: If MSA-1 (Message Acknowledgement) is not valued 'AA' or 'CA'.

# ORL^022^ORL\_022: Laboratory Order Message - Application Acknowledgement

This message structure supports application-level acknowledgment. This message provides end-to-end delivery confirmation and may also contain additional data regarding errors and warnings identified during processing by SOM. Therefore, the ORL message is sent across all the nodes between the sender and receiver back to the originator of the New and Append Order, or the Cancel Order, so that any errors can be addressed.

Table 5 - ORL^O22^ORL\_O22 Abstract Message Syntax

Segment	Name	Usage	Cardinality	Description
MSH	Message Header	R	[11]	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.
MSA	Message Acknowledgment	R	[11]	The Message Acknowledgment Segment (MSA) contains the information sent as acknowledgment to the order message received by SOM.
[{ ERR }]	Error	C(R/O)	[0*]	Condition Predicate: If ORC-1 (Order Control) is valued 'UC' or 'UA'.
[{ SFT }]	Software	0		
[{ NTE }]	Notes and Comments (for Header)	0		
[	RESPONSE Begin	R	[11]	
[	PATIENT Begin	R	[11]	
PID	Patient Identification	R	[11]	
[{	ORDER Begin	R	[1*]	
ORC	Common Order	R	[11]	
[{	TIMING Begin	0		
TQ1	Timing/Quantity	0		
[{ TQ2 }]	Timing/Quantity Order Sequence	0		
}]	TIMING End			
	OBSERVATION_REQUEST begin	R	[11]	
OBR	Observation Request	R	[1*]	
[{	SPECIMEN Begin	0		
SPM	Specimen	0		
[{ SAC }]	Specimen Container Details	0		
}]	SPECIMEN End			
]	OBSERVATION_REQUEST End			
}]	ORDER End			
]	PATIENT End			
]	RESPONSE End			

# ACK^022^ACK: Laboratory Order Message - Accept Acknowledgement

The receiver will send an Accept Level Acknowledgement message using the following message syntax.

Table 6 - ACK^O22^ACK Abstract Message Syntax

Segment	Name	Usage	Cardinality	Description
MSH	Message Header	R	[11]	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	0		
MSA	Message Acknowledgment	R	[11]	The Message Acknowledgment Segment (MSA) contains the information sent as acknowledgment to the order message received by SOM.
[{ERR }]	Error	C(R/O)	[0*]	Condition predicate: If MSA-1 (Message Acknowledgement) is not valued 'AA' or 'CA'.

# 3. Segment and Field Descriptions

This messaging guide provides notes for required (non-optional) fields for each of the non-optional segments. For each segment the segment table defines the applicable constraints on usage for its fields for this implementation guide, see Section 1.2.2. Message Element Attributes for a description of the columns in the Segment Attribute Tables. All the relevant conformance statements and general usage notes are located at the end of each table.

# 3.1. MSH - Message Header Segment

Table 7 - MSH - Message Header Segment

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Field Separator	ST	R	[11]		
2	Encoding Characters	ST	R	[11]		Constrained to the literal values '^~\&' always appearing in the same order.
3	Sending Application	HD_02	R	[11]	HL70361	Required for Michigan HIE platform-related routing requirements. During implementation and routing there may be certain requirements.  See Section 4.4.1. Message Header Validation.
4	Sending Facility	HD_02	R	[11]	HL70362	Required for Michigan HIE platform-related routing requirements. During implementation and routing there may be certain requirements.  This facility will receive any related acknowledgment message.
5	Receiving Application	HD_MI01	R	[11]	HL70361	For OML^O21 SHALL be the literal value of 'LAN^23D0650909^CLIA' Required for Michigan HIE platform-related routing requirements.
6	Receiving Facility	HD_MI01	R	[11]	HL70362	For OML^O21 SHALL be the literal value of 'MDHHS^2.16.840.1.114222.4.3.2.2.3.161.1^ISO' Required for Michigan HIE platform-related routing requirements. This facility originates any related acknowledgment message.
7	Date/Time Of Message	TS_1	R	[11]		The time zone offset is included in MSH-7 (Date/Time Of Message) 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.
8	Security		0			
9	Message Type	MSG	R	[11]		

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SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
10	Message Control ID	ST	R	[11]		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	[11]	HL70103 (constrained)	Used during testing and onboarding. See Section 4.2 Onboarding Instructions for more information on this field. Constrained to the literal values of 'T' or 'P'.
12	Version ID	VID	R	[11]		HL7 version number used to interpret format and content of the message. Constrained to the literal value '2.5.1'.
13	Sequence Number		0			
14	Continuation Pointer		0			
15	Accept Acknowledgment Type	ID	R	[11]	HL70155	For OML^O21 SHALL be the literal value 'AL' For ORL^O22 SHALL be the literal value 'AL' For ACK SHALL be the literal value of 'NE'
16	Application Acknowledgment Type	ID	R	[11]	HL70155	For OML^O21 SHALL be the literal value 'AL' For ORL^O22 SHALL be the literal value 'NE' For ACK SHALL be the literal value of 'NE'
17	Country Code		0			
18	Character Set		0			
19	Principal Language Of Message		0			
20	Alternate Character Set Handling Scheme		0			
21	Message Profile Identifier		0			

#### **USAGE NOTE**

### **MSH-21** (Message Profile Identifier)

In the national Laboratory Orders Implementation Guide (LOI IG) the MSH-21 field is used to assert that the message conforms to a given profile and/or valid combination of components. The Michigan Implementation Guide does require the use of MSH-21 to declare profiles, but sending systems are expected to meet the constraints of a set of LOI IG component profiles as listed below.

**Table 8 - Orders Profiles** 

LOI Profile	Pre-Coordinated OID	Component OIDs	Component Name
LOI_NG_PRN_Profile	2.16.840.1.113883.9.88	2.16.840.1.113883.9.66	LOI_Common_Component
		2.16.840.1.113883.9.79	LOI_NG_Component
		2.16.840.1.113883.9.81	LAB_PRN_Component
		2.16.840.1.113883.9.80	LAB_FI_Component
		2.16.840.1.113883.9.94	LOI_PH_Component
		2.16.840.1.113883.9.22	LAB_TO_Component
		2.16.840.1.113883.9.83	LAB_FRU_Component

#### **Example:**

MSH|^~\&|SENDINGAPP|SENDINGFAC|LAN^23D0650909^CLIA|MDHHS^2.16.840.1.114222.4.3.2.2.3.161.1^ISO|202406031 40003||OML^021^OML 021|BOLO 000 NG PRN|T|2.5.1|||AL|AL

#### **Conformance Statements: LOI Order Messages**

- MSH-1 (Field Separator) SHALL contain the constant value '|'.
- MSH-2 (Encoding Characters) **SHALL** contain the constant value '^~\&'.
- MSH-9 (Message Type) SHALL contain the constant value 'OML^O21^OML\_O21'.
- MSH-12.1 (Version ID) **SHALL** contain the constant value '2.5.1'.
- MSH-15 (Accept Acknowledgement Type) SHALL contain the constant value 'AL'.
- MSH-16 (Application Acknowledgement Type) SHALL contain the constant value 'AL'.

#### **Conformance Statements: LOI\_Acknowledgement\_Messages**

- MSH-1 (Field Separator) **SHALL** contain the constant value '|'.
- MSH-2 (Encoding Characters) **SHALL** contain the constant value '^~\&'.
- MSH-9 (Message Type) **SHALL** contain the value 'ACK^O21^ACK' or 'ORL^22^ORL^O22'.
- MSH-12.1 (Version ID) **SHALL** contain the constant value '2.5.1'.
- If MSH-9 (Message Type) is 'ACK^O21^ACK', MSH-15 (Accept Acknowledgement Type) SHALL contain the constant value 'NE'.
- If MSH-9 (Message Type) is 'ACK^O21^ACK', MSH-16 (Application Acknowledgement Type) SHALL contain the constant value 'NE'.
- If MSH-9 (Message Type) is 'ORL^22^ORL^22', MSH-15 (Accept Acknowledgement Type) SHALL contain the constant value 'AL'.
- If MSH-9 (Message Type) is 'ORL^22^ORL^22', MSH-16 (Application Acknowledgement Type) SHALL contain the constant value 'NE'.

# 3.2. MSA - Acknowledgement Segment

Note that the MSA segment is included as part of the LOI\_Acknowledgement\_Messages (ACK and ORL) types.

Table 9 - MSA - Acknowledgement Segment

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Acknowledgment Code	ID	R	[11]	HL70008	
2	Message Control ID	ST	R	[11]		
3	Text Message		Χ			Excluded for this Implementation Guide
4	Expected Sequence Number		0			
5	Delayed Acknowledgment Type		Χ			Excluded for this Implementation Guide
6	Error Condition		Χ			Excluded for this Implementation Guide

#### Example:

MSA|AA|20230126ML084149717

# 3.3. ERR - Error Segment

The ERR segment is used to add error comments to the LOI\_Acknowledgement\_Message (ACK and ORL) types.

Table 10 - ERR - Error Segment

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Error Code and Location		Χ			Excluded for this Implementation Guide
2	Error Location	ERL_01	RE	[01]		Each error will have an individual ERR segment.
3	HL7 Error Code	CWE_02	R	[11]	HL70357	Used to identify issues based on conformance profile in message or to indicate an application error was identified  See Section 4.3. Error Handling for more details.
4	Severity	ID	R	[11]	HL70516	
5	Application Error Code	CWE_02	RE	[01]	HL70533	
6	Application Error Parameter		0			
7	Diagnostic Information	TX	RE	[01]		
8	User Message	TX	RE	[01]		
9	Inform Person Indicator		0			
10	Override Type		0			
11	Override Reason Code		0			
12	Help Desk Contact Point		0			

#### Example: ACK^021^ACK message

#### Example: ORL^22^ORL message

ERR|||207^Application internal error^HL70357^^^^^Missing AOE question or response|E

### 3.4. PID - Patient Identification Segment

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

**Table 11 - Patient Identification Segment** 

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Set ID – PID	SI	R	[11]		Constrained to the literal value '1'.
2	Patient ID		Χ			Excluded for this Implementation Guide
3	Patient Identifier List	CX_02	RE	[01]		This field is used by the healthcare facility to uniquely identify the patient.  Send only the patient's primary identifier (i.e., medical record number).
	Alternate Patient ID – PID		Χ			Excluded for this Implementation Guide
5	Patient Name	XPN_03	R	[11]		For anonymous testing of an HIV related test, use first name = testing and last name = anonymous.  See Section 4.2.4. Anonymous Testing for more details.
6	Mother's Maiden Name	XPN_03	RE	[01]		
7	Date/Time of Birth	TS_5	R	[11]		Shall include year, month, and day. May include hours, minutes, and seconds.
8	Administrative Sex	IS	R	[11]	HL70001	Patient's gender.
9	Patient Alias		Χ			Excluded for this Implementation Guide
10	Race	CWE_02	RE	[0*]	HL70005	The PID-10 (Race) value is provided for demographic/billing purposes, not clinical use. If the race is unknown this field should be left blank.
11	Patient Address	XAD_01	RE	[0*]		
12	County Code		Χ			Excluded for this Implementation Guide
13	Phone Number – Home	XTN_01	RE	[0*]		
14	Phone Number – Business	XTN_01	RE	[0*]		
15	Primary Language		0			

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
16	Marital Status		0			
17	Religion		0			
18	Patient Account Number		RE			
19	SSN Number – Patient		Χ			Excluded for this Implementation Guide
20	Driver's License Number – Patient		Χ			Excluded for this Implementation Guide
21	Mother's Identifier		0			
22	Ethnic Group	CWE_02	RE	[01]	HL70189	
23	Birth Place		0			
24	Multiple Birth Indicator		0			
25	Birth Order		0			
26	Citizenship		0			
27	Veterans Military Status		0			
28	Nationality		Χ			Excluded for this Implementation Guide
29	Patient Death Date and Time	TS_3	C(RE/O)	[01]		Condition Predicate: If PID-30 (Patient Death Indicator) is valued 'Y'.
30	Patient Death Indicator	ID	RE	[01]	HL70136	
31	Identity Unknown Indicator		Х			Excluded for this Implementation Guide
32	Identity Reliability Code		0			
33	Last Update Date/Time		0			
34	Last Update Facility		0			
35	Species Code		Χ			The BOL does not support animal orders and results via HL7
36	Breed Code		Х			The BOL does not support animal orders and results via HL7
37	Strain		Х			Excluded for this Implementation Guide
38	Production Class Code		Х			Excluded for this Implementation Guide
39	Tribal Citizenship		X			Excluded for this Implementation Guide,

### **USAGE NOTE**

### PID-10 (Race), PID-22 (Ethnic Group)

The use of CWE is pre-adopted from HL7 V.2.7.1.

# **Conformance Statements: LOI\_Common\_Component**

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

#### Example 1:

PID|1||PATID0001^^^ASSIGNINGAUTHORITY^MR||Brady^Bobby^^^^L|Brady^Carol^A^^^M|20220501|M||2054-5^Black or African American^HL70005|111 Main Street^Apartment 2A^DOUGLAS^MI^49406^USA^H||^^PH^^^533^336555|^^PH^^^533^337555||||^^^^^^|||H^Hispanic/Latino^HL70189||||

#### Example 2:

PID|1|||Anonymous^TESTING^^^^L||20000501|U|||||||MIDAP12345|||||||||

#### 3.5. NK1 - Next Of Kin / Associated Parties Segment

The NK1 documents the next of kin of the patient. This is particularly important for lead testing of minors, since the NK1 is used to document information about the parent or guardian for follow-up care or risk monitoring. Any associated person or organization may be identified. For anonymous testing, it is recommended that no NK1 segments be sent with the order.

Table 12 - NK1 - Next of Kin / Associated Parties Segment

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Set ID - NK1	SI	R	[11]		
2	Name	XPN_03	R	[11]		
3	Relationship	CWE_02	R	[11]	HL70063	
4	Address	XAD_01	RE	[02]		This field is required in most cases; the only case that this field may be empty is if the person the NK1 segment is referring to does not have a permanent address (i.e., homeless).
5	Phone Number	XTN_01	RE	[04]		This field is required in most cases; the only case that this field may be empty is if the person the NK1 segment is referring to does not have a phone number.
6	Business Phone Number		0			
7	Contact Role		0			
8	Start Date		0			
9	End Date		0			
10	Next of Kin / Associated Parties Job Title		0			
11	Next of Kin / Associated Parties Job Code/Class		0			
12	Next of Kin / Associated Parties Employee Number		0			

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
13	Organization Name - NK1		0			
14	Marital Status		0			
15	Administrative Sex		0			
16	Date/Time of Birth		0			
17	Living Dependency		0			
18	Ambulatory Status		0			
19	Citizenship		0			
20	Primary Language		0			
21	Living Arrangement		0			
22	Publicity Code		0			
23	Protection Indicator		0			
24	Student Indicator		0			
25	Religion		0			
26	Mother's Maiden Name		0			
27	Nationality		0			
28	Ethnic Group		0			
29	Contact Reason		Х			Excluded for this Implementation Guide
30	Contact Person's Name		Х			Excluded for this Implementation Guide
31	Contact Person's Telephone Number		0			
32	Contact Person's Address		X			Excluded for this Implementation Guide
33	Next of Kin/Associated Party's Identifiers		0			
34	Job Status		0			
35	Race		0			
36	Handicap		0			
37	Contact Person Social Security Number		Х			Excluded for this Implementation Guide
38	Next of Kin Birth Place		0			
39	VIP Indicator		0			

#### **USAGE NOTE**

### NK1-3 (Relationship), NK1-7 (Contact Role)

The use of CWE is pre-adopted from HL7 v2.7.1.

### **Conformance Statements: LOI\_Common\_Component**

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

#### **Example:**

 $\label{lem:nk1|lemady^carol^A^^^L|MTH^Mother^HL70063|111 Main Street^Apartment $2A^DOUGLAS^MI^49406^USA^H|^^PH^^^533^336555|^^PH^^^533^337555||$ 

# 3.6. IN1 - Insurance Segment

The IN1 segment contains insurance policy coverage information necessary to produce patient and insurance bills. IN1 is required for billed tests. Failing to provide both Patient and Insurance information may result in the ordering facility getting billed for testing.

Table 13 – IN1 – Insurance Segment

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Set ID - IN1	SI	RE	[01]		
2	Insurance Plan ID	CWE_02	RE	[01]	HL70072 HL70353	If no user components of HL70072 or locally defined table, use the default value of 'NA' (not applicable) from Table HL70353 CWE Status Codes or draw another appropriate value from Table HL70353.
3	Insurance Company ID	CX_02	RE	[01]		
4	Insurance Company Name	XON_04	RE	[01]		
5	Insurance Company Address	XAD_01	RE	[01]		
6	Insurance Co Contact Person		0			
7	Insurance Co Phone Number		0			
8	Group Number	ST	RE	[01]		This field contains the group number of the insured's insurance.
9	Group Name		0			
10	Insured's Group Emp ID		0			
11	Insured's Group Emp Name		0			
12	Plan Effective Date		0			
13	Plan Expiration Date	DT	RE	[01]		
14	Authorization Information		0			
15	Plan Type		0			
16	Name Of Insured	XPN_02	RE	[01]		
17	Insured's Relationship To Patient	CWE_02	RE	[01]	HL70063	
18	Insured's Date Of Birth	TS_2	RE	[01]		
19	Insured's Address	XAD_01	RE	[01]		
20	Assignment Of Benefits		0			
21	Coordination Of Benefits		0			
22	Coord Of Ben. Priority		0			
23	Notice Of Admission Flag		0			

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SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
24	Notice Of Admission Date		0			
25	Report Of Eligibility Flag		0			
26	Report Of Eligibility Date		0			
27	Release Information Code	IS	C(R/O)	[01]	HL70093 (V2.7.1)	Condition Predicate: Shall be populated when confidential testing is required. Set to 'N' in cases where confidential testing is required, and insurance should not be billed for testing.  Note: submitter is responsible for any fees related to confidential test. In all other cases it may be set to 'Y' or left blank. See <a href="Section 4.2.5">Section 4.2.5</a> . Confidential <a href="Testing">Testing</a> for additional information.
28	Pre-Admit Cert (PAC)		0			
29	Verification Date/Time		0			
30	Verification By		0			
31	Type Of Agreement Code	IS	RE	[01]	HL70098	
32	Billing Status		0			
33	Lifetime Reserve Days		0			
34	Delay Before L.R. Day		0			
35	Company Plan Code		0			
36	Policy Number	ST	RE	[01]		This field contains the individual Policy Number of the insured to uniquely identify this patient's plan.
37	Policy Deductible		0			
38	Policy Limit - Amount		0			
39	Policy Limit - Days		0			
40	Room Rate - Semi-Private		Χ			Excluded for this Implementation Guide
41	Room Rate - Private		Χ			Excluded for this Implementation Guide
42	Insured's Employment Status		0			
43	Insured's Administrative Sex		0			
44	Insured's Employer's Address		0			
45	Verification Status		0			
46	Prior Insurance Plan ID		0			

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
47	Coverage Type		0			
48	Handicap		0			
49	Insured's ID Number		0			
50	Signature Code		0			
51	Signature Code Date		0			
52	Insured's Birth Place		0			
53	VIP Indicator		0			

#### **USAGE NOTE**

### IN1-2 (Insurance Plan ID), IN1-17 (Insured's Relationship

**To Patient)** The use of CWE is pre-adopted from HL7 V.2.7.1.

#### **Conformance Statements: LAB FI Component**

• IN1-1 (Set ID – IN1) **SHALL** be valued with the constant value '1'.

### Example 1:

### Example 2:

IN1|2|NA|38334|Molina Healthcare of Michigan|PO Box
6789^^Lansing^MI^48933^USA^L|||G001234567|||||||Brady^Bobby^^^^L|SEL|19770323|111 Main Street^Apartment
2A^DOUGLAS^MI^49406^USA^H|||||||||||||ZYX123458-1

# 3.7. ORC - Common Order Segment

The Common Order segment (ORC) is used to transmit fields that are common to all orders (all types of services that are requested).

Table 14 - ORC - Common Order Segment

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Order Control	ID	R	[11]	HL70119 (constrained)	
2	Placer Order Number	EI_MI01	R	[11]		
3	Filler Order Number	EI_MI01	RE	[01]		Filler order number is usually not known for a new order but may be known for cancel orders.
4	Placer Group Number	EI_MI01	RE	[01]		
5	Order Status		0			
6	Response Flag		0			
7	Quantity/Timing		Χ			Excluded for this Implementation Guide
8	Parent		0			
9	Date/Time of Transaction	TS_4	R	[11]		
10	Entered By		0			
11	Verified By		0			
12	Ordering Provider	XCN_MI01	R	[11]	NPI	Providers SHALL be identified using a valid NPI, the correct assigning authority for the NPI, and the name.
13	Enterer's Location		0			
14	Call Back Phone Number	XTN_01	RE	[02]		
15	Order Effective Date/Time		0			
16	Order Control Code Reason		0			
17	Entering Organization		0			
18	Entering Device		0			
19	Action By		0			
20	Advanced Beneficiary Notice Code	CWE_02	RE	[11]	HL70339	
21	Ordering Facility Name	XON_MI01	R	[11]	StarLIMS Agency ID	Ordering facilities SHALL include their StarLIMS Agency ID in ORC-21.10 and the literal value of 'StarLIMS_Agency' in ORC-21.6
22	Ordering Facility Address	XAD_01	R	[11]		

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
23	Ordering Facility Phone Number	XTN_01	R	[1*]		
24	Ordering Provider Address		0			
25	Order Status Modifier		0			
26	Advanced Beneficiary Notice Override Reason		0			
27	Filler's Expected Availability Date/Time		0			
28	Confidentiality Code		0			
29	Order Type		0			
30	Enterer Authorization Mode		0			
31	Parent Universal Service Identifier		0			

#### **USAGE NOTE**

#### **ORC-4 (Placer Group Number)**

This field allows a Laboratory Order Sender to group sets of orders together and subsequently identify them. In some environments this might be considered a single document sometimes referred to as a test requisition or test request form. In other instances, it may be group orders placed for the same instance of care or diagnosis. All the orders with the same Placer Group Number are considered siblings of each other. Regardless of how the *identifier* that groups the siblings of a care instance is labeled, ORC-4 (Placer Group Number) is where one would convey that identifier.

#### **ORC-20 (Advanced Beneficiary Notice Code)**

The use of CWE is pre-adopted from HL7 V.2.7.1.

This field provides information from the ordering provider regarding those tests that are not covered under the patient's plan, and that the patient understands the test is not covered, that the patient will be billed, and that the patient has accepted the responsibility for the cost of those tests.

#### Conformance Statements: LOI\_Common\_Component

- ORC-2 (Placer Order Number) **SHALL** be identical to the value of OBR-2 (Placer Order Number) within the same Order Group.
- ORC-3 (Filler Order Number) **SHALL** be identical to the value of OBR-3 (Filler Order Number) within the same Order Group.
- ORC-12 (Ordering Provider) **SHALL** be identical to the value of OBR-16 (Ordering Provider) within the same Order Group.

#### Example 1:

# 3.8. OBR - Observation Request Segment

Table 15 - OBR - Observation Request Segment

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Set ID - OBR	SI	R	[11]		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_MI01	R	[11]		
3	Filler Order Number	EI_MI01	RE	[01]		Filler order number is usually not known for a new order but may be known for cancel orders.
4	Universal Service Identifier	CWE_01	R	[11]	L	Local Panel Codes shall be used as the standard vocabulary to identify the ordered test in OBR-4 (Universal Service Identifier). See the Laboratory Services Guide available on the BOL website for a list of the local codes:  BOL Test Order List
5	Priority – OBR		Χ			Excluded for this Implementation Guide
6	Requested Date/Time		Χ			Excluded for this Implementation Guide
7	Observation Date/Time	TS_5	R	[11]		This represents the start date/time of the specimen collection.  Since a test may also involve drawing specimens at different times, i.e., 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.
8	Observation End Date/Time	TS_5	RE	[01]		This represents the end date/time of the specimen collection.
9	Collection Volume		0			
10	Collector Identifier		0			
11	Specimen Action Code		0			
12	Danger Code		0			
13	Relevant Clinical Information		0			

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
14	Specimen Received Date/Time		Χ			Excluded for this Implementation Guide.
15	Specimen Source		Χ			Excluded for this Implementation Guide
16	Ordering Provider	XCN_MI01	R	[11]	NPI	Providers SHALL be identified using a valid NPI, the correct assigning authority for the NPI, and the name.
17	Order Call-back Phone Number	XTN_01	RE	[02]		The number the laboratory can call with questions regarding the order. This should be a phone number associated with the original order placer.
18	Placer Field 1		0			
19	Placer Field 2		0			
20	Filler Field 1		0			
21	Filler Field 2		0			
22	Results Rpt/Status Chng - Date/Time		Χ			Excluded for this Implementation Guide.
23	Charge to Practice		0			
24	Diagnostic Service Sect ID		0			
25	Result Status		Χ			Excluded for this Implementation Guide.
26	Parent Result		0			
27	Quantity/Timing		Χ			Excluded for this Implementation Guide.
28	Result Copies To	XCN_MI02	RE	[05]		SHALL be identified using a valid StarLIMS Agency ID <sup>3</sup> , the assigning authority of 'StarLIMS', and the provider's family/last name.  NOTE: a corresponding PRT segment is required for each Result Copies To. See Section 3.10. PRT – Participation Information Segment for details.
29	Parent		0			
30	Transportation Mode		0			
31	Reason for Study	CWE_02	RE		BOL_0001	Used to identify the primary reason for the test, options include Diagnosis, Surveillance, Outbreak, etc. See the Laboratory Services Guide available on the BOL website for the local value set: BOL Reasons for Study
32	Principal Result Interpreter		0			
33	Assistant Result Interpreter		0			
34	Technician		0			
35	Transcriptionist		0			
36	Scheduled Date/Time		0			
37	Number of Sample Containers		0			

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
38	Transport Logistics of Collected Sample		0			
39	Collector's Comment		0			
40	Transport Arrangement Responsibility		0			
41	Transport Arranged		0			
42	Escort Required		0			
43	Planned Patient Transport Comment		0			
44	Procedure Code		0			
45	Procedure Code Modifier		0			
46	Placer Supplemental Service Information		0			
47	Filler Supplemental Service Information		0			
48	Medically Necessary Duplicate Procedure Reason		0			
49	Result Handling		Х			Excluded for this Implementation Guide  Note: BOL will ignore Result Handling (OBR-49) and always send results to all orders.
50	Parent Universal Service Identifier		0			

<sup>&</sup>lt;sup>3</sup> Contact the DASH unit at 517-335-8059 to find StarLIMS Agency IDs.

#### **USAGE NOTE**

# **OBR-4 (Universal Service Identifier)**

The use of CWE is pre-adopted from HL7 V.2.7.1.

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

If any of OBR-7 (Observation Date/Time), OBR-8 (Observation End Date/Time), SPM-17.1 (Range Start Date/Time), or SPM-17.2 (Range End Date/Time) contain time

zone offset, then all must contain a time zone offset.

# **OBR-28 (Result Copies To)**

Note that under the PRT segment there are two associated Conformance Statements that must be considered. See Section <u>3.10. PRT – Participation Information Segment</u>.

#### Conformance Statements: LOI\_Common\_Component

- If present, OBR-8 (Observation End Date/Time) **SHALL** be equal to or later than OBR-7 (Observation Date/Time).
- The value of OBR-1 (Set ID OBR) **SHALL** start at '1' and be incremented sequentially across the Order groups.

**Note:** For the first occurrence of the OBR segment, the Sequence number shall be one (1), for the second occurrence, the Sequence number shall be two (2), etc. For each order group, the prior results OBR-1 is set to 1 with the first occurrence, and then increments sequentially, as shown in the example below:

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

#### Conformance Statements: LAB\_FRU\_Component

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

#### **Example:**

```
OBR|1|P01042261|F01042261|1320^HIV Ag/Ab - Serum^L||202405211400||||||0001011111^PROVIDERLASTNAME^PROVIDERFIRSTNAME^^^^^NPI^^^NPI|^^PH^^^313^3 456789|||||||||RFS01^Diagnosis^BOL_0001
```

# 3.8.1. Result Handling and Result Copies To

In this implementation guide OBR-28 (Result Copies To) is populated with the identities of any providers to whom the ordering provider would like to send copies of the test result (copy-to providers). This is limited to five (5) Result Copies To.

While a method of identifying result copies has been provided in this specification, the SOM is not obligated to comply with result copy requests when the lab is unable to validate the end point.

When OBR-28 is populated, additional information describing the address or other contact information of the copy-to provider(s) shall also be provided in the PRT segment. The number and sequence of the copy-to providers listed in the PRT segments shall match the number and sequence of the copy-to providers listed in the OBR-28 field of the preceding OBR segment.

# 3.9. NTE - Notes and Comments Segment

Table 16 - NTE - Notes and Comments Segment

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Set ID – NTE	SI	R	[11]		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		0			
3	Comment	FT	R	[1*]		Comment contained in the segment.
4	Comment Type		0			

# 3.10. PRT - Participation Information Segment

In this guide, PRT shall only be used in support of Result Copies to as describe in <u>Section 4.2.6</u>. Results Copied To; any other use is beyond the scope of this guide. Note this segment is from version 2.7.1.

**Table 17 - PRT - Participation Information Segment** 

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Participation Instance ID	EI_MI01	R	[11]		
2	Action Code	ID	R	[11]		Constrained to 'AD' from HL7 0287 Action Codes
3	Action Reason		0			
4	Participation	CWE_02	R	[11]		Constrained to 'RCT' from HL7 0912 Participation
5	Participation Person	XCN_MI02	R	[11]		SHALL be identified using a valid StarLIMS Agency ID <sup>4</sup> , the assigning authority of 'StarLIMS', and the provider's family/last name.
6	Participation Person Provider Type		0			
7	Participant Organization Unit Type		0			
8	Participation Organization		0			
9	Participant Location		0			
10	Participation Device		0			
11	Participation Begin Date/Time (arrival time)		0			
12	Participation End Date/Time (departure time)		0			
13	Participation Qualitative Duration		0			
14	Participation Address	XAD_01	C(R/RE)	[01]		Condition Predicate: If PRT-15 is not valued.
15	Participant Telecommunication Address	XTN_01	RE	[05]		

<sup>&</sup>lt;sup>4</sup> Contact the DASH unit at 517-335-8059 to find StarLIMS Agency IDs.

# **USAGE NOTE**

If the proceeding OBR segment has three providers listed in OBR-28 (Results Copy To) field, then exactly three PRT segments shall follow the OBR segment. **PRT segments MUST be in the same order as the order of providers listed in OBR-28.** 

#### Conformance Statements: LOI\_Common\_Component

- PRT-2 (Action Code) **SHALL** be valued with 'AD'.
- For each value in OBR-28 (Result Copies To) a corresponding PRT (Participant Information) **SHALL** be present with PRT-4.1 (Participation Identifier) valued 'RCT'.
- For each PRT (Participant Information) where PRT-4.1 (Participation Identifier) is valued 'RCT', there must be a corresponding value in OBR-28 (Result Copies To) equal to PRT-5 (Participation Person).

#### **Example:**

PRT|1|AD||RCT^Result Copies To^HL70912|8175000004^Dorian^JD^^^^^StarLIMS|||||||3255 122nd Avenue Suite 200^^Allegan^MI^49010|^^PH^^^586^4560987 
PRT|2|AD||RCT^Result Copies To^HL70912|8175000005^Turk^Christopher^^^^^StarLIMS|||||||8923 Miami St^Sterling Heights^MI^48313|^PH^^^586^9081287 
PRT|3|AD||RCT^Result Copies To^HL70912|8175000006^Reid^Elliot^^^^StarLIMS||||||5643 Guitar Rd^^Lansing^MI^49010|^PH^^^517^7089087 
PRT|4|AD||RCT^Result Copies To^HL70912|8175000007^Cox^Perry^^^StarLIMS||||||6547 Drums St^\*Iint^MI^48507|^PH^^^810^4502369 
PRT|5|AD||RCT^Result Copies To^HL70912|8175000008^Kelso^Bob^^^^StarLIMS||||||300 Monroe Avenue NW^Grand Rapids^MI^49503|^PH^^^734^3127896

# 3.11. DG1 - Diagnosis Segment

DG1 Segment is required for all billable tests and is strongly encouraged for all others.

Table 18 - DG1 - Diagnosis Segment

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Set ID - DG1	SI	R	[11]		
2	Diagnosis Coding Method		Χ			Excluded for this Implementation Guide.
3	Diagnosis Code - DG1	CWE_02	R	[11]	ICD-10CM	
4	Diagnosis Description		Χ			Excluded for this Implementation Guide.
5	Diagnosis Date/Time		0			
6	Diagnosis Type	IS	R	[11]	HL70052	
7	Major Diagnostic Category		Χ			Excluded for this Implementation Guide.
8	Diagnostic Related Group		Χ			Excluded for this Implementation Guide.
9	DRG Approval Indicator		Χ			Excluded for this Implementation Guide.
10	DRG Grouper Review Code		Χ			Excluded for this Implementation Guide.
11	Outlier Type		Χ			Excluded for this Implementation Guide.
12	Outlier Days		Χ			Excluded for this Implementation Guide.
13	Outlier Cost		Χ			Excluded for this Implementation Guide.
14	Grouper Version And Type		Χ			Excluded for this Implementation Guide.
15	Diagnosis Priority	ID	RE	[01]	HL70359	
16	Diagnosing Clinician		0			
17	Diagnosis Classification		0			
18	Confidential Indicator		0			
19	Attestation Date/Time		0			
20	Diagnosis Identifier		Χ			Excluded for this Implementation Guide.
21	Diagnosis Action Code		Χ			Excluded for this Implementation Guide.

# **USAGE NOTE**

# DG1-3 (Diagnosis Code - DG1)

The use of CWE is pre-adopted from HL7 V.2.7.1.

# Conformance Statements: LOI\_Common\_Component

- The value of DG1-1 (Set ID DG1) **SHALL** be valued sequentially starting the value '1' within a given OBSERVATION\_REQUEST segment group.
- Only one instance of DG1-15 (Diagnosis Priority) in the message **SHALL** contain the value '1'.

# **Example:**

DG1|1||Z11.3^Screen for STD (sexually transmitted disease)^I10|||F||||||

# 3.12. OBX - Observation/Result Segment

Note: Components 26 through 29 are pre-adopted from Version 2.8.1

Table 19 - OBX - Observation/Result Segment

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Set ID – OBX	SI	R	[11]		For the first repeat of the OBX segment, the sequence number shall be one (1), for the second repeat, the sequence number shall be two (2), etc.
2	Value Type	ID	C(R/X)	[01]	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_01	R	[11]	Local Codes	For Ask at Order Entry (AOE), use correct local code.  Note: AOEs are required for some lab tests. See the Laboratory Services Guide available on the BOL website for the list of BOL AOEs by Test Order Code. See 4.2.2. Asked at Order Entry (AOE) Observations for more details.
4	Observation Sub-ID	ST	C(R/O)	[01]		Condition Predicate: If there are multiple OBX segments associated with the same OBR segment that have the same Local Code in OBX-3.
5	Observation Value	Varies	R	[01]		Note: Allowable data types for this field are described in HL7 table 0125 (from OBX-2).
6	Units	CWE_03	C(R/O)	[01]		Condition Predicate: If OBX-2 (Value Type) is 'SN' or 'NM' Use of UCUM is required as the units when the data type in OBX-2 is 'SN' or 'NM'
7	References Range		0			
8	Abnormal Flags		0			
9	Probability		0			
10	Nature of Abnormal Test		0			
11	Observation Result Status		0			
12	Effective Date of Reference Range		0			
13	User-Defined Access Checks		0			
14	Date/Time of the Observation	TS_5	C(R/O)	[01]		Condition Predicate: If OBX-5 is valued.

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SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
15	Producer's Reference		0			
16	Responsible Observer		0			
17	Observation Method		0			
18	Equipment Instance Identifier		0			
19	Date/Time of the Analysis		0			
20	Reserved for harmonization with Version 2.6.		X			Excluded for this Implementation Guide.
21	Reserved for harmonization with Version 2.6.		Х			Excluded for this Implementation Guide.
22	Reserved for harmonization with Version 2.6.		Х			Excluded for this Implementation Guide.
23	Performing Organization Name		0			
24	Performing Organization Address		0			
25	Performing Organization Medical Director		0			
26	Patient Results Release Category		0			
27	Root Cause		0			
28	Local Process Control		0			
29	Observation Type	ID	R		HL70936 (V2.8.1)	Constrained to 'QST' from HL7 0936 Observation Type

#### **USAGE NOTE**

# **OBX-3 (Observation Identifier)**

The use of CWE in, OBX-5 (Observation Value) and OBX-6 (Units) is pre-adopted from HL7 V.2.7.1.

#### **OBX-5 (Observation Value)**

Note that OBX-5 (Observation Value) does not repeat in this IG. When an AOE allows for multiple answers, then each response SHALL be sent in a separate OBX (Observation/Result Segment). For each OBX segment under the OBR segment, the combination of OBX-3 (Observation Identifier) and OBX-4 (Observation Sub-ID) SHALL create a unique identification.

# **OBX-29 (Observation Type)**

AOEs are sent as OBX segments after the OBR it applies to, but before the SPM. AOE OBX segments include OBX-29 (Observation Type) as valued "QST", a

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#### Conformance Statements: LOI\_Common\_Component

- The value of OBX-1 (Set ID OBX) **SHALL** be valued sequentially starting the value '1' within a given segment group.
- The value of OBX-5 (Observation Value) **SHALL NOT** be truncated.
- If there are multiple OBX segments associated with the same OBR segment that have the same OBX-3 (Observation Identifier) values for (OBX-3.1 (Identifier) and OBX-3.3 (Name of Coding System) or (OBX-3.4 (Alternate Identifier) and OBX-3.6 (Name of Alternate Coding System)), a combination of (OBX-3.1 and OBX-3.3) or (OBX-3.4 and OBX-3.6) and OBX-4 (Observation Sub-ID) SHALL create a unique identifier under a single OBR.

#### **Examples:**

# Limited Response AOE OBX|1|ST|AOE25^Pregnant?^BOL\_0002||No||||||202406031400|||||||||QST Free Text Response AOE OBX|1|ST|AOE01^MDHHS Prior Approval Name^BOL\_0002||Test Approved by C. Dixon||||||202406031400|||||||||QST Date Response AOE OBX|1|ST|AOE13^Onset Date^BOL 0002||10/23/2022|||||||202406031400||||||||QST

# 3.13. SPM - Specimen Segment

#### Table 20 - SPM – Specimen Segment

SEQ	Element Name	DT	Usage	Cardinality	Value	Description/Comments
					Set	
1	Set ID – SPM	SI	R	[11]		
2	Specimen ID	EIP_MI01	RE	[01]		
3	Specimen Parent IDs		0			
4	Specimen Type	CWE_03	R	[11]	SNOMED CT / Local	See the Laboratory Services Guide available on the BOL website for a list of valid specimen sources for each test order.  BOL Specimen Source List
5	Specimen Type Modifier		0			
6	Specimen Additives		0			
7	Specimen Collection Method		0			

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SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
8	Specimen Source Site		0			
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	ST	RE			
15	Specimen Handling Code		0			
16	Specimen Risk Code		0			
17	Specimen Collection Date/Time	DR_1	R	[11]		SPM-17.1 and SPM-17.2 must use TS_5 for the data type definition.
18	Specimen Received Date/Time		0			
19	Specimen Expiration Date/Time		0			
20	Specimen Availability		0			
21	Specimen Reject Reason		0			
22	Specimen Quality		0			
23	Specimen Appropriateness		0			
24	Specimen Condition		0			
25	Specimen Current Quantity		0			
26	Number of Specimen Containers		0			
27	Container Type		0			
28	Container Condition		0			
29	Specimen Child Role		0			

# **USAGE NOTE**

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

# **Example:**

SPM|1|SID1042261||119364003^Serum specimen (specimen)^SCT|||||||20240521140

# 4. Use Case, Special Cases and Error Conditions

#### 4.1. Use Case

This Use Case has four scenarios:

- Scenario 1: Electronic Ordering of New or Scheduled Laboratory Test(s)
- Scenario 2: Electronic Ordering of Add-On Laboratory Test(s)
- Scenario 3: Requesting the Cancellation of a Previously Placed Laboratory Order
- Scenario 4: Laboratory Cancellation of a Previously Placed Laboratory Order

# 4.1.1. Scenario 1: Electronic Ordering of New or Scheduled Laboratory Test(s)

Using an EHR System, a Provider (*Order Placer*) orders one or more new laboratory tests or scheduled laboratory tests (including future tests) to be performed by a laboratory.

Table 21 - Scenario 1 Electronic Ordering of New or Scheduled Laboratory Test

SEQ	System	Requirements	Main Messages and Key Data
1	EHR-S	Generates an Electronic Laboratory Order with Standardized Structured Data	
2	EHR-S to SOM	Sends Laboratory Order Requisition	OML^O21^OML_O21: ORC-1 (Order Control Code) is valued 'NW'. ORC-2/OBR-2 (Placer Oder Number) is valued. ORC-3/OBR-3 (Filler Order Number) is empty. MSH-15 (Accept Acknowledgement Type) is valued '(AL)', MSH-16 (Application Acknowledgement Type) is valued '(AL)'.
3	SOM	Receives and Processes Electronic Laboratory Order	
4	SOM to EHR-S	Generates and Sends Laboratory Order Acknowledgement (Accept Level Acknowledgement)	ACK^021^ACK: MSA-2 (Message Control ID) is valued same as MSH-10 in the message being acknowledged. MSH-15 is valued 'NE', MSH-16 is valued 'NE'.
5	EHR-S	Receives and Processes Laboratory Order Acknowledgement (Accept Level Acknowledgement)	
6	SOM to EHR-S	Generates and Sends Laboratory Order Acknowledgement (Application Level Acknowledgement)	ORL^O22^ORL_O22: ORC-1 (Order Control Code) is valued 'OK' or 'UA'. ORC-2/OBR-2 (Placer Oder Number) is valued (echoed). ORC-3/OBR-3 (Filler Order Number) is valued. MSH-15 is valued '(AL)', MSH-16 is valued 'NE'.
7	EHR-S	Receives and Processes Laboratory Order Acknowledgement (Application Level Acknowledgement)	
8	EHR-S to SOM	Generates and Sends Acknowledgement to Laboratory Order Acknowledgement (Accept Level Acknowledgement)	ACK^022^ACK: MSA-2 (Message Control ID) is valued same as MSH-10 in the message being acknowledged. MSH-15 is valued 'NE', MSH-16 is valued 'NE'.
9	SOM	Receives and Processes Acknowledgement to Laboratory Order Acknowledgement (Accept Level Acknowledgement)	

#### 4.1.2. Scenario 2: Electronic Ordering of Add-On Laboratory Test(s)

Using an EHR System, a Provider (Order Placer) adds one or more additional tests to a previously transmitted test requisition. Any electronic changes to the order by the Order Placer, including adding a test, must be done <u>before</u> the specimen has been received by the laboratory. See <u>Section 4.2.1. Order Cancellation or Add-On Request After Specimen Received</u>.

Note that if there is no need to relate the additional order to the specimen associated with a prior order, the regular new order must be followed.

At the time the provider requests an order to be added, this may occur when the specimen is already drawn or still needs to be drawn. The provider may not know which situation is in place.

Therefore, this guide suggests that until there is more clarity on how the provider's ordering system is updated with specimen collection information, the provider's add-on order request is communicated as a regular order and may use, if known:

- The placer order number, when using non-unique order numbers, of the original order; and/or
- The placer group number that was used when the original order was placed; and/or
- The specimen data of the specimen the order is intended to be added to.

Using the first two methods make it appear, other than the transaction date/time, as if the order was placed together and consistent with the original order.

The third method clearly associates the new order with the same specimen that was already collected for a prior order. Note that depending on the state of the order fulfillment, the Laboratory may not be able to perform the requested test against the intended specimen as it may be too late for several reasons (e.g., insufficient specimen, specimen too old).

# 4.1.3. Scenario 3: Requesting the Cancellation of a Previously Placed Laboratory Order

The Provider (*Order Placer*) determines that one or more orders from a previously transmitted electronic laboratory requisition needs to be cancelled and requests via the EHR that the Laboratory cancel the performance of the laboratory order(s). Any electronic changes to the order by the Order Placer must be made <u>before</u> the specimen has been received by the laboratory.

The Provider must use the use the LOI Cancel Request message in <u>OML^O21^OML\_O21</u>: <u>Laboratory Order Message – Cancel Order</u>, given they do not know if the laboratory has received the patient specimen or begun the testing process.

The Laboratory determines whether the test can be cancelled, or whether the order has progressed too far to cancel. In either case the Laboratory should reply with an Application Level Acknowledgment as defined in <a href="Mailto:ORL^O22\*ORL">ORL O22: Laboratory Order Message — Application Acknowledgment</a> and populate the ORC-1 Order Control field appropriately. ("CR" for Canceled as Requested, or "UC" for Unable to Cancel.)

Once the Provider receives any preliminary or final results, the test cannot be cancelled anymore, and the Provider shall not use the LOI Cancel Request message anymore. See <u>Section 4.2.1. Order Cancellation or Add-On Request After Specimen Received.</u>

Table 22 - Scenario 3 Requesting the Cancellation of a Previously Placed Laboratory Order

SEQ	System	Requirements	Main Messages and Key Data
1	EHR-S	Generates Laboratory Order Cancellation Request	
2	EHR-S to SOM	Sends Laboratory Order Cancellation Request	OML^O21^OML_O21: ORC-1 (Order Control Code) is valued 'CA'. ORC-2/OBR-2 (Placer Oder Number) is valued. ORC- 3/OBR-3 (Filler Order Number) is valued if known. MSH-15 is valued '(AL)', MSH-16 is valued '(AL)'.
3	SOM	Receives and Processes Laboratory Order Cancellation Request	
4	SOM to EHR-S	Sends Acknowledgement of Cancellation Request	ACK^O21^ACK: MSH-15 is valued 'NE', MSH-16 is valued 'NE'.
5	SOM	Processes Order Cancellation Request (Determines whether it can cancel the order or not)	
6	SOM to EHR-S		ORL^O22^ORL_O22: ORC-1 (Order Control Code) is valued 'CR' or 'UC'. ORC-2/OBR-2 (Placer Oder Number) is valued. ORC-3/OBR-3 (Filler Order Number) is valued. MSH-15 is valued '(AL)', MSH-16 is valued 'NE'.
7	EHR-S	Receives Notification of Laboratory Order Cancellation	
8	EHR-S	Sends Acknowledgement of Laboratory Order Cancellation Notification	ACK^O22^ACK: MSH-15 is valued 'NE', MSH-16 is valued 'NE'.
9	SOM	Receives and Processes Acknowledgement to Laboratory Order Cancellation Notification (Accept Level Acknowledgement)	

#### 4.2. Special Cases

In addition to the items below, as Special Cases and Error Conditions emerge, the most current information maybe found on the Laboratory Services Guide website at <u>BOL Test Orders (OML) and Results</u> (ORU) by HL7 Messaging.

# 4.2.1. Order Cancellation or Add-On Request After Specimen Received

Cancelling and appending an order is only supported <u>before</u> the specimen has been received by the laboratory. After that, orders can only be changed or canceled by contacting the lab directly by calling DASH at 517-335-8059.

If appending an order before the specimen has been received, include the original order in the message.

# 4.2.2. Asked at Order Entry (AOE) Observations

Ask at Order Entry responses are recorded as observations that provide critical information for the calculation or interpretation of some lab results or to satisfy state and federal health agency mandated information gathering requirements.

AOE responses can take several formats, including but not limited to:

- Free Text Response AOEs AOEs answers are sent in the data type of ST.
   Example: Free form fields to document prior results like "Results of Syphilis Testing Performed"
- Limited Response AOEs AOEs answers are sent in the data type of ST but are constrained to a limited value set of answers. Note possible answers are separated by commas and are case-sensitive (must be in UPPER CASE).

Example: Yes/No (or coded pick lists) to answer questions like "Pregnant?"

• Date Response AOEs - AOEs answers are sent in the data type of DT, and all have the data type of TS\_5. Example: A date format for the date when symptoms first started like "Onset Date"

Many of the tests performed by the BOL <u>require</u> Asked at Order Entry (AOE) observations. Refer to the Asked at Order Entry (AOE) Observations link on the Laboratory Services website for the most up-to-date required AOEs by test order in red text at <a href="https://www.michigan.gov/mdhhs/">https://www.michigan.gov/mdhhs/</a>-

/media/Project/Websites/mdhhs/Folder1/Folder2/MDHHS Bureau of Laboratories Asked at Order Entry Observations by Test.pdf?rev=cc64b5668a4d449fbe0d5f031026a3d9&hash=A3D5DF51C7CB37DEE7E8CF6C5203A28

Depending on the test that is being ordered, failure to provide AOE(s) may result in an error handling, delays in testing, delays in results availability and follow-up from lab staff to collect the AOE information. When required AOEs are not provided, a Reject ORL^O22^ORL\_O22 response will require error handling. See <a href="Section 4.3. Error Handling">Section 4.3. Error Handling</a>.

#### **MDHHS Prior Approval AOE**

MDHHS Prior Approval is provided after consultation with the MDHHS Bureau of Disease Control, Prevention and Epidemiology (517-335-8165) for tests that require them.

Providers may consult the Laboratory Services Guide at (<a href="http://www.michigan.gov/mdhhs/0,5885,7-339-71551">http://www.michigan.gov/mdhhs/0,5885,7-339-71551</a> 2945 5103 26138-362966--,00.html) for the most current BOL tests that require prior approval.

#### **Table 23 - MDHHS Prior Approval AOE**

Value	Description	Value Set	Comments
AOE01	MDHHS Prior Approval: Name	BOL_0002	The "Name" data type is ST. The AOE response requires the name of the MDHHS Epidemiology staff member who provided the consult.

#### **Outbreak Identifier AOE**

An Outbreak Identifier name is provided after consultation with the MDHHS Bureau of Disease Control, Prevention and Epidemiology (517-335-8165) for tests that require them.

Providers may consult the Laboratory Services Guide at (<a href="http://www.michigan.gov/mdhhs/0,5885,7-339-71551">http://www.michigan.gov/mdhhs/0,5885,7-339-71551</a> 2945 5103 26138-362966--,00.html) for the most current BOL tests that require an Outbreak Identifier.

#### **Table 24 - Outbreak Identifier AOE**

Value	Description	Value Set	Comments
AOE05	Outbreak Identifier	BOL_0002	The data type is ST. The AOE response requires the Outbreak Id name provided by MDHHS Epidemiology.

#### **Prepaid AOEs**

Prepaid test requisitions must be ordered from MDHHS and are used to circumvent fees associated with some billable tests. Prepaid test requisitions must be included with the specimen when packaged and the form control number inputted as an AOE response.

Providers may consult the Laboratory Services Guide at (<a href="https://www.michigan.gov/mdhhs/doing-business/providers/labservices/test-request-forms">https://www.michigan.gov/mdhhs/doing-business/providers/labservices/test-request-forms</a>) to order the prepaid test requisitions.

**Table 25 - Prepaid AOEs** 

Value	Description	Value Set	Comments
AOE04	Form Control Number (please list)	BOL_0002	The data type is ST. The AOE response requires the control number on the prepaid requisition.
AOE09	Accounting Control#	BOL_0002	The data type is ST. The AOE response requires the control number on the prepaid requisition.

#### 4.2.3. 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.

#### 4.2.4. Anonymous Testing

Anonymous testing is allowed for HIV-related tests, but the specimen must be labeled with at least two unique identifiers as described in <u>Section 4.2.8</u>. <u>Labeling of Clinical Specimens</u>. For anonymous testing, Release Information Code (IN1-27) shall be populated with an 'N', and the patient's first name should be

set to 'testing' and last name set to 'anonymous' in PID-5. It is also recommended that no NK1 segments are sent with the order. See the Laboratory Services Guide available at (<a href="http://www.michigan.gov/mdhhs/0,5885,7-339-71551">http://www.michigan.gov/mdhhs/0,5885,7-339-71551</a> 2945 5103 26138-362966--,00.html) for more information on what tests this anonymous testing applies to. The Michigan Drug Assistance Program number (or MIDAP#), if applicable, may be input as an AOE Observation.

#### 4.2.5. Confidential Testing

Although all test results are considered confidential, some of the tests conducted by BOL require, by Michigan law, additional confidentiality, and will not be submitted to insurance for billing. These can include sexually transmitted diseases on minors and HIV related tests. To indicate an order is being submitted for confidential testing, Release Information Code (IN1-27) shall be populated with an 'N'. These orders will not be submitted to insurance or billed. Note, that the submitter is responsible for any fees related to confidential testing.

# 4.2.6. Results Copied To

This guide supports the use of OBR-28 (Result Copies To). Both OBR-28 and a corresponding PRT segment are required for each Result Copies To destination. Result Copies To destinations are limited to 5. Submitters are required to properly identify the destination, ensure that they have a legal right to see the results, and notify the destination that results may be coming. BOL will make every effort to deliver results to each Result Copies To destination in the message, but if the destination cannot be located or contacted by BOL staff, results may NOT be sent. Submitters are strongly encouraged to have any destination contact the BOL at the information listed in Section 1.5 MDHHS Point of Contact prior to including the destination in any orders. Destinations should also be listed in the MiHIN Health Provider Directory (HPD) with full contact information. Destinations are also encouraged to have populated the MiHIN HPD with Electronic Services Information (ESI) for lab results; this will allow for HL7 delivery of results for the destination.

PRT segments MUST be in the same order as the order of providers listed in OBR-28.

See Section <u>3.8 OBR – Observation Request Segment</u>, <u>3.10 PRT – Participation Information Segment</u> and <u>XCN - Extended Composite ID Number and Name for Persons for more details</u>.

# 4.2.7. Laboratory Requisition

The Laboratory Requisition is a set of information that constitutes an official request for one or more laboratory tests to be performed on an individual patient. A laboratory requisition is specified in a clinical setting and communicated to a laboratory as a discrete paper or electronic artifact. Laboratory requisitions always include at least one test order. In terms of an HL7 order transaction, the Laboratory Requisition represents one or more orders (ORC/OBR pairs) transmitted as part of the same OML^O21^OML\_O21 new or append order message.

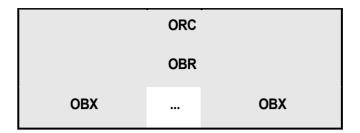
MDHHS HL7 Version 2.5.1 Implementation Guide: Lab Orders – Bureau of Laboratories

**Orderable Test or Laboratory Order** – A request to perform an individual test or panel. A single Order (ORC/OBR pair) requests one or more measurements (Observation Groups (OBXs)).

A single Order (ORC)

Which contains an Orderable Test (OBR)

Which requests one or more Measurements (OBXs)



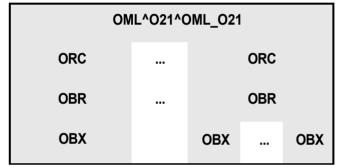
**Requisition** – One or more Orderable Test (ORC/OBR pairs) transmitted as a new or appended order message (OML^O21^OML O21).

A requisition (OML)

Which Contains multiple Orders (ORCs)

Which contains an Orderable Test OBR)

Which requests one or more Measurements (OBXs)



# 4.2.8. Labeling of Clinical Specimens

Please read instructions pertaining to individual test units for more specific instructions.

- 1. Use containers (mailing units) are provided by the MDHHS Bureau of Laboratories for the collection and transport of specimens.
- 2. The specimen must be properly identified with <u>two</u> unique identifiers clearly written on the specimen container; both identifiers must match the HL7 order exactly. Examples of acceptable patient identifiers include patient last & first name, date of birth, medical record number (MRN), MIDAP#, and specimen accession number. The BOL reserves the right to not report testing results unless all required information is provided. Unlabeled or mislabeled specimens will not be tested.
- 3. If the patient (or a family member) is to collect the specimen, it may be necessary to write the patient's name on the container prior to dispensing the container. Please instruct the patient on the proper specimen collection method.
- 4. Please submit specimens in the appropriate transport containers. Do not submit cultures in petri plates as they are easily broken.
- 5. The use of barcodes is encouraged for key identifiers.

#### 4.2.9. Required Packing Slip

A packing list is required. This packing list must include:

- 1. Date shipped
- 2. Ordering facility's:
  - a. Name
  - b. Address
  - c. Telephone number, fax number and/or an email address where problems may be reported by the receiving laboratory
- 3. Count of specimens included in shipment
- 4. For each included specimen:
  - a. Same two unique specimen identifiers that appear on the specimen. See Section 1.6.
  - b. Patient information, unless anonymous testing is required:
    - i. Full Name
    - ii. Date of birth
    - iii. Medical Record Number or equivalent
  - c. Test(s) requested
  - d. Type of specimen

This packing list may be combined with items to address US DOT and IATA regulations related to shipping clinical specimens. The use of barcodes is encouraged for key identifiers. An example of a preferred specimen packing list may be found on the BOL Laboratory Services Guide website at <a href="http://www.michigan.gov/mdhhs/0,5885,7-339-71551">http://www.michigan.gov/mdhhs/0,5885,7-339-71551</a> 2945 5103 26138-362966--,00.html.

# 4.2.10. Shipping Clinical Specimens

When shipping clinical specimens, US DOT and IATA regulations require an itemized list of contents be included in the package and placed between the secondary and outer containers. A packing list of specimens being submitted will suffice to meet these regulations. Example of a preferred specimen packing list: See IATA Packing Instructions 650 and Packing Instructions 620 and US DOT 49 CFR Part 173.196.

# 4.3. Error Handling

This section describes the error conditions that might happen, related message acknowledgments, and expected or required actions of the submitter. SOM's default is to Acknowledge all messages, even successful messages.

Content in MSA-1, ERR-3, and ERR-5 is being combined to differentiate between "hard" and "soft" errors.

See <u>APPENDIX E - Error Conditions and Related Codes</u> for a full listing of error codes and related information.

In the cases where a message was not completely successful, the submitter will receive an Acknowledge message with an Error ("CE" or "AE") or Reject ("CR" or "AR") Acknowledgment Code. Table 28 Below outlines the various error connections and corresponding Acknowledgment Code (MSA-1) and Error Codes

(ERR-3). Any message that receives a Reject Acknowledgment Code will require error handling. Any message that receives an Error Acknowledgment Code and Severity (ERR-4) of "E" will require error handling. Any message that receives an Error Acknowledgment Code and Severity (ERR-4) of "W" or "I" may require error handling. See below for more details.

Table 26 - Example Error Conditions and Related MSA and ERR Codes

Error Condition	MSA-1	ERR-3 <sup>5</sup>
Missing Required Segment	Reject or Error	100
Missing Required Field	Reject or Error	101
Data Type Error	Reject or Error	102
Wrong Message Type	Reject	200
Unsupported Event Code	Reject	201
Unsupported HL7 Version ID	Reject	203
Unknown Key Identifier	Reject	204
Duplicate key identifier	Reject	205
Application Internal Error	Reject or Error	207
Application Unavailable	Reject	900
Application Down for Planned Maintenance	Reject	901
Unauthorized Submitter	Reject	952

<sup>&</sup>lt;sup>5</sup> This is a combination of the HL7 Table 0357 and additional HIE-related (MiHIN) error codes.

#### 1.1.8. Successful Messages – AA or CA

Any message that receives an Accept ("AA" or "CA") Acknowledgment Code is considered a successful message, and no error handling is needed.

#### 1.1.9. Non-Fatal Processing Errors – AE or CE

Any message that receives an Error ("AE" or "CE") Acknowledgment Code is considered to have a non-fatal processing error(s) and *may* require error handling. All Error messages should be investigated by the original sender. Any message with an ERR-4 Severity of "E" or error must be investigated. This means the transaction was unsuccessful, and the receiving system did NOT receive the required information. Note that most Error messages will have a severity of "I" or "W". Most severe Error messages are addressed during the testing and onboarding processes. For sending systems that do not support the ERR segment, all Error messages should be investigated, as there is no way to determine severity. It is strongly recommended utilizing the ERR segment.

In some cases, Error messages may be able to be remediated out-of-band through some human or third-party data quality tool.

#### 1.1.10. Fatal Processing Errors – AR or CR

Any message that receives a Reject ("AR" or "CR") Acknowledgment Code is considered to have a fatal processing error (s) and *will* require error handling. All Reject messages require some level of error handling, but in some cases it can be automated. For example, if a receiving system is down, an

automatic re-transmission after 10 minutes is appropriate. See System Unresponsive – Special Case below for more details.

If there are any errors, especially in the MSH, PID, and required OBX segments, then the message is rejected, and SOM will respond with an ACK error message.

Examples of issues that may cause a message to be rejected include:

- Message violates HL7 2.5.1 standard.
- Message is missing required field or segment.
- Value is not valid for the given type (i.e., there is an alphanumeric data value in a date field) or is not a recognized valid value.
- Value is inconsistent with other values given in the same message.

#### 1.1.11. System Unresponsive – Special Case

Since these messages will flow though HIEs and include multiple hops, a special error case is needed if the intermediary hops are available, but the end destination is not. In this case a Reject ACK and a special unresponsive ERR-3 Error Code and MSA-3 Text Message entries are used. It is recommended that the sending system retransmit the message once every ten (10) minutes until it receives a responsive ACK. The special unresponsive ERR-3 Error Code and MSA-3 Text Message entries are any items listed in Table 46 - HL7 Table 0357 —

Message Error Condition Codes. This currently includes 900 "Receiving system unresponsive" and 901 "Receiving system down for maintenance." In some cases, the HIE will already handle this error; contact your HIE for more information.

# 1.2. Health Information Exchanges (HIE) and Related Requirements

#### 1.2.1. Message Header Validation

Health Information Exchanges or other intermediaries should evaluate the message header for required fields before submission to the State.

Table 27 - OML^O21 Message Header Validation

MSH Field	Field Name	Requirements
MSH-4	Sending Facility	Must be populated with an OID
MSH-5	Receiving Application	Must be populated with 'LAN'23D0650909^CLIA'
MSH-6	Receiving Facility	Must be populated with 'MDHHS^2.16.840.1.114222.4.3.2.2.3.161.1^ISO'
MSH-11	Processing ID	"T" (training or testing) or "P" (production). See Section 4.2 "On- boarding Instructions" for details on this field during the onboarding process.
MSH-12	Version ID	Must be populated with 2.5.1

# 1.2.2. ACK Messages Handling

Health Information Exchanges or other intermediaries will receive ACK messages from MDHHS and shall return these messages back to the provider site that submitted them to MDHHS. The return of all ACK messages, including 'AA' messages, is required. In cases where returning the ACK to the original sender site would cause undue harm, this requirement can be waved on a case-by-case basis.

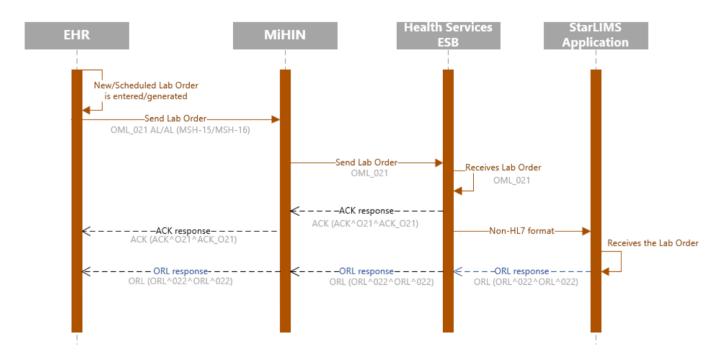
# 5. Message Transport and Onboarding

# 5.1. Message Transport Options

Messages must be sent through Michigan's Health Information Exchange (HIE) infrastructure or other SOM approved methods to Health Services ESB at the SOM. 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 <a href="http://mihin.org/exchanges/">http://mihin.org/exchanges/</a>. For additional information, contact the staff listed in <a href="Section 1.4 SOM Point of Contact">Section 1.4 SOM Point of Contact</a> Contact for other options.

Figure 1 - Message Dataflow

Scenario: Electronic ordering of new/ scheduled Lab Test



MiHIN is a pass-through intermediary (there may be hops between the EHR & MiHIN). For the Lab Order (OML\_O21), Enhanced Acknowledgment Mode, i.e., MSH-15 (Accept Acknowledgment Type = AL) and MSH-16 (Application Acknowledgement Type = AL) are valued by the message sender and control the creation of a node-to-node accept level message and an end-to-end application level acknowledgement message by the message receiver, or a node that enables transmission of the message across the various systems that may be between the sender and receiver (e.g., integration engines, HIEs, etc.). The flow from Health Services ESB to the StarLIMS application may not be HL7 format.

# **5.2. Onboarding Instructions**

The onboarding process ensures that all messages are complete and of good quality before allowing a new submitter to enter production. It is a multi-step process described below.

#### 5.2.1. Pre-Production Onboarding

Prior to entering 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 SOM 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 items via a different process. All Pre-Production Onboarding must be coordinated with SOM staff. Contact staff listed in <a href="Section 1.4">Section 1.4</a> SOM Point of Contact to start pre-production testing and onboarding.

#### 5.2.2. 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.** 

#### **5.2.3. Testing After Entering into Production**

If for any reason a submitter wishes to test messages after entering into production (i.e., 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.

#### **5.2.4. 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 listed in <a href="Section 1.4 SOM Point of Contact">Section 1.4 SOM Point of Contact</a>. The onboarded ordering facility must provide a contact to the SOM in the case that there is retesting needed. If system updates impact functionality, then the ordering facility must stop transmitting electronic orders until the problem is resolved.

# 6. 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 coded 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 allowed for use in a particular message.

The subsets of the codes that are allowed for a particular field are identified by a 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.

#### **6.1. LOINC**

The code values passed in OBR-4 (Universal Service Identifier) and OBX-3 (Observation Identifier) are drawn from a code system that may have either a globally unique identifier, such as the Logical Observation Identifiers Names and Codes (LOINC) vocabulary value set, or a locally defined identifier (local test code).

The laboratory's local test code and coding system shall be sent to identify the order, and the test name should be sent. In addition, LOINC shall be used as the standard vocabulary to identify the ordered test in the Universal Service Identifier (OBR-4) when an applicable LOINC code is available and identified by the laboratory. If an appropriate orderable LOINC code is provided by the laboratory (i.e. in its electronic Directory of Service/Test Compendium [eDOS]), it SHOULD be sent along with a LOINC test description as defined in the published LOINC specification.

When no valid orderable LOINC code exists, the local code may be the only code sent. Notes:

- The LOINC Common Laboratory Orders Value Set is available and can be used as a 'starter set' for
  mapping commonly used laboratory orders. It does not attempt to include all possible laboratory order
  codes. For additional information on LOINC Common Laboratory Orders Value Set, refer to
  www.loinc.org/usage/orders.
- 2. The sender shall always populate the first triplet before populating other triplets; the receiver shall examine all triplets to find relevant values. A triplet consists of three components: the code, the text description of the code, and the code system name. When populating the 3<sup>rd</sup> component to indicate the laboratory's local test order code, the name of the coding system SHOULD be formatted "99zzz", where zzz is replaced by an alphanumeric character sequence that identifies the lab. The use of "L" is also allowed. If a LOINC code is sent as an identifier, the name of the coding system shall be "LN".

3. Universal Service Identifier is a required field in the OBR segment. However, the values transmitted by the order placer in this field for an order message may not be the same values placed in this field of a generated result message created by the order filler.

#### **EXAMPLES:**

An OML Order transmitted by the placer for BOL's Syphilis Panel consisting of the BOL local order code.

| 1120°C. TRACHOMATIS AND N. GONORRHOEAE NON-CULTURE - BILLING°L|

The generated ORU Result by the filler for BOL's Syphilis Panel consisting of both the local order code and the corresponding LOINC order code

|45076-7^CHLAMYDIA TRACHOMATIS+NEISSERIA GONORRHOEAE RRNA^LN^2748^C. TRACHOMATIS + N. GONORRHOEAE NON-CULTURE^L|

For further information on LOINC and access to tools, please visit <a href="http://loinc.org/">http://loinc.org/</a>

#### 6.2. SNOMED CT

SNOMED CT is a recommended vocabulary as specified throughout this guide, i.e., for specimen source terms in SPM-4 (Specimen type) when a SNOMED CT code is available.

Note that in some instances, a code must be drawn from a declared hierarchy in SNOMED CT, i.e., SPM-4 (Specimen type); terms should be drawn from the "specimen hierarchy"; see the field comments wherever SNOMED CT is identified as the value set.

Support for SNOMED CT shall include the code and the description text as described by IHTSDO. Further information on SNOMED CT can be found at the National Library of Medicine (http://www.nlm.nih.gov/research/umls/Snomed/snomed\_main.html).

#### 6.3. UCUM

Use of UCUM is recommended as one of the delivered units (could be in addition to the local units). Further information on UCUM can be found at <a href="http://unitsofmeasure.org/">http://unitsofmeasure.org/</a>

#### 6.4. Unconstrained Code Systems

This section provides a list of unconstrained code systems and value sets used in this IG; refer to the base standard. It also provides information about the source of the vocabulary. The name found in the Value Set column corresponds with the value set identified in the Value Set column of the data type and segment attribute tables in this guide.

**Table 28 - Unconstrained Code System Summary** 

Name	Value Set	Source	Comments
Administrative Sex	HL70001	HL7 Version 2.5.1	
Patient Class	HL70004	HL7 Version 2.5.1	
Race Category	HL70005	HL7 Version 2.5.1	
Acknowledgment Code	HL70008	HL7 Version 2.5.1	
Diagnosis Type	HL70052	HL7 Version 2.5.1	
Relationship	HL70063	HL7 Version 2.5.1	
Yes/No Indicator	HL70136	HL7 Version 2.5.1	
Accept/Application Acknowledgment Condition	HL70155	HL7 Version 2.5.1	
Ethnic Group	HL70189	HL7 Version 2.5.1	
Address Type	HL70190	HL7 Version 2.5.1	
Telecommunication equipment type	HL70202	HL7 Version 2.5.1	
Advanced Beneficiary Notice Code	HL70339	HL7 Version 2.5.1	Represents the minimum required set of values supported by this IG; the set can be expanded.
CWE Status Codes	HL70353	HL7 Version 2.5.1	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.
Diagnosis Priority	HL70359	HL7 Version 2.5.1	
Application	HL70361	HL7 Version 2.5.1	User defined; there are no suggested values.
Facility	HL70362	HL7 Version 2.5.1	User defined; there are no suggested values.
Country Value Set	HL70399	HL7 Version 2.5.1	This identifies the codes for the representation of names of countries, territories and areas of geographical interest. Use 3-character (alphabetic) form of ISO 3166 for HL7 Table 0399 as defined in HL7 Chapter 2, Section 2.15.9.17. The complete set of 3166-1 codes is available at <a href="http://www.iso.org/iso/home/standards/country_codes.htm">http://www.iso.org/iso/home/standards/country_codes.htm</a>
Error severity	HL70516	HL7 Version 2.5.1	
County	FIPS 6-4		Codes representing county of origin, address county, reporting county.
Logical Observation Identifiers Names and Codes	LOINC	LOINC	http://www.loinc.org
National Provider Identifier	NPI	NPI	NPI Search
SNOMED CT		SNOMED CT	http://www.nlm.nih.gov/research/umls/Snomed/snowed/snomed/snomed/snomed/snomed/snomed/snowed/snomed/snowed/snomed/snowed/snomed/
State Value Set	USPS	USPS	Identifies addresses within the United States are recorded using the USPS two-letter alphabetic codes for the State, District of Columbia, or an outlying area of the United States or associated area. See <a href="http://pe.usps.com/text/pub28/28apb.htm">http://pe.usps.com/text/pub28/28apb.htm</a>

#### 6.5. Constrained HL7 Tables - Value Sets

This section provides a list of the modified code systems and value sets based on HL7 defined tables used in this IG. Modifications are either constraints or additions to HL7 tables by pre-adopting future versions of the tables. The name found in the Value Set column corresponds with the value set identified in the Value Set column of the data type and segment attribute tables found elsewhere in this document.

**Table 29 - Constrained Code System Summary** 

Name	Value Set	Source	Comments
Message Type	HL70076	HL7 Version 2.5.1	
Release Information	HL70093	HL7 Version 2.7.1	
Processing ID	HL70103	HL7 Version 2.5.1	
Order Control Codes	HL70119	HL7 Version 2.8.1	
Value Type	HL70125	HL7 Version 2.5.1	
Action Code	HL70287	HL7 Version 2.5.1	Constrained to 'AD'
Name Type Code	HL70200	HL7 Version 2.5.1	
Identifier Type	HL70203	HL7 Version 2.7.1	
Universal ID Type	HL70301	HL7 Version 2.7.1	
Message structure	HL70354	HL7 Version 2.5.1	
Coding Systems	HL70396	HL7 Version 2.5.1	
Participation	HL70912	HL7 Version 2.7.1	Constrained to 'RCT'
Observation Type	HL70936	HL7 Version 2.8.1	Constrained to 'QST'

# 6.5.1. HL7 TABLE 0076 - Message Type (V2.5.1)

Table 30 - HL7 TABLE 0076 - Message Type

Value	Description	Comments
OML	Unsolicited transmission of an observation message	
ACK	General acknowledgment message	
ORL	Application acknowledgement message	

# 6.5.2. HL7 TABLE 0093 - Release of Information (V2.7.1)

Table 31 - HL7 TABLE 0093 - Release of Information

Value	Description Comments	
N	No	
Υ	Yes	

# 6.5.3. HL7 TABLE 0103 - Processing ID (V2.5.1)

Table 32 - HL7 TABLE 0103 - Processing ID

	Value	Description Comments	
	T	Training	
Γ	Р	Production	

# 6.5.4. HL7 TABLE 0119 - Order Control Codes (V2.8.1)

Table 33 - HL7 TABLE 0119 - Order Control Codes

Value	Description	Comments
CA	Cancel order/service request	
CR	Canceled as requested	
NW	New order/service	
OC	Order/service canceled	
OK	Order/service accepted & OK	
UA	Unable to accept order/service	
UC	Unable to cancel	

# 6.5.5. HL7 TABLE 0125 - Value Type (V2.5.1)

# Table 34 - HL7 TABLE 0125 - Value Type

Value	Description	Comments
DT	Date	The Date Response AOEs answers all have the data type of TS_5 (YYYYMMDD) and may be sent as either the DT or ST data type
ST	String Data	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.  The Date Response AOEs, Free Text Response AOEs, and the Limited Response AOEs may be sent as ST data type.

# 6.5.6. HL7 TABLE 0200 - Name Type (V2.5.1)

# Table 35 - HL7 TABLE 0200 - Name Type

Value	Description	Comments
L	Legal Name	
S	Coded Pseudo-Name to ensure anonymity	
M	Maiden Name	
U	Unspecified	

# 6.5.7. HL7 TABLE 0203 - Identifier Type (V2.7.1)

#### Table 36 - HL7 TABLE 0203 - Identifier Type

Value	Description	Comments
ANON	Anonymous identifier	
MR	Medical record number	
NPI	National provider identifier	
XX	Organization identifier	

# 6.5.8. HL7 TABLE 0301 - Universal ID Type (V2.7.1)

# Table 37 - HL7 TABLE 0301 - Universal ID Type

Value	Description	Comments
CLIA	Clinical Laboratory Improvement Amendments	Allows for the ability to designate organization identifier as a "CLIA" assigned number (for labs)
ISO	International Standards Organization Object Identifier (OID), in accordance with ISO/IEC 8824	
L	Locally defined coding entity identifier	

# 6.5.9. HL7 TABLE 0354 - Message Structure (V2.5.1)

#### Table 38 - HL7 TABLE 0354 - Message Structure

Value	Description	Comments
OML_021	Unsolicited transmission of an observation message	
ACK	General Acknowledgment Message for unsolicited transmission of an observation message	
ORL_022	General laboratory order response message	

# 6.5.10. **HL7 TABLE 0396 - Coding Systems Code (V2.5.1)**

All the values in this code set are supported with the addition of the values in the table below.

Table 39 - HL7 TABLE 0396 - Coding Systems Code

Value	Description	Comments
HL7nnnn	HL7 defined tables	Note that the literal value of "HL7nnnn" should never be sent in an instance of a message, rather, "nnnn" should be replaced with the table ID. For example, HL70005 for the HL7 table used in PID-10 (Patient Race).
L	Local	
LN	LOINC	
SCT	SNOMED Clinical	
	Terms	
I10	ICD-10CM	

#### 6.6 User-Defined HL7 Tables and Extended Value Sets

This section provides a list of the user defined HL7 tables as well as other code systems and value sets used in this IG; extensions are also noted here. It also provides information about the source of the vocabulary and an identifier for the vocabulary. The name found in the Value Set column corresponds with the value set identified in the Value Set column of the data type and segment attribute tables found elsewhere in this document.

**Note:** In some cases, the tables below represent extensions to the user defined HL7 table in the underlying standard and only the extensions to the base are provided, not the entire vocabulary.

**Table 40 - User Defined or Extended Code System Summary** 

Name	Value Set	Source	Comments
Insurance Plan ID	HL70072	HL7 Version 2.5.1	
Agreement Code	HL70098	HL7 Version 2.5.1	All of the values defined in the base plus one custom value (W).
Message Error Condition Codes	HL70357	HL7 Version 2.5.1	This is a combination of the HL7 Table 0357 and additional HIE-related (MIHIN) error codes.
Reason for Study	BOL Reasons for Study		This is a locally defined and dynamic value set.
Observation Identifier	BOL AOEs by Test Order Code		This is a locally defined and dynamic value set.
Universal Service Identifier	BOL Test Order List		This is a locally defined and dynamic value set.
Specimen Type	BOL Specimen Source List	HL7 Version 2.7.1	This is a combination of the HL7 Table 0487 and additional SNOMED CT Specimen hierarchy codes.

# 6.6.1. HL7 TABLE 0098 - Agreement Code

Table 41 - HL7 TABLE 0098 - Agreement Code

Value	Description	Comments
M	Maternity	
S	Standard	
U	Unified	

# 6.6.2. HL7 Table 0357 - Message Error Condition Codes

Table 42 - HL7 Table 0357 - Message Error Condition Codes

Value ERR-3.1	Description ERR-3.2	Comments ERR-3.9	Code Set ERR-3.3	Typical Severity
0	Message accepted	Success. Optional, as the AA conveys success. Used for systems that must always return a status code.	HL70357	NOT USED
100	Segment sequence error	Error: The message segments were not in the proper order, or required segments are missing.	HL70357	E
101	Required field missing	Error: A required field is missing from a segment	HL70357	Е
102	Data type error	Error: The field contained data of the wrong data type, e.g., an NM field contained "FOO".	HL70357	Е

Value ERR-3.1	Description ERR-3.2	Comments ERR-3.9	Code Set ERR-3.3	Typical Severity
103	Table value not found	Error: A field of data type ID or IS was compared against the corresponding table, and no match was found.	HL70357	Varies
200	Unsupported message type	Rejection: The Message Type is not supported.	HL70357	Е
201	Unsupported event code	Rejection: The Event Code is not supported.	HL70357	Е
202	Unsupported processing id	Rejection: The Processing ID is not supported.	HL70357	Е
203	Unsupported version id	Rejection: The Version ID is not supported.	HL70357	Varies
204	Unknown key identifier	Rejection: The ID of the patient, order, etc., was not found. Used for transactions other than additions, i.e., transfer of a non-existent patient.	HL70357	Е
205	Duplicate key identifier	Rejection: The ID of the patient, order, etc., already exists. Used in response to addition transactions (Admit, New Order, etc.).	HL70357	Varies
206	Application record locked	Rejection: The transaction could not be performed at the application storage level, i.e., database locked.	HL70357	Е
207	Application internal error	Rejection: A catchall for internal errors not explicitly covered by other codes.	HL70357	Varies

# **6.6.3. MIHIN Message Error Condition Codes**

Table 43 - HL7 Table 0357 - Message Error Condition Codes

Value ERR-3.1	Description ERR-3.2	Comments ERR-3.9	Code Set ERR-3.3	Typical Severity
900	Receiving system unresponsive	Down: The receiving system is not responsive or is down. Please retransmit the message in 10 minutes.	MIHINERR	E
901	Receiving system down for maintenance	Down: The receiving system is down for planned maintenance. Please consult mihin.org for known system maintenance windows or retransmit the message in 10 minutes.	MIHINERR	Varies
950	General routing error	Routing: A catchall for all other routing errors.	MIHINERR	Varies
951	Destination is unknown	Routing: The destination or receiving system is unknown.	MIHINERR	Е
952	Not authorized	Routing: The sending system is not authorized to send to this destination.	MIHINERR	E

# 6.6.4. BOL Table 0001 - Reason for Study OBR-31

This is a locally defined and dynamic value set. See the Laboratory Services Guide available on the BOL website for the most up to date table values: BOL Reasons for Study

# 6.6.5. BOL Table 0002 - Asked at Order Entry (AOE) Observations

This is a locally defined and dynamic value set. See the Laboratory Services Guide available on the BOL website for the most up to date table values: <u>BOL AOEs by Test Order Code</u>

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#### 6.6.6. BOL Test Order List

This is a locally defined and dynamic value set of Test Panel Codes. See the Laboratory Services Guide available on the BOL website for the most up to date table values: BOL Test Order List

# 6.6.7. BOL Specimen Source List

This is a locally defined and dynamic value set of Specimen Types incorporating HL70487 Version 2.7.1 and SNOMED CT codes. See the Laboratory Services Guide available on the BOL website for the most up to date table values: <u>BOL Specimen Source List</u>

# **APPENDIX A - Document Origins and Conformance**

#### **Conformance to this Guide**

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

The components must be combined to create a valid profile for a particular transaction.

As of this version, a valid order profile consists of the following components when the order placer sends messages to a laboratory:

- LOI\_Common\_Component
- LOI NG Component (Non-Globally Unique)
- LAB PRN Component (Non-Unique Placer Order Number)
- LAB\_FRN\_Component (Non-Unique Filler Order Number)
- LAB\_FI\_COMPONENT (Financial Information)
- LOI PH COMPONENT (Public Health)
- LAB\_TO\_COMPONENT (Time Offset)

The profile component descriptions below are taken from the National LOI IG:

#### LOI\_Common\_Component - ID: 2.16.840.1.113883.9.66

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.

#### LOI\_NG\_Component (Non-Globally Unique) - ID: 2.16.840.1.113883.9.79

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 "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-5 Receiving Application
- MSH-6 Receiving Facility
- PID-3 Patient Identifier List
- ORC-2 Placer Order Number
- ORC-3 Filler Order Number
- ORC-4 Placer Group Number
- ORC-12 Ordering Provider
- ORC-21 Ordering Facility Name
- OBR-2 Placer Order Number
- OBR-3 Filler Order Number
- OBR-16 Ordering Provider
- OBR-28 Result Copies To

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- OBR-29 Parent
- SPM-2 Specimen ID
- NK1-13 Organization Name NK13
- IN1-3 Insurance Company ID
- IN1-4 Insurance Company Name
- IN1-11 Insured's Group Emp Name
- GT1-21 Guarantor Organization Name
- PRT-1 Participation Instance ID
- PRT-5 Participation Person

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

#### LAB\_PRN\_Component (Non-Unique Placer Order Number) - ID: 2.16.840.1.113883.9.81

This component indicates that the test ordered shall be identified using the universal identifier in conjunction with the placer order number. The placer order number must be combined with the universal service identifier to uniquely identify the test ordered. This must also be taken into account when creating parent-child relationships in subsequent messages. This component can only be declared in MSH-21 by the placer and subsequently copied if the copier (e.g., filler upon responding, or another party forwarding the message) did not change the placer order number value.

#### LAB\_FRN\_Component (Non-Unique Filler Number) - ID: 2.16.840.1.113883.9.84

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

#### LAB\_FI\_Component - ID: 2.16.840.1.113883.9.80

This optional component indicates that the following segment groups and segments are specifically relevant to financial processes such as billing that may be communicated through other means than the lab order or results messages, e.g., ADT or other financial transactions.

- Visit group
- Insurance group
- GT1 segment.

#### LOI\_PH\_Component (Public Health) - ID: 2.16.840.1.113883.9.94

When a laboratory result is sent to public health, additional data is required. The PH component facilitates the inclusion of information necessary for public health reporting in the larger test order and result process between ordering providers/laboratories and performing laboratories to ensure that the data is available to be sent to PH when necessary. This profile is used to identify those fields that are to be considered for Public Health according to condition predicates and conformance statements referencing this profile component. The fields that are effectively added and/or modified by this profile are:

- PID-6 Mother's Maiden Name
- PID-13 Phone Number Home
- PID-14 Phone Number Business

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- NK1-30 Contact Person's Name
- NK1-32 Contact Person's Address
- ORC-21 Ordering Facility Name
- ORC-22 Ordering Facility Address
- ORC-23 Ordering Facility Phone Number
- SPM-5 Specimen Type Modifier
- SPM-6 Specimen Additives
- SPM-7 Specimen Collection Method
- SPM-8 Specimen Source Site
- SPM-9 Specimen Source Site Modifier
- SPM-10 Specimen Collection Site

# LAB\_TO\_Component (Time Offset) - ID: 2.16.840.1.113883.9.22

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

Note that this is a domain component, and the following fields may or may not be required in this IG:

- PID-7 Date/Time of Birth
- IN1-18 Insured's Date Of Birth
- OBR-7 Observation Date/Time
- OBR-8 Observation End Date/Time
- OBR-22 Results Rpt/Status Chng Date/Time
- TQ1-7 Start Date/Time
- TQ1-8 End Date/Time
- OBX-5 Observation Value (when OBX-2 is 'TM' or 'TS')
- OBX-14 Date/Time of the Observation
- OBX-19 Date/Time of the Analysis
- SPM-17 Specimen Collection Date/Time

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

#### **Relationship to Results**

This implementation guide imposes 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 either the original value from the order, or the best value the lab is aware of in the result message at the time the result message is generated.

This guide is intended to be compatible with the <u>HL7 Version 2.5.1 Implementation Guide: Laboratory</u> Results Interface (LRI), Edition 5 - US Realm.

## **APPENDIX B - 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. The usage of data type components for some data types varies based on the requirements of the field or component using the data type. To clearly indicate specific requirements, each data type that has a varying definition based on profile or location will be documented with multiple variations. Where possible, data type flavors defined by the National LOI IG have been used to promotes consistency with Michigan implementations. Where Michigan specific data type flavors are necessary, they have been assigned the "MI" suffix in the following sections.

#### **CWE - Coded with Exceptions**

#### CWE\_01 - Coded With Exceptions - Code Required

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

Table 44 - CWE\_01 - 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_01.1 (Identifier).
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_01.4 (Alternate Identifier) is valued.
7	Coding System Version ID	ST	C(RE/O)		Condition Predicate: If CWE_01.3 (Name of Coding System) is not an HL7 defined table or user defined.
8	Alternate Coding System Version ID	ST	0		
9	Original Text	ST	RE		Original Text is used to convey the text that was the basis for coding.
10	Second Alternate Identifier		0		
11	Second Alternate Text		0		
12	Second Name of Alternate Coding System		0		
13	Second Alternate Coding System Version ID		0		
14	Coding System OID		0		
15	Value Set OID		0		
16	Value Set Version ID		0		
17	Alternate Coding System OID		0		
18	Alternate Value Set OID		0		
19	Alternate Value Set Version ID		0		
20	Second Alternate Coding System OID		0		
21	Second Alternate Value Set OID		0		
22	Second Alternate Value Set Version ID		0		

The CWE\_01 data type is used where it is necessary to communicate a code, text, or coding system, and the version of the coding system the code was drawn from, and alternate codes drawn from another coding system. Many coded fields in this specification identify coding systems or value set attributes that must be used for the field. When populating the CWE\_01 data types with these values, this guide does not give preference to the triplet in which the standard code should appear. The receiver is expected to examine the coding system names in components CWE\_01.3 (Name of Coding System) and, if valued, CWE\_01.6 (Alternate Name of Coding System) and, if valued, to determine if it recognizes the coding system or value set.

#### CWE\_02 - Coded With Exceptions - Code Required - Second Triplet Optional

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

Table 45 - CWE\_CR1 - Coded With Exceptions - Code Required - Second Triplet Optional

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		0		
5	Alternate Text		0		
6	Name of Alternate Coding System	ID	C(R/X)	HL70396	Condition Predicate: If CWE_02.4 (Alternate Identifier) is valued.
7	Coding System Version ID	ST	C(RE/O)		Condition Predicate: If CWE_02.3 (Name Of Coding System) is valued.
8	Alternate Coding System Version ID	ST	0		
9	Original Text	ST	RE		Original Text is used to convey the text that was the basis for coding.
10	Second Alternate Identifier		0		
11	Second Alternate Text		0		
12	Second Name of Alternate Coding System		0		
13	Second Alternate Coding System Version ID		0		
14	Coding System OID		0		
15	Value Set OID		0		
16	Value Set Version ID		0		
17	Alternate Coding System OID		0		
18	Alternate Value Set OID		0		
19	Alternate Value Set Version ID		0		
20	Second Alternate Coding System OID		0		
21	Second Alternate Value Set OID		0		
22	Second Alternate Value Set Version ID		0		

#### **USAGE NOTE**

The CWE 02 data type is used where it is necessary to communicate a code was drawn from.

## CWE\_03 - Coded With Exceptions - Code Required, But May Be Empty

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

Table 46 - CWE\_03 - 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_03.1 (Identifier) is valued. It is strongly recommended that text be sent to accompany any identifier. When a coded value is not known, the original text element (CWE_03.9) is used to carry the text, not the text (CWE_03.2) element.
3	Name of Coding System	ID	C(R/X)	HL70396	Condition Predicate: If CWE_03.1 (Identifier) is valued.
4	Alternate Identifier	ST	C(RE/X)		Condition Predicate: If CWE_03.1 (Identifier) is valued. The alternate identifier (from the alternate coding system) should be the closest match for the identifier found in CWE_03.1 (Identifier).
5	Alternate Text	ST	C(RE/ X)		Condition Predicate: If CWE_03.4 (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_03.4 (Alternate Identifier) is valued.
7	Coding System Version ID	ST	C(RE/O)		Condition Predicate: If CWE_03.3 (Name Of Coding System) is not an HL7 defined table or user defined.
8	Alternate Coding System Version ID	ST	0		
9	Original Text	ST	C(R/RE)		Condition Predicate: If CWE_03.1 (Identifier) and CWE_03.4 (Alternate Identifier) are not valued. Original Text is used to convey the text that was the basis for coding. If neither the first or second triplet has values, this contains the text of the field.
10	Second Alternate Identifier		0		
11	Second Alternate Text		0		
12	Second Name of Alternate Coding System		0		
13	Second Alternate Coding System Version ID		0		
14	Coding System OID		0		
15	Value Set OID		0		
16	Value Set Version ID		0		
17	Alternate Coding System OID		0		
18	Alternate Value Set OID		0		
19	Alternate Value Set Version ID		0		
20	Second Alternate Coding System OID		0		
21	Second Alternate Value Set OID		0		
22	Second Alternate Value Set Version ID		0		

The CWE 03 data type is used where it is necessary to communicate a code was drawn from.

#### **CX - Extended Composite ID with Check Digit**

#### CX\_02 - Extended Composite ID with Check Digit (Non-Globally Unique)

Table 47 - 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	0		
3	Check Digit Scheme		0		
4	Assigning Authority	HD_02	RE		
5	Identifier Type Code	ID	R	HL70203	
				(V2.7.1)	
6	Assigning Facility		0		
7	Effective Date		0		
8	Expiration Date		0		
9	Assigning Jurisdiction		0		
10	Assigning Agency or Department		0		

#### **USAGE NOTE**

The CX\_02 data type is used to carry identifiers for individuals. 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 in this implementation guide, 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 Assigning Authority represents the identifier's name space, i.e., Healthy Hospital Medical Record Numbers, or Healthy Hospital Order Numbers. Consequently, the Identifier Type Code is technically not necessary.

## **DR - Date/Time Range**

#### DR\_1 - Date/Time Range 1

#### Table 48 - DR\_1 - Date/Time Range 1

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

## **EI - Entity Identifier**

#### EI\_MI01 - Entity Identifier (Identifier Only)

#### Table 49 - EI\_MI01 - Entity Identifier (Identifier Only)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Entity Identifier	ST	R		
2	Namespace ID	IS	0		
3	Universal ID	ST	0		
4	Universal ID Type	ID	C(R/X)	HL70301	Condition Predicate: If EI_MI01.3 (Universal ID) is valued.
	• •		, ,	(V2.7.1)	, , ,

#### **USAGE NOTE**

The EI\_MI01 data type is used to carry identifiers for the placer and filler order numbers, specimen ID, and Participation Instance ID.

#### **EIP - Entity Identifier Pair**

#### EIP\_MI01 - Entity Identifier Pair

#### Table 50 - EIP\_MI01 - Entity Identifier Pair

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Placer Assigned Identifier	EI_MI01	R		
2	Filler Assigned Identifier	El_MI01	0		

#### **USAGE NOTE**

The EIP data type has two components each of which uses the EI data type.

#### **ERL\_01 - Error Location**

#### Table 51 - ERL\_01 - Error Location

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Segment ID	ST	R		
2	Segment Sequence	NM	R	Absolute position of this segment in the message (e.g., 5th	
				OBX, regardless of the number of intervening OBRs)	

SEQ	Component Name	DT	Usage	Value Set	Comments
3	Field Position	NM	RE		
4	Field Repetition	NM	RE		
5	Component Number	NM	RE		
6	Sub-Component Number	NM	RE		

## **HD - Hierarchic Designator**

#### HD\_MI01 - Hierarchic Designator (Fully Populated)

Table 52 - HD\_MI01 - Hierarchic Designator (Fully Populated)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Namespace ID	IS	R		
2	Universal ID	ST	R		
3	Universal ID Type	ID	R		

#### **USAGE NOTE**

The HD\_MI01 data type is used directly to identify facilities and applications in the MSH segment.

#### HD\_02 - Hierarchic Designator (Non-Globally Unique)

Table 53 - HD 02 - Hierarchic Designator (Non-Globally Unique)

S	EQ	Component Name	DT	Usage	Value Set	Comments
1		Namespace ID	IS	C(R/O)		Condition Predicate: If HD_02.2 (Universal ID) is not valued.
2		Universal ID	ST	C(R/O)		Condition Predicate: If HD_02.1 (Namespace ID) is not valued.
3		Universal ID Type	ID	C(R/X)	HL70301 (V2.7.1)	Condition Predicate: If HD_02.2 (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\_02 data type is used 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.

If used, the HD\_02.2 (Universal ID) does not have to be an ISO compliant OID. It is permissible to use a human readable text string, i.e., full name of the hospital, or other value that both trading partners agree to, as long as it meets any requirements as defined by the Universal ID Type.

### **MSG - Message Type**

Table 54 - MSG - Message Type

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

## **PT - Processing Type**

Table 55 - PT - Processing Type

5	SEQ	Component Name	DT	Usage	Value Set	Comments
1	1	Processing ID	ID	R	HL70103 (constrained)	Constrained to the literal values of 'T' or 'P'
2	2	Processing Mode		0		

## **SAD - Street Address**

Table 56 - SAD - Street Address

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Street or Mailing Address	ST	R		
2	Street Name		0		
3	Dwelling Number		0		

## **TS - Time Stamp**

It is strongly recommended that the time zone offset always be included in the DTM, particularly if the granularity includes hours, minutes, seconds, etc. Specific fields in this implementation guide may require Date/Time to a specific level of granularity, which may require the time zone offset. The granularity of the DTM as well as whether the time zone offset is required is defined in the Time Stamp patterns TS 0 through TS 5, below.

#### TS\_1 - Time Stamp - Precise to Second

Table 57 - TS\_1 - Time Stamp - Precise to Second

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Time	DTM	R		
2	Degree of Precision		Χ		Excluded for this Implementation Guide.
The DT	M component of this Tim	ie Stamp l	nas the follo	owing constrair	nts:
	YYYY	DTM	R		
	MM	DTM	R		
	DD	DTM	R		
	HH	DTM	R		
	MM	DTM	R		
	SS	DTM	R		
	[.S[S[S[S]]]]		0		
	+/- ZZZZ	DTM	C(R/O)		Condition Predicate: If 'HH' is valued and the TO Component is invoked.

TS\_2 - Time Stamp - Precise to the Year, Potentially to Day

Table 58 - TS\_2 - Time Stamp - Precise to the Year, Potentially to Day

SEQ	Component Name	DT	Usage	Value Set	Comments				
1	Time	DTM	R						
2	Degree of Precision		Χ		Excluded for this Implementation Guide.				
The DT	The DTM component of this Time Stamp has the following constraints:								

SEQ	Component Name	DT	Usage	Value Set	Comments
	YYYY	DTM	R		
	MM	DTM	RE		
	DD	DTM	RE		
	HH		0		
	MM		0		
	[SS[.S[S[S]]]]]		0		
	+/- <u>7777</u>	DTM	C(RE/O)		Condition Predicate: If 'HH' is valued and the TO Component is invoked.

TS\_3 - Time Stamp - Precise to Year, Potentially to Minute

Table 59 - TS\_3 - Time Stamp - Precise to Year, Potentially to Minute

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Time	DTM	R		
2	Degree of Precision		Χ		Excluded for this Implementation Guide.
The DTI	M component of this Time	Stamp ha	s the followi	ng constraint	s:
	YYYY	DTM	R		
	MM	DTM	RE		
	DD	DTM	RE		
	HH	DTM	RE		
	MM	DTM	RE		
	[SS[.S[S[S]]]]]		0		
	+/- <u>ZZZZ</u>	DTM	C(RE/O)		Condition Predicate: If 'HH' is valued and the TO Component is invoked.

TS\_4 - Time Stamp - Unknown Date/Time In Required Field, If Year Available, Must Be Precise to Day, Potentially to Minutes

Table 60 - TS\_4 - Time Stamp - Unknown Date/Time In Required Field, If Year Available, Must Be Precise to Day, Potentially to Minutes

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Time	DTM	R		
2	Degree of Precision		Χ		Excluded for this Implementation Guide.
The DTN	A component of this Time	Stamp has	s the followi	ng constraints	
	YYYY	DTM	R		
	MM	DTM	C(R/X)		Condition Predicate: If TS_4.1 (YYYY) is not valued '0000'.
	DD	DTM	C(R/X)		Condition Predicate: If TS_4.1 (YYYY) is not valued '0000'.
	HH	DTM	C(RE/X)		Condition Predicate: If TS_4.1 (YYYY) is not valued '0000'.
	MM	DTM	C(RE/X)		Condition Predicate: If TS_4.1 (YYYY) is not valued '0000'.
	[SS[.S[S[S]]]]]		C(O/X)		Condition Predicate: If TS_4.1 (YYYY) is not valued '0000'.
	+/- ZZZZ	DTM	C(RE/O)		Condition Predicate: If 'HH' is valued and the TO Component is invoked.

When the date is not known, then value YYYY with '0000' and leave everything else empty.

#### TS\_5 - Time Stamp - Precise to Day, Potentially to Minute

Table 61 - TS\_5 - Time Stamp - Precise to Day, Potentially to Minute

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Time	DTM	R		
2	Degree of Precision		Χ		Excluded for this Implementation Guide.
The DT	M component of this Tim	e Stamp I	has the follo	owing constrai	nts:
	YYYY	DTM	R		
	MM	DTM	R		
	DD	DTM	R		
	HH	DTM	RE		
	MM	DTM	RE		
	[SS[.S[S[S]]]]]		0		
	+/- ZZZZ	DTM	C(RE/O)		Condition Predicate: If 'HH' is valued and the TO Component is invoked.

#### **VID - Version Identifier**

Table 62 - VID - Version Identifier

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Version ID	ID	R		Constrained to '2.5.1' from HL7 0104 Version ID
2	Internationalization Code		0		
3	International Version ID		0		

#### Conformance Statement – LOI\_Common\_Component

• VID.1 (Version Identifier) **SHALL** be valued with '2.5.1'.

## XAD\_01 - Extended Address

Table 63 - 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	
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		0		
9	County/Parish Code		0		
10	Census Tract		0		
11	Address Representation Code		0		

SEQ	Component Name	DT	Usage	Value Set	Comments
12	Address Validity Range		Χ		Excluded for this Implementation Guide.
13	Effective Date		0		
14	Expiration Date		0		

## **XCN - Extended Composite ID Number and Name for Persons**

## **XCN\_MI01 - Extended Composite ID Number and Name for Persons**

Table 64 - XCN\_MI01 - Extended Composite ID Number and Name for Persons

SEQ	Component Name	DT	Usage	Value Set	Comments
1	ID Number	ST	R		The ID Number component combined with XCN_MI01.13 (Identifier Type Code) must uniquely identify the associated person.
2	Family Name	FN	R		
3	Given Name	ST	R		I.e., first name.
4	Second and Further Given Names or Initials Thereof		0		
5	Suffix (i.e., JR or III)		0		
6	Prefix (i.e., DR)		0		
7	Degree (i.e., MD)		Χ		Excluded for this Implementation Guide.
8	Source Table		C(O/O)		NOTE: This component is (C) in the v2.5.1 standard with no condition predicate defined; none is defined in this IG.
9	Assigning Authority	HD_NG	0		
10	Name Type Code	ID	0		
11	Identifier Check Digit		0		
12	Check Digit Scheme		C(O/X)		Condition Predicate: If XCN_GU.11 is valued.
13	Identifier Type Code	ID	R	HL70203 (V2.7.1)	
14	Assigning Facility		0		
15	Name Representation Code		0		
16	Name Context		0		
17	Name Validity Range		Χ		Excluded for this Implementation Guide.
18	Name Assembly Order		0		
19	Effective Date		0		
20	Expiration Date		0		
21	Professional Suffix		0		
22	Assigning Jurisdiction		0		
23	Assigning Agency or Department		0		

## XCN\_MIO2 - Extended Composite ID Number and Name for Participation Persons (StarLIMS Identifier and Assigning Authority Required)

Table 65 - XCN\_MI02 - Extended Composite ID Number and Name for StarLIMS Participation Persons

SEQ	Component Name	DT	Usage	Value Set	Comments
1	ID Number	ST	R		The StarLIMS Agency ID. The ID component combined with XCN_MI02.2 (Family Name) and XCN_MI02.3 (Given Name) must uniquely identify the associated person
2	Family Name	FN	R		
3	Given Name	ST	R		I.e., first name.
4	Second and Further Given Names or Initials Thereof		0		
5	Suffix (i.e., JR or III)		0		
6	Prefix (i.e., DR)		0		
7	Degree (i.e., MD)		Χ		Excluded for this Implementation Guide.
8	Source Table		C(O/O)		NOTE: This component is (C) in the v2.5.1 standard with no condition predicate defined; none is defined in this IG.
9	Assigning Authority	HD_NG	R		The Assigning Authority component is used to identify the system, application, organization, etc. that assigned the value in XCN.1 (ID Number).
10	Name Type Code	ID	Χ		Excluded for this Implementation Guide.
11	Identifier Check Digit		Χ		Excluded for this Implementation Guide.
12	Check Digit Scheme		Χ		Excluded for this Implementation Guide.
13	Identifier Type Code	ID	Χ		Excluded for this Implementation Guide.
14	Assigning Facility		Χ		Excluded for this Implementation Guide.
15	Name Representation Code		Χ		Excluded for this Implementation Guide.
16	Name Context		Χ		Excluded for this Implementation Guide.
17	Name Validity Range		Χ		Excluded for this Implementation Guide.
18	Name Assembly Order		Χ		Excluded for this Implementation Guide.
19	Effective Date		Χ		Excluded for this Implementation Guide.
20	Expiration Date		Χ		Excluded for this Implementation Guide.
21	Professional Suffix		Χ		Excluded for this Implementation Guide.
22	Assigning Jurisdiction		Χ		Excluded for this Implementation Guide.
23	Assigning Agency or Department		Х		Excluded for this Implementation Guide.

#### **USAGE NOTE**

Used for OBR-28 (Result Copies To) and PRT-5 (Participation Person) where XCN.1 = the StarLIMS Agency ID assigned by SOM and XCN.9 = 'StarLIMS'. PRT segments MUST be in the same order as the order of providers listed in OBR-28.

# **XON – Extended Composite Name and Identification Number for Organizations**

**XON\_MIO1 – Extended Composite Name and Identification Number for Organizations** (Name and Identifier Required)

Table 66 - XON\_MI01 - Extended Composite Name and Identification Number for Organizations (Name and Identifier Required)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Organization Name	ST	R		
2	Organization Name Type Code		0		
3	ID Number		Χ		Excluded for this Implementation Guide.
4	Check Digit		0		
5	Check Digit Scheme		C(O/X)		Condition Predicate: If XON.4 is valued.
6	Assigning Authority	HD_NG	R		The Assigning Authority component is used to identify the system, application, organization, etc. that assigned the value in XON.10 (Organization Identifier).
7	Identifier Type Code	ID	0		
8	Assigning Facility		0		
9	Name Representation Code		0		
10	Organization Identifier	ST	R		

#### **USAGE NOTE**

Used for ORC-21 (Ordering Facility Name) where XON.6 = 'StarLIMS\_Agency' and XON.10 = StarLIMS Agency ID assigned by SOM.

## **XON\_02 - Extended Composite Name and Identification Number for Organizations (Non-Globally Unique)**

Table 67 - XON\_02 - 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		0		
3	ID Number		Χ		Excluded for this Implementation Guide.
4	Check Digit		0		
5	Check Digit Scheme		C(O/X)		Condition Predicate: If XON_02.4 is valued.
6	Assigning Authority	HD_02	C(R/X)		Condition Predicate: If XON_02.10 (Organization Identifier) is valued. The Assigning Authority component is used to identify the system, application, organization, etc. that assigned the value in XON_02.10 (Organization Identifier).
7	Identifier Type Code	ID	C(R/X)	HL70203 (V2.7.1)	Condition Predicate: If XON_02.10 (Organization Identifier) is valued.
8	Assigning Facility		0		
9	Name Representation Code		0		
10	Organization Identifier	ST	C(R/RE)		Condition Predicate: If XON_02.1 (Organization Name) is not valued.

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

XON\_04 - Extended Composite Name and Identification Number for Organizations (Name Only for Insurance)

Table 68 - XON\_04 - Extended Composite Name and Identification Number for Organizations (Name Only for Insurance)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Organization Name	ST	R		
2	Organization Name Type Code		0		
3	ID Number		Χ		Excluded for this Implementation Guide.
4	Check Digit		Χ		Excluded for this Implementation Guide.
5	Check Digit Scheme		Χ		Excluded for this Implementation Guide.
6	Assigning Authority		Χ		Excluded for this Implementation Guide.
7	Identifier Type Code		Χ		Excluded for this Implementation Guide.
8	Assigning Facility		Χ		Excluded for this Implementation Guide.
9	Name Representation Code		Χ		Excluded for this Implementation Guide.
10	Organization Identifier		Χ		Excluded for this Implementation Guide.

#### **USAGE NOTE**

Data Type XON\_04 is a specialization of the XON data type for the IN1 segment, specifically IN1-4 (Insurance Company Name). To avoid the duplication of information that can be messaged in the IN1-3 (Insurance Company ID) in the subcomponent of the data type (CX) that match subcomponents of the IN1-4 data type (XON), the XON data type for IN1-4 has been reduced to the XON\_04.1 (Organization Name) and XON\_04.2 (Organization Name Type Code) components which provide the unique information not provided in any other field's data component.

#### **XPN - Extended Person Name**

XPN\_03 - Extended Person Name; Family Name Required, Others Required but May Be Empty, Name Type Code Required but May Be Empty

Table 69 - XPN\_03 — Extended Person Name; Family Name Required, Others Required but May Be Empty, Name Type Code Required but May Be Empty Extended Person Name

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Family Name	FN	R		I.e., first name.
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)		0		
6	Degree (e.g., MD)		Χ		Excluded for this Implementation Guide.
7	Name Type Code	ID	RE	HL70200	

SEQ	Component Name	DT	Usage	Value Set	Comments
8	Name Representation Code		0		
9	Name Context		0		
10	Name Validity Range		Χ		Excluded for this Implementation Guide.
11	Name Assembly Order		0		
12	Effective Date		0		
13	Expiration Date		0		
14	Professional Suffix		0		

XTN\_01 - Extended Telecommunication Number

Table 70 - XTN\_01 - Extended Telecommunication Number

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Telephone Number		Χ		Excluded for this Implementation Guide.
2	Telecommunication Use Code		0		
3	Telecommunication Equipment Type	ID	R	HL70202	
4	Email Address	ST	C(R/X)		Condition Predicate: If XTN_01.3 (Telecommunication Equipment Type) is valued 'X.400' or 'Internet'.
5	Country Code		0		
6	Area/City Code	NM	C(R/X)		Condition Predicate: If XTN_01.3 (Telecommunication Equipment Type) is valued 'PH', 'CP', 'SAT', 'FX', or 'TDD'.
7	Local Number	NM	C(R/X)		Condition Predicate: If XTN_01.3 (Telecommunication Equipment Type) is valued 'PH', 'CP', 'SAT', 'FX', or 'TDD'.
8	Extension	NM	C(RE/X)		Condition Predicate: If XTN_01.3 (Telecommunication Equipment Type) is valued 'PH', 'CP', 'SAT', 'FX', or 'TDD'.
9	Any Text		0		
10	Extension Prefix		0		
11	Speed Dial Code		0		
12	Unformatted Telephone number		C(O/X)		Condition Predicate: If XTN_01.3 (Telecommunication Equipment Type) is valued 'PH', 'CP', 'SAT', 'FX', or 'TDD'.

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

## **APPENDIX C - Additional Implementation Guidance - Other**

#### I. 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 test requiest requirements. Specifics on the CLIA Regulation are found in the Federal Register <a href="https://www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments/regulations-federal-register">https://www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments/regulations-federal-register</a>.

#### II. MANDATORY ORDERING REQUIREMENTS

Section 42 CFR 493.1241 – Test Request of the CLIA Regulations requires the laboratory to have a written or electronic request for patient testing from an authorized person, and defines items that must appear as part of a clinical laboratory test request. The laboratory may accept oral requests for laboratory tests if it solicits a written or electronic authorization within 30 days of the oral request and maintains the authorization or documentation of its efforts to obtain the authorization.

Interpretative guidelines on the elements required in a test requisition may be found at <a href="https://www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments/guidelines-laboratories">https://www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments/guidelines-laboratories</a>. Specific fields impacted include the following:

**Table 71 - Mandatory Test Request Requirements** 

Segment	Field	CLIA Requirement
PID-3 PID-5	Patient Identifier List Patient Name	The patient's name or unique patient identifier.
PID-7 PID-8	Date/Time of Birth Administrative Sex	The sex and age or date of birth of the patient.
OBR-16 ORC-12 OBR-28	Ordering Provider Ordering Provider Result Copies To	The name and address or other suitable identifiers of the authorized person requesting the test and the individual responsible for using the test results.
ORC-21 ORC-22 ORC-23	Ordering Facility Name Ordering Facility Address Ordering Facility Phone Number	The name and address of the laboratory submitting the specimen
ORC-14	Call Back Phone Number	Contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values.
OBR-4	Universal Service Identifier	The test(s) to be performed.
OBX-5 (AOE)	Observation Value	For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy.
SPM-4	Specimen Type	The source (type) of the specimen, when appropriate. See Section 2.5.14 SPM – Specimen Segment for vocabulary use.
SPM-17	Specimen Collection Date/Time	The date and, if appropriate, time of specimen collection.
OBR-13 OBX-5 (AOE) OBX-3	Relevant Clinical Information Observation value Observation Identifier	Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.

#### III. REGULATORY COMPLIANCE

There may be local, state or federal regulations where the electronic message from an ordering provider is presumed to be the legal request for 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.

#### IV. AUTHORIZED PARTIES

Local laws, generally at the State level, govern who is authorized to order laboratory testing. CLIA restricts the availability of those authorized to order laboratory testing to just those approved at the local level and sets no national standards. Testing laboratories may not accept laboratory orders from unauthorized parties under CLIA.

Testing laboratories either have a trusted relationship with the ordering party or presume that the ordering party is authorized to order laboratory testing.

## **APPENDIX D - SPM Requirement**

This implementation requires the use of Specimen Information in the OML^O21^OML\_O21 Laboratory Order message. ORM^O01^ORM\_O01 messages are not supported. The OBR-15 (Specimen Source) element was retained for backward compatibility as of HL7 v2.5 and has since been withdrawn and removed from the HL7 standard as of v2.7 in favor of a dedicated specimen segment (SPM). The SPM segment takes advantage of the specimen and container extensions required in laboratory automation and contains unique attributes specific only to the SPM segment when the specimen cannot be implied in the test name. For systems which may need to convert an ORM\_O01 message to the required OML\_O21 message, the following table maps SPM fields to equivalent data elements in the OBR segment.

**Table 72 - SPM Requirement** 

SPM Segment	Field	OBR v2.5 Data Element	OBR v2.5 Data Element Name
SPM-2	Specimen ID	N/A	
SPM-4	Specimen Type	OBR-15.1	Specimen Source Name or Code
SPM-5	Specimen Type Modifier	N/A	
SPM-6	Specimen Additives	OBR-15.2	Additives
SPM-7	Specimen Collection Method	OBR-15.3	Specimen Collection Method
SPM-8	Specimen Source Site	OBR-15.4	Body Site
SPM-9	Specimen Source Modifier	OBR-15.5	Site Modifier
SPM-10	Specimen Collection Site	N/A	
SPM-14	Specimen Description	N/A	
SPM-17	Specimen Collection Date/Time	OBR-7	Observation Date/Time

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

Any message with an ERR-4 Severity of "E" or error must be investigated.

Fatal Processing Errors (Reject Acknowledgements) are NOT added to the Order application, and the submitter SHALL correct the issue(s) and resubmit the message.

Non-Fatal Processing Errors (Error Acknowledgements) are added to the Order application but are flagged as errors. StarLIMS Order staff may contact the submitter to investigate.

**Table 73 - Error Conditions and Related Codes** 

ERR-3	ERR-5	ERR-8	Error Condition	Likely causes
100^Segment sequence error^HL70357	1001^Required segment missing	PID Segment	Used when PID Segment is not in message.	<ul> <li>Missing required segment</li> </ul>
100^Segment sequence error^HL70357	1001^Required segment missing	ORC Segment	Used when ORC Segment is not in message.	<ul> <li>Missing required segment</li> </ul>
100^Segment sequence error^HL70357	1001^Required segment missing	OBR Segment	Used when OBR Segment is not in message.	Missing required segment
100^Segment sequence error^HL70357	1002^Required group missing	SPECIMEN Segment	Used when SPM Segment is not in message.	<ul> <li>Missing required segment</li> </ul>
101^Required field missing^HL70357	LIMS-FR0706A	Processing ID	Used when MSH-11 is empty.	Missing required field
101^Required field missing^HL70357	LIMS-FR0705A	Version ID	Used when MSH-12 is empty.	Missing required field
101^Required field missing^HL70357	1006^Required field missing	PatientName	Used when PID-5 is missing from the message	Missing required field
101^Required field missing^HL70357	1006^Required field missing	DateTimeOfBirth/Time/ Year	Used when patient's DOB is missing from the message	Missing required field
101^Required field missing^HL70357	1006^Required field missing	AdministrativeSex	Used when PID-8 is missing from the message	Missing required field
101^Required field missing^HL70357	1006^Required field missing	Relationship/Identifier	Used when NK1-3 is missing from the message	Missing required field
101^Required field missing^HL70357	1006^Required field missing	ORC PlacerOrderNumber	Used when ORC-2 is missing from the message	Missing required field
101^Required field missing^HL70357	1006^Required field missing	DateTimeOfTransaction/ Time/Year	Used when ORC-9 is missing from the message	Missing required field
101^Required field missing^HL70357	1006^Required field missing	OrderingProvider	Used when ORC-12, NPI is missing from the message	Missing required field
101^Required field missing^HL70357	1006^Required field missing	OrderingFacilityName	Used when ORC-21 is missing from the message	Missing required field
101^Required field missing^HL70357	1006^Required field missing	OrderingFacilityAddress	Used when ORC-22 is missing from the message	Missing required field
101^Required field missing^HL70357	1006^Required field missing	OrderingFacilityPhone Number	Used when ORC-23 is missing from the message	Missing required field
101^Required field missing^HL70357	1006^Required field missing	OBR PlacerOrderNumber	Used when OBR-2 is missing from the message	Missing required field

ERR-3	ERR-5	ERR-8	Error Condition	Likely causes
101^Required field missing^HL70357	1006^Required field missing	UniversalServiceIdentifier	Used when OBR-4 is missing from the message	Missing required field
101^Required field missing^HL70357	1006^Required field missing	OBR-OrderingProvider	Used when OBR-16, NPI is missing from the message	Missing required field
101^Required field missing^HL70357	1006^Required field missing	Comment	Used when NTE-3 is missing from the message	Missing required field
101^Required field missing^HL70357	1006^Required field missing	ActionCode	Used when PRT-2 is missing from the message	Missing required field
101^Required field missing^HL70357	1006^Required field missing	Participation	Used when PRT-4 is missing from the message	Missing required field
101^Required field missing^HL70357	1006^Required field missing	ParticipationPerson	Used when PRT-5 is missing from the message	Missing required field
101^Required field missing^HL70357	1006^Required field missing	DiagnosisCode	Used when DG1-3 is missing from the message	Missing required field
101^Required field missing^HL70357	1006^Required field missing	DiagnosisType	Used when DG1-6 is missing from the message	Missing required field
101^Required field missing^HL70357	1006^Required field missing	ObservationIdentifier	Used when OBX-3 is missing from the message	Missing required field
101^Required field missing^HL70357	1006^Required field missing	ObservationType	Used when OBX-29 is missing from the message	Missing required field
101^Required field missing^HL70357	1006^Required field missing	SpecimenType	Used when SPM-4 is missing from the message	Missing required field
101^Required field missing^HL70357	1006^Required field missing	SpecimenCollectionDate Time	Used when SPM-17 is missing from the message	Missing required field
101^Required field missing^HL70357	1006^Required field missing	ObservationDateTime/Time / Year	Used when OBR-7 is missing from the message	Missing required field
101^Required field missing^HL70357	1006^Required field missing	OrderingProvider/Family Name/Surname	Used when ORC-12, Last Name is missing from the message	Missing required field
203^Unsupported processing ID ^HL70357	LIMS-FR0706B	Rejection: The processing ID is not supported	Used when MSH-11 includes a not supported processing ID.	<ul> <li>MSH-11 does not equal T or P</li> </ul>
203^Unsupported Version ID^HL70357	LIMS-FR0705B	Rejection: The Version ID is not supported	Used when MSH-12 includes a not supported version.	<ul> <li>MSH-12 does not equal 2.5.1</li> </ul>
200^Failed to parse message^HL70357		Rejection: MessageType is not supported	Used when MSH-9 includes a not supported Message type	<ul> <li>MSH-9 does not equal to OML^O21^OML_O21</li> </ul>
204^Unknown key identifier^HL70357	LIMS-FR081102A	OrderingProvider/ID Number	Used when ORC-12 NPI field length is not equal to 10	<ul> <li>Invalid Ordering provider's NPI</li> </ul>
204^Unknown key identifier^HL70357	LIMS-FR081102C	OrderingProvider/ID Number	Used when OBR-16 NPI field length is not equal to 10	<ul> <li>Invalid Ordering provider's NPI</li> </ul>
204^Unknown key identifier^HL70357	LIMS-FR0810	StarLIMS agency ID for Ordering Facility	Used when the StarLIMS agency ID is not in ORC-21.10	Missing required field
204^Unknown key identifier^HL70357	LIMS-FR081102A	Ordering Provider's NPI	Used when the Ordering Provider's NPI is not in ORC-12.1	<ul><li>Missing required field</li><li>Ordering provider field length is not equal to 10</li></ul>

ERR-3	ERR-5	ERR-8	Error Condition	Likely causes
204^Unknown key identifier^HL70357	LIMS-FR081102C	Ordering Provider's NPI	Used when the Ordering Provider's NPI is not in OBR-16.1	<ul><li>Missing required field</li><li>Ordering provider field length is not equal to 10</li></ul>
204^Unknown key identifier^HL70357	LIMS-FR081102B	Ordering Provider's NPI	Used when the Ordering Provider's NPI is not in ORC-12.1	<ul> <li>Missing required field</li> <li>Ordering provider field length is not numeric</li> </ul>
204^Unknown key identifier^HL70357	LIMS-FR081102D	Ordering Provider's NPI	Used when the Ordering Provider's NPI is not in OBR-16.1	<ul><li>Missing required field</li><li>Ordering provider field length is not numeric</li></ul>
204^Unknown key identifier^HL70357	LIMS-FR081201A	StarLIMS Agency ID for Results Copies	Used when the StarLIMS agency ID is not in CC Provider's	<ul> <li>CC provider's StarLIMS Agency ID is not in the OML message</li> </ul>
204^Unknown key identifier^HL70357^^^^^Unknown Specimen Source			Used when the specimen source is not in the BOL Specimen Source List	Unknown Specimen Source
205^Duplicate key identifier^HL70357^^^^Duplicate Placer Order Number			Used when the Placer Order of a new order matches a previously placed order	Duplicate Placer Order
207^Application internal error^HL70357^^^^Missing AOE question or response			Used when a required AOE is not in the OML message	Missing AOE question or response
207^Application internal error^HL70357^^^^Order already received			Used when an LOI Cancel Request message is attempted after the specimen has been received at BOL	The order has progressed too far to cancel
207^Application internal error^HL70357	LIMS-FR020101-LOI- 36	PlacerOrderNumber	Used when the Filler Order Number in OBR-2 must be identical to ORC-2 in the message	Value not identical
207^Application internal error^HL70357	LIMS-FR020101-LOI- 37	FillerOrderNumber	Used when the Filler Order Number in OBR-3 must be identical to ORC-3 in the message	Value not identical
207^Application internal error^HL70357	LIMS-FR020101-LOI- 38	OrderingProvider	Used when ORC-12 and OBR-16 must be identical in the message	Value not identical
207^Application internal error^HL70357	LIMS-FR020101-LOI- 39	ParentUniversalService Identifier	Used when the Filler Order Number in OBR-31 must be identical to ORC-31 in the message	Value not identical
207^Application internal error^HL70357	LIMS-FR02010301B	Specimen Collection Date/Time is Prior to patient's DOB	Used in the case that the Specimen collection date/time in the message is prior to the patient's date of birth (DOB).	Time Stamp Error
207^Application internal error^HL70357	LIMS-FR02010302	Patient Date of Birth cannot be after the message receive date	Used in the case that the Patient's date of birth(DOB) in the message after the message Received date/time	Time Stamp Error
207^Application internal error^HL70357	LIMS-FR02010303	Observation Date/time cannot be after the message receive date	Used in the case that the observation date/time in the message is after the message Received date/time	Time Stamp Error

ERR-3	ERR-5	ERR-8	Error Condition	Likely causes
207^Application internal error^HL70357	LIMS-FR02010304	Observation EndDate/time cannot be after the message receive date	Used in the case that the observation enddate/time in the message is after the message Received date/time	Time Stamp Error
207^Application internal error^HL70357	LIMS-FR02010305	Date/time of Transaction cannot be after the message receive date	Used in the case that the date/time of transaction in the message is after the message Received date/time	Time Stamp Error
207^Application internal error^HL70357	LIMS-FR02010306B	ObservationDateTime/Time	Used when SPM-17 must be less than 60 days old in the message	Time Stamp Error
207^Application internal error^HL70357	LIMS-FR081201A	StarLIMS Agency ID for Results Copies	Used when the StarLIMS agency ID is not in CC Provider's	<ul> <li>CC provider's StarLIMS         Agency ID is not in the         OML message     </li> </ul>
207^Application internal error^HL70357	LIMS-FR020101-LOI- 50	No corresponding PRT-5 to OBR-28	Used when the OBR-28 must be identical to PRT-5 in the message	<ul> <li>Value not identical in the message</li> </ul>
900^Receiving system unresponsive^MIHINERR	FR0701	LIMS is down. Please retransmit in a few minutes	Used when the StarLIMS application is down or unresponsive.	•
901^Receiving system down for maintenance^MIHINERR	FR0702	LIMS is down for maintenance. Please retransmit after February 24, 2016 4:00:00 PM EST	Used when the StarLIMS application is down for maintenance.	•
951^Destination is unknown.^MIHINERR		MSH-5 and MSH-6	Used when Routing: The destination or receiving system is unknown.	Rejection
952^Not Authorized^MIHINERR	LIMS-FR080902	Unauthorized Submitter	Used when StarLIMS Agency ID not authorized to submit the messages	Rejection: Invalid StarLIMS Agency ID

#### **Definitions**

ERR-3 = From HL7 "HL7 Error Code to identify issues based on conformance profile in message (structure and vocabulary) or to indicate an application error was identified."

ERR-5 = From HL7 "Application Error Code to indicate error in content.." These are the SOM Order application error codes and are only meaningful to the SOM Order application technical team to uniquely identify and support troubleshooting of the error condition.

ERR-8 = From HL7 "User Message can be used to communicate the text message to be displayed to the application user." These are additional "plain English" explanations of the error condition and are included to support troubleshooting by the submitter.

## **APPENDIX F - Sample Messages**

The sample messages contained in this section of the document are for illustration purposes and should not form the basis of system design. Readers should not infer any requirements solely from these messages.

## **New Order in the OML Message**

```
MSH|^~\&|SENDINGAPP|SENDINGFAC|LAN^23D0650909^CLIA|MDHHS^2.16.840.1.114222.4.3
.2.2.3.161.1^ISO|20240521140002||OML^O21^OML O21|BOLO 000 Multi PRT 1|T|2.5.1|
||AL|AL||||LOI NG PRN Profile^LOI NG PRN PROFILE^2.16.840.1.113883.9.88^ISO
PID|1||PATID0001^^^ASSIGNINGAUTHORITY^MR||Brady^Bobby^^^^L|Brady^Carol^A^^^M
|20220501|M||2054-5^Black or African American^HL70005|111 Main
Street^Apartment
2A^DOUGLAS^MI^49406^USA^H||^^PH^^^533^336555|^^PH^^^533^337555||||^^^^^^|||H^
Hispanic/Latino^HL70189|||||N
NK1|1|Brady^Carol^A^^^M|MTH^Mother^HL70063|111 Main Street^Apartment
2A^DOUGLAS^MI^49406^USA^H|^^PH^^^533^336555|^^PH^^^533^337555||
IN1|1|NA|00111|Medicaid - Michigan|PO Box
12345^^Lansing^MI^48933^USA^L|||||||||Brady^Bobby^^JR^^^L|SEL|20220501|111
Main Street^Apartment 2A^DOUGLAS^MI^49406^USA^H||||||Y||||S||||MID01234567
GT1|1||Brady^Mike^^SR^^^L||111 Main Street^Apartment
2A^DOUGLAS^MI^49406^USA^H|||19750323|||PAR|||||||||""
ORC|NW|P0104227|F0104227|G0104227|||||202405211400||0001011111^PROVIDERLASTNA
ME^PROVIDERFIRSTNAME^^^^^NPI^^^NPI||^^PH^^^313^3456789||||||MDHHS - QUALITY
ASSURANCE SECTION^^^^StarLIMS Agency^^^345|3255 122nd Avenue Suite
200^^Lansing^MI^49010^USA^L|^^PH^^^269^6735411
OBR|1|P0104227|F0104227|1320^HIV Ag/Ab -
Serum^L|||202405211400||||||||0001011111^PROVIDERLASTNAME^PROVIDERFIRSTNAME^^
^^^^NPI^^^NPI|^^PH^^^313^3456789|||||||||8175000004^Dorian^JD^^^^^StarLIMS
~8175000005^Turk^Christopher^^^^^StarLIMS~8175000006^Reid^Elliot^^^^^StarLIM
S~8175000007^Cox^Perry^^^^^StarLIMS~8175000008^Kelso^Bob^^^^^StarLIMS|||RFS0
1^Diagnosis^BOL 0001
NTE | 1 | | Note Comment
PRT | 1 | AD | | RCT^Result Copies
To^HL70912|8175000004^Dorian^JD^^^^^StarLIMS|||||||3255 122nd Avenue Suite
200^^Allegan^MI^49010|^^PH^^^586^4560987
PRT | 2 | AD | | RCT^Result Copies
To^HL70912|8175000005^Turk^Christopher^^^^^StarLIMS|||||||8923 Miami
St^^Sterling Heights^MI^48313|^^PH^^^586^9081287
PRT | 3 | AD | | RCT^Result Copies
To^HL70912|8175000006^Reid^Elliot^^^^^StarLIMS|||||||5643 Guitar
Rd^^Lansing^MI^49010|^^PH^^^517^7089087
PRT | 4 | AD | | RCT^Result Copies
To^HL70912|8175000007^Cox^Perry^^^^^StarLIMS||||||6547 Drums
St^^Flint^MI^48507|^^PH^^^810^4502369
PRT | 5 | AD | | RCT^Result Copies
To^HL70912|8175000008^Kelso^Bob^^^^^StarLIMS|||||||300 Monroe Avenue
NW^^Grand Rapids^MI^49503|^^PH^^^734^3127896
DG1|1||Z11.3^Screen for STD (sexually transmitted disease)^I10|||F||||||
OBX|1|ST|AOE25^Pregnant?^BOL 0002||No||||||||202405211400|||||||||||||||OST
SPM|1|SID104227||119364003^Serum specimen
(specimen) ^SCT | | | | | | | | | 202405211400 |
```

#### **Cancel Order in the OML Message**

```
MSH|^~\&|SENDINGAPP|SENDINGFAC|LAN^23D0650909^CLIA|MDHHS^2.16.840.1.114222.4.3
.2.2.3.161.1^ISO|20240521140002||OML^O21^OML O21|BOLO 000 Multi PRT 1 CA|T|2.5
.1|||AL|AL||||LOI NG PRN Profile^LOI NG PRN
PROFILE^2.16.840.1.113883.9.88^ISO
PID|1||PATID0001^^^ASSIGNINGAUTHORITY^MR||Brady^Bobby^^^^L|Brady^Carol^A^^^M
|20220501|M||2054-5^Black or African American^HL70005|111 Main
Street^Apartment
2A^DOUGLAS^MI^49406^USA^H||^^PH^^^533^336555|^^PH^^^533^337555||||^^^^^^||||H^
Hispanic/Latino^HL70189|||||N
ORC|CA|P0104227|F0104227|G0104227|||||202405211400||0001011111^PROVIDERLASTNA
ME^PROVIDERFIRSTNAME^^^^NPI^^^NPI||^^PH^^^313^3456789||||||MDHHS - QUALITY
ASSURANCE SECTION^^^^StarLIMS Agency^^^345|3255 122nd Avenue Suite
200^^Lansing^MI^49010^USA^L|^^PH^^^269^6735411
OBR|1|P0104227|F0104227|1320^HIV Ag/Ab -
Serum^L|||202405211400||||||||0001011111^PROVIDERLASTNAME^PROVIDERFIRSTNAME^^
^^^^NPI^^^NPI|^^PH^^^313^3456789||||||||||8175000004^Dorian^JD^^^^^^StarLIMS
~8175000005^Turk^Christopher^^^^^StarLIMS~8175000006^Reid^Elliot^^^^^StarLIM
S~8175000007^Cox^Perry^^^^^StarLIMS~8175000008^Kelso^Bob^^^^^StarLIMS|||RFS0
1^Diagnosis^BOL 0001
NTE | 1 | | Note Comment
SPM|1|SID104227||119364003^Serum specimen
(specimen) ^SCT | | | | | | | | | | 202405211400 |
```

## **APPENDIX G - Revision History**

Version	Date	Author	Comments
0.9	07/11/2016	J. Shaw	First draft released for "Pilot and Trial Implementations Only"
1.0	11/30/2024	Altarum	First released version

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