Michigan Department of Health and Human Services

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

Version 1.0

MDHHS | Bureau of Laboratories

Michigan Department of Health & Human Services

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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 systems 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 Results Interface (LRI), 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.

- LRI_COMMON_COMPONENT
- LRI_NG_COMPONENT (Non-Globally Unique)
- LRI_FRN_COMPONENT (Non-Unique Filler Number)
- LRI_PH_COMPONENT (Public Health)

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

- Local codes will be used to identify the ordered test in OBR-4. When an applicable LOINC code is available by the laboratory it will also be sent in OBR-4. When no valid LOINC code exists, the local code may be the only code sent.
- SNOMED CT will be reported as Coded Elements (CE) data types (and identified as CE in OBX-2).
- Michigan HIE platform-related routing requirements. See Section 4.4. Health Information Exchanges (HIE) and Related Requirements and Section 5.2. On-boarding 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, BOL Test Orders (OML) and Results (ORU) by HL7 Messaging.

1.1. Audience

This guide is designed for use by analysts and developers who require guidance on data elements and components of the *HL7 Version 2.5.1 ORU Unsolicited Observation Message* relative to the Laboratory Results 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

- Michigan Department of Health and Human Services HL7 Version 2.5.1 Implementation Guide: LabOrders – Bureau of Laboratories
- HL7 V2.5.1, V2.7, V2.7.1, V2.8.1 Messaging (www.HL7.org)

- SNOMED (http://browser.ihtsdotools.org/?)
- LOINC (http://loinc.org)
- UCUM (http://unitsofmeasure.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

1.2.1. Conventions

This guide adheres to the following conventions:

- The guide is constructed assuming the implementer has access to the 2.5.1, 2.7.1 and 2.8.1 versions of the HL7Standard. Although some information from the standard is included in this implementation guide, much information from the standard has not been repeated here.
- The "HL7 Version 2 Conformance Methodology Release 1" document provides rules for constraining HL7 v2 message specifications (both message profiles and implementation guides). These rules are used to document the use case for, and constraints applied to, the messages described in this guide.
- Data types have been described separately from the fields that use the data types. See Appendix B - Data Types.
- No conformance information is provided for optional message elements ("O") or unsupported ("X"). Thisincludes cardinality, value sets, and descriptive information. Implementers who want to use optional message elements should refer to the base HL7 V2.5.1 Standard to determine how these optional message elements will be used.
- This guide uses "X" as a conformance usage indicator very sparingly. Where the underlying standard indicates the segments/field/component is present for backwards compatibility ("B") or withdrawn ("W"), an "X" will be used. A small number of other message elements that are clearly out of scope for the use case have been given the "X" usage. All other message elements have either been further constrained to R/RE/C (a/b) or have been left as "O" to enable trading partners to explore additional capabilities. Labs would have insufficient information to populate these fields, and if they would, it would cause potential confusion with information present on the provider's system. Note that without aclearly agreed to complementary profile between trading partners, a Lab does not have to send any elements marked as an "O", nor does a receiver of a lab result have to process any elements marked as an "O". Neither trading partners can mandate the other to accept any such complementary profiles to enable basic laboratory results interfacing "out-of-the-box".

1.2.2. Message Element Attributes

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

Table 1 - Message Element Attributes

Attribute	Definition
SEQ	Sequence of the elements as numbered in the HL7 message element. The SEQ attribute applies to the data type attribute table and the segment attribute table.
Component Name	Short name for the component
Segment	Three-character code for the segment and the abstract syntax (e.g., the square and curly braces). [XXX] Optional and singular {XXX} Required and may repeat. XXX Required and singular. [{XXX}] Optional and may repeat. Note that for segment groups there is no segment code present, but the square and curly braces will still be present. The Segment attribute only applies to the Message attribute table.
DT	Data type used by this profile for HL7 element. The data type attribute applies to data type attribute tables and segment attribute tables.
Usage	Usage of the message element for this profile. Indicates whether the message element (segment, segment group, field, component, or subcomponent) is R, RE, O, X or C (a/b) in the corresponding message element. Usage applies to the message attribute table, data type attribute table, and the segment attribute table, see Section 1.2.4 Usage Conformance Testing Recommendations.
Cardinality	Minimum and maximum number of times the element may appear. [0...0] Element never present. [0...1] Element may be omitted and can have, at most, one occurrence. [1...1] Element must have exactly one occurrence. [0..n] Element may be omitted or may repeat up to *n* times. [1..n] Element must appear at least once and may repeat up to *n* times. [0..*] Element may be omitted or repeat an unlimited number of times. [1..*] Element must appear at least once and may repeat unlimited number of times. [M...n] Element must appear at least *m*, and at most, *n* times. Cardinality applies only to message attribute tables and segment attribute tables.
Value Set	The set of coded values to be used with the field. The value set attribute applies only to the data type attribute tables and the segment attribute tables. The value set may equate with an entire code system, part of a code system, or codes drawn from multiple code systems. Constrained tables are included in Section 5.7 Constrained HL7 Tables
Name	HL7 descriptor of the message element. Name applies to the message attribute table, data type attribute table, and the segment attribute table.
Description/Comments	Context and usage for the element. Description/Comments applies to the message attribute table, data type attribute table, and the segment attribute table.

1.2.3. Keywords

The key words "**MUST**", "**MUST NOT**", "**REQUIRED**", "**SHALL**", "**SHALL NOT**", "**SHOULD**", "**SHOULD NOT**", "**RECOMMENDED**", "**MAY**", and "**OPTIONAL**" in this document are to be interpreted as described in RFC 2119[1].The following definitions are excerpted from the RFC:

- **MUST** or the terms "**REQUIRED**" or "**SHALL**", mean that the definition is an absolute requirement of thespecification.
- **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 circumstancesto 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 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**", means 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** beprepared to interoperate with another implementation which does include the optional segment/field/component, though perhaps with reduced functionality. In the same vein an implementation which includes a particular segment/field/component marked as optional **MUST** be prepared to interoperate with another implementation which does not include the optional segment/field/component.

1.2.4. Usage Conformance Testing Recommendations

The following text is pre-adopted from the HL7 V2.7.1 Conformance (Chapter 2B, 2.B.7.5). Please refer to thebase 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 theoptionality codes defined in the HL7.

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

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 expressedby 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 elementis 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 dependenton 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 anon-empty value.
RE	Required but may be empty	The application shall implement “RE” elements.	The application shall populate “RE” elements with anon-empty value if there is relevant data. The term “relevant” has a confounding interpretation in this definition[2].
C(a/b)	Conditional	An element with a conditional usage code has an associated condition predicate (Seesection 2.B.7.9, “Condition predicate” that determines the operational requirements (usage code) of the element. If the condition predicate associated with the element is true, follow the rules for ***a*** whichshall be one of “R”, “RE”, “O” or X”: If the condition predicate associated with the element is false, follow the rules for ***b*** whichshall be one of “R”, “RE”, “O” or X”. ***a*** and ***b*** can be valued the same.	

X	Not supported	The application (or as configured) shall not implement "X" elements.	The application shall not populate "X" elements.
O	Optional	None. The usage indicator forthis element has not yet been defined. For an implementation profile all optional elements must be profiled to R, RE, C(a/b), orX.	Not Applicable.

[2] 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 bya required element. A receiving application shall raise an exception due tothe 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 isomitted (that is, an exception shall not be raised because the element is missing).
C(a/b)	Conditional	The usage code has an associated condition predicate true (See section 2.B.7.9,"Condition predicate"). If the condition predicate associated with the element is true, follow the rules for ***a*** which shall be one of "R", "RE", "O" or X": If the condition predicate associated with the element is false, follow the rules for ***b*** which shall be one of "R", "RE", "O" or X". ***a*** and ***b*** can be 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, ignore it, and raise an exception. The receiving application shall not process (save/print/archive/etc.) the information conveyed by a not-supported element.
O	Optional	None. The usage indicator for this element has not yet been defined. For an implementation profile all optional elements must be profiled to R, RE, C(a/b), orX.	None.

end citation

1.2.5. Relationship to Orders

This implementation guide imposes no constraints on data elements where the origination of the content forthose data elements is a lab order. See the corresponding BOL implementation guide for Lab Orders for those details.

1.2.6. Snapshot Mode

Result messages shall always be sent in snapshot mode, meaning that all information related to the smallest individually identifiable units are complete. For this message type that would be the OBR and all related segments (OBX, NTE and SPM, OBX). I.e., if a correction and/or status update to at least one of the OBX segments under one OBR is necessary, all OBX segments, even if previously sent, shall be re-sent with the correction and/or status and/or current values. For example, when a Complete Blood Count with manual differential is ordered, the blood count will be released and then later the manual differential will be performed and released. When the blood count is released, the report will provide only the final results. When the differential is completed, Snapshot Reporting will send all previous results as well as the new results, in this case the blood count and the differential. Also see sections 4.2.3. Parent/Child Reporting for Culture and Susceptibility Testing, 4.2.4. Reflex Testing, and 4.2.5. Add-On Testing regarding related tests/orders that may be under other one or more additional OBR/OBX(s) or under a new order but must be included in the same message.

1.2.6.1. REPEATING SEGMENTS

In the "snapshot" mode, the information contained in the set of repeating segments or segment groups from the incoming message replaces the corresponding information in the receiving application. This is meant to overwrite the prior information with the newly supplied information. In this mode, everything (all repeating segments and segment groups) must be sent with every subsequent message in the series of messages. There is no other way to indicate which ones changed and which ones did not.

To specify "delete all the segments in this repeating group" in the snapshot mode, send a single segment with "delete data" (indicated by a value of "") in all fields. This actively signals the receiver that there is information that needs to be deleted. If no segment were sent, this would equate to "no information." No information should signal the receiver to take action.

1.2.6.2. REPEATING FIELDS

Snapshot processing for repeating fields requires sending a full list of repetitions for each transaction. If the intent is to delete an element, the element is left off the list. This is analogous to the snapshot mode for repeating segments and segment groups. Repetitions of fields shall not have empty repetitions followed by repetitions containing data, except where the HL7 standard clearly reserves certain repetitions for specific purposes.

1.2.6.3. MESSAGE SNAPSHOTS

Snapshot processing for messages simply means that the content of the current message is used to replace the contents from a prior message for the same information object. In this case, the information object is a laboratory result associated with a specific patient. The primary problem associated with message snapshots is making sure the appropriate information object is updated. In this case, the information object is a laboratory result associated with a specific patient. To do the snapshot update properly, key identifiers must be shared across the messages and

must together uniquely identify the specific laboratory result that is to be updated. The implementer will need to look at the Universal Service Identifier (OBR-4) in conjunction with the Placer Number (ORC-2/OBR-2) or Filler Order number (ORC-3/OBR-3). Other identifiers in the message that can be used to verify the correct results are being updated include the patient identifier in PID-3. If these identifiers don't match across messages, even when the placer and filler order numbers match, then it's very likely the two messages are for different patients.

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.

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: https://www.michigan.gov/mdhhs/doing-business/providers/labservices/labservicesguide/test-orders-oml-and-results-oru-by-hl7-messaging for new versions. Revisions, along with major items changed, are tracked in APPENDIX D - Revision History.

1.6. Copyright Information

2. Messages

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

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

ORU^R01^ORU_R01: Laboratory Result Message

This message structure supports the use case of Laboratory Results as defined in the HL7 Version 2.5.1 Implementation Guide: Lab Results Interface (LRI), Release 1, STU Release 5

Table 2 - ORU^R01^ORU_R01 Abstract Message Syntax

Segment	Name	Usage	Cardinality	Description
MSH	Message Header	R	[1..1]	The message header (MSH) segment contains information describing how to parse and process the message. This includes identification of message delimiters, sender, receiver, message type, timestamp, etc.
[{SFT}]	Software Segment	RE	[0..1]	
{	*PATIENT_RESULT Begin*	R	[1..1]	
[	*PATIENT Begin*	R	[1..1]	
PID	Patient Identification	R	[1..1]	The patient identification (PID) segment is used to provide basic demographics regarding the subject of the testing. The subject shall be a person.
[PD1]	Additional Demographics	X		Excluded for this Implementation Guide
[{NTE}]	Notes and Comments for PID	X		
[{NK1}]	Next of Kin/Associated Parties	X		Excluded for this Implementation Guide
[	*VISIT Begin*	O		
PV1	Patient Visit	RE	[0..1]	HL7 requires that the patient visit (PV1) segment be present if the VISIT group is present.
[PV2]	Patient Visit – Additional Information	X		
]	*VISIT End*			

Segment	Name	Usage	Cardinality	Description
]	*PATIENT End*			
{	*ORDER_OBSERVATION Begin*	R	[1..*]	The ORDER_OBSERVATION is required and can repeat. This means that multiple ordered tests may be performed on a specimen. Snapshot processing of the result message involves processing as a snapshot all the repeats of the ORDER_OBSERVATION group together as a group. This is especially important when dealing with parent/child results (such as cultures and sensitivities) which will span multiple ORDER_OBSERVATION groups. All these must be processed from both a message sender and message receiver perspective as a single snapshot.
[ORC]	Order Common	R	[1..1]	The common order (ORC) segment identifies basic information about the order for testing of the specimen. This segment includes identifiers of the order, who placed the order, when it was placed, what action to take regarding the order, etc.
OBR	Observations Request	R	[1..1]	The observation request (OBR) segment is used to capture information about one test being performed on the specimen. Most importantly, the OBR identifies the type of testing performed on the specimen and ties that information to the order for the testing.
[{NTE}]	Notes and Comments for OBR	RE	[0..*]	The notes and comment (NTE) segment will carry comments related to the observation being reported in the OBR segment.
[{	*TIMING_QTY Begin*	X		Excluded for this Implementation Guide
TQ1	Timing/Quantity	X		Excluded for this Implementation Guide
[{TQ2}]	Timing/Quantity Order Sequence	X		Excluded for this Implementation Guide
}]	*TIMING_QTY End*			
[CTD]	Contact Data	O		
[{	*OBSERVATION Begin*	C(R/X)	[0..*]	Condition Predicate: If OBR-25 (Result Status) is valued “A”, “C”, “F”, “P”, or “R” Multiple Observation groups, each containing a single OBX and a potentially repeating NTE, may be associated with a single order.
OBX	Observation related to OBR	R	[1..1]	The observation/result (OBX) segment contains information regarding a single observation (analyte) result. This includes identification of the specific type of observation, the result for the observation, when the observation was made, etc.
[{NTE}]	Notes and Comments	RE	[0..*]	The notes and comment (NTE) segment will carry comments related to the result being reported in the OBX segment. Each NTE is a standalone comment.
}]	*OBSERVATION End*			
[{FTI}]	Financial Transaction	X		
{[CTI]}	Clinical Trial Identification	X		

Segment	Name	Usage	Cardinality	Description
[{	*SPECIMEN Begin*	RE	[0..*]	The specimen group is required if known in the ORU and is used to carry specimen information that is no longer contained in the OBR segment. It also provides a place for the specimen number. Each specimen group documents a single sample.
SPM	Specimen Information related to OBR	R	[1..1]	The specimen information (SPM) segment describes the characteristics of a single sample. The SPM segment carries information regarding the type of specimen, where and how it was collected, who collected it, and some basic characteristics of the specimen.
[{OBX}]	Observation related to Specimen	O		
}]	*SPECIMEN End*			
}	*ORDER_ OBSERVATION End*			
}	*PATIENT_RESULT End*			
[DSC]	Continuation Pointer	X		Excluded for this Implementation Guide

USAGE NOTE

NTE Segment – Notes and comments (NTE) segment should contain notes or comments pertaining to the information in the segment immediately preceding it.

ACK^R01^ACK: Laboratory Result Message – Acknowledgement

This message structure supports basic acknowledgment of the order message. Guaranteed delivery is required. All messages will receive an ACK. This applies to intermediaries' nodes between an EHR-S and a Laboratory Result Sender such as HIEs and interface engines, as well as to the final EHR-S or LIS destination.

Table 3 - ACK^R01^ACK Abstract Message Syntax

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

3. Segment and Field Descriptions

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

3.1. MSH – Message Header Segment

Table 4 - MSH – Message Header Segment

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Field Separator	ST	R	[1..1]		
2	Encoding Characters	ST	R	[1..1]		Constrained to the literal values '^~\&' always appearing in the same order.
3	Sending Application	HD_MI01	RE	[0..1]	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_MI01	R	[1..1]	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		O			Required for Michigan HIE platform-related routing requirements. Contact your HIE for more information on what this field will include.
6	Receiving Facility	HD_NG	RE	[0..1]	HL70362	Required for Michigan HIE platform-related routing requirements. Contact your HIE for more information on what this field will include. This facility originates any related acknowledgment message.
7	Date/Time of Message	TS_1	R	[1..1]		Date/Time the message was created by the sending system. If the time zone offset is included in MSH-7 it becomes the default time zone for the message instance and applies to all other date/time fields in that same message instance where a time zone offset is not valued.
8	Security		O			
9	Message Type	MSG	R	[1..1]		

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
10	Message Control ID	ST	R	[1..1]		String that identifies the message instance from the sending application. Example formats for message control IDs include GUID, timestamp plus sequence number, OID plus sequence number or sequence number. The important point is that care must be taken to ensure that the message control id is unique within the system originating the message.
11	Processing ID	PT	R	[1..1]	HL70103 (constrained)	Constrained to the literal values of 'T' or 'P'.
12	Version ID	VID	R	[1..1]		HL7 version number used to interpret format and content of the message. Constrained to the literal value '2.5.1'.
13	Sequence Number		O			
14	Continuation Pointer		O			
15	Accept Acknowledgment Type	ID	R	[1..1]	HL70155	
16	Application Acknowledgment Type	ID	R	[1..1]	HL70155	
17	Country Code		O			
18	Character Set		O			
19	Principal Language of Message		O			
20	Alternate Character Set Handling Scheme		O			
21	Message Profile Identifier		O			

Example:

```
MSH|^~\&|STARLIMS.MI.STAG^2.16.840.1.114222.4.3.3.2.32.2^ISO|LAN^23D0650909^CLIA|^4^STARLIMS_AGENCY|ESI-
LOOKUP^2.16.840.1.114222.4.3.2.2.3.161.1.3282.374^ISO|20230817142828||ORU^R01^ORU_R01|L00023843_202308171
42828|T|2.5.1|||NE|NE|USA||||
```

Conformance Statements: LRI_Result_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 'ORU^R01^ORU_R01'.

- 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 'NE'.

Conformance Statements: LRI_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 constant value 'ACK^R01^ACK'.
- MSH-12 (Version ID) **SHALL** contain the constant value '2.5.1'.
- MSH-15 (Accept Acknowledgement Type) **SHALL** contain the constant value 'NE'.
- MSH-16 (Application Acknowledgement Type) **SHALL** contain the constant value 'NE'.

3.2. SFT – Software Segment

The software segment provides information about the sending application or other applications that manipulate the message before the receivingapplication processes the message. This guide imposes no additional constraints on the base specification HL7 v2.5.1, Chapter 2.

3.3. MSA – Acknowledgement Segment

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

Table 5 - MSA – Acknowledgement Segment

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

3.4. ERR – Error Segment

Note that the ERR segment is used to add error comments to acknowledgment messages.

Table 6 - ERR – Error Segment

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Error Code and Location		X			Excluded for this Implementation Guide
2	Error Location	ERL_01	RE	[0..1]		
3	HL7 Error Code	CWE_02	R	[1..1]	HL70357	
4	Severity	ID	R	[1..1]	HL70516	
5	Application Error Code		O			
6	Application Error Parameter	TX	RE	[0..1]		
7	Diagnostic Information	TX	RE	[0..1]		
8	User Message		O			
9	Inform Person Indicator		O			
10	Override Type		O			
11	Override Reason Code		O			
12	Help Desk Contact Point		O			

3.5. PID – Patient Identification Segment

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

Table 7 - PID – Patient Identification Segment

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Set ID – PID	SI	R	[1..1]		Constrained to the literal value '1'.
2	Patient ID		X			Excluded for this Implementation Guide
3	Patient Identifier List	CX_02	RE	[0..1]		
4	Alternate Patient ID – PID		X			Excluded for this Implementation Guide
5	Patient Name	XPN_03	RE	[0..1]		
6	Mother's Maiden Name		O			
7	Date/Time of Birth	TS_2	RE	[0..1]		
8	Administrative Sex	IS	R	[1..1]	HL70001	Patient's gender.
9	Patient Alias		X			Excluded for this Implementation Guide

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
10	Race	CWE_02	RE	[0..*]	HL70005	Note that state regulations may dictate other behaviors.
11	Patient Address		O			
12	County Code		X			Excluded for this Implementation Guide
13	Phone Number – Home		O			
14	Phone Number – Business		O			
15	Primary Language		O			
16	Marital Status		O			
17	Religion		O			
18	Patient Account Number		O			
19	SSN Number – Patient		X			Excluded for this Implementation Guide
20	Driver's License Number – Patient		X			Excluded for this Implementation Guide
21	Mother's Identifier		O			
22	Ethnic Group		O			
23	Birth Place		O			
24	Multiple Birth Indicator		O			
25	Birth Order		O			
26	Citizenship		O			
27	Veterans Military Status		O			
28	Nationality		X			Excluded for this Implementation Guide
29	Patient Death Date and Time		O			
30	Patient Death Indicator		O			
31	Identity Unknown Indicator		X			Excluded for this Implementation Guide
32	Identity Reliability Code		O			
33	Last Update Date/Time		O			
34	Last Update Facility		O			
35	Species Code		X			Excluded for this Implementation Guide
36	Breed Code		X			Excluded for this Implementation Guide
37	Strain		X			Excluded for this Implementation Guide
38	Production Class Code		X			Excluded for this Implementation Guide
39	Tribal Citizenship		X			Excluded for this Implementation Guide

Conformance Statements: Base Profile

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

EXAMPLE:

```
PID|1||16
UAT^^^STARLIMS.MI.STAG&2.16.840.1.114222.4.3.3.2.37.2&ISO^PI^MI.Lansing.SPHL&2.16.840.1.114222.4.1.103423
&ISO||CHOCULA^COUNT^^^^^L||19910101|M||2106-3^White^CDCREC^WHITE OR CAUCASIAN^WHITE OR
CAUCASIAN^L^04/24/2007^v unknown|^^NEW RICHMOND^MI^^^H^^ALLEGAN||||||||||N^Not Hispanic or
Latino^HL70189^NONHISPANIC^NONHISPANIC^L^2.5.1^v unknown
```

3.6. PV1 – Patient Visit Segment

The Patient Visit Segment (PV1) is only used to indicate the patient class or if the patient was reported to be pregnant, all other fields will be blank.

Table 8 - PV1 - Patient Visit Segment

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Set ID - PV1	SI	R	[1..1]		
2	Patient Class	IS	R	[1..1]	HL70004	A gross identification of the classification of the patient's visit.
3	Assigned Patient Location		O			
4	Admission Type		O			
5	Preadmit Number		O			
6	Prior Patient Location		O			
7	Attending Doctor		O			
8	Referring Doctor		O			
9	Consulting Doctor		X			Excluded for this Implementation Guide
10	Hospital Service		O			
11	Temporary Location		O			
12	Preadmit Test Indicator		O			
13	Re-admission Indicator		O			
14	Admit Source		O			
15	Ambulatory Status	IS	RE	[1..1]	HL70009 (Constrained)	This field is used to indicate if the patient was reported to be pregnant. This does not mean that the BOL tested for pregnancy or confirmed what was reported.
16	VIP Indicator		O			
17	Admitting Doctor		O			

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
18	Patient Type		O			
19	Visit Number		O			
20	Financial Class		O			
21	Charge Price Indicator		O			
22	Courtesy Code		O			
23	Credit Rating		O			
24	Contract Code		O			
25	Contract Effective Date		O			
26	Contract Amount		O			
27	Contract Period		O			
28	Interest Code		O			
29	Transfer to Bad Debt Code		O			
30	Transfer to Bad Debt Date		O			
31	Bad Debt Agency Code		O			
32	Bad Debt Transfer Amount		O			
33	Bad Debt Recovery Amount		O			
34	Delete Account Indicator		O			
35	Delete Account Date		O			
36	Discharge Disposition		O			
37	Discharged to Location		O			
38	Diet Type		O			
39	Servicing Facility		O			
40	Bed Status		X			Excluded for this Implementation Guide
41	Account Status		O			
42	Pending Location		O			
43	Prior Temporary Location		O			
44	Admit Date/Time		O			
45	Discharge Date/Time		O			
46	Current Patient Balance		O			
47	Total Charges		O			
48	Total Adjustments		O			

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
49	Total Payments		O			
50	Alternate Visit ID		O			
51	Visit Indicator		O			
52	Other Healthcare Provider		X			Excluded for this Implementation Guide

3.7. ORC – Common Order Segment

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

Table 9 - ORC – Common Order Segment

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Order Control	ID	R	[1..1]	HL70119 (constrained)	
2	Placer Order Number	EI_MI01	RE	[0..1]		
3	Filler Order Number	EI_MI01	R	[1..1]		
4	Placer Group Number	EI_MI01	RE	[0..1]		
5	Order Status		O			
6	Response Flag		O			
7	Quantity/Timing		X			Excluded for this Implementation Guide
8	Parent		O			
9	Date/Time of Transaction		O			
10	Entered By		O			
11	Verified By		O			
12	Ordering Provider	XCN_ MI01	RE	[0..1]		
13	Enterer's Location		O			
14	Call Back Phone Number		O			
15	Order Effective Date/Time		O			
16	Order Control Code Reason		O			
17	Entering Organization		O			
18	Entering Device		O			

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
19	Action By		O			
20	Advanced Beneficiary Notice Code		X			Excluded for this Implementation Guide
21	Ordering Facility Name		O			
22	Ordering Facility Address		O			
23	Ordering Facility Phone Number		O			
24	Ordering Provider Address		O			
25	Order Status Modifier		O			
26	Advanced Beneficiary Notice Override Reason		X			Excluded for this Implementation Guide
27	Filler's Expected Availability Date/Time		O			
28	Confidentiality Code		O			
29	Order Type		O			
30	Enterer Authorization Mode		O			
31	Parent Universal Service Identifier		O			

USAGE NOTE

ORC-12 (Ordering Provider) – This will contain the original ordering provider (even if the specimen or isolate from that same specimen is being referred by the filler lab to another lab).

Conformance Statements: Base Profile

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

EXAMPLE:

```
ORC|RE|LO104188|CL23-
290005^STARLIMS.MI.STAG^2.16.840.1.114222.4.3.3.2.37.2^ISO||CM|||||||0001011119^Support^Pat^^^^^^NPI|||||
||||ALLEGAN COUNTY HEALTH DEPARTMENT^^^^^StarLIMS_Agency^^^^4|3255 122nd Avenue,Suite
200^^ALLEGAN^MI^49010^USA^B|^WPN^PH^^1^269^6735411
```

3.8. OBR – Observation Request Segment

The Observation Request Segment (OBR) is used to capture information about one test being performed on the specimen. Most importantly, theOBR identifies the type of testing performed on the specimen and ties that information to the order for the testing.

Table 10 - OBR – Observation Request Segment

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Set ID - OBR	SI	R	[1..1]		
2	Placer Order Number	EI_MI01	RE	[0..1]		
3	Filler Order Number	EI_MI01	R	[1..1]		Note: The filler order number must be combined with the universal service identifier (OBR-4) to uniquely identify the order.
4	Universal Service Identifier	CWE_01	R	[1..1]	Local	Local codes will be used to identify the ordered test in OBR-4. When an applicable LOINC code is available by the laboratory it will also be sent in OBR-4. When no valid LOINC code exists, the local code may be the only code sent.
5	Priority – OBR		X			Excluded for this Implementation Guide
6	Requested Date/Time		X			Excluded for this Implementation Guide
7	Observation Date/Time	TS_4	R	[1..1]		This reflects the specimen collection date/time when the test involves a specimen. 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. When the collection date/time is unknown, “0000” will be sent.
8	Observation End Date/Time	TS_5	RE	[0..1]		
9	Collection Volume		O			
10	Collector Identifier		O			
11	Specimen Action Code	ID	O			
12	Danger Code		O			
13	Relevant Clinical Information		O			
14	Specimen Received Date/Time		X			Excluded for this Implementation Guide
15	Specimen Source		X			Excluded for this Implementation Guide
16	Ordering Provider	XCN_MI01	RE	[0..1]		Note that ORC-12 Ordering Provider is constrained to contain the same value as this field.
17	Order Call-back Phone Number		O			
18	Placer Field 1		O			
19	Placer Field 2		O			

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
20	Filler Field 1		O			
21	Filler Field 2		O			
22	Results Rpt/Status Chng - Date/Time	TS_1	R	[1..1]		Applies to the entire report. Receipt of a subsequent message with the same Filler Number and a different timestamp in this field implies that processing may need to occur at the receiving application level to update a previous report.
23	Charge to Practice		O			
24	Diagnostic Service Sect ID		O			
25	Result Status	ID	R	[1..1]	HL70123 (constrained)	The value of OBR-25 is derived from the OBX-11 values that follow the OBR.
26	Parent Result	PRL	C(R/RE)	[0..1]		Used with OBR-29 (Parent) and OBR-50 (Parent Universal Service Identifier); allows linkages with specific OBX segment associated with another OBR. Condition Predicate: Required if OBR-4 is a child observation (i.e., antimicrobial susceptibility testing) for linking parent/child results.
27	Quantity/Timing		X			Excluded for this Implementation Guide
28	Result Copies To	XCN_MI02	C(R/X)	[0..*]		Condition Predicate: If CWE_03.1 (Identifier) or CWE_03.4 (Alternate Identifier) of at least one occurrence of OBR-49 is valued CC or BCC NG
29	Parent	EIP_MI01	C(R/RE)	[0..1]		Condition Predicate: Required if OBR-4 is a child observation (i.e., antimicrobial susceptibility testing) for linking parent/child results.
30	Transportation Mode		O			
31	Reason for Study		O			
32	Principal Result Interpreter		O			
33	Assistant Result Interpreter		O			
34	Technician		O			
35	Transcriptionist		O			
36	Scheduled Date/Time		O			
37	Number of Sample Containers		O			
38	Transport Logistics of Collected Sample		O			
39	Collector's Comment		O			
40	Transport Arrangement Responsibility		O			
41	Transport Arranged		O			

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
42	Escort Required		O			
43	Planned Patient Transport Comment		O			
44	Procedure Code		O			
45	Procedure Code Modifier		O			
46	Placer Supplemental Service Information		O			
47	Filler Supplemental Service Information		O			
48	Medically Necessary Duplicate Procedure Reason		O			
49	Result Handling	CWE_03	RE	[0..*]	HL70507 (Constrained)	
50	Parent Universal Service Identifier	CWE_01	C(R/X)	[0..1]		Contains the universal service identifier (OBR-4) of the parent order to uniquely identify a linking relationship. Condition Predicate: If OBR-29 (Parent) is valued

USAGE NOTE

OBR-3 (Filler Order Number)

In the circumstance where some of the lab results are generated by the lab but others are performed by a reference lab, the sending lab will choose what filler order number to use in OBR-3. The Filler ID for a single orderable will be the same for all messages for that orderable, e.g., the filler ID must be the same for the ORC/OBR pair reporting a preliminary, final, or corrected result.

Conformance Statements: Base Profile

- If present, OBR-8 (Observation End Date/Time) **SHALL** be equal or later than OBR-7 (Observation Date/Time).
- The value of OBR-1 (Set ID – OBR) **SHALL** be valued sequentially starting with the value '1' across the Order Observation Groups.

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

```
MSH|...<cr>
PID|...<cr>
// First order group
ORC|RE|...<cr>
OBR|1|...<cr>
SPM|1|...<cr>
SPM|2|...<cr>
// end first order group
// Second order group - Microbiology Parent
ORC|RE|...<cr>
OBR|2|...<cr>
SPM|1|...<cr>
// end second order group - Microbiology Parent
// Third order group - Microbiology Child #1
ORC|RE|...<cr>
OBR|3|...<cr>
SPM|1|...<cr>
//end third order group - Microbiology Child #1
// Fourth order group - Microbiology Child #2
ORC|RE|...<cr>
OBR|4|...<cr>
SPM|1|...<cr>
// end fourth order group - Microbiology Child #2
// Fifth order group
ORC|RE|...<cr>
OBR|5|...<cr>
SPM|1|...<cr>
SPM|2|...<cr>
//end fifth order group
```

EXAMPLE 1:

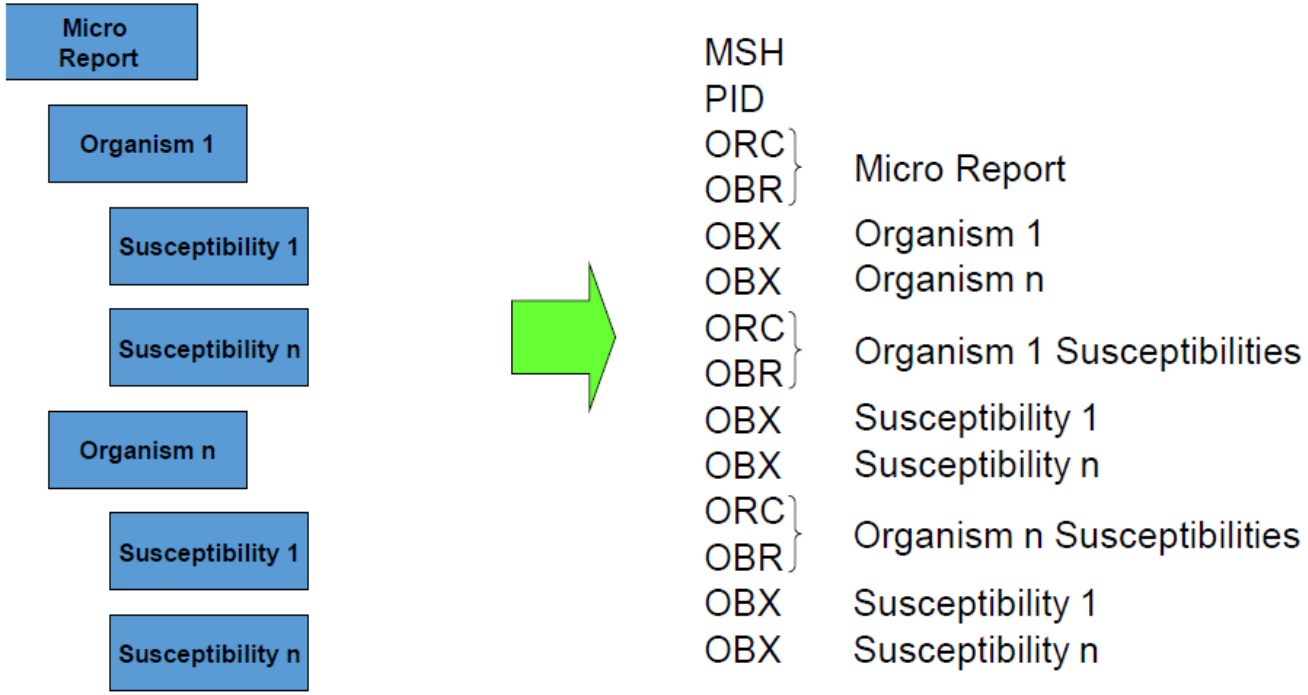
```
OBR|1|LO104188|CL23-290005^STARLIMS.MI.STAG^2.16.840.1.114222.4.3.3.2.37.2^ISO|13955-0^Hepatitis C virus
Ab^LN^2844^Anti-HCV IgG Chemiluminescent Immunoassay (CLIA)^L^2.34^v
unknown^2844|||20230224101500|||||||||0001011119^Support^Pat^^^^^^NPI||||||20230623152937|||P
NTE|1||Anti-HCV IgG Chemiluminescent Immunoassay (CLIA) comments: Reference Range:  NON-REACTIVE
```

3.8.1. Reporting Results with a Parent/Child Relationship

When communicating results with a parent/child relationship, such as microbiology results and reflex tests, the use of the right segments and fields is essential to consistently convey the structure and content of the culture, organisms, and susceptibilities. The following diagrams summarize the concepts and are followed by the formal LRI_FRN Profile conformance statements to implement Parent/Child relationships.

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

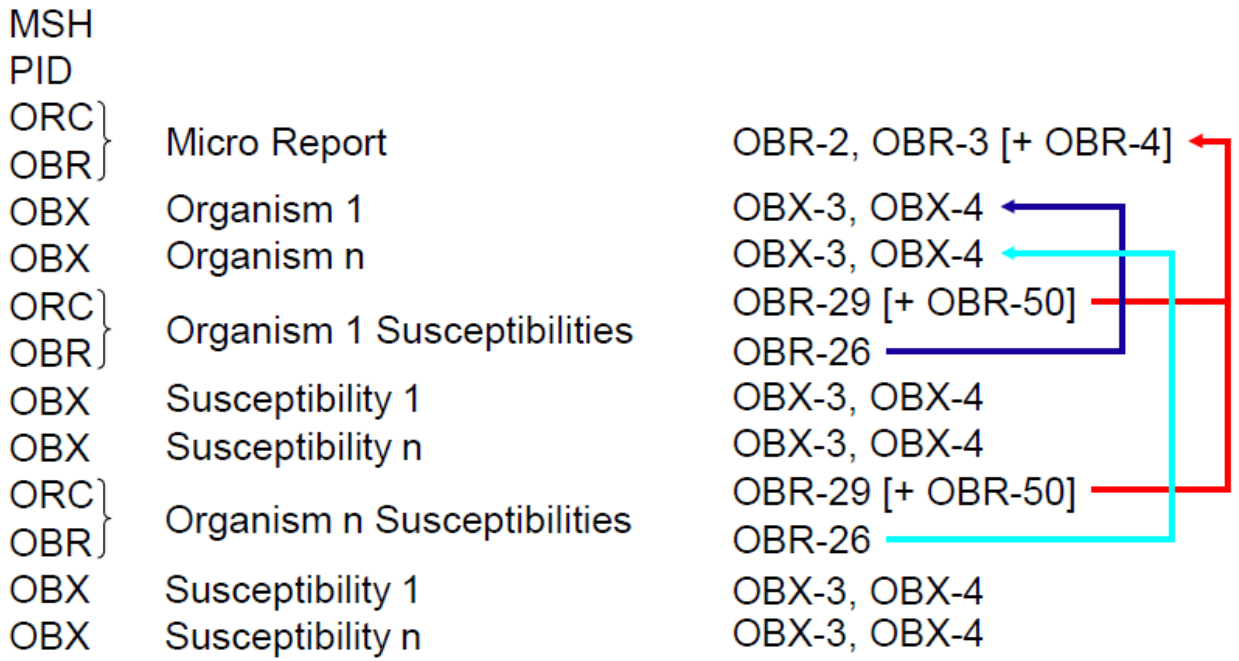
Figure 1 - Sample Report Structure Represented as Message Structure



Sample Report Structure Represented as Message Structure shows the use of the ORC, OBR, and OBX segments. Copyright 2022 by Health Level Seven International in the installation HL7 Version 2.5.1 Implementation Guide: Lab Results Interface (LRI), Edition 5 – US Realm

Figure 1 Sample Report Structure Represented as Message Structure shows the use of the ORC, OBR, and OBX segments. The arrows illustrate how the child Organism refers to value in the parent OBR and OBX to clearly link the child to the parent. (For example, the dark blue line illustrates how the value in the child's OBR-26 matches the value of its parents OBX-3 and OBX-4.)

Figure 2 - Parent-Child Relationships



The following conformance statements express this more formally.

Conformance Statements: LRI_FRN Profile

- Results with a Parent/Child relationship **MUST** provide proper linking from the Child result to the Parent OBR and OBX as detailed below:
- Parent OBR matching: Any OBR with a value in OBR-26 (Parent Result), henceforth referred to as the Child OBR, **SHALL** be successfully matched to a Parent OBR in a previously occurring Order Observation Group in the following ways:

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

AND
The child OBR-29.2 (Filler Assigned Identifier) is valued the same as the Parent OBR-3 (Filler Order Number) value (taking into account the conversion of component delimiters into the sub-component delimiters).
AND
The child OBR-50 (Parent Universal Service Identifier) is valued the same as the Parent OBR-4 value.

- Parent OBX matching: Any OBR with a value in OBR-26, henceforth referred to as the Child OBR, **SHALL** be successfully matched to an OBX segment within the previously identified Parent Order Observation Group in the following ways:
  The child OBR-26.1 (Parent Observation Identifier) is valued the same as the Parent OBX-3 (taking into account the conversion of component delimiters into the sub-component delimiters).
  AND
  The child OBR-26.2 (Parent Observation Sub-Identifier) is valued the same as the Parent OBX-4 (Observation Sub-Identifier) value (taking into account the conversion of component delimiters into the sub-component delimiters).

3.8.2. Relationship Between OBR-25 (Result Status) and OBX-11 (Observation Status)

The OBR-25 (Result Status) is a summary of the OBX-11 statuses that follow the OBR. This is most easily understood in the case where an OBR contains only one OBX with an 'F' (Final), one would naturally expect the OBR-25 value to be 'F' (Final) as well. This guide will prescribe the expected OBR-25 value given multiple and various combinations of OBX-11 values.
Before we can discuss how OBR-25 is derived from the OBX-11 values we must first examine the value set for OBR-25 and understand in what order the values can (or cannot) transition from one value to the same or another value in a series of transactions.

Conformance Statements for LRI_Common_Component

- If OBR-25 is valued 'I' then all occurrences of OBX-11 within the same Order-Observation group **SHALL** be valued 'I'.
- If OBR-25 is valued 'P' then at least one occurrence of OBX-11 within the same Order-Observation group **SHALL** be valued 'P'.
- If OBR-25 is valued 'P' then an occurrence of OBX-11 within the same Order-Observation group **SHALL NOT** be valued 'C'.
- If OBR-25 is valued 'F' then at least one occurrence of OBX-11 within the same Order-Observation group **SHALL** be valued 'F'.
- If OBR-25 is valued 'F' then an occurrence of OBX-11 within the same Order-Observation group **SHALL NOT** be valued 'I', 'P', or 'C'.
- If OBR-25 is valued 'C' then at least one occurrence of OBX-11 within the same Order-Observation group **SHALL** be valued 'C'.
- If OBR-25 is valued 'C' then an occurrence of OBX-11 within the same Order-Observation group **SHALL NOT** be valued 'I' or 'P'.

Example results with Parent/Child relationship can be found in Section 4.2.3.3. Examples of Culture and Susceptibility Results.

3.8.2.1. ALLOWED RESULT STATUS (OBR-25) TRANSITIONS

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

How to Read This Table

1st row: An existing OBR-25 valued 'I' (In Process) can take on the following values in a subsequent transaction: 'I' (In Process), 'P' (Preliminary), or 'F' (Final). It cannot be changed to 'C' (Corrected, final).

2nd row: An existing OBR-25 valued 'P' can take on the following values in a subsequent transaction: 'P', 'F', or 'C'. It cannot be changed to 'I'.

3rd row: An existing OBR-25 valued 'F' can take on the following values in a subsequent transaction: 'C' and 'F'. It cannot be changed to 'I' or 'P'.

4th row: An existing OBR-25 valued 'C' can remain ONLY 'C' on the following values in a subsequent transaction. It cannot be changed to 'I', 'P', or 'F'.

Table Legend

A = Allowed
Not Allowed

Table 11 - Allowed OBR-25 to OBR-25 Transitions

From OBR-25 (existing result)		To OBR-25			
		I	**P**	**F**	**C**
I	Incomplete	A	A	A	
P	Preliminary		A	A	A
F	Final			A(1)	A
C	Corrected				A

Notes

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

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

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

How to Read This Table

- The combination of OBX-11 values determines the allowable OBR-25 value.
- When viewing the possible OBR-25 values (column), the value is only valid if there is an OBX-11 status that is marked 'R'.
- The status of the report is indicated in OBR-25 status. Only certain OBX-11 combinations are allowed for specific OBR-25 values.
- ***1ST column***: An order (ORC/OBR) with multiple analytes (OBXs) is reported via LRI, where all OBXs have OBX-11 valued 'I'. The status for the order in OBR-25 shall be 'I' indicating work in progress, without available results.
- ***2ND column***: An order (ORC/OBR) with multiple analytes (OBXs) is reported via LRI, where one or more OBX has OBX-11 valued 'P' and the other OBXs are valued either 'F' or 'I'. None of the OBXs have an OBX-11 status of 'C'. The status for the order in OBR-25 shall be 'P' indicating a preliminary report.
- ***3RD column***: An order (ORC/OBR) with multiple analytes (OBXs) is reported via LRI, where one or more OBX has OBX-11 valued 'F'. None of the OBXs have an OBX-11 status of 'I', 'P', or 'C'. The status for the order in OBR-25 shall be 'F' indicating a final report.
- ***4TH column***: An order (ORC/OBR) with multiple analytes (OBXs) is reported via LRI, where one or more OBX has OBX-11 valued 'C'. No OBX has a status indicating either a 'P' or 'I'. The status for the order in OBR-25 shall be 'C' indicating a correction in a final report.

Table Legend

R = Required
A = Allowed
Not Allowed

Table 12 - Required/Allowed OBX-11, and OBR-25 Values in Same Order

From OBX-11		OBR-25			
		I	P	F	C
		Incomplete	Preliminary	Final	Corrected
I	In Process	R	A		
P	Preliminary		R		
F	Final	A(1)	A	R	A
C	Corrected				R(2)

Notes

(1) Only allowed upon specimen receipt. See "Specimen Status Received" in Section 4.2. Special Cases

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

3.8.3. Results Handling and Results Copy To

In this Implementation Guide OBR-28 (Result Copies to) is populated based on the value in OBR-49 (Result Handling) based on two values 'BCC' (Blind copy) and 'CC' (Copy to) in OBR-49. When the order is submitted to the laboratory, the Ordering Provider includes the identifier (StarLIMS Agency ID) and the name of the colleagues that the provider would like to also receive the patients results, up to five (5).

When the laboratory prepares the report, the one sent back to the original ordering provider will include in OBR-28 all the copies to colleagues that were requested to receive the reports. For all other reports, defined as the copy to, the receiving colleague will get the report with OBR-28 containing only the colleague's information.

Example: Physician_1 orders a CBC and Electrolytes for a patient. Because physician_1 intends to go on vacation starting tomorrow and three other colleagues have agreed to a rotating coverage, physician_1 requests that the lab also report the results to Colleague_A, Colleague_B and Colleague_C. This will create 4 reports with unique values in OBR-28 as noted below:

Table 13 - OBR-16, -28, Examples

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

3.9. OBX – Observation/Result Segment

The Observation/Result Segment (OBX) contains information regarding a single observation related to a single test (OBR) or specimen (SPM).

This includes identification of the specific type of observation, the result for the observation, when the observation was made, etc.

Table 14 - OBX – Observation/Result Segment

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Set ID – OBX	SI	R	[1..1]		
2	Value Type	ID	R	[0..1]	HL70125 (constrained)	This field identifies the data type used for OBX-5.
3	Observation Identifier	CWE_01	R	[1..1]	Logical Observation Identification Name and Codes (LOINC)	LOINC shall be used as the standard coding system for this field if an appropriate LOINC code exists. Appropriate status is defined in the LOINC Manual Section 11.2 Classification of LOINC Term Status. If a local coding system is in use, a local code will also be sent to help with identification of coding issues. When no valid LOINC exists the local code may be the only code sent. When populating this field with values, this guide does not give preference to the triplet in which the standard (LOINC) code should appear.
4	Observation Sub-ID	ST	C(R/RE)	[0..1]		Condition Predicate: If there are multiple OBX segments associated with the same OBR segment that have the same OBX-3 (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)).
5	Observation Value	Varies	R	[0..1]		Note: Allowable data types for this field are described in HL7 table 0125 (from OBX-2). See Section 6.2. SNOMED CT for guidance on how to value this field for Microbiology.
6	Units	CWE_03	C(R/RE)	[0..1]		Condition Predicate: If OBX-2 (Value Type) is valued “NM” or “SN” and OBX-11 is not valued “X” or “N”. Note: If there is not a unit of measure available while the Condition Predicate is True, the value “NA” shall be used in CWE_03.1 (Identifier) and “HL70353” in CWE_03.3 (Name of Coding System). See Section 6.4. UCUM
7	References Range	ST	RE	[0..1]		Reference ranges will always be located here.
8	Abnormal Flags	IS	RE	[0..*]	HL70078 (2.5.1)	This field will be populated with Table 0078 when appropriate. Therefore, if a laboratory populates OBX-8 with a coded interpretation, regardless of the coded interpretation sent, the EHR shall consume and display it. See HL70078 Interpretation Codes (V2.5.1) for value set. Microbiology Example: Ceftazidime susceptibility (LOINC 133-9) value = |<=^1|, units = ug/ml, Abnormal flag = S
9	Probability		O			
10	Nature of Abnormal Test		O			

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
11	Observation Result Status	ID	R	[1..1]	HL70085 (constrained)	
12	Effective Date of Reference Range		O			
13	User-Defined Access Checks		O			
14	Date/Time of the Observation	TS_5	RE	[0..1]		
15	Producer's Reference		O			
16	Responsible Observer		O			
17	Observation Method		O			
18	Equipment Instance Identifier		O			
19	Date/Time of the Analysis	TS_5	RE	[0..1]		
20	Reserved for harmonization with *Version 2.6.*		X			Excluded for this Implementation Guide
21	Reserved for harmonization with *Version 2.6.*		X			Excluded for this Implementation Guide
22	Reserved for harmonization with *Version 2.6.*		X			Excluded for this Implementation Guide
23	Performing Organization Name	XON_MI01	R	[1..1]		
24	Performing Organization Address	XAD_01	R	[1..1]		
25	Performing Organization Medical Director	XCN_MI01	RE	[0..1]		

USAGE NOTE

This guide **recommends** the use of SNOMED CT for senders, with a reminder, that a future release of this guide will require the use of the SNOMED CT vocabulary for Microbiology related results reported as Coded With Exception (CWE) data types in OBX.5 (and identified as CWE in OBX-2). As of this version, the SOM uses SNOMED CT reported as Coded Element (CE) in OBX-5 (and identified as CE in OBX-2). See Section 6.2. SNOMED CT.

If either OBX-3.3 or OBX-3.6 is 'LN' (LOINC) then the data type identified in OBX-2 should be drawn from Table 15 below. Data Types for LOINC Scale Part based on the LOINC Scale Part of the code in OBX-3.1 or OBX-3.4, except when OBX-11 equals 'I', 'X' or 'N'. The scale of the LOINC code used in OBX-3 (Observation Identifier) prescribes what kinds of OBX-2 (Observation Type) values are expected to be used in OBX-5 (Observation Value).

Table 15 - Observation Value Data Types for LOINC Scale Part

LOINC Scale Part	OBX-2 Value Type
QN - Quantitative	NM, SN, TS, TM, DT
ORD - Ordinal	CE, CWE, SN
NOM – Nominal	CE, CWE
NAR – Narrative	FT, TX or ST
ORDQN - Quantitative or Ordinal	NM, SN, TS, TM, DT, CE, CWE
MULTI - Multi	FT, TX or ST

OBX-14 (Date/Time of the Observation) will be identical to **OBR-7 (Observation Date/Time).**

Conformance Statements: Base Profile

- The value of OBX-5 (Observation Value) **SHALL NOT** be truncated.
- The value of OBX-1 (Set ID – OBX) **SHALL** be valued sequentially starting the value '1' within a given segment group.
- If there are multiple OBX segments associated with the same OBR segment that have the same OBX-3 values for (OBX-3.1 + OBX-3.3) or (OBX-3.4 + OBX-3.6), a combination of (OBX-3.1 + OBX3.3) or (OBX-3.4 + OBX-3.6) and OBX-4 **SHALL** create a unique identification under a **single** OBR**.**
- If OBX-2 (Observation Type) is valued, then the data type format for OBX-5 **SHALL** conform to the corresponding constrained data type identified in the "Data Type Flavor" column of HL7 Table 0125 found in Section 6.6.7. HL7 Table 0125 – Value Type (V2.5.1) of this guide.
- If OBX-5 (Observation Value) is CE (as indicated in OBX-2), then CE.1 (Identifier) and CE.3 (Name of Coding System) or CE. 4 (Alternate Identifier) and CE.6 (Name of Alternate Coding System) **SHALL** be valued.

EXAMPLE 1:

```
OBX|1|CE|47236-5^Treponema pallidum Ab.IgG+IgM^LN^Syphilis Antibody^Syphilis Antibody^L^2.34^v
unknown^Syphilis Antibody||131194007^NON-REACTIVE^2.16.840.1.113883.6.96^NON-REACTIVE^NON-
REACTIVE^L^01/31/2011^v unknown^NON-REACTIVE|||N^Normal (applies to non-numeric
results)^HL70078^N^N^L^v2.5|||F|||20230224101500|||||20230629113500|||Michigan Dept of Health and Human
Services - Bureau of Laboratories^D^^^^CLIA&2.16.840.1.113883.19.4.6&ISO^XX^^^23D0650909|3350 N. Martin
Luther King Jr Blvd^^Lansing^MI^48906
```

EXAMPLE 2:

```
OBX|1|ST|Gram Stain^Gram Stain^LN^Gram Stain^Gram Stain^L^2.34^v unknown^Gram Stain|1|Epithelial
cells|||N|||F|||20230323170000|||||20230801162013||||Michigan Dept of Health and Human Services - Bureau
```

```
of Laboratories^D^^^^CLIA&2.16.840.1.113883.19.4.6&ISO^XX^^^23D0650909|3350 N. Martin Luther King Jr
Blvd^^Lansing^MI^48906
OBX|2|ST|Gram Stain^Gram Stain^LN^Gram Stain^Gram Stain^L^2.34^v unknown^Gram Stain|2|Gram positive
bacilli|||N|||F|||20230323170000|||||20230801162013||||Michigan Dept of Health and Human Services -
Bureau of Laboratories^D^^^^CLIA&2.16.840.1.113883.19.4.6&ISO^XX^^^23D0650909|3350 N. Martin Luther King
Jr Blvd^^Lansing^MI^48906
```

3.9.1. Allowed OBX-11 Transitions

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

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

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

How to Read This Table

1st row: An existing OBX-11 valued 'I' (In Process) can take on the following values in a subsequent transaction: 'I' (In Process), 'P' (Preliminary), or 'F' (Final). It cannot be changed to 'C' (Corrected).
2nd row: An existing OBX-11 valued 'P' can take on the following values in a subsequent transaction: 'P' or 'F'. It cannot be changed to 'I' or 'C'.
3rd row: An existing OBX-11 valued 'F' can take on the following values in a subsequent transaction: 'F' or 'C'. It cannot be changed to 'I' or 'P'.
4th row: An existing OBX-11 valued 'C' can take on the following values in a subsequent transaction: 'C'. It cannot be changed to 'I', 'P', or 'F'.

Table Legend

A = Allowed
Not Allowed

Table 16 - Allowed OBX-11 Transitions

From OBX-11 (existing result)		To OBX-11 (new result)			
		I	**P**	**F**	**C**
I	In Process	A	A	A	
P	Preliminary		A	A	
F	Final			A	A
C(1)	Corrected				A

Notes

(1) Once Corrected, always Corrected.

3.10. SPM – Specimen Segment

The Specimen Information Segment (SPM) describes the characteristics of a single sample. The SPM segment carries information regarding the typeof specimen, where and how it was collected, who collected it, and some basic characteristics of the specimen.

Table 17 - SPM – Specimen Segment

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Set ID – SPM	SI	R	[1..1]		
2	Specimen ID	EIP_MI01	R	[1..1]		
3	Specimen Parent IDs		O			
4	Specimen Type	CWE_03	R	[1..1]	BOL Specimen Source List	See the Laboratory Services Guide available on the BOL website for a list of valid specimen sources for each test order.
5	Specimen Type Modifier		O			
6	Specimen Additives		O			
7	Specimen Collection Method		O			
8	Specimen Source Site		O			
9	Specimen Source Site Modifier		O			
10	Specimen Collection Site		O			
11	Specimen Role		O			
12	Specimen Collection Amount		O			
13	Grouped Specimen Count		O			
14	Specimen Description		O			
15	Specimen Handling Code		O			
16	Specimen Risk Code		O			

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
17	Specimen Collection Date/Time	DR	RE	[0..1]		SPM-17.1 must use TS_4 for the data type definition. SPM-17.2 must use TS_5 for the data type definition. For OBXs reporting observations based on this specimen, OBX-14 should contain the same value as component 1 of one of the SPM-17.1 values under the OBR.
18	Specimen Received Date/Time		O			
19	Specimen Expiration Date/Time		O			
20	Specimen Availability		O			
21	Specimen Reject Reason		O			
22	Specimen Quality		O			
23	Specimen Appropriateness		O			
24	Specimen Condition		O			
25	Specimen Current Quantity		O			
26	Number of Specimen Containers		O			
27	Container Type		O			
28	Container Condition		O			
29	Specimen Child Role		O			

USAGE NOTE

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

Conformance Statements: Base Profile

- The value of SPM-1 (Set ID – SPM) **SHALL** be valued sequentially starting the value '1'.
- SPM-4.3 (Name of Coding System) **SHALL NOT** be valued with HL70353.
- SPM-4.6 (Name of Alternate Coding System) **SHALL NOT** be valued with HL70353.
- SPM-2 shall not repeat with in a given order group.

EXAMPLE:

```
SPM|1||LO105649^CL23-132113&STARLIMS.MI.STAG&2.16.840.1.114222.4.1.103423&ISO||119395005^Specimen
from uterine cervix (specimen)^SCT^CERVIX^CERVIX^CERVIX||||||||||||20231120093500|20231121
```

3.11. NTE – Notes and Comments Segment

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

Table 17 - Notes and Comments Segment (NTE)

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Set ID – NTE	SI	R	[1..1]		For the first repeat of the NTE segment, the sequence number shall be one (1), for the second repeat, the sequence number shall be two (2), etc.
2	Source of Comment		O			
3	Comment	FT	R	[1..*]		Comment contained in the segment. Note: The SOM uses the '~' repetition separator as a line break indicator.
4	Comment Type		O			

EXAMPLE 1:

```
NTE|1||Lead - Whole Blood comments: For laboratory test footnotes, please see:
https://www.michigan.gov/mdhhs/-/media/Project/Websites/mdhhs/BOL/HL7---Laboratory-Test-
Footnotes/Lead---Whole-Blood v06-12-
23.pdf?rev=cfba7b986cd04cfd8469fb8f9479c96bandhash=6F5107A5CA980D2A6AAF1F883C64ED6F
```

EXAMPLE 2:

```
NTE|1||Final MALDI-TOF Identification - Staphylococcus aureus~Final MALDI-TOF Identification -
Enterococcus faecalis
```

4. Use Case, Special Cases and Error Conditions

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 BOL Test Orders (OML) and Results (ORU) by HL7 Messaging.

4.1. Use Case – Laboratory Results

Laboratory results are accurately reported and successfully transmitted electronically from the SOM to the Ordering Provider's (order placer's) EHR-S, module, or another results receiver.
The LRI result receiver will electronically receive the laboratory results, incorporated in a standardized structured format, and if available, associated with a patient and laboratory order. It is assumed that the receiving system is an EHR-S that can receive lab results even if it is not aware of the request, as there is no assumption that the receiving EHR-S provided the request for lab services.

Table 18 - Functional Requirements

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

Table 19 - System Requirements

Systems	System Requirements
SOM	Form a laboratory message with standardized structured data meeting CLIA and other federal and state regulatory requirements.
Electronic Health Record System	Incorporate and display test data from the laboratory message as standardized structured data.

4.2. Special Cases

4.2.1. Test Referred to CDC for Testing

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

4.2.2. Specimen Status Received

The SOM will confirm the receipt of shipped clinical specimens by sending a specimen status received ORU once the specimen has been accessioned into the laboratory. The Specimen Received ORUs are identified by the Observation Identifier (OBX-3) of "Specimen Status" and an Observation Value (OBX-5) of "Received".

Note that the result status (OBR-25) for a Specimen Received ORU will be "I" (No results available; specimen received procedure *incomplete*) since this is a notification message and no actual testing has been performed and that the Observation Result Status (OBX-11) will be "F" since no further specimen updates will be sent.

4.2.3. Parent/Child Reporting for Reflex and Culture/Susceptibility Testing

It must be understood that an observation (test result value) can be the catalyst for additional tests (orders), e.g., reflex tests (orders). When looking at those test orders and results, it is important to understand which is the originator (Parent), and which test orders and results are generated as Children. For example, an order has a result that yields a reflexive test based on the test result value, or an order yields a culture that in turn is identified to

contain an organism that yields a specific susceptibility for an identified drug. Note that there is no information in the Parent that indicates the presence of a Child. It is the function of the Child pointing to a Parent that defines the relationship.

Both parent and child(ren) must be in the same message and the parent must precede its child(ren). Child observations will have its own Common Order (ORC)/Observation Request (OBR) group. The Child's "Parent Result" field (OBR-26), and "Parent" field (OBR-29), and "Parent Universal Service Identifier" field (OBR-50) are all required in order to link to the Parent as described below.

4.2.3.1. PARENT OBX MATCHING

OBR-26 – Parent Result is populated in the Child observations, and this provides a link between the Child OBR, and the OBX in the Parent that generated the new tests. It will contain the two subfields, the first (OBR-26.1) will be valued with the Parent's "Observation Identifier" (OBX-3), and the second (OBX-26.2) will be valued with the Parent's "Observation Sub-ID" (OBX-4). (Please Note: The Parent's "Observation Identifier" (OBX-3) component separators will need to be converted to *sub-component* separators when placed into the Child's OBR)

Parent OBX:

```
OBX|1|CE|6463-4^Bacteria identified^LN^Isolate^Isolate^L^2.34^v
unknown^Isolate|1|3092008^Staphylococcus
aureus^SCT|||A|||F|||20230323170000|||||20230801162041||||Michigan Dept
of Health and Human Services - Bureau of
Laboratories^D^^^^CLIA&2.16.840.1.113883.19.4.6&ISO^XX^^^23D0650909|335
0 N. Martin Luther King Jr Blvd^^Lansing^MI^48906
```

Child OBR:

```
OBR|3|LO104336|CL23-
209990^STARLIMS.MI.STAG^2.16.840.1.114222.4.3.3.2.37.2^ISO|2821-
87^Aerobic Culture - Antimicrobial Susceptibility
Results^L|||20230323170000|||||||||0001011119^Support^Pat^^^^^^NPI|||||
|20230821161958|||F|6463-4&Bacteria
identified&LN&Isolate&Isolate&L&2.34&v unknown&Isolate^1^Staphylococcus
aureus|||LO104336^CL23-
209990&STARLIMS.MI.STAG&2.16.840.1.114222.4.3.3.2.37.2&ISO||||||||||||
||||||||2821-85^Aerobic Culture - Culture Results^L
```

4.2.3.2. PARENT OBR MATCHING

OBR-29 – Parent and **OBR-50 – Parent Universal Service Identifier** are populated in the Child observations and provide a link between the Child OBR, and the Parent OBR. The child's OBR-50 matches the value of its parent OBR-4 (Universal Service Identifier). The child's OBR-29 contains two fields the first (OBR-29.1) will be populated with the Parent's OBR-2 value, and the second field (OBR-29.2) will be populated with the Parent's OBR-3 value. (Please Note: The Parent's OBR-2, and OBR-3, component separators will need to be converted to *sub-component* separators when placed into the Child's OBR)

Both OBR-29 and OBR-50 are required to uniquely identify the linking relationship in the Parent OBR since a test can only be identified using the order number (OBR-2/OBR-3) in combination with the Parent Universal Service Identifier (OBR-4).

Non-Parent OBR:

```
OBR|1|LO104336|CL23-
209990^STARLIMS.MI.STAG^2.16.840.1.114222.4.3.3.2.37.2^ISO|2821-
84^Aerobic Culture - Gram
Stain^L|||20230323170000||||||||0001011119^Support^Pat^^^^^^NPI||||||2
0230821161958|||F
```

Parent OBR:

```
OBR|2|LO104336|CL23-
209990^STARLIMS.MI.STAG^2.16.840.1.114222.4.3.3.2.37.2^ISO|2821-
85^Aerobic Culture - Culture
Results^L|||20230323170000||||||||0001011119^Support^Pat^^^^^^NPI|||||
|20230821161958|||F
```

Child OBR:

```
OBR|3|LO104336|CL23-
209990^STARLIMS.MI.STAG^2.16.840.1.114222.4.3.3.2.37.2^ISO|2821-
87^Aerobic Culture - Antimicrobial Susceptibility
Results^L|||20230323170000||||||||0001011119^Support^Pat^^^^^^NPI|||||
|20230821161958|||F|6463-4&Bacteria
identified&LN&Isolate&Isolate&L&2.34&v unknown&Isolate^1^Staphylococcus
aureus|||LO104336^CL23-
209990&STARLIMS.MI.STAG&2.16.840.1.114222.4.3.3.2.37.2&ISO||||||||||||
||||||||2821-85^Aerobic Culture - Culture Results^L
```

4.2.3.3. EXAMPLES OF CULTURE AND SUSCEPTIBILITY RESULTS

Microbiology testing involves culturing a clinical sample for several days to determine if anything grows. If nothing grows, the culture is "negative" and gets reported in a relatively simple v2.5.1 message. If something grows, then observations are collected, and more tests are done. Observations can include:

- "normal flora"
- Growth Quantity
- Gram stain
- The actual identified organism(s)
- Antimicrobial Susceptibility testing on each isolate independently

Message Structure for a Culture and Susceptibility Result

```
MSH…
PID…
ORC...
OBR – gram stain
OBX – gram stain observations (non-isolate or specimen observations)
OBR – culture
OBX – culture level observations
OBR – organism 1 susceptibility
OBX – antimicrobial (organism 1) susceptibility observations
OBR – organism 2 susceptibility
OBX – antimicrobial (organism 2) susceptibility observations
SPM – specimen
```

Template for Culture Results

A template report for the specimen gram stain and initial identification of three organisms from a single wound culture is presented below.

EXAMPLE

```
MSH|…
PID|…
ORC|…
OBR|1|Placer number (OBR-2)|Filler number (OBR-3)|Identifier code for
the requested test or panel of tests(OBR-4)|...
OBX|1||Other identifier (OBX-3)|Sub-id for the first observation
(OBX-4)|Observation on the specimen (OBX-5)|...|
OBX|n||Other identifier (OBX-3)|Sub-id for the second observation
(OBX-4)|Observation on the specimen (OBX-5)|...|
OBX|n+1||Other identifier (OBX-3)|Sub-id for the third observation
(OBX-4)|Observation on the specimen (OBX-5)|...|
OBR|2|Placer number (OBR-2)|Filler number (OBR-3)|Identifier code for
the requested test or panel of tests(OBR-4)|...
OBX|n||Specific organism identifier (OBX-3)|Sub-id for the first
organism (OBX-4)|Description of organism (OBX-5)|...|
OBX|n+1||Specific organism identifier (OBX-3)|Sub-id for the second
organism (OBX-4)|Description of organism (OBX-5)|...|
OBX|n+1||Specific organism identifier (OBX-3)|Sub-id for the third
organism (OBX-4)|Description of organism (OBX-5)|...|
SPM|1|Specimen identifier for the specimen being tested|
```

This report has the MSH (Message Header), the PID (Patient Identification Segment), *multiple* OBRs (Observation Request Segment), and *multiple* OBX (Observation/Results) segments, and a single SPM (Specimen Segment). Note that the Set ID in the first field of each OBX is sequential, while the Sub-ID in the fourth field of each OBX is not sequential but acts as a link for all of the OBX segments that are reporting information for a related observation. The Sub-ID field in the template above has the words "first," "second" and "third" in **bold** and highlighted in green. Note how multiple OBX segments associated with the same OBR segment have the same OBX-3 values for (OBX-3.1 + OBX-3.3) or (OBX-3.4 + OBX-3.6), and that a combination of (OBX-3.1 + OBX3.3) or (OBX-3.4 + OBX-3.6) and OBX-4 SHALL create a unique identification, and discrete result, under a single OBR.

Example message for Culture Results

In this example, a preliminary culture result for a specimen gram stain and initial identification of two organisms from a single Aerobic Culture from wound (specimen) is sent. There are three distinct, related observations for the gram stain OBR segment and two distinct, related observations for the Culture Results OBR segment.

EXAMPLE

```
MSH|…
PID|…
ORC|RE|LO104336|CL23-209990…|GRP#|
OBR|1|LO104336|CL23-209990…|2821-84^Aerobic Culture - Gram Stain^L|…
OBX|1|ST|Gram Stain^Gram Stain^LN^Gram Stain^Gram Stain^L^2.34^v
unknown^Gram Stain|1|Epithelial cells|…
```

```
OBX|2|ST|Gram Stain^Gram Stain^LN^Gram Stain^Gram Stain^L^2.34^v
unknown^Gram Stain|2|Gram positive bacilli|…
OBX|3|ST|Gram Stain^Gram Stain^LN^Gram Stain^Gram Stain^L^2.34^v
unknown^Gram Stain|3|Gram positive cocci|…
OBR|2|LO104336|CL23-209990…|2821-85^Aerobic Culture - Culture
Results^L|…
OBX|1|CE|6463-4^Bacteria identified^LN^Isolate^Isolate^L^2.34^v
unknown^Isolate|3|3092008^Staphylococcus aureus^SCT|…
OBX|2|CE|6463-4^Bacteria identified^LN^Isolate^Isolate^L^2.34^v
unknown^Isolate|2|78065002^Enterococcus faecalis^SCT|…
SPM|1|LO104336^CL23-209990…||119365002^Specimen from wound
(specimen)^SCT^WOUND^WOUND^WOUND|||||||||||20230323170000|20230801
```

Template for Culture and Susceptibly Results

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

EXAMPLE

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

```
MSH|…
PID|…
ORC|…
```

Non-Parent OBR Segment

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

OBX Segments for Non-Isolate Related Specimen Observations

```
OBX|1||Other identifier (OBX-3)|Sub-id for the first observation
(OBX-4)|Observation on the specimen (OBX-5)|...|
OBX|n||Other identifier (OBX-3)|Sub-id for the second observation
(OBX-4)|Observation on the specimen (OBX-5)|...|
OBX|n+1|| Other identifier (OBX-3)|Sub-id for the third observation
(OBX-4)|Observation on the specimen (OBX-5)|...|
```

Parent OBR Segment

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

Parent OBX Segments for First Organism Identified

```
OBX|n||Specific organism identifier (OBX-3)|Sub-id for the first
organism (OBX-4)|Description of organism (OBX-5)|...|
```

Parent OBX Segments for Second Organism Identified

```
OBX|n+1||Specific organism identifier (OBX-3)|Sub-id for the second
```

organism (OBX-4)|Description of organism (OBX-5)|...|
SPM|1|Specimen identifier for the specimen being tested|

Parent OBX Segments for Third Organism Identified

OBX|n+1||**Specific organism identifier (OBX-3)**|**Sub-id for the third organism (OBX-4)**|Description of organism (OBX-5)|...|

SPM Segment

SPM|1|Specimen identifier for the clinical specimen being tested||clinical specimen type|...

Child OBR Group for First Organism identified

OBR|3| Placer number (OBR-2)| Filler order number (OBR-3) | Identifier code for the requested test or panel of tests (OBR-4) ||||||| Specimen Action Code ||||||||||||||**(OBR-26) The parent OBX segment that contained the identification of the first organism**|||**(OBR-29) Parent order number** |||||||||||||||||||| **Parent identifier code for the requested test or panel of tests (OBR-50)**|...

Child OBX Segments for Susceptibilities of First Organism Identified

OBX|n||Specific susceptibility identifier for first antimicrobial (OBX-3) || Susceptibility finding (OBX-5) ||| Susceptibility interpretation (OBX-8) |…
OBX|n+1||Specific susceptibility identifier for second antimicrobial (OBX-3)|| Susceptibility finding (OBX-5) ||| Susceptibility interpretation (OBX-8) |…
OBX|n+2||Specific susceptibility identifier for third antimicrobial(OBX-3)|| Susceptibility finding (OBX-5) ||| Susceptibility interpretation (OBX-8) |…

Child OBR Segment for Susceptibilities of Second Organism Identified

OBR|4| Placer number (OBR-2)| Filler order number (OBR-3) | Identifier code for the requested test or panel of tests (OBR-4) ||||||| Specimen Action Code ||||||||||||||**(OBR-26) The parent OBX segment that contained the identification of the second organism**|||**(OBR-29) Parent order number**||||||||||||||||||||**(OBR-50) The parent identifier code for the requested test or panel of tests (or OBR-4 of Parent OBR)**|...

Child OBX Segments for Susceptibilities of Second Organism Identified

OBX|n||Specific susceptibility identifier for first antimicrobial (OBX-3) || Susceptibility finding (OBX-5) ||| Susceptibility interpretation (OBX-8) |…
OBX|n+1||Specific susceptibility identifier for second antimicrobial (OBX-3)|| Susceptibility finding (OBX-5) ||| Susceptibility interpretation (OBX-8) |…
OBX|n+2||Specific susceptibility identifier for third antimicrobial(OBX-3)|| Susceptibility finding (OBX-5) ||| Susceptibility interpretation (OBX-8) |…

Child OBR Segment for Susceptibilities of Third Organism Identified

OBR|4| Placer number (OBR-2)| Filler order number (OBR-3) | Identifier code for the requested test or panel of tests (OBR-4) ||||||| Specimen Action Code ||||||||||||||**(OBR-26) The parent OBX**

segment that contained the identification of the third organism|||**(OBR-29) Parent order number** ||||||||||||||||||||**(OBR-50) The parent identifier code for the requested test or panel of tests (or OBR-4 of Parent OBR)**|...

Child OBX Segments for Susceptibilities of Second Organism Identified

OBX|n||Specific susceptibility identifier for first antimicrobial (OBX-3) || Susceptibility finding (OBX-5) ||| Susceptibility interpretation (OBX-8) |…
OBX|n+1||Specific susceptibility identifier for second antimicrobial (OBX-3)|| Susceptibility finding (OBX-5) ||| Susceptibility interpretation (OBX-8) |…
OBX|n+2||Specific susceptibility identifier for third antimicrobial(OBX-3)|| Susceptibility finding (OBX-5) ||| Susceptibility interpretation (OBX-8) |…

SPM Segment

SPM|1|Specimen identifier for the clinical specimen being tested||**clinical specimen type**|...

Example message for Culture and Susceptibly Results

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

Using the template above, this example shows a Culture and Susceptibility result for the specimen gram stain and identification of two organisms with their respective antimicrobial susceptibility tests. Fields bolded and highlighted in green are used for linking parent and child results as identified in the template above.
Note that since the gram stain has no Parent/Child relationships, the Sub-ID (OBX-4) for those non-isolate specimen observations serve to create a unique identification for reporting the gram stain observations under the OBR.

EXAMPLE

MSH|…
PID|…
ORC|RE|LO104336|CL23-209990…|GRP#|
OBR|1|LO104336|CL23-209990…|2821-84^Aerobic Culture - Gram Stain^L|…
OBX|1|ST|Gram Stain^Gram Stain^LN^Gram Stain^Gram Stain^L^2.34^v unknown^Gram Stain|**1**|Epithelial cells|…
OBX|2|ST|Gram Stain^Gram Stain^LN^Gram Stain^Gram Stain^L^2.34^v unknown^Gram Stain|**2**|Gram positive bacilli|…
OBX|3|ST|Gram Stain^Gram Stain^LN^Gram Stain^Gram Stain^L^2.34^v unknown^Gram Stain|**3**|Gram positive cocci|…
OBR|2|**LO104336|CL23-209990…**|**2821-85^Aerobic Culture - Culture Results^L**|…
OBX|1|CE|**6463-4^Bacteria identified^LN^Isolate^Isolate^L**^2.34^v unknown^Isolate|3|3092008^Staphylococcus aureus^SCT|…
OBX|2|CE|6463-4^Bacteria identified^LN^Isolate^Isolate^L^2.34^v unknown^Isolate|2|78065002^Enterococcus faecalis^SCT|…
OBR|3|LO104336|CL23-209990…|2821-87^Aerobic Culture - Antimicrobial

```
Susceptibility
Results^L|||20230323170000|||||||||0001011119^Support^Pat^^^^^^NPI|||
|||20230817144824|||F|6463-4&Bacteria
identified&LN&Isolate&Isolate&L&2.34&v
unknown&Isolate^1^Staphylococcus aureus|||LO104336^CL23-
209990&STARLIMS.MI.STAG&2.16.840.1.114222.4.3.3.2.37.2&ISO||||||||||
||||||||||2821-85^Aerobic Culture - Culture Results^L
OBX|1|SN|18906-
8^Ciprofloxacin^LN^Ciprofloxacin^Ciprofloxacin^L^2.34^v
unknown^Ciprofloxacin|1| <=^0.5|||S|||F|…
OBX|2|SN|18928-2^Gentamicin^LN^Gentamicin^Gentamicin^L^2.34^v
unknown^Gentamicin|1|^8|||I|||F|…
OBX|3|SN|19000-9^Vancomycin^LN^Vancomycin^Vancomycin^L^2.34^v
unknown^Vancomycin|1|^128|||R|||F|…
OBR|4|LO104336|CL23-209990…|2821-87^Aerobic Culture - Antimicrobial
Susceptibility
Results^L|||20230323170000|||||||||0001011119^Support^Pat^^^^^^NPI|||
|||20230817144824|||F|6463-4&Bacteria
identified&LN&Isolate&Isolate&L&2.34&v unknown&Isolate^2^Enterococcus
faecalis|||LO104336^CL23-
209990&STARLIMS.MI.STAG&2.16.840.1.114222.4.3.3.2.37.2&ISO||||||||||
||||||||||2821-85^Aerobic Culture - Culture Results^L
OBX|1|ST|18906-
8^Ciprofloxacin^LN^Ciprofloxacin^Ciprofloxacin^L^2.34^v
unknown^Ciprofloxacin|2|See Comments|||N|||F|…
OBX|2|SN|7018-5^Gentamicin.high potency^LN^Gentamicin 500^Gentamicin
500^L^2.34^v unknown^Gentamicin 500|2| <=^500|||S|||F||…
BX|4|SN|19000-9^Vancomycin^LN^Vancomycin^Vancomycin^L^2.34^v
unknown^Vancomycin|2| >^128|||R|||F|…
SPM|1|LO104336^CL23-209990…||119365002^Specimen from wound
(specimen)^SCT^WOUND^WOUND^WOUND|||||||||||||20230323170000|20230801
```

4.2.4. Reflex Testing

Definition: Confirmatory or additional laboratory testing that is automatically included in the original test request by a laboratory under its standard operating procedures for patient specimens when the laboratory's findings indicate test results that are abnormal, are outside a predetermined range, or meet other pre-established criteria for additional testing. Reflex tests may not have orderable test codes. For more information on performed testing please see the SOM website Lab Services guide: A-Z Test Listing.

CLIA Compliance: The initial test request received in the laboratory is adequate to demonstrate an order for both the initial and the additional testing for CLIA compliance and CMS auditing purposes.

The **LIS** will report the reflexed test as one or more additional OBR/OBX(s). Microbiology results with multiple isolates will contain parent-child relationships.

The **EHR** should support reporting a reflexed test and associate it with the original test request for the specimen.

4.2.5. Add-On Testing

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

CLIA Compliance: CLIA requires the laboratory to obtain a written or electronic test request for the add-on testing from the authorized provider for its records. If the test request is verbal the laboratory must document its efforts to receive a written or electronic test request within 30 days. [42CFR493.1241(b)]

The **LIS** will report the add-on test as one of the following:

- one or more additional OBR/OBX(s) or
- a new order.

The **EHR** should support both of these methods of reporting an add-on test.

4.2.6. Preliminary, Final, and Corrected Messages

Each order is identified in the EHR by a placer order number [ORC 2/OBR 2] in conjunction with the ordered test [OBR 4], which may lead to one or more performed tests, and the status of all results under that order [OBR 25]. From an HL7 message perspective, this is considered a report unit and requires the use of the report date [OBR 22]. The report date (OBR 22) is used to identify if the data in the HL7 message is an update to already existing information or not and is used to trigger the replacement of data whereas the status flags [OBR 25 and OBX 11] are only used to display the status of the report and the individual results. Refer to Section 1.2.6. Snapshot Mode for a discussion of snapshot mode.

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

Preliminary Message

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

```
MSH...
...
OBR|1|...| 57782-5^CBC with Ordered Manual Differential panel in
Blood^LN... |20141106102631|||P|...
OBX|1|NM|26453-1^Erythrocytes [#/volume] in
Blood^LN...|4.41|10*6/uL^million per microliter^UCUM|4.3 to 6.2|N|||F|...
...
OBX|10|...|F|...
...
```

Final Message

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

```
MSH...
...
OBR|1|...| 57782-5^CBC with Ordered Manual Differential panel in
Blood^LN...|20141106112601|||F|...
OBX|1|NM|26453-1^Erythrocytes [#/volume] in
Blood^LN...|4.41|10*6/uL^million per microliter^UCUM|4.3 to 6.2|N|||F|...
...
OBX|24|TX|779-9^Poikilocytosis [Presence] in Blood by Light
microscopy^|None seen|...|F|...
```

Corrected Message

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

```
MSH...
...
OBR|1|...| 57782-5^CBC with Ordered Manual Differential panel in Blood^LN...
|20141106132601|||C|...
OBX|1|NM|26453-1^Erythrocytes[#/volume] in Blood^LN...|4.41|10*6/uL^million per
microliter^UCUM|4.3 to 6.2|N|||F|...
...
OBX|24|TX|779-9^Poikilocytosis [Presence] in Blood by Light
microscopy^|Moderate Poikilocytosis|...|C|...
...
```

4.2.7. Out of Order Messages

The EHR must be able to update laboratory results over time. Since per LRI guide OBR-22 must be updated by the laboratory with any change in the respective OBR segment or any associated segment under that OBR, the following rules apply:

1) Report succession is determined by OBR-22.
2) OBR-25 and OBX-11 shall not be used to determine chronological order, separate status change restrictions are described in Relationship Between OBR-25 (Result Status) and OBX-11 (Observation Status).

If the previous OBR-22 value is:

- **greater than or equal to** the current OBR-22 associated with a previously received report, then the EHR SHALL replace the report with the new version.
- **less than** the current OBR-22 associated with a previously received report, then this is an error and SHOULD be evaluated as soon as possible to determine the cause.

The **EHR** SHALL always display the most recent version of a laboratory order and its results.
The **EHR** should use the result status codes (OBR-25) to properly identify the CLIA required status of the report and the result(s) for the currently displayed report.

4.2.8. Laboratory Report

As of this writing, the SOM is unable to support embedded PDF lab reports. Implementers are required to create the Laboratory Test Report comprised of the data elements specified below. Such data are meant to be displayed concurrently in their entirety by the EHR technology and the content must be presented in a human readable format. Human readable format means a format that enables a human to read and easily comprehend the information presented to him or her regardless of the method of presentation. [45 CFR 170.102]. See APPENDIX C - Additional Implementation Guidance – Other for a discussion on mandatory reporting requirements.

For each order, the following information must be displayed on the Laboratory Test Report:

1) Patient information

- Patient name [PID-5 (Patient Name)]
- Unique patient Identification number [PID-3 (Patient Identifier List)]
- DOB [PID-7 (Date/Time of Birth)]
- Gender [PID-8 (Administrative Sex)]

2) Order information

- Ordered test [OBR-4 (Universal Service Identifier)]
- Order status [OBR-25 (Result Status)]
- Ordering Provider [ORC-12/OBR-16]
- Ordering Facility Name [ORC-21] and Address [ORC-22]
- Report Date [OBR-22 (Results Rpt/Status Chng - Date/Time)]
- Order Notes [NTE-3] where applicable

3) Specimen Information

- Specimen Source [SPM-4 (Specimen Type)] when applicable
- Specimen ID or Filler Order Number [SPM-2.2.1 or OBR-3.1]
- Specimen Collection Date/Time [SPM-17]
- Specimen Received Date/Time [SPM-18]

4) Test information

- Test name [OBX-3 (Observation Identifier)]
- Test result [OBX-5]
- Units [OBX-6] where applicable
- Reference range(s) [OBX-7]
- Interpretation [OBX-8]
- Result status [OBX-11]
- Any notes or additional information regarding the result or its interpretation [NTE-3] (NTE immediately following that OBX)

5) Performing Organization

- Performing Organization Name [OBX-23]
- Performing Organization Address [OBX-24]

Note: all components of a single ordered test (e.g., CBC or Micro culture) must be included in a single "test report". This includes all parent child relationships that are part of a single HL7 R01 result transaction.

4.3. Error Conditions

4.3.1. Delivery Failure

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

4.4. Health Information Exchanges (HIE) and Related Requirements

4.4.1. Message Header Validation

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

Table 20 - Message Header Validation

MSH Field	Field Name	Requirements
MSH-4	Sending Facility	Contact your HIE for more information on what this field will include.
MSH-5	Receiving Application	Contact your HIE for more information on what this field will include.
MSH-6	Receiving Facility	Contact your HIE for more information on what this field will include.
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 on boarding process.
MSH-12	Version ID	Must be populated with 2.5.1

4.4.2. ACK Messages Handling

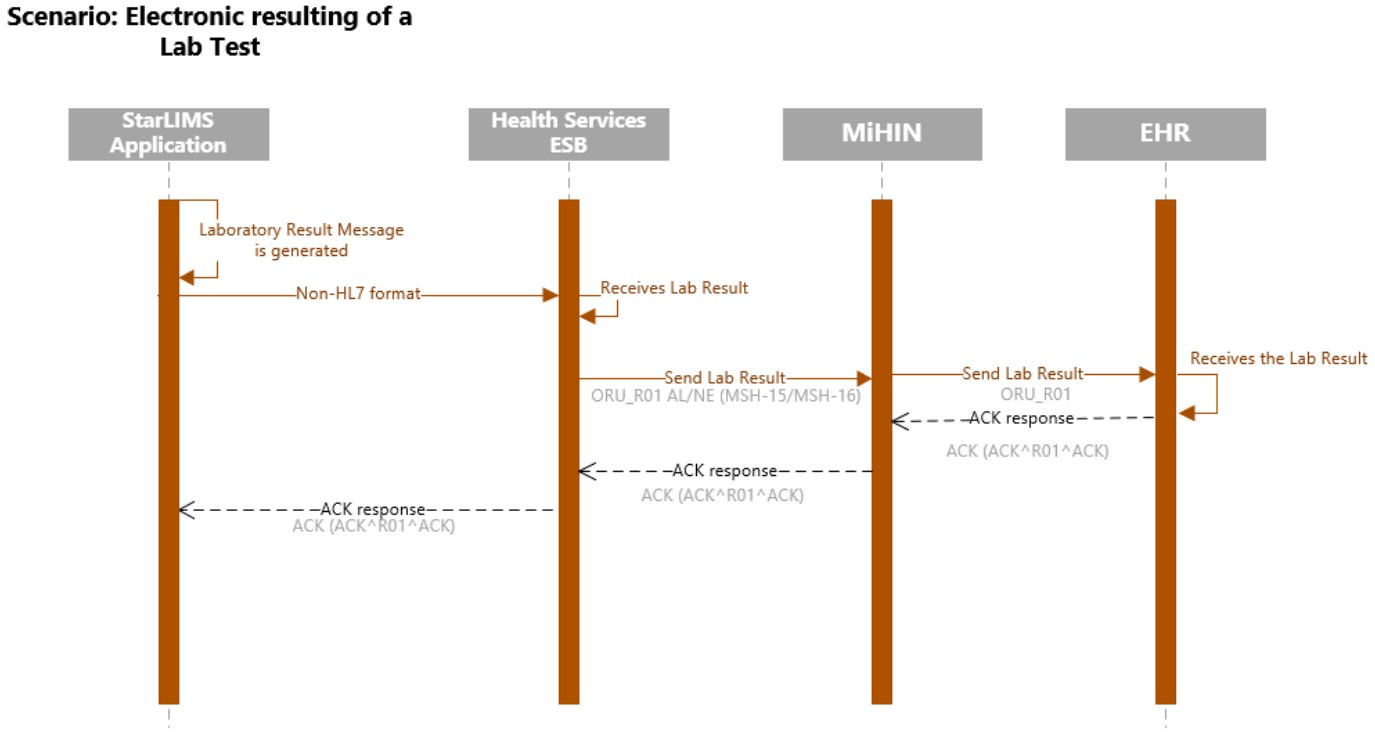
Health Information Exchanges or other intermediaries will receive ACK messages from the provider site and shall return these messages back to the SOM.

5. Message Transport and On Boarding

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 https://mihin.org/exchanges/. For additional information, contact the staff listed in Section 1.4 SOM Point of Contact. Out-of-state providers may use the HIE infrastructure or contact the staff listed in Section 1.4 SOM Point of Contact for other options.

Figure 3 - Message Dataflow



MiHIN is a pass-through intermediary (there may be hops between the EHR & MiHIN). For the Lab Result (ORU_R01), Basic Acknowledgements, i.e., MSH-15 (Accept Acknowledgment Type = AL) and MSH-16 (Application Acknowledgement Type = NE) are valued by the message sender and control the creation of a node-to-node accept level 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 StarLIMS application to the Health Services ESB may not be HL7 format.

5.2. On-boarding Instructions

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

5.2.1. Pre-Production Onboarding

Prior to entering into full production, submitters are required to go through a data/message quality phase for Pre-Production Onboarding. During this phase, real messages are sent, just as in production, but MSH-11 “Processing ID” is to be set to the literal value of “T”. Messages are reviewed for completeness and quality by 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 Section 1.4. 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 (e.g., during an EHR upgrade), they may request an additional round of Pre-Production Onboarding testing. This must be coordinated with BOL staff, and the MSH-11 “Processing ID” must be set to the literal value of “T” for any test message. Production messaging can continue during additional rounds of Pre-Production Onboarding testing aslong as the MSH-11 “Processing ID” is set to the literal value of “P” for production messages, and BOL staff haveapproved.

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 Section 1.4. SOM Point of Contact. 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 validvalues for coded fields. It is important to note that code sets are relatively dynamic and subject to change between publications of these implementation guides.

Every code value passed in a message instance is drawn from a code system that either may have a globally unique identifier, such as an OID, an HL7 identifier (Table 0396), or a locally defined identifier. In general, the coded values allowed in a field (a) may be drawn from more than one code system, and (b) may be a subset of the codes from a given coding system. Combining (a) and (b) makes it possible for the allowed code value to be a combination of multiple subsets drawn from multiple coding systems. In most cases, only subsets of the codes defined in a code system are legal for use in a particular message.

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

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

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

6.1. LOINC

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

LOINC shall be used as the standard coding system to identify the Resulted Test in the Observation Identifier(OBX-3) if an appropriate LOINC code exists. Appropriate status is defined in the LOINC Manual Section 11.2 Classification of LOINC Term Status. If a local coding system is in use, a local code should also be sent to help with identification of coding issues. When no valid LOINC exists, the local code may be the only code sent.

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

1. If the result is related to a reportable condition and the laboratory provides a LOINC code, Regulations may require the EHR to send the LOINC code to public health.
2. If the LOINC code is the only code sent to the lab in OBX-3, then the EHR must store and retain thatcode as part of the CLIA report of record.
3. LOINC codes may be used for secondary data exchange purposes and other partner exchangeagreements.

For further information on LOINC and access to tools, please visit http://loinc.org/

6.2. SNOMED CT

For receivers, SNOMED CT is a required vocabulary for Microbiology related results. When received, certified EHR technology shall be capable of supporting SNOMED CT codes (Concept ID, and if sent, Description as provided by IHTSDO.) For senders, SNOMED CT is the recommended vocabulary in this release of the Implementation Guide.

The majority of coded results for reportable laboratory results fall into three categories: microorganism names (e.g. 88274000^Trypanosoma cruzi^SCT), presence or absence findings (e.g. 260373001^Detected^SCT), and, less commonly, substances (255835006^Shiga toxin^SCT). If a SNOMED code is not published for a Microbiology coded result, it is acceptable to use an alternate or local coding system by itself.

For this implementation, when coded results are used in OBX-5 and reported as CE, CE.2 shall contain the laboratory's original text which is used for printing and/or display to satisfy CLIA regulation of report on record.

6.3. Specimen Type

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

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

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

6.4. UCUM

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

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

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

6.5. 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 21 - 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	
Accept/Application Acknowledgement Condition	HL70155	HL7 Version 2.5.1	
Address Type	HL70190	HL7 Version 2.5.1	
Type of Referenced Data	HL70191	HL7 Version 2.5.1	
Name Type	HL70200	HL7 Version 2.5.1	
Telecommunication Equipment Type	HL70202	HL7 Version 2.5.1	
Encoding	HL70299	HL7 Version 2.5.1	
CWE Status	HL70399	HL7 Version 2.5.1	This table is not constrained for this implementation guide. It is however constrained on where it can be used. Table HL70353 can be used for coded values except for OBX-5 and SPM-4.
Message Error Condition Codes	HL70357	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 https://www.iso.org/iso-3166-country-codes.html
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	LOINC	LOINC	http://www.loinc.org

Name	Value Set	Source	Comments
and Codes			
National Provider Identifier	NPI	NPI	https://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/NationalProvIdentStand
State Value Set	USPS	USPS	Addresses within the United States are identified by 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 https://pe.usps.com/text/pub28/28apb.htm

6.6. 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 in this guide.

Table 22 - Constrained Code System Summary

Name	Value Set	Source	Comments
Ambulatory Status	HL70009	HL7 Version 2.5.1	
Message Type	HL70076	HL7 Version 2.5.1	
Observation Result Status	HL70085	HL7 Version 2.5.1	
Processing ID	HL70103	HL7 Version 2.5.1	
Version ID	HL70104	HL7 Version 2.5.1	Constrained to '2.5.1'
Order Control	HL70119	HL7 Version 2.8.1	
Result Status	HL70123	HL7 Version 2.5.1	
Value Type	HL70125	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 2.8.1	
Result Handling	HL70507	HL7 Version 2.7.1	
MIME type (ED Type of Data)	HL70834	HL7 Version 2.7.1	

6.6.1. HL7 Table 0009 – Ambulatory Status (V2.5.1)

Only the value in the table below is supported.

Table 23 - HL7 Table 0076 – Message Type

Value	Description	Comments
B6	Pregnant	

6.6.2. HL7 Table 0076 – Message Type (V2.5.1)

Table 24 - HL7 Table 0076 – Message Type

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

6.6.3. HL7 Table 0085 – Observation Results Status (V2.5.1)

Table 25 - HL7 Table 0085 – Observation Results Status

Value	Description	Comments
C	Record coming over is a correction and thus replaces a final result	
F	Final results; Can only be changed with a corrected result.	
I	Specimen in lab; results pending	
P	Preliminary results	

6.6.4 HL7 Table 0103 – Processing ID (V2.5.1)

Table 26 - HL7 Table 0103 - Processing ID

Value	Description	Comments
T	Training	
P	Production	

6.6.5. HL7 Table 0119 – Order Control (V2.8.1)

Table 27 - HL7 Table 0119 – Order Control Constrained to just "RE"

Value	Description	Comments
CA	Cancel order/service request	
NW	New order/service	
XO	Change order/service request	

6.6.6. HL7 Table 0123 – Results Status (V2.5.1)

Table 28 - HL7 Table 0123 – Results Status

Value	Description	Comments
C	Correction to results	
F	Final results; results stored and verified. Can only be changed with a corrected result.	
I	No results available; specimen received, procedure incomplete	
P	Preliminary: A verified early result is available, final results not yet obtained	

6.6.7. HL7 Table 0125 – Value Type (V2.5.1)

Table 29 - HL7 Table 0125 – Value Type

Value	Description	Comments
CE	Coded Element	This data type transmits codes and the text associated with the code. See Section 6.2. SNOMED CT for details.
CWE	Coded with Exceptions	This data type specifies a coded element and its associated detail. The CWE data type is used when 1) more than one table may be applicable or 2) the specified HL7 or externally defined table may be extended with local values or 3) when text is in place, the code may be omitted. Pre- adopted from *Version 2.6.* See Section 6.2. SNOMED CT for details.
DT	Date	
FT	Formatted Text (Display)	Field using the FT data type to carry a text result value. This is intended for display. The text may contain formatting escape sequences as described in the data types section. Numeric results and numeric results with units of measure should not be reported as text. These should be reported as NM or SN numeric results, with the units of measure in OBX-6.
NM	Numeric	Field using the NM data type to carry a numeric result value. The only non-numeric characters allowed in this field are a leading plus (+) or minus (-) sign. The units for the numeric value should be reported in OBX-6.
SN	Structured Numeric	Field using the SN data type to carry a structured numeric result value. Structured numeric include intervals (^0^-^1), ratios (^1^/^2 or ^1^:^2), inequalities (<^10), or categorical results (2^+). The units for the structured numeric value should be reported in OBX-6.
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.
TM	Time	The time zone offset shall adhere to the use of the TimeZone Offset profile.
TS	Time Stamp (Date &Time)	The time zone offset shall adhere to the use of the TimeZone Offset profile and associated discussion if the granularity involves hh or “more”.
TX	Text Data (Display)	Field using the TX data type to carry a text result value. This is intended for display.

6.6.8. HL7 Table 0203 – Identifier Type (V2.7.1)

Table 30 - HL7 Table 0203 – Identifier Type

Value	Description	Comments
NPI	National provider identifier	
PI	Patient internal identifier	
XX	Organization identifier	

6.6.9. HL7 Table 0301 – Universal ID Type (V2.7.1)

Table 31 – 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	An International Standards Organization Object Identifier	Used as the Universal ID Type in the EI and HD datatypes.

6.6.10. HL7 Table 0354 – Message Structure (V2.5.1)

Table 32 – HL7 Table 0354 – Message Structure

Value	Description	Comments
ORU_R01	Unsolicited transmission of an observationmessage	
ACK	General Acknowledgment Message for unsolicited transmission of an observationmessage	

6.6.11. HL7 Table 0396 – Coding Systems Code

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

Table 33 – 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).
LN	LOINC	
SCT	SNOMED Clinical Terms	

6.6.12. HL7 Table 0507 – Observation Result Handling (V2.7.1)

Table 34 – HL7 Table 0507 – Observation Result Handling

Value	Description	Comments
CC	Copies Requested	
BCC	Blind Copy	

6.6.13. HL7 Table 0834 – MIME Type (V2.7.1)

Table 35 - HL7 Table 0834 – MIME Type

Value	Description	Usage	Comments
application	Application data	O	
audio	Audio data	O	
image	Image data	R	
model	Model data	O	
text	Text data	R	
video	Video data	O	
multipart	MIME multipart package	O	

6.7. 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 in this guide.

Table 36 - User Defined or Extended Code System Summary

Name	Value Set	Source	Comments
Interpretation Codes	HL70078	HL7 Version 2.5.1	This is a combination of the HL7 Table 0078 and additional BOL–related interpretation codes.
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.
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.

6.7.1. HL7 Table 0078 – Interpretation Codes (V2.5.1)

This value set is defined by BOL and includes codes from the following code system: HL70078 (V2.5.1).

Table 37 - HL7 Table 0078 – Interpretation Codes

Value	Description	Comments
A	Abnormal	Applies to non-numeric results.
H	Above high normal	
I	Intermediate	Indicates for microbiology susceptibilities only.
^	Intermediate – see footnote	Indicates for microbiology susceptibilities only.
L	Below low normal	
N	Normal	Applies to non-numeric results.
NS	Not Susceptible – see footnote	Indicates for microbiology susceptibilities only.
R	Resistant	Indicates for microbiology susceptibilities only.
S	Susceptible	Indicates for microbiology susceptibilities only.
SDD	Susceptible – Dose Dependent	Indicates for microbiology susceptibilities only.
*	See footnote	Indicates a footnote will be included in the result.
**	See footnote	Indicates a footnote will be included in the result.

APPENDIX A – Document Origins and Conformance

This document is a derivation of the HL7 Version 2.5.1 Implementation Guide: Laboratory Results Interface (LRI), Release 1 STU Release 4. Implementers of this document are referred to the National LRI IG for an in-depth discussion of electronic orders and results messaging as well as a glossary of relevant terms.

Conformance to this Guide

This implementation guide defines components that are combined into profiles to define specific conformance requirements. See the National LRI IG for a thorough definition of all possible component profiles.

The Components must be combined to create a valid Profile for a particular transaction.

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

- LRI_COMMON_COMPONENT
- LRI_NG_COMPONENT (Non-Globally Unique)
- LRI_FRN_COMPONENT (Non-Unique Filler Number)
- LRI_PH_COMPONENT (Public Health)

This guide defines this component:

1. LRI_TO_Component – Time Offset

LRI_COMMON_COMPONENT –ID: 2.16.840.1.113883.9.195.3.15

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

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

LRI_NG_COMPONENT (Non-Globally Unique) –ID: 2.16.840.1.113883.9.13

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

- MSH-3 – Sending Application
- MSH-4 – Sending Facility
- MSH-6 – Receiving Facility
- PID-3 – Patient Identifier List
- ORC-2 – Placer Order Number
- ORC-3 – Filler Order Number
- ORC-4 – Placer Group Number
- OBR-2 – Placer Order Number
- OBR-3 – Filler Order Number
- OBR-28 – Result Copies To
- OBR-16 – Ordering Provider
- OBR-29 – Parent

- OBX-16 – Responsible Observer
- OBX-25 – Performing Organization Medical Director

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

LRI_FRN_COMPONENT (Non-Unique Filler ID) –ID: 2.16.840.1.113883.9.84

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

LRI_PH_COMPONENT (Public Health) – ID: 2.16.840.1.113883.9.195.3.17

This profile component indicates the additional information required for Public Health Reporting is supported. The PH component facilitates the inclusion of information necessary for public health. This profile is used to identify those fields that are to be considered for Public Health according to table attributes; conformance statements referencing this profile component are identified as “LRI-PH-nn”.

Note: The LRI_PH_Component restricts the choice on the minimally required components: it may only be used with the LRI_Common_Component_V2 (2.16.840.1.113883.9.195.3.15), the GU_component (2.16.840.1.113883.9.12) or the NG_component (2.16.840.1.113883.9.13) AND the FRU_Component (2.16.840.1.113883.9.83) or by using the precoordianted LRI_GU_FRU_Component_V2 (2.16.840.1.113883.9.195.3.18) or the precoordinated LRI_NG_FRU_Component_V2 (.2.16.840.1.113883.9.195.3.20).

LAB_TO_COMPONENT (Time Offset) –ID: 2.16.840.1.113883.9.22

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

- PID-7 – Date/Time of Birth
- OBR-7 – Observation Date/Time
- OBR-8 – Observation End Date/Time
- OBR-22 – Results Rpt/Status Chng – Date/Time
- TQ1-7 – Start Date/Time
- TQ1-8 – End Date/Time
- OBX-5 – Observation Value (when OBX-2 is “TM”)
- OBX-14 – Date/Time of the Observation
- OBX-19 – Date/Time of the Analysis
- SPM-17 – Specimen Collection Date/Time

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

APPENDIX B - Data Types

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

While CLIA requires a laboratory to maintain positive identification of a specimen reporting, that information aspart of the result is n–t required.

CE – Coded Element

Table 38 - CE – Coded Element

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

USAGE NOTE

The CE data type is used in OBX-5 (Observation Value) when OBX-2 (Value Type) is valued "CE". This data type transmits codes and the text associated with the code. The sender shall always populate the first triplet before populating other triplets; the receiver shall examine alltriplets to find relevant values.

Conformance Statements: Base Profile

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

CWE – Coded with Exceptions

CWE_01 – Coded with Exceptions – Code Required

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

Table 39 - 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.
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		O		
8	Alternate Coding System Version ID		O		
9	Original Text	ST	RE		Original Text is used to convey the text that was the basis for coding.
10	Second Alternate Identifier		O		
11	Second Alternate Text		O		
12	Second Name of Alternate Coding System		O		
13	Second Alternate Coding System Version ID		O		
14	Coding System OID		O		
15	Value Set OID		O		
16	Value Set Version ID		O		
17	Alternate Coding System OID		O		
18	Alternate Value Set OID		O		
19	Alternate Value Set Version ID		O		
20	Second Alternate Coding System OID	O	20		
21	Second Alternate Value Set OID	O	21		
22	Second Alternate Value Set Version ID	O	22		

USAGE NOTE

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

The CWE_01 data type is used where it is necessary to communicate a code, text, coding system and the version

of coding system the code was drawn from. It also allows the communication of an alternate code drawn from another coding system. Many coded fields in this specification identify coding systems or value sets that must be used for the field. **When populating the CWE_01 data types with these values, this guidedoes not give preference to the triplet in which the standard code should appear.** The receiver is expectedto examine the coding system names in components 3 and 6 to determine if it recognizes the coding system.

CWE_02 – Coded with Exceptions – Code Required, Second Triplet Optional

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

Table 40 - CWE_02 – 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		O		
5	Alternate Text		O		
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	C(RE/O)		Condition Predicate: If CWE_02.6 (Name of Alternate Coding System) is not an HL7 defined table or user defined table.
9	Original Text	ST	RE		Original Text is used to convey the text that was the basis for coding.
10	Second Alternate Identifier		O		
11	Second Alternate Text		O		
12	Second Name of Alternate Coding System		O		
13	Second Alternate Coding System Version ID		O		
14	Coding System OID		O		
15	Value Set OID		O		
16	Value Set Version ID		O		
17	Alternate Coding System OID		O		
18	Alternate Value Set OID		O		
19	Alternate Value Set Version ID		O		
20	Second Alternate Coding System OID		O		
21	Second Alternate Value Set OID		O		
22	Second Alternate Value Set Version ID		O		

USAGE NOTE

The CWE_02 data type is used where it is necessary to communicate a code, text coding system, and the code was drawn from.

CWE_03 – Coded with Exceptions – Code Required, but May Be Empty

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

Table 41 - 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_C03.9) 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.
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 (Alternate Identifier)	Condition Predicate: If CWE_03.4 is valued
7	Coding System Version ID		O		
8	Alternate Coding System Version ID		O		
9	Original Text	ST	C(R/RE)		Condition Predicate: If CWE_03.1 (Identifier) is not valued. Original Text is used to convey the text that was the basis for coding. If neither the first nor second triplet has values, this contains the text of the field.
10	Second Alternate Identifier		O		
11	Second Alternate Text		O		
12	Second Name of Alternate Coding System		O		
13	Second Alternate Coding System Version ID		O		
14	Coding System OID		O		
15	Value Set OID		O		
16	Value Set Version ID		O		

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

USAGE NOTE

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

The CWE_03 data type is used where it is necessary to communicate a code, text, coding system and the version of coding system the code was drawn from. It also allows the communication of an alternate code drawn from another coding system. Many coded fields in this specification identify coding systems or value sets that must be used for the field.

Note: When populating the CWE_03 data type with these values, this guide does not give preference to the triplet in which the standard code should appear.

CX – Extended Composite ID with Check Digit

CX_02 – Extended Composite ID with Check Digit (Non-Globally Unique)

Table 42 - CX_02 – Extended Composite ID with Check Digit (Non-Globally Unique)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	ID Number	ST	R		
2	Check Digit	ST	O		
3	Check Digit Scheme		O		
4	Assigning Authority	HD_02	RE		
5	Identifier Type Code	ID	R	HL70203 (V2.7.1)	
6	Assigning Facility		O		
7	Effective Date		O		
8	Expiration Date		O		
9	Assigning Jurisdiction		O		
10	Assigning Agency or Department		O		

USAGE NOTE

The CX_02 data type is used to carry identifiers. This guide requires that assigning authorities accompany all identifiers if known, and that all identifiers carry an identifier type. This method allows the exchange of unique identifiers for the associated object across organizational and enterprise boundaries, enabling broad interoperability.

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

DR – Date/Time Range

Table 43 - DR – Date/Time Range

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

DT – Date

Table 44 - DT – Date

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

ED_01 – Encapsulated Data

Table 45 - ED_01 – Encapsulated Data

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Source Application	HD	O		Identifier of the application that is the source of the ED
2	Type of Data	ID	R	HL70834 (V2.7.1)	Identifier of the type of data found in component 5.
3	Data Subtype	ID	O		
4	Encoding	ID	R	HL70299 (V2.7.1)	
5	Data	TX	R		The data must be properly escaped after encoding. Receivers will need to un-escape the text prior to decoding.

USAGE NOTE

The ED_01 data type is required to send a pre-formatted version of a report, e.g., a PDF file.

EI – Entity Identifier

EI_MI01 – Entity Identifier (Identifier Only)

Table 46 - EI_MI01 – Entity Identifier (Identifier Only)

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

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_MI01 – Entity Identifier Pair

Table 47 - EIP_MI01 – Entity Identifier Pair

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

USAGE NOTE

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

ERL – Error Location

Table 48 - ERL – 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., 3rd NTE in message, regardless of the number or type of intervening segments).
3	Field Position		O		
4	Field Repetition		O		
5	Component Number		O		
6	Sub-component Number		O		

FN – Family Name

Table 49 - FN – Family Name

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Surname	ST	R		
2	Own Surname Prefix		O		
3	Own Surname		O		
4	Surname Prefix from Partner/Spouse		O		
5	Surname From Partner/Spouse		O		

FT – Formatted Text Data

Table 50 - FT – Formatted Text Data

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

USAGE NOTE

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

HD – Hierarchic Designator

HD_MI01 – Hierarchic Designator (Fully Populated)

Table 51 - 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 52 - HD_02 – Hierarchic Designator (Non-Globally Unique)

SEQ	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 53 - MSG – Message Type

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Message Code	ID	R	HL70076 (constrained)	
2	Trigger Event	ID	R		Constrained to 'R01' from HL7 Table 0003 Event Type Code
3	Message Structure	ID	R	HL70354 (constrained)	

Conformance Statement – LRI_Common_Component

- MSG-2 (Trigger Event) **SHALL** be valued with 'R01'

NM – Numeric

Table 54 - NM – Numeric

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

PRL – Parent Result Link

Table 55 - PRL – Parent Result Link

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Parent ObservationIdentifier	CWE_CR	R		
2	Parent ObservationSub-Identifier	ST	RE		
3	Parent ObservationValue Descriptor		O		

PT – Processing Type

Table 56 - PT – Processing Type

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

SAD – Street address

Table 57 - SAD – Street address

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

SN – Structured Numeric

Table 58 - SN – Structured Numeric

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Comparator	ST	RE	ST	
2	Num1	NM	RE	NM	
3	Separator/Suffix	ST	RE	ST	
4	Num2	NM	RE	NM	

USAGE NOTE

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

ST – String Data

Table 59 - ST – String Data

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

USAGE NOTE

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

TM – Time

Table 60 - TM – Time

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

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 61 - TS_1 – Time Stamp – Precise to Second

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

TS_2 – Time Stamp – Precise to the Year, Potentially to Day

Table 62 - 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	ID	X		Excluded for this Implementation Guide
The DTM component of this Time Stamp has the following constraints:					
	YYYY		R		
	MM		RE		
	DD		RE		
	HH		O		
	MM		O		
	[SS[.S[S[S]]]]		O		
	+/- ZZZZ		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 63 - 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	ID	X		Excluded for this Implementation Guide
The DTM component of this Time Stamp has the following constraints:					
	YYYY		R		
	MM		RE		
	DD		RE		
	HH		RE		
	MM		RE		
	[SS[.S[S[S]]]]		O		
	+/- ZZZZ		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 64 - TS_4 – Time Stamp

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

USAGE NOTE

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

TS_5 – Time Stamp – Precise to Day, Potentially to Minute

Table 65 - 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	ID	X		Excluded for this Implementation Guide
The DTM component of this Time Stamp has the following constraints:					
	YYYY		R		
	MM		R		
	DD		R		
	HH		RE		
	MM		RE		
	[SS[.S[S[S[S]]]]]		O		
	+/- ZZZZ		C(RE/O)		Condition Predicate: If 'HH' is valued and the TO Component is invoked.

TX – Text Data

Table 66 - TX – Text Data

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

USAGE NOTE

The TX data type is used to carry string data intended for display purposes. It can contain leading blanks (spacecharacters). In this implementation guide, the only allowed escape sequences are those allowed in HL7 Version2.5.1, Chapter 2, Section 2.7.4 - Special Characters. These are the escape sequences for the message delimiters(i.e., |^&~\ or |^&~\#).

VID – Version Identifier

Table 67 - VID – Version Identifier

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

Conformance Statement – LRI_Common_Component

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

XAD_01 – Extended Address

Table 68 - XAD_01 – 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		O		
9	County/Parish Code	IS	RE	FIPS_6-4	
10	Census Tract		O		
11	Address Representation Code		O		

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

XCN – Extended Composite ID Number and Name for Persons

XCN_MI01 - Extended Composite ID Number and Name for Persons

Table 69 - 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		O		
5	Suffix (i.e., JR or III)		O		
6	Prefix (i.e., DR)		O		
7	Degree (i.e., MD)		X		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	O		
10	Name Type Code	ID	O		
11	Identifier Check Digit		O		
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		O		
15	Name Representation Code		O		
16	Name Context		O		
17	Name Validity Range		X		Excluded for this Implementation Guide.
18	Name Assembly Order		O		
19	Effective Date		O		
20	Expiration Date		O		
21	Professional Suffix		O		
22	Assigning Jurisdiction		O		
23	Assigning Agency or Department		O		

XCN_MI02 - Extended Composite ID Number and Name for Participation Persons (StarLIMS Identifier and Assigning Authority Required)

Table 70 - XCN_MI02 - Extended Composite ID Number and Name for 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		O		
5	Suffix (i.e., JR or III)		O		
6	Prefix (i.e., DR)		O		
7	Degree (i.e., MD)		X		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	X		Excluded for this Implementation Guide.
11	Identifier Check Digit		X		Excluded for this Implementation Guide.
12	Check Digit Scheme		X		Excluded for this Implementation Guide.
13	Identifier Type Code	ID	X		Excluded for this Implementation Guide.
14	Assigning Facility		X		Excluded for this Implementation Guide.
15	Name Representation Code		X		Excluded for this Implementation Guide.
16	Name Context		X		Excluded for this Implementation Guide.
17	Name Validity Range		X		Excluded for this Implementation Guide.
18	Name Assembly Order		X		Excluded for this Implementation Guide.
19	Effective Date		X		Excluded for this Implementation Guide.
20	Expiration Date		X		Excluded for this Implementation Guide.
21	Professional Suffix		X		Excluded for this Implementation Guide.
22	Assigning Jurisdiction		X		Excluded for this Implementation Guide.
23	Assigning Agency or Department		X		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'`.

XON – Extended Composite Name and Identification Number for Organizations

XON_MI01 – Extended Composite Name and Identification Number for Organizations (Name and Identifier Required)

Table 71 - 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		O		
3	ID Number		X		Excluded for this Implementation Guide.
4	Check Digit		O		
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	O		
8	Assigning Facility		O		
9	Name Representation Code		O		
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 72- 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		O		
3	ID Number		X		Excluded for this Implementation Guide.
4	Check Digit		O		
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		O		
9	Name Representation Code		O		

USAGE NOTE

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

XPN – Extended Person Name

XPN_03 – Extended Person Name

Table 73 - XPN_03 – Extended Person Name

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Family Name	FN	RE		
2	Given Name	ST	RE		I.e., first name.
3	Second and Further Given Names or Initials Thereof	ST	RE		
4	Suffix (e.g., JR or III)	ST	RE		
5	Prefix (e.g., DR)		O		
6	Degree (e.g., MD)		X		Excluded for this Implementation Guide
7	Name Type Code	ID	RE	HL70200	
8	Name Representation Code		O		
9	Name Context		O		
10	Name Validity Range		X		Excluded for this Implementation Guide
11	Name Assembly Order		O		
12	Effective Date		O		
13	Expiration Date		O		
14	Professional Suffix		O		

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 reporting requirements, report retention and display, and those authorized to receive a report. Specifics on the CLIA Regulation are found in the Federal Register https://www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments/regulations-federal-register.

II. Mandatory Reporting Requirements

Section 42 CFR 493.1291 - Test Report of the CLIA Regulations defines items that must appear on a clinical laboratory report. Note that the value(s) of some items that are supplied on the order and flow through to the Test Report are defined in 42 CFR 493.1241 – Test Request. Interpretative Guidelines on the elements required in a report may be found at https://www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments/guidelines-laboratories. Additionally, CLIA grants deeming authority to private or nonprofit laboratory accreditation organizations, such as the College of American Pathologists (CAP), which may define additional mandatory reporting requirements more stringent than CLIA. Specific report fields impacted include the following:

Table 74 - Mandatory Reporting Requirements

Segment	Field	CLIA / CAP Requirement
PID-3 PID-5	Patient Identifier List Patient Name	For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. Clarification: Patient name includes, when available, the patient's legal name consisting of a first name, middle name or initial, and last name [PID-5] The unique patient Identification number assigned by the facility (may be used when the patient's name is not available) and the unique identification number for the order [PID-3] which may contain either numbers or letters or both numbers and letters.
PID-7 PID-8	Date/Time of Birth Administrative Sex	The sex and age or date of birth of the patient.
OBR-7	Observation Date/Time	The date and, if appropriate, time of specimen collection.
OBR-13	Relevant Clinical Information	Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results.
OBR-22	Results Rpt/Status Chng Date/Time	The test report date. Clarification: The date (e.g., mm/dd/yyyy hh/mm) the test report/status change was finalized by the laboratory.
OBX-11 OBR-25	Observation Result Status Result Status	The laboratory's status of the test result/report (preliminary, partial, final, corrected, etc.) [OBX-11/OBR-25]. The coded values received from the laboratory may be translated in the EHR to an equivalent concept prior to display.

Segment	Field	CLIA / CAP Requirement
OBR-4 OBX-3	Universal Service Identifier Observation Identifier	The test performed is required. Clarification: The specific name of the test/analyte that is assigned by the laboratory. Use of LOINC codes for additional tests is strongly encouraged. Addition of a local laboratory code is allowed. For certain tests CLIA requires additional information: Laboratories using manufacturer's instruments, kits or test systems labeled for "investigational use only" or "research use only" must clearly state that the test results are not to be used for treatment or diagnostic purposes. If results of such tests are being reported without a disclaimer statement or are being used by the provider for patient care, they are in the same category as in-house developed tests and the laboratory must establish performance specifications in accordance with §493.1253. The disclaimer for Analyte Specific Reagents (ASR) should state, "This test was developed, and its performance characteristics determined by (Laboratory Name). It has not been cleared or approved by the U.S. Food and Drug Administration." The ASR disclaimer on the test report is required by the FDA under *21 CFR, Part 809.30, "Restrictions on the sale, distribution, and use of analyte -specific reagents."*
OBX-5	Observation Value	The laboratory result is required.
OBX-6 NTE-3	Units Comment	The Units of measurement [OBX-6] if applicable. The laboratory's additional, miscellaneous notes, comments, interpretations regarding the test/analyte/report [NTE-3].
OBX-7	Reference Range	When available reference range shall be valued.
OBX-8	Abnormal Flag	The laboratory's interpretation communicated by defined text/symbols indicating test results that do not fall within the established reference/normal range [OBX-8]. The coded values received from the laboratory may be translated in the EHR to an equivalent description prior to display.
OBX-19	Date/Time of Analysis	This field is used to transfer the time stamp associated with generation of the analytical result by the instrument specified in Equipment Instance Identifier.
OBX-23 OBX-24	Performing Org Name Performing Org Address	The name and address of the laboratory location where the test was performed. Clarification: The name of the laboratory as indicated on the CLIA certificate [OBX-23] and the actual physical location of the laboratory facility or location within the facility (including room, suite, floor as applicable) where testing is performed, as indicated on the CLIA certificate [OBX-24]. Note: Populating with the CLIA ID Number in OBX-23 meets the requirement if the receiving EHR-S has the ability to populate the Organization Name and Address in the Laboratory Test Report based on the CLIA ID Number.
SPM-4	Specimen Type	The specimen source, which equates at minimum to the Specimen Type in the SPM segment. Clarification: The type of specimen submitted for testing and/or the collection site/method of collection as applicable.
SPM-18	Specimen Received Date/Time	CAP reporting requirements require the date of specimen receipt in the laboratory.
SPM-21 SPM-24	Specimen Reject Reason Specimen Condition	Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. Clarification: When available, the laboratory's defined comment(s) denoting specimen suitability or not for testing [any of OBX-5/NTE-3/SPM-21]. The coded values received from the laboratory may be translated in the EHR to an equivalent description prior to display. When available, the laboratory's comment(s) denoting the condition of the specimen (hemolysis, lipemia, icterus, clotted, etc.) [any of OBX-5/NTE-3/SPM-24]. The coded values received from the laboratory may be translated in the EHR to an equivalent concept prior to display. SPM-21: Use this field in connection with OBX-11 if a test is cancelled for specimen related reason. SPM-24: Use this field in combination with SPM-21 to further specify the reason for specimen rejection.

III. Regulatory Compliance

There may be local, state or federal regulations where the electronic message from a performing laboratory is presumed to be the legal report of the tests performed. Hence, the receiver may be required to save the formator 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 receive laboratory reports. CLIA restricts the availability of those authorized to receive laboratory reports to just those approved at the local level and sets no national standards. Testing laboratories may not report results to unauthorized parties under CLIA.

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

V. CLSI Definitions – Quantitative, Semi-quantitative, Qualitative Results

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

Quantitative

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

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

Qualitative

1) When used to describe a test, means a test that produces a result that is descriptive rather than numerical. For example, a urine pregnancy test might generate a result of ‘positive’ or negative’ forurinary HCG. In contrast, a quantitative test generates a numerical result. The quality control and reporting procedures differ significantly for quantitative and qualitative tests.
2) Characterization applied to laboratory tests that detect and/or identify a particular analyte,constituent, or condition.

NOTE 1: This term is applied to tests that detect whether a particular analyte, constituent, orcondition is present or absent, and is sometimes assigned a positive degree (i.e., 1+, 2+); NOTE 2: It may also be called semi-quantitative tests;
NOTE 3: Specific identification may be performed.

Semi-quantitative

3) A test that has a dose-response gradient that may be included in the reported result, but for whichno authoritative calibration scale exists to determine inaccuracy and imprecision; tests that yield results in an approximate range of values (e.g., trace, moderate);

NOTE: This definition includes tests with subjective readout of quantification such as IF- ANA titers,and it includes tests with an instrumental readout of quantification such as ELISA-ANA when the instrument scale cannot be referenced to an authoritative calibration scale.

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

APPENDIX D -Laboratory Result Message Development Resources

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

The National Institute of Standards and Technology (NIST) has established a website (https://www.nist.gov/itl/products-and-services/healthcare-standards-testing) tosupport the HIT developer community. The site has a number of tools and related materials to assist implementers with the development and testing of software in preparation for ONC Certification.

To support the Laboratory Messaging community, a repository has been established to function as a dynamiclibrary of V2.x.x example messages, technical corrections, and other materials with the intent of providing continuous growth of resources without being time bound to future publications of this guide. The repository is available at NIST HL7 V2 Resource Portal.

APPENDIX E – Sample Messages

Incomplete Message (Specimen Status Received):

```
MSH|^~\&|STARLIMS.MI.STAG^2.16.840.1.114222.4.3.3.2.32.2^ISO|LAN^23D065
0909^CLIA|^4^STARLIMS_AGENCY|ESI-
LOOKUP^2.16.840.1.114222.4.3.2.2.3.161.1.3282.374^ISO|20231121080840||O
RU^R01^ORU_R01|L00024610_20231121080840|T|2.5.1|||NE|NE|USA||||
SFT|STARLIMS|10|STARLIMS|binary ID unknown||20080101
PID|1||22BOL1000^^^STARLIMS.MI.STAG&2.16.840.1.114222.4.3.3.2.37.2&ISO^
PI^MI.Lansing.SPHL&2.16.840.1.114222.4.1.103423&ISO||POPPINS^MARY^J^^^^
L||19640827|F||U^UNKNOWN^CDCREC^^^^04/24/2007|1
UAT^^ALLEGAN^MI^49010^^H^^ALLEGAN||||||||||U^Unknown
ORC|RE|LO105649|CL23-
132113^STARLIMS.MI.STAG^2.16.840.1.114222.4.3.3.2.37.2^ISO||CM|||||||11
54385672^Arias^Abby^^^^^^NPI|||||||||ALLEGAN COUNTY HEALTH
DEPARTMENT^^^^^StarLIMS_Agency^^^^4|3255 122nd Avenue,Suite
200^^ALLEGAN^MI^49010^USA^B|^WPN^PH^^1^269^6735411
OBR|1|LO105649|CL23-
132113^STARLIMS.MI.STAG^2.16.840.1.114222.4.3.3.2.37.2^ISO|45076-
7^Chlamydia trachomatis+Neisseria gonorrhoeae rRNA^LN^2748^C.
trachomatis + N. gonorrhoeae Non-Culture^L^2.34^v
unknown^2748|||20231120093500||||||||1154385672^Arias^Abby^^^^^^NPI|||
|||20231121080841|||I
OBX|1|ST|Specimen Status^Specimen Status^L^Specimen Status^Specimen
Status^L||Received||||||F|||20231121080837|||||||||Michigan Dept of
Health and Human Services - Bureau of
Laboratories^D^^^^CLIA&2.16.840.1.113883.19.4.6&ISO^XX^^^23D0650909|335
0 N. Martin Luther King Jr Blvd^^Lansing^MI^48906
SPM|1|LO105649^CL23-
132113&STARLIMS.MI.STAG&2.16.840.1.114222.4.1.103423&ISO||119395005^Spe
cimen from uterine cervix
(specimen)^SCT^CERVIX^CERVIX^CERVIX||||||||||||20231120093500|20231121
```

Preliminary Message:

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MSH|^~\&|STARLIMS.MI.STAG^2.16.840.1.114222.4.3.3.2.32.2^ISO|LAN^23D065
0909^CLIA|^4^STARLIMS_AGENCY|ESI-
LOOKUP^2.16.840.1.114222.4.3.2.2.3.161.1.3282.374^ISO|20230818142319||O
RU^R01^ORU_R01|L00024077_20230818142319|T|2.5.1|||NE|NE|USA||||
SFT|STARLIMS|10|STARLIMS|binary ID unknown||20080101
PID|1||PH1542089^^^STARLIMS.MI.STAG&2.16.840.1.114222.4.3.3.2.37.2&ISO^
PI^MI.Lansing.SPHL&2.16.840.1.114222.4.1.103423&ISO||TEST^PAT^^^^^L||20
180505|F||2028-9^ASIAN^CDCREC^ASIAN^ASIAN^L^04/24/2007^v unknown|202
MIDENHALL WAY^^LANSING^NC^27513^^H^^INGHAM||||||||||H^Hispanic or
Latino^HL70189^HISPANIC^HISPANIC^L^2.5.1^v unknown
ORC|RE|LO104316|CL23-
177900^STARLIMS.MI.STAG^2.16.840.1.114222.4.3.3.2.37.2^ISO||CM|||||||00
```

```
01011119^Support^Pat^^^^^^NPI||||||||||ALLEGAN COUNTY HEALTH
DEPARTMENT^^^^^StarLIMS_Agency^^^^4|3255 122nd Avenue,Suite
200^^ALLEGAN^MI^49010^USA^B|^WPN^PH^^1^269^6735411
OBR|1|LO104316|CL23-
177900^STARLIMS.MI.STAG^2.16.840.1.114222.4.3.3.2.37.2^ISO|2904-168^-E.
coli Cultural Isolate - E.coli STX PCR
Result^L|||20230323063600|||||||||0001011119^Support^Pat^^^^^^NPI||||||
20230818142320|||P
OBX|1|CE|53946-0^Escherichia coli shiga toxin Ag^LN^EC Toxin^EC
Toxin^L^2.34^v unknown^EC Toxin||NEGPOS^STX 2 Positive and STX 1
Negative^SN|||A|||P|||20230323063600|||||20230818142120||||Michigan
Dept of Health and Human Services - Bureau of
Laboratories^D^^^^CLIA&2.16.840.1.113883.19.4.6&ISO^XX^^^23D0650909|335
0 N. Martin Luther King Jr Blvd^^Lansing^MI^48906
NTE|1||This test was developed and its performance characteristics
determined by the Michigan Department of Health and Human Services
(MDHHS). It has not been cleared or approved by the U.S. Food and Drug
Administration (FDA). The FDA has determined that such clearance or
approval is not necessary if performance characteristics are verified
at the testing laboratory.
SPM|1|LO104316^CL23-
177900&STARLIMS.MI.STAG&2.16.840.1.114222.4.1.103423&ISO||119339001^Sto
ol specimen
(specimen)^SCT^STOOL^STOOL^STOOL||||||||||||20230323063600|20230818
```

Final Message:

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MSH|^~\&|STARLIMS.MI.STAG^2.16.840.1.114222.4.3.3.2.32.2^ISO|LAN^23D065
0909^CLIA|^4^STARLIMS_AGENCY|ESI-
LOOKUP^2.16.840.1.114222.4.3.2.2.3.161.1.3282.374^ISO|20230822134842||O
RU^R01^ORU_R01|L00024078_20230822134842|T|2.5.1|||NE|NE|USA||||
SFT|STARLIMS|10|STARLIMS|binary ID unknown||20080101
PID|1||PH1542089^^^STARLIMS.MI.STAG&2.16.840.1.114222.4.3.3.2.37.2&ISO^
PI^MI.Lansing.SPHL&2.16.840.1.114222.4.1.103423&ISO||TEST^PAT^^^^^L||20
180505|F||2028-9^ASIAN^CDCREC^ASIAN^ASIAN^L^04/24/2007^v unknown|202
MIDENHALL WAY^^LANSING^NC^27513^^H^^INGHAM||||||||||H^Hispanic or
Latino^HL70189^HISPANIC^HISPANIC^L^2.5.1^v unknown
ORC|RE|LO104316|CL23-
177900^STARLIMS.MI.STAG^2.16.840.1.114222.4.3.3.2.37.2^ISO||CM|||||||00
01011119^Support^Pat^^^^^^NPI||||||||||ALLEGAN COUNTY HEALTH
DEPARTMENT^^^^^StarLIMS_Agency^^^^4|3255 122nd Avenue,Suite
200^^ALLEGAN^MI^49010^USA^B|^WPN^PH^^1^269^6735411
OBR|1|LO104316|CL23-
177900^STARLIMS.MI.STAG^2.16.840.1.114222.4.3.3.2.37.2^ISO|2906-177^-
Salmonella/Shigella Serotyping - Human - Serotyping
Result^L|||20230323063600|||||||||0001011119^Support^Pat^^^^^^NPI||||||
20230822134844|||F
OBX|1|CE|40440-0^XXX microorganism serotype^LN^Enteric Typing^Enteric
Typing^L^2.34^v unknown^Enteric Typing||73525009^Salmonella
Enteritidis^SCT|||A|||F|||20230323063600|||||20230822134551||||Michigan
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Dept of Health and Human Services - Bureau of
Laboratories^D^^^^CLIA&2.16.840.1.113883.19.4.6&ISO^XX^^^23D0650909|335
0 N. Martin Luther King Jr Blvd^^Lansing^MI^48906
NTE|1||Disclaimer:  Testing has confirmed the identification of
Salmonella or Shigella spp. Serotyping results are for epidemiologic or
research purposes only and must not be used for diagnosis, treatment or
for the assessment of patient health. Reagents used for individual O
and H antigens have not been cleared or approved by the U.S. Food and
Drug Administration.~This test was developed, and its performance
characteristics determined by the Michigan Department of Health and
Human Services (MDHHS). It has not been cleared or approved by the U.S.
Food and Drug Administration (FDA). The FDA has determined that such
clearance or approval is not necessary if performance characteristics
are verified at the testing laboratory.~Serotype determined by PCR.
SPM|1|LO104316^CL23-
177900&STARLIMS.MI.STAG&2.16.840.1.114222.4.1.103423&ISO||119339001^Sto
ol specimen
(specimen)^SCT^STOOL^STOOL^STOOL||||||||||||20230323063600|20230818
```

Corrected Message:

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MSH|^~\&|STARLIMS.MI.STAG^2.16.840.1.114222.4.3.3.2.32.2^ISO|LAN^23D065
0909^CLIA|^4^STARLIMS_AGENCY|ESI-
LOOKUP^2.16.840.1.114222.4.3.2.2.3.161.1.3282.374^ISO|20230823091705||O
RU^R01^ORU_R01|L00024078_20230823091705|T|2.5.1|||NE|NE|USA||||
SFT|STARLIMS|10|STARLIMS|binary ID unknown||20080101
PID|1||PH1542089^^^STARLIMS.MI.STAG&2.16.840.1.114222.4.3.3.2.37.2&ISO^
PI^MI.Lansing.SPHL&2.16.840.1.114222.4.1.103423&ISO||TEST^PAT^^^^^L||20
180505|F||2028-9^ASIAN^CDCREC^ASIAN^ASIAN^L^04/24/2007^v unknown|202
MIDENHALL WAY^^LANSING^NC^27513^^H^^INGHAM||||||||||H^Hispanic or
Latino^HL70189^HISPANIC^HISPANIC^L^2.5.1^v unknown
ORC|RE|LO104316|CL23-
177900^STARLIMS.MI.STAG^2.16.840.1.114222.4.3.3.2.37.2^ISO||CM|||||||00
01011119^Support^Pat^^^^^^NPI|||||||||ALLEGAN COUNTY HEALTH
DEPARTMENT^^^^^StarLIMS_Agency^^^^4|3255 122nd Avenue,Suite
200^^ALLEGAN^MI^49010^USA^B|^WPN^PH^^1^269^6735411
OBR|1|LO104316|CL23-
177900^STARLIMS.MI.STAG^2.16.840.1.114222.4.3.3.2.37.2^ISO|2906-177^-
Salmonella/Shigella Serotyping - Human - Serotyping
Result^L|||20230323063600|||||||||0001011119^Support^Pat^^^^^^NPI||||||
20230823091706|||C
OBX|1|CE|40440-0^XXX microorganism serotype^LN^Enteric Typing^Enteric
Typing^L^2.34^v unknown^Enteric Typing||19374001^Salmonella
Enteritidis, phage type
4^SCT|||A|||C|||20230323063600|||||20230823091221||||Michigan Dept of
Health and Human Services - Bureau of
Laboratories^D^^^^CLIA&2.16.840.1.113883.19.4.6&ISO^XX^^^23D0650909|335
0 N. Martin Luther King Jr Blvd^^Lansing^MI^48906
NTE|1||CORRECTED REPORT: Result changed from Salmonella Enteritidis to
Salmonella Enteritidis, phage type 4 on 8/23/23~Disclaimer:  Testing
```

```
has confirmed the identification of Salmonella or Shigella spp.
Serotyping results are for epidemiologic or research purposes only and
must not be used for diagnosis, treatment or for the assessment of
patient health.  Reagents used for individual O and H antigens have not
been cleared or approved by the U.S. Food and Drug Administration.~This
test was developed, and its performance characteristics determined by
the Michigan Department of Health and Human Services (MDHHS). It has
not been cleared or approved by the U.S. Food and Drug Administration
(FDA). The FDA has determined that such clearance or approval is not
necessary if performance characteristics are verified at the testing
laboratory.~Serotype determined by PCR.
SPM|1|LO104316^CL23-
177900&STARLIMS.MI.STAG&2.16.840.1.114222.4.1.103423&ISO||119339001^Sto
ol specimen
(specimen)^SCT^STOOL^STOOL^STOOL||||||||||||20230323063600|20230818
```

Culture and Susceptibility Message:

```
MSH|^~\&|STARLIMS.MI.STAG^2.16.840.1.114222.4.3.3.2.32.2^ISO|LAN^23D065
0909^CLIA|^4^STARLIMS_AGENCY|ESI-
LOOKUP^2.16.840.1.114222.4.3.2.2.3.161.1.3282.374^ISO|20231012131507||O
RU^R01^ORU_R01|L00024418_20231012131507|T|2.5.1|||NE|NE|USA||||
SFT|STARLIMS|10|STARLIMS|binary ID unknown||20080101
PID|1||PH1542089^^^STARLIMS.MI.STAG&2.16.840.1.114222.4.3.3.2.37.2&ISO^
PI^MI.Lansing.SPHL&2.16.840.1.114222.4.1.103423&ISO||TEST^PAT^^^^^L||20
180505|F||2028-9^ASIAN^CDCREC^ASIAN^ASIAN^L^04/24/2007^v unknown|202
MIDENHALL WAY^^LANSING^MI^48906^^H^^INGHAM||||||||||H^Hispanic or
Latino^HL70189^HISPANIC^HISPANIC^L^2.5.1^v unknown
ORC|RE|LO104336|CL23-
209990^STARLIMS.MI.STAG^2.16.840.1.114222.4.3.3.2.37.2^ISO||CM|||||||00
01011119^Support^Pat^^^^^^NPI|||||||||ALLEGAN COUNTY HEALTH
DEPARTMENT^^^^^StarLIMS_Agency^^^^4|3255 122nd Avenue,Suite
200^^ALLEGAN^MI^49010^USA^B|^WPN^PH^^1^269^6735411
OBR|1|LO104336|CL23-
209990^STARLIMS.MI.STAG^2.16.840.1.114222.4.3.3.2.37.2^ISO|2821-
84^Aerobic Culture - Gram
Stain^L|||20230323170000|||||||||0001011119^Support^Pat^^^^^^NPI||||||2
0231012131508|||F
NTE|1||Aerobic Culture comments: 16S rRNA Sequencing, PCR, and MALDI-
TOF tests were developed, and their performance characteristics
determined by the Michigan Department of Health and Human Services
(MDHHS). They have not been cleared or approved by the U.S. Food and
Drug Administration (FDA). The FDA has determined that such clearance
or approval is not necessary if performance characteristics are
verified at the testing laboratory.
OBX|1|ST|Gram Stain^Gram Stain^LN^Gram Stain^Gram Stain^L^2.34^v
unknown^Gram Stain|1|Gram negative
bacilli|||N|||F|||20230323170000|||||20231012130702||||Michigan Dept of
Health and Human Services - Bureau of
Laboratories^D^^^^CLIA&2.16.840.1.113883.19.4.6&ISO^XX^^^23D0650909|335
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0 N. Martin Luther King Jr Blvd^^Lansing^MI^48906
OBX|2|ST|Gram Stain^Gram Stain^LN^Gram Stain^Gram Stain^L^2.34^v
unknown^Gram Stain|2|Gram positive
bacilli|||N|||F|||20230323170000|||||20231012130702||||Michigan Dept of
Health and Human Services - Bureau of
Laboratories^D^^^^CLIA&2.16.840.1.113883.19.4.6&ISO^XX^^^23D0650909|335
0 N. Martin Luther King Jr Blvd^^Lansing^MI^48906
OBX|3|ST|Gram Stain^Gram Stain^LN^Gram Stain^Gram Stain^L^2.34^v
unknown^Gram Stain|3|Gram positive
cocci|||N|||F|||20230323170000|||||20231012130702||||Michigan Dept of
Health and Human Services - Bureau of
Laboratories^D^^^^CLIA&2.16.840.1.113883.19.4.6&ISO^XX^^^23D0650909|335
0 N. Martin Luther King Jr Blvd^^Lansing^MI^48906
OBR|2|LO104336|CL23-
209990^STARLIMS.MI.STAG^2.16.840.1.114222.4.3.3.2.37.2^ISO|2821-
85^Aerobic Culture - Culture
Results^L|||20230323170000||||||||0001011119^Support^Pat^^^^^^NPI|||||
|20231012131508|||F
OBX|1|CE|6463-4^Bacteria identified^LN^Isolate^Isolate^L^2.34^v
unknown^Isolate|1|80166006^Streptococcus
pyogenes^SCT|||A|||F|||20230323170000|||||20231012130738||||Michigan
Dept of Health and Human Services - Bureau of
Laboratories^D^^^^CLIA&2.16.840.1.113883.19.4.6&ISO^XX^^^23D0650909|335
0 N. Martin Luther King Jr Blvd^^Lansing^MI^48906
NTE|1||Final MALDI-TOF Identification - Streptococcus pyogenes~Final
MALDI-TOF Identification - Staphylococcus aureus~Final MALDI-TOF
Identification - Klebsiella aerogenes~Final MALDI-TOF Identification -
Enterococcus ratti
OBX|2|CE|6463-4^Bacteria identified^LN^Isolate^Isolate^L^2.34^v
unknown^Isolate|2|3092008^Staphylococcus
aureus^SCT|||A|||F|||20230323170000|||||20231012130752||||Michigan Dept
of Health and Human Services - Bureau of
Laboratories^D^^^^CLIA&2.16.840.1.113883.19.4.6&ISO^XX^^^23D0650909|335
0 N. Martin Luther King Jr Blvd^^Lansing^MI^48906
NTE|1||Final MALDI-TOF Identification - Streptococcus pyogenes~Final
MALDI-TOF Identification - Staphylococcus aureus~Final MALDI-TOF
Identification - Klebsiella aerogenes~Final MALDI-TOF Identification -
Enterococcus ratti
OBX|3|CE|6463-4^Bacteria identified^LN^Isolate^Isolate^L^2.34^v
unknown^Isolate|3|243299003^Klebsiella
aerogenes^SCT|||A|||F|||20230323170000|||||20231012130802||||Michigan
Dept of Health and Human Services - Bureau of
Laboratories^D^^^^CLIA&2.16.840.1.113883.19.4.6&ISO^XX^^^23D0650909|335
0 N. Martin Luther King Jr Blvd^^Lansing^MI^48906
NTE|1||Final MALDI-TOF Identification - Streptococcus pyogenes~Final
MALDI-TOF Identification - Staphylococcus aureus~Final MALDI-TOF
Identification - Klebsiella aerogenes~Final MALDI-TOF Identification -
Enterococcus ratti
OBX|4|CE|6463-4^Bacteria identified^LN^Isolate^Isolate^L^2.34^v
```

```
unknown^Isolate|4|431989005^Enterococcus
ratti^SCT|||A|||F|||20230323170000|||||20231012130823||||Michigan Dept
of Health and Human Services - Bureau of
Laboratories^D^^^^CLIA&2.16.840.1.113883.19.4.6&ISO^XX^^^23D0650909|335
0 N. Martin Luther King Jr Blvd^^Lansing^MI^48906
NTE|1||Final MALDI-TOF Identification - Streptococcus pyogenes~Final
MALDI-TOF Identification - Staphylococcus aureus~Final MALDI-TOF
Identification - Klebsiella aerogenes~Final MALDI-TOF Identification -
Enterococcus ratti
OBR|3|LO104336|CL23-
209990^STARLIMS.MI.STAG^2.16.840.1.114222.4.3.3.2.37.2^ISO|2821-
87^Aerobic Culture - Antimicrobial Susceptibility
Results^L|||20230323170000||||||||0001011119^Support^Pat^^^^^^NPI|||||
|20231012131508|||F|6463-4&Bacteria
identified&LN&Isolate&Isolate&L&2.34&v unknown&Isolate^2^Staphylococcus
aureus|||LO104336^CL23-
209990&STARLIMS.MI.STAG&2.16.840.1.114222.4.3.3.2.37.2&ISO||||||||||||
||||||||2821-85^Aerobic Culture - Culture Results^L
OBX|1|SN|19000-9^Vancomycin^LN^Vancomycin^Vancomycin^L^2.34^v
unknown^Vancomycin|2|
<=^0.016|||S|||F|||20230323170000||||||||Michigan Dept of Health and
Human Services - Bureau of
Laboratories^D^^^^CLIA&2.16.840.1.113883.19.4.6&ISO^XX^^^23D0650909|335
0 N. Martin Luther King Jr Blvd^^Lansing^MI^48906
NTE|1||S = Susceptible - implies the isolate is inhibited by usually
achievable concentrations of antimicrobial agent when the recommended
dosage is used for site of infection.SDD = Susceptible - Dose
Dependent.I = Intermediate - implies clinical efficacy in body sites
where drugs are physiologically concentrated or when higher than normal
dosage of drug can be used.R = Resistant - implies the isolate is not
inhibited by usually achievable concentrations of the agent with normal
dosage schedules.NS = Not Susceptible - the absence or rare occurrence
of resistant strains precludes defining any result category other than
quot;susceptible quot;.**If no interpretation is indicated, there are
no CLSI approved breakpoints or they are under
investigation.Intermediate based on the known ability of these agents
to concentrate in urine.MIC units in mcg/mL***Unable to interpret ◆
lowest dilution on panel cannot determine if antibiotic is Intermediate
or Susceptible.~NOT ALL ANTIMICROBICS ARE APPROPRIATE FOR TREATMENT OF
INFECTIONS AT ALL ANATOMIC SITES.
OBR|4|LO104336|CL23-
209990^STARLIMS.MI.STAG^2.16.840.1.114222.4.3.3.2.37.2^ISO|2821-
87^Aerobic Culture - Antimicrobial Susceptibility
Results^L|||20230323170000||||||||0001011119^Support^Pat^^^^^^NPI|||||
|20231012131509|||F|6463-4&Bacteria
identified&LN&Isolate&Isolate&L&2.34&v unknown&Isolate^3^Klebsiella
aerogenes|||LO104336^CL23-
209990&STARLIMS.MI.STAG&2.16.840.1.114222.4.3.3.2.37.2&ISO||||||||||||
```

||||||||2821-85^Aerobic Culture - Culture Results^L
OBX|1|ST|18888-8^Cefoxitin^LN^Cefoxitin^Cefoxitin^L^2.34^v unknown^Cefoxitin|3|S|||S|||F|||20230323170000|||||||||Michigan Dept of Health and Human Services - Bureau of Laboratories^D^^^^CLIA&2.16.840.1.113883.19.4.6&ISO^XX^^^23D0650909|3350 N. Martin Luther King Jr Blvd^^Lansing^MI^48906
NTE|1||S = Susceptible - implies the isolate is inhibited by usually achievable concentrations of antimicrobial agent when the recommended dosage is used for site of infection.SDD = Susceptible - Dose Dependent.I = Intermediate - implies clinical efficacy in body sites where drugs are physiologically concentrated or when higher than normal dosage of drug can be used.R = Resistant - implies the isolate is not inhibited by usually achievable concentrations of the agent with normal dosage schedules.NS = Not Susceptible - the absence or rare occurrence of resistant strains precludes defining any result category other than quot;susceptible quot;.**If no interpretation is indicated, there are no CLSI approved breakpoints or they are under investigation.Intermediate based on the known ability of these agents to concentrate in urine.MIC units in mcg/mL***Unable to interpret lowest dilution on panel cannot determine if antibiotic is Intermediate or Susceptible.~NOT ALL ANTIMICROBICS ARE APPROPRIATE FOR TREATMENT OF INFECTIONS AT ALL ANATOMIC SITES.
OBX|2|ST|18893-8^Ceftazidime^LN^Ceftazidime^Ceftazidime^L^2.34^v unknown^Ceftazidime|3|R|||R|||F|||20230323170000|||||||||Michigan Dept of Health and Human Services - Bureau of Laboratories^D^^^^CLIA&2.16.840.1.113883.19.4.6&ISO^XX^^^23D0650909|3350 N. Martin Luther King Jr Blvd^^Lansing^MI^48906
OBR|5|LO104336|CL23-209990^STARLIMS.MI.STAG^2.16.840.1.114222.4.3.3.2.37.2^ISO|2821-208^Aerobic Culture - vanA PCR Result^L|||20230323170000|||||||||0001011119^Support^Pat^^^^^^NPI||||||20231012131509|||F|6463-4&Bacteria identified&LN&Isolate&Isolate&L&2.34&v unknown&Isolate^2^Staphylococcus aureus|||LO104336^CL23-209990&STARLIMS.MI.STAG&2.16.840.1.114222.4.3.3.2.37.2&ISO||||||||||||||||||||2821-85^Aerobic Culture - Culture Results^L
OBX|1|CE|48814-8^vanA gene^LN^vanA PCR^vanA PCR^L^2.34^v unknown^vanA PCR|2|260415000^vanA gene Not Detected^SCT|||N|||F|||20230323170000|||||20231012130927||||Michigan Dept of Health and Human Services - Bureau of Laboratories^D^^^^CLIA&2.16.840.1.113883.19.4.6&ISO^XX^^^23D0650909|3350 N. Martin Luther King Jr Blvd^^Lansing^MI^48906
OBR|6|LO104336|CL23-209990^STARLIMS.MI.STAG^2.16.840.1.114222.4.3.3.2.37.2^ISO|2821-208^Aerobic Culture - vanA PCR Result^L|||20230323170000|||||||||0001011119^Support^Pat^^^^^^NPI||||||20231012131509|||F|6463-4&Bacteria identified&LN&Isolate&Isolate&L&2.34&v unknown&Isolate^4^Enterococcus

```
ratti|||LO104336^CL23-
209990&STARLIMS.MI.STAG&2.16.840.1.114222.4.3.3.2.37.2&ISO||||||||||||
||||||||2821-85^Aerobic Culture - Culture Results^L
OBX|1|CE|48814-8^vanA gene^LN^vanA PCR^vanA PCR^L^2.34^v unknown^vanA
PCR|4|260373001^vanA gene
Detected^SCT|||A|||F|||20230323170000|||||20231012131016||||Michigan
Dept of Health and Human Services - Bureau of
Laboratories^D^^^^CLIA&2.16.840.1.113883.19.4.6&ISO^XX^^^23D0650909|335
0 N. Martin Luther King Jr Blvd^^Lansing^MI^48906
SPM|1|LO104336^CL23-
209990&STARLIMS.MI.STAG&2.16.840.1.114222.4.1.103423&ISO||119365002^Spe
cimen from wound
(specimen)^SCT^WOUND^WOUND^WOUND||||||||||||20230323170000|20231011
```

APPENDIX F – Sample Laboratory Reports

Incomplete Report (Specimen Status Received):

Lab result for POPPINS, MARY J #22BOL1000

Collected 11/20/2023 9:51:00 AM **Received** 11/21/2023 **Provider** Ufkes Kylie

Lab Name : MDHHS Bureau of Laboratories

Report Status: Incomplete

Specimen Information		Patient Information		Practice Information
Accession	LO105650	**Name**	POPPINS, MARY J	Ufkes Kylie
Collected	11/20/2023 9:51:00 AM	**DOB**	8/27/1964	Allegan County Health Department
Received	11/21/2023	**Gender**	F	3255 122nd Avenue Suite 200 Allegan MI 49010
Reported	11/21/2023 8:24:12 AM	**Pat ID**	22BOL1000	(269)673-5411
Sender	MDHHS Bureau of Laboratories	**Address**	1 UAT ALLEGAN MI, 49010	**Account Number**
Total Vol.	SpecimenID : CL23-132115 Specimen Type : Specimen from uterine cervix (specimen)			
		Fasting		

Comments :
User Comments :
Additional Information :

Test Name	In Range	Out of Range	Units	Reference Range	Lab
C. trachomatis + N. gonorrhoeae Non-Culture					
Specimen Status	Received				23D0650909

SpecimenID : CL23-132115
Specimen Type : Specimen from uterine cervix (specimen)

23D0650909	Michigan Dept of Health and Human Services - Bureau of Laboratories 3350 N. Martin Luther King Jr Blvd Lansing MI 48906

Electronically signed by Richard Tooker on 11/21/2023 11:21 AM

11/27/2023 9:22 AM Page 1 / 1

Preliminary Report:

Lab result for TEST, PAT #PH1542089

Collected 3/23/2023 6:36:00 AM **Received** 8/18/2023 **Provider** Support Pat

Lab Name : MDHHS Bureau of Laboratories **Report Status: Preliminary**

Specimen Information

Accession	LO104316
Collected	3/23/2023 6:36:00 AM
Received	8/18/2023
Reported	8/18/2023 2:16:43 PM
Sender	MDHHS Bureau of Laboratories
Specimen Info	SpecimenID : CL23-177900 Specimen Type : Stool specimen (specimen)

Patient Information

Name	TEST, PAT
DOB	5/5/2018
Gender	F
Pat ID	PH1542089
Address	202 Midenhall Way
	cary NC, 27513
	(111)222-2222
Fasting	

Practice Information

Support Pat

Allegan County Health Department

3255 122nd Avenue Suite 200 Allegan MI 49010

(269)673-5411

Account Number

Comments :
User Comments :
Addtional Information :

Test Name	In Range	Out of Range	Units	Reference Range	Lab
-E. coli Cultural Isolate					
Specimen Status	Received				23D0650909
-E. coli Cultural Isolate - E.coli STX PCR Result					
EC Toxin		STX 2 Positive and STX 1 Negative (A)			23D0650909

This test was developed and its performance characteristics determined by the Michigan Department of Health and Human Services (MDHHS). It has not been cleared or approved by the U.S. Food and Drug Administration (FDA). The FDA has determined that such clearance or approval is not necessary if performance characteristics are verified at the testing laboratory.

-Salmonella/Shigella Serotyping - Human					
Specimen Status	Received				23D0650909

SpecimenID : CL23-177900
Specimen Type : Stool specimen (specimen)

23D0650909 Michigan Dept of Health and Human Services - Bureau of Laboratories
3350 N. Martin Luther King Jr Blvd Lansing MI 48906

8/22/2023 8:47 AM Page 1 / 1

Final Report:

Lab result for TEST, PAT #PH1542089

Collected 3/23/2023 6:36:00 AM **Received** 8/18/2023 **Provider** Support Pat

Lab Name : MDHHS Bureau of Laboratories **Report Status: Final**

Specimen Information

Accession	LO104316
Collected	3/23/2023 6:36:00 AM
Received	8/18/2023
Reported	8/18/2023 2:16:43 PM
Sender	MDHHS Bureau of Laboratories
Specimen Info	SpecimenID : CL23-177900 Specimen Type : Stool specimen (specimen)

Patient Information

Name	TEST, PAT
DOB	5/5/2018
Gender	F
Pat ID	PH1542089
Address	202 Midenhall Way cary NC, 27513 (111)222-2222
Fasting	

Practice Information

Support Pat

Allegan County Health Department

3255 122nd Avenue Suite 200 Allegan MI 49010

(269)673-5411

Account Number

Comments :
User Comments :
Addtional Information :

Test Name	In Range	Out of Range	Units	Reference Range	Lab
-E. coli Cultural Isolate					
Specimen Status	Received				23D0650909
-E. coli Cultural Isolate - E.coli STX PCR Result					
EC Toxin		STX 2 Positive and STX 1 Negative (A)			23D0650909

This test was developed and its performance characteristics determined by the Michigan Department of Health and Human Services (MDHHS). It has not been cleared or approved by the U.S. Food and Drug Administration (FDA). The FDA has determined that such clearance or approval is not necessary if performance characteristics are verified at the testing laboratory.

-Salmonella/Shigella Serotyping - Human					
Specimen Status	Received				23D0650909
-Salmonella/Shigella Serotyping - Human - Serotyping Result					
Enteric Typing		Salmonella Enteritidis (A)			23D0650909

Disclaimer: Testing has confirmed the identification of Salmonella or Shigella spp. Serotyping results are for epidemiologic or research purposes only and must not be used for diagnosis, treatment or for the assessment of patient health. Reagents used for individual O and H antigens have not been cleared or approved by the U.S. Food and Drug Administration.
This test was developed and its performance characteristics determined by the Michigan Department of Health and Human Services (MDHHS). It has not been cleared or approved by the U.S. Food and Drug Administration (FDA). The FDA has determined that such clearance or approval is not necessary if performance characteristics are verified at the testing laboratory.
Serotype determined by PCR

Electronically signed by Richard Tooker on 8/22/2023 1:04 PM

8/23/2023 1:53 AM Page 1 / 2

Lab result for TEST, PAT #PH1542089

Collected 3/23/2023 6:36:00 AM **Received** 8/18/2023 **Provider** Support Pat

-E. coli Cultural Isolate - E. coli non-O157 Serotyping Result

EC non-O157 Serotype	Escherichia coli Serotype Unknown	23D0650909

This isolate forwarded to Centers for Disease Control and Prevention for serotyping.
Serotyping performed by Polymerase Chain Reaction (PCR)
This test was developed and its performance characteristics determined by the Michigan Department of Health and Human Services (MDHHS). It has not been cleared or approved by the U.S. Food and Drug Administration (FDA). The FDA has determined that such clearance or approval is not necessary if performance characteristics are verified at the testing laboratory.

SpecimenID : CL23-177900
Specimen Type : Stool specimen (specimen)

23D0650909	Michigan Dept of Health and Human Services - Bureau of Laboratories 3350 N. Martin Luther King Jr Blvd Lansing MI 48906

Electronically signed by Richard Tooker on 8/22/2023 1:04 PM

8/23/2023 1:53 AM Page 2 / 2

Corrected Report:

Lab result for TEST, PAT #PH1542089

Collected 3/23/2023 6:36:00 AM **Received** 8/18/2023 **Provider** Support Pat

Lab Name : MDHHS Bureau of Laboratories **Report Status: Corrected**

Specimen Information		Patient Information		Practice Information
Accession	LO104316	**Name**	TEST, PAT	Support Pat
Collected	3/23/2023 6:36:00 AM			
Received	8/18/2023	**DOB**	5/5/2018	Allegan County Health Department
Reported	8/18/2023 2:16:43 PM	**Gender**	F	3255 122nd Avenue Suite 200 Allegan MI 49010
Sender	MDHHS Bureau of Laboratories	**Pat ID**	PH1542089	(269)673-5411
		Address	202 Midenhall Way	**Account Number**
Specimen Info	SpecimenID : CL23-177900 Specimen Type : Stool specimen (specimen)		cary NC, 27513	
			(111)222-2222	
		Fasting		

Comments :
User Comments :
Addtional Information :

Test Name	In Range	Out of Range	Units	Reference Range	Lab
-E. coli Cultural Isolate					
Specimen Status	Received				23D0650909
-E. coli Cultural Isolate - E.coli STX PCR Result					
EC Toxin		STX 2 Positive and STX 1 Negative (A)			23D0650909

This test was developed and its performance characteristics determined by the Michigan Department of Health and Human Services (MDHHS). It has not been cleared or approved by the U.S. Food and Drug Administration (FDA). The FDA has determined that such clearance or approval is not necessary if performance characteristics are verified at the testing laboratory.

-Salmonella/Shigella Serotyping - Human					
Specimen Status	Received				23D0650909
-Salmonella/Shigella Serotyping - Human - Serotyping Result					
Enteric Typing		Salmonella Enteritidis, phage type 4 (A)			23D0650909

CORRECTED REPORT: Result changed from Salmonella Enteritidis to Salmonella Enteritidis, phage type 4 on 8/23/23
Disclaimer: Testing has confirmed the identification of Salmonella or Shigella spp. Serotyping results are for epidemiologic or research purposes only and must not be used for diagnosis, treatment or for the assessment of patient health. Reagents used for individual O and H antigens have not been cleared or approved by the U.S. Food and Drug Administration.
This test was developed and its performance characteristics determined by the Michigan Department of Health and Human Services (MDHHS). It has not been cleared or approved by the U.S. Food and Drug Administration (FDA). The FDA has determined that such clearance or approval is not necessary if performance characteristics are verified at the testing laboratory.
Serotype determined by PCR

Electronically signed by Richard Tooker on 8/22/2023 1:04 PM

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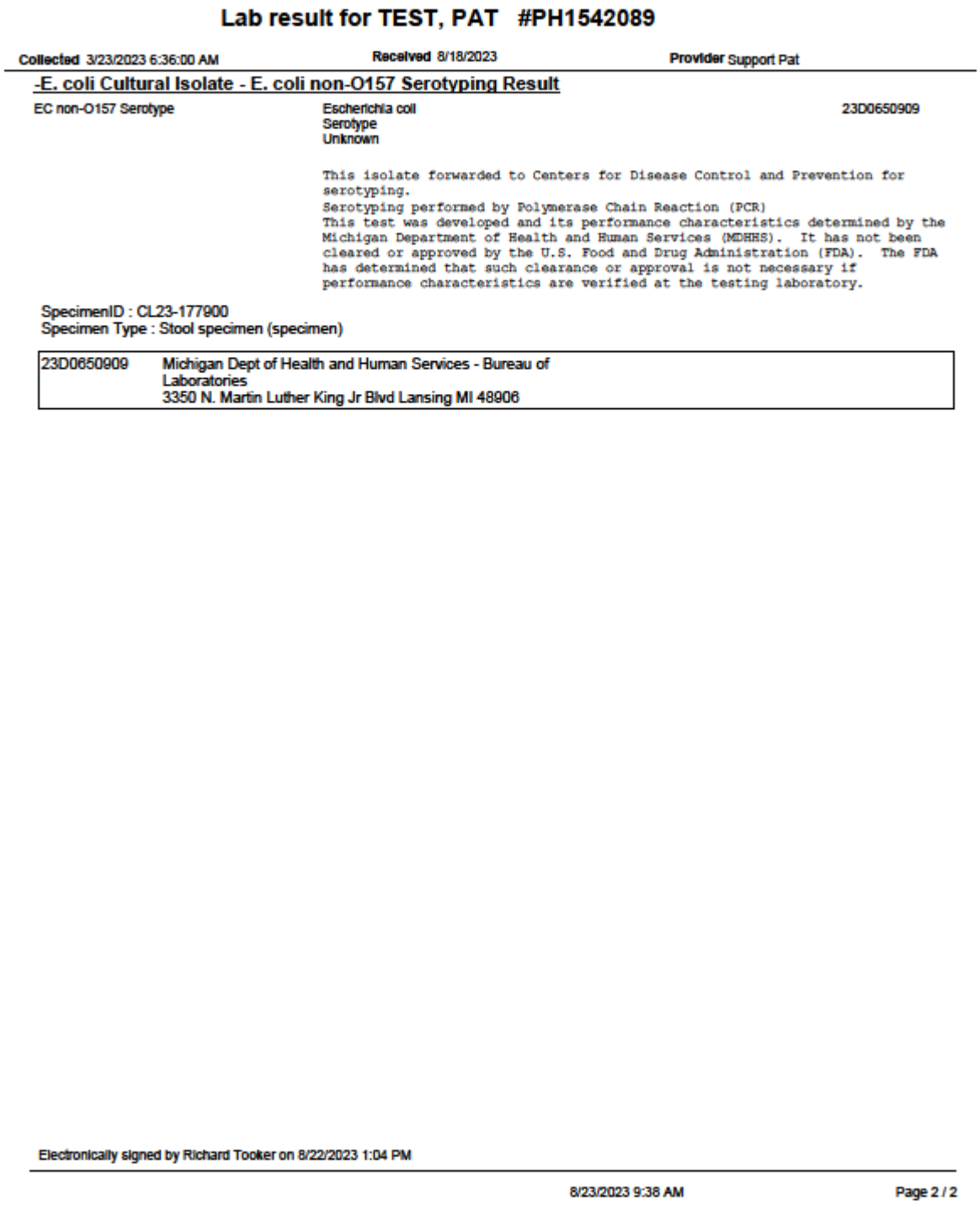

Lab result for TEST, PAT #PH1542089

Collected 3/23/2023 6:36:00 AM **Received** 8/18/2023 **Provider** Support Pat

-E. coli Cultural Isolate - E. coli non-O157 Serotyping Result

EC non-O157 Serotype	Escherichia coli Serotype Unknown	23D0650909

This isolate forwarded to Centers for Disease Control and Prevention for serotyping.
Serotyping performed by Polymerase Chain Reaction (PCR)
This test was developed and its performance characteristics determined by the Michigan Department of Health and Human Services (MDHHS). It has not been cleared or approved by the U.S. Food and Drug Administration (FDA). The FDA has determined that such clearance or approval is not necessary if performance characteristics are verified at the testing laboratory.

SpecimenID : CL23-177900
Specimen Type : Stool specimen (specimen)

23D0650909	Michigan Dept of Health and Human Services - Bureau of Laboratories 3350 N. Martin Luther King Jr Blvd Lansing MI 48906

Electronically signed by Richard Tooker on 8/22/2023 1:04 PM

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Culture and Susceptibility Report:

Lab result for TEST, PAT #PH1542089

Collected 3/23/2023 5:00:00 PM **Received** 10/11/2023 **Provider** Support Pat

Lab Name : MDHHS Bureau of Laboratories **Report Status: Final**

Specimen Information

Accession	LO104336
Collected	3/23/2023 5:00:00 PM
Received	10/11/2023
Reported	10/12/2023 1:15:08 PM
Sender	MDHHS Bureau of Laboratories
Total Vol.	SpecimenID : CL23-209990 Specimen Type : Specimen from wound (specimen)

Patient Information

Name	TEST, PAT
DOB	5/5/2018
Gender	F
Pat ID	PH1542089
Address	202 Midenhall Way cary NC, 27513 (111)222-2222
Fasting	

Practice Information

Support Pat

Allegan County Health Department
3255 122nd Avenue Suite 200 Allegan MI 49010
(269)673-5411

Account Number

Comments :
Aerobic Culture comments: 16S rRNA Sequencing, PCR, and MALDI-TOF tests were developed and their performance characteristics determined by the Michigan Department of Health and Human Services (MDHHS). They have not been cleared or approved by the U.S. Food and Drug Administration (FDA). The FDA has determined that such clearance or approval is not necessary if performance characteristics are verified at the testing laboratory.
User Comments :
Addtional Information :

Test Name	In Range	Out of Range	Units	Reference Range	Lab
Aerobic Culture - Gram Stain					
Gram Stain (1)	Gram negative bacilli				23D0650909
Gram Stain (2)	Gram positive bacilli				23D0650909
Gram Stain (3)	Gram positive cocci				23D0650909
Aerobic Culture					
	Received				23D0650909
Aerobic Culture - Culture Results					
Isolate (1)		Streptococcus pyogenes (A)			23D0650909
	Final MALDI-TOF Identification - Streptococcus pyogenes Final MALDI-TOF Identification - Staphylococcus aureus Final MALDI-TOF Identification - Klebsiella aerogenes Final MALDI-TOF Identification - Enterococcus ratti				
Isolate (2)		Staphylococcus aureus (A)			23D0650909

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Lab result for TEST, PAT #PH1542089

Collected 3/23/2023 5:00:00 PM **Received** 10/11/2023 **Provider** Support Pat

	Final MALDI-TOF Identification - Streptococcus pyogenes Final MALDI-TOF Identification - Staphylococcus aureus Final MALDI-TOF Identification - Klebsiella aerogenes Final MALDI-TOF Identification - Enterococcus ratti	
Vancomycin (2)	<=0.016 (S)	23D0650909
	S = Susceptible - implies the isolate is inhibited by usually achievable concentrations of antimicrobial agent when the recommended dosage is used for site of infection.SDD = Susceptible - Dose Dependent.I = Intermediate - implies clinical efficacy in body sites where drugs are physiologically concentrated or when higher than normal dosage of drug can be used.R = Resistant - implies the isolate is not inhibited by usually achievable concentrations of the agent with normal dosage schedules.NS = Not Susceptible - the absence or rare occurrence of resistant strains precludes defining any result category other than quot;susceptible quot;.**If no interpretation is indicated, there are no CLSI approved breakpoints or they are under investigation.Intermediate based on the known ability of these agents to concentrate in urine.MIC units in mcg/mL***Unable to interpret - lowest dilution on panel cannot determine if antibiotic is Intermediate or Susceptible. NOT ALL ANTIMICROBICS ARE APPROPRIATE FOR TREATMENT OF INFECTIONS AT ALL ANATOMIC SITES.	
vanA PCR (2)	vanA gene Not Detected	23D0650909
Isolate (3)	Klebsiella aerogenes (A)	23D0650909
	Final MALDI-TOF Identification - Streptococcus pyogenes Final MALDI-TOF Identification - Staphylococcus aureus Final MALDI-TOF Identification - Klebsiella aerogenes Final MALDI-TOF Identification - Enterococcus ratti	
Cefoxitin (3)	S (S)	23D0650909
	S = Susceptible - implies the isolate is inhibited by usually achievable concentrations of antimicrobial agent when the recommended dosage is used for site of infection.SDD = Susceptible - Dose Dependent.I = Intermediate - implies clinical efficacy in body sites where drugs are physiologically concentrated or when higher than normal dosage of drug can be used.R = Resistant - implies the isolate is not inhibited by usually achievable concentrations of the agent with normal dosage schedules.NS = Not Susceptible - the absence or rare occurrence of resistant strains precludes defining any result category other than quot;susceptible quot;.**If no interpretation is indicated, there are no CLSI approved breakpoints or they are under investigation.Intermediate based on the known ability of these agents to concentrate in urine.MIC units in mcg/mL***Unable to interpret - lowest dilution on panel cannot determine if antibiotic is Intermediate or Susceptible. NOT ALL ANTIMICROBICS ARE APPROPRIATE FOR TREATMENT OF INFECTIONS AT ALL ANATOMIC SITES.	
Ceftazidime (3)	R (R)	23D0650909
Isolate (4)	Enterococcus ratti (A)	23D0650909
	Final MALDI-TOF Identification - Streptococcus pyogenes Final MALDI-TOF Identification - Staphylococcus aureus Final MALDI-TOF Identification - Klebsiella aerogenes Final MALDI-TOF Identification - Enterococcus ratti	

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Lab result for TEST, PAT #PH1542089

Collected 3/23/2023 5:00:00 PM **Received** 10/11/2023 **Provider** Support Pat

vanA PCR (4)	vanA gene Detected (A)	23D0650909

SpecimenID : CL23-209990
Specimen Type : Specimen from wound (specimen)

23D0650909	Michigan Dept of Health and Human Services - Bureau of Laboratories 3350 N. Martin Luther King Jr Blvd Lansing MI 48906

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APPENDIX G - Revision History

Version	Date	Author	Comments
0.5	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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