# Preface

**NOTE: This document is not a complete profile and must be used in conjunction with the HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Release 1 – US Realm Draft Standard For Trial Use ,July 2012 (LRI).**

# Introduction

*HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health,Release 2 - US Realm* (ELR251R2) is the public health profile component for use with the *HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Release 1 – US Realm Draft Standard For Trial Use ,July 2012 (LRI)[[1]](#footnote-1)*. This profile component describes the additional constraints and guidance needed to transmit laboratory-reportable findings to appropriate local, state, territorial and federal health agencies using the HL7 2.5.1 ORU^R01 message. This document is not a complete profile and must be used in conjunction with the LRI profile. This is described in detail in Section 4.1 below.

LRI\_PH is the successor to The *HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health (US Realm), Release 1(*ELR251R1). It is the product of several related efforts that directly impacted ELR251R1 as well as a wealth of experience gained through the implementation of Release 1. The ELR251R1 errata and clarifications document, that was approved and published in September of 2011[[2]](#footnote-2), was incorporated into this profile. Also incorporated is the 2.5.1 Clarification Document for EHR Technology Certification V1.1 that was created for 2014 EHR certification criteria.[[3]](#footnote-3) In addition, all references to Lab Sender, NHSN, and Lab to EHR which were present in ELR251 R1 were removed. This profile is written to match the content and style of the LRI Implementation Guide. This allows the creation of a Public Health profile component that, in combination with the LRI base profile, creates a complete EL251 R2 message profile. The decision was made to create the Draft Standard for Trial Use to further align the ELR guide development with the family of S&I Framework laboratory interface guides.[[4]](#footnote-4) Although every attempt was made to be backward compatible to ELR251R, it was not always possible. In light of the developments in the laboratory messaging space in the US Realm, the decision was made to align rather than preserve backwards compatibility, where a choice had to be made. Appendix A provides a link to additional resources that summarizes in detail the differences between ELR251 R1 and ELR251 R2 and where backwards compatibility was not possible.

## Purpose

Electronic Laboratory Reporting to Public Health (PH) is a specific piece in a larger test order-test result process. The PH profile facilitates the inclusion of information necessary for public health reporting in the larger test order and result process between ordering providers/laboratories and performing laboratories to ensure that the data is available to be sent to PH when necessary. Harmonizing the technical specifications (format and vocabulary) for the test order (orderer sends order to lab), test result (lab sends result to orderer), and reportable test result (lab sends result to PH) enhances interoperability and data quality thus improving the overall laboratory result reporting process for both the sender and the receiver.

This guide used in conjunction with the LRI guide contains the necessary specifications for laboratory results reporting to local, state, territorial and federal health agencies including messaging content and dynamics related to the transmission of Reportable Laboratory Result Messages. Each state and territory has requirements for laboratories to report certain findings to health officials. With computerization of laboratories, it has become possible for laboratories to send reportable data to health departments electronically. The message described in this guide is not specific to any pathogen or reportable condition and is applicable for most biological and chemistry laboratory-reportable findings.

This document is intended to meet the needs and requirements of implementation guidance in Public Health entities, replacing the previous documentation regarding Electronic Laboratory Reporting (ELR). However, it does not replace the need for each public health jurisdiction to document the constraints of their specific implementation. Further guidance on how to apply constraints is given in Section 7.3 below.

### Condition Reporting

Authority to establish a list of reportable conditions and to specify the content of those reports resides with the individual public health jurisdiction. A joint Centers for Disease Control and Prevention (CDC) – Council of State and Territorial Epidemiologists (CSTE) project is underway, which has the goal of creating a national knowledge management system containing this information. For information on current status, email <<RCKMS\_ email address>>.

Until the knowledge management system is completed, reporters can access further information about reportable conditions at the website for their own Public Health jurisdiction relevant to their service area

## Audience

In addition to the audience specified in LRI section 1.2, this guide is designed for use by analysts and developers who require guidance on data elements and components of the *HL7 Version 2.5.1 ORU Unsolicited Observation Message* relative to the *Public Health Lab Result/ELR Use Case*. 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.

### Requisite Knowledge

Refer to LRI section 1.2.1.

## Organization of this Guide

### Conventions

Refer to LRI section 1.3.1.

### Message Element Attributes

Refer to LRI section 1.3.2.

### Keywords

Refer to LRIsection 1.3.3.

### Usage Conformance Testing Recommendations

Refer to LRI section 1.3.4.

## Scope

For the use case of sending laboratory-reportable findings to appropriate local, state, territorial and federal health agencies, the following scope statements are in addition to those listed in section 1.4 of the LRI guide. Note that in the context of ELR, the receiving system is the Public Health Disease Surveillance System not the Electronic Health Record System (EHR-S).

*In Scope*

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

*Out of Scope*

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

## REsults for ELR Use Case and Context Diagrams

Refer to LRI section 1.5 “Results for Ambulatory Care Use Case and Context Diagrams”. Note that in the context of ELR, the receiving system is the Public Health Disease Surveillance System, defined as ELR Receiver below, and not the Electronic Health Record System (EHR-S) defined in LRI.

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

## USer STory

Refer to LRI section 1.6.

For ELR, the User Story continues as follows:

The laboratory result is determined to be a reportable laboratory result for the patient’s and/or the provider’s public health jurisdiction. The laboratory LIS (results sender) transmits the results to the appropriate public health jurisdiction. The public health jurisdiction’s ELR Receiver incorporates the results in their disease surveillance system allowing for the appropriate follow up by the public health jurisdiction.

## Use Case Assumptions

For ELR, the following use case assumptions are in addition to those listed in the LRI guide section 1.7. Note that in the context of ELR, the receiving system is the ELR Receiver and not the EHR-S.

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

### PRE-CONDITIONS

Refer to LRI guide section 1.7.1. Note that in the context of ELR, the receiving system is the ELR Receiver and not the EHR-S.

### POST-CONDITIONS

Refer to LRI guide 1.7.2. Note that in the context of ELR, the receiving system is the ELR Receiver and not the EHR-S.

### FUNCTIONAL-REQUIREMENTS

Refer to the LRI guide section 1.7.3. Note that in the context of ELR, the receiving system is the ELR Receiver and not the EHR-S.

## SEquence Diagrams

The Figures below are a further clarification adapted from the LRI guide and show the interactions between the Lab Results Sender and the ELR Receiver in the order that they occur. The horizontal lines are used to identify the specific activity between the systems. The solid lines represent the data being transmitted using an HL7 message. Each step has a number associated with it to emphasize the order of the events. Internal Lab system functions (retry, next and log options) are shown as closed loops on the side of the Lab Results Sender.

### Sequence Diagram for Laboratory Result without Acknowledgement

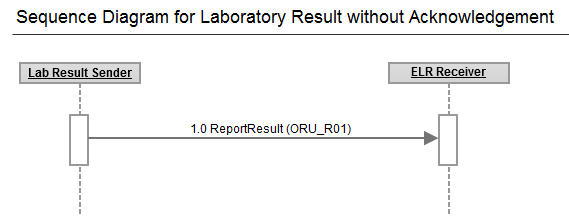


Figure 1. Sequence Diagram for Laboratory Result without Acknowledgment

The sequence consists of Lab Results Sender transmitting an ELR ORU\_R01 message to the ELR Receiver (1.0). No acknowledgement is sent by the ELR Receiver.

### Sequence Diagram for Laboratory Result with Acknowledgement

#### Message Accepted

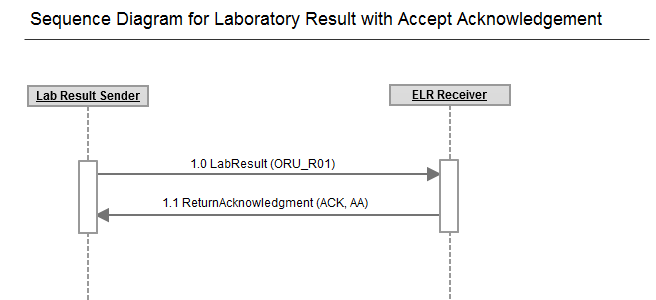


Figure 2. Sequence Diagram for Laboratory Result with Acknowledgement - Message Accepted

The sequence begins with the Lab Results Sender transmitting an ELR ORU\_R01 message to the ELR Receiver (1.0). The message is accepted by the ELR Receiver and an ELR ACK AA message is returned to the Lab system (1.1).

#### Message Rejected

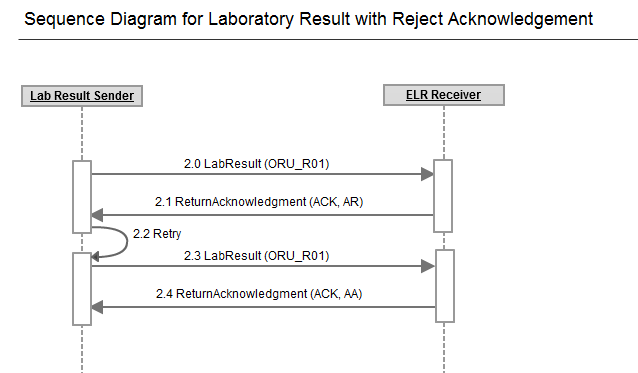


Figure 3. Sequence Diagram for Laboratory Result with Acknowledgement - Message Rejected

The sequence begins with the Lab Results Sender transmitting an ELR ORU\_R01 message to the ELR Receiver (2.0). The message is rejected by the ELR Receiver and an ELR ACK AR message is returned to the Lab system (2.1) which may fix the problem and retry (2.2). The resulting transaction (2.3) is acknowledged as correct (2.5).

#### Message Error

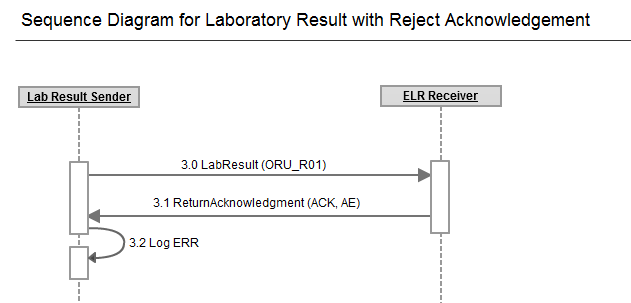


Figure 4. Sequence Diagram for Laboratory Result with Acknowledgement - Message Accepted

The sequence begins with the Lab Results Sender transmitting an ELR ORU\_R01 message to the ELR Receiver (3.0). The message contains serious errors and is rejected by the ELR Receiver, and an ELR ACK AE message is returned to the Lab system (3.1), which may log the error (3.3).

### Batch Messaging

### 

Figure 5. Sequence Diagram for Batch Processing of Laboratory Result without Acknowledgements

The sequence consists of Lab Results Sender transmitting zero or more ELR ORU\_R01 messages to the ELR Receiver (1.0) using the batch protocol. No acknowledgement is sent by the ELR Receiver.

### Interactions

| Table 1‑1 Interactions  Individual Transaction with Acknowledgements (Ack),  Individual Transaction without Acknowledgements (NoAck),  Individual Transaction without Acknowledgements/Batch (Batch) | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| Event | Description | Use Case | Message Type | Receiver Action | Sender | Data Values |
| Preliminary Result | Preliminary: A verified early result is available; final results not yet obtained | Ack[[5]](#footnote-5)  NoAck  Batch | ORU^R01^ORU\_R01 | Commit Accept, Commit Reject or Commit Error | Laboratory Result Sender | ORC-1=RE  OBR-25=P |
| Final Result | Final results; results stored and verified. Can be changed only with a corrected result. | Ack  NoAck  Batch | ORU^R01^ORU\_R01 | Commit Accept, Commit Reject or Commit Error | Laboratory Result Sender | ORC-1=RE  OBR-25=F |
| Correction | Correction to results | Ack  NoAck  Batch | ORU^R01^ORU\_R01 | Commit Accept, Commit Reject or Commit Error | Laboratory Result Sender | ORC-1=RE  OBR-25=C |
| No Results Available | No results available; Order canceled, Testing Not Done | Ack  NoAck  Batche | ORU^R01^ORU\_R01 | Commit Accept, Commit Reject or Commit Error | Laboratory Result Sender | ORC-1=RE  OBR-25=X |
| Commit/Application Accept | Accept acknowledgment/ Application Accept/ Application acknowledgment | Ack | ACK^R01^ACK | None | ELR Receiver | MSA-1=AA |
| Commit/Application Error | Accept acknowledgment:/ Application Error/ Application acknowledgment:  Error | Ack | ACK^R01^ACK | None | ELR Receiver | MSA-1=AE |
| Commit/Application Reject | Accept acknowledgment/ Application Reject/Application acknowledgment:  Reject | Ack | ACK^R01^ACK | None | ELR Receiver | MSA-1=AR |

## Key Technical Decisions

Refer to LRI section 1.9.

### Use of ISO Object Identifier (OID)

Refer to the LRI guide section 1.9.1 for a discussion on the use of OIDs. The following organization OIDs below are provided for the reader’s convenience.

|  |  |  |
| --- | --- | --- |
| Table 1‑2. Common Organization OIDs | | |
| **Organization** | **OID** | **Notes** |
| NPI | 2.16.840.1.113883.4.6 | U.S. National Provider Identifier |
| CLIA | 2.16.840.1.113883.4.7 | The Centers for Medicare & Medicaid Services (CMS) regulates all laboratory testing (except research) performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments (CLIA). |

### Use of Vocabulary Standards

Refer to LRI section 1.9.2.

### Snapshot Mode

Refer to LRI section 1.9.2.

### Field Length and Truncation

Refer to LRI section 1.9.4.

## Referenced Profiles - Antecedents

The following profiles were used as source materials in the development of this guide:

1. *HL7 U.S. Realm – Interoperability Specification: Lab Result Message to EHR, Version 1.0,* November 2007
2. *Harmonized Use Case for Electronic Health Records (Laboratory Result Reporting)*
3. *Implementation Guide for Transmission of Laboratory-Based Reporting of Public Health Information using version 2.3.1 of Health Level Seven (HL7) Standard Protocol,* March 2005*.*
4. *HL7 Version 3 Standard: Abstract Transport Specification, Normative Edition 2009*
5. *HL7 Version 2.5.1 Implementation Guide: Laboratory Results Interface for US Realm, Release 1, HL7 Version 2.5.1: ORU^R01, Draft Standard for Trial Use, July 2012*
6. [*Standards and Interoperability Laboratory Results Interface Use Case, Laboratory Results Reporting to Primary Care Providers (in an Ambulatory Setting) v1.0*](http://sibrowser.siframework.org/siclient/view?type=artifact&id=39481918-9dc7-4f55-aa77-f978b4c13d8b&name=SIFramework_LRI_UC.docx)
7. *HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Orders from EHR, Release 1 – US Realm January 2013 10 HL7 DSTU Ballot*

## Actors

Refer to LRI section 1.11.

## Conformance to this Guide

This implementation guide defines elements that are combined into profiles components to define specific conformance requirements for Electronic Laboratory Reporting to Public Health. These profile components must be combined with the LRI\_GU\_RU profile to create a valid profile for a particular transaction. As of this version the Public Health profile component consists at minimum of a single component:

1. LAB\_PH\_COMPONENT

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

1. LAB-NoAck\_COMPONENT – Acknowledgement not used

MSH-21 (Message Profile Identifier) is populated with the profile identifier of all applicable profile components used in addition to the LRI\_GU\_NU base profile. Multiple profiles or profile components can be present in MSH.21, provided the combination of profiles do not conflict with each other. Additional definitions and guidance for MSH-21 can be found in Section 4.1.

### Result Profile Components

LRI Section 1.12.1 lists several optional profile components that can be used in addition to those listed below. Note that this guide restricts usage to the LRI\_GU\_RU base profile – it can be identified using the pre-coordinated profile OID, or listing all 3 profile component OIDs.

#### LAB\_PH\_COMPONENT – ID: 2.16.840.1.113883.9.OO

Public Health profile components for use with the LRI results message. This profile component specifies the conformance attributes for the additional elements needed for the public health reporting use case.

#### LAB\_NoAck\_COMPONENT - ID: 2.16.840.1.113883.9.NN

No Acknowledgement profile component for use with the LRI Public Health profile component. This component is used to indicate that no Acknowledgement Messages are to be sent. This conforms to the use case described above where acknowledgements are not used.

Support for this profile component is optional.

### RESULT PROFILES (PRE-COORDINATED COMPONENTS)

Refer to the LRI guide section 1.12.2. Note, this guide restricts usage to the LRI\_GU\_RU pre or post-coordinated profile component. The other profiles in this section are not compatible with the LAB\_PH profile component.

### Response Components

Refer to LRI section 1.12.3.

### Response Profiles (Pre-Coordinated Components)

Refer to LRI section 1.12.4.

### Extended Profile Use

Refer to LRI section 1.12.5.

### Scope of Implementation

Refer to LRI section 1.12.6.

### Relationship to Orders

Refer to LRI section 1.12.7.

# Data types

Refer to section 2.0 of the LRI guide for a discussion on the use of Data types. The following sections detail additional constraints to the LRI data types and list additional data types required by this guide. See section 1.3.2 (Message Element Attributes) for a description of the column headers in the tables below.

**The following sections detail only the additional constraints to the LRI data types. The specific attributes that have been further constrained are underlined.**

## CE – Coded Element

| Table 2‑1. CE – Coded Element | | | | | |
| --- | --- | --- | --- | --- | --- |
| 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. 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 | R | HL70396 |  |

## CWE\_CRE – Coded with Exceptions – Code Required, but May Be Empty[[6]](#footnote-7)

| Table 2‑2. CWE\_CRE – Coded with Exceptions- Code Required, but May Be Empty | | | | | |
| --- | --- | --- | --- | --- | --- |
| SEQ | Component Name | DT | Usage | Value Set | Comments |
| 7 | Coding System Version ID | ST | RE |  |  |
| 8 | Alternate Coding System Version ID | ST | RE |  |  |
| 9 | Original Text | ST | C(R/RE) |  | Condition Predicate: If CWE\_CRE.1 (Identifier) AND CWE\_CRE.4 (alternate identifier) are not valued.  If a code is used, Original Text is used to convey the text that was the basis for coding.  If neither the first or second triplet has values, this contains the text of the field. |

## CWE\_CR – Coded with Exceptions – Code Required7

| Table 2‑3. CWE\_CR – Coded with Exceptions – Code Required | | | | | |
| --- | --- | --- | --- | --- | --- |
| SEQ | Component Name | DT | Usage | Value Set | Comments |
| 7 | Coding System Version ID | ST | RE |  |  |
| 8 | Alternate Coding System Version ID | ST | RE |  |  |

## CWE\_CRO – Coded with Exceptions – Code and Original Text Required7

| Table 2‑4. CWE\_CRO – Coded with Exceptions – Code and Original Text Required | | | | | |
| --- | --- | --- | --- | --- | --- |
| SEQ | Component Name | DT | Usage | Value Set | Comments |
| 7 | Coding System Version ID | ST | RE |  |  |
| 8 | Alternate Coding System Version ID | ST | RE |  | . |

## CX\_GU – Extended Composite ID with Check Digit (globally unique)

Refer to LRI section 2.5.

| Table 2‑5. CX – Extended Composite ID with Check Digit | | | | | |
| --- | --- | --- | --- | --- | --- |
| SEQ | Component Name | DT | Usage | Value Set | Comments |
| 6 | Assigning Facility | HD | RE |  |  |

## CX\_NG– Extended Composite ID with Check Digit (non-globally unique)

**Not Supported**

## DR – Date/Time Range

Refer to LRI section 2.7.

## DT – Date

Refer to LRI section 2.7.

## DTM – Date/Time

Refer to LRI section 2.9.

## EI \_GU– Entity Identifier (globally unique)

Refer to LRI section 2.10.

## EI \_GN– Entity Identifier (non-globally unique)

**Not Supported**

## EIP\_GU – Entity Identifier PAIR (globally unique)

Refer to LRI section 2.11.

## EIP\_GN – Entity Identifier PAIR (NON-globally unique)

**Not Supported**

## ERL – error location

Refer to LRI section 2.14

## FN – Family Name

Refer to LRI section 2.15.

## FT – Formatted Text Data

Refer to LRI section 2.16.

## HD\_GU – Hierarchic Designator (globally unique)

| Table 2‑6. HD\_GU – Hierarchic Designator | | | | | |
| --- | --- | --- | --- | --- | --- |
| SEQ | Component Name | DT | Usage | Value Set | Comments |
| 2 | Universal ID | ST | R |  | Must be an OID except for Sending Facility (MSH-4) where a CLIA identifier is allowed. |
| 3 | Universal ID Type | ID | R | HL70301 | Fixed to ‘ISO’ except for Sending Facility (MSH-4) where the value ‘CLIA’ is allowed. |

**Conformance Statements:**

ELR-003: HD.3 (Universal ID Type) IF element is MSH-4.3 (Universal ID type), then HD.3 (Universal ID type) SHALL contain the value "ISO" OR "CLIA", ELSE HD.3 (Universal ID type) SHALL contain the value "ISO".

## HD\_GN – Hierarchic Designator (Non-globally unique)

**Not Supported**

## ID – Coded Value for HL7-Defined Tables

Refer to LRI section 2.19.

## IS – Coded Value for User-Defined Tables

Refer to LRI section 2.20.

## MSG – Message Type

Refer to LRI section 2.21.

## NM – Numeric

Refer to LRI section 2.22.

## PRL – Parent Result Link

| Table 2‑7. PRL – Parent Result Link | | | | | |
| --- | --- | --- | --- | --- | --- |
| SEQ | Component Name | DT | Usage | Value Set | Comments |
| 3 | Parent Observation Value Descriptor | TX | RE |  | Taken from the OBX-5 of the parent result. If OBX-5 contains coded data, this will be the value of the text component of the CE or CWE data type or the original text component of the CWE data type when there is no coded component. |

## PT – Processing Type

Refer to LRI section 2.24

## SAD – Street Address

Refer to LRI section 2.25.

## SI – Sequence ID

Refer to LRI section 2.26.

## SN – Structured Numeric

Refer to LRI section 2.27.

## ST – String Data

Refer to LRI section 2.28.

## TM – Time

| Table 2‑8. TM - Time | | | | | |
| --- | --- | --- | --- | --- | --- |
| SEQ | Component Name | DT | Usage | Value Set | Comments |
| 1 | Time | - | R |  | Format: HH[MM[SS[.S[S[S[S]]]]]][+/-ZZZZ] |

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

## TS\_0 – Time STAMP

Refer to LRI section 2.30.

## TS\_1 – Time Stamp

| Table 2‑9. TS\_1 Time Stamp | | | | | |
| --- | --- | --- | --- | --- | --- |
| SEQ | DT | Usage | Value Set | Component Name | Comments |
|  |  | R |  | +/- ZZZZ |  |

## TS\_2 – Time stamp

Refer to LRI section 2.31.

## TS\_3 – Time Stamp

Refer to LRI section 2.32.

## TS\_4 – TIME STAMP

Refer to LRI section 2.33.

## TS\_5 – Time stamp

Refer to LRI section 2.34.

## TX\_6 – Time Stamp

Refer to LRI section 2.35.

## TX – Text Data

Refer to LRI section 2.36.

## VID – Version Identifier

Refer to LRI section 2.37.

## XAD – Extended Address

Refer to LRI section 2.38.

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

| Table 2‑10. XCN\_GU – Extended Composite ID Number and Name for Persons | | | | | |
| --- | --- | --- | --- | --- | --- |
| SEQ | Component Name | DT | Usage | Value Set | Comments |
| 14 | Assigning Facility | [HD](https://www.aphlweb.org/aphl_departments/Strategic_Initiatives_and_Research/Informatics_Program/Projects/Eric/Documents/kreislera/My%20Documents/HL7/Documents/hl725/std25/ch02A.html#HD) | RE |  |  |
| 21 | Professional Suffix | [ST](https://www.aphlweb.org/aphl_departments/Strategic_Initiatives_and_Research/Informatics_Program/Projects/Eric/Documents/kreislera/My%20Documents/HL7/Documents/hl725/std25/ch02A.html#ST) | RE | HL70360 |  |

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

**Not Supported**

## XON\_GU – Extended Composite Name and Identification Number for Organizations (globally Unique)

| Table 2‑11. XON\_GU – Extended Composite Name and Identification Number for Organizations | | | | | |
| --- | --- | --- | --- | --- | --- |
| SEQ | Component Name | DT | Usage | Value Set | Comments |
| 2 | Organization Name Type Code | [IS](https://www.aphlweb.org/aphl_departments/Strategic_Initiatives_and_Research/Informatics_Program/Projects/Eric/Documents/kreislera/My%20Documents/HL7/Documents/hl725/std25/ch02A.html#IS) | RE | HL7[0204](https://www.aphlweb.org/aphl_departments/Strategic_Initiatives_and_Research/Informatics_Program/Projects/Eric/Documents/kreislera/My%20Documents/HL7/Documents/hl725/std25/ch02A.html#Heading552) |  |

## XON\_GN – Extended Composite Name and Identification Number for Organizations (non-globally Unique)

**Not Supported**

## XPN – Extended Person Name

| Table 2‑12. XPN – Extended Person Name | | | | | |
| --- | --- | --- | --- | --- | --- |
| SEQ | Component Name | DT | Usage | Value Set | Comments |
| 14 | Professional Suffix | [ST](https://www.aphlweb.org/aphl_departments/Strategic_Initiatives_and_Research/Informatics_Program/Projects/Eric/Documents/kreislera/My%20Documents/HL7/Documents/hl725/std25/ch02A.html#ST) | RE | HL70360 |  |

**The following sections detail data types that are specific to this guide and not in the LRI Guide**

## CNN – Composite ID Number and Name Simplified

| Table 2‑13. CNN – Composite ID Number and Name Simplified | | | | | |
| --- | --- | --- | --- | --- | --- |
| SEQ | Component Name | DT | Usage | Value Set | Comments |
| 1 | ID Number | [ST](https://www.aphlweb.org/aphl_departments/Strategic_Initiatives_and_Research/Informatics_Program/Projects/Eric/Documents/kreislera/My%20Documents/HL7/Documents/hl725/std25/ch02A.html#ST) | RE |  | The ID Number component combined with the Assigning Authority – Universal ID component (component 10) must uniquely identify the associated person. Note - despite the component being named “ID Number” this component is an ST string data type, not numeric, so the component is not limited to just numbers. |
| 2 | Family Name | ST | RE |  |  |
| 3 | Given Name | [ST](https://www.aphlweb.org/aphl_departments/Strategic_Initiatives_and_Research/Informatics_Program/Projects/Eric/Documents/kreislera/My%20Documents/HL7/Documents/hl725/std25/ch02A.html#ST) | RE |  | I.e., first name. |
| 4 | Second and Further Given Names or Initials Thereof | [ST](https://www.aphlweb.org/aphl_departments/Strategic_Initiatives_and_Research/Informatics_Program/Projects/Eric/Documents/kreislera/My%20Documents/HL7/Documents/hl725/std25/ch02A.html#ST) | RE |  |  |
| 5 | Suffix (e.g., JR or III) | [ST](https://www.aphlweb.org/aphl_departments/Strategic_Initiatives_and_Research/Informatics_Program/Projects/Eric/Documents/kreislera/My%20Documents/HL7/Documents/hl725/std25/ch02A.html#ST) | RE |  |  |
| 6 | Prefix (e.g., DR) | [ST](https://www.aphlweb.org/aphl_departments/Strategic_Initiatives_and_Research/Informatics_Program/Projects/Eric/Documents/kreislera/My%20Documents/HL7/Documents/hl725/std25/ch02A.html#ST) | RE |  |  |
| 7 | Degree (e.g., MD) | [IS](https://www.aphlweb.org/aphl_departments/Strategic_Initiatives_and_Research/Informatics_Program/Projects/Eric/Documents/kreislera/My%20Documents/HL7/Documents/hl725/std25/ch02A.html#IS) | RE | HL70360 |  |
| 8 | Source Table |  | X |  | Not supported. |
| 9 | Assigning Authority – Namespace ID | IS | RE | Local | The coding system for this component is locally managed. |
| 10 | Assigning Authority - Universal ID | ST | C(R/X) |  | Condition Predicate: If CNN.1 (Identifier) is valued. |
| 11 | Assigning Authority - Universal ID Type | ID | C(R/X) | HL70301 | Condition Predicate: If CNN.10 (Assigning Authority - Universal ID) is valued. |

**Conformance Statements:**

**ELR-004** CNN.10 (Assigning Authority - Universal ID) SHALL be valued with an ISO-compliant OID.

**ELR-005** CNN.11 (Assigning Authority - Universal ID Type) SHALL contain the value "ISO".

## CQ – Composite Quantity with Units

| Table 2‑14 CQ - Composite Quantity with Units | | | | | |
| --- | --- | --- | --- | --- | --- |
| SEQ | Component Name | DT | Usage | Value Set | Comments |
| 1 | Quantity | NM | R |  |  |
| 2 | Units | CWE\_CRE | RE | Unified Code for Units of Measure (UCUM) |  |

## NDL - Name With Date And Location

| Table 2‑15. NDL - NAME WITH DATE AND LOCATION | | | | | |
| --- | --- | --- | --- | --- | --- |
| SEQ | Component Name | DT | Usage | Value Set | Comments |
| 1 | Name | CNN | R |  |  |
| 2 | Start Date/time |  | X |  | Not supported. |
| 3 | End Date/time |  | X |  | Not supported. |
| 4 | Point of Care |  | X |  | Not supported. |
| 5 | Room |  | X |  | Not supported. |
| 6 | Bed |  | X |  | Not supported. |
| 7 | Facility |  | X |  | Not supported. |
| 8 | Location Status |  | X |  | Not supported. |
| 9 | Person Location Type |  | X |  | Not supported. |
| 10 | Building |  | X |  | Not supported. |
| 11 | Floor |  | X |  | Not supported. |

## RP – Reference Pointer

| Table 2‑16. RP – Reference Pointer | | | | | |
| --- | --- | --- | --- | --- | --- |
| SEQ | Component Name | DT | Usage | Value Set | Comments |
| 1 | Pointer | [ST](https://www.aphlweb.org/aphl_departments/Strategic_Initiatives_and_Research/Informatics_Program/Projects/Eric/Documents/kreislera/My%20Documents/HL7/Documents/hl725/std25/ch02A.html#ST) | R |  | Pointer to the object. For URIs, it contains the path and query parts.  Example:  /phin/library/documents/pdf/DRAFT\_PHIN\_ORU\_ELR\_v2.5.1\_20061221.pdf |
| 2 | Application ID | [HD](https://www.aphlweb.org/aphl_departments/Strategic_Initiatives_and_Research/Informatics_Program/Projects/Eric/Documents/kreislera/My%20Documents/HL7/Documents/hl725/std25/ch02A.html#HD) | R |  | Unique identifier of the application that holds the object being pointed to. For URIs, it contains the scheme and authority parts.  Note that the HD data type used for this component is specialized for use in the RP data type, and is different that what is defined in section (HD). |
| 2.1 | Source Table |  | O |  |  |
| 2.2 | Universal ID | ST | R |  | This component is restricted to a universal resource identifier (URI). For URIs, contains the scheme and authority parts. Example: http://www.cdc.gov |
| 2.3 | Universal ID Type | ID | R | HL70301 | This component is constrained to support only universal Resource Identifier. Literal value: ‘URI’ |
| 3 | Type of Data | [ID](https://www.aphlweb.org/aphl_departments/Strategic_Initiatives_and_Research/Informatics_Program/Projects/Eric/Documents/kreislera/My%20Documents/HL7/Documents/hl725/std25/ch02A.html#ID) | RE | HL70834 (2.7) | Identifier of the type of data pointed to. For the URI example referenced above, this is '"application." |
| 4 | Subtype | [ID](https://www.aphlweb.org/aphl_departments/Strategic_Initiatives_and_Research/Informatics_Program/Projects/Eric/Documents/kreislera/My%20Documents/HL7/Documents/hl725/std25/ch02A.html#ID) | RE | HL7[0291](https://www.aphlweb.org/aphl_departments/Strategic_Initiatives_and_Research/Informatics_Program/Projects/Eric/Documents/kreislera/My%20Documents/HL7/Documents/hl725/std25/ch02A.html#Heading407) (2.7) | Identifier of the subtype of data pointed to. For the URI example above, this is "pdf," indicating portable document format. |

Implementation Note:

The field uses the RP data type to allow communication of pointers to images, sound clips, XML documents, HTML markup, etc. The RP data type is used when the object being pointed to is too large to transmit directly.

This specification defines the mechanism for exchanging pointers to objects, but does not address the details of applications actually accessing and retrieving the objects over a network.

This guide constrains this data type to support only Universal Resource Identifiers (URI). See <http://ietf.org/rfc/rfc2396.txt> for a detailed definition. The general format of a URI is in the form <scheme>://<authority><path>?<query>. The scheme and authority portions appear in the Application ID component, Universal ID subcomponent. The path and query portion of the URI appear in the Pointer component of the RP data type.

## XTN - Extended Telecommunication Number

| Table 2‑17. XTN – Extended Telecommunication Number | | | | | |
| --- | --- | --- | --- | --- | --- |
| SEQ | Component Name | DT | Usage | Value Set | Comments |
| 1 | Telephone Number |  | X |  | Not supported. |
| 2 | Telecommunication Use Code | ID | RE | HL70201 | Should use ‘NET’ if component 4 (Email Address) is present. |
| 3 | Telecommunication Equipment Type | [ID](https://www.aphlweb.org/aphl_departments/Strategic_Initiatives_and_Research/Informatics_Program/Projects/Eric/Documents/kreislera/My%20Documents/HL7/Documents/hl725/std25/ch02A.html#ST) | RE | HL70202 | Should use ‘X 400’ if component 4 (Email Address) is present. |
| 4 | Email Address | ST | C(R/X) |  | Condition Predicate: IF XTN.7 (local number) is not valued. |
| 5 | Country Code | NM | C(RE/X) |  | Condition Predicate: IF XTN.7 (local number) is valued.. |
| 6 | Area/City Code | [NM](https://www.aphlweb.org/aphl_departments/Strategic_Initiatives_and_Research/Informatics_Program/Projects/Eric/Documents/kreislera/My%20Documents/HL7/Documents/hl725/std25/ch02A.html#IS) | C(RE/X) |  | Condition Predicate: IF XTN.7 (local number) is valued. |
| 7 | Local Number | NM | C(R/X) |  | Condition Predicate: IF XTN.4 (Email Address) is not valued. |
| 8 | Extension | [NM](https://www.aphlweb.org/aphl_departments/Strategic_Initiatives_and_Research/Informatics_Program/Projects/Eric/Documents/kreislera/My%20Documents/HL7/Documents/hl725/std25/ch02A.html#ID) | C(RE/X) |  | .Condition Predicate: IF XTN.7 (local number) is valued. |
| 9 | Any Text | [ST](https://www.aphlweb.org/aphl_departments/Strategic_Initiatives_and_Research/Informatics_Program/Projects/Eric/Documents/kreislera/My%20Documents/HL7/Documents/hl725/std25/ch02A.html#CE) | RE |  | For example: “Regular hours 8 am to 5 pm.” |
| 10 | Extension Prefix |  | X |  | Not supported. |
| 11 | Speed Dial Code |  | X |  | Not supported. |
| 12 | Unformatted Telephone number |  | X |  | Not supported. |

Implementation Note:

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

# Messages

Refer to section 3 of the LRI guide for a discussion on Message Structure. The following sections detail additional constraints to the LRI Message structure required by this guide and support of optional batch protocol. See section 1.3.2 (Message Element Attributes) for a description of the columns in the tables below.

**The following sections detail only the additional constraints to the LRI Message Structure. The specific attributes that have been further constrained are underlined.**

## ORU^R01^ORU\_R01

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

| Table 3‑1. ORU^R01^ORU\_R01 | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| Segment | Name | Cardinality | Usage | Description/Comments | | |
| … |  |  |  |  | | |
| {SFT} | Software Segment | [1..\*] | R | Each HL7 aware application that touches the message on the way to the destination application must add a SFT segment for its application. For instance, PHIN MS is not HL7 aware and would not be expected to add an SFT. On the other hand, an integration engine is HL7 aware and would be expected to add an SFT.  The first repeat (i.e., the Laboratory Result Sender actor) is required. Any other application that transforms the message must add an SFT segment for that application. Other applications that route or act as a conduit may add an SFT but are not required to do so. | | |
| … |  |  |  |  | | |
| [{NTE}] | Notes and Comments for PID | [0..\*] | RE | This notes and comments (NTE) segment should contain notes or comments pertaining to the patient identified in the PID segment. It should not contain order or result related comments. | | |
| … |  |  |  |  | | |
| [{NK1}] | Next of Kin/Associated Parties | [0..\*] | RE | The next of kin (NK1) segment can be used to document the patient’s next of kin, employer, guardian, etc. Particular jurisdictions may require the NK1 segment to contain parent/guardian information when reporting lead testing results for children. When reporting results of animal testing (for example testing animals for rabies) the NK1 segment can be used to identify the owner of the animal. | | |
| … |  |  |  |  | | |
| [ | VISIT Begin | [0..1] | RE |  | | |
| … |  |  |  |  | | |
| { | SPECIMEN Begin | [0..\*] | RE | The specimen group is required at least one time in the ORU and is used to carry specimen information that is no longer contained in the OBR segment. | | |
| … |  |  |  |  | | |
| [{OBX}] | Observation related to Specimen | [0..\*] | RE | The Observation related to Specimen is generally used to report additional characteristics related to the specimen. It is not used to report the results of the requested testing identified in OBR-4 (Universal Service ID). The observations associated with the specimen are typically information that the ordering providing sends with the order. The laboratory forwards that information as part of the result message. | | |
| … |  |  |  |  |  |  |

**Conformance Statements:**

ELR-006: Specimen (Specimen Group) SHALL be present in at least one occurrence of one Order\_Observation Group.

## ACK^R01^ACK

| Table 3‑2. ACK^R01^ACK | | | | |
| --- | --- | --- | --- | --- |
| Segment | Name | Cardinality | Usage | Description/Comments |
| … |  |  |  |  |
| {SFT} | Software Segment | [1..\*] | R | Each HL7 aware application that touches the message on the way to the destination application must add a SFT segment for its application. For instance, PHIN MS is not HL7 aware and would not be expected to add an SFT. On the other hand, an integration engine is HL7 aware and would be expected to add an SFT.  The first repeat (i.e., the originator) is required. Any other application that transforms the message must add an SFT segment for that application. Other applications that route or act as a conduit may add an SFT but are not required to do so. |
| … |  |  |  |  |

## HL7 Batch Protocol

The frequencies of batch transmissions are left to specific implementations. Batches may be sent more often if the message size or resource requirements dictate. Acknowledgement methods for batch messaging are beyond the scope of this document. . The reader is directed to HL7 Version 2.7.1, Chapter 2, Section 2.10.3 *HL7 batch protocol* for further guidance

## Segment and Field Descriptions

Refer to section 3.3 of the LRI guide for a discussion on the segment and field descriptions. The following sections detail additional constraints to the segments and field descriptions and list additional segments and fields required by this guide. See section 1.3.2 (Message Element Attributes) for a description of the columns in the tables below.

**The following sections detail only the additional constraints to the LRI segments and fields. Where segments are defined by the LRI guide, specific attributes that have been further constrained are underlined. Where segments are defined only for this guide, the entire segment is described. These include:**

**SFT - Software Segment**

**NK1 – Next of Kin/Associated Party Segment**

**PV1 – Patient Visit Segment**

**FHS – File Header Segment**

**FTS – File Trailer Segment**

**BHS – Batch Header Segment**

**BTS- Batch Trailer Segment**

### MSH – Message Header Segment

| Table 3‑3. MSH – Message Header Segment | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| Seq | HL7 Element Name | DT | Cardinality | Usage | Value Set | Description/Comments | |
| 3 | Sending Application | HD\_GU | [1..1] | R | HL70361 |  | |
| 4 | Sending Facility | HD\_GU | [1..1] | R | HL70362 | If acknowledgments are in use, this facility will receive any related acknowledgment message.  For laboratories originating messages, the CLIA identifier is allowed for the Universal ID component of the HD\_GU data type. Non-laboratory facilities taking on the Laboratory Result Sender actor role will use an OID for this field. | |
| 5 | Receiving Application | HD\_GU | [1..1] | R | HL70361 |  | |
| 6 | Receiving Facility | HD\_GU | [1..1] | R | HL70362 | If acknowledgments are in use, this facility originates any related acknowledgment message. | |
| 7 | Date/Time Of Message | TS\_1 | [1..1] | R |  | Note that the time zone offset is required and applies to all other date/time fields in the same message instance where a time zone offset is not valued | |
| 15 | Accept Acknowledgment Type | ID | [1..1] | R | HL70155 (Constrained) | Value is “NE” if LAB\_NoAck\_Component is used, otherwise the value is “AL”. | |
| 16 | Application Acknowledgment Type | ID | [1..1] | R | HL70155 (Constrained) | Value is “NE” if LAB\_NoAck\_Component is used, otherwise the value is '‘AL’, 'NE', 'ER', or 'SU'. | |

Implementation Note:

In addition to the guidance in the LRI Guide, the table below indicates valid MSH-21 combinations for declaring conformance to the ELR result profile.

| Table 3‑4. MSH 21 Result Profile Combinations | | |
| --- | --- | --- |
| Component Name | Component OIDs | Description/Comments |
| LRI\_GU\_RU\_Profile + LAB\_PH\_Component | 2.16.840.1.113883.9.17  2.16.840.1.113883.9.NNN | Message is conformant to the pre-coordinated LRI\_GU\_RU profile and Public Health component, which support the (ELR) Laboratory Result with Acknowledgement use case. |
| LRI\_Common\_Component +  LRI\_GU\_Component +  LRI\_RU\_Component +  LAB\_PH\_Component | 2.16.840.1.113883.9.16  2.16.840.1.113883.9.12  2.16.840.1.113883.9.14  2.16.840.1.113883.9.NNN | Message is conformant to the post-coordinated LRI\_GU\_RU profile and Public Health component, which support the (ELR) Laboratory Result with Acknowledgement use case. |

In addition to those described in the LRI Guide, for each of the combinations illustrated, the following additional profile component identifiers can be specified:

* LAB\_NoAck\_Component - 2.16.840.1.113883.9.NNN

**Example: LRI\_GU\_RU\_Profile using pre-coordinated component OID and the LAB\_PH\_Component**

MSH…|||||LRI\_GU\_RU\_Profile^^2.16.840.1.113883.9.17^ISO~LAB\_PH\_Component^^2.16.840.1.113883.9.NNN^ISO

**Example: LRI\_Common\_Component + LRI\_GU\_Component + LRI\_RU\_Component + LAB\_PH\_Component using Component OIDs**

MSH…|||||LRI\_Common\_Component^^2.16.840.1.113883.9.16^ISO~ LRI\_GU\_Component^^2.16.840.1.113883.9.12^ISO~ LRI\_RU\_Component^^2.16.840.1.113883.9.14^ISO~LAB\_PH\_Component^^2.16.840.1.113883.9.NNN^ISO

**Conformance Statements:**

**ELR-006**: MSH-15 (Accept Acknowledgment Type) SHALL contain the constant value ‘NE’ IF an occurrence of MSH-21.3 (Entity Identifier) is valued 2.16.840.1.113883.9.NNN (LAB\_NoAck\_Component), ELSE SHALL contain the constant value 'AL'

**ELR-007**: MSH-16 (Application Acknowledgement Type) SHALL contain the constant value ‘NE’ IF an occurrence of MSH-21.3 (Entity Identifier) is valued 2.16.840.1.113883.9.NNN (LAB\_NoAck\_Component), ELSE, if valued, SHALL contain the value '‘AL’, 'NE', 'ER', or 'SU'.

**ELR-008**: An occurrence of MSH-21 (Message Profile Identifier) SHALL be valued with 2.16.840.1.113883.9.17 (LRI\_GU\_RU\_Profile) or three occurrences SHALL be valued with 2.16.840.1.113883.9.16 (LRI\_Common\_Component), 2.16.840.1.113883.9.12 (LRI\_GU\_Component) and 2.16.840.1.113883.9.14 (LRI\_RU\_Component) in any order.

**ELR-009**: An occurrence of MSH-21 (Message Profile Identifier) **SHALL** be valued with 2.16.840.1.113883.9.NNN (LAB\_PH\_Component).

Note: **In addition to those listed in the LRI guide,** additional occurrences of MSH-21 (Message Profile Identifier) may be valued with:

* LAB\_NoAck\_Component - 2.16.840.1.113883.9.NNN

### SFT – Software segment

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

| Table 3‑5. SFT – Software Segment | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| Seq | HL7 Element Name | DT | Cardinality | Usage | Value Set | Description/Comments |
| 1 | Software Vendor Organization | XON | [1..1] | R |  |  |
| 2 | Software Certified Version or Release Number | ST | [1..1] | R |  |  |
| 3 | Software Product Name | ST | [1..1] | R |  |  |
| 4 | Software Binary ID | ST | [1..1] | R |  |  |
| 5 | Software Product Information |  |  | O |  |  |
| 6 | Software Install Date | TS\_0 | [0..1] | RE |  |  |

### MSA – Acknowledgement Segment

Refer to LRI section 2.10.

### ERR – Error Segment

| Table 3‑6. ERR – Error Segment | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| Seq | HL7 Element Name | DT | Cardinality | Usage | Value Set | Description/Comments |
| 3 | HL7 Error Code | CWE\_CRE | [1..1] | R | HL70357 |  |
| 8 | User Message | TX | [0..1] | RE |  |  |
| 12 | Help Desk Contact Point | XTN | [0..\*] | RE |  |  |

### PID – Patient Identification Segment

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

| Table 3‑7. PID – Patient Identification Segment | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Seq | | HL7 Element Name | DT | Cardinality | Usage | Value Set | Description/Comments | |
| 6 | | Mother’s Maiden Name | XPN | [0..1] | RE |  | May be included for identification purposes. Name type code is constrained to the value "M." | |
| 7 | | Date/Time of Birth | Varies | [0..1] | RE |  | Base Profile: TS\_2  Newborn Screening Profile: TS\_3  Patient’s date of birth. Note that the granularity of the birth date may be important. For a newborn, birth date may be known down to the minute, while for adults it may be known only to the date.  Note: If a birth date is not provided in the PID, then the patient age must be reported as an observation associated with the Order. | |
| 10 | | Race | CWE\_CRE | [0..\*] | RE | HL70005 |  | |
| 11 | | Patient Address | XAD | [0..\*] | RE |  |  | |
| 13 | | Phone Number – Home | XTN | [0..\*] | RE |  |  | |
| 14 | | Phone Number – Business | XTN | [0..\*] | RE |  |  | |
| 22 | | Ethnic Group | CWE\_CRE | [0..\*] | RE | HL70189 |  | |
| 29 | | Patient Death Date and Time | TS\_2 | [0..1] | RE |  |  | |
| 30 | | Patient Death Indicator | ID | [0..1] | RE | HL70136 | If PID-29 is valued, then this field should be populated with “Y” since the patient is known to be dead. | |
| 33 | | Last Update Date/Time | TS\_5 | [0..1] | RE |  | The intent of this field is to serve as flag for messages with updated demographic information. | |
| 34 | | Last Update Facility | HD\_GU | [0..1] | C(R/O) |  | Condition Predicate: IF PID-33 (Last Update Date/Time) is valued.  This is the facility that originated the demographic update. | |
| 35 | | Species Code | CWE\_CRE | [0..1] | C(R/RE | PHVS\_Animal\_CDC | Condition Predicate: IF PID-36 (Breed Code) or PID-37 (Strain) is valued.  Population of this field supports animal rabies testing by public health laboratories as it relates to human rabies testing. Note that the condition predicates will yield “ RE -Required, but can be empty” unless this profile is constrained further for PID-37 (Strain) and PID-36 (Breed Code). This conditions is only stated as it reflects the base standard | |
| 36 | | Breed Code | CWE\_CRE | [0..1] | C(R/O) |  | Condition Predicate: IF PID-37 (Strain) is valued.  Note that the condition predicates will yield “ O - Optional” unless this profile is constrained further for PID-37 (Strain) This conditions is only stated as it reflects the base standard | |
| 37 | Strain | |  |  | O |  |  | |
| 38 | Production Class Code | |  |  | O |  |  | |

**Conformance Statements:**

**ELR-010**: If valued, PID- 6.7 (Name Type Code) SHALL contain the constant value ‘M'.

**ELR-011:** If PID-7 (Date/Time of Birth) is not valued, then an OBX segment associated with the SPM segment SHALL be present to report “Age at specimen collection” (LOINC in OBX-3.1 = 35659-2).

### NK1 – Next of Kin Segment

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

| Table 3‑8. NK1 – Next Of Kin Segment | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| Seq | HL7 Element Name | DT | Cardinality | Usage | Value Set | Description/Comments |
| 1 | Set ID – NK1 | SI | [1..1] | R |  |  |
| 2 | Name | XPN | [0..\*] | C(R/X) |  | Condition Predicate: IF NK1-13 (Organization Name – NK1) is not valued.  Name of the next of kin or associated party. Multiple names for the same entity are allowed, but the legal name must be sent in the first sequence. If the legal name is not sent, the repeat delimiter must be sent in the first sequence.  If next of kin or associated party is a person use this field, otherwise, use field NK1-13 |
| 3 | Relationship | CWE\_CRE | [0..1] | RE | HL70063 | Description of the relationship between the next of kin/related party and the patient. It is of particular importance when documenting the parent or guardian of a child patient or the owner of an animal patient. |
| 4 | Address | XAD | [0..\*] | RE |  | Field that may contain the address of the next of kin/associated party. |
| 5 | Phone Number | XTN | [0..\*] | RE |  | Field that may contain the telephone number or email address of the next of kin/associated party. Multiple phone numbers are allowed |
| 6 | Business Phone Number |  |  | X |  | Not supported. |
| 7 | Contact Role | CWE\_CRE | [0..1] | RE | HL70131 |  |
| 8 | Start Date |  |  | X |  | Not supported. |
| 9 | End Date |  |  | X |  | Not supported. |
| 10 | Next of Kin / Associated Parties Job Title |  |  | X |  | Not supported. |
| 11 | Next of Kin / Associated Parties Job Code/Class |  |  | X |  | Not supported. |
| 12 | Next of Kin / Associated Parties Employee Number |  |  | X |  | Not supported. |
| 13 | Organization Name – NK1 | XON | [0..1] | C(R/X) |  | Condition Predicate: IF NK1-2 (Name) is NOT valued.  If next of kin or associated party is an organization use this field, otherwise, use field NK1-2. |
| 14 | Marital Status |  |  | X |  | Not supported. |
| 15 | Administrative Sex |  |  | X |  | Not supported. |
| 16 | Date/Time of Birth |  |  | X |  | Not supported. |
| 17 | Living Dependency |  |  | X |  | Not supported. |
| 18 | Ambulatory Status |  |  | X |  | Not supported. |
| 19 | Citizenship |  |  | X |  | Not supported. |
| 20 | Primary Language |  |  | O |  |  |
| 21 | Living Arrangement |  |  | X |  | Not supported. |
| 22 | Publicity Code |  |  | X |  | Not supported. |
| 23 | Protection Indicator |  |  | X |  | Not supported. |
| 24 | Student Indicator |  |  | X |  | Not supported. |
| 25 | Religion |  |  | X |  | Not supported. |
| 26 | Mother’s Maiden Name |  |  | X |  | Not supported. |
| 27 | Nationality |  |  | X |  | Not supported. |
| 28 | Ethnic Group |  |  | X |  | Not supported. |
| 29 | Contact Reason |  |  | X |  | Not supported. |
| 30 | Contact Person’s Name | XPN | [0..\*] | C(R/X) |  | Condition Predicate: IF NK1-13 (Organization Name) is valued |
| 31 | Contact Person’s Telephone Number | XTN | [0..\*] | C(RE/X) |  | Condition Predicate: IF NK1-13 (Organization Name) is valued |
| 32 | Contact Person’s Address | XAD | [0..\*] | C(RE/X) |  | Condition Predicate: IF NK1-13 (Organization Name) is valued |
| 33 | Next of Kin/Associated Party’s Identifiers |  |  | X |  | Not supported. |
| 34 | Job Status |  |  | X |  | Not supported. |
| 35 | Race |  |  | X |  | Not supported. |
| 36 | Handicap |  |  | X |  | Not supported. |
| 37 | Contact Person Social Security Number |  |  | X |  | Not supported. |
| 38 | Next of Kin Birth Place |  |  | X |  | Not supported. |
| 39 | VIP Indicator |  |  | X |  | Not supported. |

1

**Conformance Statements:**

**ELR-012:** NK1-1 (Set ID – NK1) SHALL be valued sequentially starting with the value ‘1’

### PV1 – Patient Visit Information

This segment contains basic inpatient or outpatient encounter information.

| Table 3‑9. PV1 – Patient Visit Information | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| Seq | HL7 Element Name | DT | Cardinality | Usage | Value Set | Description/Comments |
| 1 | Set ID - PV1 | SI | [1..1] | R |  |  |
| 2 | Patient Class | IS | [1..1] | R | HL70004 | A gross identification of the classification of patient’s visit |
| 3 | Assigned Patient Location |  |  | O |  |  |
| 4 | Admission Type | IS | [0..1] | RE | Admission Type Value Set |  |
| 5 | Preadmit Number |  |  | O |  |  |
| 6 | Prior Patient Location |  |  | O |  |  |
| 7 | Attending Doctor |  |  | O |  |  |
| 8 | Referring Doctor |  |  | O |  |  |
| 9 | Consulting Doctor |  |  | O |  |  |
| 10 | Hospital Service |  |  | O |  |  |
| 11 | Temporary Location |  |  | O |  |  |
| 12 | Preadmit Test Indicator |  |  | O |  |  |
| 13 | Re-admission Indicator |  |  | X |  | Not supported. |
| 14 | Admit Source |  |  | O |  |  |
| 15 | Ambulatory Status |  |  | X |  | Not supported. |
| 16 | VIP Indicator |  |  | X |  | Not supported. |
| 17 | Admitting Doctor |  |  | O |  |  |
| 18 | Patient Type |  |  | O |  |  |
| 19 | Visit Number |  |  | O |  |  |
| 20 | Financial Class |  |  | O |  |  |
| 21 | Charge Price Indicator |  |  | X |  | Not supported. |
| 22 | Courtesy Code |  |  | X |  | Not supported. |
| 23 | Credit Rating |  |  | X |  | Not supported. |
| 24 | Contract Code |  |  | X |  | Not supported. |
| 25 | Contract Effective Date |  |  | X |  | Not supported. |
| 26 | Contract Amount |  |  | X |  | Not supported. |
| 27 | Contract Period |  |  | X |  | Not supported. |
| 28 | Interest Code |  |  | X |  | Not supported. |
| 29 | Transfer to Bad Debt Code |  |  | X |  | Not supported. |
| 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 |  | Not supported |
| 41 | Account Status |  |  | O |  |  |
| 42 | Pending Location |  |  | O |  |  |
| 43 | Prior Temporary Location |  |  | O |  |  |
| 44 | Admit Date/Time | TS\_5 | [0..1] | RE |  | Date and time patient arrived for services |
| 45 | Discharge Date/Time | TS-5 | [0..1] | RE |  | Date and time patient services ended |
| 46 | Current Patient Balance |  |  | O |  |  |
| 47 | Total Charges |  |  | O |  |  |
| 48 | Total Adjustments |  |  | O |  |  |
| 49 | Total Payments |  |  | O |  |  | |
| 50 | Alternate Visit ID |  |  | O |  |  |
| 51 | Visit Indicator |  |  | O |  |  |
| 52 | Other Healthcare Provider |  |  | X |  | Not supported. |

**Conformance Statements:**

**ELR-013:** PV1-1 (Set ID - PV1) SHALL contain the constant value ‘1’.1

### PV2 – Patient Visit

Refer to LRI section 2.10.

### ORC – Common Order Segment

| Table 3‑10. ORC – Common Order Segment | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| Seq | HL7 Element Name | DT | Cardinality | Usage | Value Set | Description/Comments |
| 14 | Call Back Phone Number | XTN | [0..2] | RE |  | This should be a phone number associated with the original ordering provider. |
| 21 | Ordering Facility Name | XON | [1..1] | R |  | The name of the facility where the order was placed. If the order was placed in a single providrer office, the value in this field may be the same as in ORC-12.. |
| 22 | Ordering Facility Address | XAD | [1. 1] | R |  | The address of the facility where the order was placed. |
| 23 | Ordering Facility Phone Number | XTN | [1..\*] | R |  | The telephone number of the facility where the order was placed |
| 24 | Ordering Provider Address | XAD | [0..\*] | RE |  | This should be the address associated with the original ordering provider |

**Conformance Statements:**

**ELR-014**: ORC-1 (Order Control) SHALL contain the constant value ‘RE'.

**ELR-015**: ORC-14 (Call Back Phone Number) SHALL be the same value as OBR-17 (Call Back Phone Number) within same Order\_Observation Group.

**ELR-016**: ORC-12 (Ordering Provider) SHALL be the same value as OBR-16 (Ordering Provider) within same Order\_Observation Group.

### OBR – Observation Request Segment

| Table 3‑11. OBR – Observation Request Segment | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| Seq | HL7 Element Name | DT | Cardinality | Usage | Value Set | Description/Comments |
| 4 | Universal Service Identifier | CWE\_CR | [1..1] | R | LOINC ( see Description and Comments for further guidance) | OBR.4 (Universal Service Identifier is a test, panel or battery code for the requested observation.  For lab test orders in general LOINC SHOULD be used as the standard coding system for this field if an appropriate LOINC code exists.9  For reportable lab test orders, the Reportable Condition Mapping Table (RCMT) Lab Test name value sets SHOULD be used.  A local code and local test name SHOULD also be sent to help with identification of coding issues. When no valid LOINC exists, the local code may be the only code sent.  When populating this field with values, this guide does not give preference to the triplet in which the standard (LOINC) code should appear. |
| 9 | Collection Volume |  | X |  |  | Not supported |
| 17 | Order Callback Phone Number | XTN | [0..2] | RE |  | This should be a phone number associated with the original ordering provider. |
| 31 | Reason for Study | CWE\_CRE | [0..\*] | RE | ICD-9CM or ICD-10-CM and/or CORE Problem List Subset of SNOMED CT. |  |
| 32 | Principal Result Interpreter | NDL | [0..1] | RE |  | Used for pathology results. |

**Conformance Statements:**

#### REPORTING A MICROBIOLOGY CULTURE WITH SUSCEPTIBILITY

Refer to LRI section 3.3.10.1.

### RESULTS HANDLING AND RESULTS COPY TO

Refer to LRI section 3.3.11.

### TQ1 – Timing/Quantity Segment

Refer to LRI section 3.3.12.

### TQ2 – Timing/Quantity Segment

Refer to LRI section 3.3.13.

### OBX – Observation/Result Segment

| Table 3‑12. OBX – Observation/Result Segment | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| Seq | HL7 Element Name | DT | Cardinality | Usage | Value Set | Description/Comments |
| 3 | Observation Identifier | CWE\_CR | [1..1] | R | LOINC OR “NAV”  See Description and Comments for further guidance | LOINC SHALL be used as the standard coding system for this field.  For reportable laboratory tests, the Reportable Condition Mapping Table (RCMT) Lab Test value sets [[7]](#footnote-8) SHOULD be used.  For Ask at Order Entry (AOE) questions refer to the Guidance Section 6.6 below.  A local code and local test name SHOULD also be sent to help with identification of coding issues.  If an appropriate LOINC code does not exist[[8]](#footnote-9), then value “NAV” (Not available) from HL7 table 353 SHALL be used AND the local code and local test name SHALL be sent  When populating this field with values, this guide does not give preference to the triplet in which the standard (LOINC) code should appear. |
| 5 | Observation Value | Varies | [0..1] | C(RE/X) | SNOMED CT For coded values:  ( See Section 3.1.13.1 for further guidance) | Condition Predicate: IF OBX-11 (Observation Result Status) is not valued 'X' or ‘N’.  See Section , HL7 Table 0125 for the data types that will be supported for this field.  Either OBX-5 or OBX-8 (Abnormal flags) must be present in the message except if OBX-11 is ‘X” or ‘N’, result cannot be obtained.[[9]](#footnote-10)  For coded lab test results, SNOMED CT SHALL be used as the standard coding system for this field if an appropriate SNOMED CT code exists. See section 3.1.13.1 below for further guidance.  For AOE question responses refer to the Guidance Section 6.6 below |
| 8 | Interpretation Codes | CWE\_CRE | [0..\*] | C(RE/X) | HL70078 (Constrained V2.7.1), | Condition Predicate: IF OBX-11 (Observation Result Status) is not valued 'X' or ‘N’.  See section 3.1.13.1 below for examples.  Either OBX-5 (Observation Value) or OBX-8 must be present in the message except if OBX-11 is ‘X” or ‘N’, result cannot be obtained. |
| 14 | Date/Time of the Observation | TS\_4 | [0..1] | RE |  | For specimen-based laboratory reporting, this field shall contain the specimen collection date/time and will be the same value as an occurrence of SPM.17.1. The date/time testing was performed should be reported in OBX-19. |
| 17 | Observation Method | CWE\_CRE | [0..\*] | RE | Observation Method Value Set | This can be useful to further specify information about the specific method to a more granular level than what is defined by the LOINC used in OBX-3. |

Implementation Notes:

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

**Conformance Statements:**

**ELR-019**: Either OBX-3.3 (Coding System) OR OBX-3.6 (Alternate Coding System) SHALL be valued "LN" OR "HL70353"

**ELR-022**: OBX-3.3 (coding System): IF OBX-3.6 (Alternate Coding System) value is “HL70353”, then OBX-3.3 (coding System) SHALL be valued “L” or “99zzz”.

**ELR-023**: OBX-3.6 (Alternate Coding System): IF OBX-3.3 (Coding System) value is “HL70353”, then OBX-3.6 (Alternate Coding System) SHALL be valued “L” or “99zzz”.

**ELR-024**: OBX-5 (Observation Value) MUST be valued IF OBX-8 (Abnormal Flags) is empty AND OBX-11 (Observation Result Status) is not valued ‘X’ or ‘N’.

**ELR-025**: 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 constrained HL7 Table 0125 found in this guide.

**ELR-026**: OBX-8 (Abnormal Flags) MUST be valued IF OBX-5 (Observation Value) is empty AND OBX-11 (Observation Result Status) is not valued ‘X’ or ‘N’.

**ELR-027**: OBX-14 (Date/Time of the Observation) For observation related to testing of specimen (OBX's following the OBR), SHALL be identical to an occurrence of SPM-17.1 (Range Start Date/Time) value within the same Order\_Observation Group.

#### Observation Identifiers, Observation Values, Interpretations and Comments

Refer to the discussion in the LRI guide. Additional clarifications and constraints are detailed in the table below.

| Table 3‑13. Observation Identifiers | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Testing situation Discussion | OBX.2 Observation Type | OBX.3 Observation Identifier: LOINC part = scale | OBX.5 Observation value | OBX.6 Units | OBX.8 Abnormal Flags | OBX.7 Reference Range | NTE Segment |
| Numeric result | NM | QN | number | UCUM Units required unless OBX-11 = ‘X’ or ‘N’. | May be populated with an Interpretation Code. Examples: “H^Above high normal^HL70078” or RR^Reactive^HL70078 | May be populated | May be populated with comments, not clinical findings. |
| Numerical intervals, ratios, inequalities | SN | QN | structured numeric | UCUM Units required unless OBX-11 = ‘X’ or ‘N’. | May be populated with an Interpretation Code. See above examples | May be populated | May be populated with comments, not clinical findings. |
| Ordinal result | CWE | ORD | (CWE\_CRO Datatype)  For coded ordinal test results SNOMED CT SHALL be used if a suitable code exist. The ELR Ordinal Value Set MAY be used to further constrain the ordinal test results.  A local code and/or local test name SHOULD also be sent to help with identification of coding issues. When no valid SNOMED CT code 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 (SNOMED CT) code should appear. | [empty] | May be populated with an Interpretation Code. Example: “A^Abnormal^HL70078” | May be populated | May be populated with comments, not clinical findings. |
| Ordinal result | SN | ORD | Ordinal as structured numeric for example ^2^+ | UCUM Units required unless OBX-11 = ‘X’ or’N’. \*\* | May be populated with an Interpretation Code. See above examples | Required | May be populated with comments, not clinical findings. |
| Conveys numeric or ordinal value | NM | ORDQN | Number | UCUM Units required unless OBX-11 = ‘X’ or ‘N’. \*\* | May be populated with an Interpretation Code. Example for Microbial Sensitivity: “S^Susceptible^HL70078” | May be populated | May be populated with comments, not clinical findings. |
| Conveys numeric or ordinal value | CWE | ORDQN | CWE\_CRO Datatype:  For coded Ordinal test results see comments above | [empty] | May be populated with an Interpretation Code. See above examples | May be populated | May be populated with comments, not clinical findings |
| Conveys observation | CWE | NOM | CWE\_CRO Datatype:  For coded nominal test results SNOMED CT SHALL be used if a suitable code exist.  For reportable laboratory results, the Reportable Condition Mapping Table (RCMT) Lab Results value sets SHOULD be used.  A local code and local test name SHOULD also be sent to help with identification of coding issues. When no valid SNOMED CT code 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 (SNOMED CT) code should appear. | [empty] | May be populated with an Interpretation Code. See above examples | May be populated | May be populated with comments, not clinical findings. |

### SPM – Specimen Segment

| Table 3‑14. SPM – Specimen Segment | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| Seq | HL7 Element Name | DT | Cardinality | Usage | Value Set | Description/Comments | |
| 2 | Specimen ID | EIP\_GU | [1..1] | R |  | Unique identifier for the specimen as referenced by the Placer application, the Filler application, or both.  Note that the specimen id is not the same thing as the placer/filler order number. Order numbers identify the specific test to be performed on a specimen. A particular specimen may be associated with multiple orders (and multiple placer/filler order numbers). The specimen id may be the same as an accession number, depending on how the particular lab assigns accession numbers. | |
| 4 | Specimen Type | CWE\_CRE | [1..1] | R | Specimen Type Value Set | The standard vocabulary for this field. SHALL be based upon the SNOMED CT Specimen hierarchy. | |
| 5 | Specimen Type Modifier | CWE\_CRE | [0..\*] | RE | SNOMED CT | Modfiers or qualifiers for Specimen typeThis allows use of post-coordinated expressions for specimen type. | |
| 6 | Specimen Additives | CWE\_CRE | [0..\*] | RE | Specimen Additives Value Set |  | |
| 7 | Specimen Collection Method | CWE\_CRE | [0..1] | RE | Specimen Collection Value Set. |  | |
| 8 | Specimen Source Site | CWE\_CRE | [0..1] | RE | Specimen Source Site Value Set | Source from which the specimen was obtained. For biological samples, it represents the anatomical site from which the specimen was collected. | |
| 9 | Specimen Source Site Modifier | CWE\_CRE | [0..\*] | C(RE/X) | SNOMED CT Topographical modifier hierarchy | Condition Predicate: If SPM.8.3 (Coding System) OR SPM.8.6 (Alternate Coding System) is valued “SCT”.  Topographical modifier ( such as “left” or “right” ) for the specimen source site (SPM-8). Only used if SPM-8 is a SNOMED code. This allows use of post-coordinated terminologies for specimen source site. | |
| 12 | Specimen Collection Amount | CQ | [0..1] | RE | Unified Code for Units of Measure (UCUM) | Use this field instead of OBR.9 ( Collection Volume) | |
| 17 | Specimen Collection Date/Time | DR | [1..1] | R |  |  | |
| 18 | Specimen Received Date/Time | TS\_5 | [1..1] | R |  | Time the specimen was received at the diagnostic service. The actual time that is recorded is based on how specimen receipt is managed, and may correspond to the time the sample is logged in. | |

**Conformance Statements:**

**ELR-028**: The earliest SPM-17.1 (Range Start Date/Time) value SHALL be equal to or before OBR-7 (Observation Date/Time) value within the same Order\_Observation Group.

**ELR-029**: If present, the latest SPM-17.2 (Range End Date/Time) value SHALL be equal to or after OBR-7 (Observation Date/Time) value within the same Order\_Observation Group.

**ELR-030**: IF present, the latest SPM-17.2 (Range End Date/Time) value SHALL be equal to or after OBR-8 (Observation End Date/Time) value within the same Order\_Observation Group

### NTE – Notes and Comments Segment

| Table 3‑15. NTE –Notes And Comments Segment | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| Seq | HL7 Element Name | DT | Cardinality | Usage | Value Set | Description/Comments |
| 2 | Source of Comment | ID | [0..1] | RE | HL70105 |  |
| 4 | Comment Type | CWE\_CRE | [0..1] | RE | HL70364 |  |

### FHS – FILE HEADER SEGMENT

| Table 3‑16. FHS – File Header Segment | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| Seq | HL7 Element Name | DT | Cardinality | Usage | Value Set | Description/Comments |
| 1 | File Field Separator | ST | [1..1] | R |  |  |
| 2 | File Encoding Characters | ST | [1..1] | R |  |  |
| 3 | File Sending Application |  |  | O |  |  |
| 4 | File Sending Facility |  |  | O |  |  |
| 5 | File Receiving Application |  |  | O |  |  |
| 6 | File Receiving Facility |  |  | O |  |  |
| 7 | File Creation Date/Time |  |  | O |  |  |
| 8 | File Security |  |  | X |  | Not Supported. |
| 9 | File Name/ID |  |  | O |  |  |
| 10 | File Header Comment |  |  | X |  | Not Supported. |
| 11 | File Control ID |  |  | X |  | Not Supported. |
| 12 | Reference File Control D |  |  | X |  | Not Supported. |

**ELR-031**: FHS-1 (Field Separator) **SHALL** contain the constant value ‘|’.

**ELR-032**:FHS-2 (Encoding Characters) **SHALL** contain the constant value ‘^~\&’ or the constant value ‘^~\&#’.

### FTS – FILE TRAILER SEGMENT

| Table 3‑17. FTS – File Trailer Segment | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| Seq | HL7 Element Name | DT | Cardinality | Usage | Value Set | Description/Comments |
| 1 | File Batch Count |  |  | O |  |  |
| 2 | File Trailer Comment |  |  | X |  | Not supported. |

### BHS – BATCH HEADER SEGMENT

| Table 3‑18. BHS – Batch Header Segment | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Seq | | HL7 Element Name | DT | Cardinality | Usage | Value Set | Description/Comments |
| 1 | | Batch Field Separator | ST | [1..1] | R |  |  |
| 2 | Batch Encoding Characters | | ST | [1..1] | R |  |  |
| 3 | Batch Sending Application | |  |  | O |  |  |
| 4 | Batch Sending Facility | |  |  | O |  |  |
| 5 | Batch Receiving Application | |  |  | O |  |  |
| 6 | Batch Receiving Facility | |  |  | O |  |  |
| 7 | Batch Creation Date/Time | |  |  | O |  |  |
| 8 | Batch Security | |  |  | X |  | Not supported. |
| 9 | Batch Name/ID/Type | |  |  | O |  |  |
| 10 | Batch Comment | |  |  | X |  | Not supported. |
| 11 | Batch Control ID | |  |  | X |  | Not supported. |
| 12 | Reference Batch Control D | |  |  | X |  | Not supported. |

**ELR-033**: BHS-1 (Field Separator) **SHALL** contain the constant value ‘|’.

**ELR-034**:BHS-2 (Encoding Characters) **SHALL** contain the constant value ‘^~\&’ or the constant value ‘^~\&#’.

### BTS – Batch TRAILER SEGMENT

| Table 3‑19. BTS – Batch Trailer Segment | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| Seq | HL7 Element Name | DT | Cardinality | Usage | Value Set | Description/Comments | |
| 1 | Batch Message Count | NM | [1..1] | R |  | This is the total number of messages contained in the batch. | |
| 2 | Batch Comment |  |  | X |  | Not supported. | |
| 3 | Batch Totals |  |  | X |  | Not supported. | |

# Code Systems and Value Sets

Refer to section 4.0 of the LRI guide for a general discussion of Code Systems and Value sets. Additional constraints and guidance for the LRI\_PH profile component are discussed below.

## LOINC

The LOINC long common name SHOULD be sent in addition to the LOINC in order to facilitate debugging and message validation between the sender and the public health agency. See the Section 7 below for further guidance and examples when a valid LOINC does not exist.

## SNOMED CT

Where a SNOMED CT code is available, SNOMED CT SHALL be used for coded reportable laboratory results using either CWE\_CRO, identified as CWE in OBX-2 or CE in OBX.5. Each SNOMED CT Concept has a permanent unique **numeric Identifier** which is known as the “Concept ID” and only these shall be used for this IG[[10]](#footnote-12). In other words, SNOMED alphanumeric legacy codes shall not be used for this IG.

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

## example HL7 Messages

See LRI guide.

## Specimen Type

SNOMED CT drawn from the specimen hierarchy in SNOMED CT SHALL be used for SPM-4 (Specimen type). A cross-mapping between HL70487 and SNOMED CT is available at PHIN-VADS. ( see Section-N below).

## UCUM

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

A table of commonly used example UCUM units for electronic messaging is available here: [http://loinc.org/downloads/usage/units](http://loinc.org/downloads/usage/units%20) .

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

## Vocabulary Constraints

In addition to Table 4-2 in the LRI guide Table 4-1 Value Set/Code System Summary, below, shows the additional vocabulary constraints used in this guide

### PHIN-VADS ELR Value Set Resource

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

PHIN VADS provides as a resource to implementers all the ELR related value sets listed below and those listed in the LRI guide. Additionally, an *ELR IG to VADS Vocab Mapping* table is available that cross references the ELR values sets to the PHIN VADS value sets. These resources can be accessed on the PHIN VADS home page: (<http://phinvads.cdc.gov/vads/SearchHome.action>)

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

| Table ‑. Value Set. Code System Summary | | | | |
| --- | --- | --- | --- | --- |
| **Value Set Name** | **Source ID/Reference** | **Source** | **Unique Identifier** | **Comments** |
| Admission Type | HL70007 | HL7 Version 2.5.1 | 2.16.840.1.113883.12.7 |  |
| RCMT Associated Lab Tests |  | LOINC | 2.16.840.1.114222.4.11.6053 | This value set includes only the lab test LOINCS related to reportable conditions and is available from PHIN-VADs as PHVS\_LabTestName\_ReportableConditions (see above). This value set can be further constrained or extended locally by the public health jurisdiction |
| RCMT Associated Lab Test Results |  | SNOMED CT | 2.16.840.1.114222.4.11.6054 | This value set includes only the lab result SNOMED CT concept ID codes related to reportable conditions and is available from PHIN-VADs as PHVS\_LabTestResult\_ReportableConditions (see above). This value set can be further constrained or extended locally by the public health jurisdiction |
| ELR Ordinal Value Set |  | SNOMED CT |  | This value set is constrained to SNOMED CT concepts related to reporting of qualitative laboratory test. See Section N for values.. |
| Observation Method Value Set |  | HL7 V3 Observation Method  and/or  SNOMED CT procedure hierarchy  (108252007) |  | Either HL7 V3 Observation Method and/or SNOMED CT procedure hierarchy may be used. Current effort is underway to make this value set more complete as well as to provide a cross-mapping between them[[11]](#footnote-13). Note: Code System Source (HL7 table 0396 Code) HL7 V3 Observation Method is “OBSMETHOD”. |
| Relationship | HL70063 | HL7 Version 2.5.1 | 2.16.840.1.113883.12.63 |  |
| Contact Role | HL70131 | HL7 Version 2.5.1 | 2.16.840.1.113883.12.131 |  |
| Interpretation Codes | HL70078 | HL7 Version 2.7.1 | 2.16.840.1.113883.12.78 | Previously known as Abnormal Flag. See Section N for values. |
| Source of Comment | HL70105 | HL7 Version 2.5.1 | 2.16.840.1.113883.12.105 |  |
| Value Type | HL70125 | HL7 Version 2.5.1 | 2.16.840.1.113883.12.125 | See Section N for values. |
| Ethnic Group | HL70189 | HL7 Version 2.5.1 | 2.16.840.1.113883.12.189 |  |
| Telecommunication Use Code | HL70201 | HL7 Version 2.5.1 | 2.16.840.1.113883.12.201 |  |
| Telecommunication Equipment Type | HL70202 | HL7 Version 2.5.1 | 2.16.840.1.113883.12.202 |  |
| Organization Name Type Code | HL70204 | HL7 Version 2.5.1 | 2.16.840.1.113883.12.204 |  |
| Degree/License/Certificate | HL70360 | HL7 Version 2.5.1 | 2.16.840.1.113883.12.360 |  |
| Comment Type | HL70364 | HL7 Version 2.5.1 | 2.16.840.1.113883.12.364 |  |
| Reason For Study Value Set |  | ICD- 9-CM and/or  ICD-!)-CM  And.or  CORE Problem List Subset of SNOMED CT |  | Either ICD-9CM and/or ICD-10-CM and/or CORE Problem List Subset of SNOMED CT may be used. The CORE Problem List Subset of SNOMED CT is available from Unified Medical Language System( UMLS) Terminology Service at at <https://uts.nlm.nih.gov//home.html> . |
| MIME Types | HL70834 | HL7 Version 2.7.1 | 2.16.840.1.113883.12.834 | See Section N for values. |
| PHVS\_Animal\_CDC |  | PHVS\_Animal\_CDC | 2.16.840.1.114222.4.11.1074 | Animal Type based on SNOMED CT |
| Specimen Type Value Set |  | SNOMED CT Specimen hierarchy (12303009) |  | A cross mapping from HL7 table Hl7086 to SNOMED CT is available at PHIN-VADS (see above). |
| Specimen Type Modifier | SCT | SNOMED CT | 2.16.840.1.113883.6.96 | A constrained SNOMED CT value set for this field is under development and may replace this in the future. |
| Specimen Additives Value Set |  | HL7 Version 2.5.1  And/or  SNOMED CT |  | Specimen Additives: Either HL70371 and/or SNOMED CT may be used. It should be noted that in the future a SNOMED CT subset may become the only recommended value set so trading partners should consider moving in that direction. |
| Specimen Collection Method Value Set |  | HL7 Version 2.5.1  And.or  SNOMED CT Procedure hierarchy. (128927009) |  | Either HL7 Table 0488 and/or SNOMED CT Procedure (128927009) hierarchy may be used. .A constrained SNOMED CT value set for this field is under development and may replace this in the future. |
| Specimen Source Site Value Set |  | SNOMED CT Anatomical Structure hierarchy (91723000) |  |  |
| Specimen Source Site Modifier |  | SNOMED CT Topographical modifier hierarchy (106233006) |  |  |



## Constrained HL7 Tables

Refer to the LRI guide for the HL7 tables that are constrained by it. These sections describe the additional HL7 table constraints for this guide. The tables in the sections below are as specified in the HL7 Version 2.5.1 Standard, except as noted:

* HL7 Table 0078- Interpretation Codes (Abnormal Flag) is pre-adopted from HL7 Version 2.7.1
* HL7 Table 0834-MIME Types is pre-adopted from HL7 Version 2.7.1.

**The following sections detail only the additional constraints to the LRI constrained HL7 tables. Where Segments are defined by the LRI guide specific attributes that have been further constrained are underlined**.

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

Refer to LRI section 4.7.1.

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

Refer to LRI section 4.7.2

### HL7 Table 0078 – Interpretation Codes (V2.7.1)

| Table 4‑3. HL7 Table 0078 Interpretation Codes (V2.7.1) | | |
| --- | --- | --- |
| Value | Description | Comment |
| L | Below low normal |  |
| H | Above high normal |  |
| LL | Below lower panic limits |  |
| HH | Above upper panic limits |  |
| < | Below absolute low-off instrument scale |  |
| > | Above absolute high-off instrument scale |  |
| N | Normal (applies to non-numeric results) |  |
| A | Abnormal (applies to non-numeric results) |  |
| AA | Very abnormal (applies to non-numeric units, analogous to panic limits for numeric units) |  |
| null | No range defined, or normal ranges don't apply |  |
| U | Significant change up |  |
| D | Significant change down |  |
| B | Better—use when direction not relevant |  |
| W | Worse—use when direction not relevant |  |
| S | Susceptible. Indicates for microbiology susceptibilities only. |  |
| R | Resistant. Indicates for microbiology susceptibilities only. |  |
| I | Intermediate. Indicates for microbiology susceptibilities only. |  |
| MS | Moderately susceptible. Indicates for microbiology susceptibilities only. |  |
| VS | Very susceptible. Indicates for microbiology susceptibilities only. |  |
| POS | Positive | Added in HL7 Version 2.7 |
| NEG | Negative | Added in HL7 Version 2.7 |
| IND | Indeterminate | Added in HL7 Version 2.7 |
| DET | Detected | Added in HL7 Version 2.7 |
| ND | Not Detected | Added in HL7 Version 2.7 |
| AC | Anti-complementary substances present | Added in HL7 Version 2.7 |
| TOX | Cytotoxic substance present | Added in HL7 Version 2.7 |
| QCF | Quality Control Failure | Added in HL7 Version 2.7 |
| RR | Reactive | Added in HL7 Version 2.7 |
| WR | Weakly reactive | Added in HL7 Version 2.7 |
| NR | Non-reactive | Added in HL7 Version 2.7 |

### HL7 TABLE 0123 – RESULTS STATUS (V2.5.1)

Refer to LRI section 4.7.4.

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

| Table 4‑4Table 6-n HL7 Table 0125 – Value Type (V2.5.1) | | | |
| --- | --- | --- | --- |
| Value | Description | Usage | Comment |
| CE | Coded Entry | R | The Use of CE datatypes for coded results is discouraged in preference to CWE\_CRO. |
| CWE (CWE\_CRO) | Coded with Exceptions | R | Data type to be used where it is important to communicate the coding system and coding system version with the coded result being reported. Pre-adopted from Version 2.6.  This Implementation Guide has specially constrained versions of the CWE data type in Section 2.2 through 2.4. The CWE\_CRO format shall be used for OBX-5. When sending text data in OBX-5, use either the ST, TX or FT data types. |
| CX | Extended Composite ID With Check Digit | O |  |
| DT | Date | R |  |
| ED | Encapsulated Data | R | Field using the ED data type to allow communication of images, sound clips, XML documents, html markup, etc. |
| FT | Formatted Text (Display) | R | Field using the FT data type to carry a text result value. This is intended for display. The text may contain formatting escape sequences as described in the data types section. Numeric results and numeric results with units of measure should not be reported as text. These should be reported as NM or SN numeric results, with the units of measure in OBX-6. |
| NM | Numeric | R | Field using the NM data type to carry a numeric result value. The only non-numeric characters allowed in this field are a leading plus (+) or minus (-) sign. The structured numeric (SN) data type should be used for conveying inequalities, ranges, ratios, etc. The units for the numeric value SHALL be reported in OBX-6. |
| RP | Reference Pointer | R | Field using the RP data type to allow communication of pointers to images, sound clips, XML documents, html markup, etc. The RP data type is used when the object being pointed to is too large to transmit directly.  This specification defines the mechanism for exchanging pointers to objects, but it does not address the details of applications actually accessing and retrieving the objects over a network.  The most common scheme for passing a pointer is to use a Universal Resource Identifier (URI). See <http://ietf.org/rfc/rfc2396.txt> for detailed definition. The general format of a URI is in the form: <scheme>://<authority><path>?<query>. The scheme and authority portions appear in the Application ID component, Universal ID subcomponent. The path and query portion of the URI appear in the Pointer component of the RP data type. |
| SN | Structured Numeric | R | Field using the SN data type to carry a structured numeric result value. Structured numeric include numerals (^10), intervals (^0^-^1), ratios (^1^/^2 or ^1^:^2), inequalities (<^10), or categorical results (^2^+). The units for the structured numeric value SHALL be reported in OBX-6. |
| ST | String Data | R | Field using the ST data type to carry a short text result value. Numeric results and numeric results with units of measure SHALL not be reported as text. These SHALL be reported as NM or SN numeric results, with the units of measure in OBX-6. |
| TM | Time | R |  |
| TS | Time Stamp (Date & Time) | R |  |
| TX | Text Data (Display) | R | Field using the TX data type to carry a text result value this is intended for display. Numeric results and numeric results with units of measure should not be reported as text. These should be reported as NM or SN numeric results, with the units of measure in OBX-6. |

### HL7 TABLE 0203 – IDENTIFIER TYPE (V2.7.1)

Refer to LRI section 4.7.6.

### HL7 TABLE 0291 – SUBTYPE OF REFERENCED DATA (V2.7.1)

Refer to LRI section 4.7.7.

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

Refer to LRI section 4.7.9:

### HL7 TABLE 0353 – CWE STATUS CODES

Refer to LRI section 4.7.9.

### HL7 TABLE 0354 – MESSAGE STRUCTURE (V2.5.1

Refer to LRI section 4.7.10.

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

Refer to LRI section 4.7.11.

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

| Table 4‑5. HL7 Table 0834 – MIME Type (V2.7.1) | | | |
| --- | --- | --- | --- |
| Value | Description | Usage | Comments |
| Audio | Audio data | R |  |
| Video | Video data | R |  |

**The following sections describe additional constrained tables for ELR.**

### HL7 Table 0155 – Accept/Application Acknowledgment Conditions (V2.5.1)

| Table 4‑6. HL7 Table 0155 – Accept/Application Acknowledgment Conditions (V2.5.1) | | | |
| --- | --- | --- | --- |
| Value | Description | Usage | Comment |
| AL | Always | O |  |
| NE | Never | R |  |
| ER | Error/reject conditions only | O |  |
| SU | Successful completion only | O |  |

### ELR Ordinal Results Value Set

|  |  |  |  |
| --- | --- | --- | --- |
| Table 4‑7. Ordinal Results Value Set | | | |
| Value | Description | Usage | Comment |
| 260347006 | + |  |  |
| 260348001 | ++ |  |  |
| 260349009 | +++ |  |  |
| 260350009 | ++++ |  |  |
| 260373001 | Detected |  |  |
| 263776006 | Heavy growth |  |  |
| 7882003 | Identified |  |  |
| 46651001 | Isolated |  |  |
| 263812008 | Moderate growth |  |  |
| 10828004 | Positive |  |  |
| 260411009 | Presence findings |  |  |
| 52101004 | Present |  |  |
| 89292003 | Rare |  |  |
| 11214006 | Reactive |  |  |
| 260405006 | Trace |  |  |
| 260408008 | Weakly positive |  |  |
| 373066001 | Yes |  |  |
| 272519000 | Absence findings |  |  |
| 2667000 | Absent |  |  |
| 281297005 | Analyte not detected |  |  |
| 260385009 | Negative |  |  |
| 373067005 | No |  |  |
| 264868006 | No growth |  |  |
| 27863008 | No organisms seen |  |  |
| 131194007 | Non-Reactive |  |  |
| 17621005 | Normal |  |  |
| 23506009 | Normal flora |  |  |
| 280413001 | Normal result |  |  |
| 260415000 | Not detected |  |  |
| 264887000 | Not isolated |  |  |
| 47492008 | Not seen |  |  |
| 42425007 | Equivocal |  |  |
| 280414007 | Equivocal result |  |  |
| 419984006 | Inconclusive |  |  |
| 82334004 | Indeterminate |  |  |
| 280416009 | Indeterminate result |  |  |

# Laboratory Result Message Development Resources

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

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

To support the Laboratory Messaging community, a repository has been established to function as a dynamic library of V2.x 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 [<<Future Nist LINK>>](http://hl7v2labtesting.nist.gov:8081/)

# Additional Implementation Guidance – Reflex And Culture/Susceptibility Testing

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

See LRI section 6.1. Please note that for the ELR guide ONLY the GU and RU examples are applicable.

## Culture and Susceptibilities Reporting

See LRI section 6.2. Please note that for the ELR guide ONLY the RU-GU examples are applicable (section 6.2.5.1).

## Confirmatory and Reflex Testing

See LRI errata section 6.3

## Add-On Testing

See LRI errata section 6.4

## Epidemiological important information from ask at Order Entry responses

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

For this profile, appropriate AOE answers should be sent along to the local public health jurisdiction as an observation in an OBX segment under the respectiveOrder\_ Observation group (ORC/OBR segment pair). They should not be under the Specimen Group (SPM). In addition, OBX-11 (Observation Result Status) should be valued ‘A’ to mark this as an AOE answer rather than an actual result. A table of LOINC encoded AOE examples are provided in Appendix B in the HL7 Version 2.5.1 Implementation Guide: Laboratory Test Compendium Framework, Release 2, US Realm, May 2013 (eDOS) as guidance and focus on commonly used Ask at Order Entry questions including those of interest to public health.

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

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

MSH...

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

OBX|2|CWE|11449-6^Pregnancy status^LN...||7738600^Patient currently pregnant^SCT…|A|...

…

## Reference test results

There may be occasions when the sending laboratory (Filler) needs to transmit and ELR message for reportable results that did not originate from their facility. Examples include when the specimen is forwarded by the Filler to a reference lab or to another lab as a “pass-through” test. The criterion for reporting results that did not originate with the sender is beyond the scope of this IG, and needs to be negotiated between the Sender and their local public health jurisdiction.

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

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

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

MSH…

…

OBR|1…

OBX|1|CWE|625-4^Bacteria identified in Stool by Culture^LN…|| 27268008^Salmonella^SCT...|…|Filler Lab Name^…|123 Filler Lab Street^…|Director^Filler^L^^Dr.…

OBX|2|CWE|20951-0^Salmonella sp serotype [Identifier] in Isolate by Agglutination…||50136005^Salmonella Typhimurium^SCT...|…|State Lab Name^…|123 State Lab Street^…|Director^State^L^^Dr.….

...

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

415564008^Specimen sent to reference laboratory for testing (situation)

## When no standard coding exists for CWE datatypes

### CWE\_CRE

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

Example for SPM.4 (Specimen type):

SPM|1|…||NW^Nasal Wash^L…|**…**

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

Example for SPM.4 (Specimen type):

SPM|1|…||^^^^^^^^Nasal Wash|**…**

### CWE\_CR for coded results in OBR.4

**For coded results in OBR.4 :** If you have a local order code but no valid LOINC exists then the first triplet must be populated with the local code.

Example for OBR.4 (Observation Identifier):

OBR|1|…|…|1234^Syphilis Panel^L…|||…

### CWE\_CR for coded results in OBX.3

For coded results in OBX.3 : If you have a local order code but no valid LOINC exist then **the CWE Status value NAV(Not available ) must populate the first triplet** **and** the local code must **populate the second triplet**.

Example for OBX.3 (Observation Identifier): OBX|1|…|NAV^NotAvailable^HL70353^123^Reportable test^L…|||…

### CWE\_RO For coded results in OBX.5:

For OBX.5 CWE data type, the first triplet and original text field (CWE.1,CWE.3 and CWE.9 =R) must be populated. When a standard SNOMED CT concept ID is not available, the local code must populate the first triplet, the original text field must also be populated.

Example for OBX.5 (Observation Value):

OBX|1|CWE|20951-0^Salmonella sp serotype [Identifier] in Isolate by Agglutination^LN…||167^Salmonella subspecies I:Rough:i:1,2^L^^^^1.2^^Salmonella subspecies I:Rough:i:1,2||…

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

Example for OBX.5 (Observation Value):

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

## Specimen type when testing isolates/reference cultures

Based on feedback from multiple jurisdictions, sending information about the original clinical specimen type/source (e.g. Stool) in SPM.4 is preferred over reporting a derivative of the specimen (e.g. an isolate , DNA, or RNA).

## Snapshot processing: example of partial, Final and corrected messages

Refer to Section 1.9.3 of LRI guide for a discussion of snapshot processing.

**The following Testing scenario gives context for the example Partial and Final and Corrected ELR message below (**The ellipses represent uncompleted details)**:**

Partial Message: *A Clinician orders a complete blood count with manual differential. The specimen is collected and the laboratory completes and releases the automated blood count as a partial report prior to completion of the manual differential. Only the count is reported as final results.*

MSH…

…

OBR|1|...| 57782-5^CBC with Ordered Manual Differential panel in Blood^LN...|||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, both the differential and the blood count are sent as ”F” final results*

MSH…

…

OBR|1|...| 57782-5^CBC with Ordered Manual Differential panel in Blood^LN...|||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**:** *Later an error is detected for poikilocytes results and the results for the entire order are resent 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...|||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|...

…

# Additional Implementation Guidance - Other

## Clinical Laboratory Improvement Amendments Considerations

See LRI section 7.1

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

See LRI section 7.2

## How to Further constrain this Constrainable profile

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

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

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

R 🡪 R

RE🡪 R, RE

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

O 🡪 R, RE, C(a/b), X

X🡪X

* Cardinality: Usage Rules above outlines the cardinalities allowed for various usage constraints. Refer to the cardinality table from the V2.7.1 Section 2.B.7.4 base standard. Additionally, for the purposes of creating an implementable profile from this guide, consider the cardinalities as the minimum allowed. If the receiver is expecting fewer repetitions of an element that the bound set by the implementable profile, the burden is on the receiver to determine which repetitions it is interested in receiving.
* Length: For the purposes of creating an implementable profile from this guide, the upper limit of allowed length published above will be considered the conformance length. Truncation characters ( #,=) can be assigned a to all lengths not already defined.
* Data types: the data types cannot be changed, except IS can be extended to CWE (example is OBX-8) and ID can be extended to CNE.

Vocabulary: The vocabulary can be further constrained and still maintain broad interoperability. If on the other hand, a jurisdiction need to locally extend the vocabulary to meet their requirements, the local vocabulary may not be compatible with neighboring jurisdictions and the sender should be made aware of this.

Appendix A: Guidance for migration from ELR 251 R1 to ELR 251 R2

The following section summarizes the differences between Release 2 and Release 1 of the ELR 251 IGs. Although every attempt was made to be backwards compatible with the earlier release it was not always possible. The major reasons for this was the intent to conform to the LRI profile component as well as technical corrections to ELR 251 R1. The summary consists of table for the various data types, message segments and fields where differences occur. Table N-N describes the column headings used in the tables in the following .

|  |  |
| --- | --- |
| **Column Heading** | **Description** |
| Element | The specific Data Type, Data Type component, Message Group, Messgae Segment, or Field, Field component or Field subcomponent. |
| Attribute | The specific attribute that has changed from ELR251 R1 to ERL251 R2. This includes Usage, Cardinality, Value set, Data type, Condition Predicate, and Conformance Statement. Note that Cardinality is only discussed here if not a result of a usage change. The reader will need to consult the guide for cardinality where the usage has changed. |
| R2 Message Element Attribute Value | The various attributes used by the ELR251 R2 guide to document data type attribute tables, message structure attribute tables and segment attribute tables. Not all attributes apply to all attribute tables. |
| R1 Message Element Attribute Value | The various attributes used by the ELR251 R1 guide to document data type attribute tables, message structure attribute tables and segment attribute tables. Not all attributes apply to all attribute tables. |
| Backward Compatible? | Yes or No answer to whether the change is backwards compatible. Backwards Compatibility means a R1 message can be received by a R2 Receiver without the potential of causing the receiving application to raise an exception as described in HL7 V2.7.1 Conformance (Chapter 2B, 2.B.7.5). Note that an ELR Receiver may or may not raise exceptions depending on its individual business rules. Note also that this is not an assertion of conformance to either guide. |
| Comments | Further description of the change as well as justification. Comments that repeat over several rows are listed as footnotes at the end of each table |

Data Types differences between Release 2 and Release 1 of the ELR 251 IGs

A major change between R1 and R2 involves the adoption of the various “flavors” of CWE Coded with Exceptions and TS Timestamp data types. There are flavors of other data types involve “globally unique” and “non-globally unique” identifiers, however, for both releases of ELR only the “globally unique” identifiers are supported so the change is in name only. The TS flavors replace individual conformance statements regarding the timestamp format with a TS data type preformatted to the proper precision and timezone offset optionality. The reader is directed to the LRI guide sections where these are described. The timestamp data type flavors are covered below in Section A.3.

There are three flavors for CWE Coded with Exception; CWE\_CR - Coded with Exception Code Required, CWE\_RE - - Coded with Exception Code Required but can be empty and CWE-CRO - Coded with Exception Code and Original Text Required. Additional constraints are placed upon the various CWE data type flavors in order to meet the LRI conformance requirement to populate the first triplet prior to populating second. Therefore a conformant R1 message populated with a CWE datatype like “ ^^^1123-5^blah^LN” is no longer conformant in R2. The reader is directed to the LRI guide sections where these data type flavors are described. The table below summarized these and other data type differences.

| Table 7‑1: Data Types differences between R1 and R2 | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Element** | **Attribute** | **R2 Message Element Attribute Value** | **R1 Message Element Attribute Value** | **Backward Compatible?** | **Comments** |
| CE.1 : Identifier | Usage | R | - | ? | Comment 1 |
| CE.2 : Text | Usage | RE | - | ? | Comment 1 |
| CE.3 : Name of Coding System | Usage | R | - | ? | Comment 1 |
| CE.4 : Alternate Identifier | Usage | RE | - | ? | Comment 1 |
| CE.5 : Alternate Text | Usage | RE | - | ? | Comment 1 |
| CWE\_CR.1 : Identifier | Usage | R | RE | NO | Comment 2/ Comment 6 |
| CWE\_CR.2 : Text | Usage | RE | C(RE/X) | YES | Comment 2/ Comment 6 |
| CWE\_CR.3 : Name of Coding System | Usage | R | C(R/X) | YES | Comment 2/ Comment 6 |
| CWE\_CR.5 : Alternate Text | Usage | RE | C(RE/X) | YES | Comment 2/ Comment 6 |
| CWE\_CR.9 : Original Text | Usage | RE | C(R/X) | YES | Comment 2/ Comment 6 |
| CWE\_CR.15 : Value Set OID | Usage | O | X | YES | Comment 2/ Comment 6 |
| CWE\_CR.16 : Value Set Version ID | Usage | O | X | YES | Comment 2/ Comment 6 |
| CWE\_CR.17 : Alternate Coding System OID | Usage | O | X | YES | Comment 2/ Comment 6 |
| CWE\_CR.18 : Alternate Value Set OID | Usage | O | X | YES | Comment 2/ Comment 6 |
| CWE\_CR.19 : Alternate Value Set Version ID | Usage | O | X | YES | Comment 2/ Comment 6 |
| CWE\_CR.20 : Second Alternate Coding System OID | Usage | O | X | YES | Comment 2/ Comment 6 |
| CWE\_CR.21 : Second Alternate Value Set OID | Usage | O | X | YES | Comment 2/ Comment 6 |
| CWE\_CRE.4 : Alternate Identifier | Usage | C(RE/X) | RE | NO | Comment 3/ Comment 6. |
| CWE\_CRE.15 : Value Set OID | Usage | O | X | YES | Comment 3/ Comment 6 |
| CWE\_CRE.16 : Value Set Version ID | Usage | O | X | YES | Comment 3/ Comment 6 |
| CWE\_CRE.17 : Alternate Coding System OID | Usage | O | X | YES | Comment 3/ Comment 6 |
| CWE\_CRE.18 : Alternate Value Set OID | Usage | O | X | YES | Comment 3/ Comment 6 |
| CWE\_CRE.19 : Alternate Value Set Version ID | Usage | O | X | YES | Comment 3/ Comment 6 |
| CWE\_CRE.20 : Second Alternate Coding System OID | Usage | O | X | YES | Comment 3/ Comment 6 |
| CWE\_CRE.21 : Second Alternate Value Set OID | Usage | O | X | YES | Comment 3/ Comment 6 |
| CWE\_CRE.22 : Second Alternate Value Set Version ID | Usage | O | X | YES | Comment 3/ Comment 6 |
| CWE\_CRO.9 : Original Text | Usage | R | RE | NO | Comment 4/Comment 6 |
| CWE\_CRO.15 : Value Set OID | Usage | O | X | YES | Comment 4/ Comment 6 |
| CWE\_CRO.16 : Value Set Version ID | Usage | O | X | YES | Comment 4/ Comment 6 |
| CWE\_CRO.17 : Alternate Coding System OID | Usage | O | X | YES | Comment 4/ Comment 6 |
| CWE\_CRO.18 : Alternate Value Set OID | Usage | O | X | YES | Comment 4/ Comment 6 |
| CWE\_CRO.19 : Alternate Value Set Version ID | Usage | O | X | YES | Comment 4/ Comment 6 |
| CWE\_CRO.20 : Second Alternate Coding System OID | Usage | O | X | YES | Comment 4/ Comment 6 |
| CWE\_CRO.21 : Second Alternate Value Set OID | Usage | O | X | YES | Comment 4/ Comment 6 |
| CWE\_CRO.22 : Second Alternate Value Set Version ID | Usage | O | X | YES | Comment 4/ Comment 6 |
| EIP\_GU.1 : Placer Assigned Identifier | Usage | RE | O | YES | Comment 6/ Used in SPM.2 Specimen ID and OBR.29 Parent for Parent Child messaging |
| EIP\_GU.2 : Filler Assigned Identifier | Usage | C(R/RE) | R | YES | Comment 6/ Used in SPM.2 Specimen Id and OBR.29 Parent for Parent Child messaging |
| XAD.4 : State or Province | Value Set | FIPS5\_2 | State Value Set | YES | Name change, Content is same |
| XAD.5 : Zip or Postal Code | Value Set | USPS | Postal Code Value Set | YES | Name change, Content is same |
| XAD.6 : Country | Value Set | 399 | Country Value Set | YES | Name change, Content is same |
| XAD.9 : County/Parish Code | Value Set | FIPS6\_4 | PHVS\_County\_FIPS\_6-4 | YES | Name change, Content is same |
| XCN\_GU.12 : Check Digit Scheme | Usage | C(O/X) | O | YES | Comment 5 |
| XCN\_GU.7 : Degree (e.g., MD) | Usage | X | O | NO | Comment 7/Deprecated as of v 2.5 |
| XON\_GU.1 : Organization Name | Usage | RE | C(R/RE) | YES | Comment 6/ the condition predicate is moved from XCN.10 to XCN.1 for R2, but the conformance is the same. |
| XON\_GU.10 : Organization Identifier | Usage | C(R/RE) | RE | YES | Comment 6/ the condition predicate is moved from XCN.10 to XCN.1 for R2, but the conformance is the same. |
| XON\_GU.5 : Check Digit Scheme | Usage | C(O/X) | O | YES | Comment 5 |
| XPN\_GU.5 : Prefix (e.g., DR) | Usage | O | RE | YES | Comment 6 |
| XPN\_GU.6 : Degree (e.g., MD) | Usage | X | O | NO | Comment 7/Deprecated as of v 2.5 |
| XTN.11 : Speed Dial Code | Usage | O | X | YES | Comment 6 |

* **Comment 1**: Never defined for ELR Receiver Profile in R1
* **Comment 2**: CWE\_CR corresponds to NON OBX.5\_CWE in R1 and is used for OBR.4 : Universal Service Identifier and OBX.3 : Observation Identifier.
* **Comment 3**: CWE\_CRE corresponds to NON OBX.5\_CWE in R1 and is used for all CWE element except OBR.4, OBX.3, and OBX.5. This includes the following following fields:
  + ELRR2\_Location
  + PID.10 : Race
  + PID.22 : Ethnic Group
  + PID.35 : Species Code
  + NTE.4 : Comment Type
  + NK1.3 : Relationship
  + OBR.13 : Relevant Clinical Information
  + OBR.31 : Reason for Study
  + OBR.49 : Result Handling
  + OBX.6 : Units
  + OBX.8 : Interpretation Codes
  + OBX.17 : Observation Method
  + SPM.4 : Specimen Type
  + SPM.5 : Specimen Type Modifier
  + SPM.6 : Specimen Additives
  + SPM.7 : Specimen Collection Method
  + SPM.8 : Specimen Source Site
  + SPM.9 : Specimen Source Site Modifier
  + SPM.11 : Specimen Role
  + SPM.21 : Specimen Reject Reason
  + SPM.24 : Specimen Condition
* **Comment 4**: CWE\_CRO Corresponds to OBX.5\_CWE in R1 and is used for OBX.5 : Observation Value.
* **Comment 5**: This is relevant only if the profile is constrained further
* **Comment 6**: Changed to Conform to the LRI guide
* **Comment 7**: Changed as a technical correction to ELR 251 R1

Message Structure differences between RElease 1 and RElease 2 of the ELR IG.

| Table 7‑2: Message Structure differences between R1 and R2 | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Element** | **Attribute** | **R2 Message Element Attribute Value** | **R1 Message Element Attribute Value** | **Backward Compatible?** | **Comments** |
| ORC: Common Order Segment | Usage | R | CE | NO | Comment 8 / Untestable condtion predicate in R1. |
| TIMING\_QTY Group | Usage | RE | O | YES | Comment 8 |
| TQ1: Timing/Quantity Segment | Usage | R | O | NO | Errata in R1 conforms to base standard. |
| OBSERVATION Group | Usage | C(R/X) | C(R/RE) | NO | Comment 8/ R1 Conditional based on IG comments for this group. |
| Specimen Group | Usage | RE | CE | ? | Untestable condtion predicate in R1. |
| Specimen Group | Conformance Statement | ELR-006: Specimen (Specimen Group) SHALL be present in at least one occurrence of one Order\_Observation Group. | none | No | Replaces untestable Condition predicate from R1. |
| Specimen Group | Carodinality | [0..\*] | [1..1] | YES | R1 Specimen Group Cardinality based upon IG comments. |
| ERR: Error Segment | Usage | C(R/O) | C(R/X) | NO | Comment 8/ R1 Conditional based on IG comments attribute for this group. |

* **Comment 8**: Changed to Conform to the LRI guide

Segment differences between Release 1 and Release 2 of the ELR IG.

| Table 7‑3: Segment differences between R1 and R2 | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Element** | **Attribute** | **R2 Message Element Attribute Value** | **R1 Message Element Attribute Value** | **Backward Compatible?** | **Comments** |
| MSH.2 : Encoding Characters | Conformance Statement | ELR-NNN : MSH.2 (Encoding Characters) SHALL contain the constant value '^~\&' or the constant value '^~\&#'. | ELR-013:MSH.2 (Encoding Characters) SHALL contain the constant value '^~\&#'. | YES | technical correction |
| MSH.7 : Date/Time Of Message | Data type | TS\_1 | YYYYMMDDHHMMSS[.S[S[S[S]]]]+/-ZZZZ | YES | Precision same |
| MSH.15 : Accept Acknowledgment Type | Usage | R | C(R/RE) | NO | Comment 9 |
| MSH.15 : Accept Acknowledgment Type | Conformance Statement | ELR-nnn: MSH-15 (Accept Acknowledgment Type) SHALL contain the constant value ‘NE’ IF an occurrence of MSH-21.3 (Entity Identifier) is valued 2.16.840.1.113883.9.NNN (PHLabReport-NoAck), ELSE SHALL contain the constant value 'AL'.PHReturnAck Component: | ELR-019:MSH.15 (Accept Acknowledgment Type) SHALL contain the constant value 'AL' IF any occurrence of MSH.21.1 (Entity Identifier) is 'PHLabReport-Ack' , ELSE, if valued, SHALL contain the constant value 'NE'. | NO | Comment 9/Using OIDs instead of static and dynamic definitions in R1. Net result is same. AL or NE |
| MSH.16 : Application Acknowledgment Type | Usage | R | C(R/RE) | NO | Comment 9 |
| MSH.16 : Application Acknowledgment Type | Conformance Statement | ELR-nnn: MSH-16 (Application Acknowledgement Type) SHALL contain the constant value ‘NE’ IF an occurrence of MSH-21.3 (Entity Identifier) is valued 2.16.840.1.113883.9.NNN (PHLabReport-NoAck), ELSE, if valued, SHALL contain the value '‘AL’, 'NE', 'ER', or ‘SU’ | ELR-020:MSH.16 (Application Acknowledgement Type) SHALL contain the constant value 'AL', 'NE', 'ER', or 'SU' ,'SU',IF any occurrence of MSH.21.1 (Entity Identifier) is 'PHLabReport-Ack', ELSE, if valued, SHALL contain the constant value 'NE' . | NO | Comment 9/Using OIDs instead of static and dynamic definitions in R1. Net result is same. |
| SFT.6 : Software Install Date | Data type | TS\_0 | YYYY[MM[DD[HH[MM[SS[.S[S[S[S]]]]]]]]][+/-ZZZZ] | Yes | Precision same |
| PID.7 : Date/Time of Birth | Data type | TS\_2 | YYYY[MM[DD[HH[MM[SS[.S[S[S[S]]]]]]]]][+/-ZZZZ] | Yes | Precision same |
| PID.7 : Date/Time of Birth | Conformance Statement | ELR-027: If PID-7 (Date/Time of Birth) is not valued, then an OBX segment associated with the SPM segment SHALL be present to report "Patient age at specimen collection" (LOINC in OBX-3.1 = 35659-2 . |  | NO | No - Addition of Conformance Statement based on comments in R1 and R2 |
| PID.8 : Administrative Sex | Usage | R | RE | NO | Comment 9 -( the value set contains U, Unknown) |
| PID.29 : Patient Death Date and Time | Data type | TS\_2 | YYYY[MM[DD[HH[MM[SS[.S[S[S[S]]]]]]]]][+/-ZZZZ] | YES | Precision same |
| PID.33 : Last Update Date/Time | Data type | TS\_5 | YYYY[MM[DD[HH[MM[SS[.S[S[S[S]]]]]]]]][+/-ZZZZ] | NO | Comment 14 |
| PID.31 : Identity Unknown Indicator | Usage | X | O | ? | Comment 9 |
| PID.35 : Species Code | Usage | C(R/RE) | RE | YES | Technical Correction to align with base standard |
| PID.36 : Breed Code | Usage | C(R/O) | O | YES | Technical Correction to align with base standard |
| NK1.7 : Contact Role | Usage | RE | O | RE | This field is being supported by the S & I Orders IG |
| NK1.31 : Contact Person's Telephone Number | Usage | C(RE/X) | RE | NO | Comment 13 |
| NK1.32 : Contact Person's Address | Usage | C(RE/X) | RE | NO | Comment 13 |
| PV1.44 : Admit Date/Time | Data type | TS\_5 | YYYY[MM[DD[HH[MM[SS[.S[S[S[S]]]]]]]]][+/-ZZZZ] | NO | Comment 14 |
| PV1.45 : Discharge Date/Time | Data type | TS\_5 | YYYY[MM[DD[HH[MM[SS[.S[S[S[S]]]]]]]]][+/-ZZZZ] | NO | Comment 14 |
| ORC.2 : Placer Order Number | Usage | RE | C(R/X) | YES | Comment 9/ Comment 10 |
| ORC.2 : Placer Order Number | C(R/X) | LRI-31 : The value of ORC.2 (Placer Order Number) SHALL NOT be valued identical to another instance of ORC.2 (Placer Order Number) in the message. |  | NO | Comment 9 |
| ORC.3 : Filler Order Number | R | LRI-32 : The value of ORC.3 (Filler Order Number) SHALL NOT be valued identical to another instance of ORC.3 (Filler Order Number) in the message. |  | NO | Comment 9 |
| ORC.12 : Ordering Provider | Usage | R | C(R/X) | NO | Comment 9/ Comment 10 |
| ORC.14 : Call Back Phone Number | Usage | RE | C(R/X) | YES | Comment 9/ Comment 10 |
| ORC.20 : Advanced Beneficiary Notice Code | Usage | O | X | YES | Comment 9 |
| OBR.4 : Universal Service Identifier | Value Set | LOINC(See Description and Comments for further guidance) | Laboratory Order Value Set | YES | Expansion to LOINC and CWE statuses with guidance to use RCMT for reportable laboratory results when available |
| OBR.7 : Observation Date/Time | Data type | TS\_4 | YYYYMMDD[HH[MM[SS[.S[S[S[S]]]]]]][+/-ZZZZ] OR contain the value "0000” when the collection date/time is unknown. | YES | Precision same |
| OBR.8 : Observation End Date/Time | Data type | TS\_5 | YYYYMMDD[HH[MM[SS[.S[S[S[S]]]]]]][+/-ZZZZ] OR contain the value "0000” when the collection date/time is unknown. | NO | Comment 9/Precision same but no condition predicate if collection end date unknown – technical correction |
| OBR.8 : Observation End Date/Time | C(R/X) | ELR-NN : If present, OBR-8 (Observation End Date/Time) SHALL be equal or later than OBR-7 (Observation Date/Time). |  | YES | Comment 9/ Note the date format is part of datatype definition and this is a clarifying CS |
| OBR.11 : Specimen Action Code | Usage | RE | O | YES | Comment 9/Comment11 |
| OBR.13 : Relevant Clinical Information | Cardinality | [0,\*] | [0,1] | YES | Comment 9 |
| OBR.13 : Relevant Clinical Information | Data type | CWE\_CRE | ST | NO | Comment 9/ Structure of field will need to change. |
| OBR.16 : Ordering Provider | Usage | R | RE | NO | Comment 9 |
| OBR.22 : Results Rpt/Status Chng - Date/Time | Data type | TS\_6 | YYYYMMDDHHMM[SS[.S[S[S[S]]]]]+/-ZZZZ | Yes | Precision same but Time Zone offset no longer required. |
| OBR.26 : Parent Result | Usage | C(R/RE) | CE | YES | This a technical change since the original Condition predicate is not testable from message. |
| OBR.28 : Result Copies To | Usage | C(R/X) | O | NO | Comment 9/ Comment 11 |
| OBR.29 : Parent | Usage | C(R/RE) | CE | YES | This a technical change since the original Condition predicate is not testable from message. |
| OBR.30 : Transportation Mode | Usage | O | X | YES | Comment 9 |
| OBR.37 : Number of Sample Containers \* | Usage | O | X | YES | Comment 9 |
| OBR.40 : Transport Arrangement Responsibility | Usage | O | X | YES | Comment 9 |
| OBR.41 : Transport Arranged | Usage | O | X | YES | Comment 9 |
| OBR.42 : Escort Required | Usage | O | X | YES | Comment 9 |
| OBR.43 : Planned Patient Transport Comment | Usage | O | X | YES | Comment 9 |
| OBR.49 : Result Handling | Usage | RE | O | YES | Comment 9/Comment11 |
| OBX.3 : Observation Identifier | Value Set | LOINC OR “NAV” (See Description and Comments for further guidance.) | Laboratory Observation Identifier Value Set | YES | Yes - Expansion to LOINC and CWE statuses with guidance to use RCMT for reportable laboratory results when available |
| OBX.5 : Observation Value | Conformance Statement | **ELR-ONN**: 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 constrained HL7 Table 0125 found in this guide. |  | Yes | Designed to bind OBX.2 and OBX.5 |
| OBX.6 : Units | Condition Predicate | If OBX-2 (Value Type) is valued "NM" or "SN" and OBX-11 is not valued "X" or "N" | If OBX.2 (Value Type) is valued 'NM' , 'SN' AND OBX.11 is not valued 'X'. |  | No – Errata correction |
| OBX.14 : Date/Time of the Observation | Data type | TS\_4 | YYYYMMDD[HH[MM[SS[.S[S[S[S]]]]]]][+/-ZZZZ]  OR contain the value "0000"" when the collection date/time is unknown. | YES | Precision same |
| OBX.17 : Observation Method | RE | HL7 V3 Observation Method and SNOMED procedure hierarchy codes | HL7 V3 Observation Method | YES | Expand to allow SNOMED |
| OBX.19 : Date/Time of the Analysis | Data type | TS\_5 | YYYY[MM[DD[HH[MM[SS[.S[S[S[S]]]]]]]]][+/-ZZZZ] | NO | Comment 9/ Comment 14 |
| TQ1.1 : Set ID - TQ1 | Usage | R | O | NO | Comment 9/ Comment 12 |
| TQ1.7 : Start date/time | Usage | RE | O | YES | Comment 9/ Comment 12 |
| TQ1.8 : End date/time | Usage | RE | O | YES | Comment 9/ Comment 12 |
| OBX.6 : Units | Usage | C(R/RE) | C(R/X) | YES | Comment 9/ Comment 12 |
| OBX.14 : Date/Time of the Observation | Usage | RE | CE | YES? | Comment 10/ The original Condition predicate is not testable from the message |
| SPM.4 : Specimen Type | Value Set | SNOMED CT specimen hierarchy | Specimen Type Value Set (VS\_SNOMED\_HL70487) | NO | Constrain to SNOMED CT only. Give reference to HL7-> SCT mapping |
| SPM.5: Specimen Type Modifier | Usage | C(RE/X) | RE | NO | Comment 13 |
| SPM.5: Specimen Type Modifier | Value Set | SNOMED CT | PHVS\_ModifierOrQualifier\_CDC | YES | Expand to allow other subtrees in SNOMED CT |
| SPM.6:Specimen Additives | Value Set | HL70371 and/or SNOMED CT | HL70371 | YES | Expand to allow SNOMED CT |
| SPM.7: Specimen Collection Method | Value Set | Table 0488 and/or SNOMED CT Specimen Collection hierarchy. | Specimen Collection Method Value Set | YES | Name change, content is same |
| SPM.8: Specimen Source Site | Value Set | SNOMED CT Anatomical Structure hierarchy. | Body Site Value Set | YES | Name change, content is same |
| SPM.9 : Specimen Source Site Modifier | Usage | C(RE/X) | RE | NO | Comment 13 |
| SPM.9 : Specimen Source Site Modifier | Value Set | SNOMED CT Topographical modifier hierarchy | PHVS\_ModifierOrQualifier\_CDC | NO | Constrain to appropriate values |
| SPM.11 : Specimen Role | Usage | O | RE | YES | Role is always P for ELR Use case |
| SPM.17 : Specimen Collection Date/Time | Conformance Statement | ELR-NNN: The earliest SPM-17.1 (Range Start Date/Time) value SHALL be equal to or before OBR-7 (Observation Date/Time) value within the same Order\_Observation Group.  ELR-NNN: If present, the latest SPM-17.2 (Range End Date/Time) value SHALL be equal to | ELR-057:SPM.17.1 (Range Start Date/Time) SHALL be identical to OBR.7 (Observation Date/Time) value within the same Order\_Obsvervation Group. | YES | Yes reflects change in cardinality for specimen group/order. |
| SPM.17.2: Specimen Collection Date/Time Range Start Date/Time | Data type | TS\_4 | YYYYMMDD[HH[MM[SS[.S[S[S[S]]]]]]][+/-ZZZZ]  OR contain the value "0000"" when the collection date/time is unknown. | Yes | Precision same |
| SPM.17.2: Specimen Collection Date/Time Range End Date/Time | Data type | TS\_5 | YYYYMMDD[HH[MM[SS[.S[S[S[S]]]]]]][+/-ZZZZ]  OR contain the value "0000". | NO | Comment 9/Precision same but no condition predicate if collection end date unknown – technical correction |
| SPM-18: Specimen Received Date/Time | Data type | TS\_5 | YYYYMMDD[HH[MM[SS[.S[S[S[S]]]]]]][+/-ZZZZ]. | YES | Precision same |
| SPM.24 : Specimen Condition | Usage | RE | O | YES | Comment 9/ Comment11 |

* **Comment 9**: Changed to Conform to the LRI guide
* **Comment 10**: The conditionals have been replaced with conformances statements for clarity.
* **Comment 11**: New field from LRI
* **Comment 12:**  Technical Correction to R1
* **Comment 13:** Technical Correction to clarify intent of field
* **Comment 14**: To be meaningful, precision required to day in R2

1. http://www.hl7.org/implement/standards/product\_brief.cfm?product\_id=279 [↑](#footnote-ref-1)
2. R1 Errata Document is available as part of the ELR251 R1 download from Hl7 [↑](#footnote-ref-2)
3. http://www.cdc.gov/ehrmeaningfuluse/Docs/1ELR251\_Clarification\_EHR\_Tech\_Cert\_v1\_1-20121016.pdf. [↑](#footnote-ref-3)
4. There are several documents that are part of a product group to support multiple of Implementation Guides in support of the Office of the National Coordinator (ONC) under the Standards and Interoperability Framework Initiative (S&I Framework) to have consistent processes and documentation format criteria. Those documents include but are not limited to:

   * + The Laboratory Results Interface (LRI) Implementation Guide (IG)
     + This guide the Laboratory Orders Interface (LOI IG)
     + The electronic delivery of the Directory of Services (eDOS)**Error! Bookmark not defined.Error! Bookmark not defined.**
     + The profiles that make up modifications of both the LRI and LOI IG to support the Electronic Laboratory Reporting (ELR) or the addendum to those guides.

   [↑](#footnote-ref-4)
5. Conditional on certain reportable conditions and also dependent upon individual state laws/regulations. [↑](#footnote-ref-5)
6. Summary of the CWE types ( Coded with Exception types) in this Guide:

   | **CWE\_Types – Coded with Exceptions** | | |
   | --- | --- | --- |
   | **Section** | **CWE Type** | **Comments** |
   | 2.2 | CWE\_CRE – Code-Required, but may be empty | This type of the CWE is used with all CWE elements except OBR-4, OBX-3 and OBX-5 |
   | 2.3 | CWE\_CR - Code Required | This type of the CWE is used only with OBR-4 and OBX-3. A code is required in the first component (CWE\_CR.1) |
   | 2.4 | CWE\_CRO - Code and Original Text Required | This type of the CWE is used only with OBX-5. A code is required in the first component (CWE\_CRO.1) and “original text” in the ninth component (CWE\_CRO.9) |

   [↑](#footnote-ref-7)
7. See vocabulary section, RCMT is available under PHINVADS Hot Topics <http://phinvads.cdc.gov/vads/SearchVocab.action> [↑](#footnote-ref-8)
8. Appropriate status is defined in the LOINC Manual Section 11.2 Classification of LOINC Term Status. [**http://loinc.org/downloads/files/LOINCManual.pdf**](http://loinc.org/downloads/files/LOINCManual.pdf) [↑](#footnote-ref-9)
9. Valid structure:

   Case 1: OBX.5 populated, OBX.8 empty and OBX.11 <> X

   Case 2: OBX.5 empty, OBX.8 populated and OBX.11 <> X

   Case 3: OBX.5 populated, OBX.5 populated and OBX.11 <> X

   Case 4: OBX.5 empty, OBX.8 empty and OBX.11 = X

   Invalid structure:

   Case 5, 6 and 7:   OBX.5 and/or OBX.8 populated and OBX.11 = X

   Case 8: OBX.8 empty, OBX.5 empty and OBX.11 <> X [↑](#footnote-ref-10)
10. From Section 3.1.2. Concept Identifiers SNOMED CT User Guide- July 2012 International Release (US English), ([www.snomed.org/ug.pdf](http://www.snomed.org/ug.pdf)). [↑](#footnote-ref-12)
11. Reference to the method vocabulary work. [↑](#footnote-ref-13)