V251\_IG\_SIF\_LABRESULTS\_R1\_N1\_2011SEP



**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**

**WIP: 0.18**

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**Sponsored by:**

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Reviewers Notes

The review of this draft specification is encouraged to provide feedback that will ensure broad support and adoption, as well as further the goals of interoperability of information between exchange mechanisms for structured data (v2.x message, xml, etc.). This guide therefore directs the reviewer to several areas where the authors seek broader input from the community in addition to any other items noted about this guide.

1) **Pre-adoption** - This implementation guide is dependent on both existing V2.x versions, as well as a new version, V2.7.1, that is going through ballot at the same time. We encourage the balloter to review both this implementation guide and the V2.7.1 ballot to ensure your concerns are addressed in the related documents.

2) **Component Length Conformance** - The introduction of V2.7.1 Conformance Length (C.LEN) and position on truncation.

3) **Minimalism** – The content is intended to focus on that which represents unique constraints to the base standard(s).

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Use of this Guide for Pilot Implementation

It is understood by pilot participants that the activity of creation of the guide is occurring in parallel to pilot & demonstration implementations. It is an expectation by the authors of this guide that real-world implementation activity will inform key assumptions of this guide, specifically in the use of universal identifiers and standardized clinical terminology and value sets.

As such, implementers also recognize that this document is a work in progress and that any version that contains this text does not necessarily imply a complete review and release by the authoring community, but is offered as-is with the assurance that unresolved errors are still present and are being addressed. It is recommended that Pilot Participants return often to the S&I Laboratory Results Interface Initiative for updates to this document. A review of the most current ballot reconciliation spreadsheet will identify changes that have been completed, as well as those approved by committee but not yet applied.

TABLE OF CONTENTS

1. Introduction 1

1.1 Purpose 1

1.2 Audience 1

1.2.1 Requisite Knowledge 1

1.3 Scope 1

1.4 Results for Ambulatory Care Use Case And Context Diagrams 2

1.4.1 User Story 3

1.4.2 Use Case Assumptions 3

1.4.3 Pre-Conditions 4

1.4.4 Post Condition 5

1.4.5 Functional Requirements 5

1.5 Key Technical Decisions 6

1.5.1 Use of ISO Object Identifier (OID) 6

1.5.2 Use of Vocabulary Standards 7

1.5.3 Field Length and Truncation 7

1.5.4 Referenced Profiles 7

~~1.5.5~~ ~~Actors~~ 8

1.5.6 Conformance to this Guide 8

1.5.7 Relationship to Orders 10

1.6 Organization of this Guide 10

1.6.1 Conventions 10

1.6.2 Message Element Attributes 11

1.6.3 Keywords 12

1.6.4 Usage Conformance Testing Recommendations 13

1.6.4.1 Usage 13

1.6.4.1.1 Definition of Conditional Usage 13

1.6.4.1.2 Sending and Receiving Application Conformance Requirements 14

2. Data Types 16

2.1 CE – Coded Element 16

2.2 CWE-CRE – Coded with Exceptions – CodE Required, but May BE Empty 17

2.3 CWE-CR– Coded with Exceptions – Code Required 19

2.4 CX-GU – Extended Composite ID with Check Digit (Globally Unique) 21

2.5 CX-NG – Extended Composite ID with Check Digit (Non-Globally Unique) 22

2.6 DR – Date/Time Range 23

2.7 DT – Date 23

2.8 DTM – Date/Time 23

2.9 ED – Encapsulated Data 23

2.10 EI GU – Entity Identifier (Globally Unique) 24

2.11 EI NG – Entity Identifier (Non-Globally Unique) 25

2.12 EIP – GU – Entity Identifier Pair (Globally Unique) 25

2.13 EIP – NG – Entity Identifier Pair (Non-Globally Unique) 26

2.14 ERL – Error Location 26

2.15 FN – family name 26

2.16 FT – Formatted Text Data 27

2.17 HD-GU – Hierarchic Designator (Globally Unique) 27

2.18 HD-NG – Hierarchic Designator (Non-Globally Unique) 28

ID – Coded Value for HL7-Defined Tables 28

2.19 28

2.20 IS – Coded Value for User-Defined Tables 28

2.21 MSG – Message Type 29

2.22 NM – Numeric 29

2.23 PRL – Parent Result Link 29

2.24 PT – Processing Type 30

2.25 RP – Reference Pointer 30

2.26 SAD – Street address 32

2.27 SI – Sequence ID 32

2.28 SN – Structured Numeric 32

2.29 ST – String Data 33

2.30 TM – Time 33

2.31 TS – Time Stamp 33

2.32 TX – Text Data 34

2.33 VID – Version Identifier 34

2.34 XAD – Extended Address 34

2.35 XCN – GU – Extended Composite ID Number and Name for Persons (Globally Unique) 36

2.36 XCN – NG – Extended Composite ID Number and Name for Persons (Non-Globally Unique) 37

2.37 XON GU – Extended Composite Name and Identification Number for Organizations Globally Unique) 39

2.38 XON NG – Extended Composite Name and Identification Number for Organizations (Non-Globally Unique) 40

2.39 XPN – Extended Person Name 40

3. Messages 42

3.1 ORU^R01^ORU\_R01 42

3.2 ACK^R01^ACK 45

3.3 Segment and Field Descriptions 45

3.3.1 MSH – Message Header Segment 46

3.3.2 SFT – Software Segment 49

3.3.3 ERR – Error Segment 50

3.3.4 PID – Patient Identification Segment 51

3.3.5 NK1 – Next of Kin Segment – make ref 54

3.3.6 PV1 – Patient Visit Information 54

3.3.7 PV2 – Patient Visit – Additional Information Segment insert ref to base 55

3.3.8 ORC – Common Order Segment 55

3.3.9 OBR – Observation Request Segment 57

3.3.10 TQ1 – Timing/Quantity Segment 65

3.3.11 OBX – Observation/Result Segment 66

3.3.11.1 Observation Identifiers, Observation Values, Interpretations and Comments 71

3.3.12 SPM – Specimen Segment 74

3.3.13 NTE – Notes and Comments Segment 77

4. Code Systems and Value Sets 78

4.1 HL7 Tables 78

4.2 LOINC 78

4.3 SNOMED CT 79

4.4 UCUM 80

4.5 Vocabulary Constraints 82

4.6 HL7 Tables 88

4.6.1 HL7 Table 0065 – Specimen Action Code from HL7 V2.7.1 Message - Constrained 88

4.6.2 HL7 Table 0076 – Message Type 2.5.1 (constrained) 88

4.6.3 HL7 Table 0078 – Interpretation Codes from HL7 V2.7.1 Message 88

4.6.4 HL7 Table 0125 – Value Type (Constrained from the Full HL7 Table) 90

4.6.5 HL7 Table 0203 – Identifier Type from HL7 V2.7.1 92

4.6.6 HL7 Table 0291 – Subtype Of Referenced Data 96

4.6.7 HL7 Table 0301 - Universal ID Type 97

4.6.8 HL7 Table 0354 – Message Structurefrom 2.5.1 (constrained) 98

4.6.9 HL7 Table 0834 – MIME Type 98

4.6.10 HL7 Table new – ??? from 2.7.1 98

5. Example Laboratory Result Messages 99

6. Additional Implemenation Guidance 100

6.1 Culture and Susceptibilities Reporting 100

6.1.1 Introduction 100

6.1.2 Template for Culture Results 100

6.1.3 Examples of Culture Results 101

6.1.4 Template for Culture and Susceptibility Results 104

6.1.5 Examples of Culture and Susceptibility Results 107

6.2 Linking Parent and Child Results 111

6.3 Clinical Laboratory Improvements Amendment Considerations 111

6.3.1 Mandatory Reporting Requirements 111

6.4 Regulatory Compliance 113

6.5 Authorized Parties 113

INDEX OF TABLES

Table 1‑1. Information Interchange Requirements 5

Table 1‑2. System Requirements 5

Table 1‑3. Message Element Attributes 11

Table 1‑4. Sending Application Conformance 14

Table 1‑5. Receiving Application Conformance 14

Table 2‑1. Coded Element (CE) 16

Table 2‑2. Coded with Exceptions − Code Required But May Be Empty (CWE-CRE) 17

Table 2‑3. Coded with Exceptions – Code Required – (CWE-CR) 19

Table 2‑4. Extended Composite ID with Check Digit (CX GU) 21

Table 2‑5. Extended Composite ID with Check Digit (CX NG) 22

Table 2‑6. Date/Time Range (DR) 23

Table 2‑7. Date (DT) 23

Table 2‑8. Date/Time (DTM) 23

Table 2‑9. Encapsulated Data (ED) 23

Table 2‑10. Entity Identifier (EI GU) 24

Table 2‑11. Entity Identifier (EI NG) 25

Table 2‑12. Entity Identifier Pair (EIP GU) 25

Table 2‑13. Entity Identifier Pair (EIP NG) 26

Table 2‑14. Error Location (ERL) 26

Table 2‑15. Formatted Text Data (FT) 27

Table 2‑16. Hierarchic Designator (HD GUHD-GU) 27

Table 2‑17. Hierarchic Designator (HD-NG) 28

Table 2‑18. Coded Value for HL7-Defined Tables (ID) 28

Table 2‑19. Coded Value for User-Defined Tables (IS) 28

Table 2‑20. Message Type (MSG) 29

Table 2‑21. Numeric (NM) 29

Table 2‑22. Parent Result LInk (PRL) 29

Table 2‑23. Processing Type (PT) 30

Table 2‑23. Reference Pointer (RP) 30

Table 2‑24.SEQuence ID (SI) 32

Table 2‑25. Structured Numeric (SN) 32

Table 2‑26. String Data (ST) 33

Table 2‑27. Time (TM) 33

Table 2‑28. Time Stamp (TS) 33

Table 2‑29. Text Data (TX) 34

Table 2‑30. Version Identifier (VID) 34

Table 2‑31. Extended Address (XAD) 34

Table 2‑32. Extended Composite ID Number and Name for Persons (XCN GU) 36

Table 2‑33. Extended Composite ID Number and Name for Persons (XCN NG) 37

Table 2‑34. Extended Composite Name and Identification Number for Organizations (XON GU) 39

Table 2‑35. Extended Composite Name and Identification Number for Organizations (XON NG) 40

Table 2‑36. Extended Person Name (XPN) 40

Table 3‑1. ORU^R01^ORU\_R01 Abstract Message Syntax 42

Table 3‑2. ACK^R01^ACK Abstract Message Syntax 45

Table 3‑3. Message Header Segment (MSH) 46

Table 3‑4. Acknowledgment Segment (MSA) 50

Table 3‑5. Error Segment (ERR) 50

Table 3‑6. Patient Identification Segment (PID) 51

Table 3‑8. Common Order Segment (ORC) 55

Table 3‑9. Observation Request Segment (OBR) 57

Table 3‑10. TimING/QuaNTity Segment for Order Group 65

Table 3‑11. Observation Result Segment (OBX) 66

Table 3‑12. Observation Identifiers 72

Table 3‑13. Specimen Segment (SPM) 74

Table 3‑14. Notes and Comments Segment (NTE) 77

Table 4‑1. Value Set/Code System Summary 82

Table 4‑2. HL7 Table 0065 Specimen Action Code - constrained 88

Table 4‑3. HL7 Table 0078 from 2.7.1 88

Table 4‑4. HL7 Table 0125 – Value Type 90

Table 4‑5. HL7 Table 0291 – Subtype Of Referenced Data 96

Table 4‑6. HL7 Table 0301 - Universal ID Type 97

Table 4‑7. HL7 Table 0834 – MIME Type 98

Table 6‑1. Mandatory Reporting Requirements 112

INDEX of Figures

Figure 1‑1. Use Case Diagram 3

Figure 1‑2. Context Diagram 3

Figure 1‑3. Sequence Diagram 6

# Introduction

The *HL7 Version 2.5.1 Implementation Guide: Laboratory Results Interface for US Realm, Release 1 (US Realm)* is the result of collaborative efforts between HL7 and the Health and Human Services Standards and Interoperability Framework Laboratory Results Interface Initiative. By consensus the HL7 V2.5.1 ORU^R01 Message was selected as the basis to define the profile constraints expressed in this guide to meet the requirements of the transmission of laboratory reports, initially focused on the Results for Ambulatory Providers Use Case.

## Purpose

The Laboratory Results Interface Initiative focuses on identifying the requirements, specifications and standards, and on providing the implementation guidance for electronic reporting of laboratory test results to ambulatory care providers in the US Realm. The scope of this Use Case includes requirements to enable the incorporation of clinical laboratory test results into an Electronic Health Record (EHR) as standardized structured data using the defined inter-organizational laboratory transaction. The Use Case requirements are directed at laboratory test results reporting between a laboratory information system and an ambulatory EHR system in different organizational entities, e.g., different corporate structure, ownership or governance. Future versions of this Guide may harmonize with existing guides to extend interoperability of laboratory results across care settings, e.g., acute care and public health.

## Audience

This guide is designed for use by analysts and developers who require guidance on data elements and components of the *HL7 Version 2.5.1 ORU Unsolicited Observation Message* relative to the Lab Results Interface (LRI) initiative. Users of this guide must be familiar with the details of HL7 message construction and processing. This guide is not intended to be a tutorial on that subject.

### Requisite Knowledge

* HL7 V2.5.1, V2.7, V2.7.1 Messaging ([www.HL7.org](http://www.HL7.org))
* SNOMED (www. <http://www.ihtsdo.org/snomed-ct>)
* LOINC (<http://loinc.org>)
* UCUM (<http://unitsofmeasure.org>)
* OIDS (<http://www.hl7.org/oid>)

## Scope

The scope is the sending of lab results from a laboratory to an ambulatory provider. The implementation design is as a series of constraining profiles on a base specification, itself a constraint on the HL7 V2.5.1 Message standard, for future use case expansion.

*In Scope*

* Defining the core data elements required for ambulatory care clinical laboratory test results.
* Reporting of clinical laboratory test results for ambulatory care in the US Realm.
* Sending clinical laboratory test results as standardized structured data so they can be incorporated that way into an EHR.
* Supporting Stage 2 certification criteria and Meaningful Use (MU) requirements by developing requirements for an interface that enables the incorporation of clinical laboratory test results into EHRs when data is sent as standardized structured data
* Reporting test results for an order that was placed either manually or electronically.
* Some order specific data has been included to enable the receiving EHR to correlate the results back to the originating order.
* Covering all CLIA reporting requirements, including but not limited to: result report statuses: preliminary, final, appended, corrected and/or amended.
* Receiving of laboratory results as a non-order placer.

*Out of Scope*

* Specifications and implementation guidance on laboratory ordering transactions. However, the establishment of requirements in the laboratory result message that will allow the matching of the reported result to an existing order initiated from the ordering clinician’s EHR is within the scope of this effort.
* Querying for laboratory results.
* Querying for historical laboratory results.
* Receiving historical laboratory results.
* Secondary use of laboratory data (i.e., public health or bio surveillance uses of the reported laboratory results).
* In hospital ordering and reporting of laboratory results.
* Advanced error messages related to application transport.
* Results not transmitted using a standardized structured format.

## Results for Ambulatory Care Use Case And Context Diagrams

A laboratory is defined as any facility which performs laboratory testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention, treatment of disease, or impairment or assessment of health[[1]](#footnote-1). In this Use Case, the Laboratory provides results based on a request for laboratory services from an authorized Provider. It is assumed that the receiving system is an EHR that can receive lab results even if it is not aware of the request, as there is no assumption that the receiving EHR provided the request for lab services. It does assume that the EHR can receive lab results even if it is not aware of the request.



Figure 1‑1. Use Case Diagram



Figure 1‑2. Context Diagram

### User Story

A Provider *(order placer)* may enter a laboratory order into an ambulatory EHR. A laboratory requisition is generated (paper or electronic) and is communicated to the laboratory. The information in the laboratory requisition is entered manually or captured electronically into the Laboratory Information System (LIS). After the specimen(s) has been collected and, if necessary, shipped or delivered to the laboratory, the laboratory processes the specimen(s). The laboratory performs or attempts to perform the test(s). If testing is successful, results are obtained and entered/released in the laboratory information system. An authorized person at the laboratory reviews and approves the laboratory test results to be sent to the ordering provider.

The laboratory's LIS *(results sender)* transmits the results to the provider’s EHR *(results receiver).* The EHR incorporates the results into the patient’s electronic record. The provider logs into his/her EHR and views the laboratory results in order to inform patient care decisions.

### Use Case Assumptions

* Providers securely access clinical information through an EHR system.
* Appropriate security and transport protocols; patient identification methodology; requisition (order) identification methodology; consent; privacy and security procedures; coding, vocabulary and normalization standards have been agreed to by all relevant participants.
* This Use Case only addresses the exchange of laboratory results that are associated with the In Scope laboratory tests.
* All relevant parties have agreed on a structured laboratory test results message format.
* This Use Case covers all CLIA reporting requirements, including but not limited to: result reports statuses; preliminary, final, appended, corrected and/or amended.
* For the specimen collection process the data included in the dataset considerations table are assumed to be available and reported in the result.
* Legal and governance issues regarding data access authorizations, data ownership, and data use are in effect.
  + Established network and policy infrastructure to enable consistent, appropriate, and accurate information exchange across provider systems, data repositories and locator services. This includes, but is not limited to:
    - Methods to identify and authenticate users;
    - Methods to identify and determine Providers of care;
    - Methods to enforce data access authorization policies;
    - Methods to ensure the veracity of data;
  + Detailed audit trails are kept as necessary by all participating systems.
* Security and privacy policies, procedures and practices are commonly implemented to support acceptable levels of patient privacy and security; i.e. HIPAA, HITECH and EHR certification criteria.
* A LIS will be the sender of laboratory test results while an EHR will be the receiver.
* The transport mechanism will provide guaranteed delivery and error handling
* This Use Case acknowledges the variations in requirements for reporting across local, state, tribal, and territorial boundaries as well as voluntary versus mandatory requirements.
* Laboratories meet accreditation criteria according to jurisdiction requirements or agency criteria.

### Pre-Conditions

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

### Post Condition

* Laboratory results are accurately reported and successfully transmitted electronically from the laboratory LIS system to the Ordering Provider's EHR System, module or other results receiver (as determined by the laws in each locale).
* The provider’s EHR system has electronically received the laboratory results, incorporated in a standardized structured format, and if available, associated with a patient and laboratory order.

### Functional Requirements

| Table 1‑1. Information Interchange Requirements | | | | |
| --- | --- | --- | --- | --- |
| Information Initiating System |  | Information Interchange Requirement Name |  | Receiving System |
| Laboratory Information System | Sends | Laboratory Test Result | Receives | Electronic Health Record System |

|  |  |
| --- | --- |
| Table 1‑2. System Requirements | |
| System | System Requirement |
| Laboratory Information System | Form a laboratory message with standardized structured data[[2]](#footnote-2) meeting CLIA and other federal and state regulatory requirements |
| Electronic Health Record System | Incorporate test data from the laboratory message as standardized structured data. |



Figure 1‑3. Sequence Diagram

## Key Technical Decisions

One of the primary features of this implementation guide is its focus on key points of broad interoperability. The HL7 implementation guides in Section 1.5.4-Referenced Profiles informed the content of this specification as analysis indicated that none of the candidate guides could satisfy the use case requirements without some adjustment. This guide is the result of combining the best practices from the current body of work while making further adjustment to meet the needs of ambulatory reporting and preparing for increased consistency of lab result reporting across care settings.

### Use of ISO Object Identifier (OID)

This guide defines multiple profiles, one of which employs the use of an ISO Object Identifier (ISO/IEC 8824:1990(E)) (OID) for universally unique identifiers. The ISO OID specification is the globally accepted technology for this purpose and is recommended as the means to satisfy the requirement for a universally unique identifier. HL7 has developed an implementation guide for the use of OIDs, “HL7 Implementation Guidance for Unique Object Identifiers (OIDs), Release 1[[3]](#footnote-3)”, which provides guidance on how organizations can use and manage OIDs.

OIDs provide a strong identifier that uniquely identifies the object in question and is global in scope. Examples of information that OIDs can identify are items about patients, orders, providers and organizations. This means the identifier includes enough information to remain unique when taken out of the context within which the identifier was created.

### Use of Vocabulary Standards ­

This guide calls for specific vocabulary standards for the exchange of laboratory information such as LOINC and SNOMED. Standard vocabularies, particularly coded laboratory results, enable automated decision support for patient healthcare, as well as for public health surveillance of populations.

### Field Length and Truncation

This guide pre-adopts field length definition conventions and the stated lengths from HL7 Version 2.7.1, Chapter 2 Control; it also provides further constraints to support the use case and scope defined in this guide.

The Conformance Length parameter (Version 2.7.1, Chapter 2 Control, Section 2.5.5.3, Conformance Length) has also been adopted in this guide and is defined in this excerpt from the base standard:

*--------- start citation ---------*

If populated, the conformance length column specifies the minimum length that applications must be able to store. Conformant applications SHALL not truncate a value that is shorter than the length specified. The conformance length is also the minimum value that maybe assigned to maximum length in an implementation profile.

In addition, the conformance length may be followed by a “=” or a “#”. The “=” denotes the value may never be truncated, and the “#” denotes that the truncation behavior defined for the data type applies.

*--------- end citation ---------*

Note that truncation is not allowed in this guide except for the FT primitive datatype, where the base standard defines truncation behavior.

### Referenced Profiles

This specification documents a message profile for Laboratory Reporting Results Interface (LRI) profile for Senders and Recievers based on the HL7 version 2.5.1 [[4]](#footnote-4). Other laboratory results profiles were referenced and used as source materials in the development of this guide, including:

* HL7 Ambulatory Care Laboratory Result Implementation Guide: EHR-Laboratory Interoperability And Connectivity Specification (ELINCS) - Release 1, July 1, 2008
* HL7 Version 2.5.1 Implementation Guide: Orders And Observations; Interoperable Laboratory Result Reporting To EHR (US Realm), Release 1, November, 2007
* HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm)

This document should not be considered the source of truth for any statement or assertion in regards to the referenced profiles. They are provided here as antecedent documentation and are not required for successful implementation of this Guide.

### ~~Actors~~

~~There are two actors that have responsibilities related the conformance profiles defined in this document~~

* ~~Laboratory Result Sender – A sender of laboratory result messages that declares conformance to a profile defined in this guide.~~
* ~~Lab Result Receiver – A receiver of laboratory result messages that declares conformance to a profile defined in this guide.~~

### Conformance to this Guide

This implementation guide uses five profile components combined as four profiles to define specific conformance requirements without defining a full implementation profile in accordance with HL7 V2 Chapter 2B.

The profile components are:

**LRI Common Profile Component** – ID: 2.16.840.1.113883.9.16

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

**GU Profile Component** – ID: 2.16.840.1.113883.9.12

This profile component indicates that the following fields use Globally Unique Identifiers through ISO OID according to section 1.5.1. for at least the assigning authority within the data type used.

* MSH.3 – Sending Application
* MSH.4 – Sending Facility
* MSH.6 – Receiving Facility
* PID.3 – Patient Identifier List
* ORC.2 – Placer Order Number
* ORC.3 – Filler Order Number
* ORC.4 – Placer Group Number
* OBR.2 – Placer Order Number
* OBR.3 – Filler Order Number
* OBR.28 – Result Copies To
* OBR.16 – Ordering Provider
* OBR.29 – Parent
* OBX.16 – Responsible Observer
* OBX.25 – Performing Organization Medical Director

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

**NG Profile Component** – ID: 2.16.840.1.113883.9.13

This profile component indicates that the identification method has been negotiated between the trading partners where none or some may use ISO OIDs according to section 1.5.1. while others use any of the identification methods allowed through the base standard. Consequently, these identifiers are not guaranteed to be globally unique.

* MSH.3 – Sending Application
* MSH.4 – Sending Facility
* MSH.6 – Receiving Facility
* PID.3 – Patient Identifier List
* ORC.2 – Placer Order Number
* ORC.3 – Filler Order Number
* ORC.4 – Placer Group Number
* OBR.2 – Placer Order Number
* OBR.3 – Filler Order Number
* OBR.28 – Result Copies To
* OBR.16 – Ordering Provider
* OBR.29 – Parent
* OBX.16 – Responsible Observer
* OBX.25 – Performing Organization Medical Director

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

**RU Profile Component** –ID: 2.16.840.1.113883.9.14

This profile component indicates that the test can be identified by either the placer order number only and/or the filler order number only.

**RN Profile Component** – ID: 2.16.840.1.113883.9.15

This profile component indicates that the test can be only be identified using the placer order number or the filler order number in combination with the universal service identifier.

The profile components must be combined to create a valid profile for a particular transaction. A valid profile consists of three profile components:

1. The LRI Common Profile Component
2. The GU Profile Component **OR** the NG Profile Component
3. The RU Profile Component **OR** the RN Profile Component

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

1. Common Profile Component + GU Profile Component + RU Profile Component
   * Profile ID: 2.16.840.1.113883.9.17
2. Common Profile Component + GU Profile Component + RN Profile Component
   * Profile ID: 2.16.840.1.113883.9.18
3. Common Profile Component + NG Profile Component + RU Profile Component
   * Profile ID: 2.16.840.1.113883.9.19
4. Common Profile Component + NG Profile Component + RN Profile Component
   * Profile ID: 2.16.840.1.113883.9.20

One may add other profile components that are defined outside of this implementation guide. However, those profile components are strictly voluntary and shall not conflict with any of the profile components defined in this implementation guide, nor shall any additional profile be marked by any exchange party as minimally required to successfully send or receive Lab Results when the LRI Common Profile Component, or any of the profile IDs listed above is present in MSH.21.

**Acknowledgement Profile -** ID: 2.16.840.1.113883.9.21

This ID is used to indentify an ACK that is constrained for the profiles defined within this Guide.

### Relationship to Orders

This implementation guide imposes no constraints on data elements where the origination of the content for those data elements is a lab order. For all such data elements, the expectation is that the message will support and echo back, without alteration, the content supplied by an order where designated within this guide. The definition of a common order is outside the scope of this Guide.

## Organization of this Guide

### Conventions

This guide adheres to the following conventions:

* The guide is constructed assuming the implementer has access to the 2.5.1 version of the HL7 Standard. Although some information from the standard is included in this implementation guide, much information from the standard has not been repeated here.
* The rules outlined in *HL7 2.7.1*, *Chapter 2B*, *Section 2B5*, *Conformance Using Message Profiles*, were used to document the use case for, and constraints applied to, the messages described in this guide.
* Data types have been described separately from the fields that use the data types.
* No conformance information is provided for optional message elements. This includes length, usage, cardinality, value sets and descriptive information. Implementers who want to use optional message elements should refer to the HL7 Standard to determine how these optional message elements will be used. Any information provided in this guide for optional elements is to be considered suggested best practices; this is particularly true of vocabulary and value sets associated with optional components.
* This guide uses “X” as a conformance usage indicator very sparingly. Where the underlying standard indicates the segments/field/component is present for backwards compatibility (“B”) or withdrawn ("W") an “X” will be used. For all other fields/components “O” is used to enable trading partners to explore additional capabilities. Note that without a clearly agreed to complementary profile between trading partners, a Lab does not have to send any elements marked as an "O", nor does a receiver of a lab result have to process any elements marked as an "O". Neither trading partners can mandate the other to accept any such complementary profiles to enable basic laboratory results interfacing "out-of-the-box".

### Message Element Attributes

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

| Table 1‑3. Message Element Attributes | | | |
| --- | --- | --- | --- |
| Attribute | | Definition | |
| Seq | | Sequence of the elements as numbered in the HL7 message element. The SEQ attribute applies to the data type attribute table and the segment attribute table. | |
| Segment | | Three-character code for the segment and the abstract syntax (e.g., the square and curly braces).  [ XXX ] Optional  { XXX } Repeating  XXX Required  [{ XXX }] Optional and Repeating  Note that for segment groups there is no segment code present, but the square and curly braces will still be present.  The Segment attribute only applies to the Message attribute table. | |
| Length – (V2.7.1) | | For each component in the data type table and field in a segment there is a normative length column (LEN) and conformance length (C.LEN).  This guide follows the length definitions and conventions from V2.7.1.  LEN – If populated, defines the minimum and maximum length that must be supported.  The minimum or the maximum may be blank, e.g., “..20” or “2..”. indicating there is no minimum or maximum.  C.LEN – If populated, the conformance length column specifies the minimum length that applications must be able to store.  Note the following behaviors for the C.LEN:  = - Truncation is not permitted  # - Truncation behavior defined for the data type applies | |
| DT | | Data type used by this profile for HL7 element.  The data type attribute applies to data type attribute tables and segment attribute tables. | |
| Usage | | Usage of the message element for this profile. Indicates whether the message element (segment, segment group, field, component, or subcomponent) is R, RE, O, X or C(a/b) in the corresponding message element. Usage applies to the message attribute table, data type attribute table and the segment attribute table; see Section XXXX | |
| Cardinality | | Minimum and maximum number of times the element may appear.  [0..0] Element never present.  [0..1] Element may be omitted and can have, at most, one occurrence.  [1..1] Element must have exactly one occurrence.  [0..n] Element may be omitted or may repeat up to *n* times.  [1..n] Element must appear at least once, and may repeat up to *n* times.  [0..\*] Element may be omitted or repeat an unlimited number of times.  [1..\*] Element must appear at least once, and may repeat unlimited number of times.  [m..n] Element must appear at least *m*, and at most, *n* times.  Cardinality applies only to message attribute tables and segment attribute tables. | |
| Value Set | | The set of coded values to be used with the field. The value set attribute applies only to the data type attribute tables and the segment attribute tables. The value set may equate with an entire code system part of a code system, or codes drawn from multiple code systems.  Note: Where a table constraint is indicated, or where HL7 Version 2.7.1 standards are pre-adopted, the constrained or specified HL7 table is included below the data type table. | |
| Name | | HL7 descriptor of the message element. Name applies to the message attribute table, data type attribute table and the segment attribute table. | |
| Description/Comments | | Context and usage for the element. Description/Comments applies to the message attribute table, data type attribute table and the segment attribute table. | |

### Keywords

The following keywords in this document are to be interpreted as follows:

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

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

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

**SHOULD NOT** or the phrase "**NOT RECOMMENDED**" mean that there may exist valid reasons in particular circumstances when the particular behavior is acceptable or even useful, but the full implications should be understood and the case carefully weighed before implementing any behavior described with this label.

**MAY** or the adjective "**OPTIONAL**", mean that an item is truly optional. One software supplier may choose to include the item to enable certain capabilities while another software supplier may omit the same item. In either case, the communication partner cannot be expected to either provide it (sender) or process it (receiver) without clear and voluntary agreement between the partners.

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

### Usage Conformance Testing Recommendations

The following text is pre-adopted from the HL7 V2.7.1 Conformance (Chapter 2B) Draft Version (Aug 31, 2011) as revised by the S&I Framework Lab Implementation Guide Recommendations (Sept 2, 2011). Please refer to the base standard documentation for a full explanation of conformance concepts. Usage is described here as it introduces the revised approach to conditional element handling; upon successful ballot and publication this material will be replaced with a reference to the normative documentation.

*---------- start citation---------*

#### Usage

Message content is governed by the cardinality specification associated (explicitly or implicitly) with each element of an HL7 message. Message content is governed by the cardinality specification associated (explicitly or implicitly) with each element of an HL7 message. **Usage rules govern the expected behavior of the sending application and place limited restrictions on the receiving application with respect to the element.** These usage codes expand/clarify the optionality codes defined in the HL7 standard. The usage codes expand/clarify the optionality codes defined in the HL7 standard. Usage codes are employed in a message profile to constrain the use of elements defined in the standard. The usage code definitions are given from a sender and receiver perspective and specify operational and implementation requirements.

The standard allows broad flexibility for the message structures that HL7 applications must be able to receive without failing. But while the standard allows that messages may be missing data elements or may contain extra data elements, it should not be inferred from this requirement that such messages are conformant. In fact, the usage codes specified in a message profile place strict conformance requirements on the behavior of the application.

##### Definition of Conditional Usage

The conditional usage is defined as follows:

C(a/b) - “a” and “b” in the expression are placeholders for usage codes representing the true (“a”) predicate outcome and the false (“b”) predicate outcome of the condition. The condition is expressed by a conditional predicate associated with the element (“See section 2.B.7.9, Condition Predicate" in V2.7.1 Chapter 2B). “a” and “b” shall be one of “R”, “RE”, “O” and/or “X”. In order not to render the condition statement redundant, “a” and “b” shall be different.

The example C(R/RE) is interpreted as follows. If the condition predicate associated with the element is true then the usage for the element is R-Required. If the condition predicate associated with the element is false then the usage for the element is RE-Required but may be empty.

##### Sending and Receiving Application Conformance Requirements

| Table 1‑4. Sending Application Conformance | | | |
| --- | --- | --- | --- |
| Symbol | Definition | Implementation Requirement | Operational Requirement |
| R | Required | The application **SHALL** implement “R” elements. | The application **SHALL** populate “R” elements with a non-empty value. |
| RE | Required, but may be empty | The application **SHALL** implement “RE” elements. | The application **SHALL** populate “RE” elements with a non-empty value if there is relevant data. The term “relevant” has a confounding interpretation in this definition[[5]](#footnote-5). |
| C(a/b) | Conditional | An element with a conditional usage code has an associated condition predicate (See section 2.B.7.9, Condition Predicate in V2.7.1 Chapter 2B") that determines the operational requirements (usage code) of the element.  If the condition predicate associated with the element is true, follow the rules for ***a*** which shall be one of “R”, “RE”, “O” or X”:  If the condition predicate associated with the element is false, follow the rules for ***b*** which shall be one of “R”, “RE”, “O” or X”.  ***a*** and ***b*** **SHALL** be different and defined by the message profile. | |
| X | Not supported in this guide | The application **SHALL NOT** implement “X” elements. | The application **SHALL NOT** populate “X” elements. |
| O | Optional | None. The usage indicator for this element has not yet been defined. For an implementation profile all optional elements must be profiled to R, RE, C(a/b), or X. | Not Applicable. |

| Table 1‑5. Receiving Application Conformance | | | |
| --- | --- | --- | --- |
| Symbol | Definition | Implementation Requirement | Operational Requirement |
| R | Required | The application **SHALL** implement “R” elements. | The receiving application **SHALL** process (save/print/archive/etc.) the information conveyed by a required element.  A receiving application **SHALL** raise an exception due to the absence of a required element. A receiving application **SHALL** **NOT** raise an error due to the presence of a required element, |
| RE | Required, but may be empty | The application **SHALL** implement “RE” elements. | The receiving application **SHALL** process (save/print/archive/etc.) the information conveyed by a required but may be empty element. The receiving application **SHALL** process the message if the element is omitted (that is, an exception **SHALL** **NOT** be raised because the element is missing). |
| C(a/b) | Conditional | The usage code has an associated condition predicate true (See section 2.B.7.9, Condition Predicate in V2.7.1 Chapter 2B").  If the condition predicate associated with the element is true, follow the rules for ***a*** which may be one of “R”, “RE”, “O” or X”:  If the condition predicate associated with the element is false, follow the rules for ***b*** which may be one of “R”, “RE”, “O” or X”.  ***a*** and ***b*** **SHALL** be different and defined by the message profile. | |
| X | Not supported in this guide | The application **SHALL** **NOT** implement “X” elements. | None, if the element is not sent.  If the element is sent the receiving application may process the message, **SHALL** ignore the element, and **MAY** raise an exception. The receiving application **SHALL** **NOT** process (save/print/archive/etc.) the information conveyed by a not-supported element. |
| O | Optional | None. The usage indicator for this element has not yet been defined. For an implementation profile all optional elements must be profiled to R, RE, C(a/b) or X. | None. |

*--------- end citation ---------*

# Data Types

Data types are included for all fields that are R, RE, C(A/B), refer to the base standard for optional data types.

## CE – Coded Element

| Table 2‑1. Coded Element (CE) | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| SEQ | Component Name | DT | Usage | LEN | C.LEN | Value Set | Comments |
| 1 | Identifier | ST | RE | 1..20 | = |  |  |
| 2 | Text | ST | C(R/RE) | 1..199 | = |  | Condition Predicate: If CE.1 (Identifier) is not valued  It is strongly recommended that text be sent to accompany any identifier. When a coded value is not known, text can still be sent, in which case no coding system should be identified. |
| 3 | Name of Coding System | ID | C(R/X) | 1..12 | = | HL70396 | Condition Predicate: If CE.1 (Identifier) is valued |
| 4 | Alternate Identifier | ST | RE | 1..20 | = |  | The alternate identifier (from the alternate coding system) should be the closest match for the identifier found in component 1. |
| 5 | Alternate Text | ST | RE | 1..199 | = |  | It is strongly recommended that alternate text be sent to accompany any alternate identifier. |
| 6 | Name of Alternate Coding System | ID | C(R/X) | 1..12 | = | HL70396 | Condition Predicate: If CE.4 (Alternate Identifier) is valued |

Usage Note

Senders should always populate the first triplet before populating other triplets; the receiver needs to examine all triplets to find relevant values.

Conformance Statements: Base Profile

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

**Example**

**Release Note:** Examples will be provided for each datatype defined in this section that are conformant to the statements in the final version of this Release (R1).

## CWE-CRE – Coded with Exceptions – CodE Required, but May BE Empty

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

| Table 2‑2. Coded with Exceptions − Code Required But May Be Empty (CWE-CRE) | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| SEQ | Component Name | DT | Usage | LEN | C.LEN | Value Set | Comments |
| 1 | Identifier | ST | RE | 1..20 | = |  |  |
| 2 | Text | ST | C(RE/X) | 1..199 | = |  | Condition Predicate: If CWE\_CRE.1 (Identifier) is valued  It is strongly recommended that text be sent to accompany any identifier. When a coded value is not known, the original text attribute (CWE\_CRE.9) is used to carry the text, not the text component. |
| 3 | Name of Coding System | ID | C(R/X) | 1..12 | = | HL70396 | Condition Predicate: If CWE\_CRE.1 (Identifier) is valued  See section 4 for description of the use of coding systems in this implementation guide. |
| 4 | Alternate Identifier | ST | C(RE/X) | 1..20 | = |  | Condition Predicate: If CWE\_CRE.1 (Identifier) is valued The alternate identifier (from the alternate coding system) should be the closest match for the identifier found in CWE\_CRE.1. |
| 5 | Alternate Text | ST | C(RE/X) | 1..199 | = |  | Condition Predicate: If CWE\_CRE.4 (Alternate Identifier) is valued  It is strongly recommended that alternate text be sent to accompany any alternate identifier. |
| 6 | Name of Alternate Coding System | ID | C(R/X) | 1..12 | = | HL70396 | Condition Predicate: If CWE\_CRE.4 (Alternate Identifier) is valued  See section 4 for description of the use of coding systems in this implementation guide. |
| 7 | Coding System Version ID | ST | O | 1..10 | = |  |  |
| 8 | Alternate Coding System Version ID | ST | O | 1..10 | = |  |  |
| 9 | Original Text | ST | C(R/RE) | 1..199 | = |  | Condition Predicate: If CWE\_CRE.1 (Identifier) is not valued  Either original Text is used to convey the text that was the basis for coding, or when there is no code to be sent, only free text.  If neither the first or second triplet has values, this contains the text of the field. |
| 10 | Second Alternate Identifier | ST | O | 1..20 | = |  |  |
| 11 | Second Alternate Text | ST | O | 1..199 | = |  |  |
| 12 | Second Name of Alternate Coding System | ID | O | 1..12 | = |  |  |
| 13 | Second Alternate Coding System Version ID | ST | O | 1..10 | = |  |  |
| 14 | Coding System OID | ST | O | 1..199 | = |  |  |
| 15 | Value Set OID | ST | O | 1..199 | = |  |  |
| 16 | Value Set Version ID | DTM | O | 1..8 | = |  |  |
| 17 | Alternate Coding System OID | ST | O | 1..199 | = |  |  |
| 18 | Alternate Value Set OID | ST | O | 1..199 | = |  |  |
| 19 | Alternate Value Set Version ID | DTM | O | 1..8 | = |  |  |
| 20 | Second Alternate Coding System OID | ST | O | 1..199 | = |  |  |
| 21 | Second Alternate Value Set OID | ST | O | 1..199 | = |  |  |
| 22 | Second Alternate Value Set Version ID | DTM | O | 1..8 | = |  |  |

Usage Note

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

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

## CWE-CR– Coded with Exceptions – Code Required

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

| Table 2‑3. Coded with Exceptions – Code Required – (CWE-CR) | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| SEQ | Component Name | DT | Usage | LEN | C.LEN | Value Set | Comments |
| 1 | Identifier | ST | R | 1..20 | = |  | Note: The identifier component is always required. |
| 2 | Text | ST | RE | 1..199 | = |  | It is strongly recommended that text be sent to accompany any identifier. When a coded value is not known, the original text attribute is used to carry the text, not the text component. |
| 3 | Name of Coding System | ID | R | 1..12 | = | HL70396 | See Section 4 for description of the use of coding systems in this implementation guide. |
| 4 | Alternate Identifier | ST | RE | 1..20 | = |  | The alternate identifier (from the alternate coding system) should be the closest match for the identifier found in component 1. |
| 5 | Alternate Text | ST | RE | 1..199 | = |  | It is strongly recommended that alternate text be sent to accompany any alternate identifier. |
| 6 | Name of Alternate Coding System | ID | C(R/X) | 1..12 | = | HL70396 | Condition Predicate: If CWE\_CR.1 (Alternate Identifier) is valued  See section 4 for description of the use of coding systems in this implementation guide. |
| 7 | Coding System Version ID | ST | O | 1..10 | = |  |  |
| 8 | Alternate Coding System Version ID | ST | O | 1..10 | = |  |  |
| 9 | Original Text | ST | R | 1..199 | = |  | Original Text is used to convey the text that was the basis for coding. |
| 10 | Second Alternate Identifier | ST | O | 1..20 | = |  |  |
| 11 | Second Alternate Text | ST | O | 1..199 | = |  |  |
| 12 | Second Name of Alternate Coding System | ID | O | 1..12 | = |  |  |
| 13 | Second Alternate Coding System Version ID | ST | O | 1..10 | = |  |  |
| 14 | Coding System OID | ST | O | 1..199 | = |  |  |
| 15 | Value Set OID | ST | O | 1..199 | = |  |  |
| 16 | Value Set Version ID | DTM | O | 1..8 | = |  |  |
| 17 | Alternate Coding System OID | ST | O | 1..199 | = |  |  |
| 18 | Alternate Value Set OID | ST | O | 1..199 | = |  |  |
| 19 | Alternate Value Set Version ID | DTM | O | 1..8 | = |  |  |
| 20 | Second Alternate Coding System OID | ST | O | 1..199 | = |  |  |
| 21 | Second Alternate Value Set OID | ST | O | 1..199 | = |  |  |
| 22 | Second Alternate Value Set Version ID | DTM | O | 1..8 | = |  |  |

Usage Note

This version of the CWE is used only with OBX-5. The CWE data type is used where it is necessary to communicate a code, text, coding system and the version of coding system the code was drawn from. It also allows the communication of an alternate code drawn from another coding system. Many coded fields in this specification identify coding systems or value sets that must be used for the field. **When populating the CWE data types with these values, this guide does not give preference to the triplet in which the standard code should appear.** The receiver is expected to examine the coding system names in components 3 and 6 to determine if it recognizes the coding system. CWE.9 is always expected to be sent in this CWE to comply with CLIA regulation of matching result statements between reports of record at both sender and receiver system.

The CWE data type allows communication of "null flavors", referred to as CWE Status(es), where the values are drawn from HL7 Table 0353. The CWE Statuses are not supported in this guide.

## CX-GU – Extended Composite ID with Check Digit (Globally Unique)

| Table 2‑4. Extended Composite ID with Check Digit (CX GU) | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| SEQ | Component Name | DT | Usage | LEN | C.LEN | Value Set | Comments |
| 1 | ID Number | ST | R | 1..15 | = |  | The ID Number component combined with the Assigning Authority component must uniquely identify the associated object, i.e., any object with which the field is associated.  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 | Check Digit | ST | O | 1..4 | = |  |  |
| 3 | Check Digit Scheme | ID | C(O/X) | 3..3 | = |  | Refer to base standard |
| 4 | Assigning Authority | HD-GU | R |  | # |  | The Assigning Authority component is used to identify the system, application, organization, etc. that assigned the ID Number in component 1. |
| 5 | Identifier Type Code | ID | R | 2..5 | = | HL70203 |  |
| 6 | Assigning Facility | HD | O |  | # |  |  |
| 7 | Effective Date | DT | O |  | = |  |  |
| 8 | Expiration Date | DT | O |  | = |  |  |
| 9 | Assigning Jurisdiction | CWE | O |  | # |  |  |
| 10 | Assigning Agency or Department | CWE | O |  | # |  |  |

Usage Note

The CX data type is used to carry identifiers. The GU profile requires that all identifiers be accompanied by assigning authorities, and that all identifiers carry an identifier type. This method allows the exchange of universally unique identifiers for the associated object across organizational and enterprise boundaries, enabling broad interoperability.

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

## CX-NG – Extended Composite ID with Check Digit (Non-Globally Unique)

| Table 2‑5. Extended Composite ID with Check Digit (CX NG) | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| SEQ | Component Name | DT | Usage | LEN | C.LEN | Value Set | Comments |
| 1 | ID Number | ST | R | 1..15 | = |  | The ID Number component combined with the Assigning Authority component must uniquely identify the associated object, i.e., any object with which the field is associated.  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 | Check Digit | ST | O | 1..4 | = |  |  |
| 3 | Check Digit Scheme | ID | C(O/X) | 3..3 | = |  | Condition Predicate: |
| 4 | Assigning Authority | HD-NG | RE |  | # |  | The Assigning Authority component is used to identify the system, application, organization, etc. that assigned the ID Number in component 1. |
| 5 | Identifier Type Code | ID | R | 2..5 | = | HL70203 |  |
| 6 | Assigning Facility | HD | O |  | # |  |  |
| 7 | Effective Date | DT | O |  | = |  |  |
| 8 | Expiration Date | DT | O |  | = |  |  |
| 9 | Assigning Jurisdiction | CWE | O |  | # |  |  |
| 10 | Assigning Agency or Department | CWE | O |  | # |  |  |

Usage Note

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

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

## DR – Date/Time Range

| Table 2‑6. Date/Time Range (DR) | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| SEQ | Component Name | DT | Usage | LEN | C.LEN | Value Set | Comments |
| 1 | Range Start Date/Time | TS | RE |  | # |  |  |
| 2 | Range End Date/Time | TS | RE |  | # |  |  |

## DT – Date

| Table 2‑7. Date (DT) | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| SEQ | Component Name | DT | Usage | LEN | C.LEN | Value Set | Comments |
| 1 | Date | - | R | 4..8 | = |  | Format: YYYY[MM[DD]] |

## DTM – Date/Time

| Table 2‑8. Date/Time (DTM) | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| SEQ | Component Name | DT | Usage | LEN | C.LEN | Value Set | Comments |
| 1 | Date/Time | - | R | 4..24 | = |  | Format: YYYY[MM[DD[HH[MM[SS[.S[S[S[S]]]]]]]]][+/-ZZZZ] |

Usage Note

It is strongly recommended that the time zone offset always be included in the DTM particularly if the granularity includes hours, minutes, seconds, etc. Specific fields in this implementation guide may require Date/Time to a specific level of granularity, which may require the time zone offset. The granularity of the DTM as well as whether the time zone offset is required or recommended is set for each field separately in the comments section.

## ED – Encapsulated Data

| Table 2‑9. Encapsulated Data (ED) | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| SEQ | Component Name | DT | Usage | LEN | C.LEN | Value Set | Comments |
| 1 | Source Application | [HD](file:///D:\Jean's%20Documents\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#HD) | RE |  | # |  | Identifier of the application that is the source of the encapsulated data. |
| 2 | Type of Data | [ID](file:///D:\Jean's%20Documents\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#ID) | R | 4..11 | = | HL70834 (from HL7 2.7.1) | Identifier of the type of data found in component 5.  See section 0 for details of HL70834. |
| 3 | Data Subtype | [ID](file:///D:\Jean's%20Documents\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#ID) | RE | 1..32 | = | HL7[0291](file:///D:\Jean's%20Documents\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#Heading407) (from HL7 2.7.1) | Identifier of the subtype of data found in component 5. |
| 4 | Encoding | [ID](file:///D:\Jean's%20Documents\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#ID) | R | 1..6 | = | HL70299 | Identifier of the type of encoding to be performed in the data component |
| 5 | Data | [TX](file:///D:\Jean's%20Documents\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#TX) | R |  | = |  | The data in this component must be properly escaped after encoding. Receivers will need to un-escape the text prior to decoding.  Be aware that this can be very big, e.g., large documents, images, etc. Trading partners must agree whether they can support this, thus the field using this (OBX.2 and OBX.5) mark this data type as optional. |

Usage Note

Specific MIME type/MIME subtypes to be supported will be worked out for specific implementations.

## EI GU – Entity Identifier (Globally Unique)

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Table 2‑10. Entity Identifier (EI GU) | | | | | | | |
| SEQ | Component Name | DT | Usage | LEN | C.LEN | Value Set | Comments |
| 1 | Entity Identifier | ST | R | 1..199 | = |  |  |
| 2 | Namespace ID | IS | RE | 1..20 | = | Local | See profile for stronger requirements. The coding system for this component is locally managed. |
| 3 | Universal ID | ST | R | 1..199 | = |  |  |
| 4 | Universal ID Type | ID | R | 3..3 | = | HL70301 | Constrained to the value "ISO" |

Usage Note

The EI data type is used to carry identifiers. This guide requires that all entity identifiers be accompanied by assigning authorities. This allows the exchange of unique identifiers for the associated object across organizational and enterprise boundaries, enabling broad interoperability.

In the EI data type, the Namespace ID, Universal ID and Universal ID type correspond to the HD data type identified elsewhere. These types, together, are commonly considered the assigning authority for the identifier.

Conformance Statement: LRI-GU Profile

**LRI-EI-1**: EI.4 (Universal ID Type) **SHALL** contain the value “ISO”.

**LRI-EI-2**: EI.3 (Universal ID) **SHALL** be valued with an ISO-compliant OID.

## EI NG – Entity Identifier (Non-Globally Unique)

| Table 2‑11. Entity Identifier (EI NG) | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| SEQ | Component Name | DT | Usage | LEN | C.LEN | Value Set | Comments |
| 1 | Entity Identifier | ST | R | 1..199 | = |  |  |
| 2 | Namespace ID | IS | O | 1..20 | = |  |  |
| 3 | Universal ID | ST | C(R/RE) | 1..199 | = |  | Condition Predicate: If EI\_NG.1 (Namespace ID) is not valued |
| 4 | Universal ID Type | ID | C(R/X) | 1..6 | = | HL70301 | Condition Predicate: If EI\_NG.2 (Universal ID) is valued |

Usage Note

The EI data type is used to carry identifiers. This guide requires that all entity identifiers be accompanied by assigning authorities. This allows the exchange of unique identifiers for the associated object across organizational and enterprise boundaries, enabling broad interoperability.

In the EI data type, the Namespace ID, Universal ID and Universal ID type correspond to the HD data type identified elsewhere. These types, together, are commonly considered the assigning authority for the identifier.

Conformance Statement LRI-NG Profile

**LRI-EI-1**: EI.3 (Universal ID) **SHALL** be valued with an ISO-compliant OID.

**LRI-EI-2**: EI.4 (Universal ID Type) **SHALL** contain the value “ISO”.

## EIP – GU – Entity Identifier Pair (Globally Unique)

| Table 2‑12. Entity Identifier Pair (EIP GU) | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| SEQ | Component Name | DT | Usage | LEN | C.LEN | Value Set | Comments |
| 1 | Placer Assigned Identifier | EI GU | RE |  | # |  |  |
| 2 | Filler Assigned Identifier | EI GU | C(R/RE) |  | # |  | Condition Predicate: If EIP\_GU.1 is not valued |

## EIP – NG – Entity Identifier Pair (Non-Globally Unique)

| Table 2‑13. Entity Identifier Pair (EIP NG) | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| SEQ | Component Name | DT | Usage | LEN | C.LEN | Value Set | Comments |
| 1 | Placer Assigned Identifier | EI\_NG | RE |  | # |  |  |
| 2 | Filler Assigned Identifier | EI\_NG | C(R/RE) |  | # |  | Condition Predicate: if EIP\_NG.1 is not valued |

## ERL – Error Location

| Table 2‑14. Error Location (ERL) | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| SEQ | Component Name | DT | Usage | LEN | C.LEN | Value Set | Comments |
| 1 | Segment ID | ST | R | 3..3 | = |  | The 3-character name for the segment (i.e., PID). |
| 2 | Segment Sequence | NM | R | 1..2 | = |  |  |
| 3 | Field Position | NM | O | 1..2 | = |  |  |
| 4 | Field Repetition | NM | O | 1..2 | = |  |  |
| 5 | Component Number | NM | O | 1..2 | = |  |  |
| 6 | Sub-component Number | NM | O | 1..2 | = |  |  |

## FN – family name

| Table 2‑14. Family name (FN) | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| SEQ | Component Name | DT | Usage | LEN | C.LEN | Value Set | Comments |
| 1 | Surname | ST | R |  | 50# |  |  |
| 2 | Own Surname Prefix | ST | O |  | 20# |  |  |
| 3 | Own Surname | ST | O |  | 50# |  |  |
| 4 | Surname Prefix From Partner/Spouse | ST | O |  | 20# |  |  |
| 5 | Surname From Partner/Spouse | ST | O |  | 50# |  |  |

## FT – Formatted Text Data

| Table 2‑15. Formatted Text Data (FT) | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| SEQ | Component Name | DT | Usage | LEN | C.LEN | Value Set | Comments |
|  | Formatted Text Data | - | R | 1..65536 | 64,000 |  |  |

Usage Note

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

## HD-GU – Hierarchic Designator (Globally Unique)

| Table 2‑16. Hierarchic Designator (HD GUHD-GU) | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| SEQ | Component Name | DT | Usage | LEN | C.LEN | Value Set | Comments |
| 1 | Namespace ID | IS | RE | 1..20 | = | Local | The coding system for this component is locally managed. |
| 2 | Universal ID | ST | R | 1..199 | = |  |  |
| 3 | Universal ID Type | ID | R | 3..3 | = | HL70301 |  |

Usage Note

The HD data type is used directly to identify objects such as applications or facilities. It is used also as a component of other data types, where it is typically an assigning authority for an identifier. Where this capability is used in this specification, the usage is described separately. Note that the HD datatype has been constrained to carry an OID identifying an application, a facility, or an assigning authority. The only exception to the use of OID’s for the HD is for the Lab Result Receiver profile for MSH-4 (Sending Facility)

Conformance Statement: LRI-GU Profile

**LRI-HD-1**: HD.2 (Universal ID) **SHALL** be valued with an ISO-compliant OID.

**LRI-HD-2**: HD.3 (Universal ID Type) **SHALL** contain the value “ISO”.

## HD-NG – Hierarchic Designator (Non-Globally Unique)

| Table 2‑17. Hierarchic Designator (HD-NG) | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| SEQ | Component Name | DT | Usage | LEN | C.LEN | Value Set | Comments |
| 1 | Namespace ID | IS | O | 1..20 | = |  |  |
| 2 | Universal ID | ST | C(R/RE) | 1..199 | = |  | Condition Predicate: If HD\_NG.1 (Namespace ID) is not valued |
| 3 | Universal ID Type | ID | C(R/X) | 1..6 | = | HL70301 | Condition Predicate: If HD\_NG.2 (Universal ID) is valued  Note: Conditions need to be negotiated by the trading partners |

Usage Note

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

## ID – Coded Value for HL7-Defined Tables

| Table 2‑18. Coded Value for HL7-Defined Tables (ID) | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| SEQ | Component Name | DT | Usage | LEN | C.LEN | Value Set | Comments |
| 1 | Coded Value for HL7-Defined Tables | - | R | 1..15 | = |  |  |

## IS – Coded Value for User-Defined Tables

| Table 2‑19. Coded Value for User-Defined Tables (IS) | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| SEQ | Component Name | DT | Usage | | LEN | C.LEN | Value Set | Comments |
| 1 | Coded Value for User-Defined Tables | - | | R | 1..20 | = |  |  |

## MSG – Message Type

| Table 2‑20. Message Type (MSG) | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| SEQ | Component Name | DT | Usage | LEN | C.LEN | Value Set | Comments |
| 1 | Message Code | ID | R | 3..3 | = | HL70076 |  |
| 2 | Trigger Event | ID | R | 3..3 | = | HL70003 |  |
| 3 | Message Structure | ID | R | 3..7 | = | HL70354 |  |

## NM – Numeric

| Table 2‑21. Numeric (NM) | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| SEQ | Component Name | DT | Usage | LEN | C.LEN | Value Set | Comments |
| 1 | Numeric | - | R | 1..16 | = |  |  |

## PRL – Parent Result Link

| Table 2‑22. Parent Result LInk (PRL) | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| SEQ | Component Name | DT | Usage | LEN | C.LEN | Value Set | Comments |
| 1 | Parent Observation Identifier | CWE\_CR | R |  | # |  | Identifier of the OBX-3 Observation ID of the parent result. Typically, this is used in microbiology results where the sensitivities are linked to the specific culture OBX where the organism was identified. |
| 2 | Parent Observation Sub-Identifier | ST | RE | 1..20 | = |  | Identifier of the OBX-4 Observation Sub-ID associated with the OBX-3 Observation ID of the parent result. Typically, this is used in microbiology results where the sensitivities are linked to the specific culture OBX where the organism was identified. The combination of OBX-3 and OBX-4 must be unique within a particular OBR. |
| 3 | Parent Observation Value Descriptor | TX | O |  | = |  |  |

Usage Note

See Section *6.1* of this document for details on how this data type and the EIP data type are used in parent/child result linking. Use of data type CWE for sequence 1 reflects a pre-adoption of *HL7 Version 2.7.1* standards.

## PT – Processing Type

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Table 2‑23. Processing Type (PT) | | | | | | | |
| SEQ | Component Name | DT | Usage | LEN | C.LEN | Value Set | Comments |
| 1 | Processing ID | [ID](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#ID) | R | 1..1 | = | HL70103 |  |
| 2 | Processing Mode | [ID](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#ID) | O | 1..1 | = |  |  |

## RP – Reference Pointer

| Table 2‑23. Reference Pointer (RP) | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| SEQ | Component Name | DT | Usage | LEN | C.LEN | Value Set | Comments |
| 1 | Pointer | [ST](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#ST) | R | 1..999 | = |  | 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](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\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 than what is defined in section 2.18 (HD). |
| 2.1 | Namespace ID | ID | O | 1..20 | = |  |  |
| 2.2 | Universal ID | ID | R | 1..199 | = |  | 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 | 1..6 | = | HL70301 | This component is constrained to support only universal Resource Identifier. Literal value: ‘URI’ |
| 3 | Type of Data | [ID](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#ID) | RE | 4..11 | = | HL70834 (2.7.1) | Identifier of the type of data pointed to. For the URI example referenced above, this is '"application." |
| 4 | Subtype | [ID](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#ID) | RE | 1..32 | = | HL7[0291](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#Heading407) (2.7.1) | Identifier of the subtype of data pointed to. For the URI example above, this is "pdf," indicating portable document format. |

Usage 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.

## SAD – Street address

| Table 2‑24.STREET ADDRESS (SAD) | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| SEQ | Component Name | DT | Usage | LEN | C.LEN | Value Set | Comments |
| 1 | Street or Mailing Address | ST | R |  | 120# |  |  |
| 2 | Street Name | ST | O |  | 50# |  |  |
| 3 | Dwlling Number | ST | O |  | 12# |  |  |

## SI – Sequence ID

| Table 2‑24.SEQuence ID (SI) | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| SEQ | Component Name | DT | Usage | LEN | C.LEN | Value Set | Comments |
| 1 | Sequence ID | - | R | 1..4 | = |  | Non-negative integer up to 9999. May be further constrained to limit the number of times a segment may repeat. |

## SN – Structured Numeric

| Table 2‑25. Structured Numeric (SN) | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| SEQ | Component Name | DT | Usage | LEN | C.LEN | Value Set | Comments |
| 1 | Comparator | [ST](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#ST) | RE | 1..2 | = |  | Component that must be one of ">" or "<" or ">=" or "<=" or "=" or "<>". This component defaults to "=" if empty. |
| 2 | Num1 | [NM](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#NM) | RE |  | = |  |  |
| 3 | Separator/Suffix | [ST](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#ST) | RE | 1..1 | = |  | Component that must be one of "-" or "+" or "/" or "." or ":". |
| 4 | Num2 | [NM](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#NM) | RE |  | = |  |  |

Usage Note

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

## ST – String Data

| Table 2‑26. String Data (ST) | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| SEQ | Component Name | DT | Usage | LEN | C.LEN | Value Set | Comments |
| 1 | String Data | - | R |  |  |  |  |

Usage Note

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

## TM – Time

| Table 2‑27. Time (TM) | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| SEQ | Component Name | DT | Usage | LEN | C.LEN | Value Set | Comments |
| 1 | Time | - | R | 2..16 |  |  | Format: HH[MM[SS[.S[S[S[S]]]]]][+/-ZZZZ] |

Usage 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 – Time Stamp

| Table 2‑28. Time Stamp (TS) | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| SEQ | Component Name | DT | Usage | LEN | C.LEN | Value Set | Comments |
| 1 | Time | [DTM](file:///D:\Jean's%20Documents\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#DTM) | R |  |  |  |  |
| 2 | Degree of Precision | [ID](file:///D:\Jean's%20Documents\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#ID) | X |  |  |  | Deprecated as of *HL7 Version 2.3*. See component 1 (DTM) for the current method of designating degree of precision. |

## TX – Text Data

| Table 2‑29. Text Data (TX) | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| SEQ | Component Name | DT | Usage | LEN | C.LEN | Value Set | Comments |
| 1 | Text Data | - | R |  |  |  |  |

Usage Note

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

## VID – Version Identifier

| Table 2‑30. Version Identifier (VID) | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| SEQ | Component Name | DT | Usage | LEN | C.LEN | Value Set | Comments |
| 1 | Version ID | [ID](file:///D:\Jean's%20Documents\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#ID) | R | 5..5 | = | HL7[0104](file:///D:\Jean's%20Documents\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02.html#Heading224) | See MSH.12 for conformance statement. |
| 2 | Internationalization Code | [CE](file:///D:\\Jean's%20Documents\\AppData\\Local\\Microsoft\\kreislera\\My%20Documents\\HL7\\Documents\\hl725\\std25\\ch02A.html" \l "CE) | O |  | # |  |  |
| 3 | International Version ID | [CE](file:///D:\\Jean's%20Documents\\AppData\\Local\\Microsoft\\kreislera\\My%20Documents\\HL7\\Documents\\hl725\\std25\\ch02A.html" \l "CE) | O |  | # |  |  |

## XAD – Extended Address

| Table 2‑31. Extended Address (XAD) | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| SEQ | Component Name | DT | Usage | LEN | C.LEN | Value Set | Comments |
| 1 | Street Address | [SAD](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#SAD) | RE |  | # |  |  |
| 2 | Other Designation | [ST](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#ST) | RE | 1..120 | = |  | Example: Suite 555 |
| 3 | City | [ST](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#ST) | RE | 1..50 | = |  |  |
| 4 | State or Province | [ST](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#ST) | RE | 1..50 | = | * 1. State Value Set | The 2 letter (alpha) codes should be used here. |
| 5 | Zip or Postal Code | [ST](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#ST) | RE | 1..12 | = | * 1. Postal Code Value Set | In the US, the zip code takes the form 99999[-9999], while the Canadian postal code takes the form A9A9A9. |
| 6 | Country | [ID](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#ID) | RE | 3..3 | = | HL70399 |  |
| 7 | Address Type | [ID](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#ID) | RE | 1..3 | = | HL70190 |  |
| 8 | Other Geographic Designation | [ST](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#ST) | O | 1..50 | = |  |  |
| 9 | County/Parish Code | [IS](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#IS) | RE | 1..20 | = | PHVS\_County\_FIPS\_6-4 |  |
| 10 | Census Tract | [IS](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#IS) | O | 1..20 | = |  |  |
| 11 | Address Representation Code | [ID](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#ID) | O | 1..1 | = |  |  |
| 12 | Address Validity Range | [DR](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#DR) | X |  |  |  | Deprecated as of *HL7 Version 2.5*. See XAD-13 Effective Date and XAD-14 Expiration Date components. |
| 13 | Effective Date | [TS](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#TS) | O | 1..8 | = |  |  |
| 14 | Expiration Date | [TS](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#TS) | O | 1..8 | = |  |  |

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

| Table 2‑32. Extended Composite ID Number and Name for Persons (XCN GU) | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| SEQ | Component Name | DT | Usage | LEN | C.LEN | Value Set | Comments |
| 1 | ID Number | ST | RE | 1..15 | = |  | The ID Number component combined with the Assigning Authority component (component 9) must uniquely identify the associated person. Note: despite the component being named “ID Number” this component is an ST string data type, not numeric, so the component is not limited to just numbers. |
| 2 | Family Name | FN | RE |  | # |  |  |
| 3 | Given Name | ST | RE | 1..30 | = |  | I.e., first name. |
| 4 | Second and Further Given Names or Initials Thereof | [ST](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#ST) | RE | 1..30 | = |  |  |
| 5 | Suffix (e.g., JR or III) | [ST](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#ST) | RE | 1..20 | = |  |  |
| 6 | Prefix (e.g., DR) | [ST](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#ST) | RE | 1..20 | = |  |  |
| 7 | Degree (e.g., MD) | IS | X | 1..20 | = |  |  |
| 8 | Source Table | [IS](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#IS) | O | 1..20 | = |  |  |
| 9 | Assigning Authority | HD-GU | C(R/X) |  | # |  | Condition Predicate: If XCN\_GU.1 (ID Number) is valued The Assigning Authority component is used to identify the system, application, organization, etc. that assigned the ID Number in component 1. |
| 10 | Name Type Code | [ID](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#HD) | RE | 1..5 | = | HL70200 |  |
| 11 | Identifier Check Digit | [ST](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#ID) | O | 1..4 | = |  |  |
| 12 | Check Digit Scheme | ID | C(O/X) | 3..3 | = |  | Condition Predicate: If XCN\_GU.11 (Identifier Check Digit) is valued |
| 13 | Identifier Type Code | [ID](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#ID) | C(R/X) | 2..5 | = | HL70203 | Condition Predicate: If XCN\_GU.1 (ID Number) is valued |
| 14 | Assigning Facility | [HD](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#ID) | O |  | # |  |  |
| 15 | Name Representation Code | ID | O | 1..1 | = |  |  |
| 16 | Name Context | CE | O |  | # |  |  |
| 17 | Name Validity Range | [DR](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#CE) | X |  |  |  | Deprecated as of *HL7 Version 2.5*. See XCN-19 Effective Date and XCN-20 Expiration Date components. |
| 18 | Name Assembly Order | ID | O | 1..1 | = |  |  |
| 19 | Effective Date | [TS](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#ID) | O | 1..8 | = |  |  |
| 20 | Expiration Date | [TS](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#TS) | O | 1..8 | = |  |  |
| 21 | Professional Suffix | [ST](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#TS) | O | 1..199 | = |  | Suggest using values from HL7 table 360. |
| 22 | Assigning Jurisdiction | CWE | O |  | # |  |  |
| 23 | Assigning Agency or Department | CWE | O |  | # |  |  |

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

| Table 2‑33. Extended Composite ID Number and Name for Persons (XCN NG) | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| SEQ | Component Name | DT | Usage | LEN | C.LEN | Value Set | Comments |
| 1 | ID Number | ST | RE | 1..15 | = |  | The ID Number component combined with the Assigning Authority component (component 9) must uniquely identify the associated person. Note: despite the component being named “ID Number” this component is an ST string data type, not numeric, so the component is not limited to just numbers. |
| 2 | Family Name | FN | RE |  | # |  |  |
| 3 | Given Name | ST | RE | 1..30 | = |  | I.e., first name. |
| 4 | Second and Further Given Names or Initials Thereof | [ST](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#ST) | RE | 1..30 | = |  |  |
| 5 | Suffix (e.g., JR or III) | [ST](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#ST) | RE | 1..20 | = |  |  |
| 6 | Prefix (e.g., DR) | [ST](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#ST) | RE | 1..20 | = |  |  |
| 7 | Degree (e.g., MD) | IS | X | 1..20 |  |  |  |
| 8 | Source Table | [IS](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#IS) | O | 1..20 | = |  |  |
| 9 | Assigning Authority | HD-NG | C(RE/X) |  | # |  | Condition Predicate: If XCN\_NG.1 (ID Number) is valued The Assigning Authority component is used to identify the system, application, organization, etc. that assigned the ID Number in component 1. |
| 10 | Name Type Code | [ID](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#HD) | RE | 1..5 | = | HL70200 |  |
| 11 | Identifier Check Digit | [ST](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#ID) | O | 1..4 | = |  |  |
| 12 | Check Digit Scheme | ID | C(O/X) | 3..3 | = |  | Condition Predicate: |
| 13 | Identifier Type Code | [ID](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#ID) | C(R/X) | 2..5 | = | HL70203 | Condition Predicate: If XCN\_GU.1 (ID Number) is valued |
| 14 | Assigning Facility | [HD](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#ID) | O |  | # |  |  |
| 15 | Name Representation Code | ID | O | 1..1 | = |  |  |
| 16 | Name Context | CE | O |  | # |  |  |
| 17 | Name Validity Range | [DR](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#CE) | X |  |  |  | Deprecated as of *HL7 Version 2.5*. See XCN-19 Effective Date and XCN-20 Expiration Date components. |
| 18 | Name Assembly Order | ID | O | 1..1 | = |  |  |
| 19 | Effective Date | [TS](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#ID) | O | 1..8 | = |  |  |
| 20 | Expiration Date | [TS](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#TS) | O | 1..8 | = |  |  |
| 21 | Professional Suffix | [ST](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#TS) | O | 1..199 | = |  |  |
| 22 | Assigning Jurisdiction | CWE | O |  | # |  |  |
| 23 | Assigning Agency or Department | CWE | O |  | # |  |  |

## XON GU – Extended Composite Name and Identification Number for Organizations Globally Unique)

| Table 2‑34. Extended Composite Name and Identification Number for Organizations (XON GU) | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| SEQ | Component Name | DT | Usage | LEN | C.LEN | Value Set | Comments |
| 1 | Organization Name | [ST](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#ST) | RE | 1..50 | = |  |  |
| 2 | Organization Name Type Code | [IS](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#IS) | O | 1..20 | = |  |  |
| 3 | ID Number | [NM](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#NM) | X |  |  |  | Deprecated as of *HL7 Version 2.5*. Use XON-10 Organization Identifier. |
| 4 | Check Digit | [NM](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#NM) | O | 1..4 | = |  |  |
| 5 | Check Digit Scheme | [ID](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#ID) | C(O/X) | 3..3 | = |  |  |
| 6 | Assigning Authority | [HD](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#HD) GU | C(R/X) |  | # |  | Condition Predicate: If XON\_GU.10 (Organization Identifier) is valued  The Assigning Authority component is used to identify the system, application, organization, etc. that assigned the ID in component 10. |
| 7 | Identifier Type Code | [ID](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#ID) | C(R/X) | 2..5 | = | HL70203 | Condition Predicate: If XON\_GU.10 (Organization Identifier) is valued |
| 8 | Assigning Facility | [HD](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#HD) | O |  | # |  |  |
| 9 | Name Representation Code | [ID](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#ID) | O | 1..1 | = |  |  |
| 10 | Organization Identifier | [ST](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#ST) | C(R/RE) | 1..20 | = |  | Condition Predicate: If XON\_GU.1 (Organization Name) is not valued |

Conformance Statement: Base Profile

**Note**: both XON.1 and XON.10 may be populated, but at least one of them must be valued.

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

| Table 2‑35. Extended Composite Name and Identification Number for Organizations (XON NG) | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| SEQ | Component Name | DT | Usage | LEN | C.LEN | Value Set | Comments |
| 1 | Organization Name | [ST](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#ST) | RE | 1..50 | = |  |  |
| 2 | Organization Name Type Code | [IS](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#IS) | O | 1..20 | = |  |  |
| 3 | ID Number | [NM](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#NM) | X |  |  |  | (Deprecated as of *HL7 Version 2.5*.) Use XON-10 Organization Identifier. |
| 4 | Check Digit | [NM](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#NM) | O | 1..4 | = |  |  |
| 5 | Check Digit Scheme | [ID](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#ID) | C(O/X) | 3..3 | = |  |  |
| 6 | Assigning Authority | [HD](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#HD) NG | C(RE/X) |  | # |  | Condition Predicate: If XON\_NG.10 (Organization Identifier) is valued  The Assigning Authority component is used to identify the system, application, organization, etc. that assigned the ID in component 10. |
| 7 | Identifier Type Code | [ID](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#ID) | C(R/X) | 2..5 | = | HL70203 | Condition Predicate: If XON\_NG.10 (Organization Identifier) is valued |
| 8 | Assigning Facility | [HD](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#HD) | O |  | # |  |  |
| 9 | Name Representation Code | [ID](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#ID) | O | 1..1 | = |  |  |
| 10 | Organization Identifier | [ST](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#ST) | C(R/RE) | 1..20 | = |  | Condition Predicate: If XON\_NG.1 (Organization Name) is not valued |

Conformance Statement: Base Profile

**Note**: both XON.1 and XON.10 may be populated, but at least one of them must be valued.

## XPN – Extended Person Name

| Table 2‑36. Extended Person Name (XPN) | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| SEQ | Component Name | DT | Usage | LEN | C.LEN | Value Set | Comments |
| 1 | Family Name | [FN](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#FN) | RE |  | # |  |  |
| 2 | Given Name | [ST](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#ST) | RE | 1..30 | = |  | I.e., first name. |
| 3 | Second and Further Given Names or Initials Thereof | [ST](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#ST) | RE | 1..30 | = |  |  |
| 4 | Suffix (e.g., JR or III) | [ST](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#ST) | RE | 1..20 | = |  |  |
| 5 | Prefix (e.g., DR) | [ST](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#ST) | O | 1..20 | = |  |  |
| 6 | Degree (e.g., MD) | [IS](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#IS) | X | 1..20 |  | HL70360 |  |
| 7 | Name Type Code | [ID](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#ID) | RE | 1..5 | = | HL70200 |  |
| 8 | Name Representation Code | [ID](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#ID) | O | 1..1 | = |  |  |
| 9 | Name Context | CE | O |  | # |  |  |
| 10 | Name Validity Range | [DR](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#DR) | X |  |  |  | Deprecated as of *HL7 Version 2.5*. See XPN-12 Effective Date and XPN-13 Expiration Date components. |
| 11 | Name Assembly Order | [ID](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#ID) | O | 1..1 | = |  |  |
| 12 | Effective Date | [TS](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#TS) | O |  | = |  |  |
| 13 | Expiration Date | [TS](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#TS) | O |  | = |  |  |
| 14 | Professional Suffix | [ST](file:///D:\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\kreislera\My%20Documents\HL7\Documents\hl725\std25\ch02A.html#ST) | O | 1..199 | = |  | Suggest using values from HL7 table 360. |

# Messages

The following sections detail the structure of each message, including segment name, usage, cardinality and description. See Section 1.6.2 for a description of the columns in the Abstract Message Syntax Tables.

## ORU^R01^ORU\_R01

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

| Table 3‑1. ORU^R01^ORU\_R01 Abstract Message Syntax | | | | |
| --- | --- | --- | --- | --- |
| Segment in Standard | Name | Usage | Cardinality | Description |
| MSH | Message Header | R | [1..1] | The message header (MSH) segment contains information describing how to parse and process the message. This includes identification of message delimiters, sender, receiver, message type, timestamp, etc. |
| [{SFT}] | Software Segment | O | [0..\*] |  |
| { | PATIENT\_RESULT Begin | R | [1..1] |  |
| [ | PATIENT Begin | R | [1..1] |  |
| PID | Patient Identification | R | [1..1] | The patient identification (PID) segment is used to provide basic demographics regarding the subject of the testing. The subject shall be a person. |
| [PD1] | Additional Demographics | O | [0..1] |  |
| [{NTE}] | Notes and Comments for PID | O | [0..1] |  |
| [{NK1}] | Next of Kin/Associated Parties | O | [0..\*] |  |
| [ | VISIT Begin | O | [0..1] |  |
| PV1 | Patient Visit | R | [1..1] | HL7 requires that the patient visit (PV1) segment be present if the VISIT group is present. |
| [PV2] | Patient Visit – Additional Information | O | [0..1] |  |
| ] | VISIT End |  |  |  |
| ] | PATIENT End |  |  |  |
| { | ORDER\_OBSERVATION Begin | R | [1..\*] | The ORDER\_OBSERVATION is required and can repeat. |
| [ORC] | Order Common | R | [1..1] | The common order (ORC) segment identifies basic information about the order for testing of the specimen. This segment includes identifiers of the order, who placed the order, when it was placed, what action to take regarding the order, etc. |
| OBR | Observations Request | R | [1..1] | The observation request (OBR) segment is used to capture information about one test being performed on the specimen. Most importantly, the OBR identifies the type of testing to be performed on the specimen, and ties that information to the order for the testing. |
| [{NTE}] | Notes and Comments for OBR | RE | [0..\*] |  |
| [{ | TIMING\_QTY Begin | RE | [0..1] | Although Timing/Quantity may be necessary for orders, it’s not necessary for result reporting. |
| TQ1 | Timing/Quantity | R | [1..1] |  |
| [{TQ2}] | Timing/Quantity Order Sequence | O | [0..\*] |  |
| }] | TIMING\_QTY End |  |  |  |
| [CTD] | Contact Data | O | [0..1] |  |
| [{ | OBSERVATION Begin | C(R/X) | [0..\*] | Condition Predicate: If OBR.25 (Result Status) is valued “A”, “C”, “F”, “P”, or “R”  Multiple Observation groups, each containing a single OBX and an optional repeating NTE, may be associated with a single order. |
| OBX | Observation related to OBR | R | [1..1] | The observation/result (OBX) segment contains information regarding a single observation (analyte) result. This includes identification of the specific type of observation, the result for the observation, when the observation was made, etc.  For laboratory testing, the OBX is normally reporting the results of a test performed on a specimen, Because the ORU^R01^ORU\_R01 message structure allows multiple specimens to be associated with a single OBR, there is no direct way to tell which specimen this OBX is associated with. There are other HL7 messages for laboratory results where this ambiguity does not exist, but were not chosen for this implementation guide. |
| [{NTE}] | Notes and Comments | RE | [0..\*] | The notes and comment (NTE) segment may carry comments related to the result being reported in the OBX segment. |
| }] | OBSERVATION End |  |  |  |
| [{FTI}] | Financial Transaction | O | [0..\*] |  |
| {[CTI]} | Clinical Trial Identification | O | [0..\*] |  |
| - [{ | SPECIMEN Begin | RE | [0..\*] | The specimen group is required if known in the ORU and is used to carry specimen information that is no longer contained in the OBR segment. It also provides a place for the specimen number. Each specimen group documents a single sample. |
| SPM | Specimen Information related to OBR | R | [1..1] | The specimen information (SPM) segment describes the characteristics of a single sample. The SPM segment carries information regarding the type of specimen, where and how it was collected, who collected it, and some basic characteristics of the specimen. |
| [{OBX}] | Observation related to Specimen | O | [0..\*] |  |
| }] | SPECIMEN End |  |  |  |
| } | ORDER\_ OBSERVATION End |  |  |  |
| } | PATIENT\_RESULT End |  |  |  |
| [DSC] | Continuation Pointer | X | [0..0] |  |

## ACK^R01^ACK

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

| Table 3‑2. ACK^R01^ACK Abstract Message Syntax | | | | | |
| --- | --- | --- | --- | --- | --- |
| Segment in Standard | Name | Usage | Cardinality | C.LEN | Description |
| MSH | Message Header | R | [1..1] |  | The message header (MSH) segment contains information describing how to parse and process the message. This includes identification of message delimiters, sender, receiver, message type, timestamp, etc. |
| [{SFT}] | Software Segment | O | [0..\*] |  |  |
| MSA | Message Acknowledgment | R | [1..1] |  |  |
| [{ ERR }] | Error | C(R/O) | [0..\*] |  | Condition predicate: If MSA.1 (Message Acknowledgement) is not valued AA or CA |

## Segment and Field Descriptions

This messaging guide provides notes for required (non-optional) fields. The following format is used in this document for listing and defining message segments and fields. First, the message segment use is defined and then a segment attribute table listing all fields defined in the segment is shown. See Section 1.6.2 for a description of the columns in the Segment Attribute Tables.

Note that any optional segments that are brought forward from the base will have to be used within the constraints set forth in this guide, e.g., constraint statements will be required to use the GU or NG profiles, or to use the correct CWE datatype.

## MSH – Message Header Segment

| Table 3‑3. Message Header Segment (MSH) | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| SEQ | Element Name | DT | Usage | Cardinality | LEN | C.LEN | Value Set | Description/Comments |
| 1 | Field Separator | ST | R | [1..1] | 1..1 |  |  | Character to be used as the field separator for the rest of the message.  Constrained to the literal value: ‘|’ [ASCII (124)]. |
| 2 | Encoding Characters | ST | R | [1..1] | 4..5 |  |  | Constrained to the literal values ‘^~\&’ or ‘^~\&#’, always appearing in the same order. |
| 3 | Sending Application | HD | O | [1..1] |  |  |  |  |
| 4 | Sending Facility | Varies | R | [1..1] |  |  |  | GU Datatype: HD\_GU  NG Datatype: HD\_NG  Field that uniquely identifies the facility associated with the application that plays the Laboratory Result Sender actor that sends the message. If acknowledgments are in use, this facility will receive any related acknowledgment message. |
| 5 | Receiving Application | HD | O | [0..1] |  |  |  |  |
| 6 | Receiving Facility | Varies | RE | [1..1] |  |  |  | GU Datatype: HD\_GU  NG Datatype: HD\_NG  Field that uniquely identifies the facility for the application that plays the Laboratory Result Receiver actor and receives the message. If acknowledgments are in use, this facility originates any related acknowledgment message. |
| 7 | Date/Time Of Message | TS | R | [1..1] |  |  |  | Field containing the date/time the message was created by the sending system. Format: YYYYMMDDHHMMSS[.S[S[S[S]]]]+/-ZZZZ. Note that the time zone offset is required, and the minimum granularity is to the second, although more precise time stamps are allowed. |
| 8 | Security | ST | O | [0..1] | 1..40= |  |  |  |
| 9 | Message Type | MSG | R | [1..1] |  |  |  | Constrained to the literal value ‘ORU^R01^ORU\_R01’ for the result message.  Constrained to the literal value for the acknowledgement message. |
| 10 | Message Control ID | ST | R | [1..1] | 1..199= | 199= |  | String that uniquely identifies the message instance from the sending application. Example formats for message control IDs include GUID, timestamp plus sequence number, OID plus sequence number or sequence number. The important point is that care must be taken to insure that the message control id is unique. The sending application (MSH-3) plus MSH-10 (message control id) needs to be globally unique. |
| 11 | Processing ID | PT | R | [1..1] |  |  |  | Field that may be used to indicate the intent for processing the message, such as "T" (training,) "D" (debug,) or "P" (production.) |
| 12 | Version ID | VID | R | [1..1] |  |  |  | HL7 version number used to interpret format and content of the message. Constrained to the literal value ‘2.5.1’.  Note that receivers must examine MSH-21 (Message Profile Identifier) to understand which message profile the message instance conforms with. |
| 13 | Sequence Number | NM | O | [0..1] |  |  |  |  |
| 14 | Continuation Pointer | ST | O | [0..1] | 1..180= |  |  |  |
| 15 | Accept Acknowledgment Type | ID | R | [1..1] | 2..2 |  | HL70155 |  |
| 16 | Application Acknowledgment Type | ID | R | [1..1] | 2..2 |  | HL70155 |  |
| 17 | Country Code | ID | O | [0..1] | 3..3 |  |  |  |
| 18 | Character Set | ID | O | [0..\*] | 5..15 |  |  |  |
| 19 | Principal Language Of Message | CWE | O | [0..1] |  |  |  |  |
| 20 | Alternate Character Set Handling Scheme | ID | O | [0..1] | 3..13 |  |  |  |
| 21 | Message Profile Identifier | EI GU | R | [1..\*] |  |  |  | Field used to reference or assert adherence to one or more message profiles.  The sender asserts that the message conforms to all the profiles whose identifiers are included. It must include one of the sender profiles defined in this implementation guide ("base profile"); see Section 1.5.6.  The combination of profiles cannot create conflicts, and the additional profiles must be properly constrained against the base profile.  The indication whether to uniquely identify a result based on placer/filler order number + universal service identifier or just placer/filler order number is done through declaring a profile in this field. |

Usage Note

The Message Header Segment (MSH) contains information describing how to parse and process the message. This includes identification of message delimiters, sender, receiver, message type, timestamp, etc.

Note: When there is no performing lab is specified in the OBX, use the combination of MSH-3 and MSH-4 to define a local coding system. It is assumed that:

* Different applications within an organization with a single CLIA number may have different local coding systems (e.g., a clinical pathology application vs. an anatomic pathology application).
* A single application within an organization with a single CLIA number has a single local coding system. That coding system may contain multiple value sets, for example, it may contain local value sets for observation identifier, observation value, interpretation code, race, ethnicity, reason for study, and others.

Conformance Statement: Base Profile

LRI-XXX-X MSH.1 (Field Separator) SHALL contain the constant value ‘|’.

LRI-XXX-X MSH.2 (Encoding Characters) SHALL contain the constant value ‘^~\&’ or the constant value ‘^~\&#’.

LRI-XXX-X MSH.9 (Message Type) SHALL contain the constant value ‘ORU^R01^ORU\_R01’.

LRI-XXX-X MSH.12.1 (Version ID) SHALL contain the constant value ‘2.5.1’.

LRI-XXX-X MSH.15 (Accept Acknowledgement Type) SHALL contain the constant value ‘AL’.

LRI-XXX-X MSH.16 (Application Acknowledgement Type) SHALL contain the constant value ‘NE’.

**LRI-XXX-X:** MSH.21 (Message Profile Identifier) **SHALL** be valued with 2.16.840.1.113883.9.16 (LRI Common Profile Component)

Conformance Statement: Acknowledgement Message Profile

LRI-XXX-X MSH.1 (Field Separator) SHALL contain the constant value ‘|’.

LRI-XXX-X MSH.2 (Encoding Characters) SHALL contain the constant value ‘^~\&’ or the constant value ‘^~\&#’.

LRI-XXX-X MSH.9 (Message Type) SHALL contain the constant value ‘ACK^R01^ACK’.

LRI-XXX-X MSH.12.1 (Version ID) SHALL contain the constant value ‘2.5.1’.

LRI-XXX-X MSH.15 (Accept Acknowledgement Type) SHALL contain the constant value ‘NE’.

LRI-XXX-X MSH.16 (Application Acknowledgement Type) SHALL contain the constant value ‘NE’.

**LRI-XXX-X:** MSH.21 (Message Profile Identifier) **SHALL** be valued with 2.16.840.1.113883.9.21 (Acknowledgment Profile)

Conformance Statement: LRI-GU Profile

**LRI-MSH-3:** MSH.21 (Message Profile Identifier) **SHALL** be valued with 2.16.840.1.113883.9.16 (LRI Common Profile Component) and with 2.16.840.1.113883.9.12 (GU – Globally Unique) and **SHALL** also be valued with either the OID 2.16.840.1.113883.9.14 (RU – Unique Placer/Filler Order Number) or 2.16.840.1.113883.9.15 (RN – Non-Unique Order Numbers) but not both

Conformance Statement: LRI-NG Profile

**LRI-MSH-5:** MSH.21 (Message Profile Identifier) **SHALL** be valued with 2.16.840.1.113883.9.16 (LRI Common Profile Component) and with 2.16.840.1.113883.9.13 (NG – Non-Globally Unique) and **SHALL** also be valued with either the OID 2.16.840.1.113883.9.14 (RU– Unique Placer/Filler Order Number ) or 2.16.840.1.113883.9.15 (RN – Non-Unique Order Numbers) but not both.

## SFT – Software Segment

The software segment provides information about the sending application or other applications that manipulate the message before the receiving application processes the message. This guide imposes no additional constraints on the base specification HL7 V2.5.1, Chapter 2.MSA – Acknowledgement Segment

The Message Response Segment (MSA) contains the information sent as acknowledgment to the order message received by a Laboratory Information System.

| Table 3‑4. Acknowledgment Segment (MSA) | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| SEQ | Element Name | DT | Usage | Cardinality | LEN | C.LEN | Value Set | Description/Comments |
| 1 | Acknowledgment Code | ID | R | [1..1] | 2..2 |  | HL70008 | Acknowledgment code indicating receipt of message. (Refer to *HL7 Table 0008 - Acknowledgment Code* for valid values.) |
| 2 | Message Control ID | ST | R | [1..1] | 1..199 |  |  | Identifier that enables the sending system to associate this response with the message for which it is intended. This value will be the MSH.10 message control ID from the message being acknowledged. |
| 3 | Text Message | ST | X | [0..0] |  |  |  | Deprecated as of *HL7 Version 2.4*. See ERR segment. |
| 4 | Expected Sequence Number | NM | O | [0..1] |  |  |  |  |
| 5 | Delayed Acknowledgment Type | ID | X | [0..0] |  |  |  | Deprecated as of *HL7 Version 2.2* and the detail was withdrawn and removed from the standard as of *HL7 Version 2.5*. |
| 6 | Error Condition | CWE | X | [0..0] |  |  |  | Deprecated as of *HL7 Version 2.4*. See ERR segment. |

## ERR – Error Segment

The ERR segment is used to add error comments to acknowledgment messages.

| Table 3‑5. Error Segment (ERR) | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| SEQ | Element Name | DT | Usage | Cardinality | LEN | C.LEN | Value Set | Description/Comments |
| 1 | Error Code and Location | ELD | X | [0..0] |  |  |  | Deprecated as of *HL7 Version 2.5*. See ERR-2 Error Location and ERR-3 HL7 Error Code fields. |
| 2 | Error Location | ERL | O | [0..1] |  |  |  |  |
| 3 | HL7 Error Code | CWE | R | [1..1] |  |  | HL70357 | Identifies the HL7 (communications) error code. |
| 4 | Severity | ID | R | [1..\*] | 1..1 |  | HL70516 | Identifies the severity of an application error. Knowing if something is Error, Warning, or Information is intrinsic to how an application handles the content. |
| 5 | Application Error Code | CWE | O | [0..1] |  |  |  |  |
| 6 | Application Error Parameter | ST | O | [0..10] | 1..80 |  |  |  |
| 7 | Diagnostic Information | TX | RE | [0..1] | 1..2048 |  |  | Information that may be used by help desk or other support personnel to diagnose a problem. |
| 8 | User Message | TX | O | [0..1] | 1..250 |  |  |  |
| 9 | Inform Person Indicator | IS | O | [0..\*] | 1..20 |  |  |  |
| 10 | Override Type | CWE | O | [0..0] |  |  |  |  |
| 11 | Override Reason Code | CWE | O | [0..\*] |  |  |  |  |
| 12 | Help Desk Contact Point | XTN | RE | [0..\*] |  |  |  |  |

Conformance Statement: Base Profile

## PID – Patient Identification Segment

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

| Table 3‑6. Patient Identification Segment (PID) | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| SEQ | Element Name | DT | Usage | Cardinality | LEN | C.LEN | Value Set | Description/Comments |
| 1 | Set ID – PID | SI | R | [1..1] | 1..4 |  |  | Constrained to the literal value ‘1’. |
| 2 | Patient ID | CX | X | [0..0] |  |  |  | Deprecated as of *HL7 Version 2.3.1*. See PID-3 Patient Identifier List. |
| 3 | Patient Identifier List | Varies | R | [1..\*] |  |  |  | GU Datatype: CX\_GU  NG Datatype: CX\_NG  Field used to convey all types of patient/person identifiers. This includes social security numbers, driver’s license numbers, medical record numbers, etc. |
| 4 | Alternate Patient ID – PID | CX | X | [0..0] |  |  |  | Deprecated as of *HL7 Version 2.3.1*. See PID-3. |
| 5 | Patient Name | XPN | R | [1..\*] |  |  |  | Patient name or aliases. When the name of the patient is not known, a value must still be placed in this field since the field is required. In that case, the second occurrence shall be valued with the following content: |~^^^^^^U|. The "U" for the name type code in the second name indicates that it is unspecified. Since there may be no name components populated, this means there is no legal name, nor is there an alias. This guide will interpret this sequence to mean there is no patient name. |
| 6 | Mother’s Maiden Name | XPN | RE | [0..1] |  |  |  | May be included for identification purposes. Name type code is constrained to the value "M." |
| 7 | Date/Time of Birth | TS | RE | [0..1] | 4..24 | = |  | Patient’s date of birth. The time zone component is optional. 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. Birth date may be used by the lab to calculate an age for the patient, which may affect what normal ranges apply to particular test results. Format: YYYY[MM[DD[HH[MM[SS[.S[S[S[S]]]]]]]]][+/-ZZZZ]  Timezone offset is optional.  Be as precise as appropriate and available. Particularly important for newborns. Precision at least YYYY  Note: If a birth date is not provided in the PID, then the patient age at specimen collection must be reported as an observation associated with the specimen. |
| 8 | Administrative Sex | IS | R | [0..1] | 1..20 |  | HL70001 | Patient’s gender. |
| 9 | Patient Alias | XPN | X | [0..0] |  |  |  | Deprecated as of *HL7 Version 2.4*. See PID-5 Patient Name. |
| 10 | Race | CE | RE | [0..\*] |  |  | HL70005 | One or more codes that broadly refer to the patient’s race(s). Note that state regulations may dictate other behaviors. |
| 11 | Patient Address | XAD | O | [0..\*] |  |  |  |  |
| 12 | County Code | IS | X | [0..0] | 1..20 |  |  | Deprecated as of *HL7 Version 2.3*. See PID-11 - Patient Address, component 9 County/Parish Code. |
| 13 | Phone Number – Home | XTN | O | [0..\*] |  |  |  |  |
| 14 | Phone Number – Business | XTN | O | [0..\*] |  |  |  |  |
| 15 | Primary Language | CWE | O | [0..\*] |  |  |  |  |
| 16 | Marital Status | CWE | O | [0..1] |  |  |  |  |
| 17 | Religion | CWE | O | [0..1] |  |  |  |  |
| 18 | Patient Account Number | CX | O | [0..1] |  |  |  |  |
| 19 | SSN Number – Patient | ST | X | [0..0] |  |  |  | Deprecated as of HL7 Version 2.3.1. See PID-3 Patient Identifier List. |
| 20 | Driver’s License Number – Patient | DLN | X | [0..0] |  |  |  | Deprecated as of HL7 Version 2.5. See PID-3 Patient Identifier List. |
| 21 | Mother’s Identifier | CX | O | [0..\*] |  |  |  |  |
| 22 | Ethnic Group | CWE | O | [0..\*] |  |  |  |  |
| 23 | Birth Place | ST | O | [0..1] | 1..250 |  |  |  |
| 24 | Multiple Birth Indicator | ID | O | [0..1] | 1..1 |  |  |  |
| 25 | Birth Order | NM | O | [0..1] | 1..2 |  |  |  |
| 26 | Citizenship | CWE | O | [0..\*] |  |  |  |  |
| 27 | Veterans Military Status | CWE | O | [0..1] |  |  |  |  |
| 28 | Nationality | CWE | X | [0..0] |  |  |  | Deprecated as of *HL7 Version 2.4*. See PID-10 Race, PID-22 Ethnic Group, and PID-26 Citizenship. |
| 29 | Patient Death Date and Time | TS | O | [0..1] |  |  |  |  |
| 30 | Patient Death Indicator | ID | O | [0..1] | 1..1 |  |  |  |
| 31 | Identity Unknown Indicator | ID | X | [0..1] | 1..1 |  |  |  |
| 32 | Identity Reliability Code | IS | O | [0..\*] | 1..20 |  |  |  |
| 33 | Last Update Date/Time | TS | O | [0..1] |  |  |  |  |
| 34 | Last Update Facility | HD | O | [0..1] |  |  |  |  |
| 35 | Species Code | CWE | X | [0..1] |  |  |  |  |
| 36 | Breed Code | CWE | X | [0..1] |  |  |  |  |
| 37 | Strain | ST | X | [0..1] |  |  |  |  |
| 38 | Production Class Code | CWE | X | [0..2] |  |  |  |  |
| 39 | Tribal Citizenship | CWE | X | [0..\*] |  |  |  |  |

Conformance Statement: Base Profile

LRI-XXX-X PID.1 (Set ID - PID) SHALL be valued with the constant value ‘1’.

**LRI-PID-1:** PID.7 (Date/Time of Birth) **SHALL** be valued with precision to the Year (YYYY) and **SHOULD** be precise to the hour.

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

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

**LRI-XXX-X PID.6.1 (**Name Type Code) **SHALL** be valued with the constant value ‘M’.

## NK1 – Next of Kin Segment

The Next of Kin segment is optional; please refer to the base standard for detailed information.

## PV1 – Patient Visit Information

The PV1 egment is optional; please refer to the base standard for detailed information.



## PV2 – Patient Visit

The PV2 segment is an optional segment that is a continuation of information contained in the PV1 segment; refer to the base standard.

## ORC – Common Order Segment

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

| Table 3‑8. Common Order Segment (ORC) | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| SEQ | Element Name | DT | Usage | Cardinality | LEN | C.LEN | Value Set | Description/Comments |
| 1 | Order Control | ID | R | [1..1] | 2..2 |  | HL70119 | Determiner of the function of the order segment. In the ORU^R01 this should be the literal value: "RE." |
| 2 | Placer Order Number | Varies | RE | [0..1] |  |  |  | GU Datatype: EI\_GU  NG Datatype: EI\_NG  Conformance Guidance: Echo as received from the order. |
| 3 | Filler Order Number | Varies | R | [1..1] |  |  |  | GU Datatype: EI\_GU  NG Datatype: EI\_NG  Note: In the circumstance where some of the lab results are generated by the lab, but others are performed by a reference lab, the sending lab can choose what filler order number to use. Regardless of what is used, the sending lab is expected to be able to trace all the observations in the lab result back to the appropriate source lab based on the filler order number provided in ORC-3. |
| 4 | Placer Group Number | Varies | RE | [0..1] |  |  |  | GU Datatype: EI\_GU  NG Datatype: EI\_NG  Conformance Guidance: Echo as received from the order.  The placer group number is used to identify a group of orders. In the laboratory setting this is commonly referred to as a "requisition number." |
| 5 | Order Status | ID | O | [0..1] | 2..2 |  |  |  |
| 6 | Response Flag | ID | O | [0..1] | 1..1 |  |  |  |
| 7 | Quantity/Timing |  | X |  |  |  |  |  |
| 8 | Parent | EIP | O | [0..1] |  |  |  |  |
| 9 | Date/Time of Transaction | TS | O | [0..1] |  |  |  |  |
| 10 | Entered By | XCN | O | [0..\*] |  |  |  |  |
| 11 | Verified By | XCN | O | [0..\*] |  |  |  |  |
| 12 | Ordering Provider | Varies | R | [1..1] |  |  |  | GU Datatype: XCN\_GU  NG Datatype: XCN\_NG |
| 13 | Enterer's Location | PL | O | [0..1] |  |  |  |  |
| 14 | Call Back Phone Number | XTN | O | [0..\*] |  |  |  |  |
| 15 | Order Effective Date/Time | TS | O | [0..1] |  |  |  |  |
| 16 | Order Control Code Reason | CWE | O | [0..1] |  |  |  |  |
| 17 | Entering Organization | CWE | O | [0..1] |  |  |  |  |
| 18 | Entering Device | CWE | O | [0..1] |  |  |  |  |
| 19 | Action By | XCN | O | [0..\*] |  |  |  |  |
| 20 | Advanced Beneficiary Notice Code |  | X |  |  |  |  |  |
| 21 | Ordering Facility Name | XON | O | [0..\*] |  |  |  |  |
| 22 | Ordering Facility Address | XAD | O | [0.\*] |  |  |  |  |
| 23 | Ordering Facility Phone Number | XTN | O | [0..\*] |  |  |  |  |
| 24 | Ordering Provider Address | XAD | O | [0..\*] |  |  |  |  |
| 25 | Order Status Modifier | CWE | O | [0..1] |  |  |  |  |
| 26 | Advanced Beneficiary Notice Override Reason | CWE | C(X/X) | [0..0] |  |  |  |  |
| 27 | Filler's Expected Availability Date/Time | TS | O | [0..1] |  |  |  |  |
| 28 | Confidentiality Code | CWE | O | [0..1] |  |  |  |  |
| 29 | Order Type | CWE | O | [0..1] |  |  |  |  |
| 30 | Enterer Authorization Mode | CNE | O | [0..1] |  |  |  |  |
| 31 | Parent Universal Service Identifier | CWE\_CR | C(R/X) | [0..1] |  |  |  | Condition Predicate: If OBR.50 (Parent Universal Service Identifier) is valued |

Conformance Statement: Base Profile

**LRI-ORC-1:** The value of ORC.2 (Placer Order Number) **SHALL** be identical to the value of OBR.2 (Placer Order Number).

**LRI-ORC-2:** The value of ORC.3 (Filler Order Number) **SHALL** be identical to the value of OBR.3 (Filler Order Number).

**LRI-ORC-3:** The value of ORC.12 (Ordering Provider) **SHALL** be identical to the value of OBR.16 (Ordering Provider).

Conformance Statement: LRI-NG Profile

**LRI-ORC-6:** The value of ORC.31 (Parent Universal Service Identifier) **SHALL** be identical to the value of OBR.50 (Parent Universal Service Identifier).

## OBR – Observation Request Segment

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

| Table 3‑9. Observation Request Segment (OBR) | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| SEQ | Element Name | DT | Usage | Cardinality | LEN | C.LEN | Value Set | Description/Comments |
| 1 | Set ID ‑ OBR | SI | R | [1..1] | 1..4 |  |  | For the first occurrence of the OBR segment, the Sequence number shall be one (1), for the second occurrence, the Sequence number shall be two (2), etc. |
| 2 | Placer Order Number | Varies | RE | [0..1] |  |  |  | GU Datatype: EI\_GU  NG Datatype: EI\_NG  Conformance Guidance: Echo as received from the order.  This identifier is assigned by the placer of the order being fulfilled by this result message. This identifier distinguishes the placer’s order from all other orders created by the placer where an order is interpreted to be the testing identified in a single OBR segment. Normally, it is a type of system identifier assigned by the placer software application.  The Placer Order Number and the Filler Order Number are essentially foreign keys exchanged between applications for uniquely identifying orders and the associated results across applications. |
| 3 | Filler Order Number | Varies | R | [1..1] |  |  |  | GU Datatype: EI\_GU  NG Datatype: EI\_NG  Order number associated with the Filling Application. This number is assigned to the test by the organization performing the test. This field should not contain the accession number or specimen identifier for a specimen unless these identifiers meet the criteria for a filler order number. The specimen or accession identifier should be placed in SPM-2. The Filler Order Number identifies this order as distinct from all other orders being processed by this filler where an order is interpreted to be the testing identified in a single OBR segment. Normally, this is a type of system identifier assigned by the filler software application.  The Filler Order Number, along with the Placer Order Number, is essentially foreign keys exchanged between applications for uniquely identifying orders and the associated results across applications.  In messages containing multiple OBRs, each OBR must be identified by a unique Filler Order Number. This is critical for making parent/child results relationships work properly. Microbiology cultures and sensitivities are linked in this fashion in this profile. See *Appendix A, Section 6.2. Linking Parent and Child Results,* of this document for more information on linking parent/child results. |
| 4 | Universal Service Identifier | CWE\_CR | R | [1..1] |  |  |  | Identifier code for the requested observation/test/ battery. |
| 5 | Priority – OBR | ID | X | [0..0] |  |  |  | Deprecated as of *HL7 Version 2.3*. See TQ1-9 Priority Field. |
| 6 | Requested Date/Time | TS | X | [0..0] |  |  |  | Deprecated as of *HL7 Version 2.3*. See TQ1-8 Start Date/Time. |
| 7 | Observation Date/Time | TS | RE | [1..1] | 8..24 | = |  | This reflects the specimen collection date/time when the test involves a specimen.  For specimen-based observations, the date/time the specimen was collected. Since a test may also involve drawing specimens at different times, e.g., tolerance tests, this date/time only covers the draw of the first specimen. All other specimen collection date/times, including the first one, are communicated in the SPM segment  For unknown collection date/time use "0000".  Format: YYYYMMDD[HH[MM[SS[.S[S[S[S]]]]]]]]+/-ZZZZ] except when reporting an unknown date of ‘0000”  Timezone offset is optional, but encouraged.  Be as precise as possible; particularly important for newborns. At least YYYYMMDD, and prefers HH and MM for newborns as well. |
| 8 | Observation End Date/Time | TS | RE | [0..1] | 8..24 | = |  | For specimen-based observations where the specimen was collected over a period of time, this represents the end point in time when the specimen was collected.  Timezone offset is optional but encouraged.  Be as precise as appropriate and available. Particularly important for newborns. At least YYYYMMDD, and prefers HH for newborns as welll. |
| 9 | Collection Volume | CQ | O | [0..0] |  |  |  |  |
| 10 | Collector Identifier | XCN | O | [0..\*] |  |  |  |  |
| 11 | Specimen Action Code | ID | RE | [0..1] | 1..1 |  | HL70065 |  |
| 12 | Danger Code | CWE | O | [0..1] |  |  |  |  |
| 13 | Relevant Clinical Information | CWE\_CRE | RE | [0..\*] |  |  |  |  |
| 14 | Specimen Received Date/Time | TS | X | [0..0] |  |  |  | Deprecated as of *HL7 Version 2.5*. See SPM-18 Specimen Received Date/Time. |
| 15 | Specimen Source | SPS | X | [0..0] |  |  |  | Deprecated as of *HL7 Version 2.5*. See SPM-4 Specimen Type. |
| 16 | Ordering Provider | Varies | R | [1..1] |  |  |  | GU Datatype: XCN\_GU  NG Datatype: XCN\_NG  Identifier of the provider who ordered the testing being performed. The National Provider Identifier (NPI) may be used as the identifier.  Note that ORC.12 Ordering Provider is constrained to contain the same value as this field. |
| 17 | Order Call-back Phone Number | XTN | O | [0..\*] |  |  |  |  |
| 18 | Placer Field 1 | ST | O | [0..1] | 1..199 |  |  | Conformance Guidance: Echo as received from the order. |
| 19 | Placer Field 2 | ST | O | [0..1] | 1..199 |  |  | Conformance Guidance: Echo as received from the order. |
| 20 | Filler Field 1 | ST | O | [0..1] | 1..199 |  |  |  |
| 21 | Filler Field 2 | ST | O | [0..1] | 1..199 |  |  |  |
| 22 | Results Rpt/Status Chng - Date/Time | TS | R | [1..1] | 8..24 | = |  | Required field in this message. Applies to the entire report. Receipt of a subsequent message with the same Filler Number and a different status in this field implies that processing may need to occur at the receiving application level to update a previous report.  Format: YYYYMMDDHHMMSS.SS[…]+/-ZZZZ  Timezone offset is optional and encouraged. |
| 23 | Charge to Practice | MOC | O | [0..1] |  |  |  |  |
| 24 | Diagnostic Service Sect ID | ID | O | [0..1] | 2..3 |  |  |  |
| 25 | Result Status | ID | R | [1..1] | 1..1 |  | HL70123 |  |
| 26 | Parent Result | PRL | C(R/RE) | [0..1] |  |  |  | Condition Predicate: If OBR.11 (Specimen Action Code) is valued “G”  Field that, together with OBR-29 Parent, allows this result to be linked to a specific OBX segment associated with another OBR segment. See *Section 6.2. Linking Parent and Child Results,* of this document for more information on linking parent/child results. |
| 27 | Quantity/Timing | TQ | X | [0..0] |  |  |  | Deprecated as of *HL7 Version 2.5*. See TQ1 and TQ2 segments. |
| 28 | Result Copies To | Varies | C(R/X) | [0..\*] |  |  |  | Condition Predicate:  GU Profile: XCN\_GU  NG Profile: XCN\_NG |
| 29 | Parent | Varies | C(R/RE) | [0..1] |  |  |  | Condition Predicate: If OBR.11 (Specimen Action Code) is valued “G”  GU Profile: EIP\_GU  NG Profile: EIP\_NG  Used to link this OBR with a parent OBR. Commonly used with microbiology messages to link a susceptibility result with the parent culture that identified the organism. For this linkage to work properly, the Placer Order Number and the Filler Order Number must uniquely identify the specific parent OBR. This means that the same Filler Number cannot be used to identify multiple OBRs. See *Appendix A, Section 6.2. Linking Parent and Child Results*, of this document for more information on linking parent/child results. |
| 30 | Transportation Mode | ID | O | [0..1] | 4..4 |  |  |  |
| 31 | Reason for Study | CWE | O | [0..\*] |  |  |  |  |
| 32 | Principal Result Interpreter | NDL | O | [0..1] |  |  |  |  |
| 33 | Assistant Result Interpreter | NDL | O | [0..\*] |  |  |  |  |
| 34 | Technician | NDL | O | [0..\*] |  |  |  |  |
| 35 | Transcriptionist | NDL | O | [0..\*] |  |  |  |  |
| 36 | Scheduled Date/Time | TS | O | [0..1] |  |  |  |  |
| 37 | Number of Sample Containers | NM | O | [0..1] | 1..16 |  |  |  |
| 38 | Transport Logistics of Collected Sample | CWE | O | [0..\*] |  |  |  |  |
| 39 | Collector's Comment | CWE | O | [0..\*] |  |  |  |  |
| 40 | Transport Arrangement Responsibility | CWE | O | [0..1] |  |  |  |  |
| 41 | Transport Arranged | ID | O | [0..1] | 1..1 |  |  |  |
| 42 | Escort Required | ID | O | [0..1] | 1..1 |  |  |  |
| 43 | Planned Patient Transport Comment | CWE | O | [0..\*] |  |  |  |  |
| 44 | Procedure Code | CWE | O | [0..1] |  |  |  |  |
| 45 | Procedure Code Modifier | CWE | O | [0..\*] |  |  |  |  |
| 46 | Placer Supplemental Service Information | CWE | O | [0..\*] |  |  |  |  |
| 47 | Filler Supplemental Service Information | CWE | O | [0..\*] |  |  |  |  |
| 48 | Medically Necessary Duplicate Procedure Reason | CWE | O | [0..1] |  |  |  |  |
| 49 | Result Handling | IS | O | [0..1] |  |  |  |  |
| 50 | Parent Universal Service Identifier | Varies | Varies | [0..1] |  |  |  | GU Usage: O  NG Usage: C(R/X)  NG Condition Predicate: If OBR.29 (Parent) is valued  GU Datatype: CWE  NG Datatype: CWE\_CR  OBR.50 contains the universal service identifier of the parent order. |

Usage Note

In the circumstance where some of the lab results are generated by the lab, but others are performed by a reference lab, the sending lab can choose what filler order number to use. Whichever filler order number is used, the sending lab is expected to be able to trace all the observations in the lab result back to the appropriate source lab based on the filler order number provided in OBR-3.

Conformance Statement: Base Profile

**LRI-XXX-X:** The value of OBR.1 (Set ID – OBR) **SHALL** be valued sequentially starting with the value ‘1’.

**LRI-OBR-1:** The value of OBR.2 (Placer Order Number) **SHALL** be identical to the value of ORC.2 (Placer Order Number).

**LRI-OBR-2:** The value of OBR.3 (Filler Order Number) **SHALL** be identical to the value of ORC.3 (Filler Order Number).

**LRI-OBR-3:** The value of OBR.7 (Observation Date/Time) and OBR.8 (Observation End Date/Time) **SHALL** be precise to the DAY (YYYYMMDD) and **SHALL** be capable of being precise to the minute (YYMMDDHHMM).

**LRI-OBR-4:** The value of OBR.22 (Results Rpt/Status Chng - Date/Time) **SHALL** be precise to the DAY (YYYYMMDD) and **SHOULD** be precise to the second (YYYYMMDDHHMMSS).

**LRI-OBR-5:** If SPM segment is present, the value of OBR.7 (Observation Date/Time) **SHALL** be identical to SPM.17 (Specimen Collection Date/Time).

**LRI-OBX-6:** If an OBX segment is related to this OBR, the value of OBX.14 (Date/Time of the Observation) **SHALL** be identical to OBR.7 (Observation Date/Time).

**LRI-OBR-7:** If valued, OBR.11 (Specimen Action Code) **SHALL** be a value with “A”, “G”, “L”, or “O”.

**LRI-OBR-8:** The value of OBR.12 (Ordering Provider) **SHALL** be identical to the value of ORC.3 (Ordering Provider).

Conformance Statement: LRI-NG Profile

**LRI-OBR-11:** The value of OBR.50 (Parent Universal Service Identifier) **SHALL** be identical to the value of ORC.31 (Parent Universal Service Identifier).

## TQ1 – Timing/Quantity Segment

The TQ1 segment is used to specify the timing of events and actions such as those that occur in order management and scheduling systems.

| Table 3‑10. TimING/QuaNTity Segment for Order Group | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| SEQ | Element Name | DT | Usage | Cardinality | LEN | C.LEN | Value Set | Description/Comments |
| 1 | Set ID - TQ1 | SI | R | [1..1] | 1..4 |  |  | Sequence number of the timing specification, the first of which shall be 1; the second of which shall be 2; and so on. |
| 2 | Quantity | CQ | O | [0..1] |  |  |  |  |
| 3 | Repeat Pattern | RPT | O | [0..\*] |  |  |  |  |
| 4 | Explicit Time | TM | O | [0..\*] |  |  |  |  |
| 5 | Relative Time and Units | CQ | O | [0..\*] |  |  |  |  |
| 6 | Service Duration | CQ | O | [0..1] |  |  |  |  |
| 7 | Start date/time | TS | C(R/RE) | [0..1] | 4..24 | = |  | Condition Predicate: If TQ1.8 (End date/time) is not valued  Conformance Guidance: Echo as received from the order. |
| 8 | End date/time | TS | C(R/RE) | [0..1] | 4..24 | = |  | Condition Predicate: If TQ1.7 (Start date/time) is not valued  Conformance Guidance: Echo as received from the order. |
| 9 | Priority | CWE | O | [0..\*] |  |  |  |  |
| 10 | Condition text | TX | O | [0..1] | 1..250 |  |  |  |
| 11 | Text instruction | TX | O | [0..1] | 1..250 |  |  |  |
| 12 | Conjunction | ID | O | [0..1] | 1..1 |  |  |  |
| 13 | Occurrence duration | CQ | O | [0..1] |  |  |  |  |
| 14 | Total occurrence's | NM | O | [0..1] | 1..10 |  |  |  |

Usage Note

In the circumstance where some of the lab results are generated by the lab, but others are performed by a reference lab, the sending lab can choose what filler order number to use., Which ever filler order number is used, the sending lab is expected to be able to trace all the observations in the lab result back to the appropriate source lab based on the filler order number provided in OBR-3.

Conformance Statement: Base Profile

**LRI-TQ1-1:** The value of TQ1.1 (Set ID – T Q1) **SHALL** be valued sequentially starting the value ‘1’.

**LRI-TQ1-2:** The value of TQ1.7 (Start Date/Time) and TQ1.8 (End Date/Time) **SHALL** be echoed from the order.

## OBX – Observation/Result Segment

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

| Table 3‑11. Observation Result Segment (OBX) | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| SEQ | Element Name | DT | Usage | Cardinality | LEN | C.LEN | Value Set | Description/Comments |
| 1 | Set ID – OBX | SI | R | [1..1] | 1..4 |  |  | For the first repeat of the OBX segment, the sequence number shall be one (1), for the second repeat, the sequence number shall be two (2), etc. |
| 2 | Value Type | ID | C(R/X) | [0..1] | 2..3 |  | HL70125 | Condition Predicate: If OBX.5 (Observation Value) is valued  This field identifies the data type used for OBX-5. |
| 3 | Observation Identifier | CWE\_CR | R | [1..1] |  |  | Logical Observation Identification Name and Codes (LOINC) | LOINC shall be used as the standard coding system for this field if an appropriate LOINC code exists. Appropriate status is defined in the LOINC Manual Section 11.2 Classification of LOINC Term Status. If a local coding system is in use, a local code should also be sent to help with identification of coding issues. When no valid LOINC exists the local code may be the only code sent.  LOINC is used as the coding system for this field. Local codes may also be used in conjunction with LOINC codes  When populating this field with values, this guide does not give preference to the triplet in which the standard (LOINC) code should appear. |
| 4 | Observation Sub-ID | ST | C(R/RE) | [0..1] | 1..20 |  |  | Condition Predicate: |
| 5 | Observation Value | Var | RE | [0..1] |  |  | SNOMED CT shall be used when a code exists for Microbiology results; otherwise a local code. |  |
| 6 | Units | CE | C(R/RE) | [0..1] |  |  |  | Condition Predicate: If OBX.2 (Value Type) is valued as “NM” or “SN” and OBX.11 is not “X”  UCUM (Unified Code for Units of Measure) will be evaluated during the pilot for potential subsequent inclusion. As part of the pilot test, for dimensionless units the UCUM representation could be {string}, e.g., for titer the pilot might use {titer} to test feasibility. When sending units of measure as text, they must be placed in the correct component of OBX.6 (CE.2 or CE.5). |
| 7 | References Range | ST | RE | [0..1] | 1..60 | = |  | Interpretation range that applies to the value reported in OBX-5. It should provide enough information to understand the abnormal flags reported in OBX-8.  Note: It is not appropriate to send the reference range for a result in an associated NTE segment. It would be appropriate to send information amplifying the reference range provided in this field in an NTE associated with this OBX. |
| 8 | Abnormal Flags | IS | RE | [0..\*] | 1..4 | # | HL70078 (2.7.1) | Indicator of the normalcy of the result found in OBX-5. Cardinality indicates the possible need for multiple abnormal flags, as in the following example: *Example: Hemoglobin has a normal range of 12-16  Initial result (reported in a separate ORU message based on testing an earlier specimen): HGB = 15.9 (results normal)  Current result (in this OBX based on current specimen): HGB = 11.9 abnormality: (L) below low normal and a (D) significant change down (delta > 3).*  In this example, OBX-8 would be set to |*L~D*|.  Microbiology example:  Ceftazidime susceptibility (LOINC 133-9) value = |<=^1|, units = ug/ml, Abnormal flag = S  Note that this IG is adopting HL70078 from 2.7.1. |
| 9 | Probability | NM | O | [0..1] | 1..5 |  |  |  |
| 10 | Nature of Abnormal Test | ID | O | [0..1] | 1..2 |  |  |  |
| 11 | Observation Result Status | ID | R | [1..1] | 1..1 |  | HL70085 | Status of the observation result. |
| 12 | Effective Date of Reference Range | TS | O | [0..1] |  |  |  |  |
| 13 | User-Defined Access Checks | ST | O | [0..1] | 20 |  |  |  |
| 14 | Date/Time of the Observation | TS | RE | [0..1] | 8..24 | = |  | Emphasize that it reflects the clinically relevant date/time, not when it is run on the machine or interpreted.  For specimen based test, if it is valued it must be the same as SPM.17  If SPM.17 is present and relates to the same observation, then OBX.14 must be within the DR range.  Timezone offset is optional, but strongly encourage, format: YYYYMMDDHHMMSS.SS[…]+/-ZZZZ)  Be as precise as appropriate and available. Shall support at least YYYYMMDDHHMM. For newborn needs to be down to YYYYMMDDHH, possibly minutes, while other YYYYMMDD could be appropriate. |
| 15 | Producer’s Reference | CE | O | [0..1] |  |  |  |  |
| 16 | Responsible Observer | Varies | RE | [0..\*] |  |  |  | GU Datatype: XCN\_GU  NG Datatype: XCN\_NG |
| 17 | Observation Method | CWE | RE | [0..\*] |  |  | HL7 V3 Observation Method | Method of testing by the laboratory. |
| 18 | Equipment Instance Identifier | EI | O | [0..\*] |  |  |  |  |
| 19 | Date/Time of the Analysis | TS | RE | [0..1] |  |  |  | Time at which the testing was performed.  Be as precise as appropriate and available. Timezone offset is required.  Sender: Must support at least YYYYMMDDHHMM.  Receiver: Must support at least YYYYMMDDHHMM |
| 20 | Reserved for harmonization with *Version 2.6.* | (TBD) | X | [0..0] |  |  |  | Not supported. |
| 21 | Reserved for harmonization with *Version 2.6*. | (TBD) | X | [0..0] |  |  |  | Not supported. |
| 22 | Reserved for harmonization with *Version 2.6*. | (TBD) |  | [0..0] |  |  |  | Not supported. |
| 23 | Performing Organization Name | Varies | R | [1..1] |  |  |  | GU Datatype: XON\_GU  NG Datatype: XON\_NG  The information for producer ID is recorded as an XON data type.  For laboratories, this field specifies the laboratory that produced the test result described in this OBX segment. This information supports CLIA regulations in the US. For producing laboratories that are CLIA-certified, the CLIA identifier should be used for the organization identifier (component 10). |
| 24 | Performing Organization Address | XAD | R | [1..1] |  |  |  | Address of the laboratory that actually performed the test when used as a reference laboratory. |
| 25 | Performing Organization Medical Director | Varies | RE | [0..1] |  |  |  | GU Datatype: XCN\_GU  NG Datatype: XCN\_NG  Name of the Medical Director of the reference laboratory. Required when OBX-24 indicates the performing lab is in a jurisdiction that requires this information. |

Conformance Statement: Base Profile

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

**LRI-OBX-2:** If there are multiple OBX segments with the same OBX-3 values under the same OBR, a combination of OBX-3 and OBX-4 **SHALL** create a unique identification under a singl**e OBR.**

**LRI-OBX-3:** If OBX.5 (Observation Value) is valued, then OBX.2 (Value Type) **SHALL** support datatypes CE, DT, NM, SN, ST, TM, TS, TX, FT and CWE.

**LRI-OBX-4:** If OBX.5 (Observation Value) is valued, then OBX.2 (Value Type) **MAY** support datatypes CX, ED, and RP.

**LRI-OBX-5:** If OBX.5 (Observation Value) is valued, then OBX.2 (Value Type) **SHALL NOT** support remaining datatypes in Table HL70125.

**LRI-OBX-7:** If OBX.5 (Observation Value) is CE, then CE.1 (Identifier) and CE.3 (Name of Coding System) or CE. 4 (Alternate Identifier) and CE.6 (Name of Alternate Coding System) **SHALL** be valued.

**LRI-OBX-8:** If OBX.2 (Value Type) is valued as “NM” or “SN” and OBX.11 is not “X”, then OBX.6 (Units) **SHALL** be required/mandatory.

**LRI-OBX-10**: OBX.14 (Date/Time of the Observation) **SHALL** be precise to the hour (YYYYMMDDHH) and **MAY** include the timezone offset.

**LRI-OBX-11**: OBX19 (Date/Time of the Analysis) **SHALL** be precise to the hour (YYYYMMDDHH) and **SHALL** include the timezone offset.

## Observation Identifiers, Observation Values, Interpretations and Comments

Laboratory results fall into several broad categories or types of results. The first type of result is a quantitative measure of some property of a specimen and is typically numerical in nature. Often these numeric results are also associated with some sort of interpretation, typically in terms of the normality or abnormality of the measured quantity in relationship to a reference range or normal range. Another type of result is a qualitative result related to the testing of a specimen. This is typically coded or textual in nature. Qualitative results may actually be interpretations of more detailed quantitative measurement. Finally, both quantitative and qualitative results may have comments associated with them. These comments may provide additional clarification, information regarding how the result was obtained, etc.

This guide assumes that LOINC is normally being used for the identification of observations if an appropriate LOINC code exists. Appropriate status is defined in the LOINC Manual Section 11.2 Classification of LOINC Term Status. LOINC identifiers can easily be classified as quantitative or qualitative. The LOINC scale property QN (quantitative) indicates that the LOINC identifier is quantitative. All other LOINC identifiers can be treated as qualitative for the purpose of this discussion. Those OBX’s associated with quantitative LOINC identifiers should be using OBX-5 with either the NM (numeric), SN (structured numeric), TS (timestamp), DT (date) or TM (time) data types. These quantitative results can be accompanied by an interpretation. Coded interpretations should be reported using OBX-8 (abnormal flags) when the values have been drawn from HL7 table 0078.

The LOINC scale property for qualitative results can fall into four types:

1. Ordinal (ORD): OBX-3 observations with qualitative LOINC test codes using ordinal result scales may fully specify the analyte/component measured in OBX-3, thus only requiring a “Presence/Absence” code to fully specify the observation.
2. Nominal (NOM): OBX-3 observations with "presence or identity" LOINC test codes using nominal result scales to fully specify the observation.
   * Bacterial cultures may require a SNOMED CT concept from the "organism" hierarchy
3. Narrative (NAR): OBX-3 observations with narrative LOINC test codes use ST or TX data type in OBX.5.
4. Ordinal or Quantitative (OrdQn): This type is used by Susceptibility tests that may be reported as qualitative (i.e. susceptible, resistant) or as quantitative, numeric results (e.g. Minimum Inhibitory Concentration MIC).

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

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

The above discussion has focused on actual clinical findings, whether they are quantitative or qualitative. Often, additional clarifying documentation is sent along with the clinical findings. These should be handled as comments, conveyed in an NTE segment(s) following the OBX in question. Comments typically fall into the following categories:

* Comments about how a clinical finding was reached
* Clarification regarding the meaning of a clinical finding
* Additional information not directly related to the clinical finding such as contact information for the lab, disclaimers, etc.
* Most canned, or boiler plate text associated with a result falls into the comment category

The following table gives examples of how the different fields in the OBX segment interact to create the complete observation.

| Table 3‑12. 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 along with interpretation | NM | QN | number | May be populated with UCUM Units | May be populated with codes from HL7 table 0078 | May be populated | May be populated with comments, not clinical findings. |
| Numerical intervals, ratios, inequalities | SN | QN | structured numeric | May be populated with UCUM Units | May be populated with codes from HL7 table 0078 | May be populated | May be populated with comments, not clinical findings. |
| Time like quantitative result with interpretation | TS, TM, DT | QN | timestamp, time or date | [empty] | May be populated with codes from HL7 table 0078 | May be populated | May be populated with comments, not clinical findings. |
| Conveys ordinal value and interpretation | CWE | ORD | Ordinal as a code. SNOMED CT shall be used when code exists for Microbiology results; otherwise a local code. | [empty] | May be populated with codes from HL7 table 0078 | May be populated | May be populated with comments, not clinical findings. |
| Conveys ordinal value and interpretation | SN | ORD | Ordinal as structured numeric | [empty] | May be populated with codes from HL7 table 0078 | Required | May be populated with comments, not clinical findings. |
| Conveys observation and interpretation | CWE | NOM | Coded observation. SNOMED CT shall be used when code exists for Microbiology results; otherwise a local code. | [empty] | May be populated with codes from HL7 table 0078 | May be populated | May be populated with comments, not clinical findings. |
| Conveys observation and interpretation | FT, TX or ST | NAR | text | [empty] | May be populated with codes from HL7 table 0078 | May be populated | May be populated with comments, not clinical findings. |
| Conveys numeric or ordinal value and interpretation | NM | ORDQN | Number | May be populated with UCUM Units | May be populated with codes from HL7 table 0078 | May be populated | May be populated with comments, not clinical findings. |
| Conveys numeric or ordinal value and interpretation | CWE | ORDQN | Ordinal as a code. SNOMED CT shall be used when code exists for Microbiology results; otherwise a local code. | [empty] | May be populated with codes from HL7 table 0078 | May be populated | May be populated with comments, not clinical findings. |
| Conveys observation and interpretation | FT, TX or ST | MULTI | text | [empty] | May be populated with codes from HL7 table 0078 | May be populated | May be populated with comments, not clinical findings. |
| Conveys imbedded object (ED) or pointer to object (RP) | ED, RP | Varies | Object pointer or imbedded object | [empty] | [empty] | [empty] | May be populated with comments, not clinical findings. |

## SPM – Specimen Segment

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

| Table 3‑13. Specimen Segment (SPM) | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| SEQ | Element Name | DT | Usage | Cardinality | LEN | C.LEN | Value Set | Description/Comments |
| 1 | Set ID – SPM | SI | R | [1..1] | 1..4 |  |  | For the first repeat of the SPM segment, the sequence number shall be one (1), for the second repeat, the sequence number shall be two (2), etc. |
| 2 | Specimen ID | EIP | O | [0..1] |  |  |  |  |
| 3 | Specimen Parent IDs | EIP | O | [0..\*] |  |  |  |  |
| 4 | Specimen Type | CWE\_CRE | R | [1..1] |  |  | SNOMED CT and/or  HL70487 | Description of the precise nature of the entity that is the source material for the observation. |
| 5 | Specimen Type Modifier | CWE | O | [0..\*] |  |  |  |  |
| 6 | Specimen Additives | CWE | O | [0..\*] |  |  |  |  |
| 7 | Specimen Collection Method | CWE | O | [0..1] |  |  |  |  |
| 8 | Specimen Source Site | CWE | O | [0..1] |  |  |  |  |
| 9 | Specimen Source Site Modifier | CWE | O | [0..\*] |  |  |  |  |
| 10 | Specimen Collection Site | CWE | O | [0..1] |  |  |  |  |
| 11 | Specimen Role | CWE | O | [0..\*] |  |  |  |  |
| 12 | Specimen Collection Amount | CQ | O | [0..1] |  |  |  |  |
| 13 | Grouped Specimen Count | NM | O | [0..1] | 1..6 |  |  |  |
| 14 | Specimen Description | ST | O | [0..1] |  |  |  |  |
| 15 | Specimen Handling Code | CWE | O | [0..\*] |  |  |  |  |
| 16 | Specimen Risk Code | CWE | O | [0..\*] |  |  |  |  |
| 17 | Specimen Collection Date/Time | DR | RE | [1..1] | 8..24 | = |  | Time range over which the sample was collected, as opposed to the time the sample collection device was recovered. This value should be the same as OBR.7, unless a new specimen was drawn at the testing laboratory.  The first component of the date range must match OBR-7 Observation Date/Time. The second component must match OBR-8 Observation End Date/Time. For OBXs reporting observations based on this specimen, OBX-14 should contain the same value as component 1 of this field.  A minimum of year, month and day must be provided when the actual date/time is known. For unknown collection date/time use "0000".  Format: |YYYYMMDD[HH[MM[SS[.S[S[S[S]]]]]]][+/-ZZZZ]^YYYYMMDD[HH[MM[SS[.S[S[S[S]]]]]]][+/-ZZZZ]|  Timezone offset is required.  Be as precise as appropriate and available. At least YYYYMMDD. For newborn needs to be down to the hours, possibly minutes. |
| 18 | Specimen Received Date/Time | TS | O | [0..1] |  |  |  |  |
| 19 | Specimen Expiration Date/Time | TS | O | [0..1] |  |  |  |  |
| 20 | Specimen Availability | ID | O | [0..1] | 1..1 |  |  |  |
| 21 | Specimen Reject Reason | CWE | RE | [0..\*] |  |  | HL70490 |  |
| 22 | Specimen Quality | CWE | RE | [0..1] |  |  | HL70491 |  |
| 23 | Specimen Appropriateness | CWE | RE | [0..1] |  |  | HL70492 |  |
| 24 | Specimen Condition | CWE | RE | [0..\*] |  |  | HL70493 |  |
| 25 | Specimen Current Quantity | CQ | O | [0..1] |  |  |  |  |
| 26 | Number of Specimen Containers | NM | O | [0..1] | 1..4 |  |  |  |
| 27 | Container Type | CWE | O | [0..1] |  |  |  |  |
| 28 | Container Condition | CWE | O | [0..1] |  |  |  |  |
| 29 | Specimen Child Role | CWE | O | [0..1] |  |  |  |  |

## NTE – Notes and Comments Segment

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

| Table 3‑14. Notes and Comments Segment (NTE) | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| SEQ | Element Name | DT | Usage | Cardinality | LEN | C.LEN | Value Set | Description/Comments |
| 1 | Set ID – NTE | SI | R | [1..1] |  |  |  | For the first repeat of the NTE segment, the sequence number shall be one (1), for the second repeat, the seqence number shall be two (2), etc. |
| 2 | Source of Comment | ID | O | [0..1] | 1..1 |  |  |  |
| 3 | Comment | FT | R | [1..\*] |  |  |  | Comment contained in the segment. |
| 4 | Comment Type | CE | O | [0..1] |  |  |  |  |

# Code Systems and Value Sets

Successful message implementation requires that transmitted messages (message instances) contain valid values for coded fields. It is important to note that code sets are relatively dynamic and subject to change between publications of these implementation guides.

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

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

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

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

## HL7 Tables

Tables in this guide are as specified in the HL7 Version 2.5.1 Standard, except as noted below.

* HL7 Table 0065-Specimen Action Code is pre-adopted from HL7 Version 2.7.1
* HL7 Table 0078-Interpretation Codes is pre-adopted from HL7 Version 2.7.1
* HL7 Table 0203-Identifier Type is pre-adopted from HL7 Version 2.7.1
* HL7 Table 0291-Subtype of referenced data is pre-adopted from HL7 Version 2.7.1
* HL7 Table 0301-Universal ID Type is pre-adopted from HL7 Version 2.7.1
* HL7 Table 0834-MIME Types is pre-adopted from HL7 Version 2.7.1

## LOINC

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

Further information on LOINC and access to tools, please visit <http://loinc.org/>

## SNOMED CT

OBX.5

SNOMED CT is a required vocabulary for communicating Microbiology related results reported as Coded With Exception (CWE) data types in OBX.5 (and identified as CWE in OBX.2), when a SNOMED code has been published. It is not intended as a required vocabulary for any other specialty. For results other than Microbiology, the use of SNOMED would need to be negotiated between trading partners. If a SNOMED code is not published for a Microbiology coded result, it is acceptable to use an alternate coding system (and identified as CWE in OBX.2). If results are reported as text only and not coded, the string (ST) data type should be used in OBX.5 (and identified as ST in OBX.2). When SNOMED CT is used in OBX.5, CWE.9 shall contain the laboratory’s original text which is used for printing and/or display.

For Microbiology coded results, the following hierarchies are applicable.

1. Organism identification using SNOMED CT organism hierarchy
2. Organism-related substances (e.g. toxin, DNA, RNA, antigen, antibody, etc.) from the SNOMED CT substance hierarchy
3. Organism presence and absence findings using SNOMED CT qualifier values (e.g. positive, negative, present, absent)

Example HL7 Messages

General Format for OBX.2 = CWE (SNOMED CT required when published)

OBX|1|CWE|LOINC code^Loinc Longname^LOINC code sytemID|| CWE.1=SNOMED CT ConceptID^CWE.2=description^CWE.3=SNOMED CT code systemID^CWE.4=alt. code ^CWE.5=alt. description ^CWE.6=alt. code system ^CWE.7=SNOMED CT code system version ^CWE.8=alt. code system version ^CWE.9=original text ||||||F|||200808151030-0700|||0086^Bacterial identification^OBSMETHOD^^^^501-20080815||200808161030-0700||||Reliable Labs, Inc^L^^^^CLIA&2.16.840.1.113883.19.4.6&ISO^XX^^^1236|3434 Industrial Loop^^Ann Arbor^MI^99999^USA^B|9876543^Slide^Stan^S^^^^^NPPES&2.16.840.1.113883.19.4.6&ISO^L^^^NPI

1. SNOMED-Specific Format for OBX.2 = CWE (SNOMED CT required when available code is published)
   1. Example of organism finding with generic LOINC in Nominal scale:

OBX|1|**CWE**|626-2^ Bacteria identified in Throat by Culture^LN||413643004^Beta-hemolytic Streptococcus, group A^SCT^bstrep^beta hemolytic Streptococci^L^20110731^1^ beta-hemolytic streptococcus isolated||||||F|||200808151030-0700|||0086^Bacterial identification^OBSMETHOD^^^^501-20080815||200808161030-0700||||Reliable Labs, Inc^L^^^^CLIA&2.16.840.1.113883.19.4.6&ISO^XX^^^1236|3434 Industrial Loop^^Ann Arbor^MI^99999^USA^B|9876543^Slide^Stan^S^^^^^NPPES&2.16.840.1.113883.19.4.6&ISO^L^^^NPI

* 1. Example of substance finding with generic LOINC in Nominal scale:

OBX|1|**CWE**|6551-6 ^Streptococcus agalactiae Ag [Presence] in Throat by Immunofluorescence^LN|| 260208006^Group B Streptococcus antigen^SCT^bstrepAG^beta hemolytic Streptococci Antigen identified^L^20110731^1^ beta-hemolytic streptococcus antigen detected||||||F|||200808151030-0700|||0086^Bacterial identification^OBSMETHOD^^^^501-20080815||200808161030-0700||||Reliable Labs, Inc^L^^^^CLIA&2.16.840.1.113883.19.4.6&ISO^XX^^^1236|3434 Industrial Loop^^Ann Arbor^MI^99999^USA^B|9876543^Slide^Stan^S^^^^^NPPES&2.16.840.1.113883.19.4.6&ISO^L^^^NPI

* 1. Example for presence finding with organism specific LOINC in Ordinal scale:

OBX|1|**CWE**|546-2^Streptococcus.beta-hemolytic [Presence] in Throat by Organism specific culture^LN||46651001^isolated^SCT^bstrep^beta hemolytic Streptococci^L^20110731^1^ beta-hemolytic streptococcus isolated||||||F|||200808151030-0700|||0086^Bacterial identification^OBSMETHOD^^^^501-20080815||200808161030-0700||||Reliable Labs, Inc^L^^^^CLIA&2.16.840.1.113883.19.4.6&ISO^XX^^^1236|3434 Industrial Loop^^Ann Arbor^MI^99999^USA^B|9876543^Slide^Stan^S^^^^^NPPES&2.16.840.1.113883.19.4.6&ISO^L^^^NPI

2. General Format for OBX.2 = ST (SNOMED CT not required)

OBX|1|**ST**|546-2^Streptococcus.beta-hemolytic [Presence] in Throat by Organism specific culture^LN^^^^||beta-hemolytic streptococcus isolated||||||F|||200808151030-0700|||0086^Bacterial identification^OBSMETHOD^^^^501-20080815||200808161030-0700||||Reliable Labs, Inc^L^^^^CLIA&2.16.840.1.113883.19.4.6&ISO^XX^^^1236|3434 Industrial Loop^^Ann Arbor^MI^99999^USA^B|9876543^Slide^Stan^S^^^^^NPPES&2.16.840.1.113883.19.4.6&ISO^L^^^NPI

SPM.4

SNOMED CT is a suggested vocabulary for specimen source terms in SPM.4 when a SNOMED CT code is available for the specimen source, pending the outcome of pilot testing. Specimen type/source terms in SPM.4 should be drawn from the specimen hierarchy in SNOMED CT or may be drawn from HL7 table 0487 as it is a commonly used vocabulary, for example in use with NAACCR (until deprecated by HL7).

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

Further information on SNOMED can be found at the [National Library of Medicine](http://www.nlm.nih.gov/research/umls/Snomed/snomed_main.html).

## UCUM

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

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

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

## Vocabulary Constraints

Table 4‑1. Value Set/Code System Summary shows the various value sets/code systems used in this IG. It also provides information about the source of the vocabulary and an identifier for the vocabulary. The name found in the Value Set/Code System Name column corresponds with the value set identified in the Value Set column of the data type and segment attribute tables found above.

| Table 4‑1. Value Set/Code System Summary | | | | |
| --- | --- | --- | --- | --- |
| Name | Source ID/ Reference | Source | Unique Identifier | Comments |
| Country Value Set | HL70399 | HL7 Version 2.5.1 |  | Refer to HL7 V2.5.1 Message, Chapter 2, Section 2.15.9.1  This identifies the codes for the representation of names of countries, territories and areas of geographical interest. The complete set of 3166-1 codes. <http://www.iso.org/iso/iso-3166-1_decoding_table> |
| Administrative Sex | HL70001 | HL7 Version 2.5.1 | 2.16.840.1.113883.12.1 |  |
| Marital Status | HL70002 | HL7 Version 2.5.1 | 2.16.840.1.113883.12.2 |  |
| Event Type | HL70003 | HL7 Version 2.5.1 | 2.16.840.1.113883.12.3 | Constrained to ‘R01’ |
| Patient Class | HL70004 | HL7 Version 2.5.1 | 2.16.840.1.113883.12.4 |  |
| Race Category | HL70005 | HL7 Version 2.5.1 | 2.16.840.1.113883.6.238 |  |
| Acknowledgment Code | HL70008 | HL7 Version 2.5.1 | 2.16.840.1.113883.12.8 |  |
| Check Digit Scheme | HL70061 | HL7 Version 2.5.1 | 2.16.840.1.113883.12.61 |  |
| Specimen Action Code | HL70065 | HL7 Version 2.7.1 | 2.16.840.1.113883.12.65 | Constrained to A, G, L, O |
| Message Type | HL70076 | HL7 Version 2.5.1 | 2.16.840.1.113883.12.76 | Constrained to ORU, ACK |
| Observation Interpretation | HL70078 | HL7 Version 2.7.1 | 2.16.840.1.113883.12.78 |  |
| Observation Result Status | HL70085 | HL7 Version 2.5.1 | 2.16.840.1.113883.12.85 |  |
| Processing ID | HL70103 | HL7 Version 2.5.1 | 2.16.840.1.113883.12.103 |  |
| Version ID | HL70104 | HL7 Version 2.5.1 | 2.16.840.1.113883.12.104 | Constrained to ‘v2.5.1’ |
| Order Control | HL701119 | HL7 Version 2.5.1 | 2.16.840.1.113883.12.119 |  |
| Observation Result Status | HL70123 | HL7 Version 2.5.1 | 2.16.840.1.113883.12.123 |  |
| Value Type | HL70125 | HL7 Version 2.5.1 | 2.16.840.1.113883.12.125 | Constrained as follows:  R for CE, DT, NM, SN, ST, TM, TS, TX, FT, CWE  RE for CX, ED, RP (requires agreement between trading partners) |
| Accept/Application Acknowledgment Condition | HL70155 | HL7 Version 2.5.1 | 2.16.840.1.113883.12.155 |  |
| Ethnic Group | HL70189 | HL7 Version 2.5.1 | 2.16.840.1.113883.6.238 |  |
| Address Type | HL70190 | HL7 Version 2.5.1 | 2.16.840.1.113883.12.190 | . |
| Type of Referenced Data | HL70191 | HL7 Version 2.5.1 | 2.16.840.1.113883.12.191 |  |
| Name type | HL70200 | HL7 Version 2.5.1 | 2.16.840.1.113883.12.200 |  |
| Identifier type | HL70203 | HL7 Version 2.7.1 | 2.16.840.1.113883.12.203 |  |
| Subtype of referenced data | HL70291 | HL7 Version 2.7.1 | 2.16.840.1.113883.12.291 |  |
| Encoding | HL70299 | HL7 Version 2.5.1 | 2.16.840.1.113883.12.299 |  |
| Universal ID type | HL70301 | HL7 Version 2.7.1 | 2.16.840.1.113883.12.301 |  |
| Message structure | HL70354 | HL7 Version 2.5.1 | 2.16.840.1.113883.12.354 | Constrained to ORU\_R01, ACK |
| Message Error Condition Codes | HL70357 | HL7 Version 2.5.1 | 2.16.840.1.113883.12.357 |  |
| Coding Systems | HL70396 | HL7 <http://www.hl7.org/special/committees/vocab/table_0396/index.cfm> | 2.16.840.1.113883.12.396 | HL7 Table 0396 defines the standard coding systems recognized by HL7. The table defines a mechanism by which locally defined codes can be transmitted. Any code/coding system not defined in HL7 Table 0396 is considered a “local” coding system from the HL7 perspective. Coding systems that are identified in this implementation guide will be identified according to the recommended HL7 nomenclature from table 0396 as “99-zzz” where “zzz” represents a string identifying the specific non-standard coding system. To maintain backwards compatibility with the 2.3.1 ELR implementation Guide, coding systems defined locally (i.e., not identified in this guide) and not defined in HL7 Table 0396 can continue to identify the coding system as “L”. It is strongly suggested that implementers instead adopt the use of “99zzz” approach to identifying local coding systems since HL7 has indicated that use of the “L” for local coding systems is retained only for backwards compatibility, and its use may be withdrawn in a subsequent 2.x version. Note that the local use of “99zzz” should not collide with any of the “locally” defined coding systems identified in this implementation guide.  HL7 now maintains HL7 table 0396 “real time”. This means that values may be added to the table at any time so that implementers can have an up-to-date source of truth for the codes to be used to identify coding systems in any 2.x message. Users of this IG should acquire the latest version of HL7 table 0396. The latest version of HL7 table 0396 (independent of HL7 version) is available for download from HL7 at: <http://www.hl7.org/special/committees>/vocab/table\_0396/index.cfm. |
| Specimen Type | HL70487 | HL7 Version 2.5.1 | 2.16.840.1.113883.12.487 |  |
| Sequence Condition Code | HL70504 | HL7 Version 2.5.1 | 2.16.840.1.113883.12.504 |  |
| Cyclic Entry/Exit Indicator | HL70505 | HL7 Version 2.5.1 | 2.16.840.1.113883.12.505 |  |
| Service Request Relationship | HL70506 | HL7 Version 2.5.1 | 2.16.840.1.113883.12.506 |  |
| Error severity | HL70516 | HL7 Version 2.5.1 | 2.16.840.1.113883.12.516 |  |
| MIME Types | HL70834 | HL7 Version 2.7.1 | 2.16.840.1.113883.12.834 | Imported Table 0834  Note that the HITSP Lab to EHR IG uses HL70191, which can be directly mapped to the 2.7.1 values imported from IANA. |
| Laboratory Coded Observation Value Set |  | TBD | TBD | Drawn from SNOMED CT. See Usage Notes. |
| Laboratory Observation Identifier Value Set |  | TBD | TBD | Unique identifiers for the type of observations. Values must be drawn from LOINC and is required for use with any test on the in-scope test list. |
| LOINC |  | LOINC | 2.16.840.1.113883.6.1  (code system) | Logical Observation Identifiers Names and Codes  http://www.loinc.org |
| New codesystem for new OBR Field |  | TBD | TBD | Values are:  R-Results Copy Requested  E - Result Copy Enclosed per Order Provider's request |
| County () | FIPS 6-4 |  | 2.16.840.1.114222.4.11.829 | Codes representing county of origin, address county, reporting county  Also referred to as HL70289 |
| Language () | ISO\_639-2\_Alpha3 | ISO | 2.16.840.1.114222.4.11.831 | Primary spoken language  Note that HITSP identifies a language value set as follows:  “The value set is defined by Internet RFC 4646 (replacing RFC 3066). Please see ISO 639 language code set maintained by Library of Congress for enumeration of language codes and Frequently Asked Questions.”  RFC4646 seems to point to ISO 639 as the source of the actual language codes, so this value set is consistent with the HITSP value set. |
| Postal Code Value Set |  | US Postal Service via HITSP C-80, 20090708 V1.1 | 2.16.840.1.113883.3.88.12.80.2 | This identifies the postal (ZIP) Code of an address in the United States  <http://zip4.usps.com/zip4/welcome.jsp> |
| SNOMED CT |  | SNOMED CT | 2.16.840.1.113883.6.96 | SNOMED CT  http://www.nlm.nih.gov/research/umls/Snomed/snomed\_main.html |
| Specimen Type Value Set |  | TBD | TBD | Specimen Type  Union of HL70487 and SNOMED CT Specimen hierarchy |
| State Value Set | FIPS 5-2 | HITSP C-80,20090708 V1.1 | 2.16.840.1.113883.3.88.12.80.1 | Identifies addresses within the United States are recorded using the FIPS 5-2 two-letter alphabetic codes for the State, District of Columbia, or an outlying area of the United States or associated area. <http://www.itl.nist.gov/fipspubs/fip5-2.htm> |
| Unified Code for Units of Measure (UCUM) |  | Regenstrief Institute, Inc. <http://www.regenstrief.org/medinformatics/ucum> | 2.16.840.1.113883.3.88.12.80.29 | Units of measure concepts that includes atomic UCUM units as well as UCUM expression. Commonly used UCUM units of measure concepts can be obtained from UCUM Web Site <http://www.regenstrief.org/medinformatics/ucum>  A tool for converting non-UCUM units of measure to the equivalent UCUM units is available at:  <http://www.regenstrief.org/medinformatics/ucum/unit-conversion-tool> |

Usage Notes

**Laboratory Coded Observation Value Set**

For specific result categories:

Organisms

* Identify using codes from the SNOMED CT “organism” hierarchy
  + This will normally exclude the use of codes from the “clinical finding” hierarchy representing the presence of a specific organism (e.g., "312210001^methicillin resistant staphylococcus aureus positive^SCT”, "431256002^culture positive for vancomycin resistant enterococcus^SCT”, "441070005^Human enterovirus present^SCT”). However, in some cases a specific absence finding may be appropriate (e.g., "404520004^no Chlamydia trachomatis found^SCT”).

Organism-related substances (e.g. toxin, DNA, RNA, antigen, antibody, etc.)

* Identify using codes from the SNOMED CT “substance” hierarchy (e.g., "12671002^Clostridium difficile toxin^SCT”, "121181000^Chlamydia trachomatis DNA^SCT”, "121006005^influenza virus A antigen^SCT”)
  + This will normally exclude the use of codes from the “clinical finding” hierarchy representing the presence of a specific organism-related substance (e.g., "310541005^Clostridium difficile toxin A detected^SCT”). Currently (as of the January 2011 release) we are not aware of any SNOMED CT codes representing the absence of an organism-related substance.

Presence and absence findings

* Identify using codes from the SNOMED CT “qualifier value" hierarchy (e.g., "52101004^present^SCT”, "10828004^positive^SCT”, "2667000^absent^SCT”, "260385009^negative^SCT”)

Anatomic Pathology

* Use of SNOMED CT codes is recommended, but further evaluation is needed to determine which hierarchies are appropriate for use
  + The NAACCR examples list "abnormal morphology" codes

Clinical genomics and additional clinical areas

* Consider whether other vocabularies in addition to, or in place of, SNOMED CT might apply

## HL7 Tables

This section provides values for HL7 tables that have had constraints applied to them in this IG.

## HL7 Table 0065 – Specimen Action Code from HL7 V2.7.1 Message - Constrained

| Table 4‑2. HL7 Table 0065 Specimen Action Code - constrained | | |
| --- | --- | --- |
| Value | Description | Comment |
| A | Add ordered tests to the existing specimen |  |
| G | Generated order; reflex order |  |
| L | Lab to obtain specimen from patient |  |
| O | Specimen obtained by service other than Lab |  |

## HL7 Table 0076 – Message Type 2.5.1 (constrained)

| Table 4‑3. HL7 Table 0076 from 2.5.1 - constrained | | |
| --- | --- | --- |
| Value | Description | Comment |
| ORU | Unsolicited transmission of an observation message |  |
| ACK | General acknowledgment message |  |

## HL7 Table 0078 – Interpretation Codes from HL7 V2.7.1 Message

| Table 4‑3. HL7 Table 0078 from 2.7.1 | | |
| --- | --- | --- |
| 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 2.7.1 |
| NEG | Negative | Added in HL7 Version 2.7.1 |
| IND | Indeterminate | Added in HL7 Version 2.7.1 |
| DET | Detected | Added in HL7 Version 2.7.1 |
| ND | Not Detected | Added in HL7 Version 2.7.1 |
| AC | Anti-complementary substances present | Added in HL7 Version 2.7.1 |
| TOX | Cytotoxic substance present | Added in HL7 Version 2.7.1 |
| QCF | Quality Control Failure | Added in HL7 Version 2.7.1 |
| RR | Reactive | Added in HL7 Version 2.7.1 |
| WR | Weakly reactive | Added in HL7 Version 2.7.1 |
| NR | Non-reactive | Added in HL7 Version 2.7.1 |

## HL7 Table 0125 – Value Type (Constrained from the Full HL7 Table)

| Table 4‑4. HL7 Table 0125 – Value Type | | | | |
| --- | --- | --- | --- | --- |
| Value | Description | Use | C.LEN | Comment |
| CE | Coded Entry | R |  |  |
| CWE | Coded with Exceptions | R |  | This Implementation Guide has a specially constrained version of the CWE data type in section 0 above which is used for OBX-5. The CWE\_CRE shall not be used for OBX-5. The version of the CWE constrained for use with OBX-5 requires sending coded data. If the lab is trying to send only string data, the ST, TX or FT data types should be used.  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.* |
| CX | Extended Composite ID With Check Digit | O |  |  |
| DT | Date | R |  |  |
| ED | Encapsulated Data | O |  | Field using the ED data type to allow communication of images, sound clips, XML documents, html markup, etc.  Requires agreement between trading partners |
| FT | Formatted Text (Display) | R |  | Field using the FT data type to carry a text result value. This is intended for display. The text may contain formatting escape sequences as described in the data types section. Numeric results and numeric results with units of measure should not be reported as text. These should be reported as NM or SN numeric results, with the units of measure in OBX-6. |
| NM | Numeric | R |  | Field using the NM data type to carry a numeric result value. The only non-numeric characters allowed in this field are a leading plus (+) or minus (-) sign. The structured numeric (SN) data type should be used for conveying inequalities, ranges, ratios, etc. The units for the numeric value should be reported in OBX-6. |
| RP | Reference Pointer | O |  | 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 intervals (^0^-^1), ratios (^1^/^2 or ^1^:^2), inequalities (<^10), or categorical results (2^+). The units for the structured numeric value should be reported in OBX-6. |
| ST | String Data | R |  | Field using the ST data type to carry a short text result value. Numeric results and numeric results with units of measure should not be reported as text. These shall be reported as NM or SN numeric results, with the units of measure in OBX-6. |
| TM | Time | R |  |  |
| 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 from HL7 V2.7.1

| Table 4‑6. HL7 Table 0203 – from 2.7.1 | | |
| --- | --- | --- |
| Value | Description | Comment |
| AM | American Express |  |
| AN | Account number |  |
| ANC | Account number Creditor |  |
| AND | Account number debitor |  |
| ANON | Anonymous identifier |  |
| ANT | Temporary Account Number |  |
| APRN | Advanced Practice Registered Nurse number |  |
| BA | Bank Account Number |  |
| BC | Bank Card Number |  |
| BR | Birth registry number |  |
| BRN | Breed Registry Number |  |
| CC | Cost Center number |  |
| CY | County number |  |
| DDS | Dentist license number |  |
| DEA | Drug Enforcement Administration registration number |  |
| DFN | Drug Furnishing or prescriptive authority Number |  |
| DI | Diner\_s Club card |  |
| DL | Driver\_s license number |  |
| DN | Doctor number |  |
| DO | Osteopathic License number |  |
| DPM | Podiatrist license number |  |
| DR | Donor Registration Number |  |
| DS | Discover Card |  |
| EI | Employee number |  |
| EN | Employer number |  |
| FI | Facility ID |  |
| GI | Guarantor internal identifier |  |
| GL | General ledger number |  |
| GN | Guarantor external identifier |  |
| HC | Health Card Number |  |
| IND | Indigenous/Aboriginal |  |
| JHN | Jurisdictional health number (Canada) |  |
| LI | Labor and industries number |  |
| LN | License number |  |
| LR | Local Registry ID |  |
| MA | Patient Medicaid number |  |
| MB | Member Number |  |
| MC | Patient's Medicare number |  |
| MCD | Practitioner Medicaid number |  |
| MCN | Microchip Number |  |
| MCR | Practitioner Medicare number |  |
| MD | Medical License number |  |
| MI | Military ID number |  |
| MR | Medical record number |  |
| MRT | Temporary Medical Record Number |  |
| MS | MasterCard |  |
| NE | National employer identifier |  |
| NH | National Health Plan Identifier |  |
| NI | National unique individual identifier |  |
| NII | National Insurance Organization Identifier |  |
| NIIP | National Insurance Payor Identifier (Payor) |  |
| NNxxx | National Person Identifier where the xxx is the ISO table 3166 3-character (alphabetic) country code |  |
| NP | Nurse practitioner number |  |
| NPI | National provider identifier |  |
| OD | Optometrist license number |  |
| PA | Physician Assistant number |  |
| PCN | Penitentiary/correctional institution Number |  |
| PE | Living Subject Enterprise Number |  |
| PEN | Pension Number |  |
| PI | Patient internal identifier |  |
| PN | Person number |  |
| PNT | Temporary Living Subject Number |  |
| PPN | Passport number |  |
| PRC | Permanent Resident Card Number |  |
| PRN | Provider number |  |
| PT | Patient external identifier |  |
| QA | QA number |  |
| RI | Resource identifier |  |
| RN | Registered Nurse Number |  |
| RPH | Pharmacist license number |  |
| RR | Railroad Retirement number |  |
| RRI | Regional registry ID |  |
| SID | Specimen identifier |  |
| SL | State license |  |
| SN | Subscriber Number |  |
| SR | State registry ID |  |
| SS | Social Security number |  |
| TAX | Tax ID number |  |
| TN | Treaty Number/ (Canada) |  |
| U | Unspecified identifier |  |
| UPIN | Medicare/CMS (formerly HCFA)\_s Universal Physician Identification numbers |  |
| VN | Visit number |  |
| VS | VISA |  |
| WC | WIC identifier |  |
| WCN | Workers\_ Comp Number |  |
| XX | Organization identifier |  |

## HL7 Table 0291 – Subtype Of Referenced Data

| Table 4‑5. HL7 Table 0291 – Subtype Of Referenced Data | | |
| --- | --- | --- |
| Value | Description | Comment |
|  | Source RFC 2046 | MIME media subtypes established in accordance with RFC 2046 (http://ietf.org/rfc/rfc2046.txt) and registered with the Internet Assigned Numbers Authority (http://www.iana.org/numbers.html). Note that the MIME media subtype values are case-insensitive, in accordance with RFC 2045. |
| x-hl7-cda-level-one | HL7 Clinical Document Architecture Level One document | Not supported. |

## HL7 Table 0301 - Universal ID Type

| Table 4‑6. HL7 Table 0301 - Universal ID Type | | | |
| --- | --- | --- | --- |
| Value | Description | Use | Comments |
| CLIA | Clinical Laboratory Improvement Amendments. Allows for the ability to designate organization identifier as a "CLIA" assigned number (for labs) | RE | Use in MSH.4 allowed |
| DNS | An Internet dotted name. Either in ASCII or as integers | ? | ? |
| GUID | Same as UUID. | ? | ? |
| CEN | The CEN Healthcare Coding Scheme Designator. (Identifiers used in DICOM follow this assignment scheme.) | ? | ? |
| HL7 | Reserved for future HL7 registration schemes | ? | ? |
| ISO | An International Standards Organization Object Identifier | R | Used as the Universal ID Type in the CNN, EI and HD data types. |
| L,M,N | These are reserved for locally defined coding schemes. | ? | ? |
| Random | Usually a base64 encoded string of random bits.  The uniqueness depends on the length of the bits. Mail systems often generate ASCII string \_unique names," from a combination of random bits and system names. Obviously, such identifiers will not be constrained to the base64 character set. | ? | ? |
| URI | Uniform Resource Identifier | R | Used as the Universal ID Type in the RP data type |
| UUID | The DCE Universal Unique Identifier | ? | ? |
| x400 | An X.400 MSH format identifier | ? | ? |
| x500 | An X.500 directory name | ? | ? |

## HL7 Table 0354 – Message Structurefrom 2.5.1 (constrained)

Table 4‑8. HL7 Table 0354 – from 2.5.1 (constrained)

| Value | Description | Use | Comments |
| --- | --- | --- | --- |
| ORU\_R01 | Unsolicited transmission of an observation message | R |  |
| ACK\_R01 | General Acknowledgment Message for unsolicited transmission of an observation message | R |  |

## HL7 Table 0834 – MIME Type

Adopted from V2.7.1

Table 4‑7. HL7 Table 0834 – MIME Type

| Value | Description | Use | Comments |
| --- | --- | --- | --- |
| application | Application data | ? |  |
| audio | Audio data | R |  |
| image | Image data | R |  |
| model | Model data | ? |  |
| text | Text data | R |  |
| video | Video data | R |  |
| multipart | MIME multipart package | ? |  |

## HL7 Table new – ??? from 2.7.1

Table 4‑10. HL7 Table 0??? – from 2.7.1

| Value | Description | Usage | Comments |
| --- | --- | --- | --- |
| E | Result Copy Enclosed per Order Provider's request | R |  |
| R | Results Copy Requested | R |  |

# Example Laboratory Result Messages

**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 information in this section is informative and not normative.

**Release Note:** Examples will be provided for this section that are conformant to the statements in the final version of this Release (R1).

# Additional Implemenation Guidance

## Culture and Susceptibilities Reporting

## Introduction

Parent-child relationships, such as culture and sensitivities, can be reported using the HL7 electronic messaging standard. However, this is an area where many vendors and large laboratories have augmented the standard to account for variations in the systems with which they work. This usually does not present a problem until these messages must be shared between systems (for instance, between laboratories and sub-contracted laboratories, or between laboratories and public health agencies).

Parent-child information such as culture and susceptibilities (*e.g.*, reporting of multi-resistant tuberculosis or drug-resistant gonococcus or pneumococcus) is a critical component of electronic, laboratory-based public health reporting.

The approach described here is required for use in reporting microbiology results for this message profile.

## Template for Culture Results

A template report for the initial identification of three organisms from a single stool culture is presented below. For each field (*i.e.*, the space between the pipes, "|"), a description of what should appear in that particular field is given, along with the segment-field number in parentheses (*e.g.*, OBR-3) for some of the fields. Note that these examples use the ORU^R01 message type.

**Release Note:** Revised examples will be provided for this section that are conformant to the statements in the final version of this Release (R1). The examples in the shaded below are all subject to change.

|  |
| --- |
| MSH|…  PID|…  OBR|1| Placer number | Filler number | Identifier code for the requested test or panel of tests(OBR-4) |…  OBX|1|CE| Specific organism identifier (OBX-3) | Sub-id for the **first** organism (OBX-4) | Description of organism (OBX-5) |…  OBX|2|SN| Other identifier (OBX-3) | Sub-id for the **first** organism (OBX-4) | Observation on the organism (OBX-5) |…  OBX|3|CE| Specific organism identifier (OBX-3) | Sub-id for the **second** organism (OBX-4) | Description of organism (OBX-5) |…  OBX|4|SN| Other identifier (OBX-3) | Sub-id for the **second** organism (OBX-4) | Observation on the Organism (OBX-5) |…  OBX|5|CE| Specific organism identifier (OBX-3) | Sub-id for the **third** organism (OBX-4) | Description of organism (OBX-5) |…  OBX|6|SN| Other identifier (OBX-3) | Sub-id for the **third** organism (OBX-4) | Observation on the organism (OBX-5) |…  SPM|1| Specimen identifier for the specimen being tested|\_ |

This report has the MSH (Message Header), the PID (Patient Identification Segment), a single OBR (Observation Request Segment), and six OBX (Observation/Results) segments, and a single SPM (Specimen Segment). Note that the Set ID in the first field of each OBX isSEQuential, while the Sub-ID in the fourth field of each OBX is notSEQuential, but acts as a link for all of the OBX segments that are reporting information for a related observation. The Sub-ID field in the template above has the words "first," "second" and "third" in **bold** and highlighted in green. This is done to show that the identification of the first organism is the relating observation for the first two OBX segments (*e.g.*, Set-ID numbers 1 and 2). The identification of the second organism is the relating observation for the second two segments (*e.g.*, Set-ID numbers 3 and 4), and so on. An example using the template above is presented below.

## Examples of Culture Results

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

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

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

Identified organisms must be reported as coded data instead of text data. Coded data enables machine processing of results. String data can normally be interpreted only by humans.

|  |
| --- |
| MSH|^~\&|Lab1^1234^CLIA|Reliable^1234^CLIA|ELR^2.16.840.1.113883.19.3.2.3^ISO|SPH^2.16.840.1.113883.19.3.2^ISO|20070701132554-0400||ORU^R01^ORU\_R01|20070701132554000008|P^T|2.5.1|||NE|NE|USA||||USELR1.0^^2.16.840.1.113883.19.9.7^ISO  SFT|1|Level Seven Healthcare Software, Inc.^L^^^^&2.16.840.1.113883.19.4.6^ISO^XX^^^1234|1.2|An Lab System|56734||20080817  PID|1||36363636^^^MPI&2.16.840.1.113883.19.3.2.1&ISO^MR^A&2.16.840.1.113883.19.3.2.1&ISO~444333333^^^&2.16.840.1.113883.4.1^ISO^SS||Everyman^Adam^A^^^^L^^^^^^^BS|Mum^Martha^M^^^^M|19750602|M||2106-3^White^CDCREC^^^^04/24/2007|2222 Home Street^^Ann Arbor^MI^99999^USA^H||^PRN^PH^^1^555^5552004|^WPN^PH^^1^955^5551009|eng^English^ISO6392^^^^3/29/2007|M^Married^HL70002^^^^2.5.1||||||N^Not Hispanic or Latino^HL70189^^^^2.5.1||||||||N|||200808151000-0700|Reliable^2.16.840.1.113883.19.3.1^ISO  ORC|RE|23456^EHR^2.16.840.1.113883.19.3.2.3^ISO|9700123^Lab^2.16.840.1.113883.19.3.1.6^ISO|||||||||1234^Admit^Alan^A^III^Dr^^^&2.16.840.1.113883.19.4.6^ISO^L^^^EI^&2.16.840.1.113883.19.4.6^ISO^^^^^^^^MD||^WPN^PH^^1^555^5551005|||||||Level Seven Healthcare, Inc.^L^^^^&2.16.840.1.113883.19.4.6^ISO^XX^^^1234|1005 Healthcare Drive^^Ann Arbor^MI^99999^USA^B|^WPN^PH^^1^555^5553001|4444 Healthcare Drive^Suite 123^Ann Arbor^MI^99999^USA^B  OBR|1|23456^EHR^2.16.840.1.113883.19.3.2.3^ISO|9700123^Lab^2.16.840.1.113883.19.3.1.6^ISO|625-4^Bacteria identified^LN^3456543^ CULTURE, STOOL^99USI^2.26|||200808151030-0700||||||diarrhea|||1234^Admit^Alan^A^III^Dr^^^&2.16.840.1.113883.19.4.6^ISO^L^^^EI^&2.16.840.1.113883.19.4.6^ISO^^^^^^^^MD|^WPN^PH^^1^555^5551005|||||2008081830-0700|||P||||||787.91^DIARRHEA^I9CDX^^^^07/09/2008|1235&Slide&Stan&S&&Dr&MD&&DOC&2.16.840.1.113883.19.4.6&ISO  OBX|1|CWE|625-4^Bacteria identified:Prid:Pt:Stool:Nom:Culture^LN^^^^2.26|**1**|66543000^Campylobacter jejuni^SCT^^^^January 2007||||||P|||200808151030-0700|||0086^Bacterial identification^OBSMETHOD^^^^501-20080815||200808161030-0700||||Reliable Labs, Inc^L^^^^CLIA&2.16.840.1.113883.19.4.6&ISO^XX^^^1236|3434 Industrial Loop^^Ann Arbor^MI^99999^USA^B|9876543^Slide^Stan^S^^^^^NPPES&2.16.840.1.113883.19.4.6&ISO^L^^^NPI  OBX|2|SN|564-5^COLONY COUNT:NUM:PT:XXX:QN:VC^LN^^^^2.26|**1**|^10000^-^90000|1^^UCUM^^^^1.6|||||P|||200808151030-0700|||||200808161030-0700||||Reliable Labs, Inc^L^^^^CLIA&2.16.840.1.113883.19.4.6&ISO^XX^^^1236|3434 Industrial Loop^^Ann Arbor^MI^99999^USA^B|9876543^Slide^Stan^S^^^^^NPPES&2.16.840.1.113883.19.4.6&ISO^L^^^NPI  OBX|3|CWE|625-4^Bacteria identified:Prid:Pt:Stool:Nom:Culture^LN^^^^2.26|**2**|302620005^Salmonella group B phase 1 a-e^SCT^^^^January 2007||||||P|||200808151030-0700|||0086^Bacterial identification^OBSMETHOD^^^^501-20080815||200808161030-0700||||Reliable Labs, Inc^L^^^^CLIA&2.16.840.1.113883.19.4.6&ISO^XX^^^1236|3434 Industrial Loop^^Ann Arbor^MI^99999^USA^B|9876543^Slide^Stan^S^^^^^NPPES&2.16.840.1.113883.19.4.6&ISO^L^^^NPI  OBX|4|SN|564-5^COLONY COUNT:NUM:PT:XXX:QN:VC^LN^^^^2.26|**2**|>^100000|1^^UCUM^^^^1.6|||||P|||200808151030-0700|||||200808161030-0700||||Reliable Labs, Inc^L^^^^CLIA&2.16.840.1.113883.19.4.6&ISO^XX^^^1236|3434 Industrial Loop^^Ann Arbor^MI^99999^USA^B|9876543^Slide^Stan^S^^^^^NPPES&2.16.840.1.113883.19.4.6&ISO^L^^^NPI  OBX|5|CWE|625-4^Bacteria identified:Prid:Pt:Stool:Nom:Culture^LN^^^^2.26|**3**|77352002^Shigella^SCT^^^^January 2007||||||P|||200808151030-0700|||0086^Bacterial identification^OBSMETHOD^^^^501-20080815||200808161030-0700||||Reliable Labs, Inc^L^^^^CLIA&2.16.840.1.113883.19.4.6&ISO^XX^^^1236|3434 Industrial Loop^^Ann Arbor^MI^99999^USA^B|9876543^Slide^Stan^S^^^^^NPPES&2.16.840.1.113883.19.4.6&ISO^L^^^NPI  OBX|6|SN|564-5^COLONY COUNT:NUM:PT:XXX:QN:VC^LN^^^^2.26|**3**|<^1000|1^^UCUM^^^^1.6|||||P|||200808151030-0700|||||200808161030-0700||||Reliable Labs, Inc^L^^^^CLIA&2.16.840.1.113883.19.4.6&ISO^XX^^^1236|3434 Industrial Loop^^Ann Arbor^MI^99999^USA^B|9876543^Slide^Stan^S^^^^^NPPES&2.16.840.1.113883.19.4.6&ISO^L^^^NPI  SPM|1|23456&EHR&2.16.840.1.113883.19.3.2.3&ISO^9700122&Lab&2.16.840.1.113883.19.3.1.6&ISO||119339001^Stool specimen^SCT^^^^20080131|||||||P^Patient^HL60369^^^^2.5.1|10^g&gram&UCUM&&&&1.6|||||200808151030-0700|200808151100-0700 |

## Template for Culture and Susceptibility Results

The template and example in the *Template for Culture Results* section of this appendix describe a report for a culture. The following template shows how antimicrobial susceptibility results are reported for the culture described in that section. The connection of the culture to the susceptibilities is a "parent-child" relationship, where the culture is the parent result and the susceptibilities are the child results. This means that there can be many child results for a single parent result. In other words, there can be multiple OBR child segments for the single OBR parent segment presented in the *Template for Culture Results* section of this appendix. The template for the report containing the culture and susceptibilities appears below. The titles in *Italics* are given to highlight the individual parent and child segments and are not found in an actual HL7 message transmission. It is important to note that in each of the OBR child segments there is a pointer back to the parent result. This pointer is found in OBR-26 (Parent Result) and in OBR-29 (Parent Number).

|  |
| --- |
| ***Message Header and Patient Identification Segment for the Parent-Child Message***  MSH|…  PID|…  ***Parent OBR Segment***  OBR|1| Placer number (OBR-2) | Filler order number (OBR-3) | Identifier code for the requested test or panel of tests (OBR-4) |…  ***Parent OBX Segments for First Organism Identified***  OBX|1|CE| Specific organism identifier (OBX-3) | Sub-id for the **first** organism (OBX-4) | Description of organism (OBX-5) |…  OBX|2|SN| Other identifier (OBX-3) | Sub-id for the **first** organism (OBX-4) | Observation on the organism (OBX-5) |…  ***Parent OBX Segments for Second Organism Identified***  OBX|3|CE| Specific organism identifier (OBX-3) | Sub-id for the **second** organism (OBX-4) | Description of organism (OBX-5) |…  OBX|4|SN| Other identifier (OBX-3) | Sub-id for the **second** organism (OBX-4) | Observation on the Organism (OBX-5) |…  ***Parent OBX Segments for Third Organism Identified***  OBX|5|CE| Specific organism identifier (OBX-3) | Sub-id for the **third** organism (OBX-4) | Description of organism (OBX-5) |…  OBX|6|SN| Other identifier (OBX-3) | Sub-id for the **third** organism (OBX-4) | Observation on the organism (OBX-5) |…  ***Child OBR for First Organism identified***  OBR|2| Placer number (OBR-2)| Filler order number (OBR-3) | Identifier code for the requested test or panel of tests (OBR-4) |||||||||||||||||||||| A **pointer** back to the parent OBX segment that contained the identification of the **first** organism, see below for description of "Pointers" (OBR-26) ||| Parent Filler order number (OBR-29) |...  ***Child OBX Segments for Susceptibilities of First Organism Identified***  OBX|1|CE|Specific susceptibility identifier for first antimicrobial (OBX-3) || Susceptibility finding (OBX-5) ||| Susceptibility interpretation (OBX-8) |…  OBX|2|CE|Specific susceptibility identifier for second antimicrobial (OBX-3) || Susceptibility finding (OBX-5) ||| Susceptibility interpretation (OBX-8) |…  OBX|3|CE|Specific susceptibility identifier for third antimicrobial (OBX-3) || Susceptibility finding (OBX-5) ||| Susceptibility interpretation (OBX-8) |…  ***Child OBR Segment for Susceptibilities of Second Organism Identified***  OBR|3| Placer number (OBR-2)| Filler order number (OBR-3) | Identifier code for the requested test or panel of tests (OBR-4) |||||||||||||||||||||| A **pointer** back to the parent OBX segment that contained the identification of the **second** organism, see below for description of "Pointers" (OBR-26) ||| Parent Filler order number (OBR-29) |...  ***Child OBX Segments for Susceptibilities of Second Organism Identified***  OBX|1|CE|Specific susceptibility identifier for first antimicrobial (OBX-3) || Susceptibility finding (OBX-5) ||| Susceptibility interpretation (OBX-8) |…  OBX|2|CE|Specific susceptibility identifier for second antimicrobial (OBX-3) || Susceptibility finding (OBX-5) ||| Susceptibility interpretation (OBX-8) |…  OBX|3|CE|Specific susceptibility identifier for third antimicrobial (OBX-3) || Susceptibility finding (OBX-5) ||| Susceptibility interpretation (OBX-8) |…  ***Child OBR Segment for Susceptibilities of Third Organism Identified***  OBR|3| Placer number (OBR-2)| Filler order number (OBR-3) | Identifier code for the requested test or panel of tests (OBR-4) |||||||||||||||||||||| A **pointer** back to the parent OBX segment that contained the identification of the **third** organism, see below for description of "Pointers" (OBR-26) ||| Parent Filler order number (OBR-29) |...  ***Child OBX Segments for Susceptibilities of Third Organism Identified***  OBX|1|CE|Specific susceptibility identifier for first antimicrobial (OBX-3) || Susceptibility finding (OBX-5) ||| Susceptibility interpretation (OBX-8) |…  OBX|2|CE|Specific susceptibility identifier for second antimicrobial (OBX-3) || Susceptibility finding (OBX-5) ||| Susceptibility interpretation (OBX-8) |…  OBX|3|CE|Specific susceptibility identifier for third antimicrobial (OBX-3) || Susceptibility finding (OBX-5) ||| Susceptibility interpretation (OBX-8) |…  ***SPM Segment***  SPM|1| Specimen identifier for the specimen being tested|… |

## Examples of Culture and Susceptibility Results

Using the template above, this example shows a report of three pathogens identified from a stool specimen with their respective antimicrobial susceptibility tests.

|  |
| --- |
| MSH|^~\&| Lab1^1234^CLIA|Reliable^1234^CLIA|ELR^2.16.840.1.113883.19.3.2.3^ISO|SPH^2.16.840.1.113883.19.3.2^ISO|20070701132554-0400||ORU^R01^ORU\_R01|20070701132554000008|P^T|2.5.1|||NE|NE|USA||||USELR1.0^^2.16.840.1.113883.19.9.7^ISO  SFT|1|Level Seven Healthcare Software, Inc.^L^^^^&2.16.840.1.113883.19.4.6^ISO^XX^^^1234|1.2|An Lab System|56734||20080817  PID|1||36363636^^^MPI&2.16.840.1.113883.19.3.2.1&ISO^MR^A&2.16.840.1.113883.19.3.2.1&ISO~444333333^^^&2.16.840.1.113883.4.1^ISO^SS||Everyman^Adam^A^^^^L^^^^^^^BS|Mum^Martha^M^^^^M|19750602|M||2106-3^White^CDCREC^^^^04/24/2007|2222 Home Street^^Ann Arbor^MI^99999^USA^H||^PRN^PH^^1^555^5552004|^WPN^PH^^1^955^5551009|eng^English^ISO6392^^^^3/29/2007|M^Married^HL70002^^^^2.5.1||||||N^Not Hispanic or Latino^HL70189^^^^2.5.1||||||||N|||200808151000-0700|Reliable^2.16.840.1.113883.19.3.1^ISO  ORC|RE|23456^EHR^2.16.840.1.113883.19.3.2.3^ISO|9700123^Lab^2.16.840.1.113883.19.3.1.6^ISO|||||||||1234^Admit^Alan^A^III^Dr^^^&2.16.840.1.113883.19.4.6^ISO^L^^^EI^&2.16.840.1.113883.19.4.6^ISO^^^^^^^^MD||^WPN^PH^^1^555^5551005|||||||Level Seven Healthcare, Inc.^L^^^^&2.16.840.1.113883.19.4.6^ISO^XX^^^1234|1005 Healthcare Drive^^Ann Arbor^MI^99999^USA^B|^WPN^PH^^1^555^5553001|4444 Healthcare Drive^Suite 123^Ann Arbor^MI^99999^USA^B  OBR|1|23456^EHR^2.16.840.1.113883.19.3.2.3^ISO|9700123^Lab^2.16.840.1.113883.19.3.1.6^ISO|625-4^Bacteria identified^LN^3456543^ CULTURE, STOOL^99USI^2.26|||200808151030-0700||||||diarrhea|||1234^Admit^Alan^A^III^Dr^^^&2.16.840.1.113883.19.4.6^ISO^L^^^EI^&2.16.840.1.113883.19.4.6^ISO^^^^^^^^MD|^WPN^PH^^1^555^5551005|||||2008081830-0700|||F||||||787.91^DIARRHEA^I9CDX^^^^07/09/2008|1235&Slide&Stan&S&&Dr&MD&&DOC&2.16.840.1.113883.19.4.6&ISO  OBX|1|CWE|625-4^Bacteria identified:Prid:Pt:Stool:Nom:Culture^LN^^^^2.26|**1**|66543000^Campylobacter jejuni^SCT^^^^January 2007||||||F|||200808151030-0700|||0086^Bacterial identification^OBSMETHOD^^^^501-20080815||200808161030-0700||||Reliable Labs, Inc^L^^^^CLIA&2.16.840.1.113883.19.4.6&ISO^XX^^^1236|3434 Industrial Loop^^Ann Arbor^MI^99999^USA^B|9876543^Slide^Stan^S^^^^^NPPES&2.16.840.1.113883.19.4.6&ISO^L^^^NPI  OBX|2|SN|564-5^COLONY COUNT:NUM:PT:XXX:QN:VC^LN^^^^2.26|**1**|^10000^-^90000|1^^UCUM^^^^1.6|||||F|||200808151030-0700|||||200808161030-0700||||Reliable Labs, Inc^L^^^^CLIA&2.16.840.1.113883.19.4.6&ISO^XX^^^1236|3434 Industrial Loop^^Ann Arbor^MI^99999^USA^B|9876543^Slide^Stan^S^^^^^NPPES&2.16.840.1.113883.19.4.6&ISO^L^^^NPI  OBX|3|CWE|625-4^Bacteria identified:Prid:Pt:Stool:Nom:Culture^LN^^^^2.26|**2**|302620005^Salmonella group B phase 1 a-e^SCT^^^^January 2007||||||F|||200808151030-0700|||0086^Bacterial identification^OBSMETHOD^^^^501-20080815||200808161030-0700||||Reliable Labs, Inc^L^^^^CLIA&2.16.840.1.113883.19.4.6&ISO^XX^^^1236|3434 Industrial Loop^^Ann Arbor^MI^99999^USA^B|9876543^Slide^Stan^S^^^^^NPPES&2.16.840.1.113883.19.4.6&ISO^L^^^NPI  OBX|4|SN|564-5^COLONY COUNT:NUM:PT:XXX:QN:VC^LN^^^^2.26|**2**|>^100000|1^^UCUM^^^^1.6|||||F|||200808151030-0700|||||200808161030-0700||||Reliable Labs, Inc^L^^^^CLIA&2.16.840.1.113883.19.4.6&ISO^XX^^^1236|3434 Industrial Loop^^Ann Arbor^MI^99999^USA^B|9876543^Slide^Stan^S^^^^^NPPES&2.16.840.1.113883.19.4.6&ISO^L^^^NPI  OBX|5|CWE|625-4^Bacteria identified:Prid:Pt:Stool:Nom:Culture^LN^^^^2.26|**3**|77352002^Shigella^SCT^^^^January 2007||||||F|||200808151030-0700|||0086^Bacterial identification^OBSMETHOD^^^^501-20080815||200808161030-0700||||Reliable Labs, Inc^L^^^^CLIA&2.16.840.1.113883.19.4.6&ISO^XX^^^1236|3434 Industrial Loop^^Ann Arbor^MI^99999^USA^B|9876543^Slide^Stan^S^^^^^NPPES&2.16.840.1.113883.19.4.6&ISO^L^^^NPI  OBX|6|SN|564-5^COLONY COUNT:NUM:PT:XXX:QN:VC^LN^^^^2.26|**3**|<^1000|1^^UCUM^^^^1.6|||||F|||200808151030-0700|||||200808161030-0700||||Reliable Labs, Inc^L^^^^CLIA&2.16.840.1.113883.19.4.6&ISO^XX^^^1236|3434 Industrial Loop^^Ann Arbor^MI^99999^USA^B|9876543^Slide^Stan^S^^^^^NPPES&2.16.840.1.113883.19.4.6&ISO^L^^^NPI  SPM|1|23456&EHR&2.16.840.1.113883.19.3.2.3&ISO^9700122&Lab&2.16.840.1.113883.19.3.1.6&ISO||119339001^Stool specimen^SCT^^^^20080131|||||||P^Patient^HL60369^^^^2.5.1|10^g&gram&UCUM&&&&1.6|||||200808151030-0700|200808151100-0700  OBR|2||9700124^Lab^2.16.840.1.113883.19.3.1.6^ISO|50545-3^Bacterial susceptibility panel:-:Pt:Isolate:OrdQn:MIC^LN^^^^2.26|||200808151030-0700|||||||||1234^Admit^Alan^A^III^Dr^^^&2.16.840.1.113883.19.4.6^ISO^L^^^EI^&2.16.840.1.113883.19.4.6^ISO^^^^^^^^MD|^WPN^PH^^1^555^5551005|||||2008081830-0700|||F|**625-4&Bacteria identified:Prid:Pt:Stool:Nom:Culture&LN^1^Campylobacter jejuni**|||**23456&EHR&2.16.840.1.113883.19.3.2.3&ISO^9700123&Lab&2.16.840.1.113883.19.3.1.6&ISO**||787.91^DIARRHEA^I9CDX^^^^07/09/2008|1235&Slide&Stan&S&&Dr&MD&&DOC&2.16.840.1.113883.19.4.6&ISO  OBX|1|SN|6979-9^AMPICILLIN:SUSC:PT:ISLT:ORDQN:GRADIENT STRIP^LN^^^^2.26|1|<^0.06|ug/mL^^UCUM^^^^1.6||S|||F|||200808151030-0700|||||200808161030-0700||||Reliable Labs, Inc^L^^^^CLIA&2.16.840.1.113883.19.4.6&ISO^XX^^^1236|3434 Industrial Loop^^Ann Arbor^MI^99999^USA^B|9876543^Slide^Stan^S^^^^^NPPES&2.16.840.1.113883.19.4.6&ISO^L^^^NPI  OBX|2|SN|7016-9^GENTAMICIN:SUSC:PT:ISLT:ORDQN:GRADIENT STRIP^LN^^^^2.26|1|^0.05|ug/mL^^UCUM^^^^1.6||S|||F|||200808151030-0700|||||200808161030-0700||||Reliable Labs, Inc^L^^^^CLIA&2.16.840.1.113883.19.4.6&ISO^XX^^^1236|3434 Industrial Loop^^Ann Arbor^MI^99999^USA^B|9876543^Slide^Stan^S^^^^^NPPES&2.16.840.1.113883.19.4.6&ISO^L^^^NPI  OBX|3|SN|7002-9^CIPROFLOXACIN:SUSC:PT:ISLT:ORDQN:GRADIENT STRIP^LN^^^^2.26|1|^0.05|ug/mL^^UCUM^^^^1.6||S|||F|||200808151030-0700|||||200808161030-0700||||Reliable Labs, Inc^L^^^^CLIA&2.16.840.1.113883.19.4.6&ISO^XX^^^1236|3434 Industrial Loop^^Ann Arbor^MI^99999^USA^B|9876543^Slide^Stan^S^^^^^NPPES&2.16.840.1.113883.19.4.6&ISO^L^^^NPI  OBR|3||9700125^Lab^2.16.840.1.113883.19.3.1.6^ISO|50545-3^Bacterial susceptibility panel:-:Pt:Isolate:OrdQn:MIC^LN^^^^2.26|||200808151030-0700|||||||||1234^Admit^Alan^A^III^Dr^^^&2.16.840.1.113883.19.4.6^ISO^L^^^EI^&2.16.840.1.113883.19.4.6^ISO^^^^^^^^MD|^WPN^PH^^1^555^5551005|||||2008081830-0700|||F|**625-4&Bacteria identified:Prid:Pt:Stool:Nom:Culture&LN^2^Salmonella group B phase 1 a-e**|||**23456&EHR&2.16.840.1.113883.19.3.2.3&ISO^9700123&Lab&2.16.840.1.113883.19.3.1.6&ISO**||787.91^DIARRHEA^I9CDX^^^^07/09/2008|1235&Slide&Stan&S&&Dr&MD&&DOC&2.16.840.1.113883.19.4.6&ISO  OBX|1|SN|6979-9^AMPICILLIN:SUSC:PT:ISLT:ORDQN:GRADIENT STRIP^LN^^^^2.26|1|<^0.06|ug/mL^^UCUM^^^^1.6||S|||F|||200808151030-0700|||||200808161030-0700||||Reliable Labs, Inc^L^^^^CLIA&2.16.840.1.113883.19.4.6&ISO^XX^^^1236|3434 Industrial Loop^^Ann Arbor^MI^99999^USA^B|9876543^Slide^Stan^S^^^^^NPPES&2.16.840.1.113883.19.4.6&ISO^L^^^NPI  OBX|2|SN|7016-9^GENTAMICIN:SUSC:PT:ISLT:ORDQN:GRADIENT STRIP^LN^^^^2.26|1|^0.05|ug/mL^^UCUM^^^^1.6||S|||F|||200808151030-0700|||||200808161030-0700||||Reliable Labs, Inc^L^^^^CLIA&2.16.840.1.113883.19.4.6&ISO^XX^^^1236|3434 Industrial Loop^^Ann Arbor^MI^99999^USA^B|9876543^Slide^Stan^S^^^^^NPPES&2.16.840.1.113883.19.4.6&ISO^L^^^NPI  OBX|3|SN|7002-9^CIPROFLOXACIN:SUSC:PT:ISLT:ORDQN:GRADIENT STRIP^LN^^^^2.26|1|^0.05|ug/mL^^UCUM^^^^1.6||S|||F|||200808151030-0700|||||200808161030-0700||||Reliable Labs, Inc^L^^^^CLIA&2.16.840.1.113883.19.4.6&ISO^XX^^^1236|3434 Industrial Loop^^Ann Arbor^MI^99999^USA^B|9876543^Slide^Stan^S^^^^^NPPES&2.16.840.1.113883.19.4.6&ISO^L^^^NPI  OBR|4||9700126^Lab^2.16.840.1.113883.19.3.1.6^ISO|50545-3^Bacterial susceptibility panel:-:Pt:Isolate:OrdQn:MIC^LN^^^^2.26|||200808151030-0700|||||||||1234^Admit^Alan^A^III^Dr^^^&2.16.840.1.113883.19.4.6^ISO^L^^^EI^&2.16.840.1.113883.19.4.6^ISO^^^^^^^^MD|^WPN^PH^^1^555^5551005|||||2008081830-0700|||F|**625-4&Bacteria identified:Prid:Pt:Stool:Nom:Culture&LN^2^Shigella**|||**23456&EHR&2.16.840.1.113883.19.3.2.3&ISO^9700123&Lab&2.16.840.1.113883.19.3.1.6&ISO**||787.91^DIARRHEA^I9CDX^^^^07/09/2008|1235&Slide&Stan&S&&Dr&MD&&DOC&2.16.840.1.113883.19.4.6&ISO  OBX|1|SN|6979-9^AMPICILLIN:SUSC:PT:ISLT:ORDQN:GRADIENT STRIP^LN^^^^2.26|1|<^0.06|µg/mL^^UCUM^^^^1.6||S|||F|||200808151030-0700|||||200808161030-0700||||Reliable Labs, Inc^L^^^^CLIA&2.16.840.1.113883.19.4.6&ISO^XX^^^1236|3434 Industrial Loop^^Ann Arbor^MI^99999^USA^B|9876543^Slide^Stan^S^^^^^NPPES&2.16.840.1.113883.19.4.6&ISO^L^^^NPI  OBX|2|SN|7016-9^GENTAMICIN:SUSC:PT:ISLT:ORDQN:GRADIENT STRIP^LN^^^^2.26|1|^0.05|µg/mL^^UCUM^^^^1.6||S|||F|||200808151030-0700|||||200808161030-0700||||Reliable Labs, Inc^L^^^^CLIA&2.16.840.1.113883.19.4.6&ISO^XX^^^1236|3434 Industrial Loop^^Ann Arbor^MI^99999^USA^B|9876543^Slide^Stan^S^^^^^NPPES&2.16.840.1.113883.19.4.6&ISO^L^^^NPI  OBX|3|SN|7002-9^CIPROFLOXACIN:SUSC:PT:ISLT:ORDQN:GRADIENT STRIP^LN^^^^2.26|1|^0.05|µg/mL^^UCUM^^^^1.6||S|||F|||200808151030-0700|||||200808161030-0700||||Reliable Labs, Inc^L^^^^CLIA&2.16.840.1.113883.19.4.6&ISO^XX^^^1236|3434 Industrial Loop^^Ann Arbor^MI^99999^USA^B|9876543^Slide^Stan^S^^^^^NPPES&2.16.840.1.113883.19.4.6&ISO^L^^^NPI |

## Linking Parent and Child Results

The previous example uses the information in OBR-26 as a pointer to the parent OBX where the culture result is reported. OBR-26 has three components. The three components of OBR-26 are the OBX-3, OBX-4 and part of the OBX-5 from the parent OBX segment. The pointer to the parent (using PRL data type) requires only the first two components.

## Clinical Laboratory Improvements Amendment Considerations

In the United States, Clinical Laboratory testing of human specimens is regulated by the Clinical Laboratory Improvements Amendments of 1988 (CLIA). Several sections of the regulations implementing CLIA impact how electronic laboratory is formatted for the US Realm and these changes are outlined in this appendix. Impacted areas include mandatory reporting requirements, report retention and display, and those authorized to receive a report. Specifics on the CLIA Regulation are found at <http://wwwn.cdc.gov/clia/regs/toc.aspx>.

## Mandatory Reporting Requirements

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

Table 6‑1. Mandatory Reporting Requirements

| Segment | Field | CLIA Impact |
| --- | --- | --- |
| PID-3 | Patient Identifier List | A unique patient identification number is required |
| PID-5 | Patient Name | Positive patient identification required. If the patient’s name is known, this must be that name. If it is not known, a unique patient identifier must be assigned. |
| OBX-3 | Observation Identifier[[6]](#footnote-6) | Unique identification of the test performed is required. LOINC® is an HL7-approved code system and shall be used for the Observation Identifier as described in the appropriate HITSP Interoperability Specification. Use of LOINC codes for additional tests is strongly encouraged. See *Section 6* for more details. Addition of a local laboratory code is allowed.  For certain tests CLIA requires additional information:  Laboratories using manufacturer's instruments, kits or test systems labeled for "investigational use only" or "research use only" must clearly state that the test results are not to be used for treatment or diagnostic purposes. If results of such tests are being reported without a disclaimer statement, or are being used by the provider for patient care, they are in the same category as in-house developed tests and the laboratory must establish performance specifications in accordance with §493.1253.  The disclaimer for Analyte Specific Reagents (ASR) should state, "This test was developed and its performance characteristics determined by (Laboratory Name). It has not been cleared or approved by the U.S. Food and Drug Administration." The ASR disclaimer on the test report is required by the FDA under *21 CFR, Part 809.30, "Restrictions on the sale, distribution and use of analyte -specific reagents."* |
| OBX-5 | Observation Value | The laboratory result is required. No regulatory requirements are specified, outside of readability, regarding result appearance. |
| OBX-6 | Units | Units, if required, or an interpretation must be given. For tests such as genetic screens the interpretation may actually be the test result. |
| OBX-7 | Reference Range | Required. |
| OBX-8 | Abnormal flag. | Use is not required, but a laboratory may use this field as part of its interpretation guidance. If reported, it should be displayed by an EHR. |
| OBX-11 | Observation Result Status | Used to reflect CLIA required conditions such as specimen acceptability, result corrections, cancellations as well as report status (§493.1291 (c)(7) and (k)(1,2). See SPM-21 and -22 below. |
| OBX-19 | Date/Time of Analysis | Use this field to meet the requirement for test report time. |
| OBX-23, 24, 25 | Laboratory Identification Fields | The identification of the performing laboratory is required. Populating with the CLIA ID Number in OBX-23 meets the requirement if this receiving EHR has access to a look-up table that will convert the CLIA ID number to full demographics comprising OBX-23,Performing Organization Name; OBX-24, Performing Organization Address; and OBX-25, Performing Organization Medical Director. If the CLIA ID number is not used, all demographic fields (OBX-23, OBX-24 and OBX-25) must be populated with appropriate information. |
| SPM-4 | Specimen Type | Reporting requirements call for the specimen source, which equates to the Specimen Type in the SPM segment. |
| SPM-21 | Specimen Reject Reason | Use this field in connection with OBX-11 if a test is cancelled for specimen related reason. |
| SPM-22 | Specimen Quality | Use this field to provide a coded version for Specimen Description. For Electronic Health Records, it is preferred that this field be used in place of, or in connection with, SPM-14. |

## Regulatory Compliance

There may be local, state or federal regulations where the electronic message from a performing laboratory is presumed to be the legal report of the tests performed. Hence, the receiver may be required to save the format or content of the message for the same time period as required for any other legal document.

## Authorized Parties

Local laws, generally at the State level, govern who is authorized to receive laboratory reports. CLIA restricts the availability of those authorized to receive laboratory reports to just those approved at the local level and sets no national standards. Testing laboratories may not report results to unauthorized parties under CLIA.

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

1. Derived from the CLIA definition (https://www.cms.gov/CLIA/07\_Program\_Descriptions\_Projects.asp#TopOfPage). Future Use Cases may require expansion to include non-human subjects. [↑](#footnote-ref-1)
2. See the [S&I LRI Use Case, Section 2.3 Structured Data Definition](http://wiki.siframework.org/LRI+-+FINAL+Use+Case) [↑](#footnote-ref-2)
3. The current version of the HL7 Implementation Guidance for Unique Object Identifiers (OIDs), Release 1 is available from HL7 ([www.hl7.org](http://www.hl7.org)). Members may obtain a copy without charge in the Members-only area of the site, others may purchase a copy for a nominal fee via the HL7 Store [↑](#footnote-ref-3)
4. The referenced documents are all available from HL7 ([www.hl7.org](http://www.hl7.org)) – Members may obtain a copy without charge in the Members-only area of the site, others may purchase a copy for a nominal fee via the HL7 Store. [↑](#footnote-ref-4)
5. There are multiple interpretations of “RE” when a value is known. One is “the capability must always be supported and a value is sent if known”, the other is “the capability must always be supported and a value may or may not be sent even when known based on a condition external to the profile specification. The condition may be noted in the profile but cannot be processed automatically”. This is what can be interpreted from the “relevant” part of the definition. Regardless of the interpretation the “RE” usage code, a set of test circumstances can be developed to sufficiently test the “RE” element. See the “Conformity Assessment of Conformance Constructs” section for more details. [↑](#footnote-ref-5)
6. While CLIA requires a laboratory to maintain positive identification of a specimen reporting, that information as part of the result is not required. [↑](#footnote-ref-6)