HL7 Version 2.5.1 Implementation Guide: Laboratory Orders from EHR (LOI)

Release 1, STU Release 3 - US Realm

HL7 Standard for Trial Use

May 2018

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Logical Observation Identifiers Names & Codes (LOINC)	Regenstrief Institute
International Classification of Diseases (ICD) codes	World Health Organization (WHO)
NUCC Health Care Provider Taxonomy code set	American Medical Association. Please see www.nucc.org. AMA licensing contact: 312-464-5022 (AMA IP services)

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Acknowledgements

This work has been sponsored by the HL7 Orders and Observations Work Group in collaboration with the Health and Human Services Standards and Interoperability Framework Laboratory Result Interface Working Group.

Questions or comments regarding this document should be directed to the Orders and Observations Workgroup (ord@lists.hl7.org).

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The authors would also like to acknowledge the efforts and support for development of this guide by the following organizations:

The Association of Public Health Laboratories (APHL). APHL supported by Cooperative Agreement # U60HM000803 from the Centers for Disease Control and Prevention (CDC) and/or Assistant Secretary for Preparedness and Response. The content is solely the responsibility of the authors and do not necessarily represent the official views of CDC and/or Assistant Secretary for Preparedness and Response.

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1 INTRODUCTION

The *HL7 Version 2.5.1 Implementation Guide: Laboratory Orders from EHR (LOI); Release 1, STU Release 3 (US Realm); HL7 Standard for Trial Use; May 2018* is the result of collaborative efforts between HL7 and the Office of the National Coordinator (ONC) Standards and Interoperability (S&I) Framework Laboratory Orders Interface (LOI) Initiative.

By consensus the HL7 V2.5.1 OML^O21 Message was selected as the basis to define the profile constraints expressed in this guide to meet the requirements of the transmission of laboratory orders. The California Health Care Foundation's *EHR-Laboratory Interoperability and Connectivity Specification for Orders, ELINCS Orders, v1.0 June 28, 2011* and the Standards and Interoperability (S&I) Framework's Laboratory Orders Interface Use Case (LOI UC) were leveraged for the development of this Implementation Guide. In addition, the ELINCS Orders and LOI UC were revised, where agreed upon by the Standards and Interoperability (S&I) Framework's Laboratory Orders Interface and HL7 communities, to provide the Use Case content, diagrams and requirements for this Implementation Guide.

1.1 Purpose

The Laboratory Orders Interface Initiative identifies the requirements, defines specifications and standards, and provides implementation guidance for electronic ordering of laboratory tests in the US Realm. The scope of the Laboratory Orders Interface Use Case includes requirements to enable a particular implementation of Electronic Health Record System (EHR-S) to use standardized structured data in a defined inter-organizational laboratory transaction. The Use Case requirements are directed at laboratory test orders between an EHR-S and a Laboratory's Laboratory Information System (LIS) in different organizations.

1.2 Audience

This guide is designed for use by analysts and developers who require guidance on data elements and components of the HL7 Version 2.5.1 OML Laboratory Order Message relative to the Laboratory Orders Interface (LOI) 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.

1.2.1 RELEVANT LABORATORY IMPLEMENTATION GUIDES

There are multiple Implementation Guides that have been developed under the Office of the National Coordinator's (ONC) Standards and Interoperability Framework Initiative. These guides have been created using the same processes, are stylistically similar and designed to work together. The set includes but is not limited to:

- This publication[1], the *HL7 Version 2.5.1 Implementation Guide: Laboratory Orders from EHR (LOI); Release 1, STU Release 3 (US Realm); HL7 Standard for Trial Use; May 2018*, in support of the lab test ordering in the inter-organizational care setting and to provide data needed for reporting to Public Health;
- *HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Test Compendium Framework (eDOS); Release 2, STU Release 3 (US Realm); HL7 Standard for Trial Use; May 2018* in support of the transmission of a laboratory's directory of services to an EHR using HL7 Master File messages;

[1] This is the product brief page for all versions of the IG, this ballot document is only available through the HL7 ballot portal until published.

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- *HL7 Version 2.5.1 Implementation Guide: Lab Results Interface (LRI); Release 1, STU Release 3 (US Realm); HL7 Standard for Trial Use; May 2018* in support of the lab result reporting to ambulatory care providers and Public Health;
- *HL7 Version 2 Implementation Guide: Laboratory Value Set Companion Guide; Release 1.3 (US Realm); HL7 Standard for Trial Use; May 2018* providing cross-IG value set definitions and harmonized requirements.
- *HL7 EHR-S Functional Requirements: S&I Framework Laboratory Results Messages, Release 1, US Realm*, providing processing, display, and storage requirements for regulated result data.

The EHR-S and LIS will conform to this family of Implementation Guides; a laboratory that receives an order conforming to the LOI IG should be capable of reporting results with a conformant LRI message.

1.2.2 REQUISITE KNOWLEDGE

- HL7 V2.5.1 through V2.8.2 Messaging (www.HL7.org)
- SNOMED CT (http://www.ihtsdo.org/snomed-ct) referenced throughout as SNOMED CT or SNOMED_CT_USL
- LOINC (http://loinc.org)
- OIDS (http://www.hl7.org/oid)
- Standards and Interoperability Laboratory Results Interface Use Case, Laboratory Results Reporting to Primary Care Providers (in an Ambulatory Setting) v1.0

1.2.3 REFERENCED PROFILES – ANTECEDENTS

This specification documents a message profile for Laboratory Orders Interface (LOI) profile for Senders and Receivers based on the HL7 version 2.5.1[2]. Other laboratory ordering profiles were referenced and used as source materials in the development of this guide, including:

- EHR-Laboratory Interoperability and Connectivity Specification for Orders, ELINCS Orders, v1.0 June 28, 2011

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.

1.3 Organization of this Guide

1.3.1 CONVENTIONS

This guide adheres to the following conventions:

- The guide is constructed assuming the implementer has access to the V2.5.1 through V2.8.2 versions of the HL7 Standard as called out in this document where specific version concepts and constraints apply. Although some information from the standard is included in this Implementation Guide, much information from the standard has not been repeated here.

[2] The referenced documents are all available from HL7 (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.

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- 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; see Section 1.3.4 Usage Conformance Rules.
- Data types have been described separately from the fields that use the data types.
- No conformance information is provided for fully optional message elements and segments (“O”) or unsupported message elements and segments (“X”). This includes cardinality, value sets and descriptive information. Implementers who want to use optional message elements should refer to the base HL7 V2.5.1 Standard to determine how these optional message elements will be used. Conformance information is provided when a conditional predicate resolves to an “R” or “RE” on either the “a” or “b” part of the expression, regardless of the opposite value, e.g., C(R/O).
- This guide provides conditional predicates for some fields; note that the condition may be dependent on data elements that are marked as “O” (optional). In these cases, the interpretation by the reader should be “if the optional element is used, then these additional constraints are now required.” That is, if the optional element is present, then these additional constraints are now active. This guidance is included as it is logically true but these conditional elements are not tested.
- This guide uses “X” as a conformance usage indicator very sparingly. Where the underlying standard indicates the segments/field/component is present for backwards compatibility (“B”) or withdrawn ("W") an “X” will be used. A small number of other message elements that are clearly out of scope for the use case have been given the "X" usage. All other message elements have either been further constrained to R/RE/C(a/b) or have been left as "O" to enable trading partners to explore additional capabilities. Note that without a clearly agreed to complementary profile between trading partners, an EHR-S that is compliant with this Implementation Guide does not have to send any elements marked as an "O", nor does a receiver of a laboratory order that is compliant with this Implementation Guide have to process any elements marked as an "O". Neither trading partner can mandate the other to accept any such complementary profiles to enable basic laboratory orders interfacing "out-of-the-box". The recipient should not return an error unless there is a clinical or regulatory impact as a result of discarding optional information.

1.3.2 MESSAGE ELEMENT ATTRIBUTES

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

TABLE 1-1. MESSAGE ELEMENT ATTRIBUTES

Attribute	Definition
SEQ	Sequence of the elements as numbered in the HL7 message element. The SEQ attribute applies to the data type attribute table and the segment attribute table.
Component Name	Short name for the component.

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TABLE 1-1. MESSAGE ELEMENT ATTRIBUTES	
Attribute	Definition
Segment	Three-character code for the segment and the abstract syntax (e.g., the square and curly braces). [XXX] Optional and singular { XXX } Required and may repeat XXX Required and singular [{ XXX }] Optional and may repeat Note that for segment groups there is no segment code present, but the square and curly braces will still be present. The Segment attribute only applies to the Message attribute table.
DT	Data type used by this profile for HL7 element. The data type attribute applies to data type attribute tables and segment attribute tables.
Usage	Usage of the message element for this profile. Indicates whether the message element (segment, segment group, field, component, or subcomponent) is R, RE, O, X or C(a/b) in the corresponding message element. Usage applies to the message attribute table, data type attribute table and the segment attribute table; see Section 1.3.4 Usage Conformance Rules.
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. See Sections 1.4.8 Value Sets and 8 Code Systems.
Name	HL7 descriptor of the message element. Name applies to the message attribute table, data type attribute table and the segment attribute table.
Description/Comments	Context and usage for the element. Description/Comments applies to the message attribute table, data type attribute table and the segment attribute table.

1.3.3 KEYWORDS

The key words "**MUST**", "**MUST NOT**", "**REQUIRED**", "**SHALL**", "**SHALL NOT**", "**SHOULD**", "**SHOULD NOT**", "**RECOMMENDED**", "**MAY**", and "**OPTIONAL**" in this document are to be interpreted as described in RFC 2119[3]. The following definitions are excerpted from the RFC:

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

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

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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.

Any further constraining of optional segments/fields/components must be agreed to by both parties and cannot be made pre-requisite to sending/receiving messages to achieve the basic interoperability described in this guide. Therefore, a sender shall not require a receiver to accept any segments/fields/components marked as optional to successfully send a message, Likewise, a receiver shall not require a sender to send any segment/fields/components marked as optional to successfully receive such a message.

1.3.4 USAGE CONFORMANCE RULES

The following text is pre-adopted from the HL7 V2.7.1 Conformance (Chapter 2B, 2.B.7.5). Please refer to the base standard documentation for a full explanation of conformance concepts. Usage is described here as it introduces the revised approach to conditional element handling.

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

2.B.7.5 USAGE

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

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

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"Condition predicate"). “a” and “b” shall be one of “R”, “RE”, “O” and/or “X”. The values of “a” and “b” can be the same.

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

There are cases where it is appropriate to value “a” and “b” the same. For example, the base standard defines the usage of an element as “C” and the condition predicate is dependent on the presence or non-presence of another element. The profile may constrain the element that the condition is dependent on to X; in such a case the condition should always evaluate to false. Therefore, the condition is profiled to C(X/X) since the desired effect is for the element to be not supported. Note it is not appropriate to profile the element to X since this breaks the rules of allowable usage profiling (see table HL7 Optionality and Conformance Usage).

Usage Rules for a Sending Application

Optionality /Usage Indicator	Description	Implementation Requirement	Operational Requirement
R	Required	The application shall implement “R” elements.	The application shall populate “R” elements with a non-empty value.
RE	Required but may be empty	The application shall implement “RE” elements.	The application shall populate “RE” elements with a non-empty value if there is relevant data. The term “relevant” has a confounding interpretation in this definition[4].
C(a/b)	Conditional	An element with a conditional usage code has an associated condition predicate (See section 2.B.7.9, “Condition predicate” that determines the operational requirements (usage code) of the element. If the condition predicate associated with the element is true, follow the rules for **a** which shall be one of “R”, “RE”, “O” or X”: If the condition predicate associated with the element is false, follow the rules for **b** which shall be one of “R”, “RE”, “O” or X”. a and b can be valued the same.	
X	Not supported	The application (or as configured) shall not implement “X” elements.	The application shall not populate “X” elements.
O	Optional	None. The usage indicator 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.

[4] 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.

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Usage Rules for a Receiving Application

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

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

1.4 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 1.2.1 Relevant Laboratory Implementation Guides have 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 aims to utilize best practices to address current ambulatory inter-organizational ordering needs and to promote laboratory ordering consistency and best practices across the health care continuum.

1.4.1 RELATIONSHIP TO OTHER LAB GUIDES

This guide is intended to be compatible with the *HL7 Version 2.5.1 Implementation Guide: Lab Results Interface (LRI), Release 1, STU Release 3 – US Realm*; the most current copy can be found at the main page for this document on the HL7 website at HL7 Version 2.5.1 Implementation Guide: Lab Results Interface (LRI), Release 1 – US Realm.

For 'R' data elements that are common between the order and the result, the expectation is that the result message will support those elements as defined in the guide with the expectation that the

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laboratory will provide either the original value from the order, or the best value the laboratory is aware of in the result message at the time the result message is generated.

Note that the LRI IG constraints apply only when sending prior laboratory results to the segments in the PRIOR_RESULT group in the order message.

This guide is also intended to be compatible with the HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Test Compendium Framework (eDOS) R2, STU Release 3 - US Realm.

1.4.2 PROFILE AND COMPONENT ARCHITECTURE

This guide extensively uses constrainable profiles to define a minimum set of requirements to enable the successful exchange of laboratory orders. The main objective is to ensure that an EHR-S and an LIS can exchange laboratory orders with minimum if any modifications from one combination to another combination of software, while maintaining flexibility to enable software developers to provide more capabilities using the same core message definitions. Section 4 Conformance to this Guide describes the mandatory and optional profiles to be used, as well as the rules on further constraining the guide.

1.4.3 USE OF ISO OBJECT IDENTIFIER (OID)

OIDs, or Object Identifiers, provide a strong identifier that uniquely identifies the object in question and is global in scope. OIDs identify information such as items about patients, orders, providers and organizations. Each identifier includes enough information to remain unique when taken out of the context within which the identifier was created. The ISO OID specification (ISO/IEC 8824:1990(E)) is the globally accepted technology for this purpose and is recommended as the means to satisfy the requirement for a universally unique identifier.

This guide defines a Globally Unique Component (LOI_GU_Component) (see Section 4.2.1.2) that prescribes the use of an ISO Object Identifier (OID) for a specific set of fields.

The GU/NG profile definition discusses use of OIDs for identifiers' assigning authority only. Other identifiers could use OIDs as well for the assigning authority. Note that OIDs are not intended to be used to identify a coding system as referenced in CWE-03/CWE-06.

HL7 has developed an Implementation Guide for the use of OIDs, “HL7 Implementation Guidance for Unique Object Identifiers (OIDs), Release 1”[5], which provides guidance on how organizations can use and manage OIDs.

1.4.4 USE OF VOCABULARY STANDARDS

This guide calls for specific vocabulary standards for the exchange of laboratory information such as LOINC and SNOMED CT. Standard vocabularies, particularly coded laboratory tests and their results, enable automated decision support for patient healthcare, as well as for public health surveillance of populations. Terminology is updated periodically and it is best practice to use the most current version of the coding system.

1.4.5 FIELD LENGTH AND TRUNCATION

This guide is silent as to field length definition conventions, lengths, and truncation rules and directs the reader to HL7 Version 2.7.1, Chapter 2 Control for informative guidance.

[5] The current version of the HL7 Implementation Guidance for Unique Object Identifiers (OIDs), Release 1 is available from HL7 (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.

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The sole exception to truncation guidance in the base specification is that OBX-5 (Observation Value) **SHALL NOT** be truncated.

1.4.6 CONFORMANCE STATEMENTS

This guide includes conformance statements to clarify the requirements that will be tested to determine conformance to this guide and the profiles it defines; note the following conventions are followed in this guide:

- Conformance IDs have the naming convention of **AAA-N** where **AAA** is the mnemonic of the IG in which the statement is made, e.g., **eDOS-**, **LRI-**, **LOI-**, and **N** is a number to uniquely identify the statement from all others. IDs that begin with **LAB-** are applicable to any Lab US Realm IG; they are not IG specific.

Conformance IDs are not reused, and they do not imply any sequence. In subsequent releases statements may appear to be out of sync as older statements are retired and new ones created.

1.4.7 DATA TYPE FLAVORS

A particular data type can be referenced by different fields. Depending on the field's purpose, including which profile components are used, specific use of the associated data type may vary. For example, an observation identifier in the OBX segment using CWE may not require the same components or value sets as an HL7 error code in the ERR segment which is also using CWE. Or, an HD data type used for an identifier as part of a public health focused message may need to be more unique.

Rather than providing data type specifications in-line with each field within a segment, we opted to create data type "flavors" where each flavor is constrained to the unique requirements of the field usage as defined for a component or profile. Whenever a data type is used differently depending on the field referencing it, a new flavor is created, e.g., DTM_01, DTM_02, … where DTM is the data type and _01, _02, … indicates the flavor (note the definitions in the base standard are considered to be "00"). Where requirements are the same, multiple fields can reference the same data type flavor. Each Implementation Guide lists only the datatype flavors used in it, which may result in skipped numbering (e.g. DTM_07, DTM_10), because the numbers are assigned across datatypes for all Lab US Realm Implementation Guides. This approach will reduce the number of data type definitions, thus reducing the size of this Implementation Guide.

Additionally, the segment will mark a data type on a field as "varies" when use of a profile component or other condition requires the use of a different data type flavor.

1.4.8 VALUE SETS

This Implementation Guide provides detailed value set definitions in a separate publication. See Section 4.1 Value Sets for the minimum version associated with the release of this document.

This separation is intended to set a minimum release version to be associated with the release of a Laboratory US Realm Implementation Guide such that the value sets can be versioned over time without always requiring a revision of the referring Implementation Guide. Thus, the value set version stated at the time of publication OR NEWER can be used to satisfy the requirements of this IG at the time of implementation, and trading partners should agree on the version and an update mechanism over time.

This additional documentation includes introductory material, and a master index that links to a spreadsheet for each value set. This spreadsheet contains the detailed requirements for each component or field in each Implementation Guide.

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1.4.8.1 VALUE USAGE REQUIREMENTS

The spreadsheets describe the detailed usage requirement indicators for implementations intending to be conformant to this guide (e.g., required values, permitted values). These concepts are fully detailed in the Companion Document.

In the case of a single fixed value, e.g., the value of MSH-12.1 (Version ID.Version ID) the table is listed but is also constrained by a Conformance Statement. Other code systems such as LOINC, SNOMED CT, USPS, etc. are also listed with any additional constraints noted.

Note: This guide does **NOT** address coordination of use of updates between trading partners. See the Value Set Companion Guide for full details on how values sets are created, managed, and the scope and expectations for use.

1.4.8.2 BINDING STRENGTH

Value Sets declared in this Implementation Guide in the Value Set column of the Data Type and Segment definitions are considered to have a binding strength of 'R' (Required) unless otherwise declared to be Suggested or Recommended. The interpretation of 'R' is that values MUST be drawn from the identified set whereas implementations may choose to use an alternate code system than those that are suggested or recommended.

When implementing optional fields, this guide recommends use of the code system(s) defined for the field in companion Lab IGs (if present). E.g., if Field A is optional in Guide A but required in Guide B with a defined value set, implementers are encouraged to adopt the value set as defined in Guide B.

1.4.9 SCOPE OF IMPLEMENTATION

The base standard indicates that receiving applications "…shall process (save/print/archive/etc.)…". For order-specific segments, e.g., ORC, OBR, SPM, this typically means saving that data. For other segments, e.g., MSH, the receiving application may not always have to save the data as the segment is focused on ensuring the order-specific data arrives in the appropriate place and therefore may have shorter-term value.

Due to receiving system variations and need, this guide does not specifically indicate for each field whether to store it or not. Storage determinations are left up to each individual implementation.

1.4.10 ASK AT ORDER ENTRY (AOE) OBSERVATIONS

Ask at Order Entry (AOE) responses are communicated as observations which provide critical information for the calculation or interpretation of some laboratory results or to satisfy state and federal health agency mandated information gathering requirements, e.g., for blood lead testing. AOE questions and associated observations will not be required for every order. The laboratory will indicate if and which AOEs to include with the order in their test compendium.

Examples of the type of information gathered from a patient include employment information, pregnancy status, the date of the last menstrual period, mother's age, and questions about family and personal history. In some cases there may be AOEs that request the outcome of previous results phrased as a question, e.g., "Was your previous pap abnormal?"

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

- Yes/No (and coded) to answer questions like "Is this your first pregnancy?"

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- What type of diabetes mellitus has the patient been diagnosed with and the possible answers are "none". "gestational", "Type I", or "Type II".
- A number with units for the mother's age
- A date format for the patient's last menstrual period.
- The OBX segments under the ORC/OBR pair should be used in the order messages to convey these Ask at Order Entry questions unless otherwise directed in the eDOS IG. When required AOEs are not provided, trading partners need to agree on resolution.

Although not strictly asked at order entry, other supporting clinical information about the patient collected during specimen collection, e.g., pregnancy status, recent travel, etc., are considered AOE observations for purposes of this guide and must be communicated by the means the laboratory identifies in its directory of services - for example using OBR-13 for "Fasting Status" or OBX under the ORC/OBR segment.

LOINC shall be used as the standard coding system for AOE questions if an appropriate LOINC code exists. The LOINC and local code describing the question will be placed in OBX-3 (Observation Identifier). If a local coding system is in use, both the LOINC and the local code should also be sent to help with identification of coding issues. When no appropriate LOINC exists, the local code may be the only code sent.

1.4.10.1 SPECIAL CONSIDERATIONS

Note that various Ask at Order Entry questions may appear to have specific fields in PID, NK1, or other segments. When a clinically relevant value is asked through an Ask at Order Entry question it must be conveyed through the OBX segments as described above as these values are used for clinical interpretations rather than through a seemingly similar field in PID, NK1, or other segment. The following provide specific examples and guidance whether to use an existing field or the OBX segment. This is list is not meant to be exhaustive.

- Date of Birth – Always use PID-7 (Date/Time of Birth) and should never be asked as an AOE as there is only one at any point in time.
- Race – PID-10 (Race) is provided for demographic (administrative/billing), not clinical use. The laboratory must provide an AOE for those tests where Race drives the interpretation of results. The value must be determined by the Ordering Provider and must be sent as an AOE OBX. Note that state and/or national regulations may dictate other behaviors.
- Ethnicity – PID-22 (Ethnic Group) is provided for demographic (administrative/billing), not clinical use. The laboratory must provide an AOE where Ethnicity drives the interpretation of results. The value must be determined by the Ordering Provider and must be sent as an AOE OBX. Note that state and/or national regulations may dictate other behaviors.

Note: More specific PID-10 (Race) and PID-22 (Ethnicity) values are available, but not limited to, those found in the CDCREC document (http://www.cdc.gov/nchs/data/dvs/Race_Ethnicity_CodeSet.pdf).

1.4.11 COMMUNICATION OF OTHER CLINICAL INFORMATION OR PRIOR RESULTS

Should the need arise to send results not obtained at the time of order entry or specimen collection and/or those requiring full results report structure such as culture/sensitivity reports, the Prior Results segment group in the message structure should be used, which follow the rules of the LRI guide.

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1.4.12 EXTENDED PROFILE USE

The sender may create other profile components or profiles that are defined outside of this Implementation Guide for use in conjunction with the profiles and profile components defined in this guide. However, those profiles and profile components are strictly voluntary and shall be properly constrained against the base standard and the profiles and profile components defined in Section Neither the sender nor the receiver shall require the use of any additional profiles and profile components in combination with the profiles and profile components defined in this guide to achieve a successful send or receive of Laboratory Orders.

1.4.13 ERROR HANDLING

Error Handling: Content in MSA-1, ERR-3, and ERR-5 is being combined to differentiate between "hard" and "soft" errors. Error handling is important to address to ensure that errors in the messages are properly communicated and addressed. The HL7 Version 2.5.1 Implementation Guide: Lab Results Interface (LRI), Release 1, STU Release 3 – US Realm has an complementary EHR-System functional requirements document that describes in further detail error handling and other essential capabilities for certain recipients of a result to address. The HL7 EHR-S Functional Requirements: S&I Framework Laboratory Results Messages, Release 1, US Realm, Draft Standard for Trial Use, April 20166 (EHR-FR-LR) has been released to support the result counterpart of this Implementation Guide and defines responses to specific error types. A similar guide is intended to be created for the LOI as well focusing on the minimum LIS responsibilities. The concepts described there are applicable to this Implementation Guide as well and are described below:

The LIS is required to be able to respond to an LOII transaction with one or more success or failure responses. In most cases, the LIS will provide two responses; the first in a System acknowledgement (MSA-1 = CR or CA) to indicated that it has received the LOI transaction from the previous sender (this may be a gateway or other system managing the flow of lab orders to their destination such as a reference lab network) and the second is an application level response to indicate the success (MSA-1 = AA or AE) or failure (MSA-1 = AR) of the transaction to meet the standards for the LOI guide and application requirement specified in this guide. In enhanced Acknowledgment mode, details about soft errors (MSA-1 = AE) or hard errors (MSA-1 = AR) are communicated through the use of the appropriate ERR segment elements (ERR-3 and/or ERR-5) as defined in the LOI IG.

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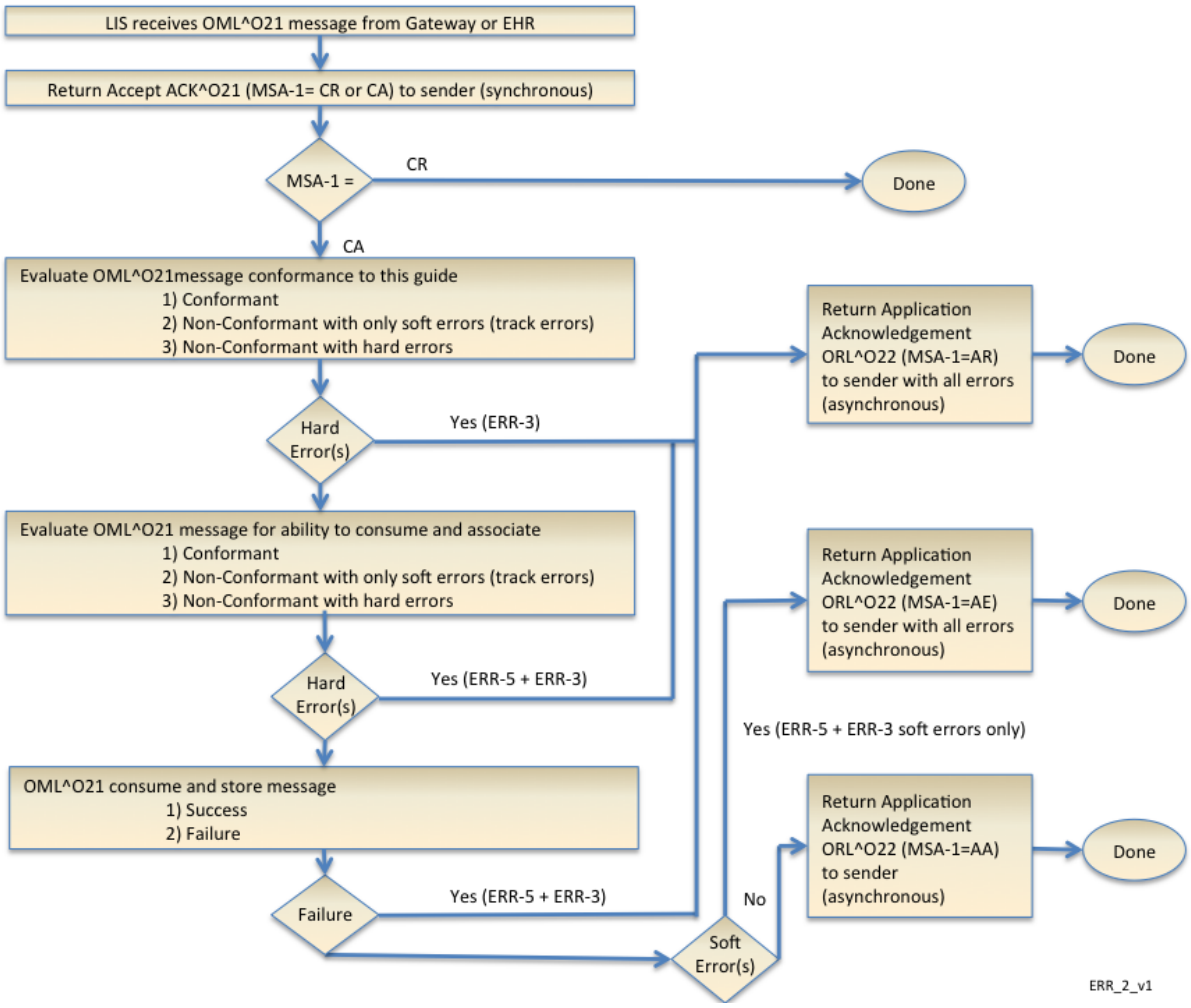

Figure 1-1. LOI Message Evaluation and Application Acknowledgement

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2 USE CASE – INTER-ORGANIZATIONAL CARE SETTING

This use case was developed as a collaborative effort between the HHS/ONC Standards and Interoperability Framework Laboratory Orders Initiative, the California Health Care Foundation, and the HL7 Orders and Observations Work Group.

2.1 Definitions

This guide defines the following terms from the historic paper-based workflows in relation to the supported use cases for electronic exchange of laboratory order information to the OML message structure as:

Measurement – a single observation value, ancillary data needed by the clinical laboratory (Ask at Order Entry Questions), or calculation recorded using a single Observation Segment (OBX). Note that multiple representations of the same measurement may require multiple observation segments, e.g., quantitative and qualitative statement of the same measurement.

Order Message – one or more Observation Request Groups (ORC/OBR pair) requesting one or more tests.

	OML^O21^OML_O21		
A single Laboratory Order (ORC)	ORC		
Which contains an Orderable Test (OBR)	OBR		
And may include Ask-At-Order Entry questions/responses (OBX of type Question)	OBX	...	OBX

	OML^O21^OML_O21				
One or more Laboratory Orders (ORCs)	ORC	...	ORC		
Which contains an Orderable Test (OBR)	OBR	...	OBR		
And may include Ask-At-Order Entry questions/responses (OBX of type Question)	OBX		OBX	...	OBX

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Results Report – a set of Observation Request Groups (ORC/OBR pairs) each including one or more measurements for each of the ordered and/or additional/reflexed tests as an unsolicited results message (ORU^R01^ORU_R01).

A results report (ORU)

Contains one or more Laboratory Orders (ORCs)

Each of which contains an Orderable Test (OBR)

And may echo the original Ask-At-Order Entry questions and their responses (OBX of type Question)

The individual measurements/results for each of the tests ordered (OBX of type Result)

ORU^R01^ORU_R01				
ORC	...	ORC		
OBR	...	OBR		
OBX		OBX	...	OBX
OBX		OBX	---	OBX

2.2 Scope

The scope of this Use Case is the electronic communication of laboratory order information between an EHR-S and an LIS in an inter-organizational care setting. Examples include, but are not limited to, from a physician practice EHR-S to an external laboratory's LIS such as a local lab, hospital-based lab, a public health lab or a national lab.

This Use Case has four scenarios:

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

2.2.1 IN SCOPE

- Electronic ordering of laboratory tests and/or panels in inter-organizational setting for the US Realm.
- Defining the core data elements required for ordering ambulatory laboratory tests and/or panels.
- Laboratory Order Placer (i.e., Ordering Provider) may designate other parties, on record with the laboratory, to receive copies of the results.
- Harmonization of data elements that are used in both laboratory orders and results.
- All applicable CLIA requirements, see Section 10.1 Clinical Laboratory Improvement Amendments Considerations.
- Support for acknowledgement messages at the accept and application level in order to that can better convey errors between originating system and final destination.

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2.2.2 OUT OF SCOPE

- In hospital referral ordering and reporting of laboratory results.
- Requesting Status on a previously placed laboratory order.
- Electronic ordering of laboratory tests and/or panels in an acute care setting, internally within a laboratory, referral orders placed between laboratories, and laboratory orders outside the US Realm.
- Note that the authors of this guide did not validate whether constraints on components should be loosened to support these use cases. This will be addressed in a future version, including definition of minimal incremental profiles to support these use cases. Until such time, implementers are not discouraged from attempting to use this guide for those use cases but should recognize that they may not be able to remain fully conformant. The authors invite comments from implementers on their experience to inform the next version, specifically to identify areas where the guides do not yet support intra-organizational workflows for future creation of an intra-organizational profile.
- Concepts related to: order queues, clearing houses, or other transport-level mechanisms and protocols that may be used to transfer or hold laboratory orders for later retrieval by a laboratory selected to perform the laboratory service.
- Multi-order status requests (for one patient or multiple patients).
- Laboratory orders not transmitted electronically.
- Secondary uses of laboratory order data.
- The human mechanisms required to resolve differences between the order identifier and the specimen label.
- Specimen labeling and transport.
- Physical transport level confirmations.
- Interactions between the LIS and EHR-S for add-on orders beyond the transmission of the order (to address scenarios such as insufficient specimen or late arrivals of add-on orders).
- The sending of an order that would require the laboratory to create multiple orders based on recurring collection date and time (e.g., future recurring orders.)
- Ordering procedures for workload leveling and dealing with capacity limit, commonly but not exclusively, a public health lab issue.

2.3 Actors

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

- Laboratory Order Sender – A sender of laboratory order messages that declares conformance to a profile defined in this guide. This actor is referred to as the Order Placer within the V2 message components.
- Laboratory Order Receiver – A receiver of laboratory order messages that declares conformance to a profile defined in this guide. This actor is referred to as the Order Filler within the V2 message components.

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2.4 Orders for Inter-organizational Care Context Diagram

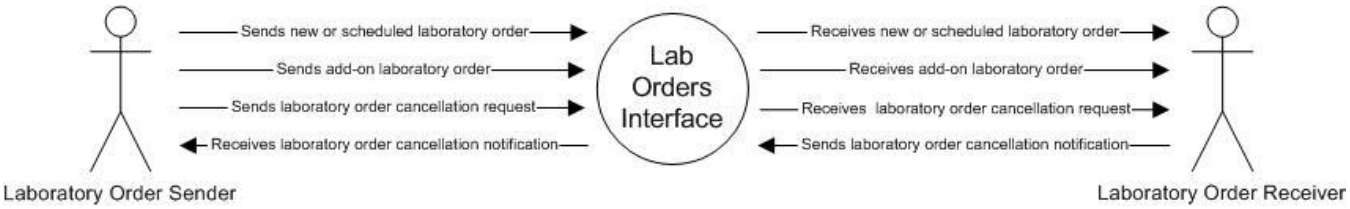

Figure 2-1. Context Diagram

2.5 User Story

A laboratory order interface automates the electronic communication of test order information between an EHR-S and an LIS. Implementation guidance that defines the communication (the message structure, data elements, and vocabularies) of laboratory orders between an EHR-S and an LIS, based on accepted industry standards, can:

- Improve care delivery and clinical outcomes through the tight coupling of order and result messages.
- Reduce implementation efforts and costs.
- Reduce on-going support and maintenance-related activities and costs.
- Provide an extensible foundation for use in other settings such as acute care and public health.
- Provide the data elements in the correct format and vocabulary for subsequent reporting of lab results to public health authorities without contacting the order placer for missing data.

2.6 Use Case Assumptions

- Providers (Order Placers) securely access clinical information through an EHR-S.
- Users have a need to exchange laboratory order data between ambulatory care EHR-Ss and Laboratory Information Systems (LISs) utilized in clinical laboratories.
- An EHR-S has the ability to manage a laboratory order, including generating the laboratory requisition and sending it to a laboratory.
- Requisitions are defined by laboratory practice and their exact instantiation is determined by trading partner agreement.
- An EHR-S is capable of generating an order electronically and is capable of receiving and processing acknowledgements, results and cancellations.
- A LIS is capable of receiving orders and cancellation requests, as well as generating acknowledgements and cancellation notifications.
- The Laboratory is capable of receiving laboratory orders electronically and in standardized structured format.
- The EHR-S and LIS both use data models that include discrete representations of data elements and the relationships between them for elements such as patients, clinician end-users, laboratory requisitions, laboratory orders (which include tests and panels), and laboratory test results (minimally at the level of individual analytes).

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- The Laboratory Results Interface (LRI) Implementation Guide7, the electronic Directory of Service Implementation Guide (eDOS), the profiles in LRI for Electronic Result Reporting (ELR) to Public Health and other specialized reporting use cases and this LOI IG will be synchronized with the goal that a laboratory that receives an order conforming to the LOI should be capable of responding with a message conforming to the LRI and the ELR IGs.
- Appropriate security and transport protocols, patient identification methodology, order identification methodology, patient consent, privacy and security procedures, coding, vocabulary, error handling, and normalization standards have been agreed to by all relevant participants.
- Legal and governance issues regarding data access authorizations, data ownership, and data use are in effect.
- Established network and policy infrastructure exists 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-S certification criteria.
- Adherence to all appropriate regulatory and legal requirements pertaining to the laboratory. Some of these legal requirements may include requirements with which the EHR-S and/or the ordering provider need to be compliant, even though they are located outside of the clinical laboratory. Regulatory compliance may be needed with all local, state, and federal laws related to laboratory testing, such as CLIA and/or FDA requirements, and any laboratory accreditation requirements. Regulatory requirements may differ for each laboratory depending on which apply (i.e. specific interface requirements may be required by some laboratories for accreditation).
- The Provider (Order Placer) has performed all of the necessary checks for medical necessity, insurance eligibility and any needed pre-authorizations.

2.6.1 PRE-CONDITIONS

Note: The pre- and post-conditions may not apply to all scenarios.

- The Laboratory's test compendium has been entered (manually or via automation) into the EHR-S. The EHR system assembles the information necessary to create an electronic

[7] The IG referenced here is the HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Results Interface, Release 1, DSTU Release 2 – US Realm, September 2015 available at www.hl7.org

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laboratory order message containing pertinent information as well as appropriate identifiers, such as patient, order, and specimen (if collected).

- Information for the cancellation requests for laboratory orders has been accurately captured within the EHR-S.
- All appropriate billing information is available within the EHR-S.
- Specimens are labeled in accordance with required policies and procedures for specimen submission and can be linked to the order8.

2.6.2 POST CONDITIONS

- Laboratory orders (and any ancillary information required for ordering) are successfully transmitted electronically from the Provider's (Order Placer's) EHR-S to the laboratory's LIS. The receiving laboratory's LIS electronically transmits acknowledgement of receipt of the laboratory order.
- The received order may be placed into an electronic queue for further processing depending on laboratory workflow (although order queues are out of scope for this Use Case).
- Specimen(s) associated with the laboratory order are collected and transported to the laboratory.
- The laboratory processes the laboratory order and associated specimen(s). This step may include retrieval and processing of laboratory orders from a queue or list of received orders. Order queues may be used in the LIS to hold electronic laboratory orders until associated specimens are received and the appropriate patient matching and registration occur (although order queues are out of scope for this Use Case). After patient matching and registration, the electronic order may be electronically processed in the LIS.
- If the laboratory order and specimen(s) are satisfactory for testing the laboratory will perform, or attempt to perform, the test(s).
- The laboratory test result is obtained, entered/released in the LIS, and sent to the Provider's (Order Placer's) EHR-S. This is covered within the Laboratory Results Interface Use Case.
- Successfully transmit laboratory order cancellation request from the Provider's (Order Placer's) EHR-S to the Laboratory's LIS.
- The Laboratory's LIS has electronically received the laboratory order cancellation request.

2.6.3 SCENARIO 1 – ELECTRONIC ORDERING OF NEW OR SCHEDULED LABORATORY TEST(S)

Using an EHR-S, a Provider *(Order Placer)* orders one or more new laboratory tests or scheduled laboratory tests (including future tests) to be performed by a laboratory. One or more Intermediary Exchanges (IE) may be used to convey the order from the EHR-S to the LIS.

[8] CLSI. *Specimen Labels: Content and Location, Fonts, and Label Orientation; Approved Standard.* CLSI document AUTO12-A. Wayne, PA: Clinical and Laboratory Standards Institute; 2011; ISBN 1-56238-748-0; ISSN 0273-3099, Volume 31 Number 7.

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2.6.3.1 FUNCTIONAL REQUIREMENTS

TABLE 2-1. INFORMATION INTERCHANGE REQUIREMENTS				
Initiating System	Action	Requirement	Action	Receiving System
EHR-S	Initiate and Send	Laboratory Test Order	Receive	LIS
LIS	Send	Acknowledgement for Received Laboratory Order (Accept Level Acknowledgement)	Receive	EHR-S
LIS	Send	Notification of Laboratory Order Acceptance (Application Level Acknowledgement)	Receive	EHR-S
EHR-S	Send	Acknowledgement for Received Notification of Laboratory Order Acceptance (Accept Level Acknowledgement)	Receive	LIS

TABLE 2-2. SYSTEM REQUIREMENTS		
System	Step#	System Requirement
EHR-S	1	Generate and Send an Electronic Laboratory Order with Standardized Structured Data
LIS	2	Receive and Process Electronic Laboratory Order
LIS	3	Generate and Send Laboratory Order Acknowledgement (Accept Level Acknowledgement)
EHR-S	4	Receive and Process Laboratory Order Acknowledgement (Accept Level Acknowledgement)
LIS	5	Generate and Send Laboratory Order Acknowledgement (Application Level Acknowledgement)
EHR-S	6	Receive and Process Laboratory Order Acknowledgement (Application Level Acknowledgement)
EHR-S	7	Generate and Send Acknowledgement to Laboratory Order Acknowledgement (Accept Level Acknowledgement)
LIS	8	Receive and Process Acknowledgement to Laboratory Order Acknowledgement (Accept Level Acknowledgement)

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2.6.3.2 SEQUENCE DIAGRAM

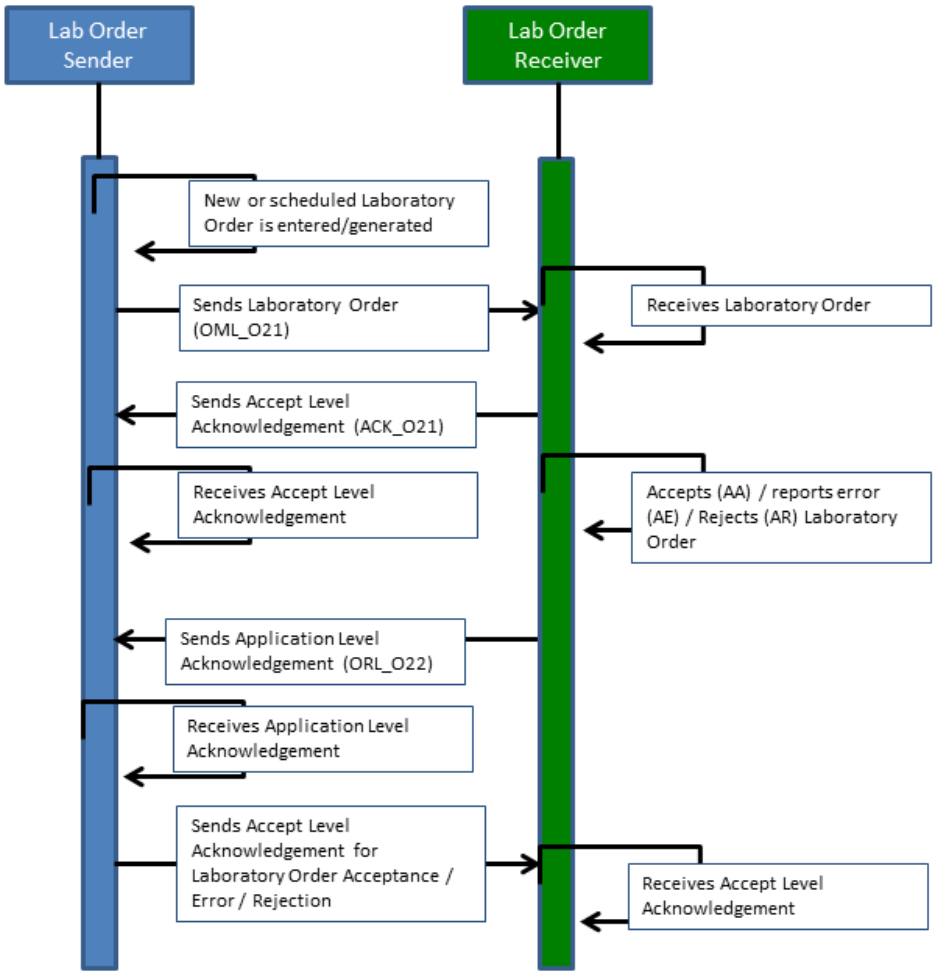

Figure 2-2. Scenario 1 Sequence Diagram

Note: Depending on the acknowledgement choreography chosen as described in Section 5.3 Acknowledgements, the accept and/or application level acknowledgement may or may not be present.

TABLE 2-3. SCENARIO 1 – ELECTRONIC ORDERING OF NEW OR SCHEDULED LABORATORY TEST(S)

SEQ	System(s)	Transaction	Main Messages and Key Data
1	EHR-S	New or Scheduled Laboratory Order is entered/generated	
2	EHR-S to LIS	Sends Laboratory Order	OML^O21^OML_O21: ORC-1 (Order Control Code) is valued 'NW'(New order/service); ORC-2/OBR-2 (Placer Order Number) is valued; ORC-3/OBR-3 (Filler Order Number) is empty; MSH-15 (Accept Acknowledgment Type) - see Section 5.3.1 for values; MSH-16 (Application Acknowledgment Type) - see Section 5.3.1 for values.

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TABLE 2-3. SCENARIO 1 – ELECTRONIC ORDERING OF NEW OR SCHEDULED LABORATORY TEST(S)			
SEQ	System(s)	Transaction	Main Messages and Key Data
3	LIS	Receives Laboratory Order	
4	LIS to IE and/or EHR-S	Sends Accept Acknowledgement for Received Laboratory Order	ACK^O21^ACK – MSA-2 (Message Control ID) is valued the same as MSH-10 (Message Control ID) in the message being acknowledged.
5	LIS to EHR-S	Sends Application Acknowledgement for Laboratory Order Acceptance	ORL^O22^ORL_O22: ORC-1 (Order Control Code) is valued 'OK' (Order accepted); ORC-2/OBR-2 is valued with the placer order number (echoed); ORC-3/OBR-3 is valued with the filler order number **OR** ORC-1 (Order Control Code) is valued 'UA' (Unable to Accept Order); ORC-2/OBR-2 is valued with the placer order number (echoed); ORC-3/OBR-3 is empty; MSH15 (Accept Acknowledgement Type) - see section 5.3.1.3 for values; MSH-16 (Application Acknowledgement Type) - see section 5.3.1.3 for values.
6	IE and/or EHR-S to LIS	Sends Accept Acknowledgement for Laboratory Order Acceptance	ACK^O22^ACK – MSA-2 (Message Control ID) is valued the same as MSH-10 (Message Control ID) in the message being acknowledged.

2.6.4 SCENARIO 2 – ELECTRONIC ORDERING OF ADD-ON LABORATORY TEST(S)

Using an EHR-S, the Order Placer adds one or more tests to a previously transmitted test requisition.

Note that if there is no need to relate the additional order to the specimen associated with a prior order, Section 2.6.3 Scenario 1 – Electronic Ordering of New or Scheduled Laboratory Test(s) must be followed.

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

Depending on the state of the order fulfillment, the Laboratory may not be able to perform the requested test against the intended specimen for a number of reasons (e.g., insufficient specimen, specimen too old).

Therefore, the Order Placer's add-on order request is communicated as a regular order and may include reference to, if known:

- The placer order number, when using non-unique order numbers, of the original order; and/or
- The placer group number that was used when the original order was placed; and/or
- Data pertaining to the specimen for which the order will be added.

As noted above, however, this does not guarantee the Laboratory will perform the order on the same specimen, nor on the same schedule as the original order.

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2.6.5 SCENARIO 3 – REQUESTING THE CANCELLATION OF A PREVIOUSLY PLACED LABORATORY ORDER

The Order Placer determines that one or more orders from a previously transmitted electronic laboratory requisition needs to be cancelled and requests the cancellation of the performance of the previously sent laboratory order(s) via the EHR-S to the LIS.

The Order Placer must use the LOI Cancel Request message in Section 5.2 OML^O21^OML_O21: Laboratory Order Message – Cancel Order, given they do not know if the laboratory has received the patient specimen or begun the testing process.

The Laboratory determines whether the test can be cancelled, or whether the order has progressed too far to cancel. In either case the Laboratory should reply with an Application Level Acknowledgment as defined in Section 5.3.1.3 ORL^O22^ORL_O22: Laboratory Order Message – Application Level Acknowledgement, and populate the ORC-1 Order Control field appropriately. ("CR" for Canceled as Requested, or "UC" for Unable to Cancel.)

However, this guide recognizes that some Laboratories may still use the LRI Result message using the result status as described in the LRI Implementation Guide.

Once any preliminary or final results have been incorporated into the EHR-S the test cannot be cancelled by the provider. The Order Placer shall not use the LOI Cancel Results message in these instances.

2.6.5.1 FUNCTIONAL REQUIREMENTS

TABLE 2-4. INFORMATION INTERCHANGE REQUIREMENTS

Initiating System	Action	Requirement	Action	Receiving System
EHR-S	Initiate and Send	Laboratory Order Cancellation Request	Receive	LIS
LIS	Send	Acknowledgement of Laboratory Order Cancellation Request (Accept Level Acknowledgement)	Receive	EHR-S
LIS	Send	Notification of Laboratory Order Cancellation	Receive	EHR-S
EHR-S	Send	Acknowledgement of Laboratory Order Cancellation Notification (Accept Level Acknowledgement)	Receive	LIS

TABLE 2-5. SYSTEM REQUIREMENTS

System	Step#	System Requirement
EHR-S	1	Generate Laboratory Order Cancellation Request
LIS	2	Process Laboratory Order Cancellation Request
LIS	3	Generate and Send Laboratory Order Cancelation Acknowledgement (Accept Level Acknowledgement)
EHR-S	4	Receive and Process Laboratory Order Cancelation Acknowledgement (Accept Level Acknowledgement)
LIS	5	Generate and Send Notification of Laboratory Order Cancelation (Application Level Acknowledgement)
EHR-S	6	Receive and Process Notification of Laboratory Order Cancelation (Application Level Acknowledgement)
EHR-S	7	Generate and Send Acknowledgement of Laboratory Order Cancellation Notification (Accept Level Acknowledgement)

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TABLE 2-5. SYSTEM REQUIREMENTS		
System	Step#	System Requirement
LIS	8	Process Acknowledgement of Laboratory Order Cancellation Notification (Accept Level Acknowledgement)

2.6.5.2 SEQUENCE DIAGRAM

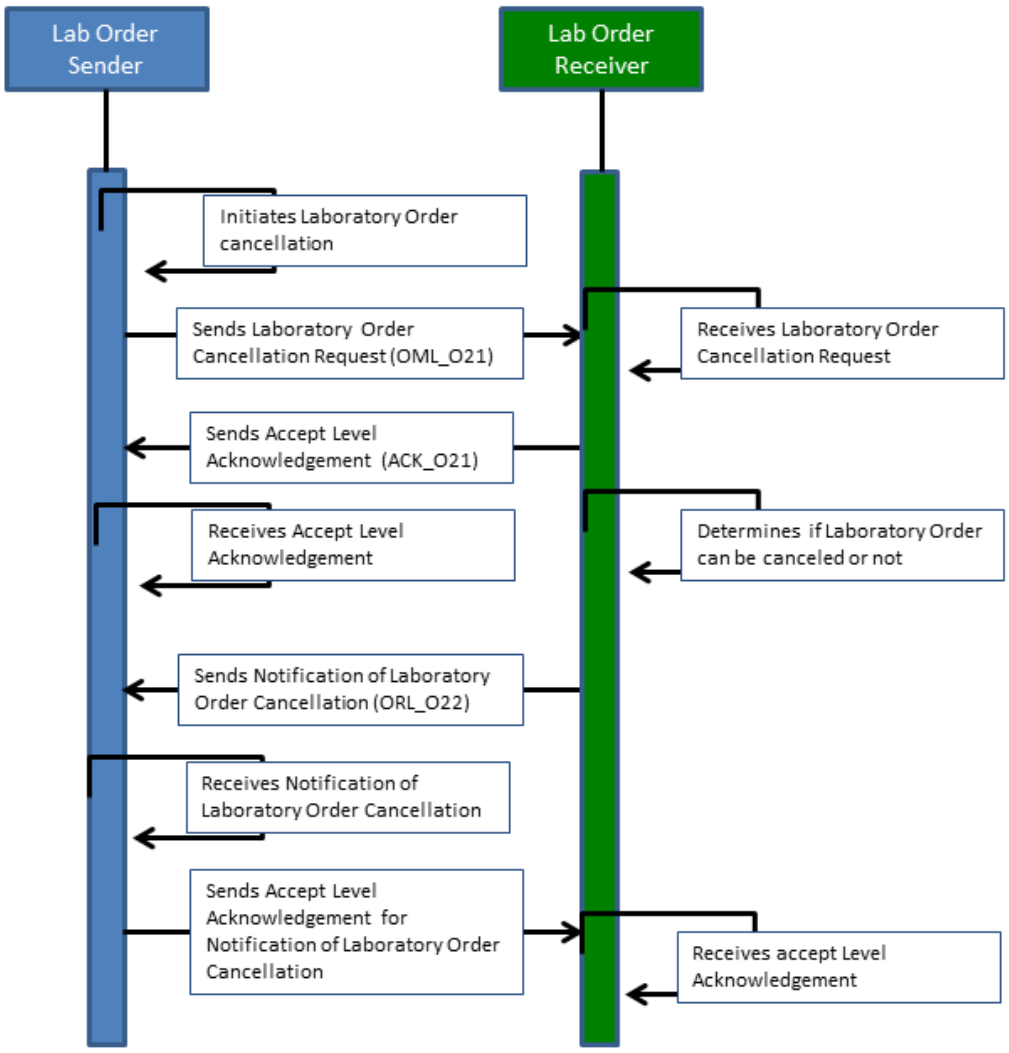

Figure 2-3. Scenario 3 Sequence Diagram

Note: Depending on the acknowledgement choreography chosen as described in Section 5.3 Acknowledgements, the accept and/or application level acknowledgement may or may not be present.

TABLE 2-6. SCENARIO 3 – REQUESTING THE CANCELLATION OF A PREVIOUSLY PLACED LABORATORY ORDER			
SEQ	System(s)	Transaction	Main Messages and Key Data
1	EHR-S	Initiates Order Cancellation	

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TABLE 2-6. SCENARIO 3 – REQUESTING THE CANCELLATION OF A PREVIOUSLY PLACED LABORATORY ORDER			
SEQ	System(s)	Transaction	Main Messages and Key Data
2	EHR-S to LIS	Sends Cancellation Request	OML^O21^OML_O21: ORC-2/OBR-2 (Placer Order Number)is valued; ORC-3/OBR-3 (Filler Order Number) is valued if known; ORC-1 (Order Control Code) is valued 'CA' (Cancel order/service request); MSH-15 (Accept Acknowledgement Type) see Section 5.3.1 for values; MSH-16 (Application Acknowledgement Type) see Section 5.3.1 for values.
3	LIS	Receives Laboratory Order Cancellation Request	
4	LIS to IE and/or EHR-S	Sends Accept Acknowledgement of Cancellation Request	ACK^O21^ACK – MSA-2 (Message Control ID) is valued the same as MSH-10 (Message Control ID) in the message being acknowledged.
5	LIS	Determines whether the order can be canceled or not	
6	LIS to EHR-S	Sends Application Acknowledgement for the Notification of Laboratory Order Cancellation	ORL^O22^ORL_O22: ORC-1 (order Control Code) is valued 'CR' (Canceled as requested) or 'UC' (Unable to cancel); ORC-2/OBR-2 is valued with the placer order number; ORC-3/OBR-3 is valued with the filler order number; MSH15 (Accept Acknowledgement Type) - see section 5.3.1.3 for values; MSH-16 (Application Acknowledgement Type) - see section 5.3.1.3 for values.
7	EHR-S	Receives Notification of Laboratory Order Cancellation	
8	IE and/or EHR-S to LIS	Sends Accept Acknowledgement for Notification of Laboratory Order Cancellation	ACK^O22^ACK – MSA-2 (Message Control ID) is valued the same as MSH-10 (Message Control ID) in the message being acknowledged.

2.6.6 SCENARIO 4 – LABORATORY CANCELLATION OF A PREVIOUSLY PLACED LABORATORY ORDER

The Laboratory *(Order Filler)* may cancel laboratory orders and send a cancellation notification message to the EHR-S of the Provider *(Order Placer)* because the test associated with the laboratory order is unable to be performed, independent of the Provider requesting cancellation. This applies to an original/initial order or an add-on order.

Laboratories can cancel a test request any time before the test report (preliminary or final) is transmitted to the provider(s).

It is strongly recommended the Laboratory use the LOI Cancel Order up to the point that the specimen starts to be processed.

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After that, the Laboratory could either use the LOI Cancel Order message described in Section 5.2 OML^O21^OML_O21: Laboratory Order Message – Cancel Order, or use the LRI Result Cancel Notification depending on how far the testing process progressed before the determination to cancel the test was made.

Note: cancellation of part of an order must be done through a results message as defined in the LRI IG.

2.6.6.1 FUNCTIONAL REQUIREMENTS

TABLE 2-7. INFORMATION INTERCHANGE REQUIREMENTS

Initiating System	Action	Requirement	Action	Receiving System
LIS	Initiate and Send	Cancellation Notification	Receive	EHR-S
EHR-S	Send	Acknowledgment (Accept Level Acknowledgement)	Receive	LIS
EHR-S	Send	Acknowledgment (Application Level Acknowledgement)	Receive	LIS

TABLE 2-8. SYSTEM REQUIREMENTS

System	Step#	System Requirement
LIS	1	Generate and Send Laboratory Order Cancellation Notification
EHR-S	2	Receive and Process Cancellation Notification
EHR-S	3	Generate and Send Cancellation Notification Acknowledgement (Accept Level Acknowledgement)
LIS	4	Receive and Process Cancellation Notification Acknowledgement (Accept Level Acknowledgement)
EHR-S	5	Generate and Send Cancellation Notification Acknowledgement (Application Level Acknowledgement)
LIS	6	Receive and Process Cancellation Notification Acknowledgement (Application Level Acknowledgement)

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2.6.6.2 SEQUENCE DIAGRAM

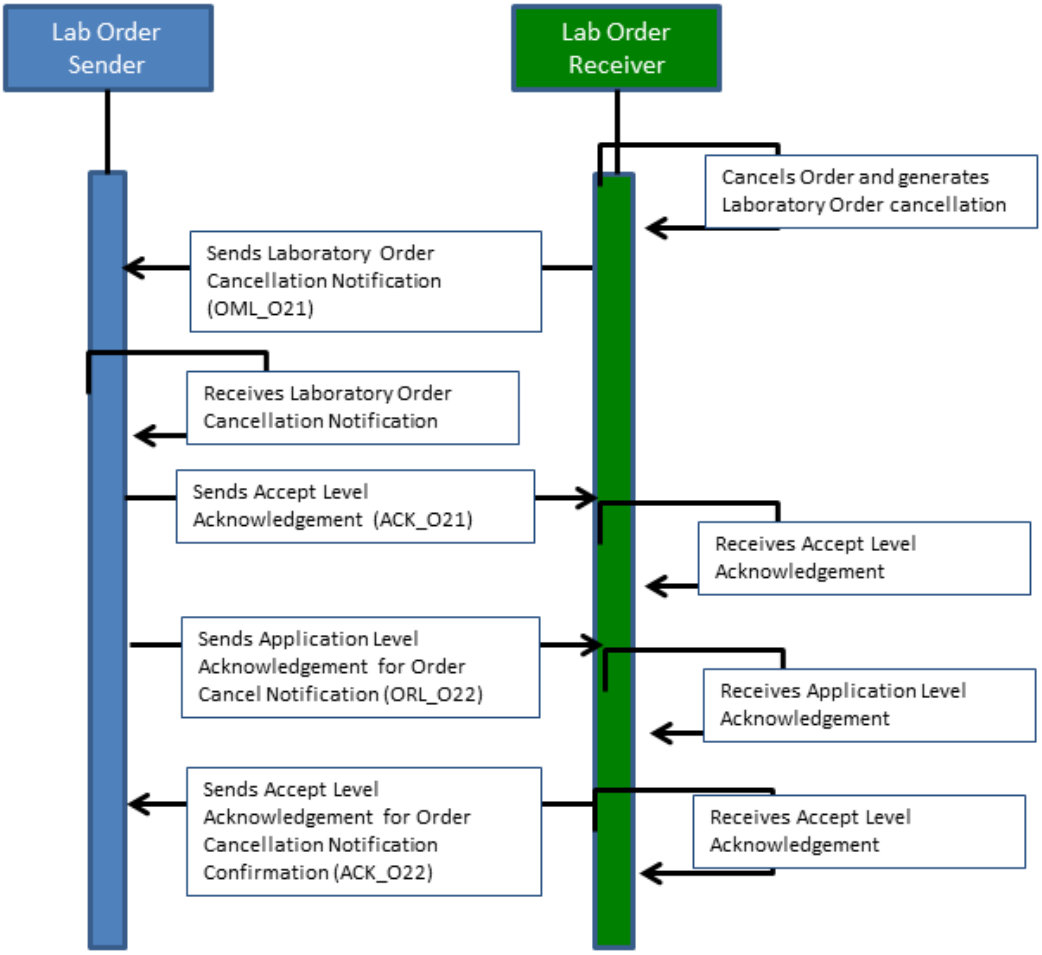

Figure 2-4. Scenario 4 Sequence Diagram

Note: Depending on the acknowledgement choreography chosen as described in Section 5.3 Acknowledgements, the accept and/or application level acknowledgement may or may not be present.

TABLE 2-9. SCENARIO 4 – LABORATORY CANCELLATION OF A PREVIOUSLY PLACED LABORATORY ORDER

SEQ	System(s)	Transaction	Main Messages and Key Data
1	LIS	Cancels order and generates Laboratory Order Cancellation	

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TABLE 2-9. SCENARIO 4 – LABORATORY CANCELLATION OF A PREVIOUSLY PLACED LABORATORY ORDER			
SEQ	System(s)	Transaction	Main Messages and Key Data
2	LIS to EHR-S	Sends Laboratory Order Cancellation Notification	OML^O21^OML_O21: ORC-1 (Order Control Code) is valued 'OC' (Order/service cancelled), ORC-2/OBR-2 is valued with the placer order number, ORC-3/OBR-3 is valued with the filler order number, MSH-15 (Accept Acknowledgement Type) - see section 5.3.1.3 for values MSH-16 (Application Acknowledgement Type) see section 5.3.1.3 for values.
3	EHR-S	Receives Laboratory Order Cancellation Notification	
4	LIS to IE and/or EHR-S	Sends Accept Acknowledgement for Received Cancellation Notification	ACK^O21^ACK – MSA-2 (Message Control ID) is valued the same as MSH-10 (Message Control ID) in the message being acknowledged.
5	EHR-S to LIS	Sends Application Acknowledgement for Order Cancel Notification	ORL^O22^ORL_O22: ORC-1 (Order Control Code) is valued 'OK' (Order/service accepted & OK), ORC-2/OBR-2 is valued with the placer order number, ORC-3/OBR-3 is valued with the filler order number, if one had been assigned, MSH-15 (Accept Acknwoledgement Type) - see section 5.3.1.3 for values MSH-16 (application Acknowledgement Type) - see section 5.3.1.3 for values.
6	IE and/or EHR-S to LIS	Sends Accept Acknowledgement of Order Cancellation Notification Confirmation	ACK^O22^ACK – MSA-2 (Message Control ID) is valued the same as MSH-10 (Message Control ID) in the message being acknowledged.

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3 USE CASE – ORDERS FOR NEWBORN DRIED BLOOD SPOT (NDBS) SCREENING

This use case is supported by the LOI_NDBS_Component; see Section 4.2.1.15 LOI_NDBS_Component (Newborn Dried Bloodspot Screening) – ID: 2.16.840.1.113883.9.195.2.11

Newborn Dried Blood Spot Screening is used to screen newborns routinely for certain genetic, metabolic, hormonal, and functional disorders and is often part of state specific regulations. While these disorders are rare, diagnosing them allows for early treatment to improve a baby's health and to prevent possible disabilities and, in some cases, death. As with many aspects of healthcare, the organization and delivery of newborn care is information-intensive and can be facilitated by automating information management, usually in the form of electronic health records (EHR) or health information systems.

In this Use Case, the Newborn Screening Laboratory receives NDBS orders from an authorized data exchange receiver.

3.1 Scope

The scope is the sending of NDBS orders to a newborn screening laboratory from the primary care physicians, midwives and birth centers, birth hospitals, public health agencies as well as health information exchanges (HIEs). Any variations that are specific to Newborn Dried Blood Spot (NDBS) are identified in separate subsections where appropriate and prefacing them with "LOI_NDBS_Component".

In addition to the items in Section 2.2 Scope, the following are specific to the design of the LRI_NDBS_Component:

3.1.1 IN SCOPE

- Describing the specifications that may be used for the sending of electronic lab orders in the current state of business process flow in Newborn Dried Blood Spot Screening.
- Specifying the interaction between laboratories that conduct NDBS testing and the requesters of the testing, that include primary care physicians, birth hospitals, health information exchanges (HIEs).

3.1.2 OUT OF SCOPE

- Ordering of point of care results for newborn screening for Early Hearing Detection and Intervention (EHDI) and Critical Congenital Heart Disease (CCHD)
- NDBS screening practices and specifications of electronic messages exchanged for newborn screening conducted internationally outside of the United States. However, NDBS programs outside the U.S. could adopt this Implementation Guide.
- This Implementation Guide provides a general set of specifications for an electronic NDBS laboratory orders message. It does not identify, eliminate or override variations in state or local jurisdiction requirements for data collection, reporting, or protection of privacy and security of patient data. Variations in local laws and practices may result in additional data requirements for NDBS screening.

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3.2 User Story

Some states by policy test and report unsatisfactory specimens, otherwise the user story is identical to Section 2 Use Case – Inter-organizational Care Setting.

3.3 Use Case Assumptions

- Each OML^O21 message contains laboratory test order information for a single Newborn Dried Blood Spot card (the specimen).
- The specimen has already been collected BEFORE the order is sent.

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4 CONFORMANCE TO THIS GUIDE

4.1 Value Sets

Conformance to this guide requires an implementation to adhere to sets of constraints as defined in the profile components and profiles below, as well as the Value Set requirements as set forth in the following publication:

HL7 Version 2 Implementation Guide: Laboratory Value Set Companion Guide; Release 1.3 (US Realm); HL7 Standard for Trial Use; May 2018

Note that newer versions of the Value Set Companion Guide may be used with this IG and be considered conformant.

4.2 Profiles and Profile Components

This Implementation Guide defines profile components that are combined into profiles to define specific conformance requirements. Profile components and profiles can be specific to a very narrow set of requirements for an IG, or broadly defined for use in all US Realm Laboratory interactions. This latter set is referred to as “domain” profile components in this guide.

The profile components must be combined to create a valid complete Profile for a particular transaction by populating MSH-21 (Message Profile Identifier) with a valid set of identifiers. Multiple profiles or profile components can be present in MSH-21 provided the combined requirements do not conflict with each other. Additional definitions and guidance for MSH-21 can be found in Section 6.1 MSH – Message Header Segment.

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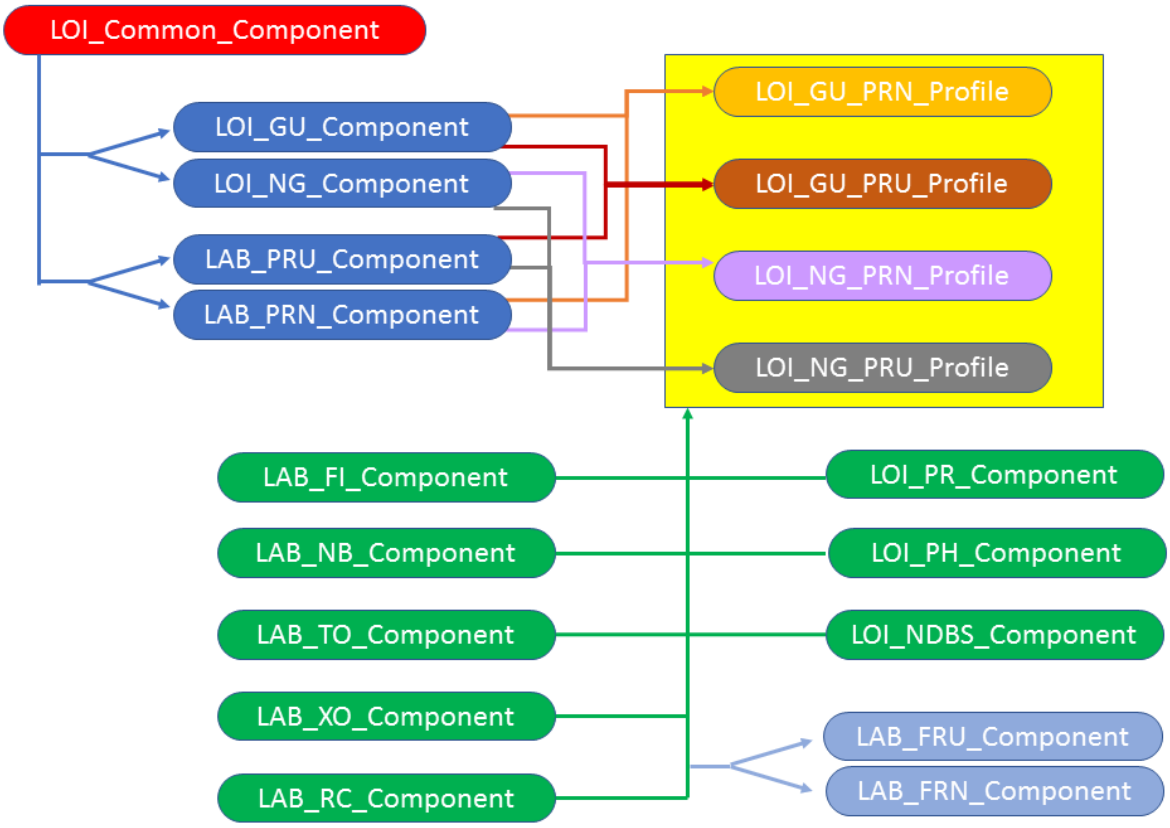

Figure 4-1. Profile and Component Architecture

Legend:

- Red background label for Common component – required for all profiles
- Dark blue background label for Choice components – required to choose one of the two options for each
- Green background label for optional Add-On components - can be added to any profile depending on the domain that needs to be covered or what functionality is desired
- Mixed colored background labels in the yellow box - pre-coordinated profiles with each of the required components for convenience

As of this version a valid order Profile consists of, at minimum, a set of profile components identified in 1-3 below when the order placer sends messages to a laboratory:

1. The LOI_Common_Component (4.2.1.1) (red)
2. The Choice Profile Components (dark blue):
    a. LOI_GU_Component (Globally Unique) **OR** the LOI_NG_Component (Non-Globally Unique) (4.2.1.2, 4.2.1.3)
    b. LAB_PRU_Component (Unique Placer Order Number) **OR** the LAB_PRN_Component (Non-Unique Placer Order Number) (4.2.1.7, 4.2.1.8)

When a laboratory responds to an existing order it must include a fourth profile component:

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3. The LAB_FRU_Component (Unique Filler Order Number) **OR** the LAB_FRN_Component (Non-Unique Filler Order Number) (4.2.1.5, 4.2.1.6) (green)

The LOI_GU and LOI_NG profile components declare that the message conforms (or not) to the use of ISO Object Identifiers (OIDS) to establish global uniqueness for identifier fields as noted in Section 1.4.3 Use of ISO Object Identifier (OID) and Section 4.2.1.3.

The LAB_PRU and the LAB_PRN profile components declare if the placer order number is globally unique (or not), see Section 4.2.1.4 and Section 4.2.1.8.

The LAB_FRU and the LAB_FRN profile components declare if the filler order number is globally unique (or not), see Section 4.2.1.5 and Section 4.2.1.6.

Use of LAB_GU, LAB_PRU, and LAB_FRU are strongly recommended as the intent is to deprecate LAB_NG, LAB_PRN, and LAB_FRN when adoption of unique identifiers is more commonplace.

Additional profile components, also referred to as Add-On Profile Components, are optional but may be included when supported by both trading partners. This guide defines eight such profile components:

1. LAB_FI_Component (Financial Information) (4.2.1.4)
2. LAB_NB_Component (Newborn BirthTime) (4.2.1.9)
3. LAB_TO_Component (Time Offset) (4.2.1.10)
4. LAB_XO_Component (Exclusions) (4.2.1.11)
5. LOI_PH_Component (Public Health) (4.2.1.12)
6. LOI_PR_Component (Prior Results) (4.2.1.13)
7. LAB_RC_Component (Results Copies) (4.2.1.14)
8. LOI_NDBS_Component (Newborn Dried Bloodspot Screening) (4.2.1.15)

As of this version a valid response Profile consists of two profile components from the following list:

1. The LOI_O21_Acknowledgement_Component (4.2.3.3) OR the LOI_O22_Acknowledgement_Component (4.2.3.4) OR the LOI_ORL_Acknowledgement_Component (4.2.3.7)
2. The LOI_GU_Acknowledgement_Component (4.2.3.5) OR the LOI_NG_Acknowledgement_Component (4.2.3.6)

plus applicable optional profiles as needed.

4.2.1 ORDER PROFILE COMPONENTS

Note that the FI, TO, XO, NB, PH, PR and RC profile components are not included in the pre-coordinated profiles; rather they are added to MSH-21 when applicable, e.g., the LOI_PR_Component would be included to support sending of prior results relevant for the order. A receiver may reject the message with optional profile components if not addressed by partner agreements.

In addition to trading partner agreement on the use of optional profile components, trading partners need to agree on the required Profile, either NG or GU.

The components that can be assembled into profiles are:

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4.2.1.1 LOI_COMMON_COMPONENT – ID: 2.16.840.1.113883.9.66

This profile component indicates that the message adheres to the rules set out in this Implementation Guide.

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

4.2.1.2 LOI_GU_COMPONENT (GLOBALLY UNIQUE) – ID: 2.16.840.1.113883.9.78

This profile component indicates that the following fields use Globally Unique Identifiers according to Section 1.4.3 Use of ISO Object Identifier (OID) for at least the assigning authority within the data type used.

- MSH-3 – Sending Application
- MSH-4 – Sending Facility
- MSH-5 – Receiving Application
- MSH-6 – Receiving Facility
- PID-3 – Patient Identifier List
- ORC-2 – Placer Order Number
- ORC-3 – Filler Order Number
- ORC-4 – Placer Group Number
- ORC-12 – Ordering Provider
- ORC-21 – Ordering Facility Name
- OBR-2 – Placer Order Number
- OBR-3 – Filler Order Number
- OBR-16 – Ordering Provider
- OBR-28 – Result Copies To
- OBR-29 – Parent
- OBX-16 – Responsible Observer
- OBX-23 – Performing Organization Name
- OBX-25 – Performing Organization Medical Director
- SPM-2 – Specimen ID
- NK1-13 – Organization Name - NK13
- IN1-3 – Insurance Company ID
- IN1-4 – Insurance Company Name
- IN1-11 – Insured’s Group Emp Name
- GT1-21 – Guarantor Organization Name

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- PRT-1 – Participation Instance ID
- PRT-5 – Participation Person

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

4.2.1.3 LOI_NG_COMPONENT (NON-GLOBALLY UNIQUE) – ID: 2.16.840.1.113883.9.79

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 1.4.3 Use of ISO Object Identifier (OID) while others use any of the identification methods allowed through the base standard. Consequently, these identifiers are not guaranteed to be globally unique.

- MSH-3 – Sending Application
- MSH-4 – Sending Facility
- MSH-5 – Receiving Application
- MSH-6 – Receiving Facility
- PID-3 – Patient Identifier List
- ORC-2 – Placer Order Number
- ORC-3 – Filler Order Number
- ORC-4 – Placer Group Number
- ORC-12 – Ordering Provider
- ORC-21 – Ordering Facility Name
- OBR-2 – Placer Order Number
- OBR-3 – Filler Order Number
- OBR-16 – Ordering Provider
- OBR-28 – Result Copies To
- OBR-29 – Parent
- SPM-2 – Specimen ID
- NK1-13 – Organization Name - NK13
- IN1-3 – Insurance Company ID
- IN1-4 – Insurance Company Name
- IN1-11 – Insured’s Group Emp Name
- GT1-21 – Guarantor Organization Name
- PRT-1 – Participation Instance ID
- PRT-5 – Participation Person

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

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4.2.1.4 LAB_FI_COMPONENT – ID: 2.16.840.1.113883.9.80

This optional profile component indicates that the following segment groups and segments, which are specifically relevant to financial processes such as billing, are part of the LOI message rather than communicated through other means than the laboratory order or results messages, e.g., ADT or other financial transactions.

- Visit group
- Insurance group
- GT1 segment

4.2.1.5 LAB_FRU_COMPONENT (UNIQUE FILLER NUMBER) – ID: 2.16.840.1.113883.9.83

This profile component indicates that the filler order number uniquely identifies the test ordered. No additional information is necessary, such as the universal service identifier in OBR-4 (Universal Service Identifier), since the identifier on its own is unique. This profile component can only be declared in MSH-21 by the filler and subsequently copied if the copier (e.g., placer upon responding, or another party forwarding the message) did not change the filler order number value.

4.2.1.6 LAB_FRN_COMPONENT (NON-UNIQUE FILLER NUMBER) – ID: 2.16.840.1.113883.9.84

This profile component indicates that the test ordered shall be identified using the universal identifier in conjunction with the filler order number. The filler order number must be combined with the universal service identifier to uniquely identify the test ordered.

This must also be taken into account when creating parent – child relationships in subsequent messages.

This profile component can only be declared in MSH-21 by the filler and subsequently copied if the copier (e.g., placer upon responding, or another party forwarding the message) did not change the filler order number value.

4.2.1.7 LAB_PRU_COMPONENT (UNIQUE PLACER ORDER NUMBER) – ID: 2.16.840.1.113883.9.82

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

4.2.1.8 LAB_PRN_COMPONENT (NON-UNIQUE PLACER ORDER NUMBER) – ID: 2.16.840.1.113883.9.81

This profile component indicates that the test ordered shall be identified using the universal identifier in conjunction with the placer order number and, if available, the filler order number. The order numbers (placer/filler) must be combined with the universal service identifier to uniquely identify the order. This must also be taken into account when creating parent-child relationships in subsequent messages.

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This component can only be declared in MSH-21 by the placer but may be echoed back or forwarded.

4.2.1.9 LAB_NB_COMPONENT (NEWBORN BIRTHTIME) – ID: 2.16.840.1.113883.9.24

This profile component declares behaviors and constraints that apply to ANY lab testing performed on newborns (up to 28 days old), except newborn dried bloodspot screening (see 4.2.1.15 for specific constraints for that use case). Specifically the LAB_NB_Component indicates that the data type TS_02 or, when TO_Component is also invoked TS_03, is used in PID-7 (Date/Time of Birth) to support Newborn Screening lab tests that require this precision in the Date/Time of Birth data element.

4.2.1.10 LAB_TO_COMPONENT (TIME OFFSET) – ID: 2.16.840.1.113883.9.22

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

When LAB_TO_Component is applied the listed datatypes for each of the fields changes as follow:

Listed datatype	becomes datatype
TS_02	TS_03
TS_06	TS_07
TS_08	TS_09
TS_10	TS_11
TS_12	TS_13

Note: This is a laboratory domain profile component and the following fields may or may not be required in this IG:

- MSH-7 – Date/Time of Message
- PID-7 – Date/Time of Birth
- IN1-18 – Insured’s Date Of Birth
- ORC-9 – Date/Time of Transaction
- OBR-7 – Observation Date/Time
- OBR-8 – Observation End Date/Time
- OBR-22 – Results Rpt/Status Chng – Date/Time
- TQ1-7 – Start Date/Time
- TQ1-8 – End Date/Time
- OBX-5 – Observation Value (when OBX-2 is ‘TM’ or ‘TS’)
- OBX-14 – Date/Time of the Observation
- OBX-19 – Date/Time of the Analysis
- SPM-17 – Specimen Collection Date/Time

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It is important that the sending application has appropriately resolved the time zone offsets for PID-7, INI-18, TQ1-7, TQ1-8, OBR-7, OBR-8, and SPM-17 as these date/times may be managed through ADT/Registration and Orders interfaces.

4.2.1.11 LAB_XO_COMPONENT (EXCLUSIONS) – ID: 2.16.840.1.113883.9.23

One of the basic premises of this guide is to enable senders to compose transactions that may satisfy multiple purposes, e.g., multiple Implementation Guides that share the same required fields and vocabulary. They therefore may populate any of the fields/components marked 'O' (optional). At the same time this Implementation Guide wants to expressly reinforce that if data is sent in optional fields/segments, the receiver can completely ignore those. Therefore, the usage code 'X' is used sparingly, while the usage code 'O' is mostly used when the field/component is not necessary for the use case at hand. The rationale is that according to the definition of 'X' per the base standard is "For conformant sending applications, the element shall not be sent. Conformant receiving applications may ignore the element if it is sent, or may raise an application error."

However to accommodate those implementations where the population of any optional fields remaining is not desirable, the LAB_XO_Component is defined to indicate that all of the remaining optional segments and fields that are marked O (Optional) are now considered to be marked with an X (Not Supported). Its use yields, in combination with the other profile components, a fully implementable Profile in accordance with Chapter 2B. Note though that this profile component is strictly voluntary and its use cannot be mandated by either trading partner to enable a successful results transaction.

4.2.1.12 LOI_PH_COMPONENT (PUBLIC HEALTH) – ID: 2.16.840.1.113883.9.94

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

- PID-6 – Mother's Maiden Name
- PID-13 – Phone Number – Home
- PID-14 – Phone Number – Business
- NK1-30 – Contact Person's Name
- NK1-32 – Contact Person's Address
- ORC-21 – Ordering Facility Name
- ORC-22 – Ordering Facility Address
- ORC-23 – Ordering Facility Phone Number
- SPM-5 – Specimen Type Modifier
- SPM-6 – Specimen Additives

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- SPM-7 – Specimen Collection Method
- SPM-8 – Specimen Source Site
- SPM-9 – Specimen Source Site Modifier

4.2.1.13 LOI_PR_COMPONENT (PRIOR RESULTS) – ID: 2.16.840.1.113883.9.95

Inclusion of this optional profile component in MSH-21 (Message Profile Identifier) indicates that prior results are included in the message using the Prior Result segment group. Results that were obtained before this order was placed are considered prior results. When the original structure needs to be preserved, e.g., microbiology results, the Prior Result segment group would enable the transmission of a fully structured result set.

Prior laboratory results should be encoded so as to conform to the LRI IG whenever possible; prior results should reflect the original coding.

4.2.1.14 LAB_RC_COMPONENT (RESULTS COPIES) – ID: 2.16.840.1.113883.9.96

Inclusion of this profile component in MSH-21 (Message Profile Identifier) indicates that the number of recipients of copies of the results can be greater than five.

4.2.1.15 LOI_NDBS_COMPONENT (NEWBORN DRIED BLOODSPOT SCREENING) – ID: 2.16.840.1.113883.9.195.2.11

Inclusion of this profile component in MSH-21 (Message Profile Identifier) indicates that specific constraints are applied to convey orders and related information specific to newborn dried blood spot (NDBS) screening. It can be used with any of the base profiles.

4.2.2 ORDER PROFILES (PRE-COORDINATED COMPONENTS)

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

4.2.2.1 LOI_GU_PRU_PROFILE – ID: 2.16.840.1.113883.9.85

This profile component pre-coordinates the use of the LOI_Common_Component, LOI_GU_Component, and the LAB_PRU_Component.

4.2.2.2 LOI_GU_PRN_PROFILE – ID: 2.16.840.1.113883.9.86

This profile component pre-coordinates the use of the LOI_Common_Component, LOI_GU_Component, and the LAB_PRN_Component.

4.2.2.3 LOI_NG_PRU_PROFILE – ID: 2.16.840.1.113883.9.87

This profile component pre-coordinates the use of the LOI_Common_Component, LOI_NG_Component, and the LAB_PRU_Component.

4.2.2.4 LOI_NG_PRN_PROFILE – ID: 2.16.840.1.113883.9.88

This profile component pre-coordinates the use of the LOI_Common_Component, LOI_NG_Component, and the LAB_PRN_Component.

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4.2.3 RESPONSE COMPONENTS

4.2.3.1 LOI_ACCEPT_ACKNOWLEDGEMENT_COMPONENT – ID: 2.16.840.1.113883.9.195.2.9

This profile component indicates that the acknowledgement message adheres to the rules set out in this Implementation Guide for an accept level acknowledgement, used both with the basic and end-to-end scenarios.

This profile component sets the minimum constraints on the base specification for the acknowledgement and may be further constrained by additional profile components.

4.2.3.2 LOI_APPLICATION_ACKNOWLEDGEMENT_COMPONENT – ID: 2.16.840.1.113883.9.195.2.10

This profile component indicates that the acknowledgement messages must adhere to the rules set out in this Implementation Guide for application level acknowledgements, used with the end-to-end acknowledgements only.

This profile component sets the minimum constraints on the base specification for the end-to-end acknowledgement and may be further constrained by additional profile components.

4.2.3.3 LOI_O21_ACKNOWLEDGEMENT_COMPONENT – ID: 2.16.840.1.113883.9.195.2.8

This profile component indicates that the acknowledgement message adheres to the rules set out in this Implementation Guide in 5.3.1.2.

Note: This profile component sets the minimum constraints on the base specification for the acknowledgement and may be further constrained by additional profile components.

4.2.3.4 LOI_O22_ACKNOWLEDGEMENT_COMPONENT – ID: 2.16.840.1.113883.9.195.2.5

This profile component indicates that the acknowledgement message adheres to the rules set out in this Implementation Guide in Section 5.3.1.4.

Note: This profile component sets the minimum constraints on the base specification for the acknowledgement and may be further constrained by additional profile components.

4.2.3.5 LOI_GU_ACKNOWLEDGEMENT_COMPONENT – ID: 2.16.840.1.113883.9.90

This profile component is used to identify an ACK that is constrained for the profiles defined within this guide in response to the OML message where MSH-21 (Message Profile Identifier) contains '2.16.840.1.113883.9.85' (LOI_GU_PRU_Profile), **OR** '2.16.840.1.113883.9.86' (LOI_GU_PRN_Profile), **OR** '2.16.840.1.113883.9.78' (LOI_GU_Component).

4.2.3.6 LOI_NG_ACKNOWLEDGEMENT_ COMPONENT – ID: 2.16.840.1.113883.9.91

This profile component is used to identify an ACK that is constrained for the profiles defined within this guide in response to the OML message where MSH-21 (Message Profile Identifier) contains '2.16.840.1.113883.9.87' (LOI_NG_PRU_Profile), **OR** '2.16.840.1.113883.9.88' (LOI_NG_PRN_Profile), **OR** '2.16.840.1.113883.9.79' (LOI_NG_Component).

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4.2.3.7 LOI_ORL_ACKNOWLEDGEMENT_COMPONENT – ID: 2.16.840.1.113883.9.195.2.2

This component indicates that the ORL application level acknowledgement message adheres to the rules set out in this Implementation Guide in Section 5.3.1.3.

Note: This component sets the minimum constraints on the base specification for the ORL application acknowledgement and may be further constrained by additional components.

4.2.4 RESPONSE PROFILES (PRE-COORDINATED COMPONENTS)

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

4.2.4.1 LOI_GU_ ACK_ O21_PROFILE – ID: 2.16.840.1.113883.9.92

This Profile pre-coordinates the use of the LOI_O21_Acknowledgement_Component and the LOI_GU_Acknowledgement_Component.

4.2.4.2 LOI_NG_ ACK_ O21_PROFILE – ID: 2.16.840.1.113883.9.93

This Profile pre-coordinates the use of the LOI_O21_Acknowledgement_Component and the LOI_NG_Acknowledgement_Component.

4.2.4.3 LOI_GU_ACK_ O22_PROFILE – ID: 2.16.840.1.113883.9.195.2.6

This Profile pre-coordinates the use of the LOI_O22_Acknowledgement_Component and the LOI_GU_Acknowledgement_Component.

4.2.4.4 LOI_NG_ACK_ O22_PROFILE – ID: 2.16.840.1.113883.9.195.2.7

This Profile pre-coordinates the use of the LOI_O22_Acknowledgement_Component and the LOI_NG_Acknowledgement_Component.

4.2.4.5 LOI_GU_ORL_RESPONSE_PROFILE – ID: 2.16.840.1.113883.9.195.2.3

This Profile pre-coordinates the use of the LOI_ORL_Acknowledgement_Component and the LOI_GU_Acknowledgement_Component.

4.2.4.6 LOI_NG_ORL_RESPONSE_PROFILE – ID: 2.16.840.1.113883.9.195.2.4

This profile pre-coordinates the use of the LOI_ORL_Acknowledgement_Component and the LOI_NG_Acknowledgement_Component.

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5 MESSAGES

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

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

The OML^O21^OML_O21 message is constrained for transmitting laboratory orders from the Sender to the Receiver as defined in each Use Case.

5.1 OML^O21^OML_O21: Laboratory Order Message – New and Add-on Order

This message structure supports the use as defined in Section 2.6.3 Scenario 1 – Electronic Ordering of New or Scheduled Laboratory Test(s) and Section 2.6.4 Scenario 2 – Electronic Ordering of Add-On Laboratory Test(s).

TABLE 5-1. OML^O21^OML_O21 NEW AND ADD-ON ORDER

Segment	Name	Usage	Cardinality	Description
MSH	Message Header	R	[1..1]	The message header (MSH) segment contains information describing how to parse and process the message. This includes identification of message delimiters, sender, receiver, message type, timestamp, etc.
[{SFT}]	Software Segment	O		
[{NTE}]	Notes and Comments for Header	O		
[	***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 except when LOI_PH_Component is invoked.
[PD1]	Additional Demographics	O		
[{NTE}]	Notes and Comments for PID	O		
[{NK1}]	Next of Kin/Associated Parties	Varies	[0..5]	Sender usage: 'RE' Receiver usage: 'O'
[	***VISIT Begin***	Varies	Varies	Financial Information Profile usage: 'R' Financial Information Profile cardinality: [1..1] Usage for all other components: 'O'

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TABLE 5-1. OML^O21^OML_O21 NEW AND ADD-ON ORDER				
Segment	Name	Usage	Cardinality	Description
PV1	Patient Visit	R	[1..1]	HL7 requires that PV1 (Patient Visit) segment be present if the VISIT group is present.
[PV2]	Patient Visit – Additional Information	O		
]	***VISIT End***			
[{	***INSURANCE Begin***	Varies	Varies	Financial Information Profile usage: C(R/O) Condition Predicate: If PV1-20.1 (Financial Class.Financial Class Code) is valued 'T' (third party). Financial Information Profile cardinality: [0..1] All other Profile usage: 'O'
IN1	Insurance	R	[1..1]	
[IN2]	Insurance – Additional Information	O		
[IN3]	Insurance – Additional Information – Cert.	O		
}]	***INSURANCE End***			
[GT1]	Guarantor	Varies	Varies	Financial Information Profile usage: 'RE' Financial Information Profile cardinality: [0..1] Usage for all other components: 'O'
[{AL1}]	Allergy Information	O		
]	***PATIENT End***			
{	***ORDER Begin***	R	[1..*]	
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.
[{	***TIMING_QTY Begin***	RE	[0..1]	
TQ1	Timing/Quantity	R	[1..1]	
[{TQ2}]	Timing/Quantity Order Sequence	O		
}]	***TIMING_QTY End***			
	OBSERVATION_REQUEST Begin	R	[1..1]	
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.

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TABLE 5-1. OML^O21^OML_O21 NEW AND ADD-ON ORDER				
Segment	Name	Usage	Cardinality	Description
[TCD]	Test Code Details	O		
[{NTE}]	Notes and Comments for Detail	RE	[0..*]	
[{PRT}]	Participation (for Obs Request)	C(R/O)	Varies	Condition Predicate: If OBR-28 (Result Copies To) is valued. **Note:** There should be one PRT for each occurrence of OBR-28 (Result Copies To). Sender and receiver must also support PRT where PRT-4 is 'RCT'. LAB_RC_Component cardinality is [0..*] Cardinality for all other components: [0..5]
[CTD]	Contact Data	O		
[{DG1}]	Diagnosis	R	[1..*]	
[{	***OBSERVATION Begin***	RE	[0..*]	
OBX	Observation/Result	R	[1..1]	
[TCD]	Test Code Details	O		
[{NTE}]	Notes and Comments for Details	O		
}]	***OBSERVATION End***			
[{	***SPECIMEN Begin***	C(R/RE)	[0..*]	Condition Predicate: If OBR-7 (Observation Date/Time) in the same Observation Request group is valued.
SPM	Specimen Information	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		
[{	***CONTAINER Begin***	X		Excluded for this Implementation Guide, see Section 1.3.1.
SAC	Specimen Container	R	[1..1]	SAC is not supported in this message definition because the Container group is prohibited
[{OBX}]	Observation related to Container	O		
}]	***CONTAINER End***			
}]	***SPECIMEN End***			
[SGH]	***Segment Header***	RE	[0..1]	Only needed if sending prior results. Pre-adopted from V2.8.2.
[{	***PRIOR_RESULT Begin***	Varies	[0..*]	LOI_PR_Component usage: 'RE' Usage for all other components: 'O'

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TABLE 5-1. OML^O21^OML_O21 NEW AND ADD-ON ORDER				
Segment	Name	Usage	Cardinality	Description
[	***Patient prior Begin***	O		
PID	Patient Identification	R	[1..1]	
[PD1]	Additional Demographics	O		
]	***Patient prior End***			
[	***Visit Begin***	O		
PV1	Patient Visit	R	[1..1]	
[PV2]	Patient Visit – Additional Information	O		
]	***Patient Visit End***			
[{AL1}]	Allergy Information	O		
{	***Order Prior Begin***			
[ORC]	Order Common	RE	[0..1]	
OBR	Observations Request	R	[1..1]	
[{NTE}]	Notes and Comments for Details	O		
[{	***Timing Prior Begin***	RE	[0..*]	
TQ1	Timing/Quantity	R	[1..1]	
[{TQ2}]	Timing/Quantity Order Sequence	O		
}]	***Timing Prior End***			
{	***Observation Prior Begin***	R	[1..*]	
OBX	Observation/Result	R	[1..1]	
[{NTE}]	Notes and Comments for Details	O		
}	***Observation Prior End***			
}	***Order Prior End***			
}]	***PRIOR_RESULT End***			
[SGT]	***Segment Trailer***	R	[1..1]	Pre-adopted from V2.8.2.
}	***OBSERVATION_ REQUEST End***			
[{FT1}]	Financial Transaction	O		
{[CTI]}	Clinical Trial Identification	O		

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TABLE 5-1. OML^O21^OML_O21 NEW AND ADD-ON ORDER				
Segment	Name	Usage	Cardinality	Description
[BLG]	Billing Segment	O		
}	***ORDER End***			

Usage Note

If the specimen is not drawn at time of order entry, or if the specimen is implied in the test name as is common in chemistry, hematology, and serology, no specimen group is required at time of the order. Each specimen group documents a single sample.

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

5.2 OML^O21^OML_O21: Laboratory Order Message – Cancel Order

This message structure supports Section 2.6.5 Scenario 3 – Requesting the Cancellation of a Previously Placed Laboratory Order and Section 2.6.6 Scenario 4 – Laboratory Cancellation of a Previously Placed Laboratory Order.

The control code in ORC indicates if the Ordering Provider or the Laboratory initiated the cancellation.

Note the use of the conditional statement C(X/O) in this table; in this cancel message the 'O' actually means revert to the requirements as described in Table 5-1.

TABLE 5-2. OML^O21^OML_O21 CANCEL ORDER				
Segment	Name	Usage	Cardinality	Description
MSH	Message Header	R	[1..1]	The message header (MSH) segment contains information describing how to parse and process the message. This includes identification of message delimiters, sender, receiver, message type, timestamp, etc.
[{SFT}]	Software Segment	O		
[{NTE}]	Notes and Comments for Header	O		
[	***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 except when LOI_PH_Component is invoked.
[PD1]	Additional Demographics	O		
[{NTE}]	Notes and Comments for PID	O		

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TABLE 5-2. OML^O21^OML_O21 CANCEL ORDER				
Segment	Name	Usage	Cardinality	Description
[{NK1}]	Next of Kin/Associated Parties	C(X/O)		Condition Predicate: If all of the ORC-1 (Order Control Code) fields in the message are valued either 'CA' or 'OC'.
	VISIT Begin	C(X/O)		Condition Predicate: If all of the ORC-1 (Order Control Code) fields in the message are valued either 'CA' or 'OC'.
PV1	Patient Visit	R	[1..1]	
[PV2]	Patient Visit – Additional Information	O		
	VISIT End			
[{	***INSURANCE Begin***	C(X/O)		Condition Predicate: If all of the ORC-1 (Order Control Code) fields in the message are valued either 'CA' or 'OC'.
IN1	Insurance	R	[1..1]	
[IN2]	Insurance – Additional Information	O		
[IN3]	Insurance – Additional Information – Cert.	O		
}]	***INSURANCE End***			
GT1	***Guarantor***	C(X/O)		Condition Predicate: If all of the ORC-1 (Order Control Code) fields in the message are valued either 'CA' or 'OC'.
[{AL1}]	Allergy Information	C(X/O)		Condition Predicate: If all of the ORC-1 (Order Control Code) fields in the message are valued either 'CA' or 'OC'.
]	***PATIENT End***			
{	***ORDER Begin***	R	[1..*]	
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.
[{	***TIMING_QTY Begin***	O		
TQ1	Timing/Quantity	R	[1..1]	
[{TQ2}]	Timing/Quantity Order Sequence	O		
}]	***TIMING_QTY End***			
	OBSERVATION_REQUEST Begin	R	[1..1]	

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TABLE 5-2. OML^O21^OML_O21 CANCEL ORDER				
Segment	Name	Usage	Cardinality	Description
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.
[TCD]	Test Code Details	O		
[{NTE}]	Notes and Comments for Detail	RE	[0..*]	
[CTD]	Contact Data	C(X/O)		Condition Predicate: If ORC-1 (Order Control Code) within the same ORDER group is valued 'CA' or 'OC'.
[{DG1}]	Diagnosis	C(X/O)		Condition Predicate: If ORC-1 (Order Control Code) within the same ORDER group is valued 'CA' or 'OC'.
[{	***OBSERVATION Begin***	C(X/O)		Condition Predicate: If ORC-1 (Order Control Code) within the same ORDER group is valued 'CA' or 'OC'.
OBX	Observation/Result	R	[1..1]	
[TCD]	Test Code Details	O		
[{NTE}]	Notes and Comments for Details	O		
}]	***OBSERVATION End***			
[{	***SPECIMEN Begin***	C(X/O)		Condition Predicate: If ORC.1 (Order Control Code) within the same ORDER group is valued 'CA' or 'OC'.
SPM	Specimen Information	R	[1..1]	
[{OBX}]	Observation related to Specimen	O		
[{	***CONTAINER Begin***	X		Excluded for this Implementation Guide, see Section 1.3.1.
SAC	Specimen Container	R	[1..1]	SAC is not supported in this message definition because the Group is prohibited
[{OBX}]	Observation related to Container	O		
}]	***CONTAINER End***			
}]	***SPECIMEN End***			
[{	***PRIOR_RESULT Begin***	C(X/O)		Condition Predicate: If ORC.1 (Order Control Code) within the same ORDER group is valued 'CA' or 'OC'.
…	Prior result segments excluded			
}]	***PRIOR_RESULT End***			
}	***OBSERVATION_ REQUEST End***			

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TABLE 5-2. OML^O21^OML_O21 CANCEL ORDER				
Segment	Name	Usage	Cardinality	Description
[{FT1}]	Financial Transaction	C(X/O)		Condition Predicate: If all of the ORC-1 (Order Control Code) fields in the message are valued either 'CA' or 'OC'.
{[CTI]}	Clinical Trial Identification	O		
[BLG]	Billing Segment	C(X/O)		Condition Predicate: If all of the ORC-1 (Order Control Code) fields in the message are valued either 'CA' or 'OC'.
}	***ORDER End***			

Usage Note

Timing/Quantity information is not necessary upon canceling an order as the current scope only includes individual instances of future orders.

5.3 Accept Acknowledgements

This guide requires support for Acknowledgement messages to both the OML messages (whether a New and Append Order or the Cancel Order) to provide the ability to determine whether the message has been received in good order by the intended recipient. A mechanism is provided to support both node-to-node accept level acknowledgement (the receiving system has taken responsibility of the message and lets the preceding system know, **without** sending those acknowledgements all the way back to the originating EHR-S), and the end-to-end application level acknowledgement choreography (the intended recipient not only took on responsibility of the message after the message may have passed through multiple systems such as integration engines, but can also consume the message's application specific data and lets the preceding system know **with** the expectation that this acknowledgement is passed all the way back to the originating EHR-S through any of the intermediate systems). This requires the use of the Enhanced Acknowledgment Mode, i.e. MSH-15 (Accept Acknowledgment Type) and MSH-16 (Application Acknowledgement Type) are valued by the message sender and control the creation of an accept level message and an application level acknowledgement message by the message receiver, or a node that enables transmission of the message across the various systems that may be between the sender and receiver (e.g., integration engines, HIEs, etc.). For a complete definition of an Accept Level acknowledgement and an Application Level acknowledgement, see V2.5.1 (or higher) Chapter 2.

The diagram in Figure 5-1. LOI Message and Guaranteed Delivery Notification Flow summarizes the flow of Acknowledgements from the order sender (EHR-S) to the order receiver (LIS) and back through the different gateways.

The numbers for O = Order indicate the step in the respective flow. For example, the step marked O2 indicates that for the flow of the Order message – the green arrow labeled OML and its related Accept Acknowledgement (ACK), the dotted black arrow between Gateway 2 and Gateway 1 – would be step 2.

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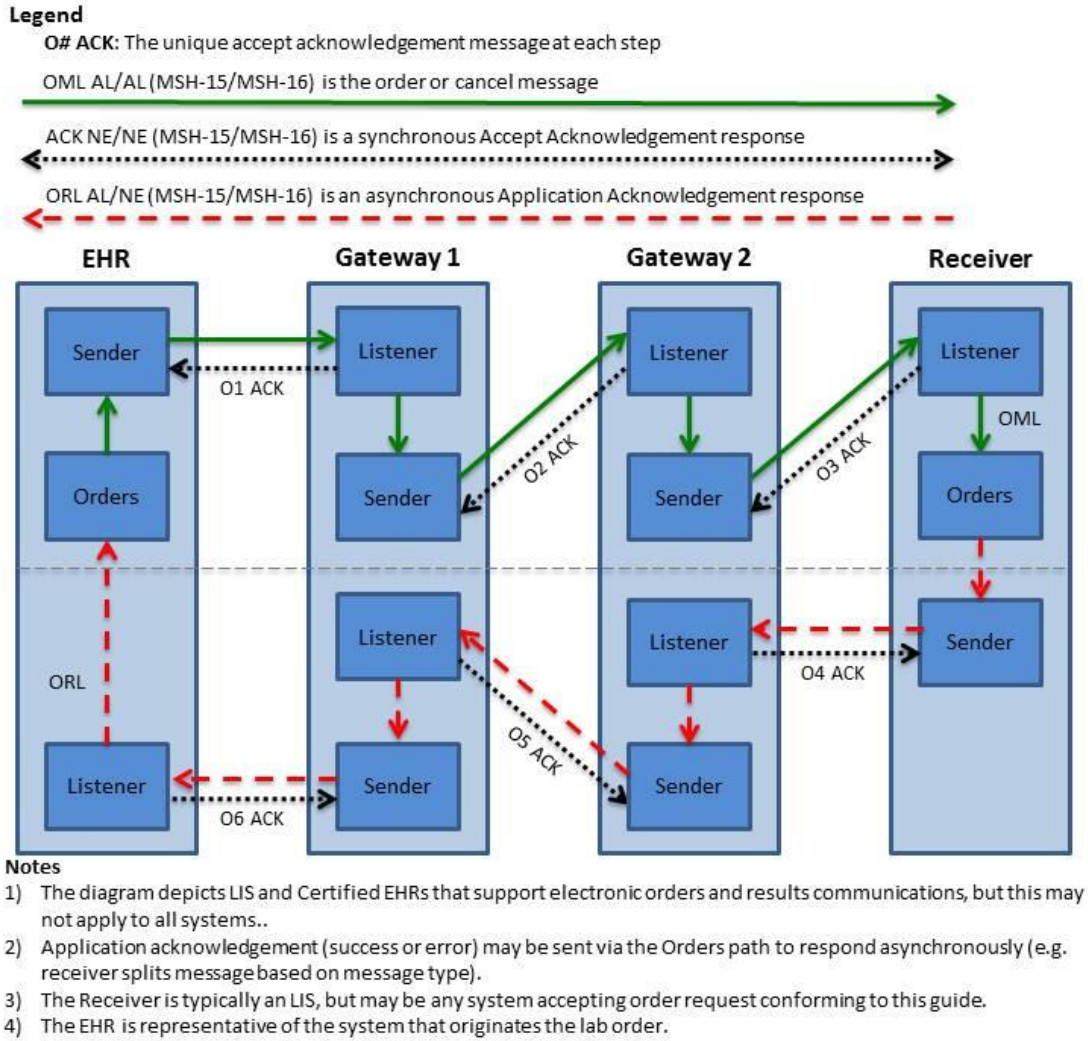

Figure 5-1. LOI Message and Guaranteed Delivery Notification Flow

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5.3.1 ACKNOWLEDGEMENT CHOREOGRAPHY APPLIED

5.3.1.1 OML^O21^OML_O21: LABORATORY ORDER MESSAGE

The acknowledgement choreography starts with the initial New and Append Order, or the Cancel Order (both using the OML^O21^OML_O21 message) indicating in MSH-15 and MSH-16 how the receiving system is to respond. The following MSH-15 and MSH-16 values are required or permitted:

The communication partners must agree whether they will support basic acknowledgements, i.e., accept level acknowledgements only, or end-to-end acknowledgements, including application level acknowledgements as well.

For basic, accept level acknowledgements only, the following MSH-15 and MSH-16 values must be supported.

TABLE 5-3. OML ACKNOWLEDGEMENT CODES

Requirement	MSH-15	MSH-16
SHALL support	AL	NE
MAY support*	NE	NE

*ONLY in point-to-point environments, where the transport protocol guarantees delivery to the intended recipient.

When the communication partners agree to support end-to-end application level acknowledgements as well, then the following values must be supported for MSH-15 and MSH-16:

TABLE 5-4. OML ACKNOWLEDGEMENT CODES

Requirement	MSH-15	MSH-16
SHALL support	AL	AL
MAY support	AL	ER
MAY support*	NE	AL

*ONLY in point-to-point environments, where the transport protocol guarantees delivery to the intended recipient.

All other values and combinations are NOT allowed.

Note that, as of the upcoming Normative Edition and based on industry adoption, support for only basic, accept acknowledgements will be removed, and only end-to-end acknowledgements covering both accept level acknowledgements and application level acknowledgements to the originator are supported.

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5.3.1.2 ACK^O21^ACK: LABORATORY ORDER MESSAGE – ACCEPT ACKNOWLEDGEMENT

Based on the actual values in the OML^O21^OML_O21 MSH-15 and MSH-16 values, the receiver will send an Accept Level Acknowledgement message using the following message syntax and must use the appropriate response profiles or component in MSH-21, while using either “CA” or “CR in MSA-1: Acknowledgement Code.

TABLE 5-5. ACK^O21^ACK ABSTRACT MESSAGE SYNTAX

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

This message is only used between nodes that the messages travels along per Figure 5-1. The message uses values MSA-1 Acknowledgement code to either “CA” or “CR” to the immediately preceding sender. This applies to intermediaries between a Laboratory Result Sender and an EHR-S such as HIEs and interface engines, as well as to the final LIS or EHR-S destination.

To avoid this acknowledgement from generating a response back to the originating node of the Accept Level Acknowledgement message and effectively start a never-ending series or accept acknowledgement messages between two nodes, the originating node must use the Accept Acknowledgement message (ACK^O21^ACK) with the following code combinations:

TABLE 5-6. ACCEPT ACKNOWLEDGEMENT CODES

Requirement	MSH-15	MSH-16
SHALL support	NE	NE

All other values and combinations are NOT allowed.

5.3.1.3 ORL^O22^ORL_O22: LABORATORY ORDER MESSAGE – APPLICATION LEVEL ACKNOWLEDGEMENT

Based on the actual values in the OML^O21^OML_O21 MSH-15 and MSH-16 values, the receiver will send an ORL^O22^ORL_O22 Application Level Acknowledgement message using the following message syntax and must use the appropriate response profiles or component in MSH-21, while using either “AA”, “AE”, or “AR in MSA-1: Acknowledgement Code:

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TABLE 5-7. ORL^O22^ORL_O22 ABSTRACT MESSAGE SYNTAX				
Segment	Name	Usage	Cardinality	Description
MSH	Message Header	R	[1..1]	The message header (MSH) segment contains information describing how to parse and process the message. This includes identification of message delimiters, sender, receiver, message type, timestamp, etc.
MSA	Message Acknowledgment	R	[1..1]	The Message Acknowledgment Segment (MSA) contains the information sent an acknowledgment to the order message received by a LIS or EHR-S.
[{ ERR }]	Error	C(R/O)	[0..*]	Condition Predicate: If any ORC-1 (Order Control) is valued 'UC' or 'UA'.
[{ SFT }]	Software	O		
[{ NTE }]	Notes and Comments (for Header)	O		
[	***RESPONSE Begin***	R	[1..1]	
[	***PATIENT Begin***	R	[1..1]	
PID	Patient Identification	R	[1..1]	
[{	***ORDER Begin***	R	[1..*]	
ORC	Common Order	R	[1..1]	
[{	***TIMING Begin***	O		
TQ1	Timing/Quantity	R	[1..1]	
[{ TQ2 }]	Timing/Quantity Order Sequence	O		
}]	***TIMING End***			
[	***OBSERVATION_REQUEST begin***	R	[1..1]	
OBR	Observation Request	R	[1..1]	
[{	***SPECIMEN Begin***	O		
SPM	Specimen	R	[1..1]	
[{ SAC }]	Specimen Container Details	O		
}]	***SPECIMEN End***			
]	***OBSERVATION_REQUEST End***			
}]	***ORDER End***			

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TABLE 5-7. ORL^O22^ORL_O22 ABSTRACT MESSAGE SYNTAX				
Segment	Name	Usage	Cardinality	Description
]	***PATIENT End***			
]	***RESPONSE End***			

This message provides the end-to-end delivery confirmation, including whether the receiver could consume the application specific content. It therefore is sent across all the nodes that may have been between the sender and receiver back to the originator of the New and Append Order, or the Cancel Order.

The following MSH-15 and MSH-16 values are required or permitted:

TABLE 5-8. APPLICATION ACKNOWLEDGMENT CODES		
Requirement	MSH-15	MSH-16
SHALL support	AL	NE
MAY support*	NE	NE

*ONLY in point-to-point environments, where the transport protocol guarantees delivery to the intended recipient.

All other values and combinations are NOT allowed.

5.3.1.4 ACK^O22^ACK: LABORATORY ORDER MESSAGE – ACCEPT ACKNOWLEDGEMENT

Based on the actual values in the ORL^O22^ORL_O22 MSH-15 and MSH-16 values, the receiver will send an Accept Level Acknowledgement message using the following message syntax and must use the appropriate response profiles or component in MSH-21 while using either “CA” or “CR in MSA-1: Acknowledgement Code:

TABLE 5-9. ACK^O22^ACK ABSTRACT MESSAGE SYNTAX				
Segment	Name	Usage	Cardinality	Description
MSH	Message Header	R	[1..1]	The message header (MSH) segment contains information describing how to parse and process the message. This includes identification of message delimiters, sender, receiver, message type, timestamp, etc.
[{SFT}]	Software Segment	O		
MSA	Message Acknowledgment	R	[1..1]	The Message Acknowledgment Segment (MSA) contains the information sent as an acknowledgment to the order message received by a LIS or EHR-S.

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TABLE 5-9. ACK^O22^ACK ABSTRACT MESSAGE SYNTAX				
Segment	Name	Usage	Cardinality	Description
[{ERR }]	Error	C(R/O)	[0..*]	Condition Predicate: If MSA-1 (Message Acknowledgement) is not valued 'AA' or 'CA'.

This message is only used between nodes that the messages travels along per Figure 4-1. The message uses values MSA-1 Acknowledgement code to either "CA" or "CR" to the immediately preceding sender. This applies to intermediaries between a final LIS destination and an LIS such as HIEs and interface engines, as well as to the Laboratory Order Sender (EHR-S).

To avoid this acknowledgement from generating a response back to the originating node of the Accept Level Acknowledgement message and effectively start a never-ending series or accept acknowledgement messages between two nodes, the originating node must use the Accept Acknowledgement message (ACK^O21^ACK) with the following code combinations:

TABLE 5-10. ACCEPT ACKNOWLEDGEMENT CODES		
Requirement	MSH-15	MSH-16
SHALL support	NE	NE

All other values and combinations are NOT allowed.

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6 SEGMENT AND FIELD DESCRIPTIONS

This messaging guide provides notes for required (non-optional) fields for each of the non-optional segments. For each segment the segment table defines the applicable constraints on usage for its fields for this Implementation Guide, see Section 1.3.2 Message Element Attributes for a description of the columns in the Segment Attribute Tables. All the relevant conformance statements and general usage notes are located at the end of each table.

Note that any segments that are marked as optional in this guide and that are included as part of a local implementation must use the same constraints as defined in this guide when the fields/components are in common with fields/components marked as R, RE, or C(a/b) in this guide. Constraint statements will be required to use the GU or NG profiles, and agreement about which data type flavors to use, etc. needs to be reached.

6.1 MSH – Message Header Segment

TABLE 6-1. MESSAGE HEADER SEGMENT (MSH)

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Field Separator	ST	R	[1..1]		
2	Encoding Characters	ST	R	[1..1]		Constrained to the literal values '^~\&' or '^~\&#', always appearing in the same order.
3	Sending Application	Varies	RE	[0..1]	HL70361_USL	GU data type: HD_01 NG data type: HD_02
4	Sending Facility	Varies	R	[1..1]	HL70362_USL	GU data type: HD_01 NG data type: HD_02 If acknowledgments are in use, this facility will receive any related acknowledgment message.
5	Receiving Application	Varies	RE	[0..1]	HL70361_USL	GU data type: HD_01 NG data type: HD_02
6	Receiving Facility	Varies	Varies	Varies	HL70362_USL	LOI_NDBS_Component usage: R, cardinality: 1..1 All other profiles usage: RE, cardinality 0..1 GU data type: HD_01 NG data type: HD_02 If acknowledgments are in use, this facility originates any related acknowledgment message.

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TABLE 6-1. MESSAGE HEADER SEGMENT (MSH)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
7	Date/Time Of Message	Varies	R	[1..1]		LAB_TO_Component Data Type: TS_11 Data Type for all other components: TS_10 If the time zone offset is included in MSH-7 (Date/Time Of Message) it becomes the default time zone for the message instance and applies to all other date/time fields in that same message instance where a time zone offset is not valued, except as otherwise indicated through the use of the LAB_TO_Component profile as defined in Section 4.2.1.10 in MSH-21 (Message Profile Identifier).
8	Security		O			
9	Message Type	MSG_01	R	[1..1]		
10	Message Control ID	ST	R	[1..1]		String that identifies the message instance from the sending application. Example formats for message control IDs include GUID, timestamp plus sequence number, OID plus sequence number or sequence number. The important point is that care must be taken to ensure that the message control id is unique within the system originating the message.
11	Processing ID	PT_01	R	[1..1]		
12	Version ID	VID_01	R	[1..1]		HL7 version number used to interpret format and content of the message. Constrained to the literal value '2.5.1'.
13	Sequence Number		O			
14	Continuation Pointer		O			
15	Accept Acknowledgment Type	ID	R	[1..1]	HL70155_USL	The value set constraints are described in Sections 5.3.1.2 for the OML, 5.3.1.4 for the Accept Acknowledgement, and 5.3.1.4 for the Application Acknowledgment.
16	Application Acknowledgment Type	ID	R	[1..1]	HL70155_USL	The value set constraints are described in Section s 5.3.1.2 for the OML, 5.3.1.4 for the Accept Acknowledgement, and 5.3.1.3 for the Application Acknowledgment.
17	Country Code		O			
18	Character Set		O			
19	Principal Language Of Message		O			
20	Alternate Character Set Handling Scheme		O			
21	Message Profile Identifier	EI_01	R	[1..*]		The sender asserts that the message conforms to a given profile and/or valid combination of components.

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Usage Note for LOI_Common_Component

MSH-21 (Message Profile Identifier)

The MSH-21 field shall identify exclusively one lab orders interface profile (i.e., MSH-21 shall not be populated with conflicting LOI profiles or LOI components).

Additional compatible profiles or components can be present in MSH-21; for example, if an LOI profile or component is further constrained.

6.1.1 LOI ORDER PRE-COORDINATED PROFILES

The table below indicates valid MSH-21 combinations for declaring conformance to a particular pre-coordinated LOI profile or the equivalent LOI profile components.

TABLE 6-2. MSH 21 PROFILE COMBINATIONS

LOI Profile	Pre-Coordinated OID	Profile Component OIDs	Component Name
LOI_GU_PRU_Profile	2.16.840.1.113883.9.85	2.16.840.1.113883.9.66 2.16.840.1.113883.9.78 2.16.840.1.113883.9.82	LOI_Common_Component LOI_GU_Component LAB_PRU_Component
LOI_GU_PRN_Profile	2.16.840.1.113883.9.86	2.16.840.1.113883.9.66 2.16.840.1.113883.9.78 2.16.840.1.113883.9.81	LOI_Common_Component LOI_GU_Component LAB_PRN_Component
LOI_NG_PRU_Profile	2.16.840.1.113883.9.87	2.16.840.1.113883.9.66 2.16.840.1.113883.9.79 2.16.840.1.113883.9.82	LOI_Common_Component LOI_NG_Component LAB_PRU_Component
LOI_NG_PRN_Profile	2.16.840.1.113883.9.88	2.16.840.1.113883.9.66 2.16.840.1.113883.9.79 2.16.840.1.113883.9.81	LOI_Common_Component LOI_NG_Component LAB_PRN_Component

For each of the combinations illustrated, the following additional profile component identifiers can be specified:

- LAB_FI_Component – ID: 2.16.840.1.113883.9.80
- LAB_NB_Component – ID: 2.16.840.1.113883.9.24
- LOI_PH_Component – ID: 2.16.840.1.113883.9.94
- LAB_TO_Component – ID: 2.16.840.1.113883.9.22

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- LAB_XO_Component – ID: 2.16.840.1.113883.9.23
- LOI_PR_Component – ID: 2.16.840.1.113883.9.95
- LOI_NDBS_Component - ID: 2.16.840.1.113883.9.5
- LAB_RC_Component – ID: 2.16.840.1.113883.9.96
- LAB_FRU_Component – ID: 2.16.840.1.113883.9.83
- LAB_FRN_Component – ID: 2.16.840.1.113883.9.84

Examples

LOI_NG_PRN_Profile Using Component OIDs

```
MSH…|||||LOI_Common_Component^^2.16.840.1.113883.9.66^ISO~LOI_NG_Component^^2.16.840.
   1.113883.9.79^ISO~LAB_PRN_Component^^2.16.840.1.113883.9.81^ISO
```

LOI_NG_PRN_Profile Pre-Coordinated Profile OID

```
MSH…|||||LOI_NG_PRN_Profile^^2.16.840.1.113883.9.88^ISO
```

LOI_NG_PRN_Profile using Pre-Coordinated Profile OID and the LAB_NB_Component

```
MSH…|||||LOI_NG_PRN_Profile^^2.16.840.1.113883.9.88^ISO~LAB_NB_Component^^2.16.840.1.
   113883.9.24^ISO
```

Conformance Statements: LOI_Common_Component

LOI-5: MSH-12.1 (Version ID.Version Identifier) **SHALL** be valued with '2.5.1' drawn from the code system HL70104.

LOI-7: MSH-1 (Field Separator) **SHALL** contain the constant value '|'.

LOI-8: MSH-2 (Encoding Characters) **SHALL** contain the constant value '^~\&' or the constant value '^~\&#'.

LOI-9: MSH-9.1 (Message Type.Message Code) **SHALL** contain the constant value 'OML' drawn from code system HL70076_USL.

LOI-10: MSH-9.2 (Message Type.Trigger Event) **SHALL** contain the constant value 'O21' drawn from code system HL70003_USL.

LOI-11: MSH-9.3 (Message Type.Message Structure) **SHALL** contain the constant value 'OML_O21' drawn from code system HL70354_USL.

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Conformance Statements: LOI_GU_PRN_Profile

LOI-14: An occurrence of MSH-21.3 (Message Profile Identifier. Universal ID) **SHALL** be valued with '2.16.840.1.113883.9.86' (LOI_GU_PRN_Profile) or three occurrences **SHALL** be valued with '2.16.840.1.113883.9.66' (LOI_Common_Component), '2.16.840.1.113883.9.78' (LOI_GU_Component) and '2.16.840.1.113883.9.81' (LAB_PRN_Component) in any order.

Note: Additional occurrences of MSH-21 (Message Profile Identifier) may be valued with any combination of:

LAB_FI_Component – ID: 2.16.840.1.113883.9.80

LAB_NB_Component – ID: 2.16.840.1.113883.9.24

LOI_PH_Component – ID: 2.16.840.1.113883.9.94

LAB_TO_Component – ID: 2.16.840.1.113883.9.22

LAB_XO_Component – ID: 2.16.840.1.113883.9.23

LOI_PR_Component – ID: 2.16.840.1.113883.9.95

LOI_NDBS_Component - ID: 2.16.840.1.113883.9.5

LAB_RC_Component – ID: 2.16.840.1.113883.9.96

LAB_FRU_Component – ID: 2.16.840.1.113883.9.83

LAB_FRN_Component – ID: 2.16.840.1.113883.9.84

Conformance Statements: LOI_NG_PRU_Profile

LOI-15: An occurrence of MSH-21.3 (Message Profile Identifier. Universal ID) **SHALL** be valued with '2.16.840.1.113883.9.87' (LOI_NG_PRU_Profile) or three occurrences **SHALL** be valued with '2.16.840.1.113883.9.66' (LOI_Common_Component), '2.16.840.1.113883.9.79' (LOI_NG_Component) and '2.16.840.1.113883.9.82' (LAB_PRU_Component) in any order.

Note: Additional occurrences of MSH-21 (Message Profile Identifier) may be valued with any combination of:

LAB_FI_Component – ID: 2.16.840.1.113883.9.80

LAB_NB_Component – ID: 2.16.840.1.113883.9.24

LOI_PH_Component – ID: 2.16.840.1.113883.9.94

LAB_TO_Component – ID: 2.16.840.1.113883.9.22

LAB_XO_Component – ID: 2.16.840.1.113883.9.23

LOI_PR_Component – ID: 2.16.840.1.113883.9.95

LOI_NDBS_Component - ID: 2.16.840.1.113883.9.5

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LAB_RC_Component – ID: 2.16.840.1.113883.9.96

LAB_FRU_Component – ID: 2.16.840.1.113883.9.83

LAB_FRN_Component – ID: 2.16.840.1.113883.9.84

Conformance Statements: LOI_NG_PRN_Profile

LOI-16: An occurrence of MSH-21.3 (Message Profile Identifier. Universal ID) **SHALL** be valued with '2.16.840.1.113883.9.88' (LOI_NG_PRN_Profile) or three occurrences **SHALL** be valued with '2.16.840.1.113883.9.66' (LOI_Common_Component), '2.16.840.1.113883.9.79' (LOI_NG_Component) and '2.16.840.1.113883.9.81' (LAB_PRN_Component) in any order.

Note: Additional occurrences of MSH-21 (Message Profile Identifier) may be valued with any combination of:

LAB_FI_Component – ID: 2.16.840.1.113883.9.80

LAB_NB_Component – ID: 2.16.840.1.113883.9.24

LOI_PH_Component – ID: 2.16.840.1.113883.9.94

LOI_NDBS_Component - ID: 2.16.840.1.113883.9.5

LAB_TO_Component – ID: 2.16.840.1.113883.9.22

LAB_XO_Component – ID: 2.16.840.1.113883.9.23

LOI_PR_Component – ID: 2.16.840.1.113883.9.95

LAB_RC_Component – ID: 2.16.840.1.113883.9.96

LAB_FRU_Component – ID: 2.16.840.1.113883.9.83

LAB_FRN_Component – ID: 2.16.840.1.113883.9.84

Conformance Statements: LOI_GU_PRU_Profile

LOI-17: An occurrence of MSH-21.3 (Message Profile Identifier. Universal ID) **SHALL** be valued with '2.16.840.1.113883.9.85' (LOI_GU_PRU_Profile) or three occurrences **SHALL** be valued with '2.16.840.1.113883.9.66' (LOI_Common_Component), '2.16.840.1.113883.9.78' (LOI_GU_Component) and '2.16.840.1.113883.9.82' (LAB_PRU_Component) in any order.

Note: Additional occurrences of MSH-21 (Message Profile Identifier) may be valued with any combination of:

LAB_FI_ Component – ID: 2.16.840.1.113883.9.80

LAB_NB_ Component – ID: 2.16.840.1.113883.9.24

LOI_PH_ Component – ID: 2.16.840.1.113883.9.94

LAB_TO_ Component – ID: 2.16.840.1.113883.9.22

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LAB_XO_ Component – ID: 2.16.840.1.113883.9.23

LOI_PR_ Component – ID: 2.16.840.1.113883.9.95

LOI_NDBS_Component - ID: 2.16.840.1.113883.9.5

LOI_RC_ Component – ID: 2.16.840.1.113883.9.96

LAB_FRU_Component – ID: 2.16.840.1.113883.9.83

LAB_FRN_Component – ID: 2.16.840.1.113883.9.84

Conformance Statements: LOI_PH_Component

LOI-28: An occurrence of MSH-21.3 (Message Profile Identifier. Universal ID) **SHALL** be valued with '2.16.840.1.113883.9.94'.

Conformance Statement: LAB_FI_Component

LOI-29: An occurrence of MSH-21.3 (Message Profile Identifier. Universal ID) **SHALL** be valued with '2.16.840.1.113883.9.80'.

Conformance Statement: LAB_NB_Component

LOI-30: An occurrence of MSH-21.3 (Message Profile Identifier. Universal ID) **SHALL** be valued with '2.16.840.1.113883.9.24'.

Conformance Statement: LAB_TO_Component

LOI-31: An occurrence of MSH-21.3 (Message Profile Identifier. Universal ID) **SHALL** be valued with '2.16.840.1.113883.9.22'.

Conformance Statement: LAB_XO_Component

LOI-32: An occurrence of MSH-21.3 (Message Profile Identifier. Universal ID) **SHALL** be valued with '2.16.840.1.113883.9.23'.

Conformance Statement: LOI_PR_Component

LOI-33: An occurrence of MSH-21.3 (Message Profile Identifier. Universal ID) **SHALL** be valued with '2.16.840.1.113883.9.95'.

Conformance Statement: LAB_RC_Component

LOI-34: An occurrence of MSH-21.3 (Message Profile Identifier. Universal ID) **SHALL** be valued with '2.16.840.1.113883.9.96'.

Conformance Statement: LAB_FRU_Component

LOI-79: An occurrence of MSH-21.3 (Message Profile Identifier. Universal ID) **SHALL** be valued with '2.16.840.1.113883.9.83'

Conformance Statement: LAB_FRN_Component

LOI-80: An occurrence of MSH-21.3 (Message Profile Identifier. Universal ID) **SHALL** be valued with '2.16.840.1.113883.9.84'

Conformance Statement: LOI_NDBS_Component

LOI-90: An occurrence of MSH-21.3 (Message Profile Identifier. Universal ID) **SHALL** be valued with '2.16.840.1.113883.9.5'

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6.1.2 LOI ACKNOWLEDGEMENT COMPONENTS

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

TABLE 6-3. MSH 21 ACKNOWLEDGMENT PROFILE COMBINATIONS

LOI Profile	Pre-Coordinated OID	Component OIDs	Component Name
LOI_GU_Response_Profile	2.16.840.1.113883.9.92	2.16.840.1.113883.9.195.2.8 2.16.840.1.113883.9.195.2.5 2.16.840.1.113883.9.90	LOI_O21_Acknowledgement_Component LOI_O22_Acknowledgement_Component LOI_GU_Acknowledgement_Component
LOI_NG_Response_Profile	2.16.840.1.113883.9.93	2.16.840.1.113883.9.195.2.8 2.16.840.1.113883.9.195.2.5 2.16.840.1.113883.9.91	LOI_O21_Acknowledgement_Component LOI_O22_Acknowledgement_Component LOI_NG_Acknowledgement_Component

Conformance Statements: LOI_O21_Acknowledgement_Component

LOI-18: MSH-1 (Field Separator) **SHALL** contain the constant value '|'.

LOI-19: MSH-2 (Encoding Characters) **SHALL** contain the constant value '^~\&' or the constant value '^~\&#'.

LOI-20: MSH-9.1 (Message Type.Message Code) **SHALL** contain the value 'ACK' drawn from the code system HL70076.

LOI-65: MSH-9.2 (Message Type.Trigger Event) **SHALL** contain the value 'O21' drawn from the code system HL70003_USL.

LOI-66: MSH-9.3 (Message Type.Message Structure) **SHALL** contain the value 'ACK' drawn from the code system HL70354_USL.

LOI-67: MSH-15 (Accept Acknowledgement Type) **SHALL** contain the constant value 'NE' drawn from the code system HL70155_USL.

LOI-68: MSH-16 (Application Acknowledgement Type) **SHALL** contain the constant value 'NE' drawn from the code system HL70155_USL.

Conformance Statements: LOI_O22_Acknowledgement_Component

LOI-83: MSH-1 (Field Separator) **SHALL** contain the constant value '|'.

LOI-84: MSH-2 (Encoding Characters) **SHALL** contain the constant value '^~\&' or the constant value '^~\&#'.

LOI-85: MSH-9 (Message Type) **SHALL** contain the value 'ACK' drawn from the code system HL70076.

LOI-86: MSH-9.2 (Message Type.Trigger Event) **SHALL** contain the value 'O22' drawn from the code system HL70003_USL.

LOI-87: MSH-9.3 (Message Type.Message Structure) **SHALL** contain the value 'ACK' drawn from the code system HL70354_USL.

LOI-88: MSH-15 (Accept Acknowledgement Type) **SHALL** contain the constant value 'NE' drawn from the code system HL70155_USL.

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LOI-89: MSH-16 (Application Acknowledgement Type) **SHALL** contain the constant value 'NE' drawn from the code system HL70155_USL.

Conformance Statements: LOI_GU_Response_Profile

LOI-81: An occurrence of MSH-21.3 (Message Profile Identifier. Universal ID) **SHALL** be valued with '2.16.840.1.113883.9.92' (LOI_GU_Response_Profile) or two occurrences **SHALL** be valued with '2.16.840.1.113883.9.195.2.8' (LOI_O21_Acknowledgement_Component) and '2.16.840.1.113883.9.90' (LOI_GU_Acknowledgement_Component) in any order.

Conformance Statements: LOI_NG_ Response_Profile

LOI-82: An occurrence of MSH-21.3 (Message Profile Identifier. Universal ID) **SHALL** be valued with '2.16.840.1.113883.9.93' (LOI_NG_Response_Profile) or two occurrences **SHALL** be valued with '2.16.840.1.113883.9.195.2.8' (LOI_O21_Acknowledgement_Component) and '2.16.840.1.113883.9.91' (LOI_NG_Acknowledgement_Component) in any order.

Conformance Statements: LOI_ORL_Acknowledgement_Component

LOI-69: MSH-9.1 (Message Code) **SHALL** contain the value 'ORL' drawn from code system HL70076_USL.

LOI-70: MSH-9.2 (Trigger Event) **SHALL** contain the value 'O22' drawn from code system HL70003_USL.

LOI-71: MSH-9.3 (Message Structure) **SHALL** contain the value 'ORL_O22' drawn from code system HL70354_USL.

LOI-72: MSH-12.1 (Version ID) **SHALL** contain the constant value '2.5.1' drawn from code system HL70104_USL.

LOI-74: MSH-16 (Application Acknowledgement Type) **SHALL** contain the constant value 'NE' drawn from code system HL70155_USL.

Conformance Statements: LOI_GU_ORL_Response_Profile_Component

LOI-75: MSH-21.3 (Message Profile Identifier. Universal ID) **SHALL** be valued with '2.16.840.1.113883.9.195.2.3' (LOI_GU_ORL_Response_Profile_Component) or two occurrences **SHALL** be valued with '2.16.840.1.113883.9.195.2.2' (LOI_ORL_Acknowledgement_Component) and '2.16.840.1.113883.9.90' (LOI_GU_Acknowledgement_Component) in any order, when acknowledging OML GU profiles where MSH-21.3 contains '2.16.840.1.113883.9.85' (LOI_GU_PRU_Profile), or '2.16.840.1.113883.9.86' (LOI_GU_PRN_Profile), or '2.16.840.1.113883.9.78' (LOI_GU_Component).

Conformance Statements: LOI_NG_ORL_Response_Profile_Component

LOI-76: MSH-21.3 (Message Profile Identifier. Universal ID) **SHALL** be valued with '2.16.840.1.113883.9.195.2.4' (LOI_NG_ORL_ Response_Profile) or two occurrences **SHALL** be valued with '2.16.840.1.113883.9.195.2.2' (LOI_ORL_Acknowledgement_Component) and '2.16.840.1.113883.9.91' (LOI_NG_Acknowledgement_Component) in any order, when acknowledging OML NG profiles where MSH-21.3 contains '2.16.840.1.113883.9.87' (LOI_NG_PRU_Profile), or '2.16.840.1.113883.9.88' (LOI_NG_PRN_Profile), or '2.16.840.1.113883.9.79' (LOI_NG_Component).

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6.2 MSA – Acknowledgement Segment

TABLE 6-4. ACKNOWLEDGMENT SEGMENT (MSA)

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Acknowledgment Code	ID	R	[1..1]	HL70008_USL	
2	Message Control ID	ST	R	[1..1]		
3	Text Message		X			Excluded for this Implementation Guide, see Section 1.3.1.
4	Expected Sequence Number		O			
5	Delayed Acknowledgment Type		X			Excluded for this Implementation Guide, see Section 1.3.1.
6	Error Condition		X			Excluded for this Implementation Guide, see Section 1.3.1.

6.3 ERR – Error Segment

TABLE 6-5. ERROR SEGMENT (ERR)

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Error Code and Location		X			Excluded for this Implementation Guide, see Section 1.3.1.
2	Error Location	ERL_01	RE	[0..1]		To reduce ambiguity, each error will have an individual ERR segment.
3	HL7 Error Code	CWE_02	R	[1..1]	HL70357_USL	Used to identify issues based on conformance profile in message (structure and vocabulary) or to indicate an application error was identified and is communicated via ERR-5 (Application Error Code).
4	Severity	ID	R	[1..1]	HL70516_USL	
5	Application Error Code	CWE_02	C(RE/O)	[0..1]	HL70533_USL	Condition Predicate: If ERR-3.1 (HL7 Error Code.Identifier) is valued '207'. Used to indicate error in content; there is nothing wrong with the message structure, but systems cannot use the data.
6	Application Error Parameter		O			
7	Diagnostic Information	TX	RE	[0..1]		Use to help IT personnel fix the error. Gives additional detail to ERR-3 (HL7 Error Code) and ERR-5 (Application Error Code).
8	User Message	TX	RE	[0..1]		Can be used to communicate error/instructions to the initiating system if an alternate interpretation to the text in ERR-7 (Diagnostic Information) is available to inform the appropriate users.
9	Inform Person Indicator		O			

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TABLE 6-5. ERROR SEGMENT (ERR)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
10	Override Type		O			
11	Override Reason Code		O			
12	Help Desk Contact Point		O			

Usage Note

ERR-2 (Segment Sequence) identifies the occurrence of the segment identified in ERR-1 (Segment ID) within the message. The following example illustrates how ERR-2 is valued 'TQ1^3' since the error occurred in the third occurrence of a TQ1 segment. Note this is not the same as the segment's Set ID element.

Example ERL Data Type: |TQ1^3|

```
MSH...
...
ORC|NW|...
TQ1|1|...
OBR|1|...
ORC|NW|...
TQ1|1|...
OBR|2|
ORC|NW|...
TQ1|1|...***invalid TQ1 segment***
OBR|3|...
SPM|1|...
```


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6.4 PID – Patient Identification Segment

TABLE 6-6. PATIENT IDENTIFICATION SEGMENT (PID)

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Set ID – PID	SI	R	[1..1]		Constrained to the literal value '1'.
2	Patient ID		X			Excluded for this Implementation Guide, see Section 1.3.1.
3	Patient Identifier List	Varies	R	[1..*]		GU data type: CX_01 NG data type: CX_02
4	Alternate Patient ID – PID		X			Excluded for this Implementation Guide, see Section 1.3.1.
5	Patient Name	XPN_03	R	[1..1]		LOI_NDBS_Component Commentt: It is required that the name on the blood spot card matches the name sent in the HL7 message. In the special case that an infant has not yet received a first or middle name at time of screening, we recommend submitters use the literal "BabyBoy" or "BabyGirl" for the first name. For unknown last name just use 'Doe'.
6	Mother's Maiden Name	XPN_01	Varies	[0..1]		PH Component Usage: 'RE' Usage for all other components: 'O'
7	Date/Time of Birth	Varies	R	[1..1]		LAB_NB_Component data type: TS_02 or TS_03 LOI_NDBS_Component data type: TS_06 or TS_07 LOI_NDBS_Component comment: For the purpose of NDBS, the newborn's birth date/time shall be fully specified to the minute, if known, in PID-7 (Date of Birth). Data type for all other components: TS_01
8	Administrative Sex	IS	R	[1..1]	HL70001_USL	Patient's gender.
9	Patient Alias		X			Excluded for this Implementation Guide, see Section 1.3.1.
10	Race	CWE_02	RE	[0..*]	HL70005_USL	Note that state and/or national regulations may dictate other behaviors. The PID-10 (Race) value is provided for demographic/billing purposes, not clinical use. If race is unknown this field should be left blank.
11	Patient Address	Varies	C(R/RE)	[0..*]		LOI_NDBS_Component data type: XAD_02 Data type for all other components: XAD_01 Condition Predicate: If PV1-20.1 (Financial Class.Financial Class Code) is valued 'T' (third party).

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TABLE 6-6. PATIENT IDENTIFICATION SEGMENT (PID)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
12	County Code		X			Excluded for this Implementation Guide, see Section 1.3.1.
13	Phone Number – Home	XTN_01	Varies	[0..*]		PH Component Usage: 'RE' Usage for all other components: 'O'
14	Phone Number – Business	XTN_01	Varies	[0..*]		PH Component Usage: 'RE' Usage for all other components: 'O'
15	Primary Language		O			
16	Marital Status		Varies			LOI_NDBS_Component usage: X Usage for all other components: O
17	Religion		O			
18	Patient Account Number		O			
19	SSN Number – Patient		X			Excluded for this Implementation Guide, see Section 1.3.1.
20	Driver's License Number – Patient		X			Excluded for this Implementation Guide, see Section 1.3.1.
21	Mother's Identifier		O			
22	Ethnic Group	CWE_02	RE	[0..1]	HL70189_USL	Note that state and/or national regulations may dictate other behaviors. The PID-22 (Ethnic Group) value is provided for demographic/billing purposes, not clinical use. If ethnicity is unknown this field should be left blank.
23	Birth Place		O			
24	Multiple Birth Indicator	Varies	Varies	Varies		LOI_NDBS_Component usage: RE, cardinality: 0..1, data type: ID, Value Set HL70136_USL Usage for all other components: O
25	Birth Order	Varies	Varies	Varies		LOI_NDBS_Component usage: RE, cardinality: 0..1, datatype: NM Usage for all other components: O
26	Citizenship		O			
27	Veterans Military Status		Varies			LOI_NDBS_Component usage: X Usage for all other components: O
28	Nationality		X			Excluded for this Implementation Guide, see Section 1.3.1.

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TABLE 6-6. PATIENT IDENTIFICATION SEGMENT (PID)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
29	Patient Death Date and Time	Varies	C(RE/O)	[0..1]		Condition Predicate: If PID-30 (Patient Death Indicator) is valued 'Y'. LOI_NDBS_Component data type: TS_06 or TS_07 Data type for all other components: TS_03
30	Patient Death Indicator	ID	RE	[0..1]	HL70136_USL	
31	Identity Unknown Indicator		O			LOI_NDBS_Component usage: X Usage for all other components: O
32	Identity Reliability Code		O			
33	Last Update Date/Time		O			
34	Last Update Facility		O			
35	Species Code		Varies			LOI_NDBS_Component usage: X Usage for all other components: O
36	Breed Code		X			Excluded for this Implementation Guide, see Section 1.3.1.
37	Strain		X			Excluded for this Implementation Guide, see Section 1.3.1.
38	Production Class Code		X			Excluded for this Implementation Guide, see Section 1.3.1.
39	Tribal Citizenship		O			

Usage Note

PID-5 (Patient Name)

This Guide pre-adopts the concept that nothing is implied by the sequence of occurrences, i.e., the first occurrence cannot be assumed to be the legal name.

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

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

LOI_NDBS_Component

When PID-24 (Multiple Birth Indicator) is 'Y' then should have PID-25 (Birth Order) valued with the respective number indicating if this patient is the first (1), the second (2) etc.

An OBX segment, where OBX-3.1 (Observation Identifier.Identifier) is valued "57722-1" (Birth plurality of pregnancy), can be sent in addtion to PID-25 to indicate the total number of babies delivered for the same pregnancy.

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Conformance Statements: LOI_Common_Component

LOI-35: PID-1 (Set ID - PID) **SHALL** be valued with the constant value '1'.

LOI-36: If PV1-20.1 (Financial Class.Financial Class Code) is 'T' (Third Party) or 'P' (Patient) then PID-11 (Patient Address) **SHALL** include an occurrence where PID-11.7 (Address Type) SHALL be valued 'H' drawn from table HL70190.

LOI-37: If PV1-20.1 (Financial Class.Financial Class Code) is valued 'T' (Third Party) or 'P' (Patient), PID-5.7 (Patient Name.Name Type Code) **SHALL** be valued 'L' drawn from table HL70190.

6.5 NK1 – Next of Kin / Associated Parties Segment

TABLE 6-7. NEXT OF KIN / ASSOCIATED PARTIES SEGMENT (NK1)

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Set ID - NK1	SI	R	[1..1]		
2	Name	XPN_03	C(R/O)	0..1		
3	Relationship	CWE_02	R	[1..1]	HL70063_USL	
4	Address	Varies	RE	[0..2]		LOI_NDBS_Component data type: XAD_02 Data type for all other components: XAD_01
5	Phone Number	XTN_01	RE	[0..4]		
6	Business Phone Number		O			
7	Contact Role	CWE_02	RE	[0..1]	HL70131_USL	
8	Start Date		O			
9	End Date		O			
10	Next of Kin / Associated Parties Job Title		O			
11	Next of Kin / Associated Parties Job Code/Class	JCC_01	C(R/O)	[0..1]		Condition Predicate: If NK1-7.1 (Contact Role.Identifier) is 'E' (employer).
12	Next of Kin / Associated Parties Employee Number		O			
13	Organization Name - NK1	Varies	Varies	[0..1]		Condition Predicate: If NK1-2 (Name) is not valued. LOI_NDBS_Component usage: C(R/O) Usage for all other components: C(R/X) GU data type: XON_01 NG data type: XON_02
14	Marital Status		O			

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TABLE 6-7. NEXT OF KIN / ASSOCIATED PARTIES SEGMENT (NK1)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
15	Administrative Sex		O			
16	Date/Time of Birth		O			
17	Living Dependency		O			
18	Ambulatory Status		O			
19	Citizenship		O			
20	Primary Language		O			
21	Living Arrangement		O			
22	Publicity Code		O			
23	Protection Indicator		O			
24	Student Indicator		O			
25	Religion		O			
26	Mother's Maiden Name		O			
27	Nationality		O			
28	Ethnic Group		O			
29	Contact Reason		O			
30	Contact Person's Name	XPN_02	Varies	[0..1]		PH Component Usage: 'C(RE/X)' Condition Predicate: If NK1-13 (Organization Name - NK1) is valued. Usage for all other components: 'O'
31	Contact Person's Telephone Number		O			
32	Contact Person's Address	XAD_01	Varies	[0..1]		PH Component Usage: 'C(RE/X)' Condition Predicate: If NK1-13 (Organization Name - NK1) is valued. Usage for all other components: 'O'
33	Next of Kin/Associated Party's Identifiers		O			
34	Job Status		O			
35	Race		O			
36	Handicap		O			

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TABLE 6-7. NEXT OF KIN / ASSOCIATED PARTIES SEGMENT (NK1)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
37	Contact Person Social Security Number		O			
38	Next of Kin Birth Place		O			
39	VIP Indicator		O			

Usage Note

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

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

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

LOI_NDBS_Component

NK1-2 – Name: A Baby's mother/father/caregiver's name. If mother's info is not provided, then provide available caregiver, guardian, adoption agency, or social services information. Additional repeat for Father's information - reported in some states. Additional repeat for Care Giver's information - This indicates a caregiver /guardian in adoption/foster situations, etc., other than the birth mother or father.

NK1-3-Relationship: This is primarily intended for information on the baby's birth mother, if that is not available, provide information for the person responsible for the baby.

NK1-5-Phone Number This field is required for the mother (NK1.3.1 is valued 'MTH').

Additional repeats for information about the father (NK1.3.1 is valued 'FTH'), the caregiver in a foster situation (NK1-3.1 is valued 'CGV' or the guardian in the case of adoption (NK1-3.1 is valued 'GRD') are supported in some jurisdictions.

If collected, NK1-5 (Phone Number) SHALL be valued when NK1-3.1 (Relationship.Identifier) is valued 'MTH'.

Conformance Statements: LOI_Common_Component

LOI-38: NK1-1 (Set ID – NK1) **SHALL** be valued sequentially with the starting value '1'.

6.6 PV1 – Patient Visit Segment

TABLE 6-8. PATIENT VISIT SEGMENT (PV1)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Set ID - PV1	SI	R	[1..1]		

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TABLE 6-8. PATIENT VISIT SEGMENT (PV1)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
2	Patient Class	IS	R	[1..1]	HL70004_USL	
3	Assigned Patient Location		O			
4	Admission Type	Varies	Varies	[0..1]		LRI_PH_Component Data Type: 'IS'; Usage: 'RE'; Cardinality: [0..1]; Value Set: HL70007_USL All others usage: O
5	Preadmit Number		O			
6	Prior Patient Location		O			
7	Attending Doctor		O			
8	Referring Doctor		O			
9	Consulting Doctor		X			Excluded for this Implementation Guide, see Section 1.3.1.
10	Hospital Service		O			
11	Temporary Location		O			
12	Preadmit Test Indicator		O			
13	Re-admission Indicator		O			
14	Admit Source		O			
15	Ambulatory Status		O			
16	VIP Indicator		O			
17	Admitting Doctor		O			
18	Patient Type		O			
19	Visit Number		O			
20	Financial Class	FC	R	[1..1]	HL70064_USL	
21	Charge Price Indicator		O			
22	Courtesy Code	CWE_02	C(RE/O)	[0..1]	HL70045_USL	Condition Predicate: If PV1-20.1 (Financial Class.Financial Class Code) is not valued 'T' (Third Party).
23	Credit Rating		O			
24	Contract Code		O			
25	Contract Effective Date		O			
26	Contract Amount		O			

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TABLE 6-8. PATIENT VISIT SEGMENT (PV1)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
27	Contract Period		O			
28	Interest Code		O			
29	Transfer to Bad Debt Code		O			
30	Transfer to Bad Debt Date		O			
31	Bad Debt Agency Code		O			
32	Bad Debt Transfer Amount		O			
33	Bad Debt Recovery Amount		O			
34	Delete Account Indicator		O			
35	Delete Account Date		O			
36	Discharge Disposition		O			
37	Discharged to Location		O			
38	Diet Type		O			
39	Servicing Facility		O			
40	Bed Status		X			Excluded for this Implementation Guide, see Section 1.3.1.
41	Account Status		O			
42	Pending Location		O			
43	Prior Temporary Location		O			
44	Admit Date/Time	Varies	Varies	Varies		LRI_PH_Component Data Type: 'TS_06'; Usage: 'RE', Cardinality: [0..1] Usage for all other components: 'O'
45	Discharge Date/Time		O			
46	Current Patient Balance		O			
47	Total Charges		O			
48	Total Adjustments		O			
49	Total Payments		O			
50	Alternate Visit ID		O			
51	Visit Indicator		O			
52	Other Healthcare Provider		X			Excluded for this Implementation Guide, see Section 1.3.1.

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Usage Note

PV1-22 (Courtesy Code)

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

Conformance Statements: LOI_Common_Component

LOI-39: PV1-1 (Set ID – PV1) **SHALL** be valued with the constant value '1'.

6.7 IN1 – Insurance Segment

TABLE 6-9. INSURANCE SEGMENT (IN1)

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Set ID - IN1	SI	R	[1..1]		
2	Insurance Plan ID	CWE_02	R	[1..1]	HL70072_USL	
3	Insurance Company ID	Varies	R	[1..1]		GU data type: CX_01 NG data type: CX_02
4	Insurance Company Name	XON_04	R	[1..1]		
5	Insurance Company Address	XAD_01	R	[1..1]		
6	Insurance Co Contact Person		O			
7	Insurance Co Phone Number		O			
8	Group Number	ST	RE	[0..1]		
9	Group Name		O			
10	Insured's Group Emp ID		O			
11	Insured's Group Emp Name	Varies	C(R/O)	[0..1]		Condition Predicate: If IN1-31 (Type of Agreement Code) is valued 'W' (Workman's Comp). GU data type: XON_01 NG data type: XON_02
12	Plan Effective Date		O			
13	Plan Expiration Date	DT	RE	[0..1]		
14	Authorization Information		O			
15	Plan Type		O			
16	Name Of Insured	XPN_02	R	[1..1]		
17	Insured's Relationship To Patient	CWE_02	R	[1..1]	HL70063_USL	

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TABLE 6-9. INSURANCE SEGMENT (IN1)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
18	Insured's Date Of Birth	TS_01	RE	[0..1]		
19	Insured's Address	XAD_01	RE	[0..1]		
20	Assignment Of Benefits		O			
21	Coordination Of Benefits		O			
22	Coord Of Ben. Priority		O			
23	Notice Of Admission Flag		O			
24	Notice Of Admission Date		O			
25	Report Of Eligibility Flag		O			
26	Report Of Eligibility Date		O			
27	Release Information Code		O			
28	Pre-Admit Cert (PAC)		O			
29	Verification Date/Time		O			
30	Verification By		O			
31	Type Of Agreement Code	IS	RE	[0..1]	HL70098_USL	
32	Billing Status		O			
33	Lifetime Reserve Days		O			
34	Delay Before L.R. Day		O			
35	Company Plan Code		O			
36	Policy Number	ST	R	[1..1]		
37	Policy Deductible		O			
38	Policy Limit - Amount		O			
39	Policy Limit - Days		O			
40	Room Rate - Semi-Private		X			Excluded for this Implementation Guide, see Section 1.3.1.
41	Room Rate - Private		X			Excluded for this Implementation Guide, see Section 1.3.1.
42	Insured's Employment Status		O			
43	Insured's Administrative Sex		O			
44	Insured's Employer's Address		O			

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TABLE 6-9. INSURANCE SEGMENT (IN1)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
45	Verification Status		O			
46	Prior Insurance Plan ID		O			
47	Coverage Type		O			
48	Handicap		O			
49	Insured's ID Number		O			
50	Signature Code		O			
51	Signature Code Date		O			
52	Insured's Birth Place		O			
53	VIP Indicator		O			

Usage Note

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

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

Conformance Statements: LAB_FI_Component

LOI-78: IN1-1 (Set ID – IN1) **SHALL** be valued with the constant value '1'.

6.8 GT1 – Guarantor Segment

TABLE 6-10. GUARANTOR SEGMENT (GT1)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Set ID - GT1	SI	R	[1..1]		
2	Guarantor Number		O			
3	Guarantor Name	XPN_02	R	[1..1]		Beginning with Version 2.3, if the guarantor is an organization, send a null value ("") in GT1-3 (Guarantor Name) and put the organization name in GT1-21 (Guarantor Organization Name). Either Guarantor Name or Guarantor Organization Name is required.
4	Guarantor Spouse Name		O			
5	Guarantor Address	XAD_01	R	[1..1]		
6	Guarantor Ph Num – Home		O			

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TABLE 6-10. GUARANTOR SEGMENT (GT1)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
7	Guarantor Ph Num – Business		O			
8	Guarantor Date/Time Of Birth		O			
9	Guarantor Administrative Sex		O			
10	Guarantor Type		O			
11	Guarantor Relationship	CWE_02	R	[1..1]	HL70063_USL	
12	Guarantor SSN		O			
13	Guarantor Date - Begin		O			
14	Guarantor Date - End		O			
15	Guarantor Priority		O			
16	Guarantor Employer Name		O			
17	Guarantor Employer Address		O			
18	Guarantor Employer Phone Number		O			
19	Guarantor Employee ID Number		O			
20	Guarantor Employment Status		O			
21	Guarantor Organization Name	Varies	R	[1..1]		Beginning with Version 2.3, if the guarantor is a person, send a null value ("") in GT1-21 (Guarantor Organization Name) and put the person name in GT1-3 (Guarantor Name). Either guarantor person name or guarantor organization name is required. GU data type: XON_01 NG data type: XON_02
22	Guarantor Billing Hold Flag		O			
23	Guarantor Credit Rating Code		O			
24	Guarantor Death Date And Time		O			
25	Guarantor Death Flag		O			
26	Guarantor Charge Adjustment Code		O			
27	Guarantor Household Annual Income		O			
28	Guarantor Household Size		O			
29	Guarantor Employer ID Number		O			

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TABLE 6-10. GUARANTOR SEGMENT (GT1)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
30	Guarantor Marital Status Code		O			
31	Guarantor Hire Effective Date		O			
32	Employment Stop Date		O			
33	Living Dependency		O			
34	Ambulatory Status		O			
35	Citizenship		O			
36	Primary Language		O			
37	Living Arrangement		O			
38	Publicity Code		O			
39	Protection Indicator		O			
40	Student Indicator		O			
41	Religion		O			
42	Mother's Maiden Name		O			
43	Nationality		O			
44	Ethnic Group		O			
45	Contact Person's Name		O			
46	Contact Person's Telephone Number		O			
47	Contact Reason		O			
48	Contact Relationship		O			
49	Job Title		O			
50	Job Code/Class		O			
51	Guarantor Employer's Organization Name		O			
52	Handicap		O			
53	Job Status		O			
54	Guarantor Financial Class		O			
55	Guarantor Race		O			
56	Guarantor Birth Place		O			

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TABLE 6-10. GUARANTOR SEGMENT (GT1)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
57	VIP Indicator		O			

Usage Note

GT1-11 (Guarantor Relationship)

The use of CWE_02 is pre-adopted from HL7 V.2.7.1.

Conformance Statements: LOI_Common_Component

LOI-40: GT1-1 (Set ID – GT1) **SHALL** be valued with the constant value '1'.

LOI-41: If GT1-3 (Guarantor Name) is ' "" ' then GT1-21 (Guarantor Organizational Name) **SHALL** be valued with any other string except ' "" '.

LOI-42: If GT1-21 (Guarantor Organization Name) is valued ' "" ' then GT1-3 (Guarantor Name) **SHALL** be valued with any other string except ' "" '.

Note: The ' "" ' means that the literal string of two double-quotes are conveyed in the message, the field is not empty.

6.9 ORC – Common Order Segment

TABLE 6-11. COMMON ORDER SEGMENT (ORC)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Order Control	ID	R	[1..1]	HL70119_USL	
2	Placer Order Number	Varies	R	[1..1]		GU data type: EI_01 NG data type: EI_02
3	Filler Order Number	Varies	RE	[0..1]		Filler order number is usually not known for a new order but may be known for cancel orders and sending application acknowledgements for new or append orders. GU data type: EI_01 NG data type: EI_02
4	Placer Group Number	Varies	RE	[0..1]		GU data type: EI_01 NG data type: EI_02
5	Order Status		O			
6	Response Flag		O			

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TABLE 6-11. COMMON ORDER SEGMENT (ORC)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
7	Quantity/Timing		X			Excluded for this Implementation Guide, see Section 1.3.1.
8	Parent		O			
9	Date/Time of Transaction	Varies	R	[1..1]		LAB_TO_Component Data Type: TS_13 All other components Data Type: TS_12
10	Entered By		O			
11	Verified By		O			
12	Ordering Provider	Varies	R	[1..1]		Providers should be identified using their NPI. GU data type: XCN_01 NG data type: XCN_02
13	Enterer's Location		O			
14	Call Back Phone Number	XTN_01	RE	[0..2]		
15	Order Effective Date/Time		O			
16	Order Control Code Reason		O			
17	Entering Organization		O			
18	Entering Device		O			
19	Action By		O			
20	Advanced Beneficiary Notice Code	CWE_02	RE	[0..1]	HL70339_USL	
21	Ordering Facility Name	Varies	Varies	Varies		Ordering facilities should be identified using their NPI LOI_NDBS_Component and PH Component Usage: 'R', Cardinality: [1..1] Usage for all other components: 'O' GU data type: XON_01 NG data type: XON_02
22	Ordering Facility Address	Varies	Varies	Varies		PH Component Usage: 'R', cardinality: 1..1, datatype: XAD_01 Usage for all other components: 'O'

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TABLE 6-11. COMMON ORDER SEGMENT (ORC)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
23	Ordering Facility Phone Number	Varies	Varies	Varies		PH Component Usage: 'R', cardinality: 1..*, data type: XTN_01 Usage for all other components: 'O'
24	Ordering Provider Address	Varies	Varies	Varies		LRI_PH_Component Data Type: XAD_01; Usage: 'R'; Cardinality: [1..*] Usage for all other components: 'O'
25	Order Status Modifier		O			
26	Advanced Beneficiary Notice Override Reason		C(X/X)			
27	Filler's Expected Availability Date/Time		O			
28	Confidentiality Code		O			
29	Order Type		O			
30	Enterer Authorization Mode		O			
31	Parent Universal Service Identifier		O			

Usage Note

ORC-4 (Placer Group Number)

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

ORC-20 (Advanced Beneficiary Notice Code)

The use of CWE_02 is pre-adopted from CWE in HL7 V.2.7.1.

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

Conformance Statements: LOI_Common_Component

LOI-44: The value of ORC-2 (Placer Order Number) **SHALL** be identical to the value of OBR-2 (Placer Order Number) within the same Order Group.

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LOI-45: ORC-3 (Filler Order Number) **SHALL** be identical to the value of OBR-3 (Filler Order Number) within the same Order Group.

LOI-46: The value of ORC-12 (Ordering Provider) **SHALL** be identical to the value of OBR-16 (Ordering Provider) within the same Order Group.

Conformance Statements: LAB_PRU_Component

LOI-47: The value of ORC-2 (Placer Order Number) **SHALL NOT** be valued identical to another instance of ORC-2 (Placer Order Number) within the same message excluding the Prior Result group(s).

Conformance Statements: LAB_FRU_Component

LOI-48: If valued, ORC-3 (Filler Order Number) **SHALL NOT** be valued identical to another instance of ORC-3 (Filler Order Number) within the same message excluding the Prior Result group(s).

6.10 TQ1 – Timing/Quantity Segment

TABLE 6-12. TIMING/QUANTITY SEGMENT FOR ORDER GROUP (TQ1)

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Set ID - TQ1	SI	R	[1..1]		
2	Quantity		O			
3	Repeat Pattern		O			
4	Explicit Time		O			
5	Relative Time and Units		O			
6	Service Duration		O			
7	Start date/time	Varies	RE	[0..1]		LAB_TO_Component Data Type: TS_07 All other components Data Type: TS_06 The start date should be the expected date the order should begin or the anticipated date when the order will be fulfilled by the patient arriving at the Patient Service Center (PSC). If this is a future order this should have a date, otherwise it may be empty. A future order is an order with a start date/time where that start date/time indicates the earliest time the specimen can be collected. Leaving this field empty would indicate that the test may be performed at the earliest available date or when the patient arrives to have specimen drawn.
8	End date/time	Varies	RE	[0..1]		LAB_TO_Component Data Type: TS_07 Data type for all other components: TS_06 The latest date and time by which the specimen should be collected.
9	Priority	CWE_02	R	[1..1]	HL70485_USL	

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TABLE 6-12. TIMING/QUANTITY SEGMENT FOR ORDER GROUP (TQ1)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
10	Condition text		O			
11	Text instruction		O			
12	Conjunction		X			Excluded for this Implementation Guide, see Section 1.3.1.
13	Occurrence duration		O			
14	Total occurrence's		O			

Usage Note

TQ1-12 (Conjunction)

Since the TQ group can only appear once in each Observation Group use of the conjunction field is not permitted, including further constrained profiles as this would conflict with TQ group only appearing once.

Conformance Statements: LOI_Common_Component

LOI-49: The value of TQ1-1 (Set ID – TQ1) **SHALL** be valued '1'.

6.11 OBR – Observation Request Segment

TABLE 6-13. OBSERVATION REQUEST SEGMENT (OBR)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Set ID - OBR	SI	R	[1..1]		For the first occurrence of the OBR segment in the message, the Sequence number shall be one (1), for the second occurrence, the Sequence number shall be two (2), etc.
2	Placer Order Number	Varies	R	[1..1]		GU data type: EI_01 NG data type: EI_02
3	Filler Order Number	Varies	RE	[0..1]		GU data type: EI_01 NG data type: EI_02
4	Universal Service Identifier	CWE_01	R	[1..1]	LOINC	LOINC shall be used as the standard vocabulary to identify the ordered test in OBR-4 (Universal Service Identifier) when an applicable LOINC code is available and provided by the laboratory. When no valid orderable LOINC code exists, the local code may be the only code sent. See Section 8.1 LOINC.

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TABLE 6-13. OBSERVATION REQUEST SEGMENT (OBR)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
5	Priority – OBR		X			Excluded for this Implementation Guide, see Section 1.3.1.
6	Requested Date/Time		X			Excluded for this Implementation Guide, see Section 1.3.1.
7	Observation Date/Time	Varies	Varies	Varies		LOI_NDBS_Component usage: R, cardinality: 1..1 Usage for all other components: RE, cardinality: 0..1 LAB_TO_Component Data Type: TS_07 Data typ for all other components: TS_06 This reflects the specimen collection date/time when the test involves a specimen. Since a test may also involve drawing specimens at different times, e.g., tolerance tests, this date/time only covers the draw of the first specimen. All other specimen collection date/times, including the first one, are communicated in the respective SPM segment(s).
8	Observation End Date/Time	Varies	C(RE/X)	[0..1]		LAB_TO_Component Data Type: TS_07 Data type for all other components: TS_06 Condition Predicate: If OBR-7 (Observation Date/Time) is valued LOI_NDBS_Component comment: Due to the nature of the specimen being collected, this element will never be used.
9	Collection Volume		O			
10	Collector Identifier		O			
11	Specimen Action Code		O			
12	Danger Code		O			
13	Relevant Clinical Information	CWE_02	RE	[0..1]	HL70916_USL	This field pre-adopts the V2.7.1 definition. Constrained to indicate Fasting only. LOI_NDBS_Component comment: Due to the nature of the specimen being collected, this element will never be used.
14	Specimen Received Date/Time		X			Excluded for this Implementation Guide, see Section 1.3.1.
15	Specimen Source		X			Excluded for this Implementation Guide, see Section 1.3.1.

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TABLE 6-13. OBSERVATION REQUEST SEGMENT (OBR)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
16	Ordering Provider	Varies	R	[1..1]		Providers should be identified using their NPI. GU data type: XCN_01 NG data type: XCN_02
17	Order Call-back Phone Number	XTN_01	RE	[0..2]		
18	Placer Field 1		O			
19	Placer Field 2		O			
20	Filler Field 1		O			
21	Filler Field 2		O			
22	Results Rpt/Status Chng - Date/Time		X			Excluded for this Implementation Guide, see Section 1.3.1.
23	Charge to Practice		O			
24	Diagnostic Service Sect ID		O			
25	Result Status		X			Excluded for this Implementation Guide, see Section 1.3.1.
26	Parent Result		O			
27	Quantity/Timing		X			Excluded for this Implementation Guide, see Section 1.3.1.
28	Result Copies To	Varies	RE	Varies		GU Profile: XCN_01 NG Profile: XCN_02 LAB_RC_Component cardinality: '[0..*]' Cardinality for all other components: '[0..5]'.
29	Parent		O			
30	Transportation Mode		O			
31	Reason for Study		O			
32	Principal Result Interpreter		O			
33	Assistant Result Interpreter		O			
34	Technician		O			
35	Transcriptionist		O			
36	Scheduled Date/Time		O			
37	Number of Sample Containers		O			
38	Transport Logistics of Collected Sample		O			

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TABLE 6-13. OBSERVATION REQUEST SEGMENT (OBR)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
39	Collector's Comment		O			
40	Transport Arrangement Responsibility		O			
41	Transport Arranged		O			
42	Escort Required		O			
43	Planned Patient Transport Comment		O			
44	Procedure Code		O			
45	Procedure Code Modifier		O			
46	Placer Supplemental Service Information		O			
47	Filler Supplemental Service Information		X			Excluded for this Implementation Guide, see Section 1.3.1.
48	Medically Necessary Duplicate Procedure Reason		O			
49	Result Handling		O			
50	Parent Universal Service Identifier		O			

Usage Note

When used in prior results see Section 4.2.1.13 LOI_PR_Component (Prior Results) – ID: 2.16.840.1.113883.9.95 for guidance on proper use of OBR segment.

OBR-4 (Universal Service Identifier), OBR-13 (Relevant Clinical Information)

OBR-4 and OBR-13 pre-adopt the use of CWE replacing CE and ST respectively from HL7 V.2.7.1.

OBR-28 (Result Copies To)

Note that under PRT segment there are two Conformance Statements (LRI-57 and LOI-58) that must be considered.

LOI_NDBS_Component

When a newborn screening test is ordered where an ordering provider is not always clearly documented, still there is a provider who is responsible for the placement of that order by protocol or otherwise, who is therefore expected to be identified in this field, e.g., attending provider, medical director responsible for the protocol, or other provider overseeing the protocol.

Conformance Statements: LOI_Common_Component

LOI-79: If any of OBR-7 (Observation Date/Time), OBR-8 (Observation End Date/Time), SPM-17.1 (Range Start Date/Time) or SPM-17.2 (Range End Date/Time) contain a time zone offset then all **SHALL** contain a time zone offset.

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LOI-50: If present, OBR-8 (Observation End Date/Time) **SHALL** be equal to or later than OBR-7 (Observation Date/Time).

LOI-51: The value of OBR-1 (Set ID – OBR) **SHALL** start at '1' and be incremented sequentially across the Order groups.

Note: The sequence numbering of the OBRs in the LOI is independent of the sequence numbering of OBRs in the prior results.

```
MSH|...<cr>
PID|...<cr>
// First order group
ORC|NW|...<cr>
OBR|1|...<cr>
SPM|1|...<cr>
SPM|2|...<cr>
// end first order group
// Second order group
ORC|NW|...<cr>
OBR|2|...<cr>
SPM|1|...<cr>
SPM|2|...<cr>
//end second order group
// PRIOR_RESULTS_Group
SGH<cr>
PID|1|...<cr>
ORC|PR|...<cr>
TQ1|1|...<cr>
OBR|1|...<cr>
OBX|1|...<cr>
OBX|2|...<cr>
SGT<cr>
//end PRIOR_RESULTS_Group
```


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6.11.1 RESULT HANDLING AND RESULT COPIES TO

In this Implementation Guide OBR-28 (Result Copies To) is populated with the identities of any providers to whom the ordering provider would like to send copies of the test result (copy-to providers). To accommodate most common scenarios, the LAB_RC_Component profile is defined to determine whether the message may contain any number of recipients (MSH-21 contains this profile), or whether up to 5 recipients may be sent.

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

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

Ordering systems should handle copy-to for providers in the same system as the ordering provider internally, e.g., after results are received by the ordering system. If the report is to be sent using the LRI to the copy-to providers the appropriate messaging between the LIS and EHR–S needs to be resolved by the respective parties to ensure that multiple messages for different copy-to providers to the same system do not conflict. Without this understanding the systems need to be aware that multiple reports may be generated that may inadvertently be considered duplicates. It is up to the laboratory to determine how to satisfy the copy-to request.

6.12 NTE – Notes and Comments Segment

TABLE 6-14. NOTES AND COMMENTS SEGMENT (NTE)

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

Usage Note

One NTE segment shall contain a single complete comment. If several distinct comments are to be conveyed in the message, one NTE segment shall be used for each comment. The use of formatting commands in the base standard V2.7.1, Section 2.7.6, allows for appropriate formatting of the comment within the NTE-3 (Comment) field if desired. Specifically, for representation of line breaks use the formatting command "\.br\" as defined in the base standard V2.7.1, section 2.7.6. Use of '~', hexadecimal, or local escape sequences as a line break indicator is NOT allowed.

The receiver shall not concatenate separate NTEs in any way that displays any part of multiple NTEs on the same line; see the EHR-S FR Implementation Guide.

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Conformance Statements: LOI_Common_Component

LOI-55: NTE-1 (Set ID – NTE) **SHALL** be sequentially numbered starting with the value '1' within a given segment group.

6.13 PRT – Participation Information Segment – From 2.7.1

In this guide, PRT only takes into account use in support of Result Copies To as described in Section 6.11.1 Result Handling and Result Copies To; any other use is beyond the scope of this guide, except by trading partner agreement. Users are encouraged to submit comments for other uses

TABLE 6-15. PARTICIPATION INFORMATION SEGMENT (PRT)

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Participation Instance ID	Varies	R	[1..1]		GU Usage: EI_01 NG Usage: EI_02
2	Action Code	ID	R	[1..1]	HL70287_USL	
3	Action Reason		O			
4	Participation	CWE_02	R	[1..1]	HL70912_USL	
5	Participation Person	Varies	R	[1..1]		GU Usage: XCN_01 NG Usage: XCN_02
6	Participation Person Provider Type		O			
7	Participant Organization Unit Type		O			
8	Participation Organization		O			
9	Participant Location		O			
10	Participation Device		O			
11	Participation Begin Date/Time (arrival time)		O			
12	Participation End Date/Time (departure time)		O			
13	Participation Qualitative Duration		O			
14	Participation Address	XAD_01	C(R/RE)	[0..1]		Condition Predicate: If PRT-15 is not valued.
15	Participant Telecommunication Address	XTN_01	RE	[0..5]		

Usage Note

The number of PRT segments following the OBR segment shall be at least as many as the number of providers listed in OBR-28 (Results Copy To). For example, If the proceeding OBR segment has three providers listed in OBR-28, then at least three PRT segments shall follow.

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Conformance Statements: LOI_Common_Component

LOI-56: PRT-2 (Action Code) **SHALL** be valued with 'AD' drawn from code system HL70287_USL.

LOI-57: For each value in OBR-28 (Result Copies To) a corresponding PRT (Participant Information) **SHALL** be present with PRT-4.1 (Participation.Identifier) valued 'RCT' drawn from HL70912_USL.

LOI-58: For each PRT (Participant Information) where PRT-4.1 (Participation.Identifier) is valued 'RCT' there **MUST** be a corresponding value in OBR-28 (Result Copies To) equal to PRT-5 (Participation Person).

6.14 DG1 – Diagnosis Segment

TABLE 6-16. DIAGNOSIS SEGMENT (DG1)

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Set ID - DG1	SI	R	[1..1]		
2	Diagnosis Coding Method		X			Excluded for this Implementation Guide, see Section 1.3.1.
3	Diagnosis Code - DG1	CWE_02	R	[1..1]	ICD-10CM	Note that Use of ICD-10_CM is recommended (SHOULD), but other codes or CWE.9 can be used when no codes are available.
4	Diagnosis Description		X			Excluded for this Implementation Guide, see Section 1.3.1.
5	Diagnosis Date/Time		O			
6	Diagnosis Type	IS	R	[1..1]	HL70052_USL	
7	Major Diagnostic Category		X			Excluded for this Implementation Guide, see Section 1.3.1.
8	Diagnostic Related Group		X			Excluded for this Implementation Guide, see Section 1.3.1.
9	DRG Approval Indicator		X			Excluded for this Implementation Guide, see Section 1.3.1.
10	DRG Grouper Review Code		X			Excluded for this Implementation Guide, see Section 1.3.1.
11	Outlier Type		X			Excluded for this Implementation Guide, see Section 1.3.1.
12	Outlier Days		X			Excluded for this Implementation Guide, see Section 1.3.1.
13	Outlier Cost		X			Excluded for this Implementation Guide, see Section 1.3.1.
14	Grouper Version And Type		X			Excluded for this Implementation Guide, see Section 1.3.1.
15	Diagnosis Priority	ID	RE	[0..1]	HL70359_USL	
16	Diagnosing Clinician		O			
17	Diagnosis Classification		O			
18	Confidential Indicator		O			

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TABLE 6-16. DIAGNOSIS SEGMENT (DG1)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
19	Attestation Date/Time		O			
20	Diagnosis Identifier		C(X/X)			The condition predicate does not apply to any message in this guide.
21	Diagnosis Action Code		C(X/X)			The condition predicate does not apply to any message in this guide.

Usage Note

DG1-3 (Diagnosis Code - DG1)

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

Conformance Statements: LOI_Common_Component

LOI-59: The value of DG1-1 (Set ID – DG1) **SHALL** be valued sequentially starting the value '1' within a given OBSERVATION_REQUEST segment group.

LOI-60: Only one instance of DG1-15 (Diagnosis Priority) in the Observation_Request_group **SHALL** contain the value '1'.

6.15 OBX – Observation/Result Segment

Note: Components 26 through 30 are pre-adopted from Version 2.8.2.

TABLE 6-17. OBSERVATION RESULT SEGMENT (OBX)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Set ID – OBX	SI	R	[1..1]		
2	Value Type	ID	C(R/X)	[0..1]	HL70125_USL	Condition Predicate: If OBX-5 (Observation Value) is valued. This field identifies the data type used for OBX-5.
3	Observation Identifier	CWE_01	R	[1..1]	Logical Observation Identification Name and Codes (LOINC) and/or Local Codes	When populating this field with values, this guide does not give preference to the triplet in which the standard (LOINC) code should appear. See Section 8.1 LOINC.
4	Observation Sub-ID	OG_01	C(R/RE)	[0..1]		Condition Predicate: If there are multiple OBX segments associated with the same OBR segment that have the same OBX-3 (Observation Identifier) values for (OBX-3.1 (Identifier) and OBX-3.3 (Name of Coding System)) or (OBX-3.4 (Alternate Identifier) and OBX-3.6 (Name of Alternate Coding System)).

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TABLE 6-17. OBSERVATION RESULT SEGMENT (OBX)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
5	Observation Value	Varies	Varies	Varies	HL70125_USL	LOI_NDBS_COMPONENT usage: R, cardinality: 1..1 Usage for all other components: RE, cardinality: 0..1 **Note:** If value is coded, ST should not be valued in OBX-2. Allowable data types for this field are described in HL70125_USL (from OBX-2).
6	Units	CWE_03	RE	[0..1]	UCUM	See Section 8.3 UCUM
7	References Range		O			
8	Abnormal Flags		O			
9	Probability		O			
10	Nature of Abnormal Test		O			
11	Observation Result Status	ID	R	[1..1]	HL70085_USL	
12	Effective Date of Reference Range		O			
13	User-Defined Access Checks		O			
14	Date/Time of the Observation	Varies	C(R/O)	[0..1]		LAB_TO_Component Data Type: TS_07 Data type for all other components: TS_06 Condition Predicate: If OBX-5 is valued.
15	Producer's Reference		O			
16	Responsible Observer		O			
17	Observation Method		O			
18	Equipment Instance Identifier		O			
19	Date/Time of the Analysis		O			
20	Reserved for harmonization with Version 2.6.		X			Excluded for this Implementation Guide, see Section 1.3.1.
21	Reserved for harmonization with Version 2.6.		X			Excluded for this Implementation Guide, see Section 1.3.1.
22	Reserved for harmonization with Version 2.6.		X			Excluded for this Implementation Guide, see Section 1.3.1.
23	Performing Organization Name		O			
24	Performing Organization Address		O			

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TABLE 6-17. OBSERVATION RESULT SEGMENT (OBX)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
25	Performing Organization Medical Director		O			
26	Patient Results Release Category		O			
27	Root Cause		O			
28	Local Process Control		O			
29	Observation Type	ID	R	[1..1]	HL70936_USL	**Note:** This field is pre-adopted from v2.8.2.
30	Observation Sub-Type	ID	RE	[0..1]	HL70937_USL	**Note:** This field is pre-adopted from v2.8.2.
31	Action Code	ID	O			**Note:** This field is pre-adopted from V2.9.
32	Observation Value Absent Reason	CWE_04	C(R/X)	[0..*]	HL70960	**Note:** This field is pre-adopted from V2.9. Condition Predicate: If OBX-11 (Observation Result Status) is valued "X" or "D"

Usage Note

When used in prior results see Section 4.2.1.13 LOI_PR_Component (Prior Results) – ID: 2.16.840.1.113883.9.95 for guidance on proper use of OBX segment.

When the OBX under the OBR is used it typically reflects responses to the AOEs.

Note that OBX-5 (Observation Value) does not repeat in this IG. When one AOE allows for multiple answers, then the responses shall be sent using multiple OBX segments using the same OBX-3, different OBX-5 and OBX-4 shall increment within the OBR.

OBX-3 (Observation Identifier)

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

Examples

Example AOE using OBX for blood lead test in adults; the highlighted 1 and 2 indicate how to use OBX-4 (Observation Sub-ID) to link the Name to an Address when more than one employer is communicated.

Employer 1 Name – Organization

```
OBX|1|XON|63741-3^For whom did you work at your main job or
   business?^LN^123^Employer^99Lab|^1^1|Good Health
   Hospital^L^4544^3^M10^CMS^XX^^A||||||O|||201210310800|||||||||||||||QST|AOE
```


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Employer 1 Address

```
OBX|2|XAD|63758-7^What was the location of this company?^LN
   ^345^EmpAdd^99lab|^1^2|1000 Hospital Lane^Suite 123^Ann Arbor
   ^MI^99999^USA^B^^WA||||||O|||201210310800|||||||||||||QST|AOE
```

Employer 2 Name – Person

```
OBX|4|XPN|63741-3^For whom did you work at your main job or
   business?^LN^123^Employer^99lab|^2^1|
   Everyman^Adam^A^III^DR^^L^^^^^^^PHD||||||O|||201210310800|||||||||||||QST|AOE
```

Employer 2 Address

```
OBX|5|XAD|63758-7^What was the location of this company?^LN ^345^EmpAdd^99lab|^2^2|65
   South Street^^Ann Arbor
   ^MI^99999^USA^B^^WA||||||O|||201210310800|||||||||||||QST|AOE
```

Conformance Statements: LOI_Common_Component

LOI-61: The value of OBX-5 (Observation Value) **SHALL NOT** be truncated.

LOI-62: The value of OBX-1 (Set ID – OBX) **SHALL** be valued sequentially starting the value '1' within a given segment group.

LOI-63: If there are multiple OBX segments associated with the same OBR segment that have the same OBX-3 (Observation Identifier) values for (OBX-3.1 (Observation Identifier.Identifier) **and** OBX-3.3 (Observation Identifier.Name of Coding System) or (OBX-3.4 (Observation Identifier.Alternate Identifier) **and** OBX-3.6 (Observation Identifier.Name of Alternate Coding System)), a combination of (OBX-3.1 **and** OBX3.3) or (OBX-3.4 **and** OBX-3.6) and OBX-4 (Observation Sub-ID) **SHALL** create a unique identification under a single OBR.

LAB-4: OBX-11 (Observation Result Status) **SHALL** be valued "O", when OBX-29 (Observation Type) is valued "QST".

6.16 SPM – Specimen Segment

TABLE 6-18. SPECIMEN SEGMENT (SPM)

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Set ID – SPM	SI	R	[1..1]		

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TABLE 6-18. SPECIMEN SEGMENT (SPM)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
2	Specimen ID	Varies	RE	[0..1]		GU Usage: EIP_01 NG Usage: EIP_02
3	Specimen Parent IDs		O			
4	Specimen Type	CWE_03	R	[1..1]	SNOMED CT and/or HL70487_USL	Either HL70487 or SNOMED CT Specimen hierarchy codes may be used. It should be noted that in the future SNOMED CT Specimen hierarchy may become the only recommended value set so trading partners should consider moving in that direction. LOI_NDBS_Component Value Set Fixed to: '440500007^Blood spot specimen^SCT'
5	Specimen Type Modifier	Varies	Varies	[0..*]		PH Component Data Type: 'CWE_04', Usage: 'C(RE/X)' Condition Predicate: If SPM-4.3 (Specimen Type.Name of Coding System) or SPM-4.6 (Specimen Type.Name of Alternate Coding System) is valued 'SCT', Value Set: SNOMED CT_USL Usage for all other components: 'O'
6	Specimen Additives	Varies	Varies	[0..*]		PH Component Data Type: 'CWE_04', Usage: 'RE', Value Set: HL70371_USL Usage for all other components: 'O'
7	Specimen Collection Method	Varies	Varies	[0..1]		PH Component Data Type: 'CWE_04', Usage: 'RE', Value Set: HL70488_USL Usage for all other components: 'O'
8	Specimen Source Site	Varies	Varies	[0..1]		PH Component Data Type: 'CWE_03', Usage: 'RE', Value Set: SNOMED CT Anatomical Hierarchy is recommended. Usage for all other components: 'O'
9	Specimen Source Site Modifier	Varies	Varies	[0..*]		PH Component Data Type: 'CWE_04', Usage: 'C(RE/X)', Condition Predicate: If SPM-8.3 (Specimen Source Site.Name of Coding System) or SPM-8.6 (Specimen Source Site.Alternate Coding System ID) is valued 'SCT', Value Set: SNOMED CT_USL Usage for all other components: 'O'
10	Specimen Collection Site		O			
11	Specimen Role		O			
12	Specimen Collection Amount		O			
13	Grouped Specimen Count		O			

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TABLE 6-18. SPECIMEN SEGMENT (SPM)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
14	Specimen Description		O			
15	Specimen Handling Code		O			
16	Specimen Risk Code		O			
17	Specimen Collection Date/Time	Varies	R	[1..1]		SPM-17.1 and SPM-17.2 must use: LAB_TO_Component Data Type: DR_03 Data type for all other components: DR_02
18	Specimen Received Date/Time		O			
19	Specimen Expiration Date/Time		O			
20	Specimen Availability		O			
21	Specimen Reject Reason		O			
22	Specimen Quality		O			
23	Specimen Appropriateness		O			
24	Specimen Condition		O			
25	Specimen Current Quantity		O			
26	Number of Specimen Containers		O			
27	Container Type		O			
28	Container Condition		O			
29	Specimen Child Role		O			
30	Accession ID		O			**Note:** This field is pre-adopted from V2.7.1.
31	Other Specimen ID	Varies	Varies	Varies		**Note:** This field is pre-adopted from V2.7.1. NDBS_Component: Datatype: CX_01 or CX_02, Usage: RE Cardinality: 0..*, Comment: When the State assigned Bloodspot card number is sent here SPM-31.5, drawn from HL70203 will be valued 'SNBSN'. Usage for all other components: O

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Usage Note

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

Conformance Statements: LOI_Common_Component

LOI-64: The value of SPM-1 (Set ID – SPM) **SHALL** start at '1' and be incremented sequentially within the Order Group.

Conformance Statements: LOI_Common_Component

LOI-92: Either SPM-31 OR an OBX with LOINC "57716-3" in OBX-3.1 **SHALL** be present in the message to represent the State assigned Bloodspot card number must be sent here and SPM-31.7 **SHALL** be valued 'SNBSN'.

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7 DATA TYPES

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

Note that the CE data type has been deprecated in V2.5.1; this IG uses CWE or CNE as appropriateNote that the CE data type has been withdrawn and removed in V2.6, this IG uses CWE or CNE in lieu of CE as appropriate.

7.1 CWE – Coded with Exceptions

Note the following rules for display purposes only when more than one triplet is available in the specific flavor of CWE in use:

1) CWE.9 (Original Text) should not contain an entry unless it is different from what is in either triplet and then it must be used for the display.
2) If there is only one triplet, use it;
3) If two triplets, use the one containing the local code;
4) Where two triplets are present with two local or two non-local codes, the receiver should use the first triplet.
5) Additional constraints may apply, see individual elements using CWE.

7.1.1 CWE_01 – CODED WITH EXCEPTIONS; CODE REQUIRED

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

TABLE 7-1. CODED WITH EXCEPTIONS; CODE REQUIRED (CWE_01)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Identifier	ST	R		
2	Text	ST	RE		It is strongly recommended that text be sent to accompany any identifier.
3	Name of Coding System	ID	R	HL70396	
4	Alternate Identifier	ST	RE		The alternate identifier (from the alternate coding system) should be the closest match for the identifier found in CWE_01.1 (Identifier).
5	Alternate Text	ST	RE		It is strongly recommended that alternate text be sent to accompany any alternate identifier.
6	Name of Alternate Coding System	ID	C(R/X)	HL70396	Condition Predicate: If CWE_01.4 (Alternate Identifier) is valued.
7	Coding System Version ID	ST	C(RE/O)		Condition Predicate: If CWE_01.3 (Name of Coding System) is not an HL7 defined table or user defined.
8	Alternate Coding System Version ID		O		
9	Original Text	ST	RE		Original Text is used to convey the text that was the basis for coding.
10	Second Alternate Identifier		O		

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TABLE 7-1. CODED WITH EXCEPTIONS; CODE REQUIRED (CWE_01)					
SEQ	Component Name	DT	Usage	Value Set	Comments
11	Second Alternate Text		O		
12	Second Name of Alternate Coding System	ID	C(R/O)	HL70396	Condition Predicate: This component is required when CWE_01.10 is populated and CWE_01.20 is not populated. Both CWE_01.6 and CWE_01.17 may be populated.
13	Second Alternate Coding System Version ID		O		
14	Coding System OID	ST	C(R/O)		Condition Predicate: This component is required when CWE_01.1 is populated and CWE_01.3 is not populated. Both CWE_01.3 and CWE_01.14 may be populated. The value for this component is 2.16.840.1.113883.12.#### where "####" is to be replaced by the HL7 table number in the case of an HL7 defined or user defined table. For externally defined code systems the OID registered in the HL7 OID registry SHALL be used.
15	Value Set OID		O		
16	Value Set Version ID	ID	C(R/O)		Condition Predicate: This component is required if CWE_01.15 is populated.
17	Alternate Coding System OID	ST	C(R/))		Condition Predicate: This component is required when CWE_01.4 is populated and CWE_01.6 is not populated. Both CWE_01.6 and CWE_01.17 may be populated. The value for this component is 2.16.840.1.113883.12.#### where "####" is to be replaced by the HL7 table number in the case of an HL7 defined or user defined table. For externally defined code systems the OID registered in the HL7 OID registry SHALL be used.
18	Alternate Value Set OID		O		
19	Alternate Value Set Version ID	ID	C(R/O)		Condition Predicate: Value set version ID is required if CWE_01.18 is populated.
20	Second Alternate Coding System OID	ST	C(O/X)		Condition Predicate: This component is optional when CWE_01.17 is valued and cannot be valued if CWE_01.17 is empty. The value for this component is 2.16.840.1.113883.12.#### where "####" is to be replaced by the HL7 table number in the case of an HL7 defined or user defined table. For externally defined value sets, the OID registered in the HL7 OID registry SHALL be used.
21	Second Alternate Value Set OID		O		

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TABLE 7-1. CODED WITH EXCEPTIONS; CODE REQUIRED (CWE_01)					
SEQ	Component Name	DT	Usage	Value Set	Comments
22	Second Alternate Value Set Version ID	ID	C(R/O)		Condition Predicate: This component is required when CWE_01.10 is populated and CWE_01.12 is not populated. Both CWE_01.12 and CWE_01.20 may be populated. The value for this component is 2.16.840.1.113883.12.#### where "####" is to be replaced by the HL7 table number in the case of an HL7 defined or user defined table. For externally defined value sets, the OID registered in the HL7 OID registry SHALL be used.

Usage Note

The CWE_01 data type is used where it is necessary to communicate a code, text, or coding system and the version of the coding system the code was drawn from and alternate codes drawn from another coding system. Many coded fields in this specification identify coding systems or value set attributes that must be used for the field. When populating the CWE_01 data types with these values, this guide does not give preference to the triplet in which the standard code should appear. The receiver is expected to examine the coding system names in components CWE_01.3 (Name of Coding System) and, if valued, CWE_CR.6 (Name of Alternate Coding System) to determine if it recognizes the coding system or value set.

7.1.2 CWE_02 – CODED WITH EXCEPTIONS; CODE REQUIRED, SECOND TRIPLET OPTIONAL

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

TABLE 7-2. CODED WITH EXCEPTIONS; CODE REQUIRED. SECOND TRIPLET OPTIONAL (CWE_02)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Identifier	ST	R		
2	Text	ST	RE		It is strongly recommended that text be sent to accompany any identifier.
3	Name of Coding System	ID	R	HL70396	
4	Alternate Identifier		O		
5	Alternate Text		O		
6	Name of Alternate Coding System	ID	C(R/X)	HL70396	Condition Predicate: If CWE_02.4 (Alternate Identifier) is valued.
7	Coding System Version ID	ST	C(RE/O)		Condition Predicate: If CWE_02.3 (Name of Coding System) is not an HL7 defined table or user defined.
8	Alternate Coding System Version ID		O		
9	Original Text	ST	RE		Original Text is used to convey the text that was the basis for coding.

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TABLE 7-2. CODED WITH EXCEPTIONS; CODE REQUIRED. SECOND TRIPLET OPTIONAL (CWE_02)					
SEQ	Component Name	DT	Usage	Value Set	Comments
10	Second Alternate Identifier		O		
11	Second Alternate Text		O		
12	Second Name of Alternate Coding System	ID	C(R/O)	HL70396	Condition Predicate: This component is required when CWE_02.10 is populated and CWE_02.20 is not populated. Both CWE_02.6 and CWE_02.17 may be populated.
13	Second Alternate Coding System Version ID		O		
14	Coding System OID	ST	C(R/O)		Condition Predicate: This component is required when CWE_02.1 is populated and CWE_02.3 is not populated. Both CWE_02.3 and CWE_02.14 may be populated. The value for this component is 2.16.840.1.113883.12.#### where "####" is to be replaced by the HL7 table number in the case of an HL7 defined or user defined table. For externally defined code systems the OID registered in the HL7 OID registry SHALL be used.
15	Value Set OID		O		
16	Value Set Version ID	ID	C(R/O)		Condition Predicate: This component is required if CWE_02.15 is populated.
17	Alternate Coding System OID	ST	C(R/))		Condition Predicate: This component is required when CWE_02.4 is populated and CWE_02.6 is not populated. Both CWE_02.6 and CWE_02.17 may be populated. The value for this component is 2.16.840.1.113883.12.#### where "####" is to be replaced by the HL7 table number in the case of an HL7 defined or user defined table. For externally defined code systems the OID registered in the HL7 OID registry SHALL be used.
18	Alternate Value Set OID		O		
19	Alternate Value Set Version ID	ID	C(R/O)		Condition Predicate: Value set version ID is required if CWE_02.18 is populated.
20	Second Alternate Coding System OID	ST	C(O/X)		Condition Predicate: This component is optional when CWE_02.17 is valued, and cannot be valued if CWE_02.17 is empty. The value for this component is 2.16.840.1.113883.12.#### where "####" is to be replaced by the HL7 table number in the case of an HL7 defined or user defined table. For externally defined value sets, the OID registered in the HL7 OID registry SHALL be used.

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TABLE 7-2. CODED WITH EXCEPTIONS; CODE REQUIRED. SECOND TRIPLET OPTIONAL (CWE_02)					
SEQ	Component Name	DT	Usage	Value Set	Comments
21	Second Alternate Value Set OID		O		
22	Second Alternate Value Set Version ID	ID	C(R/O)		Condition Predicate: This component is required when CWE_02.10 is populated and CWE_02.12 is not populated. Both CWE_02.12 and CWE_02.20 may be populated. The value for this component is 2.16.840.1.113883.12.#### where "####" is to be replaced by the HL7 table number in the case of an HL7 defined or user defined table. For externally defined value sets, the OID registered in the HL7 OID registry SHALL be used.

Usage Note

The CWE_02 data type is used where it is necessary to communicate a code, text, or coding system and the version of the coding system the code was drawn from. Many coded fields in this specification identify coding systems or value set attributes that must be used for the field. When populating the CWE_02 data types with these values, this guide does not give preference to the triplet in which the standard code should appear. The receiver is expected to examine the coding system names in components CWE_02.3 (Name of Coding System) and, if valued, CWE_02.6 (Name of Alternate Coding System) to determine if it recognizes the coding system or value set.

7.1.3 CWE_03 – CODED WITH EXCEPTIONS; CODE REQUIRED BUT MAY BE EMPTY

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

TABLE 7-3. CODED WITH EXCEPTIONS; CODE REQUIRED BUT MAY BE EMPTY (CWE_03)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Identifier	ST	RE		
2	Text	ST	C(RE/X)		Condition Predicate: If CWE_03.1 (Identifier) is valued. It is strongly recommended that text be sent to accompany any identifier. When a coded value is not known, the original text element (CWE_03.9) is used to carry the text, not the text (CWE_03.2) element.
3	Name of Coding System	ID	C(R/X)	HL70396	Condition Predicate: If CWE_03.1 (Identifier) is valued.
4	Alternate Identifier	ST	C(RE/X)		Condition Predicate: If CWE_03.1 (Identifier) is valued. The alternate identifier (from the alternate coding system) should be the closest match for the identifier found in CWE_03.1 (Identifier).
5	Alternate Text	ST	C(RE/X)		Condition Predicate: If CWE_03.4 (Alternate Identifier) is valued. It is strongly recommended that alternate text be sent to accompany any alternate identifier.

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TABLE 7-3. CODED WITH EXCEPTIONS; CODE REQUIRED BUT MAY BE EMPTY (CWE_03)					
SEQ	Component Name	DT	Usage	Value Set	Comments
6	Name of Alternate Coding System	ID	C(R/X)	HL70396	Condition Predicate: If CWE_03.4 (Alternate Identifier) is valued.
7	Coding System Version ID	ST	C(RE/O)		Condition Predicate: If CWE_03.3 (Name of Coding System) is not an HL7 defined table or user defined.
8	Alternate Coding System Version ID		O		
9	Original Text	ST	C(R/RE)		Condition Predicate: If CWE_03.1 (Identifier) and CWE_03.4 (Alternate Identifier) are not valued. Original Text is used to convey the text that was the basis for coding. If neither the first or second triplet has values, this contains the text of the field.
10	Second Alternate Identifier		O		
11	Second Alternate Text		O		
12	Second Name of Alternate Coding System	ID	C(R/O)	HL70396	Condition Predicate: This component is required when CWE_03.10 is populated and CWE_03.20 is not populated. Both CWE_03.6 and CWE_03.17 may be populated.
13	Second Alternate Coding System Version ID		O		
14	Coding System OID	ST	C(R/O)		Condition Predicate: This component is required when CWE_03.1 is populated and CWE_03.3 is not populated. Both CWE_03.3 and CWE_03.14 may be populated. The value for this component is 2.16.840.1.113883.12.#### where "####" is to be replaced by the HL7 table number in the case of an HL7 defined or user defined table. For externally defined code systems the OID registered in the HL7 OID registry SHALL be used.
15	Value Set OID		O		
16	Value Set Version ID	ID	C(R/O)		Condition Predicate: This component is required if CWE_03.15 is populated.
17	Alternate Coding System OID	ST	C(R/))		Condition Predicate: This component is required when CWE_03.4 is populated and CWE_03.6 is not populated. Both CWE_03.6 and CWE_03.17 may be populated. The value for this component is 2.16.840.1.113883.12.#### where "####" is to be replaced by the HL7 table number in the case of an HL7 defined or user defined table. For externally defined code systems the OID registered in the HL7 OID registry SHALL be used.
18	Alternate Value Set OID		O		
19	Alternate Value Set Version ID	ID	C(R/O)		Condition Predicate: Value set version ID is required if CWE_03.18 is populated.

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TABLE 7-3. CODED WITH EXCEPTIONS; CODE REQUIRED BUT MAY BE EMPTY (CWE_03)					
SEQ	Component Name	DT	Usage	Value Set	Comments
20	Second Alternate Coding System OID	ST	C(O/X)		Condition Predicate: This component is optional when CWE_03.17 is valued, and cannot be valued if CWE_03.17 is empty. The value for this component is 2.16.840.1.113883.12.#### where "####" is to be replaced by the HL7 table number in the case of an HL7 defined or user defined table. For externally defined value sets, the OID registered in the HL7 OID registry SHALL be used.
21	Second Alternate Value Set OID		O		
22	Second Alternate Value Set Version ID	ID	C(R/O)		Condition Predicate: This component is required when CWE_03.10 is populated and CWE_03.12 is not populated. Both CWE_03.12 and CWE_03.20 may be populated. The value for this component is 2.16.840.1.113883.12.#### where "####" is to be replaced by the HL7 table number in the case of an HL7 defined or user defined table. For externally defined value sets, the OID registered in the HL7 OID registry SHALL be used.

Usage Note

The CWE_03 data type is used where it is necessary to communicate a code, text, or coding system and the version of the coding system the code was drawn from and alternate codes drawn from another coding system. Many coded fields in this specification identify coding systems or value set attributes that must be used for the field. When populating the CWE_03 data types with these values, this guide does not give preference to the triplet in which the standard code should appear. The receiver is expected to examine the coding system names in components CWE_03.3 (Name of Coding System) and, if valued, CWE_03.6 (Name of Alternate Coding System) to determine if it recognizes the coding system or value set.

7.1.4 CWE_04 – CODED WITH EXCEPTIONS; CODE REQUIRED BUT MAY BE EMPTY, SECOND TRIPLET OPTIONAL

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

TABLE 7-4. CODED WITH EXCEPTIONS; CODE REQUIRED BUT MAY BE EMPTY, SECOND TRIPLET OPTIONAL (CWE_04)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Identifier	ST	RE		
2	Text	ST	C(RE/X)		Condition Predicate: If CWE_04.1 (Identifier) is valued. It is strongly recommended that text be sent to accompany any identifier. When a coded value is not known, CWE_04.9 (Original Text Element) is used to carry the text, not CWE_04.2 (Text) element.

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TABLE 7-4. CODED WITH EXCEPTIONS; CODE REQUIRED BUT MAY BE EMPTY, SECOND TRIPLET OPTIONAL (CWE_04)					
SEQ	Component Name	DT	Usage	Value Set	Comments
3	Name of Coding System	ID	C(R/X)	HL70396	Condition Predicate: If CWE_04.1 (Identifier) is valued.
4	Alternate Identifier		O		
5	Alternate Text	ST	C(RE/X)		Condition Predicate: If CWE_04.4 (Alternate Identifier) is valued. It is strongly recommended that alternate text be sent to accompany any alternate identifier.
6	Name of Alternate Coding System	ID	C(R/X)	HL70396	Condition Predicate: If CWE_04.4 (Alternate Identifier) is valued.
7	Coding System Version ID	ST	C(RE/O)		Condition Predicate: If CWE_04.3 (Name of Coding System) is not an HL7 defined table or user defined.
8	Alternate Coding System Version ID		O		
9	Original Text	ST	C(R/RE)		Condition Predicate: If CWE_04.1 (Identifier) and CWE_04.4 (Alternate Identifier) are not valued. Original Text is used to convey the text that was the basis for coding. If neither the first or second triplet has values, this contains the text of the field.
10	Second Alternate Identifier		O		
11	Second Alternate Text		O		
12	Second Name of Alternate Coding System	ID	C(R/O)	HL70396	Condition Predicate: This component is required when CWE_04.10 is populated and CWE_04.20 is not populated. Both CWE_04.6 and CWE_04.17 may be populated.
13	Second Alternate Coding System Version ID		O		
14	Coding System OID	ST	C(R/O)		Condition Predicate: This component is required when CWE_04.1 is populated and CWE_04.3 is not populated. Both CWE_04.3 and CWE_04.14 may be populated. The value for this component is 2.16.840.1.113883.12.#### where "####" is to be replaced by the HL7 table number in the case of an HL7 defined or user defined table. For externally defined code systems the OID registered in the HL7 OID registry SHALL be used.
15	Value Set OID		O		
16	Value Set Version ID	ID	C(R/O)		Condition Predicate: This component is required if CWE_04.15 is populated.

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TABLE 7-4. CODED WITH EXCEPTIONS; CODE REQUIRED BUT MAY BE EMPTY, SECOND TRIPLET OPTIONAL (CWE_04)					
SEQ	Component Name	DT	Usage	Value Set	Comments
17	Alternate Coding System OID	ST	C(R/)		Condition Predicate: This component is required when CWE_04.4 is populated and CWE_04.6 is not populated. Both CWE_04.6 and CWE_04.17 may be populated. The value for this component is 2.16.840.1.113883.12.#### where "####" is to be replaced by the HL7 table number in the case of an HL7 defined or user defined table. For externally defined code systems the OID registered in the HL7 OID registry SHALL be used.
18	Alternate Value Set OID		O		
19	Alternate Value Set Version ID	ID	C(R/O)		Condition Predicate: Value set version ID is required if CWE_04.18 is populated.
20	Second Alternate Coding System OID	ST	C(O/X)		Condition Predicate: This component is optional when CWE_04.17 is valued, and cannot be valued if CWE_04.17 is empty. The value for this component is 2.16.840.1.113883.12.#### where "####" is to be replaced by the HL7 table number in the case of an HL7 defined or user defined table. For externally defined value sets, the OID registered in the HL7 OID registry SHALL be used.
21	Second Alternate Value Set OID		O		
22	Second Alternate Value Set Version ID	ID	C(R/O)		Condition Predicate: This component is required when CWE_04.10 is populated and CWE_04.12 is not populated. Both CWE_04.12 and CWE_04.20 may be populated. The value for this component is 2.16.840.1.113883.12.#### where "####" is to be replaced by the HL7 table number in the case of an HL7 defined or user defined table. For externally defined value sets, the OID registered in the HL7 OID registry SHALL be used.

Usage Note

The CWE_04 data type is used where it is necessary to communicate a code, text, or coding system and the version of the coding system the code was drawn. Many coded fields in this specification identify coding systems or value set attributes that must be used for the field. When populating the CWE_04 data types with these values, this guide does not give preference to the triplet in which the standard code should appear. The receiver is expected to examine the coding system names in components CWE_04.3 (Name of Coding System) and, if valued, CWE_04.6 (Name of Alternate Coding System) to determine if it recognizes the coding system or value set.

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7.2 CX – Extended Composite ID with Check Digit

7.2.1 CX_01 – EXTENDED COMPOSITE ID WITH CHECK DIGIT (GLOBALLY UNIQUE)

TABLE 7-5. EXTENDED COMPOSITE ID WITH CHECK DIGIT (CX_01)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	ID Number	ST	R		
2	Check Digit		O		
3	Check Digit Scheme		O		
4	Assigning Authority	HD_01	R		The Assigning Authority component is used to identify the system, application, organization, etc. that assigned the value in CX_01.1 (ID Number).
5	Identifier Type Code	ID	R	HL70203_USL	
6	Assigning Facility		O		
7	Effective Date		O		
8	Expiration Date		O		
9	Assigning Jurisdiction		O		
10	Assigning Agency or Department		O		

Usage Note

The CX_01 data type is used to carry identifiers. The GU profile requires that assigning authorities accompany all identifiers 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 in this Implementation Guide, it is not a part of the actual identifier. Rather, it is metadata about the identifier. The ID Number and Assigning Authority component, together, constitute the actual identifier. The Assigning Authority represents the identifier's name space, e.g., Healthy Hospital Medical Record Numbers, or Healthy Hospital Order Numbers. Consequently, the Identifier Type Code is technically not necessary. However, due to various naming practices, organizational mergers, and other challenges, it is not always clear through the Assigning Authority OID what identifier type is being indicated by the identifier name space (note that it is highly recommended that this detail be associated with the OID in the registry metadata about the OID). Therefore, to maintain forward compatibility with V3, while recognizing the current practical challenges with understanding the identifier type/namespace at hand, this guide opted to keep the Identifier Type Code component as required.

7.2.2 CX_02 – EXTENDED COMPOSITE ID WITH CHECK DIGIT (NON-GLOBALLY UNIQUE)

TABLE 7-6. EXTENDED COMPOSITE ID WITH CHECK DIGIT (CX_02)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	ID Number	ST	R		

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TABLE 7-6. EXTENDED COMPOSITE ID WITH CHECK DIGIT (CX_02)					
SEQ	Component Name	DT	Usage	Value Set	Comments
2	Check Digit	ST	O		
3	Check Digit Scheme		O		
4	Assigning Authority	HD_02	RE		
5	Identifier Type Code	ID	R	HL70203_USL	
6	Assigning Facility		O		
7	Effective Date		O		
8	Expiration Date		O		
9	Assigning Jurisdiction		O		
10	Assigning Agency or Department		O		

Usage Note

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

Although the Identifier Type Code component is required in this Implementation Guide, it is not a part of the actual identifier. Rather, it is metadata about the identifier. The ID Number and Assigning Authority component, together, constitute the actual identifier. The Assigning Authority represents the identifier's name space, e.g., Healthy Hospital Medical Record Numbers, or Healthy Hospital Order Numbers. Consequently, the Identifier Type Code is technically not necessary. However, due to various naming practices, organizational mergers, and other challenges, it is not always clear through the Assigning Authority OID what identifier type is being indicated by the identifier name space (note that it is highly recommended that this detail be associated with the OID in the registry metadata about the OID). Therefore, to maintain forward compatibility with V3, while recognizing the current practical challenges with understanding the identifier type/namespace at hand, this guide opted to keep the Identifier Type Code component as required.

7.3 DR – Date/Time Range

7.3.1 DR_02 – DATE/TIME RANGE 2

TABLE 7-7. DATE/TIME RANGE 2 (DR_02)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Range Start Date/Time	TS_06	R		
2	Range End Date/Time	TS_06	RE		

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7.3.2 DR_03 – DATE/TIME RANGE 3; TIME ZONE OFFSET REQUIRED BUT MAY BE EMPTY

TABLE 7-8. DATE/TIME RANGE 3; TIME ZONE OFFSET REQUIRED BUT MAY BE EMPTY (DR_03)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Range Start Date/Time	TS_07	R		
2	Range End Date/Time	TS_07	RE		

7.4 DTM – Date/Time

It is strongly recommended that the time zone offset always be included in the DTM particularly if the precision includes hours, minutes, seconds, etc. Specific fields in this Implementation Guide may require Date/Time to a specific level of precision, which may require the time zone offset.
For precision only to year, the base DTM is used and is not represented in this document.

7.4.1 DTM_01 – DATE/TIME 1: PRECISE TO YEAR, POTENTIALLY TO DAY

TABLE 7-9. DATE/TIME 1: PRECISE TO YEAR, POTENTIALLY TO DAY (DTM_01)

SEQ	Component Name	DT	Usage	Value Set	Comments
	YYYY		R		
	MM		RE		
	DD		RE		
	HH		O		
	MM		O		
	[SS[.S[S[S[S]]]]]		O		
	+/- ZZZZ		O		

7.4.2 DTM_02 – DATE/TIME 2: PRECISE TO YEAR, POTENTIALLY TO THE MINUTE

TABLE 7-10. DATE/TIME 2: PRECISE TO YEAR, POTENTIALLY TO MINUTE (DTM_02)

SEQ	Component Name	DT	Usage	Value Set	Comments
	YYYY		R		
	MM		RE		
	DD		RE		
	HH		RE		
	MM		RE		
	[SS[.S[S[S[S]]]]]		O		
	+/- ZZZZ		O		

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7.4.3 DTM_03 – DATE/TIME 3: PRECISE TO THE YEAR, POTENTIALLY TO THE MINUTE, TIME ZONE OFFSET REQUIRED

Used when the Lab_TO_Component is invoked.

TABLE 7-11. DATE/TIME 3: PRECISE TO THE YEAR, POTENTIALLY TO THE MINUTE, TIME ZONE OFFSET REQUIRED (DTM_03)

SEQ	Component Name	DT	Usage	Value Set	Comments
	YYYY		R		
	MM		RE		
	DD		RE		
	HH		RE		
	MM		RE		
	[SS[.S[S[S[S]]]]]		O		
	+/- ZZZZ		C(R/X)		Condition Predicate: If 'HH' is valued.

7.4.4 DTM_05 – DATE/TIME 5: PRECISE TO DAY

TABLE 7-12. DATE/TIME 4: PRECISE TO DAY (DTM_05)

SEQ	Component Name	DT	Usage	Value Set	Comments
	YYYY		R		
	MM		R		
	DD		R		
	HH		O		
	MM		O		
	SS		O		
	[.S[S[S[S]]]]		O		
	+/- ZZZZ		O		

7.4.5 DTM_06 – DATE/TIME 6: PRECISE TO DAY, POTENTIALLY TO MINUTE

TABLE 7-13. DATE/TIME 6: PRECISE TO DAY, POTENTIALLY TO MINUTE (DTM_06)

SEQ	Component Name	DT	Usage	Value Set	Comments
	YYYY		R		
	MM		R		
	DD		R		
	HH		RE		
	MM		RE		
	[SS[.S[S[S[S]]]]]		O		
	+/- ZZZZ		O		

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7.4.6 DTM_07 – DATE/TIME 7: PRECISE TO DAY, POTENTIALLY TO MINUTE; TIME ZONE OFFSET REQUIRED BUT MAY BE EMPTY

Used when the Lab_TO_Component is invoked.

TABLE 7-14. DATE/TIME 7: PRECISE TO DAY, POTENTIALLY TO MINUTE; TIME ZONE OFFSET REQUIRED BUT MAY BE EMPTY (DTM_07)

SEQ	Component Name	DT	Usage	Value Set	Comments
	YYYY		R		
	MM		R		
	DD		R		
	HH		RE		
	MM		RE		
	[SS[.S[S[S[S]]]]]		O		
	+/- ZZZZ		C(R/X)		Condition Predicate: If 'HH' is valued.

7.4.7 DTM_10 – DATE/TIME 10: PRECISE TO SECOND

TABLE 7-15. DATE/TIME 10: PRECISE TO SECOND (DTM_10)

SEQ	Component Name	DT	Usage	Value Set	Comments
	YYYY		R		
	MM		R		
	DD		R		
	HH		R		
	MM		R		
	SS		R		
	[.S[S[S[S]]]]		O		
	+/- ZZZZ		O		

7.4.8 DTM_11 – DATE/TIME 11: PRECISE TO THE SECOND; TIME ZONE OFFSET REQUIRED

Used when the Lab_TO_Component is invoked.

TABLE 7-16. DATE/TIME 11: PRECISE TO THE SECOND; TIME ZONE OFFSET REQUIRED (DTM_11)

SEQ	Component Name	DT	Usage	Value Set	Comments
	YYYY		R		
	MM		R		
	DD		R		
	HH		R		
	MM		R		
	SS		R		
	[.S[S[S[S]]]]		O		
	+/- ZZZZ		R		

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7.4.9 DTM_12 – DATE/TIME 12: UNKNOWN DATE/TIME IN REQUIRED FIELD, IF YEAR AVAILABLE, MUST BE PRECISE TO DAY, POTENTIALLY TO MINUTES

TABLE 7-17. DATE/TIME 12: UNKNOWN DATE/TIME IN REQUIRED FIELD, IF YEAR AVAILABLE, MUST BE PRECISE TO DAY, POTENTIALLY TO MINUTES (DTM_12)

SEQ	Component Name	DT	Usage	Value Set	Comments
	YYYY	DTM	R		
	MM	DTM	C(R/X)		Condition Predicate: If DTM_12.1 (YYYY) is not valued '0000'.
	DD	DTM	C(R/X)		Condition Predicate: If DTM_12.1 (YYYY) is not valued '0000'.
	HH	DTM	C(RE/X)		Condition Predicate: If DTM_12.1 (YYYY) is not valued '0000'.
	MM	DTM	C(RE/X)		Condition Predicate: If DTM_12.1 (YYYY) is not valued '0000'.
	[SS[.S[S[S]]]]]	DTM	C(O/X)		Condition Predicate: If DTM_12.1 (YYYY) is not valued '0000'.
	+/- ZZZZ	DTM	O		

Usage Note

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

7.4.10 DTM_13 – DATE/TIME 13: UNKNOWN DATE/TIME IN REQUIRED FIELD, IF YEAR AVAILABLE, MUST BE PRECISE TO DAY, POTENTIALLY TO MINUTES; TIME ZONE OFFSET CONDITIONALLY REQUIRED

Used when the Lab_TO_Component is invoked.

TABLE 7-18. DATE/TIME 13: UNKNOWN DATE/TIME IN REQUIRED FIELD, IF YEAR AVAILABLE, MUST BE PRECISE TO DAY, POTENTIALLY TO MINUTES; TIME ZONE CONDITIONALLY OFFSET REQUIRED (DTM_13)

SEQ	Component Name	DT	Usage	Value Set	Comments
	YYYY	DTM	R		
	MM	DTM	C(R/X)		Condition Predicate: If DTM_13.1 (YYYY) is not valued '0000'.
	DD	DTM	C(R/X)		Condition Predicate: If DTM_13.1 (YYYY) is not valued '0000'.
	HH	DTM	C(RE/X)		Condition Predicate: If DTM_13.1 (YYYY) is not valued '0000'.
	MM	DTM	C(RE/X)		Condition Predicate: If DTM_13.1 (YYYY) is not valued '0000'.
	[SS[.S[S[S]]]]]	DTM	C(O/X)		Condition Predicate: If DTM_13.1 (YYYY) is not valued '0000'.
	+/- ZZZZ	DTM	C(R/X)		Condition Predicate when 'HH' is valued.

Usage Note

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

7.5 EI – Entity Identifier

7.5.1 EI_01 – ENTITY IDENTIFIER (GLOBALLY UNIQUE)

TABLE 7-19. ENTITY IDENTIFIER (EI_01)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Entity Identifier	ST	R		
2	Namespace ID	IS	RE		

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TABLE 7-19. ENTITY IDENTIFIER (EI_01)					
SEQ	Component Name	DT	Usage	Value Set	Comments
3	Universal ID	ST	R		
4	Universal ID Type	ID	R		Fixed to 'ISO'.

Usage Note

The EI_01 data type is used to carry identifiers. This GU profile 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 Statements: LOI_GU_Component

LOI-1: EI_01.3 (Universal ID) **SHALL** be valued with an ISO-compliant OID.

LOI-2: EI_01.4 (Universal ID Type) **SHALL** contain the value 'ISO' drawn from code system HL70301.

7.5.2 EI_02 – ENTITY IDENTIFIER (NON-GLOBALLY UNIQUE)

TABLE 7-20. ENTITY IDENTIFIER (EI_02)					
SEQ	Component N...	DT	Usage	Value Set	Comments
1	Entity Identifier	ST	R		
2	Namespace ID	IS	C(R/O)		Condition Predicate: If EI_02.3 (Universal ID) is not valued.
3	Universal ID	ST	C(R/O)		Condition Predicate: If EI_02.2 (Namespace ID) is not valued.
4	Universal ID Type	ID	C(R/X)	HL70301_USL	Condition Predicate: If EI_02.3 (Universal ID) is valued.

Usage Note

The EI_02 data type accommodates identifiers that are not globally unique and therefore may not have the assigning authority (components 3-4) populated. Local arrangements determine how uniqueness is established.

In fields like ORC-2/OBR-2 (Placer Order Number) or ORC-3/OBR-3 (Filler Order Number) the assigning authority of the identifier may be a facility, which in the case of a laboratory often has a CLIA number assigned.

Example

```
TEST000123A^^01D1111111^CLIA
```


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7.6 EIP – Entity Identifier Pair

7.6.1 EIP_01 – ENTITY IDENTIFIER PAIR (GLOBALLY UNIQUE)

TABLE 7-21. ENTITY IDENTIFIER PAIR (EIP_01)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Placer Assigned Identifier	EI_01	RE		
2	Filler Assigned Identifier	EI_01	C(R/RE)		Condition Predicate: If EIP_01.1 (Placer Assigned Identifier) is not valued.

7.6.2 EIP_02 – ENTITY IDENTIFIER PAIR (NON-GLOBALLY UNIQUE)

TABLE 7-22. ENTITY IDENTIFIER PAIR (EIP_02)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Placer Assigned Identifier	EI_02	RE		
2	Filler Assigned Identifier	EI_02	C(R/RE)		Condition Predicate: If EIP_02.1 (Placer Assigned Identifier) is not valued.

7.7 ERL_01– Error Location

TABLE 7-23. ERROR LOCATION (ERL_01)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Segment ID	ST	R		
2	Segment Sequence	NM	R		Absolute position of this segment in the message (e.g. 5th OBX, regardless of the number of intervening OBRs)
3	Field Position	NM	RE		
4	Field Repetition	NM	RE		
5	Component Number	NM	RE		
6	Sub-Component Number	NM	RE		

7.8 FN _ 01 – Family Name; Surname Required

TABLE 7-24. FAMILY NAME (FN_01)

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

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7.9 HD – Hierarchic Designator

7.9.1 HD_01 – HIERARCHIC DESIGNATOR (GLOBALLY UNIQUE)

TABLE 7-25. HIERARCHIC DESIGNATOR (HD_01)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Namespace ID	IS	RE		This value reflects a local code that represents the combination of HD_01.2 (Universal ID) and HD_01.3 (Universal ID Type).
2	Universal ID	ST	R		
3	Universal ID Type	ID	R		Fixed to 'ISO'.

Usage Note

The actual value of and use of HD_01.1 (Namespace ID) and HD_01.2 (Universal ID) must be negotiated between trading partners for each of the fields where this data type is used.

The HD_01 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_01 data type has been constrained to carry an ISO Compliant OID identifying an application, a facility, or an assigning authority.

Conformance Statements: LOI_GU_Component

LOI-3: HD_01.2 (Universal ID) **SHALL** be valued with an ISO-compliant OID.

LOI-4: HD_01.3 (Universal ID Type) **SHALL** contain the value 'ISO' drawn from code system HL70301.

7.9.2 HD_02 – HIERARCHIC DESIGNATOR (NON-GLOBALLY UNIQUE)

TABLE 7-26. HIERARCHIC DESIGNATOR (HD_02)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Namespace ID	IS	C(R/O)		Condition Predicate: If HD_02.2 (Universal ID) is not valued.
2	Universal ID	ST	C(R/O)		Condition Predicate: If HD_02.1 (Namespace ID) is not valued.
3	Universal ID Type	ID	C(R/X)	HL70301_USL	Condition Predicate: If HD_02.2 (Universal ID) is valued.

Usage Note

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

The HD_02-2 (Universal ID) does not have to be an ISO compliant OID, as is the case for the HD_01 data type flavor, it is permissible to use a human readable text string, e.g., full name of the hospital, or other value that both trading partners agree to.

The HD_02 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.

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In fields like MSH-4 (Sending Facility) or MSH-6 (Receiving Facility) these facilities can be identified using a CLIA number in the case of a laboratory.

Example

```
^01D1111111^CLIA or UniversityHospLab^01D1111111^CLIA
```

7.10 JCC_01 – Job Code/Class

TABLE 7-27. JOB CODE/CLASS (JCC_01)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Job Code		O		
2	Job Class		O		
3	Job Description Text	TX	R		

7.11 MSG_01 – Message Type

TABLE 7-28. MESSAGE TYPE (MSG_01)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Message Code	ID	R	HL70076_USL	
2	Trigger Event	ID	R	HL70003_USL	
3	Message Structure	ID	R	HL70354_USL	

7.12 OG_01 – Observation Grouper

TABLE 7-29. OBSERVATION GROUPER (OG_01)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Original Sub-Identifier	ST	O		
2	Group	NM	R		
3	Sequence	NM	R		
4	Identifier	ST	RE		

7.13 PT_01 – Processing Type

TABLE 7-30. PROCESSING TYPE (PT_01)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Processing ID	ID	R	HL70103_USL	
2	Processing Mode		O		

7.14 SAD_01 – Street Address

TABLE 7-31. STREET ADDRESS (SAD_01)

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

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TABLE 7-31. STREET ADDRESS (SAD_01)					
SEQ	Component Name	DT	Usage	Value Set	Comments
3	Dwelling Number		O		

7.15 SN_01 – Structured Numeric

TABLE 7-32. STRUCTURED NUMERIC (SN_01)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Comparator	ST	RE		
2	Num1	NM	R		
3	Separator/Suffix	ST	C(R/O)		Condition Predicate: If SN_01.2 (Num1) and SN_01.4 (Num2) are valued.
4	Num2	NM	RE		

Usage Note

The SN_01 data type carries a structured numeric result value. Structured numeric values include intervals (^0^-^1), ratios (^1^/^2 or ^1^:^2), inequalities (<^10).

7.16 TS – Time Stamp

7.16.1 TS_01 – TIME STAMP 1: PRECISE TO YEAR, POTENTIALLY TO DAY

TABLE 7-33. TIME STAMP 1– PRECISE TO YEAR, POTENTIALLY TO DAY (TS_01)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Time	DTM_01	R		
2	Degree of Precision	ID	X		Excluded for this Implementation Guide, see Section 1.3.1.

7.16.2 TS_02 – TIME STAMP 2: PRECISE TO YEAR, POTENTIALLY TO MINUTE

TABLE 7-34. TIME STAMP 2: PRECISE TO YEAR, POTENTIALLY TO MINUTE (TS_02)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Time	DTM_02	R		
2	Degree of Precision	ID	X		Excluded for this Implementation Guide, see Section 1.3.1..

7.16.3 TS_03 – TIME STAMP 3: PRECISE TO YEAR, POTENTIALLY TO MINUTE, TIME ZONE OFFSET REQUIRED BUT MAY BE EMPTY

TABLE 7-35. TIME STAMP 3: PRECISE TO YEAR, POTENTIALLY TO MINUTE, TIME ZONE OFFSET REQUIRED BUT MAY BE EMPTY (TS_03)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Time	DTM_03	R		
2	Degree of Precision	ID	X		Excluded for this Implementation Guide, see Section 1.3.1.

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7.16.4 TS_06 – TIME STAMP 6: PRECISE TO DAY, POTENTIALLY TO MINUTE

TABLE 7-36. TIME STAMP 6: PRECISE TO DAY, POTENTIALLY TO MINUTE (TS_06)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Time	DTM_06	R		
2	Degree of Precision	ID	X		Excluded for this Implementation Guide, see Section 1.3.1.

7.16.5 TS_07 – TIME STAMP 7: PRECISE TO DAY, POTENTIALLY TO MINUTE; TIME ZONE OFFSET REQUIRED BUT MAY BE EMPTY

TABLE 7-37. TIME STAMP 7: PRECISE TO DAY, POTENTIALLY TO MINUTE; TIME ZONE OFFSET REQUIRED BUT MAY BE EMPTY (TS_07)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Time	DTM_07	R		
2	Degree of Precision	ID	X		Excluded for this Implementation Guide, see Section 1.3.1.

7.16.6 TS_10 – TIME STAMP 10: PRECISE TO SECOND,

TABLE 7-38. TIME STAMP 10: PRECISE TO SECOND (TS_10)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Time	DTM_10	R		
2	Degree of Precision	ID	X		Excluded for this Implementation Guide, see Section 1.3.1.

7.16.7 TS_11 – TIME STAMP 11: PRECISE TO SECOND; TIME ZONE OFFSET REQUIRED

TABLE 7-39. TIME STAMP 11: PRECISE TO SECOND, TIME ZONE OFFSET REQUIRED (TS_11)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Time	DTM_11	R		
2	Degree of Precision	ID	X		Excluded for this Implementation Guide, see Section 1.3.1.

7.16.8 TS_12 – TIME STAMP 12: UNKNOWN DATE/TIME IN REQUIRED FIELD, IF YEAR AVAILABLE, MUST BE PRECISE TO DAY, POTENTIALLY TO MINUTES

TABLE 7-40. TIME STAMP 12: UNKNOWN DATE/TIME IN REQUIRED FIELD, IF YEAR AVAILABLE, MUST BE PRECISE TO DAY, POTENTIALLY TO MINUTES (TS_12)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Time	DTM_12	R		
2	Degree of Precision	ID	X		Excluded for this Implementation Guide, see Section 1.3.1.

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7.16.9 TS_13 – TIME STAMP 13: UNKNOWN DATE/TIME IN REQUIRED FIELD; IF AVAILABLE, PRECISE TO DAY, POTENTIALLY TO MINUTES; TIME ZONE OFFSET CONDITIONALLY REQUIRED

TABLE 7-41. TIME STAMP 13: UNKNOWN DATE/TIME IN REQUIRED FIELD; IF AVAILABLE, PRECISE TO DAY, POTENTIALLY TO MINUTES; TIME ZONE OFFSET CONDITIONALLY REQUIRED (TS_13)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Time	DTM_13	R		
2	Degree of Precision	ID	X		Excluded for this Implementation Guide, see Section 1.3.1.

7.17 VID_01 – Version Identifier

TABLE 7-42. VERSION IDENTIFIER (VID_01)

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

Conformance Statements: LOI_Common_Component

LOI-91: VID_01.1 (Version ID) **SHALL** contain the value '2.5.1' drawn from code system HL70104.

7.18 XAD – Extended Address

7.18.1 XAD_01 – EXTENDED ADDRESS

Note: If all XAD_01 components are blank while the field using XAD_01 is required, Senders and Receivers need to resolve what components should be valued and how, or agree to another process.

TABLE 7-43. EXTENDED ADDRESS (XAD_01)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Street Address	SAD_01	RE		
2	Other Designation	ST	RE		
3	City	ST	RE		
4	State or Province	ST	RE	USPS Alpha State Codes	
5	Zip or Postal Code	ST	RE		.
6	Country Code	ID	RE	HL70399_USL	Use 3-character (alphabetic) form of ISO 3166 for HL7 Table 0399 as defined in HL7 Chapter 2, Section 2.15.9.17.
7	Address Type	ID	RE	HL70190_USL	
8	Other Geographic Designation		O		
9	County/Parish Code		O		
10	Census Tract		O		

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TABLE 7-43. EXTENDED ADDRESS (XAD_01)					
SEQ	Component Name	DT	Usage	Value Set	Comments
11	Address Representation Code		O		
12	Address Validity Range		X		Excluded for this Implementation Guide, see Section 1.3.1.
13	Effective Date		O		
14	Expiration Date		O		

7.18.2 XAD_02 – EXTENDED ADDRESS; STREET ADDRESS, CITY, STATE AND ZIP CODE REQUIRED

TABLE 7-44. EXTENDED ADDRESS (XAD_02)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Street Address	SAD_01	R		
2	Other Designation	ST	RE		
3	City	ST	R		
4	State or Province	ST	R	USPS_USL	
5	Zip or Postal Code	ST	R		.
6	Country Code	ID	RE	HL70399_USL	Use 3-character (alphabetic) form of ISO 3166 for HL7 Table 0399 as defined in HL7 Chapter 2, Section 2.15.9.17.
7	Address Type	ID	RE	HL70190_USL	LRI_NDBS_Component: Default value is 'H'.
8	Other Geographic Designation		O		
9	County/Parish Code	IS	RE	FIPS64_USL	
10	Census Tract		O		
11	Address Representation Code		O		
12	Address Validity Range		X		Excluded for this Implementation Guide, see Section 1.3.1.
13	Effective Date		O		
14	Expiration Date		O		

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7.19 XCN – Extended Composite ID Number and Name for Persons

7.19.1 XCN_01 – EXTENDED COMPOSITE ID NUMBER AND NAME FOR PERSONS (GLOBALLY UNIQUE)

TABLE 7-45. EXTENDED COMPOSITE ID NUMBER AND NAME FOR PERSONS (XCN_01)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	ID Number	ST	RE		The ID Number component combined with XCN_01.9 (Assigning Authority) 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_01	C(R/RE)		Condition Predicate: If XCN_01.1 (ID Number) is not valued.
3	Given Name	ST	RE		I.e., first name.
4	Second and Further Given Names or Initials Thereof		O		
5	Suffix (e.g., JR or III)		O		
6	Prefix (e.g., DR)		O		
7	Degree (e.g., MD)		X		Excluded for this Implementation Guide, see Section 1.3.1.
8	Source Table		C(O/O)		**Note:** This component is (C) in the v2.5.1 standard with no condition predicate defined; none is defined in this IG.
9	Assigning Authority	HD_01	C(R/X)		Condition Predicate: If XCN_01.1 (ID Number) is valued. The Assigning Authority component is used to identify the system, application, organization, etc. that assigned the ID Number in component 1.
10	Name Type Code	ID	RE	HL70200_USL	
11	Identifier Check Digit		O		
12	Check Digit Scheme		C(O/X)		Condition Predicate: If XCN_01.11 is valued.
13	Identifier Type Code	ID	C(R/X)	HL70203_USL	Condition Predicate: If XCN_01.1 (ID Number) is valued.
14	Assigning Facility		O		
15	Name Representation Code		O		
16	Name Context		O		
17	Name Validity Range		X		Excluded for this Implementation Guide, see Section 1.3.1.
18	Name Assembly Order		O		
19	Effective Date		O		
20	Expiration Date		O		
21	Professional Suffix		O		
22	Assigning Jurisdiction		O		
23	Assigning Agency or Department		O		

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7.19.2 XCN_02 – EXTENDED COMPOSITE ID NUMBER AND NAME FOR PERSONS (NON-GLOBALLY UNIQUE)

TABLE 7-46. EXTENDED COMPOSITE ID NUMBER AND NAME FOR PERSONS (XCN_02)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	ID Number	ST	RE		**Note:** Despite the component being named "ID Number" this component is an ST string data type, not numeric, so the component is not limited to just numbers.
2	Family Name	FN_01	C(R/RE)		Condition Predicate: If XCN_02.1 (ID Number) is not valued.
3	Given Name	ST	RE		I.e., first name.
4	Second and Further Given Names or Initials Thereof		O		
5	Suffix (e.g., JR or III)		O		
6	Prefix (e.g., DR)		O		
7	Degree (e.g., MD)		X		Excluded for this Implementation Guide, see Section 1.3.1.
8	Source Table		C(O/O)		**Note:** This component is (C) in the v2.5.1 standard with no condition predicate defined; none is defined in this IG.
9	Assigning Authority	HD_02	C(R/X)		Condition Predicate: If XCN_02.1 (ID Number) is valued. The Assigning Authority component is used to identify the system, application, organization, etc. that assigned the value in XCN_02-1 (ID Number).
10	Name Type Code	ID	RE	HL70200_USL	
11	Identifier Check Digit		O		
12	Check Digit Scheme		C(O/X)		Condition Predicate: If XCN_02.11 (Identifier Check Digit) is valued.
13	Identifier Type Code	ID	C(R/X)	HL70203_USL	Condition Predicate: If XCN_02.1 (ID Number) is valued.
14	Assigning Facility		O		
15	Name Representation Code		O		
16	Name Context		O		
17	Name Validity Range		X		Excluded for this Implementation Guide, see Section 1.3.1.
18	Name Assembly Order		O		
19	Effective Date		O		
20	Expiration Date		O		
21	Professional Suffix		O		
22	Assigning Jurisdiction		O		
23	Assigning Agency or Department		O		

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7.20 XON – Extended Composite Name and Identification Number for Organizations

7.20.1 XON_01 – EXTENDED COMPOSITE NAME AND IDENTIFICATION NUMBER FOR ORGANIZATIONS (GLOBALLY UNIQUE)

TABLE 7-47. EXTENDED COMPOSITE NAME AND IDENTIFICATION NUMBER FOR ORGANIZATIONS (XON_01)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Organization Name	ST	RE		
2	Organization Name Type Code		O		
3	ID Number		X		Excluded for this Implementation Guide, see Section 1.3.1.
4	Check Digit		O		
5	Check Digit Scheme		C(O/X)		Condition Predicate: If XON_01.4 (Check Digit) is valued.
6	Assigning Authority	HD_01	C(R/X)		Condition Predicate: If XON_01.10 (Organization Identifier) is valued. The Assigning Authority component is used to identify the system, application, organization, etc. that assigned the value in XON_01.10 (Organization Identifier).
7	Identifier Type Code	ID	C(R/X)	HL70203_USL	Condition Predicate: If XON_01.10 (Organization Identifier) is valued.
8	Assigning Facility		O		
9	Name Representation Code		O		
10	Organization Identifier	ST	C(R/RE)		Condition Predicate: If XON_01.1 (Organization Name) is not valued.

Usage Note

Both XON_01.1 and XON_01.10 may be populated, but at least one of them must be valued.

7.20.2 XON_02 – EXTENDED COMPOSITE NAME AND IDENTIFICATION NUMBER FOR ORGANIZATIONS (NON-GLOBALLY UNIQUE)

TABLE 7-48. EXTENDED COMPOSITE NAME AND IDENTIFICATION NUMBER FOR ORGANIZATIONS (XON_02)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Organization Name	ST	RE		
2	Organization Name Type Code		O		
3	ID Number		X		Excluded for this Implementation Guide, see Section 1.3.1.

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TABLE 7-48. EXTENDED COMPOSITE NAME AND IDENTIFICATION NUMBER FOR ORGANIZATIONS (XON_02)					
SEQ	Component Name	DT	Usage	Value Set	Comments
4	Check Digit		O		
5	Check Digit Scheme		C(O/X)		Condition Predicate: If XON_02.4 is valued.
6	Assigning Authority	HD_02	C(R/X)		Condition Predicate: If XON_02.10 (Organization Identifier) is valued. The Assigning Authority component is used to identify the system, application, organization, etc. that assigned the value in XON_02.10 (Organization Identifier).
7	Identifier Type Code	ID	C(R/X)	HL70203_USL	Condition Predicate: If XON_02.10 (Organization Identifier) is valued.
8	Assigning Facility		O		
9	Name Representation Code		O		
10	Organization Identifier	ST	C(R/RE)		Condition Predicate: If XON_02.1 (Organization Name) is not valued.

Usage Note

Both XON_02.1 and XON_02.10 may be populated, but at least one of them must be valued.

7.20.3 XON_04 – EXTENDED COMPOSITE NAME AND IDENTIFICATION NUMBER FOR ORGANIZATIONS (NAME ONLY FOR INSURANCE)

TABLE 7-49. EXTENDED COMPOSITE NAME AND IDENTIFICATION NUMBER FOR ORGANIZATIONS (NAME ONLY FOR INSURANCE) (XON_04)					
SEQ	Component Name	DT	Usage	Value	Comments
1	Organization Name	ST	R		
2	Organization Name Type Code		O		
3	ID Number		X		Excluded for this Implementation Guide, see Section 1.3.1.
4	Check Digit		X		Excluded for this Implementation Guide, see Section 1.3.1.
5	Check Digit Scheme		X		Excluded for this Implementation Guide, see Section 1.3.1.
6	Assigning Authority		X		Excluded for this Implementation Guide, see Section 1.3.1.
7	Identifier Type Code		X		Excluded for this Implementation Guide, see Section 1.3.1.
8	Assigning Facility		X		Excluded for this Implementation Guide, see Section 1.3.1.
9	Name Representation Code		X		Excluded for this Implementation Guide, see Section 1.3.1.
10	Organization Identifier		X		Excluded for this Implementation Guide, see Section 1.3.1.

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Usage Note

Data Type XON_04 is a specialization of the XON data type for the IN1 segment, specifically IN1-4 (Insurance Company Name). To avoid the duplication of information that can be messaged in the IN1-3 (Insurance Company ID) in the subcomponent of the data type (CX) that match subcomponents of the IN1-4 data type (XON_01 or XON_02), the XON_04 data type for IN1-4 has been reduced to the XON_04.1 (Organization Name) and XON_04.2 (Organization Name Type Code) components which provide the unique information not provided in any other field's data component.

7.21 XPN – Extended Person Name

7.21.1 XPN_01 – EXTENDED PERSON NAME

TABLE 7-50. EXTENDED PERSON NAME (XPN_01)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Family Name	FN_01	RE		
2	Given Name	ST	RE		I.e., first name.
3	Second and Further Given Names or Initials Thereof	ST	RE		
4	Suffix (e.g., JR or III)	ST	RE		
5	Prefix (e.g., DR)		O		
6	Degree (e.g., MD)		X		Excluded for this Implementation Guide, see Section 1.3.1.
7	Name Type Code	ID	R	HL70200_USL	
8	Name Representation Code		O		
9	Name Context		O		
10	Name Validity Range		X		Excluded for this Implementation Guide, see Section 1.3.1.
11	Name Assembly Order		O		
12	Effective Date		O		
13	Expiration Date		O		
14	Professional Suffix		O		

Usage Note

To convey 'unknown' name type send 'U' in XPN.7, i.e. '^^^^^^U'.

7.21.2 XPN_02 – EXTENDED PERSON NAME

TABLE 7-51. EXTENDED PERSON NAME (XPN_02)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Family Name	FN_01	R		
2	Given Name	ST	C(R/X)		Condition Predicate: If XPN_02.1 (Family Name) is not valued ' "" '. I.e., first name.

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TABLE 7-51. EXTENDED PERSON NAME (XPN_02)					
SEQ	Component Name	DT	Usage	Value Set	Comments
3	Second and Further Given Names or Initials Thereof	ST	RE		
4	Suffix (e.g., JR or III)	ST	RE		
5	Prefix (e.g., DR)		O		
6	Degree (e.g., MD)		X		Excluded for this Implementation Guide, see Section 1.3.1.
7	Name Type Code	ID	C(R/X)	HL70200_USL	Condition Predicate: If XPN_02.1 (Family Name) is not valued ' "" '.
8	Name Representation Code		O		
9	Name Context		O		
10	Name Validity Range		X		Excluded for this Implementation Guide, see Section 1.3.1.
11	Name Assembly Order		O		
12	Effective Date		O		
13	Expiration Date		O		
14	Professional Suffix		O		

Usage Note

Note that XPN_02 was developed for situations where the name cannot be unknown, therefore the value of XPN_02.7 (Name Type Code) disallows the use of the 'U' (Unknown) code value.

Conformance Statement: LOI Common Component

LOI-6: XPN_02.7 (Name Type Code) **SHALL NOT** be valued 'U'.

7.21.3 XPN_03 – EXTENDED PERSON NAME; FAMILY NAME REQUIRED, OTHERS REQUIRED BUT MAY BE EMPTY, NAME TYPE CODE REQUIRED BUT MAY BE EMPTY

TABLE 7-52. EXTENDED PERSON NAME EXTENDED PERSON NAME; FAMILY NAME REQUIRED, OTHERS REQUIRED BUT MAY BE EMPTY, NAME TYPE CODE REQUIRED BUT MAY BE EMPTY (XPN_03)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Family Name	FN_01	R		
2	Given Name	ST	RE		I.e., first name.
3	Second and Further Given Names or Initials Thereof	ST	RE		
4	Suffix (e.g., JR or III)	ST	RE		
5	Prefix (e.g., DR)		O		
6	Degree (e.g., MD)		X		Excluded for this Implementation Guide, see Section 1.3.
7	Name Type Code	ID	RE	HL70200_USL	
8	Name Representation Code		O		

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TABLE 7-52. EXTENDED PERSON NAME EXTENDED PERSON NAME; FAMILY NAME REQUIRED, OTHERS REQUIRED BUT MAY BE EMPTY, NAME TYPE CODE REQUIRED BUT MAY BE EMPTY (XPN_03)					
SEQ	Component Name	DT	Usage	Value Set	Comments
9	Name Context		O		
10	Name Validity Range		X		Excluded for this Implementation Guide, see Section 1.3.
11	Name Assembly Order		O		
12	Effective Date		O		
13	Expiration Date		O		
14	Professional Suffix		O		

7.22 XTN_01 – Extended Telecommunication Number

7.22.1 XTN_01 – EXTENDED TELECOMMUNICATION NUMBER – ALLOWS EMAIL

TABLE 7-53. EXTENDED TELECOMMUNICATION NUMBER (XTN_01)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Telephone Number		X		Excluded for this Implementation Guide, see Section 1.3.1.
2	Telecommunication Use Code		O		
3	Telecommunication Equipment Type	ID	R	HL70202_USL	
4	Email Address	ST	C(R/X)		Condition Predicate: If XTN_01.3 (Telecommunication Equipment Type) is valued ‘X.400’ or ‘Internet’.
5	Country Code		O		
6	Area/City Code	NM	C(R/X)		Condition Predicate: If XTN_01.3 (Telecommunication Equipment Type) is valued ‘PH’, ‘CP’, ‘FX’, or ‘TDD’.
7	Local Number	NM	C(R/X)		Condition Predicate: If XTN_01.3 (Telecommunication Equipment Type) is valued ‘PH’, ‘CP’, ‘FX’, or ‘TDD’.
8	Extension	NM	C(RE/X)		Condition Predicate: If XTN_01.3 (Telecommunication Equipment Type) is valued ‘PH’, ‘CP’, ‘FX’, or ‘TDD’.
9	Any Text		RE		
10	Extension Prefix		O		
11	Speed Dial Code		O		
12	Unformatted Telephone number		C(O/X)		Condition Predicate: If XTN_01.3 (Telecommunication Equipment Type) is valued ‘PH’, ‘CP’, ‘FX’, or ‘TDD’.

Usage Note

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

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LOI_NDBS_Component

The use code in XTN_01.3 is expected to be 'PH' in most cases and implementation guides can constrain the vocabulary to that value, if desired.

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8 CODE SYSTEMS

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 0001), or a locally defined identifier. In general, the coded values allowed in a field (a) may be drawn from more than one code system, and (b) may be a subset of the codes from a given coding system. Combining (a) and (b) makes it possible for the allowed coded value to be a combination of multiple subsets drawn from multiple coding systems. In most cases, only subsets of the codes defined in a code system are allowed for use in a particular message.

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

The data type and segment tables in previous sections identify the value set or coding system used for each supported component or 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 may have 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.

When extending an open value set by adding new codes to it, the code system chosen for the new code(s) is based upon the following rules:

> HL7 Table 0396 defines the standard coding systems recognized by HL7. Any code/coding system not defined in HL7 Table 0396 is considered a “local” coding system from the HL7 perspective and identified with an ‘L’ or the use of ‘99zzz’ where ‘zzz’ is an alphanumeric multi-character string identifying the specific non-standard coding system. Therefore, if the new code belongs to a code system defined in HL7 Table 0396, use that code system, otherwise use either ‘L’ or ‘99zzz’.
>
> Other than those code systems specified in the value sets associated with this Implementation Guide, all other code systems in HL7 Table 0396 are considered to be ‘P’ (Permitted), see http://www.hl7.org/special/committees/vocab/table_0396/index.cfm.

8.1 LOINC

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

LOINC shall be used as the standard coding system for this field if an appropriate LOINC code exists, i.e., the LOINC concept accurately represents the order or observation. The status of the LOINC code, as defined in the LOINC Users' Guide Section 11.2

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'Classification of LOINC Term Status', should also be taken into consideration. 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.

The laboratory's local test code and coding system shall be sent to identify the order and the test name. In addition, LOINC shall be used as the standard vocabulary to identify the ordered test in the Universal Service Identifier (OBR-4) when an applicable LOINC code is available and identified by the laboratory. If an appropriate orderable LOINC code is provided by the laboratory (e.g. in its electronic Directory of Service/Test Compendium [eDOS]), it SHOULD be sent along with a LOINC test description as defined in the published LOINC specification. When no valid orderable LOINC code exists, the local code may be the only code sent.

Notes:

1. The LOINC Common Laboratory Orders Value Set is available and can be used as a 'starter set' for mapping commonly used laboratory orders. It does not attempt to include all possible laboratory order codes. For additional information on LOINC Common Laboratory Orders Value Set, refer to www.loinc.org/usage/orders.
2. The sender shall always populate the first triplet before populating other triplets; the receiver shall examine all triplets to find relevant values. A triplet consists of three components: the code, the text description of the code and the code system name. When populating the 3rd component to indicate the laboratory's local test order code, the name of the coding system SHOULD be formatted "99zzz", where zzz is replaced by an alphanumeric character sequence that identifies the lab. The use of "L" is also allowed. If a LOINC code is sent as an identifier, the name of the coding system shall be "LN".
3. Universal Service Identifier is a required field in the OBR segment. However, the values transmitted by the order placer in this field for an **order** message may or may not be the same values placed in this field of a generated **result** message created by an order filler.

Examples

An order for a basic metabolic panel test consisting of both the laboratory's local order code and the corresponding LOINC order code

```
|BMP^Basic Metabolic Panel^99LAB^24321-2^Bas Metab 2000 Pnl
  SerP^LN^20120731^2.40|
```

An order for a new cancer antigen blood test using only the laboratory's local order code where LOINC is not yet available.

```
|CAnnn^CA-nnn^99LAB^^^^20120731|
```

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

8.2 SNOMED CT

SNOMED CT (Systematized NOmenclature of MEDicine Clinical Terms) is a recommended vocabulary as specified throughout this guide, e.g., for specimen source terms in SPM-4 (Specimen type) when a SNOMED CT code is available. 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.

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

Support for SNOMED CT shall include the code and the description text as described by IHTSDO.

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

8.3 UCUM

Use of UCUM (Unified Code for Units of Measure) is recommended as one of the delivered units (could be in addition to the local units). For dimensionless units the UCUM representation "{any string}" can be used, e.g., for a titer the UCUM representation is "{titer}^titer^UCUM". For ratios, in the units of measure, when the numerator UOM cancels the denominator UOM, may use {ratio}. To communicate that an analyte has "No units", OBX-6 should be empty.

A table of commonly used example UCUM units for electronic messaging is available here: http://loinc.org/downloads/usage/units. Further information on UCUM can be found at: http://unitsofmeasure.org/

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9 LABORATORY ORDER MESSAGE DEVELOPMENT RESOURCES

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

The National Institute of Standards and Technology (NIST) has established a website (NIST HL7 V2 Resource Portal) to support the HIT developer community. The site has a number of tools and related materials to assist implementers with the development and testing of software in preparation for ONC Certification.

To support the Laboratory Messaging community, a repository has been established to function as a dynamic library of V2.x.x example messages, technical corrections, and other materials with the intent of providing continuous growth of resources without being time bound to future publications of this guide.

The repository is available at http://hl7v2-loi-r2-testing.nist.gov.

9.1 Cardinality Testing

As part of testing message elements with unlimited cardinality, minimum testing limits have been established and are defined in a spreadsheet that will be accessible on the National Institute of Standards and Technologies HIT test support site; see the file "CardinalitySegmentFieldManagement Vxx.xlsx" at http://hl7v2-loi-r2-testing.nist.gov. Note that the version of the spreadsheet may change as technical corrections are applied; the version that was approved as of the date of this publication is V23.

Depending on the element, a failure to consume all repeats can result in either a hard or a soft error; the error type is also indicated in the spreadsheet. The error(s) must be communicated to the sender using the application acknowledgement.

A system that passes cardinality testing limits but cannot handle more than the number of tested repeats will be considered non-conformant. Trading partners shall set up error resolution protocols to handle these situations.

9.2 Length Testing

Some message elements do not have a length constraint – specifically per the underlying standard these are the FT and TX data types. For testing purposes length for these elements has been limited to 64k characters.

9.3 Attached File Size Testing

For PDF files and other attachments, testing will use 40MB as the "reasonable file size" test target.

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10 ADDITIONAL IMPLEMENTATION GUIDANCE – OTHER

10.1 Clinical Laboratory Improvement Amendments Considerations

In the United States, clinical laboratory testing of human specimens is regulated by the Clinical Laboratory Improvements Amendments of 1988 (CLIA). Several sections of the regulations implementing CLIA impact how electronic laboratory data is formatted for the US Realm and these are outlined in this section. Impacted areas include mandatory test request requirements. Specifics on the CLIA Regulation are found in the Federal Register https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Regulations_and_Federal_Register_Documents.html.

10.2 Mandatory Ordering Requirements

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

Interpretative guidelines on the elements required in a test requisition may be found at https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Interpretive_Guidelines_for_Laboratories.html. Specific fields impacted include the following requirements that are in scope of this IG, this is not a full listing of CLIA requirements.

TABLE 10-1 MANDATORY TEST REQUEST REQUIREMENTS

CLIA Reference	CLIA Requirement	Segment-Field Description
§493.1241(a) §493.1241(c)(1)	The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (**Note:** The lab maintains the contact person information – not included in LOI transaction)	OBR-16 Ordering Provider ORC-12 Ordering Provider ORC-24 Ordering Provider Address OBR-28 Result Copies To
§493.1241(c)(2)	The patient's name or unique patient identifier.	PID-3 Patient Identifier List PID-5 Patient Name
§493.1241(c)(3)	The sex and age or date of birth of the patient.	PID-7 Date/Time of Birth OBX-5 Observation Value (AOE) PID-8 Administrative Sex
§493.1241(c)(4)	The test(s) to be performed.	OBR-4 Universal Service Identifier
§493.1241(c)(5)	The source (type) of the specimen, when appropriate.	SPM-4 Specimen Type OBX-5 Observation Value (AOE)
§493.1241(c)(6)	The date and, if appropriate, time of specimen collection.	SPM-17 Specimen Date/Time of Collection
§493.1241(c)(7)	For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment or biopsy.	OBX-5 (AOE) Observation Value

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TABLE 10-1 MANDATORY TEST REQUEST REQUIREMENTS		
CLIA Reference	CLIA Requirement	Segment-Field Description
§493.1241(c)(8)	Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.	OBR-13 Relevant Clinical Information OBX-5 Observation Value (AOE, Prior Results) OBX-3 Observation Identifier

10.3 Regulatory Compliance

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

10.4 Authorized Parties

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

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

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11 NDBS LOINC REQUIREMENTS

The table below provides information about each LOINC term: its code (LOINC), long common name (LOINC Long Name), and what type of results are expected. The table includes for each code, whether it is suggested to be used for ordering by the "order only" indicator and/or suggested to be used for results as indicated by "Result Type". LOINC codes with "Both" can be used for both order and result coding. "Belongs to Order Code" in the table indicates which panel the test result is a member. Optionality status of the LOINC is indicated by the optionality (R/O/C) field value of required, optional or conditional. Cardinality of the LOINC in the table is indicated by "Cardinality." Narrative text explains each term and its use, including terms which included a coded answers list to be used as the expected test result values or where another coding system is expected for test result values as indicated in the"Comment" field. Additional details (e.g. term description/definition, related names (synonyms), and answer lists for all terms with coded answers) are available at http://loinc.org.

Because the panel contains a lot of LOINC codes related to reporting of the results for all the screening tests, that are not used in an order message we have adopted the convention to ONLY list LOINC codes for elements supported by the LOI_NDBS_Component; that includes those that are required, conditional or optional. Not supported elements are not included.

The LOINC 57715-5 Birth time is no longer supported as part of the panel; the order placer MUST report Birth time with granularity to the minutes, if known, as part of PID-7 (Date/Time of Birth).

Please note: the R/O/C and cardinality listed here are LOINC attributes that describe the "requiredness" of a LOINC term within a panel. They have no relationship to the field requirements and optionality specified in HL7, as described in 1.3.4 Usage Conformance Rules. LOINC cardinality indicates whether the term is required and how many repeats are permitted. For example, optional with no upper bound is displayed as "0..*". Required but not permitted to repeat is displayed as "1..1". When usage is listed as 'C' and cardinality as 1..1 or 1..* it means that the data element MUST be included, however the actual LOINC may not be in the message, as there are alternative message placements listed in the respective Condition statement. More details about getting started with LOINC are available at: http://loinc.org/get-started/09.html.

TABLE 11-1. NDBS LOINC PANEL REQUIREMENTS

Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements

LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
54089-8	Newborn screening panel American Health Information Community (AHIC)	Order Only	N/A	R	[1..1]	This is the high-level order panel, it will be in OBR-4 (Universal Service Identifier) in the order message. It will NOT be in the result message in OBR-4 (Universal Service Identifier), but it may be identified in OBR-50 (Parent Universal Identifier) for all related Order_Observation groups.

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TABLE 11-1. NDBS LOINC PANEL REQUIREMENTS						
Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements						
LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
57721-3	Reason for lab test in Dried blood spot	Coded	57128-1	O	[0..1]	**Normative Answer List** (LL831-9) Initial screen Subsequent screen - required by law Subsequent screen - required by protocol Subsequent screen - for clarification of initial results (not by law or protocol Subsequent screen - reason No sample collected due to parental refusal LA14132-7 **Note:** Definitions and additional details available at: http://s.details.loinc.org/LOINC/57721-3.html?sections=Simple
57717-1	Newborn screen card data panel	Order Only	54089-8	R	[1..1]	This code will be in a new Order_ObservationGroup
57716-3	State printed on filter paper card [Identifier] in NBS card	Text	57717-1	R	[1..1]	
79566-6	Collection method – Dried blood spot	Coded	57717-1	C	[0..1]	Condition: This LOINC does not appear in the message; this data element is conveyed in SPM-7 Specimen Collection Method with LRI_NDBS_Component Usage: Data Type: CWE_03; Usage: 'RE', Cardinality: [0..1], Value Set: SNOMED CT and/or LOINC **Preferred Answer List:** (LL3860-5).
8339-4	Birth weight Measured	Numeric	57717-1	C	[0..1]	Condition: Depends on state's protocol, if sending birth weight, gestational age or both.
58229-6	Body weight Measured --when specimen taken	Numeric	57717-1	O	[0..1]	

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TABLE 11-1. NDBS LOINC PANEL REQUIREMENTS						
Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements						
LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
73806-2	Newborn age in hours	TM	57717-1	O	[0..1]	**Note:** This term can be used to report the number of hours post-birth, aka Newborn Age when the newborn dried blood spot specimen is collected. For sake of simplicity and accuracy, we recommend computing this value based on the difference between birth time (PID-7 or OBX with LOINC 57715-5) and specimen collection time (SPM-17). Therefore, although this information is critical for interpretation of newborn screening results, this term is optional. If this term is used, sender should report and receiver should store and display the time using hours as units of measure.
57722-1	Birth plurality of Pregnancy	Coded	57717-1	O	[0..1]	This information differs from what can be recorded in PID-24 (Multiple Birth Indicator) with a "yes/no" response, and PID-25 (Birth Order) listing the number identifying for multiple births, whether this baby was born first, second, third, etc.. Sending this LOINC in an OBX indicates how many total babies were delivered. In cases of multiple birth, we encourage reporting all three of these attributes. Normative answers represent the number of fetuses (1 - 12), or 'unknown number' using **Normative Answer List** (LL829-3) available at http://s.details.loinc.org/LOINC/57722-1.html?sections=Simple
57714-8	Obstetric estimation of gestational age	Numeric	57717-1	C	[0..1]	Condition: Depends on state's protocol, if sending birth weight, gestational age or both. Estimate of the infant's gestation in completed weeks; include 'wk' drawn from UCUM in OBX-6 (Units).

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TABLE 11-1. NDBS LOINC PANEL REQUIREMENTS						
Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements						
LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
57713-0	Infant factors that affect newborn screening interpretation	Coded	57717-1	O	[0..*]	This information is expected to be provided with the order and will be sent back, if received. **Preferred Answer List** (LL830-1): None Infant in NICU at time of specimen collection Infant in special care setting (other than ICU) at time of specimen collection Preterm/Low birth weight (LBW) Any blood product transfusion (including ECLS/ECMO) Dopamine Topical iodine Acute illness Hypothyroxinemia of preterm birth Significant hypoxia Immature hypothalamic/pituitary axis Immature liver enzymes Immature renal system Iodine deficiency Liver disease Other conditions, such as biliary atresia, intestinal perforation, abdominal wall defects, septicemia, CMV, renal failure, T21, T18, T13 Parenteral steroid treatment Systemic antibiotics before newborn screening Meconium ileus or other bowel obstruction Thoracic surgery involving thymectomy Immunosuppressive therapy of baby or mother Total parenteral nutrition (TPN) or similar feeding Special lactose-free diet Special low protein diet Other **Note:** Definitions and additional details available at: http://s.details.loinc.org/LOINC/57713-0.html?sections=Simple
67703-9	Other infant factors that affect newborn screening interpretation Narrative	Text	57717-1	C	[0..*]	Condition: If 'other' is reported under 57713-0^Infant factors that affect newborn screening interpretation^LN, this element is required.

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TABLE 11-1. NDBS LOINC PANEL REQUIREMENTS						
Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements						
LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
67706-2	Maternal factors that affect newborn screening interpretation	Coded	57717-1	O	[0..*]	**Preferred Answer List** (LL1736-9) None HELLP syndrome Fatty liver of pregnancy Packed red blood cell (PRBC) transfusion Steroid treatment Thyroid treatment (including propylthiouracil (PTU), methimazole (Tapazole), or past treatment with radioactive iodine (I-131)) TPN Other **Note:** Definitions and additional details available at: http://s.details.loinc.org/LOINC/67706-2.html?sections=Simple
67707-0	Other maternal factors that affect newborn screening interpretation Narrative	Text	57717-1	C	[0..*]	Condition: If 'Other' is reported under 67706-2^Maternal factors that affect newborn screening interpretation^LN, this element is required.
77739-1	Mother's Hepatitis B virus surface Ag status	Coded	57717-1	O	[0..1]	**Preferred Answer List** (LL3639-3) Positive Negative Not tested Unknown **Note:** Some may prefer to report this using 67706-2 Maternal factors that affect newborn screening interpretation and 67707-0 Other maternal factors that affect newborn screening interpretation Narrative. **Note:** Definitions and additional details available at: http://s.details.loinc.org/LOINC/77739-1.html?sections=Simple

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TABLE 11-1. NDBS LOINC PANEL REQUIREMENTS						
Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements						
LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
57712-2	Mother's education	Coded	57717-1	O	[0..1]	**Normative Answer List** (LL836-8) 8th grade/less 9th - 12th grade, no diploma High school graduate or GED completed Some college credit but no degree Associate degree (e.g., AA, AS) Bachelor's degree (e.g., BA, AB, BS) Master's degree (e.g., MA, MS, MEng, MEd, MSW, MBA) Doctorate (e.g., PhD, EdD) or Professional degree (e.g., MD, DDS, DVM, LLB, JD) Unknown **Note:** Definitions and additional details available at: http://s.details.loinc.org/LOINC/57712-2.html?sections=Simple
67704-7	Feeding types	Coded	57717-1	O	[0..*]	This information is expected to be provided with the order and will be sent back, if received. **Normative Answer List** (LL1735-1): Breast milk Lactose formula Lactose free formula (including soy or hydrolyzed)* NPO TPN Carnitine MCT (medium-chain triglyceride) oil IV dextrose Other None** Unknown * Infant is on a soy or hydrolyzed formula. Only these two types of formulas do not contain lactose, which can affect galactosemia screening results because the infant does not have a sufficient lactose load. This answer is important for result interpretation. Absence of lactose can give a false negative result. ** Indicates that the infant has had no feeds of any kind (by mouth, by IV, etc.) **Note:** Definitions and additional details available at: http://s.details.loinc.org/LOINC/67704-7.html?sections=Simple

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TABLE 11-1. NDBS LOINC PANEL REQUIREMENTS						
Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements						
LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
67705-4	Other feeding types Narrative	Text	57717-1	C	[0..*]	Condition: If 'other' is reported under 67704-7^Feeding types^LN, this element is required.
79569-0	Blood product given	Coded	57717-1	O	[0..*]	**Preferred Answer List** (LL3859-7) Blood product transfusion that includes Red Blood Cells (RBC) Blood product transfusion that does NOT include Red Blood Cells (RBC) Extracorporeal life support (ECLS)/Extracorporeal membrane oxygenation (ECMO) Intrauterine Fetal Blood Transfusion that includes Red Blood Cells (RBC) Intrauterine Fetal Blood Transfusion that does not includes Red Blood Cells (RBC) Other blood product transfusion **Note:** Definitions and additional details available at: http://s.details.loinc.org/LOINC/79569-0.html?sections=Simple
62317-3	Date of last blood product transfusion	DTM	57717-1	C	[0..1]	Condition: If 79569-0^ Blood product given ^LN, this element is required.

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TABLE 11-1. NDBS LOINC PANEL REQUIREMENTS						
Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements						
LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
58232-0	Hearing loss risk indicators [Identifier]	Coded	57717-1	O	[0..*]	Please refer to existing HL7 implementation guide for Early Hearing Detection and Intervention (EHDI at http://www.hl7.org/implement/standards/product_brief.cfm?product_id=344). **Preferred Answer List** (LL862-4): None Caregiver concern about hearing Family Hx of hearing loss ICU stay > 5 days ECMO Assisted ventilation Ototoxic medication use Exchange transfusion for Hyperbilirubinemia LA12673-2 In utero infection(s) Craniofacial anomalies Physical findings of syndromes that include hearing loss Syndromes associated with hearing loss Neurodegenerative disorders Postnatal infections Head trauma Chemotherapy **Note:** Definitions and additional details available at: http://s.details.loinc.org/LOINC/58232-0.html?sections=Simple
54106-0	Newborn hearing screen method	Coded	54089-8	O	[0..1]	**Note:** This code is out of scope for this Newborn Dried Blood Spot Screening (NDBS) use case but is listed here because some state newborn screening programs do report this information with their NDBS results. Additional details available in the existing HL7 implementation guide for Early Hearing Detection and Intervention (EHDI at http://www.hl7.org/implement/standards/product_brief.cfm?product_id=344). For additional LOINC code details including definitions/descriptions and answer lists, please refer to: http://s.details.loinc.org/LOINC/73738-7.html?sections=Comprehensive
54108-6	Newborn hearing screen of Ear - left	Coded	54089-8	O	[0..1]	See Note under 54106-0^Newborn hearing screen method^LN above

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TABLE 11-1. NDBS LOINC PANEL REQUIREMENTS						
Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements						
LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
54109-4	Newborn hearing screen of Ear - right	Coded	54089-8	O	[0..1]	See Note under 54106-0^Newborn hearing screen method^LN above
73700-7	CCHD newborn screening interpretation	Coded	54089-8	O	[0..1]	**Note:** This code is out of scope for this Newborn Dried Blood Spot Screening (NDBS) use case but is listed here because some state newborn screening programs do report this information with their NDBS results. Additional details available in the existing HL7 implementation guide for Critical Congenital Heart Defects and pulse oximetry screening (CCHD at http://www.hl7.org/implement/standards/product_brief.cfm?product_id=366). For additional LOINC code details including definitions/descriptions and answer lists, please refer to: http://s.details.loinc.org/LOINC/73805-4.html?sections=Comprehensive
73698-3	Reason CCHD oxygen saturation screening not performed	Coded	54089-8	O	[0..1]	see Note under 73700-7^CCHD newborn screening interpretation ^LN above
57723-9	Unique bar code number of Current sample	Text	57717-1	C	[0..1]	This LOINC may not appear in the message as it can be conveyed either in an OBX segment using this LOINC in OBX-3 or in SPM-31.1 (Other Specimen ID.Identifier) in the message. In either case the Identifier type code (CX_01.5 or CX_02.5) SHALL be valued 'SNBSN'.
57711-4	Unique bar code number of Initial sample	Text	57717-1	O	[0..1]	
62323-1	Post-discharge provider ID [Identifier]	CX	57717-1	O	[0..1]	
62324-9	Post-discharge provider name in Provider	Text	57717-1	O	[0..1]	
62325-6	Post-discharge provider practice ID	CX	57717-1	O	[0..1]	
62326-4	Post-discharge provider practice name	Text	57717-1	O	[0..1]	

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TABLE 11-1. NDBS LOINC PANEL REQUIREMENTS						
Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements						
LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
62327-2	Post-discharge provider practice address	XAD	57717-1	O	[0..1]	
62328-0	Post-discharge provider practice telephone number	XTN	57717-1	O	[0..1]	
62329-8	Birth hospital facility ID [Identifier] in Facility	CX	57717-1	O	[0..1]	
62330-6	Birth hospital facility name	Text	57717-1	O	[0..1]	
62331-4	Birth hospital facility address	XAD	57717-1	O	[0..1]	
62332-2	Birth hospital facility phone number in Facility	XTN	57717-1	O	[0..1]	

11.1 List of Pre-adopted elements from versions beyond V2.5.1

Pre-adopted elements list for LOI base profile (in order of appearance in the guide):

OML^O21^OML_O21 NEW AND APPEND ORDER: [SGH] Segment Header R [1..1] Pre-adopted from V2.8.2.

OML^O21^OML_O21 NEW AND APPEND ORDER: [SGT] Segment Trailer R [1..1] Pre-adopted from V2.8.2.

PATIENT IDENTIFICATION SEGMENT (PID): PID-10 (Race), PID-22 (Ethnic Group) The use of CWE is pre-adopted from HL7 V.2.7.1.

NEXT OF KIN / ASSOCIATED PARTIES SEGMENT (NK1): NK1-3 (Relationship), NK1-7 (Contact Role) The use of CWE is pre-adopted from HL7 v2.7.1.

PATIENT VISIT SEGMENT (PV1): PV1-22 (Courtesy Code) The use of CWE is pre-adopted from HL7 V.2.7.1.

INSURANCE SEGMENT (IN1): IN1-2 (Insurance Plan ID), IN1-17 (Insured's Relationship To Patient) The use of CWE is pre-adopted from HL7 V.2.7.1.

GUARANTOR SEGMENT (GT1): GT1-11 (Guarantor Relationship) The use of CWE_02 is pre-adopted from HL7 V.2.7.1.

COMMON ORDER SEGMENT (ORC): ORC-16 (Order Control Code Reason) The use of CWE is pre-adopted from HL7 V.2.7.1. ORC-20 (Advanced Beneficiary Notice Code) The use of CWE_02 is pre-adopted from CWE in HL7 V.2.7.1.

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OBSERVATION REQUEST SEGMENT (OBR): 13 Relevant Clinical Information CWE_02 RE [0..1] HL70916_USL This field pre-adopts the V2.7.1 definition. Constrained to indicate Fasting only.

OBSERVATION REQUEST SEGMENT (OBR): OBR-4 and OBR-13 pre-adopt the use of CWE replacing CE and ST respectively from HL7 V.2.7.1.

PARTICIPATION INFORMATION SEGMENT (PRT): From 2.7.1

DIAGNOSIS SEGMENT (DG1): DG1-3 (Diagnosis Code - DG1) The use of CWE is pre-adopted from HL7 V.2.7.1.

OBSERVATION RESULT SEGMENT (OBX): Components 26 through 29 are pre-adopted from Version 2.8.1.

OBSERVATION RESULT SEGMENT (OBX): Components 30 through 32 are pre-adopted from Version 2.9

OBSERVATION RESULT SEGMENT (OBX): The use of CWE in, OBX-3 (Observation Identifier), OBX-5 (Observation Value), OBX-6 (Units) is pre-adopted from HL7 V.2.7.1.

SPECIMEN SEGMENT (SPM): Components 30 through 31 are pre-adopted from Version 2.7.1

CODED WITH EXCEPTIONS; CODE REQUIRED (CWE_01): Components 10-22 are pre-adopted from V2.7.1 CWE

CODED WITH EXCEPTIONS; CODE REQUIRED. SECOND TRIPLET OPTIONAL (CWE_02): Components 10-22 are pre-adopted from V2.7.1 CWE

CODED WITH EXCEPTIONS; CODE REQUIRED BUT MAY BE EMPTY (CWE_03): Components 10-22 are pre-adopted from V2.7.1 CWE

CODED WITH EXCEPTIONS; CODE REQUIRED BUT MAY BE EMPTY, SECOND TRIPLET OPTIONAL (CWE_04): Components 10-22 are pre-adopted from V2.7.1 CWE

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12 GLOSSARY

TABLE 12-1. GLOSSARY

Term	Definition
Analyte	A substance that is measured.. It is the most granular level at which measurements are made and always represented using a single Observation segment group.
Cancellation	Act of cancelling the order.
Electronic Health Record	Clinical information for a specific patient that is stored electronically within an EHR-S.
Electronic Health Record System (EHR-S)	A software application that is capable of managing clinical patient information.
Future Order	A future order is an order with a start date/time for the specimen to be collected that is later than the current date/time. The specimen shall not be collected prior to the given start date/time.
Laboratory	A facility or organization that performs laboratory testing on specimens for the purpose of providing information for the diagnosis, prevention, treatment of disease or impairment, or assessment of health for humans.
Laboratory Information System (LIS)	An information system that receives, processes, and stores information related to laboratory processes. LIS may interface with HIS and EHR applications. To meet the requirements of the LOI Use Case the LIS, at minimum, must have the following characteristics: • Data model that includes discrete representations of patients, clinician end-users, laboratory test requisitions, laboratory tests (including panels), and laboratory test results (at the level of an individual analyte); • Capability to receive electronic messages that communicate a laboratory order from a physician; • Capability to send electronic messages that report the status and results of laboratory tests that have been ordered; This definition is very minimal and omits many features and capabilities that are typically associated with laboratory information systems. This minimal characterization is intentional, as to include the broadest possible set of LIS systems in the use case. The minimal nature of the definition by no means excludes LIS with significantly greater capabilities.
Laboratory Message	An electronic communication between a Laboratory Order System and a Laboratory Information System related to laboratory testing. Laboratory messages may be used to request that one or more tests be performed, to change previous requests for testing, to report the cancellation of requested tests, or to report the results of requested tests.
Laboratory Order	Synonymous with a Requisition when referring to a single ORC/OBR pair.
Laboratory Order System	Software, either stand-alone or as part of an EHR system, used by a Provider *(Order Placer)* to manage a laboratory order, including generating the laboratory requisition, sending it to a laboratory, and monitoring/tracking of the status of the laboratory order. Typically, a laboratory order system is an integral part of an order management system that enables users to manage orders for many different types of services, procedures, supplies, etc. Since we only focus on data exchange relative to laboratory orders we are purposely using a very limited definition.
Laboratory Requisition	A set of information that constitutes an official request for one or more laboratory tests to be performed on an individual patient. A laboratory requisition is specified in a clinical setting and communicated to a laboratory as a discrete paper or electronic artifact. Laboratory requisitions always include at least one test order. In terms of an HL7 order transaction it represents one or more orders (ORC/OBR pairs) transmitted as part of the same OML^O21^OML_O21 new or append order message.

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TABLE 12-1. GLOSSARY	
Term	Definition
Newborn	A human infant from the time of birth through the 28th day of life per Mosby's Medical Dictionary, 8th edition. © 2009, Elsevier, and the World Health Organization standardization for perinatal definitions.
Orderable Test	A request to perform an individual test or panel. It always refers to a single ORC/OBR pair and may have one or more associated analytes (OBXs).
Panel	A grouping of tests defined by the laboratory and communicated in their compendium. While there are differences in the meanings of the terms “panel” among various laboratories, for the purposes of this guide, it is defined as a grouping of procedures that measure multiple analytes from a single specimen (or multiple specimens in some cases) and can be requested through one laboratory order. This is also referred to as a battery. For example, a CBC or a urinalysis may be referred to as a panel.
Recurring Order	An order for a test that is performed multiple times e.g., follows a timing pattern such as every week, every month, etc.
Request for Cancellation (RFC)	Request by the Provider *(Order Placer)* not to perform the order.
Test	A medical procedure or named set of related procedures that involves analyzing one analyte using a single sample of blood, urine, or other specimen from a patient for the purpose of diagnosing a disease or medical condition, planning or evaluating treatment, or monitoring the course of a disease.

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