# V2\_IG\_LTCF\_R2\_DSTU\_R2\_2015SEP



# HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Test Compendium Framework R2, DSTU Release 2 - US Realm

Also referred to as eDOS (Electronic Directory Of Service)

#### **Draft Standard for Trial Use**

#### September 2015

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SNOMED CT	International Healthcare Terminology Standards Developing Organization (IHTSDO)
	http://www.ihtsdo.org/snomed-ct/get-snomed-ct or info@ihtsdo.org
Logical Observation Identifiers Names &	Regenstrief Institute
Codes (LOINC)	
International Classification of Diseases	World Health Organization (WHO)
(ICD) codes	
NUCC Health Care Provider Taxonomy	American Medical Association. Please see 222.nucc.org. AMA licensing contact: 312-
code set	464-5022 (AMA IP services)

# Acknowledgments

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#### 1 INTRODUCTION

The American Clinical Laboratory Association (ACLA) represents national, regional and local laboratories that collectively have an extensive history of providing the nation's hospitals and physicians with leading-edge Health Information Technology (HIT) to streamline the laboratory test requisition process and speed the delivery of test results. A subgroup of ACLA, the HIT Data Standards Committee is dedicated to the review and development of HIT initiatives (standards and government regulatory items) that might impact the clinical laboratory industry.

The development of a framework for the Laboratory Test Compendium and associated capability of electronic exchange of Directory of Services (eDOS) content as outlined in this Implementation Guide is a critical step in the increased interoperability required between commercial Electronic Health Record (EHR), Hospital Laboratory Information System (HLIS), Health Information Exchange (HIE) vendors and Laboratory Information systems (LIS) and/or other entities hereafter defined as Compendium Consumers and laboratory service providers, hereafter defined as Compendium Producers. This development effort fills a gap in the current electronic data exchange and will enable the reduction of costs for providers, laboratories and vendors while further decreasing error rates by simplifying the exchange of data related to a DOS.

Release 2 of the eDOS Implementation Guide is the result of work by the eDOS Work Group under the sponsorship of the Office of National Coordinator (ONC) Standards and Interoperability Framework (SIF) and is designed to work in concert with the companion Lab Result Interface (LRI) and Laboratory Order Interface (LOI) Implementation Guides.

- The SIF Lab Result Interface Work Group published a V2.5.1 draft for trial use (DSTU) Implementation Guide for Lab Results through the Health Level Seven (HL7) standards development organization (SDO) in July 2012. This Implementation Guide was selected by ONC for Meaningful Use Stage 2.
- The SIF Lab Orders Interface Work Group published a V2.5.1 draft for trial use (DSTU) Implementation Guide for Laboratory Orders through the Health Level Seven (HL7) standards development organization (SDO) in December 2013.
- The SIF eDOS Work Group published this V2.5.1 draft for trial use (DSTU) Implementation Guide for the electronic directory of service (test compendium) through the Health Level Seven (HL7) standards development organization (SDO) in early 2015.
- Several elements in the laboratory's test compendium are subsequently used in the laboratory orders and laboratory results reporting. For additional detail, refer to Appendix B eDOS-LOI-LRI Field Comparison. Figure 1 below illustrates the flow of some of the data elements from eDOS to LOI and LRI uses.

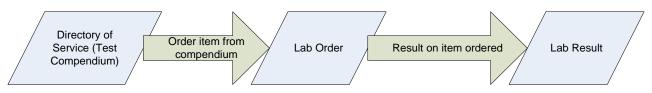


Figure 1-1. eDOS Data Flow

ARRA/HITECH rules have specified HL7 Version 2.5.1 as the requirement for laboratory reporting for both Meaningful Use 1 and Meaningful Use 2. Release 1 of the Laboratory Test Compendium Framework (eDOS) was developed using Chapter 8 of the HL7 Version 2.6 but Release 2 is defined for V2.5.1 to synch with the *HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Orders from EHR, Release 1, US Realm (November 2013)* (LOI) and the *HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Release 1 – Us Realm* (July 2012) (LRI) Implementation Guides, both of which are published as Draft Standards for Trial Use (DSTU).

#### 1.1 Purpose

The content of the Laboratory Test Compendium Framework is a Laboratory's DOS. The content is owned by the sending laboratory for the purpose of being used by the compendium consumer to be able to order laboratory services and to understand the requirements and components of those services. The consumer (and consuming systems) should not modify or delete the content unless instructed to do so by the producer via eDOS updates or some other form of written communication. Adding to the content to provide additional information specific to the consumer's needs such as cross reference to local codes and/or other performing labs, or other information that does not change or conflict with the content of the original information provided by the performing laboratory, is permitted.

#### 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 Implementation Guide: Laboratory Test Compendium Framework, Release 2* 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 several documents that are part of a product group to support multiple Implementation Guides in support of the Office of the National Coordinator (ONC) under the Standards and Interoperability Framework Initiative (SIF). The purpose is to provide consistent processes and documentation format criteria. The set includes but is not limited to:

- This publication, the HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Test Compendium Framework R2, Release 2 US Realm, Also referred to as eDOS (Electronic Directory Of Service) (January 2015)
- The <u>HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, DSTU Release 2 US Realm</u>
- The <u>HL7 Version 2.5.1 Implementation Guide</u>: <u>S&I Framework Laboratory Orders from EHR</u>, <u>Release 1 – US Realm</u>
- The profiles that allow modifications of both the LRI and LOI IG to support the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 2 US Realm (ELR) or the addendum to those guides.

#### 1.2.2 REQUISITE KNOWLEDGE

HL7 Version 2.5.1 Chapter 8 Master Files was used to develop this Implementation Guide. Pre-adoption from V2.7.1, V2.8, V2.8.1, and V2.8.2 is indicated where appropriate.

- HL7 V2.5.1 through V2.8.2 Messaging (www.HL7.org)
- LOINC (<a href="http://loinc.org">http://loinc.org</a>)
- SNOMED CT (<a href="http://www.ihtsdo.org/snomed-ct">http://www.ihtsdo.org/snomed-ct</a>)
- OIDS (http://www.hl7.org/oid)

# 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. Although some information from the standard is included in this Implementation Guide, much information from the standard has not been repeated here.
- References to Chapters, e.g., See Chapter 4, 2.2.4, indicate a chapter in the base V2.5.1 standard (unless otherwise noted.)
- The rules outlined in HL7 V2.7.1, Chapter 2B, Section 2B5, Conformance Using Message Profiles, were used to document the use case for, and constraints applied to, the messages described in this guide.
- Data types have been described separately from the fields that use the data types.
- No conformance information is provided for optional message elements 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. Additionally, this guide has pre-adopted deprecation of some fields which are also marked with an "X" and if replaced by new fields this change is noted where it occurs, e.g., the OM1 segment pre-adopts deprecation of fields which are now replaced by segments; these changes are noted in the OM1 segment.
- 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, a laboratory that is compliant with this Implementation Guide does not have to send any elements marked as an "O", nor does a receiver of an eDOS message 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 eDOS 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.

• If the Value Set is constrained to a single value, it will be represented as a conformance statement in the IG proper as well as remain part of the master listing of value sets used by this IG. Note that future versions of this IG will adopt the spreadsheet method of presenting value sets for the laboratory US Realm suite of Implementation Guides.

#### 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.		
Segment	Three-character code for the segment and the abstract syntax (e.g., the square and curly braces):  [ XXX ]		
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 Testing Recommendations.		
Cardinality	Minimum and maximum number of times the element may appear.  [00] Element never present.  [01] Element may be omitted and can have, at most, one occurrence.  [11] Element must have exactly one occurrence.  [0n] Element may be omitted or may repeat up to n times.  [1n] Element must appear at least once, and may repeat up to n times.  [0*]Element may be omitted or repeat an unlimited number of times.  [1*] Element must appear at least once, and may repeat unlimited number of times.  [mn] Element must appear at least m, and at most, n times.  Cardinality applies only to message attribute tables and segment attribute tables.		

TABLE 1-1. MESSAGE ELEMENT ATTRIBUTES			
Attribute Definition			
Value Set	The set of coded values to be used with the field. The value set attribute applies only to the data type attribute tables and the segment attribute tables. The value set may equate with an entire code system, part of a code system, or codes drawn from multiple code systems.  Unconstrained, Constrained and User Defined tables are listed or included in Section 6 Code Systems and Value Sets.		
Name  HL7 descriptor of the message element. Name applies to the message attribute table, data type attribute table and the segment attribute table.			
Description/Comments	Context and usage for the element. Description/Comments applies to the message attribute table, data type attribute table and the segment attribute table.		

#### 1.3.3 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<sup>1</sup>. The following definitions are excerpted from the RFC:

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

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

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

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

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

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

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

#### 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, "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	The application shall implement "RE" elements.	The application shall populate "RE" elements with a non-empty value if there is relevant data. The

Optionality/ Usage Indicator	Description	Implementation Requirement	Operational Requirement			
	empty		term "relevant" has a confounding interpretation in this definition <sup>2</sup> .			
C(a/b)	Conditional	An element with a conditional usage code has an associated condition predicate (See section 2.B.7.9, "Condition predicate" that determines the operational requirements (usage code) of the element.				
		If the condition predicate associated with the element is true, follow the rules for 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".				
		$\boldsymbol{a}$ and $\boldsymbol{b}$ 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 "X" elements.				
0	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.			

# 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).

<sup>-</sup>

<sup>&</sup>lt;sup>2</sup> There are multiple interpretations of "RE" when a value is known. One is "the capability must always be supported and a value is sent if known", the other is "the capability must always be supported and a value may or may not be sent even when known based on a condition external to the profile specification. The condition may be noted in the profile but cannot be processed automatically". This is what can be interpreted from the "relevant" part of the definition. Regardless of the interpretation 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.

Optionality/ Usage Indicator	Description	Implementation Requirement	Operational Requirement		
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.		
0	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 -----

#### **1.3.5 PILOTS**

During eDOS Use Case development, the community decided that eDOS pilots should pay particular attention to the notion of the "established escalation procedures" between the Compendium Consumer and the Compendium Producer. Pilots may decide that more detail is required, or that the term is sufficient. The process for removing a test from the compendium may need to be reviewed in greater detail by the Pilots.

# 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 1.2.2 Requisite Knowledge informed the content of this specification.

#### 1.4.1 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. Examples of information that OIDs can identify are items about patients, orders, providers and organizations. This means the identifier includes enough information to remain unique when taken out of the context within which the identifier was created. 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 (eDOS\_GU\_Component) (see Section 2.3.2) that prescribes the use of an ISO Object Identifier (OID) for a specific set of fields.

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

#### 1.4.2 USE OF VOCABULARY STANDARDS

This guide calls for specific vocabulary standards, such as LOINC, to be utilized in the exchange of laboratory information. This terminology is updated periodically and it is best practice to use the most current version of the coding system.

#### 1.4.3 FIELD LENGTH AND TRUNCATION

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

#### 1.4.4 VALUE SETS

This Implementation Guide provides detailed value set definitions for each component and field where they are used in a separate publication. See Section 2 Conformance to this Guide 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 Implementation Guide publication OR NEWER can be used to satisfy the requirements of this IG at the time of implementation.

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.

#### 1.4.4.1 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 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.

#### 1.4.4.2 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

<sup>&</sup>lt;sup>3</sup> The current version of the HL7 Implementation Guidance for Unique Object Identifiers (OIDs), Release 1 is available from HL7 (www.hl7.org).

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.

#### 1.4.5 SCOPE OF IMPLEMENTATION

The base standard indicates that receiving applications "...SHALL process (save/print/archive/etc.)...". Due to receiving system variations and need, this guide does not specifically indicate for each field whether to store it or not. This is left to the individual system's scope and purpose.

#### 1.4.6 ASK AT ORDER ENTRY OBSERVATIONS

Ask at Order Entry responses are recorded as observations that 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. For additional information on AOE, refer to OMC-04 (Clinical Information Request) and Appendix A – Ask at Order Entry.

#### 1.4.7 IMPLEMENTATION CONSIDERATIONS

Incremental Updates may impact the following that should be reviewed with trading partners prior to implementation:

- Impact to future/standing orders containing deactivated tests
- Order sets/"pick" list/preference list what are implications when adding/deprecating tests
- Changes to reference ranges and changes in methods may affect update (future/standing orders, pick list display, etc.)
- Potential impact to Reports and Billing

This Implementation Guide uses the Original Acknowledgment Mode for acknowledgements. Note that future versions of this IG will adopt Enhanced Mode Application-Level Acknowledgements for harmonization with the Laboratory US Realm suite of Implementation Guides.

#### 1.4.8 GROUPING OF TEST CODES

A Compendium Producer has the ability to declare a single code for ordering purposes that groups multiple orders for specific tests as mutually agreed by a Compendium Producer and a Compendium Consumer.

This IG provides no guidance on recursion other than caution. For example, a code may refer to five other codes, one of which is also a reference to multiple codes, one of which may also refer to multiple other codes. Implementations should carefully consider the impact when recursion is implemented.

#### 1.4.9 DATA TYPE FLAVORS

A particular data type can be referenced by different fields. Depending on the field's purpose, 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. Rather than providing data type specifications in-line with each field within a segment, we opted to create data type flavors. Whenever a data type is used differently depending on the field

referencing it, a new flavor is created, e.g., TS\_0 (where TS is the data type and \_0 indicates the flavor). Different fields can reference the same data type flavor. This approach will reduce the number of data type definitions, thus reducing the size of this Implementation Guide.

#### 1.5 Referenced Profiles – Antecedents

This specification documents an Electronic Directory of Service (eDOS) message profile for Senders and Receivers based on the HL7 Version 2.5.1<sup>4</sup>. Other laboratory ordering profiles are referenced and used as source materials in the development of this guide, including:

- HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Orders from EHR, Release 1 US Realm January 2013
- 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.

<sup>&</sup>lt;sup>4</sup> The referenced documents are all available from HL7 at www.hl7.org.

#### 2 CONFORMANCE TO THIS GUIDE

#### 2.1 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 companion publication <u>HL7 Version 2 Implementation Guide: Laboratory Value Set Companion Guide, Release 1- US Realm, September 2015</u>.

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

# 2.2 Profiles and Profile Components

This Implementation Guide (IG) conforms to the processes developed for the S&I Framework Initiatives with the intent to have all IGs conformance to be consistent. The S&I Framework has attempted to build IGs that are consistent for all initiatives in a specific domain, such as Laboratory, and to provide profiles that further constrain the IG to accommodate other issues within the initiative. When profiles can be reused across IGs within the domain the profile name will start with LAB\_ and the OID will remain the same across all guides. In some cases profiles are providing unique constraints to the IG and will have a profile name and OID unique to the IG, e.g., LOI\_ or LRI\_.

Profiles will always further constrain the IG and/or previously defined profiles as defined in the MSH-21 (Message Profile Identifier) field. While profiles should provide further constraints providing for a crisper more precise use of the interface, it should not violate the underlying HL7 standard. When possible, the combination of profiles should reduce the discussion between partners on what is expected of an interface. However, some profiles may be applicable to an instance of time to support the specific needs of the care situation. An example is the NB (Newborn) Profile in the Lab Order Interface (LOI) that adds the additional requirement of time stamps to include days and hours to assist with determining normal ranges but is only used when Newborn screening tests are ordered or reported.

As part of this design, some components are prefaced by LAB\_, LOI\_ or LRI\_, which indicates the following use:

- LAB\_xxx the component declares behaviors and constraints that apply to all guides.
- LOI\_xxx the component declares behaviors and constraints that apply specifically to laboratory orders.
- LRI\_xxx the component declares behaviors and constraints that apply specifically to laboratory results.
- EDOS\_xxx the component declares behaviors and constraints that apply specifically to laboratory directories of service.
- PH-xxx the component declares behaviors and constraints that apply specifically to reporting for public health (ELR)

The Components must be combined to create a valid Profile for a particular transaction by populating MSH-21 (Message Profile Identifier) with the profile identifiers. Multiple profiles or component profiles can be present in MSH.21 provided the combination of profiles does not conflict with each other (as

noted above). Additional definitions and guidance for MSH-21 can be found in Section 6.6.1 MSH – Message Header Segment.

As of this version a valid eDOS profile consists of a minimum of two components:

- 1. The eDOS\_Common\_Component (2.3.1)
- 2. The eDOS\_GU\_Component (Globally Unique) OR the eDOS\_NG\_Component (Non-Globally Unique) (2.3.2,2.3.3)

Additional components are optional but may be included when supported by both trading partners. This guide includes one such component:

1. LAB\_XO\_Component (Exclusions) (2.3.4)

As of this version a valid response profile consists of a minimum of two components:

- 1. The eDOS\_Acknowledgement\_Component (2.5.1)
- 2. The eDOS\_GU\_Acknowledgement\_Component (2.5.2) **OR** the eDOS\_NG\_Acknowledgement\_Component (2.5.3)

#### 2.3 eDOS Profile Components

The components that can be assembled into profiles are:

#### 2.3.1 EDOS COMMON COMPONENT - ID: 2.16.840.1.113883.9.67

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

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

#### 2.3.2 EDOS GU COMPONENT (GLOBALLY UNIQUE) - ID: 2.16.840.1.113883.9.68

This component indicates that the following fields use Globally Unique Identifiers according to Section 1.4.1 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
- MFI-2 Master File Application Identifier

These fields must use the GU version of the data type definitions.

#### 2.3.3 EDOS NG COMPONENT (NON-GLOBALLY UNIQUE) - ID: 2.16.840.1.113883.9.69

This component indicates that the identification method has been negotiated between the trading partners where none or some may use ISO OIDs according to Section 1.4.1 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
- ° MFI-2 Master File Application Identifier

These fields must use the NG version of the data type definitions.

#### 2.3.4 LAB\_XO\_COMPONENT (EXCLUSIONS) - ID: 2.16.840.1.113883.9.23

This component is adopted as stated in the <u>Standards and Interoperability Laboratory Results</u> <u>Interface Use Case, Laboratory Results Reporting to Primary Care Providers (in an Ambulatory Setting) v1.0, Section.</u>

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, "X" 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 component is strictly voluntary and cannot be mandated by either trading partner to be used to enable a successful results transaction.

# 2.4 eDOS Profiles (Pre-Coordinated Components)

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

#### 2.4.1 EDOS\_GU\_PROFILE ID: 2.16.840.1.113883.9.70

This profile pre-coordinates the use of the eDOS\_Common\_Component and eDOS\_GU\_Component.

#### 2.4.2 EDOS NG PROFILE ID: 2.16.840.1.113883.9.71

This profile pre-coordinates the use of the eDOS\_Common\_Component, and eDOS\_NG\_Component.

## 2.5 Response Components

#### 2.5.1 EDOS\_ACKNOWLEDGEMENT\_COMPONENT - ID: 2.16.840.1.113883.9.72

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

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

#### 2.5.2 EDOS GU ACKNOWLEDGEMENT COMPONENT - ID: 2.16.840.1.113883.9.73

This profile ID is used to identify an acknowledgment that is constrained for the profiles defined within this Guide in response to the eDOS Master File messages where MSH-21 contains 2.16.840.1.113883.9.68 (eDOS\_GU\_Component).

#### 2.5.3 EDOS NG ACKNOWLEDGEMENT COMPONENT - ID: 2.16.840.1.113883.9.74

This profile ID is used to identify an acknowledgment that is constrained for the profiles defined within this Guide in response to the eDOS Master File messages where MSH-21 contains 2.16.840.1.113883.9.69 (eDOS\_NG\_Component).

#### 2.6 Response Profiles (Pre-Coordinated Components)

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

#### 2.6.1 EDOS\_GU\_RESPONSE\_PROFILE ID: 2.16.840.1.113883.9.75

This profile pre-coordinates the use of the eDOS\_Acknowledgement\_Component and the eDOS\_GU\_Acknowledgement\_Component.

#### 2.6.2 EDOS NG RESPONSE PROFILE ID - 2.16.840.1.113883.9.76

This profile pre-coordinates the use of the eDOS\_Acknowledgement\_Component and the eDOS\_NG\_Acknowledgement\_Component.

#### 2.7 Extended Profile Use

The sender may create other components or profiles that are defined outside of this Implementation Guide for use in conjunction with the profiles/components defined in this guide. However, those profiles/components are strictly voluntary, must be agreed to by trading partners, and shall be properly constrained against the base standard and the profiles/components defined in this IG.

# 2.8 Delivery

The complete laboratory test compendium should be delivered to initialize an interface. Additional points for consideration are:

- The delivery of the complete compendium should also be available at any time upon request.
- The delivery of the test compendium, either full or partial, should be an automated process between the Compendium Producer and Compendium Consumer.
- The delivery of the compendium should not negatively impact the successful delivery of patient results into the recipient's system. Therefore, it is recommended that a separate channel of communication be instituted for transmission of the Master Files data.

• The compendium is expected to be processed by the Compendium Consumer upon receipt.

# 2.9 Maintenance Updates

Maintenance files should only contain additions, deactivations and/or updates to the test compendium. The frequency of delivery of an updated compendium is a decision between the Compendium Producer and the Compendium Consumer; "best practice" intervals are not recommended in this document.

The content of the current message will replace the contents from a prior message for the same information object. Therefore, for each update or reactivation or deactivation to the test compendium, all the information for a given test, panel, etc. must be re-sent - not just the new or revised information for that test or panel.

**Note:** This Implementation Guide does not specify maintenance procedures, schedules or other aspects of a maintenance process. These are areas of exchange that must be negotiated between Compendium Producers and Compendium Consumers.

# 2.10 File Naming Conventions

When applicable, file-naming conventions should be implemented for routing of the compendium into a consumer's system. The MSH identifier in MSH-9 will identify the type of message being transmitted. It is not the intention of this guide to recommend specific file name conventions.

#### 2.11 Transport Layer

This specification does not address network protocols or the transport layer.

# 3 MESSAGE SEQUENCE

This guide leverages four HL7 messages to communicate all Electronic Directory of Service information.

Note: Full message structures are found in Section 5 Messages.

	TABLE 3-1. MESSAGE TYPE BENEFITS					
Type	Ordering Benefit	Reporting Benefit				
MFN^M08	Lists individually ordered tests	Provides information on each potential result				
MFN^M10	Lists group tests & components	Provides analyte grouping/sequence information				
MFN^M04	Provides Procedure code information for reference/administrative validation (Medical Necessity/ABN)	None				
MFN^M18	Provides payer policy and coverage information related to each orderable test or component.	Provides payer policies driving Medicare Limited Coverage Processing (MLCP) and Medicare Approved Coverage Processing (MACP).				

The set of messages that comprise a compendium exchange must be sent and processed in the following order:

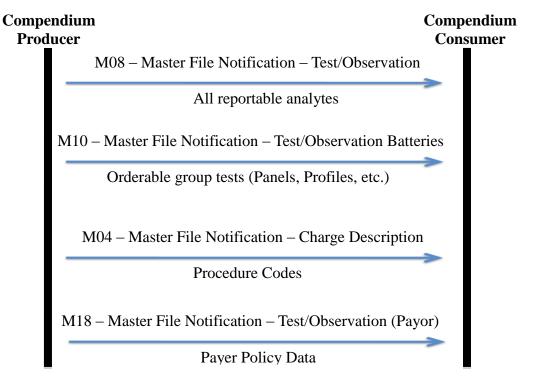


Figure 3-1. Message Exchange Sequence

- 1. **MFN^M08** Master File Notification Test/Observation: listing individually reported observations, some of which are individually orderable.
- 2. **MFN^M10** Master File Notification Test/Observation Batteries: listing each orderable battery (group test, panel, profile, etc.), when applicable.

- 3. **MFN^M04** Master File Notification Charge Description: listing procedure codes to compliment the orderable items.
- 4. **MFN^M18** Master File Notification Test/Observation (Payer): Used to communicate payer policies specific to a payer, including limited coverage/approved coverage. This message is preadopted from V2.8.2.

Each of these messages must be supported but not all of them may be supplied based on requirements defined by the laboratory. For example, the laboratory will always send an M08 but may not send associated M10, M04, and M18.

#### 3.1 Message Data Dependencies

There are several dependencies amongst the data contained in each message, processing the messages in the prescribed order builds the correct hierarchal structure:

**MFN^M08 – Test/Observation** – provides the foundation of the compendium and must be the first file processed.

**MFN^M10 – Test/Observation Batteries** – defines "groupings" of individually orderable components contained in the MFN^M08 message.

**MFN^M04 – Charge Description** – references all the individual or grouped orderable items contained in the MFN^M08 and MFN^M10 messages.

**MFN^M18** – Test/Observation (Payer) – associates additional payer information related to all previously communicated orderable components and is the last to be processed.

# 3.2 Event Triggers

There are two events that determine the set of messages to be sent, an initial load and an update to a previously sent compendium.

**Initial Load** – a Compendium Consumer will receive a minimum of two and a maximum of four messages (MFN^M08, MFN^M10, MFN^M04, MFN^M18).

**Update** – a Compendium Consumer will receive minimum of one (type varies) and maximum of four messages (MFN^M08, MFN^M10, MFN^M04, MFN^M18).

# 3.3 Message Use Examples

TABLE 3-2. MESSAGE USE EXAMPLES						
Scenario	MFN^M08	MFN^M10	MFN^M04	MFN^M18		
Individually Ordered (Atomic) Test	One record	N/A	One optional record, listing each CPT code for the Test.	One or more optional record(s), based on each diagnostic code that might be used for the test		
Panel	One record for each component test.	One record for the panel, references to each component test.	One record listing each CPT code for the panel.	One or more optional record(s), based on each diagnostic code that might be used for the panel		

TABLE 3-2. MESSAGE USE EXAMPLES								
Scenario	Scenario MFN^M08 MFN^M10 MFN^M04 MFN^M18							
Individually Ordered (Atomic) Test – Experimental	One Record	N/A	None	One or more optional record(s), based on each diagnostic code that might be used for the test				

#### 4 USE CASE – EXCHANGE OF DIRECTORY OF SERVICES

The Laboratory Test Compendium Framework, or Electronic Directory of Services (eDOS), defines the format to deliver the laboratory test menu offerings to systems that support electronic laboratory ordering, results reporting and other functionality.

This content will support the initial Laboratory Test Compendium build for each Compendium Consumer as well as on-going maintenance updates throughout the life of the interface. The Compendium Producer, in coordination with the consumer, will determine if a complete eDOS or a subset based on the specific consumer's ordering history is appropriate. The producer may also provide maintenance updates to the consumer based on the test ordering history of the consumer.

#### 4.1 Preface

The Use Cases describes:

- The operational context for the data exchange
- The stakeholders with an interest in the Use Case
- The information flows that must be supported by the data exchange
- The types of data and their specifications required in the data exchange

## 4.2 Scope

The scope of this Use Case is the electronic communication of a laboratory's directory of services (DOS) for the US Realm.

#### **4.2.1 IN SCOPE**

Highlights of the Laboratory Test Compendium Framework include the ability to communicate:

- Codesets used to order the laboratory tests (see Section 6 Code Systems and Value Sets).
- Descriptions of the laboratory tests.
- Effective date.
- Preferred name for test.
- Orderability of test (is the test orderable (y/n)).
- Nature of test (profile, single observation, etc.).
- Specimen requirements (including collection, storage and transportation instructions).
- Processing priorities (ability to order as stat, routine, or other priorities).
- Observation requirements (Ask at Order Entry (AOE) requirements).
- Reflex observations (list of what could be reflexed for this test).
- Test grouping requirements.
- Test components (analytes that will be included in the test).
- Procedure codes (CPT codes only).

#### 4.2.2 OUT OF SCOPE

- A method for requesting a test compendium or update.
- Application level acknowledgement.
- Automatic creation, selection and messaging of subsets of the test compendium, e.g., a subset for specific medical specialty.
- Application level maintenance processes relative to the receipt of an eDOS.
- The delivery mechanism has not been addressed in this document as existing technologies used for communication of laboratory orders and results messages already exist and can be adopted to accommodate an additional message to be delivered.

#### 4.3 Actors

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

In this IG the generic terms "Compendium Producer" and "Compendium Consumer" are used in lieu of more specific actors for flexibility, and because the eDOS IG might be used in other, yet undefined, scenarios in the future. For example, the IG could be used in lab information systems (LIS), health information exchanges (HIEs), or reference lab scenarios.

TABLE 4–1. ACTORS						
Actor Role Description						
Compendium Producer	eDOS Sender	A sender of messages that declares conformance to a profile defined in this guide, e.g.,. a Laboratory.				
Compendium Consumer	eDOS Requestor eDOS Receiver	A receiver of messages that declares conformance to a profile defined in this guide, e.g., an Ordering Provider's EHR system.				

# 4.4 Use Case and Context Diagrams

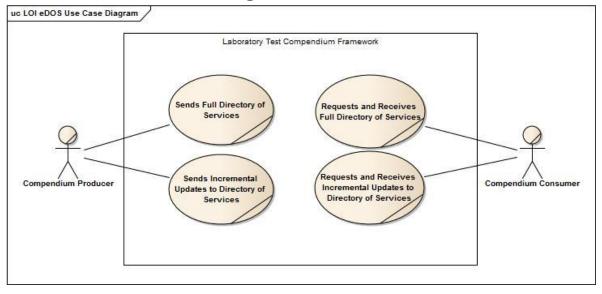


Figure 4-1. Use Case Diagram

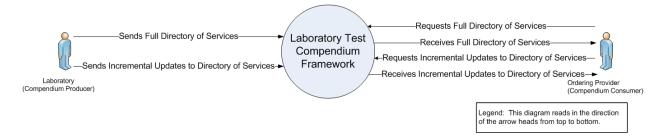


Figure 4-2. Context Diagram

# 4.5 Scenario 1 – Compendium Producer Sends Directory of Services to the Compendium Consumer

A Compendium Producer sends its Directory of Services electronically to a Compendium Consumer.

#### 4.5.1 USER STORY

A Compendium Producer and a Compendium Consumer agree to automate the process of delivering the eDOS. The initial build for a Compendium Consumer is the entire eDOS or a subset based on the Compendium Consumer's ordering history, specialty, etc., as agreed to between the Compendium Consumer and the Compendium Producer.

As scheduled or as requested, a Compendium Producer electronically sends the complete eDOS or subset. The eDOS is received and processed by a Compendium Consumer. If the Compendium Consumer is unable to process the file, or components of the file, they should notify the Compendium Producer immediately using their established escalation procedures<sup>5</sup>.

<sup>&</sup>lt;sup>5</sup> As noted in the Use Case Assumptions, this is not depicted in the following diagrams or flow, though establishing a consistent error escalation procedure is an important business requirement for success.

#### 4.5.2 ACTIVITY DIAGRAM

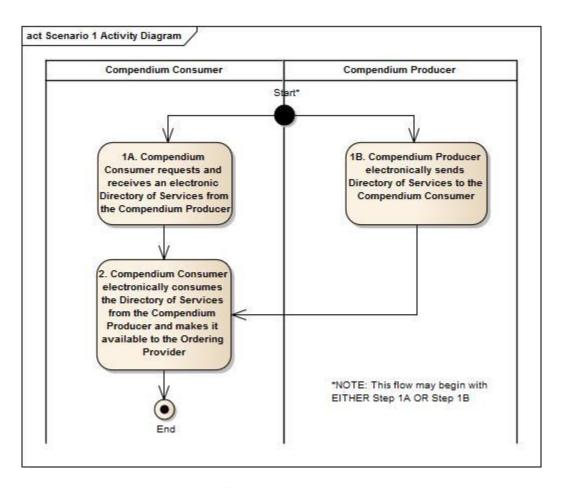


Figure 4-3. Scenario 1 Activity Diagram

#### 4.5.3 BASE FLOW

**Note:** This flow may begin with either Step 1A or Step 1B.

	TABLE 4–2. BASE FLOW						
Step	Actor	Role	Event/Description	Inputs	Outputs		
1A	Compendium Consumer	DOS Requestor, DOS Receiver	Compendium Consumer requests and receives an electronic Directory of Services from the Compendium Producer.	Electronic Directory of Services Request	Electronic Directory of Services		
1B	Compendium Producer	DOS Sender	Compendium Producer electronically sends Directory of Services to the Compendium Consumer.	Electronic Directory of Services	Electronic Directory of Services		
2	Compendium Consumer	DOS Receiver	Compendium Consumer electronically consumes the Directory of Services from the Compendium Producer and makes it available to the Ordering Provider.	Electronic Directory of Services	Directory of Services available electronically to Compendium Consumer		

#### 4.5.4 SEQUENCE DIAGRAM

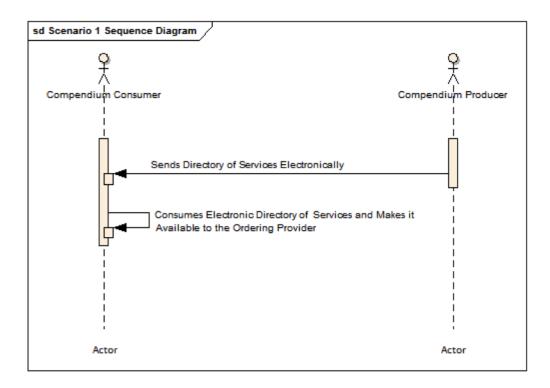


Figure 4-4. Scenario 1 Sequence Diagram

# 4.6 Scenario 2 – Compendium Producer Sends Incremental Updates to Compendium Consumer

A Compendium Producer sends incremental updates to its Directory of Services electronically to a Compendium Consumer.

#### 4.6.1 USER STORY

A Compendium Producer and a Compendium Consumer agree to automate the process of updating the Laboratory's Directory of Services throughout the life of the interface.

As scheduled or as requested, a Compendium Producer sends maintenance files containing additions, deactivations and/or updates (collectively called incremental updates), rather than the entire Directory of Services, to the Compendium Consumer. The information is received and processed by a Compendium Consumer. If the Compendium Consumer is unable to process the file, or components of the file, they should notify the Compendium Producer immediately using their established escalation procedures.

#### 4.6.2 ACTIVITY DIAGRAM

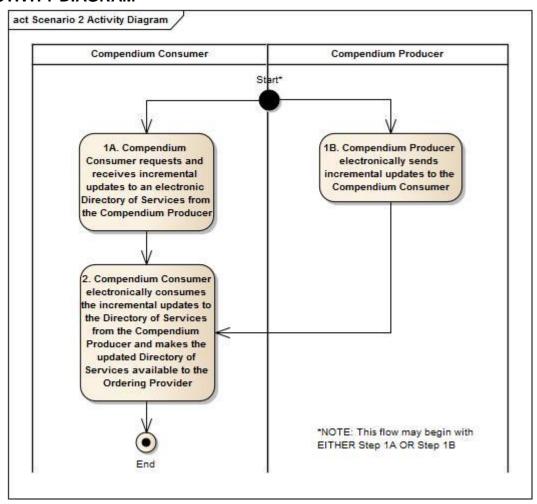


Figure 4-5. Scenario 2 Activity Diagram

#### 4.6.3 BASE FLOW

**Note:** This flow may begin with either Step 1A or Step 1B.

	TABLE 4–3. BASE FLOW						
Step	Actor	Role	Event/Description	Inputs	Outputs		
1A	Compendium Consumer	DOS Requestor, DOS Receiver	Compendium Consumer requests and receives incremental updates to an electronic Directory of Services from the Compendium Producer.	Incremental Updates to Electronic Directory of Services Request	Incremental Updates to Electronic Directory of Services		
1B	Compendium Producer	DOS Sender	Compendium Producer electronically sends incremental updates to the Compendium Consumer.	Incremental Updates to Electronic Directory of Services	Incremental Updates to Electronic Directory of Services		

	TABLE 4–3. BASE FLOW						
Step	Actor	Role	Event/Description	Inputs	Outputs		
2	Compendium Consumer	DOS Receiver	•	Incremental Updates to Electronic Directory of Services	Updated Directory of Services available electronically from Ordering Provider's EHR System (Compendium Consumer)		

#### 4.6.4 SEQUENCE DIAGRAM

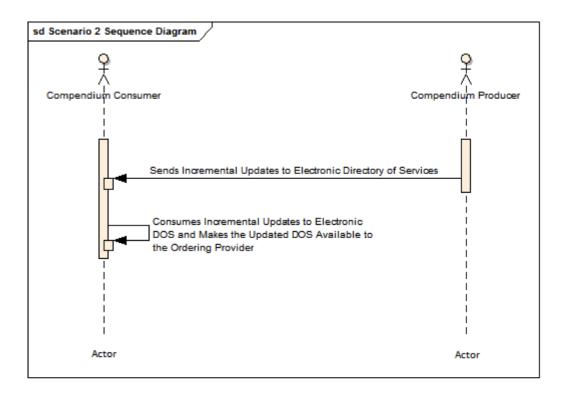


Figure 4-6. Scenario 2 Sequence Diagram

# 4.7 Functional Requirements

#### 4.7.1 INFORMATION INTERCHANGE REQUIREMENTS

In the following examples, the "Initiating System" EHR System is the "Compendium Consumer" and the LIS is the "Compendium Producer"

TABLE 4-4. INFORMATION INTERCHANGE REQUIREMENTS						
Initiating System	Initiating System   Action   Requirement   Action   Receiving System					
EHR System	Send	Request for Full Directory of Services or pre-defined subsets	Receive	LIS		
LIS	Receive	EHR System				

TABLE 4-4. INFORMATION INTERCHANGE REQUIREMENTS									
Initiating System	Action	Requirement	Action	Receiving System					
EHR System	Send	Request for Incremental Updates to Directory of Services	Receive	LIS					
LIS	Send	Incremental Updates to Directory of Services	Receive	EHR System					

## 4.7.2 SYSTEM REQUIREMENTS

TABLE 4-5. SYSTEM REQUIREMENTS							
System	Requirement						
LIS	Build Electronic Directory of Services; Process Request for Electronic Directory of Services from EHR System						
EHR System	Create Request for Electronic Directory of Services from LIS; Consume Electronic Directory of Services; Make Available Electronic Directory of Services for Ordering Providers						

## 5 DATA TYPES

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

Depending on the components used, the usage of data type components for some data types varies. To clearly indicate when to use specific data type components, each data type that has a varying definition based on profile will be documented with multiple flavors, e.g., CX\_GU vs. CX\_NG. Composite data types indicate which variety of the component's data type is applicable, while the data type of a field is marked as "varies" where the comment indicates the data type choices based on the declared profile or component.

## 5.1 CNE - Coded With No Exceptions

	TABLE 5-1. CODED WITH NO EXCEPTIONS (CNE)									
SEQ	Component Name	DT	Usage	Value Set	Comments					
1	Identifier	ST	R							
2	Text	ST	R							
3	Name of Coding System	ID	R	HL70396						
4	Alternate Identifier		0							
5	Alternate Text		0							
6	Name of Alternate Coding System		0							
7	Coding System Version ID	ST	RE							
8	Alternate Coding System Version ID		0							
9	Original Text		0							

# 5.2 CWE - Coded with Exceptions

## 5.2.1 CWE\_GEN - CODED WITH EXCEPTIONS - BASIC

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

	TABLE 5-2. CODED WITH EXCEPTIONS - BASE (CWE_GEN)								
SEQ	Component Name	DT	Usage	Value Set	Comments				
1	Identifier	ST	C(R/O)		Condition Predicate: if CWE.2 is not valued.				
2	Text	ST	C(R/RE)		Condition Predicate: if CWE.1 is not valued,				
3	Name of Coding System	ID	C(R/X)	HL70396	Condition Predicate: if CWE.1 is valued.				
4	Alternate Identifier		0						
5	Alternate Text		0						
6	Name of Alternate Coding System		0						
7	Coding System Version ID	ST	C(RE/X)		Condition Predicate: If CWE.3 (Name Of Coding System) is valued.				

	TABLE 5-2. CODED WITH EXCEPTIONS - BASE (CWE_GEN)								
SEQ	Component Name	DT	Usage	Value Set	Comments				
8	Alternate Coding System Version ID	ST	C(RE/X)		Condition Predicate: If CWE.6 (Name Of Alternate Coding System) is valued.				
9	Original Text		0						
10	Second Alternate Identifier		0						
11	Second Alternate Text		0						
12	Second Name of Alternate Coding System		0						
13	Second Alternate Coding System Version ID		0						
14	Coding System OID		0						
15	Value Set OID		0						
16	Value Set Version ID		0						
17	Alternate Coding System OID		0						
18	Alternate Value Set OID		0						
19	Alternate Value Set Version ID		0						
20	Second Alternate Coding System OID		0						
21	Second Alternate Value Set OID		0						
22	Second Alternate Value Set Version ID		0						

The CWE 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 data types with these values, this guide does not give preference to the triplet in which the standard code should appear.

# 5.2.2 CWE\_CRE - CODED WITH EXCEPTIONS - CODE REQUIRED, BUT MAY BE EMPTY

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

Т	TABLE 5-3. CODED WITH EXCEPTIONS - CODE REQUIRED BUT MAY BE EMPTY (CWE_CRE)								
SEQ	Component Name	DT	Usage	Value Set	Comments				
1	Identifier	ST	RE						
2	Text	ST	C(RE/X)		Condition Predicate: If CWE_CRE.1 (Identifier) is valued. It is strongly recommended that text be sent to accompany any identifier. When a coded value is not known, the original text element (CWE_CRE.9) is used to carry the text, not the text (CWE_CRE.2) element.				
3	Name of Coding System	ID	C(R/X)	HL70396	Condition Predicate: If CWE_CRE.1 (Identifier) is valued.				

Т	ABLE 5-3. CODED WIT	ΓH E>	CEPTIO	NS – CODI	REQUIRED BUT MAY BE EMPTY (CWE_CRE)
SEQ	Component Name	DT	Usage	Value Set	Comments
4	Alternate Identifier	ST	C(RE/X)		Condition Predicate: If CWE_CRE.1 (Identifier) is valued. The alternate identifier (from the alternate coding system) should be the closest match for the identifier found in CWE_CRE.1 (Identifier).
5	Alternate Text	ST	C(RE/X)		Condition Predicate: If CWE_CRE.4 (Alternate Identifier) is valued.  It is strongly recommended that alternate text be sent to accompany any alternate identifier.
6	Name of Alternate Coding System	ID	C(R/X)	HL70396	Condition Predicate: If CWE_CRE.4 (Alternate Identifier) is valued.
7	Coding System Version ID	ST	C(RE/X)		Condition Predicate: If CWE_CRE.3 (Name Of Coding System) is valued.
8	Alternate Coding System Version ID	ST	C(RE/X)		Condition Predicate: If CWE_CRE.6 (Name Of Alternate Coding System) is valued.
9	Original Text	ST	C(R/RE)		Condition Predicate: If CWE_CRE.1 (Identifier) and CWE.4_CRE (alternate identifier) are not valued.  Original Text is used to convey the text that was the basis for coding.  If neither the first or second triplet has values, this contains the text of the field.
10	Second Alternate Identifier		0		
11	Second Alternate Text		0		
12	Second Name of Alternate Coding System		0		
13	Second Alternate Coding System Version ID		0		
14	Coding System OID		0		
15	Value Set OID		0		
16	Value Set Version ID		0		
17	Alternate Coding System OID		0		
18	Alternate Value Set OID		0		
19	Alternate Value Set Version ID		0		
20	Second Alternate Coding System OID		0		
21	Second Alternate Value Set OID		0		
22	Second Alternate Value Set Version ID		0		

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

The CWE\_CRE 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\_CRE data types with these values, this guide does not give preference to the triplet in which the standard code should appear.

#### 5.2.3 CWE RC - CODED WITH EXCEPTIONS - REQUIRED COMPONENTS

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

	TABLE 5-4. CODED WITH EXCEPTIONS - REQUIRED COMPONENTS (CWE_RC)								
SEQ	Component Name	DT	Usage	Value Set	Comments				
1	Identifier	ST	R						
2	Text	ST	R						
3	Name of Coding System	ID	R	HL70396					
4	Alternate Identifier		0						
5	Alternate Text		0						
6	Name of Alternate Coding System		0						
7	Coding System Version ID	ST	RE						
8	Alternate Coding System Version ID		0						
9	Original Text		0						
10	Second Alternate Identifier		0						
11	Second Alternate Text		0						
12	Second Name of Alternate Coding System		0						
13	Second Alternate Coding System Version ID		0						
14	Coding System OID		0						
15	Value Set OID		0						
16	Value Set Version ID		0						
17	Alternate Coding System OID		0						
18	Alternate Value Set OID		0						
19	Alternate Value Set Version ID		0						
20	Second Alternate Coding System OID		0						
21	Second Alternate Value Set OID		0						
22	Second Alternate Value Set Version ID		0						

The CWE\_RC data type is used in OM1-2 Producer's Service/Test/Observation ID and OM1-7 Other Service/Test/Observation IDs for the Observation to support the HL7 Standard requirement that the first three components should be non-null.

#### 5.2.4 CWE\_RC1 - CODED WITH EXCEPTIONS - REQUIRED COMPONENTS

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

	TABLE 5-5. CODED WITH EXCEPTIONS - REQUIRED COMPONENTS (CWE_RC1)								
SEQ	Component Name	DT	Usage	Value Set	Comments				
1	Identifier	ST	R						
2	Text	ST	R						
3	Name of Coding System	ID	R	HL70396					
4	Alternate Identifier		RE						
5	Alternate Text		RE						
6	Name of Alternate Coding System		C(R/X)		Condition Predicate: if CWE_RC1.4 (Alternate Identifier) is valued.				
7	Coding System Version ID	ST	RE						
8	Alternate Coding System Version ID		C(RE/X)		Condition Predicate: If CWE_RC1.6 (Name Of Coding System) is valued.				
9	Original Text		0						
10	Second Alternate Identifier		0						
11	Second Alternate Text		0						
12	Second Name of Alternate Coding System		0						
13	Second Alternate Coding System Version ID		0						
14	Coding System OID		0						
15	Value Set OID		0						
16	Value Set Version ID		0						
17	Alternate Coding System OID		0						
18	Alternate Value Set OID		0						
19	Alternate Value Set Version ID		0						
20	Second Alternate Coding System OID		0						
21	Second Alternate Value Set OID		0						
22	Second Alternate Value Set Version ID		0						

#### **Usage Note**

The CWE\_RC1 data type is used in OM1-34 Reflex Tests/Observations and OM5-2 Tests/Observations Included Within an Ordered Test Battery to support the HL7 Standard

requirement that the first three components should be non-null, but allow communication of alternate codes at the same time.

#### 5.2.5 CWE\_CR - CODED WITH EXCEPTIONS - CODE REQUIRED

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

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

## **Usage Note**

The CWE\_CR 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\_CR 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\_CR-3 (Name of Coding System) and, if valued, CWE\_CR-6 (Alternate Name of Coding System) and, if valued, CWE\_CR-20 (Second Alternate Name of Coding System) to determine if it recognizes the coding system or value set.

## 5.3 CQ – Composite Quantity with Units

TABLE 5-7. COMPOSITE QUANTITY WITH UNITS (CQ)								
SEQ	Component Name	DT	Usage	Value Set	Comments			
1	Quantity	NM	R					
2	Units	CWE_GEN	RE					

## 5.4 CX – Extended Composite ID with Check Digit

#### 5.4.1 CX\_GU - EXTENDED COMPOSITE ID WITH CHECK DIGIT (GLOBALLY UNIQUE)

	TABLE 5-8. EXTENDED COMPOSITE ID WITH CHECK DIGIT (CX_GU)									
SEQ	Component Name	DT	Usage	Value Set	Comments					
1	ID Number	ST	R							
2	Check Digit		0							
3	Check Digit Scheme		C(O/X)							
4	Assigning Authority	HD_GU	R		The Assigning Authority component is used to identify the system, application, organization, etc. that assigned the ID Number in component 1.					
5	Identifier Type Code	ID	R	HL70203_USL						
6	Assigning Facility		0							
7	Effective Date		0							
8	Expiration Date		0							
9	Assigning Jurisdiction		0							
10	Assigning Agency or Department		0							

#### **Usage Note**

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

Although the Identifier Type Code component is required, it is not a part of the actual identifier. Rather, it is metadata about the identifier. The ID Number and Assigning Authority component,

together, constitute the actual identifier. The reason for this requirement is to promote forward compatibility with HL7 Version 3 identifiers, where there is no concept of identifier type codes.

# 5.4.2 CX\_NG - EXTENDED COMPOSITE ID WITH CHECK DIGIT (NON-GLOBALLY UNIQUE)

	TABLE 5-9. EXTENDED COMPOSITE ID WITH CHECK DIGIT (CX_NG)										
SEQ	Component Name	DT	Usage	Value Set	Comments						
1	ID Number	ST	R								
2	Check Digit	ST	0								
3	Check Digit Scheme		C(O/X)								
4	Assigning Authority	HD_NG	RE								
5	Identifier Type Code	ID	R	HL70203_USL							
6	Assigning Facility		0								
7	Effective Date		0								
8	Expiration Date		0								
9	Assigning Jurisdiction		0								
10	Assigning Agency or Department		0								

#### **Usage Note**

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

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

# 5.5 El\_GU – Entity Identifier – Globally Unique

	TABLE 5-10. ENTITY IDENTIFIER - GLOBALLY UNIQUE (EI_GU)									
SEQ	Component Name	DT	Usage	Value Set	Comments					
1	Entity Identifier	ST	R							
2	Namespace ID	IS	RE							
3	Universal ID	ST	R							
4	Universal ID Type	ID	R		Fixed to 'ISO'.					

## **Usage Note**

The EI\_GU 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: eDOS\_GU Profile (all message types)

eDOS-1: EI\_GU.3 (Universal ID) SHALL be valued with an ISO-compliant OID.

**eDOS-2**: EI\_GU.4 (Universal ID Type) **SHALL** be valued 'ISO' drawn from the HL7 Table HL70301.

## 5.6 HD\_GU – Hierarchic Designator

#### 5.6.1 HD GU - HIERARCHIC DESIGNATOR - GLOBALLY UNIQUE

	TABLE 5-11. HIERARCHIC DESIGNATOR - GLOBALLY UNIQUE (HD_GU)										
SEQ	SEQ Component Name DT Usage Value Set Comments										
1	Namespace ID	IS	RE		The value of HD_GU.1 reflects a local code that represents the combination of HD_GU.2 and HD_GU.3.						
2	Universal ID	ST	R								
3	Universal ID Type	ID	R		Fixed to 'ISO'.						

#### **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 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\_GU data type has been constrained to carry an OID identifying an application, a facility, or an assigning authority.

#### Conformance Statements: eDOS\_GU Profile (all message types)

eDOS-3: HD\_GU.2 (Universal ID) SHALL be valued with an ISO-compliant OID.

**eDOS-4**: HD\_GU.3 (Universal ID Type) **SHALL** be valued 'ISO' drawn from the HL7 Table HL70301.

#### 5.6.2 HD NG - HIERARCHIC DESIGNATOR - NON-GLOBALLY UNIQUE

	TABLE 5-12. HIERARCHIC DESIGNATOR - NON-GLOBALLY UNIQUE (HD_NG)											
SEQ	Component Name	DT	Usage	Value Set	Comments							
1	Namespace ID	IS	C(R/O)		Condition Predicate: If HD_NG.2 (Universal ID) is not valued.							
2	Universal ID	ST	C(R/O)		Condition Predicate: If HD_NG.1 (Namespace ID) is not valued.							
3	Universal ID Type	ID	C(R/X)		Condition Predicate: If HD_NG.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\_NG data type is used directly to identify objects such as applications or facilities. It is used also as a component of other data types, where it is typically an assigning authority for an identifier. Where this capability is used in this specification, the usage is described separately.

# 5.7 MO – Money

	TABLE 5–13. MONEY (MO)										
SEQ	Component Name	DT	Usage	Value Set	Comments						
1	Quantity	NM	R								
2	Denomination	ID	R								

## Conformance Statements eDOS\_Common\_Component (M18 messages only)

eDOS-38: MO.2 (Denomination) SHALL be valued 'USD' drawn from the HL7 Table HL70913.

## 5.8 MSG – Message Type

	TABLE 5–14. MESSAGE TYPE (MSG)										
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							

## 5.9 NR - Numeric Range

	TABLE 5-15. NUMERIC RANGE (NR)										
SEQ	Component Name	DT	Usage	Value Set	Comments						
1	Low Value	ID	RE		If the low value is unbounded, then the component is null.						
2	High Value	NM	RE		If the high value is unbounded, then the component is null.						

# 5.10 PT - Processing Type

	TABLE 5-16. PROCESSING TYPE (PT)										
SEQ	Component Name	DT	Usage	Value Set	Comments						
1	Processing ID	ID	R	HL70103_USL							
2	Processing Mode		0								

# 5.11 RFR - Reference Range

Note: CWE is pre-adopted from HL7 V2.7.1

	TABLE 5-17. RFR - REFERENCE RANGE										
SEQ	Component Name	DT	Usage	Value Set	Comments						
1	Numeric Range	NR	R								
2	Administrative Sex	CWE_GEN	RE	HL70001_USL							
3	Age Range		0								

	TABLE 5–17. RFR – REFERENCE RANGE										
SEQ	Component Name	DT	Usage	Value Set	Comments						
4	Gestational Age Range		0								
5	Species		0								
6	Race/subspecies	CWE_GEN	RE	HL70005_USL	More specific race values are available, but not limited to, those found in the CDCREC document: (http://www.cdc.gov/nchs/data/dvs/Race_Ethnicity_Co_deSet.pdf).						
7	Conditions	TX	0								

# 5.12 TS\_1 - Time Stamp 1

	TABLE 5-18. TIME STAMP 1 (TS_1)										
SEQ	Component Name	DT	Usage	Value Set	Comments						
1	Time	DTM	R								
2	Degree of Precision		Х		Excluded for this Implementation Guide, see Section 1.3.1.						
The D	ΓM component of this Time S	Stamp has	the following	ng constraints:							
	YYYY	DTM	R								
	MM	DTM	R								
	DD	DTM	R								
	НН	DTM	R								
	MM	DTM	R								
	SS	DTM	R								
	[.S[S[S[S]]]]		0								
	+/- ZZZZ		0								

## 5.13 VID - Version Identifier

	TABLE 5-19. VERSION IDENTIFIER (VID)										
SEQ	Component Name	DT	Usage	Value Set	Comments						
1	Version ID	ID	R								
2	Internationalization Code		0								
3	International Version ID		0								

## **Conformance Statement – eDOS\_Common\_Component (all message types)**

eDOS-5: VID.1 (Version Identifier) SHALL be valued '2.5.1' drawn from the HL7 Table HL70104.

# 5.14 XAD - Extended Address

	10.00								
		<b>TABLE</b>	5-20. E	XTENDED A	DDRESS (XAD)				
SEQ	Component Name	DT	Usage	Value Set	Comments				
1	Street Address	SAD	RE						
2	Other Designation		0						
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		0						
9	County/Parish Code		0						
10	Census Tract		0						
11	Address Representation Code		0						
12	Address Validity Range		Х		Excluded for this Implementation Guide, see Section 1.3.1.				
13	Effective Date		0						
14	Expiration Date		0						

## 6 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 following trigger events and messages are supported in this specification. Each of these messages must be supported but not all of them may be supplied, based on requirements defined by the laboratory. For example, the laboratory will always send an M08 but may not send associated M10, M04, and M18.

	TABLE 6-1. TRIGGER EVENTS AND MESSAGES							
Trigger Event Message Name								
M08	MFN^M08	Master File Notification – Test/Observation						
M10	MFN^M10	Master File Notification – Test/Observation Batteries						
M04	MFN^M04	Master File Notification – Charge Description						
M18	MFN^M18	Master File Notification – Test/Observation (Payer)						
MFK	MFK^M08^MFK MFK^M10^MFK MFK^M04^MFK MFK^M18^MFK	Message Acknowledgement						

## 6.1 MFN^M08^MFN\_M08 - Master File Notification - Test/Observation (Numeric)

This message is used to transmit Master File/compendium information on all tests/observations. The OM2 and OM3 segments were Conditional in Release 1 of this Implementation Guide, however, there is no data in the OM1 segment to indicate whether the OM2 or OM3 segment should be included, and occasionally, it is possible that some tests would include both the OM2 and OM3 segments. Therefore the OM2 and OM3 segment usage in Release 2 is "RE-Required but may be empty".

	TABLE 6-2. M08 - MASTER FILE NOTIFICATION - TEST/OBSERVATION (NUMERIC)								
Segment	Name	Usage	Cardinality	Description					
MSH	Message Header	R	[11]						
[{SFT}]	Software	0							
MFI	Master File Identification	R	[11]						
{	MF TEST Begin	R	[1*]						
MFE	Master File Entry	R	[11]						
OM1	General Segment (Fields That Apply to Most Observations)	R	[11]						
[{OMC}]	Supporting Clinical Information Segment	RE	[0*]	Pre-adopted from V2.8.2					
[{PRT}]	Participation	0		Pre-adopted from V2.8					
OM2	Numeric Observation Segment	RE	[01]						
OM3	Categorical Service/Test/Observation Segment	RE	[01]						
[{OM4}] Observations that Require Specimens		RE	[0*]	Pre-adopted cardinality from V2.8.					
}	MF TEST End								

## 6.2 MFN^M10^MFN\_M10 - Master File Notification - Test/Observation Batteries

This message is used to transmit Master File/compendium information on all grouped orderable items (batteries, panels, profiles, etc.).

	TABLE 6-3. M10 - MASTER FILE NOTIFICATION - TEST/OBSERVATION BATTERIES						
Segment	Name	Usage	Cardinality	Description			
MSH	Message Header	R	[11]				
[{SFT}]	Software	0					
MFI	Master File Identification	R	[11]				
{	MF BATTERY Begin	R	[1*]				
MFE	Master File Entry	R	[11]				
OM1	General Segment (Fields That Apply to Most Observations)	R	[11]				

	TABLE 6-3. M10 - MASTER FILE NOTIFICATION - TEST/OBSERVATION BATTERIES								
Segment	Name	Usage	Cardinality	Description					
[{PRT}]	Participation	0		Pre-adopted from V2.8					
[	BATTERY DETAIL Begin	R	[11]						
OM5	Observation Batteries (sets)	R	[11]						
[{OM4}]	Observations that Require Specimens	RE	[0*]						
]	BATTERY DETAIL End								
}	MF BATTERY End								

## 6.3 MFN^M04^MFN\_M04 - Charge Description Master File Message

This message is used to capture generic procedure codes (CPTs) to describe the billable activities performed with each orderable item.

**Note**: For the Lab Test Compendium, the Charge Description Master File Message (MFN^M04^MFN\_M04) must be sent after the test master updates for the Order Codes. It may also be necessary for the receiving system to update those records into their master file prior to uploading this file. This file will contain only the Order Code and the CPT codes assigned to that Order Code.

The NTE segment may also contain other information to the provider to convey other requirements or context. For example:

"Convey the status of Federal Drug Administration (FDA) approval of the test. For example, the test may have FDA approval but is not validated yet because of limited gathering of data to confirm the validity of the test."

	TABLE 6-4. M04 - CHARGE DESCRIPTION MASTER FILE MESSAGE								
Segment	Name	Usage	Cardinality	Description					
MSH	Message Header	R	[11]						
[{SFT}]	Software	0							
MFI	Master File Identification	R	[11]						
[{NTE}]	Notes and Comments	RE	[0*]	Pre-adopted from V2.8.1.					
{	MF_CDM Begin	R	[1*]						
MFE	Master File Entry	R	[11]						
[{NTE}]	Notes and Comments	RE	[0*]	Pre-adopted from V2.8.1.					

	TABLE 6-4. M04 - CHARGE DESCRIPTION MASTER FILE MESSAGE								
Segment	Usage	Cardinality	Description						
CDM	Charge Description Master	R	[11]						
[{NTE}]	Notes and Comments	RE	[0*]	Pre-adopted from V2.8.1.					
[{PRC}]	Price Segment	0							
}	MF_CDM End								

## 6.4 MFN^M18^MFN\_M18 - Master File Notification - Test/Observation (Payer)

Used to communicate payer policies specific to a payer, including limited coverage/approved coverage. This entire message, including specified segments (PM1, MCP, and DPS), is pre-adopted from V2.8.2

	TABLE 6-5. M18 - MASTER FILE NOTIFICATION - TEST/OBSERVATION (PAYER)								
Segment	Name	Usage	Cardinality	Description					
MSH	Message Header	R	[11]						
[{SFT}]	Software	0							
[UAC]	User Authentication Credential	0							
MFI	Master File Identification	R	[11]						
{	MF_PAYER Begin	R	[1*]						
MFE	Master File Entry	R	[11]						
{	PAYER MF Entry Begin	R	[1*]						
PM1	Payer Master File Segment	R	[11]	Pre-adopted from V2.8.2					
{	PAYER MF Coverage Begin	R	[1*]						
MCP	Master File Coverage Policy Segment	R	[11]	Pre-adopted from V2.8.2					
[{DPS}]	Diagnosis and Procedure Segment	0	[0*]	Pre-adopted from V2.8.2					
}	PAYER MF Coverage End								
}	PAYER MF Entry End								
}	MF_PAYER End								

## 6.5 MFK^VARIES^MFK\_M01

The HL7 Message Structure as defined in HL7 Table 0354 – Message Structure, which is used for Master File Acknowledgment by the M04, M08, M10, and M18 is the same structure: MFK\_M01. Trigger event acknowledgments are identified in the base standard as: MFK^M04^MFK\_M01, MFK^M08^MFK\_M01, MFK^M10^MFK\_M01, or MFK^M18^MFK\_M01.

	TABLE 6-6. MFK^MXX^MFK ABSTRACT MESSAGE SYNTAX									
Segment	Name	Usage	Cardinality	Description						
MSH	Message Header	R	[11]	The message header (MSH) segment contains information describing how to parse and process the message. This includes identification of message delimiters, sender, receiver, message type, timestamp, etc.						
[{SFT}]	Software Segment	0								
MSA	Message Acknowledgment	R	[11]	The Message Acknowledgment Segment (MSA) contains the information sent as acknowledgment to the order message received by a LIS or EHR-S.						
[{ERR }]	Error	C(R/O)	[0*]	Condition predicate: If MSA-1 (Message Acknowledgement) is not valued AA or CA.						
MFI	Master File Identification	R	[11]							
[{MFA]}	Master File ACK segment	0								

## 6.6 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 optional segments that are brought forward from the base will have to be used within the constraints set forth in this guide, and agreement about the respective data type flavor to use needs to be reached.

#### 6.6.1 MSH - MESSAGE HEADER SEGMENT

	TABLE 6-7. MESSAGE HEADER SEGMENT (MSH)								
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Comment			
1	Field Separator	ST	R	[11]					

			TABL	E 6-7. MESS	AGE HEADE	R SEGMENT (MSH)
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Comment
2	Encoding Characters	ST	R	[11]		Constrained to the literal values '^~\&' or '^~\&#', always appearing in the same order.</td></tr><tr><td>3</td><td>Sending Application</td><td>Varies</td><td>RE</td><td>[01]</td><td>HL70361_USL</td><td>Field that may be used to identify the sending application uniquely for messaging purposes. If populated, it will contain an OID or other unique identifier that represents the sending application instance.  GU Data Type: HD_GU  NG Data Type: HD_NG</td></tr><tr><td>4</td><td>Sending Facility</td><td>Varies</td><td>R</td><td>[11]</td><td>HL70362_USL</td><td>GU Data Type: HD_GU NG Data Type: HD_NG If acknowledgments are in use, this facility will receive any related acknowledgment message.</td></tr><tr><td>5</td><td>Receiving Application</td><td></td><td>0</td><td></td><td></td><td></td></tr><tr><td>6</td><td>Receiving Facility</td><td>Varies</td><td>RE</td><td>[01]</td><td>HL70362_USL</td><td>GU Data Type: HD_GU NG Data Type: HD_NG If acknowledgments are in use, this facility originates any related acknowledgment message.</td></tr><tr><td>7</td><td>Date/Time Of Message</td><td>TS_1</td><td>R</td><td>[11]</td><td></td><td>Date of when the file was created.  If the time zone offset is included in MSH-7 it becomes the default time zone for the message instance and applies to all other date/time fields in that same message instance where a time zone offset is not valued.</td></tr><tr><td>8</td><td>Security</td><td></td><td>0</td><td></td><td></td><td></td></tr><tr><td>9</td><td>Message Type</td><td>MSG</td><td>R</td><td>[11]</td><td></td><td></td></tr><tr><td>10</td><td>Message Control ID</td><td>ST</td><td>R</td><td>[11]</td><td></td><td>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.</td></tr><tr><td>11</td><td>Processing ID</td><td>PT</td><td>R</td><td>[11]</td><td></td><td></td></tr><tr><td>12</td><td>Version ID</td><td>VID</td><td>R</td><td>[11]</td><td></td><td></td></tr></tbody></table>

	TABLE 6-7. MESSAGE HEADER SEGMENT (MSH)								
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Comment			
13	Sequence Number		0						
14	Continuation Pointer		0						
15	Accept Acknowledgment Type		0						
16	Application Acknowledgment Type		0						
17	Country Code		0						
18	Character Set		0						
19	Principal Language Of Message		0						
20	Alternate Character Set Handling Scheme		0						
21	Message Profile Identifier	EI_GU	R	[1*]		The sender asserts that the message conforms to a given profile and/or valid combination of components.			

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

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

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

The table below indicates valid MSH-21 combinations for declaring conformance to a particular eDOS profile or eDOS components.

	TABLE 6-8. MSH 21 EDOS PROFILE COMBINATIONS									
eDOS Profile Pre-Coordinated OID Component OIDs Component Name										
eDOS GU Profile	2.16.840.1.113883.9.70	2.16.840.1.113883.9.67 2.16.840.1.113883.9.68	eDOS Common_Component eDOS GU_Component							
eDOS_NG Profile	2.16.840.1.113883.9.71	2.16.840.1.113883.9.67 2.16.840.1.113883.9.69	eDOS_Common_Component eDOS_NG_Component							

	TABLE 6-8. MSH 21 EDOS PROFILE COMBINATIONS									
eDOS Profile	Pre-Coordinated OID	Component OIDs	Component Name							
eDOS_GU_Response_Profile	2.16.840.1.113883.9.75	2.16.840.1.113883.9.72 2.16.840.1.113883.9.73	eDOS_Acknowledgement_Component eDOS_GU_Acknowledgement_Component							
eDOS_NG_Response_Profile	2.16.840.1.113883.9.76	2.16.840.1.113883.9.72 2.16.840.1.113883.9.74	eDOS_Acknowledgement_Component eDOS_NG_Acknowledgement_Component							

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

• LAB\_XO\_Component (Exclusions)

## **Examples**

#### eDOS\_NG\_Profile Using Component OIDs

```
MSH...||||eDOS_Common_Component^^2.16.840.1.113883.9.67^ISO~eDOS_NG_Component^^2.16.84 0.1.113883.9.69^ISO
```

#### eDOS\_NG\_Profile using Pre-Coordinated Profile OID

```
MSH...||||eDOS_NG Profile^^2.16.840.1.113883.9.71^ISO
```

#### Conformance Statements eDOS Common Component (all message types)

**eDOS-6**: MSH-1 (Field Separator) **SHALL** contain the constant value '|'.

eDOS-7: MSH-2 (Encoding Characters) SHALL contain the constant value '^~\&' or the constant value '^~\&#'.

eDOS-8: MSH-12.1 (Version ID. Version ID) SHALL contain the constant value '2.5.1'.

## Conformance statements eDOS\_GU\_PROFILE (all message types)

**eDOS-11:** An occurrence of MSH-21 (Message Profile Identifier) **SHALL** be valued with '2.16.840.1.113883.9.70' (eDOS\_GU\_PROFILE) or two occurrences **SHALL** be valued with '2.16.840.1.113883.9.67' (eDOS\_COMMON\_COMPONENT) and '2.16.840.1.113883.9.68' (eDOS\_GU\_COMPONENT) in any order.

## Conformance Statements eDOS\_NG\_PROFILE (all message types)

**eDOS-12:** An occurrence of MSH-21 (Message Profile Identifier) **SHALL** be valued with '2.16.840.1.113883.9.71' (eDOS\_NG\_PROFILE) or two occurrences **SHALL** be valued with '2.16.840.1.113883.9.67' (eDOS\_COMMON\_COMPONENT) and '2.16.840.1.113883.9.69' (eDOS\_NG\_COMPONENT) in any order.

## Conformance Statements LAB\_XO\_Component (all message types)

eDOS-13: An occurrence of MSH-21 (Message Profile Identifier) SHALL be valued with '2.16.840.1.113883.9.23'.

## Conformance Statements eDOS\_Common\_Component - All Messages

eDOS-39: MSH-9.1 (Message Code) SHALL be valued 'MFN' drawn from the HL7 Table HL70076.

#### Conformance Statements eDOS\_Common\_Component (M04 Message only)

eDOS-40: MSH-9.2 (Trigger Event) SHALL be valued 'M04" drawn from the HL7 Table HL70003.

eDOS-41: MSH-9.3 (Message Structure) SHALL be valued 'MFN M04' drawn from HL7 Table HL70354.

#### Conformance Statements eDOS\_Common\_Component (M08 Message only)

eDOS-42: MSH-9.2 (Trigger Event) SHALL be valued 'M08' drawn from the HL7 Table HL70003.

eDOS-43: MSH-9.3 (Message Structure) SHALL be valued "MFN M08" drawn from the HL7 Table HL70354.

## Conformance Statements eDOS\_Common\_Component (M10 Message only)

eDOS-44: MSH-9.2 (Trigger Event) SHALL be valued 'M10' drawn from the HL7 Table "HL70003.

eDOS-45: MSH-9.3 (Message Structure) SHALL be valued 'MFN M10' drawn from the HL7 Table HL70354.

#### Conformance Statements eDOS Common Component: (M18 Message only)

eDOS-46: MSH-9.2 (Trigger Event) SHALL be valued 'M18' drawn from the HL7 Table HL70003.

eDOS-47: MSH-9.3 (Message Structure) SHALL be valued 'MFN M18' drawn from the HL7 Table HL70354.

## Conformance Statements MFK - eDOS\_GU\_RESPONSE\_PROFILE (all message types)

**eDOS-19:** An occurrence of MSH-21 (Message Profile Identifier) **SHALL** be valued with '2.16.840.1.113883.9.75' (eDOS\_GU\_RESPONSE\_PROFILE) or two occurrences **SHALL** be valued with '2.16.840.1.113883.9.72' (eDOS\_ACKNOWLEDGEMENT\_COMPONENT) and '2.16.840.1.113883.9.73' (eDOS\_GU\_ACKNOWLEDGEMENT\_COMPONENT) in any order.

## Conformance Statement MFK - eDOS\_NG\_RESPONSE\_PROFILE (all message types)

**eDOS-20:** An occurrence of MSH-21 (Message Profile Identifier) **SHALL** be valued with '2.16.840.1.113883.9.76' (eDOS\_NG\_RESPONSE\_PROFILE) or two occurrences **SHALL** be valued with '2.16.840.1.113883.9.72' (eDOS\_ACKNOWLEDGEMENT\_COMPONENT) and '2.16.840.1.113883.9.74' (eDOS\_NG\_ACKNOWLEDGEMENT\_COMPONENT) in any order.

## Conformance Statements eDOS\_Acknowledgement\_Component (All Acknowledgement Messages)

eDOS-48: MSH-9.1 (Message Code) SHALL be valued 'MFK' drawn from the HL7 Table HL70076.

## Conformance Statements eDOS\_Acknowledgement\_Component (M04 Acknowledgement Message only)

eDOS-49: MSH-9.2 (Trigger Event) SHALL be valued 'M04' drawn from the HL7 Table HL70003.

eDOS-50: MSH-9.3 (Message Structure) SHALL be valued 'MFK M01' drawn from the HL7 Table HL70354.

## Conformance Statements eDOS\_Acknowledgement\_Component (M08 Acknowledgement Message only)

eDOS-51: MSH-9.2 (Trigger Event) SHALL be valued 'M08' drawn from the HL7 Table HL70003.

eDOS-52: MSH-9.3 (Message Structure) SHALL be valued 'MFK M01' drawn from the HL7 Table HL70354.

## Conformance Statements eDOS\_Acknowledgement\_Component (M10 Acknowledgement Message only)

eDOS-53: MSH-9.2 (Trigger Event) SHALL be valued 'M10' drawn from the HL7 Table HL70003.

eDOS-54: MSH-9.3 (Message Structure) SHALL be valued 'MFK M01' drawn from the HL7 Table HL70354.

## Conformance Statements eDOS\_Acknowledgement\_Component (M18 Acknowledgement Message only)

eDOS-55: MSH-9.2 (Trigger Event) SHALL be valued 'M18' drawn from the HL7 Table HL70003.

eDOS-56: MSH-9.3 (Message Structure) SHALL be valued 'MFK M01' drawn from the HL7 Table HL70354.

#### 6.6.2 MSA – ACKNOWLEDGEMENT SEGMENT

	TABLE 6-9. ACKNOWLEDGMENT SEGMENT (MSA)										
SEQ Element Name DT Usage Cardinality Value Set Description/Comments											
1	Acknowledgment Code	ID	R	[11]	HL70008_USL						
2	Message Control ID	ST	R	[11]							

	TABLE 6-9. ACKNOWLEDGMENT SEGMENT (MSA)									
SEQ Element Name DT Usage Cardinality Value Set Description/Comments										
3	Text Message		Х			Excluded for this Implementation Guide, see Section 1.3.1.				
4	Expected Sequence Number		0							
5	Delayed Acknowledgment Type		Х			Excluded for this Implementation Guide, see Section 1.3.1.				
6	Error Condition		Х			Excluded for this Implementation Guide, see Section 1.3.1.				

#### 6.6.3 ERR - ERROR SEGMENT

	TABLE 6–10. ERROR SEGMENT (ERR)										
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments					
1	Error Code and Location		Х			Excluded for this Implementation Guide, see Section 1.3.1.					
2	Error Location		0								
3	HL7 Error Code	CWE_CR1	R	[11]	HL70357_USL						
4	Severity	ID	R	[11]	HL70516_USL						
5	Application Error Code		0								
6	Application Error Parameter		0								
7	Diagnostic Information	TX	RE	[01]							
8	User Message		0								
9	Inform Person Indicator		0								
10	Override Type		0								
11	Override Reason Code		0								
12	Help Desk Contact Point		0								

#### 6.6.4 MFI – MASTER FILE IDENTIFICATION SEGMENT

			TABLE 6	5-11. MASTE	R FILE IDENT	TIFICATION (MFI)
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Comment
1	Master File Identifier	CWE_GEN	R	[11]	HL70175_USL	Example of populated CWE: OMC^Observation batteries master file^HL70175.
2	Master File Application Identifier		0			
3	File-Level Event Code	ID	R	[11]	HL70178_USL	Pre-adopted from V2.6.  Note: The replace option allows the sending system to replace a file without sending delete record-level events for each record in that file. UPD means that the events are defined according to the record-level event code contained in each MFE segment in that message.
4	Entered Date/Time		0			
5	Effective Date/Time		Х			
6	Response Level Code	ID	R	[11]		This Response Level Code acknowledgement type should be consistent with communication processes already established for orders and/or results interfaces.

#### **Conformance Statements**

## eDOS\_Common\_Component (M04 message only)

eDOS-25: MFI-1.1 (Identifier) SHALL be valued 'CDM' drawn from the HL7 Table HL70175.

## Conformance Statements eDOS\_Common\_Component (M08 message only)

eDOS-26: MFI-1.1 (Identifier) SHALL be valued 'OMA' or 'OMM' drawn from the HL7 Table HL70175.

## Conformance Statements eDOS\_Common\_Component (M10 message only)

eDOS-27: MFI-1.1 (Identifier) SHALL be valued 'OMC' or 'OMM' drawn from the HL7 Table HL70175.

#### Conformance Statements eDOS\_Common\_Component (M18 message only)

eDOS-28: MFI-1.1 (Identifier) SHALL be valued 'MLCP' or 'MACP' drawn from the HL7 Table HL70175.

#### 6.6.5 MFE - MASTER FILE ENTRY SEGMENT

	TABLE 6–12. MASTER FILE ENTRY (MFE)										
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Comment					
1	Record-Level Event Code	ID	R	[11]	HL70180_USL	This field will be used to Add, Update, Deactivate, or Reactivate a test code. Delete has been removed due to historical needs.					
2	MFN Control ID	ST	C(R/O)	[01]		Condition Predicate: Required if MFI-6 Response Level Code is any value other than 'NE'.					
3	Effective Date/Time	TS_1	R	[11]							
4	Primary Key Value – MFE	CWE_RC	R	[11]	9999						
5	Primary Key Value Type	ID	R	[11]							

#### **Conformance Statements**

## eDOS\_Common\_Component (all message types)

eDOS-30: MFE-5 (Primary Key Value Type) SHALL be valued 'CWE' drawn from the HL7 Table HL70355.

#### 6.6.6 OM1 - GENERAL SEGMENT

	TABLE 6-13. GENERAL SEGMENT (OM1)								
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Comment			
1	Sequence Number - Test/Observation Master File	NM	R	[11]					
2	Producer's Service/Test/Observation ID	CWE_RC	R	[11]	9999				
3	Permitted Data Types		0						
4	Specimen Required	ID	R	[11]	HL70136_USL	This will be Y(es) for orderable tests. This may be N(o) for non-orderable components, like laboratory-performed calculations, administrative tests (24 hr urine volume).			
5	Producer ID	CWE_GEN	R	[11]	9999				
6	Observation Description		0						

		TABLE 6-	13. GEN	IERAL SEGM	ENT (OM1)	
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Comment
7	Other Service/Test/Observation IDs for the Observation	CWE_RC	RE	[0*]	9999	Pre-adopt V2.8 definition.  For eDOS this field should be limited to other IDs associated with OM1-2 (Producer's Service/Test/Observation ID) that are order codes and may appear in OBR-4 (Universal Service Identifier) in an order message. Other IDs associated with OM1-2 (Producer's Service/Test/Observation ID) that are result codes and may appear in OBX-3(Observation Identifier) in a results message should be listed in OM1-56 (Observation Identifier(s) associated with Producer's Service/Test/Observation ID).
8	Other Names		Х			Excluded for this Implementation Guide, see Section 1.3.1.
9	Preferred Report Name for the Observation	ST	RE	[01]		
10	Preferred Short Name or Mnemonic for Observation	ST	C(R/O)	[01]		Condition Predicate: If OM1-9 (Preferred Report Name for the Observation) and OM1-11 (Preferred Long name for the observation are not valued.
11	Preferred Long Name for the Observation	ST	C(R/O)	[01]		Condition Predicate: If OM1-9 (Preferred Report Name for the Observation) and OM1-10 (Preferred Short Name or Mnemonic for Observation) are not valued.
12	Orderability	ID	R	[11]	HL70136_USL	
13	Identity of Instrument Used to Perform this Study		0			
14	Coded Representation of Method		0			
15	Portable Device Indicator		0			
16	Observation Producing Department/Section		Х			Excluded for this Implementation Guide, see Section 1.3.1.
17	Telephone Number of Section		0			
18	Nature of Service/Test/Observation	IS	R	[11]	HL70174_USL	
19	Report Subheader		0			
20	Report Display Order		0			

		TABLE 6-	13. GEN	IERAL SEGMI	ENT (OM1)	
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Comment
21	Date/Time Stamp for any change in Definition for the Observation		0			
22	Effective Date/Time of Change		0			
23	Typical Turn-Around Time		Х			Excluded for this Implementation Guide, see Section 1.3.1.
24	Processing Time		0			
25	Processing Priority		0			
26	Reporting Priority		0			
27	Outside Site(s) Where Observation may be Performed		Х			Excluded for this Implementation Guide, see Section 1.3.1.
28	Address of Outside Site(s)		Х			Excluded for this Implementation Guide, see Section 1.3.1.
29	Phone Number of Outside Site		Х			Excluded for this Implementation Guide, see Section 1.3.1.
30	Confidentiality Code		0			
31	Observations Required to Interpret the Observation		Х			Excluded for this Implementation Guide, see Section 1.3.1.
32	Interpretation of Observations	TX	RE	[01]		Examples of information included in this field are Clinical Significance, Additional Notes, and Compliance Remarks.
33	Contraindications to Observations	CWE_GEN	RE	[0*]	9999	Examples of information included in this field are Limitations or Contraindications that may affect the observations.  Pre-adopt V2.8 cardinality.
34	Reflex Tests/Observations	CWE_RC1	RE	[0*]	9999	This field contains all potential reflex tests for this test/observation.
35	Rules that Trigger Reflex Testing	TX	RE	[0*]		This repeating field refers to the corresponding position within OM1-34 (Reflex Tests/Observations). For example, the third member of this field identifies the conditions for the third reflex test listed in OM1-34.  Pre-adopt V2.8 cardinality.
36	Fixed Canned Message		0			

		TABLE 6	-13. GEN	IERAL SEGM	ENT (OM1)	
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Comment
37	Patient Preparation	TX	RE	[0*]		This field indicates any patient preparation required prior to collecting the specimen(s) for this observation. For example, 'Patient fasting required for 12 hours'.  Pre-adopt V2.8 cardinality.
38	Procedure Medication		0			
39	Factors that may Affect the Observation	TX	RE	[01]		This field shall contain information such as Causes for Rejection (i.eHemolyzed sample, Quantity not sufficient, Clotted sample, etc.).
40	Service/Test/Observation Performance Schedule	ST	RE	[0*]		An example of a performance schedule may be 'every Monday, Wednesday, Friday'. Other ways that this might be displayed are 'Mon, Wed, Fri' or 'M, W, F.'
41	Description of Test Methods		0			
42	Kind of Quantity Observed		0			
43	Point Versus Interval		0			
44	Challenge Information		0			
45	Relationship Modifier		0			
46	Target Anatomic Site Of Test		0			
47	Modality Of Imaging Measurement		0			
48	Exclusive Test	ID	RE	[01]	HL70919_USL	Pre-adopted from V2.8.
49	Diagnostic Service Sector ID	ID	RE	[01]	HL70074_USL	Pre-adopted from V2.8.  ACLA recommends referring to HL7 Table 0074 Diagnostic Service Sector ID. This is consistent with messaging in OBR-24 for orders and results.
50	Taxonomic Classification Code		0			
51	Other Names	ST	RE	[0*]		Pre-adopted V2.8 deprecation of OM1-8 (Other Names) in favor of OM1-51 (Other Names). List all alias names for the test.

		TABLE 6-	13. GEN	IERAL SEGM	ENT (OM1)	
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Comment
52	Replacement Producer's Service/Test/Observation ID	CWE_RC	C(RE/O)	[0*]	9999	Condition Predicate: If MFE-1 = 'MDC' Pre-adopted from V2.8.1.
53	Prior Results Instructions	TX	RE	[0*]		Pre-adopted from V2.8.1.
54	Special Instructions	TX	RE	[0*]		Pre-adopted from V2.8.1.
55	Test Relationship Category	CWE_GEN	RE	[0*]		Pre-adopted from V2.8.1.
56	Observation Identifier associated with Producer's Service/Test/Observation ID	CWE_CR	RE	[01]	9999	Pre-adopted from V2.8.2 This field contains the code for results, which are associated with the Producer's Service/Test/Observation ID code in OM1-2 and will appear in OBX-3 Observation Identifier in a result message.
57	Expected Turn-Around Time	CQ	RE	[01]		Pre-adopted from V2.82 This field is a replacement for OM1-23 (Typical Turn-Around Time), removes reporting restriction of minutes. This field contains the typical processing time for single test/observation. This field indicates the time from the delivery of a specimen or transport of a patient to a diagnostic service and the completion of the study. It includes the usual waiting time.
58	Gender Restriction	CWE_GEN	RE	[0*]	HL70001_USL	Pre-adopted from V2.8.2
59	Age Restriction	NR	RE	[0*]		Pre-adopted from V2.8.2

#### OM1-1 - Sequence Number - Test/Observation Master File

The OM1-1 contains a numeric value that indicates a unique set of OM1, OM2, OM3 and OM4 components; each OM*n*-1 in a set will have the same value as illustrated in the example below. Because the OM4 segment can repeat, but needs to have a unique number for use with OM4-17, the sequence number must be appended with a sequence number as shown in the second example below:

## **Example**

```
MSH|...<cr>
// start MFE Test Begin group
MFE|A|...<cr>
OM1|1|...<cr>
OM2|1|...<cr>
OM3|1|...<cr>
OM4|1|...<cr>
// end MFE Test Begin group
// start MFE Test Begin group
MFE|A|...<cr>
OM1|2|...<cr>
OM2|2|...<cr>
OM3|2|...<cr>
OM4|2.1|...<cr>
OM4|2.2|...<cr>
//end MFE Test Begin group
```

#### **OM1-2 – Producer's Service/Test/Observation ID**

The OM1-2 (Producer's Service/Test/Observation ID) contains the laboratory's primary ID for the order code.

#### OM1-7 – Other Service/Test/Observation

The OM1-7 (Other Service/Test/Observation) ID(s) for the Observation field contains any alternate IDs for the same order code. The CWE\_RC.3 and CWE\_RC.6 components of the data type can be used to identify the Laboratory that assigned the code.; e.g., 99lab or similar. LOINC codes are identified with LN as the coding system.

The field use will be:

Primary Identifier for the Laboratory Order Code<sup>^</sup>Official Name Given by Receiver of Order for this Lab Test<sup>^</sup>ID S

## **Example**

```
123456789<sup>^</sup>Glucose, Serum<sup>^</sup>991ab
24338-6<sup>^</sup>Gas panel in Blood<sup>^</sup>LN
```

#### OM1-27 – Outside Site(s) Where Observation may be Performed

Deprecated; this IG uses the PRT segment.

#### OM1-28 – Address of Outside Site(s)

Deprecated; this IG uses the PRT segment.

## **OM1-29 – Phone Number of Outside Site**

Deprecated; this IG uses the PRT segment.

## **OM1-31** – Observations Required to Interpret the Observation

Deprecated; this IG pre-adopts the use of the OMC segment from V2.8.2, see Section 6.6.13.

## Conformance Statements (all message types)

eDOS-31: OM1-2 (Producer's Service/Test/Observation ID) SHALL match MFE-4 (Primary Key Value – MFE) in M08 and M10.

#### Conformance Statements (M08 messages only)

**eDOS-32**: If MSH-9.2 (Message Type.Trigger Event) is valued 'M08' then OM1-18 (Nature of Service/Test/Observation) **SHALL** be valued 'A' or 'C'.

## **Conformance Statements (M10 messages only)**

**eDOS-33:** If MSH-9.2 (Message Type.Trigger Event) is valued 'M10' then OM1-18 (Nature of Service/Test/Observation) **SHALL** be valued 'F', 'S', or 'P'.

#### 6.6.7 OM2 - NUMERIC OBSERVATION SEGMENT

This segment is applicable to the Test/Observation (Numeric) (Event M08); see Section 5.1. It can be applied to the following observation batteries types (A, C) as defined in OM1-18 - Nature of Service/Test/Observation.

Code	Description
Α	Atomic service/test/observation (test code).
С	Single observation calculated via a rule or formula from other independent observations (e.g., Globulin or Albumin/Globulin Ratio).

	TABLE 6-14. NUMERIC OBSERVATION SEGMENT (OM2)							
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Comment		
1	Sequence Number - Test/Observation Master File	NM	R	[11]				
2	Units of Measure	CWE_CRE	RE	[01]	9999			
3	Range of Decimal Precision		0					
4	Corresponding SI Units of Measure		0					
5	SI Conversion Factor		0					
6	Reference (Normal) Range for Ordinal and Continuous Observations	RFR	RE	[0*]				
7	Critical Range for Ordinal and Continuous Observations	RFR	RE	[0*]				
8	Absolute Range for Ordinal and Continuous Observations	RFR	RE	[0*]				
9	Delta Check Criteria		0					
10	Minimum Meaningful Increments		0					

#### **OM2-2** – Units of Measure

The OM2-2 (Units of Measure) value is identified by the sender of the compendium. The Units of Measure (UoM) coding system shall be identified in the third component of the CWE data type. However, UCUM is recommended.

UCUM (Unified Code for Units of Measure) is the preferred standard for reporting units of measure when it is supported by the analytic procedure's documentation for an FDA 510k approved method. (Note: the FDA approved units must be used for reporting, regardless of the standard used) While this version of the guide does not require UCUM reporting units for test results, we encourage moving to the UCUM standard over time.

When processing HL7 results electronically, the OBX-6 Units value shall take precedence over the value contained in the compendium for the identified result code.

#### **Legend for Examples**

```
UoM Value^Text^Coding System
```

#### **Example**

```
mg/dL^milligrams per deciliter^UCUM
meq/L^milliequivalent per liter^UCUM
mg/g{creat}^milligram per gram of creatinine^UCUM
a^year^UCUM
[lb_av]^pound^UCUM
```

If the UoM is specific to the sending laboratory and does not apply to an industry accepted standard, the UoM code system shall be identifed as 'L' or '99zzz', where zzz are 3 characters as specified by HL7 Vocabulary Table 0396 to identify the (local) Name of Coding System (ID) as shown in the example below.

#### **Example**

```
IV^Index Value^99LAB
```

#### OM2-6 - Reference (Normal) Range for Ordinal and Continuous Observations

The OM2-6 (Reference (Normal) Range for Ordinal and Continuous Observations) field is repeating and shall repeat for every occurrence of a normal reference range identified in the associated OM1 segment.

Reference Ranges are applicable to the result code level. When processing HL7 results electronically, the OBX.7 Reference Ranges value shall take precedence over the value contained in the compendium for the identified result code.

#### 6.6.8 OM3 - CATEGORICAL SERVICE/TEST/OBSERVATION SEGMENT

	TABLE 6-15. CATEGORICAL SERVICE/TEST/OBSERVATION SEGMENT (OM3)								
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Comment			
1	Sequence Number - Test/Observation Master File	NM	R	[11]					
2	Preferred Coding System		0						
3	Valid Coded "Answers"		0						
4	Normal Text/Codes for Categorical Observations	CWE_GEN	RE	[0*]	9999	Identifes the result(s) that are expected to be normal for that test. Example: A drug screen with an expected result of Negative. This is a repeating field and multiple normal text answers are possible.			
5	Abnormal Text/Codes for Categorical Observations	CWE_GEN	RE	[0*]	9999	Identifies the result(s) that are expected to be abnormal for that test. Example: A drug screen with an expected result of negative could have values as 'Positive' or 'Equivocal' for the abnormal value. This is a repeating field and multiple abnormal text answers are possible.			
6	Critical Text/Codes for Categorical Observations		0						
7	Value Type	ID	RE	[01]	HL70125_USL	Declares the Data Value Type as it will be defined in OBX-2 of the result message.			

#### 6.6.9 OM4 - OBSERVATIONS THAT REQUIRE SPECIMENS SEGMENT

If multiple kinds of specimen are associated with this observation (as in the case for a creatinine clearance), multiple segments may be included, one for each specimen type.

This segment will also allow for reporting Preferred and Alternate specimens, when applicable.

	TABLE 6-16. OBSERVATIONS THAT REQUIRE SPECIMENS SEGMENT (OM4)								
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Comment			
1	Sequence Number - Test/Observation Master File	NM	R	[11]					
2	Derived Specimen		0						
3	Container Description	ТХ	RE	[0*]		Pre-adopted revised HL7 definition and cardinality from V2.8. This field should contain the description of the container to be used for collection of the specimen. Example: "Red-top tube~gel-barrier tube".  Multiple containers or alternate containers may be repeated in this field or as repeating OM4 segments. To indicate a preferred container types, use repeating OM4 segments vs. repeating fields.			
4	Container Volume	NM	RE	[0*]		Pre-adopted revised HL7 definition and cardinality from V2.8.  This field indicates the capacity associated with the container(s) in OM4-3.			
5	Container Units	CWE_GEN	RE	[0*]	9999	Pre-adopted CWE data type from V2.7.1; pre-adopt revised HL7 definition and cardinality from V2.8.  This field contains the units of measure of the container capacity associated with the container(s) in OM4-3.			
6	Specimen	CWE_CRE	RE	[01]	SNOMED CT and/or HL70487	This field should identify the specimen value or code when applicable. Refer to HL7 Table 0487 – Specimen Type for valid codes, in Chapter 7, Observation Reporting, Section 7.18.  Pre-adopted CWE data type from V2.7.1; pre-adopt revised HL7 definition from V2.8.			
7	Additive	CWE_GEN	RE	[01]	HL70371_USL				
8	Preparation		0						
9	Special Handling Requirements		Х			Excluded for this Implementation Guide, see Section 1.3.1.			

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	TABLE 6-	-16. OBSE	RVATIO	NS THAT RE	QUIRE SPEC	IMENS SEGMENT (OM4)
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Comment
10	Normal Collection Volume	CQ	RE	[01]		This field should contain the preferred volume requirements for the specimen. The normal and minimum values can be the same depending on the laboratories policies.  Example: 1.0^mL&mililiter&ISO+
11	Minimum Collection Volume	CQ	RE	[01]		This field should contain the minimum volume requirements for the specimen. The test may not be performed if the minimum volume is not received. The normal and minimum values can be the same depending on the laboratories policies.  Example: 0.5^ml&mililiter&ISO+
12	Specimen Requirements	TX	RE	[01]		This field should be used to identify specimen requirements necessary for collection and delivery of the specimen. For example, ship frozen on dry ice, ship at room temp, remove plasma from cells within one hour of collection, etc.
13	Specimen Priorities		0			
14	Specimen Retention Time		0			
15	Specimen Handling Code	CWE_GEN	RE	[0*]	HL70376_USL	Pre-adopted from V2.8.
16	Specimen Preference	ID	RE	[01]	HL70920_USL	Pre-adopted from V2.8
17	Preferred Specimen/Attribute Sequence ID	NM	RE	[01]		Pre-adopted from V2.8.

#### OM4-7 – Additive

This field should contain the description of the additive to be used for collection of the specimen. If multiple additives are referenced, then any are acceptable for the specimen attributes.

## **OM4-9 – Special Handling Requirements**

Deprecated, this IG recommends use of use OM4-12 (Specimen Requirements) instead.

#### **OM4-17 Preferred Specimen/Attribute Sequence ID**

This field will be used for Alternate Specimen/Attributes only and will refer to the Preferred Specimen/Attribute sequence number from OM4-1 for correlation between the segments.

## **Example: Preferred specimen**

```
OM4|1||Plastic Screw Top|0.5|mL|Urine|without 6N HCI| ... to field16|P||
```

#### **Example: Alternate specimen**

```
OM4|2||Red Top|... to field16|A|1|
```

## **Example**

OM4 sequence 1.1 references a Preferred Specimen of Whole Blood. The alternate specimen allowed for the test is a Paraffin-Embedded Normal Tissue. The OM4-17 for the alternate specimen will reference sequence number '1.1' as the parent preferred specimen/attribute.

```
OM4|1.1||Red Top|0.5|mL|^Blood|... to field16|P||
OM4|1.2||Plastic Screw Top|||ParaffinEmbedded Tumor Tissue|| ... to field16|P||
OM4|1.3||Plastic Screw Top|||ParaffinEmbedded Normal Tissue|| ... to field16|A|1.1|
```

## **Conformance Statements all message types**

eDOS-34: If OM4-16 (Specimen Preference) is valued 'P' then OM4-17 (Preferred Specimen/Attribute Sequence ID) SHALL NOT be valued.

eDOS-35: If OM4-16 (Specimen Preference) is valued 'A' then OM4-17 (Preferred Specimen/Attribute Sequence ID) SHALL be valued.

## 6.6.10 OM5 - OBSERVATION BATTERIES (SETS) SEGMENT

	TABLE 6-17. OBSERVATION BATTERIES (SETS) SEGMENT (OM5)											
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Comment						
1	Sequence Number - Test/Observation Master File	NM	R	[11]								
2	Test/Observations Included Within an Ordered Test Battery	CWE_RC1	R	[1*]	9999	Pre-adopted V2.7.1 CWE data type.						
3	Observation ID Suffixes		0									

#### OM5-2 Tests/Observations Included Within an Ordered Test Battery

This field repeats as many times as is necessary to provide all components of the Order Code. The data type has the ability to message two identifiers where one could be the LOINC code and the other the local code for a given analyte. There is no instruction regarding if the Universal code (LOINC, etc.) should be first. Regardless, it is recommended that when sending two codes, there should be a consistent method for placing the codes that includes defining the "Name of the Coding System", i.e., OM5.2-3 (Name of Coding System) and OM5.2-6 (Name of Alternate Coding System).

#### **Example**

|345A1^Glucose^99lab^456-8^Glucose Random^LN|

#### 6.6.11 CDM - CHARGE DESCRIPTION MASTER SEGMENT

The CDM Master Segment should only be sent for valid procedure codes. The CDM segment below is a specially designed master file segment for interfacing charge description masters. In the M04 message, the MFI-1 (Master File Identifier) should equal 'CDM.'

For the Lab Test Compendium, the Charge Description Master File Message (MFN^M04^MFN\_M04) must be sent after the test master updates for the Order Codes. It may also be necessary for the receiving system to update those records into their master file prior to uploading this file. This file will contain only the Order Code and the CPT codes assigned to that Order Code. It is important to note that the CPT code repeats under certain criteria, see the Usage Note in the HL7 Standard Version 2.5.1, Chapter 8, Section 8.10.2.7 CDM-7 Procedure Code.

**Note:** The CDM does not support CPT modifiers to depict quantity (*i.e.*, "x12").

	TABLE 6-18. CHARGE DESCRIPTION MASTER SEGMENT (CDM)											
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Comment						
1	Primary Key Value – CDM	CWE_RC	R	[11]	HL70132_USL	Pre-adopted V2.7.1 CWE data type.						
						Same code that is messaged in OM1-2 (Producer's Service/Test/Observation ID) and OBR-4 (Universal Service Identifier) in order and result messages.						
2	Charge Code Alias		0									
3	Charge Description Short	ST	R	[11]		This element should match CDM-2.2 (Charge Code Alias).  When using this segment to convey CPT codes without charge information, since CDM-3 is required in the base standard, CDM- 3 should be valued with default value of: N/A						

		TA	BLE 6-1	8. CHARGE I	DESCRIPTIO	N MASTER SEGMENT (CDM)
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Comment
4	Charge Description Long		0			
5	Description Override Indicator		0			
6	Exploding Charges		0			
7	Procedure Code	CNE	R	[1*]	HL70088_USL	Pre-adopted use of CNE from V2.7.1 in this field. Constrained to concepts from the code system CPT-4, which is defined in HL70088 (Procedure Codes) as 'C4'. 'C4' will be messaged in CNE.3, while the respective CPT code is messaged in CNE.1.  Provide each instance of the CPT codes. In some cases, the CPT code will be repeated. When the CPT code is repeated, each repeat will be adjacent to each other. For display purposes, vendors can display the CPT code once with the repeat listed in (xn) or as a superscript(n) to be consistent with how displays work best in the receivers system (note: n represents the number of repeats). Refer to example following the segment for an example of the variety of ways that Lab Order Codes could be applied.
8	Active/Inactive Flag		0			·
9	Inventory Number		0			
10	Resource Load		0			
11	Contract Number		0			
12	Contract Organization		0			
13	Room Fee Indicator		0			

The CDM-7 (Procedure Code) field has pre-adopted and constrained Table 0088 from V2.8.

# **Code Examples**

TABLE 6-19. EXAMPLE CPT TEST CODES						
Test	CPT Code(s)					
CBC (includes Differential and Platelets)	85025					

TABLE 6-19. EXAMPLE CPT TEST CODES									
Test	CPT Code(s)								
CBC (includes Differential and Platelets with Pathologist review	85025, 85060								
CAH Panel 8 (17-Hydroxylase Deficiency in Males)	82088,82528,82533,83498,84144,84403								
Legionella Ab Evaluation, Comprehensive (A&G)	86713 (x2)								
Lupus (SLE) Panel	83516 (x3), 86038, 86160 (x2), 86235 (x5), 86255 (x5), 86376, 86431								

#### Legionella Ab Evaluation Comprehensive Panel

|86713^ANTIBODY; LEGIONELLA^C4~86713^ANTIBODY; LEGIONELLA^C4|

#### **Lupus Panel**

|83516^IMMUNOASSAY FOR ANALYTE OTHER THAN INFECTIOUS AGENT ANTIBODY OR INFECTIOUS AGENT ANTIGEN; QUALITATIVE OR SEMIQUANTITATIVE, MULTIPLE STEP METHOD^C4~83516^IMMUNOASSAY FOR ANALYTE OTHER THAN INFECTIOUS AGENT ANTIBODY OR INFECTIOUS AGENT ANTIGEN; QUALITATIVE OR SEMIQUANTITATIVE, MULTIPLE STEP METHOD^C4~83516^IMMUNOASSAY FOR ANALYTE OTHER THAN INFECTIOUS AGENT ANTIBODY OR INFECTIOUS AGENT ANTIGEN; QUALITATIVE OR SEMIQUANTITATIVE, MULTIPLE STEP METHOD^C4~86038^ANTINUCLEAR ANTIBODIES (ANA)^C4~86160^COMPLEMENT; ANTIGEN, EACH COMPONENT^C4~86160^COMPLEMENT; ANTIGEN, EACH COMPONENT^C4~86235^EXTRACTABLE NUCLEAR ANTIGEN, ANTIBODY TO, ANY METHOD (EG, NRNP, SS-A, SS-B, SM, RNP, SC170, J01), EACH ANTIBODY^C4~86235^C4~86235^EXTRACTABLE NUCLEAR ANTIGEN, ANTIBODY TO, ANY METHOD (EG, NRNP, SS-A, SS-B, SM, RNP, SC170, J01), EACH ANTIBODY^C4~86235^EXTRACTABLE NUCLEAR ANTIGEN, ANTIBODY TO, ANY METHOD (EG, NRNP, SS-A, SS-B, SM, RNP, SC170, J01), EACH ANTIBODY^C4~86235^EXTRACTABLE NUCLEAR ANTIGEN, ANTIBODY TO, ANY METHOD (EG, NRNP, SS-A, SS-B, SM, RNP, SC170, J01), EACH ANTIBODY^C4~86255^FLUORESCENT NONINFECTIOUS AGENT ANTIBODY; SCREEN, EACH ANTIBODY^C4~86376^MICROSOMAL ANTIBODIES (EG, THYROID OR LIVER-KIDNEY),

EACH^C4~86431^RHEUMATOID FACTOR; QUANTITATIVE^C4|

### Conformance Statements (M04 messages only)

eDOS-36: CDM-1 (Primary Key Value – CDM) SHALL match MFE-4 (Primary Key Value – MFE) in M04.

eDOS-57: CDM-7.3 (Procedure Code.Code system) SHALL be valued 'C4' drawn from the HL7 table 0088.

#### 6.6.12 NTE - NOTES AND COMMENTS SEGMENT

	TABLE 6-20. NOTES AND COMMENTS SEGMENT (NTE)											
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Comment						
1	Set ID – NTE	SI	R	[11]								
2	Source of Comment		0									
3	Comment	FT	R	[1*]		Comment contained in the segment.						
4	Comment Type		0									

## **Conformance Statements - All Message Types**

**eDOS-58:** NTE-1 (Set ID – NTE) SHALL be sequentially numbered starting with the value '1' for each segment it is following.

Note: This conformance statement is INTENTIONALLY different than the conformance statement in LRI and LOI because eDOS is reported to be the only IG with two occurrences of NTE in same segment group.

#### 6.6.13 OMC - SUPPORTING CLINICAL INFORMATION SEGMENT

Pre-adopted from V2.8.2.

This segment will contain the Ask at Order Entry (AOE) question(s). Refer to Appendix A – Ask at Order Entry for additional information.

	TABLE 6-21. SUPPORTING CLINICAL INFORMATION SEGMENT (OMC)										
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Comment					
1	Sequence Number - Test/Observation Master File		0								
2	Segment Action Code	ID	C(R/O)	[01]	HL70206_USL	Condition Predicate: Required if OMC-3 is valued.					
3	Segment Unique Key	EI_GU	C(R/O)	[01]		Condition Predicate: Required if OMC-2 is valued.					

	TABLE 6-21. SUPPORTING CLINICAL INFORMATION SEGMENT (OMC)										
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Comment					
4	Clinical Information Request	CWE_RC1	R	[11]	9999						
5	Collection Event/Process Step	CWE_RC	R	[1*]	HL70938_USL						
6	Communication Location	CWE_GEN	R	[11]	HL70939_USL						
7	Answer Required	ID	R	[11]	HL70136_USL						
8	Hint/Help Text	ST	RE	[01]							
9	Type of Answer	ID	R	[11]	HL70125_USL						
10	Multiple Answers Allowed		0								
11	Answer Choices	CWE_GEN	RE	[0*]	9999						
12	Character Limit	NM	RE	[01]							
13	Number of Decimals	NM	RE	[01]							

## 6.6.14 PM1 – PAYER MASTER FILE SEGMENT

Pre-adopted from V2.8.2

	TABLE 6-22. PAYER MASTER FILE SEGMENT (PM1)											
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Comment						
1	Health Plan ID	CWE_GEN	R	[11]	HL70072_USL							
2	Insurance Company ID	Varies	R	[1*]		GU data type: CX_GU NG data type: CX_NG						
3	Insurance Company Name		0									
4	Insurance Company Address		0									
5	Insurance Co Contact Person		0									
6	Insurance Co Phone Number		0									
7	Group Number		0									
8	Group Name		0									

	TABLE 6-22. PAYER MASTER FILE SEGMENT (PM1)									
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Comment				
9	Plan Effective Date		0							
10	Plan Expiration Date		0							
11	Patient DOB Required		0							
12	Patient Gender Required		0							
13	Patient Relationship Required		0							
14	Patient Signature Required		0							
15	Diagnosis Required		0							
16	Service Required		0							
17	Patient Name Required		0							
18	Patient Address Required		0							
19	Subscribers Name Required		0							
20	Workman's Comp Indicator		0							
21	Bill Type Required		0							
22	Commercial Carrier Name and Address Required		0							
23	Policy Number Pattern		0							
24	Group Number Pattern		0							

Aligning identifiers to be used for PM1-1 (Health Plan ID)/IN1-2 (Health Plan ID) and PM1-2 (Insurance Company ID)/IN1-3 (Insurance Company ID) is by trading partner agreement.

#### 6.6.15 MCP - MASTER FILE COVERAGE POLICY SEGMENT

Pre-adopted from V2.8.2.

	TABLE 6-23. MASTER FILE COVERAGE POLICY SEGMENT (MCP)											
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Comment						
1	Set ID - MCP	SI	R	[11]								
2	Producer's Service/Test/Observation ID	CWE_RC	R	[11]								
3	Universal Service Price Range – Low Value	MO	RE	[01]								
4	Universal Service Price Range – High Value	MO	RE	[01]								
5	Reason for Universal Service Cost Range	ST	C(R/X)	[01]		Condition Predicate: If MCP-3 is valued.						

## **Conformance Statements (M18 messages only)**

**eDOS-59:** MCP-1 (Set ID – MCP) **SHALL** be sequentially numbered starting with the value '1' within a given PAYER MF Entry group.

eDOS-37: MCP-2 (Producer's Service/Test/Observation ID) SHALL match MFE-4 (Primary Key Value – MFE) in M18.

## 7 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 0396), or a locally defined identifier. In general, the coded values allowed in a field (a) may be drawn from more than one code system, and (b) may be a subset of the codes from a given coding system. Combining (a) and (b) makes it possible for the allowed code value to be a combination of multiple subsets drawn from multiple coding systems. In most cases, only subsets of the codes defined in a code system are legal for use in a particular message.

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

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

A unique identifier identifies value sets, 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.

#### 7.1 LOINC

The laboratory's local test code and coding system shall be used to identify the orderable test in its electronic Directory of Services. LOINC shall be used as the standard alternate vocabulary to identify an orderable test. The performing laboratory makes the determination of an applicable LOINC order code. When no applicable LOINC code exists, the local code may be the only code defined in the eDOS.

LOINC Codes may be used for both orders and observations and are applicable in the following fields:

- OM1-2 Producer's Service/Test/Observation ID
- OM1-7 Other Service/Test/Observation IDs for the Observation
- OM5-2 Tests/Observations Included Within an Ordered Test
- OMC-4 Clinical Information Request

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

#### 7.2 SNOMED CT

SNOMED CT is a recommended vocabulary as specified in this guide, e.g., for specimen source terms in OM4-6 (Specimen) when a SNOMED CT code is available. Note that in some instances a code must be drawn from a declared hierarchy in SNOMED CT, e.g., OM4-6 (Specimen) terms should be drawn from the "specimen hierarchy"; see the field comments wherever SNOMED CT is identified as the value set.

SNOMED CT may be used in the following fields:

- OM3-4 Normal Text/Codes for Categorical Observations
- OM3-5 Abnormal Text/Codes for Categorical Observations
  For fields where 9999 is the specified value set, SNOMED CT may be used when agreed upon by trading partners. Support for SNOMED CT shall include the code and the description text as described by IHTSDO, following CWE requirements as defined in Section 4.2.

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 APPENDIX A – ASK AT ORDER ENTRY

The initial text below is excerpted from HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Orders from EHR, Release 1 – US Realm, Section 2.6.6 Ask at Order Entry (AOE) Observations, to explain how Ask at Order Entry questions are "answered" in a laboratory order.

----- start citation-----

#### 2.6.6 Ask at Order Entry (AOE) Observations

Ask at Order Entry (AOE) responses are recorded as observations that provide critical information for the calculation or interpretation of some lab results or to satisfy state and federal health agency mandated information gathering requirements, e.g., for blood lead testing. Not every order will have the need for AOE questions and associated observations. The lab 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:

- 1) Yes/No (and coded) to answer questions like "Is this your first pregnancy?"
- 2) A code drawn from a value set to provide a coded response to, e.g., "What ethnicity do you consider yourself to be?"
- 3) A number with units for the mother's age
- 4) A date format for the patient's last menstrual period.

The OBX segments under the ORC/OBR pair must be used in the order messages to convey these Ask at Order Entry questions.

Although not strictly asked at order entry, other supporting clinical information about the patient collected during specimen collection, e.g., fasting status of the patient, are considered AOE observations for purposes of this guide and must be communicated using the OBX segment under the ORC/OBR segments as well.

LOINC shall be used as the standard coding system for AOE questions if an appropriate and valid LOINC code exists. The LOINC and local code describing the question will be placed in OBX-3 (Observation Identifier). Appropriate and valid status is defined in the LOINC Manual Section 11.2 Classification of LOINC Term Status. 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 valid LOINC exists, the local code may be the only code sent.

#### 2.6.6.1 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 lab 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 lab 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.

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

# 8.1 Example AOE for Race using CDC Race and Ethnicity Code Set (CDCREC)<sup>6</sup>

The example below illustrates how an AOE messaged in OMC-4 Clinical Information Request is "answered" in a laboratory order. This example uses the expanded terminology available in CDC's Race and Ethnicity Code Set (CDCREC):

#### **AOE Question in eDOS (electronic Directory of Service) message**

32624-9^Race^LN

#### **AOE** Answer in LOI IG (Laboratory Orders Interface Implementation Guide) message

OBX|1|CWE|32624-9^Race^LN||1010-8^APACHE^CDCREC|||||||201210310800|

# 8.2 Proposed AOEs with a LOINC Code

In the eDOS Implementation Guide, ask at order entry questions are associated with an orderable test using OMC-4 (Clinical Information Request). OMC-4 lists all observations that must be captured at the time the order is created. Multiple AOE questions are allowed for an individual orderable test; each instance in the OMC-4 represents a single AOE question.

Because Meaningful Use has supported "Structured Data" for lab results, beginning with Meaningful Use Stage 1, the AOE examples below suggest HL7 data types to be used when the EHR system returns the "answer" to the lab's compendium test question. For example, the XAD (Extended Address), data

<sup>6</sup> PID-10 (Race) value is provided for demographic, not clinical use. An AOE must be provided 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. Refer to LOINC for suggested answer list. More specific race values are available, but not limited to, those found in the CDCREC document if needed for AOE. (http://www.cdc.gov/nchs/data/dvs/Race\_Ethnicity\_CodeSet.pdf).

type is suggested when reporting the employer address "answer" for blood lead test question about employer address.

The LOINC encoded AOE examples in the table below are provided as guidance and focus on the most commonly used Ask at Order Entry questions. This is not an exhaustive list and does not attempt to include all possible AOEs. Implementers can incorporate additional AOEs as needed for their specific environment.

LOINC codes may change in newer versions of the data base so it is suggested you verify that the LOINC codes are valid before using. Some LOINC codes in the list below were "Trial" codes at the time of publication and are designated with an '\*' following the LOINC code. As defined on the LOINC website "Trial terms are experimental in nature. Use with caution as they may change."

A direct hyperlink to each LOINC code is provided in the table below. You will need to "Accept" the Copyright Notice and License to enable the hyperlinks. Additional information, including related names, is available on the LOINC website.

For numeric data types (e.g. age) Unified Code for Units of Measure (UCUM) is recommended but not required. If used, be sure to populate OBX-6 Units (e.g. years, months, days). Further information on UCUM can be found at <a href="http://unitsofmeasure.org/">http://unitsofmeasure.org/</a>

The data types below are suggested but not required; other data types may be used where applicable. LOINC codes may dictate additional structure for the AOE, please refer to LOINC for additional information. Data type flavors used in the Laboratory Interoperability Implementation Guides are not included but should be considered depending on your implementation.

The "Group" column is intended to provide examples of the type of test that may be applicable for the AOE, for example "any test"," pregnancy maternal serum screening", "Toxicology, Public Health", etc.

We encourage implementers to use the HL7 defined message structure to communicate AOE information where possible.

Recommended value sets for the answers are included in the Usage Notes. Other value sets may be used as agreed upon by trading partners.

	TABLE 8-1. EXAMPLE LOINC AOE QUESTIONS									
LOINC Code <sup>7</sup>	LOINC Long Name	Suggested Common Question Name	Alias Name	Suggested HL7 Data Type OBX response	Usage Note	Test Type Group				
49089-6	[Identifier] Sonographer	Sonographer ID	Sonographer ID	ST	This is a sonographer credential number that is assigned by a credentialing agency; Fetal Medicine Foundation Organization (FMF) and the Nuchal Translucency Quality Review (NTQR) are the current accepted credentialing agencies.	Pregnancy maternal serum screening				
63746-2	About how long have you worked for your employer in your occupation	About how long have you worked for your employer in your occupation		NM	Patient's current employment by one employer Be sure to populate the units in OBX-6.	Toxicology Public Health				
30525-0	Age	Patient Age		NM	Prefer to receive DOB, sent in PID-7 (Patient Date/Time of Birth). Use this as AOE, when DOB cannot be obtained or shared No method described. Be sure to populate the units in OBX-6.	Any Test				
63888-2 *	Age at first menstrual period	Age at first menstrual period		NM	Be sure to populate the units in OBX-6.	Reproductive Cancer risk				
42797-1	Age at first pregnancy	Age at first pregnancy		NM	Be sure to populate the units in OBX-6.	Reproductive Cancer risk				
63890-8 *	Age at last menstrual period	Age at last menstrual period		NM	Not needed if we have DOB and Post- menopausal years - can then be calculated. Be sure to populate the units in OBX-6.	Reproductive Cancer risk				

<sup>&</sup>lt;sup>7</sup> An \* in this column indicates the code was "trial" at time of publication.

	TABLE 8-1. EXAMPLE LOINC AOE QUESTIONS									
LOINC Code <sup>7</sup>	LOINC Long Name	Suggested Common Question Name	Alias Name	Suggested HL7 Data Type OBX response	Usage Note	Test Type Group				
35659-2	Age at specimen collection			NM	Use this AOE, when a specimen that was previously collected is re-submitted for evaluation at a later point in time Be sure to populate the units in OBX-6.	Any Test				
71471-7 *	Antibiotic administered Medication			CWE	If using CWE, RxNorm <sup>8</sup> or other code systems may be used, or you may use the CWE.9 (Original Text) component of the CWE data type.					
8302-2	Body Height (Methodless)	Patient Height	Patient Height (inches)	NM	Patient's height - no method described - this could be reported by the patient, estimated or measured.  Be sure to populate the units in OBX-6.	Any Test				
<u>3137-7</u>	Body height Measured			NM	Be sure to populate the units in OBX-6.					
<u>3138-5</u>	Body height Stated			NM	Be sure to populate the units in OBX-6.					
29463-7	Body weight	Patient Weight		NM	Methodless Be sure to populate the units in OBX-6. Patient's weight - no method described - this could be reported by the patient, estimated or measured.	Any Test				
3141-9	Body weight (measured)		Patient weight (measured)	NM	Be sure to populate the units in OBX-6.					
<u>3142-7</u>	Body weight (stated)		Patient weight (stated)	NM	Be sure to populate the units in OBX-6.					

 $<sup>^{8}\,\</sup>underline{\text{http://www.nlm.nih.gov/research/umls/rxnorm/index.html}}$ 

		TABLE 8-	-1. EXAMPLE LO	INC AOE QU	JESTIONS	
LOINC Code <sup>7</sup>	LOINC Long Name	Suggested Common Question Name	Alias Name	Suggested HL7 Data Type OBX response	Usage Note	Test Type Group
8344-4	Body weight Measuredpost dialysis		Body weight^post dialysis	NM	For Kt/v – Dialysis Be sure to populate the units in OBX-6.	
8347-7	Body weight Measuredpre dialysis		Body weight^pre dialysis	NM	For Kt/v – Dialysis Be sure to populate the units in OBX-6.	
69461-2 *	Body weight mother at delivery			NM	Be sure to populate the units in OBX-6.	
55752-0	Clinical information	Clinical history of patient pertinent to order – narrative	Additional information pertinent to order	TX	Free text answer This includes illness onset date, risk factors like exposure to infectious agents or toxins, travel history including duration and location, prior abnormal tests and relevant diagnosis not submitted as "reason for testing", for example if patient is immunocompromised, had previous infection etc. When this AOE is used, the laboratory should use the special instructions field in eDOS to specify which information might be relevant for the test in question.	Any Test
19153-6 (Timing=X XX)	Collection amount of urine	Total amount of urine collected		NM	Need to include appropriate units of the originally collected urine, especially when not all is sent to the lab for testing  Be sure to populate the units in OBX-6.	Any Test
28009-9 (Timing=Pt	Collection amount of urine	Total amount of urine collected		NM	Need to include appropriate units of the originally collected urine, especially when not all is sent to the lab for testing  Be sure to populate the units in OBX-6.	Any Test

		TABLE 8-	1. EXAMPLE LO	OINC AOE QU	JESTIONS	
LOINC Code <sup>7</sup>	LOINC Long Name	Suggested Common Question Name	Alias Name	Suggested HL7 Data Type OBX response	Usage Note	Test Type Group
11294-6	Current employment Narrative - reported	What is your current employment	Current employment	TX	free text answer about what current employment is	Toxicology Public Health
64234-8	Current smoker			CWE	Refer to LOINC for suggested answer list.	
19774-9	Cytology study comment Cervical or vaginal smear or scraping Cyto stain	Provide results of previous cytology/biopsy and the date and testing location and specimen ID		TX	Free Text for prior cytology results of cervical or vaginal smear or scraping This should really be handled in Prior result group of order message.	Reproductive Pap
30952-6	Date and time of vaccination	Date and time of vaccination		DT	This is covered by "Prior and/or current therapy relevant to this order?" and is not helpful, unless combined with the information on which vaccination this specific question refers to.	Any Test
29742-4	Date last dose	Date and time of last treatment dose		DT	This is used for drug level testing and should be asked separately for test request for peak and trough values. The diagnosis should be considered to be meaningful.	Any Test
60431-4	Date of previous biopsy	Date of previous biopsy		DT	When grouping Pap smear questions, this could be a drill down question after the type of biopsy has been identified. It is covered by the more generic relevant prior treatment AOE, but some places may want to use separately here.	AP Pap
60432-2	Date of previous Pap smear	Date of previous Pap smear		DT	Covered by 19774 9 The granularity could be left up to the year, so that precise dates are not needed, but a ball park of how many years since the last Pap smear can be established - if used.	Рар

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		TABLE 8-	-1. EXAMPLE LO	INC AOE QU	JESTIONS	
LOINC Code <sup>7</sup>	LOINC Long Name	Suggested Common Question Name	Alias Name	Suggested HL7 Data Type OBX response	Usage Note	Test Type Group
63936-9 *	Date of start of treatment or therapy PhenX	Date treatment or therapy started		DT	Use only for PhenX survey	Any Test
63939-3	Date of-treatment end or therapy completed [PhenX]	Date treatment or therapy ended		DT	This is covered by "Prior and/or current therapy relevant to this order?" and is not helpful, unless combined with the information on which treatment this specific question refers to.	Any Test
11778-8	Delivery date Estimated	Delivery date Estimated	Estimated due date	DT	Needs to be combined with method used to determine this date - this should be the future harmonized question that allows the calculation of gestational age.	Pregnancy maternal serum screening
33248-6	Diabetes status [identifier]	What type of diabetes does the patient have?		CWE	Example Answer list: Suspected Confirmed Diabetes mellitus Type I Diabetes mellitus Type II gestational Diabetes mellitus None	Pregnancy maternal serum screening
<u>8462-4</u>	Diastolic blood pressure			CWE		
<u>53948-6</u>	Donated egg [Presence]	Is the pregnancy from a donated egg?	Donor egg	CNE	Expected answers: Y/N (HL7 Table 0136)	Reproductive

		TABLE 8	-1. EXAMPLE L	OINC AOE QU	JESTIONS	
LOINC Code <sup>7</sup>	LOINC Long Name	Suggested Common Question Name	Alias Name	Suggested HL7 Data Type OBX response	Usage Note	Test Type Group
42784-9	Ethnic background Stated	Patient's clinically relevant Ethnic background		CWE	PID-22 (Ethnic Group) value is provided for demographic, not clinical use. An AOE must be provided for those tests where Ethnic Group drives the interpretation of results. The value must be determined by the Ordering Provider and should be from a limited list, like Hispanic, not Hispanic, Ashkenazi Jewish etc this should be the clinically relevant ethnic group, and must be sent as an AOE OBX. More specific ethnicity values are available, but not limited to, those found in the CDCREC document if needed for AOE. http://www.cdc.gov/nchs/data/dvs/Race_Ethnicity_CodeSet.pdf	Any Test
42784-9	Ethnic background Stated	Clinically relevant ethnicity		CWE	An AOE must be provided for those tests where ethnic group drives the interpretation of results. The value must be determined by the Ordering Provider.	
49541-6	Fasting status [Presence] - reported	Patient's reported fasting status	Fasting status	CWE	Fasting status obtained at time of specimen collection – answers are limited to Y/N (HL7 Table 0136)If extending HL7 Table 0136, additional values may be found in HL7 Table 0532 - Expanded Yes/no Indicator to accommodate unknown.  Can also be sent in OBR-13 using HL70912 values.	
11951-1	Fetal [Identifier] Identifier	Fetal Identifier	Fetus ID	ST	This is needed to identify each fetus, when there is more than one	Pregnancy

		TABLE 8-	-1. EXAMPLE LOI	INC AOE QU	JESTIONS	
LOINC Code <sup>7</sup>	LOINC Long Name	Suggested Common Question Name	Alias Name	Suggested HL7 Data Type OBX response	Usage Note	Test Type Group
11957-8	Fetal Crown Rump length US	Fetal Crown Rump Length by US	Fetal Crown Rump length	NM	Used during first Trimester screening only and needs to be repeated for each fetus. 'US' is Ultrasound Be sure to populate the units in OBX-6.	Pregnancy maternal serum screening
42479-6	Fetal Narrative Study observation general, multiple fetuses US			ST		
12146-7	Fetal Nuchal fold thickness US	Fetal Nuchal translucency by US	Nuchal translucency	NM	Used during first Trimester screening only and needs to be repeated for each fetus. 'US' is Ultrasound Be sure to populate the appropriate units in OBX-6.	Pregnancy maternal serum screening
63741-3	For whom did you work at your main job or business	For whom did you work at your main job or business		XON	Employer Name – Organization example.	Toxicology Public Health
63741-3 *	For whom did you work at your main job or business	For whom did you work at your main job or business		XPN	Employer Name - Person example.	Toxicology Public Health
11884-4	Gestational age Estimated	Gestational age Estimated	Gestational age	SN	When this AOE is used, need to also include the date estimate was made. In effort to reduce AOEs suggestion is to use Estimated delivery date (EDD) instead Be sure to populate the units in OBX-6.	Pregnancy maternal serum screening

	TABLE 8-1. EXAMPLE LOINC AOE QUESTIONS									
LOINC Code <sup>7</sup>	LOINC Long Name	Suggested Common Question Name	Alias Name	Suggested HL7 Data Type OBX response	Usage Note	Test Type Group				
49052-4	Gestational age in days	Gestational age in days	Gestational age (days)	NM	This LOINC is used in conjunction with 49051-6 and lists the days in the current week of gestation. When this AOE is used, need to also include the date estimate was made. In effort to reduce AOEs suggestion is to use Estimated delivery date (EDD) instead. Be sure to populate the units in OBX-6.	Pregnancy maternal serum screening				
49051-6	Gestational age in weeks	Gestational age in weeks	Gestational age (weeks)	NM	This LOINC is used in conjunction with 49052-4 and lists the completed weeks of gestation.  When this AOE is used, need to also include the date estimate was made.  In effort to reduce AOEs suggestion is to use Estimated delivery date (EDD) instead. Be sure to populate the units in OBX-6.	Pregnancy maternal serum screening				
21299-3	Gestational age method	Gestational age method	Gestational age calculation method	CWE	Example response may include: US LMP Ovulation Date Conception Date Quickening Date	Pregnancy maternal serum screening				
8867-4	Heart rate			NM	Be sure to populate the units in OBX-6.					
<u>58957-2</u>	Heparin given [Type]	Type of Heparin given		ST		Coagulation Studies				

	TABLE 8-1. EXAMPLE LOINC AOE QUESTIONS									
LOINC Code <sup>7</sup>	LOINC Long Name	Suggested Common Question Name	Alias Name	Suggested HL7 Data Type OBX response	Usage Note	Test Type Group				
8670-2	History of family member diseases	History of biological family member diseases relevant to the order		CWE	Refer to LOINC for suggested answer list. For each of the more common tests this should contain the list of relevant diseases in the Family History related to the disease(s) this test is designed to detect / rule out. This is NOT a LOINC to actually use, but rather to start from and create a new LOINC with a normative answer list for the respective test order - until a LOINC is obtained the local code would identify this AOE. The OMC-11 field defines the expected answers.	Any Test				
53827-2	History of neural tube defect Qualitative	Family history of neural tube defect?	History of ONTD	CNE	Multiple answers should be allowed.  Limited allowed answers are: Y/N (HL7 Table 0136)	Pregnancy maternal serum screening				
67803-7	History of Procedures - Reported	History of procedures reported by patient	Previous treatment	ST	Short text answer about previous treatment as reported by the patient for relevant disease being worked up. This is covered by relevant clinical history. When this AOE is used, the laboratory should use the special instructions field in eDOS to specify which information might be relevant for the test in question.	Any Test				

		TABLE 8-	-1. EXAMPLE LC	INC AOE QU	JESTIONS	
LOINC Code <sup>7</sup>	LOINC Long Name	Suggested Common Question Name	Alias Name	Suggested HL7 Data Type OBX response	Usage Note	Test Type Group
8691-8	History of Travel	Where has the patient traveled to and when?		CWE	The physician should ask open ended questions to illicit maximum information from the patient, and then evaluate, if it is pertinent to the test ordered to support the suspected differential diagnosis – the data element therefore is pertinent travel location and Travel start and end date/time – but that is not how the questions is to be asked This is covered by relevant clinical history. When this AOE is used, the laboratory should use the special instructions field in eDOS to specify which information might be relevant for the test in question. Should be picked from a list - can use the ISO-3166 (3 alpha) for Countries or United States Postal Service (USPS) for States. There are also some region codes from the WHO that could be applicable - for example Sub-Saharan Africa, if a specific list of visited countries is not provided.	Infection Risk/Related to Infection Public Health
11368-8	Illness or injury onset date and time	Date/time of onset of injury or illness		DT	It is covered by clinical history, but may be desired to be used separately. When this AOE is used, the laboratory should use OM1-54 (Special Instructions) field in eDOS to specify which information might be relevant for the test in question.	Any Test
44877-9	Insulin dependent diabetes mellitus [Presence]		Insulin dependent DM	CWE	Y/N (HL7 Table 0136)	

	TABLE 8-1. EXAMPLE LOINC AOE QUESTIONS									
LOINC Code <sup>7</sup>	LOINC Long Name	Suggested Common Question Name	Alias Name	Suggested HL7 Data Type OBX response	Usage Note	Test Type Group				
<u>53796-9</u>	Interferon drug given [Identifier]			ST						
8665-2	Last menstrual period start date	What is the start date of the patient's last menstrual period?		DT		Reproductive Pap Maternal serum screening				
<u>29303-5</u>	Medication administered			CWE	If using CWE, RxNorm <sup>9</sup> or other code systems may be used, or you may use the CWE.9 (Original Text) component of the CWE data type.					
<u>29305-0</u>	Medication prescribed			CWE						
<u>54125-0</u>	Name		Partner Name	XPN						
11878-6	Number of Fetuses by US	Number of Fetuses by US	Number of Fetuses	NM	'US' is Ultrasound Be sure to populate the units in OBX-6.	Pregnancy maternal serum screening				
<u>67471-3 *</u>	Pregnancy			CWE	Refer to LOINC for suggested answer list.					

<sup>&</sup>lt;sup>9</sup> http://www.nlm.nih.gov/research/umls/rxnorm/index.html

	TABLE 8-1. EXAMPLE LOINC AOE QUESTIONS								
LOINC Code <sup>7</sup>	LOINC Long Name	Suggested Common Question Name	Alias Name	Suggested HL7 Data Type OBX response	Usage Note	Test Type Group			
11449-6	Pregnancy status – Reported	Pregnancy status reported by patient		CWE	Answers from a limited list as reported by patient: Pregnant / not pregnant / unknown / pregnant can be expanded to include trimesters, if desired for certain tests, where Estimated Delivery Date (EDD) is not also asked – Should be coded using: SNOMED CT (77386006^Patient currently pregnant (finding)^SCT 60001007^Not pregnant (finding)^SCT) / HL7 null flavor (UNK) respectively  HL7 0352 was published in prior releases of eDOS IG, but maps to SNOMED-CT Y – maps to 77386006 N – maps to 60001007 Unknown – maps to U in HL70352				
<u>18771-6</u>	Provider signing name		Reading physician ID	XPN					

	TABLE 8-1. EXAMPLE LOINC AOE QUESTIONS							
LOINC Code <sup>7</sup>	LOINC Long Name	Suggested Common Question Name	Alias Name	Suggested HL7 Data Type OBX response	Usage Note	Test Type Group		
32624-9	Race			CWE	PID-10 (Race) value is provided for demographic, not clinical use. An AOE should be provided for those tests where Race drives the interpretation of results. The value should be determined by the Ordering Provider and should be from a predetermined list, like white, African American, Asian, pacific islander etc. This should be the clinically relevant race. More specific race values are available, but not limited to, those found in the CDCREC document if needed for AOE.  (http://www.cdc.gov/nchs/data/dvs/Race_Et_hnicity_CodeSet.pdf).	Any Test		

		TABLE 8-	-1. EXAMPLE LO	OINC AOE QU	JESTIONS	
LOINC Code <sup>7</sup>	LOINC Long Name	Suggested Common Question Name	Alias Name	Suggested HL7 Data Type OBX response	Usage Note	Test Type Group
46098-0	Sex	Patient's clinically relevant Gender		CWE	In most cases the administrative gender normally transmitted in PID-8 (Administrative Sex) will be sufficient. If a different value set with more clinical terms is needed than available in the Administrative Sex table (HL70001) or if known, that administrative gender is NOT the clinically relevant one, then this code can be used as AOE in an OBX. The value should be determined by the Ordering Provider and should be from a predetermined list, like male female, hermaphrodite. Refer to LOINC for suggested answer list. Answer list may be extended by agreement of trading partners to support other clinical genders.	Any Test
<u>49088-8</u>	Sonographer name	Sonographer name		XPN		Pregnancy maternal serum screening
<u>8480-6</u>	Systolic blood pressure			CWE		
72166-2	Tobacco Smoking Status	Tobacco Smoking Status	Smoking Status	CWE	For suggested answer list. (CMS requirement to capture in MU stage 2 in patient over 13 years (http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/downloads/Stage2_EPCore_5_RecordSmokingStatus.pdf)	Public Health
34970-4	Ultrasound Date	Ultrasound Date		DT		Pregnancy maternal serum screening

	TABLE 8-1. EXAMPLE LOINC AOE QUESTIONS							
LOINC Code <sup>7</sup>	LOINC Long Name	Suggested Common Question Name	Alias Name	Suggested HL7 Data Type OBX response	Usage Note	Test Type Group		
13620-0	Volume of 12 hour Urine		Specimen Volume	NM	Be sure to populate the units in OBX-6. Can also be calculated (if available) from: SPM-4 (Specimen Type) (CWE_CRE); SPM-12 (Specimen Collection Amount); Or messaged in OBR-9 (Collection Volume)			
3167-4	Volume of 24 hour Urine		Specimen Volume	NM	Be sure to populate the units in OBX-6. Can also be calculated (if available) from: SPM-4 (Specimen Type) (CWE_CRE); SPM-12 (Specimen Collection Amount); Or messaged in OBR-9 (Collection Volume).			
8280-0	Waist Circumference at umbilicus by Tape measure	Waist Circumference at umbilicus by Tape measure		NM	Waist Circumference, inches. Be sure to populate the units in OBX-6. Use only if actually obtained by the lab at specimen collection.	Pregnancy		
<u>63758-7 *</u>	What was the location of this company [Address]	Address of employer	Employer Address	XAD	Employer Address	Toxicology Public Health		

# 8.3 Proposed AOEs without a LOINC Code

The common AOE questions below are examples encountered, that are being submitted for LOINC<sup>10</sup> code requests to Regenstrief and should be available in the future. The table provides these suggested terms, data type and Usage Note - all may be modified through this process. If attempting to use any of these concepts, proceed with caution and refer to LOINC to determine if a code has been assigned before using a local code.

<sup>10</sup> http://search.loinc.org/

	TABLE 8-2. EXAMPLE AOE QUESTIONS (WITHOUT LOINC CODE) <sup>11</sup>						
AOE Question	Suggested Common Question Name	Alias Question Name, when different from LOINC Long Name, where applicable	Suggested HL7 Data Type OBX response	Usage Note	Test Type Group		
Animal Exposed to Rabies	Animal Exposed to Rabies		CWE	This is related to rabies testing and asked if the animal whose parts are being tested has been exposed to rabies.  Y/N/UNK (HL7 Table 0532 - Expanded Yes/No Indicator)	Infection Risk/Related to Infection Public Health		
Animal species	Animal species		CWE	Identifies the species name from a pick list SNOMED Organism Hierarchy may be used for the answer list.	Infection Risk/Related to Infection Public Health		
Any history of exposure to infectious disease?			CWE	Y/N/UNK (HL7 Table 0532 - Expanded Yes/No Indicator) This is typically asked in conjunction with 'Type of Exposure'.			
History of exposure to infectious disease	History of exposure to infectious disease, include when and where		ST	Free text entry	Infection Risk/Related to Infection Public Health		
Biparietal Diameter			NM	Be sure to populate the units in OBX-6.			

<sup>&</sup>lt;sup>11</sup> LOINC codes may be assigned in the future.

TABLE 8-2. EXAMPLE AOE QUESTIONS (WITHOUT LOINC CODE) <sup>11</sup>							
AOE Question	Suggested Common Question Name	Alias Question Name, when different from LOINC Long Name, where applicable	Suggested HL7 Data Type OBX response	Usage Note	Test Type Group		
Blood lead classification status	What is the reason blood lead testing is being requested?		CWE	Example answers can vary by state but examples include initial, repeat, follow up.	Specimen Blood Lead		
Blood lead source			CWE	Example answers can vary by state but examples include: initial repeat follow up  Required for State reporting; should also be reported in SPM-4 (Specimen Type)	Specimen Blood Lead		
Clinical history of patient pertinent for Pap smear order	List the clinical history of patient pertinent for Pap smear order	Additional information pertinent to order	CWE	Prescribed answer list: Pregnant Post-Partum Lactating Menopausal Hormone Therapy Postmenopausal Bleeding Postcoital Bleeding History of High Risk HPV Infection Hysterectomy, Cervix Absent Hysterectomy, Cervix Present	Рар		
Chorionicity	Chorionicity		CWE	Expected Answer list: Monochorionic Dichorionic Unknown	Reproductive maternal serum screening		

TABLE 8-2. EXAMPLE AOE QUESTIONS (WITHOUT LOINC CODE) <sup>11</sup>							
AOE Question	Suggested Common Question Name	Alias Question Name, when different from LOINC Long Name, where applicable	Suggested HL7 Data Type OBX response	Usage Note	Test Type Group		
Date of animal's death	Date of animal's death		DT	This is related to rabies testing.	Infection Risk/Related to Infection Public Health		
Treatment time for dialysis	Length of time of dialysis treatment		NM	Treatment time for dialysis. Be sure to populate the units in OBX-6.			
Egg Provider's Race			CWE	More specific race values are available, but not limited to, those found in the CDCREC document if needed for AOE. (http://www.cdc.gov/nchs/data/dvs/Race_Ethnicity_CodeSet_pdf)			
Gestational age date of calculation	Date of calculation of gestational age		DT		Reproductive Maternal serum screening		
Hip circumference, centimeters			NM	Be sure to populate the units in OBX-6.			
Hip circumference, inches			NM	Be sure to populate the units in OBX-6.			
History of exposure to animal	History of exposure to animal		CWE	Was the patient exposed to the animal tested for rabies? Answers from a list of Y/N/UNK (HL7 Table 0532 - Expanded Yes/no Indicator)	Infection Risk/Related to Infection Public Health		

TABLE 8-2. EXAMPLE AOE QUESTIONS (WITHOUT LOINC CODE) <sup>11</sup>						
AOE Question	Suggested Common Question Name	Alias Question Name, when different from LOINC Long Name, where applicable	Suggested HL7 Data Type OBX response	Usage Note	Test Type Group	
If the egg was frozen or not from the patient, what was the age of the egg at the time of egg retrieval?			NM	Be sure to populate the units in OBX-6.		
Insulin Dependent Diabetic Egg Provider			CWE	Y/N/UNK (HL7 Table 0532 - Expanded Yes/no Indicator)		
s this your first pregnancy (Y/N)	Is this your first pregnancy (Y/N)		CNE	(Y/N) HL7 Table 0136	Pregnancy	
Partner Ethnicity			CWE	More specific ethnicity values are available, but not limited to, those found in the CDCREC document if needed for AOE.  (http://www.cdc.gov/nchs/data/dvs/Race_Ethnicity_CodeSet_pdf)		

	TABLE 8-2. EXAMPLE AOE QUESTIONS (WITHOUT LOINC CODE) <sup>11</sup>						
AOE Question	Suggested Common Question Name	Alias Question Name, when different from LOINC Long Name, where applicable	Suggested HL7 Data Type OBX response	Usage Note	Test Type Group		
Prior Treatment	Prior and/or current treatment relevant to this order?		TX	Free text answer describing previous treatment This includes relevant treatment start and end dates for treatment like vaccinations, medications, transplants and other pertinent procedures, for example dialysis Physicians should evaluate the differential diagnosis and include supporting information to be meaningful. When this AOE is used, the laboratory should use the special instructions field in eDOS to specify which information might be relevant for the test in question.	Any Test		
Travel date range			DR	This should include the start and end date of the travel; setting up the travel history to ask for relevant incubation times based on suspected diseases.			

	TABLE 8-2. EXAMPLE AOE QUESTIONS (WITHOUT LOINC CODE) <sup>11</sup>						
AOE Question	Suggested Common Question Name	Alias Question Name, when different from LOINC Long Name, where applicable	Suggested HL7 Data Type OBX response	Usage Note	Test Type Group		
Type of abnormal GYN exam	What aspect of GYN exam was previously abnormal?		CWE	Expected answer list (created hierarchical by area of GYN exam also referred to as aspect): cervix - endocervix, ectocervix vagina vulva - labium majus -labium minus uterus – endometrium ovaries tube urethral orifice anus	Reproductive		
Viral load	Previously measured viral load		NM	Patient's viral load as previously determined – Expected answer list: "no known viral load" "greater than x cut off limit" Be sure to populate the units in OBX-6.	Infection Risk/Related to Infection STD		
Egg donor's age	Egg donor's age at time of egg donation		NM	Be sure to populate the units in OBX-6.	Reproductive maternal serum screening		

TABLE 8-2. EXAMPLE AOE QUESTIONS (WITHOUT LOINC CODE) <sup>11</sup>							
AOE Question	Suggested Common Question Name	Alias Question Name, when different from LOINC Long Name, where applicable	Suggested HL7 Data Type OBX response	Usage Note	Test Type Group		
Sonographer Name and ID with Assigning Authority	Sonographer Name and ID with Assigning Authority	Sonographer Name and ID with Assigning Authority	XCN	This is a sonographer name and credential number that is assigned by a credentialing agency (Assigning Authority), Fetal Medicine Foundation Organization (FMF) and Nuchal Translucency Quality Review (NTQR) are the current accepted credentialing agencies.	Pregnancy maternal serum screening		
Sonography reading physician ID with assigning authority	Sonography reading physician ID with assigning authority		CX	This is a physician certificate number that is assigned by one of the two credentialing agencies, either Fetal Medicine Foundation Organization (FMF) or the Nuchal Translucency Quality Review (NTQR)	Reproductive maternal serum screening		
Sonography site ID with assigning authority	Sonography site ID with assigning authority		XON	This is a sonography site number that is assigned by the Nuchal Translucency Quality Review (NTQR)	Reproductive maternal serum screening		

	TABLE 8-2. EXAMPLE AOE QUESTIONS (WITHOUT LOINC CODE) <sup>11</sup>								
AOE Question	Suggested Common Question Name	Alias Question Name, when different from LOINC Long Name, where applicable	Suggested HL7 Data Type OBX response	Usage Note	Test Type Group				
Clinical history of patient pertinent for Maternal Serum Screening order	List the clinical history of patient pertinent for Maternal Serum Screening order		CWE	Prescribed answer list: Donor Egg from self Donor Egg from non-self Diabetes mellitus Type I Diabetes mellitus Type II gestational Diabetes mellitus previously elevated Alpha- fetoprotein levels Family history of neural tube defect Prior pregnancy with Down Syndrome Should other information be needed send 55752-0 narrative in addition	Reproductive maternal serum screening				
Current Contraceptive Use	What method of contraception does the patient currently use?		CWE	Prescribed answer list: Birth Control Pill IUD Norplant Depo' Other	Reproductive Pap				

	TABLE 8-2. EXAMPLE AOE QUESTIONS (WITHOUT LOINC CODE) <sup>11</sup>								
AOE Question	Suggested Common Question Name	Alias Question Name, when different from LOINC Long Name, where applicable	Suggested HL7 Data Type OBX response	Usage Note	Test Type Group				
Previous cytology results for Pap Smear	Provide results of previous cytology/biopsy, along with the date, testing location, and specimen ID		CWE	This should really be handled in Prior result group of order message, to cover information about the relevant dates, but not many systems support that at this time.  Prescribed Answer list:  Negative  Abnormal result unknown  Atypical Squamous Cells of Undetermined Significance (ASC-US)  Low-grade Squamous  Intraepithelial Lesion (LSIL)  High-grade Squamous  Intraepithelial Lesion (HSIL)  Carcinoma  In order to provide additional information about the date and specimen ID for the related diagnosis use 19774-9 narrative text.					

TABLE 8-2. EXAMPLE AOE QUESTIONS (WITHOUT LOINC CODE) <sup>11</sup>							
AOE Question	Suggested Common Question Name	Alias Question Name, when different from LOINC Long Name, where applicable	Suggested HL7 Data Type OBX response	Usage Note	Test Type Group		
Prior and/or current treatment relevant for Pap smear	What type of treatment was previously or is currently received for an abnormal Pap test?		CWE	Prescribed list: None Laser Vaporization (LEEP) Cyro Surgery Conization Pelvic Radiation Colposcpy/Bioposy Hysterectomy, Total Hysterectomy, Partial (Supracervical)	Treatment pap Pap		
Prior Transplant	Has patient received a transplant?		TX	Answers from a limited list as reported by patient: Y/N/No Information (HL7 Table 0532 - Expanded Yes/no Indicator).	Any Test		

	TABLE 8-2. EXAMPLE AOE QUESTIONS (WITHOUT LOINC CODE) <sup>11</sup>							
AOE Question	Suggested Common Question Name	Alias Question Name, when different from LOINC Long Name, where applicable	Suggested HL7 Data Type OBX response	Usage Note	Test Type Group			
	Chief Complaint		CWE	For each of the more common tests this should contain the list of relevant diseases in the Family History related to the disease(s) this test is designed to detect / rule out.  This is NOT a LOINC to actually use, but rather to start from and create a new LOINC with a normative answer list for the respective test order - until a LOINC is obtained the local code would identify this AOE. The OMC-11 field defines the expected answers.  For free text, use 55752-0 Clinical Information.	Any Test			

TABLE 8-2. EXAMPLE AOE QUESTIONS (WITHOUT LOINC CODE) <sup>11</sup>								
AOE Question	Suggested Common Question Name	Alias Question Name, when different from LOINC Long Name, where applicable	Suggested HL7 Data Type OBX response	Usage Note	Test Type Group			
Ordering Diagnosis	Ordering Diagnosis		CWE	Sent in DG1-3 in the order message. If needed in a result message consider OBR-31 (Reason for study). If there is a need for an OBX, would need to consider, if the status of the diagnosis - ordering/working, final/admission/discharge is also needed, or if this could be more generic diagnosis Picked from a list of diagnosis codes, usually ICD-9 or ICD-10 - supports the reason for ordering the procedure	Any Test			
History of HPV Infection	History of high risk HPV Infection		CWE	Expected answers: Yes – history of high risk HPV infection / Yes – history of low risk HPV infection / Yes – Unknown HPV risk type No / Unknown This question is evaluating the type of HPV that caused the previous infection. Is covered under relevant clinical history question, but could be asked specifically.				

	TABLE 8-2. EXAMPLE AOE QUESTIONS (WITHOUT LOINC CODE) <sup>11</sup>								
AOE Question	Suggested Common Question Name	Alias Question Name, when different from LOINC Long Name, where applicable	Suggested HL7 Data Type OBX response	Usage Note	Test Type Group				
Does patient have postcoital bleeding	Does patient have postcoital bleeding?		CWE	Expected answers: Y/N/UNK (HL7 Table 0532 - Expanded Yes/no Indicator) Is covered under relevant clinical history question, but could be asked specifically.	Рар				
History of Down Syndrome	Has patient had a prior pregnancy with Down Syndrome?		CWE	Expected answers: Y/N/UNK (HL7 Table 0532 - Expanded Yes/no Indicator)	Pregnancy maternal serum screening				
History of Cystic Fibrosis	Has patient had a prior pregnancy with Cystic Fibrosis?		CWE	Expected answers: Y/N/UNK (HL7 Table 0532 - Expanded Yes/no Indicator)	Pregnancy maternal serum screening				
History HR HPV Infection, abnormal Pap (last 3yrs), treatment or biopsy	Does the patient have any of the following risk factors: High risk HPV Infection, abnormal Pap in the last 3yrs or treatment or biopsy for GYN abnormality?		CWE	Expected answers: Y/N/UNK (HL7 Table 0532 - Expanded Yes/no Indicator)	Рар				
Has patient been vaccinated for HPV?	Has patient been vaccinated for HPV?		CWE	Expected answers: Y/N/UNK (HL7 Table 0532 - Expanded Yes/no Indicator)	Рар				
History of abnormal bleeding (postcoital, postmenopausal)	Does the patient have a history of abnormal bleeding (postcoital, postmenopausal)!?		CWE	Expected answers: Y/N/UNK (HL7 Table 0532 - Expanded Yes/no Indicator)	Pap				

	TABLE 8-2	. EXAMPLE AOE QUEST	TONS (WITHOUT LOIN	C CODE) <sup>11</sup>	
AOE Question	Suggested Common Question Name	Alias Question Name, when different from LOINC Long Name, where applicable	Suggested HL7 Data Type OBX response	Usage Note	Test Type Group
Patient or family Hx of GYN malignancy	Does the patient have a family history of GYN malignancy?		CWE	Expected answers: Y/N/UNK (HL7 Table 0532 - Expanded Yes/no Indicator)	Pap
Pelvic irritation	Does the patient have a history of pelvic irritation?		CWE	Expected answers: Y/N/UNK (HL7 Table 0532 - Expanded Yes/no Indicator)	Рар
DES exposure	Does the patient have a history of Exposure to DES?		CWE	Expected answers: Y/N/UNK (HL7 Table 0532 - Expanded Yes/no Indicator)	Рар
Did the patient have a previous abnormal Pap report, treatment, or biopsy?	Did the patient have a previous abnormal Pap report, treatment, or biopsy?		CWE	Expected answers: Y/N/UNK (HL7 Table 0532 - Expanded Yes/no Indicator)	Рар
List the number of weeks postpartum	List the number of weeks postpartum		NM	Be sure to populate the units in OBX-6.	Pregnancy
Previously elevated Alpha- fetoprotein values?	Has patient previously had elevated Alpha-fetoprotein levels?		CWE	Expected answers: Y/N/UNK (HL7 Table 0532 - Expanded Yes/no Indicator)	Pregnancy maternal serum screening

TABLE 8-2. EXAMPLE AOE QUESTIONS (WITHOUT LOINC CODE) <sup>11</sup>							
AOE Question	Suggested Common Question Name	Alias Question Name, when different from LOINC Long Name, where applicable	Suggested HL7 Data Type OBX response	Usage Note	Test Type Group		
List the number of years postmenopausal	List the number of years postmenopausal		NM	Even though this information can be calculated from the LMP date, the LMP date is often not reliably remembered after a few years, so unless it is in the chart, may not be able to get this information. Be sure to populate the appropriate age units in OBX-6.	Reproductive		
Was there a previous abnormal GYN exam	Does the patient have a prior abnormal GYN exam?		CWE	Expected answers: Y/N/UNK (HL7 Table 0532 - Expanded Yes/no Indicator)	Reproductive		
Gestational age (decimal weeks)	Gestational age in weeks in decimal form	Gestational age (decimal)	NM	When this AOE is used, need to also include the date estimate was made In effort to reduce AOEs suggestion is to use Estimated delivery date (EDD) instead. Reported as Number of days/7. This gives you the weeks in decimal format. Be sure to populate the appropriate age units in OBX-6.	Reproductive maternal serum screening		
Self donated egg	Was the donated egg from self?		CNE	(Y/N) HL7 Table 0136	Reproductive maternal serum screening		

	TABLE 8-2. EXAMPLE AOE QUESTIONS (WITHOUT LOINC CODE) <sup>11</sup>							
AOE Question	Suggested Common Question Name	Alias Question Name, when different from LOINC Long Name, where applicable	Suggested HL7 Data Type OBX response	Usage Note	Test Type Group			
Current use of oral contraceptives	Is patient currently using oral contraceptives?		CWE	Expected answers: Y/N/UNK (HL7 Table 0532 - Expanded Yes/no Indicator) Covered by "Prior and/or current therapy relevant to this order", but could be asked specifically.	Reproductive Pap			
Current use of hormone therapy	Is patient currently on hormone therapy other than oral contraceptives?		CWE	Expected answers: Y/N/UNK (HL7 Table 0532 - Expanded Yes/no Indicator) Covered by "Prior and/or current therapy relevant to this order", but could be asked specifically.	Reproductive Pap			
Previous hysterectomy	Has the patient had a hysterectomy?		CWE	Expected answers: Yes - Total hysterectomy, Yes - hysterectomy with cervix present No Unknown Covered by "Prior and/or current therapy relevant to this order", but could be asked specifically.	Reproductive Pap			

	TABLE 8-2. EXAMPLE AOE QUESTIONS (WITHOUT LOINC CODE) <sup>11</sup>							
AOE Question	Suggested Common Question Name	Alias Question Name, when different from LOINC Long Name, where applicable	Suggested HL7 Data Type OBX response	Usage Note	Test Type Group			
History of pelvic radiation	Does the patient have a history of pelvic radiation?		CWE	Expected answers: Y/N/UNK (HL7 Table 0532 - Expanded Yes/no Indicator) Covered by "Prior and/or current therapy relevant to this order", but could be asked specifically.	Reproductive Pap			
Does patient currently have an IUD	Does patient currently have an IUD		CWE	Expected answers: Y/N/UNK (HL7 Table 0532 - Expanded Yes/no Indicator) Covered by "Current contraceptive use", but could be asked specifically.	Reproductive Pap			
Is patient lactating	Is the patient currently lactating?		CWE	Expected answers: Y/N/UNK (HL7 Table 0532 - Expanded Yes/no Indicator) Is covered under relevant clinical history question, but could be asked specifically.	Reproductive Pap			
Is patient post-menopausal?	Is patient post-menopausal?		CWE	Expected answers: Y/N/UNK (HL7 Table 0532 - Expanded Yes/no Indicator) Covered by "Prior and/or current therapy relevant to this order", but could be asked specifically.	Reproductive Pap			

TABLE 8-2. EXAMPLE AOE QUESTIONS (WITHOUT LOINC CODE) <sup>11</sup>							
AOE Question	Suggested Common Question Name	Alias Question Name, when different from LOINC Long Name, where applicable	Suggested HL7 Data Type OBX response	Usage Note	Test Type Group		
Previously treated for prior GYN malignancy	Has the patient been previously treated for prior GYN abnormality?		CWE	Expected answers: Y/N/UNK (HL7 Table 0532 - Expanded Yes/no Indicator) Covered by "Prior and/or current therapy relevant to this order", but could be asked specifically.	Reproductive Pap		
ls patient postpartum	Is patient postpartum?		CWE	Expected answers: Y/N/UNK (HL7 Table 0532 - Expanded Yes/no Indicator)	Reproductive Pap		
History of postmenopausal bleeding	Does patient have a history of postmenopausal bleeding?		CWE	Expected answers: Y/N/UNK (HL7 Table 0532 - Expanded Yes/no Indicator) Should be covered under abnormal GYN exam - aspect uterus, but is left in, because it should not be forgotten to ask for.	Reproductive Pap		
Other risk factors (early onset of sexual activity, multiple sexual partners, Hx of STD/HIV, Immunocompromised, 5 or more pregnancies	Does the patient have any of the following risk factors: early onset of sexual activity, multiple sexual partners, Hx of STD/HIV, Immunocompromised, 5 or more pregnancies?		CWE	Expected answers: Y/N/UNK (HL7 Table 0532 - Expanded Yes/no Indicator)	STD Pap		
Multiple Sexual Partners	Does the patient have a history of sexually transmitted diseases (STD)?		CWE	Expected answers: Y/N/UNK (HL7 Table 0532 - Expanded Yes/no Indicator)	STD Pap		

	TABLE 8-2.	EXAMPLE AOE QUEST	TONS (WITHOUT LOIN	C CODE) <sup>11</sup>	
AOE Question	Suggested Common Question Name	Alias Question Name, when different from LOINC Long Name, where applicable	Suggested HL7 Data Type OBX response	Usage Note	Test Type Group
HX of STD	Does the patient have a history of sexually transmitted diseases (STD)?		CWE	Expected answers: Y/N/UNK (HL7 Table 0532 - Expanded Yes/no Indicator)	STD Pap Public Health
Number of Sexual Partners in last 12 month	How many sexual partners has the patient had in the last 12 months?		NM		STD Public Health
New Sexual Partner in last 60 days	Has the patient had a new sexual partner in the last 60 days?		CWE	Expected answers: Y/N/UNK (HL7 Table 0532 - Expanded Yes/no Indicator)	STD Public Health
Male sexual partner in last 12 month	Has the patient had sex with a male partner in the last 12 months?		CWE	Expected answers: Y/N/UNK (HL7 Table 0532 - Expanded Yes/no Indicator)	STD Public Health
Sexual contact with CT or NG positive person	Has the patient had sexual contact with a Chlamydia Trachomatis and/or Neisseria Gonorrhoeae positive person?		CWE	Expected answers: Y/N/UNK (HL7 Table 0532 - Expanded Yes/no Indicator)	STD Public Health
Treatment for CT or NG in last 3 to 12 month	Has the patient had a previous positive Chlamydia Trachomatis and/or Neisseria Gonorrhoeae test and been treated ≥ 3 months but ≤ 12 months ago?		CWE	Expected answers: Y/N/UNK (HL7 Table 0532 - Expanded Yes/no Indicator)	STD Public Health

## 8.4 Specimen List

This AOE information is provided to indicate how to map former AOEs to the Specimen (SPM) segment. This IG recommends using the SPM segment instead of AOEs for the following items. If you are implementing the HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Orders from EHR, Release 1 – US Realm (LOI) or HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Results Interface (LRI), Release 1, published July for Meaningful Use in the US Realm, the SPM segment is required in the Lab Order and Lab Result messages.

For suggested data types, refer to HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Orders from EHR, Release 1 – US Realm (LOI).

	TABLE 8-3. EXAMPLE SPECIMEN LOINC AOE QUESTIONS						
LOINC Code	LOINC Long Name	Suggested Common Question Name	Alias Name	HL7 field to use	Usage Note	Test Type Group	
<u>14725-6</u>	[Type] of Body fluid	Type of Body fluid		SPM-4	Sample type sent in SPM-4 (Specimen Type).		
13363-7	Collection duration of Stool				Can be calculated from: SPM-4 (Specimen Type) (CWE_CRE) SPM-17 (Specimen Collection Date/Time) (DR_1)		
13362-9	Collection duration of Urine				Can be calculated from: SPM-4 (Specimen Type) (CWE_CRE) SPM-17 (Specimen Collection Date/Time) (DR_1)		
53903-1	Collection technique	Collection technique	Pap Test collection technique	SPM-7	Expected answers: Swab-spatula, Brush-spatula, Spatula alone, brush alone, broom alone, other technique Should be identified in SPM-7 (Specimen Collection Method)		

		TAI	BLE 8-3. EXAMPLE	SPECIMEN LOINC	AOE QUESTIONS	
LOINC Code	LOINC Long Name	Suggested Common Question Name	Alias Name	HL7 field to use	Usage Note	Test Type Group
53903-1	Collection technique	Collection technique	Blood lead collection method	SPM-7	Expected answers: Fingerstick or venous seems to be substitute for knowing if capillary or venous blood is used, so could be combined with the Blood lead specimen question. Specimen collection method should be messaged in SPM-7 (Specimen Collection Method).	
49049-0	Collection time of Unspecified Specimen	Collection date/time of Unspecified Specimen		SPM-17	Should be messaged in SPM-17 (Specimen Collection Date/Time) (DR_1.1 [Range Start Date/Time])	
48557-3	Origin of Stone			SPM-8	SPM-8 (Specimen Source Site) CWE_CRE	
<u>19151-0</u>	Specimen drawn [Date and time] of Serum or Plasma			SPM-17	SPM-17 (Specimen Collection Date/Time) (DR_1.1 [Range Start Date/Time])	
	Specimen identification	Specimen identification		SPM-2	Should be identified in SPM-2 (Specimen Identifier). If slide and/or blocks provided - enter label identifier	
19763-2	Specimen source [Identifier] in Cervical or vaginal smear or scraping by Cyto stain	GYN specimen source site	Gynecological Source	SPM-8	Should be messaged in SPM-8 (Specimen Source Site) Picked from a list of body sites – Example answers: Vagina, Cervix, Vulva, Endocervix, Endometrium, Labium Majus, Labium Minus	Рар

		TAI	BLE 8-3. EXAMPL	E SPECIMEN LOINC	AOE QUESTIONS	
LOINC Code	LOINC Long Name	Suggested Common Question Name	Alias Name	HL7 field to use	Usage Note	Test Type Group
31208-2	Specimen source [Identifier] of Unspecified specimen	Specimen source		SPM-4	Should be messaged in SPM-4 (Specimen Type) if known. If type unknown, but source is known, then message in SPM-8 (Specimen Source Site).	
31208-2	Specimen source [Identifier] of Unspecified specimen	Specimen source	Blood lead specimen type	SPM-4	Required for State reporting	
	Type of Fixative	Type of Fixative		SPM-6	Should be identified in SPM-6 (Specimen Additive) – codes should be drawn either from substance or product hierarchy in SNOMED CT or HL7 Table 371 Additives	

## 8.5 Common AOEs Which Should be Messaged Elsewhere in HL7

In the process of developing this Implementation Guide, participants submitted candidate AOE terms for inclusion. Several proposed AOEs submitted should be messaged elsewhere in the HL7 message. This IG recommends using the HL7 segment/field as documented in the Usage Note, instead of messaging as an AOE. The table below is informative guidance to indicate how to map commonly used AOEs to the specified HL7 segment. If the appropriate HL7 field is optional, trading partners should change the usage of the 'O' fields to 'RE', if the information is required for processing.

Prior laboratory results needed for testing or interpretation should be messaged in the Prior Results segment group of the lab order message, versus messaging as an AOE; refer to OM1-53 (Prior Results Instructions) for additional information.

	TABLE 8-4. COMMON AOES WHICH SHOULD BE MESSAGED ELSEWHERE IN HL7					
LOINC Code <sup>12</sup>	LOINC Long Name	Suggested Common Question Name	Alias Name	Usage Note	Test Type Group	
<u>56799-0</u>	Address	Patient's Address		PID-11 (Patient Address)		
30525-0	Age	Patient Age		Prefer to receive DOB, sent in PID-7 (Patient Date/Time of Birth). Use this as AOE, when DOB cannot be obtained or shared No method described. Need to include the applicable time units - days, months, years - in OBX-6 Be sure to populate the units in OBX-6.		
<u>21112-8</u>	Birth date	Patient's Date/Time of birth		Patient Date/Time of Birth in PID-7		
N/A	Call or Fax Results Back	Call or Fax Results Back		Indicator to Notify provider when results are ready.  OBR-49 (Result Handling) where HL70507 Observation Result Handling table Code = N (Notify provider when ready).  The actual number to use is sent in PRT-15 (Participant Telecommunication Address).		

 $<sup>^{\</sup>rm 12}\,\mathrm{An}$  \* in this column indicates the code was "trial" at time of publication.

	TABLE 8-4. COMMON AOES WHICH SHOULD BE MESSAGED ELSEWHERE IN HL7						
LOINC Code <sup>12</sup>	LOINC Long Name	Suggested Common Question Name	Alias Name	Usage Note	Test Type Group		
76541-2	Clinical Diagnosis ICD Code	Ordering Diagnosis		Sent in DG1-3 in the order message. If needed in a result message consider OBR-31 (Reason for study).			
				If there is a need for an OBX, would need to consider, if the status of the diagnosis - ordering/working, final/admission/discharge is also needed, or if this could be more generic diagnosis			
				Picked from a list of diagnosis codes, usually ICD-9 or ICD-10 - supports the reason for ordering the procedure.			
66477-1*	Country of current residence [PhenX]	Patient's country of residence	Country of current residence	Send in PID-11.6 (Patient Address)  Is picked from a list - uses ISO-3166 Country Codes (alpha 3 character codes)			
				International Organization for Standardization (ISO)			
				PhenX is a survey method in LOINC			
29308-4	Diagnosis	Diagnosis		In the order message this should be sent in DG1-3 (Diagnosis Code) In result message could be messaged in OBR-31. Picked from a list of diagnosis codes, usually ICD-9 or ICD-10.			

		TABLE 8-4	. COMMON AO	ES WHICH SHOULD BE MESSAGED ELSEWHERE IN H	L7
LOINC Code <sup>12</sup>	LOINC Long Name	Suggested Common Question Name	Alias Name	Usage Note	Test Type Group
<u>69490-1</u>	Ethnicity OMB 1997	Ethnicity limited to OMB values  Ethnicity given by Provider limited to OMB values	Ethnicity	PID-22 (Ethnic Group)  Use 42784-9 for clinically significant ethnicity.  Picklist here is limited to the OMB 1997 defined values - Refer to LOINC for normative answer list.	
<u>56794-1</u>	Internal identifier	Internal identifier		For example, patient identifier used within the ordering provider's office.  PID-3 (Patient Identifier List) where HL70203 Identifier type table code = PI (Patient internal identifier)	
<u>22020-2</u>	Maiden name			Send Patient Maiden Name in PID-5 (Patient Name), where PID-5.7 (Name type code) is 'M'.	
	Mother's Maiden Name	Mother's Maiden Name		Send Mother's Maiden Name in PID-6 (Mother's Maiden Name)	
21484-1	Mother's race			NK1-35 (Race), if NK1-3 (Relationship) (CWE_CR) = 'MTH' (Mother).	
<u>18780-7</u>	Ordering Practitioner ID	Ordering Practitioner ID		OBR-16 (Ordering Provider) component 1(ID Number) (ST). Identifier for the ordering provider - should be the NPI number, but can be any identifier.	
	Partner's Name	_	Partner Name	Send in NK1-2 (Name), where NK1-3 (Relationship) is 'DOM' (Life partner) or 'SPO' (Spouse)	

		TABLE 8-4	. COMMON AO	ES WHICH SHOULD BE MESSAGED ELSEWHERE IN H	L7
LOINC Code <sup>12</sup>	LOINC Long Name	Suggested Common Question Name	Alias Name	Usage Note	Test Type Group
44951-2	Physician NPI [Identifier]	Physician NPI		The NPI (National Provider Identifier) code for another physician involved in the care of the patient. This could be any physician involved in the care, that may need results.  Send in PRT (Participation Information Segment), where  PRT-5 (Participation Person) carries the NPI.	
44833-2	Preliminary diagnosis	Preliminary diagnosis		In the order message this should be sent in DG1-3 (Diagnosis Code) when DG1-6 is 'P' from HL70052.  In result message could be messaged in OBR-31.  Picked from a list of diagnosis codes, usually ICD-9 or ICD-10.	
72826-1	Race OMB.1997	Patient's Race		PID-10 (Race)  Use 32624-9 for clinically significant race.  An AOE should be provided for those tests where Race drives the interpretation of results. The value should be determined by the Ordering Provider and should be from a predetermined list, like white, african american, asian, pacific islander etc.	
<u>45396-9</u>	Social security number	Patient's Social security number		PID-3 (Patient Identifier List) where PID-3.5 (Identifier Type) is 'SS'	

	TABLE 8-4. COMMON AOES WHICH SHOULD BE MESSAGED ELSEWHERE IN HL7					
LOINC Code <sup>12</sup>	LOINC Long Name	Suggested Common Question Name	Alias Name		Usage Note	Test Type Group
46499-0	State of residence	State of Patient's residence			Send in PID-11.4 (Patient Address)	
42077-8	Telephone	Patient's contact information - can be home phone, work phone or email			Patient's contact information - can be home phone, work phone or email Use PID-13 (home phone) or PID-14 (business phone)	
45401-7	ZIP code	Patient's Address Zip Code			Send in PID-11.5 (Patient Address)	

## 9 APPENDIX B - EDOS-LOI-LRI FIELD COMPARISON

The table below illustrates how elements from the laboratory's electronic directory of service (eDOS) are used in the laboratory order and laboratory result messages. There are ten data elements in common across the three Implementation Guides.

There may be process issues that should be addressed during the pilot projects and outcomes/best practices documented in a subsequent version of the eDOS Implementation Guide. Data type flavors used in the Laboratory Interoperability Implementation Guides are not included but should be considered depending on your implementation

Legend used in the table below:

Segment-position Element name

Comment

TABLE 9-1. FIELD COMPARISON				
eDOS <del>Release 2</del>	LOI	LRI		
OM1-2	OBR-4	OBR-4		
Producer's Service/Test/Observation ID	Universal Service Identifier	Universal Service Identifier		
OMC-4	OBX-3	OBX-3		
Clinical Information Request	Observation Identifier	Observation Identifier		
	Ask at Order Entry	Ask at Order Entry		
OM1-34	OBR-4	OBR-4		
OM1-34 Reflex Tests/Observations	Universal Service Identifier	Universal Service Identifier		
OM1-49	OBR-24	OBR-24		
Diagnostic Serv Sect ID	Diagnostic Serv Sect ID	Diagnostic Serv Sect ID		
Pre-adopted from V2.8 by eDOS	Optional in LOI; defer to base V2.5.1	Optional in LRI; defer to base V2.5.1		
OM1-56	OBX-3	OBX-3		
Observation Identifier	Observation Identifier	Observation Identifier		

TABLE 9-1. FIELD COMPARISON				
eDOS <del>Release 2</del>	LOI	LRI		
OM2-2	OBX-6	OBX-6		
Units of Measure	Units	Units		
OM2-6		OBX-7		
Reference (Normal) Range for Ordinal and Continuous Observations		References Range		
OM5-2	OBX-3	OBX-3		
Test/Observations Included Within an Ordered Test Battery	Observation Identifier	Observation Identifier		
CDM-1	OBR-4	OBR-4		
Primary Key Value – CDM	Universal Service Identifier	Universal Service Identifier		
CDM-7	OBR-44	OBR-44		
Procedure Code	Procedure Code	Procedure Code		
Pre-adopted from V2.7.1	Optional in LOI; defer to base V2.5.1	Optional in LRI; defer base V2.5.1		

## 10 APPENDIX C - EDOS MESSAGE DEVELOPMENT RESOURCES

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

The National Institute of Standards and Technology (NIST) has established a website (<a href="http://healthcare.nist.gov/">http://healthcare.nist.gov/</a>) 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 eDOS Messaging community, a repository has been established to function as a dynamic library of V2.x.x example messages, technical corrections, , an assessment of conformance statements applicable to each message, 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: <a href="http://hl7v2-edos-r1-testing.nist.gov/edos-r1/">http://hl7v2-edos-r1-testing.nist.gov/edos-r1/</a>

11 APPENDIX D – GLOSSARY  Refer to the Glossary published in the HL7 VERSION 2.5.1 Implementation Guide: S&I Framework Laboratory Orders From EHR, Release 2, US REALM	